Thomas S. Roukis · Christopher F. Hyer
Gregory C. Berlet · Christopher Bibbo
Murray J. Penner *Editors*

Primary and Revision Total Ankle Replacement

Evidence-Based Surgical Management

Second Edition

Springer

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Preface

It is with great pleasure that I present this work titled *Primary and Revision Total Ankle Replacement: Evidence-Based Surgical Management.* Total ankle replacement as a surgical treatment for end-stage ankle arthritis is a topic of great interest, as evidenced by the growth in the number of peer-reviewed publications on the topic since 2000. It is clear that as this treatment continues to prosper, the need for total ankle replacement revision becomes imminent. Unfortunately, except for registry data and a gradually expanding volume of recent peer-reviewed publications, the described literature for primary and revision procedures for total ankle replacement is sparse. Additionally, the authoritative text on the topic of primary total ankle replacement is a full decade old (*Total Ankle Arthroplasty*, by Beat Hintermann, Springer, 2005), without an updated edition forthcoming, and is mostly with an international focus. The remaining text publications are either "how-to" manuals, monographs, or focused clinics issues with limited breadth and predominantly involving prosthesis designs not available for use in North America.

Recognizing this gap in knowledge, in the fall of 2013, Kristopher Spring, Editor in Clinical Medicine for Springer, contacted me to gauge my interest in editing a textbook that would provide great depth into all aspects of total ankle replacement. We agreed that the main focus would be on total ankle replacement prostheses available for use in North America with additional "lessons learned" from the international community. The coeditors I selected are from a mix of medical degrees and accepted as true authorities on all aspects of total ankle replacement. Surgeons who are recognized as subject matter experts on their particular chapter topics coauthor each chapter. The text is founded on evidence-based material supplemented heavily with step-by-step photographs. As a result, the chapter content is a purposeful mix of theory, data, and tips/pearls with detailed figures, tables, and up-to-date references. This work is intended to address the apprentice as much as the more experienced total ankle replacement surgeon. The time, energy, and effort invested in the preparation of this work have been immense, but the learning process has been a most rewarding experience. If this work offers useful information and provides a platform for further knowledge from which others can advance the further evolvement of total ankle replacement, I will have reached my goal.

I thank each of the coeditors and authors who were gracious enough to take substantial time from their practices and families to accommodate my tight and in many ways unrealistic goals for this textbook. It is hoped that the readers of *Primary and Revision Total Ankle Replacement: Evidence-Based Surgical Management* will enjoy this work and benefit from the surgical experience of the coeditors and authors selected, as much as I have. This work would not have been possible without the steadfast attention to detail provided by Developmental Editor Joni Fraser. She most definitely has mastered the art of "herding cats." Finally, this work is dedicated to my beautiful wife Sherri and my wonderful children Averie and Devon for their never-ending support, love, and care. I never would have been able to complete this work or garner the educational opportunities I have been blessed to receive without your sacrifice. You have my enduring love, affection, and gratitude.

La Crosse, WI, USA

Thomas S. Roukis, DPM, PhD, FACFAS

Preface (for second edition)

Much has changed since the first edition of this total ankle replacement textbook was published only 5 years ago. Each of the co-editors have worked hard to obtain chapter submissions from world authorities on the particular topics. Some chapters have remained unchanged from the first edition, some have been updated, and some are new. All of the co-editors greatly appreciate the support of Springer International to bring this textbook to fruition. We hope that the readers gain some insight from the collective efforts of all authors recruited; however, more importantly, we also hope that the material presented is scrutinized so that we may collectively answer the many still unanswered questions pertaining to total ankle replacement.

Jacksonville, FL, USA — Thomas S. Roukis , DPM, PhD, FACFAS

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Part I

Introduction

History of Total Ankle Replacement in North America

1

Sahil Kooner, Andrew Marsh, Ian R. Wilson, Joyce Fu, and Johnny Tak Choy Lau

Introduction

The use of total ankle replacement (TAR) has increased significantly since its introduction in the early 1970s [1]. It has emerged as a viable motion-preserving alternative to ankle fusion, and interest in TAR will likely continue to grow as prostheses, machining, and technical surgical advancements are developed [2]. Originally, successes in hip and knee arthroplasty lead to attempts to create and refine the first TAR. Early results were fraught with poor outcomes and numerous complications, leading many to abandon the procedure in favor of the more reliable outcomes associated with ankle fusion procedures [3]. Nonetheless, the resurgence of TAR in the last two decades has largely been driven by improved outcomes associated with more anatomic designs and improved wear properties. The Evolution of TAR in North America has, for the most part, echoed its evolution in other parts of the world and mainly Europe. Major differences from a North American perspective have mostly been guided by government regulation. Prior to 2007, the FDA had not approved a mobile-bearing 3-component design [4]. These regulations lead to the increased use and development of 2-component fixed-bearing designs in North America compared to Europe. Recently, there has been a global trend toward the use of these 2-component designs [5]. Currently, high-quality prospective studies and long-term outcomes regarding TAR are lacking in the literature; however, contemporary TAR designs have shown tremendous promise and improved survivability compared to their earlier counterparts.

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First Generation

Lord and Marotte were the first surgeons to attempt a TAR in 1970 [6]. They used an inverted total hip prosthesis, in which a femoral metal stem was inserted retrograde into the distal tibia, and a polyethylene acetabular liner was cemented into the calcaneus after complete talectomy [7]. In their case series of 25 patients, only 7 were considered to have a satisfactory outcome, and 12 failed [8]. In the decade following their first attempt, many surgeons attempted to revise their original design, often to avail. First-generation implants primarily consisted of constrained or unconstrained two-component cemented designs with a metal convex talar component and a concave polyethylene tibial component.

In North America, the Irvine total ankle implant (Howmedica, Rutherford, NJ) was developed in Irvine, California [9]. It used a nonconstrained design that was based on the anatomical measurements of 32 tali and was one of the first attempts to faithfully recreate the normal anatomy of the talus [10]. Its unique toroidal shape was touted to allow for motion in all three planes; however, because of its incongruent design, axial rotation led to implant separation, causing supraphysiologic stress to ligaments and point loading on bearing surfaces. At nine-month follow-up, 2 out of 28 patients had failed, and numerous wound healing and malalignment complications were noted [10].

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The Newton TAR (Howmedica, Rutherford, NJ) was another nonconstrained, incongruent, and cemented prosthesis. It shared similarities in design to the Richard Smith total ankle design that was popular in Europe. Contrary to the Smith TAR, however, the component metallurgy was reversed, with a convex metal talar component and concave partially cylindrical polyethylene tibial component. This prosthesis had a high rate of aseptic loosening and subsequent removal, with one series showing a 75% occurrence of aseptic loosening. At 1-year follow-up, 18 of the 50 patients in this cohort had failed [11]. This was likely related to increased polyethylene wear associated with incongruency, leading to advanced osteolysis.

The Mayo TAR was designed by Richard Stauffer in the 1970s. In contrast to the other North American implants described above, it was a highly constrained prosthesis that limited axial rotation. It consisted of a polyethylene concave tibial component and a convex congruent metal talar component, both of which were cemented [12]. Its highly congruent design increased stability of the prosthesis, while limiting axial motion, which made it act like a hinge joint. While initial results were encouraging, Kitoaoka et al. reported poor long-term outcomes in a retrospective cohort of 204 TAR. In his cohort, with an average follow-up of 9 years, the overall survivorship at 5, 10, and 15 years was 79%, 65%, and 61%, respectively [13]. Similarly, in a review by Unger et al., at a mean follow-up of 5.6 years, 14 of 15 TARs demonstrated significant loosening and subsidence, with 12 of 15 components demonstrating progressive tibial tilt [14].

The New Jersey or Cylindrical TAR was developed by Frederick Buechel and Michael Pappas in 1976. The polyethylene talar component had a cylindrical surface, whereas the tibial component consisted of mortised cobalt–chromium alloy. Both components were fixed with cement and had dual fixation fins. The fate of this design was similar to other implants of its era as its noncongruent design lead to poor wear characteristics and instability [15]. Nonetheless, its design went on to influence many second-generation implants, namely the Buechel–Pappas prosthesis (BP).

First-generation implants were marred by a myriad of complications secondary to component design and surgical technique. Unconstrained implants, such as the "ball-and-socket" Newton TARs, did not reciprocate anatomic kinematics and placed excessive stress on surrounding ligaments resulting in early failure and malalignment [11]. Conversely, highly constrained designs, such as the Mayo TAR, had unacceptable rate of aseptic loosening likely due to lack of axial rotation leading to increased transfer stress to the bone–cement interface [13]. Noncongruent designs were also more likely to result in increased instability and point loading of the bearing surfaces, leading to high rates of polyethylene wear and associated osteolysis [10]. In addition to component design, surgical technique and cement fixation also played a role in poor outcomes of first-generation implants. Over resection of the tibial plafond led to higher rates of subsidence as the patulous cancellous bone of the metaphyseal distal tibia was not as robust as the subchondral bone [16]. Poor cement techniques likely also contributed to this phenomenon, as the basic principles of pressurization were not standard practice. Cement debris from poor technique also likely contributed to increased osteolysis. Overall, this leads to the majority of first-generation implants being withdrawn from market over time. Hamblen et al. stated in his JBJS editorial that "clearly the answer to the question of replacing the ankle joint using current techniques must be no" [3]. Failure analysis of first-generation total ankle arthroplasties showed that only significant improvements in prosthetic design, change of fixation (elimination of cemented fixation), and improved anatomic access would change the arthroplasty outcome, making this procedure a valuable treatment option in patients with end-stage ankle osteoarthritis.

Second Generation

The second phase of TAR in North America largely started with the introduction of the Buechel–Pappas (BP) TAR (Endotec, South Orange, NJ) in the 1980s, which coincided with the introduction of the Scandinavian TAR (STAR; Waldemar Link, Hamburg, Germany) in Europe [17]. Shortly thereafter, the Agility TAR was introduced in 1984 [18]. These designs largely focused on the failures of the past generation by aiming to emulate more anatomic designs. Second-generation implants primarily consisted of metal talar components and metal-backed tibial components with a polyethylene liner that was either fixed to the tibial component or articulated with a polished metal tibial component, hence the mobile-bearing design. There was also a shift during this period to a transition away from cemented components, which were attributed to high rates of osteolysis and loosening. There was an increase in research on cementless implants with greater ingrowth or ongrowth surface properties to allow for stable biological fixation [19]. Many implants also focused on minimal tibial and talar resections using standardized cutting jigs to reduce the risk of subsidence and allow for more accurate and reproducible anatomic placement. There was also a greater emphasis on deformity correction and ligamentous balancing to increase TAR stability. Many modern TAR designs were based on the success of implants from the second generation, although nonanatomic designs, such as the Agility, have largely fallen out of favor.

The BP was largely the evolution of the New Jersey first-generation TAR with the addition of mobile-bearing polyethylene "meniscus." It was first known as the LCS (low contact stress) prosthesis, but later came to be known at the BP pros-

thesis [20]. Secondary to FDA restrictions, these implants were only approved for clinical trials in the USA; however, the mobile-bearing design was adopted by many prostheses and approved for use in Europe [4]. The most popular BP-type prosthesis was the Mobility implant, which like its predecessor shared the same basic design principles. It consisted of a three-component mobile-bearing design with a metal flat polished tibial tray and short conical intramedullary stem that required an anterior tibial corticotomy for insertion. The talar component was made up of a metal cylindrical component with multiple fins for stabilization. The polyethylene mobile bearing was congruent with both surfaces, as it had a flat proximal bearing surface that allowed for axial rotation, and a congruent concave distal bearing surface with a central sulcus that closely matched that of the metal talar component.

The first BP prosthesis was called the Mark 1, which was defined by the removal of the anterio-posterior constraint [20]. This feature allowed for more joint mobility without sacrificing stability; nonetheless, common postoperative complications included mobile-bearing polyethylene insert subluxation, talar component subsidence, osteolysis, and malleolar fracture. In their original series of 40 TARs using the Mark 1, the authors stated a 70% good-to-excellent outcome after a mean of 12 years. Further modification of the implant leads to the introduction of a two-finned tibial implant and a thicker polyethylene bearing with a deeper central sulcus, which was appropriately called the Mark II. In longer-term follow-up study by the implant designers, they showed improved results with the deep sulcus design, which demonstrated good to excellent results in 88% of cases and 93.5% survivability at 10 years [21].

The Mobility Total Ankle System was BP-type prosthesis that gained popularity in Europe, but due to FDA regulation, was never approved for clinical use in the USA [4]. Despite being one of the most widely implanted prostheses according to registry data, it is now discontinued [22]. In 2008, the FDA started a trial to compare the Mobility versus the Agility LP total ankle system, but further results from that study were never published [4]. In a recent prospective trial by Lefrancois et al., the Mobility showed significantly less improvement in AOS pain, disability, and total score compared to other second-generation implants, which included the STAR, Hintegra, and Agility [23]. In this cohort, mobility also had the worst survivorship among all second-generation implants.

The Agility prosthesis (DePuy, Warsaw, Indiana) was designed by Frank Alvine in the early 1980s in South Dakota [6]. It was the first and only TAR implant to receive FDA 510k clearance until 2006, thus leading it to be the most commonly used implant in the USA [22]. The Agility is a semiconstrained 2-component fixed-bearing prosthesis. It differed from most other second-generation and contemporary implants in several major features. The most notable of which was the tibial component, which was a large titanium component with a textured ongrowth proximal surface that resurfaced the media, lateral, and superior articular surfaces of the ankle. In order to this, a stable syndesmosis synostosis was necessary via fusion, which theoretically improved implant stability by improving load sharing with the fibula. A modular polyethylene liner then locks into the metal tibial component. This polyethylene liner then articulates with a cobalt–chromium talar component that is slightly shorter in width, which allows for rotation to take place within this semiconstrained articulation as the talar component can slide from side to side [4]. The Agility LP Total ankle system was a design modification introduced in 2007 in which the talar component was broadened, covering a much larger surface area of the talar dome [24]. This modification had the theoretical advantage of reduced side to side translation, resulting in a more congruent and stable implant, although studies have yet to confirm any clinical advantage.

The developers of this prosthesis published their outcomes with the Agility in both 1995 and 2004 [25, 26]. In their study, they noted that a delayed syndesmosis fusion was predictive of higher rates of peri-implant osteolysis and morbidity. The failure rate was 6.6% in 686 cases between 1995 and 2004. Interestingly, this was compared with a failure rate of 11% in 132 cases from an earlier cohort from 1984 to 1994. In a recent retrospective review of 127 consecutive cases, Raikin et al. demonstrated 78.2% survivorship at an average 9.1-year follow-up [27]. Few studies have been able to emulate the results achieved by the designers in their original study. A systematic review of 2312 TARs demonstrated a 9.7% failure rate at a mean follow-up of only 22.8 months [28]. Schuberth et al. also demonstrated similarly dismal failure rate, with only 80% survivorship at 24.2 months with 38% complication rate, which included 12% rate of syndesmosis nonunion and 28% rate of intraoperative malleolar fracture [29]. Problems with syndesmosis nonunion, nonanatomical design, and low survivorship have led to its abandonment in favor of newer prosthesis designs.

The STAR was developed in Europe by Hakon Kofoed and Waldemar Link in 1978. It has undergone many iterations and improvements over the years, but the basic design has remained relatively the same. The STAR was originally designed as an unconstrained design with a polyethylene tibial component and a stainless steel talar component that were both secured using cement [4]. It was redesigned in 1986 as a three-component design with a polyethylene meniscus, based on the mobile-bearing concept first introduced by Buechel and Pappas, to reduce rotational stresses at the implant–bone interface [30]. The 3-component design is well recognized worldwide and was popularized in Europe shortly after its introduction. Nonetheless, it was not available in the USA due to FDA regulation limiting mobile-

bearing designs until 2007, after a 7-year noninferiority controlled clinical trial comparing it to arthrodesis was completed demonstrating its noninferiority [31]. Its current design consists of a titanium tibial plate with two plasma sprayed cylindrical bars for biological noncementless fixation in the distal tibial subchondral bone. The talar component is a cobalt–chromium anatomic designs that also resurfaces the medial and lateral talar surfaces with a central fin and plasma spray finish for biologic fixation. The mobile bearing has a flat proximal surface, so it can articulate and rotate freely with the polished tibial baseplate, while its distal surface is congruent with the talar prosthesis and has a longitudinal groove that corresponds to a crest in the talar component, which theoretically increases stability and reduces risk of polyethylene dislocation [5].

The STAR developers published their outcomes and reported a 95.4% survivorship at 12 years [32]. Unfortunately, further studies have not yielded such promising results, and the literature has been confounded by numerous design iterations and geographical differences. Wood et al. demonstrated in a prospective cohort study of over 200 TAR, a 80.3% survivorship at 10 years [33]. Similarly, a systematic review with a pooled group of 2088 STAR TARs demonstrated a 71% survivorship at 10 years [34]. In a recent single surgeon retrospective cohort study on 200 consecutive TARs by Clough et al., survivorship was 76.16% at an average of 15.8 years [35]. The most common reason for revision in this study included aseptic loosening (59%), coronal malalignment and subsidence (25%), polyethylene wear/fracture (9%), delayed wound healing (15%), deep infection (3%), and late fracture (3%).

The Hintegra Total ankle prosthesis was developed and manufactured in Europe by Beat Hintermann (Switzerland), Deremaeker (Belgium), Ramon Viladot (Spain), and Patrice Diebold (France) in 2000 [6]. Similar to the STAR prosthesis, it is a noncemented nonconstrained 3-component mobile-bearing prosthesis. The tibial component is a flat metal component with a built-in 4-degree posterior inclination and has a porous ongrowth surface with six pyramidal peaks that provide rotational stability. Its tibial component was designed to resect minimal distal tibia to prevent subsidence with only 2–3 mm of subchondral resection needed. Additionally, the tibial component is also unique in that it has an anterior shield with two ovoid holes for screw fixation which act to prevent anterior subsidence, decrease stress shielding, and allow augmented screw fixation to increase initial stability, although the use of these screw holes is no longer recommended by the designers of the implant. The talar component is a metal conically shaped implant with a smaller curvature of radius medially then laterally mimicking native talar anatomy. Similar to the tibial component, it also has a porous ongrowth inferior surface and an anterior shield, which allows for screw fixation through two ovoid holes. Screw fixation for the talar component is also no longer advised by the implant designers. Since 2004, the talar component has been revised to include two posteriorly directed pegs to provide for additional rotational stability. The talar component is distinct from other designs radiographically in that there is a medial and lateral 2.5-mm rim, which acts to prevent dislocation of the high-density polyethylene bearing. The mobile polyethylene bearing has a smooth superior surface that is smaller than the tibial component to prevent malleolar impingement. The inferior surface of the polyethylene bearing is concave and congruent with the conical talar component.

The Hintegra has primarily been used in Europe and Canada, as its mobile-bearing 3-component design has only recently received FDA approval in the US [36]. Many of the studies for Hintegra were performed by the designers of the implant and have been retrospective in nature. Barg et al. in his latest study on Hintegra retrospectively reviewed the survivorship of 722 TARs [37]. The overall survivorship was 94% at 5 years and 84% at 10 years with an average follow-up period of 6.3 years. Similarly, in a recent analysis of 242 consecutive Hintegra TARs, Yang et al. demonstrated 91.7% survivorship at an average of 6.4 years [38]. They documented a 15.7% complication rate, with the most common complication being osteolysis (9%) and implant failure (5.7%). Nonetheless, AOS, AOFAS, SF-36 PCS and MCS, and VAS pain scores improved significantly after TAR. Despite its initial popularity, the Hintegra has largely fallen out of favor for newer third-generation implants.

Second-generation implants improved on the designs of first-generation implants with the widespread adoption of porous metal-backed implants with an emphasis on osseous integration; resurfacing of medial and lateral articulations; anatomic implant designs with minimal tibial resection; and the use of higher-quality polyethylene with improved wear characteristics [17]. Nonetheless, these TAR designs were still prone to a myriad of complications, including early failure due to malalignment, periprosthetic osteolysis and loosening, malleolar impingement and fracture, and syndesmosis nonunion [20, 28, 29, 35]. Some of the more anatomic designs, including the Hintegra and STAR implant, have had intragenerational changes and are still widely used today. The newest iteration of these implants can arguably be grouped together with third generation of current implants, and many of their successful design features have been adopted by these new implant designs.

Third and Fourth Generation

The third phase of TARs began in the early 2000s after the FDA 510k clearance of several new designs, which included the INBONE Total ankle system, the Salto Talaris, and the

Eclipse [5]. In the last 10 years, several other implant designs have been introduced into the market and increased in popularity including the Infinity, Cadence, Vantage, Zimmer Trabecular Metal, and the Integra XT. These so-called fourth-generation implants share many similarities to third-generation implants, and as such, we will discuss this current generation of implants together. Implants in this most current generation appear to be similar in design and generally have less variability then previous generations, indicating a convergence of design based on successful features of previous generations similar to the convergence of designs that made total hip arthroplasty so popular and successful. Most new implant designs have focused on minimal tibial and talar resection to decrease subsidence by relying on dense subchondral bone for support; superior ingrowth porous surfaces for osseous integration; the implementation of highly cross-linked polyethylene to reduce osteolysis; more anatomic designs to reduced impingement and increase surface area for support; more refined implant instrumentation to allow for more accurate and repeatable technique; a trend away from 3-component and mobile-bearing designs; and the introduction of dedicated revision type implants with stemmed components to increase stability [5].

The INBONE I prosthesis was designed by orthopaedic surgeon Mark Reiley and mechanical engineer Garret Mauldin and 510k cleared by the FDA in 2005 [5]. It was then purchased my Wright Medical Technology, Inc. in 2008. Its design was largely based on principles from total knee arthroplasty, as its unique design included a thick modular intramedullary tibial stem attached to the tibial baseplate with a Morse taper. Prior to insertion of the tibial stem, intramedullary reaming is required through an external alignment guide, which is completed in a retrograde fashion through the calcaneus, violating a portion of the subtalar joint anterior to the posterior facet. The stem and the baseplate are both made of cobalt–chromium with a titanium plasma spray coating for biological fixation. The stemmed components are assembled from multiple segments that screw into each other to adjust the length of the stem depending on the amount of bone loss and stability required. The modular stem components are placed individually through the anterior ankle arthrotomy, followed last by impaction of the tibial baseplate onto the implanted stem. The saddle-shaped talar component is also made of cobalt–chromium with a titanium plasma spray coating its inferior surface and talar stem. The talar component utilizes a flat talar cut and depends on the central talar stem, which is about 10–14 mm in length, for rotational support. The polyethylene liner locks into the tibial baseplate and is congruent with the talar component. The INBONE II was developed in response to questions regarding early failures in the literature. Some of the prominent design changes included a deeper central talar component sulcus to improve stability compared to the previous model, which was relatively flat. Additionally, the tibial baseplate had an increased anterior to posterior dimension, and the talar component added two anterior pegs in conjunction with the large central posterior peg to increase rotational stability of the implant. The INBONE prosthesis can be used for primary TAR; however, its design features make it an excellent revision stem. Some of these features include extended polyethylene heights, modular tibial stem components, extended central talar stem that achieves fixation in the calcaneus, and flat-top talar cut that preserves talar bone stalk.

The first published literature on the use of the INBONE for primary TAR was completed in 2014 by Adams et al. [39]. They looked at the early and midterm results of 194 INBONE implants. Although functional outcome scores all improved postoperatively, implant survivorship was 89% at an average of 3.7 years. There was a 13% rate of subsidence, with the majority of these showing progressive talar subsidence. These somewhat unexpectedly low survivorship rates were echoed by another retrospective study which demonstrated 77% survivorship at an average 2 -year follow-up, with six out of seven failures attributed to progressive talar subsidence [40]. An anatomic cadaveric study demonstrated that 75% of specimens had significant injury to the sinus tarsi vessels with retrograde reaming required for stem tibial stem insertion, which may have contributed to talar AVN and component subsidence [41]. The INBONE II appears to have mitigated some of the complications associated with the INBONE II, although no long-term studies have been published. In a review of 59 patients with INBONE I [28] and INBONE II [31] TARs, Hsu et al. demonstrated 44% complication rate, 24% of which required reoperation [42]. The most common reason for this was arthrofibrosis and gutter debridement; however, four out of five implants that needed revision for talar subsidence were attributed to the INBONE I. Survivorship at 2 years was 91.3% for the twenty-eight INBONE I implants and 100% for the thirty-one INBONE II implants.

As an alternative to the stemmed INBONE prosthesis, Wright Medical Technology, Inc. developed the INFINITY total ankle system as a minimally invasive implant that focused on native bone preservation. The INFINITY was released in 2013 and mirrors most contemporary TAR designs, as it is a noncemented 2-component fixed-bearing device, which does not require the use of rigid external jigs or intramedullary reamers [5]. The tibial component is a low-profile titanium rectangular implant with titanium plasma ingrowth coating on the superior, medial, and lateral surfaces. It contains three fixation pegs that provide rotational control when they are impacted into the distal tibial subchondral bone. The resurfacing talar component is made from cobalt chromium and contains two anterior pegs for rotational stability. It requires minimal anterior and posterior

chamfer cuts, and its inferior surface and anterior pegs are also coated with titanium plasma spray for osseous integration. The resurfacing component was designed with the intent to increase radiographic visualization under the component to assess for early osteolysis or cystic changes. Conversely, the flat-cut INBONE II talar prosthesis can also be used interchangeably in setting of minimal talar bone or dysplastic talus, as it has an identical talar sulcus geometry. The ultrahigh molecular weight polyethylene liner snaps into the tibial baseplate and is congruent with the talar component. Using the PROPHECY patient-specific cutting guides, preoperative CT scans can be used to create individualized cutting guides to be used with either INBONE II or INFINITY components.

There is limited literature available on functional and radiographic outcomes after TAR using INFINITY. Only short-term and intermediate results are available from a select few studies, which have all been retrospective in nature. Penner et al. reported on the results of 67 consecutive patients who underwent primary TAR with INFINITY implants [43]. At an average of 35.4 months, implant survivorship was 97%, with 2 cases requiring revision for talar component aseptic loosening. Conversely, Cody et al. reported a 10% revision rate, defined as the removal of one or more metal components, on 159 TARs with an average follow-up of 13 months [44]. Six of these patients (3.8%) were revised for infection, six (3.8%) were revised for deep infection, and 1 is for symptomatic component malalignment. They also noted that 7.4% of retained components showed asymptomatic lucencies around the tibial component. However, a recent retrospective cohort study of 20 patients with 2-year radiographic follow-up reported a 0% reoperation rate with no signs of tibial osteolysis and loosening [45].

The Cadence total ankle system is also similar in design to most contemporary TARs, as it is a noncemented 2-part fixed-bearing semiconstrained implant [5]. It was developed and released by Integra in 2016 as an alternative to the Salto Talaris total ankle system, with further emphasis of native bone preservation and recreation of anatomic kinematics. The tibial component is a low-profile cobalt–chromium alloy with titanium plasma spray coating on it superior surface for ingrowth biologic fixation. It has two anterior pegs and a posterior fin that are impacted into the distal tibia for rotational control. It is also unique in that it is side specific, as it has a concave cut out on its lateral side for the incisura and fibula, which acts to increase the surface area for implant support and prevent fibular impingement. The talar component is also side specific as it is a conical cobalt–chromium resurfacing design with a smaller radius of curvature medially then laterally to replicate native talar anatomy. Similar to the INFINITY, it also requires anterior and posterior talar chamfer cuts to preserve native bone. Its inferior surface also has a titanium plasma spray coating. The polyethylene is also unique in that it is congruent with the conical talar component, making it the only TAR system to have all side specific components. Additionally, it is also one of the only systems to use highly cross-linked polyethylene, which theoretically has better wear properties. An anterior- and posterior-biased polyethylene can also be used to improve sagittal alignment in case of subluxation.

Given its recent release, no intermediate or long-term outcomes are available for the Cadence total ankle system. Only one recent study abstract, which was presented at AOFAS 2019, by Daniels et al. reports on the 2 -year outcomes on 31 TARs [46]. All patients experienced significant improvements in functional outcomes scores with restoration of neutral alignment. There were no reported revisions, lucencies, or stress fractures in this cohort. Short-term outcomes for the Cadence appear promising, and intermediate and long-term industry-sponsored studies are currently underway and will provide more robust evidence about its efficacy in the future.

The Salto Talaris has been available as a fixed-bearing prosthesis in the USA since 2006, although a mobile-bearing design was previously in use globally since 1997 [4]. In 2015, Salto Talaris and the flat-top talar Salto Talaris XT version were acquired by Integra LifeSciences, Inc. The fixed-bearing device was based on its mobile-bearing predecessor, after a radiographic study determined that the proximal articulation between the tibial component and the superior polyethylene had limited motion [47]. In its current form, the Salto Talaris is a cemented 2-component fixed-bearing device. The cobalt–chromium talar component is coated with titanium plasma spray, and it also has a central cylindrical keel for enhanced rotation control [5]. An anterior tibial corticotomy is required for tibial implant insertion. The cobalt–chromium talar implant is available as either a flat-top talar cut or a chamfer-style cut. The inferior surface has a central peg and is also coated with titanium plasma spray. The talar component is unique in that it resurfaces the entire lateral facet and also has a conical-shaped design with radii of curvature to mimic natural talar anatomy. A dedicated revision system, the Integra XT Revision TAR shares many similar design features as the primary version; however, it has several features that make it more suited for revision setting or complex primary cases. It has a larger shark-fin-shaped tibial stem for enhanced fixation; thicker tibial baseplate options and thicker polyethylene inserts to restore height in setting of severe bone loss; and augmented posterior sloped talar components in setting of previous talar component subsidence.

A systematic review looking at the incidence of revision after Salto Talaris implantation included a total 1209 mobile-bearing designs, with an average follow-up of 55.2 months, and 212 fixed-bearing designs, with an average follow-up of 34.9 months [48]. The mobile-bearing design had a revision

rate of 5.2% compared to 2.6% for the fixed-bearing design. In the fixed-bearing cohort, 5 out of 48 patients underwent revision, with 3 patients undergoing component revision, and 2 patients receiving an ankle arthrodesis. A recent retrospective cohort study looking at midterm outcomes by Stewart et al. reported a 95.8% survivorship of 72 TARs at an average of 5 years [49]. Although 19% of patients required reoperation, only 3 patients in their cohort required revision, two of which were for aseptic loosening, and one for a chronically infected wound. These results were largely reciprocated by Hofmann et al. demonstrating a 97.5% survivorship in 78 patients at an average of 5.2 years [50]. There was a 21.8% rate of reoperation, although the most common procedure was gutter debridement. Concerns about periprosthetic fracture and osteolysis around the tibial keel due to the necessity of the anterior tibial corticotomy have not borne out in the literature.

The Trabecular Metal Total Ankle system by Zimmer is a 2-component fixed-bearing low-profile implant, like many current-generation implants; however, it has several notable characteristics that differentiate it from other TARs. It is the only FDA approved implant that utilizes a transfibular approach for insertion, which requires a fibular osteotomy and takedown of the anterior syndesmotic ligaments [5]. Both the osteotomy and syndesmotic ligaments require repair at the completion of the surgery and can be a potential cause of failure and reoperation in the setting of nonunion or instability [51]. Nonetheless, this approach has its benefits as it avoids the wound-healing issues associated with the anterior approach and additionally allows the surgeon to tension the lateral ligaments by either shortening or lengthening the lateral column through the fibular osteotomy. The tibial component is also unique in that it has a concave design with trabecular metal porous ingrowth on its proximal surface. The concave surface of the implant is meant to mimic the natural anatomy of the distal tibia, while also decreasing the amount of native bone resection, increasing surface area for ingrowth, and distributing stress evenly across the subchondral bone–implant interface. Rotational control of the tibial prosthesis is achieved by 2 trabecular metal rails that are oriented from medial to lateral on the superior surface of the implant. Injection of polymethylmethacrylate cement is performed along the rail channels to comply with FDA regulations. The conical talar component is a cobalt–chromium convex resurfacing prosthesis with similar trabecular metal and dual rail system for biological fixation and stability. It was also the first total ankle systems to use highly cross-linked polyethylene, which locks into the tibial metal component, for its theoretical improved wear characteristics [5]. Successful implantation of this prosthesis requires an external alignment jig that rigidly holds the ankle reduced in a neutral position, which allows for coupled cuts of the tibia and talus with the use of a burr.

Limited literature is available on outcomes after implantation with the Trabecular metal total ankle system. The few studies that are available are relatively small retrospective cohort studies. Barg et al. reported on 55 trabecular metal TARs with an average follow-up of 26.2 months [52]. Implant survivorship was 93% at 2 years, with 3 out of 55 patients requiring revision for aseptic loosening of the tibial component. There were no instances of fibular nonunion or delayed union, and patients reported significant improvement in VAS (7.9 ± 1.3 to 0.8 ± 1.2) and ROM (22.9° ± 12.7° to 40.2° ± 11.8°). Similarly, Tan et al. reported on a retrospective cohort of 20 TARs with an average follow-up of 18 months and again found no instances of fibular nonunion or implant failure; however, 20% of patients required reoperation for anterior impingement (1 ankle), deep infection and symptomatic fibular hardware (1 ankle), and symptomatic fibular hardware (2 ankles) [53]. Conversely, a recent retrospective cohort study by Tiusanen et al. demonstrated relatively high complication rate after transfibular approach in 104 TARs [51]. Despite significant improvement in pain and functional outcome scores postoperatively, they reported seven cases of implant subsidence with 3 talar implants and 4 tibial implants. Furthermore, additional surgery was required in 38% of their cohort, which included 3 fibular nonunions, 1 case of syndesmosis widening, 3 deep infections, and 9 superficial infections, which required removal of the fibular plate. Devries et al. also cautioned on the perioperative complications associated with the transfibular approach, as their cohort reported a 25% complication rate related to the fibular osteotomy (3 nonunion/delayed union and 1 removal of hardware for superficial infection) [54]. Overall, the trabecular metal implant has shown good short-term radiological and functional outcomes; however, the transfibular approach comes with unique set of complications, and the literature has yet to elucidate if these outweigh the theoretical advantages.

Recent Trends

There has been a renewed interest in 2-component, fixed-bearing designs with the newest generation of TARs. The reason for this is not clear, but it is likely multifactorial. Second-generation implants were primarily 3-component, mobile-bearing designs, as the Hintegra, Mobility, and STAR were increasing in popularity in Canada and in Europe throughout the early 2000s [36]. FDA regulations limited mobile-bearing designs in the USA, which likely played a role in the development and popularity of newer-generation 2-component, fixed-bearing devices. When the first mobile-bearing implant, the STAR, was finally approved for use in the USA in 2009, the fixed-bearing version of the Salto Talaris had already been introduced and shown efficacy. The

current generation of implants consists of almost all 2-component, fixed-bearing devices and includes the INFINITY, INBONE II, Salto Talaris, Salto Talaris XT, and Cadence [5]. This recent trend has not been an evidence-based movement, as both mobile- and fixed-bearing implants have shown excellent and largely equivalent clinical outcomes in the literature. A randomized control trial of 40 patients demonstrated no significant differences in gait mechanics between fixed- and mobile-bearing designs [55]. Similarly, two recent controlled comparative studies, one of which was a randomized control trial of 100 TARs, also did not demonstrate any significant differences in regard to clinical outcomes between the two implant designs [56, 57]. Nonetheless, new evidence is emerging which may favor 2-component, fixed-bearing implant designs. A systematic review comparing mobile- and fixed-bearing Salto Talaris implants demonstrated that the mobile-bearing design had a revision rate of 5.2% compared to 2.6% for the fixed-bearing design [48]. Gaudot et al. also demonstrated a significantly higher rate of periprosthetic lucencies and subchondral cystic changes in mobile-bearing designs [58]. Findings by Nunley et al. largely echoed these results as mobile-bearing implants in their study demonstrated a significantly greater incidence talar lucency/cyst formation and tibial and talar subsidence [56]. However, as demonstrated by both these studies, radiographic outcomes do not always correlate with clinical outcomes. Further longitudinal studies that are better powered are likely necessary before any definitive recommendations can be made on this contentious issue.

Conclusions

TAR continues to increase in popularity as a motion-preserving alternative to ankle arthrodesis. Early failures associated with first- and second-generation implants have contributed to the further research and development of more robust designs. Third- and fourth-generation implants have placed a greater emphasis on restoration of normal anatomy with anatomic implant designs, minimal native bone resection, biological ingrowth fixation, more wear-resistant polyethylene, and improved surgical techniques. Similarities in contemporary TAR designs likely indicates the clinical success of new implants and gives further credence that an optimal solution may soon be in our future. As implants have become more dependable, there has also been increased focus on modularity and revision components, similar to hip and knee arthroplasty. Despite the promising early results of new implants designs, caution should be exercised as long-term outcomes for these implants are not often available, and most research on the topic is derived from level IV studies that are often industry sponsored or run by the designers (Table 1.1).

Table 1.1 Commonly used North American total ankle replacement systems

Implant	Manufacturer	Generation	Fixation/Bearing
Irvine	Howmedica (Rutherford, NJ)	1	Cemented/fixed bearing
Newton	Howmedica (Rutherford, NJ)	1	Cemented/fixed bearing
Mayo		1	Cemented/fixed bearing
New Jersey		1	Cemented/fixed bearing
Buechel–Pappas	Endotec (South Orange, NJ)	2	Cemented/mobile bearing
Mobility	DePuy (Leeds, England)	2	Uncemented/mobile bearing
Agility	DePuy (Warsaw, IN)	2	Uncemented/fixed bearing
STAR	Stryker (Mahwah, NJ)	2	Uncemented/mobile bearing
Hintegra	Integra LifeSciences (Plainsboro, NJ)	2	Uncemented/mobile bearing
Salto Talaris (XT)	Integra LifeSciences (Plainsboro, NJ)	3	Uncemented/fixed bearing
Trabecular Metal	Zimmer Biomet (Warsaw, IN)	3	Uncemented/fixed bearing
INBONE I/II	Wright Medical (Memphis, TN)	3	Uncemented/fixed bearing
INFINITY	Wright Medical (Memphis, TN)	4	Uncemented/fixed bearing
Cadence	Integra LifeSciences (Plainsboro, NJ)	4	Uncemented/fixed bearing

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Total Ankle Replacement Based on Worldwide Registry Data Trends

2

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Introduction

Several countries throughout the world have adopted national joint registries (NJRs) to assess and monitor safety, outcomes, and survivorship following implant arthroplasty [1]. The vast majority of countries collecting these data, including the USA, are currently only procuring relevant information specific to total hip arthroplasty and total knee arthroplasty. Unfortunately, only six countries worldwide currently monitor the use of primary total ankle replacement (TAR) via NJR and publish these data. Currently, data pertinent to primary TAR are available from Australia [2], England/Wales/Northern Ireland [3], the Netherlands [4], New Zealand [5], Norway [6], and Sweden [7]. Finland previously maintained a NJR; however, only data through 2006 have been published, and the registry was terminated in 2016 [8, 9]. Additional countries are collecting data pertinent to primary TAR; however, they are either incomplete or significantly limited in data collected [10]. In 2013, our group published a novel analysis of observational trends from available NJR with data pertinent to primary TAR [11] and in 2015, a specific analysis of primary TAR survivorship based on NJR data [12]. More recently in 2019, Jeyaseelan et al. [13] published a review of worldwide NJR data as they pertain to primary TAR outcomes. The purpose of this chapter is to provide a current update and comprehensive investigation of primary TAR as it pertains to available NJR data.

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The first total joint registry was proposed in the USA at The Mayo Clinic in 1969. Since then, several single-institution registries within the USA have existed, including those at Kaiser Permanente and US Health East [14, 15]. In 2009, the American Academy of Orthopaedic Surgeons (AAOS) launched a joint registry pilot program in partnership with the American Joint Replacement Registry (AJRR) that included pertinent data for total joint replacement (TJR) of the hip and knee [16]. As of June of 2019, the AJRR has collected data from over 1.7 million TJR procedures from a combined 1302 institutions that includes 1133 hospitals; however, this NJR is still devoid of any data relevant to TAR [16, 17]. Despite the impressive growth over the past several years, this collection represents fewer than 20% of the 6200 hospitals potentially available to report data on total joint replacement in the USA [18]. The importance of large-scale participation and registration completeness has previously been reported from the Norwegian Arthroplasty Register in order to produce meaningful, accurate annual reports [19]. According to Heckmann et al. [20], AJRR represented 28% of all total hip and total knee arthroplasty procedures performed in 2016, while the majority of other NJRs captured 95–98.3% of all these TJR procedures performed. Obviously, the quality of the reported outcome is dependent on a high degree of participation. Ideally, over the next several years, the AJRR will continue to collect data from increasing institutions, as well as begin to implement primary TAR from all foot and ankle surgeons performing this procedure. Alternatively, if the AJRR fails to recognize primary TAR as a meaningful procedure to evaluate via joint registry, a separate entity should be poised to champion this task.

Despite profound advances in prosthesis design, accuracy of insertion, and improvement of component materials with current generation primary TAR systems, long-term survivorship remains somewhat unclear. In 2011, a report evaluating primary TAR in joint registries indicated significantly heightened incidence of revision

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compared to hip or knee arthroplasty, specifically a three-fold increase [21]. In an additional NJR study published in 2011, the reported revision rate for primary TAR at 5 years was >20% increasing to >40% at 10 years, significantly larger than that for hip or knee arthroplasty over the same interval of time [22]. These reports are largely in contrast to more recent data. In 2014, 98% survivorship was reported at a mean 3.6-year follow-up in a series of 75 consecutive primary TARs [23]. A review of survivorship based on NJR for primary TAR was carried out in 2015 by Bartel and Roukis which demonstrated survival rates of 94% at 2 years, 87% at 5 years, and 81% at 10-years [12]. Recent reports are promising, indicating a continual improvement in primary TAR survivorship. In 2019, a report of 55 consecutive primary TARs noted a 93.3% survivorship at a mean of 5 years [24]. Also, in 2019, a survival rate of 97% was reported at a mean follow-up of 3 years in 67 consecutive primary TARs [25].

Unfortunately, a large percentage of the available literature regarding primary TAR contains bias, secondary to industry sponsorship, and inventor involvement. Previously, systematic reviews of the Agility Total Ankle Replacement Systems (DePuy Synthes, Warsaw, IN) and Scandinavian Total Ankle Replacement (STAR, Waldemar Link, Hamburg, Germany) systems demonstrated stark increase in revision when evaluating non-inventor, non-paid-consultant data, compared to the available data from inventors and paid consultants [26, 27]. Although still subject to some degree of bias, collection and evaluation of NJR data may provide a better understanding of reasonable expectations of outcome for the experienced foot and ankle surgeon at large. This is not to say that the reported results of those with industry-sponsored relationships are untruthful or misleading, but rather need to be considered with a critical eye and appreciation of the potential biases. With a technically demanding procedure, such as primary TAR, those surgeons with industry-sponsored relationships are likely leading authorities in the field with some of the greatest experience. Resultantly, the learning curve associated with primary TAR is well reported and needs to be considered by any foot and ankle surgeon when evaluating the authors and respective results of reported studies [28, 29].

NJR data provide an avenue for large-scale, comprehensive data collection of both implant components and patient-related data. When properly collected, these data generally provide several findings that benefit both the surgeon and the patient:

1. Timely feedback to surgeons and industry
2. Sentinel for complications
3. Reduction in patient morbidity
4. Monitoring of new surgical techniques and implant technology
5. Indications and identification of poor implant design
6. Appreciation of implant-specific chronologic trends

The access and use of specific TAR devices in the USA compared to international use are largely different. This is, in part, secondary to the stringent process by the Food and Drug Administration to approve a mobile-bearing, three-component, cementless device, which was successfully completed by the STAR system in 2009 [30] and by the Hintermann Series H3 system in 2019 (DT MedTech, LLC, Towson, MD) [31]. Additionally, despite some industry marketing claims, studies supporting superiority of mobile-bearing devices relative to fixed-bearing devices for TAR simply do not exist. This assertion of mobile-bearing superiority has also been theorized in total knee replacement, and with recent large systematic review, and meta-regression; however, no clinical differences in terms of revision rate, outcome scores, or patient-reported outcomes were demonstrated [32]. More commonly, the metal-backed, fixed-bearing, two-component, cemented devices available for use within the USA are cleared according to 510(k) pathway. This use pattern is in stark contrast to those identified internationally, at least within the countries that report to NJR datasets. Our study in 2013 identified 97% of TAR systems within the six abovementioned countries from 2000 to 2011 were mobile-bearing, three-component, cementless devices [11]. Interestingly, in 2014, the inventors of the mobile-bearing Salto Mobile Version prosthesis (Tornier S.A.S. Montbonnot Saint Martin, France) and the fixed-bearing Salto Talaris Anatomic Ankle prosthesis (Integra, Plainsboro, NJ) reported on a "paired" comparison of the two implant designs with 2-year follow-up. They concluded statistically significant higher American Orthopaedic Foot and Ankle Society Ankle Scoring Scale ($p = 0.05$), fewer radiolucent lines ($p = 0.02$), and fewer subchondral cysts ($p = 0.01$) at most recent follow-up in the fixed-bearing group with no difference in clinical performance. They concluded that the fixed bearing is equivalent to, if not superior to, the mobile-bearing version of the Salto system [33]. Following this type of data over time specifically in countries that collect NJR data may likely provide great insight into future use and design of TAR both in the USA and internationally.

Methods

Electronic searches were completed through PubMed in December of 2019 to identify relevant publications. We employed the following Boolean operators and made no restrictions in regard to date or language of publication: "ankle arthroplasty" OR "ankle implant" OR "ankle replacement" AND "database" OR "registry" OR "revision surgery."

The identified pertinent publications were then manually searched for additional relevant manuscripts. If a reference could not be obtained through librarian assistance or electronic mail contact with the author, it was excluded from consideration. If the reference was not written in English, the entire content was translated from its native language using an online-based translator [34]. Also, a rigorous online-based search for national joint registries with data pertinent to TAR was performed. A key website was identified and utilized which identifies 29 joint registries from 25 different countries [10].

Results: Worldwide Prosthesis Usage

We identified 7 online databases and corresponding publications involving primary TAR which contained potentially eligible data for inclusion. Seven countries were found to have complete NJR data relevant to primary TAR: Australia [2], England/Wales/Northern Ireland [3], the Netherlands [4], New Zealand [5], Norway [6], and Sweden [7, 35]. The majority of studies reporting NJR data were not independently included for trend analysis as these data are assumed to have been incorporated into the respective national annual reports and would therefore provide duplicate data [2–7, 35–38]. These studies were instead reviewed and referenced for supplemental clarity as an adjunct to the respective annual report. This is with the exception of Henricson et al. [35] that provides exact data prior to the initiation of annual reports from Sweden. We arbitrarily stratified the data into two distinct timeframes: 2000–2010 and 2011–2018. The data from 24 TAR systems involving 12,743 ankles were collected worldwide from 2000 to 2018 (Fig. 2.1). Based on volume, the most commonly implanted prosthesis was the Mobility (n = 2375, 36%) (DePuy Synthes, Leeds, UK) (Table 2.1). Observational analysis of the available pertinent registry data ultimately revealed four usage trends.

Abandonment

The first identified trend is abandonment defined as zero implantations worldwide over the past 2 years or more (i.e., years 2017 and 2018). Ten of the 24 prostheses identified in national registries since 2000 can be classified as abandoned based on this criteria (Fig. 2.2). The Ankle Evolutive System (AES, Transysteme JMT Implants, Nimes, France) has not been implanted since 2008 and has been removed from the market [39]. The Agility Total Ankle Replacement System was last implanted in 2007. The Büechel–Pappas (Endotec, South Orange, NJ) was last implanted in 2011. The CCI Evolution (Implantcast GmbH, Lüneburger, Germany) was last implanted in 2016 with 12 implants that year. The Mobility Implant, with peak usage at 540 in 2011, has not been implanted since 2016 with only 2 implants that year. The Ramses (Laboratoire Fournitures Hospitalières Industrie, Heimsbrunn, France) was implanted a total of 11 times from 2004 to 2005 and not since. Several implants including the ESKA (GmbH & Company, Lübeck, Germany) and Taric (Implantcast GmbH, Buxtehude, Germany) were all implanted 3 times or less and not at all in recent years.

Minimal Use

The second identified trend from our analysis is minimal use, which is defined as implantation during 2017 and 2018, but never greater than 50 ankles worldwide in a given year. Five of the 24 prostheses can be categorized as minimal use based on these criteria (Fig. 2.3). The Alpha Ankle

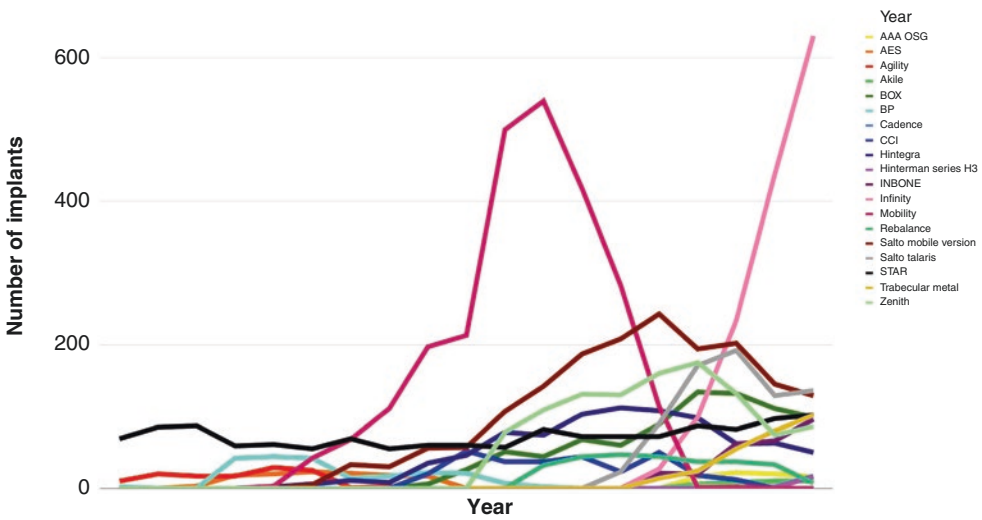


Fig. 2.1 Worldwide usage of primary total ankle replacement prostheses based on available national joint registries between 2000 and 2018

Table 2.1 Worldwide usage of primary total ankle replacement prostheses based on available national joint registries between 2000 and 2018

Year	AAA	AES	Agility	AKILE	BOX	BP	Cadence	CCI	Hintegra	Hintermann Series H3	INBONE	Infinity	Mobility	Rebalance	Salto Mobile Version	Salto Talaris	STAR	Trabecular Metal	Zenith	**Total**
2000	–	–	10	–	–	2	–	–	–	–	–	–	–	–	–	–	69	–	–	**81**
2001	–	–	20	–	–	–	–	–	–	–	–	–	–	–	–	–	85	–	–	**105**
2002	–	3	17	–	–	–	–	–	–	–	–	–	–	–	–	–	87	–	–	**107**
2003	–	18	17	–	–	42	–	–	–	–	–	–	–	–	–	–	59	–	–	**136**
2004	–	20	29	–	–	44	–	–	2	–	–	–	3	–	–	–	61	–	–	**159**
2005	–	23	25	–	–	42	–	–	4	–	–	–	42	–	5	–	55	–	–	**196**
2006	–	21	1	–	–	14	–	–	1	–	–	–	68	–	33	–	69	–	–	**207**
2007	–	18	2	–	–	17	–	–	8	–	–	–	111	–	30	–	55	–	–	**241**
2008	–	17	–	–	6	22	–	20	35	–	–	–	197	–	56	–	60	–	–	**413**
2009	–	–	–	–	26	21	–	52	46	–	–	–	213	–	57	–	60	–	–	**475**
2010	–	–	–	–	51	7	–	37	78	–	–	–	500	–	107	–	57	–	78	**915**
2011	–	–	–	–	44	2	–	37	74	–	–	–	540	32	142	–	82	–	109	**1062**
2012	–	–	–	–	68	–	–	44	103	–	2	–	418	44	187	–	72	–	131	**1069**
2013	–	–	–	–	60	–	–	23	112	–	1	–	283	47	208	23	72	–	130	**959**
2014	–	–	–	–	89	–	–	50	108	–	21	27	114	44	243	90	72	14	160	**1032**
2015	16	–	–	6	134	–	–	18	98	–	20	99	1	37	194	171	87	24	175	**1080**
2016	22	–	–	8	132	–	–	12	62	–	62	234	2	37	202	192	82	55	132	**1234**
2017	20	–	–	10	111	–	2	–	63	1	66	438	–	33	145	129	97	80	74	**1269**
2018	16	–	–	10	99	–	17	–	50	16	96	631	–	7	129	136	102	102	86	**1497**
Total	**74**	**120**	**121**	**34**	**820**	**213**	**19**	**293**	**844**	**17**	**268**	**1429**	**2492**	**281**	**1738**	**741**	**1383**	**275**	**1075**	**12237**

AAA (Alpha Ankle Arthroplasty, Alphamed, Lassnitzhöhe, Austria); Ankle Evolutive System (AES) (Transysteme JMT Implants, Nimes, France); Agility (DePuy Orthopaedics, Inc, Warsaw, IN); AKILE (Lavender Medical, Stevenage, UK); Bologna–Oxford (BOX) (Finsbury, Leatherhead, UK); Büechel–Pappas (BP) (Endotec, South Orange, NJ); Cadence (Integra, Plainsboro, NJ); CCI Evolution (Implantcast GmbH Lüneburger Schanze, Buxtehude, Germany); Hintegra (Integra, Saint Priest, France); Hintermann Series H3 (DT MedTech, LLC, Towson, MD); INBONE (Wright Medical Technology, Memphis, TN); Infinity (Wright Medical Technology, Memphis, TN); Mobility (DePuy UK, Leeds, England); Rebalance (Biomet UK Ltd, Bridgend, South Wales, England); Salto Mobile Version (Tornier S.A.S. Montbonnot Saint-Martin, France); Salto Talaris (Integra, Plainsboro, NJ); Scandinavian Total Ankle Replacement (STAR, Waldemar Link, Hamburg, Germany); Trabecular Metal (Zimmer, Warsaw, IN); Zenith (Corin Group PLC, Cirencester, England)

Cumulative data from National Joint Registries including Australia; England, Wales, and Northern Ireland; Norway; New Zealand; Sweden; and the Netherlands. (–) indicates no reported use of a product and is equivocal to zero. Implants with less than 15 total reported uses were excluded from the table, but included in individual national joint registry tables

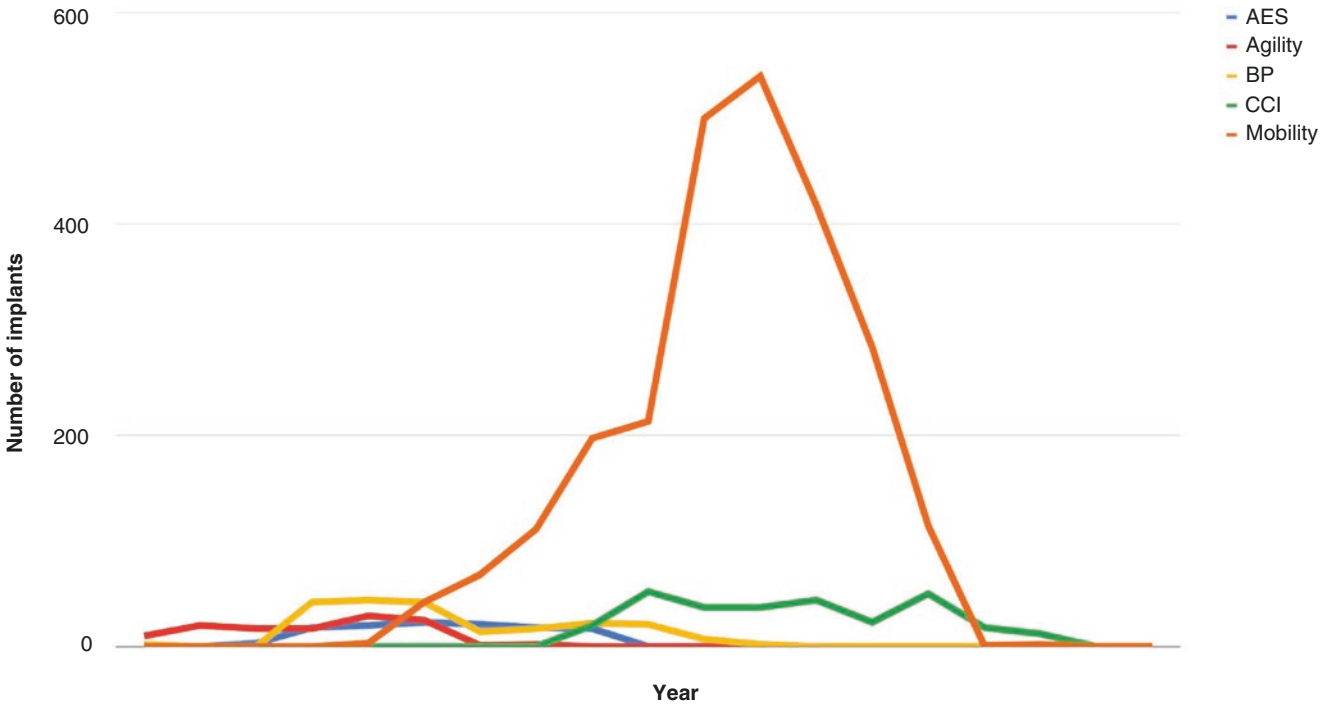


Fig. 2.2 Implants trending toward abandonment 2000–2018

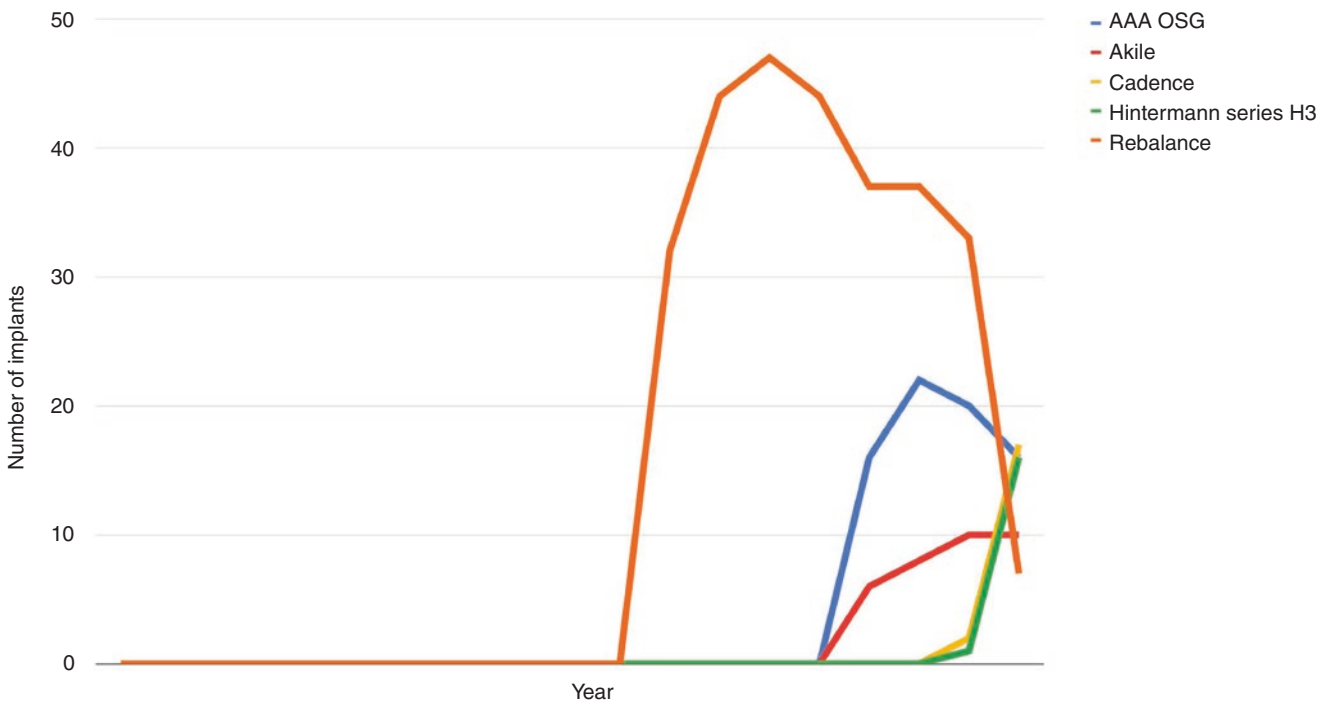


Fig. 2.3 Implants with minimal use 2000–2018

Arthroplasty (AAA, Alphamed, Lassnitzhöhe, Austria) was first implanted in 2015 and has been implanted 74 times as of 2018. The AKILE (Lavender Medical, Stevenage, UK) was also first implanted in 2015, with a total number of recorded implants at 34. The Cadence Total Ankle System (Integra, Plainsboro, NJ) was first implanted in 2017 two times and was implanted 17 times in 2018. The Hintermann Series H3 was also first reported to a NJR in 2017 and has 17 total recorded implants as of 2018. The implant with the longest record of use in this group is the Rebalance (Biomet

UK, Bridgend, South Wales, UK) with first reported implantation in 2011 and peak use at 47 times in 2013. In 2018, it was only recorded seven times.

Initial Embracement with Diminished Use

The third identified trend from our analysis is initial embracement with diminished use, which is defined as current use in 2018, implantation greater than 50 times within a given year at peak use, and reduction from peak use of 50% or greater. Three of the 24 prostheses can be categorized as embracement with diminished use based on these criteria (Fig. 2.4). The Hintegra Mobile-Bearing total ankle replacement (Integra, Saint Priest, France) was introduced in 2004 and reached peak implantation at 112 in 2013. Its use has declined since peaking to 50 reported uses in 2018 (55% reduction in use from peak). The Salto Mobile Total Ankle Replacement system has also declined in use since first introduction in 2005. It reached peak use at 243 implants in 2014, and since that time, use has been declining. One hundred twenty-nine implants were reported in 2018, a 47% reduction in use from peak. The Zenith implant (Corin Group PLC, Cirencester, England) was first introduced in 2010, and increased use was reported until it peaked at 175 in 2015. Its reported use decreased to 74 in 2017 (58% reduction from peak), but did make a slight increase in 2018 to 86.

Initial Embracement with Sustained Growth

The final trend identified from our analysis is initial embracement with sustained growth. This is defined as implantation greater than 50 at peak usage and either sustained growth at each annual interval or only minimal diminishment at a given interval with continued overall use to date. Six of the 24 prostheses can be categorized by embracement with sustained growth based on these criteria (Fig. 2.5). The Bologna–Oxford (BOX, Finsbury, Leatherhead, UK) was first recorded in 2008 with a usage of six implants. Its peak usage was 134 in 2015, and 99 implants were recorded in 2018, a 26% decrease in use. The INBONE (Wright Medical Technology, Memphis, TN) prosthesis was first implanted in 2014 and reached greater than 50 recorded implants by 2016. It has reported increases in use each year with 96 implantations in 2018. The Infinity total ankle replacement (Wright Medical Technology, Memphis, TN) was also first implanted in 2014, with an exponential increase in the number of recorded implants each year. In 2018, 631 implants were recorded, the highest number of implants included in the combined NJR for any given year. The Salto Talaris was first implanted in 2013 and reached over 50 implants by its second year. Its peak recorded use was at 192 in 2016. It was recorded 136 times in 2018, a 29% decrease from peak use. The STAR implant has been in the registries every included year and never below 50 implants. It reached peak use in 2001 at 138

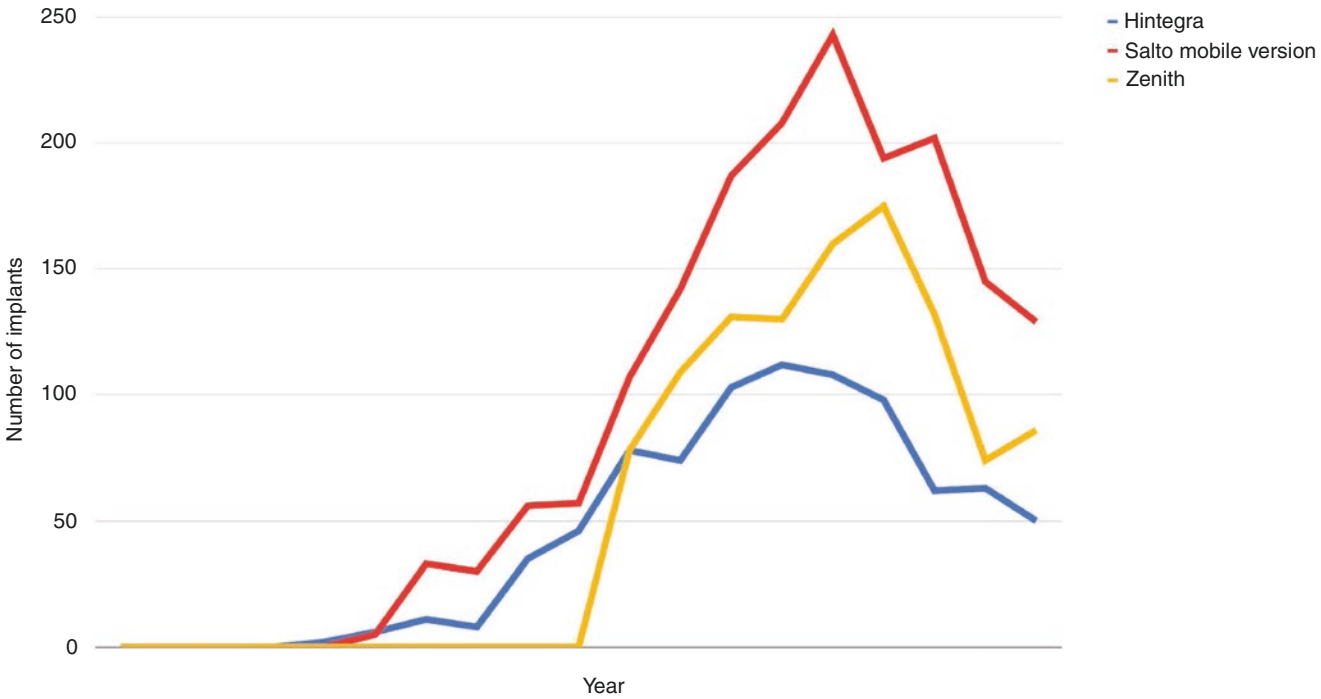


Fig. 2.4 Implants with initial embracement and diminished use 2000–2018

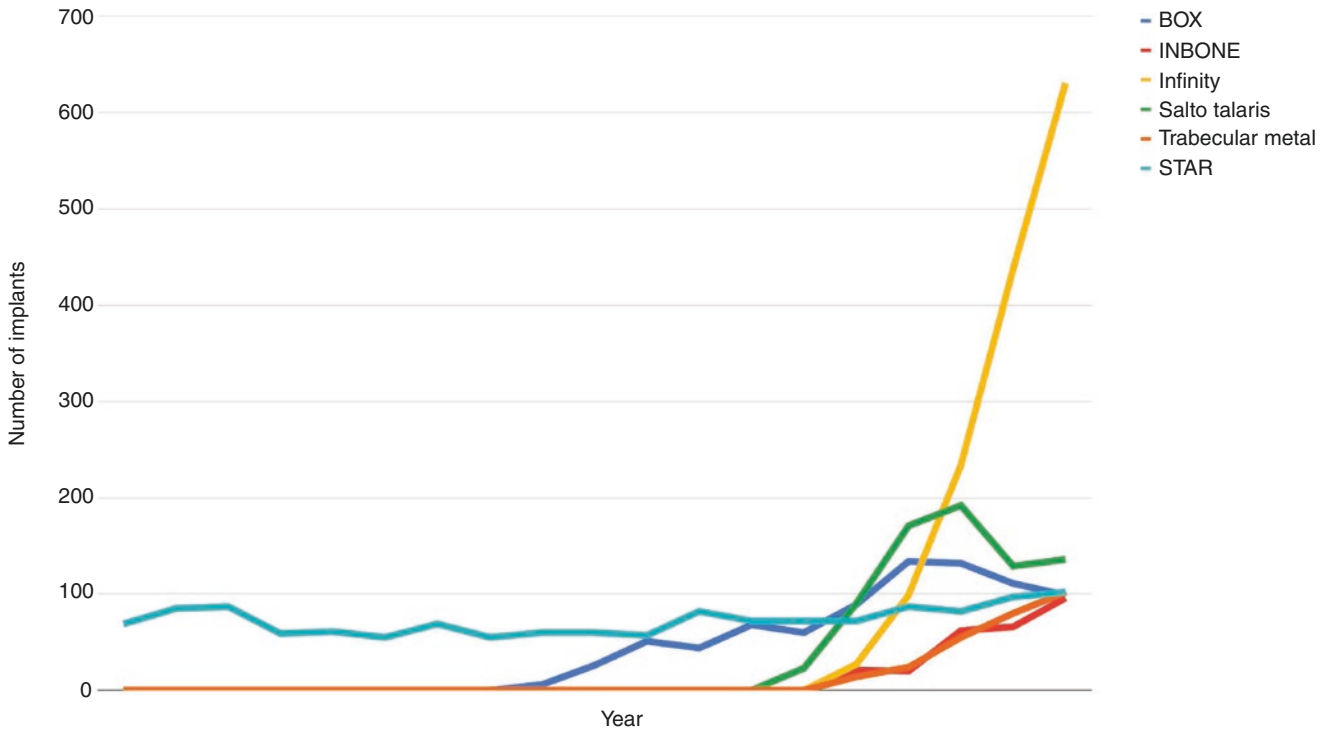


Fig. 2.5 Implants with sustained use 2000–2018

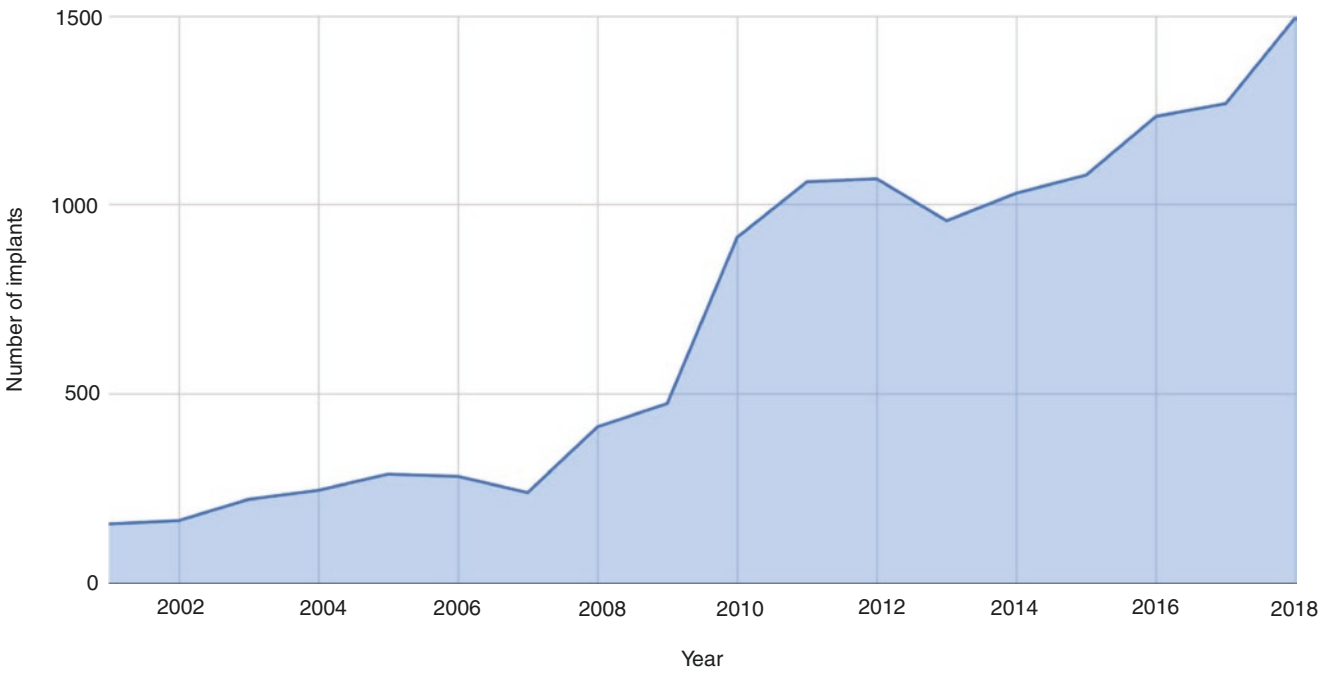


Fig. 2.6 Worldwide usage of primary total ankle replacement prostheses based on available national joint registries

implants and then decreased to the lowest recorded use of 55 in 2007. It has been, however, trending toward increase since that time, with 102 implants in 2018. The Trabecular Metal implant (Zimmer, Warsaw, IN) was first recorded in 2014 with 14 implants, and reported use has increased every year since with 102 implants in 2018.

Overall, the number of primary TARs reported to NJR has increased annually, with only limited exception since 2000 (Figs. 2.6 and 2.7). In 2006 and 2007, there were slight decreases in reported usage compared to 2004, but then a significant rise in 2007. This decrease correlated with problems with STAR and Hintegra coatings. There was again a slight

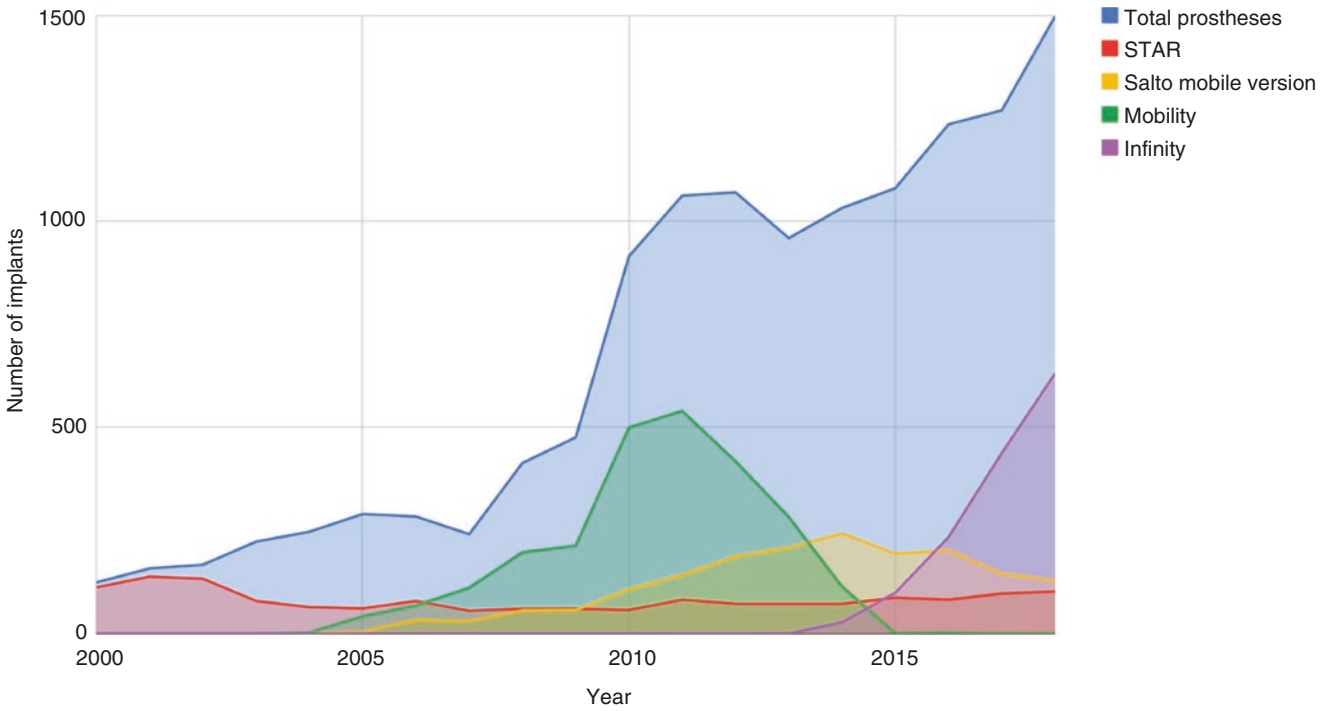


Fig. 2.7 Most popular implants recorded in national joint registries 2000–2018

decrease in 2013 and 2014 compared to 2012, but continued incremental growth reported since that time. This decrease correlates with the timeframe Mobility was withdrawn from use (Fig. 2.7). The highest number of implants was in 2018 with 1497 reported to NJR. From 2000 to 2010, the average usage per year was 321 prostheses. From 2010 to 2018, the average usage per year is 1150 prostheses. It cannot be concluded with certainty whether this increase can be attributed to a larger volume of primary TAR occurring worldwide over these intervals in time or to a heightened awareness of the importance of collecting NJR data and improved registry completeness, but it is likely a combination of both factors.

Results: Individual Country Data

The Australian Orthopaedic Association's "National Joint Replacement Registry" was initiated on July 28, 2006. Available data are reported through December 31, 2018. The "Demographics and Outcomes of Ankle Arthroplasty Supplementary Report 2019" contains data pertinent to TAR performed from 2007 through 2018 [2]. A total of 2237 prostheses involving 16 prosthesis designs were identified. From 2007 through 2010, 652 primary TARs were reported (mean 163 per year), and from 2011 through 2018, 1585 primary TARs were performed (mean 198 per year). The most frequently implanted prosthesis was the Mobility (n = 565; 25%), although its last reported use was in 2014. The next most commonly implanted prosthesis was the Hintegra Mobile Bearing (n = 437; 20%) (Table 2.2). Since 2014, the most commonly implanted prosthesis was the Salto Talaris (n = 335) followed by the Salto Mobile Version (n = 152). In 2016, a single custom TAR was implanted and reported through the NJR; however, this was excluded from Table 2.2.

The England, Wales, and Northern Ireland National Joint Replacement Registry was established in 2010; however, initially reported data for 2010 included 13 TARs implanted prior to 2010 [3]. In total, 5463 prostheses involving 13 different implant designs have been reported. From 2010 through 2018, 5463 primary TARs were reported (mean 683 per year). The Infinity was the most common prosthesis (n = 1207, 22%) with first documented use in 2014. The next most common prosthesis was the Mobility (n = 1093, 20%); however, its last reported use was in 2014 (Table 2.3).

The Finnish Arthroplasty Register, initiated in 1980, included primary TAR since that point. According to direct correspondence, the registry was unfortunately discontinued in 2016 [9]. Relevant data are limited to the most recent publications and include 2000 through 2006. Accordingly, from January 1, 2000, through December 31, 2006, primary TAR was identified involving 3 prosthetic designs [8]. The AES was the most commonly implanted prosthesis (n = 298; 61%), while the second most common was the STAR (n = 181; 37%) (Table 2.4). We chose to exclude the data from the Finnish Arthroplasty Register in Table 2.1 as it has not been updated and does not reflect current trends. Removing the data extrapolated from the Finnish NJR and implants with less than 15 total uses decreases the total number of implants reported to NJRs from 2000 through 2018 from 12,743 to 12,237.

Table 2.2 Australian Orthopaedic Association's National Joint Replacement Registry specific to primary total ankle replacement between 2007 and 2018

Year	Agility	BOX	BP	CCI	ESKA	Hintegra	Hintermann Series H3	INBONE	Infinity	Mobility	Salto Mobile Version	Salto Talaris	STAR	Trabecular Metal	Zenith	**Total**
2007	2	–	11	–	–	6	–	–	–	37	1	–	1	–	–	**58**
2008	–	6	18	–	1	34	–	–	–	98	11	–	–	–	–	**168**
2009	–	24	21	–	1	45	–	–	–	75	19	–	3	–	–	**188**
2010	–	28	7	1	–	63	–	–	–	101	35	–	3	–	–	**238**
2011	–	14	2	3	–	56	–	–	–	121	70	–	4	–	1	**271**
2012	–	23	–	–	–	64	–	–	–	70	65	–	2	–	6	**230**
2013	–	11	–	–	–	46	–	–	–	50	63	–	2	–	6	**178**
2014	–	6	–	–	–	40	–	–	–	13	52	28	12	–	3	**155**
2015	–	1	–	–	–	34	–	1	1	–	33	63	4	10	18	**159**
2016	–	1	–	–	–	12	–	5	2	–	25	92	4	10	21	**172**
2017	–	–	–	–	–	24	1	15	11	–	21	83	–	22	14	**191**
2018	–	–	–	–	–	13	16	31	53	–	21	69	1	15	9	**228**
Total	**2**	**114**	**59**	**4**	**2**	**437**	**17**	**52**	**67**	**565**	**416**	**335**	**36**	**61**	**78**	**2236**

Agility (DePuy Orthopaedics, Inc, Warsaw, IN); Bologna–Oxford (BOX) (Finsbury, Leatherhead, UK); Büechel–Pappas (BP) (Endotec, South Orange, NJ); CCI Evolution (Implantcast GmbH Lüneburger Schanze, Buxtehude, Germany); Eska (Eska Implants GmbH, Lubeck, Germany); Hintegra (Integra, Saint Priest, France); Hintermann Series H3 (DT MedTech, LLC, Towson, MD); INBONE (Wright Medical Technology, Memphis, TN); Infinity (Wright Medical Technology, Memphis, TN); Mobility (DePuy UK, Leeds, England); Salto Mobile Version (Tornier S.A.S. Montbonnot Saint-Martin, France); Salto Talaris (Integra, Plainsboro, NJ); Scandinavian Total Ankle Replacement (STAR, Waldemar Link, Hamburg, Germany); Trabecular Metal (Zimmer, Warsaw, IN); Zenith (Corin Group PLC, Cirencester, England)

Table 2.3 England, Wales, and Northern Ireland National Joint Replacement Registry specific to total ankle replacement between 2010 and 2018

Year	AKILE	BOX	Cadence	Hintegra	INBONE	Infinity	Mobility	Rebalance	Salto Mobile Version	STAR	Taric	Zenith	**Total**
2010[a]	–	23	–	15	–	–	254	–	23	14	–	78	**407**
2011	–	29	–	18	–	–	294	4	28	28	–	108	**509**
2012	–	44	–	34	2	–	280	13	38	31	1	125	**568**
2013	–	47	–	62	1	–	180	13	43	32	–	124	**502**
2014	–	83	–	50	21	27	85	7	55	60	–	157	**545**
2015	6	133	–	53	19	92	–	4	55	82	–	157	**601**
2016	8	125	–	39	57	213	–	13	51	78	–	111	**695**
2017	10	109	–	22	51	381	–	7	9	97	–	60	**746**
2018	10	95	11	25	65	494	–	2	10	101	–	77	**890**
Total	**34**	**688**	**11**	**318**	**215**	**1207**	**1093**	**63**	**312**	**523**	**1**	**1024**	**5463**

AKILE (Lavender Medical, Stevenage, UK); Bologna–Oxford (BOX) (Finsbury, Leatherhead, UK); Cadence (Integra, Plainsboro, NJ); Hintegra (Integra, Saint Priest, France); INBONE (Wright Medical Technology, Memphis, TN); Infinity (Wright Medical Technology, Memphis, TN); Mobility (DePuy UK, Leeds, England); Rebalance (Biomet UK Ltd, Bridgend, South Wales, England); Salto Mobile Version (Tornier S.A.S. Montbonnot Saint-Martin, France); Scandinavian Total Ankle Replacement (STAR, Waldemar Link, Hamburg, Germany); Taric (Taric (Implantcast GmbH, Buxtehude, Germany); Zenith (Corin Group PLC, Cirencester, England). [a]2010 data includes 13 TAR implanted prior to 2010

Table 2.4 Finnish Arthroplasty Register specific to total ankle replacement between 2000 and 2006

Year	AES	Hintegra	STAR	**Total**
2000	–	–	43	**43**
2001	–	–	53	**53**
2002	14	–	46	**60**
2003	67	–	20	**87**
2004	79	–	3	**82**
2005	81	2	6	**89**
2006	57	10	10	**77**
Total	**298**	**12**	**181**	**491**

Ankle Evolutive System (AES) (Transysteme JMT Implants, Nimes, France); Hintegra (Integra, Saint Priest, France); Mobility (DePuy U.K., Leeds, England); Scandinavian Total Ankle Replacement (STAR, Waldemar Link, Hamburg, Germany)

The Dutch Arthroplasty Register was initiated in 2007 and has included TARs since 2014. The Dutch Arthroplasty Register "Annual Report 2019" in addition to previously published annual reports was accessed to compile data from 2014 through 2018 [4]. A total of 605 prostheses were reported. There is a discrepancy between the total numbers of primary implants with not all specific prosthesis reported. The most common prosthesis was the Salto Mobile ($n = 271$; 44.8%). The next most common prosthesis was the AAA implant ($n = 74$; 12.2%); however, an increase in the use of the Infinity implant is evident beginning in 2017 (Table 2.8).

The New Zealand National Joint Registry, initiated in January 2000, has included primary TAR since inception [5]. From our previous publication, we were able to procure additional data relevant to primary TARs performed from 2000 to 2006 [11]. In total, 1627 prostheses involving 10 different implant designs have been reported. From 2000 through 2010, 727 primary TARs were reported (mean 66 per year), and from 2011 through 2018, 900 primary TARs were performed (mean 113 per year). The Salto Mobile Version was the most common prosthesis ($n = 727$; 45%). The next most common prosthesis was the Mobility ($n = 450$; 28%); however, this prosthesis underwent a sharp decline in use beginning in 2012 with the last reported use in 2014 (Table 2.5).

The Norwegian Arthroplasty Register, initiated in 1987, has included primary TARs since January 1994. The Norwegian Arthroplasty Register "Report 2019" in addition to previous publications compiled a complete dataset from 2000 through 2018 [6, 38]. A total of 1183 prostheses were reported. From 2000 through 2010, 549 primary TARs were reported (mean 55 per year), whereas from 2011 through 2018, 634 primary TARs were recorded (mean 79 per year). The most frequently implanted prosthesis was the STAR ($n = 576$; 48.7%); however, it has been implanted only once since 2013. The next most common prosthesis from 2013 onward has been the Salto Talaris ($n = 317$; 26.8%) (Table 2.6).

The Swedish Joint Registry for total ankle replacements was initiated in 1997. "The Swedish Joint Registry Annual Report for 2018," along with previously published relevant manuscripts, offers pertinent data for primary TAR from 2000 through 2018 [7, 35]. A total of 1250 prostheses were reported. From 2000 through 2010, 713 primary TARs were reported (mean 71 per year), whereas from 2011 through 2018, 537 primary TARs were performed (mean 67 per year). The most common prosthesis was the Mobility ($n = 282$; 22.6%), but it has not been in use since 2015. The next most common prosthesis was the Rebalance ($n = 203$; 16.2%); however, its use underwent a sharp decline in 2018 in favor of the Trabecular Metal implant (Table 2.7).

Several other countries have included ankle replacements in NJR that are at too young of an age or too limited in scope to provide significant data. The German Orthopaedic Foot and Ankle Society established a voluntary register in 2011. A 2014 report indicated that less than 10% of the providers performing TAR were involved in the register and approximately 12% of the annual prostheses implanted were included; thus, it is far from inclusion as a NJR. If reports to this register were completed at 100% and all 1300 TARs

Table 2.5 Norwegian Arthroplasty Register specific to total ankle replacement between 2000 and 2018

Year	AES	Cadence	CCI	Hintegra	Mobility	Rebalance	Version	Salto Talaris	STAR	Metal	**Total**
2000	–	–	–	–	–	–	–	–	18	–	**18**
2001	–	–	–	–	–	–	–	–	29	–	**29**
2002	–	–	–	–	–	–	–	–	36	–	**36**
2003	–	–	–	–	–	–	–	–	25	–	**25**
2004	3	–	–	2	–	–	–	–	34	–	**39**
2005	–	–	–	4	–	–	–	–	36	–	**40**
2006	–	–	–	1	–	–	–	–	62	–	**63**
2007	–	–	–	2	4	–	–	–	52	–	**58**
2008	–	–	4	1	2	–	–	–	60	–	**67**
2009	–	–	12	1	25	–	–	–	57	–	**95**
2010	–	–	13	–	26	–	–	–	40	–	**79**
2011	–	–	17	–	16	7	–	–	50	–	**90**
2012	–	–	12	–	12	8	11	–	39	–	**82**
2013	–	–	11	–	15	–	1	26	38	–	**91**
2014	–	–	9	–	–	–	–	62	0	3	**74**
2015	–	–	–	–	–	–	–	85	1	3	**89**
2016	–	–	–	–	–	–	–	81	–	16	**97**
2017	–	2	–	–	–	–	–	28	–	22	**52**
2018	–	4	–	–	–	–	–	35	–	20	**59**
Total	**3**	**6**	**78**	**11**	**100**	**15**	**12**	**317**	**576**	**64**	**1183**

Ankle Evolutive System (AES) (Transysteme JMT Implants, Nimes, France); Cadence (Integra, Plainsboro, New Jersey)CCI Evolution (Implantcast GmbH, Lüneburger Schanze, Buxtehude, Germany); Hintegra (Integra, Saint Priest, France); Mobility (DePuy UK, Leeds, England); Rebalance (Biomet UK Ltd, Bridgend, South Wales, England); Salto Mobile Version (Tornier S.A.S., Montbonnot Saint-Martin, France); Salto Talaris (Integra, Plainsboro, New Jersey); Scandinavian Total Ankle Replacement (STAR, Waldemar Link, Hamburg, Germany); Trabecular Metal (Zimmer, Warsaw, Indiana)

Table 2.6 New Zealand National Joint Registry specific to total ankle replacement between 2000 and 2018

Year	Agility	BOX	Hintegra	Infinity	Mobility	Ramses	Version	Salto Talaris	STAR	Metal	**Total**
2000	10	–	–	–	–	–	–	–	6	–	**16**
2001	20	–	–	–	–	–	–	–	8	–	**28**
2002	17	–	–	–	–	–	–	–	11	–	**28**
2003	17	–	–	–	–	–	–	–	9	–	**26**
2004	29	–	–	–	3	6	–	–	10	–	**48**
2005	25	–	–	–	34	5	5	–	1	–	**70**
2006	1	–	–	–	47	–	33	–	–	–	**81**
2007	–	–	–	–	49	–	29	–	1	–	**79**
2008	–	–	–	–	62	–	45	–	–	–	**107**
2009	–	2	–	–	79	–	38	–	–	–	**119**
2010	–	–	–	–	76	–	49	–	–	–	**125**
2011	–	1	–	–	64	–	44	–	–	–	**109**
2012	–	1	5	–	29	–	73	–	–	–	**108**
2013	–	2	4	–	6	–	101	–	–	–	**113**
2014	–	–	3	–	1	–	96	–	–	2	**102**
2015	–	–	8	6	–	–	64	23	–	–	**101**
2016	–	–	2	19	–	–	70	19	–	9	**119**
2017	–	–	–	41	–	–	50	18	–	13	**122**
2018	–	–	–	45	–	–	30	32	–	19	**126**
Total	**119**	**6**	**22**	**111**	**450**	**11**	**727**	**92**	**46**	**43**	**1627**

Agility (DePuy Orthopaedics, Inc, Warsaw, IN); Bologna–Oxford (BOX) (Finsbury, Leatherhead, UK); Hintegra (Integra, Saint Priest, France); Infinity (Wright Medical Technology, Memphis, TN); Mobility (DePuy UK, Leeds, England); Ramses (Laboratoire Fournitures Hospitalières Industrie, Heimsbrunn, France); Salto Mobile Version (Tornier S.A.S. Montbonnot Saint-Martin, France); Salto Talaris (Integra, Plainsboro, NJ); Scandinavian Total Ankle Replacement (STAR, Waldemar Link, Hamburg, Germany); Trabecular Metal (Zimmer, Warsaw, IN)

Table 2.7 Swedish Joint Registry Register specific to total ankle replacement between 2000 and 2018

Year	AES	BP	CCI	Hintegra	Mobility	Rebalance	STAR	Metal	**Total**
2000	–	2	–	–	–	–	45	–	**47**
2001	–	0	–	–	–	–	48	–	**48**
2002	3	0	–	–	–	–	40	–	**43**
2003	18	42	–	–	–	–	25	–	**85**
2004	17	44	–	–	–	–	17	–	**78**
2005	23	42	–	–	8	–	18	–	**91**
2006	21	14	–	–	21	–	7	–	**63**
2007	18	6	–	–	21	–	1	–	**46**
2008	17	4	16	–	35	–	–	–	**72**
2009	–	–	40	–	34	–	–	–	**74**
2010	–	–	23	–	43	–	–	–	**66**
2011	–	–	17	–	45	21	–	–	**83**
2012	–	–	32	–	27	23	–	–	**82**
2013	–	–	12	–	32	34	–	–	**78**
2014	–	–	4	–	15	37	–	5	**61**
2015	–	–	2	3	1	33	–	11	**50**
2016	–	–	–	8	–	24	–	20	**52**
2017	–	–	–	17	–	26	–	23	**66**
2018	–	–	–	12	–	5	–	48	**65**
Total	**117**	**154**	**146**	**40**	**282**	**203**	**201**	**107**	**1250**

Ankle Evolutive System (AES) (Transysteme JMT Implants, Nimes, France); Büechel–Pappas (BP) (Endotec, South Orange, NJ); CCI Evolution (Implantcast GmbH, Lüneburger Schanze, Buxtehude, Germany); Hintegra (Integra, Saint Priest, France); Mobility (DePuy UK, Leeds, England); Rebalance (Biomet UK Ltd, Bridgend, South Wales, England); Scandinavian Total Ankle Replacement (STAR, Waldemar Link, Hamburg, Germany); Trabecular Metal (Zimmer, Warsaw, Indiana)

Table 2.8 Dutch Arthroplasty Register specific to total ankle replacement between 2014 and 2018

Year	AAA	Box	Cadence	CCI	Hintegra	Infinity	Mobility	Salto	**Total**
2014	–	–	–	37	15	–	–	40	**107**
2015	16	–	–	16	0	–	–	42	**106**
2016	22	6	–	12	1	–	2	56	**132**
2017	20	2	–	–	–	5	–	65	**116**
2018	16	4	2	–	–	39	–	68	**144**
Total	**74**	**12**	**2**	**65**	**16**	**44**	**2**	**271**	**605**

AAA (Alpha Ankle Arthroplasty, Alphamed, Lassnitzhöhe, Austria); Bologna-Oxford (BOX) (Finsbury, Leatherhead, UK); Cadence (Integra, Plainsboro, New Jersey); CCI Evolution (Implantcast GmbH, Lüneburger Schanze, Buxtehude, Germany); Hintegra (Integra, Saint Priest, France); Infinity (Wright Medical Technology, Memphis, Tenessee); Mobility (DePuy UK, Leeds, England)

implanted annually in Germany were included in our study, it would almost double the total number of implants reported to NJRs on an international level and be the single largest country contribution. The registry does not include data regarding which specific implant was utilized; however, it does note that all primary TARs included in the study were 3-component, mobile-bearing, cementless prostheses [40].

Additional registries of note include the Portuguese Arthroplasty Register, which has been active since 2009, however has only one annual report from 2010 that included 6 TARs [41]. The Italian Arthroplasty Registry Project started to publish annual reports in 2014, with the 2017 annual report being the first to include TAR. In total, 492 primary TARs were reported, but few further specifics were defined [42]. The Scottish Arthroplasty Project has collected data on primary TAR since 1997 and demonstrates an increase from 14 in 2001 to a high of 101 performed in 2017. Unfortunately, the Scottish Arthroplasty does not provide prosthesis specific information [43]. In Japan, data pertaining to TAR have been extracted from the Diagnostic Procedure Combination database, a national inpatient acute care registry; however, this represents only approximately 50% of all patients with a total of 465 TARs identified between 2007 and 2013 [44].

Discussion

The purpose of this analysis was to investigate and interpret the available NJRs with data pertinent to primary TAR and provide observational trends. A total of 24 TAR systems were identified for use between 2000 and 2018 from seven countries that reported data on a national level. A total of 12,743 primary TARs were identified throughout the studied timeframe with 24 unique prosthetic models identified. Removing the Finnish NJR data due to lack of recent

updates and TARs with less than 15 total uses decreases the total number of implants reported to NJRs from 2000 through 2018 from 12,743 to 12,237. Since 2013, eight new TAR models have been introduced. The majority of these models are fixed, 2-component prostheses. Although the Mobility is no longer in use, the STAR has remained in consistent use in some markets and, until recently, was the only mobile-bearing option in the USA market. Fixed-bearing designs with 2-components allow for stable articulation and a decreased risk of subluxation, however may be at a higher risk of loosening at the tibial component secondary to shear forces if mal-aligned [45]. A mobile-bearing prosthesis allows for more flexible articulation, however may be more susceptible to subluxation [45]. The conceptual argument regarding mobile versus fixed bearing can be demonstrated in comparisons between the Salto Mobile and Salto Talaris models. Roukis and Elliott performed a systematic review comparing the incidence of revision in Salto Mobile and Salto Talaris prostheses [46]. The overall revision rate for Salto Mobile was 4% and 2.4% in the Salto Talaris. Gaudot et al. performed an often-cited retrospective comparison of matched Salto Mobile and Salto Talaris cases [33]. They found no significant difference in clinical outcomes between groups, based on reported short-term outcomes. Continuing to follow usage trends of primary TAR implantation over the next several years via NJR data will provide great surgeon and industry insight regarding categorical TAR selection, while the current trend demonstrates a growing interest in and usage of 2-component, fixed-bearing systems.

Overall, four usage trends were identified by our analysis. Some prostheses remained in the same categories as previous publications. However, the use of other prostheses deviated from the previously speculated trend. The most commonly implanted prosthesis, the Infinity, is newer to the market and not included in previous publications. In 2018, it was recorded in NJR 631 times, or 42% of all recorded implants for the year. In previous publications, the Mobility was the most commonly implanted TAR based on NJR data. It is now categorized in the abandonment group and has been removed from the market [39]. The Hintegra Mobile Bearing, Salto Mobile, and Zenith TAR which were all previously classified in the sustained growth category are now demonstrating diminished use. In the current sustained group, only the BOX total ankle system has remained in comparison to previous studies. Overall, older models have demonstrated a decrease in use in favor of new market options. The STAR, which was classified as diminished use in previous publications, is the only exception and has reported increased use in NJR in recent years. It has not, however, returned to peak use, and the implant is primarily only reported to the England, Wales, and Northern Ireland National Joint Replacement Registry. This demonstrates the importance of continual monitoring of available NJR data and depicts the rapid evolution of the topic of primary TAR.

It is also important to recognize the significant contribution made to our overall dataset by the NJR from England, Wales, and Northern Ireland since 44.2% of the TAR included in our publication and analysis are derived from this NJR (Fig. 2.8). Australia makes the second largest contribution at

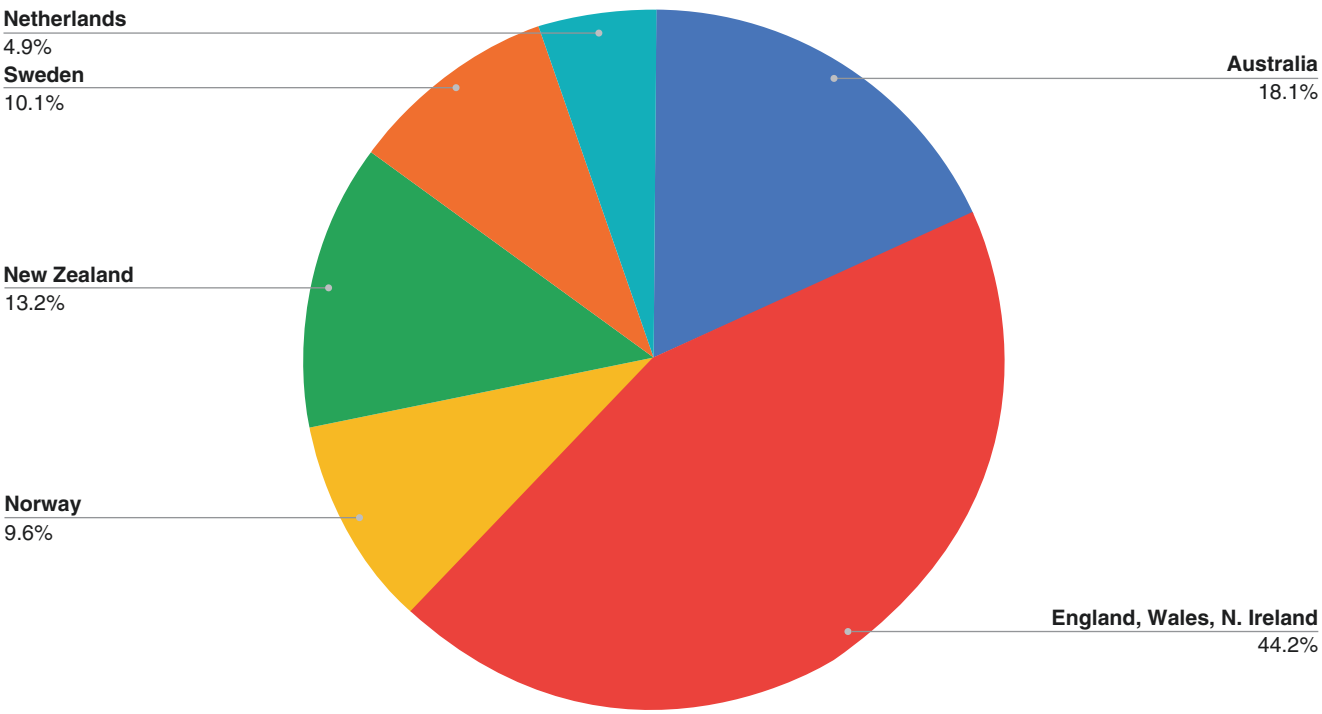


Fig. 2.8 Cumulative contribution of individual national joint registries 2000–2018

18.1%. The trends we report must be interpreted with the underlying knowledge that each country is not represented equally and factors at stake outside of the quality of the implant, such as delays in regulatory approval, play a role in TAR use on a national level.

Although the benefits of an international joint registry are obvious, to date one has not yet been created. The data collected by individual NJRs are variable and tailored to address each country's objectives. For each NJR, individual strengths exist, but none is without flaw. In Sweden, as of 2018, the registry completeness is reported as 100% for primary TARs and provides >20 years' worth of data [7]. Importantly, it also provides comparative data regarding ankle arthrodesis. New Zealand provides extensive detail about the primary TAR procedure including type of operative theater, antibiotic usage, cement usage, surgical approach, and bone grafting, in addition to detailed patient demographics [5]. Australia provides detailed information regarding revision TAR while accurately identifying the difference between a simple polyethylene exchange and a major metallic component revision when categorizing revision TAR captured by the registry [2]. Ultimately, several examples of quality data collection exist and many of the available NJR annual reports publish the questionnaire that is completed by the surgeon or institution at the time of the procedure to detail the pertinent data.

NJR data are not without flaw. In some of the countries providing pertinent data, registry completeness is not well understood which offers uncertainty if usage patterns described within the registry accurately depict the overall usage of various prostheses within that country. Additionally, a risk of reporting duplicate data exists when surgeons submitting results to the respective NJR are additionally publishing manuscripts involving the same patient cohorts in peer-reviewed journals. In addition, some complications, such as below-the-knee amputations, may not be included in NJR relying on surgeon reports because the surgeon performing the amputation may be of a different specialty and not responsible to the registry. This needs to be well understood by surgeons interpreting these data, as well as by researchers performing meta-analyses or systematic reviews to accurately interpret the data. Selection bias may exist in those registries that allow voluntary participation. Also, the interpreter of NJR data needs to be cognizant that inventor data may be included and associated bias likely still exists [27]. The data collection process is highly dependent on the individual surgeon reporting the data, and unfortunately, a lack of uniformity may exist among various submissions to an individual registry by different surgeons, as well as to an even greater extent when comparing submissions among various registries as the requested information for collection is not standardized on an international level.

Conclusions

We performed an observational analysis and update to our groups previous work regarding trends in primary TAR use based on NJRs from 2000 through 2018 including all pertinent worldwide data. We identified 12,743 primary TARs from seven countries. From the available data, we identified four distinct use patterns: abandonment, minimal use, embracement with diminished use, and embracement with sustained growth. Interestingly, when compared to our groups' previous work on this topic, several prostheses are categorized differently. This indicates that primary TAR based on NJR data is a rapidly evolving topic requiring close monitoring and frequent reporting of pooled data. Changes in trends are likely to continue in the coming years especially with more two-component fixed-bearing prostheses available in the international market. We encourage surgeons and industry to remain cognizant of this important yearly data as it becomes freely available to the public via annual reports. We should continue to make informed choices about patient and implant selection when performing primary TAR. Ultimately, supporting continued efforts to collect NJR data in the USA pertinent to primary and revision TAR would be beneficial and help guide evidence-based medical decisions.

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Mobile-Bearing Versus Fixed-Bearing Total Ankle Replacement

3

Murray J. Penner and Husam A. Al-Rumaih

Introduction

Much controversy exists in the general arthroplasty literature regarding bearing options [1]. One particularly robust facet of this debate has revolved around the choice between fixed-bearing designs and mobile-bearing designs. Although the majority of this discussion over the past few decades has focused on bearing choices in total knee arthroplasty, the controversy remains very active within the total ankle replacement (TAR) domain as well. One of the primary reasons for the ongoing debate is that both mobile- and fixed-bearing concepts have noteworthy theoretical advantages and disadvantages. At the same time, both designs are capable of yielding excellent patient outcomes as well as potential failures.

Origins of the Mobile-Bearing Concept: Total Knee Arthroplasty

In total knee arthroplasty, a fixed-bearing design (Fig. 3.1) relies on motion occurring between the femoral component and polyethylene bearing. Kinematic studies of the normal knee demonstrate that a complex motion occurs at the bearing surface involving not only angular sagittal plane range of motion, but also anterior–posterior translation, axial rotation, and femoral condylar liftoff [2]. In order to accommodate these additional movements, fixed-bearing designs feature a lower degree of conformity within the bearing design [3]. This type of design results in a round-on-flat articulation with increased sliding anterior–posterior translation movements along the bearing. These may result in higher contact pressures, polyethylene delamination, and ultimately increased polyethylene wear [4]. In order to decrease wear, the bearing may be designed with a higher degree of conformity which maximizes contact area and bearing wear characteristics but, as a consequence, may transmit greater translational and rotational stresses to the bone–implant interface. These potentially greater stresses may contribute to aseptic loosening [5].

In order to obtain the wear benefits of a highly conforming bearing surface, the mobile-bearing concept was developed to allow anteroposterior translation and axial rotation to occur between the polyethylene bearing's undersurface and a high polished tibial component [6, 7]. These are typically either rotating platform bearings (Fig. 3.2a) or meniscal bearings (Fig. 3.2b). However, these designs also introduce a potential new source of "backside wear" at this interface [8–10].

Since its inception, there have been multiple reports on the theoretical benefits of mobile bearings over fixed bearings [11]. However, despite these theoretical issues, numerous clinical studies comparing the two designs have failed to show a significant difference in any outcome parameters [12–17]. Moreover, in a landmark study by Kim et al. [18], a prospective study of 108 patients under age 51 with bilateral knee arthritis where patients were randomized to receive a fixed-bearing total knee arthroplasty in one knee and a mobile-bearing version of the otherwise identical total knee arthroplasty in the contralateral knee, no difference between fixed- and mobile-bearing designs, was found in range of motion, functional scores, complications, or radiographic loosening at 16.8-years mean follow-up. In fact, the editorial comment on this paper went on to call for the cessation of further research in this area given the clear, well-defined fact that there is no meaningful clinical difference between the two designs [19]. Even further support for this perspective followed in 2013 in an authoritative meta-analysis of 6861 knees which concluded there was no difference in the

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Fig. 3.1 Total knee system demonstrating a fixed-bearing design where polyethylene is locked into the tibial baseplate

incidence of radiolucent lines, osteolysis, aseptic loosening, or survival between mobile- and fixed-bearing knee designs [20]. Despite this recent clarity in the total knee arthroplasty domain, the issue continues to be a topic of debate in the field of TAR.

TAR Bearing Designs

Bearing Configurations

Currently, two general bearing designs exist in TAR. A two-part prosthesis refers to a fixed-bearing design where the polyethylene bearing is fixed to the tibial component via a locking mechanism (Fig. 3.3a). A three-part prosthesis refers to a mobile-bearing design (Fig. 3.3b). In mobile-bearing designs, the flat superior surface of the polyethylene articulates with a highly polished tibial component, while the concave inferior surface of the polyethylene articulates with a convex talar component.

Rationale for Alternative Bearing Designs

The rationale for considering various bearing configurations parallels that seen in total knee arthroplasty. Since polyethylene wear debris has been strongly linked to aseptic loosening in total hip replacement [3] and since aseptic loosening has been identified as the leading cause of failure in TAR [21, 22], reduction of wear debris has been assumed to be important in TAR. However, only one study has thus far quantified in vivo wear debris in TAR [23] and the few studies available thus far suggest the role of polyethylene debris in early aseptic loosening may be minimal [24, 25]. Nevertheless, as with knee arthroplasty, the mobile bearing was introduced in TAR in an attempt to utilize the theoretical advantages of potentially decreased polyethylene wear and potentially improved kinematics of the ankle.

Advantages of Fixed-Bearing Ankle Designs

Fixed-bearing designs are felt to offer some benefits over mobile-bearing designs. Proposed advantages include a prosthesis which recreates the normal anatomy of the ankle with stable fixed "plafond" of the tibial component/polyethylene which articulates with a mobile talus which has been resurfaced with a highly polished component. Additionally, avoidance of some of the concerns associated with mobile-bearing designs described below is also noted as a potential benefit.

Concerns with Fixed-Bearing Ankle Designs

Much like the knee, range of motion at the ankle does not occur purely in the sagittal plane but also includes axial rotation [26, 27]. In TAR designs with fixed bearings and highly congruent bearing interfaces, stresses transferred to the bone–implant interface may be increased. This has been demonstrated in finite element analysis, and this has led some designers to incorporate intramedullary fixation in an attempt to transfer stress proximally to the tibial shaft [28]. However, this was not the case with modern fixed-bearing designs [29]. Additionally, the use of fixed-bearing prostheses may result in a thicker tibial component overall to accommodate the locking mechanism for the polyethylene bearing; this in turn may result in the need for a more substantial tibial bone resection. Since distal tibial metaphyseal bone becomes weaker moving proximal from the tibial pla-

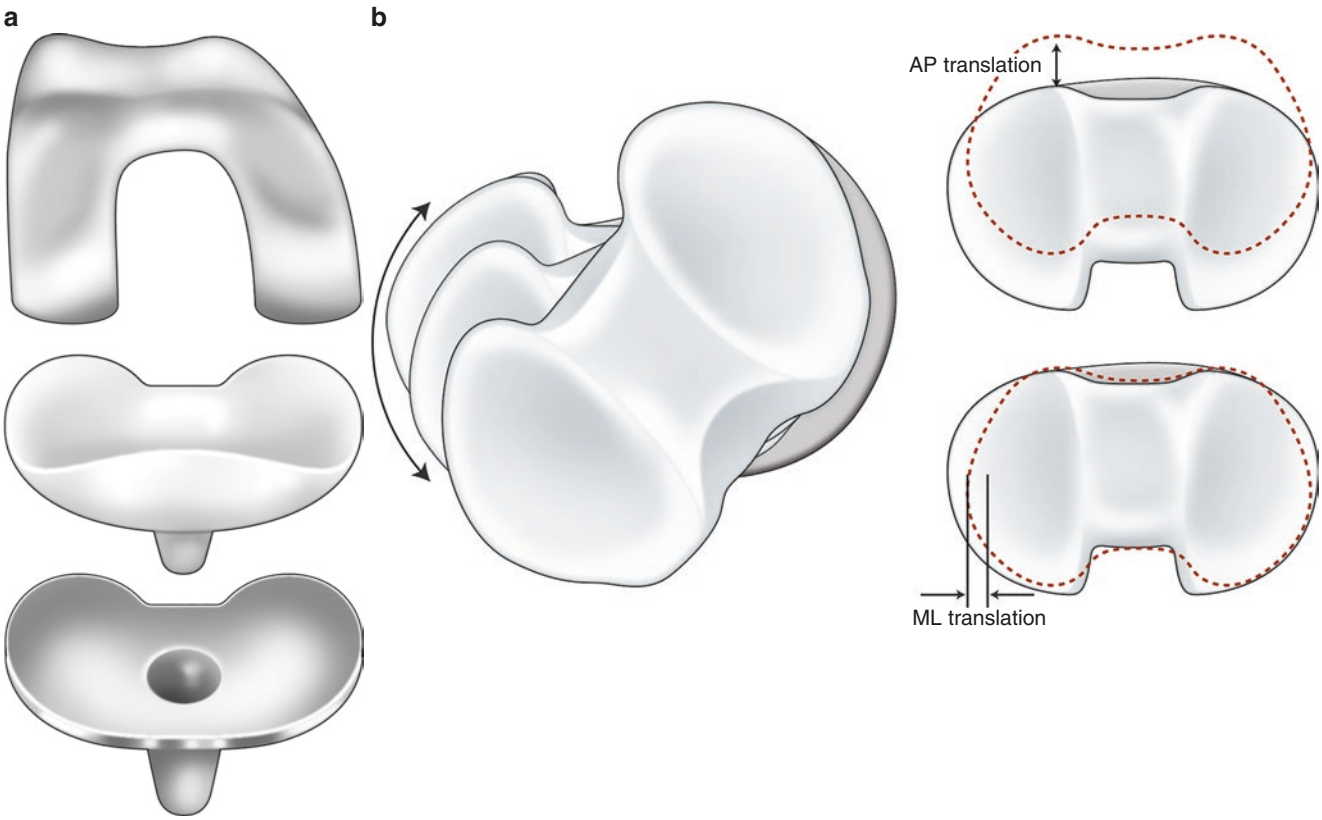


Fig. 3.2 Examples of mobile bearings in total knee arthroplasty. (**a**) Rotating hinge-type design where a conical polyethylene post exits the inferior surface of the polyethylene bearing and loosely fits into a matching cone on the tibial base plate to permit rotation at this interface. (**b**) Meniscal bearing type demonstrating AP and ML translation as well as rotation at the polyethylene/tibial baseplate interface

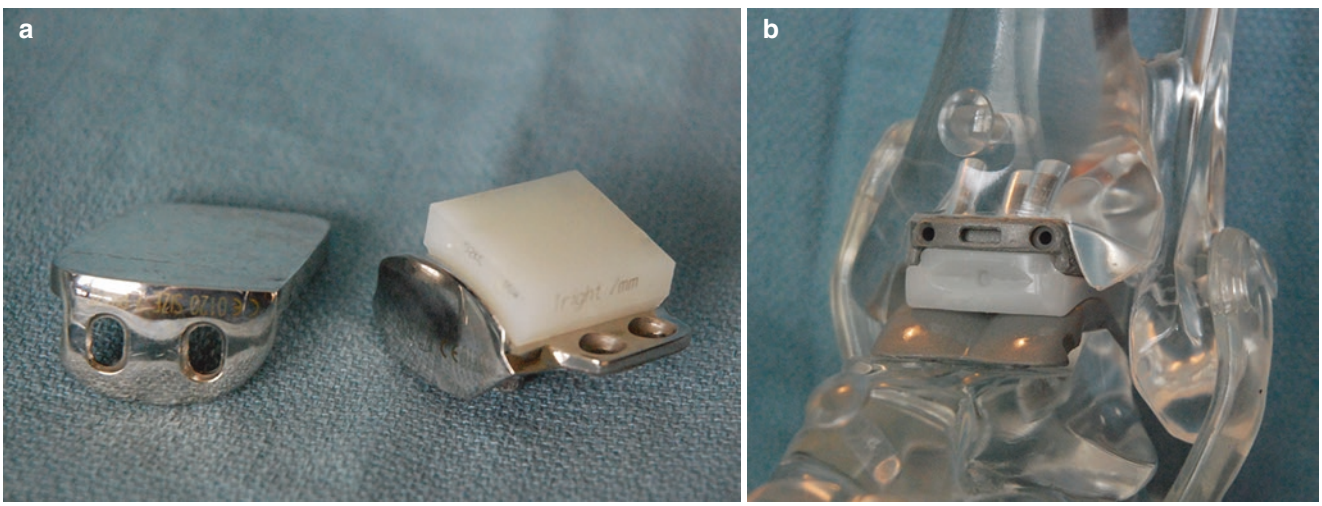


Fig. 3.3 Examples of bearings in total ankle replacements. (**a**) Hintegra mobile-bearing total ankle (Newdeal, Lyon, France/Integra, Plainsboro, New Jersey). (**b**) Wright Medical Infinity Total Ankle (Wright Medical, Memphis, TN)

fond, a more proximal resection may cause the tibial component to rest on the weaker proximal metaphyseal bone as opposed to the firm subchondral bone [30]. Without good rim fit of the prosthesis along the anterior and posterior cortices, early subsidence of the prosthesis may be a risk. However, in view of these issues, modern tibial component design, including most fixed-bearing designs, has now focused on resurfacing-type cuts with relatively thin tibial components such that subchondral plate can provide support (Fig. 3.3).

Implantation of TAR components in the correct position of axial rotation is critical for satisfactory function. Correct axial rotation includes the rotational alignment of the tibial component to the ankle mortise (tibia and fibula), the rotational alignment of the talar component to the talus, and the correct alignment of the talar component to the tibial component. In a mobile-bearing design, this latter issue is generally avoided, since the talar component can take on any axial position in relation to the tibial component in an unconstrained way. However, in fixed-bearing design, this alignment is made to occur through the relative constraint of the bearing. Hence, achieving appropriate axial positioning of both components is vital in fixed-bearing designs. Because of the relatively congruent articulation between fixed-bearing components, malrotation of the components in relation to each other can result in incronguency and accelerated wear of the bearing. In an in vitro study of the now-historic Agility Total Ankle Replacement System (DePuy Orthopaedics, Warsaw, IN) fixed-bearing prosthesis, six fresh-frozen cadavers were used to evaluate the effects of malrotated talar components. The investigators applied static axial loads and ten different simulated dynamic loads to the Agility Total Ankle Replacement System implanted with the talar component in neutral, 7.5 degrees of internal and 7.5 degrees of external rotation. Using pressure sensors, the authors were able to show significantly decreased contact area, increased peak pressure, and increased rotational torque on the bearings in malrotated implants, indicating that this particular fixed-bearing design is not highly tolerant of malrotation [30, 31]. Other authors who also studied the fixed-bearing Agility Total Ankle Replacement System design, comparing it to the Mobility (DePuy Orthopaedics, Warsaw, IN) mobile-bearing design, found that for both designs, malrotations greater than 5° resulted in increased pressures [32]. However, the mobile-bearing design showed somewhat less sensitivity to misalignment. Nevertheless, most modern fixed-bearing designs have been developed to accommodate some rotational malalignment in order to minimize any peak stresses to the polyethylene bearing and bone–implant interface (Fig. 3.4).

In comparison to fixed-bearing designs, mobile-bearing designs allow rotation and anterior–posterior translation to occur between the polyethylene and the tibial components. Theoretically, malrotated components may correct their alignment through this flat-on-flat articulation while maintaining congruency in the talar component/polyethylene bearing articulation, potentially avoiding a transfer of significant stress to the bone–implant interface. Thus, the use of a mobile-bearing design may seem less technically demanding on the surgeon since emphasis on tibial component rotation may not be as crucial. However, the tolerance for malrotation between the tibial and talar components in a mobile-bearing design remains very limited, since significant malrotation may still yield increased peak pressures [32] and will cause the bearing to become uncovered by the tibial component, leading to edge loading of the bearing and



Fig. 3.4 Wright Medical Infinity Total Ankle (Wright Medical, Memphis, TN) with fixed bearing, demonstrating decreased conformity at the bearing interface to allow internal and external rotation. *Arrows* indicate internal and external rotation through the bearing surface at the ankle joint

accelerated polyethylene wear. Further, axial positioning of the talar component on the talus remains crucial to avoid any binding within the malleoli.

In a biomechanical finite element study to compare bone loading with both bearing configurations, Terrier et al. [33] found only slight differences between fixed and mobile bearing, with no evident superiority of one of these implant configurations regarding their reaction to axial compression. Queen et al. compared the gait mechanics between the two designs and did not identify any significant differences [34].

Despite what may be perceived as biomechanical advantages of the mobile bearings, there are a number of potential disadvantages. The additional flat-on-flat articulation creates "backside" wear, which can be an additional source of wear and polyethylene debris. Although aseptic loosening has not been directly linked to polyethylene debris in TAR literature [35], extrapolation from the total knee and hip literature would suggest that its presence in the effective joint space may still be a contributor to prosthetic loosening. Thus, any additional sources of debris may be detrimental to the longevity of the implant. Without a locking mechanism, the polyethylene insert may dislocate, though this has proven to be relatively rare.

Further concerns with respect to the mobile-bearing designs include the need for flat-on-flat articulation at the tibial component-bearing interface. Such designs lead to edge loading of the polyethylene bearing in any situation where there is any ligamentous imbalance and perfect flat-on-flat contact is lost. This has been described for the Scandinavian Total Ankle Replacement (STAR) (Stryker Orthopaedics, Inc., Kalamazoo, MI) in particular and may contribute to the high rates of polyethylene bearing fracture described by some investigators [36, 37].

Additionally, and perhaps most importantly, in mobile-bearing designs, the talus may translate medially and laterally through the flat-on-flat articulation, in addition to rotating axially, which can result in malleolar impingement and may be a significant cause of medial and lateral ankle pain (Fig. 3.5).

Unlike the total knee arthroplasty literature where a plethora of comparative studies exist, other than the above-noted biomechanical studies, few clinical studies exist comparing mobile-bearing ankle designs to fixed-bearing designs. In a 2014 retrospective study comparing 33 consecutive fixed-bearing Salto Talaris Anatomic Ankle (Tornier, Bloomington, MN) ankles to 33 paired mobile-bearing Salto Mobile Prosthesis, no statistical difference was found between the two in terms of radiographic assessment of component positioning, clinical and radiographic range of motion, and morbidity at 24-month follow-up [39]. However, the fixed-bearing group had significantly higher American Orthopaedic Foot and Ankle Society scores at final follow-up (90 vs. 85), less radiolucent lines (4 vs. 13), and fewer subchondral cysts (1 vs. 8). The authors concluded there was no evidence to suggest any inferiority of the fixed-bearing design compared to the mobile bearing. More recently, Nunley et at. and his group published the results of their randomized clinical trial with a minimum 2-year follow-up and a mean of 4.5 years comparing mobile-bearing (STAR) (Stryker Orthopaedics, Inc., Kalamazoo, MI) with fixed-baring (Salto Talaris Anatomic Ankle (Tornier, Bloomington, Bloomington, MN) TAR [40]. In their study, they concluded there was no significant difference in patient reported outcomes between the two groups. However, the mobile-bearing group had a higher revision rate mainly due to talar cyst formation and talar component subsidence. Talar lucency/cyst formation occurred in 24.3% of the mobile-bearing group compared to 2.0% in the fixed-bearing group. The authors anticipated that a longer follow-up may identify clinical correlation to their radiological findings.



Fig. 3.5 Anterior–posterior radiograph of a STAR with medial malleolar impingement and contact with the medial mortise [38]. (Reprinted from Richardson et al. [38]. With permission from Springer Nature)

Conclusion

As noted above, there is little biomechanical data and even less clinical data currently available to inform the choice between mobile- and fixed-bearing designs in TAR. Most of the data that are available have studied a historic fixed-bearing design that is nonsimilar to current designs, rendering most of this sparse literature irrelevant. The remaining information suggests that any differences that may exist are likely small at most, with many other design and implementation factors likely to be substantially more important. Though extrapola-

tion of total knee arthroplasty literature to the TAR realm must be done with caution, the lack of any significant difference between bearing types seen in knee replacement despite vigorous study lends support to the likelihood that the minimal or nonexistent differences between bearing designs thus far seen in TAR literature are representative.

In conclusion, evidence to date points away from any clinically significant differences between the two bearing designs. Surgeons are likely best advised to focus on other areas known to affect implant survival such as patient selection, deformity correction and realignment of both the ankle and foot, ligamentous stability, and surgeon experience [35, 41].

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Total Ankle Replacement Versus Ankle Arthrodesis

4

Anthony Habib, Monther Abuhantash, Kevin Wing, and Andrea Velkjovic

Introduction

Hip, knee, and ankle arthritis is a debilitating condition, and the prevalence usually increases with age. Arthritis currently affects an estimated 60% of the US population over the age of 65 [1], with end-stage ankle arthrosis being 6% of the population [2]. Glazebrook et al. [3] demonstrated that the mental and physical disability associated with end-stage ankle arthrosis is as severe as that associated with hip arthrosis with poorer mental component scores. Osteoarthritis remains the primary etiology of hip and knee arthritis, whereas post-traumatic arthritis (78%) is the most common etiology for end-stage ankle arthritis [4]. Traditionally, end-stage ankle arthrosis has been managed with ankle arthrodesis. Total ankle replacement (TAR) has become an increasingly popular option due to recent advances in prosthetic design and implantation, as well as improved clinical results (new design article and previous chapter reference). The goal of this chapter is to provide an updated evidence-based review of the literature on ankle arthrodesis which includes open vs arthroscopic arthrodesis, TAR, and direct comparison of both procedures. An extensive review of the literature has been undertaken, with a focus on recently published studies. Although the literature has improved since 2013 in terms of advantages and disadvantages of arthrodesis vs arthroplasty, it is still not sufficiently robust to provide a simple algorithm for determining the best surgical option for a particular patient. Furthermore, the chapter aims to provide surgeons with the best evidence currently available to allow for informed surgical decision making including information from the previous edition.

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Ankle Arthrodesis

Ankle arthrodesis has long been considered the most reliable surgical option for end-stage ankle arthrosis [5–22]. This section will review the current literature surrounding various topics related to ankle arthrodesis, including surgical technique, the increased use of arthroscopic ankle arthrodesis, gait analysis, complications, adjacent joint degeneration, and functional outcomes.

Surgical Techniques

Historically, ankle arthrodesis was performed using immobilization in a plaster of Paris cast [23]. In 1951, Sir John Charnley described an arthrodesis technique using external fixation [12], which was used by surgeons for many years until internal fixation became more prominent in the 1970s. Internal fixation is now considered the preferred technique for ankle arthrodesis. To date, more than 40 different methods of internal fixation have been described [7, 12, 14, 16, 23–40], with screw fixation as the most common technique currently utilized. Compared to external fixation, modern screw fixation has demonstrated lower nonunion and infection rates in Level III and IV studies [16, 19, 25, 26, 30, 41–45]. Today, external fixation is reserved mainly for complex cases involving infection, severe bone loss, severe deformity, or compromised soft-tissue integument [46–48].

Various screw sizes, numbers and locations of screws, and configurations for internal fixation have been evaluated.

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Friedman et al. [49] reported that the cross-screw technique was more rigid than parallel screws, especially in torsion. Ogilvie-Harris et al. [50] demonstrated that 3 screws are biomechanically more stable than 2 screws, in particular when it came to improved torsional strength compared to a two screw construct. Nevertheless, good results have been found with both two and three screw constructs [16, 25, 26, 42, 43, 45]. They also showed that an optimal position for satisfactory functional outcome can usually be achieved when the foot is in 0 of flexion, 0–5 of valgus, 5–10 of external rotation, with slight posterior displacement of the talus [17, 51, 52]. If the optimal ankle fusion position is not achieved, such as in equinus, the result can lead to medial collateral insufficiency and recurvatum of the ipsilateral knee, and overload of the midfoot with midfoot degeneration [17, 53]. Approximately 95–100% of the patients that undergo ankle fusion will develop radiographic subtalar joint arthritis and 33% of which will require fusions of the ipsilateral hindfoot joint [54].

The efficacy of plating in isolation or in addition to screw fixation has been demonstrated in both biomechanical and clinical studies [18, 24, 32, 36, 52]. Supplementation of standard screw fixation with an anterior plate has been demonstrated to increase construct rigidity and decrease micromotion in a biomechanical cadaver study [52]. The efficacy of anterior plating was subsequently demonstrated in clinical studies [18, 24]. Although evidence does exist to support the use of anterior plating, this may require more soft-tissue dissection and may not be suitable for patients with hostile soft tissue envelopes or risk factors for wound healing (i.e., diabetes, active tobacco use). Internal fixation with just screw constructs has demonstrated good results; therefore, the extra dissection required for plate fixation may preclude its benefit.

Open ankle arthrodesis traditionally has been the preferred surgical method to treat ankle arthritis, thereby providing patients with less pain and improved function. However, since 1983, arthroscopic ankle arthrodesis (AAA) has gained momentum with some studies such Wing et al. done in 2013, indicating faster fusion rates and shorter hospital stays than open ankle arthrodesis (OAA) [21].

Arthroscopic Arthrodesis

In the past, the benefit of arthroscopic ankle arthrodesis was largely theoretical; however, with recent literature, arthroscopic ankle arthrodesis has been adopted and gained traction by surgeons as a surgical technique for ankle arthrodesis. Arthroscopic joint preparation is less invasive and is theoretically a better option for patients who are at higher risk soft tissue complications including patients with diabetes, compromised vascularity, previous surgical scars, skin grafts, and prior history of infection. The most recent literature has demonstrated shorter hospital stays and decreased risk of soft tissue morbidity while maintaining fusion rates equivalent to those associated with open techniques [21].

Multiple studies in the past decade have demonstrated the utility of arthroscopic arthrodesis. Level III and IV studies have demonstrated at least equivalent fusion rates with open techniques, with shorter hospital stays, less blood loss, and potentially improved outcome scores [13, 21, 55–60]. In 2005, Ferkel and Hewitt evaluated 35 patients who underwent arthroscopic arthrodesis with 72-month mean follow-up [13]. Thirty-four of the 35 patients (97%) achieved joint fusion, with a meantime to fusion of 12 weeks. Three patients required bone stimulators for delayed union. No other complications were recorded. Also in 2005, Winson et al. reported a meantime to union of 12 weeks, with 9 of 105 (7.6%) ankles demonstrating nonunion rate at a mean follow-up of 65 months [60]. Four of the nine nonunions occurred within the first eight operations performed, indicating the increased technical difficulty with this procedure and the learning curve involved.

Open Versus Arthroscopic Ankle Arthrodesis

To date, only four studies have directly compared arthroscopic and open ankle arthrodesis [21, 55, 56, 61]. Myerson and Quill [55] evaluated 17 patients who underwent arthroscopic arthrodesis and 16 patients who underwent open arthrodesis with a malleolar osteotomy. Meantime to fusion was 8.7 weeks in the arthroscopic group and 15.5 weeks in the open group. Complication rates were similar in both groups. The patients who underwent open arthrodesis had more complex pathology, including deformity and poor bone quality. The authors reported that the extent of deformity, quality of circulation, presence of prior infection, and vascularity of the talus and distal tibia all played a role in patient selection. Thus, the comparisons in this study have limited value due to the inherent selection bias. O'Brien et al. [56] performed a retrospective review of 19 patients who underwent arthroscopic fusion and 17 patients who underwent open fusion. Arthroscopic arthrodesis demonstrated shorter tourniquet times, less blood loss, and shorter hospital stays. There were no differences in operative times, nonunion rate, radiographic fusion position, and complications. In a comparison of 58 arthroscopic ankle arthrodeses and 49 open arthrodeses, Nielsen et al. [61] found that the arthroscopic group was discharged on average 2.3 days earlier than the open group and reported significant differences in bony union at 12 weeks. Ninety percent of patients in the arthroscopic group and 57% in the open group demonstrated union. After 1 year, these numbers had increased to 95% and 84%, respectively, and were statistically similar. The only

baseline difference between the groups was the preoperative malalignment: Patients in the open group had a coronal plane malalignment exceeding 5°, indicating a greater complexity in the open arthrodesis group that may have had an influence on the results of this study. Recently, Townshend et al. [21] directly compared patients with arthroscopic and open ankle arthrodesis in a multicenter comparative case series. Ankle Osteoarthritis Scale (AOS) and Short Form-36 (SF-36) scores, length of hospital stay, and radiographic alignment were reviewed in 30 patients in each group. Patients undergoing arthroscopic arthrodesis had a shorter hospital stay (2.5 versus 3.7 days) and greater AOS scores at 1 and 2 years postoperative. The SF-36 scores, complications, surgical time, and alignment were similar between the two groups.

Although no Level I randomized controlled trial has been performed to compare arthroscopic and open arthrodesis, the literature provides Level III and IV evidence supporting the use of arthroscopic techniques. Arthroscopic techniques have shown similar fusion rates, shorter time to fusion, shorter hospital stays, and potentially lower infection rates compared to open arthrodesis. Most authors have reported on arthroscopic fusion for ankles with minimal deformity; however, there is increasing evidence demonstrating efficacy with greater degrees of deformity [59, 60], potentially further expanding its indications.

On the other hand, some considerations need to be made when choosing the right patient candidate for arthroscopic ankle fusion. Active infection, extensive avascular necrosis of the talus, large bone defects, and severe angular deformities are some patient conditions that are considered contraindications to the arthroscopic approach [55, 60, 62, 63]. Myerson and Quill [55] found that arthroscopic ankle fusion for patients with bone defects larger than one-third of the talar dome surface yielded unfavorable outcomes compared to the open technique. Similarly, Zvijac et al. [62] found that preoperative avascular necrosis involving more than 50% of the talus increases the failure risk of arthroscopic ankle fusion. As such, open ankle fusion may be more beneficial for these patients possibly with bone grafting. It has been long considered that no to minimal deformity could be corrected through arthroscopic ankle fusion, and thus, severe deformities were considered contraindications [60, 63]. However, some studies showed that the arthroscopic technique could yield high fusion rate and correction of the malalignment of both mild (<15°) and severe (15–45°) deformities [59, 64].

Gait

Studies on the effects of ankle arthrodesis on gait and foot and ankle kinematics have dated back over 30 years. The literature has demonstrated significant alterations in gait kinematics after ankle arthrodesis [17, 51, 65–71]. The most recent studies show similar results, with some variability. Sealey et al. [72] performed a prospective analysis of sagittal plane motion in 48 patients who underwent ankle arthrodesis. The mean sagittal motion was 37.2° preoperatively and decreased to 22.6° postoperatively. Compensation for lack of motion through the ankle joint occurred through a 10.8% increase in motion through the subtalar joint and medial column postoperatively. Fuentes-Sanz et al. [67] found that sagittal plane range of motion in the ankle joint decreased significantly compared to the contralateral limb. They found no differences in plantar pressures or other gait parameters. In another gait analysis of 26 patients who had undergone ankle arthrodesis, Thomas et al. [66] found significant differences in stride length, cadence, and sagittal, coronal, and transverse range of motion of the hindfoot and midfoot.

Although these studies have demonstrated some variability in results, patients with ankle arthrodesis generally have the following alterations in gait:

- Slower walking speeds
- Shortened stride length
- Decreased cadence
- Earlier heel rise
- Increased anterior tilt of the tibia during midstance
- Increased forefoot plantar pressures
- Posterior shift of ground reactive forces during terminal stance
- Increased hip flexion
- Decreased hindfoot range of motion

Adjacent Joint Arthrosis

One of the most commonly discussed sequelae of ankle arthrodesis is the development and/or progression of peritalar joint arthrosis, particularly the subtalar joint. The mechanical explanation for the development or accelerated progression of peritalar joint disease following ankle arthrodesis patients was proposed by Beyaert et al. [65], who performed gait analysis on ankle arthrodesis patients. They found that decreased hindfoot motion resulted in a decrease in forward progression of the tibia during the midportion of the stance phase, creating early heel rise and increased shear forces through the midfoot. They suggested that abnormal gait mechanics after arthrodesis can lead to the development or progression of arthrosis in adjacent joints. Currently, Level III and IV evidence confirms that ipsilateral adjacent joint arthrosis following ankle arthrodesis may be a source of disability [9, 11, 44, 65, 66, 73–80]. Coester et al. [74] followed 23 patients who underwent ankle arthrodesis for posttraumatic arthrosis for a mean of 22 years and found a greater

incidence of ipsilateral subtalar, talonavicular, calcaneocuboid, naviculocuneiform, tarsometatarsal, and first metatarsalphalangeal joint arthrosis compared to the contralateral side. The ipsilateral foot was consistently more symptomatic, and significant differences between the feet were found for activity limitation, pain, and disability. Other studies have also demonstrated poorer outcomes in the presence of subtalar arthrosis following arthrodesis [73, 76]. Buchner and Sabo [73] found that 47% of 48 patients had moderate and severe subtalar arthrosis following tibiotalar arthrodesis. Furthermore, these patients had a worse long-term outcome compared to patients with mild or no degenerative changes in adjacent joints. Fuchs et al. [76] assessed 17 patients with 18 ankle arthrodesis with minimum 20-year follow-up. They found an increased tendency for degenerative changes in the subtalar joint compared to the midtarsal joint. Subtalar arthrosis was associated with poorer clinical outcome, but no significant correlation between midtarsal degeneration and outcome was found.

Many studies demonstrating ipsilateral joint arthrosis following arthrodesis fail to assess patients for evidence of preexisting arthrosis. One Level III [81] and one Level IV study [66] compared preoperative and postoperative adjacent joint arthrosis. Sheridan et al. [81] reviewed 71 ankle arthrodeses in 70 patients with end-stage ankle arthrosis. Of the 71 ankles, 68 (95.8%) demonstrated preexisting radiographic arthrosis in either the hindfoot or midfoot. The subtalar joint was most commonly affected (77.5%). These authors concluded that ipsilateral joint arthrosis is commonly present in patients with ankle arthrosis, and consequently, changes observed postoperatively may not be a direct consequence of the arthrodesis. However, Thomas et al. [66] retrospectively assessed 26 patients who had undergone ankle arthrodesis at a mean follow-up of 4 years. Four patients (15%) with no, doubtful, or minimal subtalar joint arthrosis preoperatively progressed to moderate or severe arthrosis postoperatively.

Although studies have demonstrated the progression of ipsilateral hindfoot arthrosis following ankle arthrodesis, many patients still derive great benefit from the procedure and are satisfied overall despite the adjacent joint changes [17, 45, 74, 76]. Ipsilateral joint degeneration is a concern for both the surgeon and patient; however, resolution of pain from the arthrodesis predictably improves patient outcomes and function.

Outcomes

Ankle arthrodesis is still considered a reliable surgical procedure for the treatment of end-stage ankle arthrosis by many authors, notwithstanding the emergence of TAR. Despite concerns regarding alterations in gait, adjacent joint arthrosis, and loss of motion, functional outcomes and patient satisfaction remain adequate following arthrodesis. Good clinical outcomes have been reported in 66–90% of patients in the intermediate term [5, 6, 11, 12, 15, 16, 19, 23, 34, 36, 43, 45, 79, 82, 83]. Most of this literature consists of Level IV retrospective noncomparative studies with small patient cohorts and assessment using unvalidated outcome scores.

Recent studies using modern surgical techniques demonstrate the utility of arthrodesis in end-stage ankle arthrosis. Modern surgical techniques, including rigid internal fixation, improved soft-tissue handling, and minimal periosteal stripping, have all contributed to superior results. Thomas et al. [66] evaluated functional outcomes in 26 patients who underwent ankle arthrodesis. Although significant differences were present in hindfoot function and gait, pain relief was reliable and patient satisfaction was high. Twenty of 26 patients were completely satisfied or satisfied with their surgical outcome, and 25 patients stated they would undergo surgery again. Hendrickx et al. [15] evaluated 60 patients (66 ankles) with isolated ankle arthrodesis using an open, two-incision, three-screw technique. At mean follow-up of 9 years, 91% of patients were satisfied with their result. Fusion was achieved in 91%, and revision for nonunion was required in six patients. Fuentes-Sanz et al. [67] followed 20 patients who underwent an isolated ankle arthrodesis for a mean of 3 years. All patients were satisfied with their arthrodesis and had no significant restriction with their daily activities. Functional scores showed good results in 80% of patients. Seventy percent returned to their previous work and activity level. Strasser and Turner [20] reported that 90% of patients over 70 years of age had achieved union at an average of 2.2-year follow-up, and functional outcomes were satisfactory.

Total Ankle Replacement

TAR was originally introduced in the 1970s, but early aseptic loosening in these first-generation prostheses led to poor clinical and functional results [84, 85]. TAR has made a resurgence due to an increased understanding of the complexities of ankle arthroplasty, improved third-generation implant designs, and improved surgical technique. In 1991, 72 TARs were performed through Medicare billings, compared to 888 in 2010, representing an increase in TAR volume of more than 1000% [86]. Additionally, the proportion of US hospitals performing TAR increased from approximately 3% in 1991 to 13% in 2010. This growth in TAR has led to a steady increase in clinical data. This chapter examines the most recent literature in varying aspects of TAR, including gait analysis, survival rates, outcomes, and complications.

Gait

One of the perceived benefits of TAR over ankle arthrodesis is more normal gait parameters postoperatively. Gait analysis studies of modern TAR designs have demonstrated more normalized gait patterns [87–91]; however, many of these studies are limited by short follow-up and small patient numbers.

Brodsky et al. [87] prospectively conducted three-dimensional gait analysis on 50 patients who underwent TAR preoperatively and at a mean follow-up of 49 months. TAR provided significant improvements in gait parameters. Walking velocity increased as a function of both cadence and stride length following TAR. Ankle range of motion increased from a mean of 14.2° preoperatively to 17.9° postoperatively. TAR was also associated with more normal ankle function and gait when compared to previous studies on ankle arthrodesis. Valderrabano et al. [91] studied 15 patients with post-traumatic ankle arthrosis and 15 matched controls. Patients underwent three-dimensional ankle-hindfoot kinematic analysis. Preoperative gait analysis demonstrated significant differences between the groups in all spatiotemporal parameters of the affected leg, including cadence, walking speed, stride time, step time, stride length, and step length. Twelve months after surgery, all parameters in the operated patients demonstrated no significant differences from control subjects. Cadence in the TAR group was 95.7% of the control group, walking speed was 92.3%, stride time was 97.2%, step time was 94.3%, stride length was 97.0%, and step length was 95.7%. Detrembleur and Leemrijse [88] assessed 20 patients preoperatively and 7 months after TAR. Improvements were found in spatiotemporal parameters, highlighting the beneficial effects of TAR on gait after only 7 months. In another study, Valderrabano et al. [91] demonstrated significant improvement in gait parameters from 3 to 12 months after TAR. At 3-month follow-up, patients actually experienced a worsening of gait. This would suggest that Detrembleur and Leemrijse [88] may have demonstrated greater improvements in gait parameters with longer follow-up.

Based on the literature to date, TAR with third-generation prostheses has demonstrated improved gait parameters compared to preoperative states, as well as more comparable parameters to normal controls. Further reports of gait analysis after TAR are discussed in the section comparing gait following arthrodesis and following TAR.

Survival Rates

Total hip and total knee arthroplasty have benefited from long-term studies which have revealed excellent survival rates. Early first-generation TARs were fraught with high complication rates, poor outcomes, and low survival rates. Since the emergence of third-generation ankle prostheses, survival rates have steadily improved. Reports of survival rates are inherently biased, due to a lack of high-quality Level I or II trials; most studies to date are Level III and IV [54, 92–114].

Haddad et al. [99] performed a meta-analysis of ten studies of ankle arthroplasty in 852 patients published between 1998 and 2005. Five-year implant survival rate was 78%, and 10-year survival rate was 77%. Hosman et al. [102] reported a 5-year survival of 86% of 202 TARs from the New Zealand Registry. Fevang et al. [98] reported overall 5-year and 10-year survivals of 257 ankle arthroplasties of 89% and 76%, respectively, from the Norwegian Joint Registry. Swedish registry analysis of 780 TARs reported a 5-year survival of 81% and a 10-year survival rate of 69% [115]. More recent studies have also demonstrated favorable survival rates. Mann et al. [106] studied 84 TARs in 80 patients. At an average follow-up of 9.1 years, 91% of prostheses remained implanted. In a survival analysis of 684 patients (722 ankles) with the Hintegra ankle implant, overall implant survival was 94% at 5 years and 84% at 10 years [95]. In 88 TARs done in 85 patients, Sproule et al. found survival was 89.6% at 3 years and 88.4% at 4 years [111]. In a 2013 systematic review and meta-analysis of 58 studies and 7942 TARs, Zaidi et al. found overall survivorship was 89% at 10 years, with an annual failure rate of 1.2% [54].

Overall, studies with short- to medium-term follow-up demonstrate survival rates from 67.7 to 98.7%. Most studies reviewed are Level III and IV studies, which are inherently fraught with biases; however, TAR survival appears to be increasing with modern prosthetic designs, improved surgical technique, and greater surgeon experience.

Outcomes

Initial studies of TAR using first-generation prostheses demonstrated poor outcomes [84, 85]. With the advent of second- and third-generation prostheses, outcomes, survivorship, and patient satisfaction after TAR have steadily improved. Most recent publications report improved pain and function scores following TAR [116]; however, many patients still do not report being pain-free postoperatively [92, 117–120]. Patient satisfaction has been reported in multiple studies to range from 80% to 97% [103, 104, 106, 108, 113, 117–119, 121–124]. However, many of these studies had limited use of validated outcome measures.

Many factors, including surgeon experience, preoperative alignment, and arthrosis etiology, may have an impact on the outcome of TAR. One of the key determinants is surgeon experience. Higher complication rates and early failures can

be expected in the first 50 ankle replacements performed compared to the next 50 procedures performed [100, 109, 114, 125]. Schuberth et al. [109] retrospectively reviewed the initial 50 TARs of a single surgeon at an average 2-year follow-up and identified 19 intraoperative malleolar fractures, 12 postoperative incidents of malalignment, 6 syndesmotic nonunions, 8 ankles requiring revision, and 10 wound complications. Aside from the wound issues, the rate of complications decreased with surgeon experience. Lee et al. [125] retrospectively studied 50 TARs and compared complication rates between the first 25 and subsequent 25 cases. In the first 25 cases, 60% had a perioperative complication, while only 20% had a complication in the subsequent 25 cases. These complications included intraoperative malleolar fractures, as well as tibial and talar component malpositioning. Improvements in the ability of a more experienced surgeon to choose appropriate candidates for TAR are more difficult to measure.

The extent of coronal deformity which is amenable to TAR remains controversial. Initial studies on TAR in the setting of deformity reported lower survival rates, higher early failures, and increased edge loading [97, 114, 126, 127]. The management of coronal deformity and the importance of ancillary procedures in deformity correction are now better understood and have led to improved outcomes of TARs in patients with coronal plane deformity [128–132]. In 2009, both Hobson et al. [128] and Kim et al. [129] demonstrated good results in patients with preoperative varus deformity. Reddy et al. [130] subsequently demonstrated successful correction of moderate to severe coronal plane deformity in TAR. More recently, Sung et al. [131] reported the results of 24 TARs with a coronal deformity greater than 20° and 79 TARs with less than 20° deformity. At short-term follow-up, the average American Orthopaedic Foot and Ankle Society (AOFAS) score and visual analogue scale (VAS) pain scores improved in both groups, as did patient satisfaction levels. There were no differences in postoperative complications or early implant failures. This study demonstrated the efficacy of TAR in the setting of deformity, but it was limited by short-term follow-up and the use of unvalidated outcome measures. Trajkovski et al. [132] compared 26 TARs with a preoperative varus deformity ≥10° (varus group) and 36 prospectively matched TARs with a varus deformity of <10° (neutral group). Eighteen ankles in the varus deformity group had a preoperative deformity of more than 20°. There were significantly more ancillary procedures in the varus deformity group (81% versus 47%). Both groups showed improvements in AOFAS, AOS, and Short Form-36 (SF-36) scores, with no differences between the groups. Complications occurred in 19% of the TARs in the varus group and 14% in the neutral group. The authors concluded TAR in the setting of varus malalignment ≥10° provides satisfactory results, but stressed the importance of meticulous surgical techniques to address the deformity.

The underlying etiology of arthrosis has been suggested as a potential factor in TAR outcome; however, no definitive evidence currently exists to reveal any consistent differences. Naal et al. [133] reported lower patient satisfaction rates, and Bai et al. [134] demonstrated higher complication rates in patients with posttraumatic arthrosis compared to patients with primary osteoarthritis. However, other studies have not found differences in outcomes based on underlying etiology. Kofoed and Sorensen [135] assessed 25 patients with osteoarthritis and 27 patients with rheumatoid arthritis and found no differences in complication rates, revision rates, or survivorship. Anderson et al. [93] also found no differences in outcome scores between patients with primary arthrosis, posttraumatic arthrosis, and rheumatoid arthritis. More recently, Kraal et al. [136] prospectively followed 93 TARs in 76 patients with inflammatory disease and found that outcome scores and survivorship at a mean of 15-year follow-up were comparable to other patients who underwent TAR. Other studies have also demonstrated good outcomes and survivorship in patients with inflammatory disease [108, 137].

Various patient factors considered to potentially impact the outcome of TAR include age, gender, and weight. To date, no study has definitively correlated poor outcomes with these factors. The ideal patient age for TAR has long been debated and remains controversial [113, 138–140]. Initial studies cautioned against the use of TAR in younger patients [138, 140], but more recent literature demonstrated no significant differences in outcomes based on age. Kofoed and Lundberg-Jensen [139] studied 30 TARs in patients <50 years of age and 70 TARs in patients ≥50 years. The median ages were 46 and 63 years in the two groups, respectively. These patients were followed for a median of 5 years, and no differences were found in survivorship or revision rates. Valderrabano et al. [113] demonstrated similar findings at 4-year follow-up. Norwegian Joint Registry data also showed no significant influence of age [98].

Gender has been studied as a potential factor in TAR outcomes. Both the Norwegian [98] and Swedish [100] registries demonstrated no significant influence of gender on outcomes following TAR.

Patient weight at time of surgery has been assessed in two recent studies [141, 142]. Barg et al. [141] performed a retrospective review of 118 obese patients (123 ankles), specifically subjects with a minimum body mass index (BMI) of 30 kg/m^2. Both radiographic and clinical outcomes were reviewed at mean follow-up of 67 months. Patients experienced significant pain relief, functional improvement, and increased range of motion. Prosthetic metal component survival was 93% at 6 years. Deep venous thrombosis (DVT) occurred in 9.8% of patients, which is higher than a previ-

ously reported incidence of 3.9% symptomatic DVT following TAR [143]. While Barg et al. [141] did not directly compare TAR in obese patients to that in normal-weight patients (i.e., with BMI <30 kg/m^2), based on previous literature, they concluded TAR was a viable option in obese patients. Noelle et al. [142] studied complication rates after TAR in 100 patients. Patients with a BMI >30 kg/m^2 had a statistically greater rate of aseptic loosening. There was also a trend toward delayed wound healing, but this was confounded by low numbers and confounding variables.

Ankle Arthrodesis Versus TAR

Ideally, the best surgical option for end-stage arthrosis would be determined by a large, well-constructed, randomized clinical trial comparing ankle arthrodesis and TAR subdivided by deformity. However, the perceived advantages of TAR and perceived disadvantages of arthrodesis make patient enrolment into a randomized trial difficult. Although excellent pain relief and functional outcomes have been demonstrated for both arthrodesis and TAR, many patients prefer TAR for the benefit of maintained ankle range of motion. While no Level I randomized controlled trials exist to date, numerous studies have directly compared functional outcomes, gait, quality of life, complications, and reoperations following ankle arthrodesis and TAR [71, 99, 123, 154].

Gait Comparison

Gait mechanics following ankle arthrodesis has long been a concern for both surgeons and patients. When a surgeon is discussing arthrodesis for end-stage arthrosis, patients commonly express concerns regarding changes in their gait due to the increased stiffness imparted by ankle arthrodesis. The surgeon may emphasize that pain relief is the first concern, and with pain relief, gait will often improve after an ankle fusion or TAR. Gait following arthrodesis has been extensively studied [17, 51, 65–70], and those results were summarized in an earlier section of this chapter.

Five recent Level II studies [71, 144, 147, 148, 150] have directly compared gait parameters following TAR to those following arthrodesis. In 2003, Valderrabano et al. [155, 156] demonstrated kinematic differences following arthrodesis and TAR using cadaveric specimens and an axial loading device. TAR was found to more closely replicate normal range of motion [155] and decrease movement transfer between the foot and the leg [156]. In a comparative gait analysis of 12 patients following TAR and 12 patients following arthrodesis and 12 healthy controls, Piriou et al. [150] found that neither TAR nor arthrodesis was able to restore normal movement or velocity. However, the arthrodesis group demonstrated faster gait, longer stride length, and a more asymmetric gait pattern than the TAR group. The TAR group had greater range of motion, more symmetry in gait, and a closer to normal restoration of the pattern of ground reaction force. The main limitation to this study was the lack of preoperative gait comparisons between the groups, resulting in potential baseline differences.

Hahn et al. [148] compared nine patients with TAR and nine patients with arthrodesis at one-year post-surgery. Hip range of motion increased more in the arthrodesis group compared to the TAR group, whereas ankle range of motion increased more in the TAR group compared to the arthrodesis group. Interestingly, this study found only slight improvements in dorsiflexion, with the majority of improvement occurring in plantarflexion. This finding contradicts other studies which have reported preferential improvements in ankle dorsiflexion after TAR [71, 147].

Singer et al. [71] compared 17 patients with TAR, 17 patients with arthrodesis, and 10 matched controls. Patients were matched for age, sex, and BMI. Gait was assessed at a mean of 1.6 years after arthrodesis and 1.3 years after TAR. The control group had a statistically greater sagittal plane range of motion of 27.9° ± 5.3° than both the TAR and arthrodesis groups, and patients who underwent TAR had a significantly greater sagittal plane motion (18.1°) compared to the arthrodesis group (13.7°). The main difference was observed in dorsiflexion: The TAR group demonstrated a greater mean dorsiflexion (11.9°) compared to the arthrodesis group (6.8°), and the TAR and control groups had equal dorsiflexion. Plantarflexion was limited in both the TAR group (6.2°) and arthrodesis group (6.8°) compared to controls (16°). Tibial tilt was also greater in the TAR group compared to the arthrodesis group; however, tibial rotation and coronal plane motion were similar. The authors concluded that neither TAR nor arthrodesis restored normal gait patterns postoperatively, largely due to limited plantarflexion. The authors hypothesized that the implant used did not recreate the posterior malleolus of the ankle, and this lack of posterior support may prevent functional plantar flexion during the terminal stance phase of gait. Despite this limitation, gait patterns following TAR more closely resembled normal gait, largely due to greater dorsiflexion.

Flavin et al. [147] compared spatiotemporal measurements and kinematic parameters between 14 patients who underwent TAR, 14 patients who underwent arthrodesis, and 14 normal controls. Patients in both surgical groups demonstrated improvements in various gait parameters when compared to their preoperative state. Patients who underwent TAR had greater increases in walking velocity, greater stride length and cadence, and more normalized first and second rockers of the gait cycle compared to patients who under-

went arthrodesis. Sagittal range of motion increased a mean of 4.1° in the TAR group (from 15.6° to 19.2°), but remained unchanged in the arthrodesis group. Specifically, sagittal dorsiflexion was greater in the TAR group; however, plantarflexion was significantly greater in the arthrodesis group. This offsetting effect resulted in no statistical differences in overall sagittal plane motion.

These Level II studies demonstrated differences in gait between ankle arthrodesis and TAR. Despite some minor inconsistencies, they generally showed that TAR results in greater sagittal plane range of motion and more normal gait parameters such as walking velocity, stride length, cadence, and symmetry of gait compared to arthrodesis.

Comparison of Outcomes

Six recent Level II studies [123, 145, 146, 151–153], one Level III study [154], and one Level IV study [99] have directly compared functional outcomes, quality of life, complications and reoperations of ankle arthrodesis, and TAR. Although these studies do not provide Level I evidence, they have greatly increased our understanding and expectations of TAR as an alternative to ankle arthrodesis. These studies do not provide a treatment algorithm, but they allow surgeons to better educate patients on the advantages, disadvantages, and expectations of TAR and ankle arthrodesis and help them make more informed decisions about their care.

Haddad et al. [99] performed a systematic review of 49 studies, which included a total of 852 patients who underwent TAR and 1262 patients who underwent ankle arthrodesis. This meta-analysis showed that 38% of patients with a TAR had an excellent result, 30.5% had a good result, and 34% had a poor result, compared to 31%, 37%, and 13% in the ankle arthrodesis group, respectively. The revision rate was 7% following TAR and 9% following arthrodesis. In the TAR group, loosening and/or subsidence were the most common reasons for revision (28%), while nonunion was the most common reason in the arthrodesis group (65%). Finally, 1% of TAR patients and 5% of arthrodesis patients required a below-the-knee amputation. Although a meta-analysis is limited by the quality of the individual studies, this was the first study to directly compare arthrodesis and TAR.

Slobogean et al. [153] performed a multicentered prospective cohort study comparing quality of life following TAR or arthrodesis using health state values derived from SF-36 questionnaire. One hundred and seven patients in the arthrodesis and TAR groups demonstrated significantly improved health state values from baseline to 1 year postoperative. There were no significant differences between the treatment groups 1 year after surgery.

Saltzman et al. [151] compared 37 patients who underwent TAR to 23 patients who underwent arthrodesis at a mean follow-up of 4.2 years. Only patients with posttraumatic or primary ankle arthrosis were included. When comparing SF-36 Physical Component Summary (PCS), SF-36 Mental Component Summary (MCS), and AOS pain and AOS disability scores, the TAR group fared better in each of the outcome scores. Significant differences were found in the SF-36 MCS and AOS pain scores. Following surgery, 15 of 37 (41%) patients in the TAR group required additional surgery, including debridement and bony resection, bone grafting, polyethylene bearing exchange, revision skin closure for dehiscence, and prosthetic metal component revision. In the arthrodesis group, 5 of 23 (22%) patients required additional surgery for nonunion, hardware removal, and one case of naviculocuneiform arthrodesis. Prior to this study, Saltzman et al. [123] reported early results comparing TAR and ankle arthrodesis. Although their follow-up period was only 24 months, their initial results demonstrated better function and equivalent pain relief in patients who underwent TAR.

In 2012, Schuh et al. [152] retrospectively compared postoperative sports and recreational activities as well as clinical and functional outcome in 21 patients who had undergone arthrodesis and 20 patients who had undergone TAR, at a mean follow-up of 34.5 months. Preoperatively, 90% of patients in the arthrodesis group and 86% in the TAR group were actively engaged in sports and recreational activities. Postoperatively, this decreased to 76% in both groups. The differences between the groups, and from preoperative to postoperative, were not statistically significant. The authors also investigated patient satisfaction: In the arthrodesis group, 80% of patients were very satisfied, 5% were satisfied, and 5% were unsatisfied, compared to 76%, 10%, and 0%, respectively, in the TAR group. Again, there was no statistical difference in patient satisfaction rates between the groups.

SooHoo et al. [154] performed an observational study exploring reoperation rates and complications in 4705 ankle arthrodeses and 480 TARs over a 10-year period. Data were collected from California's hospital discharge database. A review of short-term complications demonstrated a higher rate of major revision surgery at 90 days postoperatively in the TAR group. Subtalar arthrodesis rates were compared at 5 years postoperative. In the arthrodesis group, 2.8% of patients underwent subtalar arthrodesis, compared to only 0.7% in the TAR group. However, 23% of patients in the TAR group required major revision surgery, whereas only 11% required major revision in the arthrodesis group. The authors concluded there is a greater risk of reoperation and complications with TAR, but a decreased risk of requiring subtalar arthrodesis.

Krause et al. [149] evaluated the number of complications and the impact of these complications in 114 TARs in

112 patients at a mean follow-up of 39 months and 47 ankle arthrodeses in 47 patients at a mean follow-up of 37 months. Significant improvements in mean AOS scores were found in both groups. However, 54% of patients experienced complications following TAR, and 26% of patients experienced complications following arthrodesis. Complications in the TAR group included aseptic loosening, intraoperative or postoperative fracture, infection, nonunion of adjacent joint fusion, medial or lateral gutter impingement, excessive polyethylene wear or breakage, or malalignment. Complications in the arthrodesis group included adjacent joint arthrosis, nonunion, varus malalignment, medial-gutter-related discomfort, ongoing nonspecific pain, an intraoperative lesion of the superficial peroneal nerve, and one intraoperative fracture. The authors noted that there were significantly more complex cases (according to the Canadian Orthopaedic Foot and Ankle Society (COFAS) end-stage ankle arthritis classification system [157]), as well as more patients with rheumatoid arthritis, in the TAR group. This may have contributed to the higher overall complication rate in the TAR group.

Recently, Daniels et al. [145] evaluated intermediate-term results in patients who underwent ankle arthrodesis or TAR. The outcomes of 321 ankles, including 232 TARs and 89 arthrodeses, were reviewed with a minimum of 4 years of follow-up. The AOS total scores and SF-36 scores were better in the TAR group; however, after adjusting for baseline patient characteristics (i.e., age, sex, operatively treated side, smoking status, BMI, inflammatory arthritis, baseline AOS score, and surgeon), the difference was substantially attenuated. Revision rates in the TAR group were approximately twice as high as in the arthrodesis group (17% versus 7%). The authors concluded the clinical outcomes were comparable between the groups, with the TAR group experiencing higher rates of additional surgery and major complications.

Ankle arthrodesis may precipitate adjacent joint arthrosis, alter gait, and decrease range of motion; however, functional outcomes and patient satisfaction remain high. In 2019, Veljkovic et al. [158] reviewed and compared AOS pain and disability total scores preoperatively and postoperatively, along with reoperation rates among patients who underwent total ankle replacement, arthroscopic ankle fusion, and open ankle fusion. Over 238 patients were included in the study with an average follow up of 1.5 years. Patients in this cohort study were diagnosed with COFAS type 1 ankle arthritis, which meant they had no associated ankle deformity or arthritis in the adjacent joints. 88 patients underwent total ankle arthroplasty, 50 arthroscopic ankle fusion and 100 open ankle fusion with 55% of patient being female. The study assessed the revision rate of the primary replacement/fusion and the reoperation rate which looks at surgeries done outside the primary site, e.g., osteotomies, ligament repair, and gutter debridement. The reoperations rate (other than revisions) was significantly higher in the arthroplasty group. However, the revision rate was not statistically different amongst the three groups. Interestingly, improvement in AOS total score was greater in the TAR and AAA compared to the OAA. However, these improvements did not meet the minimal clinically important difference.

In an unpublished data which were presented at IFFAS Lisbon in September of 2017, Penner et al. investigated the deformity and hindfoot arthritis on midterm outcomes of TAR and AA. They found that for patients with COFAS type 1 ankle arthritis, TAR and AA yield similar postoperative AOS scores. While for patients with COFAS type 3 and 4, TAR has better results than AA.

The recent literature directly comparing functional outcomes, quality of life, complications, and reoperations between ankle arthrodesis and TAR has demonstrated some consistent trends. Ankle arthrodesis and TAR have comparable clinical outcomes, including improved pain scores, patient satisfaction, and quality of life. TAR has a higher complication rate, reoperation rate, and revision rate, whereas ankle arthrodesis has a higher rate of adjacent joint arthrosis requiring arthrodesis. The latter may be accounted for by longer follow-up in the ankle fusion cohorts. What has been difficult to measure is patient satisfaction and perception of a successful outcome. More work is required in this area.

Summary

Both ankle arthrodesis and TAR are viable options for the surgical management of end-stage ankle arthrosis. Ankle arthrodesis can predictably decrease pain and improve function, but results in alterations in gait, decreased hindfoot range of motion, and adjacent joint arthrosis. TAR has had a recent resurgence with third-generation prostheses, due to its ability to produce more normal gait parameters, improve range of motion, and potentially avoid adjacent joint arthrosis. However, TAR results in more reoperations and higher complication rates as compared to arthrodesis. Based on the current literature, no definitive recommendations can be made when deciding between these two procedures. Each patient must be assessed individually, and the risks and benefits of each procedure must be considered based on individual patient characteristics. Future research assessing the role of TAR and ankle arthrodesis for end-stage ankle arthrosis will need to focus on patient expectations, as well as the benefits of improved hindfoot motion during activities other than steady-state walking on a flat surface (i.e., uneven ground, inclinations, declinations, stairs, and changing directions of movement).

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Current Indications and Contraindications for Primary Total Ankle Replacement

5

Mitchell J. Thompson, Andrew D. Elliott, and Thomas S. Roukis

Primary total ankle replacement (TAR) arose out of the successes of primary hip and knee replacements in the 1970s. Unfortunately, these first-generation TARs failed at such a high rate that the technique was almost abandoned. Since the early days of TAR, there have been several phases of refinement. Due to improvements in both surgical technique and the implants themselves, long-term survival of the implants has increased. It was not just the techniques and implants that improved but also a better understanding of when TAR was appropriate. As with all procedures, with an increase in the number performed, the indications are refined and many, at the same time, broadened.

Initially, the indications for TAR were vague and limited. A 1979 study by Demottaz et al. of 21 TARs of various designs and just over a year average follow-up determined that ankle arthrodesis was still the primary procedure for isolated disabling end-stage ankle arthritis and that TAR should be reserved for patients with limited motion in the midpart of the foot and use in the elderly as there was very limited follow-up data [1]. In 1982, S.E. Newton, M.D., published a larger study with longer follow-up of TARs he, himself, had performed [2]. His conclusions as to when a TAR was indicated changed during the course of his investigation. Initially, he believed the only absolute contraindication for TAR was recent infection in the ankle. As the study progressed, further limitations became apparent. For those with osteoarthritis, he felt a TAR is indicated if several conditions applied: First, the patient should have good ligament stability and not have significant preoperative instability; second, the patient needed reasonably normal anatomy by which he meant the presence of the lateral malleolus or lack of severe anterior angulation of the tibial articular surface; and third, no varus or valgus deformity of the talus greater than 20°, particularly if the subtalar or midtarsal joints, or both were diseased. For patients with rheumatoid arthritis, he did not recommend TAR if they had significant bone erosion of the talus, lateral tibial plafond, or fibula. He also felt long-term prednisone therapy was a relative contraindication. For patients with pseudoarthrosis from a failed fusion and avascular necrosis of the talus, because of his poor results, he was unable to recommend TAR as a treatment option. In his closing remarks, he did state that ankle fusion remained the procedure of choice for end-stage ankle arthritis, especially if the subtalar and midtarsal joints are not involved and if the patient is very active.

The preference for ankle arthrodesis continued. In a 1985 study, Bolton-Maggs et al. published a long-term review of 62 TARs performed between 1972 and 1981 at the London Hospital with an average follow-up of five and a half years [3]. The authors' results were not encouraging for TAR. Of the patients who underwent TAR, only 21% described themselves as satisfied. Given the high incidence of poor results, the authors concluded that it was only a matter of time before all of the implanted prostheses failed and required ankle arthrodesis as a salvage procedure.

While not as grim an outlook at the Bolton-Maggs postulated, a study by McGuire et al. published in 1988 was still fairly restrictive on when TAR was indicated [4]. This was a retrospective examination of 25 TARs with an average follow-up of 3.8 years and 18 ankle arthrodeses with an average follow-up of 3.3 years. One of the stated purposes of the study was to develop a clearer understanding of the indications for TAR. The initial indications for TAR included rheumatoid arthritis with multijoint involvement as well as older patients with posttraumatic arthrosis. Contraindications to TAR were acute or chronic septic arthritis, absent or inade-

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quate soft tissue, neuropathic joints, necrosis of any sort of the talus, and as a salvage procedure for failed ankle arthrodesis. The authors' finding as to when TAR was indicated was based primarily on the activity level of the patient. They assumed an increase in activity level was likely the cause of internal loosening of the TAR and the subsequent need for revision surgery. While the authors did note an improved outcome in patients with multijoint rheumatoid arthritis, they attributed that primarily to the patients' decreased demands on the replacement. By its very nature, rheumatoid arthritis is a debilitating disease forcing a more sedentary lifestyle. This philosophy was carried over to those patients with osteoarthritis where the age of the patient was more of a consideration than in those with rheumatoid arthritis. The authors explicitly stated there was no meaningful age cutoff for TAR. Instead, it was the activity level of the patient that would dictate the success or failure of the implant [4]. Total ankle replacements continued to gain popularity through the 1990s and into the 2000s. In a study performed by Fevang and colleagues in 2007 looked at 257 total ankle replacements over a 12-year period beginning in 1994. The overall 5-year survival rate was 89%, and the 10-year survival rate reached 76%. There was an 11% revision rate over this time period, which is much higher compared to hip or knee replacements. Interesting to note, this study indicated an overall increase in total ankle replacements due to osteoarthritis over the time period of this study, comparable to the increase seen in total hip replacements over the same time period [5].

As the number of total ankle replacements began to grow over time and with a revision rate of up to 22% [6], it was only a matter of time before revision total ankle arthroplasties became a higher center of focus. Over the last 5 years, the amount of total ankle implants who's indications included revisional surgeries has doubled and deserves recognition in this chapter for their newer role in total ankle arthroplasty.

The initial generations of TAR implants had fairly limited indications and almost universal contraindications. However, surgical techniques improved as did the prosthetics themselves. Currently, in the USA the newer generations of implants are being used with much greater success and in a more diverse patient population than their earlier counterparts. Of the new generations of TAR implants being used in the USA, the following have been approved by the United States Food and Drug Administration (FDA) either with 510(k) approval or through the premarket approval application process: the *Scandinavian Total Ankle Replacement System (STAR Ankle)* by Stryker Corp. (Kalamazoo, MI); *Eclipse Total Ankle Implant* by Integra, Inc. (Plainsboro, NJ); *Infinity Total Ankle System* by Wright Medical Technology, Inc. (Arlington, TN); *INBONE I&II* Total Ankle System by Wright Medical Technology, Inc. (Arlington, TN); *Agility LP and Agility Total Ankle* Prostheses by DePuy Orthopaedics, Inc. (Warsaw, IN); *Zimmer Trabecular Metal Total Ankle* by Zimmer, Inc. (Warsaw, IN); *Integra Total Ankle Replacement System* by Ascension Orthopaedics (Austin, TX); *Integra Salto Total Ankle Replacement System* by Ascension Orthopaedics (Austin, TX); *Invision Total Ankle Revision System* by Wright Medical Technology (Arlington, TN); *Exactech Vantage Total Ankle System* by Exactech Inc. (Gainesville, FL); and *Hintermann Series H2 Total Ankle System* by Wright Medical Technology Inc. (Arlington, TN),

As a requirement for application, indications for use were identified for each TAR system [7–17]. Likely by design, these listed indications were both vague and limited. Universally, the indications included osteoarthritis, posttraumatic arthritis, and rheumatoid arthritis systemic/inflammatory arthritis (rheumatoid and/or hemochromatosis). Of the above-listed TAR systems, nine stated they were indicated for use after failed prior ankle surgery or for revision surgery (see Table 5.1). Only two of the TAR systems stated any contraindications in their FDA approval process: STAR Ankle and Eclipse Total Ankle Implant. Of these two, the Eclipse Total Ankle Implant is no longer used in any significant numbers. The contraindications listed were active sepsis or infection; insufficient bone stock; osteonecrosis; insufficient blood supply; Charcot neuropathy; peripheral neuropathy; age, weight, or activity level that introduce unnecessary risk of failure; insufficient bone or musculature such that proper component positioning or alignment is not possible; and joint malalignment. The STAR Ankle alone added the following to their list of contraindications: prior infection; skeletal immaturity; insufficient ligament support unable to be repaired; prior arthrodesis of ankle joint; and poor skin/soft tissue. These were the only contraindications recognized as part of the FDA approval process. While the other systems did not include a list of contraindications as part of their FDA approval process, it should not be inferred that the companies felt there were no contraindications.

All of the companies listed both indications and contraindications in their surgical technique guides for implantation of their respective implants with the exception of the Eclipse Total Ankle Implant [18–28]. The Eclipse Total Ankle

Table 5.1 TARs indicated for revision of prior ankle surgeries

Infinity Total Ankle System
INBONE I & II
Agility Ankle Revision Prosthesis
Eclipse Total Ankle Implant
Cadence
Salto Talaris
Vantage
Invision
Zimmer Trabecular
Integra XT

Implant surgical technique guide was not available at time of publication likely due to its disuse. The indications listed in the technique guides mirrored the ones listed on the FDA applications; however, the contraindications varied among the different systems. There was significant overlap in the contraindications listed such that some of those contraindications could be said to be generally agreed upon amongst the different companies, while other contraindications were limited to only a few systems (see Table 5.2). Some companies listed warnings in the guides as well as contraindications. These warnings were included in the table as no discernable difference could be determined between a warning and a contraindication. This is not to say that each system has its own specific contraindications. One system may list avascular necrosis (AVN) of the talus as a contraindication, while another system may argue that stating "insufficient bone stock" is a broader phrase that covers that contingency. Other contraindications may be the result of individual company experience with various patient populations although that is difficult to determine from the literature. Mental illness is unlikely to be a specific contraindication for one system but not a contraindication for another. All of the companies' contraindications must be viewed together, not to look for specific wording but rather as general guidelines that paint a picture of what conditions in the patient as a whole as well as the patient's limb but more specifically their ankle and hindfoot, should be avoided. Using the conditions listed in Table 5.2 for guidance, the technique guides narrow the appropriate patient to a skeletally mature, relatively healthy patient with the ability not only to successfully incorporate the implant but also have the capacity to be compliant with the immediate post-procedure protocols and

Table 5.2 Surgical technique Guides

Generally Accepted as Contraindicated (listed in >10 technique guides)	Contraindicated (7–10)	Mentioned as Contraindicated (<7)	
Active/prior deep infection in AJ or adjacent bones	Lower extremity vascular insufficiency demonstrated by Doppler arterial pressure	Malalignment or severe deformity of involved or adjacent anatomic structure	
Skeletal Immaturity	Prior arthrodesis at the AJ	Prior surgery/injury that has reduced the bone quality	
Inadequate bone stock to support device	Poor skin/Soft-tissue quality at the surgical site	AVN Talus	
Osteoporosis/osteopenia	Sepsis	Hindfoot/forefoot malalignment precluding a plantar grade foot	
Neuromuscular disease resulting in lack of normal muscle function about affected ankle	Nonfunctioning Lower Limb Muscle/ weakness	Significant malalignment of the knee	
Charcot Joint or neuropathy that might lead to a Charcot joint of affected ankle	Pregnancy	Insufficient Ligament support that cannot be repaired with soft-tissue stabilization	
	Pt weight	Elevated WBC	
		Local Inflammation	
	Manual Labor	Mental Disorder	*Italics are "warnings" in surgical guide*
	High Activity level	Neurobiologic Disease	
	Drug/etOH addiction	Known Allergy to component	
	Other disabilities	Steroid use	
	Poor Bone stock	Hepatitis/HIV	
	Metabolic disorders/medical treatment that progressive deterioration of bone	*Dementia*	
	Sensitivity/allergy to component	*Drug abuse*	
		Local bone tumors	
		Distant foci of infection	
		Absence of medial/lateral malleoli	
		Likelihood of falls	
		Diseases affected quality of soft tissue	
		Severe joint deformity	
		Tumors of surrounding bones	
		Unexplained high ESR	
		Bone loss that for which adequate fit of prosthesis cannot be achieved	
		Nonfunctioning STJ in active individual	

long-term reduced demand on the affected ankle after being healed. The patient should have healthy soft tissue to heal the initial insult to the ankle to decrease any chances of wounding postoperatively. Mentioned more frequently in the later model technique guides is having proper malleolar alignment and ligamentous strength to support the ankle and implant once it is in place and to maintain this placement. If the patient meets these criteria, then it is a question of if any deformities in the limb or ankle can be corrected to allow for proper realignment of the ankle. There is one indication that is implant dependent meaning that not all TARs are designed for this condition: revision of prior TAR or arthrodesis (see Table 5.1). Many of these TAR technique guides did list as an indication, "revision of failed prior ankle surgery, implant, or reconstruction." Only one TAR, the Integra XT, specifically stated their implant is specifically indicated for revision surgeries [29].

Insurance companies are increasingly providing coverage for TAR, and as of 2019, all commercial insurance plans cover total ankle replacements as long as it is considered medically necessary [29–31]. The criteria to meet to be considered medically necessary often includes significant burden to daily life, failed conservative measures with verified arthritis [29–31]. Each insurance policy dictates the conditions under which TAR is deemed medically necessary as well as when TAR is considered experimental and investigational, thus not being covered by insurance. As few patients pay for TAR out of pocket, insurance policies act as de facto guidelines for TARs. A review of the policies of three of the top four private insurers in the country (Anthem, Cigna, and Aetna Group) [32] reveals a considerable increase in the amount of agreement between the companies as to when a total ankle replacement is indicated when compared to insurance models just 5 years ago. All agree on several things including: Only FDA approved TAR systems should be used; TAR is indicated for osteoarthritis, systemic/inflammatory arthritis, and post-traumatic arthritis of the ankle. Revision total ankle replacements are now agreed upon by all three insurance groups as medically necessary when meeting medical necessary guidelines after primary TAR. Charcot collapse, active infection, and malalignment of the joint not correctable by surgery are contraindications (See Table 5.3).

Although insurance companies have become much more streamlined and consistent in their policies for TAR, there are also some significant differences between insurers. After thorough review of all policies, it should be noted that the Cigna policy is the only one to not designate avascular necrosis of the talus as an absolute contraindication, and avascular necrosis of the talus is not listed in the policy statement [29]. All three insurance companies did report an active infection as a contraindication, but only Aetna stated a prior deep infection of the ankle joint as a contraindication for TAR. Aetna is also the only insurance company reviewed to have a prior arthrodesis of an ankle joint as a contraindication to TAR, even in the new age of revision TAR. Charcot neuropathy is listed as a contraindication in all three insurance policies, but Anthem is the only policy not to list peripheral neuropathy as a contraindication to TAR [31]. Cigna and Aetna were the only two companies to list both absence of a malleolus and inadequate ankle ligamentous support as contraindications to TAR. Of the insurance companies reviewed Aetna is the only one to list the social complexities of a psychiatric issues and inability of patients to follow postoperative instructions [30].

This cursory review reveals increased parallels between the insurance companies in contrast to when the first edition of this book was released. The core indications are relatively the same for all companies, and it comes down to the more detailed specifics of a potential patient's health status where the differences in contraindications appear to arise. We would like to note that we did reach out to the United Health Group for their coverage stance on TAR, though received no response.

Table 5.3 Health insurance-dictated conditions, considered indications, and contraindications

Conditions	Health Insurance		
Indications	Anthem (subsidiary of WellPoint, Inc)	*Cigna*	Aetna Group
Osteoarthritis	Yes	Yes	Yes
Post-traumatic arthritis	Yes	Yes	Yes
Rheumatoid arthritis	Yes	Yes	Yes
Prior ankle surgery	*No*	*No*	No
Arthritis in Surrounding Joints	Yes	Yes	*Yes*
Contralateral Arthrodesis	Yes	Yes	*Yes*
Contralateral Severe Arthritis	Yes	Yes	*Yes*
Failed 6 Months of Conservative therapy	Yes	Yes	Yes
Contraindications			
Active Sepsis or infection	Yes	Yes	Yes
Insufficient bone stock	Yes	Yes	Yes
Osteonecrosis	Yes	Yes	Yes
Insufficient blood supply	Yes	Yes	Yes
Charcot Neuropathy	Yes	Yes	Yes
Peripheral Neuropathy	No	*Yes*	Yes
Avascular Necrosis of the Talus	Yes	*No*	Yes
Insufficient bone or musculature such that proper component positioning or alignment is not possible; malalignment	Yes	Yes	Yes
Prior Infection	No	No	*Yes*
Skeletal immaturity	Yes	Yes	Yes
Insufficient ligament support unable to be repaired	No	Yes	Yes
Prior arthrodesis of Ankle Joint	No	No	Yes
Poor skin/soft tissue	Yes	Yes	Yes

The medical community lacks uniformity as well. A review of four professional organizations (American Academy of Orthopaedic Surgeons, American Orthopaedic Foot and Ankle Society, European Foot and Ankle Society, and the American College of Foot and Ankle Surgeons) for position statements or opinions on TAR was inconclusive. The American Orthopaedic Foot and Ankle Society last revised a position paper on TAR in April of 2018 [33]. In the paper, they state that TAR is indicated in patients with primary, post-traumatic, or inflammatory arthritis who have moderate or severe pain, loss of mobility, and loss of function of the involved ankle. The paper goes on to list other indications that include patients with previous hindfoot fusion or significant arthritic change in neighboring joints. The paper is clear to indicate that patients should have exhausted or failed all conservative cares prior to surgery. It should be universally accepted that patients must have satisfactory vascular perfusion in the involved extremity, and appropriate current or planned soft-tissue coverage about the ankle. This position statement does cite a study by Nunely and colleagues which proves an overall marked improvement in quality of life, pain, and function after a total ankle replacement [34]. The paper also cites a review article by Krause et al. in which several major criteria for TAR were discussed [35]. Age, cause of arthritis, deformity, instability, ankle motion, and adjacent joint arthritis were all discussed as major considerations when selecting the appropriate procedure for a patient. The paper did not make a specific endorsement of Krause et al.'s criteria but did state that careful patient selection was necessary for successful TAR.

The American College of Foot and Ankle Surgeons also published a position paper on TAR [36]. The July 2016 paper is fairly broad in its description of who should be considered for TAR. They state select patients with end-stage ankle arthritis should be considered after a careful history and physical. Beyond that, they do not list any specific indications or contraindications.

As part of the research process for this book, we reached out to The American Academy of Orthopaedic Surgeons (AAOS) for their position or guidelines regarding total ankle replacement and their response was at this time they have neither a position statement nor any guidelines in relation to total ankle replacements. The authors recognize that TAR's are performed well outside of the USA and all over the world. The European Foot and Ankle Society was contacted in regard to their position on TAR, but no response was received.

Having reviewed all of these interested parties and what they list as contraindication and indications, it is widely agreed upon that TAR is indicated for treatment of painful, end-stage osteoarthritis, inflammatory arthritis or secondary arthritis, and newly added revisional ankle surgeries in a select group of patients [7–31]. These patients should be carefully chosen based on their overall health, the health of the limb, and the health of the ankle. Table 5.4 lists the considerations most often mentioned by the TAR industry itself, the private insurance industry, and the medical organizations. There is some overlap in terminology, and some contraindications may be better considered as a subset of a broader contraindication rather than as an individual contraindication itself.

A systematic approach to patient selection for TAR should be employed. By scrutinizing the patient in their entirety, a determination of patient eligibility may be made without even examining the ankle. The age, weight, and activity level were frequently cited as considerations (See Table 5.4). Age was primarily a consideration to ensure skeletal maturity only and less of a concern when considering the chances of implant failure due to long-term use. Once the patient is skeletally mature, very few of the guides put a restriction on the patient due to their age. More often cited was the patient's weight and activity level. However, as younger age is often referenced by the medical literature as a contraindication to TAR, the accuracy of this contraindication will also be examined [35].

Table 5.4 Considerations when selecting a patient for TAR

≥11 guides	7–10 guides	<7 guides
Obesity (patient weight) *Activity level* (manual labor, high activity level) *Active infection* (sepsis, elevated WBC) *Insufficient bone stock* (osteoporosis, osteopenia, osteonecrosis, prior surgery that reduced the bone quality, metabolic disorder/medical treatment that reduced bone stock, steroid use) *Insufficient blood supply* *Malalignment of joint* (severe deformity of joint, hindfoot/forefoot malalignment precluding a plantar grade foot, absence of medial/lateral malleoli) *Charcot Neuropathy* (neuropathy that might lead to Charcot joint, neurobiologic disease) *Poor soft-tissue quality at surgical site* (insufficient ligament support that cannot be repaired with soft-tissue stabilization, disease-affecting quality of soft tissue) *Neuromuscular disease* (nonfunctioning lower limb musculatures, weakness at the ankle joint)	*AVN of talus* *Prior arthrodesis* *Sensitivity to component* (known allergy to component) *Pregnancy* *Metabolic disorders* (progressive deterioration of bone)	*Drug/alcohol addiction* *Mental illness* *Significant malalignment of the knee* *Local inflammation* *Likelihood of falls* *Local Bone Tumors* *Unexplained high ESR* *HIV/Hepatitis infection* *Distant foci of infection* *Dementia*

The data regarding age as a contraindication to TAR are mixed. Studies can be cited to both support and refute age as a consideration. The cutoff for a patient to be considered too young for TAR is usually listed as somewhere between 50 and 55 years old [37]. Several large medium- and long-term studies over the last 20 years have examined TAR in younger patients. A 1999 study by Kofoed et al. involving 100 ankles specifically compared TAR in patients under and over 50 years old [37]. This study involved a device no longer currently on the market (STAR cemented prosthesis). The follow-up averaged 6 years, and the results between the two groups were considered equal. Both had a statistically similar survival rate: 75% for the younger group vs 80% for the older group at 6 years postoperatively. After the primary operation, each group showed equal statistically relevant improvement in pain, function, and mobility. The authors concluded that "ankle arthroplasty is a safe and lasting treatment for patients with Rheumatoid Arthritis and Osteoarthritis in both younger and elderly persons." These results are supported by a 2019 study Lee et al. [38] involving 123 ankles who underwent primary TAR using the Hintegra prothesis with a mean follow-up of 78 months. Thirty-eight of these ankles were in patient 55 years old and younger. The overall TAR survivorship was 91.4%. There was no statistically significance difference between the older and younger age groups, but survivorship for the younger group was 97.0%. The authors postulated that the overall survival rate surpassed those of the Kofoed study due to use of a newer generation of TAR. Of note, the lack of revision options for TAR in the older generation of implants has been a concern and a reason to delay surgery until the patient was older. In a 2015 study by Demtracopoulos et al. [39], all the patient under 55 that required revision were able to be revised with another TAR prosthesis. This suggests that newer prosthesis with additional revision options may allow younger patient to undergo TAR.

There are studies that show the contrary and suggest a more advanced patient age is preferred. A 2004 study by Spirt et al. supported this assertion, stating the "age was found to be the only significant predictor of reoperation and failure after TAR." This was an analysis of 2nd generation TARs, specifically the DePuy Agility Total Ankle System, and a group of 85 TARs needing revision surgery. The study determined that patients with a median age of 54 years or less had a 1.45-times greater risk of reoperation and 2.65-times greater risk of failure than did older patients [40]. This trend continued with later generations of TARs. An analysis of 531 TAR in the Swedish Ankle Arthroplasty Register by Henricson et al. published in 2007 on the survival rate of third-generation TARs implanted between 1993 and 2005. This study was weighted toward the STAR with 318 of the TARs being of that brand. The investigators estimated that the overall 10-year survival rate was 62% when using TAR revision as an endpoint. The lower the age at the initial surgery, the higher the risk of having to undergo a revision [41].

Not only the age but also the weight of the patient plays a role in the survival of the TAR. Obesity, traditionally defined as body mass index (BMI) $\geq$30 kg/m^2, is often cited as a contraindication to TAR (Table 5.2). Some studies even exclude the obese from being considered for TAR, and large-scale studies of obese recipients are rare [42]. A 2007 study of 35 uncemented, unconstrained TARs with an average follow-up of 5 years and an average BMI of 30 kg/m^2 reported a 97% satisfaction rating among the patients. A more recent study, published in 2011 by Barg et al., specifically looked at TAR using the Hintegra® (Newdeal SA, Lyon France) in obese patients [43]. There were 123 TARs performed in patients with an average BMI of 32.9 kg/m^2 with an average age of 59.8 years. The authors noted that the TAR survival rate at 6 years was 93% and that they did not observe any trend for obesity to influence the rate of aseptic loosening in TAR. They concluded that their results were comparable to those reported in the literature for nonobese patients. A systematic review of the effects of obesity on TAR published in 2018 included 4 studies totaling 400 implants and 392 patients [44]. The authors found the incidence rate of complications requiring revisional surgery of $\geq$17.8%. The most commonly reported revisional surgeries were revision of the metallic components and ankle gutter debridement. Of note for the physicians hoping that the TAR would help their patients lose weight, the BMI average decreased during the first 2 years after TAR but only by 0.7 kg/m^2 [43].

The TAR is a device like any other and will eventually fail with use and time. Age and obesity are merely factors surrounding that consideration. A young, obese, sedentary person would likely have a lower chance of reoperation than an older, thin active person. While intuitively this may make sense, the literature is vague when describing that third component: activity. Unlike the knee and hip, the primary cause of end-stage ankle arthritis is a history of trauma [43]. This tends to indicate that those people considering TAR are often younger and more active than those seeking other arthroplasties. Defining the term activity and what constitutes sports is difficult to define. The general trend in the literature is that active people seeking TAR are involved in low-impact sports such as swimming, bicycling, and hiking. Using these activities as benchmarks, the studies available report good results in the short and medium term [45].

A 2006 study by Valderrabano et al. of 152 TARs showed an increase in sports participation of 23% from pre- to post-TAR. The average follow-up was only 2.8 years, and the revision rate was 9%, but they found no correlation between revision rate and sports activity. Despite these encouraging results, the authors offered general guidelines on sporting activity after TAR that was based on recommendations for ankle arthrodesis as well as recommendations for those

undergoing hip and knee replacement. These recommendations included the need for the TAR to have radiologic evidence of osteointegration with no signs of loosening or migration. They recommended high-impact activities should be avoided but said that activities such as stationary biking, ballroom dancing, bowling, golfing, swimming, and walking should be allowed [46]. A study with a slightly longer follow-up average of 4.5 years found similar results. Bommin et al. examined 145 Salto Total Ankles and concluded that return to recreational activities was generally possible but the return to impact sports was rarely possible. The average age in the study was 60.9 years, while the average BMI was 25.6 kg/m^2. Only 8 (4.4%) of the prostheses had to be revised, but none of those were in patients considered active [47]. In 2017, Usuelli et al. published a 1-year follow-up suggesting there is no difference in return to activity at 1 year between a mobile-bearing (Hintegra®) and fixed-bearing (Zimmer Trabecular Metal Total Implant®) TAR [48].

The results reported so far demonstrate that the patient's desired activity level can either be an indication or a contraindication for TAR. If the patient desires to maintain or even begin some level of mild exercise such as swimming or bicycling, then TAR is acceptable. These types of activities do not appear to increase the TAR revision rate over the short term. There is no good evidence suggesting that the patient will be able to return to intense, impact heavy athletic activities. Moreover, the general consensus among practitioners is that TAR would not be an appropriate procedure in such patients. Despite the positive results from these studies, the authors always advise that TAR patient's limit their activities. Certainly, long-term and focused studies need to be performed looking into revision rates and specific, well-defined levels of activity.

In a more practical vein, a prospective study by Gagne et al. in 2018 looked at the employment status of working-age patients after recovery from ankle arthritis surgery [49]. This study looked at both TAR and ankle arthrodesis patients. There were a total of 194 patients enrolled with 103 undergoing TAR. Being of working age, the cohort was slightly younger with an average age of 47 years. The study did not show any statistically significant difference between employment prior to surgery and after surgery or unemployment prior to surgery and after surgery. However, the data indicated a trend toward employment and away from unemployment with 109 employed prior to surgery and 121 employed after surgery. From a societal cost, the study was able to demonstrate significantly fewer patients were continuing subsidized programs postoperatively.

After considering whether the patient as a whole would generally be a good candidate for TAR, the practitioner should look at more local factors. Poor bone stock or osteoporosis is almost universally considered a contraindication (see Table 5.2). When implanting a TAR, bone loss is a result of the osteotomy. This changes the local anatomy and decreases the ability of the bone to resist the normal axial loading forces crossing the ankle. Complications from this include implant subsidence, periprosthetic fracture, compromise to the integrity of the implant–bone interface, accelerated osteolysis, and catastrophic or insidious implant failure [50, 51].

Almost all of the available TARs are FDA approved for use with polymethylmethacrylate (PMMA) cementation to assist in the implant–bone interface. Often, physicians concerned about significant bone loss, fracture, or retention of infected PMMA do not use PMMA to fixate the TAR during their procedures. Some have turned to injectable bone graft substitute as an alternative [42]. There is also evidence to support the use of hydroxylapatite-coated prosthetic in an uncemented TAR in patients with osteoporosis. Zerahn et al. found an increase in bone mineral density over the first year in the area around the implant–bone interface in the distal tibia which they interpreted to mean that the fixation of the TAR was good [52]. An interesting study using only computationally obtained results for micromotion in the three most commonly implanted TARs in the 2010s— BOX® (MatOrtho, Leatherhead, UK), Mobility® (DePuy, Warsaw, IN, USA), and Salto® (Tornier, Amsterdam, The Netherlands)—was published in 2017 [53]. They found any malpositioning of the implant created a gap between it and bone resulting in considerable increases in micromotion and bone strains. Even more important than implant design was when a gap was present at the fixation surface of the device. It would seem, then, that any filler such as PMMA that enhances implant–bone interface would help to reduce the micromotion and reduce the risk of failure. Poor bone stock may also risk a more immediate problem in the form of insufficiency fractures. In a study of 503 TARs by Manegold et al., the identified incidence of periprosthetic fracture was 4.2% (21 patients), and of those patients that did suffer a fracture, 38% were stress fractures due to insufficient bone stock [54].

An area of specific concern is the condition of the patient's talus because it is the smallest of the three bones of the ankle and is often the site of greatest damage related to underlying arthritis. The talus is also the most common site for subsidence. The presence of necrosis in this bone, therefore, is of greater concern than similar defects in the tibia or fibula. A longstanding practice has been for physicians not to recommend TAR for patients with avascular necrosis of the talus [55, 56].

When deciding whether to pursue TAR, it is helpful to separate the amount of necrosis into two categories: partial or complete. If the talus is partially dead, there is the difficulty of getting the prosthetic to bind to the surrounding bone. The use of cementless TAR is contraindicated because the potential for good bony ingrowth and component fixation is low. However, if the talus is revascularized, this may

increase the likelihood of success in TAR [56]. The downside of this is of course the uncertainty of knowing if and when the necrotic aspects of the talus may become revascularized and to what extent. If the vascular supply of the talus is of concern, the risk of damaging it by TAR and inducing avascular necrosis would certainly be a contradiction to the procedure. A more detailed examination of the microvascular supply of the talus with TAR in mind has been explored. This has led to concerns about specific implants disrupting specific vasculature within or near the talus itself [57, 58]. While these are cadaveric studies without clinical correlations, the idea of the implant itself as a cause of necrosis of the talus is intriguing and certainly deserves further study.

If the talus is completely necrotic or absent, whether due to subsidence or AVN, a common opinion is that arthrodesis or even amputation is more viable options. A cited tipping point has been greater than 50% loss of talar bone means that arthrodesis with bulk allograft is the appropriate salvage procedure [59]. However, several techniques have been proposed that allow for the preservation of the ankle joint when the talus has been destroyed. These studies have been from revision TAR surgeries, but the theory can be applied to primary cases with massive talar loss. Schuberth et al. reported good results reinforcing the remaining talar body with three large screws through the calcaneus into the talar region and then putting a talar prosthetic on top of them [59]. Another technique involved the use of custom or long-stemmed talar components. The subtalar joint is often arthritic due to talar collapse. The long-stemmed component fuses the subtalar joint but also gains purchase and stability in the calcaneus. Ketz et al. reported on 33 of these custom implants and reported that they were a reasonable alternative to traditional arthrodesis procedures [60]. While loss of talar bony structure is not an ideal setting for TAR, there are proposed surgical techniques that have reported success [59, 60].

As stated above, bone quality is only half the consideration when looking at the local condition of the ankle. The soft tissue and blood supply must be in good order as well or the patient risks delayed healing, infection of the implant, and even below-knee amputation. Studies have varied on what is considered significant when evaluating patients for possible wound-healing difficulties. One of the first studies to thoroughly examine wound problems after TAR was a study published in 2010 by Whalen et al. [61]. The overall rate of wound complications was higher in this study (28%) than typically reported, but the authors felt this was due to their poor patient selection. In the study, the authors defined breakdown as a prolonged lack of healing of the incision with full-thickness necrosis of the skin edges and development of ulceration, or acute wound breakdown in the early postoperative period. Smoking greater than 12 pack years, peripheral vascular disease, and cardiovascular disease were the possible risk factors that showed a statistically significant increase in rate of wound breakdown. Those factors that did not show a significant difference were tourniquet time, history of diabetes, nonsteriodal anti-inflammatory use, prednisone use, and antitumor necrosis factor agents. Of note, 3 of the 4 patients that required removal of the TAR had either an occluded or absent anterior tibial artery. This suggests that if the patient does suffer from known risk factors, vascular studies are advisable prior to the procedure. If findings from those studies show poor perfusion of the anterior ankle region due to absence of an anterior tibial artery or other factors, alternate anterior and posterior incisional approaches to TAR have been proposed [62, 63].

A 2010 study by Raikin et al. of 106 arthroplasties divided wound-healing complications into three categories: no complications, minor complications, and major complications. Factors examined included diabetes, peripheral vascular disease, cigarette smoking, inflammatory connective-tissue disease, steroid and rheumatoid medication use, BMI, sex, age, implant size, and tourniquet time. Minor wound complications were those that resolved uneventfully with local wound care, while major complications were those that required surgical intervention. Diabetes was the only significant factor in the occurrence of minor wound complications. The study found a significant association between female gender, inflammatory connective-tissue disease, and corticosteroid use in patients with major complications and cited the odds of having complications requiring reoperation increased 14.03 times if the patient had a diagnosed inflammatory connective-tissue disease [64]. A later study by van Heiningen et al. published in 2013 seems to dispute the findings of the Raikin et al. study. In it, van Heiningen et al. performed a systematic review of studies including those undergoing TAR with rheumatoid arthritis. This revealed an incidence of wound-healing problems of 9% (20 of 293) which was lower than the Raikin et al. study [65]. Without clear evidence to guide the decision-making process, the practitioner should be cautious. Careful examination of the soft-tissue envelope surrounding the ankle should be undertaken, and adequate vascular supply should be confirmed.

Intraoperative considerations regarding the soft-tissue envelope should not be discounted either. In a retrospective comparative series of 762 primary TARs published in 2017, Gross et al. compared the demographics, operative characteristic, and functional scores to see if any difference existed between patients with and without major wound complications [66]. They were able to identify 26 patients out of this group that developed incisional wounds requiring additional surgeries such as operative debridement, split-thickness skin grafting, and soft-tissue reconstruction. The authors found that both the control and wound group had similar preoperative health comorbidities, including diabetes. What was different in the wound group was a higher rate of primary osteoarthritis, longer mean operative time (214.8 vs

189.3 min), and longer mean tourniquet time (151 vs 141 min. The authors postulated that the reason for the increase in wounding with primary osteoarthritis was due to prior corticosteroid injections into the operative ankle. As for the reasons for increased risk of wounding with longer operative time and longer tourniquet time, these carry the obvious concerns of decreased blood flow to the surgical area as well as increased tissue handling. Both are described risks in arthroplasty of knees and hips. Surgeons willing to undertake TAR should be mindful of these intraoperative risk factors and choose their support staff accordingly.

Even with good bone quality and blood supply, the alignment of the tibiotalar joint can dictate whether TAR is appropriate or not. Uncorrectable malalignment of the joint is an accepted contraindication but the boundaries of what constitutes such a deformity are unknown. Certainly, the malalignment in the tibiotalar joint may be the result of a more proximal deformity and these must be corrected first [67]. When focusing on the joint itself, the goal is to return the joint to a plantigrade state, which may pose difficulties. A study by Henricson and Ågren of 196 second-generation TARs found that of the ankles with preoperative varus or valgus deformities, just over 50% (29/55 varus and 23/46 valgus) retained some malalignment after the procedure with 15° of deformity having a significant increase in failure rates [59]. The major problem of remaining malalignment in the joint after the TAR is a phenomenon known as edge loading, which is an asymmetric force affecting the polyethylene component and indirectly the implant–bone interface. This leads to uneven and increased wear of the polyethylene and higher risk of implant loosening [68].

Determining significant malalignment is difficult. Different studies use different cutoff for neutral, mildly, moderately, and severely deformed ankles. In a prospective, randomized study by Wood et al. of 200 second-generation TARs, the authors determined that there was a hazard ratio of 1.64 for each 5° of deformity. This reached a significantly greater incidence of failure in joints with greater than 15° of deformity [69]. This is not a universally held opinion however. In a 2009 study by Hobson et al. of 123 TAR and a 4 -year follow-up, 32 TARs had preoperative deformities greater than 10°. They reported that patients with a preoperative deformity of the hindfoot of up to 30° did not have an increased risk of failure, complication, or adverse clinical outcomes.

They, and most other studies, have found the predominate deformity to be varus and stated that any deformity should be corrected at the time of primary surgery with standard bony cuts and soft-tissue releases. Should failure occur due to gross instability, it cannot be addressed by lateral ligament reconstruction alone [70]. A 2013 study by Sung et al. that examined 20 ankles with severe coronal plane deformities of greater than 20° and 79 ankles with deformities less than 20° showed no difference between the outcomes at 2 years. They felt that careful attention to adjunct procedures such as lateral ligament repair and transfer of peroneus longer to brevis performed during the TAR to ensure the entire foot and ankle were in proper alignment was key to their success [71]. In 2013, Trajkovski et al. published a prospective matched cohort study demonstrating that the clinical outcome of TAR performed in ankles with preoperative varus alignment of greater than or equal to 10° was comparable with those in more neutrally aligned ankles at the mean follow-up of 35 months. More importantly, 50% (18 ankles) in the varus group had a deformity of greater or equal to 20°. Due to the small number, the researchers were unable to find a significant difference in outcome between this group and the group with 10–20° of deformity. The researchers did note that more ancillary procedures were required during the primary surgery to achieve a plantigrade foot in those ankles with greater malalignment [72]. A larger, long-term study by Lee et al. published in 2018 supports these findings [73]. In this study, 144 consecutive ankles were divided into three groups based on whether the ankle at the time of TAR was in neutral alignment or had a varus or valgus deformity between 5° and 20°. The median preoperative tibiotalar ankle was 11.5° in the varus group, 7.6° in the valgus group, and 2.5° in the neutral group. While the varus groups had more concomitant procedures, there was no difference in major complications between the three groups at a mean follow-up of 7.4 years. Interestingly, the overall rate of survivorship was 91.1% using the cementless 3-component HINTEGRA prosthesis. What the authors found to be the most important aspect regardless of preprocedure deformity was a stable and neutrally aligned ankle after TAR.

An important point mentioned in a 2013 study by Queen et al. was that much of the data regarding TAR are with mobile-bearing prostheses developed prior to 2004 and that a new generation of fixed-bearing TARs (INBONE and Salto Talaris) is coming into greater use. Therefore, the data using the mobile bearing devices should be taken with a grain of salt. The study by Queen et al. of 103 patients confirmed prior studies showing no difference existed between those with neutral, moderate, or severe malalignment after 2 years but pointed out that there was a significant increase in the number of additional surgical procedures performed at the time of TAR in those ankles with greater malalignment [74].

On occasion, the deformity at the ankle may be so great that a staged approach is needed to first correct the local osseous deformity and then perform the TAR. This is most often seen in patients with history of severe trauma to the ankle. In a case report by Lee et al., 3 such cases involved gradual correction of the ankle deformity via the Ilizarov technique, and then, TAR was performed. The corrections achieved included 35° of varus and 2 cm of shortening in one ankle and 15° of varus and 4 cm of shortening in another.

The authors felt that using the Ilizarov technique decreased the significance of the ankle malalignment when planning for TAR [75]. The boundaries for correcting tibiotalar malalignment are expanding. Studies showing satisfactory correction of deformities greater than 15° indicate that this may no longer be the contraindication it once was. The caveat being that the physician must correctly identify appropriate adjunctive soft tissue and osseous procedures to augment the TAR to return the ankle to a neutral position.

There are a few generalized contraindications that should be examined. While it would be contraindicated to perform a TAR in a patient with an active infection, whether in the ankle joint or elsewhere in the body, doing the same in a patient with a history of infection is possible, though not so straight forward. Data are limited on TAR performed in a formerly septic ankle [76]. However, using a protocol-driven, standardized approach to the treatment of septic ankles can eliminate the recurrence of joint infection [77]. A 2019 systematic review by Mazzotti et al. was able to find 32 papers addressing at total of 152 infected ankles arthroplasties [78]. The authors found no clear consensus on the treatment of infected TAR exists and no protocols had been validated, nor were the authors able to develop evidence-based guidelines for the treatment of the infected TAR. The authors found incision and drainage, revision arthroplasty, arthrodesis, cement arthroplasty, and amputation all viable treatment options. On a positive note, limb salvage was accomplished in 89.5% of cases. With this in mind, the physician should proceed with caution as the sequelae of an infected TAR can be devastating, but prior ankle joint infection should not be considered an absolute bar to the procedure.

Another condition, diabetes mellitus, plays a prominent role in the foot and ankle surgeons' world. A broadly accepted contradiction to TAR is the risk for a neuroarthropathy or a Charcot joint (Table 5.2). While this seems reasonable, it is not to imply that anyone with diabetes mellitus is barred receiving from a TAR. In a 2014 study of trends in treatment in TAR, Raikin et al. make note of the fact that while neuroarthropathy and diabetes mellitus are often considered a relative contraindication, this is based on poor results from physicians experience with hip and knee replacements. There are few actual studies on the effect of diabetes mellitus on patient outcomes following TAR [79]. However, in their 2010 study of incision healing complications, they did find that even well-controlled diabetes mellitus with no evidence of peripheral neuropathy or neuroarthropathy increased the risk of minor wound-healing complications [63]. These findings are consistent with an earlier study of 65 TARs of which 4 patients had diabetes mellitus, 2 of which ended in failure. While this may be too small a sample size for any generalized conclusions to be drawn, taken as a whole, even well-controlled diabetes poses concerns for patients undergoing TAR [80]. In a 2015 study by Gross et al., the authors found TAR to be a safe and effect means for providing pain relief and improving function in the diabetic patients [81]. However, they restricted patient with diabetes receiving TAR to those with no indication of peripheral neuropathy or loss of protective sensation. Evidence of Charcot arthropathy in any joint of either foot was also an absolute bar to TAR. Still, there are some surgeons willing to attempt TAR even in patients with a Charcot ankle. A 2008 case report by Lee et al. demonstrates a successful implantation of a TAR in a woman during the coalescence stage. The authors theorized that stable bone ingrowth into the implant could be achieved in the beginning of the reparative process as well as very early in the destructive phase before extensive osteopenia develops [82].

As surgical techniques improve, TAR is being considered for the management of arthropathies where arthrodesis had been the preferred treatment, for instance, in Hemophilic arthropathy. There is a paucity of literature regarding the use of TAR in this patient population, but what does exist is encouraging. In 2010, Barg et al. published a case series on 10 ankles afflicted with hemophilic arthropathy. They proposed that TAR was a viable option to arthrodesis because of the high incidence of involvement of the neighboring joints in the disease process. With an average follow-up of 5 years, the results were impressive: All the patients were satisfied, and no intraoperative or perioperative complications were reported. They did question their long-term results as none of the patients were seropositive for the human immunodeficiency virus (HIV) [83]. This issue was addressed in a later study of hemophiliacs done by Strauss et al. in 2014. They reported on 11 TAR's with a 3 -year average follow-up done on similarly affected ankles but with 5 of the patients being HIV seropositive and 9 hepatitis C seropositive. The results were similar with significant pain reduction and a high level of patient satisfaction. There was, however, a periprosthetic infection rate of 18.2% (2 out of 11) with failed implant salvage. Studies have shown that immunocompromising viral diseases do increase the rate of periprosthetic infections. Although the authors point out that one of the infections was a patient who tested positive for neither HIV nor hepatitis C but had been a heavy smoker for many years [84]. Mid- to long-term outcomes of those with hemophilic arthropathy treated with TAR are also encouraging. In 2017, Eckers et al. published the results of 17 TARs with a mean follow-up of 9.3 years [85]. The clinical results compared favorably with those published for nonhemophilic populations. Radiographs taken for the study did show a majority of the TARs had component loosening and/or periprosthetic lucency. This plus the relatively young age at which the patients underwent the index TARs indicates the high likelihood for eventual revision TAR.

Another generally accepted contraindication and what once was almost universally accepted to be in the purview of

ankle arthrodesis were neuromuscular paralysis about the ankle. This usually manifested itself in a "drop foot" deformity or paralytic muscle dysfunction resulting in ankle arthrosis. Two case studies have attempted to bring some of these patients into the realm of TAR. Bibbo et al., in 2011, reported on a case of a gentleman that suffered an L-5 injury during a motor vehicle crash that left him with a drop foot deformity and severe ankle arthrosis. The authors performed an arthroplasty and a modified Bridle tendon transfer that at the 2-year follow-up allowed the patient 5° of dorsiflexion, enough for foot clearance during gait [86]. A second case report was by Morgan et al. reporting a polio patient with a deformed ankle joint and neuromuscular deficits. They reported good success at 2 years [87]. The common thread between these cases was that the paralysis or neuromuscular disease was static or at least not progressing and that adequate muscle strength either existed or could be brought to bear through tendon transfers to allow the ankle to dorsiflex. Both case studies cautioned that these were rare cases and that the applications of their techniques were limited.

While conversion of a failed TAR to an ankle arthrodesis is often cited as a viable revision procedure, prior arthrodesis of the ankle joint is considered a contraindication to TAR. The options for revision of painful or malaligned ankle arthrodesis are amputation, revision arthrodesis, and also conversion to TAR. The advantage of revising an arthrodesis to a TAR would be pain relief but more importantly delaying degenerative joint disease in joints adjacent to the ankle joint. There are few published studies on the conversion, and the results are mixed, but this is becoming a more popular option. A 2004 study by Greisberg et al. of 19 ankles reports an almost 50% intraoperative malleolar fracture rate and only a 57.9% survival rate at 39 months using the Agility Total Ankle. The authors were hopeful that newer, wider talar implants, and selecting patients with preserved anatomy would improve the outcomes [88]. A more optimistic study on the use of TAR for revision came from Barg and Hintermann in 2010. They reported on 33 TARs followed for an average of 5.7 years. The results were very good. Only one tibial component required revision; however, only 6 ankles (18.2%) were completely pain-free. The authors emphasized the need for appropriate planning of the osteotomy site for the new ankle joint and the need for wide contact area at the implant–bone interface between the prosthesis and the tibia or talus [89]. In 2018, Coetzee et al. published early results of a prospective longitudinal study on functional outcomes after conversion of ankle arthrodesis to TAR [90]. At a mean follow-up of 22.19 months, the cohort of 25 patients showed improvement in several outcome measurements including the Veterans Rand Health Survey, Ankle Osteoarthritis Scale, Visual Analog Scale, and the American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Score form. Overall, patients were satisfied with their results. This study should give insight into how these takedown TARs compare with primary TARs.

TAR is a demanding surgery on the patient. Considerations that are often not taken into account are the willingness to participate in the recovery process necessary for TAR success. While people of low socioeconomic status are often associated with poor compliance, there is also evidence that even physicians may fail in this regard [91]. Along those lines, the patient must be invested in the recovery. As TAR is often the result of traumatic osteoarthritis, it is not unlikely that the patient will be involved in some sort of legal dispute associated with their injury and subsequent care. A 2005 meta-analysis showed a summary odds ratio for unsatisfactory outcomes with patients involved in Worker Compensation type claims to be 3.79. This means that people in these situations are significantly more likely to have poor outcomes across all types of procedures including orthopaedic surgeries [92]. Physicians must do their due diligence to ensure the patient will be able to comply with the demanding postoperative course.

TAR is a challenging procedure with a well-established learning curve. Although the implants and surgical techniques are improving, it is not a universally applicable procedure. The indications for a TAR have remained fairly static over the years with painful, end-stage primary osteoarthritis, posttraumatic osteoarthritis, or inflammatory arthridities being the vast majority of presenting conditions. What constitutes a contraindication continues to be in a state of flux. With improvements in implant design and techniques as well as familiarity with the procedure, the bounds of what is possible are being pushed out and blanket contraindications such as a malaligned ankle have very little meaning. When contemplating if TAR is appropriate, the physician should no longer just look at the condition of the ankle joint, but now has a whole host of important and evolving factors to consider.

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A Guide to Surgical Consent for Primary Total Ankle Replacement

6

Timothy M. Clough and Joseph Ring

Introduction

Total ankle replacement (TAR) was first introduced in the 1970s as an alternative to ankle fusion for the treatment of end-stage ankle arthritis [1]. Initially, results were very poor, resulting in an editorial by Hamblen in 1985 to suggest the ankle joint could not be replaced [2]. However, with the advent of more modern implants, and potentially those now implanted under X-ray guidance, total ankle replacement is becoming an increasingly attractive treatment alternative to ankle arthrodesis, which for years has been considered the gold standard for the treatment of end-stage ankle arthritis. Nevertheless, TAR surgery remains a technically complex procedure and carries with it a wide variety of associated risks. It is important for both the operating surgeon and the patient, to understand these risks in order that they may be able to make an informed decision about their treatment options.

In this chapter, we discuss 'informed consent' principles for TAR and the potential risks associated with the procedure. It is important to understand that this book is aimed at an international audience and that consent practices and legalities will be different in each country. However, we hope that this chapter will provide evidence to support this process, regardless of the legal or cultural requirements.

The consent process is an integral part of the duty of patient care. The consent process should not be static in nature or occur at one sitting, but instead should be a process from first contact with the patient until the time of surgery. It is not simply completing a consent form and listing the risks of surgery. The consent discussion should be tailored to each individual patient, to their relative risks and also to their level of understanding. The procedure and compilations should be explained in clear layman's terms to ensure clarity and understanding. Ideally, the process should be supported by additional written information and sufficient time should be given to allow the patient to reflect upon the information and make a gathered informed decision.

Evolution of the Consent Process within the UK

The evolution in the consent process in the UK has gone hand in hand with the evolution of the medicolegal process, and to understand the former we would have to understand the latter. The Bolam test has, up until recently, been the benchmark level of medicolegal test within the UK, since the case came to Court in 1957 (Bolam v Friern Barnet Hospital Management Committee) [3]. This medicolegal test has been applied to all areas of medical judgement and practice, including decision to treat, consent, acceptable risks and complications of surgery and post-operative care [4]. It is worthwhile analysing and reviewing this case, as it provides an excellent insight into historical levels of medicolegal precedent, and provides a contrast to the modern changes. Hector Bolam was depressed and his doctors prescribed him treatment with electroconvulsive therapy (ECT). He was not restrained or sedated for the procedure and unfortunately was thrown violently onto the floor, during the procedure, sustaining leg fractures. He subsequently sued his psychiatrist. Expert medical opinion was gathered on both sides, with the experts for the defence arguing that sedation and restraint carried risks, and were not, at that time, deemed mandatory. The Judge presiding, Justice McNair, concluded that, 'a doctor is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical men skilled in that particular art. Putting it another way, a doctor is not negligent, if he is acting in accordance with such a practice,

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merely because there is a body of opinion who would take a contrary view' [3].

This legal ruling 'set the bar' for many years until the Bolitho v City and Hackney Health Authority (1996/8) ruling, where the House of Lords decreed that a judge was entitled to choose between two bodies of expert opinion and to reject an opinion if they felt it was 'logically indefensible' [5].

The case of Montgomery v Lanarkshire Health Board (2013) completely changed the focus of consent process in the UK [6]. Mrs Montgomery, a Type 1 diabetic, was not told of her increased risk of shoulder dystocia during vaginal delivery. Complications unfortunately ensued with the delivery, resulting in the baby being born with cerebral palsy. She subsequently sued her Obstetrician. Again, expert medical opinion was gathered on both sides. The case went to the Supreme Court in 2015, where James Badenoch QC (Appellant), Lead Counsel, was scathing in his attack of the Bolam test, subsequently reporting the Montgomery case as … 'spelling the beginning of the end for the Bolam test in all its applications' and advocating finally 'the slaughter of the Bolam sacred cow' [7]. Lord Scarman reported that, '…if, therefore, the failure to warn a patient of the risks inherent in the operation…does constitute a failure to respect the patient's right to make their own decision, I can see no reason in principle why, if the risk materialises and injury or damage is caused, the law should not recognise and enforce a right in the patient to compensation by way of damages' [6]. He went on further to say, '…I think that English Law must recognise a duty of the doctor to warn their patient of risk inherent in the treatment which they are proposing...the test of material risk being that a reasonable person in the patient's position would be likely to attach significance to that risk…' [6].

Thus the focus of the consent process in the UK has changed, from one in which initially a 'reasonable body of medical evidence' (i.e. a consensus view of medical experts) would decide medicolegal precedent, initially to one in which the judge presiding would be allowed to rule which medical consensus view he would choose (based upon the information presented to him by the different 'medical experts' in Court), to finally the current situation, of where the patient chooses their own treatment plan based upon both the presentation of all the relevant information being laid before them, and the patient understanding that, and any/all potential risks or side effects of that and alternative treatment.

Thus Montgomery ruling changed the consent focus, from one in which the surgeon would explain the procedure to the patient and obtain their signed consent to proceed, to one in which the surgeon sets out the range of treatment options and allows the patient to decide. This change requires the surgeon to take time to explore the patient's values and wishes about their care and to understand the risks and benefits that are material to that patient.

Guidelines have now been produced to help the treating clinician through the modern consent process [8]. Several key issues are emphasised as follows:

(i) the patient should be given a clear explanation of the nature of their diagnosis in a way that they can understand.
(ii) the patient should be given a clear explanation of the range of treatment options available, including 'do nothing', conservative measures and surgical options.
(iii) risks and benefits for each of the treatment options should be given, again in a descriptive format that the patient can understand, and also in a way that the consequences of any such risk would potentially have on the patient are outlined.
(iv) there should be a contemporaneous record of any such discussions with the patient and ideally the patient should be sent copies of any such letters, together with any further material (either written patient information leaflets or web sites to review).
(v) there should be sufficient time for the patient (in an elective situation) between the dispensing of such information and treatment, to make an informed decision to ensure that they can fully digest and reflect on the information and ask any further questions that may ensue.
(vi) the surgeon needs to confirm with the patient before undertaking the procedure that they fully understand the material risks of the treatment, the complications and the potential effect any such complications could have on them.

In order to facilitate these processes, it is vital to understand that modern consent is a process that takes time, and is not just a case of signing a form. Similarly, doctors cannot, and must not, act in a paternalistic manner, advising patients upon what they perceive to be their best course of treatment. Patients must now have all relevant information put before them, in a format and language that they can reasonably understand, and be allowed time to review and question that information, before making 'their' informed choice, based upon an understanding of that information, their personal circumstances and their specific needs. The clinician should also have a clear knowledge of their own Unit's complication rates, particularly in comparison to National averages.

Treatment Options

Options available for the treatment of end-stage ankle arthritis thus include 'do nothing', non-operative and operative options. Often, by the time referral is made to the surgeon,

patients will have tried and exhausted many of the non-operative management options. However, these still need to be explored as part of a detailed consent discussion.

Benefits of Surgery

As with any joint arthroplasty, the benefits of TAR should be a pain free, mobile and stable joint, with a view to restoring function and improving quality of life with a long-lasting durable prosthesis. We feel that when discussing TAR, it is vitally important not only to be able to offer National survival rates (from Implant Registries and the literature), but also to offer realistic local figures specific to the Unit for the implant currently in use, in relation to success with this procedure including relative survival rates and complication rates.

Survivorship of ankle replacements is not as good as hip or knee replacements, although they are improving. The Swedish joint registry has reported on TARs performed between April 1993 and December 2016, with a 5 and 10 year failure rates of 19% and 31% with 'older' designs (pre2008) compared to 5 and 10 year failure rates of 12% and 16% with 'newer' designs (post2008) [9]. The New Zealand registry has been collecting data since January 2000 and has 1737 primary procedures recorded, with a 5 year cumulative failure rate of 8.7%, 10 year failure rates of 15.8% and 15 year failure rates of 22% [10]. A recent meta-analysis reported failure/revision rates for TAR ranging from 1.3% to 32.3%, with a mean of 9.8% at a weighted average of 5 years follow-up [11]. The 2020 National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, which has been collecting TAR data since 2010, and now has 6589 primary ankle replacements, reports slightly better cumulative revision rates of 6.9% (95% CI 6.0–7.8) at 5 years and 8.5% (95% CI 7.5–9.7) at 7 years [12]. The largest single consecutive series of ankle replacements in the literature, with longest follow-up, report survival rates of 90% 5 years, 83% 10 years and 76% 15 years, respectively [13]. The annual failure rate across a variety of implant types has been reported at 1.2% (95% CI 0.7–1.6) [14].

Risks and Complications

With informed consent, there should be a clear and honest discussion of the surgical risks with a view to highlighting those specific to that patient, both in terms of relative risk and also in terms of impact on lifestyle. For example, for a younger, more active patient the risk of revision surgery due to implant loosening and wear is likely to be higher, whereas in a patient with rheumatoid arthritis the risks of infection, wound-healing problems and subsidence are likely to be greater.

There is a wide variation in the reported rate of complications associated with TAR surgery, ranging from 13.5% to 54.5% [15]. The Canadian Orthopaedic Foot and Ankle Society (COFAS) Ankle Arthritis Study Group has developed a standardised reporting system for adverse events and reoperations, known as the COFAS Reoperation Coding System (CROCS) [16]. The Editorial Board of Foot and Ankle International (FAI) has discussed the need for more consistent reporting of complications and recently published their recommendations [17]. Clough et al. performed a comprehensive literature review providing detailed analysis of complication rates associated with TAR surgery, in order to help with the informed consent process [15]. The authors present these, based upon the recommendations of the Editorial Board of FAI.

Overall complication rates of TAR vary in the literature from 13.5% to 54.5% [15]. An awareness of these potential complications and the quoted incidences from the literature is important (Table 6.1). However, this is not a substitute for being able to accurately quote the relative risks of these compilations in that individual surgeons or Units' practice. There is evidence in TAR literature that there is a surgical learning curve and complications are lower for more experienced surgeons [16–23]. In addition, it is important to understand the significance and implications of these complications on implant survival [24, 25]. Glazebrook et al. [24] attempted to classify the severity of complications following TAR in terms of risk to implant survival. High-grade complications included deep infection, aseptic loosening and implant failure. They reported that these complications would have at least a 50% risk of implant failure (implant failure 69–81%

Table 6.1 Quoted complication rates from the literature for primary TAR

Complication	Literature % Range
Overall complications	13.5–54.5%
Intraoperative fracture: Medial	3.1–9.7
Intraoperative fracture: Lateral	0.05–2.1
Post-operative Fracture Early (<4 months)	1.5
Post-operative Fracture Late (>4 months)	2.0–5.0
Malpositioning	1.1–6.0
Wound Problems	0.9–14.7
Superficial infection	1.3–7.2
Deep Infection	0.5–5.7
Aseptic Loosening	3.2–19.0
Polyethylene fracture/dislocation	0–14.0
Edge Loading	2.5–23.0
Gutter pain	2.0–23.5
Residual pain	3.5–60.0
Stiffness	0–1.8
Soft tissue injuries (nerve/tendon)	0.5–15.3
Subsidence	0.9–46.0
Venous Thromboembolic Events	0–4.8
Chronic Regional Pain Syndrome (CRPS)	0–4.4
Amputation	0.4–2.6

of the time). Medium grade compilations included technical error, subsidence and post-operative fracture. These complications resulted in implant failure less than 50% of the time (17–45%). Low-grade complications included intraoperative fractures and wound-healing issues. These did not lead to implant failure in any cases. However, Gadd et al. [25] reported their collective complications in 217 TARs in 198 patients, finding that both the high and medium risk complications of Glazebrook had, in their hands, at least a 50% risk of implant failure. Thus they felt complications should be simplified into merely high or low risk.

Simonson and Roukis [20] performed a systematic review of 25 studies and found a reported overall complication rate with primary TAR surgery of 44.2%, which is similar to that reported by Clough et al. of 41.7% [15]. Using the above classification system of Glazebrook et al. [24], they assessed that 10.3% of these complications would be high-grade complications and thus likely to lead to failure of the prosthesis, 35.5% were medium grade (and thus, on the balance of probabilities, unlikely to lead to failure of the prosthesis) and 54.2% were low grade, and thus not affect the lifespan of the prosthesis [20]. Clough et al. reported, in their series of 278 TARs in 251 patients, that 17.1% of the complications led to an adverse clinical outcome (7.6% cases) [15].

Given the complexity of TAR surgery, the surgical learning curve has attracted much discussion. Myerson and Mroczek reported a reduction in surgical perioperative complications in the second 25 patients when compared to a surgeons initial 25 patients for the Agility (DePuy, Warsaw IN) TAR [21]. Lee KB et al. similarly reported a reduction in perioperative complications when comparing a surgeons subsequent 25 cases with their initial 25 cases for the HINTEGRA prosthesis [22]. Haskell and Mann reported a threefold decrease in perioperative adverse events in the surgeons second 5 cases when compared to their initial 5 cases, for the STAR prosthesis [18]. However, Lee KT et al. reported that whilst there was some reduction in the perioperative complication rate in the second 30 patients when compared to the surgeons initial 30 patients, for the Mobility prosthesis, this difference was not significant [19]. Saltzman et al. looked at three surgical training methods (trained by observing the surgeon, trained by completing a structured hands-on surgical training course or trained by completing a 1 year foot and ankle Fellowship) to identify if this would affect surgical complication rate or influence the learning curve specifically for TAR surgery [23]. They found that none of these training methods had a statistically significant difference with respect to complications, revisions or malalignment. Thus, it is impossible to quantify exactly how many TARs need to be performed before the surgeon has likely escaped the surgical learning curve, as there are too many multi-factorial variables. Similarly, it seems that there may be no one teaching strategy that is better than another in attempting to optimise surgical prowess and performance. However, it does make common sense, that for particularly complex and challenging surgery, such as TAR surgery, a new surgeon or Consultant should optimally perform such complex procedures initially under close supervision, potentially as joint procedures, with a trained and experienced surgeon in that procedure.

Table 6.1 illustrates the rates of complications experienced from TAR we will discuss each of these in detail in this chapter.

Fracture

Fractures can occur either intraoperatively or post-operatively (early or late). Early post-operative fractures are those not seen on the immediate post-op X-ray, but are seen within the first 4 months following surgery. Late post-operative fractures occur after this time. Medial malleolar fractures are the most common, but fractures of the anterior or lateral tibial plafond can occur, as can fractures of the fibular. Some of these fractures require fixation and some require an additional period of immobilisation.

Intraoperative Fractures

These most often involve the medial malleolus. The incidence of medial malleolar fractures is quoted between 3.1% and 9.7% [14, 15, 20]. Zaidi et al. [14] reported a mean of 6% in their meta-analysis. Lateral malleolar (fibular) fractures can occur, but are much rarer (0.05–2.1%) [14, 26]. The exact incidence varies depending on type of implant used, surgical technique, surgeon experience and patient demographics [15, 18, 20].

If a fracture occurs intraoperatively and is recognised, the authors would recommend surgical stabilisation during the index TAR procedure (Fig. 6.1). Medial malleolar fractures can be reduced via the anterior approach used for the TAR and fixed through a small percutaneous extra medial incision, often with one or two screws, whilst lateral malleolar fractures usually require a separate incision with plate and screw fixation. When recognised and treated intraoperatively, there are usually no long-term sequalae [25]. Standard fixation techniques can usually be employed, but one should ensure that the equipment and implants for this are available, especially if working in a Unit which does not routinely operate on trauma cases.



Fig. 6.1 Intraoperative medial malleolar fracture recognised and stabilised with a single malleolar screw at the time of surgery. This united without any long-term consequence to the lifespan of the TAR prosthesis

Post-Operative Early

Fractures that occur in the early post-operative period (not seen on the immediate post-operative X-ray, but seen within the first 4 months following surgery) usually can be managed non-operatively, as long as the implant is stable. This complication is less well reported within the literature. In a series from our Unit, the overall incidence was 1.5% [15]. The authors managed this complication conservatively, with a period of immobilisation either in a plaster cast or a boot with protected weight-bearing. In our series, all of these fractures healed uneventfully and did not affect the implant function or survival. However, it is important to recognise these fractures, as if missed or not appropriately treated, then they could displace leading to loss of implant position, and potentially therefore to premature implant failure [27].

Post-Operative Late

Late fractures are also not well reported in the literature. The incidence lies between 2% and 5% [15, 24, 26]. In our experience, they usually occur at least a year post-surgery. Unlike early post-operative fractures, these fractures usually carry a worse prognosis [28, 29]. They are often stress fractures related to overload, often due to edge loading of the implant or recurrent hindfoot malalignment. They need to be assessed carefully and, in some cases, may require surgical stabilisation, to prevent progressive hindfoot drift, worsening of the fracture and deformity. Additionally, in some, one may need to consider corrective hindfoot surgery to overcome the loss of position and to restore the mechanical axis.

Malpositioning/Technical Error

The function and long-term survival of the implant is critically dependent on the surgeon's ability to restore ankle and hindfoot alignment, correcting any preoperative deformity, achieve ligament balancing and implant the prosthesis in the correct orientation, alignment and stability. TAR surgery is particularly complex and attracts a steep learning curve [18–22]. Reported rates of this complication range from between 1.1% and 6% [24, 25]. Lower rates have been reported with modern jigged implants and with the use of intraoperative fluoroscopy to guide implantation [30]. The UK NJR reported malalignment as the fourth commonest indication for revision of the primary ankle replacement, accounting for 7.7% of the cases [12].

Malpositioning (Fig. 6.2) almost invariably requires revisional surgery, with Gadd et al. reporting revisional surgery rates of 81% for this complication [25]. Glazebrook et al. found that in 45% of the cases, this complication leads to premature implant failure [24].

Wound Complications

The skin and soft tissues over the ankle, especially anteriorly, which is the most common surgical approach for TAR surgery, are particularly sensitive and should be handled sparingly and with great care. The reported rates of wound-healing problems vary between 0.9% and 14.7% [11, 24, 25]. There are both patient and surgeon related factors [31]. Patient factors include inflammatory arthritis, with rheumatoid arthritis carrying a fourteenfold increased risk of wound-healing problems [31]. This is due both to the condition itself and the



Fig. 6.2 Significant malpositioning of implants requiring revisional TAR surgery

use of the immunosuppressive medications used to control it. Other patient factors include diabetes, steroid use, obesity and smoking [32, 33]. Surgical factors include poor soft tissue management and the inappropriate use of self-retainers in the wound. Haskell et al. reported wound-healing problems to decrease from 34% to 14% after a surgeons first five TARs [18]. Most wound-related problems can be managed conservatively and do not affect the outcome or lifespan of the prosthesis [15, 24, 25].

Infection

Infection after any arthroplasty can be a devastating complication. This infection can be superficial or deep.

Superficial Infection

Superficial Infection after TAR has a reported incidence of 1.3–7.2% [14, 15]. Risk factors include inflammatory arthropathy and diabetes, as well as other conditions and medications which lead to immunocompromise [31–33]. The incidence of infection for rheumatoid patients has been reported as 6.5% and for diabetics, the risk is double that of non-diabetic patients [32]. Although superficial infection usually responds well to simple treatment, there is always a concern of it progressing to deep infection.

Deep Infection

This is the feared complication for any arthroplasty and often caries a poor prognosis. The reported rate of deep infection after TAR surgery varies from 0% to 5.7% [11, 14, 24, 25]. Myerson et al. [34] reported an incidence of deep infection after TAR surgery of 3% over 10 years (19 of 633 TARs). Zaidi et al. [14] however, in their meta-analysis of 58 studies (7942 TARs), reported an incidence of 1.1%. The 2019 National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) reports a database currently including 5587 primary ankle replacements, with 63 cases of revision for deep infection (suggesting also an incidence of around 1.1%). From the UK NJR, deep infection was the second commonest indication for revision of the primary ankle replacement, accounting for 10.8% cases [12].

Risk factors for deep infection include diabetes, rheumatoid arthritis, previous ankle surgery and delayed wound-healing of greater than 14 days. These rates are higher after revision surgery, with Patton et al. reporting almost a doubling of the incidence (2.4% incidence after primary TAR and 4% incidence after revision surgery) [35]. Treatment of deep infection generally requires revision surgery in the vast majority of cases and is a significant burden both to the patient and to the healthcare system [24, 25]. This usually involves a two-stage procedure with implant removal, joint debridement and insertion of an antibiotic loaded spacer with additional and extended systemic antibiotic coverage. Careful microbiological sampling at the time of surgery is essential to try to isolate the causative organism and best guide antibiotic treatment. It is recommended that five specimens are taken at the time of surgery, each with a clean set of instruments, from areas of visible inflammation, as well as the implant/bone interface [36]. Once the treating surgeon is happy the infection is eradicated, one can proceed to a second stage or re-implantation, often with a revision implant if there is sufficient bone stock. Conversion to fusion, either tibiotalar, but usually tibio-talo-calcaneal (TTC), is the other common alternative. In a minority of cases, it is not possible to proceed to a second stage and the patient is left with the spacer, or an amputation is required.

Aseptic Loosening/Osteolysis

Implant loosing due to osteolysis, in the absence of infection, is a major delayed complication and a common cause of implant failure, with a reported incidence of 3.2–19% [11, 24, 25, 37]. A number of factors have been implicated in this process. Component malalignment and an incongruent polyethylene articulation, often due to recurrent hindfoot or ankle malalignment, are key factors in this process [38]. This may be

due to poor initial implantation technique, failure to correct malalignment at the primary procedure or a gradual recurrence of hindfoot malalignment at a later stage. For this latter reason, it is therefore critical to consider the upper threshold of indication for TAR surgery. Wood and Deakin [39] reported recurrent malalignment, with edge loading of the implant, to re-develop in 18% of patients (7/39) with preoperative coronal plane deformities of more than 15°, compared to just 1.2% (2/161) in those with preoperative deformities of less than 15°. A neutrally aligned, stable, ligament balanced ankle with end-stage symptomatic arthritis is clearly the optimal indication for TAR surgery. Any progressive deviation away from these criteria can therefore increase the risk of complications and lead to premature implant failure.

Another key factor is the implant type and design. The AES implant (Ankle Evolution System, Biomet Merck, Netherlands) had a very high rate of ballooning osteolysis [40, 41] and has consequently been discontinued. There can also be considerable variability in the rates of progression of osteolysis, even in those implants of the same design [42]. The key features of aseptic loosening/osteolysis are either progressive/ballooning peri-prosthetic cysts, or lucent lines/demarcation at the bone/implant interface. These can be seen on plain films, but CT scanning is a useful adjunct [43]. Zaidi et al., from their meta-analysis, report they are more commonly seen adjacent to the tibial component, with an incidence of 21% on the tibial component and 1.4% on the talar component at a mean of 4.4 years follow-up. The UK NJR however reports there being a much more even, 50:50 tibia talar component, split, in terms of demarcation rates [12].

The majority of these cases require revision surgery (40–85%) [11, 24, 44]. Indeed, from the UK NJR, it was the most common indication for revision of the primary TAR (45.1% cases) [12].

Implant Problems

TAR continues to evolve and each generation of implants show improvements in design and longevity. However, different implants by their nature demonstrate differing failure mechanisms.

Polyethylene Fracture or Dislocation

Polyethylene fracture after TAR surgery has a variable reported incidence, with two recent large meta-analyses not reporting this complication [14, 24]. However, Brunner et al. [37] reported an incidence of 14% in their series of 72 patients with STAR implants (Stryker, Mahwah, New Jersey) and suggested it was more likely to occur if the preoperative coronal plane deformity was greater than 5°. Scott and Nunley [45] reported thinner inserts were more likely to fracture and fail. Polyethylene fracture (Fig. 6.3) accounted for only 2.1% of the causes of revision following primary TAR on the UK NJR database.



Fig. 6.3 Polyethylene fracture of a STAR prosthesis 8 years after implantation, with broken polyethylene fragment extruded posteriorly into the back of the ankle. This was treated merely with revision of the polyethylene bearing, as the implants were well aligned and not loose

Polyethylene bearing dislocation is only rarely reported through case reports, suggesting it is an infrequent complication [46]. Ligament laxity of the ankle, not addressed at the time of the initial TAR surgery, is thought to play a key role in this latter complication. Polyethylene bearing dislocation accounted for 1.9% of the causes of revision following primary TAR on the UK NKR database. Management options range from simple exchange of the bearing to major corrective hindfoot re-alignment, often associated with full revision of the implant.

Edge Loading

Edge loading (Fig. 6.4) is defined as where there is uneven tibiotalar conformity across the implant bearing interface, resulting in high pressure contact areas on the bearing.



Fig. 6.4 Recurrent edge loading of a STAR prosthesis. Patient previously had a varus ankle with lateral ligament laxity and had undergone primary TAR with lateral ligament reconstruction

Correct ankle and hindfoot alignment and correction of any ligament imbalance are essential to prevent the development of edge loading following TAR surgery. Preoperative coronal plane deformity of more than 10° has been associated with a tenfold risk of progressive edge loading of the polyethylene compared with congruent joints [18]. Wood and Deakin reported edge loading in 18% patients (7/39) with preoperative coronal plane deformities of more than 15°, compared with 1.2% (2/161) in those with preoperative deformities less than 15° [39]. A systematic review on survival of the STAR prosthesis that included 16 studies (2088 patients) reported 18% failure due to implant malalignment and edge loading of polyethylene [47].

Implant Failure

There are a number of reasons for failure of the TAR implant, which can be related to implant design, surgeon and patient factors. Meta-analyses of several implants reported a 90% survival rate at 5 years, and a survival rate between 73% and 89% at 10 years, with a wide variability between various implants and centres [11]. Understanding the mechanisms of how individual implants fail is the key to potential management of revision options.

Chronic Pain

The quoted incidence of ongoing pain after TAR surgery is extremely variable. Gougoulis et al. in their meta-analysis of 13 studies (1105 TARs) reported rates of ongoing pain after TAR surgery of between 27% and 60% [11]. As a complication, this is the third most common indication for revision of the primary TAR (10.2% cases) [12]. The causes of ongoing pain are often classified into gutter pain, heterotopic ossification, residual pain and stiffness. However, it is important to recognise that ongoing pain may not actually be related to the prosthesis itself, but may instead originate from adjacent pathology: anteriorly (talonavicular joint, neuralgic pain), posteriorly (tibialis posterior tendon), laterally (subfibular impingement, sinus tarsi syndrome, subtalar arthrosis, peroneal tendon impingement) or medially (medial ankle stress reaction).

Gutter Pain

Gutter pain is normally noticeable from around three to 6 months following TAR surgery. There are often no obvious factors that could aid preoperative identification of patients at risk. The literature suggests an incidence of 2–23% [26, 48, 49]. The largest study of this complication reported a 7% incidence of medial or lateral gutter pain that was sufficient to require reoperation, in a series of 489 TARs [48]. The exact aetiology of painful gutter disease is unknown. Various factors have been proposed, including certain implant types (potentially those with metallic medial or lateral surfaces), oversizing implants and implant malalignment, as in all these situations, the component can encroach on either malleolus causing impingement and pain [50]. Other reported causes of gutter pain include progression of the natural arthritic change in the medial gutter of the ankle and localised bone cyst formation. This latter complication can be caused by polyethylene wear, joint fluid penetration into bone, pre-existing subchondral cysts that are enlarging or disease-specific cysts (RA or haemochromatosis) [49, 51]. The management of post-TAR ankle gutter pain is difficult, and treatment should be aimed at identifying and addressing the causes of the pain. Due to the numerous causes, it makes any meaningful analysis of the effectiveness of surgical gutter debridement from the literature difficult, as we are often comparing ‘apples with oranges’. Kim et al. [51] however reported surgical gutter debridement to be effective in 86% of patients, with VAS pain scores reducing from 7.1 down to 2.7. However, Richardson et al. [52] were less enthusiastic, reporting a high recurrence rate of 37.5%.

Heterotopic Ossification

Heterotopic ossification is the abnormal formation of mature bone in soft tissues. Risk factors include soft tissue trauma (extensive soft tissue dissection), excessive osseous trauma during the procedure, failure to clear excess bone debris and post-operative haematoma formation [53]. Usually, this process leads to stiffness rather than pain [54]. The authors have found it most commonly occurs posteriorly, involving the posterior joint capsule, but it can occur anteriorly and also in the medial gutter. Rarely would it require revisional surgery. By contrast, painful osteophyte formation, which usually occurs at the tips of either malleoli, can lead to painful gutter impingement type symptoms (rather than stiffness). Treatment of this includes either targeted injection therapy or osteophyte debridement and gutter clearance.

Residual Pain and Stiffness

Some patents may experience more generalised ongoing pain after TAR. This pain may be related to the implant malpositioning, loosening, subsidence, infection (low grade, chronic), impingement (soft tissue or bony), but in some cases no obvious cause can be identified [54]. From the UK NJR database, currently including 5587 primary ankle replacements, 29 cases of revision for stiffness are reported (suggesting an incidence of significant painful stiffness of around 0.5%). It is the fifth most common indication for revision of the primary TAR (accounting for 5.0% causes of revision) [12].

Soft Tissue Injuries (Nerve or Tendon)

The ankle joint shares an intimate relationship with a range of anatomical structures, all of which are at risk during TAR surgery. The reported rate of intraoperative nerve or tendon injury varies from 0.5% to 15.3%, with most studies reporting a rate of around 1.3% [14, 20, 55]. The main cause is often quoted as surgeon inexperience, but even in the most experienced hands, these injuries can still occur [20]. The approach will often govern which structures are most at risk. The anterior approach to the ankle places both the superficial and deep peroneal nerves at direct risk, together with the anterior tibial artery. Inadvertent or prolonged use of the retractors during surgery may cause a neuropraxia. The posterior tibial nerve and vessels can be injured during tibial resection, either directly with the saw, even when using jigged instrumentation, or indirectly by the heat produced by the cut. This complication is often not noticed until postoperatively. Careful clinical examination and documentation is important and ultrasound examination is recommended to assess the integrity of the nerve together with electrophysiological testing [55].

Primadi et al. reported a 6% incidence of posterior tibial nerve injury, 4% incidence of deep peroneal nerve, 4% incidence of superficial peroneal nerve, 0.7% incidence of sural nerve injury and 0.7% incidence of saphenous nerve injury with TAR surgery [55]. Most nerve injuries were found to recover fully (57%), with a partial recovery in 39% case and no recovery in 4% cases [55].

Subsidence

Implant subsidence (Fig. 6.5) has been an issue through the history of TAR. A number of factors play a role in implant subsidence, including poor bone quality (osteoporotic bone), poor bone ingrowth, cyst formation beneath the implant, progressive avascular necrosis, overstuffing or overloading the joint. Stress shielding can lead to bone resorption and implant subsidence [46]. The reported incidence of subsidence in the literature varies widely from 0.9% to 46% [11, 24, 25], with Glazebrook et al. [24] reporting an incidence of 10.7% in their meta-analysis at a mean of 5 years follow-up. This complication has a poor prognosis for implant survival with revision required in 32–100% of cases [24, 25].



Fig. 6.5 Subsidence of the talar component (STAR prosthesis) after 10 years

Venous Thromboembolic Events

The incidence of venous thromboembolism (VTE) after foot and ankle surgery, including TAR surgery, is rare. The quoted literature incidence after TAR surgery is between 0% and 4.8%, with a mean incidence of 0.3% in a recent systematic review (58 papers, 7942 TARs) [14]. Patient with higher levels of co-morbidities has been shown to have a higher risk for VTE and subsequent pulmonary embolism (PE). It is recommended that all patients have an individual assessment of VTE risk, which includes application of the National Institute for Health and Care Excellence (NICE) risk assessment tool for venous thromboembolism [56] or similar local proforma. A recent UK based study, based on data from the National Joint Registry, reported a 0.51% incidence of non-fatal pulmonary embolism (PE) within 90 days of TAR surgery [57]. The use of venous thromboembolic prophylaxis varies between Units and its use remains controversial, with patients developing a PE even when protected with both chemical and mechanical prophylaxis [57].

Complex Regional Pain Syndrome (CRPS)

CRPS can potentially occur after any extremity surgery including TAR. The diagnosis is primarily clinical, and although there are no specific diagnostic tests available, the Budapest Criteria have recently been validated to aid diagnosis [58]. The incidence of CRPS following general foot and ankle surgery has been reported as 4.4% [59]. Risk factors include female sex, past history of anxiety and depression and previous history following surgery [59]. This can be a debilitating complication and remains a challenging condition to treat.

Amputation

TAR, like any major lower limb surgery of this complexity, has a small risk of catastrophic complication ultimately ending up in below knee amputation. Whilst this complication is rare, it is clearly a major life changing event and patients should be informed accordingly of the risk preoperatively. Spirt et al. reported an incidence of 2.6% in their series of 306 primary TARs, noting amputations were more likely in patients with a history of previous severe trauma and multiple procedures prior to their TAR [60]. Gadd et al. reported an incidence of 0.9% in their series of 212 TARs, whilst Gougoulias et al. reported an incidence of 1% in their systematic review [11, 25].

Consent in Revision TAR

We have discussed the compilations associated with primary TAR. In those cases that require revision, the same consent principles must be applied. It must be remembered however that whilst primary TAR is a challenging surgical procedure, revision TAR surgery is even more complex and should be reserved for those surgeons experienced in it and those with the appropriate Institutional set up to support good volumes of revision TAR practice. This is a growing and evolving area, and there is less evidence in the literature to reference when looking at such complications. However in our experience, complication rates are higher and outcomes are less predictable following revision TAR. This should be clearly expressed to the patient, as well as a discussion surrounding all the potential options available.

Conclusions

In this chapter, we have explored the consent process for TAR and discussed the range of potential compilations that can occur, supporting this with reference to the literature where available. It is the responsibility of the treating clinician not only to be aware of these risks, but also complication rates in their own local Unit. These need to be clearly explained to the patient before surgery, in a way that they can fully understand and appreciate. Such consent discussion must also be individualised to the patient so that is relevant to their personal situation.

It must be remembered that TAR surgery is a complex and challenging surgical procedure. Whilst the complication rate for TAR surgery appears high, most complications are minor and do not affect the function or survival of the implant. Surgeon experience plays a key role in complication rate, and appropriate training, volume and governance should be in place in any Institution performing TAR surgery.

With the continued evolution of TAR surgery, and, as our understanding and experience develops, along with improvements in implant design and implantation techniques, complication rates and outcomes should continue to improve.

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Risk Factors for Failure of Primary Total Ankle Replacement

7

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Introduction

Historically, total ankle arthroplasty (TAA) was fraught with high complication and failure rates [1, 2]. First-generation systems included both constrained and unconstrained implants. Constrained implants were prone to aseptic loosening due to an increased torsional force on the component. The unconstrained implants developed instability due to inability of the soft tissues to provide sufficient restraint to the ankle. In addition, large bone resections were required of the earlier implants, in part to make room for cementation. This led to poor fixation and component instability as the bone strength of the distal tibia decreases the further away from the joint line [3]. In addition to problems with component loosening and instability, poor cementation techniques, poor wound handling leading to wound-healing issues, and inadequate soft tissue balancing contributed to the high failure rates [1]. This led to the development of second-generation implants which proved to be more successful. However, these were still plagued by high complication rates which led to the prevailing ideology in the 1990s that TAA should only be performed in older, low-demand patients [4].

Continued improvements in implant design have led to our current generation of TAA implants. In addition, improved understanding of soft tissue handling and alignment balancing has led to improved outcomes and survivorship as demonstrated by multiple studies [5–13]. These improved outcomes have led to greater adoption of the procedure as evidenced by the 12-fold increase in TAA utilization from 2007 to 2013 [14–16]. With each new study supporting its safety and longevity, the indications for TAA continue to expand. As such, it is imperative to understand the risk factors for failure according to the most recent evidence. Traditional, yet unsubstantiated, risk factors for TAA failure include young age, obesity, smoking, diabetes, and preoperative deformity. However, much of this is based off of total joint literature and unsupported dogma rather than actual clinical evidence. In this chapter, we look at the most recent evidence for these risk factors as well as others in order to produce evidence-based indications for this procedure.

Obesity

In total knee literature, obesity is a known risk factor for perioperative complications such as superficial wound infection, pulmonary embolism, and pain as well as lower implant survivorship [17–19]. It thus stands to reason that the same would apply to TAA. However, Bouchard et al. performed a retrospective cohort study comparing 39 obese patients (defined as BMI $\geq$30 kg/m^2) followed for 3.76 years to 48 non-obese patients (defined as BMI $\leq$30 kg/m^2) followed for 3.92 years [20]. They measured outcome scores, complication rates, and revision rates. They found that the obese patients, which had a BMI average of 36.28 kg/m^2, had significantly worse preoperative SF-36 Physical Component Summary scores than the non-obese patients, which had a BMI average of 25.84 kg/m^2. Despite this, there was no significant difference in the proportion of complications or revisions between the groups and both groups had similar significant improvements in Ankle Osteoarthritis Scale (AOS) pain, disability, and SF-36 Physical Component Summary scores. They conclude that TAA is a reliable treatment for obese patients as well as non-obese patients.

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Gross et al. prospectively studied a consecutive series of 455 primary TAAs with a minimum of 2-year follow-up [21]. They divided their patients into the control group of BMI <30 (266 patients followed for 45 months), the Obese 1 group defined as BMI between 30 and 35 (166 patients followed for 45 months), and the Obese II group defined as BMI >35 (73 patients followed for 43 months). They reported no significant difference in complication, infection, or failure rates among the groups. They did find that the Obese II group had significantly lower functional outcome scores compared to the control group, although still significantly improved compared to preoperative scores.

Schipper et al. also examined their series of obese and non-obese patients as defined by BMI greater than or less than 30 kg/m^2 [22]. Like the previous studies, they found no significant difference in implant survivorship at 5 years. However, this study followed their patients for an average of 8.2 years in the obese group and 7.7 years in the non-obese group, longer than the prior studies, and found that by final follow-up, obese patients had a significantly greater probability of implant failure (adjusted odds ratio of 2.8). Taken together, these studies suggest that obesity may not be a risk factor for failure or complication in the short to intermediate time frame, but the greater force placed on the implant may jeopardize its longevity in the long-term. Figure 7.1 demonstrates seven-year follow-up radiographs of a TAA placed in a patient with BMI 47.

Smoking

The effects of smoking on tissue and bone healing are well recognized on the biochemical level [23–25]. As such, smoking is a known modifiable risk factor for complications in total joint replacement surgery [26–28]. Lampley et al. examined the effect of cigarette use on TAA in 34 current smokers, 249 former smokers, and 359 nonsmokers [29]. They found that active smokers had a statistically significant increased risk of wound complications (hazard ratio 3.08), and while not statistically significant, active smokers tended to have less improvement in their outcome scores than nonsmokers at 1- and 2-year follow-up. There were no significant differences in outcomes between nonsmokers and former smokers.

Cottom et al. also did a comparison of 114 patients who underwent TAA and divided his cohort into active smokers (11 subjects), former smokers (38 subjects), and never smokers (65 subjects) [30]. They also found that the active smokers had a statistically significant increased rate of wound complications compared to the never smokers and no statistically significant difference in wound complications between former smokers and never smokers. The results of these two studies are consistent with the current total joint literature demonstrating negative effects of nicotine use on musculoskeletal surgery and suggest that TAA can safely be performed in patients who are able to successfully cease their nicotine use.

Diabetes

Uncontrolled diabetes mellitus (DM) is a known risk factor for complications including infections, venous thromboembolism, increased likelihood of readmission, and increased likelihood of death in total knee arthroplasty [31]. The immune system alterations of diabetics include reduced neutrophil and monocyte activity, impaired phagocytosis and bacterial killing, and impaired release of inflammatory cytokines in response to infectious stimuli [32]. As such, many providers attempt to achieve HgbA1C below 6.5–7.5% prior

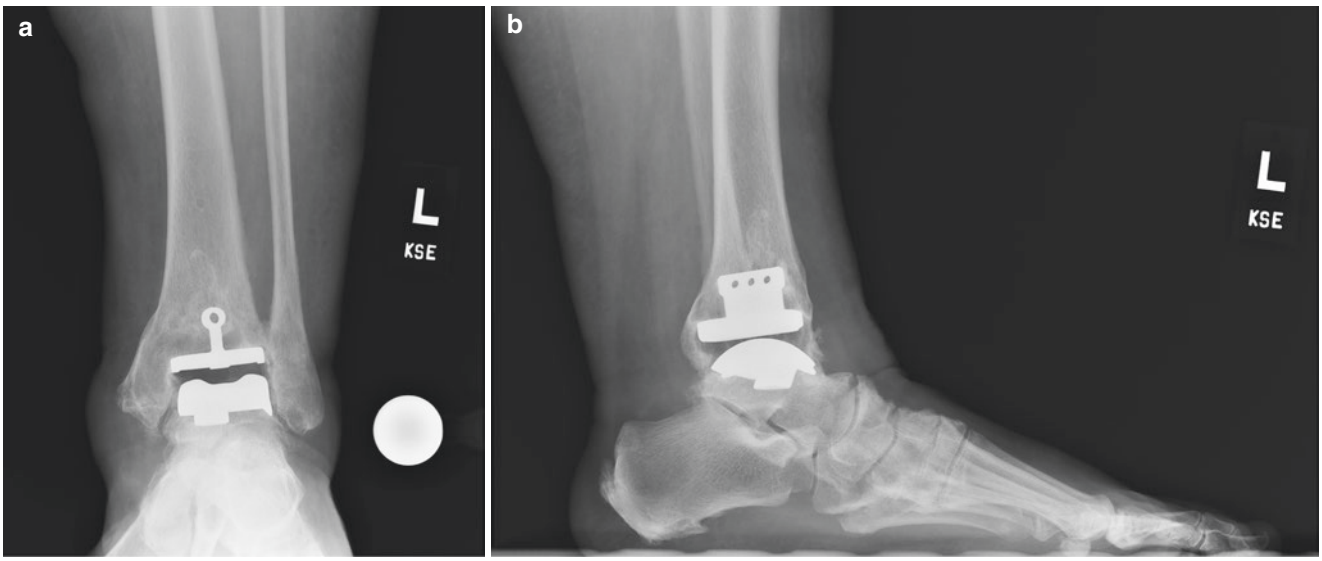


Fig. 7.1 Seven-year follow-up (**a**) AP and (**b**) lateral radiographs of a patient with a BMI of 47

to performing total knee arthroplasty. There have been several studies in TAA which attempt to determine the effect of uncontrolled diabetes on outcomes and complications.

Gross et al. examined 50 patients with DM and 55 patients without DM undergoing TAA that were followed for at least 1 year postoperatively [33]. They discovered that at an average of 2.3-year follow-up for the DM group and 3.1-year follow-up for the control group, there were no statistical differences in secondary operations, revisions, and failure rates. Functional outcomes improved in both groups and were not statistically different except that at 1 year, the magnitude of improvement in SF-36 General Health was significantly better in the control group.

In contrast to these results, Choi et al. compared outcomes and radiographs in 130 non-diabetic and 43 diabetic patients, broken up into controlled (25 patients) and uncontrolled (18 patients) diabetic individuals [34]. They discovered that the mean AOS and American Orthopaedic Foot and Ankle Society (AOFAS) scores were significantly better in the non-diabetic group. In addition, 21% of TARs in the diabetic group had clinical failure at 5 years as compared to 11.6% of those in the non-diabetic group. They also found that the incidence of early-onset osteolysis was higher in the diabetic group than the non-diabetic group. The uncontrolled diabetic subgroup had a significantly poorer outcome than the non-diabetic group along with a higher rates of delayed wound-healing.

Schipper et al. performed a national database study of the Nationwide Inpatient Sample database [35]. Of 2973 patients in that database who underwent TAA from 2002 to 2011, 7.8% of diabetic patients sustained complications compared to 4.7% of non-diabetics. They found an association of DM with an increased risk of blood transfusion (RR = 9.8) and overall complication rate (RR = 4.1). In addition, there was a statistically significant association of DM with increased length of hospital stay and more frequent nonhome discharge. Finally, Escudero et al. attempted to develop a predictive model for failure of TAA in a retrospective review of 107 patients [36]. DM was one of four factors they found to be predictive of failure. Overall, these data indicate that the presence of DM portends a worse outcome for TAA.

History of Infection

In the total joint literature, prior infection of the joint is a known risk factor for infection following joint replacement, and thus, it stands to reason that the same could be applied to TAA. Shi et al. examined 22 patients who underwent TAA with previous history of ankle joint sepsis or osteomyelitis [37]. He found that there were no deep infections in these patients. Eleven of these patients were followed for more than 2 years and these patients had significant improvements in pain and function. Winters et al. provided a consensus recommendation that all patients with prior infections in the affected ankle have a thorough workup including history and physical examination as well as serologic tests including complete blood count (CBC), erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP) levels. In addition, joint aspiration should be considered as well. During the TAA procedure, antibiotics should be added to the cement if used and intraoperative bone and soft tissue cultures should be obtained. There are not enough data to recommend against TAA in the setting of prior infection.

Age

Previously, age less than 50 years was considered a relative contraindication to total ankle arthroplasty [38]. Spirt et al. published in a 2004 study of 360 second-generation total ankle arthroplasties using the Agility implant that age was found to be the only significant predictor of reoperation and failure after total ankle arthroplasty. Overall, the five-year survival rate for all patients was 80% but 89% for patients greater than 54 years of age.

However, more recent studies using third-generation implants seem to contradict historical thought. Rodrigues-Pinto et al. studied 103 patients prospectively for a mean follow-up of 41 months [39]. They found that when comparing patients under the age of 50 and older than the age of 50, postoperative range of motion and AOFAS scores were significantly higher in the age under 50 group. Complication and survivorship rates were not significantly different between the two groups. The findings in this study were corroborated by Demetracopoulos et al. who studied 395 consecutive total ankle patients for a mean follow-up of 3.5 years [40]. They grouped their patients into those less than 55 years of age, those between 55 and 70, and those greater than 70 years old. They found that the patients less than 55 years of age had greater improvement in SF-36 vitality and AOFAS scores compared to the patients greater than 70 years of age. Otherwise, there was no difference in VAS pain score, physical performance outcomes, wound complications, need for reoperation, and revision rate between the groups. Finally, Lee et al. demonstrated that in 123 TAAs with mean follow-up of 78 months, there was no difference in outcomes or complication/failure rates between patients younger and older than 55 years [41]. The findings of these studies suggest that with third-generation implants, younger patients may do just as well or even better with TAA than older patients at least in the short- to mid-term without any difference in complication or reoperation rates.

The question remains, however, of how long these implants will last. Even with the reported high survivorship of current generation total ankles, younger patients will

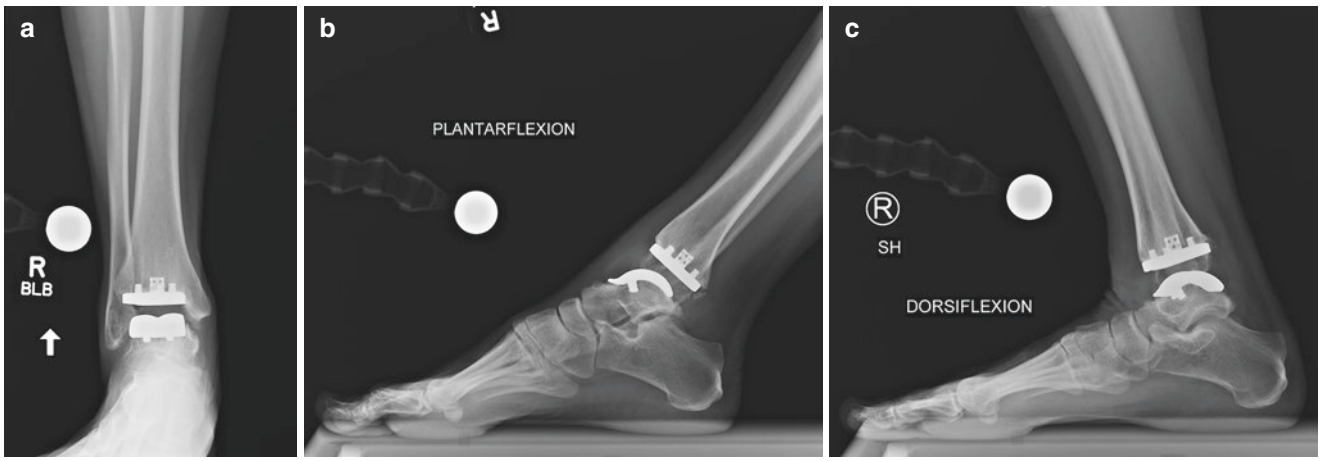


Fig. 7.2 (**a**) AP and (**b**) plantarflexion and (**c**) dorsiflexion lateral radiographs of a 37yo female at 1 year after TAA

likely outlive their components and need revision surgery. However, the alternative procedure, an arthrodesis, is not without its own challenges in the younger population. Following arthrodesis, a significant increase in range of motion of the adjacent joints has been demonstrated [42]. This may accelerate the progression of degenerative arthritis in the subtalar and talonavicular joints. In comparison, the rate of progression of subtalar joint arthritis at an average of 6.5 years after TAA was shown to be 40%, most of which was mild [43]. In addition, fusion rates for subtalar arthrodesis following TAA was shown to be higher than fusion rates following ankle arthrodesis [44]. Thus, while age should still be a factor when considering a TAA, the evidence does not support it as an absolute contraindication and the decision should be tailored for the individual patient. Figure 7.2 shows lateral radiographs of a 37-year-old patient with a TAA demonstrating the range of motion that can be preserved.

Preoperative Deformity

Historical contraindications for TAA include significant preoperative deformity [4]. Inability to correct this deformity leads to increased instability and torsional or shear forces on the implant, affecting its longevity and placing the ankle at risk for deformity recurrence. Even as recently as 2011, it was shown that coronal plane deformities greater than 25 degrees were prone to recurrences [45]. However, since then, several studies have supported the use of TAA in patients with preoperative deformity.

Trajkovski et al. prospectively examined 36 patients with greater than 10 degrees preoperative varus deformity who underwent TAA with a matched control group of 36 patients with less than 10 degrees varus deformity [46]. They found that both groups had similar final outcome scores at mean follow-up of 34.7 months and the varus group had significant improvement in their deformity toward a normal weight-bearing axis. Queen et al. examined 103 patients undergoing TAA and grouped them according to coronal plane tibiotalar alignment [47]. Seventeen patients had severe deformity defined as >15 degrees of varus or valgus, 21 patients had moderate valgus alignment defined as between 5 and 15 degrees of valgus, 27 patients had moderate varus alignment defined as between 5 and 15 degrees of varus, and 38 patients had neutral alignment defined as <5 degrees of varus or valgus. Outcome scores and gait analysis were tracked. About 95% of patients achieved neutral alignment postoperatively, demonstrating the efficacy of modern surgical techniques in correcting coronal plane imbalance. Subgroup analysis of outcome scores including AOFAS and SF-36 scores along with gait measures such as walking speed, timed up and go test, and four square step test were not found to be significantly different on final follow-up based upon preoperative coronal plane alignment.

Likewise, Lee et al. examined 144 consecutive ankles that underwent primary TAA using a mobile-bearing HINTEGRA implant with a minimum follow-up of 4 years [48]. They divided the patients into three groups based on coronal plane alignment: neutral alignment (51 ankles, <5 degrees malalignment), varus group (59 ankles, 5–20 degrees varus), and valgus group (34 ankles, 5–20 degrees valgus). They found that the overall implant survivorship was 97.7% in the varus group, 81.1% in the valgus group, and 90.0% in the neutral group at a mean follow-up of 7.3 years. There was no difference with regard to outcome scores. There were more concomitant procedures in the varus group compared to the neutral group in order to improve the alignment. The authors conclude that as long as neutrally aligned ankles were achieved postoperatively, TAA did well in preoperatively malaligned ankles. These recent studies provide evidence that with current techniques, coronal plane deformity should no longer be considered a risk factor for failure.

Other Risk Factors

In a large retrospective review of 533 TAAs in a prospectively collected database, Cody et al. attempted to identify individual risk factors for implant failure at mid to long-term follow-up [49]. They followed patients for an average of 7 years and determined that the only independent risk factors for failure were the use of the INBONE I prosthesis and ipsilateral hindfoot fusion prior to or at the time of surgery. They did not find an association of failure with age, BMI, or amount of preoperative deformity. The authors postulated that an ipsilateral hindfoot fusion alters the biomechanics of the tibiotalar joint such that eccentric stresses may be placed upon the implant which could lead to early failure. This was also corroborated clinically by Lewis et al. who found a significantly increased risk of failure in patients who underwent a hindfoot fusion before, at the time of, or after TAA [50].

Cunningham et al. reviewed 668 patients to determine if patient characteristics had an effect on outcome [51]. They found that depression, increased American Society of Anesthesiologists (ASA) score, current smoking, increased length of stay, a prior surgical procedure, and staged bilateral TAA were significantly associated with a negative impact on improvement. Kim et al. also looked at the effect of depression on outcome after 40 TAA (13 with depression, 27 without depression) and found that final VAS score was significantly higher and final AOFAS score significantly lower in the depression group [52]. These studies suggest that depression may be a potentially modifiable risk factor for poor outcome after TAA.

Causes of TAA Failure from Large Studies and Registries

Several large studies and registries have examined outcomes following TAA [53–58]. Henricson et al. published on the 10-year survival of 780 TAAs from the Swedish Ankle Register and found that women under the age of 60 with a diagnosis of osteoarthritis or posttraumatic arthritis were at a higher risk of revision, but this was not a risk factor for patients with a diagnosis of rheumatoid arthritis [53]. In addition, the most common reason for revision surgery was technical error at the index surgery. A follow-up study which followed patients for up to 20 years in the same registry demonstrated that newer prosthetic designs had better 5- and 10-year survival rates [54]. However, they did not report on patient-specific risk factors such as age, gender, or preexisting deformity.

The New Zealand Orthopaedic Association Joint Registry's 20-year report from January 1999 to December 2018 showed that 116 out of 672 patients under the age of 65 years required revision while 65 out of 946 patients 65 years old or greater required revision [57]. The National Joint Registry from the United Kingdom also shows a higher risk of revision with younger age [58]. Males less than 65 years of age had a 1.05%, 5.23%, 8.62%, and 10.65% chance of revision at 1-, 3-, 5-, and 7-year time points, respectively, compared to 0.53%, 1.77%, 3.12%, and 3.12% for males greater than 75 years. Females less than 65 years of age had a 0.89%, 5.54%, 10.30%, and 12.30% chance of revision at 1-, 3-, 5-, and 7-year time points, respectively, compared to 0.20%, 1.36%, 1.72%, and 1.72% for females greater than 75 years.

Skytta et al. published on 515 cases of TAA performed from 1982 to 2006 from the Finnish Arthroplasty Register [55]. They found an 83% 5-year overall survivorship but demonstrated no association of age, sex, diagnosis, and hospital volume with TAA survival. Lafrancois et al. prospectively studied 451 TAAs using four different implants with a mean follow-up of 4.5 years [56]. They found that gender, laterality, diagnosis of inflammatory arthritis, diabetes, age, BMI, and smoking status all did not have a statistically significant effect on the odds ratio for time to implant failure. In all, these large studies and registry data show conflicting evidence on the association of young age and risk of revision and find no evidence for an association of other factors.

Summary

With the increasing popularity of TAA, surgeons should have an understanding of evidence-based preoperative risk factors which may jeopardize the outcome of the procedure. While it is easy to extrapolate established evidence from the total knee and total hip literature, the ankle presents its own unique challenges. Currently, evidence exists that smoking, depression, diabetes, and ipsilateral hindfoot arthrodesis may be risk factors that hinder outcomes and increase complications (Table 7.1). Obesity does not appear to have a short- and mid-term effect; however, its long-term effect on implant survivability is unknown. Preoperative deformity does not appear to be a risk factor as long as neutral alignment can be obtained at the time of surgery. A history of

Table 7.1 Summary of Risk Factors for Failure

Likely no adverse effect	Risk factor for complication or failure	Risk factor for poor clinical outcome	Unknown
Obesity (short-term)	Smoking	Depression	Young age
History of infection	Diabetes mellitus	Diabetes mellitus	Obesity (long-term)
Deformity	Subtalar fusion		

previous ankle infection does not appear to place the patient at risk of further infection if measures are taken to ensure that the prior infection is cleared, although more studies on the subject are needed. Young age also does not appear to be a risk factor for complications or poor outcomes; however, there is some evidence suggesting a higher revision rate, and thus, implant longevity relative to patient age must be considered. As total ankle arthroplasty is an evolving and expanding field, constantly inundated with new innovations and improved surgical technique, it is important for surgeons to continue to conduct high-quality clinical studies in order to better understand contraindications and risk factors in order to optimize patient outcomes.

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8 Cemented, Biocemented, and Cementless Total Ankle Replacement Fixation Methods

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Foot and ankle procedures have evolved as other orthopaedic procedures have, in particular total ankle arthroplasty. We have learned a great deal from the techniques utilized in total knee and total hip arthroplasties. As we glance at the history of its development, ankle arthroplasty implantation methods have undergone tremendous alterations and advancements, as well as the prostheses themselves. A brief history illustrated the early findings and subsequent pitfalls in total ankle replacement implantation methods as well as component design. This chapter focuses on the methods of implantation. Upon thorough review of these techniques, review of FDA guidelines and FDA-approved total ankle systems, and individual conversations with well-respected surgeons, debate and further controversy is unavoidable. The facts as presented represent a best attempt to include these issues and concerns. Information presented will be free from personal bias and you, the surgeon and reader, must interpret the information as such.

The development of total knee and hip arthroplasties serves as a template from which to develop and implement total ankle replacements. Cement had been the gold standard for total hips and knees, and therefore, most early total ankle designs indeed were unsurprisingly cemented. Polymethylmethacrylate (PMMA), or bone cement, has been improved upon as well as the methods in which PMMA is prepared (Table 8.1). Antibiotics may be added to the cement as prophylaxis to infection. A special note is needed to clarify that PMMA or bone cement is a misnomer. It does not adhere to the underlying bone, but rather serves as a grout. There are no inherent "adhesion" properties.

All of the early total ankle replacements were cemented. The Mayo total ankle replacement was a constrained, cemented total ankle arthroplasty implanted from 1974 to 1988. Their series consisted of 160 arthroplasties, with a failure rate of 36 percent at 4.4 years. Therefore, they concluded that the Mayo total ankle could longer be recommended [1]. Takakura et al. had similar poor results with ankle arthroplasties performed with cement [2]. The early failure rate of these ankle arthroplasties led the authors to abandon this type of ankle fixation method. As the total hip arthroplasty began developing non-cemented "press-fit" hip stems and acetabular shells, data showed that this technique provides immediately sufficient stabilization with the further benefit of being "biologic" and allowing further bone ingrowth for enhanced long-term stabilization. Therefore, as the total ankle arthroplasty concept resurged, it was no surprise that cementless techniques would be investigated and expanded the repertoire of available ankle arthroplasty systems.

The prosthesis must also be redesigned to accommodate for a press-fit method. The first obvious design implementation is a porous-coated surface at the bone-prosthesis interface. This may be hydroxyapatite, titanium plasma spray, tantalum-coated, or sintered beads. This technique allows for thinner bone cuts than cemented designs, therefore preserving bone stock. Numerous characteristics concerning implant surfaces have been well-documented by Matassi et al. [3] (Table 8.2).

Table 8.1 Cementation technique evolution

	First Generation	Second Generation	Third Generation
Bone Preparation	Limited	Bulb Syringe	Pulse Lavage
Mixing	Hand	Hand	Vacuum

Table 8.2 Press-fit properties

Biocompatibility
Mechanical properties
Pore size
Physical properties
Production reducibility
Material costs

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The substrate must be compatible with the human body and allow for cellular ingrowth without toxicity. Optimally, the material should be osteoinductive and osteoconductive. Osteoconductive means the material serves as a scaffold which allow for bone ingrowth and enhanced mechanical stability of the prosthesis. Osteoinductive refers to biologic agents that stimulate the recruitment of mesenchymal cells and differentiation to osteoblasts. The mechanical properties should mimic host bone to allow for optimal bone ingrowth without stress shielding. Hence the use of titanium plasma sprayed given the similarities of Young's modulus of elasticity of titanium and bone. The porous structure should be optimized for bony ingrowth, which has been produced varying results in the literature [4, 5]. Physical properties relate to initial processing and sterilization as well as in vivo performance and survival. The material must be reliably reproduced from implant to implant during manufacturing, and the cost has implications on total health costs. The main limitation of simply porous surfaces is the lack of a true biologic substrate for bony ingrowth. Also, as described above, stress shielding could occur at the bone-implant interface leading to host bone resorption. The metallic natures of the implant and surface preparation could have the potential to release metal ions. The extensive metallurgy of arthroplasty is outside the scope of this chapter.

A brief examination of individual prostheses and the history of total ankle arthroplasty shed much light on the pitfalls and expansion to current day trends and designs. As mentioned above, early total ankle implants were cemented and these implants failed at an alarmingly early rate. The method of failure was loosening of the implant. This led to ankle fusion as the gold standard for ankle arthritis and a relative abandonment of the total ankle arthroplasty. The cement-prosthesis interface could not withstand long-term wear patterns and cycles of load. The ankle inherently has a small cross-sectional area. The forces measured at the ankle with normal gait are quite high. The ankle is not a simple hinge joint as rotation moments are also present and stability is dependent on ligamentous balancing and stabilization. These parameters together represent a challenge for the total ankle arthroplasty. These coupled forces are likely responsible for the failure of cemented total ankle replacements. Myerson and Won [6] noted that the cemented, static interface deteriorated with time and was therefore prone to loosening.

Takanura et al. [2] investigated a cemented metal prosthesis and an uncemented ceramic implant. Sixty-nine ankles were implanted between 1975 and 1987. Prior to 1980, a 316L stainless steel mated with a high-density polyethylene. There were two implant sizes and the components were cemented. The surgical approach was lateral and 30 such ankles were implanted. After 1980, the implants were ceramic coupled with high-density polyethylene and implanted without cement. The ceramic implant did include a new design with the addition of a medial facet. Three implant sizes were available and inserts through an anterior surgical approach. Of the 39 ceramic implants, five consisted of a cemented tibial component, and four had both the tibial and talar components cemented. The remaining 30 were implanted without cement. Their cemented cases had a 27% satisfactory rate and unsatisfactory in 73%. In contrast, the uncemented had a satisfaction rate of 67%. The cemented prostheses, whether metal or ceramic, exhibited a linear decrease in ankle range of motion 3 years post-operatively, while the uncemented cases showed a relatively stable improvement in post-operative range of motion. They noted "loosening and sinking" to begin 5 years post-operatively, especially in the cemented cases which also increased with time. This loosening was observed in 85% of the cemented group compared to 23% for the uncemented group. They concluded that prostheses implanted with cement gave "very poor results."

Recently, Yano et al. [7] reported on the FINE Total Ankle System (Teijin-Nakashima Medical, Okayama, Japan) for rheumatoid arthritis. These 3-component, mobile-bearing, cemented prostheses were found to have an 88.4% 10-year survival. Radiolucent lines were noted in 73.7%, all within 2 years of implantation. Tibial migration was noted in 21.1% and talar subsidence in 28.9%. Radiographic success rate 24.3% at 9 years. Haytmanek et al. [8] investigated the STAR and found periprosthetic lucencies in 55.7% of ankles. In comparison, Hirao et al. [9] saw no cases of tibial component migration with the use of the FINE Total Ankle System in rheumatoid patients; however, hydroxyapatite augmentation of the distal tibia was performed. In Canada, Daniels et al. [10] evaluated 88 Mobility prostheses and lucencies were found in 43% of which 91% involved the tibia-bone interface. Survival was 89.6% at 3 years and 88.4% at 4 years. The clinical significance of these radiolucencies is yet to be determined. Longer follow-up will hopefully provide useful insight.

Upon review of the Swedish Ankle Registry, the first-generation STAR (Scandinavian Total Ankle Replacement; Stryker, Mahwah, New Jersey) which was a constrained, cemented design was abandoned in the early 1990s due to poor outcomes [11–13]. In addition, 59% of the revision cases were due to loosening and 13% for polyethylene wear or failure. In 2011, this design of the STAR yielded a 10-year survival of 69%. The Norwegian Arthroplasty Registry utilized primarily uncemented implants (96%), the most common being the Link STAR. Other common systems included Salto Talaris (Integra Lifesciences, Plainsboro, NJ) and Mobility (DePuy, Raynham MA). The mode of failure was tibial component loosening in 26% and talar loosening in 20% [13]. The New Zealand Joint Registry in 2017 noted that the most common prostheses included the Salto Talaris (Integra Lifesciences, Plainsboro, NJ) and Infinity (Wright Medical, Memphis, TN). These uncemented cases yielded a

5-year survival of 90% and a ten-year survival of 83%. The most common mode of failure in revision cases was talar loosening (30%) and tibial loosening (22%) [13] Uncemented or press-fit ankle arthroplasty developed in an attempt to reexamine the ankle replacement and enhance the long-term stabilization of life of the implant. The press-fit implant would "remodel" and become more "biologic" in its fixation. In a pilot study in 2014, Kotela et al. [14] concluded that cementless fixation is optimal for total ankle arthroplasty.

One must also interpret the literature carefully as the success or failure of a total ankle arthroplasty is multifactorial. First-generation prostheses utilized an all-polyethylene tibial component coupled with a cemented metallic talar component. Thus, these implants were clearly "nonmodular." The documented mode of failure was loosening at the cement interface. PMMA served as an excellent "initial" stabilization the prosthesis but was hypothesized to not withstand cyclic loading in the ankle. The failure was likely a combination of a "nonbiologic" fixation method and a nonmodular protheses. The nonmodular prosthesis biomechanically transmits increased forces to the implant-bone interface.

Second-generation total ankle arthroplasties were designed to minimize bone cuts and therefore preserve native bone. These implants were thus also implanted without cement, utilizing a more biologic interface allowing for bone ingrowth [6]. Design changes also included larger surface area implants thus allowing for more cortical contact. The Agility LP ankle (DePuy, Warsaw, Indiana) technique includes fusion of the distal syndesmosis in an attempt to increase the size and surface area of the tibial component.

Third generation and possibly fourth generation implants expanded on the cementless, biologic fixation with additions of hydroxyapatite coatings and design features including less constraint and three-component "mobile-bearing." Newer designs have also focused special attention on ligament balancing and component alignment with the mechanical axis. These precise details will likely long-term survival implications. The Scandinavian Total Ankle Replacement (STAR) (Stryker, Mahwah NJ) was the first FDA-approved three-component mobile-bearing available in the USA. The Hintermann H3 (DT MedTech, Towsin MD) recently gained approval in the USA in 2019. The Hintermann H3 is a three-component, non-constrained implant. The European nomenclature refers to this as the Hintegra. Barg et al. [15] documented the Hintegra survival at 5 and 10 years at 94% and 84%, respectively. They also noted no polyethylene failures. This study did include three different designs, and they noted increase risk for failure of the older designs. Lefrancois et al. [16] reported a 5-year survival of the Hintegra implant of 88%. Raikin et al. [17] evaluated 127 consecutive Agility total ankles from 2002 and 2009 and found that 78.2% retained their implant. Roukis et al. [18] examined 14 studies involving the Agility prosthesis and found an overall revision rate of 9.7%, with a mean follow-up of 22 months. The mobile-bearing Salto and the fixed-bearing Salto Talaris (Integra Lifesciences, Plainsboro, NJ) have been investigated. Stewart et al. [19] reported on the Salto Talaris and noted a 95.8% 5-year survival. Hoffman et al. [20] reported a 5-year survival of 97.5% with the Salto Talaris. In 2018, the mobile-bearing Salto was reported to have a 94.9% survival at 3 years [21]. The Infinity total ankle system (Wright Medical, Arlington TN) is a fixed-bearing design, was found to have a 97% overall survival with three-year data [22]. Saito et al. [23] with 18-month data reported survival at 95.3%. Cody et al. [24] with 12-month follow-up revealed a 3.8% revision rate for loosening. The Trabecular Metal (Zimmer Biomet) utilizes trabecular metal at the bone-prosthesis interface. Barg et al. [25] found implant survival was 93% at 2 years. Usuelli et al. [26] reported on 42-month follow-up and found a 98.9% survival. Colombier et al. [27] reported on the Salto (Tornier, France) prosthesis, which had two designs, one a fixed-bearing and one a mobile-bearing. This prosthesis has a titanium plasma spray coating with a second layer of hydroxyapatite. They noted that the near anatomic tibiotalar kinematics with this system had led them to develop the fixed-bearing version. Their initial series, including the first implantations, yielded a survival of 85% at 10 years. After removal of the first implantation, i.e., outside the respective learning curve, survivorship rose to 90.7% at nearly 9 years [27]. Schenk et al. [28] determined a survival of 86.6% at 5 years for 218 Salto prostheses. San Giovanni et al. [29] reported 93% overall survival at 8.3 years with the minimally constrained, uncemented, mobile-bearing Buechel-Pappas Total Ankle Replacement (Endotec, South Orange, NJ). Hsu and Haddad [30] investigated the INBONE I and II (Wright Medical, Arlington, TN) prostheses. They found improved survival with the INBONE II, which has a pegged talar sulcus implant. Table 8.3 lists current FDA-approved ankle prostheses currently available in the USA, as well as listed characteristics. The Cadence (Integra LifeSciences, Plainsboro NJ) and Vantage (Exactech, Gainesville FL) total ankle systems are also available.

Table 8.3 Current FDA-approved total ankle arthroplasties

	Components	FDA-approved fixation/features
Cadence	Two, fixed	Cement/tibial and talar pegs
INBONE	Two, fixed	Cement/intramedullary tibia
Infinity	Two, fixed	Cement/tibial/talar pegs
Salto Talaris	Two, fixed	Cement/tibial fin, talar pegs
STAR	Three, mobile	Press-fit/cylindrical keel
Vantage	Two, fixed	Cement/large tibial peg
Zimmer Trabecular Metal	Two, fixed	Cement/transverse keels
Hintermann H3	Three, mobile	Press-fit/screws tibia/talus

The persistence, development, and expansion of periprosthetic bone cysts have caused some concern. This was first reported by Pyevich et al. [31] in 1998. Knecht et al. [32]subsequently reported on this and classifies as two types, mechanical and expansive. Mechanical osteolysis occurred early within the first months after implantation and resulted due to micromotion at the prosthesis-bone interface. This was also discussed by Goodman et al. [33] in 1997 on his reports of cemented total ankle arthroplasties. Expansive osteolysis occurred late and in areas not at the prosthesis-bone interface and was due to polyethylene wear debris. The clinical significance of these cysts or osteolysis is not completely understood. Wood and Deakin [34] recorded several tibial cysts of cases in 2003, then reported that cysts were found in 12.5% of cases (25 patients with cysts), 10 of which were asymptomatic in 2008 [35]. Colombier et al. postulated that small, nonprogressive cysts are likely mechanical phenomenon, and large cysts likely due to wear particles, such as polyethylene, titanium, or hydroxyapatite. Polyethylene debris was evaluated and confirmed by Kobayashi et al. [36] and Valderrabano et al. [37] Dalat et al. [38] revealed high percentage of polyethylene debris in the zones of osteolysis. Vaupel et al. [39] determined microscopic and macroscopic polyethylene wear patterns in eight Agility ankles. Koivu et al. [40] determined the risk of osteolysis is three-fold for double coating of hydroxyapatite and titanium as compared to a single coating of hydroxyapatite. Singh et al. [41] also reported that hydroxyapatite ankle replacements are prone to cyst formation. However, Wood et al. [34, 35] determined an improvement in outcomes with the titanium and hydroxyapatite dual coating. As did Sundfeldt et al. [42] and Reikeras et al. [43], which revealed HA-coated prostheses have less issues with polyethylene debris. Pertaining to total hip arthroplasties, some investigators have found no osteolysis with HA alone while others have reported increased osteolysis and polyethylene wear with implants coated with HA [44, 45]. This raises the concern of joint fluid and the concept of overall joint space [44]. One adaptation of the Salto keel implanted in the tibia is to close this space off with the placement of bone graft in an attempt to isolate from the synovial fluid.

A special note concerning the reported data and studies is warranted. As noted, these studies are retrospective. Most investigational studies provide level IV evidence. There are no prospective studies available for review. Many studies included various designs of the same implant. Most of these early studies have been performed by implant designers or consultants, which raise the concern over bias and a conflict of interest. Also, surgeon experience can bias the results, as a steep learning curve has been found when performing ankle arthroplasty. Needless to say, some important information may be gathered from these studies. The available follow-up length is insufficient in many reports to thoroughly come to a reliable conclusion. We have learned that previous ankle systems had adequate short and intermediate results, only to faulter with longer follow-up. That being said, these newer designs hold promise, and long-term prospective trials are warranted.

The geometry of the implants, both at the polyethylene surface and bone interface, has gone through several redesigns. Fin, peg, or keel placements on the tibial and talar implants have been altered with newer designs. These design variations and alterations may and likely do have a direct effect on implant survival. The design of the implant, i.e., two-component or a three-component "mobile-bearing," also likely contributes to the longevity of an implant design. There is no consensus on the advantages or shortcomings of mobile and fixed-bearing implants. Valderrabano et al. [46] summarized the types of ankle replacements and reviewed numerous studies of these implants including kinematics. Even though the biomechanics of the ankle can be improved with mobile-bearings, there has been no clinical significance to justify fixed-bearing over mobile-bearings [47]. Suffice it to say, cemented implants have clearly been documented to fail at an unacceptably early timeframe. Ankle arthroplasty with cementless designs has become the gold standard, thus allowing long-term biologic fixation. Scholz [48] in 1987 stated that total ankle arthroplasty should shift focus to porous-coated, uncemented prosthetic components.

As we review cemented and cementless, press-fit designs, one must be cognizant of the current FDA guidelines and approval status of these ankle systems. Detailed information pertaining to each implant is easily reviewable of the FDA website.

The FDA has defined bone cement (PMMA) in the following manner:

PMMA is a device intended to be implanted that is made from methyl methacrylate, polymethylmethacrylate, esters of methacrylic acid, or copolymers containing polymethylmethacrylate and polystyrene. The device is intended for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone. (Title 21, Chapter I, Subchapter H, Part 888, Subpart D, Section 888.3027)

The FDA defines a combination product as "a product composed of any combination of a drug, a device, and a biological product." These include orthopaedic combination products.

FDA Ankle Arthroplasty Classifications

Title 21, Chapter I, Subchapter H, Part 888, Subpart D

888.3100: Ankle joint metal/composite semi-constrained cemented prosthesis

An ankle joint metal/composite semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits translation and rotation: in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type

of device includes prostheses that consist of a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component fabricated from ultra-high molecular weight polyethylene with carbon fibers composite, and is limited to those prostheses intended for use with bone cement

888.3110: Ankle joint metal/polymer semi-constrained cemented prosthesis

An ankle joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces and has no linkage across-the-joint. This generic type of device includes prostheses that has a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement.

888.3120: Ankle joint metal/polymer non-constrained cemented prosthesis

An ankle joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits minimally (less than normal anatomic restraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a tibial component made of alloys, such as cobalt-chromium-molybdenum, and a talar component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement.

Unclassified: Prosthesis, Ankle, Uncemented, Non-Constrained

These were last updated 9/19/2019.

For information pertaining to the FDA testing and position on the metallurgy and modified metallic surface for orthopaedic implants please refer to the following link:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-document-testing-orthopaedic-implants-modified-metallic-surfaces-apposing-bone-or-bone

The FDA has also stated their organization will not dictate the practice of medicine and allows physicians to use a device "off-label." Most implants are FDA approved for "cemented" only in the USA. The attached reference may be used to locate the entire document. This is where the utilization of these implants may be difficult to interpret. After speaking with numerous well-respected surgeons, both orthopaedic and podiatric, who perform ankle arthroplasty, numerous methods have been utilized. Some surgeons were even unaware of this language and FDA-approval status. Needless to say, the surgical technique manuals clearly state: "Caution: In the United States, the ankle prosthesis is intended for cement use only."

Well, how do surgeons in the USA handle this concern? Some avoid it and use implants that are approved for press-fit cementless fixation. Others ignore the "recommendation" and press-fit the implants. Some studies even state "the surgical technique followed manufacturer guidelines." However, the reported technique was press-fit, which does not correlate with the technique manual. While some place a "dab" of cement of the pegs only. Others use "biocementation" which is a relatively new term in medicine. Therefore, many of these prostheses are implanted "off-label." "Off-label" however, means this: the practice of using an FDA-approved drug or device for a purpose that the FDA has not approved. The FDA states that physicians may use devices "off-label," if exercising their best judgment and are well-informed concerning "firm scientific rationale and sound medical evidence and maintain records of its use and effects." The use of devices not approved by the FDA would likely be a riskier practice. However, interpretation may be difficult. "Off-label" by the above definition would be to use an ankle prosthesis for a different purpose, such as a separate anatomic site for example. Even though the FDA may not regulate a given practice, it does not restrict its potential in case law and malpractice. An attorney could argue the practice of using devices "off-label" or unapproved devices as a breach of the standard of care. The standard of care, however, being stated as what a reasonable physician within a specific specialty would do under similar circumstances. In the author' opinion, from a thorough review of the literature and results, implantation of these "cemented only" prostheses without cement would indeed be completed within the standard of care.

Biocementation refers to the use of bone graft or bone graft substitutes to augment the biologic properties when implanted. It does not serve as a "cement" or "grout" such as PMMA. This places osteoinductive cells at the bone-implant interface thereby promoting more rapid and efficient ingrowth. This technique had been performed on press-fit hip stems for decades, but never coined the term biocementation. Biocementation may also be performed with bone graft substitutes such as calcium sulfate and calcium phosphate. Other substitutes could easily qualify as a biocement. These compounds are biocompatible and have similar crystalline structure as apatite.

Bibbo [49] described "temporary" fixation in total ankle arthroplasty in 2013. Essentially, there existed a need for a "bone friendly" cementation method, especially in patients with poor bone stock. An injectable bone graft of 75% calcium sulfate and 25% calcium phosphate (PRO-DENSE, Wright Medical Technology, Memphis, TN) was utilized in a similar fashion as PMMA and "sets" or hardens in a grout fashion. The PRO-DENSE is then replaced by host bone by creeping substitution. Also, PRO-DENSE has a compressive strength superior to those seen at the total ankle inter-

face(40 MPa) [50, 51]. In addition, antibiotics may be added and do not appear to affect the mechanical properties of the biocement [49]. Calcium phosphate has been studied with the addition of vascular endothelial growth factor (VEGF) which promoted angiogenesis. The adsorption of VEGF to calcium phosphate was termed BiocementD (BioD). Variations of these compounds are being studied and hold promise for the future. Further study is necessary to enhance our understanding at the biochemical level as well as their clinical application and utility. Osteocalcin may also improve the adherence of osteoblasts and promote bone proliferation [52].

A rabbit study evaluating nanostructured ceramics and bone formation found the amount of bone tissue to be significantly higher in these nanoceramics than nanostructured bone cement, blood clot, and microstructured particles [53]. Important characteristics of bone cement include wettability, moldability, and setting time. Franczak et al. [54] more recently studied the characteristics of biocements and found them to offer excellent wettability, hydration, and easily moldable. Jia et al. [55] worked with magnesium calcium phosphate biocement (MCPB) and found hardening to occur in 7 min and reached compressive strength of 43 MPa at 1 h. In addition, they found enhanced cell proliferation as compared to calcium phosphate biocement.

Strontium-modified biocements have previously been investigated [56]. Strontium ions have been shown to enhance osteoblast activity [57]. Much research continues in this arena including tissue engineering such as the addition of bone morphogenic proteins [58]. Needless to say, these biocements represent a vital and expanding science that will enhance foot and ankle surgery. Some examples of biocement and their compositions include the following:

Biocement D	carbonated apatite + CaHPO(4) + CaHPO(3)
Biocement F	carbonated apatite + CaHPO(4)
Biocement H	calcium-deficient apatite
Biocement B1	Biocement H + CaCO(3) + hydroxyapatite
Biocement B2	Biocement H + CaCO(3)

Total ankle arthroplasty design and implantation methods have evolved over the past several decades. Cemented total ankle replacements failed at an unacceptable rate in the 1970s and 80s. However, most were also constrained implants. More recent total ankle implants have improved anatomic designs with less constraint. In addition, the instrumentation improvements for bone cuts allow more precise alignment with the mechanical axis. Recent studies have shown excellent ten-year results with a cemented prosthesis [7]. However, patient-specific measures of body mass index (BMI) were not mentioned. Therefore, it may be difficult to extrapolate these findings to other patient populations.

The success and failure of total ankle arthroplasty is clearly multifactorial. Patient characteristics such as BMI, activity level, occupation, expectations, etc., all have a significant impact on outcomes. The literature allows for an insight on different fixation methods and prostheses. However, many studies included various designs of the same implant. Certainly, there is also concern for bias, given many studies were performed by implant designers. However, the literature does support improving trends.

The use of cement or PMMA for total ankle arthroplasty has become obsolete in the USA, with all available implants designed with a press-fit model. Biologic fixation to the prostheses has resulted in overall improved results and outcomes. Press-fit components preserve native bone stock, which improves initial implantation and possibly subsequent revision. The addition of titanium sprays and hydroxyapatite show mixed results in the literature, but overall seem to enhance bone ingrowth.

The realm of biocementation continues to evolve and holds much promise in the future of foot and ankle surgery. Numerous biocements have been produced, and tissue engineering is taking it one step further with the adjunct of growth factors. The biocement serves as an initial grout-type fixation, which is later replaced with bone. The concern for biocements is cost. Further study of total ankle implantation with and without biocement would be useful. If biocements improved the longevity of the implants, its initial cost certainly would be justified.

The future of total ankle arthroplasty appears promising. Regardless of the implant chosen, or the method of implantation, strict patient selection criteria coupled with sound surgical technique will have the most impact on the survival of these implants. We as surgeons must continue to study the implications of our techniques without bias. A significant learning curve exists when performing total ankle arthroplasty. Surgeons performing ten or less ankle arthroplasties a year may not achieve these same results. Performing ankle arthroplasty can be a humbling experience. Remember to do the right thing and put the patient first and foremost.

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3D Orthopaedic Preoperative Surgical Planning for Total Ankle Replacement

9

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A History of 3D Preoperative Planning

The future of TAR technology advancements can be predictable since it generally follows behind the total knee replacement (TKR). What we have witnessed as new developments in the knee market are often copied in the ankle market. Several examples exist such as the mobile bearing and the many material changes that have come to the poly insert, all of which were first developed in TKR. With the knee replacement market being highly competitive and over 50 times larger than the ankle market [1], these companies willingly devote resources for advancing their products and technology. These historical advancements can be applied as possible future developments for TAR, including more advanced 3D preoperative planning.

Of the recent developments in orthopaedic technologies, several helped to drive 3D preoperative planning. These include 2D preoperative planning software, patient-specific implants and instruments (PSI), and surgical navigation systems.

2D Preoperative Planning Software

Of course, the earliest form of preoperative planning was sketching by hand on fluoroscopic images with the most diligent surgeons using a ruler and protractor. This 2D preoperative planning required a lot of skill and was limited by off-axis views and magnification errors. Software developers converted this method to several app's that could be loaded onto a laptop or tablet, so that a surgeon could manipulate the images in a similar way to hand sketching. The advantage was the ability to make changes quickly and has some assurance to the magnification if radiographic reference balls were included in the images. Yet it was still vulnerable to off-axis views and was only a little better than hand sketching. Nevertheless, the 2D software development was the precursor to 3D.

PSI as a Precursor

One of the more popular developments from TKR was patient-specific instruments and implants (PSI), first commercially available by ConforMIS, Inc., Billerica, MA, in 2006 [2]. PSI is becoming more mainstream due to its many benefits including "accuracy, simplicity…, benefit of preplanning the surgery, reduced blood loss, reduced risk of fat embolism, reduced risk of infection, less equipment necessary compared to other techniques, less of a learning curve, reduced operating time and reduced radiation exposure." [3] As for TAR, in 2011 [4, 5] Wright Medical Group N.V., Memphis, TN started doing patient-specific instruments, although not patient-specific implants (using appropriately sized stock implants). And relatively recently in 2012, 4WEB Medical, Frisco, TX, was among the first to begin using patient-specific TAR components in conjunction with stock components, as well as patient-specific instruments if needed. And, on 4WEB's heels came a direct competitor using almost the same methodology, Additive Orthopaedics, LLC, Little Silver, NJ, in 2018 [6] (Fig. 9.1).

Initially, PSI (instruments and implants) was a primary goal for TKR, with the benefits of having implants matched to the patient's anatomy and ensuring the accurate implantation using anatomically matching cutting guides. It is confusing that PSI stands for both implants and instruments, but PS-implants have fallen out of favor for stock implants in the joint replacement market. So, when PSI is referenced from this point on, it will be for patient-specific instruments, unless otherwise noted. This primarily means that the guides for both pins or saws have surfaces that match the specific

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Fig. 9.1 PSI instruments for the iTotal PS product line from ConforMIS. (Courtesy of Conformis, Inc.)



Fig. 9.2 Special software was developed to convert CT scan DICOM data into 3D models where the bone is isolated from the soft tissues by differentiating densities. This is called segmentation [7]. (Reprinted from Wu et al. [7]. With permission from Springer Nature.)

patient's anatomy to properly register the guide for the intended cutting path.

3D preoperative planning was developed as a necessary means to create PSI. It was initially done using special 3D conversion software and standard off the shelf Computer Aided Design (CAD) software. By manual brute force effort, clinical engineers would create a 3D plan using verbal instruction from the surgeon along with 2D sketches and x-rays. After the surgeon approved the final plan of implant size and location, then another manual effort by the clinical engineer was needed to build accurate PSI matched to the specific anatomical surfaces of the patient. The entire process could take as long as 2–3 months, and included:

1. Coordinating CT scans with the patient.
2. Sketching a 2D plan by the surgeon.
3. Communicating with the clinical engineer.
4. Sending the CT DICOM data to the clinical engineer.
5. Converting the DICOM data into a 3D format that could accurately isolate the bones as 3D CAD models. This required a special software through which "segmentation" (an industry term) removed the soft tissue information and left only the bone. This was done by interpreting the different densities between bone and soft tissues as recorded from the DICOM data.
6. Using standard CAD software, fit the implant 3D models to the newly created bone models. These could be patient-specific implants or stock implants.
7. Getting final surgeon approval of the 3D plan. If any changes were needed, this would further extend the process.
8. Designing the PSI guides to match the implant location and conform to the surface of the patient's bone for proper registration.
9. Building the patient-specific implant and instruments via 3D printing or machining.
10. Packaging and delivering the implants and instruments to the surgeon or hospital.
11. Scheduling the surgery.
12. Performing the surgery (Fig. 9.2).

As software development advanced, these complicated processes have been automated. One of the first industries to automate this and give surgeons more control was the shoulder replacement market in 2015 [8] with BLUEPRINT™, Wright Medical Group N.V., Memphis, TN (formerly Tornier, Inc.). Since shoulder replacement is based on finding one primary axis in the glenoid, the automation task was an easier first step for software developers. Here, the patient-specific instrument was a single pin guide that found landmarks on the glenoid's articulating surface to accurately register the pin location. In the website portal, the surgeon could see, in multiple cross-sectional views, if the implant's stem was breaking out of the glenoid or safely bordered by bone and could tell if the axis and ball diameter closely matched the patient. Furthermore, he or she could take account of any deformity corrections, and purposely size and locate the implant for the best results. A lot of valuable information could be gathered through the software alone by the placement of only one pin.

Interestingly, this is where the concept of 3-D preoperative planning departed from PSI. Because the on-line software was very easy to use and provided valuable information besides just pin placement (as mentioned above), the pin could be placed by a skilled surgeon without a PSI guide. This not only saved time and the cost of manufacturing a guide, but also gave the surgeon confidence that the prescribed plan would match his intentions and the patient's anatomy. This new process with surgeon control and automated location results will be described as a surgeon-driven 3D preoperative planning (with or without PSI) and will be discussed further in the "Current State" section.

Navigation as a Precursor

A separate development that also led to 3D preoperative planning is the use of navigation in the OR. Initially, this technology was developed to make cutting and drilling more accurate using real-time images during surgery. Once again, the process is based on CT or MRI scans of bone, but the planning is done more immediately in the OR. The key to viewing bones in real-time imaging is to rigidly attach reflective ball targets to the bone which can then be seen optically with a special stereo-optic infrared system. The patient is then scanned on the operating table, and the exact bone to targeting device relationship can be established then interpreted and seen in real-time space on a computer screen. The instruments also have reflective ball targets so that the stereo-optic system can see the cutting tips and edges in real-time space. This means the alignment and position of a drill can be very accurately driven into bone. The greater accuracy lends itself well to the spinal and cranial orthopaedic markets, where a misplaced drill could cause permanent nerve or brain damage. Also, because of the high cost of the navigation machines, it has been primarily relegated to these markets that are traditionally reimbursed very well. As we will see in the next section, these technologies have progressed into a new era of more advanced 3D preoperative planning (Fig. 9.3).



Fig. 9.3 O-arm navigation system from Medtronic PLC, Dublin, Ireland. This complete surgical suite includes the in-room CT scanner (O-arm™), infrared stereo-optic system, control monitors, and specific instruments that can be used under navigation. (Courtesy of Medtronic.com)

Current State of 3-D Preoperative Planning

PSI Led 3D Preoperative Planning

3D preoperative planning for shoulder arthroplasty has advanced far enough that surgeons use only the plan without a PSI guide 10 times to one. As for TKR, true surgeon-driven software is in use similarly to the shoulder but has been tailored to the specific adjustments and deformities of the knee (should be similar for the ankle in the future). Here, the surgeon can place the implant in the 3D space in any location and in any orientation on both the femoral and tibial side. He/she can pick from an array of implants and sizes to get the desired performance for the patient. In TKR, PSI guides are used more often due to the complexity and number of guides required. Also knee component and instrument delivery systems have been stripped down to the essentials for surgery. The general and current advanced 3D preoperative plan follows these steps for stock implants, which is a slimmed down version of past processes:

1. Coordinate CT scans with the patient.
2. Upload CT scan data to desired company's 3D preoperative website portal.
3. The software automatically segments the DICOM data to present the 3D bone models on to the surgeon's interactive screen. With the use of 3D tools in the software, the surgeon manipulates the bone to correct deformities if desired, and then manipulates the implant models changing size, location, and orientation. This becomes the surgeon's approved plan. And, this above plan is done in one sitting, where before it may have taken weeks with a clinical engineer.
4. Here, the surgeon may stop and just use the plan going on to Step 8 below. Or, he/she may choose to use PSI.
5. Based on the approved plan, new patient-specific instruments are automatically generated and sent to the manufacturer.
6. Build the PSI guides by 3-D printing or machining.
7. Deliver the implants and instruments to the surgeon or hospital.
8. Schedule the surgery.
9. Perform the surgery.

The automated process and surgeon-driven software brings the process from a couple of months to a couple of weeks. And, if PSI implants or instruments are not needed, it can be just a matter of days.

Another advantage to this system is the "one-box surgery." This, of course, is opposed to traditional joint replacement surgery where there are multiple instrument trays to allow for a full range of sizes for the patient population and many boxes of implants for every size available. Just for poly inserts alone, an implant system has 5–6 different sizes, left and right sides, neutral-anteriorly-posteriorly biased options, and as many as 10 thicknesses. The resulting permutation is over 300 poly inserts. Now, with high confidence in the TKR preoperative plan, a surgeon only needs one implant size. So as advertised, in one box the surgeon will have PSI guides, disposable saws and pins, a few insertion tools, the selected stock size of metal implants, and only a few poly insert thicknesses to account for soft tissue variation (Fig. 9.4).



Fig. 9.4 An example of the one-box solution, iTotal G2 by ConforMIS, Inc., Billerica, MA. (Courtesy of Conformis, Inc.)

Shoulder, knee, and hip arthroplasties can boast true surgeon-driven 3D preoperative planning software, but the ankle is still lagging. The closest ankle systems to have 3D preoperative planning are the Prophecy system by Wright Medical Group, 4WEB Medical and Additive Orthopaedics. These companies have clinical engineer driven 3D planning. And, that means the surgeon is still communicating with a 2D format to the clinical engineers which comes with a longer cycle time.

A detailed description of Wright Medical Group's process was published in this book's first edition and has been moderately advanced. The updates are a refined preoperative plan showing more detail when deformities are present. And, Wright Medical recently worked with CurveBeam, Hatfield, PA (extremity CT imaging company) to develop and validate protocols for a weight-bearing CT imaging system. Prior to this development, weight-bearing CT scans were done in the surgeon's office, but only went to the mid tibia. Prophecy PSI guides need the full tibia up to the tibial tubercle, which led to surgeons sending the patient to a CT/MRI facility that could do the full tibia but were often non-weight-bearing. The convenience of in-office full tibia weight-bearing CT scans reduces the turnaround time for PSI guides and may increase accuracies in preoperative planning (Fig. 9.5).

4WEB Medical, Frisco, TX, follows a streamlined process where a written prescription is provided by the surgeon detailing the patient health information including diagnosis and indication. This prescription is generally accompanied with patient CT data. The data are prepared in segmentation software which allows for 3D model generation. Secondarily, it is transferred to another software platform where manipulation of bone, joints, and bone fragments can occur. Here, the surgeon and 4WEB's clinical engineers participate in a webinar where the surgeon reviews the anatomy, identifies anatomical repositions, defines resection areas, and designs the implant volume. Once the surgeon determines appropriate implant size, secondary sizes (generally one implant smaller and/or larger) can be incorporated as fitment alternatives (Fig. 9.6).

Additive Orthopaedics, LLC, Little Silver, NJ, has just entered the market as a direct competitor to 4WEB Medical and using a similar process. Additive Orthopaedics make patient-specific plates and bone segments, specializing in complex reconstructions, and implant revisions, and limb salvage. Unlike 4WEB's "face to face" live webinar planning session, they use an app called Game Plan that allows the surgeon and engineer to communicate over a smart phone. Similar to the 4WEB Medical webinar, this incorporates real-time visualization of the 3D implant and patient anatomy. GAME PLAN also allows you to access implant design, manufacturing and delivery status.

Navigation Led Preoperative Planning

The progression of navigation systems has made its way to total joint replacement. And, this is where 3D preoperative planning becomes a bigger part of the process. Joint replacement requires more exacting positioning and orientation since more than just pedicle screws are being added to the bone. And new to joint replacement, is the advantage

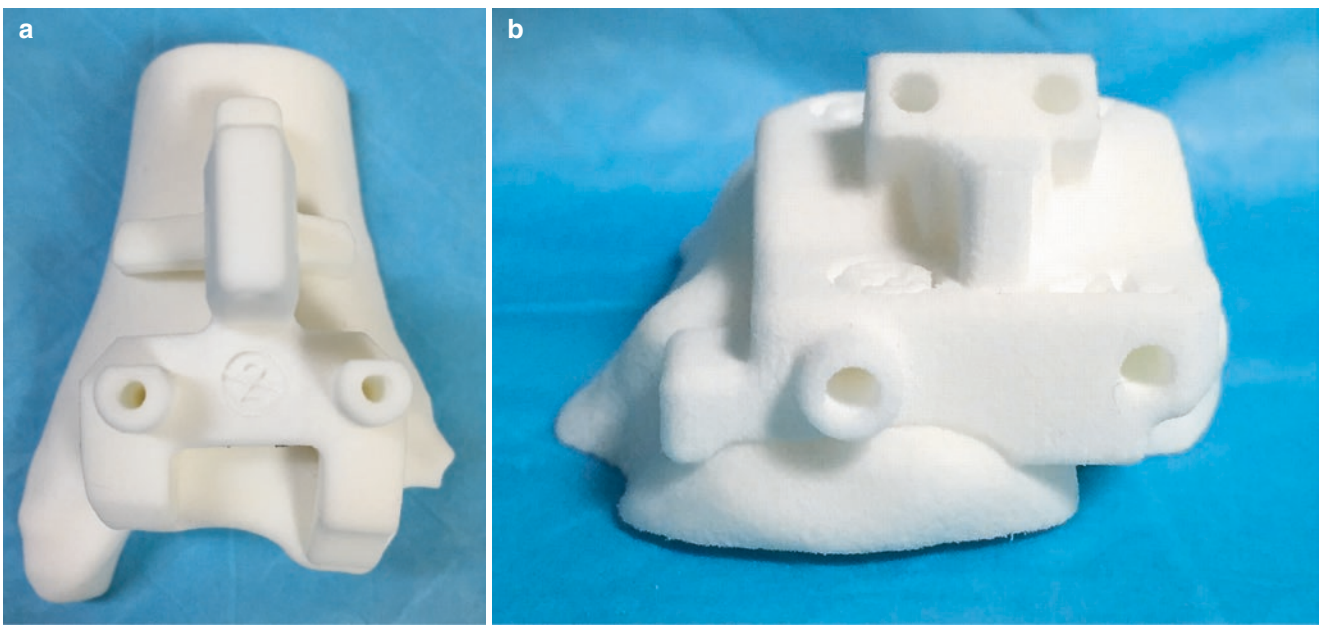


Fig. 9.5 (**a**, **b**) Wright Medical Group N.V., Memphis, TN PSI guides built from the PROPHECY™ System, and serves all of Wright's TAR choices (INFINITY™, INBONE™, INVISION™) [5]. Both the guides and patient bones are 3D printed to show proper orientation

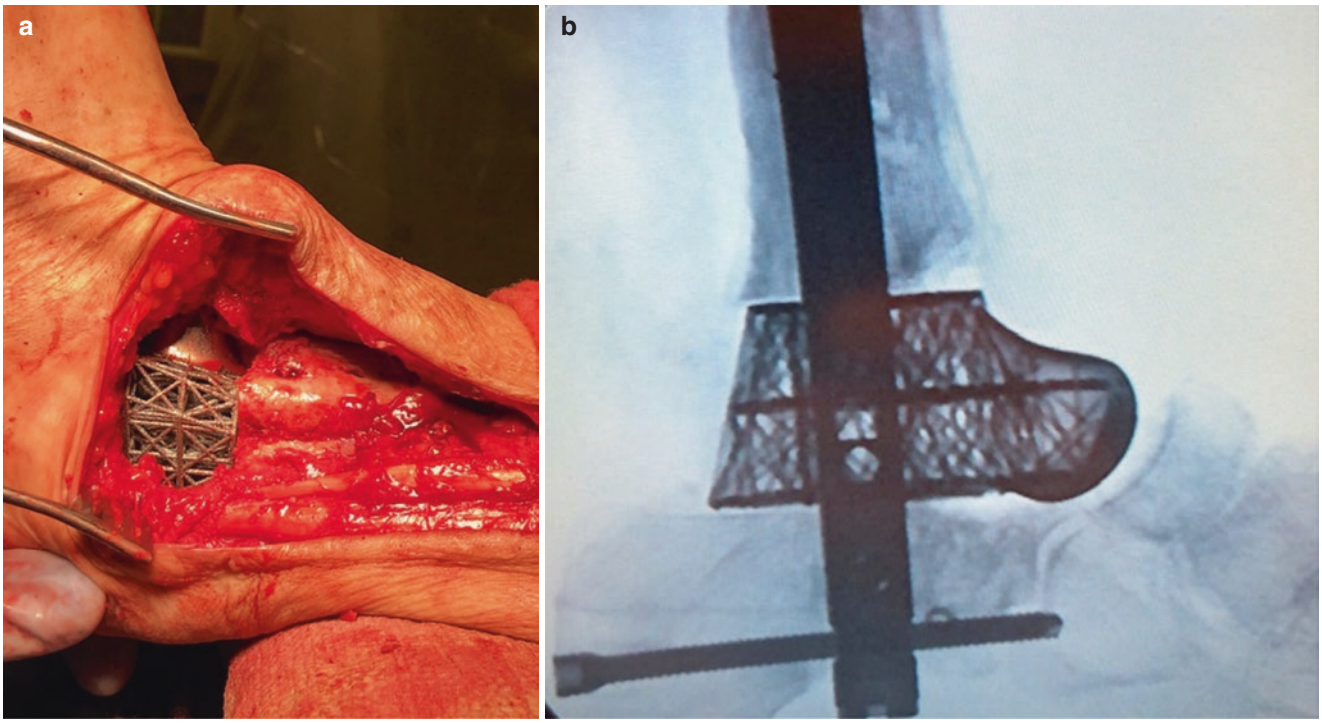


Fig. 9.6 (**a**, **b**) 4WEB Medical, Frisco, TX provides clinical engineers to work with surgeons and to help devise the 3D preoperative plan in which to build custom implants. (Courtesy of 4WEB Medical © 2019)

of seeing the full range of motion (ROM) recorded on the navigation's computer system. The analysis of ROM creates 4D preoperative planning where the fourth "D" is time. Because ROM defines the true rotational axis and possible misalignments, the joint replacement can be selected and positioned more accurately than just using a static image.

Different than PSI 3D preoperative plans, navigation plans are done on the OR table before bone is cut. For instance, for a TKR, a CT scan is done of the bones, with reflective reference devices attached to the femur and tibia, while the patient is on the table. By moving the joint in a full ROM, the rotation axis can be found and varus/valgus misalignment can be detected. The only downside is that the ROM is not weight-bearing. The surgeon can install a 3D model of the implant like other planning software and select the appropriate size and location. In addition, he/she can change the cut according to the system's recommendations from the ROM analysis and then proceed with implantation. Importantly, a second check can be made after implantation, to make sure the ROM has been corrected. If not corrected as desired, the surgeon can make poly changes or perform soft tissue techniques to get to the final ROM.

Unfortunately, navigation may not be the best option for TAR, but the 4D aspect is very promising, which will be addressed in the section discussing the future of 3D planning.

Advancements in 3D Imaging

So far, all 3D preoperative plans need DICOM data. This is typically done by MRI or CT scans, in which the former is the mainstream technique. Traditional CT scanners lay the patient in a non-weight-bearing state. Now CT scanners are made specifically for extremities and can be positioned to allow for weight-bearing. This is particularly important for TAR since weight-bearing has a greater effect on the ankle than on any other joint in the body. CurveBeam, Hatfield, PA, in particular is taking the next step and adding 3D preoperative planning to their system. They have developed a separate software package called CubeVue Software, which directly takes the DICOM data it generated and automatically segments the bone. By use of tools and multiple imaging options, they can take measurements of distance and angle to help with a surgical plan (Fig. 9.7).

Another player in advanced 3D imaging is Planmed OY, Helsinki, Finland, with their Planmed Verity® CBCT scanner, also with weight-bearing capabilities and partnering with Disior Ltd., Helsinki, Finland. Disior has created a stand-alone software package, Disior Analytics, that also takes DICOM data directly from Planmed's scanner and creates a segmented bone model. By analyzing the geometries of the solid bone models, Disior Analytics software generates axes of the bones and automatically creates a list of measurements based on these axes. A surgeon can analyze these measurements to find the root cause of deformities and create a surgical plan (Fig. 9.8).



Fig. 9.7 CubeVue Software, CurveBeam, Hatfield, PA, custom visualization software used for bone segmentation and tools to take measurements. (Courtesy of CurveBeam)

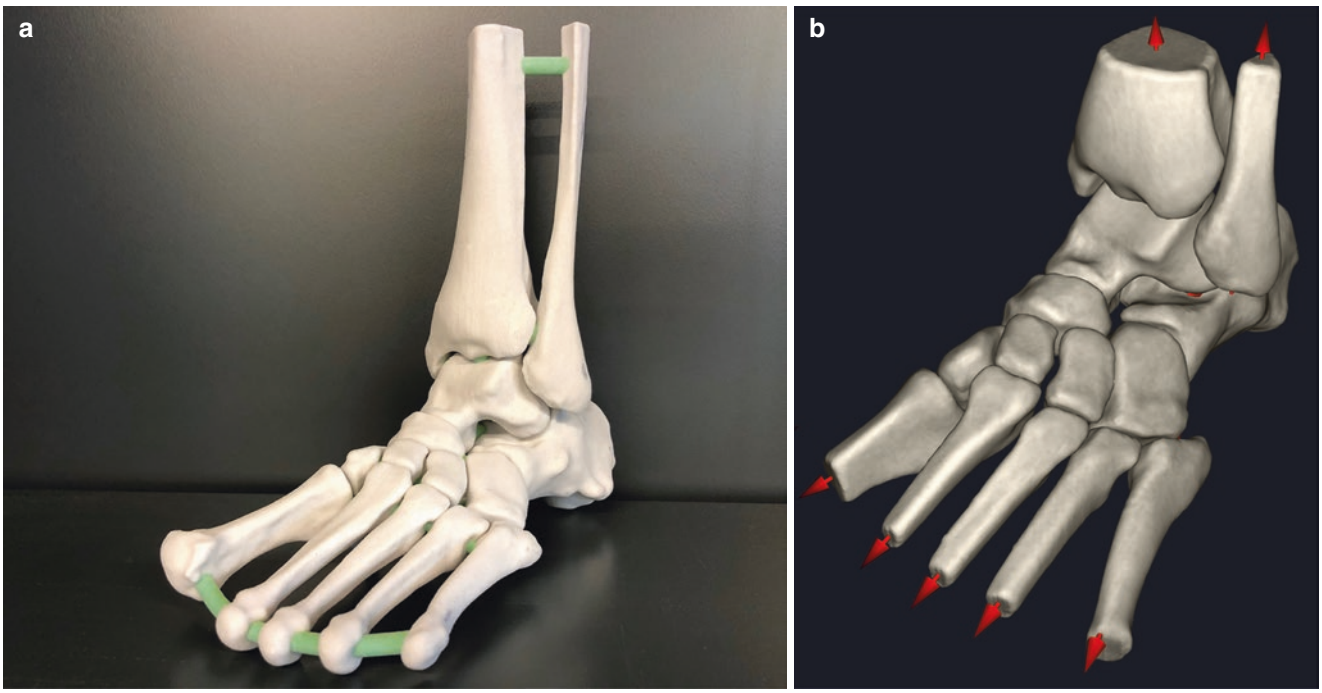


Fig. 9.8 (**a**–**d**) Disior Ltd, Helsinki, Finland, Disior Analytics software defines axes of the bones and creates automatic lists of measurements

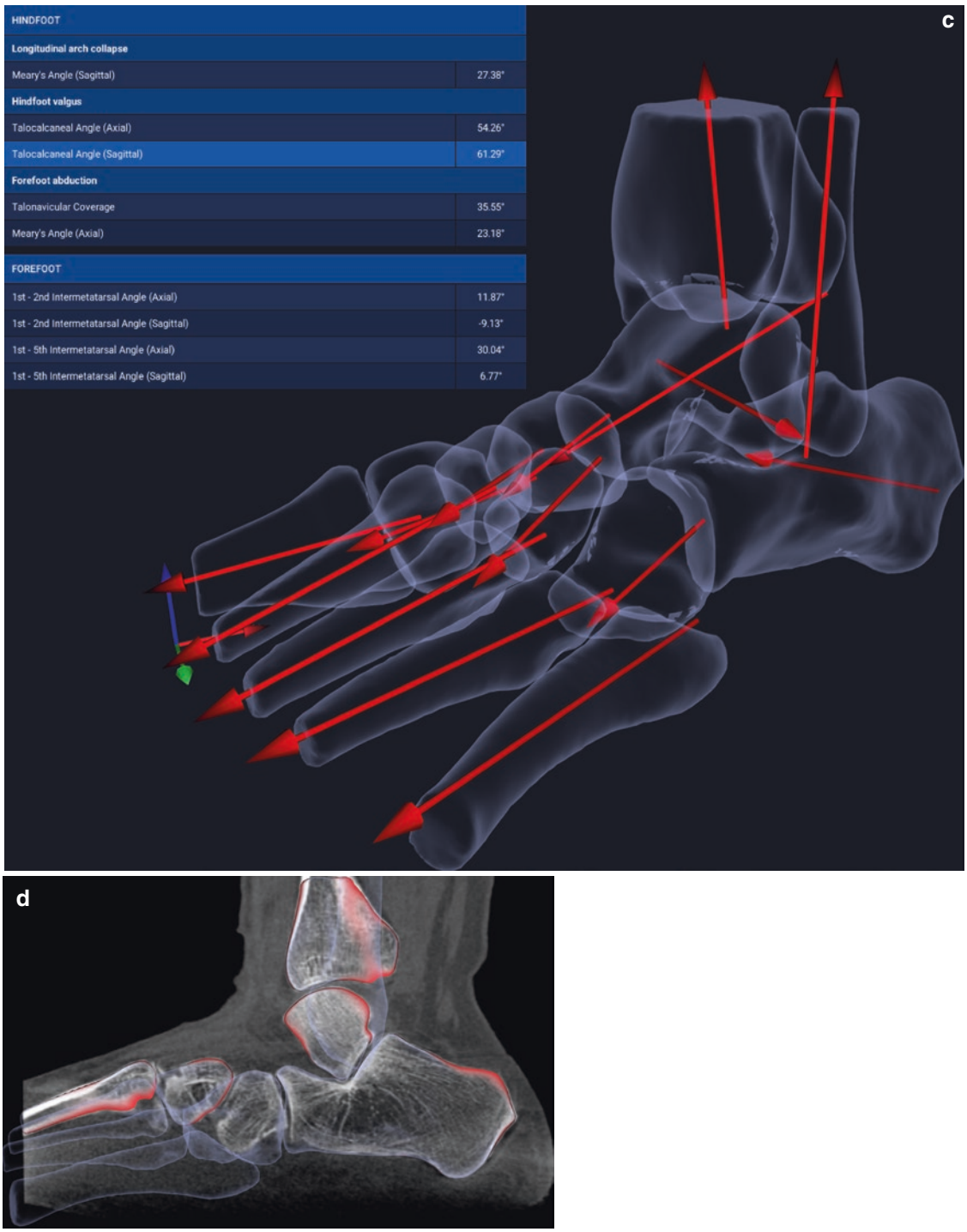


Fig. 9.8 (continued)

Stand-Alone 3D Preoperative Planning Software

One last company to mention that is a big part of the PSI thrust in recent years but has mainly been working in the background with other companies is 3D Systems Corporation, Rockhill, SC. They are the father of 3D additive manufacturing, first developing 3D SLA plastic parts in 1986. And, they have been on the forefront of making 3D printed metal implants, being suppliers and clinical engineers behind many medical device companies. They are now taking strides in doing 3D preoperative planning with

their new software package, D2P™ DICOM-to-PRINT. Now a healthcare professional can cut out the middle man and make their printed models using this stand-alone software. In one step, the DICOM data are automatically converted in to segmented bone ready for printing. The static images and models are good for planning and patient education, but currently do not have the ability to manipulate the bone or add implants.

Certainly, in the future this system and those mentioned above will make strides to provide TAR with real surgeon-driven 3D preoperative planning, with the ability to manipulate bone, make cuts and add implant models.

Projected Future of 3-D Preoperative Planning

We can expect similar developments in TAR as seen in TKR, but there are challenges to overcome in the ankle market. Primarily timing and cost of development are big hurdles since the ankle revenue stream is much smaller than the knee. Also, the ankle is one of the most challenging joints in the body to replace. The surgical approach is much more limited in comparison to the knee, and articulation is very limited as well. The ankle joint sees more body weight than the knee and has half the surface area. This means small misalignment errors have drastic effects and is why the accuracy of a TAR 3D preoperative plan and its components are paramount to success. Another hurdle is cost to the patient. Not only are CT scans required but using PSI is a premium service that the patient must pay. And, due to the above-stated complications, TAR will likely need to rely on PSI, unlike the shoulder. If Wright Medical's Prophecy system is any indication, PSI instruments will be needed nearly 90 percent of the time.

The planning and PSI trend have been established by Wright Medical Group, 4WEB Medical and Additive Orthopaedics. Although they do not have surgeon-driven planning software, they must certainly be contemplating this or already have plans in development. More and more surgeons are becoming dependent on preoperative planning and patient-specific instruments. There are many next generation surgeons who have never put in a TAR using traditional extramedullary fixtures and cutting blocks. This growing population of surgeons will overlook the traditional TARs and demand new TARs with 3D planning and PSI options.

There are other foot and ankle applications for preoperative planning beyond just TAR. Once true surgeon-driven 3D planning is available, the manipulation of bone can be extended to other areas of the foot. For instance, a surgeon may find that after correcting deformities in the hindfoot and/or forefoot in the 3D space, the kinematics of the ankle are restored and the need for an ankle replacement is delayed or even prevented. Staging corrective surgeries before TAR can be done more accurately, and after these surgeries, the surgeon can go through another 3D preoperative exercise to fine tune the TAR location and any other deformity correction. Also, concomitant surgeries could be planned then accomplished with much more confidence.

And, probably one of the most important motivations to push 3D preoperative planning in the future is that hospital and insurance companies will start to realize their benefits. Hospitals will see the OR time cut, with improved efficiency of the plan and elimination of surprises. Additionally, surgeries using PSI are quicker and easier to set up than traditional extramedullary fixtures and cutting guides. With the potential of lower cost and better outcomes, insurance companies may start to support and advocate 3D preoperative planning in TAR's.

Navigation is another technology that will push 3D preoperative planning in the future but may have limited application to the TAR. For TKR, the key to accurate navigation is the attachment of reflective ball targets to the defining bones of articulation (the long bones of the femur and tibia). And to its benefit, the knee's ROM is very large to help define the rotational axis. Of course, for TAR the defining articulating bones are the tibia and talus, and this is where the difficulty lies. The tibia will be easy to attach a reflective ball target device onto, but the talus is a very small bone with limited access, and it will pose a significant challenge. Plus, the limited articulation of the ankle will hamper the interpretation of the axis. One great benefit of navigation that can be borrowed is applying the fourth dimension of time, creating a 4D preoperative planning software as the next step.

Rather than using navigation, the ROM can be simulated using the original CT data and bone segmentation software. Further development is needed to either take CT scans while executing ROM, or ROM can be interpreted through the 3D modeled articulating surfaces and their axes. The interpretation of ROM using just the static image will be problematic, so the best option would be to do real ROM under weight-bearing conditions and recorded by CT. This is a tall order for the limitations of CT scanning technologies but may be better addressed using fluoroscopic imaging as detailed below.

A new development on the horizon which may lower the hurdle for the ankle replacement market is removing CT scans from the equation. One company, Enhatch, Hoboken, NJ, is working on 3D preoperative planning software based on fluoroscopic imaging under their product, The Intelligent Surgery Platform™. With this method, multiple images at different views are taken of the foot, and by means of extensive 3D libraries of information and mathematically converting 2D information from several images, a 3D model of the bone can be constructed. Then preoperative planning can be accomplished using surgeon-

driven software package. Obviously, the price of CT scans is avoided, but additional benefits include a patient getting x-rays done in the same visit and receiving less radiation. Plus, the conversion of the 3D models to a software package could be done in the same day at the doctor's office, and a plan could be conceived while the patient waits. Enhatch has already seen success in TKR, and we can anticipate this will follow with TAR.

Furthermore, the use of fluoroscopy could lower the hurdle for adding the fourth "D" element of time. Here it would be much easier to create a series of x-ray images over time, during ROM and with weight-bearing. This would be an advantage over navigation since it does not include weight-bearing ROM (Fig. 9.9).

Technologies supporting the 3D preoperative planning are also advancing. Most often 3D printed parts (additive manufacturing) are used for both patient-specific instruments and implants. 3D additive manufacturing is becoming more commonplace and the price points for machines and processes are coming down. Especially for plastic components like those made for patient-specific instruments, the prices are low enough for the average consumer to afford. For instance, a hospital could have a 3D printer on-site to build patient-specific instruments for a multitude of surgical applications, saving time and cost. Metal 3D additive manufacturing is still at its early stages, but many manufacturers, such as 4WEB Medical and Additive Orthopaedics are already using this process for implants. Metal 3D additive manufacturing is still at a higher price point, so it may be a long time before these are seen in the hospital.

An extension of 3D preoperative planning is intraoperative checking, based on the preoperative plan. This is something that Stryker Corporation, Kalamazoo, MI, already has on the market for the hip, HipMap and HipCheck. It is 3D

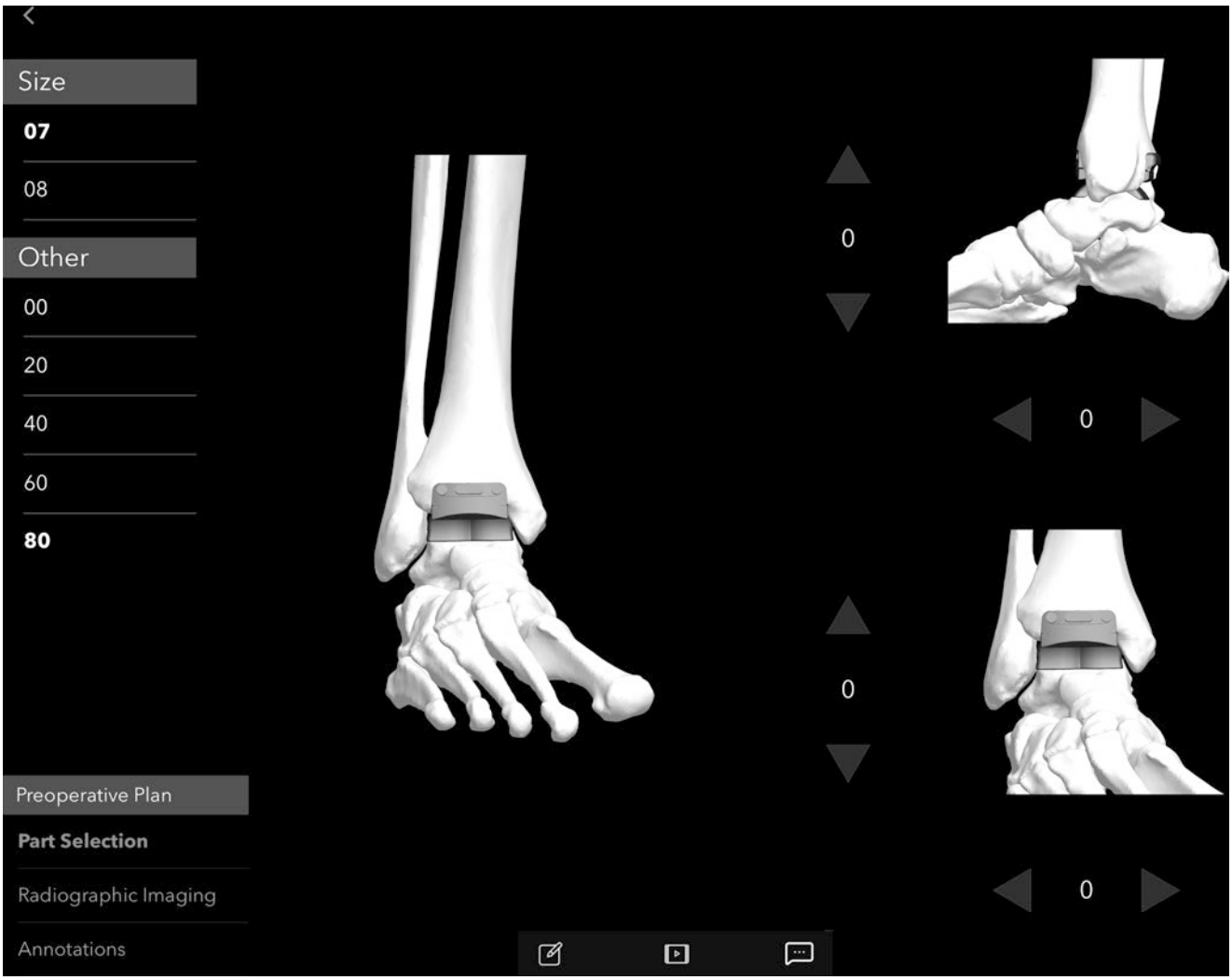


Fig. 9.9 In this image from Enhatch's The Intelligent Surgery Platform™, the bone has been generated by fluoroscopic images and now can be manipulated and implants inserted to create the 3D preoperative plan. (Courtesy of Enhatch, Inc.)

preoperative planning with clinical decision-making and real-time intraoperative feedback that helps measure and resect cam lesions to a desired alpha angle. Basically, it is a real-time assessment using fluoroscopy to compare to the original plan. Somewhat similar to what can be done in navigation systems with result checking, but without the million-dollar machines.

Yet another new technology that will impact 3D preoperative planning is virtual reality (VR) headsets and software. Currently, this technology is being developed for training purposes, but Precision OS, Vancouver, Canada, is investigating using its ability to do realistic surgical applications and applying it to do surgical planning. "This will allow surgeons to plan and execute in the virtual world and make small but important adjustments to their approach to help optimize the case outcome" [9].

Lastly, robotic-assisted surgery is on the horizon for TAR. It has yet to fully break into joint replacement surgery, but when it does it will require 3D preoperative planning as part of the process. This technology will be in development for many years before it is commonplace, but for any joint replacement, the surgeon will need to plan for product type, location and orientation, and deformity corrections. With robotic-assisted surgery and the above technologies pushing ahead, eventually 3D preoperative planning will no longer be an elective, but a requirement.

Conclusion

3D preoperative planning for TAR is in its infancy compared to other joint replacement markets. Historically, as technological advancements are made, the ankle market is usually one of the last to benefit due to the unique challenges the ankle joint presents. Namely, the TAR revenue stream is much smaller than those of the knee and hip, and anatomically the ankle has more challenges, as discussed earlier. The precursor technology of patient-specific instruments and implants has already made its way into the TAR market, supported by clinical engineers and surgeons working together to do a 3D preoperative plan. The combination of new technologies, market pressure, and increasing the efficiencies in the OR will help push true surgeon-driven 3D preoperative planning in the TAR market. These technologies are already proven in the knee market and include advanced on-line software (with or without PSI), advanced in-OR imaging software, in-OR navigation systems, one-box surgery methodology, 4D preoperative planning software (ROM analysis), weight-bearing CT scans, and conversion of fluoroscopic imaging to 3D models. One of the bigger monetary hurdles is the use of CT scans, so the new technologies incorporating fluoroscopic imaging to create the 3D bone models will help pave the way. We may also see a change in the way we do planning away from computers and instead by the use VR headset software. And finally, on the horizon robotic-assisted surgery, will mandate more sophisticated 3D/4D preoperative planning.

Surgeons today who have not already done TAR with PSI should be prepared for more products using this technology along with more capabilities in the preoperative plan. Soon some TAR products may not have the option of using an extramedullary fixture and cutting blocks. And, it is only a matter of time when TAR's will see surgeon-driven 3D preoperative planning software supplied by every contending medical device company.

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Part II

Primary Total Ankle Replacement

Cadence Total Ankle Arthroplasty

10

Christopher F. Hyer, Selene G. Parekh, David I. Pedowitz, William Austin Hester, Jermonte Lowe, and Timothy R. Daniels

Introduction

There has been increased demand and use of total ankle arthroplasty over the past 10–15 years. This experience has brought a better overall understanding of ankle arthroplasty and helped to drive continued technique and technology improvement with respect to implant and instrument design. Further understanding of the limitation and failure points of other implant designs and a better appreciation for bone preservation have also been gained. In addition, it has become clear that joint replacement procedures would become more frequently performed in an outpatient surgery setting and technique and instrument optimization would be needed for this care setting.

The Cadence® total ankle replacement (TAR), (Integra LifeSciences) was developed as a primary total ankle replacement implant, with an efficient and reproducible technique that preserved bone volume and critical osseous vascular supply and could easily be performed using mini-fluoroscopy in an outpatient setting.

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Design Rationale and Goals

In the development of any total joint prosthesis, the broad mandate for the design team is to improve design and outcomes. This can be accomplished by changing instrumentation to make the procedure safer, improving the reproducibility of the technique for large numbers of surgeons with different abilities and experience, making component improvements which enhance the longevity of the implant based on established data and increasing the likelihood that a revision, if needed, can be performed with the greatest predictability. The Cadence® TAR was designed to address common theoretical modes of early failure seen in earlier generations of implants.

Cadence has several key improvements and design features:

1. Tibial tray fixation with anterior pegs and a unique posterior "fin" to better engage the posterior implant up in the posterior tibial surface.
2. Unique Right and Left implants in order to have a more customized fit and natural range of motion.
3. Highly cross-linked UHMWPE inserts for improved wear and longevity.
4. An industry first; biased poly inserts (anterior, neutral, and posterior) to allow better retention of preoperative anterior and posterior listhesis of the ankle.
5. An industry first; anatomic shaped tibial tray component with "cutout" for the syndesmosis to reduce fibular impingement and syndesmotic pain.
6. A superiorly chamfered talar component which maintains medial and lateral cortical wall support of the talus, limits bone and vascular supply insult, and improves imaging surveillance.

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Description of Cadence System

The Cadence total ankle replacement is a fixed-bearing device with three components: a tibial tray (Fig. 10.1a), a talar dome (Fig. 10.1b, c), and a polyethylene insert (Fig. 10.1d).

Just as the normal human ankle is different from right to left, so too are the Cadence ankle replacement components. There are specific Right and Left components to provide a customized, anatomic fit and range of motion. The implant is meant to be bone sparing, with minimal bone resections through use of reliable cutting guides. In addition, care is taken to minimize damage to the talar vascular supply with minimal pin fixation into the talus and careful targeting of pins away from blood supply channels.

Contemporary research of other implant systems noted difficulty with recurrent anterior and posterior listhesis post ankle arthroplasty which was associated with diminished outcomes. Cadence offers the surgeon the option of three polyethylene inserts (neutral, anterior, and posterior biased) to use to enhance sagittal stability when needed. Finally, the system allows for a high degree of customization, including mismatching tibial and talar sizing which results in over 630 combinations that can be constructed allowing for a system which can accommodate a variety of human anatomy (Fig. 10.2).

Tibial Component

The tibial tray is made of a titanium alloy and has two anterior pegs and a posterior "fin" to engage the posterior plafond and prevent post-operative migration. The tibial tray comes in as both right and left implants, sizes 1–4 in standard and X and a size 5 standard. The X size has an increased anterior to posterior dimension as the next size up for improved posterior coverage without growing size from medial to lateral.

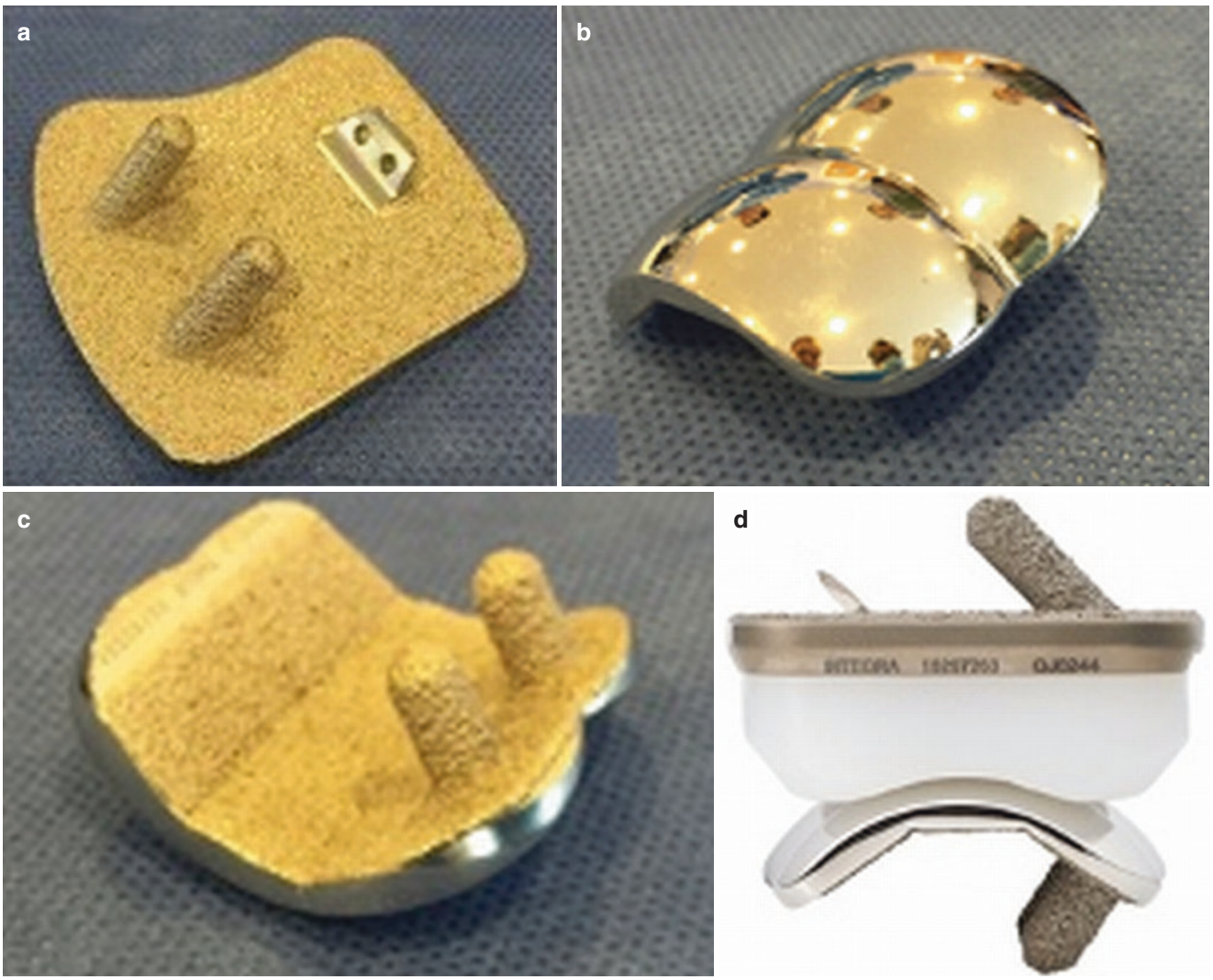


Fig. 10.1 Cadence total ankle replacement; 3 component ankle. (**a**): superior view, Tibial implant with 2 anterior pegs, 1 posterior "fin." (**b**): superior view, Talar implant, bi-condylar radius surface with central groove. (**c**): underside view, Talar implant, anterior peg fixation with 3 chamfer cut surfaces. (**d**): lateral view of full assembled Cadence TAR with neutral poly insert



Fig. 10.2 Cadence TAR system: Sizes 1–5 tibia in standard and X, talus sizes 1–5, both components in Left and Right, Polyethylene inserts in Neutral, Anterior Biased, Posterior Biased sizes 6 mm–12 mm

For example, a 2× will still have the same medial to lateral sizing of the standard 2, but will have the anterior to posterior sizing of a 3 standard. This added sizing allows for a good match to the overall dimension of the tibial and avoids too much overhang or underhang posteriorly of the implant; a problem frequently encountered in other systems.

The tibial component is designed to have 3 cortical rim support: anteriorly, posteriorly, and laterally. The tray has a lateral incisura that allows for "nestling" of the fibula, theoretically eliminating fibular impingement and allows the syndesmosis to function normally and unhindered by the tibial tray (Fig. 10.3a–c). The tibial implant "wraps around" the fibula and respects the syndesmotic anatomy (Fig. 10.4). Additionally, the anterior two pegs are positioned in the same location for all sizes of the tibial tray. This allows the surgeon to seamlessly upsize or downsize the tibia accordingly.

Talar Component

The talar dome is made of a cobalt chrome alloy (CoCrMo) and has two anterior pegs. It fits onto the talus by way of both anterior chamfer and posterior chamfer cuts and a flat top central dome. The talar preparation is optimized to minimize damage to the talar blood supply by utilizing pinholes in areas where the blood vessels do not enter the talus. The talar resection is minimized to be maximally bone sparing.

The talar components also come in a right and left implant, with two different radius of curvatures for the medial and lateral domes of the talus. There is a central sulcus present in the talar component providing further stability. Finally, the anterior two pegs are positioned in the same location for all sizes of the talus. Just as with the tibia, this allows the surgeon to seamlessly upsize or downsize the talus accordingly to maximize medial and lateral coverage of the talus.

Polyethylene

The Cadence is a fixed-bearing device. The polyethylene is made of highly cross-linked, ultra-high molecular weight polyethylene and is rigidly fixed to the tibial tray through a dovetail locking mechanism. This insert comes in neutral, anterior, and posterior biased options to help address cases of sagittal misalignment (Fig. 10.5a–c).

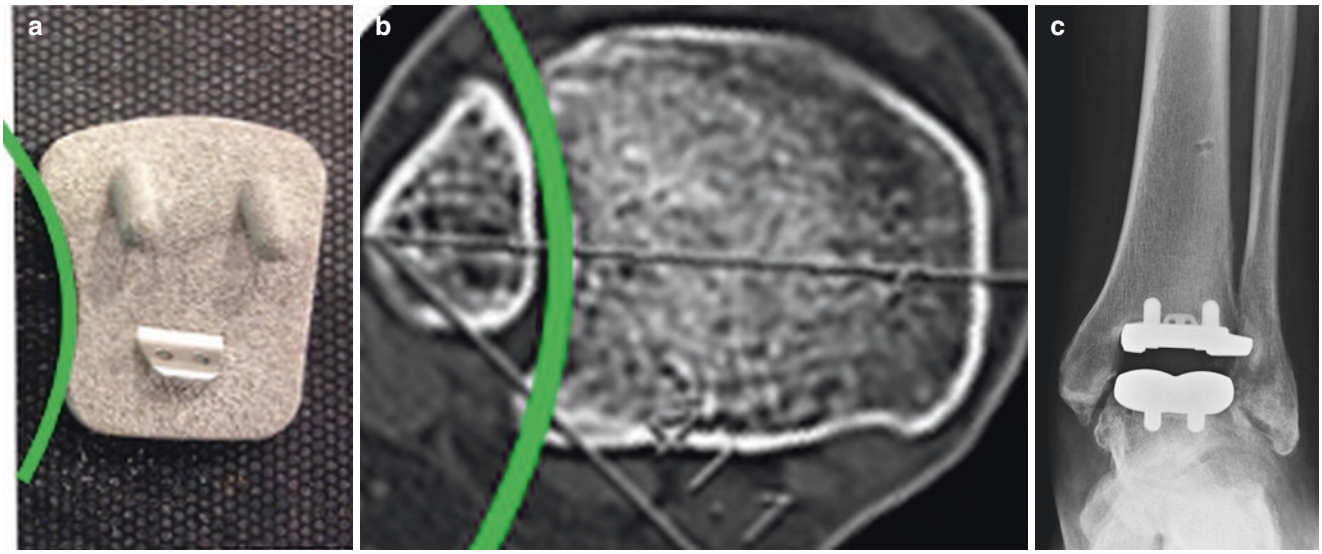


Fig. 10.3 (**a**) superior view of Cadence tibial component. Note, this is a Left tibial implant with a lateral incisura to "wrap around" the fibula. (**b**). Axial CT scan demonstrating similar footprint as the tibial implant. (**c**) Mortise ankle radiograph with implanted Cadence TAR. An standard AP ankle will have the appearance that the tibial implant is notched into the fibula due to the incisura flare of the implant

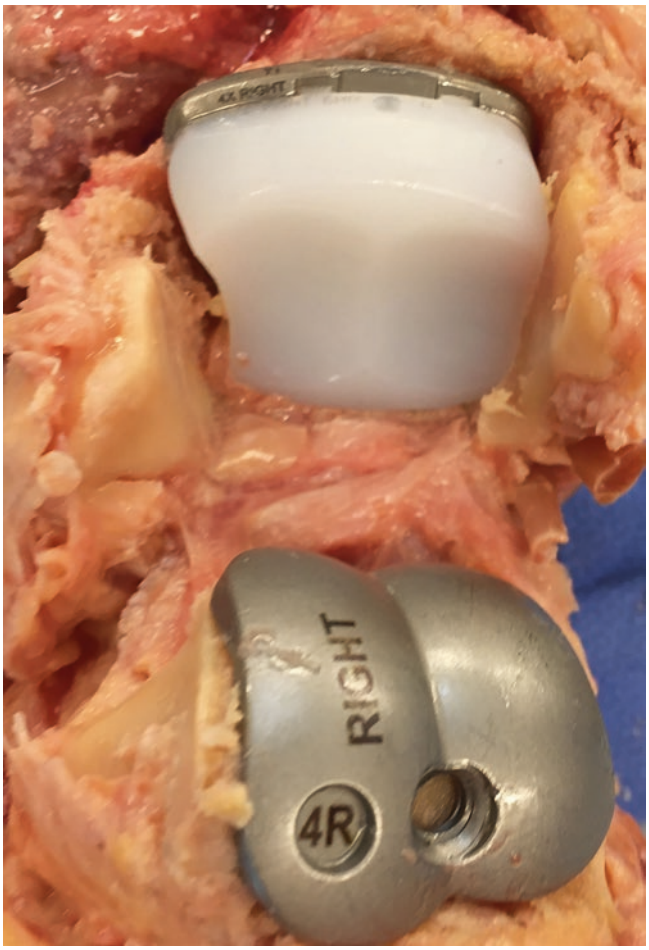


Fig. 10.4 Dissected cadaver specimen with Cadence trial implants. Note the "syndesmotic notch" to the lateral side of the tibial tray which allows 3 cortices support to the tray and minimized impingement into the syndesmosis or fibula

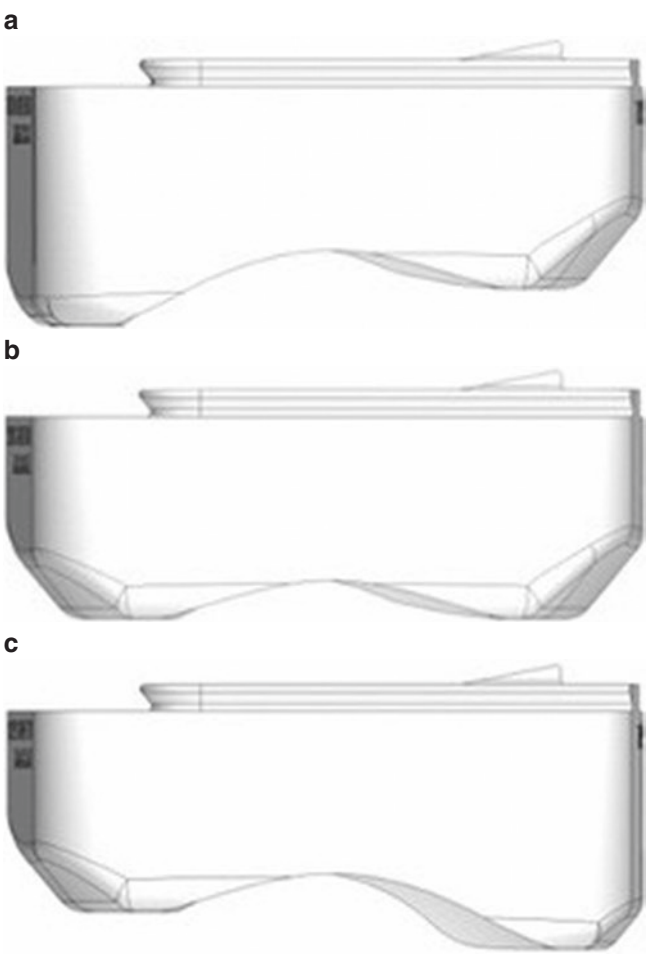


Fig. 10.5 (**a**) Lateral view, poly insert, posterior biased. (**b**) Lateral view, poly insert, neutral. (**c**) Lateral view, poly insert, anterior biased

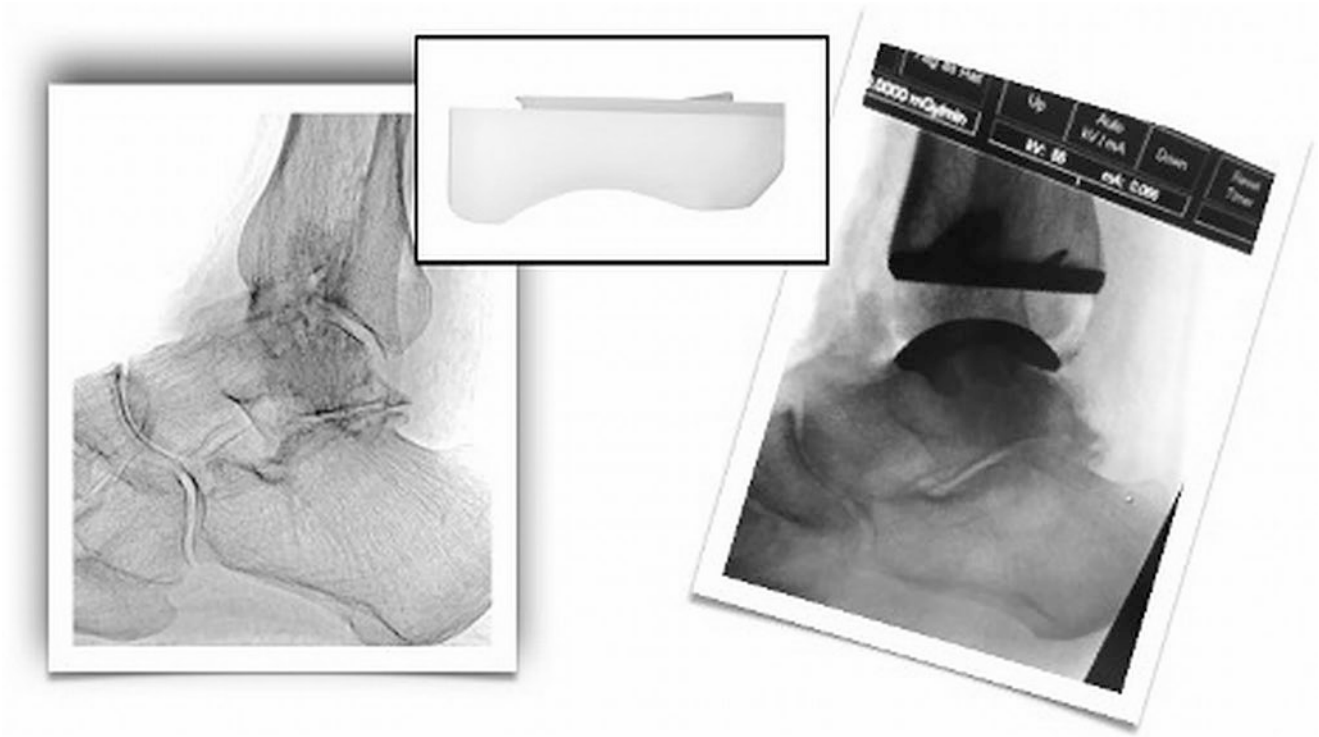


Fig. 10.6 Preoperative anterior listhesis of the talus in an arthritic ankle. Anterior biased poly for added anterior support, and intraoperative Cadence ankle with anterior biased poly

The anterior bias has a 2 mm anterior lip, providing additional anterior support for patients with a pre-existing anterior translated talus (Fig. 10.6). Correspondingly, there is a posterior bias with a 2 mm posterior lip. This provides additional posterior support for patients with pre-existing posterior translation of the talus. The posterior bias poly can be a useful adjunct in patients with deltoid ligament insufficiency. It is imperative that the talus is reducible under the tibial before implantation of the biased polyethylene liner. The surgeon should not rely on the biased poly as a corrective force, it simply is additional sagittal support where required. A neutral polyethylene is available for those patients who have appropriate, preoperative sagittal alignment. Poly trials are available in all sizes, including the biased options.

Cadence TAR Surgical Technique

The patient is positioned on the operating table in the supine position with a bump under the ipsilateral hip such that the foot and patella are colinear and facing the ceiling. Additionally, a sterile bump is used under the tibia so that the heel is elevated off the table so as to eliminate any anterior drawer type of force on the joint. If a tourniquet is used, it should be placed at the thigh level to allow visualization and draping of the tibial tubercle.

A standard anterior, 15 cm incision that exploits the plane between tibialis anterior (TA) and extensor hallucis longus (EHL) is utilized. An alternative, extensile anteromedial approach is preferred in patients at risk of wound-healing difficulties (Diabetes, inflammatory arthropathies, previous incisions, and/or trauma, etc.) The superficial peroneal nerve (SPN) should be identified and protected prior to incising the retinaculum. This can be accomplished by localizing the nerve in the distal lateral part of the incision and following it proximally. After incising the retinaculum, the TA is retracted medially while the EHL and soft tissues deep to it (including the neurovascular bundle) are retracted laterally; this allows safe sharp dissection to bone deep to TA. The soft tissues are sharply elevated until the medial and lateral malleoli are visualized. The anterior joint capsule and any overhanging osteophytes are excised.

The tibial alignment guide is assembled on the back table, and it is then positioned on the patient. Proximally, it is secured with a clamp around the calf at the level of the tibial tubercle. Distally, the guide is positioned in the center of the metaphysis with the distal most part of the guide at the level of the native ankle joint. At this point, the distal guide is pinned to the tibia. After pinning, the tibia guide rod is adjusted so that it is parallel to the tibia shaft in both the frontal and sagittal planes.

Sagittal plane alignment is accomplished by attaching an external rod to the guide and adjusting the guide proximally

so that the rod is parallel to the tibia in the lateral x-ray. The "angel wing" can also be used to assess resection level, flexion angle, and alignment. Ideally, the "vertical barrels" of the wing will be parallel to the long axis of the tibia and the barrels will be just touching the talar dome on the lateral radiograph (Figs. 10.7, 10.8, and 10.9). The guides all have multiple check points on fluoroscopy to confirm "true views." The preferred location of the cut is at or just below the physeal line of the tibia. It should be noted that in patients with ligament laxity, traction views may show that the tibial cut can be made at a more distal level/less tibial bone.

Next, rotational alignment is accomplished with medial and lateral gutter indicators or the alignment rod placed into the tibial guide. The guide is rotated distally to match these indicators. Once this is complete, it is checked by using an angle bisector aligned with the second metatarsal.

Medial-lateral positioning of the distal tibial cutting guide is undertaken next.

The tibial resection template is attached to the cutting guide. There are two options of sizes to template the medial to lateral width of the implant (1-2-3 guide or 3-4-5 guide). The medial holes of the cutting guide are aligned with the shoulder of the medial malleolus/medial talus (Fig. 10.10). This is then confirmed using fluoroscopy.

Distal tibial bone resection is performed at this point. The malleoli are protected using pins in the cutting guide. The medial pin is placed above the shoulder of the medial malleolus (this position was confirmed above). The lateral pin is placed just medial to the medial most aspect of the lateral malleolus. There should be 11 mm of bridging bone at the thinnest part of the medial malleolus. If there is any concern



Fig. 10.7 Intraoperative Lateral c-arm view: Tibial cut guide too low. The "wing" should be near with epiphyseal scar and the inferior tips of the vertical barrel low enough to just touch the top of the talar dome. Note the "perfect circle" on the wing itself and to the right on the tibial block giving the surgeon confirmation of a true lateral view



Fig. 10.8 Intraoperative Lateral c-arm view: Tibial cut guide too high

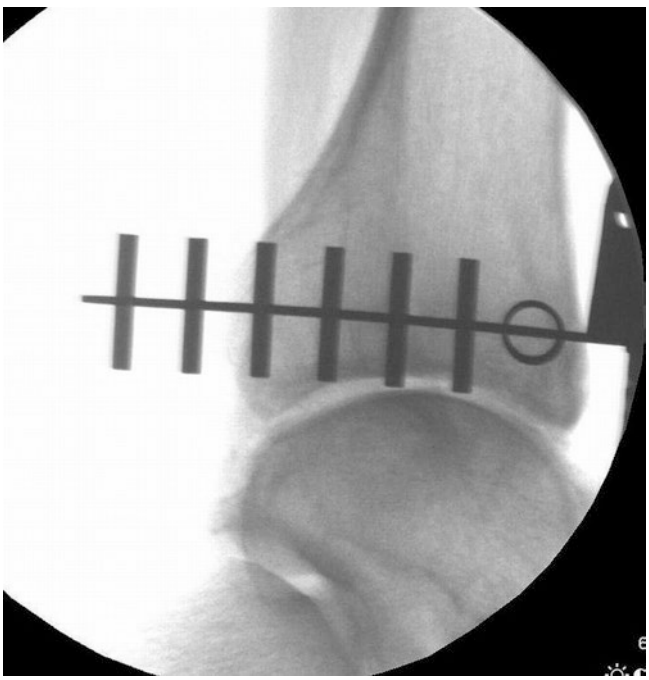


Fig. 10.9 Intraoperative Lateral c-arm view: Tibial cut guide at correct level with the inferior tips of the vertical barrels just touching the top of the talar dome

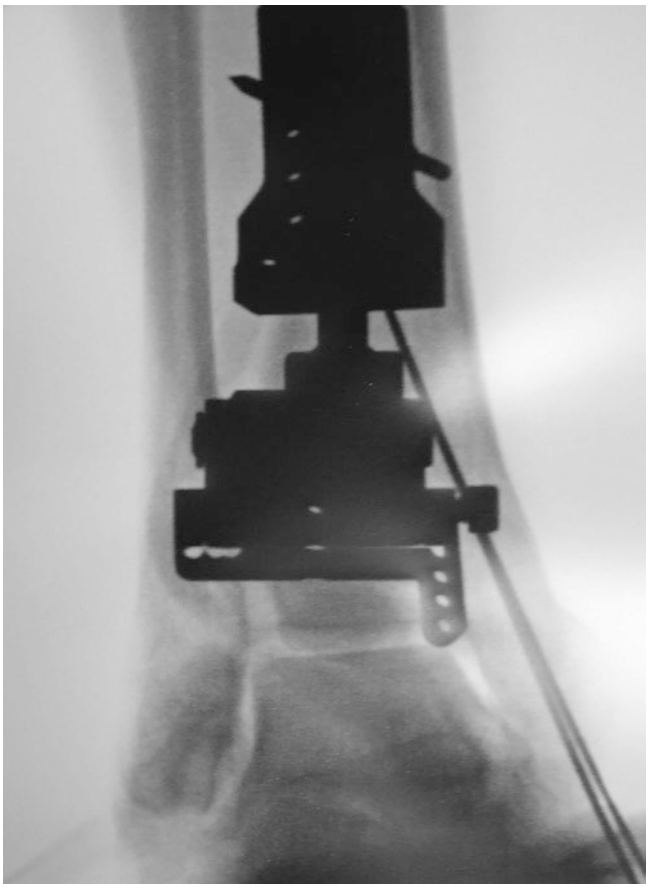


Fig. 10.10 Intraoperative AP c-arm view: Tibial block with Tibial cut guide assembled. The vertical drill holes for the medial cut are lined up with the medial gutter/medial shoulder of the talus. Again, obtain true "perfect circles" to confirm a true AP view. Note prophylactic tibial fixation of the medial malleolus with Steinman pins used in cases of fragile bone

as to whether the medial malleolus is at risk for fracture, it should be prophylactically protected with screw or temporary wire fixation inserted at an angle steep enough to allow for distal tibial resection (Fig. 10.11).

A drill tipped pin is used to perforate the vertical medial resection line through the cutting guide. Take care to carefully drill bi-cortically but refrain from plunging out posteriorly. The distal tibia cut is then performed using a narrow sagittal saw. The cutting guide is removed, and the corner cuts are made with a corner osteotome. Optionally, a small reciprocating saw can be used for the corner cuts if there is concern of weak bone and possible fracture. Again, care must be taken in this step to not fracture the medial malleolus. The resected bone is removed using a combination of osteotomes, rongeurs, and other surgical instruments as necessary. It is helpful to cut the resected distal tibia into multiple pieces and excise. Resist the urge to lever against the distal cut as anterior impaction can occur with this maneuver. Internal and external rotation levering may fracture the

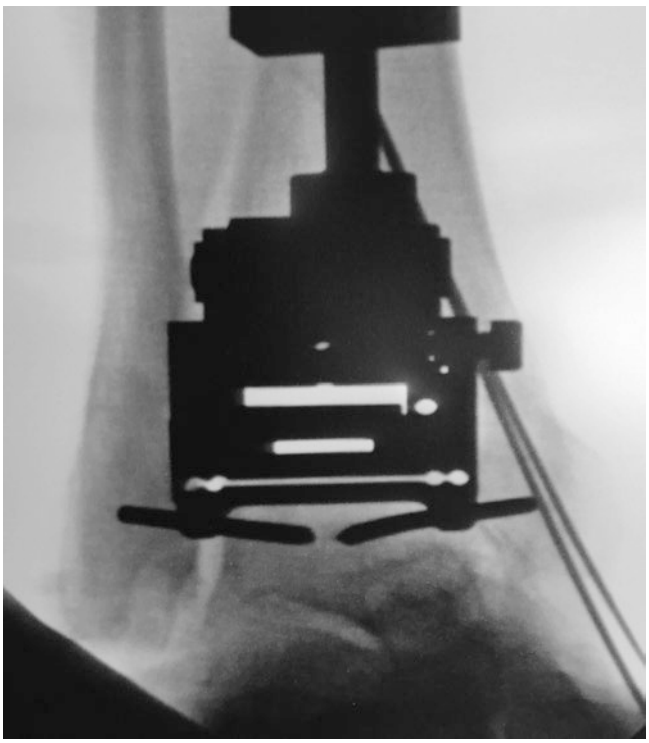


Fig. 10.11 Intraoperative AP c-arm view. Talar resection guide has been pinned to the talus. Note pins are directed away from talar vascular supply. Protective medial and lateral gutter pins can be selected from this view

medial or lateral malleoli. In some cases, the posterior part of the tibial resection is easier removed after the flat cut of the talus has been made.

Select the appropriately sized talar cutting guide and attach it to the distal tibia alignment block and tighten the locking screw to secure it to the alignment block. Loosen the distal/proximal locking screw and advance the jig using the lamina spreader(s) until the collateral ligaments are tensioned. Keep the ankle at a neutral position and ensure that the talus is in neutral position in the coronal and sagittal planes prior to tightening the distal/proximal locking screw on the jig. After the jig is locked into place, remove the lamina spreaders.

A long shouldered bone pin is then inserted in the distal holes of talar cut guide. It is advised to drop these pins in by hand to confirm the trajectory prior to powering them in. These pins secure the talus to the talar cut guide. AP fluoroscopy views are used to evaluate protective pin placement for the medial and lateral gutters (Fig. 10.11). Straight bone pins inserted in the saw slot help protect the medial and lateral malleoli during resection.

Lateral fluoroscopic image should confirm the talus is in a neutral position in the sagittal plane. Take care to confirm the ankle is neutral and the talus is neutral under the guide. If the guide is pinned with the talus plantarflexed, this will set all of the talar cuts in an anteriorly rotated orientation.



Fig. 10.12 Intraoperative view of dorsal talar dome resection. Cadence cuts are extremely bone sparing on the talus

Perform dorsal talar resection extending through the posterior cortex of the talus. The Cadence is bone sparing to the tibial, and the dorsal cut just removes the superior portion of the dome to set a flat surface (Fig. 10.12). Remove the entire tibial alignment guide and all the bone pins. Using an osteotome and rongeur, remove the resected talar bone and any remaining resected distal tibia. Take care to confirm there are no loose fragments or proud edges that need to be removed. It is important to avoid range of motion of the ankle at this point as this can place the medial and lateral malleoli at increased risk for iatrogenic fracture.

Insert the gap sizer to confirm enough bone has been removed to allow for insertion of the smallest implant. If the gap sizer will not fit or is too tight, a 2 mm resection cut guide allows additional resection from the distal tibia. Use a lamina spreader placed posteriorly to hold the resection guide opposed to the distal tibia. Pin the guide in place and resect additional bone. A fluoroscopic AP view of the ankle with the gap sizer in place allows for coronal alignment verification.

The system is talar implant driven, and the talar size will help determine the tibial implant size. There can be a one size down mismatch between the tibia and the talus. Slide the talar sizer onto the holder until it clicks, and place this on the cut surface of the talus. The sizer outline exactly matches the outline of the talar implant. If the patient's anatomy is between two sizes, the smaller size should be selected.

Align the sizer with the handle pointing toward the second ray with the foot in a plantigrade position. This sets rotation of the device. Verify there is no medial or lateral overhang of the sizer and gently expand the holder against the distal tibia to maintain alignment. Fluoroscopic AP and MO views can confirm appropriate sizing for medial and lateral talar support.

A lateral fluoroscopic view will show the posterior aspect of the talar sizer to be continuous with the radius of curvature of the talus if the sizer is properly positioned in the sagittal plane. There is a perfect circle guide on the expander to assist with obtaining a correct lateral view. There is also a triangle at the top of the sizer to indicate the center of the anterior/posterior position; this helps with centering the implant under the tibia. A true lateral view will also reveal the posterior chamfer captured cut through the guide itself (Fig. 10.13).

Once proper alignment is obtained, pin the talar sizer in place, as this is also the posterior chamfer cut guide. Use a shoulder pin on the surgeon's dominate-hand side and a straight bone pin on the surgeon's non-dominate side. This allows the next jig to be easily switched at a later step. Remove the talar sizer holder from the talar sizer and perform the posterior chamfer resection with a sagittal saw through the cutting guide.

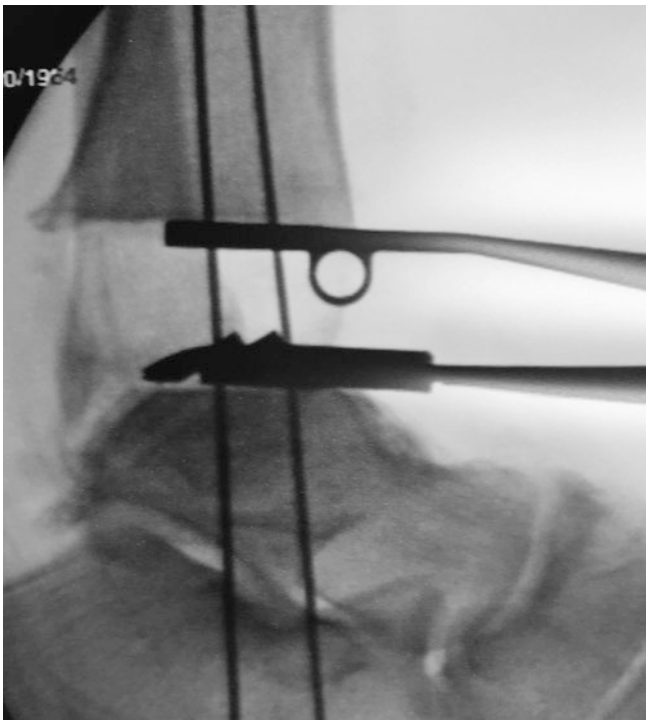


Fig. 10.13 Intraoperative Lateral c-arm view: Talar implant trial is also the posterior chamfer cut guide. Note perfect circle on top "laminar spreader" arm, confirming true lateral view. Note first triangle on top of the talar guide lines up with lateral process of talus to help orient A-P position. Also note matching of posterior slope of guide with remaining posterior slope of talar done. The captured posterior chamfer cut goes between the top two triangles and through the clear triangle on the underside of the guide

Re-attach the talar sizer holder and gently expand it against the tibia to maintain the talar sizer in place. Remove the shouldered pin and replace it with another straight bone pin. Release the holder and slide the talar sizer and holder off the smooth pins (leaving the pins in place in the talus). Align the pins with the holes of the talar anterior chamfer cut guide (inside holes if size 1 or 2; outside holes if size 3, 4, or 5) and slide the guide down until it is flush with the cut surface of the proximal talus. In smaller ankles, it is helpful to use a bump under the ankle to allow some plantarflexion to gain a flush fit of the guide against the talus. Place two shouldered pins in the top holes to hold the guide in place and remove the smooth bone pins.

Place the talar anterior chamfer reamer guide in the cut guide with the #1 on top when placed correctly. Ensure that the reamer guide is flush with the cut guide and protect the soft tissues with retractors. Check the medial two most holes to ensure that the medial malleolus will not be violated while reaming. Use the talar reamer to ream each hole in the guide. Avoid pulling down on the jig as this will flex the talar implant. Remove and rotate the reamer guide 180 degrees so that #2 is on top and repeat reaming as above.

Remove the talar anterior chamfer reamer guide from the cut guide and replace with the talar chamfer drill guide. Check that "TOP/PROXIMAL" and "BOTTOM/DISTAL" markings on the guide are properly oriented. Drill these holes using the post drill to a positive stop and save the bone from the drill for possible future use. Remove all instrumentation and use osteotomes, rongeurs, and other surgical instruments to remove all resected bone including the posterior chamfer cut (Figs. 10.14 and 10.15). At this point, a thorough lavage and reinspection is performed to confirm all debris is removed (Fig. 10.16).



Fig. 10.14 Intraoperative view of posterior talar chamfer resection



Fig. 10.15 Intraoperative view of posterior talar chamfer resection. Note minimal bone resection with preservation of talar bone content

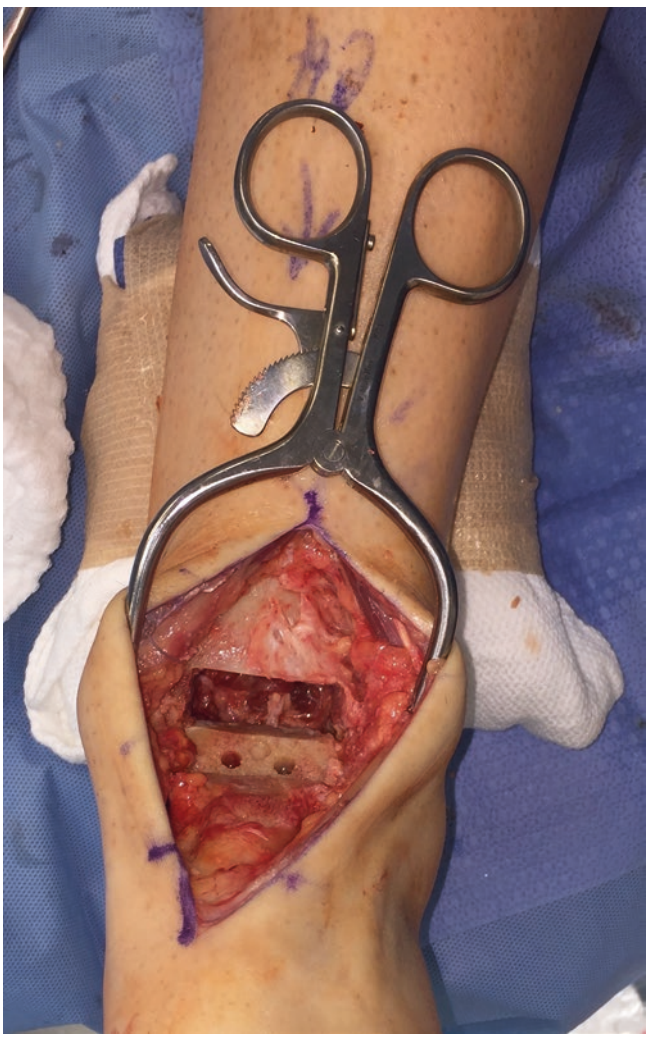


Fig. 10.16 Intraoperative AP view of completed joint preparation ready for implant trials

During the course of preparing the ankle joint, both the medial and lateral gutters are inspected anteriorly, laterally, and intraarticularly. If on the preoperative weight-bearing lateral radiographs, there is sagittal instability of the talus (anterior or posterior translation), it is imperative that the surgeon adequately release the gutters to allow the talus to be reduced under the midline of the tibia. Particularly with anterior talar translation, new bone may have formed in the gutters preventing the talus from being reduced. Re-sculpting the ankle mortise with a combination of saws, burs, osteotomes, and/or curettes and managing the malleolar dysplasia may be needed if it exists.

Select that talar trial that corresponds with the talar sizer cut guide used above and place the posts of the trial in the holes drilled into the talus. Use the talar impactor to seat the trial. Take care to impact both anteriorly and posteriorly to ensure full seating of the trial. A fluoroscopic lateral image will show whether the talar trial is fully seated. If the trial isn't seating flush, re-inspect for debris or slight uneven edge on the dorsal or posterior cuts and correct as needed (Fig. 10.17). Leave the talar trial in place.

Use the tibial implant sizer to measure the anterior/posterior length of the distal tibia and select the appropriately sized component. Select the tibial trial that corresponds to the lateral pin placed through the tibial cut guide during resection and length measured above. Again, the tibia can be same size as talus or 1 up from the talus. For tibial sizes 1–4, there is a standard and an X length. For a size 5, there is only standard.

Select the 6 mm thickness insert trial (smallest) corresponding in size to the talar trial chosen. Slide the insert trial into the dovetail of the tibia trial; the appropriate side (R or L) should be facing anteriorly. Insert the tibia and trial together into the joint. A lateral fluoroscopic view is used to determine if tibial coverage is adequate from anterior to posterior with either the standard or X trial (Figs. 10.18 and 10.19). Also, this view can help determine if anterior or posterior biased inserts are needed. If a posterior biased insert is needed, the tibial trial and insert will need to be removed, assembled, and reinserted (Figs. 10.20 and 10.21). The anterior biased trial can simply be attached in situ.

Perform flexion and extension of the ankle to seat the tibial tray. This allows it to settle into its optimal position in the frontal, sagittal, and rotational planes. If the joint is too loose, then remove the tibial tray with its insert and increase the thickness of the insert until optimal joint kinematics and tension are achieved. Balancing of sagittal range of motion versus frontal plane varus and valgus stability is assessed.

A lateral fluoroscopic view should demonstrate the following: (a) anterior aspect of the tibial tray is flush with the anterior tibial cortex, (b) the posterior aspect of the tibial tray extends to, but not significantly past the posterior tibial cortex, (c) the



Fig. 10.17 Intraoperative Lateral c-arm view: Tibial and talar trials are in place. Note the slight posterior lift off of the talar trial due to a slight prominent edge at the most posterior aspect of the posterior chamfer. This was corrected with a hand rasp and trial was reinserted

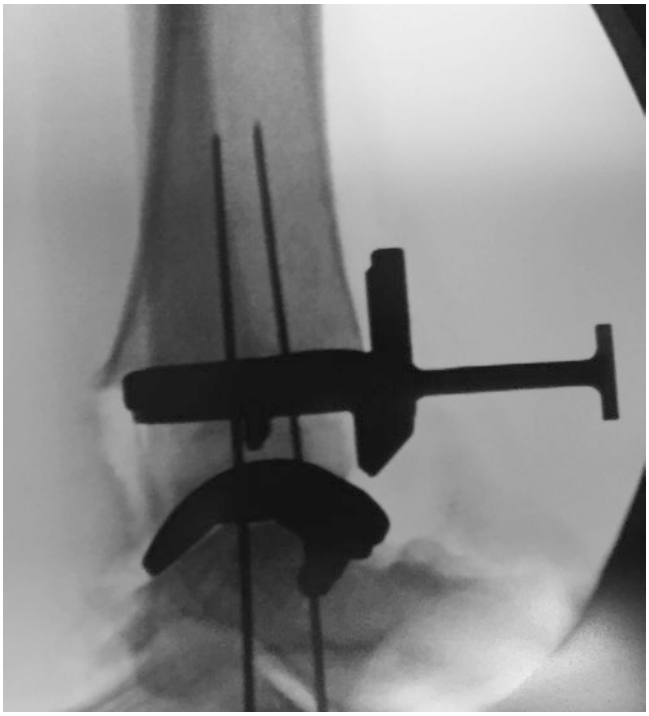


Fig. 10.18 Intraoperative Lateral c-arm view: Note standard tibial trial with "underhang" on the posterior tibia. The tibia trial is slightly off the anterior tibia and should be set back further, but likely the Standard size will still be undersized



Fig. 10.19 Intraoperative Lateral c-arm view: Now the X sized tibial trial inserted and tibial trial fully seated against anterior tibia. Excellent tibial coverage noted anteriorly and posteriorly with the X size trial



Fig. 10.20 Intraoperative Lateral c-arm view: standard neutral poly trial in ankle with preoperative posterior translation. Note the continued posterior translation of the midline of the talus in respect to the midline of the tibia



Fig. 10.21 Intraoperative Lateral c-arm view: posterior biased poly trial now attached (note peg in posterior trial). Anatomical alignment in sagittal plane is now established indicating a posterior biased poly is warranted in this case

proximal surface of the tibial tray is sitting flush with the distal cut surface of the tibia, (d) chamfered surfaces of the talar trial are sitting flush with the resected chamfered surfaces of the proximal talus. If there is anterosuperior or posterosuperior gapping, the talar implant can be grafted with the bone that was previously saved. This gapping is usually caused by pushing or pulling on the anterior chamfer guide while reaming. Also, reinspection should be made for any loose bone or slight inconsistence with the plane of the posterior chamfer cut.

Place two shouldered pins in the holes on the anterior face of the tibial trial. Use either the post drill or flex shaft drill to prepare both peg holes for the tibial implant. Both options have a positive stop. Remove the shouldered pins from the tibial trial and remove all trial components. The tibial impactor handle can be screwed into the talar trial to facilitate removal if needed.

Confirm and open the appropriate implants. If cementing, apply bone cement to the flat surface of the tibial tray. Do not apply cement to the pegs or posterior tab. Bone grafting, BMA, or biologic augmentation can be used per surgeon preference. Insert the tibial implant using the tibial impactor

handle assembly. Engage the anterior peg tips of the tibial tray in the prepared holes. Gently Impact the implant with a mallet. Allow the implant to follow the tracks of the pegs with the implant parallel to the cut surface of the tibia during impaction. Impaction is complete when the anterior edge of the implant is flush with the anterior edge of the tibia. Check a lateral fluoroscopic view to ensure the posterior edge is well seated against the posterior portion of the cut surface of the tibia. Release the impactor assembly from the implant once the implant is flush.

Insert the implant protector onto the tibial tray prior to implanting the talar implant. Select the appropriate talar dome implant and if cementing, apply bone cement to the flat surfaces only. If not cementing, then apply bone graft or biologics if necessary to the proximal anterior or posterior chamfer. Place the posts of the talar dome implant into the prepared holes in the talus. It is helpful to use a pickup or clamp on the pegs to help position the talar dome implant. Use the talar impactor and a mallet to fully seat the implant. Rotate the impactor to selectively impact anteriorly or posteriorly. Remove the implant protector from the tibial tray.

Perform one final lavage of the joint. Select the appropriate poly insert implant from trialing. Attach it to the insert inserter using the dovetail mechanism. Match the exposed portion of the dovetail of the insert implant with the dovetail of the tibial implant and push the insert implant onto the tibial implant as far as possible or until a click is heard. Use a mallet with the gap sizer to fully seat the poly insert implant if there is no audible click (Fig. 10.22).

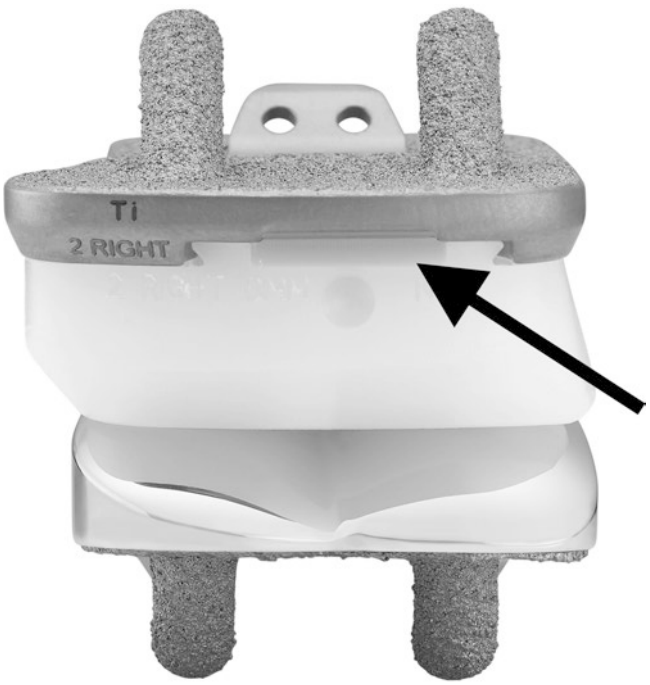


Fig. 10.22 Fully engaged Poly insert within assembled tibial tray. Arrow points to dovetail locking mechanism

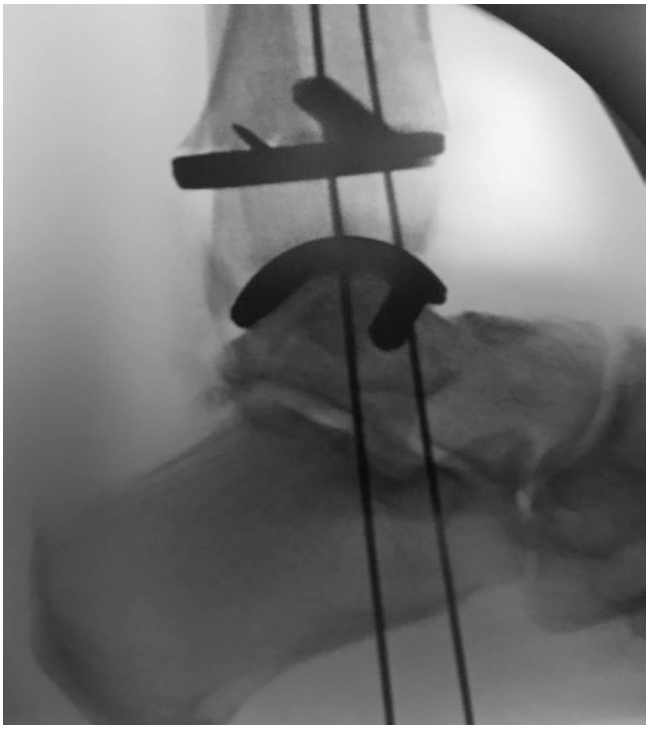


Fig. 10.23 Intraoperative Lateral c-arm view: Fully seated final implant placement confirmed. Prophylactic Steinman pins in medial malleolus still present

Obtain final fluoroscopic views. On the lateral check for the following: (a) the proximal surface of the tibial implant should be sitting flush across the cut distal surface of the tibia, (b) the posterior aspect of the tibial implant extends to, but not significantly past the posterior tibial cortex, (c) the chamfered surfaces of the talar implant are sitting flush with the resected chamfered surfaces of the proximal talus. Visually inspect the implant to ensure the anterior aspect of the tibial implant is flush with the anterior tibia cortex and that the insert implant is fully seated in the tibial implant without gapping between the two (Fig. 10.23). Perform a dynamic flexion/extension test on the foot to evaluate range of motion and tension of the joint. Perform varus/valgus stress tests to check for stability.

Standard soft tissue closure is then performed taking care to close any tendon sheathes and the extensor retinaculum. A well padded Jones' type compression dressing is recommended.

Pearls and Further Discussion Points on the CADENCE System

I. A defined minimal amount of bone must be resected with all implant systems to allow clearance for the tibial and talar components and the poly insert. Bone must be taken

from both the tibia and the talus. There is a greater appreciation of the importance of preserving talar bone stock, avoiding subsidence or collapse, and preserving talar blood supply. To that end, Cadence preferentially resects more bone on the tibial side and is very sparing on the talar resection. These are un-coupled cuts and the tibial cut can be adjusted downward to preserve bone there as well. The green gap sizer can be used during the case to confirm that the minimal amount of bone resection has been removed for the smallest poly insert to be applied.

II. Adjusting height of tibial cut: In very stiff and arthritic ankles, more bone is necessarily resected to allow ease of implantation of the implants and to achieve motion. This typically corresponds to using the physeal scar as the resection level—or alternatively, having the short hash-marks of the angel wing aligned with a level just below the apex of the dome of the talus. When sufficient motion is present however, it is possible and advisable to resect less tibia to preserve bone stock while maintaining a sufficient range of motion. The ability to do this is best assessed while looking at a lateral X-ray with the tibial resection template engaged in the tibial resection jig. When the X-ray beam is orthogonal to the guide, traction is then placed on the ankle to see how much space is created at the level of the tibiotalar joint, and how much the guide can be lowered and still be just below the apex of the dome of the talus while under traction. IF this is performed, and the jig is lowered, the guide will typically need to be adjusted in the coronal plane to center it in the plafond.

III. Varus/valgus alignment: This is a complex topic that is covered in other chapters. The most important concept in correcting coronal talar deformities is to understand the etiology, the status of the subtalar joint complex (ROM, any compensation to accommodate talar deformity, arthritis) and to apply appropriate balancing to the ankle joint which can include malleolar osteotomies, ligament reconstruction, osteotomies, and tendon transfers. Over 85% of patients with a talar valgus or varus deformity require one or more ancillary procedures to balance the foot and ankle. Staged reconstructions can also be considered in more significant coronal deformities.

Technical Pearls

- Making the distal incision slightly medial to the midline minimizes risk of injury to the superficial peroneal nerve.
- Laminar spreaders can be left in the joint for ~ 1 minute to allow for gradual lengthening of the ankle ligaments and joint capsule. If desired range of motion is not achieved, the surgeon can progress to release of medial and/or lateral ankle ligaments.
- Using an osteotome to remove the most anterior aspect of the distal tibial plafond will allow visualization of the tibial articular surface and flush placement of tibial resection guide.
- Osteotomies, fusions, and soft tissue releases may be necessary before or following implantation to achieve desired range of motion. Assess the lateral and medial aspects of the talar body and neck. The talar body can be widened by the presence of osteophytes or bone formation similar to what is seen in talar neck bossing. The surgeon should continue the debridement until they are able to dorsiflex the ankle and watch both the medial and lateral borders of the talus articulate with the corresponding malleoli.
- Using medial/lateral adjustment screws on distal tibial alignment block to align medial holes of tibial cut guide with proximal medial border of talus. If the ankle joint is subluxed medially, the medial holes should be aligned with the medial gutter.
- During tibial bone resection, avoid levering medial to lateral with the corner osteotome, and this maneuver increases risk of fracturing the medial malleolus. Additionally, resection of bone with internal/external rotation levering while using a bone pin will also increase risk of fracture. Anteriorly directed force is advised.
- During final stages of talar preparation, avoid forcefully manipulating the joint while pins are placed through subtalar joint. This may cause injury to articular cartilage.
- When selecting tibial tray size, avoid oversizing. This can be achieved by downsizing one size from a tibial trial size that fits snug into the joint space. Use caution when using the tibial impactor during the final tibial bone prep. If the tibial tray is not parallel to the resected tibia, posterior tibial fractures may result.

Early-Intermediate Term Results

Pedowitz et al. reported on the early radiographic and clinical outcomes as well as the complications following the introduction of the Cadence® TAA system to the US market, with a minimum of 2 years follow-up [1]. A retrospective chart review was performed of patients who underwent a primary Cadence TAA with at least 2 years clinical and radiographic follow-up.

All surgeries were performed by a single author (DP) who was one design surgeons for the implant, but was not involved in any of the data or radiographic analysis. Primary outcomes included complications and reoperations. Secondary outcomes included patient-rated function based on Foot and Ankle Ability Measure (FAAM), SF-12 scores, and Visual Analog Scale (VAS) pain levels. Five views of the ankle were used to assess range of motion (ROM), component

alignment, peri-implant osteolysis, and component loosening or subsidence. The authors identified 60 patients with 60 Cadence TAAs. FAAM-ADL, FAAM-Sports, SF-12 PCS, and VAS pain scores all improved significantly from preoperatively to post-operatively at mean 2.27 years post-op ($P < 0.001$, mean change +19.4.3; $P = 0.001$, mean change +26.2; $P = 0.005$, mean change +6.9; $P = 0.0001$, mean change −30.2, respectively). There was no significant change in SF-12 MCS score. Ten patients (6.7%) had operative complications requiring 15 surgeries, with mean 265 days (SD233) to first reoperation. Three patients (5%) required removal of one or both components. Two of these revisions were for infection and one for osteolysis, giving a failure rate in the absence of infection of 1/60 (1.7%), or a survival rate of 98.3% at 2 years.

Hyer et al. also reported on 32 ankles with a mean 2-year follow-up [2]. Likewise, a high survivorship of 94% was noted in this smaller series in which 34% of patients had prior deformity reconstruction involving a subtalar and/or talonavicular fusion. Statistically significant coronal and sagittal alignments were achieved and maintained at final follow-ups. Intraoperative medial malleolar fracture was experienced in 5 cases as part of the early learning curve of the technique. No further fractures were experienced after adoption of the technique pearls discussed here including the use of prophylactic pinning of the tibia/medial malleolus and careful use of the corner chisel. Two cases of tibial component loosening and pain were successfully revised and re-cemented. One case was converted to fusion after a late term infection.

Daniels et al. also have reported on 2-year outcomes in the Canadian market [3]. Their group of 69 patients showed statistically significant improvements in AAOS pain and disability scores as well as SF36 physical score. They noted restoration of neutral coronal plane alignment in 97% of patients with 100% implant survivorship at 2 year. In their series, there were also some cases of fibrous ingrowth of the tibial component noted but no revisions or decreased outcomes scores noted in this subgroup analysis.

In all three early reports, no signs of component subsidence or cystic changes have been noted. Prospective, multicenter, observational studies continue both in North America and in Europe on the CADENCE implant and further detailed reports should be forthcoming. Anecdotally, the authors all continue to use CADENCE as their primary TAR implant and note that many patients' report functioning "more normally" with the side specific CADENCE that were reported with their experience with prior implants.

Revision Options

At the time of publication, a "flat top" talar implant is soon to be released to the market. This implant is applicable as a primary talus implant option or as a revision option of a chamfered talar component. Integra does market a revision ankle replacement system based off the Salto talaris implant. Currently, this does not dovetail with Cadence and could not be used to revision either one of its components.

Using the chamfered talus option, the Cadence is very bone sparing and depending on the reason for failure, should be easily converted and revised to any one of the stemmed ankle replacements or revision systems currently on the market.

Conclusions

The CADENCE total ankle replacement system is one of the latest generation of total ankle arthroplasty implants. The system was designed to improve on deficiencies of previous systems, provide an efficient and reproducible technique suitable for an outpatient setting, and maintain as much bone stock as possible as a primary total ankle replacement (Figs. 10.24 and 10.25). The system provides a neutral as well as anterior or posterior biased poly insert



Fig. 10.24 Preoperative Lateral radiograph revealing extensive ankle arthritis with anterior ankle and talar neck osteophytes



Fig. 10.25 1 year post-operative Lateral radiographs of Cadence Total ankle replacement

option to help provide sagittal plane stability of the ankle which until now had not been addressed by other implant systems.

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11 INBONE 2 Total Ankle Replacement System Including Prophecy Specific Alignment Guides

Robert D. Santrock, Steven K. Neufeld, Ryan T. Scott, Christopher F. Hyer, and Gregory C. Berlet

Introduction

The treatment of degenerative joint disease of the ankle has experienced a renaissance in the past decade as total ankle replacement (TAR) has become a predictable alternative to ankle fusion for end-stage degenerative ankle arthritis (Fig. 11.1). Recent literature has shown that the survivorship of TAR is at 94.1% for a mean follow-up of 10 years and from 80% to 95% at 8–12 years [1–3]. Increasing patient age and activity demands, improved prosthetic design, and surgeon comfort has helped in the evolution of TAR into a mainstream approach for management of debilitating ankle arthritis.

First-generation TARs were highly constrained and fixed primarily with polymethylmethacrylate cement [4]. The design of these prostheses was very stable; however, a large amount of shear, compression, and rotatory stress was placed through the bone–prosthesis interface, leading to osteolysis, component loosening, and failure. Due to the challenges of these first-generation components, engineering resources were employed to develop concepts focused around less constraint and cementless fixation and the addition of anatomic talar sulci, medial and lateral flanges, and stable immediate fixation. These changes have led to the relative success reflected in the contemporary literature [5–7].

The INBONE Total Ankle System (Wright Medical Technologies, Inc., Arlington, TN) was US Food and Drug Administration 510-k cleared for use in 2005 and consists of a saddle-shaped, fixed-bearing, two-component design with the polyethylene-bearing surface locked into the tibial baseplate [8–10]. This fixed-bearing design helps address backside wear in comparison to the TARs with mobile-bearing designs. Another design advantage of a fixed-bearing TAR is



Fig. 11.1 Degenerative change to the ankle joint with narrowing of the joint space, subchondral sclerosis, and osteophyte formation

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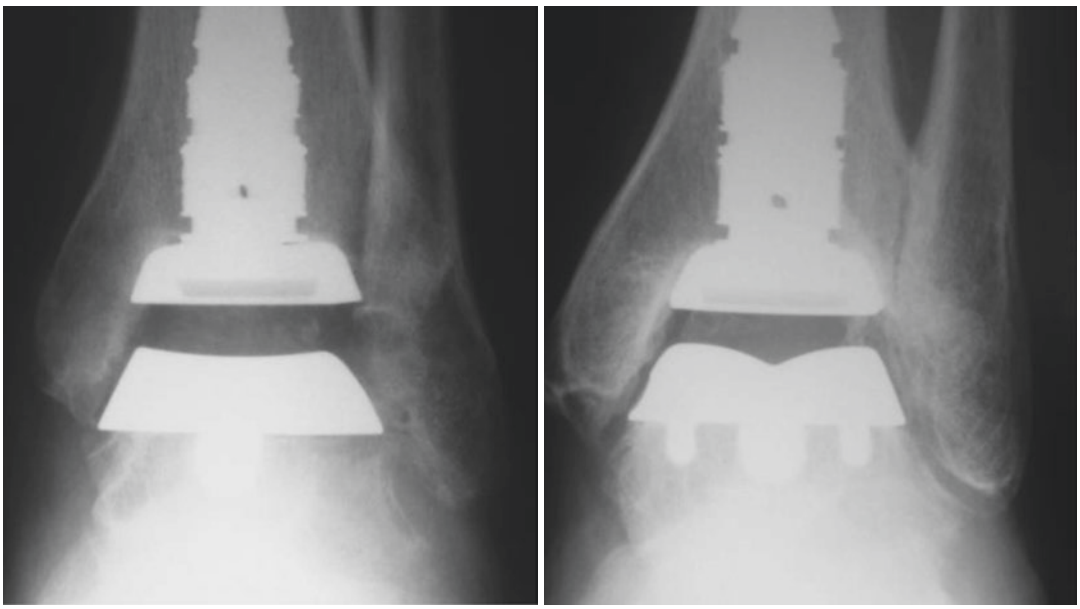


Fig. 11.2 Anterior–posterior weight-bearing radiographs comparing the talar components for the INBONE Total Ankle System (*left*) and the INBONE II Total Ankle System (*right*). The sulcus shape and dual anterior pegs were added to INBONE II Total Ankle System talar component for increased stability

less risk of bearing dislocation that has been noted to occur in mobile-bearing devices.

The INBONE II Total Ankle System (Wright Medical Technologies, Inc., Arlington, TN) is an evolution of the original INBONE Total Ankle System design. This new system retains several important design characteristics of the INBONE Total Ankle System design, including the modular tibial stems, thicker polyethylene bearings, and intramedullary guidance. In addition to these design principles, the INBONE II Total Ankle System has enhancements including sulcus articulation, additional talar fixation, anterior–posterior long tibial trays for complete tibial coverage, mobile instrumentation during trial placement of the talar component, and bone removal instrumentation (Fig. 11.2) [11, 12].

The role of patient-specific alignment guides and preoperative navigation technology in improving patient outcomes has been well documented in total knee arthroplasty. The experience with the PROPHECY preoperative navigation system (Wright Medical Technologies, Inc., Arlington, TN) suggests a new standard for TAR with enhanced component placement reproducibility. This chapter aims, in part, to review the PROPHECY preoperative navigation technology and its evolving role in TAR.

Use of INBONE II Alignment Jig for Implantation

The INBONE Total Ankle System incorporates an intramedullary targeting guide that allows for reproducible and accurate tibial and talar osseous cuts. The jig system allows

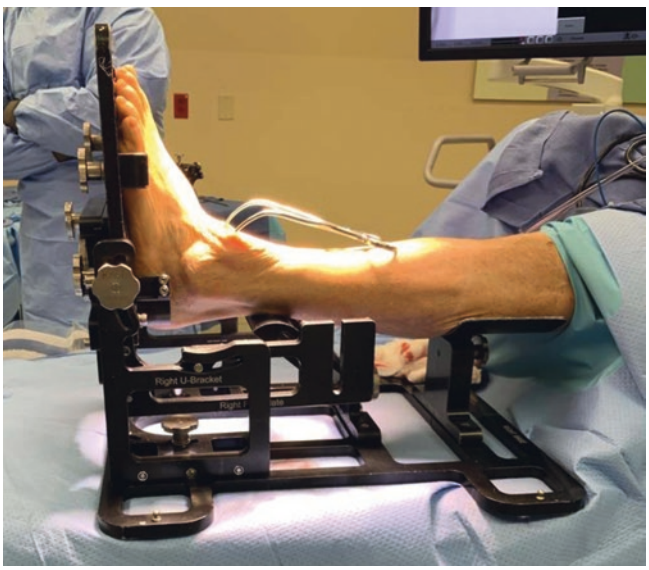


Fig. 11.3 Lateral view identifying alignment of the ankle, calf, and knee within the jig

for accurate and reproducible placement of the intramedullary 6-mm guide pin on the intended target of the anatomic or mechanical axis. This intramedullary guide pin passes anterior to the posterior facet of the subtalar joint through the center of the talar body preserving the posterior facet of the subtalar joint and arterial anastomoses on the inferior talar neck [13]. The modular reamer is then attached to the reaming rod in situ within the ankle joint for preparation of the tibia for the stemmed components (Figs. 11.3, 11.4, 11.5, and 11.6).

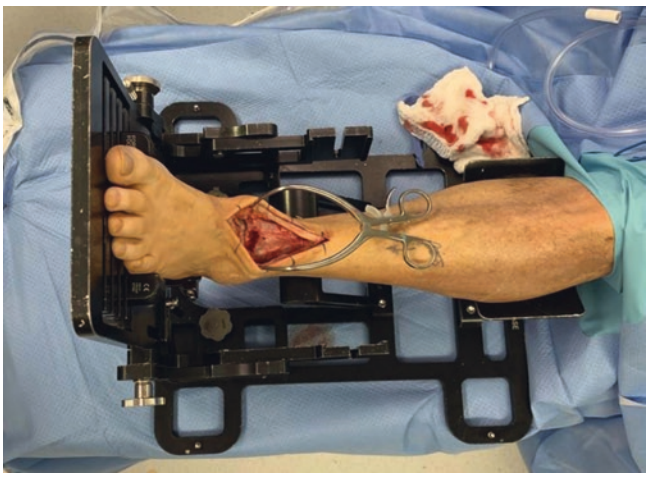


Fig. 11.4 Anterior view identifying alignment of the ankle, calf, and knee

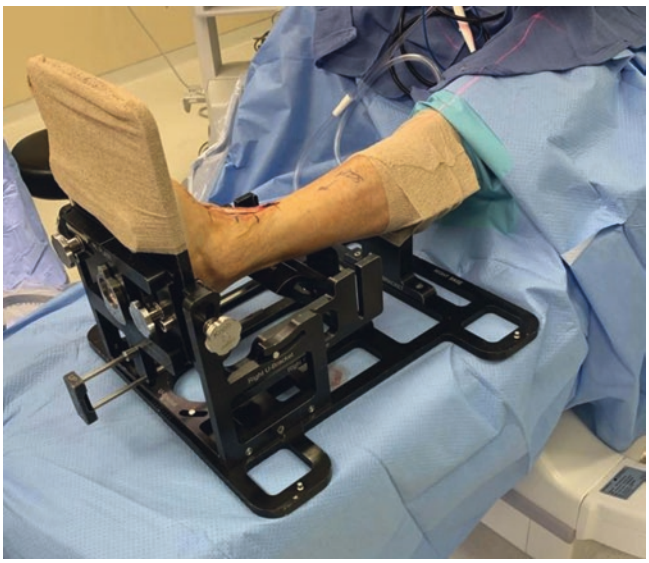


Fig. 11.5 Foot and calf are then fixated to the jig once the ankle is appropriately positioned with 2.6 mm wires and Coban

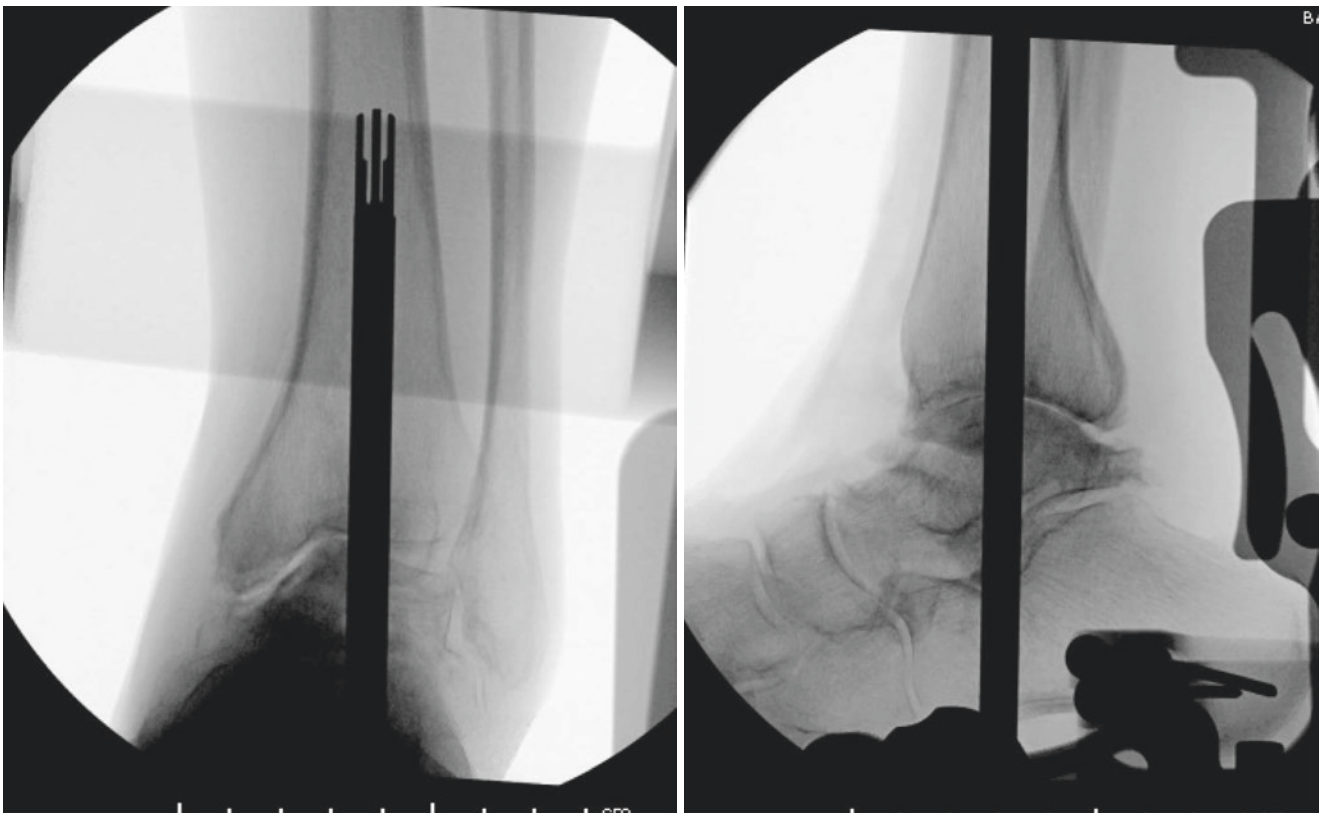


Fig. 11.6 Intraoperative photograph demonstrating the use of the INBONE II Total Ankle System jig to gain anatomic alignment in both the sagittal and frontal planes

Cut Guides

The INBONE II Total Ankle System comes in sizes 1/2–5 that have proportional increases in width and length of the trapezoidal tibial bone cut. The cut guide size is based on preoperative planning and confirmed by intraoperative imaging on the anterior–posterior and lateral intraoperative C-arm image intensification views. The cut guides are lined off of the intramedullary alignment pin established in the prior step. The joint line is established on the lateral images and

the medial–lateral placement based on the anterior–posterior views. The bias is to accurately reestablish the joint line while leaving adequate talus and provide full coverage of the anterior and posterior tibial cortex.

The cuts are made with the appropriate saws and bone removed with tools. The authors recommend removing the posterior capsule to improve postoperative range of motion.

PROPHECY Preoperative Navigation System: Application and Surgical Technique

The PROPHECY system is designed to set the optimal position of the tibial and talar bone cut guides. This is achieved by accurately positioning pins into the tibia and talus as determined by a preoperative computed tomography (CT) scan. Bone cut guides slide over these pins. The key elements of this work flow are (1) obtaining an accurate CT scan with three-dimensional (3D) rendering of the patient's ankle joint, (2) surgeon-mediated selection of the intended position of the components, and (3) a computer-aided design and manufacture of patient-specific guides, which guide pin positioning and bone cut guides [5].

The PROPHECY INBONE II, INFINITY, INVISION preoperative navigation systems require a protocol-driven, simulated weight-bearing CT scan incorporating specific scanning parameters. Newer cone beam technology has allowed for weight-bearing CT scans, which are now being utilized with the Prophecy protocol.

In the CT protocol , the foot, ankle, and ipsilateral knee are scanned at the same time. It is helpful to provide the engineers with any additional weight-bearing radiographic studies for comparison. The knee is scanned 5 cm proximal and 5 cm distal to the joint line, while the ankle is scanned 10 cm proximal to the joint and incorporates the entire foot, including the toes. The recommended slice increment is $\leq$1.25 mm. Eight anatomic landmarks, including reference points at the proximal tibia, distal tibia, fibula, and talus, are identified with the scanning protocol. These eight landmarks are essential for optimizing the tibial and talar implant position relative to the mechanical and/or anatomic axis of the patient's operative limb. Failure to follow the specific PROPHECY CT scan protocol will render the study incomplete and is not appropriate for analysis and subsequent generation of patient-specific guides. If the index CT scan is rejected, then another study with strict adherence to the specified protocol will be required to proceed with PROPHECY technique.

The CT scan is utilized to generate a 3D bone model, which, in conjunction with the 3D CAD models of the INBONE II, INFINITY, OR INVISION TARs and instrumentation, determines the optimal component position, rotation, and sizing according to predetermined surgeon preferences (Fig. 11.7). Any adjustments to the sizing of the TAR components, positioning, or rotation can be facilitated along with company engineers preoperatively (Fig. 11.8). Ultimately, the process yields patient-specific surface-matched operative guides for the tibia (Fig. 11.9) and talus (Fig. 11.10). The guides are provided with mockups of the patient's distal tibia and talus so that the operative surgeon can appreciate the fine match details between the guides and the patients' anatomy. Intraoperatively, it is critical to preserve anterior osteophytes on both the tibia and talus as this is the surface detail on which the engineers have keyed the patient-specific guides. The guides fit only in one location, and once confidence in the position is established, the guides are then pinned in place and the surgical axes are confirmed using intraoperative image intensification. The purpose of the guides is to set the position of the pins that hold and establish the location of the bone cut guides and ultimately the implant position. The guide is then removed, and the appropriately sized INBONE II, NFINITY, OR INVISION operative cut block is slid onto the pins (Fig. 11.11).

INBONE II Arthroplasty Components

Tibial Component

The INBONE I and INBONE II Total Ankle Systems tibial components offer a modular stem system composed of small interconnecting tibial stem pieces creating a variety of customized tibial stem lengths. This modularity allows for increased component stability within the medullary canal of the tibia based on patient specific requirements. Force distribution through the tibial shaft and decreased shear on the tibial plafond–baseplate interface are attributed due to a more vertically oriented tibial component. This design decreases the risk of osteolysis, implant loosening, and ultimately TAR failure. The INBONE I and INBONE II Total Ankle System cut guides allow for preservation of both the medial and lateral malleolus increasing the stability of the tibial baseplate. This also acts as a buttress for rotation of the prosthesis once it is appropriately seated.

The sizes of the tibial tray range from 1/2 to 5 based on the medial–lateral surface area of the tibia, as well as a standard and long version when viewed in the anterior–posterior orientation. This allows for appropriate coverage of the tibia without increasing the risk of prosthesis impingement in the medial–lateral dimension.

There is a tight press fit of the tibial stem pieces within the medullary canal providing robust fixation (vertical fixation) independent of the polymethylmethacrylate cement required by the US Food and Drug Administration.

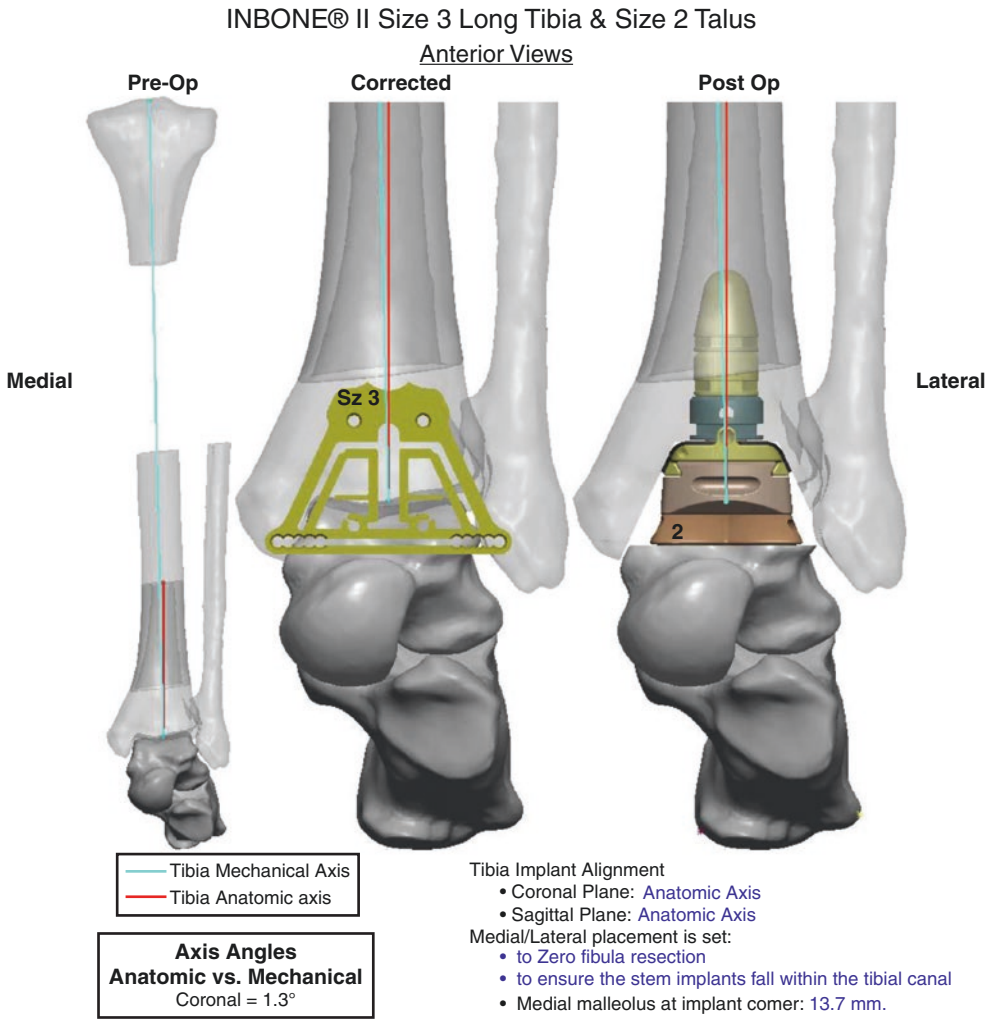


Fig. 11.7 A computed tomography scan demonstrating the assessment of the mechanical and anatomic axis in relation to tibial component alignment and resection level on anterior–posterior views

Talar Component

The INBONE I talar component is saddle shaped and designed to anatomically match the superior articular surface of the talar body. The talar component is produced in sizes 1/2–5 with anterior–posterior diameters of 33.4 mm and 48 mm, respectively. Furthermore, the talar component allows for maximum coverage of the talar cut surface utilizing cortical wall support of the remaining talus to limit talar component subsidence. The large surface area of the talar component allows for decreased load per square millimeter and ultimately less polyethylene wear.

The INBONE II Total Ankle System talar component has a sulcus-shaped articulating geometry to allow a balance between stability and natural joint motion. The anatomical-shaped geometry of the talar component affords inherent stability and limits axial rotation of the ankle joint when weight bearing. This new sulcus-shaped design has twice the coronal plane stability of the saddle-shaped design of the INBONE Total Ankle System. In addition, the INBONE II talar component has the addition of two anterior fixation pegs for added stability and resistance to subsidence.

In the INBONE Total Ankle System, the talar component is affixed to the talar cut surface via a single talar stem measure either 10 or 14 mm. Talar stem length is determined by best-fit length without violating the subtalar joint.

In INBONE II Total Ankle System, there is a central peg with the addition of two 4-mm long anterior pegs. The anterior pegs help eliminate the ability of the talar implant to rotate in the transverse plane.

Polyethylene Insert

Current TAR systems have no standard polyethylene thickness. Thicknesses are reported as maximal thickness where the weight-bearing area of the polyethylene is much less in some cases. Because the stresses across the ankle are at least 60% higher than those across the knee, it is likely that polyethylene thickness will gravitate toward a thicker insert to facilitate reliable, long-lasting prostheses. The INBONE II Total Ankle System has polyethylene inserts ranging from 6 to 16 mm. This allows for appropriate sizing to ensure there is adequate stability of the ankle joint. The sulcus-shaped

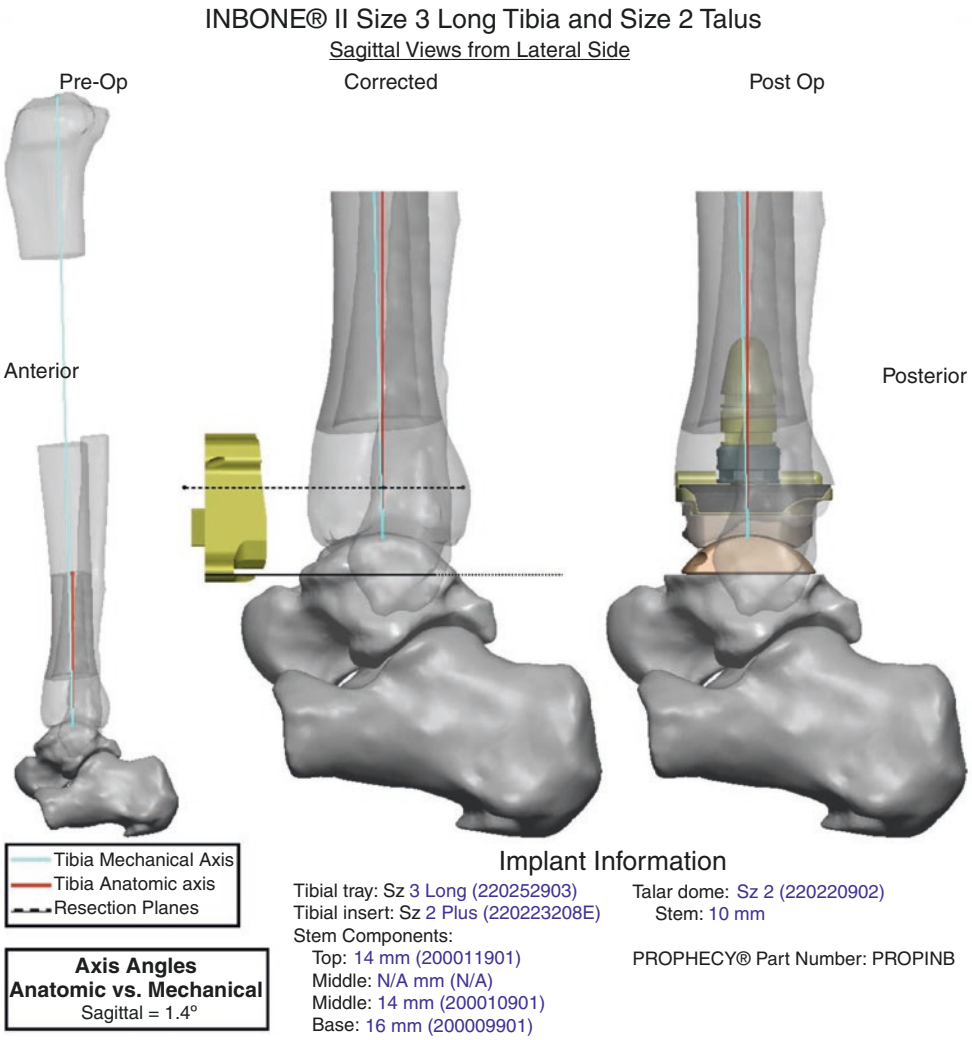


Fig. 11.8 A computed tomography scan demonstrating the assessment of the mechanical and anatomic axis in relation to tibial component alignment and resection level on lateral view

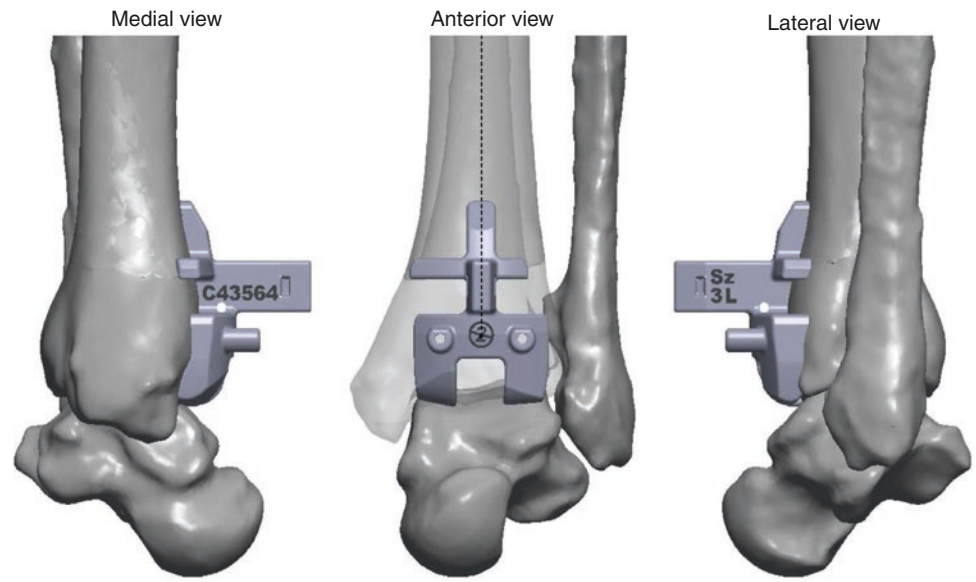


Fig. 11.9 Patient-specific tibial guide on a surface-matched distal tibia

Tibia Guide Comments:

- The tibia guide as designed is in close proximity to the patient's talar bone, therefore the talus may need to be plantarflexed prior to placing the tibia alignment guide. Ensure a bump is placed under the distal tibia.

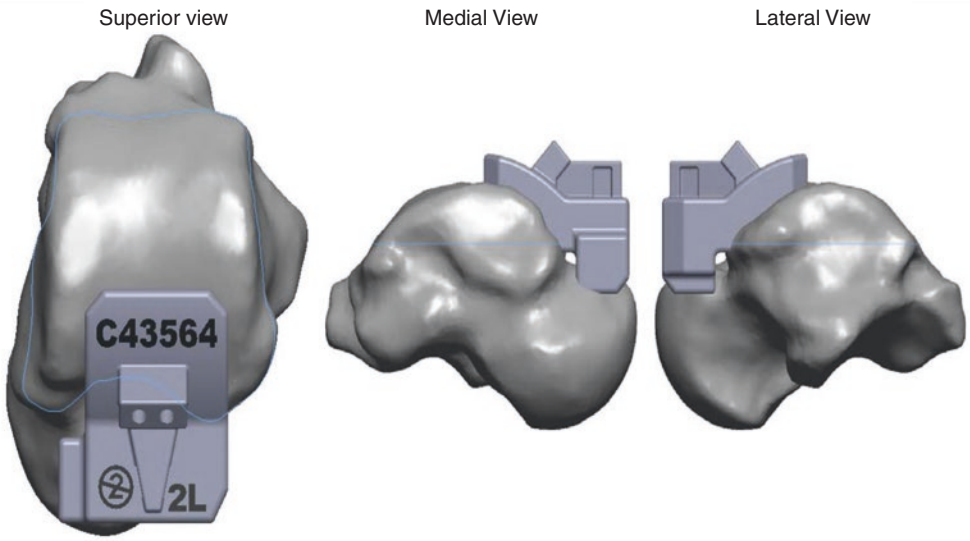


Fig. 11.10 Patient-specific talar guide on a surface-matched talar dome

Talus Guide Comments:

- **Talar guide designed for use with:** size 2 resection guide.
- The talar dome alignment guide is designed to surface match the bone (visible in CT); therefore, removing cartilage is appropriate for best fit of the alignment guide.
- Due to the talar neck morphology, the ratus alignment guide may be difficult to remove without removing one or more of the k-wires. Special care may be needed to find the holes in the bone after removing the guide.

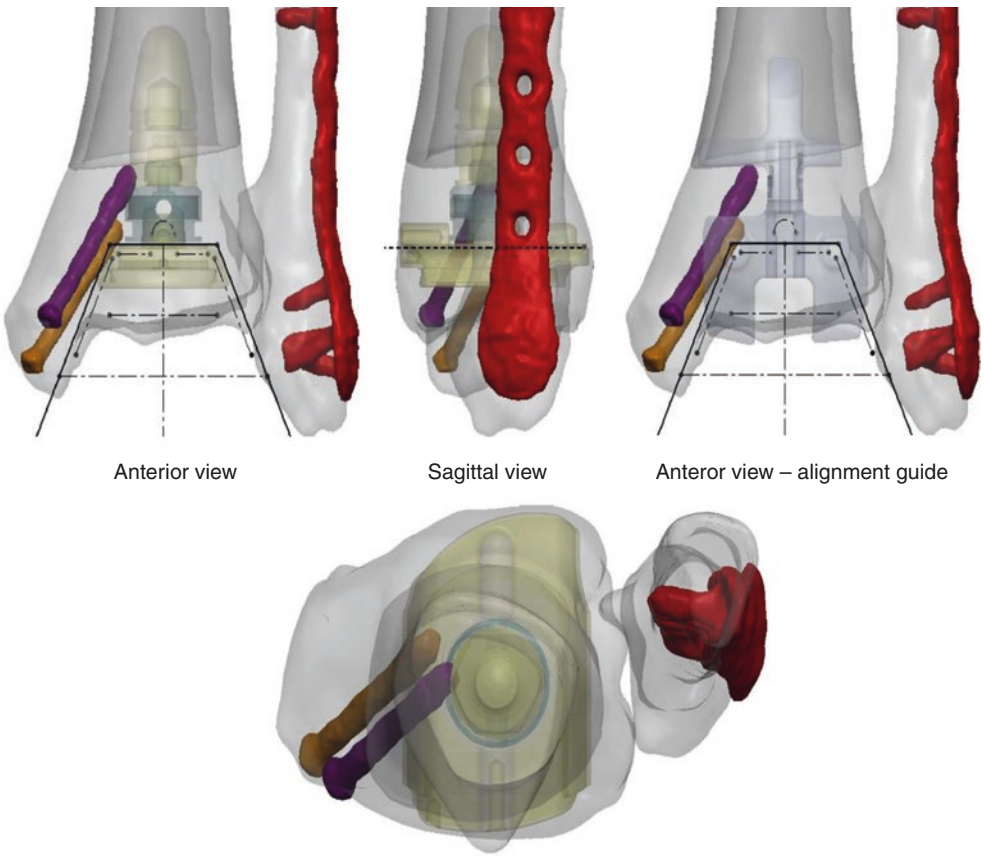


Fig. 11.11 PROPHECY scan analysis can help identify the position of residual hardware and whether this will encroach upon the intended position of the TAR implant

design of the polyethylene inserts ensures proper alignment and reduces excessive frontal plane motion.

Insertion

The standard anterior midline approach is preferred when utilizing the INBONE and INBONE II Total Ankle Systems. However, the posterior approach has also been documented in revision cases [14, 15].

Once appropriate dissection and anatomic alignment have been established using the INBONE Total Ankle System jig (Fig. 11.12) and the bone cuts are performed, the insertion of the tibial stem is performed. As a modular system, first attach the apex to a midstem and insert into the tibia on a clip. Insert the distal stem and affix via the x-driver and the appropriate diameter wrench. Ensure that the morse taper is anterior. Insert the tibial base and impact until the morse taper is engaged. Drive the tibia baseplate proximal until well seated. The foot and lower leg are then removed from the alignment jig (Figs. 11.12, 11.13, 11.14, and 11.15).

A trial talus and polyethylene insert are introduced. The ankle is then placed through a range of motion, allowing the talus to find its natural position (mobile instrumentation). Once pinned in place, the anterior and posterior peg holes are created. The talus is inserted with polymethylmethacrylate cement. The final ultrahigh molecular weight polyethylene insert is secured in place using the jackscrew (Figs. 11.16, 11.17 and 11.18).

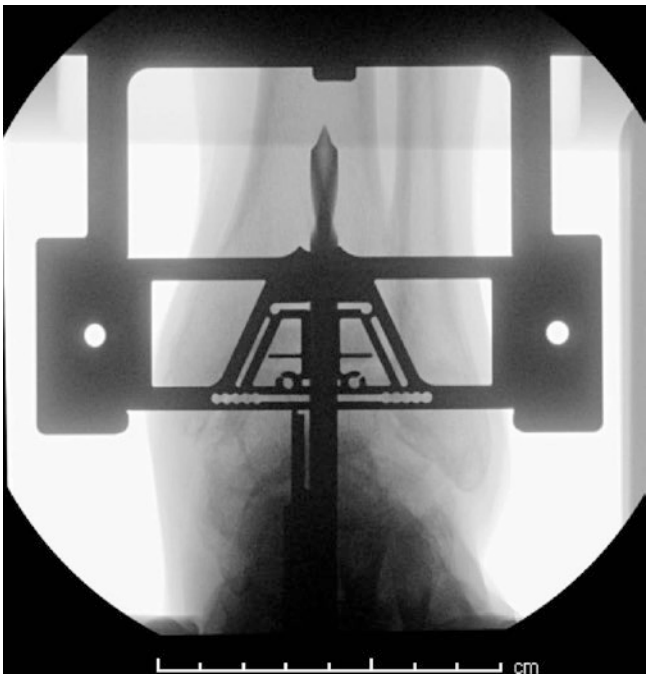


Fig. 11.12 Intraoperative photograph(demonstrating the use of the INBONE II Total Ankle System jig to gain anatomic alignment in both the sagittal and frontal planes

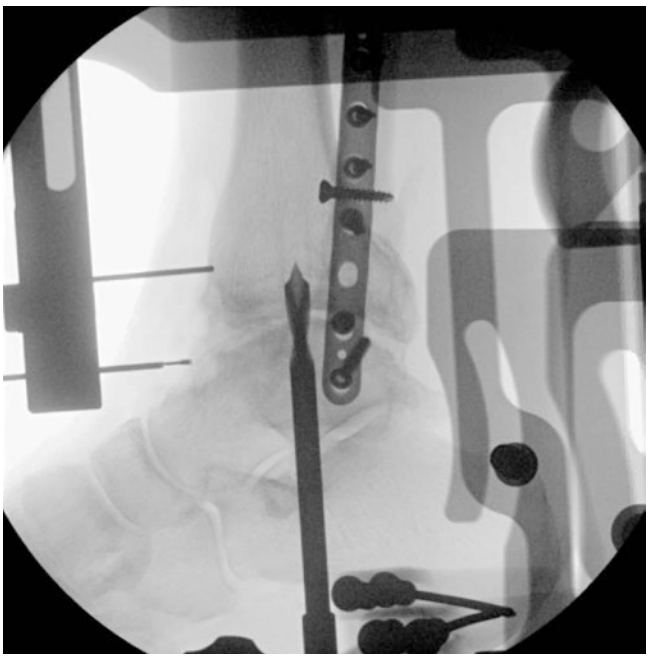


Fig. 11.13 Intraoperative lateral C-arm image intensification view demonstrating the level of osseous resection



Fig. 11.14 Bone removal from the tibial and talus for implantation of INBONE II system. The bone may bemeasured on the back table with the trial talus to ensure adequate bone coverage



Fig. 11.15 Tibial reaming (for INBONE II system. Use of Fluoroscopy to ensure adequate reaming height is based on preoperative planning



Fig. 11.17 Final intraoperative anterior-posterior C-arm image intensification views demonstrating appropriate prosthetic component position, talar coverage, and gutter decompression



Fig. 11.16 Intraoperative image of INBONE II

Pearls for INBONE II with Traditional Jig

- Adequate preoperative planning
  - Weight-bearing radiographs (including long leg calcaneal axial)
  - Computed tomography scan
- Ensure anatomic alignment before moving forward. Always "zero out" your intraoperative C-arm image intensification views using targeting arms to ensure accurate views.
- Slowly peck drill while establishing the position of the 6-mm guide pin on the anatomical/mechanical axis. A steady peck technique is essential to ensure that you do not skive off the obliquity of the medial calcaneus during entry.
- Ensure not to lever medial–lateral with the corner cut chisel when removing the tibial bone as this will fracture the malleolus.
- Press fit the tibial stem to obtain sound fixation.
- Guarantee the morse taper is anterior.
- Confirm appropriate sizing of the tibial and talar components.

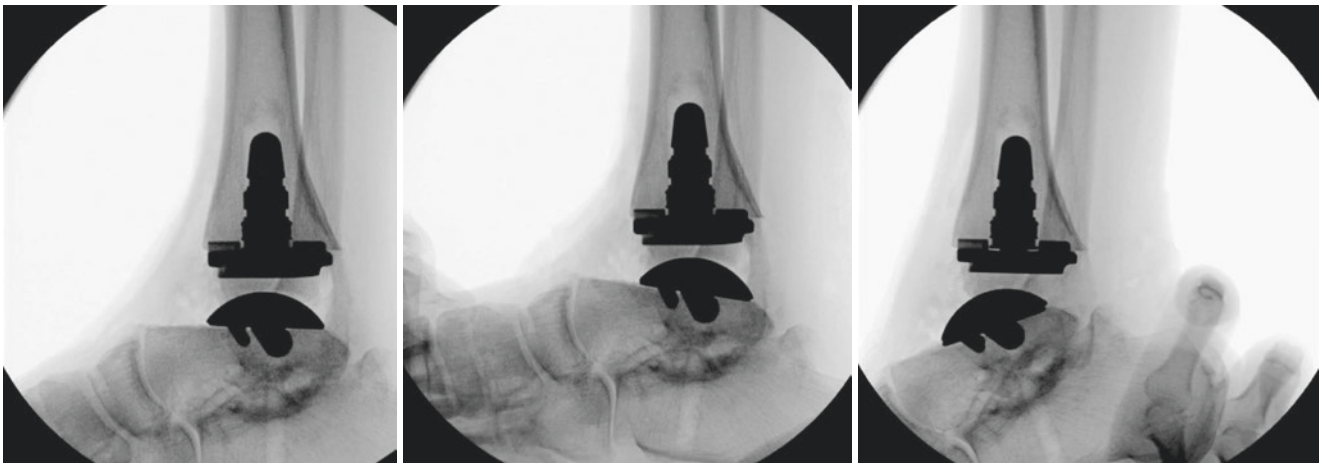


Fig. 11.18 Final intraoperative lateral C-arm image intensification views demonstrating appropriate prosthetic component position in neutral, dorsiflexed, and plantarflexed alignment with INBONE II system

Pearls for Prophecy

- *To PROPHECY or Not to PROPHECY?* The authors suggest limiting the indications to ankles with neutral alignment at first, then with experience, expanding the deformity correction. In keeping with all learning curve studies, minimizing coronal and sagittal plane deformities will aid the learning surgeon's results.
- *Leave the Bone Alone*: Do not resect any anterior osteophytes off the distal tibia or anterior talus as these are key landmarks for the guides, unless instructed to by the preoperative template plans. The surface-matched PROPHECY guides will mirror the patient's exact anatomy, so the exposure should preserve the bony landmarks on the anterior distal tibia and talus. The CT images show bone detail but not soft tissue detail. Careful dissection of the soft tissue from the anterior aspect of the tibia and talus is best achieved with sharp dissection and gentle curettage.
- *Residual Cartilage on the Talus*: It is essential to remove any remaining articular cartilage prior to placing the surface-matched guide for the talus. The CT scan images bone detail, and the residual cartilage has the risk of elevating the guide proximally instead of referencing the intended subchondral bone.
- *Loose Bodies*: Occasionally, the generated CT scan may reveal a loose anterior osteophyte that requires removal to accommodate the surface-matched PROPHECY guide. This will be clearly elucidated in the PROPHECY preoperative navigation plan and emphasized in the appendix of the PROPHECY report.
- *Follow the Rules with Your Imaging*: It is imperative that the CT scan is conducted with strict adherence to the PROPHECY protocol. The protocol should be set up in conjunction with the radiology department prior to ordering any preoperative imaging. Weight-bearing radiographs may also be useful adjuncts in the planning process.
- *Know the Basics*: The authors suggest being comfortable with the INBONE II and INFINITY operative techniques *prior* to attempting a PROPHECY.

Outcomes INBONE I and INBONE II

The outcomes on the INBONE I and INBONE II Total Ankle Systems are only recently reflected in the published literature. Adams et al. [16] showed an overall survival rate of 89.6% at 3.7 years postoperative in 194 uncemented INBONE Total Ankle System prostheses. Lewis et al. [17] presented a consecutive series of 193 uncemented INBONE Total Ankle System prostheses with a mean follow-up of 3.7 years and 56 uncemented INBONE II Total Ankle System prostheses with a mean follow-up of 2.1 years. Significant improvements in all clinical measurements were observed at 1 year postoperatively, and these improvements were maintained at 2-year follow-up for both design types. Improvement in visual analog scale scores was significantly better in the INBONE II Total Ankle System group at 1 year postoperatively, but this was not maintained at 2 years. The incidence of reoperation at 2 years postoperatively in the INBONE Total Ankle System group (18.5%) was higher compared to the INBONE II Total Ankle System group (15.9%). Additionally, the incidence of failure was higher in the INBONE Total Ankle System group (6%) compared to the INBONE II Total Ankle System group (2.6%) at 2 years postoperatively, but the time until failure was not significantly different ($p = 0.295$). Similarly, Hsu and Haddad [18]

reported improved patient-reported outcomes with increased ankle range of motion at a minimum of 2 years follow-up involving 28 uncemented INBONE and 31 uncemented INBONE II Total Ankle Systems. The estimated survival rate at 2 years was 91.3% in the INBONE Total Ankle System group and 100% in the INBONE II Total Ankle System group when revision of the tibial and/or the talar component was used as the end point. The mean total ankle sagittal plane range of motion improved from 29° to 38° ($p < 0.01$). Fourteen patients (24%) required a reoperation because of a postoperative complication. Five of these patients (four INBONE Total Ankle System and one INBONE II Total Ankle System; 8% of the entire cohort) required revision surgery at a mean of 32.4 months due to symptomatic talar subsidence. Talar revisions utilized INBONE II Total Ankle System components for definitive management. The patients who underwent revision surgery had mean total ankle sagittal plane range of motion of 41.6°, neutral alignment, and no further reoperations at the time of the latest follow-up.

The effect of stem length on coronal plane deformity was studied by Berlet et al. [19]. Stem lengths above 2 stems were not shown to influence position of the tibial component more than stem lengths of 2 stems. Any recurrence of deformity was minor and was blamed on the soft tissues.

Summarizing the above, it appears that the early results of the INBONE and INBONE II Total Ankle Systems demonstrated improved patient-reported outcomes and increased ankle sagittal plane range of motion at a minimum follow-up of 2 years. Talar component subsidence was the main postoperative complications that required revision, and these predominantly affected the original saddle-design INBONE Total Ankle System.

Preoperative Navigation in Orthopaedic Surgery

Patient-specific instrumentation and preoperative navigation technologies have been utilized in total knee arthroplasty with the goal of optimizing component positioning and in turn improving prosthesis durability and survivorship [20, 21]. Additional benefits of patient-specific instrumentation and preoperative navigation may include improved operating room efficiency and a blunting of the learning curve seen between high-volume and low-volume surgeons when compared to conventional instrumentation. An improved learning curve should pay longer-term dividends with reproducible surgical accuracy and theoretically improved longevity of the TAR. Secondary gains may also include reduced perioperative complications associated with intramedullary referencing guides or extramedullary referencing pins and a simplified operative room instrument set with a decreased cost of sterile instrument processing.

The ability to navigate the surgery preoperatively and rely on patient-specific instrumentation intraoperatively eliminates any need for intraoperative reference point acquisition [21]. Predictability with patient-specific guides allows for less potential for user variability and improved operating room efficiency compared with both intraoperative computer navigation and traditional instrumentation. Patient-specific instrumentation has consistently demonstrated improved accuracy over both traditional instrumentation techniques and computer navigation. Patient-specific instrumentation led to accurate prediction of femoral component sizing in 92% of cases compared with 43% of computer-navigated total knee cases [22]. Restoration of the mechanical axis through the central third of the knee approached 87% with patient-specific instrumentation compared with 77% using traditional instrumentation [22]. Heyse et al. [23] evaluated rotational alignment of the femoral component and found patient-specific instrumentation yielded only 2% outliers, defined as component malrotation outside the standard ±3° of rotation. In comparison, traditional instrumentation resulted in a 21.2% incidence of outliers with >3° of rotational malposition.

Development of patient-specific instrumentation and a reproducible preoperative navigation system in TAR is a natural evolution of the technology well established in total knee arthroplasty. Reducing outliers in terms of component positioning, decreasing operative time in the hands of both high-volume and low-volume surgeons, and ultimately improving TAR durability and survivorship are among the primary goals of this innovation.

Since the launch of the only patient-specific instrumentation and navigation system in 2012 (PROPHECY, Wright Medical Technologies, Inc.), the market growth has been consistent at 10–20% year on year growth of USA TAR volume. Here, we will explore the following questions regarding patient-specific instrumentation and navigation (PSI):

- *Does PSI work?*
- *Does PSI improve accuracy and/or reproducibility?*
- *Does PSI improve function and/or satisfaction?*
- *Does PSI save time and/or money?*
- *Does PSI decrease complications?*

Does PSI work?

With several years of experience of PSI being utilized in TAR, it is important to ask if patient-specific instrumentation works? The first study to be published on the utilization of PROPHECY PSI was done by Berlet et al. in 2014 [24]. This cadaveric study was designed to show deviations from the predicted plans for guides. The study was statistically significant and concluded that there is a strong likelihood of final alignment being within 3 degrees of the predicted ideal

alignment. This bench study supports the conclusion that PROPHECY patient-specific instrumentation is accurate and effective.

The second study to further explore PROPHECY's accuracy was a clinical study by Daigre et al. [25]. This multicenter retrospective case series explored the radiographic outcomes of PROPHECY TAR. Overall, 79.5% of positions were within 3 degrees of the predicted plan (Tibial stem position: 100%, Tibial tray coronal position: 97.7%, Tibial tray sagittal position: 81.8%, and Talar component position: 79.5%). The results concluded that PROPHECY patient-specific instrumentation in a real-world application works with a high percentage of success.

Does PSI improve accuracy and/or reproducibility?

Before we present the data on PSI accuracy, it is important to understand the rationale behind the need for accuracy and reproducibility in TAR.

The first theory is implant survivorship. In today's modern TAR, an important factor in survivorship is attributed to accurate implantation and soft tissue balancing [25]. In other words, surgical technique and experience have a heavy influence on the success of TAR. However, inherent surgical skill, training, and experience vary greatly among surgeons. Before the advent of patient-specific instrumentation, the key influence on accuracy and reproducibility had been individual surgeon's skill at using the instrumentation. PSI adds computed navigation designed by a team of engineers to help improve accuracy by augmenting the individual surgeon's skill.

The second theory about the need for accuracy is about implant function. TAR implant function is a factor of accurate implant placement. The TAR implants must be placed within the anatomical and physiological-functioning ankle joint [26]. Studies have shown that the closer the implant is placed in an accurate anatomical position of the functional joint, the better it performs.

The third theory on the need for accuracy is about complications. The more accurate the TAR is placed, the less short and long-term complications will occur [27]. Specifically, polyethylene wear, bone lysis, implant loosening, pain, and stiffness can all be decreased with accurate prosthetic implantation. It has been shown that improved pain relief, increased range of motion, better stability, superior function, and ultimate better satisfaction are a factor of TAR implant accuracy.

Saito et al. studied the radiographic outcomes of the PROPHECY INFINITY TAR (patient-specific instrumentations) vs. standard INFINITY instruments [28]. The PROPHECY system was accurate 97% of the time. The difference in accuracy between the standard instrumentation and PROPHECY instrumentation was not significant; however, there was a significant decrease in operative time and fluoroscopic time with the PROPHECY system. The study concluded that using standard instruments required more time and fluoroscopy to achieve the same level of implantation accuracy and established that Prophecy patient-specific instrumentation is accurate and reproducible.

Does PSI improve function and/or satisfaction?

Currently, there are no studies to compare the function and satisfaction of patient-specific instrumentation-implanted TARs with standard-instrumented TARs. However, the literature does lend itself to some conclusions regarding these topics. Cenni et al. designed a study to look at the effect of implant position on function – range of motion [26]. They found that the anterior-posterior position of the implants had a significant impact on the final range of motion of the implanted prosthesis. The study suggested that the implant position needs to be as accurate as possible to achieve the best function.

Barg et al. also looked into implant position and its impact on the ultimate function of the TAR [27]. They concluded that AOFAS scores (functional measure) improve with the accuracy of implant position. Additionally, pain scores decreased with implant position accuracy. One can assume that decreased pain would increase patient satisfaction.

Finally, Hsu and Haddad looked at the INBONE II ankle replacement with 2-year follow-up [18]. The authors were investigating which outcomes resulted in revision. In their series, there were a few cases with arthrofibrosis or decreased range of motion. Was this a factor implant design, position, or size? It is hard to tell from the data, however, if talar subsidence was a factor of inaccurate talar component sizing, and if range of motion was affected by component position, this could be a reflection of the importance of both implant sizing and alignment. Size and alignment are both factors that are greatly influenced by PSI.

By inferencing the conclusions of these nonPSI studies, one can state the need for accuracy to improve TAR function and patient satisfaction. Unfortunately, there have been no studies to date that directly prove that PSI will improve function and patient satisfaction.

Does PSI save time and/or money?

Hamid et al. looked at the additional cost of adding patient-specific instrumentation to TAR [29]. The study found that there was no difference in accuracy of standard instrumentation vs. PSI, yet there was an average operating room time savings of 34 min. This resulted in a cost savings seen despite the additional cost of the patient-specific instrumentation. The cost savings is perhaps even more notable in that this time/cost savings was found in cases performed by extremely experienced total ankle replacement surgeons. It would be easy to conclude that the time/cost savings will be magnified in the less experienced surgeon.

Additionally, the study by Saito et al. also showed a significant time savings (23 min on average) in cases utilized patient-specific instrumentation [28]. The cost per minute in the operating room is perhaps one of the greatest measures of expense, and therefore, it is our conclusion that PSI can save expense in TAR.

Does PSI decrease complications?

To date, there have not been any studies designed to answer the question of complication reduction in cases utilizing PSI. However, by looking at the literature surrounding the most common complication in TAR – wound complications – one can infer a benefit of PSI.

Gross et al. reported on wound complications following total ankle arthroplasties and rates of return to the operating room for these complications. The study showed that both total surgery time and tourniquet time were linked to the occurrence of wound complications [30]. Therefore, time matters, and from the previous discussions and studies, time can be saved with the use of patient-specific instrumentation.

Early Clinical Results with PROPHECY Preoperative Navigation System

Currently, the published scientific literature supports an 89% overall prosthesis survival rate for intramedullary guided (nonCT), modular TAR systems with a mean clinical follow-up of 3.7 years [16]. The learning curve for TAR, which has been shown in short-term evidence-based medicine level III studies involving a mobile-bearing three-component TAR, recommends surgeons to be more selective for the first 50 cases due to a predicated learning curve [31]. Component accuracy and soft tissue management in primary TAR also remains a concern, especially when dealing with any variability in coronal plane malalignment and preoperative deformity [32–34]. The benefits of preoperative CT scan-guided patient-specific guides aim to reduce this variability, improve accuracy of implantation, a reduction in the learning curve, and an improvement in implant longevity.

Conclusions

TAR is a viable option for the contemporary treatment of end-stage ankle arthritis.

The INBONE II Total Ankle Systems offer the advantages of a robust technique with advanced instrumentation. The goal of the advanced instrumentation is to allow for reproducibility and accuracy of component implantation. The INBONE II Total Ankle System offers enhanced fixation of the talar component, longer tibial components to ensure complete tibial cortex coverage, and talar geometry to facilitate coronal plane stability.

The evolution of TAR from an experimental concept to a proven treatment option has largely mirrored changes in prosthesis design and instrumentation. The intellectual discussion of TAR has evolved from how much bone we are removing to which type of polyethylene bearing is selected (mobile bearing vs. fixed bearing) to the most important conversation—are we implanting the TAR with accuracy and with high reproducibility? In this conversation, PROPHECY provides a compelling argument that technology can be safely and effectively harnessed to help the surgeon decide on the most appropriate position and then use patient-specific guides to achieve these goals to within 2° of the intended targets. PROPHECY has changed the conversation from "Which TAR is the most forgiving of inaccuracy?" to "Where do I want the prosthetic components to go as now, we have the technology to reliably place the implant where I want it?" Accuracy and reliability are the most appropriate goals of contemporary TAR systems, and patient-specific guides using the PROPHECY system allow for optimization of both.

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INFINITY® Total Ankle Replacement Including PROPHECY® Patient-Specific Alignment Guides

12

Mark A. Prissel, Justin L. Daigre, Murray J. Penner, and Gregory C. Berlet

Introduction

The INFINITY® Total Ankle System (Wright Medical Technology, Inc., Memphis, TN) (WMT) is a modern, fourth-generation, fixed-bearing, two-component total ankle replacement, which consists of a talar dome and an ultrahigh molecular weight polyethylene (UHMWPE) component that is inserted into the tibial tray. This prosthesis is intended for use in osteoarthritic ankle joints secondary to rheumatoid, post-traumatic, or degenerative arthritis. Indications broaden for use in patients with a failed previous ankle surgery. Specific parameters of deformity correction achievable with this prosthesis, like any other, are based on the experience of the surgeon more so than by the engineered characteristics of the implant itself. However, as with other resurfacing-type prostheses, this prosthesis is ideal for patients with limited deformity and relatively younger patients where maintenance of bone stock is the goal. The contraindications of this implant are consistent with those of total ankle replacement in general. This system is intended for cemented use in the USA and for both cemented and uncemented fixation elsewhere. This modern design affords the stability of a fixed-bearing total ankle replacement system and allows for an excellent range of motion arc. This resurfacing-type prosthesis provides limited bone resection, especially on the talar side of the joint. Optimal maintenance of talar bone stock is a principle that is accepted by total ankle replacement surgeons and allows maximal surgical options when revision surgery is required.

Product Design

The INFINITY® Total Ankle System design is predicated on many of the development concepts of WMT's other modern generation total ankle replacement—INBONE II® (WMT). The addition of INFINITY® to WMT's total ankle replacement portfolio provides a comprehensive armamentarium for the total ankle replacement surgeon, from resurfacing to complex deformity depending on patient-specific needs (Fig. 12.1). Additionally, INFINITY® is compatible with PROPHECY® patient-specific CT scan-guided instrumentation (WMT) (Fig. 12.2). When PROPHECY® guidance is not utilized, the INFINITY® technique incorporates an *extramedullary* guide system, which has adapted the same proprietary advantages of the unique INBONE II® *intramedullary* guidance system (i.e., gun sites) for accurate and precise insertion. The system provides five sizes (1–5) and, the surgeon has the ability to downsize the talus by one size relative to the tibia when most appropriate for the patient's anatomy. UHMWPE components and poly trials are specifically made to properly articulate when downsizing is needed. The sulcus articular geometry of the INFINITY® talus is identical to the INBONE II® (sulcus design) talus, allowing for insertion of the INBONE II® talus in conjunction with an INFINITY® tibial tray and bearing. (Technique tip: The INBONE II® talus may be desired if the patient's talar dome anatomy is flat and the chamfer cut will notch the talar neck.)

The tibial tray is engineered from titanium alloy consisting of approximately 90% titanium, 6% aluminum, and 4% vanadium. The back surface of the component is coated with a titanium plasma spray (approximately 100% titanium with trace amounts of iron). Tibial fixation is achieved by the porous titanium coating, as well as by three press-fit tibial pegs in a triangular configuration in the anterior half of the component. The tibial tray design optimizes anterior delivery into the prepared joint space. Standard and long sizing options are available so the tibial tray covers the anterior and

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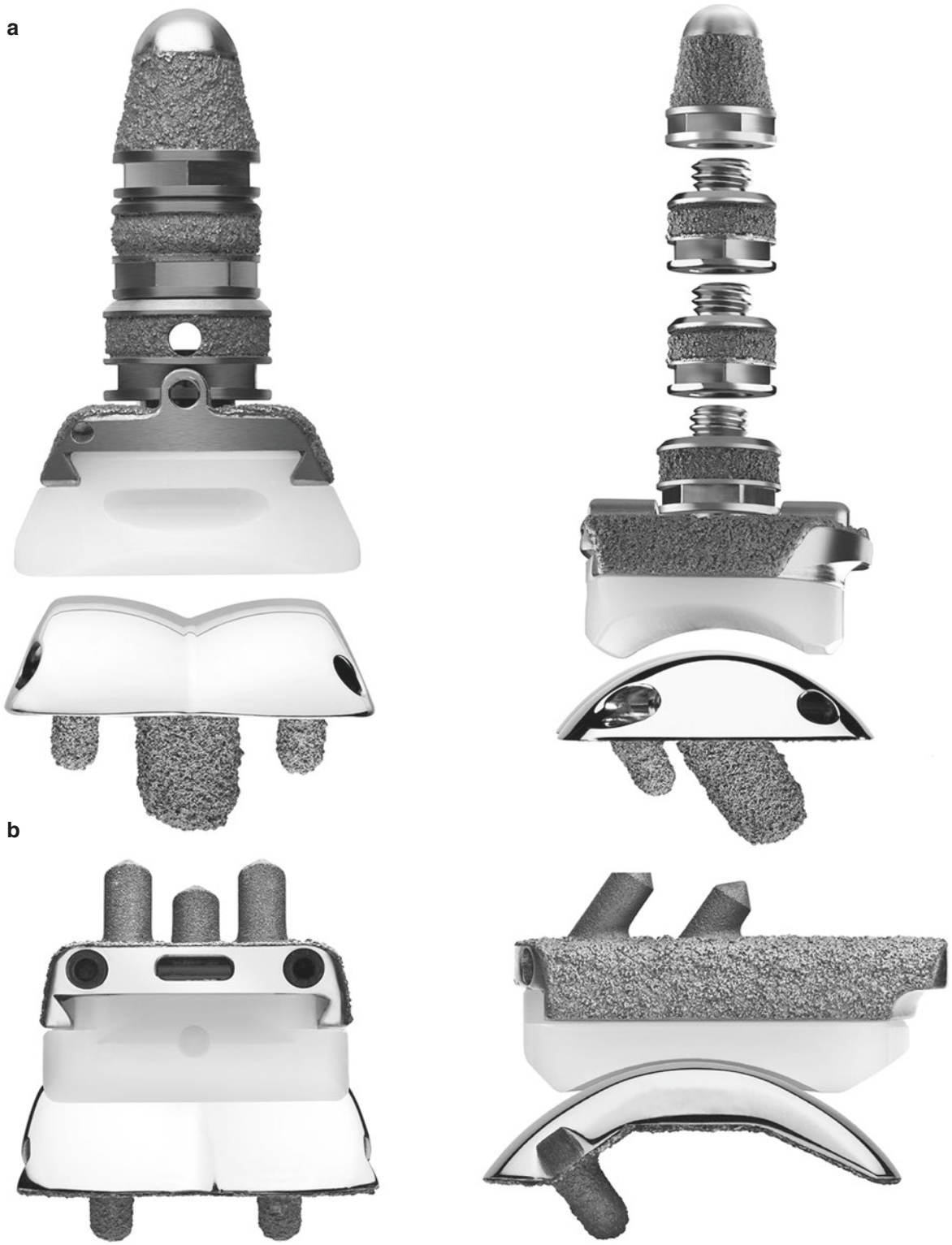


Fig. 12.1 Photographs of INBONE II® (**a**) and INFINITY® (**b**). (Image provided courtesy of Wright Medical Technology, Inc.)

posterior cortices, thereby maximizing cortical bone support.

The UHMWPE component is noncross-linked, compression-molded GUR-1020 polyethylene. The sterilization process is completed by gaseous ethylene oxide. This fixed-bearing design locks into the tibial tray after implantation of the tibial tray and talar dome. The UHMWPE is front loaded and can be exchanged without removal of either of

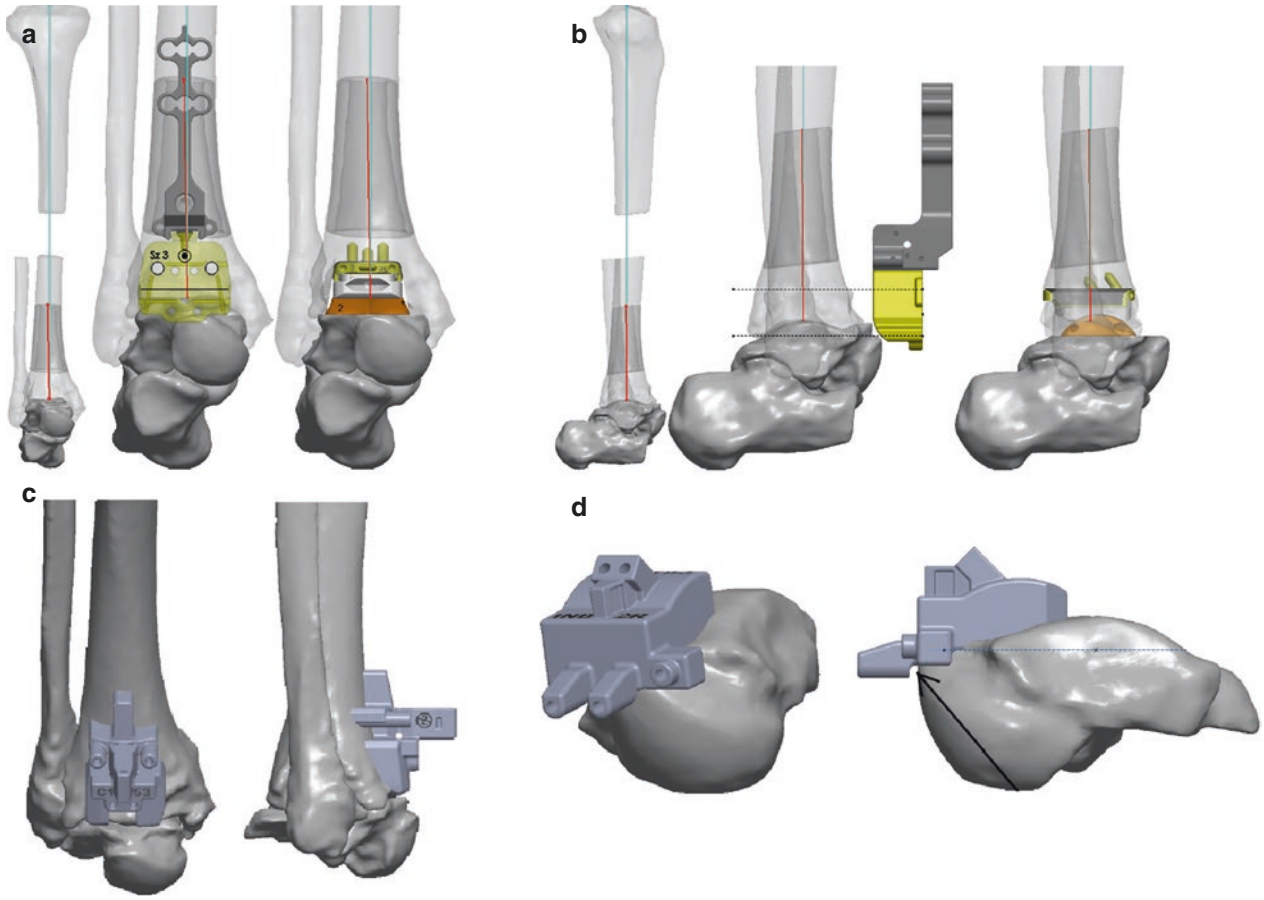


Fig. 12.2 Example of PROPHECY® with INFINITY® tibial tray and INBONE II® talar dome recommended secondary to patient-specific anatomy: AP sizing and alignment (**a**), lateral sizing and alignment (**b**), tibial alignment guide (**c**), and talar alignment guide (**d**)

the metallic components. Minimum UHMWPE thickness is 6 millimeters (mm), and thicknesses up to 13 mm are available based on implant size.

The talar dome is engineered from a cobalt chrome alloy consisting of approximately 60% cobalt, 28% chromium, 6% molybdenum, and 1% nickel. The back surface is coated with the same titanium plasma spray as the tibial tray. Talar fixation is achieved by the porous coating, as well as by the two anterior press-fit talar pegs. The anterior talar pegs and the configuration of the chamfer cuts provide rotational stability to the component. The sulcus design of the talar component maintains frontal plane stability when articulating with the corresponding sulcus design of the UHMWPE component.

The INFINITY® prosthesis design affords proper visualization of tibial and talar bone stock on a lateral radiographic image. Complete visualization of the bone–implant interface allows the surgeon to verify intraoperatively that the implants are fully seated and allows proper postoperative surveillance for tibial and talar bone loss (Fig. 12.3).

Surgical Technique

Approach

The patient is placed in the supine position on the operating table; a bump may be required under the ipsilateral hip to neutralize external rotation. The involved lower extremity is sterilely prepared in the surgeon's preferred fashion. It is imperative that the surgical field includes the knee to ensure proper rotational alignment and to allow appropriate room for the extramedullary guide. A standard anterior ankle incision is made centrally with care taken to protect neurovascular structures. Instrument-based skin retraction is avoided until dissection is deepened. The extensor retinaculum is sectioned, and the extensor hallucis longus (EHL) tendon is identified. Care is taken to maintain the tibialis anterior (TA) tendon sheath intact, and the dissection is deepened at the interval between the EHL and TA mobilizing and retracting the anterior neurovascular bundle laterally. An anterior ankle capsulotomy is performed with appropriate reflection of

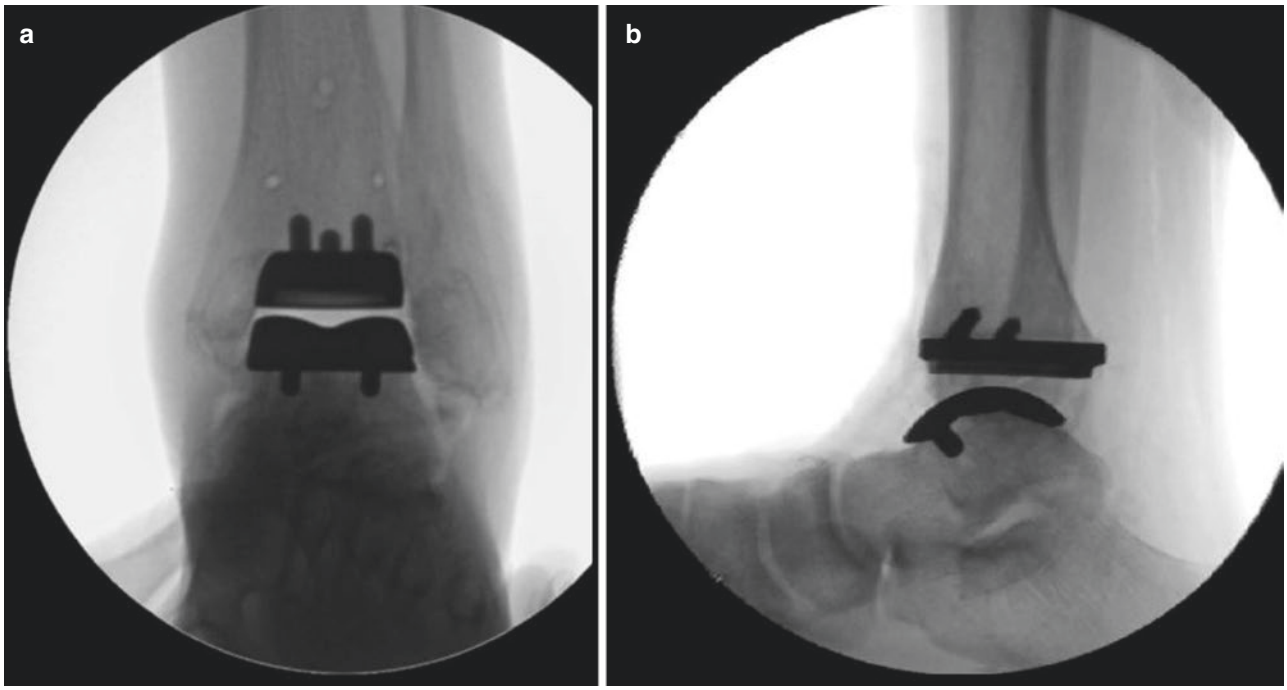


Fig. 12.3 Fluoroscopic images demonstrating INFINITY® bone stock visualization: AP (**a**) and lateral (**b**) view. (Image provided courtesy of Wright Medical Technology, Inc.)

periosteum and capsule to ensure proper visualization and limit skin tension. Exposure should include visualization of the medial malleolus to the fibula. The dorsal talonavicular joint can usually be identified in the inferior aspect of the incision. Retraction is minimized to only what is essential throughout the procedure to maintain the viability of the anterior soft tissues. Self-retained retraction is only used when essential. Anterior osteophytes may be excised either with an osteotome or rongeur to aid in proper visualization and achieve neutral ankle dorsiflexion. When using PROPHECY® for alignment, *do not* remove the osteophytes. Only clean the soft tissue off the bone enough to allow proper seating of the guides.

Alignment with PROPHECY

It is important to keep all osteophytes and boney anatomy intact since the guides reference the patient's bone anatomy. Remove any cartilage left on the talus where the guide will sit. Since the guides are based off the bone anatomy from the CT scan, failing to remove any remaining cartilage on the talus will alter the bone cut. Place the PROPHECY tibia alignment guide on the anterior tibia and match the surface of the guide to the bone. The guide should fit well and not have much wobble. Place one 2.4 mm Steinmann pin in one of the proximal holes of the guide. Use two small cut Steinmann pins and one long Steinmann pin and place them in the vertical slots in the tibia alignment guide. Obtain an AP fluoroscopic image to check alignment. Make sure the vertical pins line up appropriately to minimize parallax. If alignment is not satisfactory, remove the 2.4 mm Steinmann pin and make sure all soft tissue is cleared around the footprint of the guide. Sometimes, it is beneficial to plantarflex the foot and place a bump of towels under the distal tibia. This helps decrease interference from the talus. Replace the tibia alignment guide and check a fluoroscopic image. Once satisfactory alignment is achieved, place a total of four 2.4 mm Steinmann pins through the guide. Remove the guide and place the Coronal Sizing Guide over the two distal pins. Slide the PROPHECY Conversion Instrument over the proximal two pins and dovetail into the Coronal Sizing Guide. Lock in position with the anterior screw. Fluoroscopic AP and lateral imaging is used to confirm correct alignment. Proceed to Bone Cuts and Trialing for completing the tibia cuts.

After the tibia has been cut, use an osteotome to cut down toward the talus at approximately 60°. This will remove enough tibia to place the talar alignment guide. Make sure all soft tissue and cartilage is removed from the surface-match area before fitting the guide to the bone. Planter flex the foot and place the PROPHECY talus alignment guide in the best fit location. Pin the alignment guide into place with one 2.4 mm Steinmann pin in the hole on top. Place two 2.4 mm Steinmann pins into the anterior holes on the guide and remove the top pin. A lateral image can be obtained to verify the top talar cut and the flexion/extension angle. The top cut

will be 2 mm proximal to the top of the pins. Remove the talar alignment guide and place the appropriate INFINITY resection guide. Place two pins in the gutters to protect the malleoli. Use a sagittal saw to make the top cut of the talus. Proceed to Bone Cuts and Trialing for completion of the procedure.

Alignment without PROPHECY®

The medial ankle gutter is identified, and the medial gutter fork is placed perpendicular to the long axis of the tibia. Axial rotation of the tibial component is established based on the position of the medial gutter fork. This guide references the ankle isometric point of the deep deltoid. The axial rotation guide is placed on the medial gutter fork and centered on the tibia with the pointer aligned to the tibial mechanical axis. A 3.2 mm pin (distal pin) is inserted through the axial rotation guide. The axial rotation guide and medial gutter fork are then removed. The alignment frame is placed over the distal pin, the tibial tuberosity is identified, and a second 3.2 mm pin (proximal pin) is placed through the alignment frame into the tibial tuberosity. The alignment frame is tightened with two fingerbreadths between the tibial crest and the alignment frame both distally and proximally (Fig. 12.4). If the surgeon prefers, a knee bracket is available to avoid the proximal pin in the tibial tuberosity. The alignment wing is then placed, and coronal plane alignment is achieved under anterior–posterior (AP) view fluoroscopic guidance. Gun sites are located on the alignment wing to ensure a well-aligned fluoroscopic image, minimizing parallax. A proper fluoroscopic image includes the alignment wing as a thin uniform line and the gun sites centered. It is important to note that the alignment frame is adjusted proximally, and this view is only used to obtain coronal plane alignment (Fig. 12.5). When deformity exists in the distal tibia, the alignment wing may not be parallel to the tibial plafond, resulting in an incongruous resection of distal tibial bone in order to aid in deformity correction. In most cases, the tibial cut should be perpendicular to the mechanical axis of the tibia. Judicious analysis of preoperative imaging and appreciation of the relationship of the mechanical and anatomic

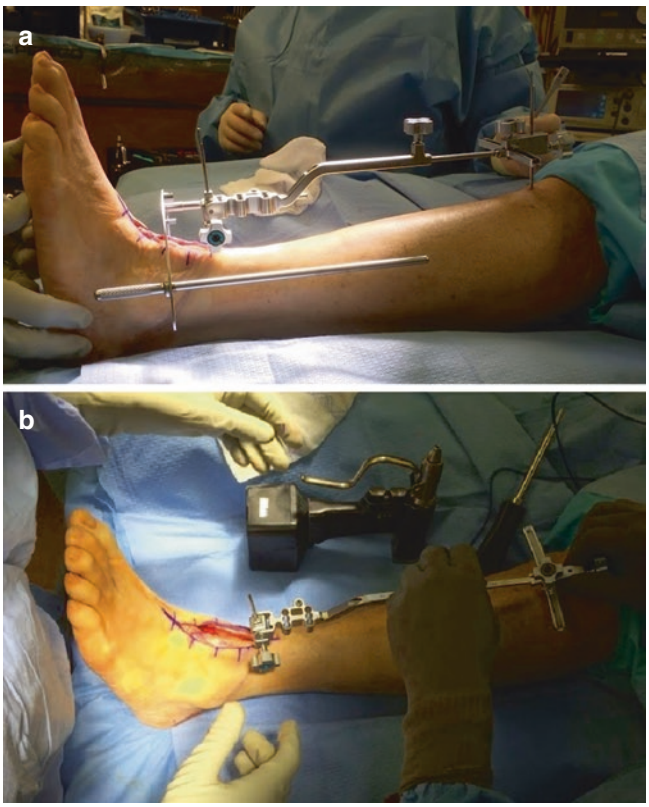


Fig. 12.4 Alignment guide placement: lateral view (**a**) and AP view (**b**)

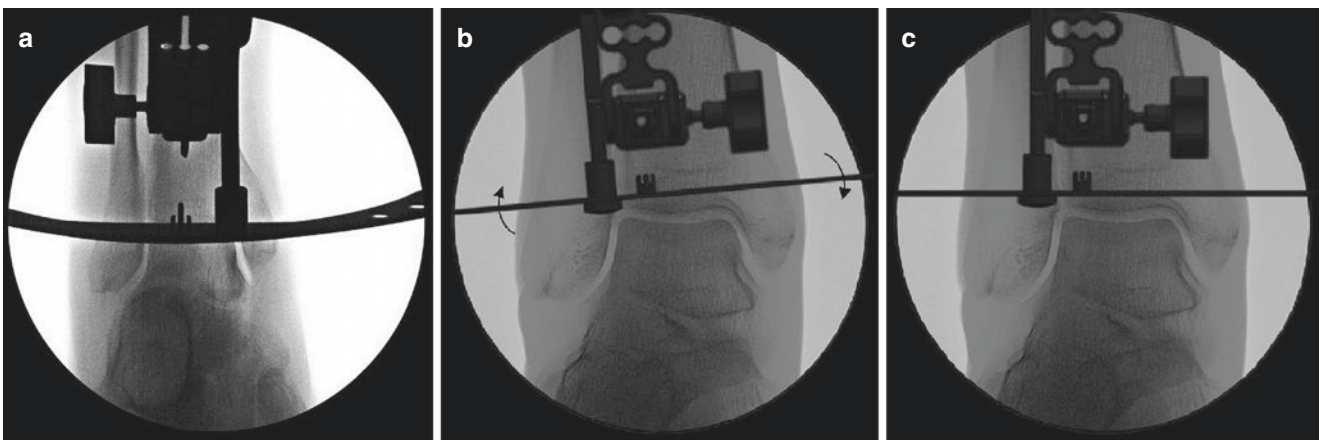


Fig. 12.5 Coronal alignment fluoroscopic image in AP view: incorrect alignment (**a**) corrected by tilt of C-arm to obtain alignment wing appearing as thin line, properly imaged alignment wing to evaluate for desired frontal plane positioning (**b**), and corrected frontal plane alignment (**c**). (Image provided courtesy of Wright Medical Technology, Inc.)

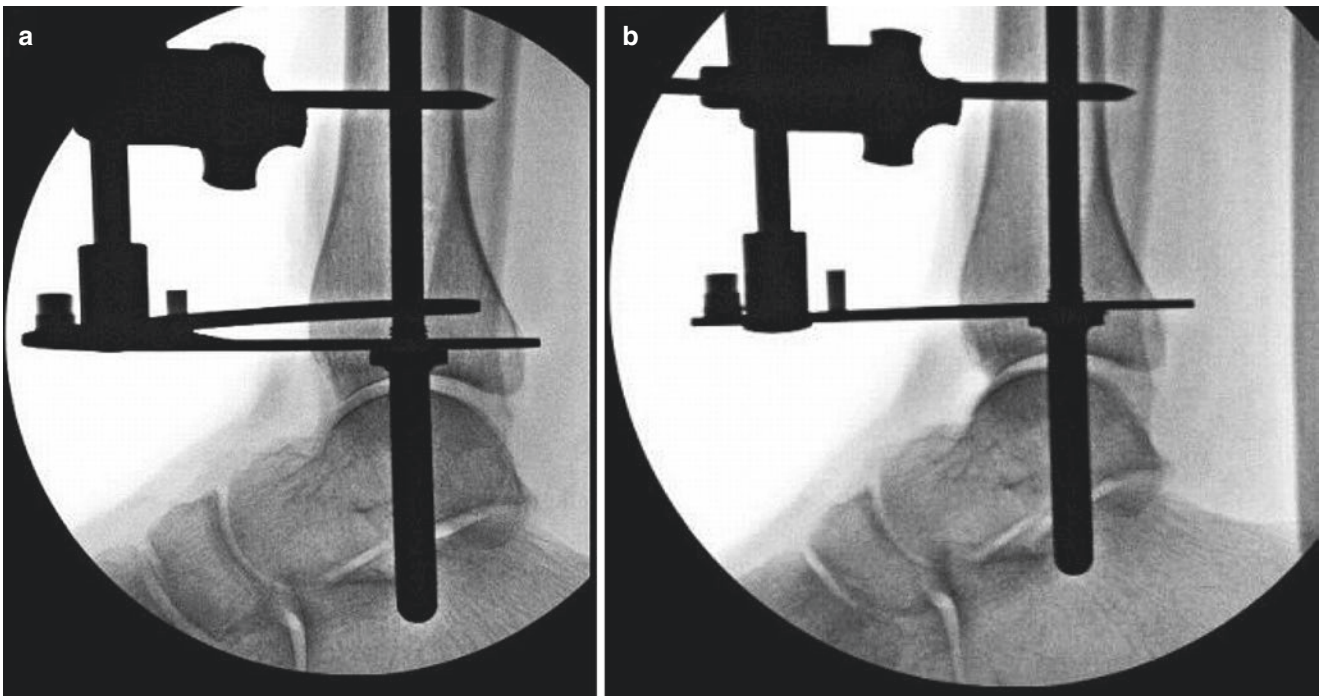


Fig. 12.6 Sagittal alignment fluoroscopic image in lateral view: incorrect alignment (**a**) corrected by tilt of C-arm to obtain alignment wing appearing as thin line, properly imaged alignment wing to evaluate for desired frontal plane positioning with desired corrected plane alignment (**b**). (Image provided courtesy of Wright Medical Technology, Inc.)

tibial axes are essential for proper alignment and resection. Next, the alignment rod is placed and a lateral fluoroscopic image is obtained to determine sagittal plane alignment. The alignment wing should be seen as a single line, and the alignment rod should be parallel to the anterior (or posterior) tibial diaphysis. Flexion or extension is adjusted at either the proximal or distal end of the alignment frame (Fig. 12.6). At this point, all three planes have been aligned, as transverse (axial) rotation was set initially with the medial gutter fork.

Next, two pin sleeves are placed in one of the three aligned pairs of holes (proximal and distal) on the alignment frame. This offers maximal bone purchase with 3.2 mm pins placed bicortically through each of the pin sleeves (Fig. 12.7). Now, the alignment frame, pin sleeves, and initially placed distal and proximal 3.2 mm pins can be removed. The adjustment block is now placed on the parallel tibial pins and secured. The coronal sizing guide is placed on the adjustment block, with approximately 1 mm of clearance between the coronal sizing guide and the tibial plafond. The preoperatively templated coronal sizing guide is initially placed (technique tip: our most common tibial component size is 3); however, ultimate sizing is based on intraoperative decision-making. Under AP view fluoroscopic imaging, a "pin-in-circle" feature exists to correct parallax. The coronal sizing guide is adjusted medial/lateral to obtain an optimal position centered on the ankle joint. It is important to note that during sizing

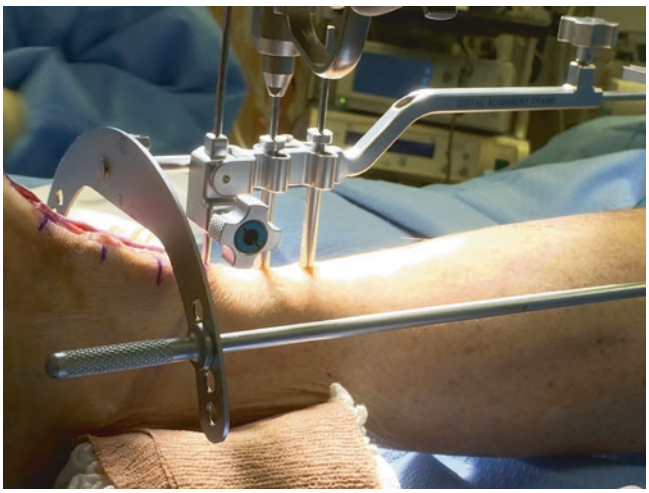


Fig. 12.7 Insertion of pins into the selected aligned pair of holes in the alignment frame

and positioning with the coronal sizing guide, the foot needs to be at 90° to the leg (neutral dorsiflexion) to obtain an accurate assessment of appropriate position and size. If a neutral position is not attainable, any impinging anterior osteophytes should be removed, and if necessary, an Achilles tendon lengthening is performed. Once proper position and size are determined on the AP view, sagittal sizing and resection

height are assessed from a lateral fluoroscopic view. The corresponding sagittal sizing guide arm is placed in the coronal sizing guide, and a lateral image is obtained. In the image, the sagittal sizing arm displays alignment pins at the level of the initial talar resection; these pins should be viewed "end on" to ensure a true lateral view. (Technique tip: A proper lateral fluoroscopic view [when all alignment pins appear as true solid circles] may be best obtained by the surgeon rotating and moving the foot rather than the radiologic technician moving the C-arm.) The superior line demonstrates the level of tibial resection. The length of the superior line indicates the length of the tibial tray with the posterior notch differentiating between "standard" and "long" length tibial trays. The next inferior solid line is placed at the joint line. The dotted line depicts the level of the initial talar resection. The most inferior line (anterior and posterior) demonstrates the anterior and posterior chamfer cut inferior extents; if the INBONE II® talus is determined most appropriately by the surgeon, the talar flat cut is represented by the most inferior line on the sagittal sizing guide. Once final size and position are determined, the sagittal sizing guide is removed and an AP fluoroscopic image can be obtained to verify position (Fig. 12.8).

Bone Cuts and Trialing

Four 2.4 mm Steinman pins are placed bicortically in the coronal sizing guide with the foot held at 90°. (Note: Foot position is critical for this step.) It is important to retract the soft tissues before inserting these pins. Our practice is to use Freer elevators and Army/Navy retractors to protect the soft tissues medially and then laterally while inserting the pins. The tibial corners are then drilled bicortically. The coronal sizing guide is removed, and the appropriate resection guide is placed (Fig. 12.9). (Note: If the INBONE II® talus is selected, an INBONE II®, resection guide must be placed.) Two gutter pins are placed, one medial and one lateral to protect the surrounding bony and soft tissues from the saw blade. The Steinman pins are then cut close to the resection guide to allow saw blade clearance. Saw cuts are made through each proximal, distal, medial, and lateral slots of the resection guide. The resection guide and all Steinman pins in the resection guide are removed. The cuts are completed, if necessary, with either a reciprocating/microsagittal saw or osteotome. The corner chisel is utilized to finish off the proximal corner cuts. Caution is used not to lever proximally on the anterior tibia during cut completion or bone resection as

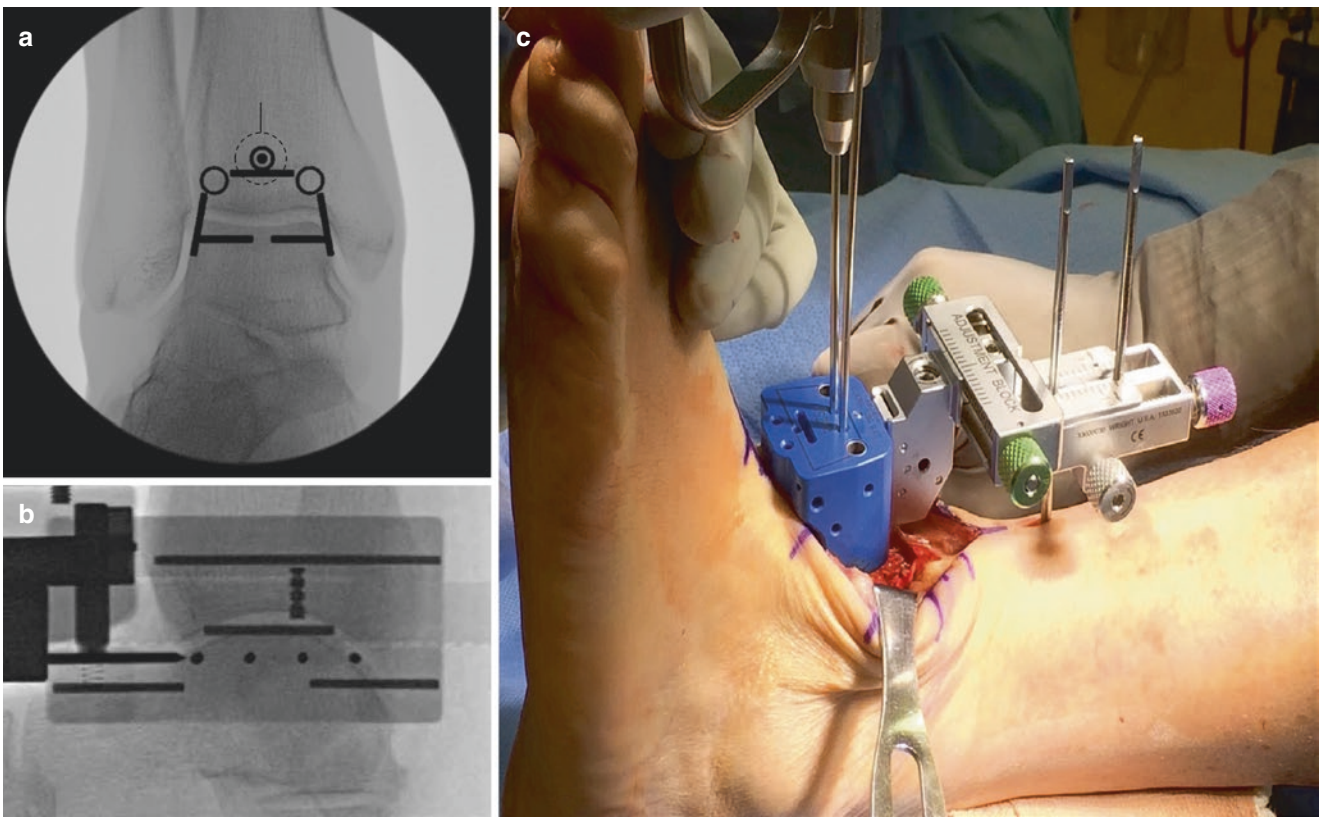


Fig. 12.8 Tibial component sizing: AP fluoroscopic image demonstrating proper sizing of the coronal sizing guide (**a**), lateral fluoroscopic image demonstrating proper position of sagittal sizing arm (**b**), and clinical photograph of placement of coronal sizing guide (**c**). **a**, **b**: (Image provided courtesy of Wright Medical Technology, Inc.)

this may cause plastic deformation and alter the anterior tibial anatomy, which directly supports the tibial component. Instrumentation is available to aid in bone resection/removal including the bone removal screw and a posterior capsule release tool (Fig. 12.10). (Technique tip: We remove the talar bone first using an osteotome. Next, we utilize the bone removal screw, drilling it into the tibial cut bone and pulling the fragment out [ideally in one piece, if not the remaining bony pieces are removed in fragments].) If bony overhang exists with inadequate resection (most commonly seen on the medial and lateral talus), a microsagittal saw or bone rasp may be used in line with the previous cut to finish the resection (Fig. 12.11).

Once appropriate bone removal is completed, the tibial tray trial is placed flush against the tibial cut surface and seated against the anterior cortex. A padded lamina spreader is used to hold the tibial tray in place, while it is fixated with two 2.4 mm Steinman pins. There is a set screw in the tibial tray trial that allows a 3 mm anterior–posterior adjustment to obtain the most appropriate cortical coverage. (Technique tip: It is better to have slight overhang of the tibial component than to undersize the component and risk subsidence.) The Steinman pins are cut flush. A lateral fluoroscopic view is obtained to confirm optimal positioning and size of the tibial tray. The posterior tibial broach is used by malleting it

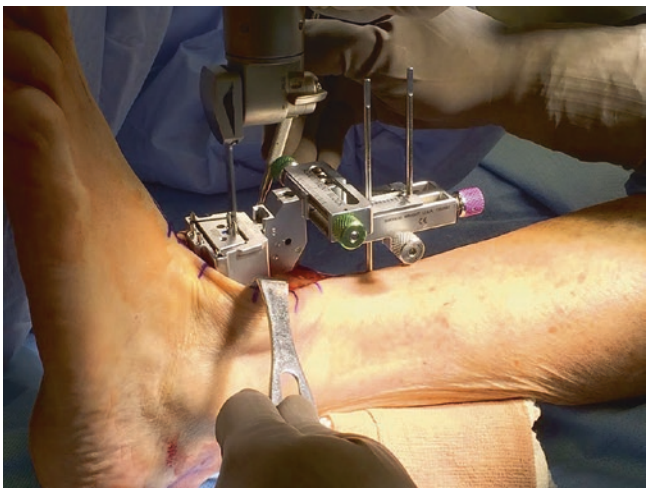


Fig. 12.9 Clinical photograph of resection guide placement [*note*: six placed Steinman pins including gutter pins] and bone resection with reciprocating saw

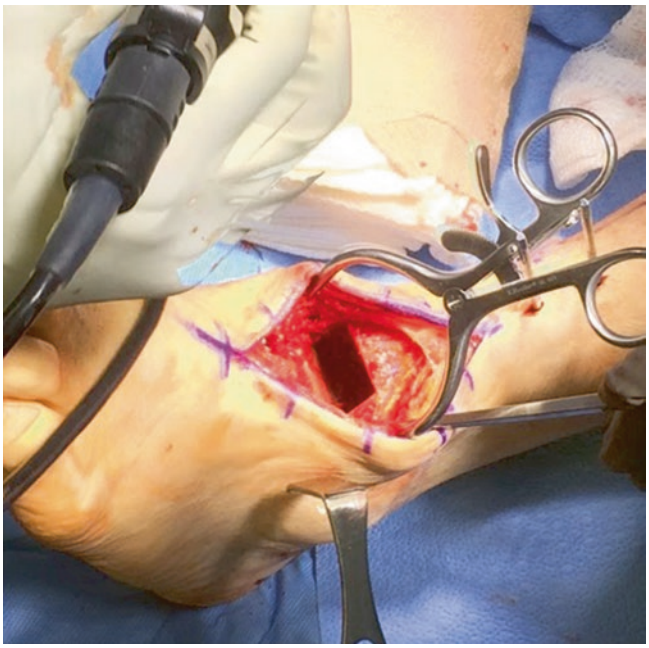


Fig. 12.11 Completed bone resection

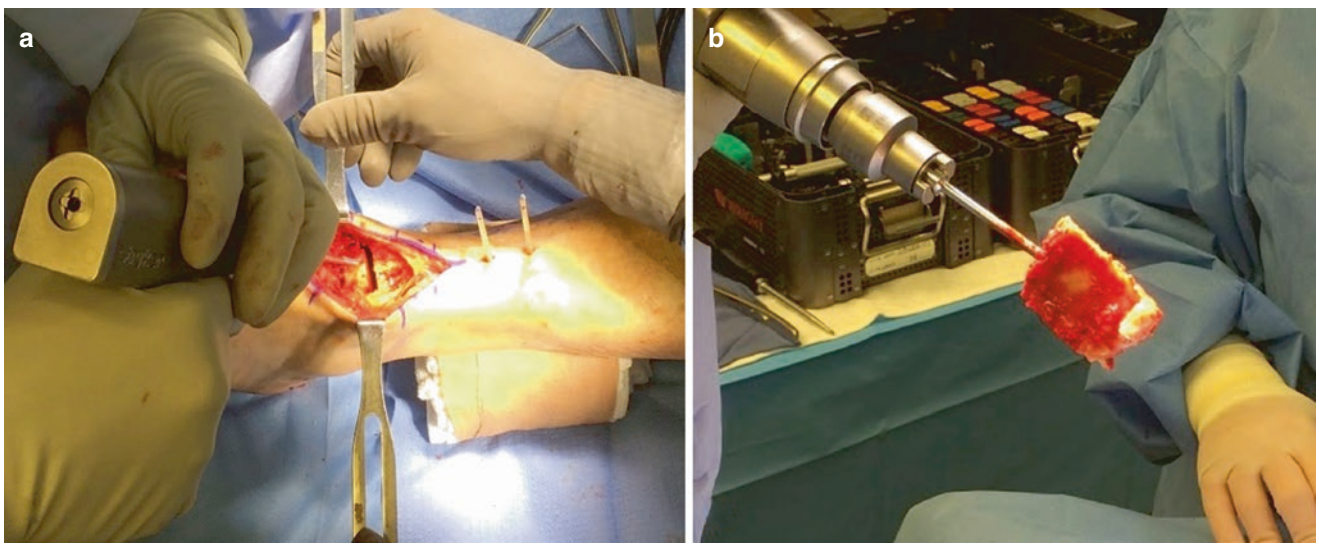


Fig. 12.10 Tibial bone removal using bone removal screw (**a**) and demonstration of en bloc excision of tibial bone using bone removal screw (**b**)

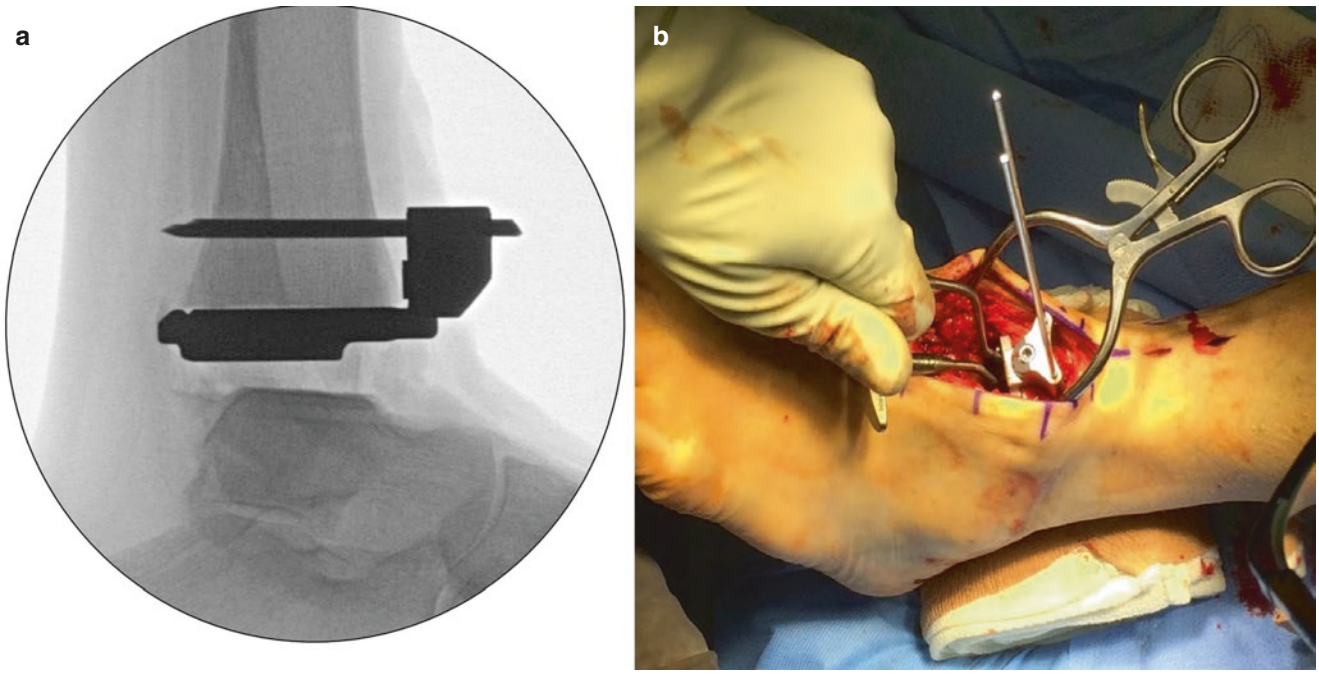


Fig. 12.12 Sagittal sizing and broaching for the tibial component: lateral fluoroscopic image demonstrating appropriately placed tibial trial component [*note*: posterior notch of tibial trial verifies "standard" length] (**a**) and clinical photograph depicting broaching for the tibial component through the trial tibial component (**b**). **a**: (Image provided courtesy of Wright Medical Technology, Inc.)

through the posterior hole in the tibial tray trial. The posterior broach is left in place to provide additional stability while broaching the two anterior holes with the anterior broach (Fig. 12.12). The anterior and posterior broaches are removed.

The talar component sizing is performed next by inserting the appropriate-sized talar dome trial and poly insert trial. The talar implant can either be the size of the tibial implant or one size smaller (this allows optimal talar coverage minimizing overhang, which may result in prosthetic gutter impingement). An AP fluoroscopic image should be obtained to assess the medial/lateral size of the talar trial. (Technique tip: It is important at this time to evaluate the medial and lateral gutters and anticipate how much bone may be needed to resect to decompress the gutter [which comes at a later step].) Lateral fluoroscopic imaging is then used to assess anterior–posterior size and check chamfer cuts (Fig. 12.13). Various poly trial thicknesses can also be trialed at this point. (Technique tip: Slight axial compression with plantarflexion and dorsiflexion of the ankle helps the talar and poly trials achieve the correct center of rotation.) Once optimum position is achieved, two 2.4 mm Steinman pins are delivered in the talar trial. Both the talar and poly trials are removed, and the talar resection guide is slid onto the talar Steinman pins and seated flush on the resected talar surface. Two temporary fixation screws are placed through the talar resection guide base. (Technique tip: Caution is warranted to avoid overtorquing the threaded temporary fixation screws either during insertion or removal; overtorquing may result in inadvertent screw fracture.) The posterior chamfer cut is then completed with a saw through the slot in the talar resection guide. The anterior pins are removed, and one of the pins is placed in the anterior pin hole in the resection guide base. The anterior talar pilot guide is then placed (pegs down), and the talar reamer is used to plunge cut all four pilot guide holes (Fig. 12.14). The anterior talar finish guide is placed, and the talar reamer is used to perform the finishing cuts. This process is then repeated with the anterior talar pilot

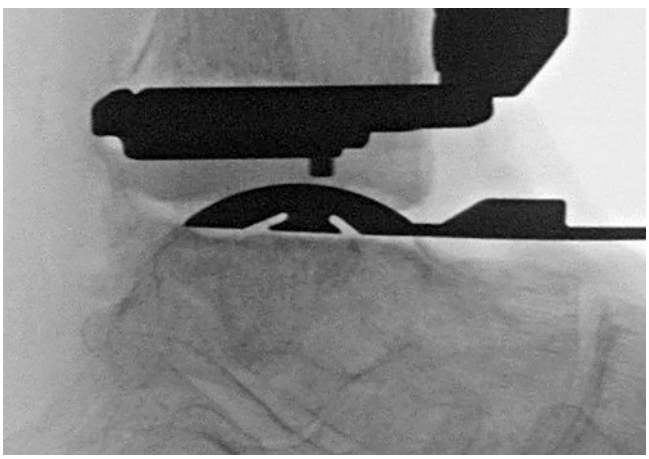


Fig. 12.13 Lateral fluoroscopic image of trial components. (Image provided courtesy of Wright Medical Technology, Inc.)

guide with the pegs up, followed by the finish guide. Remove the talar fixation pins. (Note: The talar fixation pins are threaded so use reverse on the wire driver to prevent screw breakage.) The chamfer cuts should be evaluated to ensure all residual bone is removed and smooth chamfered surfaces are present for proper seating of the final talar component. Now is the time to evaluate the medial and lateral gutters for impingement and osteophytes. A microsagittal saw or osteotome can be utilized to resect bone off the talus to decompress the gutters. Care must be taken to not over-resect the gutters and either cause talar implant overhang or destabilize the ankle joint.

Reinsert the tibial tray trial over the tibial pins and insert the appropriately sized talar dome trial. UHMWPE-bearing thickness can now be evaluated with multiple thickness trials to determine proper tensioning of the ankle joint. Once the proper UHMWPE thickness is determined, the poly trial is removed. A 2.4 Steinman pin is placed through the talar peg drill guide, and the anterior talar pegs (medial and lateral) are drilled with a 4.0 mm anterior peg drill. All trialing components and pins are now removed. The wound is then copiously irrigated, and all debris removed as the ankle joint is prepared for component implantation.

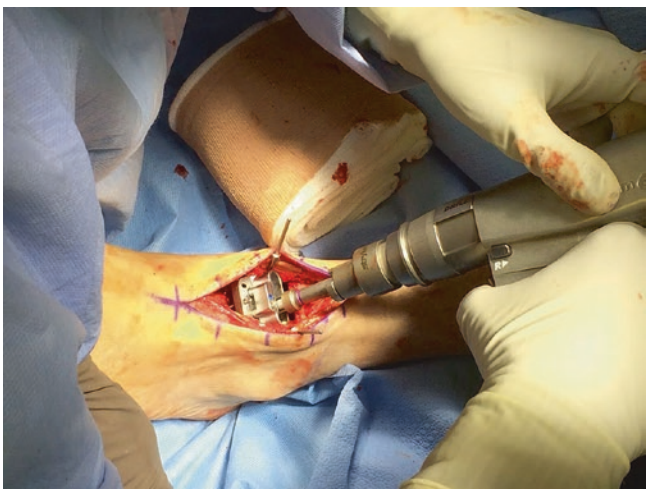


Fig. 12.14 Clinical photograph of anterior talar chamfer pilot guide

Implantation

The appropriately sized tibial component is selected, and bone cement is applied when required to the top of the tibial component taking care not to get cement on the anterior or bottom surfaces of the tibial tray. Using the tibial tray impaction insert, the tibial tray is introduced into the joint with care taken to properly align all three pegs with the corresponding holes in the tibia. The offset tibial tray impactor is then utilized to complete the seating of the tibial tray. The tibial tray impaction insert has two (anterior and posterior) impaction notches. It is recommended that impaction is initiated using the posterior notch first and subsequently the anterior notch continuing in an alternating technique until the component is fully inserted. Fluoroscopic imaging should be utilized throughout this process to aid in proper and complete insertion. (Note: The lateral image will show whether your implant is fully seated.) Care is taken to obtain contiguous contact between the anterior cortex of the tibia and the tibial tray so proper load is sustained with weightbearing. Caution is taken not to excessively impact the tibial tray after it is properly seated as posterior translation may result, thereby limiting the quality of the anterior cortical contact (Fig. 12.15).

Next, the appropriate-sized tibial tray protector is placed in the tibial component to protect the superior surface of the talar dome. Bone cement is applied when required to the undersurface of the talar dome. The talar dome is inserted into the joint by hand aligning the anterior pegs with the corresponding drilled holes. The tibial tray protector is removed, and the talar dome impactor is placed. With the foot plantarflexed, the impactor is malleted to seat the talar component. Care is taken to not lever on the tibial component as posterior translation could result. Fluoroscopic imaging is used to ensure proper and complete seating of the talar dome (Fig. 12.16).

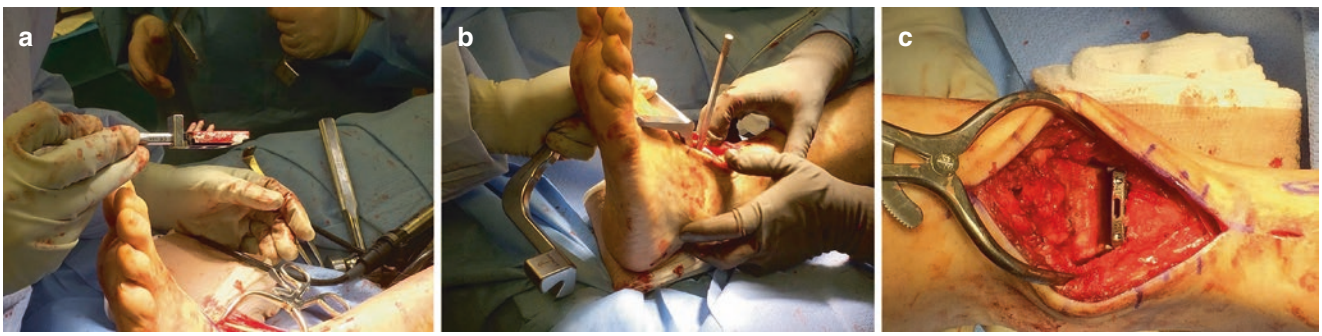


Fig. 12.15 Clinical photographs of tibial component insertion: tibial component prior to insertion with cement applied to the superior surface for initial stability and bone marrow aspirate applied for improved osseous ongrowth (**a**), offset tibial impactor employed for seating of tibial component (**b**), and implanted and fully seated tibial component with maintained anterior cortical purchase (**c**)



Fig. 12.16 Clinical photograph of talar component insertion



Fig. 12.17 Postoperative weightbearing radiograph demonstrating posteriorly translated tibial component

The UHMWPE bearing is then inserted into the tibial tray by placing two attachment screws into the tibial tray. The poly insert guide housing loaded with the selected UHMWPE bearing is then placed onto the attachment screws and secured. The UHMWPE bearing is then advanced into the tibial tray. Once maximal depth is achieved, the housing is removed along with the attachment screws. If the UHMWPE bearing is not fully seated, the straight tibial tray impactor can be utilized to complete the insertion using distal to proximal gentle malleting. Utmost caution should be maintained as overzealous malleting may result in posterior translation of the tibial tray and loss of proper anterior cortical purchase (Fig. 12.17). Final fluoroscopic imaging is employed to ensure proper implantation of all components on orthogonal views. Ankle motion is verified intraoperatively, as further improvement in range of motion beyond what is available during the surgery should not be expected (Fig. 12.18).

Closure

Layered closure is then obtained with closure of the extensor retinaculum, subcutaneous tissues, and skin by the surgeons' preferred method. (Note: The use of a surgical drain is at the discretion of the implanting surgeon, although it is not a part of our routine practice.) A dry sterile dressing is applied, and a well-padded posterior splint is placed with the foot in a neutral to slightly plantarflexed position.

Infinity Experience

INFINITY® has taken advantage of the best aspects of the INBONE II® total ankle replacement and translated them into a bone-preserving, resurfacing design with a vastly simplified, yet highly accurate technique ideal for younger patients and those with good bone quality and minimal deformity. The ability to vertically impact both the tibial and talar components to ensure rigid seating and minimize micromotion, as is done with INBONE II®, is a major advance over prior resurfacing designs. The use of a fixed bearing ensures greater stability and a more anatomic articulation, avoiding the potential malleolar stress pain that may be seen in mobile-bearing designs with unconstrained medial/lateral motion of the talar component (see the chapter on Mobile vs. Fixed Bearing). The mobile-trial instrumentation for the talus is critical as it allows for positioning of the talus directly under the kinematic axis of the tibia, which is the most important issue in any total ankle replacement implantation technique. As ankle replacement longevity has improved with current-generation devices, osteolysis has become progressively increasing concern. The simplified bone interface geometry of the INFINITY® components, in contrast to designs with flanges or fins, ensures that the entire bone–implant interface can be readily monitored with X-ray or CT scan over the lifetime of the prosthesis. Further, this simplified bone–implant interface requires accurate machining and surface matching of only three surfaces for each component, rather than up to seven as seen on some other designs, ensuring a much higher likelihood of full bone–implant contact at insertion, minimizing the risk of stress shielding, micromotion, and fluid access to the interface. The ability to fully visualize the bone–implant interface ensures that full seating of the components can be confirmed.

The ability to utilize INFINITY® and INBONE II® talar components interchangeably is a major advance. In settings



Fig. 12.18 AP and lateral initial postoperative weightbearing radiographs (**a**) and most recent 1.5 year follow-up postoperative weightbearing radiographs (**b**)

with normal tibial bone but a flat-topped talus, the use of an INBONE II® talus restores joint height and avoids taking unnecessary bone away through the chamfers, while the ability to match this to a resurfacing INFINITY® tibial component ensures preservation of tibial bone stock.

To date, available reported data regarding the INFINITY® Total Ankle System appear satisfactory and generally consistent with other fourth generation total ankle implants due to the relatively short Follow-up remains relatively short and continued monitoring with extended follow-up is necessary

to determine long-term survivorship. In 2019, Cody et al. identified concern for increased early revision rate with the INFINITY prosthesis in a series of 159 patients at mean follow-up of 20 months. The identified revision rate of 10% (16 of 159) included six deep infections and six symptomatic cases of tibial component loosening with the remaining cases resulting from alternate modes of failure [1]. These findings with an increased early rate of revision have not been replicated by other available studies within the literature. In 2019, Penner et al. evaluated 67 consecutive patients from 2013 to 2015 with two to four year follow-up and identified an implant survival rate of 97% at mean follow-up of 35.4 months. The two revisions were for talar component aseptic loosening. In the 65 nonrevised cases, no radiographic incidence of talar or tibial component loosening was identified [2]. Similarly, in 2019, King et al. studied, as part of a comparative analysis, 20 INFINITY® with minimum follow-up of two years and no revision cases were encountered [3].

Penner Literature Review

The Infinity total ankle replacement system became available for clinical use in 2014. Since that time, use of the Infinity system has steadily increased, with it now accounting for 57% of all primary ankle replacement in the National Joint Registry [1]. Clinical outcomes with the Infinity total ankle replacement system have been reported in four publications and have been very satisfactory thus far.

In 2018, a preliminary series with 18 month minimum follow-up and mean follow-up of 24 months described 64 consecutive cases [2]. Two revisions were reported for a septic subsidence, for a survivorship of 95.3%.

The first series with 2 year minimum follow-up was published in 2019 by Penner et al. [3] This report evaluated 67 consecutive patients from 2 different centers with surgery performed between 2013 and 2015 with follow-up of 27–47 months (mean 35.4 months). Implant survival was 97% at a mean of 35.4 months. The 2 revisions were for aseptic talar component loosening. There were no deep infections. In the 65 nonrevised cases, there was no radiographic evidence talar or tibial component loosening. The ankle osteoarthritis score was seen to improve by a mean of 34 points postoperatively, consistent with excellent patient-reported outcomes.

Short-term results in 159 cases performed by 2 surgeons with minimum 12 months follow-up (mean 20 months) were reported by Cody et al in 2019 [4]. They reported a deep infection rate of 3.8% requiring revision. Additionally, 3.8% underwent revision for aseptic loosening. An additional 2.5% underwent revision for other causes, including component malrotation and medial malleoli fracture. As noted in a commentary by Haddad [5], this series included numerous complex cases with deformity up to 27.4° as well as a large number of cases with adjacent hindfoot arthrodesis. Further, questions with respect to implant insertion technique were raised. Nevertheless, when cases where revision for infection or causes unrelated to aseptic loosening are excluded, reported survivorship, despite the complex nature of this series, was 96%.

Finally, in 2019, King et al. published a consecutive series of 20 Infinity ankle replacements compared with 20 previous Zenith ankle replacements, with minimum 2 year follow-up [6]. No revision surgery was required. The authors concluded that implant alignment was improved with the Infinity system compared to the zenith.

In summary, the literature thus far has demonstrated low levels of aseptic loosening together with high levels of improvement in patient-reported outcomes. Longer-term studies are required to better define long-term survivorship and patient outcomes.

Acknowledgment G.C.B. and M.J.P. are consultants for Wright Medical Technology.

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Vantage Total Ankle Replacement

13

James K. DeOrio, James A. Nunley, Mark Easley, and Victor Valerrabano

The Vantage ankle prosthesis has unique design features [1]. There is an anterior flange on the talus to help prevent possible subsidence, three vertical fixation pegs on the tibia, which allow immediate weight bearing, a bone cage with fenestration on the tibia, which can be impacted with patient's autologous bone prior to insertion, almost complete coverage of the cut tibial surface with a small posterolateral cutout for the fibula, and a thicker central portion of the top of the talar component. In addition, it avoids any violation of the anterior cortex of the tibia and has a completely round undersurface of the talar component, which matches the prepared curved surface of the talus and allows for uniform load transfer. The polyethylene insert is molded with a biconcave surface, which is locked in place with a clip. Another unique feature is the ability to match any size tibia with any size talus.

The insertion of the Vantage ankle requires some special insertion techniques as well as some tried and true methods for inserting the ankle.

1. Prepare the leg with a thigh-high tourniquet just as you do for other procedures. A pressure of less than 300 mm Hg is recommended and should not be used longer than 2½ hours. A sequential compression device is used on the nonoperative leg.
2. Covering the toes with Coban or similar covering is recommended because numerous studies show one cannot reliably sterilize the interstices of the toes.
3. An anterior tibial incision is made approximately 1–1.5 centimeters lateral to the tibial crest [2]. While there are some variations, a direct anterior incision from proximal to distal is recommended. Alternative exposures may be considered if incorporating previous incisions. The superficial peroneal nerve is uncovered so it can be avoided. A cut is made through the retinaculum immediately adjacent to the anterior tibial tendon. Following the tendon helps avoid injuring the neurovascular bundle and is a clear marker to get exposure of both sides of the ankle. It is important to keep the retinacular incision lateral to the anterior tibial tendon to avoid difficulty in closure or "bowstringing". Complete the exposure by peeling the soft tissue back to expose the medial and lateral gutters.
4. The *Medial Shim (Sword)* is placed into the medial gutter to establish talar rotation. Then, a 5 mm threaded pin is placed in the proximal tibial tubercle parallel to the *Sword*. Slight inclination of the pin toward the foot is intended to keep the distal portion of the *Alignment Guide* forced down onto the bone. The height of the proximal portion of the *Alignment Guide* off the proximal tibial surface is around two fingers width (authors prefer to use ring and 5th finger) and is fine-tuned with x-ray to ensure a 90 degree cut of the distal tibia is made in the sagittal plane (Fig. 13.1). The proximal portion of the guide is initially placed in valgus (about ½ way between the center and full valgus) (Fig. 13.2). The distal *Tibial Cutting Block* is attached to the *Alignment Guide*. Generally, the size 1–2 *Tibial Cutting Block* is recommended for smaller people and 3–4 for medium-sized and larger people. The blocks have indicators for size that can be assessed using x-ray. A longer 2.4 mm pin is placed in the proximal hole of the guide through the anterior tibia to loosely hold the guide while

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Fig. 13.1 The anterior alignment guide is placed on the tibia with a pin in the proximal tibia and another more narrow pin through the diaphysis

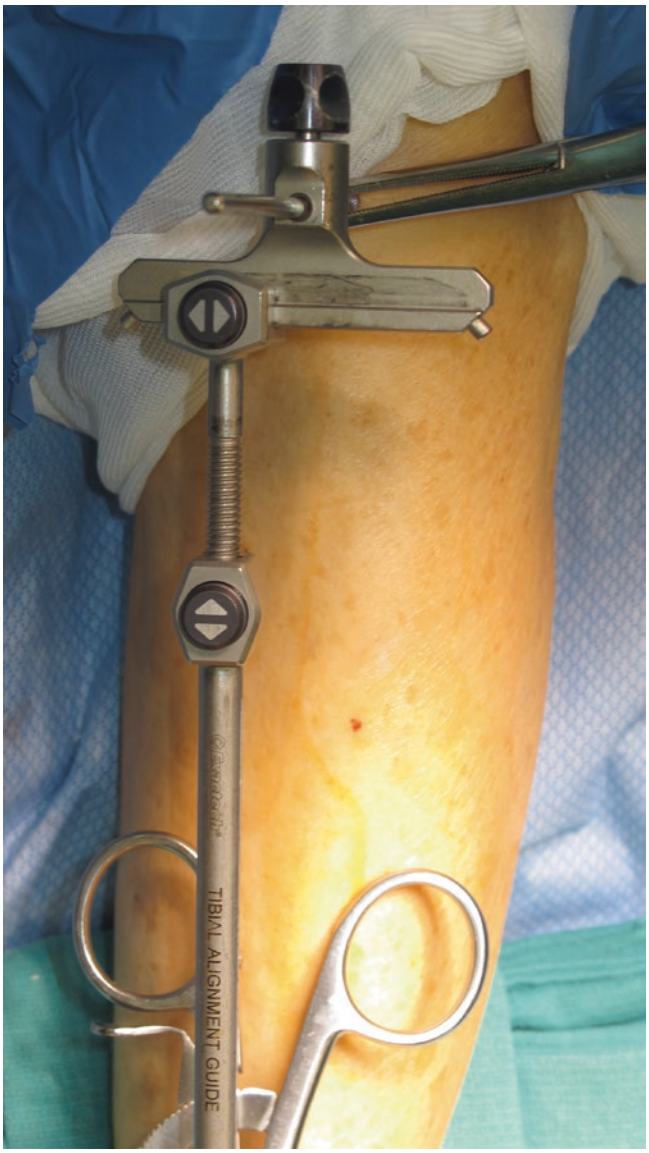


Fig. 13.2 The guide is purposely placed into valgus to begin with to save time

correcting alignment. The distal portion of the guide is shortened using the proximal button to approximate a 7 mm cut (Note: Make sure the adjustable vertical position of the distal cutting guide is at the ½ way mark in order to move the guide up or down). The *Rotation Alignment Rod (Flag)* is now inserted in the tibial cut guide to ensure rotation is correct by aligning the *Flag* in the cutting guide parallel to the *Sword* in the medial gutter. Use the *Standard Hex Driver (Screwdriver)* to loosen the guide in rotation, correct the rotation, and then tighten the rotation screw with the *Screwdriver.* Using fluoroscopy, align the guide in the neutral, varus-valgus position. The first confirmation of alignment is making the shaft of the alignment guide above the distal block parallel on x-ray to the lateral surface of the tibia (Fig. 13.3). The second is to use an anterior x-ray to look through the cutting guide and ensure proper correction of varus or valgus. The anterior view also provides visual feedback on the thickness of the medial malleolus. Now is a good time to place a pin for a cannulated screw into the medial malleolus for prophylactic fixation if you feel the bone is weak. Some surgeons might prefer to make a posterior medial incision to place a malleable 1″ retractor to protect the posterior structures during bone cuts. Adjust the medial lateral portion of the cutting guide using the *Screwdriver* so that when the *Sword* is placed in the vertical slot, it touches the talus. Placing it in the cornice of the medial gutter can result in tibial placement that is too medial. This can especially happen

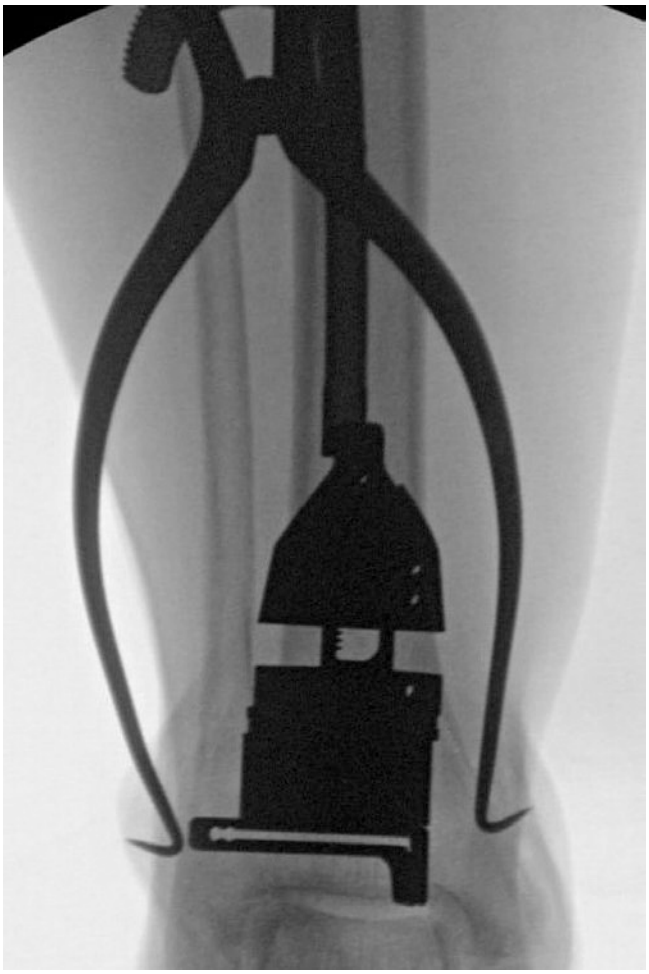


Fig. 13.3 One good way to get correct alignment in the coronal plane is to make sure the anterior guide rod is parallel to the lateral tibia just above the trapezoidal block

in a varus ankle where the medial malleolus is worn away.

5. Place pins in the two medial holes of the adjusting blocks of the *Anterior Guide*. The height of the cutting block is adjusted with the screw driver using the *Angel Wing* and x-rays. Get the 7 mm tabs to be in line with the top of the plafond when the *Angel Wing* is made parallel to the x-ray beam (thin metal line on the radiograph). The cut is intended to be made perpendicular to the tibial axis in the sagittal plane (Fig. 13.4). The medial and lateral borders of the cut are protected by pins placed in the cutting block. The medial pin sets the position of the medial corner of the implant. The lateral side provides options for either size 1–2 or size 3–4. The pin location can provide guidance on the maximum width of the component. The location of the hole relative to the fibula in the anterior x-ray provides guidance on which size to choose and helps prevent cutting into the fibula. Authors' tip: Prior to cutting the tibia, a posterior medial incision may be made



Fig. 13.4 A guide pin for a later screw may now be placed in the medial malleolus. The use of a posterior malleolus incision allows for insertion of a 1″ malleable retractor to protect posterior structures



Fig. 13.5 With a lateral x-ray, the surgeon now moves the leg medial and lateral to get a "thin" view of the angel wing flange. Then, the adjustable guide is moved up or down so that the 7 mm post extensions just touch the plafond

to place a malleable 1″ retractor to protect the posterior structures. The retractor acts to prevent the medial pin driving too deeply and affecting the posterior tibial nerve. The retractor can also keep the saw from penetrating too deeply [3] (Fig. 13.5). Cut the distal tibial bone inclining the saw slightly inferiorly to keep the cut in the line with the slot of the cutting block. Use the *Reciprocating Saw* to make the vertical cut through the *Cutting Block*. Insert a ½″ curved osteotome and pull the cut piece of tibia distally. Lever the bone toward you with the tip of the osteotome nestled about 1/3 of the way down the cut bone and push the more proximal portion of the osteotome against

the *Alignment Guide*. It is possible to pull the entire piece of tibial bone loose using this technique. However, most of the time, it will break and should be removed in a piecemeal fashion. The fastest way to do this is to distract the joint using a toothless or flat lamina spreader to create space and cut the remaining cut piece into thirds using the small reciprocating saw. Loosen the fragments using a small right-angle curette or rongeur. Finally, when the piece is judged to be loose, remove it with the rongeur (a 7″ long single-action rongeur with a 4 mm bite works best). When the bone is removed, proceed to cutting the top of the talus.

6. Exchange the distal tibial cutting guide for the *Talar Cutting Guide*. Here, you may use the 4 mm cutting block if you have a fairly normal height of the talus or the 2 mm cutting block if you have a flat top talus (defined when cut parallels the top of the foot across the talonavicular joint will not take off any bone from the top of the talus). Using the screwdriver, drive the cutting platform firmly down on top of the talus. It is important to hold the foot in 90 degrees of flexion and several degrees of valgus when the *Talar Cutting Guide* is pinned in place (Fig. 13.6). Pin the talus into position and cut the talus. An x-ray may be taken at this point to ensure the the cut of the top of the talus is appropriate by placing the angel wing in the cut guide and taking a lateral x-ray. It is also important to keep the saw in the middle of the talar cutting guide slot when cutting the top of the talus. Any attempt to go to the sides of the talar cutting guide with the saw will likely result in putting a cut mark on the malleoli. Then, when the cut guide is removed, you can complete the talar cut under direct vision. If, for example, the ankle is in varus and soft tissue contracture prevents moving the ankle into valgus, a medial release should be performed. The medial deltoid release technique is commonly used to balance the ankle and has not resulted in excessive or symptomatic medial instability cases [4]. The correct talar cut will obviate having to do a calcaneal slide later. Rarely, when it is not possible to get the hindfoot into valgus with a medial release, a free cut on the talus taking off 2 mm of lateral talus may be performed. You may also have excessive lateral laxity. In that situation, be prepared to perform a Brostrom ligament reconstruction at the end of the case to tighten the lateral side [5, 6].



Fig. 13.6 The surgeon holds the foot at 90 degrees while the talar cutting guide is pinned in place. X-rays may also be taken to make sure the guide is at 90 degrees

A flat cut component is recommended in cases of talar collapse or the presence of talar cysts that would compromise the round talar body preparation. Place the specific size *Gap Check* device in the ankle with the cut-out for the fibula placed correctly and verify enough bone has been resected for the implant. Remove any extra bone pieces and clean the gutters medially and laterally to discourage any gutter impingement postoperatively.

7. Select the size of the component and place the *Talar Lollipop* inside the ankle. Look at the medial lateral dimensions of the *Lollipop* on the cut talus and determine the size that best fits the cut surface. When placing the *Lollipop*, a good place to start is to place the anterior edge of the lollipop ¼” posterior to the anterior cut surface of the talus. Before the barbs on the bottom of the lollipop are engaged, make sure you rotate the lollipop in line with the 2nd metatarsal. Now take the guide and press it into place with the provided spreader in the bone to engage the barbs and take a lateral x-ray with *the Distraction Tool (Chicken Wing)* holding it in place (Fig. 13.7). Find the correct position for the x-rays by moving the ankle left and right until the posterior edge of the lollipop is a single point, not two. Then, rotate the foot and ankle to find the center hole of the lollipop. Check to make sure the hole in the *Lollipop* is immediately above the lateral process of the talus. If not, do this over until the hole in the *Lollipop* is immediately above the lateral process of the talus (Fig. 13.8). If it is, fix the *Lollipop* with two pins going from anterior to posterior. Remove the *Lollipop* in a vertical direction leaving two pins sitting in the talus (Fig. 13.9).
8. Place the *Milling Guide (Chamfer Guide)* in by sliding the anterior holes over the two short guide pins. Make sure the guide is flush to the talus by checking the posterior slot and make sure the metal is in direct contact with the bone. Fix the *Chamfer Guide* medially and laterally with additional long pins (Fig. 13.10).
9. Place the large oscillating saw through the larger rectangular cutting slot in the guide and cut the posterior chamfer (Fig. 13.11). Cut only about ¼ inch deep to avoid cutting the posterior structures. Make sure you lift your hand to drive the cutting blade into the bone.



Fig. 13.7 The lollipop and the chicken wing hold the guide in place

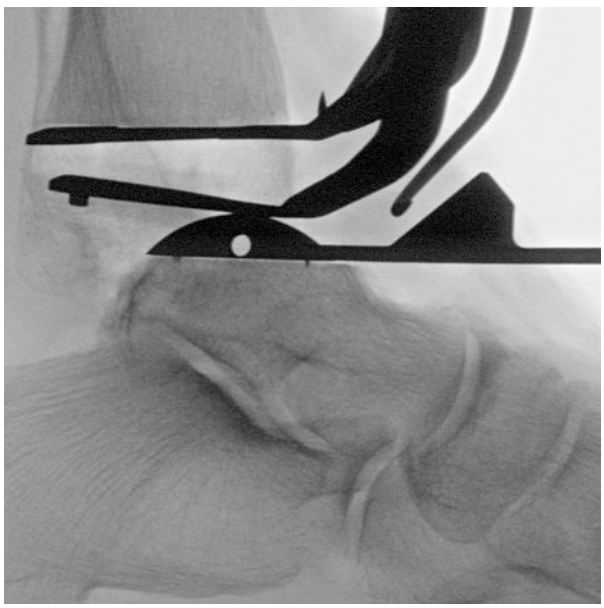


Fig. 13.8 A lateral x-ray will now confirm that the hole in the guide is directly above the lateral process of the talus



Fig. 13.9 The lollipop is removed leaving the two anterior pins in place

Otherwise, the saw could angle superiorly and leave too much bone on the talus. Should the saw miss the posterior bone, it is an indication the mill block is placed too posterior on the talus. The *Mill Tool (Router)* should be inserted through the first of the two slots in the chamfer guide (Fig. 13.12). Then, make two holes in the medial and lateral sides of the slots. Now, drive the *Router* forward back and forth until most of the bone is removed from the talus (Fig. 13.13). With the *Router* running, move the *Router* perpendicularly back and forth through the *Chamfer Guide* removing as much bone as possible within the constraint of the *Chamfer Guide*. Finally, remove the two anterior pins and cut the more dorsal chamfer bone by cutting about ¼ inch deep, again, to avoid the posterior structures (Fig. 13.14). Remove the

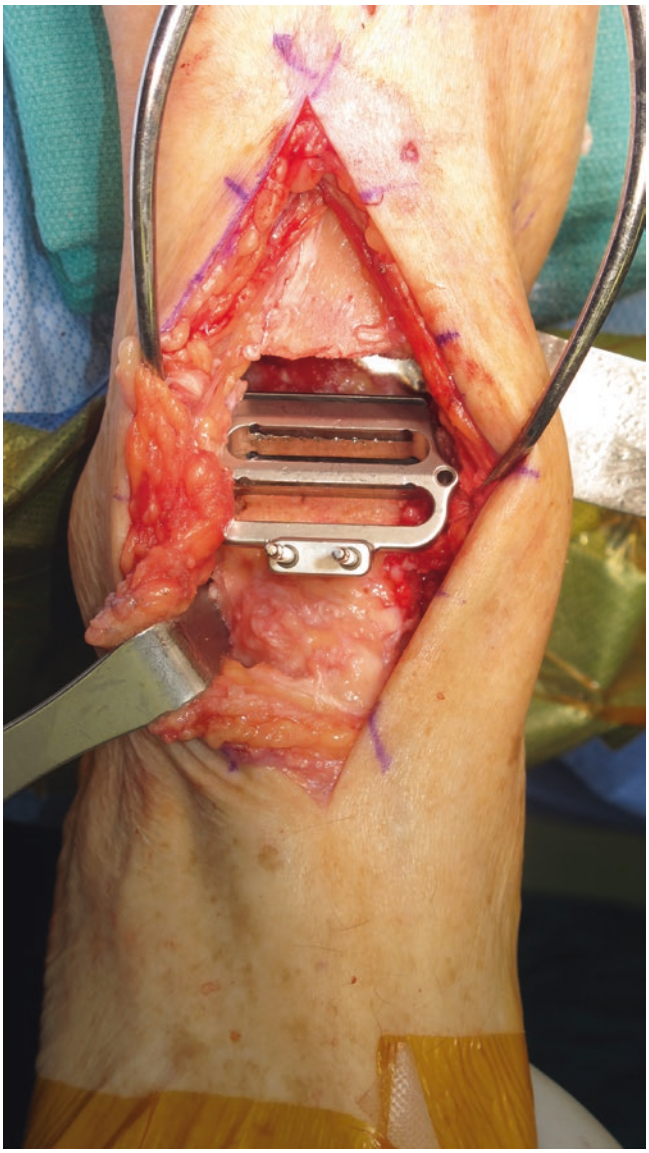


Fig. 13.10 The router guide is now placed over the two pins

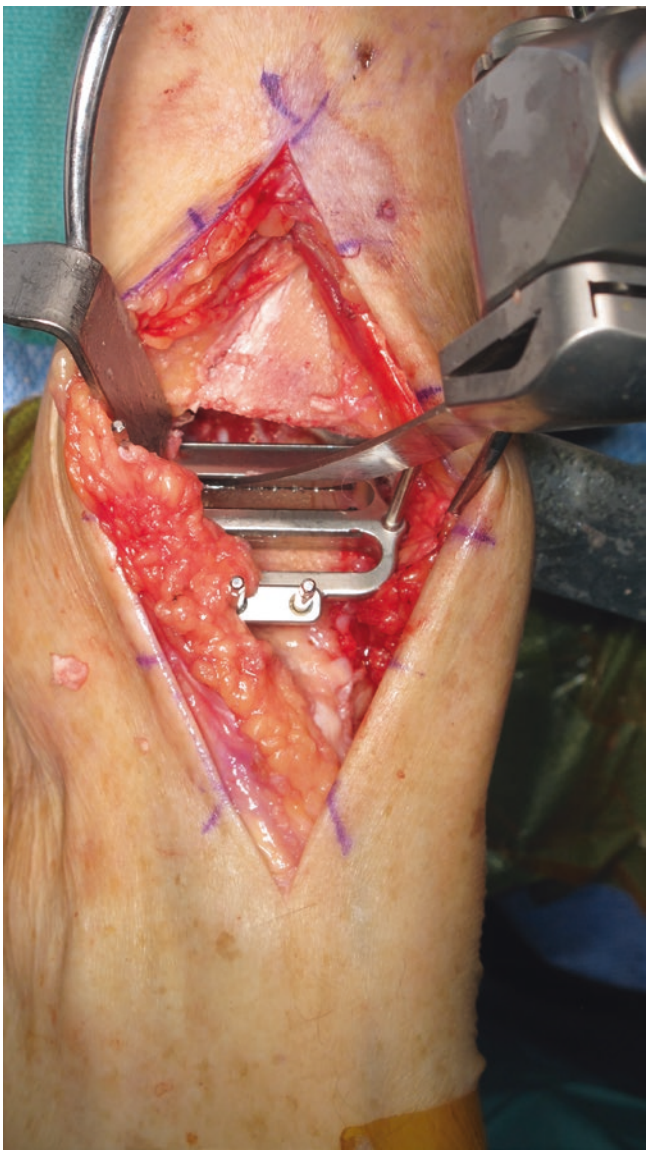


Fig. 13.11 The saw is now taken, and the bone is cut through the posterior slot in the router guide

remaining two pins securing the *Chamfer Guide*. Remove bone from the chamfer cut posteriorly (Fig. 13.15). Here, it is quite easy to use the small reciprocating saw to complete the chamfer cuts if there is any bone left medially or laterally on the talus. Remove any bone left in the ankle.

10. Remove approximately ¼″ of anterior talar bone in line with the cut surface of the top of the talus. This may be done with a Cushing rongeur or by using a small oscillating saw with a transverse cut made as deep as the dome curve (Fig. 13.16) and then removing it with a curved osteotome (Fig. 13.17). Here, you may use a small curved rasp to make sure the bone on the anterior talus is relatively flat (Fig. 13.18). Finally, take the *Large Rasp* that corresponds to the size of the talus and follow the curve of the talus you have created by removing the ¼ mm height of the chamfered bone on the dome of the talus (Fig. 13.19).
11. Insert the correct size of the *Talar Trial*. Place it all the way anteriorly and equidistant medially and laterally. Insert the *Screw* to hold it in place (Fig. 13.20). Now, insert the tibial trial, add a poly (Fig. 13.21), and take an x-ray to make sure you have placed the trials in the correct position. The *Talar Trial* should be directly on top of the talus and be equally spaced medially and laterally. If it is not, consider placing a smaller or larger *Talar Trial* in place and see if that fits better. You may have to

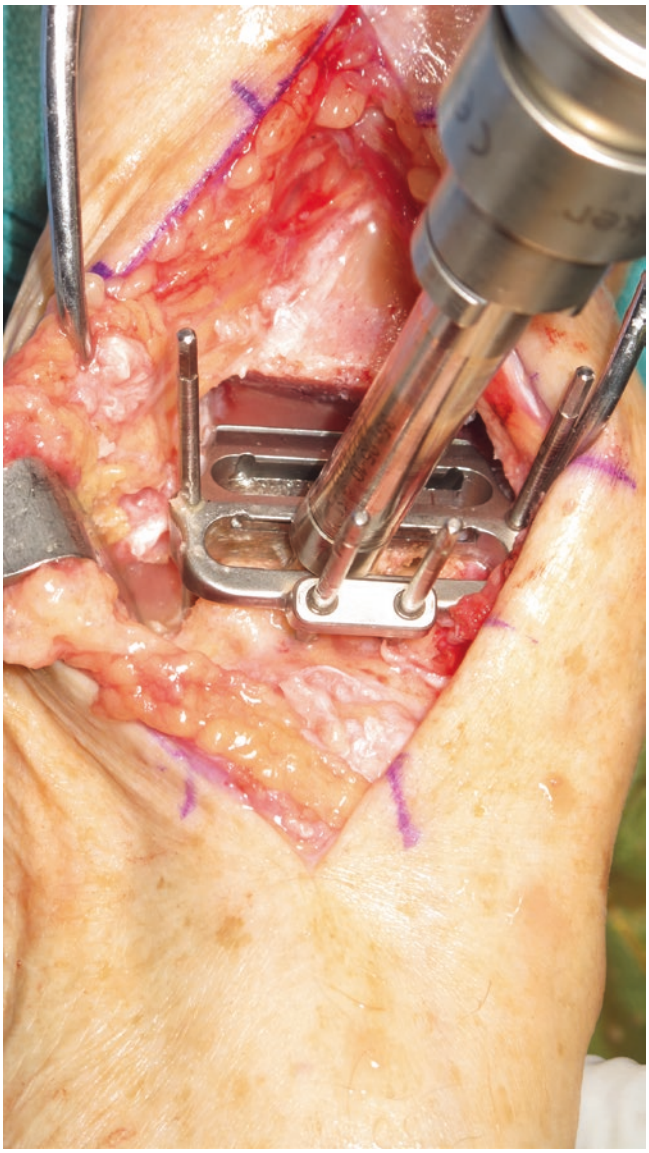


Fig. 13.12 The router is now used to make two central holes in the first slot and later the medial and lateral parts of the slot

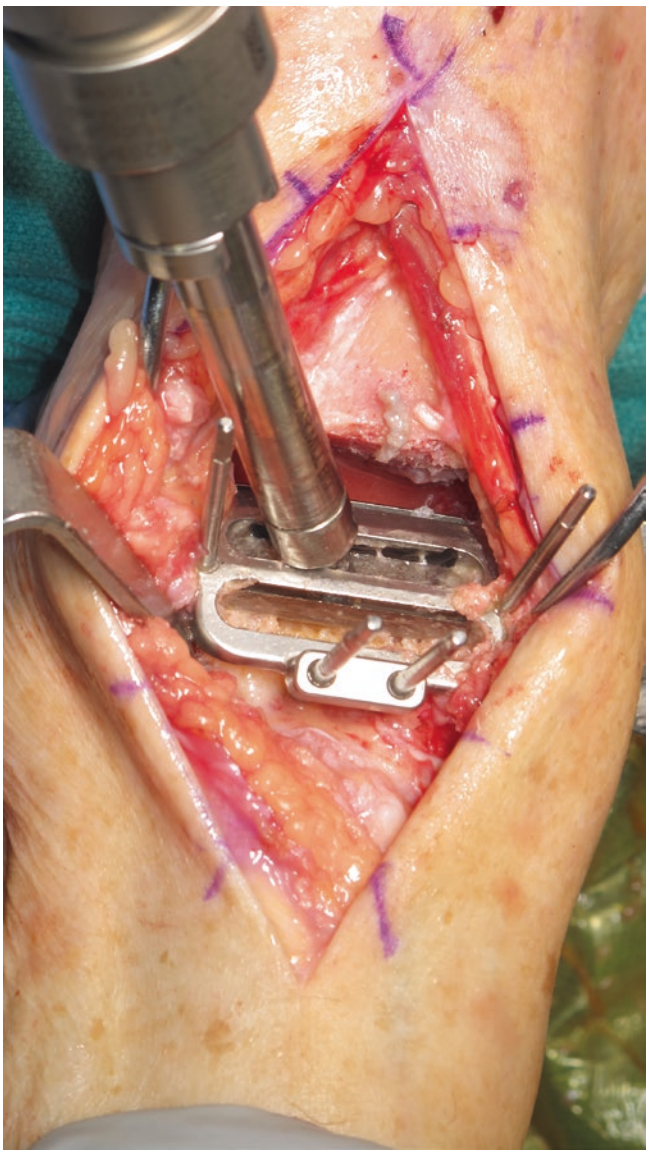


Fig. 13.13 By pushing the router forward and then later at a perpendicular angle, all the bone may be removed from the slot

rasp again and even look for the posterior chamfer bone that was missed. Once you have the correct position of the talus found, drill the two anterior holes that are used for fixation through the *Talar Trial*.

12. The *Tibial Trial* should be aligned against the medial malleolus, but may be adjusted based on the trial step through range of motion. Push the bottom of the heel to put pressure on the *Tibial Trial* or remove the *Talar Trial* and use lamina spreader to force the *Tibial Trial* into the bone. Then, secure the *Tibial Trial* in place making sure the anterior edge of the tibial trial is flush with the bone. If not, it can be adjusted anteriorly with the thumb screw. If you need it to move posteriorly, unscrew the thumb screw and push it back. It is critical to check with x-ray to make sure the tibial trial is in the proper position. The posterior slot will demark where the posterior pin will be located and the central slot denotes the cage. Finally, the anterior slot marks the anterior 2 pegs. Now, place pins in the *Tibial Trial*. Use the peripheral punch to make the holes for the prostheses' three pegs. Change to the center cage punch. Insert the larger punch, and when it is fully seated, rock medially and laterally and anteriorly and posteriorly and try to break off the portion of bone within cage hole creator. Inform the scrub nurse whether or not you have removed bone. If so, they will fully impact the cage with patient's own bone, and if not,

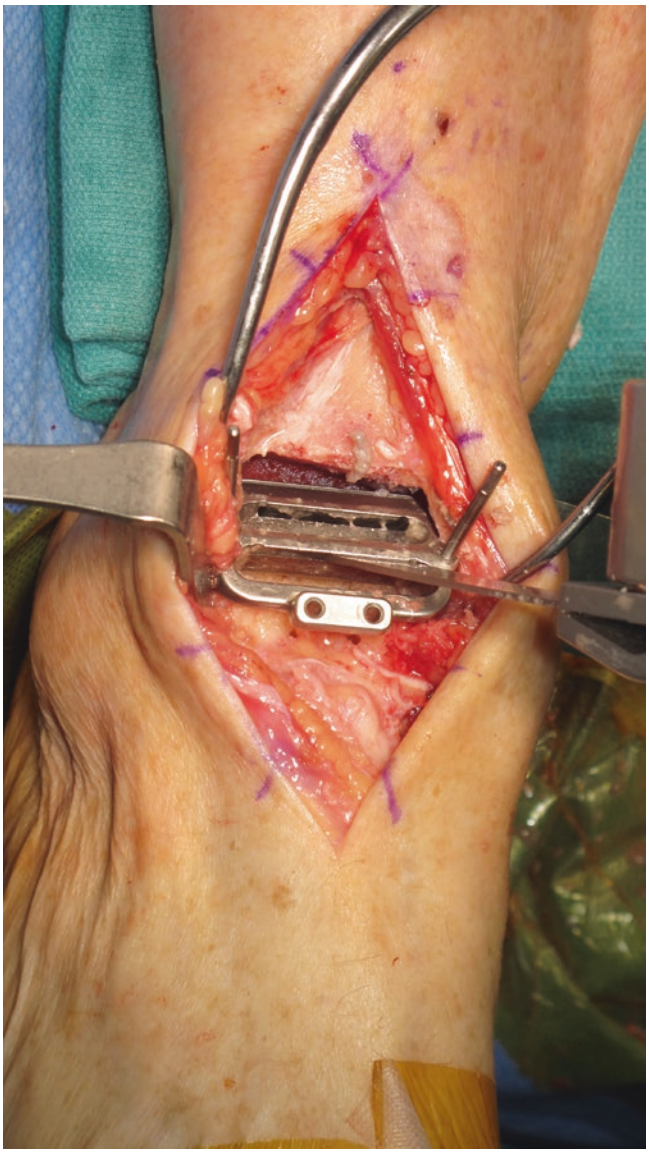


Fig. 13.14 The front pins are now removed, and the posterior chamfer cut is made

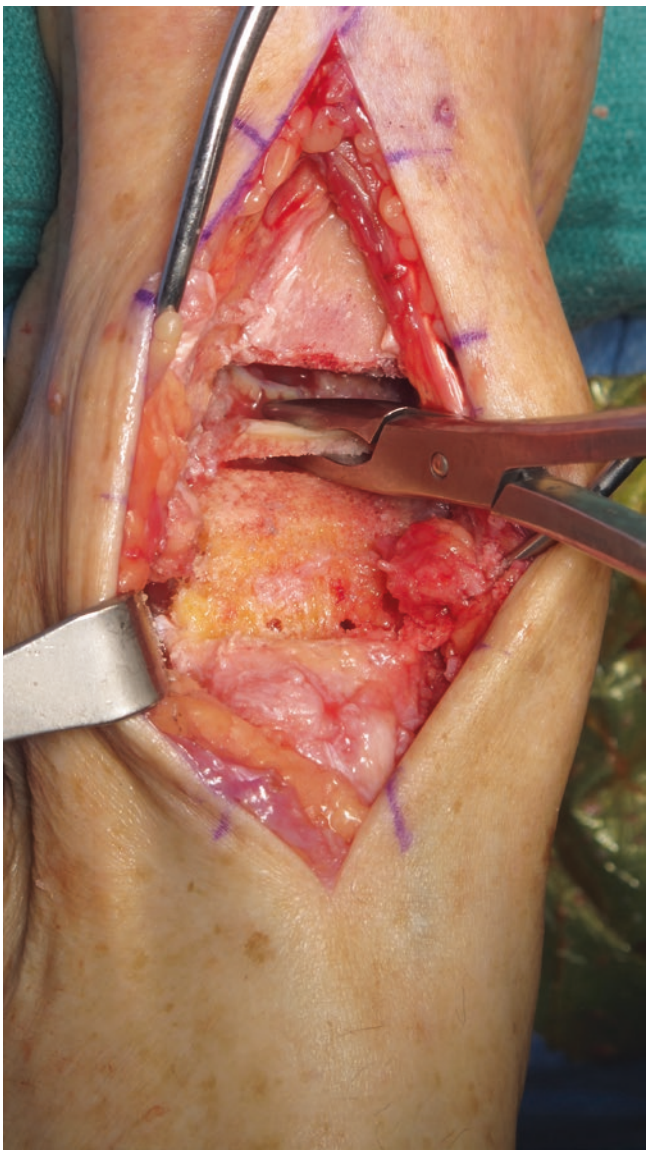


Fig. 13.15 The cuts posteriorly on the talus may be completed with a small reciprocating saw and removed with a rongeur

they will add only ½ bone height to the cage. Remove the tibial trial. In the case of hard bone, which is frequently present after fixation of a pilon fracture, it is recommended to revisit the peripheral and center holes with the punch after removal of the tibial trials.

13. Insert the *Tibial Component.* Using ink to outline the holes can help you see them in the shadows. The tibial inserter instrument may be used to guide placement of the tibial component. It can also be placed by hand using the spatula inside the *Tibial Component* and tap it home. Make sure you hit the posterior edge of the prosthesis with the spatula to drive in the posterior portion of the prosthesis. Now, you may take a square impactor and strike the *Tibial Component* to further drive it up. After this, take a lateral x-ray to make sure the *Tibial Component* is flush. If not, repeat the impaction technique. You do not have to worry about scratching the surface because the polyethylene component is fixed.
14. Insert the *Talar Component* into the two holes. Again, ink outlining the holes makes these easier to see in the shadows of the prosthesis. Once the pegs are in the

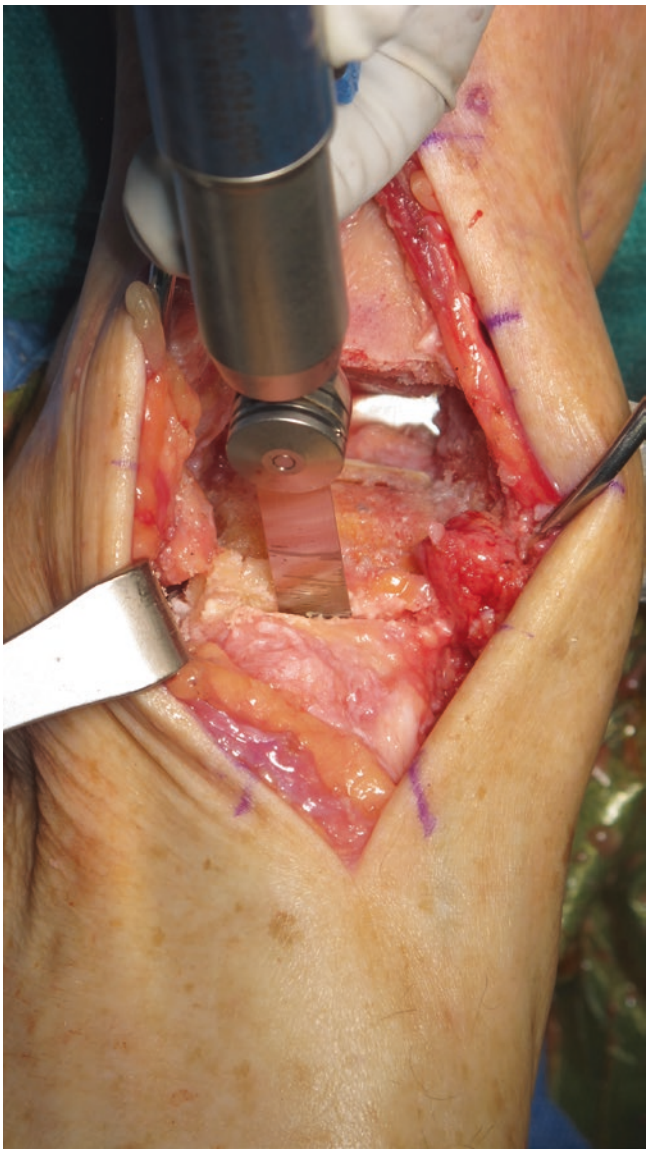


Fig. 13.16 To remove the bone anteriorly for the prosthesis flange, an oscillating saw may be used to make a cut about ¼ inch anteriorly from the rasped bone

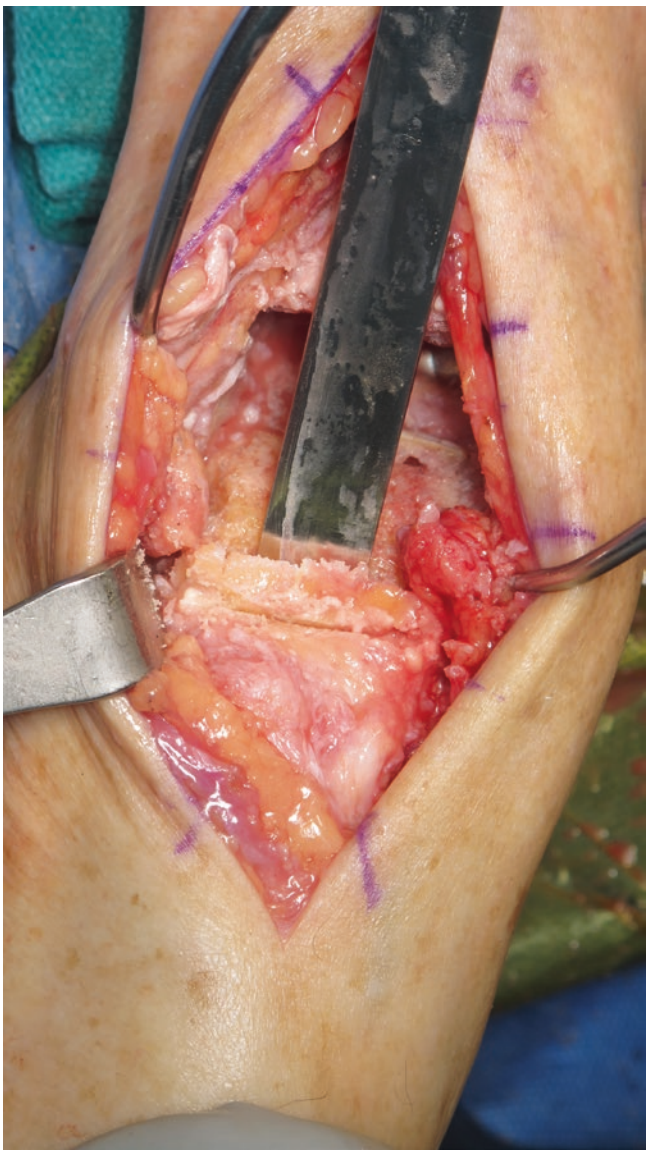


Fig. 13.17 Now a ½ inch curved osteotome can be used to remove the bone anteriorly

holes, you may use the talar impactor to drive the talar component all the way down.

15. Trial the *Polyethylene*. Pull down on the heel directly and make sure no gap greater than 1 mm exists. If it does, place a larger *Polyethylene* component in place. Test medial and lateral opening. If there is greater than 1 mm lateral opening, perform a medial release and try a larger poly. If the opening is laterally and you cannot overcome the lateral opening with a medial release and a larger polyethylene, then make a separate lateral incision and perform a Brostrom ligament reconstruction. Remember to remove the *Polyethylene* when you do this so you can get an extra tight repair.
16. When you are satisfied that stability exists, repeat an x-ray with the trial *Polyethylene* in place to make sure you have the component in good alignment. If you cannot achieve 10 degrees dorsiflexion, this is the time for the gastrocnemius recession [7] or triple hemi section of the Achilles tendon. When you are satisfied, remove the trial *Polyethylene*, and with your thumbs, insert the real *Polyethylene*. Make sure you are pushing it all the way posteriorly. If not, use an impactor to push it further.

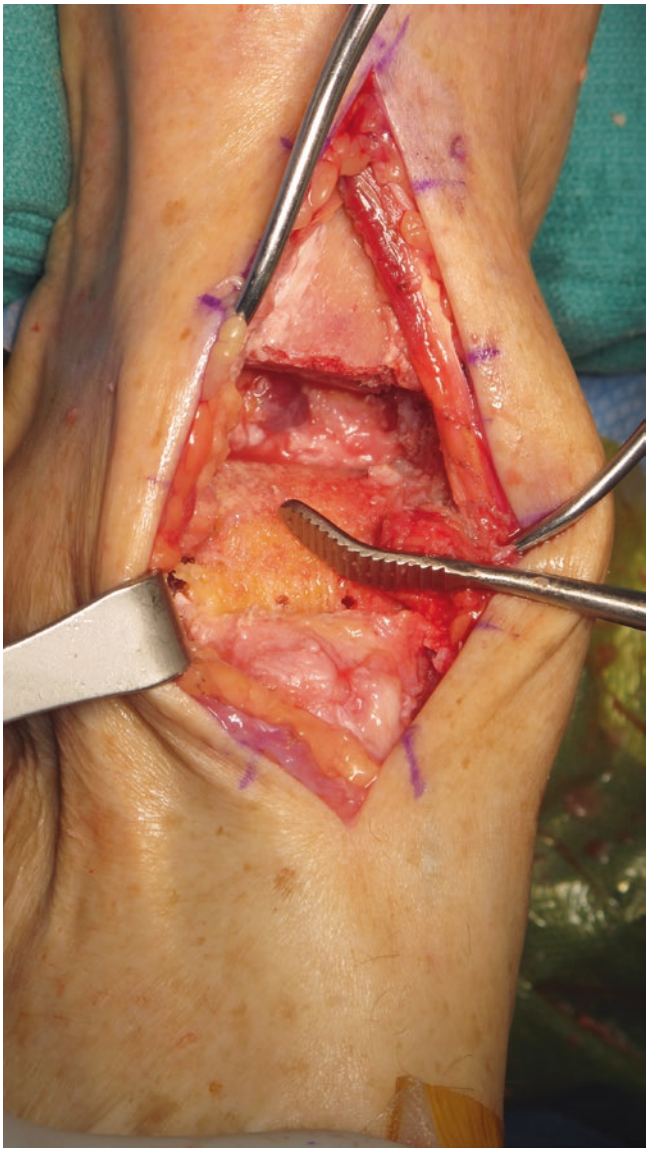


Fig. 13.18 A small nasal rasp may be used to smooth out the anterior talus

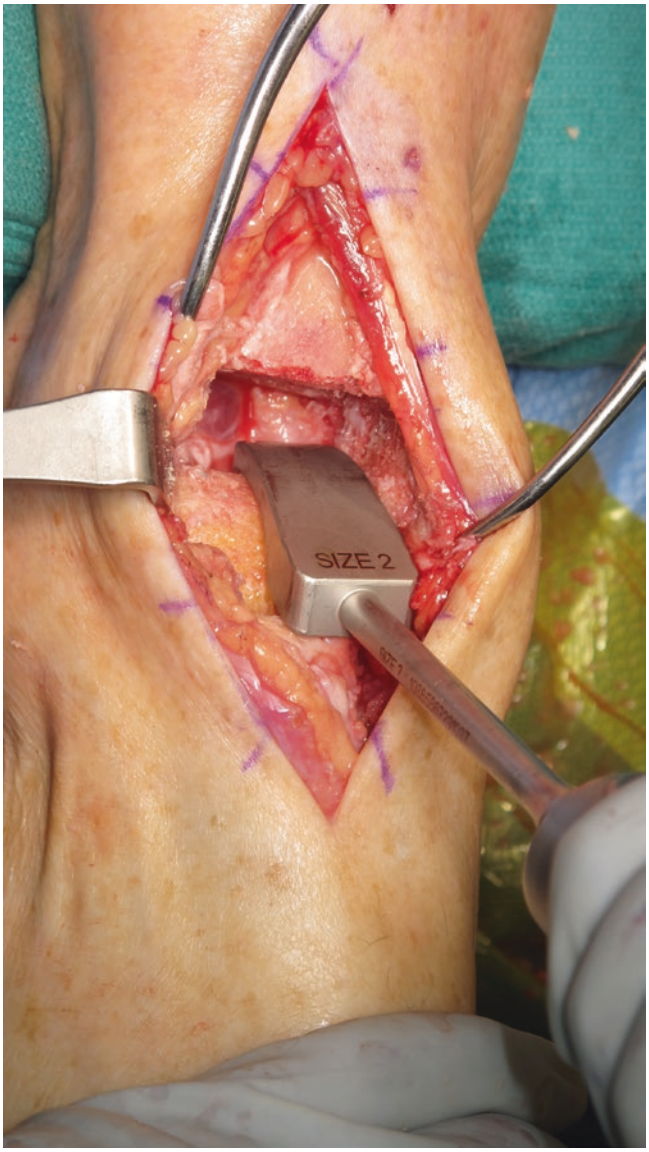


Fig. 13.19 Followed by the large curved rasp to smooth out the top of the talus

Then, insert the spring locking clip and ensure that the spring locking clip has pushed all the way down to the poly (Fig. 13.22). Take an x-ray and make sure everything is in the correct place (Figs. 13.23 and 13.24).

17. Close the deep ankle capsule with several stitches. Close the extensor retinaculum, then the subcutaneous tissue, and finally the skin. Place the leg in a firm compression dressing. We normally use a fiberglass case with extra padding to prevent irritation of the skin.

Thus far, over 2600 Vantage ankle replacements have been implanted worldwide in the last 3 years. The results are promising and will be published after a minimum two-year follow-up.

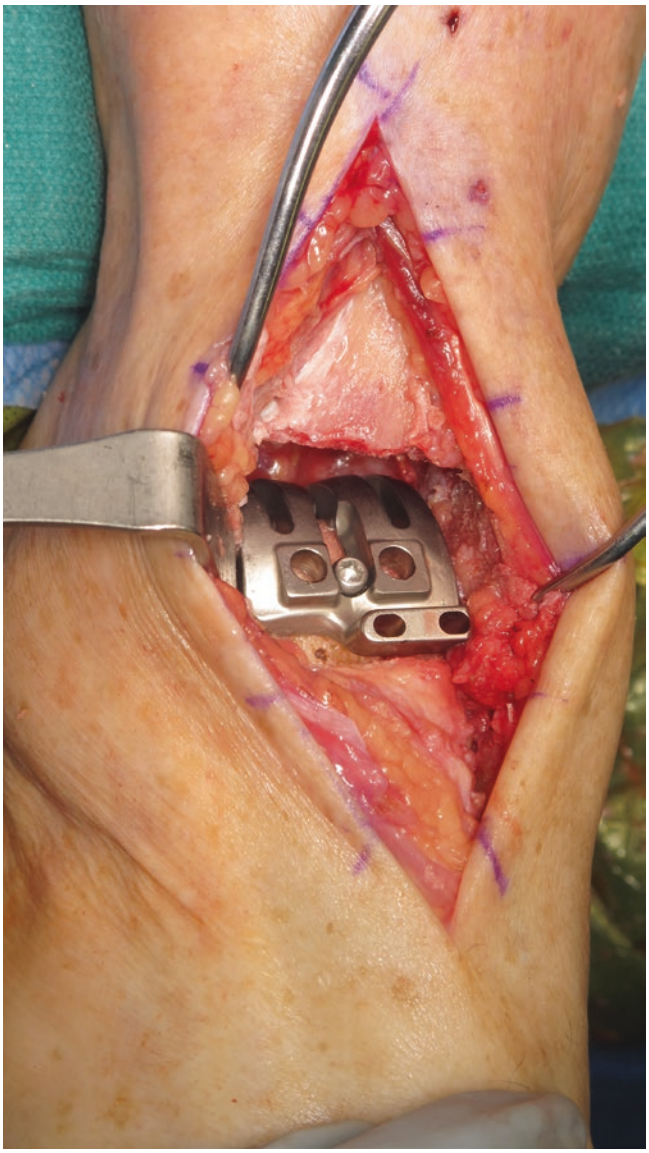


Fig. 13.20 The trial talus is now seated as far anteriorly as possible and secured with a screw being careful that you have placed the trial equidistant from the sides of the talus

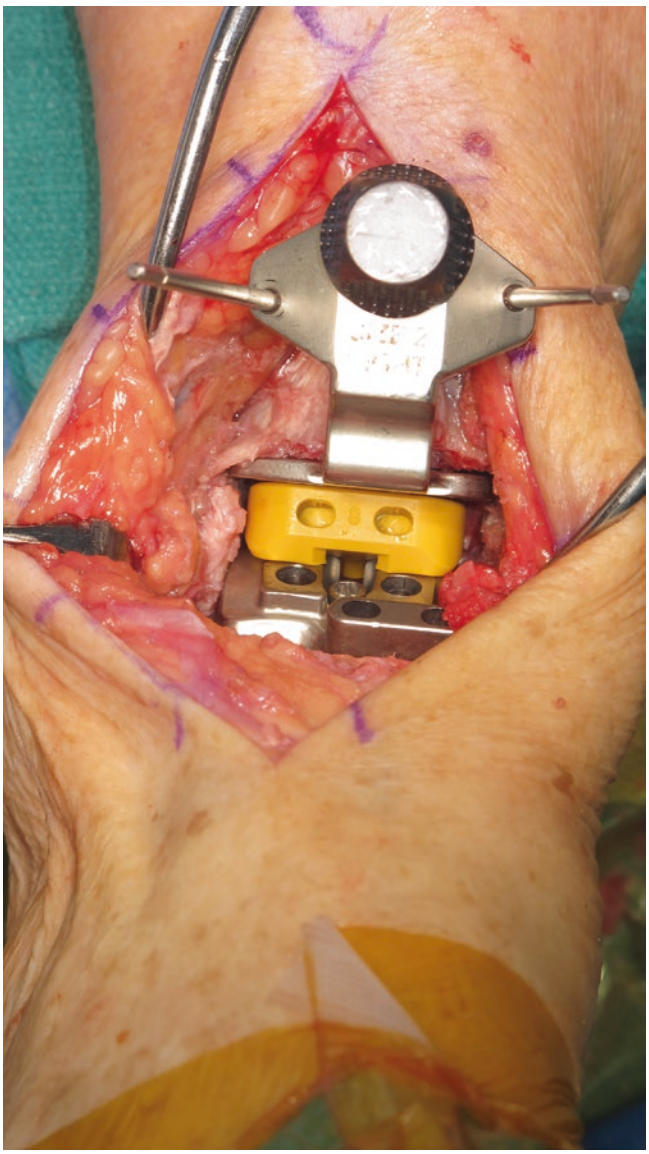


Fig. 13.21 The trial tibia is now inserted, a trial polythene is inserted, and once x-rays confirm proper position, it may be pinned in place

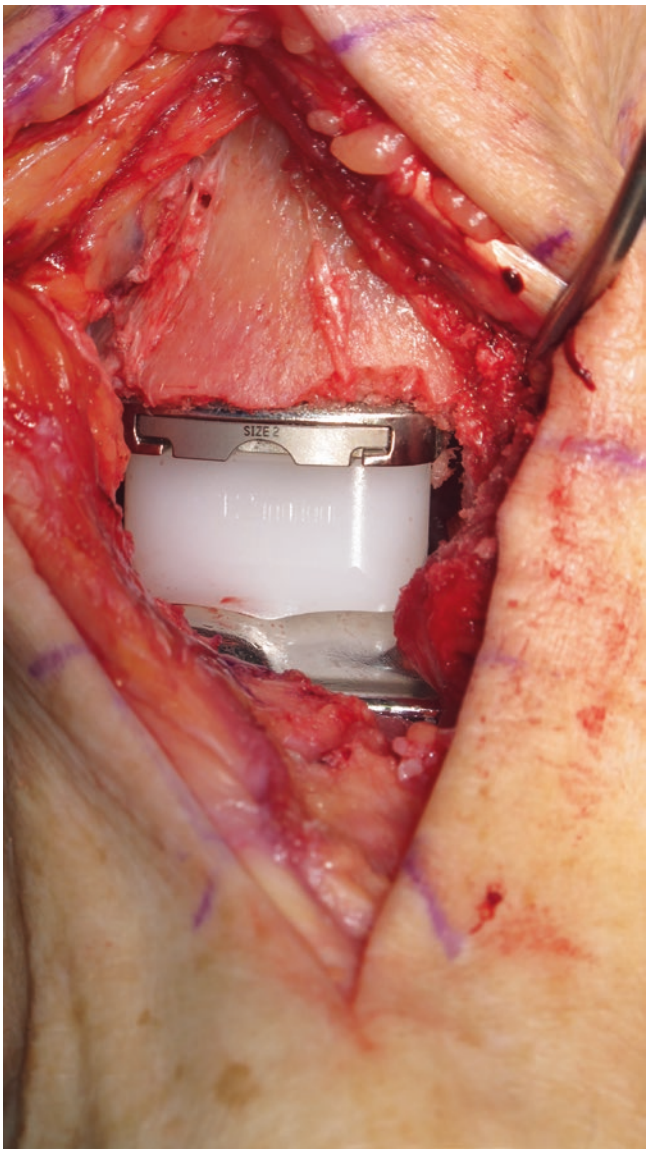


Fig. 13.22 The final prosthesis in place with the locking clip lying on the polyethylene confirming it is locked down



Fig. 13.23 Final AP x-ray with prophylactic medial malleolar screw in place



Fig. 13.24 Final lateral x-ray with prophylactic medial malleolar screw in place

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14 Hintermann Series H2 Fixed and H3 Mobile-Bearing Total Ankle Replacement Systems

James M. Cottom and Charles A. Sisovsky

Introduction

Total ankle arthroplasty (TAA) is an alternative to ankle arthrodesis for the treatment of end-stage ankle osteoarthritis (OA). TAA attempts to preserve functional range of motion (ROM), which would otherwise be sacrificed with ankle arthrodesis. The Hintermann Total Ankle Replacement System consists of a fixed- and mobile-bearing prosthesis, consisting of the H2 and H3 Series, respectively. The Hintermann TAA system was released in Switzerland in 2000 with the first short term study being published in 2004 [1]. It was first approved in the United States by the Food and Drug Administration in 2017 with the introduction of the H2 design and was first implanted in the United States in May 2018. Subsequently, the H3 design was FDA approved in 2019 and first being implanted in the US in September 2019, both by the lead author.

Design Rationale

The Hintermann Total Ankle Arthroplasty system is composed of two designs: the H2 fixed-bearing and the H3 mobile-bearing. Both designs use the identical surgical approach, including instrumentation. The H2 system requires the use of cemented implants in the United States; however, the H3 system does not. In the H3 design, the tibial and talar components are double-coated with titanium plasma spray and hydroxyapatite for uncemented or biologic fixation.

The Hintermann ankle uses all available bone surfaces for support. The anatomically shaped flat tibial component (Fig. 14.1) and talar components essentially resurface the tibia and the talar dome, respectively, and wings on the talar component replace degenerate medial and lateral gutters, which is a potential source of pain. Both the tibial and talar components are anatomical in shape to minimize contact stresses. A minimum of 2–3 mm and 4–5 mm of bone resection is required for implantation of the tibial and talar components of the H3 and H2 Series, respectively. On the tibial side, most importantly, the bony architecture is intact, and particularly, the anterior cortex is preserved. On the talar side, additional support is provided anteriorly by a shield, and press-fit is provided by the slightly curved wings on the medial and lateral aspect of the implant [1].



Fig. 14.1 Anatomically shaped flat tibial cut with 6 pyramidal peaks and an anterior shield to allow fixation to the tibia and to minimize stress shielding

The tibial component consists of a flat, 4-mm thick loading plate with six pyramidal peaks facing the tibia and an anterior shield that allows fixation to the tibia. This fixation concept prevents stress shielding from occurring.

The talar component is conically shaped with a smaller radius on the medial side. The articular surface has a 2.5-mm high rim on the medial and lateral side, which ensures a stable position and guided rotation of the polyethylene inlay. Furthermore, the design allows for maximum contact of the

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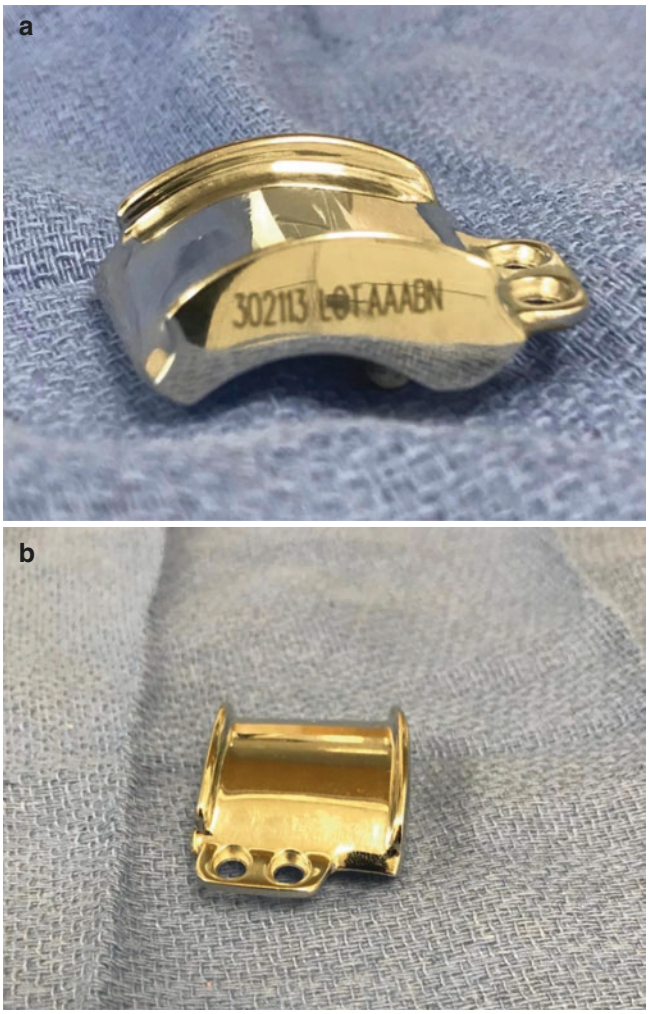


Fig. 14.2 (**a**) Lateral and (**b**) anterior views of the talar component highlighting the 2.5 mm medial and lateral rails with an anterior shield to increase stability in the sagittal plane and to prevent adherence of scar tissue that might restrict motion

polyethylene insert with the metal components. The anterior shield increases the bone support on the weaker bone at the talar neck to increase stability in the sagittal plane and to prevent the adherence of scar tissue that might restrict motion (Fig. 14.2a, b).

Overall, the uniqueness of this implant is that it uses patient-specific, physiologic anatomy to reduce wear and inversion-eversion stress. Furthermore, it is crucial to allow the talus to intraoperatively find a position that corresponds to the patient's individual anatomy [2]. Finally, it is also important to note that the H3 system requires stability in the coronal plane, for example, an intact or stable/fused syndesmosis before implantation [3].

Indications

The primary indications for the Hintermann Series H2 and H3 TAA systems are for the treatment of end-stage ankle arthritis most commonly from rheumatoid, post-traumatic, or primary arthritis. The H2 system is also indicated for patients with failed previous ankle surgery and for revision surgeries following failed TAR or nonunion/mal-union of ankle arthrodesis, provided sufficient bone stock is present. The patient must also have an adequate soft-tissue envelope to allow for safe and appropriate closure over the prosthesis. Furthermore, the vascular health of the limb must be thoroughly evaluated.

Body mass index and age are also two factors to seriously consider when counseling patients who desire a TAA. It has been reported that good outcomes can be expected short and long term with TAA despite the presence of obesity [4, 5]. In a study by Barg et al. in 2011, they looked at 123 TAAs performed in patients with a mean BMI of 32.9 kg/m^2 and with a mean age of 59.8 years. The authors noted the TAA survival rate at 6 years was 93% and that they did not observe any trend for obesity to influence the rate of aseptic loosening in TAA [6]. With respect to age, in a study by Rodrigues-Pinto et al. involving 103 TAAs, they found that younger patients (<50 years old) displayed better clinical and functional scores while having comparable complications and survivorship rates as older patients with a mean follow-up of 3.5 years [7]. Similarly, in a study by Cottom et al., 112 total ankle replacements were evaluated over a 5-year period. They found that there was no statistical difference in complication rates between 3 different age groups. Furthermore, there was no statistical difference in pre- and postoperative AOFAS and FFI scores between the three groups [8].

Contraindications

Active infection, avascular necrosis (AVN) of more than one third of the talus, unmanageable instability and malalignment, neuromuscular disorder, Charcot neuroarthropathy, suspected or documented metal allergy or intolerance, and highest demands for physical activity (eg, contact sports and jumping) are the most common contraindications for TAA. Some controversial indications for TAA are diabetic syndrome without polyneuropathy and AVN of the talus with less than one third of the bone being affected [9].

Procedure Technique

The patient is placed on the operating table in a supine position. A small bump is placed under the ipsilateral hip to ensure the tibial tuberosity is facing directly upward. The foot and leg are then exsanguinated, and a thigh tourniquet is inflated. A 10-cm longitudinal incision is then made 1 cm lateral to the tibial crest at the lateral aspect of the tibialis anterior tendon and is anteriorly centered over the ankle between the tibialis anterior and extensor hallucis longus tendons. The superficial peroneal nerve will be visualized

and should be retracted laterally. At this time, the extensor retinaculum is incised between the tibialis anterior and extensor hallucis longus tendons. The authors prefer to tag the retinaculum at this stage so there is no trouble locating it during final closure. At this point, the deep peroneal nerve and anterior tibial artery should be identified and retracted laterally and dissection is carried down to the ankle joint for the full length of the incision. It is important to visualize the medial malleolus and the most lateral aspect of the distal tibia. Releasing the tissue over the superior-lateral talar neck may help with the visualization of the lateral aspect of the joint. The ankle joint is now fully visualized, and any spurs on the distal tibia, especially laterally, can be removed with an osteotome or rongeur. It is important to identify the tibial plafond at this time as it will help with setting the extramedullary jig in the appropriate position. It is at this time that the authors recommend placing prophylactic guidewires in the medial malleolus to reduce the chance of intraoperative fracture.

Placement of the Extramedullary Jig and Preparation of the Tibia

The tibial positioning jig with the attached tibial cutting block is placed around the proximal tibia at the level of the tibial tuberosity (Fig. 14.3). Attention must be paid not to expose the fibular head to compression (of the common peroneal nerve). A half-inched straight osteotome can be placed within the joint and can be used as a reference point for how distal to place the cutting guide. The tibial rod must be placed parallel to the anterior border of the tibia in the sagittal plane and in the center of the tibia in the coronal plane. The tibial rod to the anterior border of the tibial crest should be equidistant from the proximal aspect of the rod to the distal aspect of the rod. This can be measured objectively by holding the shank of the screwdriver and ensuring the distance from the tip of the screwdriver to your fingers is the same, proximally and distally (Fig. 14.4a–c).

Next, the distal tibial cutting block is moved proximally until the desired resection height is achieved. It is at this time where the authors recommend utilizing the angel wing in order to determine the proper amount of bone to be resected from the tibia, which is confirmed under fluoroscopic imaging (Fig. 14.5a, b). As a general rule, a resection of approximately 2–3 mm from the apex of the tibial plafond is desired if implanting the H3 Series and 4–5 mm if using the H2 Series.

In varus ankles, more tibial resection is needed, whereas in valgus ankles or in the presence of increased joint laxity, less bone resection is advised. Fluoroscopic imaging is then used to determine the varus/valgus alignment of the tibial cutting block. Finally, the rotation of the tibial cutting block is assessed by making sure the medial aspect of the cutting block is parallel to the medial surface of the talus. Once the desired rotational position is confirmed, the inferior screw is tightened.



Fig. 14.3 Application of the extramedullary jig at the level of the tibial tuberosity, ensuring you are parallel to the tibial crest

Now that all planes of the tibial cut guide have been confirmed, a 2.4 mm K-wire is inserted in the medial aspect of the tibial tuberosity through the extramedullary tibial positioning jig. Next, 2 converging shoulder pins are placed in the tibial cutting guide (Fig. 14.6). Typically, the size medium capture cut guide is used to protect the medial and lateral malleoli. A transverse distal tibial cut is made through the window of the tibial cutting block. Careful attention is paid

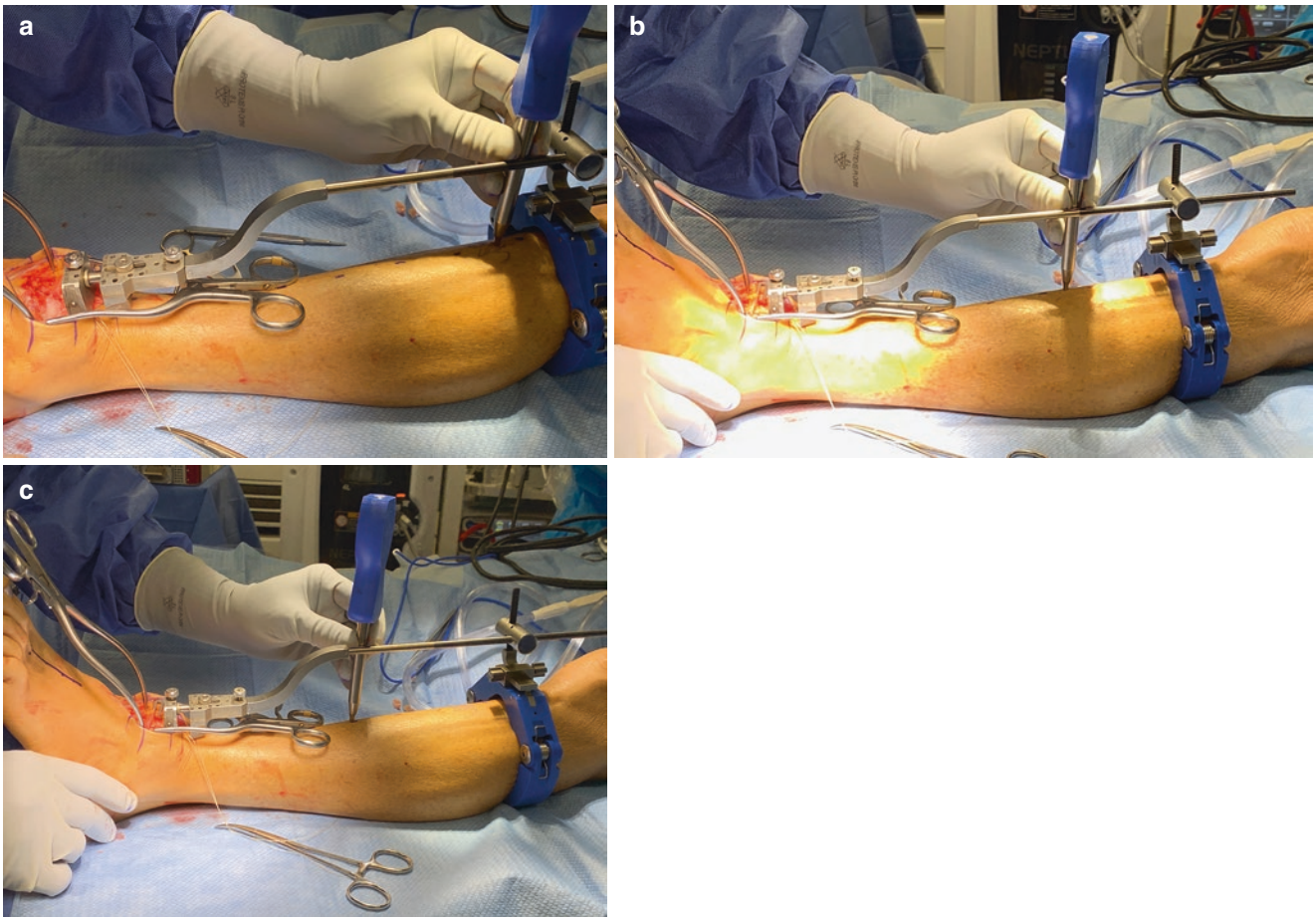


Fig. 14.4 Measuring the tibial crest-to-rod distance proximally (**a**), centrally (**b**), and distally (**c**)

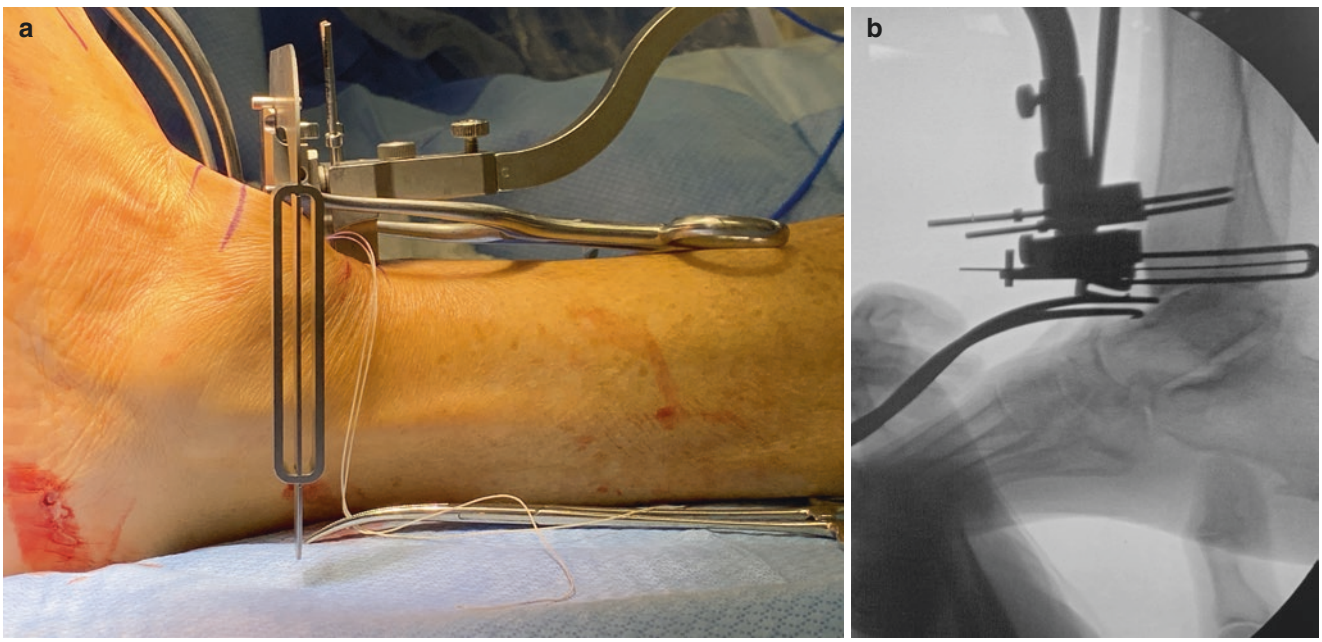


Fig. 14.5 (**a**) Angelwing within the tibial capture cut guide. (**b**) Fluoroscopic image of angelwing to determine the desired resection of the tibial cut

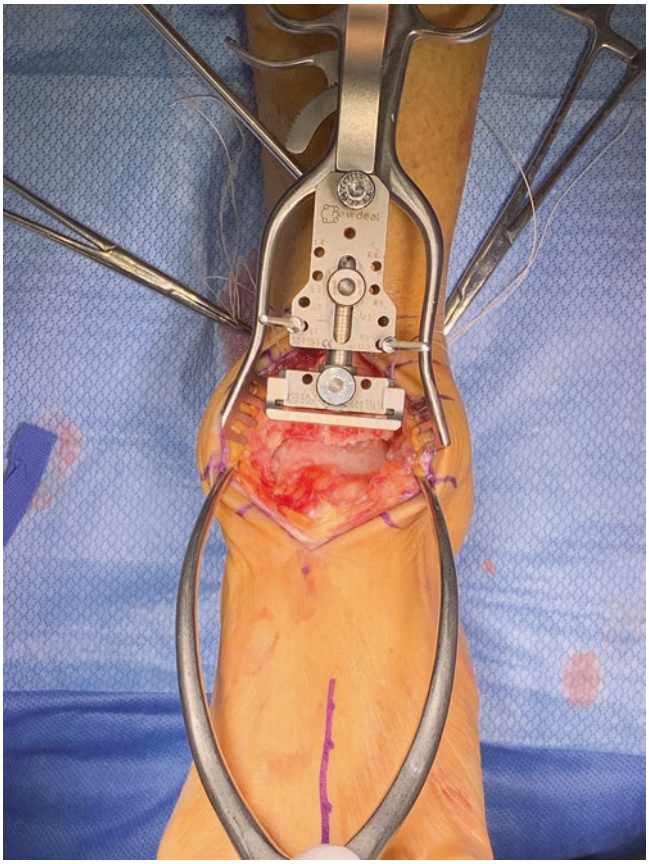


Fig. 14.6 Converging shoulder pins securing the tibial capture cut guide to the tibia



Fig. 14.7 Horizontal tibial cut ensuring to keep the blade anterior to posterior so as to not cut the malleoli

to direct the saw blade from anterior to posterior and not cut into the malleoli (Fig. 14.7). Next, A Hintermann distractor is used to distract the ankle joint. Two 2.4 mm K-wires are inserted on the anteromedial aspect of the distal tibia above

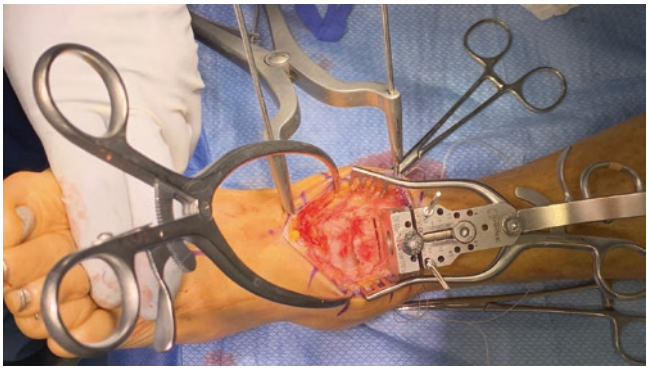


Fig. 14.8 Hintermann distractor placed medially to gain access to the ankle joint

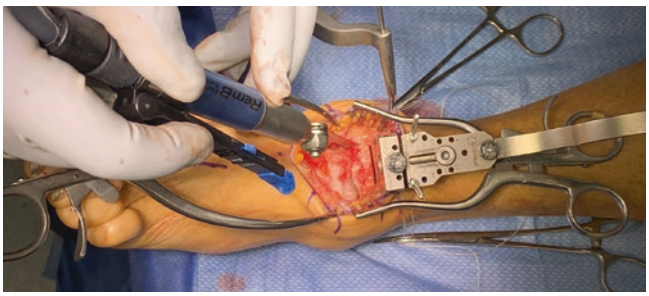


Fig. 14.9 Completing vertical tibial cut medially utilizing a sagittal saw

the horizontal cut in the distal tibia and one in the anteromedial aspect of the talus placed medially so it will not interfere with the talar preparation (Fig. 14.8). The Hintermann distractor is primarily used to distract the ankle joint to allow the surgeon access to perform the medial tibial cut. Its secondary uses are to assist in retrieving residual bone debris and for easier implantation of the trial inlays and final poly, as needed. It is the author's recommendation to leave the pins for the Hintermann distractor in place until all components have been successfully inserted.

Next, a sagittal saw is then used to finalize the cuts, particularly for the vertical cut on the medial side. The medial vertical cut should be in line with the medial gutter and meet the horizontal cut at 90° being careful not to damage the neurovascular structures posterior-medially. It is the authors' recommendation to use a sagittal saw to perform this cut (Fig. 14.9). Remove the resected tibia with a curved osteotome or rongeur. It is the authors' recommendation to utilize the green chisel to pry the resected tibial piece while leveraging on the extramedullary jig (Fig. 14.10a, b). It is important not to rush this step as you will likely break the resected tibia. If this does occur, use the sagittal saw to cut the resected tibia into thirds, remove what you can, and once the talus has been resected, you will be able to retrieve any deep portions of the remaining tibia.

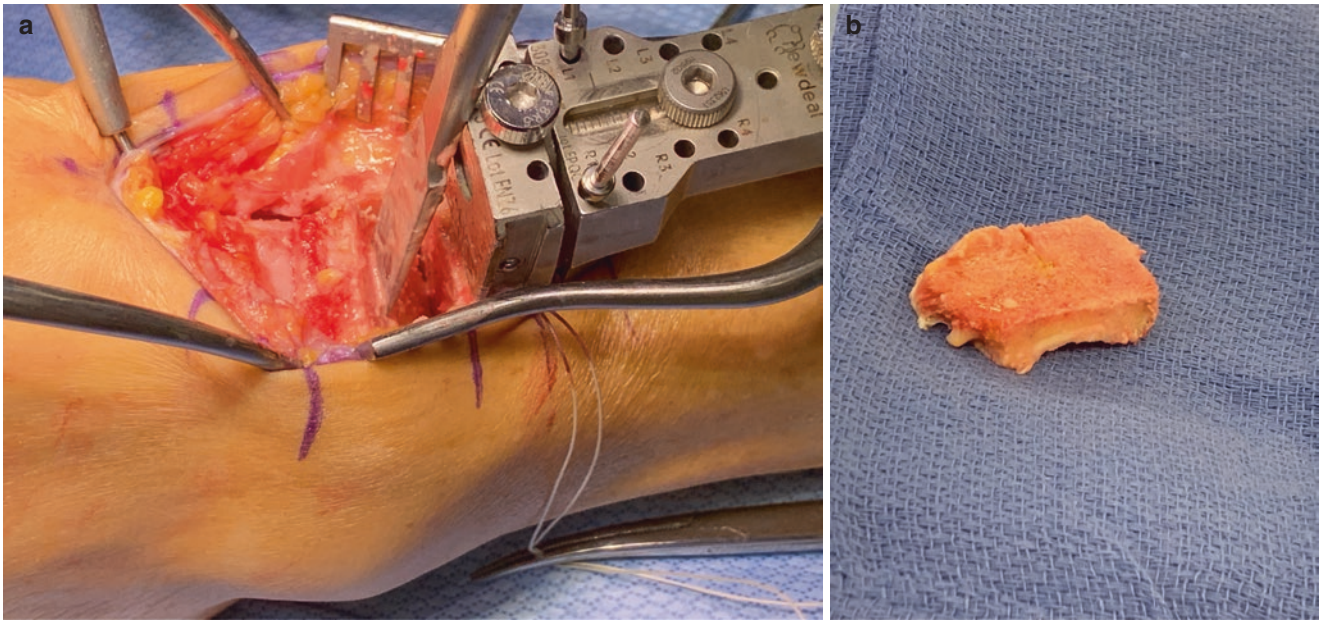


Fig. 14.10 (**a**) Utilizing the green chisel to remove resected tibia by leveraging against the extramedullary jig. (**b**) Anterior-to-posterior and dorsal-to-plantar views of the fully resected tibial piece. This is an example of a 4 mm resection

Preparation of the Talus

Insert the talar cutting block into the tibial cutting block. The Hintermann distractor is disengaged, the central screw is unlocked, and the distal tibial cutting block is translated distally as possible to properly tension the collateral ligaments. The foot is placed in neutral position, and the ankle is placed at 90-degrees with the heel in slight valgus. The central screw is then retightened, and two pins are placed medially and laterally to secure the talar cut guide to the talus (Fig. 14.11). It is important to make sure the talar paddle is in contact with the superior aspect of the talus. This can be confirmed by direct visualization as well as with C-arm (Fig. 14.12).

The resection of the talar dome is performed with the oscillating saw in a captured cut guide. The extramedullary jig is now removed, and the superior talar cut can be removed. At this time, it is important to make sure there is no bone remaining that could impact final implant placement. If there are any areas that need to be removed, a power rasp is the authors' preferred method to achieve this. We will also use copious amounts of irrigant solution with pulse lavage to remove any small debris of bone within the joint (Fig. 14.13). Next, the tibial depth gauge is then used to determine the size of the tibial component by inserting the depth gauge so the posterior edge hooks around the posterior tibia (Fig. 14.14). The measurement is read from the scale on the depth gauge, located on the upper side of the anterior tibia. It's important

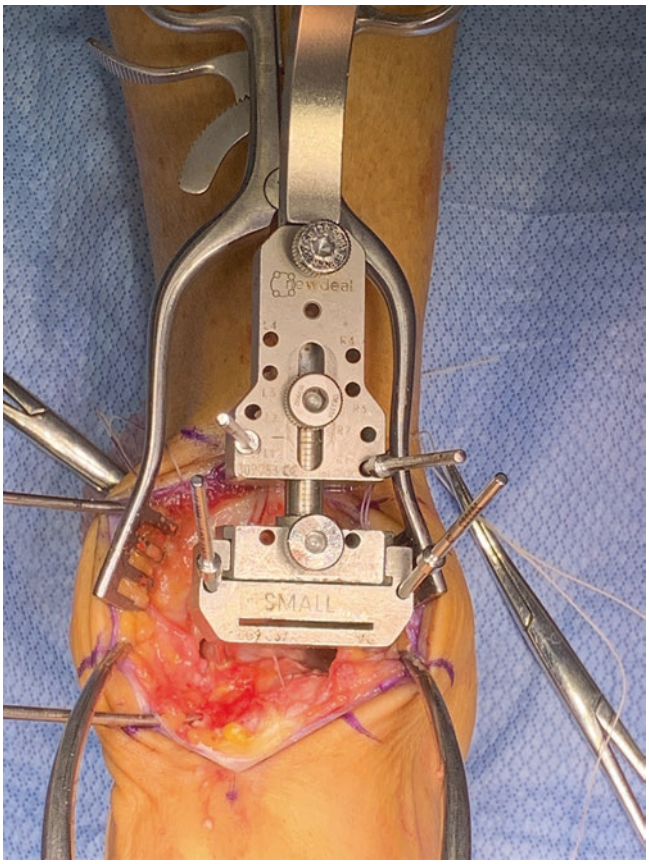


Fig. 14.11 Talar capture cut guide inserted onto the tibial cutting block and pinned into place

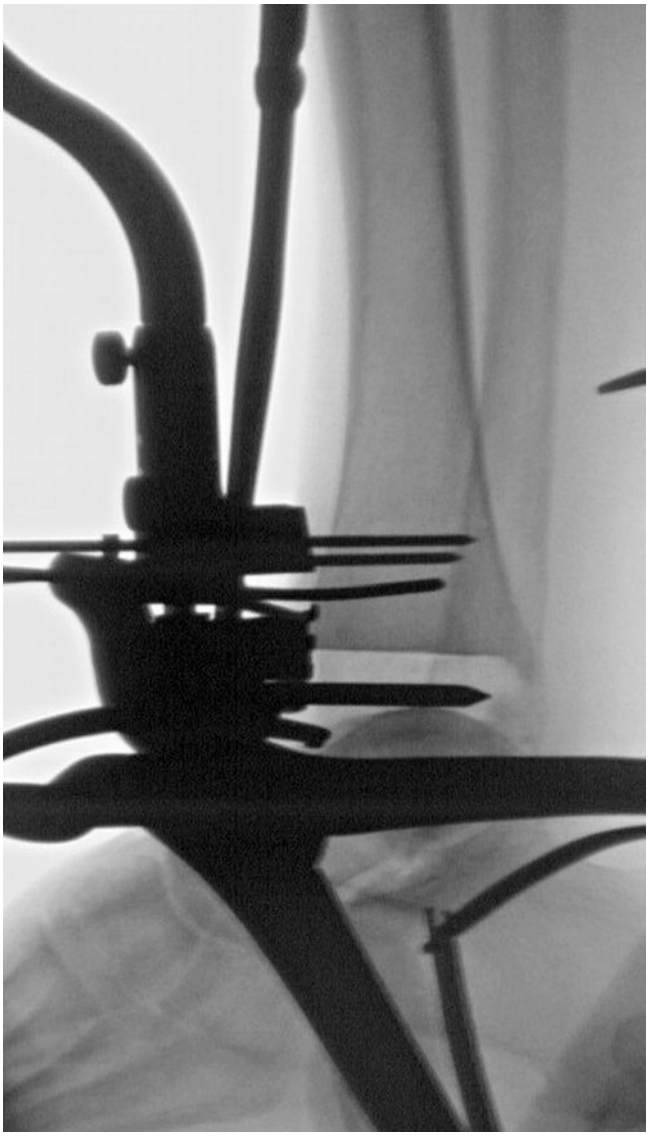


Fig. 14.12 Fluoroscopic imaging confirming proper placement of the talar cut guide. Note the talar paddle is flush with the superior aspect of the talus



Fig. 14.13 Pulse lavage system mixed with anitibiotics used to irrigate bone debris within the ankle joint

to note that if the anterior tibia is between two marks, the larger size should be selected.

Once the tibial size is confirmed, the appropriate talar size, which must be within one size of the tibial component, is chosen. The selected talar cutting guide is placed on the flat surface of the talus maintaining the hooks carefully positioned on the posterior aspect of the talus, and the guide is flush with the superior talus. Using fluoroscopic guidance, it is recommended to obtain a lateral x-ray to ensure the hooks of the talar cut guide are flush to the posterior aspect of the talus (Fig. 14.15). Prior to securing the cutting guide to the talus, you must have at least 2-mm on the medial side and 1–3 mm on the lateral side of the talus. If margins are larger or smaller than indicated, the surgeon chooses a size up or down, ensuring that the size is matched to the tibial implant size +/− one size.

It is important to ensure that the handle of the talar cutting guide is parallel to the second ray, while the foot is in neutral position. Once confirmed, the cut guide is secured to the talus using 2–4 pins (Fig. 14.16). The handle is then removed, and the posterior cut is made through the posterior slot using the oscillating saw blade. Medial and lateral cuts are made using a reciprocating saw paying attention that the saw blade strictly follows the cutting guide. It is important to remember that the medial side cut is approximately 6 mm deep, and the lateral side is approximately 8 mm deep (Fig. 14.17). Finally, the anterior aspect of the talus is reamed with a 6 mm diameter talar reamer, making sure it is perpendicular to the slot and goes as deep as possible to the end-stop (Fig. 14.18). The pins and the talar cut guide are then removed. It is the author's recommendation to use a 4 mm straight osteotome and mallet to retrieve the medial and lateral talar cuts (Fig. 14.19a, b). The authors also recommend utilizing a power rasp to remove any residual bone from the tibial and talar cuts to ensure proper fitting of the implants (Fig. 14.20).

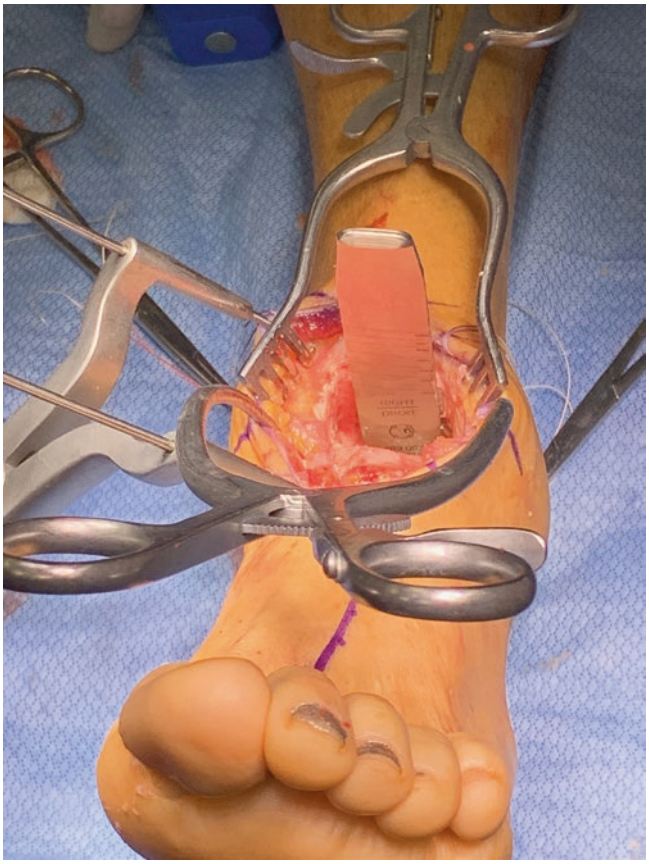


Fig. 14.14 Tibial measuring guide. Remember the measurement is read from the superior surface of the guide with respect to the anterior tibial cortex

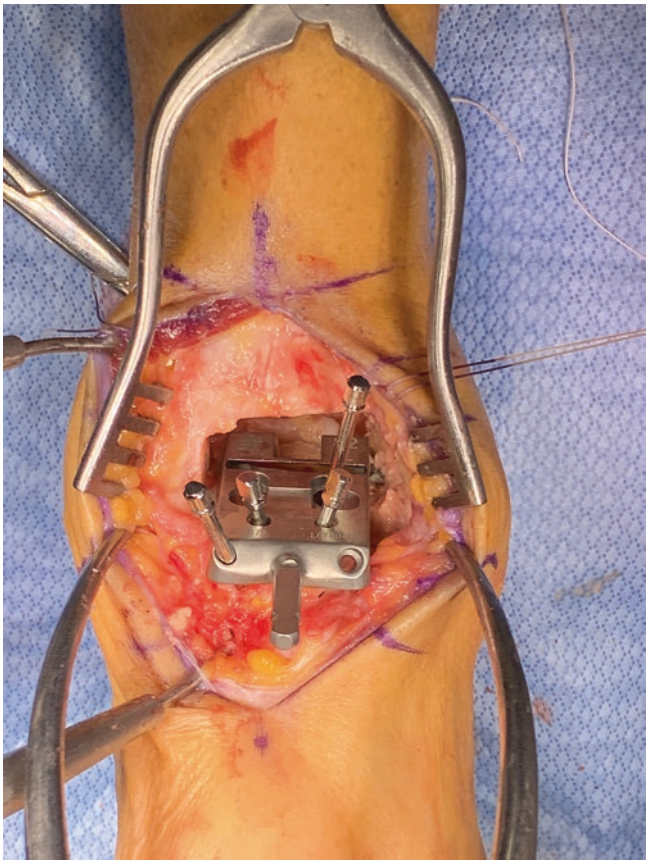


Fig. 14.16 Placement of the talar cut guide ensuring at least 2 mm of bone medially and 1–3 mm laterally. You can appreciate the slot for the posterior chamfer cut on the talus

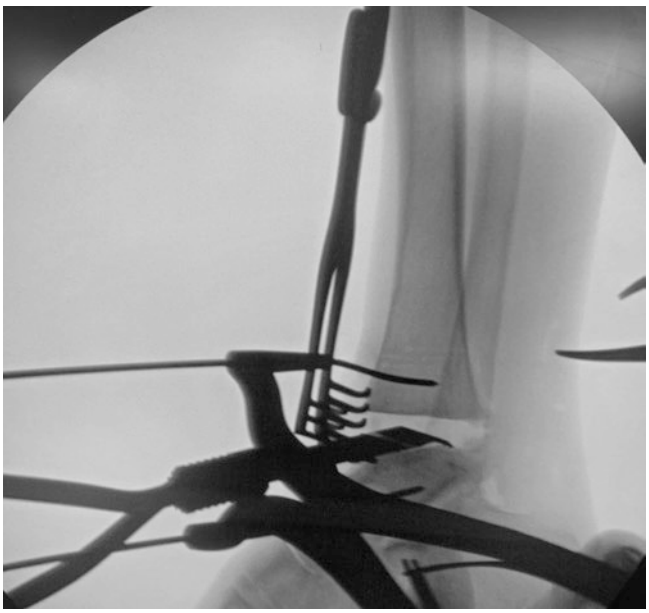


Fig. 14.15 Fluoroscopic image showing the prongs of the talar cut guide adequately seated along the posterior aspect of the talus and the cut guide flush with the superior talus

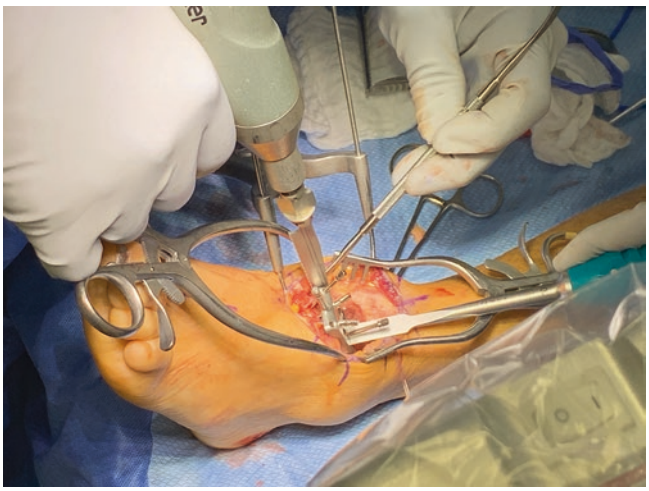


Fig. 14.17 Securing the talar cut guide while using the reciprocating saw to perform the medial and lateral chamfer cuts. Medially is 6 mm deep, while laterally is 8 mm deep

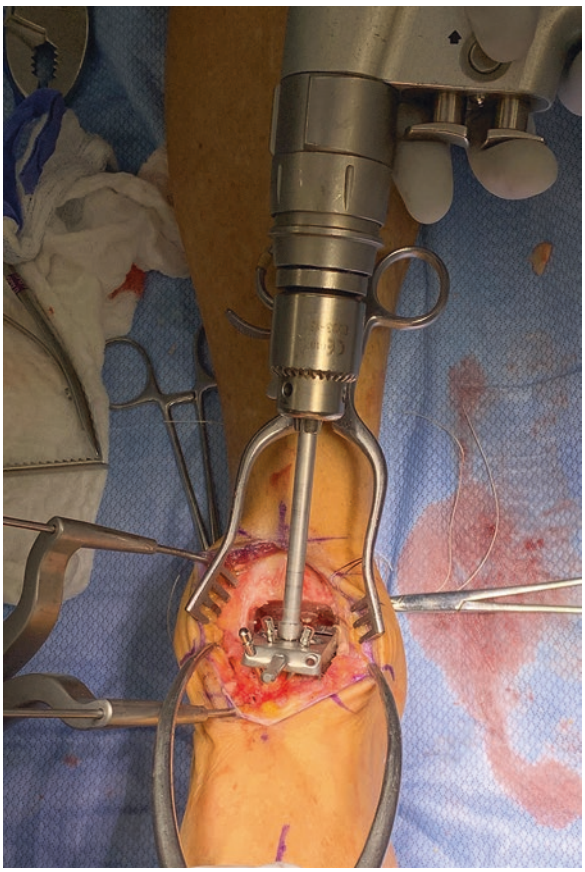


Fig. 14.18 Anterior chamfer cut utilizing the 6 mm reamer, making sure to go as deep as possible to the end-stop

Checking Alignment, Cuts, and Stability

The 12-mm thick spacer is then inserted to assess the alignment and stability of the ankle (Fig. 14.21). The surgeon should check (1) Whether an appropriate amount of bone has been resected, (2) Whether the achieved alignment is appropriate, and (3) Whether the medial and lateral stability are ensured. If more bone is to be resected at this point, a 2 mm cut block can be secured to the tibia. It is important to note that if any adjustments need to be made that they be made on the tibial side as opposed to the talar side.

Implant Sizing, Trial Implantation, & Finalizing Cuts

At this point, the size of the implants is determined. First, insert the talar trial using the given impactor (Fig. 14.22). The window on the posterior aspect of the trial allows a surgeon to check its proper fit to the posterior resection surface of the talus. Care must be taken to avoid posterior displacement of the trial component while impacting. If proper seating of the component cannot be achieved, the medial and/or lateral gutters may need to be cleaned again.

Next, the tibial trial is selected from prior measurement. Attention should be paid to approximate the tibial component against the medial malleolus. If remaining osteophytes on the anterior-lateral side of the distal tibia inhibit proper

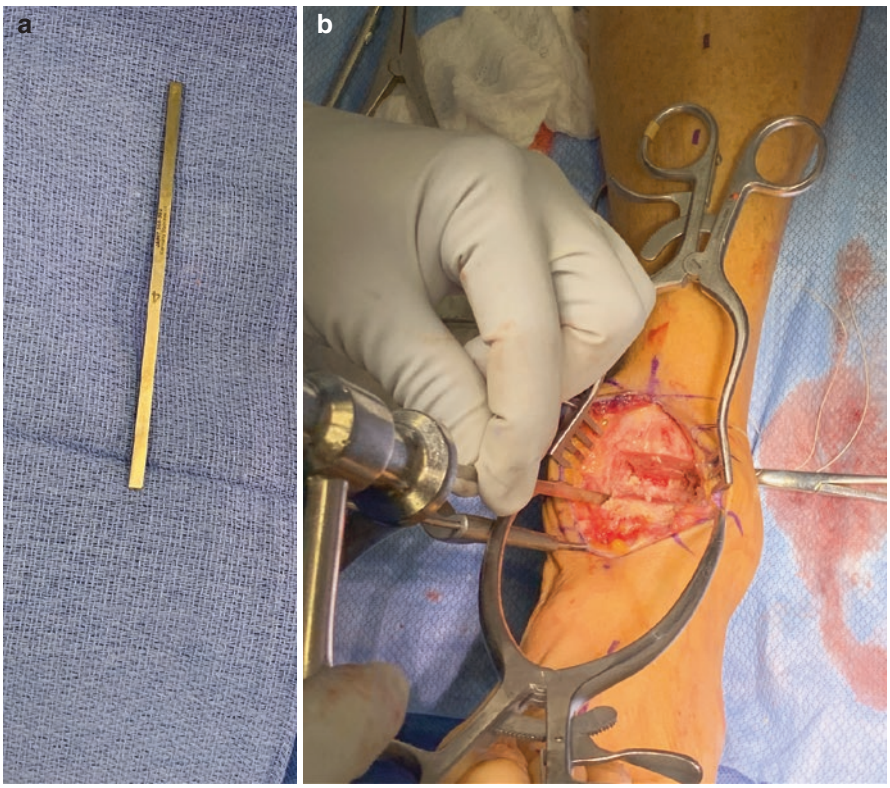


Fig. 14.19 (**a**) 4 mm osteotome the authors recommend to mobilize the medial and lateral cuts with. (**b**) 4 mm osteotome and mallet being used to mobilize the medial chamfer cut



Fig. 14.20 Utilization of the power rasp to remove any residual bone within the corners of the tibial and talar cuts. This is important prior to the placement of the trial guides to ensure proper fitting

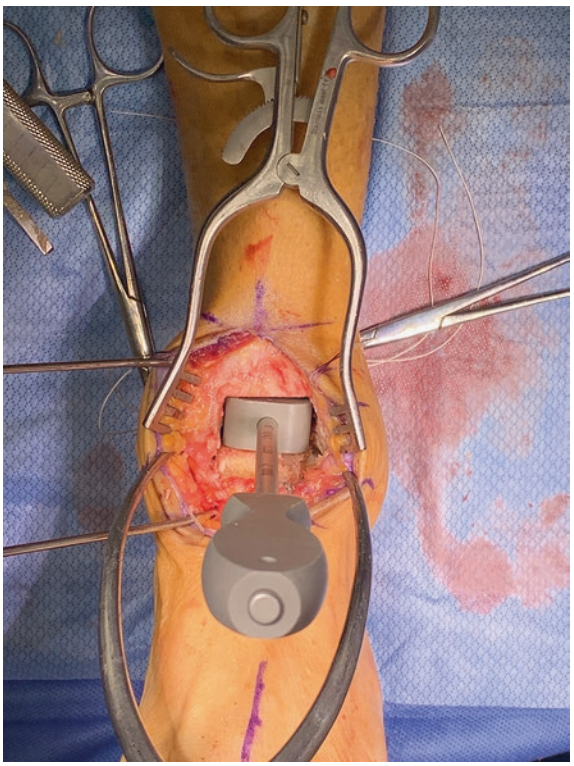


Fig. 14.21 The 12 mm spacer inserted to check the overall alignment and stability of the ankle joint. This spacer represents the thickness of the tibial and talar components and the thinnest 5 mm poly insert

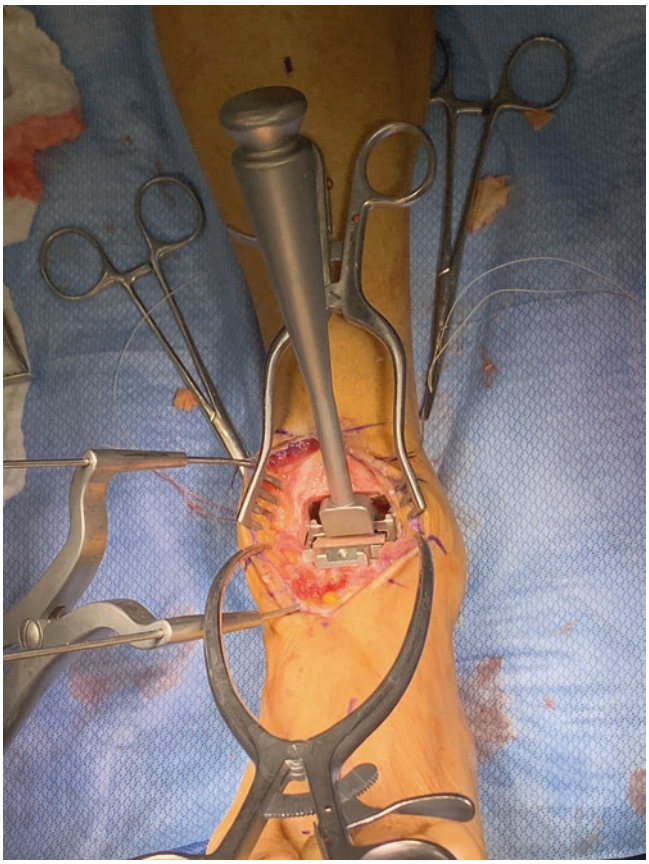


Fig. 14.22 Impaction of the talar trial with the fitted trial impactor

contact of the shield of the component and/or if close contact along the medial malleolus cannot be achieved, while the tibial shield is fitted against the anterior border of the tibia, removal of osteophytes and/or smoothening of the anterolateral tibia is advised. Again, a power rasp is very useful at this step. During this step, the Hintermann distractor can be useful to allow more room to insert the trial components.

Next, the 5 mm trial inlay is inserted and the Hintermann distractor is disengaged. If not enough soft tissue tension can be achieved, the 6 mm, 7 mm, or 9 mm trials are inserted. Using fluoroscopic guidance, it is imperative to check the alignment of the trials. On the lateral view, the posterior border of the tibial trial should be aligned with the posterior aspect of the tibia ensuring the tibial surface is fully covered (Fig. 14.23). Furthermore, the talar trial should be aligned with the posterior surface of the talus. Finally, with respect to the prepared bone surfaces, the tibial and talar components should be parallel with one another.

Once proper positioning of the talar trial is confirmed, resection of the anterior window is resected using a feathering technique. The authors recommend using a power rasp for this step as it is smaller and more stable and allows for easy maneuvering around the corners of the window. The talar drilling guide is then inserted over the window. If the drill guide does not secure to the talar trial, additional bone



Fig. 14.23 Tibial trial showing proper alignment with the posterior aspect of the tibia ensuring adequate coverage

from the window must be removed, most commonly from the distal medial and distal lateral corners (Fig. 14.24a, b). Once the guide is secured, 2 holes are drilled with the 4.5 mm peg drill, ensuring the shoulder of the peg meets the drill guide surface (Fig. 14.25).

Implant Sizing and Insertion

At this time, the talar implant is inserted, first by hand so that the pegs can be readily inserted into the 2 holes. Next, it is impacted using the straight impactor and mallet to ensure proper fit of the component to the bone. Then, the posterior aspect of the implant is impacted using the curved impactor and mallet (Fig. 14.26a, b). The tibial implant is then inserted with the medial surface flush with the medial tibial bone cut in a similar fashion until proper fit to the anterior tibia is achieved. However, before inserting, it is recommended to insert the trial inlay in a retrograde fashion in order to avoid contact between the metallic surfaces of the tibial and talar components (Fig. 14.27). The implant is impacted using a mallet and straight impactor. It is recommended to position the tibial impactor in an oblique position relative to the tibial component axis while impacting in order to obtain good contact between the tibial cut and tibial component on the entire surface. The 5 mm trial inlay is then inserted (Fig. 14.28). If sufficient soft tissue tension cannot be achieved, the 6 mm,

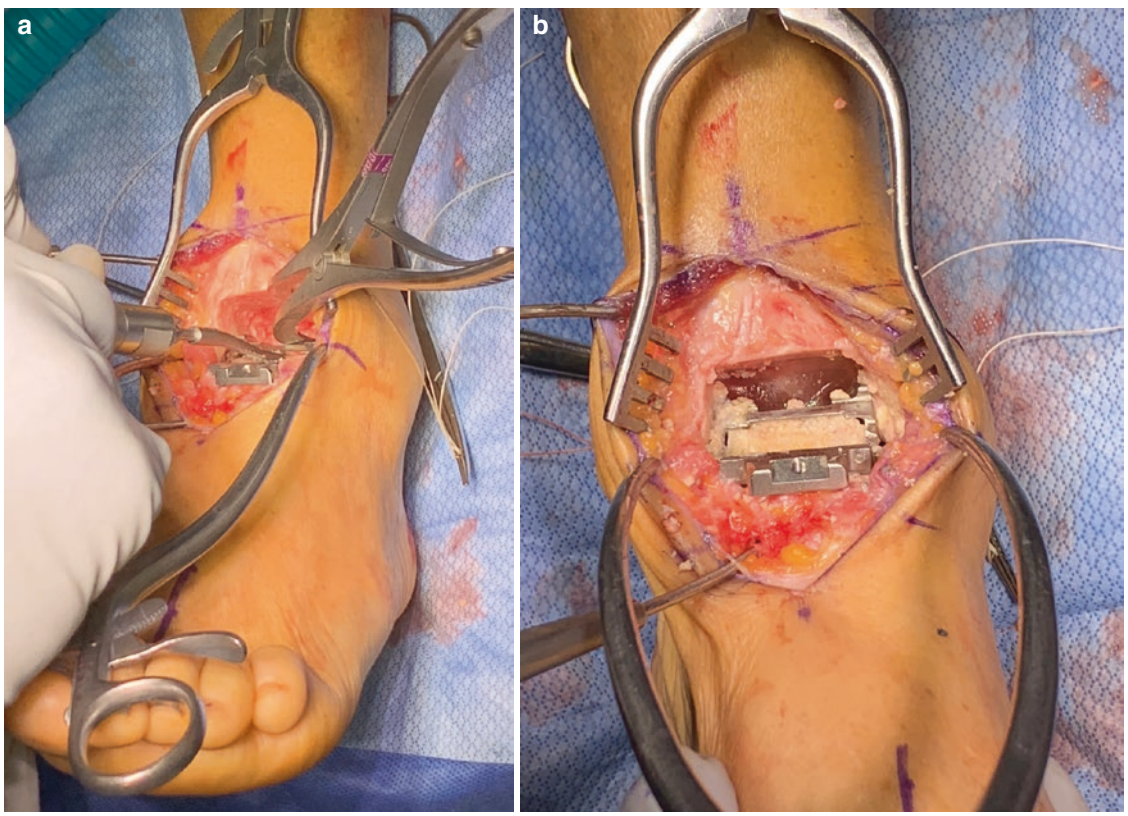


Fig. 14.24 (**a**) Resecting the anterior surface of the talus utilizing the authors' recommended technique with a power rasp. (**b**) Final resection of the anterior surface of the talus

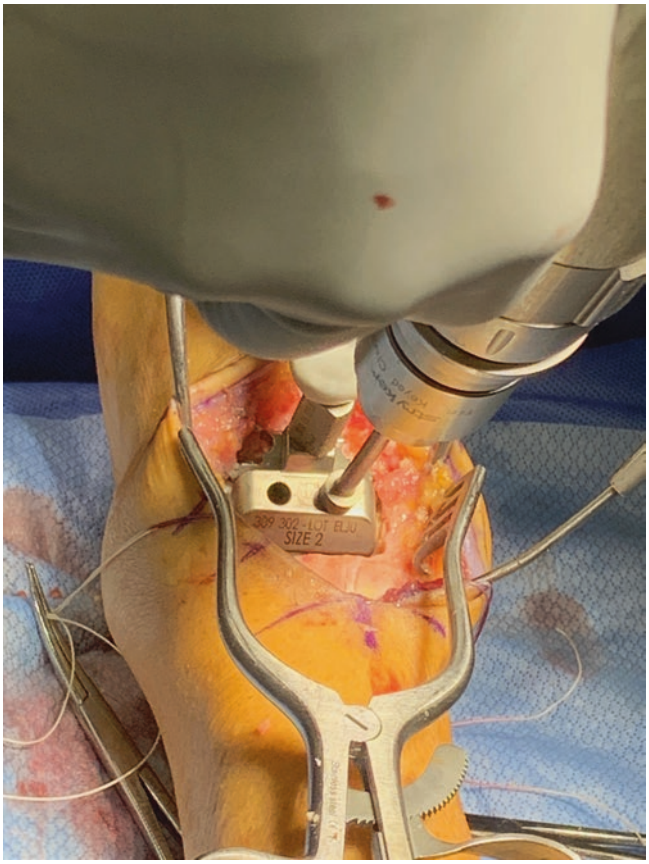


Fig. 14.25 Drilling anterior talus with the 4.5 mm reamer ensuring the shoulder of the peg meets the drill guide surface

7 mm, or 9 mm trial inlays can be used, which would correspond to the implant thickness chosen to complete the implantation. Subsequently, the polyethylene inlay is inserted. The inlay is inserted by hand with the 'M' marking on the implant directed medially (Fig. 14.29). If implanting the H3 Series, this is the final step; however, if implanting the H2 Series, you first have to measure the amount anterior or posterior talar subluxation by using the offset measuring tool, which is inserted between the tibial and talar components (Fig. 14.30a, b). Once the proper offset is determined, the respective inlay is selected and inserted by hand, again, ensuring the 'M' is directed medially and the teeth of the metallic ring are facing anteriorly toward the surgeon. The tibial slide is then inserted until it seats into the tibial implant. With the implants in place, while visually observing the congruency of the implants, the ankle should be flexed to its maximal allowable range of motion to provide for the poly implant to find its anatomic position. What is unique regarding the H2 Series implant is that the polyethylene insert finds its isometric position based on the patient's individual anatomy prior to being locked in place (Fig. 14.31). Once the range of motion evaluation is complete, the poly inlay is locked in place utilizing the torque-limiting tibial slide device, securing it with a screwdriver and turned clockwise until the clutch mechanism disengages at its predetermined torque level (Fig. 14.32). It is recommended to turn the screwdriver until there are three audible clicks appreciated. Once all components are in place, final fluoroscopic images are taken and wound closure ensues (Fig. 14.33a, b).

Conclusions

TAA is a viable option for individuals affected by end-stage ankle arthritis. The Hintermann Total Ankle Replacement System, consisting of both a fixed- and mobile-bearing design, allows for a smaller incision and minimal bone resection and uses patient-specific, physiologic motion to provide lower contact stresses, minimal wear, and intrinsic stability against eversion-inversion forces. Currently, the authors are conducting prospective research and have seen excellent early outcomes. We routinely take postprocedural radiographs to objectively evaluate the implants and evaluate the patient's range of motion by obtaining weight-bearing maximal dorsiflexion and plantarflexion views (Fig. 14.34a, b). Ankle arthrodesis is still an option for patients with end-stage ankle arthritis; however, TAA has shown good, comparable short- and intermediate-term results with respect to pain relief and function [10, 11]. Furthermore, TAA has been shown to have fully recovered bilateral gait mechanics (BGM), whereas ankle arthrodesis patients have altered BGM [12]. In conclusion, the Hintermann TAR System has proved to be a viable option for patients with painful ankle osteoarthritis.

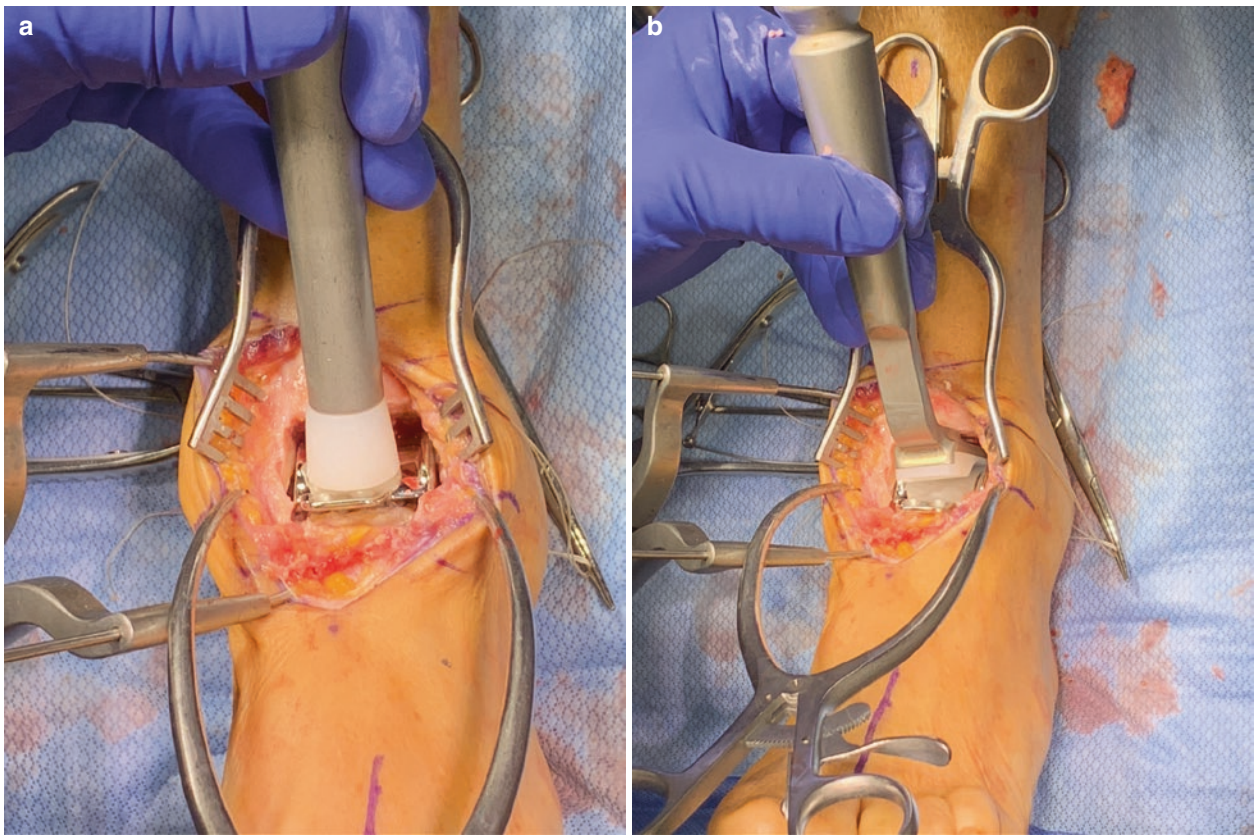


Fig. 14.26 (**a**) Impacting anterior aspect of the talus utilizing the straight impactor and mallet. (**b**) Impacting the posterior aspect of the talus with the curved impactor and mallet

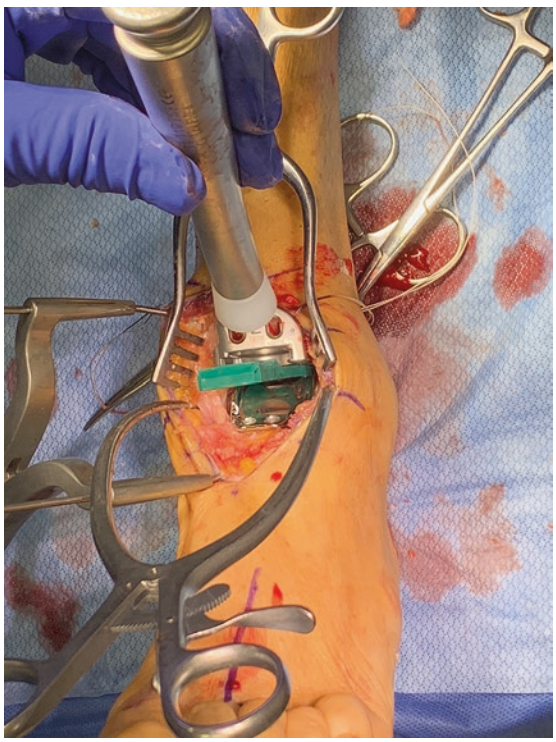


Fig. 14.27 Inserting the tibial component by inserting the 5 mm trial inlay in a retrograde fashion in order to protect the metallic surfaces of the tibial and talar implants

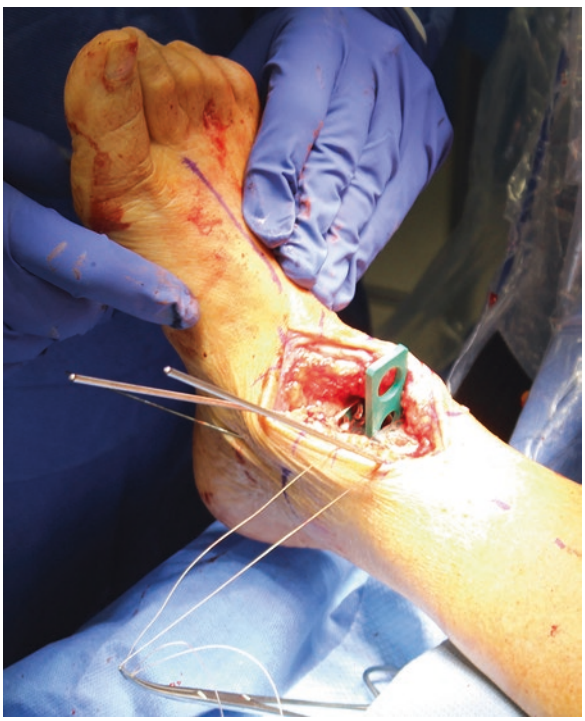


Fig. 14.28 The 5 mm trial inlay is inserted between the tibial and talar components to ascertain adequate motion and soft tissue tension. If uncertain, the 6 mm, 7 mm, or 9 mm trial inlays can be inserted

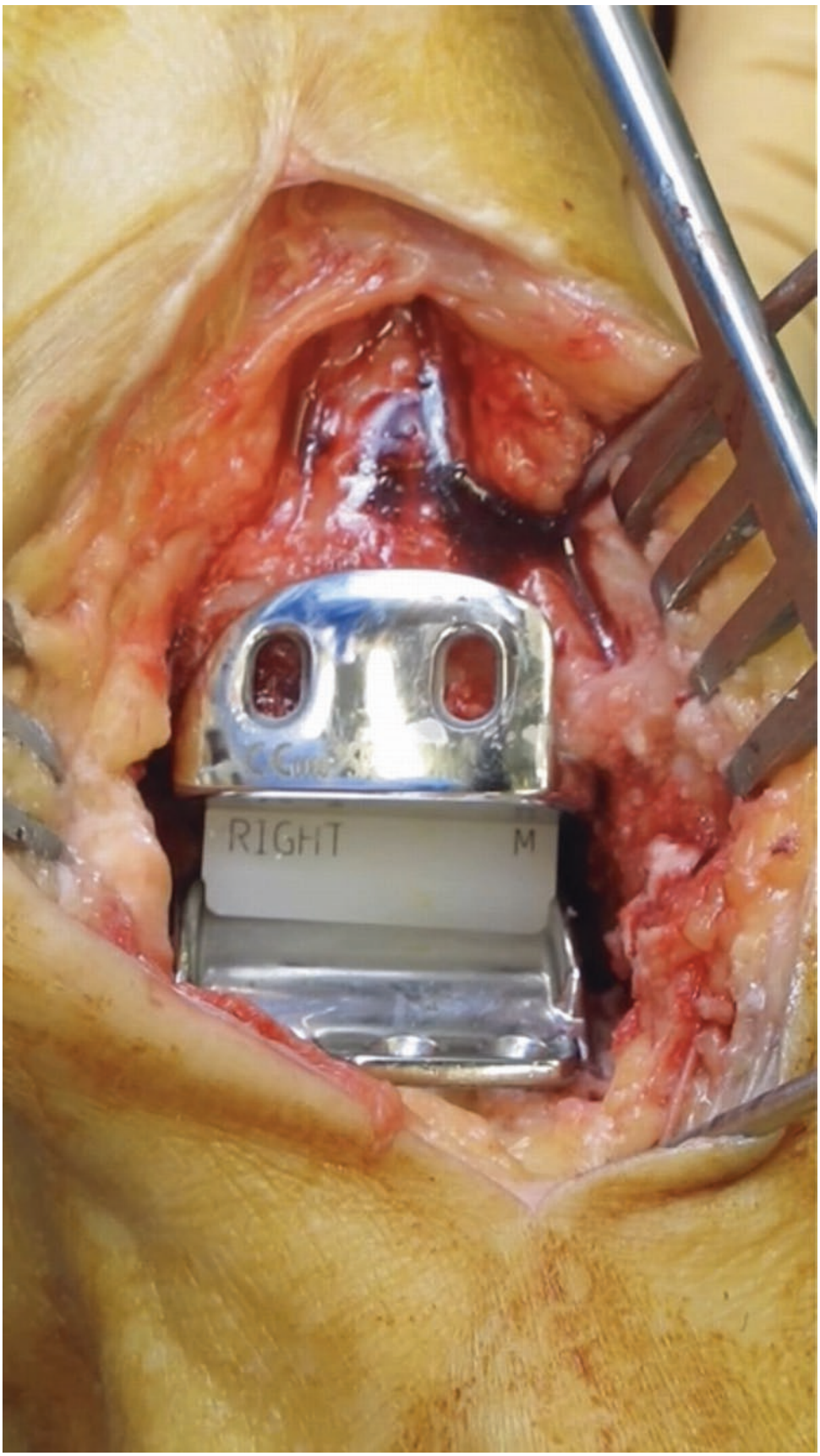


Fig. 14.29 Insertion of the polyethylene inlay in the H3 System. This is the final step of this design

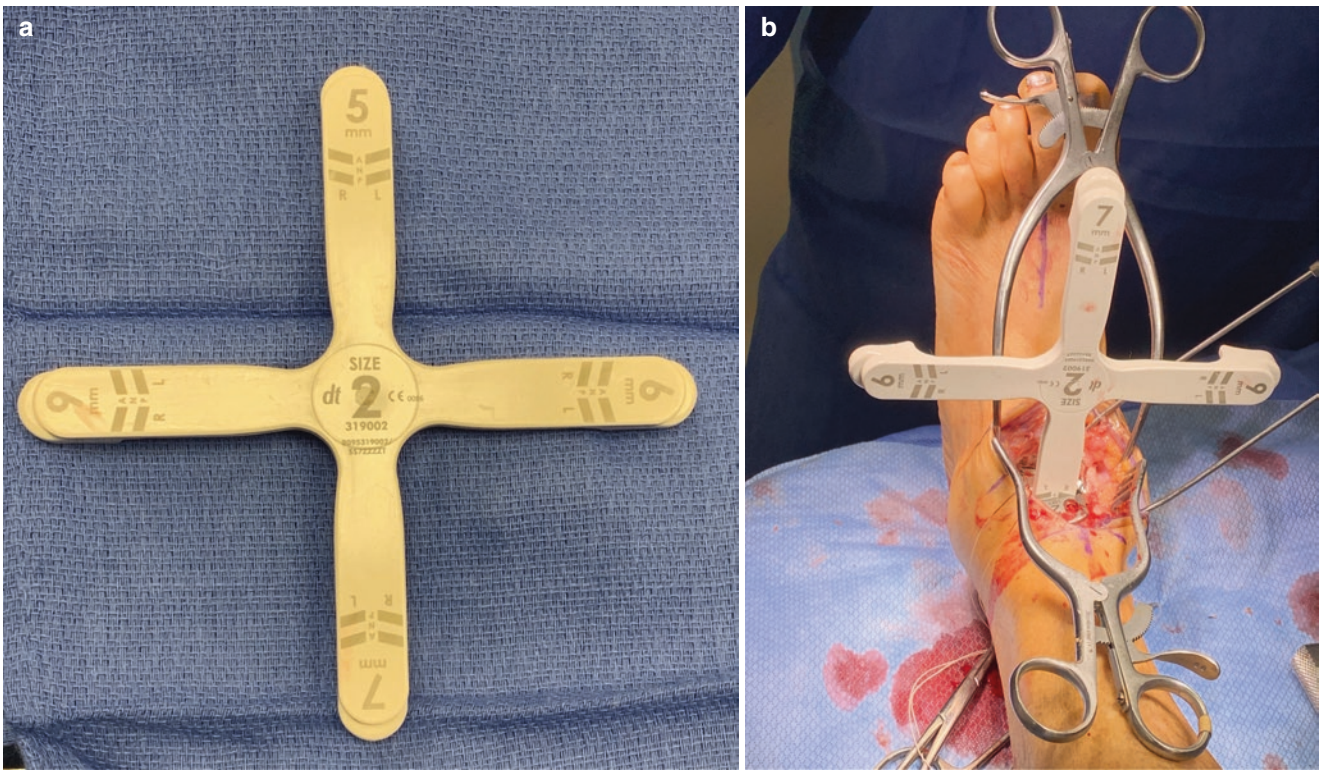


Fig. 14.30 (**a**) Talar offset trial guides for the H2 Series. (**b**) The 5 mm talar trial offset guide inserted between the tibial and talar components corresponding with a posterior-subluxed talus

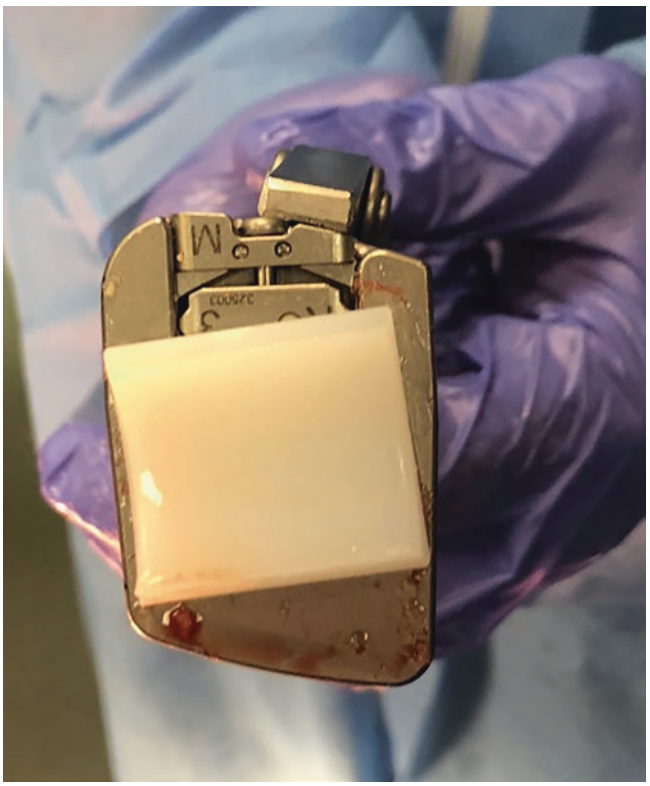


Fig. 14.31 Superior view of the polyethylene inlay. Notice the amount of axial rotation that is considered its isometric position based on the patient's individual anatomy

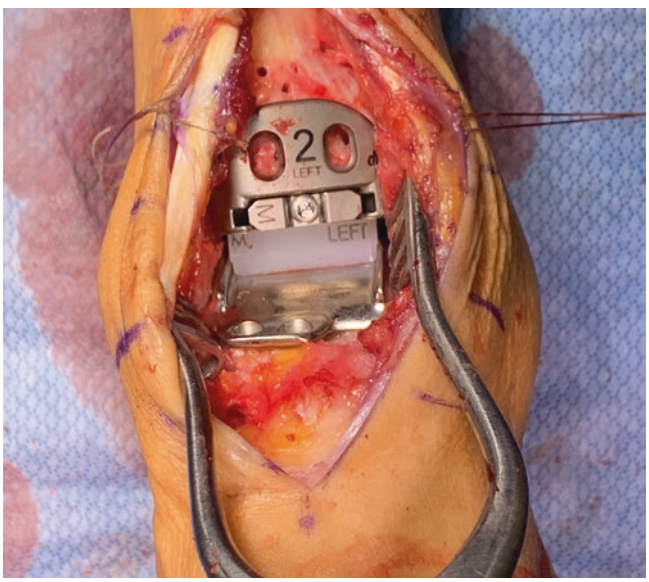


Fig. 14.32 The H2 Series polyethylene inlay with the locking mechanism engaged. Notice the amount of axial rotation of the talar component relative to the tibial component

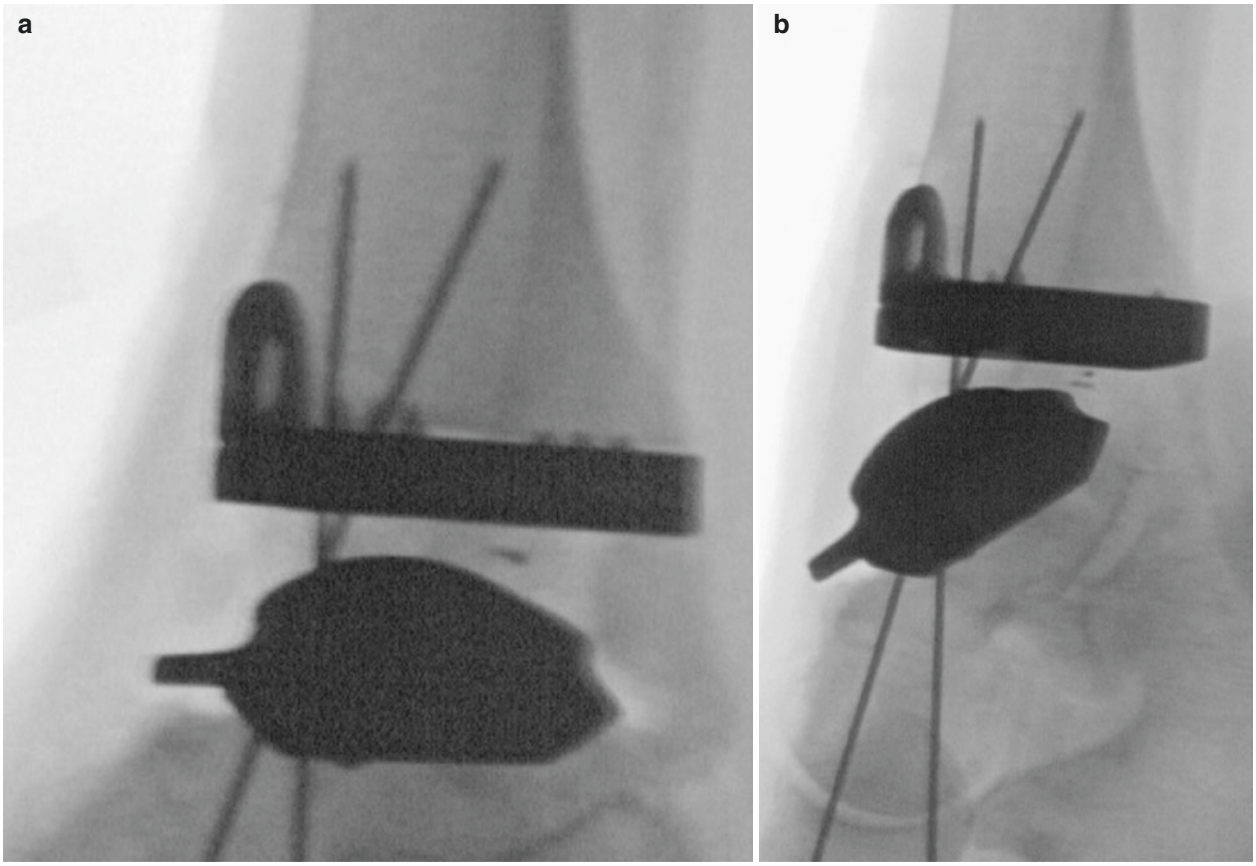


Fig. 14.33 (**a**) Lateral fluoroscopic image of the final H2 Series implantation. Notice the locking mechanism is flush with the anterior shield. (**b**) Maximum plantarflexion view of the final implantation

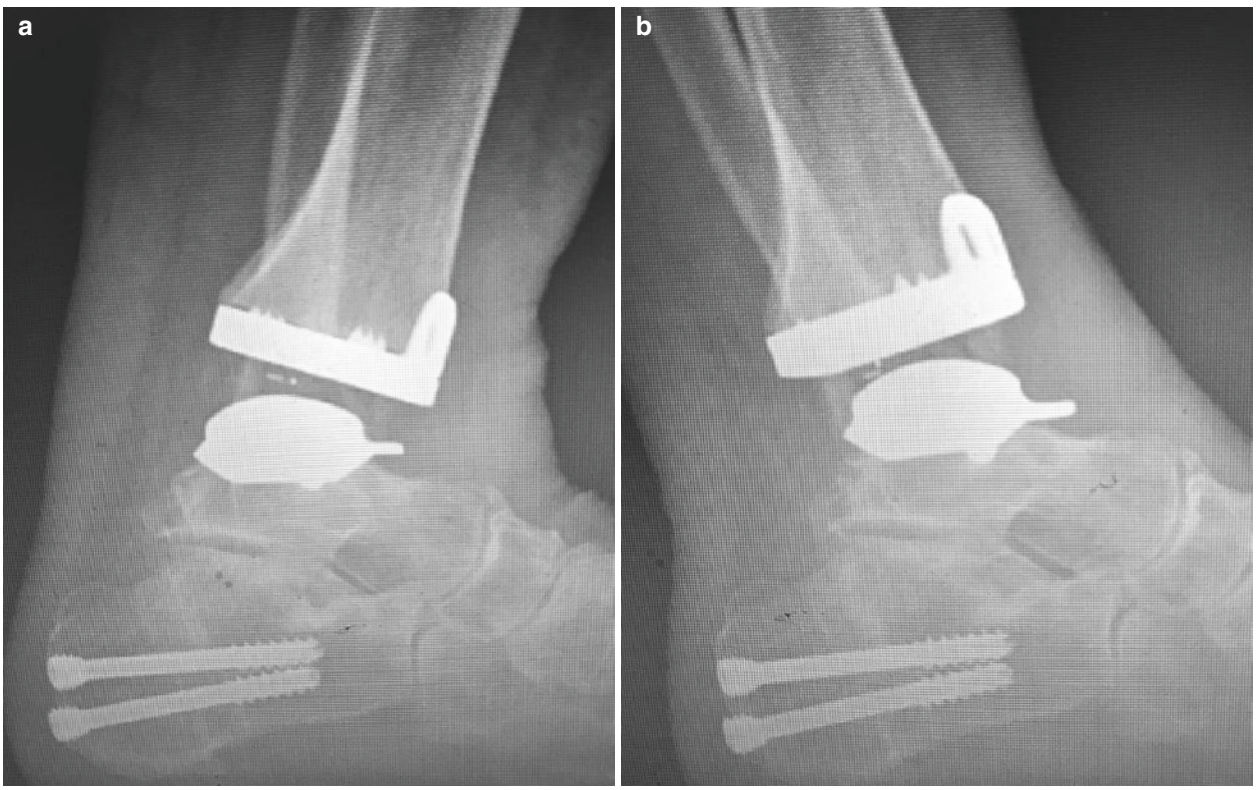


Fig. 14.34 Postoperative weight-bearing dorsiflexion (**a**) and plantarflexion (**b**) views of the H2 Series Hintermann total ankle replacement system

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Salto Talaris Total Ankle System and Salto Talaris XT Primary and Revision Total Ankle System

15

Thomas S. Roukis

Introduction

The Salto Mobile Version prosthesis (Tornier NV, Amsterdam, The Netherlands) is a third-generation prosthesis that was invented by Michael Bonnin, MD, Jean-Alain Colombier, MD, Thierry Judet, MD and Alain Tornier between 1994 and 1996 based upon anatomical studies of the ankle joint. Subsequent mechanical engineering studies have validated that the multicylinder on multicylinder, saddle-shaped skewed truncated cone with lateral apex contact surfaces of the Salto Talaris design replicates normal ankle joint motion [1, 2]. The device was first implanted in January 1997 and was limited to these surgeon inventors between 1997 and 1999 [3, 4]. The first clinical results were published by this group in 2000 [4–6]. Subsequently, the in vivo kinematics of the Salto Mobile Version was investigated in 20 patients using fluoroscopy with 2D to 3D registration technique. In this study, translation between the Ultra-High Molecular Weight Polyethylene (UHMWPE) mobile-bearing insert and tibial base plate averaged 1.5-mm during gait and the insert remained in internal rotation throughout the arc of motion [7]. In another study involving stress lateral radiographs from 20 patients, variation of anterior-posterior translation of UHMWPE mobile-bearing insert relative to the tibial base was not noticeable in 17 patients and was only 1-mm in the remaining 3 patients [8, 9]. These studies indicate that the UHMWPE insert did not function as a mobile-bearing system but rather remained essentially fixed to the tibial component. Based on this realization in conjunction with problems associated with malleolar impingement and UHMWPE wear debris-induced osteolysis, [10] the fixed-bearing Salto Talaris Total Ankle System (Tornier, Inc., Bloomington, MN/Wright Medical Technology, Inc., Memphis, TN) was developed. The Salto Talaris Total Ankle System and Salto Talaris XT Primary and Revision Total Ankle System are currently owned and marketed by Integra Lifesciences Corporation, Plainsboro, NJ.

The Salto Talaris Total Ankle System was initially available in three sizes (i.e., 1, 2, and 3) until 2009 when a fourth size (i.e., 0) was added. The Salto Talaris Total Ankle System prosthesis tibial component base is 3-mm thick, and the UHMWPE inserts are available in actual thickness of 5, 6, 7, and 8-mm. It should be noted that the UHMWPE insert thickness and the tibial tray thickness are added together to achieve the total combined height or "monoblock," and this is composite number, which is listed in the technique guide and sales sheets. As such, the total combined height of the tibial tray and UHMWPE insert thicknesses are listed as 8, 9, 10, and 11-mm. Both the tibial and talar components are made of cobalt-chromium and are single-coated with 200-μm plasma-sprayed titanium (T40) to promote osseous integration. In 2013, the tibial component was redesigned to add 1-mm to the width and 2-mm to the length to improve tibial coverage in addition to rounding off the anterior-medial and anterior-lateral surfaces to reduce overhang. Tibial component fixation is achieved primarily with anterior cortical contact of the flat surface and a 12-mm long central keel attached to a hollow tapered anterior-posterior conical fixation plug that is impacted into the tibial metaphysis [11–13]. The tibial component is designed for insertion with a 7° or 3° posterior slope relative to the long axis of the tibia. The tibial base can be the same or one size larger than the talar component, allowing for mismatching the tibial and talar components based on patient anatomy. The tibial components are interchangeable, but the talar components have dedicated left and right sides due to the double radii (i.e., medial radius smaller than lateral radius) and biconvex articular surface resembling the native morphology of the talar dome [1, 2]. In 2015, the instrumentation for the Salto Talaris Total Ankle System was redesigned and marketed as version 2.1 with all changes providing improved accuracy of prosthesis placement and

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consolidating the number of steps. In 2019, the Salto Talaris Total Ankle System and Salto Talaris XT Primary and Revision Total Ankle System tibial tray, which are the same design for both systems, were redesigned to include a 15% increase in the posterior extension based on CT scan morphological analysis of the tibia to afford more complete coverage of the tibial plafond. This extended tibial tray is marketed as the XL Tibial Tray. The UHMWPE inserts for the Salto Talaris XT Primary and Revision System are available in actual thickness of 10, 12, and 14-mm. As noted above, the corresponding total combined height of the tibial tray and UHMWPE insert thicknesses listed in the technique guide are 13, 15, and 17-mm.

The undersurface of the Salto Talaris Total Ankle System talar component matches 3 sharply angulated bone cuts about the posterior, anterior, and lateral talar body affording primary stability in the anterior-posterior and medial-lateral planes. Secondary talar component fixation for component sizes 1, 2, and 3 includes a posterior angled 11.6-mm deep, 12.7-mm outer diameter, medially offset hollow fixation plug, while the size 0 has a 10.4-mm deep, 8-mm outer diameter, solid fixation plug. The center of the fixation plug is a constant distance from the concave lateral facet for each talar component. Talar component sizes 1, 2, and 3 remove 7-mm of talar bone height, and size 0 removes 5.5-mm. The undersurface of the Salto Talaris XT Primary and Revisions Total Ankle System talar component is flat. Primary talar component medial-lateral fixation stability for component sizes 1, 2, and 3 is achieved by a 70° posterior angled medially offset hollow fixation plug, while the size 0 has solid fixation plug. Each of the fixation plugs match the location of the corresponding Salto Talaris Total Ankle System talar components but extend an additional 3-mm into the talar body to allow for enhanced fixation in the dense talar bone. The center of the fixation plug is a constant distance from the lateral edge for each XT flat-topped talar component and matches the corresponding Salto Talaris Total Ankle System talar components. Secondary rotational stability is achieved with a tapered flange extending from the posterior aspect of the fixation plug. Talar bone height resection is 10.2-mm for size 0, 10.5 mm for size 1, 11.4-mm for size 2, and 11.9-mm for size 3.

For the fixed-bearing Salto Talaris Total Ankle System and the Salto Talaris XT Primary and Revision Total Ankle System prostheses, the mobile-bearing concept with the Salto Mobile Version has been moved from the implant design to the instrumentation at the stage of the trial reduction. According to the surgical technique guides, accurate and reproducible tibial and talar component alignment are possible by first performing a measured resection with equal implant replacement for the distal tibia and talus. Next, the trial tibial base, featuring a highly polished surface that remains mobile against the resected distal tibia, is allowed to rotate into anatomically aligned position during ankle range of motion and tracking of the talar component through a securely fixed, highly conforming articulating trial fixed-bearing insert. Only after this intrinsic ankle alignment is achieved are the final bone cuts for the tibial keel and plug completed, fixing the tibial base and insert assembly into the optimized position. The instrumentation ensures proper positioning of the tibial implant and UHMWPE insert in relation to the talar implant. Dedicated instrumentation including an external alignment jig with tibial and pedal referencing is employed to resect the distal tibia and talus, as well as insert the trial and final prosthesis components. The accuracy of tibial component alignment using this extramedullary referencing guide was tested in 83 ankles and determined to be within a mean of 1.5° and 4.1° in the coronal and sagittal planes, respectively, from the surgeons intended position [14]. In 2019, the surgical instrumentation underwent an additional upgrade intended to ensure proper positioning of the tibial component in relation to the talar component for enhanced accuracy of component implantation, as well as reduce the number of steps involved to reduce operating room time.

The anatomic design of the talar component for both the Salto Talaris Total Ankle System and the Salto Talaris XT Primary and Revision Total Ankle System is intended to reproduce normal ankle kinematics without over-stressing the deltoid ligament complex. The UHMWPE inserts' articular surface is size matched to the talar component and have dedicated left and right sides. The talar components have deep biconvex medial and lateral articular surfaces with a concave trochlear groove and a 12° apex medial frontal plane axis to allow for external rotation of the foot with dorsiflexion and internal rotation during plantarflexion. The contact area between the UHMWPE insert and talar component allows ±2-mm varus/valgus motion, 5° internal/external rotation, 2-mm anterior-to-posterior translation, and a sagittal plane arc of motion from 20° dorsiflexion to 25° plantarflexion.

The results of a recent systematic review make clear the low incidence of revision and high survivorship following primary implantation of the Salto Mobile Version prostheses, which was 4% at a weighted mean follow-up of 55.2-months and the Salto Talaris Total Ankle System prostheses, which was 2.4% at a weighted mean follow-up of 34.9-months [15]. Data isolated to the inventor, design team, or disclosed consultants had an incidence of revision of 5.2% for the Salto Mobile Version and 2.6% for the Salto Talaris Total Ankle System prostheses. In contrast, data that excluded these individuals had an incidence of revision of 2.8% for the Salto Mobile Version and 2% for the Salto Talaris Total Ankle System prostheses. The authors could not identify any obvious difference in the etiology responsible for, or incidence of, revision between these fixed- and mobile-bearing

prosthesis systems. The incidence of revision for the Salto Mobile Version and Salto Talaris Total Ankle System prostheses was lower than those reported through systematic review for the uncemented Agility Total Ankle Replacement system (DePuy Orthopaedics, Inc, Warsaw, IN) [16, 17] and Scandinavian Total Ankle Replacement system (STAR, Stryker Orthopaedics, Inc, Mahwah, NJ) [18] without obvious selection (inventor) or publication (conflict of interest) bias.

Since this systematic review [15], additional manuscripts on the incidence of revision and survivorship of the Salto Talaris Total Ankle System prosthesis including short- to mid-term follow-up have been published. Oliver et al. [19] reported a 4.1% revision rate for 245 primary Salto Talaris Total Ankle System prostheses at a mean follow-up of 38.9-months (range: 24–84.5-months). Pangrazzi et al. [20] reported an 11% revision rate for 104 primary Salto Talaris Total Ankle System prostheses at a mean follow-up of 46-months (range: 20–81-months). Of note, this study involved high-risk patients for primary total ankle replacement, such as those having undergone Charcot midfoot reconstruction and with neuromuscular disorders, and, in this authors' opinion, represents the worst case scenario. Marks [21] reported a 0% revision rate for 40 primary Salto Talaris Total Ankle System prostheses at a mean follow-up of 58.8-months (range: 11–103-months). Hofman et al. [22] reported a 2.5% revision rate for 81 primary Salto Talaris Total Ankle System prostheses at a mean follow-up of 62.4-months (range: 40.8–98.2-months). Finally, Stewart et al. [26] reported a 4.2% revision rate for 72 primary Salto Talaris Total Ankle System prostheses at a mean follow-up of 81.1-months (range: 60–115-months). All told, the primary Salto Talaris Total Ankle System demonstrates a 96.4% survivorship for 813 prostheses at 3.8-years follow-up and a 96.3% survivorship for 308 prostheses at 5.4-years follow-up. Taken collectively, the available literature reveals a remarkably consistent low incidence of revision and high survivorship for the Salto Talaris Total Ankle System regardless of duration of follow-up or potential author bias as long a proper indications are adhered to. Unfortunately, no published clinical outcome data are currently available for the Salto Talaris XT Primary and Revision Total Ankle System.

Extramedullary Alignment Guide and Tibial Resection

Following anterior soft-tissue dissection using the interval between the anterior tibial and extensor hallucis longus tendons, the ankle joint is exposed such that the lateral half of the medial malleolus and the medial half of the lateral malleolus are exposed. The dissection should expose the distal 8–10-cm of the tibia and the talus to the level of the talonavicular joint. The inflamed synovium and any scar tissue are excised from the ankle joint, as well as the medial/lateral gutters and any release of the deltoid or lateral ankle ligaments is performed to reduce contractures (Fig. 15.1a). Alternatively, the soft-tissue balancing can be performed at the time of trial prosthesis implantation and "fine-tuned" after implantation of the definitive prosthetic components. Next, under a lateral image intensification view, the ankle joint is assessed for any osteophytes (Fig. 15.1b). This is followed by resection of the anterior tibial osteophytes and expose the proximal tibial articular surface or "roof" of the tibial pilon

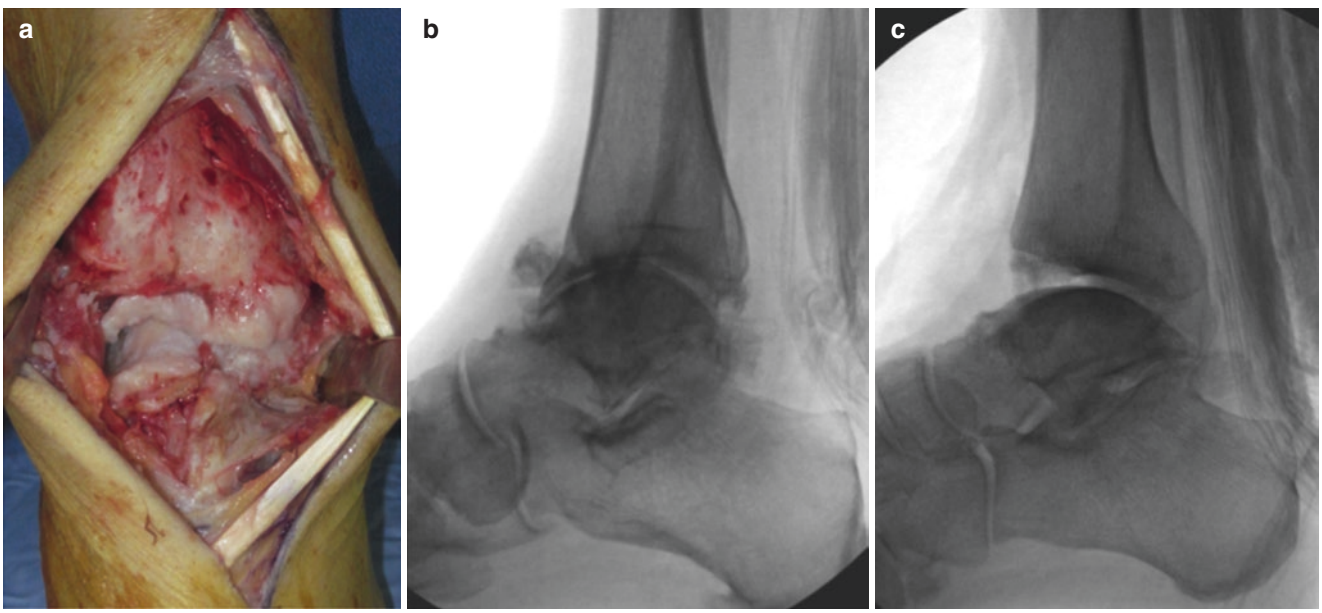


Fig. 15.1 Intraoperative photograph (**a**) demonstrating the exposure required to perform the Salto Talaris Total Ankle Prosthesis. Lateral C-arm image intensification view prior to (**b**) and following (**c**) resec-

lowed by resection of the anterior tibial osteophytes at the level of the tibial plafond such that the high point of the tibial pilon "roof" (i.e., the proximal tibial articular surface) is exposed (Fig. 15.1c). This is an important landmark since it determines the reference position for placement of the tibial alignment guide. A 110-mm drill-tipped pin is inserted with a pin driver just inferior to the anterior tibial tubercle through a small skin incision (Fig. 15.2a). It is advisable to place this pin with continuous irrigation to limit thermal necrosis to the fragile skin at this level of the leg. The pin should be placed perpendicular to the tibial crest on a lateral view (Fig. 15.2b). In the frontal plane, the axis of the tibial alignment guide should be parallel to the mechanical axis of the tibia (Fig. 15.2c) with any adjustments for varus or valgus tibial alignment made by choosing the most appropriate of the 13 holes in the proximal pin guide, which are from (−) 6 to (+)

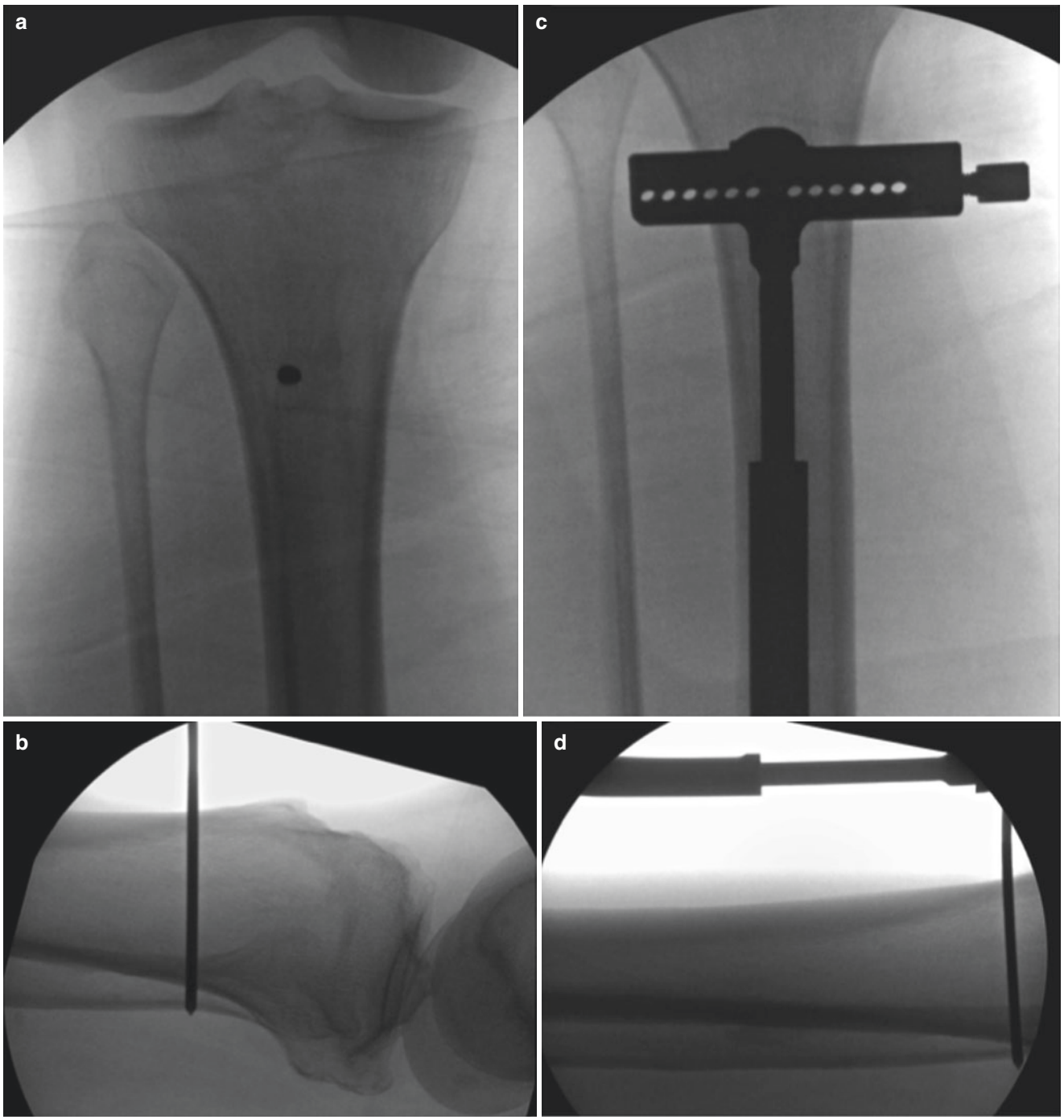


Fig. 15.2 Anterior-posterior (**a**) and lateral (**b**) C-arm image intensification views following proximal tibial tubercle pin placement. Anterior-posterior (**c**) and lateral (**d**) C-arm image intensification views following application of the tibial alignment guide

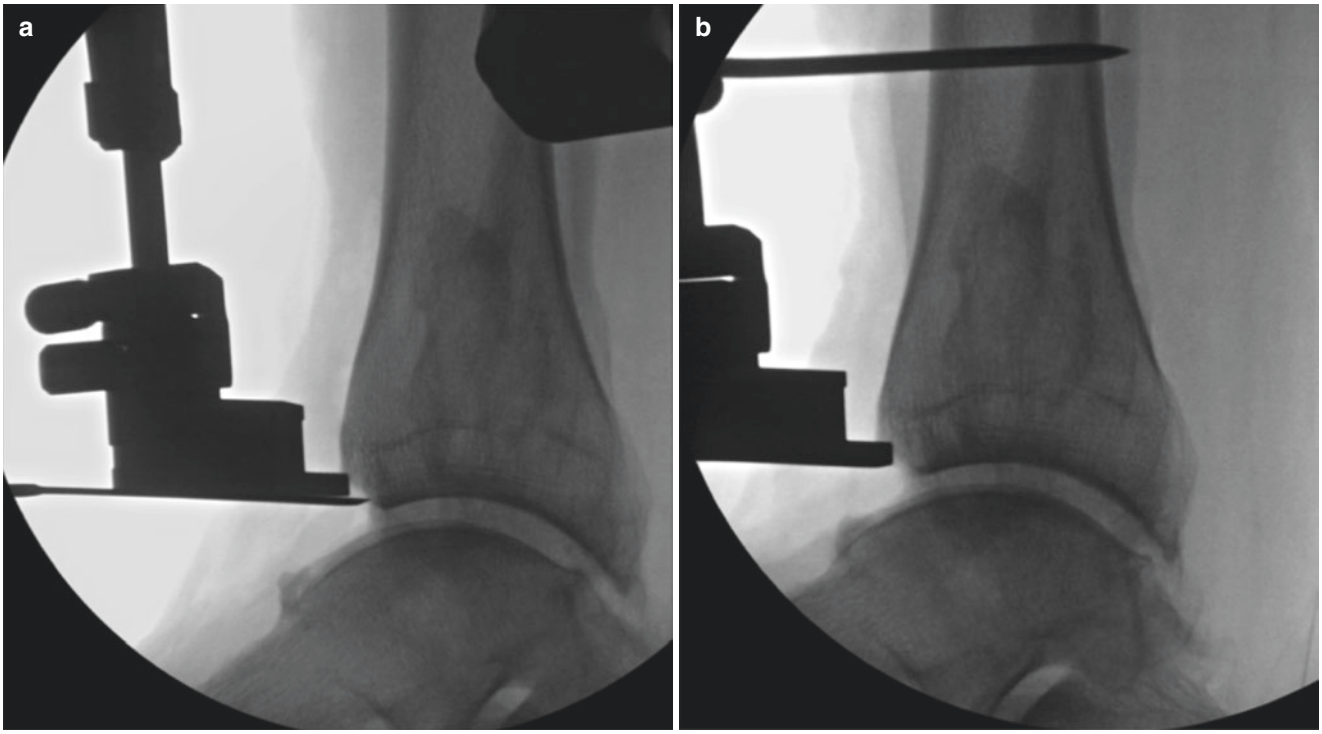


Fig. 15.3 Lateral C-arm image intensification view demonstrating proper alignment of the distal flange of the tibial alignment guide at the level of the proximal tibial articular surface prior to (**a**) and after (**b**) pin placement to secure the guide. In these images, the built-in 7° apex posterior angle has been retained

6, with 0 being neutral. With all the knobs loosened, the tibial alignment guide should be held off the tibial surface by two finger breadths and parallel to the anterior tibial crest when viewed from the side (Fig. 15.2d). The distal flange of the tibial alignment guide should be set to the 0-mm position, as well as in neutral rotation and medial/lateral alignment. Next, the central knob on the tibial alignment guide is loosened and the distal portion is translated distally until it aligns with the proximal tibial articular surface (Fig. 15.3a). The distal flange of the tibial alignment guide should be elevated slightly off the tibial bone so that the tibia does not impede proximal translation of the guide. Once the appropriate distal flange angle is identified, the central knob is tightened and a 110-mm drill-tipped pin is inserted most commonly through the guide's medial hole (Fig. 15.3b) to secure the position of the alignment guide in the center of the distal tibial metaphysis and this knob is tightened as well. It should be noted that the flange of the original distal tibial resection guide has a built-in 7° apex posterior angle (i.e., more bone resected anteriorly than posteriorly) intended to restore the normal anterior distal tibial angle. This would be captured with the tibial alignment guide directly parallel to the anterior tibial crest; however, in patients with chronic lateral ankle instability, anterior tibial bone loss and/or anterior subluxation of the talus this angle would be undesirable. In this situation, or whenever it is deemed desirable to have posterior stabilization of the talar component, the version 2.1 distal tibial resection guide with built-in 3° apex posterior angle can be employed. With either distal tibial resection guide, if additional posterior stabilization of the talar component is necessary, the proximal aspect of the tibial alignment guide can be raised further off the tibia to reduce the distal tibial resection guide angle (Fig. 15.4). The distal tibial resection guide is then translated proximally 9-mm using the height adjustment knob that is the opposite knob that was used to secure the distal flange to the tibial metaphysis. This 9-mm translation is 1-mm thicker than the thickness of the tibial base plate of 3-mm and the thinnest available UHMWPE insert of 5-mm. However, it is important to realize that this 9-mm translation would be appropriate for an ankle without significant wear to the distal tibial articular surface. In situations where significant wear exists or extremely lax medial and lateral ligaments are encountered, the proximal translation should be reduced to accommodate for this wear and allow proper ligamentous tensioning. Once the ideal resection height is identified the knob is tightened to prevent migration. It is critical at this point that the foot is capable of achieving neutral (i.e., 0°) dorsiflexion, and if this is not possible, then soft-tissue releases should be performed until the foot is plantigrade. A foot holder device can be employed at this time to both verify that the foot can achieve this neutral position and help maintain it while adjusting the guides. Next, the tibial alignment



Fig. 15.4 Lateral C-arm image intensification view demonstrating translation of the distal flange of the tibial alignment guide 9-mm proximal to the level of the proximal tibial articular surface. Note that the built-in 7° apex posterior angle has been reduced to 0° due to the presence of chronic anterior subluxation of the talus

jig is slid over the distal tibial resection guide and adjusted by first obtaining rotational alignment and then medial-lateral positioning (Fig. 15.5). To achieve rotational alignment, a 110-mm smooth pin is placed into each of the malleolar gutters and a third pin is placed into the guide's adjustable arm. The rotation is correct when the guide's adjustable arm pin bisects the other two pins. It is important to note that this step is independent of the talus, and accordingly, attention should remain on the distal tibia to set the rotation not the talus. Once the rotation is set, the medial-lateral positioning is adjusted using the 4 paired size indicator holes on the medial and lateral aspect of the tibial alignment jig corresponding to the four tibial prosthesis sizes (i.e., 0, 1, 2, and 3). One 75-mm pin is placed in the appropriate medial hole, and a second 75-mm pin is placed in the corresponding lateral hole. The ideal tibial prosthesis size is the one that corresponds with a line drawn from the junction of the medial malleolus proximal and perpendicular to the joint line and a second line drawn from the syndesmosis proximal and perpendicular to the joint line. It should be noted that the final tibial prosthesis size is not committed to with this step and that it is important to verify the talar sizing prior to committing to a tibial prosthesis size. It should be noted that the holes in the guide are not drilled and pins are not placed into the bone at this time; instead, they are used for referencing and sizing only. The talar prosthesis size is confirmed by using the medial-lateral talar sizing guide for the corresponding size or one smaller than the tibial prosthe-

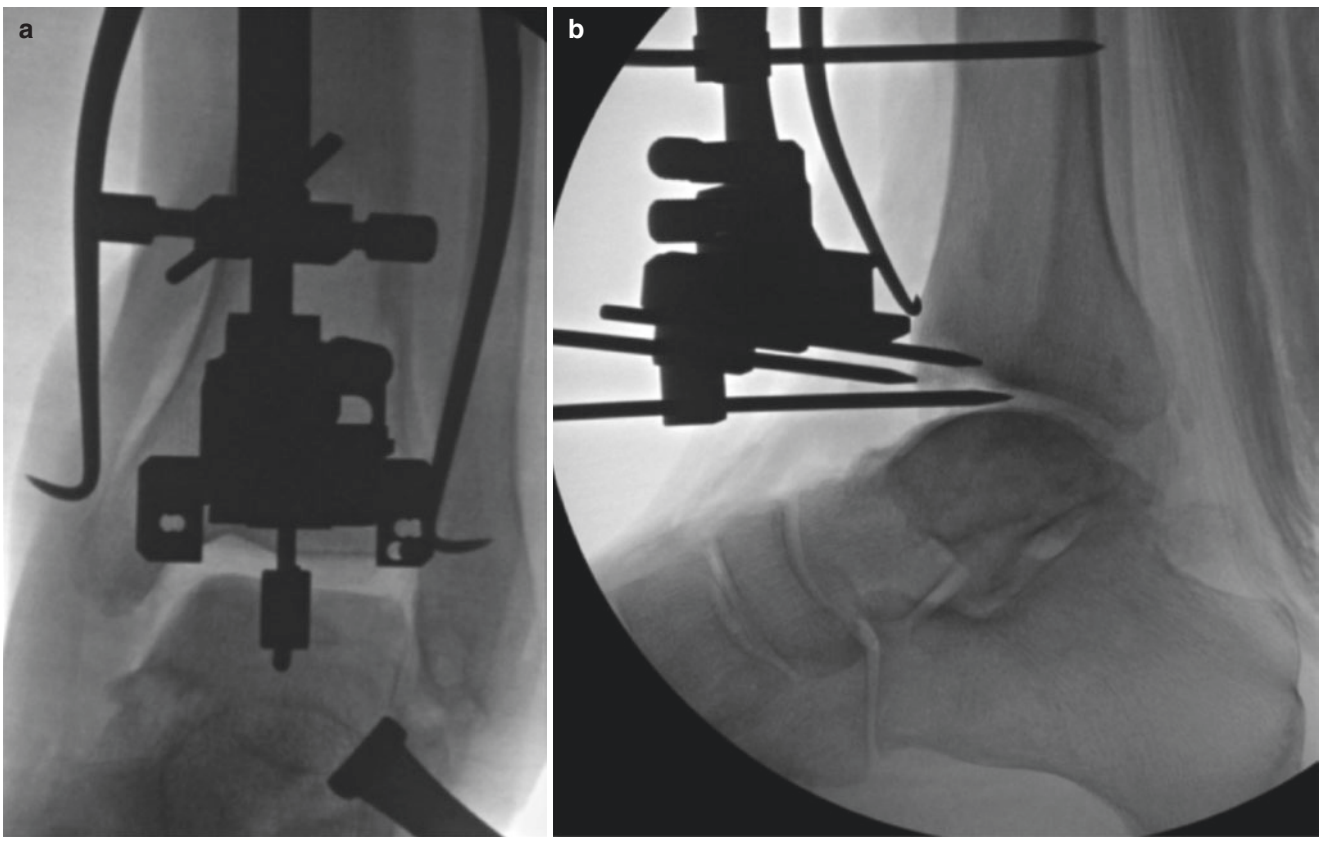


Fig. 15.5 Anterior-posterior (**a**) and lateral (**b**) C-arm image intensification views demonstrating the tibial alignment jig

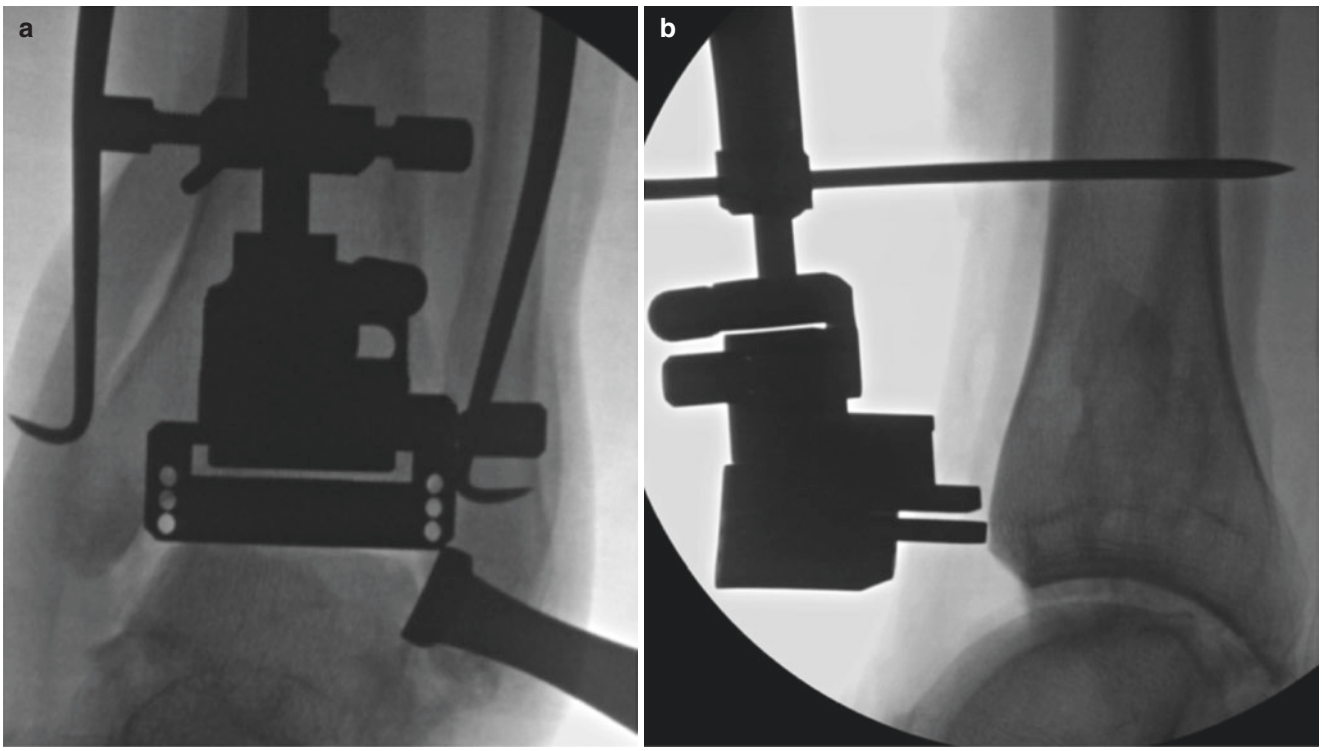


Fig. 15.6 Anterior-posterior (**a**) and lateral (**b**) C-arm image intensification views demonstrating the tibial resection guide

sis size on the anterior 1/3rd of the talar dome. Following these sizing steps, the selected tibial resection guide is placed on the tibial alignment jig and secured by tightening the knob (Fig. 15.6). At this point, it is critical to verify that the distal flange and resection guide is resting on the tibia and that all the knobs are firmly tightened. Next, a 2.9-mm drill is used to drill through the proximal medial and proximal lateral holes in the tibial resection guide bicortically (Fig. 15.7a) followed by insertion of a 75-mm pin into both these holes bicortically (Fig. 15.7b). These pins protect the malleoli from the sweep of the saw blade during the horizontal tibial resection cut. The inferior two holes on the medial and lateral sides of the original guide are also drilled bicortically to aid in identifying the proper osteotomy path; however, it is common for the distal most hole of the tibial resection guide to miss drilling any bone. The newer version 2.1 tibial cutting guide has replaced the original tibial resection guide and uses drill-tipped pins to perform the tibial cutting guide stabilization in one step, as well as vertical resection slots instead of the distal 2 holes to more create a more accurate osteotomy of the distal tibia and reduce the number of steps. The horizontal tibial resection is then performed extending to the posterior tibial cortex (Fig. 15.8a). Regardless of which guide is employed, the two retained pins in the tibial resection guide will usually migrate out of their holes during the chatter that occurs during the sweep of the saw blade, and efforts should be made to hold them down with an instrument during the horizontal resection. Once the horizontal tibial resection is completed ,the retained pins are removed followed by the tibial resection guide itself. The anterior ½ to 2/3rd of the distal tibia should be osteotomized and removed, taking care to protect the malleoli and leaving the remaining posterior portion as this can be more easily removed once the talar resection is completed (Fig. 15.8b).

Talar Bone Resection

The talar pin setting guide is placed on the distal tibial alignment guide followed by placement of a 2.9-mm drill placed in one of the three holes within the guide corresponding to the base of the talar neck at the anterior articular cartilage of the talar dome (Fig. 15.9a). The angle of the talar drill is such that if it exited the talus, it would be within the posterior 1/3rd of the subtalar joint (i.e., drill pointing to the superior 20% of the subtalar joint). It is critical that the foot is held at a 90° angle (i.e., neutral alignment) in the sagittal plane with no varus or valgus angulation (Fig. 15.9b). The foot holder available I the version 2.1 set can help with this positioning. If the foot is held in dorsiflexion, the talar dome resection will be too anterior, and if the foot is held in plantarflexion, the talar dome resection will be too posterior. If a stack of sterile towels has not already been employed under the lower leg from the beginning of the surgery, it would be

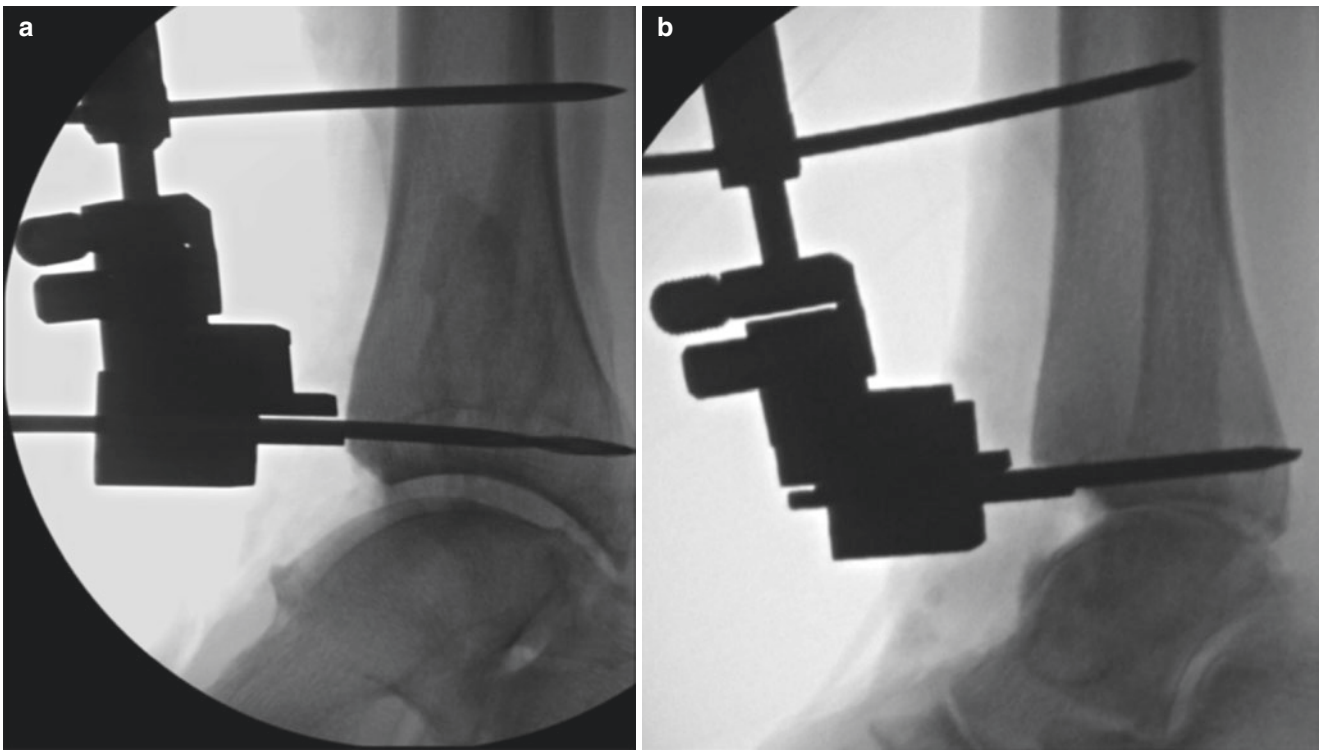


Fig. 15.7 Lateral C-arm image intensification views demonstrating bicortical drill (**a**) and pin (**b**) placement for the superior medial and lateral holes within the tibial resection guide

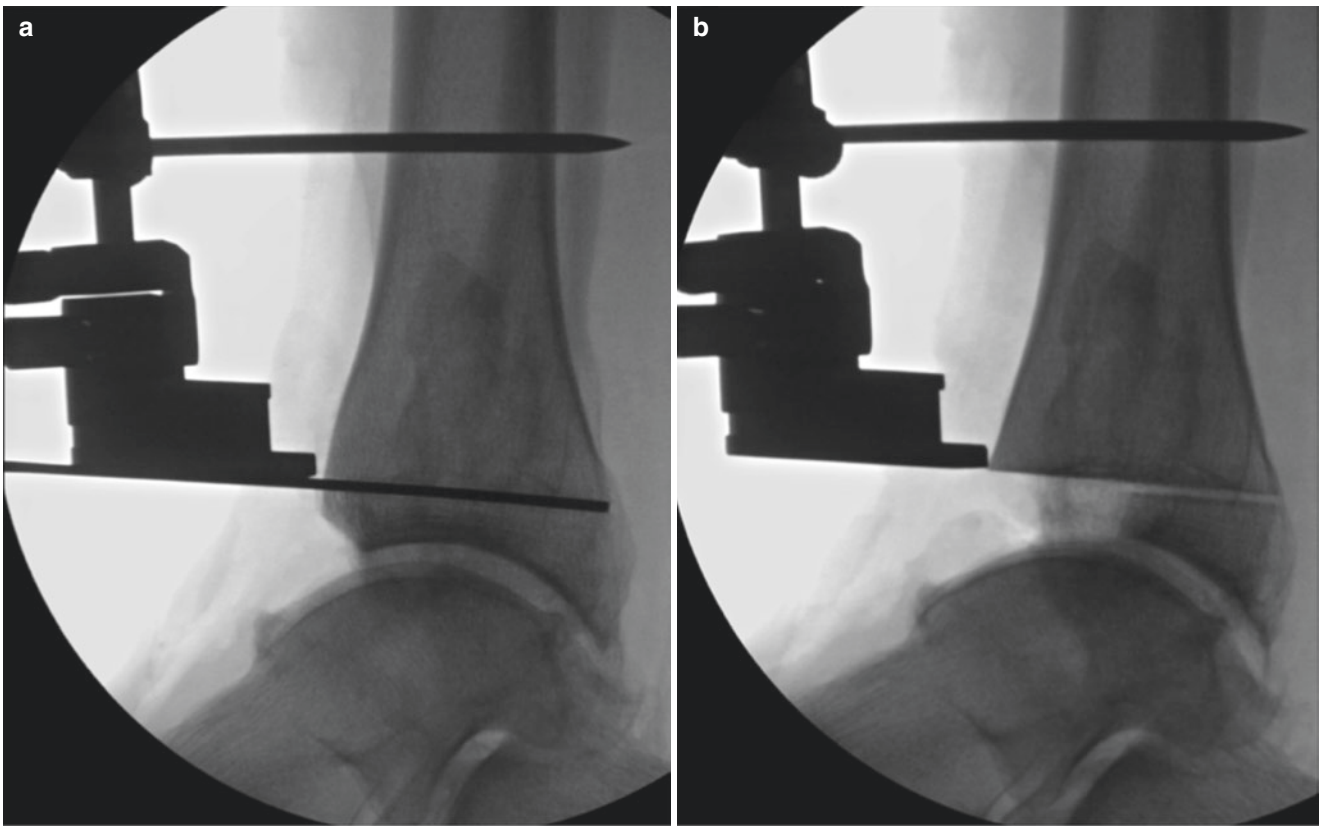


Fig. 15.8 Lateral C-arm image intensification views demonstrating the path of the saw blade within the tibial resection guide (**a**) and resected anterior one half of the tibia (**b**)

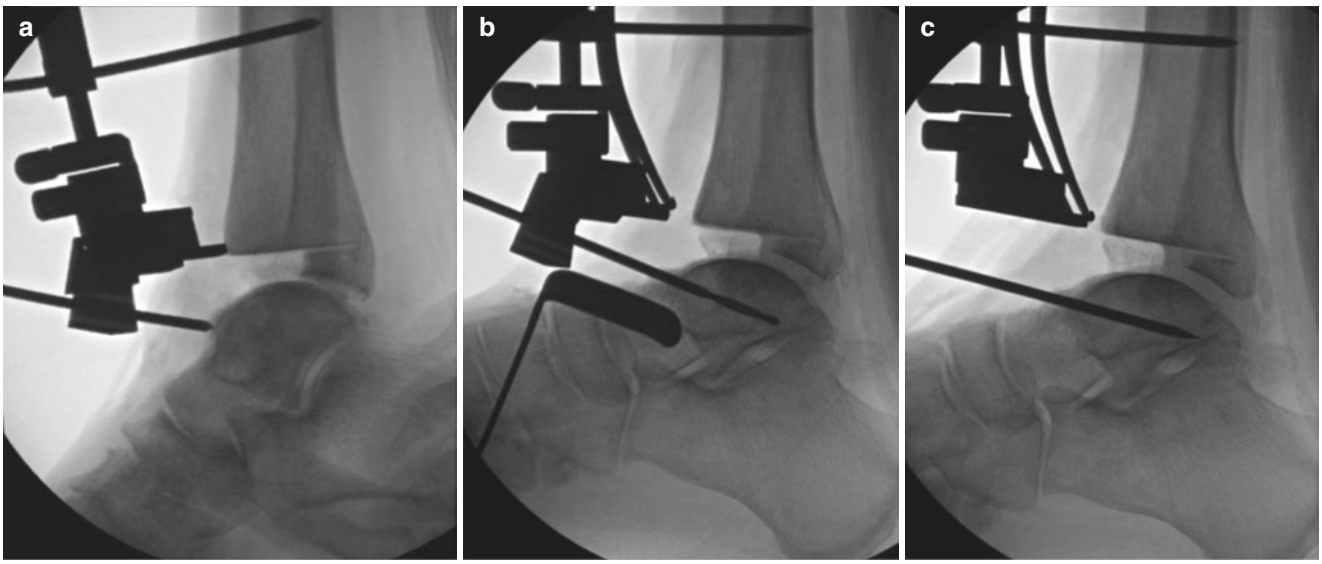


Fig. 15.9 Lateral C-arm image intensification views demonstrating the talar pin setting guide prior to (**a**) and following drill (**b**) and pin (**c**) placement. Note the angle of the drill and pin are such that they would exit the talus within the posterior facet of the subtalar joint

helpful to place them now behind the ankle just proximal to the calcaneal tuber to prevent anterior translation of the talus on the tibia secondary to posterior pressure from the operating room table. The drill is removed, and a 75-mm or 110-mm guide pin is inserted into the drill hole (Fig. 15.9c). It is useful to use the shorter 75-mm pin initially since the talar pin setting guide can more easily be removed with the short pin in place, and once the guide has been removed, the shorter pin can be removed and the longer 110-mm pin is placed. This eliminates the need to find the drill hole after the talar pin setting guide is removed. The drill-tipped pins available in the version 2.1 set eliminate the extra step needed to drill and then place a separate pin. There are 2 posterior talar dome resection guides: one for size 0 and the other for size 1, 2, and 3 talar implants. The size 0 talar component is infrequently used in clinical practice and has specific steps that are required for preparation. The surgical technique guide should be consulted if a size 0 talar component is to be implanted with the Salto Talaris Total Ankle System. However, it is useful to use the size 0 posterior talar dome resection guide if the talar dome is very flattened as it will only remove 5.5-mm of talar bone compared with 7-mm of talar bone with the size 1, 2, and 3 posterior talar dome resection guide. The tibial alignment guide and proximal tibial tubercle pin can be removed, but the distal tibial pin and adjustments made to the guide should be retained incase a tibial recut is needed. The appropriate posterior talar dome resection guide is slid over the talar pin, and the medial and lateral paddles are placed over their respective portions of the talar dome (Fig. 15.10a). Six augments are provided to achieve 1, 2, or 3-mm of height compensation for the paddles. When there is symmetrical talar dome wear (i.e., no varus of valgus wear), no height-compensating augmentations should be employed. However, if asymmetrical wear is appreciated, the appropriate height-compensating augments should be placed over the corresponding paddle to compensate for this asymmetry. The paddles should be placed underneath any remaining tibial bone and then stabilized against the talar dome without bending the talar pin. The stabilization can be enhanced with the use of two joint distractors placed between the resected tibia and the paddles (Fig. 15.10b); however, these prove cumbersome to place and difficult to maintain appropriate tension without tipping the posterior talar dome resection guide anteriorly. Another option is to use a large bone graft impaction handle wedged between the resected tibia and the paddles (Fig. 15.10c). Once the paddles are properly positioned, the front knob on the posterior talar dome resection guide is tightened. Next, the four drill holes in the posterior talar dome resection guide are drilled bicortically one at a time and then filled with a 75-mm pin in each hole (Fig. 15.10d–f). The superior portion of these pins define was the talar resection will be made. It is useful to start with the central holes and work toward the outer ones to minimize any movement of the guide during the drilling and pin placement. The posterior talar dome resection guide is removed along with the talar guide pin leaving the four talar resection pins (Fig. 15.11a). Malleable metallic ribbon retractors are carefully placed in the medial and lateral gutters at the level of the talar resection to protect the medial and lateral malleoli from iatrogenic injury. To follow the planned resection accurately, the saw should cut flush on the superior surface of the pins being careful not to create gouges in the talar bone between the pins (Fig. 15.11b, c). The resected posterior talar dome

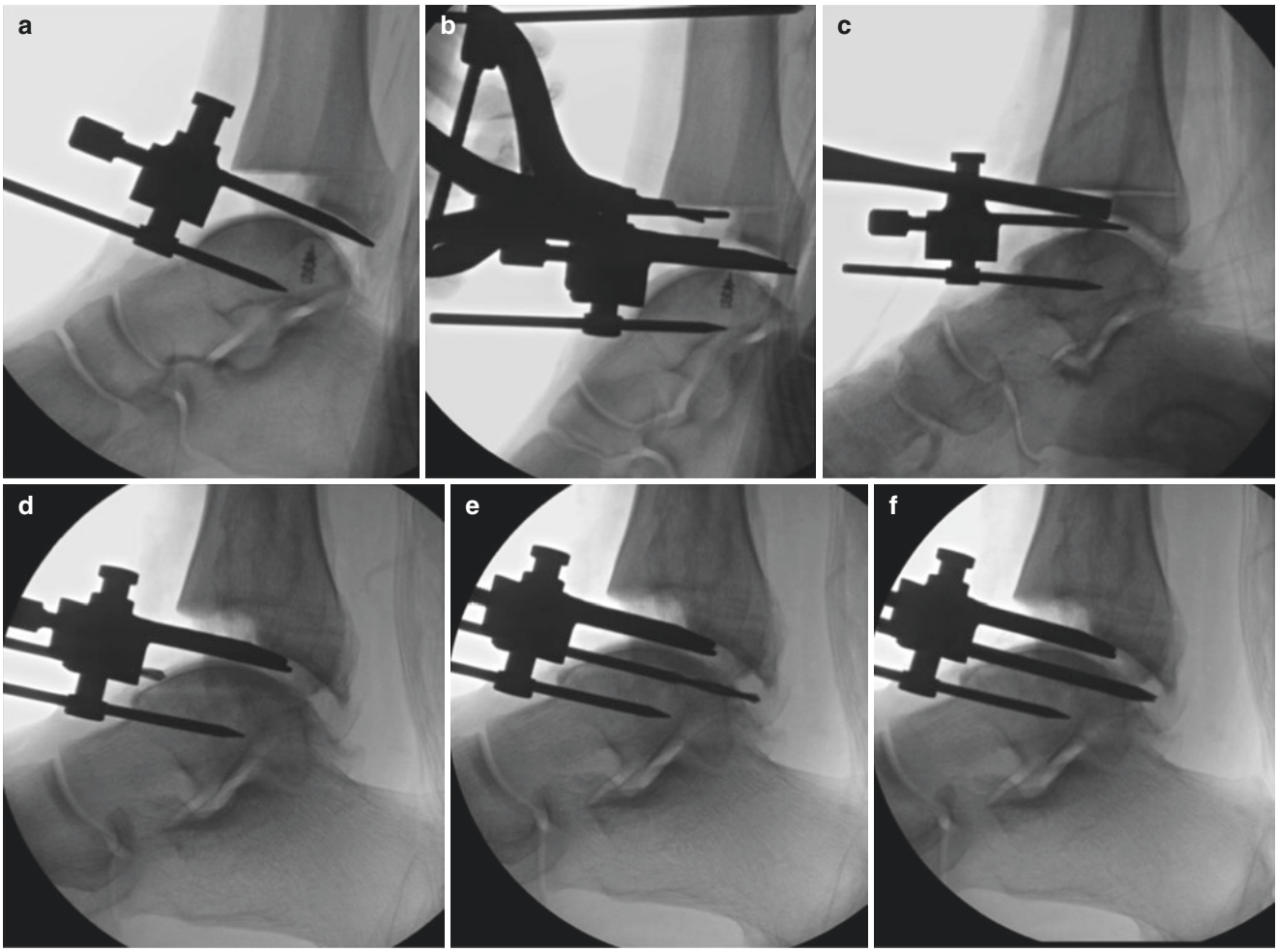


Fig. 15.10 Lateral C-arm image intensification views demonstrating the posterior talar dome resection guide slid over the talar pin (**a**) and stabilized with joint distractors (**b**) and a large bone graft impaction handle (**c**). The four drill holes are then placed from anterior (**c**) through the posterior cortices (**b**) and replaced with bicortical pins (**c**) Lateral intra-operative image intensification views demonstrating starting point for drill (**d**), full depth of drill (**e**) and replacement of the drill with a solid pin (**f**)

segment and all four pins are then removed (Fig. 15.11d, e). The version 2.1 posterior talar dome resection guide reduces the number of steps required to perform the posterior chamfer cut. It is simply slid over the talar pin and pressed against the superior surface of the talar dome with two paddles followed by placement of medial and lateral 75-mm drill-tipped pins on either side of the built in cutting slot. The posterior talar dome is then cut through the cutting slot using a narrow or wide saw blade depending on the width/size of the talus. Although the version 2.1 posterior talar dome resection guide simplifies the posterior chamfer cut, the author maintains that the original posterior talar dome resection guide allows for greater deformity correction. Accordingly, it is important that surgeons are familiar with the steps involved for both the original and updated version 2.1 talar cutting guides.

The retained posterior tibial bone segment can now be removed, and the tibial preparation is completed (Fig. 15.11f). Next, the trial tibial base plate, either standard or XL length, corresponding to the size selected at the time of tibial resection is placed into the surgical site, and contact with both the anterior and posterior distal tibial surface is confirmed (Fig. 15.12). Care should be taken to verify that the laser line on the tibial trial base is posterior to the anterior tibial cortex so that the final component will have appropriate anterior cortical coverage while also optimizing posterior tibial plafond coverage. The next step involves placement of the anterior talar chamfer that determines the anterior-posterior positioning of the final talar component beneath the tibial component. It is important to resect any talar neck osteophytes at this time so the anterior talar chamfer guide can rest congruently on the apex of the posterior talar dome resection cut. The anterior talar chamfer guide has a roughened inferior surface that should rest flush on the posterior talar dome resection cut. It is not uncommon to have a space between the anterior talus and the guide, so care must be taken to

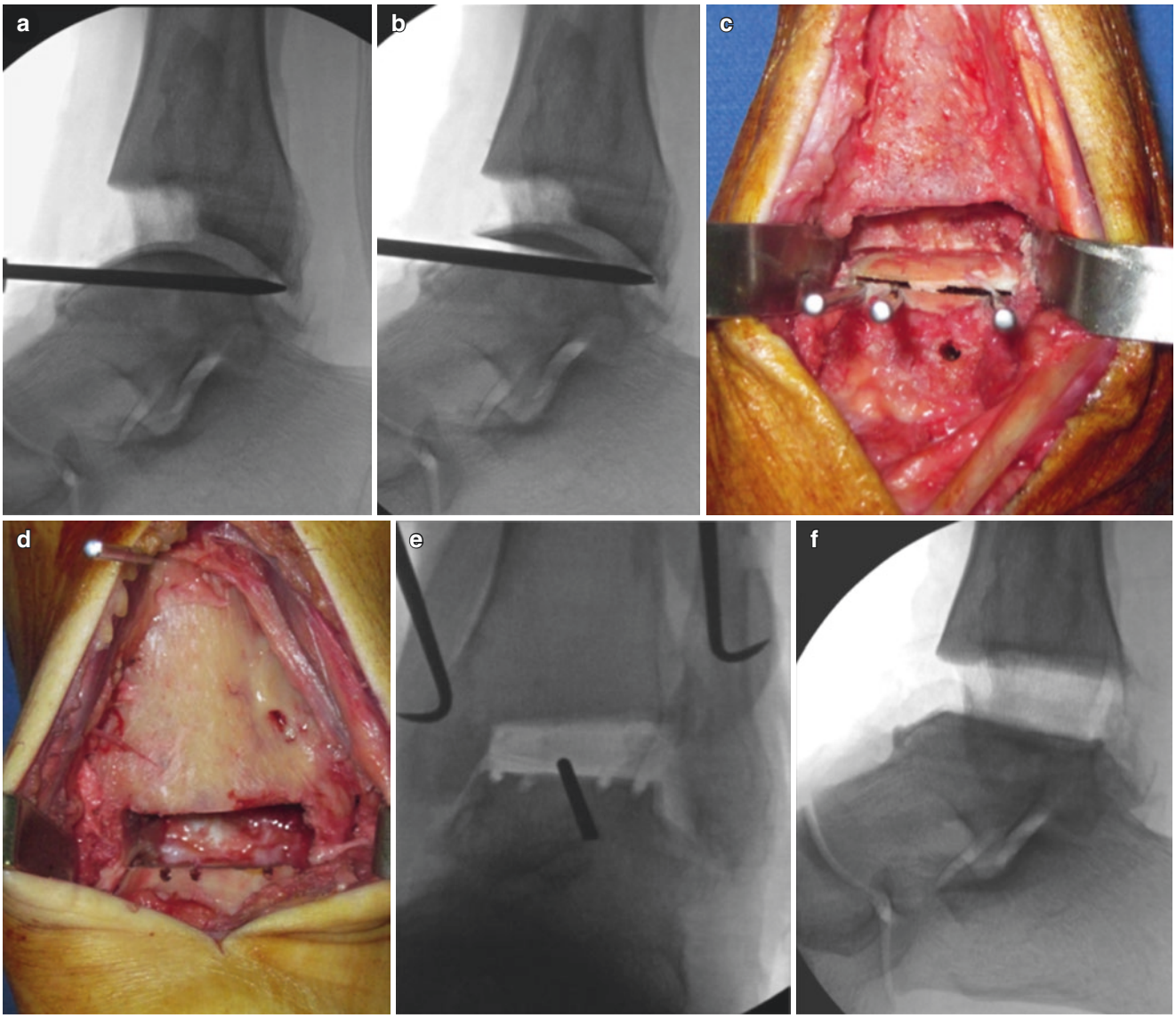


Fig. 15.11 Lateral C-arm image intensification views prior to (**a**) and following (**b**) resection of the posterior talar dome. Intraoperative anterior-posterior photographs prior to (**c**) and following (**d**) resection of the posterior talar dome. Anterior-posterior (**e**) and lateral (**f**) C-arm image intensification views following removal of the posterior talar dome resection pins and removal of the remaining posterior tibial bone segment

verify that the guide is resting directly against the remaining anterior surface of the talar dome and the posterior talar dome resection cut (Fig. 15.13a) with the guide handle held aligned with the 3rd metatarsal. One of the previously employed joint distractors can be utilized to press the posterior portion of the anterior talar chamfer guide against the talus (Fig. 15.13b) followed by fixation of the guide with two 45-mm drill-tipped pins (Fig. 15.13c). Care should be taken at this point since damage to the artery of the tarsal canal can occur during placement of the various talar resection dorsal-to-plantar metallic pins if a pin is inadvertently driven through the inferior surface of the talus. It is intuitive that proper metallic pin insertion technique and liberal use of intraoperative C-arm image intensification will reduce this risk pattern and thereby limit avascular osteonecrosis of the talus. The talar position spacer is then inserted into the oblong window of the anterior talar chamfer guide. With the foot in neutral dorsiflexion, the medial-to-lateral calibration line should be covered by the anterior tibial cortex. If the talar component is inadvertently positioned too far anterior or posterior, the result would be poor alignment of the tibial component and this can lead to mechanical failure. The XL tibial tray has essentially replaced the original tibial tray in all cases except very proximal tibial cuts where the anterior-posterior distance is reduced or with patients who have very small tibias. The oblong window of the anterior talar cham-

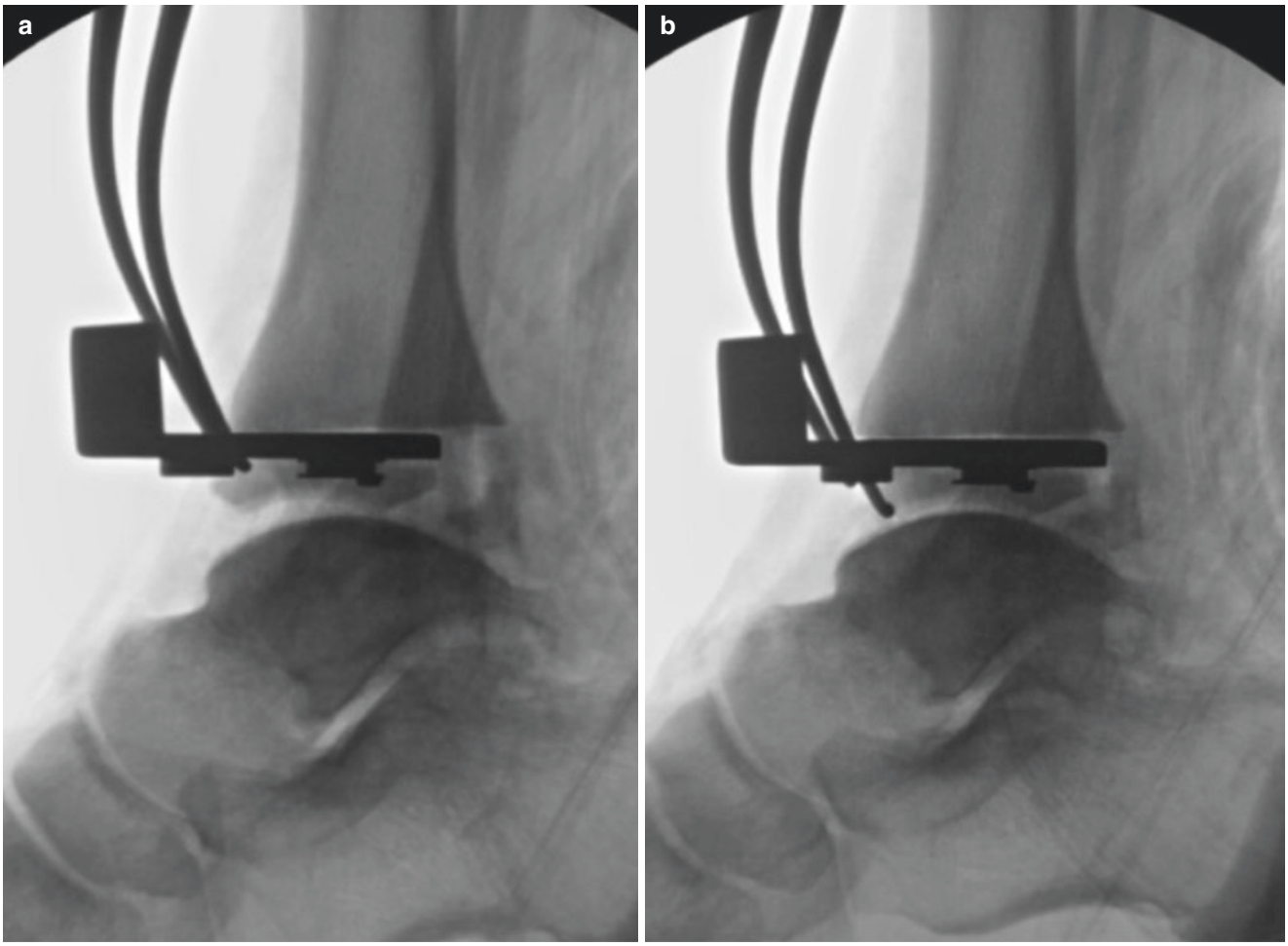


Fig. 15.12 Lateral C-arm image intensification views demonstrating placement of the standard (**a**) and XL (**b**) trial tibial base plate. Note the significant additional posterior coverage of the tibial plafond achieved with the XL tibial tray

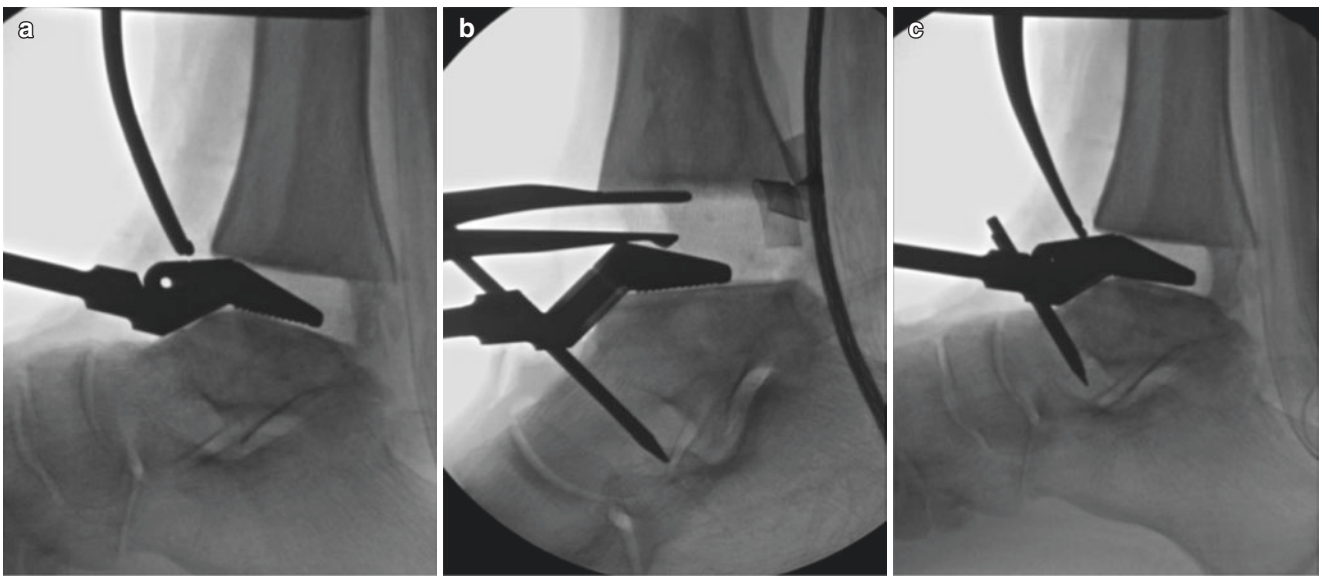


Fig. 15.13 Lateral C-arm image intensification views demonstrating placement of the anterior talar chamfer guide prior to (**a**) and after application of a joint distractor (**b**) that is maintained with two short pins (**c**). Lateral C-arm image intensification views demonstrating the anterior chamfer reamer (**d**) used to define the anterior talar surface (**e**) and obtain an apex of bone between the posterior talar resection and anterior talar surface (**f**)

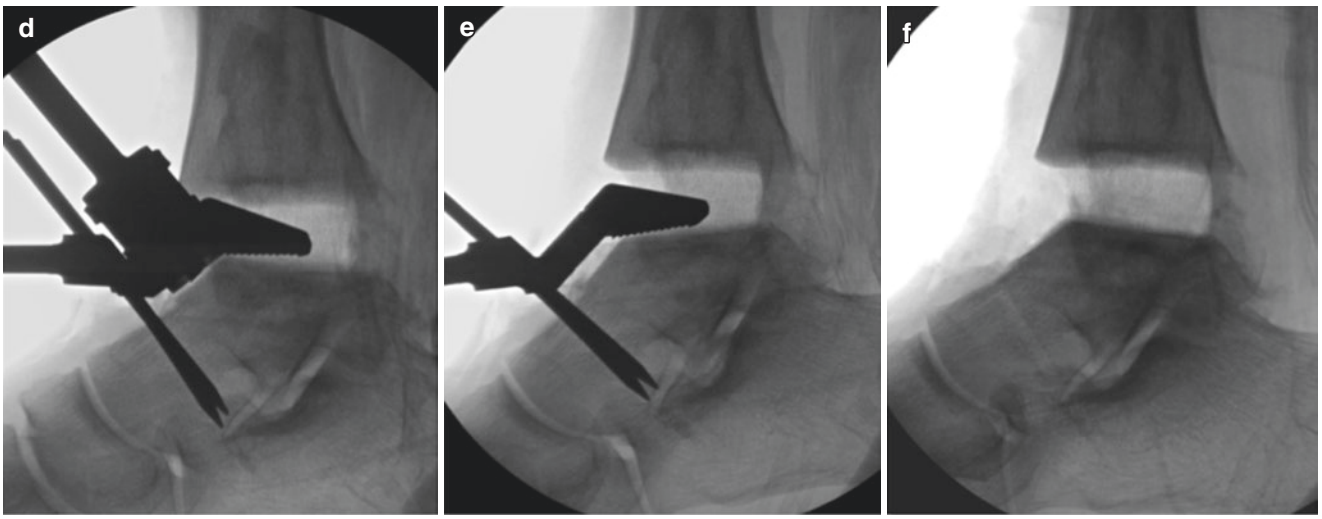


Fig. 15.13 (continued)

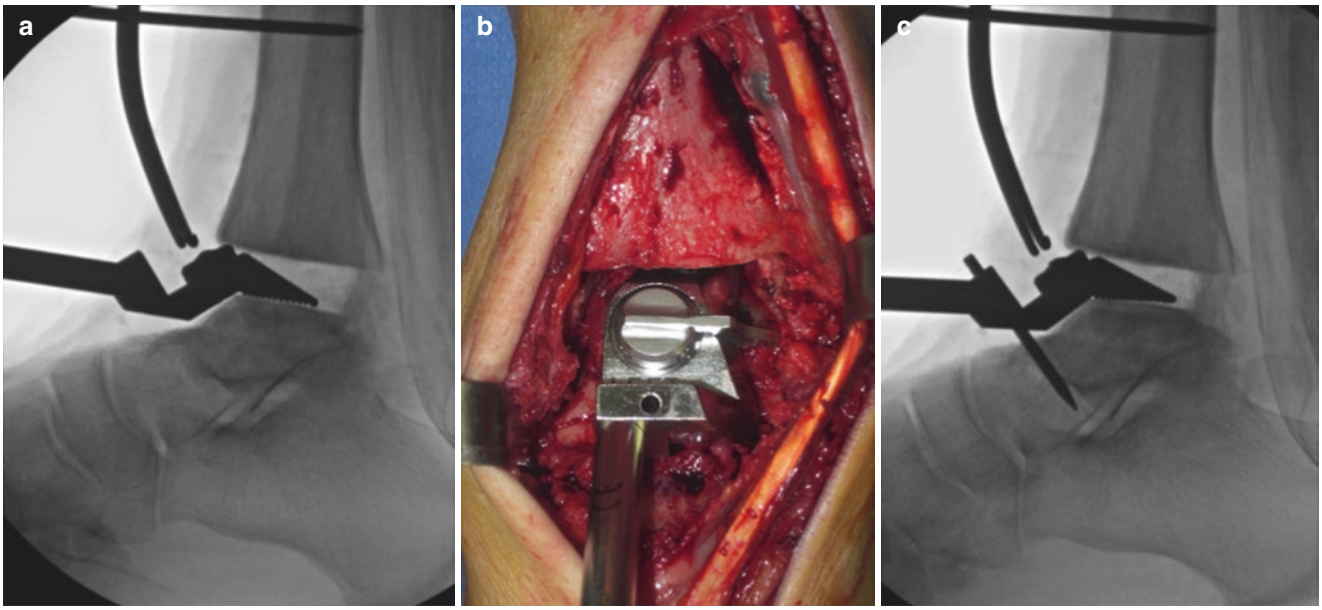


Fig. 15.14 Lateral C-arm image intensification view (**a**) and intraoperative photograph (**b**) demonstrating the plug-shaped medial-lateral positioning gauge alignment. Lateral C-arm image intensification view after pinning the guide in place (**c**)

fer guide is removed, and the reaming guide inserted. The anterior chamfer reamer is inserted into the reaming guide (Fig. 15.13d) and pressed firmly to resect the anterior talar bone. The reaming guide is then removed, rotated 180°, and set back into the anterior chamfer guide followed by reaming with the anterior chamfer reamer. This two-step process cores out the central-medial and central-lateral surfaces of the anterior talar dome and a portion of the talar neck (Fig. 15.13e). The anterior chamfer reamer and pins are then removed, and the anterior talar resection is finished at the most medial and lateral margins with a rongeur and hand rasp (Fig. 15.13f). It is not necessary to resect any further anterior talar bone, and great care must be taken not to disrupt the apex created by the anterior and posterior chamfer cuts. The corresponding right or left lateral talar resection guide with the plug-shaped medial-lateral positioning gauge bushing is then set on the anterior and posterior resected surfaces (Fig. 15.14a). The guides positioning gauge should be positioned on the apex at the junction between the anterior chamfer and posterior talar resection with tip of the wing of the medial-lateral positioning gauge bushing being on the lateral cortex of the talus or 1–2-mm medial to assure that the final component is not positioned too far lateral (Fig. 15.14b). It is imperative that the lateral talar resection guide is

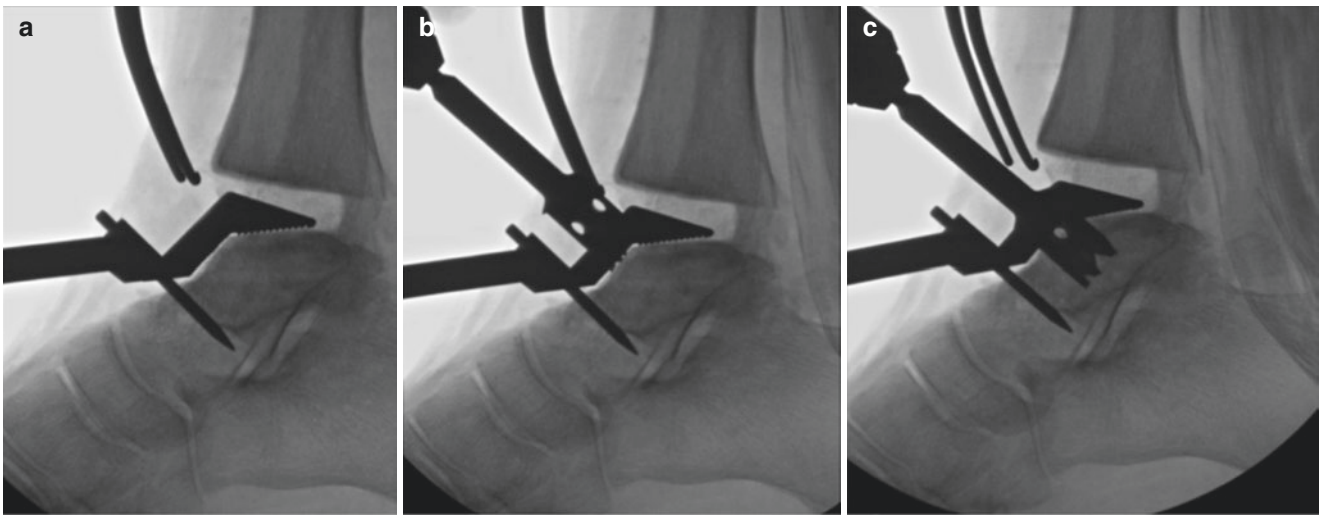


Fig. 15.15 Lateral C-arm image intensification views demonstrating removal of the plug-shaped medial-lateral positioning gauge bushing (**a**) followed by reaming of the talar hole (**b**) until a hard stop is encountered (**c**)

positioned congruent to the apex at the junction between the anterior chamfer and posterior talar resection, at the desired location relative to the lateral cortex of the talus, and with rotation aligned with the 3rd metatarsal. Once these positions have been achieved, the lateral talar resection guide is secured with a 45-mm drill-tipped pin (Fig. 15.14c) and again being careful not to violate the inferior aspect of the talus. The plug-shaped medial-to-lateral positioning gauge bushing is removed (Fig. 15.15a), and the bell saw reamer is placed into the hole in the lateral talar resection guide (Fig. 15.15b) and advanced into the talus until a hard stop is encountered (Fig. 15.15c). The bell saw reamer is removed, and a fixation plug is placed into the hole (Fig. 15.16a) and driven completely into the talus (Fig. 15.16b). Next, with the lateral malleolus protected with a malleable metallic ribbon retractor, the lateral cut on the talus is made using a reciprocating saw with the saw blade following the external slope of the guide (Fig. 15.16c, d). If necessary, the lateral talar resection guide handle can be removed by unscrewing it to facilitate access to the lateral surface of the guide.

The updated version 2.1 instrumentation contains a new anterior chamfer guide that is slid over the same talar guide pin used to position the posterior talar chamfer cut guide. A talar position spacer is inserted into the oblong window as for the original guide; however, once the optimal position is obtained, the guide is pinned to the talar neck with two 45-mm drill-tipped pins being careful not to penetrate the inferior aspect of the talar neck. The anterior talar reaming guide then replaces the talar position spacer, and the anterior chamfer reaming is completed in similar manner as for the original guide. The anterior chamfer guide and pins are then removed, and the preliminary talar trial that best fits the talus while resting on top of the posterior and anterior chamfer cuts, but does not extend past the borders of the cortical wall of the talus, is selected. Under lateral intraoperative C-arm image intensification, the preliminary talar trial should match the anterior and posterior chamfer cuts as well as align with the center of the tibial long axis. Once proper position is achieved, the preliminary talar trial is secured with a 45-mm drill-tipped pin. The bell saw bushing is inserted, the bell saw cut is completed, and the fixation plug is inserted to maintain the preliminary talar trial. Next, with the lateral malleolus protected with a malleable metallic ribbon retractor, the lateral chamfer cut is completed through the preliminary talar trial with a narrow saw blade. If necessary, the preliminary talar trial guide handle can be removed by unscrewing it to facilitate access to the lateral chamfer cut slot of the guide.

The steps to perform the Salto Talaris XT Primary and Revision Total Ankle System are simplified for the talar flat top osteotomy. The XT talar cutting guide is attached to the tibial alignment guide and advanced as close to the talar dome as possible (Fig. 15.17a). It is important to lift the proximal end of the tibial alignment guide to reduce the tibial alignment guide to 0° to allow for a level talar dome osteotomy with the foot in neutral alignment. The amount of talar dome resection is then adjusted using the height adjustment on the tibial alignment guide. Ideally, the resection should be at the level of the anterior border of the talar articular surface. Once ideal placement of the talar cutting guide is obtained, two 110-mm drill-tipped pins are placed in the capture holes to stabilize the cutting guide. The talar dome is then resected with an oscillating saw and removed along with the talar cutting guide and pins (Fig. 15.17b). Note, the bell saw cut for the fixation plug is not performed at this time.

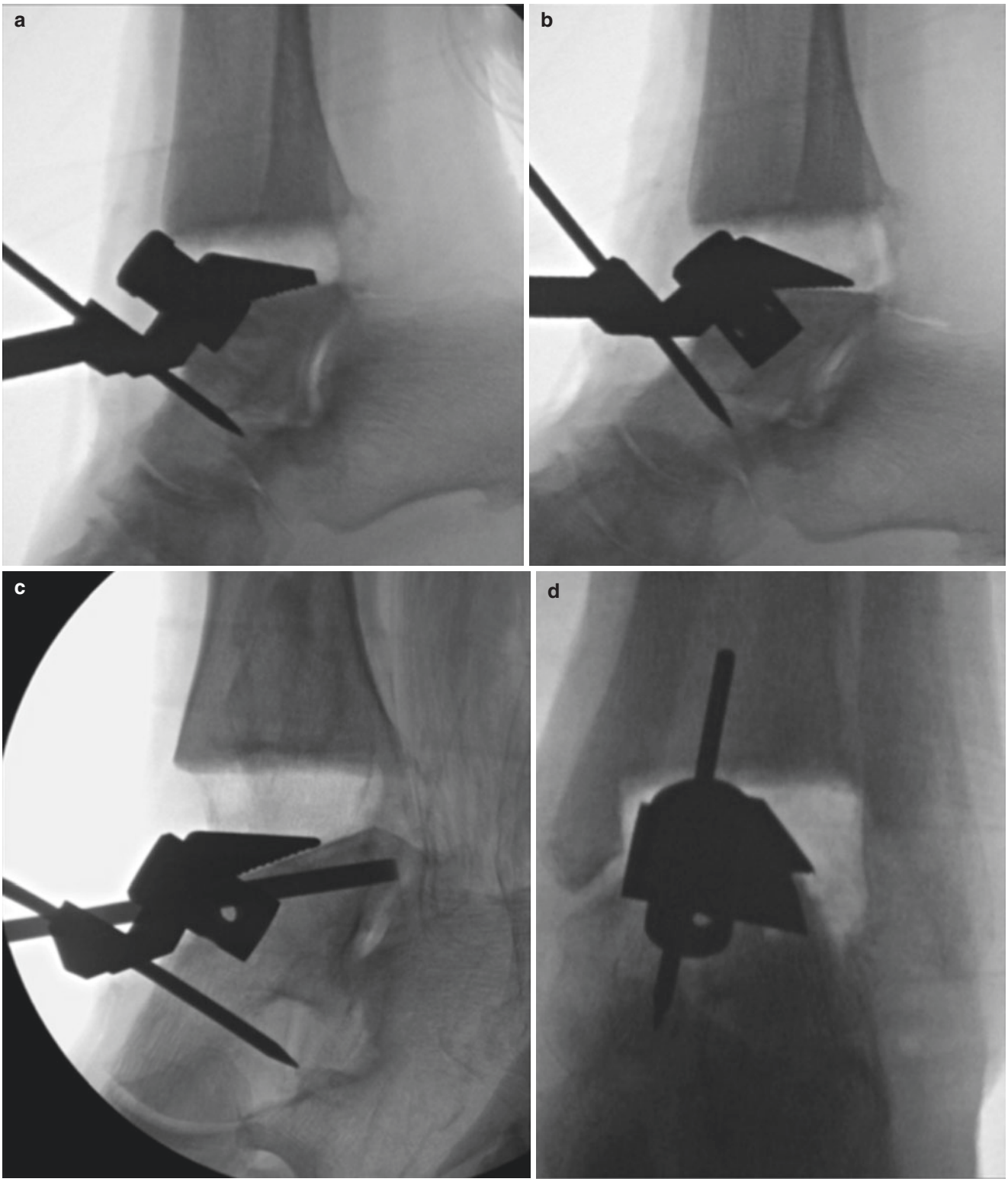


Fig. 15.16 Lateral C-arm image intensification views prior to (**a**) and after placement (**b**) of the talar fixation plug. Lateral (**c**) and anterior-posterior (**d**) C-arm image intensification views demonstrating the lateral talar resection depth and angle, respectively

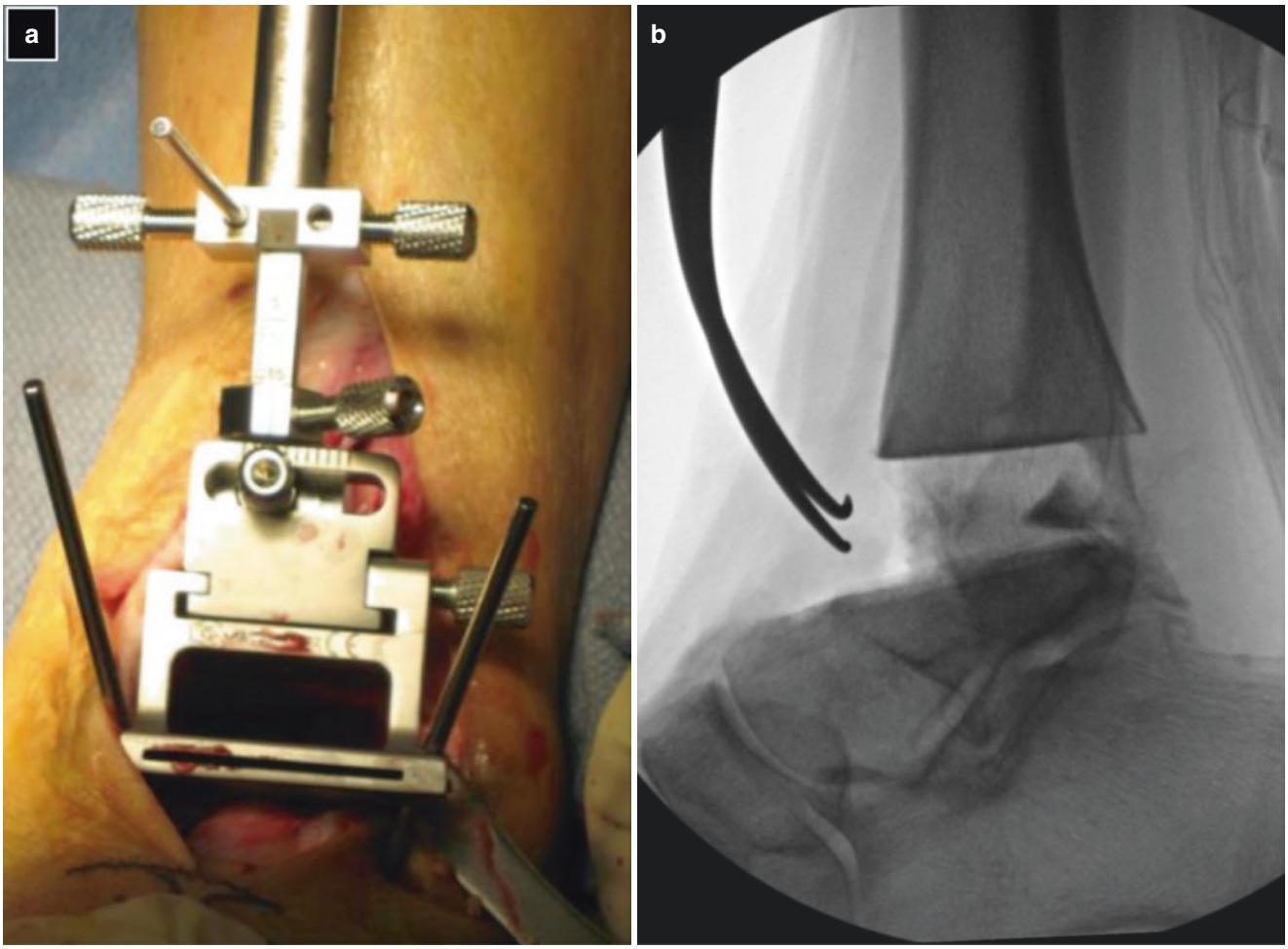


Fig. 15.17 Intraoperative photograph of the XT talar cutting guide attached to the tibial alignment guide and pinned to the talus (**a**). Lateral C-arm image intensification view following flat-top talar osteotomy (**b**). Note the residual bone segments in the posterior ankle recess that require removal

Trial Size, Prosthesis Component Positioning, and Tibial Keel Preparation

For both the original and version 2.1 updates for the Salto Talaris Total Ankle System, the right or left trial talar component is placed first with care taken to verify that the talar component plug is positioned directly over the talar hole created. The trial talar component is then gently impacted into place, and the talar coverage is verified (Fig. 15.18). For the Salto Talaris XT Primary and Revision Total Ankle System, the flat-topped talar trial is inserted verifying maximum talar body coverage and optimum anterior-posterior position. Once the ideal position for the flat-topped talar trial is obtained, the trial is secured to the underlying bone with 2, 75-mm drill-tipped pins. Care should be taken when inserting these pins since they are not parallel to one another, and any off-axis pin placement will result in rotation of the talar trial and loss of the ideal position. The trial tibial base plate corresponding to the same size or one larger than the talar component is selected, and the trial plastic insert is selected based on the thickness needed to achieve a balanced ankle joint. The trial plastic inserts correspond to the size and side of the trial talar components. The trial plastic insert is clipped to the trial tibial base forming a monoblock device. The trial tibial monoblock is then inserted between the trial talar implant and the tibia. Next, a "dynamic flexion-extension test" is performed whereby the ankle is brought through dorsiflexion and plantarflexion and the trial plastic insert, which perfectly conforms to the trial talar component surface, will force the polished trial tibial base plate to obtain its optimal position in the frontal, sagittal, and rotational planes (Fig. 15.19a). Once the optimal trial tibial base plate position is obtained, continuous dorsiflexion and plantarflexion of the ankle would not cause any further movement of the trial

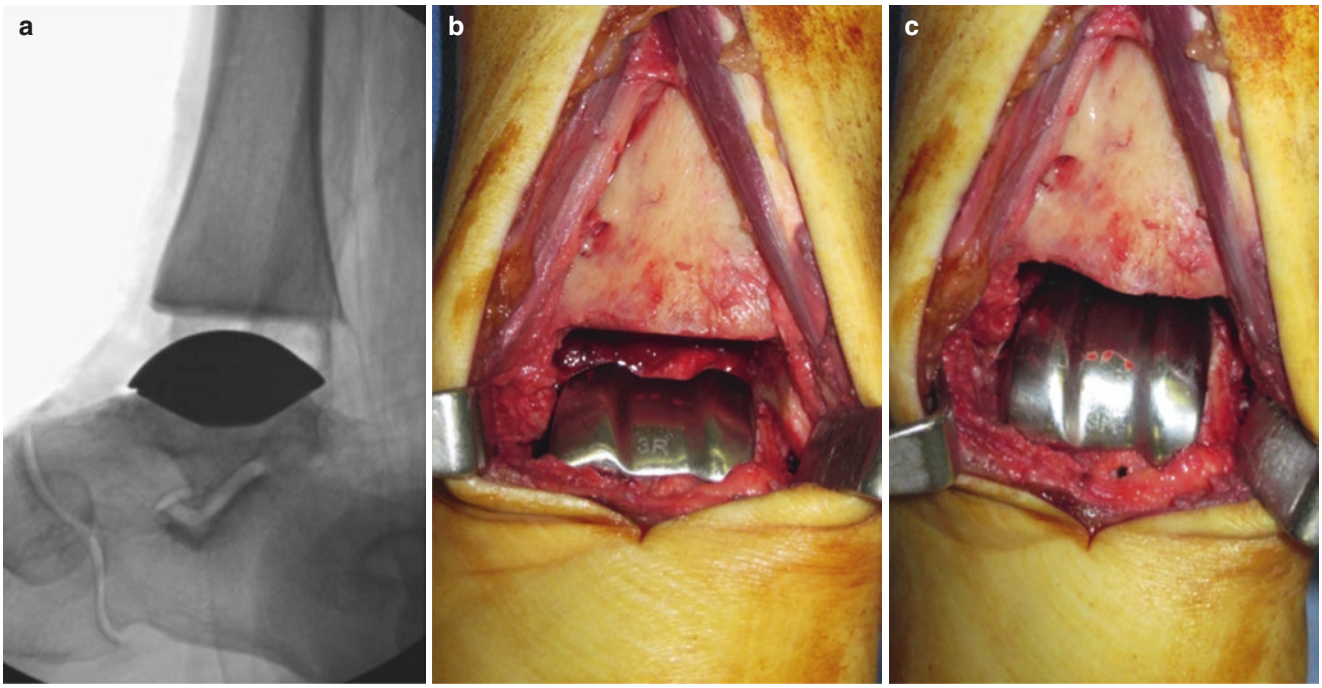


Fig. 15.18 Lateral C-arm image intensification view (**a**) as well as neutral (**b**) and plantarflexion (**c**) intraoperative views of the trial talar component

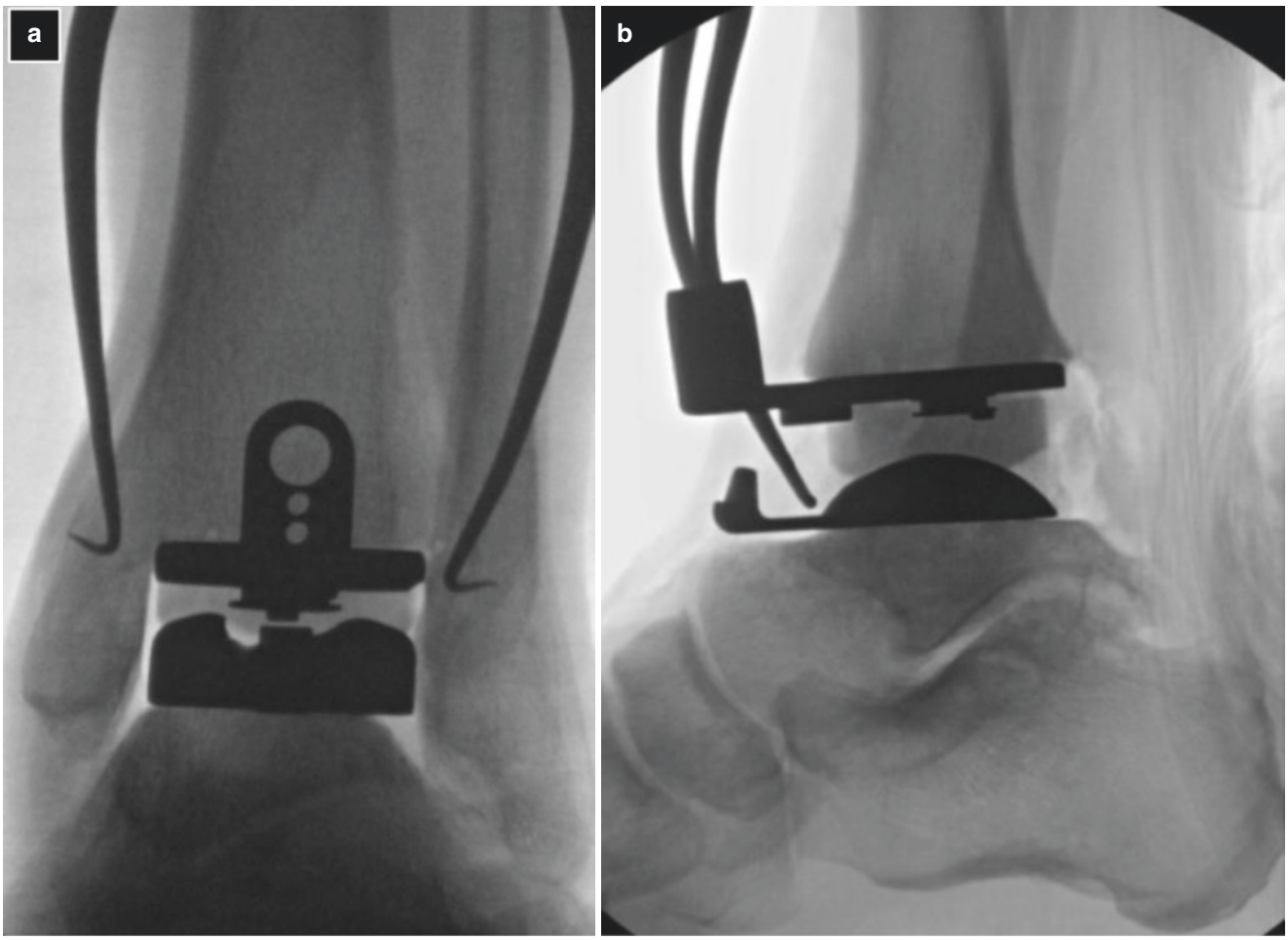


Fig. 15.19 Anterior-posterior (**a**) and lateral (**b**) C-arm image intensification views (of the trial tibia and UHMWPE insert monoblock and trial XT flat-topped talar component

component. If soft-tissue release(s) have not already been performed, then it is important to do so at this time to achieve a balanced joint especially in the frontal plane. The engraved line on the superior surface of the trial tibial base plate should be verified as aligned with the anterior cortex of the tibia prior to accepting the position of the trial tibial base plate. It is critical that the trial tibial base plate is pressed firmly against the resected tibial surface to maintain this position and a lateral C-arm image should be obtained to verify this (Fig. 15.19b). For both systems, the tibial implant keel preparation begins with a 2.9-mm drill-tipped pin through the inferior two drill holes starting with the more one directly above the trial tibial base plate (Fig. 15.20a). The drill-tipped pin is retained in the inferior hole, which secures the guide. The more superior hole is then drilled with the 2.9-mm pin and removed (Fig. 15.20b). A 7.9-mm drill bit is then employed to prepare the tibial plug through the trial tibial base plates superior most and largest drill hole until it contacts but does not penetrate the posterior tibial cortex (Fig. 15.21a). Drilling through the trial tibial base guide creates a 4° angle from the final tibial base plate that allows for a press-fit of the final prosthesis between the keel and distal tibial resection surface during final tibial component impaction. After the tibial plug has been created, the trial tibial monoblock and Salto Talaris Total Ankle System trial talar components are removed; however, the Salto Talaris XT Primary and Revision Total Ankle System talar trial must remain in situ. The bell-saw is used to create the talar plug

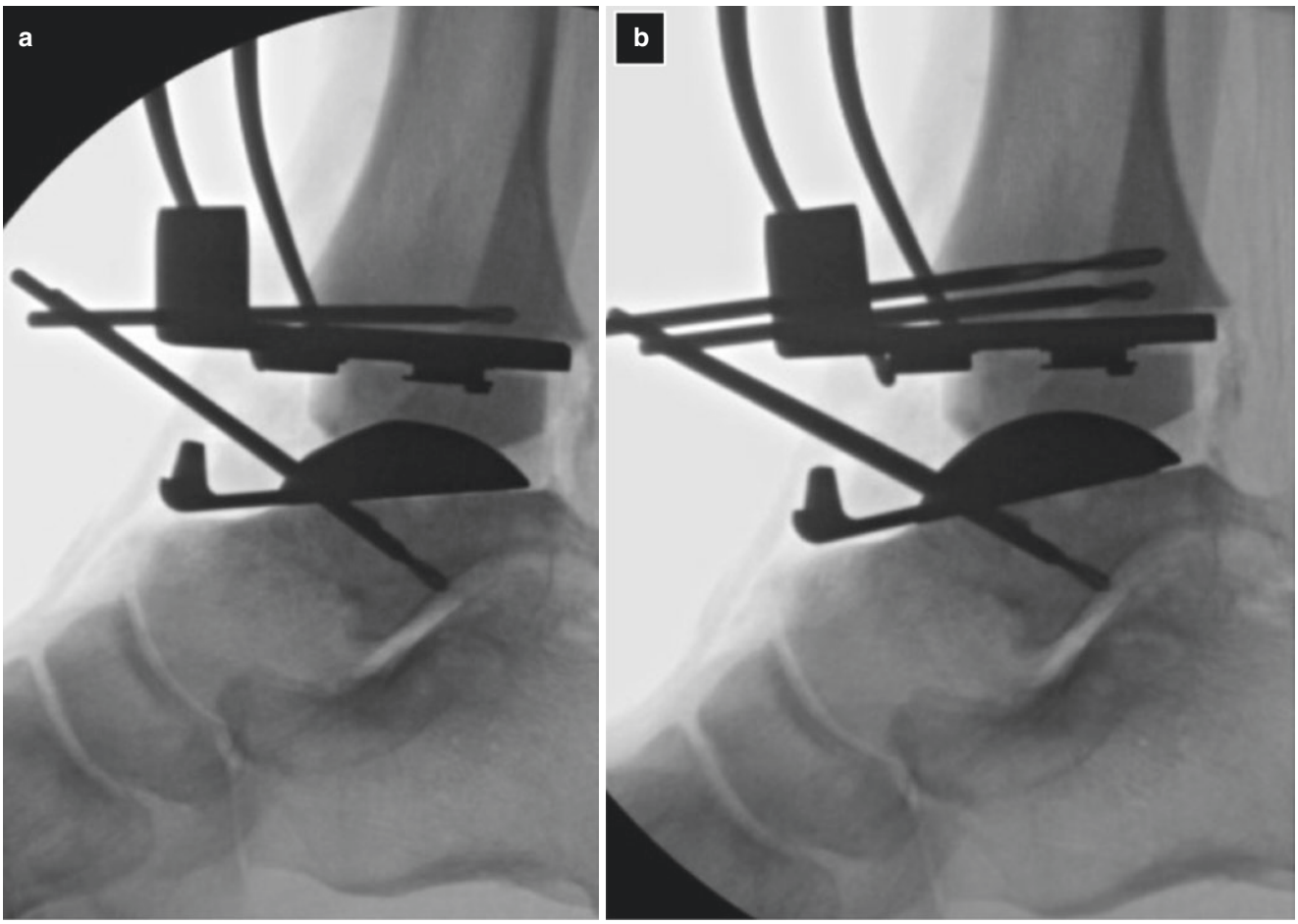


Fig. 15.20 Lateral C-arm image intensification views demonstrating the inferior (**a**) tibial keel hole filled with a drill-tipped pin followed by the superior and (**b**) tibial keel hole that is drilled but the pin removed. Care must be taken to make certain the tibial base plate is in direct contact with the resected tibial bone surface during the tibial keel preparation

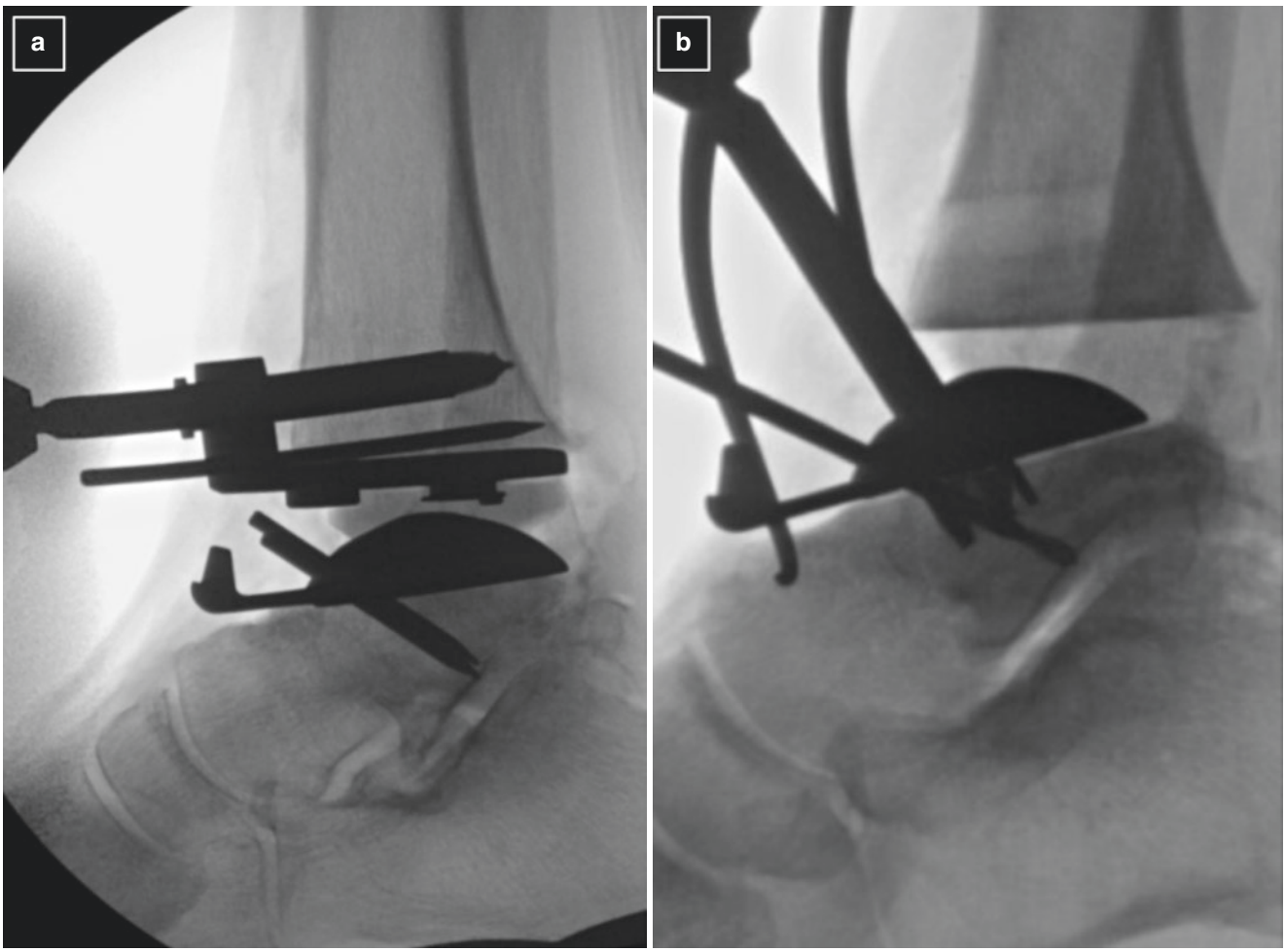


Fig. 15.21 Lateral C-arm image intensification views following (**a**) creation of the tibial fixation plug. As with the tibial keel preparation, care must be taken to make certain the tibial base plate is in direct contact with the resected tibial bone surface during the tibial fixation plug preparation. The tibial tray is then removed, and the XT flat-topped talar trial fixation plug is prepared with the bell saw (**b**)

(Fig. 15.21b) for sizes 1, 2, and 3, while a drill guide and drill are used to create a hole for the size 0 XT talar peg fixation (Fig. 15.22). Once the plug is created, a drill is used to perform the talar flange through two holes in the posterior aspect of the XT flat-topped talar trial (Fig. 15.23). Once completed, the XT flat-topped talar trial is removed and the posterior flange completed with a graduated osteotome or rotary bur (Fig. 15.24a). The two tibial keel holes are connected using a small power saw or graduated osteotome followed by beveling and bone impaction using the tibial keel rasp (Fig. 15.24b). The different tibial implant sizes (i.e., 0, 1, 2, and 3) are marked on the superior surface of the tibial keel rasp, and the impaction should correspond to the length of the final implant selected (Fig. 15.25). The surgical site is copiously irrigated, and any rough edges are smoothed with a hand rasp until both clinical observation and intraoperative C-arm imaging verify proper correspondence to the selected prosthesis components.

Final Prosthesis Implantation

Application of polymethylmethacrylate cement is required by the FDA and is usually applied as a thin layer about the anterior surface of the talar component and within the various drill holes in the talus to limit any joint fluid migration into the underlying bone that can cause cystic changes. It is important that the final talar component is aligned to exactly

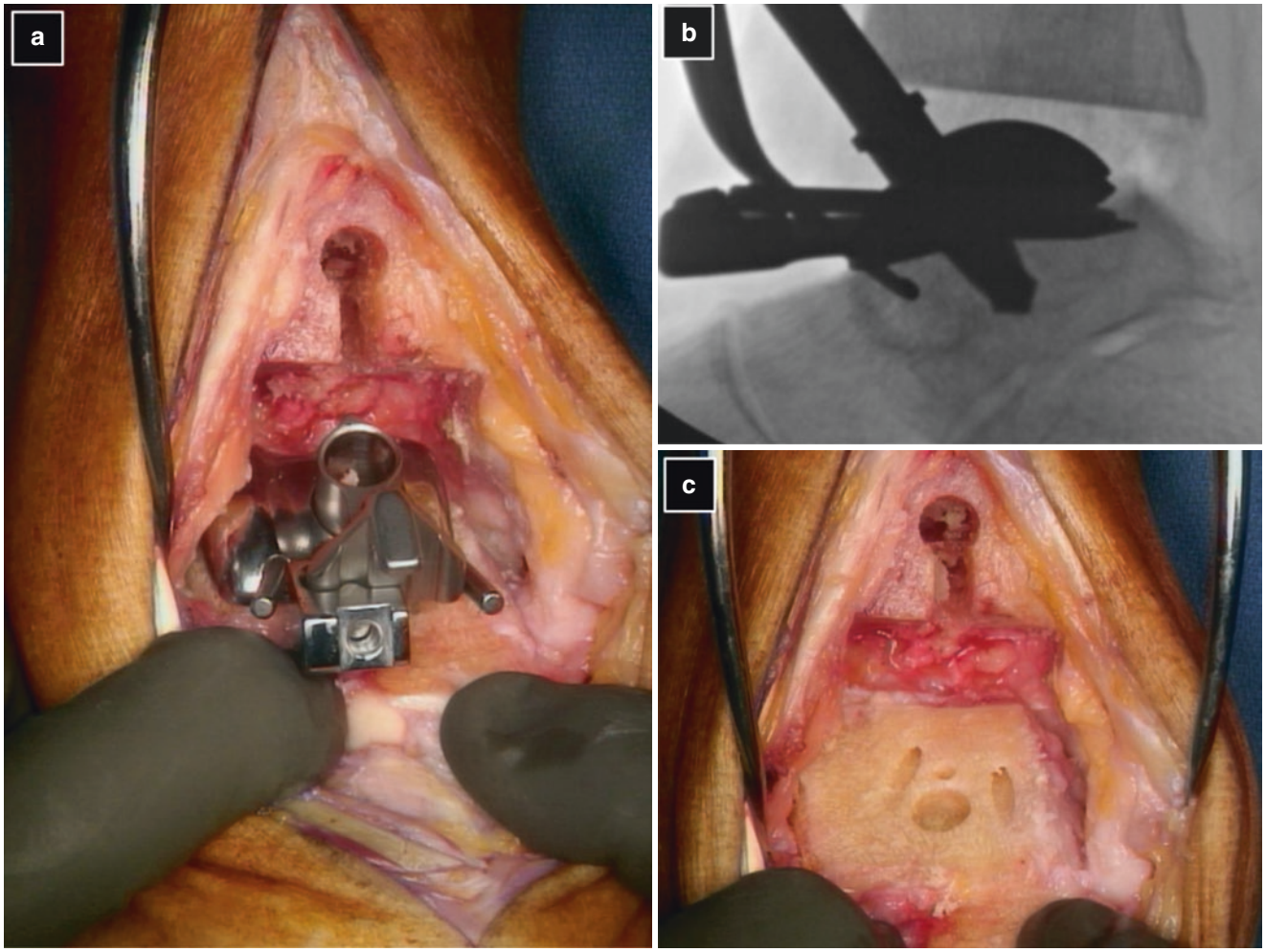


Fig. 15.22 Intraoperative photograph of the XT flat-topped size 0 talar trial secured to the talar body with 2 drill-tipped pins and the drill hole guide for the talar fixation peg secured in place (**a**). Lateral intraoperative C-arm image intensification view demonstrating full insertion of the drill to prepare the hole for the size 0 XT flat-topped talar fixation peg (**b**). Intraoperative photograph following completion of the size 0 XT flat-topped talar fixation hole (**c**)

match the talar preparation morphology (Fig. 15.26) followed by firm impaction using the talar component impactor (Fig. 15.27). The final UHMWPE insert corresponding to the size and side matching the talar component is secured to the final tibial component using the assembly clamp according to the manufacturer directions. The tibial component is now composed of the tibial base plate and the UHMWPE insert as a single unit that is grasped by the tibial impactor according to the manufacturer directions (Fig. 15.28). The tibial component is then impacted until the position of the tibial trial is reproduced. This is best performed under sequential lateral C-arm image intensification views in order to maintain contact between the superior side of the tibial base plate and the resected tibial surface to prevent any gapping (Fig. 15.29). Additionally, maintaining a slight amount of plantarflexory pressure on the tibial component impactor (i.e., tipping the handle forward upon impaction) will aid against posterior gapping of the tibial tray on the tibial plafond during insertion. Liberal use of lateral C-arm image intensification during tibial tray insertion is critical to reduce posterior gapping of the tibial tray. Despite best efforts, if a small amount of posterior gapping is appreciated between the tibial base plate

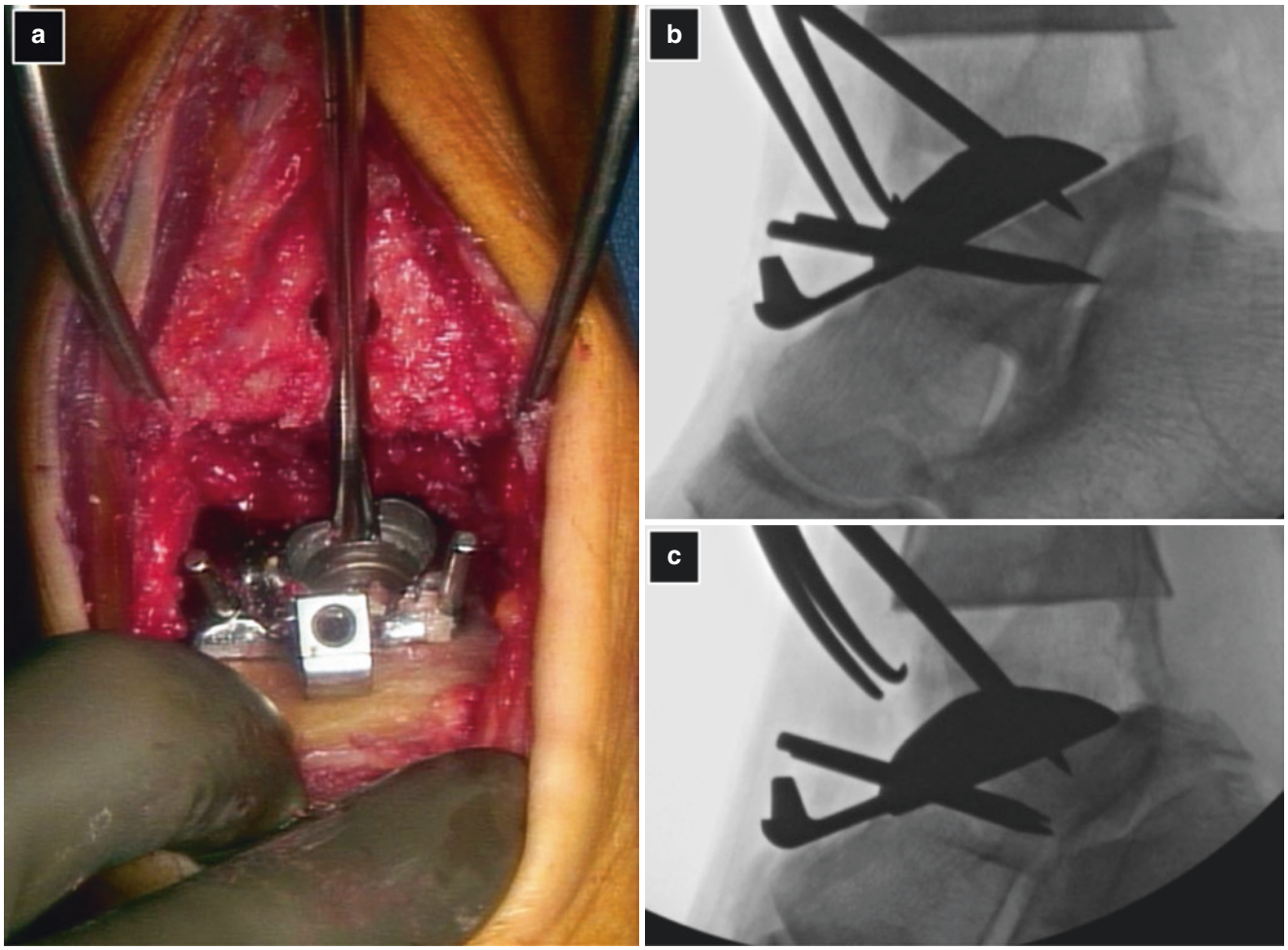


Fig. 15.23 Intraoperative photograph of the XT flat-topped talar trial secured to the talar body with 2 drill-tipped pins, and the drill is placed in one of the posterior flange holes (**a**). Lateral intraoperative C-arm image intensification view demonstrating full insertion of the drill into the proximal (**b**) and distal (**c**) drill holes to prepare the posterior flange holes

and tibial plafond, the plantar aspect of the heel can be manually impacted, while the foot is maintained in neutral alignment to properly seat the tibial base flush with the resected tibial surface. The ankle is stressed in the sagittal (Fig. 15.30a–c) and frontal (Fig. 15.30d–f) planes to verify stability and appropriate range of motion, respectively. Any gaps between the tibial component and adjacent bone are filled with cancellous bone graft harvested from the previously resected bone and a thin layer of polymethylmethacrylate cement as required by the FDA (Fig. 15.31).

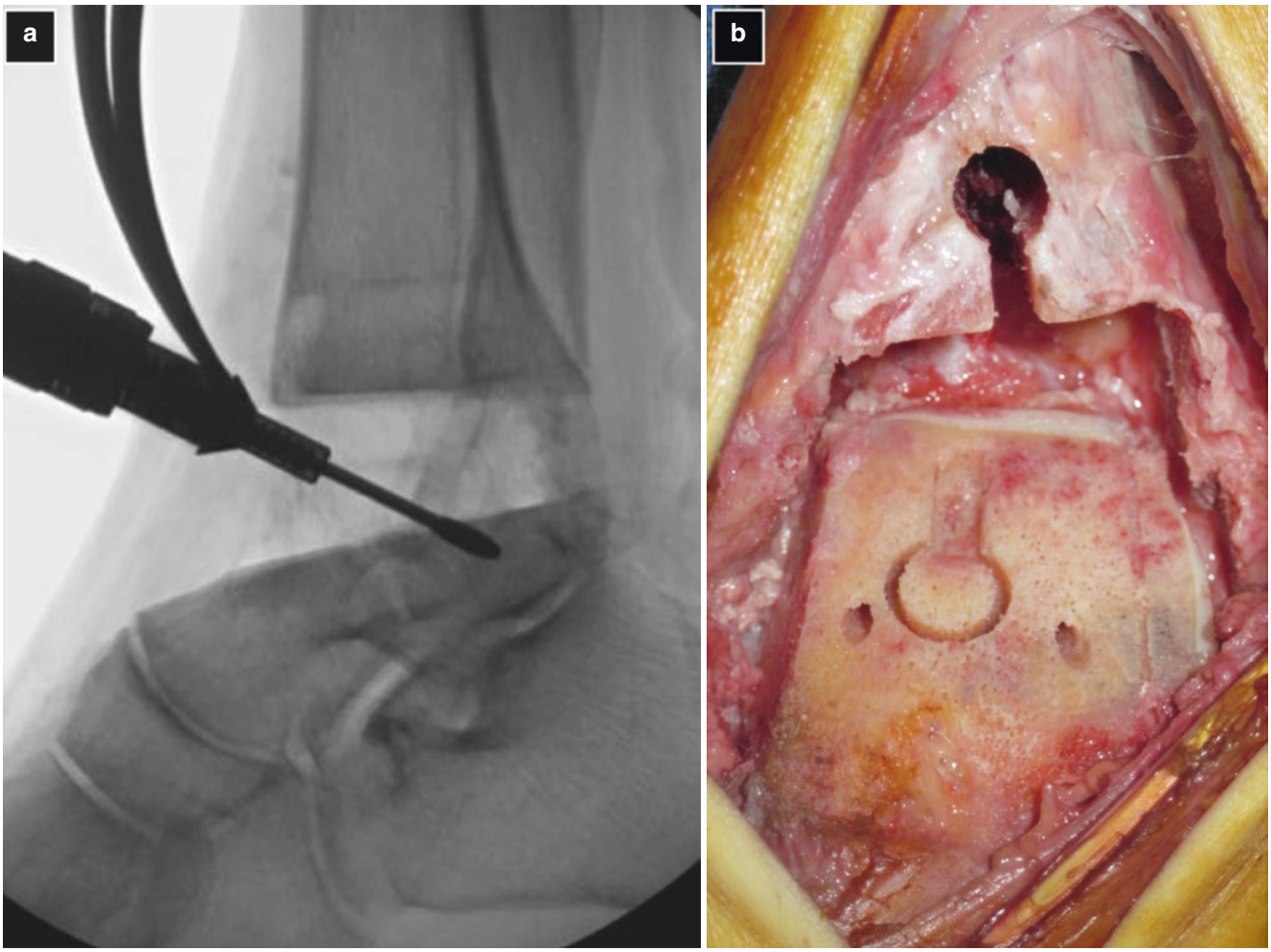


Fig. 15.24 Lateral intraoperative C-arm image intensification view demonstrating use of a rotary bur to connect the drill holes and complete the posterior flange (**a**). Intraoperative photograph following completion of the XT flat-topped posterior flange preparation (b)

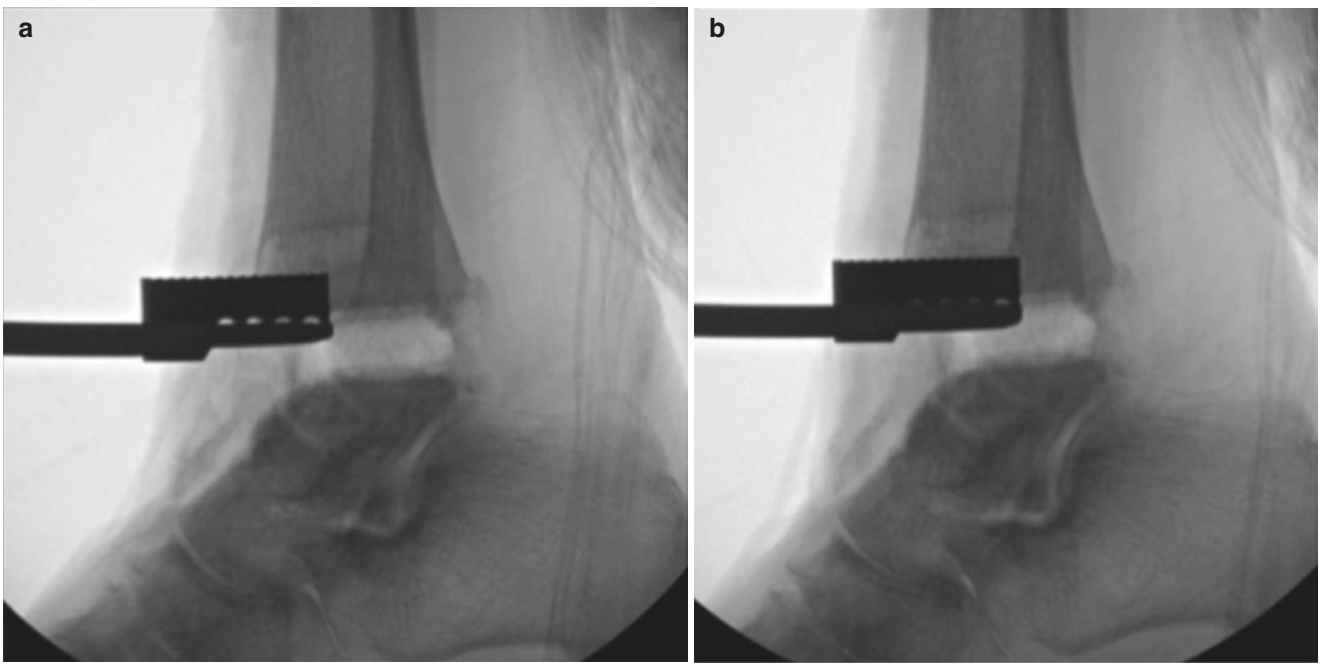


Fig. 15.25 Lateral C-arm image intensification views at the start of (**a**), midway through (**b**), near completion (**c**), and following (**d**) passage of the tibial keel rasp. As with the tibial keel and fixation plug preparation, care must be taken to make certain the tibial keel rasp is in direct contact with the resected tibial bone surface during preparation

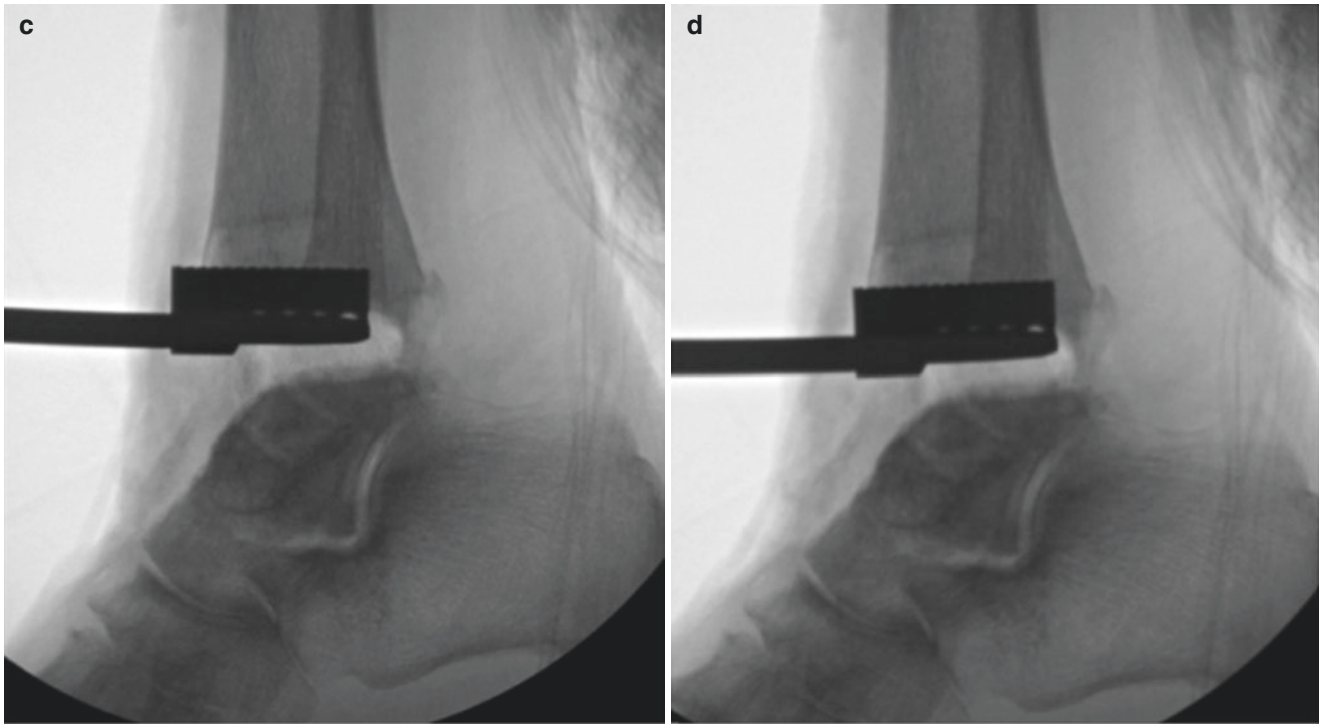


Fig. 15.25 (continued)

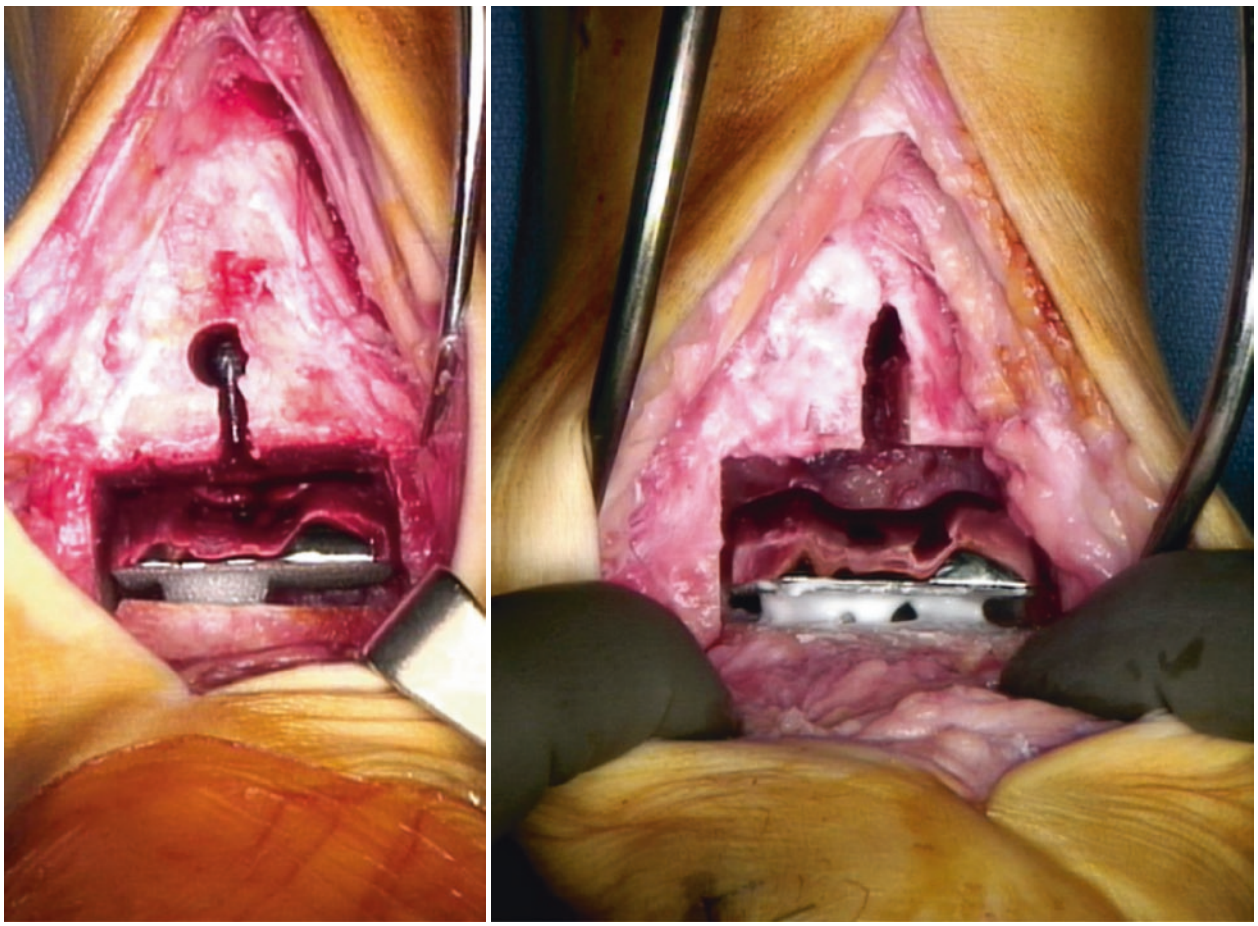


Fig. 15.26 Intraoperative photograph demonstrating partial insertion of the final XT flat-topped talar prosthesis prior to (left image) and after (right image) application of a thin layer of polymethylmethacrylate cement to the anterior surface of the talar component

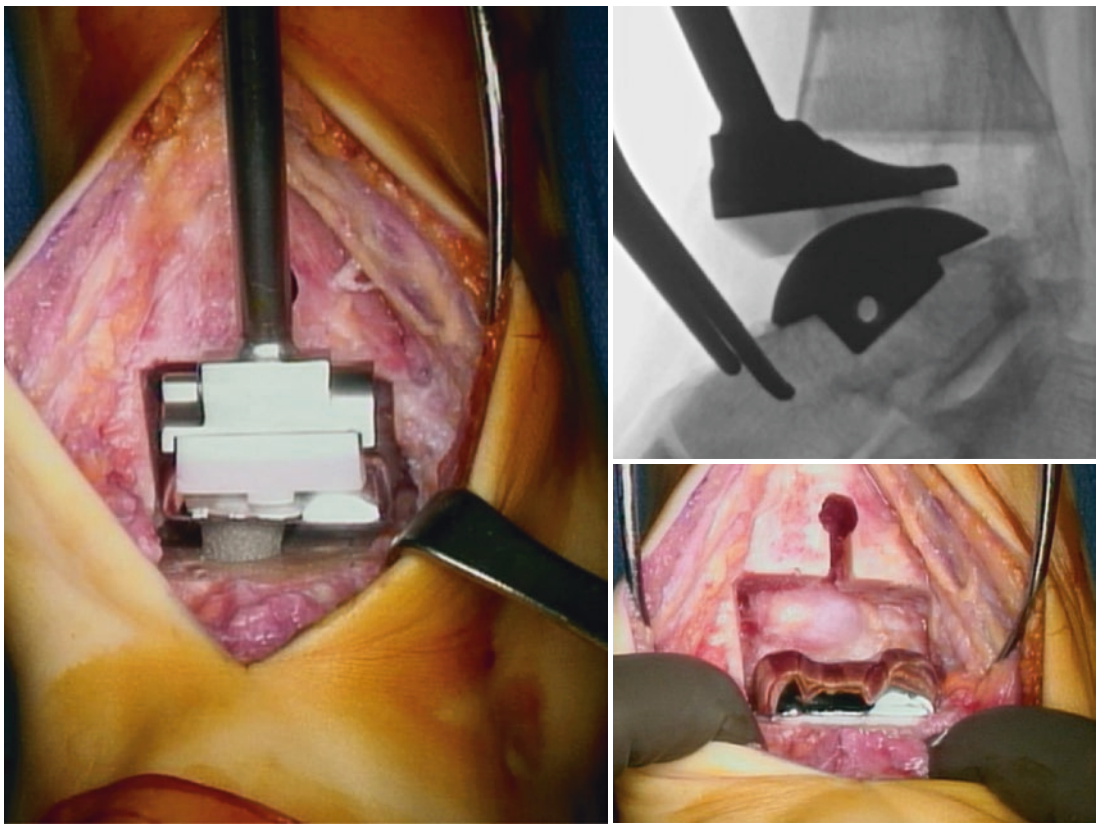


Fig. 15.27 Intraoperative photograph of the XT flat-topped talar prosthesis cupped with the impaction device (left image). Lateral C-arm image intensification view (right image) and intraoperative photograph following impaction of the final XT flat-topped talar component

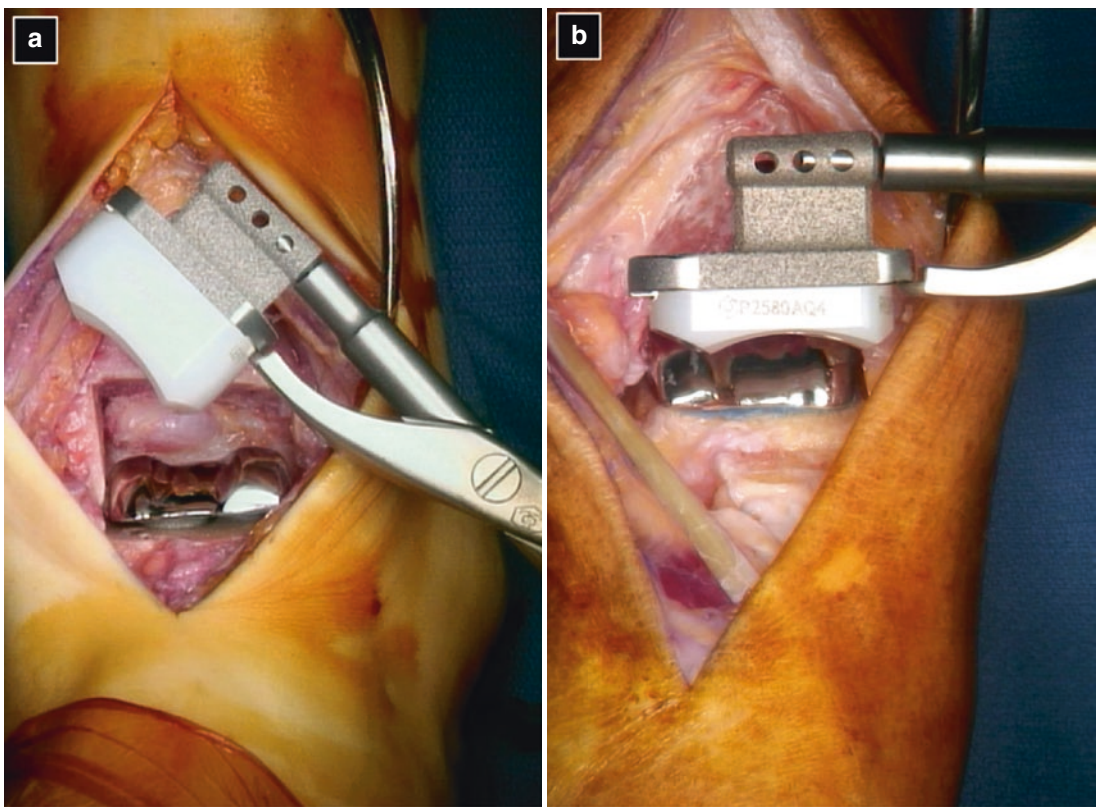


Fig. 15.28 Intraoperative photograph of the standard tibial tray (**a**) and XL tibial tray (**b**) secured to the insertion handle. Note the posterior extension of the tibial tray relative to the UHMWPE insert for the XL tray. Additionally, the 14-mm UHMWPE insert is shown connected to the standard tibial tray, allowing comparison with the 5-mm UHMWPE insert affixed to the XL tibial tray

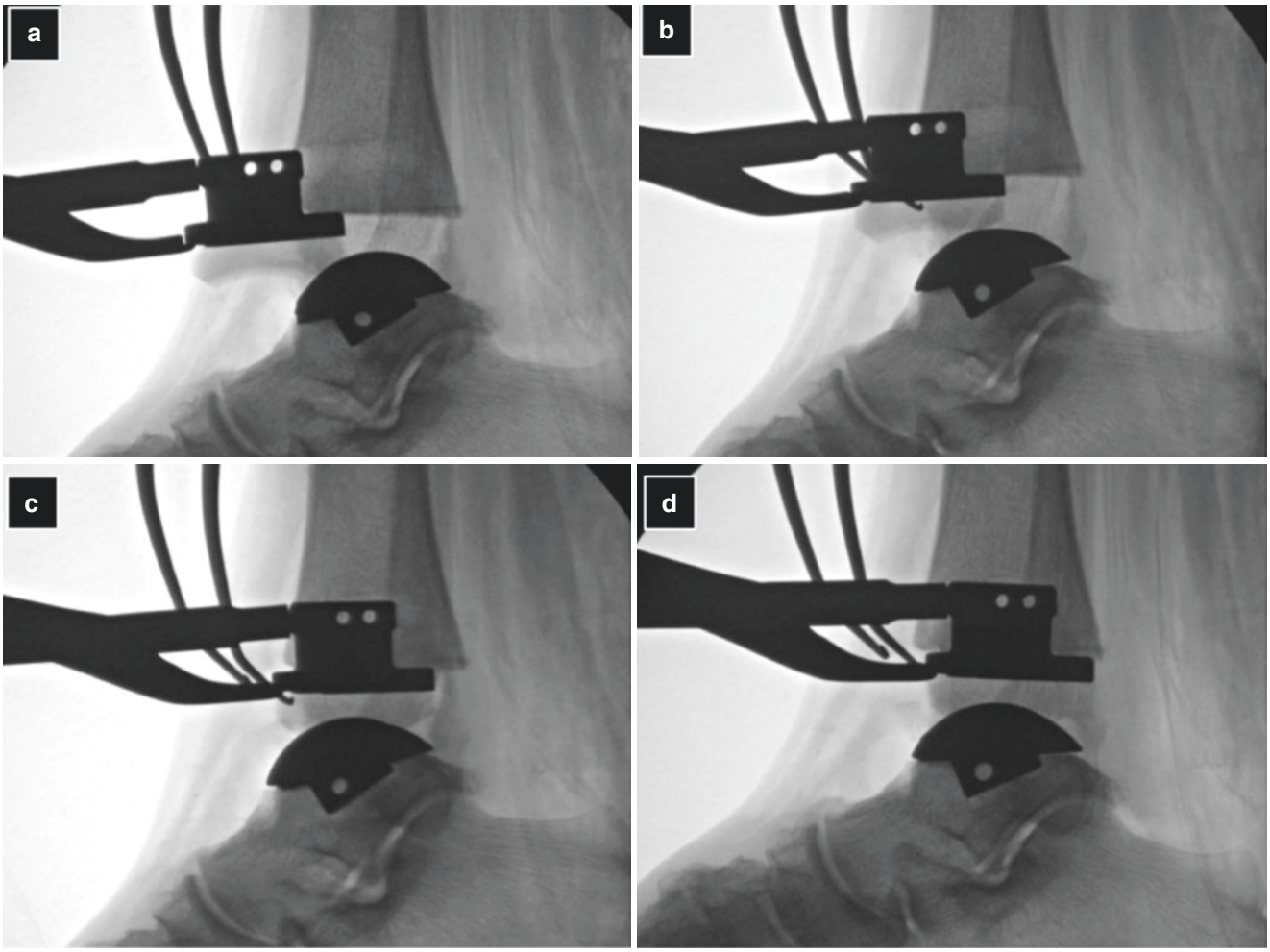


Fig. 15.29 Lateral C-arm image intensification views prior to (**a**), 1/3rd through (**b**), 2/3rd through (**c**), and following complete (**d**) impaction of the final tibial component. Care must be taken to make certain the tibial component base plate is in direct contact with the resected tibial bone surface during impaction

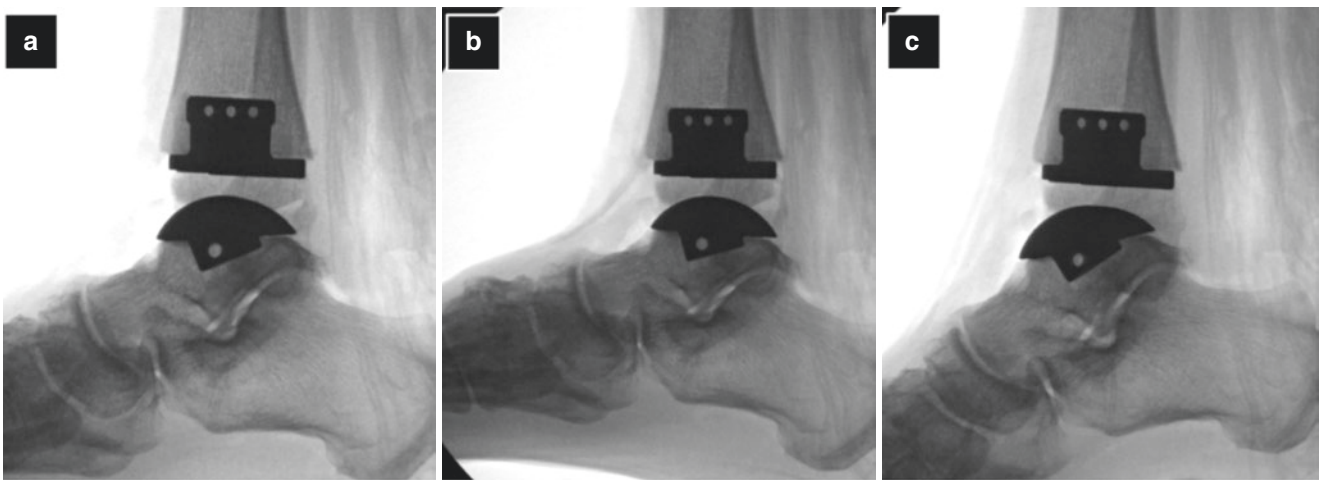


Fig. 15.30 Lateral C-arm image intensification view following impaction of the final tibial and XT talar components (**a**) as well as stress dorsiflexion (**b**) and plantarflexion (**c**) views demonstrating appropriate range of motion. Anterior-posterior C-arm image intensification view following impaction of the final tibial and XT talar components (**d**) as well as stress inversion (**e**) and eversion (**f**) views demonstrating appropriate alignment and stability

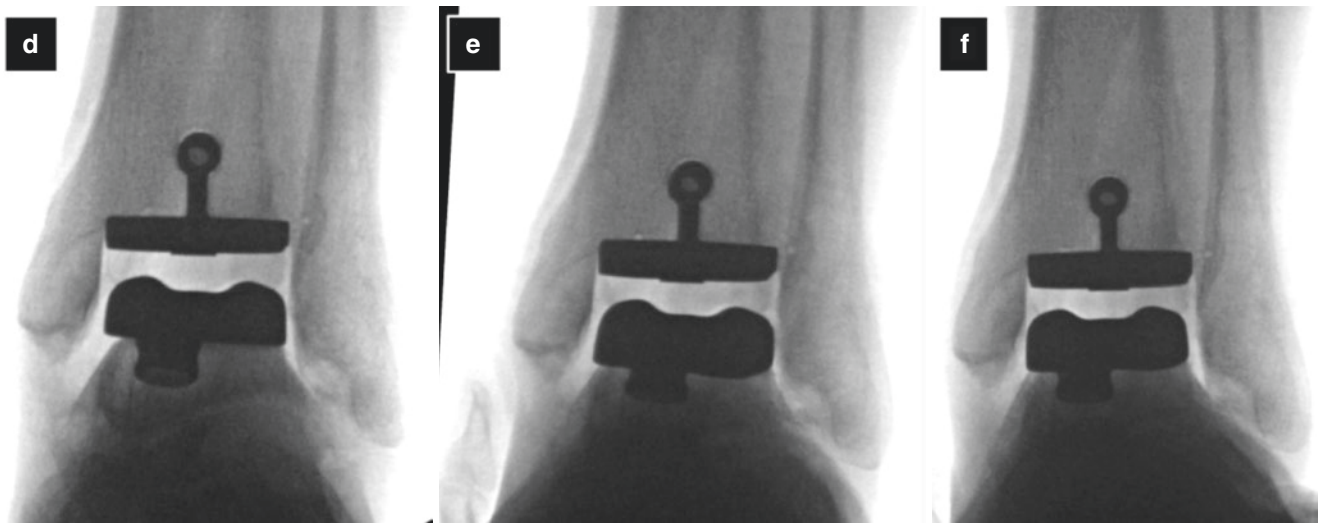


Fig. 15.30 (continued)

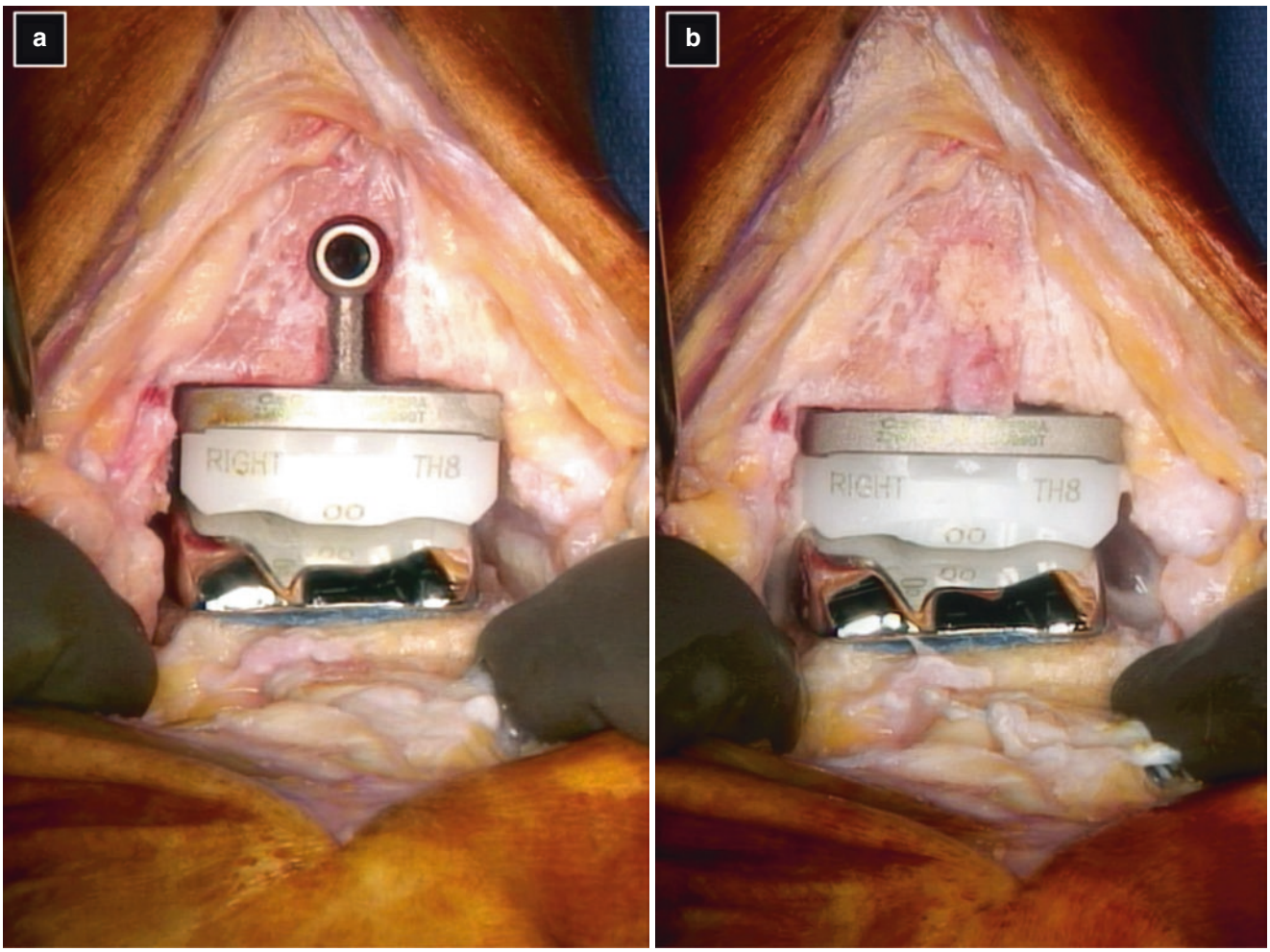


Fig. 15.31 Intraoperative photograph following impaction of the final tibial and XT talar components (**a**). Intraoperative photograph demonstrating impaction cancellous bone grafting of the tibial fixation plug and polymethylmethacrylate cement applied to the anterior tibial and talar surfaces (**b**)

Conclusions

The fixed-bearing Salto Talaris Total Ankle Prostheses and Salto Talaris XT Primary and Revision Total Ankle System were developed after in vivo kinematics of the Salto Mobile Version prosthesis revealed that the insert was not functioning as a mobile-bearing but rather remained fixed to the tibial component [6, 7]. During the subsequent redesigns and updates, specific attention was paid to improve the tibial base plate length and width for maximum tibial plafond cortical coverage, alter the talar component morphology to optimize the balance between triplane range of motion tolerance and constraint, and redesign the instrumentation to improve accuracy of implantation while also reducing the number of steps necessary. It is interesting to note that worldwide national joint registries clearly demonstrate that the fixed-bearing Salto Talaris Total Ankle Prostheses have eclipsed the mobile-bearing design that had historically dominated usage [23–25]. Although not proven, the inventors of the Salto Mobile Version prosthesis state that the rationale for developing the fixed-bearing Salto Talaris Total Ankle System was to obtain improved centering of the talar component relative to the tibial component and the ability to use smaller metallic components [10]. They hypothesized that both these attributes will reduce malleolar impingement and the secondary trabecular bone changes associated with UHMWPE insert particulate wear debris [10]. The low incidence of revision [15, 19–22, 26], minimal bone resection compared to other total ankle replacement systems [27], preservation of talar vascular supply [28], and straightforward surgical technique combined with the ongoing development of dedicated revision components with the launch of the Integra XT Revision Total Ankle Replacement System (Integra Lifesciences Corporation, Plainsboro, NJ) supports the use of the Salto Talaris Total Ankle System for most primary total ankle replacement indications and the Salto Talaris XT Primary and Revision Total Ankle System for complicated primary and revision total ankle replacement indications. The true role of polymethylmethacrylate cement fixation required for FDA compliance remains unknown, as no data exist comparing this with the off-label use of an uncemented Salto Talaris Total Ankle System implantation in the United States.

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STAR Total Ankle Replacement

16

Troy J. Boffeli, Stephen A. Brigido, W. Bret Smith, and Anson K. Chu

Introduction

The Scandinavian Total Ankle Replacement (STAR, DJO, Dallas, TX) first came into existence in 1978 [1]. The original version was a polymethyl methacrylate cemented prosthesis that was first utilized in 1981 [2]. The STAR has evolved into a three-part, mobile-bearing device. The implant prosthesis has been used with relatively good success in the European market. It underwent a lengthy Food and Drug Administration review process in the United States and was conditionally approved for implantation in the United States in 2009.

Due to the prevalent usage and length of time that the STAR implant has been available, it is one of the most reviewed and researched TAR prostheses. At the time of writing this chapter, it is estimated that over 30,000 STAR prostheses have been implanted worldwide [3].

To date, many studies have reviewed the long-term outcomes and survivorship of the STAR. Ten-year survivorship has been shown to be over 90% in several American studies [4, 5]. Contrasting studies from Europe suggest survivorship may range from 70% to 86% at 10 years [6–8]. Although studies with 15-year survivorship are not as sizable, recent data indicates STAR survivorship ranging from 63% up to 76% [8–10]. Additional long-term studies are needed to further understand survivability of this implant.

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Indications and Contraindications

Over the last decade, we have seen the indications for ankle replacement expanding. As we have progressed in our understanding of the mechanics of ankle arthroplasty, it has allowed us to offer the option to more patients.

It would be a safe assumption to consider indications for any surgical procedure to be a fairly fluid topic over time. As we become more sophisticated with our techniques and implants, we may find that certain indications are evolving. In addition to the improvements on a technical level, there is also an improved understanding of the outcomes as we collect more data and publish the results.

Currently, ankle arthroplasty is seeing an unprecedented amount of data becoming available. As this information is reviewed, indications will likely evolve as well. The common indications for total ankle replacement are end-stage ankle arthritis that has failed conservative management. Post-traumatic, osteoarthritis, and rheumatoid arthritis are usually the most commonly sighted reasons for offering a patient an ankle replacement. In patients with adjacent hindfoot arthritis, ankle arthroplasty is often considered to avoid a pantalar arthrodesis. Usually a double or triple arthrodesis is done in conjunction with the TAR. This can be done by a single or staged procedure based on preference. In some cases, the TAR is performed first, and symptoms are monitored in the adjacent arthritic joint.

Age of the patient is a very subjective matter in terms of indication for ankle arthroplasty. Traditionally, older, low-demand patients were often considered the most appropriate group for ankle arthroplasty, but as we learn more, we are understanding that younger patients can benefit as well and still have good outcomes and survivorship. Since there are no hard and fast rules, it is important to have patients understand the risks inherent to ankle arthroplasty and how that fits with the expectations for demand and lifestyle.

The rheumatoid and inflammatory arthropathy subset of patients offers unique opportunities. Due to the nature of

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their disease process, many of the hindfoot/midfoot joints may also be involved along with the ankle joint. After ankle fusion, the forces across those midfoot joints increase which may precipitate additional problems.

In addition to age and activity issues, the patient must have sufficient bone stock to allow for the implantation of the prosthesis. They must also have a healthy soft tissue envelope that will allow for adequate coverage after completion of the procedure. Soft tissue compromise or significant vascular disease may be reasons for discussion of alternative options. Caution should also be exercised if there was a history of osteomyelitis in the affected ankle in the past. It will need to be studied further if alternative approaches may offer improved results when soft tissue issues are encountered.

In general, contraindications include active ankle infection, neuropathic joint, significant areas of avascular osteonecrosis of the talus or distal tibia, complete paralysis of the operative limb, inadequate soft tissue coverage, vascular insufficiency, severe deformity that cannot be corrected, and skeletal immaturity.

Design Rationale

The STAR ankle replacement is a three-part, mobile-bearing TAR, designed for implantation without the use of polymethyl methacrylate cement. The tibial base plate and talar components for use in the United States are coated in a 200-μm-thick titanium plasma spray porous coating [11].

The three-piece design of the STAR prosthesis consists of a flat metallic tibial component that has two dorsal dowels to assist in stabilizing the tibial component. The talar component is metallic and cylindrical in shape with a small central ridge. The central component is composed of a high-density polyethylene gliding core. The top surface of the central component is flat to interface with the flat tibial tray. Due to the planar nature of this interface, it allows for some degree of internal and external rotation, as well as anterior and posterior gliding [12]. The inferior surface of the central bearing is shaped to match the cylindrical shape of the talar component to allow for plantarflexion-dorsiflexion motion.

The talar component resurfaces both the talar dome portion of the joint and the medial and lateral gutters. There is a central keel on the inferior surface of the talar component that assists in stabilization of this component.

Since the polyethylene bearing is allowed to move against both the tibial and talar components, motion is allowed in all three cardinal planes. This choice of a mobile-bearing design was selected to theoretically decrease the shear stresses at the interface between the bone and the prosthesis components. This was proposed to increase long-term stability and improve fixation [12].

Surgical Technique

The patient is placed on the operating table in the supine position. Elevating the limb on a positioning ramp aids in lateral imaging, and it is important to position the medial malleolus perpendicular to the operating table with the patella and foot facing directly upward. A small bump is placed beneath the ipsilateral hip to achieve proper positioning (Fig. 16.1).

A 20 cm longitudinal incision is then mapped out 1 cm lateral to the tibial crest and anteriorly centered over the ankle between the tibialis anterior and extensor hallucis longus (EHL) tendons (Fig. 16.2) Cheating the incision to be directly over the EHL tendon helps to avoid the prominent tibialis anterior tendon where pressure from circumferential wraps can cause wound breakdown and delayed healing. The foot and leg are then exsanguinated, and a thigh tourniquet is



Fig. 16.1 A small bump is placed under the patient's ipsilateral hip to accomplish the patella and foot facing directly upward. Total ankle replacement involves heavy use of C-arm imaging which is aided by placing the lower leg on a positioning ramp and a remote monitor at the head of the bed. Note that the toes are commonly covered prior to incision



Fig. 16.2 Incision mapping involves a 20 cm incision that extends from the talonavicular joint to a handsbreadth distance above the ankle joint. Marking out the tibialis anterior tendon (solid line), EHL (dashed line), and anterior tibial pulse (dotted line) is best accomplished in the pre-op area while the patient is awake and can actively dorsiflex the ankle (**a**). The incision is then made directly over the EHL tendon or between the EHL and tibialis anterior tendons. The medial dorsal cutaneous nerve can usually be palpated at the distal extent of the incision as it crosses the EHL as indicated by the oblique dotted line (**b**)

inflated. The superficial peroneal nerve will be visible near the distal extent of the incision and should be carefully mobilized and retracted laterally.

At this time, the extensor retinaculum is incised over the EHL with care taken to maintain the tibialis anterior tendon within the tendon sheath. The extensor retinaculum can be tagged, so there is no trouble locating it later during closure. Alternatively, the extensor retinaculum can be incised in line with the tendon. This is done by incising the retinaculum over the extensor hallucis longus tendon proximally and over the tibialis anterior tendon distally. At this point, the deep peroneal nerve and anterior tibial artery should be mobilized by tying the transverse vessels and retracted laterally prior to incision of the tibial periosteum and ankle joint capsule. A Cobb elevator is used to raise the tibial periosteum followed by sharp dissection to raise the anterior ankle capsule and

expose the dorsal talar neck. It is important to visualize the medial malleolus and most lateral aspect of the distal tibia. Releasing the tissue over the superior lateral talar neck may help with visualization at the lateral aspect of the ankle joint.

Large bone spurs on the distal tibia can be removed with an osteotome or rongeur, but most of this will be removed later with tibial resection. Proper exposure is needed to position the extramedullary jig against the bone. Increased incision length may result in less tension on the soft tissues. The authors recommend an incision 20 cms in length. If there is concern that encroachment of the medial malleolus may occur, a cannulated screw guide wire may be placed in the malleolar segment, or a prophylactic screw may also be placed (Fig. 16.3).

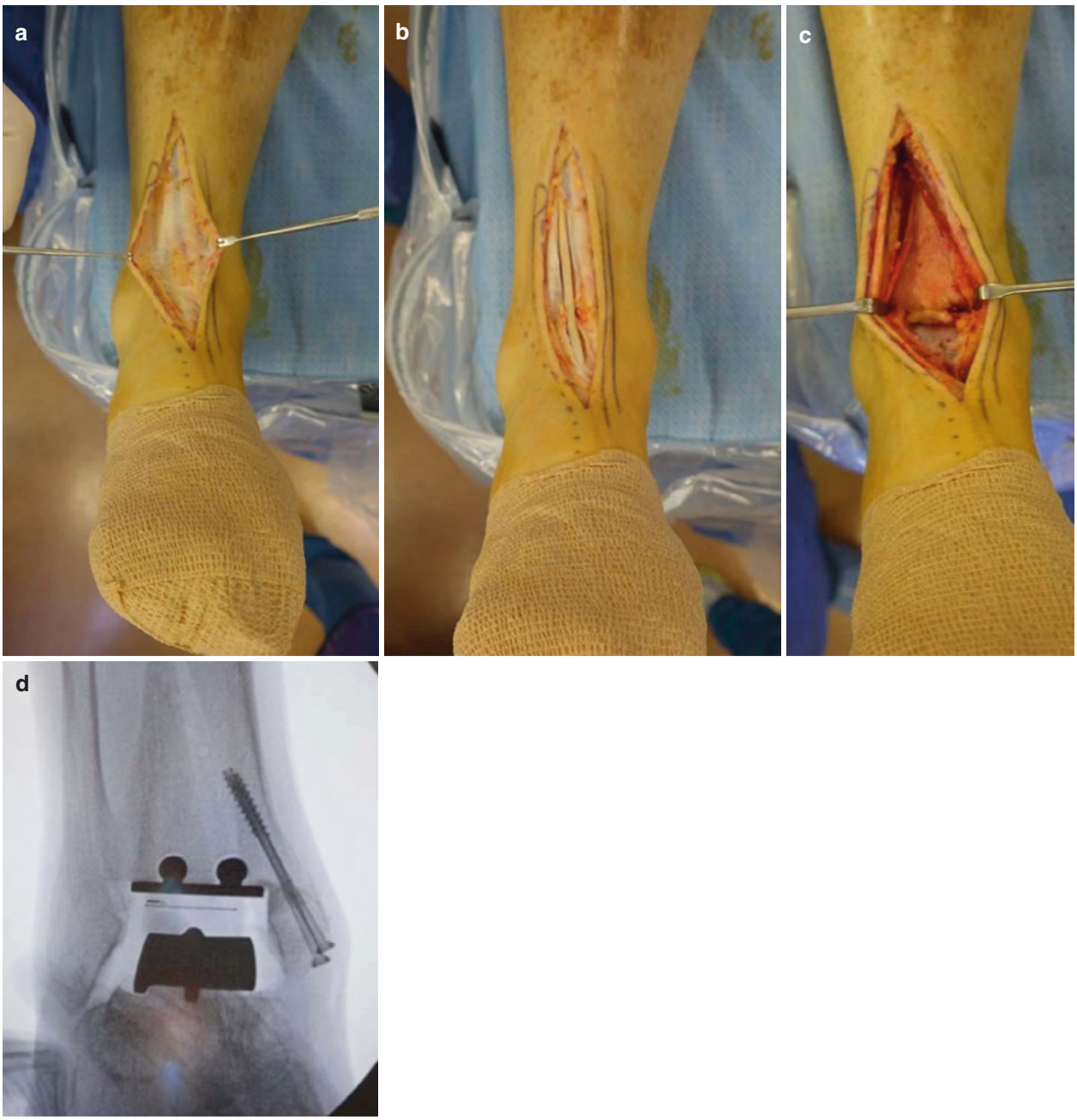


Fig. 16.3 Atraumatic tissue handling involves skin hooks due to the fragile nature of the anterior soft tissues of the ankle (**a**). The EHL tendon sheath is opened leaving the tibialis anterior tendon within the tendon sheath to avoid anterior bowstringing, desiccation, adhesions, and tendon exposure in the event of delayed wound healing (**b**). The EHL goes lateral and the tibialis anterior goes medial exposing the underlying neurovascular structures which are mobilized and retracted laterally. The periosteum and ankle joint capsule are incised and raised with a Cobb elevator. Full exposure of the anterior ankle joint allows for complete visualization (**c**). Cannulated screws were placed prophylactically in the medial malleolus along with injectable allograft due to concern for fracture through cystic bone (**d**)

Placement of the Extramedullary Jig

Under C-arm image guidance, a 3.2 mm pin is inserted into the tibial tubercle in slight plantarflexion from a line perpendicular to the long axis of the tibia. A quarter-inch osteotome is placed in the medial gutter parallel to the second metatarsal with the foot held in neutral dorsiflexion, and the pin should be placed parallel to the osteotome (Fig. 16.4). The tibial alignment guide is placed over this pin in the central hole, and the superior thumb screw is tightened to temporarily lock the guide at 0 degrees superiorly. The distal aspect of the jig is then placed roughly at the level of the tibial plafond.

A half-inch osteotome placed in the joint is a good reference point for how distal to place the cutting guide (Fig. 16.5). The pin blocks are set to a 1.5 cm gap to allow upward and downward adjustment from this point. It is also recommended to place the guide parallel to the tibial crest with equal spacing between the adjustable bar and anterior tibial crest. Two fingerbreadths is sufficient to protect the soft tissue.

The "T" guide is next inserted onto the cutting block to set the transverse plane rotational alignment of the cutting block. An osteotome is again placed in the medial gutter and aligned with the second metatarsal with the foot held in neutral dorsiflexion. The "T" guide handle is positioned parallel with the osteotome, and rotation of the jig is locked in place using the middle thumb screw (Fig. 16.6).



Fig. 16.4 A quarter-inch osteotome is placed in the medial gutter which is aligned with the second ray while the foot is positioned in neutral dorsiflexion. A 3.2 mm half pin is then placed anterior to posterior thru a stab incision at the tibial tuberosity. The pin is placed parallel to the osteotome in the transverse plane and in slight plantarflexion. A few light taps with a mallet as shown here helps to set the pin to avoid slipping off the side of the tibia

Once confirmation that the tibial alignment guide is parallel to the tibial diaphysis on C-arm imaging, a 2.4 mm pin is placed in the superior pin block assembly engaging only the near cortex. This will still allow for varus/valgus adjustment of the cutting guide as well as the position of the slope. A/P imaging is used to align the guide to be centered over the bisection and parallel with the tibia. Once the appropriate coronal plane alignment is confirmed, an oblique pin is placed through the superior pin block assembly to secure it in place (Fig. 16.7).

The tibial cut guide is next attached, and the angel wing is inserted into the cutting slot. The gear key in the superior pin block is used to adjust tibial cut height so that the inferior tip of the closest peg is just superior to the highest point of the distal tibial plafond for a minimum of 5 mm of distal tibial resection. True lateral imaging is critical in this step (Fig. 16.8). The size of the tibial component can also be preliminarily measured with the angel wing in place. There are seven pegs, each extending 5 mm from the central blade and spaced 10 mm apart. The angel wing is removed, and the set screw in the superior pin block is tightened to lock tibial cut height.

Medial to lateral adjustments of the tibial cutting guide are now made with a screwdriver in the gear key of the inferior pin block assembly. A free pin in the medial corner of the saw capture should fall into a tibial notch that was created earlier with the small sagittal saw. This establishes the medial aspect of the tibial cut, and the 2.4 mm pin should be driven bicortically to protect the medial malleolus. The lateral pin is then placed to protect the fibula from notching. If there is any question about pin location, an intraoperative C-arm image can be taken with the head of the C-arm angled 30° inferior to the ankle joint, and the pins can be visualized in the tibia. A mortise ankle view also confirms that the lateral pin is protecting the fibula. The transverse cut in the distal tibial is made through the saw capture with the sagittal saw, and then the reciprocating saw is used to cut upward along the inner edge of the medial malleolus to connect the transverse cut. Care is taken with sharp instruments to avoid injury to the posterior medial neurovascular structures (Fig. 16.9). The saw capture is then removed, and resected bone is removed from the distal tibia. A half-inch curved osteotome can be placed in the horizontal cut and levered in a downward direction to help free up the bone from the posterior joint capsule. The osteotome can then be used to break the joint fragment into smaller sections for ease of removal (Fig. 16.10).

Preparation of the Talus

The talar cutting guide is inserted and attached to the tibial alignment guide. It is important to have the paddle of the cutting guide flush with the superior aspect of the talus.

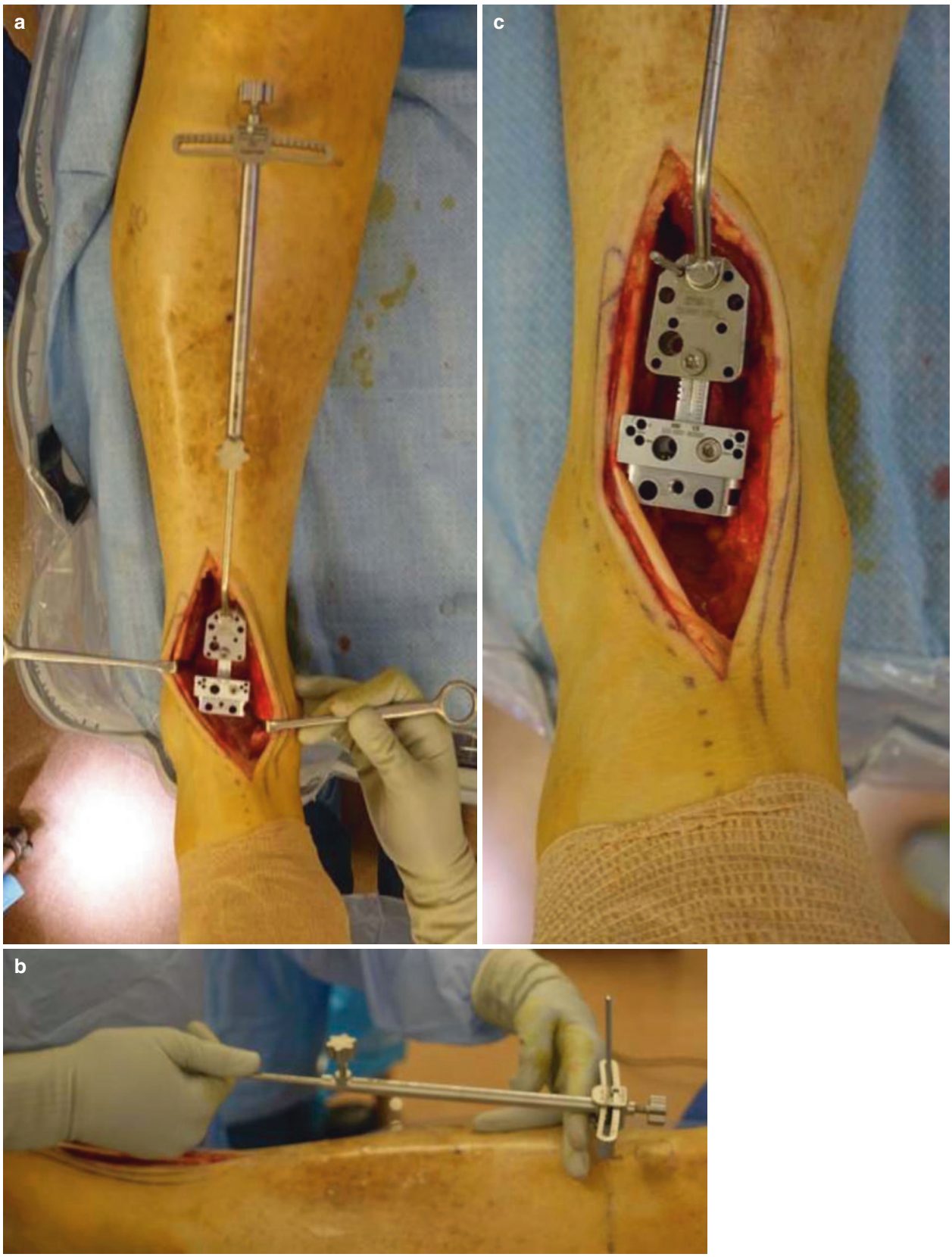


Fig. 16.5 The tibial alignment guide is placed over the proximal pin and is extended to meet an osteotome placed within the anterior ankle joint (**a**). The guide is centered over the tibial crest and evenly spaced at two fingerbreadths above the tibial crest (**b**). The superior and inferior pin blocks are set 1.5 cm apart to allow upward and downward adjustments (**c**)

Adjustments may need to be made on the tibial alignment guide to bring the talar resection guide down to the talus. Cartilage on the superior dome of the talus also needs to be removed with an osteotome or curette to ensure a tight and flat fit of the subchondral bone against the talar cut guide. Leaving cartilage will result in insufficient or angled bone resection.



Fig. 16.6 The "T" guide is placed on the cutting block which is used to establish transverse rotation of the cutting block. An osteotome placed in the medial gutter parallel to the second metatarsal is used as the reference point. The middle thumb screw is tightened while all three reference points are parallel in the transverse plane. A 2.4 mm pin is placed in the superior pin block to hold rotational alignment

The foot should be held through the heel at 90° in the sagittal plane, neutral in the coronal plane and pressed firmly against the paddle. Pins are placed in the outer holes of the talar cutting guide to secure the position of the block on the talus. In addition, pins are placed in the medial and lateral slots of the talar cut guide to protect the malleoli during resection. The dorsal 4 mm of the talus is resected through the saw capture with the sagittal saw, and the thin wafer of talar dome is removed. The joint should be evaluated to make sure all bone is removed. The 12 mm end of the joint space evaluator is placed in the resected joint space which should fit without any problem (Fig. 16.11). This step confirms that adequate space is available for the tibial and talar components to fit along with the small 6 mm bearing. If the 12 mm joint space elevator does not fit, then additional tibial resection is needed before moving on to the next step.

The talar sizer is next placed on the resected talus, and side-to-side fit is used to select the talar component size. The outer edge of the template should fit within the cartilaginous rim that is visible on the dorsal talus. Once the appropriate size is determined, the drill guide (lollipop) is attached and pinned into place on the superior aspect of the talus. It is important to line the handle of the drill guide parallel to the second metatarsal shaft. A 2.4 mm pin is then placed through

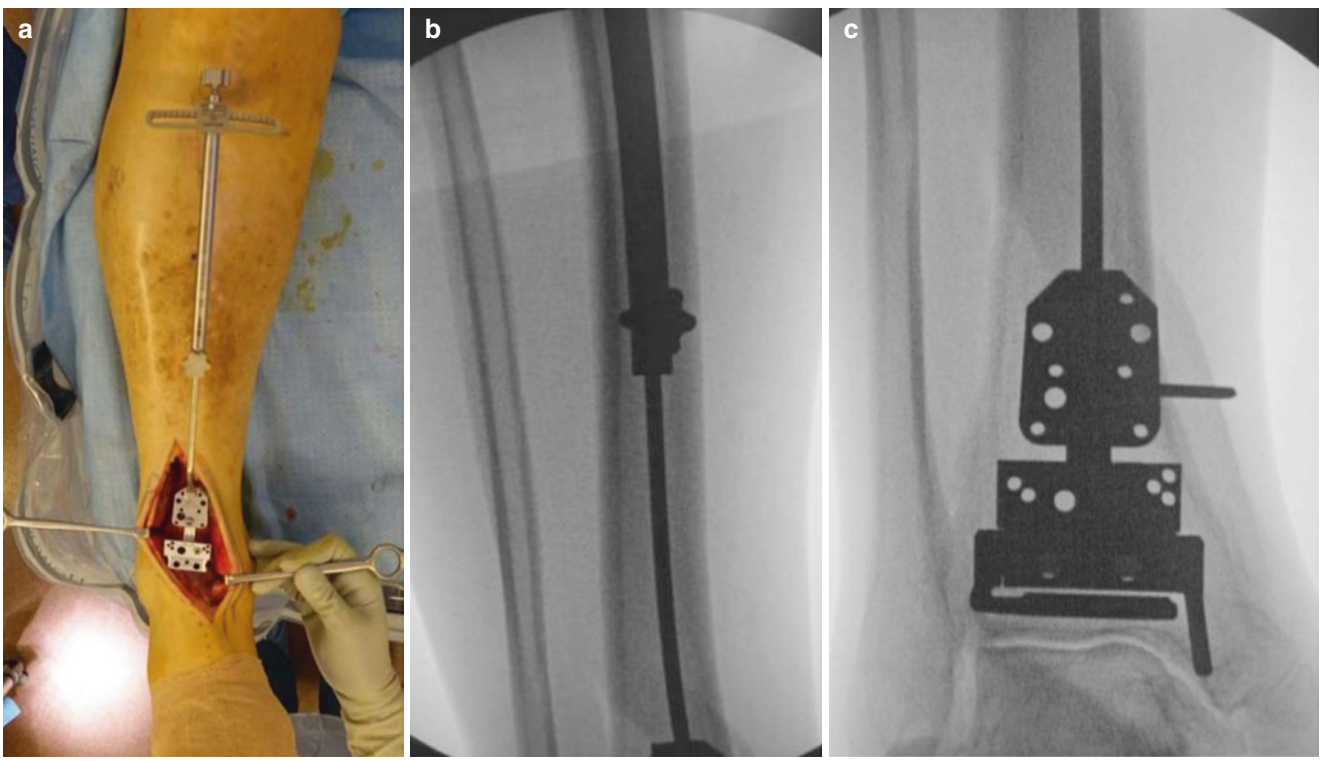


Fig. 16.7 Coronal plane alignment of the extramedullary jig is adjusted around the proximal pin while rotated around the distal pin. The proximal thumb screw is loosened to allow plus or minus adjustments to correct varus or valgus positioning which is confirmed by AP imaging (**a**). The goal is to achieve parallel bisection of the tibia (**b**) while maintaining perfect circles in the distal pin blocks (**c**). Alignment is then locked with an oblique 2.4 mm pin through the superior pin block

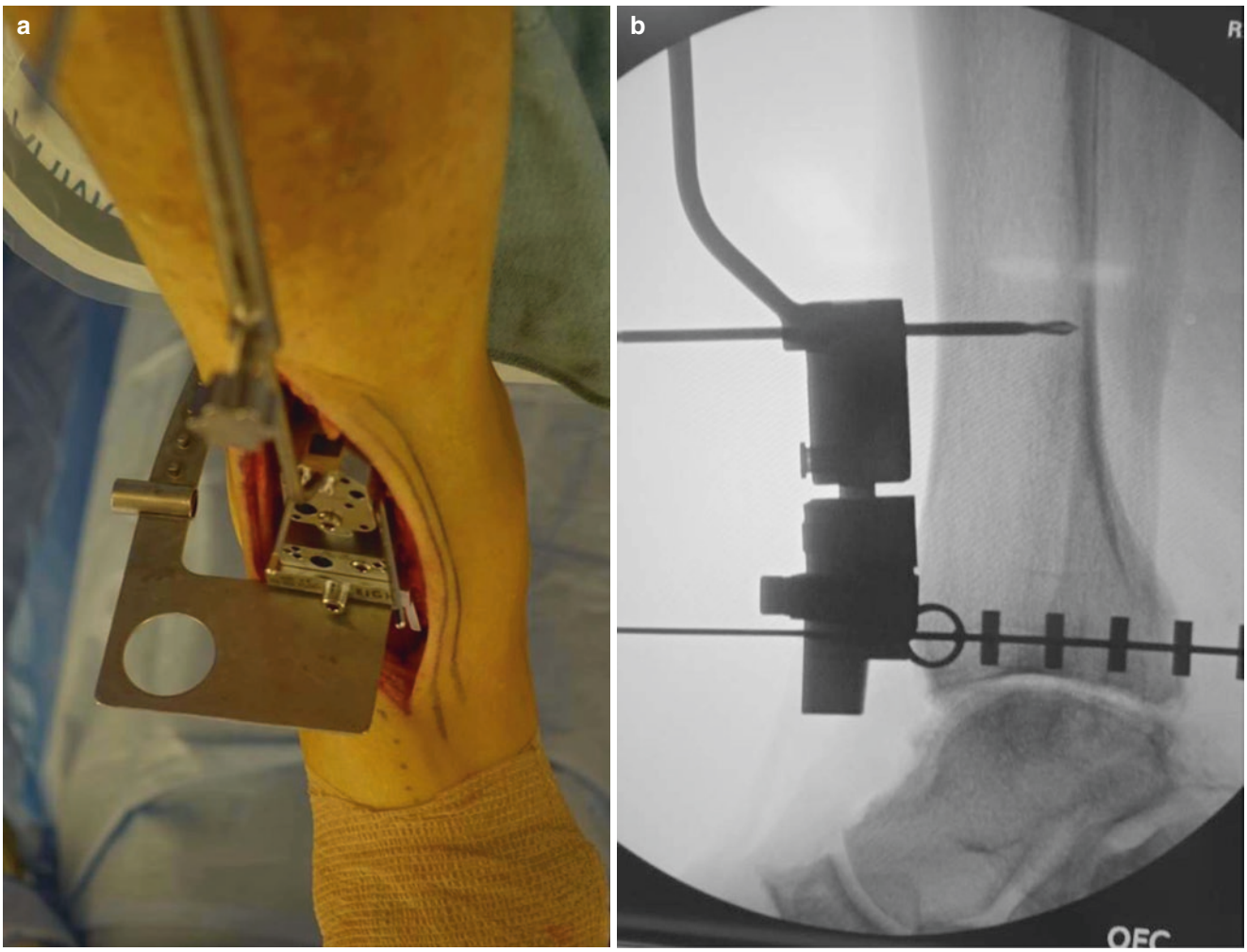


Fig. 16.8 The tibial cutting guide is next attached with a screwdriver, and the angel wing is inserted into the saw capture (**a**). True lateral imaging is achieved by swinging the leg medial or lateral in the coronal plane (wigwag) to achieve a knife blade appearance of the wide anterior portion of the angel wing (**b**). Slope of the tibial cut is checked at this time with desire for an open slope indicated by slight superior angulation of the angel wing. This can be adjusted by raising or lowering the proximal portion of the extramedullary jig by loosening the proximal thumb screw. Tibial cut height adjustment is made using the gear key in the superior pin block to accomplish a minimum of 5 mm resection indicated by the bottom of the pegs being in line with the most proximal curve of the tibial plafond. A 2.4 mm pin is then inserted in the inferior pin block to maintain cut height adjustment

the drill guide into the talus with the guide sitting flush on the superior talus. The post of the drill guide should be in line with the lateral process of the talus which is confirmed on lateral C-arm imaging (Fig. 16.12). The drill guide is then removed, and the appropriate size datum is placed over the 2.4 mm pin with the handle in line with the second metatarsal, and placement is confirmed with a lateral C-arm imaging. The datum is secured to the talus with the 15 mm drill tip shoulder pins, and the central 2.4 mm wire is temporarily removed (Fig. 16.13).

Next, insert the anterior/posterior (A/P) talar cut guide onto the datum and secure in place with the screwdriver and locking bolt and then place a 2.4 mm wire in the center of the cut guide into the talar neck. The authors prefer to make the posterior talar cut first. Attention should be made to the most posterior-medial and posterior-lateral corners to make sure all bone is cut. Next, the anterior talus is milled with the hard stop reamer. Start with the distal slot and proceed to the proximal slot by using a pecking and sweeping motion (Fig. 16.14). Once this is complete, the anterior/posterior cut guide can be removed. The reamed bone from anterior talar preparation can be collected and used later to pack the barrel holes in the tibia after the tibial component is inserted.

Next, the medial/lateral (M/L) talar cut guide can be secured to the datum with the locking bolt. The reciprocating saw is then placed into the M/L cut guide on the medial and lateral cut slots. The blade should be inserted to the laser line. The saw should be started with the blade in the

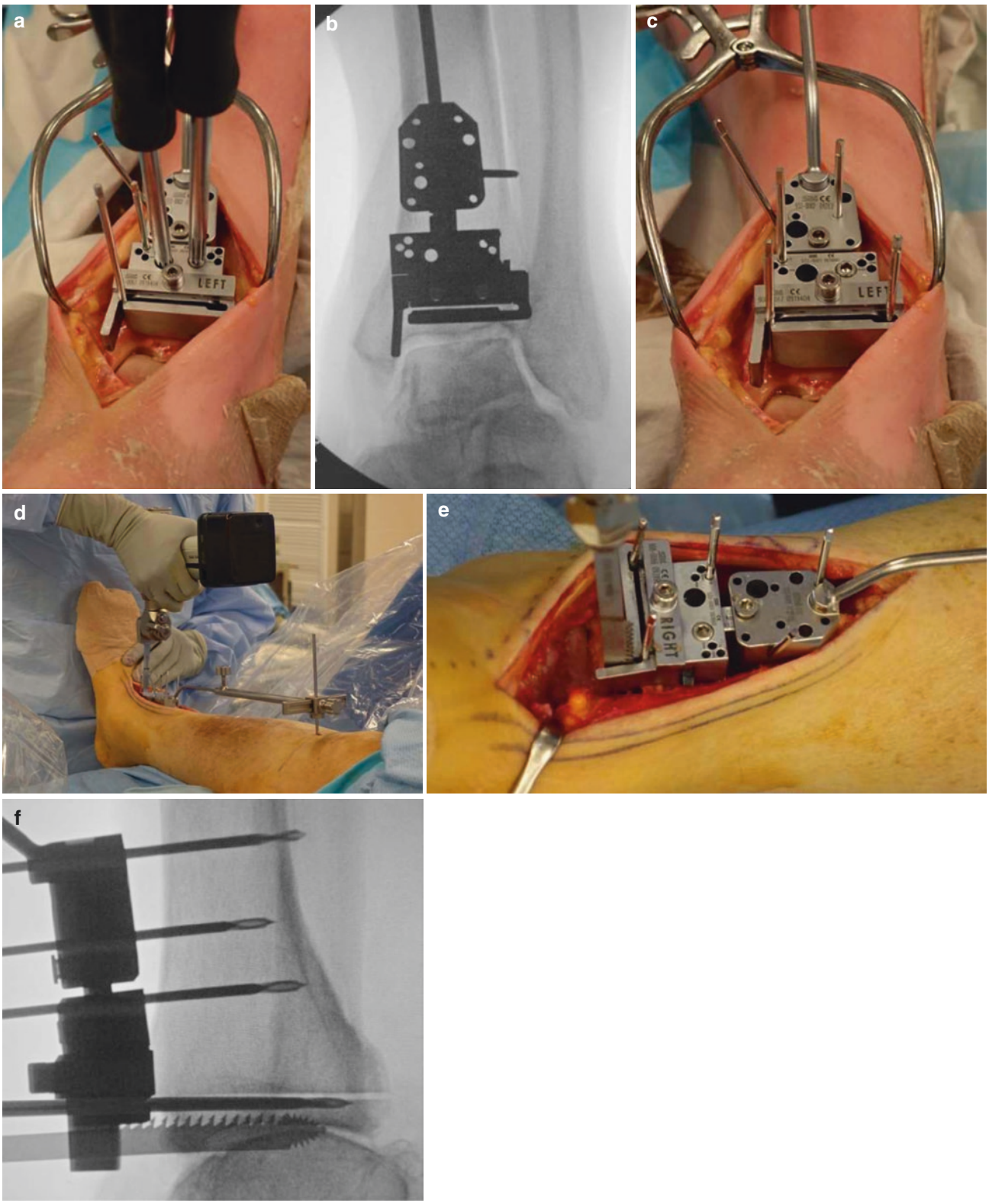


Fig. 16.9 The gear key on the inferior pin block is used to adjust the saw capture medially or laterally using the medial gutter as a reference for the medial most edge of the vertical cut in the tibia (**a**). The previously cut bone notch can be used as a reference followed by perfect circles AP imaging to confirm desired alignment (**b**). 2.4 mm pins are then inserted into the saw capture medially to protect the apex of the cut and laterally to protect the fibula (**c**). A sagittal saw is then used to make the transverse cut barely penetrating the posterior cortex (**d**). The reciprocating saw is then used to make the medial vertical cut (**e**) taking care to protect the posterior medial neurovascular structures by monitoring depth of cut on lateral imaging (**f**)

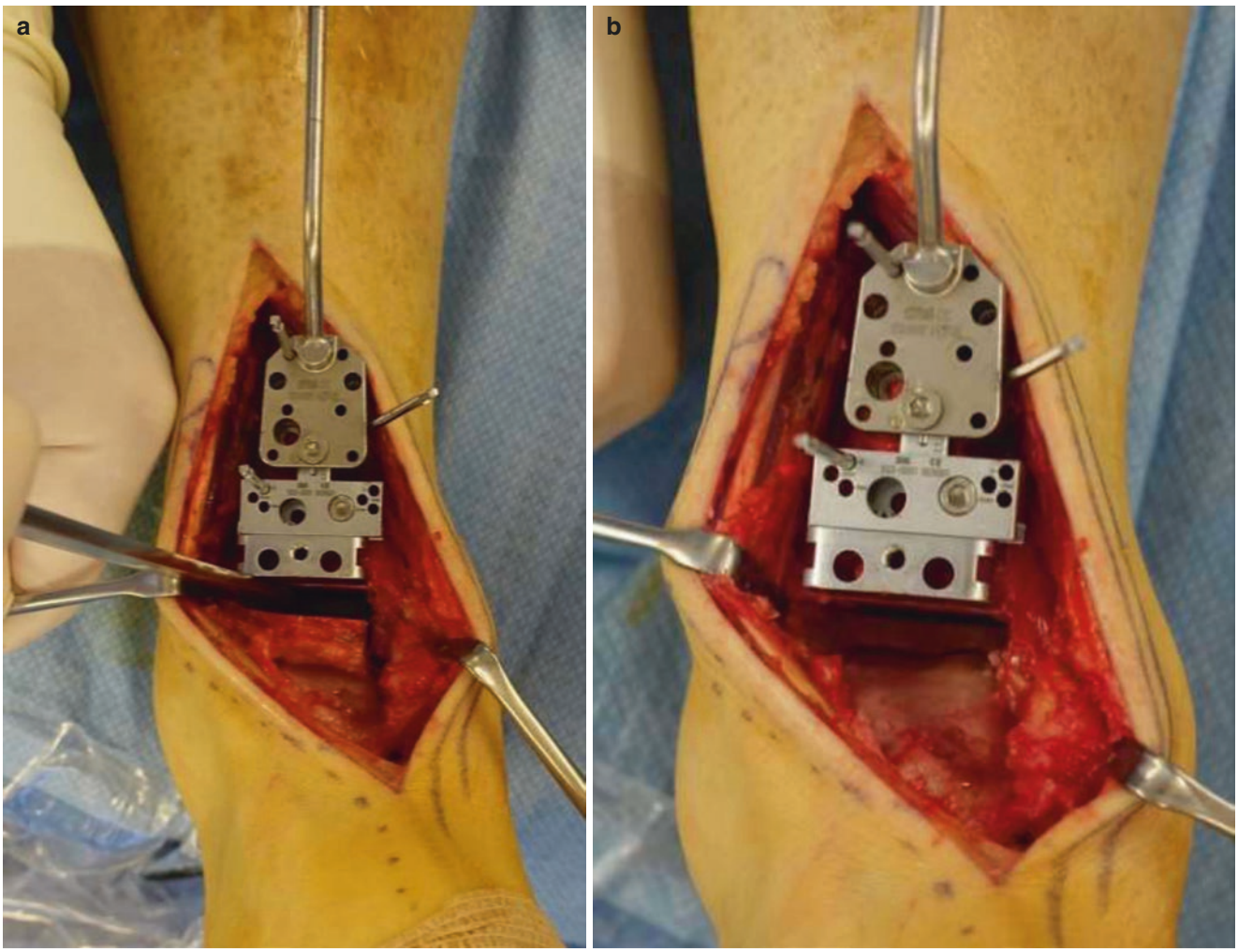


Fig. 16.10 A curved osteotome is used to remove the resected bone at the distal tibia taking care not to fracture the medial malleolus. (**a**). A small portion of the posterior tibia can be left in place for later removal once partial resection of the talus has been performed which provides better access (**b**)

joint and swept down until parallel with the laser line on the side of the guide and pulled anteriorly. It is important to take at least 10 mm of bone on the medial side and 15 mm on the lateral side. The M/L cut guide can now be removed as well as the datum. Using a small osteotome, remove the medial and lateral shoulder cuts within the talus. This can easily be accomplished by placing the osteotome in the cut bone from anterior to posterior first as this will help free up the bone from the talus, and then use the same osteotome and insert it perpendicular to the first cut inferiorly approximately 10 mm medially and 15 mm laterally. Additional bone contouring is best performed with a power rasp (Fig. 16.15).

The talar window trial is now placed over the prepared talus. It should fit without any gapping on the dorsal talus. If gapping is present, the excess bone needs to be removed with a power rasp until the window trial fits appropriately. The window is then secured into place with 2.4 mm pins or a lamina spreader. A laminar spreader can also be used to help push the talar window trial down before pinning. Pins should be placed into the anterior holes by hand at first and gently malleted into proper orientation. If not properly inserted, the pins may bind into the window trial (Fig. 16.16).

Next, insert the straight keel mill into the central slot of the window trial and make three holes. One should be as anterior as possible, the next central, and the last one posterior. Connect all the holes together with a sweeping motion making sure to drop the drill as close to the anterior tibia as possible to make sure that anterior milling is complete. The window trial is then removed, and the talar keel broach is inserted so that it is flush with the superior and posterior aspects of the talar keel (Fig. 16.17).

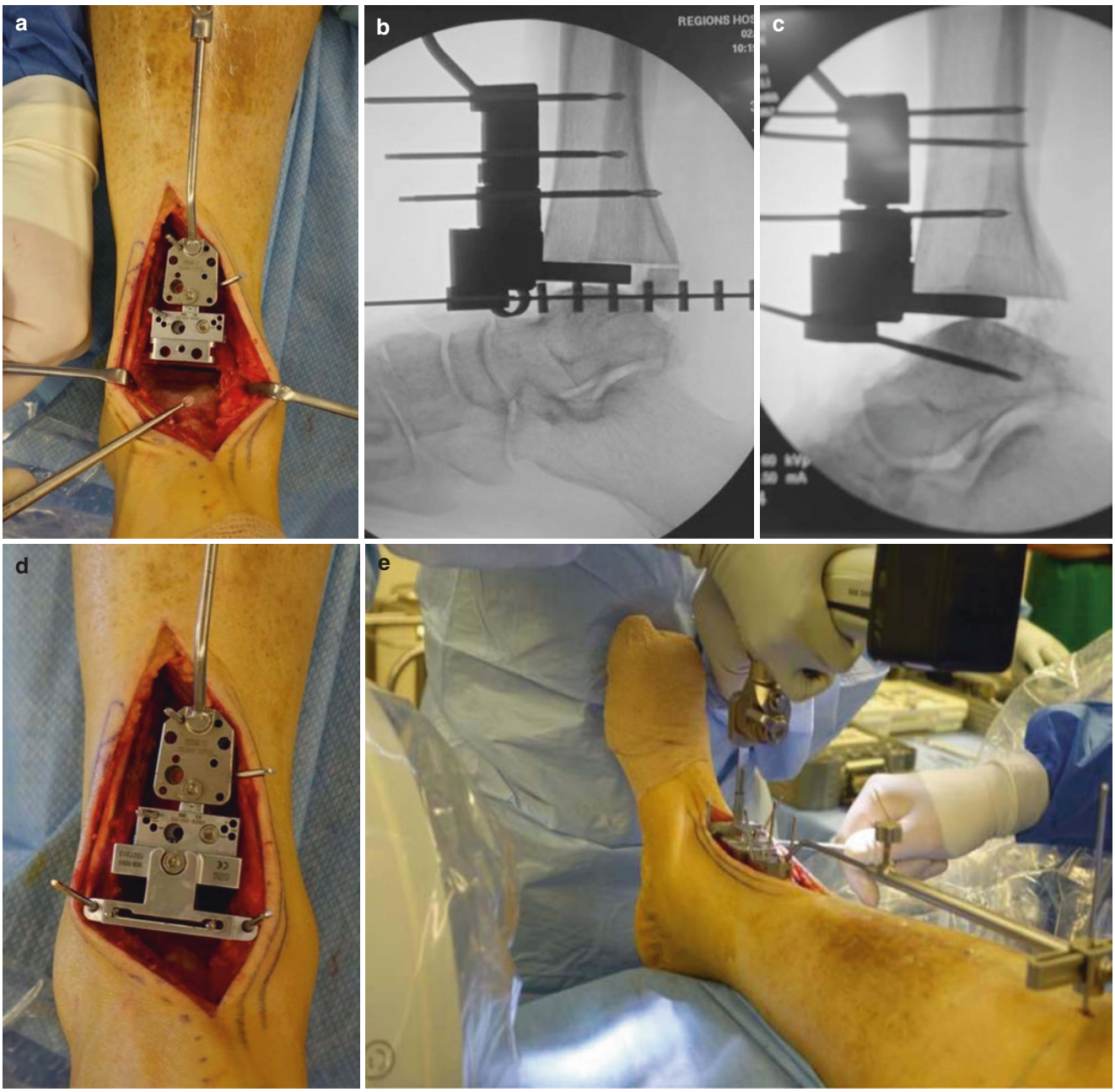


Fig. 16.11 Any remaining cartilage is removed from the top of the talar dome with an osteotome or curette in preparation of inserting the talar cut guide. This step ensures a tight fit of talar subchondral bone against the cut guide for proper thickness of dorsal talar resection without varus or valgus tilt (**a**). The paddle of the talar cut guide is then inserted into the joint and is attached to the tibial alignment guide. Note how the posterior aspect of the cut tibia remains present but is not in the way of inserting the paddle (**b**). The angel wing can be inserted into the saw capture to visualize the amount of talar resection. 2.4 mm protection pins are placed in the saw capture (**c**, **d**), and the top 4 mm of the talus is resected through the saw capture (**e**). The 12 mm end of the black joint space evaluator is inserted into the resected joint which should fit without struggling (**f**). C-arm confirmation with the joint space evaluator in position indicates that sufficient bone has been removed from the tibia and talus (**g**)

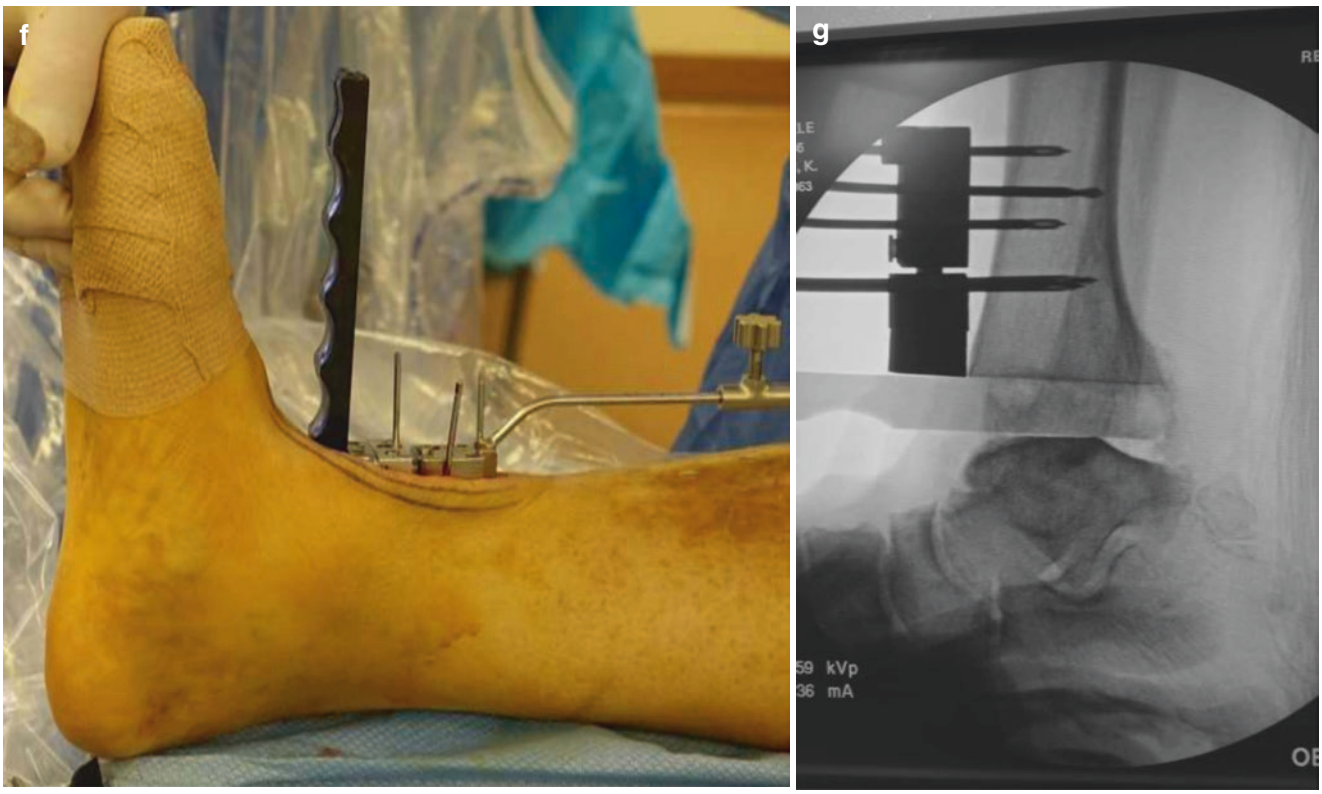


Fig. 16.11 (continued)

Implant Sizing and Implantation

Before placement of the definitive talar component, the tibial component size is determined by using the hook ruler from the tray. Hook the ruler around the posterior cortex of the distal tibia, and measure both medially and laterally (Fig. 16.18). It is also beneficial to then place the proper sized tibial barrel hole guide on the cut surface of the tibia to assess the cut, and make sure there is a flush surface. This can be done by inserting the blue spacer bar to push the trial up against the distal tibia. This can be checked with lateral C-arm imaging to make sure the trial is flush with the tibia.

Once this is complete, the definitive talar component can be inserted with the longer side of the implant lateral. It is then impacted with the talar impactor and seated into anatomical position (Fig. 16.19). The blue spacer is then reinserted on the superior aspect of the talar component to protect it and also push the tibial barrel hole guide so it is flush with the prepared tibial surface. This should also be checked with lateral C-arm imaging to make sure it is flush. Alternatively, a trial polyethylene bearing can be inserted which can assist in pushing the tibial barrel hole guide flush with the distal tibia.

The authors will often trial a few different polyethylene sizes to find the largest size that will allow placement of the tibial barrel hole guide. Next, the barrel hole guide should be secured to the tibia with a 2.4 mm pin through the distal hole in the guide after confirmation with C-arm imaging that it is in correct position relative to the talar component (Fig. 16.20). Next, drill the first 6.5 mm barrel hole with the surgeon's hand slightly dropped toward the foot to prevent skiving. Next, insert the barrel hole plug into the drilled hole while the second hole is drilled in the same manner. The barrel keyhole broach is then inserted while keeping the barrel hole plug in place, and then the process is repeated in the other hole. Remove the barrel hole guide leaving the 2.4 mm pin in place (Fig. 16.21).

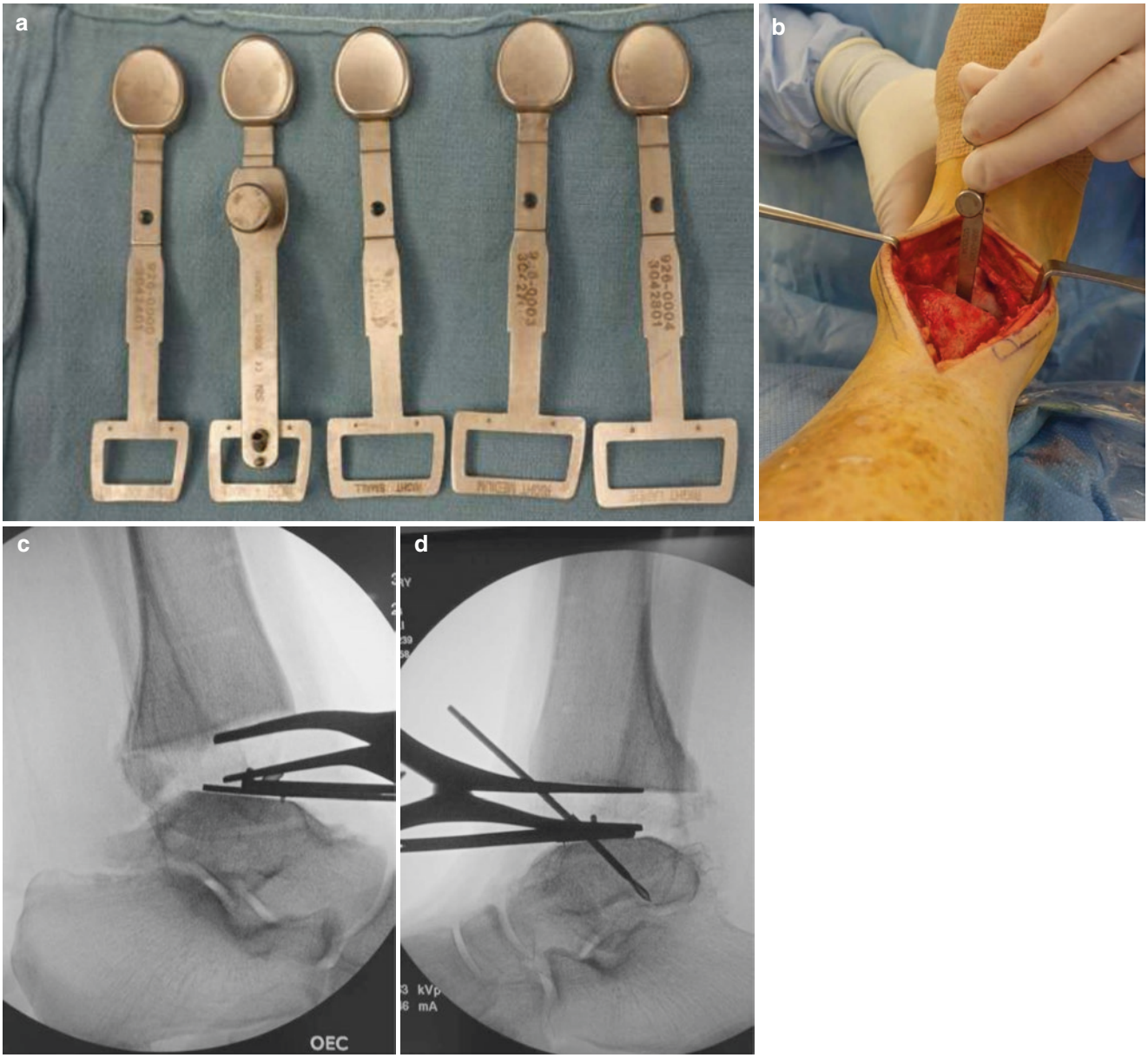


Fig. 16.12 The Post Talar Cut Template (PTCT) (**a**) is placed flush on the cut surface of the talus to assess side-to-side fit on the medial and lateral aspects of the talus. The handle should be lined up with the second metatarsal shaft with the foot in neutral dorsiflexion to ensure appropriate positioning (**b**). The post of the drill guide is lined up with the lateral process of the talus on lateral C-arm imaging. Note that the guide is sitting flush with the superior talar cut while held in place with a lamina spreader (**c**). Proper lateral imaging is confirmed with overlap of the two anterior spikes and universally thin guide. A 2.4 mm pin is placed through the drill guide of the PTCT avoiding the subtalar joint (**d**)

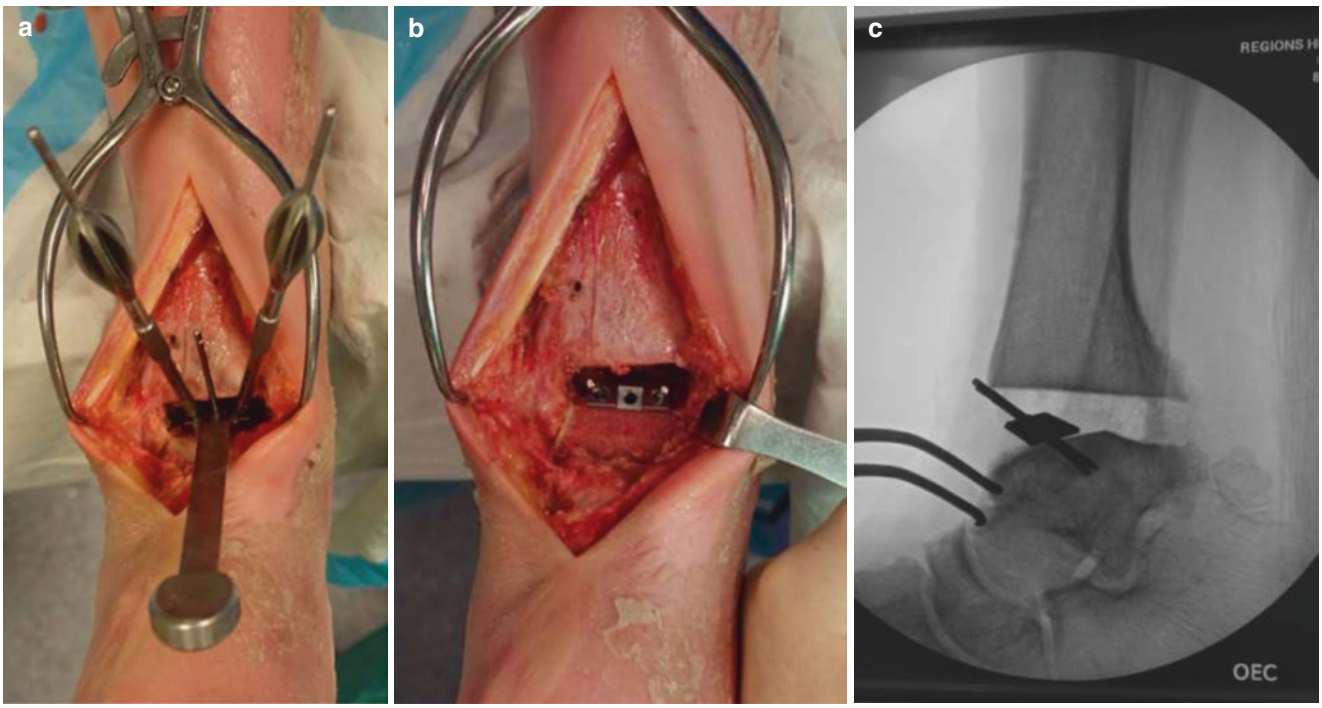


Fig. 16.13 The appropriate sized datum is placed over the talar pin to sit flush with the cut surface of the talus with the handle in line with the second metatarsal (**a**). The datum is secured with the 15 mm drill tip shoulder pins, and the handle and central 2.4 mm pin are removed (**b**). Lateral imaging can be used to assess the location of the datum. A tight fit to the dorsal talus surface is desired which is suboptimal in this image (**c**)

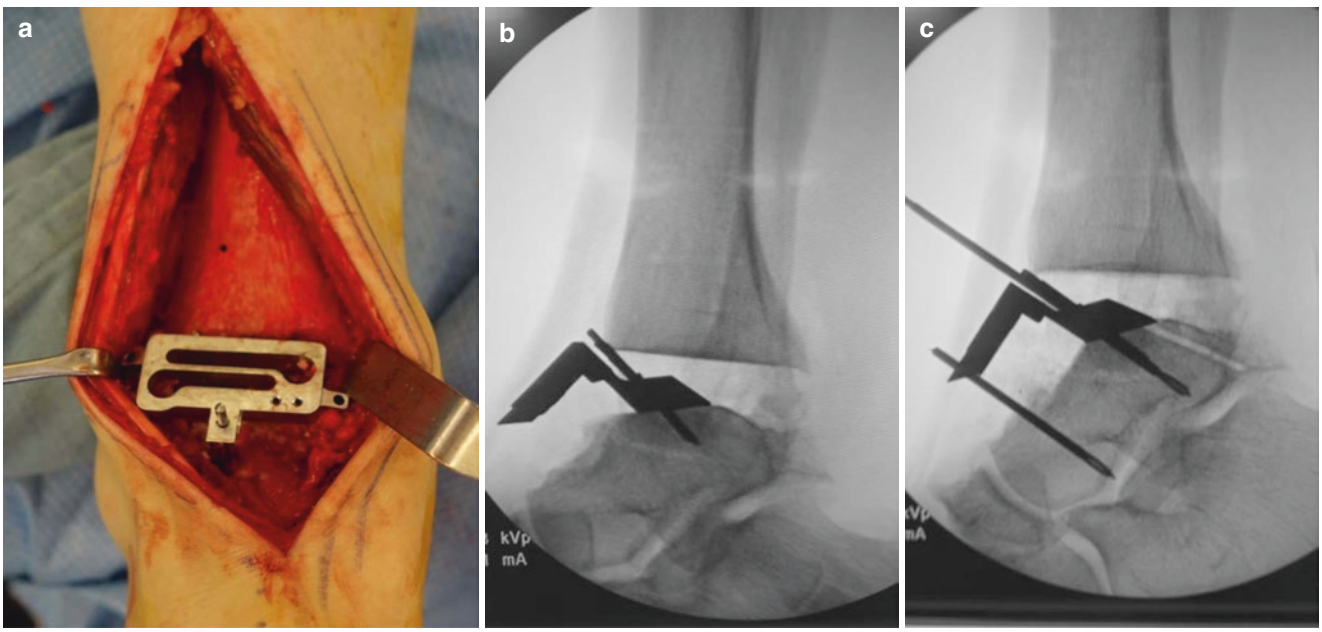


Fig. 16.14 The anterior/posterior (A/P) cut guide is placed on the datum and secured into position with a locking bolt and a 2.4 mm pin is placed in talar neck through the anterior pin hole (**a**). True lateral imaging confirms that the guide is sitting flush with the talar cut surface (**b**). The posterior talar resection and anterior milling of the talar neck are shown here (**c**)

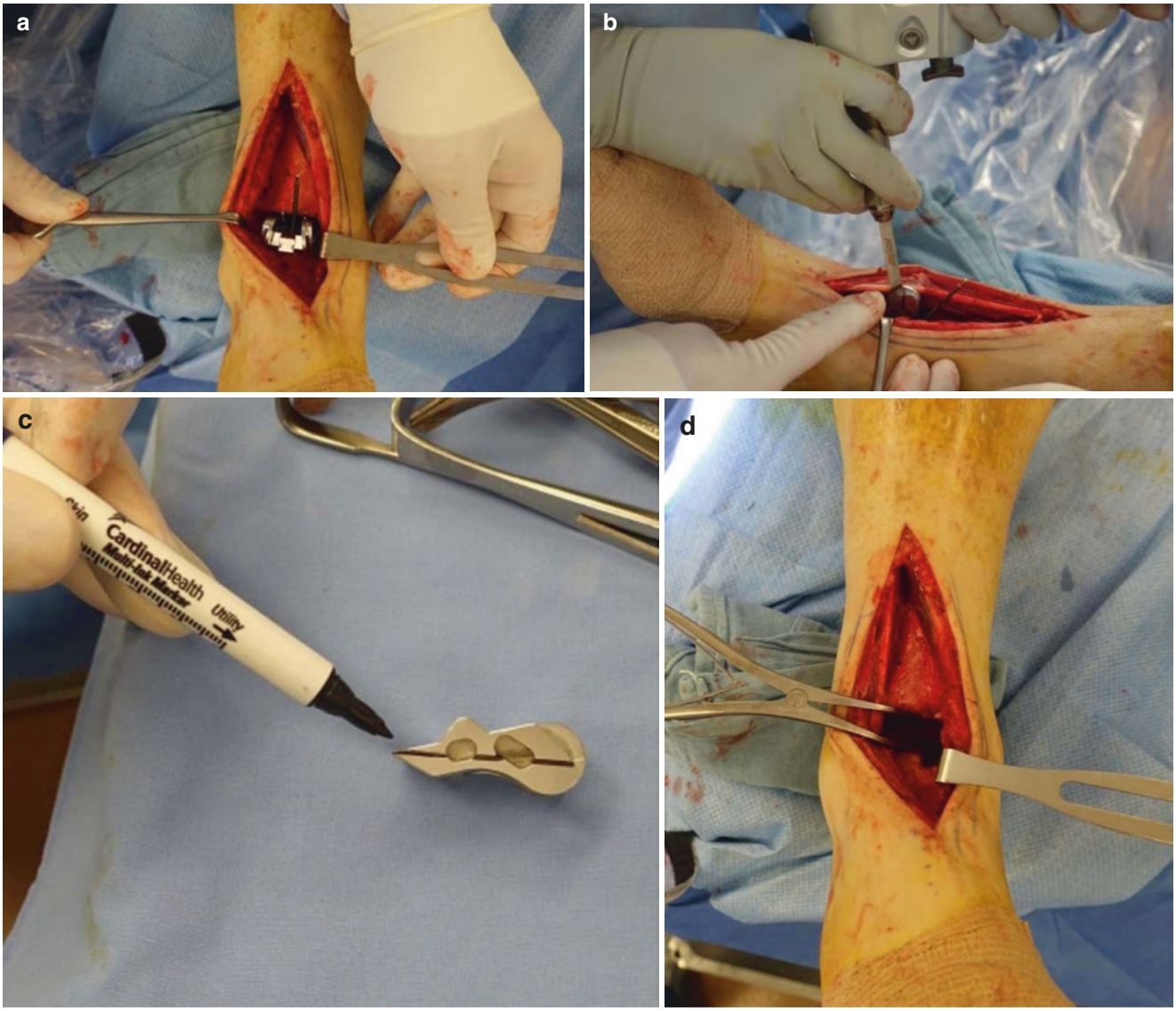


Fig. 16.15 The medial/lateral (M/L) talar cut guide is placed on the datum (**a**). Note the laser marks on the reciprocating saw and the engraved line on the guide (**b**) which can be enhanced with a marker for easier viewing (**c**). A 6 mm osteotome is used to chisel out the medial and later gutters (**d**)

The tibial component is then inserted onto the prepared tibia with the tibial inserter handle held parallel to the pin still in place in the distal tibia. It is important to have an assistant plantarflex the foot as much as possible so the tibia component does not hit the talar component and dislodge it. The surgeon's hand should be dropped toward the foot while inserting the tibial component to keep the implant flush with the prepared tibia. Impact the tibial component as deeply as the inserter will allow and then remove the inserter. Usually the anterior aspect of the tibial component is still a few millimeters proud. The end of the black joint space evaluator bar can be used to seat the implant so it is supported by both the anterior and posterior tibial cortices (Fig. 16.22). C-arm imaging is then used to confirm appropriate coverage and tight fit of the tibial component against the distal tibia (Fig. 16.23).

At this time, the trial polyethylene bearing is placed into the joint and is assessed clinically with dorsiflexion-plantar flexion arc and varus/valgus stressing (Fig. 16.24). Once the appropriate polyethylene size is determined, the

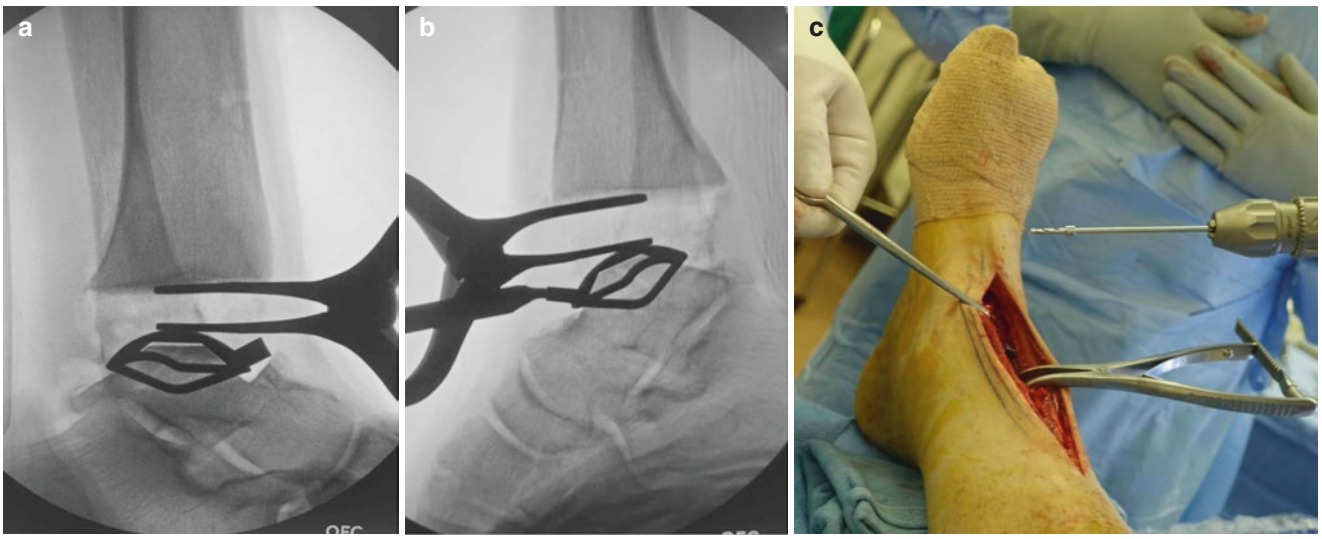


Fig. 16.16 A power rasp is used to shape the gutters to allow the window trial to sit flush on the talus. Note that the window trial is not flush on the top of the talus with original trial (**a**) but flush after deepening the shoulders with a power rasp (**b**). Anterior pins or a lamina spreader are used for secure positioning prior to reaming the keel (**c**)



Fig. 16.17 The keel broach must sit flush with the superior and posterior aspects of the talus in order to seat the talar component in the correct position (**a**). Insufficient anterior milling will result in posterior positioning of the keel broach. Additional reaming may be needed, and the surgeon's hand should be dropped toward the tibia when inserting the broach (**b**). Final preparation of the talus (**c**)

final polyethylene bearing is inserted by hand. Final intraoperative images are taken and saved to the chart (Fig. 16.25).

Bone grafting is next performed using the soft cancellous bone produced during drilling and milling which can be used to pack any pinholes and to pack the barrel holes at the anterior aspect of the tibial component. Capsular closure is performed to cover the implant components which helps take tension off the more fragile periosteal tissues during running closure. The anterior neurovascular structures are identified and protected during deep closure. The extensor retinaculum is then repaired over the EHL and tibialis anterior tendons. Retinaculum repair is important to avoid bowstringing of the tendons or tendon exposure anteriorly if there is wound dehiscence. Careful skin closure followed by soft dressing is performed. A posterior splint or cast is applied in the operating room along with a window dressing to protect the incision from anterior pressure associated with circumferential wraps (Fig. 16.26).



Fig. 16.18 The hooked ruler is used to measure the depth of the medial and lateral aspects of the distal tibia to determine the tibial component size

Postoperative Care

Obviously, postoperative care will vary based on concomitant procedures and surgeon preference.

The authors' current postoperative protocol for a primary total ankle is discussed below.

Application of a short leg weight-bearing cast with cast shoe in the operative suite. The patient may weight-bear as tolerated in the cast with crutches or walker once the peripheral nerve block has worn off. The patient maintains the cast for 2 weeks and then returns for follow-up.

The cast is removed at that time along with the sutures. The patient is then transitioned to a tall CAM boot and given a prescription for physical therapy and an ankle brace. The patient is encouraged to begin therapy as soon as possible. The therapist is directed to help the patient begin the transition to the ankle brace and progress them through the TAR PT protocol. The main focus of the protocol is to increase range of motion and decrease edema in the early phases. Later the patient works on increasing strength and proprioception and restoration of gait. The patient is encouraged to complete approximately 6–8 weeks of structured PT. The patient is seen in the clinic during this time to assess progress. After they have completed formal PT, they are encouraged to continue home-based protocols for several months. Traditionally, the patient will have yearly office visits with imaging of the ankle to monitor the implant for the first 5 years and then every 2 years after.

Any concomitant procedures will affect the timing of weight-bearing and the use of specific DME and PT.

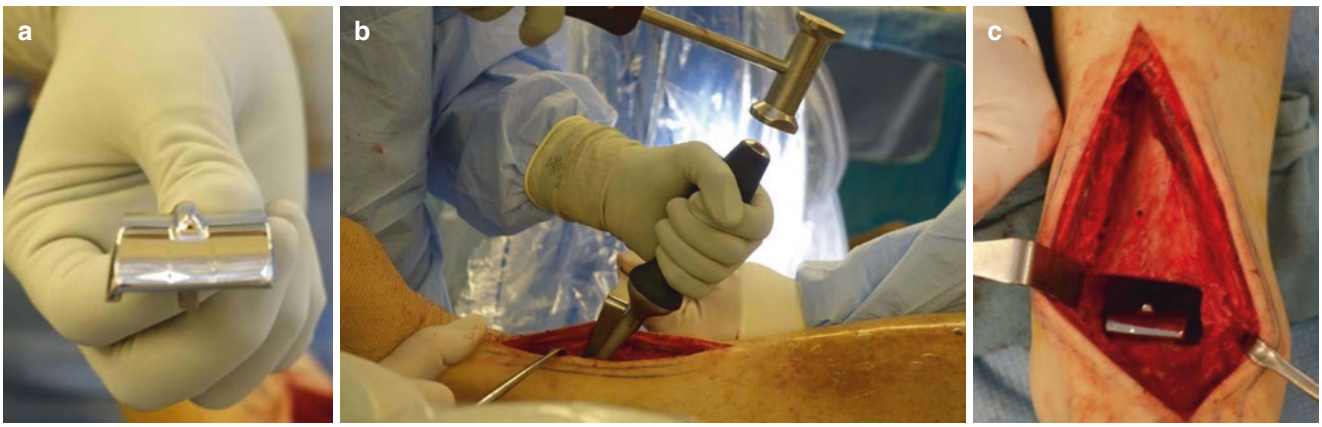


Fig. 16.19 The talar component is inserted following thorough flush of the joint and change of surgeon's gloves. The long side of the talar component is inserted laterally (**a**). The talar component is seated with the talar impactor using a medium-sized mallet (**b**) for proper impaction (**c**)

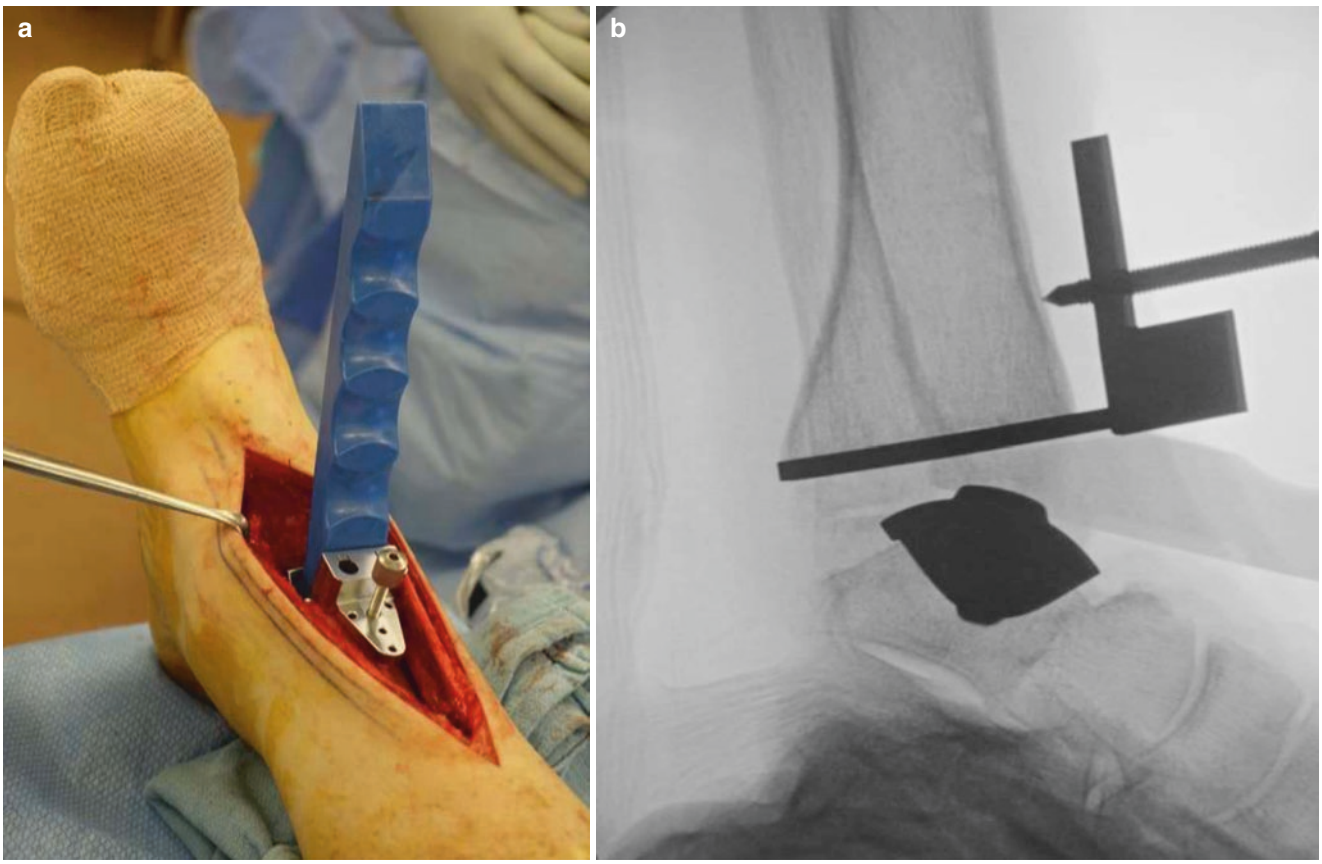


Fig. 16.20 The blue spacer bar is used to push the barrel hole guide firmly against the distal tibia (**a**) which is confirmed on lateral imaging (**b**)

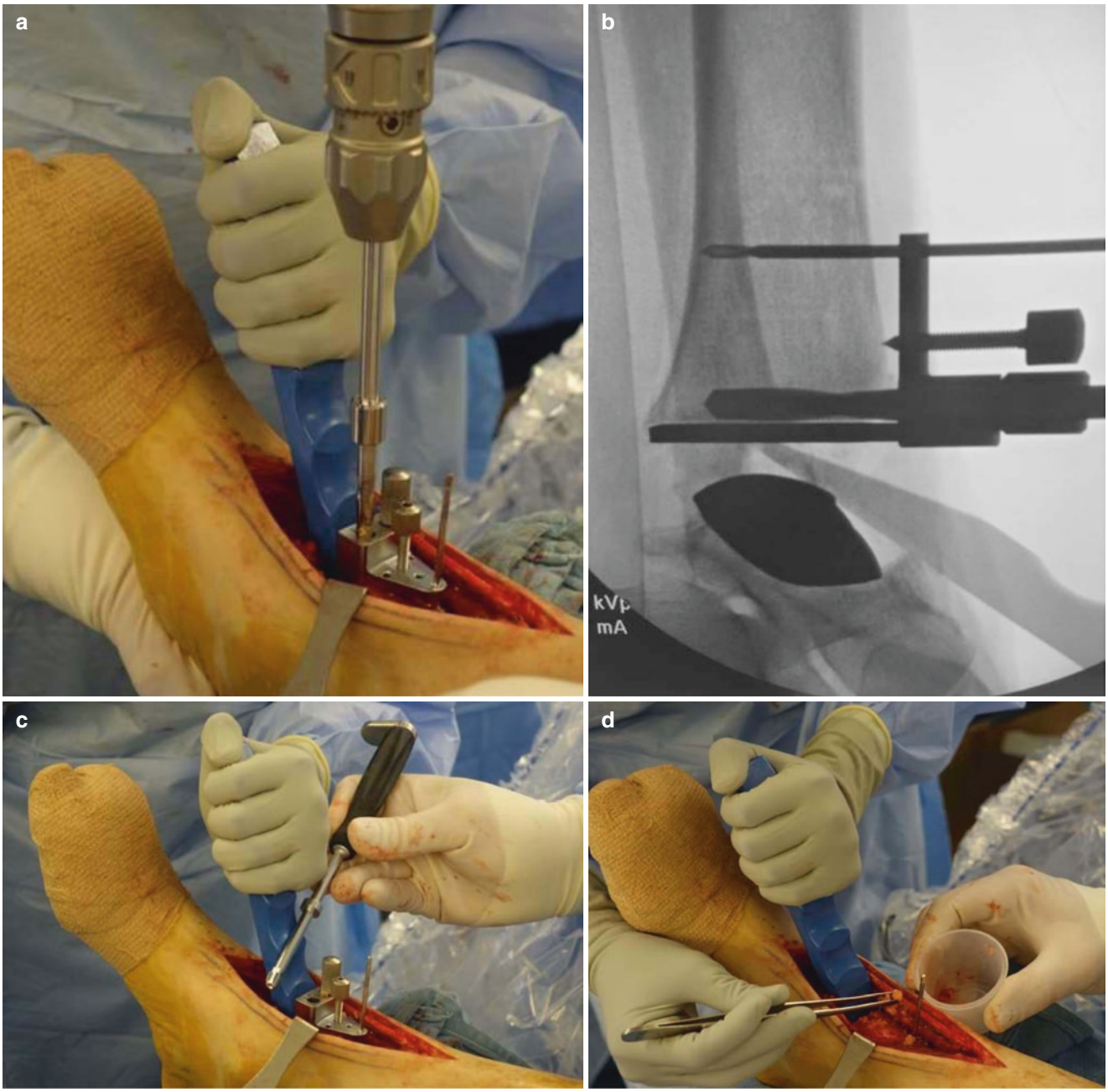


Fig. 16.21 The barrel hole guide is secured to the tibia with a 2.4 mm pin through the distal hole in the guide. The 6.5 mm barrel holes are drilled with blue spacer bar firmly wedging from below and the surgeon's hand slightly plantarflexed to avoid having the drill exit inferiorly (**a**, **b**). The tibial slots are finished with a key hole broach (**c**). The barrel hole guide is removed, and bone graft material is preserved for later packing of drill holes in the tibia (**d**)

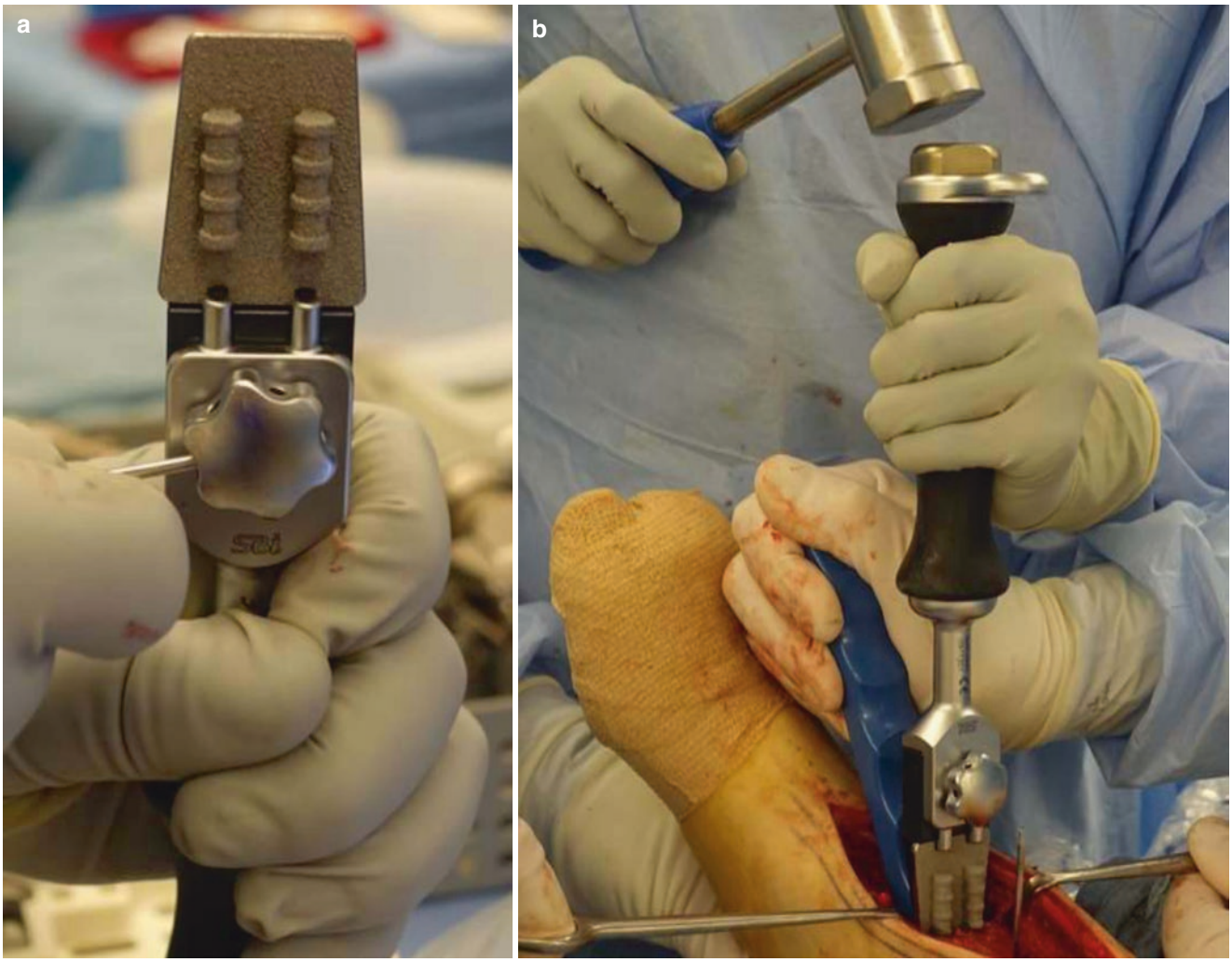


Fig. 16.22 The tibial component is loaded on the tibial inserter (**a**) and placed with a mallet in line with the pin axis guide using slight plantarflexion of the surgeon's hand (**b**). The blue spacer bar is used to maintain the leading edge firmly within the distal tibia (**c**). The inserter is removed, and the black joint space evaluator bar is used for final adjustments (**d**)





Fig. 16.22 (continued)

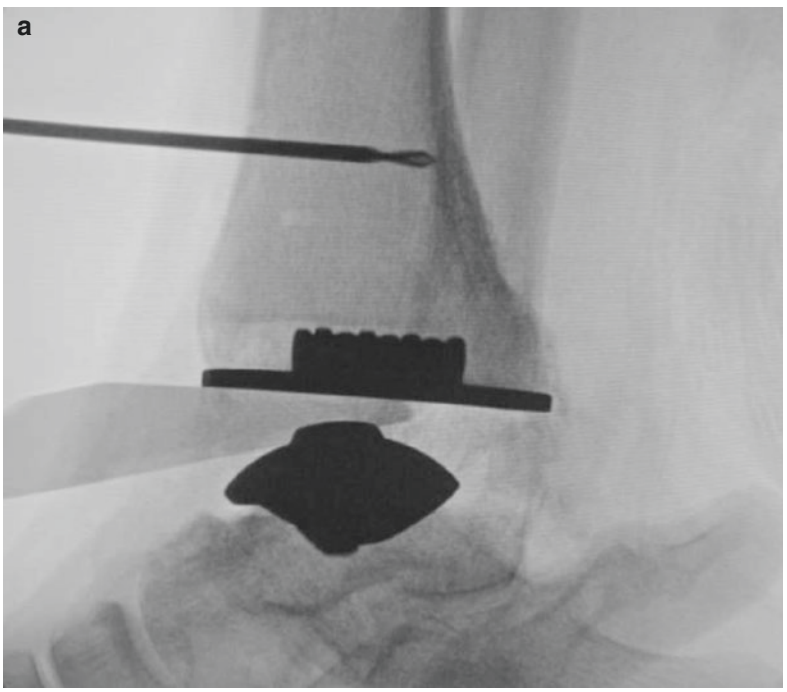




Fig. 16.23 Tibial component positioning is assessed on lateral imaging with coverage of the posterior cortex and tight fit against the distal tibia (**a**). True lateral imaging is confirmed by uniform thickness and square anterior and posterior edges of the tray. The tibial tray may protrude from the anterior lateral bone cortex due to anterior lateral tibial anatomy (**b**)

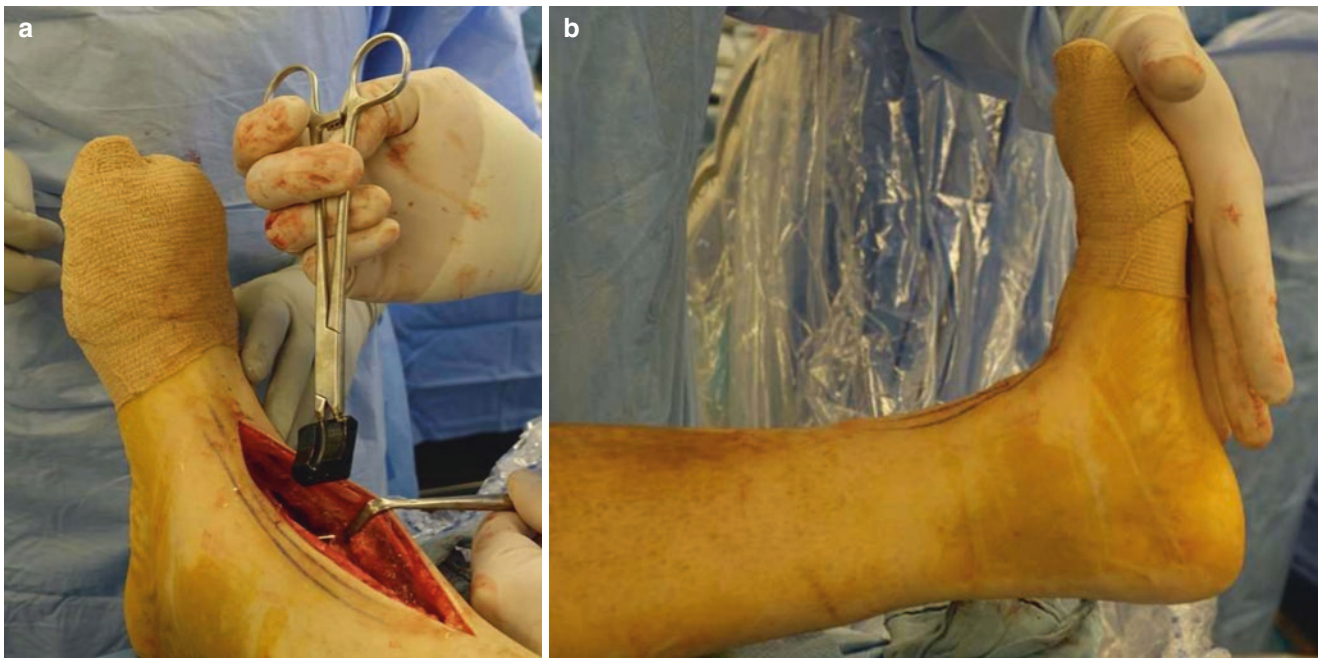


Fig. 16.24 A trial polyethylene bearing is inserted with forceps (**a**) and evaluated for correct thickness based on sagittal plane ROM and varus/valgus stability (**b**). Multiple sizes are assessed

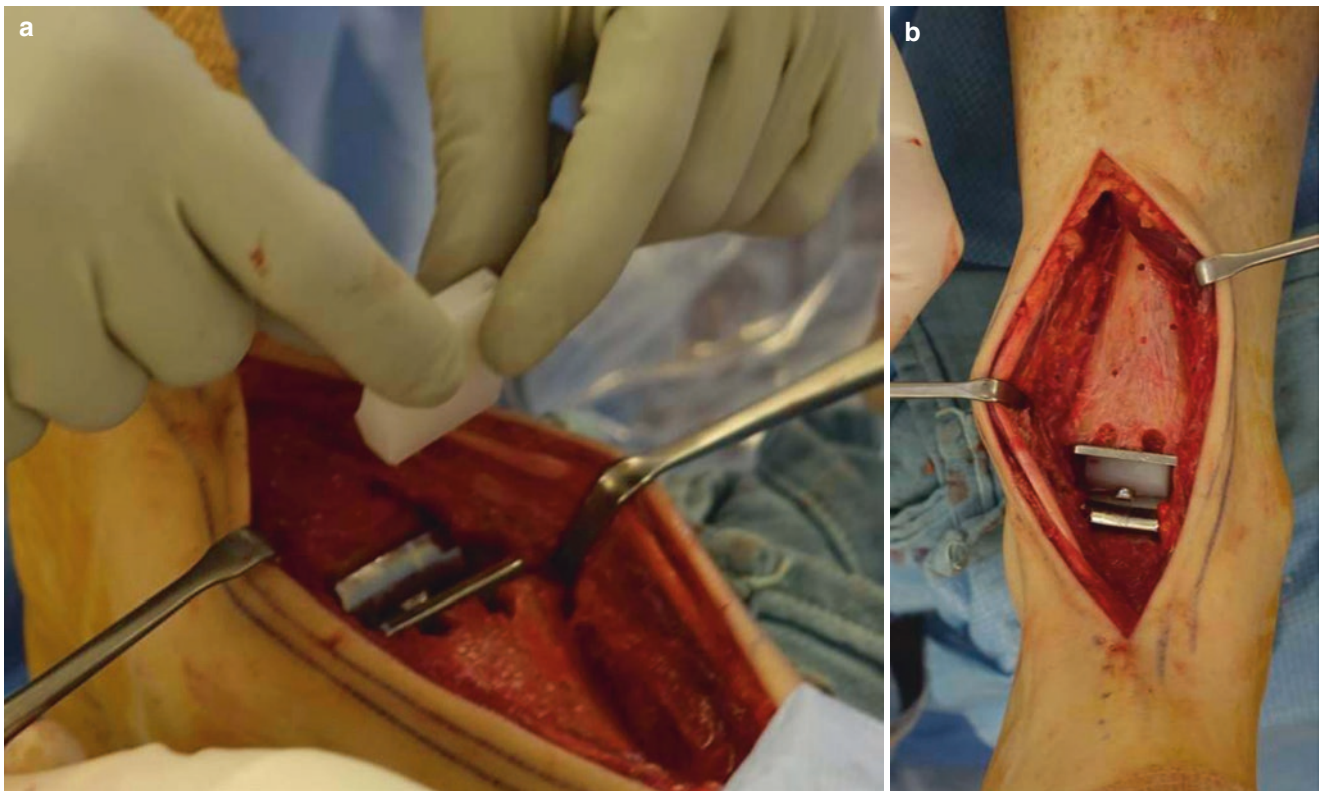


Fig. 16.25 Final placement of polyethylene bearing is by hand (**a**, **b**) which is then assessed on lateral (**c**) and AP imaging (**d**)

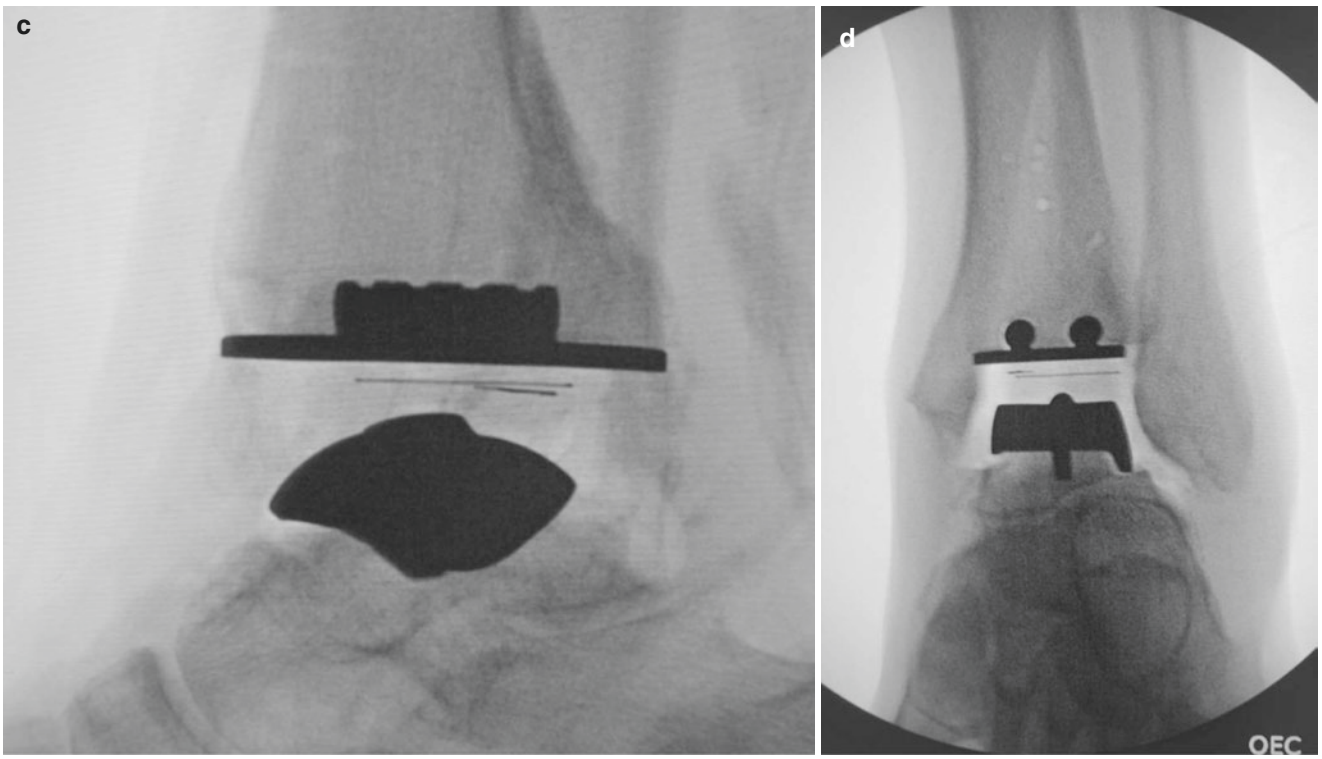


Fig. 16.25 (continued)

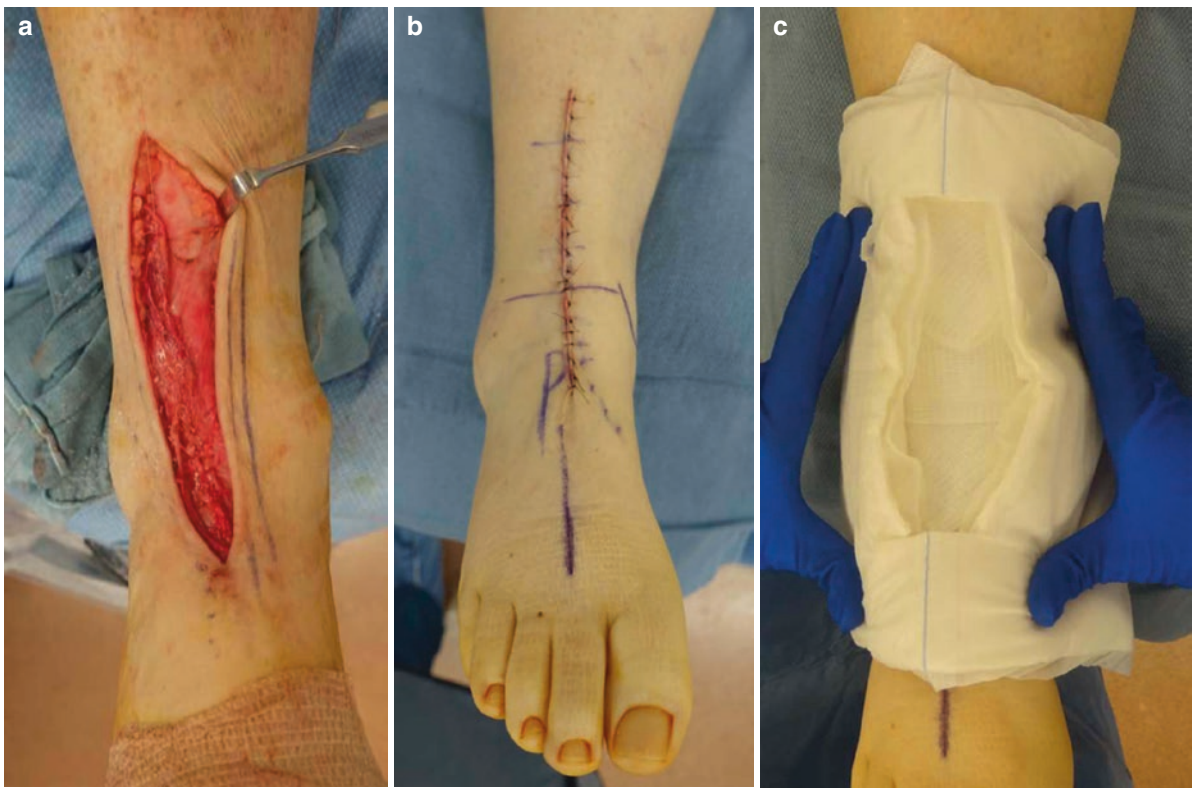


Fig. 16.26 Layered closure is performed including the anterior ankle joint capsule and tibial periosteum (**a**). The anterior skin incision is fragile in total ankle replacement (**b**) which can be protected with a window dressing cut from an ABD pad (**c**)

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The Quantum™ Total Ankle Prosthesis

17

Thibaut Leemrijse, Laurent Paul, Per-Henrik Ågren, Pit Putzeys, M. Truitt Cooper, and Jean-Luc Besse

Introduction

There is now a growing body of evidence using patient-reported outcome measures in total ankle replacement and ankle arthrodesis, describing level of function from the patient's perspective. However, they largely overlook the question of whether patients experience permanent functional limitation [1].

Bringing a new orthopaedic implant onto the market in 2020 is a difficult and confusing administrative adventure. Administrative standards have become increasingly tight, especially in Europe. The administrative burden of CE marking exceeds the legitimate requirements of the FDA. In2Bones has taken up this challenge and now offers a new range of total ankle prostheses. From the outset, it offers an innovative solution at all levels of development.

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The implant meets the current criteria of prosthetic ankle surgery: adapted size, respect of anatomy, and moderate but sufficient bone resection to respect the level of the joint line and ensure implant placement in a high-quality bone environment.

This new implant also offers a digital planning strategy. Including the implant in 3D planning accessible online via a web application allows the implant to be properly positioned, limiting risk of bone impingement and avoiding weakening the medial malleolus by respecting safety zones. Digital planning allows the surgery to be visualized, anticipating possible intraoperative difficulties. Implant alignment is optimized, limiting the risk of impingement with tendon or bone structures.

The software allows the bone structures to be repositioned in the CT scan by adjusting to standardized weight-bearing radiographs [2]. The system is capable of allowing planning of tendon and ligament release prior to implant placement.

Once the bone registration is completed, the positioning of the implants is validated and the production of the personalized surgical guides is finalized. Patient-specific instrumentation (PSI) avoids the tedious and complex instrumentation that is a source of real-life error.

The *Quantum*™ Total Ankle Prosthesis

The *Quantum*™ Total Ankle Prosthesis has been designed with the experience of 4 European surgeons, Thibaut LEEMRIJSE, MD (Belgium), Jean-Luc BESSE, MD (France), Per-Henrik AGREN, MD (Sweden), Pit PUTZEYS, MD (Luxembourg), and an engineer, Laurent PAUL (Belgium). The *Quantum*™ Total Ankle System aims to respond to unmet clinical needs such as aseptic loosening, periprosthetic fracture, technical error due to a long learning curve, stiffness, and infection, and the increasing number of total ankle revision procedures. The *Quantum*™ Total Ankle

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Prosthesis is the first of its kind to offer a complete total ankle system including solutions for primary surgery and revision within the same range of product, web-based planning software, enabling surgeons to adjust implant position according to clinical status, patient-specific instrumentation for tibia and talus with integrated resection guides, and a dedicated instrument set with up-to-date instruments.

The *Quantum*™ total ankle prosthesis is a fixed-bearing semiconstrained ankle prothesis with 2 components, available in different sizes and models (Fig. 17.1). It is composed of a tibial component made up of a metallic (TA6V) tibial tray implant fixed to a polymer (UHMWPE) inlay and a metallic (CoCr) talar implant reproducing talar dome anatomy. When all components are implanted together, with the inlay rigidly locked to the tibial tray, the polyethylene inlay acts as a single bearing along the talar dome, enabling flexion/extension and rotation of the replaced ankle joint.

Quantum™ Tibial Tray

The *Quantum*™ tibial tray is available in 24 different variants: Standard or Long models, combined with 6 sizes for each model and 2 sides (left and right). The Standard and Long models provide posterior tibial coverage adapted to the patient's anatomy, while right and left geometries allow anatomical bone coverage in the mediolateral plane (Fig. 17.2).

A fibular curve design allows better tibial bone coverage without impinging the fibula, while keeping the tibial keel aligned with the tibial axis (Fig. 17.3). This may be more appropriate: A 10 mm residual distance between the medial corner of the tibial bone resection and the medial cortex of the medial malleolus is ensured to prevent the risk of medial malleolar fracture or subsequent stress reaction [3].

The aim of this shape is to prevent stress fracture during the various surgical steps and to ensure primary stability.

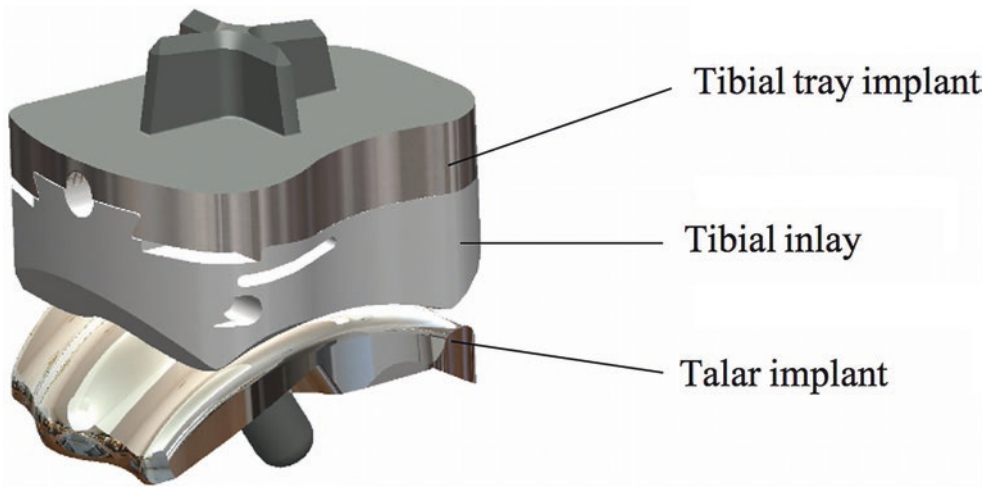


Fig. 17.1 *Quantum*™ total ankle prosthesis

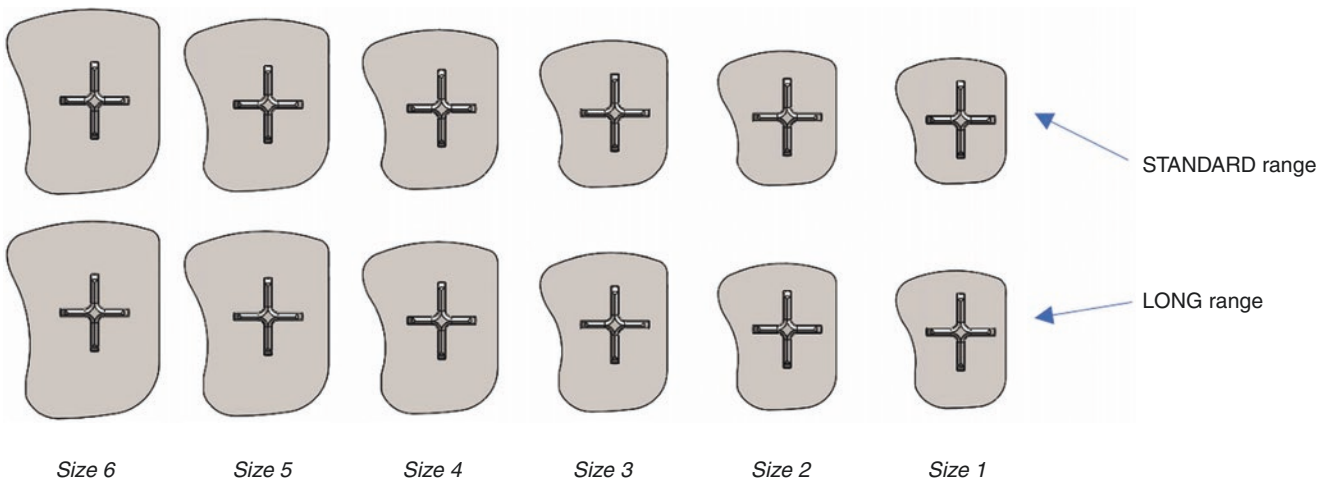


Fig. 17.2 *Quantum*™ tibial tray ranges (Left side)

The *Quantum*™ tibial tray presents a cross-shaped keel designed to provide adequate anchorage in the bone and provide rotational stability of the component once implanted. The cross-shaped keel is designed vertically to enable impaction aligned on the tibial axis, thus allowing additional remaining impaction when the patient's weightbearing is restored. The height of the keel has been designed to allow its implementation in the tibial bone without any tibial anterior window bone preparation, in order to conserve bone stock without jeopardizing primary stability.

The *Quantum*™ tibial tray presents a plasma-spray porous titanium (Ti) coating on its surface in contact with the bone for osseous integration and secondary implant stability, with cement if needed (Fig. 17.4).

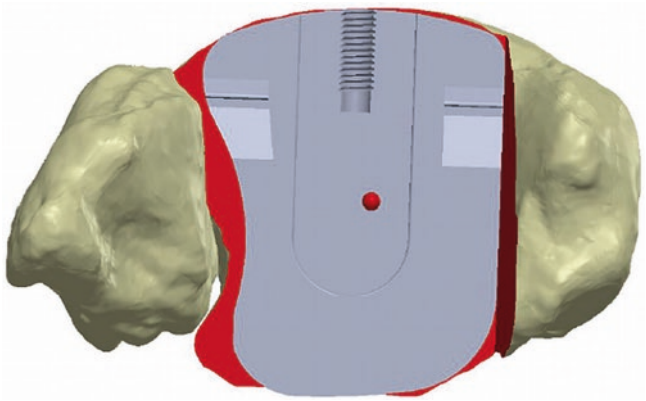


Fig. 17.3 *Quantum*™ tibial planning results showing bone coverage of the tibial implant over the tibial bone cuts thanks to the fibular curve

Quantum™ Inlay

The *Quantum*™ fixed inlay is available in 96 different variants: 6 sizes corresponding to those of the tibial tray, combined with 8 different thicknesses and with 2 sides (left and right). It is rigidly fixed to the tibial tray intraoperatively, thanks to a dovetail locking mechanism (Fig. 17.5). The inlay design presents 2 gutters on the periphery of its anterior face to allow unlocking and removal of the inlay in the case of revision.

The fibular curve design of the tibial component requires an offset in the inlay design to adapt to the anatomy of the ankle and the misalignment between the tibial and talar axes. This offset not only respects the natural anatomy of the ankle but also better distributes loading on the prosthesis (Fig. 17.6).

Fig. 17.4 *Quantum*™ tibial tray design (Left)

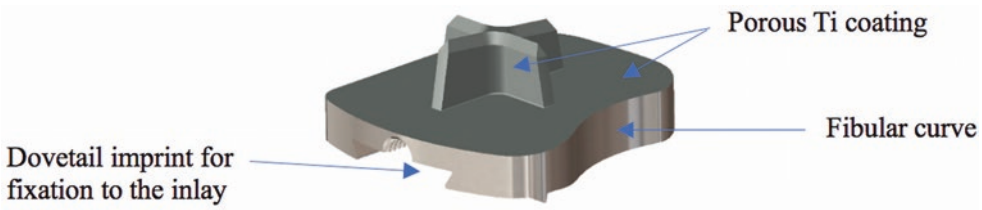
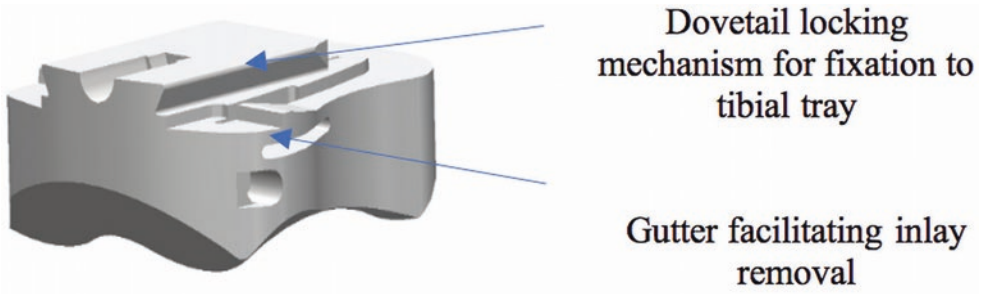


Fig. 17.5 *Quantum*™ inlay



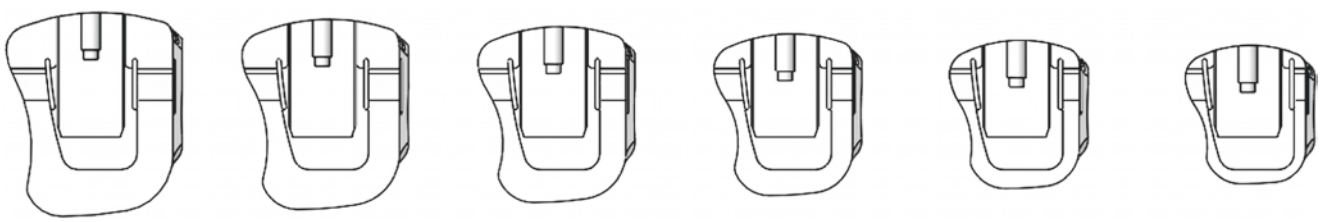


Fig. 17.6 *Quantum*™ inlay ranges (Left side)

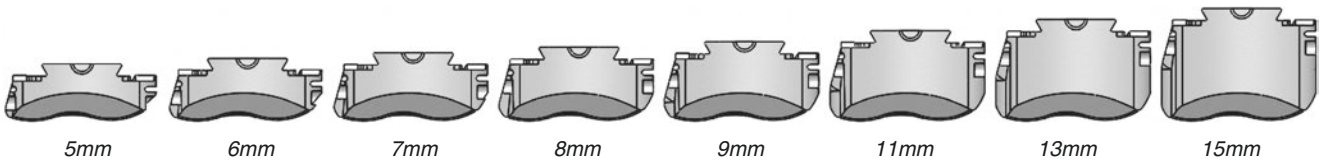


Fig. 17.7 *Quantum*™ inlay size 1 – thickness range (Left side)

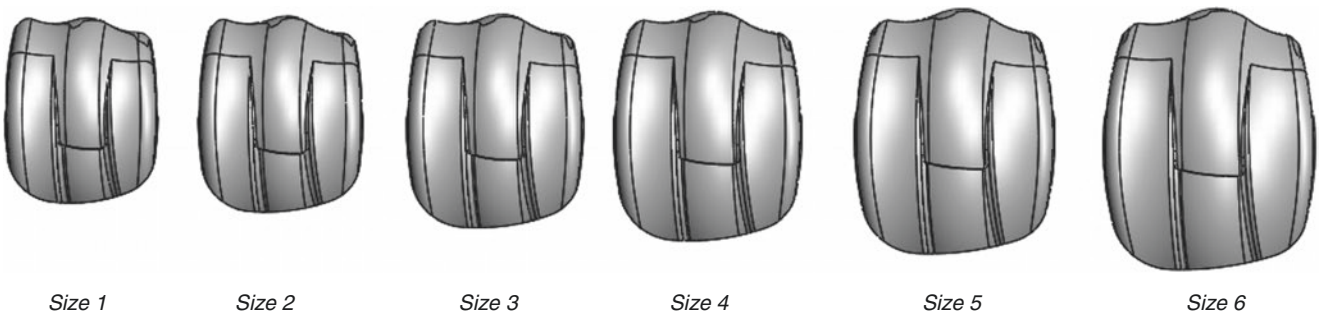


Fig. 17.8 *Quantum*™ talar implant size range (Left side)

The articular surface of the inlay matches the articular surface of the talar implant. A slight mismatch between the inlay and the talar implant articular surface has been built in to enable some axial rotation and anteroposterior translation. This feature is meant to adapt to any slight alterations in alignment of the articulation without overstressing the inlay during motion.

The inlay is also designed with an anterior and a posterior chamfer to improve dorsiflexion and plantar flexion and to prevent impingement with the talar implant (Fig. 17.7).

Quantum™ Talar Implant

The *Quantum*™ talar implant is available in 36 different variants: Standard, Flat-Cut, or Flat-Cut with keel* (*not FDA approved) models, combined with 6 sizes in each model and with 2 sides (left and right) (Fig. 17.8).

The three different models of *Quantum*™ talar implant are developed to fit varying patient anatomy:

The STANDARD model presents low thickness and is designed with anterior and posterior chamfers (Fig. 17.9). This aims to resect a limited surface of bone over the talar dome during bone preparation. It is stabilized in the talus with 2 pegs and acts as a resurfacing component.

The FLAT-CUT model is designed to adapt to specific talar anatomy with a particular flat shape or for revision surgery. It may also be used by surgeons who prefer a flat-cut bone preparation, for reasons of simplicity or reproducibility for example (Fig. 17.10). Like the STANDARD model, it is impacted in the talus with 2 pegs.

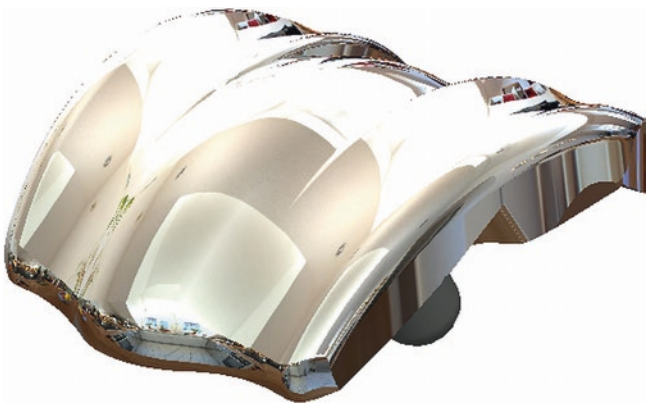


Fig. 17.9 *Quantum*™ talar STANDARD model

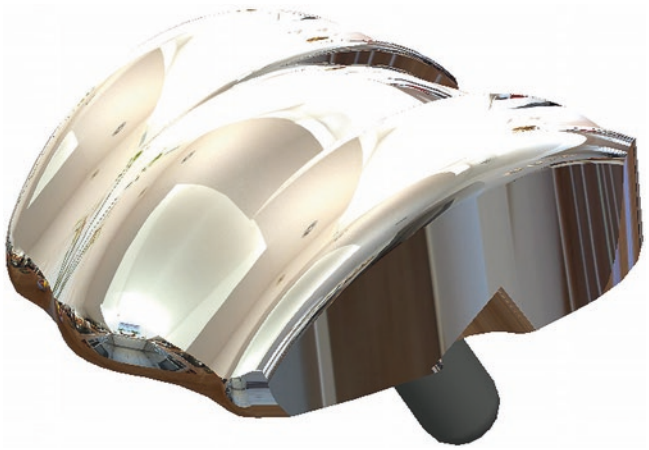


Fig. 17.10 *Quantum*™ talar FLAT-CUT model

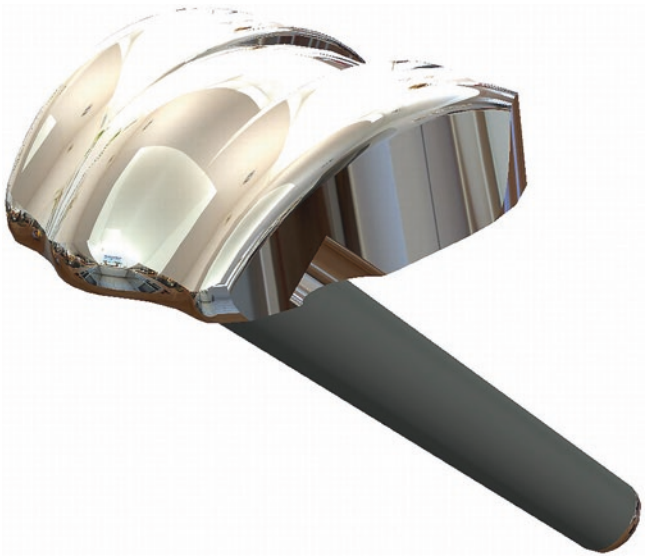


Fig. 17.11 *Quantum*™ talar FLAT-CUT with keel model

The FLAT-CUT model with keel is intended for cases where subtalar arthrodesis is necessary in addition to the total ankle replacement. The keel goes through the talus and into the calcaneus (Fig. 17.11). It may also be used in revision surgery. This variation is not available currently in the United States.

Note: optionally, an 8.0 mm I.B.S® screw may also be inserted obliquely and parallel in addition to the keel to provide stability for the subtalar arthrodesis during bone preparation, impaction, and postoperatively.

The articulating surface of the *Quantum*™ talar implant presents the same design in all the models: a bicondylar articulating surface with 2 different curvature radii in the medial and lateral parts, which replicates the original anatomy, with the goal of reproducing natural biomechanics during the gait cycle. The tronconic shape of the implant is meant to reproduce the anatomy of the talus, and the double radii of curvature offer a larger radius during plantar flexion, when weight-bearing stress is the greatest, and a smaller radius of curvature during dorsiflexion to increase the range of motion of the ankle. A posterior chamfer has been implemented to optimally reproduce the talar dome and provide greater contact between the inlay and the talar component. As a result of these features, the maximum expected global range of motion is around 40° dorsiflexion plus plantar flexion, with around 7° inversion and 8° eversion.

Concerning the undersurface of the talar implant, the pegs are inserted into the thickest portion of the component, to avoid any impingement and mispositioning of the implant during impaction.

Like the tibial tray, the *Quantum*™ talar implant undersurface is covered with a plasma-spray porous titanium (Ti) coating in contact with the bone for osseous integration and thus secondary implant stability. It is made of Cobalt Chromium (CoCr).

Surgical Planning

Prerequisites

Surgical planning requires a CT scan, as follows. The patient is supine, with the leg in extension and the ankle at a right angle. During image acquisition, an optional radiotransparent splint can be used to optimize foot and ankle positioning. The area of interest extends from the femoral condyles to the toes. The image parameters are 512 × 512 pixels, with 0.6 mm slice thickness. Table increment is 0.5 mm. Acquisition must be continuous, to avoid reconstruction abnormalities. The resulting data file comprises raw nonreconstructed DICOM images, which are transferred to the secure platform.

This aspect of planning has been thoroughly analyzed and developed in the *Quantum*™ concept. Appropriate implant planning requires correcting any ankle malalignment. The virtual model presents the same complexity as in real surgery [4]. No implant can be positioned in a misaligned ankle, and the surgeon therefore needs to master perioperative procedures such as osteotomies and fusions, releases, and, less frequently, lateral and medial ligament reconstruction [5]. The prosthesis is to be implanted in a well-aligned and stable ankle, and the software has to be able to reproduce these surgical procedures ahead of virtual planning, which is the essential link in producing the cut guides (Fig. 17.12).

In this example of valgus osteoarthritis with medial tilt, reorienting the talocalcaneopedal block is an essential preliminary to implant planning. The software has to be able to allow for bone structure reorientation and repositioning in ideal position for implantation.

The first step (performed by the engineers) is bone segmentation, followed by recentering in the bimalleolar mortise. Talocalcaneal block segmentation therefore needs to be of high quality, respecting the bone volumes, followed by correction of valgus or varus frontal malalignment. This bone repositioning simulates any possible joint release or ligament reconstruction procedures.

Sagittal correction (on lateral view) involves a reference plane that is hard to define specifically, as it varies with foot morphotype, flat feet showing a more horizontal calcaneus,

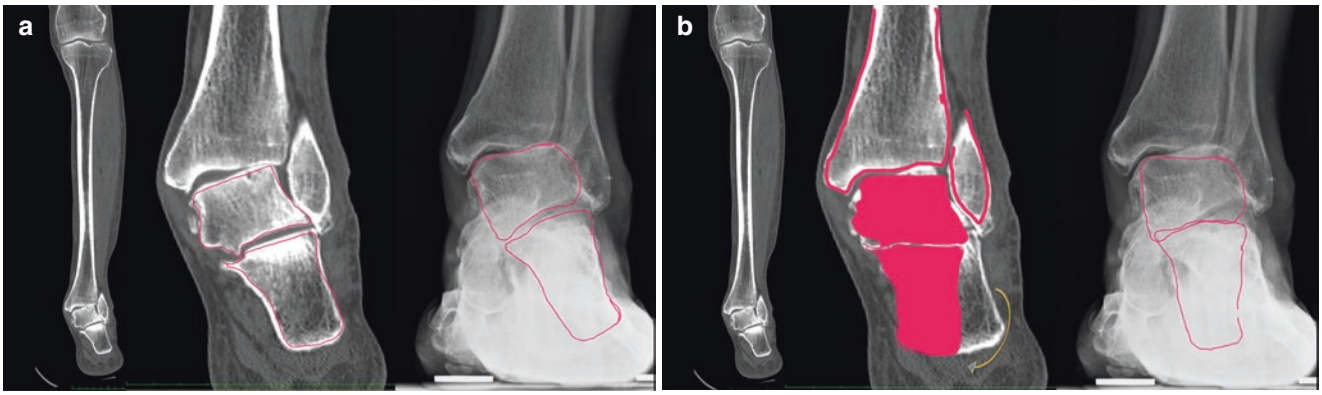


Fig. 17.12 Radiograph of hindfoot (**a**) and planned corrections (**b**)

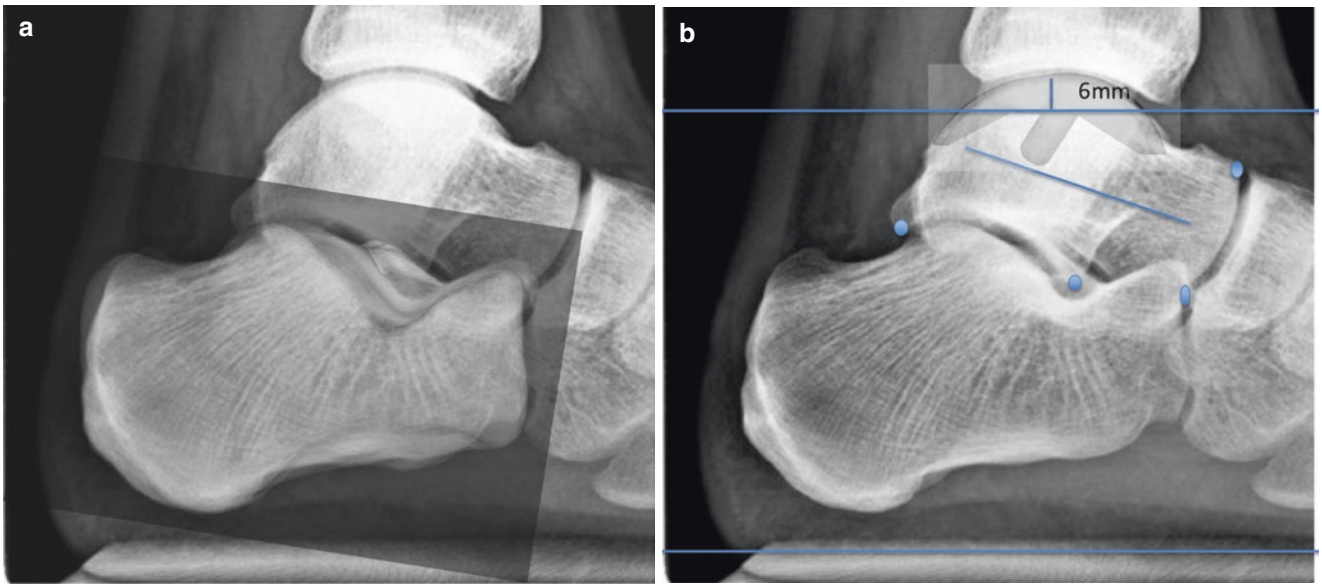


Fig. 17.13 Concept of hindfoot positioning optimization by recalibration on standard ipsi- or contralateral radiographs. (**a**) Calcaneal recalibration on 3D stereolithography (STL) reconstruction on the radiograph. (**b**) Virtual implant position on radiologic landmarks

in contrast to pes cavus. Statistical values for calcaneal slope could be used, while taking account of talocalcaneal divergence. But it is more precise to use weight-bearing X-ray data and compare them with repositioning on CT, which is most often still performed in nonweight-bearing neutral position. Weight-bearing CT has not demonstrated any significant advantage for correcting varus or valgus deformity or fixed deformity (e.g., in equinus). The data can be compared against statistically representative X-ray data or contralateral weight-bearing views (Fig. 17.13). Landmarking can help recalibrate ideal plantigrade foot positioning, so as to define a plane optimally parallel to the ground for optimal talar component positioning.

AP weight-bearing X-ray data can be optimized, for example, analyzing talar tilt and hindfoot position by automated recognition using Artificial Intelligence (AI) algorithms (Figs. 17.14, 17.15, and 17.16). In the medium term, this allows data optimization and automated digital processing. The data banks can be used to reliably optimize neutral ankle positioning for planning.

Software Planning

When guided using PSI, implant size and position must be adequately matched to individual anatomy. The preoperative planning is therefore one of the most critical stages to ensure implantation success [6].

A web-based software application specifically dedicated to ankle arthroplasty has been developed to control the appropriate sizing and positioning of implant components (*3D-Side company, ISO 13485, Mont St Guibert, Belgium*). A draft plan is computed by clinical engineers and submitted to surgeons for approval or amendment.



Fig. 17.14 Automated calculation on radiographic data for ankles in weight-bearing. (3DOrtho-Analyser, Digital Orthopaedics)



Fig. 17.15 Optimization of weight-bearing radiographic data on lateral view. (3DOrtho-Analyser, Digital Orthopaedics)



Fig. 17.16 Comparison with contralateral data (3DOrtho-Analyser, Digital Orthopaedics)

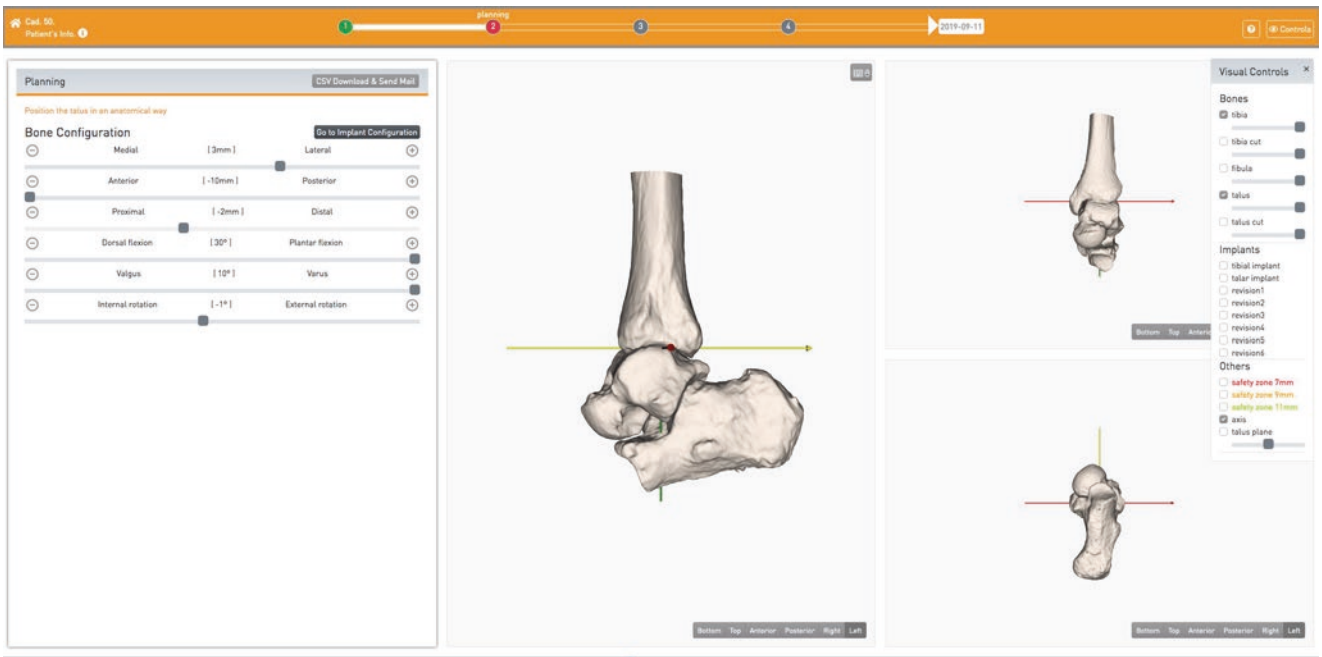


Fig. 17.17 Positioning talus with respect to the tibia. The left panel controls the translations and rotation of the talus + calcaneus complex. The right panel displays X-rays or a 3D reconstruction. The middle panel shows a 3D visualization

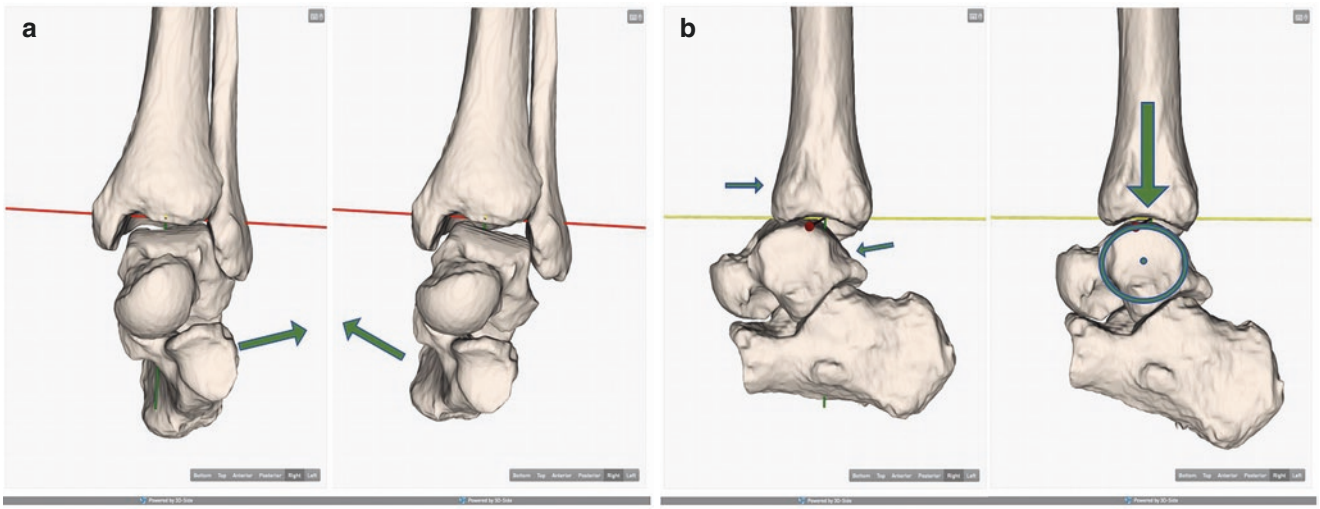


Fig. 17.18 Frequently, despite guidelines, the acquisition in the CT scan does not allow optimal positioning of the implants. Like a surgical procedure, the software allows the bones to be repositioned as if the surgeon was performing a relay or joint recentering. It is essential to have a slope centered in both planes. (**a**) Varus-valgus malalignment. (**b**) Anteposition of the talus

Foot biomechanics are taken into consideration to improve implant fit and functionality. Standardized weight-bearing X-ray views are provided alongside the CT-scan, to reproduce ankle joint specificity. 3D reconstructions are visualized alongside the X-rays.

As a first step, the surgeon has the opportunity to adapt the respective positions of the bones, to achieve optimal target joint alignment (Figs. 17.17, 17.18, and 17.19).

As a second step, implant components are displayed, and bone cuts are simulated. This allows the surgeon to see how the implants fit with the local bones. Translations and rotations can be made using the sliders on the left panel. The impact is directly visible on the 3D visualization (Figs. 17.20, 17.21, and 17.22). A control panel manages hiding/showing objects and assigning opacity on certain 3D models.

Implant positioning is predetermined by the structured algorithms.

For tibial component positioning, minimal bone resection corresponds to the height of the tibial metal back and the thinnest polyethylene pad thickness, maintaining the joint-line level. The software visualizes any risk of medial malleolar damage, on a color code: green, >11 mm safety zone; red, <7 mm.

Likewise, for talar positioning, there is a predetermined resection level that can be modified according to wear and bone deformity. Implant rotation with respect to the talar cut is presented by calculating the bisector line at the cut but, like all other positioning factors, can be modified by the surgeon. The software displays and clarifies the impact on tibial implant positioning of, for example, altering the talar implant (Figs. 17.23 and 17.24).

By moving one component, it is possible to create a conflict between the edge of the implant with the ideal distance from the malleolus and the new position of the tibial implant, which has aligned with the tibial part via the polyethylene, which is fixed (Fig. 17.24). The software, by planning, "knows" the position that the talus will have and thus optimizes resection of the cut and the tibial rotation. The system, however, still allows intraoperative adjustment [7].

When satisfied with the implant configuration, the surgeon can back up the surgical planning. The third and last step consists in visualizing the whole parameter set and the final configuration before actually sending the plan to the manufacturing stage. Once validated, the surgeon can still access the case in 'read-only' mode, which does not allow any alterations in planning (Fig. 17.25). Figure 17.26 shows the various planning options provided by the *Quantum*™ range.

Patient-Specific Instrumentation (PSI)

General Considerations

PSI seeks to optimize bone cut quality and reproducibility. It then allows optimal implant positioning to be planned. This new technology was made possible by improvements in imaging techniques with enhanced processor power and improved access.

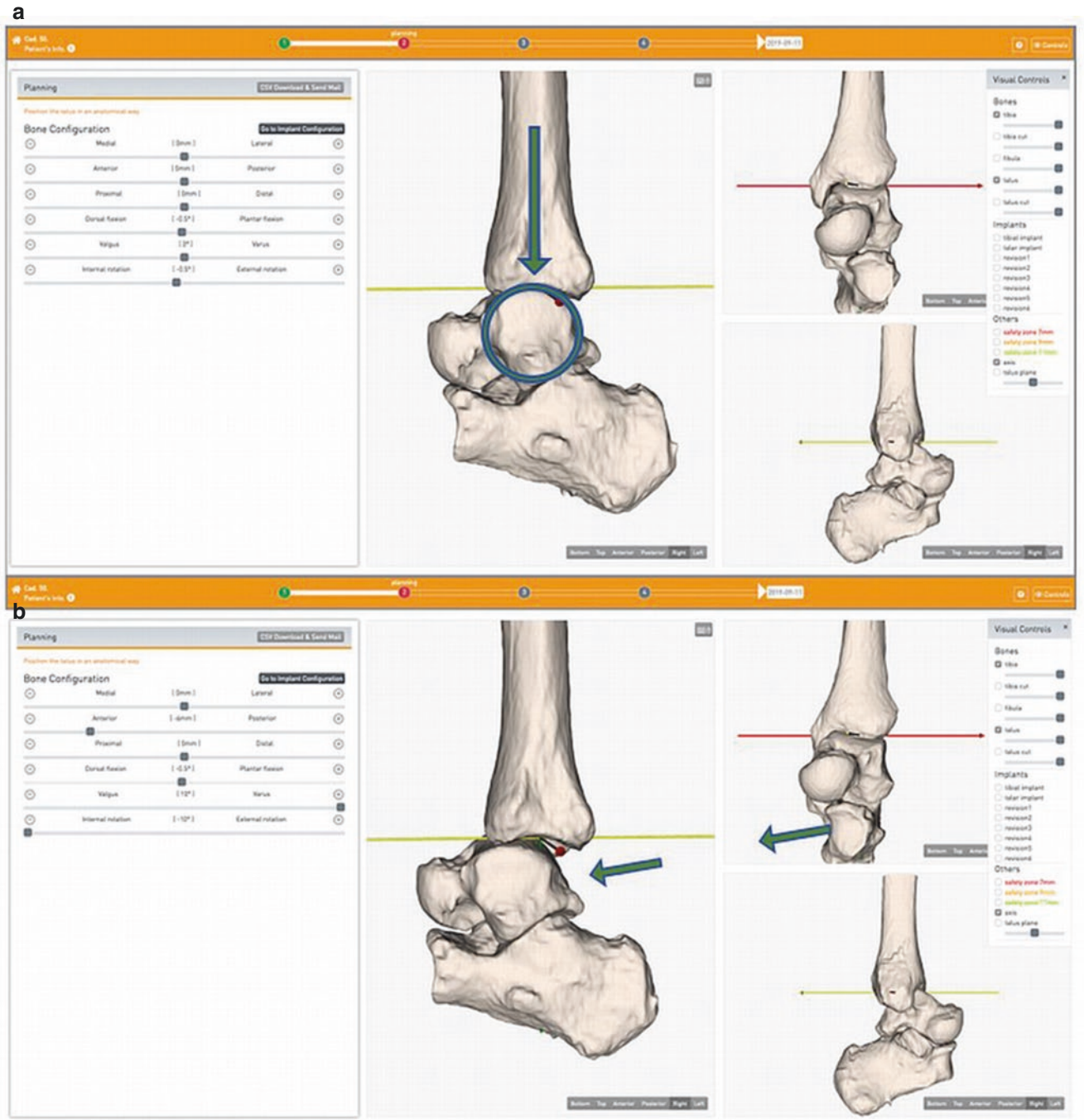


Fig. 17.19 Examples of talocalcaneal block repositioning. (**a**) Visualization of talar recentering under the tibia; (**b**) correction of talar anteposition; (**c**) correction of equinus; (**d**) alignment restoring calcaneal slope in weight-bearing



Fig. 17.19 (continued)

Cut guides are produced based on CT or MRI data, reproducing the 3D models used for surgical planning. This is thus a major change in planning – and a big change for surgeons, who still think in terms of 2D projections of reality.

This new approach applies to every procedure, whether in tumor resection [8] or in hip and knee [9] or shoulder surgery, correction of malunion, or, as here, foot and ankle surgery [2, 4].

PSI is now in competition with robotic surgery, although market size and economic restrictions limit the spread of the latter. PSI, on the other hand, is of considerable economic interest, reducing certain procedural costs.

PSI has to recognize the bone structure to allow reliable and stable repositioning, along with a precise predetermined cut executed with minimal error.

Quantum™ PSI

The *Quantum*™ Patient-Specific Instrumentation (PSI) Guides kit for Total Ankle Replacement contains patient-specific guides and bone models to assist in instrumentation positioning, dedicated to *Quantum*™ Total Ankle Replacement (Fig. 17.27). These surgical instruments must be used in association with the *Quantum*™ instrumentation and are manufactured with certain patient-specific features, which render them unusable in cases other than those for which they were designed.

These surgical instruments are supplied nonsterilely for single use only and must be cleaned and sterilized before use.

In2Bones *Quantum*™ PSI Guides are manufactured according to the preoperative planning validated by the surgeon and allow for positioning the instrumentation by which drilling and bone cuts will be performed.

Quantum™ PSI Guides for Total Ankle Replacement are composed of the following items:

- One patient-specific guide for patient tibial bone instrumentation positioning;
- One patient-specific guide for patient talar bone instrumentation positioning;

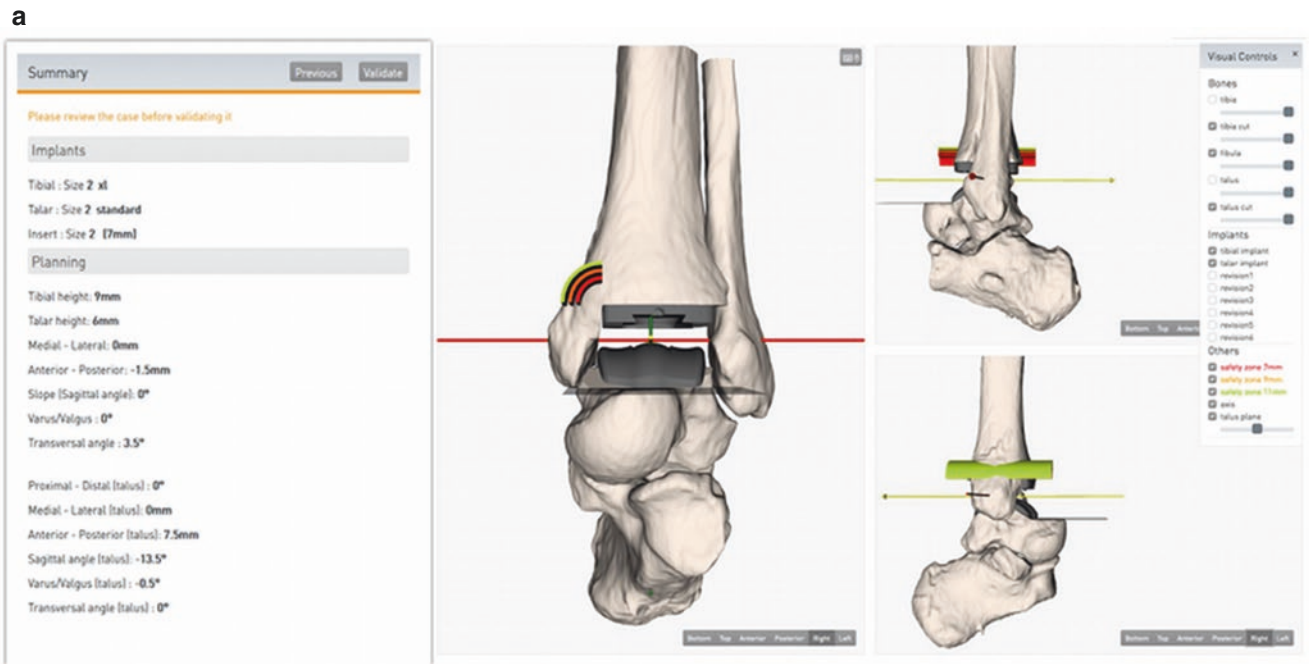


Fig. 17.20 Implant positioning step. (**a**) The left panel is now controlling implants. The middle panel displays cut bones and 3D models of the implants. The 'visual controls' panel provides visualization options of 3D models. (**b**) Radiographs can be integrated into the planning to best visualize the foot in weight-bearing

b

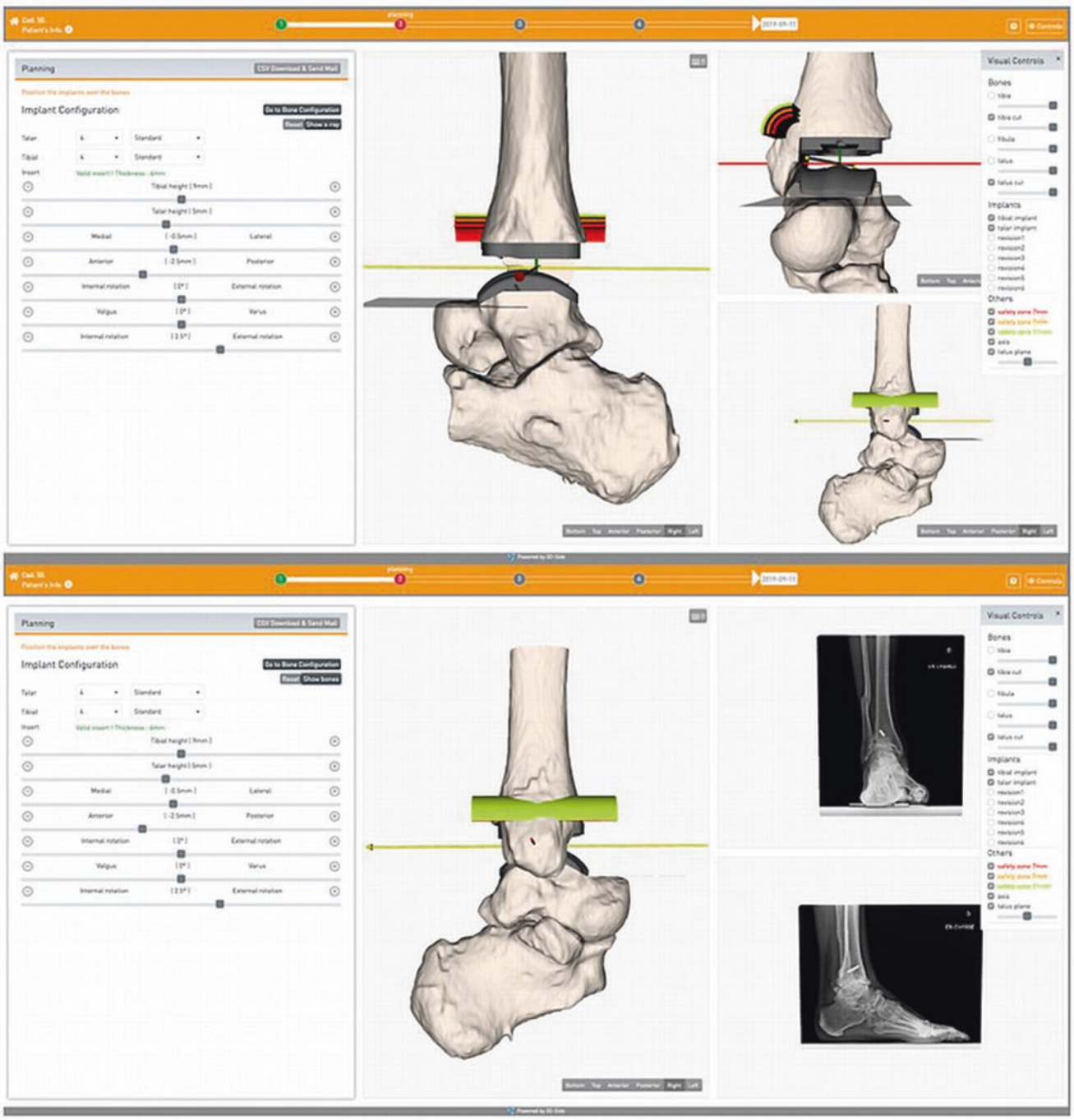


Fig. 17.20 (continued)



Fig. 17.21 The software allows predictive visualization of the position of the implants. It is exceptional to be able to project preoperatively the potential impingements not visualized intra- or postoperatively, despite radioscopic control

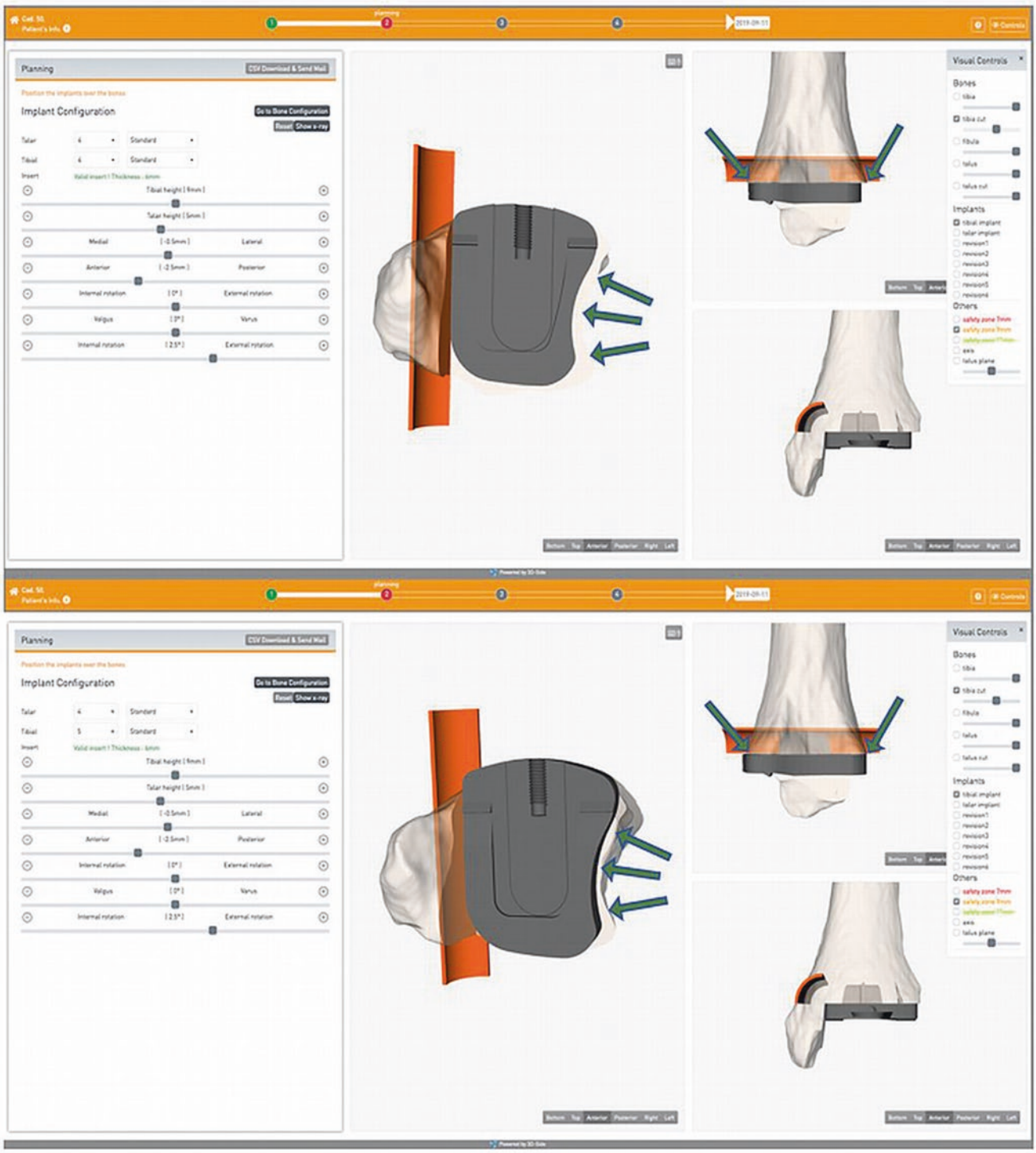


Fig. 17.22 Example of adjustment of the size of the tibial component. The probable ideal position is adjusted from size 4 to size 5. The length and width are therefore optimal. At the same time, the safety zone of the medial malleolus always remains under control

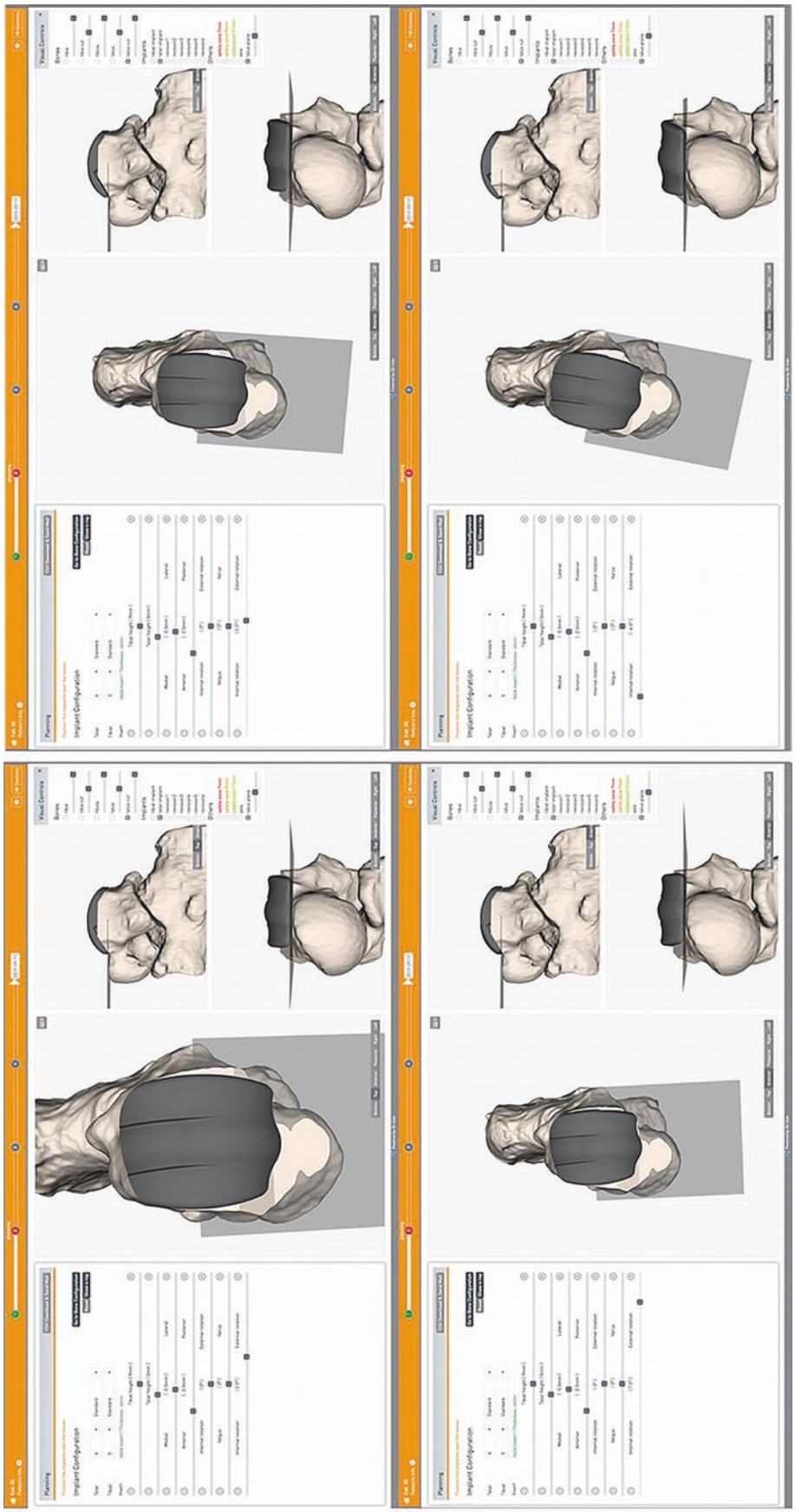
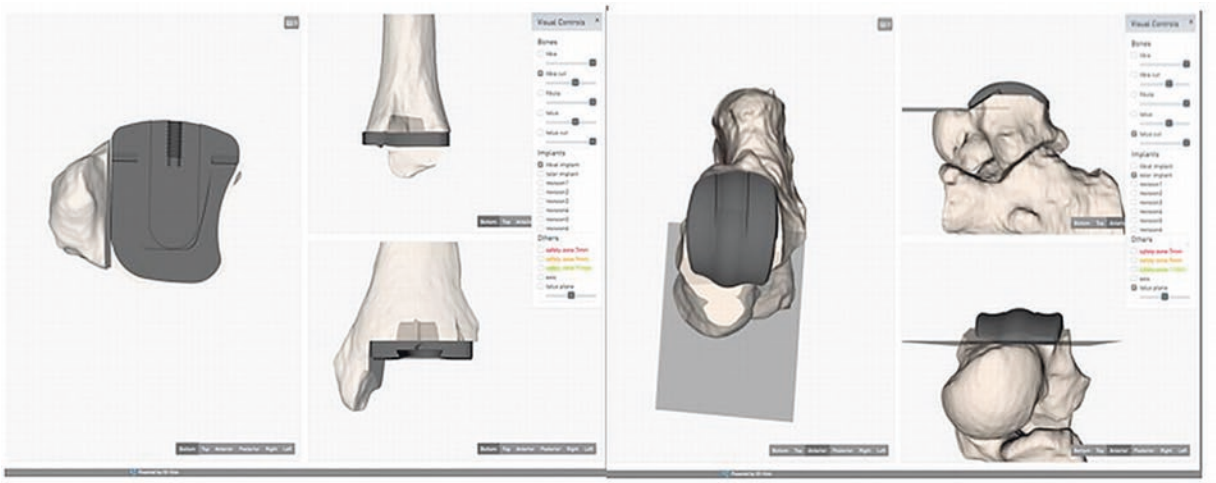
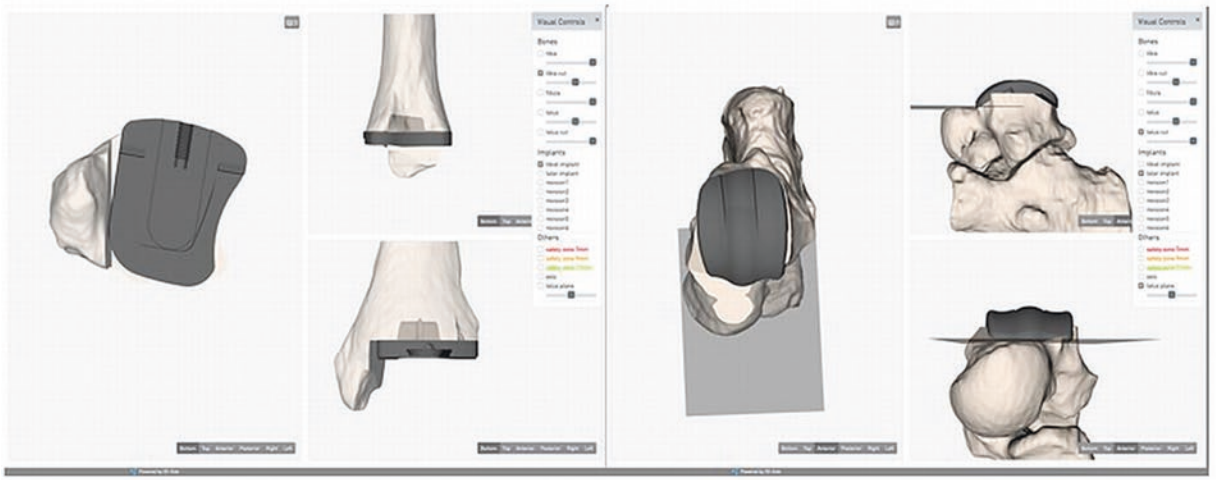


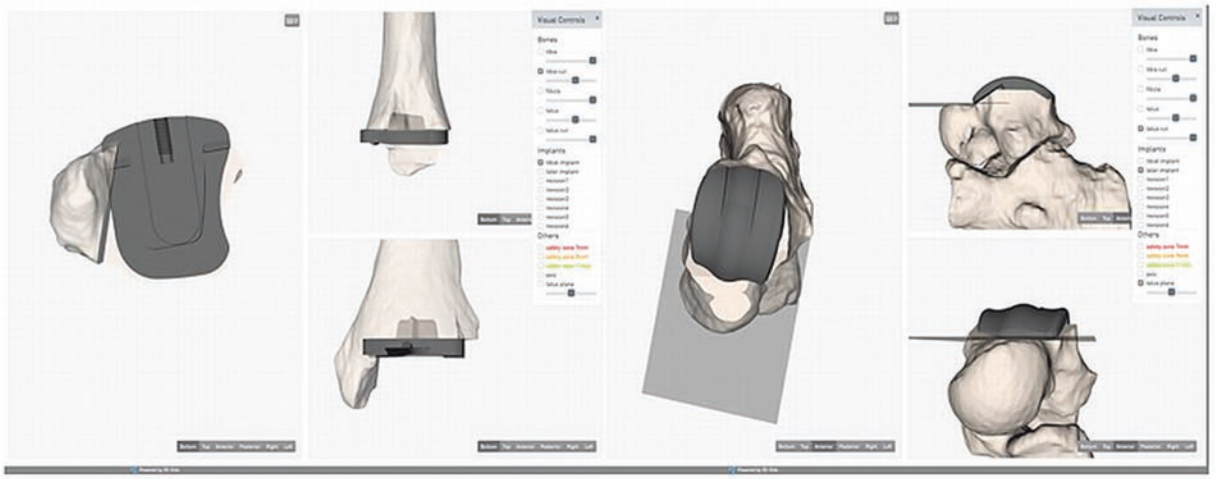
Fig. 17.23 Example of the possibilities of visualization of the optimal position of the talus component. The software reproduces perfect coverage of the implant by smoothing the bone structure. The greatest difficulty is the rotational planning, but intelligent algorithms should be able to help to find the ideal rotational center of the implant



Alignement and influence between talus and tibial component



Influence of the rotation of the talus on the medio-tibial cut, external



Influence of the rotation of the talus on the medio-tibial cut, internal

Fig. 17.24 Extreme example of the impact of an error in rotational positioning of the tibial part; planning avoids this succession of errors by allowing the optimal tibial cut to be made by the PSI, which already "knows" the positioning of the talus

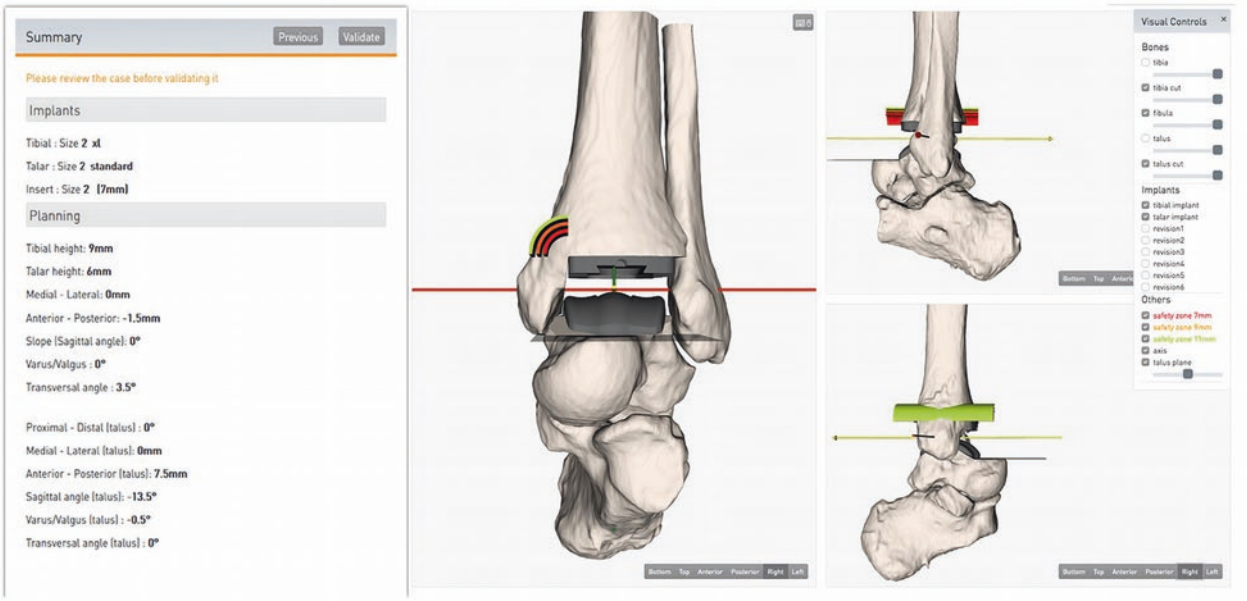


Fig. 17.25 Validation stage before sending the case to manufacturing

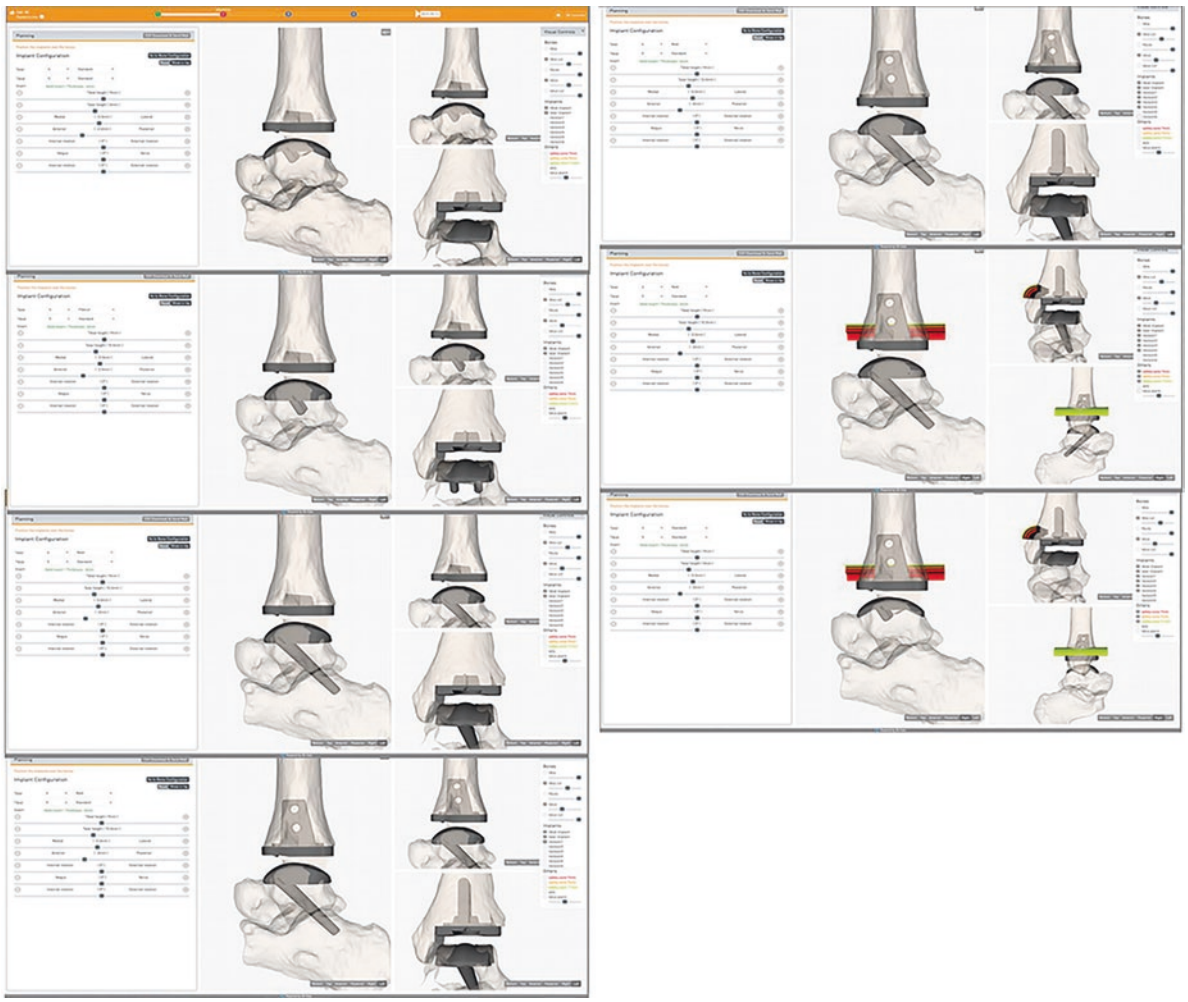


Fig. 17.26 Example of the different implants that can integrate planning according to stage and type of implant

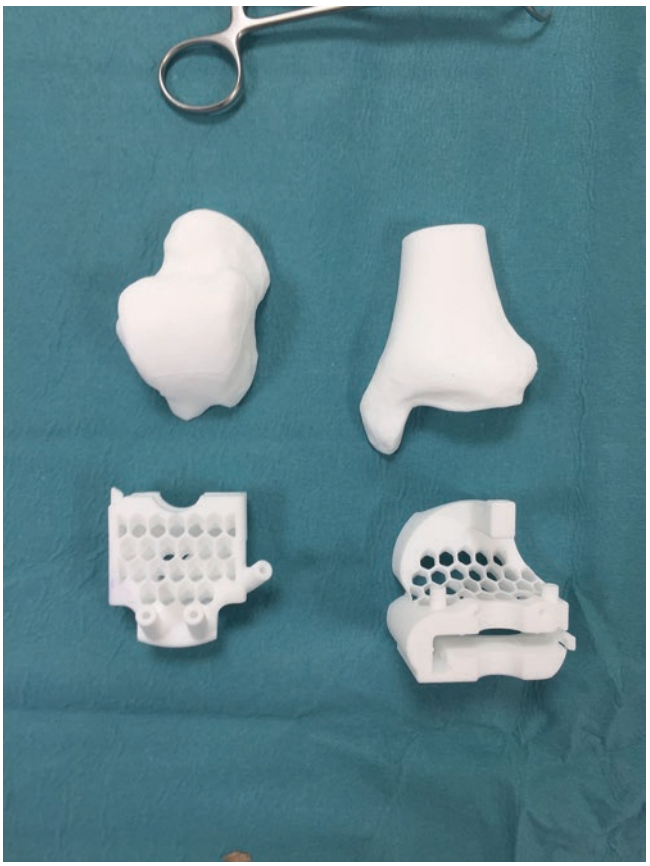


Fig. 17.27 Example of a personalized solution for planned surgery. Tibial and talar cut guides, personalized bone on reconstruction, to be sterilized

- One patient-specific tibial bone, used as visual tool for the surgeon to check the planning and control intraoperative tibial instrument positioning (*not a medical device*);
- One patient-specific talar bone, used as visual tool for the surgeon to check the planning and to control intraoperative talar instrument positioning (*not a medical device*).

Quantum™ PSI Guides are composed of the following instruments (Fig. 17.28):

Quantum™ Test and Validation

PSI Concept

In developing the PSI for *Quantum*™, a number of validation steps were carried out in the anatomy lab, backing up the expertise already acquired in ankle PSI [10]. Tibial pilon morphology recognition is relatively straightforward, as the PSI can adapt and recognize bone morphology with great precision in the anterior side of the pilon (Fig. 17.29). Talar recognition is trickier (Fig. 17.30).

The workflow for *Quantum*™ implantation requires a precise radiologic workup and clinical data as in classical ankle replacement surgery.

To optimize PSI production and orthogonal implantation, a CT acquisition of the lower limb, foot, and ankle is required, similar to that required for precise up-to-date planning in knee or hip surgery. The first step, whether in planning PSI-assisted or robot-assisted total knee replacement, usually consists in CT or, in some cases, MRI.

CT-based planning collects patient data in DICOML format, for automated or semiautomated segmentation, reproducing the bones in 3D. Depending on segmentation quality and the manual work, volume structures with a greater or lesser amount of mathematical data are available: simple bone surface reconstruction by scatter chart or computer-assisted design (CAD).

Such numerical reconstruction provides a digital copy of the bone, to produce a negative mold to be placed on the bone as precisely as possible. This negative mold is the PSI or personalized cut guide. In some examples of PSI, this may be a simple guide for positioning pin landmarks for conventional instrumentation to complete implantation. In the *Quantum*™ concept, the PSI includes direct bone fixation with an integrated metallic cut guide, which is quite different from the cut guides of the *Prophecy*™ system for positioning a key element of the implant instrumentation [11]. External fluoroscopic validation is also an option to verify positioning the PSI (Figs. 17.31 and 17.32).

The advantages of this ambitious choice are many and major:

- a personalized patient-specific solution;
- minimal intraoperative radiation, depending on the needs of surgery;
- minimal instrumentation packaging;
- minimal sterilization cost, by supplying a small-size optimal solution;
- not supplying a full range of implants that are not going to be used, but focusing needs on the right implant size (plus sizes N + 1 and N − 1, to be on the safe side).

Talar recognition is the most difficult step. The essential point in adapting the guide is to clean off excess cartilage and minimize soft-tissue interposition. Various other solutions are available, such as subtracting the cartilage volume. The main contribution of the talar guide is to allow a first horizontal cut parallel to the ground and also to plan

Fig. 17.28 Visualization of the various PSIs and bone structures in 3D reconstruction available during surgery

COMPONENT	PICTURE	QUANTITY
QUANTUM® PSI Guides Tibia Resection Guide		1
To be used with associated Metallic insert		
QUANTUM® PSI Guides Talar Standard Resection Guide		1
OR		
QUANTUM® PSI Guides Talar Flat Cut Resection Guide		
To be used with associated Metallic insert		
QUANTUM® PSI Guides Tibia bone model		1
QUANTUM® PSI Guides Talar bone model		1

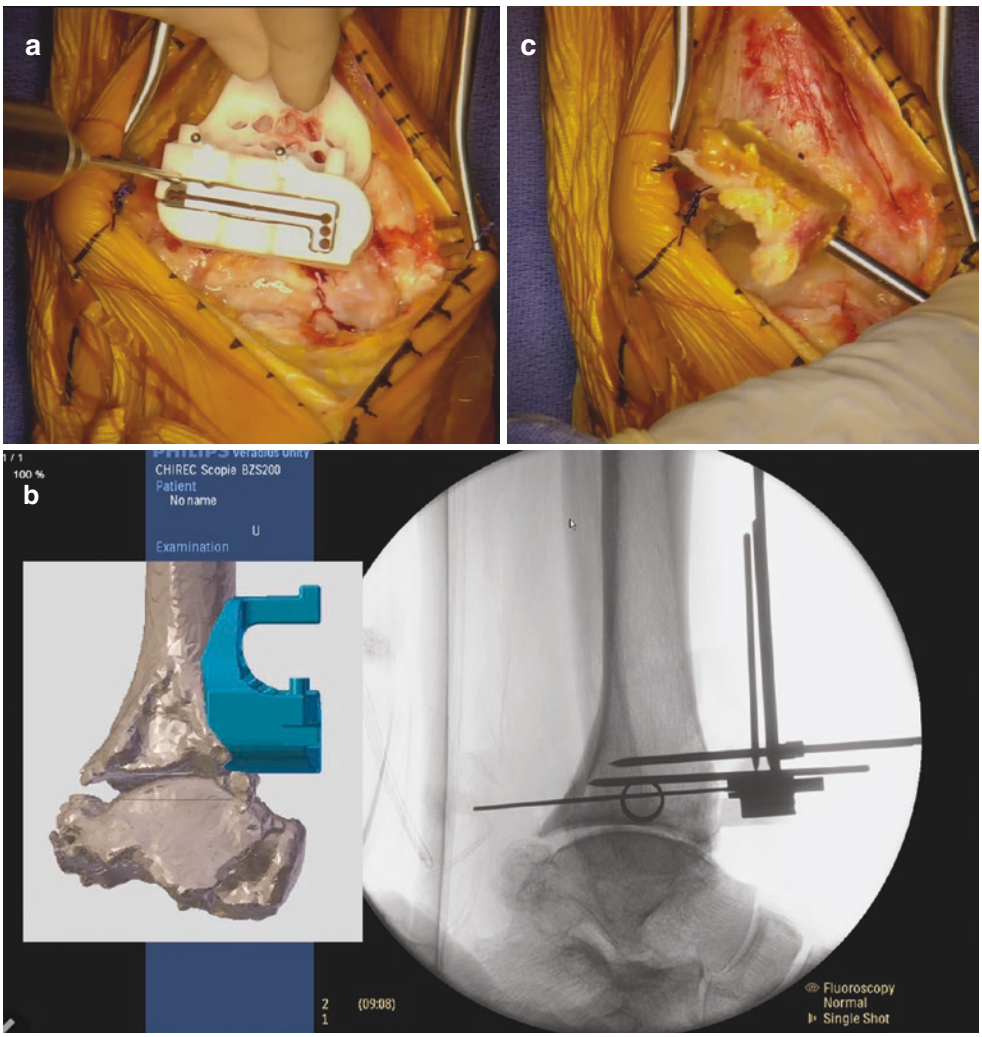


Fig. 17.29 Example of PSI in ankle surgery. (**a**) Tibial resection in complex surgery; (**b**) radiologic validation; (**c**) control of resection (PSI: 3D-Side company, ISO 13485, Mont St Guibert, Belgium) (Courtesy of T. Leemrijse, MD)

anteroposterior implant positioning and rotation (Fig. 17.32). These settings in 3 dimensions are essential, being the key difficulty of total ankle replacement.

Here again, if needed, fluoroscopic verification is possible.

In order to maximize surgical quality and meet the surgeon's individual requirements, various options, including multiple talar shapes and a wide range of implants, have been included in the *Quantum*™ project (Fig. 17.33).

- The PSI can be associated with a radio-opaque system for radioscopic validation of guide positioning, mimicking the future bone cut, whether tibial or talar.
- In the case of unplanned events, such as a guide falling or an error in manipulation, the kit also contains a simplified guide, which can easily position the implant under fluoroscopy with maximal viability (Fig. 17.34).

Validation and Reproducibility

Implantation planning and results should match as precisely as possible, with minimal slight margin of error. Various technical points have been widely studied and validated [12], such as PSI stability according to bone surface, loss of cut guide precision, and saw-blade stability and rigidity in bone resection. These factors are not specific to PSI and are found with traditional instrumentation; the primary difference is that implantation with traditional instrumentation does not begin with a precise preoperative reference, which allows for even great error.

During the development of the *Quantum*™ concept, the reproducibility and precision provided by the cut guides were validated in numerous cadaver trials.

Validation consisted of analyzing planning with comparison versus postoperative data on CT and anatomic specimens (Fig. 17.35).

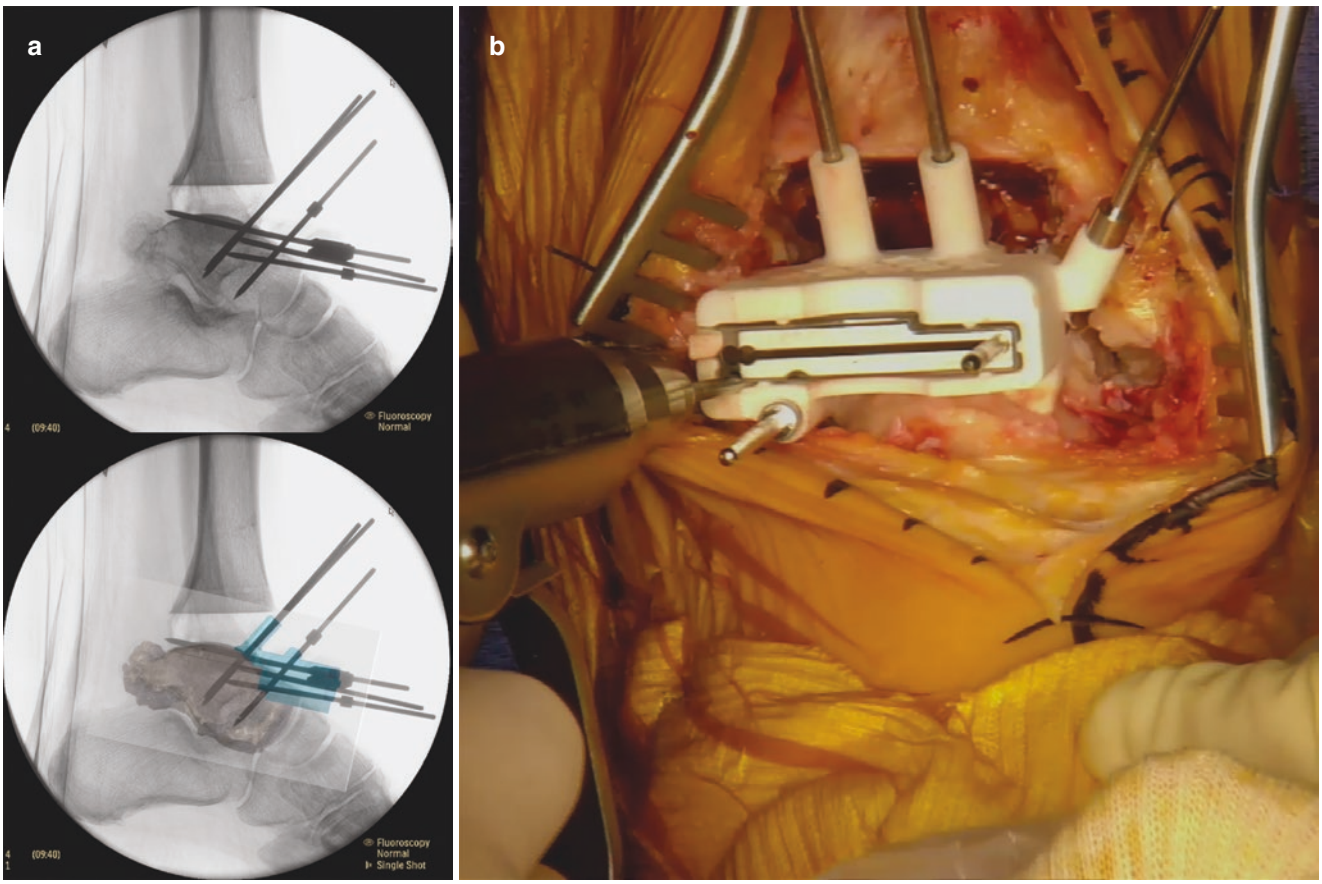


Fig. 17.30 Example of PSI in ankle surgery. Talar resection in complex surgery; (**a**) radiologic validation; (**b**) talar PSI positioning. (PSI: 3D-Side company, ISO 13485, Mont St Guibert, Belgium) [Courtesy of T. Leemrijse, MD]

Tibial bone cut superimpositions found almost perfectly aligned values. Tibial slope showed a 2° discrepancy, probably due to saw-blade bending. The tibial implant also showed optimal superimposability.

The same precision was achieved in the talus. Bone resection level was systematically respected. There was again a 2° error in talar slope, which is not enough to affect prosthetic flexion extension.

Integration of the Quantum™ Project in a Future Digital Project

Computer Modeling and Simulation

The *Quantum*™ project uses innovatory technology such as computer modeling and simulation (CM&S), already widely implemented in various industries such as aeronautics and automobiles and just beginning to be applied in the health field. It generates digital twins, enabling in-depth validation of the causes and effects of certain pathologies, analyzing individual patients' surgical risk, and testing medical devices in a virtual population under realistic biomechanical conditions.

The FDA's efforts to promote CM&S as a supplementary source of evidence in the health field necessitate drawing up a robust regulatory framework [8, 13]. Europe is heading in the same direction, more slowly, toward what is known as 'in-silico clinical trials" (ISCT) [1, 14].

Test results are presented and reproduced on a virtual model of the implant being tested. The ISCT approach consists in developing a specific digital twin into which the implant is inserted, with wear behavior estimated under realistic biomechanical conditions.

The test machine specified in the ISO standard was originally designed for knee implants and is adapted for ankle implants and the corresponding loading conditions. One consequence, and limitation, is that the talar component rotates round a fixed mechanical axis, unlike in the real life of the ankle.

Six implant samples per client are tested.

Figure 17.36 shows a virtual wear test under loading according to ISO 22622:2019 [15].

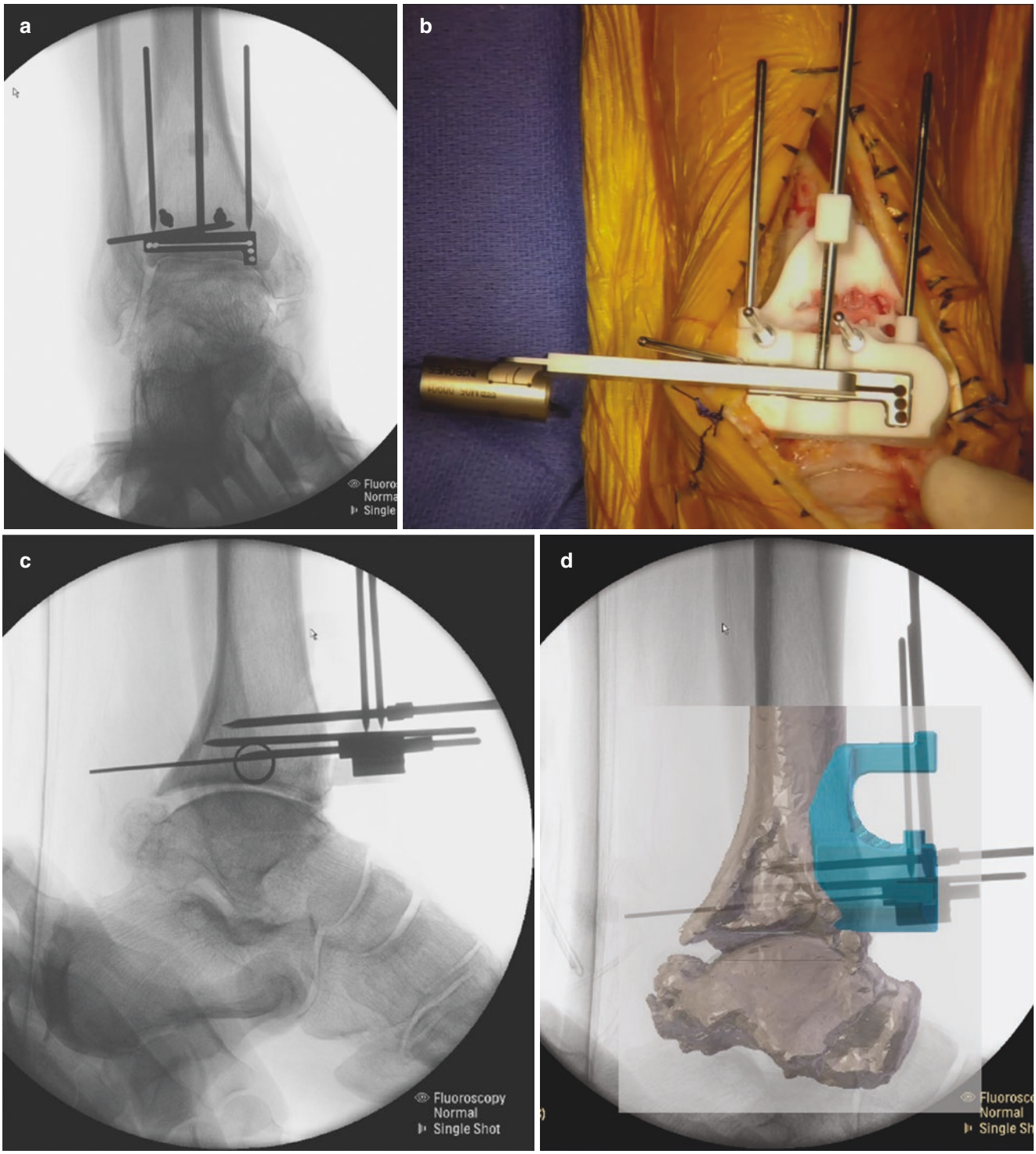


Fig. 17.31 Preparation of tibial cut. (**a**) Validation of PSI positioning on AP radioscopy. (**b**) View of the preparation and validation of tibial cut guides. (**c**) Double evaluation of PSI positioning on radioscopy and (**d**) representation of bone resection zone

ISCT Approach

In a multistep process, the workflow entry consists in a CT scan of the subject plus laboratory gait measurements; it automatically generates a multibody model to determine the individual muscle activation pattern, which then injects in a detailed anatomic finite element model to simulate the subject's gait.

Figure 17.37 shows the digital twin. The anatomic ankle axis of the twin is calculated from the shape of the subject's talocrural joint, and the implant is inserted and aligned

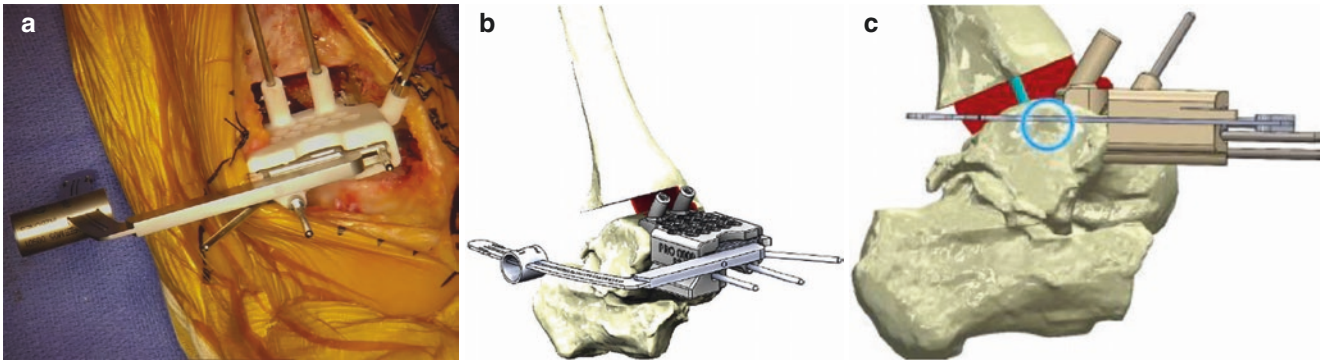


Fig. 17.32 Preparation of talar cut. (**a**) View of the preparation and validation of talar cut guides. (**b**) Schematic view of double evaluation of PSI positioning on radioscopy and (**c**) representation of bone resection zone

appropriately. The implant wear map and loss of mass are estimated on gait simulation.

Figure 17.38 shows the simulated wear map (left) in comparison with measurements (right) according to ISO 22622:2019 [15]. There is good qualitative agreement. Total PE insert mass loss, measured on 4 samples, confirmed the simulations.

The *Quantum*™ was then inserted in the subject, and the wear map and mass loss were predicted under real biomechanical conditions. Comparison between the ISO 22622:2019 wear map (Fig. 17.38, left) and the biomechanical wear map (Fig. 17.39, right) shows obvious differences: while the central regions are comparable, there are clear differences in the lateral and medial parts of the implant. Figures 17.36 (right) and 17.39 (right) show the differences in range of motion: dorsiflexion (blue), inversion/eversion (red), and adduction/abduction (green).

The interest of ISCT estimation of wear behavior for a given implant is clear: inclusion of biomechanical weight-bearing conditions in-vivo, specific pathological population with its variability, and variations in surgical insertion. These are the current recommendations in the literature [16].

The *Quantum*™ total ankle replacement was validated not only on FDA and CE approved mechanical bench tests but also on highly sophisticated digital model testing, as will certainly be increasingly used in implant design in the very near future (Fig. 17.40).

Digital Model Analysis and the Quantum™ Implant

The rich field of digital twins will certainly be a perspective which the *Quantum*™ project already adopts (Fig. 17.41). In silico implantation will certainly enable advances in personalized implantation, positioning, and predictive validation of the ideal implant position. Various projects thus focus on virtual validation of ligament tension and ankle mechanics according to an ideal virtual position.

Many validation studies will doubtless provide quantitative and qualitative data to optimize and validate treatment decision-making in the ankle. The *Quantum*™ concept has already made this leap into the digital world, offering a modern solution for patients and surgeons.

Discussion

General Considerations

Ankle osteoarthritis (OA) is a common chronic disease characterized by progressive joint degeneration, intense pain, and disability. About 1% of adults worldwide live with symptomatic ankle OA. Surgery is generally reserved to failure of first-line medical treatment by walking aids, physiotherapy, orthoses, and viscosupplementation, when functional disability is impairing quality of life. Historically, the gold standard surgical strategy has been fusion, showing relatively well-established pain relief and long-term survival [17, 18].

Ankle fusion, however, restricts occupational and leisure activity and leads to degeneration in the adjacent joints, probably due to altered mechanical load with altered ankle function. Motion-sparing procedures, such as total ankle replacement (TAR), conserve preoperative range of motion, improve gait, and protect adjacent joints [19–21].

Several articles have reported the benefit of ankle replacement in osteoarthritis [22]. Ankle arthroplasty is becoming more common around the world. For example, the 2017 annual report of Joint New Zealand (2017) [23] reported 1380 ankle arthroplasties registered between January 2000 and December 2016. There was an 18% increase over the previous year, and the rate was continuing to rise. Median age was 65.9 years, for a range of 32.3–95.9 years. Ankle replacement was performed in 842 males (61.01%) and 538 females (38.99%). Surgical revision was performed in 152 cases



Fig. 17.33 Radioscopic example of cadaver preparation. (**a**) Standard tibial part, Flat-Cut talus, and revision talus with keel and subtalar fusion by additional screw (**b**) (European market); (**c**) post-operative AP x-ray view and (**d**) lateral x-ray view of the Quantum™ prosthesis

(11%): for pain (n = 65), talar component failure (n = 46), tibial component failure (n = 32), or deep infection (n = 17). Long-term survival and performance thus need to be improved.

The registry data show wide variations in total ankle arthroplasty survival rates, with the rate between 18,4% (NZJR) and 31% (SAR) at 10 years [23, 24]. Infection and aseptic loosening are the most common indications for removal or revision. The NJR has the highest number of ankle arthroplasties recorded, and the data for 2017 show that infection, loosening, misalignment due to inaccurate cuts, and undiagnosed pain with stiffness are the most frequent indications for the revisions following primary ankle replacement [25].

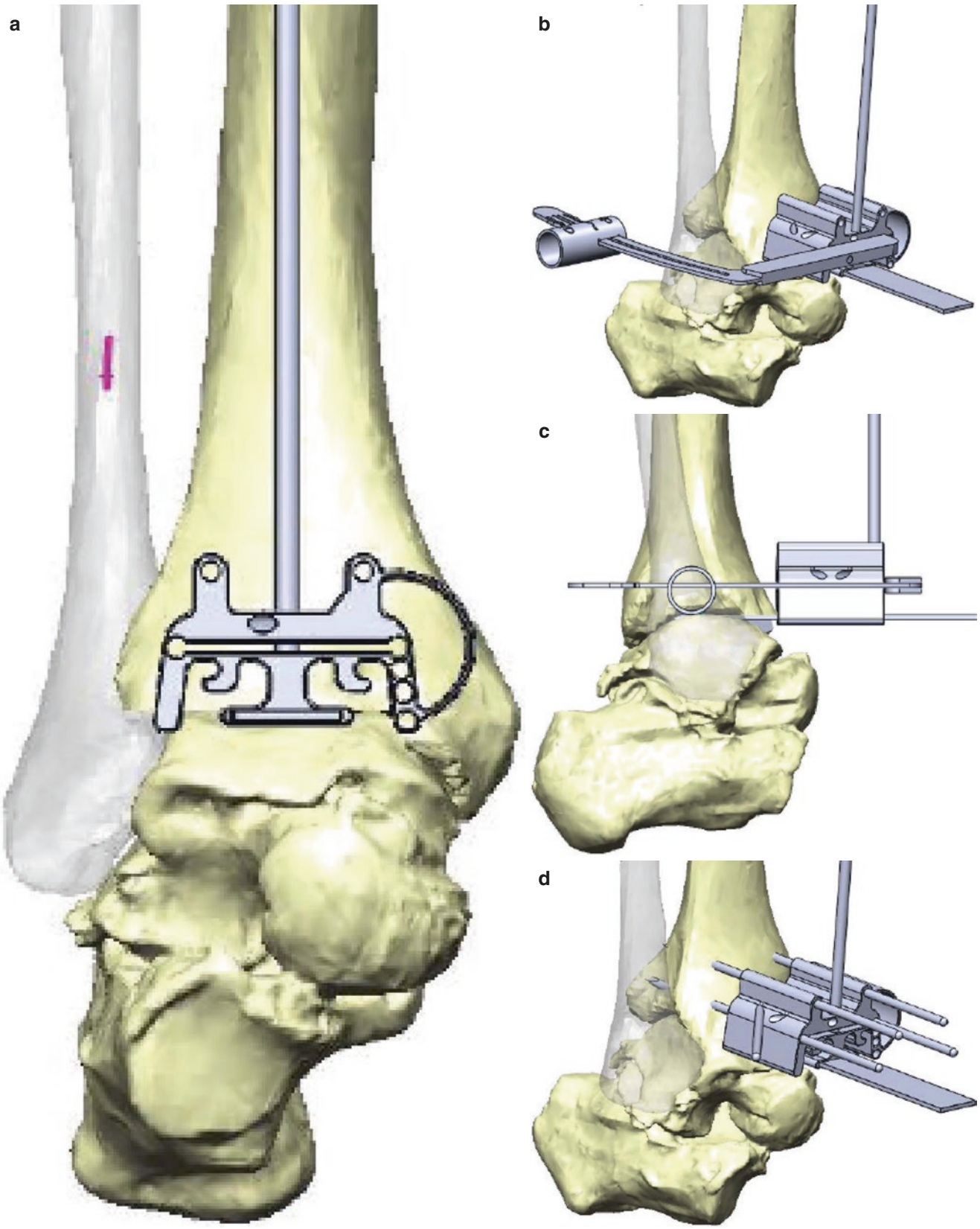


Fig. 17.34 Schematic representation of simplified instrumentation based on fluoroscopic recognition of the joint line. (**a**) AP view, conserved malleolar safety zone, and (**b**) location of joint line, fluoroscopic control of positioning; (**c**) lateral view of resection zone; (**d**) parallel talar resection

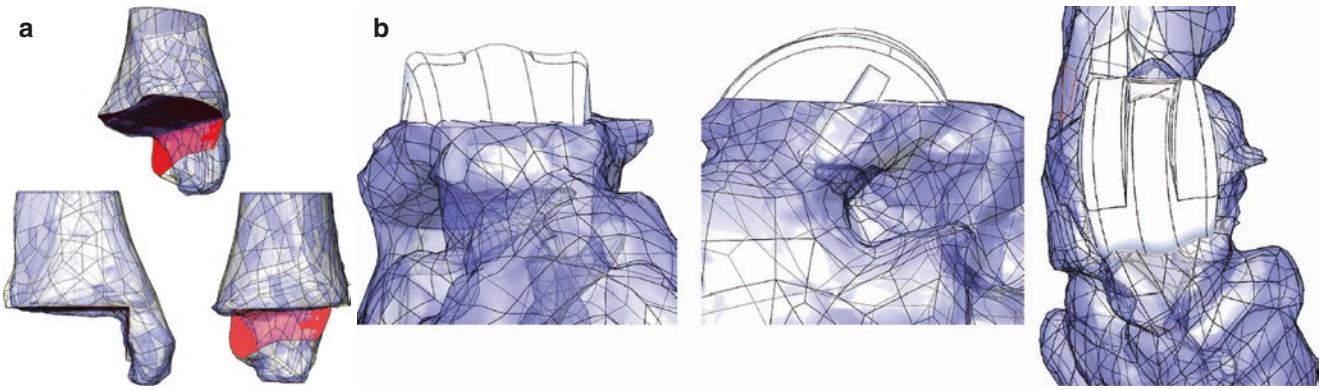


Fig. 17.35 (**a**) Comparison of planning versus postoperative CT at tibial cuts and (**b**) of Flat-Cut talar component in the same example

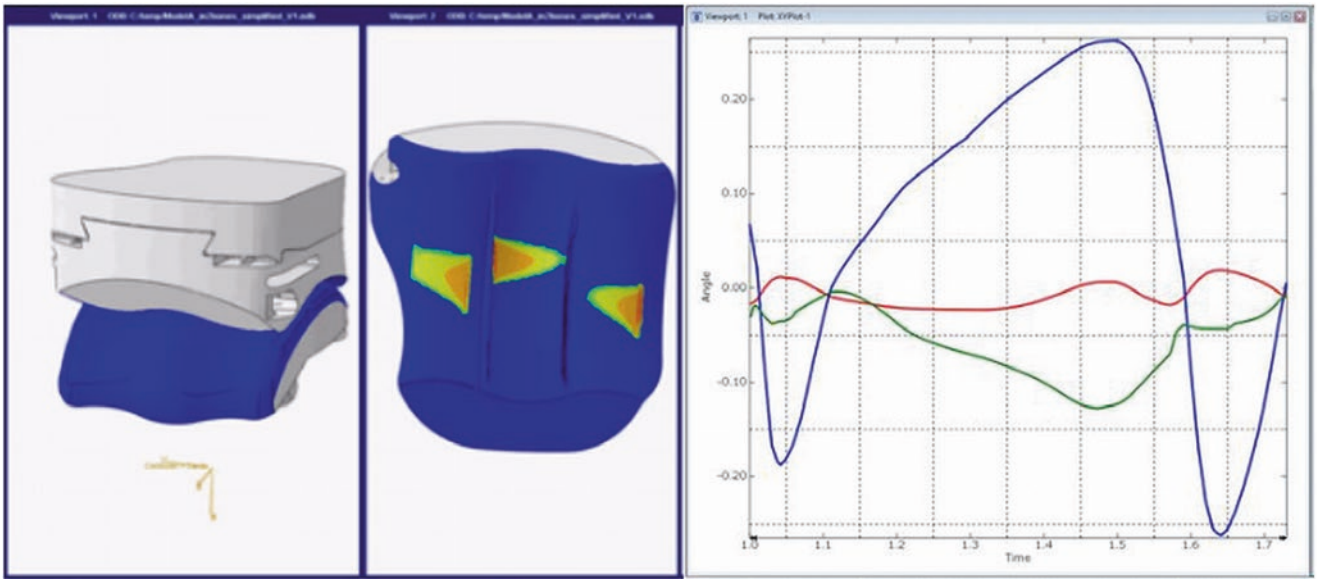


Fig. 17.36 *Quantum*™ prosthesis (left); polyethylene insert contact pressure (center); relative movement (right). (Courtesy of Digital Orthopaedics, Mont St Guibert, Belgium)

Despite progress in reliability, there is plenty room for improvement in innovation, understanding, and validation, as well as revision strategies.

History

The ankle is one of the most complex joints in the human body. Indications for TAR are usually post-traumatic (54%), followed by primary osteoarthritis (19%) and inflammatory pathology (14.6%) [26].

TAR was introduced in the 1970s. The outcomes of the initial 2-component design suffered from poor medium-term results [27]. Subsequently, 3-component mobile-bearing models approximating ankle anatomy gave good short- and medium-term results, and interest in TAR increased [28].

In the 2000s, this regain of interest was doubtless due to the long-term results in 3 types of implant: *Agility*™ [29], BP [30], and *Star*™ [31]. This stimulated the development of new mobile-bearing models: Salto™) [32], *Hintegra*™ [33], Mobility, *Box*™ [34], *G.A.S.* ™ [35], and others [19].

While most studies of TAR focus on clinical results, or sometimes on biomechanics [36, 37], little has been published on implant kinetics and biological behavior [38, 39].

Why is the ankle so different from the hip or knee? There are several points: it is in direct relation with neighboring joints; the talus has a particular vascularization [40]; considerable stress passes through this small joint, which needs to be able to support up to 6 times the body-weight [41]; the particular role played by the fibula [42]; and the ligament insertions restrict motion [43].

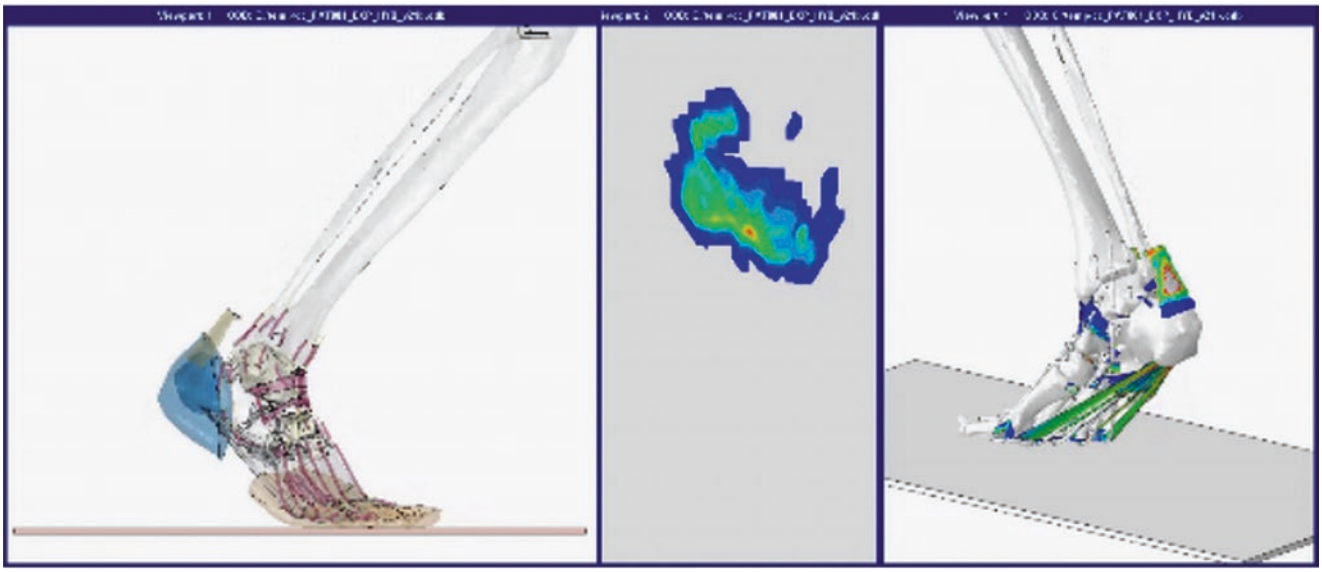


Fig. 17.37 Digital Twin (left); plantar pressures (center); and ligament and fascia tensions (right). (Courtesy of Digital Orthopaedics, Mont St Guibert, Belgium)

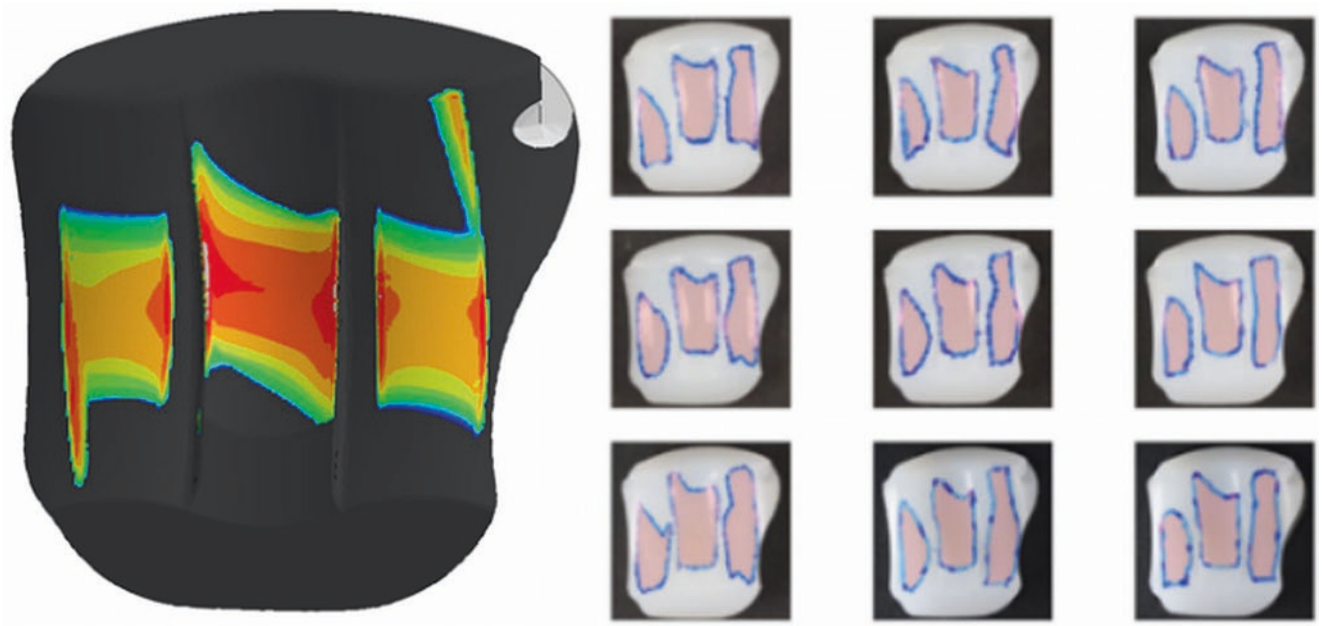


Fig. 17.38 ISO 22622.2019 simulated wear map (left) wear map measured on 9 PE samples (right)

All these particularities need to be taken into account in TAR. The final objective is to obtain a pain-free, plantigrade, balanced foot with a mobile and stable ankle.

Two or Three Components, Anchorage, and Shape

Results for fixed-bearing models now seem better than with a mobile bearing [44]. This was shown in comparative studies between *Salto*™ and *Talaris*™ (Tornier Wright) [45, 46]. There were also less pain and more rapid early recovery for the fixed bearing device [46].

Currently, most implants are 2-component [47], to improve stability and perhaps survival. Mobile-bearing translation and rotation amplitudes were found to be relatively low in in vivo kinematic and in 2D and 3D fluoroscopic studies. This "progress" toward fixed bearings is founded on reliable instrumentation able to test and restore an ideal center of rotation.

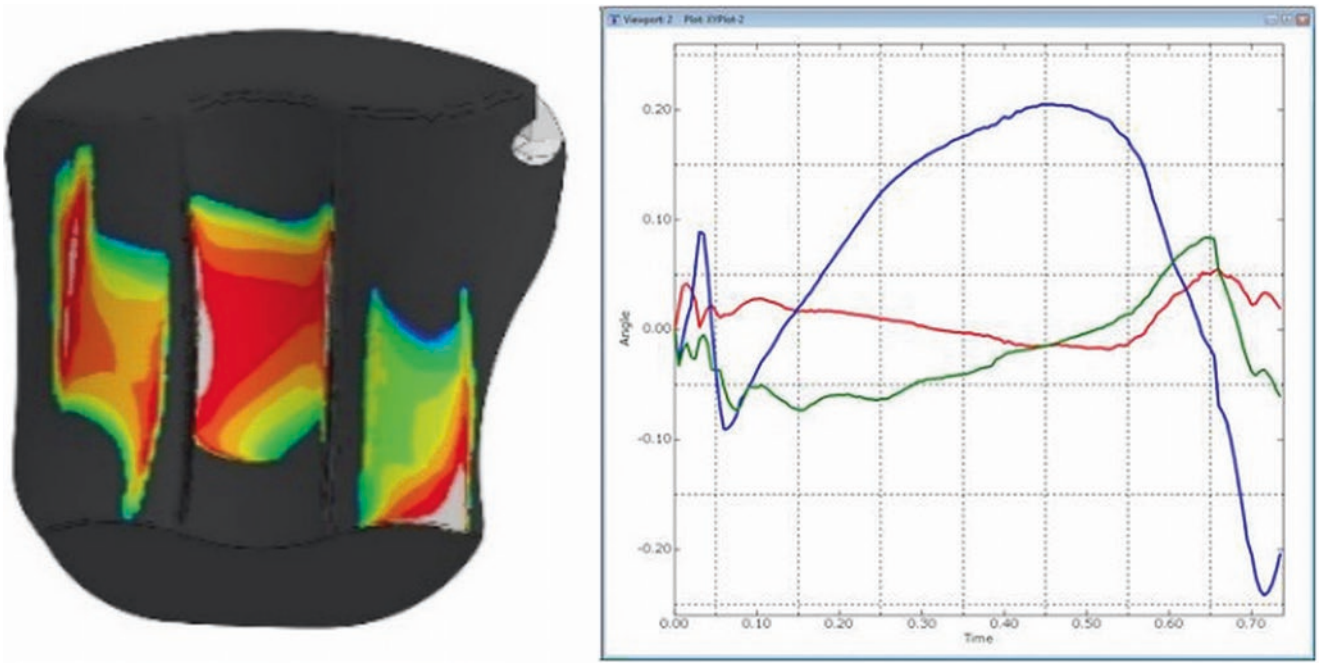


Fig. 17.39 Digital Twin. Simulated wear map under biomechanical conditions (left); relative movement (right)

Other solutions involve tibial curvature, with a component that is not planar in some models (*Box*™, German Ankle System), to optimize dynamic balance between the ligament planes [48].

It is at present difficult to choose between fixed or mobile bearing designs, as the issue is multifactorial. The perfect congruence of 2-component designs may hinder osseointegration, as argued by Cody et al., who found 7% radiolucency around the tibial component in the *Infinity*™ prosthesis[49]. With exactly the same implant, only *Vantage*™ offers a choice between fixed and mobile bearing, which will certainly eventually provide an answer to the question [50].

The *Quantum*™ concept was designed to include a large variety of options. Asymmetric curvature radii theoretically improve dorsiflexion. The anterior radius, useful in dorsiflexion, is shorter, which should limit soft-tissue tension during dorsiflexion. The low value in this sector (<3° on dynamic 3D analysis) was well demonstrated in the meta-analysis by Deleu et al. [51]. We saw this as an essential issue, requiring an innovative solution.

We also accepted a certain tolerance of incongruence between the PE and talar parts in axial rotation and in valgus/varus. This relative tolerance probably reduces the stresses found in 2nd-generation models with strict congruence between the PE tibial component and the talar component. As we have shown, this concept was analyzed in various finite element studies to validate tolerance [16, 52–54].

Tibial component anchorage and primary stability are ensured by vertical impaction, respecting the anterior and posterior cortical supports. A centered cruciate stem, easy to impact, provides immediate rotational control and primary stability. The aim is to achieve immediate contact between the tibial base and the cancellous bone of the tibial plafond. A simple cross ensures optimal impaction on rapid resumption of weight-bearing. The aim is to minimize stress shielding or the radiolucency due to a 30° oblique pegs preventing impaction on the weight-bearing axis during gait [49].

The standard talar component is supported by 3 cuts, with the superior cut being horizontal. The stabilization pegs are relatively central, once again to avoid integration defect and stress shielding. The Flat-Cut talar option uses the same trajectories as the primary model, to facilitate any revision surgery. The model with keel has an oblique tronconic stem ensuring moderate press-fit. The keel is relatively short, so as not to preclude subsequent removal.

To ensure biologic fixation, coatings are single-layer spray-on titanium; the hydroxyapatite of 2-layer Ti-HAP coatings was recently found to lead to the formation of periprosthetic cysts in ankle prostheses [55, 56].

Quantum™ offers a whole range, providing revision solutions from the outset. This is indispensable for patient safety. A "unitary" attitude in implantation surgery is incompatible with what is proposed for the various arthroplasties: knee, hip, and shoulder. Roukis et al. also reported the utility of the XT revision prosthesis (Tornier Wright) and stressed the importance of having an extensive range adapted to all surgeons and patients [57]. Unfortunately, FDA regulations do not favor revision by calcaneal keel implant, but this model will be available worldwide outside the USA.

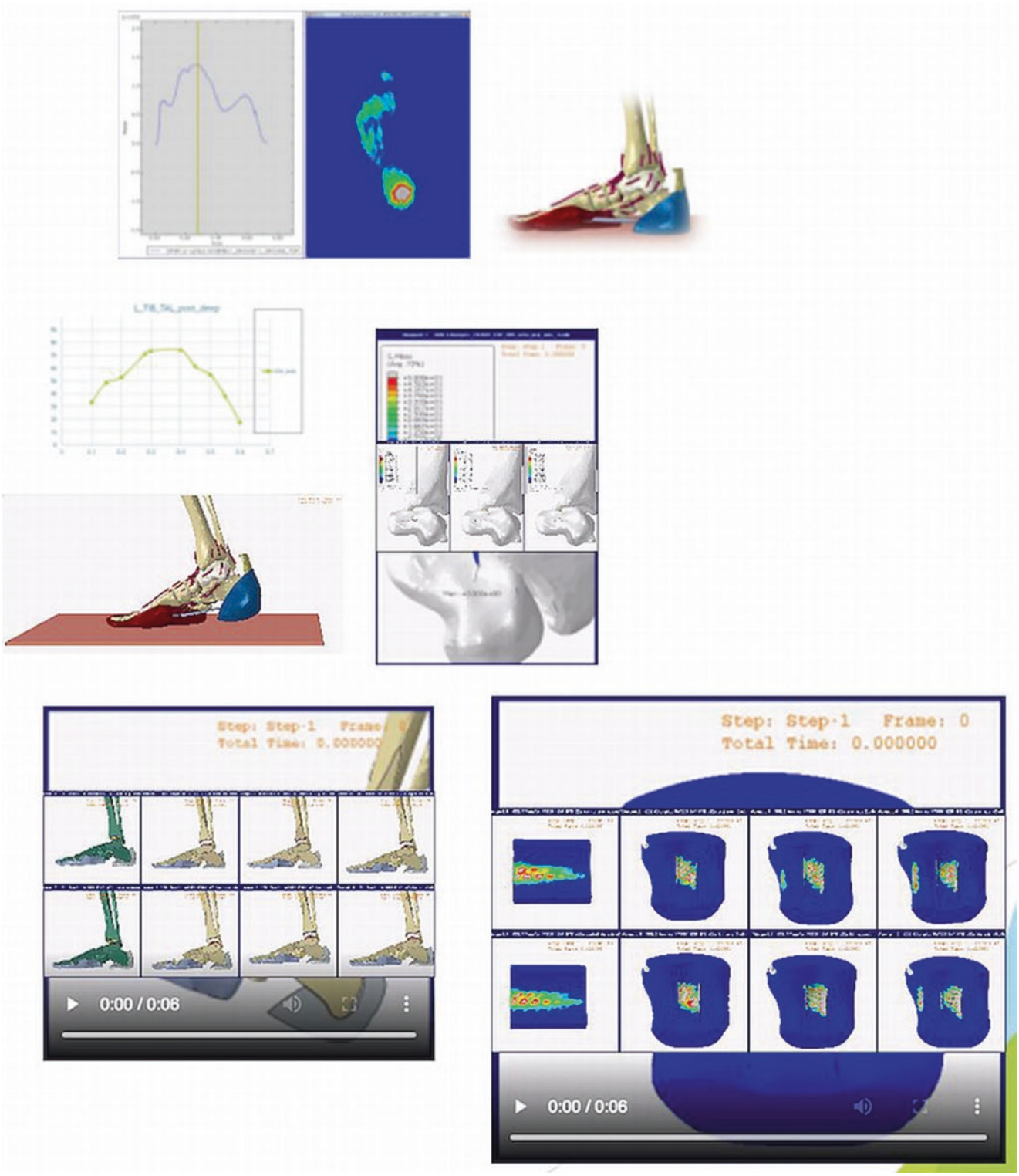


Fig. 17.40 Example of workflow dynamically and virtually integrating the *Quantum*™ prosthesis. Synchronized analysis of gait, planar pressure, ligament tension, and implant interface stress. (Courtesy of Digital Orthopaedics, Mont St Guibert, Belgium)

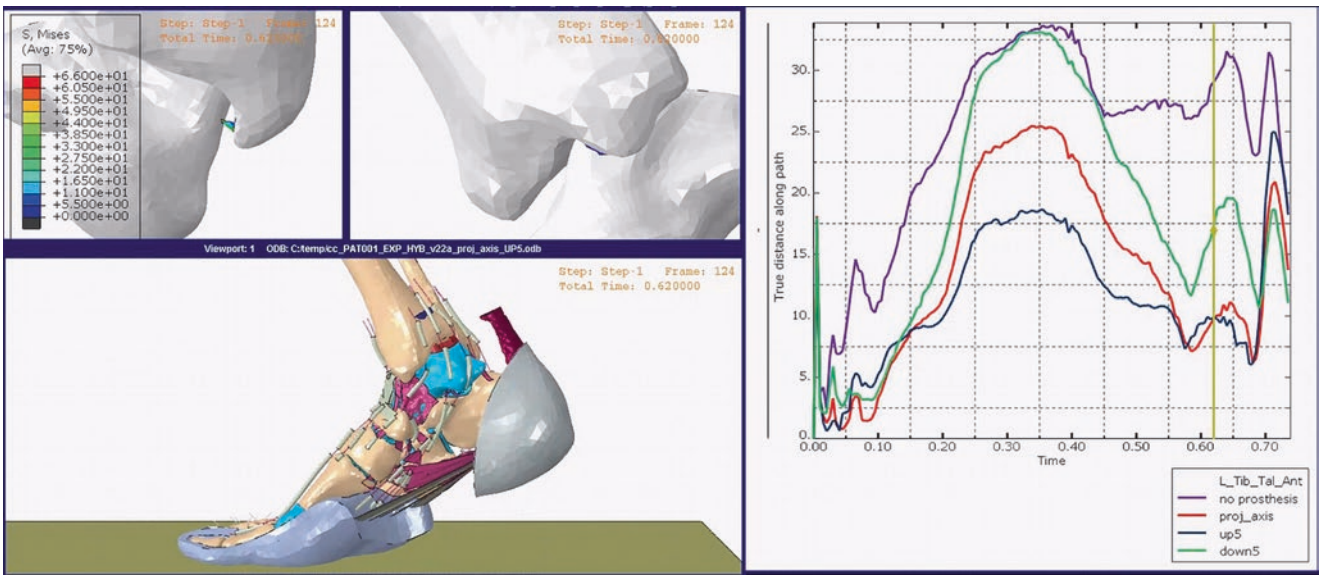


Fig. 17.41 *Quantum*™ prosthesis placement in a virtual model, to compare and analyze ligament tension during gait. (Courtesy of Digital Orthopaedics, Mont St Guibert, Belgium)

In light of the different forms seen in ankle arthritis, well-identified in the COFAS classification, it is important to be able to propose an optimally adapted implant (standard or "revision" from the outset) according to the pathologic situation [58]. The *Quantum*™ project immediately offers a range that can be used depending on preoperative severity or the need for revision. Although Cottom et al. found no significant difference in short- and medium-term results related to PE thickness >10 mm in TAR [59], the escalation toward thicker PE, however, requires ever greater bone resection with risk to the medial malleolus. It is preferable to be able to choose between standard and revision implants, to allow bone reconstruction around a stable implant, rather than increasing resection to the point of precluding secondary reconstruction [60, 61]. The problem of implant revision remains, with an insufficient range of standard models available at reasonable cost. It would be helpful to have polyvalent solutions that can be adapted for partial revision of TAR models from different manufacturers [61, 62].

Risk Factors and Impact of Implant Positioning

Implant positioning is agreed to be an essential factor for implant reliability and survival [63].

Escudero et al., in a cohort of 100 patients, analyzed predictive factors for poor results in TAR [64]. Dahang Zao et al. also analyzed the multifactorial causes positively or negatively impacting TAR implantation [60].

Regarding general factors, older patients show better tolerance, with less pain and joint stiffness. Trauma sequelae are systematically more painful and difficult to treat. Recognized factors for poor prognosis comprise type-2 diabetes, poor baseline AOS osteoarthritis score, and talar component malpositioning, whether anteroposterior or by excessive dorsiflexion [22, 64]. Regarding surgeons, those with less experience incur more intraoperative complications and positioning defects, leading to prosthetic revision or to fusion, which is high-risk surgery [62].

Regarding specific factors, traditional instrumentation seeks to limit alignment defect in the ankle. Minimal bone resection reduces the risk of periprosthetic fracture but raises the problem of respecting joint-line height.

Another essential factor is the severity of preoperative deformity. This was stressed in several studies, and it is useful to differentiate the types of osteoarthritis liable to benefit from arthroplasty, so as to compare cohorts of equivalent patients [58, 65]. The COFAS classification [65] differentiates perfectly aligned osteoarthritis, associated pathologies such as valgus or varus malalignment, and stiffness or associated peritalar osteoarthritis. This is the key to distinguishing between pathologies so as to be able to compare results between groups of comparable patients [66].

Johnson-Lynn et al. [67] reported an analysis of AOFAS and short-form SF-36 scores in 101 ankles in a retrospective cohort; there was a negative impact on scores in the case of postoperative malpositioning of the medial distal tibial angle.

This testifies to the difficulty of intraoperative implant positioning depending on the clinical and radiological situation, and it is fundamental to be able to optimize factors in TAR positioning that at present are insufficiently controlled.

All of these elements encouraged us to develop a surgical planning system based on intelligent 3D representations, able to optimally correct the preoperative deformity and optimally position the joint implant, which is simply a resurfacing stage on a virtually aligned ankle.

Postoperatively, various TAR positioning elements, such as coronal and sagittal alignment, can be analyzed on standard X-ray. In mobile bearings, offset abnormalities can also be analyzed [68].

Postoperative CT can study other factors. Limiting artifact between metal and bone now allows more precise analysis of implant positioning: e.g., rotational positioning of the talar component with respect to the anatomic talus or tibial rotation [5]. Analyzing the rotational positioning of the talar component is complicated, as in most available implants, the rotational positioning of the talar component with respect to the talar bone is assessed by the surgeon in light of his or her own experience. Weight-bearing CT also showed a possible relation between malalignment and cysts under the implant [69].

Variations of Patient-Specific Instrumentation Systems

Currently available PSI platforms differ from one another in two primary ways.

First, there are two different types of instrumentation: (1) those that provide guidance for the placement of pins, which will then be used to position a standard cutting guide; and (2) those that are used to directly place a cutting guide. In the case of the *Quantum*™ Total Ankle, the choice was made to use PSI that directly incorporates the cutting guides. This was motivated by the fact that this reduces the risk of contaminating the bone surface with debris from the guide and reduce the number of tools required [70].

Second, for other joint than ankle, they differ in the modality that is used for preoperative imaging, whether CT or MRI is used to collect the 3-dimensinal data. MRI-based guides have the advantage that they may incorporate soft tissues and allow the guides to rest on the residual cartilage of the joint surface. While this is particularly interesting in total knee arthroplasty (TKA), in the ankle, the guides will rest on the osteophytes and bony surface of the anterior distal tibia and the bony part of the anterior superior face of the talus without cartilage, therefore diminishing this advantage.

CT scan is often more readily available than MRI, easy to use, and have fewer limitations than MRI (for example, in patients with claustrophobia, those with metal implants around the ankle joint, and those with noncompatible implants such as pacemakers or cochlear implant) [71]. Several studies have reported that the CT-based systems are able to identify the bony landmarks clearly, with lower cost and reduced scanning time [50, 72]. Using specific protocols, the radiation dose from low-dose CT is comparable to long-leg standing radiographs and is therefore felt to be very safe [73].

Published clinical data comparing accuracy with both systems in TKA are conflicting, with comparable outliers because most trials use different platforms from different manufacturers and different algorithms based on different reference axis and points. A recent prospective randomized study in TKA has shown that both systems allow accurate alignment [74]. For the *Quantum*™ system, CT-based image acquisition and reconstruction are used to create the instruments because of the aforementioned arguments.

Specificities of the Software and Contribution of PSI

The contribution of PSI has been demonstrated in knee arthroplasty and osteotomy [9]. Colombelli et al. showed PSI to be very reliable, exact, and reproducible in knee realignment in total arthroplasty [75]. PSI also enhances efficacy in shoulder implant positioning, especially in the glenoid [76]. Cut guides are also widely used in long-bone tumor resection and in planning for partial pelvic resection [6, 77].

Reb and Bertlet described the interest of PSI navigation in TAR [78]. The procedure has FDA approval; however, it incurs extra cost and needs to demonstrate improved implantation quality and lower rates of revision to prove value. Moreover, PSI should limit the use of conventional instrumentation and intraoperative radiation exposure.

This is very much in line with the *Quantum*™ project, which so far as possible minimizes use of external instrumentation so as to optimize implant positioning on a continuous digital approach.

Daigre et al. analyzed TAR placement reproducibility using the Prophecy PSI [79]; agreement between pre- and postoperative values was excellent, with only a mean 3° difference at the tibia and none exceeding 5°. Predictive value in the talus was 80%. The authors concluded that the guides ensured reproducibility and reliability. The study further demonstrated intersurgeon reliability, in a multicenter design including 5 trainee surgeons.

This point adds value in shortening the learning curve, as shown in the study by Usuelli [80, 81]. Maccario et al. reported operating time ranging between 75 and 280 min, for a mean 164 min [82]. A solution that reduces both surgery time and the learning curve improved by “on-cloud” planning software for better understanding seems to us to represent added value.

It is also agreed that complications are fewer when preoperative deformity is minimal; the complication rate is much

higher in the case of associated varus or valgus [83]. Responsibility is difficult to apportion between the implant and associated procedures in osteoarthritis with malalignment. Virtual planning is certainly of interest to improve arthroplasty performance in noncentered osteoarthritis.

Few available solutions presently include digital surgical planning at the level of the *Quantum*™.

Najefi et al. analyzed medial and lateral tibial rotation with respect to the various angles of the foot and especially the medial talar groove [5] and reported that anatomic variants were insufficiently taken into account in TAR. Here again, the contribution of 3D reconstruction in surgical planning can guide personalized positioning. However, further studies are needed to assess the respective importance of each factor for implant survival and the quality of surgical results.

The advent of 3D modeling and planning invites a completely new approach and new consideration of the importance of talar implant rotation and the search for an ideal rotation plane [84]. Using bone volume in CAD reconstruction enables a fresh approach to centers of rotation and the possible impact of subtalar rotation axis, as first described by Henke [85].

Various studies have focused on 3D planning in TAR using the *Prophecy*™ PSI. Gagne et al. showed that PSI is a logical development to improve TAR quality [84], also stressing the difficulty of analyzing implant rotation in the lower limb and the precision provided by the intraoperative pin marker and the preoperative planning. The *Quantum*™ concept is different, as the PSI is included from the outset in implant positioning. It determines in a single step the cuts and the pegs used to control not only anteroposterior but also rotational talar positioning. Moreover, the *Quantum*™ project allows double intraoperative control, as with all conventional systems, by means of trial implants mimicking implant positioning ahead of definitive cutting. This is essential to guarantee ideal talar component positioning.

It is sometimes said that the larger surgical approach and potentially greater soft tissue dissection used with PSI can be a cause of complications, although this has never been reported in studies of the *Infinity*™ or *InBone*™ models using *Prophecy*™ PSI. Escudero et al., in an comparative analysis of 2-year results for *Infinity*™ between 51 implantations using PSI and 16 traditional procedures, found no significant difference in osteolysis [86].

The question of intraoperative irradiation was raised by Roukis et al., comparing doses between implant models [87]. Differences were slight, but doses were higher in the case of intraoperative complications and in revision surgery; the authors therefore recommended procedures that allow automation and thus limit surgery time. The *Quantum*™ concept integrates PSI in both standard and revision prostheses, thus probably reducing exposure time. It was previously shown that Prophecy instrumentation significantly reduced surgery time and fluoroscopy time and halved radiation exposure as compared to controls [88].

Finite Elements

Finite element analysis (FE) is one of the most effective means of resolving complex mechanical problems, whether in aeronautics or in construction [16]. 3D FE models of the foot and ankle complex are very difficult to reproduce with all the different components: bones, soft tissue, cartilage, ligament, implant component interfaces, plantar fascia, etc., each with specific mechanical and tissular properties [89].

Several studies now show the importance of FE modeling for improving implantation quality and optimizing positioning. Mondal et al. stressed the impact of tibial component orientation on the tibial bone, quantifying variation in stress between bone and implant under varus or valgus movement of 5–10° [52]. These models are interesting, but at present are static; dynamic FE models will certainly be of major interest in the years to come [12], and this is the line of research we are pursuing in order to improve implant design and rational positioning in specific clinical contexts.

To assess stress patterns, Martinelli et al. also used the FE method in the *Trabecular Metal Total Ankle*™ prosthesis (Zimmer) [90], demonstrating its interest for validation and reducing the risk of hyperpressure on the implant. Waizy et al. reported an FE numerical simulation of cyst risk [91], but stressed that cyst onset implicates not only mechanical factors but also inflammation, as demonstrated in other studies [55, 56, 92]. Terrier et al. reported a comparative analysis of stress according to use of a 2- or 3-component implant [93].

Studies based on FE and experimental analysis presently use static data. Dynamic analysis would be more useful in developing new implants. Various muscle activations could shed light on the effect of all the forces at work around the ankle joint. Modeling the bone/implant interface would also be crucial for implant assessment and design [16, 52].

Conclusion

The *Quantum*™ project offers a new vision of total ankle replacement. It provides an up-to-date solution based on optimal planning, with a wide range of implants for high-quality primary surgery and optimized revision.

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Alignment/Rebalancing Procedures for Total Ankle Replacement

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Lawrence A. DiDomenico

Balancing an unstable ankle joint soft tissue and osseous structures is mandatory in order to experience a successful implantation of an ankle joint prothesis. Repair of a pathologic ankle with multiple planes of deformity can be complex and demanding. This could be isolated to bone and or soft tissue or a combination of both. When the talus has extruded anteriorly or tilted into valgus or varus malalignment, this is represented typically with lateral collateral and/or medial deltoid ligament injuries that have been damaged. A single or two staged approach may be elected when the hind foot and or ankle is malaligned into valgus or varus involving the subtalar joint, midtarsal joint or in conjunction with other deformities involving the midfoot and forefoot. In order for an ankle joint prothesis to be implanted and survive long term, the foot and ankle must be balanced and realigned into a neutral position prior to performing the total ankle replacement (TAR). Commonly associated with this complex pathology is a tight posterior muscle group and the surgeon must assess and address this contracture.

The theory behind the survival of TAR is anatomic restoration of the foot and ankle. Reestablishment of ankle alignment and stability is perhaps the most important technical consideration and goal for a successful TAR surgery. The dynamic function of an ankle joint may have an impact of the survival of ankle joint replacement surgery. The literature demonstrates the more anatomic and well aligned ankle with stability will result with greater longevity of the prosthesis [1–3].

Attention to detail and a deep understanding of balancing an unstable foot, ankle and lower extremity when implanting a TAR is essential. The ankle and foot must be balanced and plantigrade with both the static and dynamic phases of gait. Balancing a foot, ankle joint and lower extremity in both a static and dynamic phase will provide anatomic alignment and stability about the ankle joint. Alignment and stability of the ankle joint are not mutually exclusive or independent of one another, rather they coincide tremendously during ankle joint function. The osseous quality and quantity (or lack of) will determine ankle alignment. The stability of an ankle joint is dependent upon the osseous topography and volume (or lack of) as well as the soft tissue quality. The soft tissues provide stability and balance around the ankle joint. This balance is essential for the successful performance and durability of an ankle joint prothesis (Figs. 18.1, 18.2 and 18.3).



Fig. 18.1 An intraoperative ankle view of the patient who sustained a talus fracture as well as a significant distal tibial fracture. This fluoroscopy view demonstrates the remaining hardware prior to removal of this hardware. Note the loss of the medial malleolus from the index trauma which leads to instability of the ankle joint

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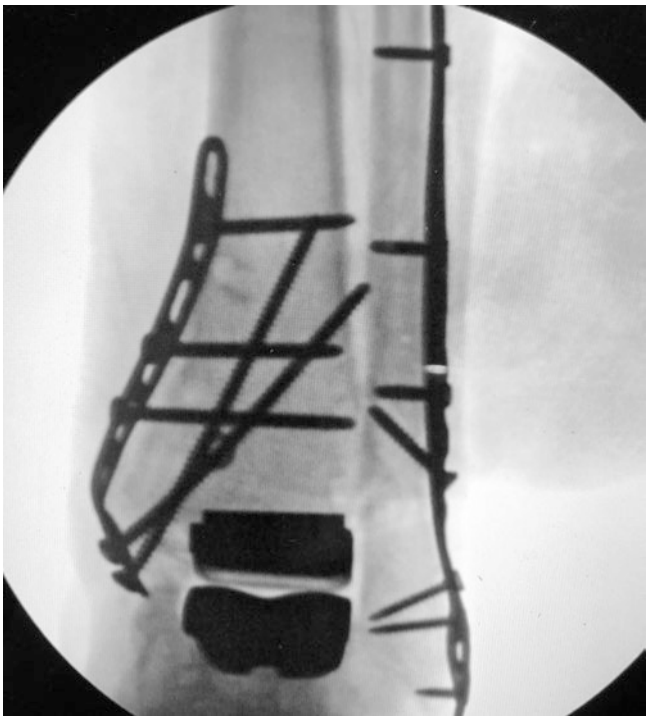


Fig. 18.2 An intraoperative ankle view demonstrating medial support and bone grafting to the remaining medial malleolus providing structural support and stability to the ankle joint prothesis



Fig. 18.3 A postoperative ankle view demonstrating medial support and well consolidated bone graft of the "built up" medial aspect of the ankle joint providing structural support and stability to the ankle joint prothesis

Alignment

Alignment is instrumental for success and long-term survival of TAR. The supramalleolar and inframalleolar deformities must be identified and addressed. This is both a clinical and radiographically analogy the surgeon must address. The ankle, foot and hindfoot alignment views allow visualization of the foot, ankle and hindfoot position relative to the tibia.

Bone quantity and quality are needed for the success of an ankle joint prosthesis especially for those patients who suffer from a previous history of trauma or patient with advanced comorbidities such as rheumatoid arthritis. TAR failures have been hampered by loosening and subsidence due to poor bone quality resulting in the malalignment and subsidence. The bone quality must be sufficient to hold, support and bond to the ankle joint prosthesis. The loss of cubic volume of bone from trauma may cause instability. If there is a loss of cubic volume of bone, the ankle will tend to become unstable and/or malaligned. The more bone present lends to stability, therefore shortening should be avoided. Following removal of bone beyond the subchondral plate in the ankle joint, compressive resistance may be found to be reduced. Removing bone near the subchondral plate may provide a reduction with bone quality and compressive resistance, thus putting the ankle prosthesis at risk for subsidence. In general, to avoid subsidence, one should perform minimal bone resection to preserve the sturdier subchondral bone. One of the benefits of utilizing the Zimmer Biomet™ Ankle Replacement System is the curvature resection on both the tibial and talar sides mimic natural anatomy. This resection yields less bone on the tibial and talar side, thus the shallow resection of bone, leaves the ankle joint with more structurally sound bone to hold the prothesis. Additionally the curvature prosthesis will provide more bone-implant interface and is more suggested of the natural anatomy of an ankle joint. This is helpful with the surgical outcome and may be useful should revision become needed or if a conversion to an arthrodesis is necessary.

Biomechanics and Stability

The biomechanics of an ankle presents a unique set of challenges for ankle joint arthroplasty surgeon. The biomechanics are not easily understood and can be challenging. In a normal ankle joint and relative normal congruency, the axis of rotation does not stay constant during range of motion. Therefore, accomplishing this in a pathologic ankle joint makes this a challenge for the foot and ankle surgeon. Permitting for rotational forces, while maintaining stability

of the joint, is also demanding and challenging. Success of the prothesis depends on how successful the surgeon understands and creates an environment for the ankle joint prosthesis. It is extremely important that the ankle joint maintains stability and alignment. It is consequential from the biomechanical standpoint that the ankle joint prosthesis mimics the alignment and stability of a normal ankle joint as much as possible. The forces exuded on the bony and soft tissue structures should be as close to normal as possible. Careful assessment of the entire lower extremity for balance and stability is required. End stage osteoarthritis of the foot and ankle can lead to erosion of the articular surfaces, consequentially changing the architecture and the dynamics of the ankle joint. Diseased articular surfaces can affect the gait drastically and affect the relationship between osseous, muscles, tendons and ligaments which in turn causes pain, breakdown, instability and eventual disability of the ankle joint.

The stability of the ankle joint depends upon the joint's osseous and ligamentous structures [4–8].

Congruity of the articular surface of an ankle joint creates a stable articulation. The soft tissue structures along with well-maintained articular structures are the main stabilizers of a nonpathologic ankle. These structures are the major inversion and eversion stabilizer along with the collateral ligaments [5, 7, 9, 10].

Ankle ligaments have a stabilizing effect on the ankle joint. Studies have shown that the deep deltoid ligament is resistive against lateral and anterior talar excursion, whereas the anterior talofibular ligament is the restraint against anterior talar excursion [4, 10, 11]. The anterior talofibular ligament is the ligament that is most commonly injured and subsequent insufficiency/instability often lead to anterolateral subluxation/dislocation of the talus from the mortise [12, 13]. An ankle joint prosthesis should be as anatomic as possible to mimic physiological joint motion and assist in ensuring proper bony and soft tissue balancing.

Soft Tissue Balancing

Proper osseous and soft tissue balancing of the prosthetic ankle is an integral component in attaining and maintaining functional alignment and stability of an ankle joint prothesis [14–19]. Correcting osseous malalignment and addressing soft tissue imbalances of the foot, ankle and lower leg during primary or revision ankle joint prothesis procedure provides a functional balance. Failure to address these features properly may lead to edge loading with asymmetric forces that can affect the wear of the polyethylene spacer, and indirectly the prosthesis bone interface, causing a breakdown. The development of edge loading may increase the risk of prosthetic component complication and ultimately failure [14–19].

The foot and ankle surgeon must assess the ankle joint balance preoperatively. Intraoperatively the foot and ankle surgeon must stress the ankle joint and use an assortment of instruments such as laminar spreaders and multiple trial sizes and placement of components to appropriately tension the ankle joint [20]. Symmetrical soft tissue balancing during TAR is an important step in optimizing the mechanical balance of an ankle joint. A soft tissue contracture that results with frontal plane deformities can pose a difficult problem. Soft tissue balancing, in the frontal plane, is critical for long-term success and patient satisfaction. Correction with a frontal plane imbalance, including malalignment or instability, has traditionally involved a sequence of procedures that complement one another or work in combination. The general theory of soft tissue balancing involves the release or loosening of the contracted soft tissue on the concave side and plication or tightening on the convex side of the ankle [14–19]. Techniques for balancing the varus ankle during TAR include, but are not limited to posterior muscle lengthening procedures (gastrocnemius lengthening vs. Achilles tendon lengthening), osteophyte resection, medial deltoid release/peal, soft tissue releases (posterior tibial recession), soft tissue tightening, tendon transfers, osteotomies and arthrodesis procedures. Techniques for balancing the valgus ankle during TAR may include, but are not limited to posterior muscle lengthening procedures, calcaneal osteotomies, hind foot arthrodesis procedures, midfoot osteotomies, stabilization of the midfoot or forefoot and tendon transfers. Based on the extent of the pathology and the extent of the disease process coupled with the patients history, these can be done in a single stage or in two staged surgical reconstruction (Figs. 18.4, 18.5, 18.6, 18.7, 18.8, 18.9 and 18.10).

Correction of a Varus Imbalance

Varus imbalance correction during primary and revision TAR involves a posterior muscle lengthening procedures, release of medial soft tissues including osteophyte resection, medial deltoid peal, soft tissue releases (posterior tibial recession), reinforcement of the lateral procedures such as tendon transfers, osteotomies and arthrodesis procedures. This may include the removal of periarticular osteophytes and debridement of the medial and lateral gutters. Release of the deltoid ligament from the medial malleolus and/or possible lengthening osteotomy of the medial malleolus. Recession of the posterior tibial tendon, correction of pedal deformities with a dorsiflexory first metatarsal osteotomy/tarsal metatarsal arthrodesis or calcaneal osteotomy slide laterally and lateral ankle ligamentous stabilization with or without tendon transfer to reinforce lateral soft tissue



Fig. 18.4 A patient on the operating table prior to the surgery. The ankle is in significant valgus with a severe flatfoot deformity (peritalar subluxation)



Fig. 18.5 Intraoperative stress view demonstrating medial deltoid insufficiency of the right ankle

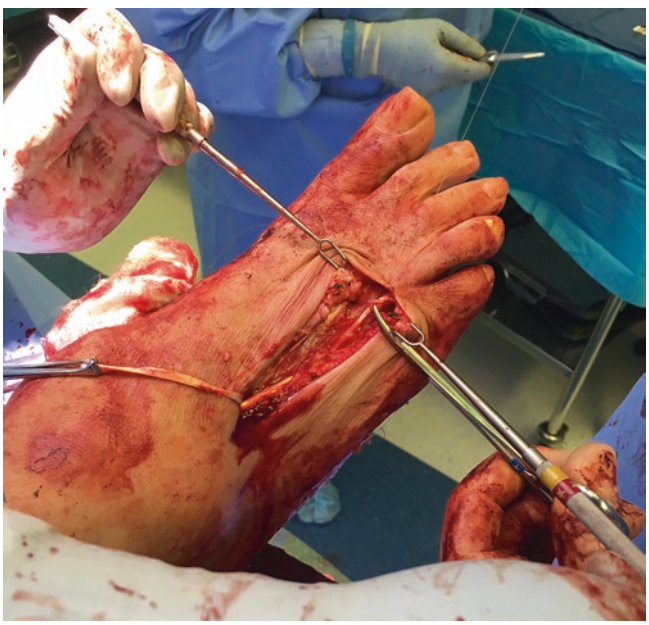


Fig. 18.6 Intraoperative view demonstrating a harvest of the proximal EDL 4th tendon. The EDL 4th tendon will be used to recreate/reconstruct the medial deltoid ligament. A tendon transfer of the proximal EDB tendon into the proximal stump of the EDL distal tendon to the toe to assist with function and dorsiflexion of the 4th toe

restraint [14–23]. Associated with a contracted varus ankle/foot, often the flexor retinaculum can tether the rearfoot while in varus. In these instances, the surgeon should perform a flexor retinaculum release/tarsal tunnel release in order to provide a soft tissue release of the concave side of the varus deformity. This will decrease the stress to the neurovascular structures as straightening the hind foot and ankle will lead to increased stress on the medial structures [20]. In the case of a lateral ankle instability, one may perform a lateral ankle stabilization procedure.

Correction of a Valgus Imbalance

Medial deltoid insufficiency is one of the most difficult procedures to obtain a reproducible result with predictability. Valgus imbalance correction may involve release of lateral tissues and reinforcement of medial tissues. This may include removal of periarticular osteophytes and debridement of the ankle joint gutters, complete release of the lateral ligament complex from the lateral malleolus and/or lengthening osteotomy of the lateral malleolus, correction of pedal deformities with medializing calcaneal osteotomy or medial column fusion, isolated or combined midfoot/hindfoot arthrodesis, forefoot procedures and deltoid ligament plication and/or tendon transfer to reinforce medial soft tissue restraints [15–21, 24–26].



Fig. 18.7 A intraoperative view following the harvest of the EDL 4th tendon in order to recreate a medial deltoid ligament to provide stability

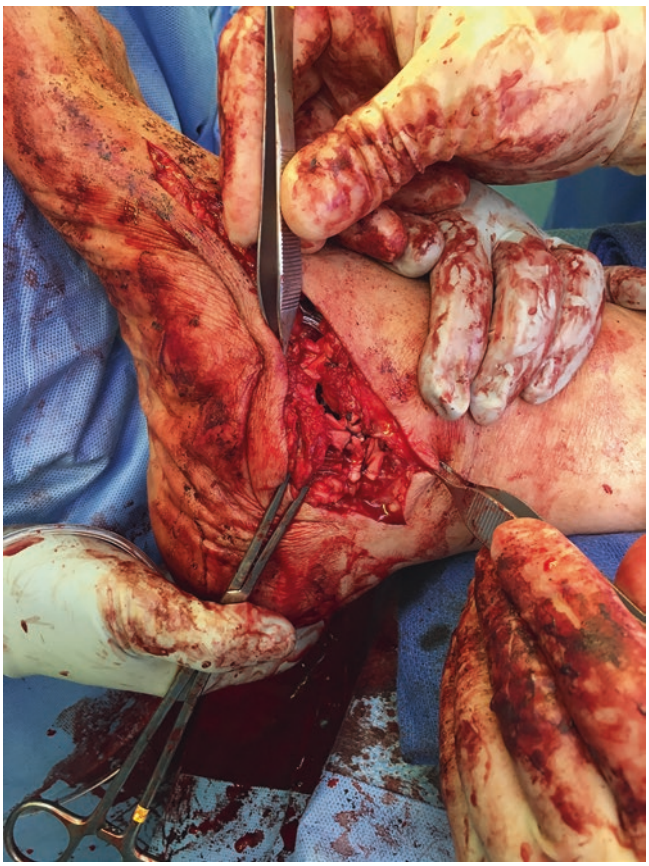


Fig. 18.8 A intraoperative view of the EDL 4th tendon utilized to enhance the medial deltoid ligament

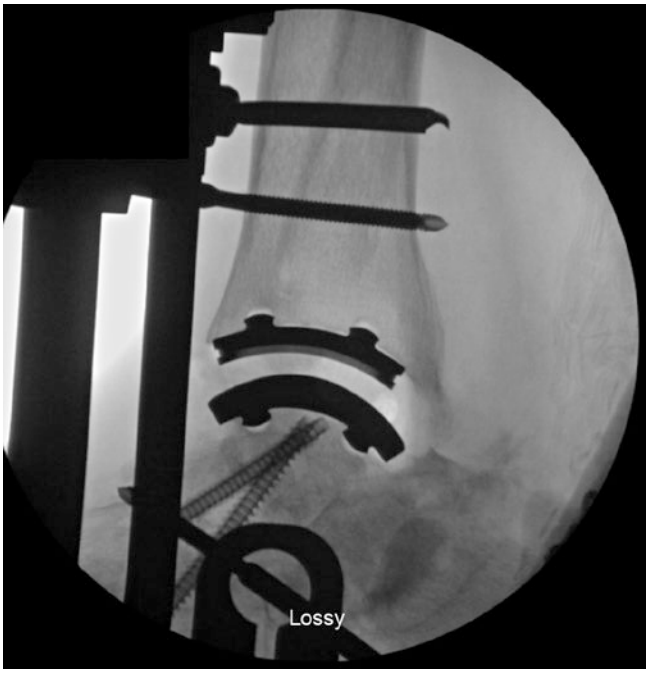


Fig. 18.9 An intraoperative lateral fluoroscopy views demonstrating a well-balanced foot and ankle following a staged reconstruction with a Zimmer Biomet™ Ankle that appears well positioned



Fig. 18.10 An intraoperative AP fluoroscopy views demonstrating a well-balanced foot and ankle following a staged reconstruction with the Zimmer Biomet™ Ankle that appears well positioned

For patients in where the remaining deltoid ligamentous structures are insufficient to provide for medial ankle stability, one may perform a tendon transfer. Once the osseous structures are balanced and the foot is positioned well under the leg, one can harvest the fourth extensor digitorum longus (EDL) which should yield approximately 8–9 cm of tendon graft. This EDL tendon graft can be utilized to recreate the medial deltoid ligament to create soft tissue stabilization to a foot and ankle that is structurally balanced. The proximal extensor digitorum brevis is then transferred into the distal stump of the EDL stump to the fourth toe for continued dorsiflexion of this digit. The EDL fourth tendon harvest is then inserted into the distal tibia, talus and calcaneus, respectively, to recreate the deltoid ligament (Figs. 18.11, 18.12 and 18.13).



Fig. 18.11 A lateral foot radiograph demonstrating a pes planus with midfoot arthritis and tarsal metatarsal-1 (TMT-1) instability along with osteoarthritis of the ankle joint



Fig. 18.12 A preoperative AP ankle radiograph demonstrating an unbalanced valgus foot and ankle

Osteotomy of the Tibia and Fibula

For deformity above the ankle joint a biplanar opening or closing wedge or a dome shaped osteotomy may correct multiplanar deformity. The osteotomy can be combined with an ankle replacement. The osteotomy is made in the metaphysis, leaving sufficient bone distally for fixation. If the fibula requires an osteotomy, it can be performed at the same level laterally, or obliquely more proximally. The ankle is then manipulated, rotated, translated or angulated in any or all planes until the desired correction is obtained. This osteotomy is particularly useful to correct deformity when the CORA is further away from the ankle joint.

In general, a closing wedge osteotomy is more kinder and predictable in comparison to an opening wedge osteotomy. Typically the medial closing wedge osteotomy heals well and is more predictable as no bone grafting is needed (Figs. 18.14, 18.15, 18.16, 18.17, 18.18, 18.19 and 18.20).

Staging

When adjacent soft tissue balancing, osteotomies or arthrodesis are needed, the surgeon needs to determine if this can be done in one surgery or should it be staged for two separate surgeries. The surgeon needs to consider the stress to the local soft tissues, bone, and take the patient comorbidities into consideration. Additionally the surgeon needs to assess the approximate amount of time the procedures may take and how much stress the patient's limb can handle as well as the surgeon's ability to manage the volume of procedures in one stage vs. two stages. Each patient is different given the circumstances and this also must be taken into consideration. Determining factors consist of how many other procedures are needed to balance the foot, ankle or leg, where the incision locations for the additional procedure are in relation to the TAR procedure. The fixation involved also needs to be kept in mind relative to how this may or may not impact the TAR surgery.

Conclusion

As total ankle prostheses continue to evolve demonstrating increasing longevity because the designs are better but equally important is the knowledge and understanding of balancing the foot, ankle and/or leg. The success of TAR depends largely on many factors including surgeon experience, appropriate patient selection and how balanced the

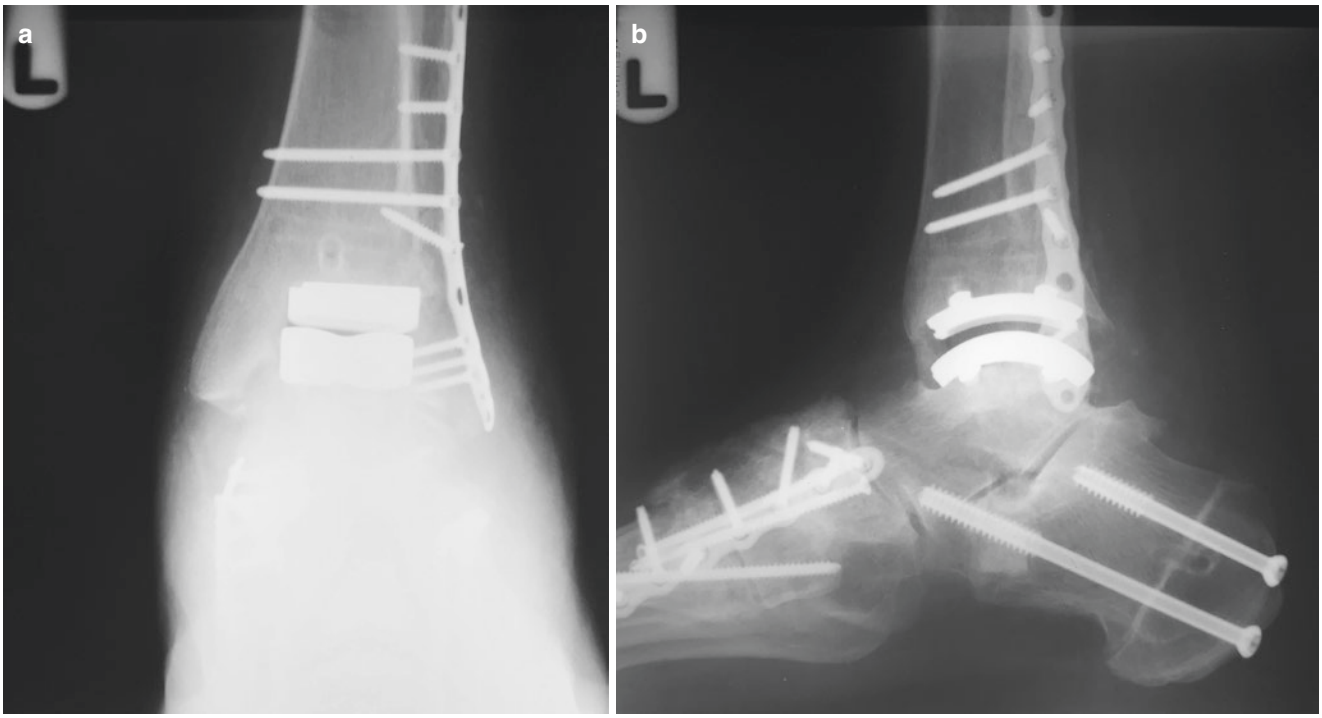


Fig. 18.13 A postoperative AP (**a**) and lateral (**b**) radiograph following insertion of a Zimmer Biomet prosthesis. This was a planned staged reconstruction. The initial surgery consisted of an endoscopic gastrocnemius recession, a double calcaneal osteotomy, a midfoot fusion and a TMT-1 arthrodesis. This balanced the valgus and foot and ankle and subsequently a Zimmer Biomet ™ Ankle joint prosthesis was implanted. The patient was a larger man who was a diabetic without peripheral neuropathy, therefore a syndesmotic fusion was performed for additional stability



Fig. 18.14 Intraoperative stress view demonstrating a patient who suffer from post-traumatic osteoarthritis with an unstable ankle valgus and secondary distal lateral osteonecrosis of the vital lateral tibia. The fibula is shortened and externally rotated with an insufficient syndesmotic ligament as well as an insufficient medial deltoid ligament



Fig. 18.15 An intraoperative view of performing an open tibial osteotomy in order to get the ankle joint realigned more anatomically and to appropriately support the ankle joint prothesis. Additionally the fibula was cut, internally rotated and brought out to length along coupled with a syndesmosis fusion. The medial deltoid ligament was repaired (soft tissue). This was a planned, staged approach surgery in order to balance the ankle to appropriately insert and support the ankle joint prosthesis



Fig. 18.16 An intraoperative view following an open tibial osteotomy to realign the ankle more anatomically. Additionally the fibula was cut, internally rotated and brought out to length along coupled with a syndesmosis fusion. The medial deltoid ligament was repaired (soft tissue). This was a planned, staged approach to balance the ankle prior to insertion of the ankle joint prosthesis



Fig. 18.18 An intraoperative ankle view demonstrating the insertion of the ankle joint prosthesis along with fibula osteotomy fixated well. This was a planned, staged reconstruction demonstrating a. was fixated a healed supramalleolar osteotomy and medial deltoid ligament repair. This ankle is now balanced ankle to hold the ankle joint prosthesis



Fig. 18.17 A staged approach was performed. Following confirmation of adequate incorporation of the inserted bone graft within the tibial osteotomy and confirmation or the syndesmotic fusion, an intraoperative ankle view, following a fibular osteotomy and insertion of the trial prosthesis



Fig. 18.19 A 4-year postoperative lateral radiograph demonstrating a well-balanced ankle with the Zimmer Biomet ankle joint prothesis following multiple planned stage reconstructive procedures

extremity is to near normal biomechanics of the ankle joint. A comprehensive evaluation including clinical, radiographic and advanced imaging assessment is extremely important as a reference for proper procedural selection in addition to the TAR. Awareness of the imbalances about the ankle and how to address them is mandatory in order to provide the most successful best long-term outcome possible.



Fig. 18.20 A postoperative ankle radiograph 8 years postoperatively demonstrating good consolidation of the tibial and fibula syndesmosis fusion as well as a balanced ankle (both osseous and soft tissue) with the Zimmer Biomet ankle joint prothesis

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Ankle Arthrodesis and Malunion Takedown to Total Ankle Replacement

19

J. George DeVries, Christopher F. Hyer, and Gregory C. Berlet

Ankle Fusion and Ankle Replacement

End-stage arthritis of the tibiotalar joint is a devastating condition that has significant negative effects on a patient's quality of life [1]. If patients fail conservative measures and joint-sparing operations, they are faced with either an ankle fusion or total ankle replacement. Both operations have been shown to improve pain and health-related quality of life [2, 3]. The decision between the two operations considers many different factors including patient characteristics such as weight, age, activity level, and smoking history as well as quality of bone and soft tissue at the ankle. Medical comorbidities such as diabetes and rheumatoid arthritis, as well as adjacent joint arthritis, are important as well. Finally, surgeon experience and comfort with the operations can impact the outcome as does appropriate surgical patient selection.

Ankle arthrodesis has been the historical "gold standard" for ankle arthritis in North America. Ankle arthrodesis offers a predictable operation that can be accomplished in almost any case of ankle arthritis including a wide range of etiologies, patient demographics, and deformities. It has been shown to be a very predictable operation with predictable results, both good and bad [4–7]. Regardless of the etiology and preoperative deformity, arthrodesis of the tibiotalar joint seeks to achieve a stable, plantigrade foot as the end result. The contralateral foot and ankle can be used as a template if there is not deformity; however the general end goal of a well-aligned ankle fusion seeks to place the foot in neutral dorsiflexion/plantarflexion, 0–5° valgus (with care to not place in varus), and 5–10° external rotation [8]. Posterior displacement of the talus within the ankle mortise is typically desired as it will decrease the lever arm in propulsion. Overall fusion rates for ankle arthrodesis are predictable and typically better than 90% using modern techniques [9, 10]. One published paper referred to a 40% nonunion rate in tibiotalar fusion, but this high nonunion rate is not reflected in more contemporary studies [11].

A key concept to remember is that even a well-executed ankle fusion with good positioning and successful bone healing will not provide satisfactory outcome for all patients. In some patients, the functional cost of a stiff ankle outweighs the pain benefit. In other patients, a once well-tolerated ankle fusion may become painful again as the adjacent joints develop osteoarthritis from the mechanical demands amplified by the ankle fusion or from post-traumatic arthritis related to the index injury. It is in these patients that the consideration can be made for an ankle fusion conversion to a total ankle replacement (TAR) prosthesis. In addition, there may be cases of attempted ankle fusion that resulted in nonunion or positional malunion that may also be candidates for conversion to TAR. All these known and predictable shortcomings of ankle arthrodesis lead to an overall decrease in quality of life for patients in long-term follow-up [12].

Multiple studies have performed gait analysis on patients after ankle fusion [13, 14]. Although the ROM at the tibiotalar joint will be completely eliminated, motion at the talonavicular and subtalar joints (STJ) will allow for some effective motion of the hindfoot. Normal gait requires between 20 and 25° of sagittal motion to prevent a limp, and as such, even with an increase in motion at the surrounding joints, patients may still have a limp after surgery [15]. As ankle replacement has become more commonplace, comparisons of gait in patients that have undergone ankle replacement to patients after ankle fusion have been published. Neither ankle fusion nor total ankle replacement can achieve normal ankle kinematics, but ankle replacement more closely resembles the gait patterns of control patients [16]. In general, ankle arthrodesis has a larger detriment to normal gait mechanics

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in speed, stride length, and symmetry when compared to total ankle replacement [17].

Loss of normal ROM and gait disturbances and the well-documented increased stress to adjacent joints can have a long-term deleterious effect on these joints. Long-term follow-up of ankle arthrodesis patients shows that when compared to the contralateral, non-fused ankle, many other foot joints demonstrate a progression in arthritis. This is not only isolated to the talonavicular and subtalar joints but also extends to the calcaneocuboid, naviculocuneiform, tarsometatarsal, and first metatarsophalangeal joints [18]. This has been born out in an analysis of reoperation rates after ankle fusion and ankle arthroplasty, with a noted higher incidence in subsequent subtalar joint arthrodesis after fusion [19].

Although most ankle fusions will go on to heal uneventfully, and a well-positioned arthrodesis is predictable, complications can occur. The failed ankle fusion, whether due to nonunion or malunion, can be a devastating complication with difficult salvage options. The malunion and nonunion of a tibiotalar arthrodesis can be very difficult to rectify and require extensive preoperative workup and surgical planning [20]. Traditionally in these cases, surgical options have been limited to revision arthrodesis of the tibiotalar joint and occasionally tibiotalocalcaneal arthrodesis. This has been described in a variety of ways. Various fixation methods have been described, including internal plates and screws, intramedullary arthrodesis nails, external fixation, and combinations of these methods. In addition to the variety of fixation options available, authors have also occasionally advocated to include the subtalar joint in addition to the ankle joint during revision surgery [21–25]. Published results of these salvage attempts show an overall salvage rate as low as 70% and demonstrate the difficulty of this complication and revision option [21, 22].

While ankle fusion has a long history in the literature and the results, complications, and revision options have been well explored, ankle replacement research is evolving and rapidly expanding recently. Due to improved understanding of the ankle, replacement strategies, and new technology, the use of total ankle replacement is expanding [26]. Contemporary conversations on total ankle arthroplasty address historical challenges of longevity, coronal plane instability, and accuracy of placement.

Longevity seems to be improving and more understood in the context of TAR. An artificial joint subject to non-regenerative wear will invariably break down and wear out. While long-term data is extensive when looking at total hip and knee replacements [27, 28], these types of results at over 15 years of follow-up are simply not available for total ankle replacements. In addition, the implants used in TAR have evolved and changed over time making true comparison studies difficult. However, some long-term data does exist and is encouraging, indicating 91% survivorship at 9 years [29] and 94.4% at 12.6 years [30].

The complexity of cases in which total ankle replacement is being performed is increasing. Deformity, particularly in the coronal plane at the tibiotalar joint, was initially a major concern, with authors indicating that patients be classified as "considerably deformed" when over 10° of coronal plane deformity is present [31]. Early authors even went too far as to say that greater than 15° of coronal plane deformity be considered a relative contraindication for total ankle replacement [32]. This was based on early failures during the TAR infancy. As comfort with the procedure has increased, as well as a better understanding of joint balancing through soft tissue and bony procedures, patients with greater preoperative deformity have been able to be corrected. With proper ligament balancing and osseous alignment, deformity up to 30° has been able to be corrected into stable alignment [33–35]. In addition, implant design has evolved toward inherent stability of the prosthesis. In general, total ankle replacement is being considered in more complicated cases than it had in the past years [36]. As a result, the number of surgeons performing this procedure has grown as has the number of TAR cases.

A crucial part of evaluating a patient with ankle joint arthritis for surgical management is the condition of the adjacent joints. This includes the joints of the ipsilateral foot but also the contralateral ankle. Gait analysis has indicated that functional outcome depends not only on the mobility of the foot joints but also on a mobile contralateral ankle, and fusion across the bilateral ankle may lead to less functional gait [13]. As has been mentioned, ankle fusion will lead to predictable deterioration of the ipsilateral foot joints, but not at the knee [17, 18]. Once a patient develops symptomatic and painful arthritis of both the ankle and the subtalar joint, surgical treatment options need to be critically evaluated. Arthrodesis of both the ankle and surrounding joints, such as a tibiotalocalcaneal or pantalar arthrodesis, can be performed in a single setting. This is a technically difficult procedure to perform and has significant reported complications, including transtibial amputation [37]. In the successful extended ankle and hindfoot fusion, reported outcomes have been mixed. In one classic report, the authors found that overall 81% of the patients reported that they were improved from their preoperative condition, but almost all patients (95%) reported that they lived with continued residual pain. In addition, due to the severe loss of motion, even a well position tibiotalocalcaneal or pantalar arthrodesis will require shoe gear modifications to allow for ambulation [38, 39].

Total ankle replacement can be performed along with subtalar or triple arthrodesis and has been reported both in staged fashion and in the same surgery. If performed in the same setting, it has been advocated to fuse only the posterior facet of the subtalar joint to preserve blood supply to the

talus [40]. Literature has indicated that ankle replacement in conjunction with hindfoot fusion will improve patient pain and function from preoperative levels but has a higher rate of complications (10% vs. 2.4%) and lower functional outcomes compared to isolated ankle replacement [41].

Ankle Fusion Taken Down to Ankle Replacement

As surgeons and patients move toward further acceptance of ankle replacement, the concept of an ankle fusion being taken down and converted to an ankle replacement has developed and evaluated. Indeed, the idea of taking a stiff, motionless ankle and restoring this to a more normal range of motion is enticing. Some patients, especially those fused at a young age, may have even considered this at the primary operation. This has been born out in other joints as well. The results of total hip and knee arthroplasty prompted previous researchers to evaluate the feasibility of fusion or ankylosis takedown to a total joint replacement. Multiple studies have shown that previously fused or immobile hips [42, 43] and knees [44, 45] can indeed be taken down to a replacement and are able to restore more normal kinematics across that section of bones. Based on the feasibility of fusion takedown based on other joints, the difficulty and complications with ankle fusion revision, and the known benefits of joint motion preservation, ankle fusion taken down to total joint replacement is a natural progression.

Indications for ankle malunion and nonunion takedown to total ankle replacement are based on a growing amount of peer-reviewed literature. Generally, it is agreed that a well-positioned, well-functioning, non-painful ankle fusion is not indicated for takedown with the hope of restoring motion to a previously stiff joint. The potential for complication and postoperative pain does not justify the takedown of an otherwise asymptomatic ankle fusion in hopes of preventing some future complication or simply improving patient function and gait.

However, in patients that have pain after ankle arthrodesis, there are certain indications where takedown and conversion may be warranted. Examples include cases of malunion of greater than 10° in any plane leading to pain and dysfunction, secondary arthritis associated with severe pain of the surrounding joints particularly the subtalar, talonavicular, and tarsometatarsal joints (Fig. 19.1a, b) and nonunion of the ankle joint despite modern techniques. Additional indications may include subtalar nonunion under an ankle fusion because the increase stresses placed on the subtalar joint after ankle fusion may continue to decrease fusion rate. Restoration of motion at the ankle joint is thought to offload these stresses and may enhance fusion rates and pain relief (Fig. 19.2a, b). Finally, tibial or fibular stress fractures due to malalignment of the hindfoot after fusion have been proposed as an indication for ankle fusion takedown and conversion to replacement [46–49].

Contraindications largely fall into line with the contraindications for primary total ankle replacement. Severe malalignment that cannot be corrected, uncorrectable soft tissue instability, peripheral vascular disease and/or neuropathy, Charcot neuroarthropathy, deep infection and osteomy-

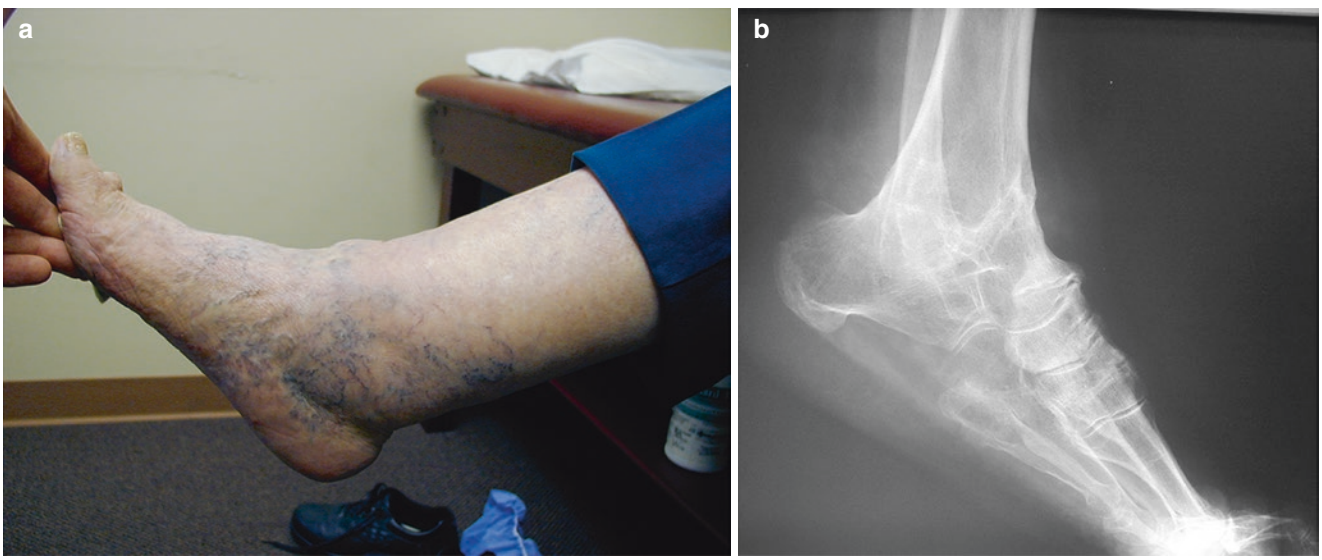


Fig. 19.1 Clinical picture of a plantarflexion malunion of ankle and subtalar joint demonstrating significant ankle swelling and equinus deformity (**a**). Lateral radiograph of the patient from Fig. 19.1, showing solid malunion of the ankle and subtalar joints in severe plantarflexion. Significant adjacent joint arthritis is demonstrated at the talonavicular joint (**b**)

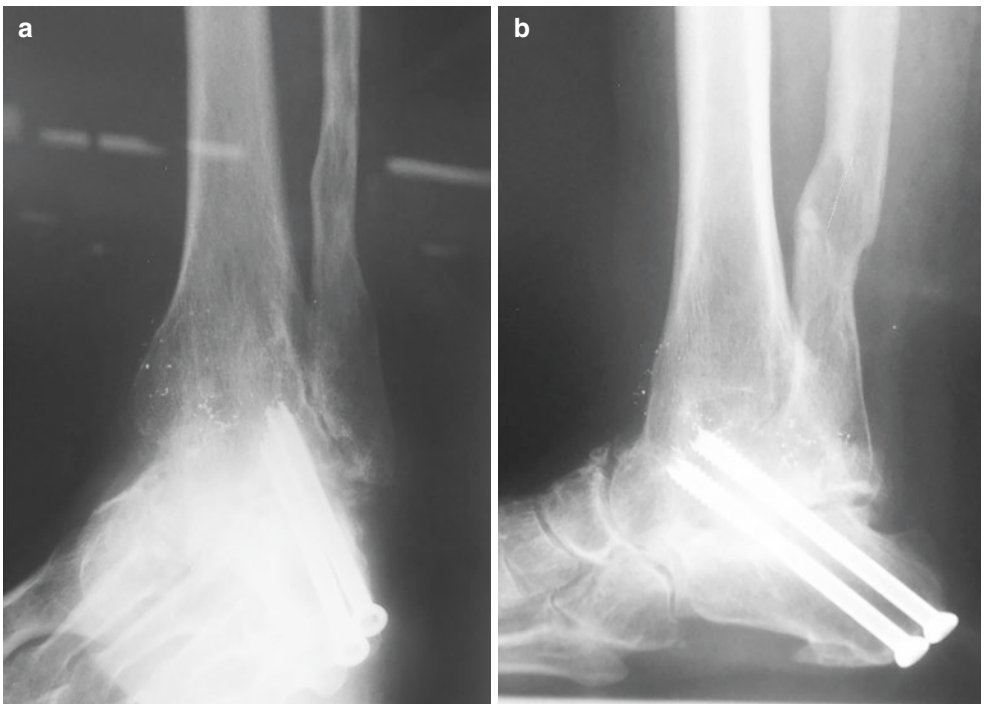


Fig. 19.2 (**a**) Lateral and (**b**) mortise radiographs demonstrating subtalar nonunion after previous ankle fusion. Overall good positioning is noted with good bone stock, preservation of both malleoli, and maintenance of the lateral gutter. Revision subtalar arthrodesis and takedown of ankle fusion to replacement were undertaken to decrease stress across the subtalar joint

elitis, and chronic pain are contraindications. High physical demands and avascular necrosis may also preclude total ankle replacement. Specifically, takedown to total ankle is contraindicated if previous interventions have left soft tissue compromise (such as anterior flap placement in anterior approach TAR) that prevents the necessary approach or have resulted in significant limb length discrepancy.

Several unique relative contraindications for total ankle replacement that apply only to previous arthrodesis have been described. The most important of these is a lack of a distal fibula due to previous fibulectomy at the time of fusion (Fig. 19.3). Several authors have offered options to recreate a fibula, and as such this may be a relative contraindication. The other is to consider the time of immobilization as the soft tissue structures may have gone through significant atrophy or uncorrectable contracture [46–50].

Careful and thorough preoperative planning and considerations are crucial to achieving success in this difficult operation. A meticulous review of the patient's medical history and any complicating comorbidities needs to be assessed and the risks weighed against the potential benefits. Both patient and surgeon should be keenly aware and involved in this decision. Previous incisions and potentially compromised vascular channels should be evaluated against the proposed incisional approach. Range of motion across the hindfoot is assessed, and in the case of tibiotalar nonunion, any range of motion across this joint is noted. Assessment of clinical appearance of coronal, sagittal, and transverse plane deformities needs to be assessed and will be compared to the radiographs. Diagnostic anesthetic injections can be per-



Fig. 19.3 Anterior-posterior radiograph of the ankle demonstrating previous ankle fusion with complete fibulectomy and lateral plate. This is a contraindication to ankle fusion takedown to total ankle replacement

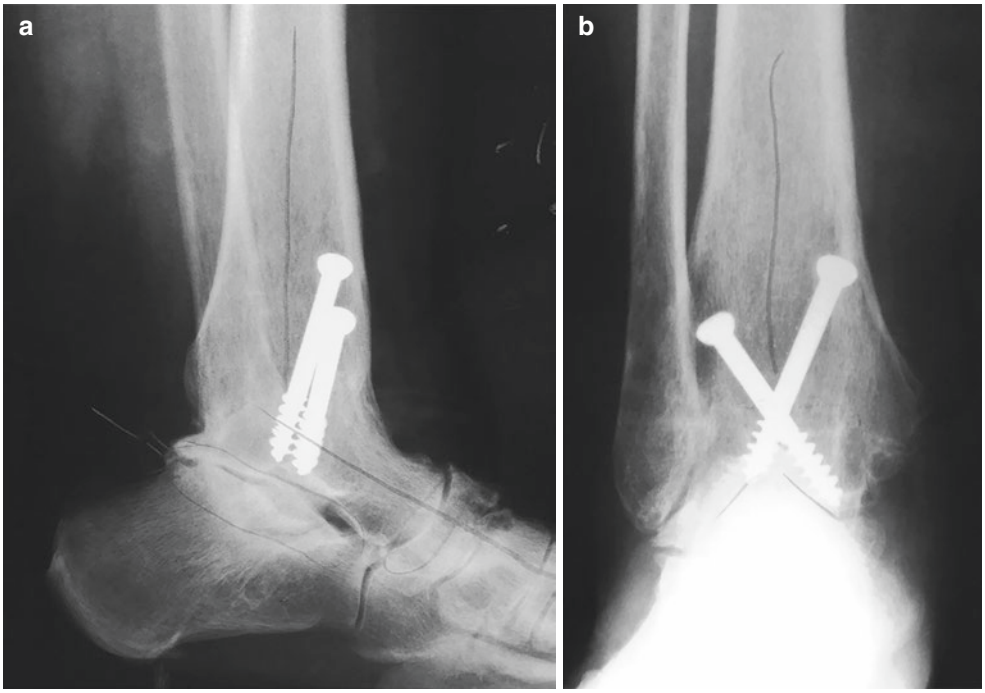


Fig. 19.4 (**a**) Lateral and (**b**) AP radiographs after previous ankle fusion. This demonstrates an anterior incision approach to the ankle and fibula-sparing technique. This is an ideal case to facilitate possible subsequent takedown to total ankle replacement as the anatomy is preserved and vascular compromise will be minimized in the secondary procedure

formed to determine where any pain is being generated. Finally, limb length discrepancy should be assessed.

After clinical evaluation of the patient, standard radiographs need to be obtained. At minimum, this should include weight-bearing images of both the affected foot and ankle, as well as a long leg calcaneal alignment, or Saltzman, view [51]. The presence of surrounding joint degeneration and arthritis in the hindfoot can be evaluated via these plain film studies. Again coronal, sagittal, and transverse deformity should be assessed and compared to the clinical picture. Remaining osseous anatomy is evaluated for the presence of available anatomic landmarks. The presence or absence of a fibular is of paramount importance, and a previous fibulectomy is a relative contraindication to takedown to ankle replacement [48, 52]. The ankle level is assessed for remaining anatomic landmarks, particularly the medial and lateral gutters (Fig. 19.4a, b). Comparison to contralateral standing ankle radiographs can also be helpful. This can help determine the level and location of the joint previously and is very helpful for proper positioning of the implant. Other images that have been advocated include whole leg radiograph, which are helpful for limb length assessment, as well as proximal joint alignment and condition. If there is difficultly with assessment, advanced imaging should be utilized as needed. Computed tomography (CT) can give accurate assessment of trabeculation across the fusion site, particularly important in the nonunion or partial union. It also gives accurate imaging of the remaining hindfoot bones (Fig. 19.5). Finally, it can assist in preoperative alignment and potentially be utilized to make custom alignment guides [53]. Magnetic resonance imaging (MRI) can be important to assess for areas of bone marrow edema and to help assess vascularity of the remaining bones and joints. If there is significant hardware left in the ankle from previous operations, this can cause significant artifact distortion. Either a different imaging modality may need to be used, or the hard-



Fig. 19.5 Computed tomographic sagittal image that clearly demonstrates solid union across the ankle joint with good trabeculation. This also shows arthritis in the posterior aspect of the subtalar joint with sclerosis and fracture through the navicular bone with preserved joint space

ware can be removed prior to MRI. Other imaging that can be used includes technitium-99 bone scans and single photon emission computed tomography (SPECT). The latter in particular has been advocated to give the most accurate assessment of surrounding joint arthropathy.

Results

The number of published peer-reviewed articles regarding the takedown of an ankle arthrodesis has continued to increase. This includes takedown for ankle malunion, nonunion, adjacent joint arthritis, and continued pain. Comfort with the expected outcomes and potential complications is developing, and various technical tips are published for this technique as well. In addition, a wider range of geography and authors have contributed their insights to this complicated topic. As such, the feasibility of this procedure is becoming more accessible. This is also increasing the general acceptance of takedown of arthrodesis to replacement, and better guidelines to acceptable patients are being established. Where only a few years ago this was a novel and cutting-edge possibility, with continued knowledge and study, this procedure is becoming increasingly available.

The published literature at this point encompasses over 100 patients that have reported outcomes. The first published study was by Greisberg et al. in 2004 [46] and involved the use of the Agility™ ankle replacement (DePuy, Warsaw, IN). Reporting on 22 patients and 23 ankles with this implant, overall satisfaction was 78.9%, but complications were common. Intraoperative fractures occurred frequently with four lateral malleolar fractures, three medial malleolar fractures, and three bimalleolar fractures. All but one of these either healed or had a stable fibrous union. Revision surgery was routine and 52.6% had 1.5 additional procedures, and 3 patients of the final included 18 patients (15.8%) resulted in transtibial amputation. While this article is important as it is the first formal reporting of ankle fusion takedown to ankle replacement, with the advancement of implant design and understanding of ankle replacement, the results are difficult to directly apply to modern implants.

Patients do well after ankle arthrodesis takedown to ankle replacement using modern implants. Pellegrini et al. [52] published a retrospective report of prospectively gathered data on 23 total ankle takedowns. Patients were followed an average of 33.1 months (12–101 months) and had statistically significant improvement of functional score parameters. The visual analog scale (VAS) improved from 65.7 ± 21.8 to 18.3 ± 17.6. Similarly, the Short Musculoskeletal Function Assessment (SMFA) bother index improved from 55 ± 22.9 to 30.6 ± 22.7, and the function index also improved from 46.7 ± 12.6 to 25.4 ± 17.4. Finally, the Short Form 36-month (SF-36) score improved from 37.7 ± 19.3 to 56.4 ± 23.1. Twenty of the 23 patients (87%) retained their metal implants at the last follow-up. Both patients with previous fibulectomy failed. Hintermann et al. [48] retrospectively reported on 29 ankles in 27 patients and also found statistically significant improvement in the American Orthopaedic Foot and Ankle Society (AOFAS) scores at an average of 55.6 months (36–90 months). This improved from 34.1 points to 70.6 points, with generally higher scores for patients over 60 years old and lower scores for patients with four or more previous surgeries and previous surgery within 1 year of the takedown. This led to 23 patients that were either satisfied or very satisfied with the outcome, although 72.4% of patients reported persistent moderate pain after surgery. The average VAS improved from 7.5 points to 1.8 points. Preis et al. [54] retrospectively evaluated 18 patients at 54 ± 27 months, with a minimum of 24 months. Statistically significant improvements of the AOFAS score from 23 ± 6 to 68 ± 14, SF-36 physical outcome score from 34 ± 5 to 74 ± 11, and SF-36 mental score from 49 ± 4 to 75.5 ± 7 were all noted among patients. Also, the VAS improved from 9 ± 1 to 2 ± 2. Huntington et al. [55] reported postoperative scores on five patients that were specifically replaced after ankle fusion nonunion at an average of 21.3 months (minimum 12 months). Good scores were noted, with the AOFAS score at 82.6, the Foot Function Index (FFI) at 28.2% and the VAS at 31.1. No preoperative scores were reported, and no statistical analysis was possible. Case reports of takedown to Salto XT prosthesis [56] and bipolar osteochondral allograft [57] also reported good outcomes.

After ankle arthrodesis, there is concern for limited ROM after takedown to ankle replacement. This is from long-term immobilization, posterior ankle scarring, and adhesions and scarring of the ankle tendinous and ligamentous structures. However, ROM can be recovered. Hintermann [48] reported on clinical and radiographic ROM after takedown. The clinical ROM was 24.3° (10°–40°) which was 55.1% of the contralateral unaffected ankle. Fluoroscopically measured ROM was slightly greater at 25.5° (8°–40°). Pellegrini [52] reported a ROM of 2° ± 2.9° in dorsiflexion and 19.9° ± 9.3° of plantarflexion. Preis [54] reported 8.5° ± 3° of dorsiflexion and 15° ± 5° of plantarflexion. They also reported a statistically significant but clinically dubious improvement from 14° ± 10° to 16° ± 10° in subtalar ROM. Greisberg [46] reported mean ankle ROM of 26° (5°–35°). A single case study reported on improved gait analysis after takedown from tibiotalocalcaneal arthrodesis [58].

Alignment and radiographic findings also have been reported to be successful in ankle arthrodesis takedown. This is most often described in terms of settling and migration. Measured angles include the α, β, and γ angles. The α angle is the coronal plane deformity defined by the mechanical tibial axis and flat surface of the tibial component. The β angle is the sagittal tibial alignment and is measured the

same way on the lateral image. The γ angle is the lateral talar position and is defined as the axis of the talar component and the bisection of the talar neck [59]. Pellegrini [52] found the α and β angles to be 1.4° ± 1.0° and 1.8° ± 1.3° from neutral, respectively. No significant change in this position was identified at the latest follow-up. The γ angle was initially 17.3° ± 3.9° and at the latest follow-up had changed to 16.7° ± 4.6° (p <0.001). The tibial component had an angular change of >2° in 4 patients (20%) while 14 patients (70%) had change in talar position of 1–5 mm or 1°–5°, all within the first year after surgery. Preis [54] reported neutral initial alignment with the α angle 88° ± 1°, β angle 86° ± 2°, and the γ angle 15° ± 2°, with no reported changes or subsidence of the talus. Hintermann [48] found talar migration in three patients, one of which was symptomatic as well as one patient with instability and subsidence of both the tibial and talar components. Huntington [55] simply reported no loosening, migration, or subsidence in the five ankles.

Complications are more common in takedown ankle arthroplasty compared to primary ankle arthroplasty. Wound healing complications not requiring surgery were seen between 7.4% and 40% [48, 52, 55], and intraoperative malleolar fractures were reported between 8.7% and 17.2% [48, 52]. Subsequent surgery that did not include component revision was frequently reported as well. This included release of arthrofibrosis or impingement between 8.7% and 11.1% [52, 54], one medial malleolar stress fracture requiring ORIF (4%) [52] and realignment and stabilization surgery between 3.4% and 8.7% [48, 52]. Failure requiring component revision or conversion to tibiotalocalcaneal arthrodesis is reported between 5.5% and 13.0% [48, 52, 54]. No reports of transtibial amputation are reported with modern implants.

Fibular resection at the time of ankle arthrodesis and implications for takedown is a debatable topic. While some authors advocate against takedown in the face of previous fibular resection [46, 52, 55], other authors have reported successful takedown in this case and offered reconstruction options [47–49]. Schuberth et al. [50] reported a retrospective series detailing functional and radiographic results in 10 patients with insufficient fibula out of a cohort of 63 ankle fusion takedowns. The average follow-up was 56.6 months (24–123 months), and the authors outlined three different fibular reconstruction options. In cases where there was no usable fibula, a two-stage approach was undertaken. First, a tricortical iliac crest autograft was harvested and fused to the lateral ankle fusion mass. After incorporation of the graft, a second stage included hardware removal and ankle arthroplasty. If there is reconstructable remnant fibula, the remaining fibula is transposed distally to be used as a buttress, with grafting of the intercalary space to create a contiguous lateral restraint. Finally, if there was a previous fibular onlay graft resulting in a narrowed fusion mass, the components were simply downsized and medialized. Using this algorithm and approach, the authors reported outcomes using a variety of modern implants. AOFAS scores improved from 47 to 81, and Buechel-Pappas (BP) score improved from 47 to 81 as well. Range of motion was an average of 16° postoperatively. Only one patient had coronal plane deformity of 8° valgus postoperatively, and this did require later grafting of the fibular defect to reinforce the lateral support. During the follow-up, three patients (30%) required subsequent surgery including repeat grafting, revision of components, and gutter debridement. Although fibular deficiency is still a clear complicating factor, options are available in select patients.

A pertinent point of discussion related to ankle fusion takedown and conversion to total ankle replacement is the method of ankle fusion than can facilitate potential takedown in the future. Incision placement is important. The standard lateral approach over the fibula and medial arthrotomy should leave adequate room to utilize a standard anterior utilitarian incision for the ankle replacement. If there is a skin bridge of at least 4 cm, it has been suggested that a standard approach can be undertaken [47–49]. If an anterior incision is to be used for the primary ankle arthrodesis, a standard anterior incision should be utilized over anterior-medial or anterior-lateral incisions. In addition, incisions that become curvilinear distally should be avoided to circumvent a potential vascular compromise. Maintenance of anatomic landmarks to allow for determination of the native ankle joint line is helpful as well. Incomplete arthrodesis of the medial or lateral gutters will allow for simple visualization of the native joint line, as well as act as a guide for a potential takedown. Arguably the most important factor is maintenance of the fibula. A fusion approached anteriorly, medially, or posteriorly typically facilitates little or no violation of the fibular. If a lateral approach is needed, the fibula is osteotomized but kept intact. The posterior blood supply is kept intact, and the fibula is rotated posteriorly instead of completely removing the fibula. Care should be taken to preserve the perforating peroneal arterial supply at the anterior margin of the fibula. Also, take care to resect only the necessary width of the medial fibula for graft material, thus allowing for a more robust fibular onlay graft that can be used in the event of a takedown to replacement.

Takedown Conversion to TAR Technique

Preoperative Planning

Routine vascular screening is performed to get an idea of vascular flexibility. A high calcium index in the vessels means a higher risk for vasospasm and ultimate vascular insufficiency. Any pre-existing vascular disease in the intended limb should be carefully evaluated as a potential contraindication for surgery.

Contralateral standing films for comparison is important. The relative relationship of the malleoli will help establish the malleolar axis in the operative limb. SPECT or standard CT scans may also be consulted to understand the topical anatomy that may influence implant positioning. A thorough review of the weight-bearing alignment of the lower limb is performed.

The condition of the anterior ankle soft tissue needs to be carefully evaluated. Review of prior incisions and state of tissue tension is very important. The soft tissue must be supple. It is not advisable to revise to a motion segment, a limb where there has been previous soft tissue reconstruction using flaps or split thickness grafts as these will invariably fail.

Bimalleolar support is necessary. The absence of a fibula from a lateral approach ankle fusion is still a contraindication in the opinion of the authors. Attempted reconstruction of an absent fibula, though possible, is not without extremely high risk and is not advocated by the authors at this time.

Approach

It is the experience of the authors to use an anterior approach for fusion to arthroplasty conversion. This allows for a full view of both malleoli, which enhances the ability to protect and establish the appropriate joint line orientation.

The neurovascular bundle may be in a deviated position relative to the normal relational anatomy, and care must be taken to identify and mobilize it.

Protect the Malleoli

The malleoli may be somewhat osteoporotic and prone to intraoperative fracture. Prophylactic stabilization is advisable. The medial malleolus is protected by placing two cannulated screws from the tip of the medial malleolus into the tibial metaphysis. In the case of using a stem medullary implant, the length and trajectory of the screws must take into consideration in respect to the location of the future intramedullary stem (Fig. 19.6). These points need to be considered with central keeled tibial prostheses as well.

The fibula is similarly protected by a vertically oriented intramedullary screw with the start point at the tip of the malleolus. Fully threaded screws can be used in both applications, typically 4.0 cannulated.

Defining the Joint Line

The joint line is defined carefully using the contralateral limb for guidance. Intraoperative fluoroscopy is compared to preoperative imaging. Often there is an indent in the healed bone segment that can aid the surgeon in identifying the tibiotalar horizontal joint line. To identify the medial and lateral gutters, it is recommended to go distal in the gutters and work from the tip of the malleoli proximally. Even in cases of medial and lateral gutter fusion, the distal extent of each gutter is still visible. Guidewires are placed in an anterior-posterior direction through the estimated horizontal and vertical joint lines, and a careful fluoroscopic evaluation is performed (Fig. 19.7a, b). It is helpful to use multiple wires to determine the horizontal joint line. Once position is established, carefully scrutinize the alignment between the wires if plan is to use the wires as cut guides (Fig. 19.8). Particular attention to the anterior-posterior flexion angle of the wires should be taken.

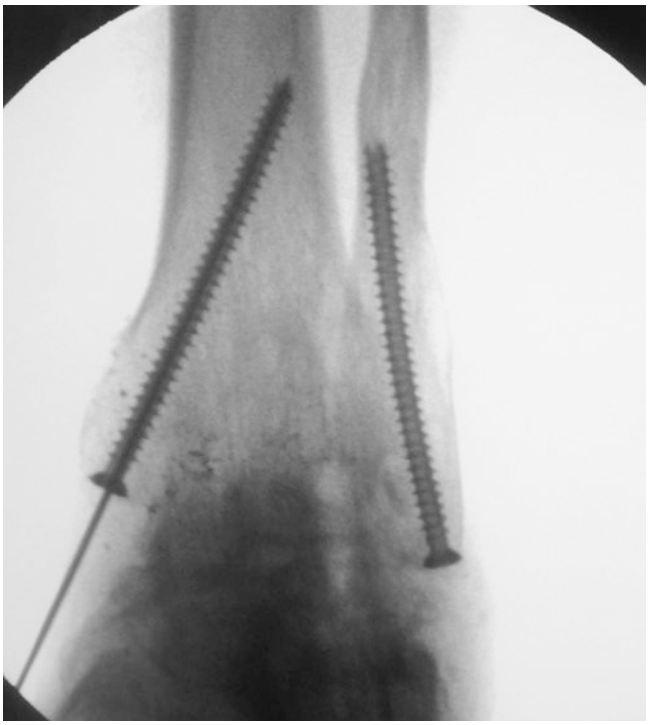


Fig. 19.6 Intraoperative fluoroscopic images demonstrating prophylactic pinning of the malleoli using fully threaded 4.0-mm cannulated screws. Trajectory of the screws must take into account later placement of the prosthesis, particularly important when using a tibial stemmed implant. Care must be taken not to impinge on the implant. This medial screw was later removed after implant placement

Making the Bone Cuts

There are two different techniques that can be utilized once the joint line is determined. Each is effective and each carries its own advantages and disadvantages. One technique may fit the particular case better than the other, so consider both options carefully.

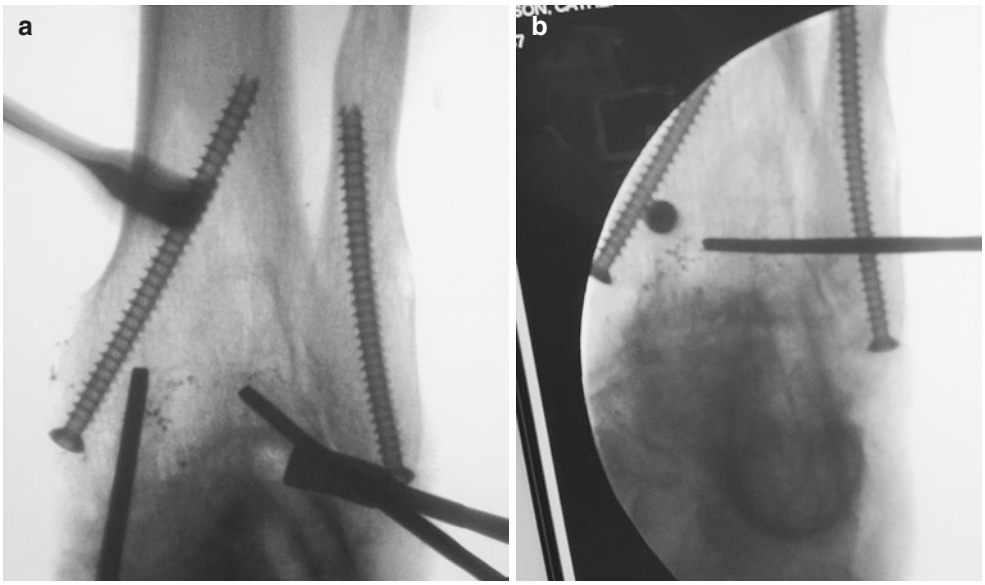


Fig. 19.7 Intraoperative fluoroscopic images using guidewires to define and plan for the tibiotalar joint line and medial and lateral gutters. (**a**) Vertical and (**b**) horizontal joint lines need to be defined

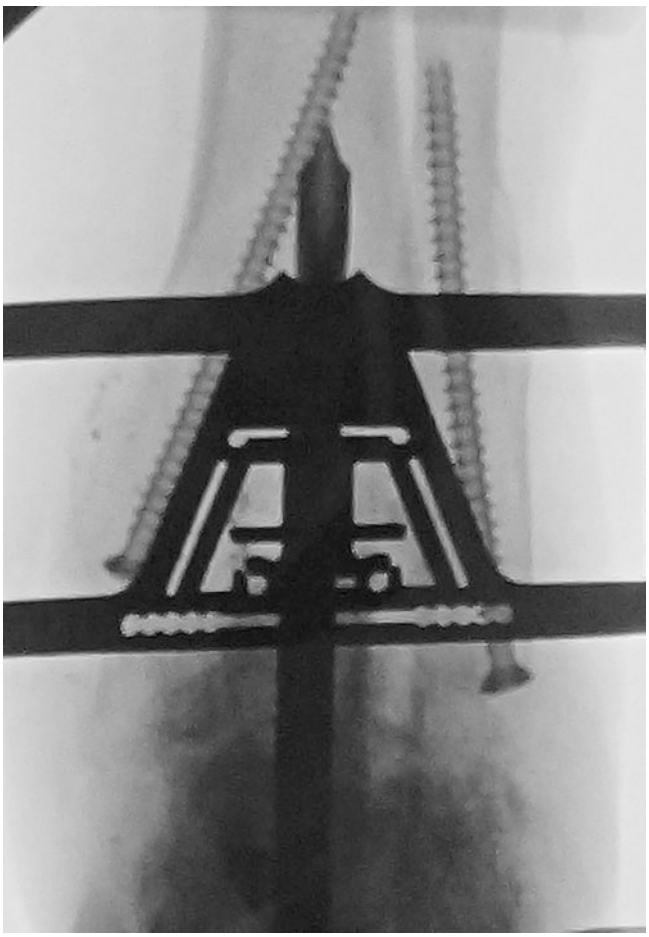


Fig. 19.8 Intraoperative fluoroscopic image assessing the planned bone cuts for the implant. Care is taken to ensure that the malleoli are preserved and that flexion of the ankle is correct. Guidewires marking the joint line and gutters can be used to assess proper positioning

Technique One Mobilize the tibia from the talus prior to placement of the cut guides. This would be performed free-hand using a power saw and osteotomes using the wires as cut guides. Angular deformities can be corrected through these cuts with careful planning.

Advantage: Allowing for free movement of the tibia with respect to the talus markedly decreases the risk for intraoperative fractures. Also, once the joint is recreated and assuming any deformity was corrected through the cuts, the remainder of the procedure would be very similar to a primary TAR. Additionally, once the ankle is recut, stability and contracture of the soft tissues can be assessed. Frequently a Achilles tendon lengthening is performed.

Disadvantage: These are free-hand cuts that are performed prior to placement of the cut guides. There may be greater chance for error using free cuts both in establishing the new joint line and its alignment or potential for injury to the malleoli through the cut.

Recommendation: Use this technique primarily in non-union conversions; conversions when only part of the ankle is fused or correction of deformity needs to be done through the bone cuts.

Technique Two Placement of cut guides, removal of resection segment, and then mobilization.

Advantage: Allows for accurate placement of cut guides with a solid and fixed reference. The cuts are most easily done with this technique, and there is less room for error.

Disadvantage: Once the cuts are made, the ankle will not yet move so removal of the cut bone segments is difficult. This can put the malleoli at risk for intraoperative fracture especially if they were not prophylactically pinned. The

remainder of the cuts to the gutters will need to be done freehand once the bone segments are removed.

Recommendation: Use this technique in solid ankle fusions where it is difficult to recreate the joint line by visual sight, and the ankle is in a neutral position. The surgeon will benefit from the cut guide systems and intraoperative fluoroscopic visualization.

Bone Cut Technique

The soft tissues may be adherent to the posterior aspect of the tibia including the FHL and neurovascular bundle. A peck cut technique is advocated. The saw blade should be marked so that the surgeon has a visual landmark of when the posterior cortex is in close proximity. In situations of poor tactile feedback, osteotomes can be used to carefully complete the posterior cut of the tibia and talus. It is often helpful to resect the anterior 50% of the bone segment and then carefully piece out any adhered posterior segments. Distraction with a laminar spreader can also be helpful at this step.

Removal of Bone Segments

The surgeon cannot lever on the medial or lateral sides in any situation. Even with the malleoli being pinned, this puts them at risk for fracture. The bone must come out from the anterior cut segment piecemeal. This is usually best achieved by dividing the bone resection into multiple small segments. The most difficult piece to remove will always be the posterior lateral piece, which is attached to the posterior lateral tibia fibular ligament. Patient use of a combination of angled curettes and osteotomes as well as threaded pins can facilitate bone removal.

Soft Tissue Releases

The ankle cannot be forcefully manipulated to create motion as this may cause fractures. The Achilles will need to be lengthened in nearly all cases. The posterior tibial tendon and peroneal tendons may need a tenolysis. There may be significant fibrosis of the deep deltoid segments as well. These all can be judged after bone resection is complete and prior to prosthesis implantation.

It has not been the experience of the authors that the tarsal tunnel needs to be released, but this can be considered.

There must be motion between the tibia and talus prior to implanting the prosthetic device.

Implanting the Tibia and Talus

The bone will usually be quite soft, and the surgeon must use a gentle and deliberate touch when placing the prosthetic device. Cementing both components of the device is recommended. Readdress motion once the implant is in place, and evaluate surrounding soft tissue contractures again.

Final Imaging

Confirm position of the implant and the internal fixation of the malleoli. It is preferred to leave the medial malleolar fixation in for additional support even if there is no evidence of intraoperative malleolar compromise (Fig. 19.9). In some cases screws in the malleoli may be removed if necessary (Fig. 19.10a, b). It is recommended to take dorsiflexion and plantarflexion views intraoperatively to confirm range of motion that was achieved after implantation (Fig. 19.11).



Fig. 19.9 Intraoperative image intensification view after final implantation of the prosthesis and screws in the malleoli. Final inspection is undertaken to ensure that the implant is properly seated, the components are congruent to each other, the gutters are open and decompressed, and the screws do not impinge on the implant

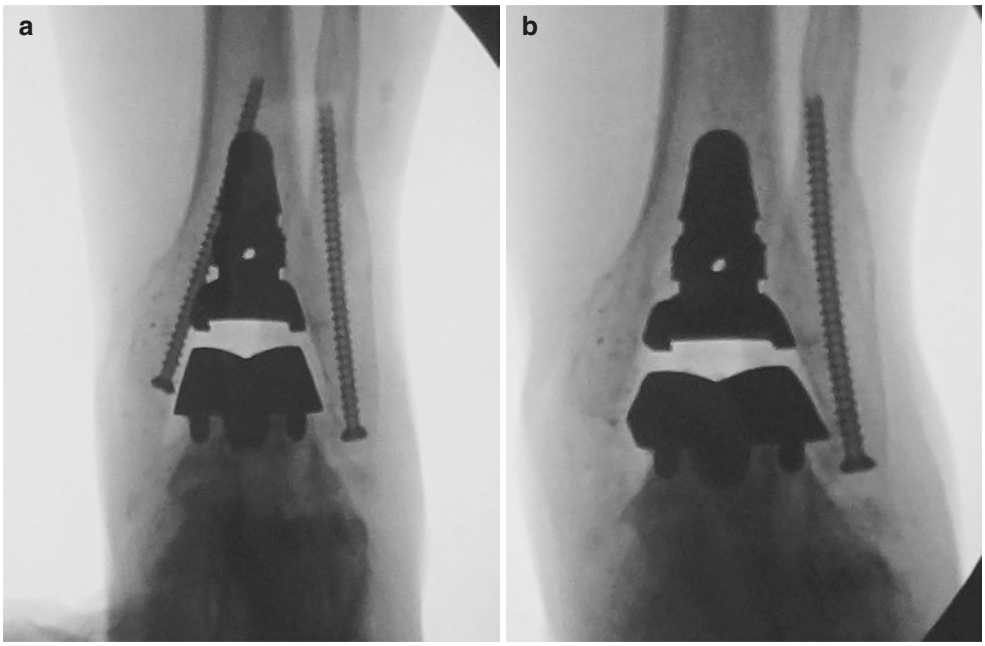


Fig. 19.10 (**a**) Final intraoperative images ensuring proper placement of the final components. (**b**) In this case, the medial malleolar screw was felt to be too close to the final implant and was subsequently removed. This was possible because of good medial bone structure with excellent implant placement and alignment

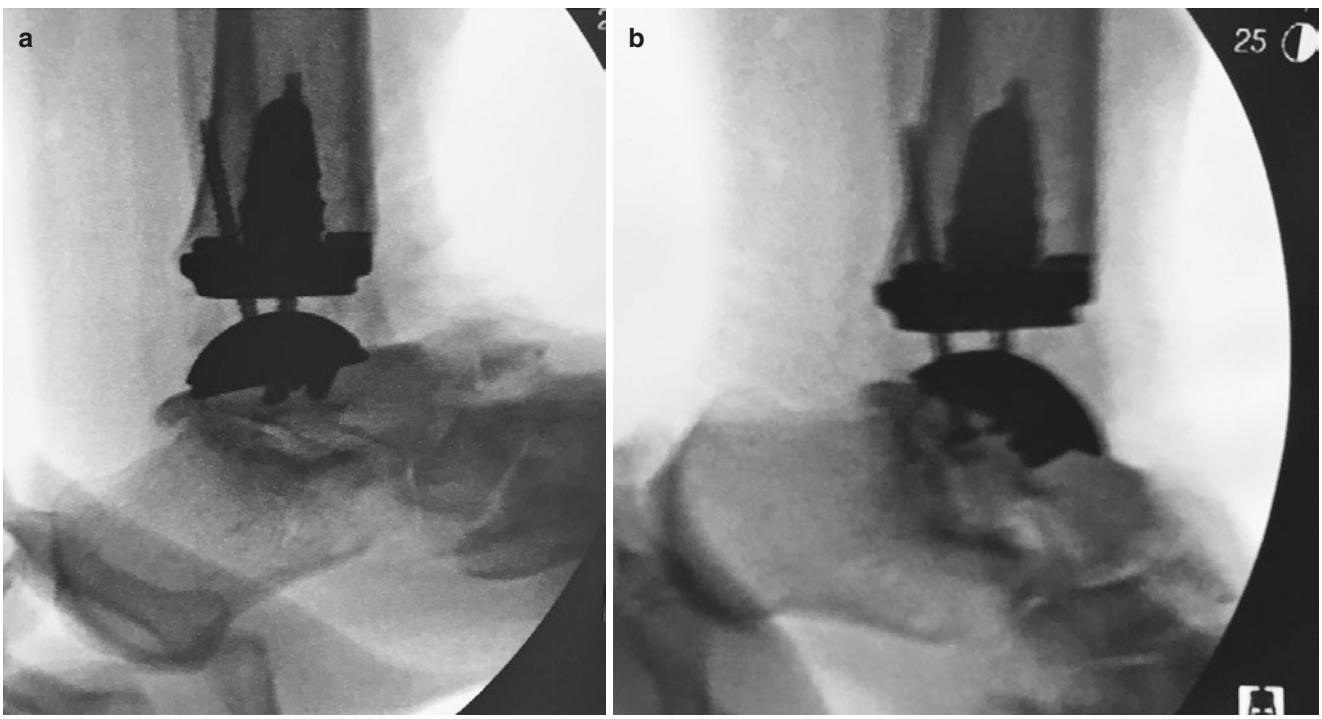


Fig. 19.11 Intraoperative lateral fluoroscopic images taken in maximal (**a**) dorsiflexion and (**b**) plantarflexion to confirm range of motion achieved after the takedown of the fusion to TAR

Letting Down the Tourniquet

It is the authors recommendation that the tourniquet be let down prior to closure. It is a known risk of total ankle arthroplasty to have vascular and neurologic compromise of the tibial nerve and artery. These risks are higher with a conversion of an ankle fusion to ankle replacement. Excessive bleeding from the posterior medial corner should be investigated for vascular compromise to the tibial artery.

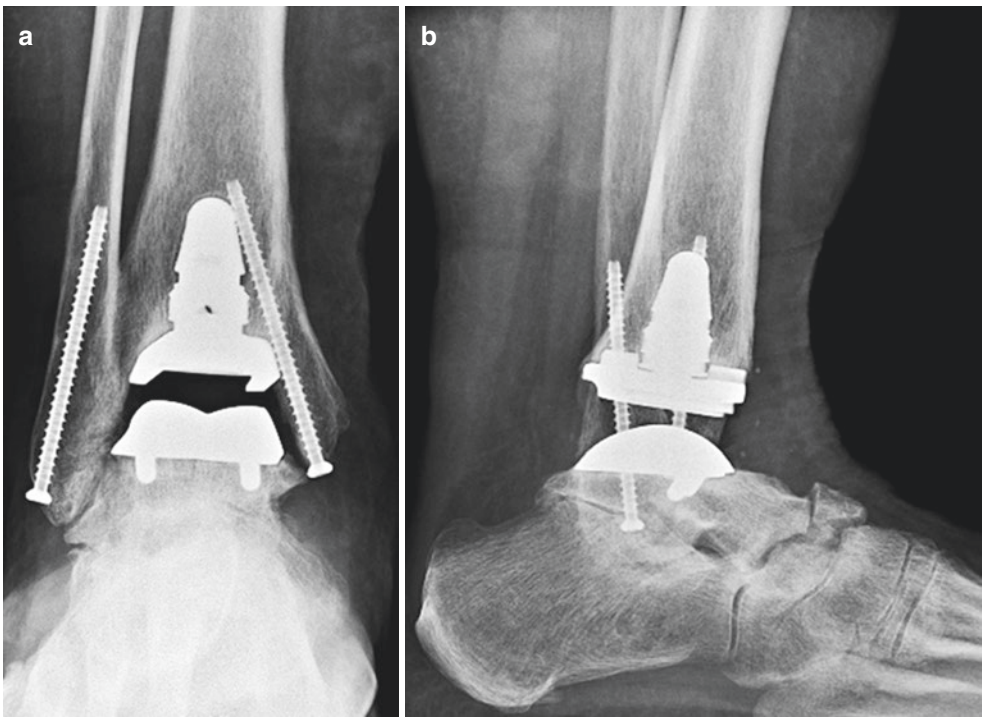


Fig. 19.12 AP (**a**) and lateral images (**b**) taken at 1 year postoperatively after ankle arthrodesis takedown and conversion to total ankle replacement. Range of motion is preserved and takes stress off of the adjacent joints providing for pain relief and a return to activity

Closure

Normal layered closure for a total ankle arthroplasty is completed. Drains are not routinely used although incisional wound vacuum-assisted closure (VAC, Kinetic Concepts, Inc., San Antonio, TX) can be helpful in some cases.

Conclusions

AA is a proven way to provide for pain relief for end-stage ankle arthritis. Advancements in fixation and biologic augmentation have improved the arthrodesis rate making this a reliable operation. There are functional consequences to an AA that include advancing surrounding joint arthritis that limits the long-term satisfaction with AA. A painful AA with an identifiable cause of pain can be successfully converted to a TAR. The indications are limited and include malunion, surrounding joint arthritis where the option of further arthrodesis is not desired, or persistent nonunion of an AA attempt. The literature support of conversion of an AA to TAR is limited but growing and demonstrates the viability of this option (Fig. 19.12). These operations have a high technical component and a higher risk profile than a primary TAR. Long-term outcome on the TAR after AA is still forthcoming.

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Part III

Secondary Procedures with Total Ankle Replacement

20 Managing Adjacent Joint Arthritis: Indications and Techniques for Concomitant or Staged Fusions of the Hindfoot and Midfoot

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Introduction

Total ankle replacement (TAR) surgery has gained increasing popularity over the last 30 years and has become the preferred treatment option for end-stage ankle arthritis in many patients and confirmed to be superior to ankle arthrodesis in COFAS III and IV ankle arthritis (Table 20.1). The most common etiology for end-stage ankle arthritis is trauma, accounting for 70% of ankle arthritis [1], followed by systemic arthropathies (i.e., rheumatoid arthritis). Traumatic cartilage damage from the initial event is thought to be the mechanism in most cases, although arthritic progression often takes several years to become symptomatic. Traumatic events and systemic arthropathies rarely only affect the ankle joint, thus making adjacent joint arthritis in these patients very common. The talonavicular (TNJ) and subtalar joints (STJ) are most commonly affected in the post-traumatic setting. It is imperative that the surgeon understand the biomechanics of the foot and ankle and how replacing the ankle joint will not only affect the function of the ankle but also will affect the arthritic adjacent joints. Modern total ankle joint prostheses have been greatly improved to better parallel the function of an anatomic ankle, which may slow progression of adjacent joint arthritis but does little to correct the already damaged adjacent joints. For this reason, separate procedures may be needed to address these adjacent arthritic joints, when TAR alone is not sufficient.

Great debate exists, with little high-level evidence, on whether adjacent joint arthritis should be addressed in the setting of a TAR. To blur the lines even more, the debate continues to address which type of procedures (arthrodesis vs. joint sparing) and the timing of those procedures in relation to the TAR. This chapter aims to address the biomechanics of the adjacent joints of the ankle, in both an undamaged anatomic ankle and arthritic ankles, and how they are affected by TAR. The authors will also take an in-depth look at the procedures of choice for each of the arthritic joints and determine the best timing for these procedures, whether it is prior to TAR at the same time as the TAR or in a post-TAR-staged fashion.

Biomechanics

The foot and ankle complex can be considered just as much an engineering feat as an anatomical one considering the complexities noted involving the multiple bones, joints, ligaments, tendons, and muscles which act in sync to provide a stable functional structure that is used on a daily basis. When one, or multiple, of the moving parts are affected by arthritis, there is an avalanche-type effect that can accelerate damage to the adjacent joints. In order to best understand how arthritis affects the ankle biomechanics and the surrounding joints, it is important to briefly review the biomechanics of a normal healthy foot and ankle complex.

When the foot and ankle are free of arthritis, the multiple joints are able to work in tandem to perform the many different motions needed to advance through the phases of gait. The ankle joint itself functions primarily in the sagittal plane, though there have been studies indicating mild internal and external rotation that can occur. When non-weight-bearing, the stability of the ankle is formed from the combination of ligaments and the recessed position of the talus between the tibia and medial and lateral malleoli. Upon weight-bearing, the stability of the joint is solely from the bone-to-bone

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Table 20.1 COFAS preoperative and postoperative classification system for end-stage ankle arthritis

	Type 1	Type 2	Type 3	Type 4
Preoperative classification	Isolated ankle arthritis	Ankle arthritis with intra-articular varus or valgus deformity, ankle instability, and/or a tight heel cord	Ankle arthritis with hindfoot deformity, tibial malunion, midfoot abd- or adductus, supinated midfoot, plantarflexed first ray, etc.	Types 1–3 plus subtalar, calcanealcuboid, or talonavicular arthritis
Postoperative classification	AA or TAR without concomitant procedure requiring second incision, except syndesmotic fusion	AA or TAR with a concomitant soft tissue procedure requiring a second separate incision	AA or TAR with an additional osteotomy including midfoot arthrodesis	AA or TAR with and additional hindfoot arthrodesis
Concurrent procedures	None, hardware removal	Deltoid ligament release, Achilles tendon lengthening, gastrocnemius recession, tendon transfer, capsule release, forefoot reconstruction, metatarsal osteotomy, dissection/decompression/release of neurovascular structures, plantar fascia release, syndesmosis reconstruction	Fibular osteotomy, calcaneal osteotomy, tibial osteotomy, midtarsal arthrodesis	Arthrodesis of any of the following joints: subtalar, talonavicular, calcanealcuboid, or a combination, i.e., double or triple arthrodesis

AA ankle arthritis, *TAR* total ankle replacement
Based on data from Wing et al. [21]

contact between the tibia and talus. The STJ lying directly inferior to the ankle joint is the primary source of frontal plane motion for the hindfoot. The normal 20° of inversion and 10° of eversion supplied by the STJ are vital for traversing uneven ground. It is hypothesized that the contoured joint articulation along with multiple ligamentous structures crossing the STJ is the reason for the firm stability of the STJ.

The midtarsal joint consists of the TNJ and the calcaneal cuboid joint which both work to help translate motion between the midfoot and the rearfoot. The motion that occurs at the midtarsal joint is tri-planar and consists of supination and pronation. The midfoot comprises the remaining tarsal bones and is responsible for transmitting forces throughout the foot and allowing the foot and ankle complexes to accommodate variable terrains that may not be very well tolerated by the hindfoot and ankle alone. Therefore, the midfoot is able to move through all three planes throughout the phases of gait. The midtarsal joint and the midfoot joints all gain stability through articular surfaces as well as extrinsic and intrinsic stabilizers [2]. All three of these areas, ankle, hindfoot, and then midfoot/forefoot, are vital to the gait mechanics used every day. The active phases of gait have been described as a three-rocker method indicating the importance of each of these joint complexes. The first phase involves the hindfoot as the heel strikes the ground with the hindfoot acting as the initial rocker as the ankle is slowly allowed to plantarflex, thus allowing the foot to purchase the ground. The second rocker is the ankle itself as the ankle goes from plantarflexion to dorsiflexion transferring the body forward to the midfoot/forefoot. Finally, the midfoot and forefoot work as the third rocker transition into swing phase. The intricacies of the foot and ankle make up along with the precision needed to carry out everyday activities making it evident how arthritic changes can have a significant effect on the mechanics.

Compensation of Adjacent Joints in Arthritic Ankle

When taking the above information into consideration, it becomes evident the importance of all joints working in sync to perform daily movements. When a major joint, such as the ankle, is limited with arthritis (Fig. 20.1), the compensation required by adjacent joints can be significant. The etiology of the arthritis and any residual deformities will have the largest effect on the adjacent joints, but ankle arthritis across the board, regardless of etiology, has shown similar changes to the biomechanics. The arthritic ankle not only has limited range of motion, making the 10° of dorsiflexion needed for a normal gait pattern unattainable, but also is usually contracted in an equinus [3]. Valderrabano et al. indicated in an end-stage arthritic ankle due to post-traumatic etiologies that the plantarflexion was reduced by 37.5%, ability of the hindfoot to invert was reduced by 28.4%, and the ability of adduction of the foot and ankle was decreased by 19.8% [4]. This type of data indicates the inability of the adjacent joints to compensate when the ankle joint is arthritic. With limitations of the ankle in the sagittal plane, compensation comes from the TNJ and adjacent midtarsal joints. The increased stress on these joints over time can lead to significant arthritic



Fig. 20.1 Anterior posterior weight-bearing radiograph displaying post-traumatic end-stage ankle arthritis

changes, again specifically at the TNJ. The STJ limitations to accommodate frontal plane compensation leave the hindfoot in a fixed valgus or varus position. This inability to compensate increases stress, which ultimately leads to increased arthritis. Finally, the inability of the midfoot and forefoot to accommodate in the transverse and frontal planes to fully transmit unequal ground forces changes the joint contacts and increases the stress to the midfoot, again accelerating arthritic changes. All of these changes significantly affect one's gait leading to increased medial ground reactive force during stance phase, increased percentage of gait which is in stance phase and increased cadence of gait. It is important to remember this is often unilateral at first with subjective pain symptoms that lead to compensation by the contralateral limb increasing likelihood of bilateral ankle arthritis at some point.

Effects on Adjacent Joints Pre- and Post-TAR

Understanding the effect a limited and arthritic ankle can have on the surrounding joints of the foot and overall function of the lower extremity magnifies the importance of having the ability to restore normal ankle function. With the advanced technology available today, including modern-generation ankle implants, the next question to ask is if and how replacing the ankle joint will affect the adjacent joints. In 2004 Coetzee and colleagues looked at 61 ankle replacements with at least 1-year follow-up to determine the total arc of motion of the foot and ankle, comparing these pre- and postoperatively [5]. The true ankle dorsiflexion doubled from preoperative to 1-year postoperative. The total tibiotalar ROM increased from 18.5° to 23.4°, while the foot ROM increased only 1.3° (6.6° to 7.9°). The total combined arc of motion of the combined foot and ankle complex increased from 25.1° to 31.3° at 1-year follow-up. These numbers indicate that prior to TAR the foot compensated for 27% of the dorsiflexion of the combined foot and ankle and after TAR that compensation dropped to 21% for dorsiflexion. The overall compensation of the foot when comparing with the combined foot and ankle complex of dorsiflexion and plantarflexion drops from 26% preoperatively to 25%. This data indicates that after TAR the entire range of motion of both the foot and ankle increased, though the amount of compensation required by the midfoot in the sagittal plane decreased [5]. Hordyk et al. looked at the sagittal plane range of motion of the ankle and midfoot before and after 33 revision TARs at a mean follow-up of 28 months. Their findings suggest an increase in mean ankle range of motion from 15.3° to 17.8° but surprisingly a decrease in average midfoot range of motion from 10.7° to 7.1° [6]. Seo et al. found four key differences in biomechanical functions observed in the TAR compared to ankle arthrodesis: faster walking speed; increased ROM in forefoot sagittal motion, especially dorsiflexion; increased hindfoot sagittal motion, especially dorsiflexion; and stronger ankle plantarflexion power. They concluded from a biomechanical perspective; these results indicate that TAR would be a more effective treatment for severe ankle arthritis compared to ankle arthrodesis [7]. The authors conclude that when a nonfunctional ankle is returned to a well-aligned and functional state the isolated ankle range of motion increases up to 15%, and due to the midfoot no longer having to compensate, the midfoot range of motion decreases nearly 30%, therefore indicating that a well-performed TAR may be protective to damaging midfoot forces. Limited data exists looking at isolated STJ motion before and after TAR, but in 2007 SooHoo et al. evaluated 4705 ankle arthrodesis and compared them to 480 TAR to determine the rate of secondary STJ arthrodesis. After a 5-year follow-up from index procedure, the rate of secondary STJ arthrodesis following an ankle arthrodesis was four times higher than after TAR (2.8% vs. 0.7%) [8]. In 2019 there was a study looking at 941 primary TARs that were followed and reviewed for progression of STJ arthritis, and it was determined that after 5-years only 2% (19/941) necessitated a secondary STJ arthrodesis. It should be noted that prior to TAR 60% of the 941 patients had significant STJ arthritis as deemed by the Kellgren-Lawrence grade of 3 to 4 [9]. Looking at this data anecdotally, conclusion can be

drawn that re-establishing an aligned and functional ankle joint also decreases deforming forces to the STJ limiting acceleration of STJ arthritis.

TAR may be protective in preventing further adjacent joint arthritis, but many times patients presenting with end-stage ankle arthritis will already have significant changes to the STJ and midfoot joints. Ancillary procedures to address these joints can be performed as needed. The general advantages of preforming adjunctive procedures at the same time as a TAR are obvious; single trip to the OR, surgical incision may be able to be planned to limit the number of incisions, single recovery, and non-weight-bearing period. The cons can be many and are similar to the risks of any surgery, but in the setting of a TAR, adjunctive procedure that may decrease survivorship of the TAR (i.e., STJ or TNJ fusions) should be done cautiously and perhaps in a staged manner. The main question is that limited data exists to allow us to properly predict how the adjacent joints, if already severely arthritic, will progress after TAR. Recently, Dekker et al. demonstrated that at least 30% of the clinical motion observed after TAA comes through the subtalar and talonavicular joints. Dekker et al. went further to publish assessment of hindfoot arthritis progression and risk following TAR at a minimum of a 5-year follow-up; they found that 60% of patients demonstrated no change in radiographic STJ arthritis. The modified Kellgren-Lawrence system was used to identify progression of peritalar hindfoot arthritis (Fig. 20.2). In their prospectively collected TAR cohort, they identified an 11% risk of conversion to STJ arthrodesis during the observed time frame. It was also stated that none of the patients without preexisting arthritis went on to have a STJ arthrodesis or STJ pain [10]. Lewis et al. evaluated the outcomes of 404 TARs performed with and without hindfoot fusion. They concluded TAR performed with ipsilateral hindfoot arthrodesis resulted in significant improvements in pain and functional outcome; in contrast to prior studies, however, overall outcome was inferior to that of isolated TAR [11]. Documented failure rate was also noted to be greater in the hindfoot fusion group (10.0%) vs. that in the control group (2.4%; $p < 0.05$) which was statistically significant [11]. This data provides key information for clinical and surgical decisions guiding joint reconstruction in addition to TAR.

Prissel et al. in 2017 looked at 399 consecutive TARs in which 41 had ipsilateral STJ arthrodesis performed for STJ arthritis [12]. The patients in the STJ arthrodesis group were matched 1:1 for age, gender, and prosthesis to compare outcomes. At the final follow-up, only 33 patients of STJ arthrodesis patients met the inclusion criteria. Seventy-nine percent of the STJ arthrodesis were performed prior to TAR, 12% simultaneously, and 9.1% after TAR. At the 2-year median follow-up, the experimental group of TAR with ipsilateral STJ arthrodesis had an 87.9% survivorship which was like the control group of isolated TAR. This study indicated no adverse effects noted when combining a STJ arthrodesis with TAR, though this study gives little indication as to the timing of the STJ arthrodesis. Additionally, this study demonstrates the paucity of cases which require adjacent joint fusions as only 10% of consecutive cases required STJ arthrodesis regardless of the timing of the fusion [12].

In 2010 Kim et al. published a review looking at 60 TARs with hindfoot fusions in comparison to a 288 isolated TAR control group [13]. Of the 60 hindfoot fusions, 39 were done simultaneously with the TAR, 17 were done at mean 8 years prior to TAR, and 4 done at a mean 14.3 months after TAR. The mean follow-up was 39.5 months, and all TARs were primary replacements. Of the 60 TARs with adjacent joint fusions, 28 were in conjunction with isolated STJ arthrodesis, 29 had STJ arthrodesis and TNJ arthrodesis, and 3 had triple arthrodesis with TAR. When comparing the groups of TAR with hindfoot fusion and isolated TAR, the authors found no significant difference in VAS scores pre- and postoperative. AOFAS scores were improved in both groups but were lower pre- and postoperative in the hindfoot fusion group when compared to the control group. The mean amount of ROM gained in the control group was 3.4° vs. 4.1° in the hindfoot fusion group. The level of overall patient satisfaction was similar in both groups with >90% in each group stating they would have the procedure again. The authors did break down TAR with hindfoot fusion group to compare outcomes of the isolated STJ arthrodesis with



Fig. 20.2 Modified Kellgren-Lawrence peritalar arthritis score of the hindfoot. Grade 0, no radiographic changes of the joint; grade 1, minor osteophyte formation with no joint space narrowing; grade 2, increased osteophyte formation with preserved joint space; grade 3, joint space narrowing and osteophyte formation; and grade 4, obliteration or severe sclerotic joint space changes

the combined group of double and triple arthrodesis with TAR. Interestingly the authors found no differences between these two groups in VAS, AOFAS, or ankle range of motion. This data led the authors to declare that hindfoot fusions should be performed with TAR when indicated and outcomes in these patients are similar to outcomes in patients who have an isolated TAR [10]. Palanca et al. found 1 in 84 patients following TAR had symptoms and required subsequent surgery as a result of adjacent joint arthritis in the STJ at a 15-year follow-up. However, they commented on the radiographic progression of arthritis into adjacent joints (14.3%) [14].

Manzi and colleagues looked at a small cohort of 11 patients who underwent simultaneous TAR with STJ arthrodesis and TNJ arthrodesis [15]. Average follow-up was 24.2 months and included postoperative CT scans at 12 months to assess arthrodesis sites. The authors had fusion rates of the STJ and TNJ at 12 months of 92% and 88%, respectively. Functional assessment of these patients also indicated an overall increase in ankle range of motion from 10.2° preoperatively to 30.8° postoperatively. AOFAS and VAS both showed statistically significant improvements postoperative when compared to preoperative scores. The authors concluded that TNJ and STJ arthrodesis at time of primary TAR is a reliable procedure when indicated. The added assessment of postoperative CT scans to verify fusion rates further indicates the success of these procedures when coupled together.

In 2016 Gross et al. published a comparative case series looking at TAR that later underwent triple, STJ, or TNJ arthrodesis [16]. The authors retrospectively reviewed 1001 primary TAR and found 18 that underwent STJ arthrodesis, 3 TNJ arthrodesis, 3 TNJ arthrodesis and STJ arthrodesis, and 2 that underwent triple arthrodesis. The mean follow-up was 70.9 months after fusion, and the mean time from TAR to secondary arthrodesis was 37.5 months. The overall fusion rate of all 26 patients who had secondary arthrodesis was 92.3%. The four operative failures were due to two nonunions and two delayed unions, three revision arthrodesis were also performed, and all of these went on to heal. The authors also indicated no secondary complications associated with the procedures. The authors indicated pain and functional scores both increased significantly with AOFAS improving an average of 15 points and VAS scores decreasing by roughly 50%. The authors then compared the outcomes of these 26 patients to 13 patients who had ankle arthrodesis performed followed by STJ arthrodesis that was published by Zanolli et al. [17]. In this study 61.5% of patients went on to nonunion suggesting patients with TAR are more likely to have successful adjacent joint arthrodesis than patients who undergo ankle arthrodesis.

Often times when evaluating a patient with ankle and adjacent joint arthritis, there are multiple deformities that may extend globally to the foot and ankle. For example, prior ankle fractures that have resulted in post-traumatic ankle arthritis may have healed in a varus or valgus position. Stage 4 posterior tibial tendon dysfunction (PTTD) will show midfoot collapse with valgus tilt of the talus and hindfoot. There is a difference between stage 4 PTTD and ankle valgus without flatfoot deformity; the ancillary procedures required for each will differ. Distal lateral tibial necrosis can occur resulting in collapse of the talar dome into the lateral tibia. This can be confused for deltoid incompetency, when really a stable medial soft tissue restraint is intact. Contrarily, stage 4 PTTD can demonstrate mild-appearing ankle valgus with complete deltoid ligament incompetency, when in reality osseous lateral impingement of the calcaneus on the distal fibula is preventing further progression of the ankle valgus. Rheumatoid arthritis can have similar effects with degeneration of the poster tibial tendon, causing collapse of the midfoot with abduction of the midfoot/forefoot. Neuromuscular disorders may result in a varus hindfoot and ankle with associated osteoarthritis. It is important to recognize these etiologies and deformities to be able to address which, if any, can be corrected with a TAR and which requires adjunctive soft tissue or osseous procedures.

TAR and Deformity Correction

Understanding that most end-stage ankle arthritis stems from post-traumatic arthritis, it is not uncommon to have malalignment, primarily in the frontal plane, at the ankle joint. There are instances when the correction obtained at the ankle joint during a TAR is sufficient to align the foot and ankle complex such that no further procedures to the adjacent joints are necessary. It should be noted when adjacent joint arthritis and subjective symptoms are evident, addressing only the ankle joint may not alleviate symptoms. Frontal plane deformities are the most predominate when discussing the ankle joint with varus deformities being more prevalent than valgus. Studies have shown that up to 44% of end-stage ankle arthritis presents with a malalignment greater than 10° of varus [18]. Ankle deformities typically occur in two patterns, one where the talus is tilted in varus or valgus due to ligamentous instability combined with deforming stresses of the hindfoot and midfoot and the other due to a congruent ankle but the tibial plafond is in a frontal plane deformity. When the deformity mainly involves the talus, adequate debridement of the ankle gutters to allow proper reposition of the talus with soft tissue plication and lengthening is typically all that is needed to properly align the joint followed by routine TAR implantation. When the tibial plafond is malformed, again typically in varus, then osseous cuts in the form of supramalleolar osteotomies or through the joint resection (i.e., uncoupled cuts), with or without soft tissue procedures,

are indicated to align the ankle joint in the frontal plane prior to implantation of the TAR.

In 2009 Kim and colleagues compared 23 ankles with a varus deformity of greater than 10° who underwent TAR with 22 ankles that were well aligned in the frontal plane who also underwent TAR. It should be noted that the varus deformity was mostly contained to the ankle joint (talus) itself in the 23 ankles. When the varus deformity was due to the talus with a well-aligned tibia, soft tissue procedures such as deltoid release, tibialis posterior tendon lengthening, and peroneal tendon transfers are performed. In the rare case, in this study, that the varus deformity was due to a varus tilt of the tibial plafond, supramalleolar osteotomies were performed. At a mean follow-up of 27 months, both groups had significant increase in overall satisfaction, and there was no statistically significant difference in clinical outcomes (AOFAS and VAS) between the varus groups in the neutral aligned group [12]. The authors concluded that TAR can be performed in ankles with deformity requiring minimal adjunctive procedures, and outcomes can be expected to be similar to those who undergo TAR in a well-aligned ankle.

In 2009 Hobson et al. looked at TAR in patients with significant preoperative hindfoot deformity [19]. They looked at 123 TARs, these were separated into two groups A and B. Group A consisted of 91 TARs all of which had a varus deformity of 10° or less, and Group B consisted of 32 subjects who all had a varus deformity >10° but not exceeding 30°. The mean follow-up of the study was 4 years, and the mean age of the patients was 64 years. Group B did have two patients that underwent preoperative hindfoot surgeries to correct deformity, one consisted of a calcaneal osteotomy and the other was the STJ arthrodesis. Seven staged procedures were performed postoperatively in Group B; there were four calcaneal osteotomies and three lateral ankle ligament reconstructions. The overall failure rate in both groups was 14.6%; there were 12 failures in Group A (13%) and 6 failures in Group B (19%). AOFAS scores at the last follow-up were 77 for Group A and 86 for Group B. Eighty-four percent of the ankles in Group B were within 5° of varus or valgus at the final follow-up which the authors determined to be a successful outcome. The authors of this study concluded that patients with varus malalignment of the ankle joint up to 30° may safely undergo TAR expecting to achieve similar outcomes as fellow patients with a neutrally aligned ankle [19].

Authors' Preferred Treatment

When considering the multiple high level of evidence and peer-reviewed studies, it is evident that patients overall tend to do quite well with preoperative deformity and adjacent joint arthrodesis in the setting of a TAR. Multiple questions though are still left without definitive answers. One of these main points is the timing of the adjacent joint arthritis correction. This is a difficult decision, especially when it is unclear if the adjacent joint is a source of pain or how significantly the adjacent joint is affecting the patient. A compounding factor to this is the inability to predict how the adjacent joints will respond after a TAR, if indeed they are already arthritic. The data supports the fact that stresses to the adjacent joints, in theory, should be decreased after a TAR and thus limit arthritic changes, but how this effects patient subjective pain scores is still undetermined.

The authors' preferred approach to this difficult problem is taken on a case-by-case basis but is usually done via staged reconstruction with deformity correction being a strongly influential variable (Fig. 20.3). If there is adjacent joint arthritis without significant deformity, the authors will use differential injections to apportion pain from each anatomic location. If it is judged that the ankle is the main pain generator, then the adjacent joints will not be addressed at the primary TAR with the expectation that improved motion will help stabilize and slow any ongoing degenerative change. If there is significant deformity requiring soft tissue reconstruction, then the foot deformity and ligament reconstruction is done at the first surgery and the TAR done as a staged approach, within 4 months of the index procedure. Often times the screws used for the STJ arthrodesis will need to be removed to make the talar cuts for the TAR, meaning the TAR is often delayed until osseous union has occurred across the STJ. The authors recommend a preoperative CT to verify osseous bridging across the STJ and then performing the TAR as soon as 8 weeks postoperative.

Although simultaneous fusion and TAR are done, the risk profile increases due to multiple incisions and length of the procedure. In these cases, care should be taken to limit open incision time to the anterior ankle wound to minimize risk of incision-related complications. If multiple incisions are required, strategically perform the ancillary procedures either before the anterior incision is exposed or after the anterior incision has been closed.

Severe medial column collapse and/or rigid forefoot varus may also be corrected by performing a TNJ arthrodesis, Cotton wedge osteotomy, Lapidus, or medial column fusion. Similarly, forefoot valgus can be corrected by TNJ arthrodesis, medial column fusion, or dorsiflexion first metatarsal osteotomy. This will provide a neutral rectus forefoot; therefore after the TAR, no external compensation for a forefoot deformity will be needed. As with hindfoot deformities, these midfoot/forefoot deformities can be corrected prior to TAR with arthrodesis in the setting of painful end-stage arthritis. Arthrodesis of an arthritic TNJ is acceptable in TAR as increasing the ankle range of motion will negate the need for TNJ sagittal plane motion to obtain proper dorsiflexion; this is a different story in ankle arthrodesis. In a midfoot

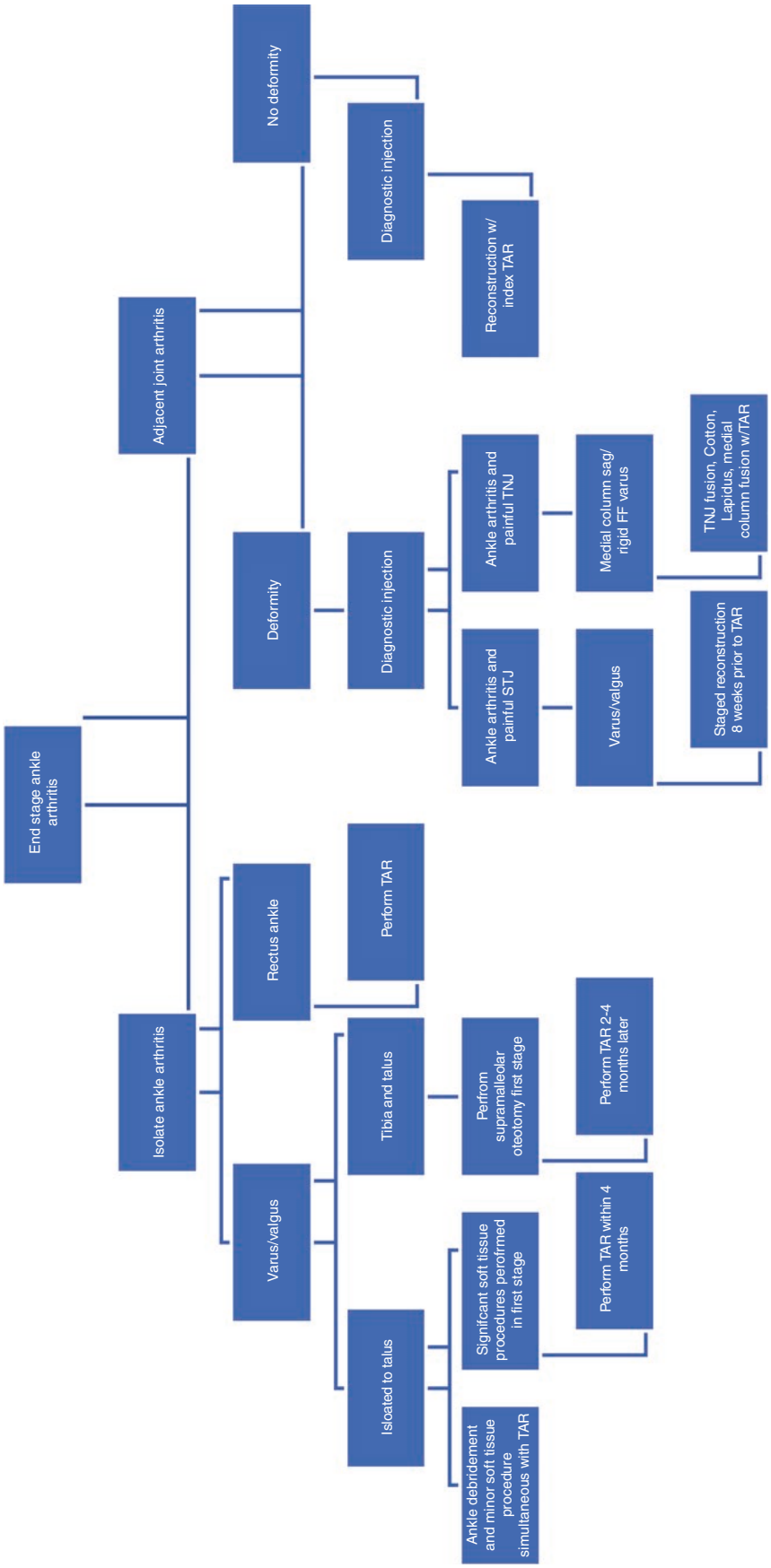


Fig. 20.3 Treatment algorithm for end-stage ankle arthritis with adjacent joint arthritis and/or deformity

arthrodesis, especially TNJ, there may be a minor concern of talar blood supply disruption; thus it is recommended to wait until osseous bridging is identified prior to performing the TAR when fusing first in a staged reconstruction. When there are arthritic adjacent joints with severe deformities that will need to be corrected to allow for proper function after the TAR, it is acceptable and even preferred in some cases to perform these via staged reconstruction prior to the TAR.

Case 1

A 54-year-old male who presented for workup of left ankle pain following a post-traumatic injury 30 years prior. He had developed post-traumatic arthritis which had begun to affect his ability to work and function. The patient had attempted multiple conservative modalities prior to being seen including high lace-up shoe gear, corticosteroid injections, NSAIDs, fixed angle AFO, and Arizona brace. Upon examination of the LLE, there were noted to be crepitus and pain through PROM of the left ankle, decreased ROM in both plantarflexion and dorsiflexion, gross swelling with point tenderness at the joint line, mild pain elicited with ROM of the STJ, ankle valgus of 5–10°, no hindfoot valgus, no collapse of the medial longitudinal arch, and stable medial ankle ligamentous complex.

Preoperative radiographs displayed severe degenerative arthritis post-traumatic in nature, bone-on-bone appearance of the lateral margin of the ankle joint and remodeling of bone including the anterior lip of the tibia, and early degenerative changes noted to the subtalar joint (Fig. 20.4).

It was ultimately decided between the surgeon and the patient that the best treatment would be to undergo an isolated TAR, using the corrective measures afforded in a TAR to best align the ankle/hindfoot. In this TAR an Integra Cadence total ankle system (Integra Life Sciences, Princeton, NJ) with size 3 tibial component, size 3 talar component, and 6-mm polymer were used (Fig. 20.5).

Case 2

A 59-year-old female presented with left foot and ankle pain of 20+ years and a history of rheumatoid arthritis. Patient did relate to a history of multiple ankle fractures that were treated conservatively with casting. Patient had been previously seen by outside providers and was advised she had progressing post-traumatic arthritis to her ankle and hindfoot likely necessitating an arthrodesis at some point. Patient is a community ambulatory who functions in an ankle brace daily with continued daily pain that she rated at a 7/10. As for adjunctive therapies, patient related to using NSAIDs daily for additional relief but had reached a point where she would like to discuss surgical reconstruction. Upon physical examination of the LLE, initial exam showed 5/5 strength to all major flexors and extenders with AROM. Significant pain was noted to the ankle joint complex LLE and with palpation of the ankle joint line and no crepitus with ROM of the ankle joint. Significant pain was also noted with ROM of the midfoot medial arch, localized to the TN joint. No pain was noted with palpation or range of motion of the subtalar joint.

After lengthy discussion with the patient about her most pressing symptoms and overall goals of treatment, it was decided to move forward with a staged approach to not only eliminate her midfoot pain but also replace her ankle. The initial procedure was a staged midfoot reconstruction with arthrodesis of the talonavicular and calcaneocuboid joints



Fig. 20.4 From left to right; weight-bearing lateral and anterior-posterior views of the left ankle



Fig. 20.5 One-year postoperative radiographs, weight-bearing lateral and anterior-posterior views; displaying neutral alignment of the ankle and implant with ingrowth of bone to the implant. No progression of STJ degeneration

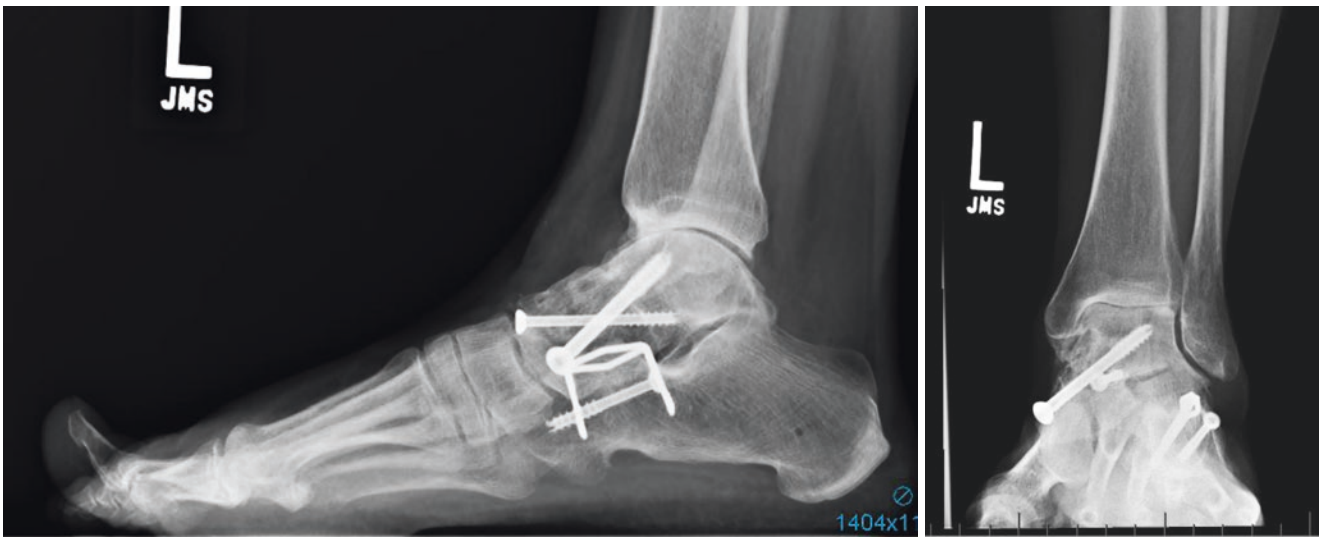


Fig. 20.6 Left to right: weight-bearing lateral and anterior-posterior radiographs after stage 1 showing changes consistent with screw and staple fixation of the calcaneocuboid and talonavicular joints. Solid bony fusion with hardware intact. Progression of ankle arthritis noted when compared to previous xrays

(Fig. 20.6). Patient transitioned through the recovery period of this initial procedure well and went on to solid osseous fusion. Patient returned for the second stage TAR at 2.5 years post op for the TNJ and CCJ fusions. The second procedure consisted of a left total ankle replacement utilizing the Infinity total ankle system (Wright Medical, Memphis, TN). A size 3 tibial component, size 2 talar component, and 6-mm polymer were implanted (Fig. 20.7).

Conclusion

Additional studies have also evaluated the progression of subtalar arthritis following TAR. Historically the advantages of TAR include preserved ankle ROM and reduction of adjacent joint arthritis [20]. Yet other studies evaluating adjacent joint arthritis following TAR note reduced instances in the ipsilateral extremity.

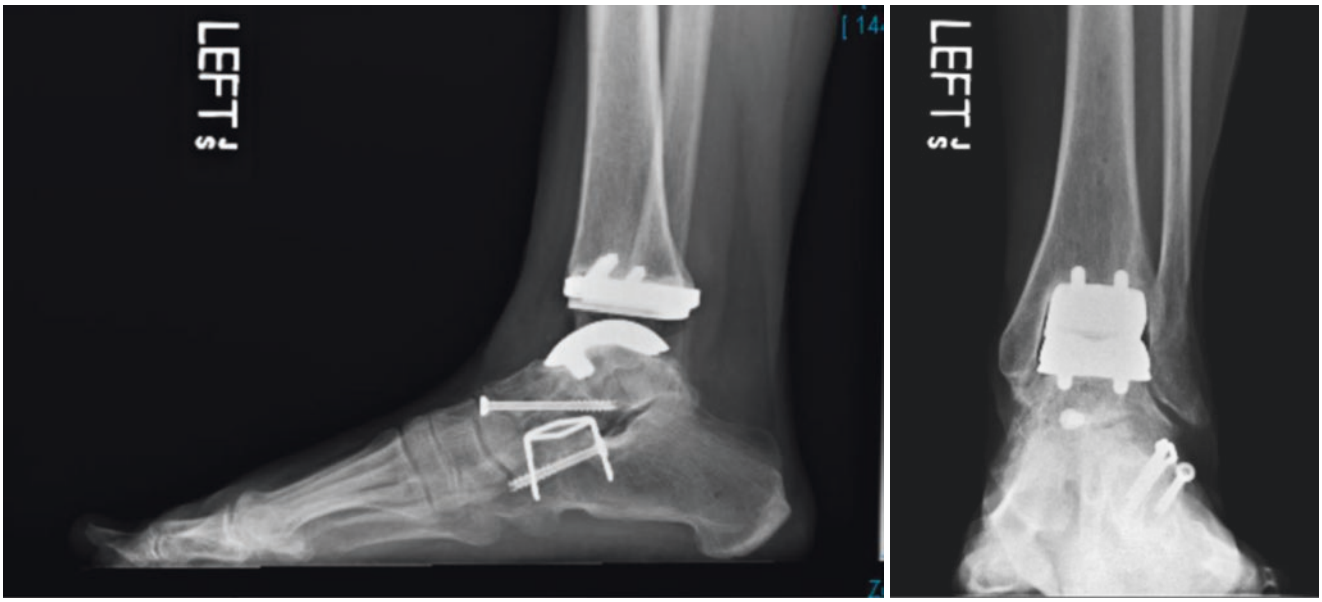


Fig. 20.7 Left to right: 2 years postoperative TAR non-weight-bearing anterior-posterior and lateral radiographs showing neutral alignment of the ankle and implant with ingrowth of bone to the implant. No progression of STJ degeneration. Continued screw and staple fixation of the calcaneocuboid and talonavicular joints. Solid bony fusion with hardware intact

In conclusion the foot and ankle have proven to be two separate complex anatomical structures that must work in sync to allow proper function. When the ankle becomes arthritic regardless etiology, there is a significant effect, not only on the function of the ankle but also on the surrounding joints. Performing a TAR in the setting of adjacent joint arthritis can pose multiple treatment questions that a surgeon needs to consider prior to operation. The literature has proven decreased stress to adjacent joints when a well-aligned TAR has been performed. In settings where adjacent joints are at ESAA or in complete deformity, data is available supporting that performing STJ arthrodesis simultaneously as the TAR does not appear to decrease the survival rate of the TAR. The authors' preferred method is to stage the procedures and multiple factors in determining whether the adjacent joint arthritis should be addressed prior to or simultaneously with the TAR. The main principles are to understand the ways an arthritic ankle can affect the adjacent joints and how regaining the ankle range of motion may benefit surrounding joints that are not already in rigid deformities. The authors find themselves performing staged procedures more often than not when dealing with adjacent joint arthritis and deformities in the setting of a TAR, though the patient's symptoms and deformities ultimately determine the timing of the surgeries. Regardless, each patient undergoing TAR with adjacent joint arthritis should have a prolonged and detailed discussion with their surgeon to determine which treatment protocol will result in the most predictable and functional outcome for the patient. As TAR continues to become the primary surgery for end-stage ankle arthritis, protocols and algorithms for addressing deformities and adjacent joint arthritis will also become more refined. Further literature is warranted to more clearly document the protective nature of TAR and its relation to worsening ipsilateral adjacent joint arthritis. TAR performed with ipsilateral rearfoot or midfoot arthrodesis results in significant improvements in pain, function, and quality of life with appropriate failure rates consistent with information provided in literature. Hence, when indicated, hindfoot and/or midfoot arthrodesis may be safely performed in conjunction with TAR.

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Managing Significant Varus and Valgus Malalignment During Total Ankle Replacement

21

Calvin J. Rushing, Bryon J. Mckenna, Christopher F. Hyer, and Gregory C. Berlet

Abbreviations

ATLAS	Anatomic lateral ankle stabilization
CLAI	Chronic lateral ankle instability
PTT	Posterior tibial tendon
TAR	Total ankle arthroplasty
TAR	Total ankle replacement
TT	Talar tilt
TTA	Tibiotalar angle

Introduction

The demand for total ankle replacement (TAR) has continued to increase among patients and surgeons alike, as studies have shown higher survivorship for newer prostheses, with better improvements in function, and higher patient-reported outcome measures (PROMS) compared to ankles treated with arthrodesis [1–4]. However, more than 50% of patients undergoing TAR have coronal deformity, which is the most common reason for additional concomitant procedures [5, 6]. Failure to adequately address coronal deformity at the time of TAR can result in asymmetric edge loading, polyethylene wear, and early implant failure; historically preoperative coronal deformity has been considered a risk factor for TAR failure [7–9]. Improved surgeon understanding regarding the importance of osteo-ligamentous balancing and refined techniques however have allowed for greater coronal deformity corrections with satisfactory outcomes [2]. The acceptable threshold of coronal deformity suited for TAR will likely continue to expand. In this chapter we detail stepwise algorithms for addressing severe incongruent coronal deformity during TAR.

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Varus Malalignment

Preoperative Radiographic Assessment

The radiographic assessment of varus ankle malalignment is made with weight-bearing anteroposterior (AP) radiographs using the tibiotalar angle (TTA) and talar tilt (TT) (Fig. 21.1). The TTA is defined as the angle between the longitudinal axis of the tibia and a line perpendicular to the talar dome, while the TT is defined as the angle formed between two lines tangent to the tibial plafond and talar dome. Negative angles denote varus alignment and positive angles valgus alignment [10]. To date, no consensus has been reached regarding what degree of coronal malalignment delineates minimal, moderate, and severe deformity [2]. For the purposes of this chapter, minimal, moderate, and severe coronal deformities are classified as a TTA of 5–10°, 10–20°, and >20°, respectively. Coronal malalignment is further subclassified as either congruent or incongruent, based on a TT of <10° or >10° [10]. Importantly, congruent varus ankle malalignment is typically amenable to correction through the TAR osseous cuts alone, while incongruent malalignment often necessitates additional concomitant soft tissue/osseous procedures in a single versus staged approach. Overall, the goal is to achieve a balanced ankle for the TAR prosthesis and a plantigrade foot posture, which help mitigate asymmetric edge loading, polyethylene wear, cyst formation, and TAR failure.

Preoperative Considerations

The presentation of severe varus malalignment (TT >20°) is most commonly incongruent (TT >10°). Unlike the mild to moderate varus ankle, "correction thru the joint" alone is often not achievable. Marginal osteophytes often need to be removed, and release of fibrosis in the medial and lateral gutters is required to allow resumption of a neutral position.

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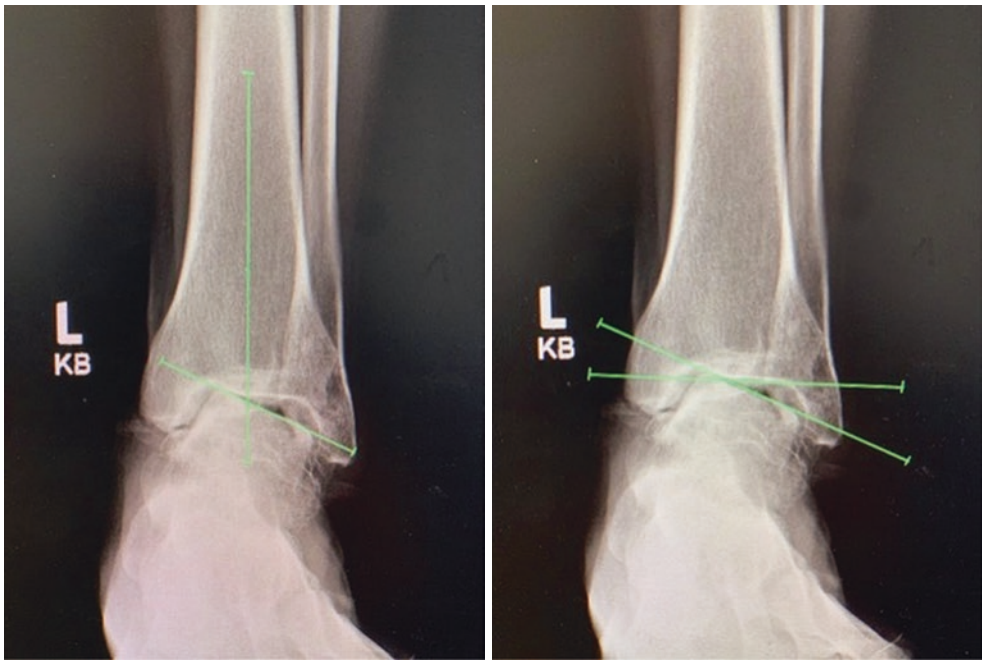


Fig. 21.1 Weight-bearing anteroposterior radiographs showing the TTA and TT. TTA is defined as the angle between the longitudinal axis of the tibia and a line perpendicular to the talar dome, while TT is defined as the angle formed between two lines tangent to the tibial plafond and talar dome

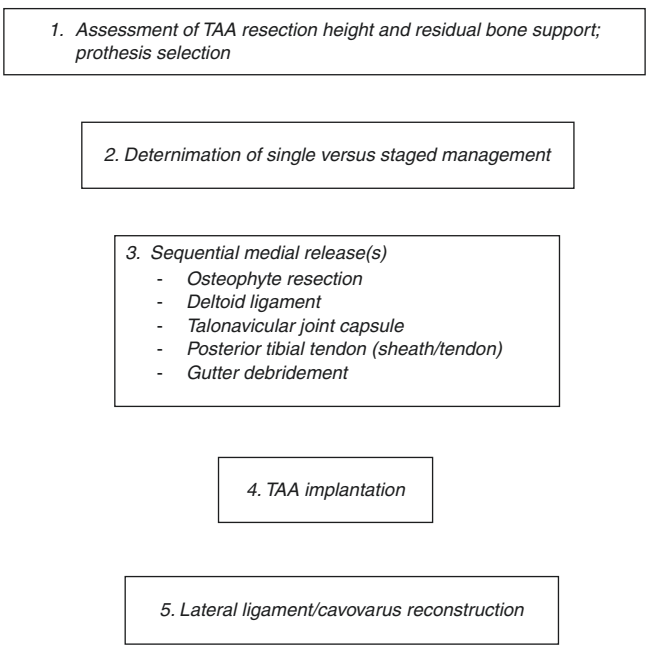


Fig. 21.2 Stepwise algorithm for determining single versus staged TAR in the varus ankle

This step prevents the utilization of preoperative computed tomography-derived patient-specific instrumentation, which is popular for mild to moderate, congruent deformities. Additionally, asymmetric wear medially can also vary considerably with an incongruent varus ankle and may necessitate additional resection(s) from the tibia/talus using "uncoupled TAR cuts." Additionally, soft tissue balancing of both static (lateral and medial collateral ligament) and dynamic stabilizers (posterior tibial tendon, peroneal tendons) through reconstruction, lengthening, or transfers becomes essential, as do other concomitant osseous procedures (Dwyer, first metatarsal dorsiflexion wedge osteotomy). With these considerations, the authors propose a stepwise algorithm which includes (1) assessment of the resection height and residual bone support for selection of the prosthesis, (2) determination of single versus staged TAR, (3) sequential medial release, (4) TAR implantation, and finally (5) lateral reconstruction and cavovarus deformity correction as needed (Fig. 21.2).

TAR Resection Height and Residual Bone Support for Prosthesis Selection

The first step in the proposed algorithm is an assessment of the planned resection height and thus residual bone support for resultant stress distribution(s) on the prosthesis. Aitken et al. found that with an intact subchondral plate, the distal tibia's elastic modulus ranged from 300 to 450 MPa [11]. With removal of the subchondral cortical plate however, a 50% reduction in the compressive resistance was observed, with virtually no compressive resistance remaining at a distance of 3 cm or more from subchondral cortical plate. Furthermore, Terrier et al. tested ankle joint reactive forces in a validated finite element analysis model using mobile- and fixed-bearing prostheses in seven tibia with maximum axial compression force during walking [12]. The authors found that bone support was mainly trabecular and was weakest posteriorly.



Fig. 21.3 Lateral radiograph showing appropriate anterior to posterior cortical coverage of the tibia after TAR

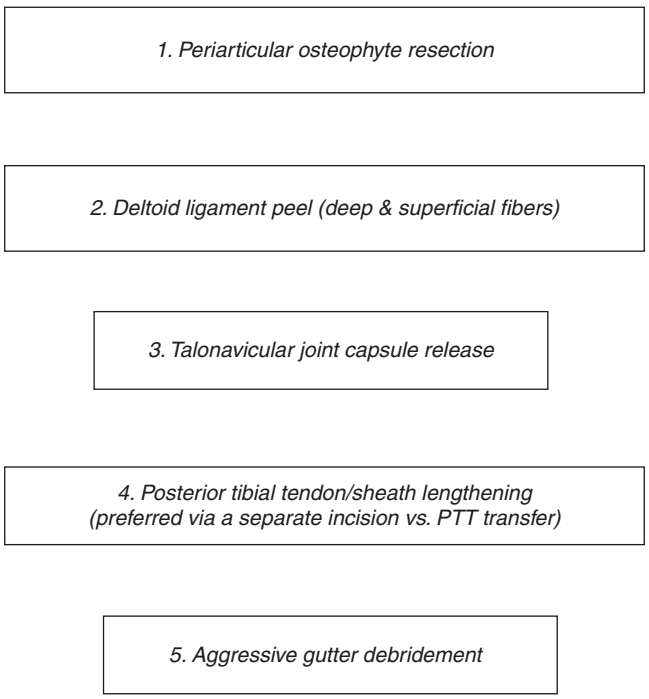


Fig. 21.4 Stepwise algorithm for sequential medial release of the severe varus malaligned ankle

From these studies, one may surmise that the volume of bone removed during TAR should be minimized and anterior to posterior implant coverage maximized to mitigate failure(s) from aseptic loosening or subsidence; however, the incongruent varus ankle may necessitate a higher resection using "uncoupled TAR cuts." In this scenario, a stemmed prostheses for the tibia is sometimes preferred by the authors over newer two-component, fourth-generation TAR prostheses, which are defined by minimal bone resection, peg or barrel fixation without stems in the distal tibia, and an anatomic contour that parallels the native talar articular geometry. Regardless of the prosthesis selected, adequate anterior to posterior cortical coverage of the tibia remains an essential tenant to long-term TAR survivorship (Fig. 21.3).

Determination of Single Versus Staged TAR

When determining single versus staged TAR in the severe incongruent varus ankle, foot and ankle surgeons are presented with a number of considerations which may include retained hardware, concomitant procedures, and the number of planned incisions. Cavovarus deformity, chronic lateral ankle instability (CLAI), peroneal tendon pathology, and contracture of the medial structures including the deltoid ligament, talonavicular joint capsule, and posterior tibial tendon should be anticipated and assessed intraoperatively, even in the setting of unequivocal clinical findings.

In many cases, the authors choose a single TAR approach involving sequential release of the medial structures, followed by implantation of the TAR prosthesis, and finally correction of any CLAI, peroneal tendon pathology, or cavovarus deformity (Fig. 21.4). However, in the presence of a significant retained hardware from previous trauma, such as a severe pilon injury, a rigid cavovarus deformity requiring arthrodesis type procedures, and/or significant midfoot/forefoot equinus with/without degenerative arthritis, staged management is preferred. Staged reconstruction of severe cavovarus deformity should be considered depending on the physiologic challenge that is appropriate for the patient, and case series is illustrated later on the chapter.

Sequential Medial Release

Sequential release of the incongruent varus ankle begins with complete osteophyte resection. Periarticular osteophytes tent the ankle joint capsule, preventing an accurate assessment of overall alignment while also blocking reduction of the talus laterally. Following the resection, a Cobb elevator may be placed inside the ankle to apply tension for assessment of medial-lateral gapping. Periarticular osteophyte resection alone is usually insufficient for release of even moderate malalignment, and lateral gapping warrants further medial release(s). Deltoid ligament release, also referred to as a "deltoid peel," is the next step in the sequential medial release and has been supported by biomechanical studies [13]. Release of both components of the deltoid, particularly the deep fibers, is essential to begin untethering the talus and closing down any lateral opening of the joint. This has been described as a release from the origin off the medial malleolus, insertion off the talus, or both [14]. Regardless, a

scalpel or curved osteotome should be used cautiously to prevent iatrogenic neurovascular injury.

Following the osteophyte resection and deltoid peel, reduction of the deformity should be attempted with a Cobb elevator or laminar spreader and the ankle pinned into position for fluoroscopic assessment. If the correction remains insufficient, additional sequential releases medially are indicated. These include both the talonavicular joint capsule, posterior tibial tendon sheath, and fractional lengthening of the posterior tibial tendon [6]. Although transfer of the posterior tibial tendon laterally to the peroneus brevis has been described, no evidence supporting the superiority of transfer versus release has been published. The authors prefer a release of the posterior tibial tendon through a separate incision, owing to the procedure simplicity, effectiveness, and time involved.

When the above sequence fails to appropriately realign the talus, aggressive medial and lateral gutter debridements are performed. During the sequential releases, it is possible for hypertrophied, elongated, lateral collateral ligaments to become interposed in the lateral gutter, blocking the reduction of the talus back into the mortise. Once aggressive gutter debridement is complete, manual manipulation of the talus into the mortise with an osteotome or lamina spreader is usually possible. If so, provisional fixation is placed for repeat fluoroscopic assessment. In a few instances, a medial malleolar osteotomy, described by Doets, may ultimately be required to allow for TAR implantation [15]. With anterior subluxation of the talus, an Achilles tendon lengthening is also often performed.

Reconstruction Following TAR Implantation

After balancing of the ankle and implantation of the TAR prosthesis, CLAI often remains. To address this residual instability, a modified Bröstrom procedure, modified Chrisman-Snook, and transfer of the peroneus longus to the fifth metatarsal base have been previously described [16]. However, the authors preferred a technique that utilizes a synthetic graft in a "Y"-shaped configuration for anatomic reconstruction, referred to as ATLAS (anatomic lateral ankle stabilization) procedure [17]. A study comparing the outcomes between the ATLAS and modified Bröstrom-Gould procedure in TAR is currently underway at the authors' institution. Finally, peroneal tendon pathology and cavovarus deformity are addressed.

Staged Varus Reconstruction: Case Example

The decision to perform a staged reconstruction is a case-by-case decision and in many cases may be the surgeon's preference in the severe deformity that requires extensive soft tissue grafting or transfers or particularly in cases when adjacent joint fusions are required. In some cases of profound cavovarus hindfoot deformity, either a subtalar joint or talonavicular fusion or both is needed to provide adequate correction of deformity. It is some surgeon's preference to stage the realignment and reconstruction first, perform the releases and rebalancing procedures as listed above, and use a cement wedge spacer and temporary pin fixation to keep the ankle balanced while the adjacent procedures heal. This is particularly the case when adjacent fusions are needed. It is felt this staged technique allows for the talus to heal the insult of joint prep from the fusion, allows the soft tissue reconstruction to heal around a balanced ankle, and will allow the later second stage of TAR to be a simpler and more direct primary technique (Fig. 21.5).

Valgus Malalignment

Preoperative Evaluation

The incidence of arthritic ankles with valgus deformity is approximately 8%, far less than the 55% of varus deformity [18]. Preoperative valgus deformity has demonstrated a more negative influence on implant survival than neutral or even varus deformity [19]. Similar to what was previously described regarding varus deformity, a TT greater than 20° is considered a severe deformity (Fig. 21.6). Knupp et al. described a technique for measuring the amount of talar tilt within the ankle joint. Using this method, they were able to classify asymmetric ankle joints as congruent or incongruent. Less than or equal to 4° of tilt was defined as a congruent ankle joint (type I), while greater than 4° was considered incongruent (type II). Based on these definitions, they were able to propose an algorithm for guiding treatment in correcting varus and valgus deformities of the ankle using supramalleolar osteotomies (SMO), as well as other ancillary procedures as dictated by the patient's individual deformity [20–22].

The preoperative evaluation for a valgus ankle starts with the clinical exam. The clinical exam is crucial for determining the alignment of the ankle and hindfoot, any degree of instability and reducibility, equinus and forefoot pronation/supination and compensation, as well as any surrounding joint arthritis. A thorough clinical exam will help the provider determine what the driving force behind the deformity is and what correction is required in order to implant a well-balanced and stable implant in the ankle. In many cases of valgus ankle deformity, underlying medial column instability, significant pes planovalgus foot deformity and/or deltoid ligament instability or failure could be at play. Surgeons are advised to take extra effort to fully evaluate the foot and



Fig. 21.5 Staged TAR in the varus ankle. Severe preoperative ankle and hindfoot varus was noted with associated severe lateral ankle ligament compromise. Stage 1 included a soft tissue release and reduction of the ankle joint supported by temporary Steinman pin fixation and a wedged cement ankle space, a synthetic graft Watson-Jones type lateral ankle reconstruction, a Dwyer calcaneal wedge osteotomy with lateral shift, and a realignment STJ fusion. CT scan at 10 weeks confirmed excellent fusion of the STJ and confirmed hardware could be removed if needed. At 12 weeks, stage 2 was performed with removal of the cement spacer and temporary pin fixation, a primary TAR replacement and removal of the anterior STJ fusion screw. WB radiographs at 1 year reveal maintenance of correction

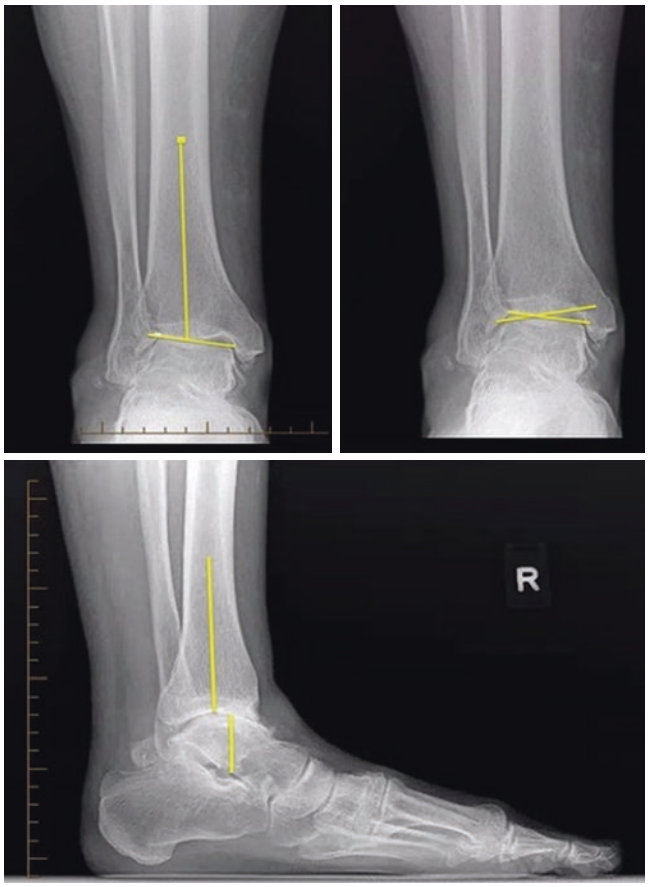


Fig. 21.6 Incongruent valgus ankle with anterolisthesis of the talus of within the ankle mortise

ankle both in weight-bearing and non-weight-bearing positions and carefully consider the influence of these other pathologies.

Ligament Stabilization and Rebalancing

Soft tissue rebalancing in a valgus ankle can often be a challenging issue and many times requires a staged procedure in order to rebalance the ankle and correct any deformity of the foot under the ankle. It is the experience of the authors that if a deltoid reconstruction is required, a staged procedure is preferred and a TAR is performed only when the reconstruction is deemed successful. A stepwise approach can be instituted when addressing a valgus deformity at the same time as performing a TAR. The final goal for rebalancing the ankle is to obtain a neutral position of the talus within the ankle mortise prior to implantation of the TAR.

Frequently release of the lateral tissues is usually not required for positioning the talus underneath the tibia, unlike in a varus deformity. However, if it is required, it is the preference of the senior author to place a Cobb elevator along the lateral wall of the talus and release the ligamentous restraints in a sleeve. If a medial ligament (deltoid) reconstruction is required, this is done in a staged procedure prior to the TAR. An Achilles tendon lengthening is almost always performed, typically with a Hoke triple hemi-section technique, but a gastrocnemius recession may also be performed in certain cases.

Tendon transfers have been described to augment rebalancing of the soft tissues as well including transfer of the peroneus brevis to the posterior tibial (PTT) tendon or simple release of the peroneus brevis. Flexor digitorum longus (FDL) tendon transfer to the navicular is often utilized to augment any repair and advancement of the PTT. The following stepwise, sequential approach is used by the senior authors when rebalancing the ligaments in a single-staged manner is possible:

1. Removal of periarticular osteophytes
2. Lateral soft tissue release as needed
3. Lateral gutter debridement
4. Tension the ankle with laminar spreader to assess the need for deltoid reconstruction
5. Deltoid reconstruction as needed
6. PTT advancement/FDL tendon transfer to navicular as needed

Between each step, assessment of the reducibility of the deformity is performed prior to advancing to the next step.

Deltoid Reconstruction

As mentioned above, if a deltoid reconstruction is required, this is preferred to be done in a staged manner. Only once the initial procedure is determined to be successful and the ankle has been rebalanced appropriately will a total ankle implant be placed. When assessing deltoid insufficiency, the preoperative evaluation and decision-making are critical, assessing for clinical and radiographic reducibility of the valgus deformity, measuring the TT angle as previously described, and assessing for anterior translation of the talus within the tibiotalar joint alignment as shown below. Often times, the talus will "kick stand" against the fibula, masking the true severity of the valgus deformity and making the deltoid appear more functional than its state. One must be very cautious with this deformity, and if kick standing of the talus is noted, this a major indication to perform a staged deltoid reconstruction or even further consideration of arthrodesis.

Preoperative advanced imaging including MRI, weight-bearing CT scan, and stress radiographs are often utilized to assess the integrity of the medial soft issues and deltoid ligament complex.

It is the experience of the senior authors that when a deformity requires a deltoid reconstruction, utilization of the

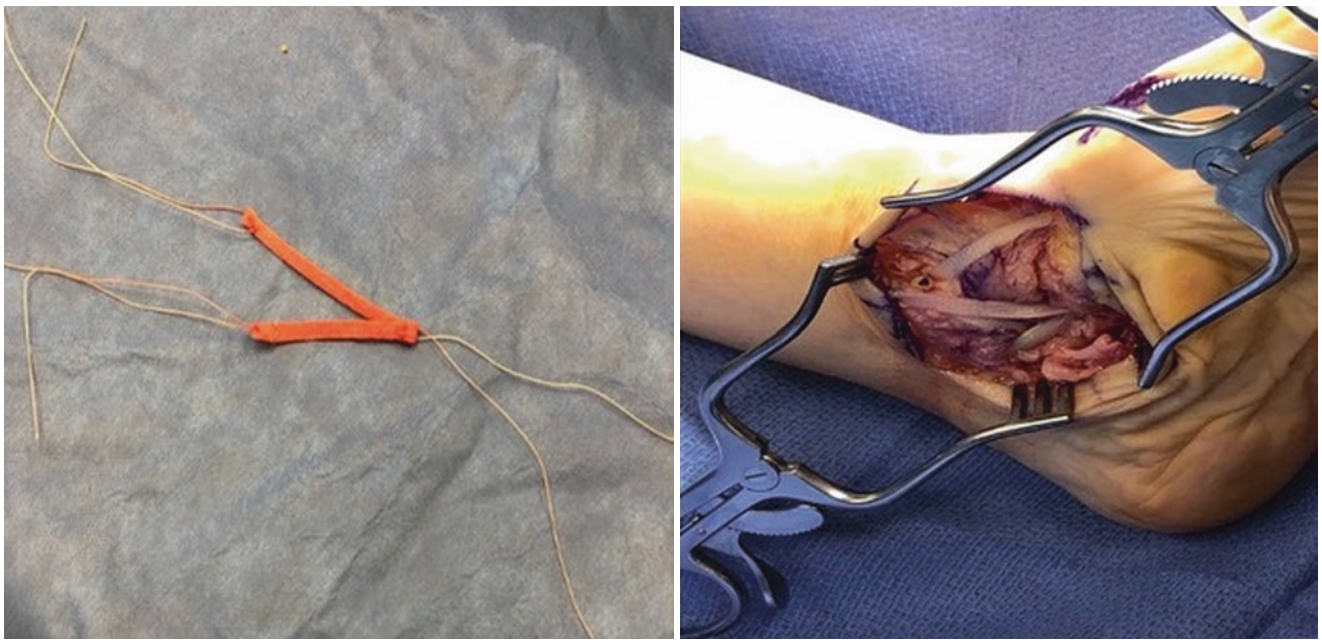


Fig. 21.7 Y configuration of synthetic absorbable allograft utilized to augment the deltoid reconstruction. The double arm is implanted into the medial malleolus and fixated with an interference anchor. The length bias is approximately 2:1 with the longer arm implanted into the navicular. The FDL tendon is transferred to the navicular as well and fixated with one interference anchor. The calcaneus arm implanted into the sustentaculum tali through a blind tunnel technique. (Photo Credit: Mark Prissel, DPM)

patient's natural tissue is insufficient for long-term results and can end in early failure. Typically, reconstruction is augmented with an allograft or synthetic graft material to bolster the repair and allow for appropriate medial ankle stability with implantation of a TAR. It is the preference of the authors to utilize a degradable synthetic allograft to perform this reconstruction; this is into a "Y configuration" and tensioned appropriately from the distal aspect of the medial malleolus in to the talus and calcaneus as pictured below (Fig. 21.7). Similarly, as discussed in the staged varus reconstruction, with a full deltoid reconstruction performed in a staged fashion, a wedge cement spacer splinting the ankle to neutral or even slight varus is used with additional temporary Steinman pin fixation. The other ancillary procedures are then used and built around the neutral ankle.

The PTT is evaluated, all pathologic tendon is debrided, the tendon is advanced and reattached to the navicular, and the FDL tendon is often transferred to the navicular as well. In the same sitting, close evaluation of the spring ligament is performed, and direct repair of the spring ligament is executed if needed with absorbable suture. When severe deformity is present, difficulty with rebalancing is experienced and a stage procedure is performed, polymethyl methacrylate cement with pinning of the joint into a neutral position is performed to protect the reconstruction (Fig. 21.8).

Once rebalancing of the hindfoot is achieved, a critical evaluation of the forefoot is essential to assess for unmasking of forefoot varus. If the medial column is unstable and/or a forefoot varus is unmasked, collapse of the medial column will ensue and loss of implant stability will result. When instability of the medial column is observed, a plantarflexory procedure must be done in order to prevent this from occurring. The recommended procedure is based on any other pathology present, the severity of the instability, and patient expectations. Often times, the authors will utilize either a Cotton osteotomy of the medial cuneiform or a plantarflexory first tarsometatarsal joint fusion to achieve this.

Component Selection and Stabilization

Prosthesis selection is critical when addressing valgus deformity. Often times, the TAR prosthesis itself is utilized in addressing the deformity and allowing the surgeon to provide further stability and augmenting the correction of the deformity. It is the authors experience that for these cases, utilization of a fixed-bearing implant increased stability. Commonly, a larger polyethylene insert is utilized in order to place tension on the ligaments to help limit recurrence of the deformity. Care must be taken to avoid altering the joint line when anticipating the use of a larger polyethylene insert. After implanting the trial polyethylene insert, intraoperative assessment both clinically and radiographically must be performed to assess coronal plane stability of the ankle while

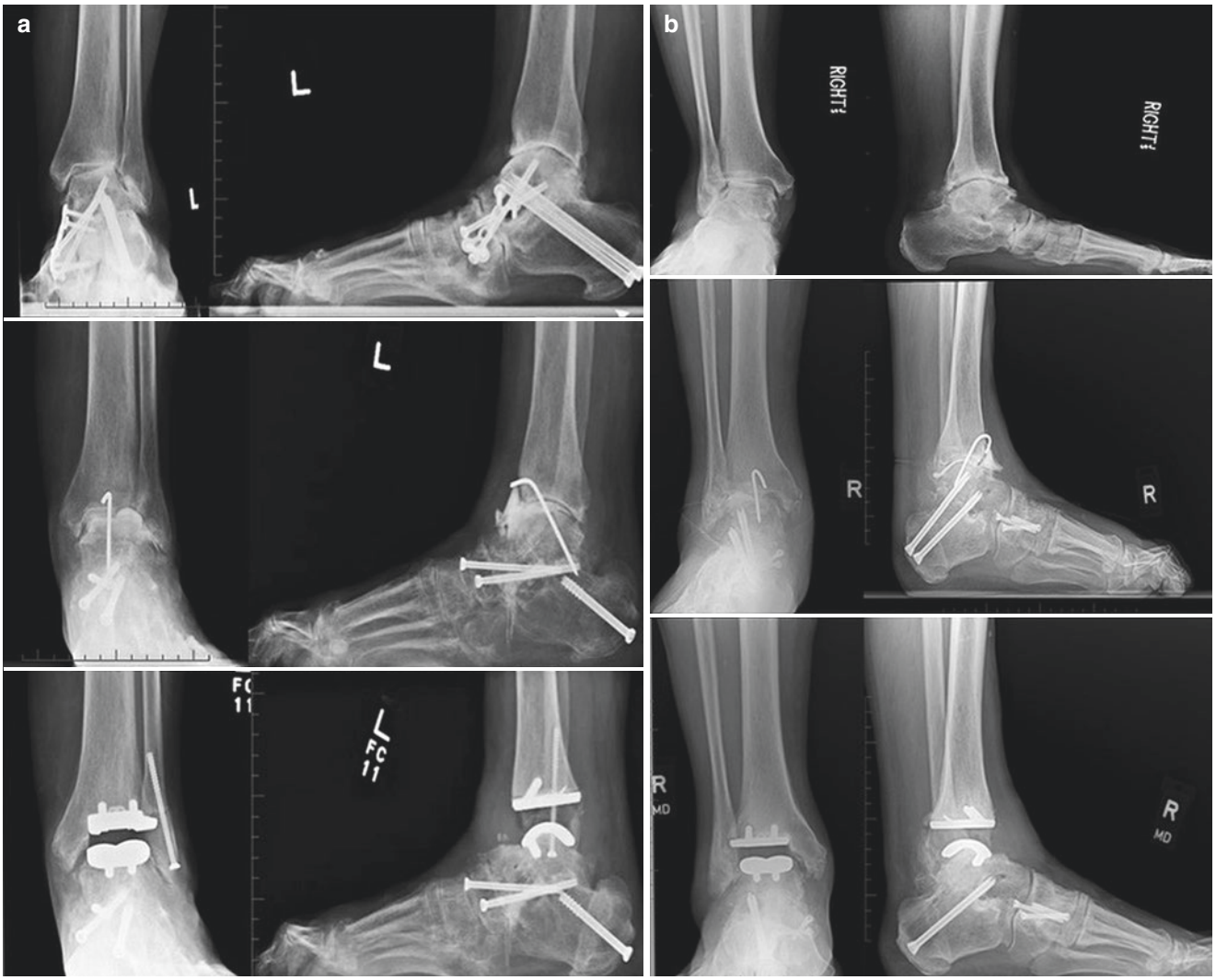


Fig. 21.8 (**a**, **b**) Staged valgus ankle reconstructions with placement of cement spacer in the ankle and pinning the ankle in position followed by total ankle replacement, two separate cases

allowing appropriate sagittal range of motion to allow propulsive gait.

Determination of Single Versus Staged TAR

A valgus ankle is more likely to require a staged procedure than a varus ankle given the difficulty with rebalancing the ligaments in the setting of deltoid insufficiency. Indications for a staged procedure include the need for deltoid reconstruction, fusion of the hindfoot in order to correct pes planovalgus deformity, need for tendon transfer, and finally patient selection and expectations. The postoperative protocol is an important consideration for determining when to stage a deformity correction and when to execute all procedures in a single stage. If the postoperative protocol requires a significant amount of time for non-weight-bearing, a staged approach may be indicated.

Outcomes

In a prospective observational study by Queen et al., no significant difference in clinical outcomes between patients with severe varus or valgus deformity was seen compared to those with neutral alignment following primary TAR [23]. In a systematic review, de Keijzer et al. evaluated the influence of preoperative tibiotalar alignment in the coronal plane on the survival of total ankle replacements. Included in the review was 17 studies, with 1692 primary TARs with a mean follow-up of 52.4 months. Preoperative tibiotalar angle greater than 10° was considered either varus or valgus. The results strongly indicated similar survival rates between varus deformity and neutral deformity; however, demonstrated preoperative valgus deformity had a negative influence on primary TAR survivorship [24].

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22 Managing Soft Tissue Ankle Equinus and Anterior/Posterior Translation of the Talus During Total Ankle Replacement

Nikolaos Gougoulias, Thanos Badekas, and Nicola Maffulli

Introduction

Ankle osteoarthritis is usually post-traumatic and accompanied by osteophyte formation (usually in the distal tibia, medial malleolus, and talar neck), capsular thickening, and ligament and muscle contractures, resulting in reduced range of movement. By the time total ankle replacement (TAR) is indicated, the ankle joint will be stiff and probably deformed. Deformity can affect all planes, and a common feature of ankle arthritis is the anterior translation of the talus in relation to the tibia in the sagittal plane [1–4]. Furthermore, reduced ankle dorsiflexion can result in calf muscle tightness and equinus contractures, over the years. Given the complex biomechanics of the hindfoot and its unique anatomic features, balancing of the TAR prosthesis in those situations is challenging. The small size of the talus does not allow extensive bone resection. Most importantly, distal tibia bone resection has to be kept minimal to reduce the risk of medial malleolus fracture (intra- or postoperative) and also to allow better quality of the bone for fixation of the tibial insert [1–4]. Malpositioning of the implants and "edge loading" of the TAR should be avoided, because this would lead to early failure [5–7]. Little is written regarding the surgical management of this challenging situation.

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Diagnosis of Anterior/Posterior Translation of the Talus

Anterior or posterior translation of the talus in relation to the tibia is appreciated on lateral weight-bearing ankle radiographs (Fig. 22.1). Obvious incongruity of the ankle (tibiotalar) joint (Fig. 22.1) is diagnostic of "translation of the talus." To quantify malalignment in the sagittal plane, the "tibiotalar ratio" has been proposed as a measure of translation of the talus, taking into consideration the position of the talus in relation to the tibial axis in lateral weight-bearing ankle radiographs [8, 9]. The tibiotalar ratio is the percentage of the length of the talus that lies behind the center of the tibia on the lateral weight-bearing radiograph (Fig. 22.1). The average tibiotalar ratio in a cohort of healthy ankles was 40° [8, 9]. The smaller the tibiotalar ratio, the more anteriorly subluxed is the talus. A tibiotalar ratio of more than 50% indicates a posteriorly displaced talus in relation to the tibia (Fig. 22.2). Comparison of pre- and postoperative measurements using the tibiotalar ratio helps in defining whether the talus has been reduced in a more anatomical position after



Fig. 22.1 The tibiotalar (TT) ratio (AX/AB %) is the percentage of the length of the talus that lies behind the center of the tibia on the lateral standing radiograph [8, 9]. In this case the TT ratio was 21%

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TAR (Figs. 22.3 and 22.4). Another radiographic measurement used to assess accuracy of placement of the components of the TAR in the sagittal plane is the inclination of the tibial insert in relation to the long axis of the tibia (Fig. 22.5) [8, 9]. Normal values are considered those between 83° and 90°; otherwise, the TAR is described as "backward facing" if the angle of inclination is higher than 90° or "forward facing" if the angle is less than 83° (Fig. 22.6) [8, 9].



Fig. 22.2 A TT ratio of 55% indicates a posteriorly translated talus

Pathomechanics of Anterior/Posterior Translation of the Talus

The pathomechanics of sagittal plane malalignment, clinically presenting as anterior or posterior translation of the talus in relation to the tibia, is not clear, whereas anterior is more common than posterior translation of the talus in arthritic ankles [8–12]. Sometimes, anterior tibial erosion or collapse after a tibial plafond fracture may result in increased anterior inclination of the tibia that allows the talus to slide forward. One explanation could be that distal tibia osteophyte formation and anterior capsule thickening restrict dorsiflexion and the talus is thus loaded in a relatively plantar-flexed position during gait. This means the posterior part of the talus is loaded. Thus, forces are "pushing" the talus anteriorly leading also to stretching of the anterior talofibular ligament. This "vicious cycle" can eventually lead to

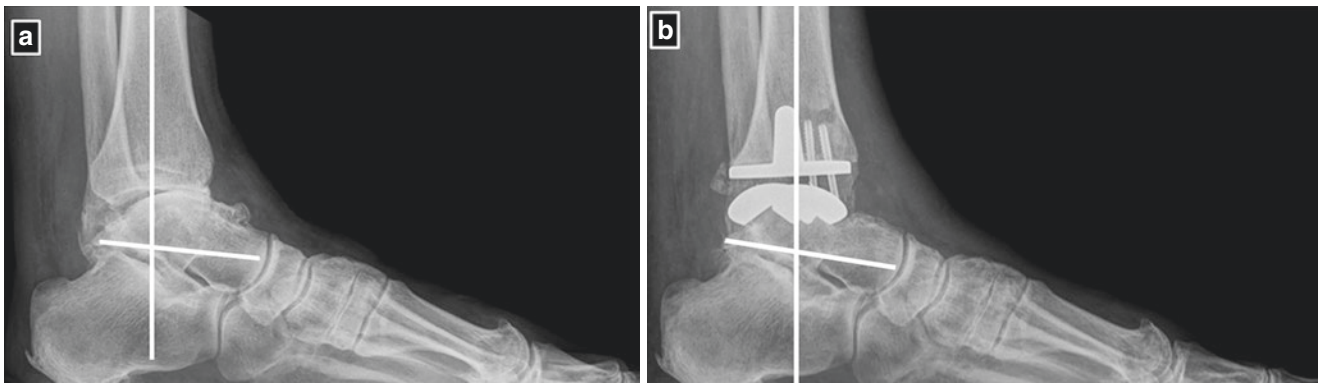


Fig. 22.3 An anteriorly displaced talus (**a**) (TT ratio = 34%) was corrected to a more neutral position (**b**) (TT ratio = 42%), performing a total ankle replacement

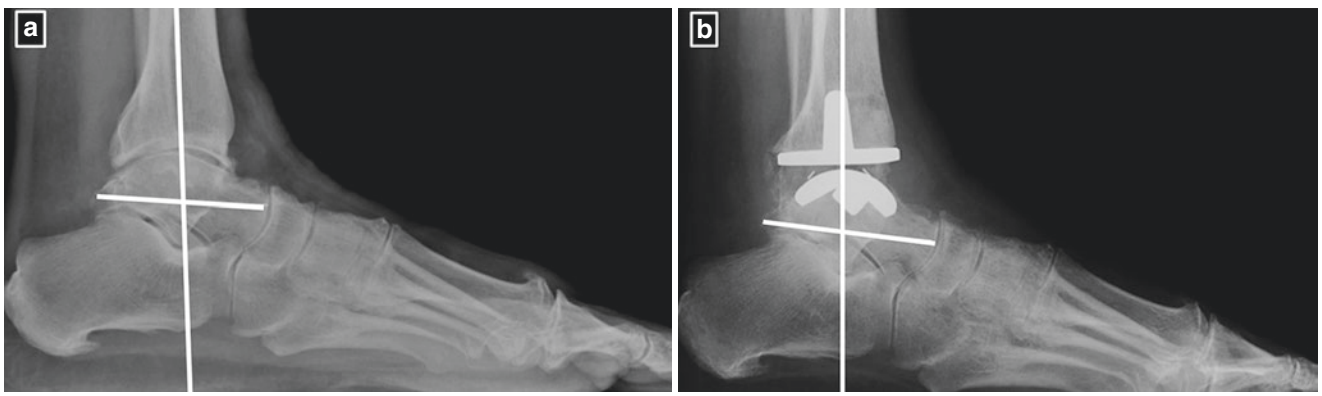


Fig. 22.4 A posteriorly displaced talus (**a**) (TT ratio = 52%) was corrected to a more neutral position (**b**) (TT ratio = 46%), performing a total ankle replacement



Fig. 22.5 The inclination of the tibial insert in the sagittal plane is measured in relation to the long axis of the tibia (angle *y*). It should be approximately 90° [8, 9]



Fig. 22.6 Excessive posterior inclination of the tibial insert in this Scandinavian total ankle replacement prosthesis ($y = 73°$) resulted in anterior translation of the talus (TT ratio =30%)

increasing the "anterior opening" of the ankle and the fixed deformity in the sagittal plane [13, 14]. We have observed (unpublished findings) that it is more common to have an anteriorly translated talus in arthritic ankles without anterior



Fig. 22.7 Chronic instability, loss of cartilage, and tibiotalar joint congruity resulted in gradual "flattening" of the tibial and talar opposing joint surfaces

osteophytes. Thus, it is possible that anterior distal tibia and talar neck osteophytes stabilize the talus in the sagittal plane.

Another mechanism (probably the most common cause of anterior translation of the talus) is that of the deficient lateral ligaments failing to resist the forces applied to the talus during gait and weight-bearing; thus, the talus translates anteromedially. This could eventually lead to deltoid ligament contracture and varus alignment in the frontal plane and, at the same time, in anterior translation of the talus in the sagittal plane. Furthermore, with the lateral side of the talus sliding forward "outside the ankle," there is progressively flattening of the tibia and talus losing their circular surface congruity (Fig. 22.7). This leads to further deterioration of talus translation. As chronic lateral instability is probably the most common cause of ankle arthritis, chronic lateral ligament insufficiency may well be the primary cause that explains the pathomechanics of anterior translation of the talus in arthritic ankles. The potential stabilizing effect of osteophytes formation, mentioned earlier, supports the latter pathomechanical hypothesis.

Ankles with frontal plane varus alignment (as a result of lateral ligament deficiency) are often malaligned in the sagittal plane, as well. We have also observed that younger patients or those with post-traumatic arthritis related to intra-articular fractures rarely present with anterior/posterior translation of the talus. This could mean that for these changes to occur, "posterior edge loading" of the talus is needed for longer periods, in combination with ligamentous instability. The above should be taken into consideration when performing TAR, to allow balancing of the ankle and optimal positioning of the prosthetic components.

Anterior translation of the talus results is reduced dorsiflexion and after some time in tightness of the posterior structures (joint capsule, gastrocnemius and soleus muscle, and Achilles tendon contractures). Thus, ankles with anterior

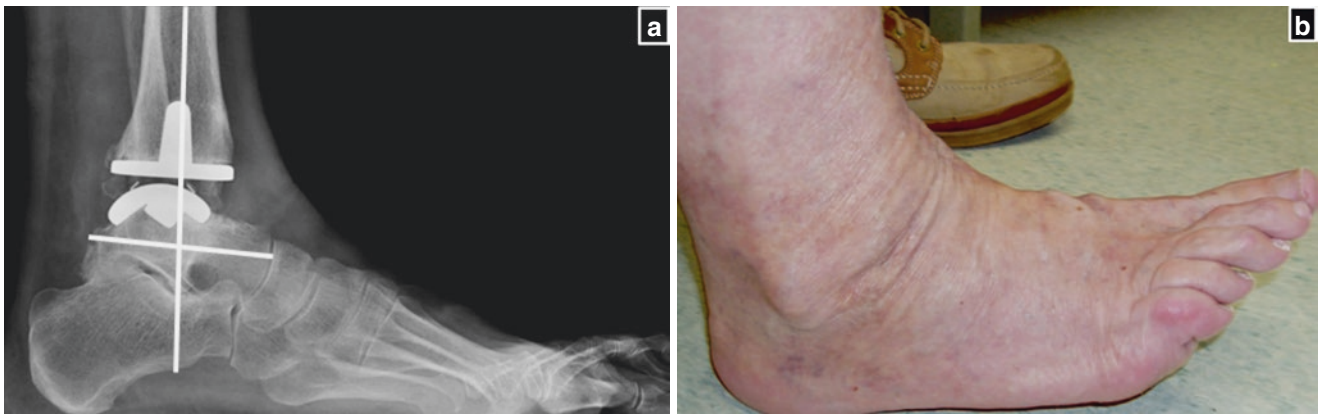


Fig. 22.8 In this case the talus was placed slightly posteriorly with a TT ratio of 50% (**a**). Although the patient was satisfied with the outcome, his ankle dorsiflexion was relatively limited (**b**)

translation of the talus may often present with equinus contractures, as well.

Posterior translation of the talus (Fig. 22.2) is less common, and no specific pathogenetic mechanism can be proposed. It could be related to anatomic abnormalities (e.g., post-traumatic after injuries involving the posterior malleolus or the posterior tibiofibular ligament) or could be iatrogenic from posterior placement of the talar prosthesis (Fig. 22.8). This will be discussed later in this chapter.

Diagnosis and Pathomechanics of Ankle Equinus

The mechanism of developing ankle equinus is probably simpler. Reduced dorsiflexion in arthritic ankles results in altered gait kinematics (reduced calf muscle stretching during heel strike) and, over time, in calf muscle tightness and contracture. Tightness may affect the gastrocnemius muscle only or the gastrocnemius-soleus complex and the Achilles tendon. Clinically this can be detected by performing the Silfverskiöld test [15]. The test is based on the fact that the gastrocnemius is attached on the femoral condyles. When the knee is extended and the ankle cannot be dorsiflexed beyond neutral, the test is considered positive for calf muscle tightness. Knee flexion will release a gastrocnemius contracture, allowing dorsiflexion of the ankle, whereas it will make no difference when gastrocnemius-soleus and Achilles tendon contracture is present [15]. Usually in arthritic ankles, the gastrocnemius-soleus complex is affected. The test is also performed intraoperatively when performing a TAR to assess residual equinus contracture.

Surgical Considerations and Results of Anterior/Posterior Talus Translation During Tar

General Considerations

The most common primary cause of anterior talus translation is probably the anterior talofibular ligament deficiency, whereas secondarily deltoid ligament contractures may develop. Furthermore, the anterior joint capsule is thick and tight. One has to think in three dimensions and realize that we are dealing with an anteromedial translation of the talus; therefore, release of the medial structures (e.g., resection of osteophytes and scar tissue, release and partial detachment of the deltoid ligament) plays a key role. It is important to remember that reduction of the anteriorly translated talus under the tibia is essential in ankle arthrodesis, as well. In performing ankle arthrodesis, in an open or arthroscopic fashion, to realign the ankle, the surgeon produces more space by resection of the osteophytes and residual cartilage first and then by clearing the medial gutter. One will find that, if the medial gutter is not clear of scar tissue or osteophytes, optimal alignment of the ankle in all planes cannot be achieved. Furthermore, if frontal plane deformity was present, more bone has to be resected on one side (medial or lateral) of the tibia. The same principles apply to TAR. Obviously, if gross varus deformity was present, one should have considered adjuvant procedures to correct frontal plane deformity (outside the scope of this chapter).

Barg et al. [5] showed how sagittal malpositioning affected the outcome of TAR. Of 317 patients undergoing TAR they studied, 103 (32.5%) showed some degree of anterior translation of the talus. This subgroup had statistically

significant more pain compared to the neutrally aligned. Functional outcome scores and range of motion were also adversely affected. Also TARs with a posteriorly positioned talus had worse outcomes [5]. Figure 22.8 illustrates the case of a TAR with slightly posteriorly positioned talus (Fig. 22.8a), resulting in relatively limited dorsiflexion of the ankle (Fig. 22.8b). Thus, it is essential that during TAR, the talus is well aligned directly under the tibia, for better function and less pain but also to avoid edge loading and loosening in the longer term [16].

Positioning

The patient is placed supine on the operating table with a thigh tourniquet and elevation of the ipsilateral hip/buttock area to de-rotate the leg, so the ankle is pointing directly upward. We recommend that a "bump" is placed under the distal tibia, to avoid any posterior pressure to the heel that would induce anterior translation of the talus.

Surgical Approach

A standard anterior approach to the ankle is routinely used. The surgical exposure requires anterior osteophyte resection and release of the anterior capsule.

Tibial Cut

In performing the tibial cut in an ankle with an anteriorly translated talus, extra care should be taken. If distal tibia erosion is present, more bone should be removed posteriorly than anteriorly. Extremely important is the slope of the tibial cut. It is best to avoid any posterior slope and remain "neutral" (Fig. 22.5), thus performing the tibial cut perpendicular to the long axis of the tibia in the sagittal plane. In other words the tibial cut is best "parallel to the floor." The use of intraoperative image intensification is recommended at this stage.

Medial Soft Tissue Release

When the talus is anteriorly translated, the deltoid ligament will require a "generous" release. A medial release involves peeling the deep deltoid ligament fibers off the medial malleolus anteriorly, extending the release slowly toward the posterior aspect of the malleolus, titrating the release. The scar tissue from the medial gutter and the medial malleolus osteophytes have to be removed. Once the bone cuts have been performed (taking into consideration the frontal plane alignment), the surgeon may have to further release the medial structures, if he "feels" the tension on the medial side.

Gutter Debridement

It is essential that both medial and lateral gutters undergo debridement of scar adhesions and osteophytes. This not only mobilizes the talus adequately to restore anatomic alignment of the ankle mortise but also improves postoperative range of movement and pain reduction. Medial gutter debridement is part of the medial soft tissue release, described before. However, to reduce the talus under the tibia in the frontal (varus) and sagittal (anteriorly translated) planes, the lateral gutter has to be thoroughly debrided of scar and synovitis tissue. Otherwise, the talus will be impinging on the lateral scar tissue, thus preventing anatomic reduction. We want to emphasize that the gutters are quite deep, extending posteriorly, as well.

Talar Cut

The talar cut should be parallel to the tibial cut (thus, parallel to the floor, as well) and ideally "centralized" in the talar body. At that stage intraoperative image intensification is essential to judge positioning of the components in two planes. If residual translation of the talus remains (on the intraoperative lateral ankle view), one can debate whether the talar component should be positioned slightly more posteriorly, to allow optimal positioning of the talar implant underneath the tibia [17]. However, the talus as a whole will still remain anteriorly translated. And although this could make the intraoperative image intensification view look better, edge loading may occur, leading to early failure of the prosthesis [16]. Any effort should be made (by bone resection and soft tissue releases) to realign the talus under the tibia in the sagittal plane and implant the talar component anatomically to replace the talar body's articular surface (talar dome) (Figs. 22.3 and 22.4).

Trial Components: Insertion and Positioning

Once the trial components are inserted, soft tissue tension is further adjusted. Care should be taken not to "overstuff" the joint using larger or thicker components. Possibly, one should choose the smaller size of implants if in between sizes. Depending on the prosthesis manufacturer and design, the tibia, talus, and polyethylene insert sizes (for three-component TARs) have to be compatible with each other. Both radiographic parameters (tibiotalar ratio and tibial

component inclination), measured on the lateral weight-bearing radiograph as described earlier, have to be taken into consideration on the assessment of positioning of TAR prostheses. Ideally, both radiographic angles should be within "normal values." If the talus is reduced under the tibia by changing the slope of the tibial cut and tibial component placement (e.g., having a "backward-facing" or "forward-facing" TAR), this carries the risk of altered distribution of contact pressures and edge loading [16], potentially accelerating polyethylene wear leading to early failure.

In performing the bone cuts, the surgeon has to, obviously, take into consideration the specific prosthesis' design characteristics and the manufacture's surgical technique recommendations.

Final Balancing of TAR

Another issue that can arise is dynamic anterior translation of the talus during ankle dorsiflexion. This can be observed intraoperatively with the trial components in situ, when the talus slides anteriorly during dorsiflexion. This indicates posterior tightness. Possible solutions include Achilles tendon lengthening and/or reducing the polyethylene thickness in mobile-bearing prostheses or performing a more proximal tibial cut. Changing polyethylene thickness may not be an option if the thinnest insert is used, and, even if possible, it may not be desirable to use a very thin polyethylene component. A "higher" (more proximal) tibial cut is not a very good option either, as it can contribute to implant subsidence and higher risk of medial malleolus fracture. We recommend a release of the posterior structures (capsule and/or Achilles tendon or gastrocnemius recession) in those cases, as a tight Achilles tendon forces the talus anteriorly. Furthermore, one should be able to achieve at least 10° of ankle dorsiflexion "on the table." The latter option will be discussed in more detail later in this article.

At the end of the procedure, one has to take into consideration the possibility of lateral ligament deficiency, resulting in instability. An anatomic (e.g., Broström-type) repair of the anterior talofibular ligament may be required, after insertion of the definitive prosthesis components.

Posterior Translation of the Talus

On the other hand, intraoperative static or dynamic (during dorsiflexion) posterior translation of the talus indicates a loose TAR. The solution may be the use of a thicker polyethylene insert and/or the repair of the anterior talofibular ligament.

Surgical Repair of Ankle Equinus During TAR

Soft tissue equinus in arthritic ankles is usually related to calf muscle and Achilles tendon contractures, as discussed earlier. Therefore, it should be managed with soft tissue releases. The surgical options include a gastrocnemius-soleus lengthening at the musculotendinous junction, a triple hemisection Achilles tendon lengthening, or an open Achilles tendon "Z-lengthening" procedure. The latter is rarely required when performing TAR. If extensive shortening of the Achilles tendon is present, then one should probably not perform a TAR or undertake a staged procedure. There is no clear answer and no clear evidence regarding the indications of a triple hemisection versus a "gastrocnemius slide" procedure. The choice seems to rely on the surgeon's preference. It seems that the triple hemisection is probably simpler, quicker to do, and effective [18].

The real question is "when" to perform the release. Is it before the bone cuts are performed or after implantation of the prosthesis? Again, no clear "guidelines" exist, and one has to realize that the surgeon may have to rely on his/her experience. We, among others, believe that if the ankle cannot be brought to sagittal plane neutral, one can misjudge the anterior/posterior slope of the bone cuts. Therefore, it is best if any preoperative soft tissue equinus contracture is managed with a Achilles tendon lengthening at the start of the procedure, before the bone cuts are performed.

Furthermore, occasionally one has to lengthen the Achilles tendon at the end if, after implantation of the prosthesis, there is still lack of dorsiflexion (e.g., if a thicker polyethylene component has been used to balance varus/valgus alignment). In such case, one should not hesitate to release the Achilles tendon. However, if that happened the surgeon should consider first whether medial and posterior soft tissue releases were adequate. It could be that the posterior capsule needs more extensive release.

Table 22.1 summarizes the surgical considerations performing TAR in the presence of sagittal plane talus malalignment and/or equinus contracture.

Results

Balancing of a TAR in all planes is essential for good clinical outcomes and for the longevity of the prosthesis. Barg et al. [5] showed in a retrospective study including 317 Hintegra TARs that anterior or posterior translation of the talar component in relation to the tibia resulted in worse functional outcome and less pain relief [5].

According to other studies, talus relocation under the tibia was possible in 87% and 96% of ankles [8–10]. The latter

Table 22.1 Anterior translation of the talus and soft tissue equinus: surgical technique considerations

Remove osteophytes (distal tibia, talar neck, gutters)
Tibial cut: avoid posterior slope; remain neutral in the sagittal plane
Do not cut the tibia more proximally: release the soft tissues instead
Release the deltoid ligament (titrate your release)
Release the posterior capsule
Avoid positioning the talar component more posteriorly than its "anatomic" position on the talar dome (use intraoperative image intensification)
Consider adjuvant procedures (e.g., osteotomies) if frontal plane deformity present
Check for dynamic anterior translation of the talus with trial implants
Have low threshold for Achilles tendon lengthening
Consider repair of lateral ligaments

study compared clinical outcomes (American Orthopaedic Foot and Ankle Society Ankle Scoring Scale, range of motion, complications) of Hintegra TARs in ankles with and without sagittal plane translation of the talus and found no differences. Approximately half of the ankles they reviewed were malaligned in the sagittal plane, and only 3.7% of all ankles showed posterior translation of the talus. The sagittal alignment in some of the ankle replacements reduced to normal within 12 months from the surgery. Interestingly, the need for additional procedures (e.g., releases, osteotomies, lateral ligament repairs) was equal in both groups [10].

Two studies examined the effect of calf muscle releases, assessing the possibility of "side effects," such as plantar flexion weakness and altered functional outcomes. Gastrocnemius-soleus release during TAR does not result in inferior plantar flexion muscle strength, and generally clinical outcomes were as good compared to a group of patients not requiring the calf muscle lengthening procedures, according to a recently published study [19]. Gastrocnemius recession allowed improvement of ankle dorsiflexion, without causing plantar flexion weakness, according to another study [20].

Discussion

Approximately half of the arthritic ankles requiring TAR can be malaligned in the sagittal plane [10], presenting with anterior translation of the talus and/or hindfoot soft tissue equinus due to calf muscle and Achilles tendon contractures. Trauma and chronic lateral ankle instability (the most common causes of ankle osteoarthritis) alter the anatomy and kinematics of the hindfoot and can result in adhesions and osteophyte formation, loss of cartilage, and tibiotalar surface incongruity [1–4]. Posterior translation of the talus is rare and usually observed intraoperatively during TAR, as a result of loose components.

The basic principles of balancing a TAR include balanced bone resection and adequate soft tissue releases, combined with adjuvant procedures (e.g., osteotomies). However, the unique anatomic characteristics of the ankle do not allow excessive bone resection for bony correction of the deformity [1–4]. The mainstay of surgical correction involves debridement of the medial and lateral gutters to allow complete mobilization of the talus. Extensive deltoid ligament release is sometimes needed. The tibial cut should be kept "parallel to the floor" avoiding a posterior slope in the sagittal plane, whereas the talar component should be centralized under the tibia. Appropriate sizing of the components is essential. We recommend the use of intraoperative image intensification at several stages during TAR. Lateral ligament repair is required if lateral instability is observed after implantation of the prosthesis. The surgeon should have a low threshold for Achilles tendon lengthening or gastrocnemius-soleus recession to manage equinus contractures and improve ankle dorsiflexion [17–20]. One cannot give an evidence-based answer regarding the superiority of one procedure over the other. Achilles tendon percutaneous lengthening is quick and simple [18], whereas two studies showed that gastrocnemius [20] and gastrocnemius-soleus [19] releases offered good clinical outcomes without plantar flexion weakness.

Malalignment and imbalance of the TAR prosthesis should be avoided, as it would lead to abnormal distribution of contact pressures and early failure [1–9, 16]. Outcomes can be expected to be as good as of those ankles without talar translation in the sagittal plane, if the talus is reduced in all planes underneath the tibia [2–4, 8, 10, 19].

Conclusions

Soft tissue ankle equinus and anterior/posterior translation of the talus are commonly encountered malalignment situations seen with end-stage ankle arthritis. These malalignments are important to recognize and correct at the time of primary TAR. The management of anterior and posterior translation of the talus revolves primarily around tibial cut location/orientation, medial deltoid and posterior capsule soft tissue release, medial and lateral gutter debridement, and lateral ligament reconstruction. The decision to perform a Achilles tendon lengthening or a gastrocnemius-soleus lengthening is based mostly on the surgeon's preference and comfort level than evidence-based medicine.

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The Science Behind Periprosthetic Aseptic Osteolysis in Total Ankle Replacement

23

Husam A. Alrumaih and Murray J. Penner

Introduction

With the improvement of ankle prosthesis designs and the advancement in surgical techniques, total ankle replacement (TAR) is becoming a popular option to treat end-stage ankle arthritis as an alternative to ankle arthrodesis. As a result, periprosthetic osteolysis associated with TAR is emerging and becoming a concern that could jeopardize the long-term survival of the implant. Although current-generation TAR, which emphasizes restoration of anatomy, kinematics, and alignment, has shown significant improvements in survivorship compared to first-generation implants, the medium- and long-term results are still inferior to total hip and knee arthroplasty. For example, the mean revision per 100 observed component years was found to be 3.29 for TAR compared to 1.29 and 1.26 for total hip and total knee arthroplasty [1].

Periprosthetic osteolysis is a well-known phenomenon that was initially described by Harris et al. in 1976 [2] and by Willert in 1977 [3]. Since then, numerous studies have been published to evaluate the pathophysiology and outcomes of periprosthetic osteolysis, but most of these studies were focused around the hip. The foot and ankle literature is still lacking strong evidence to fully understand periprosthetic osteolysis associated with TAR.

Although the incidence of periprosthetic osteolysis in the literature varied from 4.5% to 79% [4–12], three recent and large studies have estimated the incidence to be approximately 35% [9, 13, 14]. Yoon et al. [13] reported recently on 99 Hintegra (now known as H3 Total Ankle Replacement; DT MedTech LLC, Baltimore, MD) at an average follow-up of 40.8 months, and they reported an incidence of osteolysis around 37%. A similar incidence was reported in another recent study by Kohonen et al. [14] when they reviewed the radiographs of 123 patients with the Ankle Evolutive System (AES, Transysteme-JMT Implants, Nimes, France). They reported an incidence of 34.9% at a mean follow-up of 43 months. Similarly, Koivu et al. [9] reported an incidence of 37% when they reviewed 130 consecutive AES prostheses.

Histopathology

Polyethylene wear and subsequent osteolysis around hip and knee arthroplasties have generally been accepted as the leading cause of aseptic implant loosening and concomitant shortening of survival. To better understand the role of polyethylene debris in TAR, Kobayashi et al. [15] in 2004 examined and compared the size, shape, and concentration of polyethylene particles in the synovial fluid at a mean of 23 months following four Agility TARs (DePuy Synthes, Warsaw, IN), 11 Scandinavian Total Ankle Replacement prostheses (Stryker Orthopaedics, Kalamazoo, MI), and 11 posterior-stabilized total knee arthroplasties. The size, shape, and concentration of polyethylene debris were equivalent between ankle and knee arthroplasties [15]. The same author showed that a threshold of ten billion polyethylene wear particles in each gram of periarticular tissue is associated osteolysis [16]. He concluded that the anticipated long-term results of the second-generation TAR should be comparable to the posterior-stabilized total knee arthroplasty, assuming that polyethylene debris is the major factor for osteolysis. The Norwegian Joint Registry reported on a series of STAR arthroplasties, and the survivorship was found to be 75% at 10 years [17], which is inferior to the 95% survivorship at 15 years for the posterior-stabilized total knee arthroplasties [18]. The discrepancy in the survivorship could be attributed to the complex biological and biomechanical properties that

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stimulate osteolysis rather than a simple reaction to polyethylene particulate.

Koivu et al. [19] reviewed histopathology in ten AES prostheses and showed that early osteolysis is caused by RANKL-driven foreign body inflammation directed against necrotic autologous tissues and not against prosthesis-derived polyethylene particles [19]. This finding was echoed by Arafah and Penner [20] in their study which reviewed pathology reports in 18 revised STAR or Hintegra TARs; polyethylene particles or foreign body particles consistent with polyethylene were present in ten cases and absent in eight cases. All 18 cases showed some degree of giant cell reaction along with fibrous material and necrotic tissue [20]. Both studies raised a concern that factors other than polyethylene debris alone might also drive the macrophage response in the osteolytic cascade.

On the other hand, Dalat et al. [21] reviewed the histopathology results in 25 revised AES prostheses, and some polyethylene debris was present in 95% of their cases. However, 14 of 25 (56%) showed only little or no polyethylene debris at a mean of 5 years post-implantation, and no macroscopic wear was seen in any cases, calling into question whether polyethylene debris was, indeed, causative for these osteolytic lesions.

Vaupel et al. [22] examined eight polyethylene inserts retrieved from failed Agility total ankle replacement systems (DePuy Synthes, Warsaw, IN) for macroscopic and microscopic wear pattern. Pitting surface damage was found in all eight inserts, and six polyethylene inserts showed signs of abrasion. He concluded that polyethylene wear debris might ultimately lead to component loosening, which is the primary mode of failure in this implant [22].

In a much larger and more detailed histologic analysis, Schipper et al. [23] compared periarticular ankle tissue specimens from 57 cases of TAR revision or reoperation for bone grafting of osteolytic cysts (osteolysis group) with 11 control cases with intact ankles where specimens were harvested during primary TAR or open ankle debridement (control group). They showed, as expected, that polyethylene debris was much more common after total ankle replacement than in ankles without prostheses in situ. However, they also identified polarizable material or oil red O-positive material, both presumed to be polyethylene particles, in 93% and 96.5% of cases in the osteolysis group. Nevertheless, 21% of cases in the osteolysis group had minimal or no oil red O staining, and 77.2% had only moderate amounts of polarizable material, suggesting that osteolysis can occur even when minimal or no polyethylene debris is present. Since polyethylene wear must occur in all TARs with polyethylene bearings, some amount of polyethylene debris would be expected to be present in every TAR. And while this study did not compare the periarticular histology of the osteolysis group with TAR cases without significant osteolysis, the authors still showed that polyethylene debris was almost always present in cases with osteolysis and was associated with a giant cell foreign body reaction in 49% of cases.

Other studies have suggested that hydroxyapatite might be a cause of osteolysis. Singh et al. [24] have reported ballooning osteolysis in 71 failed total ankles and noted it was highly associated with increased levels of calcium in periprosthetic tissues. This was attributed to the hydroxyapatite coating of the prostheses studied.

Taken together, these studies along with the body of literature describing polyethylene-driven osteolysis in total hip replacement suggest that polyethylene wear debris likely plays a significant role in periarticular osteolysis in many TAR cases. However, it is not clear if it is the only cause or even the primary cause. The lack of clarity around this arises from the fact that osteolysis is sometimes identified very early after TAR, sometimes at less than 12 months postoperatively [13]. This finding led Yoon et al. to conclude that the "…early osteolytic lesions in TAA suggest that they were not the result of a host response to PE debris."

Other studies have also shown that cystic lesions around TAR can develop within 12 months of the index procedure [25, 26] and this early-onset failure pattern is unlikely to be caused solely by foreign body response to polyethylene particulate debris.

For total hip arthroplasty, it has been agreed that the main mode for failure is through polyethylene debris that leads to osteolysis and subsequent implant loosening [26–29]. While this is also likely a significant etiology of osteolysis in TAR, factors other than polyethylene debris, such as reaction to necrotic tissue, micromotion at the implant-bone interface, and high fluid pressure, may also play a key role in osteolysis around TAR, and further study is warranted.

Natural History

Due to the variability in the reported outcomes for different TARs and sometime for the same implant between different centers, the natural history of the periarticular cystic lesion around TAR is still unclear. In 2014, Yoon et al. [13] published a retrospective study that evaluated 99 Hintegra prostheses with a minimum follow-up of 24 months and a mean follow-up of 40.8 months (range, 24–89 months). Their study showed that 37% (37/99) of the ankles had radiological evidence of osteolysis. Kohonen reported a comparable incidence rate in 2013 [14] as did Koivu in 2009 [9]. In Yoon's study, the average time for cyst appearance was 24 months (range, 6–60 months). In 21 ankles

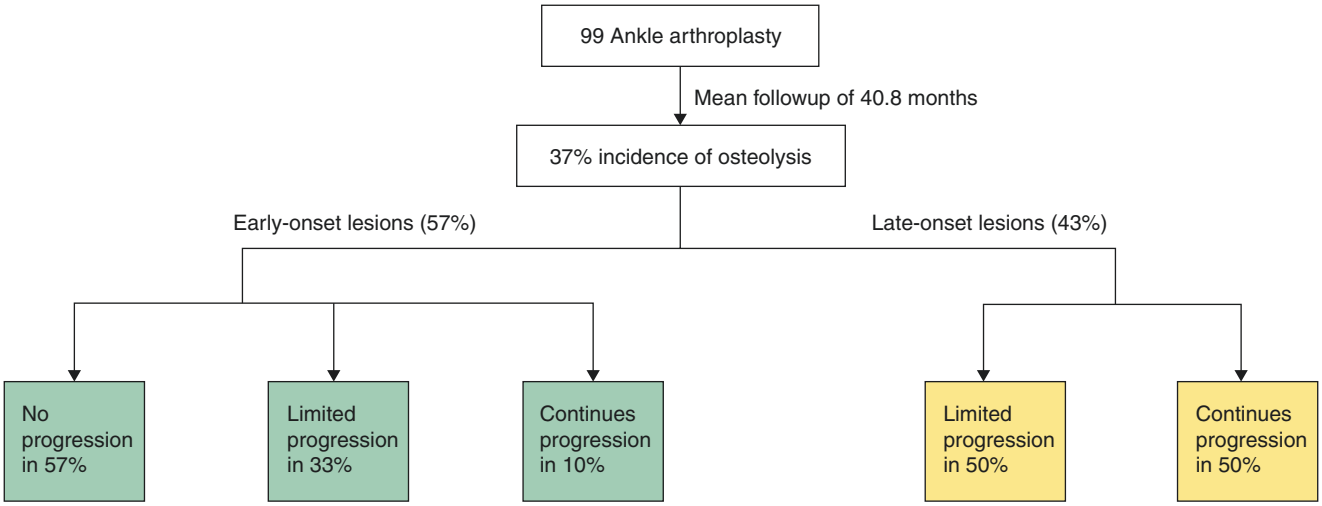


Fig. 23.1 This diagram illustrates the natural history algorithm of periprosthetic osteolytic lesions from a retrospective observation of 99 primary total ankle replacements [13]. Early-onset lesions, identified within 1 year after ankle replacement; late-onset lesions, identified more than 1 year after ankle replacement; limited progression has not progressed after 12 months from the initial appearance; and continuous progression, continued to progress after 12 months from the initial appearance

(57%), lesions appeared within 12 months (early-onset), and for the other 16 ankles (43%), lesions were identified after 12 months from the index procedure (late-onset). Of the early-onset lesions, 57% showed no progression, 33% showed statistic progression (did not progress after 12 months from initial appearance), and 10% showed continuous progression. While all late-onset lesions have had progressed, half of them showed limited progression and the other half showed continuous progression. The late-onset lesions were at a higher risk for progression (p-value < 0.001) (Fig. 23.1).

In 2017, Koivu et al. published medium- to long-term follow-up results with the AES ankle prosthesis. Their 5-year survival was 87.3% (95% confidence interval (CI) 80.0–92.0%), and 10-year survival 74.9% (95% confidence interval (CI) 65.4–82.2%) at a median follow-up time of 96 months. Peri-implant osteolysis was found in 91 (70%) ankles and was marked in 78 (60%). Forty-four ankles (34%) have been revised by filling of the cavities, 24 (18%) by fusion, and 6 by further replacement, resulting in the revision rate of 58%. Osteolysis was the main reason for all revisions [30].

Clinical Assessment

A detailed history and clinical examination are essential before proceeding with revision TAR. Although demographic history is essential in any clinical evaluation, none of the demographic parameters including age, body mass index, diagnosis, and activity level is reported to substantially differ between those who have or do not have osteolysis around the TAR [13]. Regarding symptoms associated with osteolysis around TAR, it is important to note that most patients with osteolysis remain asymptomatic despite considerable bone loss, similar to osteolysis around hip arthroplasty [7, 12, 14, 31]. Lesions are often detected incidentally on follow-up surveillance radiographs (Fig. 23.2).

History should include previous foot and ankle surgeries and the postoperative course after the index primary TAR, especially delayed wound healing or history of infection requiring antibiotics. If a different surgeon performed the index procedure, previous clinical reports, operative reports, and radiologic studies should be collected where possible.

For patients who smoke, a smoking cessation program should be offered. It has been shown that the relative risk of nonunion in hindfoot fusion is 2.7 times higher in smokers compared to nonsmokers [32]. It is crucial to optimize the healing potential not only for the soft tissue but also for the bone, especially when using bone grafts for tibial or talar cyst reconstruction.

During physical examination, attention should be given to ankle and hindfoot alignment, previous scars, and detailed neurovascular examination. Ankle and subtalar range of motion should be evaluated as limited range of motion at the subtalar joint that could be a sign of subtalar arthritis. The presence of subtalar arthritis greatly influences the intraoperative decision whether to perform a subtalar joint arthrodesis or not. Subtalar joint arthrodesis may also be a consideration if the bone stock in the talus is lacking after cystic defect debridement.

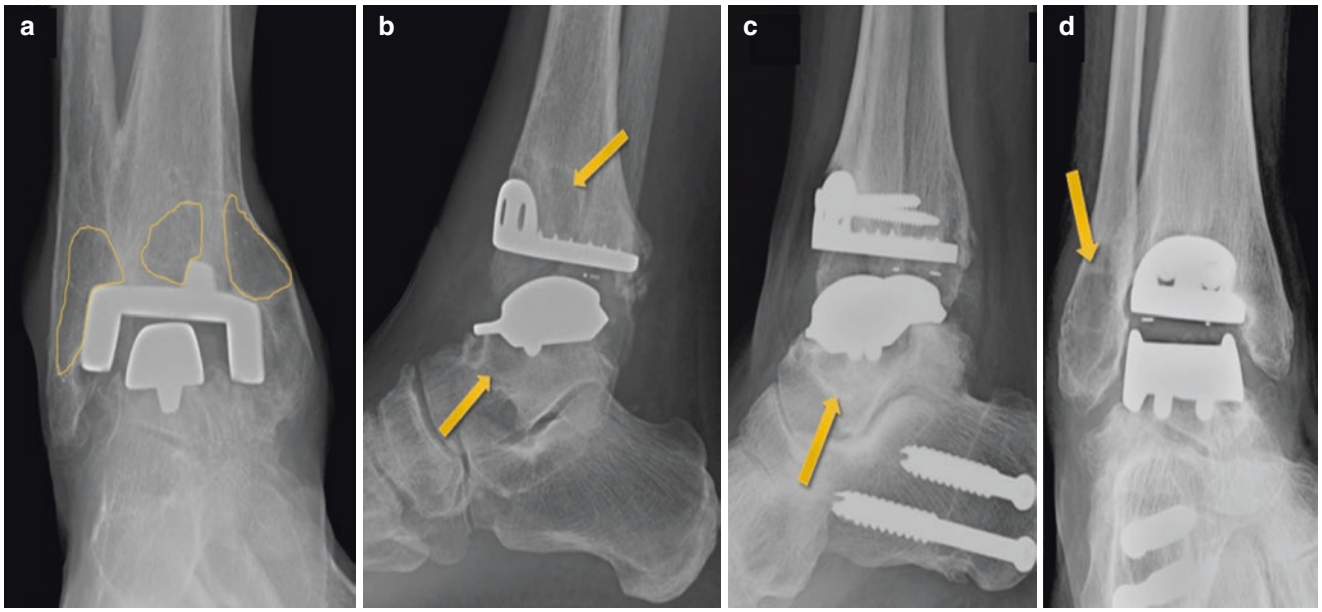


Fig. 23.2 Examples of asymptomatic patients despite having massive osteolysis. Anterior–posterior ankle radiograph of a 67-year-old woman 14 years after total ankle replacement with massive osteolysis around the tibial component (**a**). Lateral radiograph of a 69-year-old male 5 years after total ankle replacement showing both talar and tibial cysts (**b**). Anterior–posterior and lateral radiographs of a 59-year-old woman 7 years following total ankle replacement with asymptomatic fibular and talar cysts (**c**, **d**)

Radiological Assessment

Plain Radiograph

All postoperative radiographs should be thoroughly reviewed to identify the presence of any periprosthetic osteolysis, either cystic lesions or linear lesions along the bone-implant interface. A periprosthetic osteolytic lesion has been defined as "a discrete, well-demarcated area of lucency ≥2-mm wide in the periprosthetic bone" that was not present before the index primary TAR [7, 13, 14].

Weight-bearing radiographs should be carefully examined for any varus or valgus alignment of the ankle joint or the hindfoot, indicating coronal plane deformity or ankle instability. Even subtle deformity could be a potential source of polyethylene particles by edge loading and insert wear. Any malalignment or ligamentous instability should be addressed during the revision TAR [33–35].

Tibial and talar metallic prosthetic component alignment should be evaluated and compared to the alignment at the immediate postoperative radiographs to detect any angular changes or implant migration. Any change >5° or component migration of >5 mm should raise suspicion of component loosening (Fig. 23.3) [25, 26]. Ankle joint congruency should also be evaluated; incongruence is defined as >10° difference between the talar and tibial metallic component alignment as described by Haskell and Mann [36]. More recently Lintz et al. and his group have found a correlation between periprosthetic cyst volumes after total ankle replacement with postoperative hindfoot malalignment [37].

The sensitivity of plain radiograph to identify periprosthetic osteolytic lesions of any size was found to be 53% [7, 13], which is lower than the sensitivity of plain radiography to detect peri-acetabular osteolysis (74%) [38]. This low sensitivity could be explained by two reasons. First, cancellous bone is not very dense at the distal tibia and proximal talus; therefore, a substantial amount of calcium could be lost before detecting the osteolysis on plain radiograph [39]. Second, metallic components usually obscure the osseous landmarks around the ankle joint, particularly if the implant has an anterior shield [13] on the tibial component or side wall flanges on the talar component.

Any screws used for implant fixation should be examined radiologically, as osteolytic lesions could be detected around tibial or talar screws in approximately 9% (Fig. 23.4) [13]. Syndesmotic screws could also lead to lateral distal tibial and/or fibular osteolysis (ballooning osteolysis), especially with failed attempted syndesmotic fusion.

Computed Tomography

CT images should be obtained to further evaluate any known or suspected osteolytic lesions detected on plain radiographs. Patients should be scanned in the axial plane at 0.6–1.25 mm thickness, preferably with metal-artifact-minimizing proto-

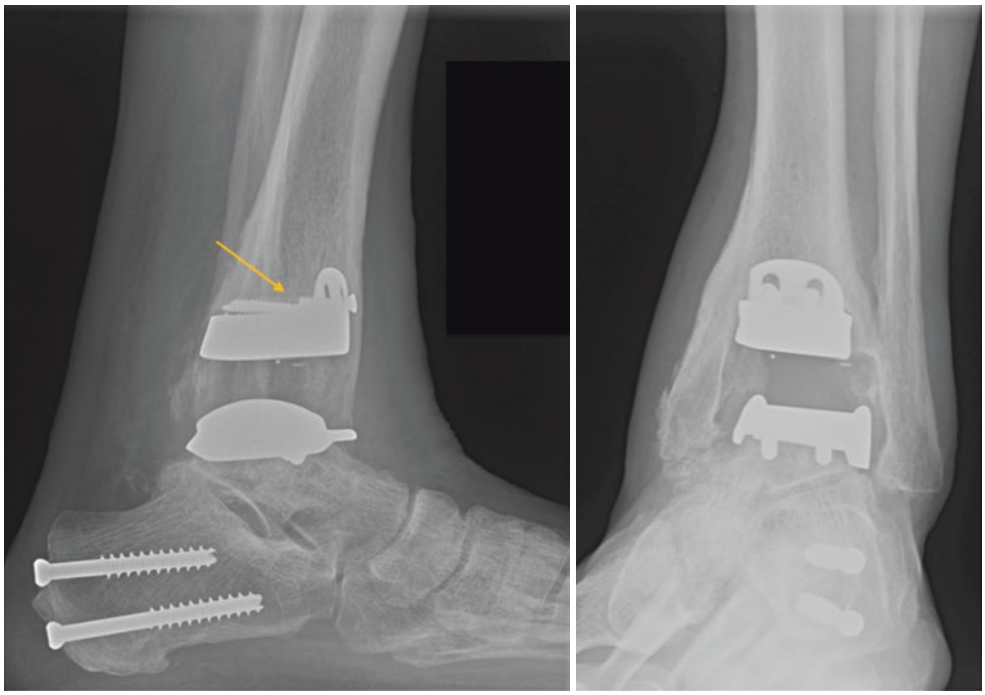


Fig. 23.3 Preoperative weight-bearing radiographs demonstrating tibial metallic component migration with broken screws (*arrow*) in a patient who had a revision total ankle replacement

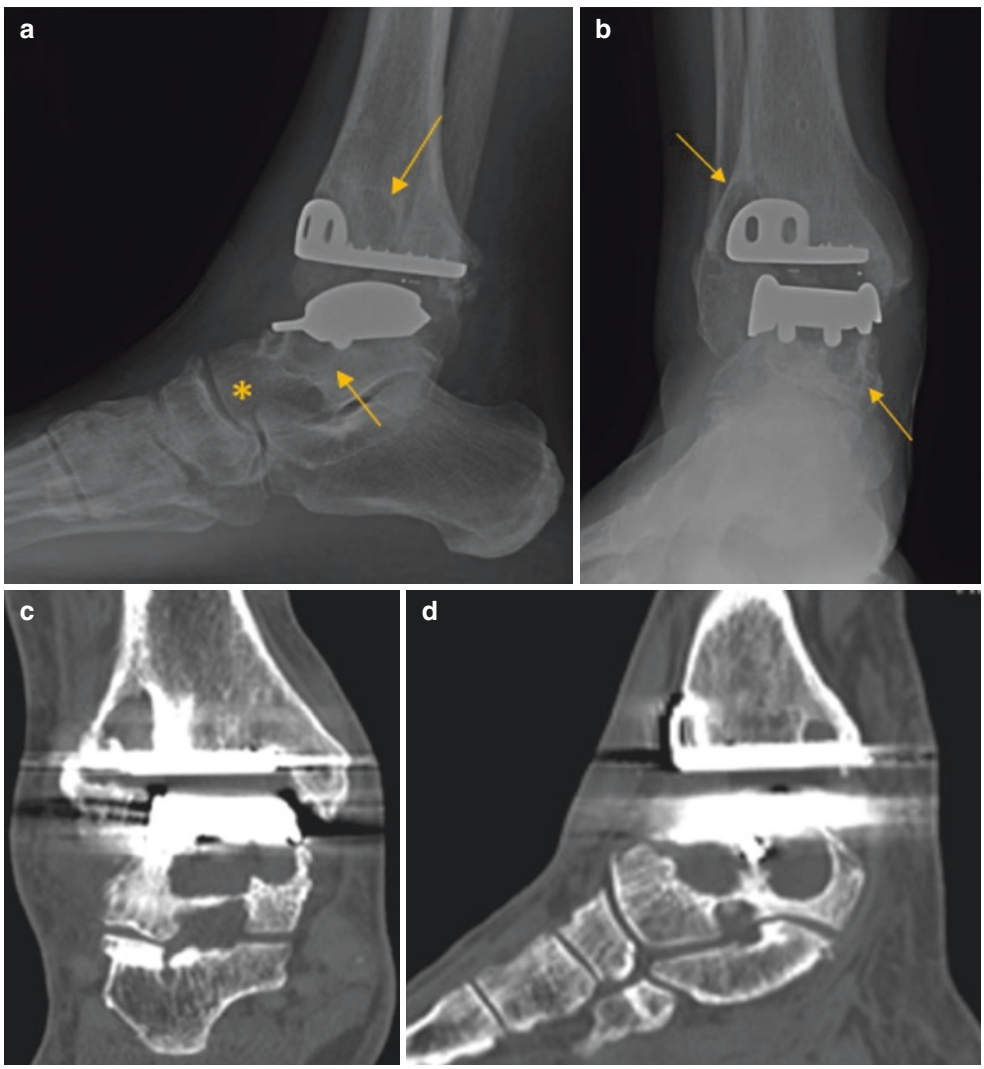


Fig. 23.4 Preoperative weight-bearing radiographs (**a**, **b**) demonstrating the underestimated lytic lesions (*arrows*), especially around the talar component if compared to the CT scan (**c**, **d**). Talar head and neck zone (*asterisk*) anterior to the talar metallic component is the only zone where computed tomography scan showed no significant difference in accurately detecting the size of lytic lesions compared to conventional radiographs

col [7, 14]. Coronal and sagittal images could be obtained by reformatting the axial images. The longest diameter of the cyst is multiplied by the longest width to measure the surface area of the lesion. CT demonstrated a higher sensitivity to detect lesions <200 mm^2 [3] compared to plain radiograph [7]. In addition, 88% of the osteolytic lesions identified by plain radiograph were inaccurately characterized, as the same lesions were three times larger when evaluated by CT scan [7, 40]. The superiority of the CT scan to accurately estimate the size of osteolytic lesions was significant in almost all zones around the tibial and talar components but mainly under the talar implant (Fig. 23.4).

The CT scan of the ankle joint is considered to be relatively safe as there are no radiosensitive organs around the ankle joint, radiation dosages are typically low, and contrast injection is not required. Excessive focus on radiogenic risk may cause a delay in the diagnosis and possible catastrophic failure [41]. Studies have shown that the standard adult effective doses for single foot imaging were 0.6 μSv for 2D plain radiography, 3.8 μSv for cone-beam CT scan, and 25 μSv for multi-detector CT scan (MDCT) [42]. Even though MDCT scan dosages are higher than plain radiography, all modalities have much lower radiation than chest x-rays which have a standard dosage of 30 μSv [43]. Modern low-dose MDCT has been shown to reduce dosage by approximately 50% compared to standard MDCT, with ankle CT scan dosages being only 20% of those seen for pelvic CT scans [44]. Other studies have shown [41] the mean effective dose of standard CT scan of the ankle was found to be 0.07 mSv, which is roughly 44% of the effective dose for knee CT scan (0.16 mSv) and 2.2% of the effective dose for hip CT scan (3.09 mSv) [45, 46].

The recent introduction of weight-bearing computerized tomography (WBCT) may lead to a better understanding of how osteolytic lesions react to physiological forces [37]. However, more research needs to be done about this new diagnostic modality in order to demonstrate its usefulness in diagnosing or predicting osteolysis.

Single-Photon Emission Computed Tomography

The foot and ankle represent a complex group of articulations; a combination of single-photon emission scintigraphy with conventional CT scan allows for sequential acquisition of both anatomical and functional information making the diagnosis more specific. In a series of 31 patients with unexplained foot pain and postsurgical pain, single-photon emission computed tomography (SPECT) scan demonstrated additional diagnostic information in 25 patients (81%) and a potential change in management in 62% of the patients [47]. Claassen et al. performed their review on 49 patients comparing MRI to SPECT in diagnosing complex foot and ankle pathologies and concluded that it had a higher intraobserver and interobserver reliability when compared to MRI alone [48]. SPECT scan also has the advantage of early detection of degenerative changes in the hindfoot, before plain radiographs and CT scans, as it can accurately detect any increase in subchondral metabolic activity associated with arthrosis (Fig. 23.5) [49].

Management

Surgery is usually not indicated for small, nonprogressive, and asymptomatic periprosthetic cysts. However, if an osteolytic lesions is identified, serial radiographs are recommended every 6 months during the first year and yearly afterward to avoid any catastrophic prosthetic failure rendering the revision procedure more complex and the outcome less predictable [50]. The following radiological findings should prompt consideration of surgical intervention:

1. Rapid progression of osteolysis on serial radiographs
2. Presence of large osteolytic lesions that span more than one-third of the bone-implant interface [13]
3. More than 5° or 5-mm change in the metallic component position indicating possible implant loosening [25]

Surgical options include:

1. Cyst curettage with impaction bone grafting and polyethylene-bearing exchange
2. Metal component revision with impaction bone grafting of osteolytic lesions
3. Ankle or tibiotalar-calcaneal (TTC) arthrodesis
4. Below-knee amputation

In this chapter, we will focus on the techniques for cyst curettage and impaction bone grafting in the setting of well-fixed tibial and talar metallic components. The details of revision and arthrodesis techniques will be described in other chapters within this textbook.

Cyst Curettage Grafting

Once osteolytic cysts reach a critical size, the surgeon's threshold should be very low for early intervention to avoid the surgical difficulties associated with the massive bone loss and implant failure [51]. The cysts are thoroughly curetted and filled with the appropriate void filler, and the polyethylene bearing should be exchanged if possible.

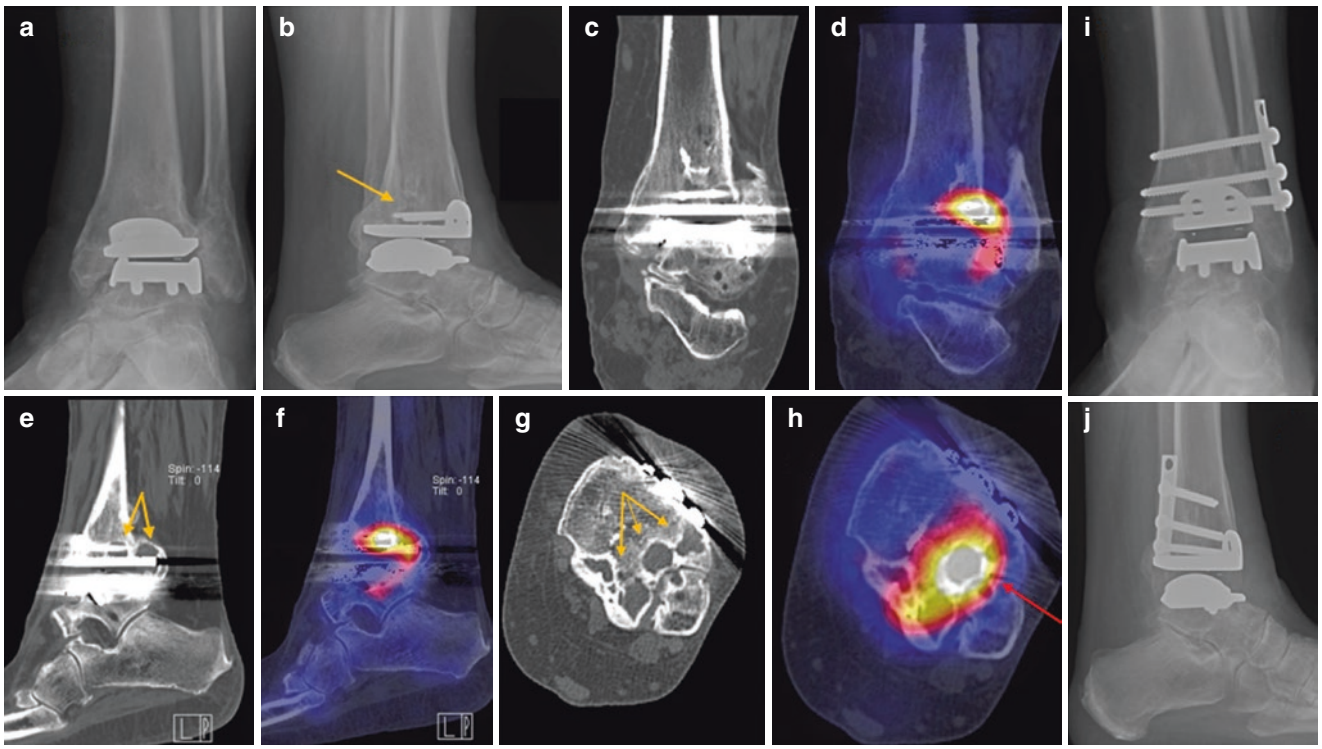


Fig. 23.5 Weight-bearing radiographs of a 65-year-old woman with a painful left ankle 5 years after total ankle replacement. Weight-bearing radiographs (**a**, **b**) and computed tomography images with corresponding single-photon emission computed tomography scans (SPECT scans) (**c**–**h**) are shown. Periprosthetic osteolytic lesions are indicated by *arrows* (**b**, **e**, **g**). Tibial osteolytic lesions are located primarily around the lateral screw (**e**, **g**). Axial SPECT scan cut (**h**) illustrating both lateral tibial osteolysis and syndesmotic joint arthrosis (*arrow*). Coronal and sagittal SPECT scan cuts (**d**, **f**) demonstrating no sign of subtalar arthritis. This patient was treated with syndesmotic joint debridement and arthrodesis, tibial cyst debridement with impaction bone grafting, and polyethylene insert exchange (**i**, **j**)

Surgical Technique

A full set of revision components with variable polyethylene thicknesses should be available in the operating room in case one or both metallic components are found to be loose during the intraoperative assessment.

Positioning

The patient is placed supine on the operative table after receiving a popliteal nerve block followed by a general anesthetic. We routinely use a popliteal block to provide adequate postoperative pain relief. A bump is placed under the ipsilateral hip to prevent undesired external rotation of the leg, and a thigh tourniquet is routinely applied.

Approach

A standard anterior approach is made following the previous incision with careful dissection to protect the neurovascular bundle. We recommend maintaining appropriate tissue planes for layered closure. Once the anterior capsule is encountered, we reflect the periosteum from the anterior tibia and proximal talus to expose the medial and lateral gutter. Once the dissection has been completed and proper visualization of both components achieved, the talar and the tibial components should be probed after removing all fixation screws to check for metallic component stability. If the components are deemed to be stable, cyst debridement with impaction bone grafting and polyethylene insert exchange is usually all that is required. However, if one or both metallic components are deemed to be unstable, full revision is required along with cyst debridement and impaction bone grafting (Fig. 23.6). If the host bone is insufficient for reconstruction, options are limited to either ankle/TTC fusion or below-knee amputation.

The cysts should be debrided to a healthy bleeding cancellous bone substrate with curettage and the use of a high-speed burr, and the contents must be sent for microbiology and histology analysis. The cysts then can be filled with cancellous autograft taken from the iliac crest, proximal tibia, or calcaneus. Allograft, synthetic bone (e.g., Augment Wright Medical, Pro-dense Wright Medical, and HydroSet, Stryker), and polymethyl methacrylate (PMMA) cement are other

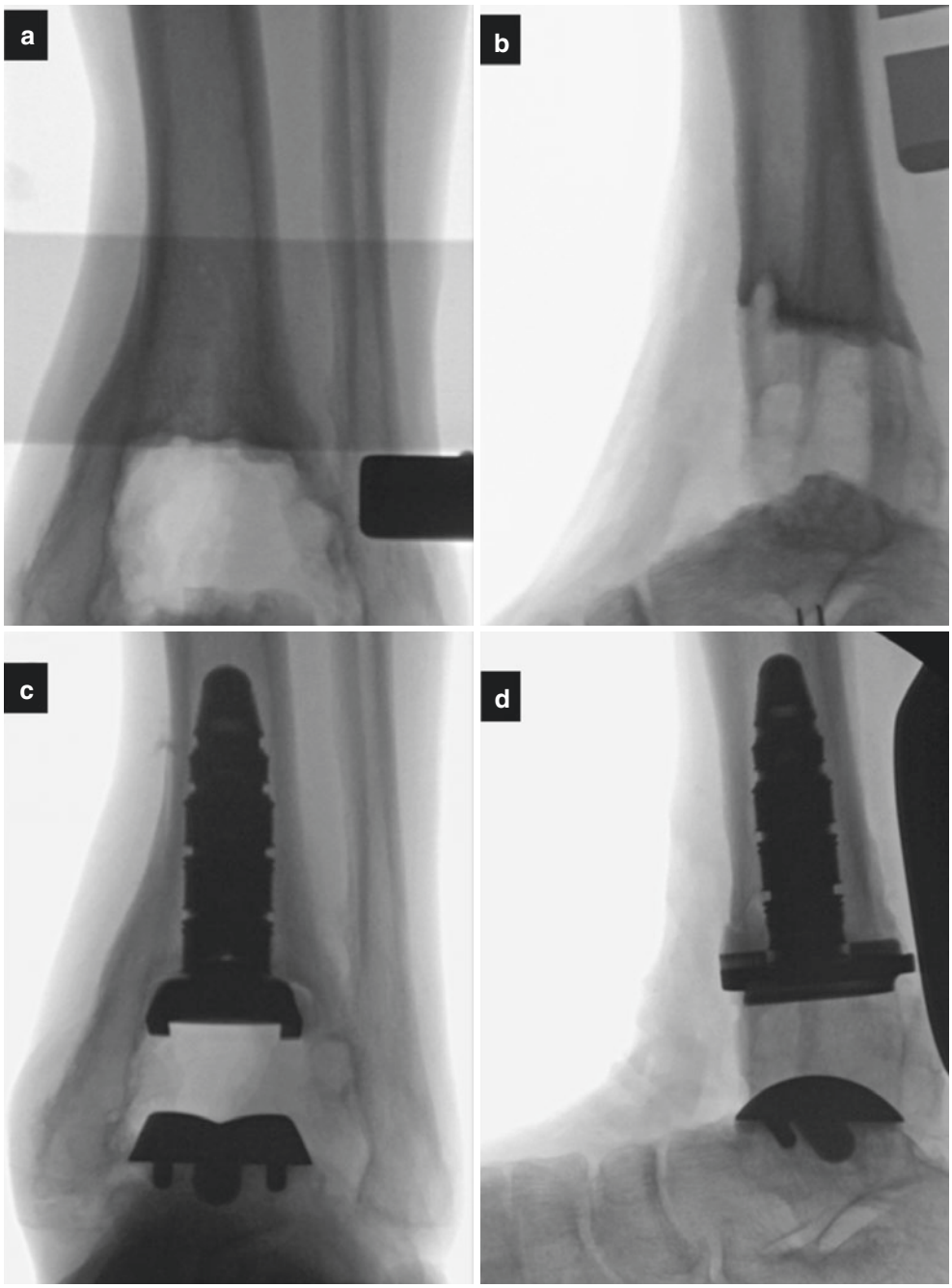


Fig. 23.6 Weight-bearing radiographs for the same patient shown in Fig. 23.2 with metallic component migration and periprosthetic osteolysis. Intraoperative C-arm image intensification (**a**, **b**) demonstrating severe bone loss following prosthesis removal and thorough debridement. The ankle joint was reconstructed using conversion to the INBONE II Total Ankle Replacement (Wright Medical Technologies, Inc., Arlington, TN) (**c**, **d**)

options to fill the void of larger cysts (Fig. 23.7). For contained lesions, autogenous or allogenic cancellous bone grafting is usually sufficient; a combination of bone graft and demineralized bone matrix (DBM) can be used for large contained defects [52]. The addition of osteogenic stimulants such as platelet-derived growth factor may be considered. For non-contained defects, when the cortex is breached, structural bone graft from the iliac crest or structural fresh-frozen allograft may act as a strut for reconstruction. If the cyst is confined to the medullary cavity and it is not accessible, a cortical window is required to access and to thoroughly debride the cystic tissue before impaction bone grafting or cementation. We routinely use intraoperative C-arm image intensification as it is essential for cyst localization and complete debridement.

Once the cyst is fully debrided and grafted, attention should be turned to the polyethylene insert. For mobile-bearing three-component TAR, the polyethylene insert can be easily removed and inspected for unusual wear. The wear pattern should be carefully evaluated, especially in early failure, as it could be a sign of excessive edge loading from uncorrected ankle instability or residual coronal

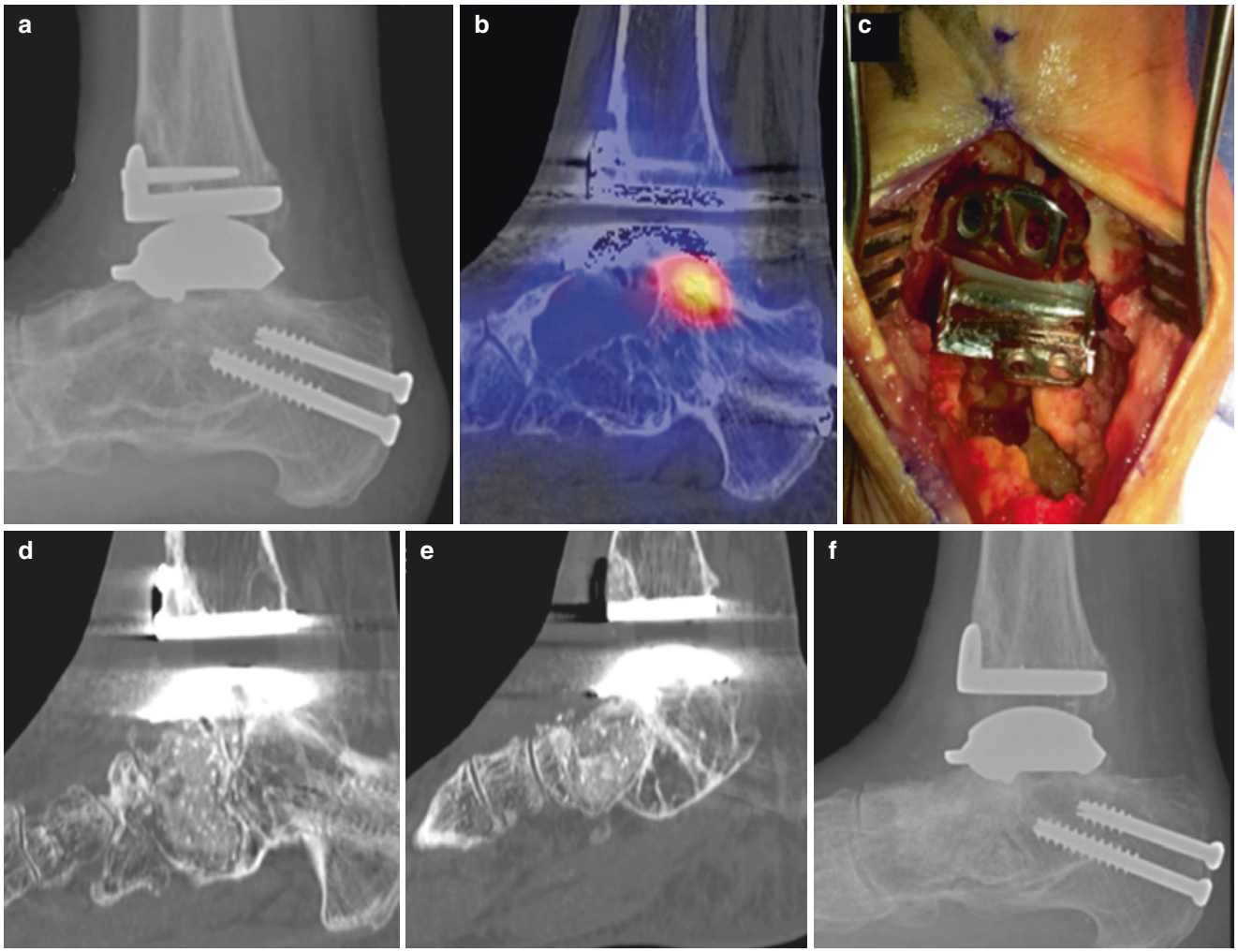


Fig. 23.7 Lateral weight-bearing radiograph (**a**). A patient with painful massive anterior talar cyst 6 years following total ankle replacement. The talar component was cantilevering on the posterior fixation as seen on a single-photon emission computed tomography scan (**b**). Intraoperative photograph (**c**) illustrating the massive tibial cyst; the defect was reconstructed with a mixture of autograft from the iliac crest, femoral head allograft, and rhPDGF bone substitute (Augment, Wright Medical Technologies, Inc., Arlington, TN). Postoperative computed tomography scan at 7 months demonstrating reasonable incorporation of bone graft mixture (**d**, **e**). A lateral weight-bearing radiograph (**f**) 1 year after reconstruction demonstrating bone consolidation with sufficient talar bone stock for future revision

malalignment [13]. The underlying pathology should be addressed at the same operation with either ligament reconstruction for instability or corrective osteotomy for malalignment (Fig. 23.8). For semi-constrained implants, isolated polyethylene exchange is not as easy, and occasionally it is not exchangeable without metallic component revision.

Outcome of Cyst Curettage Grafting

The outcome of cystic lesion debridement with impaction bone grafting and polyethylene insert exchange is still not clear in the literature. Yoon et al. reported on eight patients who underwent autogenous iliac crest bone graft with polyethylene insert exchange to treat progressive periprosthetic osteolysis (Hintegra); all patients showed evidence of healing at a mean follow-up of 15 months (range, 6–48 months) with no post-revision radiological signs of metallic component loosening [13].

Bonnin et al. [52] performed cyst curettage with iliac crest bone graft and polyethylene insert exchange for symptomatic periprosthetic osteolysis in eight patients with Salto Mobile Prosthesis (Tornier SA, Saint Ismier, France) TAR, and half of them showed complete bone graft osseointegration and the other half had residual cysts, all <5 mm.

Prissel and Roukis reported on nine consecutive patients with extensive tibial osteolysis who underwent geometric metal-reinforced PMMA cement augmentation. Although the follow-up period was limited to 18.3 months (range, 4–38.4 months), they reported no progressive osteolysis, and

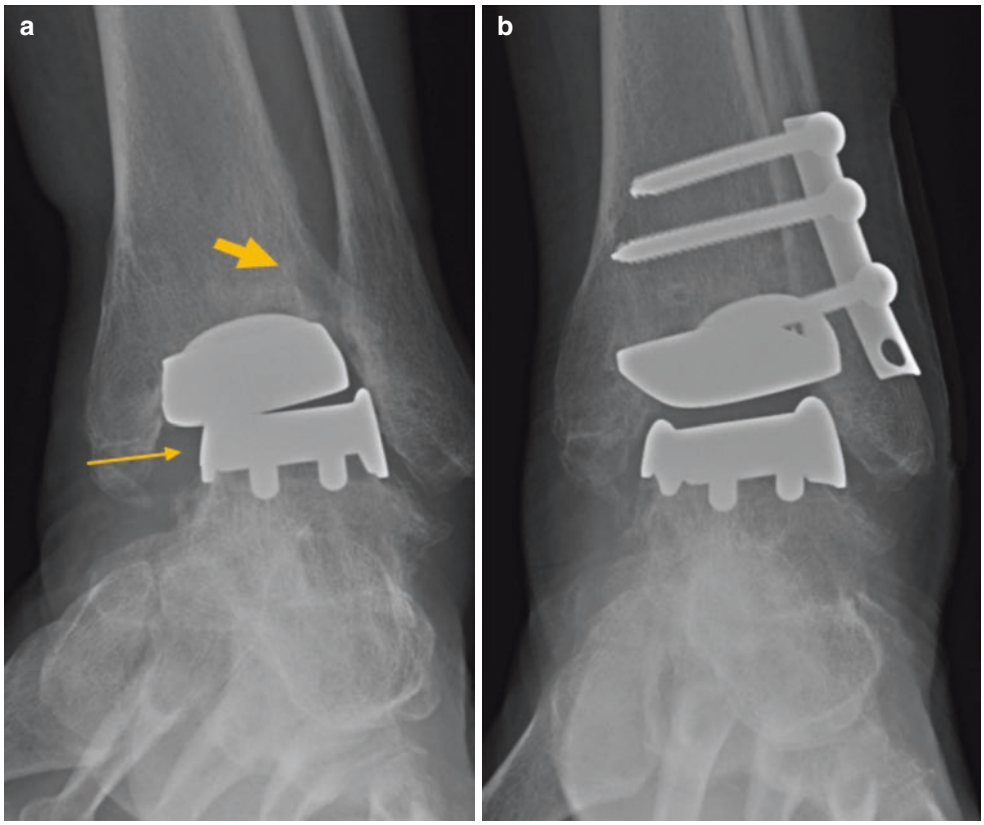


Fig. 23.8 Weight-bearing radiographs of a 65-year-old woman with painful left ankle following Hintegra total ankle replacement. (**a**) Preoperative weight-bearing oblique ankle radiograph demonstrating varus ankle tilt secondary to syndesmotic insufficiency. The *bold arrow* indicates a lateral plafond lytic lesion that led to disruption of the syndesmotic ligament and resultant syndesmotic joint instability. The talus is translated laterally (*thin arrow*). (**b**) Postoperative radiographs following debridement and arthrodesis of the syndesmotic joint, tibial cysts debridement, and impaction bone grafting with polyethylene insert exchange

all patients progressed to meaningful weight-bearing activities [53].

Besse et al. [5] reported their outcome for curettage and bone grafting on 14 consecutive patients with the AES TAR. The first seven patients had iliac crest bone grafts; for the other seven patients, one had iliac crest bone grafting mixed with calcium phosphate cement, four patients had only calcium phosphate cement, and the last two patients received PMMA alone. At a mean follow-up of 32 months (range, 9–47 months), 79% had unimproved or worsened American Orthopaedic Foot and Ankle Society Hindfoot-Ankle Score, and 92% showed signs of cyst recurrence.

More recently, Gross et al. reviewed 726 primary total ankle replacements, where 33 operative procedures for bone cysts were performed. Allograft was used in 25 procedures (75.8%), calcium phosphate in 4 (12.1%), cement in 3 (9.1%), and autograft in 1 (3.0%). The success rate for bone grafting of cysts was 90.9% (95% CI: 50.8%, 98.7%) at 24 months and 60.6% (95% CI: 25.1%, 83.4%) at 48 months [54].

Cyst curettage and grafting has also been used in total hip replacement with good results, suggesting potential value around the ankle as well. Restrepo et al. [55] reported a 10% failure rate at a 5-year follow-up in their series of 36 patients. In another study of 35 patients that underwent polyethylene insert exchange, in which 74% of the cystic lesions were impaction bone grafted, Maloney et al. [56] reported that one-third of the lesions resolved and two-thirds decreased in size whether they were bone grafted or not. These findings suggested that by decreasing the polyethylene concentration in the hip joint, osteolytic lesions decreased or resolved altogether. In contrast, resolution of osteolytic cysts around TAR after only exchange of the polyethylene bearing without grafting has not been reported. This discrepancy in the outcomes between the hip arthroplasty and TAR following cyst debridement and impaction bone grafting suggests that while polyethylene debris is a major factor in driving osteolysis in TAR, it may not the only major factor, and other factors may play significant roles as described earlier in this chapter.

Conclusion

Complete evidence about the etiology, pathophysiology, natural history, and optimal treatments of periprosthetic TAR osteolysis is still lacking. Though polyethylene wear debris is likely a major cause of osteolysis in TAR, particularly in late cases, other factors, such as reaction to necrotic tissue, micromotion, and fluid pressure at the prosthesis-bone interface, may also play a key role. Annual radiographic surveillance is recommended for early detection and treatment of osteolysis. If osteolysis is detected, CT scan, which has shown superiority in both detecting cysts and accurately determining their sizes compared with standard radiographs, should be used. The benefit of early surgical intervention in

progressive osteolysis may outweigh the risks of catastrophic failure associated with longer conservative management. For TAR metallic components deemed stable, cyst debridement with impaction bone grafting and polyethylene insert exchange is typically sufficient. However, if one or both metallic prosthesis components are unstable, component revision is required in addition to cyst debridement and impaction bone grafting.

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Management of Periprosthetic Cystic Changes After Total Ankle Replacement

24

Jean-Luc Besse, Marcelle Mercier, and Michel Fessy

Introduction

Total ankle replacement (TAR) was developed in the 1970s as an alternative to arthrodesis in selected patients with tibiotalar arthritis, giving the advantage of preserving joint mobility and function, improving the mobility of adjacent joints. The main indication for TAR is end-stage arthritis, whether post-traumatic, inflammatory, or idiopathic in origin. Short- and medium-term results seem encouraging. Ten-year implant survivorship, however, was only 62% to 72% in the Scandinavian registries [1–3], compared to 80% to 90% as in series mainly reported by the designers [4, 5], and 90% to 98% for hip and knee replacement. Indeed, the complex biomechanics of the ankle predispose TAR to some complications. Component loosening is a major concern, with high rate of revision. Periprosthetic cystic changes are a recently analyzed problem: cystic osteolysis induced mechanical complications due to tibial and talar microfracture, notably involving collapse of the talar component.

Since 2008, severe medium-term cystic bone evolution was reported with the Ankle Evolutive System (AES) total ankle replacement, inducing risk of mechanical complications. Several studies of short- and medium-term findings with the AES ankle prosthesis focused on periprosthetic osteolysis and imaging of the bone-implant interface [6–9]. In 2009, our team reported a prospective series of 50 AES TARs [6], showing 29% and 22% rates of severe (>1 cm) tibial and talar cysts, respectively, at 45 months' follow-up. Koivu [7] reported a 21% severe lesion rate at 31 months, Harris [10] a 24% rate of significant lesions at 58 months, Rodriguez [9] a 77% rate of cysts on radiographs and 100% on computed tomography (CT) scans at 39 months, and Kokkonen [8] a 79% rate of osteolysis and 40% rate of severe cysts at 28 months.

Periprosthetic osteolysis has also been reported with other TAR models. In a retrospective multisurgeon multicenter study of 173 TARs (82 Salto™, 41 Hintegra™, 19 AES™, 15 Coppelia™, 11 Star™, 4 Ramses™, and 1 Akile™, which were all three-component mobile-bearing systems), with a mean follow-up of 34 months (±5), Brilhault [11] reported bone cyst in 33% of cases, radiolucency in 72%, ossification in 39%, tibial component migration in 5%, and talar component migration in 27%. Bone cysts were more frequent in Salto™ (33/82 cases, 40%) and AES™ implants (10/19 cases, 52%), with bone cysts larger than 8 mm in 24 and 6 cases, respectively. They involved the tibia only in 33 cases, the talus only in 15 cases, and both bones in 9 cases. The largest diameter was over 8 mm in 35 of the 173 cases (20%). Bonnin [12, 13] reported a 19% rate of cysts >5 mm with the Salto prosthesis. Some authors have reported similar findings with the Agility prosthesis [14, 15]. Tibial cysts with the Scandinavian Total Ankle Replacement (STAR) prosthesis have been reported [16] in 3.5% of patients at 46 months and 17.5% at 88 months.

In 2015, Deleu [17], in a series of 50 Hintegra TARs with a mean follow-up 45 months, reported radiological evidence of cysts in 24 ankles (48%). Osteolytic lesions were first identified postoperatively within 12 months in 5 ankles, at 24 months in 7 ankles, at 36 months in 5 ankles, and later than 48 months in 7 ankles.

The management and monitoring of these cysts are therefore an essential element in the TAR follow-up.

The relative safety of a conservative curettage-graft treatment makes it an interesting therapeutic alternative for TAR salvage [6]. The different types of filling used are allografts,

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autografts, bone substitutes, or polymethylmethacrylate cement (PMMA).

Why Cysts?

Ankle bone-implant interface analysis is variable for series involving fixed and mobile bearings. The rate of bone cysts varies from 12% to 93% [6, 18–20]. This difference in the literature may be due to several factors, particularly in regard to cysts: disease severity, type of implant, patient age and weight, experience of the performing surgeon, radiographic technique, and the instrument used for radiographs or CT imaging assessment.

At present, periprosthetic bone cysts are a known finding after TAR. But, while several hypotheses may be advanced to account for the elevated rate and early onset of cysts, the cause of these cysts remains unclear.

Classically, periprosthetic osteolysis is a manifestation of an adverse cellular response to wear particles and corrosion debris. Cellular interactions and chemical mediators are involved. In hip or knee arthroplasty, Ultrahigh molecular weight polyethylene (UHMWPE) wear debris and metal debris are responsible for periprosthetic bone loss. It is a foreign body reaction. This biological activity depends more on the size than on the nature of the particles. Particles of polyethylene or any kind of metal measuring less than 7 μm may be phagocyted by macrophages. The most important cellular target for wear debris is the macrophage, which contributes to increased bone resorption. Wear debris activates proinflammatory signaling, which leads to increased osteoclast recruitment and activation [21]. Osteoblasts, fibroblasts, and lymphocytes may also be involved in the osteolysis mechanism. Moreover, wear particles activate MAP kinase cascades, NF-κB, and other transcription factors and induce expression of cytokine signaling suppressors. Recent work [22, 23] has identified the fundamental role of the RANKL-RANK-NF-kappa B pathway, not only in osteoclastogenesis but also in the development and function of the immune system. The immune system and bone homeostasis may be linked in the process of osteoclastogenesis and osteolysis.

Histology of periprosthetic osteolytic lesions after AES TAR was studied by Dalat [24]. Twenty-two histology specimens taken during revision of AES TARs were analyzed. Two identifiable types of foreign body related to implant wear were found: polyethylene in 95% of cases but also metal particles in 60%. However, the implication of polyethylene wear in these granulomatous formations, as found with polyethylene wear in hip or knee replacement, is not the only possibility, given the early onset and rapid evolution of osteolysis with no macroscopic signs of wear found on the mobile part during revision surgery.

Stress shielding may also participate in the formation of cysts, due to the difference in elastic modulus between bone and implant, as seen with hip stems [25].

Implant design has been incriminated. The stem-anchored tibial prostheses of the BP, AES, and even Salto types could be more exposed to coating fretting. Tibial stem fixation has been incriminated; cysts, however, also formed in the talus. AES and Buechel-Pappas TAR implant designs are similar, and yet survivorship in the two was not the same [6, 26].

The polyethylene of the mobile bearing may be more subject to shearing stress with the tibial component than the two-component fixed-bearing model; however, series using the Agility prosthesis have shown higher lysis rates than with mobile-bearing implants. Recently, in a randomized study with 4.5 years of follow-up, comparing 50 Star TARs (mobile-bearing TAR) versus 50 Salto Talaris (fixed-bearing TAR), Nunley [27] found similar lucency/cyst formation for the tibial component (26.8% for MB-TAR and 20.9% for FB-TAR) and greater for the talar component (21.9% for MB-TAR and 2.9% for FB-TAR). AP sliding are more complex multidirectional motion of the flat-back mobile bearing and shearing phenomena are greater with non-anatomic models having a spherical talar component (B-P, STAR, AES) than with more anatomical prostheses (Hintegra, Salto) that respect the two talar curve radii and impose less rotational and AP stress on the mobile bearing with respect to the tibial component. In vivo 3D kinematic analysis, measuring real mobile-bearing movement for the various models, accompanied by precise X-ray monitoring of the bone-implant interface would be necessary to determine the role of the mobile bearing in polyethylene wear.

The problem may lie in defective implant positioning: fitting a TAR is more operator-dependent than fitting a hip or knee replacement. In our study [6], however, there were no frontal or sagittal positioning defects of more than 5°, and 98% of implants were well centered.

Bonnin [12] suggested that some of these cysts could have evolved from osteoarthritic cysts of the pre-existing TAR. The patients of this study [12], however, had not had preoperative CT scans screening for pre-existing cysts, as was the case in our series [6] where the cysts investigated were not found on preoperative scans but appeared between the first and second years postoperatively, showing rapid evolution. Histologic analyses of curettage specimens [7, 24] failed to confirm this hypothesis, detecting titanium and hydroxyapatite particles.

Our present hypothesis is that the appearance of cysts may depend on coating properties: primary implant fixation fails due to coating delamination, with consequent foreign body reaction to titanium and hydroxyapatite particles, as described by Koivu [7]. The risk of osteolysis was found to be 3.1 times higher (95% CI, 1.6 to 5.9) with implants with Ti-HA porous coatings [7]. Our histological

study [24] confirmed these results: no patients free of cysts at 1 year went on to develop cysts later. The hypothesis we adopt is therefore that the AES TAR has insufficient primary fixation, leading to delamination of the two-layer coating and foreign body reaction to titanium and HA particles. The metallurgy and polyethylene of the implants could in principle be implicated, but all later tests confirmed that they meet current standards. All specimens showed macrophagic granulomatous inflammatory reactions with a foreign body. Some of the foreign bodies could not be identified: a brownish pigment in Ti-HA-coated implants (33, 3%) and flakey bodies in 44.4% of HA-coated implants and 18.2% of Ti-HA-coated implants. The brownish pigment was never associated with an HA coating and could derive from particles coming from the Ti-HA, although it was not possible to demonstrate this, and to the best of our knowledge, no studies have been made of this phenomenon; histopathology alone is unable to determine the exact nature of the metal and certain other foreign particles. In a comparative study of TAR with fixed (33 FB Talaris: titanium coating) versus mobile bearings (33 MB Salto: HA-Ti bilayer coating), Gaudot [28] found cysts were more frequent with the Salto prosthesis: radiolucent lines were observed in 4 FB patients versus 13 MB patients ($p = 0.02$); subchondral cysts were noted in 1 FB and 8 MB patients ($p = 0.01$). To confirm the implication of the bilayer coating in the genesis of these osteolytic lesions, it would be necessary to be able to study the adherence of the titanium and hydroxyapatite coatings in the various implant models on the market [29].

Recently, in a systematic review and meta-analysis of 21 articles on periprosthetic bone cysts after TAR [30], Arcângelo concluded that non-anatomic, mobile-bearing, hydroxyapatite-coated and non-tibial-stemmed TARs are positively associated with more periprosthetic bone cysts.

Management of Diagnosis and Follow-Up: How to Analyze Bone Cysts?

Clinical Examination

All operated patients should receive regular clinical follow-up. The purpose of clinical examination is to detect changes in clinical and/or functional signs and to locate the main area of pain or discomfort, which may be the consequence of microfracture induced by cortical lysis. Cysts are most often discovered serendipitously. In the literature [6], no relation was found between cysts and pain. In our prospective series of 84 AES TAR implants (2003–2008), global and pain scores for the 25 undergoing revision for osteolysis [24] fell from 89.7/100 at 1 year postoperatively to 72.9 before revision and from 32.5/40 to 20.6/40, respectively, although global scores were unchanged in 25% of patients.

Radiographs

All patients must undergo a strict pre- and postoperative protocol, comprising clinical examination and bilateral weight-bearing X-ray including AP ankle, Meary, and lateral foot (and ankle) views, one full-length standing AP view of both lower limbs. These radiographs must be repeated at 1 and 2 years and again later depending on the presence of lesions.

If no cysts are seen during the early years, radiographic control can be carried out every 5 years. In case of cyst, annual X-ray surveillance is recommended [6, 31].

If cysts are not evolutive, X-ray is sufficient. If not, CT should be performed.

Besse's protocol [6] was used to analyze periprosthetic bone cysts (Fig. 24.1). Osteolytic lesions were classified by size and location. Ten different areas were used for assessment. There were five AP and five lateral views. Each zone was classified as either normal, lucent (radiolucency <2 mm), or "ballooning" osteolysis, subdivided into five categories according to size, with the 30 mm tibial AES stem as measurement reference: cyst A (osteolysis 3 to 5 mm), cyst B (osteolysis >5 mm to 1 cm), cyst C (osteolysis >1 cm to 2 cm), cyst D (osteolysis >2 to 3 cm), or cyst E (osteolysis >3 cm). Grade A was considered as a mild lesion, grade B as moderate, and grades C, D, and E as severe lesions. Other classifications exist, depending on the implant design [11, 13]. By consensus, cysts >1 cm are considered severe and indicate an additional CT scan.

Computed Tomography Scan

CT scan allows earlier detection of cystic lesions, especially those under the talar implant, and precise monitoring of their evolution. Hanna [32] reported a 95% rate, with 19 ankles (Agility TAR) having one or more cysts. CT detected 21 lesions less than 200 mm^2, of which plain radiographs detected only 11. The mean size of the lesions detected on CT was over three times larger than that on plain radiographs.

In the study by Kohonen [33], 34.6% of a total of 130 ankle implants (AES TAR) had at least 1 periprosthetic osteolytic lesion larger than 10 mm on radiographs at a mean follow-up of 43 months. They found that CT depicted more osteolytic lesions than radiographs around tibial and talar components. In addition, lesions on CT were larger than on radiographs. The difference was highly significant in certain zones, all located around the talar component.

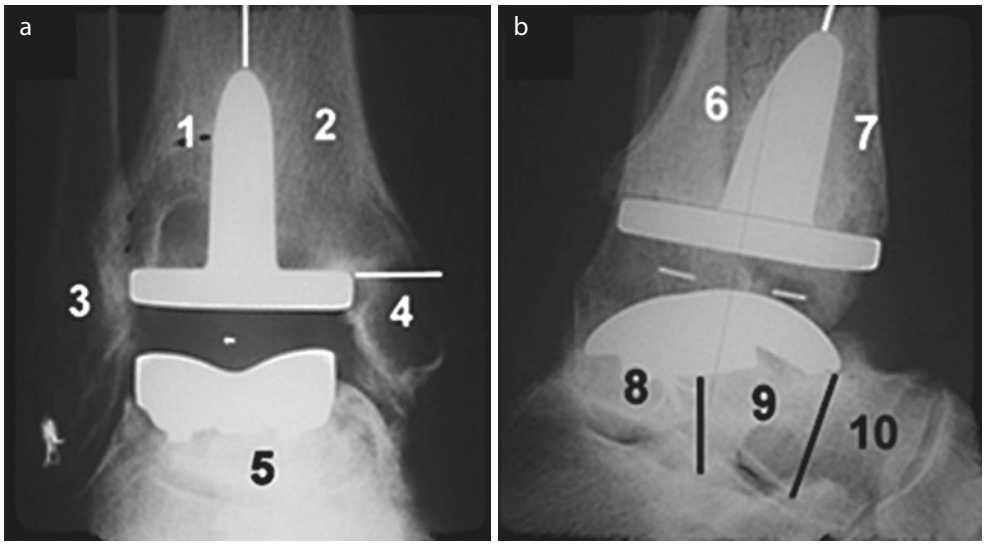


Fig. 24.1 Plain X-ray periprosthetic osteolysis assessment protocol for AES TAR, according to Besse. (**a**) On AP ankle view (five areas): Zone 1, lateral tibia; Zone 2, medial tibia; Zone 3, fibular malleolus; Zone 4, medial malleolus; Zone 5, area under the talar implant. (**b**) On lateral ankle view (five areas): Zone 6, posterior tibial; Zone 7, anterior tibial; Zone 8, posterior area under the talar implant; Zone 9, anterior area under the talar implant; Zone 10, neck and head of talus. Lesion classification by size (mm) for all ten regions: N = normal 0, L = lucency 0–2 mm, cyst grade A = 2–5 mm, cyst grade B = 5–10 mm, cyst grade C = 10–20 mm, cyst grade D = 20–30 mm, cyst grade E = >30 mm

In a prospective study of 50 AES TARs with a mean follow-up of 4 years, Viste [20] showed a dramatic progression of severe periprosthetic lysis (>10 mm) on plain radiographs: a 14% to 36% rate of interface cysts for the tibial component at, respectively, 2 and 4 years' follow-up and from 4% to 30% for the talar implant. The talar component was more accurately assessed on CT (mean frontal and sagittal talar lesion size: from 270 mm^2 to 288 mm^2 for CT vs. 133 mm^2 to 174 mm^2 for X-ray). For tibial cysts, axial views showed larger lesions (313 mm^2) than frontal (194 mm^2) or sagittal (213.5 mm^2) views.

CT, with sagittal, frontal, and axial slices, locates and measures talar and tibial cyst volume.

We recommend CT at 2 years, 10 years, and ahead of revision or in case of increased cyst size and/or pain, so as to be able to suggest implant removal before the talar component collapses. It is not necessary to perform preventive CT between 2 and 10 years: cyst onset is early and rapidly evolving [6, 20, 24]. Moreover, Bonnin [11, 13] reported non-evolutive cysts appearing in radiologic studies but remaining asymptomatic at 11 years' follow-up.

Our Recommendations

At present, we recommend systematic preoperative CT to diagnose any osteoarthritic cyst (with a view to grafting) and, for baseline control, X-ray monitoring at 1, 2, 5, and 10 years and systematic CT at 1 year (to check the bone prosthesis interface carefully and diagnose possible early cyst) and at 5 years. In case of cystic aspect, X-ray monitoring must be tighter, with new CT in case of aggravation on X-ray or pain.

Management of Treatment

First of all, we recommend assessing whether the patient is symptomatic, with systematic CT ahead of TAR, to determine location and size of cysts to adapt therapeutic management.

The management of asymptomatic periprosthetic cysts is a controversial topic. Three therapeutic options exist in case of cyst: curettage-bone grafting, arthrodesis, and revision arthroplasty.

Publications reporting TAR revision did not isolate the revision etiologies: aseptic loosening (one of the most common causes, up to 40%), subsidence of the talar component, progressive cyst formation, malalignment, instability, and septic loosening; however, aseptic loosening can also be secondary to cyst and/or implant subsidence. In the literature there is no evidence of the superiority of arthrodesis or new TAR for TAR revision. In 2015 Kamrad [34], in 69 cases of TAR exchange in the Swedish ankle registry, reported a 10-year survival of 55%, and only half of the patients were satisfied. In 2016, Kamrad [35], in 118 TARs revised with salvage arthrodesis, reported 90% arthrodesis fusion but less than 50% satisfaction and low functional scores.

There remains curettage-grafting, as option of choice.

Cyst Curettage: Bone Grafting

Curettage with bone graft is a preventive surgery to halt periprosthetic cystic changes and should prevent mechanical dislocation and reduce pain.

Few series have been published on the results of TAR cyst treatment:

- With the Salto prosthesis, Bonnin [13] found that tibial and/or talar bone cysts (>5 mm or larger) that were curetted and filled with bone graft postoperatively showed complete or almost complete remission, although three out of eight went on to arthrodesis. Some authors have reported similar findings with the Agility prosthesis. On a series of 322 Salto TARS, Trincat and Judet [36] reported 21 cases of painful evolutive cyst treated by autograft. At more than 2 years of follow-up, AOFAS score was stable (79/100), cysts resolved in 6 patients, 11 patients showed radiological improvement, cyst size increased in 2, and 2 ankles underwent arthrodesis (i.e., 19% failure rate).
- Gross in 2016 [37], in a retrospective study of 33 procedures for bone cysts after TAR (25 allograft, 4 calcium phosphate, 3 cement, 1 autograft), found a success rate of 90.9% (95% CI, 50.8–98.7%) at 24 months but deteriorating over time with a survival rate of 60.6% (95% CI, 25.1–83.4%) at 48 months. In the 19 patients who had more than 1 year's follow-up (median 31.9), ten (62.5%) had resolution of the cysts on radiographic examination, but CT scans were only available for 2 patients.
- Kohonen in 2017 [38], in a study involving 34 bone grafts for periprosthetic cysts, 29 of which were allografts, found a 68% radiological progression of osteolysis with an average follow-up of 3.8 years (2–6.2 years), generally associated with pain. In only 28%, radiological survival was excellent, and 25 out of 34 ankles showed improvement in function after bone grafting.

The previous anterior approach is used. Cysts are accessed via the cortical lysis, when present; otherwise, a cortical bone window is performed under CT guidance. Curettage is performed under visual control with a mini image intensifier, guided by 3D cyst assessment on preoperative helical CT. Spaces are filled by compression graft. The main procedural risk is of implant destabilization, which would be an indication for primary arthrodesis. It is difficult to perform curettage and complete filling of all of the cysts encountered, so as to achieve high-quality grafting: cysts are sometimes hard to access. Intraoperative fluoroscopic control of curettage improves this step of surgery, but still cannot guarantee systematic curettage of all cysts (Fig. 24.2). A bivalve plaster

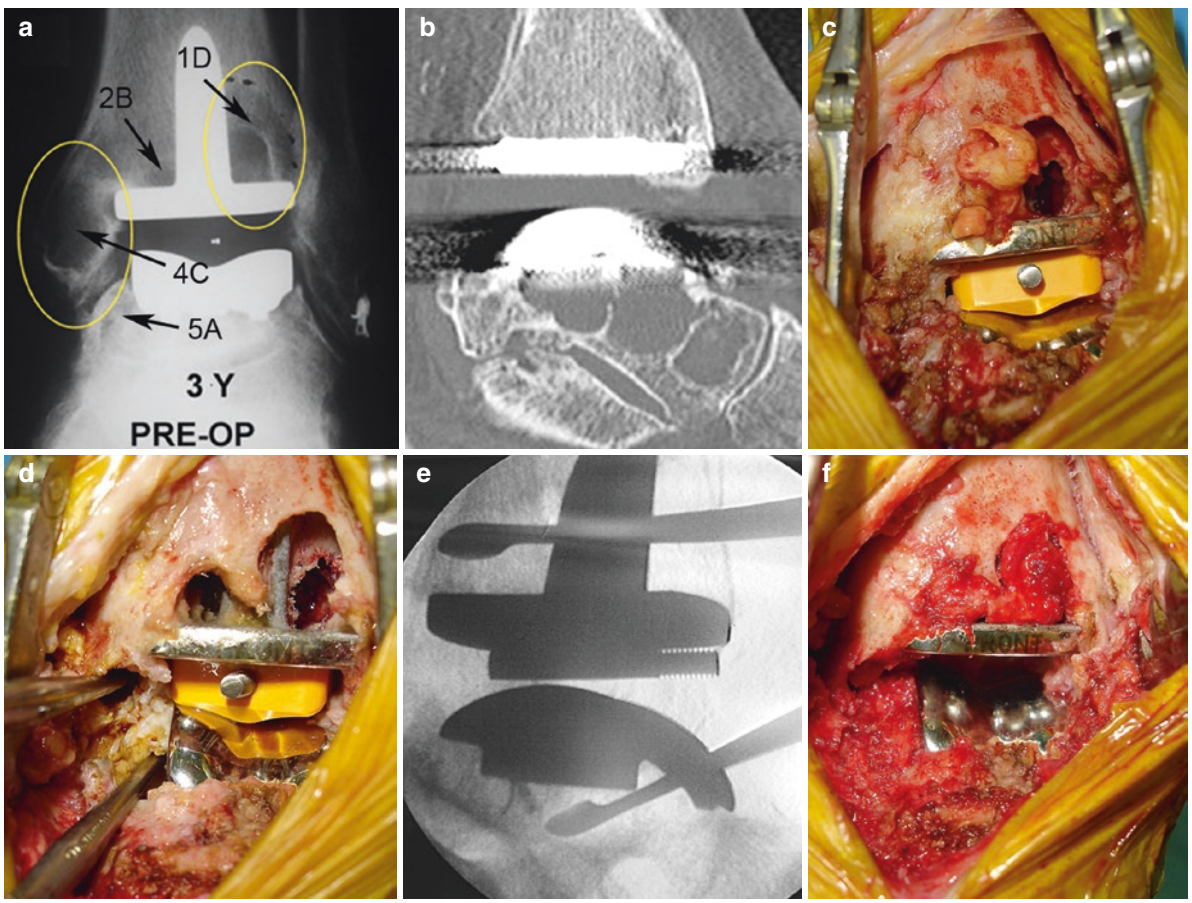


Fig. 24.2 Cyst graft protocol. Example of preventive bone graft with exchange of mobile bearing to preserve well-fixed implants. (**a**) X-ray and (**b**) CT assessment at 3 years after AES ATR, for a 77-year-old man: expansile lyses and functional degradation (AOFAS global score 71 vs. 80 at 2 years; AOFAS pain score 20 vs. 30 at 2 years). (**c**) Yellow fibrous tissue in cysts. (**d**) After tibial granuloma removal, implants were well fixed. (**e**) Fluoroscopic lateral view to check talar granuloma removal. (**f**) Intraoperative aspect after cancellous bone autograft

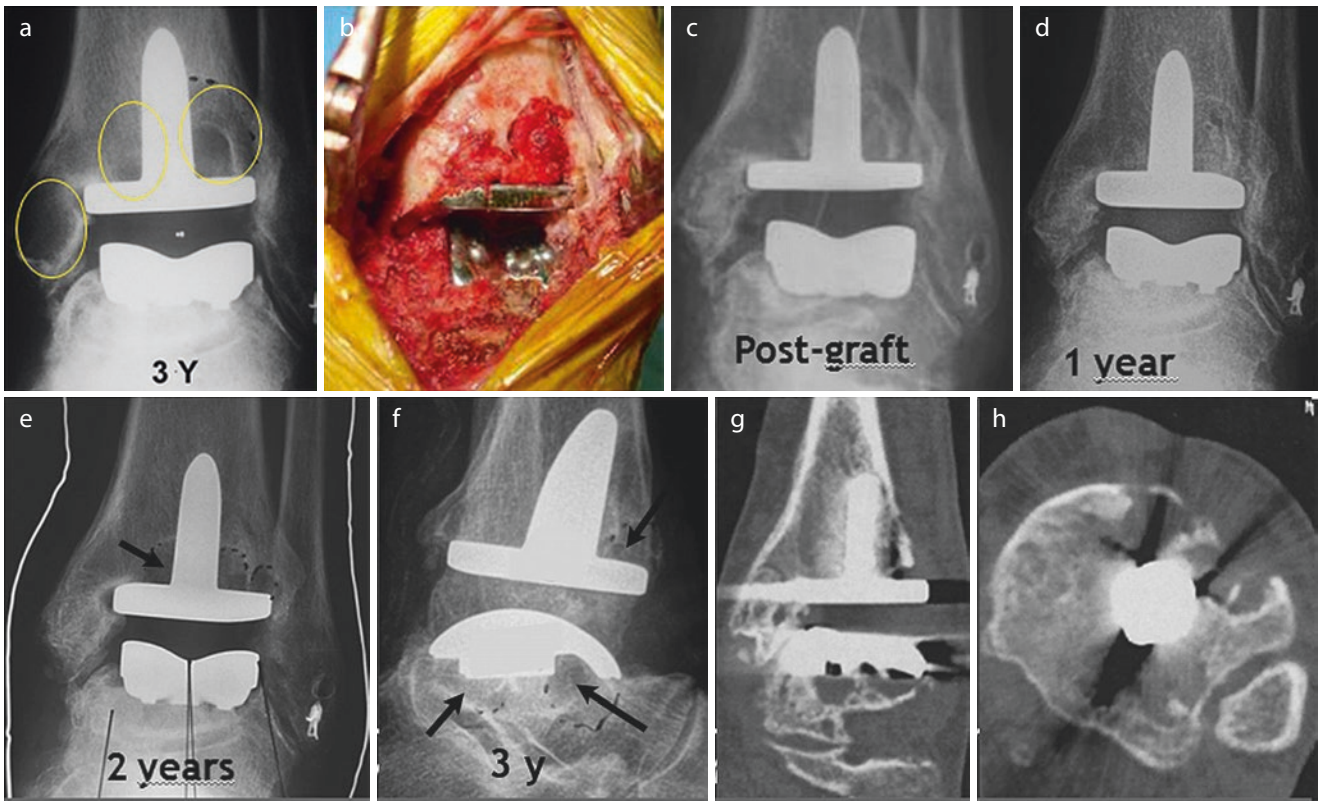


Fig. 24.3 Cyst recurrence after autograft. (**a**) Lateral X-ray assessment at 45 days for a 75-year-old man: good radiological aspect of autograft. Intraoperative aspect after cancellous bone autograft. (**b**) Intraoperative aspect after cancellous bone autograft. (**c**) Postoperative AP view. (**d**) Good radiological result at 1 year. Recurrence of cyst on tibia at 2 years (**e**) and on talus at 3 years (**f**: lateral view – **g**, **h** – CT assessment)

cast is fitted at postoperative day 2, for 3 weeks under non-weight-bearing, followed by a removable boot cast for 3 weeks, with resumption of weight-bearing and physiotherapy.

From 2003 to 2019, we implanted 374 TARs: 84 AES TARs (2008–2008), 97 Hintegra TARs (2009–2014), 193 Salto Talaris TARs, and XT TARs (2015–2019). The first curettage-graft for cyst following AES TAR was in May 2008. From January 2008 to December 2019, 91 TAR revisions were performed including 29 curettage-grafts for periprosthetic cyst (22 AES and 7 Hintegra TARs). Three types of filling were successively used: 7 with cancellous autograft (May 2008–March 2009), 4 with P-Ca cement (September 2009–April 2010), and then due to early recurrence of cyst after bone graft, 18 with PMMA cement with gentamycin (from October 2010).

In our first study in 2003 [31], we showed that it was difficult to perform curettage and complete filling of all of the cysts encountered. Out of 20 TARs (9 male, 4 female; mean age, 55.6 years) which underwent revision by cyst curettage-grafting (7 corticocancellous iliac autografts, 1 mixed P-Ca cement/autograft, 4 P-Ca cement, and 2 PMMA cement grafts), 8 patients had to be reoperated for cyst associated with cortical lysis and 6 preventively for >3 cm cyst. With a mean follow-up of 32 months, 92% of the series experienced cyst recurrence (Fig. 24.3) despite a satisfactory short-term aspect with autograft, 33% (4/12) required arthrodesis, and 41% showed evolutive cyst recurrence. Functional results were unpredictable and unrelated to graft type. Only the two patients who were managed using polymethylmethacrylate (PMMA) cement seemed to show good functional and radiological results but with insufficient follow-up to allow any firm conclusion.

Recurrence of evolutive cyst could be a matter of incomplete curettage and persistence rather than recurrence as such, given the difficulties of access, notably in the talus, and the impossibility of checking curettage quality intraoperatively. It could also be due to a continuing tumor-like foreign body effect of incrusted microparticles of titanium.

Apart from sometimes insufficient volume, the main problem entailed by autograft harvesting from the anterior iliac crest is the reduction in bone capital available for possible subsequent implant removal managed by reconstruction-arthrodesis. The P-Ca cement filling option proved

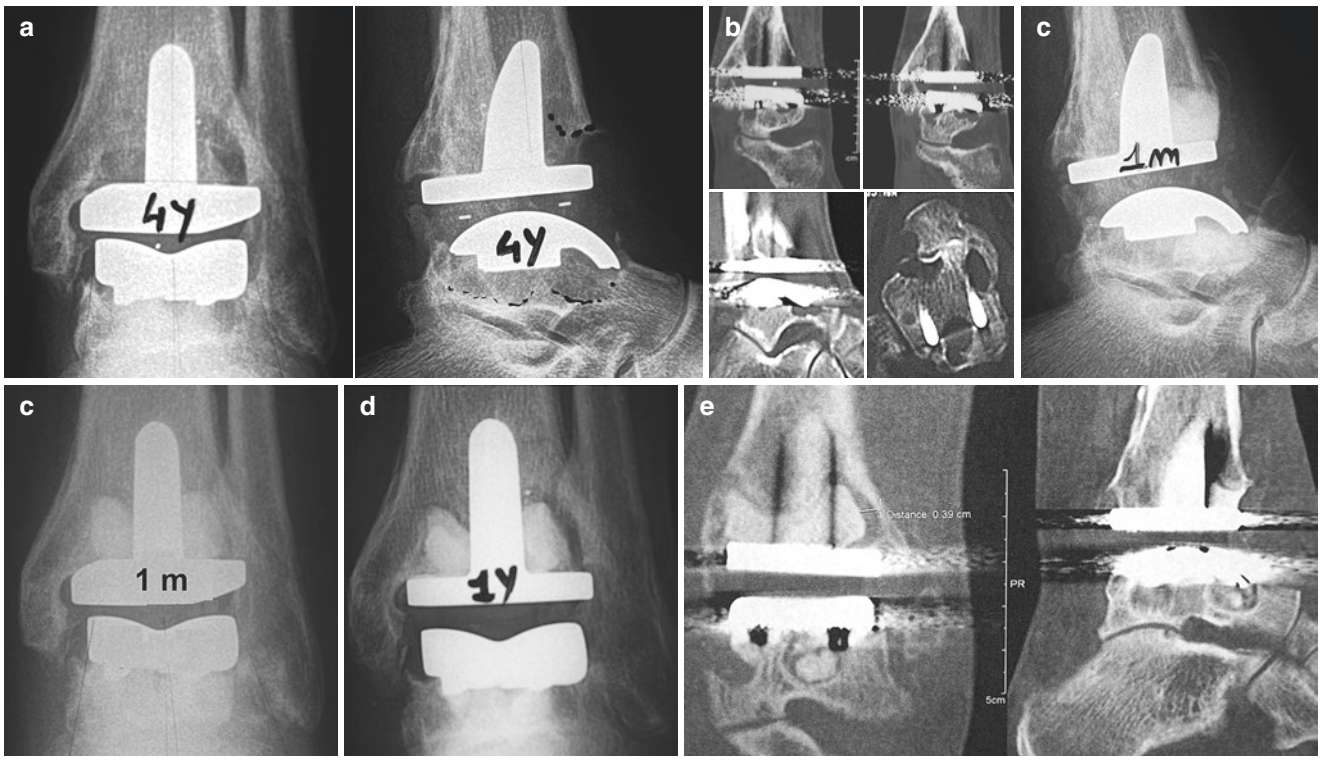


Fig. 24.4 P-Ca cement graft evolution. (**a**) X-ray and (**b**) CT assessment at 4 years for a 57-year-old man: expansile cysts and functional degradation. (**c**) Lateral and AP X-ray aspect of P-Ca cement graft at 1 month: good bone-cement contact. 2–5 mm lucent line between P-Ca cement and bone on X-ray (**d**) and CT (**e**) assessment at 1 year

disappointing, due to rapid onset of evolutive lucency associated with graft retraction, creating a bell-shaped aspect found in all cases in the present series (Fig. 24.4).

Even if PMMA cement may seem illogical with a hydroxyapatite-coated implant, it can provide a salvage solution (Fig. 24.5). With a shorter follow-up for the PMMA cement option, we had better results than with bone graft: in the 11 bone graft or P-Ca cement fillings, 7 patients required revision (6 by arthrodesis, 1 by a new filling with PMMA cement), whereas no revision was required in the PMMA group, and functional scores were better (AOFAS score 84.1 ± 10 versus 76.2 ± 14). In the PMMA cement group on CT at a mean 34 ± 26 months, filling remained of good quality in 63% (sometimes with slight radiolucency of 1–2 mm (Fig. 24.6)), 1 patient developed new talar cyst (of 1 cm), and 1 showed aggravation of talar cyst (>2.5 cm) likely to require revision in the near future.

So we therefore recommend regular X-ray and CT monitoring, and curettage-graft preventive treatment for large cyst (>3 cm) even if asymptomatic (Fig. 24.7). For this conservative treatment, we abandoned cancellous bone grafting due to cyst recurrence; PMMA-gentamycin cement filling seem to be a good option to prolong TAR implant survival and conserve bone stock.

Arthrodesis

Salvage arthrodesis after failed total ankle replacement is a difficult procedure. Arthrodesis has fusion rates ranging between 61% and 100% [39]. It appears that successful fusion and good clinical outcome can be expected in patients receiving tibiotalar or tibiotalocalcaneal (TTC) arthrodesis. Isolated tibiotalar arthrodesis as a salvage procedure for failed TAR can be considered only in patients with a normal subtalar joint and good bone stock.

Depending on the volume of graft needed to fill the bone defect, auto- or allograft or a combination of the two is used. Usually, massive graft is needed for severe lesions (grade D or E). Autograft is considered the gold standard for bone grafting, because of its good healing performance. Different kinds of autograft are used (femur reamer/irrigator/aspirator, posterior or anterior iliac crest, etc.).

To achieve and maintain the desired correction, a structural graft is often needed to fill gaps during reconstructive procedures after TAR revision:

- Massive cancellous allograft is a good alternative to compensate a large bone defect. Cancellous bone allograft has good osteoconductive properties, with no harvesting mor-

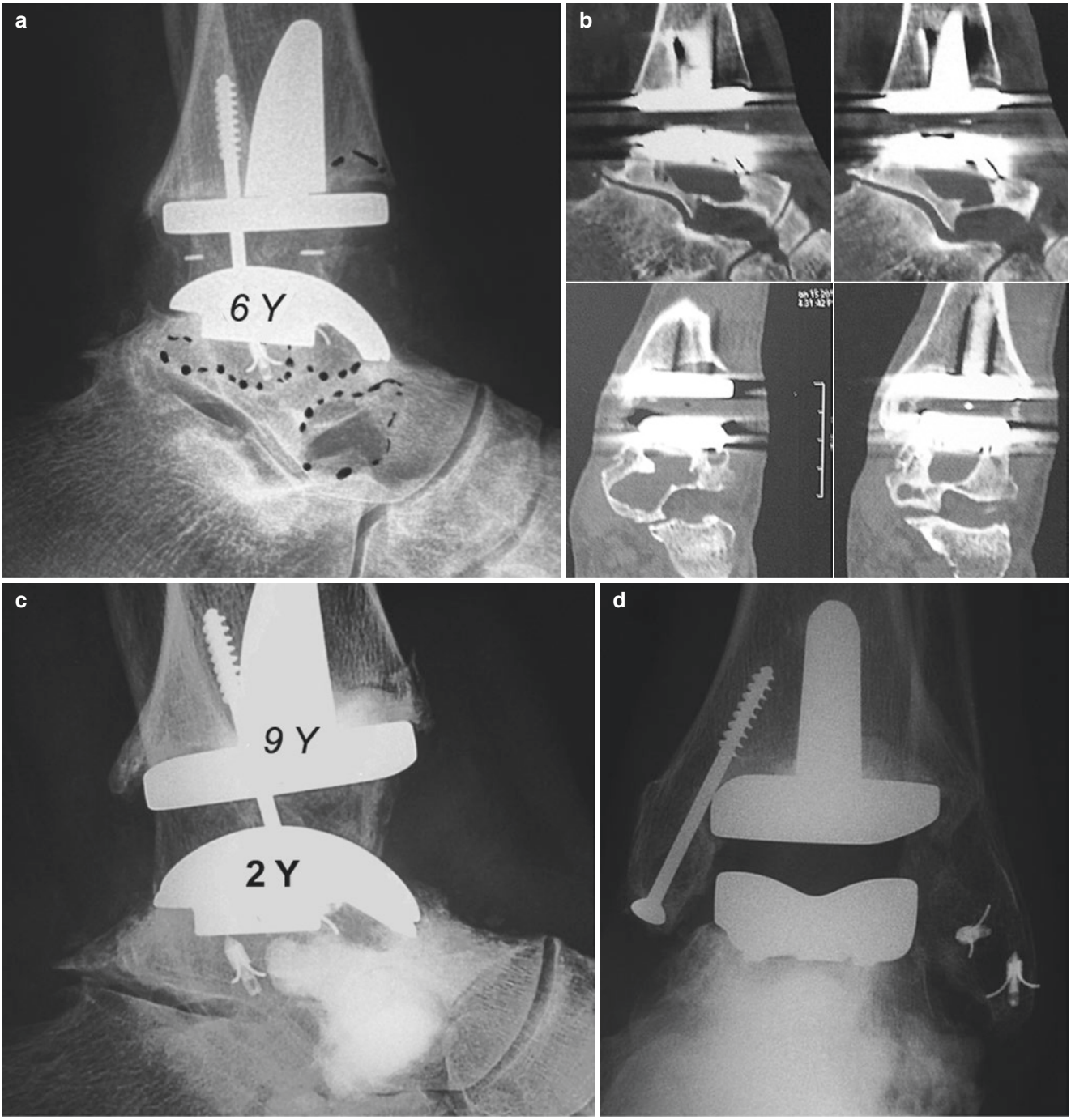


Fig. 24.5 Good radiological result of graft with PMMA cement. (**a**) X-ray and (**b**) CT assessment at 6 years for a 81-year-old man: expansile talar cysts with high risk of talar subsidence but painless (AOFAS global score 100). (**c**, **d**) Good radiological results at 2 years

bidity, but is not osteogenic or osteoinductive. Berkowitz [40] reported 12 patients with failed ankle replacements treated by TTC arthrodesis using femoral head or distal tibial allograft with only 58% fusion rate. Fixation included plates and screws, intramedullary rods, or a combination of both. Eighty percent of non-unions occurred at the subtalar joint. Jeng [41] reported similar results, with a 50% radiographic fusion rate for bone-block TTC arthrodesis using femoral head allograft. The use of allograft bone-block in the setting of TTC arthrodesis remains an important option in difficult reconstructive cases with extensive bone loss due to failed ankle replacement. However, the risk of complications is high, with 19% of patients reported as requiring below-knee amputation (Fig. 24.8).

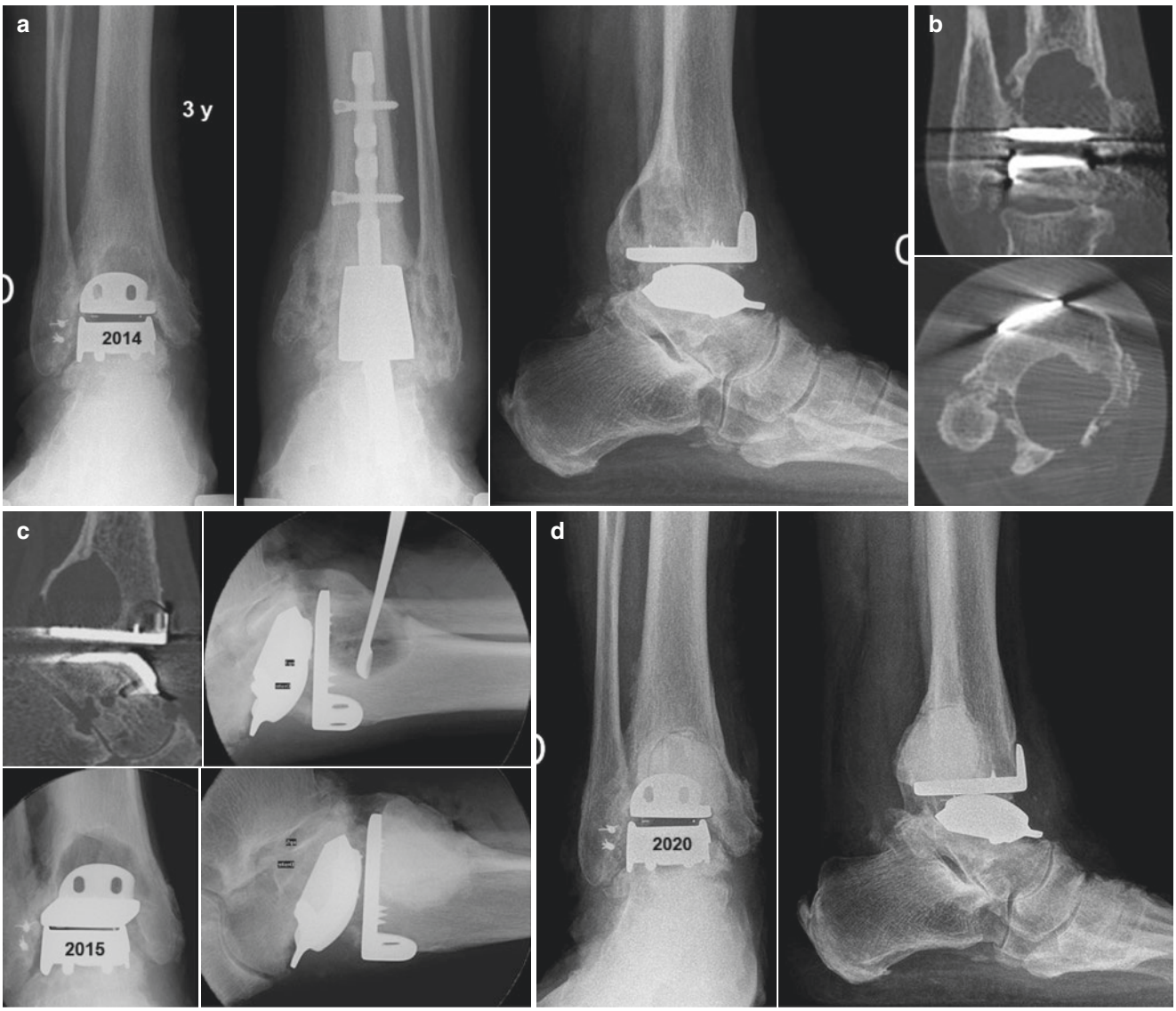


Fig. 24.6 Posterior approach for tibial curettage-graft with PMMA cement. (**a**) Diabetic patient, 63 years old at AES TAR performed on the left ankle in 2006, with talar subsidence in 2013 due to expansile cysts, treated by tibiotalocalcaneal arthrodesis with tantalum spacer (with good functional result). Hintegra TAR performed on the right ankle in 2010, with early and rapid development of posterior tibial cyst with cortical breach. (**b**) X-ray and CT assessment in 2014. (**c**) Curettage-graft with PMMA-gentamycin cement in prone position with a postero-lateral approach. (**d**) Good radiological and functional results at 5 years (AOFAS 92, ROM 10–35°, slight radiolucency of 1 mm)

- Deleu [39] proposed associating allograft to an osteoinducer such as demineralized bone matrix (DBM) or bone autograft. Adding an osteoinductive environment to the bone allograft was of primary importance to improve mechanical stability and increase fusion rate: 13 (76.4%) of the 17 ankles fused after 3.7 months and 3 after repeat arthrodesis.
- As autograft is not sufficient, and allograft requires a long period of non-weight-bearing, porous tantalum was tried as spacer (Fig. 24.9). Tantalum is a biocompatible trabecular metal with mechanical properties similar to bone, used extensively in THA and TKA revision. Its compressive strength and elastic modulus are similar to those of normal bone, which theoretically reduces stress shielding and stress concentration. Porous tantalum is used to fill the defect and reinforce arthrodesis-reconstruction.

Between September 2013 and September 2015, we operated on a continuous cohort of 11 patients (7 AES TARs, 2 Hintegra TARs, 1 Salto TAR, 1 Ramses TAR) for TAR revision with reconstruction-arthrodesis using the specially designed TM spacer. The indication for revision was collapse of the implants due to subchondral cysts in seven patients and severe misalignment with subchondral cysts in four patients. The

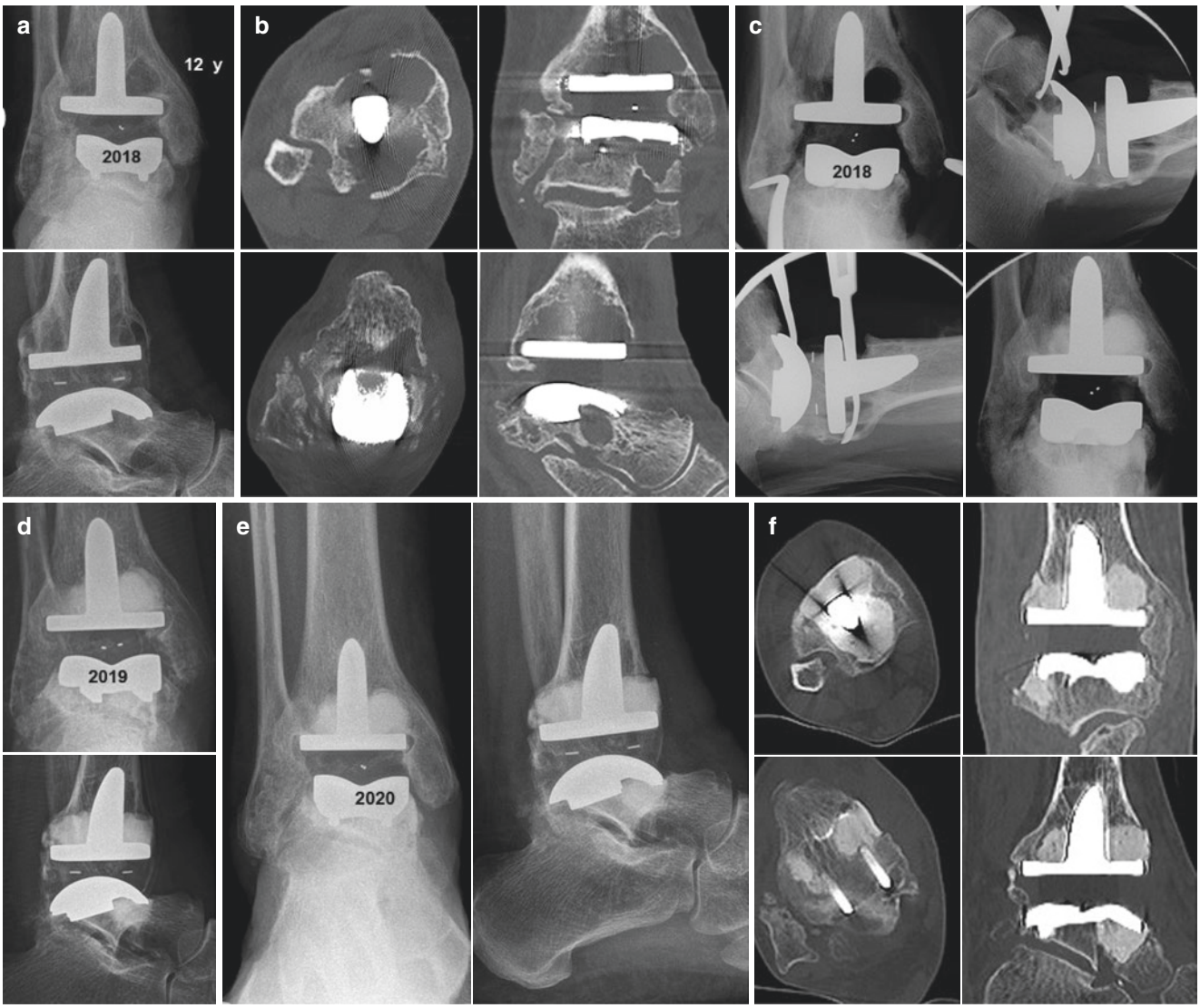


Fig. 24.7 Radiological result and CT assessment of graft with PMMA cement. (**a**) AES TAR performed in 2004 in a 60-year-old man, for post-traumatic osteoarthritis. (**b**) X-ray and CT assessment at 12 years: expansile tibial cysts (>3 cm) with cortical breach and a talar cyst (1.5 cm) but almost painless (AOFAS score 85). (**c**) Anterior approach of tibial and talar cyst, guided by the CT. Curettage under fluoroscopy control and graft with PMMA-gentamycin cement. (**d–f**) Good radiological, CT, and functional results at 2 years (AOFAS 85, ROM 15–40°, complete cementing and no new cysts)

height of the bone defects measured intraoperatively was 33 mm (25–70). A Trabecular Metal™ Ankle Interpositional Spacer (Zimmer®) was used to fill the defect and reinforce the arthrodesis. We used implants of three different widths and four different heights (8 of 25 mm, 1 of 30 mm, 1 of 35 mm, and 1 of 45 mm) to match the height and shape of the bone defects. Autograft was added to all the TM implants. This was harvested by reaming the anterior iliac crest using an acetabular reamer in nine patients. This technique provides large quantities of osteogenic corticocancellous graft material [17]. In the two other patients, autograft was harvested from the posterior iliac crest. The autograft was combined with lyophilized bone allograft chips. Ten patients underwent TTC arthrodesis fixed with a non-locked retrograde nail (AFN611TM, Tornier), one patient underwent tibiotalar (TT) arthrodesis fixed with two locking plates (Tibiaxys® Ankle Plate, Integra. The patients' ankle was immobilized for 2 months in a removable posterior resin splint, and they were not allowed to bear weight on the operated limb. Gradual return to weight-bearing was allowed after 2 months with a removable walking boot.

Despite encouraging preliminary results [42], the clinical outcomes after more than 1 year of follow-up (19.3 months) were disappointing (mean AOFAS score 56 (26–78)), as was the large number of non-union cases (5/10) and the lack of tantalum integration (4/10); three patients required surgical revision (Fig. 24.10). These technical failures [43] can be

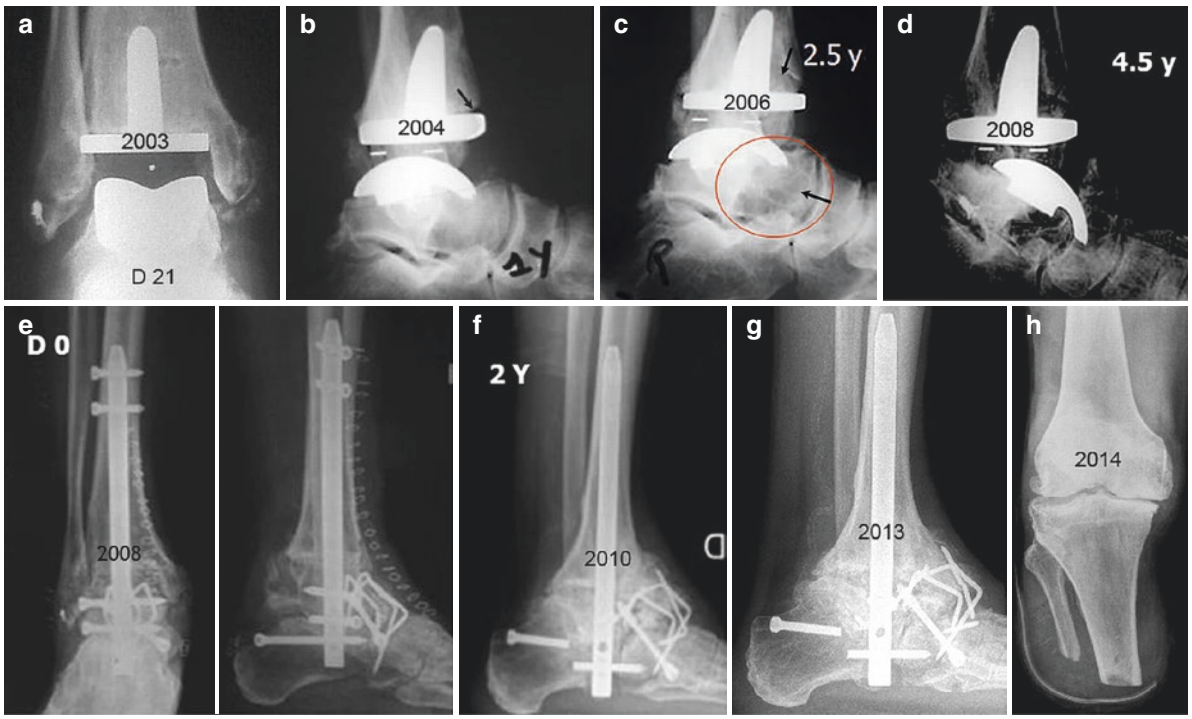


Fig. 24.8 Mechanical implant subsidence due to talar cysts and dramatic failure of TTC arthrodesis with allograft. (**a**) A 55-year-old man with OA secondary to laxity. Postoperative X-ray: good implant positioning (AES TAR). (**b**) 1-year X-ray assessment (small cyst, type A in area 7). (**c**) 2.5-year X-ray: progression of severe cysts (type C in area 7, type D in area 10); patient still asymptomatic. (**d**) 4.5-year acute (acute pain) mechanical failure with talar implant subsidence. (**e**) Revision by tibio-calcaneal-navicular arthrodesis with massive bone allograft and autograft, and osteosynthesis by retrograde nail. (**f**) Non-union and progressive collapse with nail locking-screw breakage. (**g**) Stable clinical situation with few pain but radiological non-union. (**h**) Sudden and acute severe ankle infection requiring a tibial amputation after multidisciplinary consultation with infectologists

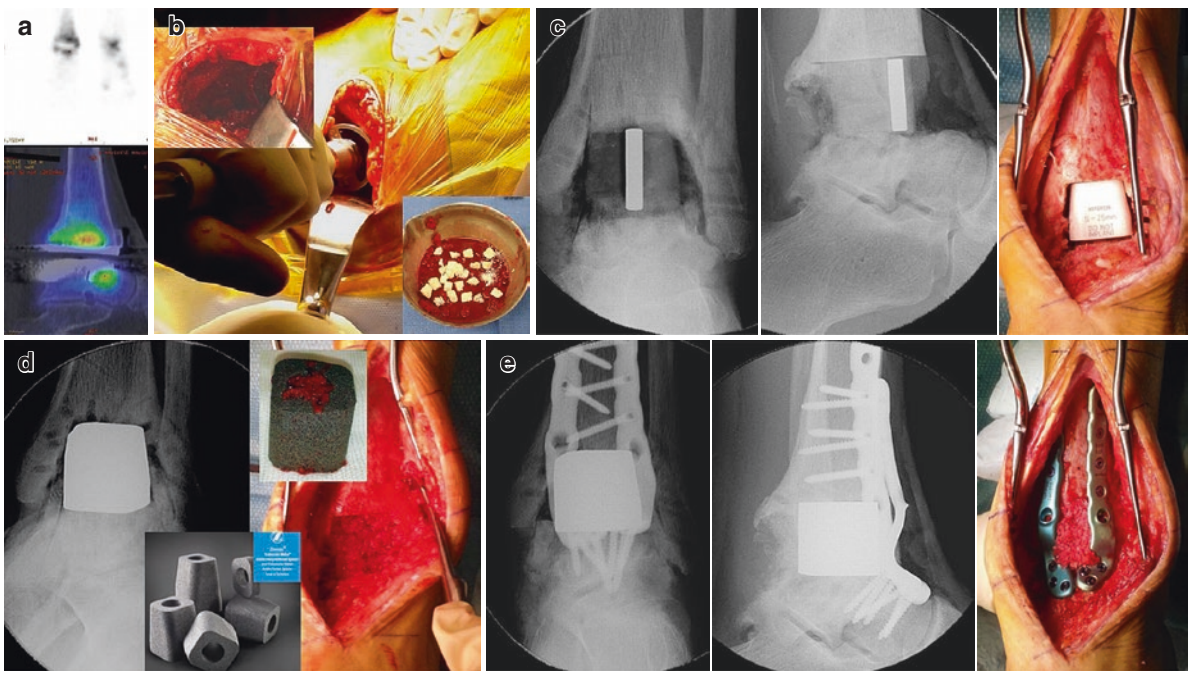


Fig. 24.9 Tantalum spacer for ankle arthrodesis-reconstruction of TAR revision. (**a**) Hintegra TAR performed in 2012 in a 55-year-old man. Chronic pain due tibial component non-integration with microcyst (Spect-CT assessment). (**b**) Anterior iliac wing harvested with hip reamers, mixed with lyophilized fragmented human bone. (**c**) Fluoroscopy aspect after implant removal, 25-mm tantalum trial filling bone defect. (**d**) 25-mm tantalum spacer (*Zimmer*™) surrounded by autologous bone graft. (**e**) Osteosynthesis with two locking plates (*Tibiaxys*™ – *Integra*™)

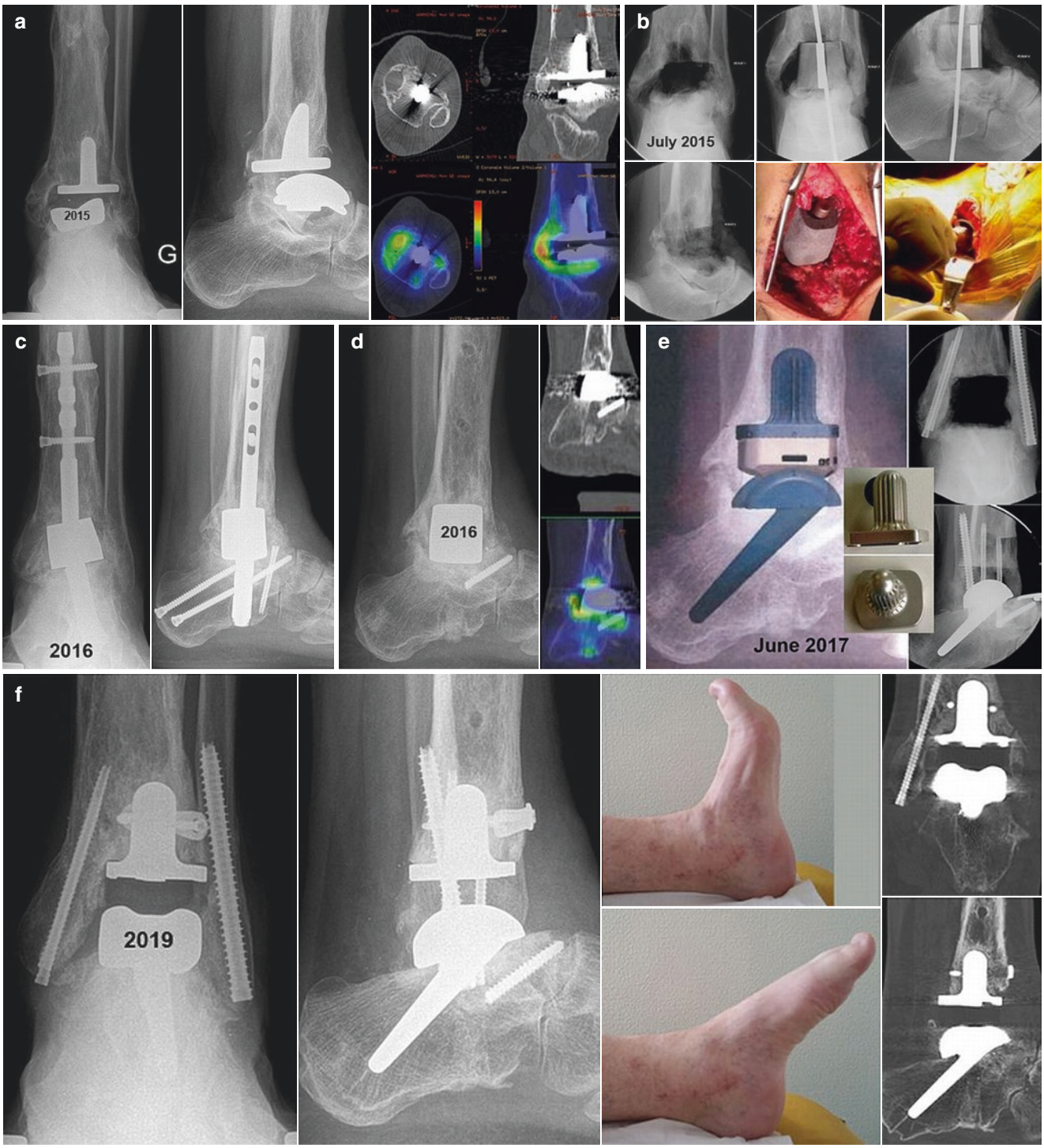


Fig. 24.10 Failure of TTC arthrodesis-reconstruction with tantalum spacer associated with angulated retrograde nail and revision by conversion to a new TAR. (**a**) AES TAR performed in 2007 in a 44-year-old man for post-traumatic osteoarthritis, with TAR subsidence associated with expansile cysts in 2015. (**b**) TTC arthrodesis with tantalum spacer, 25-mm trial implant filling bone defect; subtalar joint freshened and grafted (autograft taken from anterior iliac wing harvested with hip reamers); 25-mm tantalum spacer (*Zimmer*™); osteosynthesis with angulated retrograde nail *(AFN 611*™ *– Tornier*™) surrounded by autologous bone graft. (**c**) At 10 months, TTC seemed radiologically fused, but patient still had pain and bone scan showed hyperfixation. (**d**) Nail removal confirmed non-incorporated tantalum implant and non-union. (**e**) Conversion to TAR with custom-made tibial component and Salto XT talar component. Preventive osteosynthesis of two malleoli before tantalum implant removal. (**f**) At a 2-year follow-up, good results: little talo-navicular joint pain (AOFAS score 73), good ROM (15–45°), good TAR integration on CT

explained by insufficient construct stability and/or insufficient implant porosity.

Revision Arthroplasty

For evolutive osteolysis, some authors perform revision arthroplasty with revision implants associated or not with bone graft. Hintermann [44] reported medium-term results for revision arthroplasty after failed TAR similar to those for primary arthroplasty; the key to success was firm component anchorage to primary bone stock.

From 2007 to 2016, I did practically only TAR revision by arthrodesis; but my results were often disappointing, depending on my graft reconstruction choice: secondary collapse of femoral head allograft (always irradiated in the Lyon bone bank) and poor experience with tantalum cage (50% non-union out of 11 cases).

So after 2016, due to the arrival of the Salto Talaris system with revision range (XT) on the French market, we completely changed our attitude, in favor of re-do TAR. For these potentially long and difficult surgeries, we have some technical and medical tips: systematic associated posteromedial approach (2–3 cm) to protect posterior tibial neurovascular bundle, with a flexible aluminum strip, IV corticosteroid flash (500 mg) and IV tranexamic acid (1 gr) hemostasis during anesthesia induction, and the first step without tourniquet to reduce post-op. edema, hematoma, and associated skin complications.

For talar component failure due to cyst, we associate corticocancellous autograft (sometimes with screw fixation) with subtalar fusion and talar revision implant with keel (Fig. 24.11).

Suggested Cyst Management Algorithm

According to our experience of cyst assessment by X-ray and CT scan [6, 20], relatively bad results associated with graft [6, 24], and arthrodesis-reconstruction [36], we can propose the following algorithm for cyst management (Fig. 24.12).

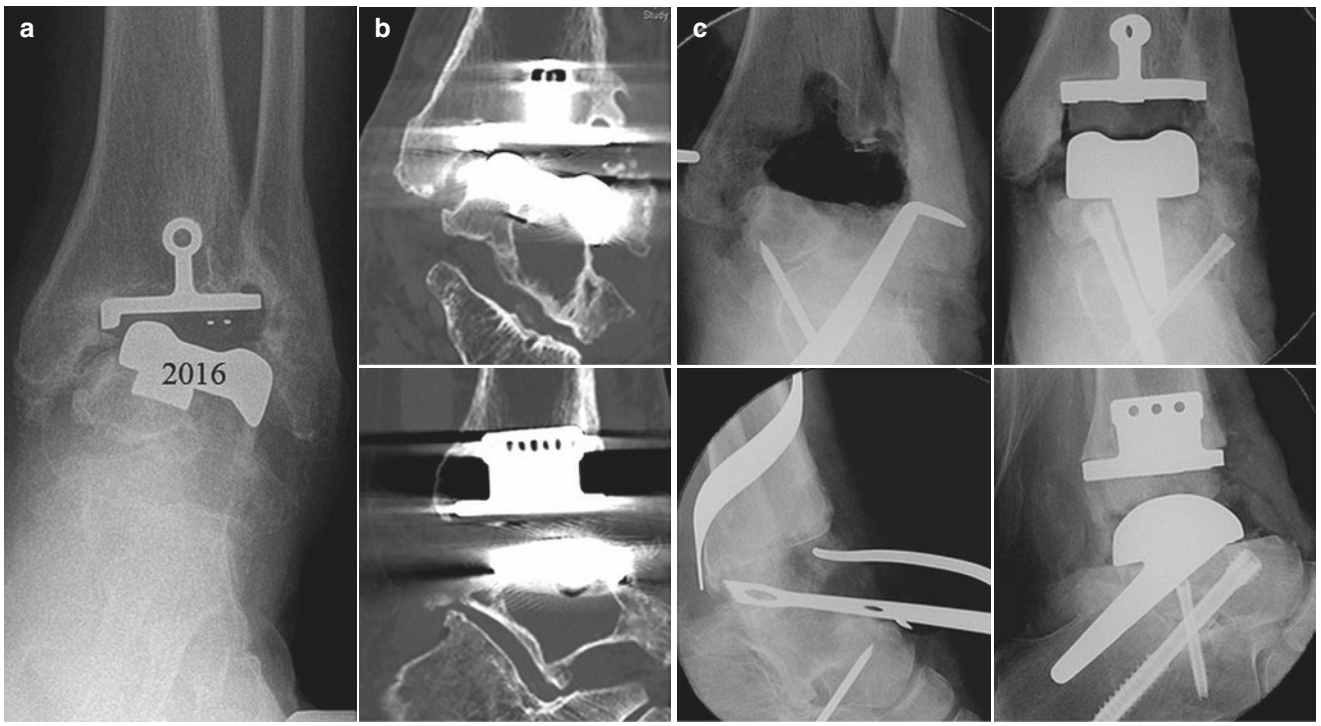


Fig. 24.11 Salto mobile TAR loosening associated with big talar cysts revised by Talaris revision TAR and subtalar fusion. (**a**) Salto mobile TAR performed in 2006 in a diabetic 62-year-old man. In 2016 complete dislocation in varus (AOFAS 22, ROM 0–40°). (**b**) On CT assessment, big talar cysts (25–30 mm). (**c**) Revision by Salto XT TAR and associated procedure: peroneal synovectomy, cyst graft and lateral talar reconstruction (with corticocancellous bone fixed by screw), subtalar arthrodesis (complementary fixation by one screw), and lateral ligament reconstruction. (**d**) Very good result at 1 year (very satisfied, AOFAS 87, ROM 15–40°). (**e**) CT scan: subtalar joint fusion, good TAR integration

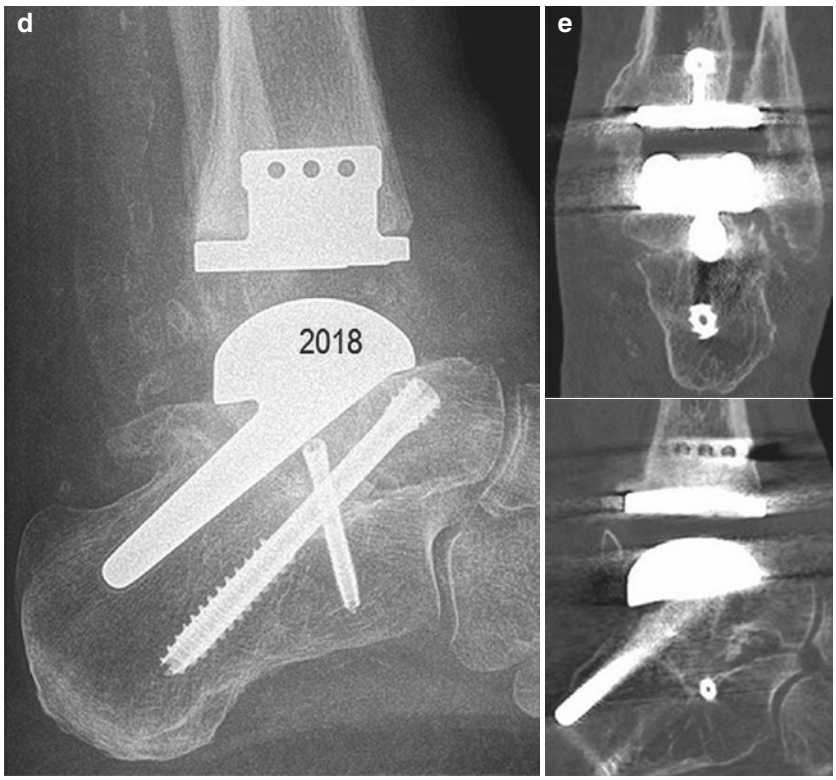


Fig. 24.11 (continued)

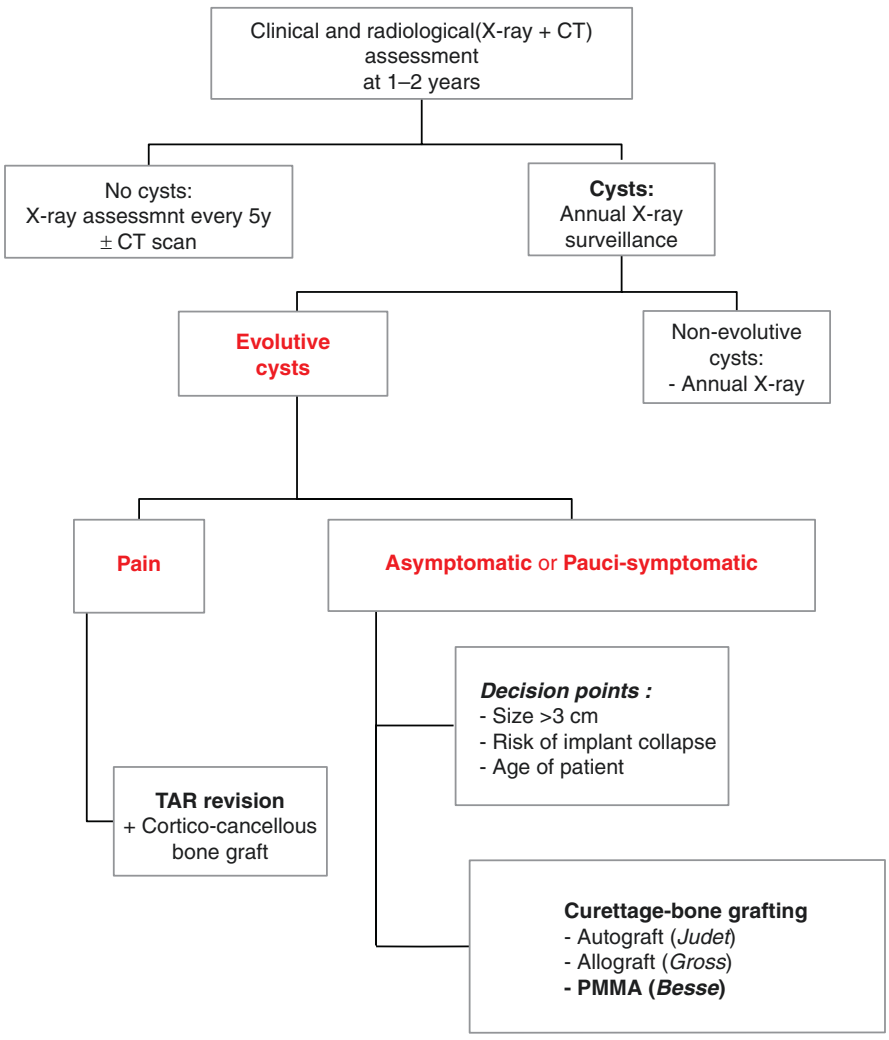


Fig. 24.12 Therapeutic flowchart

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Arthroscopic Debridement for Soft Tissue Impingement After Total Ankle Replacement

25

Bom Soo Kim and Jin Woo Lee

Persistent Pain After Total Ankle Replacement

Total ankle replacement (TAR) is being accepted as an alternative treatment modality for end-stage osteoarthritic ankle. Improved clinical outcomes and longevity, together with the increasing number of surgeons trained to perform TAR, contribute to the rapidly increasing frequency of implantation.

Despite good clinical outcomes reported in the literature, clinicians not infrequently encounter patients complaining of persistent pain in their replaced ankles. Dealing with consistent pain can be stressful both for the patient and the surgeon. Pagenstert et al. [1] showed increased pain and swelling at 3 months after surgery which gradually decreased over a 12-month period. However, most of the patients are not completely pain-free even after 1 year. Kim et al. [2] reported that among 120 uncomplicated primary TARs, pain intensity decreased in 115 (95.8%) ankles, but 91 (75.8%) still had some degree of residual pain (mean VAS 3.5, range 1–8) at a mean follow-up of 40 months (range, 14–84) after surgery. Therefore, understanding the scope of TAR and having realistic expectations before surgery and during postoperative rehabilitation period can be helpful.

Soft Tissue Impingement as a Cause of Painful TAR

What are the possible causes of persistent pain after TAR? Any evident complications can eventually develop symptoms and may require revisions. These include malalignment problems, aseptic loosening, infection, ligament imbalancing, bearing subluxation, osteolysis and periprosthetic cyst formation, and heterotopic ossifications. Most of the complications can be well detected by an experienced surgeon, and their management guidelines are provided in other chapters of this textbook.

Soft tissue impingement is a condition where synovitis or hypertrophic fibrous scar tissue is entrapped between the two opposing structures in a joint and causes pain during recurrent and extreme range of motion exercises under load [3]. When compared to arthrodesis, soft tissue impingement is unique to joint replacement because a fused joint lacking any motion would not have impingement around the lesion. Since total joint replacement allows motion, synovitis or postoperative fibrous tissues can impinge between the prostheses and cause discomfort.

The concept of soft tissue impingement as a cause of persistent pain after a total joint replacement is well established in the knee. Patellofemoral synovial hyperplasia is characterized by a diffuse proliferation of soft tissues after total knee arthroplasty that causes painful impingement during motion. Patellar clunk syndrome, a painful and audible clunk caused by a discrete prepatellar fibrous nodule, can also be considered as a form of soft tissue impingement. In the hip joint, soft tissue scar impingement, synovitis with associated scar tissue, and capsular scarring with adhesions are known to cause pain in a replaced hip joint [4].

Similar phenomena can occur in the ankle joint. Obligatory large soft tissue dissection and osseous resection itself are a massive injury to the joint, leading to the development of thick fibrous tissue around the replaced joint. Synovitis due to any lesions creating stress during motion can also cause impingement. Although the exact prevalence is not known, such impingement may explain much of the persistent pain after a joint replacement surgery. Authors believe that understanding the possible etiologies and exerting efforts to minimize soft tissue impingement will help in decreasing the residual pain after TAR.

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Table 25.1 Etiology of soft tissue impingement with total ankle replacement

Idiopathic
Recurrent synovitis or hypertrophic scar tissue formation after total ankle replacement without evident cause
Secondary
Remnant osseous lesions, loose bodies, redundant tissues
Heterotopic ossifications
Alignment problems
Prosthesis sizing or positioning problems
Ligament-imbalancing problems

Etiology of Soft Tissue Impingement

In a normal joint, synovitis usually occurs due to recurrent ankle sprain or instability. It can also be developed secondary to any intra-articular pathologies including osteochondral lesions and loose bodies.

Likewise, in a replaced ankle joint, synovitis or hypertrophic scar tissues can develop either idiopathically (primarily) or as a secondary lesion to underlying pathological conditions (Table 25.1). Ligament imbalancing or joint hypermobility can cause excess movement or subluxation of the polyethylene bearing. Structural problems including malalignment or malposition of the implants can lead to eccentric loading. Any remnant loose bodies, osteophytes, or redundant tissues in the medial or lateral gutter may cause impingement by themselves but can also lead to the development of secondary synovitis or hypertrophic fibrous tissue formation.

Diagnosis

Soft tissue impingement could explain much of the residual pain in otherwise uncomplicated TAR. However, pure soft tissue impingement without any other associated complications can be difficult to diagnose with standard diagnostic workup and can be easily neglected. Therefore, a careful examination with high threshold of suspicion is required in order to detect soft tissue impingement.

Swelling and tenderness around the joint with pain on exertion without any evident cause of pain on plain radiographs are indicative of soft tissue impingement [2]. On physical examination, localized tenderness around the joint typically aggravates when the ankle is dorsiflexed.

Unlike in bony impingement syndrome, plain radiographic images or CT scans are not helpful in diagnosing a soft tissue impingement. Magnetic resonance imaging scans are valueless in the presence of metallic implants. Recently, SPECT/CT has been reported to be useful in localizing and characterizing impingement syndrome and soft tissue pathology in patients with ankle pain [5]. However, hot uptake in SPECT/CT shows increased metabolic rate of the osteoblasts within the bone. Therefore, SPECT/CT primarily reveals the bony areas under stress and not the soft tissue itself.

Arthroscopy is the best way to confirm intra-articular synovitis or soft tissue impingement after TAR. However, due to its operative characteristics, arthroscopic exam should only be considered when the physician is confident with making a clinical diagnosis of soft tissue impingement.

Soft tissue impingement can frequently be accompanied by other various complications. As previously described, malalignment problems, ligament-balancing problems, prosthesis sizing or implantation problems, heterotopic ossification, and bony impingement can all contribute to the secondary development of synovitis or hypertrophic scar tissue leading to soft tissue impingement. For example, a varus malaligned TAR or bony impingement in the medial gutter is prone to increased stress on the medial aspect of the joint, and repeated irritation can end up inducing localized synovitis and soft tissue impingement. Acknowledging all associated problems is fundamental to designing an adequate treatment plan.

Treatment

Conservative arthroscopic debridement treatment consisting of activity modifications, stretching and muscle-strengthening exercises, physical therapies, and nonsteroidal anti-inflammatory drugs should always be primarily implemented. Most transient synovitis or acute inflammatory reactions around the joint can be resolved with nonoperative treatments. Authors suggest a minimum of 6 months of conservative management before deciding an operative treatment.

When pain persists despite the conservative management, it is usually because the fibrous tissue is too hypertrophic and continues to impinge against the opposing prostheses or bony structures. Therefore, such lesions should be removed surgically. Also, in case of secondary synovitis, pain will recur unless the underlying cause has been removed.

Debridement of the impinging soft tissue can be performed open or arthroscopically, depending on the location of the lesion and the surgeon's preference. Open excision is advantageous when the lesion is bulky or located where arthroscope cannot be introduced. However, making additional or large incision on an ankle with a previous large operative scar carries the risk of wound deterioration and infection, which can be detrimental.

Arthroscopic debridement carries the advantages related to its minimal invasiveness. The procedure can be performed under outpatient basis, and the patients' recovery period is much faster than the open surgery. Furthermore, arthroscopic approach also allows better inspection of the deep intra-articular spaces.

However, introducing arthroscope through the thick fibrotic tissues could be difficult in inexperienced surgeon's hands. Therefore, the surgeon should be skilled in the arthroscopy of the ankle joint before attempting to operate arthroscopically.

Surgical Technique

Arthroscopy of the replaced ankle is basically the same as in a normal ankle, except for the thick tissue envelope and the existence of a metallic implant and polyethylene bearing. Therefore, the surgeon can use whichever patient position and distraction method are comfortable.

The authors' preferred operative setting is to have the patient in a supine position with the operating limb bent in the knee and hanging down while the contralateral leg is fixed in a leg holder in a lithotomy position. A pneumatic tourniquet is applied to the upper thigh. After draping, a non-invasive ankle distraction (15 lb) is applied using an ankle harness.

The standard anteromedial and anterolateral portals are sufficient to manage most of the anterior and gutter lesions. The tibialis anterior tendon is palpated, and the anteromedial portal is created just medial to the tendon on the level of the joint. In a normal ankle joint, inflating the joint with saline injection is helpful to determine the joint level and to safely introduce the instrument. However, this could be difficult in a very fibrotic joint and may require careful palpation while moving the joint to determine the joint line.

Once the anteromedial portal is made, a straight mosquito is introduced into the joint and used to detach some of the fibrotic adhesions in the anterior aspect of the joint to create some working space. A 2.7-mm 30° arthroscope is carefully introduced through the anteromedial portal. Under the arthroscopic guide, a needle is inserted from just lateral to the peroneus tertius tendon to determine the location for the anterolateral portal.

When arthroscope is first introduced into the replaced joint space, it can be difficult to get oriented due to the thick fibrous tissues. In such cases, a shaver is introduced until it touches the shaft of the arthroscope. The arthroscope is gently pulled away until the tip of the shaver is visualized. The surgeon can then work his/her way out to create some more working spaces.

Once the visualization is achieved, arthroscopic examination is performed. Hypertrophic fibrotic tissues impinging against or in between the tibial and the talar components can be confirmed by dorsiflexing the ankle joint (Fig. 25.1). Sometimes, the thickened anterior capsule with severe adhesion contributes to pain and limits the plantar flexion movement. Adhesiolysis and release of the anterior capsule can be helpful in such cases.

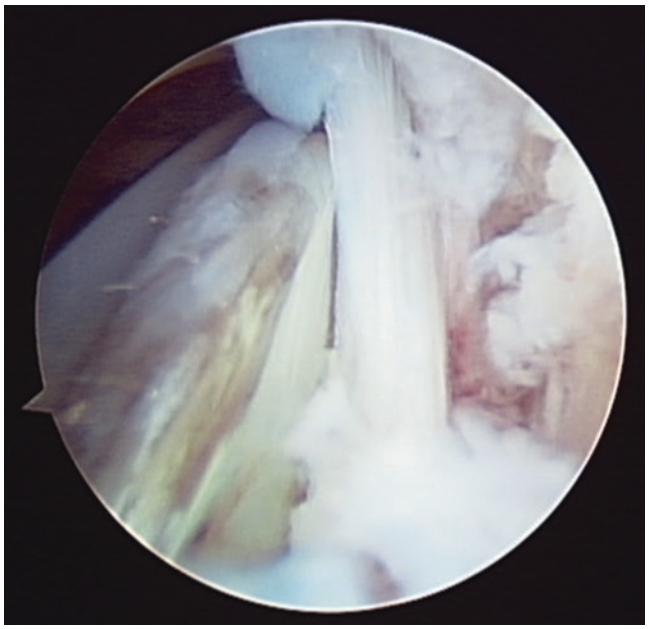


Fig. 25.1 A thick fibrotic band impinging against the talar component in the lateral gutter of a left ankle

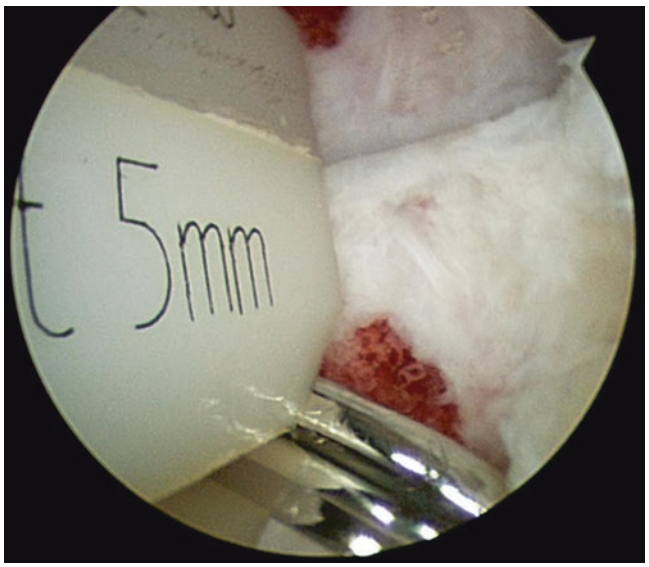


Fig. 25.2 Inflamed synovial tissue abutting the lateral aspect of the talar component of a left ankle

In patients with well-performed TAR, the residual pain is most frequently observed in the medial aspect of the joint [2]. Therefore, the gutter should be thoroughly examined for any possible cause of pain, including synovitis, loose bodies, and thick fibrous tissues (Figs. 25.2, 25.3, and 25.4). Debridement and removal of any structures causing impingement should be performed until clear gutter space is obtained.

Talar implant impinging against medial malleolus is another cause of medial joint pain. This can be due to talar

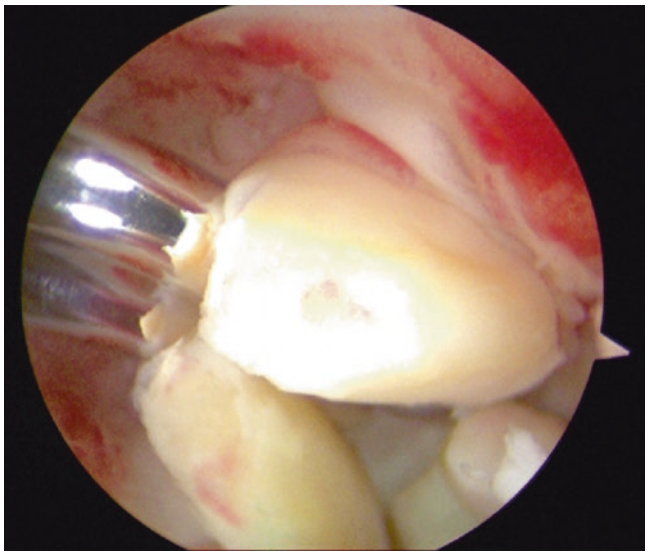


Fig. 25.3 A large loose body within the joint space and surrounding synovitis

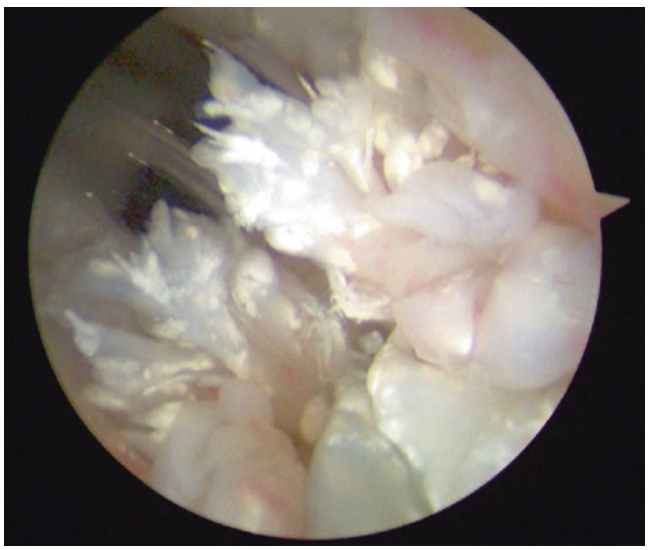


Fig. 25.4 Extensive white chalky debris consistent with uric acid that was confirmed on histology

component being relatively too large compared to the size of the mortise or due to varus or medial malposition of the prosthesis. When recurrent synovitis or soft tissue impingement is associated with underlying alignment or prosthesis problems, then open revision should be considered.

When performing arthroscopic surgery in a replaced joint, great caution should be paid in order to avoid any collision between the instruments and the prostheses. Submicron metallic debris left in the joint space can be the source of recurrent inflammatory reaction and subsequent osteolysis around the prostheses. A thorough irrigation at the end of the arthroscopic procedures can be helpful in removing the non-visible small debris.

Outcomes

Due to the relatively short history of ankle replacement, functional outcomes, survival rates, and revisions due to major complications have been the main topics of interest in the current literatures. However, adequate diagnosis and management of the pain origin in a seemingly well-performed TAR are important in order to increase the patients' overall satisfaction and quality of life.

Although soft tissue impingement is a frequent cause of residual pain after TAR, literature lacks evidence to suggest a widely accepted management guideline. Kim et al. [2] reviewed 120 uncomplicated primary TARs and reported the outcomes of arthroscopic debridement in seven patients diagnosed with soft tissue impingement after TAR. Their indications for surgery included having swelling, tenderness and pain on exertion, and no evident cause on plain radiographs. After debridement, the median VAS decreased from 7 to 3 and six patients were satisfied. Numbness around the portal occurred in one patient. Kurup and Taylor [6] diagnosed eight patients out of 34 as having a soft tissue impingement after TAR. Four received surgery, one open debridement, one arthroscopic debridement, and two decompression of the tibialis posterior tendon, and the patients were reported to be symptom-free at their follow-ups.

Bony impingement is another frequent complication that can cause persistent pain after TAR. Depending on the location and amount of the impinging bone, debridement can be performed arthroscopically. Shirzad et al. [7] reported the technique of arthroscopic debridement of bony impingement in replaced ankles. Indications for surgery included localized pain to either malleolar region with weight-bearing, isolated pain with palpation of the medial and/or lateral gutters, or standing X-ray or CT scan with evidence of prosthetic-malleolar contact. Utilizing burrs to debride all areas of osseous impingement, pain decreased in virtually all of their 11 patients. Richardson et al. [8], from the same institution as Shirzad et al., further investigated their outcomes in 20 patients. Sixteen patients (80%) had initial pain resolution after arthroscopic debridement, but six had recurred symptoms during follow-up. Four (20%) out of 20 had poor results after the arthroscopic debridement. Overall, 10 patients (50%) out of 20 in their series ended up having a non-satisfactory pain relief, requiring revisions. No wound complications or infections occurred.

Conclusion

Soft tissue impingement is a frequent cause of residual or persistent pain after TAR. Arthroscopic debridement is feasible and can be beneficial for pain relief in selected patients. Further studies are required to provide the long-term outcomes.

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Managing Heterotopic Ossification After Total Ankle Replacement

26

Benjamin D. Overley Jr and Thomas C. Beideman

Introduction

The incidence of osseous overgrowth after primary total ankle replacement (TAR) has been reported to range from 3.8% to 82%, but has not been linked to one clear causative entity. Lee et al. [1] conducted a study on 88 ankles following primary TAR and reported that 25% of patients developed ectopic bone growth. Specifically, 35% of these patients displayed bone formation at the posterior–medial and posterior–lateral quadrants of the ankle; 25% displayed only posterior–medial bone formation; 25% displayed only posterior–lateral bone formation; 10% displayed anterior–medial and posterior–lateral bone formation; and 5% developed anterior–lateral and posterior–medial bone formation [1]. It is important to note that each of the patients with ectopic bone formation had some degree of posterior bone formation that is consistent with other reports following TAR [2–5]. Lee et al. [1] also reported that only 10% of patients that developed ectopic bone ossification were symptomatic with only 2.3% of their patients requiring surgical resection. This finding is consistent with what is reported in existing orthopaedic literature relative to hip and knee replacements, with symptomatic ectopic bone ossifications resulting in severe functional loss only accounting for 1–2% of patients [6].

There exists a divide in the current foot and ankle literature in this area as many studies suggest that osteophytes and ectopic ossifications are linked to anterior and posterior impingement syndromes [4] with associated functional disabilities such as pain with traversing uneven terrain, incline ambulation, or rising from a seated position. In contrast, other authors do not associate a loss of function or postoperative pain with ectopic ossifications in TAR [1, 3, 5, 7, 8].

Orthopaedic data pertaining to ectopic ossification after knee and hip replacement have stirred similar critical evaluation in following TAR. Early attempts to identify factors that lead to, or even predispose a patient to, postoperative formation of osteophytes and/or ectopic bone ossifications are currently being conducted. It has been suggested that age, body weight (i.e., increased body mass index), presence of preoperative osteophytes, and increased preoperative serum calcium and alkaline phosphatase will increase the likelihood of postoperative osteophytes and ectopic ossification in hip and knee replacements [1, 2, 9]. Choi and Lee [7] investigated the aforementioned predisposing factors in a series of 90 ankles following primary TAR and found that the only associated risk factor for postoperative osteophytes and ectopic bone formation was gender. Specifically, they found that men were twice as likely to develop osteophytes and ectopic ossifications as women [7].

Other theories suggest that the formation of osteophytes and ectopic bone ossification could be a result of procedural factors as opposed to the previously discussed patient demographics. Potential factors that have been studied include the large amount of soft tissue dissection associated with the procedure, the amount of osseous trauma involved in the procedure, persistence of bone debris in the surgical field, postoperative hematoma, appropriate sizing of prosthetic components, as well as position of the prosthetic components leading to changes in the biomechanical axis of the ankle joint [2]. Removal of the posterior portion of the resected tibia is often difficult due to the attachment of the posterior capsular tissues and dissection occurring from the anterior aspect of the ankle for most TAR systems available in the United States. Multiple attempts at removing this portion of the tibia frequently result in morcelization of fragments. San Giovanni et al. [3] suggest that these morcelized portions of bone are not always completely resected and may lead to postoperative osteophytes or ectopic bone formation.

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King et al. [2] noted that a high percentage of patients in their study with posterior osseous overgrowth had their prosthetic components inserted at an angle that was not perpendicular to the anatomic axis of the tibia, usually placed in varus or valgus with a positive slope (i.e., apex posterior). They found a positive correlation between increased slope of the tibial component and uncovering of the posterior distal tibia. With decreased tibial coverage, there was found to be an increase in ectopic bone formation around the tibial tray, thus making size selection of prosthetic components and accurate insertion critical [2]. Surgeons choosing larger tibial component size to increase the amount of cortical coverage may do so at the cost of greater bone resection medially and laterally at the malleoli that can lead to malleolar fractures.

Studies have indicated that prolonged surgery time has been associated with increased ectopic bone formation as a result of increased osseous bleeding and inflammation at the surgical site [1]. In an attempt to decrease postoperative inflammation, D'Lima et al. [10] studied the use of prophylactic nonsteroidal anti-inflammatory drugs (NSAID), particularly indomethacin, and showed that it reduced the incidence of ectopic bone ossification following hip replacement. Valderrabano et al. [4] performed a similar study evaluating NSAID use following primary TAR; however, 63% of their patients developed ectopic ossifications despite prophylactic NSAID use.

It can be deduced by the data previously discussed that osteophytes and ectopic bone formation are frequent occurrences after primary TAR but are not always associated with painful impingement or restricted range of motion (ROM). Minimizing the rate of occurrence and/or severity of ectopic bone formation can be achieved by certain operative techniques that will be discussed, as well as strategies for managing these complications. The following will also detail procedures of choice when reoperation cannot be avoided.

Diagnosis

Diagnosis of osteophytes and ectopic bone ossification is relatively straightforward with standard radiographs showing radiodense ossifications in the ankle joint capsule, ligament attachment sites, or medial/lateral gutters (Fig. 26.1). Although visualization of these ossifications may be simple to ascertain radiographically, there may be several concurrent painful sites in the same ankle, and the relevance of the ossifications identified that may be causing pain or impeding motion may be unclear. Accordingly, a detailed history is essential to a successful diagnosis. Patients will typically relate a decrease in ROM with an increase in pain compared to their initial postoperative ROM values. This can be seen at any time during the postoperative course and can occur as soon as 3 months postoperatively. A thorough physical exam is extremely beneficial as a diagnostic tool, including palpation of the joint lines, and gutters will usually reveal to the examiner which of these ossification sites may be the culprit. Palpation with attempted rotation and motion in the sagittal and coronal planes may also assist in the determination of the causative impingement with pain in the anterior–lateral region of the lateral gutter exhibiting pain with forced dorsiflexion. More detailed diagnostic studies such as computed tomography (CT) scans or single photon emission CT scans may be beneficial in delineating impingement sites of ecto-

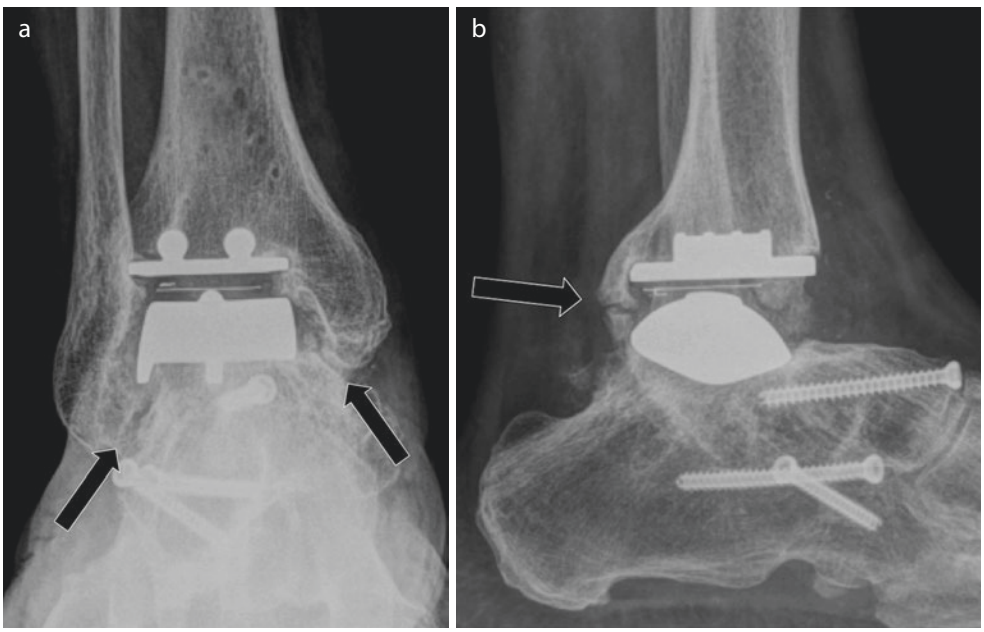


Fig. 26.1 Anterior–posterior (**a**) and lateral (**b**) weight-bearing radiographs 1 year postoperative demonstrating ectopic bone ossification within the medial and lateral gutters, as well as posterior ankle (*straight arrows*). This patient had very little range of motion to the ankle as a result of the global ectopic bone formation engulfing this primary total ankle replacement

pic ossification especially in the medial and lateral ankle gutters where talar component scatter artifact from standard CT may hide or distort the osseous impingement.

The presentation of osseous versus synovial impingement as it pertains to malleolar gutter impingement may also be difficult to delineate from a clinical or radiographic study perspective. However, it should be noted that the presence of both is usually encountered during debridement and may certainly be, if not always, coexistent in malleolar gutter impingement syndromes. Injections of these regions as a diagnosis tool may also provide pertinent diagnostic information but should be used judiciously due to the risk of prosthesis contamination and deep peri-prosthetic infection.

A careful and honest appraisal of the implant placement and sizing may show that due to lack of bone coverage or conversely "overstuffing," the joint may be the causative factor (Fig. 26.2). Once a diagnosis is made, there are several considerations to the surgical management of these conditions and questions that require answering prior to proceeding with debridement. The prosthesis must be assessed critically to determine if there is loosening, subsidence, incorrect implant sizing, inadequate polyethylene insert size with lack of gutter expansion, and prosthesis or bone infection present.

If any of the causative factors are present, then a simple debridement of the offending bone and synovium will not address the underlying index cause. In cases of chronic talar subsidence, especially with talar components that may have sacrificed talar blood supply or if the prosthesis was placed in a position of biomechanical weakness (i.e., osteochondral defect, fracture line, or cyst), the talus slowly depresses from axial load which expands the medial and lateral walls of the talus that may shower the gutters with particulate osseous debris or expand into the respective malleoli causing impingement and restricted motion. In essence, the ectopic bone formations in the malleolar gutters are from talus depression and medial lateral expansion (Fig. 26.3). In all of

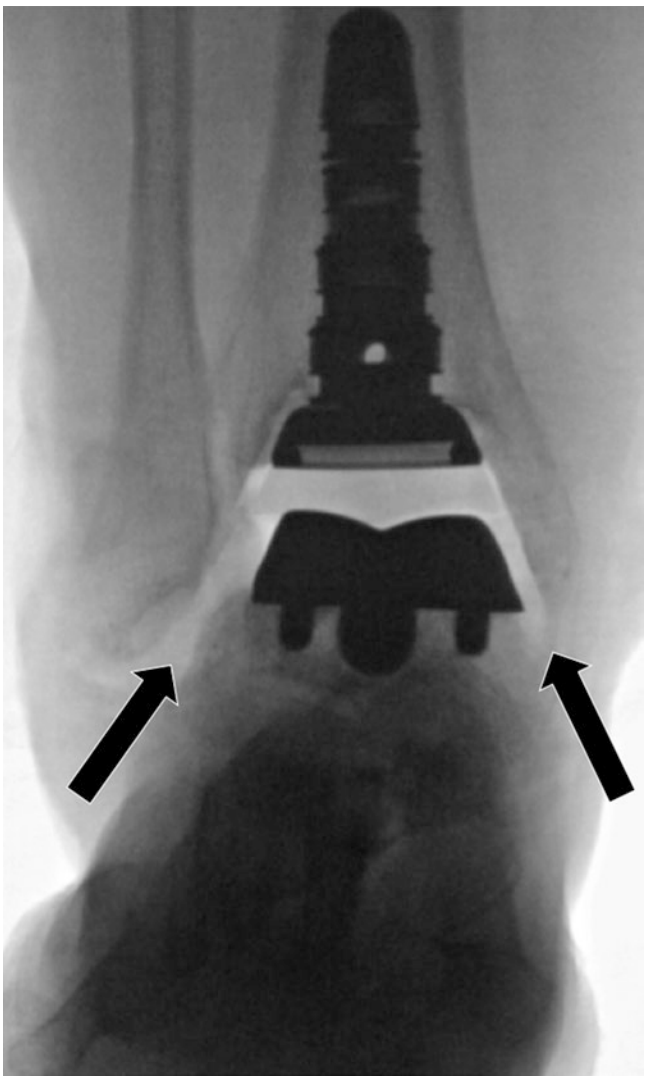


Fig. 26.2 Anterior–posterior image intensification view demonstrating complete talar dome coverage without overlap of the prosthetic component into the medial or lateral gutters that have also undergone through debridement (*straight arrows*)



Fig. 26.3 Anterior–posterior radiographs 2 years postoperative demonstrating lucency surrounding the tibial component (*curved arrow*) suggestive of component loosening, as well as large medial gutter ectopic bone formation (*straight arrow*) as a result of talar component subsidence

these cases, careful considerations of polyethylene insert exchange, component exchange, or complete removal should be entertained concomitantly with the osseous debridement. If the prosthesis is stable, in acceptable alignment, and no clinical infection is present as per diagnostic studies, the next area of focus is surgical debridement of the ectopic bone.

Surgical Technique

Arthroscopic debridement of painful osteophytes, ectopic bone, and soft tissue impingement in the malleolar gutters are addressed elsewhere in this textbook, and accordingly we will focus on the open approach for these syndromes. In general, the open approach is relatively straightforward with incision planning focused on the areas of concern (Fig. 26.4). Care should be taken to avoid neurovascular structures and tendons in close proximity to the planned incision as they may be adhered to the ectopic bone or enmeshed in soft tissue scar. Acute awareness of the proximity of the polyethylene and articulating metallic prosthetic components is also essential to avoid inadvertent TAR damage. Once the soft tissues are mobilized and the ectopic bone circumferentially exposed, a small-diameter high-speed rotary burr is used to perform bone removal (Fig. 26.5a, b). In addition to being efficient, a secondary benefit of the thermal effect created with the use of the rotary burr is that it may discourage the reformation of the ectopic bone. This must be used judiciously as the aggressiveness of the tool may rapidly remove bone and the potential for "divoting" or fracturing the malleoli may occur with overaggressive resection. Osseous debridement may also be undertaken with bone rongeurs, sharp curettes, or osteotomes with usage of an electrocautery device to cauterize the exposed cancellous bone substrate (Fig. 26.5c). Application of absorbable bone wax may also help seal the cancellous bone substrate, thereby limiting osseous regeneration and recurrence of the ectopic bone (Fig. 26.5d).

Postoperative Care

The patient is typically placed in a bulky compressive dressing and is encouraged to bear weight as soon as tolerated. The only exception is that if the anterior approach incision must be utilized, then care must be taken to not disrupt the incision for a minimum of 2–3 weeks' time. Once the incisions have healed, early active physical therapy should be undertaken with emphasis on ROM, traction, massage, and gait training.

Outcomes

Richardson et al. [11] described an arthroscopic technique to resect soft tissue and osseous impingement and reported good pain relief in 11 patients. Similarly, Shirzad et al. [12] described arthroscopic gutter debridement in a series of 20 ankles (20 patients) with 18 (90%) of them having sufficient follow-up. Sixteen patients (80%) reported an initial resolution of their pain following the procedure. Unfortunately, of these 16 patients, 6 (37.5%) developed recurrent symptoms and ultimately required further intervention likely due to talar component subsidence as the cause that required revision rather than gutter debridement [12]. Schuberth et al. [13] performed a retrospective review of 489 TARs using four different prosthetic devices and determined that symptomatic gutter disease occurred in 34 of 489 cases (7%). Interestingly, there was only

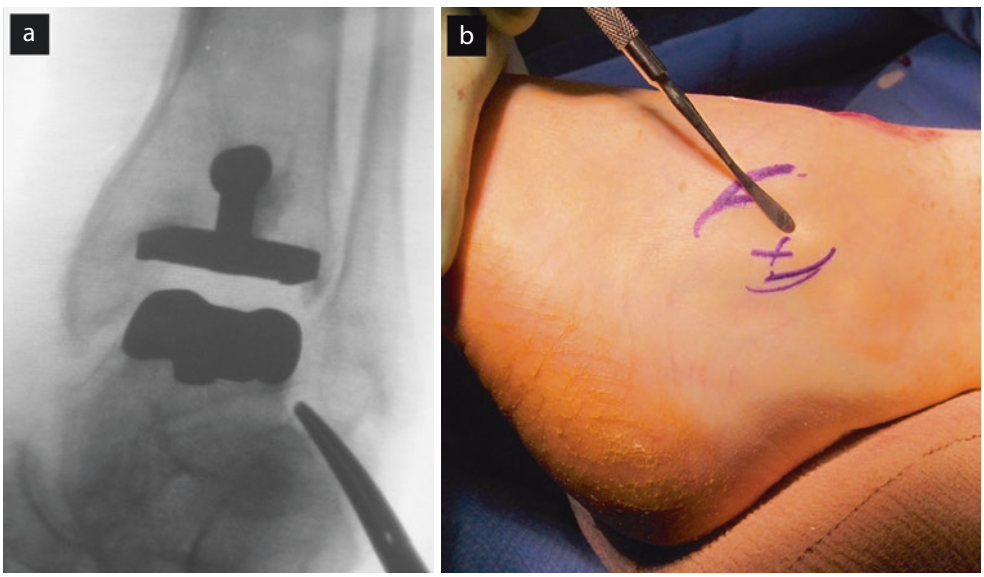


Fig. 26.4 Intraoperative anterior–posterior C-arm image intensification view (**a**) and photograph (**b**) demonstrating location of the ectopic bone in the lateral gutter which is useful for incision planning

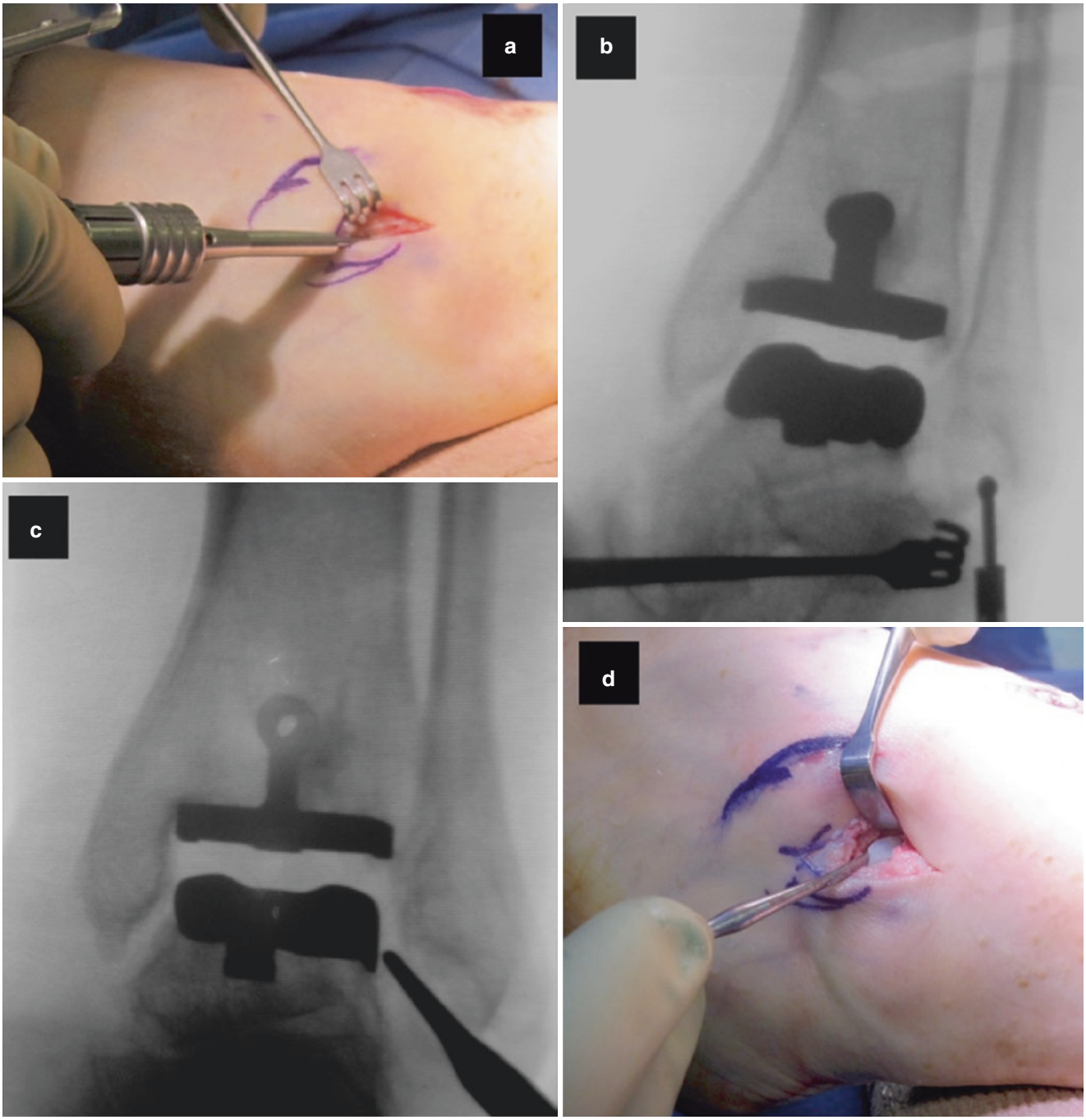


Fig. 26.5 Intraoperative photograph (**a**) and anterior–posterior C-arm image intensification view (**b**) demonstrating burring of the ectopic bone from the lateral malleolus and gutter. Anterior–posterior C-arm image intensification view demonstrating the use of a rongeur for debridement of lateral gutter following the use of the power rotary burr (**c**). Intraoperative photograph demonstrating application of bioresorbable bone wax to fill in bone pores and discourage reformation of ectopic bone (**d**)

a 2% incidence of gutter disease in the 194 ankles that had prophylactic gutter resection at the time of implantation compared with a 7% incidence in the 295 ankles that did not have gutter resection at the time of implantation. Postoperative outcomes were favorable in the 27 patients who did not have another procedure after the initial gutter debridement; however, 7 patients (21%) required reoperation following gutter debridement. The authors concluded that prophylactic gutter resection should be considered at the time of implantation to reduce the incidence of postoperative symptoms and that, although most patients had favorable outcomes following gutter debridement, there was a high reoperation rate.

Conclusions

TAR is being performed more frequently around the world, and accordingly an increase in complications associated with this procedure is inevitable and is being closely evaluated. The formation of osteophytes and ectopic bone peripherally around a TAR may be inevitable postoperative findings. However, as the data suggests, the appearance of these particular postoperative findings does not always equate to the need for further surgery. Open and arthroscopic approaches to address those instances where the osteophytes and ectopic bone have slowly restricted the prosthesis ROM or are causing impingement pain are successful at resolving these complaints in the majority of patients; however, a high reoperation rate exists especially if talar component subsidence is responsible for the bone formation.

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Management of Painful Malleolar Gutters After Total Ankle Replacement

27

Bernhard Devos Bevernage, Paul-André Deleu, Harish V. Kurup, and Thibaut Leemrijse

Introduction

Total ankle replacement (TAR) is a technically challenging and demanding surgical procedure. The main objective is to restore a stable and pain-free mobile ankle. First- and second-generation TARs had a high rate of failure due to instability and loosening, respectively [1]. Third-generation TARs have significantly improved results by using techniques of mobile bearing, cementless fixation, and minimal bone resection [2]. Despite their higher satisfaction rates reported in the literature, the number of studies reporting case series of patients complaining about painful malleolar gutters after TAR has increased in the recent years [1–4]. This issue has been reported in different TAR prosthesis designs, and the exact cause has not been fully understood, but seems to be multifactorial. Therefore, a detailed preoperative and postoperative analysis is essential to identify potential individual factors and risks. This chapter explores the potential inciting factors of residual and recurrent gutter pain after TAR and how they can be managed.

Incidence

The incidence of malleolar gutter pain after TAR varies from 2% to 23.5% between various TAR prosthesis systems and original etiology of ankle arthritis [1, 2, 4–15]. Schuberth et al. [4] showed that a prophylactic gutter resection at the time of primary TAR implantation could significantly reduce the postoperative incidence of malleolar gutter pain. Only 2% of patients with a prophylactic gutter resection required a secondary gutter resection. However, when patients did not have prophylactic gutter resection, the incidence could increase up to 18% [4]. Therefore, extra care should be taken when interpreting the reported incidences of gutter pain if prophylactic gutter resection was a component of the index TAR procedure itself [4].

Etiology

The exact cause of recurrent gutter pain after TAR has not been fully understood, but based on the available findings from the literature seems to be multifactorial [1–4]. Factors commonly incriminated for gutter pain include technical errors [10], prosthesis design [9, 16, 17], residual gutter arthritis [4], oversized or undersized TAR components [17–19], ongoing instability, soft tissue impingement [5], ectopic bone formation [2, 9, 15], and subsidence of the prosthesis [19, 20]. By far, medial impingement symptoms appear to be more common than lateral, and the reasons behind this will be examined.

Initial Ankle Arthritis Diagnosis

Initial diagnosis of ankle arthritis has been pointed out as a potential explanation for malleolar gutter pain after primary TAR. It was hypothesized that patients with posttraumatic arthritis have a higher incidence of heterotopic ossification in the gutters causing recurrent symptoms. However, Schuberth et al. [4] clearly demonstrated that there is no significant difference among specific diagnosis groups with regard to the incidence of patients requiring secondary gutter resection.

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Heterotopic Bone Formation

The development of heterotopic bone formation is not uncommon after TAR implantation and has been identified in different types of TAR prostheses [8, 14, 21]. Recent studies have demonstrated that heterotopic ossification was however not associated with the outcome after primary TAR [8, 21]. Therefore, surgeons should be extremely careful in attributing pain symptoms of TAR to the presence of heterotopic bone formation.

Aseptic Loosening

Studies reported that osseous overgrowth in the talar–malleolar articular facets could potentially be a consequence of a loose talar component [3, 14, 22]. They suggest that surgeons should look for the presence of subtle signs of loosening and test stability of the talar component on the talus perioperatively during revision surgery.

Prosthesis Design

TAR implants are composed of either fixed- or mobile-bearing polyethylene insert with each design having different benefits and drawbacks. Fixed-bearing designs are known to provide a stable joint without the risk of subluxation of the polyethylene insert [16, 23] but are prone to loosening of the tibial component due to high shear forces at the prosthesis–bone interface [24]. In contrast, mobile-bearing designs have a more flexible articulation with lower shear forces. Recently, the mobile-bearing TAR designs have been incriminated as a potential cause of malleolar gutter pain, which could be induced by excessive anterior–posterior or lateral subluxation of the mobile-bearing polyethylene insert [16, 25]. Therefore, a fixed-bearing TAR design has been adopted by surgeons to avoid the concerns of midterm and long-term pain from malleolar impingement [16]. However, recent biomechanical studies have shown only minimal movement of insert in mobile-bearing TAR implants [26–28] which is probably not sufficient to contribute to the development of malleolar gutter pain, and, to the author's knowledge, no studies yet have shown a significant difference in incidence of gutter pain between these two prosthetic bearing designs.

Prosthesis Positioning and Technical Errors

Studies suggested that the emergence of symptomatic gutter pain could potentially be linked to the subsidence of the talar component or to the migration of the talar and tibial metallic components into the mortise exposing the remaining talar–malleolar articular surfaces and talar bone mass to increasing axial loads and further degeneration and gutter impingement [19, 29]. An undersized talar component was also pointed out as a potential cause of malleolar gutter pain. Cerrato and Myerson [19] reported that insufficient support of the body of the talus under the load of the smaller talar base plate could cause subsidence of the talar component and subsequently leading to malleolar gutter pain [19].

Excessive bone resection on the tibial side can potentially cause seating of the tibial metallic component on soft metaphyseal bone. The prosthetic component sinks into the soft bone, exposing the talus to both malleoli and leading to gutter pain.

Malpositioning of the prosthesis is probably one of the most common intraoperative complications and can provoke painful malleolar gutters postoperatively (Fig. 27.1) [10]. Varus positioning of the TAR components (>4°) can lead to medial gutter pain from impingement, and a valgus position-

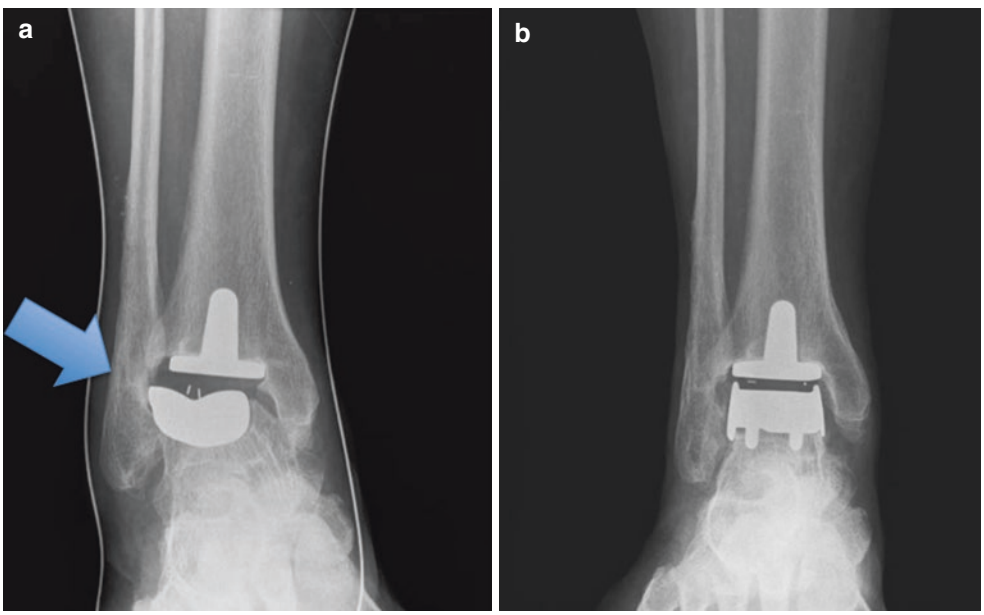


Fig. 27.1 (**a**) A 74-year-old male patient with a total ankle replacement implanted in another center was suffering from lateral pain due to excessive lateral malposition of the talar component as demonstrated on weight-bearing anterior–posterior radiograph (**a**). The delay between the implantation of the total ankle replacement and the gutter pain was less than 1 year (**b**). The talar component of the prosthesis was revised with a revision talar component

ing of the TAR components (>4°) can potentially lead to lateral gutter pain from subfibular impingement. Malpositioning of the prosthesis in these cases may be corrected by revision arthroplasty or by periprosthetic osteotomies.

Prophylactic Gutter Resection

Studies analyzing complications after TAR are still debating if gutter impingement requiring a reoperation (secondary gutter resection) can be classified as a complication [14] or as a technical error by the fact that no prophylactic gutter resection was performed at the time of the TAR implantation [10, 30]. Most of the current TAR systems do not incorporate prophylactic gutter resection in their surgical technique manuals. Therefore, in the author's opinion, failure to perform a prophylactic gutter resection cannot be classified as a technical error. However, surgeons should check for gutter-related abnormalities such as accumulated debris, osteophytes, and loose bodies at the time of primary TAR implantation [29]. Recent evidence showed that patients with prophylactic gutter resection at the time of primary TAR implantation had a significant lower incidence of secondary gutter resection (2%) compared to patients without prophylactic gutter resection at the time of primary TAR implantation (7%) [4].

Malalignment of the Ankle and Hindfoot

Correction of malalignment of the ankle and hindfoot at the time of primary TAR implantation is challenging and requires various associated additional procedures (e.g., calcaneal osteotomy, medial malleolus osteotomy, deltoid release, etc.) to balance the ankle in order to increase the chances of long-term survival of TAR. However, malalignment of the ankle and hindfoot is not always addressed at the time of the primary TAR implantation leading to painful postoperative TAR, which requires additional surgery to recreate a well-balanced ankle.

An uncorrected valgus deformity of the hindfoot at the time of primary TAR implantation can potentially cause an overloading of the medial malleolus and result in medial gutter pain. This deformity can be increased by an eccentric pull of the Achilles tendon [31]. A too medially positioned talar component in association with an uncorrected valgus deformity of the hindfoot can further increase the stress against the medial malleolus and lead to a stress fracture of the medial malleolus [32].

In the presence of a varus deformity of the hindfoot, the load concentrates typically at the medial part of the tibia and medial malleolus. If the varus deformity is not addressed at the time of primary TAR implantation, this can potentially lead to an increased translational force of the talus against the medial malleolus [32]. Over time, this could potentially lead to medial gutter pain.

Medial gutter pain after primary TAR implantation can also be the result of a varus or valgus deformity of the hindfoot, also called the "zigzag deformity" by Barg et al. [32] (Fig. 27.2). This deformity is composed of a valgus deformity of the hindfoot associated with a varus deformity at the ankle due to either a varus malpositioning of the tibial component or varus deformity of the tibia itself [32].

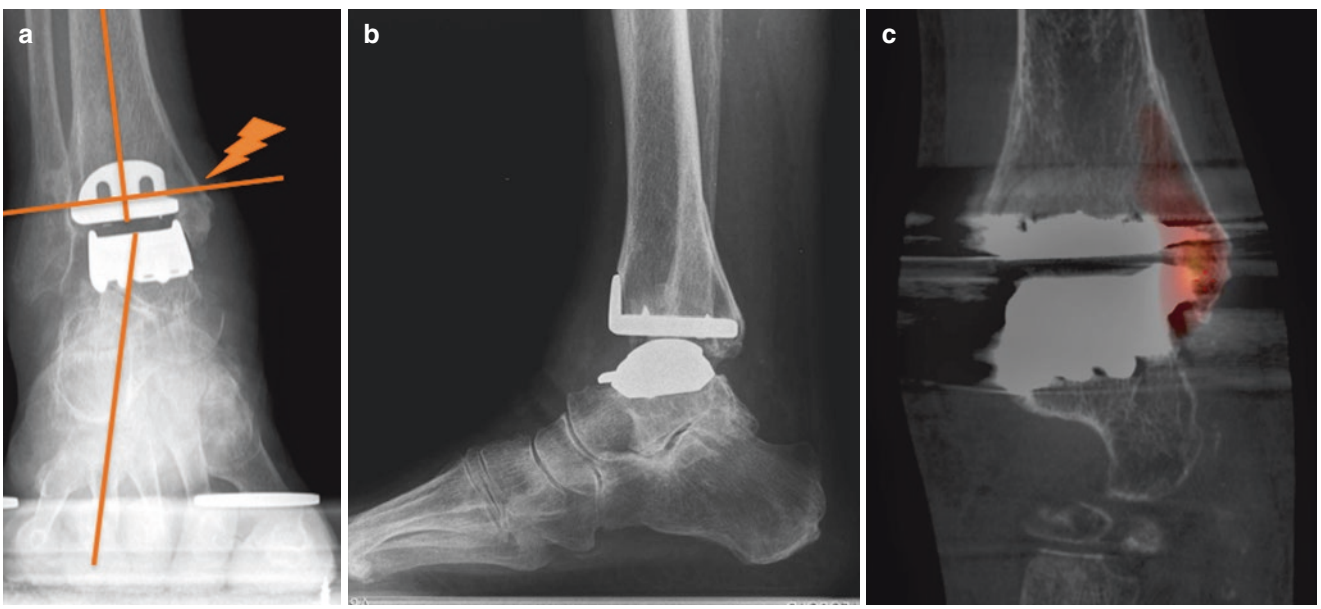


Fig. 27.2 Weight-bearing anterior–posterior (**a**) and lateral (**b**) radiographs of a 76-year-old female patient suffering from medial gutter pain after total ankle replacement induced by a "zigzag deformity" composed of a valgus deformity of the hindfoot associated with a varus of the tibial component with respect to the tibial axis. Single photon emission computed tomography scan isolated the potential symptomatic "hot" spot: medial malleolar gutter pain and subtalar joint pain due to subtalar joint arthritis (**c**, **f**). Weight-bearing anterior–posterior and lateral post-revision radiographs (**d**, **e**)

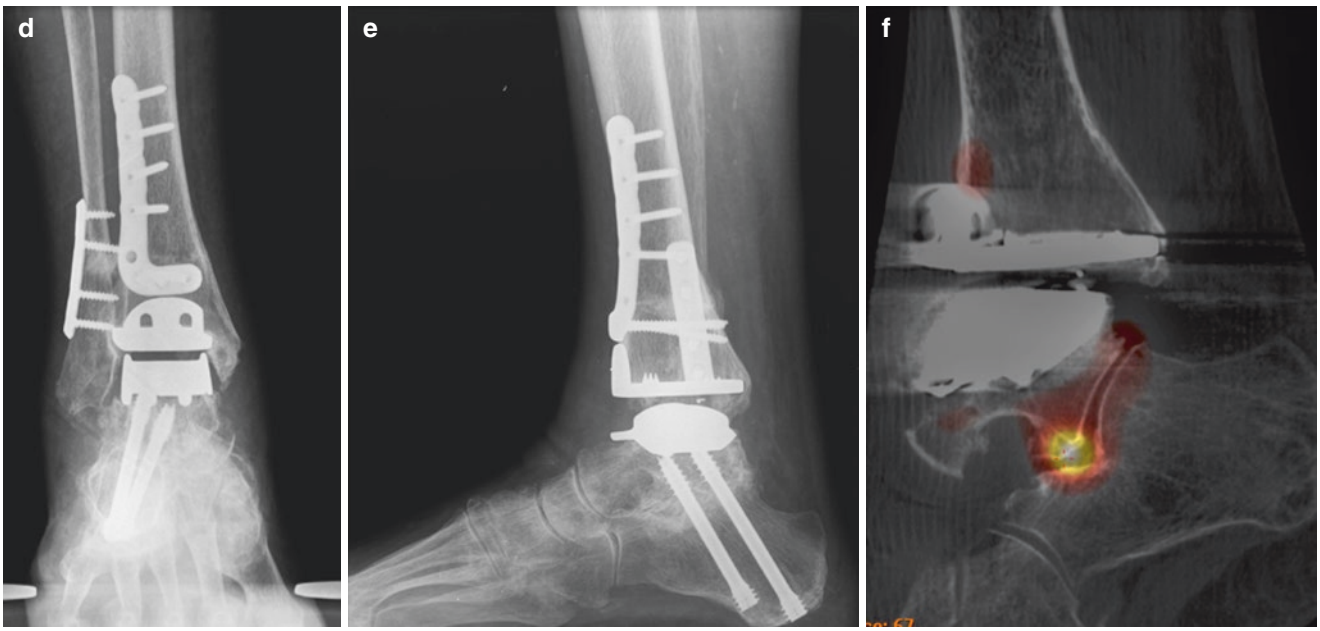


Fig. 27.2 (continued)

Additional Procedures

Surgeons often perform additional procedures at the time of primary TAR implantation to restore a neutral alignment and congruent ankle joint in order to avoid early failure. However, these procedures can potentially induce medial and lateral gutter pain, especially in cases where intra-articular deformities are corrected. For example, in cases of varus deformity at the level of the ankle joint, a distal tibial cut may not be sufficient to correct the deformity due to contracted deltoid ligament or due to altered morphology of the medial malleolus (distorted or flattened) resulting from the deformity itself [4, 33, 34]. A lengthening medial malleolar osteotomy is a procedure that has the advantage to release the tight medial structures and to also capture the medial talus by restoring a more normal shape of mortise [33]. However, sliding the medial malleolar fragment distally may result in impingement against the prosthesis, and therefore surgeons must check for any impinging bone in the newly created medial gutter following medial malleolar osteotomy [33, 34].

Differential Diagnosis

Painful Collateral Ankle Ligaments

Valgus positioning of the metallic talar and tibial TAR components in cases of preoperative varus ankle osteoarthritis (>4°) can potentially create medial ossifications due to chronic overstretching of the medial ligaments [28]. Hintermann [29] reported that it is often seen in nonanatomically shaped talar designs where the medial radius is too wide [29].

Anterior–posterior malpositioning of the TAR components leads to anisometric loading of medial and lateral ankle collateral ligaments that could potentially lead to painful restriction of motion and instability during dorsiflexion and plantar flexion movements of the ankle [28].

A varus malpositioning of the TAR components can potentially create excessive stress on the lateral ankle ligaments and provoke either lateral pain or ankle instability [30].

In the presence of a varus deformity in the ankle in association with chronic lateral instability and medial capsular ligament contracture, surgeons tend to choose a thicker polyethylene insert to achieve a perceived improvement in stability. However, this can potentially lead to an excessive stress on the medial capsular ligament and with time cause medial side pain [32–34].

Intraoperative and Postoperative Fracture of the Medial or Lateral Malleolus

Intraoperative medial or lateral malleolar fracture is a well-known complication associated with primary TAR that is almost always treated with open reduction and internal fixa-

tion during the operation [35]. Fracture can occur postoperatively due to excessive force placed across the narrowed medial or lateral malleoli or by repeated episodes of lesser force that exceed the strength gained by the remodeling process of the malleoli [10, 29].

Tibialis Posterior Muscle Pain

Patients presenting with a preoperative varus deformity at the level of the ankle joint may have a relative contracture of the posterior tibial muscle and can experience postoperative medial side pain when the contracture is not addressed at the time of the primary TAR implantation [32–34]. An oversized tibial component extending past the posterior–medial aspect of the tibia can also potentially irritate the tibialis posterior tendon and cause medial retromalleolar pain.

Distal Tibiofibular Syndesmosis Instability

A frequent sequel of posttraumatic ankle arthritis is the presence of distal tibiofibular syndesmosis instability that needs to be addressed before or at the time of primary TAR implantation.

Clinical Evaluation

Careful assessment of the patient's history is essential. The patient is questioned regarding the following aspects: pain, limitations in activities of the daily living, sports activities, and previous treatments. Alignment of the foot and ankle is assessed while standing and walking, with a special attention to obvious deformity and soft tissue condition. Ankle and syndesmotic stability is tested in both the frontal and sagittal planes. Ankle and subtalar range of motion is evaluated and determined with a goniometer. Localization of the pain is performed through palpation of the medial and/or lateral gutters: the surgeon must be able to provoke a recognizable pain on palpation of the gutters or the posterior compartment.

Investigations

The presence of painful gutter pain does not always implicate that osseous overgrowth is the primary cause of pain. Radiographic determination of true gutter impingement is subjective and sometimes difficult to correlate with clinical examination. As mentioned earlier, gutter pain can potentially be induced by prosthetic and extra-prosthetic factors.

Plain Radiographs

Weight-bearing anterior–posterior and lateral view plain radiographs of the foot and ankle are of primary importance to analyze the position of the TAR prosthesis by measuring the following variables: tibial slope, polyethylene mobile-bearing positioning, anterior–posterior position of the talar component with respect to the tibial axis, the anterior–posterior alignment of the talar component with respect to the tibial component, and the position of the tibial and talar components with respect to the tibial axis in the frontal plane [8, 36–38]. Through the Méary view [36] or the Saltzman view [38], the alignment of the hindfoot is assessed. Length or rotational discrepancy of the malleoli should be analyzed and on a comparative view of both mortises [39].

Stress radiographs in varus and valgus are useful to assess the stability of medial and lateral ligaments around the prosthesis [40].

Computed Tomography (CT) Scan

CT scan is a useful investigation tool, which not only allows evaluation of the exact positioning of the prosthetic components but also assessment of anomalies such as periprosthetic impingement at the interface between bone and the metallic TAR components [40]. Osseous impingements are often underestimated on plain radiographs compared to the more detailed information provided by the CT scan.

Sonography

Ultrasound scans can be useful to confirm any clinical suspicion of tendon injuries, such as the tibialis posterior or the peroneal tendons, which might explain the pain around the malleoli.

Magnetic Resonance Imaging (MRI)

Magnetic resonance imaging (MRI) does not allow a detailed analysis of the periprosthetic region due to the many artifacts created by the TAR metallic components and is not recommended [40].

Single Photon Emission Computed Tomography Scan

Pain around ankle prosthesis can be a diagnostic challenge given the complex anatomical relations and structural mechanics. Single photon emission computed tomography (SPECT) scan is a diagnostic tool that has an added value in clarifying a diagnosis in unexplained pain around the prosthesis (Fig. 27.2c, f). However, SPECT scan should not be used in isolation, and findings should always be correlated with the clinical findings and patient's symptoms. Williams et al. [41] have shown that not all so-called "hot" spots identified on SPECT scan are symptomatic.

Diagnostic Injection

Fluoroscopically or ultrasound-guided local anesthetic injections with or without corticosteroid can help in clarifying a diagnosis in unexplained pain around the prosthesis. Very often, the injection guided by recognizable pain on palpation will be the most effective. These injections can also have a temporary or definitive therapeutic purpose. Steroids are to be avoided if deep periprosthetic infection has not already been ruled out.

Management of Painful Malleolar Gutters

True correlation between radiographic and clinical evidence of gutter impingement should be clearly identified before planning revision surgery [6]. Studies have found that the postoperative scores were compromised when gutter impingement was only a consequence of an underlying problem which was unmasked secondarily after the gutter debridement [3, 4]. Unfortunately, meaningful literature reporting the effectiveness of conservative and surgical treatments in patients with malleolar gutter pain after TAR is scarce.

Conservative Treatment

To the authors' knowledge, no studies analyzing the effectiveness of conservative treatment in patients suffering from malleolar gutter pain exist. Kurup and Taylor [1] reported that four of the eight patients suffering from medial impingement following primary TAR were treated conservatively and had no further progression of their symptoms. Orthoses to relieve weight-bearing and contact in painful malleolar gutters after primary TAR can potentially relieve the pain in patients who are not keen on further surgery. However, it may not be advisable in well-aligned TARs as it may alter the mechanics.

Fluoroscopically or ultrasound-guided local anesthetic injections with or without corticosteroids can also have temporary or definitive therapeutic purposes. However, no studies reported their effectiveness in the literature.

Surgical Procedures

The first question to be answered is whether gutter debridement will be sufficient or not to alleviate malleolar gutter pain. From the authors' experience, additional procedures (supra- or inframalleolar osteotomies, ligamentoplasty, etc.) should be performed in association with gutter debridement in the presence of malalignment of the hindfoot and ankle or metallic component malpositioning in order to restore a stable and pain-free mobile ankle and to prevent recurrent subsidence and osseous overgrowth.

Malleolar gutters can be debrided either by open arthrotomy or arthroscopically [1–3, 5]. Arthroscopy has multiple advantages over open debridement, including a potential shorter recovery time [3, 5]. The surgical technique for arthroscopic debridement following TAR was accurately described by Shirzad et al. [5] and Richardson et al. [3]. Both publications stressed the importance of avoiding contact between the blunt end of the shaver or burr and the metallic components in order to prevent any damage to the TAR components during the surgery (Fig. 27.3).

Unfortunately, meaningful studies analyzing the effectiveness of gutter debridement are limited. Arthroscopic debridement in patients suffering from persistent pain due to osseous impingement has found to be effective in 80–100% of cases [1, 3]. Kim et al. [6] were more cautious in expressing their success rate and preferred to report the effectiveness of the arthroscopic procedure through the use of the visual analogue scale (VAS), which improved from 7.1 preoperatively to 2.7 at the final follow-up. Despite these encouraging results, Richardson et al. [3] reported a high recurrence rate of 37.5% (6/16 patients).

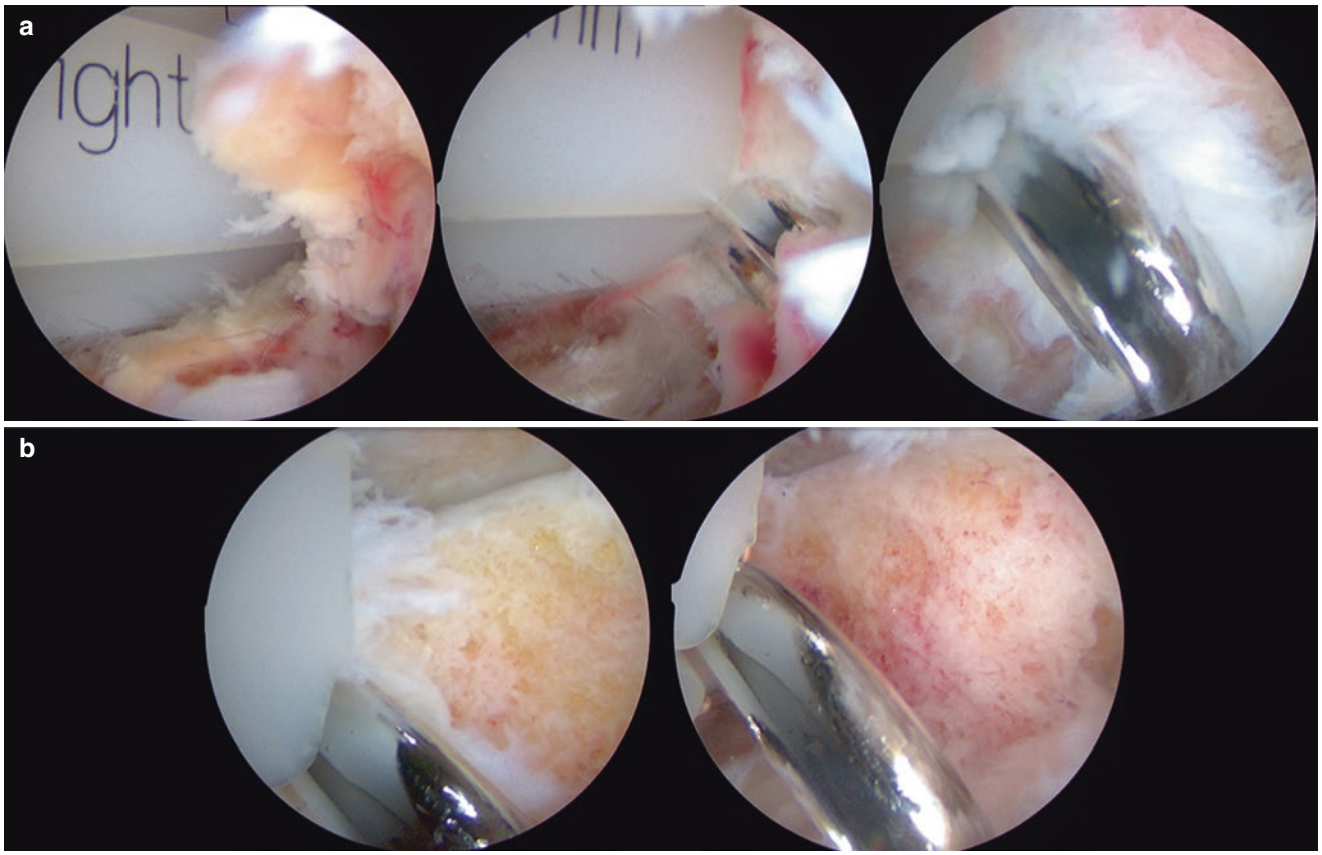


Fig. 27.3 Intraoperative C-arm image intensification views of arthroscopic debridement. Malleolar impingement and residual pain (**a**). Result of debridement under arthroscopy (**b**)

Conclusions

TAR is a challenging procedure, which has the potential to restore a pain-free mobile and stable ankle. Despite high satisfaction rates reported in the literature, patients complaining about malleolar gutter pain range from 2% to 23.5% between various prosthesis designs and ankle arthritis etiologies. Malleolar gutter pain is often a sign of overloading caused by malalignment of the hindfoot and ankle or by malpositioning of the TAR metallic components. Therefore, detailed preoperative and postoperative analyses are essential to identify the incriminating factors provoking the malleolar gutter pain. These factors should always be addressed in association with debridement of the malleolar gutters in order to prevent recurrence of the patients' symptoms.

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Managing Varus and Valgus Malalignment After Total Ankle Replacement

28

Woo Jin Choi, Moses Lee, and Jin Woo Lee

Introduction

Due to inferior clinical outcomes and complications, total ankle replacement (TAR) was once considered as unacceptable treatment modality. However, as surgical technique and implants design were improved based on the better understanding of anatomy and kinematics of the ankle, promising clinical results have been reported using the second-generation implants. Nowadays, TAR is gaining popularity as an alternative treatment modality for end-stage osteoarthritic ankle.

Among the several factors that contribute to successful outcomes after TAR, addressing varus and valgus malalignment is especially important. If the preoperative varus or valgus malalignment is not addressed simultaneously, the residual deformity can adversely affect the clinical outcome of TAR, producing instability, recurrent tilting, subluxation, or dislocation of the bearing [1]. Also, residual malalignment can produce a stress concentration on the interfaces between metal and bone and on the polyethylene liner, causing accelerated rate of polyethylene wear with subsequent production of wear particles followed by osteolysis and an increased risk of revision surgery [2–5]. Therefore, the surgeon must have a full understanding of the associated deformities around the ankle and the logical stepwise approach to correct problems. The reported proportion of moderate to severe malalignment (greater than 10° in the coronal plane) in patients with end-stage osteoarthritis is not uncommon ranging 33–44% [4, 6]. This is another reason why surgeons need to understand this topic.

The approach we describe is based on anatomic studies, literature reviews, clinical outcomes, and the authors' clinical experience.

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Classification

Setting Criteria for Malalignment in Total Ankle Arthroplasty

Since relatively poor clinical results have been described in patients with severe preoperative angular deformity after TAR [1, 4, 6–8], it is important to determine the severity of the malalignment and anticipate the necessary procedures.

However, there is controversy regarding the reference point of malalignment that guides the possibility of correction. Varus or valgus deformity of more than 20° has been considered as a non-restorable malalignment and is advised as a contraindication to TAR [9]. Wood and Deakin [7] found the development of edge loading of the polyethylene liner in ankles with a preoperative varus or valgus of more than 15°. In another report, the author also observed that the preoperative varus or valgus deformity had a significant effect on survivorship, with the likelihood of revision being directly proportional to the degree of the malalignment [6]. Haskell and Mann [4] observed eight (23%) cases of progressive edge loading in 35 ankles with preoperative varus or valgus of more than 10°. In line with other reports, Doets et al. [1] also reported inferior survival rate in ankles with preoperative malalignment of more than 10°. In summary, many authors have suggested excluding moderate to severe varus from the indications for TAR and have suggested the reference point of less than 10–15° of malalignment as a proper indication for TAR.

On the contrary, other investigators reported favorable outcomes in ankles with moderate to severe malalignment ranging 10–30° [10, 11]. Kim et al. [11] have adopted various additional procedures simultaneously with TAR to overcome accompanying coronal plane malalignment and/or instability. The reported short-term outcomes were comparable to those with neutral alignment. Hobson et al. [11] also reported favorable outcomes in patients with a preoperative angular deformity greater than 10° and stressed the

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importance of achieving neutral alignment and stability. The authors personally have corrected up to 28° of varus malalignment.

Absolute contraindications still remained for those patients who possess neurologic disorders resulting in unmanageable instability and malalignment. Patients with deformed angulation in the ipsilateral limb proximal to the ankle should have the deformity corrected before TAR [9].

In conclusion, rather than setting definite criteria, the authors believe that it is more appropriate for the surgeon to recognize their ability to tackle the anticipated difficulties. Surgeons with short experience should be extra careful when considering surgical treatment of TAR with a complex malalignment, whereas experienced surgeons can successfully handle greater degrees of malalignment than was possible in the past.

Varus Malalignment

The authors have categorized varus ankles into congruent and incongruent varus depending on the talar tilt angle and suggested different stepwise approaches in their management [11]. For the incongruent varus ankle, a neutral ankle could be achieved through sufficient medial release and ligament balancing. In the congruent varus ankle, additional neutralizing high tibial cutting is required (Figs. 28.1, 28.2, and 28.3). The purpose of ligament balancing and additional procedures is to obtain and maintain a neutral ankle. Most of the techniques are already introduced in the treatment of cavovarus or lateral ankle instability. Hence, there is a wide spectrum of procedures that surgeon can choose according to their preference (e.g., soft tissue procedures, osteotomies, and arthrodesis of adjacent joints). Understanding the associated deformity and correcting each component of the associated deformities are fundamental when performing TAR in varus unstable ankles [12].

In a similar concept, Alvine [13] developed a classification system for varus ankles undergoing TAR. In stage 1, medial bony erosion causes the ankle varus, and the deformity can be resolved by making a perpendicular tibial cut to the tibial axis. In stage 2, there is a combination of medial bony erosion and lateral ligament instability, which requires medial release and lateral augmentation procedures. A stage

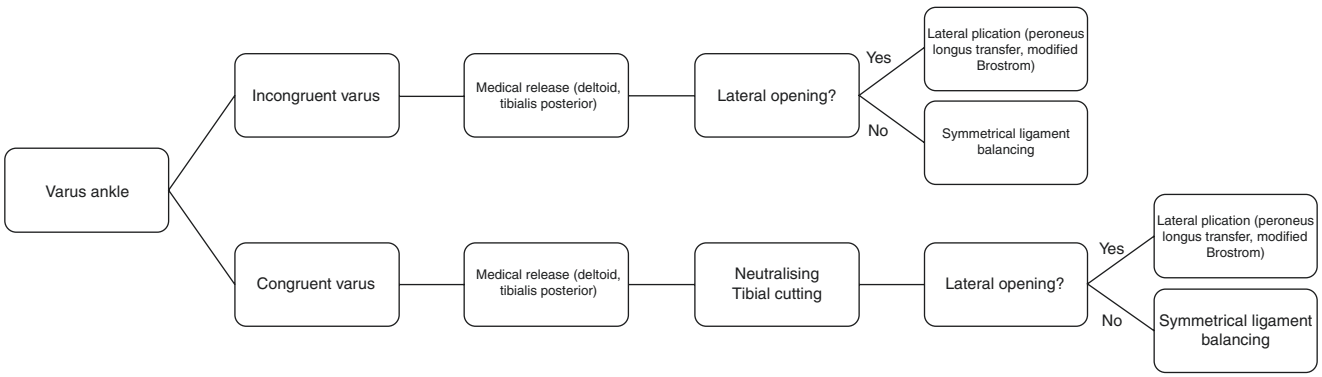


Fig. 28.1 Treatment algorithm for varus malaligned ankles

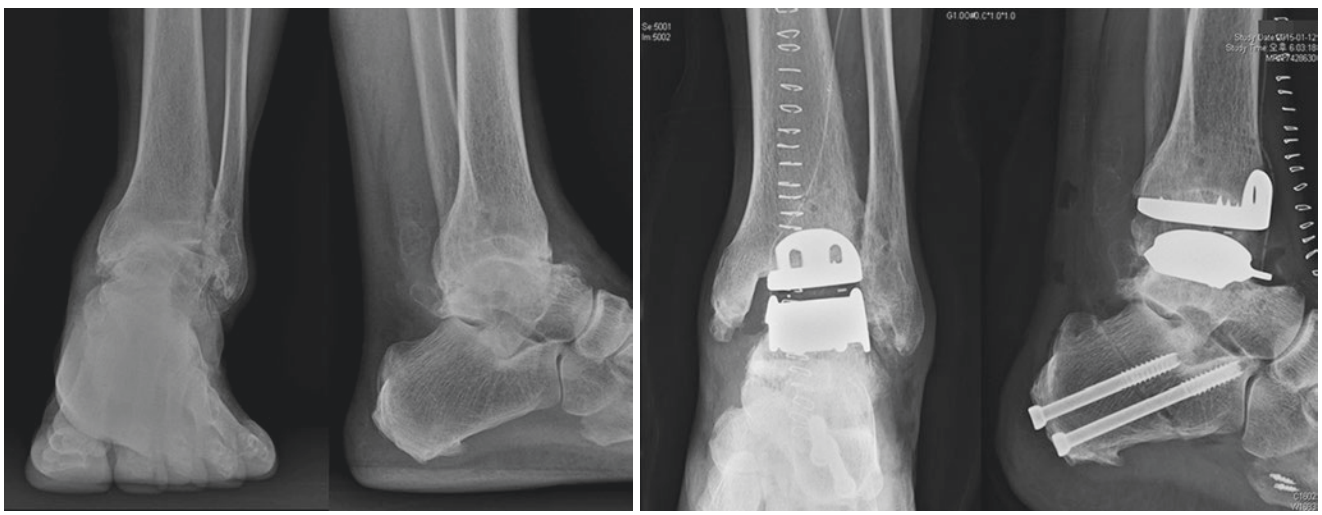


Fig. 28.2 Congruent varus ankle. Postoperative radiograph after a neutralizing tibia cutting

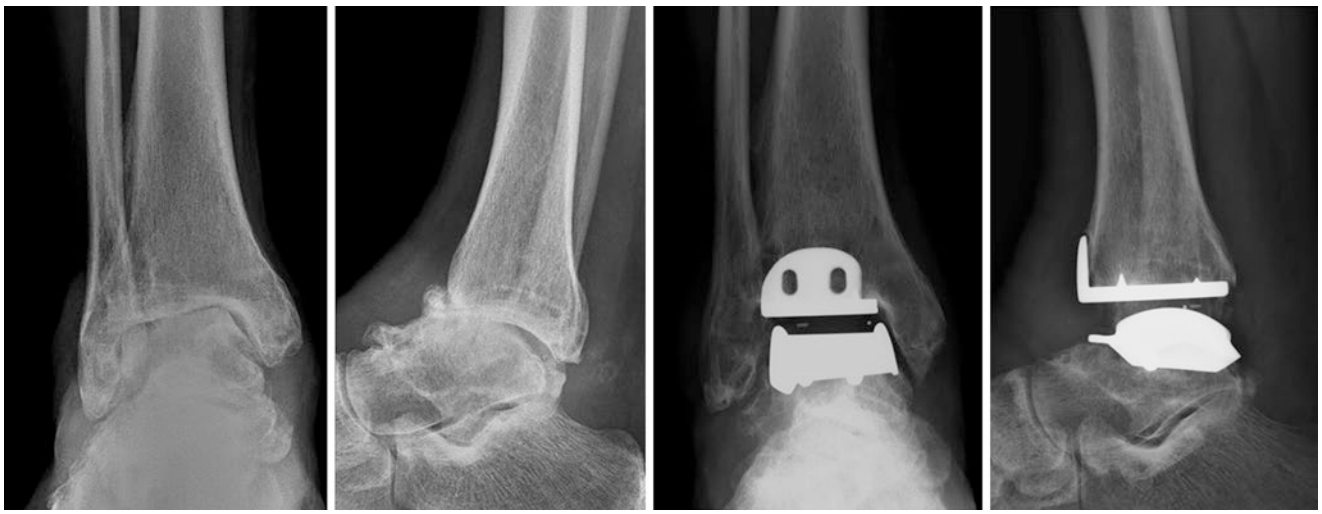


Fig. 28.3 Incongruent varus ankle. After sufficient deltoid release, lateral plication was performed using peroneus longus transfer to brevis technique (note the suture anchor on the fifth metatarsal base). Calcaneal valgization osteotomy was also performed to correct heel varus deformity

3 varus ankle accompanies subtalar joint subluxation, which can be addressed by subtalar or triple arthrodesis.

Valgus Malalignment

From the authors' experience, fibular malunion and posterior tibial tendon dysfunction are two major causes which lead to valgus ankles [14]. The incidence of fibula malunions after malleolar fractures ranges 5–68% [15, 16]. Shortening of fibula after malunion causes lateral deviation of the anatomical axis of the ankle joint. This alteration of axis eventually results in the load concentration on the lateral side of the ankle joint. The extent and the severity of attenuated medial soft tissue should be carefully evaluated in a valgus ankle. After exceeding a threshold of the deltoid ligament, posterior tibial tendon is affected [17]. In a stage 4 posterior tibial tendon dysfunction (PTTD) with a valgus ankle, TAR must then be followed by additional correction of the PTTD deformity. The authors recommended treatment algorithm for achieving ligament balance in a valgus ankle presented in Fig. 28.4.

Preoperative Evaluation

Assessment of the alignment around the ankle joint should be performed by both physical examination and radiological evaluations. Through the physical examination, it is mandatory to assess the alignment of the ankle and hindfoot, the degree of instability and reducibility of the deformity, heel cord tightness, forefoot pronation/supination, and adjacent joint osteoarthritis. Anticipated additional procedures are planned during the preoperative evaluation, but the necessity of these additional procedures is determined intraoperatively, usually after inserting the trial component.

Radiological evaluation consists of weight-bearing anteroposterior (AP) and lateral views of the ankle, weight-bearing anteroposterior and lateral views of the foot, hindfoot alignment views, and long-bone lower extremity views. Varus and valgus stress views are also necessary to compare the degree of instability and the reducibility of the deformity with physical examination. A magnetic resonance imaging is valuable when attenuation of soft tissue structure, such as peroneal or posterior tibialis tendon, is suspected.

Both varus or valgus alignment and congruency of the joint are assessed for the radiological alignment of the ankle. For the varus or valgus alignment, the tibiotalar angle (the angle between the anatomical axis of the tibia and a line drawn perpendicular to the talar dome) is measured on the standard AP radiograph of the ankle (Fig. 28.5) [1, 18]. When the angle of alignment was less than 10° of varus or valgus, the ankle is considered as in the neutral position. But, if the tibiotalar ankle is more than 10°, the ankle is considered as malaligned ankle [1]. Then, the talar tilt angle (the angle between tibial plafond and the talar dome) is measured to evaluate congruency of the joint ankle (Fig. 28.6) [4]. The ankle joint is considered as congruent if the talar tilt ankle is less than 10° and incongruent if it is greater than 10°.

Through the radiological evaluation, a malalignment of more than 10° in any plane in the supramalleolar or distal tibial region should be checked, since it requires corrective osteotomy at the level of deformity before TAR [5, 9, 19, 20].

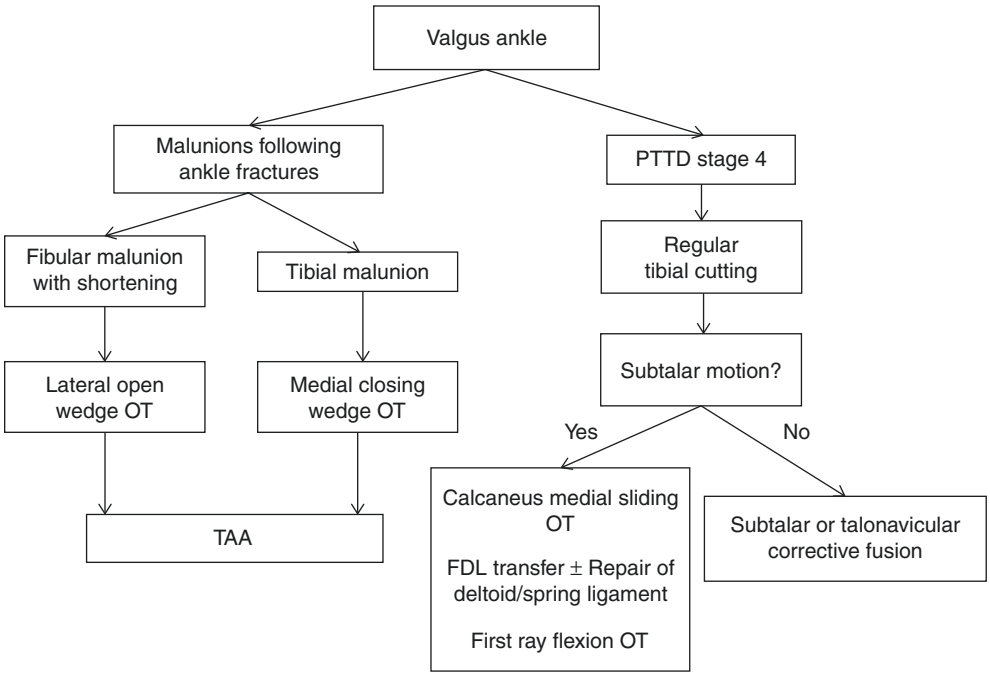


Fig. 28.4 Treatment algorithm for valgus malaligned ankles

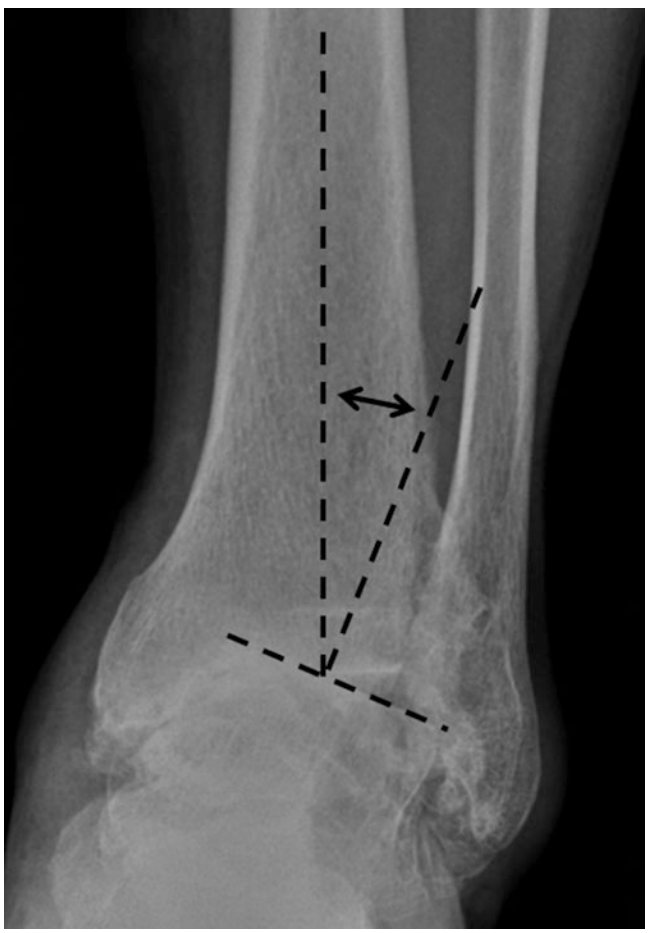


Fig. 28.5 Tibiotalar angle: the angle between the anatomical axis of the tibia and a line drawn perpendicular to the talar dome



Fig. 28.6 Talar tilt angle: the angle between tibial plafond and the talar dome

Surgical Technique for Malaligned Ankle

Varus Malaligned Ankle

In previous studies, the authors have presented their algorithmic approach to correct the varus ankle using a gradual release technique of the medial deltoid ligament with additional procedures [11, 12, 14].

TAR was prepped and performed through a standard surgical approach [21]. In an incongruent varus ankle (Fig. 28.2), the medial soft tissue structure tethers the talus to the medial malleolus causing talar tilt to the neutrally aligned mortise. Since the medial deep deltoid ligament is the key structure of tethering, sufficient release of the deltoid ligament usually brings the tilted talus parallel to the neutral plafond, restoring a neutral ankle. If residual talar tilt with lateral opening was observed even after sufficient medial release, a lateral plication procedure is mandatory (e.g., peroneus longus to peroneus brevis and/or a modified Broström procedure). In a congruent varus ankle (Fig. 28.3), the mortise is usually tilted along with the inclined talus. Thus, a neutralizing tibial cut should be performed after medial soft tissue release. The usual recommended tibial cut is a minimum of 2–3 mm from the tibial plafond to provide maximal bony support for an advantage of the prosthesis [9, 21]. A neutralizing tibial cut requires additional 2–4 mm of plafond resection [21]. Even a slight asymmetry of implant articulation in a non-weight-bearing supine position can increase subluxation or dislocation of a mobile-bearing polyethylene liner when weight is applied. Therefore, confirming symmetrical balancing of the ligaments with parallel implant articulation is a critical step before closing the wound. The need for additional procedures such as a lateral closing wedge calcaneal osteotomy is determined after insertion of the implant. The alignment of the heel, forefoot pronation, plantar flexion of the first ray, and tightness of the heel cord should be reevaluated (Fig. 28.7).

Medial Release and Gap Balancing

After the standard approach and exposure of the ankle joint, the first step is to remove all of periarticular osteophytes from the distal tibia and talus. As osteophytes could give a tenting effect to capsule-ligamentous tissue, this step should be performed thoroughly. Posterior osteophytes of the distal tibia should be also removed because they can hinder the sagittal plane motion of the ankle. Removal of the osteophytes often yields sufficient release of tension to provide a balanced gap in the varus ankle.

After removing all of osteophytes, the medial and lateral gaps can be assessed with distraction using surgeon's preference (e.g., spacer blocks, laminar spreaders, tensiometers). Then, manual varus and valgus stress are applied to assess gap balancing. When the medial and lateral joint gaps are not equal in neutral ankle position, the specific releases should be performed for a contracted side.

The deep medial deltoid ligament and the posterior tibial tendon are key structure for medial side contracture. The deep medial deltoid ligament has its origin on the medial malleolus and its talar insertion on the medial aspect of the talar body. Bonin et al. [22] introduced complete subperiosteal deltoid ligament release from its malleolar attachment and then detaching from the talus. The authors prefer a gradual release of the deltoid ligament at its distal insertion using a curved osteotome (Fig. 28.8). Using a curved osteotome, all components of the deep deltoid ligament (i.e., the anterior tibiotalar, tibionavicular, and posterior tibiotalar) are sequentially released at the distal insertion. The goal is to attain a parallel joint line between the tibial plafond and the talar dome. It may be necessary to extend the release 2–3 cm below the joint line to obtain an effective release on the entire medial aspect of the ankle joint. During this procedure, care must be taken not to injure the neurovascular structures. In this manner, appropriate amount of release can be obtained without causing overcorrection or avascular necrosis of the

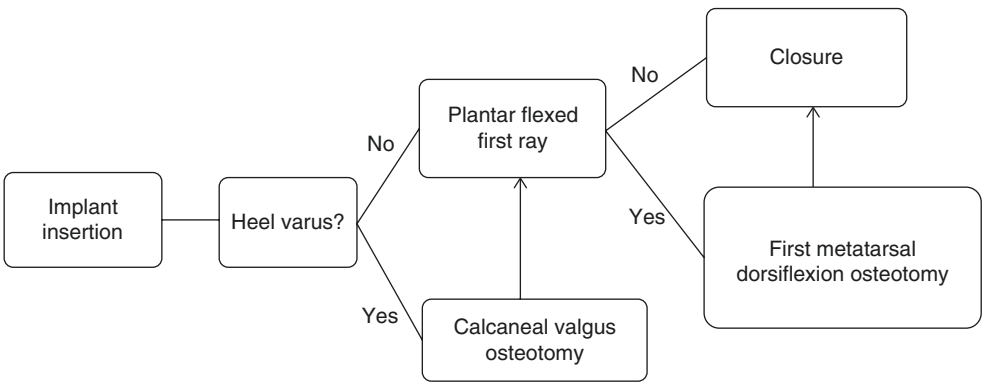


Fig. 28.7 Additional procedures algorithm for a plantigrade foot

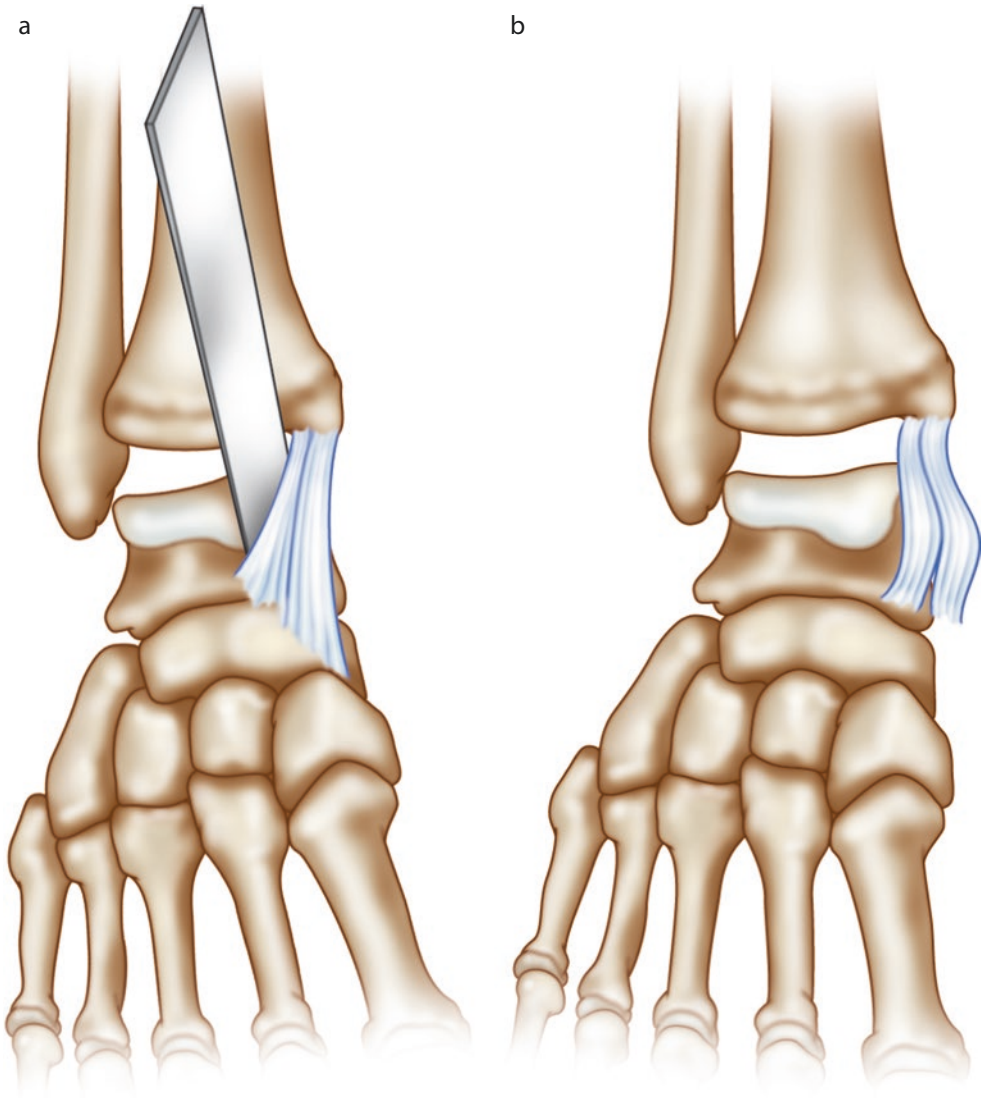


Fig. 28.8 Medial deltoid release

talus. If there is remnant contracture after a sufficient release of the deltoid ligament, the surgeon should check for an extra-articular source of medial contracture, such as a tight tibialis posterior tendon. A separate incision is mandatory to release the relevant contracture.

Other than a gradual release of medial soft tissue, Doets et al. [23] reported a result of medial malleolar osteotomy to solve medial side contracture. Overall result was positive with nonunions in two (13.3%) cases due to the lack of internal fixation of the medial malleolus. Although lengthening the medial malleolus yields instant stability after internal fixation and reduces the risk of the deltoid ligament insufficiency, it might be an aggressive technique for an ankle with mild contracture. Additionally, the technique always bears possibility of nonunion at the osteotomy site.

Lateral Plication: Peroneus Longus Transfer to Peroneus Brevis

After resolving medial side contracture, lateral side should be inspected carefully. When there is lateral opening of the joint line or any sign of polyethylene liner subluxation during a moderate degree of varus stress, lateral plication is indicated. Techniques for lateral plication vary from anatomic/nonanatomic lateral ligament reconstruction to osseous procedures, such as fibular shortening osteotomy. Fibular shortening osteotomy is indicted when fibular length is relatively long and induces redundant lateral soft tissue tension. If the lateral ligament structures are intact, anatomic reconstruction could be performed, such as a modified Broström-Gould procedure [24]. However, owing to prolonged varus deformity, the remaining anterior talofibular ligament and

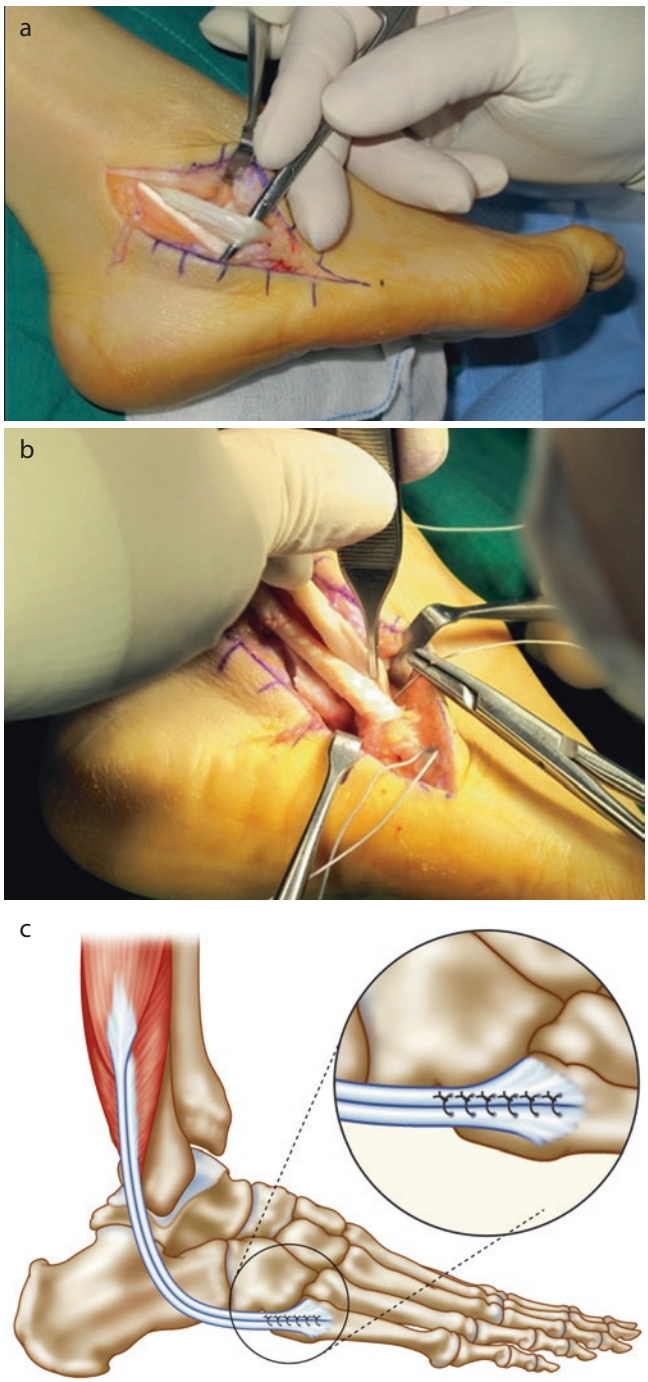


Fig. 28.9 Lateral plication: peroneus longus transfer to peroneus brevis

calcaneofibular ligament are often attenuated, and there is not much left after debridement is done in the lateral gutter. In such cases, various nonanatomic reconstruction techniques are useful. Among the many nonanatomic techniques, the authors prefer a peroneus longus tendon transfer to the base of the fifth metatarsal introduced by Kilger et al. [25]. Not only the technique is convenient to combine with TAR but also effectively stabilizes the lateral soft tissue laxity and reduces the first metatarsal plantar flexion force (Fig. 28.9).

After making a small longitudinal incision over the cuboid, careful dissection is carried out to avoid sural nerve injury. Both the peroneus longus and the peroneus brevis insertion site at the base of the fifth metatarsal are exposed. The peroneus longus tendon is harvested at its most distal portion while an assistant holds the ankle in full plantarflexion and everted position. Then, a suture anchor is inserted at the base of the fifth metatarsal, just plantar and lateral to the insertion of the peroneus brevis tendon. The peroneus longus tendon is sutured to the base of the fifth metatarsal with the foot in a slightly plantarflexed and everted position. Finally, the peroneus longus tendon is tenodesed to the brevis tendon for additional augmentation.

Calcaneal Valgization Osteotomy

After completing the ligament balancing, the alignment of the heel must be evaluated. If the heel is in varus position, the surgeon must correct into natural valgus position. Like other additional procedures, there are several techniques to choose from surgeon's preference. The authors frequently use the lateral closing wedge osteotomy introduced by Dwyer [26]. The technique is relatively easy and takes only a few extra minutes, which is beneficial when combining with TAR (Fig. 28.10).

A small oblique incision is made on the lateral border of the calcaneus after confirming the planned osteotomy site under intraoperative image intensification. Careful dissection is carried out to avoid sural nerve injury. Then a lateral-based wedge is resected using a micro-sagittal saw, while the dorsal and plantar border of the calcaneus is protected with small Hohmann retractors. After closing the wedge, the first guide pin is inserted for the leverage. A bone hook is used to maximally pull the guide pin laterally to minimize the gap and enhance compression at the osteotomy site. With the first guide pin in place, a second guide pin is inserted. Two 6.5-mm, partially threaded cannulated screws are inserted for fixation.

Dorsiflexion Osteotomy of the First Metatarsal

After correcting ankle alignment and varus hindfoot, surgeon needs to hold the foot in a neutral position and evaluate the level of the metatarsal heads. The purpose of this step is to observe a prominent plantarflexed first ray. Since a plantarflexed first ray can induce a varus moment to the ankle during gait, it should also be corrected simultaneously with TAR (Fig. 28.11).

A small skin incision is made 1 cm distal to the first metatarsal-cuneiform joint at the dorsal aspect of the first metatarsal. With care taken to avoid superficial peroneal nerve injury, subperiosteal dissection is carried out, and the

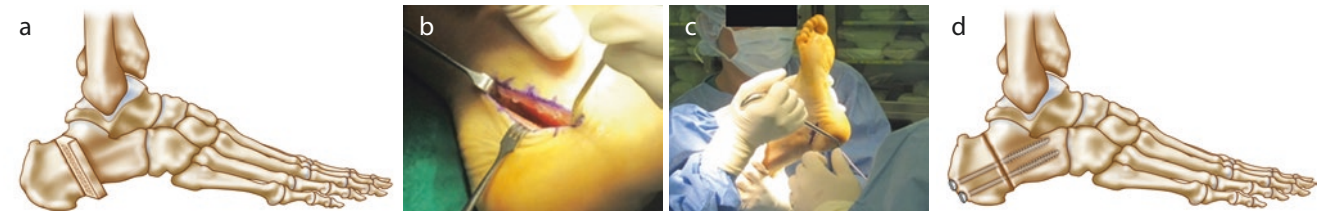


Fig. 28.10 Calcaneal valgization osteotomy

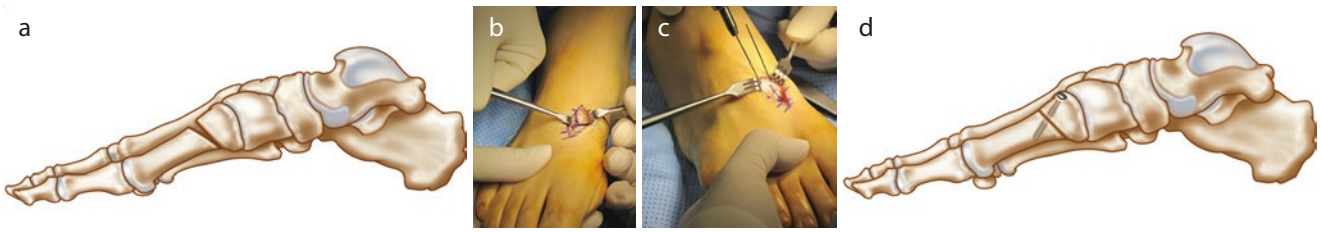


Fig. 28.11 Dorsiflexion osteotomy of the first metatarsal

medial and lateral border of the metatarsal is protected with Senn retractors. Then, a dorsal-based wedge is removed using a micro-sagittal saw. At this point surgeon should avoid excessive bone resection which might lead to elevation of the first ray and overload of the second metatarsal head. In addition, oblique orientation of the osteotomy and enough proximal fragment facilitates easy screw placement. While gently dorsiflexing and closing the osteotomy site with one hand, the operator inserts two guide pins from proximal dorsal to the plantar distal aspect of the metatarsal. Finally, two low-profile screws are used for internal fixation.

Heel Cord Lengthening

In varus ankle deformities, equinus is often observed. Limited ankle dorsiflexion can also be noted after inserting the prosthesis as the prosthesis can act as a spacer. Heel cord lengthening is recommended if less than 10° of ankle dorsiflexion is presented. Either gastrocnemius recession or percutaneous Achilles tendon lengthening is performed after checking component of tightness using the Silfverskiöld test.

When the gastrocnemius alone causes heel cord tightness, gastrocnemius recession is performed. A skin incision is made posteromedial aspect of gastrocnemius which corresponds to the myotendinous junction. After careful subcutaneous dissection, the sural nerve is protected using retractors. Then, the deep fascia of the leg is incised in line with the skin incision to expose myotendinous junction of the gastrocnemius. While the assistant holds the ankle in slight dorsiflexion, myotendinous junction of the gastrocnemius muscle is transected transversely with a surgical blade or large scissors. Finally, gentle dorsiflexion is performed to lengthen the gastrocnemius to obtain more than 10° of ankle dorsiflexion.

If physical examination reveals that both the gastrocnemius and soleus contribute to heel cord tightness, percutaneous Achilles tendon lengthening is performed (Fig. 28.12). While the assistant holds the leg and slightly dorsiflexes the ankle, the surgeon checks the medial and lateral margins of the Achilles tendon and makes three markings in the center, starting half an inch proximal to the insertion and one inch apart from each other. A No. 15 blade is introduced percutaneously and rotated 90° to hemisect the Achilles tendon. In a varus ankle, it is advantageous to make the most distal and most proximal hemisection medially. Consequently, the middle hemisection is done laterally. Like the same manner in gastrocnemius recession, the surgeon gently dorsiflexes the ankle and lengthens the Achilles tendon to obtain more than 10° of ankle dorsiflexion. Care must be taken not to completely rupture the Achilles tendon.

Hindfoot Fusion

Sometimes, a neutral aligned ankle with a stable plantigrade foot could not be achieved after previously described procedures. In such cases, fusion of the hindfoot has to be considered as an additional procedure. Isolated subtalar fusion or subtalar and talonavicular fusion is most frequently combined with TAR. The calcaneocuboid joint is usually spared unless it is arthritic. Isolated talonavicular fusion is also reported to effectively correct the hindfoot deformity [27]. Depending on the patient's condition and the surgeon's skills, hindfoot arthrodesis can be performed simultaneously with TAR or in a staged fashion before TAR.

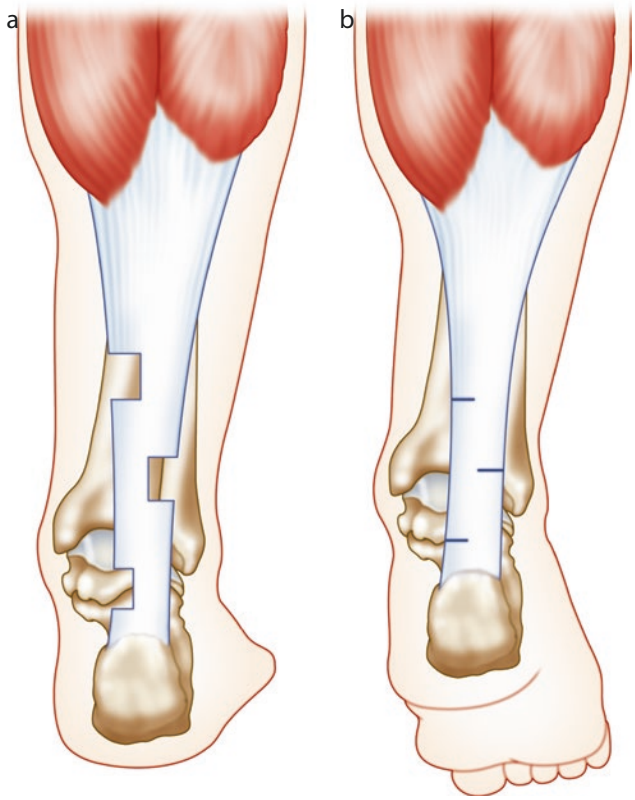


Fig. 28.12 Heel cord lengthening

Valgus Malaligned Ankle

Fibular Lengthening Osteotomy

Like varus malaligned ankle, a maximal talar tilt of 15° has been suggested as a limitation to perform TAR in valgus malaligned ankles [7]. However, the authors' experience shows a stepwise approach to restore coronal balance also makes TAR feasible in valgus malaligned ankles.

When the origin of valgus malaligned ankle arises from shortening of fibula due to lateral malleolar malunion, fibular lengthening osteotomy is recommended. Using a lateral trans-malleolar approach, an osteotomy is made at the level of a supra-syndesmotic area. Then, the syndesmosis is opened up to facilitate pull down of a distal portion of lateral malleolus. A desired length of autologous bone graft is harvested directly from the ipsilateral iliac bone. Although it is hard to determine the adequate length and rotational correction, the authors recommend referencing the contralateral ankle and articular contact between the fibula and the lateral gutter of the talus. Finally, interposed bone graft site is fixed with plate and screws.

If the valgus ankle was caused by advanced posterior tibial tendon dysfunction, various additional procedures should be incorporated. The procedures include medial sliding calcaneus osteotomy, medial soft tissue repair (flexor digitorum longus tendon transfer to navicular bone, repair of the deltoid and spring ligaments), and/or flexion osteotomy of the first metatarsal or medial cuneiform. Proper selection among various hindfoot arthrodeses (e.g., isolated subtalar arthrodesis, isolated talonavicular arthrodesis, talonavicular and calcaneocuboid arthrodesis, and triple arthrodesis) is necessary to restore a fixed forefoot-induced pes planovalgus deformity.

Postoperative Management

During the first 2 weeks after the operation, a short leg splint is applied for a temporary immobilization in a neutral position. It was converted into a short leg plaster cast after removing all sutures. For patients who received TAR with additional soft tissue procedures, partial weight-bearing is allowed after conversion to a short leg cast. For those with additional bony procedures, non-weight-bearing period was continued for 6 weeks. After removing a short leg plaster cast, patients were educated to start gentle active and passive motion including strengthening exercise. Regular follow-up is performed 3, 6, and 12 months postoperatively and yearly thereafter with standard ankle radiographs.

Complications

Other than general complications such as wound problems, deep infection, and aseptic loosening, the primary complication after TAR in malaligned ankle is the subluxation or dislocation of the polyethylene liner. In most cases, the subluxation is due to inadequate correction of malalignment at the time of initial operation. In varus malaligned ankle, residual medial tightness due to insufficient release is a frequent problem. In valgus malaligned ankle, recurrent medial instability may lead to an anteromedial dislocation of the polyethylene liner [9]. Therefore, a surgeon should confirm several times during the operation whether they have restored a neutral ankle with a plantigrade foot. Medial ligament insufficiency as a result of excessive deltoid ligament release is another concern. However, sequential deltoid release reduces such complications. Even if the subluxation or dislocation of the polyethylene liner occurs after the initial operation, rebalancing with additional procedures can maintain TAR.

Reported Outcomes

Although most of the previous studies have reported the outcomes after TAR regarding longevity, only a few series have focused on the outcomes in TAR with malalignment. To address varus deformity undergoing TAR, Doets et al. [23] devised medial malleolar lengthening osteotomy. Eighty-six percent of the patients showed good or excellent results with two nonunions at the malleolar osteotomy site after a mean follow-up of 5 years. A comparative study between varus malaligned ankles and neutral ankles was reported by Kim et al. [11]. In this study, various additional procedures were incorporated simultaneously with TAR to correct malalignment. After a mean follow-up of 27 months, no differences were observed between the varus and neutral ankles regarding all clinical and radiologic outcomes. Furthermore, comparable outcomes were shown when congruent and incongruent varus ankles were compared. A similar result was reported by Hobson et al. [10] after a mean follow-up of 4 years. The comparison was made between ankles with preoperative coronal plane deformity more than 10° and those of ankles with less than 10° of deformity. Overall outcomes were similar between the two groups including range of motion, complications, survival, and failure rates. The significant finding in this study is higher postoperative American Orthopaedic Foot and Ankle Society scores in the deformity group. The authors attributed the result to increased benefit after operation in the deformed ankles. The results after TAR with hindfoot fusion were also favorable from the study of Kim et al. [28]. Comparison between 60 ankles with TAR and simultaneous hindfoot fusion to 288 ankles with TAR only was analyzed. Patient satisfaction, overall complication rate, and failure rate showed no difference between the groups at the midterm follow-up.

Even though the long-term follow-up is needed, previous studies have shown promising outcomes after TAR in ankles with malalignment.

Conclusions

TAR formal-aligned ankle is a challenging task. Conditioned that proper correction is accomplished through ligament balancing and additional procedures, satisfactory outcomes could be expected. Even though there are no long-term studies yet, comparable outcomes were reported between malaligned ankles and neutral ankles in the midterm report. The authors recommend proposed algorithmic approach to tackle TAR with malaligned ankles. In the future, long-term follow-up is warranted to find out deeper understanding of realigned ankles after TAR.

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The Role of Periarticular Osteotomies in Total Ankle Replacement

29

Beat Hintermann and Roxa Ruiz

Introduction

The most common cause of end-stage osteoarthritis of the ankle is trauma [1]. Newer studies have shown that with progression of the osteoarthritic process, up to 60% of the affected ankles experience a talus varus or valgus tilt within the ankle mortise [2]. Besides ligamentous instability, the underlying cause is, in the majority of cases, malalignment, with its origin in a deformity above (e.g., supramalleolar) or below (e.g., inframalleolar) the ankle joint, whereas, very rarely, the deformity is located intra-articularly [3].

Ankle joint malalignment leads to a focal static and a dynamic overload within the ankle joint [4–6]. During stance, the center of force transmission is medialized in the varus ankle and lateralized in the valgus ankle. The forces within the joint are amplified by activation of the triceps surae: the Achilles tendon acts as an invertor in varus deformities and as an evertor in valgus deformities [7], respectively, acting as an additional deforming force on the hindfoot.

While periarticular corrective osteotomies have been shown to be utmost successful in balancing a malaligned ankle, as a single measure for an early stage of ankle osteoarthritis with preservation of the ankle joint [8, 9], there are only very few reports on its use in the treatment of advanced stage ankle osteoarthritis where the malaligned ankle joint cannot be preserved, and thus total ankle replacement is considered [10–12]. Theoretically, the malalignment can be treated with correcting cuts, but there are obvious limitations for obtaining a balanced ankle, and thus additional measures are necessary, in particular periarticular osteotomies (Fig. 29.1a–e). Their specific aims are (1) to realign the hindfoot, (2) to bring the ankle joint under the weight-bearing axis, and (3) to normalize the direction of the force vector of the triceps surae [3, 8]. This is particularly crucial when using three-component ankles where the second interface of the prosthesis allows the polyethylene insert to freely translate and rotate on the flat surface of the tibial component [13]. Though it has not been elucidated in detail, the success of total ankle replacement (TAR), in the long run, is highly dependent on the surgeon's ability to balance the ankle joint complex [10, 14–17].

This article summarizes the authors' experiences using simultaneous periarticular osteotomies during TAR, to balance the ankle joint complex.

Preoperative Planning

The most important aspect of preoperative planning is assessment of the deformity origin and the understanding of the deforming forces. It is mandatory to distinguish between the different types of deformities; in particular varus and valgus tilted talar deformities, which have deviations mainly in the coronal plane, however, may also show differences in the sagittal plane [18, 19].

Clinical Examination

Thorough physical examination includes clinical assessment of the hindfoot while the patient is standing. Hindfoot stability needs to be tested using routine physical examination. The function of the joint-crossing tendons is analyzed, in particular the peroneal tendons in the varus ankle and the posterior tibial tendon in the valgus ankle. Furthermore, the range of motion of the ankle joint is assessed. Finally, the forefoot is examined with regard to a plantarflexed first ray, forefoot supination, and toe deformities.

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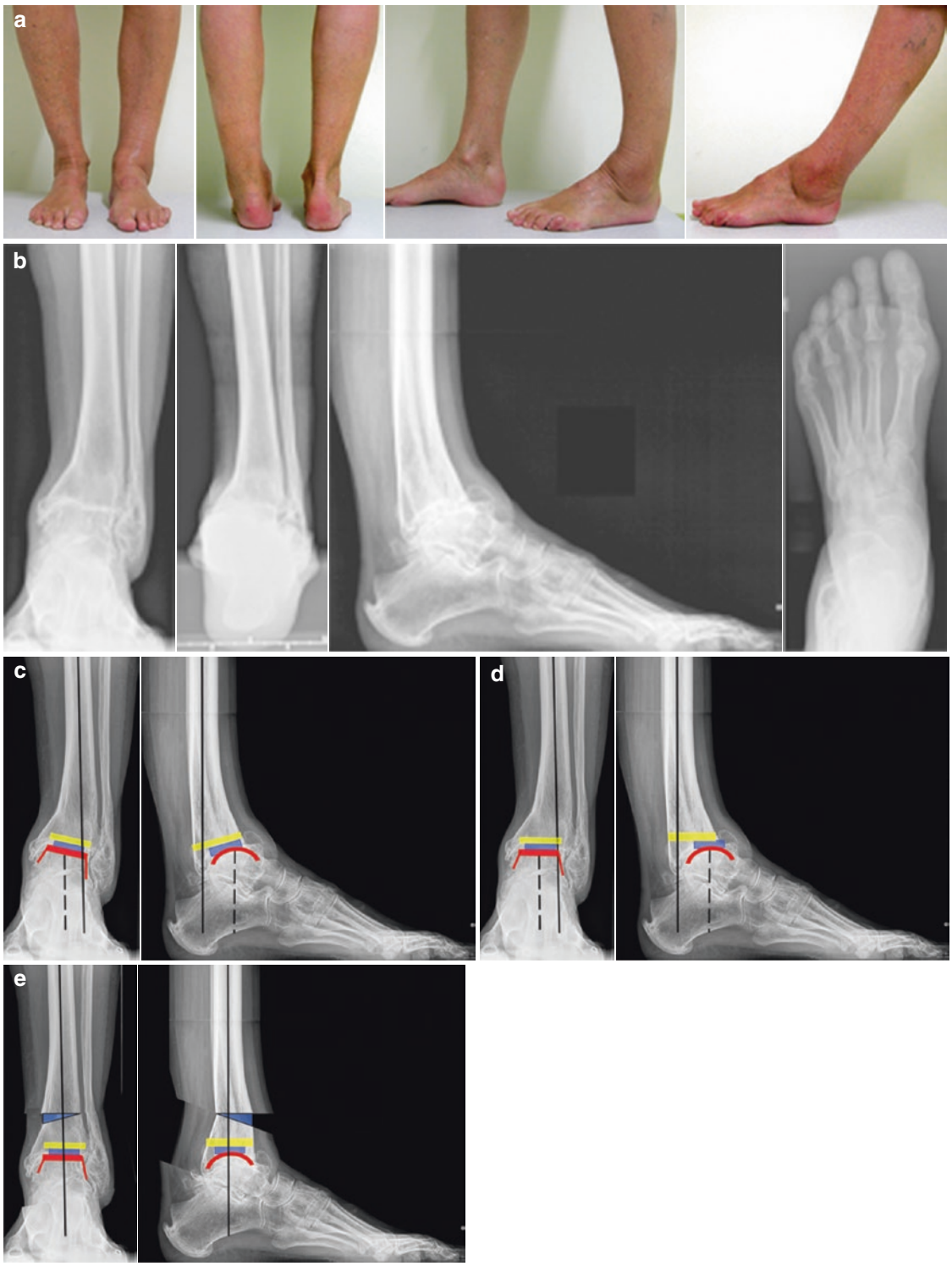


Fig. 29.1 A 58-year-old female patient with posttraumatic ankle osteoarthritis subsequent to a malunited distal tibial fracture 32 years ago. Marked varus and recurvatum deformity as seen clinically (**a**) and radiographically: AP, Saltzman, and lateral view of the ankle as well as a foot AP (**b**). Functionally, there is an equinus deformity at the ankle. (**c**) Total ankle replacement without correction of the deformity in neither the coronal (left) nor the sagittal (right) plane: though joint congruity is maintained and the ligaments are physiologically loaded, the replaced ankle would not be balanced due to the resulting translational forces of the talus toward medial and anterior. (**d**) Total ankle replacement with correcting cuts in both the coronal (left) and sagittal (right) planes: though the ankle looks balanced, it is not, as the congruity of the ankle joint is no longer maintained resulting in nonphysiological loading of the ankle ligaments, which, in turn, would result in an unstable and painful ankle. (**e**) Total ankle replacement with correcting osteotomies: the congruency of the ankle will be maintained in the coronal (left) and sagittal (right) plane, with the ligaments being physiologically loaded, thus resulting in a stable and balanced ankle

Radiographic Examination

Radiographic assessment of the malaligned ankle includes anteroposterior, lateral, and mortise views of the ankle and a dorsoplantar view of the foot. In order to assess the calcaneus position in relationship to the longitudinal axis of the tibia, the Saltzman view (i.e., hindfoot alignment view) should be performed [20]. All radiographs should be performed with weight-bearing to assess the functional deformities of the hindfoot; furthermore, the contralateral non-affected foot should be included to fully understand location and amount of deformity. The weight-bearing CT scan permits to assess the deformity and destabilization process within the ankle joint complex in all three planes. In particular, it helps to understand the rotational and translational changes in the peritalar instability (Fig. 29.2). Single-photon emission computed tomography (SPECT) might additionally be helpful to understand the deformity and plan the osteotomies, particularly in biplanar corrections [21].

Prior to surgery, the anteroposterior view radiographs are used to measure the tibial articular surface (TAS) angle (normal value, 91–93°), to determine the center of rotation of angulation (CORA), and to measure the amount of angulation in the coronal plane (Fig. 29.3a) [8, 22]. The lateral view radiographs are used to determine the CORA, to measure the amount of angulation in the sagittal plane, and to evaluate the position of the talus with regard to the axis of the distal tibia, e.g., the distance (d) between the center of rotation of the talus (CORT) and the tibial axis (Fig. 29.3b). The Saltzman view is used to assess overall alignment of the hindfoot.

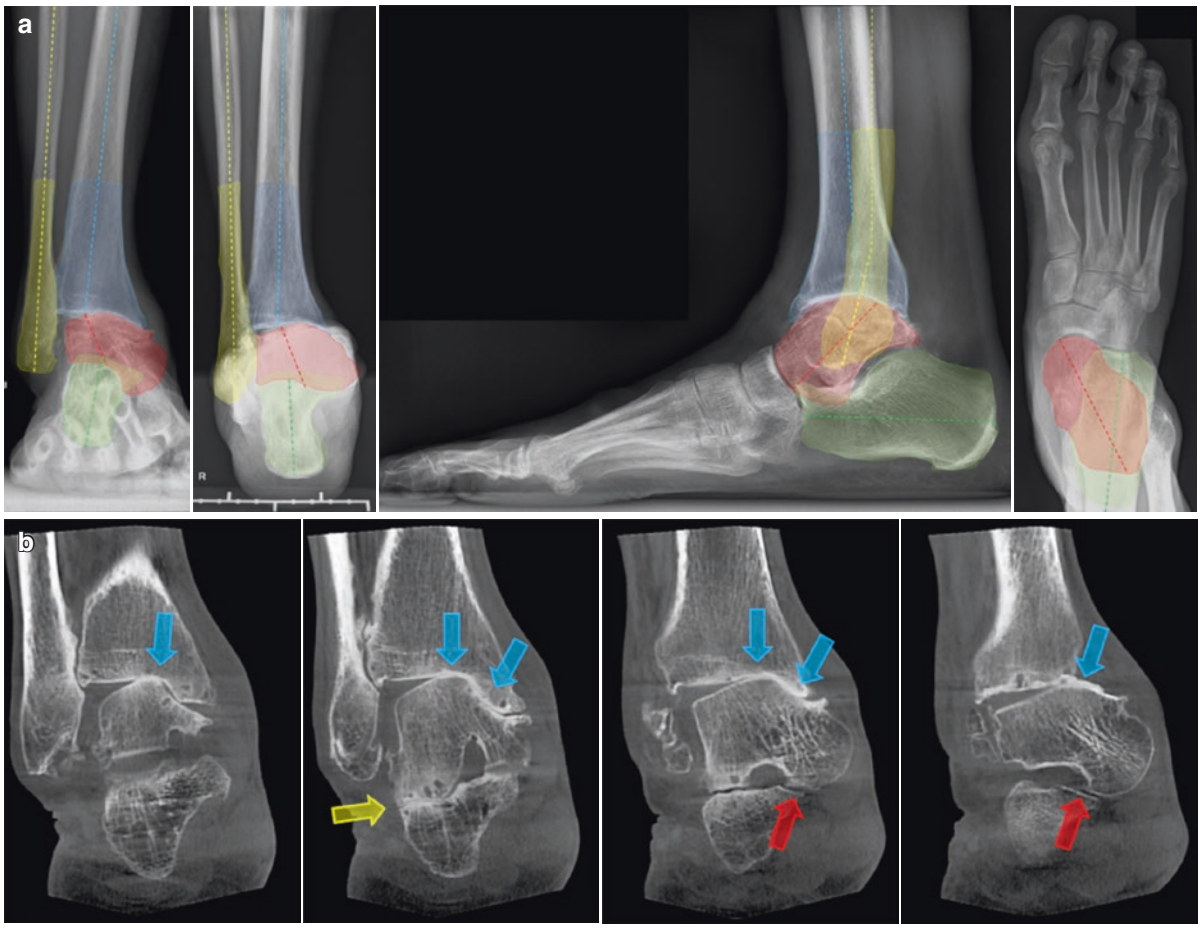


Fig. 29.2 Assessment of the deformity and destabilization process of the whole ankle joint complex with aid of weight-bearing CT scan. (**a**) The standard X-rays show the segmental alignment of the bones, but they provide little information about the articular changes and displacement, whereas weight-bearing CT scan shows more details; (**b**) in the coronal plane, the varus tilt has moved the contact area (blue arrows) medialward, and medial"nearthros" has been built up. Sinus tarsi impingement (yellow arrow) is seen in the subtalar joint, associated with subluxation (red arrow) at anterior facet of the joint, indicating compensatory pronation and translation at the subtalar joint; (**c**) in the sagittal plane, again asymmetric load at medial tibiotalar joint (blue arrows) with subsequent "nearthros" can be seen, as well as the sinus tarsi impnigment (yellow arrows) as a consequence of internal rotation and translation of talus can be seen; (**d**) in the horizontal plane, the talus moved toward medially with overuse at medial tibiotalar joint (blue arrows)

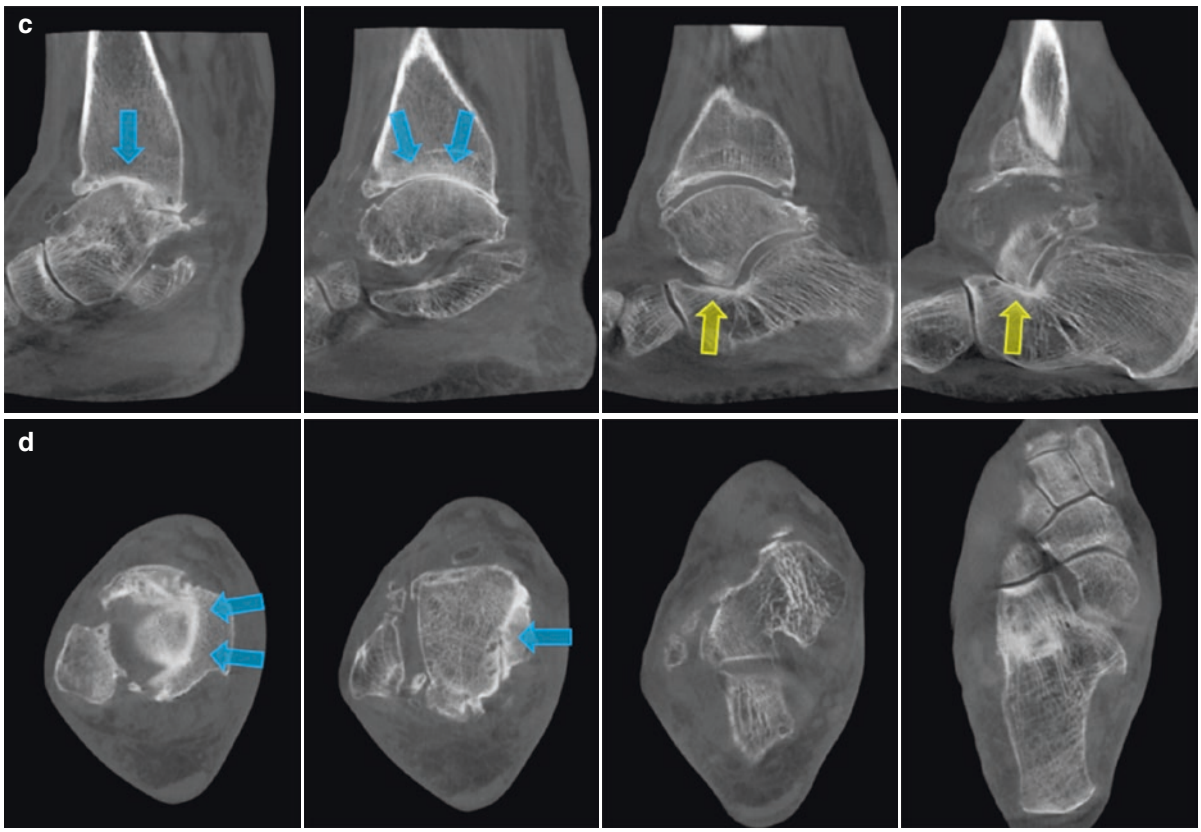


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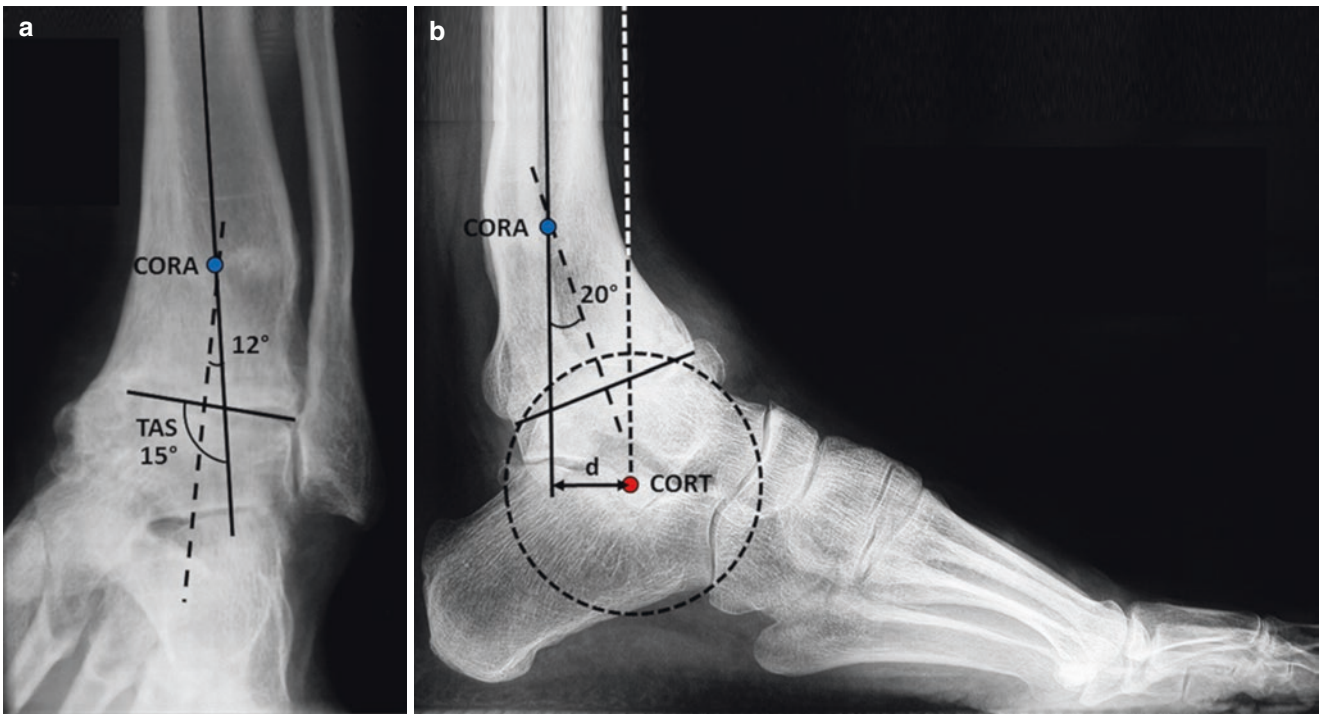


Fig. 29.3 Assessment of the deformity with the aid of the center of rotation of angulation (CORA), the distance "d," representing the deviation of the joint loading axis to the center of rotation of the talus (CORT) and the tibial articular surface (TAS) angle. (**a**) Coronal plane and (**b**) sagittal plane

Indication for Correcting Osteotomies in Total Ankle Replacement

At the time of TAR, periarticular osteotomies are indicated when the preexisting deformities cannot sufficiently be addressed by correcting resection cuts, soft tissue releases (including ligaments, capsular, and tendons), and tendon transfers, e.g., a stable and well-balanced ankle joint complex is not achieved with all these measures.

Supramalleolar Osteotomies

A supramalleolar osteotomy is considered where the origin of the deformity is located above the ankle joint. As a principle, it is done before TAR. It aims to bring the ankle joint under the weight-bearing axis and to normalize the direction of the force vector of the triceps surae, thereby realigning the hindfoot [8, 22]. An open or closing wedge osteotomy from medial or lateral or, in severe deformities, a dome-like osteotomy from anterior can be considered to achieve a neutral TAS angle and/or to correct a pathological slope of the distal tibia (Fig. 29.4a–e). The height of the osteotomy is selected according to the CORA, with the aim of moving the longitudinal axis of the tibia in such a way that it crosses the tibiotalar joint in its center.

A fibular osteotomy, solely or additionally to a tibial correcting osteotomy, is considered when addressing a malpositioning that may hinder reduction of the talus, e.g., shortening, lengthening, derotation, or abduction (Fig. 29.5a, b) [23].

Intra-articular Osteotomies

An osteotomy of the distal fibula may be necessary where a malunited fibular fracture does not allow the replaced talus to get properly positioned within the ankle mortise. This is typically the case for a recurvatum deformity (Fig. 29.6a, b).

An osteotomy of the medial malleolus serves to release the medial ankle in severe varus deformities where the tension of the deltoid ligament does not allow the talus to get properly positioned within the ankle mortise, e.g., when there is a persisting talar tilt at the end of total ankle replacement (Fig. 29.7a–e) [12, 24].



Fig. 29.4 A 61-year-old male patient with end-stage osteoarthritis with a marked varus deformity of the distal tibia after an ankle fracture with injury to the epiphysis at the age of 12 years. (**a**) AP view, Saltzman view, and lateral view of the ankle. Radiographic assessment evidences a talar tilt into varus of 32° according to a changed varus tibial surface angle, associated with a varus malalignment of the hindfoot. (**b**) After exposure through a standard anterior approach, a dome-like osteotomy, as seen in the left image, is done to rotate the whole distal tibial complex with adherent fibula and fixed with two plates, illustrated in the right image. The fibula was osteotomized through a separate lateral approach. (**c**) These interventions resulted in a balanced and stable ankle joint in the coronal (left) and sagittal (right) plane, with preservation of its congruency as seen under fluoroscopy. (**d**) Thereafter, total ankle replacement is done by the standard technique, followed by a medial sliding osteotomy of the calcaneus to obtain a well-aligned hindfoot. (**e**) AP view, Saltzman view, and lateral view of the ankle. Radiographic assessment at 5 years, with a balanced and stable ankle in both planes and a well-aligned hindfoot

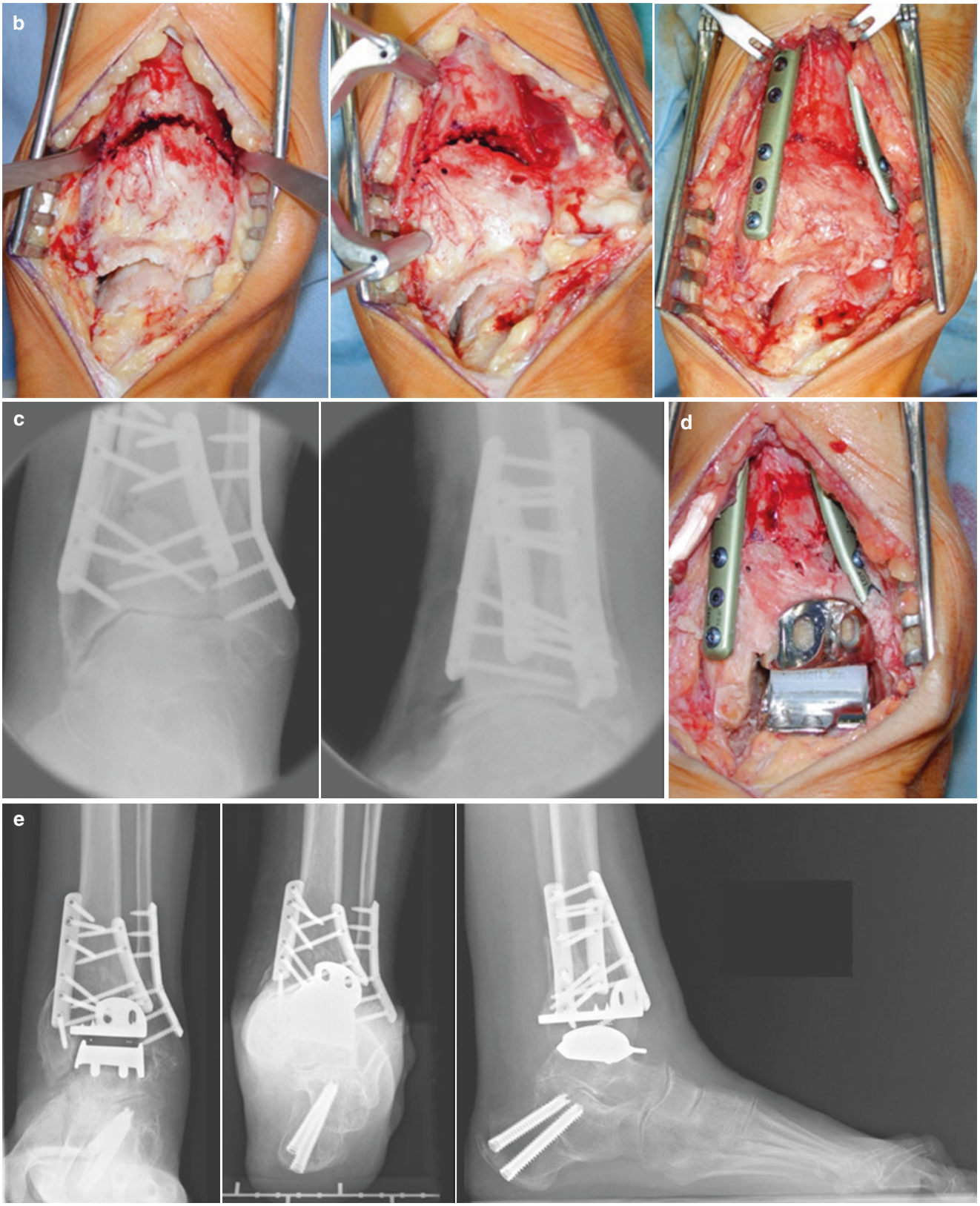


Fig. 29.4 (continued)

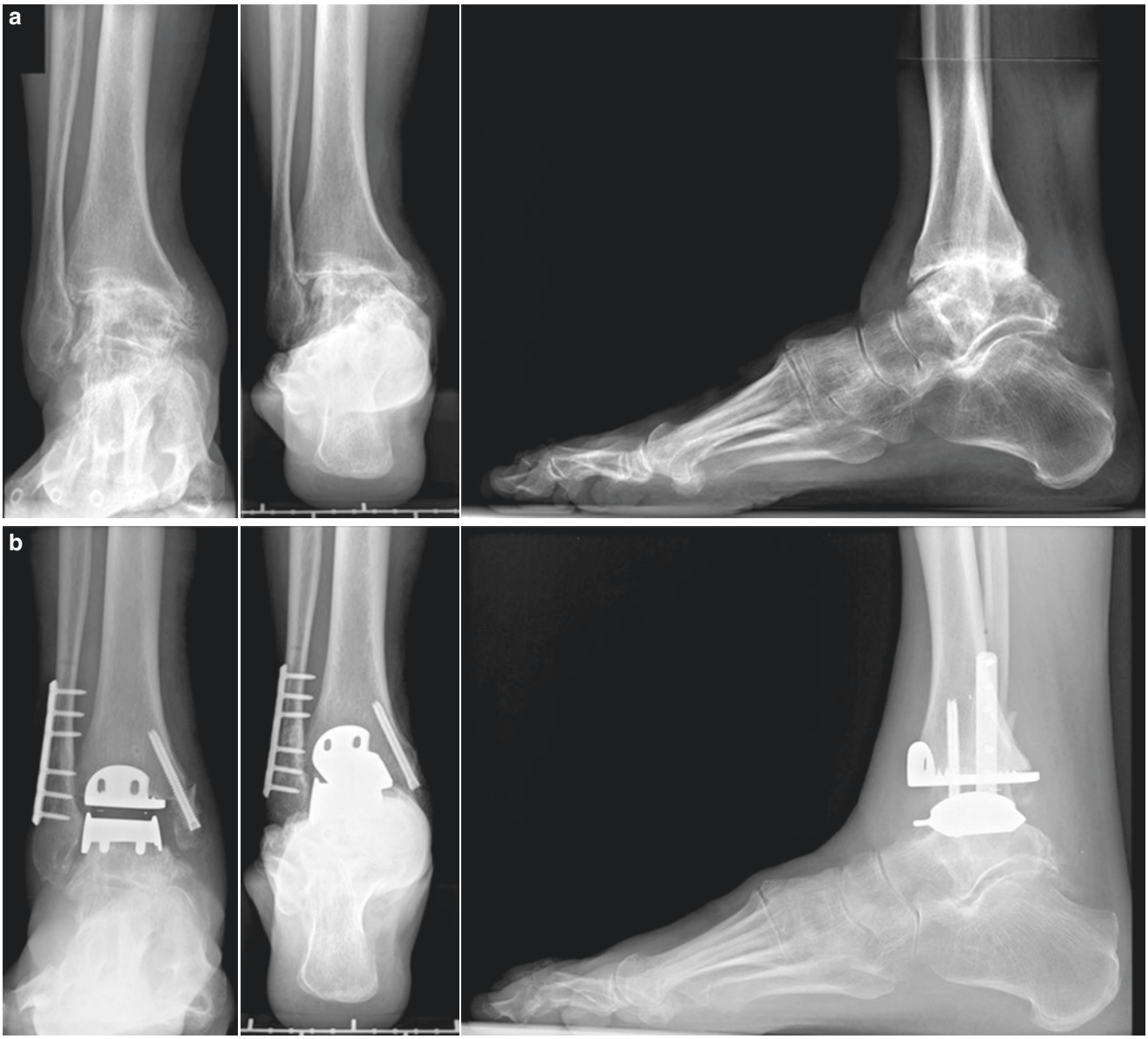


Fig. 29.5 A 48-year-old female patient with end-stage ankle osteoarthritis subsequent to an ankle fracture 24 years earlier. (**a**) AP view, Saltzman view, and lateral view of the ankle. The radiographic assessment reveals a distinct varus deformity of the distal tibia and a malunited fibula that is too long with regard to the medial malleolus. With its malunion in a slight varus position, it pushes the talus medially which, in turn, may have provoked the wearing out of the medial ankle. (**b**) AP view, Saltzman view, and lateral view of the ankle. Four months after total ankle replacement and a fibular shortening osteotomy with fixation in slight abduction, the talus is well centralized within the ankle mortise. The medial malleolus was additionally osteotomized for medial release of the ankle

Inframalleolar Osteotomies

In contrast to a supramalleolar correction, an inframalleolar osteotomy is considered after TAR if there is a persisting malalignment of the hindfoot.

A calcaneal osteotomy aims to realign the hindfoot and to normalize the direction of the force vector of the triceps surae. A medial [25] or lateral sliding osteotomy [26, 27] or a lateral closing wedge osteotomy [28] of the calcaneus can be considered to achieve a neutral alignment of the hindfoot (Fig. 29.8a–d).

Osteotomies of the medial arch aim to realign the forefoot to the hindfoot. In the case of forefoot supination, a dorsal closing wedge osteotomy of the first cuneiform or base of the first metatarsal is considered, whereas in the case of forefoot pronation, e.g., a plantarflexed first metatarsal, a dorsal opening wedge osteotomy of the first cuneiform is considered (Fig. 29.9a–c).

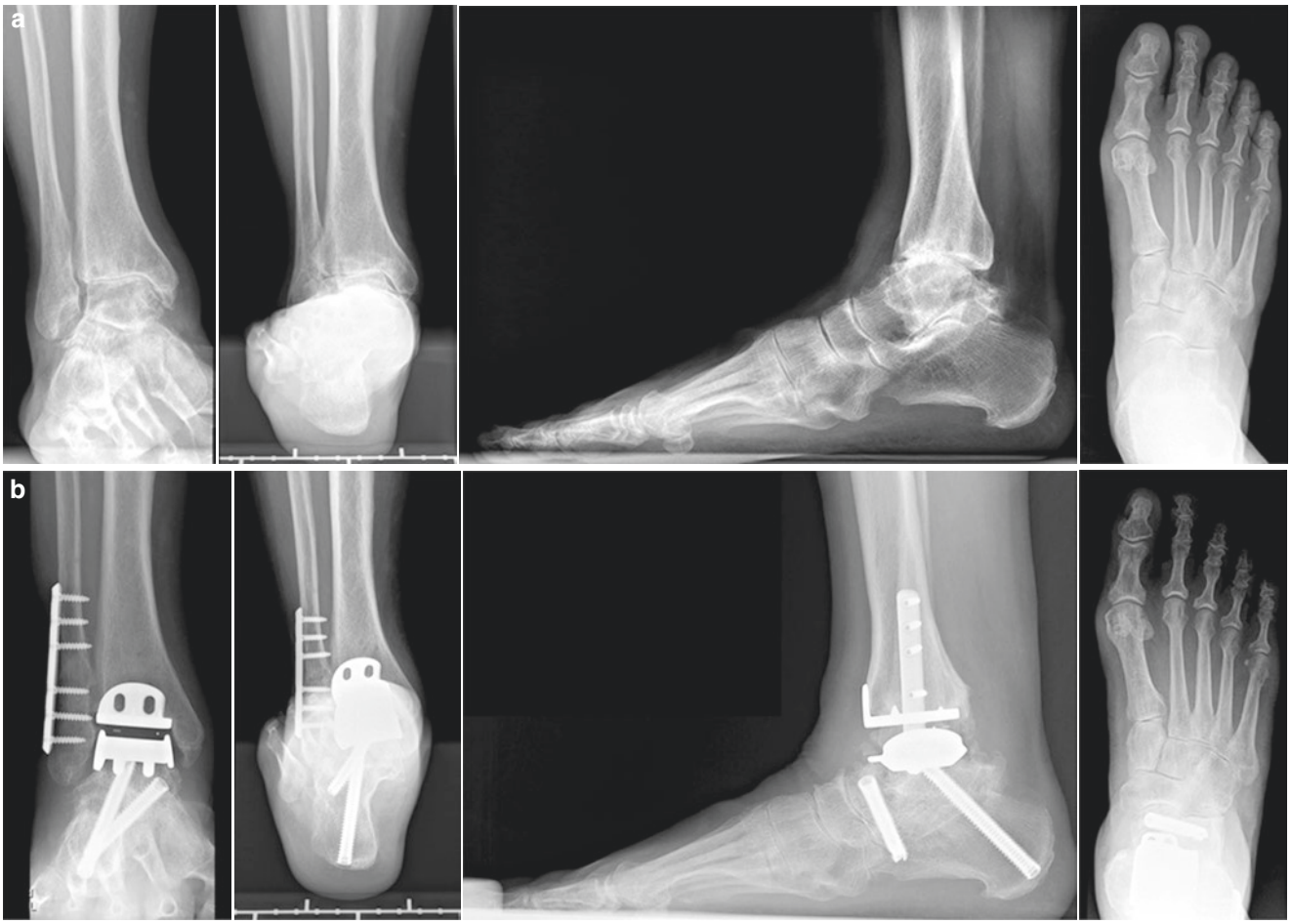


Fig. 29.6 A 54-year-old female patient with end-stage ankle osteoarthritis subsequent to an ankle fracture 18 years earlier. (**a**) AP view, Saltzman view, and lateral view of the ankle and foot AP. The preoperative radiographic assessment reveals a recurvatum malunion of the distal fibula that forces the talus in an anterior subluxed position. (**b**) AP view, Saltzman view, and lateral view of the ankle and foot AP. Two years after total ankle replacement and a correcting osteotomy of the fibula, the talus is well centralized within the ankle mortise. The subtalar joint was additionally fused due to a symptomatic degenerative disease

Additional Procedures

Though periarticular osteotomies are very effective in balancing malaligned ankles [8, 9], they may, in some instances, not be sufficient to get a stable and well-balanced ankle. Since these are major contributing factors to achieve a good outcome and to have a long-term success of the replaced ankle [10, 14–17], additional procedures are sometimes necessary.

A *subtalar arthrodesis* is considered to correct a fixed deformity, to stabilize a highly unstable joint, or to address pain originating from progressive degenerative changes. In most instances, an interposition technique with the use of a bone graft should be considered in order to tighten the collapsed ligaments of the ankle joint complex.

Tarsal arthrodeses are considered to realign the forefoot to the hindfoot, to stabilize the medial arch, and to address pain originating from degenerative changes. Depending on the origin of the problem, the arthrodesis can be considered at the level of the talonavicular, naviculocuneiform, or first tarsometatarsal joints. The ultimate goal is to obtain a neutral position of the forefoot.

Ligament reconstructions are considered to stabilize the talus in the corrected position within the ankle mortise. Anatomic repair of the remaining ligament can be augmented with the use of free tendon autografts, e.g., plantaris tendon or semitendinosus tendon. If available, the use of allografts can also be considered. Though effective for stabilization of the ankle joint complex, tenodesis techniques should not be used due to their effect on the biomechanics and the motion (limiting) of the ankle joint.

Tendon transfers are considered to restore and balance muscular forces. In the case of a dysfunction of the peroneal brevis, a peroneus longus to peroneus brevis tendon transfer is considered. In the case of a dysfunctional tibialis posterior,

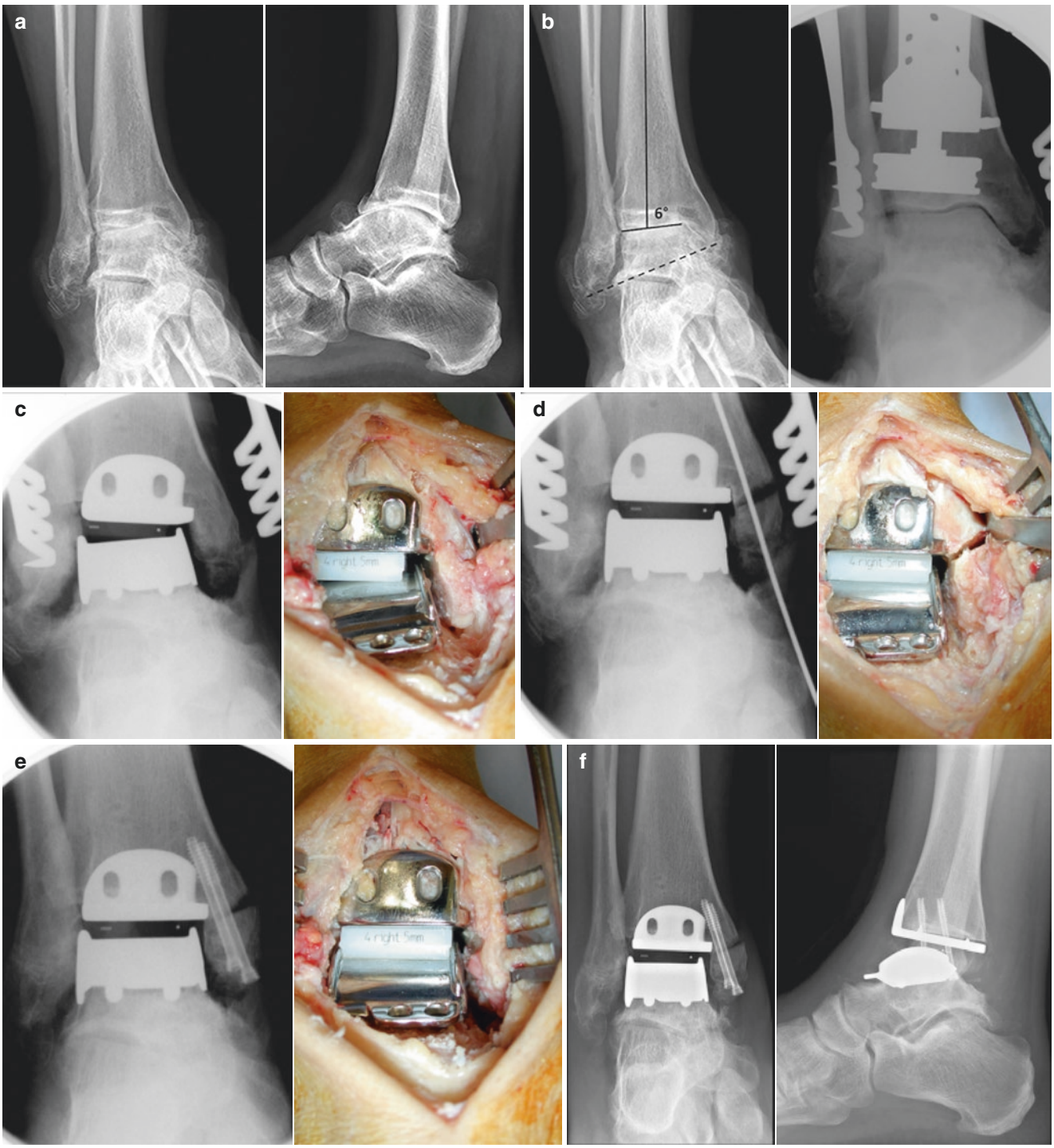


Fig. 29.7 A 51-year-old male, former soccer player, with end-stage ankle osteoarthritis subsequent to recurrent ankle sprains. (**a**) AP view and lateral view of the ankle. The preoperative radiographic assessment reveals a varus deformity of the distal tibia with a moderate varus tilt of the talus within the mortise. There is a marked bone formation around the malleoli and at the anterior tibiotalar joint. (**b**) The AP view of the ankle on the left shows a TAS angle of 6° and an overlength of the fibula as compared with the medial malleolus. With a correcting resection cut perpendicular to the anatomic axis of tibia, there will be more bone removed on the lateral aspect of distal tibia illustrated under fluoroscopy on the right. (**c**) After implant insertion, the talus persists in a varus position due to imbalanced ankle ligaments (e.g., a too tightened deltoid ligament) as seen under fluoroscopy on the left and in the intraoperative images taken on the right. (**d**) The overstuffed deltoid is successfully released by a flip osteotomy of medial malleolus, which allows the talus to get in the appropriate position as shown under fluoroscopy on the left and in the intraoperative images on the right. As the medial malleolus follows the talus, the direction of the deltoid ligament is preserved. (**e**) The final situation (as seen under fluoroscopy on the left and on the intraoperative image on the right) after having filled the osteotomy gap with resected bone pieces and after having inserted two cannulated screws. (**f**) AP and lateral view of the ankle. The postoperative X-rays show a well-balanced ankle joint



Fig. 29.8 A 56-year-old male patient with end-stage osteoarthritis associated with a severe varus deformity. (**a**) AP view, Saltzman view, and lateral view of the ankle as well as a foot AP. Radiographic assessment reveals a purely inframalleolar deformity associated with a significant incompetence of the lateral ankle ligaments. (**b**) Intraoperative assessment of the hindfoot alignment showing only a partial correction of the hindfoot varus after total ankle replacement; hindfoot realignment is well restored after a Z osteotomy of the calcaneus with resection of a horizontal wedge and subsequent lateralization and valgization of the calcaneal tuberosity. (**c**) Intraoperative fluoroscopy to show the position of the calcaneus after osteotomy in the lateral and axial view. (**d**) AP view, Saltzman view, and lateral view of the ankle as well as a foot AP. Radiographic assessment at 6 years, with a balanced and stable ankle in both planes and a well-aligned hindfoot

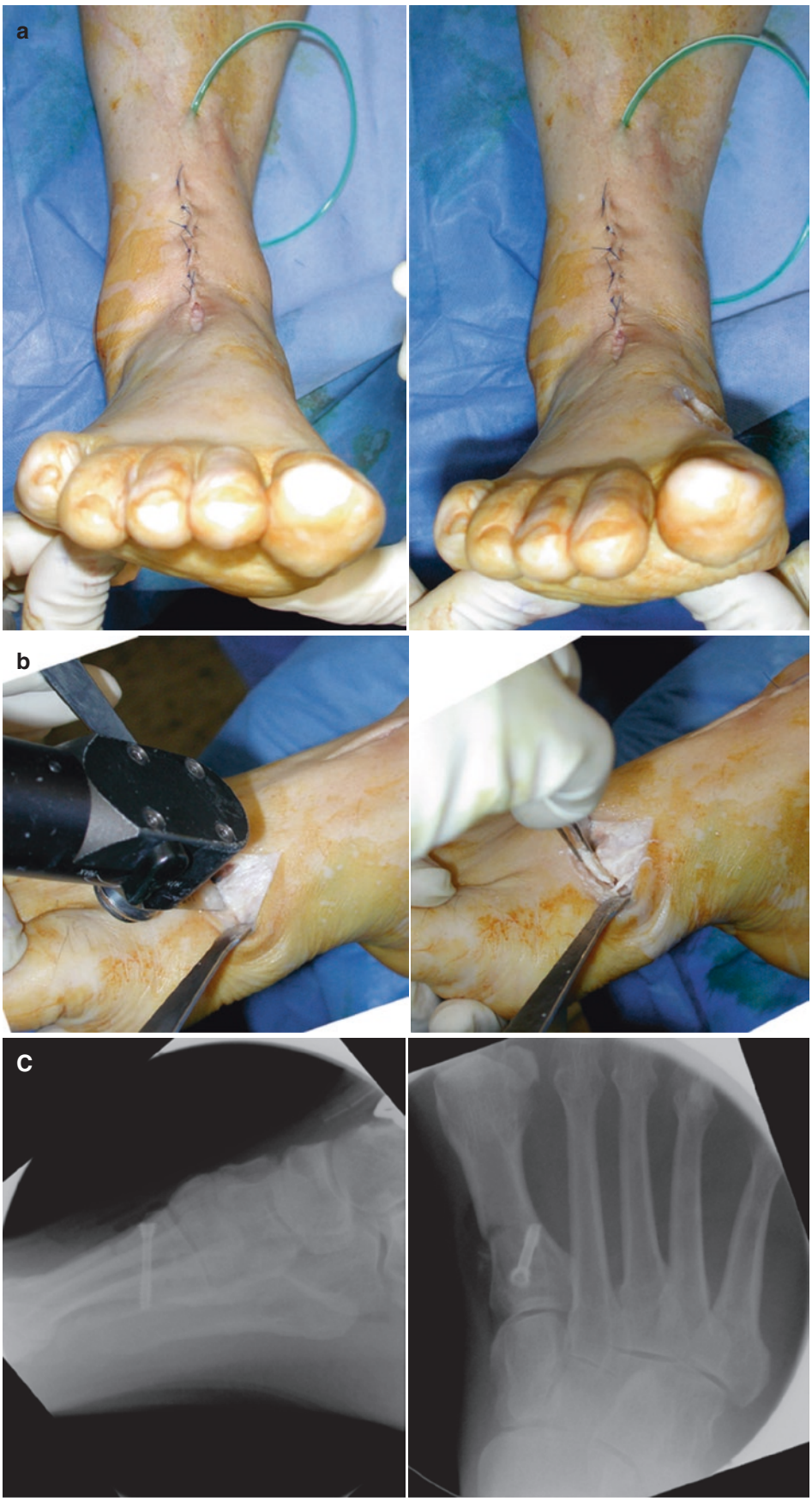


Fig. 29.9 After having finished the reconstruction of the ankle joint complex, the forefoot is meticulously assessed with regard to the remaining deformity. (**a**) While the foot is held in neutral position, the lateral forefoot is supported with one hand and the first metatarsal head with the other hand, showing a plantarflexed first ray in this patient (same patient as Fig. 28.8): before (left) and after (right) correcting osteotomy. (**b**) In this case, the base of first metatarsal is exposed, and an incomplete double osteotomy is done (left) to remove a bony wedge (right). (**c**) Control under fluoroscopy after the osteotomy was fixed by one screw

a flexor digitorum longus to tibialis posterior tendon transfer is considered.

Algorithm and Surgical Technique

Fluoroscopic assessment can be performed in the office and should then be repeated under anesthesia prior to surgery. With passive manipulation and valgus or valgus stress, the extent of correction of talar position and the amount of lateral and medial instability can be assessed.

Varus Deformity

If the varus deformity has its origin above the ankle joint, e.g., in the case of a malunited tibial fracture or a tibia vara, a supramalleolar osteotomy is done first. Usually the osteotomy can be done through the same anterior approach that later on is used for the TAR (Fig. 29.10a). While an opening wedge osteotomy is considered for minor corrections (Fig. 29.10b), a dome osteotomy is considered for a correction of more than 8°, as graft incorporation and bone healing would take too long for such an extended

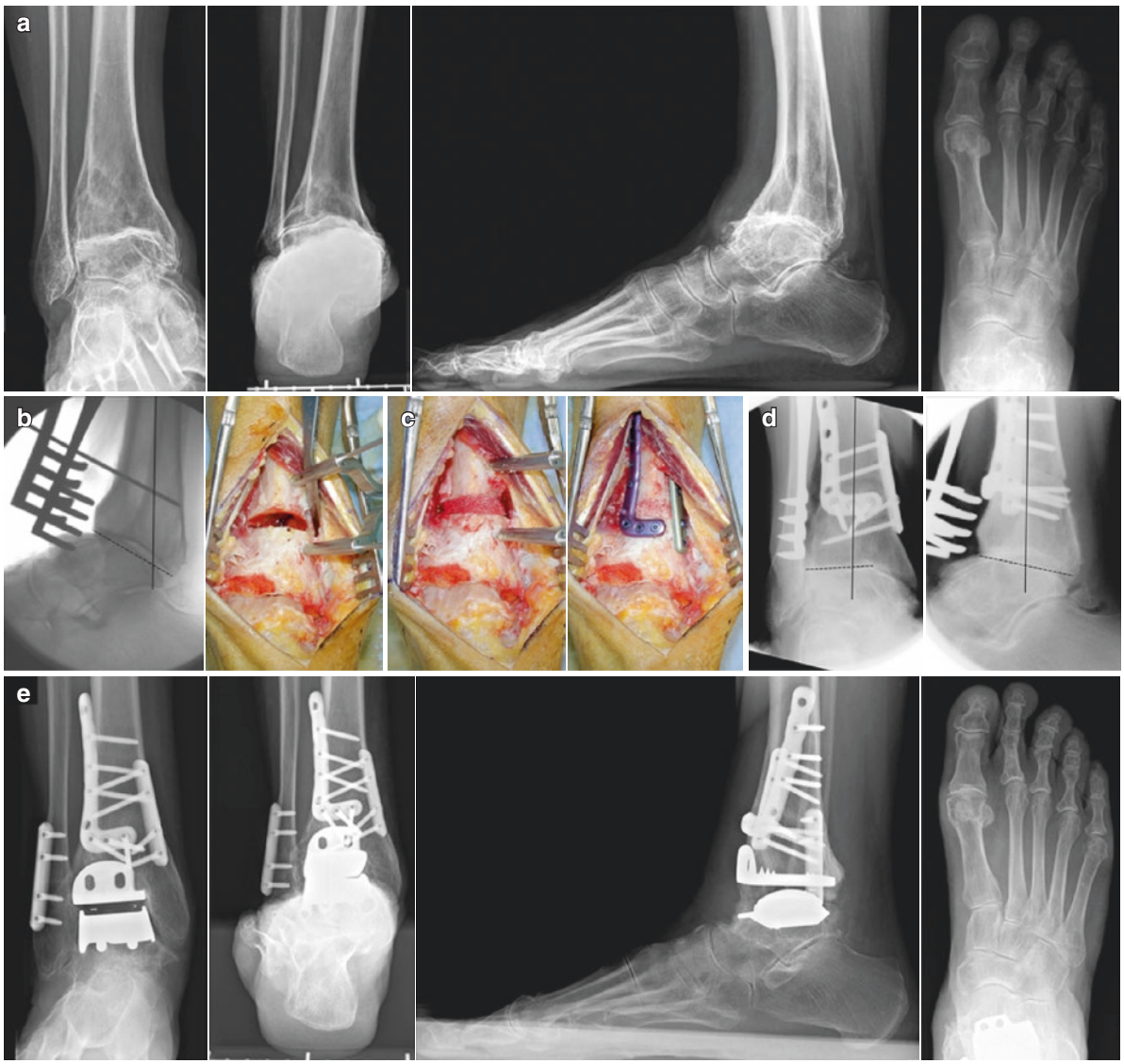


Fig. 29.10 A 60-year-old female patient with end-stage ankle osteoarthritis subsequent to a pilon tibial fracture 26 years earlier. (**a**) AP view, Saltzman view, and lateral view of the ankle as well as a foot AP. Radiographic assessment reveals a triplane deformity, e.g., a varus deformity combined with a recurvatum deformity. The ankle joint is approached to the standard anterior approach. (**b**) A K-wire, as seen under fluoroscopy on the left, is used as a marker for the planned osteotomy and then used to guide the saw blade. The osteotomy is opened step by step with a Hintermann distractor (Integra LS, Plainsboro, NY), as seen in the right image, from the anteromedial aspect to get a correction of the distal tibia in both the coronal and the sagittal planes. Attention is paid to preserve the posterior cortex. (**c**) A wedged allograft (Tutoplast) is inserted (left) and two plates are used for fixation (right). (**d**) Fluoroscopic control shows an appropriate correction of the TAS angle and the posterior tilt of the distal tibia in the coronal (left) and sagittal (right) plane. (**e**) AP view, Saltzman view, and lateral view of the ankle as well as a foot AP. Radiographic assessment at 10 years showing a well-balanced ankle in both the coronal and sagittal planes

correction (Fig. 29.4). In the case of a concomitant recurvatum deformity, the osteotomy is opened at its anterior aspect as well to realign the distal tibia in the sagittal plane (Fig. 29.10c). Plate fixation should be done such as not to interfere with the subsequent total ankle replacement (Fig. 29.10c, e). After the supramalleolar correction, the anatomical axis of the tibia should cross the tibiotalar joint in its center in both the coronal and sagittal planes (Fig. 29.10d).

After supramalleolar correction, if necessary, TAR is done using the standard technique, with taking the tuberosity of tibia as the reference for alignment of the jig in the coronal and the anterior tibial border as the reference in the sagittal plane (Fig. 29.10d). If, after insertion of all components, the talus is tilted in varus and can easily be reduced by applying an eversion torque to the hindfoot, a reconstruction of lateral ligaments is done. If the talus cannot be reduced, it may be due to a too tight medial ankle or a too long fibula (Fig. 29.5). While an extended deltoid ligament release has been advocated by others [10, 15, 16, 29–34], the authors prefer a flip osteotomy of the medial malleolus (Fig. 29.7). The advantage of this technique is that the offset position of the medial malleolus is corrected toward normal that allows the medial malleolus to guide the talus in its corrected position. Besides normalizing the external contours of the medial ankle, which may be beneficial when selecting shoe wear, it definitely normalizes the pull of the deltoid ligament. This is not the case for Doets' lengthening osteotomy of the medial malleolus [12]. In addition, this vertical translational osteotomy yields a weakening of medial shoulder of the ankle with the risk of a subsequent stress fracture. If the fibula is too long, thus not allowing the talus to get in appropriate position, a shortening osteotomy through a separate lateral approach is done (Fig. 29.5).

As a next step, the heel position is carefully checked with regard to the lower leg axis. If there is a persistent varus deformity of the heel that can easily be corrected manually by applying eversion torque, a peroneus longus to peroneus brevis transfer is done [35]. If the heel cannot be sufficiently corrected, a calcaneal osteotomy is considered. While a lateral sliding osteotomy brings with its limitations, the authors prefer a modified technique of the Italian Z osteotomy [26] that allows a valgization tilt and a lateral translation of the tuber calcanei (Fig. 29.8) [27].

Finally, the alignment of the forefoot is checked by holding the foot in neutral position. In the case of a plantarflexed first ray, the first cuneiform or base of the first metatarsal is exposed through a dorsal approach. A closing wedge osteotomy is done to achieve appropriate correction of the forefoot (Fig. 29.9).

Valgus Deformity

If the valgus deformity has its origin above the ankle joint, e.g., in the case of a malunited tibial fracture, a supramalleolar osteotomy is done first [23]. The closing wedge osteotomy can be best done through a separate medial approach; however, it can also be done through the same anterior approach as the following TAR.

TAR is then done using the standard technique, taking the tuberosity of the tibia as the reference for alignment of the jig in the coronal and the anterior tibial border as the reference in the sagittal plane. Attention is paid to resect only a minimal amount of bone on the tibial side in order to tighten the usually lax ligaments while inserting the components. Alternatively, also a thicker polyethylene insert can be used. The aim is to get a medialized, fully stable ankle [36].

If the talus tends to translate lateralward, the underlying cause can be a malunited fibula with shortening or lateral deviation. In both cases, a correcting osteotomy of the fibula is performed afterward, and the stability of the syndesmosis must be carefully checked by manually testing and if necessary combined with fluoroscopy. A knotless suture system can be used for percutaneous stabilization in the case of a subtle instability. A tibiofibular (syndesmotic) arthrodesis is advised when there is a major instability.

The heel position is carefully checked with regard to the lower leg axis. If there is a persistent valgus deformity, a medial sliding osteotomy of the calcaneus is done through a lateral incision (Fig. 29.11a–c) [25]. It allows medial displacement of up to two thirds of the calcaneal width [36].

The alignment of the forefoot is now checked by holding the foot in neutral position. In the case of a persisting forefoot supination, various options are available for getting a stable medial arch. In a subtle supination deformity of the forefoot, a plantarflexing osteotomy at the first cuneiform is considered [37, 38]. After exposure through a dorsal approach, an incomplete osteotomy is done at its center that is then opened step by step until appropriate position of the first ray is achieved. In the case of an extended deformity with major instability of the medial arch, an arthrodesis is advised. It can be done in the form of a double arthrodesis [39] or a naviculocuneiform arthrodesis [40].

Complex Triplane Deformities of the Tibia

A malunited tibial fracture can result in a complex triplane deformity that needs a correcting osteotomy through the original fracture to get an appropriate correction. Often, a correction of the malrotation needs to be included (Fig. 29.12a–c).



Fig. 29.11 A 62-year-old female patient with posttraumatic ankle osteoarthritis subsequent to an external-pronation fracture 3.5 years earlier and a progressive valgus deformity. (**a**) AP view, Saltzman view, and lateral view of the ankle. Preoperative radiographic assessment reveals a severe valgus deformity where the tilted talus has started to get impacted into the lateral tibial plafond and has started to stretch out the deltoid ligament. The overloaded syndesmosis is widened. (**b**) After replacement of the ankle, the heel persists in valgus (left); after a medial sliding osteotomy of the calcaneus, the heel is moved into a neutral position (right). (**c**) AP view, Saltzman view, and lateral view of the ankle. Radiographic assessment at 5 years shows a well-aligned and well-balanced ankle

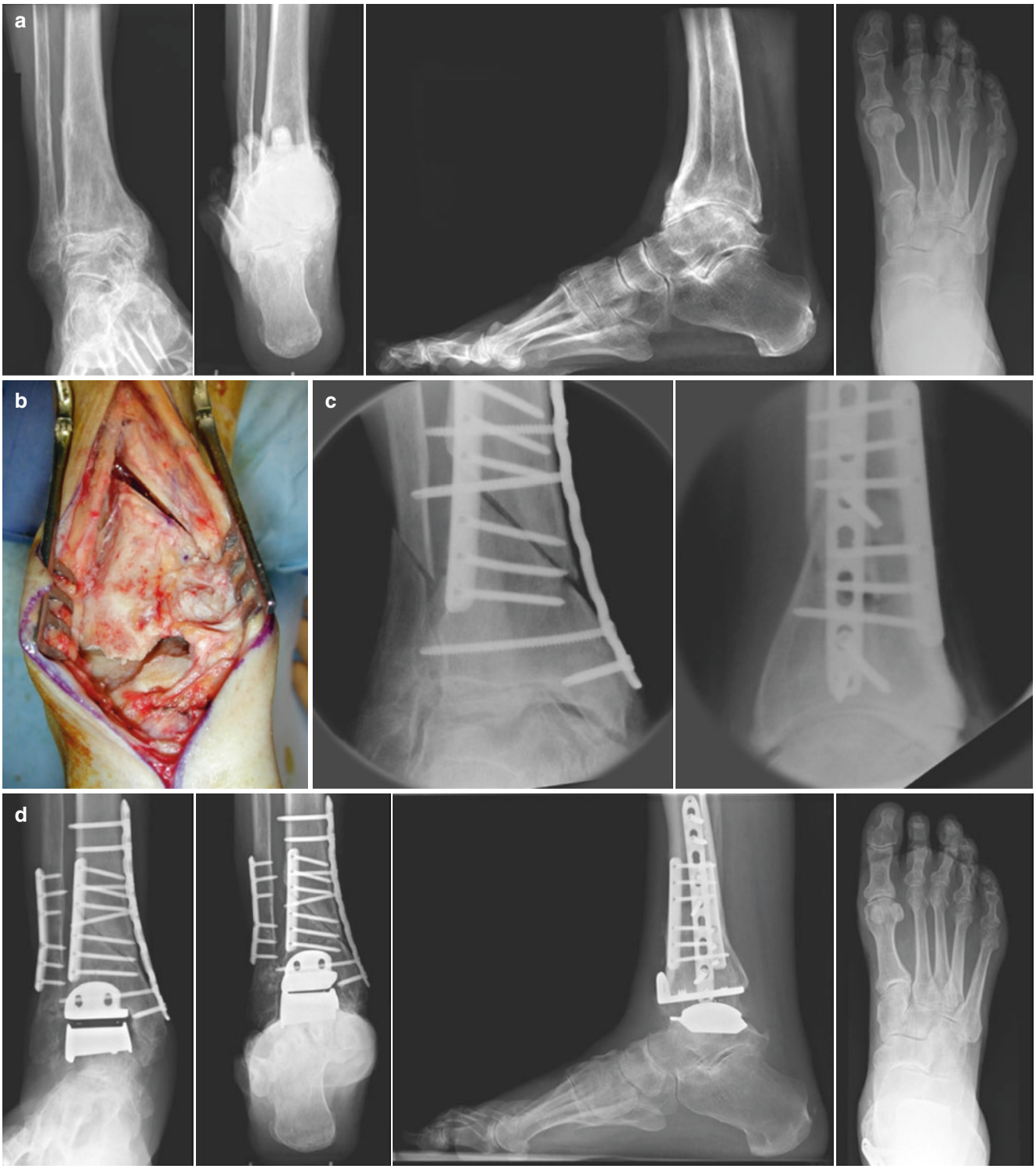


Fig. 29.12 A 68-year-old male patient with posttraumatic ankle osteoarthritis subsequent to an oblique fracture 37 years earlier that was treated conservatively. (**a**) AP view, Saltzman view, and lateral view of the ankle as well as a foot AP. Preoperative radiographic assessment reveals a combined varus and internal malrotation deformity of the distal tibia. (**b**) After exposure of the ankle to a standard anterior approach, an osteotomy through the old fracture is done with removal of a wedge. (**c**) After having added an osteotomy of the fibula through a separate lateral approach, the distal tibia can be externally rotated and fixed by two plates. The tibia is now well aligned in the coronal (left) and sagittal (right) plane. (**d**) AP view, Saltzman view, and lateral view of the ankle as well as a foot AP. Radiographic assessment at 4 months shows a well-aligned and balanced ankle; the osteotomies are healed

Deformity of the Proximal Tibia

If the deformity is located at the proximal tibia, a high tibial osteotomy should be considered with or without a correcting osteotomy of the distal tibia.

Zick-Zack Deformity

A varus deformity of the distal tibia is often compensated with a subsequent valgus movement at the subtalar joint, typically resulting in an overall neutral hindfoot alignment (Fig. 29.13a, b). A supramalleolar correcting osteotomy thus may result in a valgus deformity at the heel which needs a medial sliding osteotomy, to get an overall neutral alignment of the hindfoot and a balanced ankle, respectively.

Postoperative Management

Patients are placed in a below-knee splint for 2 weeks followed by a removable walker with instructions to remain partial weight-bearing. In the case of additional interventions such as fusions or soft tissue reconstruction, a lower leg plaster may be used. Once bone healing is achieved, usually after

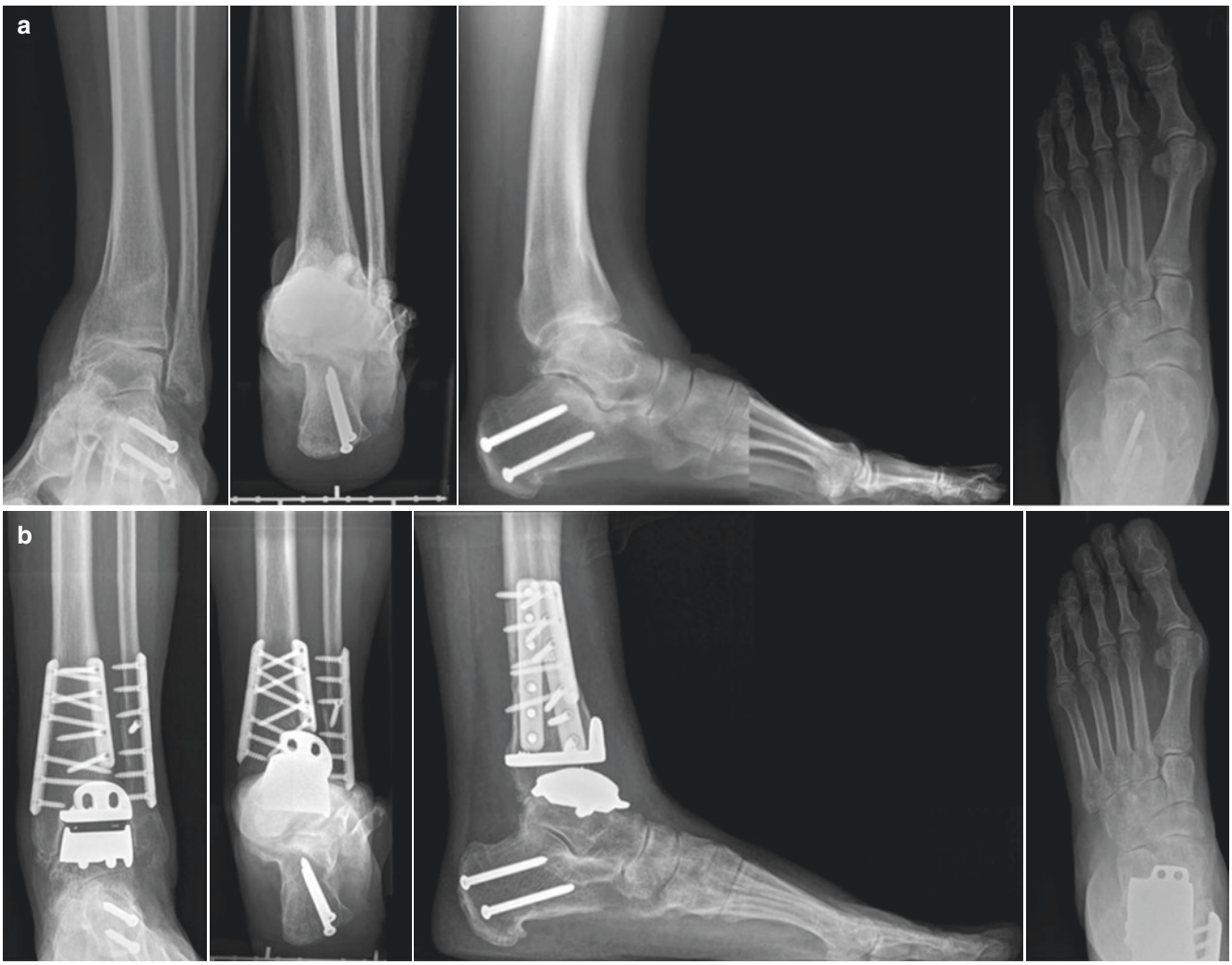


Fig. 29.13 A 64-year-old female patient with posttraumatic ankle osteoarthritis, subsequent to an oblique fracture of the distal tibia, 28 years earlier that was treated conservatively. She was treated elsewhere with a lateralizing osteotomy of the calcaneus that resulted in increased pain at the medial ankle. (**a**) AP view, Saltzman view, and lateral view of the ankle as well as a foot AP. Preoperative radiographic assessment reveals a varus ankle with an advanced osteoarthritis of the medial ankle, with an obliteration of the medial gutter and an associated valgus position of the subtalar joint, resulting in an overall neutral hindfoot alignment. (**b**) AP view, Saltzman view, and lateral view of the ankle as well as a foot AP. The patient was pain-free 3 years after supramalleolar correcting osteotomy and total ankle replacement. The radiographic assessment shows a well-aligned and well-balanced ankle

8 weeks, full weight-bearing is permitted, and a specific rehabilitation program is started.

Complications

Intraoperative complications include nerve injuries. An important consideration, especially with acute corrections, is the posterior tibial nerve. Varus-to-valgus corrections stretch this nerve. Acute tarsal tunnel syndrome can originate from acute varus-to-valgus corrections. A prophylactic tarsal tunnel release may be indicated for such acute corrections, especially in cases with previous scarring.

Perioperative wound-healing problems may result from inappropriate treatment of soft tissue during the surgery, the use of too bulky implants, and previous soft tissue damages.

Over- or undercorrection may occur following inappropriate preoperative planning or if fluoroscopy is not used for meticulous control of aimed cuts. While the resection cut may correct the created TAS angle, it cannot correct an inappropriate angular correction with regard to the tibial axis.

Delayed or nonunion may result from inappropriate fixation techniques or too aggressive loading of the leg in the early postoperative phase. Loss of correction may occur as a result of implant failure or inappropriately addressing concomitant problems such as ligamentous incompetence, muscular dysfunction, and forefoot deformities.

Summary and Conclusion

Careful radiographic assessment of the talar position in all three planes is mandatory to successfully replace an end-stage osteoarthritic ankle associated with a major deformity. The weight-bearing CT scan, in particular, helps assess segmental instability and articular changes. As correcting resection cuts for the prosthesis may not be able to restore proper position of the talus within the ankle mortise and provide overall stability of the ankle, additional osteotomies above or below the ankle or selective fusions may be necessary to obtain a well-balanced ankle joint complex. Meticulous reorientation of forefoot and, if necessary, stabilization of the medial arch are also mandatory for the long-term success of TAR. Overall, the key to success is to use all treatment modalities necessary to restore appropriate alignment of the hindfoot complex.

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Part IV

Revision Total Ankle Replacement

30

Revision of Aseptic Osteolysis With and Without Component Subsidence After Total Ankle Replacement

Norman Espinosa and Stephan Hermann Wirth

Introduction

Within the last three decades, total ankle replacement (TAR) has regained an increasing interest among foot and ankle surgeons. Due to major improvement in terms of design and biomechanical behavior [1], longevity of the implants has become improved providing a true alternative to ankle arthrodesis. Although the survival rate of current TAR designs is higher than those of the first and second generations, they still do not compare with contemporary hip and knee arthroplasties [2]. Due to improved education, the experience among foot and ankle surgeons has increased, and the availability of modern TAR prostheses has led to a raising number of TAR implantations worldwide. However, this enthusiasm must be tempered to avoid the tendency of performing TAR based on stretched indications (e.g., younger-aged patients or severe deformities). As a result the risk of premature failure is potentially increased.

However, even in case of TAR failure, modern designs have renewed interest in revision TAR as an alternative to conversion ankle arthrodesis or below-knee amputation.

In general, there are two viable options to manage aseptic loosening of a TAR: (1) conversion of TAR into ankle arthrodesis and (2) exchange of TAR components.

Salvage ankle arthrodesis is frequently used to strengthen the case of TAR against primary ankle arthrodesis [2–4]. However, salvage ankle arthrodesis after failed TAR is not easy and requires significant experience and technical skills. Recent scientific data showed that the results of salvage arthrodesis are inferior to those of primary ankle arthrodesis [3].

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Exchange of TAR components requires a prosthesis design that offers the possibility to do so. But only a few surgeons have enough experience with true revision TAR, and unfortunately little meaningful data exists to guide treatment. There is only sparse information available in the literature regarding the treatment of failed TAR with no clear indication of how to proceed in those difficult cases. Lachman et al. were able to show that clinical and patient-reported results of revision ankle arthroplasty after metal component failure improved significantly but never reached the improvements seen after primary ankle arthroplasty [5].

The current chapter reviews aseptic loosening of TAR and its management in the absence and/or presence of metallic component subsidence.

Total Ankle Replacement Failure

The normal ankle is a fascinating joint with an incredible capability to withstand high forces during gait [6]. While in a degenerated ankle joint the force transmitted through the ankle is reduced from five times down to three times body weight, in TAR the strength of bone should be at least three times greater than under normal conditions [7, 8]. Therefore, secure fixation of the metallic TAR components into the bone is needed to ensure proper stability during high-performance activities and to prevent subsidence [9]. While the tibial and talar components are metallic, the insert between them is made up of polyethylene. Current designs use ultrahigh-molecular-weight polyethylene (UHMWPE) [10, 11]. In order to prevent premature wear of the UHMWPE insert, it should have an optimal thickness and resistance to compressive and shearing forces [12]. Premature wear has been recognized as a potential factor for TAR failure and depends on strength (ultrastructure), geometry, and alignment of TAR components [10, 12]. Currently, the optimal thickness of UHMWPE insert is unknown. The best UHMWPE insert should be thin, strong, and positioned at

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the original joint line level. A "perfect" TAR replicates the ankle joint anatomically and biomechanically. Therefore, conformity should be maximized and constraints optimized. A high conformity distributes the forces over a larger contact area and reduces peak pressures and UHMWPE wear. Optimal constraint provides proper stability without increased shearing stresses at the bone-implant interfaces [13–16].

Contemporary TAR designs offer better anatomical and biomechanical behavior and imply biological integration of the metallic components into the bone [17, 18]. Usually, the surfaces are covered with calcium-hydroxyapatite variably combined with the porous metallic coating of the talar and tibial component.

Due to the anatomical design of current TAR and their cementless fixation, less bone resections are needed, smaller-sized metallic implant components can be used, third body wear is reduced, and heat destruction is omitted [19].

In aseptic loosening following TAR, the components become exposed to increased motion in the frontal, transverse, and sagittal planes. That abnormal kinematics results in stress transmissions across the supporting bone with peak stresses in different areas. According to Wolff's law, osseous remodeling processes take place, which may strengthen or weaken the osseous ultrastructure.

In case of aseptic loosening of the tibial component, the ring-shaped cortex at the metaphysis of the tibia becomes sclerotic, and, in the center, a reduction of cancellous bone mass or formation of cysts takes place. In contrary, loosening of the talar component leads to anterior–posterior and proximal–distal swinging of the implant with increased sclerosis in the anterior and posterior parts of the talus resulting in cyst formation at those locations [9, 20–22].

Total Ankle Replacement Revision

Failure of TAR encompasses several factors including improper patient selection, prosthesis specific characteristics, surgical technique, and surgeon errors [23]. Among all patient factors that could potentially influence outcome in a negative manner, severe obesity should be taken into consideration. Other factors such as medical comorbidities, medications, psychological disorders, lifestyle, and habits (i.e., smoking, occupation, and recreation) are also of importance. All those factors may result in aseptic loosening, which may occur secondary to poor osseous integration, inaccurate sizing, malalignment, and UHMWPE insert wear. Once the indication for TAR revision surgery has been made, there are several problems that need to be addressed. First, loss of bone stock occurs as a result of osseous resection for prosthetic implantation or secondary to periprosthetic osteolysis [24]. Second, the soft-tissue about the ankle is vulnerable. Due to multiple previous surgeries at the ankle joint, especially in rheumatoid patients, salvage surgery becomes more difficult for TAR revision that replacement in other in other major joints. Third, variable degrees of fixed hindfoot deformities and soft tissue contractures, which may be present due to concomitant subtalar osteoarthritis and tibial or talar component subsidence, can complicate revision surgery. Fourth, the presence of poor bone quality impairs fixation, and therefore specific fixation strategies must be selected. Fifth, any imbalance at the ankle must be identified and addressed to prevent malalignment and/or instability of the TAR, which have detrimental effects on TAR survivorship if not corrected. This process includes assessment of possible incompetence of the lateral or medial ligaments. Osteotomies or arthrodesis are occasionally required to balance and stabilize the hindfoot to restore and maintain neutral alignment [25, 26].

Preoperative Analysis

Like for all foot and ankle pathologies, the patient should be inspected barefoot during walking and in a standing position, followed by evaluation of leg and hindfoot alignment. Sagittal alignment assessment is essential. Equinus contracture involving either the gastrocnemius or the Achilles tendon should be assessed as it may play an important role in correcting the hindfoot. The examiner should be familiar with Barouk's and Silferskjoeld's technique of assessment. Equinus contracture must be addressed during the index surgery in order to improve gait mechanics. Coronal plane malalignment at the hindfoot, midfoot, and/or forefoot (e.g., varus or valgus malalignment and midfoot pronation or supination) needs to be assessed. In addition, any rigid joints or soft tissue contractures should be identified. Transversal alignment of the hindfoot is assessed using both malleoli to mark out the axis and comparing it with the patella. In addition, the condition of the soft tissues and neurovascular status must be evaluated.

Usually, a complete radiographic assessment is obtained before surgery. This consists of standardized weight-bearing anterior–posterior and lateral radiographs of the ankle and anterior–posterior and lateral views of the foot. The hindfoot alignment view or, preferably, a long-leg axial view is used to assess any valgus or varus deformity and to evaluate prosthetic migration and bone loss [27–29].

The anterior–posterior and lateral views of the ankle allow proper assessment of the tibial component in the frontal and sagittal plane. However, for some TAR systems, the bone stock underneath the talar component cannot be accurately determined with plain radiographs. In those cases, computed tomography (CT) is helpful to determine the extent of bony destruction and to anticipate possible need for

bone grafts or custom-made TAR components (when there is insufficient remaining talus). Sometimes, the use of single-photon emission CT and fluorodeoxyglucose positron emission CT might be helpful to identify pathologic processes around the TAR components [30–32].

Surgical Management

Selection of treatment depends on whether the loose TAR can be salvaged or not. If this is the case, the first author utilizes a TAR system that offers readily available revision components such as the Hintermann H2/H3 and revision total ankle prosthesis (DT MedTech, Baltimore, USA).

This is based on the work of Hintermann and colleagues who published an algorithm, which refers on the size of osseous defect at either the tibial or talar side (Fig. 30.1) [25]. The standard tibial component of the Hintegra has a thickness of 4 mm. There are revision tibial components available with 8 mm and 12 mm thickness, but they are not frequently used because most revision cases can be addressed with implantation of a standard 4-mm thick tibial component. The talar revision component has a flat undersurface and long pegs to provide strong fixation within the talar bone. The shape of the talar component is conical with different medial and lateral radii and therefore is as anatomic as possible [9].

Technique of TAR Exchange

If the prosthetic implant can be retained, the TAR components are carefully removed while avoiding further damage to the adjacent osseous, ligamentous, and/or neurovascular structures. Surgeons should take into consideration that there is scar tissue that might impair proper osseous preparation while increasing the risks of neurovascular injury. In addition, the use of sharp hooks or instruments to spread the vulnerable skin should be avoided. The superficial peroneal nerve should be protected and preserved during preparation because it crosses the operating field distally over the dorsum of the foot. The extensor retinaculum between the tendons of the anterior tibial and extensor hallucis longus muscle is incised. The authors usually try to identify the tibialis anterior tendon and to continue further preparation of the capsule underneath of it while retracting the neurovascular structures together with the extensor hallucis longus tendon

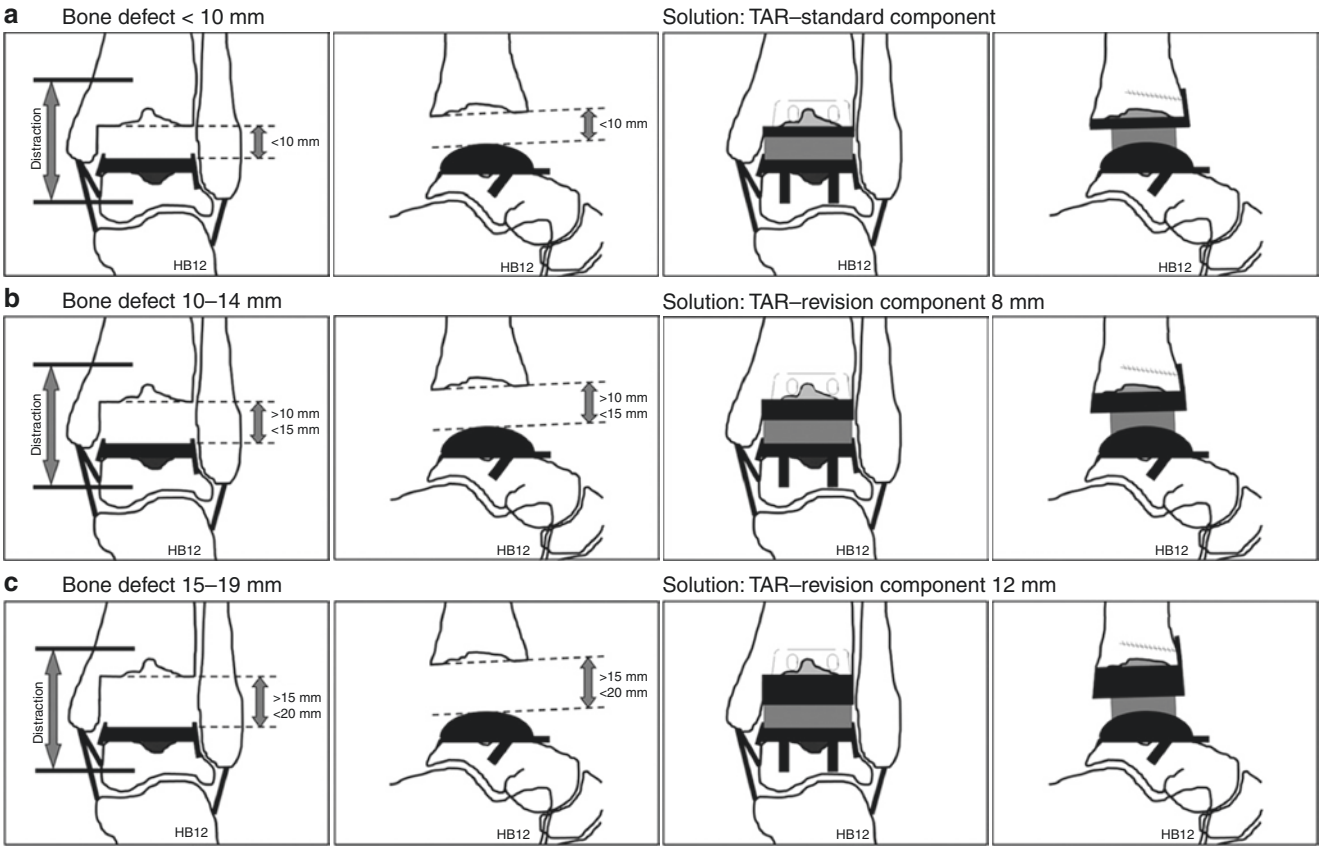


Fig. 30.1 (**a**–**c**) Classification of tibial bone defects according to Hintermann et al. [25]. (Reprinted from Hintermann et al. [25]. With permission from Wolters Kluwer Health, Inc.)

laterally. The preparation is continued until the underlying tibia, talus, and implant surfaces are exposed. At this point, the soft tissues can be retracted using blunt hooks that are placed onto the tibia medially and between tibia and fibula laterally.

Certain TAR designs use tibial stems, and in those cases, it is necessary to create an anterior cortical window to explant the tibial component. The author wants to point out that the osseous window must be limited to the absolute minimum required because any resection of the anterior distal tibia cortex weakens the bone and potentially impairs fixation of the revision TAR components. After removal of the TAR components a thorough inspection of the tibial and talar remnants is performed.

Aseptic Loosening of the Tibial Component

One of the biggest concerns when dealing with revision surgery on failed TAR is the amount of bone stock that is left after removal of the tibial component [23]. Septic loosening will not be discussed in this chapter as it is covered in a separate chapter within this textbook. Reasons for bone stock loss include:

- Over-resection during primary intervention
- Loosening and subsidence of the tibial component
- Osteolysis
- Cyst formation
- Bone loss during explantation of primary TAR
- Infection

The prerequisite for exchange of the failed TAR is a viable, good bleeding bone surface that allows reintegration of the new prosthetic metallic components. Based on the amount of tibial bone loss, there are various types of approaches that can be used (see Fig. 30.1) [2, 19, 33]. In general, the authors try to achieve a flat and perfectly aligned surface in order to reimplant the new revision TAR. Ideally, the new tibial component should be placed onto the cortical ring of the distal tibia. For this purpose it is important to maintain the anterior and posterior cortex as best as possible rather than relying on the medial and lateral parts of the distal tibia. Before removing the failed TAR, it is necessary to anticipate any weakening of the medial malleolus. If there is a potential risk that the medial malleolus could fracture, two 3.5-mm solid screws are inserted to enhance stability (Fig. 30.2) [34].

In case of small bone losses at the tibial site (between 10 and 15 mm), a standard tibial component can be used. The larger the gap at the joint line, the thicker the UHMWPE insert must be chosen. In case of excessive loss (≥15 mm), a revision thicker tibial implant must be used to correct the joint line correctly [25].

Absence of Tibial Component Subsidence

After removal of the implant, the medial and lateral gutters of the ankle are debrided. The posterior capsule is resected while avoiding the neurovascular structures at the posterior–medial aspect of the ankle. By means of the alignment jig for the specific revision TAR, the tibial cut is made from anterior to posterior. The new cut should restore both the lateral distal tibial angle and the sagittal inclination of the tibial plafond. Tibial resection should be limited to an absolute minimum. The goal is to obtain a flat cut while preserving the cortical ring of the tibial metaphysis (Fig. 30.3). In the presence of cysts or major osseous defects associated with aseptic loosening of the TAR, they need to be addressed during surgery. It is important to fill the osseous defects either with autograft or allograft or a combination of both. This is necessary to provide a good stock for future ingrowth and stability of the new tibial component. Once the graft has incorporated, it may provide osseous support (Fig. 30.4).

Cysts of different sizes can be filled with autograft that is harvested from the ipsilateral, proximal, or distal tibia or iliac crest [35]. Larger cysts may need addition of allograft bone. The graft needs to be impacted into the tibia. Only a well-impacted bone graft will provide enough stability for the metallic prosthetic components. Besides this, in the author's experience, a well-impacted bone graft is less susceptible for early resorption.

All cysts are debrided until the subchondral bone plate becomes visible. The use of a curette is recommended to achieve that goal. Then the cysts are filled with either allograft or autograft bone impacted into place [23]. Once the graft is impacted, the final tibial component can be inserted. It is important that the new revision component covers the entire anterior–posterior surface of the distal tibia. In the best case, it will also fit well in the medial-to-lateral plane. However, in case of a larger TAR removal, such as the Agility TAR system (DePuy/Synthes, Warsaw, IN), the medial and lateral gutters need to be augmented by inserting structural bone grafts on either side. To increase stability at the medial malleolus, a screw can be inserted to ensure proper ingrowth of the graft.

The literature provides some information for the use of contoured structural fresh-frozen allografts, cement application, or highly porous tantalum metal in order to reconstruct larger defects of the anterior distal tibial rim [36–38]. However, there is no meaningful evidence to guide the surgeon so far.



Fig. 30.2 Weight-bearing anterior–posterior (**a**) and lateral (**b**) radiographs of an ankle in a 79-year-old female patient who received an Agility total ankle replacement 6 years prior due to symptomatic posttraumatic end-stage arthritis. She complained about severe pain in the hindfoot and functional deficit. The images demonstrate the thin medial malleolus and the valgus deformity of the heel and subsidence of the talar component. Anterior–posterior (**c**) and lateral (**d**) radiographs of the ankle 2 years following revision total ankle replacement using the Hintegra ankle prosthesis. Because of the greater risk of malleolar fracture, a 3.5-mm screw has been inserted. In addition due to the large tibial and talar defects, a revision tibial and talar component was used. Due to the large talar cysts and bone loss, the talus has been augmented using an iliac crest graft impacted into the defect. The large screws in the revision talus component help secure the graft onto the remnants of the talus

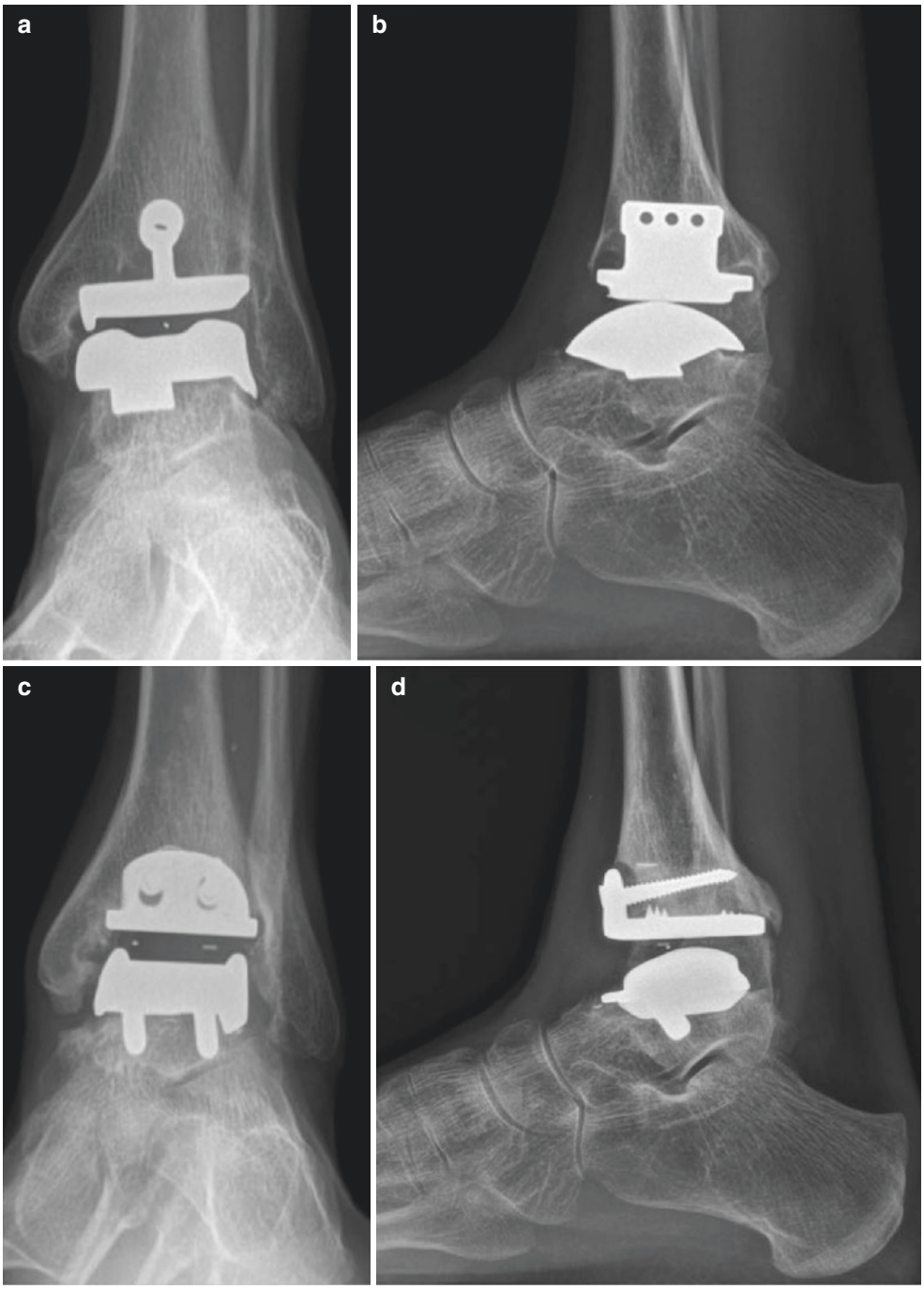


Fig. 30.3 Weight-bearing anterior–posterior (**a**) and lateral (**b**) ankle radiographs in a patient who underwent a Salto mobile ankle prosthesis (Tornier, Inc., Amsterdam, the Netherlands) 3 years prior. The patient suffered from aseptic loosening associated with a severe hindfoot valgus deformity. In addition, the talus was not well centered under the tibia. Note the tibial cysts in the anterior half of the distal tibia. Postoperative weight-bearing anterior–posterior (**c**) and lateral (**d**) radiographs following revision total ankle replacement using the Hintegra ankle prosthesis. The tibial cut was adjusted according to the tibial long axis and a standard tibial component used for exchange. The talar component was revised using a flat revision talar component

Tibial Component Subsidence

The goal is to achieve a stable, osseous support for the new revision TAR. If there is any component subsidence, the surgeon should estimate the depth and potential malalignment of the prosthesis component(s) that need to be corrected. Malalignment can be corrected or improved using the TAR-specific cutting jigs (Fig. 30.4). Current TAR designs provide excellent instruments to achieve that goal. Valuable landmarks to estimate any feasibility of revision tibial component exchange are the medial and lateral malleoli. When anticipating a higher tibial resection that leaves only a small osseous bridge between the medial corner of the tibia and the medial malleolus, it could potentially result in an intraoperative fracture and instability of the revision TAR. In those cases even revision TAR might

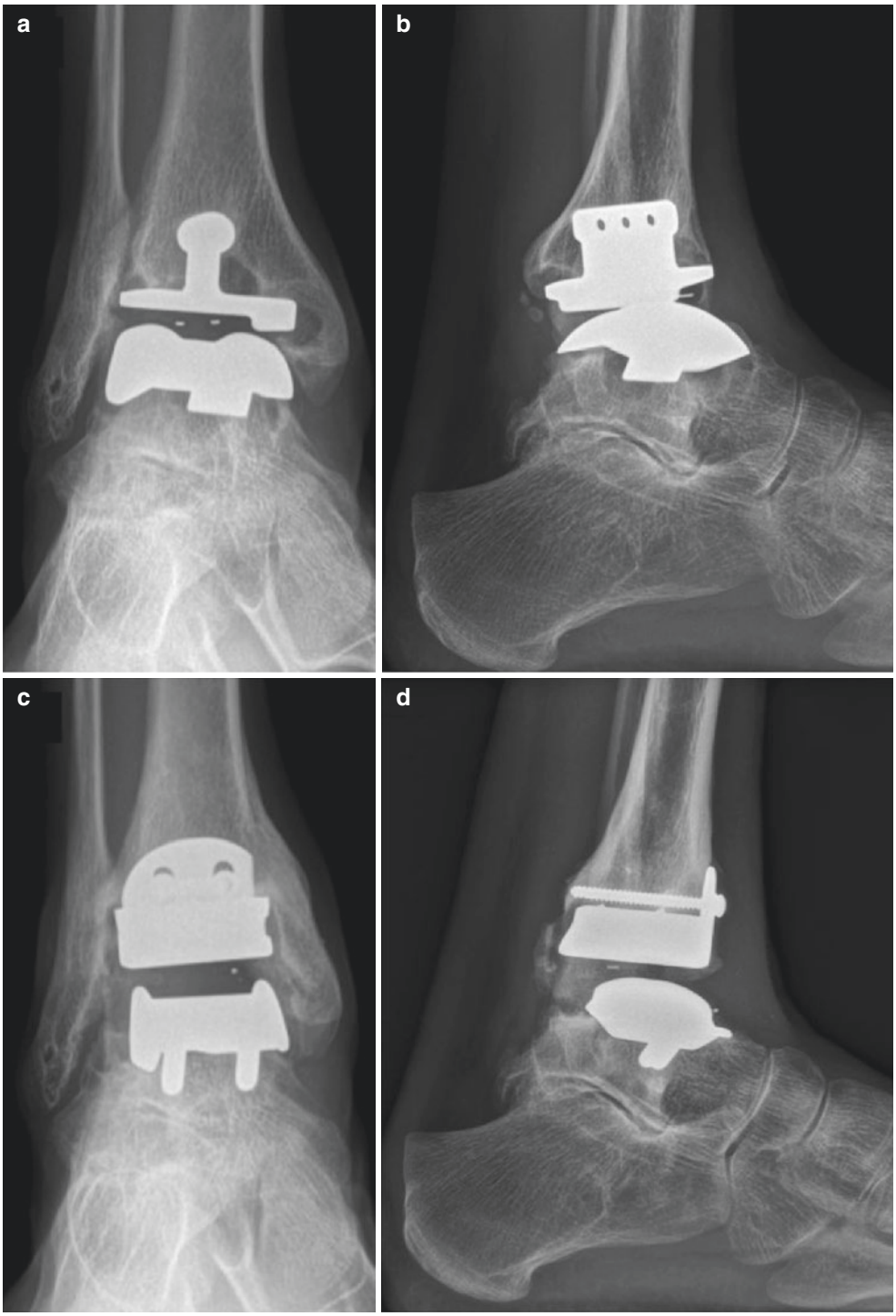


Fig. 30.4 Weight-bearing anterior–posterior (**a**) and lateral (**b**) radiographs demonstrating advanced aseptic loosening of a Salto mobile ankle prosthesis. Note the extensive cysts, which are found around the talar and tibial components. In addition, the tibial component is tilted in dorsiflexion. Weight-bearing anterior–posterior (**c**) and lateral (**d**) radiographs demonstrating revision Hintegra tibial and talar components, as well as cyst debridement and impaction bone grafting using autologous bone graft from the iliac crest. Two years postoperatively, the patient presents pain-free with acceptable range of motion and function

not be suitable, and thus salvage arthrodesis should be considered [2–4]. If tibial resection reaches the level of the syndesmosis with subsequent instability, a surgeon should consider distal tibiofibular syndesmosis arthrodesis using two 3.5-mm cortical compression screws with or without plate support. Tibial component subsidence associated with larger cysts is managed the same way as described above.

Aseptic Loosening of the Talar Component

According to the author's experience and what is proposed in the literature, there are three options to manage talar component failure:

- Revision with a revision talar component without augmentation of the bone

- Revision with a revision talar component with bony augmentation of the talus
- Revision with a custom-made talar component with or without a long calcaneal stem

When deciding on which strategy to embark on, the size of cysts and the grade of subsidence of the talar component are important to assess. The grade of subsidence can be estimated using the technique as described by Ellington and Myerson for the Agility total ankle replacement system [33]. Grade 1 is no subsidence, grade 2 is subsidence but not at the level of the subtalar joint, and grade 3 is subsidence at or below the level of the subtalar joint. The authors concluded that grade 1 subsidence of the talar component could be treated using standard revision talar components, while grade 2 and 3 subsidence should best be treated by means of implantation of a custom-made long-stemmed prosthesis extending across the subtalar joint. They also were able to demonstrate that the outcomes following revision in grade 1 subsidence were superior to the outcomes associated with grades 2 and 3.

However, in the author's experience, even grade 2 subsidence can be treated with a standard component. The most important part of the revision surgery is to augment the talar osseous defect by filling it with either autograft or allograft bone to provide a dense bone stock for the revision component.

In case of obese patients, a standard revision component is more likely to fail, and in those cases, a subtalar fusion could be performed in conjunction with the talar component exchange. The same concept applies for all cases in which symptomatic subtalar joint arthrosis is present [23].

All cysts that are present should be filled using an impaction bone grafting technique [23, 29, 39]. Otherwise, if loosely impacted, there is a high chance that the bone will resorb over time.

Hintermann et al. [25] proposed another classification (Fig. 30.5) using the amount of bone defect present after removal of the index primary TAR. In the presence of a defect <18 mm, a standard component can be used. A defect measuring between 19 and 24 mm requires the use of a revision talar component, and a bone defect >25 mm (talar body almost nonexistent) needs a custom-made implant or conversion into arthrodesis.

Although some interchangeability between current TAR designs exists, it is not recommended to use differ-

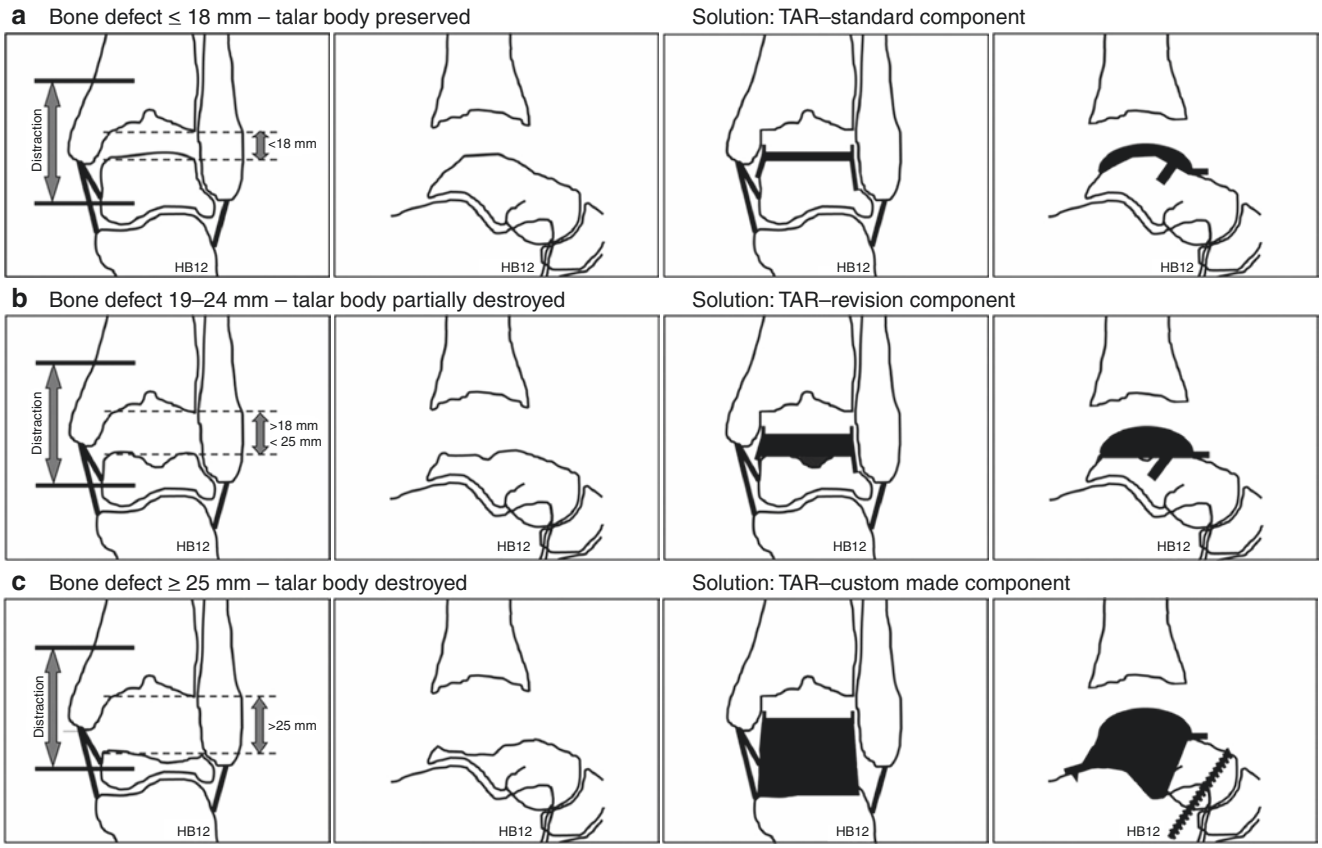


Fig. 30.5 (**a**–**c**) Classification of the talar bone defects and decision-making regarding treatment. (Reprinted from Hintermann et al. [25]. With permission from Wolters Kluwer Health, Inc.)

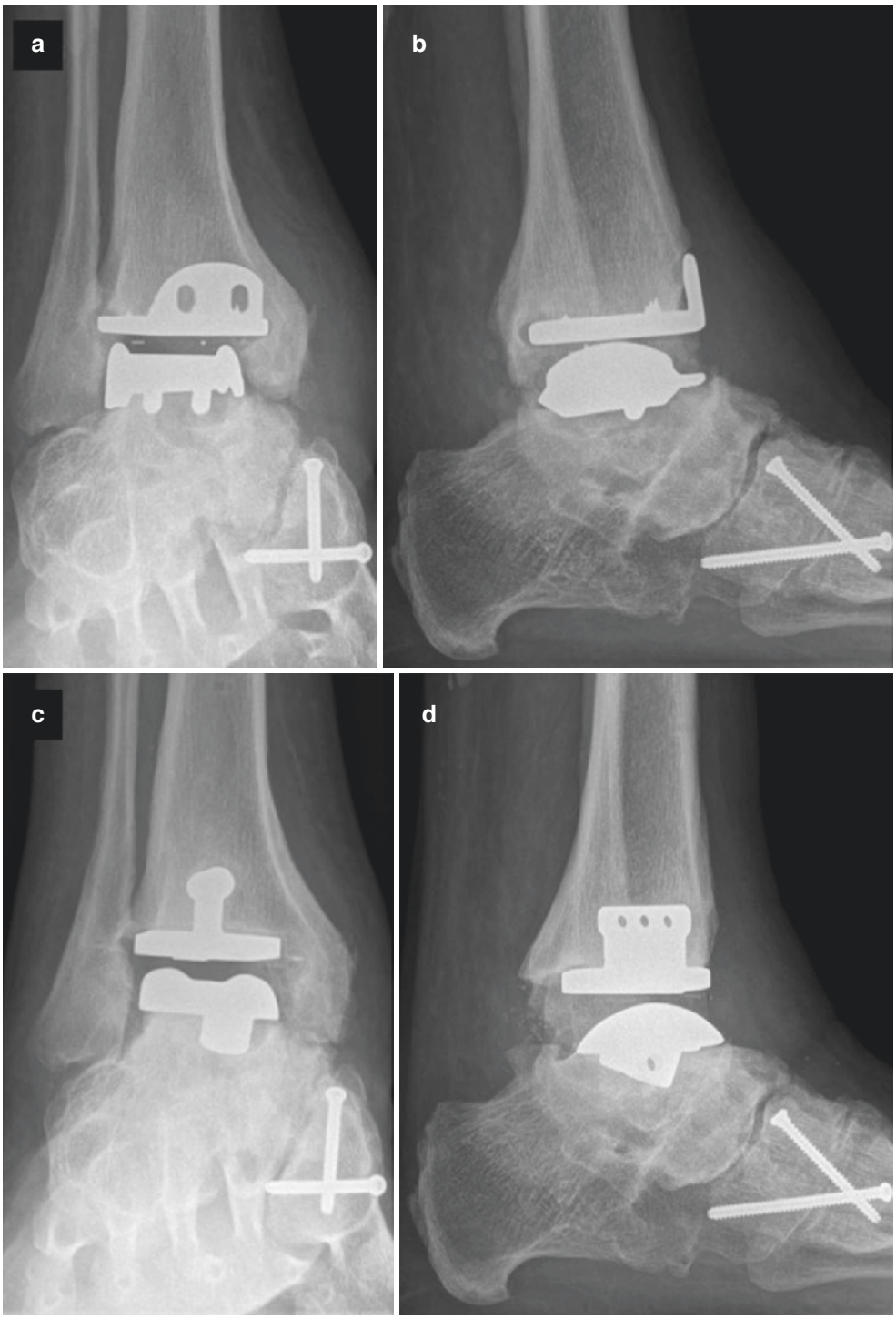


Fig. 30.6 Weight-bearing anterior–posterior (**a**) and lateral (**b**) radiographs of a failed Salto mobile total ankle replacement in a 54-year-old male patient. The patient has had a long history of residual clubfoot deformity and corrective pedal arthrodeses. The talar component subsided and caused secondary impingement due to lateral and medial abutment of the malleoli. In order to correct talar subsidence, a flat cut on the talar dome was employed using the Salto Talaris XT revision ankle prosthesis (Tornier, Inc., Bloomington, MN). Weight-bearing anterior–posterior (**c**) and lateral (**d**) radiographs demonstrate that the talar component is centered under the tibia and the medial and lateral gutters have become somewhat decompressed

ent types of implant components (e.g., retaining a STAR tibial tray and using a Hintegra talar component and polyethylene insert). Today there are some companies that provide specific revision TAR designs. In the hand of the first author, the Hintermann H2/H3 and revision total ankle prosthesis system provides an off-the-shelf revision talar component with a flat undersurface and long anterior pegs to firmly engage the remaining or augmented talar bone. The Salto Talaris XT revision ankle prosthesis has a similar concept with a flat undersurface and cylindrical stem press-fit into the talar bone (Fig. 30.6). However, the Salto Talaris ankle prosthesis system has been removed from the market. The reasons for this have not yet become clear for most foot and ankle surgeons who were using this system. In the meantime, other prostheses, as, for example, the Inbone II TAR sys-

tem™, PROPHECY™, PROPHECY™ INBONE™ (Wright Medical Technologies, Inc., Arlington, TN), also use flat undersurfaces augmented with a modular central stem and two anterior pegs. The talar cut is made flat and parallel to the tibial plane. Sometimes, if needed, a distractor mounted on the medial part of the ankle joint helps to obtain neutral alignment and will assist in balancing ligamentous tension. Infrequently, the release of the collateral ligaments is needed to achieve proper balance. This can either be achieved through a careful release of the medial collateral ligaments or – this is the favorite strategy of the first author – by an osteotomy of the medial malleolus [40]. The trial components are inserted, and the stability of the ankle joint is checked. Once a stable condition is achieved, the final components are inserted. Sometimes it is necessary to fill the medial- and lateral-deficient tibia or talar bone with autologous or allogenic bone graft to enhance component stability.

Additional Surgeries

Malalignment and instability should be addressed at the same time when revision TAR is performed. Any residual deformity at the hindfoot potentially has a strong negative impact on ankle mechanics and may lead to early failure of the revision TAR [6, 12]. Adjusting the tibial cuts can easily compensate a varus or valgus misalignment of up to 10°. Greater deformities should be corrected either by supramalleolar (closing or open wedge) or by calcaneal osteotomies (medial or lateral sliding or z-shaped) [26, 41–44]. It is up to surgeon's preference whether to perform the osteotomies during a single-staged or two-staged procedure. The authors would like to point out that hypothetically the former approach increases the risk for complications. Discrepancies in fibular length are addressed by distraction together with bone block insertion (if too short) or shortening (if too long). In case of lateral ligamentous instability, a repair of the anterior talo-fibular ligament, the calcaneal-fibular ligament, or both should be performed. When no viable ligament tissue is left, reconstruction of the lateral ligaments by transfer of an allogenic or autologous free hamstring tendon graft (gracilis or semitendinosus) or extra-anatomical autogenous peroneal tendon stabilization should be considered [45, 46]. In case of anterior–lateral ankle instability, a peroneus longus to brevis tendon transfer is an effective tool to address the problem [47]. Arthritic changes in the adjacent joints of the ankle that are associated with hindfoot, midfoot, and forefoot deformity may be addressed by arthrodesis in order to create a stable and well-aligned socket for revision TAR [26].

Postoperative Management

Postoperatively the patient is put in a short-leg splint with the foot in neutral position. The first author (NE) uses a specific wound coverage together with an indwelling suction drain, which is removed 24 h postoperatively (Fig. 30.7). After 48 h postoperatively, the splint is removed and a short-leg walking cast applied. Alternatively, a functional brace can be applied instead of a walking cast. The patient is allowed to ambulate under full-weight-bearing except those who have undergone additional foot surgery. Those patients should follow a partial or non-weight-bearing regimen. Two weeks postoperatively (after removal of the sutures), a structured rehabilitation program is commenced with active and passive mobilization of the ankle joint.



Fig. 30.7 Meticulous deep layer closure is done by means of resorbable sutures (Vicryl-0–2-0) followed by a subcutaneous, adaptive closure using Vicryl-4-0 sutures. After having done so, the skin is closed by means of an intra-cutaneous suture technique using a Monocryl-4-0 suture. Afterward, SteriStrips (Nexcare™ Steri-Strip™, 3M, USA) are placed over the suture, and a transparent dressing (Tegaderm™ Nexcare™ 3M, USA) is put to cover the entire wound-field. Now, the suction drain can be started. This dressing is intended to remove the blood from the surgical site and to enhance secure wound healing. While the suction drain is removed 24–48 h after the surgical intervention, the wound dressing itself (unless not soaked with blood) can be kept for 1 week

Results After Revision Total Ankle Replacement

The literature provides only limited information regarding revision TAR. Hintermann and coworkers have published the largest series in the German [25] and American [21] literature. In their first evidence-based medicine level IV study, 83 revision TAR surgeries in 79 patients were performed. Fifty-three percent of the cases revealed aseptic loosening, 41% suffered from painful dysfunction, and 6% from a septic loosening of the TAR. Five years postoperatively 83% of the patients were satisfied with the result of revision TAR, 14% judged the result as fair, and 2% as poor. Of all patients, 59% were completely pain-free at the time of follow-up with an acceptable total sagittal plane range of motion at the ankle joint of 34°. In addition to exchange of the metallic prosthetic components, 36 additional surgeries (i.e., arthrodeses, osteotomies, ligament repairs, and peroneus longus to brevis transfers) were performed in order to balance the hindfoot [21]. More recently, the same investigators published their evidence-based medicine level IV results on a consecutive series of 117 patients in which TAR failed after a mean time of 4 years. All of them were revised using the Hintegra ankle prosthesis with revision components. The talar component was revised in 89% and the tibial component in 91%. The authors identified an estimated survival rate at 9 years of 83%. It must be mentioned here that the end-point chosen was loosening of components. Loosening of a revision TAR was higher in prosthetic systems that used single-coated hydroxyapatite components. Obviously the authors did not find any relevant correlation between bone loss and the prevalence of component failure. Hintermann et al. [25] concluded that the medium-term results of revision arthroplasty after failed TAR were similar to those after primary TAR.

Williams et al. [34] performed a single-center retrospective study and focused on complications during revision surgery of a failed TAR. A total of 35 failed Agility TAR systems were revised to Inbone II TAR system. Patient demographics, indications for revision, radiographs, and complications were reviewed. Revision TAR was indicated due to mechanical loosening, osteolysis, periprosthetic fracture, and a dislocated prosthesis. The mean follow-up was 9.1 months. Interestingly, the Agility TAR systems lasted a mean of 6.7 years prior to revision. Additional interventions were performed in 31 of 35 cases. There were six intraoperative and five acute postoperative complications, leading to an overall 31.4% complication rate. There was one patient with continued pain postoperatively who underwent a second revision 20 months postoperatively. Based on the results obtained, the authors concluded that revision TAR was a viable treatment option for failed TAR but that the surgeons should be aware of the high risk of perioperative complications [34]. More recently, Lachman et al., in a level III study, were able to show that clinical and patient-reported results of revision ankle arthroplasty after metal component failure improved significantly but never reached the improvements seen after primary ankle arthroplasty. The mean follow-up after revision surgery averaged 3 years. In their series about 10% of revision TAR required a second revision TAR or conversion into arthrodesis. However, only 15 patients were enrolled into the study.

Salvage Arthrodesis

In case revision TAR is not be feasible, salvage arthrodesis remains a viable limb-salvage option [2–4, 34, 38, 48–52]. One of the main problems encountered is the amount of bone loss that requires the use of allogenic or autologous bone graft to achieve arthrodesis and/or structural integrity. Other issues are the precarious soft tissues due to previous surgeries and problems with fixation of the salvage arthrodesis. All those factors need to be taken into consideration.

Surgical Technique: Authors' Approach

There are different ways to approach a failed TAR. Sometimes the decision is made based on what kind of prosthesis system will be removed or which approach the surgeon prefers. Usually, the authors incorporate the same anterior incisional approach as has been used for the primary TAR. Alternatively, in case of very precarious skin conditions the authors use a lateral approach. As mentioned the skin conditions at the anterior part of the ankle joint are critical to preserve. Careful handling of the soft tissues is obligatory to limit wound-healing problems such as skin necrosis. Therefore, no sharp forceps or retractors are used during surgery. Any thickened scar tissue anterior to the TAR is excised, and, sometimes, osseous debris needs to be removed to access the failed TAR. Using osteotomes and chisels the failed and loose TAR components are removed. The authors always procure multiple different samples of tissue that are sent to pathology to rule out any infection. Debridement is continued until bleeding cancellous bone at the tibia and talus becomes visible. The neo-capsule of the TAR in the posterior part of the ankle joint is left as long as it does not impede sagittal plane range of motion. The osseous defect is measured. In general, the defects are very large and require a bulk structural bone graft (i.e., femoral head allograft). The authors developed a technique, which is based on Masquelet's induced membrane technique [53]. The posterior neo-capsule of the failed TAR is left in place and refreshed with a sharp curette. Then, anterior to the neo-capsule autologous cancellous bone is applied. Afterward, the structural bulk allograft is inserted into the defect zone. The authors would like to point out that it is important to engage the bone graft firmly between the tibia and talar bone surfaces.

Fixation can be performed either with screws, plates, or retrograde intramedullary rods [2]. The authors prefer an anterior plating system when approaching the ankle from anterior. When performing the salvage arthrodesis from lateral, a blade plate, retrograde intramedullary rod, or screw fixation can be considered. In cases, where anatomically shaped fusion plates do not perfectly fit, hybrid fixations (i.e., large compressive screws and plate systems) could be used. In certain patients even the bone needs to be trimmed to adjust for the plate.

Postoperatively, the leg is put in a short-leg cast. Patients are not allowed to bear weight on their operated limb for at least 8 weeks. Depending on the incorporation of the bone graft, gradual increase of loading is commenced. It is not unusual that incorporation happens slowly requiring prolonged immobilization of the leg.

Results of Salvage Arthrodesis

Although the literature provides articles regarding salvage arthrodesis after failed TAR, there are no high-level evidence-based medicine studies available. Zwipp and Grass [54] reported on four patients undergoing ankle arthrodesis after failed TAR. Two of them were done by screw fixation alone, while the remaining two failures were treated by anterior plating using two 3.5-mm titanium plates. Groth and Fitch [55] described tibiotalar fusion without bone grafting with the drawback of significant leg shortening. Hopgood et al. [56] published their report on 23 ankles that were converted to arthrodesis. Among those there were only eight cases that had a tibiotalar compression screw arthrodesis, but all of them achieved complete fusion. In patients with rheumatoid arthritis, tibio-talo-calcaneal screw arthrodesis performed better than ankle fusion alone. The authors of the same study stated that the TAR design plays an important role in determining whether large structural bulk allografts should be used to bridge the gap. The more resurfacing of the prosthesis, the less bone loss and the easier the reconstruction [56]. In a study by Culpan et al. [57], a more homogenous series of patients who had had conversion of failed TAR to ankle arthrodesis was investigated. All patients were treated using tibiotalar compression screw fusion with interposition of tricortical autogenous iliac crest grafts. All patients but one achieved solid union and no complications were reported. More recently, Berkowitz et al. [52] reported on salvage arthrodesis after failed TAR. They compared 12 patients who underwent salvage ankle arthrodesis with 12 patients who have had tibio-talo-calcaneal arthrodesis. In the group with tibio-talo-calcaneal arthrodesis, nonunions have been found and identified to be a risk for a worse outcome [52]. Rahm et al. [3] published their evidence-based medicine level III results of salvage arthrodesis for failed TAR in comparison with primary ankle arthrodesis. They found a significantly impaired life quality and function with higher pain levels at the time of follow-up. Patients who underwent salvage arthrodesis for failed TAR had significantly more complications and reoperations. Finally, a recent systematic review of tibio-talo-calcaneal arthrodesis for failed TAR revealed complications in 62.3% including nonunion rate of 24.2% [58]. When selecting patients for TAR, caution is advised when explaining conversion of a failed TAR into arthrodesis.

Conclusion

There is little question that current TAR designs offer improved anatomical and biomechanical behavior and the availability of dedicated revision implants to perform revision surgery. The concept to preserve hindfoot motion and function while protecting the adjacent joints, by means of exchanging a failed TAR, sounds appealing. Associated pathologies, for example, extra-articular malalignment, instability, and potential causes of impingement, should be identified and corrected at the same time. Recent reports including larger patient populations are encouraging. However, not every patient with a failed TAR qualifies for revision surgery. In those cases, conversion into arthrodesis is still an option for salvage instead of a below-knee amputation.

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Revision Total Ankle Arthroplasty

31

M. Pierce Ebaugh, William C. McGarvey, Murray J. Penner, and Gregory C. Berlet

Introduction: How Did We Get Here?

Ankle arthritis is a unique yet disabling disease pattern resulting in a poor quality of life and function [1, 2]. Compared to more common arthritic conditions such as tri-compartmental knee arthritis, it is complicated by an earlier end-stage onset and an etiology originating from prior lower-extremity trauma [1, 2]. With a younger, often more active affected population, the desire to maintain motion and prevent further hindfoot and midfoot degeneration has created continued investment in improvement of ankle prostheses.

First generation implants developed in the 1970s failed due to design, loosening, and instability [3, 4]. Continued implant evolution has resulted in third- and fourth-generation implants that have demonstrated both improved functional outcomes and survivorship [5–13]. In a 2013 landmark article, Flavin et al. used gait analysis to show that patients who received an ankle arthroplasty produced a more symmetrical ground reaction force curve closer to normal gait controls than those of arthrodesis when compared to arthrodesis patients. Strengthening the argument for improved function, Pedowtiz et al. compared 41 TAR (total ankle replacement) patients with 27 ankle arthrodesis patients revealing that TAR shows statistically significant improvement in sagittal plane range of motion, pain relief, and patient perceived function than ankle arthrodesis [5]. A meta-analysis performed in 2007 on intermediate- and long-term outcome and survivorship comparisons of TAR versus arthrodesis found that TAR had an overall 2% lower revision rate, a higher mean AOFAS hindfoot score, and lower below-knee amputation rates, along with similar percentages of excellent/good outcomes [7]. It is also important to note that this meta-analysis was performed on data published from 1998 to 2005, which includes many second-generation total ankle implant designs that are no longer in routine use today or have undergone significant design updates.

In 2010, Gougoulias et al. reviewed 1105 TARs consisting of seven different implant types (Agility®, Mobility®, STAR®, HINTEGRA®, TNK®, Buechel-Pappas®) and found no significant implant superiority over another [14]. This is reinforced by the varied availability and usage of TAR implant designs available today; however, current survivorship data is naturally biased in favor of implants with a lasting market presence. The Scandanavian Total Ankle Replacement or STAR® (Stryker) is a second-generation implant that has undergone multiple updates and is still in use by many surgeons today. As a result, much of the mid- to long-term follow-up survivorship data is based off the STAR [9–11]. Karatana et al. found STAR survivorship to be 90% at 5 years and 84% at 8 years in their cohort of 52 STAR TARs [10]. Similar results were found with mid-term results of 24 STAR TARs by Wood et al., with 93.3% and 80.3% survivorship at 5 years and 10 years, respectively [11]. Long-term data on STAR survivorship was presented by Roger Mann and colleagues who demonstrated a 73% 15-year survivorship in 84 TAR implants performed from 1998 to 2000 [9]. The authors commented that a prosthesis had a high likelihood of survival 15 years if it was still implanted at 9 years.

The Salto Talaris® total ankle implant system (Integra) was first available at the end of 2006 for use in the United States. One European survivorship study with a mean of 8.9 years of follow-up exhibited a prosthesis retention rate of 85% in 87 implants [12]. A more recent study followed 59

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Salto TARs for a mid-term mean follow-up of approximately 3 years demonstrating a 94.9% prosthesis retention rate with statistically significant improvements in VAS, AOFAS hindfoot, and Ankle Osteoarthritis Scale scores [15].

The INBONE I® and INBONE II® (Wright Medical) total ankle protheses are second- (2005) and third-generation (2010) designs, respectively, that have shown excellent survivorship track records as well. Adams et al. showed an 89% implant survival at 3.7 years with 197 INBONE I prostheses without cement fixation (off label) along with significant improvements in VAS pain, AOFAS, SMFA, and SF-36 scores at the time of final follow-up, compared with preoperative values, and in walking speed, STS time, TUG time, and 4SST time at 2 years postoperatively [16]. Regarding the INBONE II with cement fixation, Berlet et al. displayed a 95% prosthesis retention rate in 121 ankles at a mean of 28 months of follow-up [17].

Finally, analyzing European national joint registry data with application of Kaplan Meier survivability curves and controlling for prostheses that have either been removed from the market or fallen out of use, Roukis and colleagues showed a 0.90 to 0.93 survival at 5 years in 5152 primary and 591 revision TAR [8]. It is in these large data samples that we can not only elucidate implant improvement through survivability curves but also predict future trends in total ankle arthroplasty. Utilizing the Nationwide Inpatient Sample (NIS), a database released annually by the Healthcare Cost and Utilization Project (HCUP) in the United States, authors demonstrated an increase of 134% from 1999 to 2008 in the number of total *knee* arthroplasties (TKA) performed in the United States. This statistic cannot be explained via population increase or increased obesity. The greatest increase was found in the 45–64-year-old age group which represented 41% of TKA in 2008 but only 30% in 1999, suggesting increased utility in younger patients presumably due to enhanced survivability of existing implants [18].

So why such a dramatic increase in TKA utilization after the year 2000? A meta-analysis conducted by Saleh et al. and colleagues showed revision total knee arthroplasty to be a safe and effective procedure with re-revision rates of only 12.9% [19]. The advancement, surgeon approval, and ease of use of revision TKA systems in the early 2000s allowed for relaxed indications for primary implantation into younger patients and those with more complex deformities, improving quality of life for those previously deprived of this option. Total ankle arthroplasty is beginning to see a similar paradigm change, although on a smaller scale. Recently, Ramaskandhan et al. reviewed PROMIS scores of TAR versus hip and knee arthroplasty at 3- and 5-year outcome intervals. Total ankle arthroplasty maintained statistically similar outcome scores of both disease specific and mental health domains when compared to hip and knee at both intervals. Also, in three of four physical domains, TAR was similar to TKR; however, at 5 years, both THR and TKR showed significant improved over TAR in both stiffness and function [20]. With increased implantation of any orthopaedic prosthesis, there is a natural increase in complications and failures, so comprehension of revision implant indications, componentry, and technique must be a part of the surgeon's repertoire.

Defining Complications

Complication rates are notoriously high in total ankle arthroplasty, but few of these complications lead to metallic componentry revision [7, 9, 15, 21, 22]. Therefore, for the purpose of this chapter, we focus on the definition of revision total ankle as defined by Henricson and colleagues being removal or exchange of the prosthetic components of the implant excluding simple polyethylene exchange [23].

Glazebrook et al. performed an extensive literature review and defined a useful classification system for TAR complications, equating their probability for implant failure. The review concluded nine main complications in descending order of frequency: subsidence (10.7%), aseptic loosening (8.7%), intraoperative fracture (8.1%), wound healing (6.6%), technical error (6.0%), implant failure (5%), nonunion (4.4%), postoperative fracture (2%), and deep infection (1.7%). They further divided these complications into likelihood to lead to revision with *high* (aseptic loosening 80.6%, deep infection 70.3%, implant failure 68.6%), *medium* (technical error 45.0%, subsidence 32%, postoperative fracture 16.7%), and *low* grade (intra-op fracture 0% and wound healing 0%) [22]. Other studies strengthen this evidence, with subsidence and aseptic loosening being the overwhelming causes for revision [7]. Less reported but equally problematic causes of failure include residual deformity, arthrofibrosis, heterotopic ossification, polyethylene failure, and persistent pain [24–27]. While the latest generation implants show promising signs of avoiding some of the complications and failures seen with previous generations, TAR failure rate is still higher than with other joint replacements [28].

Patient Risk Factors for Failure

Elucidating which patient will ultimately go onto TAR failure requiring revision surgery is a helpful adjunct in the prevention of the failed TAR. Escudero and colleagues retrospectively analyzed a single-center TAR database for current-generation implants with associated radiographic, scoring, and patient characteristics for failures [29]. One hundred and seven patients were included in the study that included 11 aseptic failed TARs. Using multivariate regression analysis, diabetes mellitus and an Ankle Osteoarthritis

Scale score of >63 preoperatively were independently associated with TAR failure. Additionally, a talar dorsiflexion gamma angle of >19° and an anteriorly or posteriorly translated talar component relative to the axis of the tibia (ratios, <0.32 or >0.39) were also determined to be independent risk factors for failure. These four factors are combined into a scoring system that can help predict TAR failure and ultimately guide surgeon patient selection and intraoperative component alignment analysis.

Croft et al. performed a multicenter prospective study that enrolled both TAR and ankle arthrodesis patients [30]. Three hundred and sixty-two TAR were evaluated with revisions performed in 62 TAR (17%) after a mean follow-up of 3.4 years of all ankle patients. Prior to and following their index arthroplasty, the patients were evaluated using the Ankle Arthritis Score (AAS) which includes both basic and advanced activities. The authors concluded that based on this scoring system, it is not possible to predict which patient will *preoperatively* go onto revision. However, a *postoperatively* elevated AAS predicts a statistically significant increase in the likelihood for revision surgery of 1% with each additional point on the scale. Importantly, they also noted with passage of the time low postoperative AAS still demonstrates an increase in revision surgery.

In one of the largest implant failure risk factor studies to date, Cody and colleagues analyzed 533 TAR with a minimum follow-up of 5 years (mean 7 years) [31]. Using multivariate regression analysis in 34 failed ankles (6.4%), the authors found only hindfoot arthrodesis (prior to or during index procedure) as the only patient-related risk factor. This confirms findings of a previous study from the same institution [32]. Severe varus deformity (>20°) and diabetes mellitus also showed strong trend toward significance. Interestingly, the authors indicate that age, BMI, and other types of deformity were not associated with increased failure.

With this aforementioned data, we are able to better choose primary arthroplasty patients as well as identify and follow at risk ones.

Revision Arthroplasty Versus Salvage Arthrodesis: Choosing the Correct Path

Arthrodesis

Traditionally, total ankle arthroplasty failure resulted in an attempt at salvage arthrodesis or, unfortunately, amputation. Tibiotalocalcaneal (TTC) arthrodesis is often the choice of treatment in this situation; however, it is does not produce predictable outcomes radiographically or clinically [33–36]. Donnenwerth et al. reviewed 62 cases of TTC arthrodesis in the setting of severe bone loss following failed TAR in the literature [34]. They noted a first-time arthrodesis nonunion rate of 24.2%, an overall complication rate of 62.3%, and a weighted mean modified AOFAS hindfoot score of only 67.6/100. The authors discovered in a more recent systematic review of 82 cases of TTC arthrodesis following failed TAR a 35.3% construct nonunion rate and recommended the addition of iliac crest bone graft for any defects of over 2 cm [35].

As a response to the increased risk of nonunion, surgeons have recently turned to custom 3-D printed titanium cage constructs to combat significant bone loss and deformity in these patients. Bejarano-Pineda and colleagues published a small cases series of seven patients followed for a mean of 21 months who underwent TTC arthrodesis utilizing a 3-D printed cage construct [37]. Eighty-five percent of patients achieved union and limb salvage, while one patient ultimately required amputation. Despite an improved union rate, 57% of patients experienced a complication, and the mean time to union was 9.8 months. Dekker et al. followed 15 patients for 22 months who underwent a similar construct for both bone loss and deformity correction. At final follow-up, 87% of patients established union and were satisfied with their surgery [38]. The authors noted that the average cost of just the 3-D printed implant was $11,700. While promising in terms of obtaining union, the use of 3-D printed cages to account for severe bone loss in TTC arthrodesis is expensive, not without complications, and prolonged time to union which often results in substantial non-weight-bearing time.

These challenging fusions are also highlighted by poor functional outcomes and low patient satisfaction [33, 36]. When compared to initial primary fusion of their ankle arthritis, 23 matched salvage arthrodesis patients demonstrated significantly lower SF36 scores along with Foot Function Index scores that were dramatically worse in both function and pain [33]. Kamrad et al. reported on a comparison of 188 TAR failures, 118 of which were treated with salvage arthrodesis, while 70 underwent revision TAR. Only 47% of the patients were satisfied with their arthrodesis; additionally, the mean functional SF36 scores in nearly all categories were higher in the revision TAR group [36].

Revision Arthroplasty

Unfortunately, there is a paucity of quality literature following total ankle arthroplasty revision with most studies limited by follow-up and power. Recent trends of patient-reported outcome measures (PROMs) have shown that patients undergoing revision TAR exhibit significant improvement relative to pre-revision values but fail to reach the level of primary arthroplasty [39]. Ellington et al. retrospectively reviewed 41

patients at a mean of nearly 50 months who underwent revision TAR with a custom Agility® prosthesis [25]. They reported the etiology of revision as subsidence in 63% of these patients. Ultimately, five patients were converted to salvage arthrodesis, and two underwent amputation. Sixty-eight percent of patients perceived good to excellent results at follow-up with 83% percent stating they would have the procedure again. Preoperative talar subsidence correlated with postoperative AOFAS and Ankle Osteoarthritis Scale scores. Those with less subsidence performed better.

Williams and colleagues retrospectively reviewed 35 patients who underwent revision to Wright Medical INBONE II® from a failed Depuy Agility® prosthesis [40]. The vast majority of these patients underwent revision secondary to talar subsidence/osteolysis (88%). During revision, the talar defects were managed with local tibial autograft, cancellous chips, bone graft substitute, or femoral head allograft depending on size and location. At a mean of 9.1 months of follow-up, three patients had significant subsidence of the talar component, but were asymptomatic and did not require re-revision. The complication rate was 31.4% in this series with the most frequent complications being intraoperative fracture [6] and wound dehiscence [2]. The authors concluded that revision TAR is a viable procedure for failed primary TAR; however, the surgeon should prepare for and be able to manage all complications.

Hintermann et al. published the largest series to date of 117 patients who underwent revision to the HINTEGRA® implant from a failed TAR [27]. The majority of the revised implants were HINTEGRA (44%), STAR (33%), or Mobility (9%). Fifty-one percent of revisions were due to issues with metallic componentry, while osseous (28%), soft tissue (17%), and infection (8%) problems comprised the rest. The authors did note poor correlation between the extent of bone loss at the resection surface and the prevalence of component failure. The majority of the ankles required additional osseous or soft tissue procedure (74%). Seventeen patients (15%) required further revision surgery, but the estimated mean time to failure of the revisions was 9 years. Of these patients, 11 underwent a repeat revision, while six were converted to arthrodesis. AOFAS hindfoot scores improved greatly from mean of 44/100 preoperatively to 72/100 postoperatively. In conclusion, the authors stated that revision arthroplasty intermediate outcomes were similar to the primary surgery.

It is with this preceding data that this chapter focuses on revision total ankle arthroplasty as the ideal option for a failed total ankle replacement. The senior authors' goal is to address risk factors, patient selection, preoperative evaluation and planning, causes of failure, and surgical technique to guide the readers through the management of this challenging and increasingly common problem.

Patient Evaluation

A successful revision surgery begins with an appropriate plan tailored to the patient and the etiology of failure. The clinical and radiographic evaluation of the patient along with scrutiny of the patient's prior imaging, operative reports, and medical records is critical to success. Understanding the previous prosthesis and associated hardware limits explant time and potential blood loss. Recognizing under corrected or overlooked foot deformity from preoperative index procedure imaging can help the surgeon allocate intraoperative correction time and ensure any additional hardware or grafts are readily available. Analysis of prior operative reports can point the revision surgeon toward noted areas of osteolysis, avascular necrosis, or technical error so that augmentation or correction of these may be addressed. Familiarity with the primary implant's common modes of failures helps predict osseous defects that will require reconstruction.

As with any surgical procedure, a thorough physical exam should be performed. A careful neurological exam is paramount, as compromised function in the form of neuropathy can lead to revision failure via implant loosening or progressive foot deformity. Vascular concerns should be addressed with ankle/brachial index evaluation, advanced Doppler ultrasound, or CT angiography. As with a neuropathic limb, jeopardized vascularity precludes revision arthroplasty, and other forms of salvage should be considered if possible. In office, gait analysis should be attempted to help clarify range of motion limitations and possible spinopelvic, hip, and knee deformity which may be contributing to limb malalignment. Seated range of motion and stability evaluation teases out fibrosis or ligamentous attenuation, which can be further evaluated with plantar/dorsiflexion and stress radiography, respectively, to assist in addressing these issues intraoperatively. Particularly painful areas about the foot and ankle can be further evaluated with diagnostic injection under fluoroscopy. This may provide valuable information regarding gutter impingement and/or axial rotation malalignment (addressed later in the chapter). Finally, the soft tissue envelope should be carefully examined for prior surgical incisions, flaps that may need to be raised, and signs of venous or arterial compromise.

Deep infection of the implant must be ruled out as a cause of failure, as with any failed orthopaedic joint replacement. After physical exam for any obvious signs of deep infection such as sinus tracts or expressible purulence, laboratory evaluation via ESR, CRP, procalcitonin, and CBC with differential is essential in every patient workup. If the returning laboratory values are concerning for a prosthetic joint infection (PJI), further confirmation may be obtained using aspiration for synovial fluid analysis along and synovial alpha

defensin, along with an Indium labeled tagged WBC scan [41]. Single photon emission computed tomography (SPECT) can provide another lens to display septic loosening and provide other pertinent information such as non-integration of implant surfaces [42, 43].

Overall limb alignment should be assessed with a CT scanogram or full-length radiographs to assess for malalignment or leg length discrepancy. A full bilateral, weight-bearing ankle and foot series radiographs, including a Saltzman hindfoot alignment view, should be performed. As previously mentioned, plantar/dorsiflexion radiographs and stress views should strongly be considered here as well. Finally, weight-bearing CT with metal subtractions protocol should be performed to assess for bone loss, component subsidence, adjacent joint arthritis, and residual ankle/foot deformity. After a thorough preoperative evaluation, the etiology of failure should be revealed to the surgeon and comprehensive corrective plan created.

Of note, while the senior authors advocate for revision arthroplasty, this option is not always in the patient's or surgeon's best interest [44]. A patient selection algorithm is useful in selecting patients who would continue to benefit from a revision arthroplasty over an attempted salvage arthrodesis or below-knee amputation.

Etiology and Treatment of Primary Arthroplasty Failure

Septic Failure

The initial evaluation of a suspected PJI is outlined previously in this chapter. Following confirmation of infection, the surgeon must determine the approximate length of time the prosthesis has been inoculated. For cases 3 weeks or less, an attempt at a very thorough irrigation, debridement, and polyethylene exchange can be attempted [45]. Antibiotics should be held if possible until intraoperative swab and tissue cultures have been obtained. An infectious disease physician should be consulted, preferably prior to operation. For infections longer than 4 weeks, explantation of the entire prosthesis and implantation of an antibiotic impregnated spacer should be performed along with the previously mentioned operative steps in line with a two-stage revision. Short and colleagues describe a technique for creating an articulating spacer using a small surgical measuring cup [46]. Articulating spacers have been shown to improve final range of motion and shorten hospital stays in one randomized controlled trial of two-stage revision total knee arthroplasty [47]. The overall goal of the two-stage exchange revision arthroplasty is reimplantation of a revision total ankle replacement; however, in some cases, this, or conversion to a salvage arthrodesis, is not possible. Ferrao and colleagues were able to perform limb salvage in seven of nine patients with long-term use of antibiotic impregnated spacers; the authors state that this is a viable option for patients with significant medical or surgical comorbidities that preclude revision surgery [48].

Periprosthetic Fracture

Periprosthetic fracture is a relatively uncommon complication in primary TAR with intraoperative incidence reported as 1.2–2.2% and postoperative incidence from 1.6% to 2% [49–51]. Avoidance of periprosthetic fracture begins with prevention and identifying at-risk patients. Cody and colleagues performed a retrospectively study of 198 TARs that underwent preoperative CT to identify those who sustained a pre- or postoperative periprosthetic fracture. Using Hounsfield units (a method of measuring bone mineral density on CT with correlation to DEXA scan, threshold for osteoporosis being 122.45 HU tibial and 311.37 HU talus) measured at approximate levels of tibial and talar bone cuts, the authors determined that those patients with tibial HU measurements below 200 were at risk for both intraoperative and postoperative periprosthetic fracture. In TAR candidates who have risk factors for osteoporosis, they suggest a preoperative workup that includes DEXA scan and treatment with bisphosphonates as indicated to reduce this risk [52]. Their suggestion is reflected in hip and knee arthroplasty where a meta-analysis displayed decreased revision rates for patients who received bisphosphonate treatment; in particular, denosumab treatment has resulted in a lower implant migration in total knee arthroplasty [53, 54].

A classification system for periprosthetic fractures was proposed by Manegold and colleagues, organizing fractures by type, location, and prosthesis stability [50].

- *Type – IntraOp (1), PostOp Traumatic (2), PostOp Stress (3)*
- *Location – Medial malleolus (A), Lateral Malleolus (B), Tibia (C), Talus (D)*
- *Prosthesis Stability – Stable (S), Unstable (U)*

They analyzed 503 primary and revision TARs, determining the primary overall rate to be 3.9% and revision rate to be 7.9%, although this was not significant. Two-thirds (66%) of fractures were found in the medial malleolus. The authors comment that the majority of intraoperative fractures occurred due to saw blade excursion or oversizing of the implant with both instances increasing in osteoporotic bone, an error they correlate with surgeon experience. Prevention and treatment are based in AO osteosynthesis principles. Traumatic postoperative fractures should be assessed for implant stability, with stable prostheses undergoing standard fixation, while unstable prostheses needing implant removal, fracture fixation, and revision implantation. The authors

extensively analyzed medial malleolus stress fractures, identifying several causes: varus tibial implantation resulting in mechanical load, valgus tibial implantation resulting in deltoid tension stress fracture, oversizing of talar componentry resulting in mechanical load, and hindfoot/forefoot malalignment contributing to the previous mentioned load/tension failures. It is important for the surgeon to address both the fracture and the cause in these instances.

Lazarides et al. confirmed the previous studies findings after performing a retrospective study on 1610 primary and revision TAR, finding 32 postoperative fractures at a mean of 26 months [49]. As previously noted, they found the majority of fractures to be located in the medial malleolus but strongly suggested an operative approach to all fractures including non-displaced fractures with stable implants [49, 50]. This is consistent with the findings by McGarvey et al. who noted an incidence of nonunion in periprosthetic medial malleolus fractures treated non-operatively [55]. Lazarides highlighted that implant stability was independently correlated with the need for revision arthroplasty, an important point when creating patient expectations.

Patient-reported outcomes in patients with periprosthetic TAR fractures are generally acceptable. The previously mentioned study displayed a mean VAS of 17/100, SF36 of 64.3, and AOFAS of 72.1 at an average of 36 months from injury [49]. Tsitsilonis and colleagues advised that patients with uncorrected varus malpositioning of their implant following periprosthetic TAR did have a significantly lower AOFAS score, 67.3, than those with appropriate alignment, 87.6 [51]. These outcomes highlight the need for proper identification and aggressive surgical management of fracture and implant stability/alignment.

Lastly in a STAR ankle cohort, Lundeen and Dunaway noted persistent medial pain at a mean of 12 months following STAR implantation without radiographic signs of stress fracture or malalignment. The authors were successful in resolving the medial pain in 60% with screw augmentation of the medial malleolus, while 17% had continued mild pain, and 33% had mild pain only with activity. The width of the medial malleolus in those patients with pain was a mean of 10.2 mm, while the control group had a mean width of 12.2 mm; the authors noted that this was statistically significant. Further, they concluded that medial malleolus overload may arise from subacute stress fracture, deltoid traction, or component impingement/design [56].

Malalignment

Proximal and Multiplanar Deformity

The goal of a TAR is to align the implant with the mechanical axis of the lower limb. This requires a long leg assessment as part of the workup prior to the primary TAR. The proper diagnosis of a malaligned TAR begins with a thorough clinical and radiographic evaluation outlined in the *Patient Evaluation* section. After identification of the center of rotation of angulation (CORA) or proximal joint arthritis, addressing the alignment issue can begin. For patients with hip or knee degenerative changes leading to deformity and leg length discrepancy, the senior authors advocate for addressing these issues first via our adult reconstruction colleagues. Deformity correction relies on bony anatomic landmarks and proper proximal alignment, when altered correction at the ankle becomes increasingly difficult. Any alignment discrepancy greater than 5° or 2 cm should be addressed to prevent altered joint mechanics [57]. Tibia proximal/middle third deformity that is congenital, developmental, or post-traumatic should be addressed with osteotomy and osteoplasty using internal or external fixation via a surgeon with extensive experience in this area [57]. Deformity in the distal one third of the ankle has more pronounced effect on the ankle joint than elsewhere in the tibia [58]. This is more often addressed by orthopaedic foot and ankle surgeons and can be accomplished as an acute correction using internal fixation or gradual correction utilizing a multiplanar thin wire external fixator. Closing or opening wedge osteotomies can be employed, but the latter requires uniting bone graft, while both often require translation depending on the proximity to the CORA. Dome osteotomy is another option that does not require a translation component, but is more technically demanding. The surgeon must understand after correction of a more proximal deformity the previously implanted TAR may need revision due to the alignment changes. Distal supramalleolar osteotomies (SMO) maybe successfully performed simultaneously with revision of componentry, and staging is at the discretion of the surgeon [59]. The senior authors prefer a staged approach to large deformity correction with osteotomies confirmed to be healed via CT prior to ankle arthroplasty. Additionally, SMO can be used to correct residual varus in the painful total ankle. Deforth et al. utilized a valgus producing supramalleolar osteotomy in 22 patients who had previously undergone TAR displaying significant improvements in tibial anterior surface angle, AOFAS hindfoot score, and VAS pain scores [60]. They did warn surgeons considering this option of their high nonunion rate, 14%.

Varus Deformity/Positioning

Total ankle arthroplasty failure can occur when incongruent intra-articular varus deformity exists that is greater than 10–15° [60, 61]. Intra-articular varus deformity is addressed much in the same way as a primary ankle arthroplasty. Assuming the primary componentry is well fixed without signs of loosening and initially implanted at 90° to the mechanical axis (judging by primary arthroplasty postoperative radiographs), then the deformity is incongruent and being driven by

the soft tissues or distal to the ankle. If this is not the case, the components should be explanted and the tibial and talar cuts made 90° to the mechanical axis according to predetermined bony landmarks (see *Patient Evaluation*). Management of possible resulting bony defects and/or joint line changes will be discussed later in the chapter. Distal tibial varus of up to 10° can be compensated via intra-articular correction as well, but anything greater than this requires a proximal osteotomy described previously [57].

Soft tissues and osteophyte complexes are sequentially released with the correction reevaluated after each maneuver. The order for releases is as follows: bony impingement removal, deltoid peel, talonavicular capsule release, posterior tibial tendon sheath release, and lastly posterior tibial tendon lengthening/tenotomy. After removal of lateral osteophytes that prevent talar reduction, a thorough medial gutter debridement can be performed with a sagittal reciprocating saw or osteotome. A deltoid release can then be performed, beginning with the superficial deltoid by passing an elevator subperiosteally along the inferior and medial edges of the medial malleolus to elevate as much deltoid as needed to effect correction back to neutral with manipulation of the hindfoot into valgus [57]. Alternatively, a polyethylene trial can be placed to appropriate tension of the deltoid; some authors prefer this to prevent excessive medial release [62]. The talonavicular capsule can be safely incised dorsally and dorsomedial while protecting the spring ligament. The posterior tibial tendon sheath is released through an incision distal to the medial malleolus and then if necessary, the posterior tibial tendon is lengthened/tenotomized through this same incision.

Lastly, a distal sliding medial malleolus osteotomy is the final option for persistent varus. This medial oblique osteotomy is not common and can be challenged by perilous bone quality and predisposition to periprosthetic fracture [63].

With incongruent varus, the reconstruction of the limb will also include a lateral ligament reconstruction with peroneal tendon repair as indicated. Lateral ligament reconstruction is out of the scope of this chapter.

Forefoot-driven hindfoot cavus is not uncommon and is often overlooked by the primary surgeon. If the patient has a poorly corrected or neglected cavovarus deformity, the subtalar joint is assessed for rigidity. In supple, hindfoot-driven cavus, a valgus producing calcaneal osteotomy is performed and the foot reassessed. If further correction is needed, dorsiflexion of the first ray is achieved through desired technique. In a rigid cavovarus deformity, a subtalar fusion is often performed with concomitant first ray management, while severe deformity necessitates a triple arthrodesis. Some authors advocate for triple arthrodesis in other instances such as talar AVN, hindfoot arthritis, and significant talar component subsidence [62]. In many cases, if the patient requires extensive surgery involving both TAR revision with triple arthrodesis or even revision triple arthrodesis, strong consideration should be given to staging. In this event, prosthesis removal occurs first followed by aforementioned deformity correction with cement spacer insertion for maintenance. In the same setting, hindfoot and forefoot work is performed. After 13–14 weeks, there is hopeful union of fusions and osteotomies along with soft tissue healing. CT confirmation of fusion is required prior to proceeding to the revision arthroplasty.

Results have been satisfactory in multiple single-stage varus correction studies with primary arthroplasty [61, 64, 65]. Most recently, Sung and colleagues compared 24 ankles with an average tibiotalar angle of 25° with 79 ankles with an average of 4.9° over short-term follow-up [64]. There were no significant differences in final AOFAS score and VAS pain improvement, and 86% of patients were satisfied with their outcome. Lee at al reported a 97% survivorship using the HINTEGRA TAR in 59 ankles with less than 20° of varus at a mean of 7.3 years. These results can be extrapolated to revision cases that significant varus deformity correction can be done reliably [66].

Valgus Deformity/Positioning

As with varus deformity, any mechanical alignment issues proximal to the ankle joint should be addressed first. Additionally, any componentry that is loose or implanted in valgus relative to the mechanical axis should be explanted and revised accordingly. In the revision arthroplasty setting, the valgus TAR is often due to an unrecognized or progressive flatfoot deformity with possible attenuation or complete failure of the deltoid ligament and spring ligament complex.

The isometric ligaments of the hindfoot are the posteromedial deltoid and the calcaneofibular ligaments. The clinical challenge is to assess the stability of the deep deltoid and the spring ligament. If these are intact, then a rebalancing (without reconstruction) is often adequate. One technique to assess is to use a larger polyethylene insert to tension the deltoid [57, 67]. If the deltoid remains lax or greater than 10° of valgus deformity is present at the ankle joint, then a deltoid reconstruction should be performed according to preference. If explantation is being performed due to componentry issue, staging should be strongly considered. Multidirectional instability (both medial and lateral) should be considered in all valgus instability TAR. In long-standing flatfoot deformity, the sub-fibular impingement on the calcaneus often results in grinding down of the lateral ankle ligaments resulting in lateral ankle instability. Reconstruction of these ligaments should proceed according to technique preference.

The hindfoot is often rigid in long-standing pes planovalgus. If this is the case, medial double arthrodesis or triple arthrodesis should be performed to correct the deformity. For a supple hindfoot, medial displacement calcaneal osteotomy

is done to correct heel valgus and reorient the pull of the triceps surae. Evaluation of the medial column is next with careful attention being paid to individual joint laxity and deformity apex. Sequential medial column joint pinning with reassessment is one technique to tease out unstable joints for fusion and has been employed by one of the senior authors [57]. If all joints are stiff, an opening wedge medial cuneiform osteotomy alone can be performed. After appropriate position has been achieved, the flexor digitorum longus tendon is transferred adjacent to the tibialis posterior to assist in the extra-articular reconstruction (in supple deformity). Occasionally, syndesmotic widening is found in long-standing flatfoot deformity [67]. After complete reconstruction, stress radiographs should be performed to assess its stability.

Demetracopoulos et al. retrospectively examined 80 patients with a mean follow-up of 3.5 years that underwent TAR in the presence of severe valgus deformity. Preoperative valgus had an average of 15°, but 31% of patients displayed greater than 20° of valgus [68]. The authors were able to correct the valgus to a mean of 1.2° which was maintained at final follow-up. Scoring of AOFAS, SF35, SMFA, and VAS all showed significant improvement as well. Once again, Lee and colleagues reported long-term follow-up (7.3 years) of 34 ankles with less than 20° of valgus, finding an implant survivorship of 81%; it should be noted that these ankles did not require deltoid reconstruction or repair [66].

Recurvatum Deformity/Positioning and Anterior Translation of the Talus

In native ankle arthritis, recurvatum occurs from a stiff ankle being repetitively driven into the anterior plafond or, in the case of post traumatic arthritis, the intrusion of the talus into avascular anterior tibial bone. Regardless of etiology, it results in contraction of the posterior soft tissue structures [57]. If not properly recognized and addressed in primary arthroplasty, this can lead to dorsiflexion of the tibial component and anterior translation of the talus [69]. Primary tibial resection is referenced from healthy bone at anterior tibia. Under-resection distally into bone with questionable vascularity can result in dorsiflexion and settling of the tibial component. In a revision scenario, the tibial cut is referenced to healthy bone, and the resultant bone loss with joint line elevation is managed with modularity (discussed later in the chapter). Malpositioning of the talar component directly increases probability of failure leading to a pseudo-recurvatum deformity [29].

In a revision scenario with apparent anterior translation of the talus, current and proper talar station should be calculated [69]. The anterior position of the talus is referenced off the tibia by measuring the tibial axis on a lateral weight-bearing view and then examining the position of the central axis of the talar component [70]. The surgeon should be aware that plantarflexion artifact can produce this appearance; otherwise, the anterior translation is due to the foot position relative to the tibia or the component itself being implanted anteriorly. If the tibia is implanted in slight extension in a mobile-bearing TAR, the talus will begin to slip out anteriorly [69]. This is corrected via tibial osteotomy or revision of the tibial component. Contraction of the posterior structures and resulting equinus deformity can be from lack of initial release at primary arthroplasty or from overstuffing the talar component. In either case, removal of polyethylene and posteriomedial release with careful attention being paid to stay lateral the flexor hallucis longus tendon should be performed. Tendoachilles lengthening is included; the approach to both is at the discretion of the surgeon, but the structures can often be released through the anterior incision after removal of the polyethylene. After placement of a new polyethylene, reduction of the anterior translation should be visualized along with full dorsiflexion under fluoroscopy.

Lateral ankle instability can also give an anteriorly translated and internally rotated appearance [69]. Osteophyte buildup in the lateral gutter also results. The remedy for both is a thorough debridement and lateral ligament reconstruction of choice with talar derotation. Finally, in a situation where the component is positioned anteriorly on the talus, simply revise the component to a more posterior position while preserving as much bone as possible.

Procurvatum Deformity/Positioning

Procurvatum deformity is the least common malalignment issue that results from posterior wear and concomitant heel cord contracture [57]. Continued procurvatum after primary arthroplasty is secondary to remittance of the deformity initially. The tibial component cut should be based off of the distal posterior cortical margin followed by performing a heel cord contracture release.

Usuelli and colleagues noted that significant talar shifting occurs within the first 6 months following mobile-bearing TAR; this should be kept in mind before attempting revision for possible soft tissue related alignment issues [71, 72]. Failure to address anterior or posterior translation of the talar componentry was determined to be an independent risk factor for TAR failure using multivariate analysis by Escudero et al. The authors mentioned that maintaining a Tibia-Talar ratio between 0.32 and 0.39 was important for implant survival. This data underlines the importance of appropriate sagittal alignment in TAR.

Axial Malalignment

Recently, the complex concept of axial rotation malalignment in TAR has undergone further investigation [73, 74]. Goldberg and colleagues performed an extensive retrospective investigation of 157 patients who received INFINITY PROPHECY (Wright Medical) patient-specific instrumenta-

tion, fixed bearing total ankle arthroplasty [73]. The reconstruction CT scans performed in this series were used to investigate the relation of external tibial torsion and the transmetatarsal axis. Most TAR systems use the tibial tubercle for proximal reference to set coronal alignment, while rotation is set via bisection of the medial and lateral gutters (PROPHECY INFINITY®, Salto, Cadence®), medial gutter reference (STAR®, Vantage®, INFINITY®, HINTEGRA®, Box®), medial clear space on fluoroscopy (Zimmer trabecular metal®), or second metatarsal reference (Salto Talaris®, AAA®, Zenith®). The authors measured the external tibial torsion, transmetatarsal axis (TMA), bisection of the gutters, and foot position relative to the second metatarsal. Tibial torsion varied widely from 11.8° to 62° with no significance between men and women or right and left sides. They extrapolated further that the tibial tubercle is not a reliable reference for determining tibial torsion due to a wide range of degrees (1–44.6) relative to the TMA and that in extreme tibial torsion, the tubercle can even place the tibial component in valgus in proximally referenced alignment rod systems. The authors also determined the foot position to always be internally rotated relative to the TMA, but again, this varied greatly (0.7–38.4°). This is something to take into account in patients with an externally rotated tibia as the foot tends to be more internally rotated than usual relative to the TMA, in valgus arthritis due to increased external rotation of the foot as it drives to a achieve a plantigrade posture, or in fixed equinus as the foot internally rotates when plantarflexed. Regarding medial gutter versus both gutter axis reference, the authors found a more than 3° difference in rotation in 81% of patients and 5° difference in >50% of patients. There is no known clinical relevance of this, but they do state that their operative technique has changed accordingly. They most often reference both gutter axis when considering rotation, externally or internally rotating the talar component in some cases for patients whose foot internal rotation is at either extreme relative to their tibial torsion. After changing their rotation preference, their incidence of medial gutter impingement was 1.9% without debridement, compared to a prevalence of 7% in other series. The authors do concede that gutter debridement prevents impingement in cases of slight axial malalignment but state that extensive gutter debridement risks mortise instability and malleolar fracture and fails to preserve bone for revision cases [73, 75, 76]. Finally, they recommend a close preoperative and intraoperative assessment of tibial torsion, foot position relative to TMA, and tuberosity relationship to the center of the ankle.

Hintermann and colleagues reinforced these findings via a retrospective study of axial rotation of talar and tibial components of 48 mobile-bearing TARs intraoperatively, immediately postoperatively on radiographs, and at a minimum of 3 years with weight-bearing CT scan [74]. The authors concluded a high interindividual variability between the tibial and talar component positioning, stating that axial malpositioning may be more common than currently recognized and reported.

Our understanding of axial rotation is currently evolving, and gutter impingement remains a common issue following primary TAR [75, 76]. Whether a patient with primary TAR gutter impingement requires a complete component revision or a thorough gutter debridement can be better understood using diagnostic injection and weight-bearing CT scans. Ultimately, the best prevention of component revision is an exhaustive preoperative plan, CT-guided patient-specific instrumentation when needed, and recognition of outliers in terms of foot position relative to tibial torsion and TMA.

It is the authors' experience that gutter impingement remains the most common cause for reoperation on a well-fixed TAR in the first 5 years post implantation.

Aseptic Loosening

There are numerous potential causes for TAR aseptic loosening and subsidence of implants including progressive component migration, periprosthetic osteolysis, tibial/talar avascular necrosis, and malalignment (previously discussed) [24]. A new-onset painful total ankle in the absence of any clinical signs of infection or impingement should concern the surgeon for loose componentry [26]. This section briefly discusses the theoretical etiology of each and suggested management by the senior authors.

Component Migration

Physiologic prosthetic component migration, first described in hip and knee literature, is a common occurrence within the first few months after TAR as the implants settle and achieve bony integration [24, 77]. Newer-generation TAR have less tendency to migration. Any migration of the implants creates concern for early failure and should be closely followed [78]. There is no current "cutoff" for "how far is too far," and therefore patient follow-up should be close in those exhibiting asymptomatic component migration. Our senior authors routinely see their postoperative TARs at 1 year and 2 years postoperatively, with some stretching to 2-year intervals following the second year. In the pain-free patient who continues to perform well clinically, the only indication for intervention is a progressive loss of bony structure.

Heterotopic Ossification

Heterotopic ossification (HO) is a common occurrence following primary total ankle arthroplasty with one systematic review of over 1300 TARs reporting an incidence of 66% at a mean of 3.6 years. After analysis, the authors stated there is insufficient evidence that HO had a significant effect on functional outcome [79]. Several studies have linked the for-

mation of HO to exposed, bleeding cancellous bone following implant cuts along with implant alignment [80–82]. The current literature fails to substantiate HO as a cause of revision TAR; however, we include the aforementioned studies as a reminder to search for other sources of pain and range of motion loss in the failed TAR. Intraoperatively, the authors still recommend judicious bone resection and post-implantation covering of exposed bleeding surfaces with bone wax. The surgeon should also be cognizant of posterior tibial undercoverage by the implant; in theory, this would result in increased bleeding along the posterior capsule and subsequent HO formation along it. As with anterior undercoverage, the authors err toward a longer-size implant to ensure full anterior to posterior tibial coverage. There is no evidence to suggest that the presence of HO increases the risk of aseptic loosening (Fig. 31.1).

Periprosthetic Osteolysis and Cyst Formation

The cause of periprosthetic osteolysis in total ankle arthroplasty patients continues to be a source of debate despite extensive investigation into the subject [83–85]. Asymptomatic and non-progressive cysts exist; however, those that progress lead to implant loosening, subsidence, and failure [86]. Early, non-progressive cysts are often found and maybe the result of implant stress shielding [87]. Large, progressive cysts often appear late and have been linked to most commonly to polyethylene wear particles [84]. Other factors such as implant fluid dynamics and implant interface may contribute [87–89]. Mobile-bearing TARs have also been theorized to be at risk for increased cyst formation due to motion between both tibial and talar metal components (backside wear) [74]. Cysts are often implant specific with patterns unique to bone loading associated with the design of the implant. The complex basic science discussion of periprosthetic cysts is out of the confines of this chapter, but the authors believe that the cyst characteristics of a TAR are unique and different from similar cysts around a hip or knee arthroplasty.

Osteolysis and cyst formation can be difficult to appreciate on plain radiographs alone for several factors: osteolysis occurs in the cancellous bone of tibia and talus which are far from radio dense, significant resorption is required before change is appreciated, and the cysts tend to congregate around the implant obscured by the metallic components [83]. Concern for any cyst formation should be met with a CT, weight-bearing if possible, as the exact location and size of the cysts are better comprehended [83].

While both tibial and talar cysts occur, those in the talus are often of greater concern due to the lack of bone stock available for reconstruction. Berlet et al. described an effective CT classification system for talar cysts, allowing for size and location quantification to make progression easier to follow [85].

A. *Central defect (no cortical breach in any axial direction)*
   A1. Small (<12 mm in greatest diameter in primary cyst or additively if polycystic disease is present)
   A2. Large (>12 mm)
B. *Peripheral defect (cortical breach in any axial direction)*
   1 of 4 quadrants (primary cyst or polycystic)
   B1–4
C. *Subtalar breach into posterior facet*
D. *Fractured talus (or otherwise failed bony integrity—not amenable to component revision)*

Postoperative hindfoot alignment can also provide insight into likelihood of cyst formation and location. Lintz and colleagues noted increased total cyst volume in TARs with residual hindfoot malalignment; those with valgus malalign-

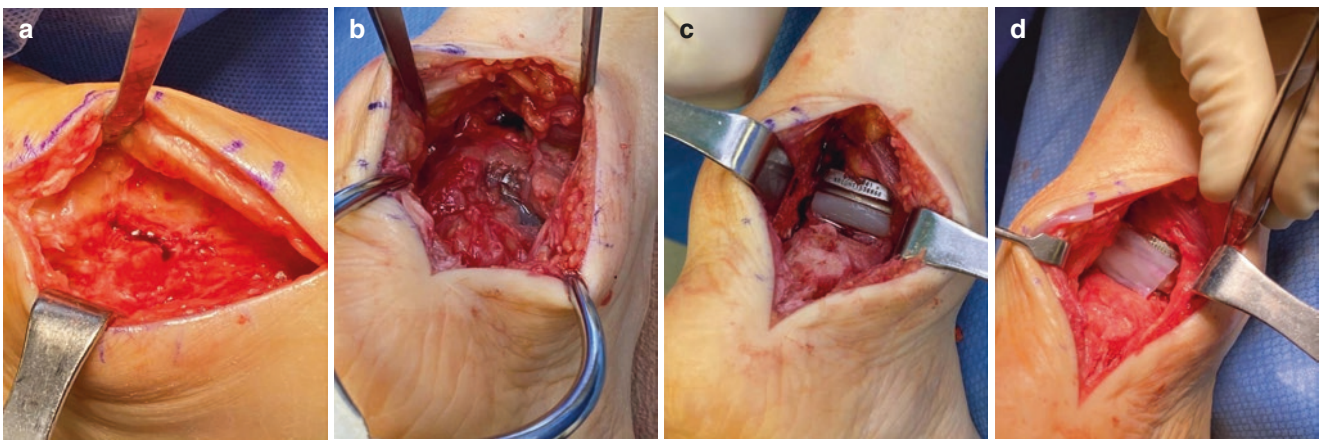


Fig. 31.1 A posterior approach to the ankle reveals bridging heterotopic ossification of the posterior ankle joint capsule (**a**, **b**). After removal of the bridging bone, an amniotic tissue allograft is placed to prevent continued formation of the heterotopic ossification (**c**, **d**). (Courtesy of Gregory C. Berlet, MD)

ment demonstrated a greater lateral cyst volume, while varus cases had a larger medial cyst volume [90]. Stress shielding due to unloaded portions of the prosthesis may be contributing to these geographical findings.

There is no current consensus on exactly when to intervene on osteolytic cyst formation. The senior authors of this chapter closely follow asymptomatic cysts that continue to progress in size, particularly when they are implant adjacent. They believe intervention should be performed on progressive, large cysts even in the asymptomatic patient. Periprosthetic cysts that are greater than 1 cm in largest diameter and have documented evidence of progression are an indication for intervention for the senior authors. Determination between complete component revision and bone grafting of the cysts depends on implant stability and alignment, along with intraoperative post debridement of the cyst. SPECT is another tool that provides valuable insight into the proper surgical path, with high correlations between probability of loosening on imaging and intraoperative findings [43]. Therefore, in the setting of an asymptomatic or symptomatic progressively enlarging cyst with SPECT findings negative for aseptic loosening, the authors recommend planning for impaction grafting utilizing cancellous allograft with or without adjunctive calcaneal autograft/bone marrow aspirate while incorporating a polyethylene exchange. Adding demineralized bone matrix to the graft creates a putty-like substance that maintains shape and sticks well into the cystic void [26]. The graft can be impacted using osteotomes in a technique akin to a mortar spatula in brick laying. The senior authors do not currently use cement in defects in the younger patient for fear of eventual mantle fatigue and cracking; however, this has been used with success via other experienced authors [91]. For older or sedentary patients, this may present a viable option in those with porotic bone in whom the surgeon is trying to retain implants and avoid risk.

Gross et al. retrospectively examined 31 patients who underwent grafting for cysts in multiple locations across several different implant designs for progressive cysts [92]. Twenty-seven patients did not need revision surgery with success of their grafting, and at 24 months, 90.9% showed cyst resolution without formation of new cysts. This study does have several limitations in that cysts existed in multiple locations, multiple different implants were involved, several grafting substitutes were used, and finally at 48 months, the success rate fell to 60.6%, with 30.3% of cysts returning in some form. Further investigation on this topic is needed, but currently grafting is the best option.

In cases that involve subsidence, loose components, or extracted polyethylene with abnormal wear patterns, the authors suggest revision of componentry as necessary (Fig. 31.2). In asymmetric polyethylene wear patterns with well-fixed, properly aligned componentry, the surgeon should look for ankle instability. In the case of loose componentry with adequate bone stock, a revision can proceed. Discussion of managing bone stock, joint line, and component subsidence will be discussed later in the chapter.

Avascular Necrosis

There are limited series in which success was achieved performing a total ankle arthroplasty in the setting of avascular necrosis [26]. In general, placing an implant that relies on bony ingrowth into sclerotic, nonviable bone is a recipe for subsidence and failure [24]. However, it is not uncommon to find localized areas of avascular necrosis under loose componentry due to subsidence and sclerosis [24]. The blood supply to the talus is notably tenuous, and in a fresh frozen cadaveric study of four different implants (Salto Talaris®, STAR®, INBONE II®, Trabecular Metal Total Ankle®), disruption of the vascularity based on implantation technique was found. The surgeon should expect to encounter some

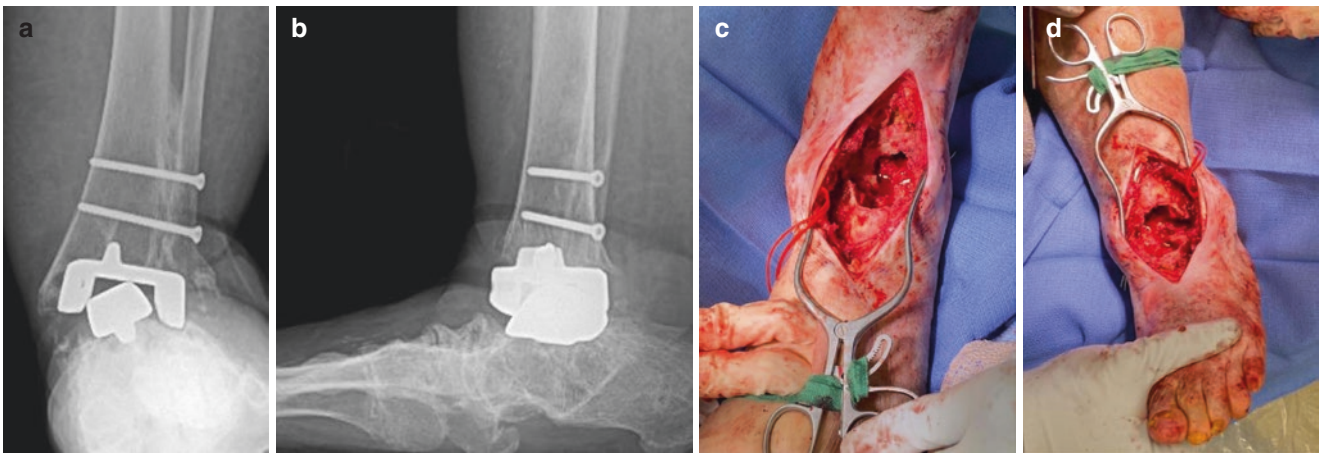


Fig. 31.2 Radiographs of a Depuy Agility® TAR implanted 15 years ago that has undergone failure secondary to deltoid ligament attenuation and massive osteolytic cyst formation (**a**, **b**). Intraoperative photographs of post-debridement cysts in the talus (**c**) and tibia (**d**). (Courtesy of William C. McGarvey, MD)

degree of avascular necrosis during revision arthroplasty and should employ different techniques in the management of the areas including debridement with bone grafting or complete resection with metallic augmentation. These techniques will be further described later in the chapter.

Component Undersizing

Failure to place componentry out to cortical margins over the greatest surface area of the bone can also lead to loosening and subsidence as the implant rests on soft, cancellous bone. Minimal resections of the tibial bone are associated with significant changes in prosthesis support, e.g., a 1 cm native distal tibia resection is associated with a 75% reduction in compressive resistance [91]. Hurowitz and colleagues describe an experience with the first Agility implant whose talar component covered barely a third of the cut surface. The talar subsidence rate was exceedingly high overall, with patients receiving a size 1 prosthesis having the highest rate at 43% [93]. In primary surgery, every effort should be made to match the prosthesis to the margin of cortical bone in both the coronal and sagittal planes. Due to the natural sagittal range of motion kinematics of the ankle, the surgeon should err on more anterior coverage (even if slight overhang is present) over posterior, if an ideal AP coverage is not possible [91].

Management of Subsidence

Subsidence in all forms is noted as the greatest source of failure for total ankle arthroplasty [7]. While there is often similar instance cystic change and bone loss on either side of the joint, due to the lack of overall bone stock, the talus can be difficult to restore and manage [24, 92]. However, the senior authors believe that achieving a successful revision arthroplasty involves respecting both sides of the joint, creating stable surfaces for implant ingrowth and maintaining ankle kinematics.

Joint Line Considerations

Alterations of joint line kinematic and biomechanics have resulted in poor postoperative range of motion, stiffness, pain, and pseudo patella baja with retropatellar impingement in total knee arthroplasty [94, 95]. Maintenance of joint line and the use of modular componentry is a mainstay in revision total knee arthroplasty. In both primary and revision total ankle arthroplasty, there is a paucity of literature regarding both kinematic change of the ankle with an altered joint line and its effect on patient outcome. Theoretical disadvantages to joint line elevation include alteration of implant arc range of motion resulting in "hinge abduction" of the talar component on the polyethylene creating loss of motion and asymmetric polyethylene wear, medialization/lateralization of tibial implant due to lack of taper fit, soft tissue and syndesmotic instability, and, in extreme cases, sub-malleolar impingement [96, 97].

Harnroongroj and colleagues devised a reliable method of measuring the pre- and post-ankle arthroplasty joint line [98]. They noted an elevation of joint line when compared to the native, non-arthritic contralateral ankle but that the pre- and post-arthroplasty joint lines of the arthritic ankle were not significantly different across five implant types (INFINITY®, INBONE II®, Cadence®, Salto Talaris®, Vantage®). Due to differences in bone quality between the tibial plafond and talar dome in an arthritic ankle, they theorized the overall elevation of joint line in a native arthritic ankle to be caused by hard dome impacting into the soft distal tibia. They related that the measured distal tibia resection level was not the major determinate in an elevated joint line, but more often surgeon choice when increased resection was required for adequate bone stock for implantation or when balancing the ankle. This is an excellent tool for preoperative planning and creating radiographic landmarks for intraoperative comparison to maintain a proper joint line level. Recreation of the joint line should be accomplished from both sides of the joint and restoration of tibial length and talar height.

Tibial Subsidence and Bone Loss

Tibial bone loss after explantation of primary componentry in revision total ankle arthroplasty can be significant. The surgeon must focus on achieving two main goals during tibial revision: recreation of joint line and implant stability. A flat, stable tibial surface must be created for bony ingrowth. This is best achieved with an uncoupled, often free hand tibial cut. For localized and contained cystic bone loss proximal to the cut, a cortical window is made with impaction grafting performed utilizing the previously mentioned technique. The tibial implant can then be placed. When choosing the correct tibial implant, the authors advocate for achieving tibial shaft fixation utilizing a tibial stem to allow for stability from weakened malleoli, poor distal tibial bone quality, and incorporation of bone graft. In cases of severe tibial metaphyseal bone loss, the authors encourage the use of modular metaphyseal componentry (INVISION® Wright Medical, Integra XT®) as metallic augments for distal tibia bone loss. This creates a stable platform for joint line recreation and has been used with success in revision total knee arthroplasty [99]. If the surgeon still needs to distalize the tibial joint line to maintain a balance, stable ankle, increasing the size of the polyethylene component should be considered. This should be done only after maximizing metal augment length. The distal extent of the polyethylene should match the native arthritic ankle joint line, using predetermined bony landmarks. Harnroongroj and colleagues utilized the posterior colliculus of medial malleolus and the tip of the

distal fibular as landmarks on AP radiograph [98]. Of note, in rare situations, custom implants have been used for patients with unique or extreme bone loss patterns. There is a paucity of literature surrounding custom implants, but clear disadvantages such as cost and lack of intra operative modularity make these implants difficult to use. With the increasing numbers of revision total ankle arthroplasty, the authors believe surgeons require an "on-call" modular revision system.

Talar Subsidence and Bone Loss

The talar side of the joint is often more complex in management due to lack of overall bone stock and the consideration of adjacent joints. Ellington and Myerson described a basic radiographic grading system of talar subsidence with *Grade 1* being loosening without subsidence, *Grade 2* subsidence but not to the subtalar joint (STJ), and *Grade 3* with subsidence to the STJ (Ellington and Myerson). *Grade 1* outcomes of this study were significantly better than those of two or three. This radiographic guide is a good starting point for planning a talar component revision: whether a primary prosthesis may be used (*Grade 1*), a revision prosthesis is needed (*Grade 2*), or an STJ arthrodesis with revision prosthesis should be considered (*Grade 3*).

After explantation of the talar component, the authors advocate for performing an uncoupled, often freehand, flat cut to the talus while taking care to maintain as much talar height as possible. The metaphysis should then be inspected for cystic defects. In accordance with Berlet et al.'s talar classification, the authors recommend proceeding with the previously described impaction bone grafting technique in contained defects with at least three intact talar zones [85]. Metal augments, such as tantalum, have also been used [26, 97]. For cases with larger talar defects, subsidence to the STJ, or an arthritic STJ, the authors recommend a subtalar joint arthrodesis in addition to grafting where applicable. If incorporating a STJ fusion, some experienced surgeons recommend a staged procedure [62]. In situations with significant loss of talar height, the flat cut must be performed distally on the talus, often through the head/neck. When this is done, or in cases where the surgeon feels the need for additional fixation, a revision prosthesis is utilized (INVISION® Wright Medical). The INVISION® allows for a broad incorporation surface area on the talus utilizing an extended anterior base plate with screw fixation (currently not approved in the US market). The INVISION® prosthesis can also be extended out across the talonavicular joint (TNJ) in cases where a previous or concurrently performed TNJ arthrodesis is present. The INVISION® system also retains modular options for height restoration using the talar base plate, with varying height additions. Steginsky and Haddad describe another augment with fully threaded 6.5 mm cancellous cannulated screws in the form of "re-bar" [91]. In this technique, wires are inserted in the retrograde fashion starting plantarly up to the point of sitting on plane with the talar flat cut. Precise measure of length is taken, and the screws are inserted over the wires, so they rest flush with the eventual implanted prosthesis surface. Metal washers can be utilized to "dial in" the proper screw length. The authors also utilize this technique with bone cement in situations with large, uncontained talar defects. These are all useful adjuncts to prevent the surgeon from driving the joint line low to create stable articulation.

Finally, in cases of complete annihilation of the talus, consideration can be given to implanting a custom, "total talus" prosthesis. Cut using 3-D printer technology from reconstruction CT data, a total talus is designed to perfectly articulate with the tibial polyethylene and STJ. In cases of an arthritic STJ, custom tali can be made with a hydroxyapatite plantar surface and screw fixation for bony calcaneal ingrowth. Kanzaki and colleagues performed primary total talus arthroplasty with a tibial component in 22 patients. After a mean follow-up of 34.9 months, all patients had retained total tali with significant improvements in patient reported outcomes. The authors concluded that total talus arthroplasty is a reliable procedure. Currently, there is no known study that evaluates this procedure as an option for revision arthroplasty, and further investigation is warranted [100].

Prosthesis Specific Tips and Tricks

Prosthesis Extraction

As with any revision joint replacement, a diverse "tool kit" allows for choice instrumentation to adapt to situations preoperatively recognized and unforeseen. Multiple sizes of micro and macro multiplane bone saws are important considerations. Excursion distance and saw thickness should not be overlooked, permitting precision resection with minimal risk to healthy bone, malleoli, and soft tissue structures. Osteotomes are a mainstay in foot and surgery; however, flexible osteotomes are less encountered but are a useful augment to the revision surgeon. A complete drill tray, bone tamps, curettes, pituitary rongeurs, power burr, and power rasp should also be available.

Prior to extraction attempts, prophylactic pinning or screw placement of the medial malleolus and intramedullary pinning or plating of the distal fibula should be considered in thin- or weak-appearing bones. To prevent against revision componentry subsidence and failure, every attempt should be made to maintain as much anterior tibial cortical bone as possible during resection of bony overgrowth to access the prosthesis. Each implant design is associated with particular difficulties. Anticipating and preparing for these difficulties decreases headaches and surgical times.

INBONE® I/II (Courtesy of Greg Berlet MD, FRCSC)

The stemmed tibial prosthesis appears to be a daunting revision opponent, but with system understanding, this is approachable. The polyethylene locking system is found in the superomedial/lateral corners of the distal portion of the tibial tray. Unlocking begins with sequential drilling from 2.0 mm up to 4.0 mm drill bits with care not to damage the mechanism (if retaining tibial component). The polyethylene is released from the anterior engagement and then engaged with a threaded K wire. With gentle traction on the K wire, the polyethylene will come forward and can be released. A loose INBONE® stem can often be levered out. In a well-fixed stem, the options for removal include osteotomy or utilizing the manufacturers removal system. For the osteotomy technique, a small cortical window is made with a drill proximal to the tip of the stem, and a bone tamp is inserted to mallet the implant in the distal direction. The Morse taper will expose itself to be disengaged. The X drive instrumentation can then be inserted to disassemble the stem piecemeal. Revision core reamers (hole saws) that remove bone ingrowth on the stems are available and helpful for removal of the stem without osteotomy.

INFINITY® (Courtesy of Greg Berlet MD, FRCSC)

Minimal resection implants like the INFINITY® can be removed with a stacked osteotome technique. The polyethylene is removed to create space for the implant to move anteriorly and decrease the risk for malleoli fracture. The polyethylene is released from its lock detail with an osteotome, and then threaded K wires are used to pull anteriorly. It is the authors' preference to remove the poly, followed by the tibia and then the talus. The tibia is accessed anteriorly with osteotomes at the bone/implant interface along the extent of the anterior aspect. Levering the implant inferiorly will release the porous ingrowth and deliver the implant from the tibia. In the case of the chamfer-cut talus, the access is created anteriorly, and then a gentle lever motion will release the bone ingrowth on the talus prosthesis. A similar technique is used in the flat top talus.

STAR® (Courtesy of Greg Berlet MD, FRCSC)

The STAR® mobile-bearing is often compromised and is commonly fractured. The polyethylene is removed by inserting a threaded K wire to the poly and then delivering anterior. The tibial component is fixed by two lugs going anterior to posterior. The tibia is accessed anteriorly with osteotomes at the bone/implant interface along the extent of the anterior aspect. Levering the implant inferiorly will release the porous ingrowth and deliver the implant from the tibia. The porous ingrowth on this prosthesis is biased toward the lugs, and the biggest risk is that as the tibia is delivered, it pulls considerable amount of the metaphysis with it. Careful attention to releasing from the tibia helps avoid this. Do not lever medially or laterally as this risks malleolar fracture. Using the curved U-shaped osteotome tool can be helpful if placed directly over these lugs to help loosen them. The talus is a central fin and is accessed anteriorly with osteotomes. One osteotomy is placed medially and one laterally, then the talus is levered up. It often pulls up easily with limited bone fixation around the talus fin.

HINTEGRA H3® (Courtesy of Murray Penner MD, FRCSC)

Revision of the HINTEGRA total ankle has a few unique challenges.

The intact polyethylene bearing is rarely challenging to remove as it is a mobile bearing with a shallow articular arc. However, on occasion, the bearing may be fractured, and retrieving the posterior fragments may be challenging. This may be facilitated by applying a large Hintermann joint distractor, which significantly improves visualization of the posterior joint space and then using a pituitary rongeur to retrieve the fragments.

Talar implant removal is typically not difficult since talar loosening is often the indication for revision. However, if the implant is very firmly bonded to the bone, a sharp 5 mm flexible osteotome may be carefully driven along the underside of the anterior flange of the talar component to initiate detachment from the bone. In similar fashion, the osteotome can be driven along the inner surfaces of the medial and lateral sidewalls of the talar component to free it from the bone. A curved osteotome may then be used to pry up the anterior flange and facilitate removal.

The more common challenge in HINTEGRA revision is addressing talar bone loss from osteolysis, as large bone defects may be present. Typically, this requires a generous flat-cut resection of the talus to reach a level with satisfactory bone quality, particularly around the periphery of the talar body, to allow support of a flat-cut revision prosthesis. Central residual cystic areas should be curetted, with sclerotic areas roughened and perforated and then filled with cancellous bone graft. In view of the low bone resection level that is often needed, a modular revision talar implant with variable thickness is optimal for reestablishing the talar joint line height.

One unique challenge in talar revision that may be seen with the HINTEGRA implant is shearing of the anterior pegs, with the pegs remaining firmly embedded in the anterior talus, broken off flush with the surface of the bone. Removal of these pegs can be very challenging. A large hollow reamer from a broken-screw removal set is needed to expose and free up the pegs from the bone, allowing it to be grasped with a screw-removal pliers and removed.

On the tibial side, the component is commonly quite well bonded to bone. However, due to its flat bone interface, removal is fairly straightforward, though the anterior flange

partially blocks direct access to the interface. A thin, sharp 5 mm flexible osteotome can be readily used on either side of the flange to access the bone interface and free the implant from the bone. Large degrees of bone loss are relatively uncommon on the tibial side. This typically allows some degree of choice in the selection of the tibial revision implant.

Zimmer TMTA® (Courtesy of Alastair Younger M.B., ChB, FRCSC)

Revision of the tabecular metal ankle can be performed by either a lateral or anterior approach and will depend on whether the components are solidly fixed to the bone or not.

If solidly fixed to the bone, the lateral approach will be required as removal from the anterior approach will result in considerable loss of bone.

From the lateral approach, flexible osteotomes can be used on each side of the rails to loosen the component. A gouge osteotome can be used over the rails. The medial malleolus may need to be protected by K wires or screws prior to ensure that the medial malleolus does not fracture with tibial implant removal. The anterior medial approach may need to be opened and an osteotome used medially also to prevent this.

With regard to revision from the lateral approach, the implant choices are limited. The replacement can be revised to a fusion using this approach. Alternatively, the lateral removal can be combined with an anterior revision either staged with a cement spacer or at the same sitting.

If an anterior approach is used, the incision may need to be curved medially to utilize the prior anterior medial approach. Loose components can be removed by this approach and the implant revised using flat cuts, bearing in mind that considerable bone loss will occur with this technique.

Integra CADENCE® (Courtesy of Christopher Hyer DPM, MS)

The CADENCE® total ankle replacement is a minimal resection, two-component device with a polyethylene insert fixated to the tibial component. The CADENCE® device is on label to be cemented to bone upon insertion, but some surgeons may choose not to use cement. Regardless, if revision is needed, the original anterior approach incision is reutilized.

Depending on the reasons or need for revision, the CADENCE® could be revised or converted as the surgeon sees fit. A "flat-cut" talar implant option is available if just the "chamfer cut" implant needs revised. If both devices need revision, since minimal bone resection is taken on initial implantation, typically, revision to a stemmed implant of choice is very feasible.

Typically, the easiest way to accomplish removal of the implants is if the polyethylene spacer is removed first. A threaded Steinman pin or the threaded bone removal pin is drilled into the poly insert. A ¼ osteotome is used to disengage the poly insert from the tibial tray. The osteotome is placed into the anterior dovetail slot (Fig. 31.3) which will disengage the poly, and then with traction on the threaded pin, the poly is removed.

Use a rongeur to remove any anterior bone overgrowth at the top of the tibial implant. Create a small trough so the anterior lip of the implant is visible. A Cobb elevator is placed on the anterior lip and is useful as a bone tamp to drive the implant down and out of the tibia. Once the anterior portion of the device has dropped out of the tibia, use forceps to carefully remove the tibia device taking care to roll it down (inferiorly) and out. Take care not to damage the tibia by pulling the device straight out as the anterior pegs or posterior fin could still be engaged in the bone.

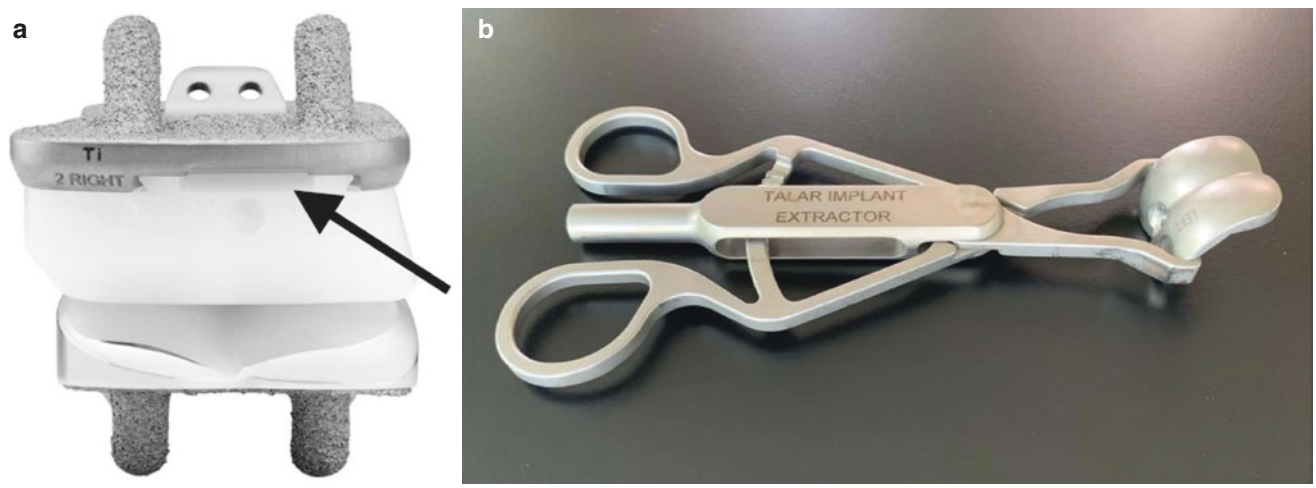


Fig. 31.3 Integra CADENCE® dovetail slot (**a**). Talar implant extractor (**b**). (Courtesy of Christopher F. Hyer, DPM)

Attention is now directed to the talar implant. A curved quarter- or half-inch osteotome is used on the front edge of the talar implant to gently lift the anterior lip of the implant. The talar removal forceps from the CADENCE® instrument tray is used to grab the medial and lateral sides of the device. With upward pull on the removal forceps and levering up with the osteotome, the talar component should be removed. A slap hammer attachment is available on the talar removal forceps to assist with implant removal.

At this point, all of the CADENCE® components have been removed, and the revision procedure of choice can be performed.

Depuy Agility® (Courtesy of William C. McGarvey, MD)

The Agility implant typically fails as a result of subsidence of the talar component, particularly the earlier generations in which the talus was designed as an undersized component resting completely on soft cancellous bone of the talar body cut surface. Other considerations for explantation of this implant are the discordant sizing dimensions. For many situations, to get good anterior-posterior coverage on the tibia, the medial-lateral width was excessive, leading to over-resection of medial malleolus, fibula, or both. That combined with the obligatory syndesmosis fusion lends itself to creating areas of weakness in the bone at each corner of the tibial component.

As a result of these fairly universal concerns, the first step performed in a planned Agility explantation is bimalleolar fixation with pins or, if malleolar thinness dictates, plating of the malleoli.

The tibial component has a sound track record, and despite instances of subsidence, usually attributed to undersizing, these are frequently well fixed. As a result, in an effort to preserve as much bone stock as possible and avoid violent movements that will result in malleolar fractures, a reciprocating saw is used.

First the lugs on the medial and lateral sides of the polyethylene are cut vertically just inside each border of tibial implant. Then the poly can be levered down and brought forward with a threaded Steinman pin technique. If the joint has subsided and the poly is incarcerated, cutting it into thirds from medial to lateral is helpful.

Next, the tibia is addressed with the reciprocating saw carefully working at the bone-porecoat interface all the way around the implant. Once loose, the keel often comes out without difficulty but occasionally will require some careful work with an osteotome from front to back.

At this point, the talus is left, and this will usually respond to gentle leverage with an osteotome under the anterior lip. If well fixed, using the reciprocating saw is a useful adjunct here too.

Since the implant is now defunct and instrumentation is hard to find for the threaded portions of the anteromedial tibia and central talus (used for insertion control), try incorporating a threaded Steinman pin of appropriate size to thread these holes in the implant to assist with removal.

Once the implant is completely removed, there are some relatively reproducible findings.

Malleoli are thin. Fixation will be necessary in many but not in all cases, depending on initial sizing of the Agility.

The distal tibial surface is often unremarkable in appearance and often can accommodate most implant varieties. If an excessive amount of bone was removed with keel extraction, a stemmed implant is a reasonable choice, but due to the low profile nature of the keel, many lower profile tibial components are often applicable.

The talus frequently has a large cavitary central defect. If that is the case, and the periphery is intact, a device that rests on remaining cortical margins is successful most often. Flat-cut talar components that get good peripheral coverage will work well, and the defect in the center can be filled with impaction grafting, bone substitute, cement, or even metallic features of the new implant or augments.

Not infrequently, the talus will have subsided to the point where it destroys a larger portion of the native talar body or even splits the remaining talus into pieces. In the former situation, being creative with rebar fixation transversely or vertically across the subtalar remnant is useful. If fusing the subtalar joint, this author will avoid the anterior half of the talus and the sinus tarsi, only working through the posterior facet for fusion surface in an effort to preserve vascularity to the body of the residual talus. If necessary, this will often necessitate aborting the ankle implantation in deference to cement block insertion to allow fusion to occur and to assess for any further collapse of talar body after this procedure over the next 3–4 months. Staged reimplantation is then undertaken if stable.

In the case of talus fracture, repair and fusion of remnants are the preference. Sometimes, this requires fusing pieces anteriorly and posteriorly to the calcaneus separately. Then the case proceeds as above in staged fashion. This will necessitate some creativity to support the revision talar component and to reestablish height to restore the joint line. This author has used bulk allograft, cement with rebar, and metallic wedges all for this purpose, both in isolation and in combination with one another to gain support for a broad surface implant to rest upon (INVISION®, Wright Medical).

In extreme cases, a 3-D printed talar replacement can be considered for the talar side, and this can be matched to articulate with the manufactured tibial component geometry.

Due to the aforementioned over-widening, of the syndesmosis, the talus may be shifted laterally and may require soft tissue releases to bring it back toward the tibial axis. This can result in an unusual appearance that seems lopsided with a large lateral gutter gap between the lateral talar wall and the fibula. Rarely, this has been felt to lead to valgus instability as a result of loss of bony support, and some anecdotal

reports exist regarding supplementing the fibular deficiency with allograft or other insert to more closely approximate the lateral talar wall.

Alternatively, a low-profile, non-stemmed implant may need to be considered and centered on the entire tibiofibular surface including syndesmosis fusion mass. This essentially makes the revision "talar-driven" and places the tibial component over the appropriate area above the talus with little regard to its position beneath the tibial shaft axis. While this is a bit of a cognitive shift from the majority of implants on the market, this is occasionally useful and sometimes necessary to get a reasonable functional result.

Cases

Case 1: Revision of STAR to INVISION Talus/ INBONE II (*Courtesy of Gregory Berlet MD*)

Description

- 65-year-old female with primary OA of ankle
- STAR TAR in 2002
  - Good function for years
- 2012 started developing pain in ankle
  - Vague and not obvious issues
  - Evolved to constant ache and CT was ordered to work it up

Preoperative Evaluation and Etiology of Failure

- Ankle aspirated, all negative
- Standing x-rays obtained (see below)
  - Show a talar cyst
  - Bearing wear suspected but no bearing fracture suspected
- CT scan performed (see below)
  - Talus cysts
  - Tibia cysts
- Based on this, a diagnosis of aseptic talar component loosening was made and a decision to proceed with revision TAR.
  - Adequate alignment and bone stock were felt to be present, making revision TAR a viable option.

Imaging

- (Fig. 31.4a, b)

Operative Procedure

- A standard anterior incision through the old scar was used, with careful dissection down to the ankle. Gutters were cleared and anterior fibrotic tissue removed. Prophylactic cannulated wires were placed medially for potential later use.
- An osteotome was placed under the anterior flange of the talar component, and it was seen to be slightly loose, confirming the preoperative diagnosis. It was readily pried up and detached from the bone, with little bone growth on the implant.
- An osteotome was then used to remove the tibial component which had some bone growth around the central pegs but was easily removed.
- Bone stock was seen to be relatively well preserved, though the talus had osteolytic cysts for which a lower flat-cut resection was needed.
- After implant removal, the leg was placed in the INVISION leg holder and the tibial and talar resection levels selected. Only a small amount of tibia required resection.
- The amount of bone loss after resection to healthy levels mandated the use of an INBONE II stemmed tibial component and a modular INVISION talar component with a 6 mm talar plate to restore talar joint line height.
- No concerns for malleolar integrity and the wires for the cannulated screws were removed at the end of the procedure without permanent prophylactic fixation of the tibia (Fig. 31.4c)

Postoperative Protocol

- The incision is dressed with a bulky soft dressing, and then a well-padded plaster splint is applied.
- The splint is left in place for 1 week and changed to a non-weight-bearing cast which is changed in 3 weeks to a bootwalker.
- The patient is asked to partial weight-bear on the operative limb for 2 weeks and then progress to full weight-bearing in boot, with discontinuation of the post-op boot at 8 weeks.
- Elevation of the limb is strongly emphasized until the wound is fully healed.
- Gentle range of motion exercise is allowed once the wound is healed, and full physical therapy is initiated at 6 weeks post-op.

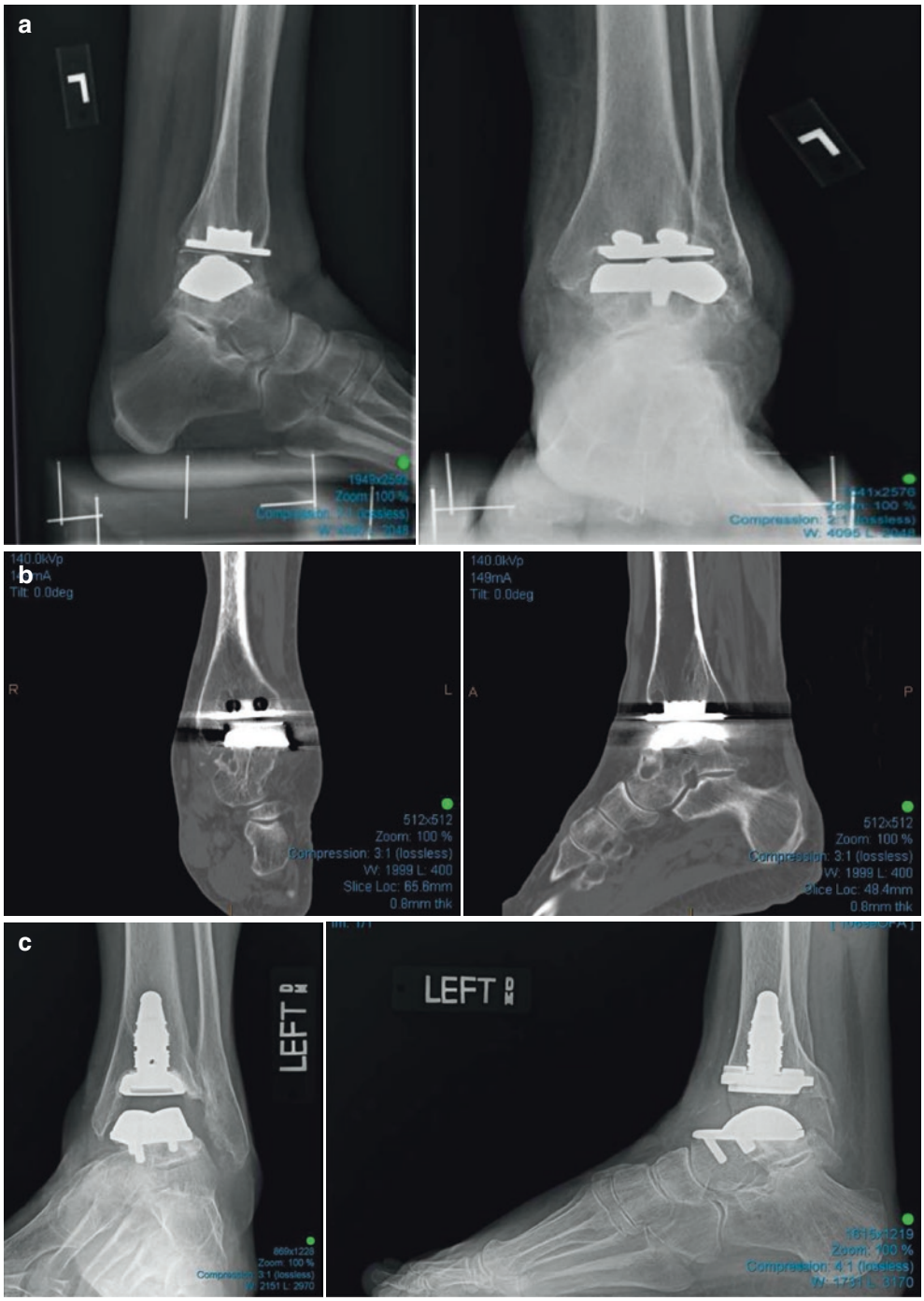


Fig. 31.4 (**a**) Preoperative standing x-rays. (**b**) Preoperative CT scan. (**c**) 3 Year standing x-rays of revision

Case 2: Revision of HINTEGRA to INVISION Tibia/Talus (*Courtesy of Murray Penner MD*)

Description

- 67-year-old female retired nurse with rheumatoid arthritis
- Numerous prior surgeries to all joints
- Previous *right* TTC fusion
- Previous *left* subtalar fusion 8 years prior
- LEFT HINTEGRA 1° TAR done for end-stage ankle arthritis with preexisting subtalar fusion and 10° varus tilt
- 3 years post-op underwent reoperation for recurrent varus, syndesmosis widening, and osteolysis
  - Bearing exchange, syndesmosis fusion, and bone grafting of cysts
- 3 years later developed worsening pain in the ankle

Preoperative Evaluation and Etiology of Failure

- C-reactive protein mildly elevated, but not beyond her normal baseline.
- Ankle aspirated, three cultures drawn, all negative.
- Standing x-rays obtained (see below):
  - Show a talar osteolytic cyst but no gross malalignment, subsidence, or loosening
- SPECT-CT scan performed (see below):
  - Shows significant talar uptake consistent with talar component loosening
  - Also shows moderately large osteolytic cyst
- Based on this, a diagnosis of aseptic talar component loosening was made and a decision to proceed with revision TAR.
  - Adequate alignment and bone stock were felt to be present, making revision TAR a viable option.
  - Her previous subtalar fusion and early talonavicular and calcaneocuboid arthritis made the option of conversion to fusion much less appealing.

Imaging

- (Fig. 31.5a, b)

Operative Procedure

- (Fig. 31.5c)
- (Fig. 31.5d)
- (Fig. 31.5e)
- (Fig. 31.5f)

Postoperative Protocol

- The incision is dressed with a bulky soft dressing, and then a well-padded plaster splint is applied.
- The splint is left in place for 2 weeks, after which sutures are removed, and a full-height post-op boot is used until 8 weeks post-op.
- The patient is asked to keep non-weight-bearing on the operative limb until 6 weeks post-op and then progress to full weight-bearing as able, with discontinuation of the post-op boot at 8 weeks.
- Elevation of the limb is strongly emphasized until the wound is fully healed.
- Gentle range of motion exercise is allowed once the wound is healed, and full physiotherapy with no restrictions is initiated at 8 weeks post-op.

Case 3: Revision of Depuy Agility to INVISION Tibia/Talus (*Courtesy of William McGarvey MD*)

Description

- 65-year-old female with right post-traumatic ankle arthritis following ipsilateral femur and tibia fractures.
- She underwent a primary Depuy Agility® TAR the year following her accident.
- Six years later, she underwent an ipsilateral subtalar fusion following a diagnosis of post-traumatic subtalar arthritis compounded by rheumatoid arthritis.
- Twelve years following her primary TAR, she presented win increasing pain in the ankle.

Preoperative Evaluation and Etiology of Failure

- Physical exam demonstrated global tenderness on the ankle and neutral alignment, but increased external rotation during both stance and swing phases of gait. Plantar flexion and dorsiflexion were demonstrated at 30° and 5°, respectively.
- Radiographs demonstrated subsidence of the earlier-generation Agility talar component with lucency around the malleoli adjacent to the tibia component. CT confirmed the radiographic findings along with a successful subtalar fusion.
- Laboratory markers ruled out any indolent infection.
- The cause of failure was determined to be due to osteolysis and talar component subsidence.

Imaging

- (Fig. 31.6a, b)

Operative Procedure

- (Fig. 31.6c)
- (Fig. 31.6d)
- (Fig. 31.6e)

Postoperative Protocol

- The patient was placed in a splint and made to non-weight-bear postoperatively. At 1 week, range of motion exercises were started. At 3 weeks, progressive weight-bearing was started.
- (Fig. 31.6f)

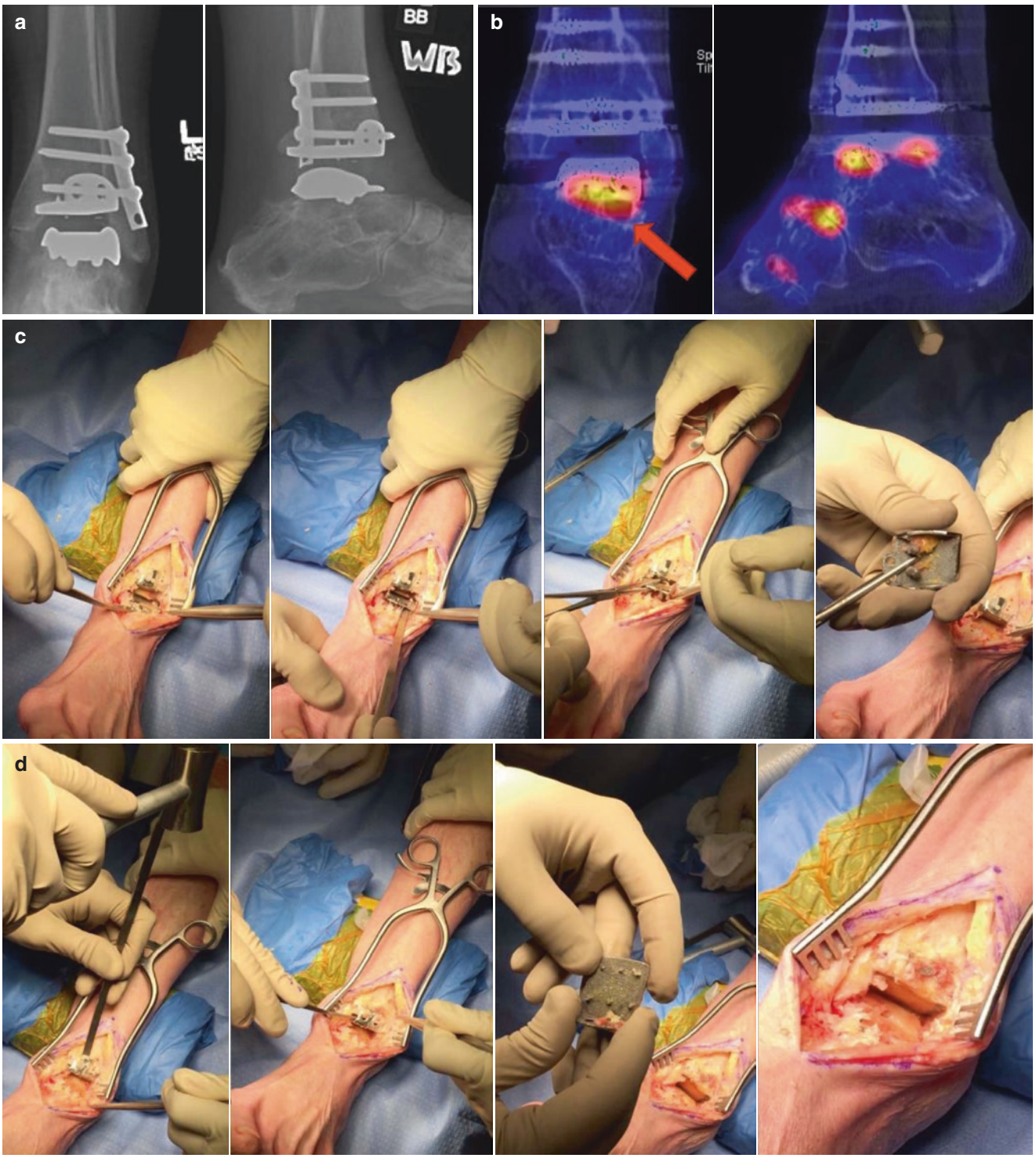


Fig. 31.5 (**a**) Preoperative standing x-rays. (**b**) Preoperative SPECT-CT scan. (**c**) A standard anterior incision through the old scar was used, with careful dissection down to the ankle. Gutters were cleared and anterior fibrotic tissue removed. An osteotome was placed under the anterior flange of the talar component, and it was seen to be slightly loose, confirming the preoperative diagnosis. It was readily pried up and detached from the bone, with little bone growth on the implant. (**d**) An osteotome was then used to remove the tibial component which was well fixed. Bone stock was seen to be relatively well preserved, though the talus had osteolytic cysts for which a lower flat-cut resection was needed. (**e**) After implant removal, the leg was placed in the INVISION leg holder and the tibial and talar resection levels selected. Only a small amount of tibia required resection. After resection of the talus to a level with healthy bone, the overall gap was reasonably large. (**f**) The amount of bone loss after resection to healthy levels mandated the use of an INVISION stemmed tibial component and a modular INVISION talar component with a 6 mm talar plate to restore talar joint line height, allowing the joint line to lie at its normal level approximately 1 cm above the tip of the medial malleolus

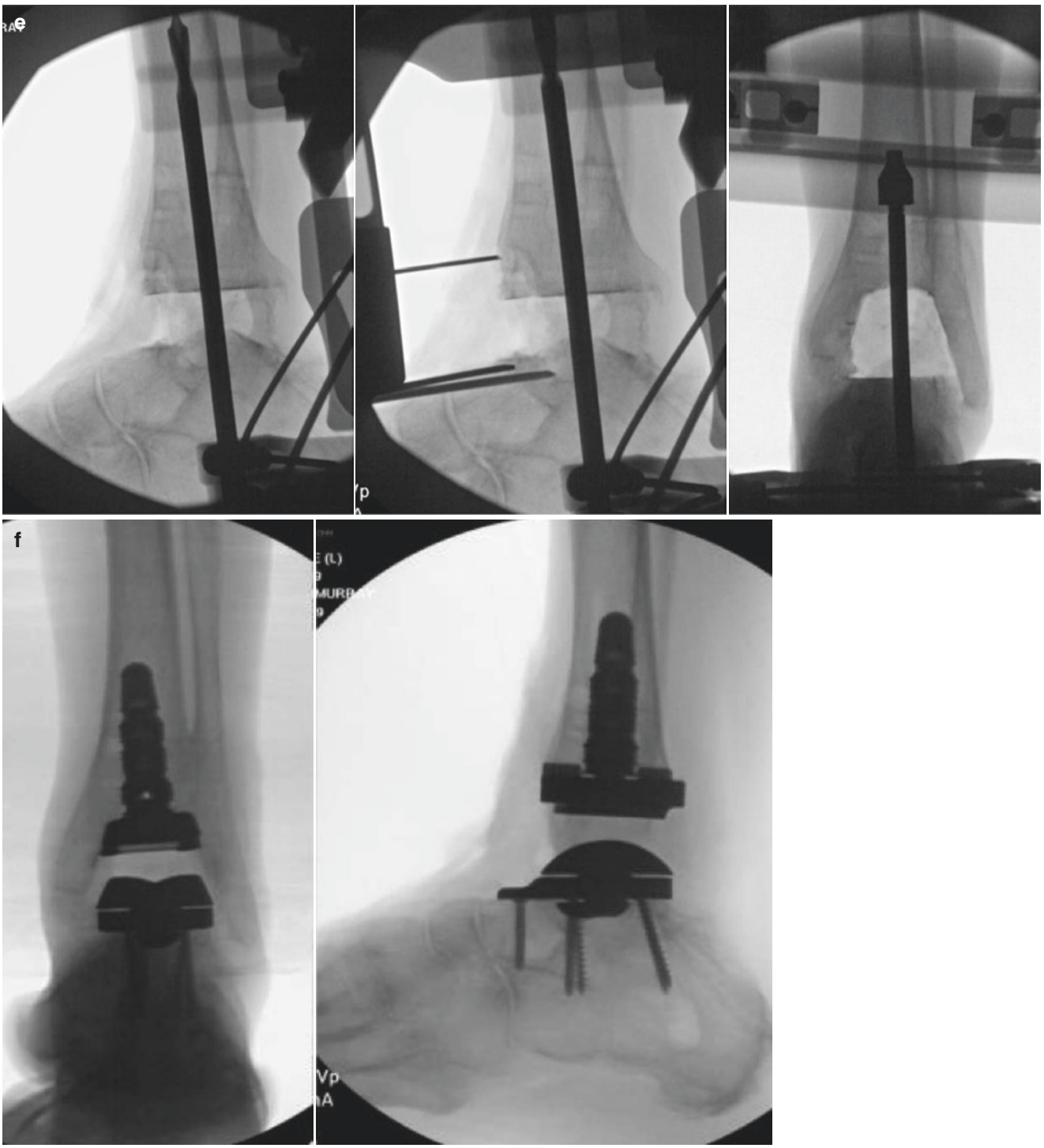


Fig. 31.5 (continued)



Fig. 31.6 (**a**) Radiographs. (**b**) CT scan. (**c**) Prophylactic pinning of medial and lateral malleoli was performed. Tourniquet was then inflated, and a standard anterior approach to the ankle was undertaken. The INVISION Prophecy® tibial guide was placed, and neutral alignment was determined. Guide pins were then placed into the tibia. (**d**) The Agility prosthesis was removed using techniques previously described. The bone cuts of the tibia and talus were performed (with the talus cut being referenced from the tibial cut). Deformity correction was minimal and achieved using the patient specific instrumentation. The INVISION stem reaming guide was then placed. (**e**) The final componentry was placed, and cannulated screws were inserted over the malleoli to help prevent against fracture. Range of motion was excellent in plantarflexion, and a gastrocnemius recession was performed to improved dorsiflexion. (**f**) Over 1 year following revision TAR, the patient continues to do well with maintenance of all components



Fig. 31.6 (continued)

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The Salto Talaris XT Revision Total Ankle Replacement System

32

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Introduction

Total ankle replacement (TAR) is a viable treatment for advanced ankle osteoarthritis, and its short-term and long-term benefits were proven in numerous clinical studies [1–8]. The number of secondary TAR operations is rising, due to the growing frequency of primary TAR and to increasing subsequent clinical follow-up. Secondary TAR includes several different techniques ranging from simple extra-articular repair (e.g., implant retrieval or tendon lengthening) to more complex procedures (e.g., bipolar revision with bone reconstruction). For clarity, we will follow the following definitions, as published by Henricson et al. [9]:

1. *Additional procedure*: non-revisional secondary surgery not involving the joint
2. *Reoperation*: revisional secondary surgery involving the joint
3. *Revision*: removal or exchange of one or more of the prosthetic components with the exception of incidental exchange of the polyethylene insert

Revision total ankle replacement has become more common in recent years. Since 2012, we have used the Salto Talaris XT revision TAR (Tornier, Inc., Bloomington, MN) at our center (Raymond Poincaré Hospital, Garches, France). Prior to that, our technique for revising failed TAR involved prosthesis retrieval followed by ankle or tibio-talocalcaneal arthrodesis with autograft bone graft, which produced acceptable results, despite sacrificing joint mobility. In this chapter, we describe our experience with the Salto Talaris XT revision TAR and present our preliminary clinical results at short-term follow-up. In the first part, we explain the basis and principles of prosthetic revision and describe the different implant components. In the second part, we describe the steps of the operative technique and discuss the various surgical considerations and options.

Principles of Revision Total Ankle Replacement

General Considerations

Recent studies reported that long-term survival of primary TAR is greater than 80% at 10-year follow-up [1, 5, 10, 11]. The complication rate is difficult to determine because the published series are considerably different in terms of patient demographics and arthritis etiology.

Except for infections, long-term TAR failures involve one of the two categories:

(a) Complications unrelated specifically to the prosthesis—their treatment could require an additional procedure or a reoperation:
- Malleolar impingement
- Periprosthetic fracture
- Vascular or neurologic problems
- Chronic instability
- Persistent pain
- Additional hindfoot surgery
- Realignment osteotomy
- Subtalar arthrodesis

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(b) Complications related specifically to the prosthesis or its anchorage—their treatment would require a revision operation or prosthesis explantation followed by ankle or tibio-talocalcaneal arthrodesis using either bone graft [12], interpositional cement spacer [13], or interpositional trabecular metal spacer [14]:
- Poor fixation of the tibial and/or talar prosthetic components
- Osteonecrosis of the talus or distal–lateral tibia
- Dislocation and/or wear of polyethylene insert leading to metal-against-metal damage to the components
- Aseptic osteolysis and cyst formation
- Malleolar pain due to eccentric loading of mobile-bearing polyethylene insert

In case of infection, synovectomy alone showed poor success rates [15], and therefore a two-stage treatment should be considered involving prosthesis explantation with antibiotic-loaded polymethyl methacrylate cement spacer interposition, followed by ankle arthrodesis, tibio-talocalcaneal arthrodesis, or revision TAR.

Revision TAR is the only option that allows preservation of joint mobility in patients with failed primary TAR. Considering the variety of failure causes and mechanisms, revision TAR cannot be performed following identical techniques in all patients and should be considered case by case, as an "à la carte" solution. By analysis of failed TAR prosthetic components, together with our experience with primary TAR [1, 7], we identified the following considerations for revision TAR:

1. In case of unipolar tibial or talar component failure, the revision prosthetic component(s) must be compatible with the primary TAR component(s).
2. In case of tibial component failure, the revision prosthesis must feature a stable anchorage mechanism, regardless of the degree of bone loss encountered.
3. In case of talar component failure, the choice of revision prosthesis depends on the quality and quantity of the remaining bone stock and on the condition of the subtalar joint. If the bone stock is satisfactory, a prosthesis with a short keel allows conservation of the subtalar joint. However, if the bone stock is insufficient and/or the subtalar joint is degenerative, the prosthesis must include calcaneal anchorage.
4. The design concepts for revision TAR should, in addition to the aforementioned considerations, meet the fundamental principles of primary TAR, specifically anatomic articular geometry, conservative bone cuts, and cementless bone anchorage (when possible).

Revision Prosthesis Specifications

The Salto Talaris XT revision TAR satisfies the abovementioned considerations for revision TAR. It includes revision components for the primary TAR Salto Talaris Anatomic Ankle Prosthesis (Tornier, Inc., Bloomington, MN) and thus features a fixed-bearing polyethylene insert assembled on the tibial component (Fig. 32.1). Cementless fixation of both tibial and talar components is possible due to the plasma-sprayed titanium on the metallic component surfaces. The articular geometry of the revision implant is exactly identical to that of the primary TAR, with an anatomic tapered talus (Fig. 32.2). The primary and revision TAR prostheses are therefore perfectly compatible, with the exception of the size "zero" primary size range, which is not available in the revision size range.



Fig. 32.1 Lateral view of the assembled Salto Talaris XT revision total ankle replacement with the revision tibial component and short-stem flat-cut talar component



Fig. 32.2 Angled view of a sloped-cut long-stem talar component demonstrating the features of the articular surface

Salto XT Revision Tibial Component

The tibial component, available in three sizes, comprises a base plate with a 40-mm-long keel that is sufficiently long for adequate anchorage within healthy metaphyseal bone, even in patients with substantial tibial bone loss. This blade-like keel is relatively thin and therefore minimizes loss of remaining bone. Its implantation requires opening a cortical window as described in more detail below. The keel may be locked in place with one or two screws up to 4.5 mm in diameter.

Salto Talaris XT Revision Polyethylene Insert

The revision polyethylene insert is identical to that of the primary polyethylene insert system. The primary polyethylene insert, when combined with the 4-mm-thick tibial component, is available in four sizes specifically 8, 9, 10, and 11 mm. The revision polyethylene insert, when combined with the 4-mm-thick tibial component, is available in an extended range of sizes including 13, 15, 17, 19, and 21 mm.

The systematic use of fixed-bearing prostheses for primary TAR, which in our opinion is a sensible choice, is yet to be clinically evaluated in the long term. For revision TAR, however, the use of fixed-bearing implants is indispensable, because of larger bone resections and greater risks of instability. The implantation of a fixed-bearing revision TAR, as for fixed-bearing primary TAR, requires accurate relative alignment of the tibial and talar components whether unipolar or bipolar revision is performed.

Salto Talaris XT Talar Component

The talar component is available in three models (Fig. 32.3) and all have identical articular geometries:

1. The "flat-cut short-stem" revision talar component (Fig. 32.3a) features a flat cut (Fig. 32.4a) and a keel slightly deeper than that of the primary talar component (Fig. 32.4b, c). The "flat cut" of the revision component is intended to compensate for bone lost during retrieval of the primary component and facilitates trials for antero-posterior, mediolateral, and rotational alignment. The keel slot is prepared after final position and orientation of the trial components, which can be verified radiographically during the operation, and rotational stability is ensured with a posterior anti-rotation fin.
2. The "flat-cut long-stem" revision talar component (Fig. 32.3b) features the same flat talar cut, combined with a 55-mm-long tapered keel to enable firm calcaneal fixation.
3. The "sloped-cut long-stem" revision talar component (Fig. 32.3c) is identical to the latter, but its cut is inclined 12° posteriorly to accommodate a 9-mm posterior talar extension augment, which helps compensate for severe talar bone loss.

Clinical Practice

Revision TAR using the Salto Talaris XT revision TAR must be preoperatively planned, after complete clinical examination and radiographic assessment, including weight-bearing ankle radiographs and high-resolution computed tomography scans with the ankle in neutral position (90° of dorsiflexion, 0° of inversion/eversion). The radiographs should be compared to all previous radiographs. The vascular condition of the lower limb must be verified in case of any doubt.

Once the cause of failure of the primary TAR is determined, the indication for revision TAR can be confirmed, and the operation can be planned in detail. The surgeon must anticipate any complementary surgical procedures that may be necessary and prepare for all potential technical difficulties that could arise:

- Unipolar or bipolar revision:
  1. In case of bipolar revision, compatibility with the previous implanted components is not necessary. Surgical exposure is better.
  2. In case of unipolar revision, compatibility with the previously implanted components is compulsory. An isolated talar revision will result in reduced exposure.

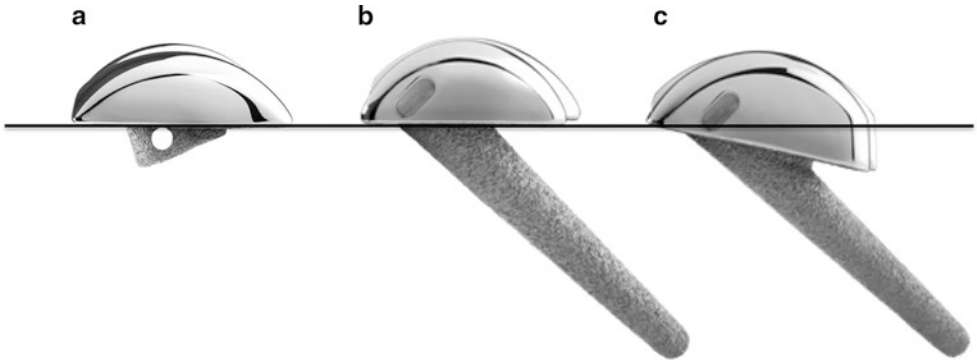


Fig. 32.3 Salto Talaris XT revision talar component, lateral view: flat cut, short stem (**a**); flat cut, long stem (**b**); and slopped cut, long stem (**c**)

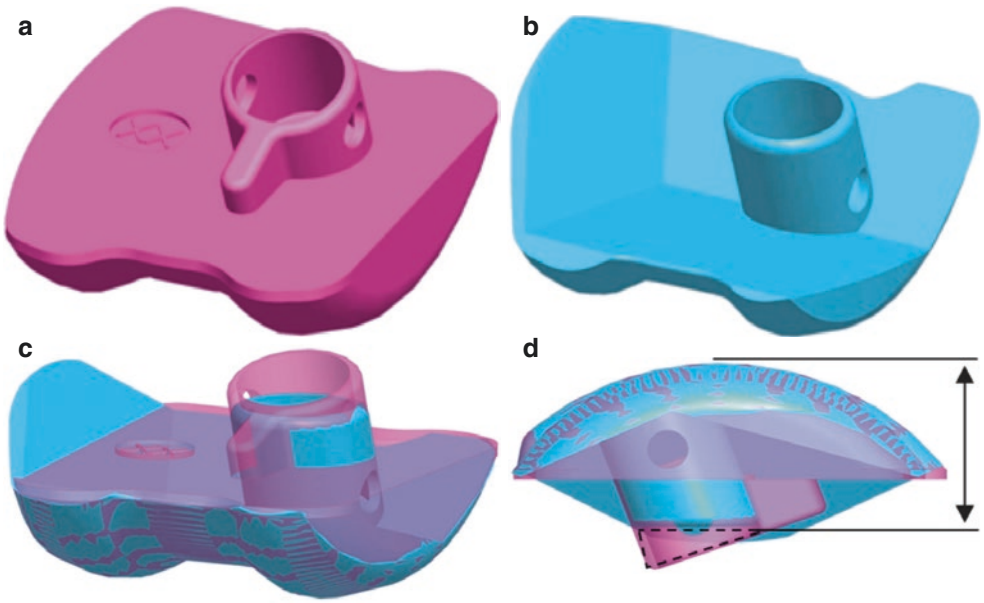


Fig. 32.4 Difference between the talar stem for the Salto Talaris XT revision flat-cut short-stem (*pink*) and Salto Talaris (*blue*) talar components. Flat cut, short stem, inferior view (**a**); Talaris talus, inferior view (**b**); overlapping of both talar components, inferior view (**c**); and overlapping of both talar components, lateral view (**d**)

- Tibial bone stock:
  For all revision cases, resections should be economical yet sufficient to grant immediate metallic component stability, which is further reinforced by the prosthetic keel. In the presence of bone cysts or cavitation, allograft or preferably autograft bone grafting may be used to fill residual gaps, but the initial metallic component stability must not rely on the grafted construct. Note that in patients with osteopenia, an intraoperative fracture is likely, and its repair must be anticipated, including osteosynthesis material and potential surgical approach.
- Talar bone stock and the subtalar joint:
  - If the talar bone stock is sufficient using a standard TAR, select a "flat-cut short-stem" component.
  - If the talar bone stock is insufficient, select a "long-stem" component, either with the "flat cut" or with the "sloped cut" which require concomitant subtalar arthrodesis.
  - The same principles of economical bone resections, initial metallic component stability, and complementary bone grafts must be respected.
- Periarticular calcifications can be observed and analyzed (i.e., number, location, and volume) using preoperative computed tomography scans. They must be completely removed at the start of the operation as this improves joint exposure.
- Ligament laxity or imbalance can be assessed during preoperative clinical examination, especially in cases of failure due to prosthetic component subluxation. The alternatives could be ligament release or reconstruction to achieve acceptable stability during kinematic tests with the trial components in place.
- Tendon lengthening may be performed if necessary, particularly tendo-Achilles lengthening in cases of stiff joints with equinus contracture.

Surgical Technique of the Salto XT

The patient is placed on the operating room table in the supine position. The tibial metaphysis usually provides sufficient volume for autogenous bone graft, but the iliac crest

must be available within the operating field, in case additional bone graft is required. A pneumatic thigh tourniquet must be used before making the incision. The same anterior approach of the primary TAR operation is usually followed. The incision must be long enough, to avoid exertion of shear forces within the skin, which could lead to cutaneous problems. Intraoperative image intensification control is often helpful for implant positioning.

Salto Talaris XT Revision Tibial Component Preparation

Tibial preparation requires, first of all, removal of failed TAR components, followed by bone debridement and lavage. The tibial alignment guide should then be fixed with two pins: the first on the anterior tibial tuberosity and the second on the tibial pilon (Fig. 32.5). The position and orientation of the tibial alignment guide can be adjusted to the tibial axis and desired slope. The optimal alignment is generally that of the tibial axis. The cutting block is fixed on the distal portion of the alignment guide. It enables selection of the required resection level, as well as the optimal component size, internal–external rotation, and mediolateral position (Fig. 32.6). It is worth noting that the tibial resection should be minimal as it is merely required to produce an even surface of fresh bone. Once the tibial resection is complete, a talar cutting block can be mounted on the distal end of the tibial alignment guide if talar revision is also required (Fig. 32.7), as described in the forthcoming section. When the tibial alignment guide is removed, a custom osteotome is used to prepare the cortical window to accommodate the tibial keel (Fig. 32.8). The trial tibial component can then be inserted and assessed for positioning and fixation.

Salto Talaris XT Revision Talar Component Preparation

Talar preparation is less straightforward to describe because of the variety of options depending on the indications for revision TAR. If a "flat-cut" prosthesis is chosen, the talar resection can be performed using the talar cutting block, mounted on the tibial alignment guide while still in place (Figs. 32.7 and 32.9). The foot must be maintained in 90° of dorsiflexion, and the hindfoot should be held with the desired physiological valgus. If a "sloped-cut" component is to be used, the talar resection must be performed freehand. Trial components are available for each model to enable adjustment of internal–external rotation and mediolateral and anteroposterior position and hence ensure perfect alignment of the tibial and talar components, which is compulsory for fixed-bearing systems (Fig. 32.10). Only after the talar trial component is placed in the optimal position and stabilized with two pins could the slot for the talar anchorage is prepared, whether for short or long stems. The slot for "long-stem" components is prepared using a cannulated reamer. Arthrodesis of the subtalar joint could be performed by a



Fig. 32.5 Tibial extramedullary alignment guide

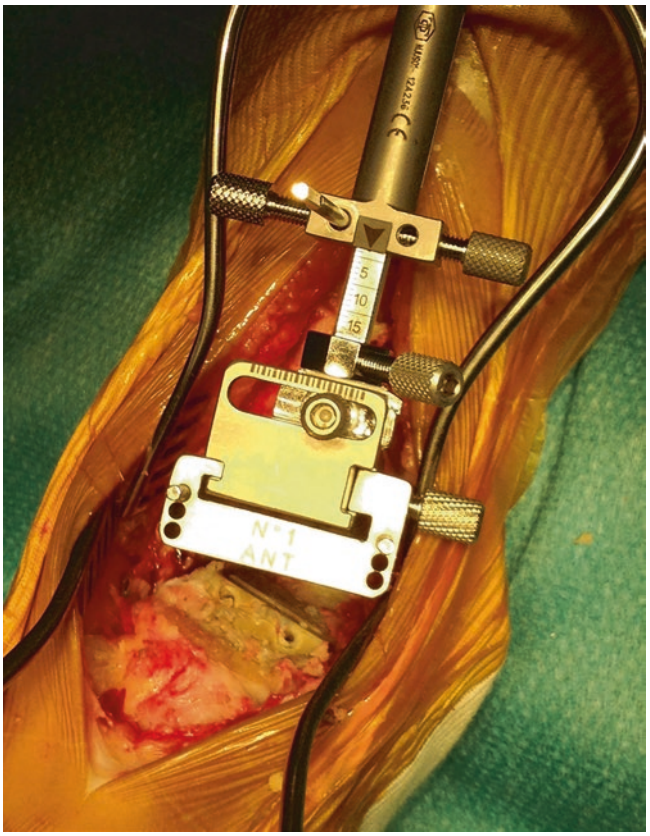


Fig. 32.6 Tibial cutting block, perioperative view

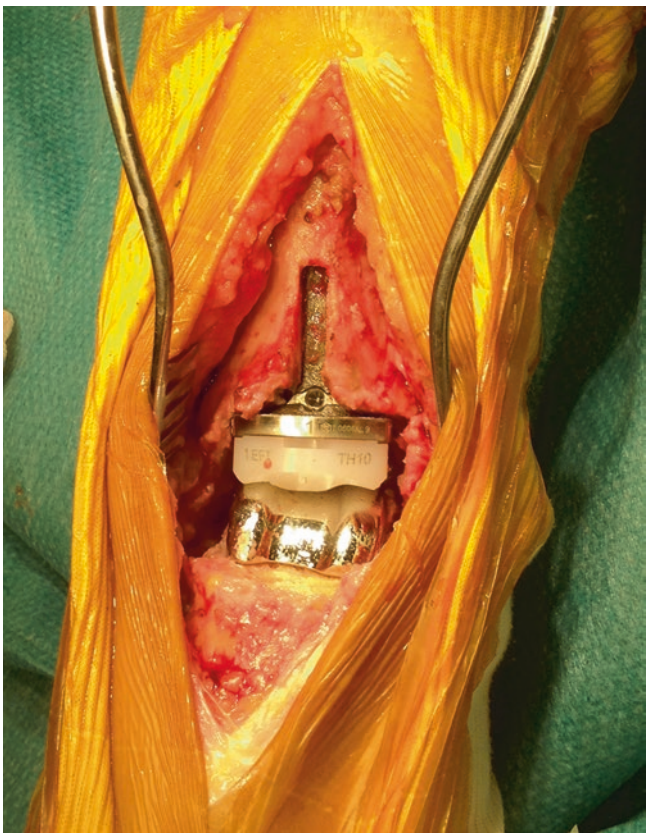


Fig. 32.8 Salto Talaris XT revision tibial and short-stem flat-top talar components, definitive components, intraoperative view

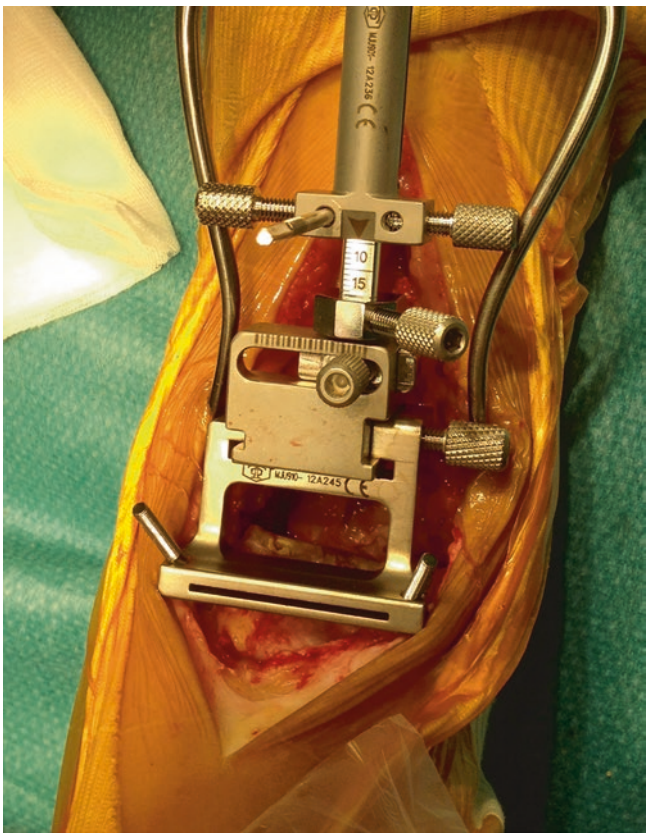


Fig. 32.7 Talar cutting block, intraoperative view

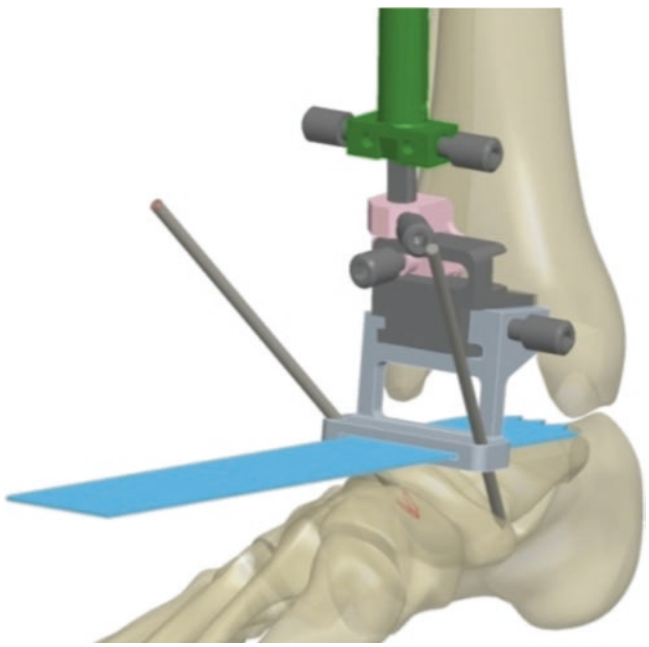


Fig. 32.9 Talar cutting block, schematic drawing of the flat-top talar preparation



Fig. 32.10 Setting of trial talar component, intraoperative view

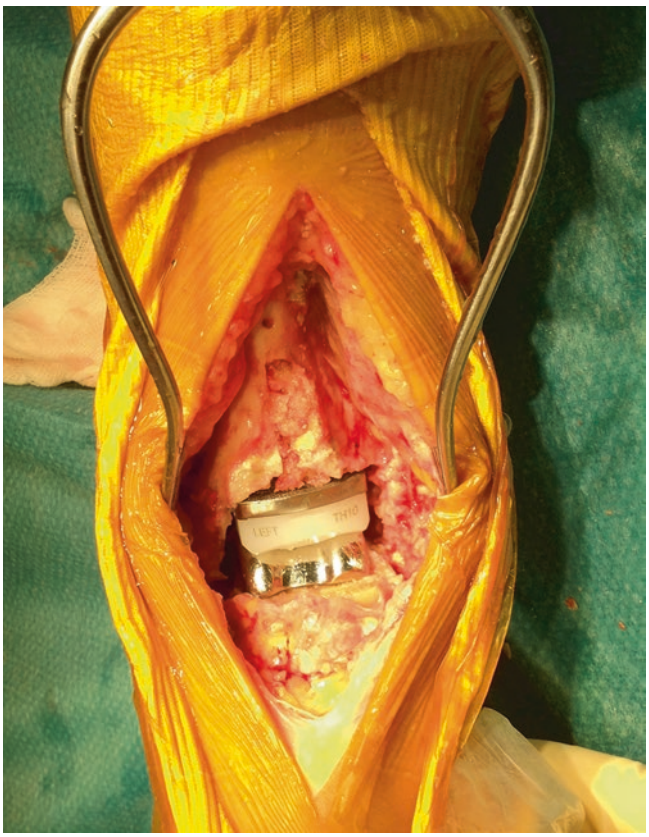


Fig. 32.11 Impaction bone grafting of the tibial window, intraoperative view

short sinus tarsi approach. When the talar trial is in place, the appropriate size of polyethylene insert can be selected and verified by laxity and kinematic tests.

Salto Talaris XT Variant Techniques

Locking of the tibial keel using additional screws is seldom needed. A slightly modified surgical technique could be used for unipolar revisions, provided that perfect alignment of the tibial and talar components can be achieved, relative to one another. In unipolar tibial revisions, the primary talar component is left in place, and the revision tibial implant must be strictly aligned to it, prior to preparation of the slot/window of the tibial keel. In unipolar talar revisions, the tibial component is unchanged, and the revision talar component must conform to its position, prior to preparation of holes for the stems.

Final Steps and Postoperative Care

After implanting the final talar component, the final tibial component is assembled with the selected polyethylene insert and implanted, locked with screws if necessary, and the tibial window is impaction bone grafted (Fig. 32.11). Hemostasis is verified and the patient is immobilized non-weight bearing for a period of 6 weeks. The incision should be examined 2 weeks postoperatively to screen for any healing problems and initiate rapid treatment if need be. Physiotherapy is started 5 weeks postoperatively, with weight bearing, after routine clinical and radiographic examination.

Our Experience

At our center, we performed 11 TAR operations using at least one Salto Talaris XT revision TAR component, between August 2012 and November 2014. The patients included nine women and two men, with mean age 56 years (range 34–81 years). There were two primary and nine revision operations, on six left and five right ankles. Their clinical records, including the American Orthopaedic Foot and Ankle Society (AOFAS) Hindfoot–Ankle Scoring Scale, are stored in two dedicated databases authorized by the national commission for information systems and liberty (the French Ankle Arthroplasty Register and a database managed internally from our center).

Primary Ankle Replacement with the Salto Talaris XT Revision System

For the two primary operations, a Salto Talaris TAR tibial component was implanted, in combination with a Salto Talaris XT revision TAR "flat-cut" talar component. The first TAR was on a patient with rheumatoid arthritis, for which a "long-stem" talar component was used to perform subtalar arthrodesis. The second TAR was on a patient with advanced osteoarthritis, for which a "short-stem" talar component was used to compensate for extensive talar lesions. There were no interoperative complications. The first patient has an AOFAS Hindfoot–Ankle score above 80/100 at a follow-up of 1 year. The second patient has a follow-up of only 3 months.

Revision Total Ankle Replacement with the Salto Talaris XT Revision System

Of the nine revision operations, six were bipolar and three were unipolar. All components are in place at 6-months' follow-up. The three unipolar revisions were all for exchange of a Salto Mobile-bearing Prosthesis (Tornier, Inc., Amsterdam, the Netherlands) that had external subluxation and malleolar impingement (Fig. 32.12). One of the unipolar revisions involved a fractured polyethylene insert and tibial component slope defect. There were no interoperative complications. The time for revision after the index operation was 6 years, 6 years, and 12 years, respectively. The mean follow-up of the revision TARs is 9 months (range 6–13 months). The results are good for two patients and fair

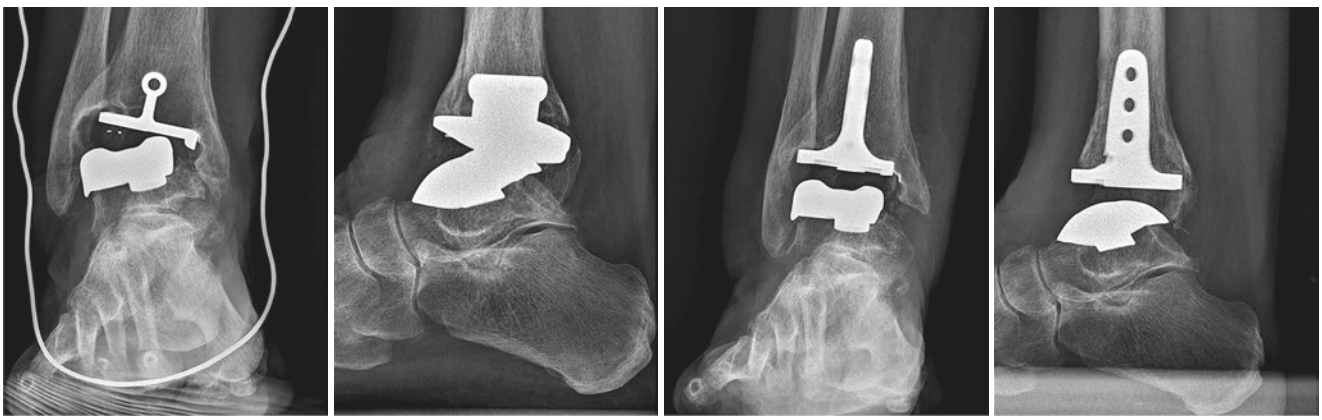


Fig. 32.12 Unipolar tibial revision procedure for subluxation of a mobile-bearing total ankle replacement. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating persistent lateral ankle instability following implantation of a Salto Mobile Prosthesis. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating removal of the index tibial component and conversion to a Salto Talaris XT revision tibial component demonstrating anatomic alignment

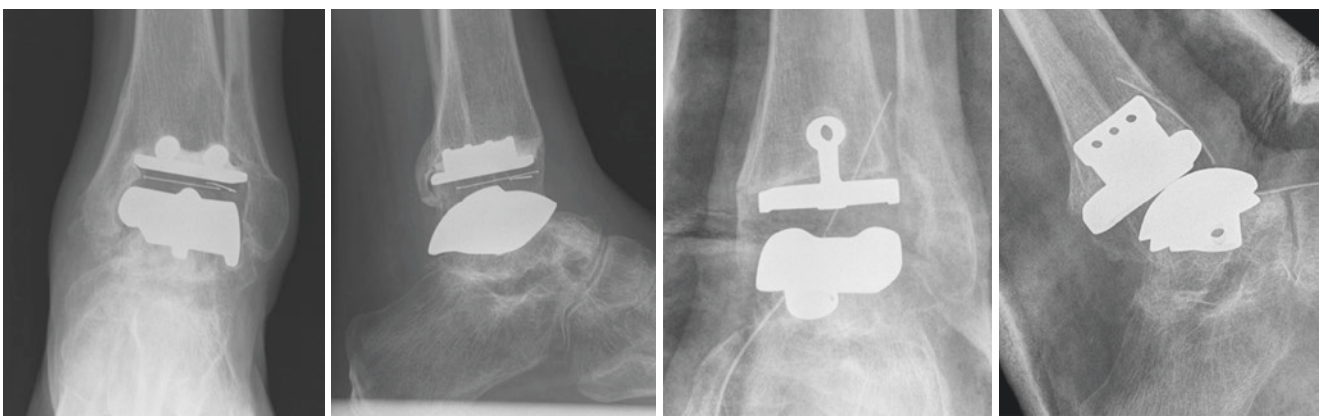


Fig. 32.13 Case of bipolar revision for talar migration. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating persistent lateral ankle instability following implantation of a STAR Prosthesis. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating explantation of the components and conversion to a Salto Talaris standard tibial component and Salto Talaris XT revision short-stem flat-cut talar component demonstrating anatomic alignment

for one patient (AOFAS Hindfoot–Ankle score = 56/100) who has persistent subtalar pain which is under observation.

The six bipolar revisions were for different indications: three for talar component migration, one for bipolar loosening, one for malalignment, and one for tibial cysts that jeopardized prosthesis stability. The retrieved TAR components were three HINTEGRA (Newdeal SA, Lyon, France), two Scandinavian Total Ankle Replacement prosthesis (STAR, Link Inc., Hamburg, Germany), and one Ankle Evolutive System (AES, Biomet Merck, France). The implanted tibial components were four Salto Talaris XT revision models and two Salto Talaris standard components. The implanted talar components were all Salto Talaris XT revision models and included two "flat cut, short stem" (Fig. 32.13); one "flat cut, long stem" (Fig. 32.14); and three "sloped cut, long stem" (Fig. 32.15). Three patients had concurrent isolated subtalar arthrodesis, two by sinus tarsi approach and one by anterior approach. In the latter, the entire talar bone was removed, and a "sloped-cut" talar component was fixed directly onto the calcaneum, and the talar head was stabilized with additional screws (Fig. 32.15). Two autografts were required and one percutaneous tendo-Achilles lengthening was performed. One medial malleolus was fractured intraoperatively and did not require stabilization without osteosynthesis.

We faced no problems specifically related to the Salto Talaris XT revision components or the techniques during any

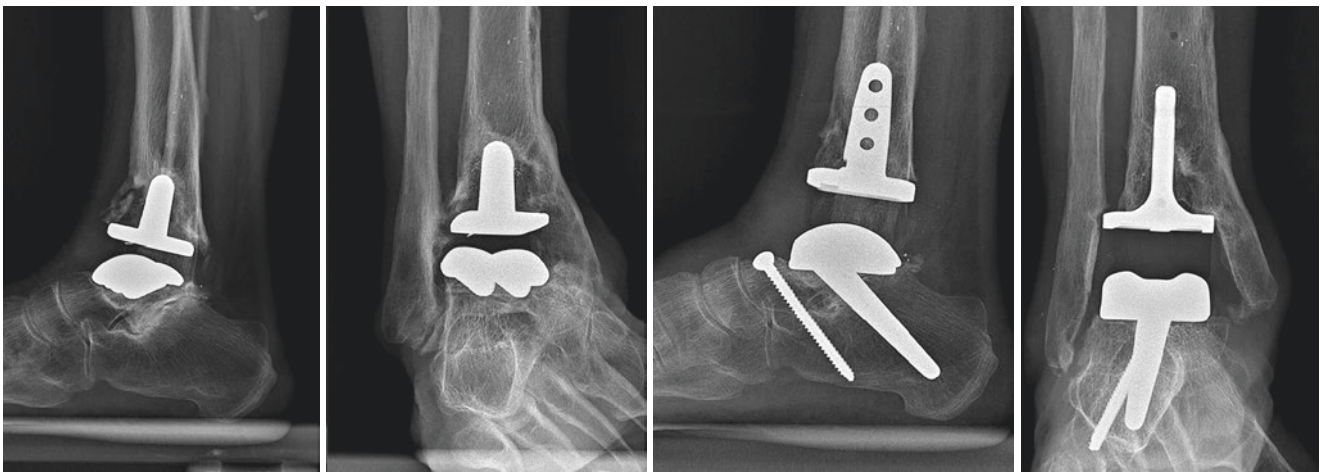


Fig. 32.14 Case of bipolar revision for tibial bone cyst formation. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating persistent lateral ankle instability following implantation of an AES total ankle replacement. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating explantation and conversion to a Salto Talaris XT revision tibial component and long-stem flat-cut talar component and arthrodesis of the subtalar joint

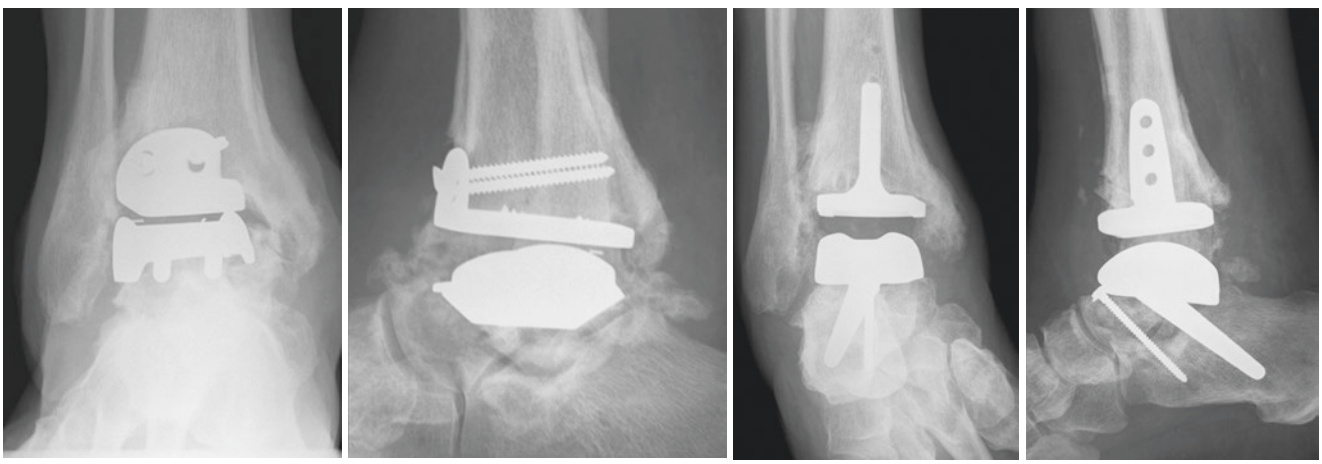


Fig. 32.15 Case of bipolar revision for talar subsidence. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating persistent lateral ankle instability following implantation of an HINTEGRA total ankle replacement prosthesis. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating explantation and conversion to a Salto Talaris XT revision tibial component and long-stem sloped-cut (posterior augmented) talar component and arthrodesis of the remaining subtalar joint

of the operations. Postoperatively, two patients presented cutaneous complications that required reoperation without implant retrieval, one of which had rheumatoid arthritis. These complications emphasize the difficulty of this revision operation in patients with multiple previous surgeries around the operated site.

Conclusions

Primary TAR has been increasingly performed over the past 25 years to treat disabling arthropathy of the ankle joint. The performance and longevity of TAR are improving due to increasing surgical experience and continuous enhancements to prosthetic component design features. Nevertheless, published series report few early or late failures and/or poor functional outcome that may require prosthesis explantation followed by ankle or tibio-talocalcaneal arthrodesis. The difficulties in achieving arthrodesis consolidation, with the frequently mediocre functional outcome of arthrodesis, have led to attempts of similar revision components as seen in hip and knee arthroplasties.

The number of secondary TAR operations is rising, due to the growing frequency of primary TAR on the one hand and because patients are increasingly demanding conservation of mobility. The Salto Talaris XT revision TAR system range offers compatibility with primary TAR components and modularity for unipolar or bipolar revisions with various degrees of bone loss. This implant system satisfies the criteria for revision TAR. Moreover, the fixed-bearing concept that it shares with primary TAR prostheses seems most suitable or even indispensable in this type of revision operation. The operation obviously requires a high level of expertise. The preliminary results seem to satisfy continuation of this option, which is worth a prospective randomized clinical assessment at a later stage.

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Custom Metallic Prostheses After Failed Total Ankle Replacement

33

Chelsea S. Mathews and Michael Brage

Introduction

The incidence of TAR has increased dramatically in the last 30 years [1, 2]. Although the techniques and implants continue to be developed, TAR is improving but has not reached the survivorship experienced in hip and knee arthroplasty. Knowledge of revision components and technique remains critical for surgeons who perform TAR. Failed total ankle replacement can be a catastrophic complication for both the patient and surgeon. The most devastating loss is usually on the talar side of the joint where there is often little to no structural support for a conventional or revision talar prosthesis. The development of a custom metallic prosthesis or total talus prosthesis (TTP) has allowed patients with significant bone loss to maintain a total ankle replacement and avoid complicated arthrodesis or amputation. Early talar prostheses were developed in the late 1970s and early 1980s for treatment of avascular necrosis (AVN) of the talar body [3, 4]. These early implants did not include a metallic talar neck or head as the distal portion of the native talus was used to stabilize the prosthesis. This implant addressed the loss of bone in the talar body but relied on an often precarious talar neck for stable fixation. Talar replacing prostheses have been altered over time in a variety of ways both in construct and in materials used. Its use in total ankle arthroplasty has been developed to replace the entire talus in conjunction with a tibial bearing surface as a revision TAR. In cases where the amount of bone loss in the talus prevents the use of revision implants, the TTP is proving to be a reliable and predictable option that provides continued motion at the tibiotalar and oftentimes the subtalar joint (Fig. 33.1).

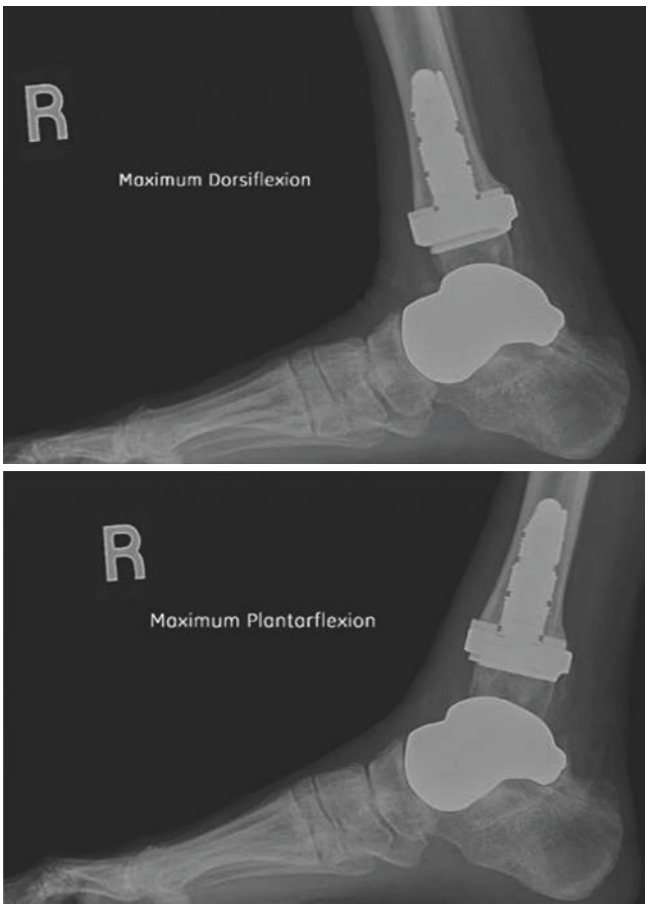


Fig. 33.1 Radiographs demonstrating an arc of 25 degrees ROM at implant interface

Indications

The main indication for TTP is subsidence of the talar component resulting in substantial bone loss (Figs. 33.1, 33.2, 33.3, 33.4, 33.5, 33.6, and 33.7). In many cases of failed TAR, there is significant metallosis or osteolysis present on

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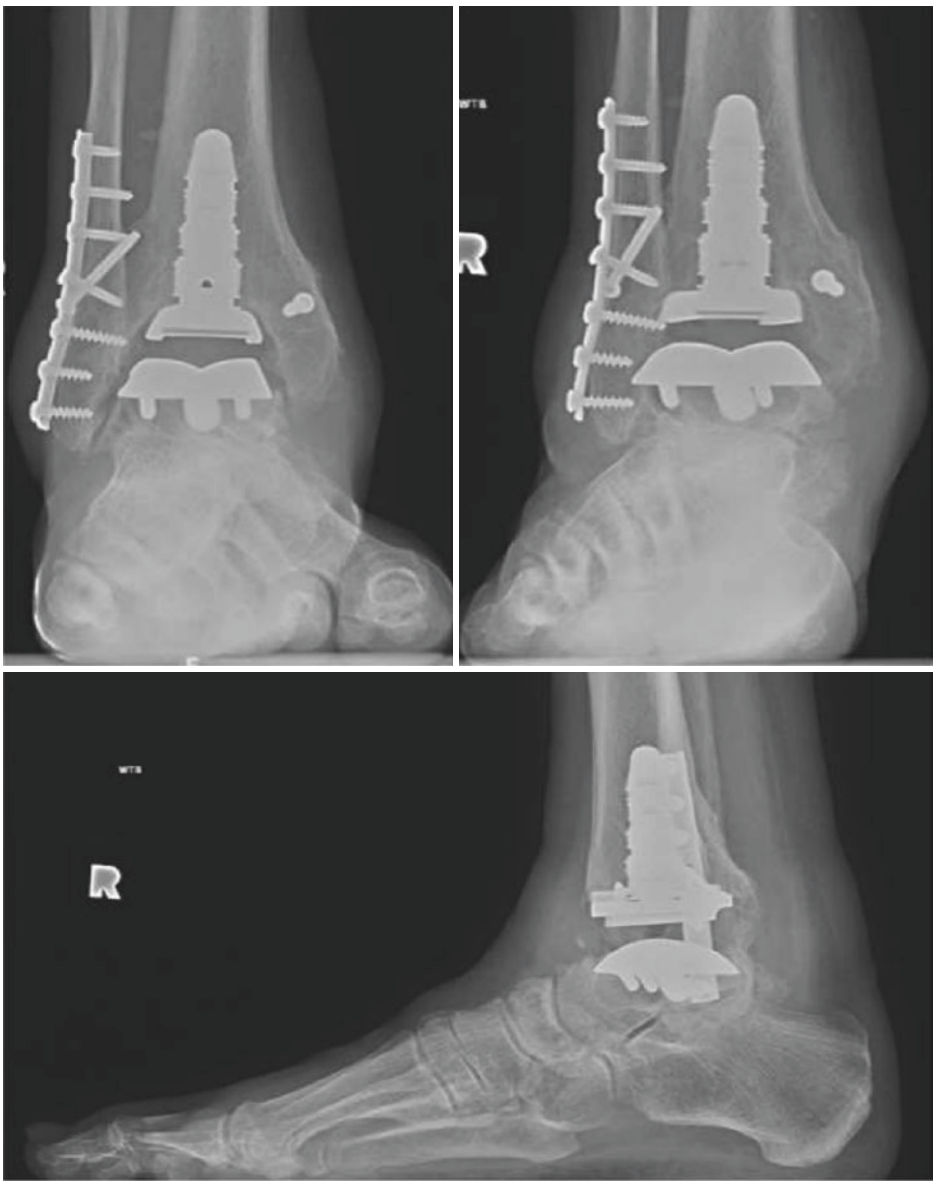


Fig. 33.2 Patient A 5 years' s/p TAR with significant osteolysis and talar bone loss



Fig. 33.3 Sagittal CT cut of Patient A showing osteolysis of the talus and fracture of the inferior talar neck

both tibial and talar sides; however, the talus has a more limited blood supply and far less volume to begin with. Talar bone loss is evaluated with standard radiographs and a CT scan. Clinical judgment is crucial as there is no definitive measure of talar bone loss to indicate whether salvage is an option or not.

Contraindications

Active infection or chronic infection of TAR is a direct contraindication to TTP. Relative contraindications include poor soft tissue conditions, vascular pathology, poorly controlled diabetes mellitus, obesity, and immunosuppression (i.e., from an organ transplant). Prior subtalar arthrodesis alters the anatomy such that TTP would be technically very difficult both to manufacture and to execute. It is not recommended in such instances.

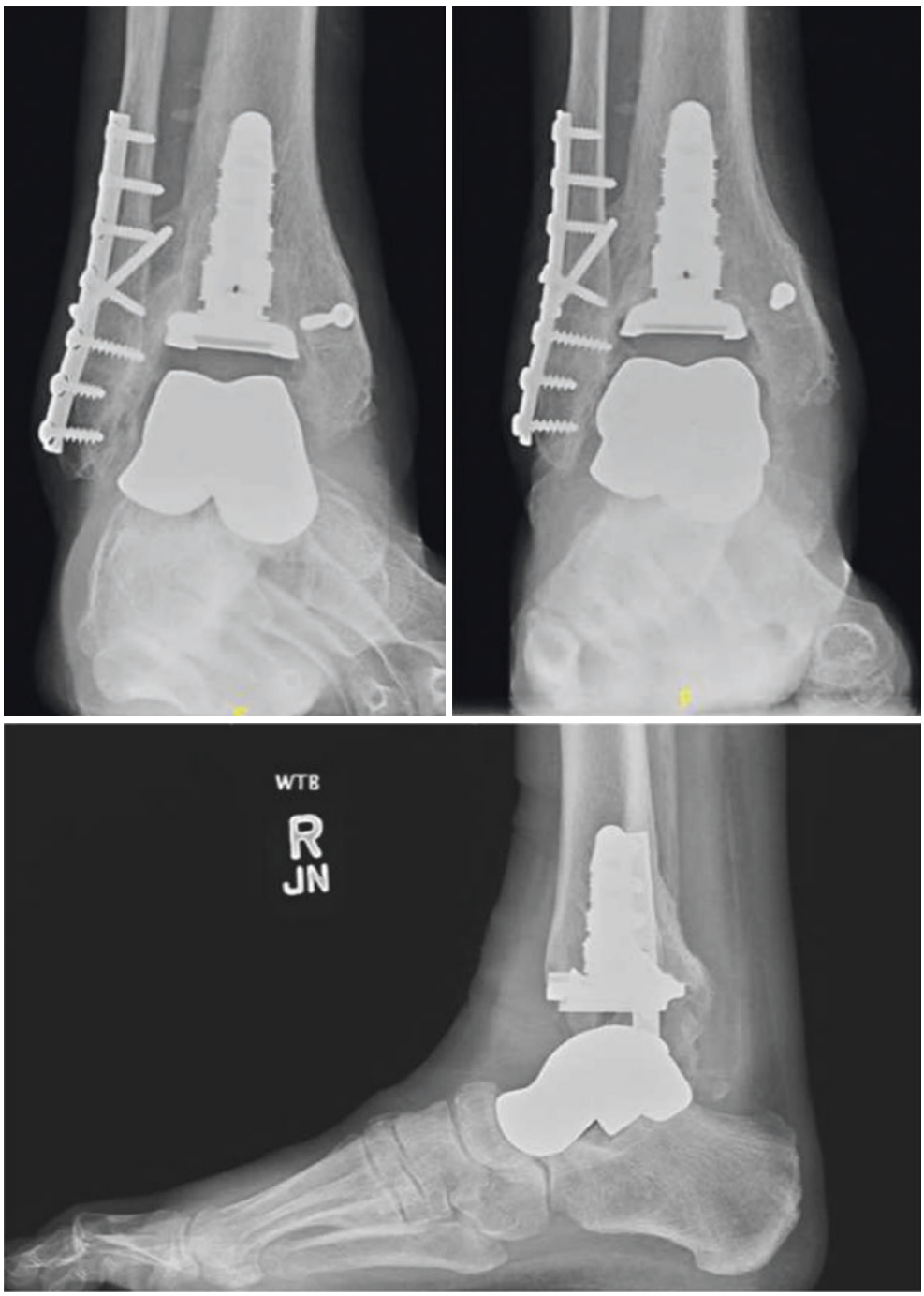


Fig. 33.4 Patient A 6 months' s/p revision TAR with TTP

Preoperative Planning

Initial evaluation and preoperative planning begins with weight-bearing radiographs of the ankle and foot. A weight-bearing CT is then used to better appreciate the bony deficit, potential arthrosis in the subtalar joint, and lower limb alignment. The CT scan must include the contralateral limb in order to evaluate the native talus anatomy. The native talus will be used as the template for the custom metallic prosthesis for reverse engineering. The custom talus is usually made in two heights; the first matched with the native talar height and a second version which is 1–1.5 mm less. The two options provide opportunity for an improved fit as there are no means for intraoperative adjustments to the prosthesis. The tibial component and size must be preoperatively planned so that the custom prosthesis can be formatted to articulate properly. If subtalar arthritis is present and treatment is



Fig. 33.5 Patient B s/p TAR in 1999 with poly-exchange in 2002, now 18 years' s/p index procedure

indicated, the TTP can be made with a plantar trabecular surface to promote osseous integration into the calcaneus (Fig. 33.8). The implant may be manufactured with pilot holes for arthrodesis screws to be placed through the neck of the prosthesis into the calcaneus (Figs. 33.8 and 33.9). The trajectory and diameter of these screws are customizable. A webinar with the company's engineers is performed when constructing the prosthesis. The talar dome is fashioned to copy the implant of the surgeon's choice. Bone deformity and ligament and muscle deficiencies must be addressed either during or before the TAR. Well-aligned, well-balanced ankles may be converted to TTP in one stage, while advanced defor-



Fig. 33.6 Sagittal CT cut of Patient B showing severe talar and tibial bone loss

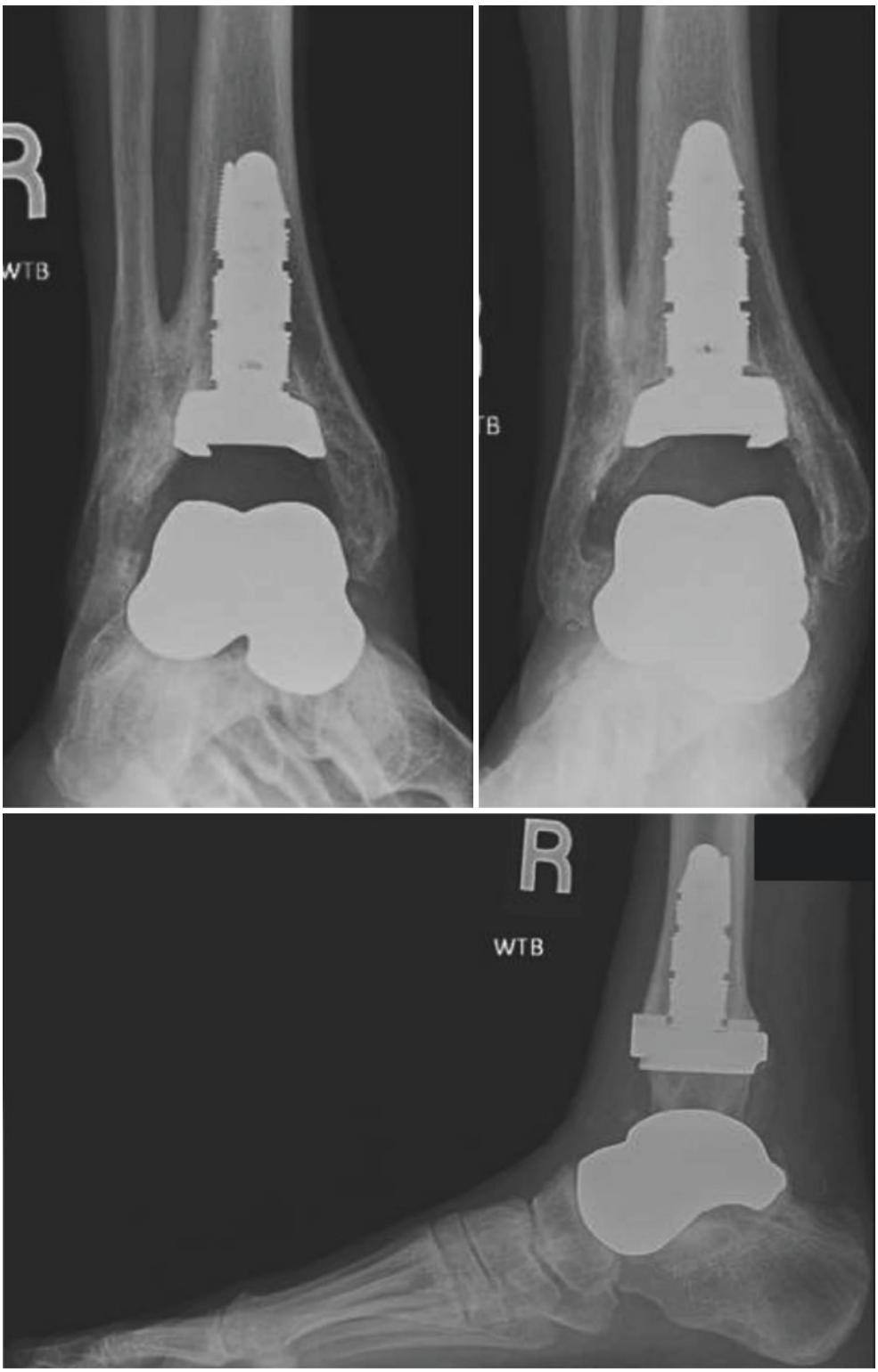


Fig. 33.7 Patient B 9 months' s/p revision TAA with TTP



Fig. 33.8 Top: Anterior superior surface of TTP – Standard design on the left and design with ST arthrodesis option on the right. Middle: Inferior aspect of the same implants. Bottom: Medial aspect of standard design TTP on the left, lateral surface of ST arthrodesis design on the right

mities and those with ligamentous insufficiency will require two-stage procedures.

Operative Technique

Standard supine position with an ipsilateral hip bump and foam block is used. The leg is prepped and draped as for standard primary or revision TAR. Access to the joint is achieved with a traditional anterior incision although its distal extension may be necessary to achieve access to the head of the talus for excision. Oftentimes, the components are loose in the joint and do not require significant force for removal. Tibial and talar components are removed, and surrounding soft tissue should be debrided to allow for complete visualization and to prevent impingement. The talus is then resected completely. Care should be taken to preserve the articular surfaces of the calcaneus and navicular as the talus is removed. Resection is often made easier by osteotomizing the remaining bone using a straight osteotome in the sagittal plane across the posterior body and along the talar neck and removing the fragments piecemeal. Intraoperative fluoroscopy is used to confirm complete excision of the talus. A complete posterior capsular debridement may be necessary to allow easier insertion of the talar prosthesis and to improve postoperative range of motion.

The tibia is then instrumented with the revision component selected preoperatively. This portion of the case is performed using standard technique of revision TAR according to the surgeon's choice of implant. It is crucial to maintain/obtain appropriate axial rotation of the tibial component when making cuts and preparing for implantation as there is no ability to correct rotation through the talar component. When the tibial implants are trialed, the provisional total talus can be inserted to ensure a stable fit. The talar trial usually has a handle attached to the anterior neck to ease insertion and removal of the trial (Fig. 33.10). This component is produced in both sizes so that the best fit can be determined prior to inserting the custom prosthesis. The trial implants should be stable to varus/valgus stress, and the talonavicular joint should be congruent on fluoroscopic evaluation.

The definitive implants can then be placed into the tibia and the talus can be inserted into the void. The surface of the implant should be protected during insertion to avoid scratching the articular portions. Insertion of the final implant can be more difficult than the trial as there is no handle or attachment device for the final implant. In our experience, we find it easiest to insert the talus into the void with the foot plantar flexed and then use a smooth instrument to shoe-horn the navicular over the head of the talar prosthesis. Again, great care must be taken to protect the cartilage of the native navicular. If subtalar arthrodesis is indicated and planned, the subtalar joint must then be prepped, and screw fixation is used through the implant as preoperatively planned. A small amount of morselized graft from the tibial cuts may be used as graft. Stability of the implant must then be assessed both clinically and radiographically. Radiographs of the foot must be obtained in addition to routine radiographic series used in TAR. The talonavicular joint congruity must be confirmed prior to closure.

Postoperatively, the patient is immobilized in a splint for 2 weeks. Gentle active range of motion is allowed at 2 weeks postoperatively. Progressive weight bearing is initiated at 6 weeks postoperatively.

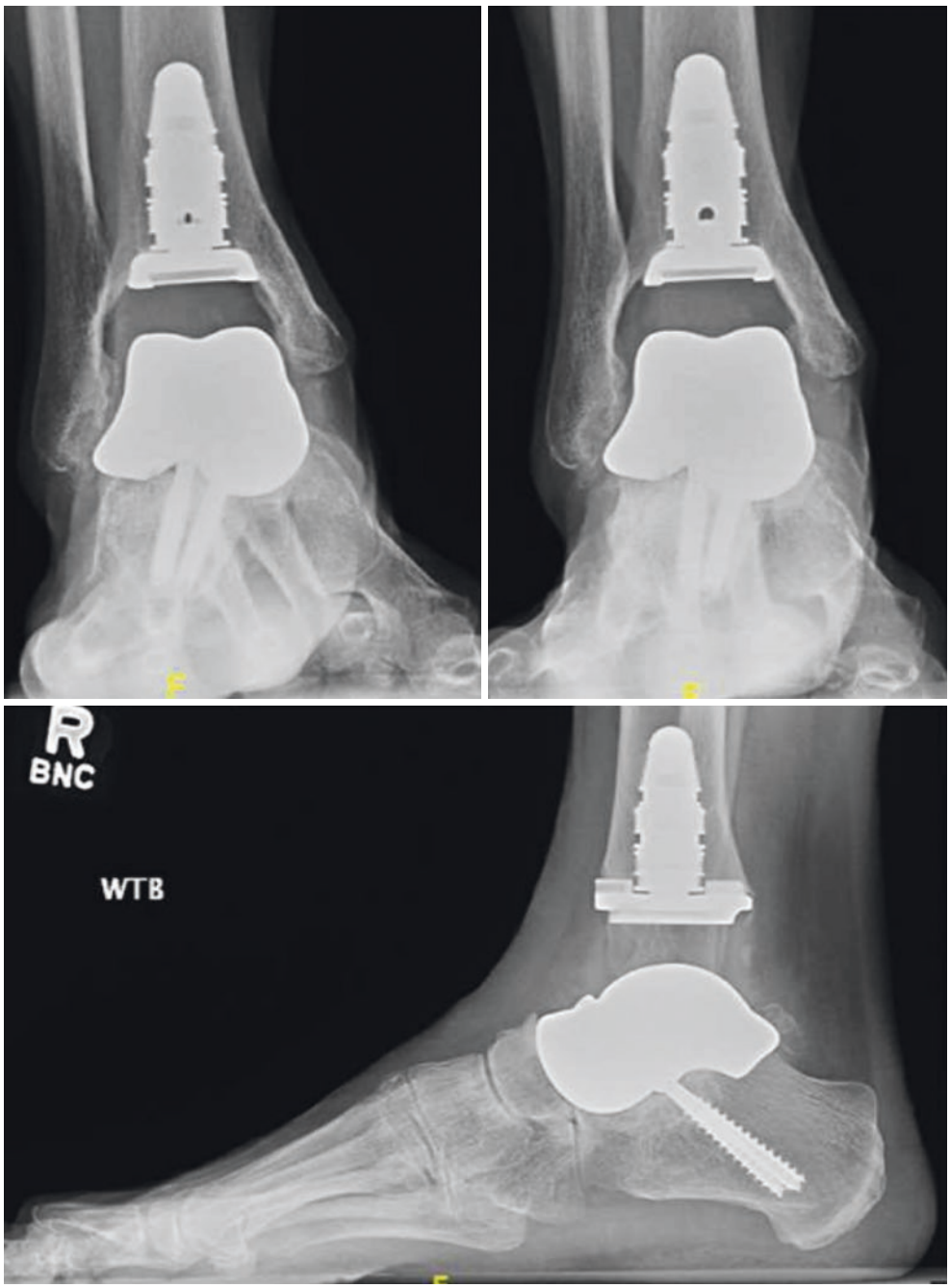


Fig. 33.9 Status-post TAR with TTP and subtalar arthrodesis

Pearls and Pitfalls

- The implant manufacturer has a CT protocol that must be followed. Confirm guidelines are in place prior to ordering scans to avoid unnecessary imaging costs/radiation.
- In the case of a collapsed talus that has shortened significantly, two lamina spreaders can be placed in the joint to stretch the soft tissues. Collateral ligaments may need to be released incrementally and a higher tibial cut may be needed as well.
- Ensure that axial rotation of tibial components is accurate prior to making bony cuts and again prior to definitive implantation. This should be carefully inspected when the talar trial is inserted.

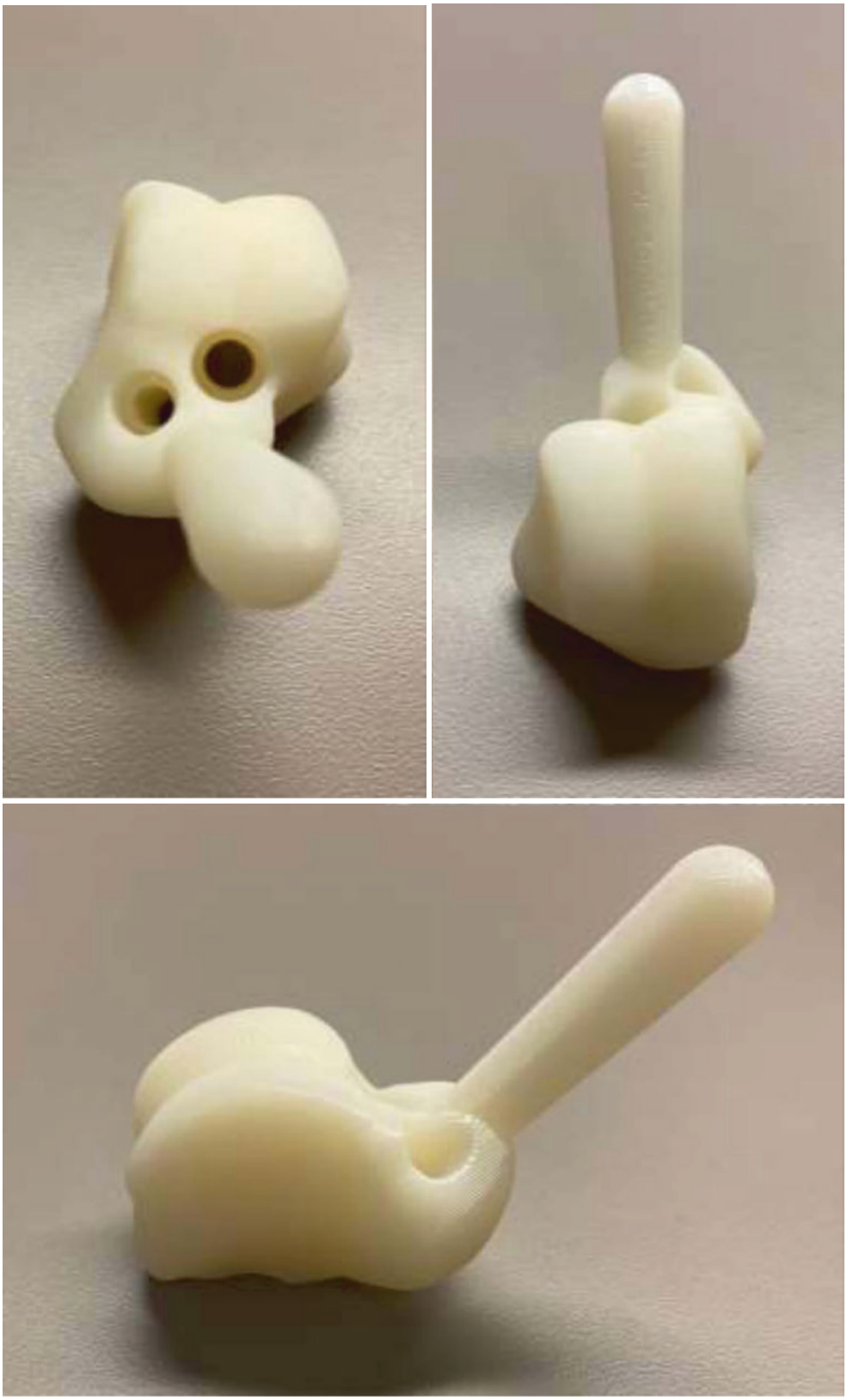


Fig. 33.10 Trial TTP with insertion handle for easier manipulation. This particular implant was designed for ST arthrodesis as well

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34 Tibio-Talo-Calcaneal Arthrodesis After Failed Total Ankle Replacement: Autograft and Bulk Structural Allograft Techniques

Mitchell J. Thompson and Thomas S. Roukis

Introduction

Total ankle replacement (TAR) is gaining popularity with comparable results to arthrodesis and even becoming the preferred treatment choice for many patients with end-stage ankle arthritis [1]. Newer primary implants and even revision implants discussed in earlier chapters have provided patients with the ability to maintain ankle range of motion. Although techniques and implants are rapidly improving, revision rates for total ankle arthroplasty have been reported to be around 17–20% over the last 10 years, which is more than double the revision rates for total knee or hip replacements [2, 3]. The most common reasons for failure of a TAR are deep infection, aseptic loosening, and implant failure. Multiple other complications may occur such as subsidence, technical errors during operative implantation resulting in a maligned implant, and fracturing of the surrounding osseous structures during the postoperative period [4, 5]. Patients who experience these complications and ultimately failure of their implant will present with increasing pain to their involved ankle with any weight-bearing activity and possibly even at rest if severe enough. The functionality of the ankle will also greatly decrease when the implant has failed, leading to decreased range of motion and ultimately decreased ability to transfer ground reactive forces through the lower extremity. Patients will also likely present with a recent history of increased swelling to the involved ankle and lower leg, concerns for infection that arise when there is swelling, and pain accompanied by increased erythema and lymphangitic streaking.

Radiographs are often the first step when a patient presents with symptoms listed above. Malalignment of the implant and loosening or subsidence of the components, joint effusion, and emphysema are all able to be seen on radiographs if present. Infection of a TAR is often the most urgent complication requiring attention and has been reported to be as high as 4.6% [6]. If clinical and radiographical assessments indicate possible infection, then an aspiration with culture of the aspirate is performed. Oftentimes if the reason for failure is not obvious, a computerized tomography scan (CT scan) can be helpful to better visualize and assess not only the implant but the integrity of the surrounding bone [7].

Once the decision to pursue surgery for a failed TAR is established, the decision needs to be made whether to pursue a revision TAR or a tibio-talo-calcaneal (TTC) arthrodesis. Multiple TAR implants are now indicated for revisional surgeries and are designed to make up for the bone loss encountered during revision surgery [8–11]. There are, however, times where revisional TAR is not a viable option often due to scarce bone stock, usually due to devitalized or minimal residual talar bone. Other challenges often faced are poor soft tissue envelopes or hindfoot malalignment after failure of a primary or revision TAR [12]. When the decision to move forward with a salvage-type procedure after failed TAR is determined, there are multiple options, and this chapter will focus on tibio-talo-calcaneal arthrodesis after a failed total ankle replacement using autogenous and allogenic bone grafting.

Indications

General indications for TTC involve any hindfoot, ankle, or combined deformities which area painful and a significant burden to ones well-being [13]. TTC arthrodesis, more specifically, is often a viable option and indicated for ankle

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and hindfoot pathologies with significant bone loss and deformities, both of which can be seen after failed TAR [14]. Structural bone graft is often needed to fill the void left over after removal of nonviable and/or infected bone after failed TAR. It should be noted that if the bone is infected, a staged approach to TTC with grafting should be utilized to ensure no residual infection is present prior to insertion of graft and hardware.

Contraindications

Contraindications for TTC with autogenic or allograft include any chronic or acute infection [15]. As noted above, infections must be treated in a staged approach usually utilizing a cement spacer with repeated bone biopsies and cultures to ensure no infection prior to implantation of hardware. Other general contraindications include peripheral vascular disease, or any comorbidity that decrease blood flow, increasing the chances of wounding or infection. Finally, patient's overall health status and ability to adhere to postoperative instructions and non-weight-bearing status must be taken into account.

Preoperative Considerations

Significant bone loss at the ankle joint with the need for structural grafting coupled with the weight-bearing nature and anatomy of the ankle joint leaves few constructs that provide the correct amount of stability. The most solid way to revise a failed TAR with bone grafting is to perform a TTC arthrodesis [16]. From our experience, in many cases, the largely destroyed talus is the key which leads to the most commonly used technique: a tibio-talo-calcaneal arthrodesis, typically with bulk allograft if the talus is severely damaged. The most obvious advantage of this procedure is that by involving the calcaneus, a well-perfused, healthy bone can be utilized as a stable basis for reconstructing leg length with the bone grafts of various sizes and origins. Another positive aspect is the ability to anchor the osteosynthesis material between the calcaneus and tibia with the intramedullary nail, plate, and screws or any other technique of fixation, allowing for a more straightforward postoperative management.

Preoperative Planning

Preoperative planning technically begins with initial evaluation, even before surgery is decided upon. If the surgeon was the one to put in the primary or revision implant, then the history may be more straightforward, but this is not always the case, magnifying the importance of a thorough history and physical exam. Important questions to consider are if there were any complications with their initial or revisional surgery, specifically any infections requiring repeat surgeries or PICC lines. This information can shed light on if there is a possibility of any latent infection occurring in the ankle that would need to be addressed prior to implantation of any new hardware and graft. Also, it is important to inquire about any wounding issues that would further compromise the soft tissue to the ankle joint.

Initial radiographs should be obtained, typically three views of the ankle with recommended additional views of a long leg axial, calcaneal axial, charger view, and plantarflexion view of the ankle (Fig. 34.1). These views allow one to assess the implant and surrounding osseous structures. The long leg axial view will allow one to assess any translation of the hindfoot in relation to the axis of the tibia. A calcaneal axial or long leg axial view will show any varus of valgus deformity of the hindfoot in relation to the ankle that would need to be taken into consideration if surgery is pursued. Finally, the charger views and plantarflexion views of the ankle will first allow one to better assess the range of motion at the ankle joint, but also assess if the dorsiflexion and plantarflexion of the foot are truly coming from the ankle itself or are the talonavicular joint compensating for the failed ankle implant.

Larger bone defects or cystic-appearing bone may be better assessed through a CT scan. A CT scan will more precisely determine the size of the boney defect that will be left over after explanation of the implant and debridement of nonviable bone (Fig. 34.2). The CT scan should be done well in advance of the surgical date to allow for proper cross-referencing of the size of the defect along with age and gender of the patient to order a properly matched bulk talar allograft or femoral head allograft.

If there is suspicion of an infection, initial vitals and lab work for infection markers should be quickly obtained. An aspiration of the ankle joint can be a definitive diagnostic tool for infection with culturing of the aspirate. If the surgeon feels comfortable, this can be done in the office the same day, but there are times, especially in revision cases, where buildup of scar tissue can obscure normal anatomical landmarks and an aspiration may best be performed under ultrasound guidance by someone who routinely performs these types of aspirations. All joint fluid aspiration should be sent for culture and await final results before determining surgical plan. If the cultures are negative, then primary TTC arthrodesis may be scheduled to be performed. If the cultures are positive, then a staged procedure will need to be performed, which will be discussed later, with a multidisciplinary care approach.

The condition of the soft tissues and previously used surgical approach(s) is an important consideration for surgical

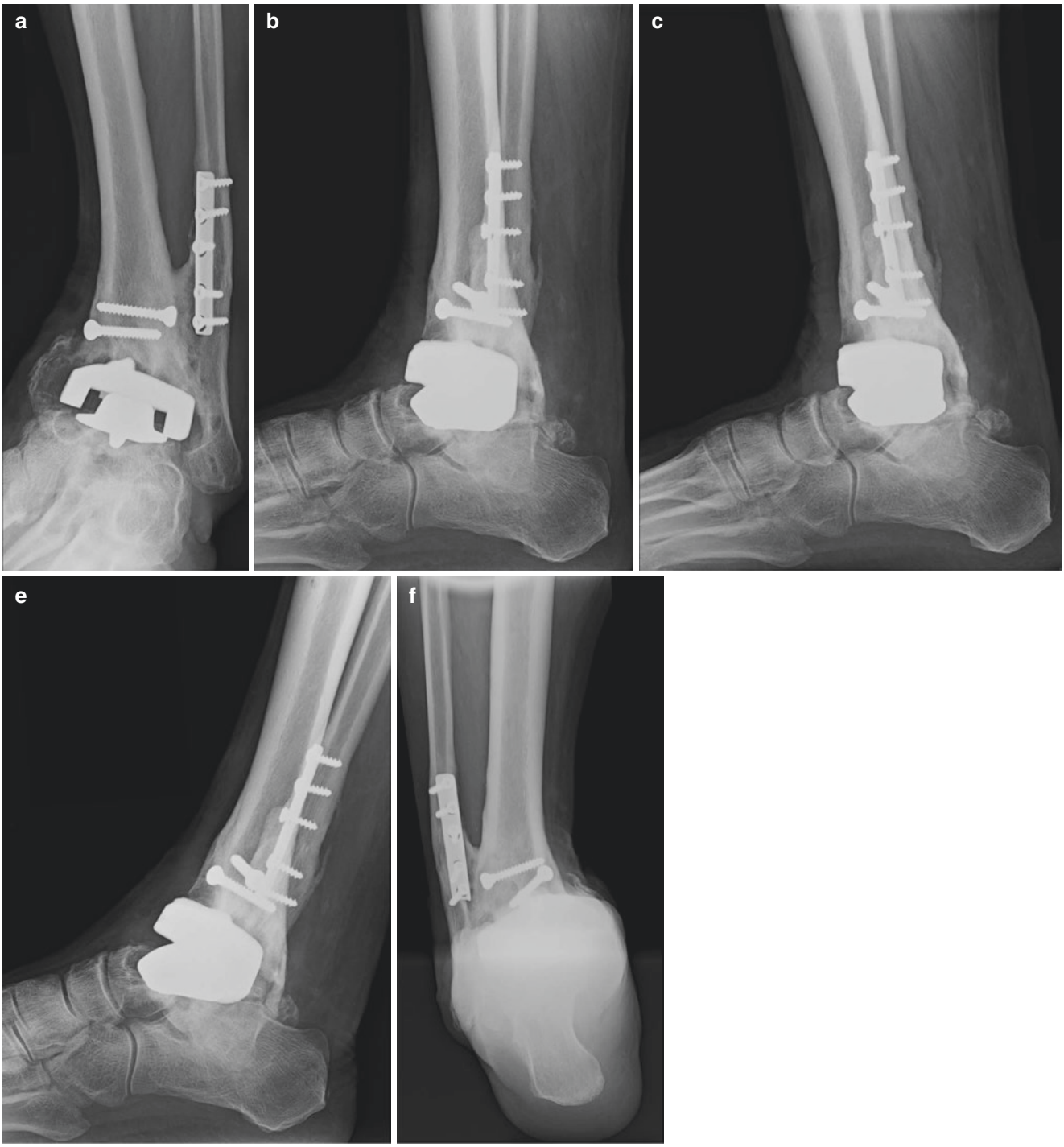


Fig. 34.1 Preoperative radiographs of failed TAR; all weight-bearing ankle views and from left to right: (**a**) Anterior posterior, (**b**) lateral, (**c**) dorsiflexion (charger), (**d**) plantarflexion, (**e**) long leg axial views

planning. It is best to not violate already vulnerable soft tissues if possible. Along these lines, a vascular workup may be needed to ensure adequate soft tissue perfusion to best avoid major complications such as wounding, increased risk of infection, or below-knee amputation.

Before surgery, the patient needs to be consented about autologous or allogenic bone grafting, possible adjacent joint arthritis (TNJ), limb length discrepancy, postoperative treatment protocol, anticoagulation, and general surgical risks such as bleeding, blood transfusions, infection, deep venous

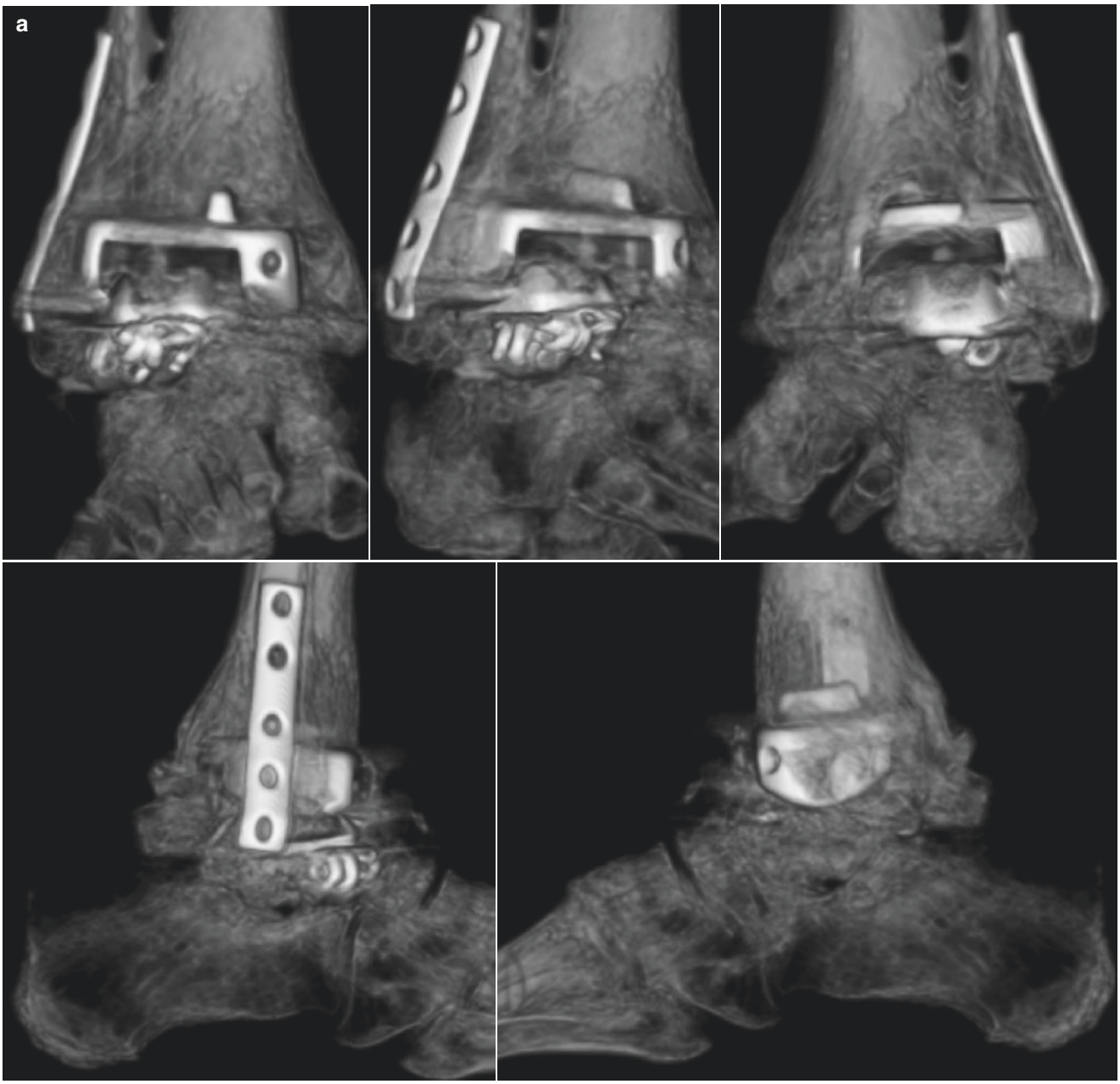


Fig. 34.2 Preoperative CT scan of failed TAR; from left to right: (**a**) 3D reconstruction, (**b**) coronal, (**c**) sagittal planes

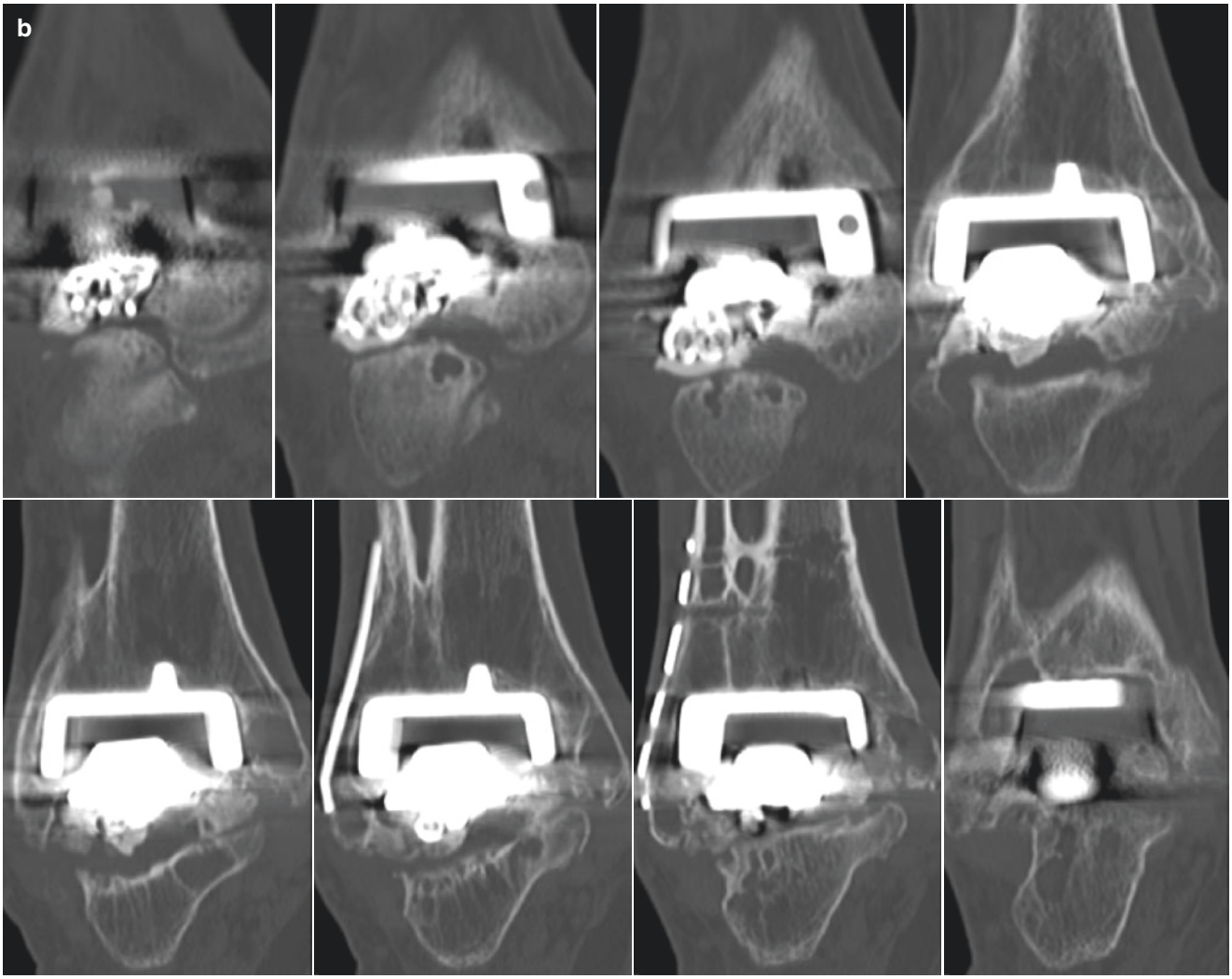


Fig. 34.2 (continued)

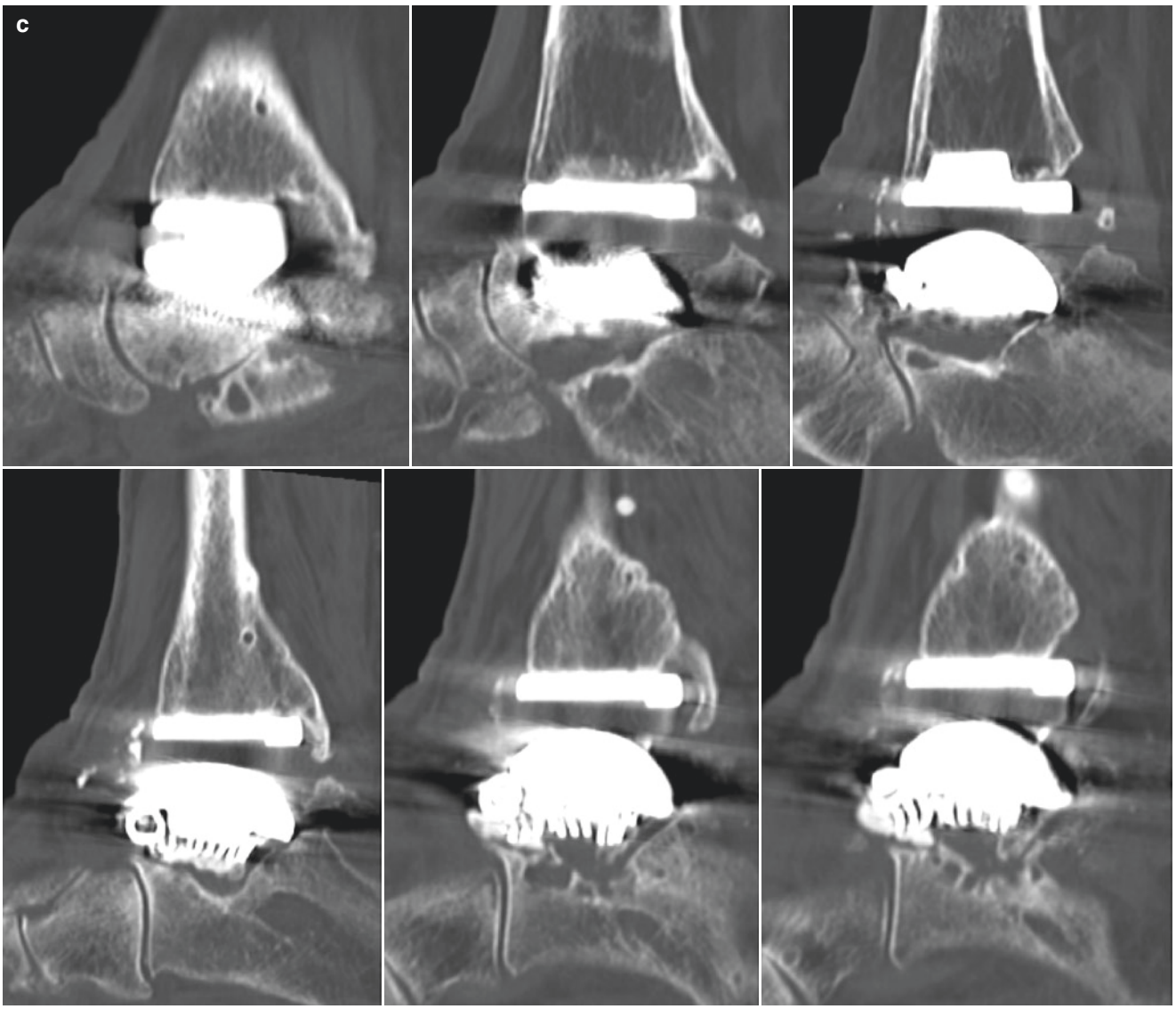


Fig. 34.2 (continued)

thrombosis, nerve damage, swelling, nonunion, hardware failure, and possible revision.

Surgical Procedure

The authors preferred treatment for a failed TAR with significant bone loss is a TTC with bulk femoral head allograft using an intramedullary nail in a retrograde fashion. For this reason, the surgical technique will focus on this procedure with alternative fixations and techniques mentioned afterward.

The patient is placed in a supine position under general anesthesia to allow axis to both medial and lateral aspects of the ankle. This position also allows for proper assessment of the foot and ankle in all three planes. General anesthesia is preferred due to the likely need for paralytics to allow proper manipulation of the foot and ankle. A proximal thigh tourniquet is then placed at the groin crease. The foot, ankle, and lower leg is then prepped using a 3-minute scrub with foam sponges impregnated with 4% chlorhexidine gluconate solution, followed by painting with 1% iodine topical solution (1 g iodine/100 mL ethyl alcohol; Spectrum Chemical Manufacturing Corporation, Gardena, CA). Furthermore, the toes were covered with an impermeable incise barrier, and the exposed skin intermittently repainted with Betadine solution (10% povidone-iodine solution; Purdue Products, LP, Stamford, CT).

The surgical procedure is initiated by obtaining bone marrow aspirate from the calcaneus or the distal tibia utilizing a large bore needle and 60 cc syringe. The thigh tourniquet is then inflated to 100 mmHg above systolic blood pressure.

An anterior lateral incision is then made from the junction of the middle and distal one third of the leg running posterior

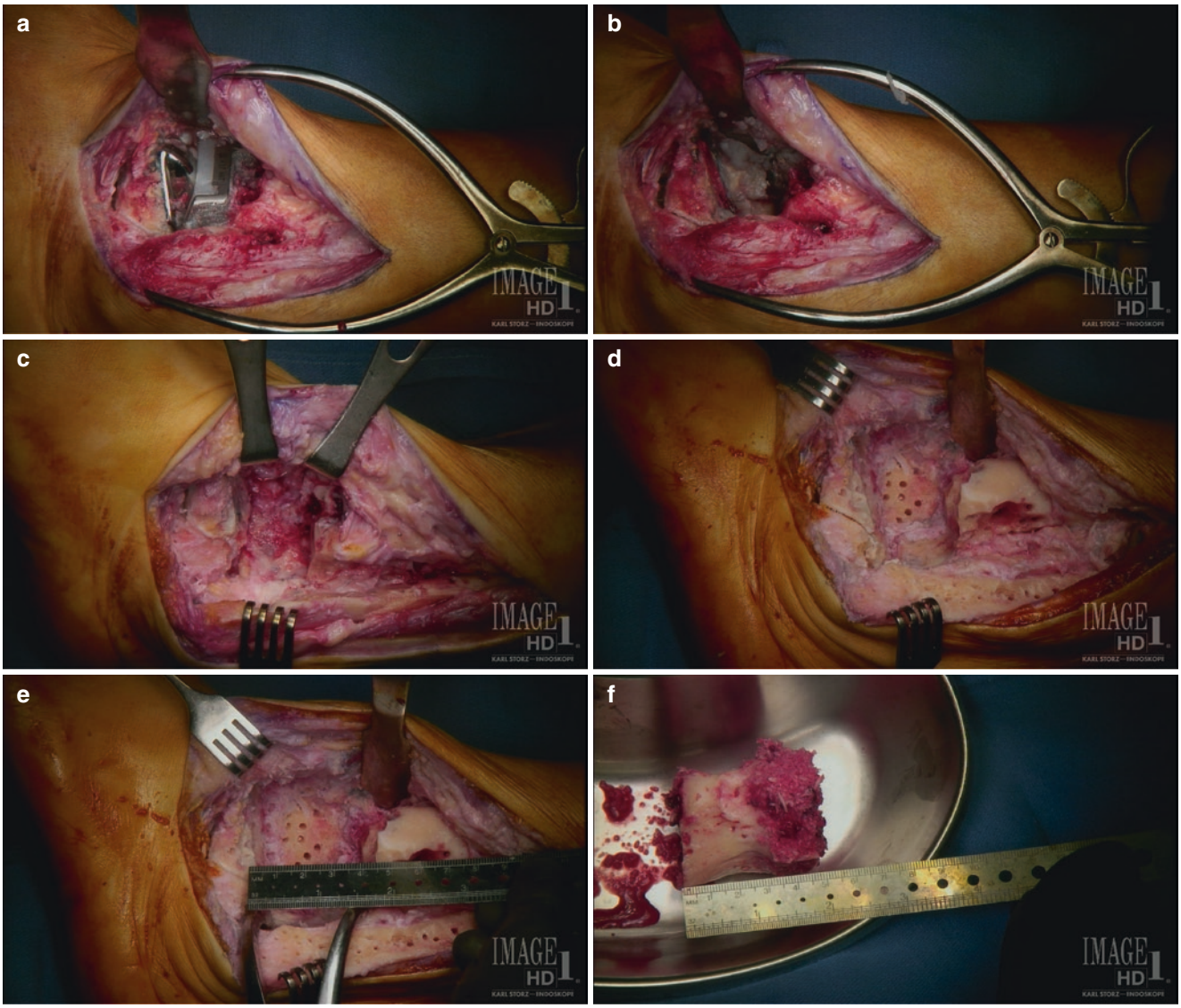


Fig. 34.3 (**a**) Intraoperative image showing anterolateral incision for access to the failed ankle implant. (**b**) Intraoperative image after removal of failed ankle implant showing nonviable bone and soft tissue previously in contact with the ankle implant. (**c**) Intraoperative image after removal of all nonviable soft tissue and bone down to bleeding subchondral bone. (**d**) Intraoperative image showing subchondral drilling of the talus, tibia, and fibula. (**e**) Intraoperative image showing measuring of the osseous defect. (**f**) Intraoperative image showing bulk femoral allograft being measured on back table to precisely fit the bone void at the ankle joint

lateral along the fibula, and distally enough to allow exposure to the subtalar joint. This incision will allow adequate exposure to TAR (Fig. 34.3a). The distal end of the incision will have a slight anterior curve. Layered dissection is then carried out down to the periosteum of the fibula and lateral malleolus; the most vital structure often encountered during this dissection is the sural nerve. The periosteum of the fibula and lateral malleolus is kept intact to decrease any embarrassment to the fibular blood supply. The interosseous membrane, along with the fascial layer between the anterior and lateral muscle compartments, is also kept intact, thus protecting and preserving the peroneal artery. To gain better access to the ankle joint and allow for removal of the implant, the distal inferior tibiofibular syndesmosis is incised from anterior to posterior to release all ligamentous attachments. Oftentimes in an ankle with repeated trauma or procedures, this syndesmosis may be scarred, making this step tedious. The fibula is then transected approximately 10 cm proximal to the distal aspect of the fibula to mobile the fibula posteriorly, while be cautious to not disrupt the peroneal artery and its branches. At this time, there is usually adequate access to the ankle implant, and due to the failed nature of the implant, the ankle itself is much more lax allowing for removal of all components of the failed implant (Fig. 34.3b). After removal of the implant, all nonviable bone on the tibial plafond and talar is debrided to healthy bleeding bone (Fig. 34.3c).

At this time, once the ankle implant is removed, any soft tissue procedures necessitated to allow the foot and ankle to be manipulated into the corrected position and sit appropriately balanced may be performed. Procedures most commonly performed are the percutaneous tendo-Achilles lengthening, posterior tibial tendon recession, tibialis anterior tendon recession, and peroneal longus to brevis transfer [17]. These procedures allow the foot to sit in the proper position without equines frontal or transverse plane deformities at the time of arthrodesis.

Oftentimes, minimal talar body is left after preparation, necessitating the bulk allograft. The subtalar joint (STJ) is debrided in a similar manner, as the cartilage to the STJ is typically still intact. It is important to also removal all cortical bone from the medial aspect of the distal fibula along with the lateral aspect of the distal tibia to allow osseous fusion of the fibular onlay graft. All arthrodesis sites are then fenestrated with a 2 mm drill (Fig. 34.3d). The defect that remains at the level of the ankle joint is then measured in all planes for proper preparation of the bulk allograft. The bulk allograft is prepared on a separated sterile back table (Fig. 34.3e, f). The bulk allograft is thawed by placing it in room temperature saline mixed with 320 mg of gentamicin for approximately 15 minutes. The graft is then removed from the antibiotic solution and contoured with a variety of hand and powered instruments to best fit the void created after ankle joint preparation. Once the exact orientation of how the allograft will sit is determined, the calcaneus and tibia are drilled and reamed to the proper size of the nail, and the allograft is independently drilled and reamed to ensure proper placement of the reaming within the graft (Fig. 34.4). When good bone stock is appreciated, the authors do prefer to obtain autograft from the tibia using a reamer-irrigator-aspirator-type device (Depuy Synthes Warsaw, IN.). The bulk allograft is then placed within the void of the ankle, and the nail is inserted per manufacturer's instructions. Next, a variety of autograft, allograft, and osteobiologics may then be placed within the joints and especially around the bulk allograft (Figs. 34.5 and 34.6).

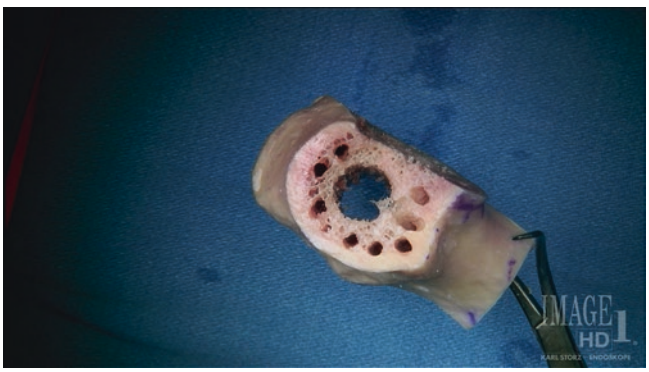


Fig. 34.4 Intraoperative image on the back table showing reaming centrally on the femoral allograft with peripheral fenestrations

Compression and stabilization of the nail with screws is then obtained per manufacturer's technique guide. The vascularized fibular onlay graft is then reflected back to overly the lateral ankle joint in situ and is fixated in place using four screws, two into the tibia, one into the talus, and one into the calcaneus (Figs. 34.7 and 34.8). The authors do prefer to place a drain and then proceed to close in layers. Sir Robert

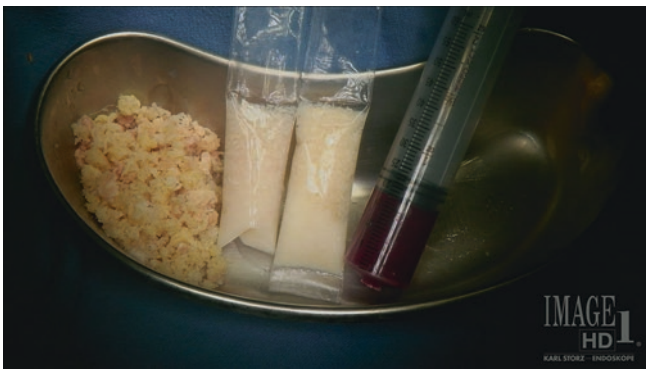


Fig. 34.5 Intraoperative image of, from left to right, cancellous bone chips, osteobiologics, and bone marrow aspirate

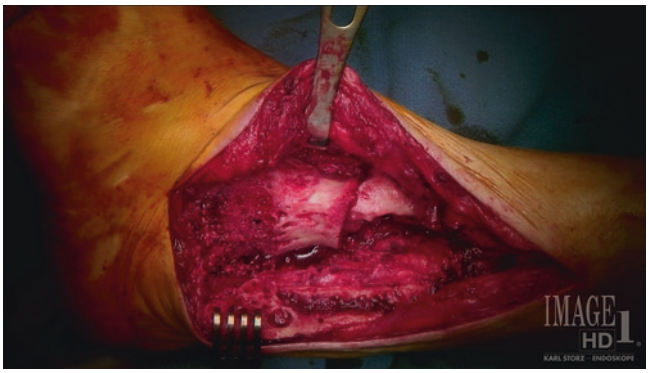


Fig. 34.6 Intraoperative image showing placement of bulk femoral allograft in the ankle joint with cancellous bone chips and osteobiologic bone grafting

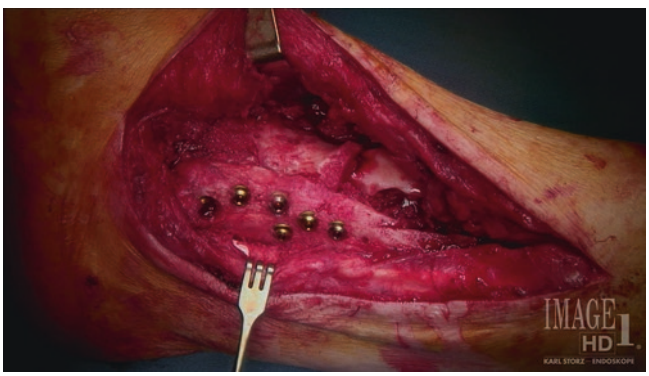


Fig. 34.7 Intraoperative image after insertion showing in situ reduction of fibular onlay graft with fixation to the tibia, bulk allograft, and calcaneus

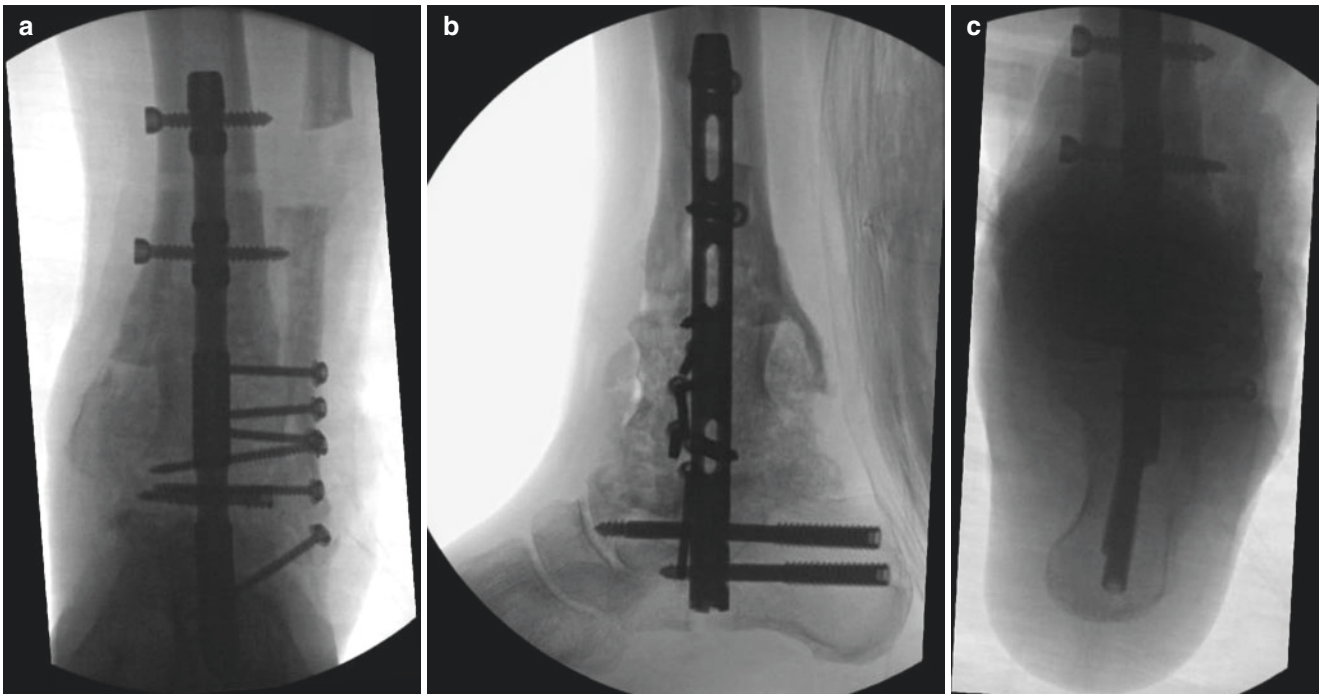


Fig. 34.8 Final radiographs showing osseous bridging across (**a**) subtalar, (**b**) syndesmotic, and (**c**) ankle joints with complete incorporation of the bulk femoral allograft

Jones dressing with posterior splint is then applied to operative lower extremity.

Postoperative Treatment

The patient is admitted after surgery for immobilization, with the ability to properly control any pain they may experience. Patient is also continued on intravenous antibiotics while the drains are in place, typically a cefazolin 2–3000 mg re-dosed every 8 hours. The patient is immobilized for 2–3 days maintaining a beach chair position to ensure the operative foot is at or above heart level to decrease swelling. Although the patient is on bed rest, they are working daily on upper body exercises to maintain strength needed later on. On day 3, the drains are pulled, and a window dressing is performed to assess the incisions for any obvious signs of complications. The antibiotics are stopped at this time. Physical therapy is initiated to perform sit to stand, turn to transfer, short-distance ambulation, and all necessary tasks for patients to return home safely or to a skilled nursing facility. Our protocol calls for the patient to remain 100% non-weight-bearing to the operative side during all activities with physical therapy. Patient typically is discharged from the hospital on postoperative day 4. Patient is seen weekly in the clinic until sutures are removed at week 3, and patient is removed from the posterior splint and placed in a Controlled Ankle Motion Walker (CAM Walker, AliMed, Inc., 297 High Street, Dedham, Massachusetts 02026) with a compression-type stockinette for edema control. Radiographs are taken at the 6–8-week mark to assess for signs of consolidation and boney ingrowth of the arthrodesis site. If osseous bridging is beginning to take place, the patient may begin partial weight-bearing to the heel while remaining in the CAM walker to promote micromotion and healing. Partial weight-bearing would be to perform transfers and short-distance ambulation within the home. Dynamization of the nail is rarely performed without protocol. Patient is seen back at the 12-week mark with new radiographs, again to assess the consolidation of the arthrodesis site. Patient will begin full weight-bearing at this time while remaining in the CAM boot. Transition to an accommodative or even custom shoe gear will take place over the following 2–4 weeks. Patients are typically seen again at the 6-month postoperative period and then yearly for surveillance.

Special Situations and Alternative Techniques

In case of an infected implant, there are several ways to proceed [18–20]. The first and most important principle is to eradicate any infection that may be present; thus, these infected revision surgeries are typically done in a staged fashion. The initial stage of the procedure would be to remove all hardware and nonviable bone and ensure to send all speci-

mens to microbiology and pathology for full assessment and as a "foreign body" which will ensure the lab will hold onto the specimens for 14 days as some bacteria will not show up until after a 7-day period. Once the implant is removed, the ankle joint is irrigated with a pulse lavage utilizing 3 liters of normal saline to irrigate all debris. Next, cultures and specimens are obtained followed by repeated pulse lavage utilizing 6 liters of normal saline impregnated with 50,000 IU bacitracin solution (Pfizer, Inc., New York, NY) per 3 L bag. Following irrigation of the ankle joint, an antibiotic spacer is placed into the ankle joint. The antibiotic spacer is used both for its antimicrobial properties and also for its structural properties; thus, nondegradable cement is used impregnated but surgeon's choice of antibiotics; the author's first choice is gentamicin. At this point after thorough irrigation and debridement with proper placement of antibiotic spacer, the incision is closed. Our recommendation is to get involvement of the infectious disease doctors to facilitate at least 6 weeks of antibiotics. It is important to also monitor infection markers during these 6 weeks to ensure proper response to the antibiotics. After 6 weeks, a "drug holiday" is given along with continued monitoring of the infection markers to ensure no underlying or latent infection is present [21]. This drug holiday typically lasts for another 4–6 weeks. Once it has been decided in conjunction with the infectious disease doctors that the infection has been eradicated, stage 2 of the procedure may be performed. The authors recommend a retrograde TTC arthrodesis for stage 2 as described earlier in this chapter due to the ability to stabilize the bulk allograft needed and the ability to address and stabilize the subtalar joint.

In true salvage situations in which the primary objective is to rid the ankle of infection and maintain the limb, regardless of functional outcome, a septic fusion may be performed using an external fixator. This surely is a salvage procedure since bone grafting is not possible in this situation which is only one of the many disadvantages. In most cases, it is better to initiate a negative pressure wound therapy system and repeated debridement as is done with infected total knee or hip arthroplasty. Once there is no more growth of bacteria, an antibiotic-loaded cement spacer is applied. If a joint aspirate 6–7 weeks afterward is negative (antibiotics need to be ceased 1 week prior), an intramedullary nail may be used as described above.

Pearls and Pitfalls

Pearls

- For TTC arthrodesis, the intramedullary nail is more stable compared to screw fixation, especially in patients with comorbidities like diabetes mellitus or rheumatoid arthritis with poor bone quality [22].
- Correct positioning of the patient is mandatory and depends on the specific used implant.
- In some cases, resection of the medial malleolus is necessary to achieve sufficient bone contact for arthrodesis.
- For easier nail insertion, an over-reaming of at least 1 mm is recommended.
- Keeping the fibula vascularized to reapproximate on the lateral ankle and use as bone graft is recommended.
- Four screws, two into the tibia, one into the talus, and one into the calcaneus, provide best fixation for fibula onlay graft.
- Reaming the bulk allograft independently will help ensure proper placement of the reaming.
- Frozen bulk allografts incorporate as well as fresh bulk allografts.
- Angled nails may allow for more purchase within the calcaneus.

Pitfalls

- Correct entry point of the nail insertion into the plantar aspect of the calcaneus is the most important. The ideal entry point should be marked with a pen and rechecked during guide wire insertion. During those steps, the ankle has to be in reduced position. Afterward, there is no option of reorientation of the nail or hindfoot.
- Before drilling/reaming, ensure the bulk allograft is not translated anteriorly, and ensure the allograft is directly below the tibia and the calcaneus is directly below the allograft.
- Correct ankle rotation has to be verified before inserting the locking screws of the nail.
- Poor soft tissue management will lead to higher complication rates.

Review of Literature

Anatomic Considerations, Complications, and Techniques Utilizing Retrograde Nails

The ability to keep the fibula vascularized can play an important role in the arthrodesis of the ankle joint. The vascularized nature of the fibula to continue to supply nutrients and growth factors to the bone and the arthrodesis site greatly aids in the incorporation of the graft. One of the main differences between vascularized and non-vascularized grafts is that when the blood supply remains intact, the supply of osteoprogenitor cells is maintained, and the immediate availability of corticocancellous vascularity is present to promote ingrowth. The creeping substitution needed for most graft incorporations is not needed when

the graft remains vascularized as the incorporation occurs by routine primary and secondary osseous healing. Maintaining the blood supply promotes graft hypertrophy and, in some cases, allows the vascularized graft to be up to 50% stronger than a frozen graft at the index surgery since they are transferred while maintaining the vascular and structural integrity. It has been noted that a vascularized fibular graft also has neovascularization that does allow for neovascularization at the graft site, which is especially important for incorporation of the vascularized graft in the setting of a poor recipient site [17].

As described in the surgical technique, it is one of the main goals to attain a perfect alignment of the hindfoot and TTC complex. This includes many variables like the entry point, bone purchase, and the central axis of the involved bones. In a cadaver study, Hyer et al. [23] showed that if a straight nail is inserted anterograde into the tibia, it will pass the talus lateral to the midline and the calcaneus medially near the sustentaculum leading to a loss of bone purchase. To improve this situation, curved nails with an incorporated valgus have been introduced. Marley et al. compared straight and curved nails in a retrospective study [24] and found that an inbuilt valgus and longer nails cause better central positioning within the tibia leading to less cortical stress reactions. Richter et al. [25] found differences in stability when comparing two different nail systems in a cadaver study: The nail system with two calcaneal locking screws was superior concerning stability although the authors conclude both systems showed a sufficient primary stability.

When it comes to the ideal insertion point of the nail at the calcaneum, Knight et al. [26] recommend a more lateral entry point at the lateral column of the calcaneus to protect the neurovascular bundle. Rausch et al. [27] describe three different approaches to TTC arthrodesis in their cadaver study from 2014. They conclude that a medial or posterolateral approach might have some advantages concerning cartilage debridement compared to the standard transfibular approach while at the same time neurovascular structures are more at risk [27]. In 2006, Roukis described the proper entry point for the guide wire, and thus the drilling and reaming for a TTC nail using both anatomic and radiographic measures. His conclusion stated the proper insertion for the guide wire when the calcaneus talus and tibia are properly aligned is 2 cm posterior to the calcaneocuboid joint and in line with the second digit on the plantar heel. In his study, Roukis found using these landmarks decreased guide wire placement attempts from 4 to 1.3 [28]. It is important to note that this guide for proper starting position is for a straight nail, and as posterior and valgus bent nails become more popular, the initial entry point for the nail will change.

Complications of TTC

TTC arthrodesis remains a technically challenging procedure, especially in revision cases; thus, we would be remised not to mention the complications associated with this procedure. The overall complication rate has been reported as high as 57%. Nonunion of the fusion sites is one of the main complications. Nonunion rates in primary TTC arthrodesis have been reported as high as 48%, while in revision cases requiring bulk allograft, it can be over 50% [29, 30]. Other complications include infection and major amputations. In a paper written by Bussewitz and colleagues looking at 25 cases where a TTC arthrodesis was performed using an intramedullary nail and bulk allograft for large osseous defects, there was a 16% transtibial amputation rate. Of the 21 remaining cases, 2 went on to nonunion, 12 went to radiographic union, and 7 were classified as pseudarthrosis [31]. Postoperative complication of major infection requiring IV antibiotics was necessitated in 38% of patients. Comparing this rate to a retrospective review of 57 TTC arthrodeses performed in 2015 by Thomas and colleagues, where TTC fusions without the need for bulk grafting reported an infection rate of 8.8%, would indicate the increased risks of infection with these more complex salvage-type procedures [32]. The overall complication rate in this study including nonunion, infection, hardware failure, and nerve injury was 34% [32]. In 2013, Devries, Berlet, and Hyer released a predictive risk assessment for major amputations following a TTC arthrodesis using an intramedullary nail [33]. One hundred and seventy-nine total TTC arthrodeses were included in the study with an average follow-up of 21.4 months. The overall amputation rate was 11.7%, leaving an 88.2% salvage rate. Looking at the amputation population of this study, the authors were able to develop odds ratios to determine if certain variables led to a higher likelihood of major amputation following a TTC arthrodesis. The odds ratio for patients with diabetes was 7.01, meaning diabetic patients were seven times more likely to have a major amputation following a TTC arthrodesis than patients without diabetes. Patients who were receiving a TTC for revision purposes showed and odds ratio of 6.23 for major amputation, and patients who had an ulceration prior to surgery had an odds ratio of 2.99 for major amputation [33].

Alternative Techniques

Other techniques do exist for arthrodesis of the ankle joint after failed TAR that do warrant mentioning in this chapter. These techniques consist of screw fixation, plate fixation, and external fixation [34]. In 2015, a complete review of the Swedish Ankle Registry was undertaken looking at 118 total

ankle replacement failures where salvage arthrodesis was performed. Multiple different techniques were used, and of the 118 salvage arthrodeses, 49% used retrograde nailing, 13% plate fixation, 6% external fixation, 5% screw fixation, and 8% a combination of these techniques with metal spacers. In the remaining 19%, the fixation technique was not recorded. Failure was considered when a repeat arthrodesis or amputation was performed. In regard to failure pertaining to each fixation technique, 43% of the external fixation group salvage arthrodesis failed, 11% of the metal spacer group, 10% of the retrograde nailing group, and 7% of the plate fixation group. There was no recording of failures in the screw fixation group [35]. A systematic review of the literature was performed in 2015 by Gross and colleagues reviewing failed TAR with salvage arthrodesis. Sixteen total studies were included in the review encompassing 193 salvage procedures with an average follow-up of 34.8 months. An overall fusion rate of 84% was found after initial salvage arthrodesis. The fusions included that used the blade plate had 100% fusion rate, the TTC with intramedullary nail fusion rate was 71%, and intramedullary nail with cage had the lowest fusion rate of 50%. The external fixator group had an overall fusion rate of 71%. Using a combination of an anterior plate along with internal screws had a 96% fusion rate [36].

Conclusion

Revision of failed TARs can pose a difficult decision between the patient and physician as to treatments moving forward. Removal of the implant leaves a large bone void making salvage arthrodesis with bulk bone grafting the likely procedure of choice. This procedure requires not only a set of skilled hands but also a high level of experience to provide the best outcomes. Although multiple viable techniques exist of the TTC arthrodesis, the authors prefer to use an intramedullary nail utilizing bulk bone graft, which has proven results through countless publications to provide stability and proper incorporation of the graft. This chapter aimed to not only provide an overview of the data regarding salvage TTC arthrodesis after a failed TAR but also the authors preferred surgical technique.

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Tibiotalocalcaneal Arthrodesis After Failed Total Ankle Replacement: Metallic 3D Printed Custom Cages

35

Samuel Bruce Adams and Gerard J. Cush

Introduction

Total ankle replacement (TAR) or arthroplasty (TAA) is a successful procedure for end-stage ankle arthritis with outcomes equivalent to ankle arthrodesis [1]. Although ankle arthrodesis is still considered the "gold" standard treatment for ankle arthritis, TAR utilization is steadily increasing [2] secondary to mid-term reports documenting positive results of multiple implants [3–9].

However, TAR is not a panacea with at least one report documenting more reoperations, revision procedures, and eventual failures compared to ankle arthrodesis [1]. Moreover, some long-term data is not favorable. For example, Labek et al. [10] used national registry data to report a primary TAR failure rate of 21.8% at 5 years and 43.5% after 10 years across multiple implants. As survivorship decreases with longer follow-up, reliable treatment options for failure are needed. TAR failure can be managed with revision TAR, salvage tibiotalar (TT), tibiotalocalcaneal (TTC) arthrodesis, or amputation. Ellington et al. [11] reported satisfactory postoperative patient-reported outcomes on 41 revision TAAs at a mean follow-up of 49.1 months. However, revision TAR is not always appropriate. In fact, the previously described study reported a 13% revision TAR failure rate leading to subsequent arthrodesis or amputation procedures.

Revision arthroplasty or isolated TT arthrodesis procedures are often impossible or inappropriate due to severe loss of tibia and/or talus bone stock or damage to the subtalar joint from the collapsing TAR components, leaving TTC arthrodesis as one of the most common treatments to salvage a failed TAR. Kitaoka described removal of the implant, malleolar resection, and compression to the tibia to the remaining hindfoot without any graft interposition [12]. This left the extremity short which can reduce extremity function even worse than length-preserved arthrodesis. Therefore, for salvage TTC arthrodesis to have optimum patient satisfaction, the void left by the TAR components and any associated bony collapse must be filled. Thomason and Eyres described the use of a femoral head allograft as a structural intercalary graft to restore length after failed TAR [13]. Subsequently, successful salvage TTC arthrodesis with a femoral head allograft has been described and become a popular option for salvage [14]. While femoral head allografts are sometimes reasonable to fill the void, there are several drawbacks to their use. First, nonunion of either the tibial or calcaneal interface is a serious concern for a devascularized graft (Fig. 35.1). Second, fracture failure and collapse of large allografts has been reported. The risk of fracture has been linked to the size of the allograft which has led some authors to recommend shortening of the limb to reduce the size of the allograft needed [15]. Finally, a femoral head allograft may not be of adequate size or shape to restore length and proper alignment for successful arthrodesis. Remember, the total defect size is the original size of the TAR components plus bony collapse which is often larger than the diameter of a human femoral head.

Additive manufacturing, also known as 3D printing, is the process of creating a predefined object via precise deposition of materials in a layer-by-layer fashion. The customizability of 3D printing with regard to material, shape, and size makes it an attractive alternative to cadaver bone allografts for salvage of failed TAR. 3D printing enables creation of implants with anatomically matched geometry for a specific patient. Moreover, 3D printing enables fabrication of complex porous architectures for bony ongrowth and ingrowth, which may be better than a femoral head allograft (Fig. 35.2). Finally, 3D printed devices have exceptional strength and are unlikely to suffer from collapse. This chapter will focus on indications,

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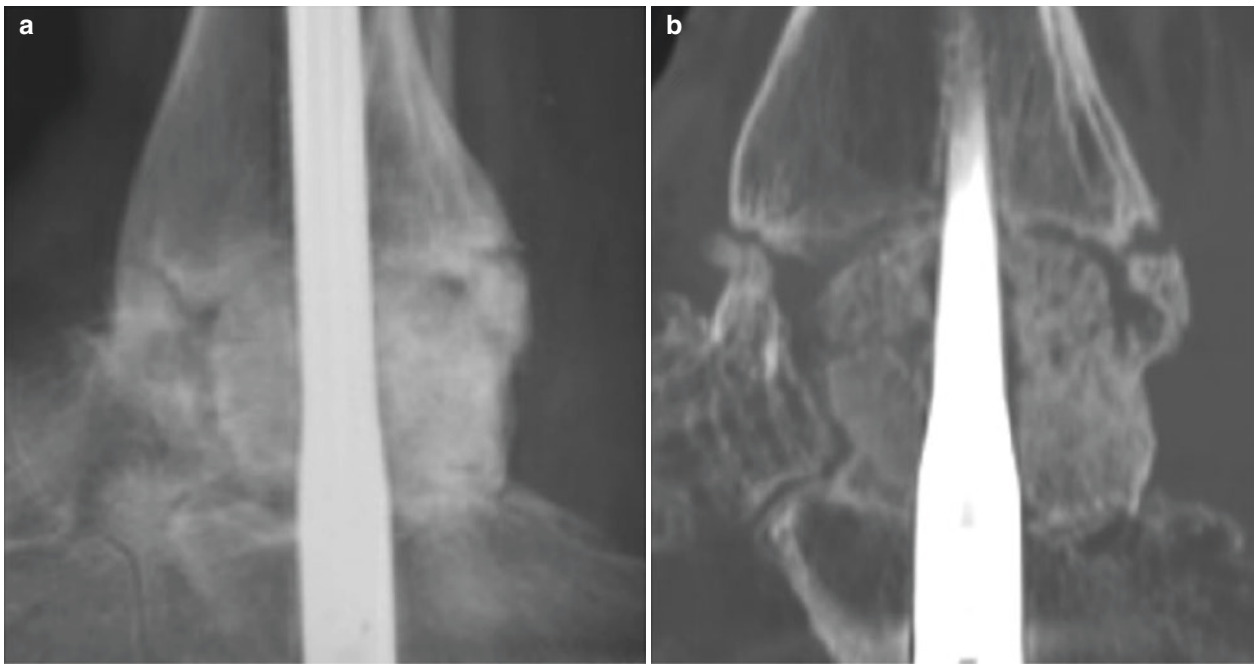


Fig. 35.1 (**a**) Lateral radiograph and (**b**) CT scan images demonstrating a nonunion and collapse of an allograft femoral head 2 years after surgery

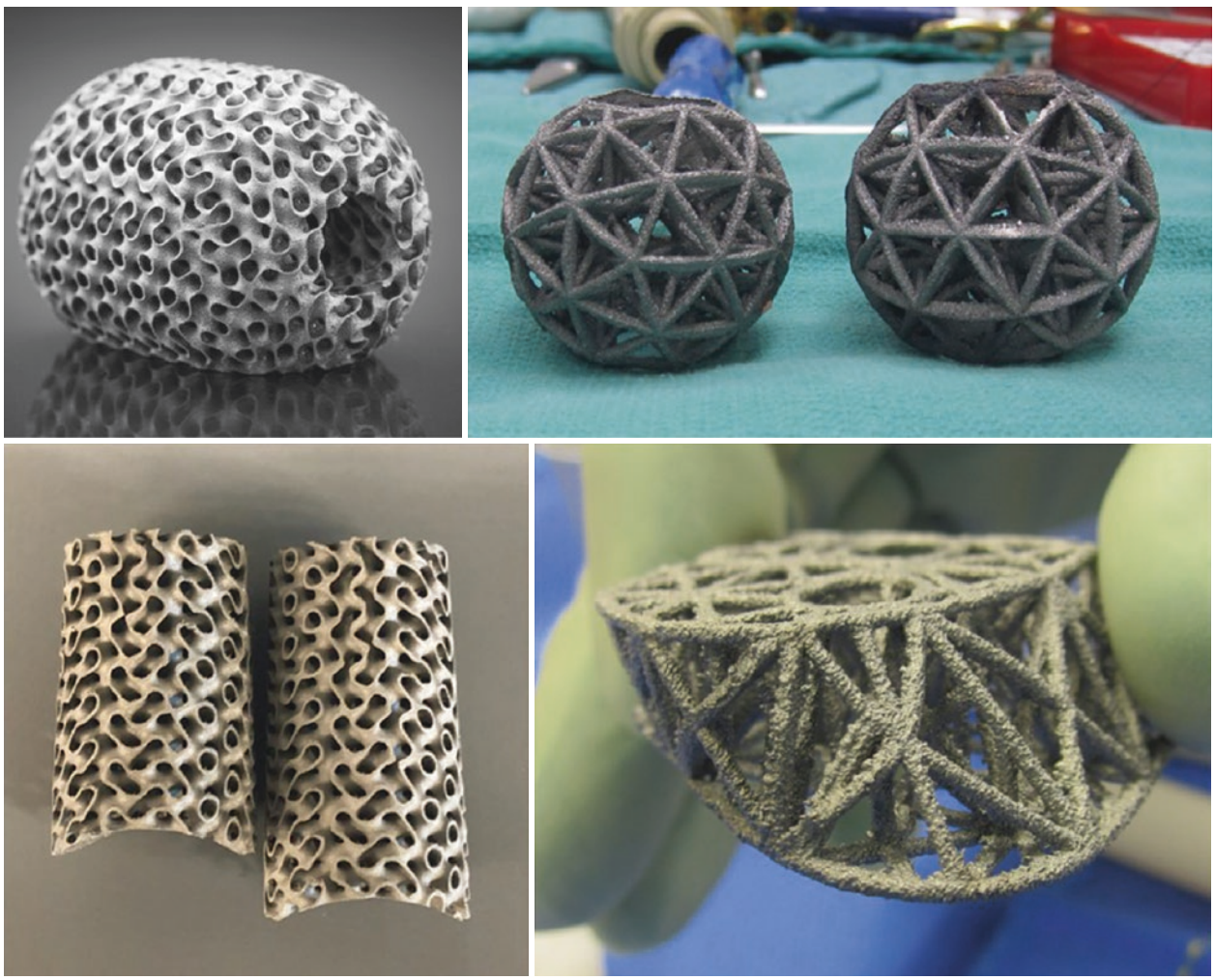


Fig. 35.2 Examples of various patient-specific geometries and porous surfaces able to be produced with 3D printing

treatment decision-making, techniques, and outcomes of the use of custom 3D printed metallic implants for salvage TTC arthrodesis for failed TAR.

Treatment Decision-Making, Indications, and Contraindications

Treatment Decision-Making and Indications

There are two important interrelated decisions that have to be made for the use of a custom 3D implant for TTC arthrodesis. These include:

1. The decision to perform TTC or TT arthrodesis
2. The decision to use a 3D printed implant over a femoral head allograft

The decision to perform TTC over TT arthrodesis can be difficult. While the focus of this chapter is mainly on TTC arthrodesis, it is important to note that TT arthrodesis can also be performed with 3D printed implants. The primary indication for salvage TTC arthrodesis over TT arthrodesis or revision TAR is inadequate bone stock (bone loss) of the talus, whereas TT arthrodesis can be considered for cases of tibial-sided bone loss with preserved talus bone stock. Secondary, but highly related, indications for salvage TTC arthrodesis are subtalar arthritis and damage to the subtalar joint by subsided talus component. Kruidenier et al., [16] in a series of TT and TTC arthrodesis, chose TTC arthrodesis when "significant bone loss" was present but there is not generally accepted criterion for determining a critical amount of bone loss. However, what can be agreed upon is that the talus is the most critical bone. The author's determinants for adequate talus bone stock are (1) can stable fixation be achieved and (2) can osseous healing occur across the interfaces. The most commonly used fixation method for TT arthrodesis in this setting is anterior plating. However, for any method, stable fixation in the talar neck and preferably the talar body must be achieved. This is less successful when the bone stock of the talus falls below the level of the navicular in the sagittal plane. Moreover, with little talus bone stock left, especially in a bone with a tenuous blood supply, the body's ability to mount a bone healing response is limited. Therefore, when the bone stock falls below the level of the navicular in the sagittal plane, the author strongly considers TTC arthrodesis over TT arthrodesis.

Once the decision to perform a TTC arthrodesis is made, the surgeon must decide what to use to fill the bony void to restore anatomic extremity length. This is especially important in cases where the resultant bony void is larger than commercially available femoral head or other allografts. Remember, that the total void height is the height of the TAR prosthesis components, plus any bony collapse of the talus and/or tibia, plus any bone intended to be resected (Fig. 35.3). However, even if the void could be spanned by a femoral head or other allograft, a 3D printed cage can be chosen because of its benefits of improved failure strength and customizable options.

If the implant is to replace the talus or is mostly limited to the volume of the failed TAR, the author prefers to use either a completely or mostly spherical 3D implant to fill the bony void. The use of spherical graft/implant provides substantial bony contact and two degrees of freedom for implant and foot positioning (Fig. 35.4). If there is even greater bone loss, especially into the tibia, an egg-shaped or truncated tear drop can be made (Fig. 35.5). These nonspherical devices are essential when the diameter of the sphere would be too great for the anatomy at the level of the ankle (Fig. 35.6).

Contraindications

Assuming reasonable indications were observed for TAR in the first place, the main contraindications to the use of a 3D metallic implant for salvage TTC arthrodesis are infection and inadequate soft tissue coverage that could lead to infection. Infection is the most complicated scenario in salvage of failed TAR as allograft bone and metal cages are not appropriate in active infection. If salvage arthrodesis is the ultimate goal, over chronic cement spacer implantation or amputation, then appropriate practices should be employed for infection eradication treatment. Consultation of an infectious disease (ID) physician should be performed. After appropriate antibiotics and an antibiotic holiday guided by the ID consultant, the patient should undergo a repeat bone biopsy with culture to determine infection status. Salvage arthrodesis should not be performed until normalization of infection laboratory values and negative bone cultures. Even then, the author is very cautious about recommending the use of a metal implant. Strong consideration should be given to a femoral head allograft. If infection is still present, then two nonamputation options exist: (1) an antibiotic impregnated spacer with continued antibiotics and further debridements or (2) continued antibiotics with limb-shortening arthrodesis using a circular external fixation can be performed. Amputation for chronic infection is also a treatment option.

Wound complications following total ankle arthroplasty range from 6.6% to 28% of patients [17, 18]. Wound complications can lead to inadequate soft tissue coverage. Inadequate soft tissues are a problem for both revision TAR and salvage arthrodesis. In cases of inadequate soft tissue coverage, a plastic surgeon should be consulted to assess soft tissue coverage options and guide treatment. If options do not exist, consideration should be given to below-the-knee amputation. If options do exist, then salvage arthrodesis can

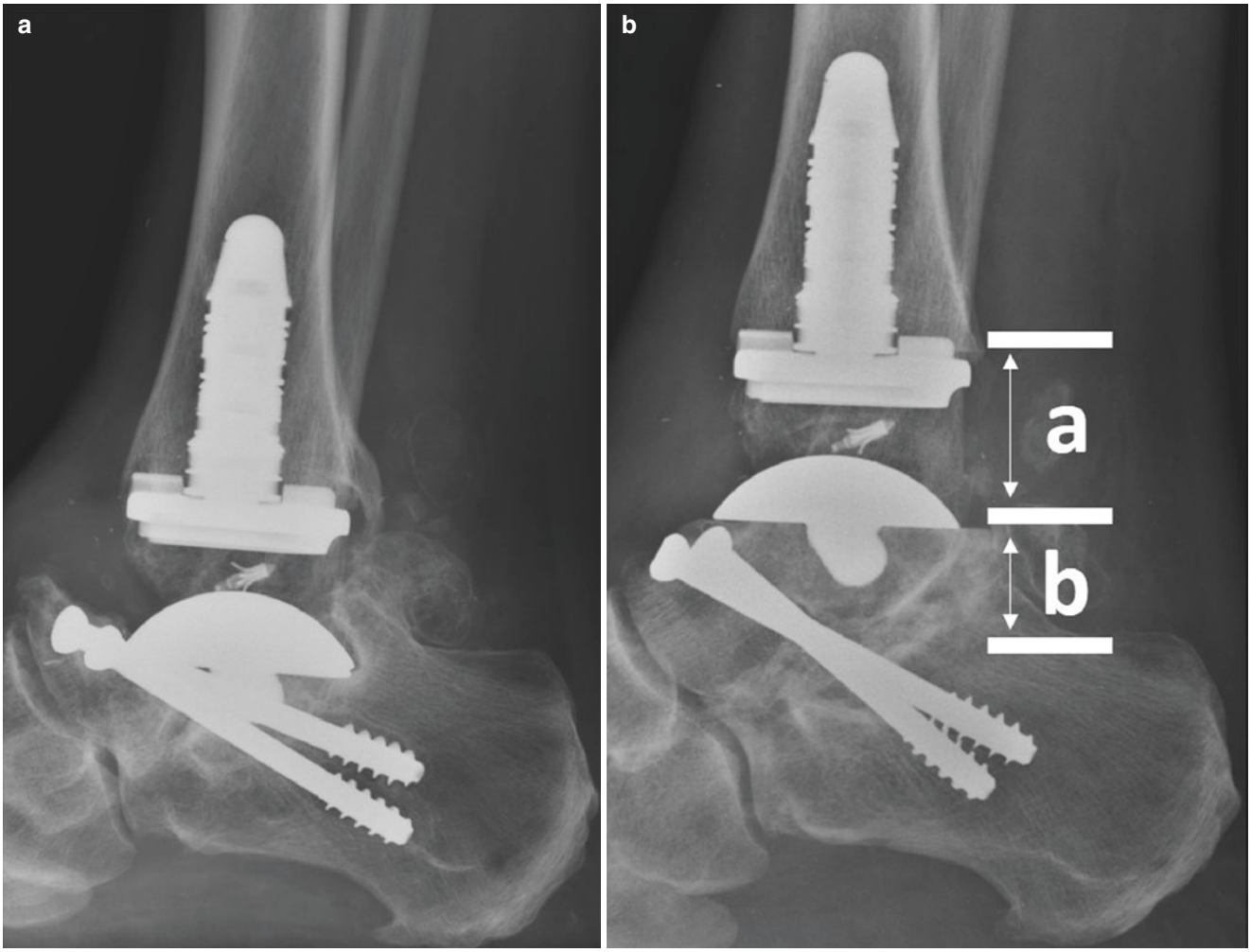


Fig. 35.3 (**a**) Example of a failed TAR. (**b**) Prior images must be assessed for the true defect size. In this case, the total height of any salvage implant must be a + b to restore leg length. In this case, a + b is greater than the diameter of any available femoral head

be performed. Typically, when using a 3D printed metal implant, the author performs salvage arthrodesis after a soft tissue coverage procedure. This allows time for ensuring that there is no infection. Unfortunately, coverage before arthrodesis typically requires a waiting period of flap maturation and additional plastic surgery coordination for flap elevation concomitant to the salvage arthrodesis. Other contraindications include dysvascular limb, metal allergy, and not enough calcaneus bone stock. In these settings, consideration should be given to amputation.

3D Printing

3D printing (additive manufacturing) is a broad term which refers to the process of fabricating a 3D part from a CAD model, typically in a layer-by-layer fashion. First commercially available in 1988, 3D printing has since transformed how we translate ideas into tactile creations. As technology advanced and accessibility to 3D printers increased, 3D printing has become more prevalent in many industries including medicine. The burgeoning popularity of 3D printing is in part fueled by its ability to create highly customized products in an efficient and accurate manner. This is in contrast to traditional manufacturing methods (subtractive manufacturing), which are often not able to physically produce geometrically complex and custom "one-off" designs such as those that might be needed for salvage TTC arthrodesis.

The use of 3D printing technology in the medical field has evolved from anatomic models to surgical cutting guides and now customized patient-matched implants. Recently, FDA scientists reported that of the 3D printed implants cleared for commercial use, most are for orthopaedics, including several subspecialties, such as arthroplasty, spinal fusion, upper extremity, and lower extremity [19].

There are several methods of 3D printing including material extrusion, material jetting, binder jetting, powder bed

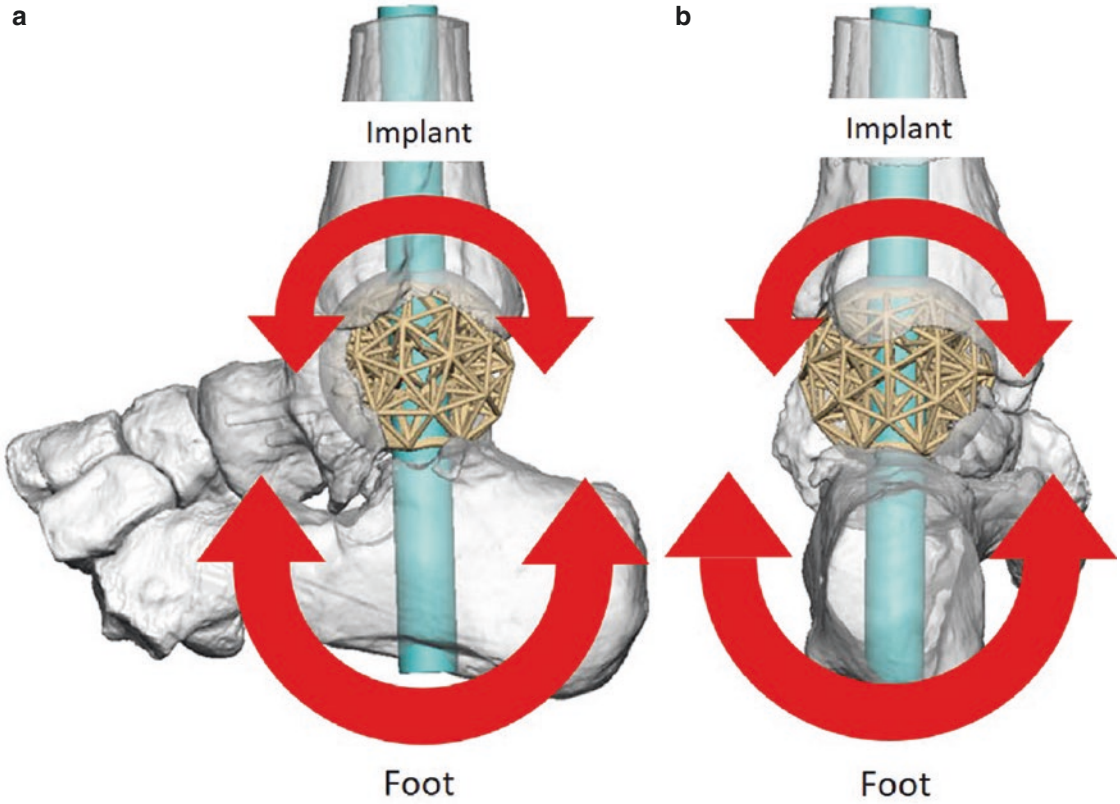


Fig. 35.4 (**a** and **b**) The use of a spherical implant allows for two degrees of freedom. The first degree is allowing the foot to rotate around the implant to get the ideal position prior to inserting the intramedullary nail. The second is to allow the implant to rotate within the body while the implant is being placed to allow the nail to maintain the ideal trajectory. These images also demonstrate the surface area of the sphere and its contact with the talus, tibia, and calcaneus

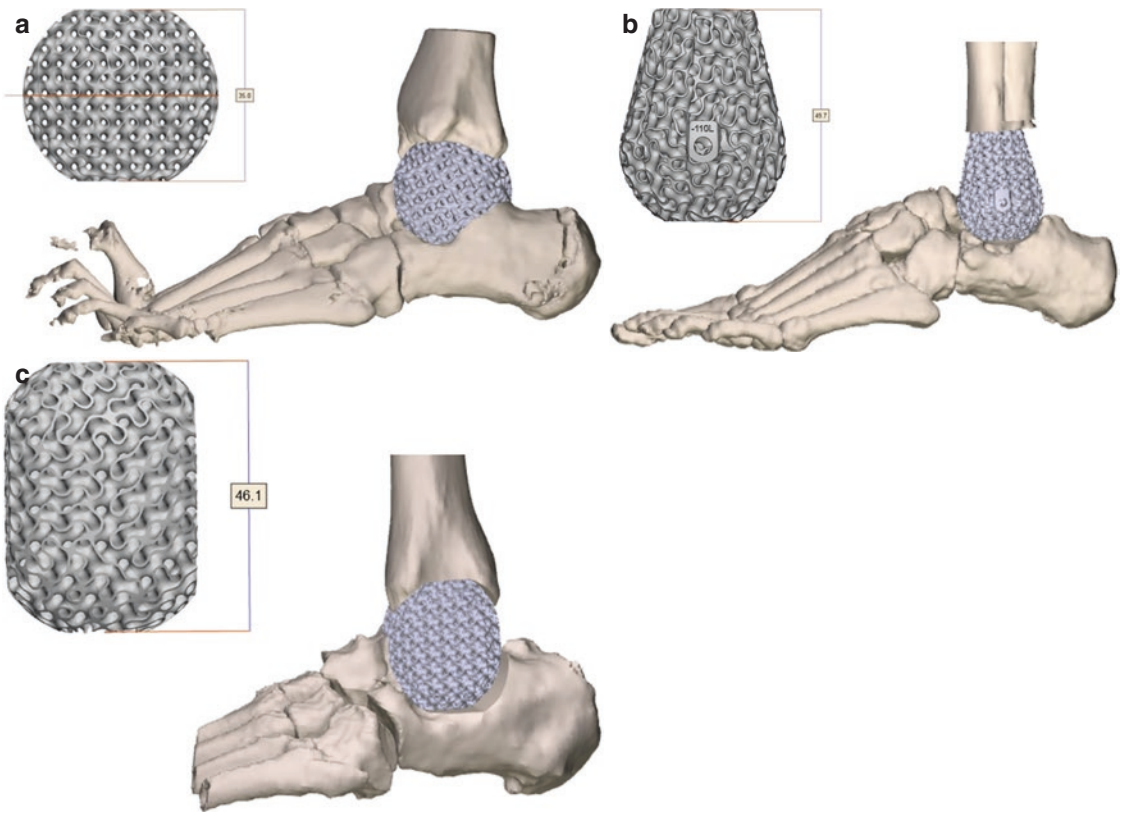


Fig. 35.5 Examples of spherical (**a**), truncated tear drop (**b**), and pill (**c**)-shaped 3D printed cages to fill the defect between the tibia and calcaneus

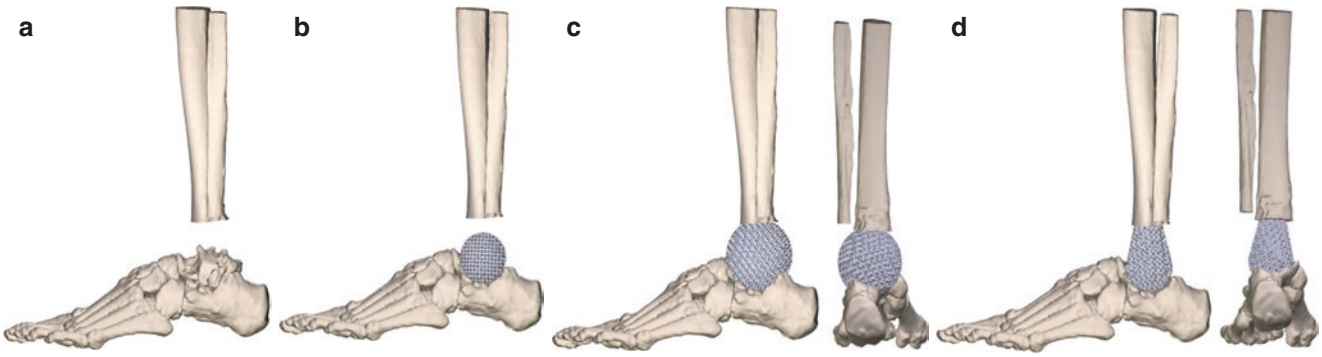


Fig. 35.6 (**a**) An example of a bone defect between the tibia and calcaneus after subtraction of failed TAR components. (**b**) A reasonable-sized sphere (of the same size as common femoral head allografts) does not completely fill the defect. (**c**) A larger sphere can be made to fill the defect, but as the sphere gets larger, it can abut important neurovascular tissues or cause difficulty with wound closure. (**d**) In these cases, a truncated tear drop or pill-shaped device is more appropriate

fusion, vat photopolymerization, directed energy deposition, and sheet lamination. Each method has its own merits, depending on the materials required for the part, the mechanical properties desired, resolution, print speed, and other factors. Most medical models are fabricated via material jetting due to the high resolution and the ability to mix materials to print full-color models. Surgical instruments and cutting guides can be 3D printed in polymeric materials by material extrusion or vat photopolymerization processes.

Powder bed fusion is the process by which metal orthopaedic implants are 3D printed. In powder bed fusion, a source of thermal energy, either from a laser or electron beam, selectively fuses regions of a thin layer of powder according to the desired design to form each 2D layer. This process is repeated until each layer has been fused together, rendering the 3D object desired [20]. The printing process typically occurs over the order of hours, but up to many days depending on the number of parts and total volume.

Laser powder bed fusion (also called selective laser melting) and electron beam melting are the two most common powder bed fusion processes, and each has unique merits depending on the desired material microstructure, mechanical properties, surface roughness, build rate, and other factors. According to a report by the FDA, 66% of cleared 3D printed devices were produced by laser powder bed fusion, compared to 25% by electron beam melting [19].

Process of Creating a 3D Printed Implant

This section will outline the process of creating a 3D printed implant with one of the manufacturers. The process is very similar among all implant providers. After identifying the patient, a prescription is required by the FDA. It should describe the indicated pathology and document the unique need for a custom implant using the following information: the specific patient's condition, why the condition requires a custom device, how the custom device will be specific to the patient's anatomy, and goals of the implant. All of these implants must adhere to the FDA's custom implant criteria. Custom implants are granted FDA approval through Section 520(b) of the Food, Drug, and Cosmetic Act (FD&C Act) [21]. There are several terms that must apply for these implants in order for them to fall within this category of custom devices. First, each implant is designed for a specific patient at the prescription of a physician. Further, the anatomy or pathology indicated must necessitate use of a custom implant and cannot be treated with an implant which is commercially available in the United States.

The patient's anatomy and implant are recreated from a CT scan that is provided to the implant company. The CT scan parameters are crucial as the implant is designed based on this cross-sectional imaging. Typically, files are best stored as Digital Imaging and Communications in Medicine (DICOM) file types, having a pixel size of 0.5 mm of less and slice spacing of 1.25 mm or less. The images must capture all relevant anatomy and be as recent as possible to ensure the engineering team can successfully reconstruct the anatomy for preoperative planning. For planning an implant for a failed ankle replacement, the author obtains a CT scan from at least midshaft of the tibia to the toes. This allows for better determination of lower extremity alignment when planning a fusion device.

Next, the surgeon must provide a clinical perspective of how the implant will be utilized and what the goals for reconstruction are. This process frequently occurs via virtual meetings, where the reconstructed CT data is displayed as 3D anatomy in the CAD workspace, and a virtual surgery can be simulated. From the initial design meeting(s), several CAD models of implant designs are engineered, which can be approved by the surgeon, or further iteration can take place. After the final design is approved by the engineering team and the primary surgeon, the process of fabricating the implant via 3D printing begins. After printing, the implant

undergoes post processing and inspection. The entire process from CT scan to final implant typically takes 4–6 weeks.

3D Implant Design Considerations Specific for Failed TAR

These cases are all unique. However, there are several design considerations for 3D implants for failed TARs. The most important part of the design is creating an implant that completely fills the void left by the TAR implants and bony collapse. As previously mentioned, the author prefers to use either a completely or mostly spherical 3D implant to fill the bony void. The use of spherical graft/implant provides substantial bony contact and two degrees of freedom for implant and foot positioning. If there is even greater bone loss, especially into the tibia, a pill-shaped or truncated tear drop can be made. These nonspherical devices are essential when the diameter of the sphere would be too great for the anatomy at the level of the ankle (Fig. 35.7).

In the preoperative planning session, it is important to have the engineers manipulate to the foot (or tibia) into anatomic position with a plantigrade foot and appropriate lower extremity length. The TAR components are subtracted from the images. The author's preference for TTC arthrodeses is slight hindfoot valgus, slight external rotation, and 5–10° of dorsiflexion at the ankle. Any collapsed bone can also be virtually removed. The unwanted bone will be removed with a saw or acetabular reamers during surgery. The resulting void, after repositioning, component removal, and bone removal, will be the shape of the 3D printed implant. The actual void volume is considered the "nominal" size. Once the shape is established, appropriate sizing must be determined. The author typically has three implants printed for each surgery. For spherical or near-spherical implants, the author has implants made with diameters 4 mm greater and 4 mm less than the nominal sized implant. For truncated tear drop or egg-shaped implants, the total height of the implant is typically of greater importance so the author will keep the nominal diameter of the spherical portion and have the total height 4 mm greater and 4 mm less than the nominal height.

Other considerations for the metal implant are fixation and pore size. Currently, there is inconclusive data on the poor size needed for these implants. The author's opinion is that the poor size should be as big as possible without compromising the strength of the implant. However, more data is needed. A larger poor size allows for better packing with bone graft. Also, a larger poor size could potentially reduce stress shielding at the implant-native bone interface. Implant fixation to bone is extremely important. The implant can be secured with an intramedullary rod, screws, or plates (either built into the implant or placed over the implant). The author's preferred fixation method is with an intramedullary rod. Therefore, there must be a cannulation in the implant. The cannulation should be several millimeters larger than the intended intramedullary rod diameter to allow for some "play" with alignment and rod insertion at the time of surgery.

In addition to the metal implant, nonmetal trial implants are also created. Trials are printed to specifically match the size and any important design features (such as cannulations for fixation) of the actual implants. These trials should be designed with handles to allow for insertion, removal, and manipulation. The handle locations should be based on surgical approach.

Surgical Technique

As the nature of salvage arthrodesis with 3D custom implants makes every case unique, after identifying the patient with a failed TAR (Fig. 35.7a) and designing the appropriate 3D implant, the following surgical technique description can be used as a guide. Many of the principles described here are similar to standard approaches to the ankle and with the use of a traditional femoral head allograft. However, the surgeon should make modifications as needed.

Patient Positioning and Approach

- Position the patient supine with a hip bump to make the toes point to the ceiling.
- Use a thigh tourniquet
- Place a commercially available foam positioning agent or stack of sheets/towels underneath the operative leg so that it is raised above the contralateral leg.
- Non-TAR failure TTC arthrodeses can be performed from the anterior, lateral, or posterior approaches. However, with regard to TTC arthrodesis for failed TAR, the implant and any associated hardware must be removed. Use the approach that is best suited for removal of the implant. In general, anterior or lateral approaches should be used.
- A lateral approach with fibular osteotomy can be made and implants removed from the lateral approach if the TAR implants have minimal intramedullary fixation.

Removal of TAR Implants and Insertion of 3D Implant

- There will be several different sized 3D implants. Place them in a basin with irrigation solution and 1 gram of vancomycin (unless the patient is allergic) powder until the correct size is chosen.
- TAR component removal will be implant specific. However, these general rules can be followed.



Fig. 35.7 (**a**) Anteroposterior (AP) and lateral radiographs of a painful TAR with talar component collapse and lucencies surrounding both implants. (**b**) The TAR components have been removed and sequential reaming of the tibia and calcaneus was performed. The radio-opaque implant trial has been placed and the foot alignment is checked on AP, lateral, and heel alignment views. You can see that some of the medial malleolus has been left to provide a medial buttress and greater bone surfaces for healing. (**c**) Successive reaming was performed with the trial device in situ. (**d**) Fluoroscopic images demonstrating intramedullary nail insertion and fixation. (**e**) AP and lateral radiographic images of this patient at 1-year follow-up

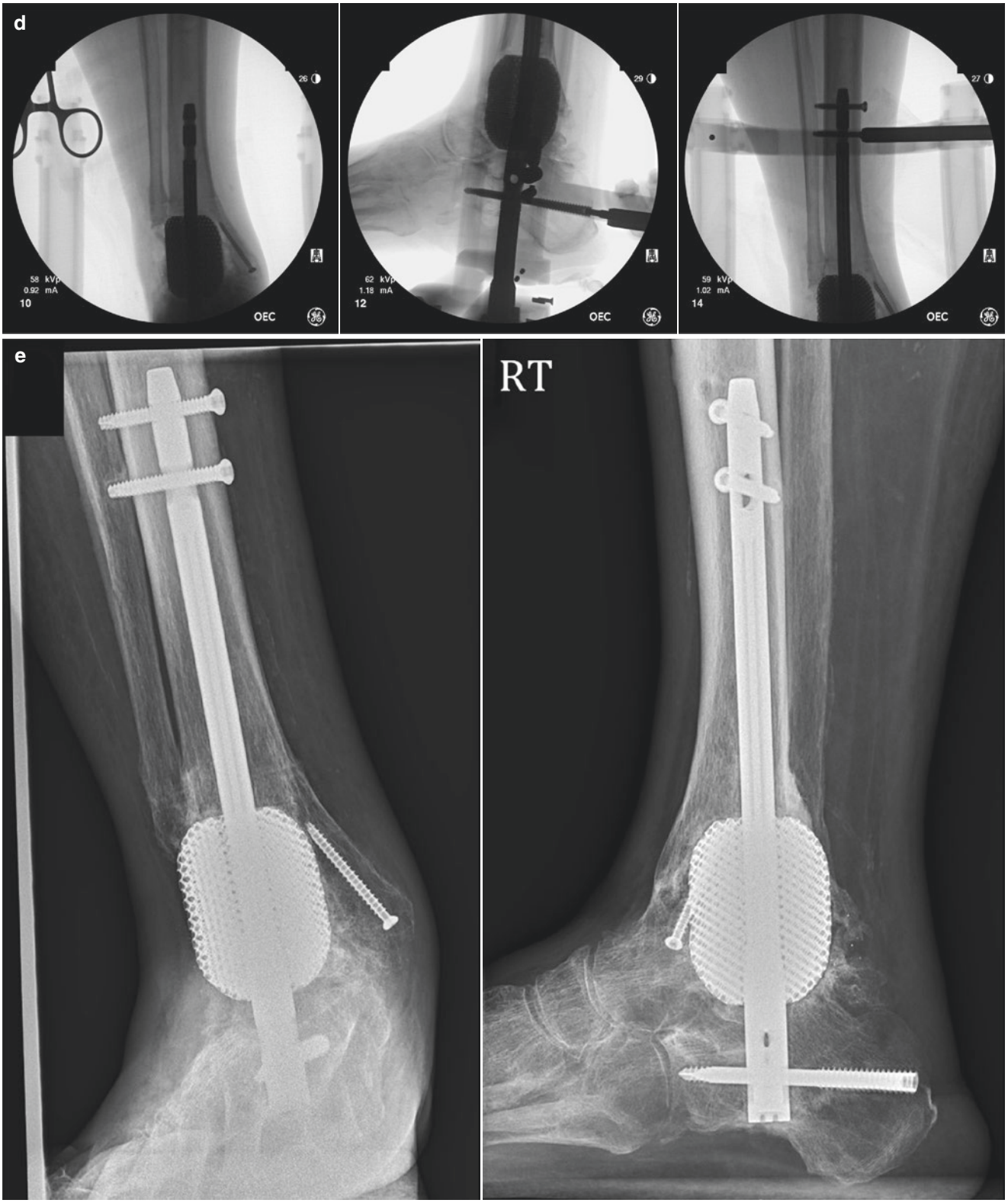


Fig. 35.7 (continued)

- Remove the polyethylene component. Use an osteotome to pry out the component. Often, a drill is used along the locking mechanism to disengage it from the tibia component.
- Next, remove the tibia component. For intramedullary components, often a cortical tibial cortical window must be made. Preserve this bone to be placed in the defect later. Components with minimal intramedullary fixation can be removed by prying with an osteotome or making an osteotomy just proximal to the tibia fixation.
- Talus component removal is similar. However, most 3D printed spherical implants do not replace the talar neck and head. Therefore, care must be taken to remove the implant without damaging the talar neck and head.
- Remove any easily visualized talar body bone. This step is not critical as the talar body will be removed with reaming.
- For spherical cages, sequential reaming using acetabular reamers is performed under fluoroscopic guidance to remove the damaged talar body, distal tibia, and dorsal calcaneus.
- Both AP and lateral fluoroscopy must be used to accurately guide reaming.
- If possible, underreaming should be performed. However, the diameter of some spherical implants is smaller than the diameter of the smallest acetabular reamer. In these cases, use the smallest reamer.
- If possible, preserve some of the medial and lateral malleoli to support the implant and create more surface area for bone ingrowth.
- Do not ream too far into the calcaneus. Only enough to create the semispherical shape, remove the cartilage and puncture into the subchondral bone of articular facets. The calcaneus is narrow dorsal to plantar, limiting the amount of fixation. Reaming too far into the calcaneus can compromise fixation.
- Copiously irrigate the wound to remove all reaming debris.
- Inspect the remaining bone surfaces. All surfaces should be denuded of any remaining cartilage back to bleeding subchondral bone.
- Assess the bony defect size and place the appropriate trial that achieves the bone defect filling and alignment goals (Fig. 35.7b).
- Align the foot and ankle and follow the manufacturer's instructions for intramedullary fusion nail placement. Guidewire placement and successive canal reaming should occur with the implant trial in place and under fluoroscopic guidance (Fig. 35.7c).
- While the reaming is occurring, an assistant can place bone graft in the actual 3D printed implant if needed. There is currently no data to determine if bone graft is necessary.
- Next, remove the trial and irrigate the cavity as needed. Care should be taken to not remove too much of the reaming slurry.
- Insert the real 3D printed implant. Use fluoroscopy to assess the position of the implant and the foot in relation to the tibia. One pass with the intramedullary rod reamer can help align implant with the calcaneus and tibia.
- Insert the intramedullary rod and follow the manufacturer's guidelines for fixation. The authors prefer to use compression (Fig. 35.7d).
- Perform a layered closure and place the patient in a non-weight-bearing splint.
- The patient is kept non-weight-bearing for 6 weeks, and then perform progressive weight-bearing for an additional 6 weeks.
- Routine follow-up of the new technology is warranted (Fig. 35.7e).

Outcomes

There are minimal data describing the results of 3D printed titanium implants for failed TARs. There are, however, many reports on the use of femoral head allografts and even non-3D printed metal implants. Jeng et al. [22] reported on the use of bulk femoral head allograft to treat bone defects of the ankle in 32 patients. They reported a 50% fusion rate, although nonunions were largely driven by diabetic patients. They also reported significant graft collapse in the nonunion group. Another study reported on the use of fresh frozen femoral heads for TTC salvage arthrodesis after failed TAR in five patients [14]. Despite the low number of patients, this study benefits the literature by reporting an average of 5-year results. In this group, three of five (60%) patients demonstrated complete healing of the graft. The nonunions occurred in one patient who had complete collapse of the graft and one patient who had a subtalar nonunion. In this series, the average limb length discrepancy at most recent follow-up was 1.6 cm, but two patients had greater than 2 cm discrepancies. This paper highlights potential problems with the use of femoral head allograft.

In an attempt to increase the union rate and avoid graft collapse, non-3D printed metal implants have been used to span large bone defects about the ankle but the data is limited. A small series of three patients who received a trabecular metal implant for TT or TTC salvage arthrodesis demonstrated radiographic (non-CT) healing and satisfactory outcomes at a mean of 57 months after surgery [23]. However, Aubret et al. [24] recently reported continued pain and difficulty assessing arthrodesis in a series of patients who received non-3D printed trabecular metal implants for failed TAR. Eleven patients underwent either TTC (ten

patients) or TT (one patient) salvage arthrodesis with a trabecular metal ankle interpositional spacer. Patients were followed for a mean of 19 months and a minimum of 1 year. CT scan analysis of the fusion rate was difficult secondary to artifact from the metal implants. Fusion at the tibia/implant interface was more common than at the implant/calcaneus interface. Patients continued to complain of pain and had a most recent follow-up average AOFAS score of 52/100.

The author of this chapter recently reported on 15 patients who received a custom 3D cage for large bone defects about the ankle [25]. Two of the 15 patients in this study underwent salvage TTC arthrodesis for failed TAR. Both successfully fused and were pain-free.

Summary

Salvage arthrodesis with a custom 3D printed titanium implant is a reliable treatment option for failed TAR. There are two important interrelated decisions that have to be made for the use of a custom 3D implant for TTC arthrodesis. These include the decision to perform TTC or TT arthrodesis and the decision to use a 3D printed implant over a femoral head allograft. If severe talus bone stock is lost, then a TTC arthrodesis should be performed. Preservation of the talar body and minimal bony loss of the tibia can be treated with a TT arthrodesis with either a femoral head or 3D printed implant. When the defect size, from proximal to distal, becomes larger than most femoral head allografts, consideration should be given to using a custom 3D printed cage. Benefits of a custom 3D printed cage are numerous. These cages can be made to infinite geometries, almost infinite sizes, increased strength over allograft, and potentially better bony incorporation. Although these implants show promising advantages over traditional methods, caution must be observed as there is no long-term data regarding the use of these implants to treat failed TARs.

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Part V

Limb Salvage of Failed Total Ankle Replacement

Preventative Measures Against Wound Healing Complications After Total Ankle Replacement

36

Ellen C. Barton and Thomas S. Roukis

Introduction

Wound healing complications are a risk with any surgical intervention, but given the potential severe consequences of total ankle replacement (TAR) wound complications, they must be taken even more seriously with this surgery in particular. The incidence of wound healing complications reported in the literature is highly variable, ranging from 0.9% to 14.7% [1]. Most ankle arthroplasties are performed through a 10-cm anterior utility incision in the interval between the tibialis anterior and extensor hallucis longus tendons. The safest surgical incisions to make are along the border between two adjacent angiosomes [2]. An anterior TAR approach requires an incision through the central aspect of a single angiosome, the anterior tibial artery, thereby increasing the risk for compromised vascular supply to the surgical wound. The anterior ankle incision is also at risk for wound healing complications because of the thin soft tissue envelope encasing the ankle, including a comparatively meager subcutaneous tissue layer for closure over highly mobile tendons [3, 4].

The definition of a "wound healing problem" is broad and open to interpretation. Various methods of documenting and reporting wound healing complications are a barrier to effectively researching and understanding this aspect of TAR. Wound healing was reported as an outcome in 52% of TAR studies included in a 2016 systematic review, but 27 unique terms were used to describe the complication [5]. In general, a minor wound healing complication has been described as one that may be addressed using local wound cares and oral medications only. A major wound healing complication is one that requires operative intervention. It would be of great benefit if a more systematic method of documentation were employed, especially on a national basis in those countries with national joint registries for TAR.

Wound healing problems that persist greater than 14 days have been cited as a significant risk factor for the development of a prosthetic infection in multiple studies [6, 7]. Reducing the risk for wound healing complications is of utmost importance and requires a multifactorial approach. It starts with careful patient selection guided by a knowledge of risk factors that place a patient at increased risk of complications. When a patient puts their trust in a surgeon and consents to the procedure, it is then the surgeon's responsibility to optimize all the factors within their control to ensure the best possible outcomes. This includes evaluation of surgical preparation, precise surgical technique, tension-free wound closure with adjunctive measures as necessary, and a systematic postoperative management protocol (Table 36.1).

Patient Selection

Patients may present with several social variables and comorbid conditions that place them at an increased risk for wound healing complications. Unlike technical aspects discussed further in the chapter which are within the surgeon's control, these may be non-modifiable variables. As such, careful patient selection for elective TAR is key.

Raikin et al. published a retrospective chart review of 106 TARs looking for independent patient risk factors associated with incisional healing complications [8]. Their findings suggest diabetes, female gender, inflammatory arthritis, and a history of oral corticosteroid use are all associated with an increased risk of wound healing complications. Diabetes was specifically associated with an increased risk of minor wound complications. Female gender, history of oral corticosteroid

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Table 36.1 Proposed benefits of incisional adjuncts

Incisional adjuncts		
Product	Class	Proposed Benefits
Intrawound antibiotics	Topical adjunct	Supratherapeutic dose with minimal systemic exposure
Platelet-rich plasma	Topical adjunct	Regulate local inflammatory reaction Recruit and help proliferate stem cells Promote angiogenesis
Amniotic membrane-umbilical cord allograft	Topical adjunct	Downregulation of inflammation Enhancement of local healing and antimicrobial factors Reduction in scar formation
Collagen matrix	Topical adjunct	Scaffold for cellular invasion and capillary growth
Negative pressure wound therapy	Mechanical adjunct	Incisional stress reduction Increased perfusion Reduction in edema and drainage Decreased pain
Continuous external tissue expansion	Mechanical adjunct	Decreased wound tension and redistribution of forces
Noninvasive skin closure device	Mechanical adjunct	Decreased wound tension and redistribution of forces Eliminates additional trauma of sutures and staples

use, and underlying inflammatory arthritis were associated with an increased risk of major wound healing complications, but inflammatory arthritis was the only variable to reach a level of significance. The authors' definition of inflammatory arthritis includes rheumatoid arthritis, psoriatic arthritis, and mixed connective tissue diseases. Of note, patients with obesity and current tobacco use were not offered a TAR, and therefore these variables were not included in this study.

Gross et al. published a retrospective comparison of patients with and without major wound healing complications requiring operative debridement [9]. Of the TAR included, 3.4% required operative wound debridement, including more advanced procedures such as split-thickness skin grafting or flaps for wound coverage. Compared to the control group, those with major wound problems had a significantly longer mean surgery time and trended toward a longer tourniquet time. There were no significant differences identified in the groups when comparing comorbid conditions such as elevated body mass index and diabetes. Those with wound healing complications were more likely to be afflicted with primary osteoarthritis versus post-traumatic arthritis. Although one may expect the skin envelope of a patient with prior trauma and surgery to be more likely to have wound complications secondary to its likely scar tissue development, the authors proposed that those with primary osteoarthritis may have had more intra-articular ankle joint steroid injections prior to surgery, a variable which they did not measure.

Based on retrospective review, Whalen et al. reported an increase in the rate of wound healing complications with a history of smoking greater than 12 pack-years, peripheral vascular disease, and cardiovascular disease [10]. Tourniquet time, diabetes, nonsteroidal anti-inflammatory use, oral corticosteroid use, and antitumor necrosis factor agents did not make a significant impact on the rate of wound healing complications.

The literature regarding the effect of comorbid conditions on TAR incision healing presents conflicting reports. This may be due to the high level of scrutiny and rigorous criteria employed by surgeons that produces a selection bias against certain conditions, limiting the ability to make conclusions regarding their effect on TAR wound healing with confidence. The literature regarding ongoing tobacco use and wound healing is a notable exception.

An estimated 13.7% of the US population is a current tobacco smoker [11]. Cottom et al. compared the wound complication rate in TAR between three different tobacco use groups. There was a significant difference in wound complication rate between active tobacco use and never tobacco use (45.5% wound complication vs. 12.5% wound complication), but those with a history of tobacco use did not have a significant difference in wound complication rates compared to never smokers (10.5%) [12]. Of note, the current tobacco use group was required to be nicotine-free for 3 months prior to surgery with lab testing confirmation, but had admitted to restarting tobacco use in the postoperative period. To be considered a former tobacco smoker, one needed to be without tobacco use for at least 24 months. This is like the data published by Lampley et al. demonstrating a significantly increased risk of incision breakdown in active tobacco use versus nonsmokers (11.8 vs. 3.9%) [13]. Based on the high risk of wound healing complications, current tobacco use should be considered a contraindication for TAR.

In addition to careful evaluation of a patient's comorbidities, a thorough preoperative physical exam must also be performed. Visual inspection of skin quality must be completed, including detailed notation of previous scar formation, edema, and overall quality of tissues. Pedal pulses should be palpated with a low clinical suspicion to include more advanced vascular studies. Arterial Doppler studies can be completed in the office and include evaluation of retrograde and antegrade flow [2]. Ankle brachial index (ABI) value should be obtained if pedal pulses are not palpable. ABI values less than 0.9 or greater than 1.2 require further evaluation prior to surgical intervention [14]. Transcutaneous oxygen values and angiography can provide additional input if necessary.

Preoperative Preparation

Adequate surgical preparation of the operative limb must not be ignored and is a variable easily within the control of the surgeon. Preparation may be standardized on an institutional basis, but it is worth careful evaluation to see if the current techniques employed meet the necessary standards for foot and ankle preparation. The foot is a difficult location to achieve adequate surgical asepsis due to intrinsic factors including a thick and heavily ridged anatomy of the plantar foot, abundant eccrine gland distribution creating an alkaline environment, close approximation of toes and webspaces limiting aeration, and the presence of thickened nail plates and larger subungual surfaces in comparison to fingers [15]. Extrinsic factors such as difficulty reaching the foot for regular hygiene, prolonged periods in socks, and using rarely cleansed shoe gear may also contribute to the "dirty" foot environment [15].

Multiple studies have been issued in the search for an ideal surgical preparation method. Keblish et al. compared four different methods on healthy volunteers [16]. They concluded that using products that contained isopropyl alcohol and scrubbing the foot with a bristled brush were both beneficial techniques. It is speculated that using a brush to scrub aids in exfoliation and introduces disinfectant products into the deeper contours of the skin, improving efficacy and bacterial kill.

Ostrander et al. completed a similar study comparing one-step povidone-iodine scrub to two-step iodophor scrub and povidone-iodine paint [17]. Based on the culture results, it was concluded that topical povidone-iodine-based agents alone are not sufficient for surgical preparation of the foot. Several years later, Ostrander et al. expanded on this initial research by developing a prospective study with 125 consecutive patients comparing three techniques: 0.7% iodine with 74% isopropyl alcohol, 3.0% chloroxylenol, and 2% chlorhexidine gluconate with 70% isopropyl alcohol [18]. They obtained quantitative cultures from three locations on the foot and ankle, which revealed 2% chlorhexidine gluconate with 70% isopropyl alcohol to be the most efficacious method. These results did not, however, correlate significantly with the rate of postoperative infections. Hunter et al. published a randomized prospective study on the order of use for 4% chlorhexidine gluconate and 70% isopropyl alcohol, which also did not correlate with clinical findings [19]. Based on previously published research including those above, Roukis et al. developed a protocol and demonstrated the efficacy of surgical prep consisting of a 3-minute scrub with chlorhexidine gluconate 4% followed by painting with ethyl alcohol and iodine 1% solution [15]. In all studies, cultures were more likely to be positive from the toe area in comparison with the ankle.

All authors agreed that the toes should be covered during surgery to limit contamination from the area most likely to have failed during prep. The value of re-prepping the surgical field in prolonged cases and prior to closure should also be considered. There is no literature to support its efficacy in limiting wound complications, but the risk versus benefit ratio would favor the most cautious approach. Other commonsense measures that should be considered include changing to a fresh pair of top gloves prior to handling the definitive prosthetic components and cleaning instrumentation of bloody debris.

Administering perioperative intravenous antibiotics per standard operating protocol, and redosing this antibiotic if time indicates, is necessary. At this time, no literature specific to TAR is available on this topic, but to not do so would violate the currently accepted standard of care.

Intraoperative Technique

TAR is a technically demanding surgery that requires a well-trained surgeon who is capable of attention to subtle detail. Gentle retraction and handling of the soft tissues are necessary to minimize trauma to the wound edges. Dissection should avoid delamination of layers and maintain the tibialis anterior within its tendon sheath whenever possible [3]. It must include meticulous hemostasis to avoid the formation of hematoma. Proper surgical technique requires limited soft tissue dissection and periosteal stripping from the distal tibial, medial, and lateral malleoli and talus. Efforts must be taken to reduce the amount of bowstringing against the anterior ankle wound by the tibialis anterior and/or the extensor hallucis longus tendon by intentionally and carefully closing the extensor retinaculum. The most common area for incisional necrosis was along the anterior-medial aspect of incision over, or adjacent to, the tibialis anterior tendon that is frequently not contained within its own sheath creating tension on the extensor retinaculum closure [10].

It would be reasonable to assume that complications would decrease with surgeon experience. Research has supported a decrease in TAR complications such as perioperative fracture and malalignment with increasing experience; however, wound complications persist despite increased experience [20]. This supports the need for a multifactorial approach to decreasing wound complications and the inherent risks present with an anterior ankle incision.

Borrowing literature from ankle fractures, every 15-minute increase in operative time past 75 minutes is independently associated with an 11% increased risk of surgical site infection and 20% increased risk of subsequent wound dehiscence [21]. A review of the Japanese national ankle arthroplasty database found an overall greater risk of any

adverse event with anesthesia time greater than 200 minutes [22]. Although wound complications do not decrease with experience, the operative time does decrease with TAR experience, and through this method, it may make an impact on the incidence of wound healing complications [23, 24].

Alternative Incisions

Although the anterior incision is the preferred approach for most surgeons and ankle implant models, it may be necessary to consider alternative incision placement in some cases. Bibbo describes the use of an alternative anterior ankle incision in patients with prior incisions in the area [25]. The incision starts midline in the lower one-third of the leg and curves toward the anterior medial ankle just lateral to the tibialis anterior tendon sheath, and then curves gently back toward the midline, finishing at the level of the tarsal joints. Full-thickness soft tissue flaps must be created with mobilization at the level of the deep crural fascia. This approach was recommended in patients with extensive anterior ankle compromise from prior injury and surgery.

Depending on the implant model, it may also be possible to approach a TAR through a posterior or lateral approach. The posterior approach for TAR has been reported for revision TARs. It requires modification of instrumentation in addition to a high degree of technical understanding and mastery [26, 27]. The posterior approach requires prone positioning and transection of the Achilles tendon. It should not be pursued as a first-choice incision placement.

Certain TAR systems, including the Trabecular Metal (Zimmer, Warsaw, IN), allow implantation from a lateral approach. Usuelli et al. compared 81 HINTEGRA TAR (Integra, Saint Priest, France) through an anterior ankle approach with 69 Trabecular Metal TAR through a lateral approach [28]. The authors did not find any significant difference in superficial or deep infections between the groups, although there was a significant difference in operative time, with the lateral approach taking longer to perform. Wound healing was not a reported outcome although the authors reported it as a key indication for considering a lateral approach. Data from this study may be difficult to extrapolate to the average practice as the authors employed an aggressive approach toward wound management with all patients, including infectious disease consultation if the incision was not healed within 2 weeks and consultation with plastic surgery if wound healing issues persisted for 4 weeks or greater. In a separate publication, Usuelli et al. reported a 2% wound complication rate through the transfibular approach [29].

Incision Closure

After implantation is complete, the incision should be closed in layers. The use of a drain is also recommended to limit hematoma formation, as this can compromise wound healing. Proper skin closure technique should be tension-free, "watertight," and without skin edge inversion. The goal of closure is to promote rapid skin healing and acceptable cosmetic results while minimizing risk of dehiscence or infection [30].

Different suture closure techniques have been explored in foot and ankle literature. Sagi et al. evaluated cutaneous blood flow via Doppler probe analysis after four different suture techniques on an animal model and found the Allgower-Donati suture negatively affected blood flow the least in comparison to vertical mattress, horizontal mattress, and simple sutures, which were all equal in testing [31]. Although the research was done on lateral incisions for ankle fractures, it has been reported using quantitative angiography that the Allgower-Donati suture technique allows for superior skin perfusion in comparison to vertical mattress sutures [32]. This could theoretically decrease the risk of wound healing complications, but it has not been correlated with clinical results.

Barbed sutures are reported to better distribute tension forces across the length of a wound in comparison to the two points of tension and relative ischemia created by traditional interrupted suture technique. Deep closure is completed with absorbable suture with the most superficial layer closed with barbed suture, followed by the application of adhesive skin strips. There have been publications regarding their use in TAR, but with mixed results. Mayet et al. reported prospective data on a mix of foot and ankle surgical incisions, including six TARs, found a 6.5% wound complication rate [33]. Possible complications associated with barbed suture include extrusion and prominence of the barbs. If considering the use of barbed sutures, the surgeon should be mindful and aware of the different resorption profiles associated with brand name products [33].

Also borrowing from ankle fracture literature, the use of metallic staples versus sutures has been researched. Staples are more efficient than sutures with no difference reported in wound complication rate [34, 35]. Staples are reported to cause less of a local immune reaction and reduce damage to peri-incisional tissues [34]. A systematic review of the use of staples in all orthopaedic procedures found no difference in outcomes in comparison to sutures, except for closure time, which was shorter with the metallic skin staples [30].

Intrawound Antibiotics

Popularized by its use in spinal surgery, topical antibiotics, specifically vancomycin powder applied to surgical incisions, have been proposed as an adjunct in orthopaedic surgery. The proposed benefits of intrawound antibiotics include a supratherapeutic dose with minimal systemic exposure. This is especially important when considering the fact that surgical wounds often have compromised vascularity that may alter the efficacy of systemic antibiotics. The possible adverse side effects of intrawound antibiotics include the development of antibiotic resistance, circulatory collapse, and decreased bone healing [36]. The use of intrawound antibiotics has been reported for total hip and knee arthroplasty. A systematic review completed found that intrawound antibiotics may reduce the rate of prosthetic joint infection in knee and hip arthroplasty but did not document any effects on wound healing [37]. The majority of literature included in this study was retrospective in nature. A prospective study regarding the use of vancomycin powder in total knee arthroplasty wounds found no significant difference in the rate of prosthetic joint infection. This study did, however, find a higher rate of wound complications and prolonged wound healing associated with the use of topical vancomycin. Wukich et al. reported specifically on the use of topical vancomycin in reconstructive foot and ankle surgery in a diabetic population [38]. A significantly decreased likelihood of deep surgical site infection was reported for a relatively inexpensive cost. The medical journal *Foot & Ankle International* published a consensus statement in 2019 indicating there was insufficient evidence to support the use of topical vancomycin in TAR [39].

Biologic Products

Platelet-rich plasma (PRP) has been widely reported with various indications in foot and ankle surgery, including TAR. PRP may be used on the incision after deep closure has been completed. PRP is proposed to help regulate local inflammatory reaction, recruit and help proliferate stem cells, increase cell adhesion, and promote angiogenesis by concentrating molecules such as platelet-derived growth factor, vascular endothelial growth factor, fibroblast growth factor, and insulin-like growth factors, among others. The combined effect is thought to enhance the natural healing response [40].

A retrospective review comparing TAR with PRP augmentation versus standard of care without augmentation revealed no statistically significant difference in minor or major complications [41]. Another study specifically sought to determine if the use of PRP would decrease surgical site infections and decrease incidence of delayed wound healing in a broad group of foot and ankle surgeries [42]. The application of PRP to the operative field and to the sutured skin was found to have no significant effect on the rate of deep surgical site infection or delayed wound healing. In addition, analysis of the PRP revealed a large variation in the concentrations of growth factor concentrations between individual patient samples.

There has been a prospective publication on the use of amniotic membrane-umbilical cord allograft as an adjunct to incision closure [43]. Standard layered closure was completed with the graft placed over the extensor retinaculum. The proposed benefits of this product include downregulation of inflammation, enhancement of local healing and antimicrobial factors, and reduction in scar formation. In comparison to the standard of care, use of the graft decreased the time to skin healing by an average of 11.5 days (28.5 days in graft group vs. 40 days in standard group). There was not, however, any difference in the rate of reoperation, dehiscence, need for local wound care, or antibiotic prescription between groups.

Collagen matrix (Integra Wound Matrix, Integra LifeSciences Corporation, Plainsboro, NJ) has also been used as an incisional adjunct. The product is indicated for the management of partial- and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, and traumatic wounds [44]. The collagen matrix is composed of a cross-linked bovine tendon collagen and glycosaminoglycan. It is proposed that this biodegradable matrix provides a scaffold for cellular invasion and capillary growth.

Negative Pressure Wound Therapy

Within the literature, there is a growing body of research to support the use of negative pressure wound therapy (NPWT) in orthopaedic procedures, including total joint arthroplasties. The proposed benefits of NPWT include incisional stress reduction, increased perfusion, reduction in edema and drainage, decreased pain, and decreased time to healing [45–47]. In a randomized controlled trial evaluating the use of NPWT for 1 week after primary total knee and hip arthroplasty, the use of NPWT trended toward a significant reduction in postoperative surgical wound complications [48].

No consensus is available in the literature regarding the ideal pressure settings and duration of use for incisional NPWT in TAR. Matsumoto et al. performed a retrospective cohort study comparing wound healing outcomes in TAR with and without the application of incisional NPWT [45]. The NPWT consisted of an incisional dressing with pressures set at (−)80-mmHg continuous for 6 days. Both cohorts were placed in bulky Sir Robert Jones dressings with a posterior splint. The use of NPWT was found to be an

independent predictor of primary incision healing without complications. DeCarbo et al. reported on the use of incisional NPWT on high-risk incisions with settings at (−)125-mmHg continuous for the first 24 postoperative hours, monitoring output in a fashion similar to the traditional use of drains [47]. No outcomes were reported, but the authors believe the use of vacuum-assisted wound closure can decrease pain and swelling and may reduce the risk of infection and time required to achieve complete healing in wounds.

Mechanical Adjuncts

Mechanical adjuncts to help decrease the tension across the anterior ankle incision have also been reported. Continuous external tissue expansion (CETE) may decrease wound complications and time to healing by placing a continuous force on the non-traumatized skin adjacent to the actual incision [4]. CETE is applied after the incision has been fully reapproximated and is an adjunct to, not a replacement for, closure with staples or suture. It provides a controlled amount of force to the tissue adjacent to the incision using multiple barbed skin anchors and a tension controller. The use of CETE in combination with NPWT has also been reported for those at high risk for wound healing problems [49].

A noninvasive skin closure device (ZipLine, Stryker Medical, Warsaw, IN) also modifies the tension across an incision. The device is secured to the borders of the incision after deep closure has been completed and replaces sutures or staples. The proposed benefits of the device include force distribution along the length of the incision that creates compression with axial forces and protects the incision from lateralizing distractive forces. A comparison between staple and device closure on TAR incisions has reported statistically significant higher blood perfusion based on laser-assisted indocyanine green angiography with the device. Four patients received the device and five were closed with staples. Two out of the five patients with staples suffered incisional dehiscence versus none in the device group [50].

Postoperative Management

Postoperative management after TAR is highly variable but may have a significant impact on wound healing complication rates. There is not an accepted standard in the literature for postoperative dressings after TAR. The ideal dressing should not create iatrogenic pressure wounds while being simple, reproducible, and inexpensive [51]. Immobilization is necessary in the postoperative period until the incision has healed because the motion of the tibialis anterior and other tendons directly under the incision may delay healing. Prolonged immobilization may be necessary if wounding occurs that can negatively affect the functional outcomes status post TAR.

Schipper et al. completed a cohort comparison of circumferential below-knee cast immobilization versus compression wrap [52]. Below-knee cast immobilization consisted of a circumferential padded fiberglass cast with windowing over the surgical incision about the anterior ankle that allowed patients to perform daily dressing changes for the first 2.5 weeks. The compression wrap protocol included a petroleum gauze dressing, gauze, rolled and tubular gauze, rolled cast padding, and compression bandage from the toes to the knee protected in a controlled ankle movement (CAM) boot. The compression wrap was then changed two to three times per week by trained staff members in the clinic. The authors identified significantly more wound complications in the cast immobilization group, both in the total number of complications and in the number of minor wound complications. Severe or moderate wound complications were equal in both groups. Hsu et al. also published on a compression wrap protocol for TAR. The dressing consisted of petroleum gauze, 4 by 4-inch gauze, tubular and rolled gauze, underpadding, cotton compression bandage, and silk tape applied from the level of the toes to the knee. The dressing was changed every 2 to 3 days by physical therapists who monitored the appearance of the incision. In a series of 100 patients treated with this dressing protocol by the authors, two major wound complications were reported. The authors claim this is an improvement in the rate of complications compared to their previous circumferential cast protocol.

Elliott and Roukis introduced the concept of aperture padding for TAR in 2017 and demonstrated its efficacy [51]. On retrospective review, there was a threefold decrease in the number of anterior incision wound healing complications with the aperture pad in comparison to Sir Robert Jones compression dressing alone. The aperture pad consists of one 6-inch by 4-yard roll of cotton undercast padding unrolled back and forth on itself to a length longer than the incision itself and then manually split along its long axis and spread open to create an area of offloading along the length of the incision. With applications of all dressings, it is important to passively dorsiflex the ankle to neutral to avoid bunching of the dressing material about the anterior ankle [53]. Multiple authors have concluded that circumferential casting with the ankle in dorsiflexion, rather than neutral position, may lead to vascular congestion at the anterior ankle incision, thereby increasing the risk for skin necrosis [52]. Literature is trending away from the use of circumferential cast in favor of compressive dressings.

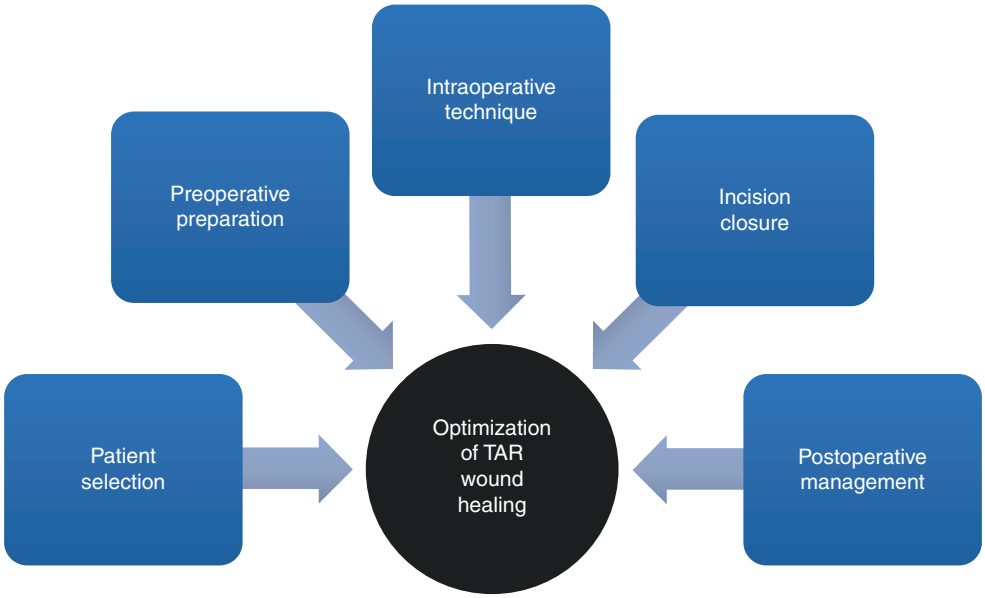


Fig. 36.1 Multifactorial approach to minimizing risk of TAR wound healing complications

Conclusion

TAR incisions are at a high risk of wound healing complications. A multifactorial approach that optimizes the incision from every angle should be employed (Fig. 36.1). While some of the measures outlined above may add additional procedural costs, the expenditure must be weighed against the possibility of time and finances spent on a prolonged healing course and repeat surgical intervention. Whalen et al. reported that the cost of treating wound healing complications with deep tissue loss exposing the TAR was five times greater than the cost of a TAR that healed without complication [10]. Judicious use of wound healing adjuncts may be a worthwhile investment, and perhaps even more so in patients with known risk factors for poor healing (Table 36.1). As Benjamin Franklin advised in 1735, "…an ounce of prevention is worth a pound of cure" [54]. Once a wound is present, it must be addressed and treated promptly.

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Managing Wound-Healing Complications After Total Ankle Replacement

37

Christopher Bibbo, Andrew Bauder, and Stephen J. Kovach

Introduction

Total ankle replacement (TAR) is gaining mainstream acceptance as the primary surgical choice in the management of ankle arthrosis. As the TAR procedure becomes more prevalent, there will be, by default, an increasing number of wound (incision) healing complications. As with total knee arthroplasty (TKA), patient selection based on an adequate soft tissue (ST) envelope and limb vascularity is just as, if not more important, as selection criteria for placing the implant-without a stable, durable ST envelope, the surgery will fail, which may lead to infection, explant, or even amputation. As with any wound management protocols, soft tissue reconstruction after TAR follows the "reconstructive ladder," starting with the simplest methods of wound care, progressing to the most powerful flaps. At times, the "reconstructive elevator" is the only level of management, and flaps may be selected immediately. The choice of operative management of wounds after TAR is determined by vascular status, comorbidities, the size of the wound, the condition of the surgical site, and the presence of infection. Unfortunately, amputation may be the procedure of choice when given that treatment of the problem portends greater morbidity than the wound itself.

Wound-healing complications after total ankle replacement (TAR) have been quoted as high as 16–28% [1, 2]. Wound-healing complications' disturbing finding is that by the end of 1 year of developing a wound-healing complication, 25% of patients with wound-healing complications may require TAR explantation, and many will be infected [2]. Clearly identifiable risk factors for developing a postoperative wound-healing problem include tobacco use, peripheral vascular disease, and cardiovascular diseases [2]. Overall, what can be gleaned is that delayed wound healing may be the single most common wound-healing issue after TAR. It should be kept in mind that the anterior ankle has a rich blood supply, but the intervening tissue planes between skin and joint capsule are scant—there is a lack of inherent "backup" richly vascularized muscle, fat, or fascia. A high shear stress area requires extremes of motion and is subject to hydrostatic dependency forces, combined with the above rendering the anterior-distal soft-tissue envelope one that requires additional time to heal and remodel. Although the entire incision may be at risk for poor healing (Fig. 37.1), the area near the tibialis anterior tendon has been found to be a consistent area of wound breakdown (Fig. 37.2) [2–4]. Clearly, the patients' health inventory and surgeon experience/technique must be factors in the development of wound-healing problems after TAR. However, it also seems apparent that wound-healing complications may be related to prosthesis design, vis-à-vis time, soft-tissue techniques required for component implantation, and biomechanical function, and may push the surgeon and host to their tolerances [1, 3, 5].

Prevention of Wound-Healing Complications

Treatment of wound-healing complications after TAR begins with prevention. Preoperatively, all patients must be evaluated for the presence of arterial inflow via palpable pedal pulses.

Maximization of Medical Comorbidities

The most recognized conditions that complicate wound healing are poorly controlled diabetes, smoking, excessive

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Fig. 37.1 Example of delayed healing that requires close follow-up. Local care may be expected to assist with expectant healing over the course of several weeks



Fig. 37.2 The area near the tibialis anterior tendon appears to be at greatest risk for wound breakdown. Techniques to temporarily suture tendinous structures together and "parachute" them down to deeper structures may help relieve pressure in this area of the incision. (Photo courtesy of Benjamin Overly, DPM)

alcohol abuse, and poor nutrition, although diabetes has been considered a contraindication to TAR. However, diabetes routinely undergo total knee and hip arthroplasty, and the course of the TAR will in time follow suite. The lead author screens type 1 diabetics for new onset and tight glycemic control. Type 2 diabetics are better candidates, again with the provision of good glucose control. The surgeon must be reminded that even type 2 diabetics may wax and wane in their blood glucose control and transition to poor blood glucose control is not uncommon.

In total knee arthroplasty (TKA), type 1 diabetes in not an exclusion criterion if blood sugars are well controlled. The evaluation of the HbA1c is helpful to assess the average blood sugar level over 3 months. However, unlike TKA, patients with dense neuropathy are poor candidates for TAR in regard to the development of Charcot neuroarthropathy—poor blood sugar control and Charcot are implicated in poor healing of surgical incisions.

Previous injuries may result in loss of antegrade tibialis anterior artery flow, with retrograde filling via the posterior tibial artery, and less commonly the peroneal artery. The "eyeball test" is performed by simply inspecting for deeply pigmented or atrophic scars, poor skin turgor, massive edema, and tissue paper skin which are visual alerts to microvascular or venous disease, even if a Doppler arterial signal is present. In revision settings, prior to any secondary surgery, transcutaneous oxygen (TCO_2) may be helpful along previous scars, as long as edema or a poor-quality chest lead does not invalidate the results. A formal preoperative vascular surgery evaluation should be prompted when a lack of arterial inflow with nonpalpable pedal pulses with poor Doppler arterial signals or TCO_2 data is poor. Computed tomography angiogram and formal angiogram with distal runoff are helpful in discovering focal stenosis amenable to stenting or extensive disease that may require vascular bypass surgery. Venous congestion of the skin makes the healing of incisions difficult; experience has shown that venous skin changes above the incision may also place the distal portion of the incision at risk. Incisions must be emplaced even more carefully.

Edema Control

Peripheral edema has several etiologies. Needless to say, edema imparts difficulty for incision placed.

On the leg, often the skin over acutely edematous tissue is thinned. Weeping of the incision may occur, resulting in gapping of incision, drainage, and seroma—all of which can pose a challenge for skin healing. Control of edema and dressings the etiology, medically or mechanically needs to be instituted.

Smoking

Smoking as well as vaping must be stopped as soon as possible. The well-known effects of smoking is vasoconstriction and poor skin healing (as well as bone); excessive alcohol abuse may compound these. Nicotine patches and gums—"chew"—must be considered in the patients' overall health profile.

Perioperative Nutrition

Well-known, but often overlooked, nutritional status is very important for wound healing. Generally, an inquiry regarding daily diet regimens may give adequate information. It must be remembered that patients with a robust body habitus may still be nutritionally challenged. Labs may be selective but when ordered must include at a minimum albumin and total protein levels. Micronutrient deficiencies as related to skin healing may be missing and are difficult to assay. When deficiencies are detected, a low glycemic high-protein diet with protein supplement is implemented, along with a daily multivitamin. The nutritional prescription is continued throughout the perioperative period.

Intraoperatively, meticulous soft-tissue handing, respect for preserving the cutaneous perforating vessels, and maintenance of hemostasis are important. Inadvertent injuries to larger vessels should be repaired, rather than tying off the vessel. Closure should be performed in multiple layers, utilizing gauges of suture appropriate to the tissue thickness of each patient. If possible, the lead author will transpose anteriorly a large low-lying peroneus tertius muscle belly, if it is present (Fig. 37.3). To cover the prosthetic components completely, tendons may be temporarily tenodesed with rapidly absorbing fine sutures and then "parachuted" deep into the incision, thereby relieving pressure in the incision and creating a tissue barrier over the TAR components (Fig. 37.4). Loss of the integrity of individual tendon sheaths or retaining structures should be addressed by reconstruction with a "tissue-friendly" product such as PriMatrix (TEI Medical, Boston, MA) (Fig. 37.4). Skin closure may be performed with nonabsorbable suture or staples. The author uses 2–0 and 3–0 polypropylene vertical mattress sutures when the skin is of poor quality. An indwelling drain is always placed to limit hematoma and removed when ≥15-cm^3/shift for two consecutive shifts.

Postoperatively, elevation is begun immediately after a well-padded splint is applied (the author uses triple padding/compression), and ice used to reduce edema and anticoagulants administered with aspirin 325 mg by mouth twice daily or low-dose unfractionated or fractionated heparin are the standard of care for in-house hospital patients for deep venous thrombosis prophylaxis but may also have a favorable effect on arteriolar rheodynamics. In the past, a trend of placing patients on high-concentration supplemental oxygen via face mask has not proven to impact wound-healing problems. The author retains sutures or staples for 4–8 weeks, depending upon extremity edema and overall quality of the overlying soft-tissue envelope. Incisional negative-pressure wound therapy dressing between 50 and 100 mmHg for 3–5 days may assist in "tight" closures or the edematous limb (Fig. 37.5).

Treatments Based on Severity of Wound-Healing Problem After Total Ankle Replacement

Local Wound Care

Wound dehiscence that is superficial and does not span the length of the incision is commonplace after lower extremity surgery. These may be avoided by allowing more time for healing prior to suture removal. Delayed wound healing/dehiscence that is superficial may be treated expectantly with saline dressings, and "spitting" sutures should be removed. Skin sutures or staples remain for all patients for 4 weeks, longer if the skin is of poor quality. We have found the combination of silver dressings, covered with an absorptive layer such as PolyMem® (Ferris Manufacturing Corp, Fort Worth, TX), and a "tissue-friendly adherent" such as Mepitel® (Mölnlycke Health Care, Gothenburg, Sweden) (Fig. 37.6) can reduce wound dressing needs to once per week. When infection is present, empiric systemic antibiotics may be commenced, and material for culture should be sought. Although a less common pathogen, unyielding low-grade wound problems with a clinically infected appearance that fail antibiotics ultimately yield *Candida* species yeast; thus,

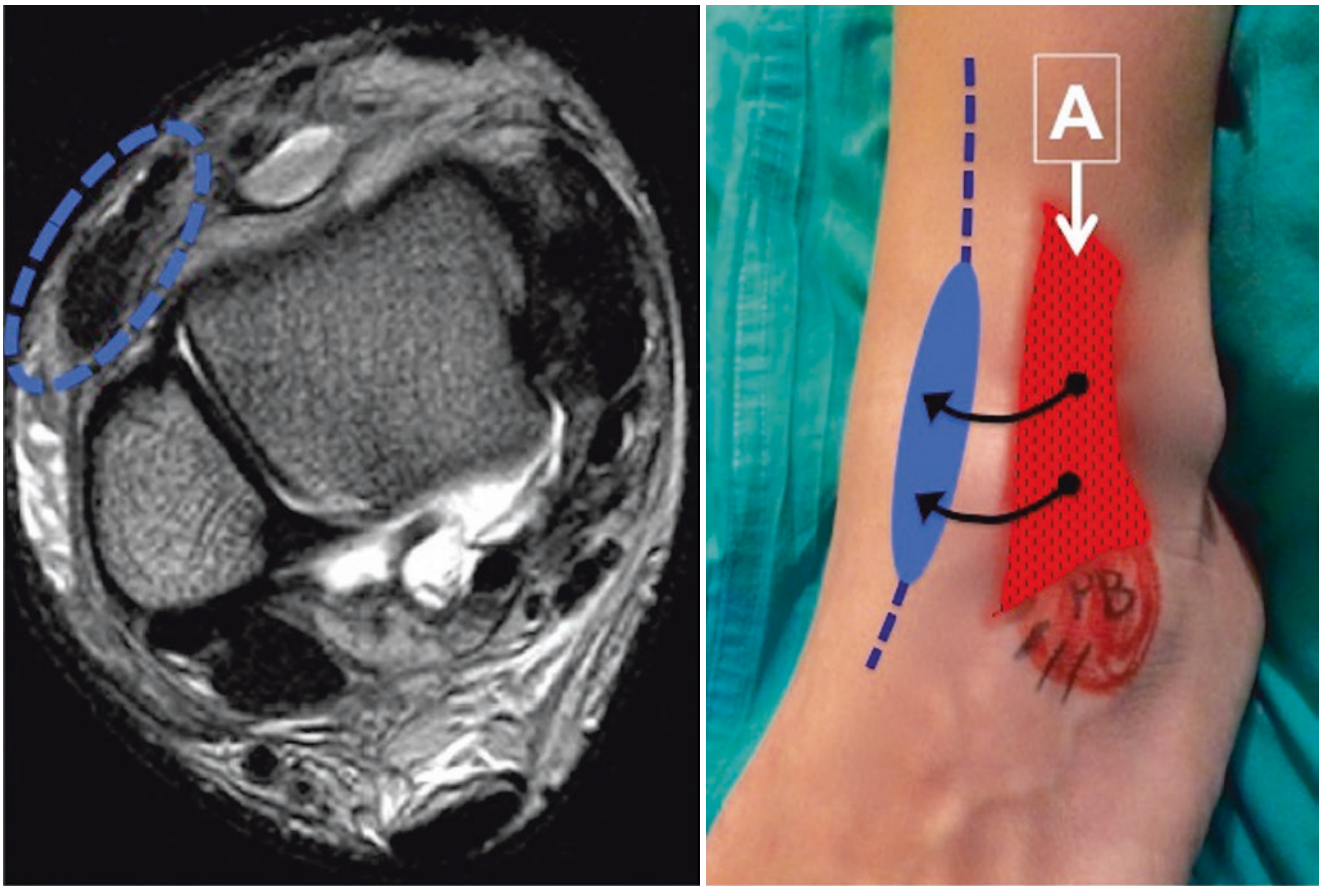


Fig. 37.3 Magnetic resonance imaging (*left image*) of a low-lying peroneus tertius muscle belly (*blue hashed circle*) and surface marking of its position (*red speckled rectangle* designated as *A*). This muscle can be transposed or formally transferred by detaching the tendon distally to assist with providing vascularized muscle locally within the central/lateral portion of a wound dehiscence (*blue-filled oval*)

fungal cultures should be included in every culture sent from the beginning of the work-up. Negative-pressure wound therapy dressings with/without instillation therapy are an excellent modality for superficial wounds, with expectant healing within a few weeks. Thick split-thickness skin grafts (14–18/1000-in.) may be placed on the granulating bed (Fig. 37.7). Full-thickness skin grafts provide a thicker coverage with less secondary contraction. However, the author has found a lower rate of take for full-thickness skin grafts in the ankle region. Due to skin excursion and tension placed on the skin by the tendons under the skin, without an excellent granulation bed, the anterior ankle may develop into a hostile area for skin grafts, resulting in an unstable soft-tissue envelope that will require flap coverage (Figs. 37.8, 37.9, and 37.10).

Operative Wound Debridement and Revision of the Incision

A full-thickness disruption of the incision, especially when full length, requires operative exploration. Cultures should be taken and infections managed as described elsewhere in this textbook. All devitalized tissue needs to be sharply excised, back to fresh bleeding tissue (Fig. 37.8). Tendons are loosely imbricated to "seal off" the underlying TAR. The peroneus tertius often has a low-lying muscle belly that may be formally transposed into the wound, introducing vascularized soft tissue into the problem area (Fig. 37.3). Reclosure may be attempted that may require "back cuts" or relaxing incisions, which is not as successful as one would hope. A layered closure is performed, with tension relief over the



Fig. 37.4 Temporary imbrication (tenodesis) of tendons and parachuting them down onto deep tissues takes pressure of the incision (**a**). Reconstruction of the retaining structures of the ankle with an ingrowth substrate (PriMatrix®, TEI Medical, Boston, MA) not only prevents bow-stringing but also relieves incision tension and provides an ingrowth medium if wound dehiscence were to occur, making negative-pressure wound therapy more effective (**b**)

central area of the wound. Skin eversion and skin line relief are best accomplished with 2–0 polypropylene simple or vertical mattress sutures. An incisional negative-pressure wound therapy dressing may be used as a supplement, set at 50 or 100 mmHg, either in a continuous or an intermittent mode if tissue is friable (Fig. 37.5). Postoperative edema control is implemented. Ankle range of motion is limited for 2–4 weeks until the revised wound "stabilizes."

Debridement and Negative-Pressure Wound Therapy Dressings

Often, the bane of the surgeon is the area just lateral to the tibialis anterior tendon (Fig. 37.2). Judicious wound debridement, with an effort to save all vascularized tissue, is performed, followed by negative-pressure wound therapy dressing. It has been the authors' experience that the KCI VAC® (KCI, Vacuum Assisted Closure, San Antonio, TX) provides the most reliable system to achieve negative-pressure wound therapy dressing treatment. When tendons are exposed, in order to prevent tendon desiccation, polyvinyl acetate foam ("white foam") should be used. Another technique to prevent tissue desiccation is instillation therapy utilized with normal sterile saline or Prontosan (R. Braun Medical, Bethlehem, PA). Infected wounds must be debrided of necrotic tissues. Negative-pressure wound therapy with installation may be initiated with a number of agents (Table 37.1). The granulation potential must be assessed carefully: vascularity of the area being treated must be one that can provide rapid granulation ingrowth; otherwise early flap coverage must be considered. If granulation of the

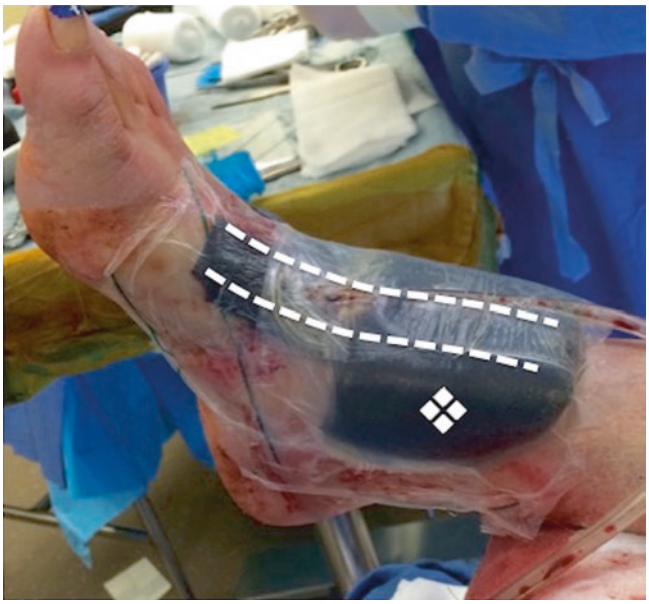


Fig. 37.5 Example of incisional negative-pressure wound therapy dressings (*arrow* and *outlines*) for tight or tenuous incision closure. The authors use spare foam to pad the skin from the suction hose (❖). Pressures are set at 50–100 mmHg continuous or intermittent for delicate skin

wound is rapid (within 1–2 weeks), tissue ingrowth substrates such as Integra Bilayer® (Integra Life Science, Plainsboro, NJ) or PriMatrix may be placed over the defect and negative-pressure wound therapy continued. It cannot be stressed enough that wound inspection must be performed at a minimum of once or twice per week; any lack of progress in healing must be declared with a low threshold. At any time, when the author is utilizing negative-pressure wound therapy dressing and is entertaining the next level of care, soft-tissue flaps and hyperbaric oxygen therapy are incorporated into the management plan when feasible.

Local Soft-Tissue Flaps

The longitudinal anterior approach to the TAR posed some technical problems for flap coverage. Adjacent soft-tissue advancement flaps can help close small defects, with the donor region backfilled with a skin graft. Available regional flaps include the reversed sural flap, the lateral supramalleolar flap, and, for the very distal extent of the incision, an islandized pedicle plantar medial artery flap (Fig. 37.11). The extensor digitorum brevis muscle flap may be useful for

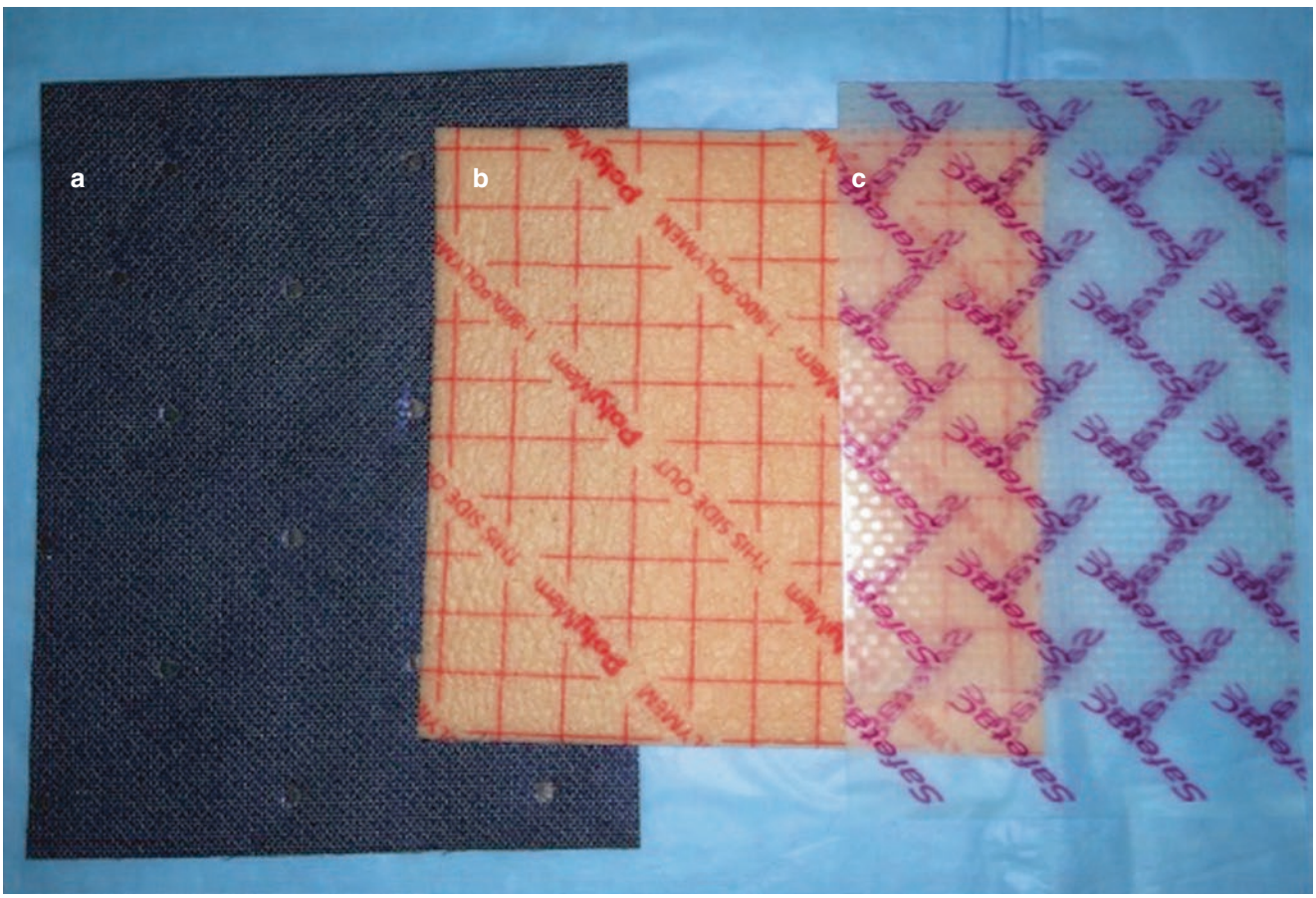


Fig. 37.6 The combination of silver-coated dressings (**a**), PolyMem (**b**), and Mepitel (**c**) will assist in providing a dressing that is bactericidal and absorbs excessive surface fluid while allowing local fluid evaporation with a "tissue-friendly" self-adhesive



Fig. 37.7 Example of wound with exposed tendon after total ankle replacement that was successfully managed by close follow-ups, serial debridements, and negative-pressure wound therapy dressings. A split-thickness skin graft is now ready to be applied. (Photo courtesy of Benjamin Overly, DPM)

small mid- to distal junction area of wound breakdown, but the size of the muscle belly is highly variable and adequate rotation may require sacrifice of the dorsalis pedis artery, making its use limited. Other muscle rotation flaps, such as the soleus and reverse peroneus brevis muscle flap (Fig. 37.12), have variable distal muscular perforator patterns and may be considered in proximal wound coverage but may not always be reliable for anterior TAR wounds, especially the soleus. Tenodesis of the peroneus brevis tendon to the peroneus longus tendon must be performed to preserve the important eversion function of the peroneus brevis tendon insertion. The use of perforator-based posterior leg propeller flaps may be useful to cover TAR surgical wounds that have laterally based soft-tissue loss, with the advantage of less donor site morbidity than other local flaps (Fig. 37.13). Donor site morbidity with these flaps is a concern, but prelamination of the donor site with PriMatrix in conjunction with flap delay techniques can help mitigate both flap complications and cosmetic issues at the donor site. These local flaps may be of great help in patients who otherwise are not medically fit to undergo a free flap procedure or when microsurgical services are not available. Large area wounds, especially with an exposed TAR, require free tissue transfer techniques.

Specific Wound-Healing Problems

Wound Closure

A number of items contribute to a difficult wound closure. Closure in layers is always recommended over drains as needed. It is not uncommon that the extensor retinaculum cannot be closed. Tendon bow-stringing is examined to assess the need to reconstruct the extensor retinaculum. Bow-stringing may be controlled by placing a small gauge suture through the tendon and, while depressing the tendon, onto the osteo-periosteal sleeve of the tibia; closure is then continued through the extensor retinaculum, deep dermis, and skin. Alternatively, a piece of human skin substitutes may be used



Fig. 37.8 Subacute wound dehiscence/necrosis with exposed tendons (**a**). Appropriate debridement to viable tissue may be followed by negative-pressure dressings prior to final free flap coverage (**b**). (Photo courtesy of David A. Ehrlich, MD)

to span the retinacular defect to prevent the bow strung tendon placing skin pressure. When available, the peroneus tertius muscle or a low-lying extensor muscle belly may be transposed to reside directly under the incision, giving the incision a vascularized muscle to close over (Fig. 37.3). The choice of skin suture is per surgeon preference. The authors' opinion is to avoid the Allgower-Donati suture, which gathers the dermis with possible "strangulation" of the skin blood supply. When intraoperative edema results in swelling, immediate temporary closure of available areas of the incision with staples or towel clips takes advantage of tissue hysteresis, allowing an easier final closure. Extensile approaches may also provide enough tissue for local tissue rearrangement. Dressings are by surgeon preference; they must be at a minimum bacteriostatic, provide a barrier, and allow for a moisture content compatible for wound healing. Incisional negative-pressure wound dressings (NPWD) help splint the skin edges during early phases of skin healing and may be indicated after closure when closure is tight.

Wound Gapping

The gaping wound indicates either swelling or loose closure. This may be treated with a NPWD, sterile surgical tape strips, or supplemental sutures/staples postoperatively. Even this minor issue must not be ignored, the wound should be inspected routinely, and early range of motion (ROM) during skin incision healing should be less than usual until the incision has shown significant progress in healing.



Fig. 37.9 Large surface area wound with tendons below a weak granulation bed. Although split-thickness skin grafting may be performed, this type of wound often results in a chronically unstable soft-tissue envelope requiring resurfacing with a free flap in order to prevent future breakdown or allow future surgical approaches to manage total ankle replacement revision. (Photo courtesy of Benjamin Overly, DPM)



Fig. 37.10 Chronic nonhealing wound after total ankle replacement. Desiccated exposed tendon surrounded by marginally viable tissue places this wound in consideration for free flap coverage. Due to extension of dysvascular soft tissue over the medial malleolar region and proximally flap coverage will need to extend beyond the confines of the visible wound (*dashed teardrop*). (Photo courtesy of Benjamin Overly, DPM)

Minor Wound Dehiscence

The definition of minor is subjective, but needless to say that one centimeter in the center of the incision is concerning and immediate action must be taken. Localized cellulitis and edema must be addressed; ROM should be discontinued; and local wound care measures should be initiated including silver-based absorptive dressings when exudate is present. If available, a small NPWD may be applied. The depth of the wound dictates the need for reclosure in the operating room (OR). A depth below the fascia mandates inspection in the OR. Debridement as needed, deep cultures, and reclosure of NPWD are indicated. In the author's opinion, 2 cm dehiscence should be managed expediently in the OR. After debridement and thorough irrigation, Gram's stain and cultures (aerobic, anaerobic, fungal) are taken. Stray deep sutures are removed. Reclosure may be attempted if edema permits. Otherwise, local advancement of skin and fascia, incision extension with local tissue rearrangement, or NPWD is used. Wounds of any size with exposed prosthetic components are very urgent and require the same measure as described above, but now, local flaps are more likely be required for successful resolution of the wound. Dehiscence of greater than 4 cm will almost always require a flap. Flaps may be fasciocutaneous, muscle, or musculocutaneous. These flap tissues may be local and regional flaps or free flaps.

Table 37.1 Antibacterial solutions used by the authors that are effective agents with negative-pressure installation wound therapy

Solution	Active ingredients	Notes	Uses
Marshfield	0.1% clindamycin (200 mg–1.33 mL)	Refrigerate up to 90 days	Acute and chronic infections
Clinic triple antibiotic solution[a]	0.1% gentamicin 200 mg–5 mL 0.005% polymyxin B (2× 500,000 unit vial); sterile H_2O to expand to 200 mL		
Dakin's solution	Buffered sodium hypochlorite ((NaClO)	Use 25% or 50% strength	Acute purulent infections, necrotizing fasciitis, methicillin resistant
			Staphylococcus species; use for only 3–5 days
Vancomycin 1%	Vancomycin		Methicillin resistant
			Staphylococcus species
Dilute acetic acid	Acetic acid (CH_3COOH)	5–6%	*Pseudomonas* contamination and to reduce surface bioburden
Prontosan®[b]	Polyhexanide (PHMB) and betaine (surfactant)	Food and Drug Administration approved with negative-pressure wound therapy	Noninfected wounds with high bioburden/surface biofilms, prevent wound desiccation
Normal sterile saline	Sterile normal physiologic saline solution		Prevent wound desiccation; minor bioburden reduction

Most are used every 6–8 h, dwell time 30 min
[a]Developed by Michael Caldwell, MD, PhD, FACS, Marshfield Clinic, Marshfield, WI
[b]R. Braun Medical, Bethlehem, PA; FDA approved with Veraflo™ VAC® (KCI, San Antonio, TX)

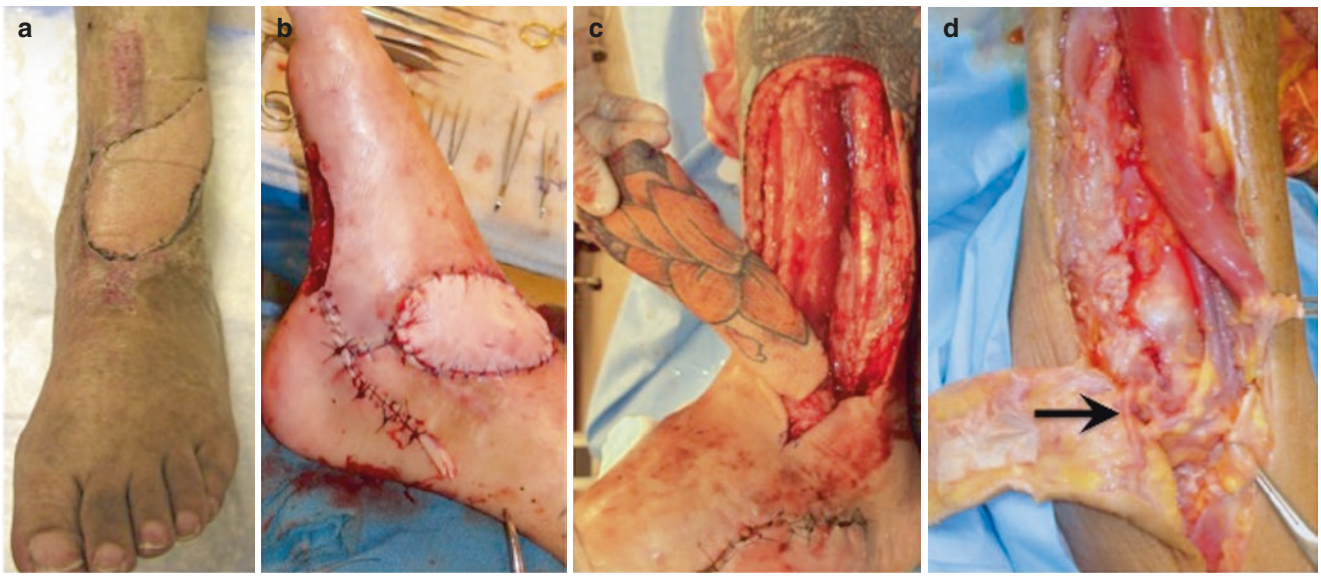


Fig. 37.11 The reverse sural flap may cover large areas of the total ankle replacement incision (**a**). The plantar medial artery flap has limited reach to the distal anterior/medial ankle (**b**). The distally based lateral supramalleolar flap can transpose large area of tissue anteriorly but may expose anterior and lateral leg structures and has the worst potential flap donor site morbidity (**c**, **d**), and previous trauma or surgery to the sinus tarsi/subtalar joint area may render the distal pedicle (*arrow*) incompetent

Large Area Wound-Healing Complications

When a large area of wound exists, flaps are an invaluable tool to prevent deep infection, supplement antibiotic therapy, prevent/assist with explant, and manage the loss of the soft-tissue envelope (STE). Tissue necrosis after TAR must not be ignored. Operative excisional irrigation and debridement are performed, taking all necrotic tissue back to fresh bleeding tissue. After a true assessment of the area needing coverage, a flap may be placed immediately or after a short delay. A NPWD with fluid instillation (Veraflo, KCI-Acelity, San Antonio, Texas) is ideal—sterile saline, surfactant fluids, dilute acetic acid, and sodium hypochlorite solution may be instilled.

Flap selection is based on local tissue available, the wound size, and considerations of secondary implant-based surgeries. If the implant will be retained (low virulence organisms, early-stage infection) or replant is planned, a fas-

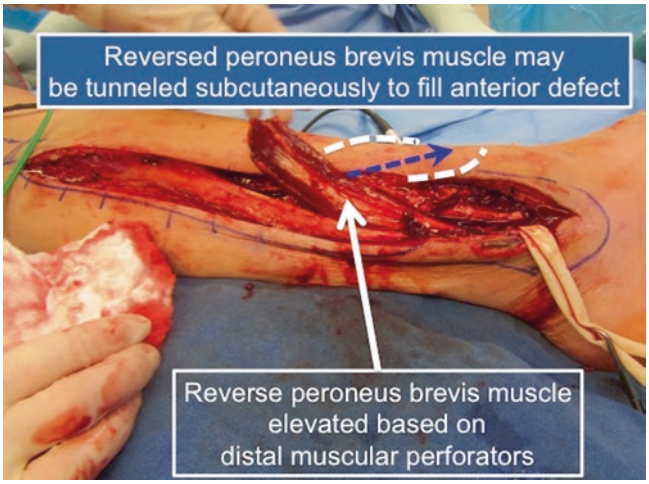


Fig. 37.12 The reversed peroneus brevis muscle flap may provide limited proximal anterior wound fill. The soleus muscle flap, either as a standard flap or a distally based hemi-soleus variation, may not prove reliable coverage for distal one-third anterior tibia and ankle region coverage

ciocutaneous flap is the first-line selection. Secondary choices are musculocutaneous and muscle flaps. Fasciocutaneous free flaps may be required for massive areas of soft-tissue loss. If ankle arthrodesis is planned, flap selection is simplified. Any flap may suffice to provide coverage. Additionally, when augmentation for bone loss is needed, local muscle flaps can be designed to include vascularized bone graft.

Specific Flaps and Surgical Indications

Local Flaps

Local flaps are relatively simple in comparison to free flaps (FF), which require specialty training and a healthcare facility that has the associated support systems. Local flaps provide several options, but when selecting such flaps, it must be able to reach the anterior ankle. Despite being relatively

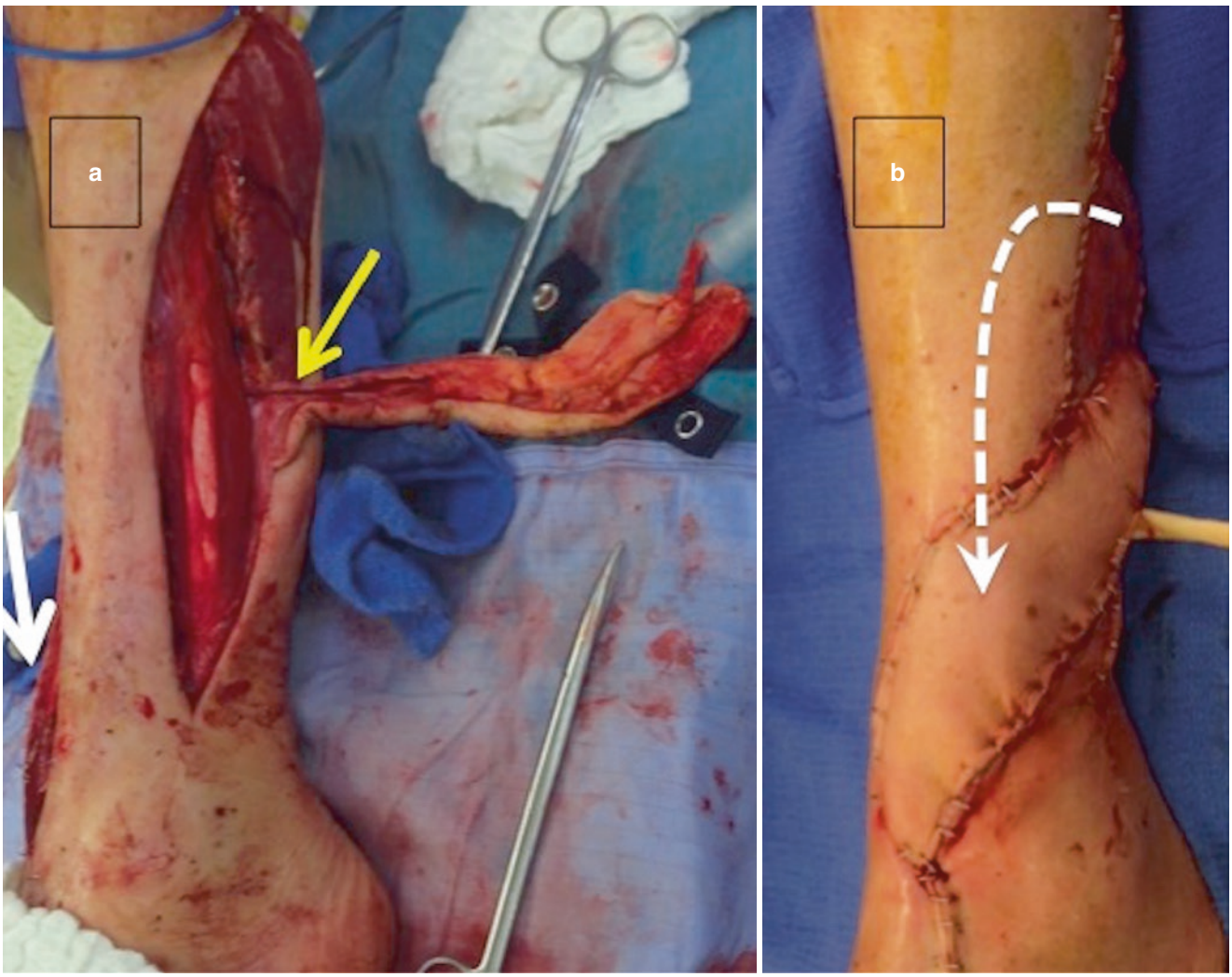


Fig. 37.13 Sural artery skin perforator-based propeller flap (perforator, *yellow arrow*) for anterior total ankle replacement wound complication (*white arrow*, **a**). Propeller flap rotated (*white dashed arrow*), inset, and small residual donor defect backfilled with a split-thickness skin graft (**b**)

simpler than a FF, each local flap has finicky characteristics which are best performed by surgeons experienced in orthopaedic and plastic reconstructive surgery ("orthoplastics"). Clear communication must exist between the arthroplasty and plastic reconstructive surgeon; this brings both surgeons to understand the plan and requirements of another. The concept of flaps is twofold: fill the defect and resurface the defect. Local flaps suitable for ankle coverage are muscle with skin graft; musculocutaneous, fasciocutaneous, and adipofascial flap are available. Fasciocutaneous flaps, whether local or free tissue transfers, offer the ability to incise through them after healing; this is possible as vascular ingrowth occurs across the edges and these types of flap act as native skin. Free flaps are best suited for ankle coverage when the soft-tissue defect is large to massive; in many cases this is a limb salvage situation.

Local flaps utilize local/regional tissues to provide tissue elevation. Local flaps may be simple fasciocutaneous rhomboid, V-Y, advancement, and rotation flaps; these are easy to perform and may be in the outpatient setting. These are restricted to smaller or narrow defects, as the skin over the anterior ankle demonstrates a paucity of elasticity. Other local flaps that transfer distant tissues to the recipient site have the advantage of a relative technical ease of execution, may provide a supple coverage of all tissue composites desired, and require a short hospital stay. Several local/regional flaps are suitable for ankle coverage: the reverse sural fasciocutaneous and adipofascial designs, anterior lateral propeller flap, the distally based (reverse) peroneus brevis +/− skin, and distally based (reverse) medial hemisoleus; the advantages and disadvantages are listed in Table 37.2.

Reverse Sural Flap

The reverse sural (RevS) flap may be elevated as either a fasciocutaneous or adipofascial, fascia flap (Fig. 37.12). The RevS flap is supple and allows for a good contour. The limits of width are 8–10 cm. The flap design may reach the ankle easily or with some difficulty, depending on the length of the defect as well as the pivot point on the perforating arteries that are limited in length by the location of the perforators (i.e., perforating vessels are more proximal). The length of flap design is typically 2 cm distal to the distal popliteal crease. Insetting of the flap may be performed by simple rotation. Transfer through the interosseous membrane should require an experienced surgeon. This flap should not be tunneled under the skin. Contouring of the distal skin paddle may be requited at a later date. An early caution is that the RevS is "fickle" in that any degree of venous congestion will

Table 37.2 Local flaps

Flap	Tissues	Blood Supply	Site	Donor site management	Reliability	Advantages	Disadvantages
Reverse Sural	Skin, fat, fascia Fat/fascia	Peroneal perforators	Posterior Calf	Skin graft; Close primarily if small	Poor in at-risk patients	Thin, pliable, provides all tissues desired. Easy elevation	May need a delay technique Venous congestion Late contouring of pedicle Does not provide deep fill of defects
Anterior propeller	Skin, fat, fascia		Anterior leg	Skin graft	Good	Thin, pliable, all composites needed Easy elevation Predictable perforators	Large visible donor site
Reverse peroneus brevis	Muscle Small skin island. May provide bone (fibula)	Peroneal perforators	Lateral leg	Primary closure	Poor to moderate	Relatively fast elevation Provides fill of deep defects	Tip necrosis limits reach to anterior ankle Variability in muscle size Requires skin graft
Reverse hemi-soleus	Muscle	Posterior tibial perforators	Posterior leg compartment	Primary closure	Good	Large volume Fills deep defects	Requires skin graft Larger dissection Perforator levels variable
Extensor digitorum brevis	Muscle	Lateral tarsal	Proximal anterolateral	Primary closure	Good	Provides fill	Only useful in small, distal defects
FHL						Difficult elevation	
P Tertius	Muscle	Tib ant	Distal anterior leg/ankle	Primary closure	Fair to good	Local in incision Easy transposition	Variability in muscle length Only for small axial wounds

quickly place the flap in jeopardy. Thus, delaying the inset of the flap (elevating sequentially), setting 7–14 days later, helps to limit venous congestion but also delays the time to coverage of the ankle wound. Harvest of the short saphenous vein allows for a veno-venous anastomosis ("supercharging" the flap), with the recipient vessel located on the foot—this requires vascular and, often, microsurgical skills. Leeches may be used to relieve congestion but most often harbor *Aeromonas hydrophila*, and patients must be placed on antibiotics (fluoroquinolones). Other species of drug-resistant organisms have been reported in leeches resulting in secondary infections [6]. Allowing venous egress by bedside exteriorization of the short saphenous vein may be performed; this, however, is labor-intensive. Removing the skin of the RevS flap in small flaps with early congestions can also reduce congestion *by allowing venous blood to drain freely.* Donor site management is simple and cosmetically acceptable especially with narrow flaps where primary closure may be performed. Marginally tight closure may be relieved by "pie crusting" the adjacent skin. Wider flaps will require an immediate or delayed skin graft. The RevS has significant limitations in patients at risk for poor skin healing, with a complication rate of 50% including partial and complete flap loss [7].

Propeller Flap

The propeller flap (PropF) is a fasciocutaneous skin flap, rotated nearly 180 degrees, pivoting on the perforating vessels (Fig. 37.11). Depending on the patient body habitus, the PropF provides a thin to moderately thick, durable, supple flap, composed of skin fat and fascia. The reach of these flaps hinges upon the design and location of the distal perforating vessels—the pivot point. Congestion is not usually a problem with the PropF but may occur. Unless primary closure may be performed, the donor site will be unsightly and requires skin grafting.

Reverse Peroneus Brevis Flap

Located in the lateral leg compartment, the peroneus brevis (PB) is a dispensable muscle since the function of PB may be transferred to the peroneus longus (PL) muscle by tenodesing the tendons distally. The reverse PB (RevPB) flap (Fig. 37.14) relies on a proximal major muscular perforator and 2–4 distal perforators. Like other distally based flaps, the lowest perforators (1–2) dictate the arc of rotation and, in

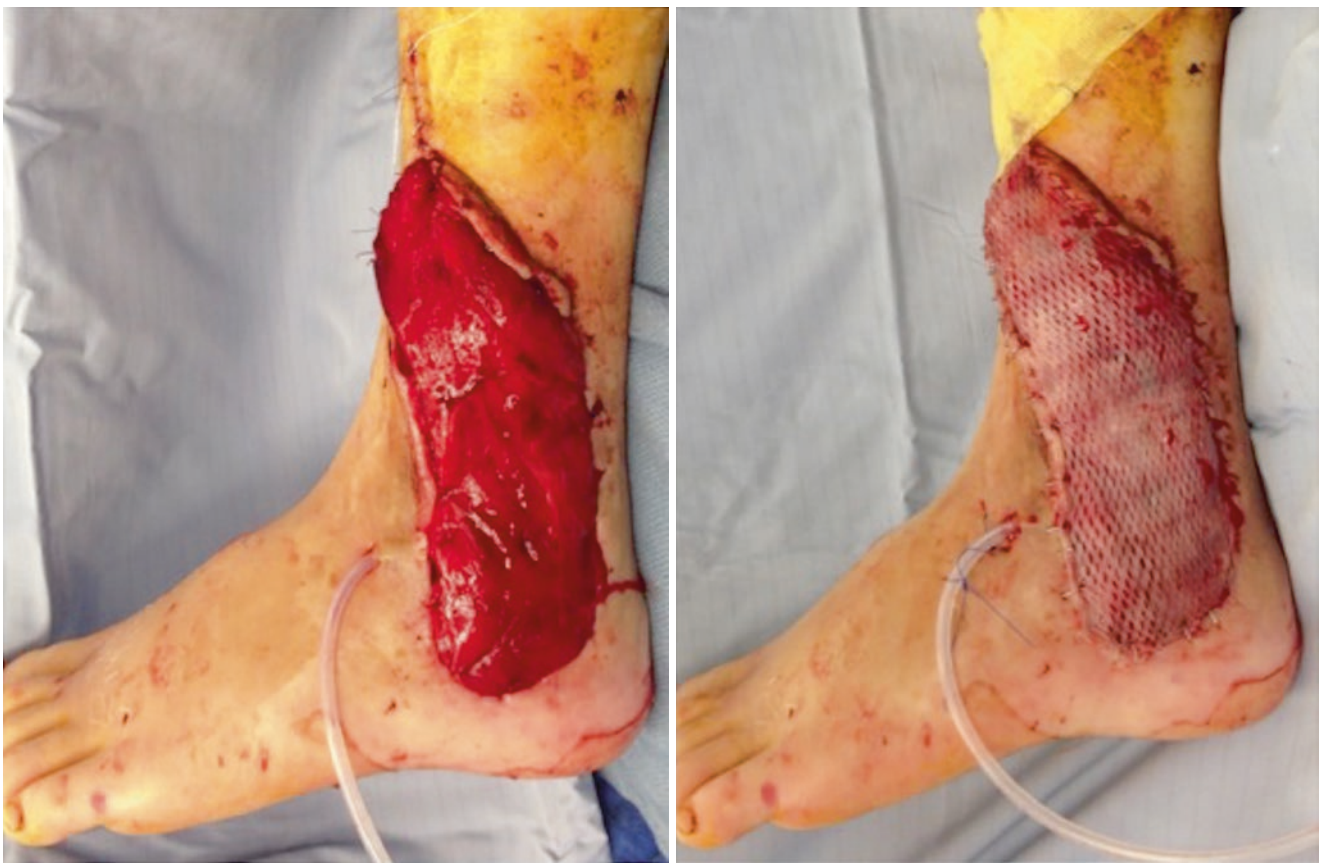


Fig. 37.14 Example of a gracilis muscle free flap for ankle coverage with lateral extension of the wound. Immediate split-thickness skin grafting is shown in the *right panel*. Although significant flap atrophy will occur over the ensuing 6 months, shoe fit can be still difficult and debulking of the muscle may then be required

part, the reach of the flap. The most proximal length of flap is determined by the position and caliber of the proximal perforator. Typically, the distal 2 cm of the flap is nonviable. In a clinical series, Bibbo found that the average number of distal muscle perforators was two, all greater than 5 cm above the tip of the lateral malleolus (5–7 cm). This implies a more precarious blood supply to the tip of the flap than previously thought, which is especially important when the wound extends below the ankle. The donor site leaves a fine scar and minimal to no loss of function when the PB tendon is tenodesed to the PL tendon. The flap will need a skin graft since a skin island is only supported in the mid- to distal length of the muscle. When a fusion is performed, a short section of fibula may be elevated with the PB muscle, providing a section of vascularized bone. Despite these shortcomings, the RevPB flap is worthwhile, as the downsides can be compensated for by either tendon tenodesis at completion simply or, if abnormal anatomy contraindicates the flap, the muscle flap may be simply placed back into its bed and a search for an alternate flap commenced. Tunneling of the flap is not recommended.

Reverse Hemi-Soleus Flap

The reverse hemi-soleus (RevHS) flap has the capacity to provide a generous amount of muscle. Located in the posterior compartment of the leg, the vascular supply is derived from the muscular vessels of the posterior tibial artery. As with other distally based flaps, the pattern of the proximal and distal muscular perforators determines the utility of this flap. The flap itself, when the vascular territory of the soleus muscle is suitable, is reliable to the medial ankle, but reach to the anterior ankle may be difficult. The medial half of the soleus muscle is dispensable, as the lateral half remains, as well as the gastrocnemius muscle. Tunneling of the flap under the skin or through the interosseous membrane is not recommended. The flap must be skin grafted. Elevation of the flap must be meticulous, as bleeding may be a concern, especially when the posterior tibial artery runs inside the edge of the muscle. The donor site is easily managed by primary deep and superficial closure over drains. Due to the technical elements of raising this flap, it is not recommended for the novice surgeon.

Free Tissue Transfers

Free flaps are the next step when local tissues are not available or suitable to cover the complex TAR wound. Free flaps may be described by their composite of tissue(s). In the past free muscle flaps were the workhorse for lower extremity coverage, such as the latissimus dorsi (Fig. 37.15), serratus anterior, rectus abdominis (Fig. 37.16), or gracilis muscles (Fig. 37.14). Split-thickness skin grafting is performed on these pure muscle flaps. On occasion, in thin patients, these muscles may be harvested with a skin paddle (musculocutaneous free flaps), but bulk may require a secondary thinning procedure and placement of a final skin graft.

The use of free skin perforator flaps, such as the anterolateral thigh flap (ALT), the scapular and parascapular flaps, the radial and ulnar artery forearm flaps, and the thoracodorsal artery perforator flap, has revolutionized soft-tissue free flap surgery. A composite of flap containing skin/subcutaneous fat/fascia ± muscle and perforator skin flaps such as the ALT free flap have been demonstrated to provide equal coverage of traditional muscle flaps, but offer the advantage of offering a very supple, easily contoured flap that provides all the elements of the integument desired to cover lower extremity soft-tissue defects [8]. From a technical standpoint, to cover the anterior ankle, the ALT free flap possesses a vascular pedicle length and caliber that is well suited to the anterior tibial vessels, and the donor site can easily be closed primarily (Fig. 37.17a). Postoperative monitoring of the flap is facilitated by simple Doppler evaluation of the skin perforators. The ALT free flap has also found great utility in resurfacing anterior knee wounds prior to re-implanting total knee prosthesis. The same concept holds for the TAR; the ALT fasciocutaneous free flap provides full defect coverage with all desired tissue layers (skin/fat/fascia), and upon final flap "take" can be elevated easily or even incised through to gain access to the anterior ankle. The ALT free flap can even be placed to resurface an unstable anterior ankle soft-tissue envelope before the index primary TAR procedures. Although often a tedious dissection, for these reasons the ALT free flap has become our "go-to" free flap to cover large anterior ankle defects or provide resurfacing prior to or after TAR (Figs. 37.16, 37.17, and 37.18). When soft-tissue coverage is needed along with a large amount of vascularized bone, the free osteocutaneous fibula flap (Fig. 37.19) can be quite

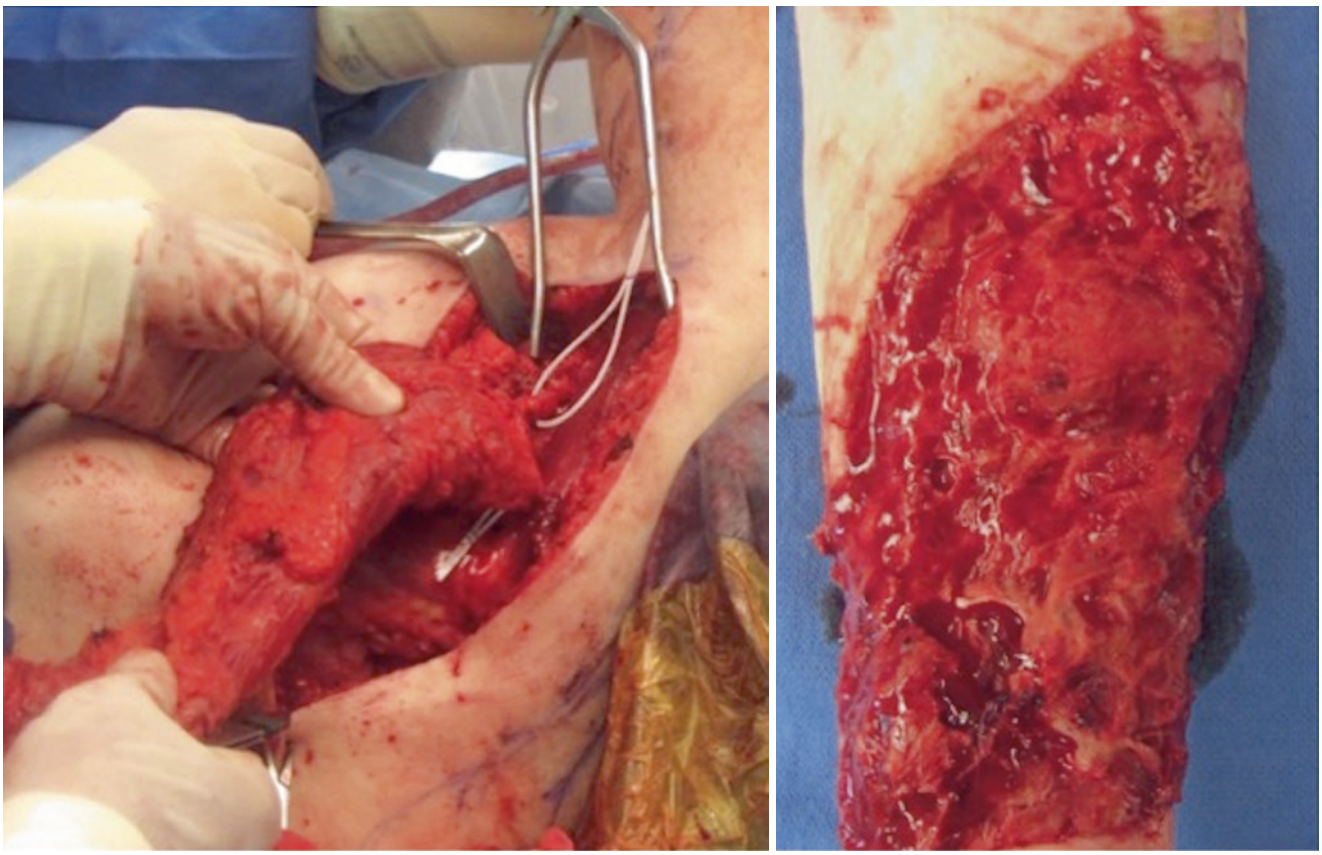


Fig. 37.15 Latissimus dorsi muscle free flap is quite large and has its greatest utility in massive wound coverage. This flap can be split based on its two main intramuscular coursing vessels to decrease bulk. It may also be taken with a small skin paddle and trimmed to fit smaller defects. A pedicled skin perforator flap based on the thoracodorsal artery ("TDAP" flap) may also be elevated, but a short pedicle length can limit its use in ankle coverage



Fig. 37.16 Appearance of a free rectus muscle flap with poor skin graft take. Bulk and a lack of subcutaneous padding are the relative disadvantages of free muscle flaps, unless a skin paddle is harvested. Nonetheless, free muscle flaps are still considered to be traditional reliable workhorse free flaps for myriad lower extremity reconstructions. The disadvantage of free muscle flaps is that elevation of the flap for secondary surgeries must be performed along the course of the pedicle. (Photo courtesy of Benjamin Overly, DPM)

useful. The free osteocutaneous deep circumflex iliac flap (Ruben's osteocutaneous free flap, anterior iliac crest bone with skin free flap) and the parascapular osteocutaneous free flap can provide coverage accompanied with smaller amounts of vascularized bone.

Conclusions

Incision breakdown of the operative incision following total ankle replacement surgery is commonly encountered as a complication. Healing problems can progress from superficial wounds to full-thickness necrosis of the skin and deeper tissues jeopardizing the ultimate retention of the prosthetic components leading to compromised patient outcomes. A multidisciplinary approach should ensure once wound breakdown is identified to expedite soft-tissue coverage and preserve function of the total ankle replacement as well as maintain options for revision in the future.

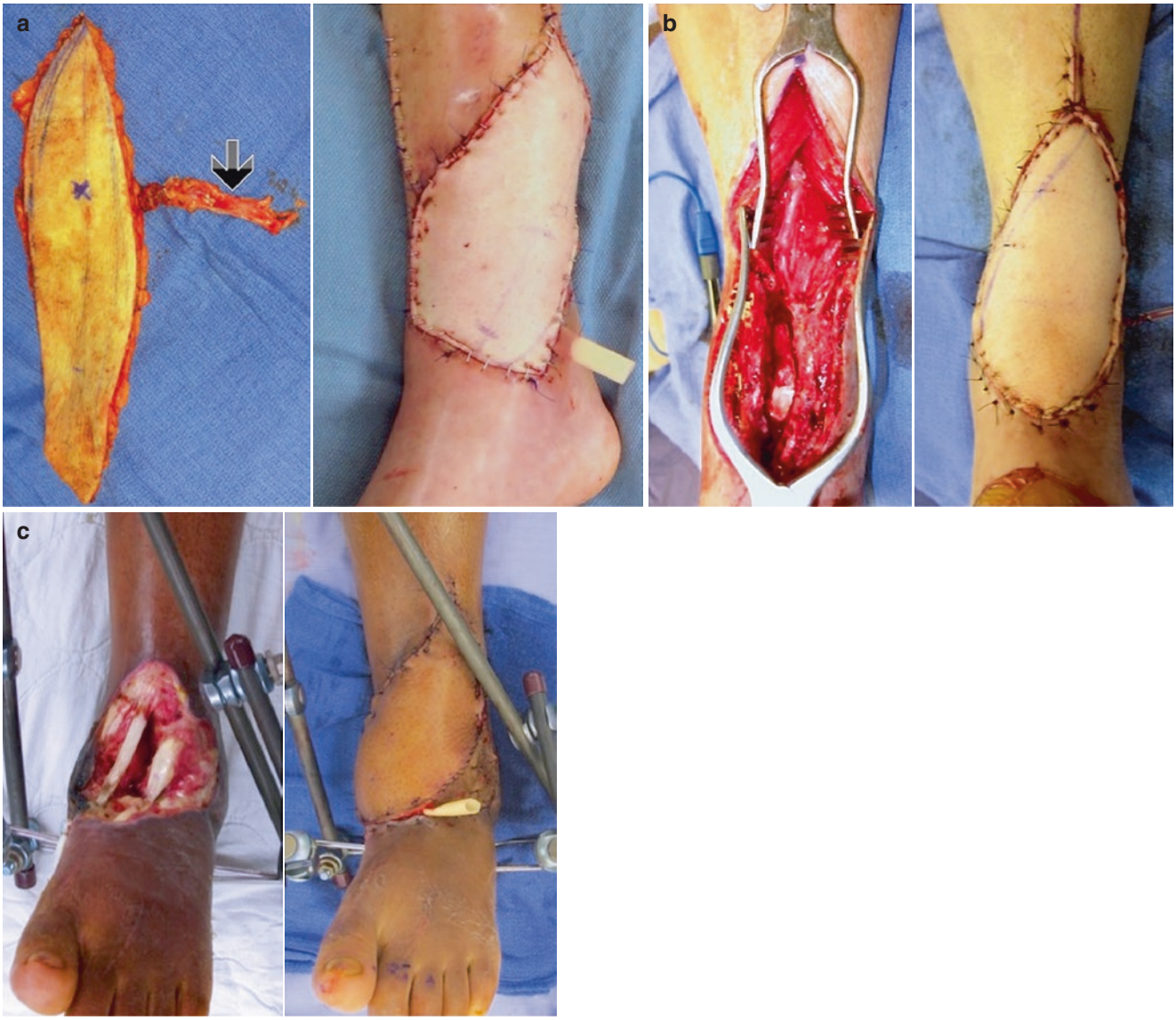


Fig. 37.17 Free anterolateral thigh (ALT) flap (**a**). Note how thin and supple the ALT flap is; "x" marks the skin perforator; *arrow* marks the vascular pedicle. Example of free ALT flap used for soft-tissue coverage after an anterior ankle incision developed extensive distal central and medial wound necrosis. The advantage of skin perforator flaps is that once the flap is mature, future incisions may be placed anywhere within the flap. Clinical example of an acute wound breakdown that is negative for deep periprosthetic infection with retention of total ankle replacement prosthetic components. Free ALT flap (*left panel*) has been placed to fill and resurface wound (*right panel*) (**a**). Clinical example of an infected total ankle replacement with a major wound complication. The total ankle replacement has been explanted and antibiotic-loaded polymethyl methacrylate cement spacer placed and free ALT flap used for wound coverage in anticipation of possible late total ankle replacement reimplantation (**b**). Another clinical example of a catastrophic anterior ankle wound treated with free ALT flap coverage and external fixation to stabilize the ankle during soft-tissue healing (**c**)

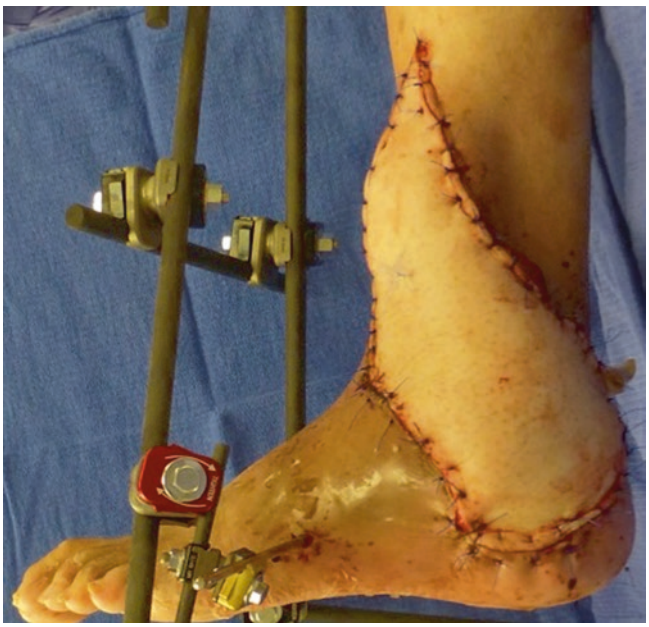


Fig. 37.18 The free anterolateral thigh flap may be used both for acute anterior incision breakdown after total ankle replacement and to resurface a large area of chronically unstable, hostile soft-tissue envelope after multiple prior surgeries

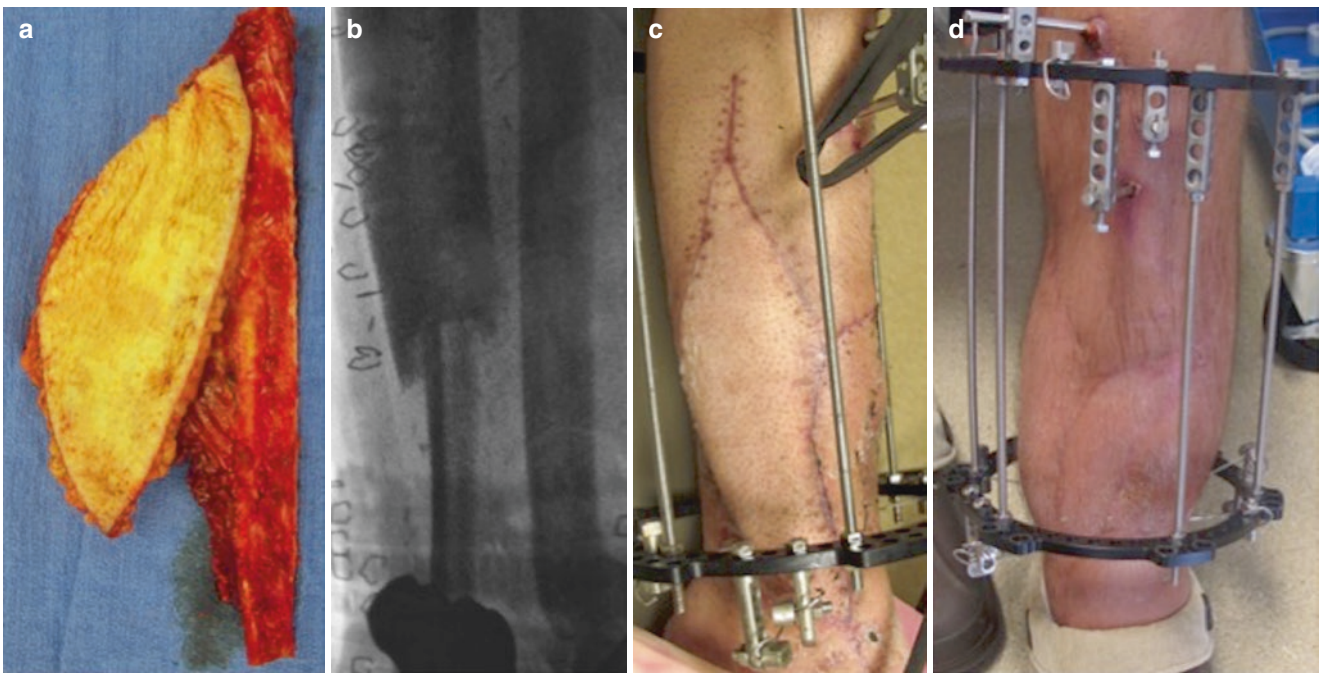


Fig. 37.19 Free fibula osteocutaneous flap for limb salvage after severe distal tibial bone loss and anterior/medial soft-tissue loss after an infected total ankle replacement with massive wound complications. Intraoperative photograph of the harvested fibula osteocutaneous flap (**a**). Intraoperative image intensification view of free osteocutaneous flap in place (**b**). Lateral (**c**) and anterior (**d**) clinical photographs at 6 months postoperatively with external fixation system in place

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Alternate Incision Approaches to Revision Total Ankle Replacement

38

Christopher Bibbo and David A. Ehrlich

Introduction

The traditional approach to total ankle replacement (TAR) requires a direct anterior incision to the ankle. Dissection proceeds between the tibialis anterior (TA) and extensor hallucis longus (EHL) tendon (Fig. 38.1). The anterior tibial neurovascular bundle is retracted to the side that places the least amount of traction tension on the vascular structures. Although the anterior approach in healthy patients with native skin is safe and reliable, patients who have suffered ankle region trauma with soft-tissue injury or have scars from repeat anterior approaches to the ankle are at greater risk for serious wound complications; unlike the hip, the anterior ankle approach incision cannot be likened to a "zipper" that can be utilized repeatedly without worry of serious wound healing complications. For this stated reason, as well as potential kinematic advances in TAR prosthesis design, surgeons find a need for alternate or modified approaches during TAR surgery.

Modifications of the Anterior Approach

In patients who have had anterior approach performed for open reduction with internal fixation of pilon fractures, tendon surgery, benign tumorous conditions, or any other reason for an extensive anterior approach to the ankle, they may be at risk of wound breakdown upon repeated approaches. Similarly, patients who have had degloving injuries and massive trauma-induced edema with resultant atrophic scars or suffer from severe venous stasis changes are also at risk of significant wound healing issues with the direct midline anterior approach to the ankle. This is also true of patients who have already had a TAR and are being revised and experienced wound healing issues after their index TAR. Thus, the anterior ankle incision region may present as a hostile area for further surgical incisions. The quality of tissue oxygenation in the area is based upon the number of anterior

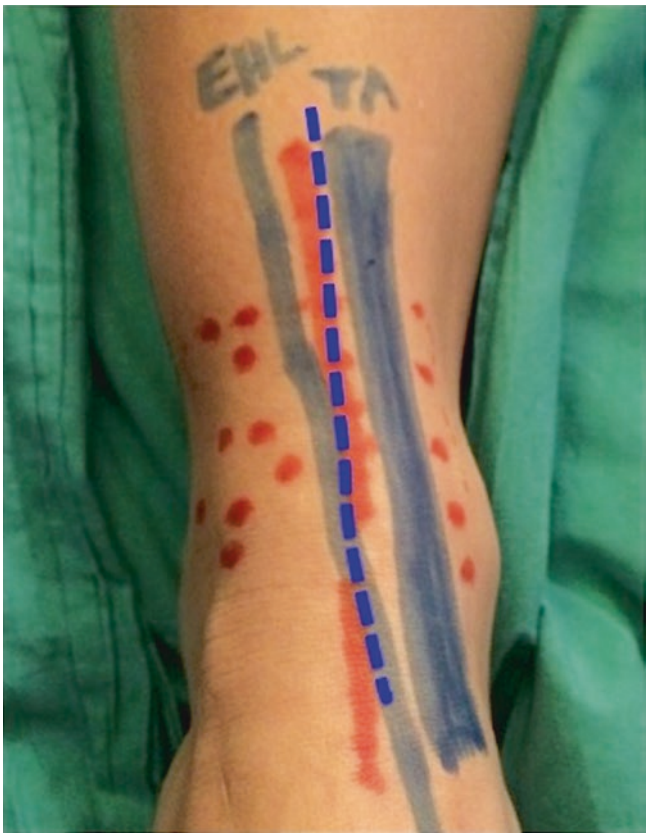


Fig. 38.1 Standard anterior incision for an anterior approach for TAR (*blue dashed line*). The incision is generally centered between the extensor hallucis longus and the tibialis anterior tendons. The anterior tibial neurovascular bundle is usually situated between the extensor hallucis longus and tibialis anterior tendons. The *red dots* depict local potential skin perforators

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skin perforating vessels and the interconnecting subdermal network between the skin perforators (Fig. 38.1). Trauma or disease states may alter this vascular network, rendering the anterior ankle to be a fragile watershed area.

To test the healing potential of the anterior ankle skin, the authors will check for palpable pedal pulses and Doppler signals. Augmentation maneuvers, by manually occluding the posterior tibial artery, can determine if the region is dependent upon retrograde flow from the posterior tibial and peroneal arterial system. In patients with scarring of any type, the use of transcutaneous skin oxygen tension measurements ($TCPO_2$) is performed along the area in question, with $TCPO_2$ leads placed at the joint line and approximately 4–6 cm above the joint line. $TCPO_2$ values that predict adequate healing potential can be accepted as a good indicator of successful healing, provided meticulous skin handling technique is used, the skin is elevated as one layer, and tourniquet usage is kept to a minimum. A tension-free skin closure and the liberal use of drains are also mandatory.

However, in certain patients, there will be instances where the risk of incision breakdown will still be high. In these patients, modification of the direct anterior approach may assist with avoiding failure of a repeat ankle incision. The use of an incision that gently curves to the junction of the anterior-medial or anterior-lateral ankle skin margins (Figs. 38.2 and 38.3), creating a thick, single-layer, wide-based skin paddle, similar to the concept of a wide-based advancement flap, can allow access to the ankle without traversing poor-quality skin [1]. This technique requires that the skin and subcutaneous structures along the modified anterior approach be elevated as one thick layer of skin and subcutaneous fat, elevated together without delaminating the "flap" of tissue that is raised. Additionally, as the "flap" elevation proceeds toward the anterior midline axis, scarring is judiciously released. Toward the base of the elevated skin, the area is inspected for any remaining skin perforator vessels, which are preserved with great care.

Retractors are used to a minimum and are best placed at the proximal and distal most aspects of incision. The skin "flap" should be gently retracted backward, providing visualization of the operative field. Gentle retention sutures can hold the elevated skin out of the operative field; attempts are to be made not to fold the skin over onto itself 180°. The remainder of the approach to the distal tibia and talus still requires great care to identify the neurovascular bundle and preserve as many vessels that branch from the anterior tibial vessels. On occasion, a transverse vessel runs directly over the distal tibia and may need to be ligated. These vessels may contribute to skin perforator's of the distal edge of the elevated skin, so vessel ligation is done sparingly. Tourniquet ischemia time should be kept to a minimum or not used at all. Elevation of the flap should be without tension on the elevated soft tissues. Gentle undermining of the normal tissue adjacent to the skin flap can relieve linear tension on the flap, thereby limiting damage to the vascular network. During the case, wet moist sponges may be used to help prevent inadvertent trauma to the delicate elevated skin. Skin closure is performed in a multilayer fashion, using fine-gauge absorbable suture in the subcutaneous tissues (Fig. 38.3). Tension on the skin from below can be relieved by gently placing a few interrupted sutures between the tendons and then parachuting the tendons deep, so there is absolutely no bowstringing; the retaining structures are repaired or reinforced as needed. For the medially based skin elevation incision, the

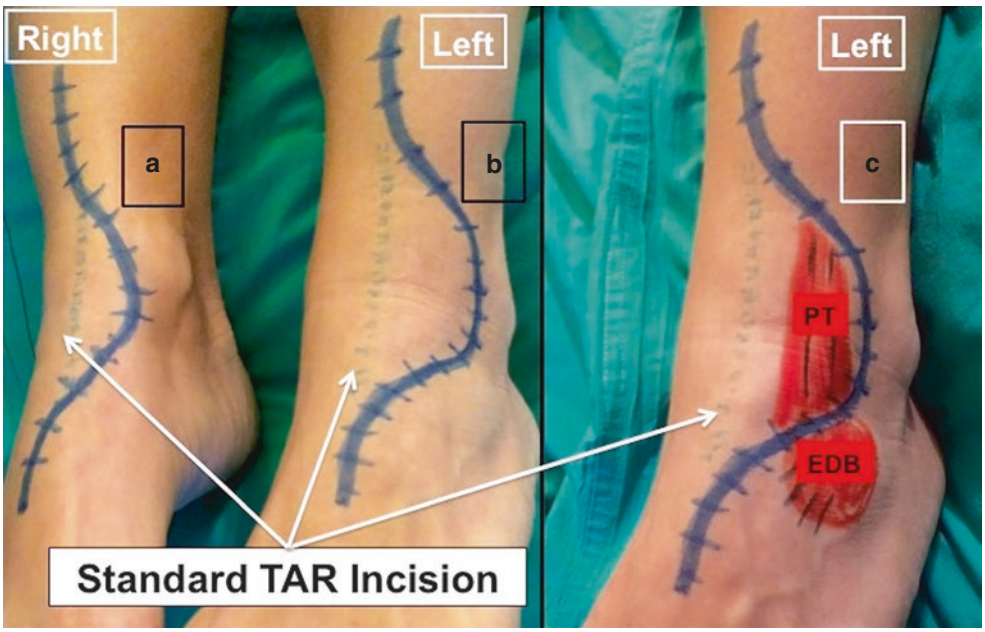


Fig. 38.2 Alternate anterior incisions to the ankle. Raising a large medial flap (**a**) may spare the area that breaks down along the tibialis anterior tendon. A large lateral flap (**b**) will allow access to the peroneus tertius muscle belly (**c**), as well as access to the extensor digitorum brevis muscle, which can also be an extremely useful source of local vascularized tissue

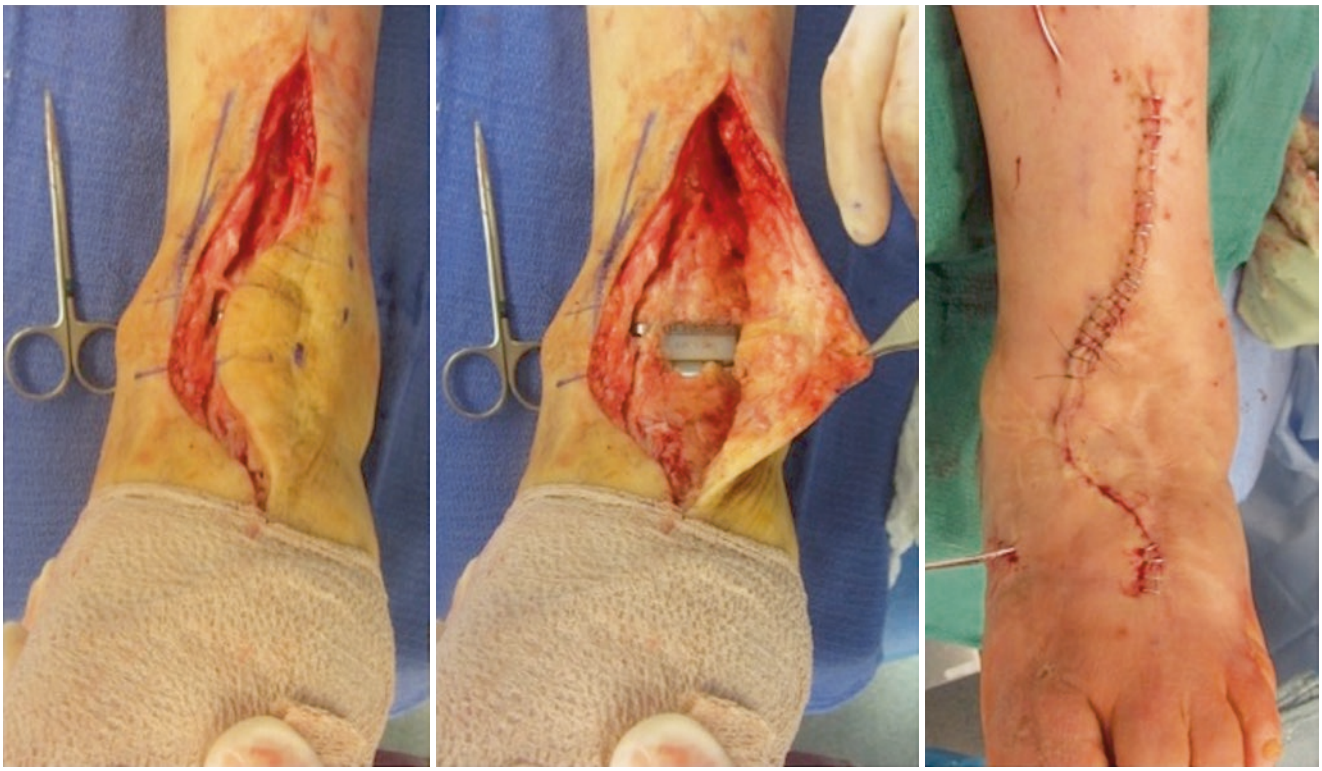


Fig. 38.3 Intraoperative photograph of lateral-based large skin flap incision for revision total ankle replacement in a patient with a poor anterior soft-tissue envelope

peroneus tertius may have a low-lying muscle belly that can be transposed or formally transferred more midline, bringing in fresh vascularized muscle under the elevated anterior skin "flap" (Fig. 38.2).

Postoperative Care

Elevation is used to prevent venous congestion. Any circumferential dressings should not be tight; the author actually will cradle the limb in a sterile cotton roll, loosely apply an elastic bandage over splints, and create an opening over the incision to allow frequent inspection of the incision and skin. Steps are taken to ensure there is no undo impediment to perfusion of the skin. This includes withholding caffeine and any sympathomimetic medications and absolutely no nicotine patches. The patient's room should be kept warm (temperature of approximately 70 °F) and the incision kept moist with an antibiotic ointment and iodophor gauze or silver sulfadiazine and petrolatum gauze. Two to three daily inspections are performed while the patient is in the hospital. Dangling is permitted for 15–20 min per day only. Drains remain in until there is <15-cm^3 drain output for two consecutive shifts, once the patient has been out of bed with the limb dependent during physical therapy.

Alternate Incisions to Total Ankle Replacement

Alternate surgical incisions for TAR, by definition, are those that do not use the same anterior access for the anterior approach to the ankle. Currently, alternate incisions include the lateral approach to the ankle as required for the Zimmer Trabecular Metal Total Ankle (Zimmer, Inc., Warsaw, IN) and the posterior approach to the ankle [2] via a direct midline incision or paramedian poster incision between the Achilles and the flexor hallucis longus (FHL) muscle belly and its tendon [2].

The Lateral Approach for Primary Total Ankle Replacement

The Zimmer Trabecular Metal TAR is designed for insertion through a direct lateral approach to the ankle, with joint access via a fibular osteotomy. This lateral incision can be easily converted to an extensive approach distally and proximally. This approach has been used for decades for fixation of lateral ankle fractures, ankle arthrodesis, tibiotalocalcaneal arthrodesis, and tendon surgery. The major structures that may be crossing the lateral incision are small

branches of the superficial peroneal nerve proximally and sural nerve distally, providing cutaneous and articular sensation to the lateral ankle. The vascular structures crossing the lateral aspect of the ankle include the lesser saphenous vein. When encountered, it is prudent to spare the lesser saphenous vein, as the skin directly over it is supplied by some degree by the vein and its associated small capillary network. The authors have personally observed a number of patients with skin breakdown when the lesser saphenous vein is injured and then cauterized or ligated. Accordingly, the authors choose to repair this vein with 6-0 nonabsorbable suture when it is injured during surgery. The remainder of the lateral ankle approach requires protection of the tendinous structures. Tourniquet ischemia times should be kept to a minimum. After TAR implantation, closure of the subcutaneous tissues should be performed in a layered fashion with fine in sutures. Depending on skin quality, either vertical mattress sutures skin or staples may be used on the skin. Again, drains should be used liberally to prevent hematoma formation underneath the skin, as in this area it is quite thin and there is little room for hematoma accumulation.

Posterior Approach to the Ankle for Revision Ankle Replacement

The posterior approach to the ankle is a well-known surgical approach for managing disorders of the Achilles tendon and the flexor hallucis longus tendon and to gain access to the posterior calcaneus and talus. Although well known by most surgeons for these reasons, the posterior approach to the distal tibia is less well known and has utility in fixation of comminuted posterior pilon fractures. Utilizing the posterior approach to the ankle for revision TAR is uncommon but may have utility under extenuating circumstances. Example of an extenuating circumstance would be a very hostile anterior ankle soft-tissue envelope, which possesses a high likelihood of catastrophic incisional failure requiring free tissue transfer placement, but the patient does accept that potential risk and refuses an ankle arthrodesis. Another relative indication for a posterior approach is acquired vascular disease of the anterior vasculature structures that is not amenable to endovascular interventions or arterial bypass grafting, rendering even the modified anterior incision a poor option. In these instances, patients would typically undergo an ankle fusion utilizing mini-open techniques. However, in patients who refuse ankle arthrodesis, possess absolute contraindications for anterior approach is to the ankle, to posterior approach may be considered. The posterior approach is quite simple in concept. The patient is placed in the prone position; a thigh tourniquet is utilized. Thigh tourniquet ischemia time is kept to a minimum, or a tourniquet is not used at all. There are two variations on the posterior approach. First is a direct midline incision centered over the Achilles tendon, extending 8–10 cm proximal to the ankle joint line; distally, the incision is carried to the insertion of the Achilles tendon onto the calcaneus (Fig. 38.4). By carefully incising the skin, the very thin subcutaneous tissue is raised as one layer with the skin. Care is taken to preserve any visible skin perforating vessels. The Achilles tendon may be split completely vertically or transversely. The author has found the best technique is to create a sliding "Z"-step lengthening of the Achilles tendon [2]. The ends of the Achilles tendon are then retracted proximally and distally and may be temporarily tacked down to the skin, keeping it the operating field (Fig. 38.5). Dissection then continues down through the retro-Achilles fat pad, and the flexor hallucis longus muscle belly is identified. The incision is extended as needed proximally to minimize skin tension from self-retaining retractors. Proximally, the sural nerve and the lesser saphenous vein must be preserved. The soleus muscle may have a low-lying muscle belly with one or two muscular perforating vessels which should be preserved. The muscle bellies are retracted, and sharp dissection of the posterior joint ankle capsule is performed (Fig. 38.5). Variations to the posterior approach include medial and lateral paramedian incisions (Fig. 38.6). These offer no true advantages but rather may limit access and visualization to the posterior ankle joint during instrumentation. Vigorous retraction of the Achilles tendon may be required, potentially compromising adjacent skin or the posterior tibial neurovascular bundle. Access to the ankle may be easier when the foot and ankle are internally rotated. Difficulty retracting the Achilles tendon from a lateral or medial paramedian incision may be assisted by performing a proximal gastrocnemius recession.

The posterior approach requires that the flexor hallucis longus (FHL) muscle belly be mobilized and its tendon protected. At this point, instrumentation to insert TAR becomes quite a challenge and is a tactical exercise which requires modifications of the original surgical technique and jigs (Fig. 38.7). Due to current prosthesis designs, the author has only performed a posterior approach with the INBONE Total Ankle System (Wright Medical Technology, Inc., Arlington, TN). After the TAR components are inserted (Fig. 38.8) and an acceptable position confirmed with fluoroscopy or radiographs, closure may commence. Drains are placed, and contrary to conventional thought, the authors exit the drains superiorly, so that if a large seroma would accumulate, inadvertent early drain removal will not lead to a potential distal draining sinus but, rather, fluid is absorbed through the proximal bed of muscle.

Closure of the poster incision is performed with great care. The FHL and soleus muscles are placed in their anatomic positions. If the Achilles tendon was simply retracted and not divided, the Achilles tendon is now lengthened in either a percutaneous fashion or under direct visualization.

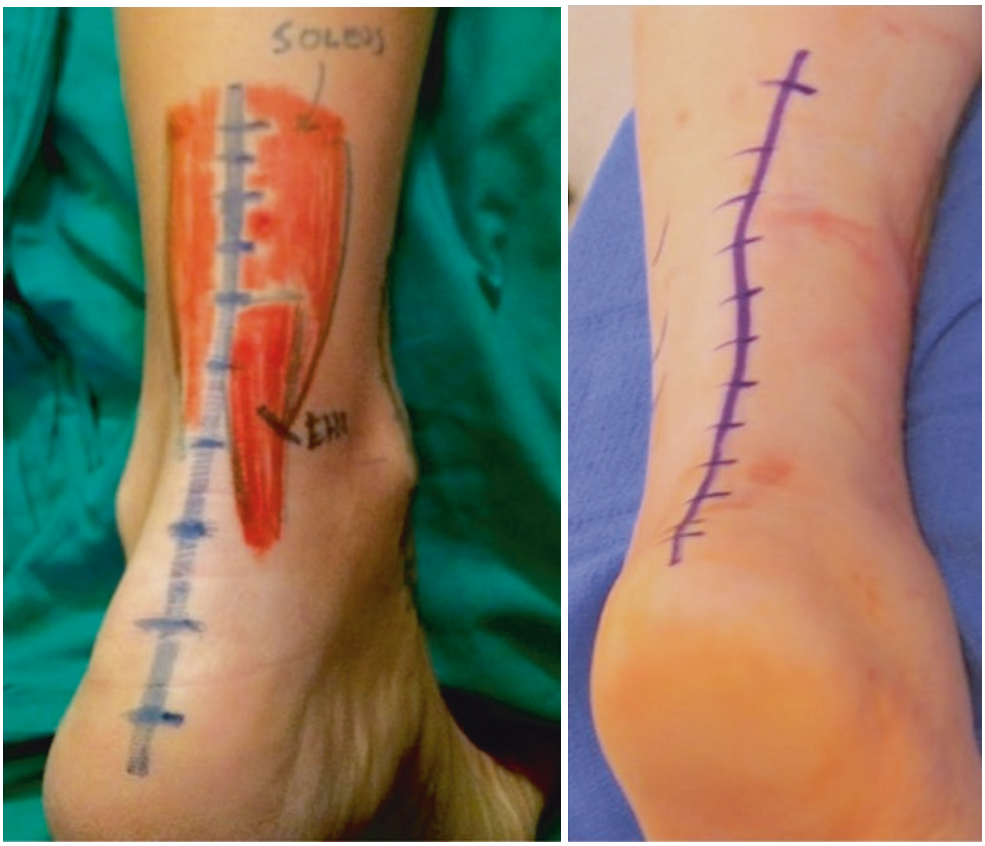


Fig. 38.4 Posterior midline approach for primary and revision total ankle replacement

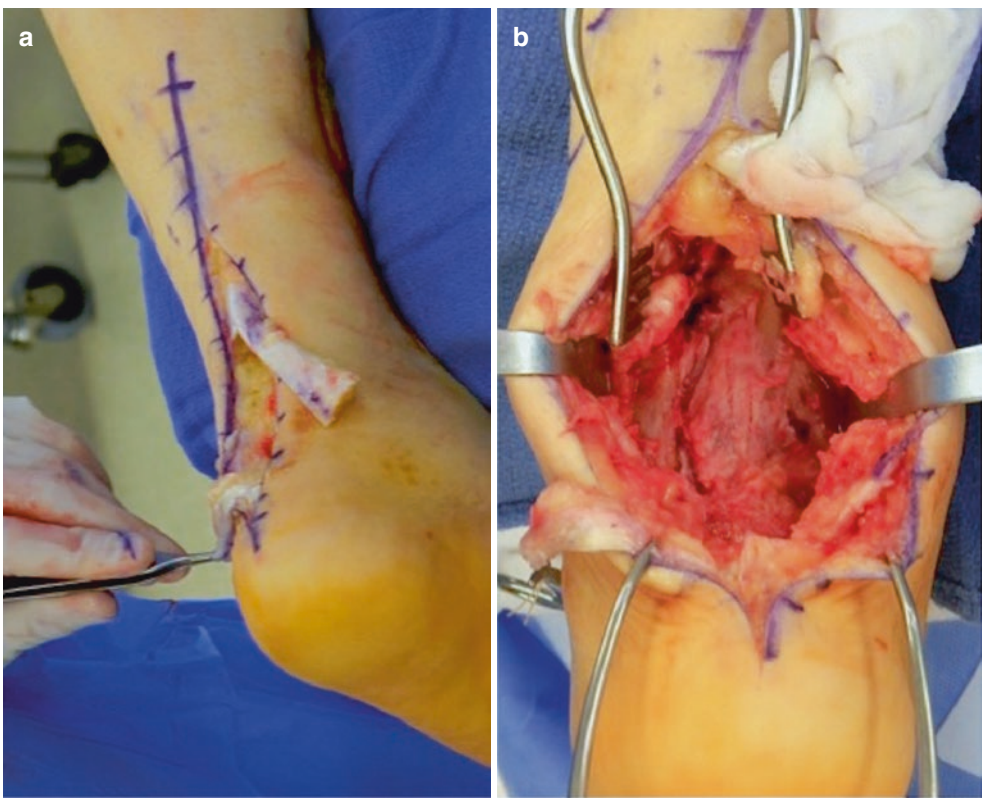


Fig. 38.5 After the posterior skin incision, the Achilles tendon is split in a "Z" fashion and retracted (**a**). Deep dissection continues with retraction of the posterior compartment muscles and tendons, exposing direct access to the posterior ankle and subtalar joints (**b**)



Fig. 38.6 The paramedian lateral variation of the posterior approach to the ankle is just slightly off the direct posterior midline; the same concept for incision placement holds for the paramedian medial incision, but a more medial approach puts the neurovascular bundle at greater risk for injury

Alternatively, a gastrocnemius recession may be performed. If the Achilles tendon was split, it is repaired by the surgeons' preferred technique, but the surgeon must provide adequate lengthening to correct an equinus deformity. However, overlengthening of the tendon must be avoided, in order to prevent a calcaneus deformity. If there is any question regarding the potential healing of the Achilles tendon,

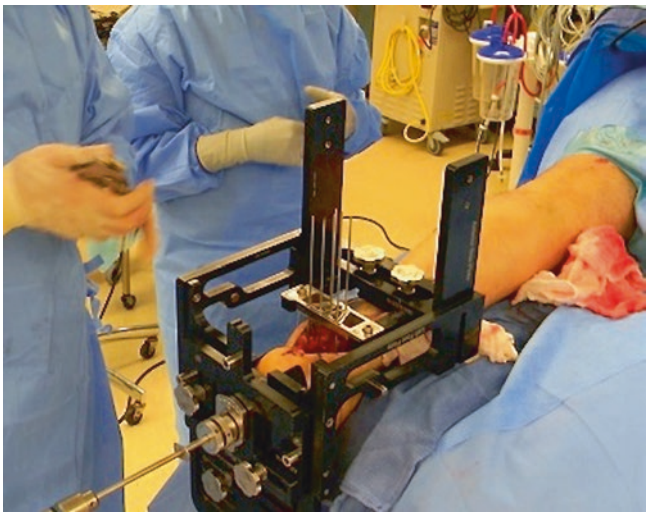


Fig. 38.7 Modified use of instrumentation is required for the posterior approach. This also necessitates more intraoperative C-arm image intensification to ascertain appropriate bone cuts and proper seating of the total ankle replacement components

the flexor hallucis longus muscle belly may be pulled forward and gently sutured to the repaired Achilles tendon, bringing vascularized muscle tissue to the area. The tendon sheath is closed with fine absorbable suture. After closure of the thin subcutaneous layer, the skin is closed with vertical mattress sutures; very thick skin may be closed with staples.

The postoperative surgical dressing is extremely important. The authors will typically use an iodophor dressing with bacitracin ointment. In edematous or friable skin, the dressing also includes a silver dressing and PolyMem (Ferris Manufacturing Corp., Fort Worth, TX), followed by a large amount of sterile cast padding. Elasto-Gel™ (Southwest Technologies, Inc., North Kansas City, MO) is placed over the cast padding along the Achilles tendon and posterior calcaneus. The foot is held in neutral position, and a posterior and stirrup plaster splint is applied.

Postoperatively, the limb is elevated. Any agents that can potentially cause vasoconstriction, such as caffeine and sympathomimetic agents, are held. Indwelling pain sheath catheters are very useful to provide pain relief and vasodilation to the skin. Weight bearing is commenced not only based upon TAR component stability but also upon healing of the Achilles tendon. Early sagittal plane ankle range of motion is encouraged by the first or second postoperative week. If the Achilles tendon was surgically divided, healing of the Achilles tendon is the second consideration as when to initiate weight bearing and, in general, may be treated in the same manner as a surgically repaired ruptured Achilles tendon. Early tendon gliding, followed by progressive weight bearing, is recommended. A low peel-away heel lift may be used in a walking boot, which is decreased in height each week. Additional postoperative TAR protocols may need to be fine-tuned to accommodate the posterior approach.

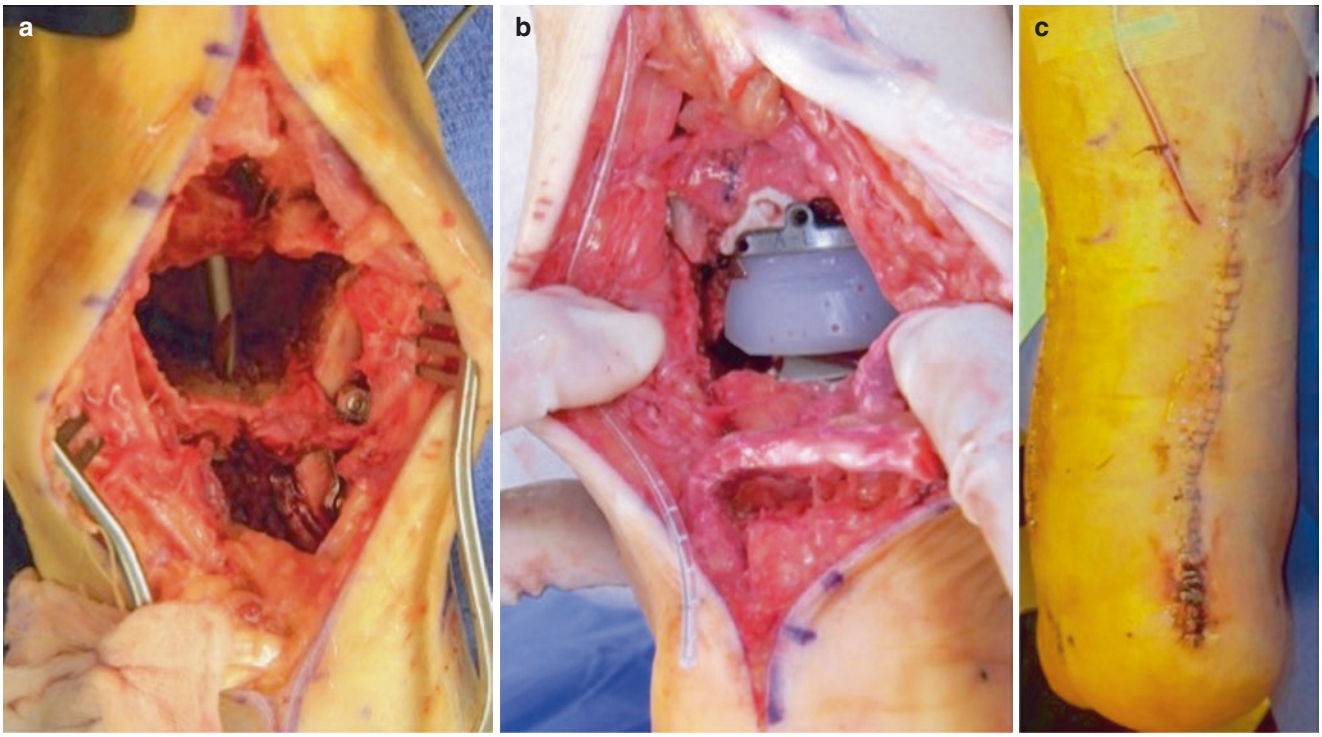


Fig. 38.8 Intraoperative photographs demonstrating the posterior approach for bone resection (**a**), final seating of the INBONE Total Ankle System prosthetic components implanted (**b**), and incision closure over drains (**c**)

Conclusions

Total ankle replacement is a technically challenging reconstruction, with soft-tissue complications posing potential significant morbidity, especially when the anterior ankle soft-tissue envelope is hostile secondary to scarring and a suboptimal soft-tissue envelope for healing. Alternate approaches to the ankle for arthroplasty may need to be sought in unique cases. These include the authors' modified approach to the anterior ankle, lateral approach for select prosthetic designs, as well as posterior surgical approach for complex primary and revision total ankle replacement. Attention to soft-tissue handling and strict postoperative cares is required to obtain predictable soft-tissue healing with these procedures. It remains to be seen if the lateral approach has benefit over the traditional anterior extensile incision for primary total ankle replacement.

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Management of the Infected Total Ankle Replacement

39

Christopher Bibbo and Stephen J. Kovach

Introduction

Infection of a total ankle replacement (TAR) is one of the dreaded complications that face the surgeon. Infection after TAR has been demonstrated to result in TAR failure in greater than 50% of cases and, as such, is considered a high-grade complication [1]. Although data that estimates overall deep periprosthetic infection rates for after primary TAR is poor, the risk being as high as 14% [2], analysis of studies reveals that superficial infections (Fig. 39.1) range from 2.5% to 9% [2–4]. When infection after TAR is stratified, deep periprosthetic infections may be less than 2% [3]. Thus, the authors surmised that if data were available from a national TAR registry, the incidence of deep periprosthetic infection after TAR may be lower than previously reported, perhaps even lower than hip and knee arthroplasty-infected total ankle replacement, with factors such as overall surgeon experience, TAR volume, patient health inventory stratification/TAR indications, and health-care facility microbiogram data correlating with all complications, including infection.

Infections after TAR are categorized as superficial (simple soft-tissue infections), which are usually associated with some degree with wound healing problems, and deep infections. Deep periprosthetic infections are the focus of this chapter. Management of any deep periprosthetic infection requires a swift and thorough protocol with the primary goal being to save the lower extremity and then, if possible, the TAR prosthesis.



Fig. 39.1 Cellulitis 3 weeks after primary total ankle replacement. Antibiotics should be started targeting skin flora or resistant organisms in high-risk/institutionalized patients and a work-up for deep periprosthetic infection initiated

Prevention of Infection in Total Ankle Replacement Surgery

Any treatise on deep periprosthetic joint infection would be remiss if the prevention of infection was not discussed. It may be simply stated that the standard of care is to follow preventative measures in patients undergoing TAR.

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Preoperative Work-Up

All patients undergo a preoperative screening urinalysis with microbiologic assay, especially if the patient requires frequent catheterization. Urinary tract infection (UTI) must be treated prior to TAR surgery and repeat urinalysis performed to prove eradication of the UTI. Contrarily, the elderly female patients often acquire a state of "asymptomatic bacteriuria" (ASBU), where they have persistent proximal urethral and bladder colonization but do not exhibit signs and symptoms of a UTI. Although considered a "steady-state" condition and an unproven risk for deep periprosthetic joint infections at the time of surgery, the authors have seen so numerous late total hip and knee deep periprosthetic infections under these ASBU conditions that they believe the benefits of treating ASBU on the day of surgery as a potential source for a subacute or chronic deep periprosthetic infection far exceed blind neglect [5, 6]. Furthermore, the condition of ASBU has been recently recognized to a factor of multiple molecular traits and etiologies among different patient populations and, in relatively compromised hosts (e.g., diabetes mellitus), may progress to infection [7]. Thus, the authors will treat the condition with preoperative antibiotics and postoperative antibiotics while an indwelling bladder catheter is in place or intermittent catheterization may be needed [8] but proceed with the surgery. Indwelling bladder catheters inserted at surgery should be removed on the first postoperative day or as soon as feasible [9].

Patients with a history of methicillin-sensitive *Staphylococcus aureus* (MRSA) are screened with swabs of the axilla, groin, and nares. Positive results are treated with topical mupirocin ointment in the nares and daily chlorhexidine washes of the axilla and groin for 2 weeks, followed by repeat swabs. Persistent positive swabs are referred to infectious disease specialists for further recommendations on systemic agents.

The Operating Theater

Strict adherence to sterile technique is first and foremost. Common sense precautions, such as covering open instrument sets during operating room delays and following other Association of Operating Room Nurses (AORN) guidelines, are wise precautions. The use of HEPA-filtered body exhaust systems ("surgical hood and suit") to decrease infection rates as well as reduce room air contamination and therefore infection rates remains somewhat debatable [10], but it may provide a more comfortable operating attire for the surgeon. Laminar flow and ultraviolet (UV) room lights have not been consistent in hip and knee arthroplasty literature to reduce infections [11], and these have not been fully evaluated in the TAR literature. The authors do not utilize laminar flow, self-contained body exhaust suits, or UV light systems. However, the use of these techniques is still quite acceptable, and if hospital policy mandates utilization of these techniques, it is quite acceptable to implement them during TAR surgery. One item that has been recently evaluated is the amount of "traffic" in and out of the total joint operating room. Increased traffic in and out of the total joint operating room has been clearly shown to be a factor that can increase infection rates during total joint surgery and should be limited to essential personnel [12].

Preoperative and Postoperative Antibiotic Prophylaxis

In general, patients should receive a first-generation cephalosporin within 1 h of skin incision (1 g cefazolin for adults up to 70–90 kg, 2 g for patients >90 kg, and 3 g for patients >120 kg). Antibiotics are re-dosed every 4–6 h. In patients who are penicillin/cephalosporin allergic, either clindamycin 900 mg or vancomycin 1 g is used prophylactically. In patients who have had a history of MRSA infection and colonization or are at high risk for developing MRSA, cefazolin and vancomycin are administered with the dosing noted above. Postoperatively, with exception of ASBU and MRSA history, antibiotics are discontinued after 36 h. ABSU and MRSA patients will continue their antibiotics for a full 10-day course if needed; oral agents such as tetracycline 200 mg twice daily may be used as an outpatient. When patients are on immune suppression agents for disorders such as rheumatoid arthritis, the lead authors have not found it necessary to hold disease-modifying agents or immune suppression agents in the perioperative period, unless the patient has a history of prior poor wound healing or infection after surgery [13].

The Preoperative Skin Prep

Povidone-iodine 10% is a popular skin prep but has come under scrutiny. Several randomized studies have demonstrated the superiority of chlorhexidine as a preoperative skin prep agent [14, 15]. The authors prefer a single-step chlorhexidine skin prep (ChloraPrep, CareFusion, San Diego, CA) for patients who exhibit overall good foot and ankle hygiene. However, for those who have skin crusts, dry scaled skin, or suboptimal hygiene, the authors use a 4% chlorhexidine 10-min scrub followed by an isopropyl alcohol 70% rinse/pat-down. The toes are generally covered with sterile Coban (3M, St. Paul, MN) or Ioban (3M, St. Paul, MN). In patients who have severe onychomycosis and large amounts of subungual debris, they undergo informed consent that all toenails will be removed as part of the prep process once they are under anesthesia. New skin cuts and scratches are prepped within the operative field and may be covered with Ioban dressing.

Surgical Incision Care

The postoperative dressing may be simply a petrolatum/antibiotic ointment covered with sterile gauze and sterile cast padding and then plaster of Paris splinting. For "tight" or tenuous closures, an incisional negative pressure wound therapy dressing is applied and set at 50–100 mmHg for 1–3 days. Indwelling drains are used on all cases, and a multilayered closure is performed. New dressings are applied at the first postoperative office visit at 10–14 days, and from then, based on the wound condition (i.e., swelling, edema seepage, etc.), judicious ankle range of motion is initiated. When the incision is "sealed over" between 2 and 4 weeks, the patient is allowed to shower with a neutral-pH soap, followed by an antibiotic dressing and edema wrap. Any signs of redness are immediately reported to the surgeon office for evaluation.

Deep Periprosthetic Infection of the Total Ankle Replacement

Deep periprosthetic infections are generally classified as "early" and "late." Indeed these are vague terms; thus, it has become commonplace to use 4 weeks as the cutoff for "early" or "acute" versus "late" infections. These numbers are not as arbitrary as previously thought. In general, 4–6 weeks postoperatively corresponds to the development of biofilms on the implants that are difficult to eradicate. Prior to this, the bacterial burden is in a more planktonic form, which is easier to eradicate and may allow for the retention of well-fixed prosthetic components, and the infection has not progressed to periprosthetic osteomyelitis. An infected TAR implies not only an infection of the fluids bathing the prosthetic components but also surface infection of the implant, as well as infection of intracapsular soft tissues and potentially infection of peri-implant bone (osteomyelitis). Management of the infected TAR is a combined medical and surgical venture. The diagnosis is not one of exclusion; rather, it should be sought in any patients with obvious clinical signs such as redness, fever, and pain, but patients with subclinical infection may present with night pain, low-grade fever, and malaise [16].

Clinical Evaluation for an Infected Total Ankle Replacement

When a deep periprosthetic infection is suspected, joint aspiration utilizing sterile technique is the first step. Joint fluid is sent for Gram stain and cultures: aerobe, anaerobe, acid-fast, and fungal cultures. If available, specimens that are negative on final cultures are held, and 16-Svedberg unit bacterial polymerase chain reaction (16s PCR) is performed. Fluid cell counts are included in the specimen and are a helpful guide to the clinician, but ultimately culture data is what clinicians should consider as the pivotal data to determine frank TAR sepsis. On occasion, joint aspiration may be scant or technically difficult. The instillation of sterile saline with in situ aspiration may assist to yield adequate fluid for Gram stain and cultures. When a joint is difficult to enter, aspiration may be performed with fluoroscopic guidance. Empiric antibiotics may be initiated if symptomatology escalates during the interval between clinical evaluation and definitive treatment. This empiric outpatient therapy should be geared toward coverage of skin flora and common Gram-negative organisms; patients with a history of MRSA colonization or infection should be treated with antibiotics to cover MRSA (e.g., doxycycline). The use of proprietary test kits for alpha defensin levels has become popular as an evaluation tool for infected hip and knee arthroplasty patients but has not been widely applied to the evaluation of the suspected infected ankle arthroplasty. Alpha defensin testing is not recommended as a singular definitive method of evaluation of suspected infection of the total ankle arthroplasty but rather as an additional tool in the standard work-up for the suspected total ankle prosthesis. Additionally, the use of procalcitonin levels, although beneficial in critical care patients to predict sepsis, has no proven value in the setting of prosthetic joint infections.

The authors typically admit the febrile patient with an obvious diagnosis of infected TAR and start parenteral antibiotics to cover Gram-positive and Gram-negative organisms. Patients who are more prone to resistant organisms, such as a history of MRSA or previous resistant Gram-negative infections, are started on vancomycin and levofloxacin. An infectious disease consult is a vital part of the management plan. Surgical irrigation and debridement are performed in the obvious infection and are performed emergently when the patient exhibits early signs of systemic inflammatory response or frank sepsis.

Imaging of the Infected Total Ankle Replacement

Radiographs may demonstrate periprosthetic lucencies but are not diagnostic of infection (Fig. 39.2a, b). Air fluid levels or gases in the soft tissues suggest the formation of gas by bacteria and, when accompanied with systemic signs of infection, are a surgical emergency. Otherwise, radiographs in subtle infections may be indeterminate.

Magnetic resonance imaging (MRI) may be useful in late infections that have collected copious fluid volumes and progressed to osteomyelitis, but one needs to keep in mind that bone changes on MRI may persist after surgery for up to 6 months; thus, if MRI is utilized, gadolinium enhancement

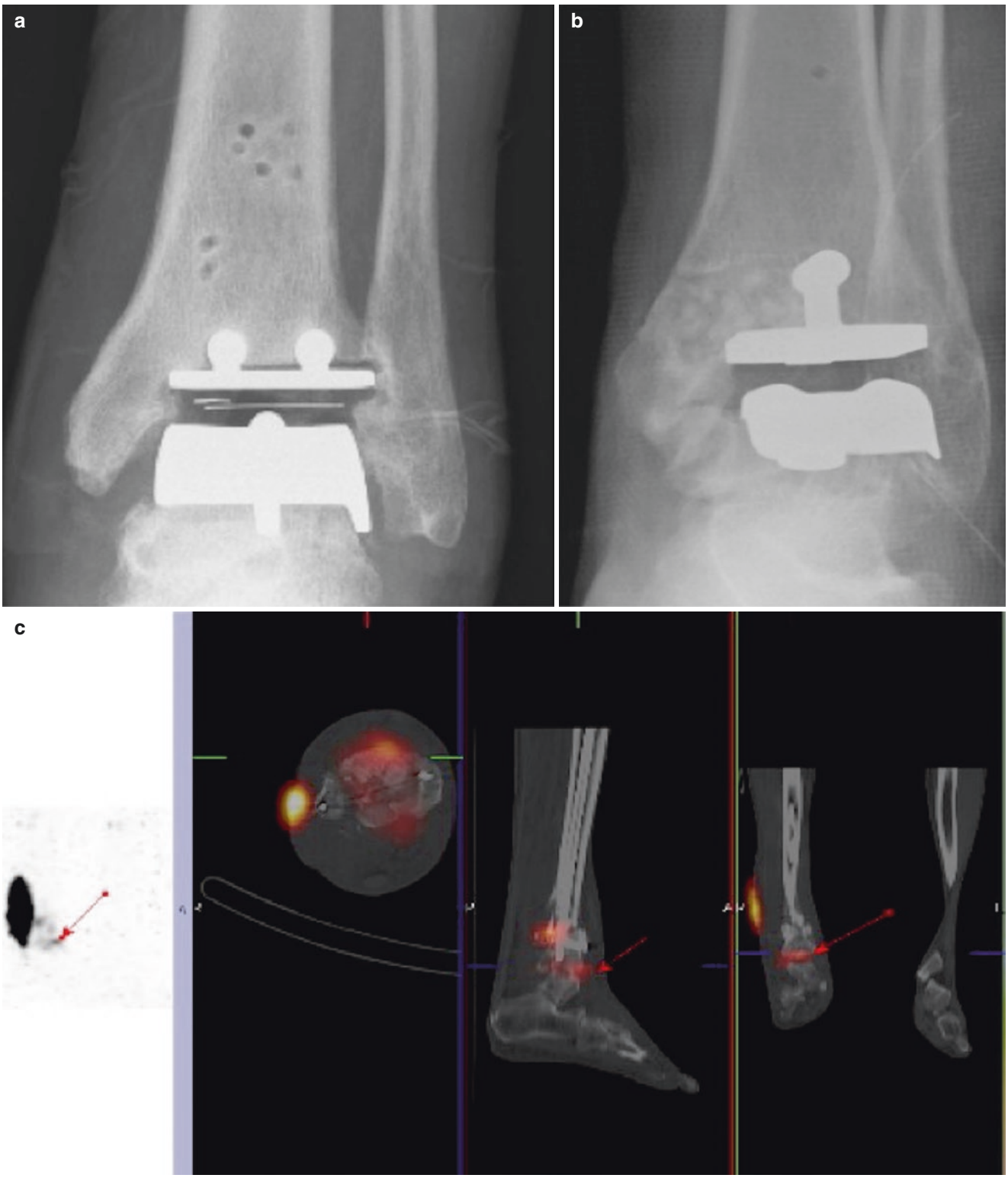


Fig. 39.2 Radiograph of infected total ankle replacement with minimal changes on radiographs (**a**). Radiograph of total ankle replacement with changes within the medial malleolus suspicious for infection or avascular osteonecrosis. Indium-111 scan can assist in differentiating an infectious etiology (**b**). Indium-111 WBC scan complimented by color-enhanced spot computed tomography scan. In the depicted patient, bone infection is detected in the ankle and distal tibia away from the lateral soft tissues (**c**)

is mandatory. MRI is an excellent modality to search for abscess and phlegmon. Bone scintigraphy has limited predictability alone for detecting septic joint prosthesis, and (99m)Tc-ciprofloxacin imaging also does not differentiate infection well from aseptic inflammation [17]. Due to subtle differences between infection and white blood cell phagocytic activity related to polyethylene debris wear (a.k.a. aseptic inflammation), in order to maximize imaging accuracy and specificity, the authors always utilize an indium-111 radionuclide scan in combination with a technetium scan (I-111/Tc99m dual window scan) [18]. Color-enhanced spot computed tomography imagery is helpful in chronic infection (Fig. 39.2c), as the uptake patterns of low-grade osteomyelitis may mimic periprosthetic lucency by phagocytic osteolysis due to polyethylene wear. Laboratory markers are ordered to follow trends in response to therapy. These include erythrocyte sedimentation rate (ESR), complete white blood cell count (WBC) with differential, and C-reactive protein (CRP). The use of procalcitonin has become common in medical patients but has still proven only to be useful in patients in the intensive care unit setting with occult sepsis.

Surgical and Medical Management of the Infected Total Ankle Replacement

Operative irrigation and debridement must be thorough. The polyethylene insert is exchanged in acute infections with susceptible organisms; well-seated implants in acute infections may be retained, unless there is overwhelming joint sepsis. In this setting, as well as infections that are detected beyond 6 weeks, all prosthetic components are removed and antibiotic-loaded polymethyl methacrylate (PMMA) cement spacers or beads are utilized (Fig. 39.3a). After prosthetic component removal, bone is debrided judiciously. It is a fine line between retaining infected bone versus performing an overzealous resection of bone (Figs. 39.3b and 39.4); all devitalized soft tissue needs resection as well. Antibiotics used in PMMA cement must be heat stable [16, 19] and available in a lyophilized form. A complete list of antibiotics for PMMA- and calcium-based delivery forms is presented in Tables 39.1 and 39.2. The authors' opinion is that calcium-based products impregnated with antibiotics only have marginal prophylactic value at final reconstruction, and only after proven microbiologic sure of an infected ankle implant, and should never be relied upon during the treatment course of any musculoskeletal infection.

Since 2005, the primary authors have utilized negative pressure wound therapy treatments with direct instillation of antiseptics, such as sodium hypochlorite (Dakin's solution), in the setting of massive purulent and necrotizing infections. After being performed three to four times per day for 3–5 days, the instillation fluid may be then switched to a triple antibiotic solution, normal saline, various antibiotic solutions, or commercially available products that contain surfactants plus bactericidal preservatives, such as Prontosan (B. Braun Medical Inc., Bethlehem, PA) (Table 39.3). The authors have found that with negative pressure wound therapy installation regimens, the number of repeat debridements can be reduced.

In patients with suspected infection or suspected occult infection, the work-up may proceed with labs and imaging, as mentioned above. In suspected occult infections, antibiotics may be held until deep intraoperative cultures are taken. Prosthetic components that are removed may be sent for direct cultures. If all fluid and tissue are negative, 16s bacterial PCR is performed and the prosthetic components are sonicated. The sonicant fluid is centrifuged and cultured and 16s PCR performed. Sonication is a method to remove biofilms and "uncover" hidden pathogens embedded in complex bacterially protective biofilms [20].

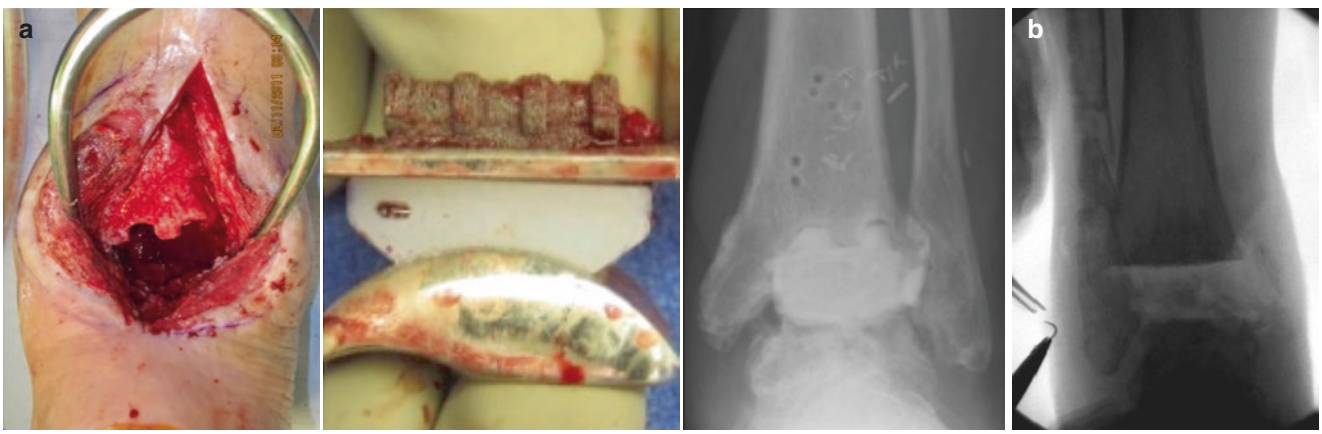


Fig. 39.3 Infected total ankle replacement (*left panel*) that is easily explanted (*center panel*) and the residual osseous defect is filled with antibiotic-loaded polymethyl methacrylate cement spacer (*right panel*) (**a**). Bone resection should be kept to the minimum needed if replantation is planned. Explant of total ankle replacement and resection to clean bone margins after deep periprosthetic infection (**b**). Loss of the medial malleolus wound mandates its reconstruction prior to total ankle replacement replantation

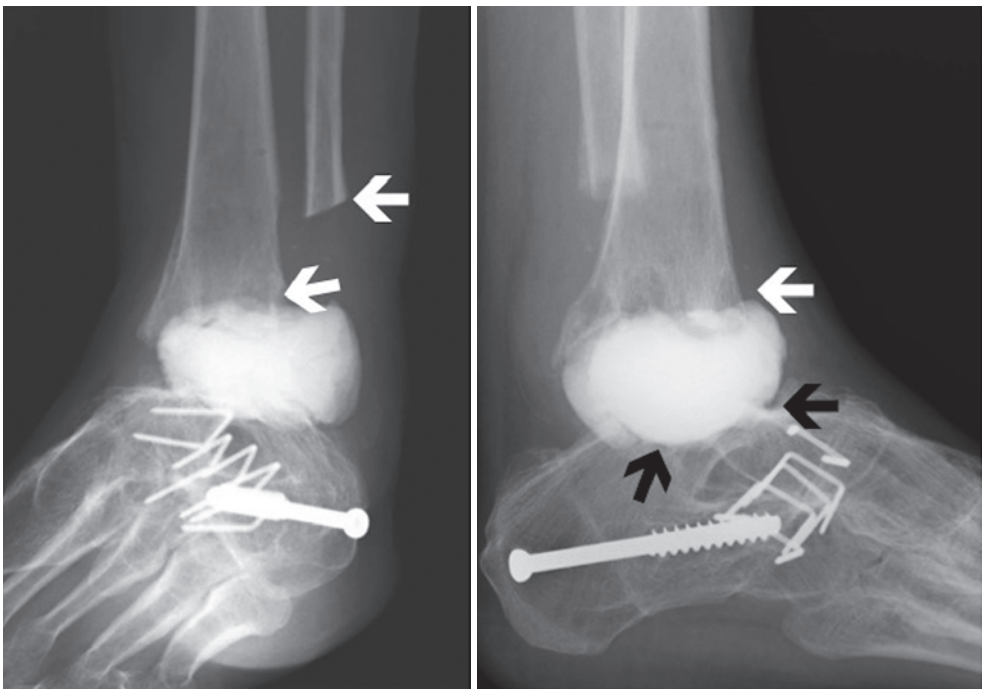


Fig. 39.4 Antibiotic-loaded polymethyl methacrylate cement spacer after explant of infected total ankle replacement. Note the bone loss on both the tibia and fibula (*white arrows*) and the near total loss on the talar side (*black arrows*). This setting mandates a fusion with reconstitution of the bone that has been resected to maintain functional limb length

Table 39.1 Antibiotics (Abx) compatibility with polymethyl methacrylate (PMMA)

Abx mixable with PMMA (heat stable)	Decreased activity (heat unstable)	Curing decreases activity	Tips
Amikacin	Chloramphenicol; colistimethate; tetracyclines; quinupristin/dalfopristin	Liquid gentamicin and clindamycin; Rifampicin	ABX elute better from spacers, beads, rods with micro-imperfections:
Amoxicillin			1. Hand mix
Ampicillin			2. No vacuum
Amphotericin-B			3. Need an extra bottle of PMMA monomer for beads, spacers, rods
Bacitracin			4. ABX elute better when combinations of different ABX are used
Cefamandole cefazolin			
Cefuroxime, cefuzonam			
Cephalothin			
Ciprofloxacin			
Clindamycin (power) colistin			
Daptomycin			
Erythromycin			
Gentamicin (powder) lincomycin			
Methicillin			
Novobiocin			
Oxacillin, penicillin			
Polymyxin B			
Streptomycin			
Ticarcillin			
Tobramycin, vancomycin			

Table 39.2 Suggested antibiotic delivery ratio developed by the authors for use in PMMA

Antibiotic	Dose for prosthesis fixation	Dose for spacers, beads, rods
Amikacin	1 g	2 g
Amoxicillin	NR	Quadruple standard dose[a]
Amphotericin-B (1–2× total QD IV dose [0.5–1.5 mg/kg]) (j.)	0.5–1.5 mg/kg (?)	0.5–1.5 mg/kg
Bacitracin	NR	Quadruple standard dose[a]
Cefamandole (Mandol®)	NR	Quadruple standard dose[a]
Cefazolin (Ancef®)	NR	4–8 g
Cefotaxime (Claforan®)	3 g	4–6 g
Ceftazidime (Fortaz®)	NR	10–16 g [3 g in 20 g Palacos]
Cefuroxime (Ceftin®)	1.5–3 g	6–9 g
Cephalothin	NR	Quadruple standard dose[a]
Ciprofloxacin (powder for oral suspension)	NR	1 g
Clindamycin	NR	4–8 g
Colistin (polymyxin E) (comes in 150-mg vial)	NR (NL dose = 2.5–5 mg/kg/day)	Quadruple standard dose[a]
*Potentially heat unstable!	MDR *Acinetobacter* two million units/day (k.)	MDR *Acinetobacter*: add rifampin (Osteoset) and doxycycline (Osteoset)
Daptomycin	NR	Quadruple standard dose[a]
Erythromycin	0.5–1 g	2–4 g
Fluconazole	400–800 mg	400–800 mg
Gentamicin	1 g	2–5 g
Linezolid (Zyvox®)	NR	2.4 g
Lincomycin	NR	Quadruple standard dose[a]
Methicillin	NR	Quadruple standard dose[a]
Novobiocin	NR	Quadruple standard dose[a]
Oxacillin	NR	Quadruple standard dose[a]
Polymyxin B	NR	Quadruple standard dose[a]
Quinupristin-dalfopristin (Synercid®)	Unstable in PMMA: use Osteoset®	2 g in 50 cm^3 D5 into Osteoset®
Rifampin	Unstable in PMMA, use Osteoset®	2.4–3 g into Osteoset®
Streptomycin	NR	7 g
Ticarcillin (Timentin®)	Not appropriate	5–13 g
Tobramycin (Nebcin®)	1.2 g	2.4–9.6 g
Vancomycin	1 g (powdered vancomycin)	3–9 g (powdered or lyophilized)

[a]Osteoset and is Wright Medical Technologies, Inc., Arlington, TN

Table 39.3 Antibacterial solutions that are effective agents with negative pressure wound therapy installation

Solution	Active ingredients	Notes	Uses
Marshfield	0.1% clindamycin (200 mg per 1.33 mL)	Refrigerate up to 90 days	acute and chronic infections
Clinic triple-antibiotic solution[a]	0.1% gentamicin 200 mg per 5 mL		
	0.005% polymyxin B (2 × 500,000 unit vial); sterile H_2O to expand to 200 mL		
Dakin's solution	Buffered sodium hypochlorite (NaClO)	Use 25% or 50% strength	acute purulent infections, necrotizing fasciitis, MRSA; use for only 3–5 days
Vancomycin 1%	Vancomycin		Methicillin resistant
			Staphylococcus species
Dilute acetic acid (5%)	Acetic acid (CH3 COOH)		Good for *Pseudomonas* contaminations and reduce surface bioburden
Prontosan®[b]	Polyhexanide (PHMB) and betaine (surfactant)	FDA approved with VAC®	Noninfected wounds with high bioburden/surface biofilms, prevent wound desiccation
Normal sterile saline	Normal sterile physiologic saline solution		Prevent wound desiccation; minor bioburden reduction

Most are used every 6–8 h with a dwell time of 30 min
[a]Developed by Michael Caldwell, M.D., Ph.D., F.A.C.S., Marshfield Clinic, Marshfield, WI
[b]R. Braun Medical, Bethlehem, PA; FDA approved with Veraflow® VAC® (KCI, San Antonio, TX)

Parenteral antibiotics are the author's preference, as monitoring of dosing (i.e., patient compliance) is easier and a broader range of options exists. Oral antibiotics are acceptable in low-virulence infections. All antibiotic therapy is guided by the results of deep intraoperative cultures. Therapy should last 6–8 weeks and the ESR and CRP be followed biweekly. All antibiotics have serious, even life-threatening side effects that may affect nearly every organ system. Thus, patients need routine clinical follow-up to assess for antibiotic-related side effects. Signs of systemic antibiotic toxicity are monitored clinically and with laboratory data (i.e., basic metabolic panel for creatinine and liver enzymes for antibiotics cleared by the liver). Diarrhea is worked up with *C. difficile* toxin assays. Lethargy and nausea should prompt an evaluation for antibiotic-induced neutropenia or even potentially fatal neutropenic enterocolitis [21]. All these parameters are coordinated with the infectious disease team.

Replantation of the Total Ankle Replacement After Infection: When Is It Possible?

Timing of TAR reimplantation after infection is critical, with a need for maximum antimicrobial treatment and resumption of patient function. In general, prosthetic joint replantation should not be performed until after a 6–8-week course of antibiotics is completed and subsequent operative cultures are negative and laboratory data normalized. Revision TAR after infection requires that the benefits outweigh any further risks. Requisites to be fulfilled include eradication of the infection from soft tissues and bone, adequate residual bone stock of good quality, and other surgical site characteristics that are required for a primary TAR.

The question arises at replantation whether antibiotic-loaded PMMA should be used to secure the prosthetic components especially if there is a need for implant support and to provide a local repository for antibiotics. From a microbiologic standpoint, the authors believe that some benefit may be derived from antibiotic-loaded PMMA cement. However, the antibiotics must be more than one, have broad coverage including the previous offending organisms, and be prepared in a manner to achieve very high minimal inhibitory concentration (MIC). The downside of antibiotic-loaded PMMA is that the strength characteristics of PMMA are lowered with the addition of high levels of antibiotics. Further TAR failure, be it from infection or component-related failure, creates a scene of difficult extraction, with the usual result of bone being removed along with the PMMA cement. Techniques to avoid excessive bone removal, such as ultrasonic bone cement removal systems (Oscar, Orthosonics, Edinburgh, UK), are best suited to a cortical bone/PMMA cement interface. Thus, antibiotic-loaded PMMA cement is best used judiciously. Temporary "biologic" cements may be used with clinician-determined amounts of antibiotic to allow the fill of voids [22].

Replantation of a TAR after infection may be embarked upon if after 6–8 weeks of culture-specific antibiotics, serum markers (i.e., ESR and CRP) have normalized and residual infection has been effectively ruled out by indium-111/Tc-99 m dual window scans (Fig. 39.2) and surgical biopsy of bone and soft tissue with cultures and 16s PCR. The soft-tissue envelope must be cared for or reconstructed as described elsewhere in this textbook. Custom TAR components vary by manufacturer so the authors consider the INBONE and INBONE II total ankle replacement system (Wright Medical Technologies, Inc., Arlington, TN) to be a satisfactory revision choice with bone loss. Other qualifications for replantation include a stable soft-tissue envelope and a thorough assessment of the value of TAR replantation over ankle or tibio-talo-calcaneal arthrodeses.

At times, a compromised host, highly virulent multidrug-resistant organisms, massive bone loss, or an unstable soft-tissue envelope prohibits the replantation of a TAR. In this setting, complex fusion procedures may be performed, a variety of which exist. A common choice is retrograde intramedullary fixation. Placing such a device is feasible after infection, but to avoid secondary infection of the intramedullary device (Fig. 39.5), the protocol described by Bibbo et al. [23] should be followed.

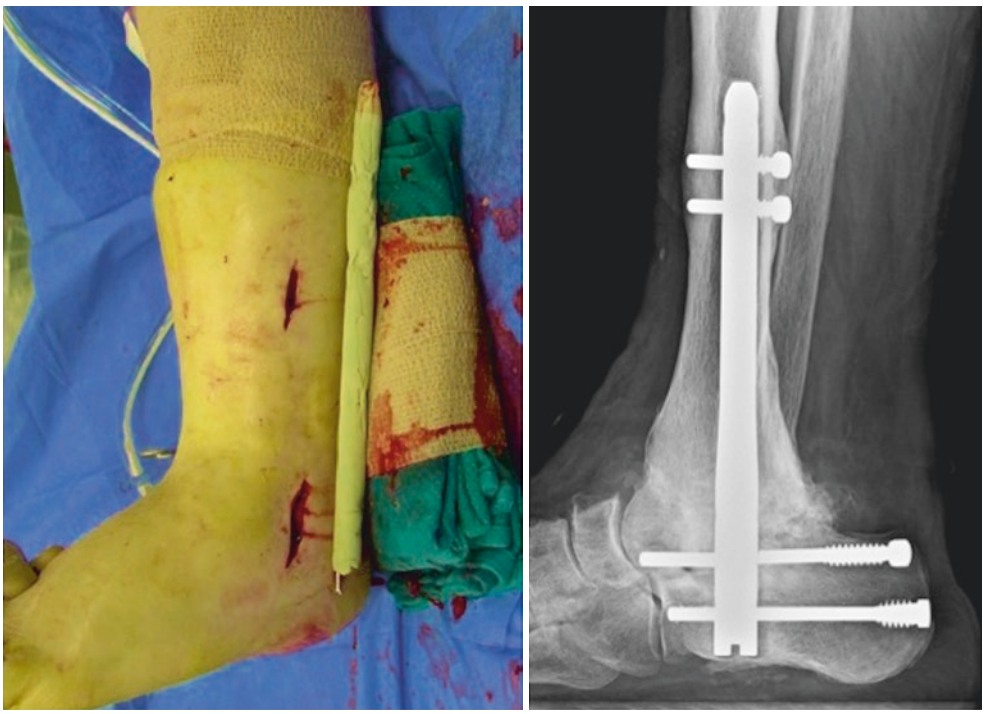


Fig. 39.5 Extended ankle fusion with retrograde intramedullary nail (*right panel*) after surgical cultures was negative following serial debridements, culture-specific systemic antibiotics, and exchanges of the antibiotic-loaded polymethyl methacrylate cement impregnated nail (*left panel*)

When bone loss is present and structural bone is required for a late reconstruction, several options exist. The authors prefer to utilize fine-wire circular external fixation and autologous bone grafting (Fig. 39.6). Fine-wire circular external fixation with bifocal compression/distraction osteogenesis avoids permanent metallic implants in the previously infected field and can assist with compensating for bone loss up to 5 cm (Fig. 39.7). Patients at extreme high risk for nonunion may require vascularized bone graft procedures, such as vascularized free fibula or free iliac crest (Fig. 39.8) or free fibula (Fig. 39.9) [24]. The authors' preferred fixation technique in conjunction with free vascularized bone graft remains fine-wire circular external fixation; internal fixation may be used but not in the face of residual infection.

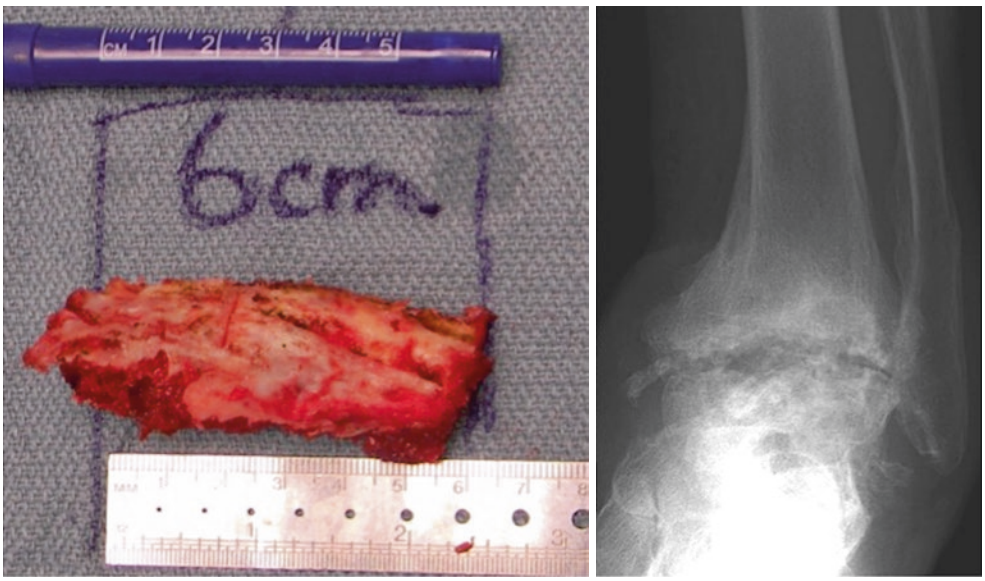


Fig. 39.6 Intraoperative photograph of a 6-cm autologous iliac crest bone graft. Typically, a single 6-cm graft combined with banked bone and rhBMP-2 will suffice for the ankle radiograph shown on the *right* that demonstrates both talar and tibial plafond bone loss. For massive local bone loss, the authors have used non-vascularized grafts as large as 9 cm from each iliac crest to salvage to the ankle after deep periprosthetic infection

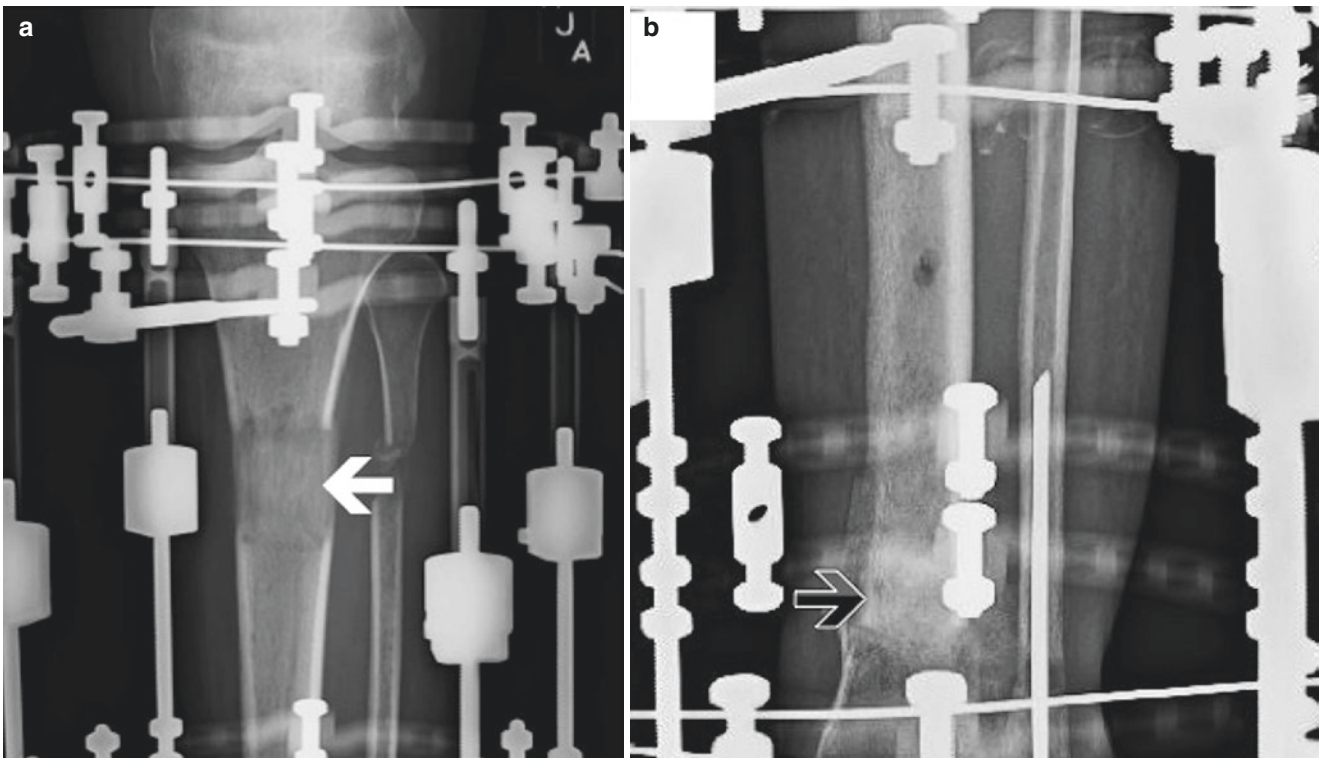


Fig. 39.7 Radiograph of bifocal Ilizarov technique (*white arrow*) for 4-cm bone loss. Proximal distraction osteogenesis is carried out (**a**, *white arrow*) at the same time as distal compression osteogenesis (**b**, *black arrow*)

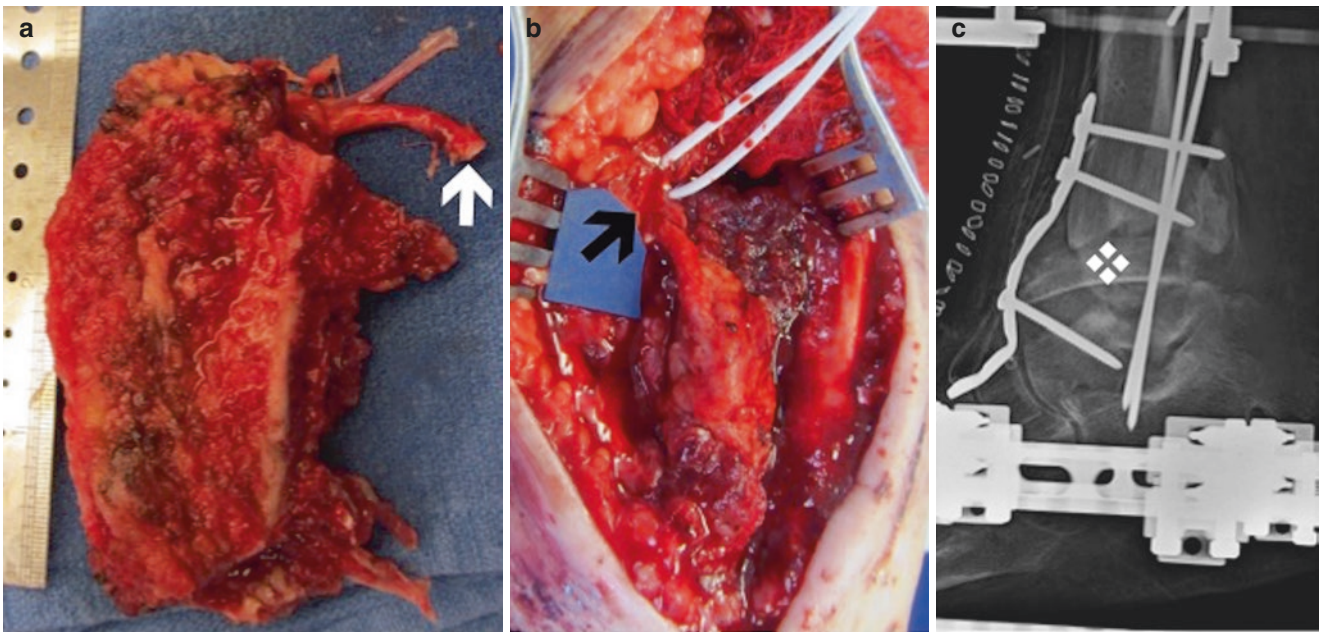


Fig. 39.8 Free vascularized iliac crest bone flap to treat a recalcitrant nonunion for limb salvage after explanted total ankle replacement. Free flap with pedicle (**a**, *arrow*); inset of bone free flap with anastomosis to tibialis anterior vessels (**b**, *arrow*); radiograph of free bone flap (**c**)

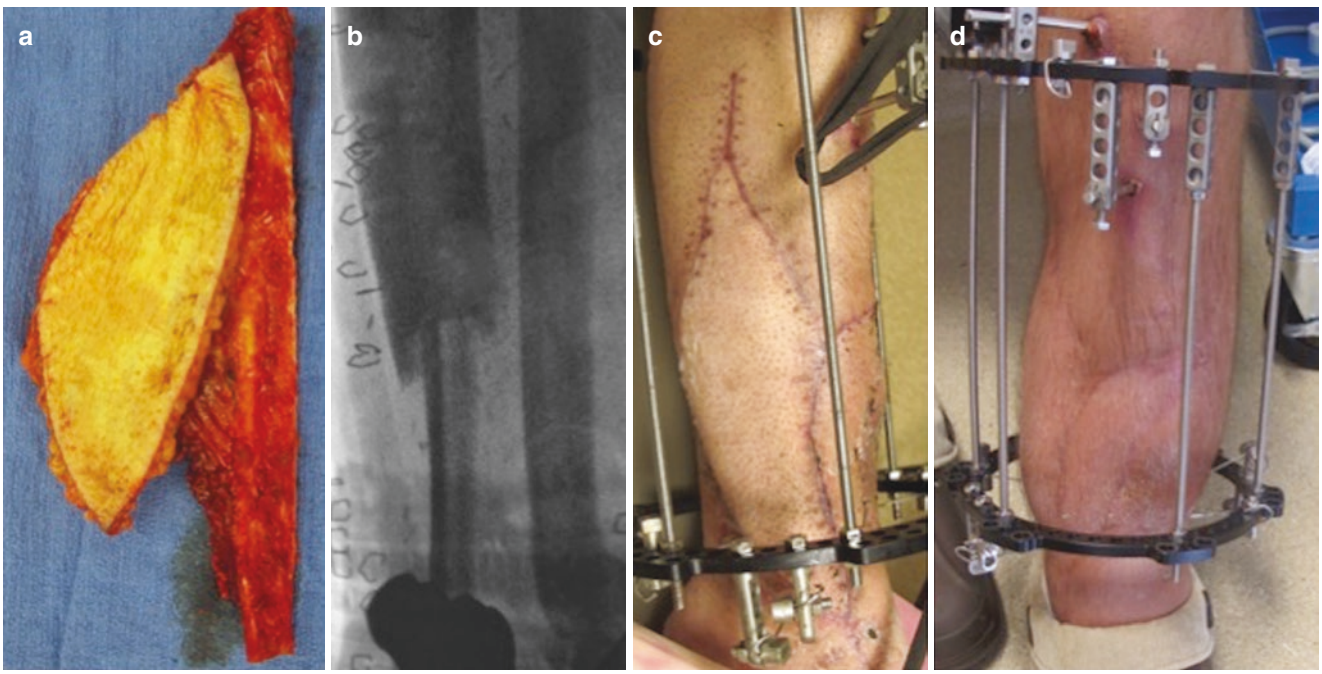


Fig. 39.9 Free fibula osteocutaneous flap for limb salvage after severe distal tibial bone loss and anterior/medial soft-tissue loss after an infected total ankle replacement with massive wound complications. Intraoperative photograph of the harvested fibula osteocutaneous flap (**a**). Intraoperative image intensification view of free osteocutaneous flap in place (**b**). Lateral (**c**) and anterior (**d**) clinical photographs at 6 months postoperatively with external fixation system in place

Conclusions

Infections following total ankle replacement are a serious complication, about which there is little information in the current literature to guide diagnosis and treatment. Infections are classified as acute postoperative, late chronic, or remote hematogenous. Prosthesis removal for infection following primary or revision total ankle replacement along with a thorough debridement and parenteral culture-driven antibiotic therapy is the mainstay of treatment. Only a limited number of patients who develop a deep periprosthetic infection following primary or revision total ankle replacement can expect to undergo successful joint-preserving revision total ankle replacement. Instead, ankle or tibio-talo-calcaneal arthrodesis usually with significant volumes of bone graft is required to obtain a functional limb. Given the morbidity of infected total ankle replacement, careful consideration should be made about performing these procedures in patients with multiple prior surgeries and comorbidities that predispose to wound healing difficulties. Prompt diagnosis and involvement of a multidisciplinary care team are essential to a successful outcome.

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40 Permanent Polymethyl Methacrylate Antibiotic Spacer for Definitive Management of Failed Total Ankle Replacements

Jason R. Miller and Benjamin L. Marder

Introduction

Painful end stage ankle joint arthritis has been reported to present in 1% of adults and has many different treatment options discussed elsewhere in this text [1]. Surgical management can consist of ankle fusion or total ankle replacement (TAR) when performed in optimal candidates [2]. Unfortunately, prosthetic joint infection (PJI) following TAR can result in devastating complications. Joint infections following a TAR have been reported between 0% and 8.9% [3–6]. Once presented with a PJI, treatment to eliminate this infection remains a controversial topic. Overall, surgical goals are eradication of the underlying infection and then restore a painless functional limb. Currently, surgical management aimed at salvaging the limb and ultimately the prosthesis consist of irrigation and debridement with or without polyethylene exchange, one-stage revision arthroplasty, and two-stage revision arthroplasty with a staged antibiotic cement spacer [7].

In certain scenarios, poor soft tissue coverage, extensive bone loss, or patient morbidity limit the ability of the surgeon to perform revision TAR. When revision TAR is determined to be fraught with a poor outcome, the surgeon must decide if conversion to ankle arthrodesis or permanent antibiotic-loaded polymethyl methacrylate (PAL-PMMA) cement spacer will result in a painless functional limb. In the low demand patient with surgical or medical comorbidities, PAL-PMMA cement spacer has shown to be a successful alternative [8, 9].

Properties of Bone Cement

Bone cement has played an important role in joint arthroplasty since the early 1950 when Haboush was the first to use PMMA to clinically secure a femoral stemmed prosthetic hip implant [10]. Subsequently, PMMA cement became widely adopted following Charnley's implementation of its use in a two-component hip prosthetic [11, 12]. Following Charnley's work, PMMA is now the material of choice for securing prosthetic joint components due to its advantageous mechanical properties, its reliable long-term fixation to bone, and its ability to serve as a vehicle for local antibiotic delivery.

PMMA is produced in an exothermic reaction following the addition of a polymethyl methacrylate (PMMA) copolymer and a liquid methyl methacrylate (MMA) monomer. The initiator, benzoyl peroxide (BPO), serves as a catalyst for polymerization in this reaction. The radio-opaque nature of cement is formed by the addition of barium sulfate ($BaSO_{4)}$ or zirconium dioxide ($ZrO_{2)}$ compounds to the powder [13, 14].

Bone cement curing takes anywhere from 5 to 20 min and is described in three stages: (1) mixing phase, (2) working phase, and (3) hardening phase (Table 40.1). Mixing phase begins once the polymer powder is mixed with the monomer liquid forming a dough-like material. Working phase is defined as the time in which the cement remains malleable and has not hardened. Hardening phase is a short period during the final curing process resulting in the development of polymerization heat [13, 14]. Various factors are known to influence the overall handling characteristics of bone cement

Table 40.1 Bone cement curing

Phase of curing	Time of curing	Key component
Mixing phase	0–2 min	Vacuum/bowl mix
Working phase	2–10 min	Malleable
Hardening phase	10–20 min	Polymerization heat

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and include ambient temperature, mixing method (vacuum mixing or hand mixing), and the composition of constituents in cement [15, 16].

Viscosity

Viscosity plays an important role in bone cement, as it is the resistance of liquid to flow. Varying cement characteristics lead to the alteration of the working time of this biomaterial. Generally speaking, bone cements are divided into three kinds: low, medium, and high viscosity. Depending on the utilization of this cement, varying viscosities may benefit the surgeon in different surgical settings. Ideal viscosity should be high enough to avoid mixing into the local and systemic vasculature and low enough to penetrate bone sufficiently. Varying the proportion of liquid to powder, changing the molecular weight, adjusting copolymers, or varying the sterilization method will lead to different working times of PMMA cement [14].

Antibiotic-Loaded PMMA Cement

Antibiotic-impregnated cement was first reported by Buchholz and Englebrecht in 1970 after treating prosthetic joint infections with gentamicin-infused PMMA [17]. The use of antibiotic-impregnated acrylic cement has expanded over the recent half century to include prophylaxis during primary joint arthroplasty [18], to manage foot infections in the setting of vascular compromise [19], and to manage soft tissue contracture while providing local antibiotic delivery during the first stage of a two-stage revision arthroplasty [20]. In the foot and ankle, Schade and Roukis were able to show the benefits of PMMA antibiotic-loaded cement in combination with debridement in eradicating infections [21].

Appropriate antibiotic selection for combination with PMMA cement requires careful consideration of a number of factors. Antibiotics combined with PMMA need to be heat stable [22], should possess a broad spectrum of activity [23], and overall have a low allergenic rate [24]. Whichever antibiotic is ultimately chosen, it must be released in high enough concentrations to exceed the minimum inhibitory concentration (MIC) of any possible colonizing bacterial organism.

Gentamicin has been extensively studied throughout the literature as an ideal additive to PMMA cement as it possesses all of the supreme characteristics required to function in synergy with local acrylic cement [13]. Antibiotics such as tobramycin (Simplex P, Stryker Orthopaedics Mahwah, NJ) or gentamicin (Palacos R+G, Heraeus Medical LLC, Yardley, PA) are current commercially available preloaded PMMA bone cements. Additionally, various antibiotics can be added manually at the time of surgery. Please refer to Table 40.2 for a list of commercially available antibiotic containing PMMA bone cements.

Table 40.2 Commercially available antibiotic containing bone cements

Name	Company	Antibiotic
Cemex Genta	Tecres	Gentamicin
CMW	DePuy Synthes	Gentamicin
Cobalt G-HV	DJO Global INC	Gentamicin
Palacos R + G	Heraeus Medical	Gentamicin
Refobacin Bone Cement R40	Zimmer Biomet	Gentamicin
Simplex P with tobramycin	Stryker	Tobramycin
VersaBond AB	Smith & Nephew	Gentamicin

The mechanism of antibiotic release to the surrounding tissue is based on surface and diffusion processes [25]. Chemical molecules added to commercially available PMMA cement alter the level of hydrophobicity and hence the elution of various antibiotics [26]. The majority of antibiotic release is within the first few hours to days postimplantation [27]. Wahlig and Dingeldein were able to show sustained released of Palacos cement infused with gentamicin at up to 5 years following total hip replacement (THR) [28].

The ideal dose concentration of antibiotic formulation has not yet been elucidated in the currently available literature. However, it has been shown that when doses of gentamicin exceed 4.5 g per 40-g package of cement, there is compromise of the compressive strength of cement [29]. Additionally, in vitro studies have shown that antibiotics pose a synergistic effect in their elution characteristics resulting from increased porosity [30]. Penner et al. [30] were able to illustrate that when 1.0 g vancomycin and 2.4 g of tobramycin were combined with Palacos-R cement, the release of vancomycin and gentamicin was increased by 103% and 68%, respectively, when compared to an individual antibiotic alone. However, recent studies have displayed that higher-dose combination antibiotic concentrations are not necessarily associated with higher elution properties, while the added concentration is having a detrimental impact on the mechanical properties of the PMMA cement [31]. The benefits of high concentrations of antibiotic within acrylic bone cement need to be weighed against the risk of decreased mechanical properties, especially when expecting patients to maintain a permanent antibiotic-loaded PMMA spacer within the ankle joint [32]. The mixing mechanism of various commercially available bone cements is postulated to be preferred without the use of vacuum as this leads to increased porosity and the potential for higher elution properties [33]. However, the clinical significance of this is still to be determined [34].

In the present landscape of antibiotic stewardship, current concerns regarding bacterial resistance of antibiotic-infused acrylic cement have been shown in total hip arthroplasty (THA) and total knee arthroplasty (TKA) liter-

ature [29]. Garvin et al. noted colonization of the initial infective pathogen to be present in 42% of their cases of re-revisional THA and TKA cases [35]. With the possibility of growing antibiotic resistance and the knowledge that elution of antibiotics decrease over time [36], the decision to utilize a PAL-PMMA cement spacer should be considered in only the most severe cases.

Antibiotic-Loaded PMMA Cement in Joint Arthroplasty

Permanent antibiotic-loaded PMMA cement has been infrequently described in the literature for large joints let alone the ankle joint. Advances in revisional implant design and potential of custom 3D printing have likely contributed to the decreased incidence of PAL-PMMA cement spacers. Nevertheless, there are reports of PAL-PMMA within TAR, THA, TKA, and total shoulder arthroplasty (TSA) [8, 37–39].

Dynamic and Static Spacers

The rate of joint infection following THA, TKA, and TSA is seen in 1–2%, 2–3%, and 1–3%, respectively [22, 37, 40]. The current standard of practice for management of stage one of a chronic PJI within the United States involves resection arthroplasty of TAR, THA, TKA, and TSA with static or dynamic acrylic cement. The reported success rate of this two-stage approach has been 65% [41], 82–100% [42], 91% [43], and 60–100% [44] for TAR, THA, TKA, and TSA, respectively.

Various forms of dynamic articulating cement spacers are described in the literature for hip, knee, and shoulder prosthetic infections. Handmade spacers are spacers in the shape of a hemiarthroplasty and can be reinforced with implantable hardware such as Kirschner wires or larger Steinman pins [45]. Alternative forms of dynamic cement spacers include those that are commercially made [22] and custom-molded spacers made in the operating room which contain a metal endoskeleton [46]. The components of dynamic cement spacers may be high friction [38] and consist of all PMMA cement or may be a commercially available prosthesis of antibiotic-loaded acrylic cement (PROSTALAC) with a metal on polyethylene articular surface [22].

The evolution of dynamic articulating spacers within TKA was based on the theory that there would be superior knee motion and better function during stage one of a two-stage revision, culminating in better functional outcomes after reimplantation [47]. However, a recent meta-analysis found no significant differences in eradication of infection, in prevention of soft tissue contracture, or in reduction of knee pain scores when utilizing a dynamic cement spacer within TKA [48].

Currently, the majority of literature dedicated to prosthetic ankle joint infections involve the use of a static antibiotic-loaded acrylic cement (Fig. 40.1) [8]. However, Short et al. [49] have described a technique for creating an articulating antibiotic acrylic spacer with the assistance of a small surgical measuring cup (Fig. 40.2). The aforementioned technique was demonstrated to show the potential for retained ankle motion while awaiting joint reimplantation. Furthermore, it has been hypothesized that the articulating antibiotic spacer can be utilized on a permanent basis if the patient is not medically fit to undergo revisional surgery.

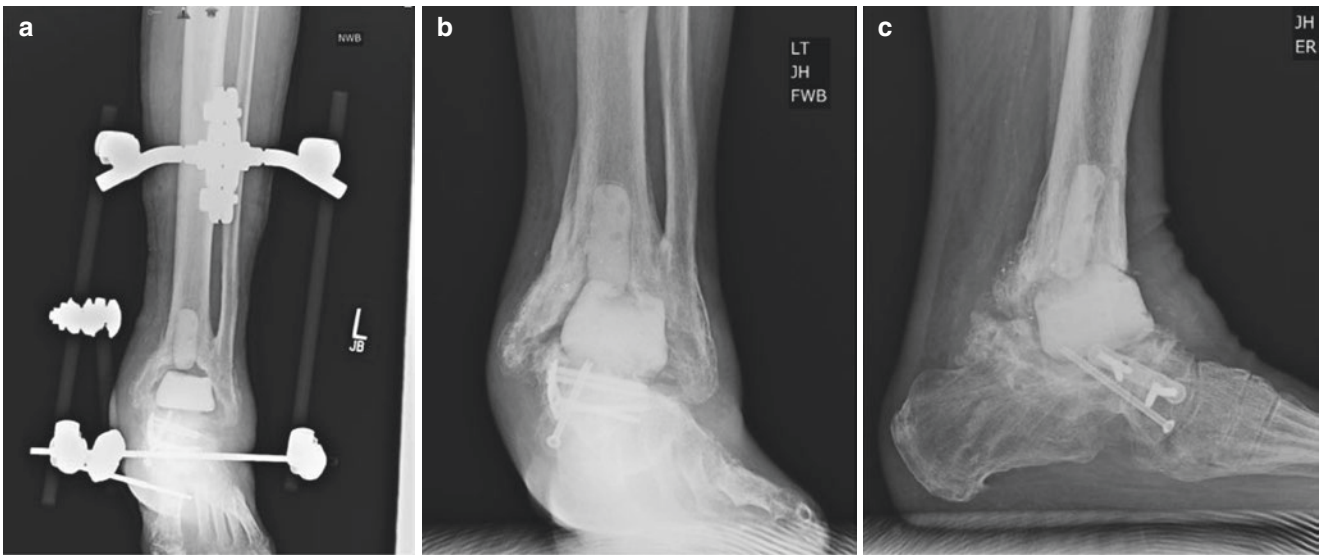


Fig. 40.1 Static permanent antibiotic-infused PMMA cement. (**a**) Immediately postoperative, (**b**) AP, 4 years postoperative, (**c**) lateral, 4 years postoperative. (Courtesy of Adam Budney, DPM, FACFAS)

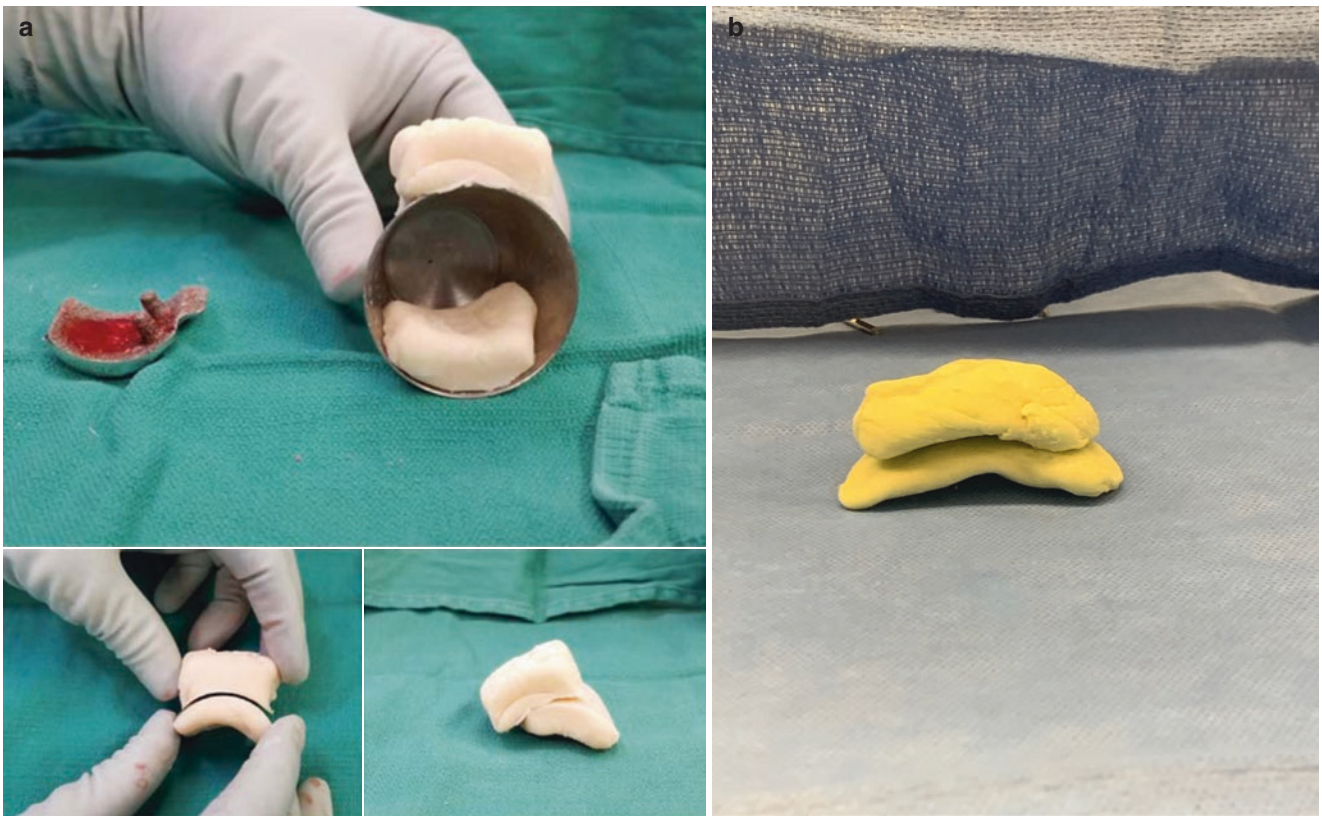


Fig. 40.2 (**a**) Short et al. [49] dynamic articulating antibiotic-infused PMMA cement; (**b**) antibiotic acrylic spacer recreated using Short et al. [49] technique. (Reprinted from Short et al. [49]. With permission from Elsevier)

Permanent Antibiotic-Loaded PPMA Cement Spacer: Hip, Knee, and Shoulder

Hip/Knee

Evidence supporting PAL-PMMA cement for hip and knee joint infections is severely lacking in the orthopaedic literature. Much of the literature is limited to single case studies or retrospective reviews [39, 50]. More recently, a large single institution review of 1106 cases with PJI showed prolonged spacer retention in 5.5% and 4.3% of THA and TKA, respectively [51]. Nearly 70% of TKA and 53% of the THA patients with spacer retention were due to medical comorbidities such as advanced age, elevated American Society of Anesthesiologist (ASA) score, or elevated Charlson comorbidity index (CCI) [52, 53]. The remaining patients noted satisfactory pain relief and good clinical function, or the proposed treatment (amputation or arthrodesis) was not amendable to the patient population. As the literature has remarked, the judicious use of retained spacers should be implemented as revision of THA and TKA was reported in 13.4% and 18.2% of the patients respectively. Furthermore, mechanical failure related to the PAL-PMMA cement spacer was reported in 50% and 56% of the hip and knee groups at 1 year.

A smaller-sized retrospective review of 18 patients with retained knee and hip antibiotic-laden cement spacers reported 83% spacer retention at an average of 3.5 years postintervention. Of the three patients with reported failure, loosening of the bone cement interface was noted at 50 and 74 months. Ultimately, the authors of this paper propose a life expectancy of a well-functioning cement spacer to be limited to 6 years postimplantation [50].

Shoulder

Similar to a documented increase in ankle arthroplasty within the first decade of the twenty-first century [54], the incidence of shoulder arthroplasty has increased from 24.5 arthroplasties per 100,000 to 54.4 arthroplasties per 100,000 over the same time period [55]. With the increase in shoulder arthro-

plasty, so has the literature regarding PJI and the options for treatment. Similar to the US hip and knee literature, the current "gold standard" of management of a PJI involves two-stage revision. However, a distinct subset of patients will not complete the second stage of reimplantation for a variety of medical or surgical reasons.

Literature has shown favorable outcomes when patients do not ultimately undergo the second stage of reimplantation following total shoulder arthroplasty. A national Medicare database from 2005 to 2012 was evaluated for prosthesis removal and spacer placement for PJI. Ultimately, 975 patients were evaluated with 35.8% of the cohort opting for retention of the antibiotic-laden spacer with statistical significance found when this would occur in a patient population with advanced age, i.e., over 80 [44]. With this recent data, it has been proposed that a significant number of the patient population undergoing TSA might ultimately end up with permanent PMMA antibiotic spacer for pain relief and satisfactory function.

Permanent Antibiotic-Loaded PPMA Cement Spacer: Ankle

Ankle

As surgeon experience and implant modification continue to improve, so does the appetite for ankle replacement in patients with debilitating ankle joint arthritis. A recent study by Law et al. reviewed US Medicare data from 2005 to 2012 showing a 16.4% annual growth increase in the utilization of total ankle replacement. However, with the aforementioned increase in TAR, so does a 7.7% increase in the rate of revision over that same time period [56]. Furthermore, as the age of ankle arthroplasty candidates continues to evolve, so too does the need and knowledge base of the surgeon to undertake such challenging revisions [57].

As previously mentioned, the rate of total ankle arthroplasty (TAA) joint infection has been reported to range between 0% and 8.9% [3–6]. Kessler et al. [4] have published the largest study evaluating a single cohort-center experience on 34 patients. In this cohort, 90% of the patients treated with two-stage revision were reported to be infection-free with implant survival at 2 years postoperative. None of the patients in this cohort were reported to be treated with permanent cement spacers. Myerson et al. [5] retrospectively evaluated 19 cases of PJI over a time period from 2002 to 2011 with 36.8% (7/19) treated with permanent antibiotic cement spacer. Six of the seven patients treated with PAL-PMMA cement spacer were asymptomatic at most recent follow-up for an average of 13.4 months (range 12–64 months), with one patient requiring operative intervention for spacer migration during the follow-up period. Patton et al. [41] retrospectively reviewed 29 cases of infected TAR over a 17-year time period with a reported limb salvage rate of 79% with 3.4% (1/29) resulting in permanent cement spacer of unknown duration.

Dedicated investigations of permanent cement arthroplasty following total ankle replacement are severely limited with only two studies reported in the English literature. Ferrao et al. [8] reported on nine patients who underwent permanent cement spacer for deep ankle infection following ankle replacement or ankle arthrodesis. Six of the nine patients in the cohort had a total ankle replacement prior to permanent cement spacer. The reported average age was 63.3 (51–75 years) with an average time of spacer retention noted to be 20.1 months (6–62 months). All patients were initially treated with a two-stage protocol of joint infection which included 6 weeks of culture-driven antibiotics managed by an infectious disease specialist and culture-driven antibiotic cement. The authors would utilize 2 g of vancomycin and 1.9 g of gentamicin mixed into cement when no culture was available. Joint infections were classified by Fitzgerald et al. [58] periprosthetic infection classification (Table 40.3) with 75% of cases reported as stage II. The majority of patients in the permanent cement spacer cohort were deemed medically unfit to undergo a revisional procedure while two patients were asymptomatic and therefore refused revisional surgery. Ultimately, limb salvage was noted in 77.8% of patients in this cohort.

More recently Lee et al. [9] reported on cement arthroplasty as a primary salvage procedure after ankle joint destruction due to prosthetic joint infection, nonunion, or a large bone defect or tumor. In this cohort of 16 patients, 5 were treated following failed TAR with 4 female and 1 male patient, a mean age of 64.2 (55–74), and a mean follow-up of 47 months (14–78 months). Each patient was initially treated with removal of implant and debridement of all devitalized and infected tissue, and three out of five patients were treated with CMW 3 gentamicin bone cement (DePuy Synthes, West Chester, PA) which contains 1 g of gentamicin mixed with 1 g of vancomycin and 1 g of cefazolin. Two patients who

Table 40.3 Fitzgerald classification

Stage	Time from surgery	Description
1	0–3 months	Acute postoperative infection; generally hospital origin
2	3 months–2 years	Deep late infections, presumed nosocomial origin
3	>2 years	Late hematogenous source of a asymptomatic joint; dental, skin, GI sources, etc.

Table 40.4 Outcomes for permanent antibiotic-laden PMMA cement

Patient	Age (yr)	Diagnosis	Comorbidity	AOFAS preop./ postop.	VAS preop./ postop.	Subjective improvement compared with preop. function (%)	Screw fixation	Duration of follow-up (mo)
1	60	Infection, TAR	Diabetes mellitus	63/88	8/1	80–90	No	78
2	67	Infection, TAR	Diabetes mellitus	31/68	9/1	50–60	No	53
3	55	Infection, TAR	Rheumatoid arthritis	31/68	7/2	70–80	No	72
4	74	Implant loosening after TAR	Diabetes mellitus	11/68	9/2	70–80	Yes	18
5	65	Failed ankle fusion after TAR	Rheumatoid arthritis	9/68	8/2	70–80	Yes	14

Based on data from Ref. [9]

ultimately needed cement arthroplasty for a noninfectious cause were treated with CMW 1 bone cement (DePuy Synthes, West Chester, PA) and additional screw augmentation for stability. The patients in the aforementioned cohort were assessed with functional questionnaires, American Orthopaedic Foot and Ankle Score (AOFAS) and visual analogue scale (VAS). All patients in this cohort showed improvement in their AOFAS and VAS score with a subjective improvement ranging from 50% to 90% (Table 40.4). This study supports the longest follow-up, 78 months, of PAL-PMMA cement arthroplasty following a PJI with ultimate failure reported due to peri-cement osteolysis.

Lee et al. [9] provided three important and practical points when performing permanent cement ankle arthroplasty. Firstly, alignment of the ankle joint within the frontal plane must be maintained while cement is applied. As has been shown in ankle joint arthroplasty, malalignment can lead to increase in pain and loss of function of the ankle prosthesis, and therefore this should be continued in the cemented ankle [59]. Second, joint space should be adequately maintained in comparison to preoperative levels during the cement molding process. Maintaining limb length and joint space will preserve the soft tissue envelope from contracture and allow the patient and surgeon the opportunity for revisional arthroplasty or fusion at a later date, if indicated. Thirdly, the cement must be stable to be used as a definitive weight-bearing surface within the ankle joint. The composition of antibiotic-loaded cement per 40-g packet remains controversial as current studies have not shown more than 3.9 g of antibiotic per 40-g of PMMA cement. However, it has been shown that exceeding 4.5 g per 40-g package of cement leads to compromise of the compressive strength of cement and the surgeon should be mindful to not exceed this amount when attempting to perform PAL-PMMA cement for a prosthetic ankle joint infection [29]. Furthermore, anterior skin overlying an overzealous PAL-PMMA cemented ankle can quickly lead to wound compromise. Ferrao et al. [8] were quick to point out that this can be minimized by ensuring the cement spacer does not protrude anterior to the tibia on a sagittal radiographic image (Fig. 40.3a). Figure 40.3b offers a clinical image of a smooth anterior tibial crest with antibiotic-infused Palacos cement.

Conclusion

Ankle replacement in a compromised host can lead to serious consequences when complicated by an infection. A more troublesome complication may result when a PJI results in poor bone stock and a tenuous soft tissue envelope leading to limited salvage options. As has been shown in the literature, surgical options for limb salvage revolve around ankle arthrodesis, revision arthroplasty, amputation, and permanent antibiotic-laden PMMA cement. When a patient is eventually left with limited revision options due to lack of bone stock and strongly wishes to prevent amputation, permanent antibiotic PMMA cement spacer can be a viable alternative in the low-demand patient. Ultimately, cement arthroplasty should be utilized as a late-stage limb salvage option in only a unique and patient-specific circumstance as prolonged implantation exceeding 7 years has not been reported in the currently available literature.

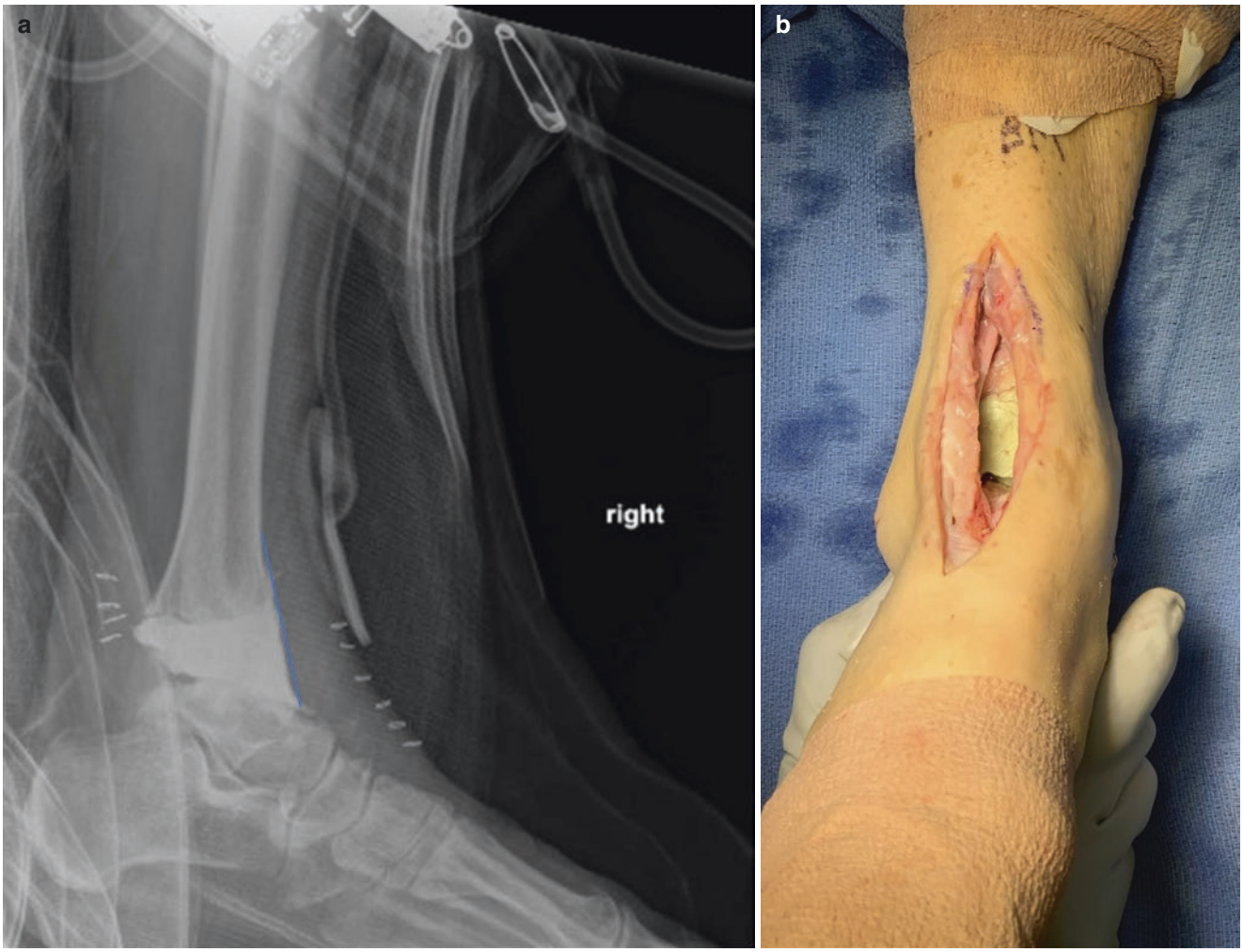


Fig. 40.3 (**a**) Anterior tibial crest cement image; (**b**) intraoperative view of smooth anterior tibial crest with Palacos cement. (Courtesy of Jason R. Miller, DPM, FACFAS)

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