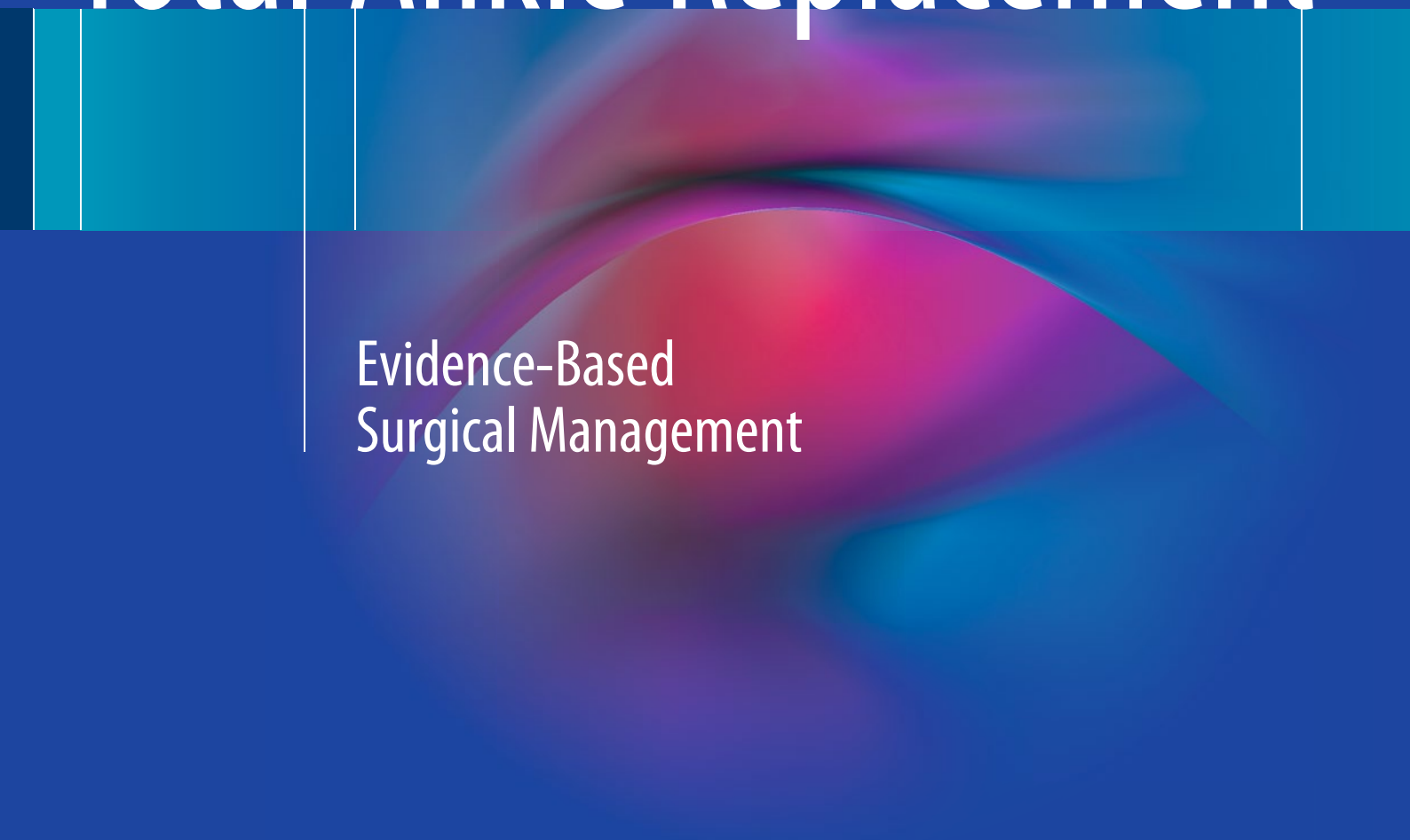
Thomas S. Roukis · Gregory C. Berlet
Christopher Bibbo · Christopher F. Hyer
Murray J. Penner · Markus Wünschel
Editors

Primary and Revision Total Ankle Replacement

Evidence-Based Surgical Management



Springer

Primary and Revision Total Ankle Replacement

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Springer

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ISBN 978-3-319-24413-6 ISBN 978-3-319-24415-0 (eBook)
DOI 10.1007/978-3-319-24415-0

Library of Congress Control Number: 2015955752

Springer Cham Heidelberg New York Dordrecht London
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Content Editor: Mark A. Prissel

Printed on acid-free paper

Springer International Publishing AG Switzerland is part of Springer Science+Business Media (www.springer.com)

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

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Part I

Introduction

History of Total Ankle Replacement in North America

1

Nikolaos Gougoulias and Nicola Maffulli

Introduction

Recent advances and stimulus in total ankle replacement (TAR) are probably derived from ankle arthritis patients' demanding for a mobile, in contrast to a fused, pain-free ankle [1–6]. The success of total hip and knee arthroplasty [7, 8] has obviously led to the expansion of the indications of total joint replacement, to include the ankle. Furthermore, it was realized that, although ankle arthrodesis has reproducible results and allows patients to mobilize without pain, a fused ankle produces abnormal gait mechanics [9, 10] and can lead to degeneration of the adjacent joints over the years [11]. The idea of TAR is not new, and the "journey" started long before most people think. Although initial attempts, on either side of the Atlantic, can be considered "experimental," gradually research became more systematic, leading to the development of the contemporary TAR prostheses that can be considered a "viable alternative to ankle arthrodesis" [1–6, 12–14]. Evolution of TAR in North America was not independent of the progress made in Europe over the years (Table 1.1); instead, "globalization" involving TAR was alive and well worldwide!

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The First Attempts

Although most articles addressing TAR history claim that the French authors, Lord and Marotte [15], were the first to perform an ankle replacement in 1973 using an "upside-down hip" prosthesis, the first reported attempt to avoid arthrodesis of the painful arthritic ankle takes us a back to 1913, when Leo Eloesser, MD, performed ankle surface allograft transplantation in San Francisco, California [16]. The need for "implant arthroplasty" of the ankle leads to the attempt of "hemiarthroplasty" of the ankle joint, using a custom Vitallium talar dome resurfacing implant, in a 31-year-old man (a heavy laborer suffering from post-traumatic arthritis following a Weber C ankle fracture) in Iowa in 1962 [17]. The surgeon Carol Larson, MD, applied the concept of "cup arthroplasty" of the hip popularized at the time in the ankle. A talar dome replacing prosthesis was implanted through a lateral approach. The patient was able to bear full weight 3 months postoperatively and continued to work in a factory as a heavy laborer for many years. Against all odds, the "primitive" implant survived, and 40 years later, at the age of 71 years, the patient presented for follow-up with minimal hindfoot malalignment and slightly decreased ROM (25° plantar flexion), AOFAS score of 85, no pain, and no activity limitation [17].

In the first "total" ankle replacement, Lord and Marotte [15, 18] implanted an inverted hip stem into the tibia. They removed the talus completely and implanted a cemented acetabular cup in the calcaneus. This procedure was performed in 25 consecutive patients and only seven patients reported satisfaction postoperatively. Twelve of the 25 arthroplasties failed, and therefore the authors did not recommend the further use of this prosthesis design. At the time, the authors recognized the complexity of ankle biomechanics and concluded that a simple hinge prosthesis system with plantarflexion and dorsiflexion would not mimic the normal ankle joint and should be avoided [18].

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_1

Table 1.1 Total ankle replacements used over the years comparing North America with Europe

	North America	Europe
First attempts	• Vitallium made talus resurfacing	• "Reverse hip" ankle prosthesis
1970s	• Irvine	• St. Georg–Buchholz
	• Newton ankle	• Imperial College London hospitals
	• Mayo TAR	• Richard Smith
	• New Jersey TAR	• Conaxial Beck–Steffee
		• Thompson Richards
1980s	• Buechel–Pappas	• STAR
	• Agility I	
Current	• STAR (3-component)	• STAR (3-component)
	• Salto (2-component)	• HINTEGRA
	• INBONE I and II	• Salto (3-component)
	• Agility LP	• BP-type implants (several)
	• Zimmer Trabecular Metal	
	• Hintegra (Canada only)	
	• Infinity	

The First-Generation TARs

Surgeons started then to design more "conventional" prostheses, tailored to match the native ankle joint, developing the so-called first-generation TARs. These were more or less constrained, consisting of two components [1, 2]. It seems that surgeons around the world started designing TAR prostheses in the 1970s.

In Europe the St. Georg–Buchholz ankle prosthesis (semi-constrained) introduced in 1973 [19, 20], the Imperial College of London Hospital prosthesis (constrained, with a polyethylene tibial component) [21, 22], the Conaxial Beck–Steffee ankle prosthesis (a very constrained prosthesis type) [23], the Bath and Wessex (unconstrained, two components) [24], and the Thompson Parkridge Richards (TPR, Richards International, Memphis, TN) prosthesis (semi-constrained) [25, 26] were used in the 1970s. Published results showed high failure rates in the short to midterm, and the use of these implants was later abandoned [25–27]. The Richard Smith TAR was a non-constrained, but incongruent, spherocentric ("ball-and-socket") prosthesis that was used from 1975 to 1979 in England and showed not a lot better results, with loosening rates of 14 % and 29 % after 2 and 7 years, respectively [28].

A different implant, the Takakura Nara Kyocera prosthesis (TNK, Kyocera Medical, Kyoto, Japan), was first used in 1975 in Japan [29]. Since then it has undergone many modifications to address the material of the components (stainless steel, polyethylene, alumina ceramic), coating (without/with hydroxyapatite), and fixation (cement/cementless fixation). In its current version, it consists of alumina ceramic components. While studies by the designer reported good results using the third-generation TNK, independent studies in rheumatoid patients could not reproduce similar outcomes [30].

In North America Some Different TAR Prostheses Were Used

The Irvine total ankle (non-constrained) implant (Howmedica, Rutherford, NJ) was used in Irvine, California, in the 1970s. The Irvine ankle arthroplasty was one of the early designs that closely reproduced the shape of the talus, taking anatomical measurements of 32 tali to establish the shape of the talus [31]. It was initially thought that it could allow motion in three planes also allowing rotation. However, rotation of the components applied stress on the ligaments. Early results (9-month follow-up) documented two failures after 28 implants were inserted [31]. Wound healing problems and malalignment were frequent complications, without further published reports.

The Newton ankle implant (Howmedica, Rutherford, NJ) was non-constrained, incongruent, cemented, two components (high-density polyethylene tibial and Vitallium talar components) implanted in 50 patients. The tibial component was a portion of a cylinder and the talar component was a portion of a sphere with a slightly smaller radius. Incongruency may have resulted in high polyethylene wear, and therefore in 75 % aseptic loosening occurrence, whereas only 38 % of 34 prostheses implanted were left in situ, at an average of only 3 years [32].

The Mayo total ankle replacement, designed by Richard Stauffer, MD, in the 1970s was a highly congruent two-component design, including a polyethylene tibial component, using cement fixation [33]. Initial results were encouraging [33]; however, in a more recent review of outcomes of 204 ankle replacements in 179 patients at the Mayo Clinic from 1974 to 1988, only 19 % of the patients had a good result, while 36 % required implant removal [34]. Results were worse in younger patients. There was radiographic loosening of 57 talar components, complications occurred in 19 ankles, and 94 unplanned reoperations were needed. The cumulative rate of survival at 5, 10, and 15 years was 79 %, 65 %, and 61 %, respectively [34]. The authors attributed the high failure rate to the constrained design of the prosthesis and recommended against use of constrained implants.

The New Jersey or Cylindrical TAR, developed by Frederick Buechel, Sr., MD, an orthopedic surgeon, and Michael Pappas, PhD, a bioengineer [35], was first implanted in 1974. The ultrahigh molecular weight polyethylene

(UHMWPE) 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. This prosthesis was, however, the predecessor of the Buechel–Pappas (Endotec, South Orange, NJ) that will be discussed later in this chapter.

Overall, the majority of first-generation prostheses were eventually withdrawn from the market because of high failure rates with subsidence, continued patient pain, or progressive deformities.

The Evolution (or Second Generation) of TARs and the Contemporary Designs

Attempts to improve outcomes of TAR went on. Second-generation prostheses consisted of metal components both in the talus and tibia, fixed with polymethylmethacrylate (PMMA) cement [1, 2]. Those articulated with the interposition of a polyethylene component that is either fixed to the tibial component and has no independent movement or "mobile" [1, 2], hence the distinction of three- versus two-piece and fixed- versus mobile-bearing prostheses. Evolution in TAR included the move toward more "anatomic" designs that took into consideration normal hindfoot mechanics. It was realized that constrained implants lead to high impact forces leading to loosening of the prostheses. Care should be taken to reduce friction between the components, allowing unrestricted sliding between implant surfaces, guided by appropriate ligamentous balance. Furthermore, the use of PMMA cement was gradually abandoned and research focused on producing implant surfaces that could induce bone ongrowth to the prosthesis. It was realized that PMMA cement as the only means of component fixation (which was routine in hip and knee replacements in previous decades) was associated with high rates of osteolysis and loosening. Furthermore, it was shown that TAR prosthesis fitting required relatively large amounts of bone resection. It has been shown that tibial more than talar bone density and strength rapidly decreases below the surface, thus having an implication on implant fixation and stability [36]. Therefore, modern designs aim at minimal bone resection, especially on the tibial side [1, 2]. Over the years, new instrumentation allowed more accurate implant positioning, reducing bone resection and preserving bone stock [1, 2]. All the above did not just happen at once. Changes in prosthesis design, biomaterials, prosthesis surface, and implantation instrumentation took place gradually, over a period of more than 30 years. Analysis of outcomes and failures and the move toward "evidence-based medicine" were the carrier of change.

Three different second-generation implants were designed in the late 1970s to early 1980s, namely, the Agility Total Ankle Replacement System (DePuy Synthes Orthopaedics, Warsaw, IN), the Buechel–Pappas, and the Scandinavian Total Ankle Replacement (STAR, Waldemar Link, Hamburg, Germany/Stryker Orthopaedics, Mahwah, NJ). Modification of these prostheses, over the years, produced the contemporary and currently used implants [1, 2]. However, at the time of publication, the US public can receive only one of seven metal-backed fixed-bearing cemented TAR devices that are 510(k) cleared and one three-component, mobile-bearing, uncemented device approved by the Food and Drug Administration (FDA) for general use. The seven metal-backed fixed-bearing cemented TAR devices that have been FDA cleared for use are (1) Agility and Agility LP Total Ankle Replacement Systems (DePuy Synthes Orthopaedics, Inc., Warsaw, IN), (2) INBONE I and II and Infinity Total Ankle Replacement Systems (Wright Medical Technology, Inc., Arlington, TN), (3) Eclipse (Integra LifeSciences, Plainsboro, NJ), (4) Salto Talaris and Salto XT Total Ankle Prostheses (Tornier, Inc., Bloomington, MN/Wright Medical Technology, Inc., Arlington, TN), and (5) Zimmer Trabecular Metal Total Ankle (Zimmer, Inc., Warsaw, IN). Additionally, one three-component mobile-bearing uncemented TAR has received FDA pre-market approval for use: the STAR ankle. As part of the FDA pre-market approval, the STAR ankle requires ongoing data collection for the patients enrolled into the original study, and this includes 4-, 6-, and 8-year follow-up data [37].

The Agility Total Ankle Replacement System

In the early 1980s, all TAR prostheses were removed from the market in the USA. Frank Alvine, MD, from South Dakota designed the "Alvine ankle" that became the Agility Total Ankle Replacement System that has been used since 1984. It has been used for more than 25 years and was the only FDA-approved ankle implant in the USA until 2006 [1]. It remains as the most widely used two-component TAR prosthesis in the USA despite having fallen into disfavor over other TAR systems currently available in the USA. It allows space between the medial and lateral gutters, to absorb rotational forces (the talar component can slide from side to side). The Agility (Fig. 1.1) requires fusion of the distal tibiofibular syndesmosis, and this is sometimes a source of problems [38]. Furthermore, its implantation requires more bone resection [39]. This semi-constrained design, consisting of a titanium tibial and cobalt–chromium talar component, does not replicate normal ankle kinematics, as the ankle "slides" from side to side during rotation and sagittal plane movements. For improved osseous integration,

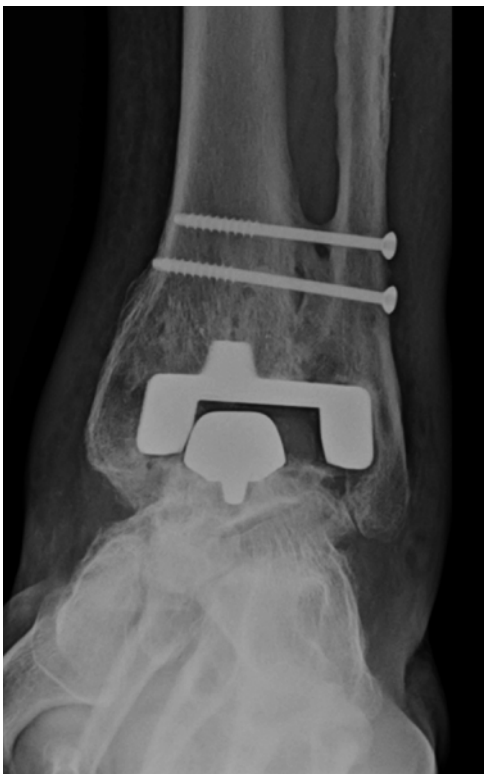

Fig. 1.1 The Agility is a semi-constrained, two-component, fixed-bearing prosthesis, requiring fusion of the syndesmosis. The iteration of the Agility allowed side-to-side "sliding" of the talus

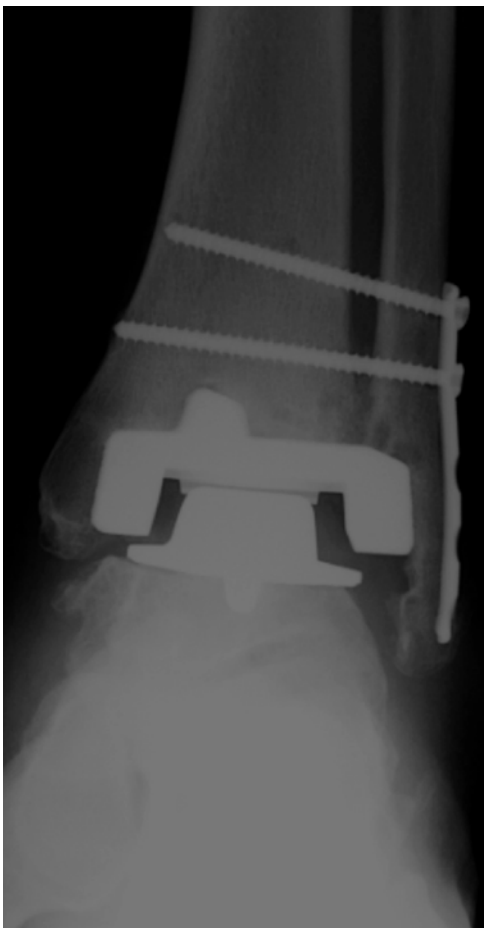

Fig. 1.2 The newer Agility LP prosthesis has a broad-based talar component

both components have a titanium bead surface. A modular polyethylene insert is "locked" into the tibial component. The designers of the implant published their results in 1998 [40] and 2004 [38], with a failure rate (revision or arthrodesis) of 6.6 % in 686 cases from 1995 to 2004, compared to 11 % in 132 TARs from 1984 to 1994 [38]. Other studies [41–43] revealed less favorable results. A systematic review of the literature showed that 9.7 % of 2312 ankle replacements had failed after a weighted mean follow-up of only 22.8 months [44]. The failure rate was 15.8 %, however, in 234 prostheses followed for longer weighted mean follow-up of 6.6 years [12]. A design modification was introduced in 2007 (Agility LP Total Ankle System, DePuy Synthes Orthopaedics, Warsaw, IN) (Fig. 1.2) [45]. The new design includes a broad-based talar component, covering much of the talar dome from side to side. Despite the updated changes, the Agility and Agility LP Total Ankle Replacement Systems seem to no longer be used, replaced by newer-generation TAR prostheses. Additional study of the Agility and Agility LP Total Ankle Replacement Systems should continue so that once we identify the exact causes for the high failures, and understand any features that were beneficial, we can apply this knowledge to future TAR designs.

The Buechel–Pappas Prosthesis and Buechel–Pappas-Type Prostheses

The LCS (low contact stress) prosthesis (DePuy, Warsaw, IN) was the evolution of the "New Jersey" TAR, with the revolutionary addition of a polyethylene "meniscus" in 1978. The LCS was first implanted in 1981 [46]. The LCS (later evolved as the "Buechel–Pappas") was the first three-component TAR, introducing the mobile-bearing joint replacement concept in ankle arthroplasty. In the USA, due to FDA restrictions, mainly two-component designs were in use for many years [47], and three-component TAR prostheses have been used as part of clinical trials. However, the "mobile-bearing" TAR concept, initially introduced by Buechel and Pappas in the USA [46], was adopted by many designs in Europe, where those were used extensively [1, 2].

Specifically, the Buechel–Pappas, a three-component prosthesis with a mobile bearing, evolved from the first-generation New Jersey and LCS ankle prosthesis [46] and was the predecessor of many modern TAR prostheses. In the first Buechel–Pappas (Mark I) design, the anteroposterior

constraint between the tibial and mobile-bearing components was removed. This shallow-sulcus design allowed more ROM without compromising the intrinsic sagittal stability of the TAR. Postoperative complications included mobile-bearing subluxation, talar component subsidence, severe UHMWPE insert wear, malleolar fracture, and osteolysis. Analysis of complications from using this prosthesis led to modifications resulting in the Mark II Buechel–Pappas prosthesis. This new design (also known as the "deep-sulcus" design) included two fins, a thicker meniscal component, and deeper sulcus with a gap in the UHMWPE insert. The concept of the mobile-bearing polyethylene ("meniscus") provided unconstrained motion with LCSs on the bearing surfaces, allowing also inversion and eversion [46, 48]. This prosthesis has further evolved concerning biomaterials and design. In their initial series of 40 TARs, the developers used the "shallow-sulcus" design, producing 70 % good-to-excellent results after 2–20 years (mean 12 years). The "deep-sulcus" design used in 75 ankles after 1990 revealed 88 % good-to-excellent results after 2–12 years (mean 5 years) [48]. Others reported 90 % survivorship at 12 years in 74 Buechel–Pappas ("deep-sulcus") prostheses [49] and 93.4 % survivorship at 8 years [50]. A systematic review article reported an overall 12 % failure rate after weighted mean follow-up of 6.3 years in 253 Buechel–Pappas TARs performed in several centers (including the developers' series) [12]. The Buechel–Pappas TAR prosthesis is not marketed anymore and has been replaced by its successors (presented later).

Buechel–Pappas-type TAR prostheses have been mainly used in Europe, but also in Australia and New Zealand [12]. Their use is restricted in the USA, due to FDA regulations, where they have only been used in clinical trials. One concern regarding all Buechel–Pappas-type TAR prostheses (with a relatively long tibial stem) is the need for opening a cortical window for insertion of the tibial component. However, no failures related to this matter have been reported in the literature. The other concern for tibial stems is that their fixation stability relies to the "weaker and fatty" cancellous supramalleolar bone [36, 50, 51].

Modifications of the Buechel–Pappas three-component mobile-bearing TAR prosthesis have been developed and used mainly in Europe. The Mobility Total Ankle System (DePuy United Kingdom, Leeds, England) (Fig. 1.3) was designed by Pascal Rippstein, MD, of Switzerland; Peter Wood, MD, of UK; and Chris Coetzee, MD, of the USA [52]. The Mobility Total Ankle System is a three-component Buechel–Pappas-type prosthesis with a conical tibial stem. The talar component matches the dome of the talus, while the medial and lateral gutters are not replaced (unlike the Buechel–Pappas prosthesis). Wood et al. [53] published early results from a prospective review of 100 Mobility TARs performed between 2003 and 2005. At a minimum follow-up of 5 years, a total of five ankles (5 %) had to undergo revision surgery, resulting in 4-year survivorship of 93.6 % (95 % CI, 84.7–97.4 %) [53]. A recent study from New Zealand revealed 14 % poor results at 4 years, mainly due to persistent medial ankle pain, for which no specific cause could be established [54]. According to the same study, 29 % of ankle appeared with radiolucencies. As of 2008, the Mobility Total Ankle System was reported to being evaluated in a US FDA-regulated investigational device exemption (IDE) trial, comparing to the Agility LP Total Ankle Replacement System [1, 2]. However, we could not obtain any reports regarding this trial more recently. Furthermore, despite being the most widely implanted TAR reported in National Joint Registry data [55], the Mobility Total Ankle System (according to unpublished reports and personal communications with implant users) is no longer available on the market.

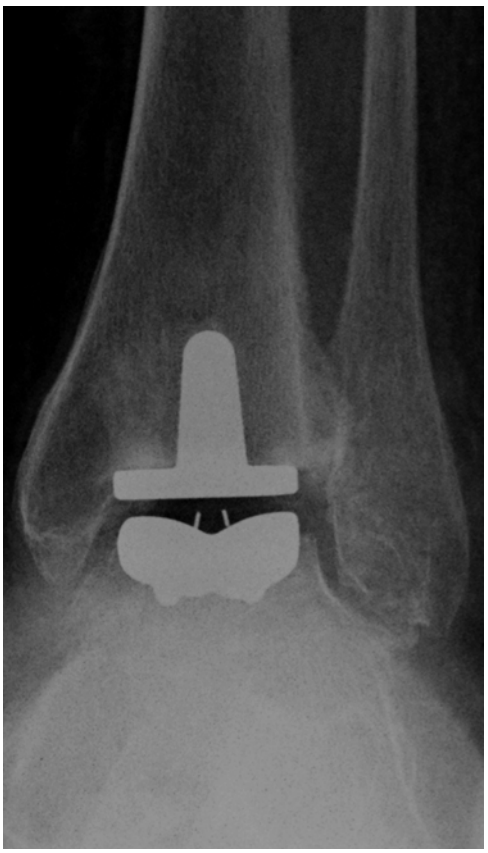

Fig. 1.3 The Mobility is a Buechel–Pappas-like prosthesis (three-component, mobile-bearing, tibial stem, for cementless implantation)

Many other Buechel–Pappas-type (three components, mobile bearing, tibial stem) prostheses have been used in Europe, but not in North America [1, 2]. We would like to highlight the case of the Ankle Evolutive System (Transysteme JMT Implants, Nimes, France) developed in France. It has been widely used in France and England for a several years [56, 57] but was subsequently withdrawn from the market due to high osteolysis rates [56, 58].

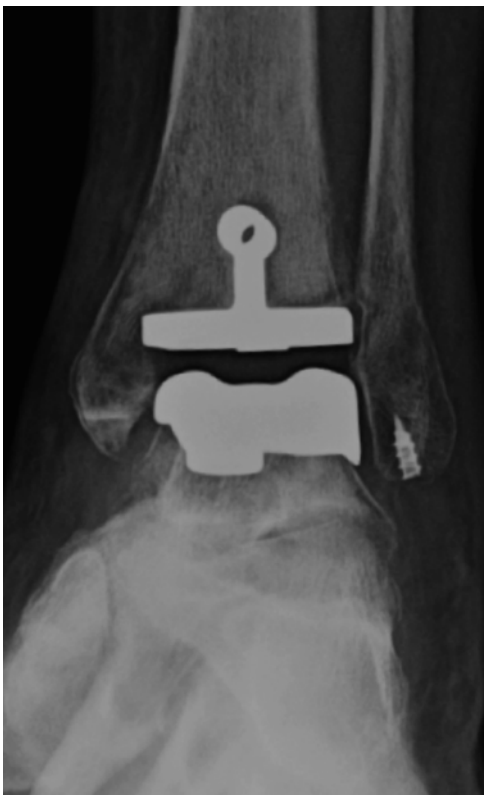

Fig. 1.4 The Salto Talaris ankle, two-component, fixed-bearing prosthesis

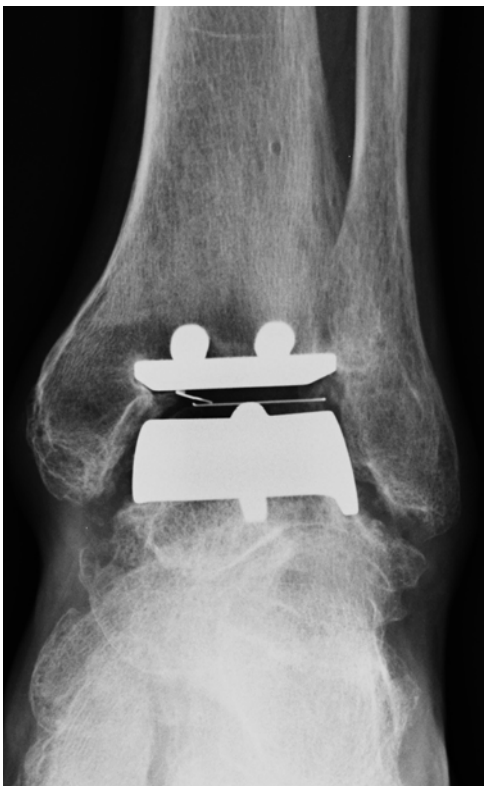

Fig. 1.5 The STAR is the only three-component cementless prosthesis approved by the FDA for use in the USA

The Salto Mobile Version and Salto Talaris Total Ankle Prostheses

The Salto mobile version ankle prosthesis (Tornier, Saint Martin, France) was developed between 1994 and 1996 by Michel Bonnin, MD; Jean Alain Colombier, MD; Thierry Judet, MD; and Alain Tornier in France [59, 60]. The "European" Salto is a three-component, uncemented, mobile-bearing prosthesis and has been used in clinical practice since 1997 in Europe. Its two-component variant was approved for marketing in the USA by the FDA in 2006 [47]. The tibial component is fixed by a hollow fixation plug (Fig. 1.4). Titanium plasma spray technology is used on the tibial and talar implants. The tibial surface of the polyethylene is flat and fits the congruent surface of the talar component with a sulcus, allowing varus/valgus motion in the coronal plane. Medial impingement is prevented by a medial metallic tibial rim [60]. For osseous integration, the component has a keel and a fixation peg. The specific shape of the talar component mimics the natural talar geometry with the anterior width being wider than the posterior and the lateral flange having a larger curvature radius than the medial. The mobile bearing is manufactured from UHMWPE and has full congruency with the talar component in flexion and extension. Results from the developer's group in France show an 85 % survivorship at 8.9 years [60]. An independent series showed an estimated 87 % 5-year survivorship [61]. Early clinical results in the USA were recently published, revealing a 96 % survivorship at 2.8-year (minimum 2-year) follow-up [62]. A study from France revealed no difference in the outcomes comparing Salto mobile-bearing versus Salto Talaris fixed-bearing prostheses [63].

The Scandinavian Total Ankle Replacement

The STAR was developed by Hakon Kofoed, MD, of Denmark and Waldemar Link GmbH & Co. (Hamburg, Germany) in 1978, as a two-component, unconstrained ankle prosthesis with congruent parts covering the medial and lateral facet joints. Since 1986, the tibial part of the STAR prosthesis has included a polyethylene component [51, 64]. This modification was performed to minimize rotational stress at the implant–bone interface, incorporating the mobile-bearing concept, initially introduced found in the Buechel–Pappas TAR [46, 48]. Two anchorage bars on the tibial component are meant to enhance fixation strength (Fig. 1.5). The longitudinal ridge on the talar component is congruent with the distal surface of the mobile meniscus. The prosthesis allows dorsiflexion and plantarflexion, but no talar tilt, whereas the flat tibial surface of the mobile-bearing insert allows rotation. Another modification was the bioactive surface coating for cementless

fixation in 1990, and a double coating addition in 1999, to enhance bone ongrowth ability.

The STAR prosthesis, one of the most popular TARs used in Europe, has one of the longest histories in TAR surgery, with several modifications made during its clinical use. The STAR prosthesis has more than 19 years of clinical experience, and the current design has been implanted in over 15,200 patients worldwide [65]. The STAR was used outside the USA, mainly in Europe, due to FDA regulations. A US investigational device exemption (IDE) clinical trial of STAR prosthesis was initiated in 2000 as a non-inferiority, prospective, multicenter controlled pivotal study to compare the safety and efficacy of STAR prosthesis to ankle fusion. More than 670 patients were enrolled in the pivotal and continued access phases of the IDE clinical trials. The STAR is the only FDA-approved TAR system and the only one allowed for cementless use. A porous plasma spray is applied to the STAR prosthesis that was implanted using the new instrumentation that has been developed in the last 5 years [65].

The inventor reported a 95.4 % survival rate for the uncemented design (1990–1995) [51], which has not been reproduced by others [12, 66–75]. Wood et al. [66] reported in his series of 200 STAR prostheses an 80 % survivorship at 10 years, similar to other authors who found 84 % survivorship at 8 years [67]. In a systematic literature review published in 2010, a 13 % failure rate in 344 STAR prostheses, followed for a weighted mean of 6.3 years, was reported [12]. A systematic review of published results on 2088 cementless STAR prostheses revealed a pooled 71 % survivorship rate at 10 years [68]. A Swedish group of surgeons [69, 70] reported a 98 % prosthesis survivorship at 5 years using 58 double-coated STAR prostheses, markedly better than the "single-coated" prosthesis used in earlier years. A potential issue with the STAR prosthesis is the lack of circumferential bone support of the tibial component, making it prone to subsiding into the distal tibia cancellous bone and possibly to periarticular ossification [66, 73].

Hintegra Total Ankle Prosthesis

The Hintegra Total Ankle Prosthesis (Integra, Saint Priest, France) is an unconstrained, cementless, three-component implant designed in 2000 by Beat Hintermann, MD, PhD, from Switzerland; Greta Dereymaeker, MD, PhD, from Belgium; Ramon Viladot, MD, from Spain; and Patrice Diebold, MD, from France. It is a "STAR-like" prosthesis. The non-articulating metallic surfaces have a porous coating with 20 % porosity and are covered by titanium fluid and hydroxyapatite to allow bone ongrowth. The tibial component has a flat, 4-mm thick loading plate with six pyramidal peaks against the tibia. Additional stability may be achieved by fixation with two screws (the use of screws is not recommended currently). The talar component is conically shaped with a smaller radius medially than laterally, mimicking the normal anatomy of talus. It has 2.5-mm high rims on each side that ensure polyethylene stability, also guiding anteroposterior translation of the mobile bearing (Fig. 1.6) [76, 77]. One of the concepts of the prosthesis' design is minimal bone resection for implantation, thus allowing revision arthroplasty a viable option [78]. The Hintegra Total Ankle Prosthesis has been used in Europe [79], Canada [80], and Korea [81, 82]. Most published studies come from the inventors' institution, and the latest study reviewing 722 ankle replacements revealed overall prostheses survival rates of 94 % and 84 % after 5 and 10 years, respectively [77].

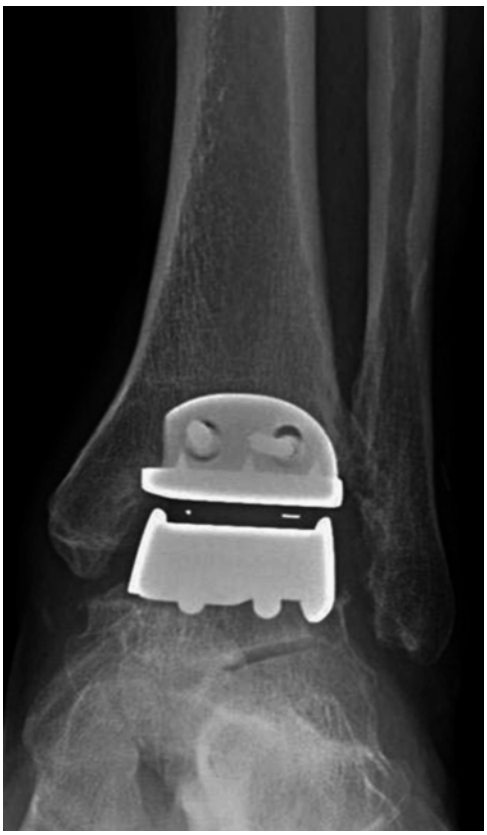

Fig. 1.6 The Hintegra ankle, three-component, cementless, mobile-bearing prosthesis

INBONE Total Ankle Replacement

The INBONE I Total Ankle Replacement System (Wright Medical Technology, Inc., Memphis, TN) is a two-component, fixed-bearing, "modular" prosthesis that has the ability to serve as both a primary and a revision TAR. A special feature of this ankle design is the modular tibial stem allowing proximal extension adding stem segments. The stem of the talar component may be short and limited to the talar body or long if it needed extending into the calcaneus, requiring subtalar fusion for greater stability (e.g., for revision surgery). The initial INBONE I implant

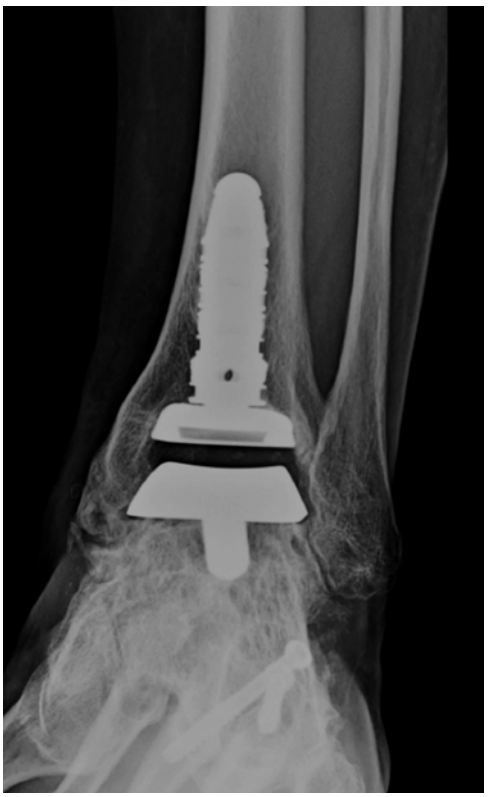

Fig. 1.7 The special feature of the INBONE prosthesis is the modular tibial stem. The INBONE I (early design) had a relatively flat talar component and was, therefore, unstable

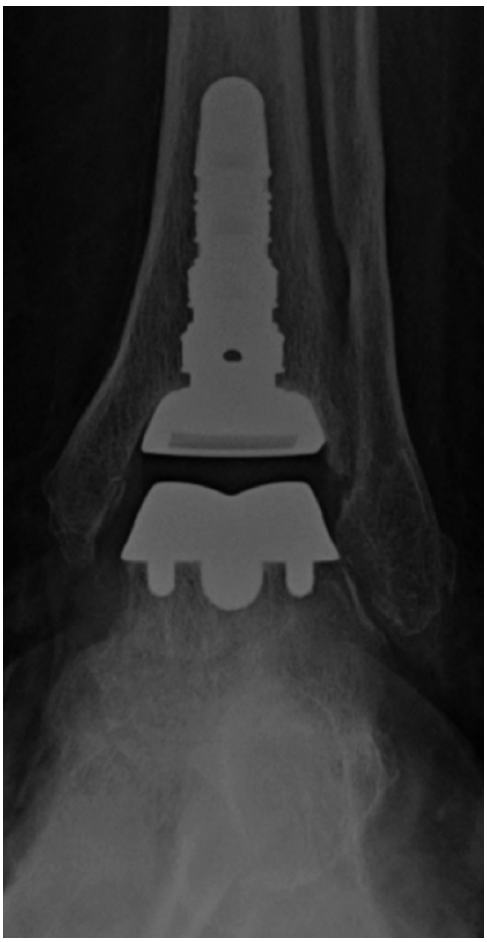

Fig. 1.8 The (modified) INBONE II prosthesis incorporated a talar sulcus to increase stability between the polyethylene and the talar component

(Fig. 1.7) had a flat talus resulting in instability. The second-generation INBONE II Total Ankle Replacement System (Fig. 1.8) received FDA approval for use in the USA in 2005. It has a talar sulcus, improving stability of the articulation between the UHMWPE insert and talar component [83–85]. To date, there are only few published studies on clinical and radiographic outcomes after implantation of the INBONE I TAR [86–89]. Early clinical results in the USA were recently published, revealing an 89 % survivorship at 3.7-year (minimum 2-year) follow-up [89]. Unfortunately, there are no biomechanical studies available that address the kinematics and biomechanical properties of this prosthesis design.

So What Has Changed Over the Years?

Failures of early TAR attempts taught lessons and pioneers of ankle arthroplasty designed better prostheses in the early 1980s. The aim was to produce less constrained implants that reduce "friction" leading to polyethylene wear, osteolysis, and loosening of the prosthesis. The Agility Total Ankle Replacement System and the Buechel–Pappas TAR in North America and the STAR in Europe were the prostheses that turned the page in TAR history. Modifications followed, leading to the contemporary designs. FDA restrictions on the use of mobile-bearing cementless TAR systems influenced the use of prostheses type in the USA. The STAR has received approval for use in the USA only a few years ago. In Canada, the Mobility and the Hintegra are also used. It is debatable whether three-component mobile-bearing prostheses provide improved kinematics, compared to two-component fixed-bearing designs, and there is no clear evidence regarding superiority of one design over the other [90]. Interestingly, some Buechel–Pappas-like prostheses, specifically the AES and Mobility, gained initially wide acceptance in Europe [55], and early results appeared "promising"; however, they were subsequently withdrawn from the market.

Not only have the implant designs improved, but also the surgeons' awareness of ankle biomechanics and their familiarity with the operative technique of TAR have increased. Surgeons in North America and most Western European

countries tend to specialize in foot and ankle surgery and are trained in performing TAR. Improved designs that incorporated features to mimic normal ankle kinematics, more sophisticated instrumentation that allows more accurate prosthesis implantation, biomaterials that allow stable implant–bone fixation and bone ongrowth, as well as improved surgical techniques resulted in improved clinical outcomes, allowing the indications for TAR to expand over the years [2, 12].

The Future of TAR

Implants, surgical techniques, and clinical outcomes have improved, but TAR prostheses are still lacking the success of those performed for hips and knees [1, 2, 8, 12, 79], although the same principles, biomaterials, implant coating surfaces, etc. are used. The reasons are probably related to: (a) the more complex mechanics of the hindfoot, (b) the fact that ankle osteoarthritis is usually post-traumatic or due to chronic lateral ankle instability, and (c) the anatomic restrictions regarding bone resection both in the tibia and the talus. One is limited regarding more generous bone resection that would allow better range of motion and "balancing" of the replaced ankle. Therefore, it appears a lot more challenging to realign the deformed arthritic ankle, avoiding a medial malleolus fracture, and "edge loading" of the prosthesis that will lead to early failure. Furthermore, extensive subchondral bone resection results in lower-quality bone available for prosthesis "fixation." Efforts should be made to design "resurfacing" implants that require resection of smaller amounts of bone, at the same time improving our knowledge and technique performing additional procedures (e.g., osteotomies, soft-tissue balancing). Biomaterials and surface coatings that enhance bone ongrowth into the prosthesis may also improve outcomes.

Conclusions

Time eliminated constrained, cemented, "first-generation" ankle replacements. Although some two-component, more anatomical designs are still used, it seems that three-component "mobile-bearing" TAR prostheses may win the race of evolution, but only time will tell if this is reality. Not only did the implants change over the years, but so did patients and surgeons. Surgeons specialize, improving their surgical outcomes and expanding the indications for TAR, in technically demanding, "complex" ankles. The future will set the limits, as enthusiasm over bright ideas was often followed by skepticism.

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Survivorship of First-, Second-, and Third-Generation Total Ankle Replacement Systems

2

Thomas S. Roukis and Annette F.P. Bartel

Introduction

The evolution of TAR is historically categorized into three generations based predominantly on (1) the number of components employed, (2) the fixation method of the components to bone, and (3) the decade(s) in use. Specifically, the first-generation TAR (1960s through 1980s) consisted of a metallic component fixated to the tibia and polyethylene (PE) component fixated to the talus and vice versa that obtained bone fixation purely with polymethylmethacrylate (PMMA) cement. Limited dedicated instrumentation for prosthetic component implantation existed. Second-generation TAR (1980s through 2000s) consisted of two metallic or ceramic components, one affixed to the tibia and the other to the talus, secured to bone predominantly with PMMA cement, but some were fixated with metallic or biologic porous coating. The PE insert was predominantly immobile and affixed to the undersurface of the tibial component, but some involved a partially mobile PE insert. Rudimentary instrumentation for prosthetic component implantation existed. Third-generation TAR (2000s to present day) consists of two metallic components, one affixed to the tibia and the other to the talus, secured to bone predominantly with metallic or biologic porous coating and rarely PMMA cement. The PE insert predominantly involves a partially mobile design or, in a few designs, is immobile and affixed to the undersurface of the tibial component. Robust instrumentation for prosthetic component implantation exists including intra- and extramedullary referencing, computer-assisted bone preparation, and CT scan-derived patient-specific guides.

It is commonly held that the first-generation TAR prostheses were far inferior to the second-generation prostheses which in turn were inferior to the current third-generation TAR systems [1]. As a result, TAR prosthesis longevity continues to be questioned and poorly understood especially the effect, if any, the specific design characteristics have had on effecting prosthesis survival. Since most TAR publications involve the prosthesis inventor, design team members, or paid company consultants, it has become more difficult to assess the effect of these various design characteristics. Therefore, it is highly probable that selection (inventor) and/or publication (conflict of interest) bias exists. This has been previously described. Labek et al. [2] studied the outcomes of second-generation TAR reported in clinical studies and national joint registries and identified significant selection (inventor) bias in nearly 50 % of clinical studies. This effect was especially strong for the Buechel–Pappas (BP, Endotec, South Orange, NJ) and Scandinavian total ankle replacement (STAR, Waldemar Link, Hamburg, Germany/Stryker Orthopaedics, Mahwah, NJ) when compared to national joint registry data. Additionally, in a systematic review of primary implantation of the Agility total ankle replacement system (DePuy Synthes Orthopaedics, Warsaw, IN), it was demonstrated that excluding the inventor increased the incidence of complications nearly twofold, from 6.6 % (68/1033) to 12.2 % (156/1279) implicating selection (inventor) bias [3]. Similarly, in a systematic review of primary implantation of the STAR, it was demonstrated that excluding the inventor or faculty consultants increased the incidence of complications more than twofold, from 5.6 % (45/807) to 13.2 % (224/1700) implicating selection (inventor) and publication (conflict of interest) bias [4].

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_2

Additionally, the published data for TAR outcomes, whether patient or prosthesis related, include little directly comparable data sets and often include large numbers of concomitant foot and/or ankle procedures to correct preexisting deformity, as well as information collected during the surgeon learning period with the specific TAR systems. Further, as a result of near-continuous modification of prosthesis component features, fixation, and instrumentation, few published studies involve follow-up of the same design TAR system >5 years. These problems interfere with the ability to determine what feature changes actually affect the long-term survival of the TAR system.

Survival Definitions

Defining TAR survivorship in the medical literature is not always consistent; however, Henricson et al. [5] have the most widely accepted definition of TAR revision being removal or exchange of one or more of the metallic component(s) with the exception of incidental exchange of the PE insert. TAR failure also encapsulates conversion to an ankle or tibio-talo-calcaneal arthrodesis and major lower limb amputation. However, despite being important, TAR revision does not include other joint-involving procedures that are termed reoperations (such as PE insert exchange, gutter débridement, peri-prosthetic infection management, etc.) or non-prosthetic joint-involving surgeries that are considered additional procedures (such as subtalar joint arthrodesis, ligamentous release or plication, Achilles tendon lengthening, etc.).

Prostheses Survivorship Analysis

Methods of survival reporting include determining the failure rate and survival rate. The failure rate consists of the number of failed TAR prostheses divided by the total number of TAR procedures performed in the study. In contrast, the survival rate consists of the TAR number with retained metallic components in situ (without revision) divided by the total number of TAR procedures performed in the study. The survival rate is considered more clinically relevant and is presented in most publications involving prosthetic joint analysis. A more precise means of reporting survival rates involves calculating the Kaplan–Meier estimator that forecasts the probability of an event to occur over time with graphic representation of the resultant survival probability curve. The survival times are censored when the patient is lost to follow-up, experiences death, or does not experience the event, such as a revision [6, 7].

Presented here are the survival rates for first-, second-, and third-generation TAR systems based on analysis of published Kaplan–Meier survival curve estimate data. Time increments of 1 year each were defined and extracted from each data set using the Kaplan–Meier curve. If a Kaplan–Meier curve was not provided, the reported values were recorded according to 1-year increments. Only first-, second-, or third-generation TAR systems with formal published Kaplan–Meier survival curves or reported values with censorship occurring at death or revision and a minimum of 5-year follow-up are discussed.

Total Ankle Preplacement Survivorship Based on Generation

First-generation TAR systems meeting our inclusion criteria included the Thompson Parkridge Richards ankle prosthesis (TPR, Richards International, Memphis, TN) [8], Mayo ankle prosthesis (Mayo Clinic, Rochester, MN) [9, 10], low-contact stress prosthesis (LCS, DePuy, Warsaw, IN) [11], and STAR (cylindrical two-component PE tibia and stainless steel talus version) [12–14]. There were a total of 346 first-generation TAR prostheses censored over an 11–15-year follow-up period. The weighted mean survival was 0.88 at 5-year, 0.76 at 10-year, and 0.61 at 15-year follow-up (Fig. 2.1).

Second-generation TAR systems included the BP prostheses [15, 16], Agility TAR [17–19], STAR (three component, uncemented, mobile-bearing PE insert) prosthesis [20–23], ESKA (GmbH & Co, Lübeck, Germany) [24], and Takakura Nara Kyocera prosthesis (TNK, Kyocera Medical, Kyoto, Japan) [25]. There were a total of 1125 second-generation TAR prostheses censored over a 12–15-year follow-up period. The weighted mean survival was 0.91 at 5-year, 0.83 at 10-year, and 0.66 at 15-year follow-up (Fig. 2.2).

Third-generation TAR systems included the Salto Mobile Version ankle prosthesis (Tornier, Saint Martin, France) [26–28], Salto Talaris total ankle prosthesis (Tornier, Inc., Bloomington, MN/Wright Medical Technology, Inc., Memphis, TN) [29], Hintegra total ankle prosthesis (Integra, Saint Priest, France) [30], Mobility total ankle system (DePuy United Kingdom, Leeds, England) [31], and Bologna–Oxford (BOX, Finsbury Orthopaedics Ltd., Leatherhead, United Kingdom) [32]. There were a total of 1,509 third-generation TAR prostheses censored over a 5–12-year follow-up period. The weighted mean survival was 0.93 at 5-year and 0.83 at 10-year follow-up (Fig. 2.3).

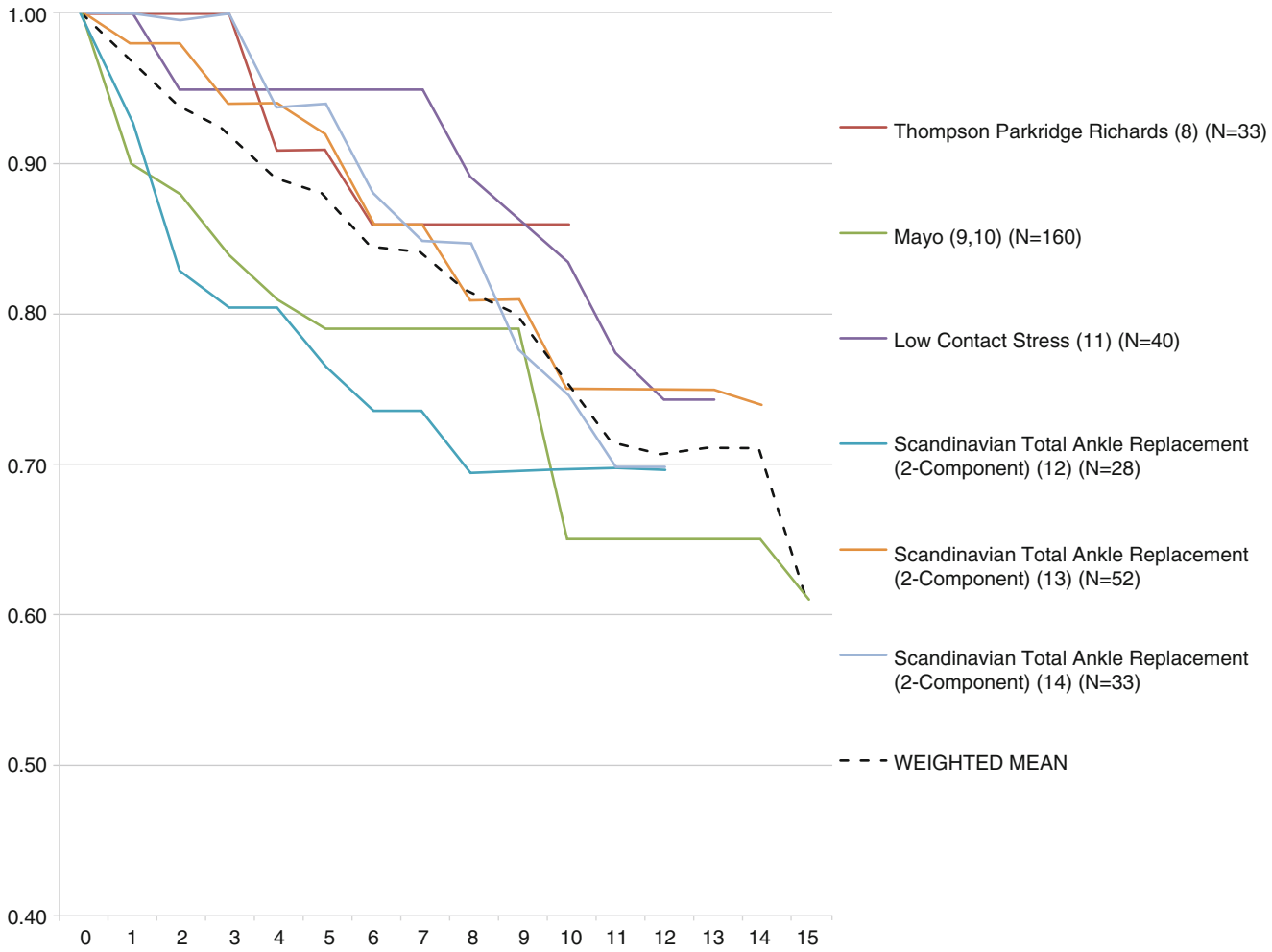


Fig. 2.1 Survival of total ankle replacements based on Kaplan–Meier estimators for first-generation prostheses censored over an 11–15-year follow-up period

Discussion

A review of our data allows for some generalized observations. First, the survival between individual TAR prostheses within each generation was narrow with the high and low survival rates ranging between 10 and 20 % difference regardless of follow-up year. Second, comparison of the weighted mean cumulative Kaplan–Meier survival estimate for each TAR generation reveals that survival between first-, second-, and third-generation TAR systems is <10 % different for the first 10 years. The difference between first- and third-generation TAR survivorship widens >15 % between 10- and 12-year follow-up when the current survival data for third-generation TAR systems ends. The difference between first- and second-generation TAR survivorship then narrows to the point where they are essentially the same between 12- and 15-year follow-up. Third, the general pattern regardless of TAR generation was survival of approximately 0.90 at 5-year, 0.80 at 10-year, and 0.65 at 15-year follow-up. Unfortunately, it is apparent that the TAR prosthesis survival rate decreases with longer-term follow-up for each generation. Taken collectively, despite obvious differences in TAR prosthesis systems, it appears that the difference in survival between first-, second-, and third-generation TAR systems is minimal (Fig. 2.4). However, it is unclear if this difference is in fact clinically significant. Further, it remains a matter for conjecture if it is possible to accurately identify the specific design

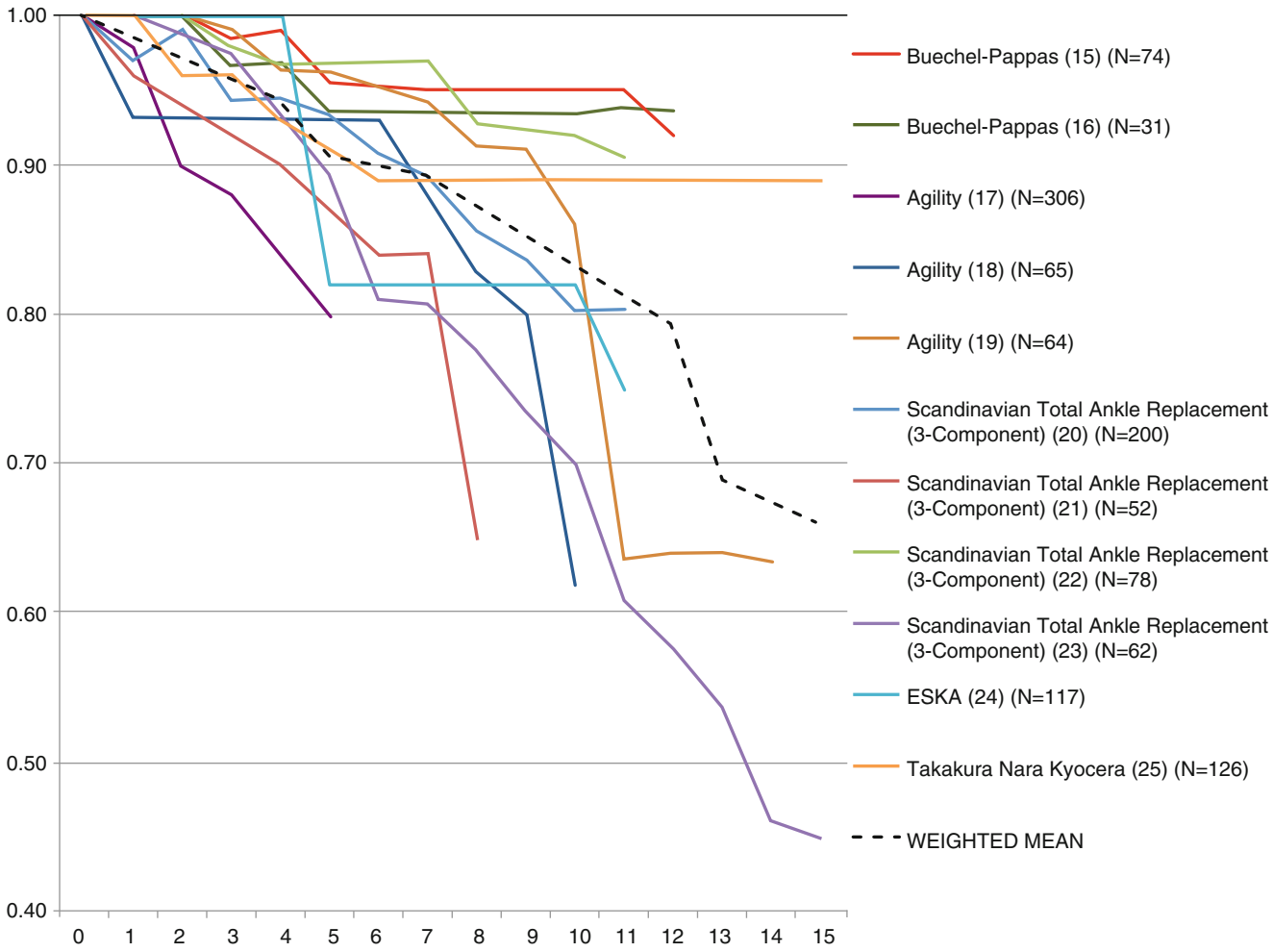


Fig. 2.2 Survival of total ankle replacements based on Kaplan–Meier estimators for second-generation prostheses censored over a 12–15-year follow-up period

characteristics that have an effect on prosthesis survival in order to improve TAR survival beyond 10 years. Based on our findings, it appears that the commonly held belief that first-generation TAR prostheses were far inferior to the second-generation prostheses and that these were in turn inferior to the current third-generation TAR systems, at face value, is not supported.

Fourth, the included studies spanned 5–15 years of data evaluating 346 first-generation, 1125 second-generation, and 1509 third-generation TAR prostheses demonstrating a lengthy follow-up period with robust patient population for evaluation and demonstrating the generational trends apparent within the evolving TAR industry. For instance, a systematic review of TAR prosthesis use in national joint registries was able to identify three general patterns of prosthesis use over a 10-year period: (1) minimal use, (2) initial embracement followed by abrupt disuse, and (3) embracement with sustained growth [33]. TAR prostheses that are in the sustained growth period should be carefully evaluated to identify any trends in use that may be a cause for concern prior to widespread abrupt disuse. For example, analysis of the Salto Mobile Version prosthesis across national joint registries up to 2011 indicates that it is has been embraced and is undergoing sustained growth [33]. However, the Salto Mobile Version prosthesis first appeared in the Norwegian Arthroplasty Register in 2012 [34] and has been abruptly replaced by the

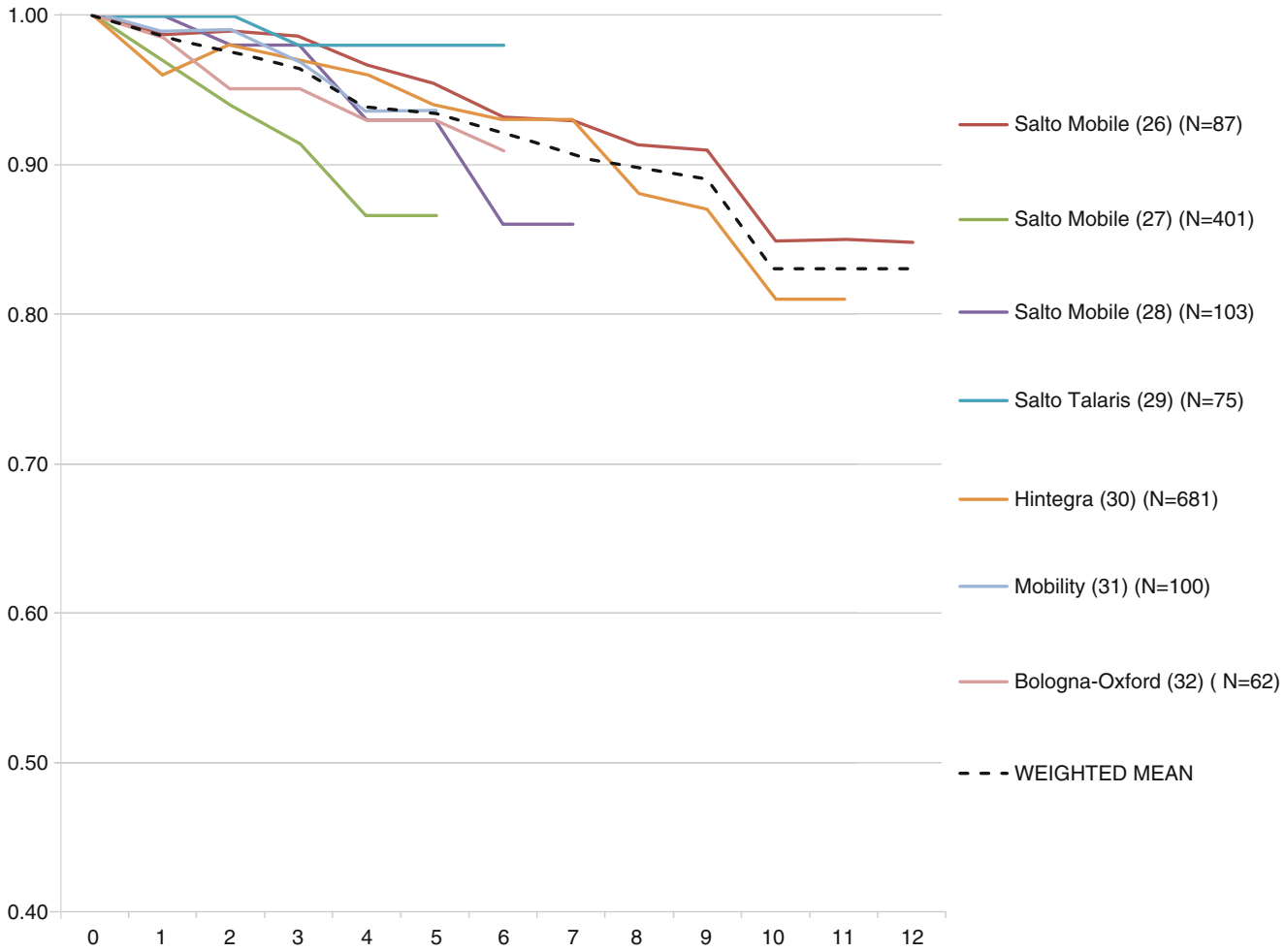


Fig. 2.3 Survival of total ankle replacements based on Kaplan–Meier estimators for third-generation prostheses censored over a 5–12-year follow-up period

fixed bearing Salto Talaris and Salto Talaris XT total ankle prostheses (Tornier, Inc., Bloomington, MN/Wright Medical Technology, Inc., Memphis, TN) in 2013 [35]. The rationale for this abrupt conversion from the mobile- to fixed-bearing version of the same TAR system, especially when the other TAR systems included in the registry have relatively consistent use over a much longer time period, is intriguing but unknown. Comparison of the weighted mean cumulative Kaplan–Meier survival estimates for representative fixed-bearing and mobile-bearing second- and third-generation TAR systems reveals little difference in survival (Fig. 2.5). It is interesting to note that the fixed-bearing Salto Talaris total ankle prostheses are currently under clinical evaluation in Europe [36] where implantation of mobile-bearing total ankle prostheses dominates [33]. This has drawn some criticism with the main concern involving the perceived difficulty in obtaining precise implantation of fixed-bearing devices [37] and the ability for mobile-bearing prostheses to more accurately "…find the correct position of the components" [38] during joint preparation and prosthetic implantation. However, a recent manuscript evaluating active weight-bearing motion of the mobile-bearing FINE Total Ankle System (Nakashima Medical, Okayama, Japan) in 12 ankles revealed anterior–posterior translation between the tibial plate and PE

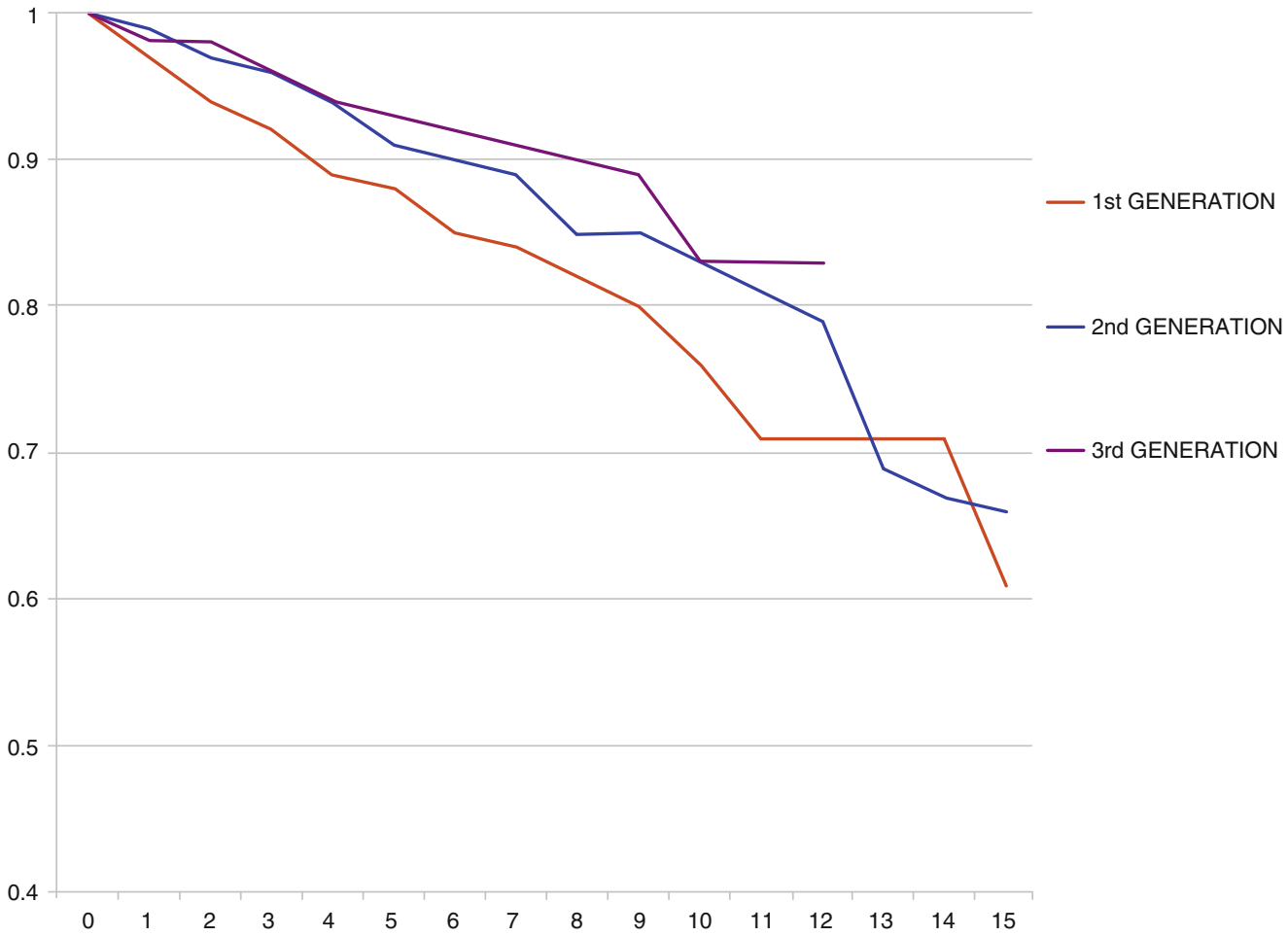


Fig. 2.4 Weighted mean survival of total ankle replacements based on Kaplan–Meier estimators for first-, second-, and third-generation prostheses censored up to 15-year follow-up

insert of only 1.6 mm [39]. Further, in vivo kinematics of the Salto Mobile Version prosthesis revealed between 1 and 1.5 mm of translation between the tibial plate and PE insert [40, 41]. Similarly, the active weight-bearing motion of the STAR system in 15 ankles revealed anterior–posterior translation between the tibial plate and PE insert of only 0.7 mm with a theoretical rotation of up to 3.3° [42]. These studies indicate that the PE mobile bearing in these TAR systems is not functioning as a mobile bearing but rather remains essentially fixed to the tibial component in situ and functions as a fixed bearing. Further, using biomechanical cadaveric analysis, it appears that mobile-bearing [43–46] TAR systems do not tolerate malalignment anymore than fixed-bearing [47–49] prostheses. Taken collectively, it is clear that TAR requires precise implantation since mobile-bearing PE inserts or more incongruity between the fixed-bearing PE insert and talar component geometry does not appear capable of predictably accommodating appreciable malalignment. Finally, the lack of clinically significant differences in outcomes between mobile- and fixed-bearing prosthesis types [50] indicates that the bearing type should not be the main criteria for surgeon adoption of a particular prosthesis. Further study is warranted to determine which of the specific design characteristics (Fig. 2.6) have

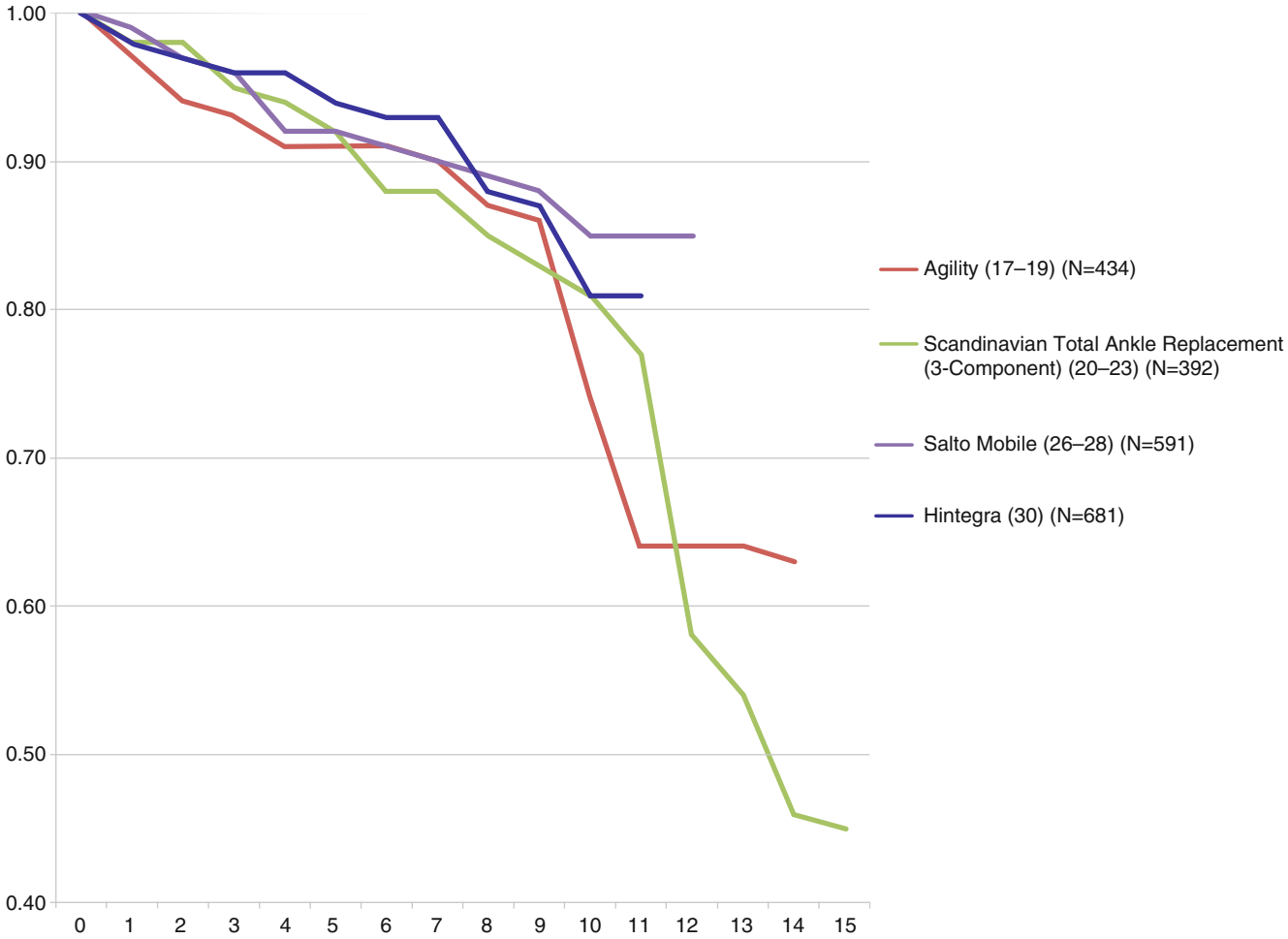
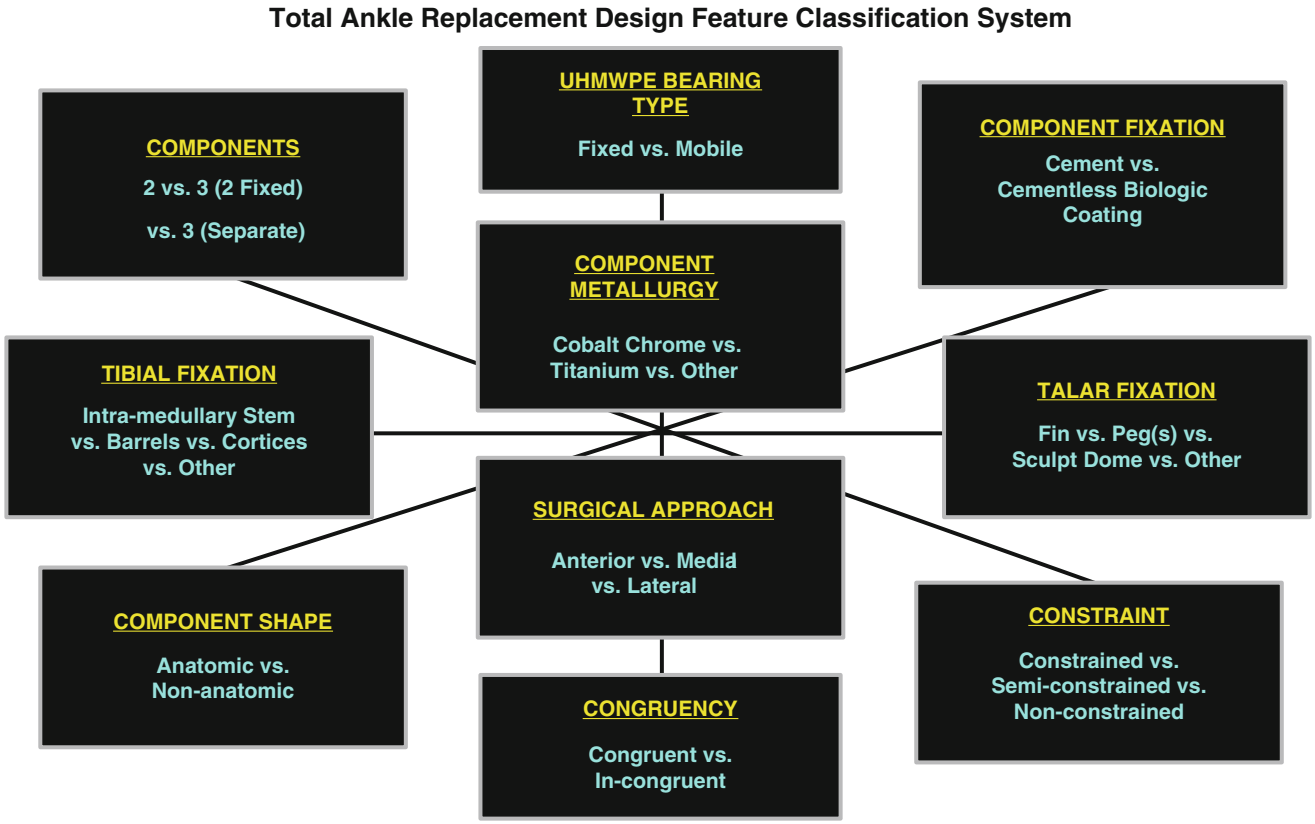


Fig. 2.5 Weighted mean survival of total ankle replacements based on Kaplan–Meier estimators for representative fixed-bearing and mobile-bearing second- and third-generation TAR systems censored up to 15-year follow-up

a predictable effect on long-term TAR prosthesis survival, as well as those that can ultimately influence TAR revision strategies [51].

Conclusions

The survival rates for first-, second-, and third-generation TAR systems based on analysis of published Kaplan–Meier survival curve estimate data or reported values with censorship occurring at death or revision, and a minimum of 5-year follow-up reveals only a small difference in survival between generations. Whether this difference is in fact clinically significant remains unanswered. However, based on our findings, it appears that the commonly held belief that first-generation TAR prostheses were far inferior to the second-generation prostheses and that these were in turn inferior to the current third generation TAR systems is not universally supported. This concept ought to be explored further to accurately identify the specific design characteristics that have an effect on ≥10-year TAR prosthesis survival.



Adapted from: Gill, L.H. Challenges in total ankle arthroplasty. Foot Ankle Int 2004;25:195–207 and Hintermann B. Current designs of total ankle prostheses, pp.69–100; In: Total Ankle Arthroplasty: Historical Overview, Current Concepts and Future Perspectives, 1st Ed.; Springer, New York 2004.

Fig. 2.6 Total ankle replacement design feature classification system. Adapted from Gill, L.H., Challenges in total ankle arthroplasty, *Foot Ankle Int*, 25(4):195–207, 2004, and Hintermann, B., Current designs of total ankle prostheses, in *Total Ankle Arthroplasty*: *Historical Overview*, *Current Concepts*, *and Future Perspectives*, pp. 69–100, Springer, New York, 2004

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Fixed Versus Mobile Bearings in Total Ankle Arthroplasty

3

Murray J. Penner and Derek Butterwick

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 lift off [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

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_3

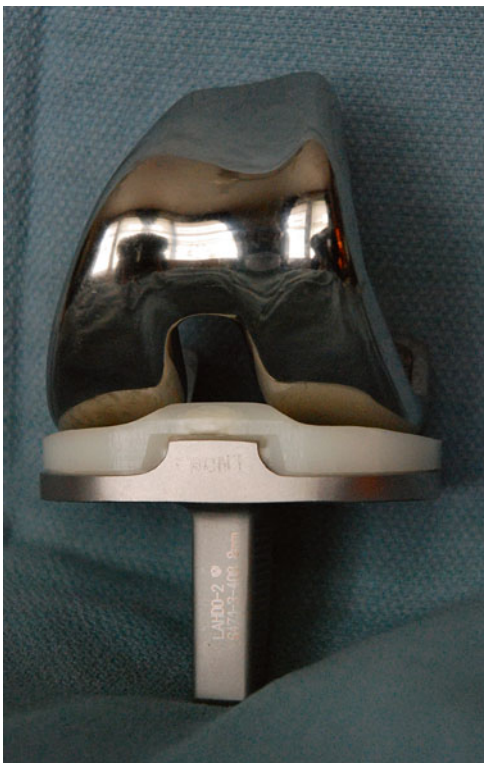

Fig. 3.1 Total knee system demonstrating a fixed-bearing design where polyethylene is locked into the tibial baseplate

6,861 knees which concluded there was no difference in the 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 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

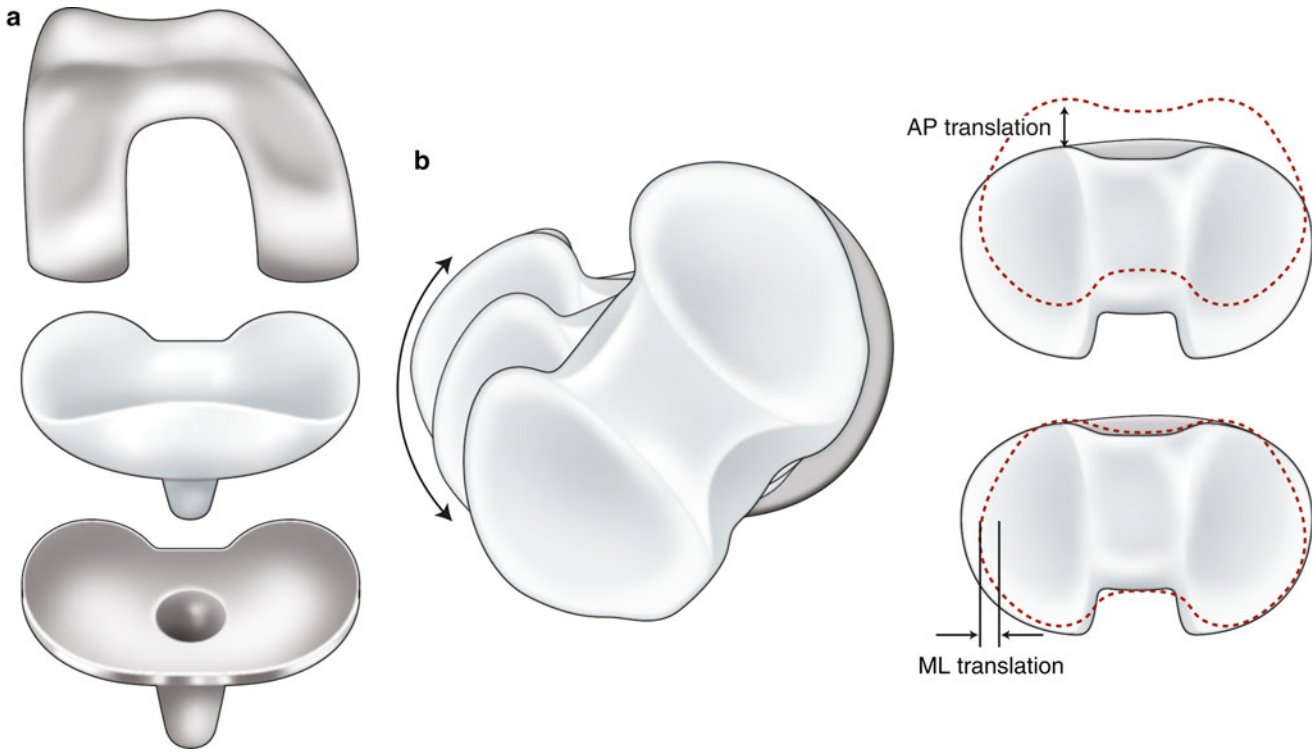

Fig. 3.2 Examples of mobile bearings in total knee arthroplasty. (**a**) Rotating hinge-type design where a conical polyethylene post exits the inferior surface of the polyethylene bearing and loosely fits into a matching cone on the tibial base plate to permit rotation at this interface. (**b**) Meniscal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

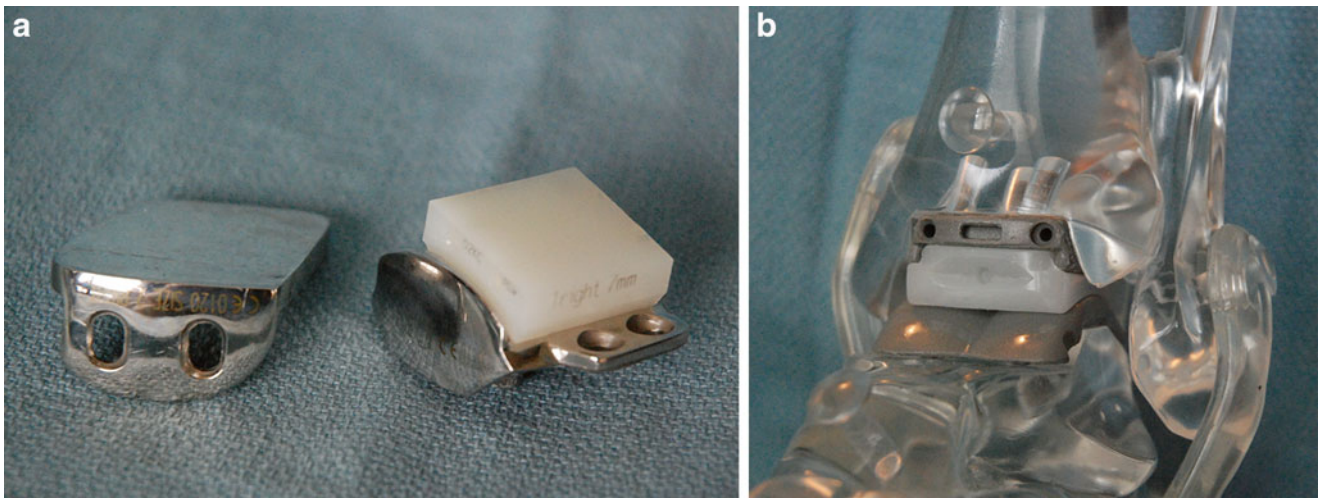

Fig. 3.3 Examples of bearings in total ankle replacements. (**a**) Hintegra mobile-bearing total ankle (Newdeal, Lyon, France/Integra, Plainsboro, New Jersey). (**b**) Wright Medical Infinity Total Ankle (Wright Medical, Memphis, TN)

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]. 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 plafond, a more proximal resection may cause the tibial component to rest on the weaker proximal metaphyseal bone as opposed to the firm subchondral bone [29]. 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 Orthopedics, 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]. Other authors who also studied the fixed-bearing Agility Total Ankle Replacement System design, comparing it to the Mobility (DePuy Orthopedics, Warsaw, IN) mobile-bearing design, found that for both designs, malrotations greater than 5° resulted in increased pressures [31]. 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 [31] and will cause the bearing to become uncovered by the tibial component, leading to edge loading of the bearing and accelerated polyethylene wear. Further, axial positioning of the talar component on the talus remains crucial to avoid any binding within the malleoli.

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 [32], 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

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

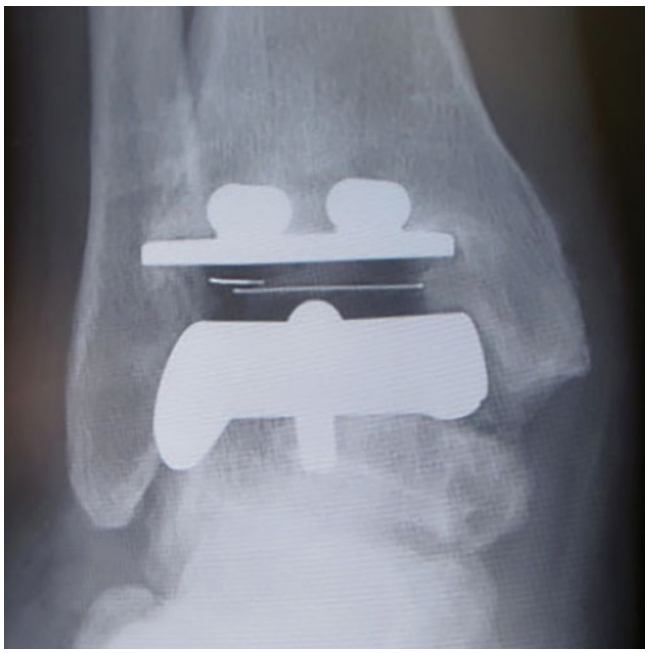

Fig. 3.5 Anterior–posterior radiograph of a STAR with medial malleolar impingement and contact with the medial mortise [36]

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 [33].

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, only a single clinical study exists 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 [34]. 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 subchondrodral 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.

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 is available has studied a historic fixed-bearing design that is non-similar 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 extrapolation 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 surgeon experience [35], foot and ankle alignment, and ligamentous stability.

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Total Ankle Replacement Based on Worldwide Registry Data Trends

4

Mark A. Prissel and Thomas S. Roukis

Introduction

Several countries throughout the world have adopted national joint registries (NJRs) to assess and monitor safety, outcomes, and survivorship following implant arthroplasty [1, 2]. The vast majority of countries collecting this 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. Data pertinent to primary TAR is currently available from Australia [3], England/Wales/Northern Ireland [4], Finland [5], New Zealand [6], Norway [7], and Sweden [8]. Additional countries in Europe, including the Netherlands [9] and Germany [10], are collecting data pertinent to primary TAR, but the findings have yet to be published in an annual report [9, 10]. In 2013, we published a novel analysis of observational trends from available NJR with data pertinent to primary TAR [11]. The purpose of this chapter is to provide an update and comprehensive investigation of primary TAR as it pertains to NJR.

Interestingly, the first total joint registry was proposed in the USA at The Mayo Clinic, by renowned orthopedic surgeon Mark B. Coventry, MD, in 1969. Since then, several single institution registries within the USA have existed, including those at Kaiser Permanente and US Health East [1]. More recently, the American Academy of Orthopedic Surgeons completed a joint registry pilot program in 2011, collecting pertinent data for total joint replacement of the hip and knee. As of October 2012, the American Joint Replacement Registry (AJRR) collected data from over 30,000 total joint arthroplasty procedures from a combined 51 institutions, including 72 hospitals [12]. As of October 2014, the AJRR has grown to include 388 hospitals, still exclusive of any data relevant to TAR [13]. Notwithstanding this impressive growth over the past few years, this collection represents fewer than 10 % of the 4200 hospitals potentially available to report data on total joint replacement in the USA. 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 [14]. 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. Alternately, 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. A previous report evaluating primary TAR in joint registries indicated significantly heightened incidence of revision compared to hip or knee arthroplasty, specifically a threefold increase [15]. In an additional study evaluating NJR data, 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 [16]. These reports are largely in contrast to a recent study reporting 98 % survivorship at a mean 3.6-year follow-up in a series of 75 consecutive primary TARs [17].

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_4

Unfortunately, a large percentage of the available literature regarding primary TAR is riddled with bias, secondary to industry sponsorship and inventor involvement. Recent systematic reviews of the Agility Total Ankle Replacement Systems (DePuy Synthes, Warsaw, IN) and Scandinavian Total Ankle Replacement (STAR, Waldemar Link, Hamburg, Germany/Stryker Orthopedics, Kalamazoo, MI) systems demonstrated stark increase in revision when evaluating non-inventor, non-paid-consultant data, compared to available data from inventors and paid consultants [18, 19]. 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 [20, 21].

NJR data provides an avenue for large-scale, comprehensive data collection of both implant component and patient-related data. When properly collected, this 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

Interestingly, the access and use of specific TAR devices in the USA compared to international use is largely different. This is impart 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 [22]. 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, recent large systematic review, and meta-regression; however, no clinical differences in terms of revision rate, outcome scores, or patient reported outcomes were demonstrated [23]. More commonly the metal-backed, fixed-bearing, two-component, cemented devices available for use within the USA are cleared according to 510(k) rules. This use pattern is in stark contrast to those identified internationally, at least within the countries that report to NJR data sets. 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, a recent study by 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 (Tornier, Inc., Bloomington, MN/Wright Medical Technology, Inc., Arlington, TN) 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 stating the fixed bearing is equivalent to, if not superior to, the mobile bearing [24]. Following this type of data over time, specifically in countries that collect NJR data may likely provide great insight to future use and design of TAR both in the USA and internationally.

Methods

An electronic database, OvidSP-Medline [25] was searched from May 2014 to December 2014, with no restriction regarding date or language of publication, using an inclusive text word query for "ankle arthroplasty" OR "ankle implant" OR "ankle replacement" AND "database" OR "registry" OR "revision surgery," in which the capitalized words represent the Boolean operators performed. The identified pertinent publications were then manually searched for additional relevant manuscripts. Also, a rigorous online-based search for NJR with data pertinent to TAR was performed reviewing in detail 33 NJR websites from 24 countries identified on a single website [1]. Additionally, using a general search engine [26] we identified NJR from an additional four countries: Argentina [27], Brazil [28], India [29], and Japan [30] for review. We additionally procured additional data relevant to the New Zealand registry from personal correspondence with the keeper of this data, which was noted and applied to our original work on this topic [11].

If a reference could not be obtained through purchase, 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 of Danish, German, Japanese, Romanian, Norwegian, or Swedish to English using an online-based translator [31].

Results: Worldwide Prosthesis Usage

We identified potentially eligible information for inclusion in five publications and five online-based updates involving primary TAR. We identified six countries with data relevant to TAR: Australia [3], England/Wales/Northern Ireland [4], Finland [5], New Zealand [6], Norway [7], and Sweden [8, 32]. With the exception of Skyttä et al. [5] as an annual report does not exist in Finland and Henricson et al. [32] which provides exact data prior this being clear in annual reports from Sweden, the remaining studies we previously included for NJR trend analysis must be assumed to have been incorporated into the respective national annual reports [3–8, 32–35]. Resultantly these studies were not independently included for trend analysis, as this would provide duplicate data; however, they were reviewed and referenced for supplemental clarity as an adjunct to the respective annual report. We then arbitrarily stratified the data into three distinct timeframes based on the release into or withdrawal from the market for specific TAR systems in countries with pertinent registry data: 2000–2006, 2007–2010, and 2011–2013. The data from 16 TAR systems involving 6630 ankles was collected worldwide from 2000 to 2013. The most commonly implanted prosthesis was the Mobility ($n=2375$, 36 %) (DePuy Synthes, Leeds, UK) (Table 4.1). 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 2012, 2013). Five of 16 prostheses can be categorized as abandoned based on this criterion. The Agility Total Ankle Replacement System was last implanted in 2007 and that year was only used twice. The Ankle Evolutive System (AES, Transysteme JMT Implants, Nimes, France) has not been implanted since 2008 and was removed from the market in 2012 [36]. The Büechel–Pappas (Endotec, South Orange, NJ) was last implanted in 2011 and only twice in that year. The ESKA (GmbH & Co, Lübeck, Germany) was implanted only twice, last in 2009. The Ramses (Laboratoire Fournitures Hospitalières Industrie, Heimsbrunn, France) was implanted a total of 11 times from 2004 to 2005 and not since.

Minimal Use

The second identified trend from our analysis is minimal use, which is defined as implantation during 2012 and 2013 but never >50 ankles worldwide in a given year. Four of the 16 prostheses can be categorized by minimal use by these criteria. The INBONE II Total Ankle Replacement System (Wright Medical Group, Inc., Memphis, TN) was first implanted in 2012 and only three times total. The Rebalance (Biomet UK, Bridgend, South Wales, UK) has data available since 2011 and was implanted 47 times in 2013, which was the highest to date for this prosthesis. The fixed bearing Salto Talaris was implanted 23 times in 2013, the only year with available registry data. The Taric (Implantcast GmbH, Buxtehude, Germany) has only been implanted one time, in 2012.

Initial Embracement with Diminished Use

The third identified trend from our analysis is initial embracement with diminished use, which is defined as implantation >50 times within a given year at peak use and reduction from peak use of ≈50 %. Three of the 16 prostheses can be categorized by embracement with diminished use based on these criteria. The CCI Evolution (Implantcast GmbH, Lüneburger Schanze, Buxtehude, Germany) reached peak usage in 2009 with 52 ankles; most recently in 2013, it was implanted only 23 times (56 % reduction in use from peak). The most commonly implanted prosthesis, the Mobility, is categorized by this trend as it was implanted 540 times at its peak in 2011, but in 2013 was only implanted 283 times (48 % reduction in use from peak). The STAR reached peak implantation in 2001 with 138 ankles and subsequently had diminished use over the next decade with only 55 implantations in 2007 (60 % reduction in use from peak) and in 2013 was implanted 72 times (47 % reduction in use from peak).

Initial Embracement with Sustained Growth

The final identified trend from our analysis is initial embracement with sustained growth, which is defined as implantation >50 at peak usage and either sustained growth at each annual interval or only minimal diminishment at a given interval with continued overall growth to current date. Four of the 16 prostheses can be categorized by embracement with sustained growth based on these criteria. The Bologna–Oxford (BOX, Finsbury, Leatherhead, UK) was first recorded in 2008 with a usage of six implants; it eclipsed 50 implantations per year in 2010 and was implanted 60 times in 2013. The Hintegra (Integra, Saint Priest, France) was first recorded in 2004 with a usage of two implants, reached 50 implantations per year in 2010 and was implanted 112 times in 2013. The Salto Mobile Version was first recorded in 2005 with a usage of five implants, reached 50 implants per year in 2008 and was implanted 208 times in 2013. The Zenith (Corin Group PLC, Cirencester, UK) was first recorded in 2010 with a usage of 78 implants, in 2013 it was implanted 130 times.

Table 4.1 Worldwide usage of primary total ankle replacement prostheses based on available national joint registries between 2000 and 2013

Year	Agility	AES	BOX	BP	CCI	ESKA	Hintegra	INBONE II	Mobility	Ramses	Rebalance	Salto Mobile Version	Salto Talaris	STAR	Taric	Zenith	Total
2000	10	–	–	2	–	–	–	–	–	–	–	–	–	112	–	–	124
2001	20	–	–	0	–	–	–	–	–	–	–	–	–	138	–	–	158
2002	17	17	–	0	–	–	–	–	–	–	–	–	–	133	–	–	167
2003	17	85	–	42	–	–	–	–	–	–	–	–	–	79	–	–	223
2004	29	99	–	44	–	–	2	–	3	6	–	–	–	64	–	–	247
2005	25	104	–	42	–	–	6	0	42	5	–	5	–	61	–	–	290
2006	1	78	–	14	–	–	11	0	68	0	–	33	–	79	0	–	284
2007	2	18	–	17	–	–	8	0	111	0	–	30	–	55	0	–	241
2008	0	17	6	22	20	1	35	0	197	0	–	56	–	60	0	–	414
2009	0	0	26	21	52	1	46	0	213	0	–	57	–	60	0	–	476
2010	0	0	51	7	37	0	78	0	500	0	–	107	–	57	0	78	915
2011	0	0	44	2	37	0	74	0	540	0	32	142	–	82	0	109	1062
2012	0	0	68	0	44	0	103	2	418	0	44	187	–	72	1	131	1070
2013	0	0	60	0	23	0	112	1	283	0	47	208	23	72	0	130	959
Total	121	418	255	213	213	2	475	3	2375	11	123	825	23	1124	1	448	6630

Agility (DePuy Orthopaedics, Inc, Warsaw, IN); Ankle Evolutive System (AES) (Transysteme JMT Implants, Nimes, France); Bologna–Oxford (BOX) (Finsbury, Leatherhead, UK); Büechel–Pappas (BP) (Endotec, South Orange, NJ); CCI Evolution (Implantcast GmbH Lüneburger Schanze, Buxtehude, Germany); ESKA (GmbH & Co, Lübeck, Germany); Hintegra (Integra, Saint Priest, France); INBONE II (Wright Medical Technology, Memphis, TN); Mobility (DePuy UK, Leeds, England); Ramses (Laboratoire Fournitures Hospitalières Industrie, Heimsbrunn, France); Rebalance (Biomet UK Ltd, Bridgend, South Wales, England); Salto Mobile Version (Tornier S.A.S. Montbonnot Saint-Martin, France); Salto Talaris (Tornier, Inc., Bloomington, MN/Wright Medical Technology, Inc., Arlington, TN); LINK Scandinavian Total Ankle Replacement (LINK STAR, Waldemar Link, Hamburg, Germany); Taric (Implantcast GmbH, Buxtehude, Germany); Zenith (Corin Group PLC, Cirencester, England)

Overall the number of primary TARs reported to NJR has increased annually, with only limited exception since 2000. In 2005 and 2006 there were slight decreases in reported usage, compared to 2004 only to rise significantly in 2007. 2012 demonstrated the largest reported primary TAR NJR usage with 1070 ankles reported, followed by a slight decrease to 959 in 2013. From 2000 to 2006 the average usage per year was 213 prostheses. From 2007 to 2010 the average usage per year is 512 prostheses. From 2011 to 2013 the average usage per year is 1030 prostheses. It is difficult to conclude whether this increase can be extrapolated to an increased volume of primary TAR occurring worldwide over these intervals in time or if this demonstrates heightened awareness of the importance of collecting NJR data regarding primary TAR and is a function of improved registry completeness.

Results: Individual Country Data

The Australian Orthopaedic Association's "National Joint Replacement Registry" was initiated on July 28, 2006. Available data is reported through December 31, 2013. The "Demographics and Outcomes of Ankle Arthroplasty Supplementary Report 2014" contains data pertinent to TAR performed from 2007 through 2013 [3]. A total of 1331 prostheses involving ten prosthesis designs were identified. From 2007 through 2010 652 primary TARs were reported (163 per year), while from 2011 through 2013 679 primary TARs were performed (226 per year). The most frequently implanted prosthesis was the Mobility ($n=552$; 41 %), although with significant decrease in 2013 ($n=50$) compared to 2011 ($n=121$). The next most commonly implanted prosthesis was the Hintegra ($n=314$; 24 %) (Table 4.2).

The National Joint Registry of England, Wales and Northern Ireland "11th Annual Report of Prostheses used in Hip, Knee and Ankle Replacement Procedures 2014" began reporting primary TARs on April 1, 2010 [4]. Available data is reported through December 31, 2013. In 2010 407 primary TARs were reported ($n=407$ per year), while from 2011 through 2013 1579 primary TARs were performed ($n=526$ per year). The most commonly implanted prosthesis was the Mobility ($n=1008$; 51 %), while the second most common was the Zenith ($n=435$; 22 %) (Table 4.3).

Table 4.2 Australian Orthopaedic Association's National Joint Replacement Registry specific to total ankle replacement between 2007 and 2013

Year	Agility	BOX	BP	CCI	ESKA	Hintegra	Mobility	Salto Mobile Version	STAR	Zenith	Total
2007	2	0	11	0	0	6	37	1	1	0	58
2008	0	6	18	0	1	34	98	11	0	0	168
2009	0	24	21	0	1	45	75	19	3	0	188
2010	0	28	7	1	0	63	101	35	3	0	238
2011	0	14	2	3	0	56	121	70	4	1	271
2012	0	23	0	0	0	64	70	65	2	6	230
2013	0	11	0	0	0	46	50	63	2	6	178
Total	2	106	59	4	2	314	552	264	15	13	1331

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 (GmbH & Co, Lübeck, Germany); Hintegra (Integra, Saint Priest, France); Mobility (DePuy U.K., Leeds, England); Salto Mobile Version (Tornier, Saint-Martin, France); LINK Scandinavian Total Ankle Replacement (LINK STAR, Waldemar Link, Hamburg, Germany); Zenith (Corin Group PLC, Cirencester, England)

Table 4.3 England, Wales, and Northern Ireland National Joint Replacement Registry specific to total ankle replacement between 2010 and 2013

Year	BOX	Hintegra	INBONE II	Mobility	Rebalance	Salto Mobile Version	STAR	Taric	Zenith	Total
2010[a]	23	15	0	254	0	23	14	0	78	407
2011	29	18	0	294	4	28	28	0	108	509
2012	44	34	2	280	13	38	31	1	125	568
2013	47	62	1	180	13	43	32	0	124	502
Total	143	129	3	1008	30	132	105	1	435	1986

[a]2010 data includes 13 TAR implanted prior to 2010

Bologna–Oxford (BOX) (Finsbury, Leatherhead, UK); Hintegra (Integra, Saint Priest, France); INBONE II (Wright Medical Technology, Memphis, TN); Mobility (DePuy UK, Leeds, England); Salto Mobile Version (Tornier, Saint-Martin, France); Rebalance (Biomet UK Ltd, Bridgend, South Wales, England); Salto Mobile Version (Tornier, Saint-Martin, France); LINK Scandinavian Total Ankle Replacement (LINK STAR, Waldemar Link, Hamburg, Germany); Zenith (Corin Group PLC, Cirencester, England); Taric (Implantcast GmbH, Buxtehude, Germany); Zenith (Corin Group PLC, Cirencester, England)

The Finnish Arthroplasty Register, initiated in 1980, included primary TAR since that point. Despite previous attempts to secure more recent data via electronic mail [11] data are limited to the most recent publication and include relevant data only from 2000 to 2006 [5]. Accordingly, from January 1, 2000 through December 31, 2006 primary TARs were identified involving three prosthetic designs. The AES was the most commonly implanted prosthesis ($n=298$; 61 %), while the second most common was the STAR ($n=181$; 37 %) (Table 4.4).

The New Zealand National Joint Registry, initiated in January 2000, has included primary TAR since inception [6]. From our previous publication we were able to procure additional data relevant to primary TARs performed from 2000 to 2006 [11]. In total 1057 prostheses involving seven different implant designs have been reported. From 2000 through 2006 297 primary TARs were reported ($n=42$ per year), whereas from 2007 through 2010 430 primary TARs were performed ($n=108$ per year) and from 2011 through 2013 330 primary TARs were performed ($n=110$ per year). The Mobility was the most common prosthesis ($n=449$; 42 %); however, over the past couple of years, this prosthesis has underwent a sharp decline in use in New Zealand with only six implants reported for 2013. The next most common prosthesis was the Salto Mobile Version ($n=417$; 39 %), with the highest volume in 2013 ($n=101$) (Table 4.5).

Table 4.4 Finnish Arthroplasty Register specific to total ankle replacement between 2000 and 2006

Year	AES	Hintegra	STAR	Total
2000	0	0	43	43
2001	0	0	53	53
2002	14	0	46	60
2003	67	0	20	87
2004	79	0	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); LINK Scandinavian Total Ankle Replacement (LINK STAR, Waldemar Link, Hamburg, Germany)

The Norwegian Arthroplasty Register, initiated in 1987, has included primary TARs since January 1994. The Norwegian Arthroplasty Register "Report 2014" in addition to previous publications compiled a complete data set from 2000 through 2013 [7, 35]. A total of 809 prostheses were reported. From 2000 through 2006 250 primary TARs were reported ($n=36$ per year), whereas from 2007 through 2010 299 primary TARs were recorded ($n=75$ per year) and from 2011 through 2013 260 primary TARs were reported ($n=87$ per year). The most frequently implanted prosthesis was the STAR ($n=576$; 71 %). The next most common prosthesis was the Mobility ($n=100$; 12 %) (Table 4.6).

The Swedish Joint Registry was initiated in April 1993. It has included primary TAR since its inception. "The Swedish Joint Registry Annual Report for 2013," along with previously published relevant manuscripts, offers pertinent data for primary TAR from 2000 through 2013 [8, 32]. A total of 956 prostheses were reported. From 2000 through 2006 455 primary TARs were reported ($n=65$ per year), whereas from 2007 through 2010 258 primary TARs were performed ($n=65$) and from 2011 through 2013 243 primary TARs were performed ($n=81$ per year). The most common prosthesis was the Mobility ($n=266$; 27 %). The next most common prosthesis was the STAR ($n=201$; 21 %), but has not been implanted since 2007 (Table 4.7).

Table 4.5 Norwegian Arthroplasty Register specific to total ankle replacement between 2000 and 2013

Year	AES	CCI	Hintegra	Mobility	Rebalance	Salto Mobile Version	Salto Talaris	STAR	Total
2000	0	0	0	0	0	0	0	18	18
2001	0	0	0	0	0	0	0	29	29
2002	0	0	0	0	0	0	0	36	36
2003	0	0	0	0	0	0	0	25	25
2004	3	0	2	0	0	0	0	34	39
2005	0	0	4	0	0	0	0	36	40
2006	0	0	1	0	0	0	0	62	63
2007	0	0	2	4	0	0	0	52	58
2008	0	4	1	2	0	0	0	60	67
2009	0	12	1	25	0	0	0	57	95
2010	0	13	0	26	0	0	0	40	79
2011	0	17	0	16	7	0	0	50	90
2012	0	12	0	12	8	11	0	39	82
2013	0	11	0	15	0	1	23	38	88
Total	3	69	11	100	15	12	23	576	809

Ankle Evolutive System (AES) (Transysteme JMT Implants, Nimes, France); 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, Saint-Martin, France); Salto Talaris (Tornier, Inc., Bloomington, MN/Wright Medical Technology, Inc., Arlington, TN); LINK Scandinavian Total Ankle Replacement (LINK STAR, Waldemar Link, Hamburg, Germany)

Table 4.6 New Zealand National Joint Registry specific to total ankle replacement between 2000 and 2013

Year	Agility	BOX	Hintegra	Mobility	Ramses	Salto Mobile Version	STAR	Total
2000	10	0	0	0	0	0	6	16
2001	20	0	0	0	0	0	8	28
2002	17	0	0	0	0	0	11	28
2003	17	0	0	0	0	0	9	26
2004	29	0	0	3	6	0	10	48
2005	25	0	0	34	5	5	1	70
2006	1	0	0	47	0	33	0	81
2007	0	0	0	49	0	29	1	79
2008	0	0	0	62	0	45	0	107
2009	0	2	0	79	0	38	0	119
2010	0	0	0	76	0	49	0	125
2011	0	1	0	64	0	44	0	109
2012	0	1	5	29	0	73	0	108
2013	0	2	4	6	0	101	0	113
Total	119	6	9	449	11	417	46	1057

Agility (DePuy Orthopaedics, Inc, Warsaw, IN); Bologna–Oxford (BOX) (Finsbury, Leatherhead, UK); Hintegra (Integra, Saint Priest, France); Mobility (DePuy UK, Leeds, England); Ramses (Laboratoire Fournitures Hospitalières Industrie, Heimsbrunn, France); Salto Mobile Version (Tornier, Saint-Martin, France); LINK Scandinavian Total Ankle Replacement (LINK STAR, Waldemar Link, Hamburg, Germany)

Table 4.7 Swedish Joint Registry Register specific to total ankle replacement between 2000 and 2013

Year	AES	BP	CCI	Mobility	Rebalance	STAR	Total
2000	0	2	0	0	0	45	47
2001	0	0	0	0	0	48	48
2002	3	0	0	0	0	40	43
2003	18	42	0	0	0	25	85
2004	17	44	0	0	0	17	78
2005	23	42	0	8	0	18	91
2006	21	14	0	21	0	7	63
2007	18	6	0	21	0	1	46
2008	17	4	16	35	0	0	72
2009	0	0	40	34	0	0	74
2010	0	0	23	43	0	0	66
2011	0	0	17	45	21	0	83
2012	0	0	32	27	23	0	82
2013	0	0	12	32	34	0	78
Total	117	154	140	266	78	201	956

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

Discussion

The purpose of this analysis was to investigate and interpret the available NJRs with data pertinent to primary TAR providing observational trends. A total of 16 TAR systems were identified for use from 2000 to 2013 in the six countries reporting data relevant to primary TAR within this interval of time. A total of 6630 ankles were identified throughout the studied timeframe of which 6473 (98 %) involved three-component mobile-bearing cementless prostheses. The overwhelming international predilection for mobile-bearing prostheses is largely similar to our findings from our previous work [11]. However, the recent publication by Gaudot et al. in 2014 regarding the direct comparison of the Salto Mobile Version (mobile-bearing) and Salto Talaris (fixed-bearing) may provide insight to an impending international paradigm shift regarding the previously theorized advantages of three-component mobile-bearing TAR prostheses [24]. 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. The ultimate outcome of Gaudot et al.'s [24] comparative analysis remains to be seen, as this is only short-term data for the Salto Talaris, whereas longer-term studies exist regarding the Salto Mobile Version [37, 38]. Unfortunately France, like the USA, does not collect data pertinent to primary TAR in its NJR. Interpretation of these results is subject to inventor bias, while the results, from France, inclusive of inventor surgeons and non-inventor surgeons regarding use of both the Salto Mobile Version and Salto Talaris are not currently available. In the coming years, if this data is embraced and use patterns are altered throughout international markets, it will be interesting to see if alternate fixed-bearing two-component TARs available and readily employed within the USA are adopted internationally. Currently, contemporary two-component fixed-bearing TAR prostheses available within the USA have only limited high-quality literature supporting their use and demonstrating survivorship. Obviously, further study including various contemporary fixed-bearing prostheses available in the USA is warranted and of great interest for surgeons who perform this procedure. At the same time, the body of literature

identifying potential problems with various mobile-bearing prostheses internationally is growing. For example, a recent Australian study of 62 consecutive primary TARs using the Mobility prostheses identified a 12 % revision rate at mean follow-up of 32 months and a 31 % reoperation rate with the initial reoperation occurring at a mean of only 14 months [20]. Interestingly, of the available NJR reporting data pertinent to primary TAR, only Norway continues to use the only mobile-bearing three-component prostheses available in the USA, STAR, despite well-reported heightened incidence of revision and frank disuse with this prostheses in alternate registries (Australia [3], Sweden [8], New Zealand [6]).

Overall, four usage trends were identified by our analysis. Interestingly, in our previous work we defined three usage trends, and in this current work, we added "abandonment" as a usage trend for prostheses no longer implanted for primary TAR. Some prostheses remained in the same categories in both the previous and current work. However, the use of other prostheses deviated from the previously speculated trend. For example, and most interestingly, although the Mobility remains the most commonly implanted primary TAR prosthesis based on available worldwide NJR data in 2013 ($n=283$), it has underwent impressively decreased use compared to its peak in 2011 ($n=540$). In our previous work the Mobility was categorized as "initial embracement with sustained growth"; however, by the current analysis, the Mobility is most accurately categorized as "embracement with diminished use." Although not identified in this series of data, which concluded on December 31, 2013, in June 2014 the Mobility was removed from the market in the UK with "commercial reasons" cited, and more recently, the implant was pulled internationally by its manufacturer in December 2014 [39]. This demonstrates the importance of continual monitoring of available NJR data and depicts the rapid evolution of the topic of primary TAR. Beyond monitoring usage trends, Kaplan–Meier trends have been applied in Sweden and New Zealand to gain insight regarding survivorship. Further, recently pooled available NJR data regarding survivorship has been explored using Kaplan–Meier analysis on a globally available level [40]. The findings included an overall 2-year survival rate of 0.94, 5-year survival rate of 0.87, and 10-year survival rate of 0.81. Interestingly when stratified of included countries with combined ≥35 % of total implanted prostheses with the AES, Büechel–Pappas, and STAR, the 5-year survival was 0.78–0.89, while countries with <35 % of total implanted prostheses from AES, Büechel–Pappas, and STAR, the 5-year survival was 0.90–0.93 [40].

Although discussion has existed within Europe to form an "international joint registry" to date none exist, and quite frankly, the collected data by the various NJR are highly variable [2]. The current perspective of NJR is formatted to address the desires of the given country with the data collection, while the future direction of joint arthroplasty registry data collection should position toward an international perspective with data collection relevant to a worldwide surgeon and industry audience. For each registry individual strengths exist, but none is without flaw. In Sweden, as of 2013 the registry completeness is reported as >95 % and provides >20 years worth of data [8]. New Zealand provides extensive detail about the primary procedure including type of operative theater, antibiotic usage, cement usage, surgical approach, and bone grafting, in addition to detailed patient demographics [6]. 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 [3]. 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/institution at the time of the procedure to detail the pertinent data.

NJR data is 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; this needs to be well understood by surgeons interpreting this data, as well as by researchers performing meta-analyses or systematic reviews to accurately describe the data. Selection bias potentially exists secondary to voluntary participation in the NJR, with the exception of government hospitals in England, Wales, and Northern Ireland. Also, the interpreter of NJR data needs to be cognizant that inventor data may be included and associated bias likely exists [19]. 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 throughout various NJR.

Conclusions

We performed an observational analysis and update to our previous work regarding trends in primary TAR use based on NJRs from 2000 through 2013 including all pertinent worldwide data. We identified 6630 primary TARs from six countries, of which 6473 (98 %) involved three-component mobile-bearing cementless prostheses. 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 previous work on this topic, several prostheses are categorized differently in this current work indicating 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 the market withdrawal of the Mobility and as more fixed-bearing prostheses available in the USA become more readily available in the international market. Time will tell if the historic monopolization of international primary TAR use with mobile-bearing prostheses will continue, despite the lack of studies exhibiting any superiority. Regardless, we encourage surgeons and industry to remain cognizant of this important yearly data as it becomes freely available to the public via annual reports to continue to make informed choices about patient and implant selection when performing primary TAR and support continued efforts to collect national registry data in the USA pertinent to primary and revision TAR.

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Total Ankle Replacement Versus Ankle Arthrodesis

5

Timothy R. Daniels and Sagar J. Desai

Introduction

End-stage ankle arthrosis is a debilitating condition that affects approximately 6 % of the population [1]. Multiple studies have demonstrated the detrimental effects of ankle arthrosis on health and function [2–4]. Glazebrook et al. [3] found the mental and physical disability associated with end-stage ankle arthrosis is at least as severe as that associated with hip arthrosis. End-stage ankle arthrosis has traditionally 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. This chapter provides an evidence-based review of the literature on ankle arthrodesis, TAR, and a direct comparison of both procedures. An extensive review of the literature has been undertaken, with a focus on recently published studies. The literature is not sufficiently robust to provide a simple algorithm for determining the best surgical option for a particular patient. Many factors must be considered when making this decision. This chapter aims to provide surgeons with the best evidence currently available to allow for informed surgical discussion making.

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, arthroscopic ankle arthrodesis, gait analysis, complications, adjacent joint degeneration, and functional outcomes.

Surgical Techniques

Historically, ankle arthrodeses were performed using immobilization in plaster of Paris casts [23]. In 1951, Sir John Charnley described an arthrodesis technique using external fixation [11], 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 [11, 13, 15, 16, 23–40]. Screw fixation is 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, 30, 31, 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. Friedman et al. [49] reported that the cross-screw technique was more rigid than parallel screws, especially in torsion. Ogilvie-Harris et al. [50] found that the addition of a third screw in the sagittal plane significantly improved compression and improved torsional strength compared to a two-screw construct; however, good results have been found with both two- and three-screw constructs [16, 30, 31, 42, 43, 45].

The efficacy of plating in isolation or in addition to screw fixation has been demonstrated in both biomechanical and clinical studies [18, 27, 29, 36, 51]. Supplementation of standard screw fixation with an anterior plate has been demonstrated to increase construct rigidity and decrease micromotion in a biomechanical cadaver study [51]. The efficacy of anterior plating was subsequently demonstrated in clinical studies

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_5

[18, 29]. 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 or risk factors for wound healing (i.e., diabetes, active tobacco use). Internal fixation only with screws has demonstrated good results; therefore, the extra dissection required for plate fixation may preclude its benefit.

Arthroscopic Arthrodesis

Arthroscopic ankle arthrodesis was originally described by Schneider in 1983 [52] and has become a more popular option for surgeons, particularly over the past decade. Arthroscopic joint preparation is less invasive and is theoretically a better option for patients with a higher risk of soft-tissue complications. This could potentially include patients with previous surgical scars, skin grafts, prior open injury, compromised vascularity, or systemic comorbidities that increase the risk of wound complications. Aside from two Level IV studies demonstrating the utility of arthroscopic arthrodesis in hemophiliac patients [53, 54], this benefit remains largely theoretical.

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 [12, 21, 55–60]. In 2005, Ferkel and Hewitt evaluated 35 patients who underwent arthroscopic arthrodesis with 72-month mean follow-up [12]. Thirty-four of the 35 patients (97 %) achieved joint fusion, with a mean time 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 mean time 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.

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. Mean time 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.

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, 62–69]. The most recent studies show similar results, with some variability. Sealey et al. [70] 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. [65] 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. [64] 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:

1. Slower walking speeds
2. Shortened stride length
3. Decreased cadence
4. Earlier heel rise
5. Increased anterior tilt of the tibia during mid-stance
6. Increased forefoot plantar pressures
7. Posterior shift of ground reactive forces during terminal stance
8. Increased hip flexion
9. 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. [62], 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 [8, 10, 44, 62, 64, 71–78]. Coester et al. [72] 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 metatarsal-phalangeal 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 [71, 74]. Buchner and Sabo [71] 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. [74] assessed 17 patients with 18 ankle arthrodeses 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 [79] and one Level IV study [64] compared preoperative and postoperative adjacent joint arthrosis. Sheridan et al. [79] 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. [64] 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, 72, 74]. 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, 10, 11, 14, 16, 19, 23, 34, 36, 43, 45, 77, 80, 81]. Most of this literature consists

of Level IV retrospective non-comparative studies with small patient cohorts and assessment using un-validated 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. [64] 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. [14] 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. [65] 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.

Ankle arthrodesis may precipitate adjacent joint arthrosis, alter gait and decrease range of motion; however, functional outcomes and patient satisfaction remain high. Further literature on outcomes in ankle arthrodeses is described in the section comparing ankle arthrodesis and TAR.

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 [82, 83]. 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 % [84]. 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 [85–89]; however, many of these studies are limited by short follow-up and small patient numbers.

Brodsky et al. [85] 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. [89] studied 15 patients with posttraumatic 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 [86] 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. [89] 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 [86] 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 compared 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 has 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 [90–113].

Haddad et al. [96] 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. [99] reported a 5-year survival of 86 % of 202 TARs from the New Zealand Registry. Fevang et al. [95] 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 % [114]. More recent studies have also demonstrated favorable survival rates. Mann et al. [104] 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 [92]. In 88 TAR in 85 patients, Sproule et al. found survival was 89.6 % at 3 years and 88.4 % at 4 years [109]. 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 % [113].

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 [82, 83]. 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 [115]; however, many patients still do not report being pain-free postoperatively [90, 116–119]. Patient satisfaction has been reported in multiple studies to range from 80 to 97 % [101, 102, 104, 106, 111, 116–118, 120–123]. 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 [97, 107, 112, 124]. Schuberth et al. [107] 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. [124] 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 [94, 112, 125, 126]. 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 [127–131]. In 2009, both Hobson et al. [127] and Kim et al. [128] demonstrated good results in patients with preoperative varus deformity. Reddy et al. [129] subsequently demonstrated successful correction of moderate to severe coronal plane deformity in TAR. More recently, Sung et al. [130] 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 un-validated outcome measures. Trajkovski et al. [131] 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. [132] reported lower patient satisfaction rates, and Bai et al. [133] 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 [134] 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. [91] also found no differences in outcome scores between patients with primary arthrosis, posttraumatic arthrosis, and rheumatoid arthritis. More recently, Kraal et al. [135] 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 [106, 136].

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 [111, 137–139]. Initial studies cautioned against the use of TAR in younger patients [137, 139], but more recent literature demonstrated no significant differences in outcomes based on age. Kofoed and Lundberg-Jensen [138] 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. [111] demonstrated similar findings at 4-year follow-up. Norwegian Joint Registry data also showed no significant influence of age [95].

Gender has been studied as a potential factor in TAR outcomes. Both the Norwegian [95] and Swedish [97] registries demonstrated no significant influence of gender on outcomes following TAR.

Patient weight at time of surgery has been assessed in two recent studies [140, 141]. Barg et al. [140] 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 previously reported incidence of 3.9 % symptomatic DVT following TAR [142]. While Barg et al. [140] 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. [141] 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. However, the perceived advantages of TAR and perceived disadvantages of arthrodesis make patient enrollment 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 [69, 96, 122, 143–153]. This section presents the most recent literature directly comparing ankle arthrodesis and TAR.

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, 62–68], and those results were summarized in an earlier section of this chapter.

Five recent Level II studies [69, 143, 146, 147, 149] have directly compared gait parameters following TAR to those following arthrodesis. In 2003, Valderrabano et al. demonstrated kinematic differences following arthrodesis and TAR using cadaveric specimens and an axial loading device [154, 155]. TAR was found to more closely replicate normal range of motion [154] and decrease movement transfer between the foot and the leg [155]. In a comparative gait analysis of 12 patients following TAR and 12 patients following arthrodesis and 12 healthy controls, Piriou et al. [149] 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. [147] 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 [69, 146].

Singer et al. [69] 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. [146] 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 underwent 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 [122, 144, 145, 150–152], one Level III study [153], and one Level IV study [96] 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. [96] 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. [152] 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. [150] 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. [122] 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. [151] 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. [153] 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. [148] 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 [156]), 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. [144] 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.

The recent literature directly comparing functional outcomes, quality of life, complications, and reoperations between ankle arthrodesis and TAR have 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 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

6

Andrew D. Elliott and Thomas S. Roukis

Introduction

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 prostheses themselves, long-term survival of the prostheses has increased. It was not just the techniques and prosthetic components 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 may, at the same time, be broadened.

Initially, the indications for TAR were vague and limited. A 1979 study by Demottaz et al. [1] of 21 TARs of various designs and just over a year mean 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 midfoot and the elderly as there was very limited follow-up data to support use in younger patients. In 1982, Newton [2] published a larger study with longer follow-up of TARs he, himself, had performed. 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. To further clarify his findings, he divided his patient population into those with osteoarthritis (34 ankles), those with rheumatoid arthritis (ten ankles), those with pseudoarthrosis after previous ankle arthrodesis (three ankles), and those with avascular necrosis (AVN) of the talus (three ankles). For those with osteoarthritis, he believed 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 believed long-term oral corticosteroid therapy was a relative contraindication. For patients with pseudoarthrosis from a failed ankle arthrodesis and AVN 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 arthrodesis 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. [3] published a long-term review of 62 TARs performed between 1972 and 1981 at the London Hospital with a mean follow-up of five and a half years. Indications included primary osteoarthritis, secondary osteoarthritis, and rheumatoid arthritis. While the implants used were not all of the same design, they were of similar design characteristics. 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

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_6

required ankle arthrodesis as a salvage procedure. They went on to opine that TAR was not indicated in any situation, regardless of the underlying etiology of the ankle arthritis.

While not as grim an outlook as Bolton-Maggs et al. [3] postulated, a study by McGuire et al. [4] published in 1988 was still fairly restrictive on when TAR was indicated. This was a retrospective examination of 25 TARs with a mean follow-up of 3.8 years and 18 ankle arthrodeses with a mean 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 multi-joint involvement, as well as older patients with post-traumatic arthrosis. Contraindications to TAR were acute or chronic septic arthritis, absent or inadequate soft tissue, neuropathic joints, any degree of talar AVN, 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 aseptic loosening of the TAR and the subsequent need for revision surgery. While the authors did note an improved outcome in patients with multi-joint rheumatoid arthritis, they attributed that primarily to the patients' decreased demands on the prosthesis. 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. An interesting indication for TAR that the authors added in their discussion was one for a patient that cannot tolerate the prolonged periods of immobilization, hospitalization, and/or reoperation that might be necessary with an ankle arthrodesis. The authors did not mention the average length of hospitalization or immobilization for ankle arthrodesis or TAR. Prior studies listed the average length of stay for hospitalization after TAR at 30 days [4].

Total Ankle Replacement FDA Approval

The initial generations of TAR prostheses had fairly limited indications and almost universal contraindications. However, surgical techniques improved as did the prosthetics themselves. Currently, in the USA the third and fourth generations of implants are being used with much greater success than their earlier counterparts. Of the new generations of TAR implants being used in the USA, the following have been approved by the US Food and Drug Administration (FDA) either with 510(k) clearance 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); Salto Talaris Ankle Prosthesis and Salto Talaris XT Ankle Prosthesis by Tornier Inc. (Bloomington, MN); INFINITY Total Ankle System by Wright Medical Technology, Inc. (Arlington, TN); INBONE I, INBONE II, and INFINITY Total Ankle System by Wright Medical Technology, Inc. (Arlington, TN); Agility and Agility LP Total Ankle Prostheses by DePuy Orthopaedics, Inc. (Warsaw, IN); and Zimmer Trabecular Metal Total Ankle by Zimmer, Inc. (Warsaw, IN).

As a requirement for application, indications for use were identified for each TAR system [5–12]. Likely by design these listed indications were both vague and limited. Universally, the indications included osteoarthritis, post-traumatic arthritis, and rheumatoid arthritis. The Agility LP Total Ankle Replacement System hedged their indications with the qualifier that their implant was for elderly individuals with decreased activity levels [9]. Of the above listed TAR systems, five stated they were indicated for use after failed prior ankle surgery or for revision surgery: Agility Ankle Revision Prosthesis, Eclipse Total Ankle Implant, INBONE I and II Total Ankle Replacement systems, and INFINITY Total Ankle System. 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 introduces 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 believed 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 [13–19]. The Eclipse Total Ankle Implant surgical technique guide was not available at the 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 among the different companies while other contraindications were

Table 6.1 Contraindications listed in total ankle replacement surgical technique guides

Generally accepted as contraindicated (listed in 6–7 technique guides)	Contraindicated (listed in 4–5 technique guides)	Mentioned as contraindicated (listed in ≤3 technique guides)
Active/prior deep infection in ankle joint or adjacent bones	Prior surgery/injury that has reduced the bone quality	Avascular necrosis of the talus
Skeletal immaturity	Malalignment or severe deformity of involved or adjacent anatomic structure	Hindfoot/forefoot malalignment precluding a plantigrade foot
Inadequate bone stock to support device	Lower extremity vascular insufficiency demonstrated by Doppler arterial pressure	Significant malalignment of the knee
Osteoporosis/osteopenia	Prior arthrodesis at the ankle joint	Insufficient ligament support that cannot be repaired with soft-tissue stabilization
Neuromuscular disease resulting in lack of normal muscle function about affected ankle	Poor skin/soft-tissue quality at the surgical site	Leukocytosis
Charcot joint or neuropathy that might lead to a Charcot joint of affected ankle	Sepsis	Local inflammation
	Nonfunctioning lower limb muscle/ weakness	Mental disorder
	Absolute body weight	Neurobiologic disease
Italics are "warnings" in surgical guide	*Obesity*	Pregnancy
	Manual labor occupation	Known allergy to component
	High activity level	Steroid use
	Drug/alcohol addiction	Hepatitis/HIV
	Other disabilities	Absence of medial/lateral malleoli
	Poor bone stock	*Likelihood of falls*
	Metabolic disorders/medical treatment that progressive deterioration of bone	*Diseases affected quality of soft tissue*
	Sensitivity/allergy to component	*Severe joint deformity*
		Tumors of surrounding bones
		Unexplained high erythrocyte sedimentation rate
		Bone loss that for which adequate fit of prosthesis cannot be achieved
		Nonfunctioning subtalar joint in active individual

limited to only a few systems (Table 6.1). 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 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 looking for specific wording but rather for general guidelines that paint a picture of what conditions in the patient, the patient's limb, and the patient's ankle should be avoided. Using the conditions listed in Table 6.1 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 to be compliant with the post procedure protocols including long-term reduced demand on the affected ankle. The patient should also have adequate bone and soft tissue to heal the initial insult to the ankle but also support the ankle and prosthesis once it is in place. If the patient meets these criteria then it is a question of if any deformities in the lower leg or foot 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. While none of the systems listed these specifically, they did list "revise prior ankle surgeries" as an indication that can be taken to mean the same thing.

Insurance Company Guidelines

Insurance companies are increasingly providing coverage for TAR, and as of 2011, 92 % of patients in commercial plans have access to TAR [20]. Their policies dictate the conditions under which TAR is deemed medically necessary, as well as when TAR is considered experimental and investigational. As few patients pay for TAR out of pocket, insurance

Table 6.2 Health insurance-dictated conditions, considered indications, and contraindications

Conditions	Health insurance			
	Anthem (subsidiary of WellPoint, Inc.)	UniCare (subsidiary of WellPoint, Inc.)	UnitedHealth Care	Aetna Group
Indications				
Osteoarthritis	Yes	Yes	Yes	Yes
Post-traumatic arthritis	Yes	Yes	Yes	Yes
Rheumatoid arthritis	Yes	Yes	Yes	Yes
Prior ankle surgery	Yes	Yes	No	No
Arthritis in surrounding joints	Yes	Yes	No	No
Contralateral ankle arthrodesis	Yes	Yes	No	No
Contralateral severe foot arthritis	Yes	Yes	No	No
Failed 6 months of conservative therapy	Yes	Yes	Yes	Yes
Contraindications				
Active sepsis or infection	Yes	Yes	Yes	Yes
Insufficient bone stock	Yes	Yes	Yes	Yes
Osteonecrosis	Yes	Yes	Yes	Yes
Insufficient blood supply	Yes	Yes	Yes	Yes
Charcot neuropathy	Yes	Yes	Yes	Yes
Peripheral neuropathy	No	No	Yes	Yes
Avascular necrosis of the talus	Yes	Yes	Yes	Yes
Insufficient bone or musculature such that proper component positioning or alignment is not possible; malalignment	Yes	Yes	Yes	Yes
Prior ankle joint infection	No	No	No	No
Skeletal immaturity	Yes	Yes	Yes	Yes
Insufficient ligament support unable to be repaired	No	No	No	Yes
Prior ankle arthrodesis	No	No	No	Yes
Poor skin/soft tissue	Yes	Yes	Yes	Yes

policies act as de facto guidelines for TARs. A review of the policies of three of the top private insurers in the USA (UnitedHealth Group, Wellpoint, Inc., and Aetna Group) reveals a lack of consensus as to when TAR is or is not indicated [21–24]. All agree on several things including: only FDA-cleared or approved TAR systems should be used; TAR is indicated for osteoarthritis, rheumatoid arthritis, and post-traumatic arthritis of the ankle; and AVN of the talus is a contraindication (Table 6.2). There are also some significant differences between insurers. Only one group, Wellpoint, Inc., stated in their policy that revision or replacement of an implanted TAR could be considered medically necessary. This stands in contrast to Aetna Group that was the only company to list a prior arthrodesis at the ankle joint as a contraindication to TAR. Aetna Group was the only company to designate a weight limit restriction, stating a patient's weight of greater than 250 lb is a contraindication. Wellpoint, Inc., was the only company that referenced the condition of the contralateral ankle or surrounding ipsilateral subtalar or midfoot joints as possibly bearing on the need for a TAR. They suggested that for TAR to be medically necessary, there needs to be at least one of the following: arthritis in the adjacent joints (subtalar or midfoot) of the affected side, arthrodesis of the contralateral ankle, or either an inflammatory arthritis or severe arthritis in the contralateral ankle. This cursory review reveals even among private insurance companies there is no agreement on when TAR should or should not be performed and under what conditions TAR is indicated.

Medical Community Position Statements

The medical community lacks uniformity as well. A review of three professional organizations (American Academy of Orthopaedic Surgeons [AAOS], American Orthopaedic Foot and Ankle Society, and the American College of Foot and Ankle Surgeons) for position statements or opinions on TAR was inconclusive. The AAOS adopted a technology overview on the surgical treatment of ankle arthritis in 2010. The document specifically states that it should not be construed as the official position of the organization, and the guide should only be used as an educational tool. However, in the paper, they address the question as to what are the factors that predict the outcome of TAR. Specifically, 14 factors were examined: type of device, age of patient, preoperative weight of patient, preoperative infection, preoperative fracture, side of surgery, sex of patient, deformity, disease, previous operations, ankylosis of the hindfoot, surgeon experience, year of surgery, and hospital surgery volume. The technical

guide stated that for the examined criteria, the literature does not conclusively demonstrate predictors of better or worse outcomes for TAR [25]. Of the 14 factors examined, only those patients with preoperative infection had worse outcomes than those without, but this was based on very low quality data. Six other factors showed conflicting results for predicting outcomes: type of prosthesis, age of the patient, deformity, disease, diagnosis, and surgeon experience. For these six prognostic factors, some study results indicated that they were significant in predicting outcome, while other studies found no association with the outcome of surgery. The remaining factors were determined to show no significant association with TAR outcomes.

The American Orthopaedic Foot and Ankle Society published a position paper on TAR in March of 2014 [26]. 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. Other indications include patients with previous hindfoot fusion or significant arthritic change in neighboring joints. Patients must have satisfactory vascular perfusion in the involved extremity and appropriate current or planned soft-tissue coverage about the ankle. The paper also cites a review article by Krause and Schmid [27] in which several major criteria for TAR were discussed. 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 and Schmid's [27] 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 [28]. The July 2013 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.

Patient-Related Criteria

Having reviewed all of these interested parties and what they list as contraindications and indications, it is widely agreed upon that TAR is indicated for treatment of painful end-stage osteoarthritis, inflammatory arthritis, or secondary arthritis in a select group of patients. These patients should be carefully chosen based on their overall health, the health of the limb, and the health of the ankle. Table 6.3 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 (Table 6.3). Age was primarily a consideration for skeletal maturity only. 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 [27].

Table 6.3 Considerations when selecting a patient for total ankle replacement

≥9 guides	5–8 guides	0–4 guides
Obesity (patient weight)	**AVN of the talus**	**Drug/alcohol addiction**
Activity level (manual labor, high activity level)	**Prior ankle arthrodesis**	**Mental illness**
Active infection (sepsis, leukocytosis)	**Sensitivity to component** (known allergy to component)	**Significant malalignment of the knee**
Insufficient bone stock (osteoporosis, osteopenia, osteonecrosis, prior surgery that reduced the bone quality, metabolic disorder/ medical treatment that reduced bone stock, steroid use)		**Local inflammation**
Insufficient blood supply		**Pregnancy**
Malalignment of joint (severe deformity of joint, hindfoot/forefoot malalignment precluding a plantigrade foot, absence of medial/lateral malleoli)		**Likelihood of falls**
Charcot neuropathy (neuropathy that might lead to Charcot joint, neurobiologic disease)		**Tumors in the surrounding bone**
Poor soft-tissue quality at surgical site (insufficient ligament support that cannot be repaired with soft-tissue stabilization, disease affecting quality of soft tissue)		**Unexplained high erythrocyte sedimentation rate**
Neuromuscular disease (nonfunctioning lower limb musculatures, weakness at the ankle joint)		**HIV/hepatitis infection**

Patient Age

The data regarding age as a contraindication to TAR is 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 [29, 30]. Several large medium- and long-term studies over the last 15 years have examined TAR in younger patients. A 1999 study by Kofoed et al. [29] involving 100 ankles specifically compared TAR in patients under and over 50 years old. 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 study by Rodriques-Pinto et al. [30] involving 103 TARs from a prospective multicenter study in Portugal and Spain using the Salto Mobile Ankle prosthesis (Tornier, Saint Ismier, France) with a mean 3.5-year follow-up. In this study, younger patients were defined as those less than 50 years old. The authors claim that younger patients actually displayed better clinical and functional scores while having comparable complication and survivorship rates as older patients.

There are studies that show the contrary and suggest a more advanced patient age is preferred. A 2004 study by Spirit et al. [31] 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 second-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. This trend continued with later generations of TARs. An analysis of 531 TARs in the Swedish Ankle Arthroplasty Register by Henricson et al. [32] was published in 2007 on the survival rate of third-generation TARs implanted between 1993 and 2005. This study was weighted toward the STAR Ankle 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.

Patient Body Weight

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) >30 kg/m^2, is often cited as a contraindication to TAR (Table 6.1). Some studies even exclude the obese from being considered for TAR, and large-scale studies of obese recipients are rare [33]. A 2007 study of 35 uncemented, unconstrained TARs with a mean follow-up of 5 years and a mean 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. [34], specifically looked at TAR using the Hintegra Ankle Prosthesis (Newdeal SA, Lyon, France) in obese patients. There were 123 TARs 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 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. 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 [34].

Activity Demands

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 [35]. This tends to indicate that 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.

A 2006 study by Valderrabano et al. [36] of 152 TARs showed an increase in sports participation of 23 % from pre- to post-TAR. The mean 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 that high-impact activities should be avoided but said that activities such as stationary biking, ballroom dancing, bowling, golfing, swimming, and walking should be allowed. A study with a slightly longer mean follow-up of 4.5 years found similar results. Bonnin et al. [37] examined 145 Salto Mobile 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 old, while the average BMI was 25.6 kg/m^2. Only eight (4.4 %) of the prostheses had to be revised, but none of those were in patients considered active [37]. 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 the patient will be able to return to intense, heavy impact 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 patients limit their activities. Certainly long-term and focused studies need to be performed looking into revision rates and specific, well-defined levels of activity.

Local Factors: Criteria to Consider

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 (Table 6.1). 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, as well as catastrophic or insidious prosthetic failure [38, 39].

Prosthetic Fixation

Almost all of the available TARs are FDA cleared only for use with polymethyl methacrylate (PMMA) cementation to assist in the implant-bone interface support. 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 [39]. There is also evidence to support the use of hydroxyapatite-coated prosthetic in an uncemented TAR in patients with osteoporosis. Zerahn et al. [40] found an increase in bone mineral density over the first year in the area around the implant-bone interface in the distal tibia that they interpreted to mean that the fixation of the TAR was good. 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. [41], 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.

Talar AVN

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 long-standing practice has been for physicians not to recommend TAR for patients with AVN of the talus [42, 43].

When deciding whether to pursue TAR, it is helpful to separate the amount of necrosis into two categories: partial or complete. If the talus has AVN, 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 [43]. 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 were of concern, the risk of damaging it by TAR and inducing AVN would certainly be a contradiction to the procedure. A more detailed examination of the microvascular supply of the talus with TAR in mind has recently been explored. This has led to concerns about specific prostheses disrupting specific vasculature within or near the talus itself [44, 45]. 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 and even below-knee amputation are more viable options. A cited tipping point has been the following: greater than 50 % loss of talar bone means that arthrodesis with bulk allograft is the appropriate salvage procedure [46]. 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. [46] reported good results reinforcing the remaining talar body with three large-diameter metallic rods/screws through the calcaneus into the talar region, then putting a talar prosthetic on top of them, and applying a mantle of PMMA cement to bind it all together. Another technique involved the use of custom-designed 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. [47] reported on 33 of these custom implants and reported that

they were a reasonable alternative to traditional arthrodesis procedures. While loss of talar bony structure is not an ideal setting for TAR, there are proposed surgical techniques that have reported success [46, 47].

Soft-Tissue Envelope and Vascular Supply

As stated above, bone quality is only half the consideration when looking at the local condition of the ankle. The soft-tissue envelope and vascular supply must be in good order as well, or the patient risks delayed healing, deep periprosthetic infection, 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. [48]. The overall rate of wound complications was higher in this study (28 %) than typically reported, but the authors believed 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. Tobacco 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, nonsteroidal anti-inflammatory use, oral corticosteroid use, and anti-tumor necrosis factor agents. Of note, three of the four 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 [49, 50].

A 2010 study by Raikin et al. [51] 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. A later study by van Heiningen et al. [52] published in 2013 seems to dispute the findings of the Raikin et al. [51] study. In it, van Heiningen et al. [52] 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) that was lower than the Raikin et al. [51] study. 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.

Ankle Malalignment

Even with good bone quality and vascular 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 or distal deformity, and these must be corrected first [53]. When focusing on the ankle joint itself, the goal is to return the joint to a plantigrade state, which may pose difficulties. A study by Henricson and Ågren [54] 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 [54]. 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 [54].

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. [55] 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 ankle joints with greater than 15° of deformity. This is not a universally held opinion however. In a 2009 study by Hobson et al. [56] of 123 TARs 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 [56]. In a 2013 study by Sung et al. [57] 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 believed that careful attention to adjunct procedures such as lateral ligament repair and transfer of peroneus longus to brevis performed during the TAR to ensure the entire foot and ankle were in proper alignment was key to their success [57]. In 2013, Trajkovski et al. [58] 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 [58].

An important point mentioned in a 2013 study by Queen et al. [59] was that much of the data regarding TAR is with mobile-bearing prostheses developed prior to 2004 and that a new generation of fixed-bearing TARs is coming into greater use. Therefore the data using the mobile-bearing devices should be taken in context. The study by Queen et al. [59] 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 [59].

On occasion, the deformity at the ankle may be so great that a staged approach is needed to first correct the local osseous deformity 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. [60], three 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. 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.

Contraindications

Infection

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 straightforward. Data is limited on TAR performed in a formerly septic ankle [61]. However, using a protocol-driven, standardized approach to the treatment of septic ankles can eliminate the recurrence of joint infection [62]. 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.

Peripheral Neuropathy

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 6.1). While this seems reasonable, it is not to imply that anyone with diabetes mellitus is barred from receiving a TAR. In a 2014 study of trends in treatment in TAR, Raikin et al. [63] 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 [63]. 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 [51]. These findings are consistent with an earlier study of 65 TARs of which four patients had diabetes mellitus, two 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 [64]. Still, there are some surgeons willing to attempt TAR even in patients with a Charcot ankle. A 2008 case report by Lee et al. [65] demonstrates a successful implantation of a TAR in a woman during the coalescence stage of Charcot ankle. 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.

Immunocompromising Viral Diseases

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. [66] published a case series on ten 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 a mean 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) [66]. This issue was addressed in a later study of hemophiliacs done by Strauss et al. [67] in 2014. They reported on 11 TARs with a 3-year average follow-up done on similarly affected ankles but with five of the patients being HIV seropositive and nine 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 % (two 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 [67].

Neuromuscular Deformities

Another generally accepted contraindication and what once was almost universally accepted to be in the purview of ankle arthrodesis was 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. [68] 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 a TAR 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. A second case report was by Moran et al. [69] reporting a polio patient with a deformed ankle joint and neuromuscular deficit. They reported good success at 2 years. 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.

Ankle Arthrodesis Takedown

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 ankle 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. A 2004 study by Greisberg et al. [70] 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 Replacement System. The authors were hopeful that newer, wider talar implants and selecting patients with preserved anatomy would improve the outcomes. A more optimistic study on the use of TAR for revision came from Barg and Hintermann [71] 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 six 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.

Patient Compliance

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 [27]. 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 orthopedic surgeries [72]. Physicians must do their due diligence to ensure the patient will be able to comply with the demanding postoperative course.

Conclusions

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, post-traumatic osteoarthritis, or inflammatory arthritides being the vast majority of presenting conditions. What constitutes a contraindication is 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. The physician should no longer just look at the condition of the ankle joint but also the patient as a whole before determining whether TAR is appropriate.

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Part II

Primary Total Ankle Replacement

Primary INBONE Total Ankle Systems

7

Ryan T. Scott, Christopher F. Hyer, and Gregory C. Berlet

Introduction

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. 7.1). 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 phalanges, and stable immediate fixation. These changes have lead to the relative success reflected in the contemporary literature [5–7].

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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 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. 7.2) [11, 12].

Alignment

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 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.

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_7

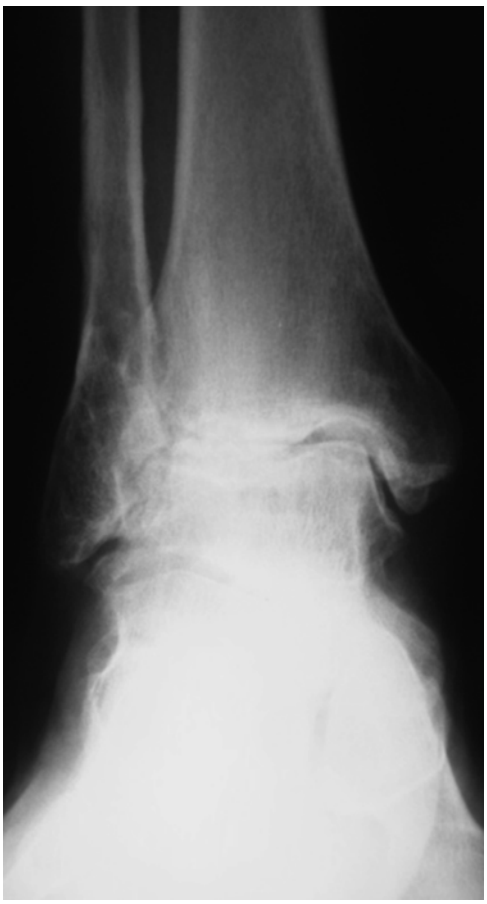

Fig. 7.1 Degenerative change to the ankle joint with narrowing of the joint space, subchondral sclerosis, and osteophyte formation

Cut Guides

The INBONE II Total Ankle System comes in sizes 2–6 that have proportional increases in width and length. The cut guide size is based off of preoperative planning and confirmed with 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.

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.

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

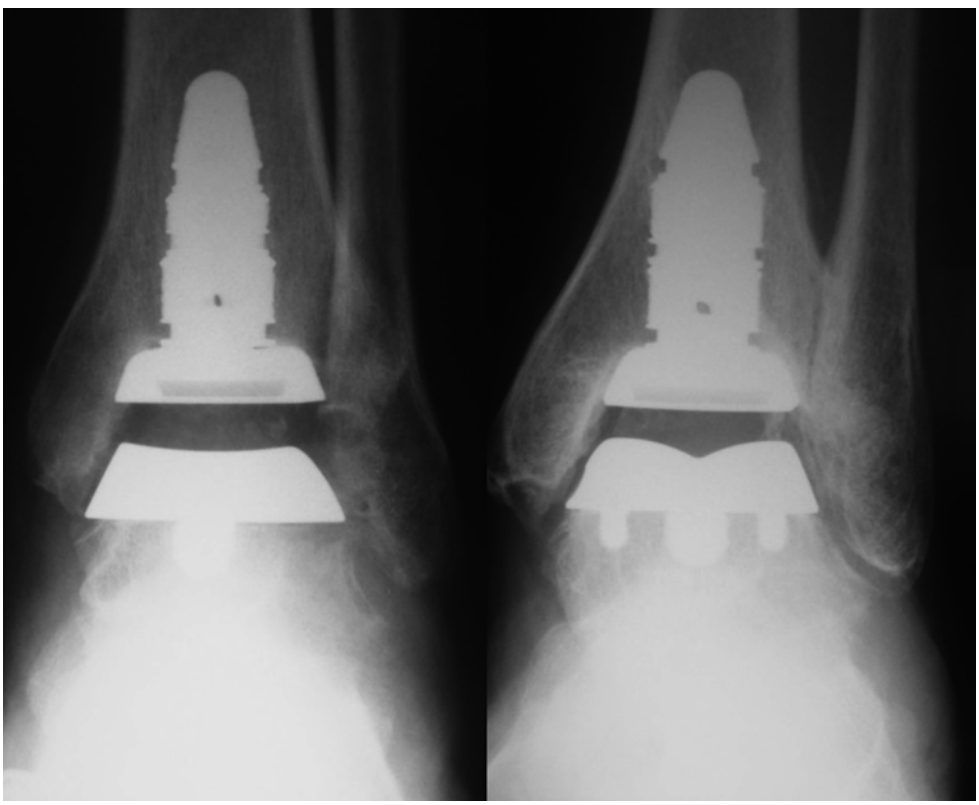

Fig. 7.2 Anterior–posterior weight-bearing radiographs comparing the talar components for the INBONE Total Ankle System (*left*) and the INBONE II Total Ankle System (*right*). The sulcus shape and dual anterior pegs were added to INBONE II Total Ankle System talar component for increased stability

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 2 to 6 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 independent of the polymethylmethacrylate cement required by the US Food and Drug Administration.

Talar Component

The INBONE 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 2–6 with anterior–posterior diameter 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 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 has been established using the INBONE Total Ankle System jig (Figs. 7.3 and 7.4) and the bone cuts are performed (Fig. 7.5), the insertion of the tibial stem is performed (Fig. 7.6). As a modular system, first attach the apex to a mid-stem 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.

A trial talus and polyethylene insert is introduced (Fig. 7.7). 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 (Fig. 7.8).

Outcomes

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

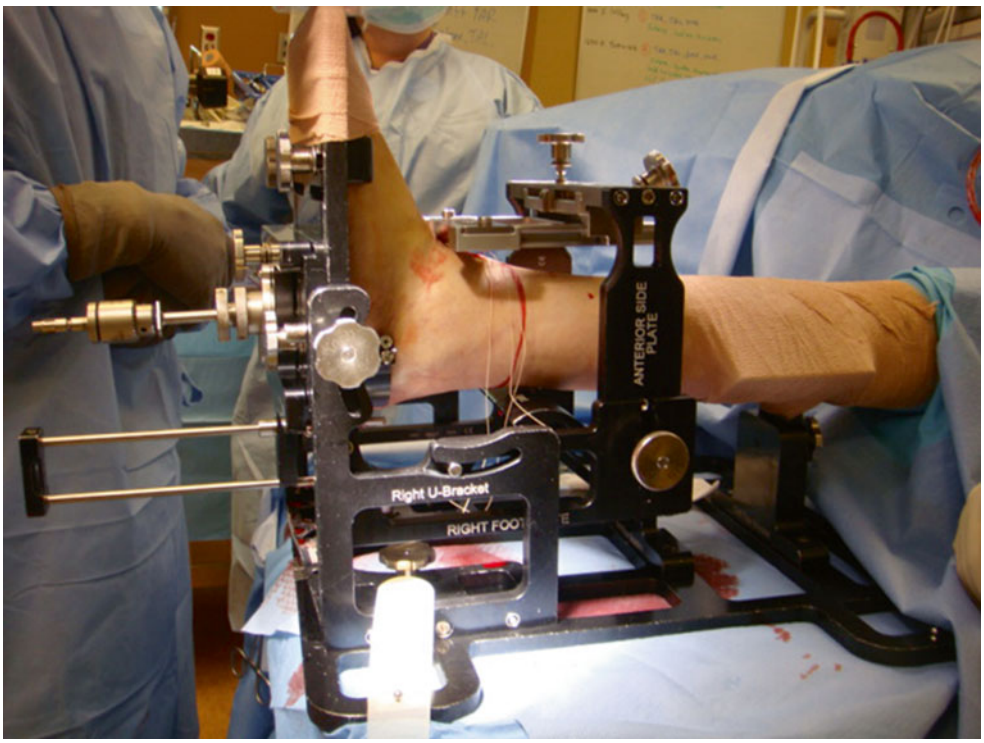

Fig. 7.3 Intraoperative photograph demonstrating the use of the INBONE Total Ankle System jig to gain anatomic alignment in both the sagittal and frontal planes

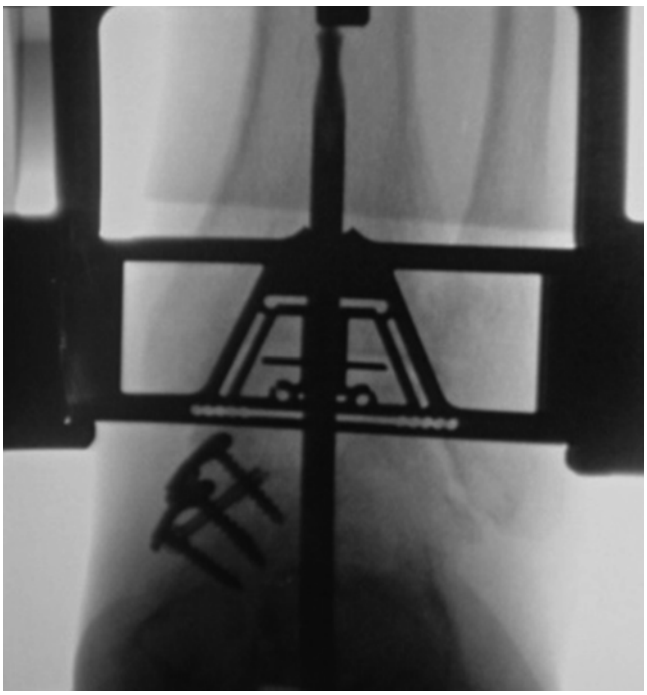

Fig. 7.4 Intraoperative anterior–posterior C-arm image intensification view demonstrating anatomic alignment of the tibia and talus. Note the sizing guide allowing for visualization of the osteotomies as well as the ankle joint line

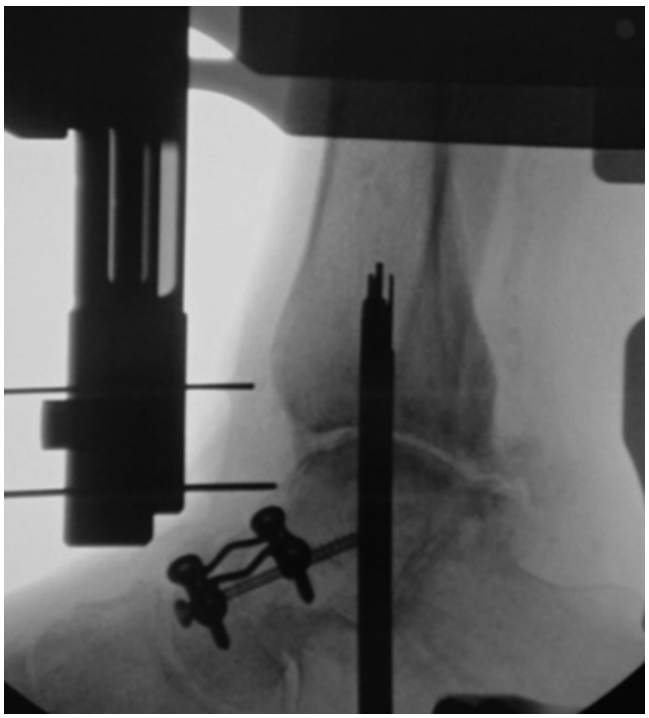

Fig. 7.5 Intraoperative lateral C-arm image intensification view demonstrating the level of osseous resection

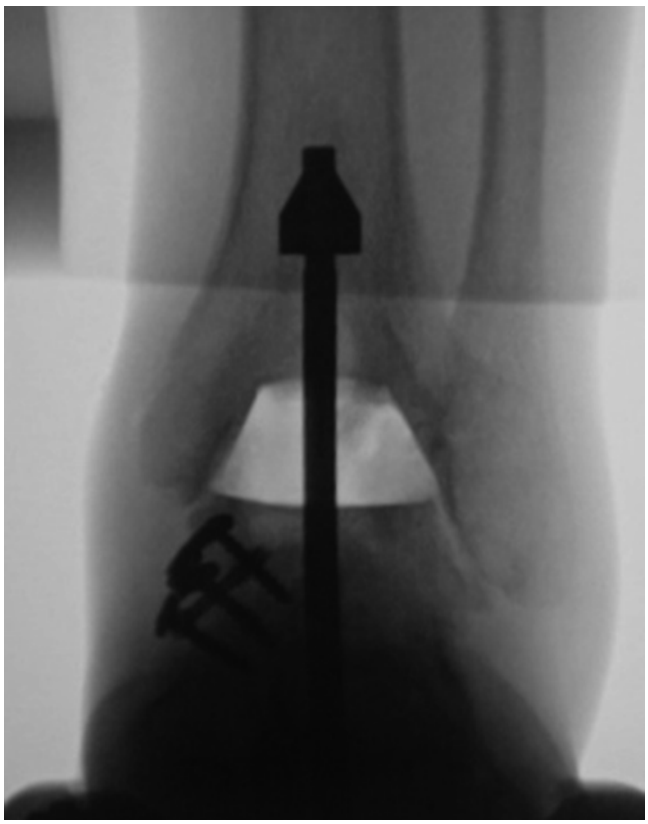

Fig. 7.6 Intraoperative anterior–posterior C-arm image intensification view demonstrating reaming of the tibia while verifying appropriate alignment and depth

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.

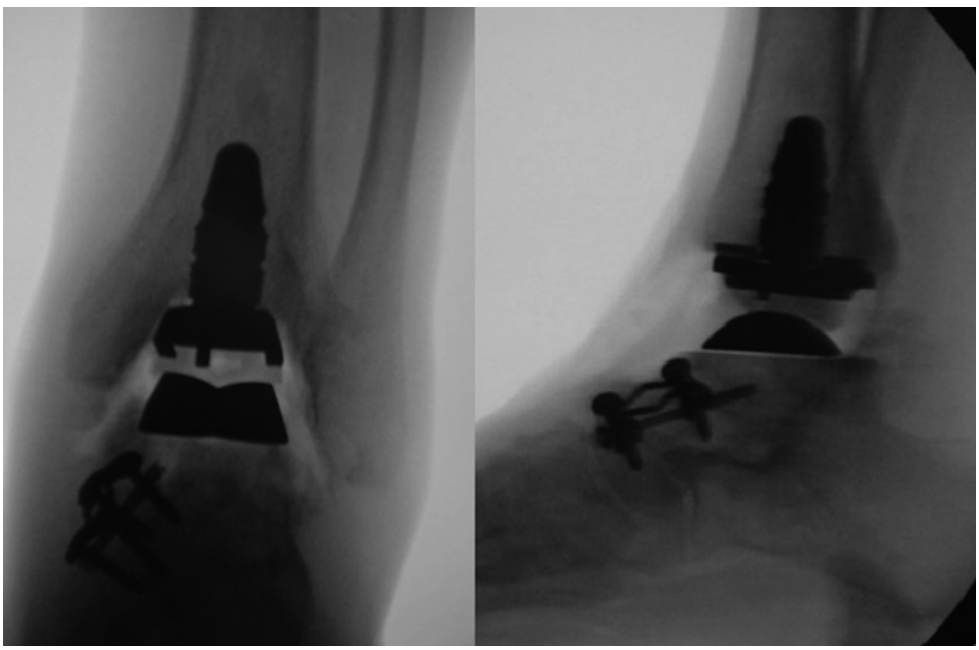

Fig. 7.7 Intraoperative anterior–posterior (*left*) and lateral (*right*) C-arm image intensification views with the tibial component in place along with trial talus and polyethylene insert components

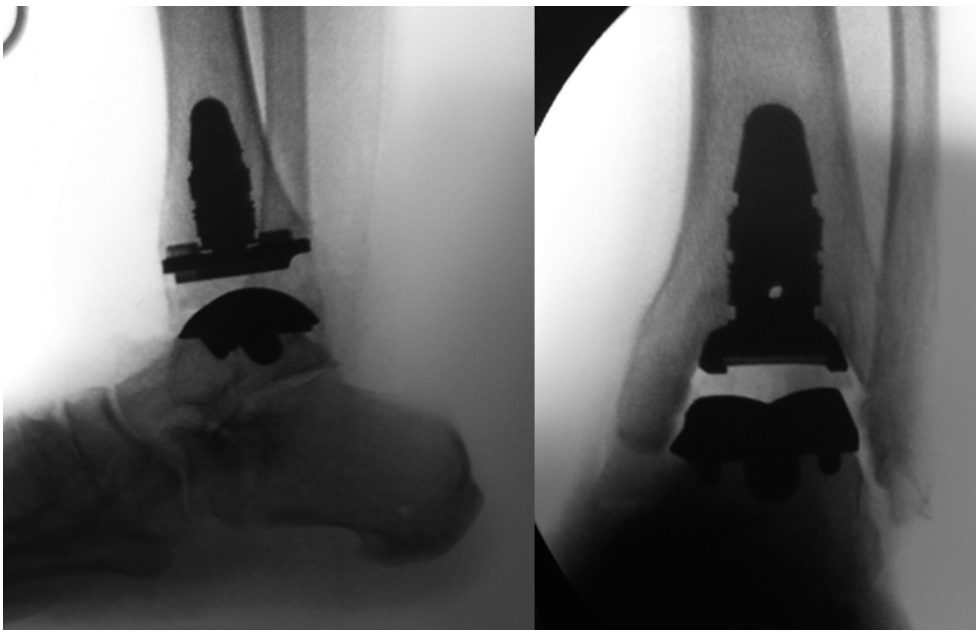

Fig. 7.8 Final intraoperative lateral (*left*) and anterior–posterior (*right*) C-arm image intensification views demonstrating appropriate prosthetic component position, talar coverage, and gutter decompression

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.

Pearls

- Adequate preoperative planning
  - Weight-bearing radiographs (including long leg calcaneal axial)
  - Computerized 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.
- Rebalance the medial and/or lateral ligaments, correct soft tissue equinus, and perform hindfoot osteotomies to correct deformity (if applicable).
- Insert the correct-sized, ultrahigh molecular weight polyethylene insert that allows full and fluid sagittal plane motion with minimal frontal plane motion.

Conclusion

The INBONE and 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.

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INFINITY® Total Ankle System

8

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 severely damaged ankle joints secondary to rheumatoid, post-traumatic, or degenerative arthritis, in addition to an indication 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 critical. 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® (Wright Medical Technology, Inc., Memphis, TN). 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. 8.1). Additionally, INFINITY® is compatible with PROPHECY® patient-specific CT scan-guided instrumentation (Wright Medical Technology, Inc., Memphis, TN) (Fig. 8.2). When PROPHECY® guidance is not utilized, the INFINITY® technique incorporates a new *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 similar to INBONE II®, 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.)

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_8

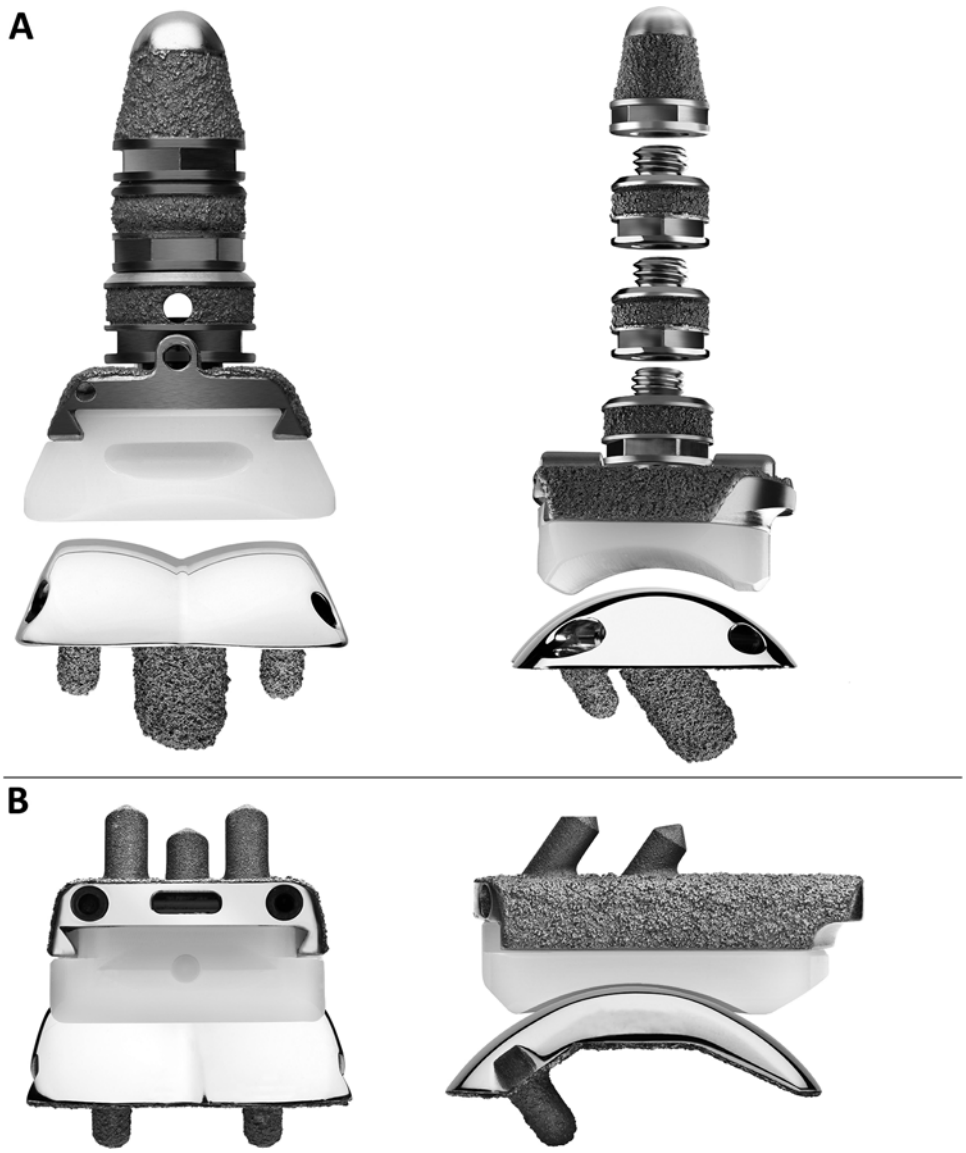

Fig. 8.1 Photographs of INBONE II® (**a**) and INFINITY® (**b**). Image provided courtesy of Wright Medical Technology, Inc.

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 posterior cortices, thereby maximizing cortical bone support.

The UHMWPE component is non-cross-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 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.

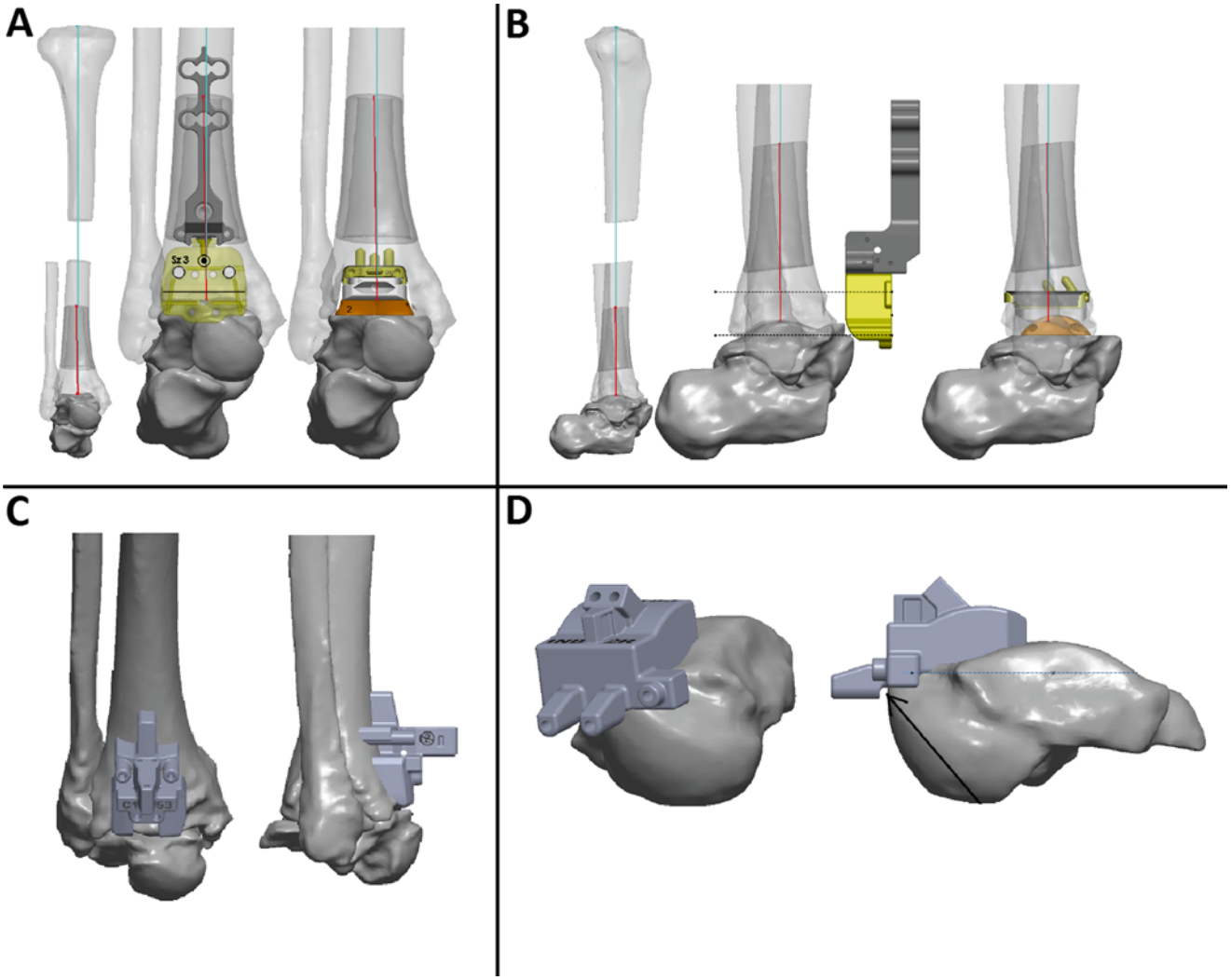

Fig. 8.2 Example of PROPHECY® with INFINITY® tibial tray and INBONE II® talar dome recommended secondary to patient-specific anatomy: AP sizing and alignment (**a**), lateral sizing and alignment (**b**), tibial alignment guide (**c**), talar alignment guide (**d**)

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. 8.3).

Surgical Technique

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 periosteum and capsule to ensure proper visualization and limit skin tension. 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.

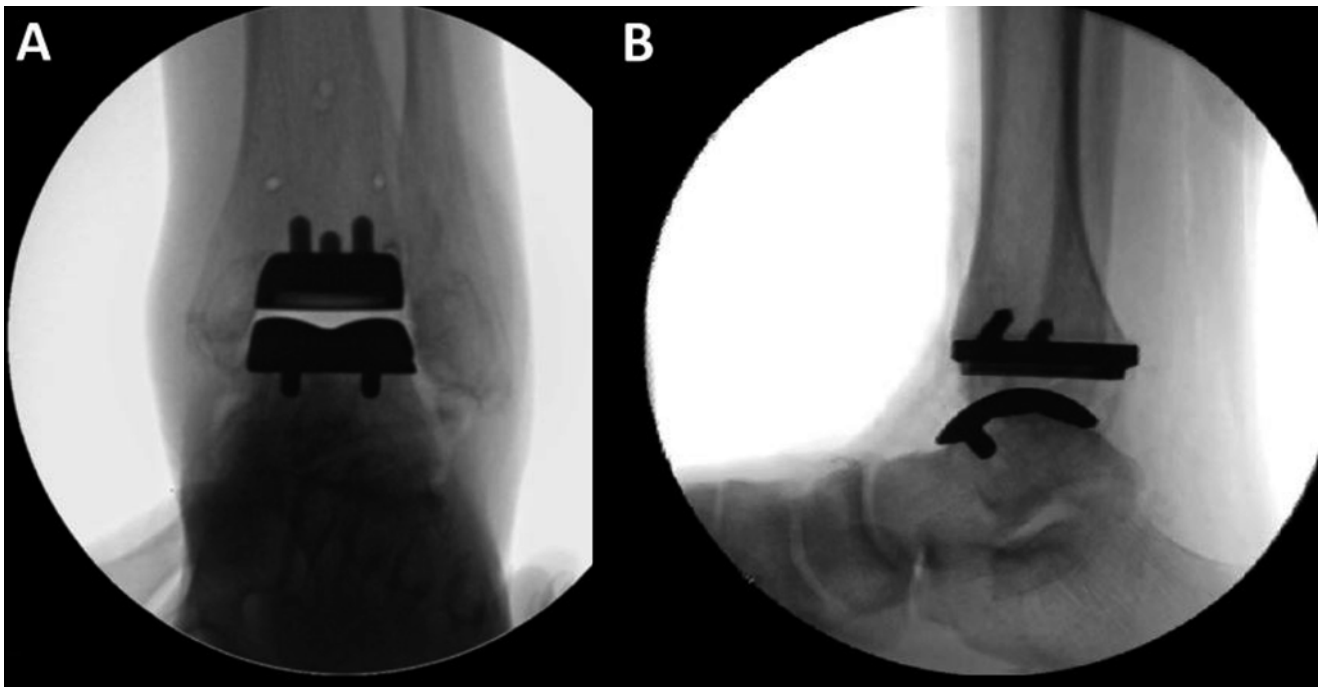

Fig. 8.3 Fluoroscopic images demonstrating INFINITY® bone stock visualization: AP (**a**) and lateral (**b**) view. Image provided courtesy of Wright Medical Technology, Inc.

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. 8.4). 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. 8.5). 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 tibial axes are essential to 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. 8.6). 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 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. 8.7). 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 a 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

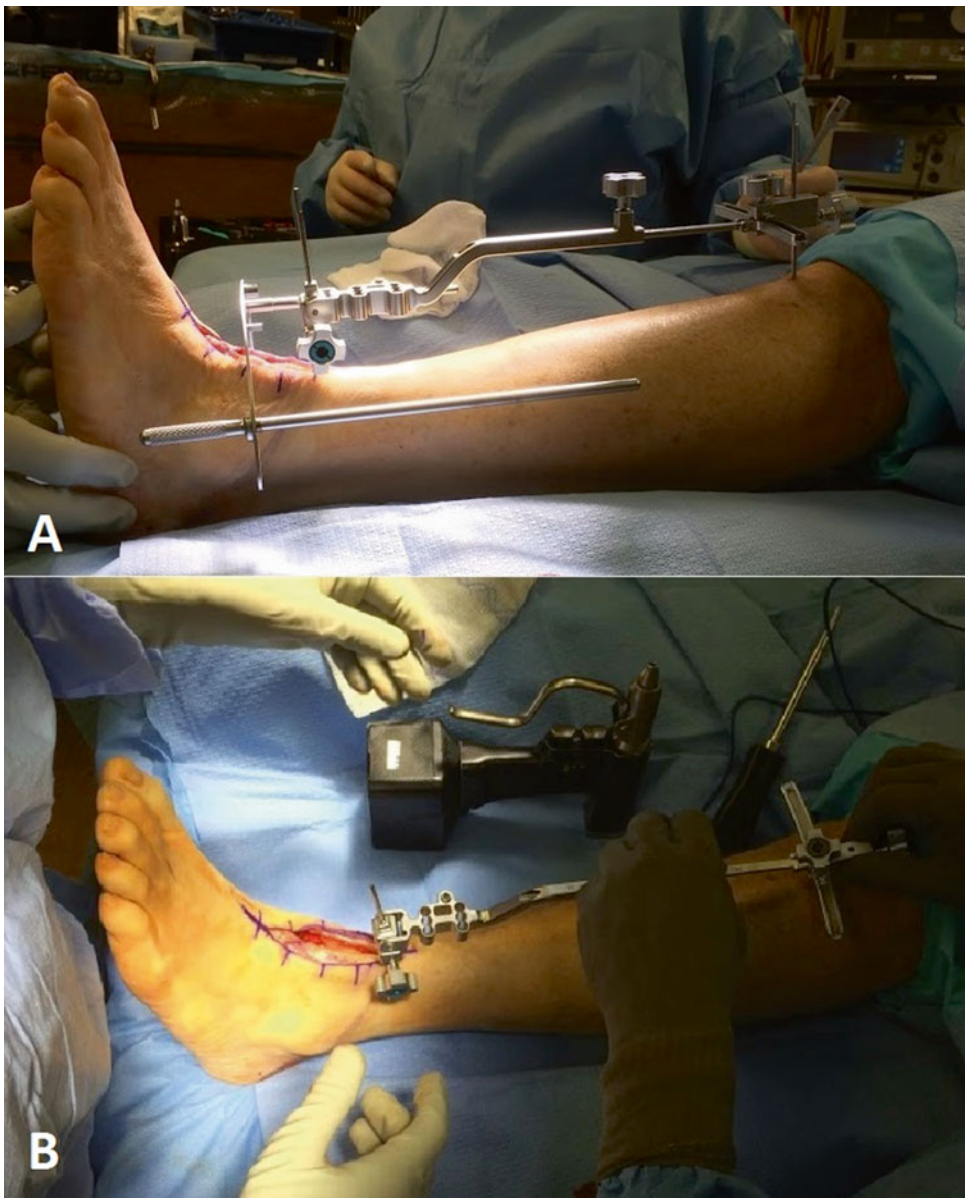

Fig. 8.4 Alignment guide placement: lateral view (**a**) and AP view (**b**)

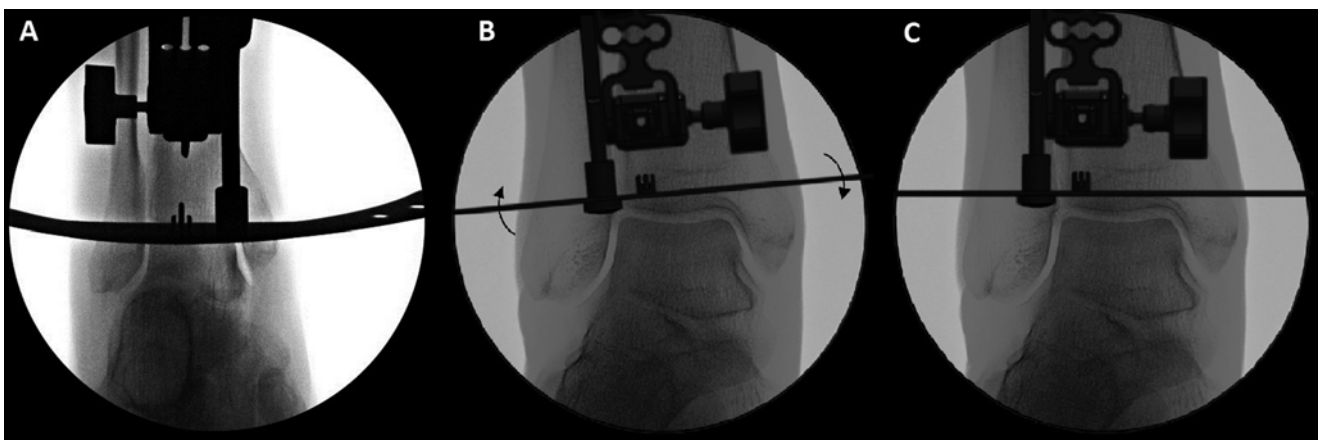

Fig. 8.5 Coronal alignment fluoroscopic image in AP view: incorrect alignment (**a**) corrected by tilt of C-arm to obtain alignment wing appearing as thin line, properly imaged alignment wing to evaluate for desired frontal plane positioning (**b**), corrected frontal plane alignment (**c**). Image provided courtesy of Wright Medical Technology, Inc.

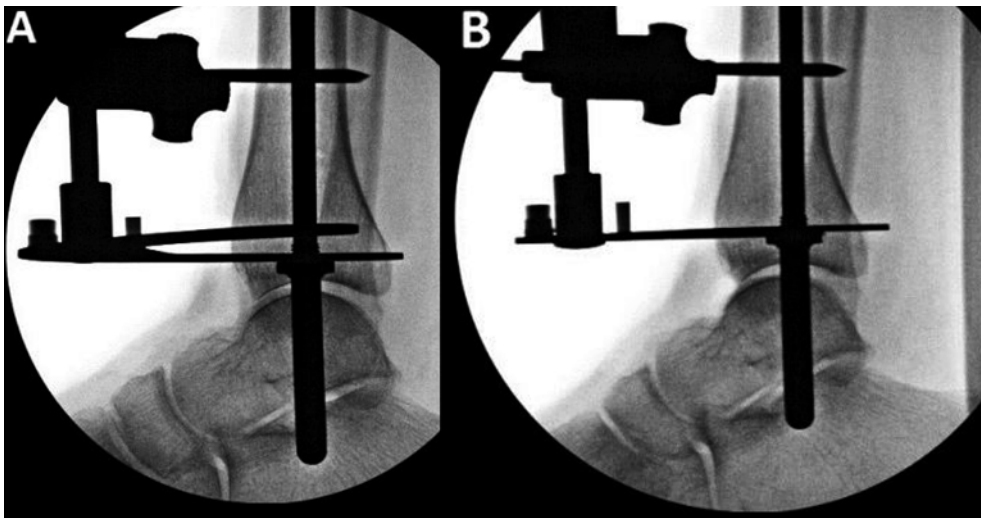

Fig. 8.6 Sagittal alignment fluoroscopic image in lateral view: incorrect alignment (**a**) corrected by tilt of C-arm to obtain alignment wing appearing as thin line, properly imaged alignment wing to evaluate for desired frontal plane positioning with desired corrected plane alignment (**b**). Image provided courtesy of Wright Medical Technology, Inc.

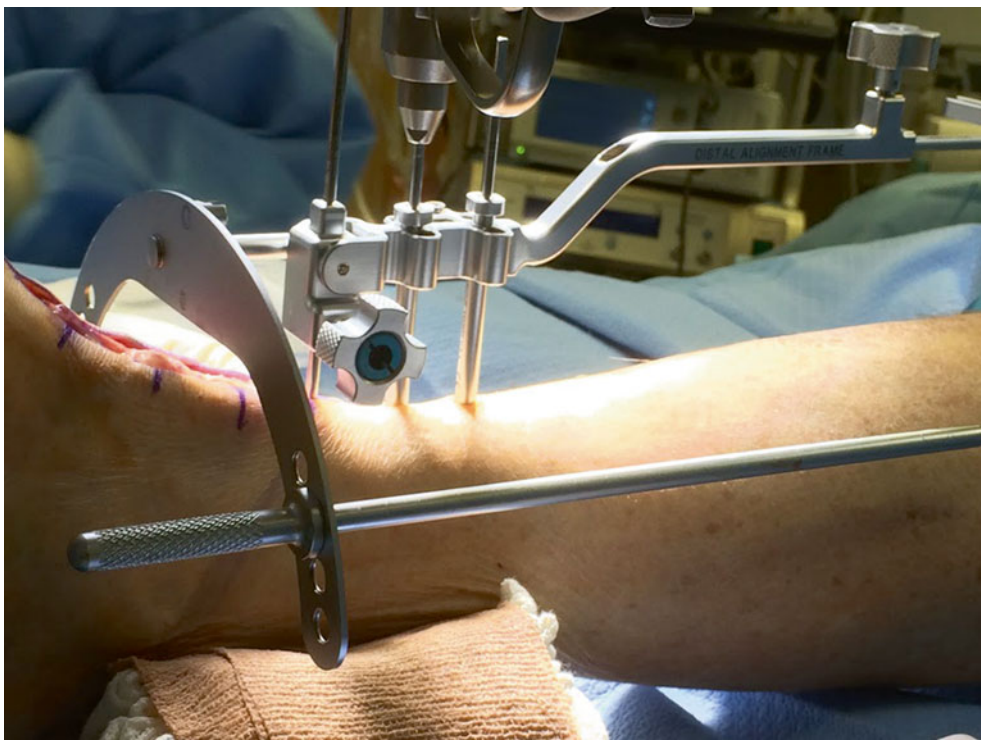

Fig. 8.7 Insertion of pins into the selected aligned pair of holes in the alignment frame

adjusted medial/lateral to obtain an optimal position centered on the ankle joint. It is important to note that during sizing 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 performed. Once proper position and size is determined on the AP view, sagittal sizing and resection height is 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. On 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.

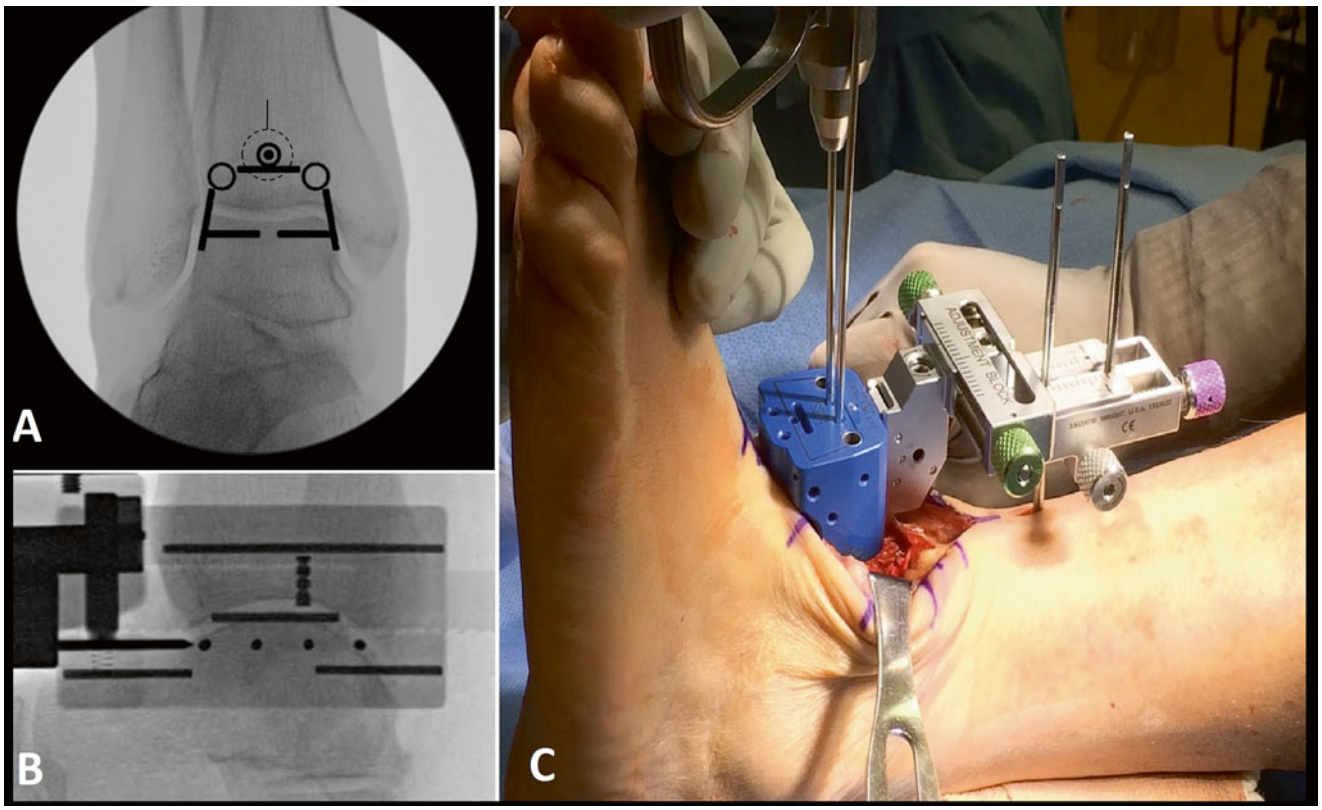

Fig. 8.8 Tibial component sizing: AP fluoroscopic image demonstrating proper sizing of the coronal sizing guide (**a**), lateral fluoroscopic image demonstrating proper position of sagittal sizing arm (**b**), clinical photograph of placement of coronal sizing guide (**c**). (**a**, **b**) Image provided courtesy of Wright Medical Technology, Inc.

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 is determined, the sagittal sizing guide is removed and an AP fluoroscopic image can be obtained to verify position (Fig. 8.8).

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. 8.9). (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 the 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.

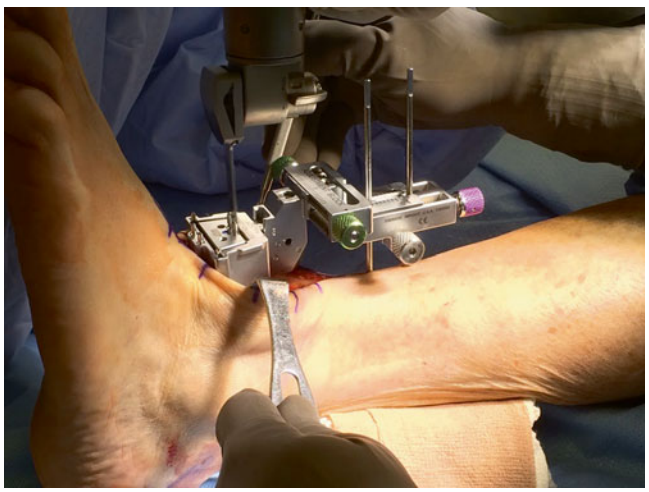

Fig. 8.9 Clinical photograph of resection guide placement [*note*: six placed Steinman pins including gutter pins] and bone resection with reciprocating saw

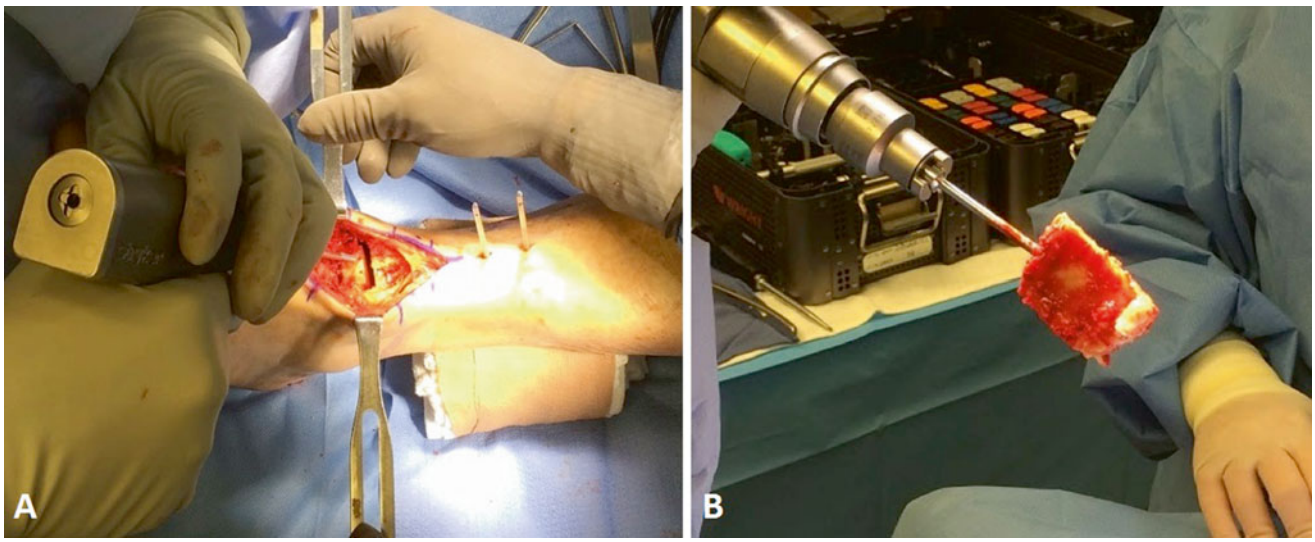

Fig. 8.10 Tibial bone removal using bone removal screw (**a**), demonstration of en bloc excision of tibial bone using bone removal screw (**b**)

Caution is used not to lever proximally on the anterior tibia during cut completion or bone resection as 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. 8.10). (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. 8.11).

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 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. 8.12). 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

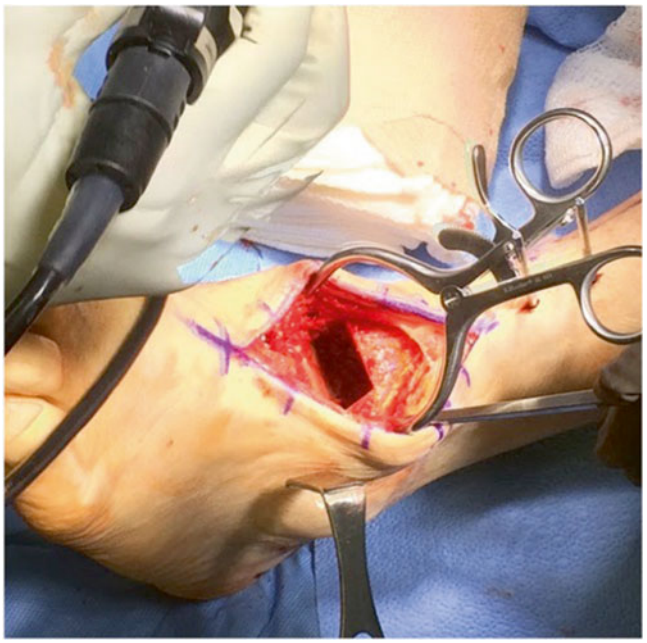

Fig. 8.11 Completed bone resection

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 need to be resected 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. 8.13). Various poly trial thicknesses can also be trialed at this point. (Technique tip: Slight axial compression with plantarflexion

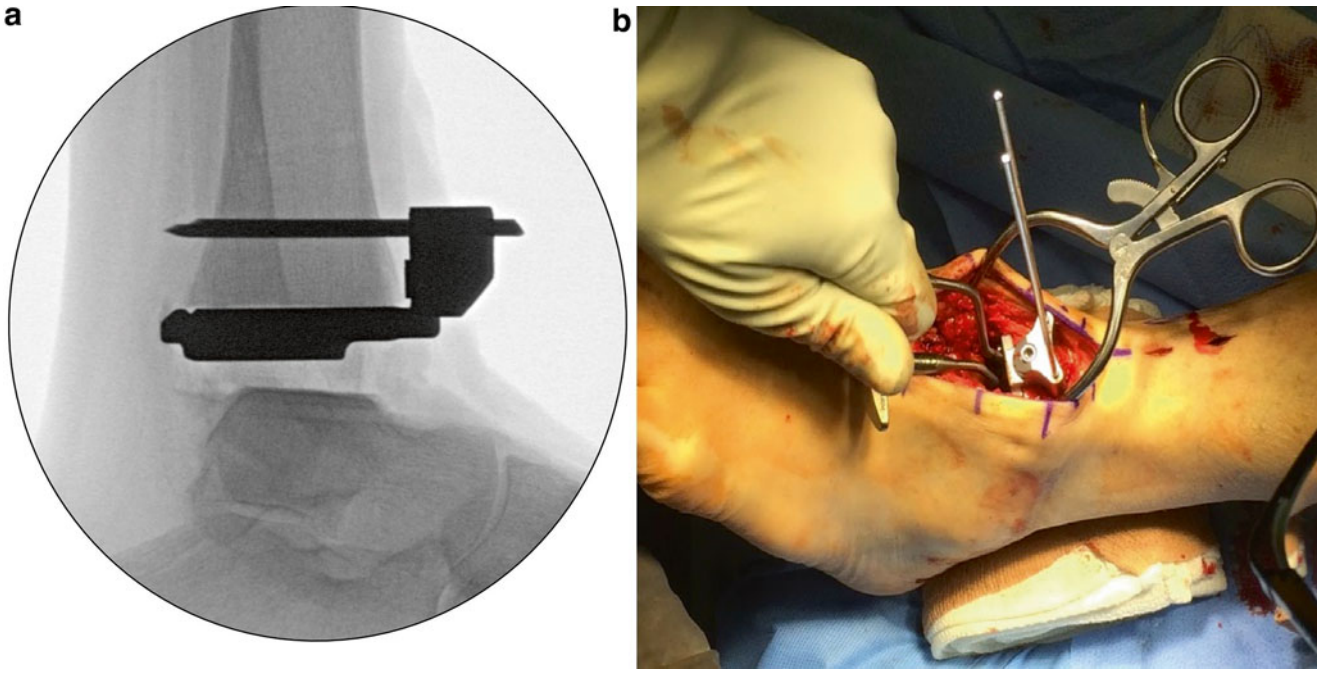

Fig. 8.12 Sagittal sizing and broaching for the tibial component: lateral fluoroscopic image demonstrating appropriately placed tibial trial component [*note*: posterior notch of tibial trial verifies "standard" length] (**a**), clinical photograph depicting broaching for the tibial component through the trial tibial component (**b**). (**a**) Image provided courtesy of Wright Medical Technology, Inc.

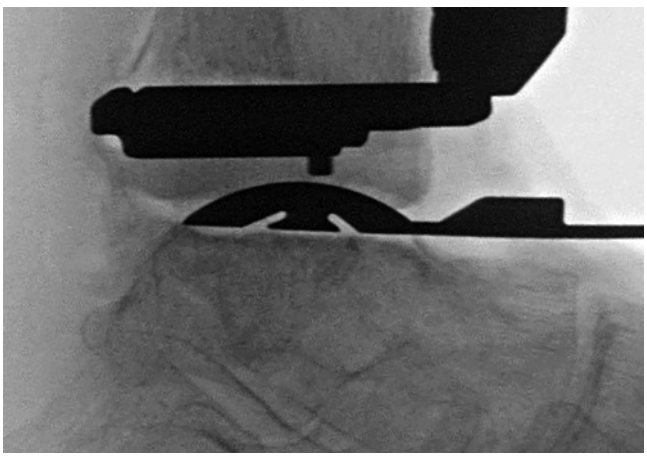

Fig. 8.13 Lateral fluoroscopic image of trial components. Image provided courtesy of Wright Medical Technology, Inc.

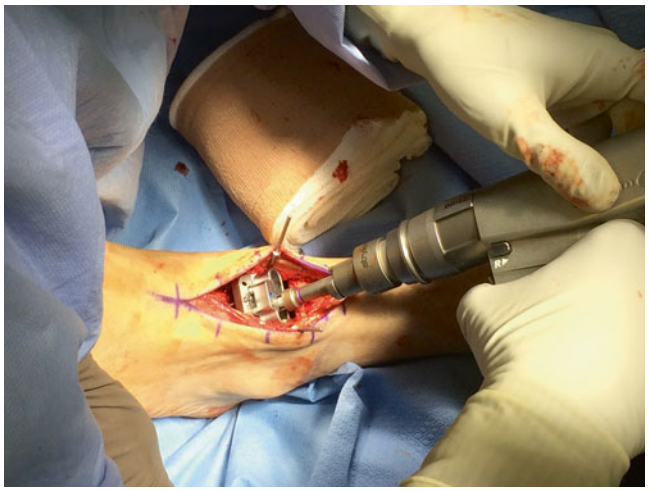

Fig. 8.14 Clinical photograph of anterior talar chamfer pilot guide

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 over-torquing the threaded temporary fixation screws either during insertion or removal; over-torquing 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. 8.14). 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 guide with the pegs up, followed by the finish guide. Remove the talar

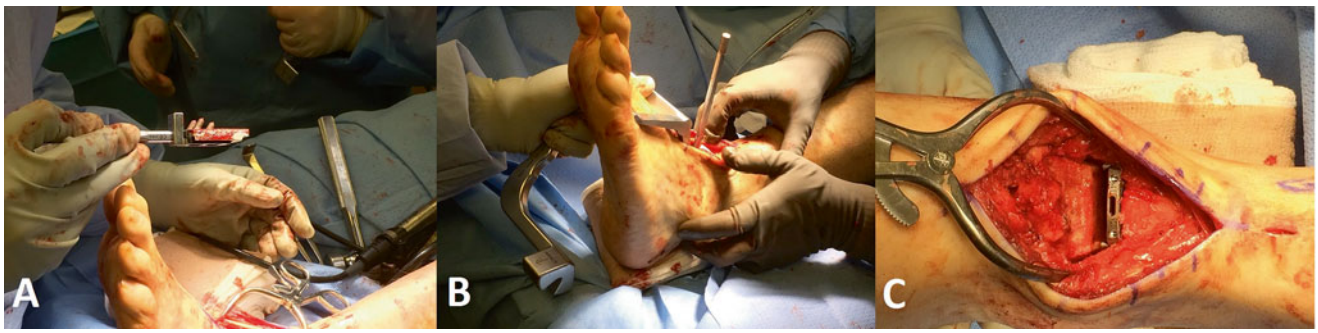

Fig. 8.15 Clinical photographs of tibial component insertion: tibial component prior to insertion with cement applied to the superior surface for initial stability and bone marrow aspirate applied for improved osseous ongrowth (**a**), offset tibial impactor employed for seating of tibial component (**b**), implanted and fully seated tibial component with maintained anterior cortical purchase (**c**)

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.

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 be 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. 8.15).

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. 8.16).

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. 8.17). 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. 8.18).

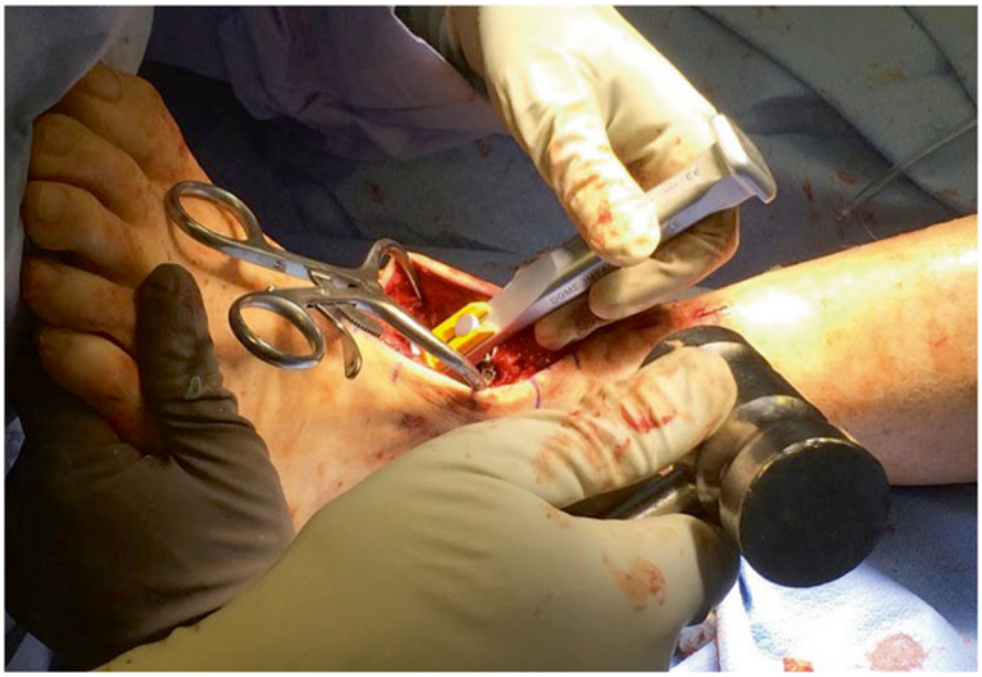

Fig. 8.16 Clinical photograph of talar component insertion

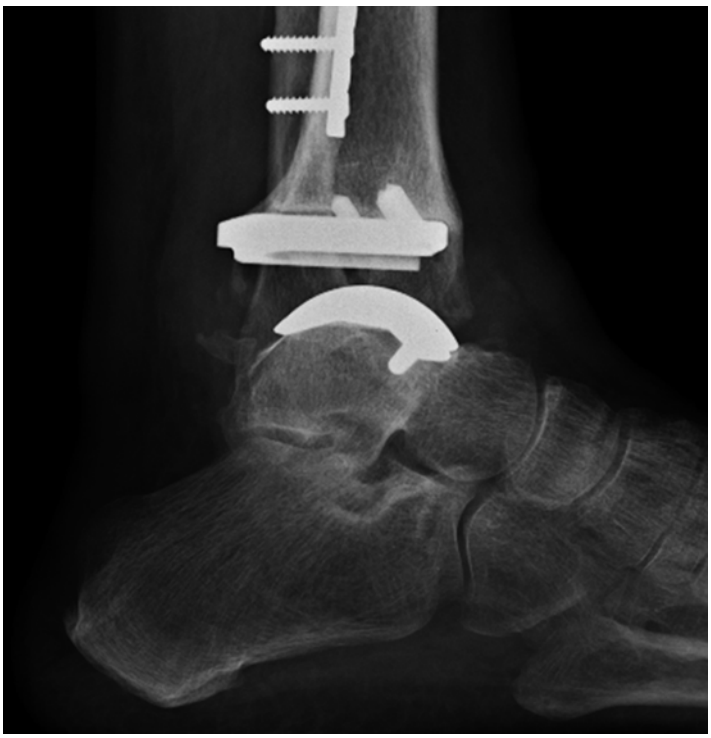

Fig. 8.17 Postoperative weightbearing radiograph demonstrating posteriorly translated tibial component

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.

Early Inventor 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

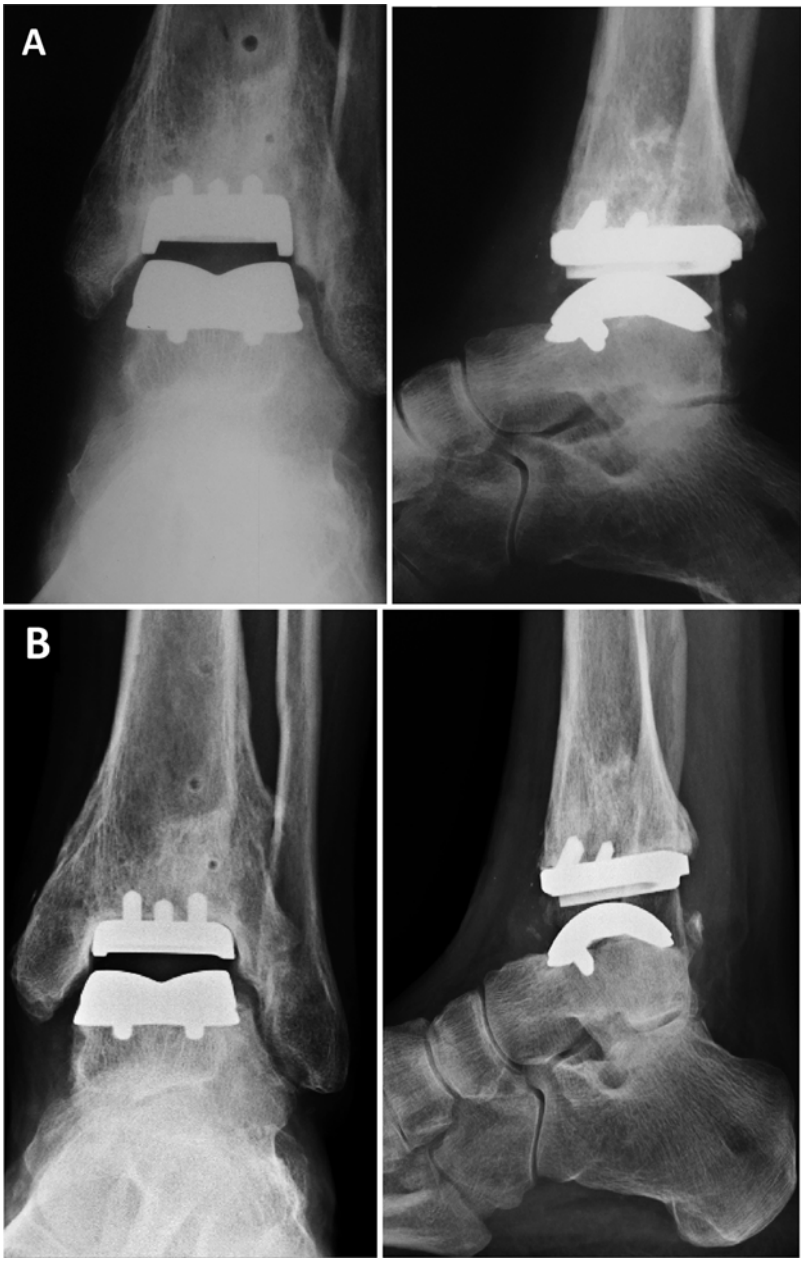

Fig. 8.18 AP and lateral initial postoperative weightbearing radiographs (**a**), most recent 1.5 year follow-up postoperative weightbearing radiographs (**b**)

patients and those with 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-bearing 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 full seating of the components can be confirmed.

The ability to utilize INFINITY® and INBONE II® components interchangeably is a major advance. It is not uncommon to have well-preserved bone quality in the talus but poor bone quality in the tibia, for example, in the setting of a previous tibial pilon fracture. If the distal tibial bone is felt insufficient to support a resurfacing implant design, then stemmed INBONE II® tibial component could be used to gain greater tibial stability and bypass the compromised bone while still using an INFINITY® talar component to preserve talar bone stock. The opposite scenario is also possible, in settings 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.

Thus far, patients have found the INFINITY® ankle replacement to provide them with excellent pain relief and improved function postoperatively. As the design has only been available for implantation for approximately 2 years, detailed follow-up reports are not yet available, though early experience and the lack of any revisions to date are very encouraging.

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

PROPHECY: Preoperative Navigation Alignment Guides

9

Safet Hatic II, Jeffrey E. McAlister, Christopher F. Hyer, and Gregory C. Berlet

Introduction

A renewed interest in total ankle replacement (TAR) for the treatment of end-stage ankle arthritis over the past few decades has contributed to considerable advancement in prosthesis design and surgical techniques. Patient-specific alignment guides and preoperative navigation technologies have evolved in an effort to enhance prosthesis durability and survivorship, increase the accuracy of component positioning and sizing, improve operating room efficiency, and in turn, improve patient outcomes. The role of patient-specific alignment guides and preoperative navigation technology in optimizing patient outcomes has been well documented in total knee arthroplasty. Early experience with the PROPHECY preoperative navigation system (Wright Medical Technologies, Inc., Arlington, TN) suggests a new standard for TAR with enhanced component placement reproducibility.

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This chapter aims to review the PROPHECY INBONE II and INFINITY preoperative navigation technology and its evolving role in TAR.

Preoperative Navigation in Orthopedic Surgery

Patient-specific instrumentation and preoperative navigation technologies have been utilized in total knee arthroplasty with the goal to optimize component positioning and in turn improve prosthesis durability and survivorship [1, 2]. 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 [2]. 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 [3]. Restoration of the mechanical axis through the central third of the knee approached 87 % with

© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_9

patient-specific instrumentation compared with 77 % using traditional instrumentation [3]. Heyse et al. [4] 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.

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 computerized tomography (CT) scan. Bone cut guides slide over the pins established with the PROPHECY technique. The key elements of this work flow are generating of an accurate CT scan with three-dimensional (3D) rendering patient anatomic model of the ankle joint, surgeon-mediated selection of the intended position of the components, and then a computer-aided design and manufacture of patient-specific guides that guide pin positioning and ultimately the bone cut guides [5].

Both the PROPHECY INBONE II and INFINITY preoperative navigation systems require a protocol-driven, simulated weightbearing CT scan incorporating specific scanning parameters. The foot, ankle, and ipsilateral knee are scanned at the same time, and it is helpful to provide the engineers with any additional weightbearing 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 ≤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 either the INBONE II or INFINITY TARs and instrumentation, determines the optimal component position, rotation, and sizing according to predetermined surgeon preferences (Fig. 9.1). Any adjustments to the sizing of the TAR components, positioning, or rotation can be facilitated along with company engineers preoperatively. Ultimately, the process yields patient-specific surface-matched operative guides for the tibia (Fig. 9.2) and talus (Fig. 9.3). The guides are provided with mock-ups 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 (Fig. 9.4). 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 under 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 or INFINITY operative cut block is slid onto the pins. The remaining operative technique for each of these TARs can be found in Chaps. 8 and 9.

Early Clinical Results with PROPHECY Preoperative Navigation System

Currently, the published scientific literature supports an 89 % overall prosthesis survival rate for intramedullary guided (non-CT), modular TAR systems with a mean clinical follow-up of 3.7 years [6]. 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 [7]. 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 [8–11]. 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.

The reproducibility and accuracy of patient-specific guides have been investigated in a cadaver model using the PROPHECY INBONE II technique [12]. The authors determined that the reproducibility of the final TAR component position, using patient-specific guides, was accurate within 2° of the intended target. These authors have established a benchmark for accuracy and reproducibility, which needs to be confirmed in clinical studies.

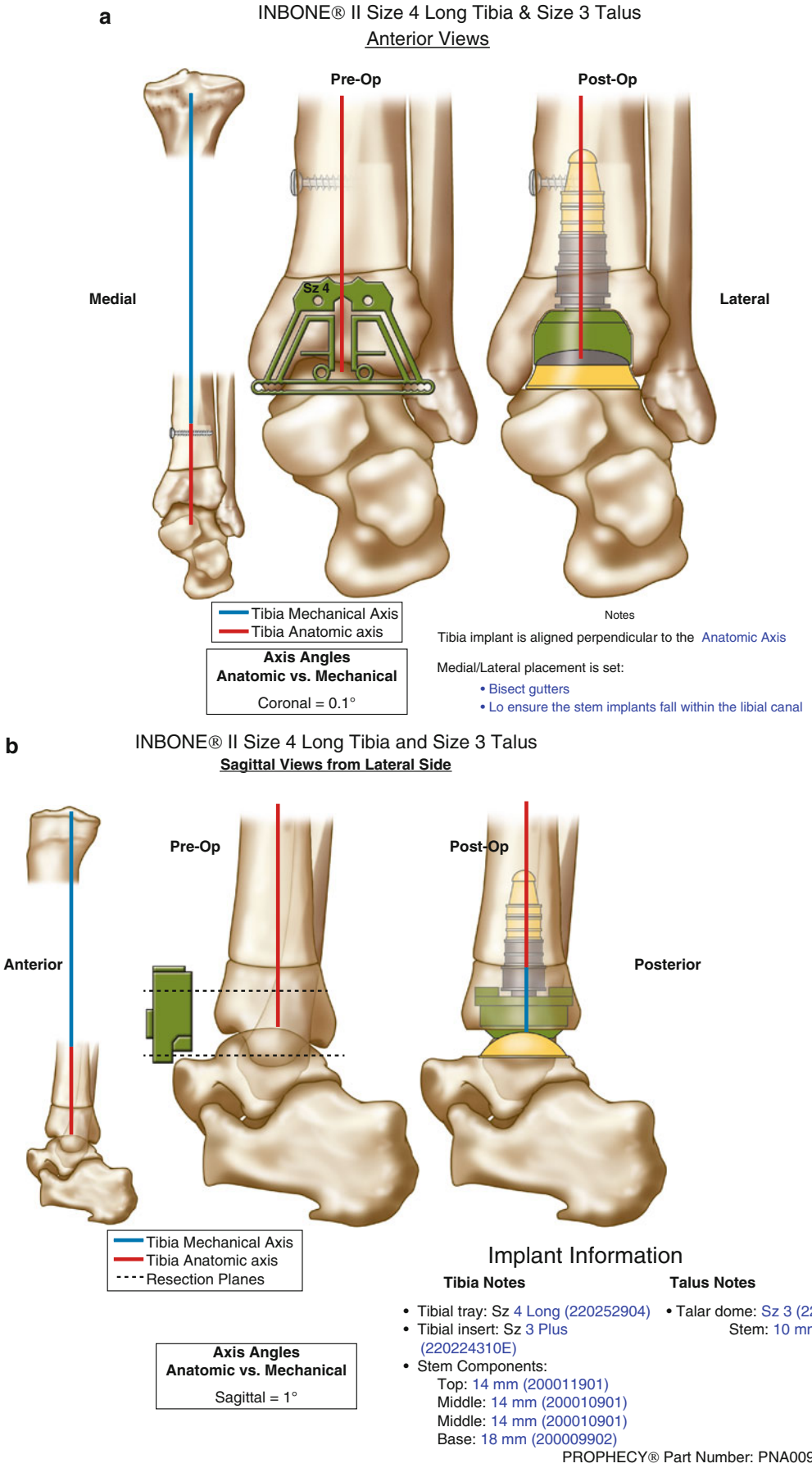

Fig. 9.1 A computed tomography scan demonstrating the assessment of the mechanical and anatomic axis in relation to tibial component alignment and resection level on anterior–posterior (**a**) and lateral (**b**) views

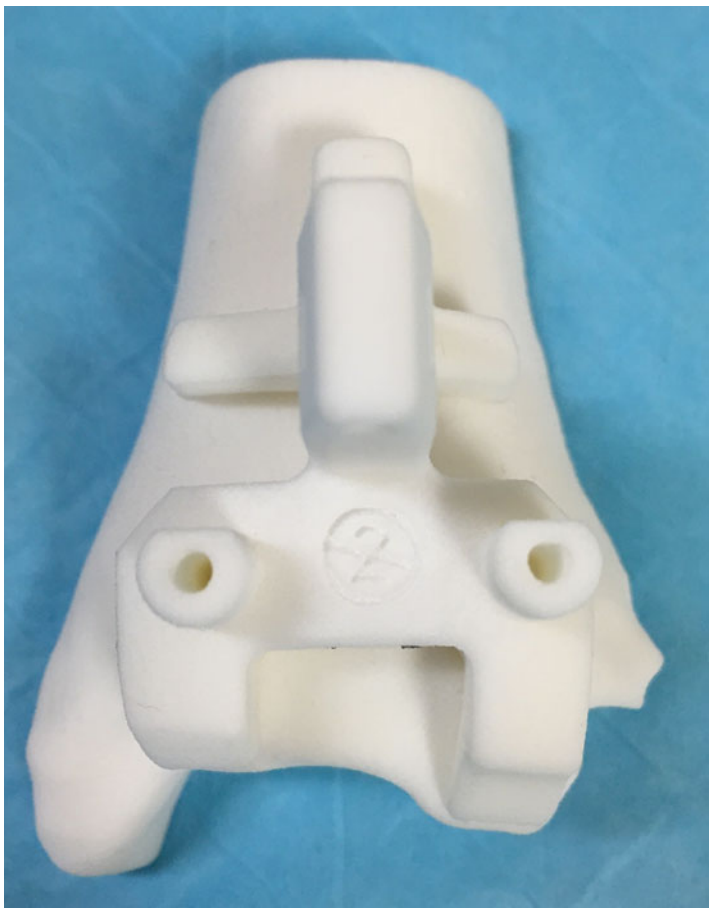

Fig. 9.2 Patient-specific tibial guide on a surface-matched distal tibia

Fig. 9.3 Patient-specific talar guide on a surface-matched talar dome

Tips and Tricks

- *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 bone detail but not soft tissue. 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 CT scan protocol may reveal a loose anterior osteophyte that may require 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.

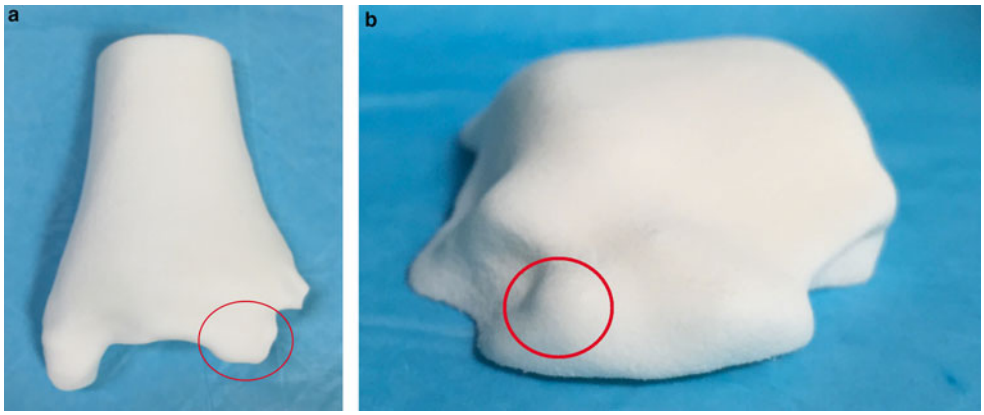

Fig. 9.4 The computed tomography scan protocol derives a surface-matched distal tibia and talus with attention directed toward a specific anatomic landmark which aids in intraoperative guidance (*red circles*). In this example, a large anterior–lateral osteophyte is used as the surface landmark for the distal tibia (**a**), and a smaller dorsal-medial osteophyte is used as the surface landmark for the talar dome (**b**)

- *Follow the Rules with Your Imaging*: It is imperative that the CT scan be 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. Weightbearing 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.

Conclusions

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

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Primary Salto Talaris Total Ankle Prosthesis

10

Thomas S. Roukis, Christopher Bibbo, Matthew D. Sorensen, and Bradly W. Bussewitz

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. The device was first implanted in January 1997 and was limited to these surgeon inventors between 1997 and 1999 [1, 2]. The first clinical results were published in 2000 [2–4]. 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 ultrahigh molecular weight polyethylene (UHMWPE) mobile-bearing insert and tibial baseplate averaged 1.5 mm during gait, and the insert remained in internal rotation throughout the arc of motion [5]. 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 three patients [6, 7]. 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 [8], the fixed-bearing Salto Talaris Total Ankle Prostheses (Tornier, Inc., Bloomington, MN/Wright Medical Technology, Inc., Memphis, TN) were developed.

The Salto Talaris Total Ankle Prosthesis was initially available in three sizes (i.e., 1, 2, 3) until 2009 when a fourth size (i.e., 0) was added. The Salto Talaris Total Ankle Prosthesis tibial component base is 4 mm thick, and the UHMWPE inserts are available in actual thickness of 5, 6, 7, and 8 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. 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. The undersurface of the talar component matches three sharply angulated bone cuts about the posterior, anterior, and lateral talar body affording primary stability in the

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_10

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. For the fixed-bearing Salto Talaris Total Ankle Prosthesis, 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 guide, 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 [9]. In 2014 the surgical instrumentation underwent an upgrade intended to ensure proper positioning of the tibial component in relation to the talar component for enhanced accuracy of component implantation.

The anatomic design of the talar component is intended to reproduce normal ankle kinematics without overstressing the deltoid ligament complex. The UHMWPE insert articular surface is size matched to the talar component and has dedicated left and right sides. The talar component has 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 and 25° plantarflexion.

The results of a recent systematic review make clear the low incidence of revision 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 Prostheses which was 2.4 % at a weighted mean follow-up of 34.9 months [10]. Seventy-one percent of the failed Salto Mobile Version prostheses underwent revision with ankle arthrodesis, 26 % implant component replacement, and 3 % below-knee amputation. 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 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 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 Prostheses was lower than those reported through systematic review for the uncemented agility total ankle replacement system (DePuy Orthopaedics, Inc, Warsaw, IN) [11, 12] and Scandinavian Total Ankle Replacement system (STAR, Stryker Orthopaedics, Inc, Mahwah, NJ) [13] without obvious selection (inventor) or publication (conflict of interest) bias.

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. 10.1a). 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. 10.1b). This is followed 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. 10.1c). This is an important landmark since it determines the reference position for placement of the tibial alignment guide. A 110-mm self-drilling pin is inserted with a pin driver just inferior to the anterior tibial tubercle through a small skin incision (Fig. 10.2a). 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. 10.2b). In the frontal plane, the axis of the tibial alignment guide should be parallel to the mechanical axis of

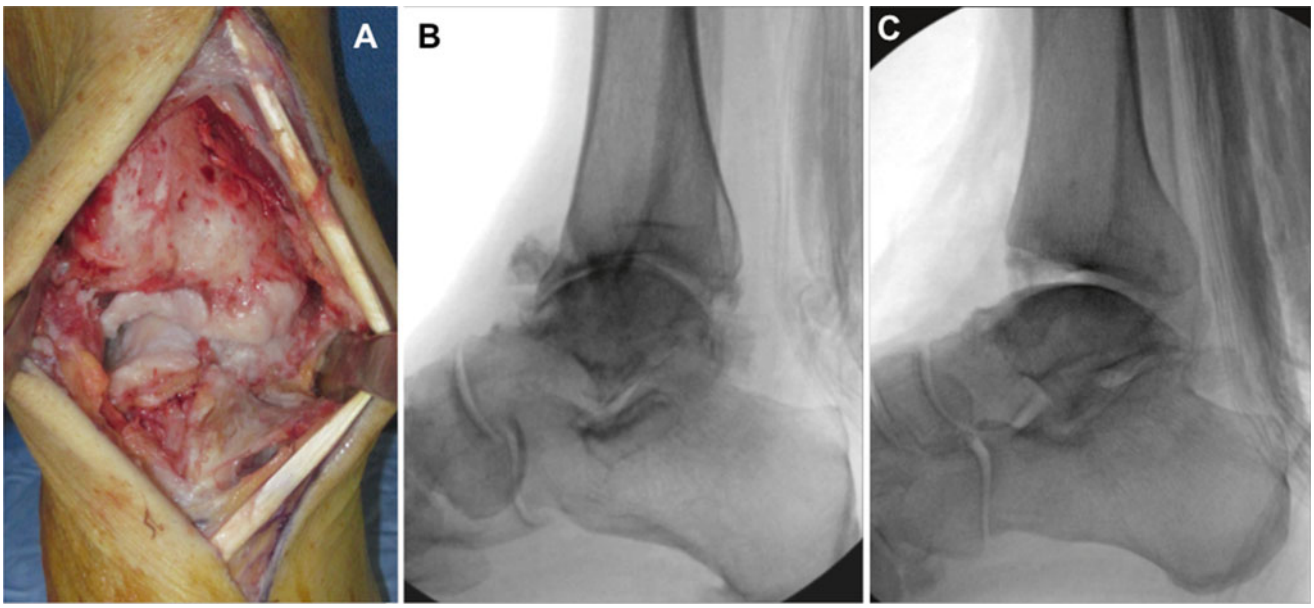

Fig. 10.1 Intraoperative photograph (**a**) demonstrating the exposure required to perform the Salto Talaris Total Ankle Prosthesis. Lateral C-arm image intensification view prior to (**b**) and following (**c**) resection of the anterior tibial osteophytes and exposing the proximal tibial articular surface or "roof" of the tibial pilon

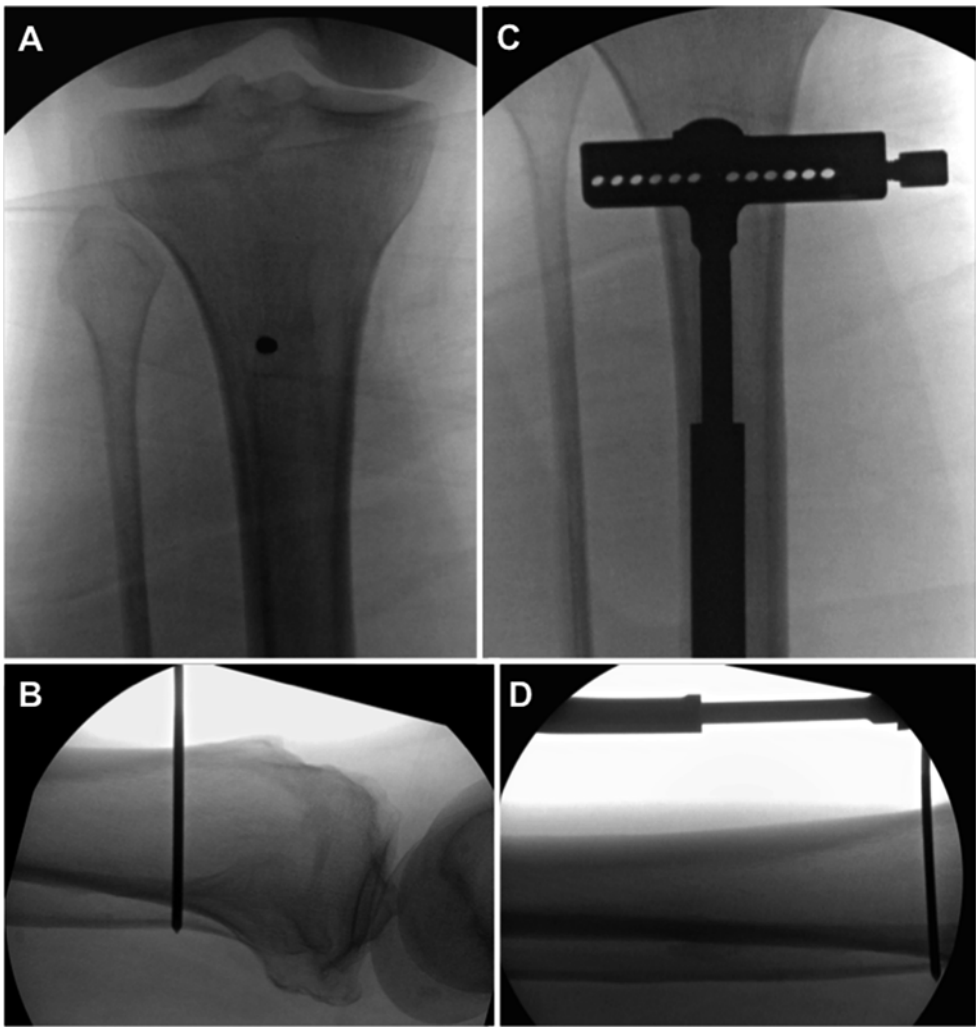

Fig. 10.2 Anterior–posterior (**a**) and lateral (**b**) C-arm image intensification views following proximal tibial tubercle pin placement. Anterior–posterior (**c**) and lateral (**d**) C-arm image intensification views following application of the tibial alignment guide

the tibia (Fig. 10.2c) 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 (+) 6 with 0 being neutral. With the knobs all loosened, the tibial alignment guide should be held off the tibial surface by two fingerbreadths and parallel to the anterior tibial crest when viewed from the side (Fig. 10.2d). 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. 10.3a). 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 self-drilling pin is inserted most commonly through the guide's medial hole (Fig. 10.3b) 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 proximal aspect of the tibial alignment guide can be raised further off the tibia to reduce the distal tibial resection guide angle (Fig. 10.4). Alternatively the newly designed distal tibial resection guide has a built-in 3° angle that can be utilized. 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 baseplate of 4 mm and the thinnest available UHMWPE insert of 4 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 as well as help maintain it while adjusting the guides. Next, the tibial alignment jig is slid over the distal tibial resection guide and adjusted by first obtaining rotational alignment and then medial–lateral positioning (Fig. 10.5). To achieve rotational alignment, a 110-mm 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 from 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 four 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, 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 one that corresponds with a

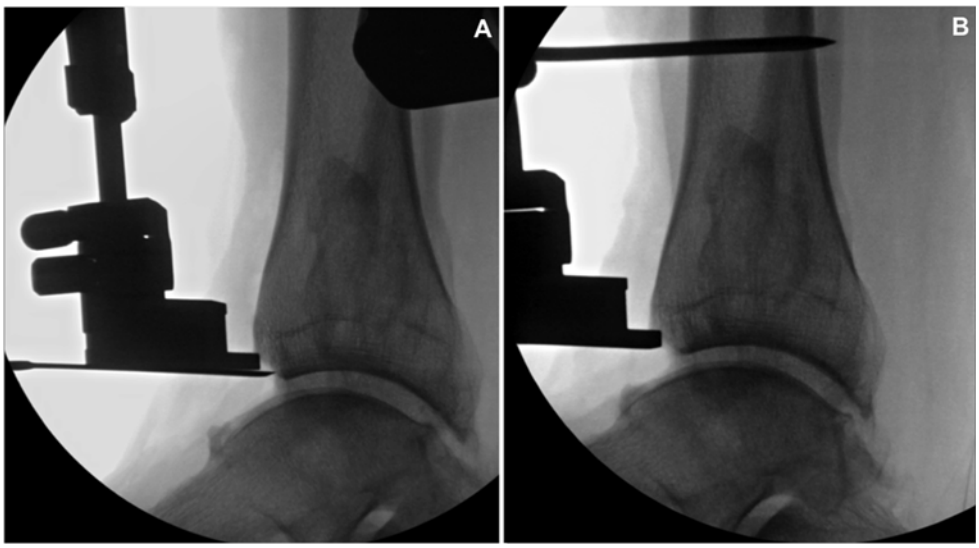

Fig. 10.3 Lateral C-arm image intensification view demonstrating proper alignment of the distal flange of the tibial alignment guide at the level of the proximal tibial articular surface prior to (**a**) and after (**b**) pin placement to secure the guide. In these images the built-in 7° apex posterior angle has been retained

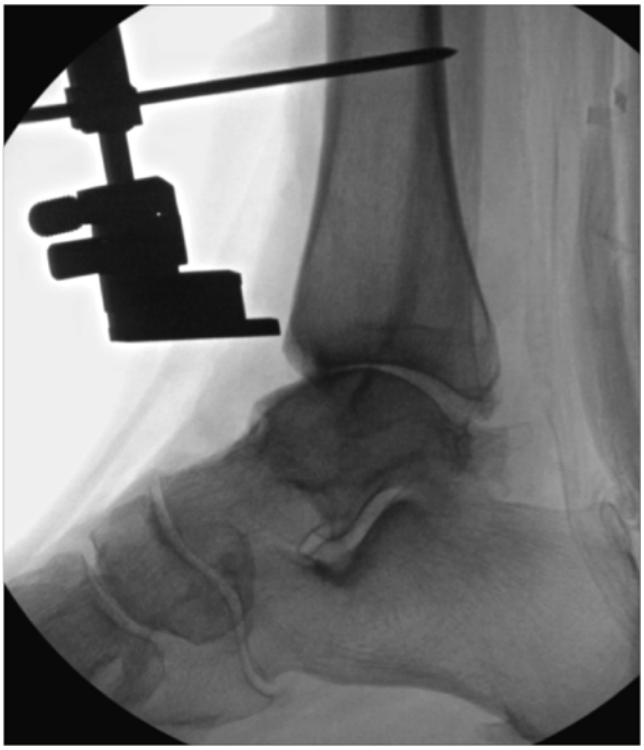

Fig. 10.4 Lateral C-arm image intensification view demonstrating translation of the distal flange of the tibial alignment guide 9 mm proximal to the level of the proximal tibial articular surface. Note that the built-in 7° apex posterior angle has been reduced to 0° due to the presence of chronic anterior subluxation of the talus

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 prosthesis size on the anterior one-third 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. 10.6). At this point, it is critical to verify that the distal flange and resection guide are 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. 10.7a) followed by insertion of a 75-mm pin into both of these holes bicortically (Fig. 10.7b). 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 aide 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 tibial cutting guide has vertical resection slots instead of the distal two holes to more accurately

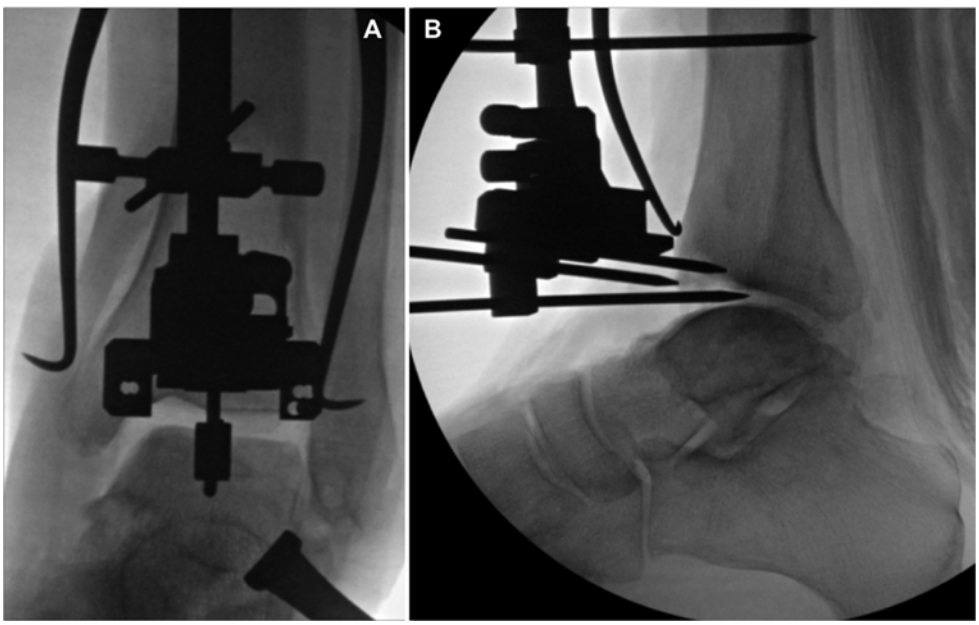

Fig. 10.5 Anterior–posterior (**a**) and lateral (**b**) C-arm image intensification views demonstrating the tibial alignment jig

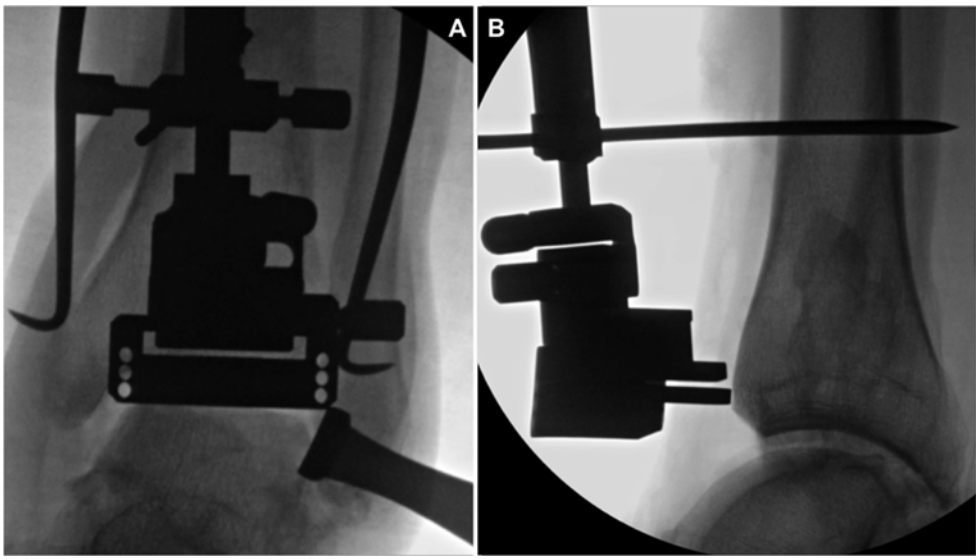

Fig. 10.6 Anterior–posterior (**a**) and lateral (**b**) C-arm image intensification views demonstrating the tibial resection guide

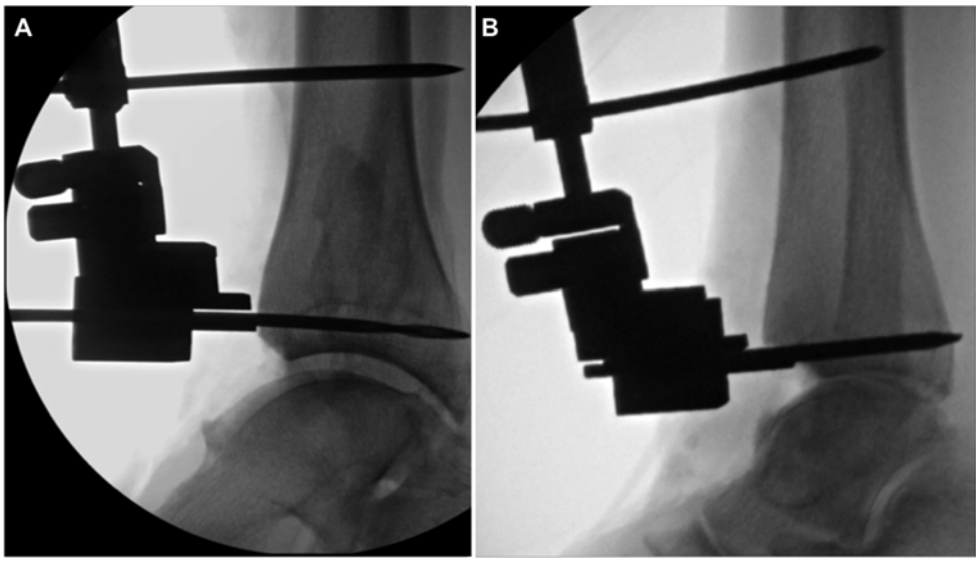

Fig. 10.7 Lateral C-arm image intensification views demonstrating bicortical drill (**a**) and pin (**b**) placement for the superior medial and lateral holes within the tibial resection guide

osteotomize the bone. The horizontal tibial resection is then performed extending to the posterior tibial cortex (Fig. 10.8a). 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 one-half to two-thirds 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. 10.8b).

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 three holes within the guide corresponding to the base of the talar neck at the anterior articular cartilage of the talar dome (Fig. 10.9a). The angle of the talar drill is such that if it exited the talus, it would be within the posterior one-third 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. 10.9b). As noted above, the foot holder can help with this positioning. If the foot is held in dorsiflexion, the talar

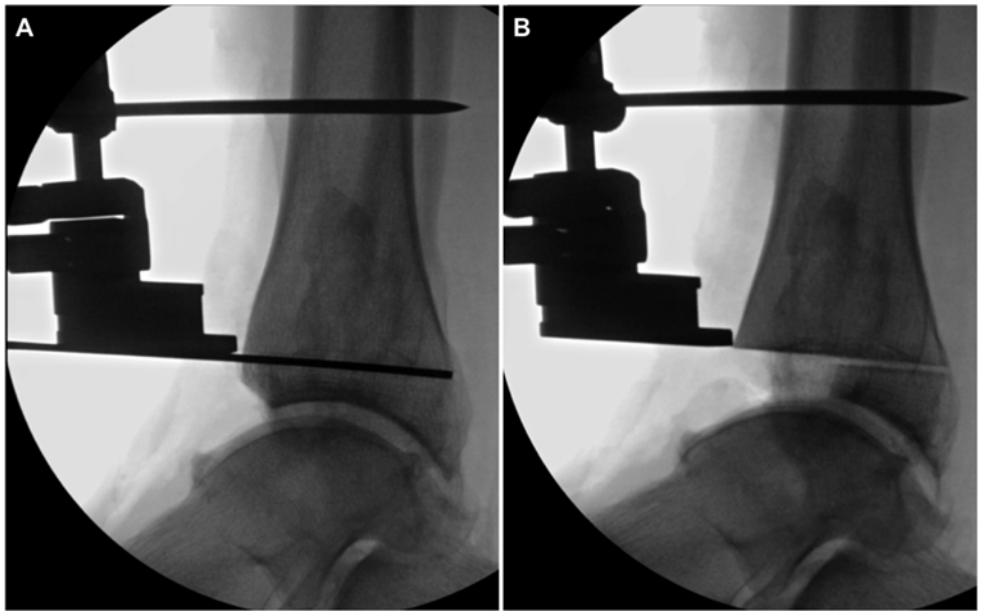

Fig. 10.8 Lateral C-arm image intensification views demonstrating the path of the saw blade within the tibial resection guide (**a**) and resected anterior one-half of the tibia (**b**)

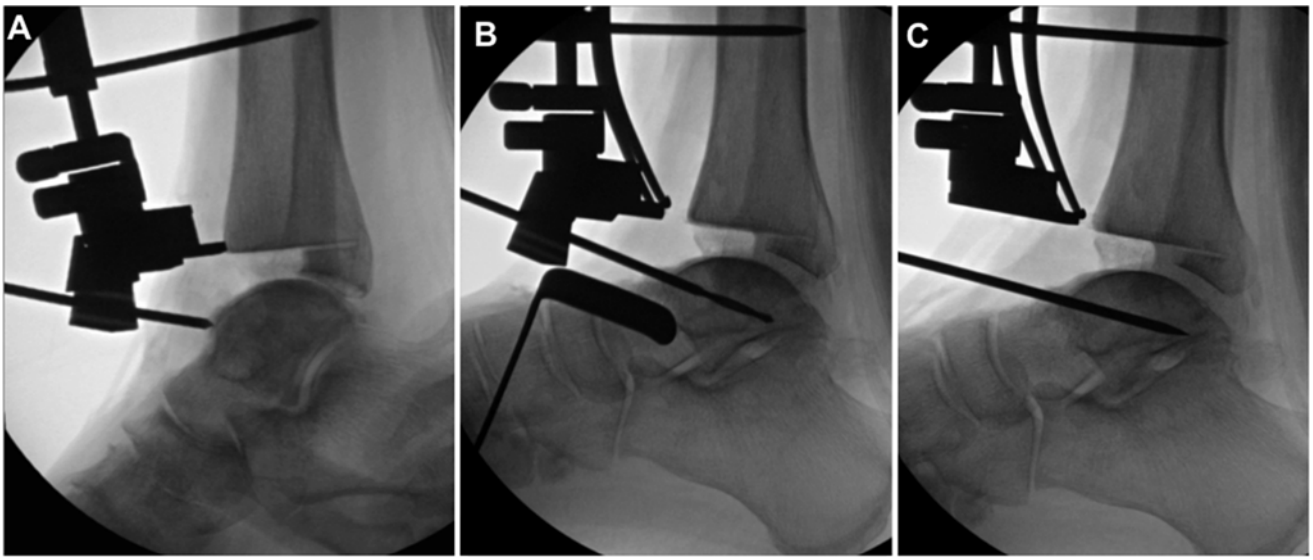

Fig. 10.9 Lateral C-arm image intensification views demonstrating the talar pin setting guide prior to (**a**) and following drill (**b**) and pin (**c**) placement. Note the angle of the drill and pin is such that they would exit the talus within the posterior facet of the subtalar joint

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, at this time it is helpful to place use 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- or 110-mm guide pin inserted into the drill hole (Fig. 10.9c). 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 placed. This eliminates the need to find the drill hole after the talar pin setting guide is removed. There are two 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. 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

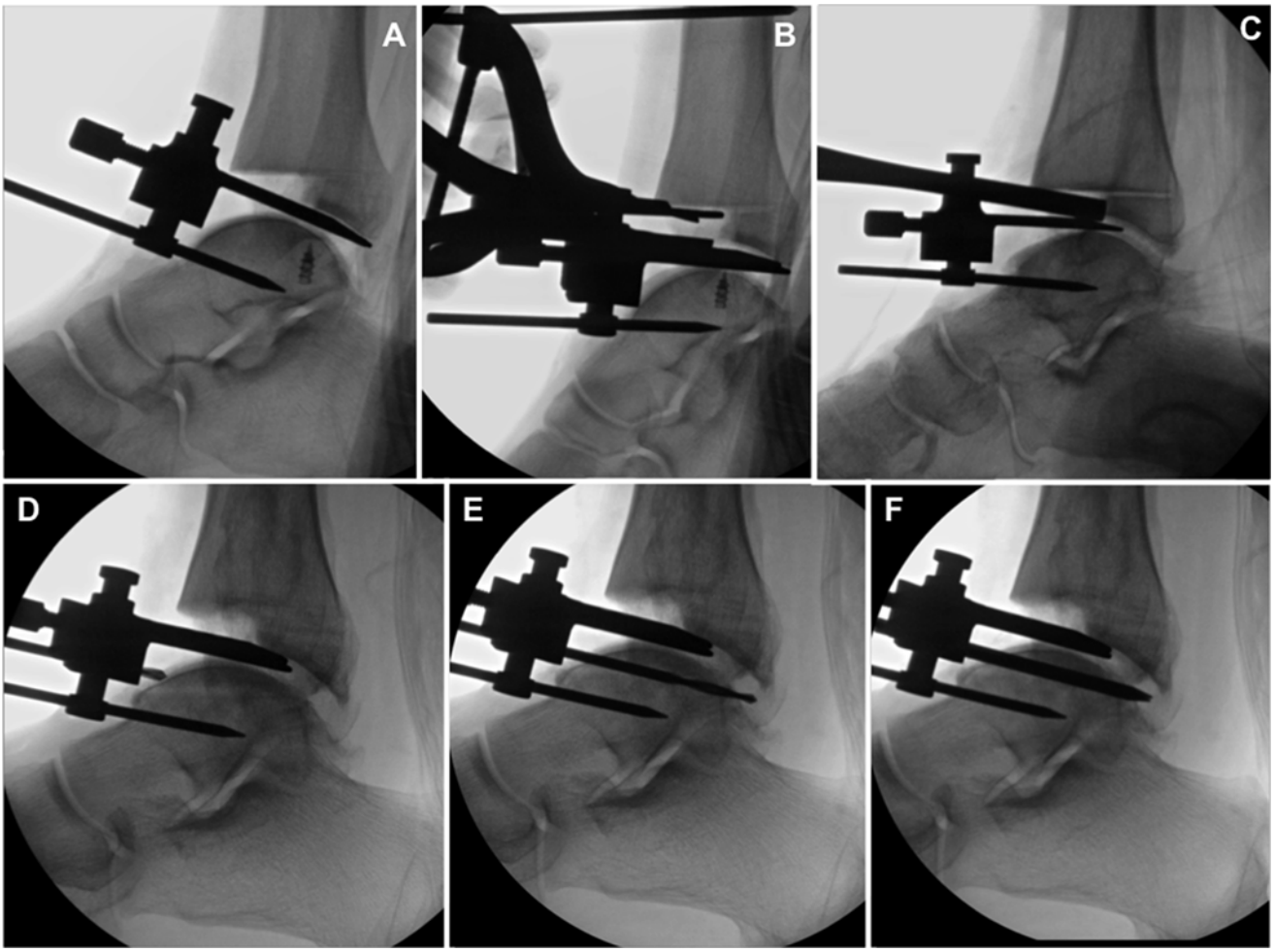

Fig. 10.10 Lateral C-arm image intensification views demonstrating the posterior talar dome resection guide slid over the talar pin (**a**) and stabilized with joint distractors (**b**) and a large bone graft impaction handle (**c**). The four drill holes are then placed from anterior (**d**) through the posterior cortices (**e**) and replaced with bicortical pins (**f**)

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 in case 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. 10.10a). 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. 10.10b); 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. 10.10c). 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. 10.10d–f). The superior portion of these pins defines where 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. 10.11a). Malleable metallic ribbon retractors are carefully placed in the medial and lateral gutters at the level of the talar resection to

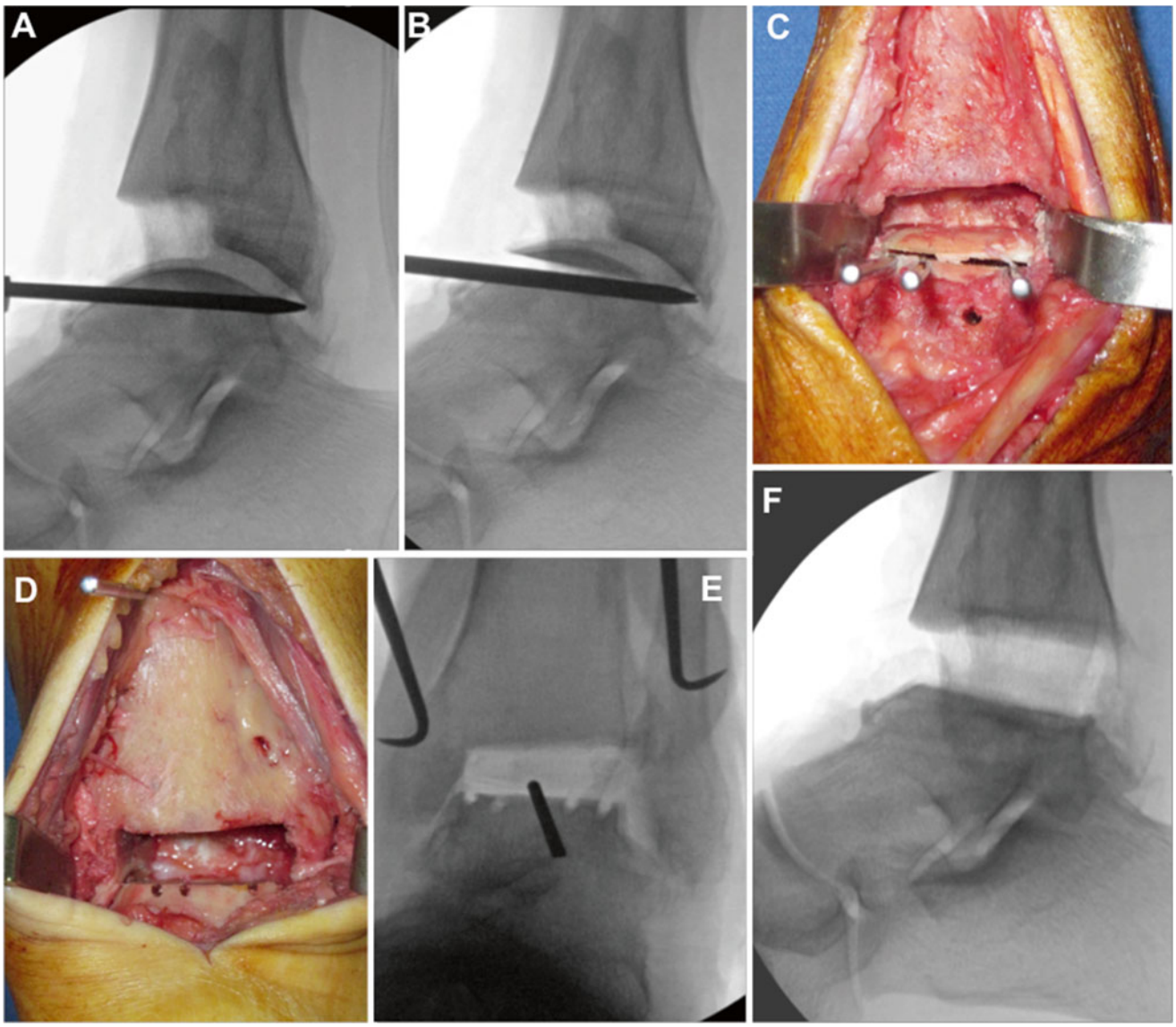

Fig. 10.11 Lateral C-arm image intensification views prior to (**a**) and following (**b**) resection of the posterior talar dome. Intraoperative anterior–posterior photographs prior to (**c**) and following (**d**) resection of the posterior talar dome. Anterior–posterior (**e**) and lateral (**f**) C-arm image intensification views following removal of the posterior talar dome resection pins and removal of the remaining posterior tibial bone segment

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. 10.11b, c). The resected posterior talar dome segment and all four pins are then removed (Fig. 10.11d, e). The new 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 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 new posterior talar dome resection guide simplifies the posterior chamfer cut, the authors maintain that the original posterior talar dome resection guide allows for greater deformity correction. Accordingly we believe that surgeons should be familiar with the steps involved for both the original and updated guides.

The retained posterior tibial bone segment can now be removed and the tibial preparation completed (Fig. 10.11f). Next, the trial tibial baseplate 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. 10.12). 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

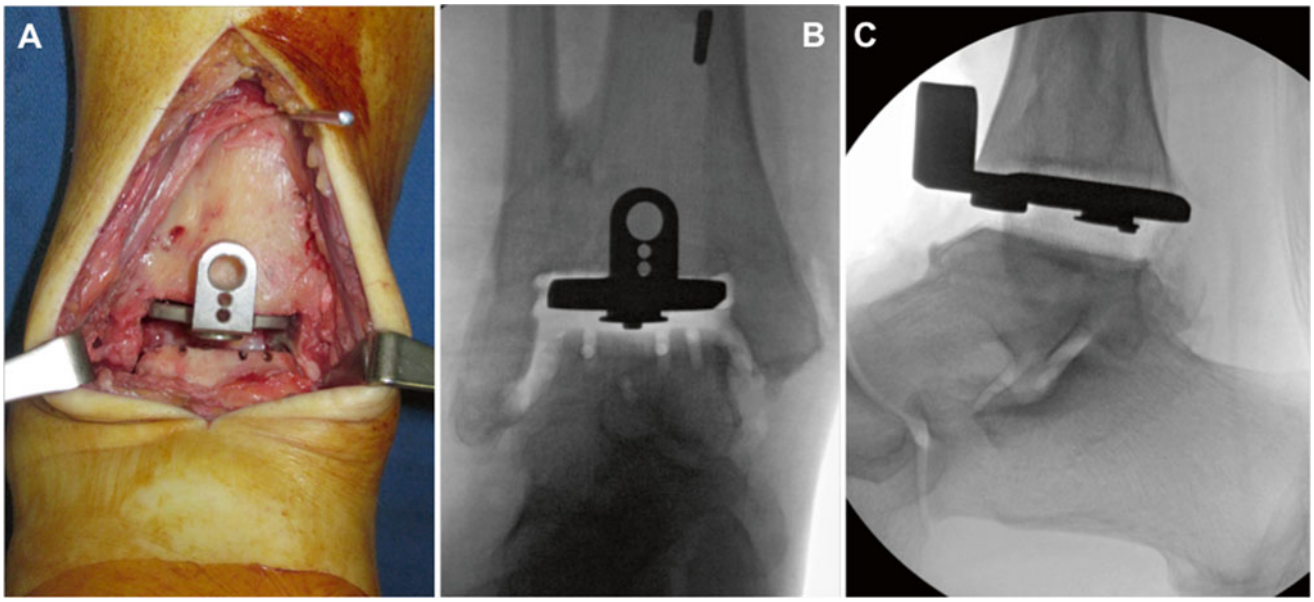

Fig. 10.12 Intraoperative photograph (**a**) as well as anterior–posterior (**b**) and lateral (**c**) C-arm image intensification views demonstrating trial tibial baseplate sizing

have appropriate anterior cortical 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 verify that the guide is resting directly against the remaining anterior surface of the talar dome and the posterior talar dome resection cut (Fig. 10.13a) with the guide handle held aligned with the third 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. 10.13b) followed by fixation of the guide with two 45-mm pins after drilling the corresponding holes (Fig. 10.13c). 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 [14]. 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 oblong window of the anterior talar chamfer guide is removed and the reaming guide inserted. The anterior chamfer reamer is inserted into the reaming guide (Fig. 10.13d) 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. 10.13e). 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. 10.13f). 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. 10.14a). 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. 10.14b). It is imperative that the lateral talar resection guide is 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

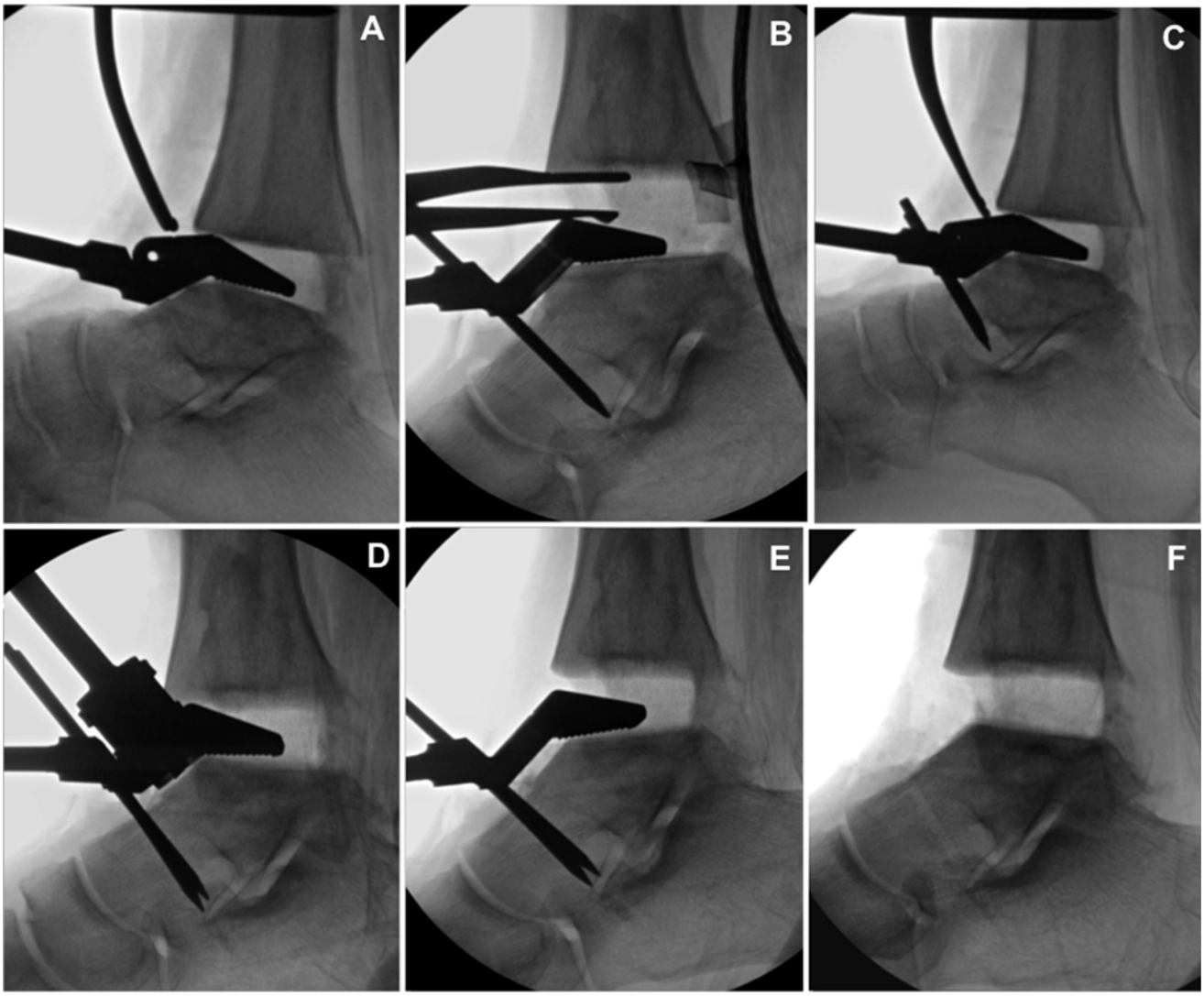

Fig. 10.13 Lateral C-arm image intensification views demonstrating placement of the anterior talar chamfer guide prior to (**a**) and after application of a joint distractor (**b**) that is maintained with two short pins (**c**). Lateral C-arm image intensification views demonstrating the anterior chamfer 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**)

of the talus, and with rotation aligned with the third metatarsal. Once these positions have been achieved, the lateral talar resection guide is secured with a 45-mm pin after drilling the corresponding hole (Fig. 10.14c) 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. 10.15a), and the bell saw reamer is placed into the hole in the lateral talar resection guide (Fig. 10.15b) and advanced into the talus until a hard stop is encountered (Fig. 10.15c). The bell saw reamer is removed, and a fixation plug is placed into the hole (Fig. 10.16a) and driven completely into the talus (Fig. 10.16b). 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. 10.16c, 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 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 pins being careful not to penetrate the inferior aspect of the talar neck. The anterior talar reaming guide then replaces the talar

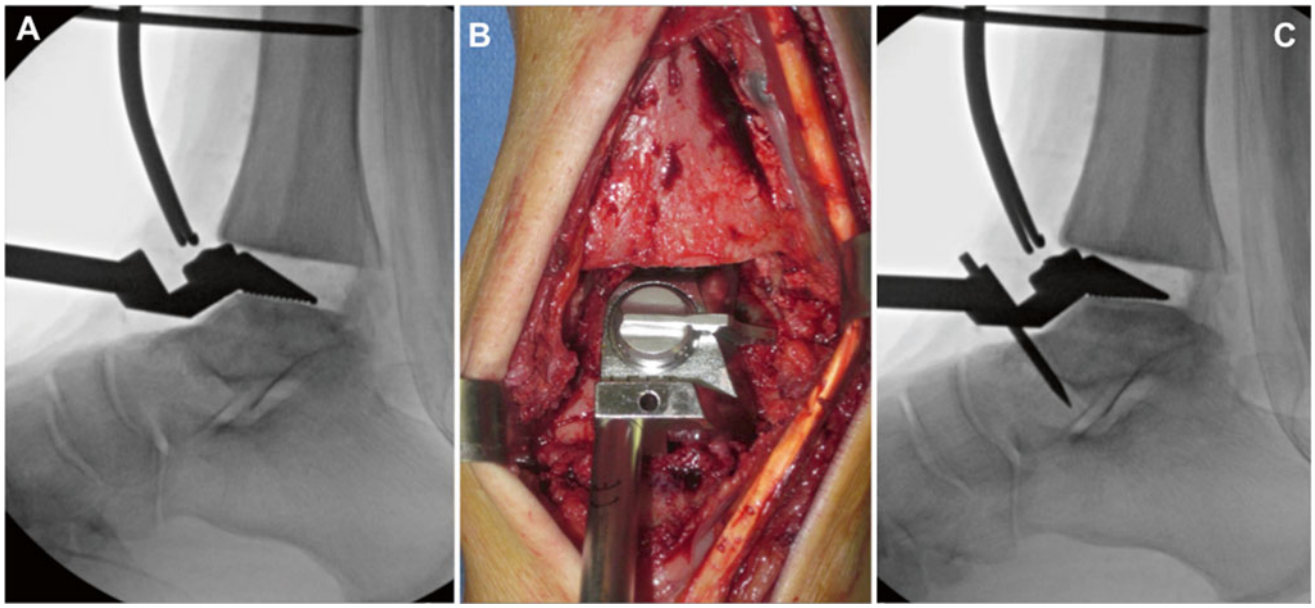

Fig. 10.14 Lateral C-arm image intensification view (**a**) and intraoperative photograph (**b**) demonstrating the plug-shaped medial–lateral positioning gauge alignment. Lateral C-arm image intensification view after pinning the guide in place (**c**)

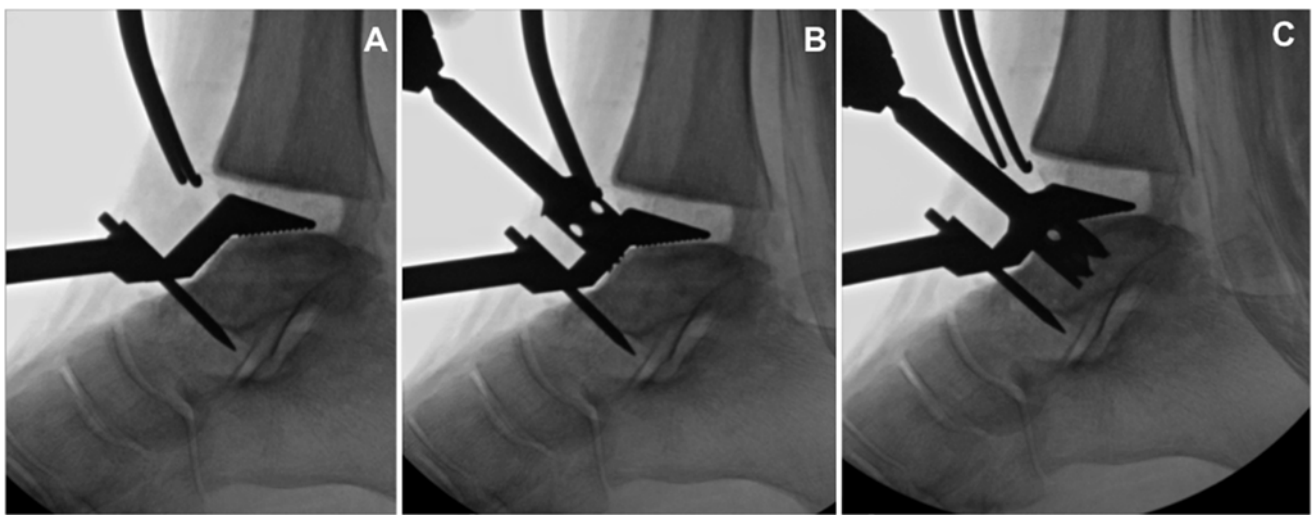

Fig. 10.15 Lateral C-arm image intensification views demonstrating removal of the plug-shaped medial–lateral positioning gauge bushing (**a**) followed by reaming of the talar hole (**b**) until a hard stop is encountered (**c**)

position spacer, and the anterior chamfer reaming is completed 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 pin. The bell saw bushing is inserted, the bell saw cut completed, and the fixation plug 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.

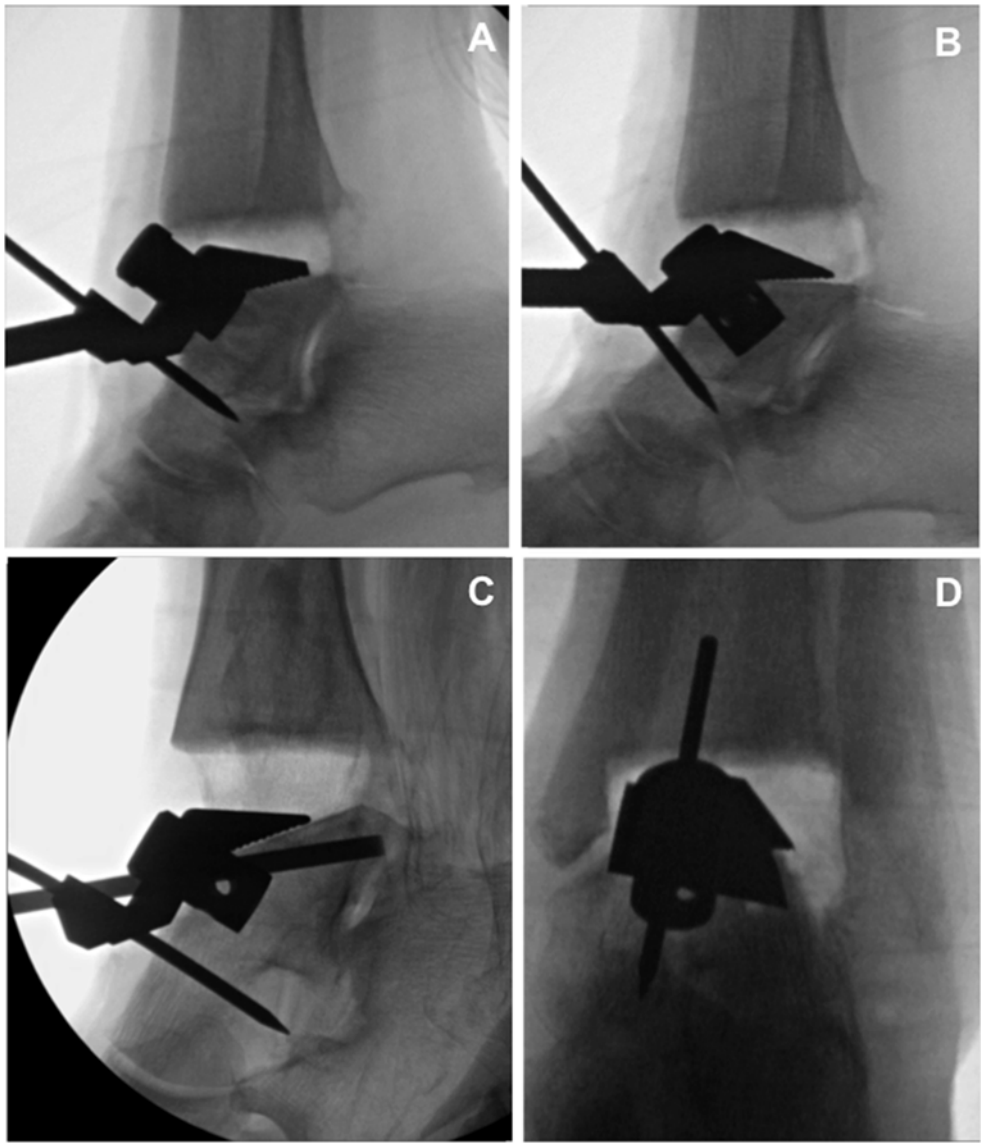

Fig. 10.16 Lateral C-arm image intensification views prior to (**a**) and after placement (**b**) of the talar fixation plug. Lateral (**c**) and anterior–posterior (**d**) C-arm image intensification views demonstrating the lateral talar resection depth and angle, respectively

Trial Size, Prosthesis Component Positioning, and Tibial Keel Preparation

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 verified (Fig. 10.17). The trial tibial baseplate corresponding to the same size or one larger than the talar component is selected and the trial plastic insert 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 with a total thickness of 8, 9, 10, or 11 mm corresponding to the 4-mm-thick tibial baseplate and the available plastic inserts of 4, 5, 6, or 7 mm. 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 baseplate to obtain its optimal position in the frontal, sagittal, and rotational planes. Once the optimal trial tibial baseplate position is obtained, continued dorsiflexion and plantarflexion of the ankle would not cause any further movement of the trial component (Fig. 10.18a). If soft-tissue releases 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 baseplate should be verified as aligned with the anterior cortex of the tibia prior to accepting the position of the trial tibial baseplate. It is critical that the trial tibial baseplate is pressed firmly against the resected tibial surface to

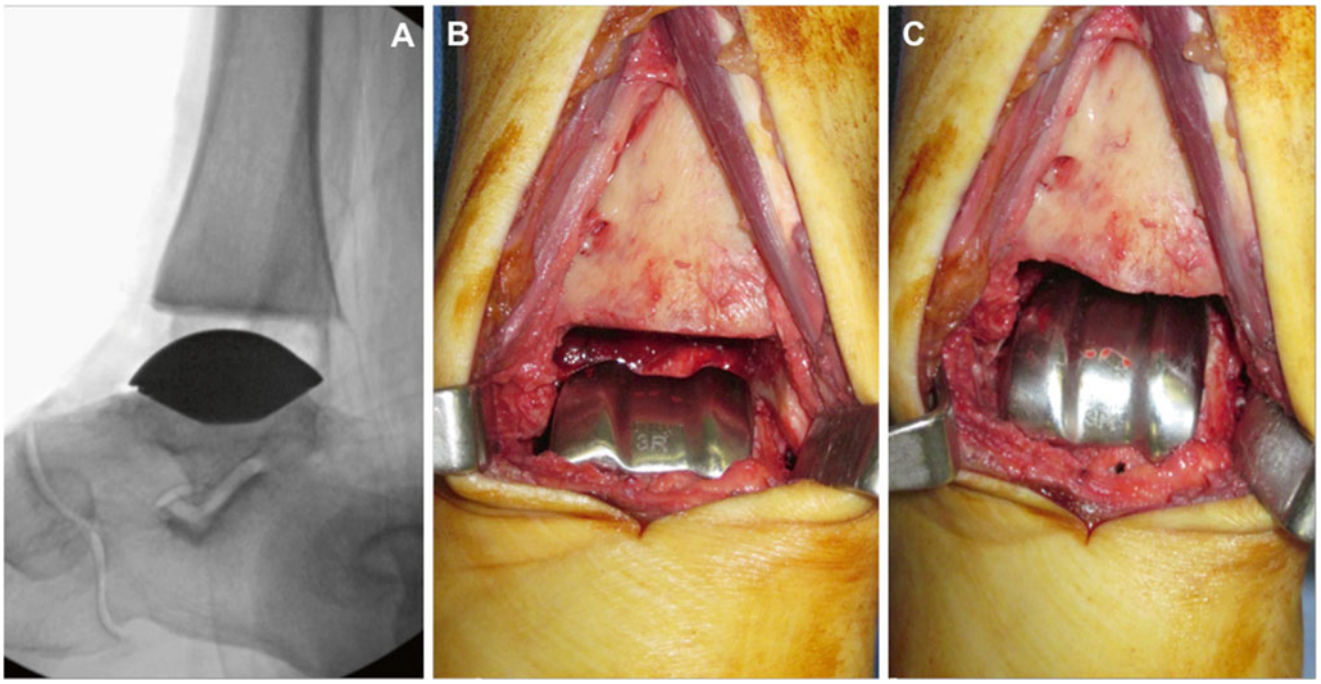

Fig. 10.17 Lateral C-arm image intensification view (**a**), as well as neutral (**b**) and plantarflexion (**c**) intraoperative views of the trial talar component

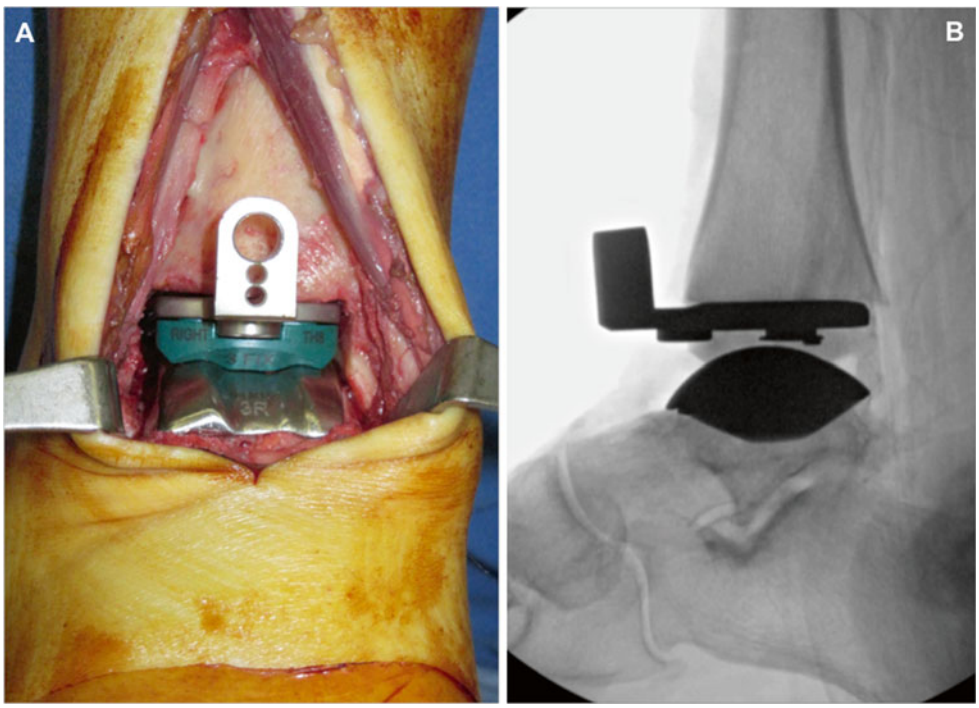

Fig. 10.18 Intraoperative photograph (**a**) and lateral C-arm image intensification view (**b**) demonstrating the trial tibial monoblock medial–lateral position and tibial coverage, respectively

maintain this position and a lateral C-arm image should be obtained to verify this (Fig. 10.18b). The tibial implant keel preparation begins with a 2.9-mm drill through the inferior two drill holes starting with the more superior of the two (Fig. 10.19a). The inferior most hole directly above the trial tibial baseplate is then drilled (Fig. 10.19b) followed by placement of a 75-mm pin which secures the guide (Fig. 10.19c). These two drill holes will define the tibial component keel. A 7.9-mm drill bit is then employed to prepare the tibial plug through the trial tibial baseplates superior most and largest drill hole (Fig. 10.20). Drilling through the trial tibial base guide creates a 4° angle from the final tibial

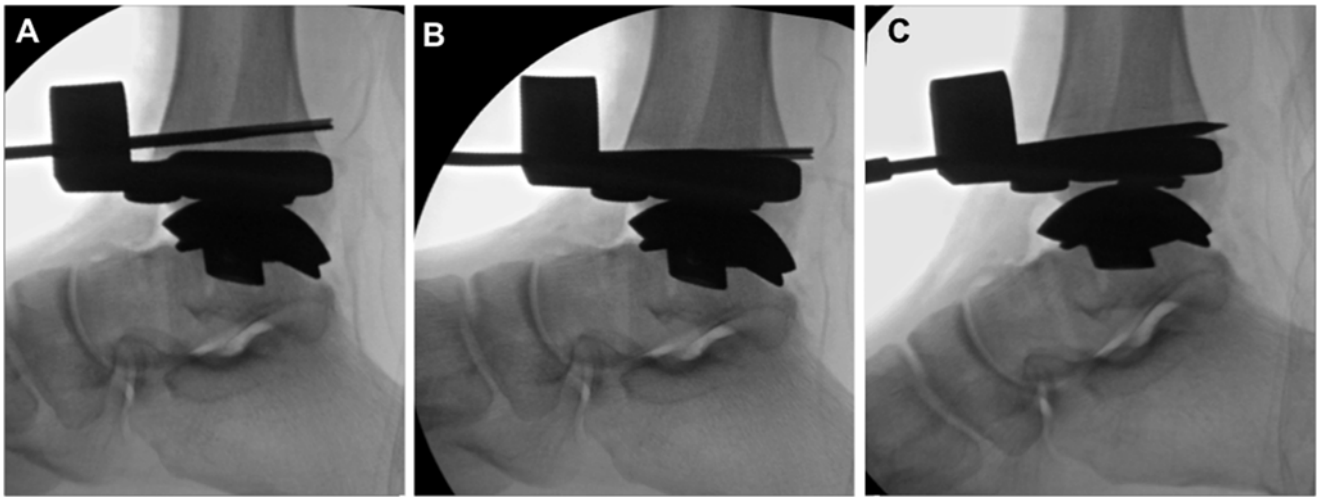

Fig. 10.19 Lateral C-arm image intensification views demonstrating the superior (**a**) and inferior (**b**) tibial keel drill holes followed by insertion of a bicortical 75-mm pin in the inferior hole directly above the trial tibial baseplate (**c**). Care must be taken to make certain the tibial baseplate is in direct contact with the resected tibial bone surface during the tibial keel preparation

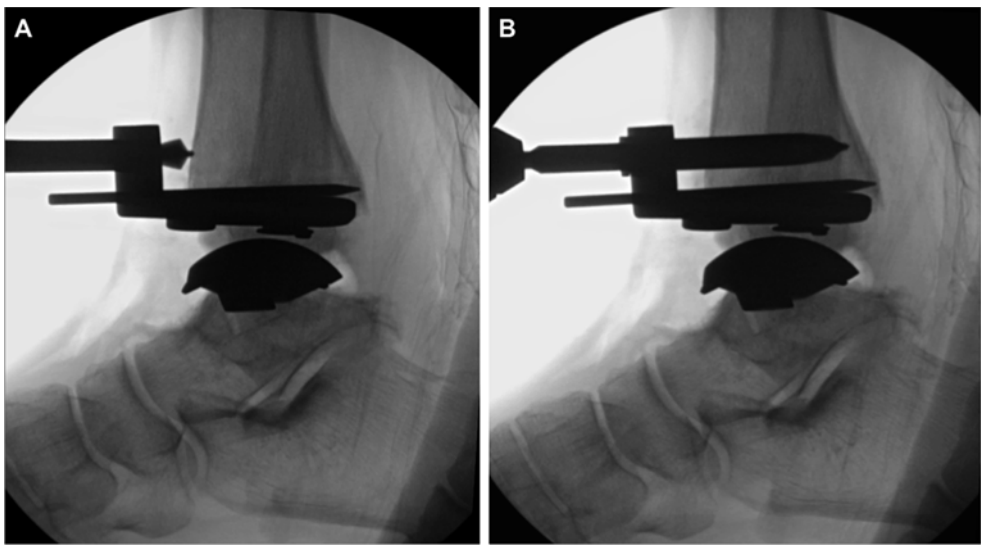

Fig. 10.20 Lateral C-arm image intensification views prior to (**a**) and following (**b**) creation of the tibial fixation plug. As with the tibial keel preparation, care must be taken to make certain the tibial baseplate is in direct contact with the resected tibial bone surface during the tibial fixation plug preparation

baseplate that allows for a press fit of the final implant 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 trial talar components are removed. The two tibial keel holes are connected using a small power saw or graduated tibial keel osteotome followed by beveling and bone impaction using the tibial keel rasp. The different tibial implant sizes (i.e., 0, 1, 2, 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. 10.21). 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 (Fig. 10.22).

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 be aligned to exactly match the talar preparation morphology (Fig. 10.23a) followed by firm impaction using the talar component impactor (Fig. 10.23b). 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

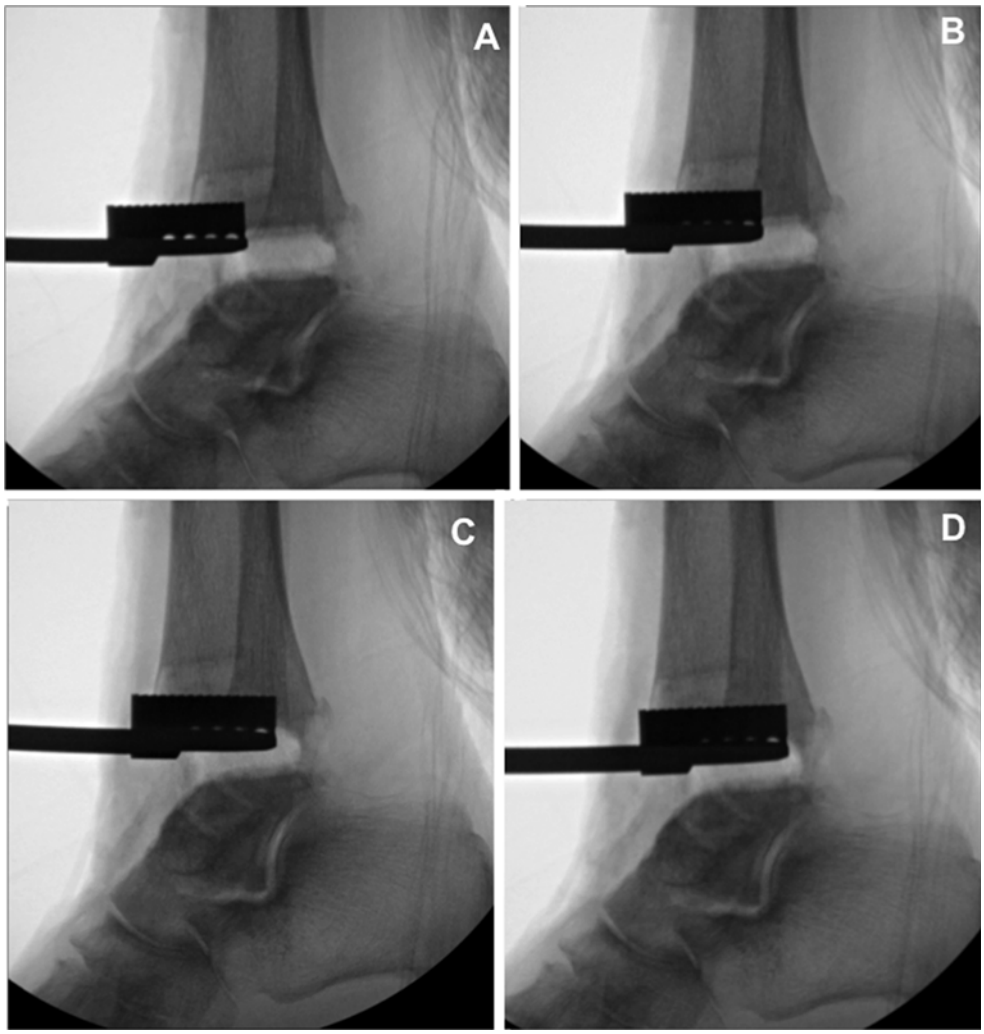

Fig. 10.21 Lateral C-arm image intensification views at the start of (**a**), midway through (**b**), near completion (**c**), and following (**d**) passage of the tibial keel rasp. As with the tibial keel and fixation plug preparation, care must be taken to make certain the tibial keel rasp is in direct contact with the resected tibial bone surface during preparation

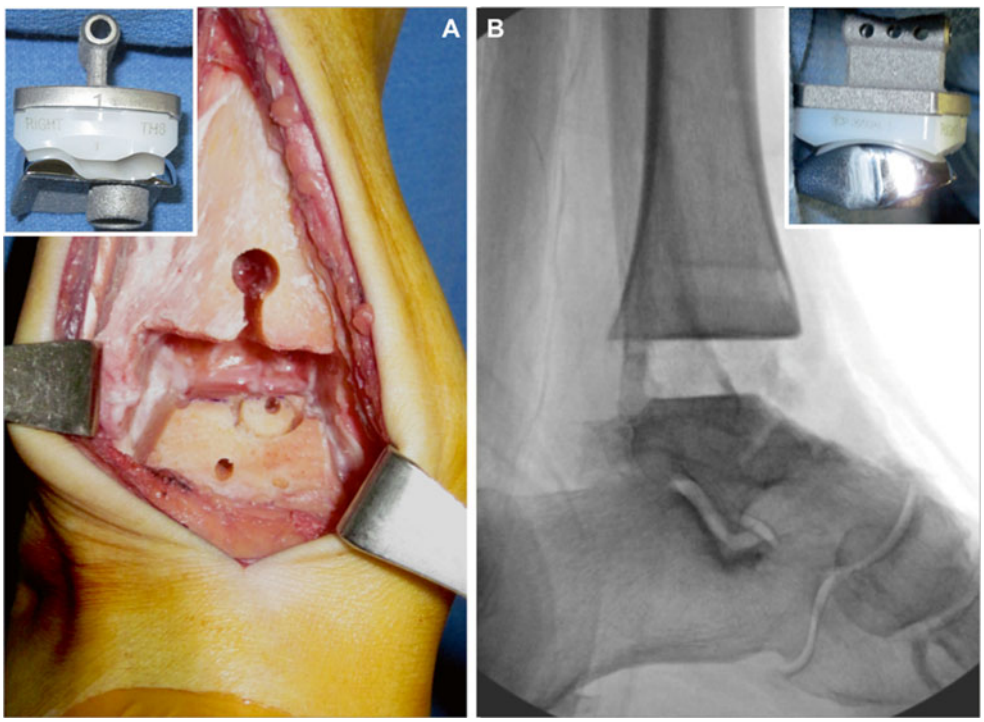

Fig. 10.22 Intraoperative photograph (**a**) and lateral C-arm image intensification view (**b**) following completion of the tibial and talar preparation with the corresponding photographs of the Salto Talaris Total Ankle Prosthesis employed shown in the insets

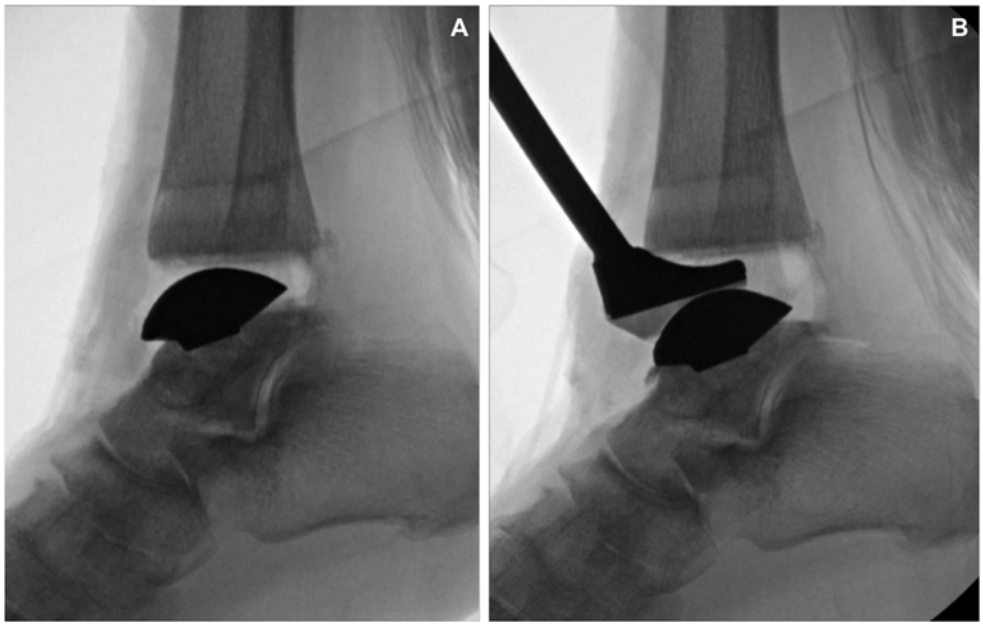

Fig. 10.23 Lateral C-arm image intensification views prior to (**a**) and following (**b**) impaction of the final talar component

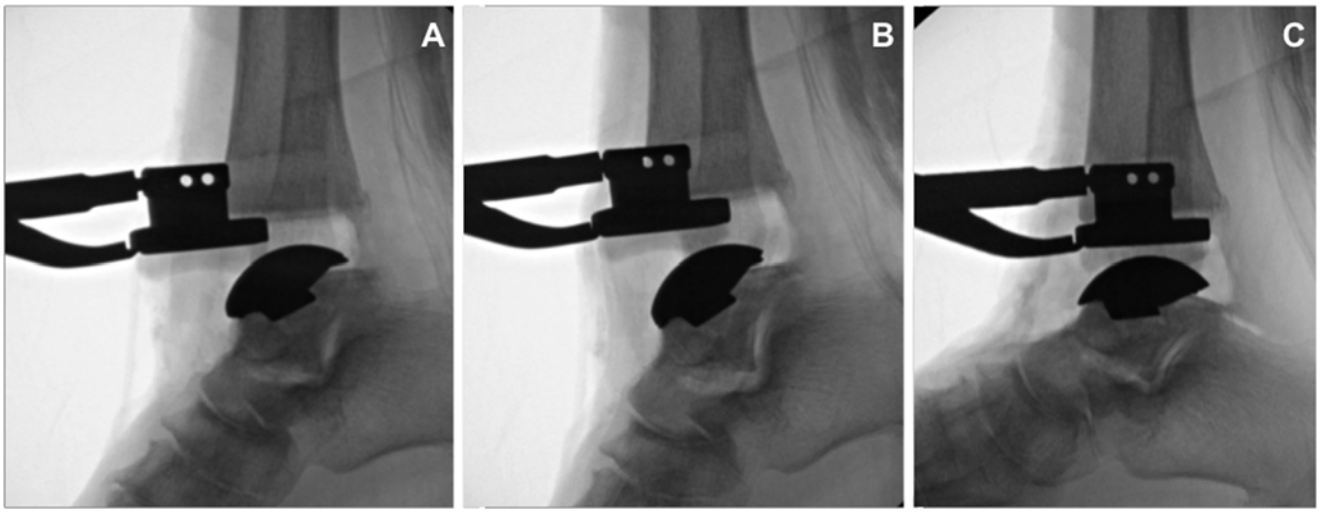

Fig. 10.24 Lateral C-arm image intensification views prior to (**a**), midway through (**b**), and following (**c**) impaction of the final tibial component. Care must be taken to make certain the tibial component baseplate is in direct contact with the resected tibial bone surface during impaction

the tibial baseplate and the UHMWPE insert as a single unit that is grasped by the tibial impactor according to the manufacturer directions. 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 baseplate and the resected tibial surface to prevent any gapping (Fig. 10.24). Additionally maintaining a slight amount of plantarflexory pressure on the tibial component impactor, tipping it forward upon impaction, will aid against posterior gapping of the tibial tray on the tibial plafond during insertion. If a small amount of gapping is appreciated between the tibial baseplate and tibia, the plantar aspect of the heel can be manually impacted on with the foot maintained in neutral alignment to properly seat the tibial base flush with the resected tibial surface. The ankle is stressed in the frontal (Fig. 10.25) and sagittal (Fig. 10.26) 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. 10.27).

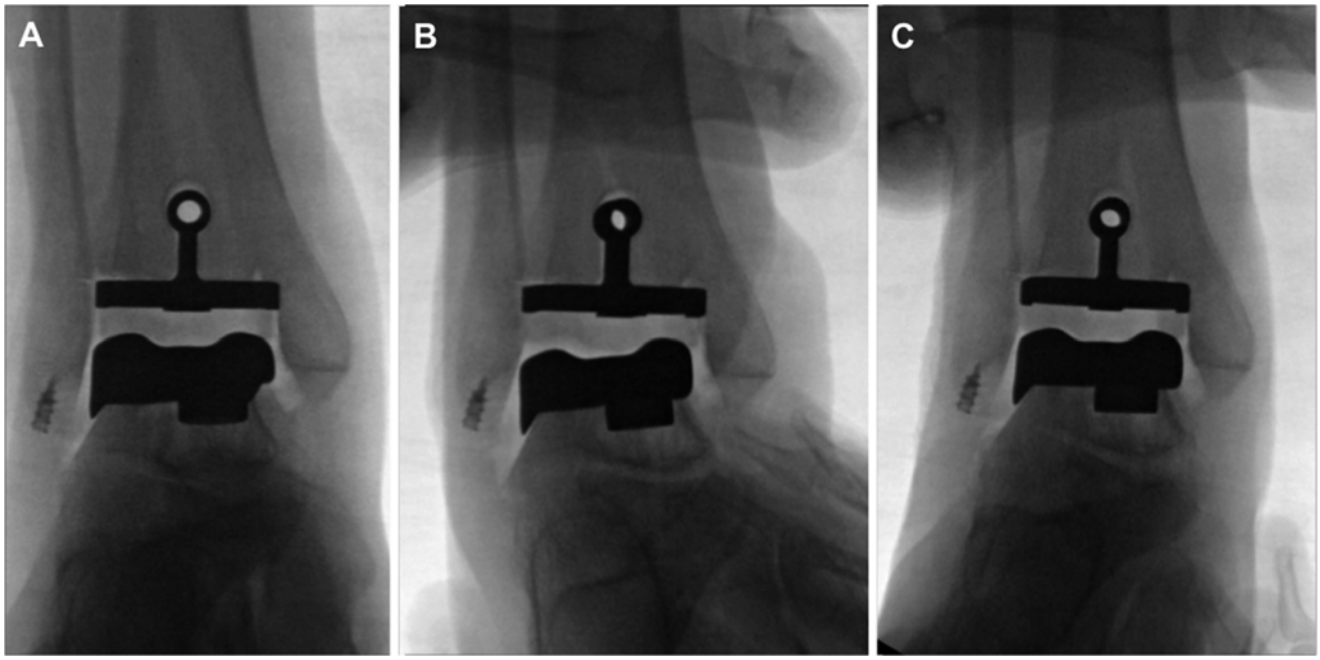

Fig. 10.25 Anterior–posterior C-arm image intensification view following impaction of the final tibial and talar components (**a**), as well as stress inversion (**b**) and eversion (**c**) views demonstrating appropriate alignment and stability

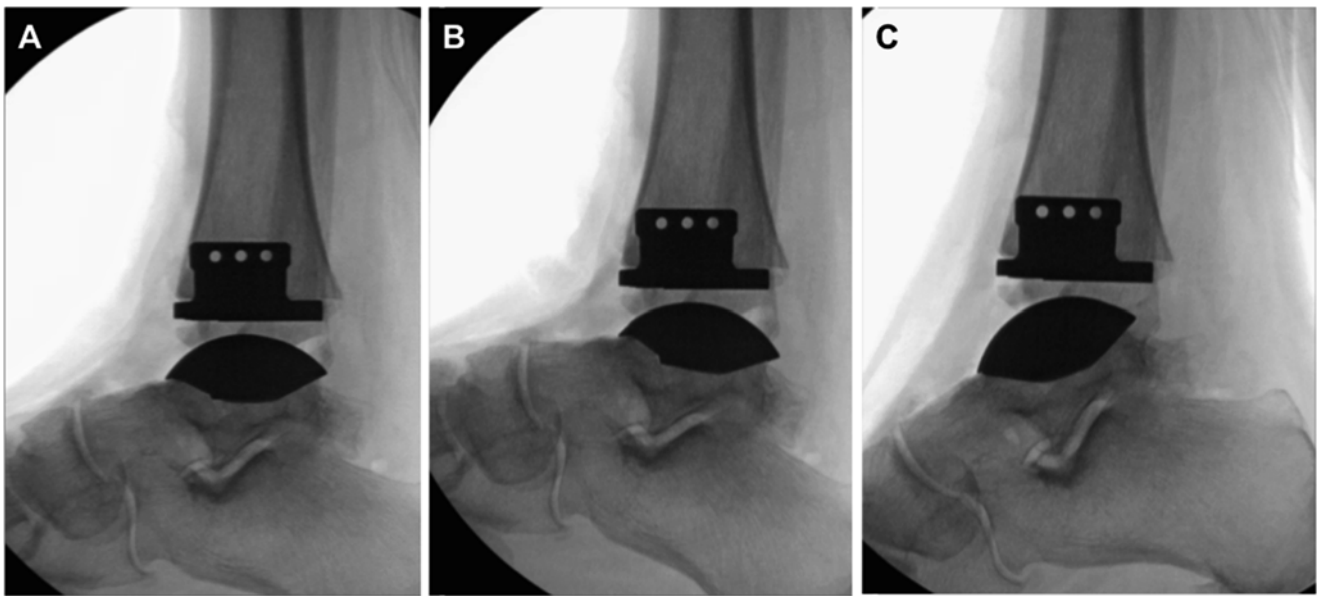

Fig. 10.26 Lateral C-arm image intensification view following impaction of the final tibial and talar components (**a**), as well as stress dorsiflexion (**b**) and plantarflexion (**c**) views demonstrating appropriate range of motion

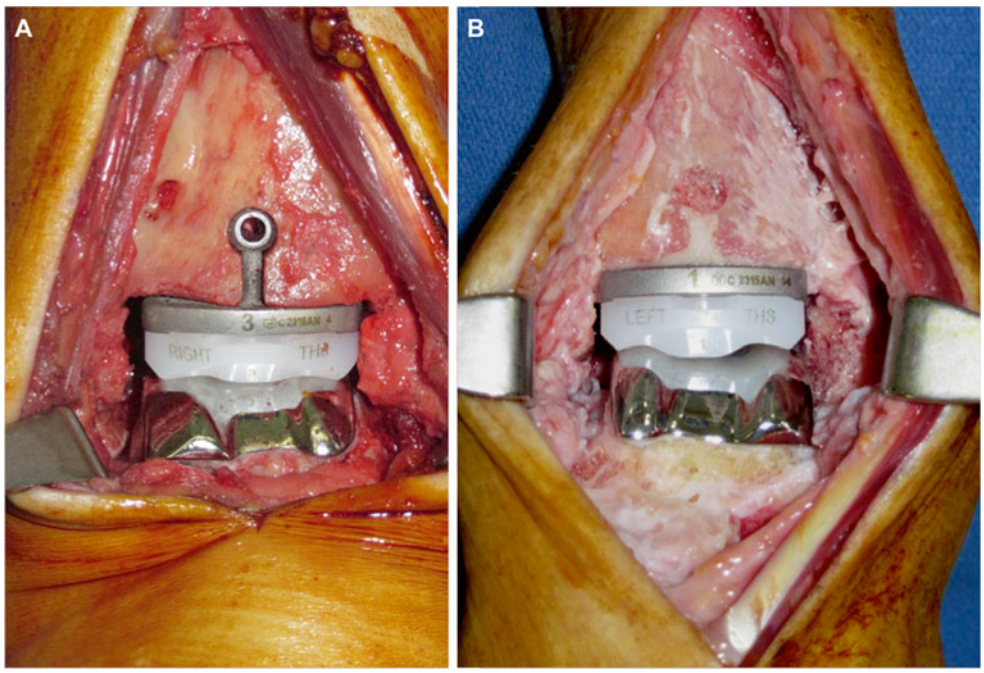

Fig. 10.27 Intraoperative photograph following impaction of the final tibial and talar components (**a**). Intraoperative photograph demonstrating impaction cancellous bone grafting of the tibial fixation plug and polymethylmethacrylate cement application to the tibial keel and anterior talar surface (**b**)

Conclusions

The fixed-bearing Salto Talaris Total Ankle prosthesis was 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 redesign, specific attention was paid to improve the tibial baseplate length and width for maximum cortical coverage, alter the talar component morphology to optimize the balance between triplane range of motion tolerance and constraint, as well as redesign the instrumentation to improve accuracy of implantation. It is interesting to note that the fixed-bearing Salto Talaris Total Ankle prosthesis is currently under clinical evaluation in Europe [8] where implantation of mobile-bearing version of this total ankle prosthesis dominates [15]. Although not proven, the inventors of the Salto Mobile Version prosthesis state that the rationale for developing the fixed-bearing Salto Talaris Total Ankle prosthesis was to obtain improved centering of the talar component relative to the tibial component and the ability to use smaller metallic components [8]. They hypothesized that both of these attributes will reduce malleolar impingement and the secondary trabecular bone changes associated with UHMWPE insert particulate wear debris [8]. The low incidence of revision [10] and straightforward surgical technique [16] combined with the ongoing development of dedicated revision components (Salto Talaris XT Revision Ankle Prosthesis, Tornier, Inc., Bloomington, MN/Wright Medical Technology, Inc., Memphis, TN) supports the use of the Salto Talaris Total Ankle Prosthesis for most primary total ankle replacement indications. The true role of polymethylmethacrylate cement fixation required for FDA compliance remains unknown, as no data exists comparing this with the off-label use of an uncemented Salto Talaris Total Ankle prosthesis implantation in the United States.

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STAR Technique

11

James M. Cottom and W. Bret Smith

Introduction

Total ankle replacement (TAR) was first introduced to the medical community in a paper published in 1973. Lord and Marotte wrote this paper about their experience with their first 12 ankle replacements [1]. Unfortunately, the initial design of ankle replacements left something to be desired and subsequently had a high rate of failure [2]. Since that time over four decades ago, numerous changes, developments, and advancements have been made in the world of TAA.

Over the last two decades, we have seen a resurgence of interest in TARs and a significant improvement in designs and outcomes. Currently, the demand for ankle replacement continues to increase every year.

End-stage ankle arthritis has been shown to significantly affect the quality of life of affected patients. The impact on patients has been shown to be similar to end-stage hip arthrosis [3–5].

The Scandinavian Total Ankle Replacement (STAR, Stryker Orthopaedics, Inc., Mahwah, NJ) first came into existence in 1978 [6]. The original version was a polymethylmethacrylate cemented prosthesis that was first utilized in 1981 [7]. The STAR is a three-part, mobile-bearing device. The STAR 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.

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The widespread usage and length of time that the STAR implant has been available have resulted in it being one of the most reviewed and researched TAR prostheses. At the time of writing this chapter, it is estimated that over 15,000 STAR prostheses have been implanted worldwide [8].

To date a number of studies have reviewed the long-term results and survivorship of the STAR ankle replacement. Several studies suggest that 10-year survivorship is over 90 % [9, 10], although contrasting studies from Europe suggest survivorship may be as low as 45 % at 10 years [11, 12]. Larger review- and registry-based papers looking at several different TARs have shown overall survivorship to be approximately 80 % at 10 years [13–15].

Design Rationale

The STAR ankle replacement is a three-part, mobile-bearing TAR, designed for implantation without the use of polymethylmethacrylate 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 [12].

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 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 [16]. The bottom surface of the central bearing is shaped to match the cylindrical shape of the talar component to allow for plantar flexion–dorsiflexion motion.

The talar component resurfaces both the talar dome portion of the joint as well as 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.

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_11

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 and the interface between the bone and the prosthesis components. This may allow for increased long-term stability and improved fixation [16].

Indications

As with all surgical procedures, indications are a constantly evolving issue. Currently TARs in the United States are to be used for the treatment of end-stage ankle arthritis in adult patients. Rheumatoid, posttraumatic, and primary arthritis are the most common indications currently [17]. TARs may be utilized in situations where there is significant adjacent hindfoot and/or midfoot joint disease as well by combing the TAR with additional adjacent joint arthrodesis procedures.

The patient must have an adequate soft tissue envelope to allow for safe application of the procedure. In addition the vascular health of the limb should be thoroughly evaluated. Bone stock must also be assessed to allow for stable implantation of the prosthesis.

Age and body-mass index are also two factors to seriously consider when counseling a patient desiring TAR. It has been reported that good outcomes can be expected long term with TAR despite the presence of obesity [10]. In regard to age, one report suggests no differences in TAR survivorship at medium-term follow-up in patients younger than 50 years when compared to those over 50 years of age [18]. There are no hard and fast rules on correct age or weight of a patient. It is important to clearly discuss outcomes and expectations with your patients prior to undergoing a TAR.

Contraindications

Active ankle sepsis, Charcot or neuropathic joint, large areas of avascular osteonecrosis of the talus or distal tibia, osteomyelitis, complete paralysis of the operative limb, inadequate soft tissue coverage, vascular insufficiency, severe deformity that cannot be corrected, and skeletal immaturity are the most common contraindications germane to TAR. Areas of partial avascular osteonecrosis that will be resected during component implantation may not be considered a contraindication to TAR.

Relative contraindications to TAR include history of infection, diabetes mellitus, morbid obesity, ligament instability, tobacco use, poor soft tissue quality, malalignment, and peripheral sensory neuropathy.

Procedure Technique

The patient is placed on the operating table in a supine manner. It is important to make sure the medial malleolus is perpendicular to the operating table and that the patella is facing directly upwards. A small bump may need to be placed beneath the ipsilateral hip to achieve proper positioning (Fig. 11.1.) 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 and is anteriorly centered over the ankle between the tibialis anterior and extensor hallucis longus tendons. The superficial peroneal nerve will be visible and should be retracted carefully laterally. At this time, the extensor retinaculum is incised between the tibialis anterior tendon and extensor hallucis longus tendons. The authors prefer to tag the extensor retinaculum at this stage so there is no trouble locating it during final closure. Alternatively, the extensor retinaculum can be cut in a staggered method to prevent the tendons from becoming exposed after closure. 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 artery should be identified and retracted laterally and dissection carried down to the ankle joint for the full length of the incision. It is important to visualize the medial malleolus and most lateral aspect of the distal tibia. Releasing the tissue over the superior lateral talar

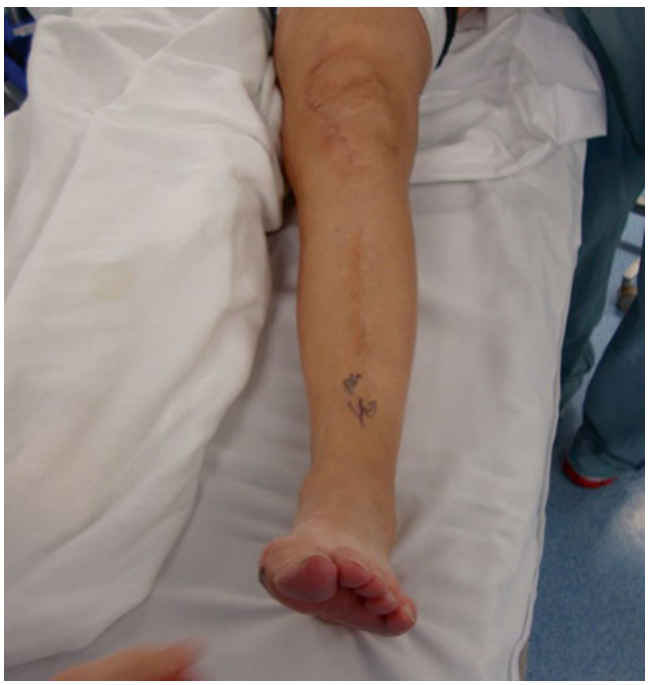

Fig. 11.1 A small bump is under the patient's ipsilateral hip and the patella is facing directly upward

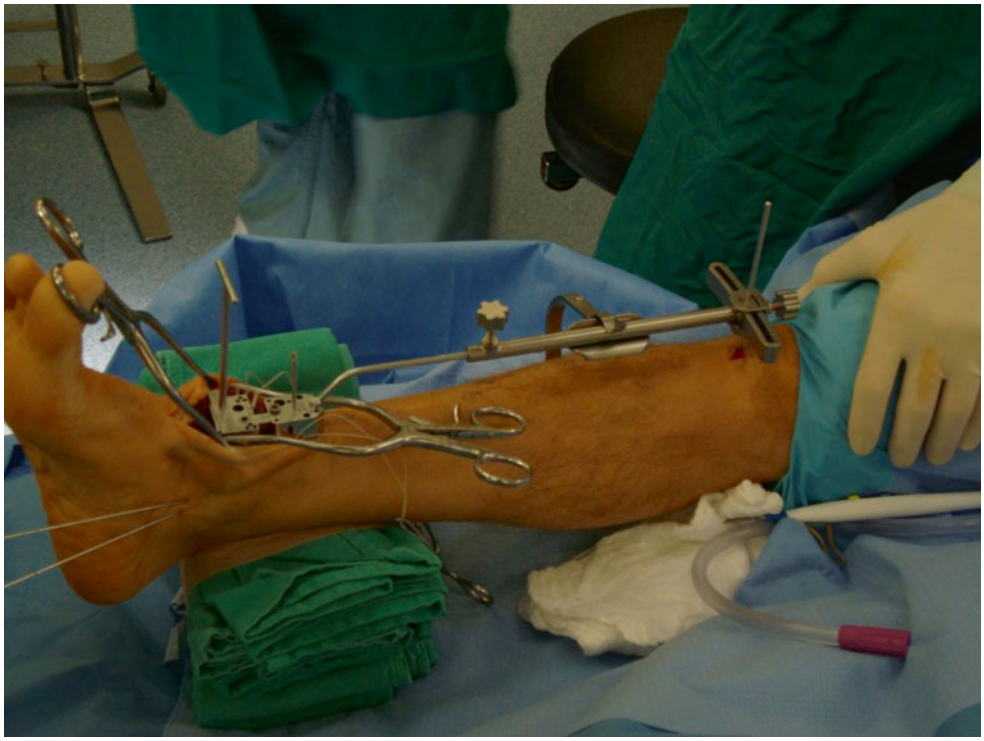

Fig. 11.2 Guide wires are placed in the medial malleolus as close to the cortex as possible to prevent intraoperative fracture. Alternatively a screw(s) can be placed prophylactically in the medial malleolus

neck may help with the visualization at the lateral aspect of the joint. The ankle joint is visualized, and any spurs on the distal tibia can be removed with an osteotome at this time. It is important to identify the tibial plafond at this time as it will help with setting the extramedullary jig out to proper length. At this time, prophylactic guide wires should be placed in the medial malleolus away from the future implant location in case intraoperative fracture of the medial malleolus occurs. Alternatively, a prophylactic screw can be placed at this time as well (Fig. 11.2). It is recommended to notch the distal tibia in a vertical fashion at the medial shoulder of the joint with a small sagittal saw. By scoring the bone 1–2 mm, it will help set the medial aspect of the distal tibial cut once the tibial resection guide is placed (Fig. 11.3).

Placement of the Extramedullary Jig

Under intraoperative C-arm image intensification guidance, a 3.2-mm pin is inserted into the tibial tubercle perpendicular to the long axis of the tibia. A quarter-inch osteotome can be placed in the medial gutter, and the pin should be placed parallel to the osteotome (Fig. 11.4). The tibial alignment guide is placed over this pin in the central hole, and the superior screw is tightened to lock the guide superiorly. The tibial cutting guide at the most 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 reference point for how distal to place the cutting guide (Fig. 11.5). It is also recommended to place the guide on the tibia with equal spacing between the adjustable bar and anterior tibial crest. Usually two finger-breadths is sufficient (Fig. 11.6).

At this point, a quarter-inch osteotome is placed in the medial gutter, and the "T-guide" is inserted into the cutting block to help set the varus/valgus position of the cutting block. The "T-guide" handle should be parallel to the osteotome in the medial gutter (Fig. 11.7).

Alternatively, the handle of the "T-guide" can be aligned with the second metatarsal with the ankle held in neutral position. Once confirmation that the tibial alignment guide is parallel to the tibia diaphysis in both the anterior/posterior and lateral planes with an intraoperative C-arm, a 2.4-mm pin is placed in the distal cutting guide only engaging one cortex. This will still allow for varus/valgus adjustment of the cutting guide as well as the position of the slope. Once the appropriate alignment is confirmed, two additional pins can be placed through the cutting guide to secure it in place (Fig. 11.8).

The level of the tibial resection is checked with the use of the angel wing on a lateral intraoperative C-arm view. The angel wing is placed in the cutting slot of the tibial resection guide for a minimum of 5 mm of the distal tibial resection. The inferior tip of the closest peg is adjusted with the most superior aspect of the distal tibial plafond (Fig. 11.9). Using the gear key on the tibial cutting guide makes adjustments. In addition, at this point the size of the final tibial component can be measured with the angel wing in place. There are seven pegs, each extending 5 mm from the central blade and spaced 10 mm apart.

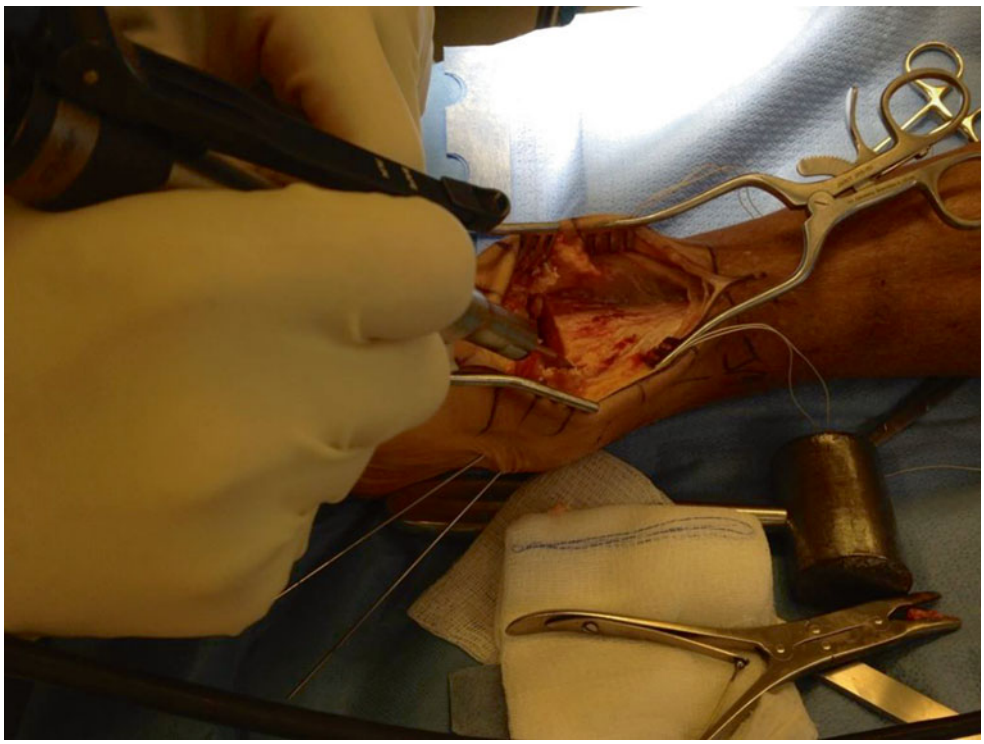

Fig. 11.3 Using a small sagittal saw, the distal medial tibia is scored 1–2 mm deep and vertically directed in line with the medial gutter

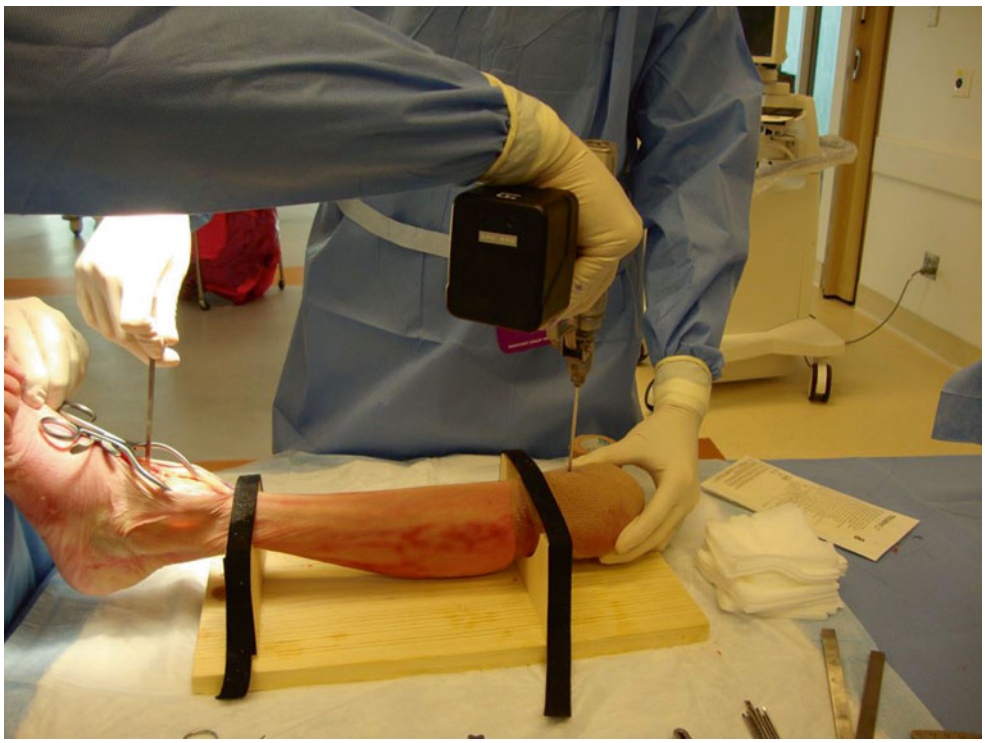

Fig. 11.4 A quarter-inch osteotome can be placed in the medial gutter from anterior to posterior, and the proximal pin should be placed parallel to the osteotome

Once the cutting guide is inserted into the jig the screwdriver can be used in the gear key to complete medial and lateral adjustments of the cutting guide. By placing a free pin in the medial aspect of the saw capture, it should fall into the tibial notch that was created earlier with the small sagittal saw (Fig. 11.10). This should determine 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

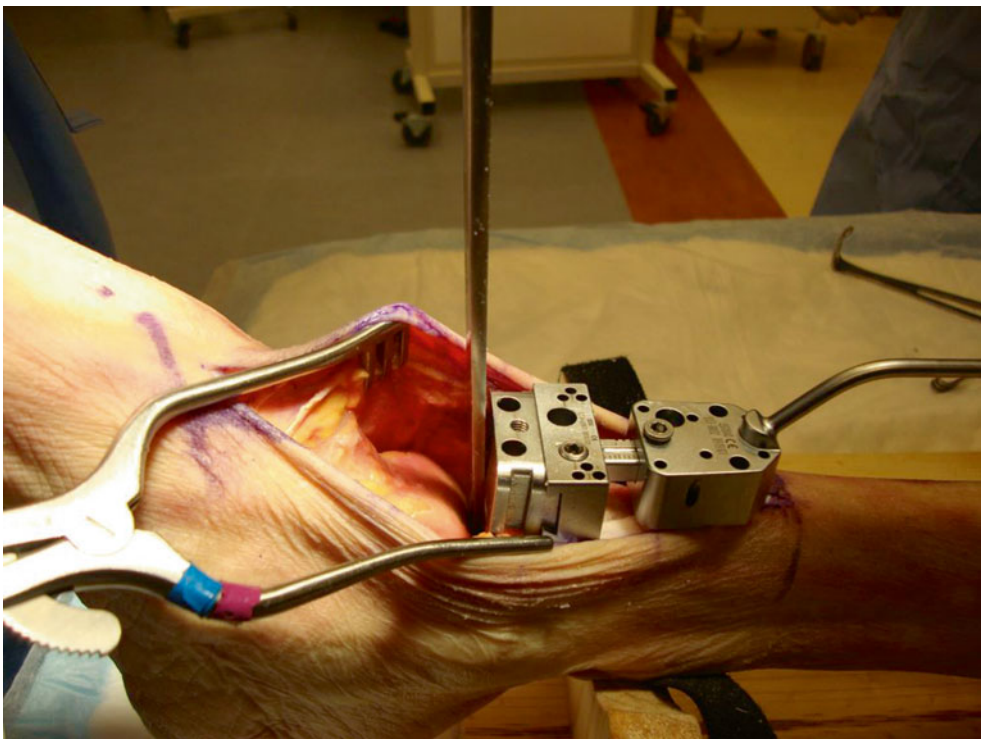

Fig. 11.5 A half-inch osteotome is placed from anterior to posterior in the central aspect of the joint, and the extramedullary jig is lowered until it rests on the osteotome. This will help with proper placement of the jig

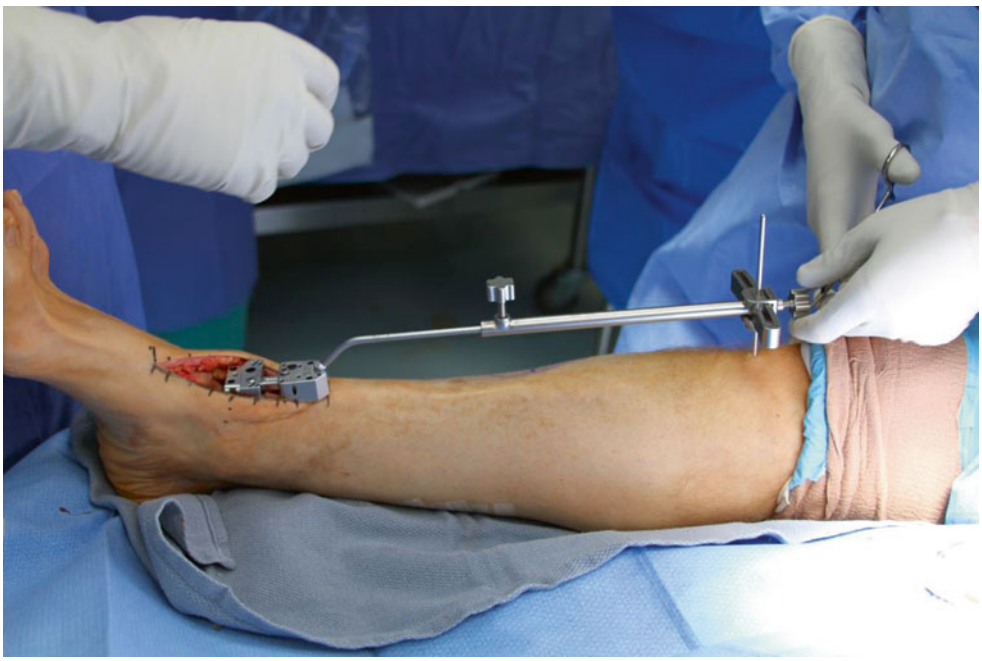

Fig. 11.6 Note the guide over the tibia with equal spacing between the adjustable bar and anterior tibial crest all the way down the tibial shaft. Usually two fingerbreadths is sufficient

can be visualized in the tibia. A transverse distal tibial cut is made through the saw capture, and then the reciprocating saw is used to cut upward along the inner edge of the medial malleolus to connect the transverse cut. The saw capture is then removed, and all 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 and can help free the bone up from the posterior joint capsule.

Preparation of the Talus

The talar cutting guide is inserted into the tibial alignment guide. It is important to have the cutting guide flush with the superior aspect of the talus. Adjustments may need to be made on the tibial alignment guide to bring the talar resection guide down to the talus. The foot should be held perpendicular (90°) to the long axis of the tibia. At this time, pins are

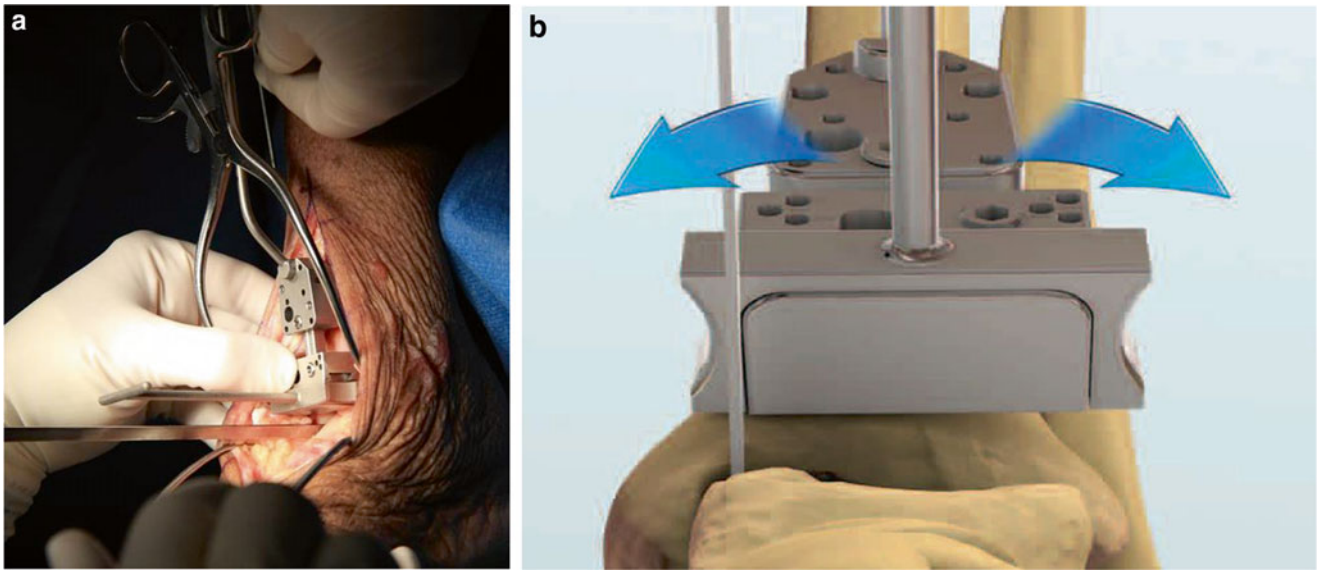

Fig. 11.7 A quarter-inch osteotome is placed from anterior to posterior in the medial gutter, and the "T-handle" is aligned so the two are parallel (**a**). Note that the "T-handle" and osteotome are parallel in the sagittal plane (**b**)

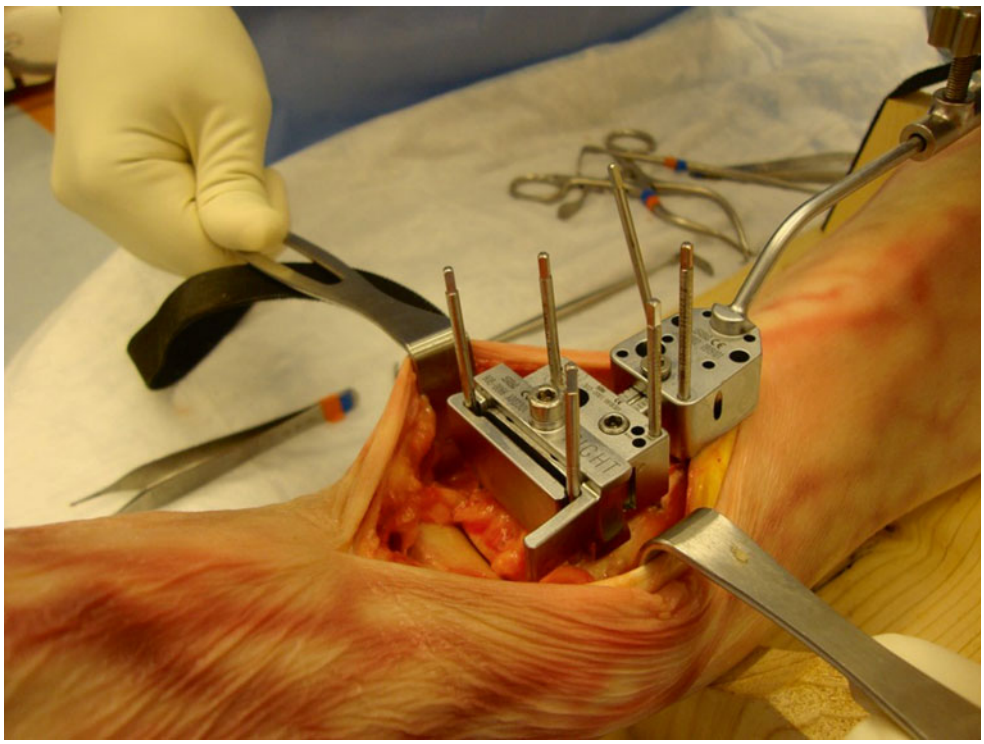

Fig. 11.8 Additional pins are placed in the cutting guide to secure it into place

placed in the outer holes of the talar resection guide to secure the position of the block on the talus. In addition, pins can be placed in the ends of the cutting slot to protect the malleoli during resection. The talus is resected through the saw capture, and the fragment of talar bone is removed. The joint should be evaluated to make sure all bone is removed. A joint space elevator is placed in the resected joint space, and the 12-mm end should fit without any problem (Fig. 11.11). If the joint space elevator does not fit, then additional tibial resection is needed.

At this time, the talar sizer is placed on the resected talus, and this should be a side-to-side fit, meaning the outer edge of the template should match the outer surface of the talus (Fig. 11.12). Once the appropriate size is determined, the

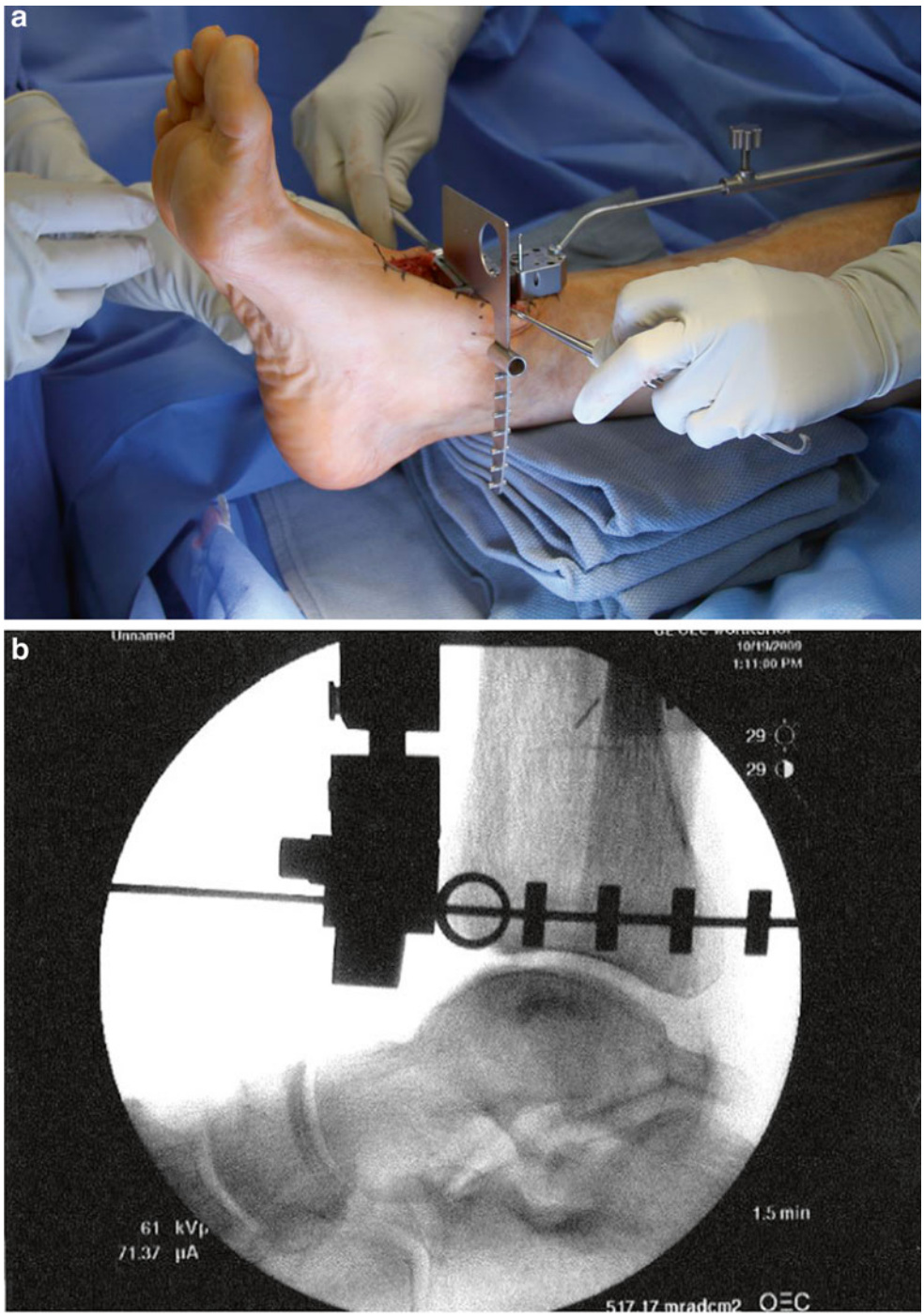

Fig. 11.9 The angel wing is placed in the saw capture, and a lateral C-arm image intensification view is taken (**a**). The angel wing resection height can be adjusted with the screwdriver in the cutting guide. Note that the inferior aspect of the closest pin is placed as close as possible to the superior aspect of the tibial plafond (**b**)

drill guide is attached and pined into place on the superior aspect of the talus. It is important to line the handle of the drill guide parallel and in line with the second metatarsal shaft (Fig. 11.13). A 2.4-mm pin is then placed through 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 that can be confirmed on a lateral C-arm image intensification view (Fig. 11.14). The drill guide is then removed, and the appropriate size datum is placed over the 2.4-mm pin in line with the second metatarsal, and placement is confirmed with a lateral C-arm image intensification view. The posterior/superior aspect of

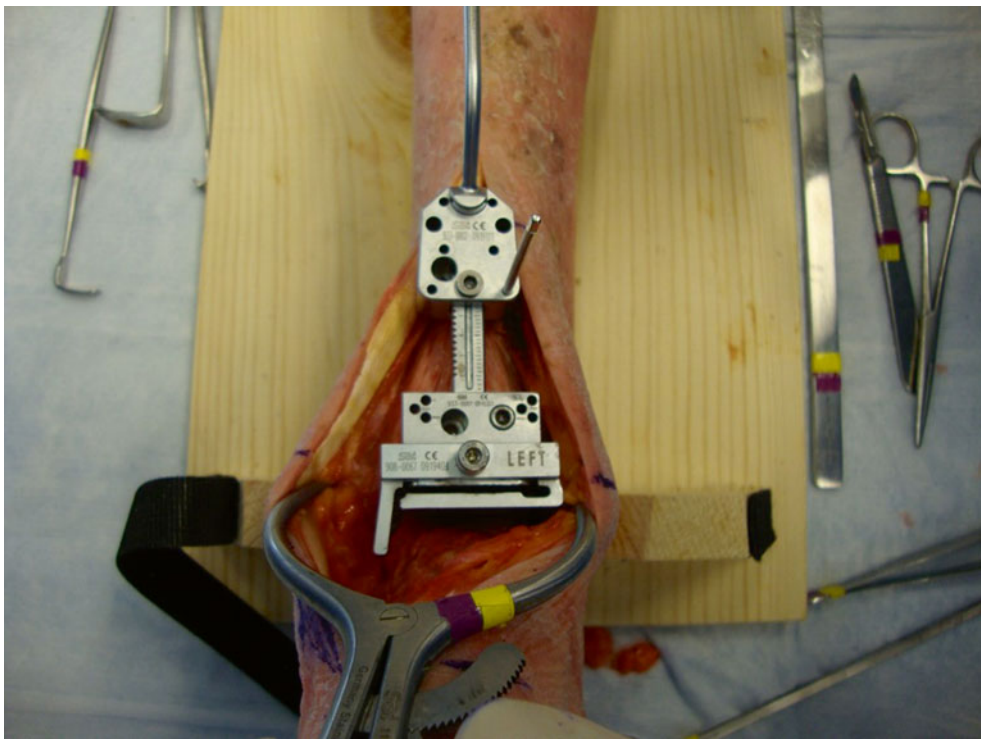

Fig. 11.10 A free pin can be placed in the medial corner of the saw capture. By adjusting the gear key, the pin will fall into the small notch previously made in the distal tibia, and the saw capture will be in perfect position

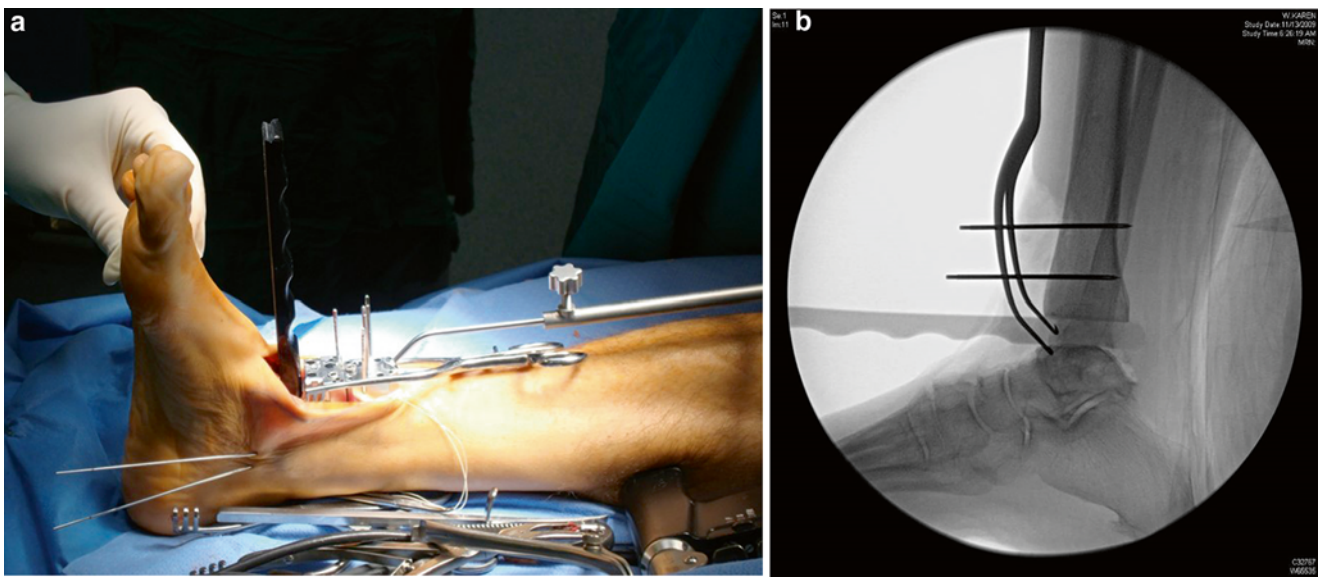

Fig. 11.11 The 12-mm end of the black joint space elevator is inserted into the resected joint (**a**). It should fit without struggling. C-arm image intensification confirmation with the joint space elevator in position demonstrating sufficient bone has been removed (**b**)

the datum should line up with the lateral talar process on a lateral C-arm image intensification view (Fig. 11.15).

Secure the datum to the talus with the drill tip pins and remove the central 2.4-mm wire. Then, insert the anterior/posterior cut guide onto the datum and secure in place with the screwdriver and locking bolt and place a 2.4-mm wire in the center of the cut guide. At this time, the authors prefer to cut the posterior talar cut through the cut guide first. Attention should be made to the most posterior-medial and posterior-lateral corners to make sure all bone is cut. Next, the anterior

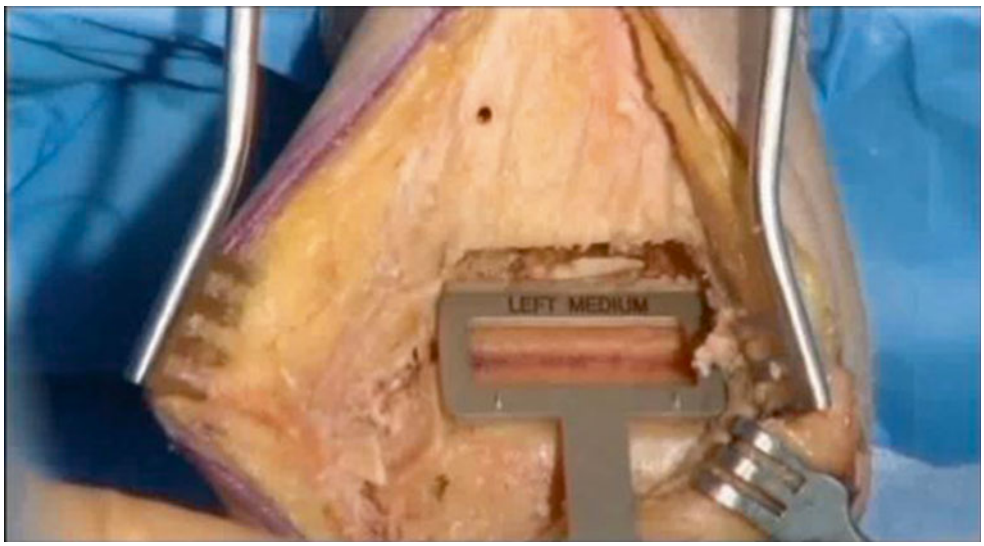

Fig. 11.12 The talar sizer is placed on the talar cut. It should fit side to side on the medial and lateral aspect of the talus

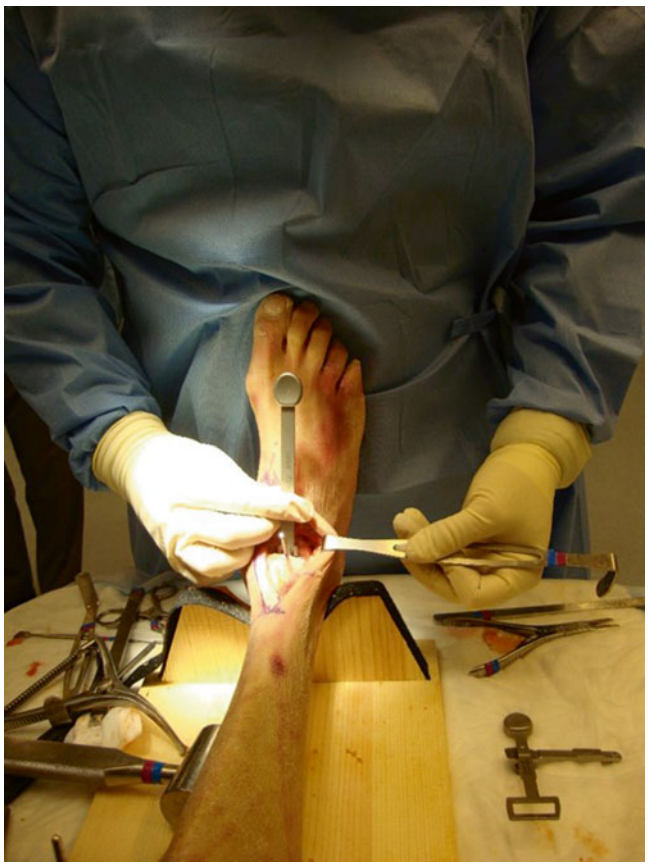

Fig. 11.13 The handle of the talar sizer should be lined up with the second metatarsal shaft to ensure appropriate positioning

talus is prepared with the hard stop reamer. Start with the distal slot and proceed to the proximal slot by using a pecking and sweeping motion (Fig. 11.16). Once this is complete, the anterior/posterior cut guide can be removed. The reamed bone from the anterior talar preparation can be collected and used to help pack the barrel holes in the tibia after the final tibial component is inserted.

Now the medial/lateral cut guide can be secured to the datum with the locking bolt. The reciprocating saw is then placed into the cut guide on the medial and lateral cut slots. The blade should be inserted to the laser line (Fig. 11.17). The saw should be started with the blade in the 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. The medial/lateral cut guide can now be removed as well as the datum. Using a small osteotome, remove the medial and lateral 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. Any additional bone contouring can be done very easily and quickly with a power rasp (Fig. 11.18).

The talar window trial is now placed over the prepared talus. It should fit without any gapping on the talus. If gapping is present, the excess bone needs to be removed. The window is then secured into place with 2.4-mm pins. A laminar spreader can be used to help push the talar window trial down before pinning if needed. 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. 11.19).

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

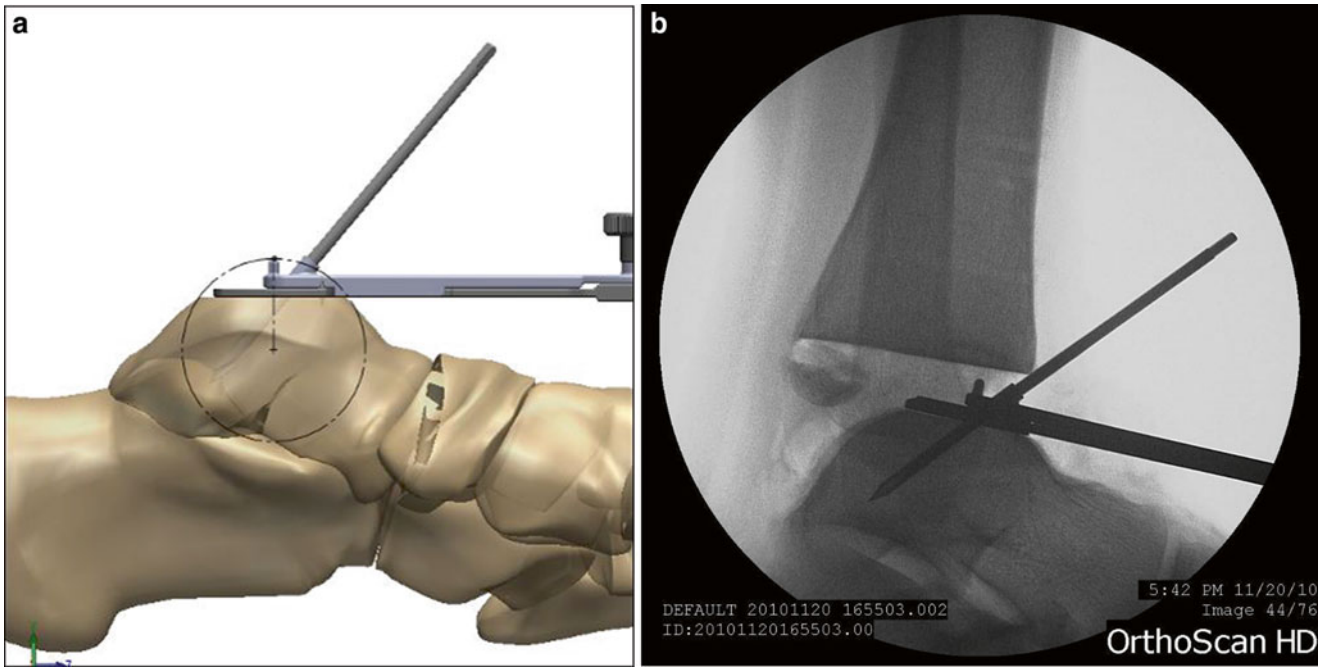

Fig. 11.14 The post of the drill guide is lined up with the lateral process of the talus (**a**). C-arm image intensification confirmation that the guide is in appropriate position (**b**). Note that the guide is also sitting flush with the superior talar cut

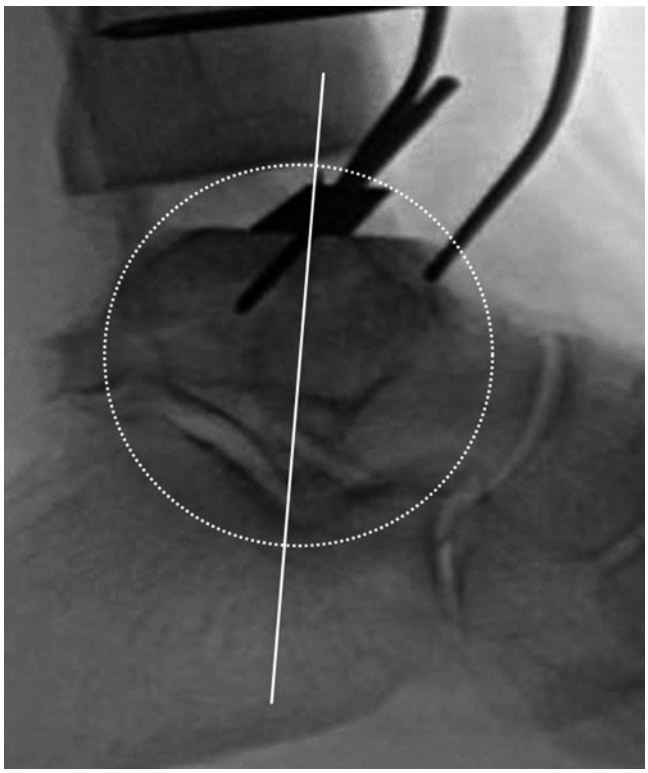

Fig. 11.15 The datum is appropriately placed when the posterior superior corner is lined up with the lateral process of the talus as confirmed with a lateral C-arm image intensification view

sure the anterior mill is complete. The window trial is then removed, and the talar keel broach is inserted so that it is flush with the superior and anterior aspect of the talar keel (Fig. 11.20).

Implant Sizing and Implantation

At this time, before placement of the definitive talar component, the tibia size can be determined by using the ruler in the tray. Hook the ruler around the posterior cortex of the distal tibia and measure both medially and laterally (Fig. 11.21). It is also beneficial to place a 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 appropriate-sized tibial barrel hole guide and inserting the blue spacer from the set to push the trial up against the distal tibia (Fig. 11.22). This can be checked with a lateral C-arm image intensification view to make sure the trial is flush with the tibia (Fig. 11.23). 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. 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 a

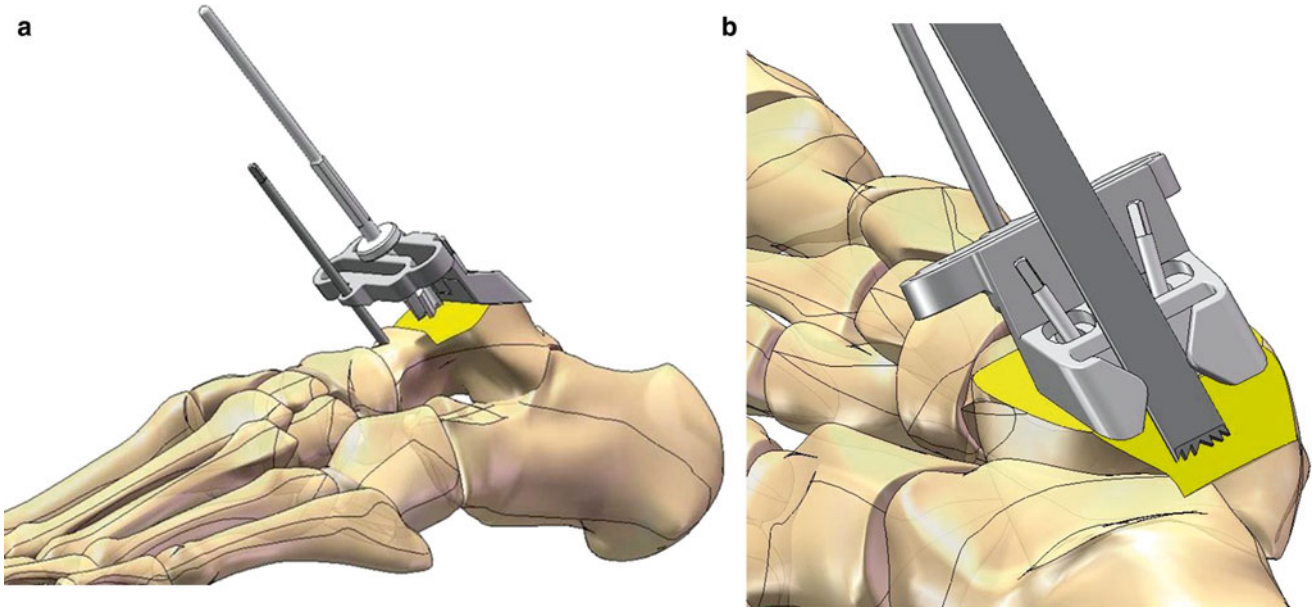

Fig. 11.16 The anterior/posterior cut guide is placed on the datum and secured into position (**a**). The anterior aspect of the talus is prepared with the hard stop reamer. The posterior cut is then made through the saw capture with attention to the most posterior, medial, and lateral aspects of the talus (**b**)

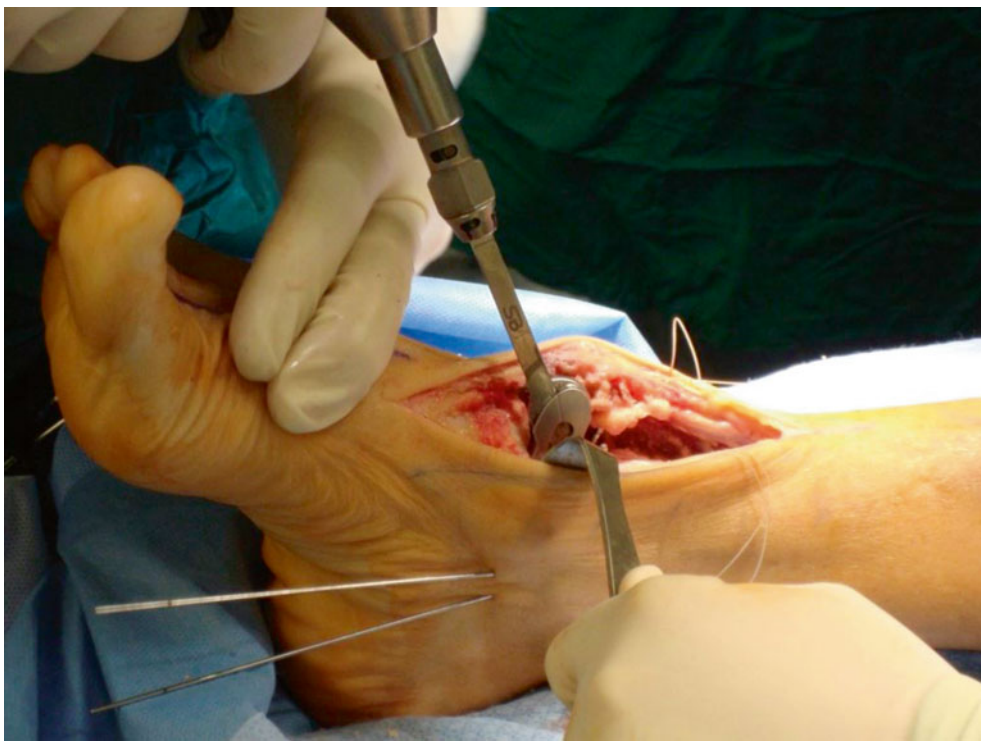

Fig. 11.17 The medial/lateral cut guide is placed on the datum. Note the laser mark on the saw and the engraved line on the guide

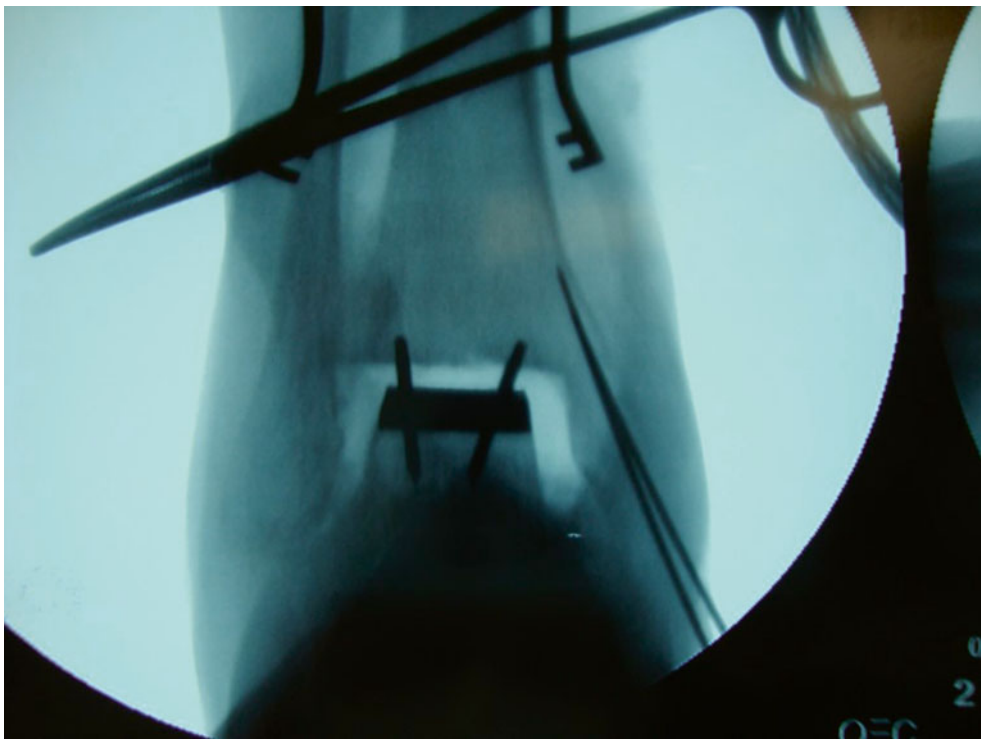

Fig. 11.18 Gutter preparation can be done very easily with a power rasp

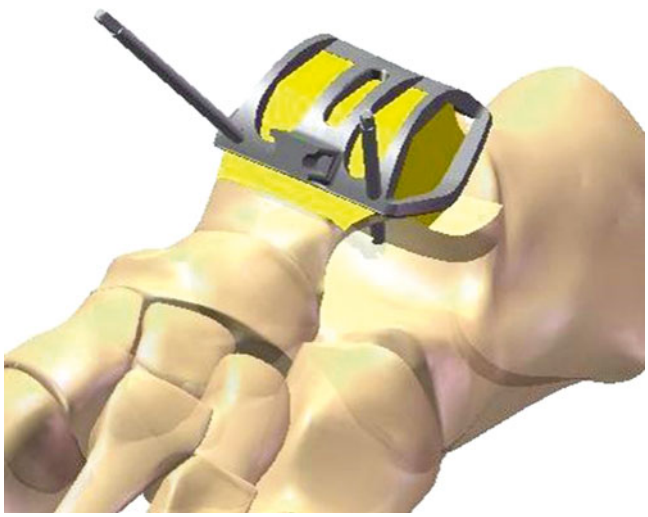

Fig. 11.19 The window trial should sit flush on the talus. The pins are placed anteriorly to secure it in position before the talar keel is reamed

lateral C-arm image intensification view to make sure it is flush. Alternatively, a trial polyethylene insert can be inserted and 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 image intensification that it is in correct position relative to the talar component (Fig. 11.24). Drill one of the barrel holes with the 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 2.2-mm pin in place. Lifting the guide straight up on the wire can usually do this. The final tibial component is then inserted into the prepared tibia with the tibial inserter handle parallel to the wire 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 space bar elevator can be used to seat the implant so it is under the anterior tibial cortex. At this time, the trial polyethylene bearing is placed into the joint and is assessed with dorsiflexion–plantar flexion arc and varus/valgus stressing (Fig. 11.25). Once the appropriate polyethylene size is noted, the final polyethylene bearing is inserted (Fig. 11.26).

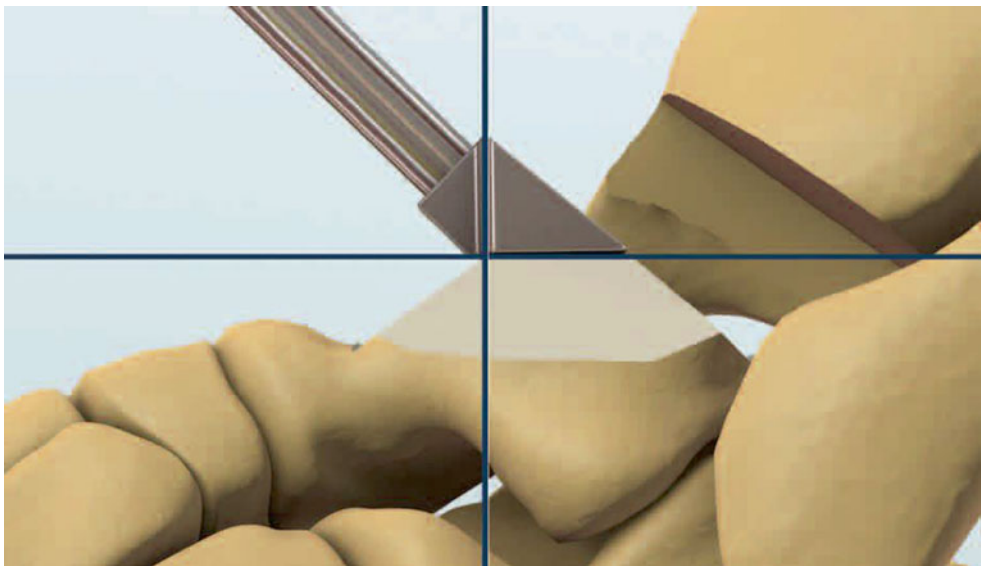

Fig. 11.20 The keel broach must sit flush with the superior and anterior aspect of the talus to seat the talar component in the correct position

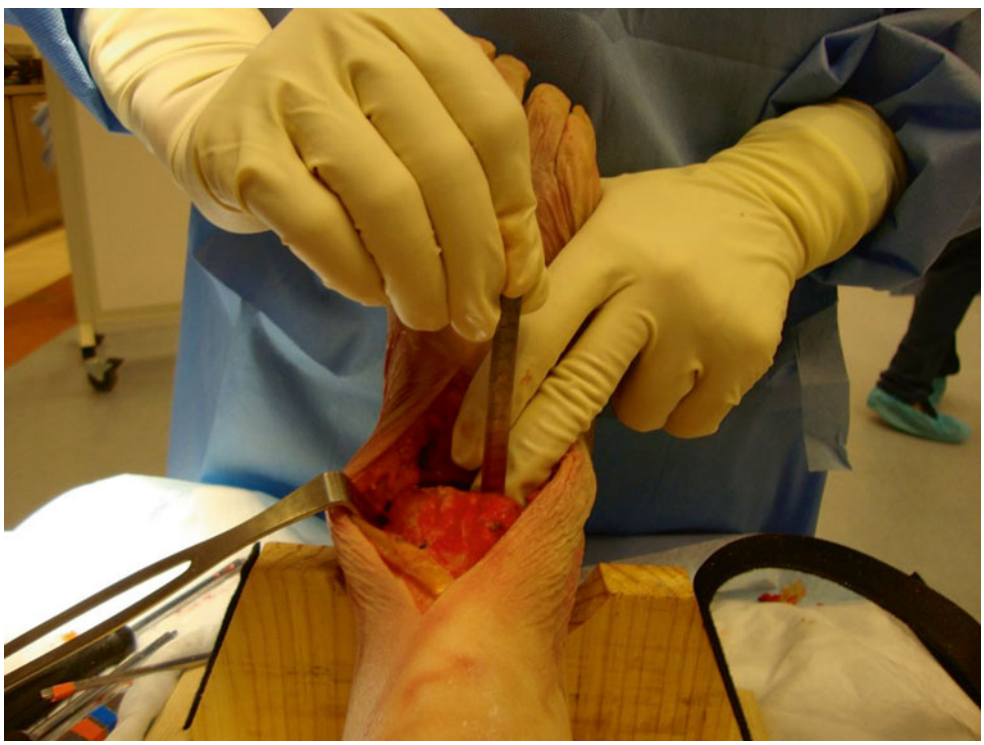

Fig. 11.21 The hooked ruler in the set is then used to grab the posterior aspect of the tibia, and measurements should be taken both medially and laterally to determine what size tibial component should be used

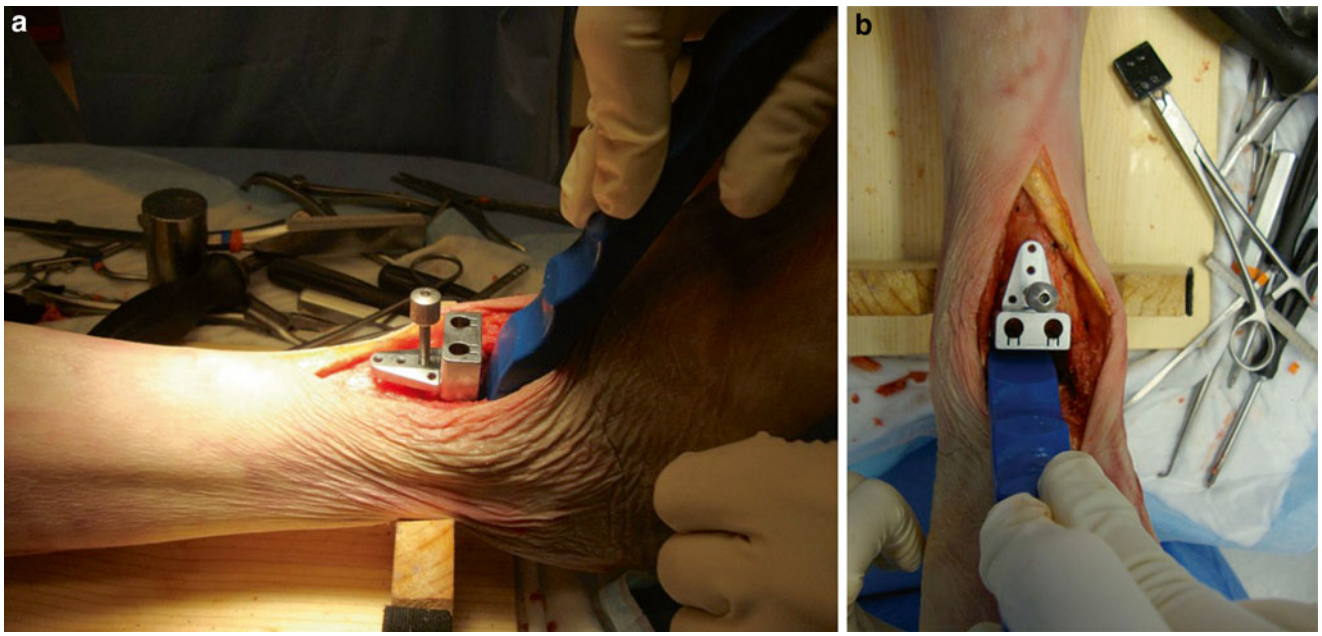

Fig. 11.22 Side (**a**) and anterior (**b**) views of the *blue spacer bar* pushing the tibial barrel hole guide so it is flush with the prepared tibia

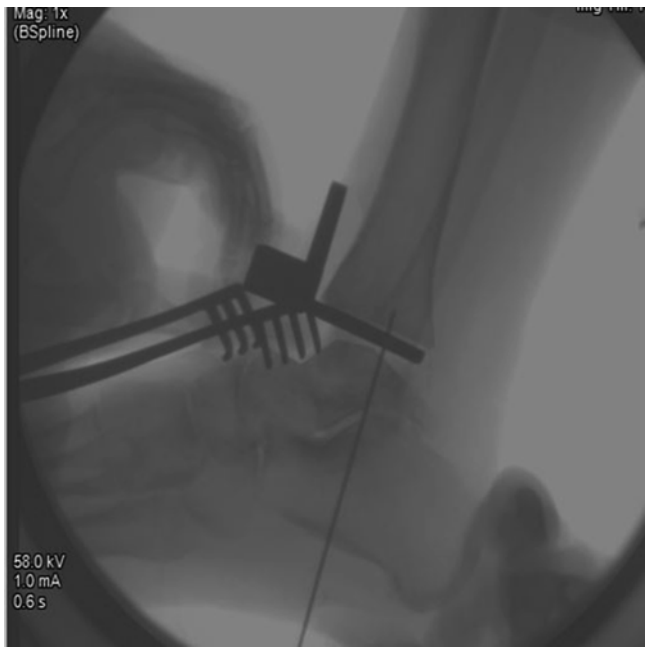

Fig. 11.23 Confirmation that the tibial barrel hole guide is flush with the resected tibia. If it is not flush, then either the bone or soft tissue impingement must be removed

Conclusions

TAR represents a viable option for individual affected by end-stage ankle arthritis. The STAR ankle replacement minimizes bone resection and allows for the implantation of a mobile-bearing implant to possibly help minimize stresses at the bone–implant interface. Ankle arthrodesis has long been considered the "gold standard" for treatment of end-stage ankle arthritis. Recently, that has been challenged in a large meta-analysis that shows a revision rate of 9 % and an amputation rate of 5 % [19]. TAR has been shown to be equal to ankle arthrodesis in terms of pain improvement [16]. In addition, improvements in quality of life [4] and gait have been reported [5, 20]. Likely the usage of TAR will continue to increase over the next decade.

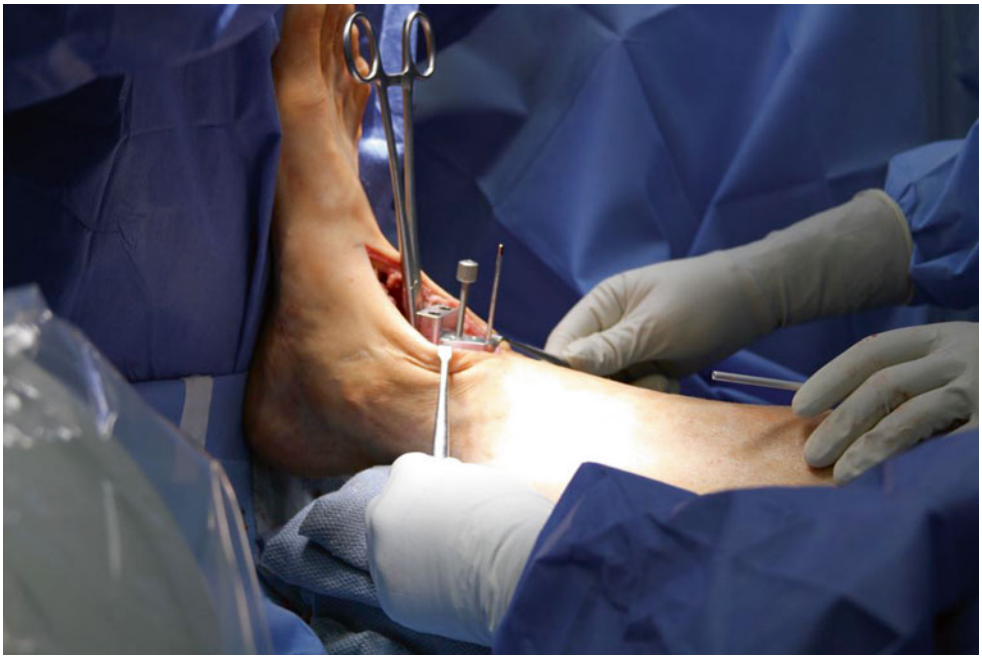

Fig. 11.24 The barrel hole guide is secured to the tibia with a 2.4-mm pin through the distal hole in the guide after confirmation with C-arm image intensification that it is in correct position relative to the talar component. Note how the hand is slightly plantarflexed while drilling the barrel holes

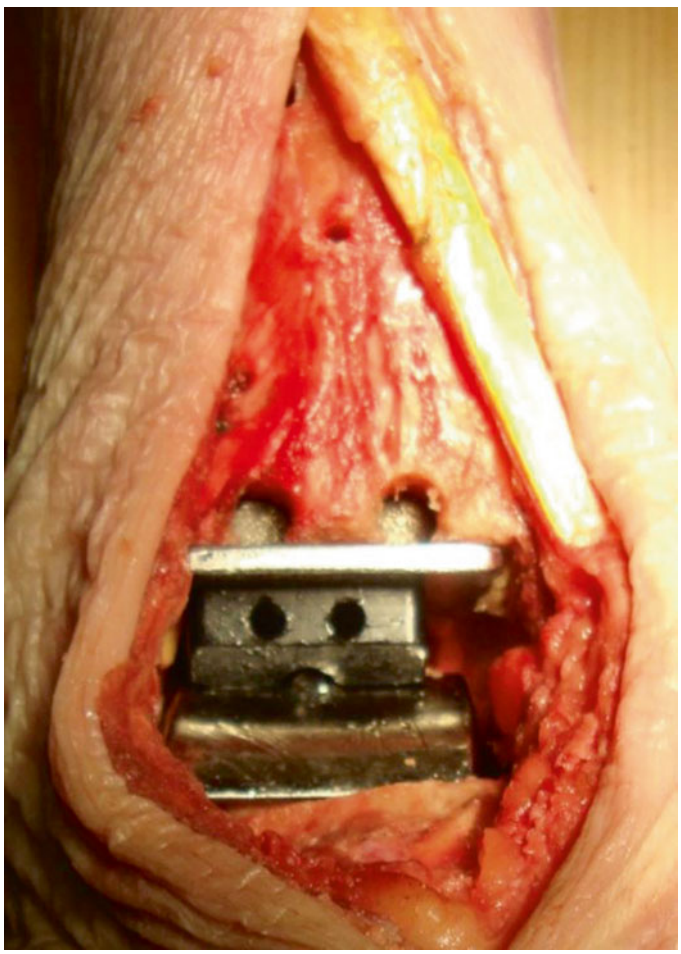

Fig. 11.25 A trial poly is inserted and evaluated for correct thickness

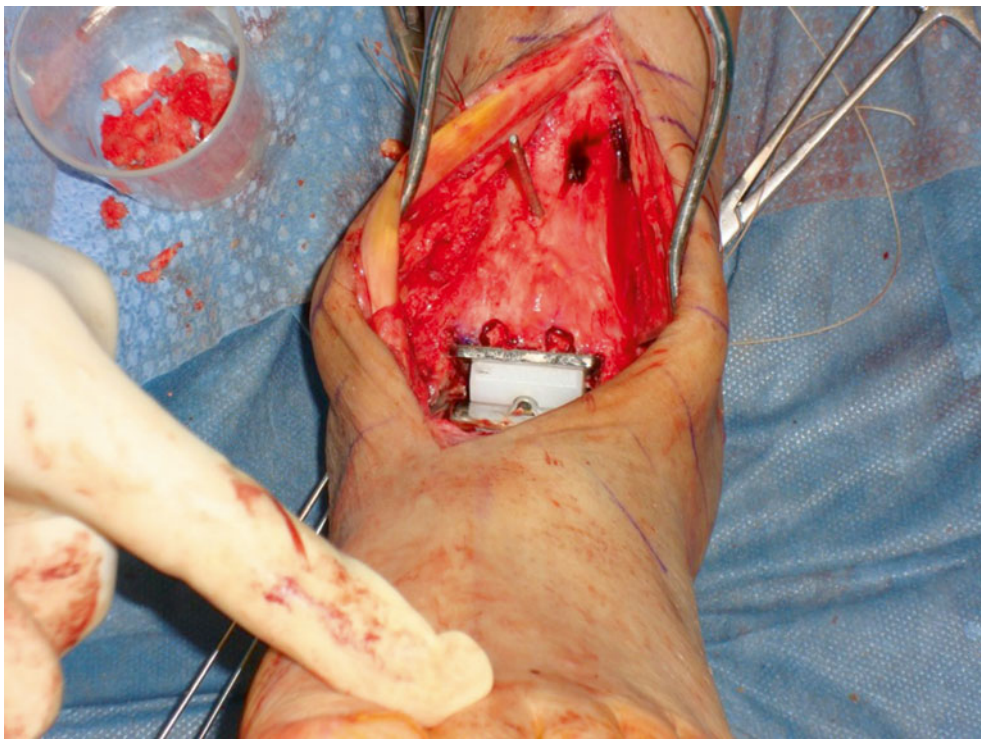

Fig. 11.26 Definitive poly is inserted

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Primary Zimmer Trabecular Metal Total Ankle Replacement

12

Stephen A. Brigido and Lawrence A. DiDomenico

Introduction

Despite increased popularity over the last several decades, total ankle replacement (TAR) continues to provide challenges for surgeons, patients, and device engineers. The Zimmer Trabecular Metal TAR (Zimmer, Warsaw, IN) was designed to address the challenges that are routinely encountered with primary TAR, such as bone fixation, excess osseous resection, and wound healing issues. This third-generation prosthetic is a semi-constrained, fixed-bearing device that is implanted through a lateral, transfibular approach. The system comes equipped with alignment and cutting guides to optimize implantation. Traditionally, TARs have utilized flat, nonanatomic tibial resection; this prosthetic differs from traditional prostheses in that the guides are designed to preserve the normal arched contour of the ankle joint, potentially maximizing joint range of motion.

The Zimmer Trabecular Metal TAR combines two formerly established patents: the "Iowa/Hospital for Special Surgery (HSS)" and the "Baltimore." The Iowa/HSS patent introduced the concepts of an alignment guide and anatomically designed implant components. The alignment guide aims to stabilize the leg in an anatomic position, minimizing error during implantation, and the anatomic prosthetic components seek to more closely mirror normal joint kinematics and biomechanics. Alternatively, the Baltimore patent contributed the use of a "cutting guide" to perform reproducible, anatomically contoured bone cuts on the opposing joint surfaces. This concept was derived from ankle allograft transplant technology where matched cuts from both the resected damaged articular surface and the donor surface were utilized to recreate an anatomically aligned joint. Incorporating these concepts, the Zimmer Trabecular Metal implant was designed with the following goals: minimize bone resection, maximize surface area, and mimic the natural anatomy of the ankle joint.

Given that survivorship is often associated with TAR component alignment, this prosthetic uses a combination of intramedullary and extramedullary guidance. The surgeon aligns the intramedullary axis guide in line with or parallel to the anatomic axis of the tibia. The extramedullary alignment guide is aligned perpendicular to the anatomic axis and is utilized to adjust for any frontal plane malalignment issues. This hybrid approach allows the surgeon to adjust the cutting guide and precisely select the joint's axis of rotation, based upon the patient's individual anatomy. The axis of rotation then serves as a reference for tibial and talar bone resection. Notably, bone resection yields one radius of curvature for the talus and a second, longer radius of curvature for the tibia, simulating normal anatomic features. Because minimal osseous resection is required for implantation, the prosthesis sits in solid subchondral/metaphyseal bone (Fig. 12.1), and in the event of revision and/or conversion to ankle arthrodesis, the subsequent procedure requires minimal bone grafting.

A unique feature of Zimmer Trabecular Metal TAR is its articular surface, which arches like the frustum of a cone (Fig. 12.2). The medial side of the prosthesis has a smaller radius of curvature than the lateral side, which avoids increased strain on the medial and lateral ligament complexes and permits dorsiflexion with slight eversion and plantar flexion with slight inversion. Within the joint, the center point of contact shifts anteriorly with dorsiflexion and posteriorly with plantar flexion, mimicking normal biomechanics. This prevents pressure discontinuity across the implant surface during gait. Compared with the flat design of the Agility and Agility LP TAR (DePuy Synthes, Warsaw, IN), the contoured design of the Zimmer

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_12

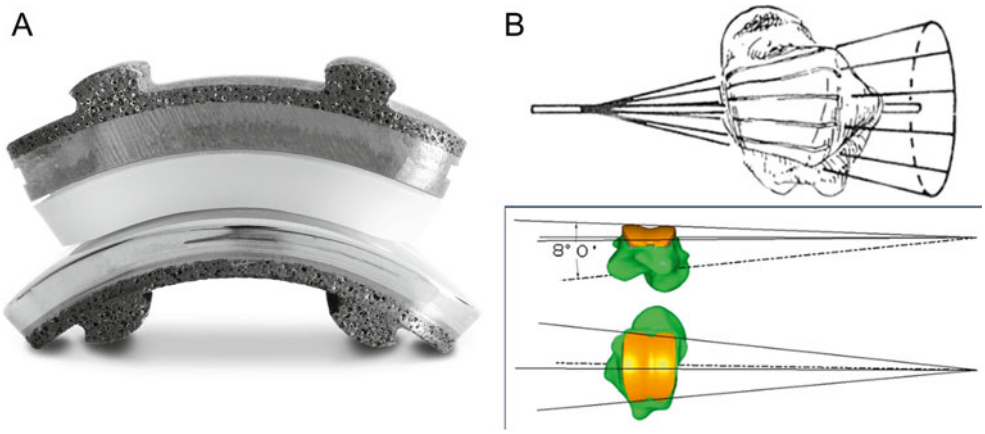

Fig. 12.1 Osseous resection. The implant rests on the subchondral bone, requiring minimal bony resection for implantation (**a**). A comparison of the arched cut and a flat cut and the amount of bony resection (**b**). Note that the Zimmer Trabecular Metal Total Ankle replacement system requires minimal, more anatomic resection (**b**). Utilized with permission from Zimmer

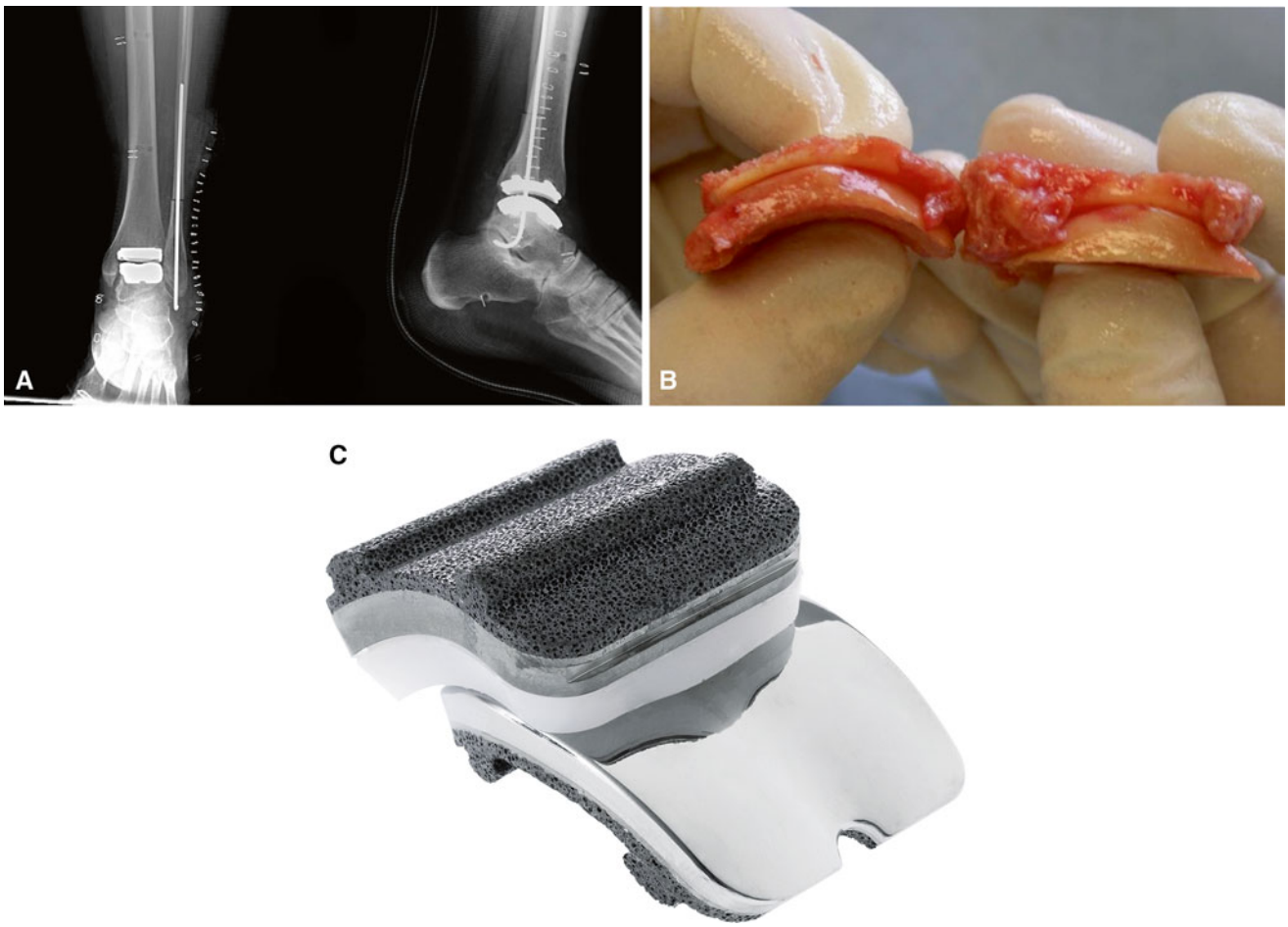

Fig. 12.2 Implant design. Medially, the talar articular surface has a smaller radius of curvature (**a**, **b**), allowing continuity during ankle joint range of motion and mimicking the frustum of a cone (**c**). Images utilized with permission from Zimmer

Trabecular Metal TAR provides twice the contact area with lower peak contact pressures [1]. The semi-constrained design of the prosthesis also permits anterior–posterior and axial rotation up to 3°. Moreover, the tibial and talar rails located at the component–bone interfaces are perpendicular to the ankle joint axis of motion, which increases initial stability of the implant permitting early range of motion without the consequence of component displacement. Since the curvature of the prosthesis aligns with the natural trabecular architecture of the tibia and talus (Fig. 12.3), bone remodeling in response to implant stresses may be reduced, while the bicondylar design may limit edge loading and resultant osteolysis.

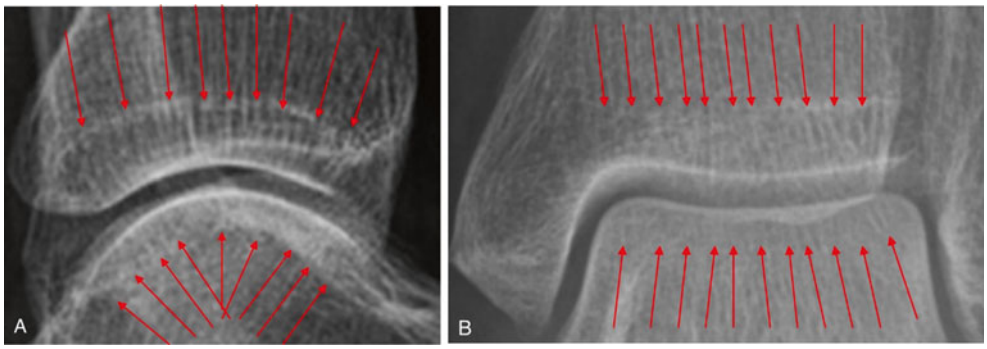

Fig. 12.3 Bone trabecular pattern. *Red arrows* indicate the natural trabecular pattern of the tibia and talus at the level of the ankle joint from a medial view (**a**) and from an anterior view (**b**). The implant aligns with the trabecular pattern, which decreases the bony response to stresses around the implant following insertion. Images utilized with permission from Zimmer

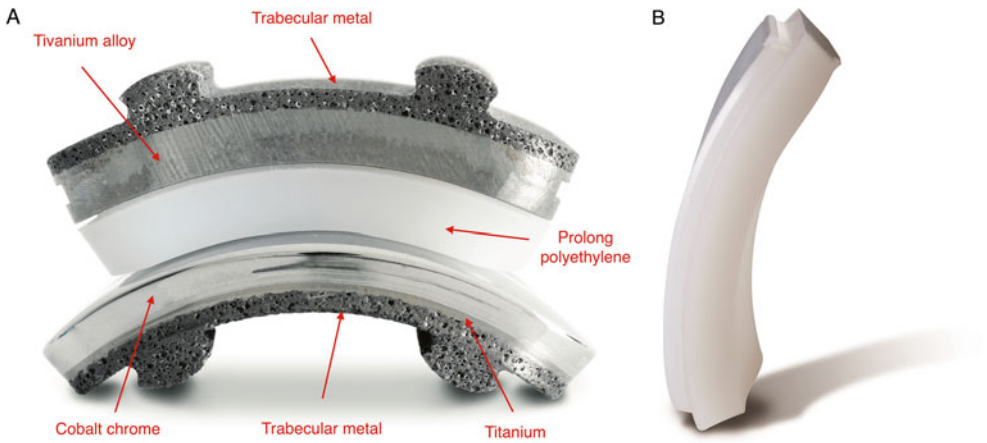

Fig. 12.4 Component materials. The tibial and talar components are comprised of multiple materials allowing for biocompatibility, bony ingrowth, and implant stability (**a**). The Prolong highly cross-linked polyethylene (HXLPE) is manufactured to create less debris and wear more slowly than traditional polyethylene components, decreasing the risk of osteolysis and failure (**b**). Images utilized with permission from Zimmer

Prosthetic Components

Tibial and Talar Components (Fig. 12.4)

The tibial component is made of a Tivanium alloy, diffusion bonded to trabecular metal. Tivanium is titanium with 6 % aluminum and 4 % vanadium (Ti-6Al-4V). The talar component consists of a Zimaloy articular surface, which is a combination of cobalt chrome and molybdenum (CoCrMo) and a trabecular metal and titanium distal surface. Trabecular metal is a highly porous biomaterial [2, 3] made of tantalum, which resembles trabecular bone [3]. Tantalum is a biocompatible metal that is chemically stable and inert, rendering it resistant to corrosion with mechanical properties that are superior to titanium [4]. The metal is 80 % porous, allowing for enhanced bone ingrowth [2, 5], improving the long-term fixation of the prosthetic components [3]. Statistically significant increases in new bone formation and greater fixation strength have been reported to occur earlier in the postoperative period when comparing a highly porous tantalum metal component with a porous-coated component [2]. Additionally, tantalum has been shown to have a high coefficient of friction [2, 6], high fatigue strength, and a modulus that allows bending before breakage [4], all of which contribute to a decreased risk of osteolysis [7] and subsequent implant failure. The use of this highly porous metal for total knee replacement has demonstrated a statistically significant lower risk of aseptic loosening at 5 years, compared with traditional cemented modular tibial components [3, 8, 9]. Trabecular metal total hip replacements have also resulted in less stress shielding of the underlying subchondral bone, compared with titanium implants. Ultimately, the changes in bone mineral density surrounding the implant are minimized [10], which lends to greater implant stability and a decreased risk of failure [10].

Polyethylene

The modular articular surface of the implant is made of Prolong highly cross-linked polyethylene (HXLPE) and is available in three thicknesses (+0-mm, +2-mm, and +4-mm) (Fig. 12.4). It is well documented that polyethylene wear can create debris and lead to aseptic loosening of the prosthesis with subsequent implant failure [11, 12]. Therefore, polyethylene components that wear more slowly generate less debris and are advantageous to the long-term success of the implant. The HXLPE utilized by the Zimmer Trabecular Metal TAR system has been shown to exhibit enhanced wear properties [13–17], resistance to oxidative degeneration [15, 16], and delamination [15] with the absence of free radicals [16], all of which decrease the risk of osteolysis and premature implant failure.

The Science behind the Transfibular Approach

The authors believe that the lateral transfibular approach yields several key benefits to TAR implantation. First, entry through the lateral aspect of the ankle respects the angiosomes of the lower extremity [18]. Attinger and colleagues recommend making foot and ankle incisions at the junction of two angiosomes to provide both sides of the incision with an adequate blood supply [18] (Fig. 12.5). With the lateral approach, an incision is placed at the junction of the anterior tibial artery and peroneal artery angiosomes. With the traditional anterior approach, however, an incision is placed roughly down the middle of the anterior tibial artery angiosome [18, 19]. Therefore, lateral incision placement may decrease postoperative wound healing complications [19].

Examining the complications following TARs implanted via an anterior midline incision, a review of the literature demonstrated that superficial wound healing complications range from 0 to 14.7 %, with a mean of 8 % [20] and deep wound complications with postoperative infections range from 0 to 4.6 %, with a mean of 0.8 % [20]. Alternatively, using a lateral approach for TAR, Rudigier reported a 5 % (8 of 159 patients) wound complication rate [21]. Notably, all wounds healed without additional complication [21]. While encouraging, additional comparative investigations are needed to draw definitive conclusions regarding the incidence of postoperative wound healing complications following TAR with an anterior approach versus a lateral approach.

A second benefit of the lateral approach is the direct visualization of the lateral tibiotalar joint once the fibula is reflected distally. This approach allows the surgeon to accurately assess the normal arc of rotation and precisely identify the center axis of each patient's ankle joint. Through the lateral cortical window, the alignment guide can be rotated around the center axis to dictate accurate bony resection and subsequent implant placement. Additionally, if a procurvatum or recurvatum deformity exists, the cutting guide can be rotated more anteriorly or posteriorly for deformity correction.

It is well known among foot and ankle surgeons that soft tissue balancing procedures are paramount to successful TAR stability and reduction of varus/valgus malalignment. However, osseous deformity that goes unaddressed can also contribute to postoperative malalignment. Through the lateral transfibular approach, the fibula can be shortened to correct for varus malalignment or lengthened to correct for valgus malalignment. Brooke and colleagues reported two cases of postoperative valgus after TAR that were successfully corrected with a fibular osteotomy [22]. These findings demonstrate that fibular osteotomies can be successfully utilized for rebalancing osseous deformity of the ankle [22].

While there are many benefits to the lateral transfibular approach, there are also drawbacks. The creation of a fibular osteotomy introduces the risk of nonunion and malunion. Following implantation of the ESKA^{T} TAR (ESKA implants, GmbH, Lubeck, Germany) through a lateral transfibular approach, Rudigier reported three (1.9 %) delayed unions and one (0.6 %) nonunion [21]. Although the risk of nonunion is minimal, postoperative protocols must be adjusted to allow for osteotomy healing. Some cases may require prolonged immobilization, which introduces the risk

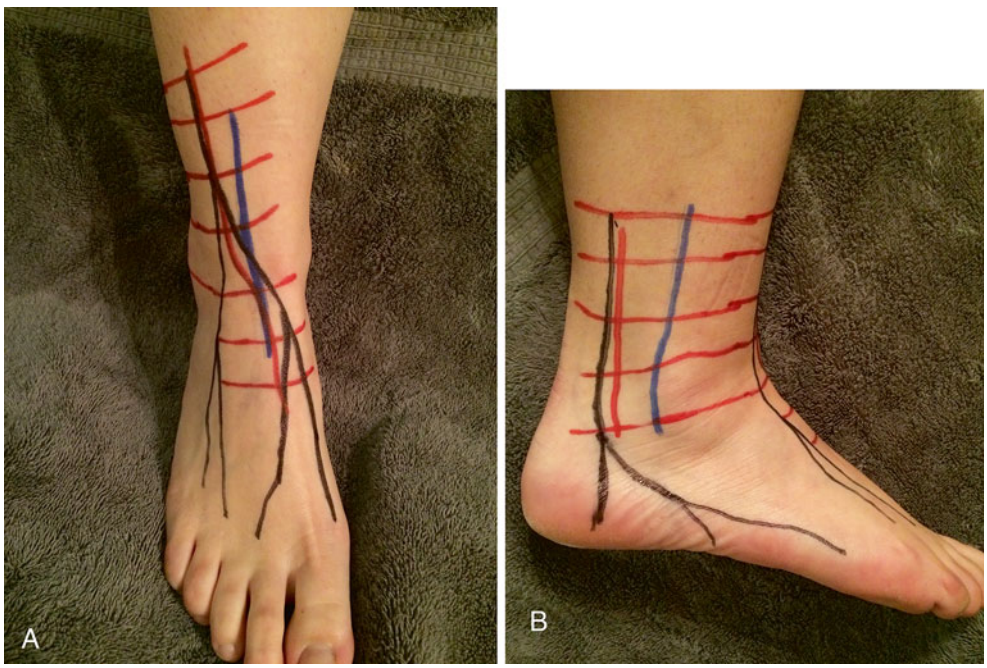

Fig. 12.5 Angiosomes. Skin incisions, for the anterior midline approach (**a**) and lateral transfibular approach (**b**), are shown in *blue*. The vascular anatomy and angiosomes are indicated in *red*, while the innervation is indicated in *black*. The anterior midline incision cuts through the anterior tibial angiosome. The lateral transfibular incision is located at the junction of the anterior tibial and peroneal angiosomes, a more ideal location for incision healing

of postoperative stiffness, while others may necessitate reoperation. Nonunion of the fibula can lead to instability of the prosthesis and subsequent malalignment and/or implant failure. The anterior talofibular ligament is sectioned to gain access to the joint and must be repaired upon closure. Delayed healing or inadequate repair can also render the ankle unstable postoperatively. Surgeons must also make a separate incision to correct or balance any medial soft tissue pathology. In many instances, this can be achieved with a "mini-open" medial arthrotomy.

Alignment System

The alignment system is designed to hold the extremity static in an anatomic position, permitting accurate bone resection (Fig. 12.6). Prior to the procedure, the majority of the alignment guide is constructed on the back surgical table. The position of the lateral cut guide, talar pin connector, and footplate is dependent upon the operative side; therefore, this information must be conveyed to the surgical technician prior to the procedure. Once the extremity is appropriately

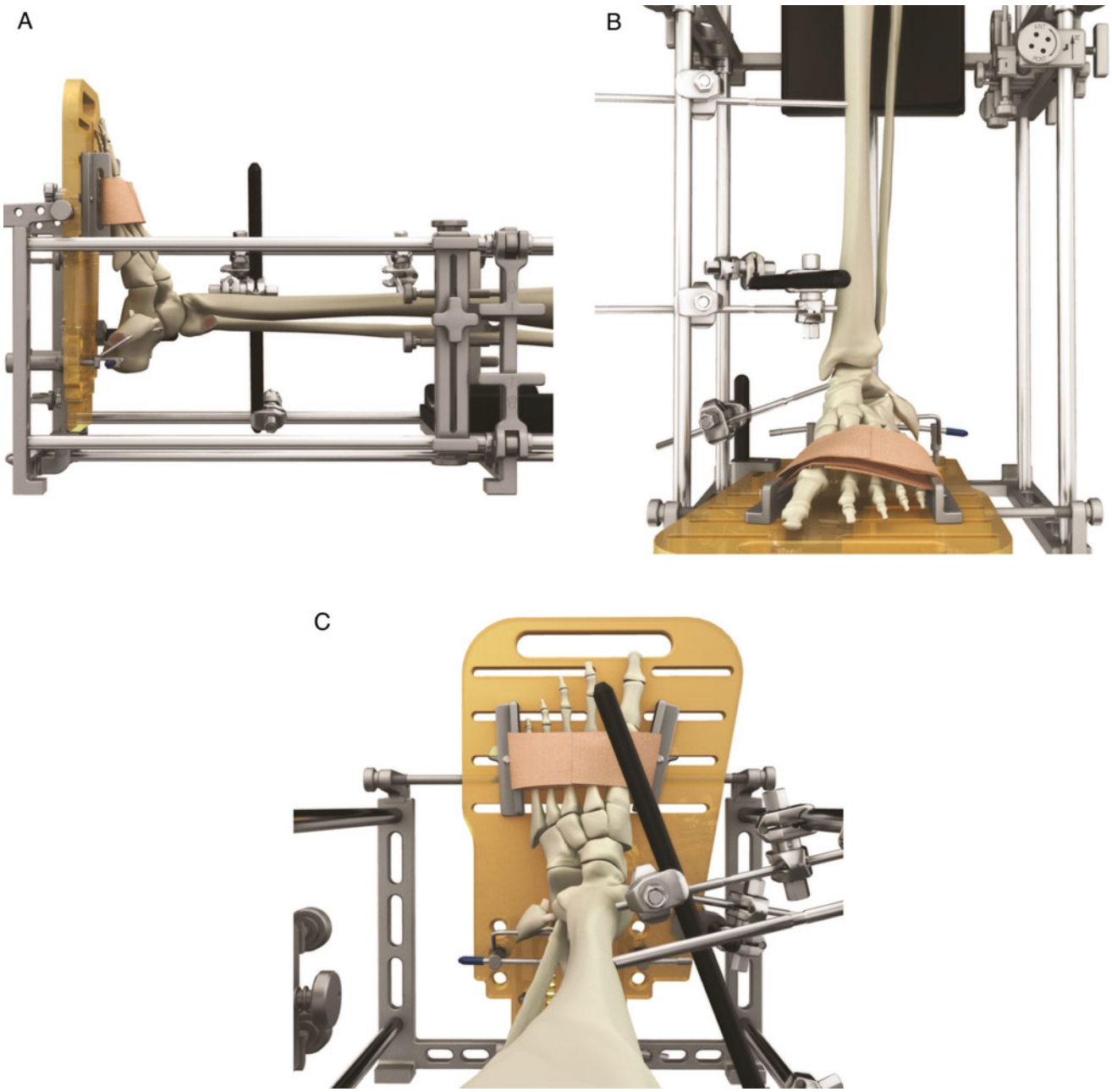

Fig. 12.6 Alignment frame. The alignment frame is specifically designed to anatomically align and hold the extremity static throughout implantation that permits reproducible osseous resection. Correct extremity positioning within the alignment frame is provided from a lateral view (**a**), an anterior view (**b**), and a top-down view (**c**). Images utilized with permission from Zimmer

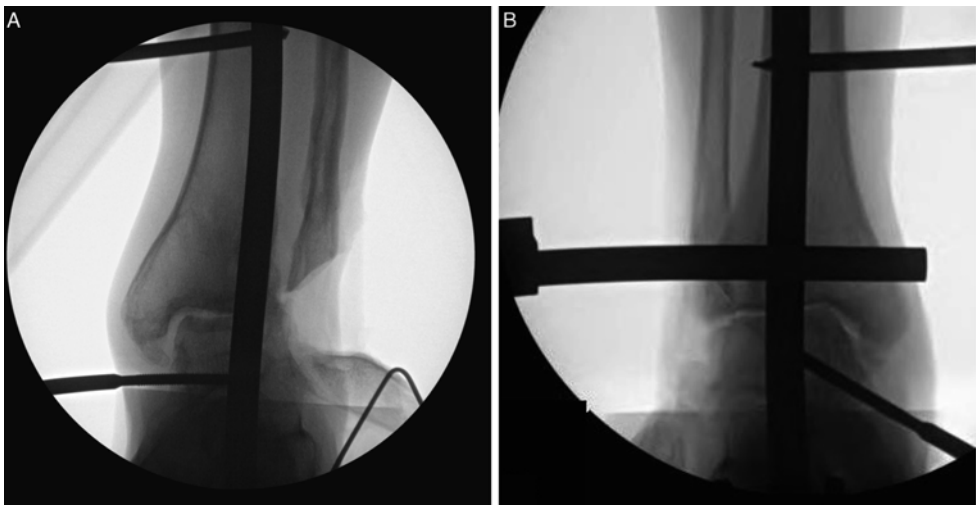

Fig. 12.7 Anterior–posterior alignment rod. The rod, which is located centrally and posteriorly within the alignment frame, provides intramedullary guidance. Before placement of the tibial half pins, the alignment rod must parallel to the anatomic axis of the tibia (**a**). Prior to resection, the "Iron Cross" is created by placing a rod through the lateral incision, in line with the projected tibial resection (**b**). The alignment rod and the lateral to medial rod should align perpendicular to one another, suggesting neutral placement of the implant

stabilized within the alignment guide, the remainder of the procedure is easily performed.

To construct the skeleton of the alignment guide, four frame rods are utilized to connect the distal base of the frame and the proximal U-frame. A tibial alignment rod is located posteriorly and centrally through the frame base and the U-frame. Extremity alignment is highly dependent upon this rod. Prior to securing the tibia to the alignment guide, this rod is aligned parallel to the anatomic axis of the tibia (Fig. 12.7). Calf supports, in varying heights, are located within the U-frame, allowing the surgeon to align the long axis of the tibia, on the sagittal plane, parallel to the longitudinal frame rods. The U-frame can be unlocked to slide distally and proximally, accommodating the patient's anatomy. These adjustments are made intraoperatively. Once the extremity is correctly positioned, the U-frame is locked.

A footplate attaches distally to the frame base, which helps to appropriately position and secure the foot with the appropriate amount of internal rotation. As previously mentioned, footplate position is dependent upon the surgical extremity. In the case of a right TAR, the word "right" should be visualized from the end of the bed looking cephalad. The reverse is true for a left TAR.

A matching footplate support attaches to the plantar surface of the footplate, and the construct is affixed to the frame base at a 90° angle to the frame rods. When the foot is fixed, it will form a 90° angle with the leg. The medial side of the footplate is sloped 10°, which is helpful when internally rotating the leg/ankle. If the surgeon aligns the forefoot with the medial slope of the footplate, 10° of internal rotation is achieved. The internal rotation ensures the appropriate orientation of the medial clear space.

An adjustable heel support cup is attached to the footplate to stabilize the heel. A talar pin connector is located medially within the footplate, which is needed for intraoperative placement of a talar half pin. Two calcaneal pin hooks thread

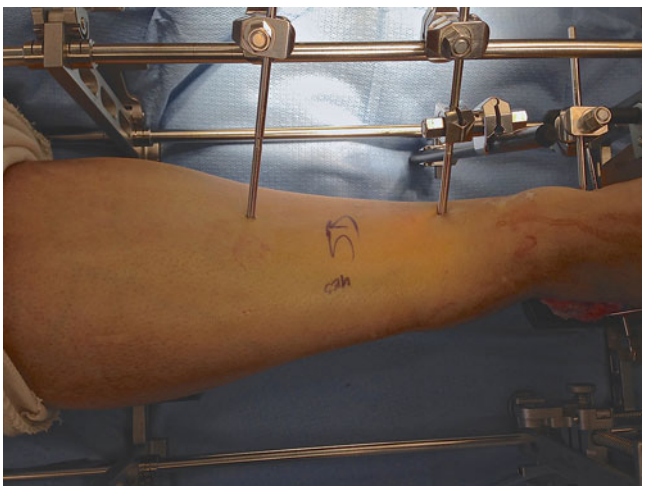

Fig. 12.8 Tibial half pins. The pins are placed in the medial tibial face at approximately 5 and 15 cm proximal to the ankle joint and are then clamped to the medial anterior frame rod

through the footplate from plantar to dorsal, which are used intraoperatively to secure the transcalcaneal pin. When the foot is aligned, the forefoot brackets, located dorsally within the footplate, are tightened, and an elastic wrap is attached to further stabilize the foot. Care should be taken to ensure that the foot and heel are firmly seated against the footplate. An insecure or improperly placed foot can result in prosthetic misalignment.

The frame rods on the medial side are utilized to secure the tibia to the alignment guide. Intraoperatively, the tibial half pins are placed (Fig. 12.8) and clamps are used to secure them to the medial anterior frame rod. A pin-to-rod clamp is then utilized with a carbon fiber rod for additional stabilization. It is placed medially and connected between the distal tibial half pin and the medial posterior frame rod.

The lateral cut guide is located on the lateral side of the alignment frame and slides along the anterior and posterior

frame rods. As previously mentioned, the lateral cut guide is dependent upon the surgical extremity. In the case of a right TAR, the letter "R" should be facing up and an arrow pointing toward the footplate. In the case of a left TAR, the letter "L" should be facing up an arrow pointing toward the footplate. The cut guide lock is located on the central lateral aspect of the cut guide, and the two slide locks are located on the anterior and posterior lateral aspects of the cut guide. Two anterior–posterior stops are located distally within the lateral cut guide. To perform tibial and talar resection, a precutting guide and cutting guide are locked into the lateral cut guide.

Surgical Indications and Contraindications

Indications

The Zimmer Trabecular Metal TAR is indicated for primary or revision surgery in patients with end-stage rheumatoid, posttraumatic, or primary degenerative arthritis of the ankle joint. The authors typically reserve this approach for patients who:

- Demonstrate compromised anterior soft tissue structures
- Are considered young for TAR
- Exhibit a low physical demand

While discussion of the appropriate patient age for TAR is beyond the scope of this chapter, the authors believe that this particular prosthetic can be considered in a wider spectrum of cases. The Zimmer Trabecular Metal TAR minimizes bone resection, averaging approximately 15 mm for both the tibia and talus, and permits revision arthroplasty or arthrodesis later in life (Fig. 12.1). It is important to note that currently no revision system is available specifically for the Zimmer Trabecular Metal TAR system. Any revisions must be performed with an alternate TAR system.

Contraindications

Contraindications to the procedure adhere to those of other TAR systems. These include, but are not limited to:

- Uncontrolled diabetes
- Charcot neuroarthropathy
- Peripheral vascular disease
- The lack of an intact fibula
- Significant tibial metaphyseal bone cyst
- Significant talar loss due to avascular necrosis

Surgical Techniques

Exposure and Sizing

Patients are situated on the operating table in the supine position. An ipsilateral hip bump can be used to position the tibial tuberosity in a rectus position. A lateral longitudinal incision is made a few millimeters posterior to the midline of the fibula, beginning approximately 15 cm proximal to the level of the joint and carried distally to the tip of the lateral malleolus (Fig. 12.9). Subperiosteal dissection of the distal fibula delivers the fibula through the surgical incision. The anterior talofibular ligament is identified and sectioned. The calcaneal-fibular and posterior talofibular ligaments should not be sectioned. If the surgeon plans to use a fibular plate for fixation, the holes can be drilled prior to creation of the fibular osteotomy. When performing the fibular osteotomy, the surgeon must follow several key steps to make the bone cut without detriment.

Step One

The first step to success is determining the proper location to create the osteotomy. Regardless of osteotomy type, the bone cut must be placed at the distal portion of the ankle syndesmosis (Fig. 12.10). Location is imperative to prevent instability of the ankle joint and widening of the distal tibiofibular joint. When evaluating the location of the distal syndesmosis, the surgeon must ensure that enough of the tibia is visible. If in an effort to preserve the syndesmosis the osteotomy was made too distal, the surgeon may have difficulty placing the tibial cutting block. In this situation, an additional fibular osteotomy may be required, which, in turn, increases the risk of poor fixation and nonunion.

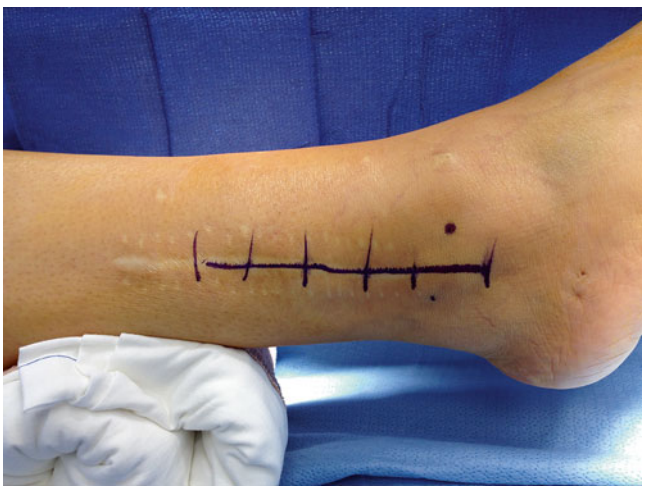

Fig. 12.9 Skin incision. The transfibular skin incision lies just posterior to the midline of the fibula, starting 15 cm proximal to the joint level and ending at the distal tip of the fibula

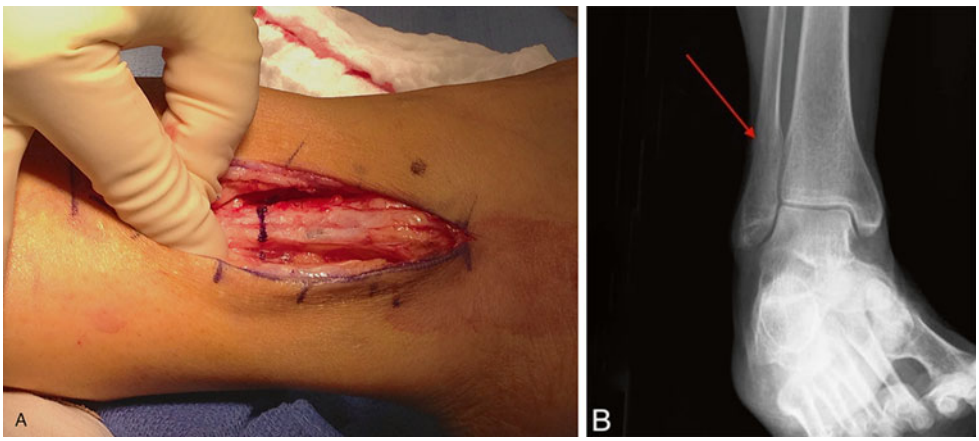

Fig. 12.10 Osteotomy location. The fibular osteotomy should be made proximally enough to allow adequate exposure of the lateral ankle joint while maintaining as much of the syndesmosis as possible to prevent postoperative tibiofibular widening and instability. Intraoperative (**a**) and radiographic (**b**) images demonstrate the proper osteotomy location

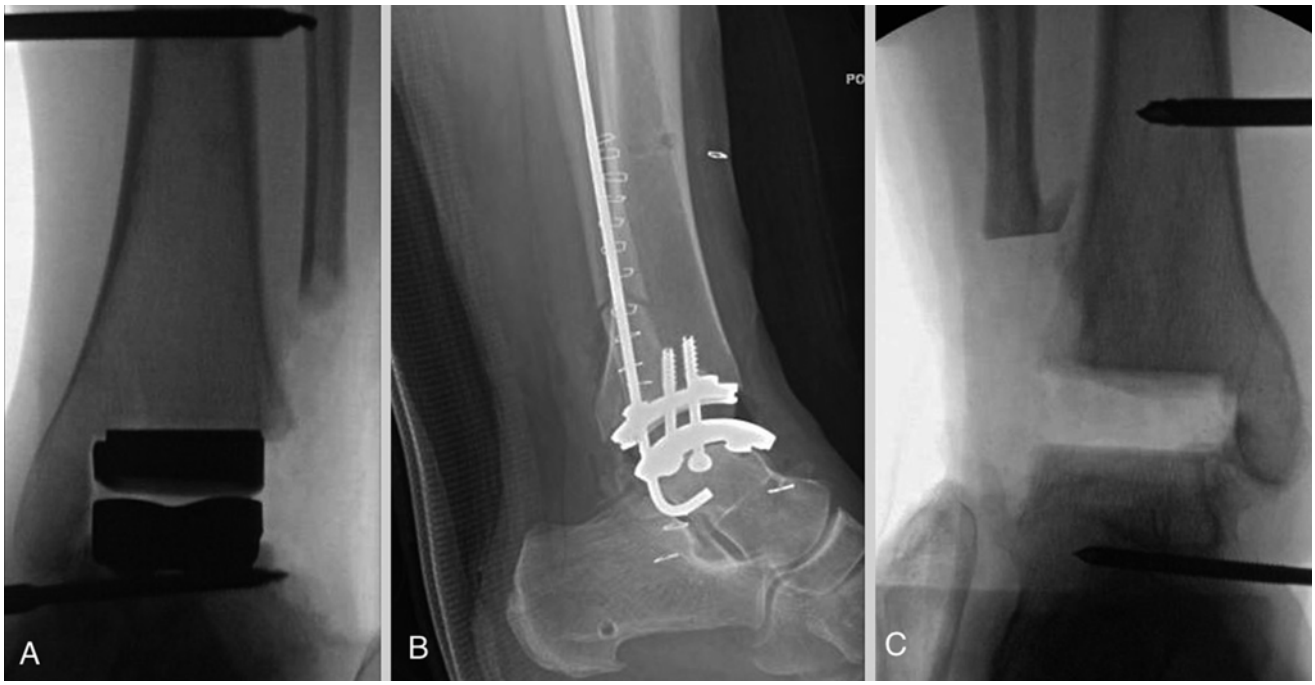

Fig. 12.11 Fibular osteotomy. The osteotomy can be performed in the surgeon's preferred fashion: oblique (**a**), chevron (**b**), or transverse (**c**). Most commonly, the oblique osteotomy is utilized

Step Two

The next step to a successful transfibular approach is determining the type of osteotomy that will be performed (e.g., oblique, chevron, or transverse) (Fig. 12.11). The authors believe that the oblique osteotomy is the most reproducible and has the highest tolerance for error, which may be beneficial for surgeons new to the transfibular approach. Dependent upon the surgeon's preference, the oblique osteotomy can be made in two orientations.

Most commonly, the oblique osteotomy is performed in the frontal plane with the osteotomy starting proximal lateral and ending distal medial. This orientation is advantageous because it allows for preservation of the syndesmosis, and a plane is easily created between the bone and soft tissue for reflection of the distal fibula. However, it can prove difficult to place inter-fragmentary compression across this osteotomy as an adjunct to plate fixation. Alternatively, the oblique osteotomy can be performed in the sagittal plane from proximal-posterior to distal-anterior. This approach also allows for syndesmosis preservation and can more easily accommodate placement of inter-fragmentary compression; however, separation of the distal fibula from the soft tissues for reflection is slightly more difficulty. For surgeons with more experience in performing the transfibular approach, the transverse and chevron osteotomies may be used, although

the authors are not convinced of any clinical benefit. If lengthening or shortening of the fibula is anticipated, the osteotomy should be selected to allow for the correction.

Step Three

The final step to success is proper fixation. Fixation of the osteotomy ranges from inter-fragmentary screw fixation with a 3.5-mm partially threaded screw and a neutralization plate or a fibular locking plate to the use of intramedullary "rush-rod" with a Steinmann pin (Fig. 12.12). All techniques have demonstrated clinical efficacy. Plate fixation provides the benefit of rigid fixation, while an intramedullary rod improves the speed of insertion and limits lateral soft tissue irritation that can be problematic with plate fixation. Once the osteotomy is created, the distal fibular segment is reflected in a distal-posterior direction and stabilized to the lateral wall of the calcaneus with a temporary wire. The wire is bent posteriorly to avoid interfering with the remainder of the procedure.

A medial ankle arthrotomy is then performed through a small "mini-open" incision, directly overlying the medial gutter. Any osteophytes identified within the lateral incision or the medial gutter should be excised. Through the lateral incision, the medial–lateral sizer is inserted and visualized on intraoperative fluoroscopy to determine the medial–lateral implant size (Fig. 12.13). Etch marks on the sizer aid in

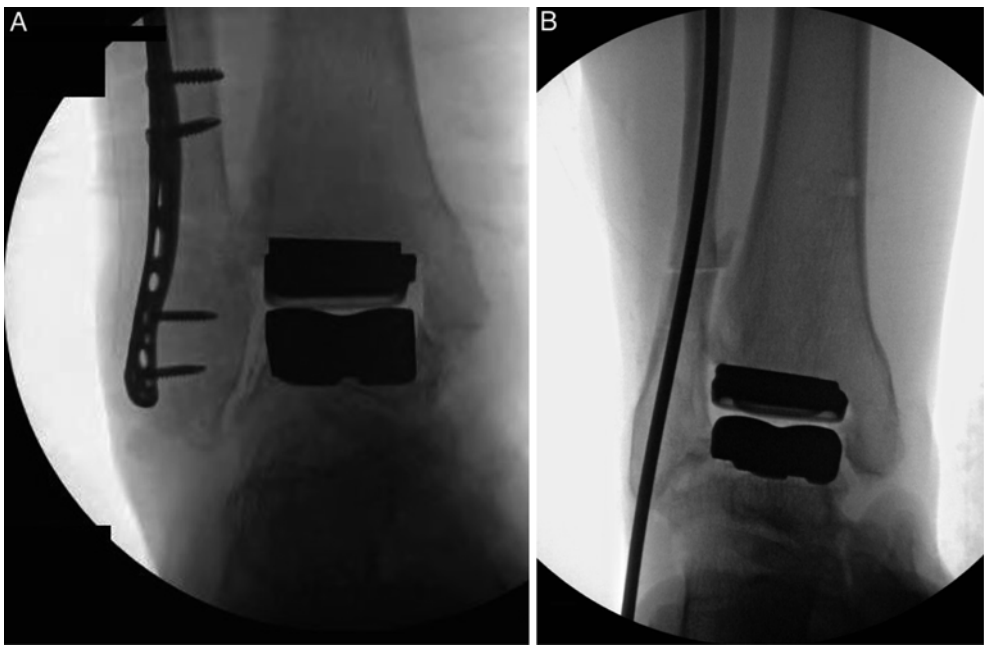

Fig. 12.12 Osteotomy fixation. Locking plate fixation (**a**) or an intramedullary rod (**b**) can be utilized to fixate the fibular osteotomy. Fixation selection is dictated by surgeon preference, osteotomy type, and the need for lengthening or shortening of the fibula for varus/valgus correction

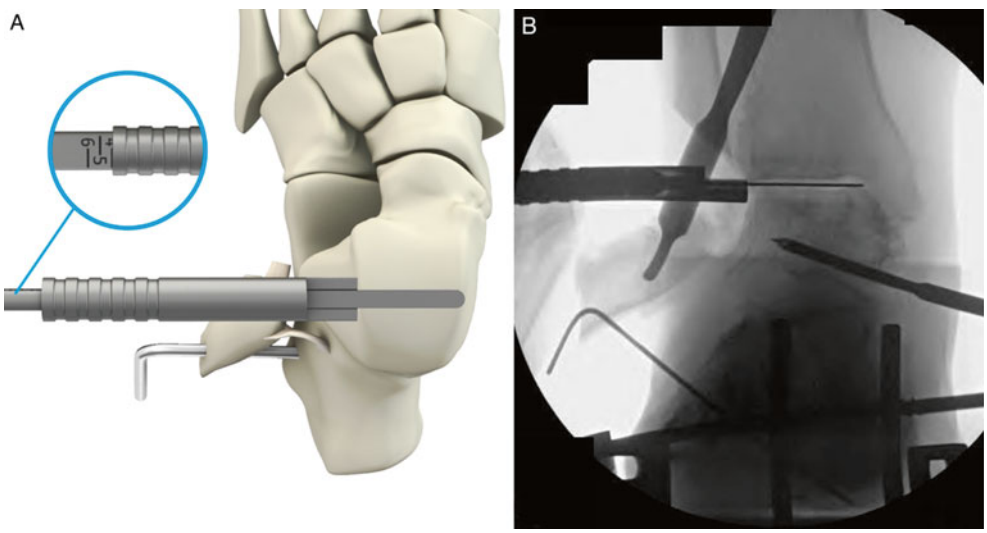

Fig. 12.13 Medial–lateral sizing. The medial–lateral sizer should be inserted into the joint and placed flush with the lateral talus. It contains etch marks to indicate the implant size (**a**). Confirmation on intraoperative C-arm image intensification is imperative to ensure no medial–lateral overhang exists (**b**). If the patient's anatomy lies between two sizes, the smaller size should be selected (**a**). Utilized with permission from Zimmer

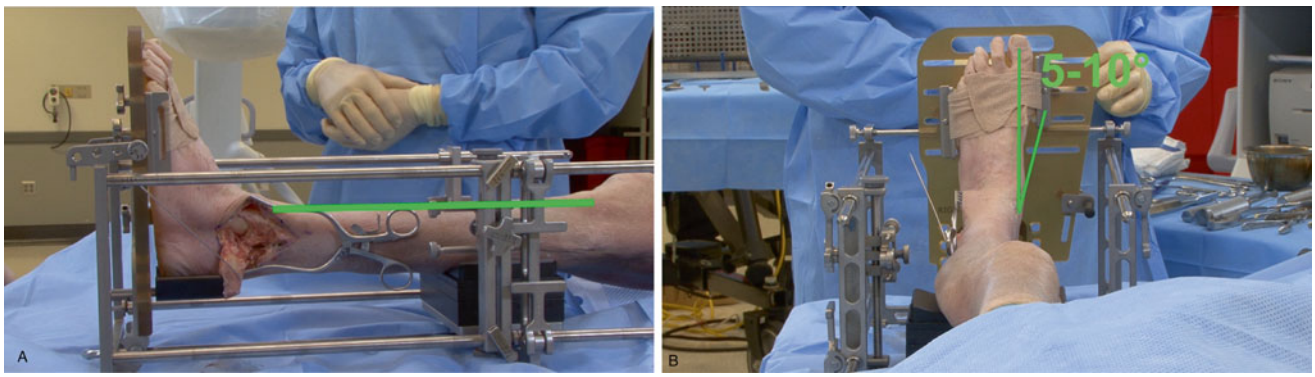

Fig. 12.14 Alignment of the lower leg in the guide. The tibial crest should parallel the frame rods in the sagittal plane (**a**), while the foot/ankle should be internally rotated 5°–10° to place the anterior half of the lateral talus vertical during bony resection (**b**). Images utilized with permission from Zimmer

appropriate selection. If the patient's anatomy is between two sizes of the implant, the smaller size should be utilized to prevent medial–lateral overhang.

Alignment and Fixation

The alignment guide that was previously constructed on the back surgical table is now brought onto the operating table, and the foot is appropriately positioned into the guide. The heel is placed into the heel cup, and the position of the heel cup is adjusted until the center of the heel is equidistant between the alignment rods in the sagittal plane. The calf supports are adjusted with insertion or removal of additional support blocks, and the U-frame is slid distally or proximally until it rests under the midportion of the proximal calf. The tibial crest should run parallel to the frame rods in the sagittal plane. Once achieved, the U-frame is locked into place (Fig. 12.14).

The foot is then appropriately positioned onto the footplate with 5°–10° of internal leg rotation (Fig. 12.14). To ensure the talus is appropriately aligned, a malleable retractor can be placed into the medial ankle arthrotomy site. It is important to understand that the internal rotation positions the anterior half of the lateral talus vertically during resection. The footplate brackets are tightened, and the elastic wrap secures the foot. The position of the foot through the plantar aspect of the footplate should be assessed. Ensure that the foot is flush with the footplate. If it is not, adjust the alignment of the extremity. If a deformity (varus/valgus) is preventing flush contact between the foot and the footplate, additional procedures or alignment guide adjustments may be needed. Intraoperative C-arm image intensification should confirm appropriate ankle joint position before securing the leg into the guide.

To secure the extremity into the alignment guide, a transcalcaneal pin and three half pins are placed. All pins are inserted from the medial side to prevent interference with lateral implantation. First, the transcalcaneal pin is placed within the posterior and plantar half of the calcaneus, parallel to the tibial plafond and footplate. Intraoperative C-arm image intensification should be utilized to ensure appropriate placement. Once placed, the calcaneal pin is secured to the footplate with calcaneal pin hooks. The hooks should be tightened simultaneously, pulling the heel against the footplate until slight bowing of the pin is appreciated. The heel support cup is then removed. The talar half pin is placed next. The pin should be inserted medially into the talar neck, just distal and anterior to the tip of the medial malleolus. The pin should be placed unicortically and on an angle from distal to proximal to avoid interfering with intraoperative imaging and bone resection. The talar pin must stay below the talar resection site, otherwise when resection is undertaken, the pin will interfere (Fig. 12.15). Once the proper position is confirmed, the pin is secured medially to the footplate with the appropriate clamp. With the talus and calcaneus secured to the alignment frame, tibial stabilization is performed. On anterior–posterior C-arm image intensification, confirm that the tibial alignment rod parallels the lateral border of the tibia at the mid-shaft level. A second rod placed lateral to medial in line with the projected tibial resection forms an "Iron Cross" and demonstrates that alignment of the implant will be perpendicular to the tibial axis (Fig. 12.7). Once confirmed, two tibial half pins are placed at 5 and 15 cm proximal to the ankle joint. The half pins can be placed unicortically or bicortically, depending on surgeon preference and bone quality. They are secured to the medial anterior frame rods with the appropriate clamps. A pin-to-rod clamp, with a carbon fiber rod for additional stabilization, is placed medially and connected between the distal tibial half pin and the medial posterior frame rod. The tibial alignment rod and calf supports can be removed. Adjustments in the setup of the alignment guide can be made to address mild deformities during implantation of the TAR (Table 12.1).

Sizing and Positioning

Prosthetic component size should be confirmed utilizing the anterior–posterior sizer. The size determined for the medial–lateral sizing at the beginning of the procedure should be used. The anterior–posterior sizer will mirror the resection curves for that implant size. The sizer should demonstrate complete coverage without anterior or posterior overhang (Fig. 12.17). If overhang is present, the next size down should be trialed. Note that the sizer can be rotated to evaluate tibial and talar resection independently. Additionally, the component sizes are not interchangeable; therefore, the same tibial and talar size must be implanted.

The cutting guide is attached to the lateral cut guide for provisional resection alignment. A probe is placed through the "position" hole on the cutting guide and aligned with the superior-most aspect of the lateral talar dome. In the unlocked

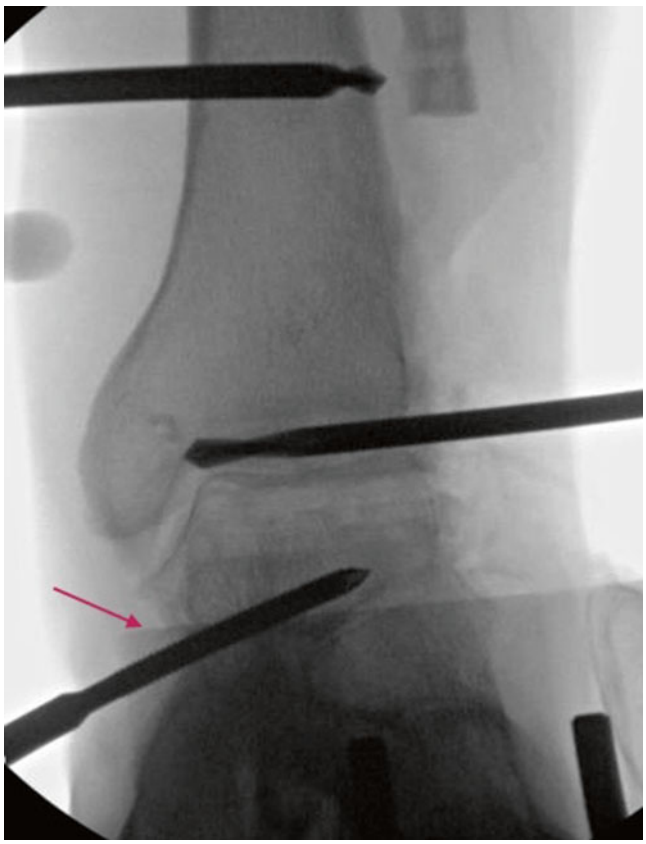

Fig. 12.15 Talar half pin placement. The talar half pin should be angulated from distal medial to proximal lateral with caution not to advance the pin too close to the joint line. If this occurs, the pin will interfere with intraoperative imaging and joint resection

Table 12.1 Patients with limb deformity

For sagittal plane deformity
• Once the leg has been secured to the alignment guide, a third tibial half pin is placed directly anterior, just proximal to the ankle joint. This half pin is secured to the alignment guide with a transverse carbon fiber rod and clamp (Fig. 12.16)
• Once the half pin is inserted, manual power is utilized to:
– Pull the tibia anteriorly to address recurvatum
– Push the tibia posteriorly to correct procurvatum
• Once the deformity is reduced, the half pin is locked into place along the carbon fiber rod, holding the reduction stable. The index procedure is then performed according to the previously described protocol
For frontal plane deformity
• Adjustments are made prior to insertion of the talar pin. Typically, half pins are placed consecutively in the calcaneus, talus, and tibia, securing the leg to the alignment guide. When addressing varus/valgus malalignment, the talar half pin should be inserted last
• Once the calcaneus and tibia are stabilized, a temporary half pin is placed into the lateral talus. This half pin is utilized as a "joystick" to manually correct varus/valgus deformity. If required, a deltoid peal can be performed to aid in correction of varus malalignment
• Once the deformity is reduced, the medial stabilizing talar half pin is inserted and secured to the footplate. The temporary lateral half pin is removed, and the index procedure is performed according to the previously described protocol

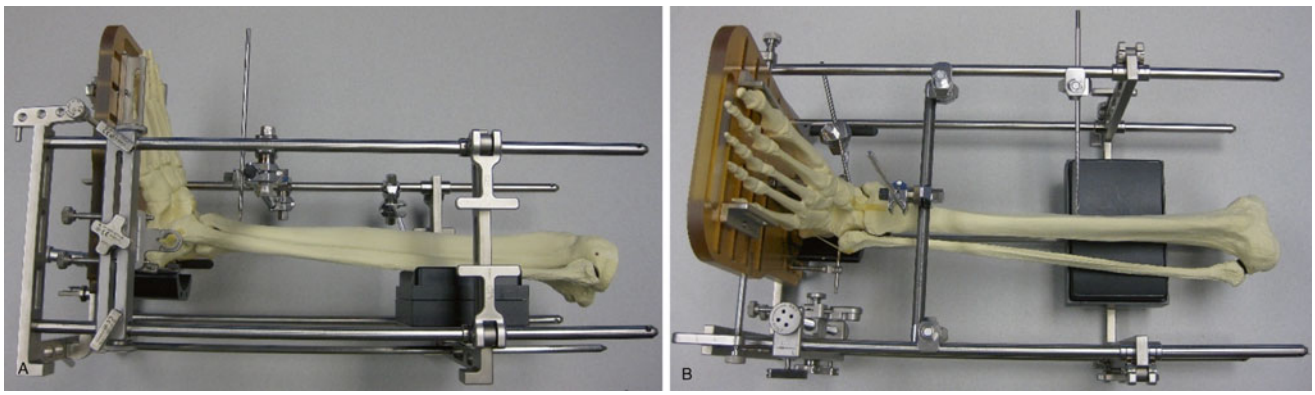

Fig. 12.16 Alignment frame for sagittal plane deformity. Placement of an anterior tibial half pin can allow the surgeon to manually adjust for recurvatum or procurvatum prior to bony resection. Placement of an anterior tibial half pin frame is shown from a lateral view (**a**) and an anterior view (**b**). Images utilized with permission from Zimmer

position, the probe should be taken through the arc of resection for visualization of the reconstructed joint line (Fig. 12.18). The slide locks and the anterior–posterior stops on the lateral cut guide can be loosened to allow adjustments to the arch of resection and locked into place when the appropriate alignment has been established. Adjustments can be made to allow for exact replication of the joint line (Fig. 12.19). The probe can be removed from the "position" hole and placed into the talus and tibial holes to evaluate the amount of tibial and talar osseous resection independently. Loosening the slide locks allows for adjustments in the proximal and distal directions. When satisfied with the alignment, verify that all assembly pieces are locked and initiate osseous resection.

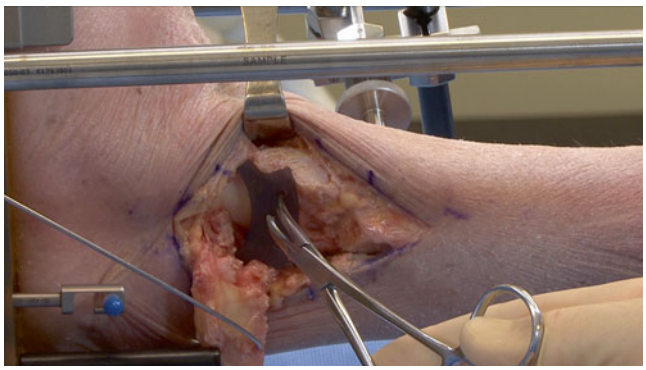

Fig. 12.17 Anterior–posterior sizing. The anterior–posterior sizer, corresponding to the selected implant size, is used to ensure that no anterior or posterior overhang exists. The tibia and talar sizes must be the same, but their resection can be evaluated independently. Image utilized with permission from Zimmer

Bone Preparation

The cutting guide is removed from the lateral cut guide and replaced with the precutting guide. This guide will allow the surgeon to create a series of pilot holes in both the talus and tibia. The precutting guide is locked in a static position, and in a peck fashion the precutting guide drill perforates the opposing joint surfaces (Fig. 12.20). The drill is etched to correspond to the size of the implant. When this etching contacts the precutting guide, intraoperative C-arm image intensification should be utilized to assess the depth, ensuring that the medial malleolus is not violated. In most cases, the drilling will need to be slightly deeper than the etch line to improve cutting efficiency. Re-chuck the drill, so that the drill contacts the edge of the pre-cut guide. This permits the efficient creation of a series of pilot holes without continually having to verify the depth fluoroscopically. The most anterior and

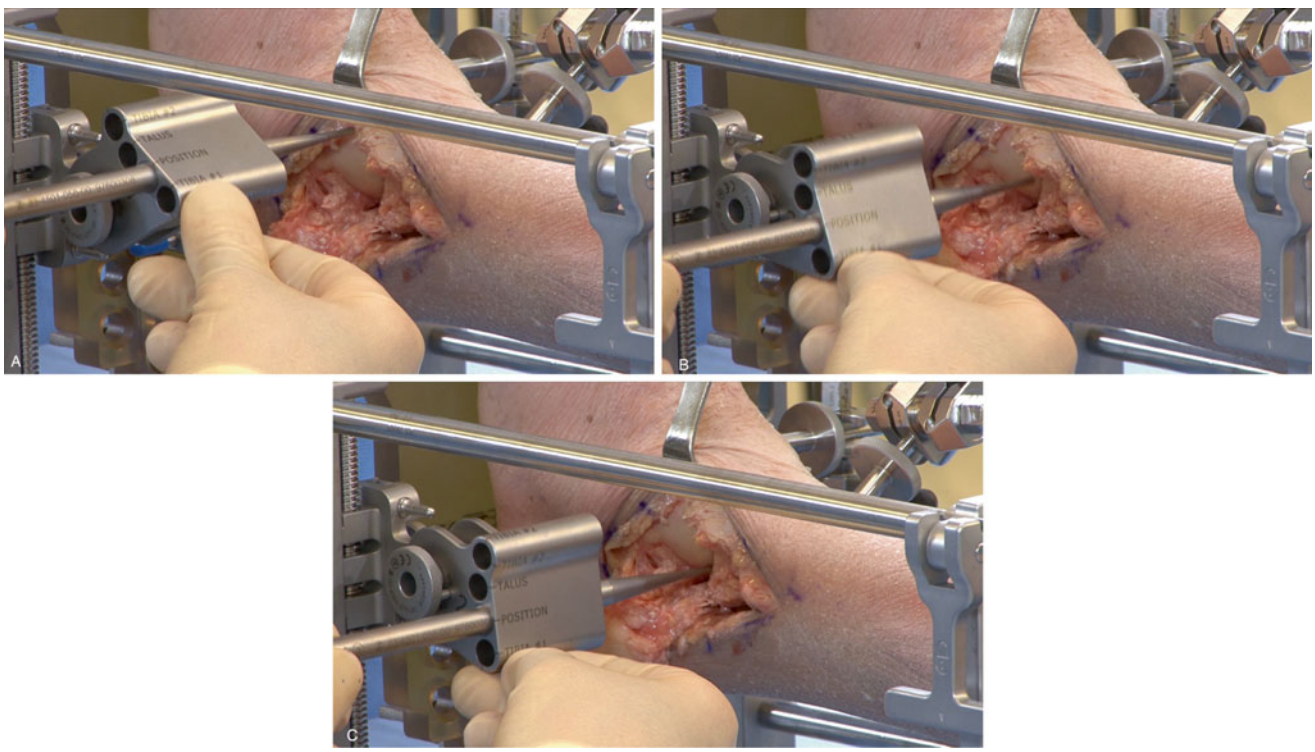

Fig. 12.18 Joint line reconstruction. With the cutting guide in place, a probe is placed through the "position" hole, which allows the surgeon to reconstruct the joint line, mirroring bony resection. Here, the probe shows the anterior (**a**), central (**b**), and posterior (**c**) joint line that matches the bony resection. Images utilized with permission from Zimmer

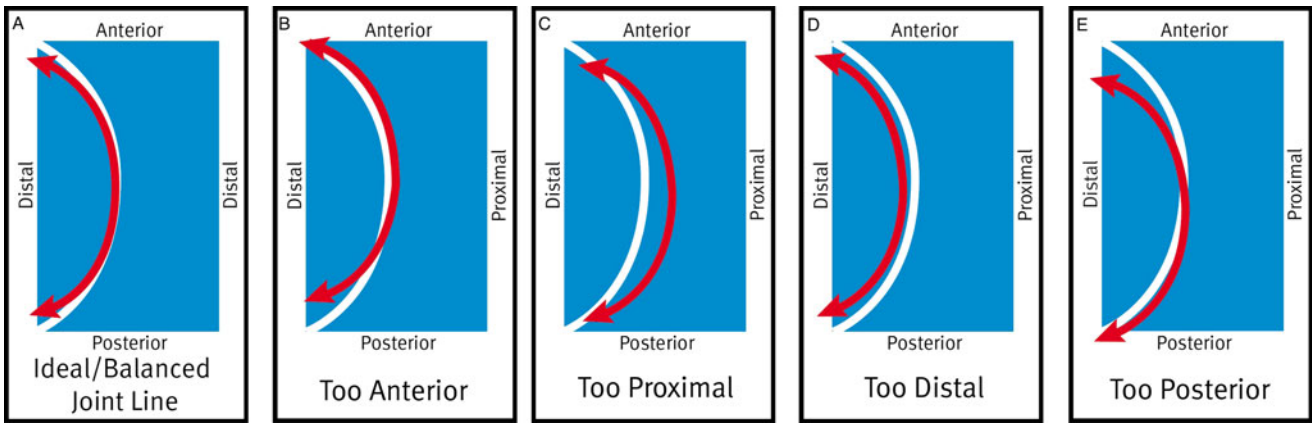

Fig. 12.19 Adjustment guide for joint line reconstruction. The slide locks and anterior–posterior stops are utilized to adjust the cutting guide and allow matching of the joint resection to the joint surfaces. The goal is to establish a balanced joint line (**a**), matching the patient's anatomy. Images show how to adjust the cutting guide if the alignment is too anterior (**b**), too proximal (**c**), too distal (**d**), or too posterior (**e**). Image utilized with permission from Zimmer

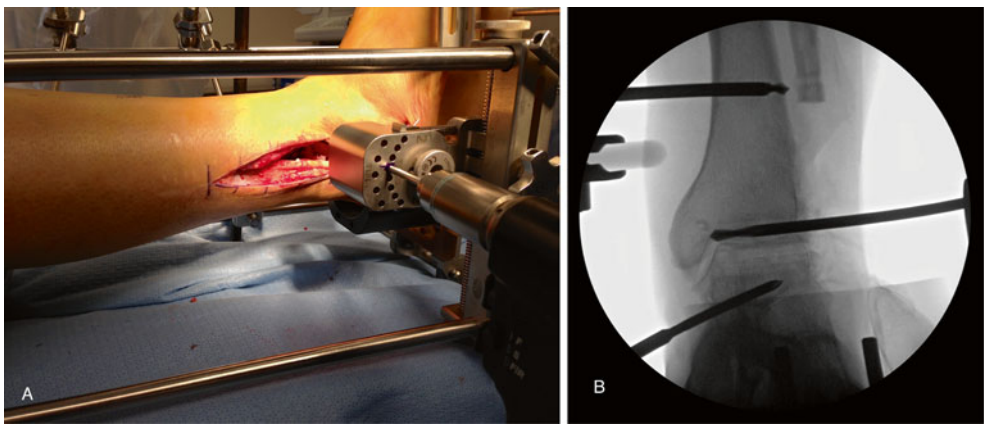

Fig. 12.20 Precutting guide. The precutting guide allows the surgeon to create a series of pilot holes in the tibia and talus to aid in burr resection (**a**). The depth of the drill utilized during the precutting step should be confirmed on intraoperative C-arm image intensification (**b**) to avoid medial malleolar impingement

posterior holes may not contact the bone and, therefore, may not be utilized, depending on the patient's anatomy. Once all of the pilot holes have been created, the precutting guide is removed, and the cutting guide is secured into place.

A burr guard is placed over the burr, and the setup is inserted into the "talus" hole of the cutting guide. The appropriate size talar provisional implant can be utilized to help set the depth (Fig. 12.21). Once the appropriate depth is determined, lock the burr guide into place; this improves efficiency during resection. The talar provision is removed and a 5-mm spacer is snapped onto the burr guard. The spacer removes 5 mm from the depth of the resection during bone preparation, which prevents violation of the medial malleolus and medial neurovascular structures (Fig. 12.21). The use of the 5-mm spacer can be omitted based upon preference. Intraoperative C-arm image intensification should be utilized to confirm resection depth. The cutting guide is unlocked and rotated along the resection arc. Osseous resection of the talus is undertaken utilizing a "plunge and sweep" method in a clockwise direction (Fig. 12.21). The anterior–posterior stops on the lateral cutting guide can be adjusted to ensure that excessive anterior and posterior resection is not performed. Lateral to medial resection is continued until the 5-mm spacer contacts the cutting guide.

The 5-mm spacer is removed and without adjusting the burr guard, the burr is placed into the "tibia #1" hole on the cutting guide. The anterior–posterior stops are adjusted, and the same plunge and sweep method is utilized in a counterclockwise direction to partially prepare the tibia (Fig. 12.21). Resection is continued until the burr guard stop contacts the cutting guide. Resected bone within the joint is removed with a rongeur, and the burr is placed into the "tibia #2" hole, without adjusting the burr guard. The remainder of tibial preparation is completed with the aforementioned technique. If the 5-mm spacer was utilized for talar preparation, the burr is placed back into the "talus" hole, and the remaining 5 mm of the bone on the medial side of the joint is resected. The joint should be irrigated thoroughly with a pulsating lavage and all resected bone should be excised (Fig. 12.21).

Rail hole preparation occurs next. Tibial and talar rail hole drill guides correspond to the selected implant size and are mated. These guides replicate the dimensions of the

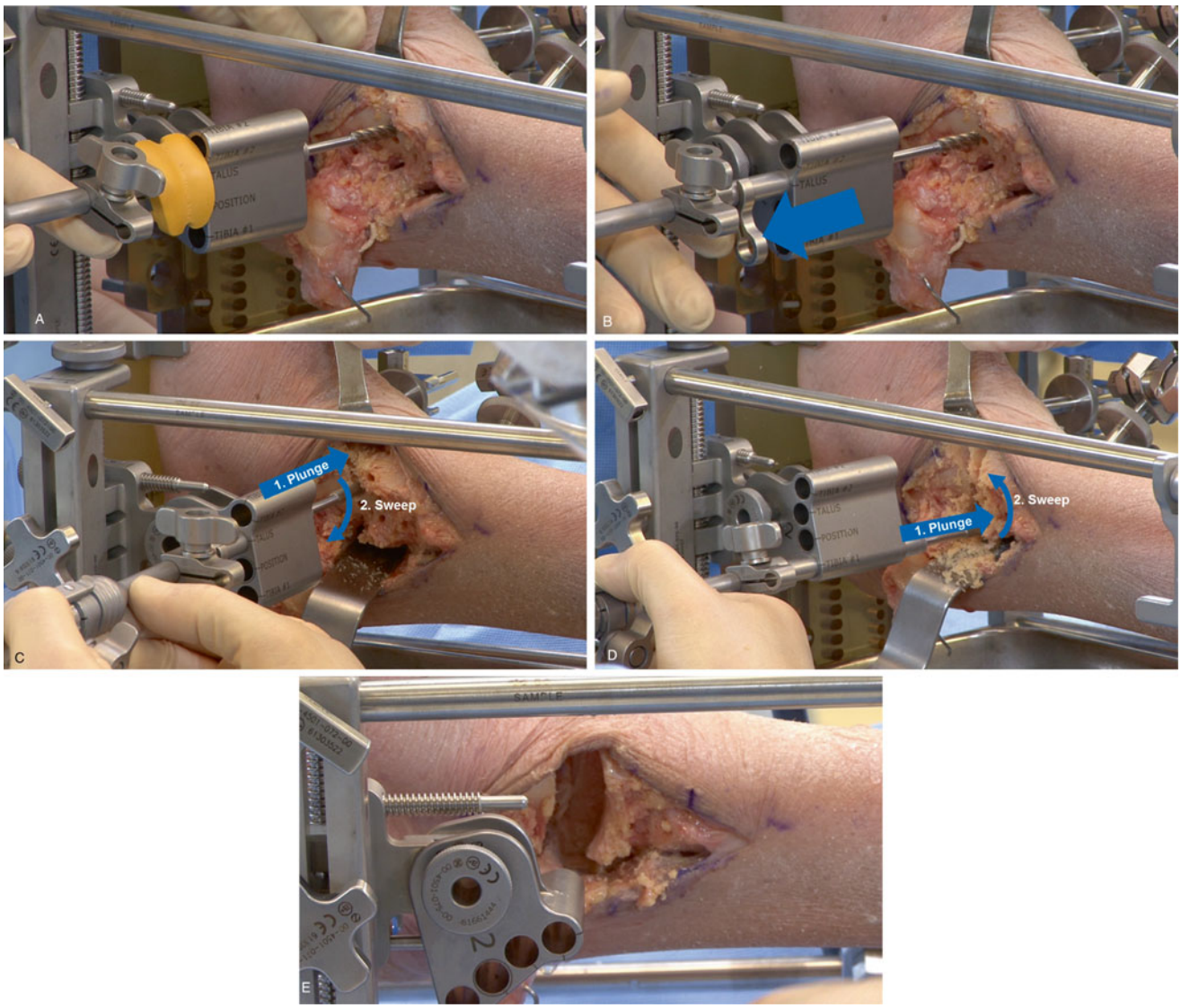

Fig. 12.21 Burr resection. The talar provisional implant is placed between the cutting guide and the burr to determine the depth of resection (**a**). Once confirmed on intraoperative C-arm image intensification, the talar provisional implant is removed and the 5-mm spacer is affixed to the burr guard (**b**), which protects the medial malleolus and medial neurovascular structures during resection. The talus is prepared first utilizing a plunge and sweep method in a clockwise direction (**c**), followed by tibial resection in a counterclockwise direction (**d**). Resected bone is removed, revealing the prepared space for the implant (**e**). Images utilized with permission from Zimmer

implant and provide a strong indication of final component positioning. The linked components should be inserted into the joint together and manually adjusted until the appropriate medial–lateral and anterior–posterior position is achieved. There should be no lateral overhang. The talar and tibial components can be rotated anteriorly and posteriorly independent of each other for implant placement that closely matches the patient's anatomy. When satisfied with the position, a spreader pin is inserted between the components, holding them static, and intraoperative C-arm image intensification is utilized to confirm the position (Fig. 12.22). On an anterior–posterior view, there should be no lateral overhang of the prosthetic components, and a small notch in the tibial rail guide should align with the anatomic axis of the tibia. On the lateral view, confirm that anterior and posterior overhang is minimized. The rail holes should be flush with the resected tibia and talus to ensure appropriate seating of the final components. If any adjustments need to be made, remove the spreader pin, adjust the spreader pin, and replace the spreader pin, confirming the adjusted position under C-arm image intensification. After the rail hole drill guides are appropriately seated, K-wires are inserted from lateral to medial through holes in the guide, securing the guide for rail hole preparation.

The appropriate rail hole drill is used in a peck fashion to prepare each of the four rails until the stop contacts the sleeve of the guide. After each hole is drilled, a rail hole stabilizer is inserted into the prepared rail to ensure the guide remains

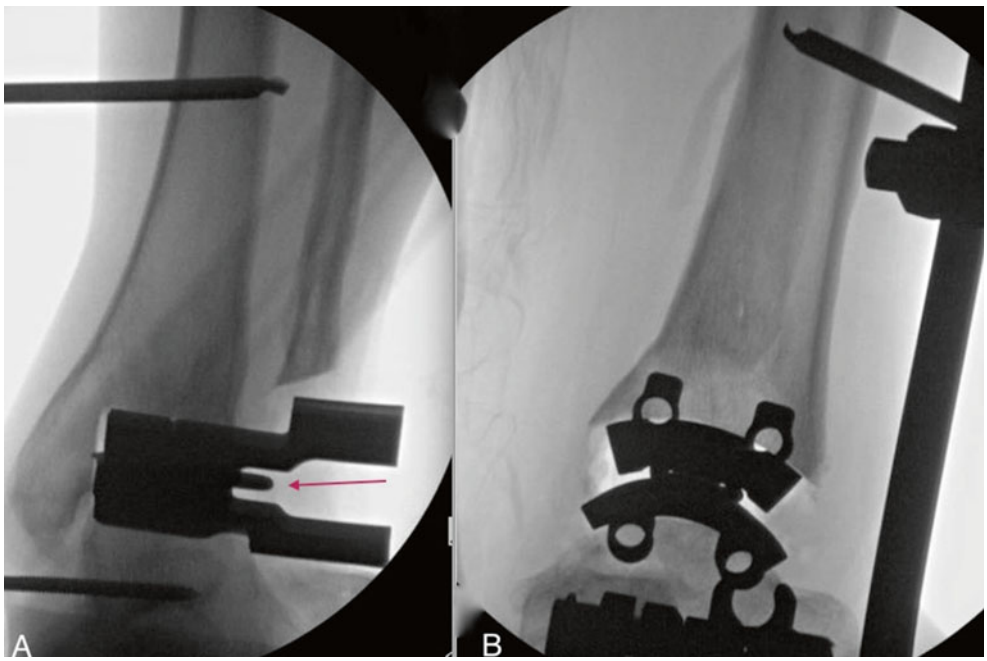

Fig. 12.22 Rail guide. When the rail guide is seated flush within the joint space, the anterior–posterior view shows a notch on the tibial side that should align with the mechanical axis of the tibia (**a**), while the lateral view shows flush placement of the components with minimal to no gapping between the rail guide and the tibia and talus (**b**). When satisfied with the position, the spreader pin, indicated by the red arrow, is inserted

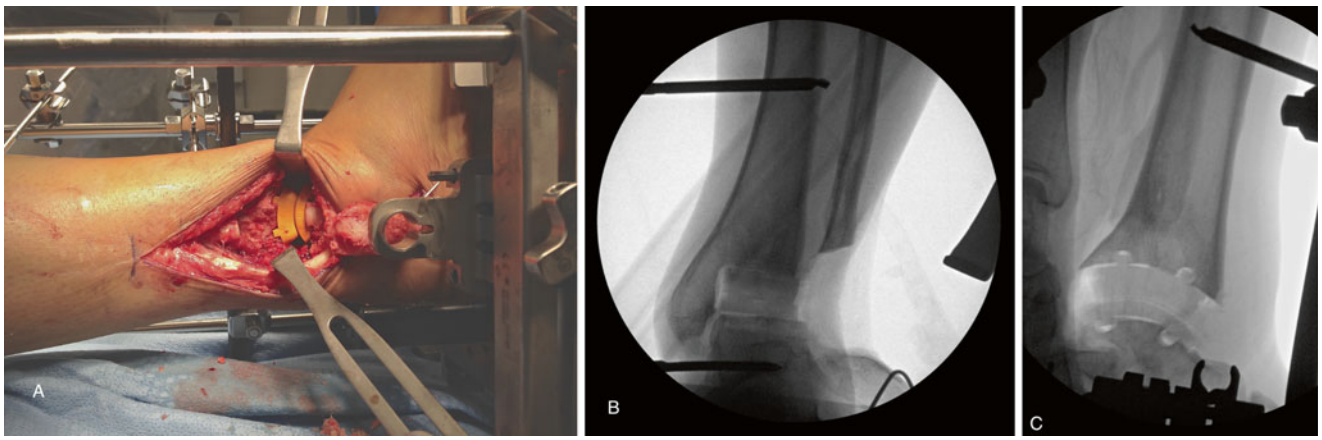

Fig. 12.23 Trial implantation. The tibial and talar trial implants are placed into the prepared joint space (**a**), and implant positioning is confirmed on intraoperative C-arm image intensification both from an anterior view (**b**) and a lateral view (**c**). No medial–lateral or anterior–posterior overhang should be evident and the rails should align with the prepared rail guide holes

seated while the other holes are drilled. Once completed, the K-wires and rail hole drill guides are removed, and the joint is irrigated.

Trial Implantation

The provisional tibial and talar trial implants can be inserted. The trial components should sit flush without overhang in any direction. Alignment of the implant with the rail guide holes should also be confirmed (Fig. 12.23). When the trial implant is seated, the footplate on the alignment guide is temporarily unlocked to assess dorsiflexion and plantar flexion of the ankle joint. The fibula can be unpinned from the calcaneus to ensure lateral impingement does not occur with fibular reduction. Medial gapping and stability through the medial arthrotomy should be evaluated and addressed as needed. If there is a restriction of dorsiflexion motion, without impingement, a tendo-Achilles lengthening or gastrocnemius recession should be considered. Once satisfied with the stability and range of motion of the ankle joint, the footplate is resecured.

Final Component Insertion

With the tibial provision implant in place, the final talar component is seated on the talar inserter in the appropriate orientation and impacted from lateral to medial (Fig. 12.24).

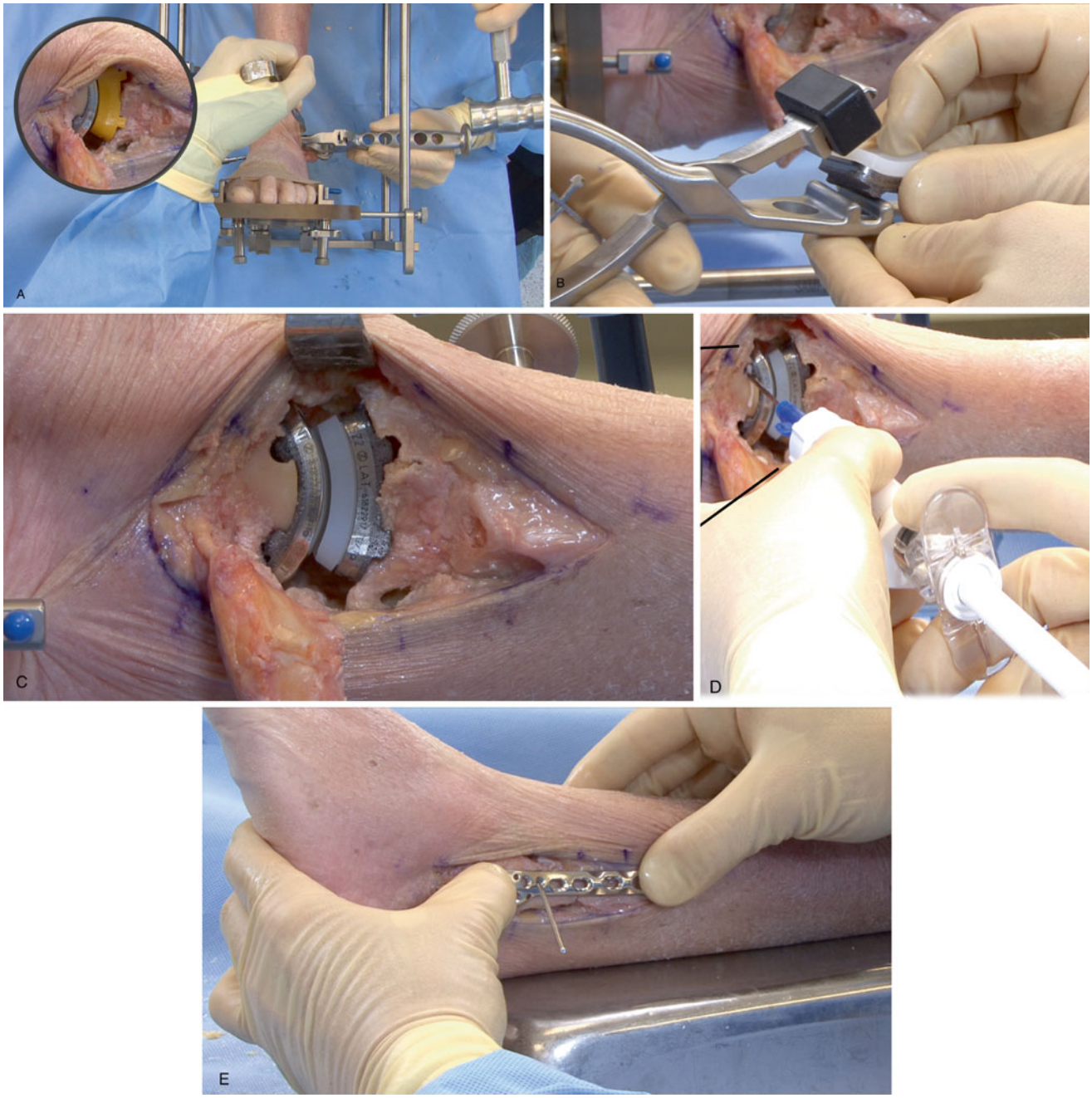

Fig. 12.24 Implant insertion. The talar component is implanted first (**a**). The tibial base and polyethylene components are snapped together (**b**) and inserted into the joint space (**c**). Bone cement is utilized around the rails to secure the implant (**d**). The fibula is reduced and fixated with a neutralization plate (**e**). Images utilized with permission from Zimmer

Be sure to align the rail holes before impaction. Once the component is appropriately seated, the talar inserter is released, completing talar component insertion. The tibial provision implant is removed. The tibial base and polyethylene components are snapped together on the back surgical table in the appropriate orientation and loaded onto the tibial inserter (Fig. 12.24). The tibial component is impacted from lateral to medial, ensuring alignment of the rail holes (Fig. 12.24). Once seated, the tibial inserter is released and C-arm image intensification is utilized to confirm final component position. Polymethylmethacrylate cement is then injected under each of the four implant rails completing implantation (Fig. 12.24).

Closure

Tibial and talar half pins and the transcalcaneal pin are removed, the extremity is freed from the alignment guide, and the guide is passed off the operating table. The temporary stabilizing wire in the fibula is removed from the lateral calcaneal wall, and the fibula is rotated back into position. As necessary to correct for varus or valgus, the fibula can be lengthened or shortened and then stabilized with a lateral fibular plate of the surgeon's choice (Fig. 12.24). Although a fibular locking plate is the most common type of fixation, a fibular "rush-rod" can also be used to stabilize an osteotomy (Fig. 12.12). Syndesmotic fixation can be utilized if the syndesmosis is rendered unstable. The authors have utilized flexible suture fixation for a questionably stable syndesmosis (Fig. 12.25). However, if the fibular osteotomy is made appropriately and does not disrupt the entirety of the distal tibiofibular syndesmosis, this is rarely required. The anterior talofibular ligament is repaired with nonabsorbable suture; if needed a drain is placed, and layered lateral closure is performed.

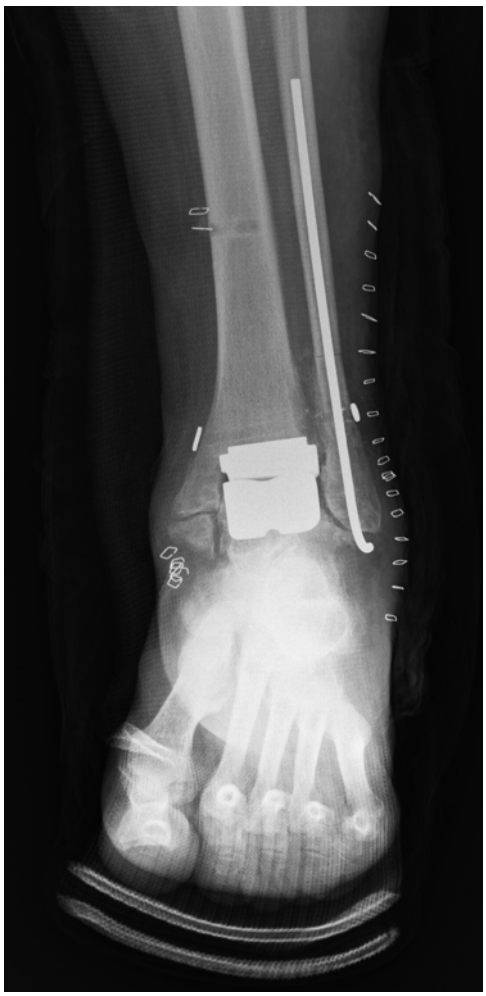

Fig. 12.25 When the syndesmosis is unstable, flexible suture fixation can be utilized

Postoperative Protocol

When TAR is performed without any additional osseous procedures, patients are kept non-weight bearing in a neutral splint for 3 weeks. At which time, the sutures are removed, and weight bearing in a controlled ankle motion device is initiated. Physical therapy is initiated at 3 weeks and continued until the patient is able to weight bear without assistance and navigate stairs safely and has regained full manual muscle strength. When osseous procedures accompany the TAR, the healing of the additional osseous procedure dictates how long the patient will be non-weight bearing. The authors are strong proponents of early weight bearing and range of motion following TAR. Because of this, the authors will often stage concomitant osseous fusions and osteotomies. All soft tissue balancing is done at the time of TAR.

Complications

Revision Patient

As with all TARs, revisions can be challenging with the Zimmer Trabecular Metal TAR. Currently, there is no revision prosthetic specifically designed for the Zimmer Trabecular Metal TAR. In settings where revision TAR is required, an alternate system may be utilized.

In situations where tibio-talo-calcaneal arthrodesis is necessary, the arched bone cuts of the Zimmer prosthetic may provide clinical benefit and technical ease. In patients with minimal bone loss, the arched cuts can be preserved and will mate like puzzle pieces during arthrodesis preparation. Special care must be taken, in the setting of infection, to make sure that the cement spacer does not damage the arched contours (Fig. 12.26). When the ankle is ready for arthrodesis, the surgeon must take care to prepare the tibia and talus to healthy bleeding bone, while following the contour of the arches. Once this occurs, the surgeon may use their fixation of choice, most commonly retrograde intramedullary nailing or plating. Loss of limb length can be reestablished with bone grafting, or in situations where minimal bone was lost, a shoe lift can be incorporated (Fig. 12.26).

Oversizing

Oversizing the prosthetic is a common problem that can cause debilitating pain in the ankle joint. It is imperative for the surgeon to accurately use the medial–lateral sizer and anterior–posterior template to properly size the implant and to confirm sizing with fluoroscopic imaging. An oversized talus can cause friction and pain along the medial gutter.

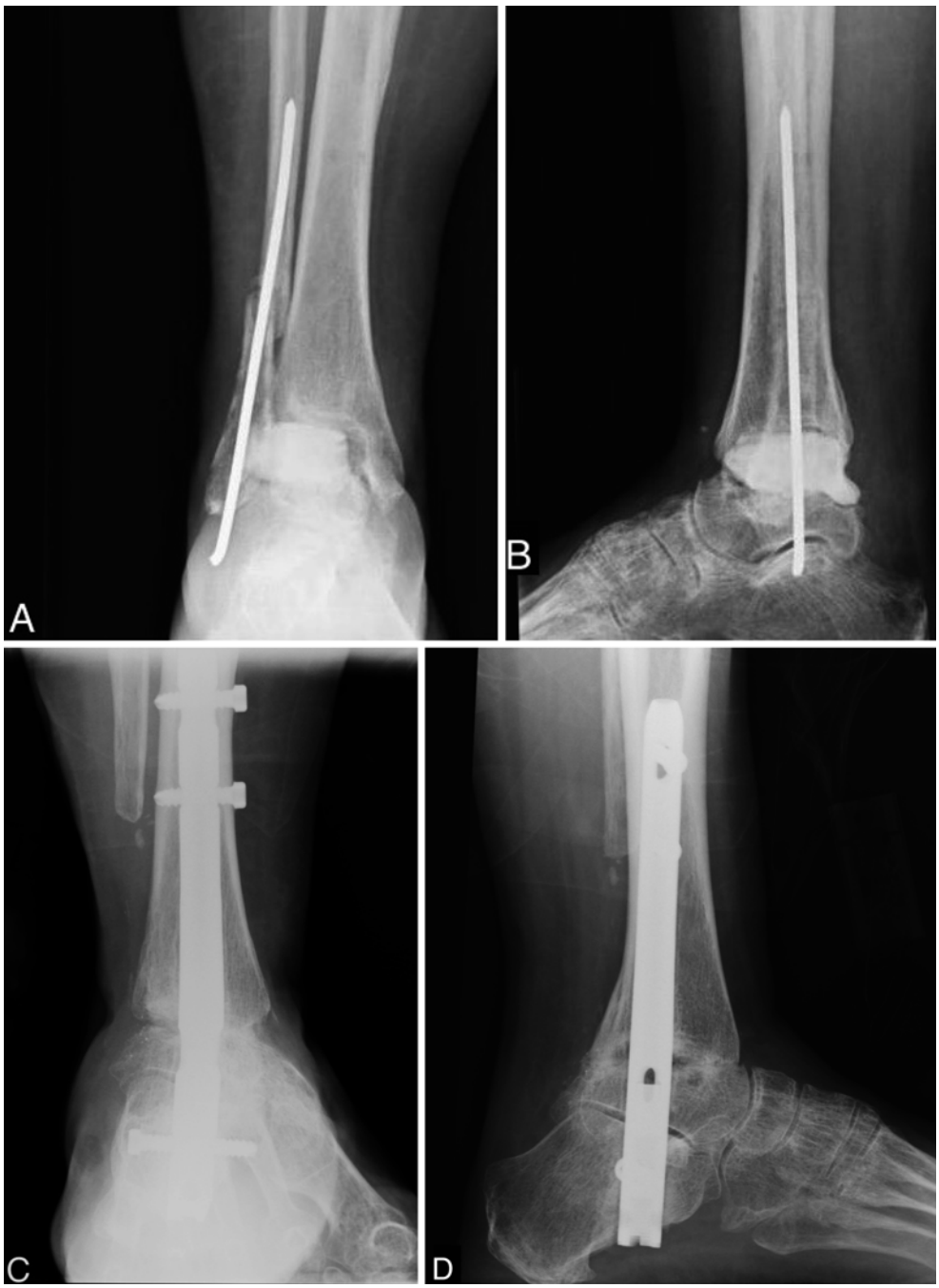

Fig. 12.26 Revision to tibio-talo-calcaneal arthrodesis. In the face of infection, a staged salvage procedure is preferable. An antibiotic-loaded polymethylmethacrylate cement spacer is utilized, with care to match the arched resection of the tibia and talus in both the frontal and sagittal planes (**a**, **b**, respectively). When the infection has resolved, a retrograde intramedullary nail can be utilized with minimal limb length loss as demonstrated on anterior–posterior (**c**) and lateral (**d**) radiographs

This can be evaluated with visual inspection through the medial arthrotomy incision. If there is any question regarding proper sizing, the authors recommend selecting the smaller prosthetic. If a patient presents with an oversized talus postoperatively, arthroscopic debridement of the medial gutter can eliminate some pain and discomfort. In situations where this does not eliminate pain, revision to a smaller prosthetic may be necessary.

Conclusions

Although relatively new, the Zimmer Trabecular Metal TAR system has a novel design that addresses many of the challenges associated with primary TAR. Surgeons should familiarize themselves with the lateral surgical approach and be comfortable performing a fibular osteotomy to gain exposure

to the joint. Surgeons will find that this system's referencing device is accurate and reproducible, and the prosthesis restores normal joint kinematics allowing for comfortable ambulation.

Acknowledgments The authors would like to thank Jennifer L. Mulhern, DPM, and Nicole M. Protzman, MS, for their contributions to the manuscript. Dr. Mulhern is a Fellow of Foot and Ankle Reconstruction at Coordinated Health in Allentown, PA. Mrs. Protzman is a Research Associate at Coordinated Health in Allentown, PA.

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Part III

Secondary Procedures with Total Ankle Replacement

Managing Wound-Healing Complications After Total Ankle Replacement

13

Christopher Bibbo and Stephen J. Kovach

Introduction

Wound-healing complications after total ankle replacement (TAR) have been quoted as high as 16–28 % [1, 2]. A 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. 13.1), the area near the tibialis anterior tendon has been found to be a consistent area of wound breakdown (Fig. 13.2) [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. 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," where simply inspecting for deeply pigmented or atrophic scars, poor skin turgor, massive edema, and tissue paper skin 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.

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,

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_13

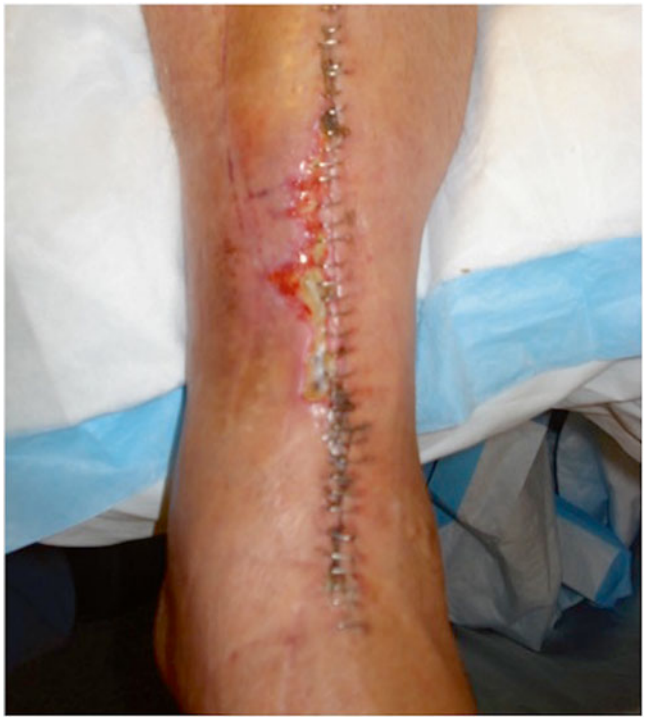

Fig. 13.1 Example of delayed healing that requires close follow-up. Local care may be expected to assist with expectant healing over the course of several weeks

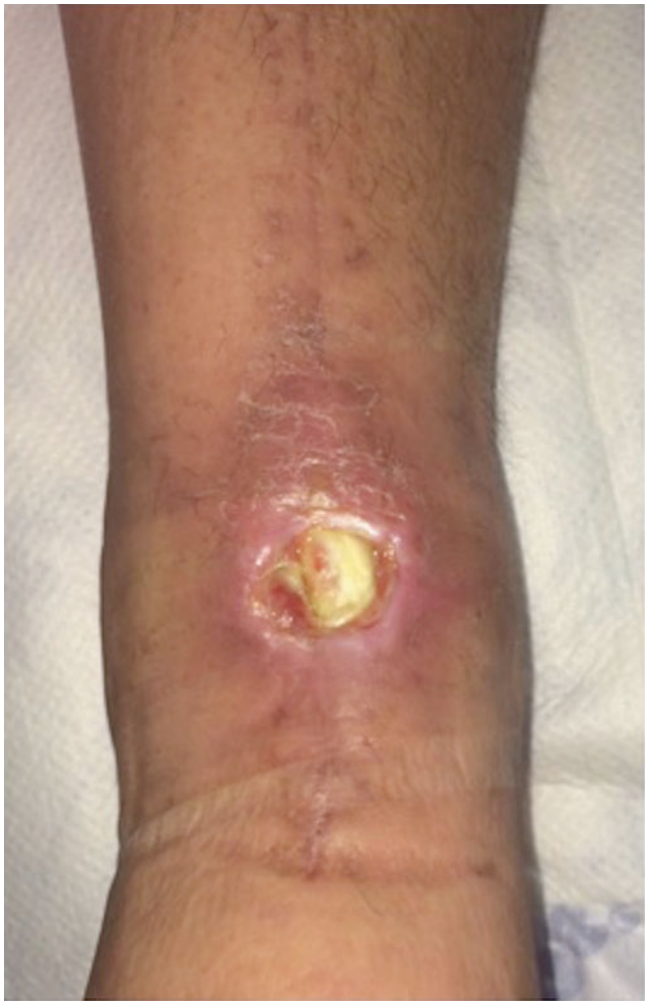

Fig. 13.2 The area near the tibialis anterior tendon appears to be at greatest risk for wound breakdown. Techniques to temporarily suture tendinous structures together and "parachute" them down to deeper structures may help relieve pressure in this area of the incision (Photo courtesy of Benjamin Overly, DPM)

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. 13.3). 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. 13.4). 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. 13.4). 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 $\geq$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 anticoagulation performed 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 affect 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. 13.5).

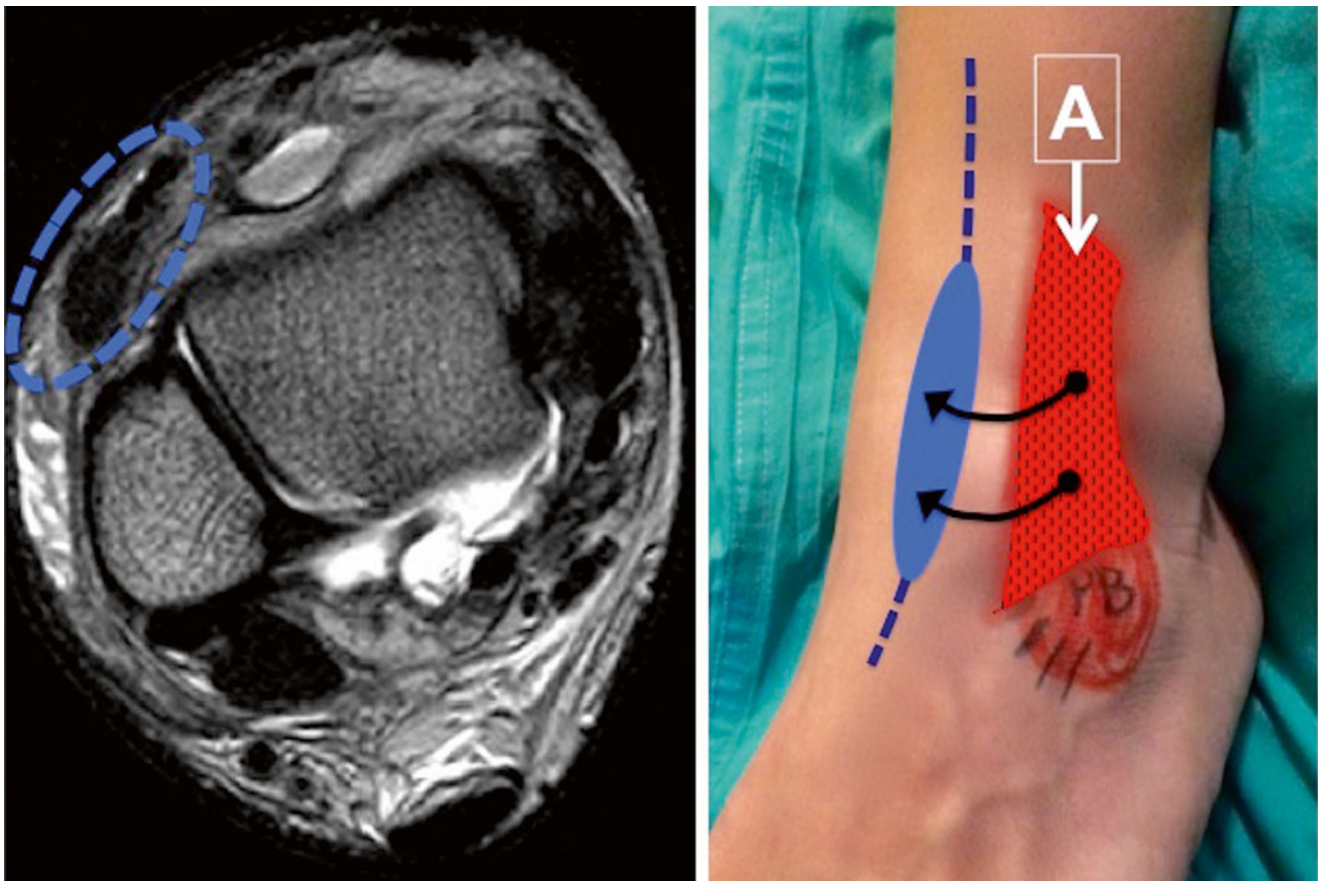

Fig. 13.3 Magnetic resonance imaging (*left image*) of a low-lying peroneus tertius muscle belly (*blue hashed circle*) and surface marking of its' position (*red speckled rectangle* designated as *A*). This muscle can be transposed or formally transferred by detaching the tendon distally, to assist with providing vascularized muscle locally within the central/lateral portion of a wound dehiscence (*blue filled oval*)

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 in 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 Polymen® (Ferris Manufacturing Corp, Fort Worth, TX) and a "tissue-friendly adherent" such as Mepitel® (Monlycke Health Care, Gothenburg, Sweden) (Fig. 13.6) 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, 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. 13.7). 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. 13.8, 13.9, and 13.10).

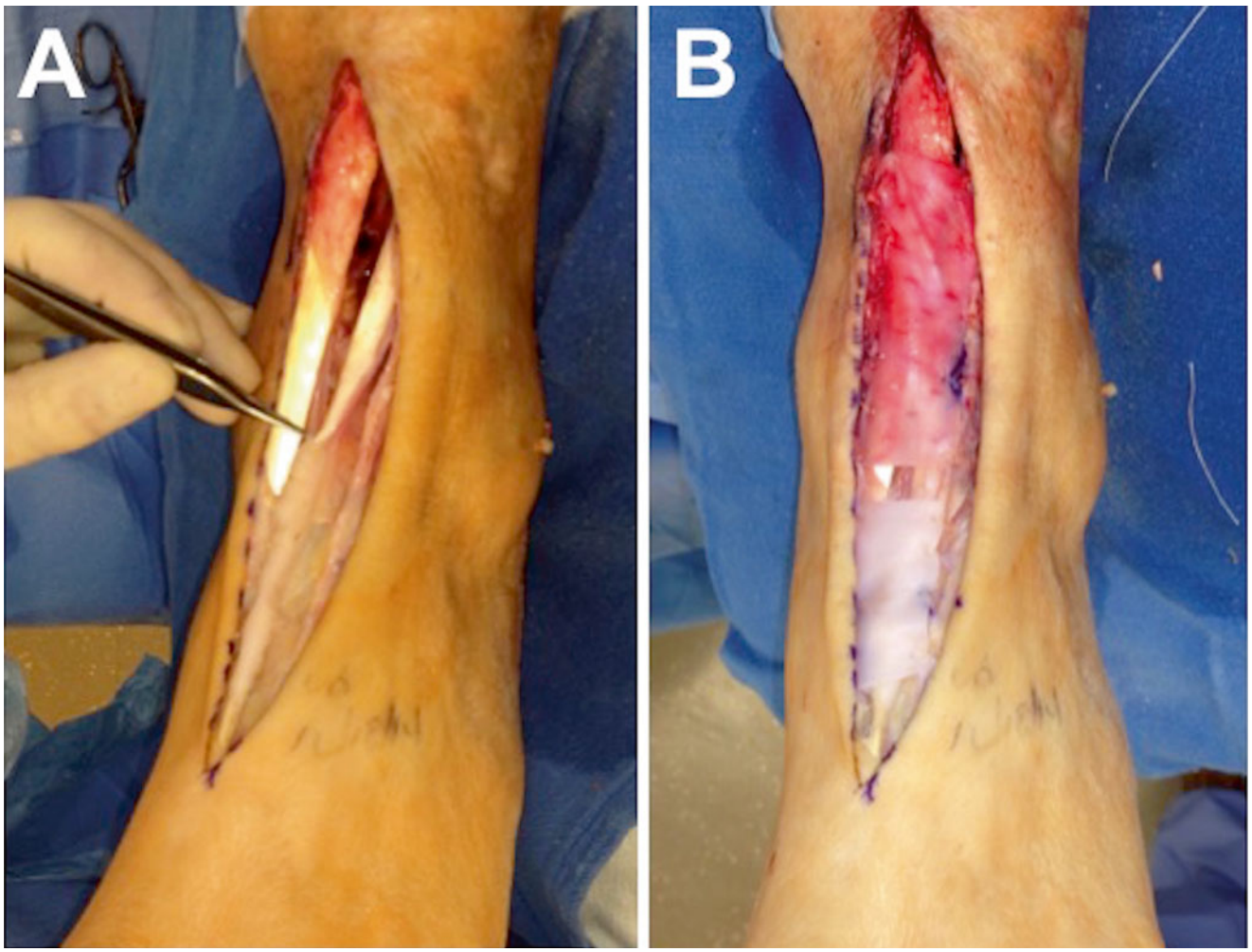

Fig. 13.4 Temporary imbrication (tenodesis) of tendons and parachuting them down onto deep tissues takes pressure of the incision (**a**). Reconstruction of the retaining structures of the ankle with an ingrowth substrate (PriMatrix®, TEI Medical, Boston, MA) not only prevents bowstringing but also relieves incision tension and provides an ingrowth medium if wound dehiscence were to occur, making negative-pressure wound therapy more effective (**b**)

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. 13.8). 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. 13.3). 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 central area of the wound. Skin eversion and skin line relief is 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. 13.5). Postoperative edema control is implemented. Ankle range of motion is limited for 2–4 weeks until the revised wound "stabilizes."

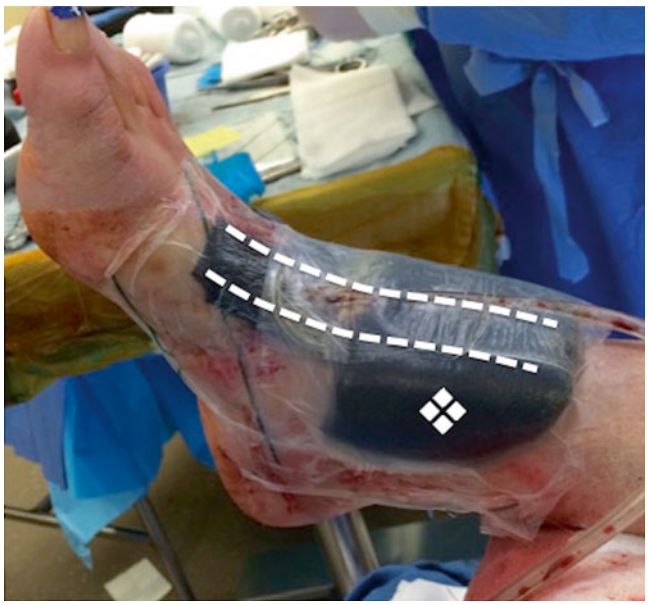

Fig. 13.5 Example of incisional negative-pressure wound therapy dressings (*arrow* and *outlines*) for tight or tenuous incision closure. The authors use spare foam to pad the skin from the suction hose (❖). Pressures are set at 50–100 mmHg continuous or intermittent for delicate skin

Debridement and Negative-Pressure Wound Therapy Dressings

Often, the bane of the surgeon is the area just lateral to the tibialis anterior tendon (Fig. 13.2). 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 13.1). 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

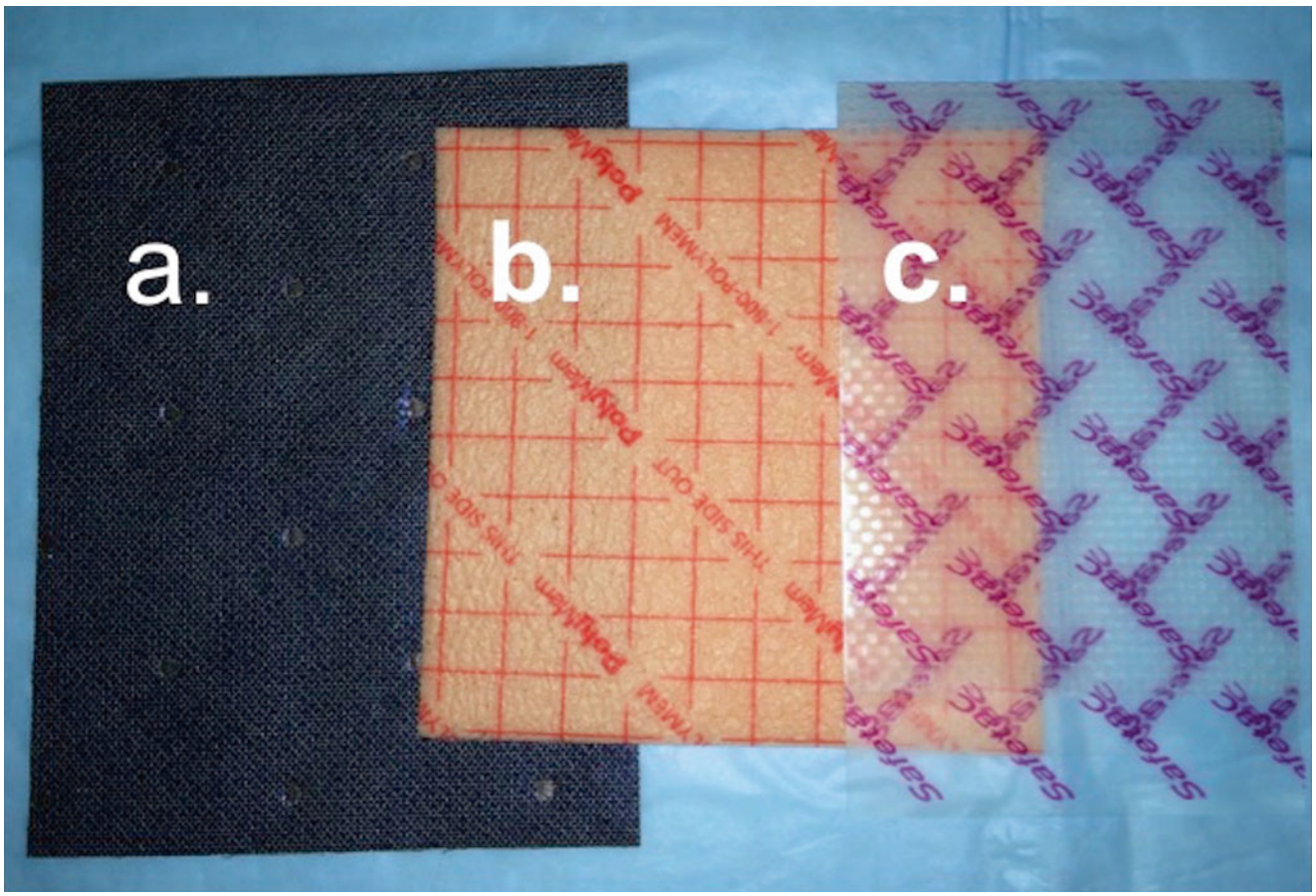

Fig. 13.6 The combination of silver-coated dressings (**a**), PolyMem (**b**), and Mepitel (**c**) will assist in providing a dressing that is bactericidal and absorbs excessive surface fluid while allowing local fluid evaporation with a "tissue-friendly" self-adhesive

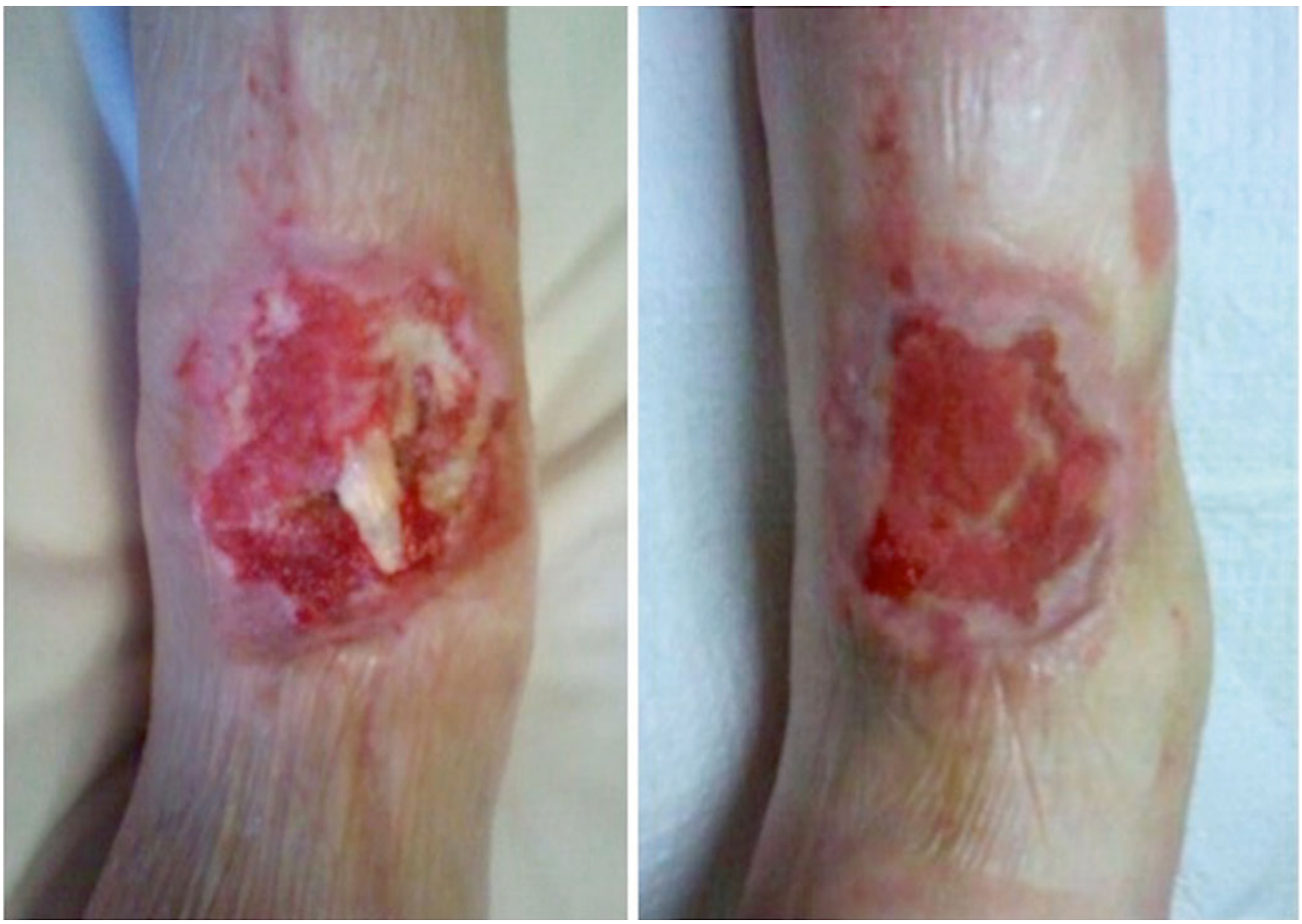

Fig. 13.7 Example of wound with exposed tendon after total ankle replacement that was successfully managed by close follow-ups, serial debridements, and negative-pressure wound therapy dressings. A split-thickness skin graft is now ready to be applied (Photo courtesy of Benjamin Overly, DPM)

the 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, hyperbaric oxygen therapy is 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. 13.11). The extensor digitorum brevis muscle flap may be useful for small mid- to distal junction area of wound breakdown, but the size of the muscle belly is highly variable and adequate rotation may

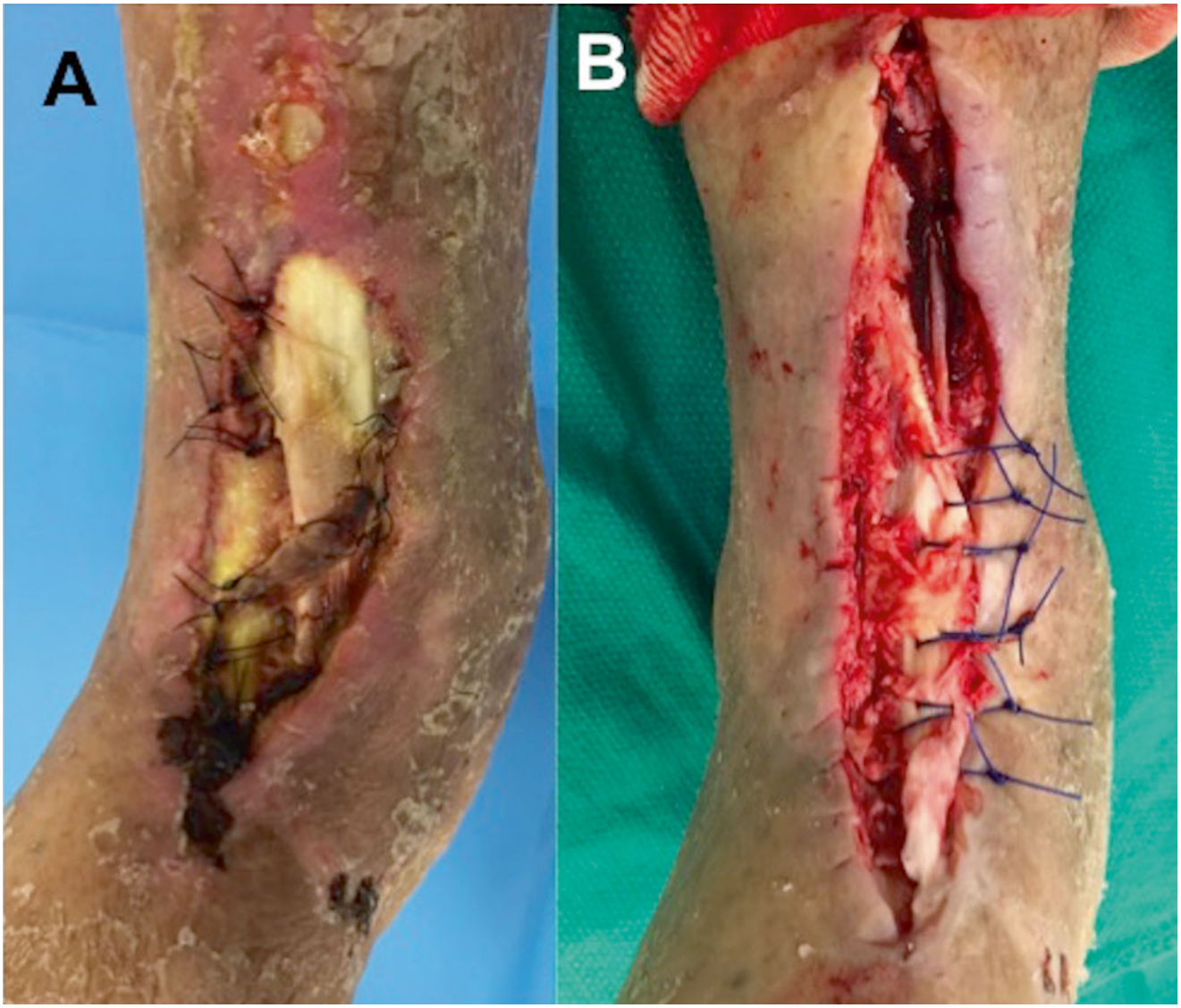

Fig. 13.8 Subacute wound dehiscence/necrosis with exposed tendons (**a**). Appropriate debridement to viable tissue may be followed by negative-pressure dressings prior to final free flap coverage (**b**) (Photo courtesy of David A. Ehrlich, MD)

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. 13.12), 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 preformed 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. 13.13). Donor site morbidity with these flaps is a concern, but pre-lamination of the donor site 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.

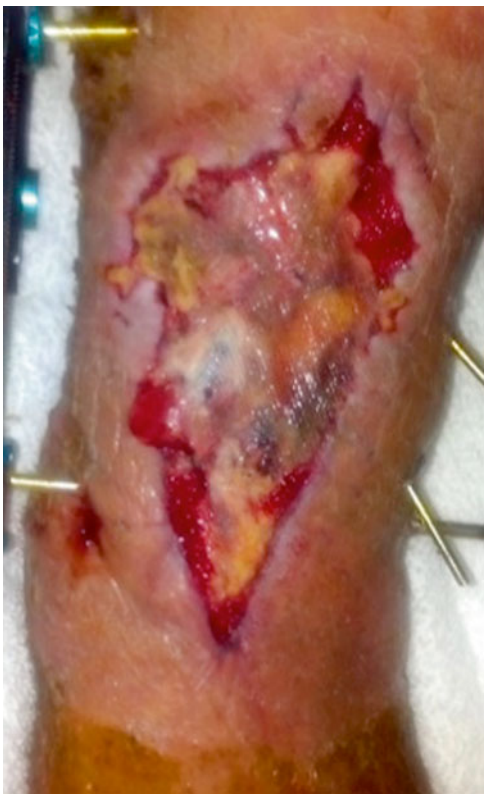

Fig. 13.9 Large surface area wound with tendons below a weak granulation bed. Although split-thickness skin grafting may be performed, this type of wound often results in a chronically unstable soft-tissue envelope, requiring resurfacing with a free flap in order to prevent future breakdown or allow future surgical approaches to manage total ankle replacement revision (Photo courtesy of Benjamin Overly, DPM)

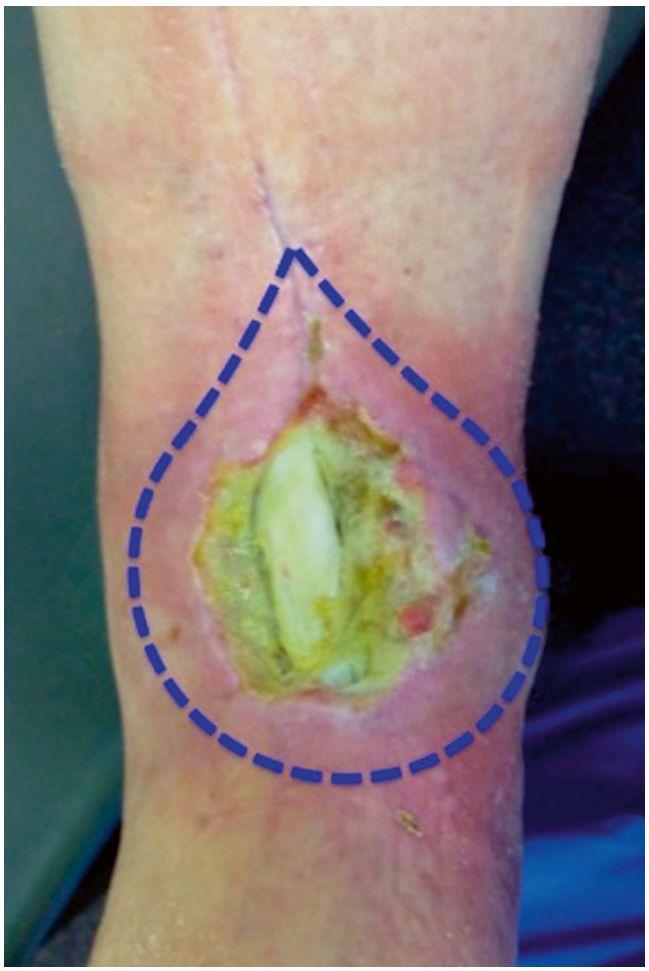

Fig. 13.10 Chronic non-healing wound after total ankle replacement. Desiccated, exposed tendon surrounded by marginally viable tissue places this wound in consideration for free flap coverage. Due to extension of dysvascular soft tissue over the medial malleolar region and proximally, flap coverage will need to extend beyond the confines of the visible wound (*dashed teardrop*) (Photo courtesy of Benjamin Overly, DPM)

Table 13.1 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 Veraflow™ VAC® (KCI, San Antonio, TX)

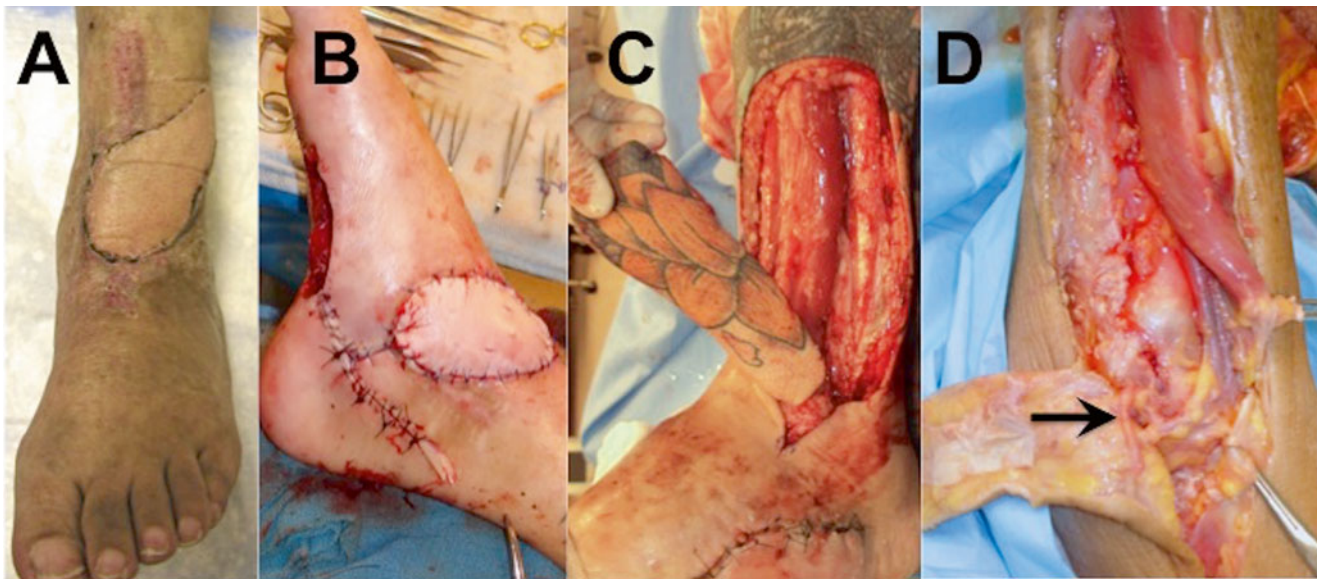

Fig. 13.11 The reverse sural flap may cover large areas of the total ankle replacement incision (**a**). The plantar medial artery flap has limited reach to the distal anterior/medial ankle (**b**). The distally based lateral supramalleolar flap can transpose large area of tissue anteriorly but may expose 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

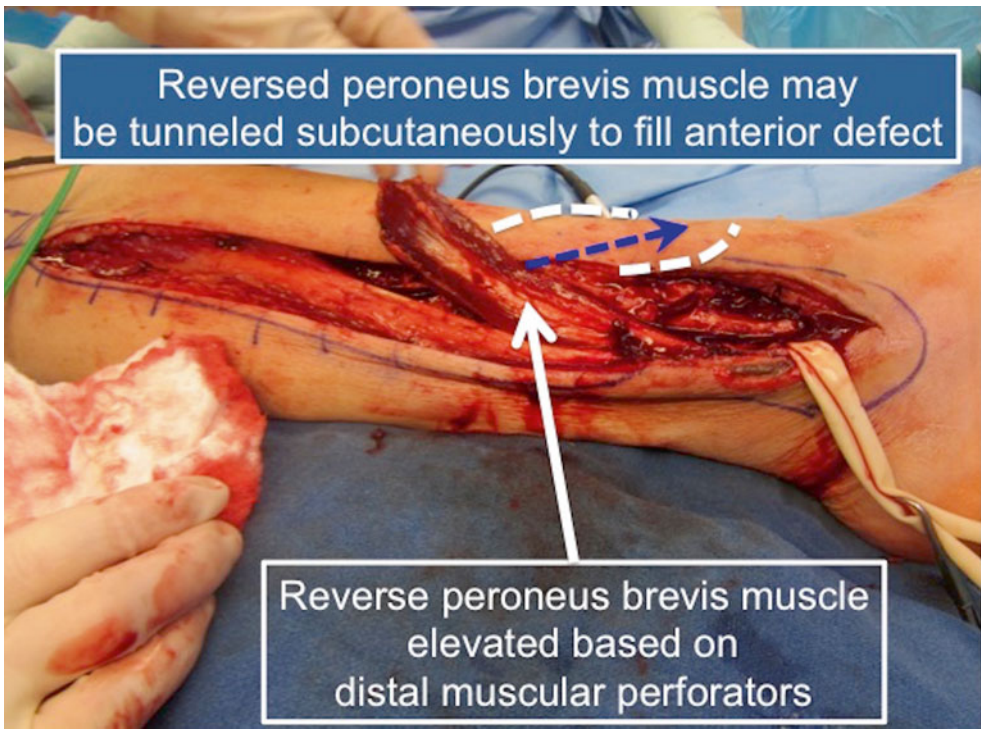

Fig. 13.12 The reversed peroneus brevis muscle flap may provide limited proximal anterior wound fill. The soleus muscle flap, either as a standard flap or a distally based hemi-soleus variation, may not prove reliable coverage for distal one-third anterior tibia and ankle region coverage

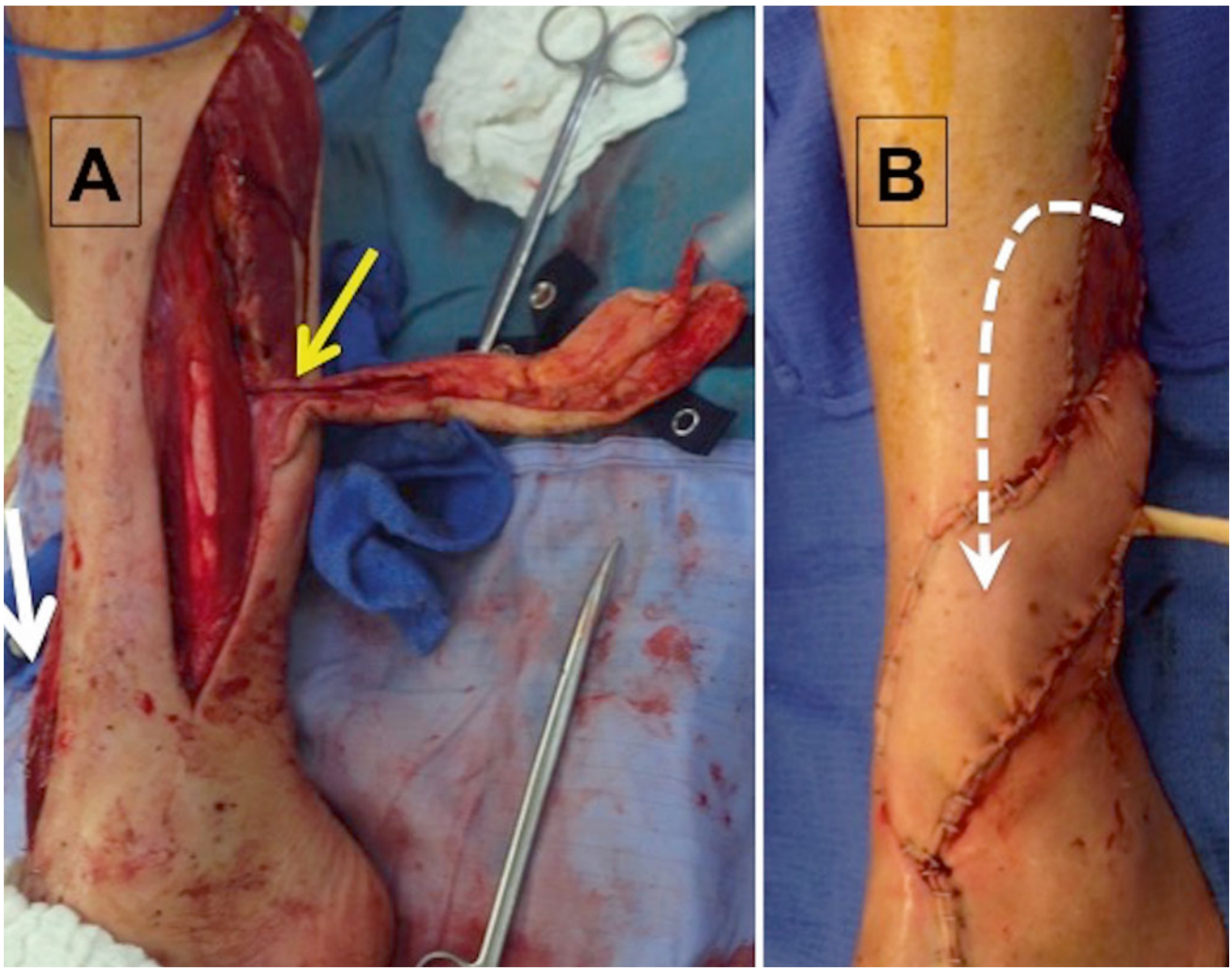

Fig. 13.13 Sural artery skin perforator-based propeller flap (perforator, *yellow arrow*) for anterior total ankle replacement wound complication (*white arrow*, **a**). Propeller flap rotated (*white dashed arrow*), inset, and small residual donor defect backfilled with a split-thickness skin graft (**b**)

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. 13.14), serratus anterior, rectus abdominis (Fig. 13.15), or the gracilis muscles (Fig. 13.16). 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, have revolutionized soft-tissue free flap surgery. A composite of flap containing

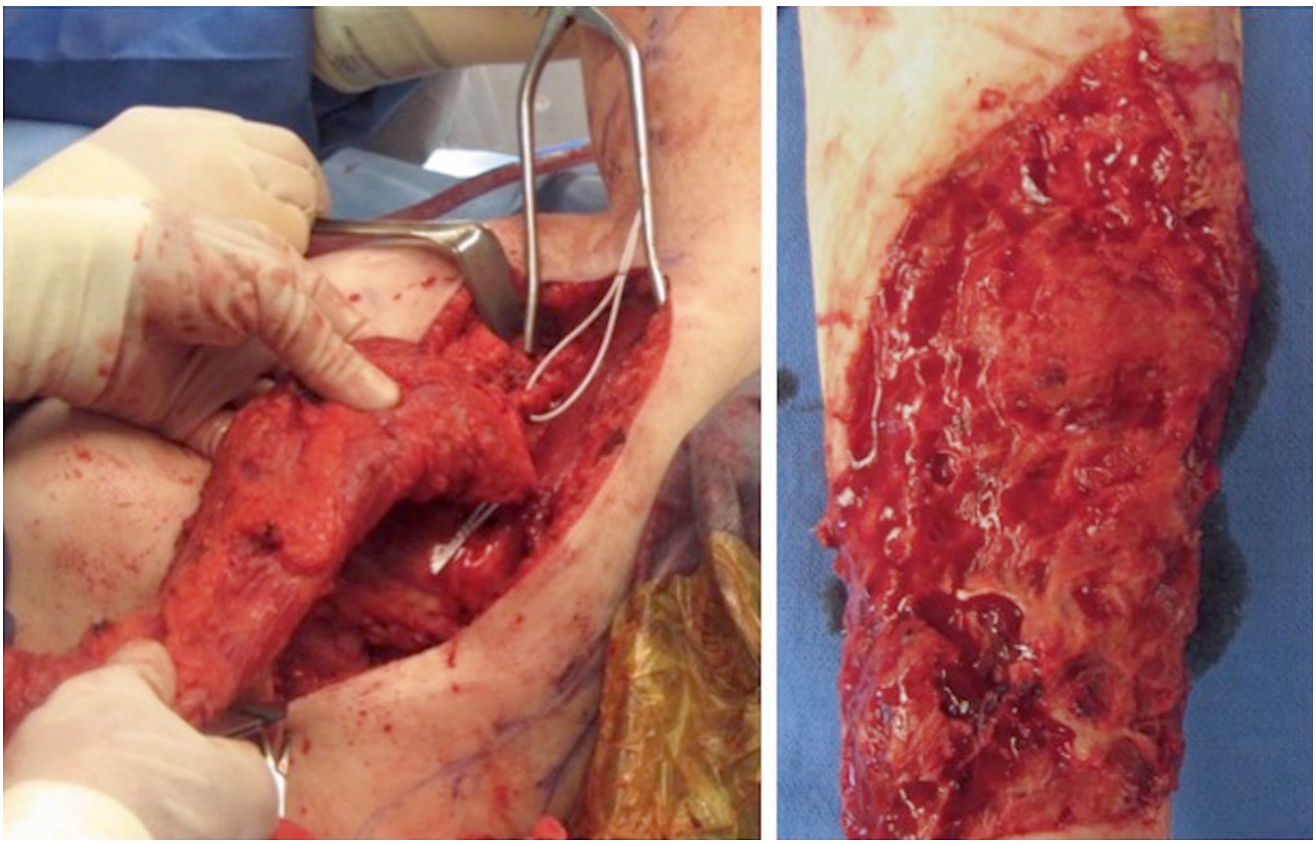

Fig. 13.14 Latissimus dorsi muscle free flap is quite large and has its greatest utility in massive wound coverage. This flap can be split based on its two main intramuscular coursing vessels to decrease bulk. It may also be taken with a small skin paddle and trimmed to fit smaller defects. A pedicled 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

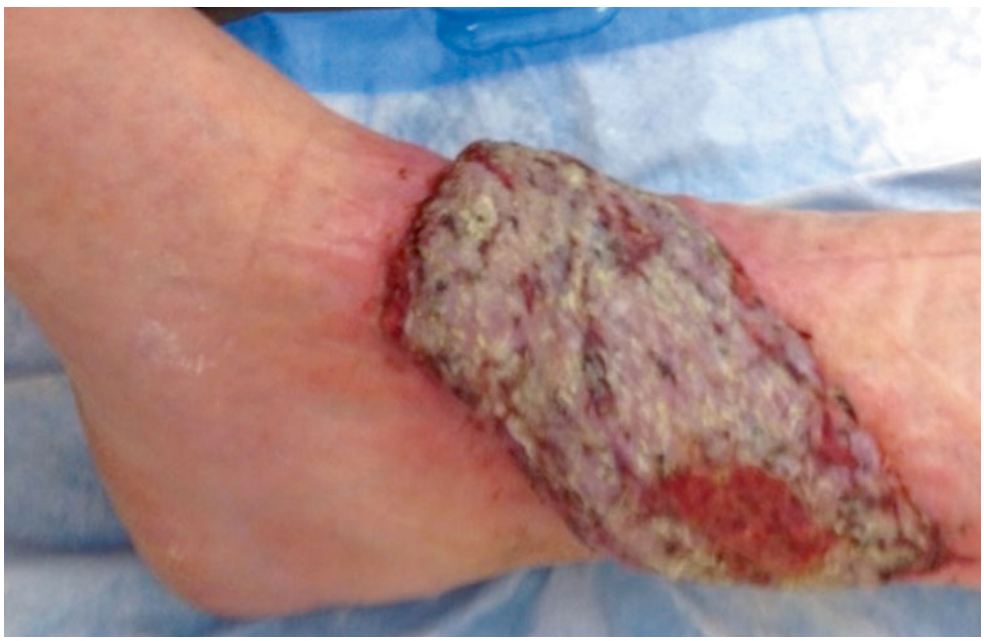

Fig. 13.15 Appearance of a free rectus muscle flap with poor skin graft take. Bulk and a lack of subcutaneous padding are the relative disadvantages of free muscle flaps, unless a skin paddle is harvested. Nonetheless, free muscle flaps are still considered to be traditional reliable workhorse free flaps 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)

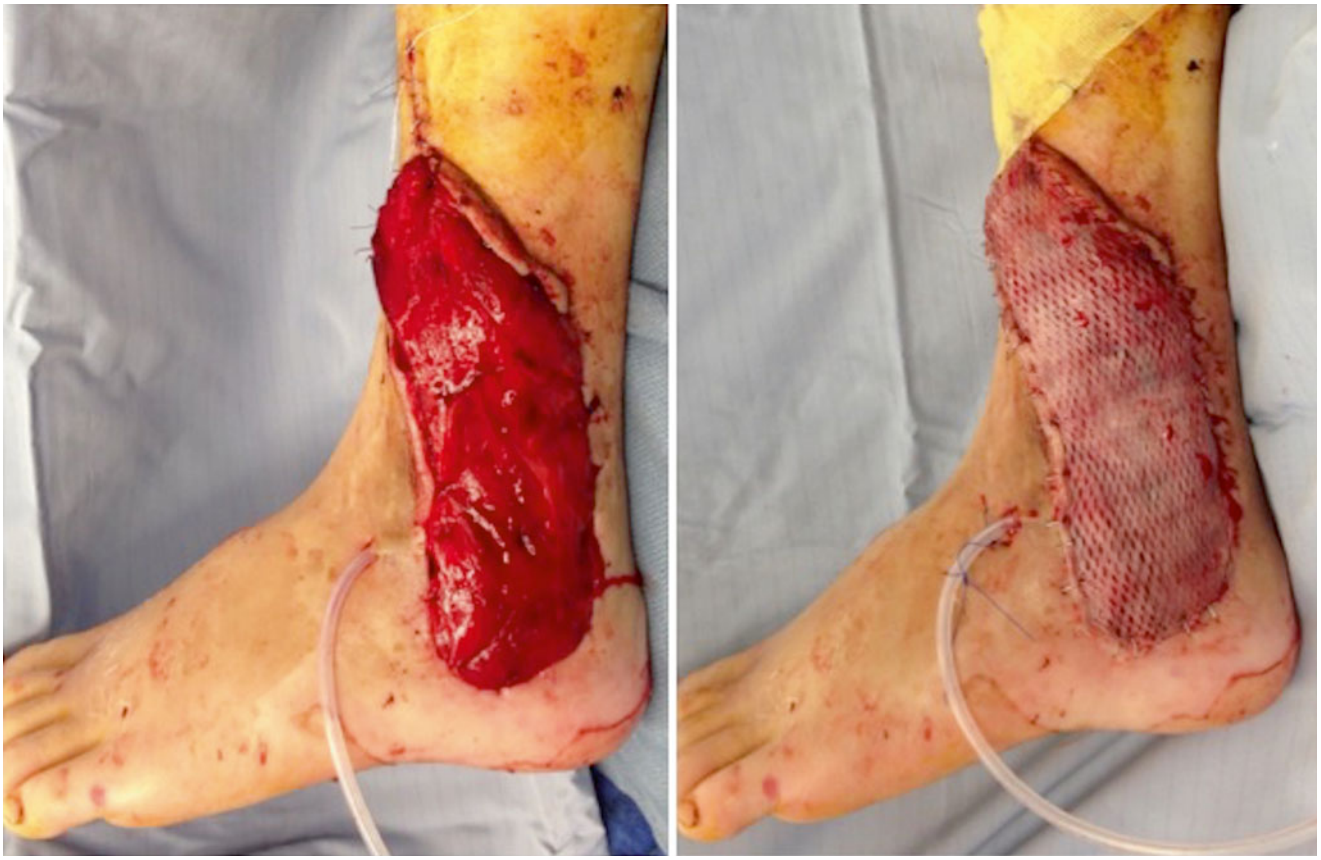

Fig. 13.16 Example of a gracilis muscle free flap for ankle coverage with lateral extension of the wound. Immediate split-thickness skin grafting is shown in *right panel*. Although significant flap atrophy will occur over the ensuing 6 months, shoe fit can be still difficult and debulking of the muscle may then be required

skin/subcutaneous fat/fascia ± muscle, 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 [6]. 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. 13.17a). 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. 13.16, 13.17, and 13.18). When soft-tissue coverage is needed along with a large amount of vascularized bone, the free osteocutaneous fibula flap (Fig. 13.19) can be quite 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.

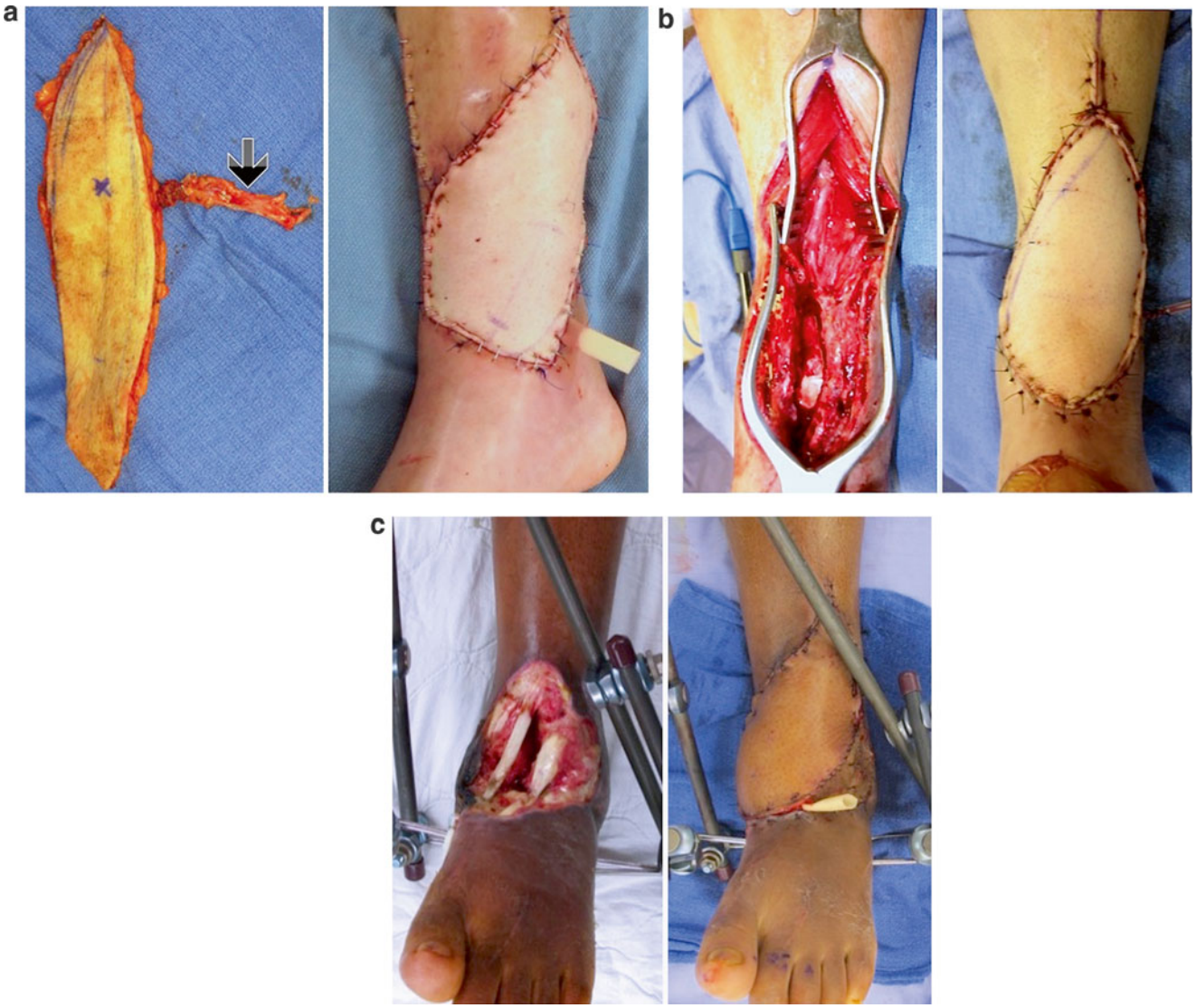

Fig. 13.17 Free anterolateral thigh (ALT) flap (**a**). Note how thin and supple the ALT flap is; "x" marks the skin perforator; *arrow* marks the vascular pedicle. Example of free ALT flap used for soft-tissue coverage after an anterior ankle incision developed extensive distal central and medial wound 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, an antibiotic-loaded polymethylmethacrylate cement spacer placed and free ALT flap used for wound coverage in anticipation of possible late total ankle replacement re-implantation (**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**)

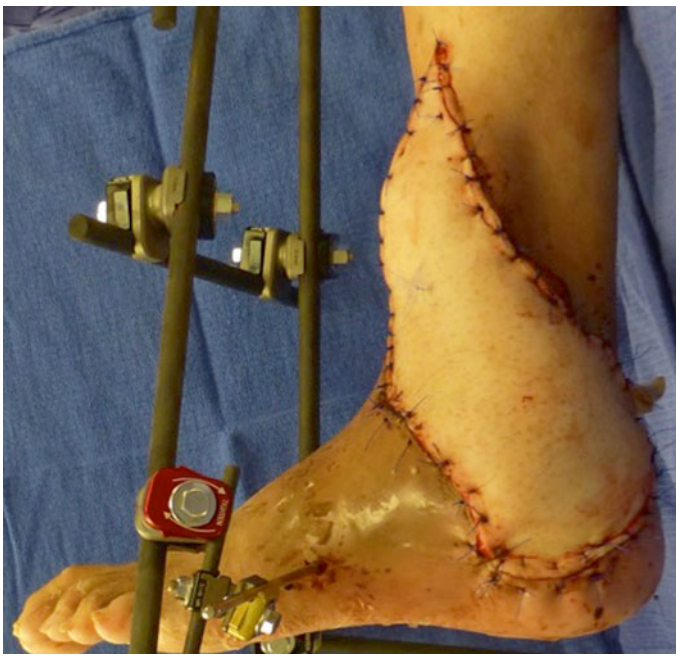

Fig. 13.18 The free anterolateral thigh flap may be used both for acute anterior incision breakdown after total ankle replacement and to resurface a large area of chronically unstable, hostile soft-tissue envelope after multiple prior surgeries

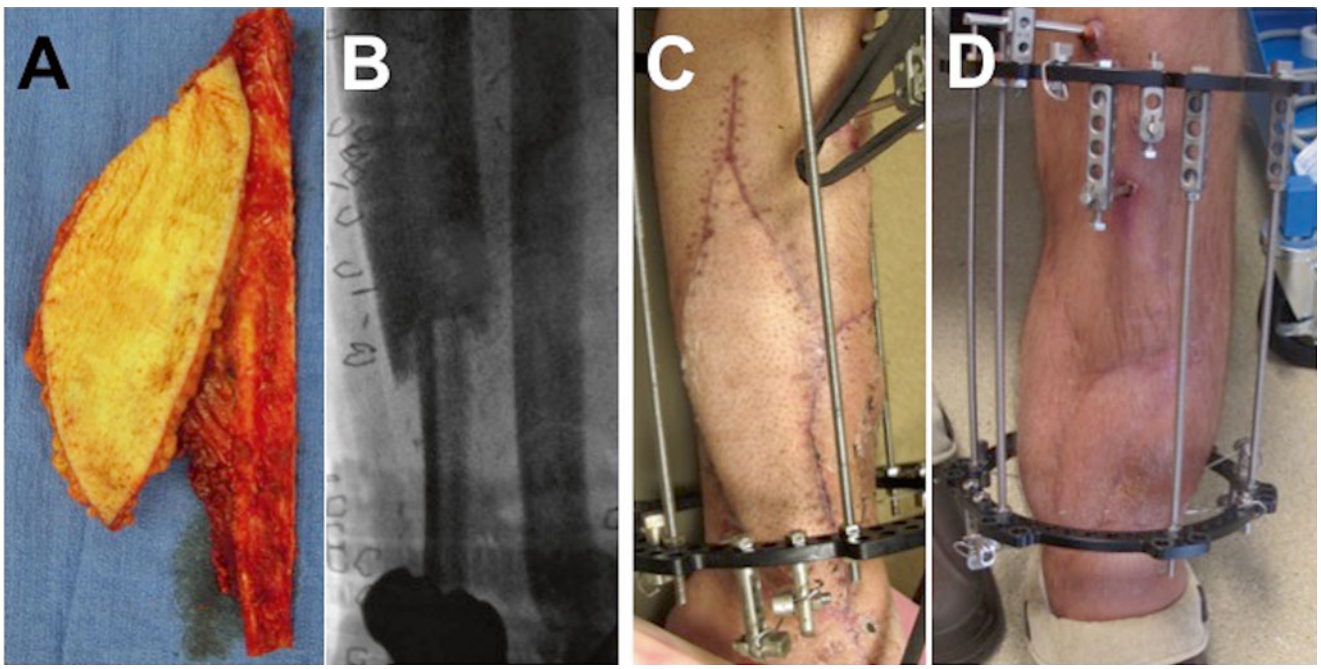

Fig. 13.19 Free fibula osteocutaneous flap for limb salvage after severe distal tibial bone loss and anterior/medial soft-tissue loss after an infected total ankle replacement with massive wound complications. Intraoperative photograph of the harvested fibula osteocutaneous flap (**a**). Intraoperative 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

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.

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14 Managing Varus and Valgus Malalignment During Total Ankle Replacement

Mark A. Prissel, Murray J. Penner, Gregory C. Berlet, Christopher Bibbo, Christopher F. Hyer, and Thomas S. Roukis

Frontal plane deformity is a frequent concern among surgeons performing total ankle replacement (TAR). Maintaining correct frontal plane stability is paramount to the initial success and ultimate longevity of the prosthesis. Inappropriate management of varus or valgus malalignment in primary TAR can result in early predictable failure requiring revision. The editors of this book are truly experts in management of the subtleties of TAR including an innate appreciation of the importance of proper management of frontal plane deformity. This chapter will function as an "ask the experts" panel with posed questions and offered responses by each panel member. The responses are truly "expert opinion" and are not intended to heavily reference peer-reviewed publications for validation, but rather detail each panelist's experience from his own practice. Some of the concepts and responses detailed throughout this chapter may initially appear redundant; however, the repetitive echoing of expert understanding demonstrates the necessity for the novice or developing TAR surgeon to acknowledge the importance of these repeated themes and agreed tenets of the management of frontal plane deformity in TAR.

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What Structures and to What Extent Do You Commonly Release for Varus Malalignment?

Penner: Varus deformity in mild degrees is very common. In the mild situations, usually with less than 10° of varus tilt, partial release of the deep deltoid ligament from the medial aspect of the talus down to the level of the sustentaculum is often required. Care to go all the way posterior to the posterior tibial tendon sheath is important to ensure the posteromedial corner, which is usually the "tight" point, is appropriately freed up. Occasionally, a lateral ligament reconstruction is still needed in these situations to ensure good coronal plane stability throughout the full range of motion.

In more severe varus cases, a more comprehensive approach is needed. Typically, a vertical medial malleolar osteotomy is used to allow the medial malleolus to slide distally, loosening the medial side. Ideally this is done at the point of final balancing and polyethylene bearing trialing. As this osteotomy will increase the joint space, it is critical to ensure that thick enough polyethylene trials are available. Sliding distally by 4–6 mm is common, and this amount still typically leaves a satisfactory contact surface across the osteotomy to allow simple percutaneous fixation with two screws placed from the medial side. If the medial malleolus

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_14

is dysplastic from prolonged severe wear against the medial talus, removal of a small anterior vertical wedge at the time of osteotomy allows "closure" of the anterior ankle mortise medially, further relaxing the medial soft-tissue structures and providing some bony resistance to varus talar tilt.

At times, varus is associated with a long lateral malleolus, and tightening up the lateral side utilizing a shortening Z-osteotomy of the lateral malleolus is necessary. This may be combined with a lateral ligament reconstruction and occasionally with a medial malleolar osteotomy as well. If despite these measures, the posteromedial corner still seems tight, release of the posterior tibial tendon with transfer to peroneus brevis is utilized.

Berlet: I start by considering if the tibia and talus are less than 10° of varus relative to each other and consider this a congruent deformity. Congruent deformities, as a general rule, have varus because of the collapse of the talus into the tibia and do not have a ligamentous cause. In congruent deformity, I will release the deep deltoid, from the medial talus with a Cobb retractor, ensure that the tibia defect is within the planned bone resection, and then test for stability once the final implant position is established. The medial release is done until the talus will sit neutral to the final intended joint line.

In rare cases where the varus is not addressed with release from the medial talus, the next options in order are:

1. Release a sleeve from the medial malleolus sharply with a knife blade.
2. If this still does not address the medial tightness, I have opened up the posterior tibial tendon sheath.
3. Fractional lengthening of the posterior tibial tendon.
4. Medial malleolar sliding osteotomy as described by Doets et al. [1].

Incongruent varus deformity (tibia and talus have >10° of malalignment relative to each other) is managed by medial release, lateral ligament reconstruction, and often excision of a non-united piece of the distal fibula where the calcaneofibular ligament was formerly attached.

Bone cuts are dependent on whether the surgeon is using a coupled cutting technique or if the tibia and talus are addressed independent of each other. In severe incongruent varus, I prefer to use systems like the INFINITY® with PROPHECY® guidance as it allows me to focus on the individual bone cuts independent of the ligament balancing. In the case where the surgeon is using an implant system that has coupled bone cuts, the talus must be reduced accurately underneath the talus before the cuts are made. In some cases, it is helpful to reduce and then pin the talus so that the position of the bones relative to each other is held while the bone cuts are aligned.

Bibbo: All structures that contribute the varus or cavovarus need to be released: tendon, muscle, and fascia, in all foot and ankle segments. The type of release is determined by the reason for the varus ("know your varus"). Osteotomies are done for intrinsic bone deformity. Soft-tissue balancing is done only for soft-tissue reasons; the surgeon does this knowing it is a surrogate and that the deforming forces may continue.

Hyer: I'll use a medial peel off the starting with portions of the deep deltoid and creating a sleeve. I'll release more and more to dial the ankle out of varus. In some cases, I've found it necessary to fractionally lengthen the posterior tibial tendon as well. It's also important to check the lateral gutter for any fibrosis that could be blocking correction of the varus. I'm also more likely to perform an Achilles tendon lengthening in varus/valgus contracture cases. I'll make the call on whether a lateral ligament reconstruction is needed after the prosthesis and polyethylene liner are inserted.

Roukis: The general tenet of soft-tissue balancing involves the release of the contracted soft tissue on the concave side and reinforcement on the convex side of the ankle. Accordingly, varus malalignment correction during primary and revision TAR involves:

1. Removal of periarticular osteophyte formation and debridement of the medial, lateral, and posterior gutters
2. Circumferential release of the deltoid ligament complex off the distal medial tibia/medial malleolus and/or the medial talus or lengthening osteotomy of the medial malleolus
3. Transection or fractional lengthening of the posterior tibial tendon as visualized posterior to the medial malleolus
4. Correction of pedal deformities with dorsiflexory first metatarsal osteotomy and lateralizing calcaneal osteotomy
5. Lateral ankle ligamentous plication and/or tendon transfer to reinforce lateral soft-tissue restraint

In addition to, and in most instances instead of, these osseous and soft-tissue procedures, I have employed four simple and reproducible soft-tissue procedures to correct varus contracture at the time of primary or revision TAR surgery.

First, it is important to appreciate that the flexor retinaculum is continuous with most of the bands or fibers of the superficial deltoid ligament layer and as such can also tether the hindfoot in varus even after sequential release of the deep deltoid off of its osseous origin(s) and/or insertion(s). In these situations, I elect to perform flexor retinaculum release commonly referred to as tarsal tunnel decompression. Unlike with the surgical treatment of tarsal tunnel syndrome, it is not routinely necessary to release the deep fascia in the lower leg or fibrous septum about the deep surface of the abductor

hallucis muscle. However, these steps may be required in severe varus ankle deformities greater than 15° when acute correction would predictably result in compression of the neurovascular components of the entire tarsal tunnel. It should be noted that the neurovascular contents of the tarsal tunnel are not actually manipulated to limit potential for scar formation and subsequent nerve entrapment.

Second, although transection or fractional lengthening of the posterior tibial tendon itself has been used to correct a varus ankle contracture, this can be difficult to perform and unreliable. Instead of lengthening the tendon itself, I routinely employ recession of the tibialis posterior tendon at the musculotendinous junction in the lower leg. After the initial steps of correction are completed, the ankle is stressed in eversion, and if the ankle cannot achieve at least 5° valgus alignment with the foot maximally everted, a posterior tibial recession is performed.

Third, although most often an open modified Broström-Gould lateral ankle stabilization is performed as a primary procedure recently, a technique was developed to perform an arthroscopic modified Broström-Gould lateral ankle stabilization. I have successfully employed the instrumentation that comes in this kit to aid in performing a limited dissection modified "all inside" Broström-Gould lateral ankle stabilization. Once the sutures are passed from inside the ankle through the extensor retinaculum the anterior-lateral soft tissues about the hindfoot/ankle are manually compressed to bring the lateral capsule and inferior extensor retinaculum against the distal-lateral tibia/fibula. The sutures are tied under tension flush on the inferior extensor retinaculum with the ankle held in neutral position.

Finally, I routinely employ a modification of the Evans peroneus brevis tendon transfer described in more detail below.

What Structures and to What Extent Do You Commonly Release for Valgus Malalignment?

Penner: Valgus ankles tend to be more globally lax and releases are not commonly required. However, at times, the peroneus brevis and/or peroneus longus tendons are tight. If this is the case, release of peroneus brevis in particular, with transfer medially to augment the posterior tibial tendon, is utilized. It is not uncommon to find valgus ankles have a short fibula, sometimes due to fracture malunion, and in these cases, a lengthening Z-osteotomy of the lateral malleolus is utilized. Again, this is ideally done at the time of final polyethylene trialing. At times, the syndesmosis is unstable in valgus ankles, and careful attention is needed to ensure this is not present. If it is, syndesmotic fusion at the time of TAR is optimal.

Berlet: Valgus malalignment is much more commonly incongruent when compared with varus ankle deformities. The thought process is similar to that of varus with a few key exceptions:

- The soft-tissue release is lateral. I prefer to take a Cobb retractor to the lateral wall of the talus and release the ligamentous restraints in a sleeve. It is my experience that in valgus I am often able to reduce the talus under the tibia more easily than in varus, and as such lateral releases are less common than medial releases in varus deformity.
- Medial ligament (deltoid) reconstructions are not done concomitantly with the TAR. If a medial ligament reconstruction must be done, it is as a staged procedure with the TAR following once the ligament reconstruction has been deemed successful.
- Always an Achilles tendon lengthening, usually in the technique of Hoke.

Bibbo: None routinely. It is generally a "tightening exercise," unless there is severe flat foot with talonavicular protrusion ("Bibbo stage 5," publication pending). In these cases, about 50 % have attenuation of the anterior talofibular ligament and lateral ligament instability.

Hyer: I'll begin with a calcaneofibular ligament and lateral gutter release and then tension the ankle out with a laminar spreader. If the ankle corrects and the deltoid is tensioned, I'll stop there. If there is still valgus, a more aggressive peel off the anterior and inferior borders of the fibula is performed. I'm more inclined to use a larger polyethylene liner in these cases to keep the deltoid appropriately tensioned. Obviously this necessitates an intact deltoid complex.

Roukis: Valgus malalignment correction mirrors those steps involved in addressing varus malalignment during primary and revision TAR and involves:

1. Removal of periarticular osteophyte formation and debridement of the medial, lateral, and posterior gutters
2. Circumferential release of the lateral ligament complex off the distal fibula or lengthening osteotomy of the lateral malleolus
3. Correction of pedal deformities with lateralizing calcaneal osteotomy or medial column, isolated or combined midfoot/hindfoot arthrodesis
4. Deltoid ligament plication and/or tendon transfer to reinforce medial soft-tissue restraint

I have employed one specific tendon transfer successfully, the modified "reverse" Evans peroneus brevis tendon transfer described below.

How and When Do You Incorporate Tendon Transfers into Management of Varus Malalignment?

Penner: As described above, posterior tibial tendon transfer to the peroneus brevis is utilized when the posteromedial corner remains tight, and the ankle has a tendency to "hinge" rather than "glide" as it moves through a range of motion, despite medial malleolar osteotomy and/or lateral side tightening (ligament reconstruction and/or shortening lateral malleolar osteotomy). No other transfers are typically used.

Berlet: The dynamic balance of the ankle is as important to consider as the static ligaments. In the case of varus deformity, almost always the causative issue is neurologic injury to the common peroneal nerve or profound and unreconstructable injury to the peroneal tendons. In most cases, these diagnoses have been considered as part of a preoperative plan. I prefer to do tendon transfers as a staged process with the dynamic balance being reestablished prior to the TAR. A flexor hallucis longus transfer to the fifth metatarsal works reasonably well to reestablish the dynamic balance in these cases, and the surgical incisions do not add risk to the TAR incision.

Bibbo: This is managed as needed, just as for any pathology to balance the ankle in the sagittal plane.

Hyer: I'm fairly conservative in taking on profound deformity in one stage. If the deformity is complex enough to require tendon transfers and hindfoot stabilization, I'll typically do these first in a separate surgery and confirm that we can achieve a stable foot alignment. Then in a separate stage, come back and perform the TAR. This is done in my mind both to prove that we can achieve stability and also to minimize surgical risk from having too many extensive procedures done all at once.

If the transfers needed are simply to augment the lateral ligament repair (e.g., modified Evans transfer) or a peroneus longus to peroneus brevis transfer, I would do this in one sitting. If it is more complex, like a posterior tibial tendon transfer through the interosseous membrane, I would stage that.

Roukis: When lateral ankle instability is appreciated despite medial soft-tissue release and appropriate congruous prosthesis implantation, I will routinely employ a modification of the Evans peroneus brevis tendon transfer in which the tendon is harvested through limited lateral incisions, then transferred deep along the calcaneus and talus, secured to the anterior-distal-lateral tibia, and secured with plate and screw fixation. In the presence of absent peroneal tendons, I have employed a cadaveric tendon and secured this to the fifth metatarsal base and anterior-distal tibia in the same fashion. Although nonanatomic, this modified Evans peroneus brevis tendon transfer is useful in providing lateral ankle and subtalar stability associated with varus contractures in TAR. Although I have limited experience with anterior tibial tendon transfer to the lateral midfoot, this tendon transfer is considered effective for reducing very severe deformities, predominantly seen with adduction of the forefoot.

How and When Do You Incorporate Tendon Transfers into Management of Valgus Malalignment?

Penner: As outlined above, transfer of the peroneus brevis tendon to the posterior tibial tendon is used when the peroneus brevis is obviously tight or when the posterior tibial tendon requires reconstruction and the degree of valgus correction is substantial (i.e., greater than 10°).

The choice to perform TAR in cases with substantial valgus talar tilt that is associated with deltoid laxity rather than lateral plafond erosion must be very carefully considered. The results of TAR in such cases are not satisfactorily predictable, and choosing the greater predictability of a fusion in such specific situations is often well warranted.

Berlet: Dynamic imbalance of valgus is usually due to posterior tibial tendon dysfunction and Achilles tendon contracture. The posterior tibial tendon is reproducibly replaced with a flexor digitorum longus tendon transfer, in addition to an Achilles tendon lengthening to protect the transfer and a calcaneal osteotomy or a medial double (i.e., talonavicular and subtalar joint) fusion.

Bibbo: To manage this, I perform more of a deltoid ligament reconstruction at the ankle. However, at times, this deformity can also require a flexor hallucis longus transfer for midfoot collapse in posterior tibial tendon dysfunction that is transmitted to the ankle joint.

Hyer: In my own experience, I have not had great success in using tendon transfers to stabilize valgus malalignment. Again, if a transfer and deltoid reconstruction is indicated, I would typically do this in a staged fashion using the technique described by Haddad and then come back later for the TAR [2]. If the deltoid has a good end feel and is intact, I'll use larger polyethylene size to stabilize the valgus.

Roukis: Although nonanatomic, the so-called modified reverse Evans peroneus brevis tendon transfer where the peroneus brevis is harvested as noted for varus malalignment above. Next, the peroneus brevis tendon is anastomosed to the peroneus longus tendon with heavy gauge nonabsorbable suture at the proximal extent of the first incision holding the first ray maximally plantarflexed and the forefoot pronated to

limit any valgus thrust that could stress the deltoid ligament repair. The peroneus brevis tendon is then retrieved through the distal incision and then brought through a 4-mm drill hole in the talus from lateral to medial aiming for the junction of the talar neck and body plantar to midline at the exit point medially. The tendon is then brought superiorly and obliquely to the anterior medial aspect of the distal tibia where it is secured under maximum tension and compressed between the tibia and an overlying plate and screw construct.

How and When Do You Incorporate Osteotomies into Management of Varus Malalignment?

Penner: This is outlined above.

Berlet: The orthopedic paradigm aligning the bone structures and balancing the soft tissues with lengthening and reconstructions, followed by internal fixation, must be respected. In the situation of significant mechanical axis deviation, this must be corrected with either osteotomies or fusions prior to the joint replacement. Although there are exceptions, I prefer to reestablish the mechanical axis with soft-tissue reconstructions as a staged surgery prior to my TAR. My preferred osteotomy for varus hindfoot alignment is a Z-cut calcaneal osteotomy that allows for the tuberosity to be aligned neutral and shifted laterally. Forefoot varus that is suspected of driving the hindfoot varus must be addressed as well.

Bibbo: For tibial deformity that cannot be corrected by "arthritic" TAR bone cuts which is especially true in proximal medial tibia and distally over 20°, it is tough to be creative with bone cuts and a supramalleolar osteotomy is required. The forefoot may contribute to this deformity and require medial cuneiform or first metatarsal dorsiflexory wedge osteotomies as well.

Hyer: We need to use whatever means necessary to achieve as neutral balance as possible. In the varus deformities, assuming this is not from an osseous deformity, I typically rely on a Dwyer calcaneal closing wedge with lateralizing shift to aid hindfoot alignment and off-load the lateral soft-tissue reconstruction. I'll also pay close attention to the first ray and determine if a dorsiflexion first metatarsal osteotomy may be needed as well.

Roukis: Rigid deformities that cannot be reduced with soft-tissue releases alone warrant osseous correction most commonly employing dorsiflexory first metatarsal osteotomy and lateralizing calcaneal osteotomy. Supramalleolar tibial osteotomy use is reserved for very severe varus deformities or more commonly translation deformities in order to achieve a neutral hindfoot/ankle alignment to the lower leg. In general, I have a high threshold for osseous realignment when addressing varus malalignment instead favoring soft-tissue release/stabilization procedures.

How and When Do You Incorporate Osteotomies into Management of Valgus Malalignment?

Penner: This is outlined above.

Berlet: The foot must be plantigrade to the ground prior to the consideration of a TAR. I prefer to stage this and do the flat foot reconstruction first followed by the TAR at another time. There is merit to either pinning the ankle neutral or placing a temporary polymethylmethacrylate spacer into the joint so that appropriate ligament tension can be established while the flat foot reconstruction is healing. MRI or CT is a useful guide to judging the arthritis in the subtalar and transverse tarsal joints. In the case of mild to moderate arthritis, I prefer to spare the hindfoot joints and not perform fusion but rather bias toward periarticular osteotomies. My preference for hindfoot osteotomy is a Z-cut calcaneal osteotomy that allows for the power of a lateral column lengthening and medial shift osteotomy in one osteotomy. This Z-cut osteotomy is powerful, versatile, and has a low complication rate in our hands.

Bibbo: Hindfoot osteotomies are used to balance heel strike in the "favor of varus" and protect tendon transfers. Plantarflexory first ray osteotomies may require consideration as well.

Hyer: I stage most of the larger deformities, so osteotomies and selected arthrodeses are typically done ahead of time during a prior surgery. In mild cases where single stage reconstruction is done, I'll use a medializing calcaneal osteotomy for valgus deformities.

Roukis: As with varus deformities, rigid valgus deformities that cannot be reduced with soft-tissue releases alone warrant osseous correction most commonly employing lateralizing calcaneal osteotomy or medial column, isolated or combined midfoot/hindfoot arthrodesis. In general, I have a low threshold for osseous realignment when addressing valgus malalignment.

When Should Management of Frontal Plane Deformity Be a Staged Procedure Prior to Total Ankle Replacement?

Penner: This decision is based upon the total amount of surgery anticipated to be necessary to obtain correct coronal plane alignment of the ankle joint in conjunction with a stable, neutrally aligned plantigrade foot. As significant foot

deformity commonly accompanies varus ankle deformity, a substantial foot corrective procedure may be required. Depending on this complexity, staging the procedure to allow for precision surgery under tourniquet control may be best.

Additionally, particularly in valgus ankles, the true status of the deltoid ligament cannot be determined preoperatively. Even severe varus ankles may prove to have deltoid insufficiency due to the erosion of the deltoid attachments on both the medial malleolus and the hindfoot, and this is often only identified intraoperatively. Since significant deltoid compromise is often associated with significant foot deformity, a staged procedure to realign the foot and simultaneously assess the viability of the deltoid ligament may be optimal.

Berlet: I address frontal plane deformity in the same setting as the TAR only when I believe that I can achieve my correction intraarticularly with osseous cuts and soft-tissue releases. Although there are exceptions, I will usually book the reconstruction of the varus and valgus ankle that needs periarticular osteotomies or fusions as the first stage followed by a second stage TAR approximately 3 months later.

Bibbo: For severe pro- or recurvatum, principles of deformity correction need to be followed, as well as for equinus that is rigid beyond 15°–20°.

Hyer: I think this is based both on surgeon experience and comfort as well as the complexity of the deformity that exists. Obviously the patient needs to be aware of the pros and cons of both options, but ultimately I believe this is the surgeon's decision. I tend to err on the side of being conservative with the valgus deformities and more often stage the deformity correction procedures first and then come back for the TAR. I'm more likely to correct varus deformities at the same sitting as the TAR as those are more easily corrected in my hands.

Roukis: Severe deformity that requires periarticular procedures such as a supramalleolar tibial osteotomy or hindfoot/midfoot arthrodesis procedures associated with significant correction should be staged. This is to allow for the soft tissue to fully heal and the osseous structures to obtain restoration of vascular supply so the eventual TAR will be able to incorporate with the bone. Additionally, it is well established that correction of these deformities often delays the patient's pain such that the TAR is delayed into the future.

Does Increasing the Height of a Polyethylene Liner Play a Role in the Management of Frontal Plane Deformity?

Penner: Increasing the thickness of the polyethylene bearing for any given level of tibial resection has the effect of lowering the ankle joint line. This will have an effect on the biomechanics of the ankle, and this effect may become unfavorable if excessive thickness is used. This may be seen in ankles with insufficient deltoid ligaments, which will allow the medial side to stretch out too far.

Berlet: Overstuffing a joint to achieve front plane stability is a rookie mistake. This will lead to a stiff joint and premature polyethylene wear and potentially implant subsidence. The surgeon must develop the skills to properly balance and joint and not depend on overstuffing as a salvage attempt.

Bibbo: No. That height increase overstuffs the joint and changes the kinematics. The only time this is appropriate is when there is equal varus and valgus laxity.

Hyer: It does for me but I don't think we can simply rely only on polyethylene height for frontal plane stability. The soft-tissue structures have to have an end point of stability for this to work. Polyethylene height can help tension the soft-tissue structures assuming they are intact. I also think a sulcus designed talar implant with a fixed bearing helps with management of frontal plane deformity.

Roukis: Adding a thicker polyethylene liner with a fixed-bearing TAR system will tighten the ankle joint in all planes including the frontal and sagittal. With a mobile-bearing prosthesis, the polyethylene insert tends to displace anteriorly or posteriorly when used to tighten the ankle joint and therefore is not an effective approach. I will use a thicker polyethylene insert to tighten the joint only if it is clearly identified that the joint requires more contact between the polyethylene insert and talar component due to over resection or improper tensioning of the ankle during trial component placement. I do not believe that relying on the polyethylene insert alone will lead to long-term joint stability.

Which Is a More Difficult Problem to Manage in Primary Total Ankle Replacement, Varus or Valgus? Why?

Penner: Valgus is much more difficult to manage due the critical role of the deltoid in a successful TAR. If the competence of the deltoid cannot be ensured, the risk of failure of the TAR is dramatically increased, and consideration of an ankle fusion is warranted. Since valgus deformities are most commonly "lax" while varus deformities are most commonly "tight," and since releasing tight structures is generally more predictable and successful than tightening lax structures, correction of varus ankles is much more predictable.

Berlet: Valgus is by far the more difficult. The medial ligamentous structures are the isometric point for the ankle, and this isometry is very difficult to recreate with reconstructions.

I warn the inexperienced TAR surgeon to be very careful and humble in approaching valgus deformities.

Bibbo: Valgus. The medial column is most important area of midfoot and forefoot, which transmits to ankle joint and is unforgiving. My experience is that severe valgus usually also has a proximal segment issue as well (e.g., knee, hip) that is very difficult to control unless these are corrected first (start with hip, then knee, then ankle). Straighten the limb like the length of a gun barrel.

Hyer: I think valgus is more difficult to deal with in TAR than varus. An incompetent deltoid ligament complex has been difficult to reconstruct and maintain itself over time. It is a complex structure with multiple attachment points, which are the pivot points for the ankle. The valgus ankle also typically has other deformities present throughout the hindfoot and medial column that are crucial in the stability of the TAR.

Roukis: Valgus deformity is more difficult because the procedures required either involve extended arthrodesis, soft-tissue manipulation, or tendon transfers that are many times underpowered or unreliable. I also believe that patients with a valgus malalignment tend to have more proximal leg, knee, and hip malalignment deformities that are obviously not addressed by working on the foot alone.

What Is Your Threshold of Severity for Varus? Valgus?

Penner: In my practice, there is no real upper limit on the degree of varus that can be dealt with. The criteria are:

1. The foot can be corrected to a stable, neutrally aligned plantigrade position.
2. The overall alignment of the lower extremity can be safely corrected to neutral (i.e., genu varum).
3. The bone stock and quality around the ankle is sufficient to allow for stable malleolar or supramalleolar osteotomies in conjunction with stable seating of the TAR implants.

Since such reconstructions have a greater tendency for recurrence of deformity, off-axis loads are more likely, and a very stable bone-prosthesis interface, such as that afforded by a stemmed implant, is critical.

With respect to valgus, the limiting factor is the deltoid ligament competence. If the ligament is obviously lax or contains a substantial amount of calcific degeneration, I do not believe it can be counted on to hold up over the expected lifetime of a TAR. Thus far, I have not been convinced of the durability of the various deltoid ligament reconstruction techniques and as a result would favor a well-performed ankle fusion to an unpredictable high-risk TAR in the setting of deltoid incompetence.

Berlet: Varus is now mostly unlimited. Valgus with greater than 20° of deformity will almost always have a staged reconstruction of the medial supports, and if it holds up, then a TAR is performed in three or more months.

Bibbo: Varus, 15°–20°. Valgus, 10°–15°.

Hyer: It's not as simple as a number of degrees for either varus or valgus of the ankle. I really need to evaluate the whole foot and determine if the deformity is only ankle based or something greater. That being said, I will take on larger varus deformities (approximately 30°) than I will with valgus deformities (approximately 10°–20°).

Roukis: For varus, I have been able to correct 40° deformities associated with revision TAR; however, my experience parallels the literature where 15°–20° is the most commonly referenced limit. For valgus, I am leery of attempting TAR with deformities of more than 10° as the current options tend to be unreliable in the long term. In very select instances, such as revision situations where the patient requires an ankle-foot orthotic regardless of procedure performed (i.e., extended ankle/hindfoot arthrodesis or revision TAR), I may push these limits.

What Cautions Do You Have for Surgeons regarding Management of Frontal Plane Malalignment?

Penner: Much has been stated already in the paragraphs above, but it bears repeating that TAR in the setting of a valgus ankle with significant deltoid laxity is very high risk and should be avoided. Care to evaluate deformity above the ankle (e.g., tibia vara or genu varum) and below the ankle is crucial. The alignment of the foot and leg must be normal, or be made to be normal, in order to expect satisfactory function and longevity from any TAR.

Berlet: A few points that can help the novice arthroplasty surgeon:

- Learn your techniques and instruments in neutral and varus deformities. Valgus deformities will benefit from an advancement along your learning curve.
- Do not expect the implant to make up for a poorly balanced ankle. Although you may win in the short term by constraining an ankle using the implant the overall alignment, if poorly balanced, the ankle will work itself back toward the pre-surgery position eventually.

- Understand the limitations of the TAR system that you are utilizing and understand that coupled cuts are different from uncoupled cuts. In the case where you are using a couple cut system, do not use the guidance jig to force the correction of the frontal plane deformity. The ankle must be balanced and the jig used to maintain, not obtain the correction.
- In severe deformity, osteotomies of the tibia and fibula can be helpful but add a considerable amount of time and risk to the procedure.

Bibbo: Never underestimate the power of loss of the medial column from the ankle to the big toe. Consider correcting these deformities; seeing how it holds up for a few months and then do the TAR.

Hyer: I would recommend being very comfortable with primary TAR in the neutral ankle first before taking on any frontal plane deformity. Then I would recommend tackling mild varus deformities next—those that require lateral ankle ligament stabilization at the same sitting as the TAR—and then work up to larger varus deformities that need deltoid peels and osteotomies or staged reconstructions. I would recommend only tackling mild valgus (less than 10°) at first and gain experience. My recommendation also would be to consider ankle fusion in severely valgus ankles.

Roukis: Start with varus deformities with a congruous joint where parallel resection will correct the bulk of the deformity and the need for medial soft-tissue release and lateral stabilization procedures are limited. Next, expand to varus deformities with an incongruous joint so you can become proficient at the soft-tissue procedures mentioned. After considerable experience with soft-tissue and osseous procedures, include valgus deformity correction. Finally, stage the procedures wherever possible so that wound-healing problems are minimized.

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15 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. 15.1). Obvious incongruity of the ankle (tibiotalar) joint (Fig. 15.1) 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. 15.1). 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. 15.2). Comparison of pre- and postoperative measurements using the tibiotalar ratio helps defining whether the talus has been reduced in a more anatomical position after TAR (Figs. 15.3 and 15.4). 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. 15.5) [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. 15.6) [8, 9].

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_15

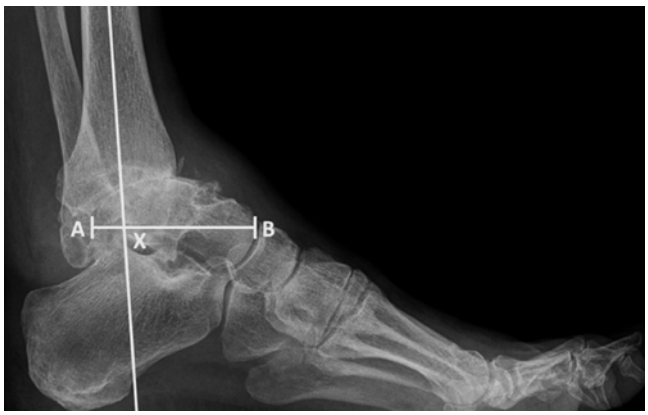

Fig. 15.1 The tibiotalar (TT) ratio (AX/AB %) is the percentage of the length of the talus that lies behind the center of the tibia on the lateral standing radiograph [8, 9]. In this case the TT ratio was 21 %

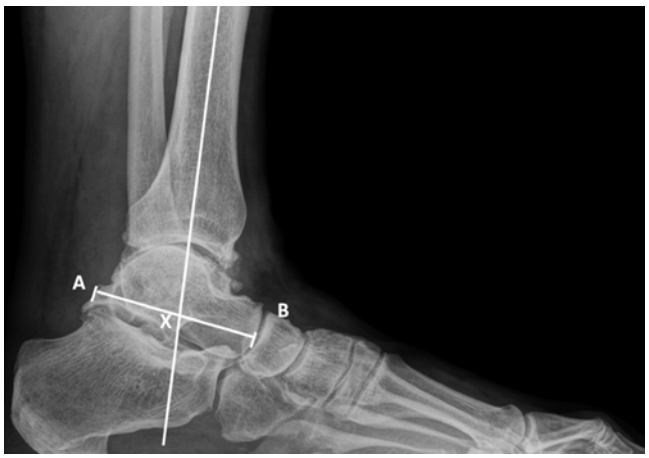

Fig. 15.2 A TT ratio of 55 % indicates a posteriorly translated talus

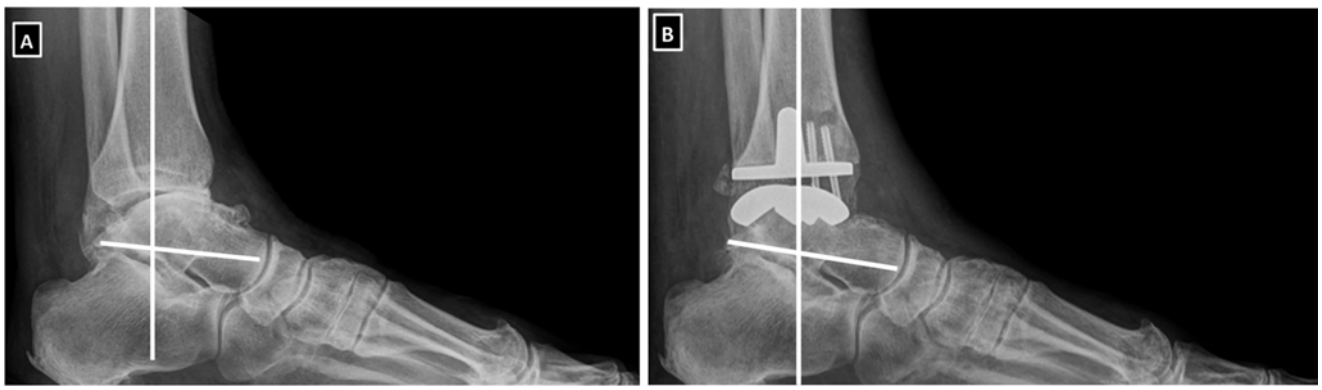

Fig. 15.3 An anteriorly displaced talus (**a**) (TT ratio = 34 %) was corrected to a more neutral position (**b**) (TT ratio = 42 %), performing a total ankle replacement

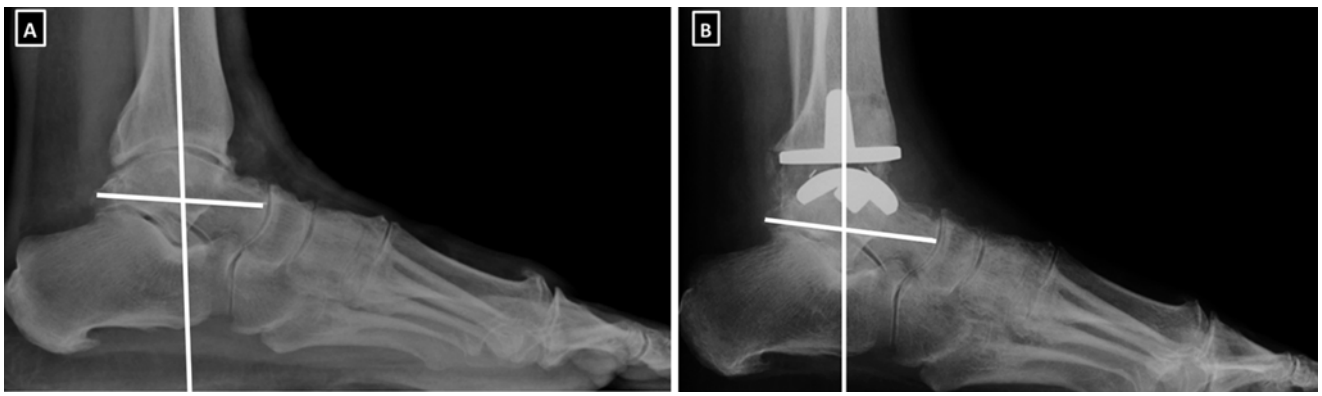

Fig. 15.4 A posteriorly displaced talus (**a**) (TT ratio = 52 %) was corrected to a more neutral position (**b**) (TT ratio = 46 %), performing a total ankle replacement

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

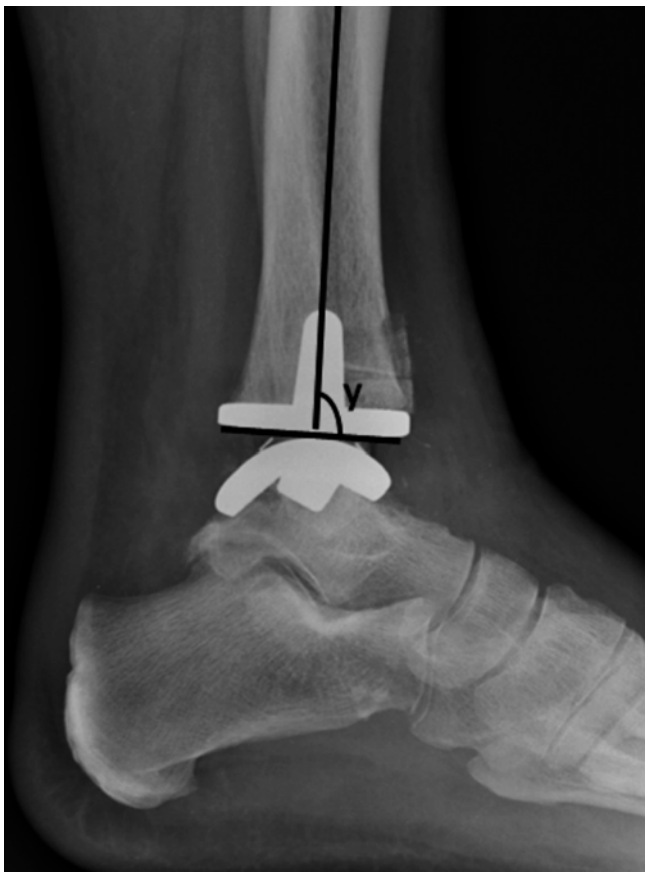

Fig. 15.5 The inclination of the tibial insert in the sagittal plane is measured in relation to the long axis of the tibia (angle *y*). It should approximate 90° [8, 9]

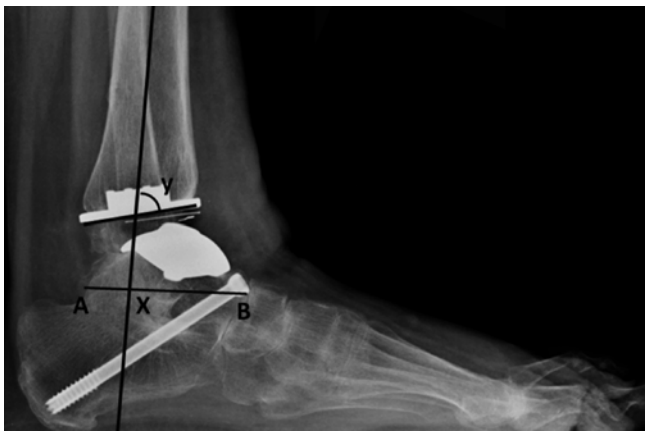

Fig. 15.6 Excessive posterior inclination of the tibial insert in this Scandinavian total ankle replacement prosthesis ($y = 73°$) resulted in anterior translation of the talus (TT ratio =30 %)

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 increasing the "anterior

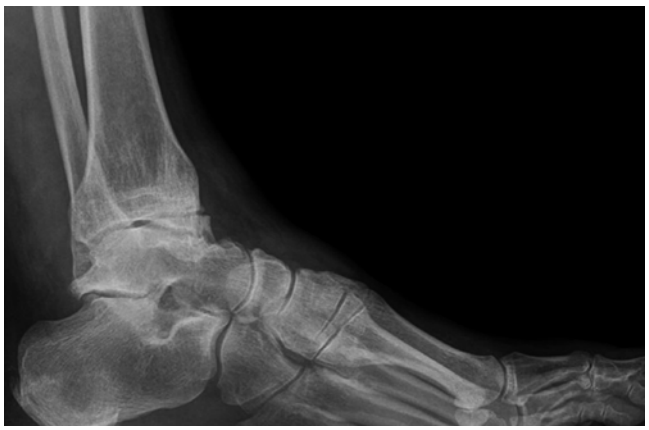

Fig. 15.7 Chronic instability, loss of cartilage, and tibiotalar joint congruity resulted in gradual "flattening" of the tibial and talar opposing joint surfaces

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 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. 15.7). 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

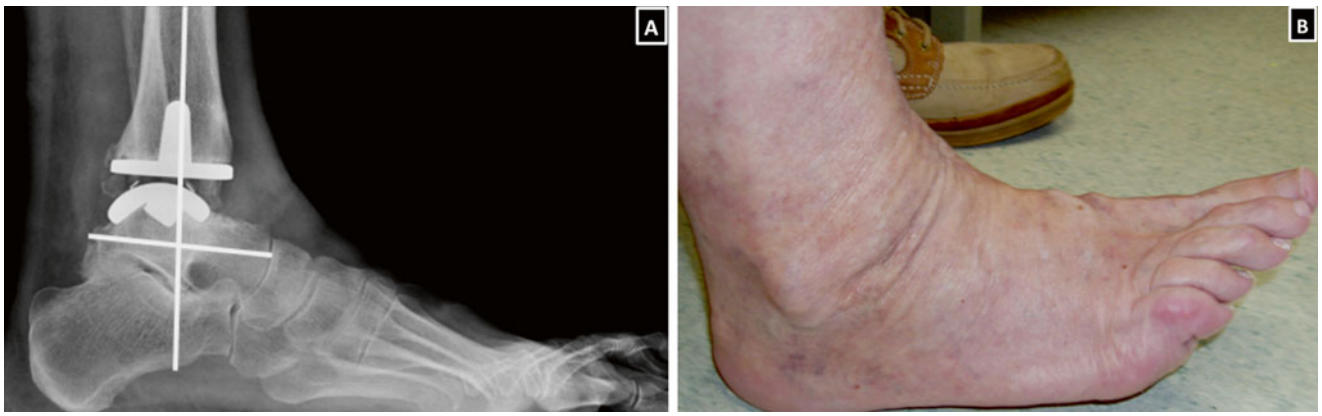

Fig. 15.8 In this case the talus was placed slightly posteriorly with a TT ratio of 50 % (**a**). Although the patient was satisfied with the outcome, his ankle dorsiflexion was relatively limited (**b**)

structures (joint capsule, gastrocnemius and soleus muscle, and Achilles tendon contractures). Thus, ankles with anterior translation of the talus may often present with equinus contractures, as well.

Posterior translation of the talus (Fig. 15.2) 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. 15.8). 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 15.8 illustrates the case of a TAR with slightly posteriorly positioned talus (Fig. 15.8a), resulting in relatively limited dorsiflexion of the ankle (Fig. 15.8b). 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 upwards. 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. 15.5), 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." 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. 15.3 and 15.4).

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 3-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 tendo-Achilles 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 prostheses 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 tendo-Achilles lengthening, or an open tendo-Achilles "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 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 tendo-Achilles 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 15.1 summarizes the surgical considerations performing TAR in the presence of sagittal plane talus malalignment and/or equinus contracture.

Table 15.1 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 tendo-Achilles lengthening
• Consider repair of lateral ligaments

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 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 tendo-Achilles 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 tendo-Achilles lengthening or a gastrocnemius-soleus lengthening is based mostly on surgeon preference and comfort level than evidence-based medicine.

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The Science Behind Periprosthetic Aseptic Osteolysis in Total Ankle Replacement

16

Orfan Arafah 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 second- and third-generation TAR, with the best effort to restore anatomy, kinematics, and alignment, showed significant improvement 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 described initially 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 a strong evidence to fully understand periprosthetic osteolysis associated with TAR.

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Although the incidence of periprosthetic osteolysis in the literature varied from 4.5 to 79 % [4–12], three recent and large studies estimated the incidence to be approximately 35 % [9, 13, 14]. Yoon et al. [13] reported recently on 99 Hintegra (Integra, Saint Priest, France) 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); he 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 arthroplasty have generally been accepted to cause aseptic loosening of the implant and concomitant shortening of the 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 6 months following 15 Scandinavian Total Ankle Replacement prostheses (STAR, Waldemar Link, Hamburg, Germany/Stryker Orthopedics, 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

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_16

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 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 particles [19]. This finding was echoed by Arafah and Penner [20] in his study when he reviewed pathology reports in 18 revised STAR or Hintegra (Integra, Saint Priest, France) 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 might 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 polyethylene debris was present in 95 % of their series. 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 may ultimately lead to components loosening which is the main mode of failure in this implant [22].

If the assumption is made that the polyethylene debris is the main driving factor for osteolysis around TAR, early appearance of lytic lesions is hard to be explained by this theory. Previous studies have shown that cystic lesions around TAR can develop within 12 months of the index procedure [23, 24] 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 is has been agreed that the main mode for failure is through polyethylene debris that lead to osteolysis and subsequent implant loosening [24–27]. In contrast to osteolysis around hip arthroplasty, factors other than polyethylene debris, such as reaction to necrotic tissue, micromotion at the implant-bone interface, and high fluid pressure may 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 [13]. A comparable incidence rate was reported by Kohonen in 2013 [14] and by Koivu in 2009 [9]. In Yoon's study, the average time for cysts appearance was 24 months (range, 6–60-months). In 21 ankles (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. 16.1).

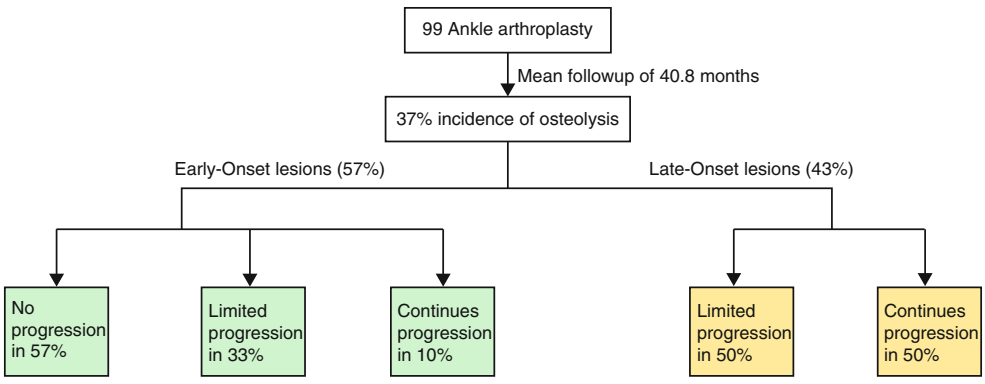

Fig. 16.1 This diagram illustrates the natural history algorithm of periprosthetic osteolytic lesions from a retrospective observation of 99 primary total ankle replacements [13]. Early-onset lesions, identified within 1 year after ankle replacement; late-onset lesions, identified more than 1 year after 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

Clinical Assessment

Detailed history and clinical examination are essential before proceeding with revision TAR. Although demographic history is important in any clinical evaluation, none of the demographic parameters including age, body mass index, diagnosis, and activity level was substantially different between those who had or did 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, 28]. Lesions are often detected incidentally on follow-up surveillance radiographs (Fig. 16.2).

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.

For smoker patients, 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 [29]. It is extremely important 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 reconstruction.

In 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. Presence of subtalar arthritis greatly influences the intraoperative decision whether to perform a subtalar joint arthrodesis or not. Subtalar joint arthrodesis comes in play if the bone stock in the talus is lacking after cystic defect debridement.

Radiological Assessment

Plain Radiograph

A periprosthetic osteolytic lesion was 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 [30, 31].

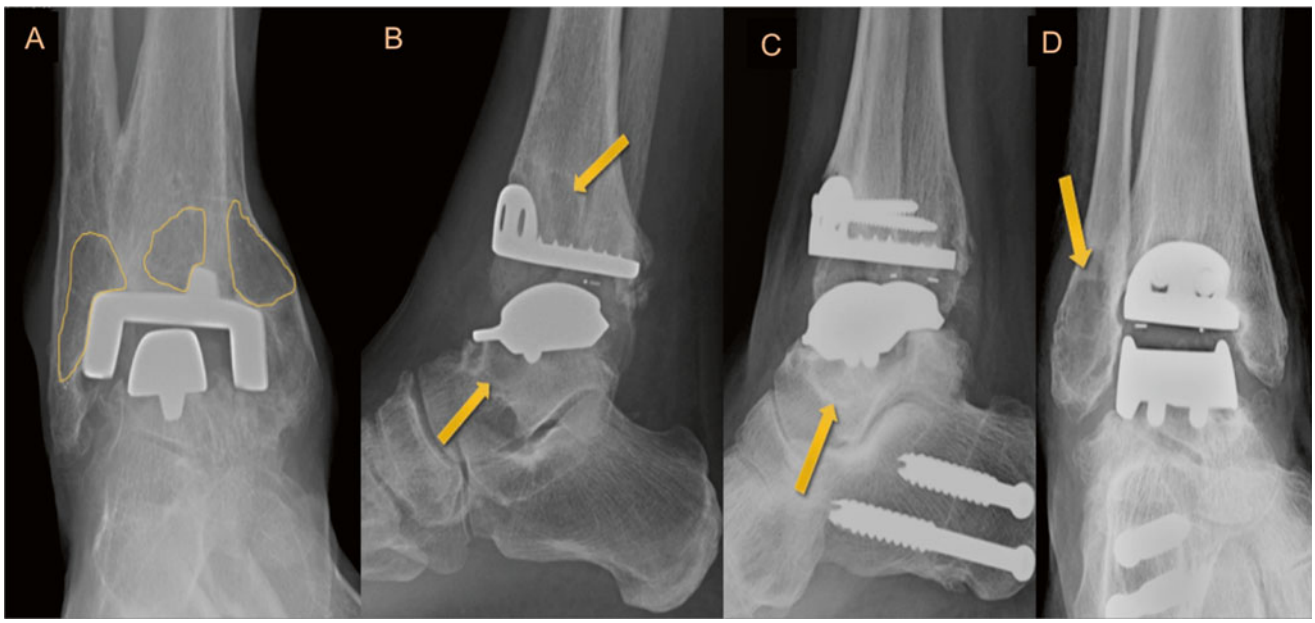

Fig. 16.2 Examples of asymptomatic patients despite having massive osteolysis. Anterior–posterior ankle radiograph of a 67-year-old woman 14 years after total ankle replacement with massive osteolysis around the tibial component (**a**). Lateral radiograph of a 69-year-old male 5 years after total ankle 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**)

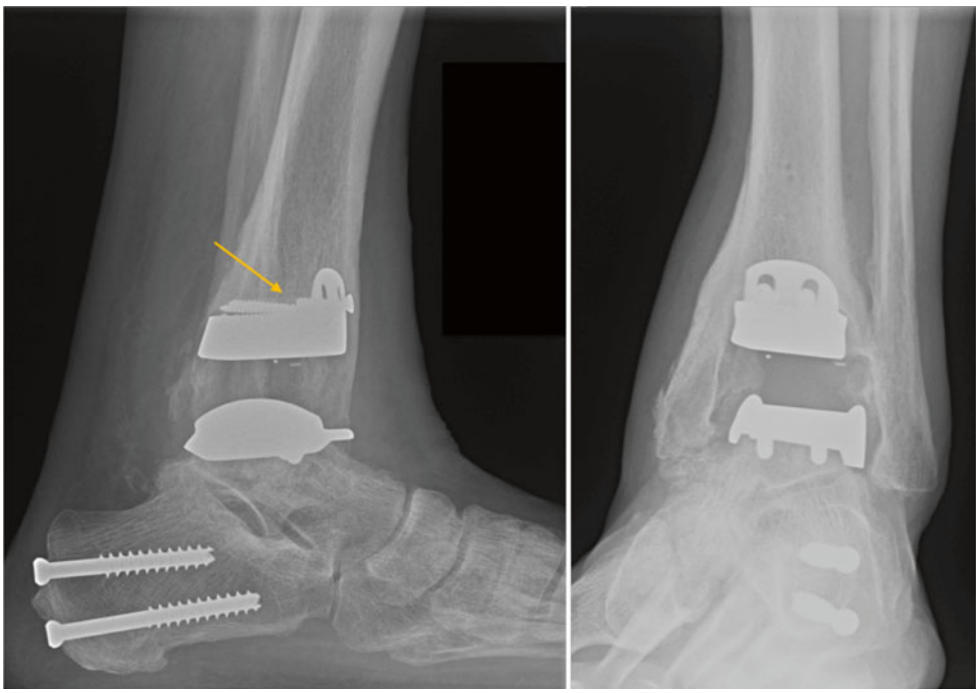

Fig. 16.3 Preoperative weight-bearing radiographs demonstrating tibial metallic component migration with broken screws (*arrow*) in a patient who had a revision total ankle replacement

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. 16.3) [23, 24]. 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 [32].

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 %) [33]. 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 [34]. Second, metallic components usually obscure the osseous landmarks around ankle joint particularly if the implant has an anterior shield [13].

All screws used for implant fixation should be examined radiologically, as osteolytic lesions could be detected around tibial or talar screws in approximately 9 % (Fig. 16.4) [13]. Syndesmotic screws could also lead to lateral distal tibial and/or fibular osteolysis (ballooning osteolysis) especially with failed attempted syndesmotic fusion.

Helical Computed Tomography (CT)

CT images should be obtained to further evaluate any known or suspected osteolytic lesions detected on plain radiographs. Patients should be scanned in axial plane at 0.6–1.25-mm thickness, preferably with metal-artifact-minimizing protocol [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 [3] if 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, 35] 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. 16.4).

The CT scan of the ankle joint is considered to be relatively safe as there are no radiosensitive organs around the ankle joint. Too much attention to radiogenic risk may cause a delay in the diagnosis and possible catastrophic failure [36]. The mean effective dose of computerized tomographic examination 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) [37]. It is also worth mentioning that the radiation dose from an ankle CT scan is slightly lower than the dose from conventional chest radiography (0.08 mSv) [38].

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

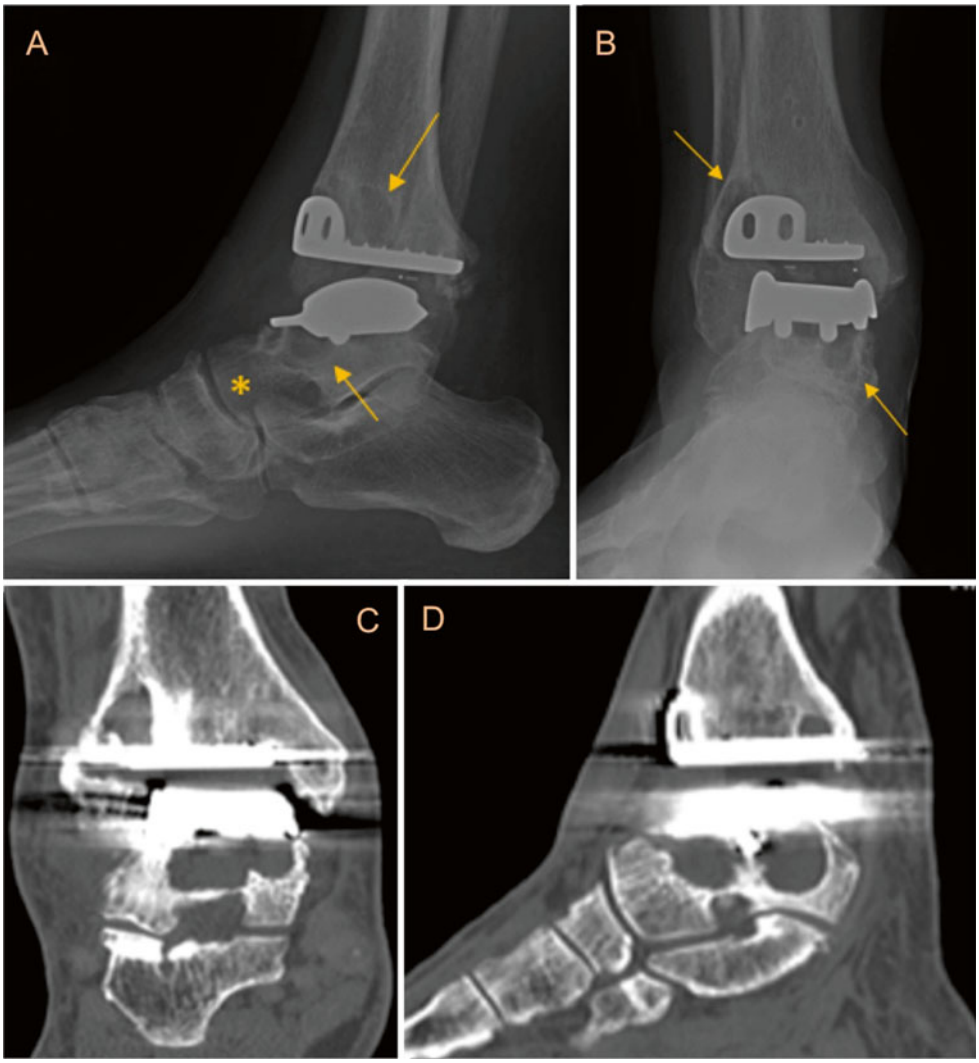

Fig. 16.4 Preoperative weight-bearing radiographs (**a**, **b**) demonstrating the underestimated lytic lesions (*arrows*) especially around the talar component if compared to the CT scan (**c**, **d**). Talar head and neck zone (*asterisk*) anterior to the talar metallic component is the only zone where computed tomography scan showed no significant difference in accurately detecting the size of lytic lesions compared to conventional radiographs

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 [39]. SPECT scan also has the advantage of early detection of degenerative changes in the hindfoot, before plain radiography and CT scans, as it can accurately detect any increase in subchondral metabolic activity associated with arthrosis (Fig. 16.5) [40].

Management

Surgery is usually not indicated for small, nonprogressive, and asymptomatic periprosthetic cysts. However, serial radiographs after cysts occurrence 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 [41]. The following radiological findings should prompt 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 metallic component position indicating possible implant loosening [23]

Surgical options include:

1. Cyst curettage with impaction bone grafting and polyethylene inserts exchange
2. Metal component revision with impaction bone grafting
3. Ankle or tibio-talar-calcaneal (TTC) arthrodesis
4. Below-knee amputation

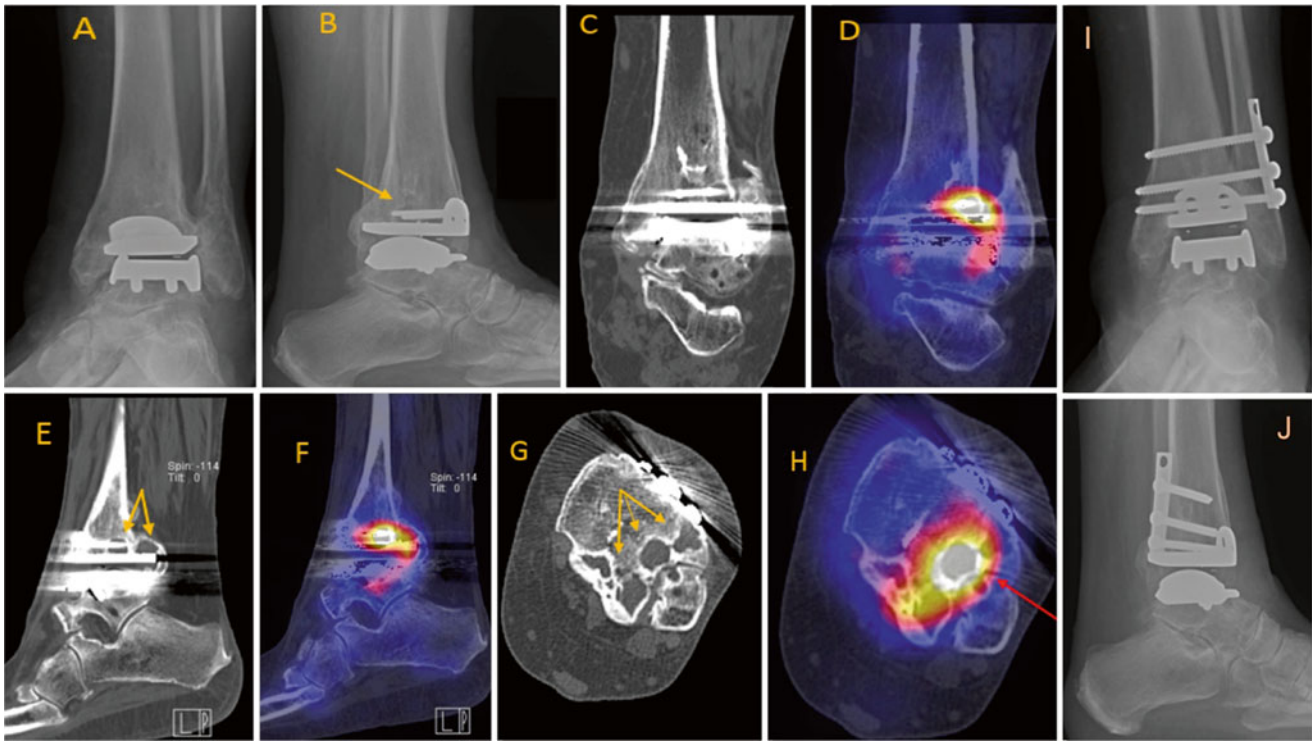

Fig. 16.5 Weight-bearing radiographs of a 65-year-old woman with a painful left ankle 5 years after total ankle replacement. Weight-bearing radiographs (**a**, **b**) and computed tomography images with corresponding single photon emission computed tomography scan (SPECT scan) (**c**–**h**) are shown. 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**)

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 (catastrophic failure) [42]. The cysts are thoroughly curetted and filled with the appropriate void filler, and the polyethylene insert should be exchanged if possible.

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 intraoperative assessment.

Positioning

The patient is placed supine on the operative table after receiving popliteal nerve block followed by general anesthetic. We routinely use 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

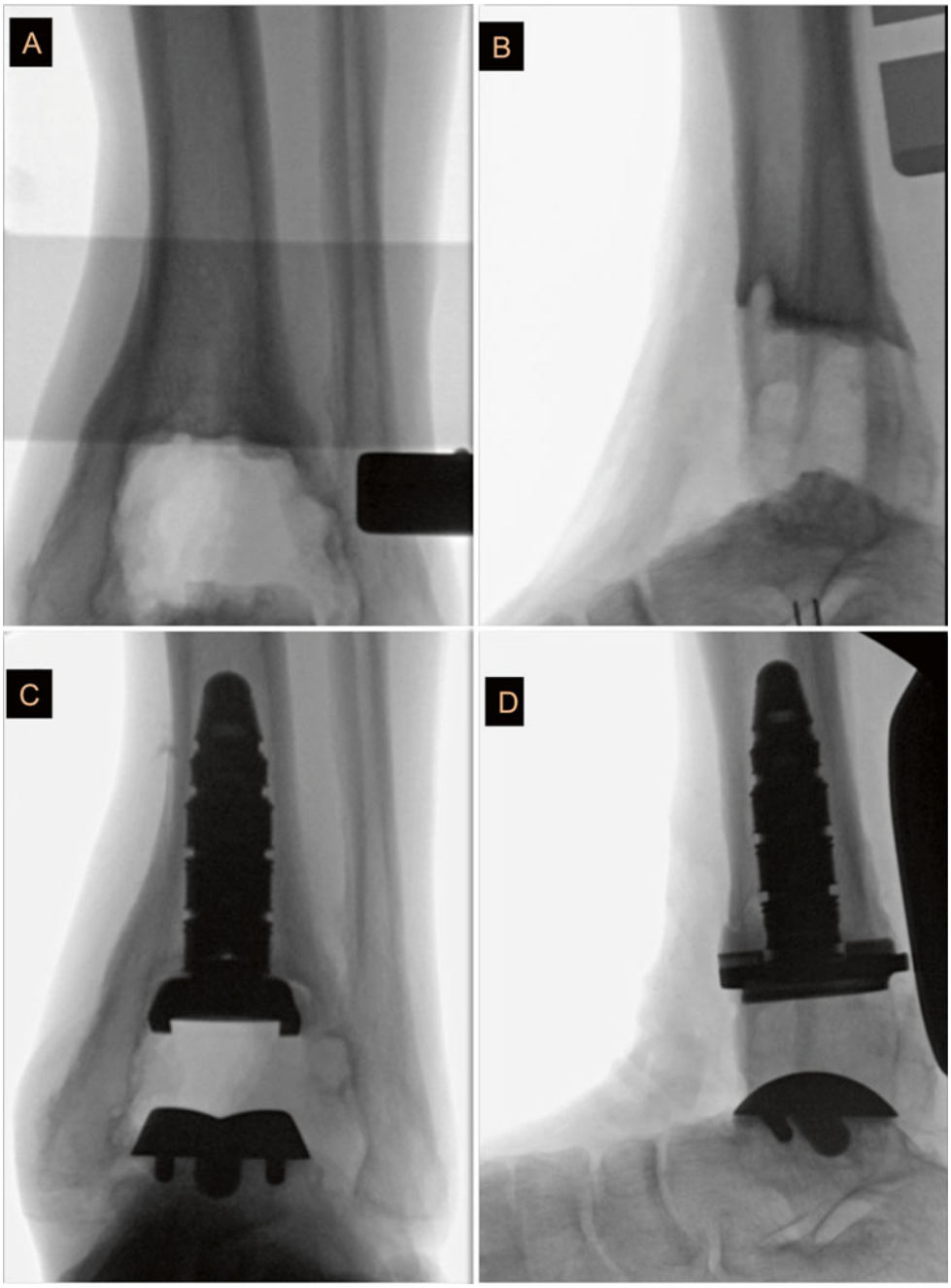

Fig. 16.6 Weight-bearing radiographs for the same patient shown in Fig. 16.2 with metallic component migration and periprosthetic osteolysis. Intraoperative C-arm image intensification (**a**, **b**) demonstrating severe bone loss following prosthesis removal and thorough debridement. The ankle joint was reconstructed using conversion to the INBONE II Total Ankle Replacement (Wright Medical Technologies, Inc., Arlington, TN) (**c**, **d**)

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. 16.6). 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, and the contents must be sent for microbiology and histology analysis. The cysts then can be impacted 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 polymethylmethacrylate (PMMA) cement are other options to fill the void of larger cysts (Fig. 16.7). 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 [43]. For non-contained defects, when the cortex is breached, structural bone graft from the iliac crest or structural fresh frozen allograft could act as strut for reconstruction. If the cyst is confined to

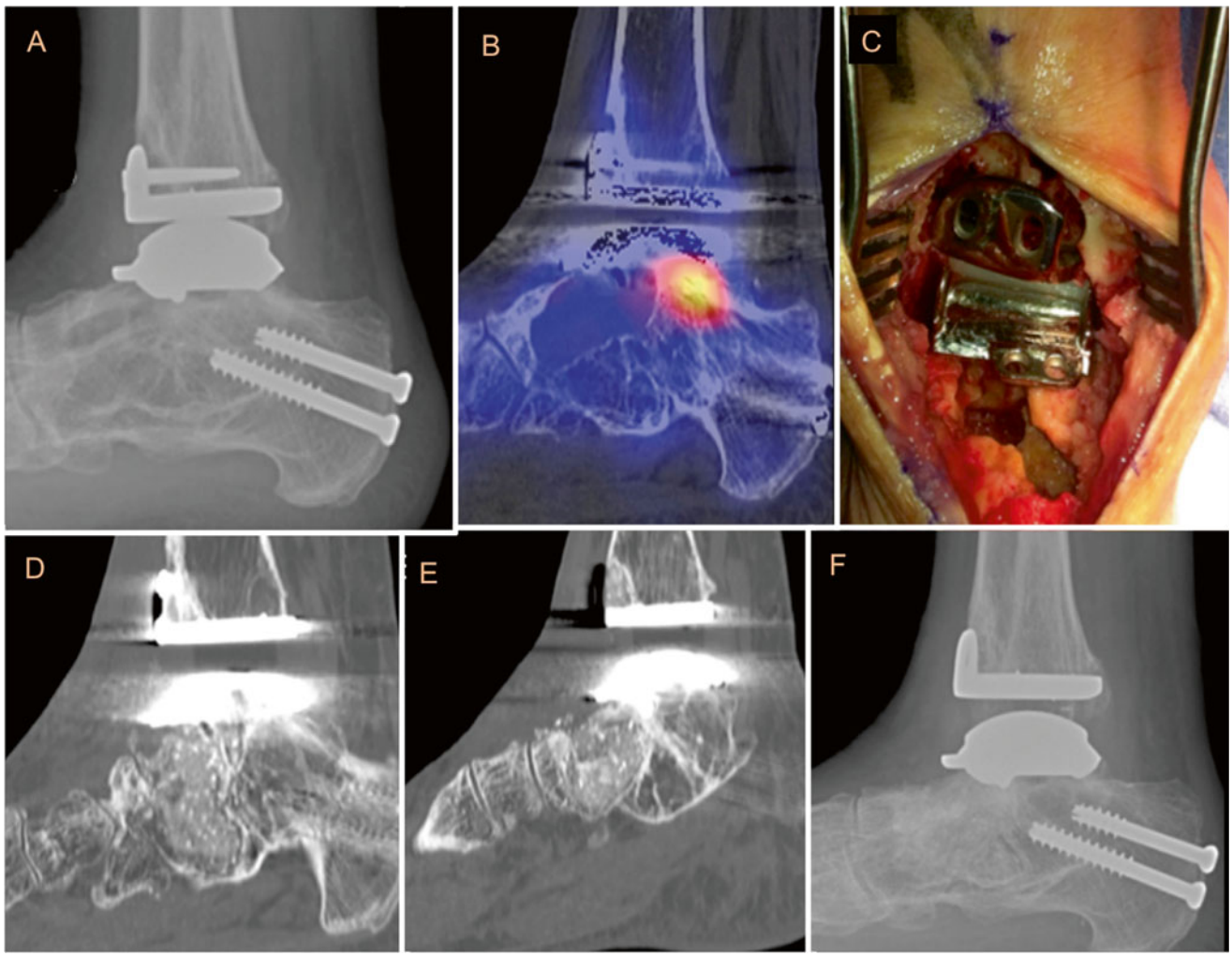

Fig. 16.7 Lateral weight-bearing radiograph (**a**) of patient with painful massive anterior talar cyst 6 years following total ankle replacement. The talar component was cantilevering on the posterior fixation as seen on single photon emission computed tomography scan (**b**). Intraoperative photograph (**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**). Lateral weight-bearing radiograph (**f**) 1 year after reconstruction demonstrating bone consolidation with sufficient talar bone stock for future revision

the medullary cavity and it is not accessible, a cortical window is required to access and to thoroughly debride the necrotic 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 malalignment [13]. The underlying pathology should be addressed at the same operation with either ligament reconstruction for instability or corrective osteotomy for malalignment (Fig. 16.8). 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

Outcome of cystic lesion debridement with impaction bone grafting and polyethylene insert exchange is still not clear in the literature. Yoon et al. [13] 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

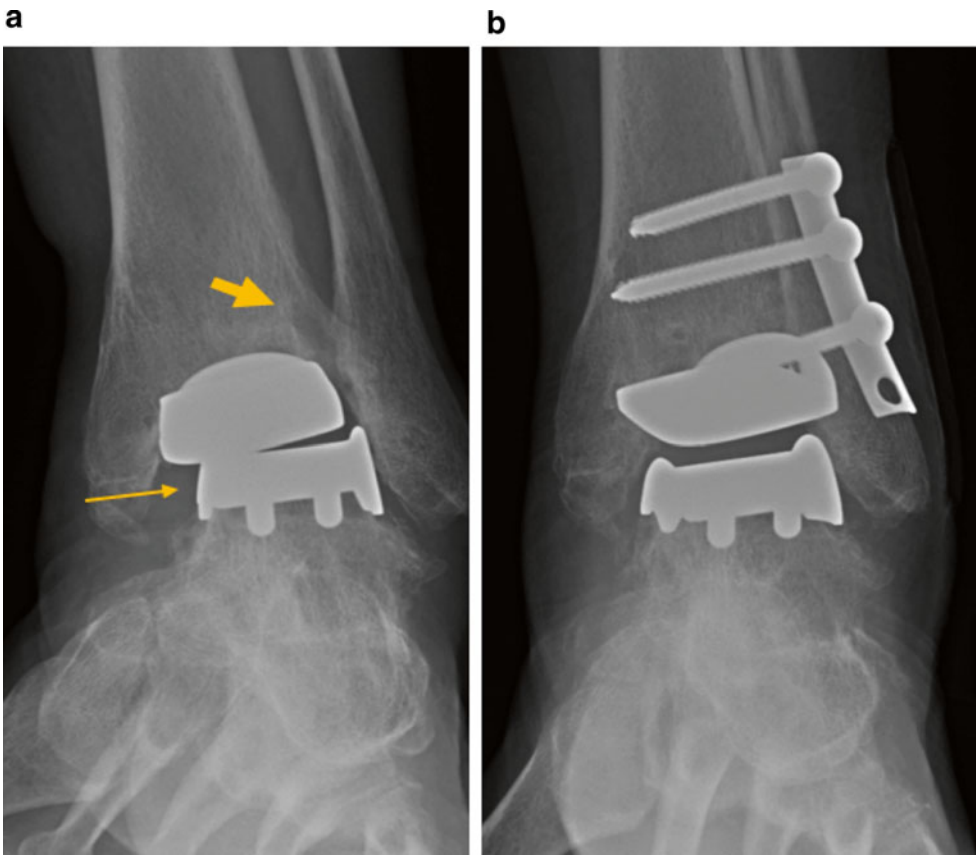

Fig. 16.8 Weight-bearing radiographs of a 65-year-old woman with painful left ankle following Hintegra total ankle replacement. (**a**) Preoperative weight-bearing oblique ankle radiograph demonstrating varus ankle tilt secondary to syndesmotic insufficiency. The *bold arrow* indicates a lateral plafond 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

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. [43] 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 [44] 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 all patients progressed to meaningful weight-bearing activities [44].

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 cements, 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.

Regarding the result of cyst curettage grafting in the hip literature, Restrepo et al. [45] reported a 10 % failure rate at 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. [46] reported that one-third of the lesions resolved and two-thirds decreased in size whether they were bone grafted or not. It is evident that by decreasing the polyethylene concentration in the hip joint, osteolytic lesions decreased or resolved altogether. This discrepancy in the outcomes between the hip arthroplasty and TAR following cyst debridement and impaction bone grafting supports the theory that polyethylene debris is not the only major factor for osteolysis around TAR and other factors play major roles as described earlier in this chapter.

Conclusion

Firm evidence about the etiology, pathophysiology, natural history, and optimal treatments of periprosthetic TAR osteolysis is still lacking. In contrast to osteolysis around hip

arthroplasty, factors other than polyethylene debris, such as reaction to necrotic tissue, micromotion at the prosthesis-bone interface, and high fluid pressure may play a key role in osteolysis around TAR. Annual radiographic surveillance is recommended for early detection and treatment of osteolysis. CT scans have shown superiority in both detecting cysts and accurately determining their sizes compared with standard radiographs. 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 sufficient. However, if one or both metallic prosthesis components are unstable, component revision is required in addition to cyst debridement and impaction bone grafting. Due to the complexity involved, only a foot and ankle surgeon who is an expert in both primary and revision TAR should manage treatment of osteolysis associated with TAR.

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Management of Periprosthetic Cystic Changes After Total Ankle Replacement

17

Jean-Luc Besse, Alexandre Di Iorio, and Michel Fessy

Introduction

Total ankle replacement (TAR) was developed in the 1970s as an alternative to arthrodesis in selected patients with ankle joint arthritis, giving the advantage of preserving joint mobility and function, as well as improving the mobility of adjacent hindfoot/midfoot joints. The main indication for TAR is end-stage arthritis, whether posttraumatic, inflammatory, or idiopathic in origin. Short- and medium-term results seem encouraging. Ten-year implant survivorship, however, was only 62–72 % in the Scandinavian registries [1–3], compared to 80–90 % as in series mainly reported by the designers [4, 5], and 90–98 % 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, specifically cystic osteolysis which 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) (Transysteme-JMT Implants, Nimes, France), 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, Morgan et al. [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 et al. [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 including 82 Salto Mobile version (Tornier, Saint Martin, France), 41 Hintegra (Integra, Saint Priest, France), 19 AES, 15 Coppélia (unknown manufacturer, France), 11 Scandinavian Total Ankle Replacement (STAR, Waldemar Link, Hamburg, Germany/Stryker Orthopaedics, Mahwah, NJ), 4 Ramses (Laboratoire Fournitures Hospitalières Industrie, Heimsbrunn, France), and 1 Akilé CLL (Centre Hospitalier Universitaire de Bordeaux, Bordeaux, France), which were all three-component mobile-bearing systems, with a mean follow-up of 34 months (±5). Preyssas et al. [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 Mobile (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 et al. [12, 13] reported a 19 % rate of cysts >5 mm with the Salto Mobile prosthesis. Some authors have reported similar findings with the Agility (DePuy Orthopaedics, Inc, Warsaw, IN) [14, 15]. Tibial cysts with the STAR prosthesis have been reported [16] in 3.5 % of patients at 46 months and 17.5 % at 88 months.

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_17

Recently, Deleu et al. [17], in a series of 50 Hintegra TARs with a mean follow-up of 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. This cyst problem was largely underestimated in the designer series.

Why Cysts?

Ankle bone–prosthesis interface analysis is variable for series involving fixed- and mobile-bearing TARs. 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 prosthesis, 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 pro-inflammatory 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, NFκB, 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-kappaB 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 et al. [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 and 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-bearing insert during revision surgery.

Stress shielding may also participate in the formation of cysts, due to the difference in elastic modulus between the bone and prosthesis, as seen with hip stems [25].

Prosthesis design has also been incriminated. The stem-anchored tibial prostheses of the Buechel–Pappas (BP, Endotec, South Orange, NJ), AES, Salto Mobile, and Salto Talaris Total Ankle Prosthesis (Tornier, Edina, MN/Wright Medical Technology, Inc., Memphis, TN) types could be more exposed to coating fretting. Tibial stem fixation has been incriminated; cysts, however, also formed in the talus. AES and BP TAR 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. Anterior–posterior (AP) sliding or more complex multidirectional motion of the flat-back mobile-bearing and shearing phenomena is greater with nonanatomic models having a spherical talar component (BP, STAR, AES) than with more anatomical prostheses (Hintegra, Salto Mobile, Salto Talaris) 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–prosthesis interface would be necessary to determine the role of the mobile bearing in polyethylene wear.

The problem may lie in defective prosthesis 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 TARs were well centered.

Bonnin et al. [12] suggested that some of these cysts could have evolved from osteoarthritic cysts preexisting TAR. The patients of this study [12], however, had not had preoperative CT scan screening for preexisting 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 year postoperatively, showing rapid evolution. Histologic analyses of curettage specimens [7, 24] failed to confirm this hypothesis, detecting titanium and hydroxyapatite (HA) 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 et al. [7]. The risk of osteolysis was found to be 3.1 times higher (95 % CI, 1.6–5.9) with TAR prostheses 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 33.3 % of Ti-HA-coated prostheses, flakey bodies in 44.4 % of HA-coated implants, and 18.2 % of Ti-HA-coated prostheses. 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 bearing (33 Salto Talaris: titanium coating) versus mobile bearings (33 Salto Mobile: HA-Ti bilayer coating), Gaudot et al. [27] found cysts were more frequent with the Salto Mobile prosthesis: radiolucent lines were observed in 4 Salto Talaris patients versus 13 Salto Mobile patients ($p=0.02$); subchondral cysts were noted in 1 Salto Talaris and 8 Salto Mobile 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 HA coatings in the various TAR prostheses on the market.

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 TARs between 2003 and 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 radiographs including AP ankle, Meary, lateral foot, and ankle views, as well as 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 identification, annual radiograph surveillance is recommended [6, 28]. If cysts are not evolutive, radiographs are sufficient. If not, CT should be performed.

Besse's protocol [6] was used to analyze periprosthetic bone cysts (Fig. 17.1). 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 3–5 mm), cyst B (osteolysis >5 mm to 1 cm), cyst C (osteolysis >1–2 cm), cyst D (osteolysis >2–3 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 TAR prosthesis 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 component and precise monitoring of their evolution. Hanna et al. [29] reported a 95 % rate, with 19 Agility TARs 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 identified on plain radiographs.

In the study by Kohonnen et al. [30], 34.6 % of a total of 130 AES TARs had at least 1 periprosthetic osteolytic lesion >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.

In a prospective study of 50 AES TARs with a mean follow-up of 4 years, Viste et al. [20] showed a dramatic progression of severe periprosthetic lysis (>10 mm) on plain radiographs: a 14–36 % rate of interface cysts for the tibial

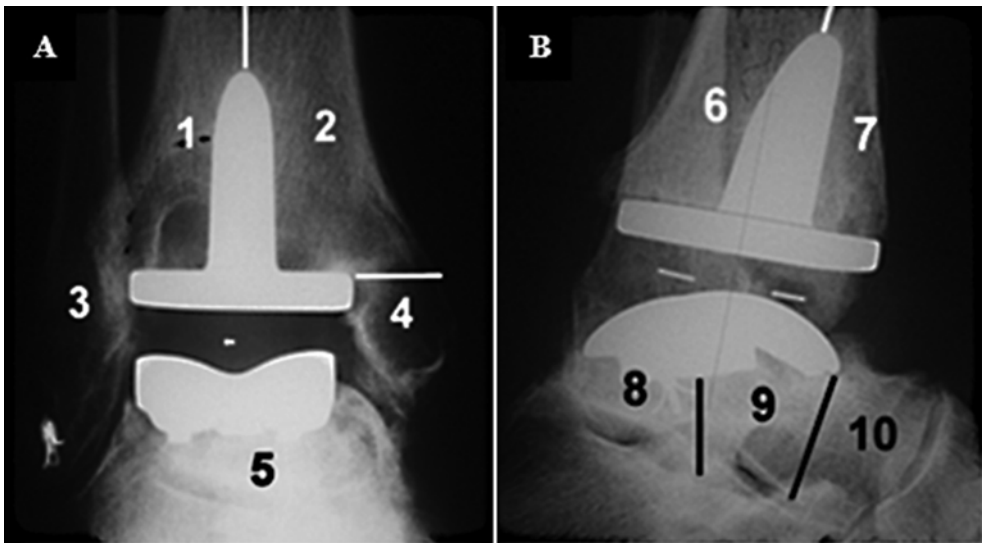

Fig. 17.1 Plain film radiograph periprosthetic osteolysis assessment protocol for AES TAR, according to Besse et al. [6]. On the anterior–posterior ankle view, there are five areas: *Zone 1*, lateral tibia; *Zone 2*, medial tibia; *Zone 3*, fibular malleolus; *Zone 4*, medial malleolus; and *Zone 5*, area under the talar implant (**a**). On the lateral ankle view, there are five zones: *Zone 6*, posterior tibial; *Zone 7*, anterior tibial; *Zone 8*, posterior area under the talar implant; *Zone 9*, anterior area under the talar implant; and *Zone 10*: neck and head of talus (**b**). 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

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 to 288 mm^2 for CT vs. 133 to 174 mm^2 for radiographs). 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 and 10 years and ahead of revision or in case of increased cyst size and/or pain, so as to be able to suggest prosthesis removal before the talar component collapses. It is not necessary to perform preventive CT between 2 and 10 years because cyst onset is early and rapidly evolving [6, 20, 24]. Moreover, Bonnin et al. [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 that we will bone graft at the time of surgery and for baseline control; radiographic monitoring at 1, 2, 5, and 10 years; and systematic CT at 1 or 2 years to check the bone–prosthesis interface carefully and diagnose possible early cyst development. In case of cystic aspect, radiographic monitoring must be more frequent, with new CT in case of worsening cyst formation on radiographs or pain on clinical examination.

Cyst Management

First of all, we recommend systematic CT prior to TAR, to determine therapeutic management. In the presence of small subchondral cysts, bone grafting should be associated concurrently with primary TAR. If the cyst volume is too large, immediate ankle arthrodesis is suggested. The study by Rahm et al. [31] demonstrated poorer clinical outcome in patients undergoing salvage arthrodesis after failed TAR compared to patients undergoing primary arthrodesis due to symptomatic end-stage arthritis.

Three therapeutic options exist in case of cyst: curettage–bone grafting, arthrodesis, or revision arthroplasty.

Cyst Curettage–Bone Grafting

The management of asymptomatic periprosthetic cysts is a controversial topic. Curettage with impaction bone grafting is a preventive surgery to halt periprosthetic cystic changes, which should prevent mechanical dislocation and reduce pain.

With the Salto Mobile prosthesis, Bonnin et al. [13] found that tibial and/or talar bone cysts (>5 mm) that were curetted and filled with bone graft postoperatively showed complete

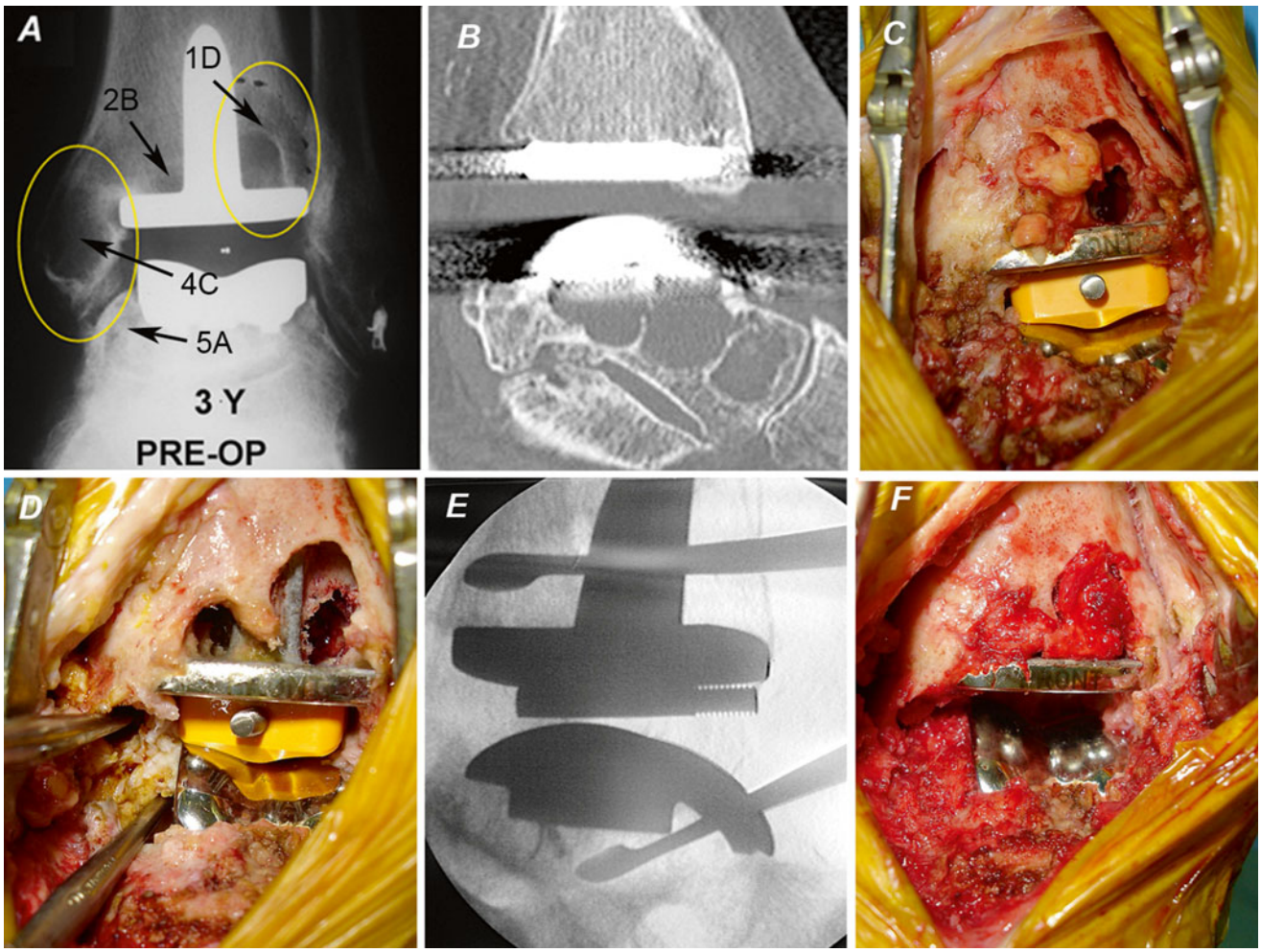

Fig. 17.2 Cyst graft protocol. Example of preventive bone graft with exchange of the mobile bearing to preserve well-fixed prosthetic components. Radiographic (**a**) and CT scan assessment (**b**) at 3 years after AES TAR, for a 77-year-old man demonstrating expansile lyses and functional degradation (AOFAS global score 71 vs. 80 at 2 years; AOFAS pain score 20 vs. 30 at 2 years). Yellow fibrous tissue in cysts (**c**). After tibial granuloma removal, prosthetic components were well fixed (**d**). Image intensification lateral view to check talar granuloma removal (**e**). Intraoperative aspect after cancellous bone autograft (**f**)

or almost complete remission, although three out of eight went on to arthrodesis. Some authors have reported similar findings with the Agility prosthesis.

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 C-arm image intensification, guided by 3D cyst assessment on preoperative helical CT. Spaces are filled by impaction grafting. The main procedural risk is of prosthesis 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 because cysts are sometimes hard to access. Intraoperative C-arm image intensification control of curettage improves this step of surgery, but still cannot guarantee systematic curettage of all cysts (Fig. 17.2). A bivalve plaster cast is fitted at postoperative day 2, and the patient remains non-weight bearing for 3 weeks, followed by a removable boot for 3 weeks, with resumption of weight bearing and physical therapy.

Besse et al. [28] 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–bone grafting (7 corticocancellous iliac crest autografts, 1 mixed P-Ca cement/autograft, 4 P-Ca cement, and 2 polymethylmethacrylate 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. 17.3) .despite a satisfactory

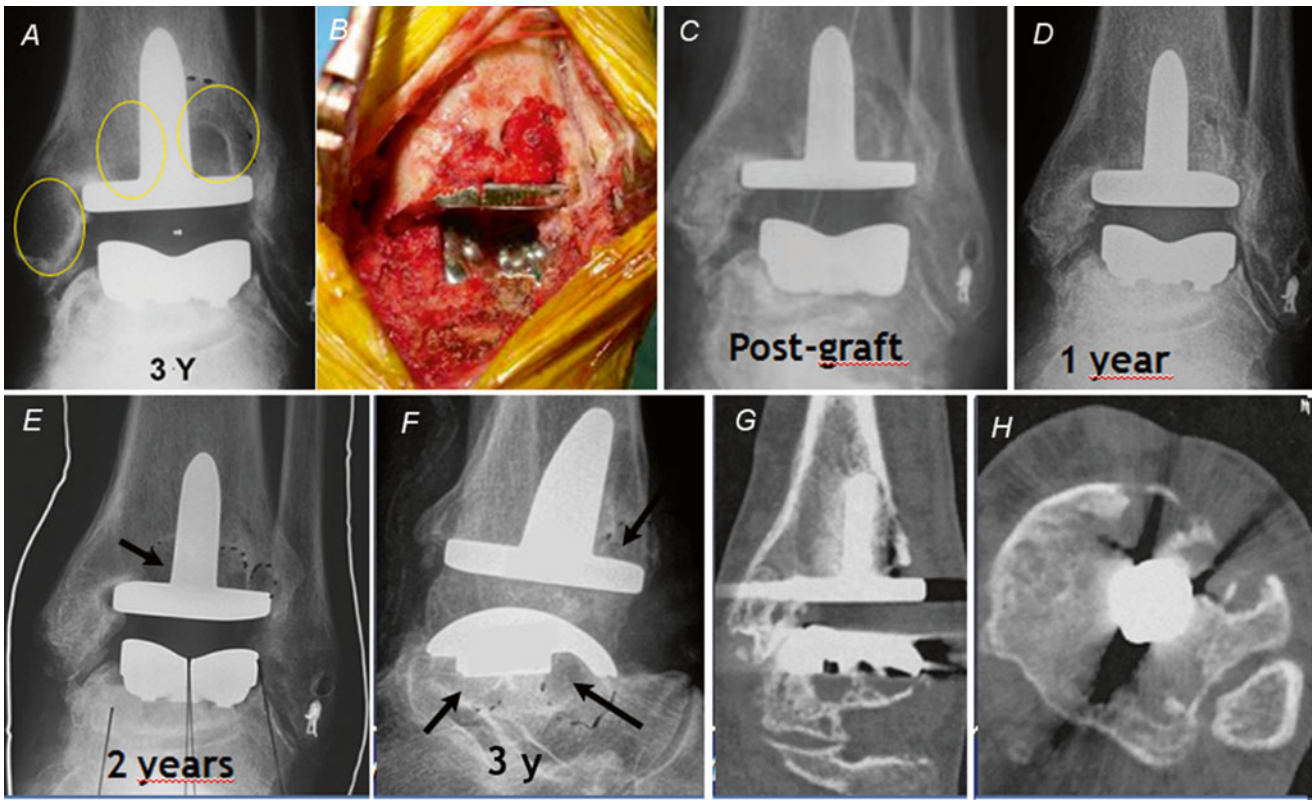

Fig. 17.3 Cyst recurrence after autograft. Lateral radiographic assessment at 45 days for a 75-year-old man demonstrating good radiological aspect of autograft (**a**). Intraoperative aspect after cancellous bone autograft (**b**). Postoperative anterior–posterior radiographic view (**c**). Good radiological result at 1 year (**d**). Recurrence of the tibial cyst at 2 years (**e**) and the talar cyst at 3 years (**f**) which were verified with CT scan imaging (**g**, **h**)

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 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 complete cyst 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 encrusted titanium microparticles.

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 ankle arthrodesis. The P-Ca cement filling option proved 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. 17.4). Using PMMA cement may seem illogical with an HA-coated TAR prosthesis but may provide a salvage solution in select situations (Fig. 17.5).

So we therefore no longer recommend this conservative preventive procedure for asymptomatic cyst, but rather annual radiological surveillance, with CT in case of increased cyst size (>3 cm) and/or pain, so as to be able to suggest prosthesis removal and reconstruction ankle arthrodesis before the talar component collapses. Onset of pain is generally related to microfracture induced by cortical lysis, detectable on CT before prosthesis migration. For painful cyst, we prefer reconstruction ankle arthrodesis. There remain some exceptional indications for grafting with PMMA in elderly patients with cyst greater than 3 cm and/or patients with ankle motion requirements (contralateral ankle arthrodesis, multiple lower limb joint osteoarthritis, etc.).

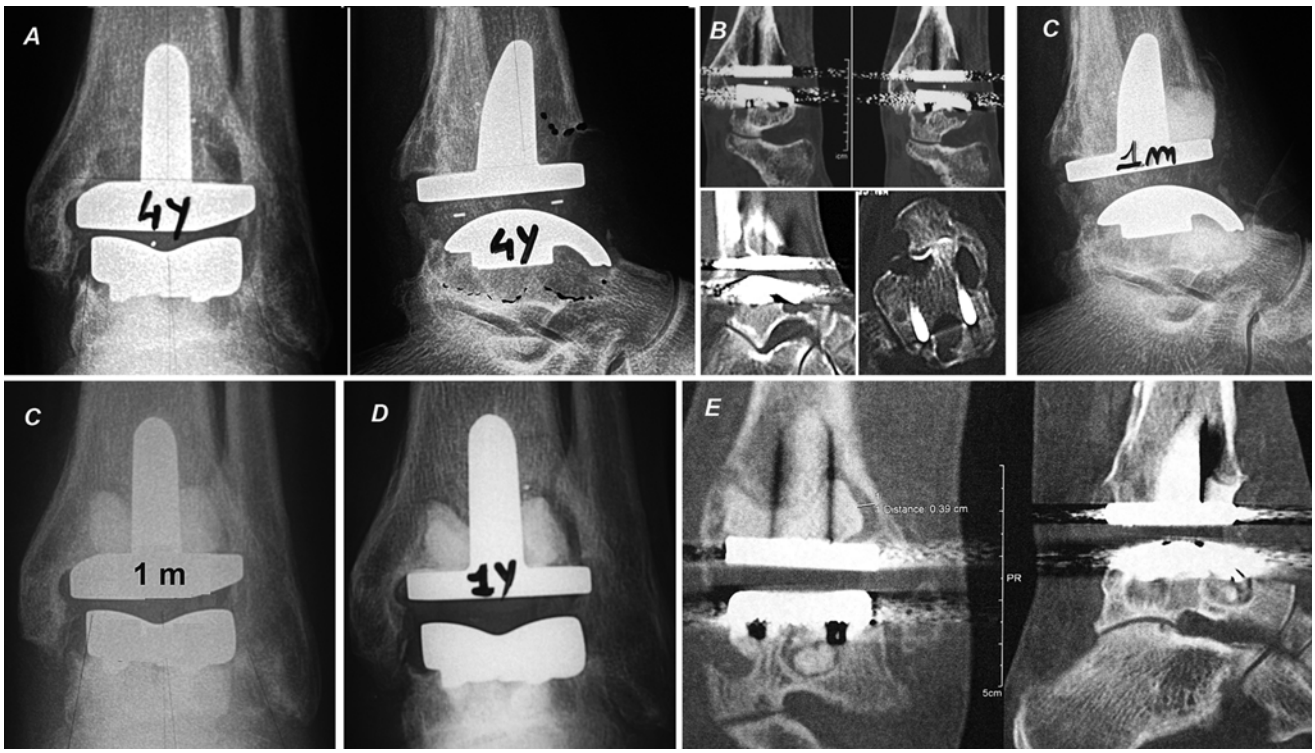

Fig. 17.4 P-Ca cement graft evolution. X-ray (**a**) and CT (**b**) assessment at 4 years for a 57-year-old man: expansile cysts and functional degradation. Lateral and AP X-ray (**c**) aspect of P-Ca cement graft at 1 month: good bone-cement contact. 2-5mm lucent line between P-Ca cement and bone on X-ray (**d**) and CT (**e**) assessment at 1 year

Revision Total Ankle Replacement

For evolutive osteolysis, some authors perform revision TAR with or without bone graft. Hintermann et al. [32] reported medium-term results for revision TAR similar to those for primary TAR; the key to success was firm component anchorage to primary bone stock. Our team does not use and does not recommend this therapeutic solution for failed TAR secondary to cyst formation (Fig. 17.6).

Ankle Arthrodesis

Salvage arthrodesis after failed TAR is a difficult procedure. Arthrodesis has fusion rates ranging between 61 and 100 % [33]. It appears that successful fusion and good clinical outcome can be expected in patients receiving ankle or tibio-talo-calcaneal (TTC) arthrodesis. Isolated ankle arthrodesis as a salvage procedure for failed TAR can be considered only in patients with a normal subtalar joint and good talar bone stock.

Depending on the volume of graft needed to fill the bone defect, autograft 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 autografts 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 morbidity, but is not osteogenic or osteoinductive. Berkowitz et al. [34] reported 12 patients with failed TARs treated by TTC arthrodesis using femoral head or distal tibial allograft with only a 58 % fusion rate. Fixation included plates and screws, intramedullary rods, or a combination of both. Eighty percent of nonunions occurred at the subtalar joint. Jeng et al. [35] 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 TAR. However, the risk of complications is

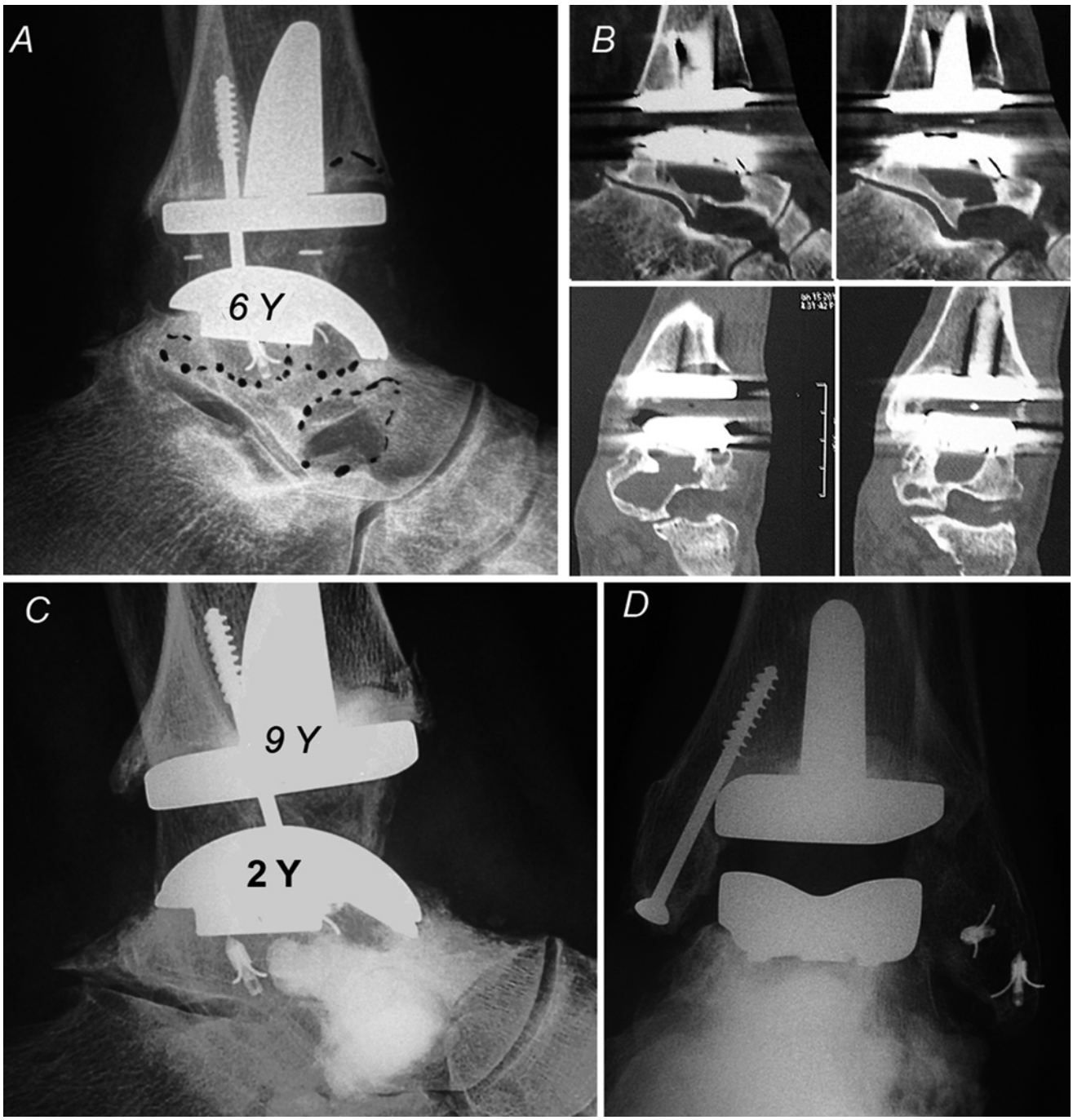

Fig. 17.5 Good radiological result of graft with PMMA cement. Radiographic (**a**) and CT scan (**b**) assessment at 6 years for an 81-year-old man demonstrating expansile talar cysts with high risk of talar subsidence, but painless with an AOFAS global score of 100. Good radiological results at 2 years (**c**, **d**)

high, with 19 % of patients reported as requiring below-knee amputation (Fig. 17.7).

Deleu et al. [33] 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.

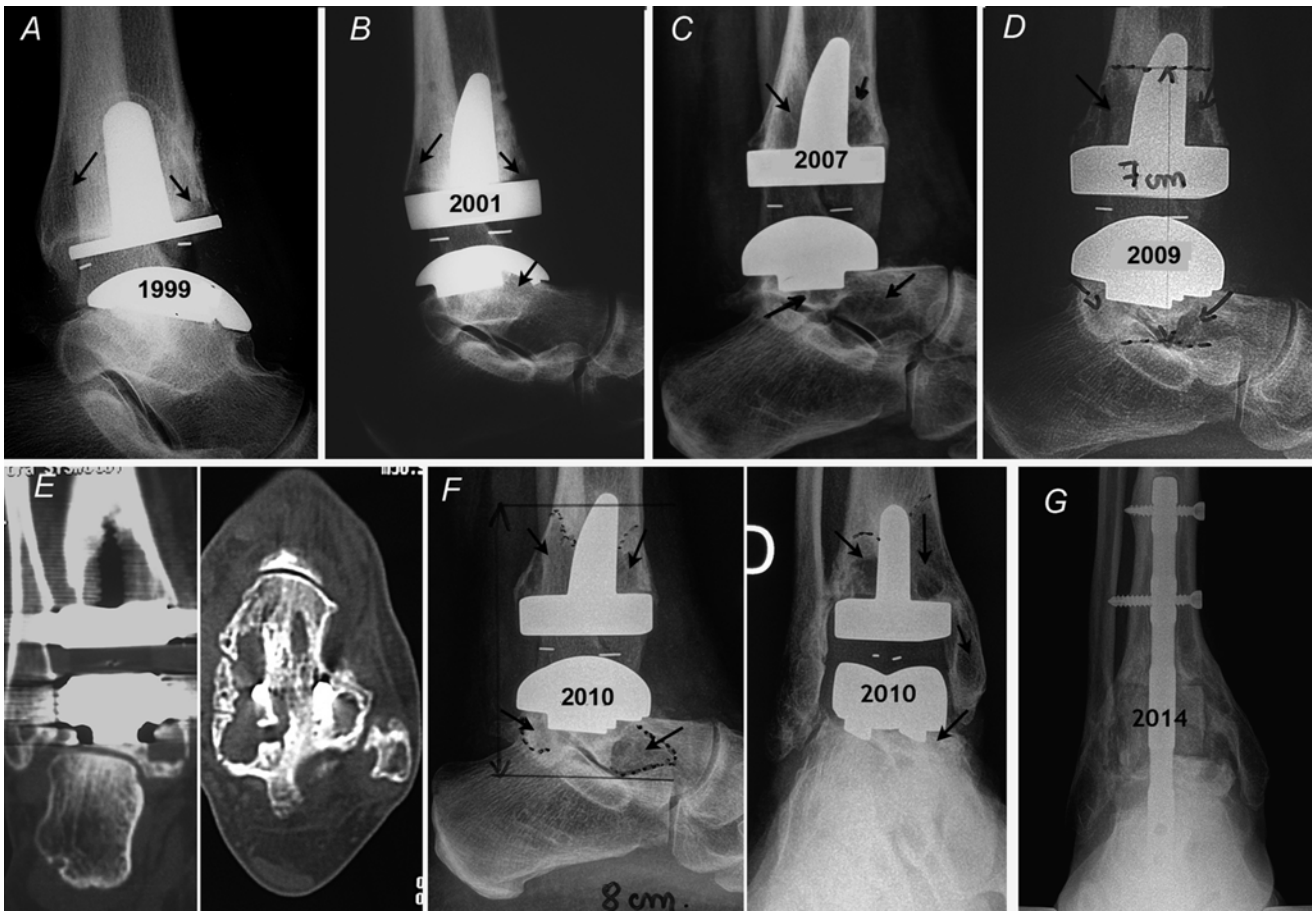

Fig. 17.6 Failure of three attempts of revision following primary TAR. Loosening of BP TAR for a 46-year-old man (**a**). Cyst recurrence 1 year following BP explantation and conversion to an AES TAR (**b**). Cyst recurrence following revision AES component use in 2003 to compensate for the bone loss secondary to cyst formation (**c**). Recurrence of cysts with expansile progression (**d**, lateral view in 2009; **e**, CT in 2009; **f**, lateral and anterior–posterior views in 2010). Tibiotalo-calcaneal arthrodesis with autograft and allograft was performed in 2012 and this is the anterior–posterior view in 2014 (**g**)

As autograft is not sufficient, and allograft requires a long period of non-weight bearing, porous tantalum could be used as spacer. Tantalum is a biocompatible trabecular metal with mechanical properties similar to the bone, used extensively in THA and TKA revision. Its compressive strength and elastic modulus are similar to those of the normal bone, which theoretically reduces stress shielding and stress concentration. Porous tantalum is used to fill the defect and reinforce arthrodesis reconstruction. In our recent experience [37], from June 2012 to September 2014, 9 patients underwent TAR revision (9 AES, 1 Hintegra, 1 Salto Mobile) by 8 TTC arthrodeses and 1 ankle arthrodesis using tantalum; 3 with Zimmer Trabecular Metal Osteonecrosis Rod (Zimmer, Warsaw, IN), dedicated to femoral head necrosis (Fig. 17.8); and 6 with the Zimmer Trabecular Metal Ankle Interpositional Spacer (Zimmer, Warsaw, IN), introduced in July 2013. All patients were prospectively followed up clinically and radiologically including plain films and CT scan at 4–6 months. In the first three cases, we used a tantalum rod (10-mm diameter, 90- or 95-mm length) and osteosynthesis by anterior locking tibial plate and two medial screws (4.5 and 7.3 mm). In the other six cases, we used a tantalum cone (25–40-mm height) and retrograde intramedullary nail (AFN-611, 10-mm diameter, 6° lateral angulation; Tornier, Saint Martin, France) in 5 TTC arthrodeses (Fig. 17.9) and a double anterior plate in 1 ankle arthrodesis (Fig. 17.10). Tantalum implants were surrounded by autologous bone graft (3 femur obtained reamer–irrigator–aspirator, 1 posterior iliac crest,

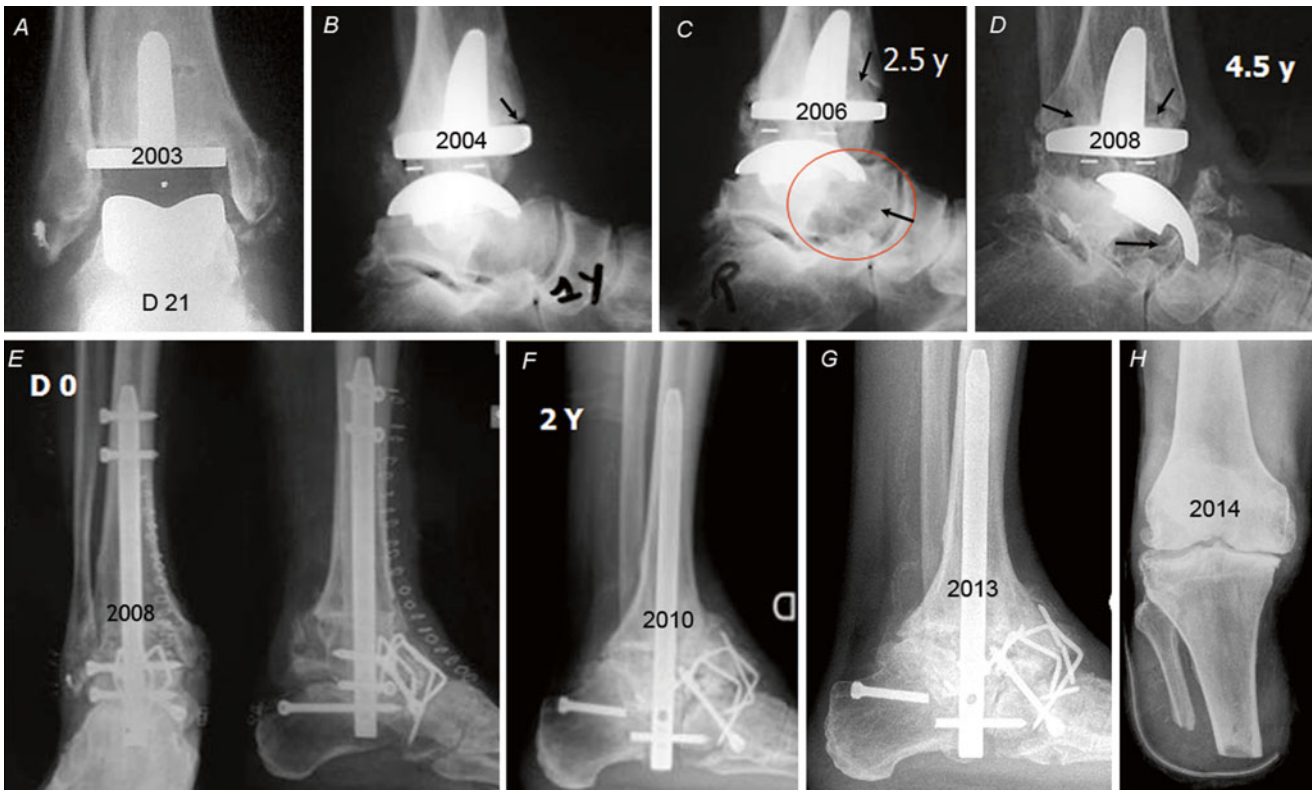

Fig. 17.7 Mechanical prosthesis subsidence due to talar cysts and dramatic failure of tibio-talo-calcaneal arthrodesis with allograft. A 55-year-old man with ankle osteoarthritis secondary to lateral ankle instability. Postoperative anterior–posterior radiograph demonstrating good AES prosthesis positioning (**a**). Lateral radiograph at 1 year demonstrating a small cyst-type A in area 7 (**b**). Lateral radiograph at 2.5 years demonstrating progression of severe cyst-type C in area and type D in area 10 but the patient is still asymptomatic (**c**). Lateral radiograph at 4.5 years with acute pain secondary to mechanical failure with talar component subsidence (**d**). Revision by tibio-calcaneal-navicular arthrodesis with massive bone autograft and allograft and osteosynthesis by retrograde nail (**e**). Nonunion and progressive collapse with nail locking-screw breakage (**f**). Stable clinical situation with little pain but radiological nonunion (**g**). Sudden and acute severe ankle infection requiring a below-knee amputation (**h**)

5 iliac wings harvested with hip reamers) mixed with lyophilized fragmented allograft. Postoperative care comprised 6 weeks of non-weight bearing, followed by 2 months with boot and weight bearing. At a mean 1-year follow-up (range: 6–18 months) for five cases, ankle fusion was confirmed on CT in all cases but with doubt for subtalar fusion in two cases. Our preliminary results are encouraging; tantalum provides primary stability of reconstruction. We need longer follow-up to analyze integration and fusion.

Suggested Cyst Management Algorithm

According to our experience of cyst assessment by radiographs and CT scan [6, 20], relatively poor results are associated with cyst curettage–bone grafting and revision TAR [6, 24] such that we recommend reconstruction ankle arthrodesis [36] according to the following algorithm for cyst management (Fig. 17.11).

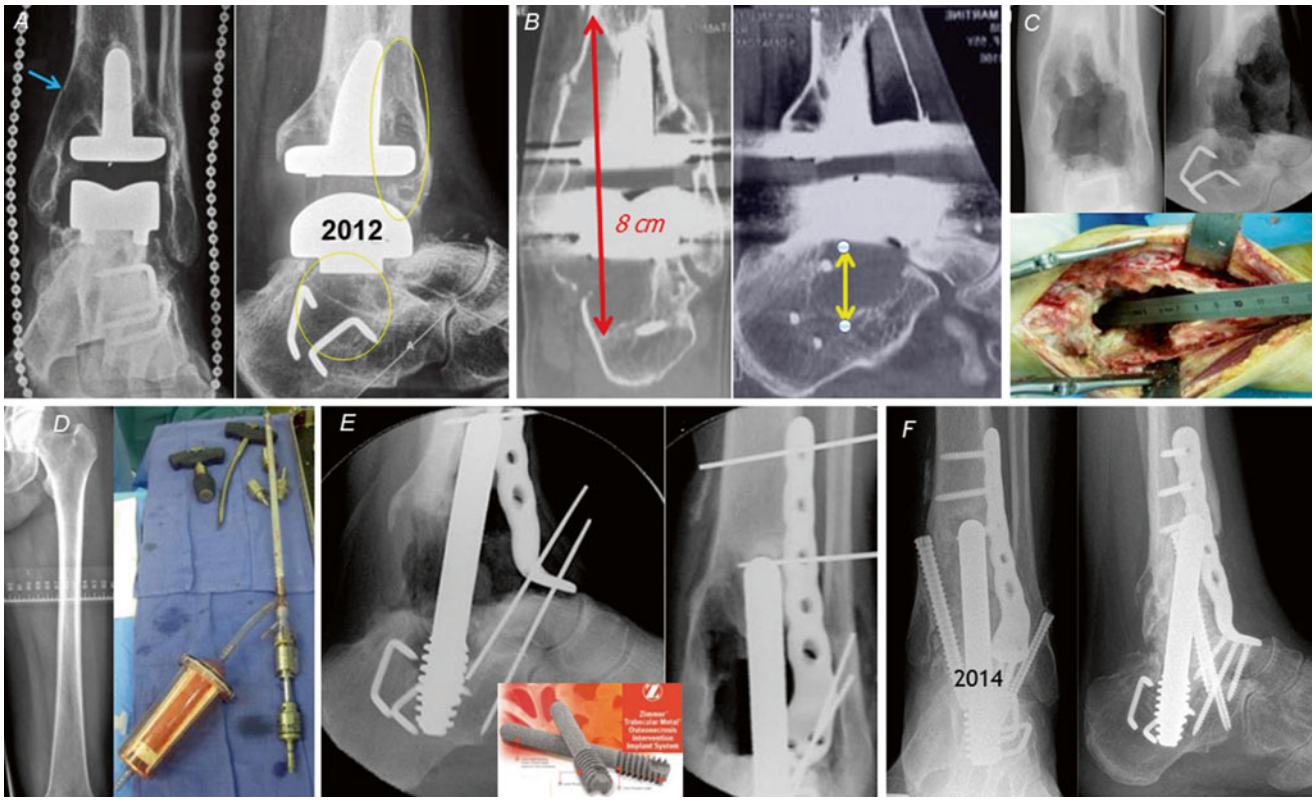

Fig. 17.8 Tantalum rod for tibio-talo-calcaneal arthrodesis reconstruction of revision total ankle replacement. Anterior–posterior and lateral radiographs following the second revision TAR performed in 2003 for a 47-year-old woman (**a**). In 2012 sudden severe pain developed on the tibial medial side due to microfracture of the tibial cortex after dramatic progression of cysts and talar component subsidence (**b**). On CT assessment, bone loss is estimated up to 8 cm with just 1 cm of calcaneus remaining (**c**). Operative and C-arm image intensification views after prosthesis removal (**d**). Autograft taken from the ipsilateral femur with a reamer–irrigator–aspirator (**e**). One 90-mm tantalum rod implant spanning the defect between the tibia and calcaneus. Osteosynthesis with two continuous thread titanium screws and neutralization with anterolateral locking plate (**f**). Anterior–posterior and lateral radiographs at 18 months' follow-up demonstrating solid tibio-talo-calcaneal arthrodesis

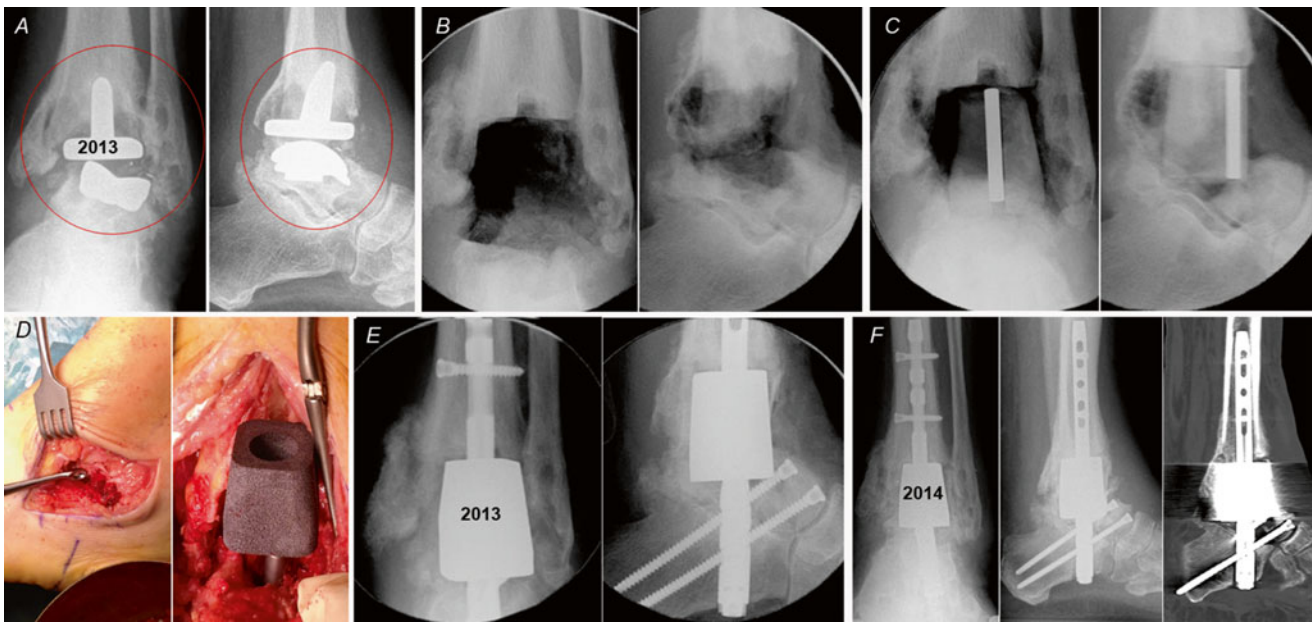

Fig. 17.9 Tantalum spacer associated with angulated retrograde nail for tibio-talo-calcaneal arthrodesis for reconstruction of a failed TAR. Anterior–posterior and lateral radiographs of an AES TAR performed in 2006 in a diabetic 53-year-old man who developed sudden pain following an ankle sprain (**a**). Expansile cysts and metallic component migration are appreciated. Intraoperative image intensification anterior–posterior and lateral views following prosthesis removal (**b**) and with a 40-mm tantalum trial filling the osseous defect (**c**). Intraoperative photograph demonstrating subtalar joint preparation with impaction bone graft taken from the posterior iliac crest (**d**). Intraoperative photograph of the final 40-mm tantalum spacer being inserted over the intramedullary nail (**e**). Anterior–posterior and lateral radiographs following osteosynthesis with an angulated retrograde nail surrounded by autologous bone graft (**f**) and at 1-year follow-up demonstrating solid tibio-tantalum spacer-talo-calcaneal arthrodesis.

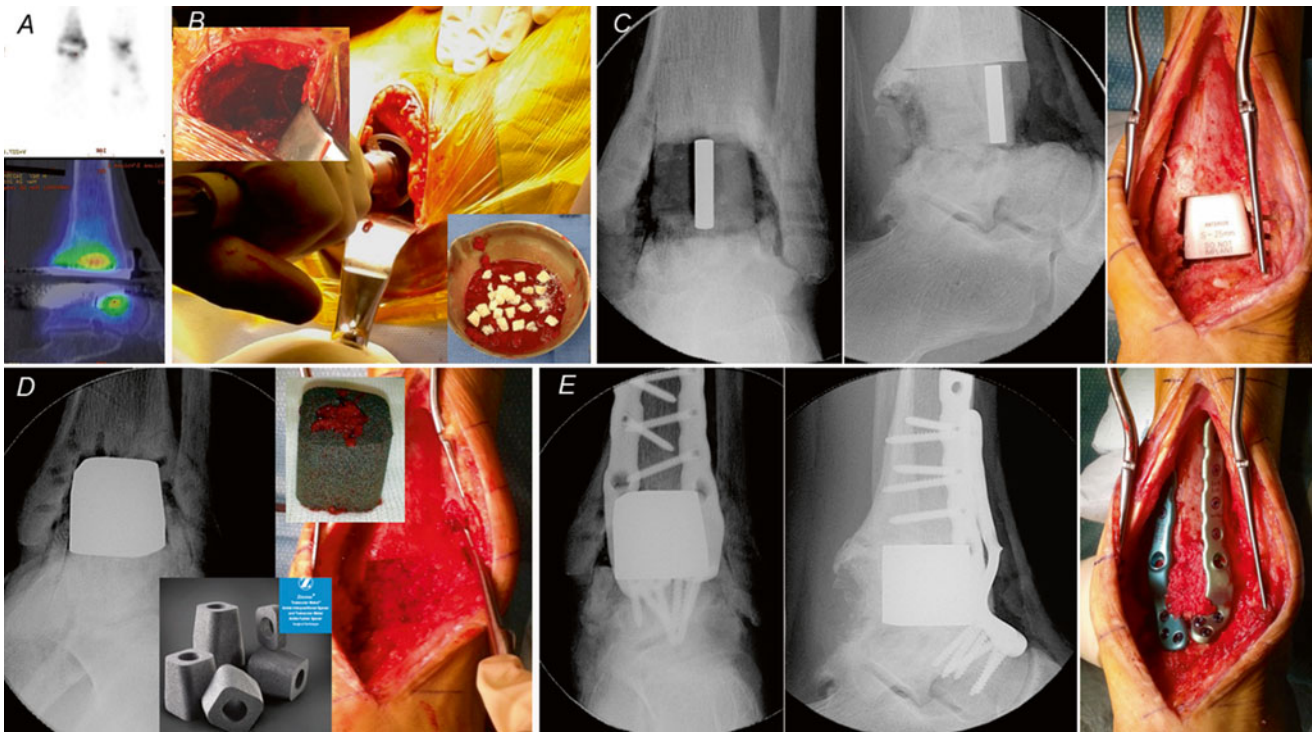

Fig. 17.10 Tantalum spacer for ankle arthrodesis reconstruction of a failed revision total ankle replacement. Hintegra total ankle replacement performed in 2012 in a 55-year-old man who developed chronic pain due to tibial component non-integration with microcyst on Spect-CT assessment (**a**). Anterior iliac wing harvested with hip reamers, mixed with lyophilized fragmented allograft (**b**). Anterior–posterior and lateral intraoperative image intensification views and intraoperative photograph following prosthesis removal and insertion of a 25-mm tantalum trial filling osseous defect (**c**). Anterior–posterior and lateral intraoperative image intensification views and intraoperative photograph demonstrating the final 25-mm tantalum spacer surrounded by autologous bone graft (**d**) and then fixated with two locking plates (**e**).

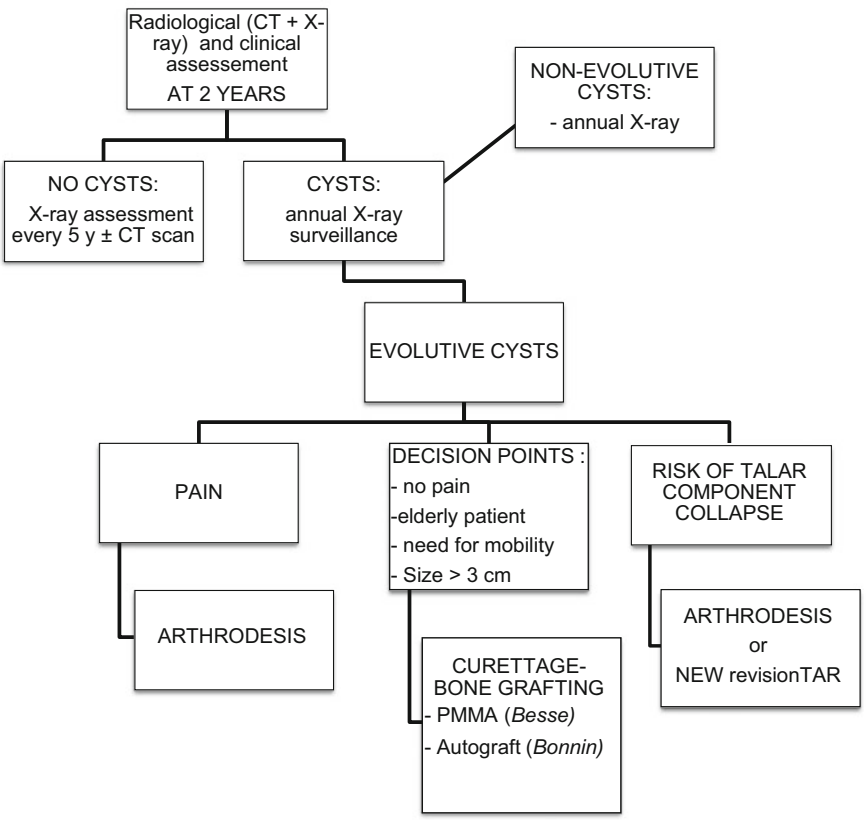

Fig. 17.11 Therapeutic flowchart for cyst management associated with total ankle replacement

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Arthroscopic Debridement for Soft-Tissue Impingement After Total Ankle Replacement

18

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.

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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

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_18

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.

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 18.1). 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 is indicative of soft-tissue impingement [2]. On physical examination, localized tenderness around the joint typically aggravates when the ankle is dorsiflexed.

Table 18.1 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

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 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 noninvasive 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 component can be confirmed by dorsiflexing the ankle joint (Fig. 18.1). 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.

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. 18.2, 18.3, and 18.4).

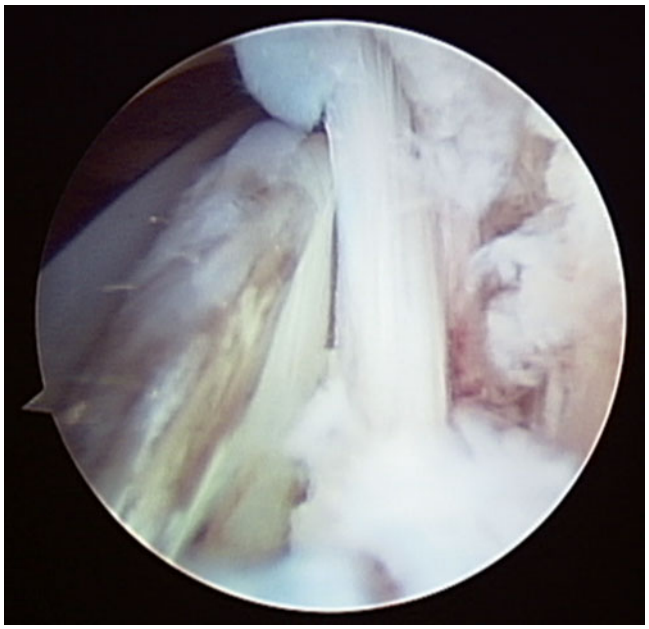

Fig. 18.1 A thick fibrotic band impinging against the talar component in the lateral gutter of a left ankle

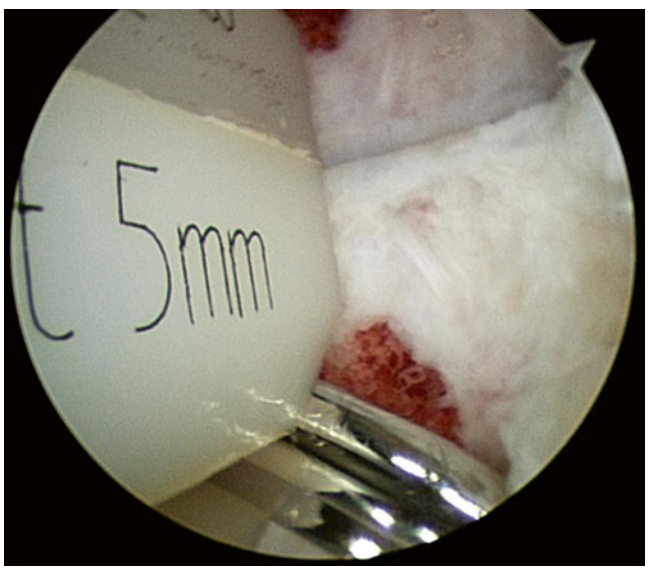

Fig. 18.2 Inflamed synovial tissue abutting the lateral aspect of the talar component of a left ankle

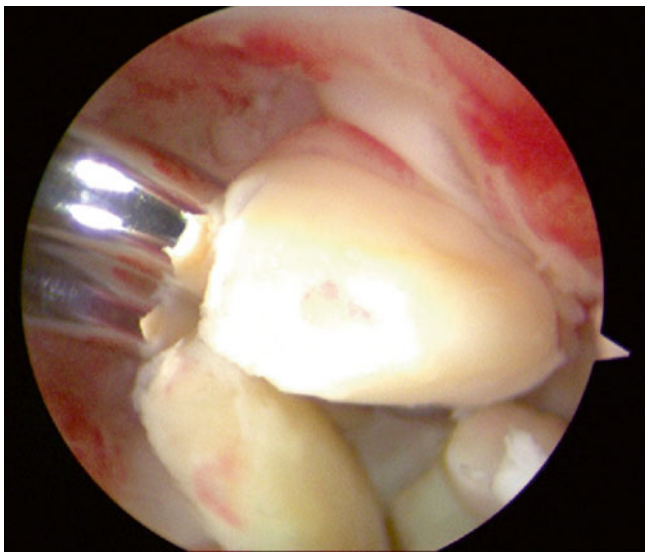

Fig. 18.3 A large loose body within the joint space and surrounding synovitis

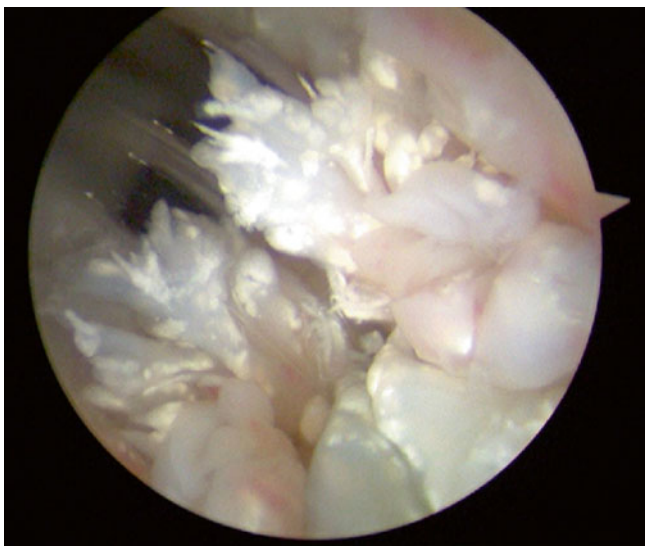

Fig. 18.4 Extensive white chalky debris consistent with uric acid that was confirmed on histology

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 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

19

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 orthopedic 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].

Orthopedic 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

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_19

of bone are not always completely resected and may lead to postoperative osteophytes or ectopic bone formation.

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. 19.1). 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 determination of the causative impingement with pain in the anterior–lateral region of the lateral gutter exhibiting pain with forced

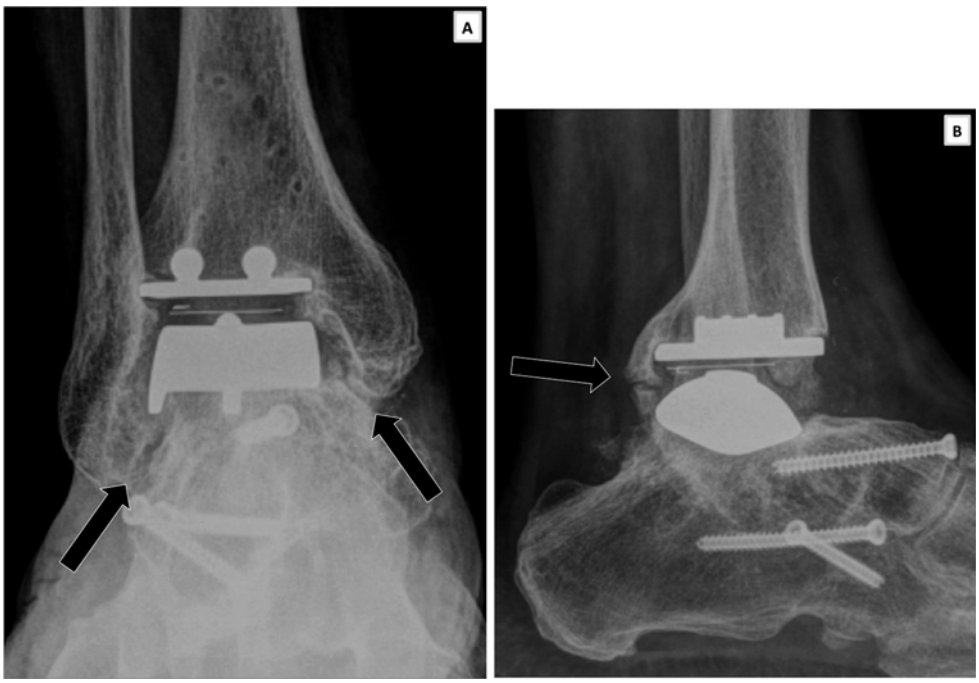

Fig. 19.1 Anterior–posterior (**a**) and lateral (**b**) weight-bearing radiographs 1 year postoperative demonstrating ectopic bone ossification within the medial and lateral gutters, as well as posterior ankle (*straight arrows*). This patient had very little range of motion to the ankle as a result of the global ectopic bone formation engulfing this primary total ankle replacement

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 ectopic 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. 19.2). 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 débridement. 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 débridement 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. 19.3). In all of these cases, careful considerations of polyethylene insert exchange, component exchange, or complete removal should be entertained concomitantly with the osseous débridement. 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 débridement of the ectopic bone.

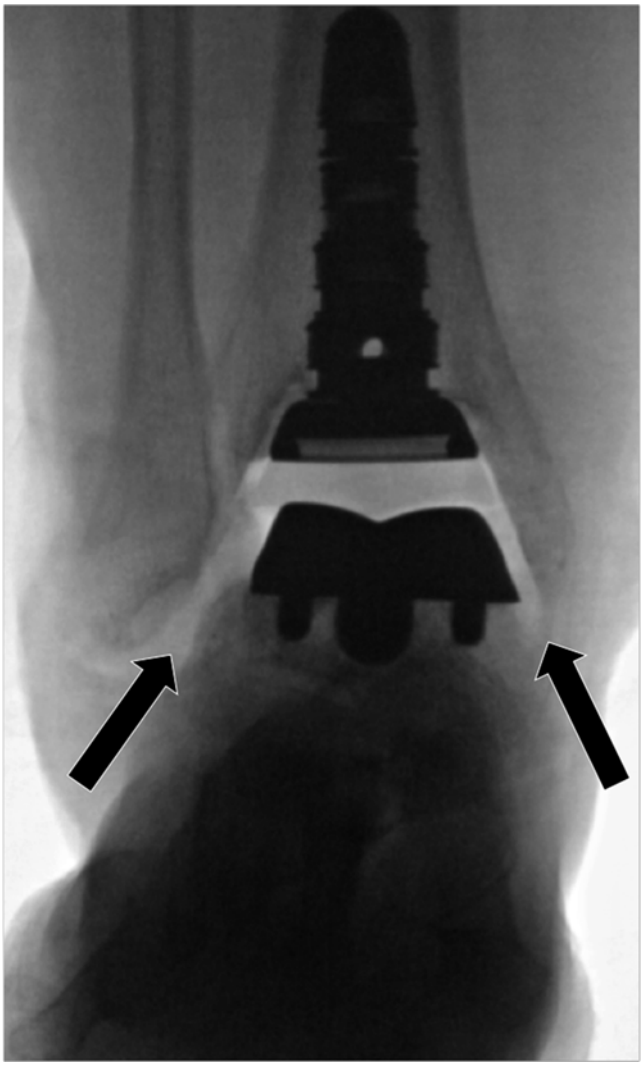

Fig. 19.2 Anterior–posterior image intensification view demonstrating complete talar dome coverage without overlap of the prosthetic component into the medial or lateral gutters that have also undergone through débridement (*straight arrows*)

Surgical Technique

Arthroscopic débridement 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 to the areas of concern (Fig. 19.4). 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. 19.5a, 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

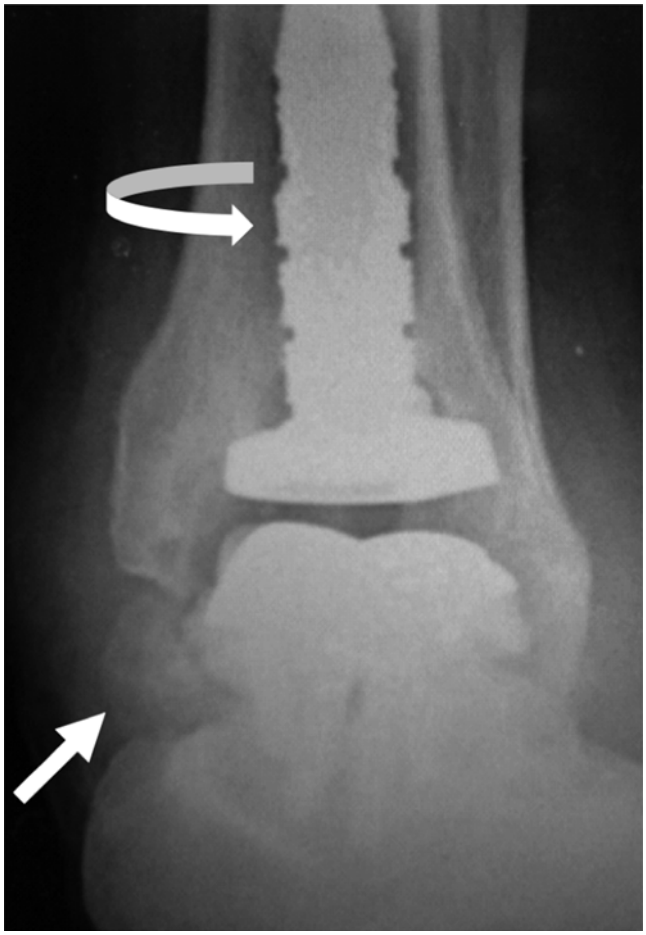

Fig. 19.3 Anterior–posterior radiographs 2 years postoperative demonstrating lucency surrounding the tibial component (*curved arrow*) suggestive of component loosening, as well as large medial gutter ectopic bone formation (*straight arrow*) as a result of talar component subsidence

aggressiveness of the tool may rapidly remove bone and the potential for "divoting" or fracturing the malleoli may occur with overaggressive resection. Osseous débridement 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. 19.5c). Application of absorbable bone wax may also help seal the cancellous bone substrate, thereby limiting osseous regeneration and recurrence of the ectopic bone (Fig. 19.5d).

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 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 débridement 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, six (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 débridement [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 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 débridement; however, seven patients (21 %) required reoperation following gutter débridement. 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 débridement, 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.

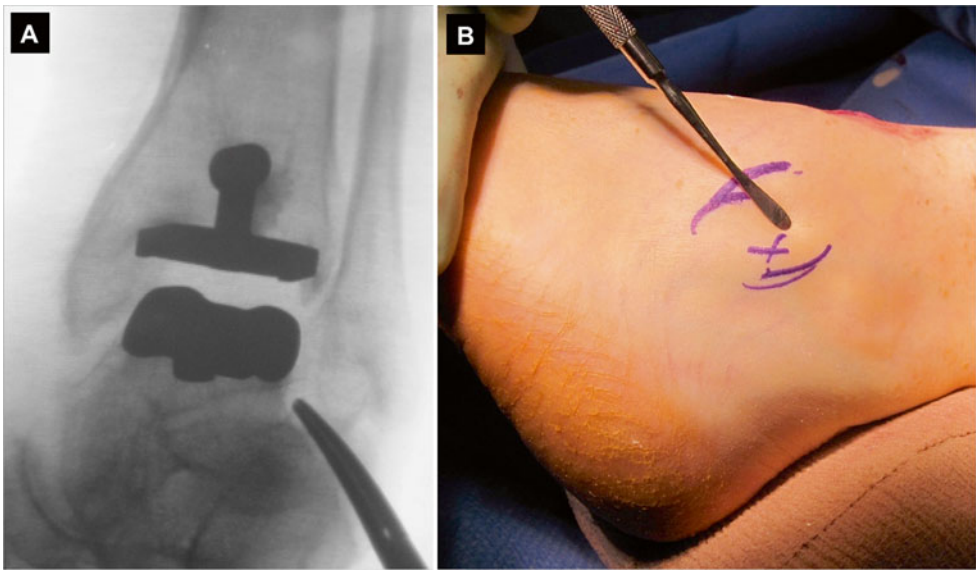

Fig. 19.4 Intraoperative anterior–posterior C-arm image intensification view (**a**) and photograph (**b**) demonstrating location of the ectopic bone in the lateral gutter which is useful for incision planning

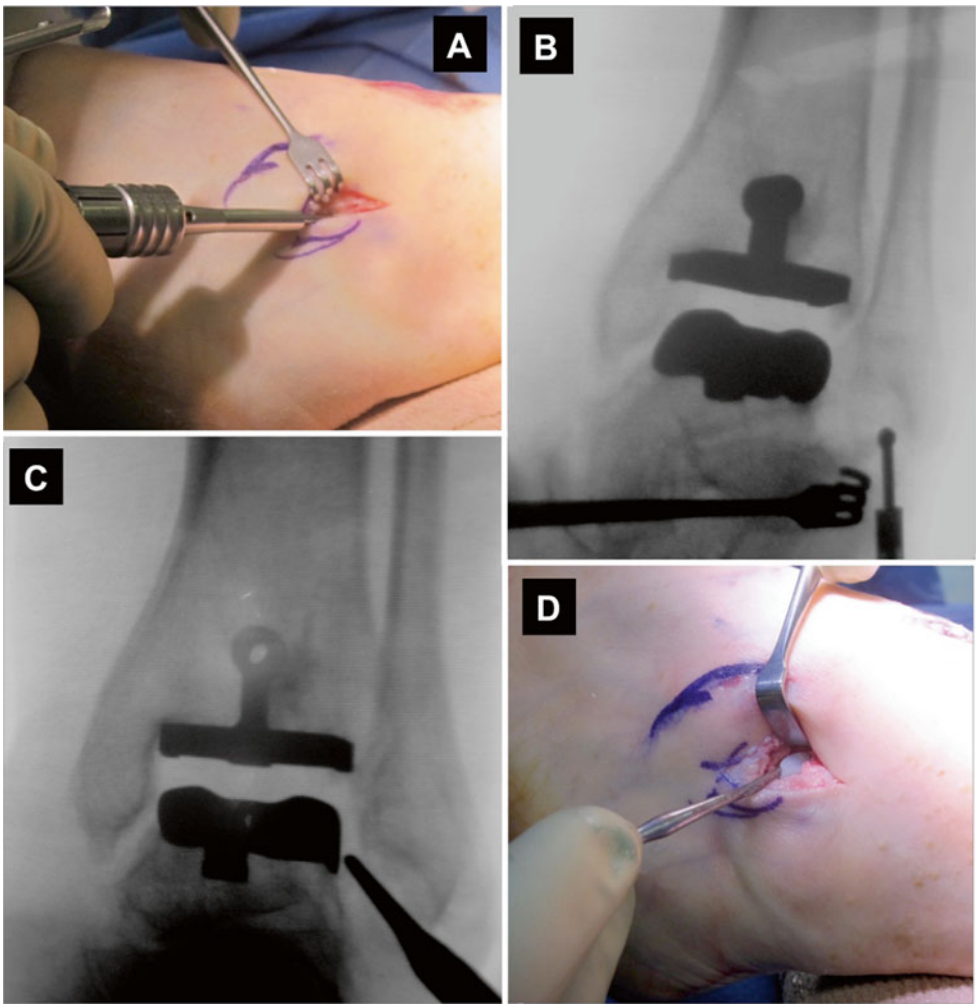

Fig. 19.5 Intraoperative photograph (**a**) and anterior–posterior C-arm image intensification view (**b**) demonstrating burring of the ectopic bone from the lateral malleolus and gutter. Anterior–posterior C-arm image intensification view demonstrating use of a rongeur for débridement of lateral gutter following 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**)

Acknowledgment The authors would like to thank Bethany Worobey, MS, who assisted in the compilation and editing of this manuscript.

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Management of Painful Malleolar Gutters After Total Ankle Replacement

20

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.

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].

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_20

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 to test stability of the talar component on the talus perioperatively during revision surgery.

Prosthesis Design

TAR implants are composed with 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 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. 20.1) [10]. Varus positioning of the TAR components (>4°) can lead to medial gutter pain from impingement, and a valgus positioning of the TAR

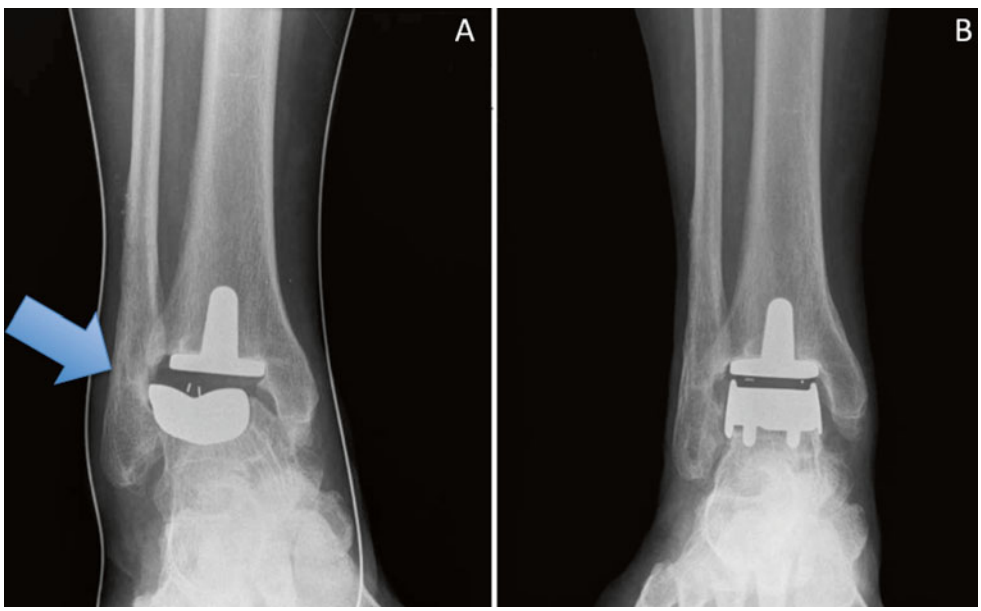

Fig. 20.1 (**a**) 74-year-old male patient with a total ankle replacement implanted in another center was suffering from lateral pain due to excessive lateral malposition of the talar component as demonstrated on weight-bearing anterior–posterior radiograph (**a**). The delay between the implantation 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

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. 20.2). 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].

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].

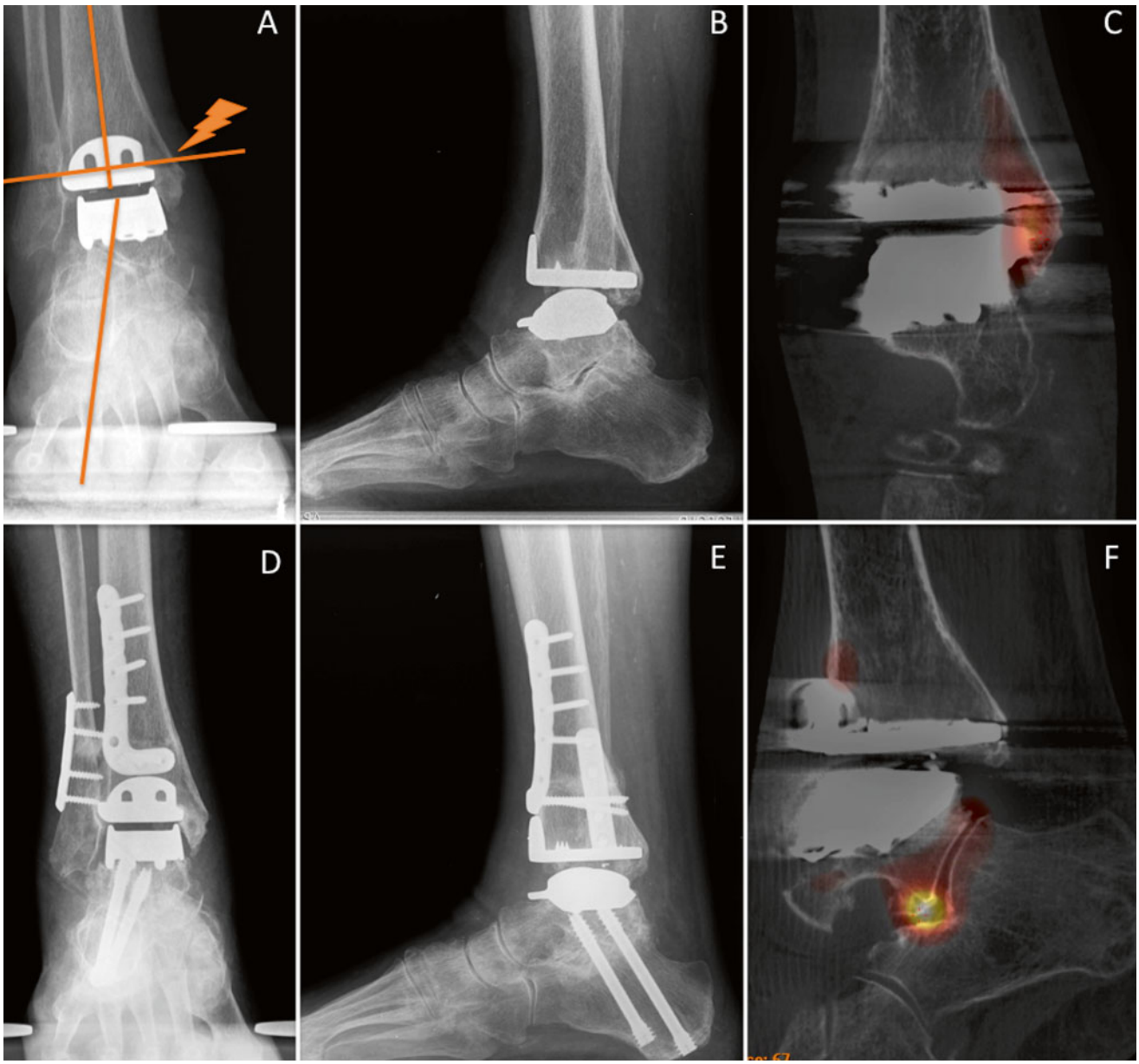

Fig. 20.2 Weight-bearing anterior–posterior (**a**) and lateral (**b**) radiographs of a 76-year-old female patient suffering from medial gutter pain after total ankle replacement induced by a "zigzag deformity" composed of a valgus deformity of the hindfoot associated with a varus of the tibial component 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**)

In 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 fixation 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

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

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 Computerized Tomography Scan

Pain around ankle prosthesis can be a diagnostic challenge given the complex anatomical relations and structural mechanics. Single photon emission computerized tomography

(SPECT) scan is a diagnostic tool that has an added value in clarifying a diagnosis in unexplained pain around the prosthesis (Fig. 20.2c, 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. 20.3).

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 final follow-up. Despite these encouraging results, Richardson et al. [3] reported a high recurrence rate of 37.5 % (6/16 patients).

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 débridement of the malleolar gutters in order to prevent recurrence of the patients' symptoms.

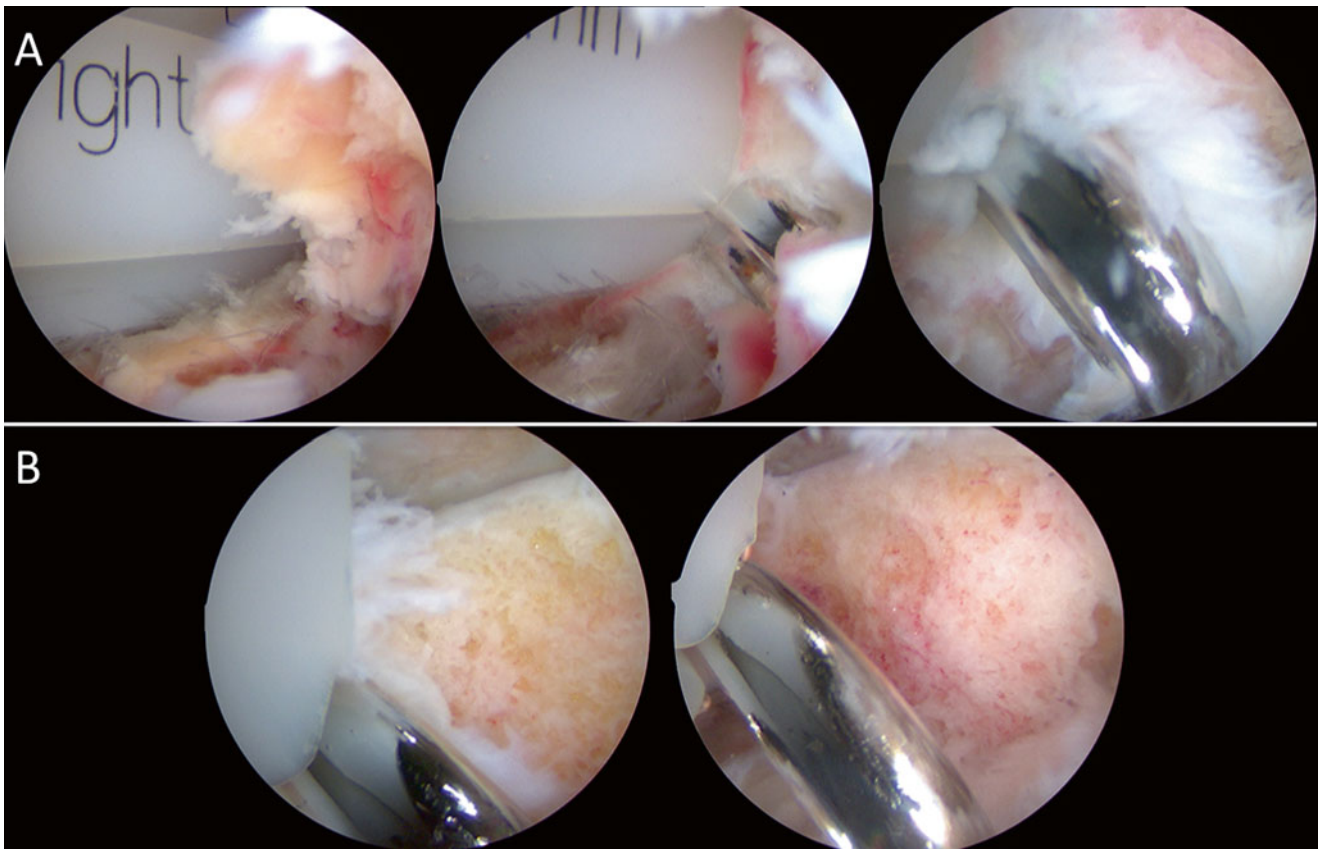

Fig. 20.3 Intraoperative C-arm image intensification views of arthroscopic debridement. Malleolar impingement and residual pain (**a**). Result of debridement under arthroscopy (**b**)

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Managing Varus and Valgus Malalignment After Total Ankle Replacement

21

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 importance of achieving

© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_21

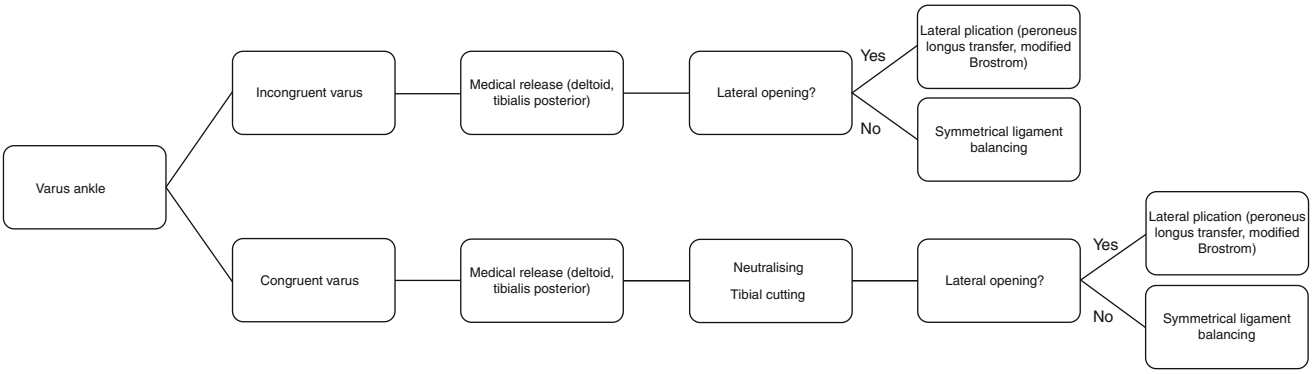

Fig. 21.1 Treatment algorithm for varus malaligned ankles

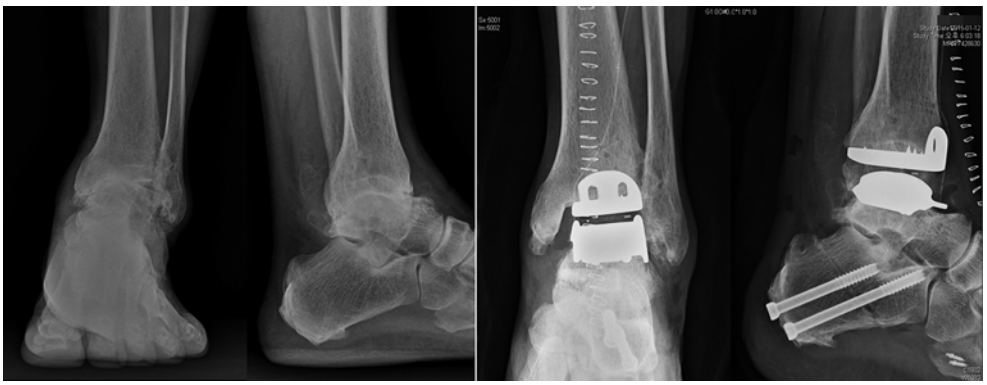

Fig. 21.2 Congruent varus ankle. Postoperative radiograph after a neutralizing tibia cutting

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. 21.1, 21.2 and 21.3). 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 3 varus ankle accompanies subtalar joint subluxation, which can be addressed by subtalar or triple arthrodesis.

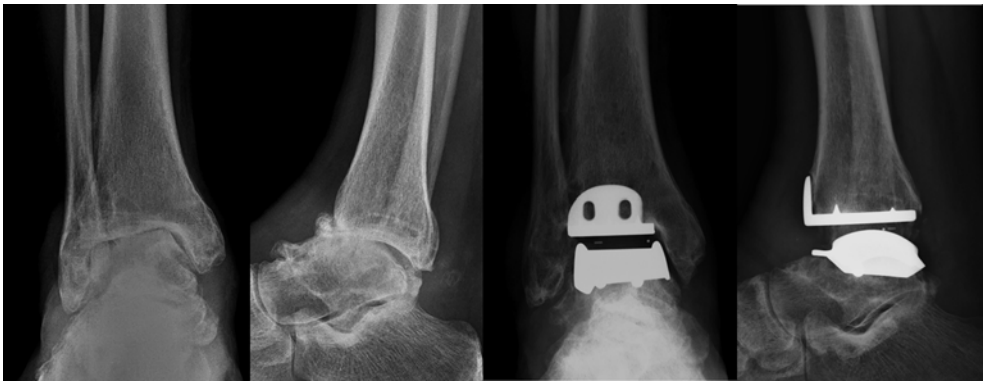

Fig. 21.3 Incongruent varus ankle. After sufficient deltoid release, lateral plication was performed using peroneus longus transfer to brevis technique (note the suture anchor on 5th metatarsal base). Calcaneal valgization osteotomy was also performed to correct heel varus deformity

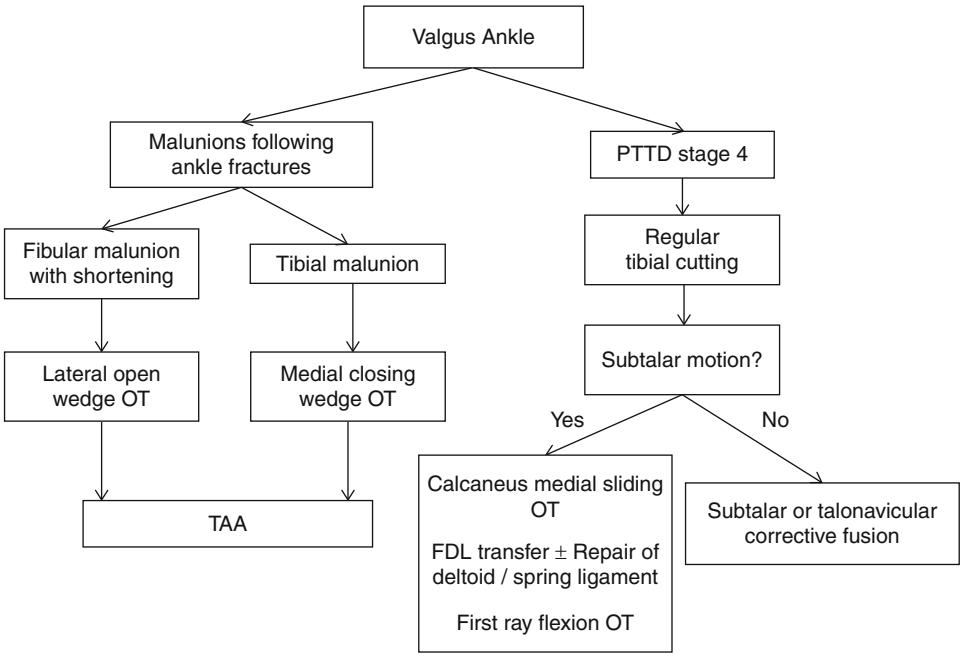

Fig. 21.4 Treatment algorithm for valgus malaligned ankles

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. 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. 21.4.

Preoperative Evaluation

Assessment of the alignment around the ankle joint should be performed by both physical examination and radiological evaluation. 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.

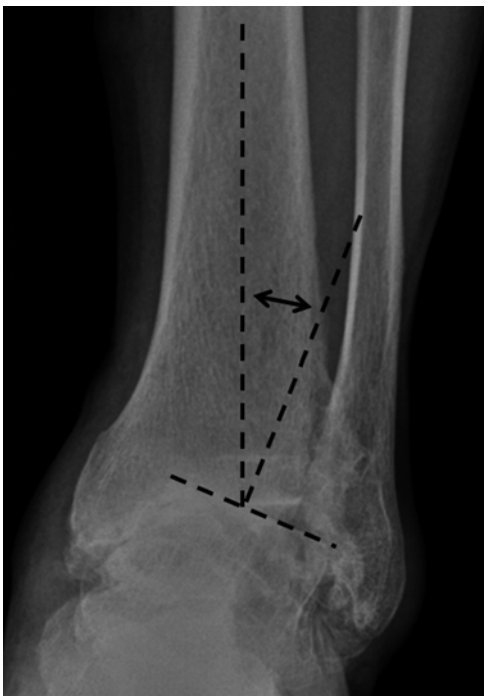

Fig. 21.5 Tibiotalar angle: the angle between the anatomical axis of the tibia and a line drawn perpendicular to the talar dome

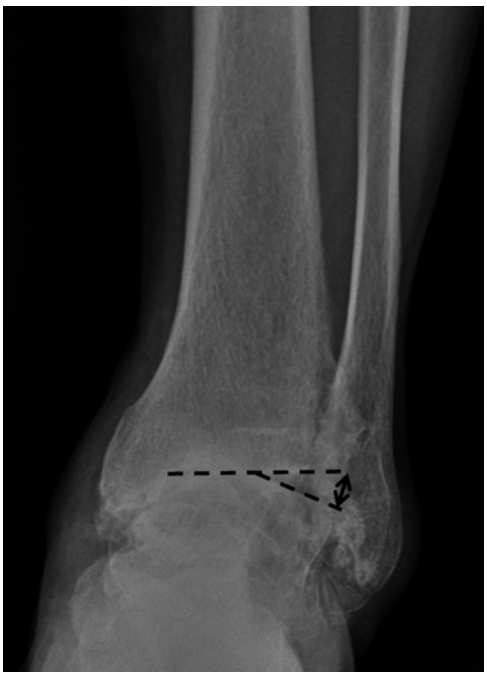

Fig. 21.6 Talar tilt angle: the angle between tibial plafond and the talar dome

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. 21.5) [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. 21.6) [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].

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. 21.2), 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. 21.3), 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

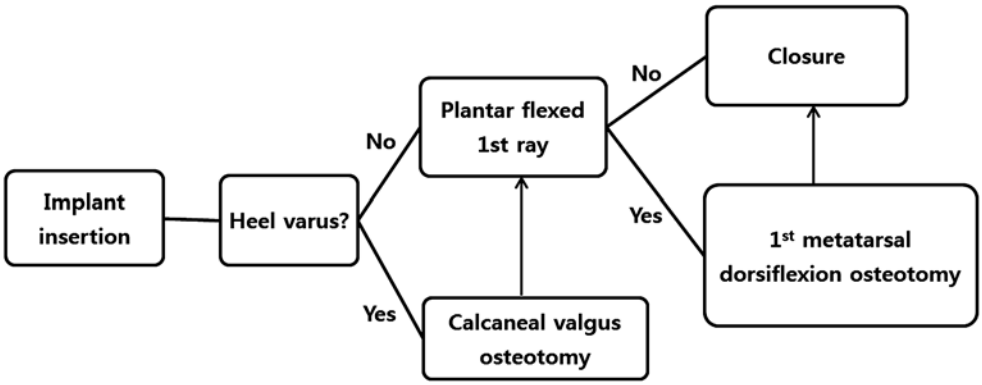

Fig. 21.7 Additional procedures algorithm for a plantigrade foot

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. 21.7).

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

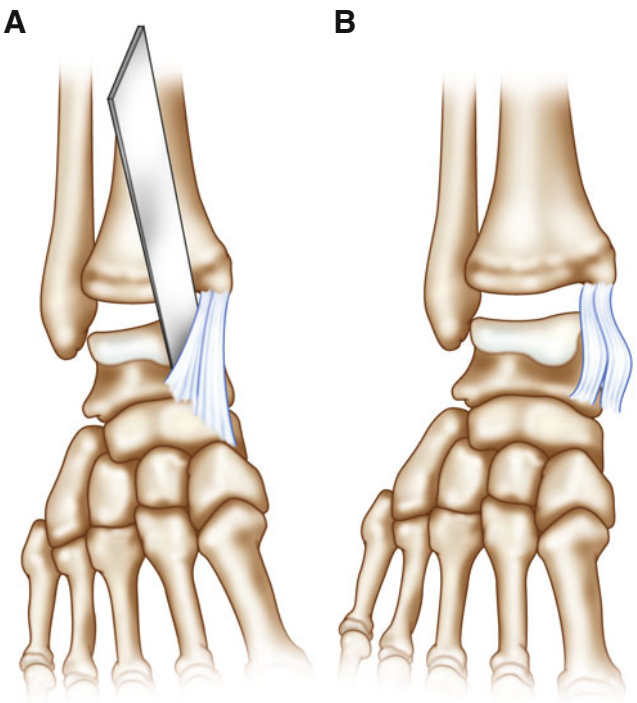

Fig. 21.8 Medial deltoid release

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. 21.8). 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 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 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. 21.9).

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.

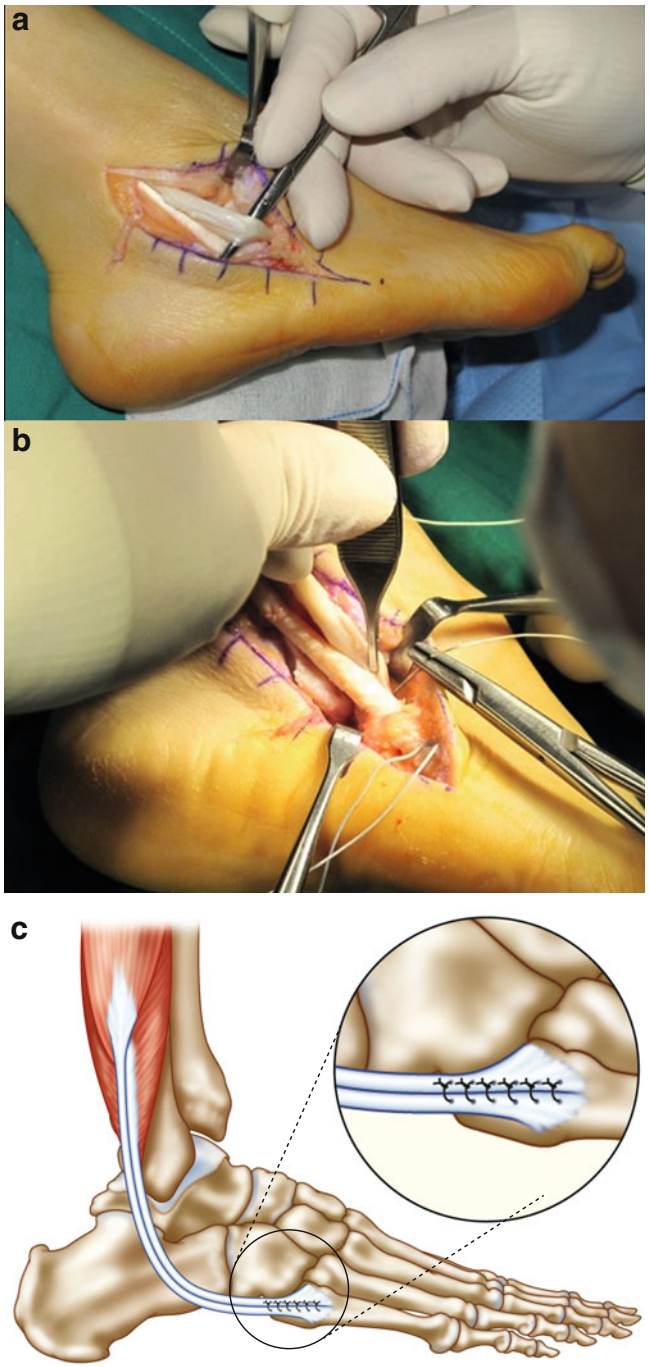

Fig. 21.9 Lateral plication: peroneus longus transfer to peroneus brevis

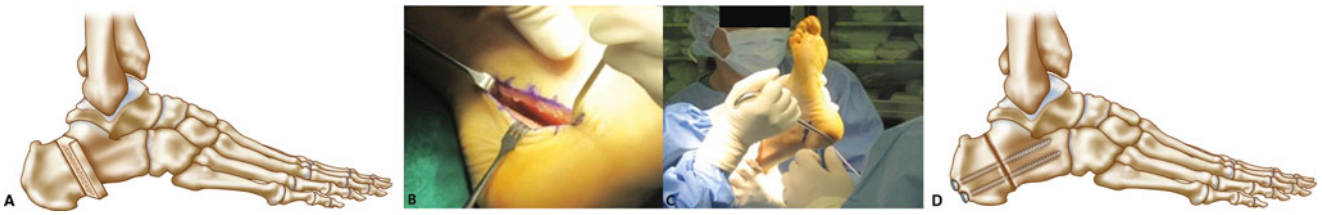

Fig. 21.10 Calcaneal valgization osteotomy

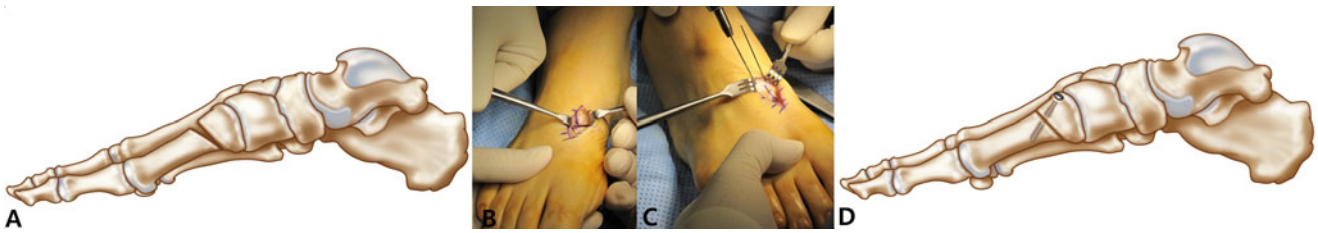

Fig. 21.11 Dorsiflexion osteotomy of the first metatarsal

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. 21.10).

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. 21.11).

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 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

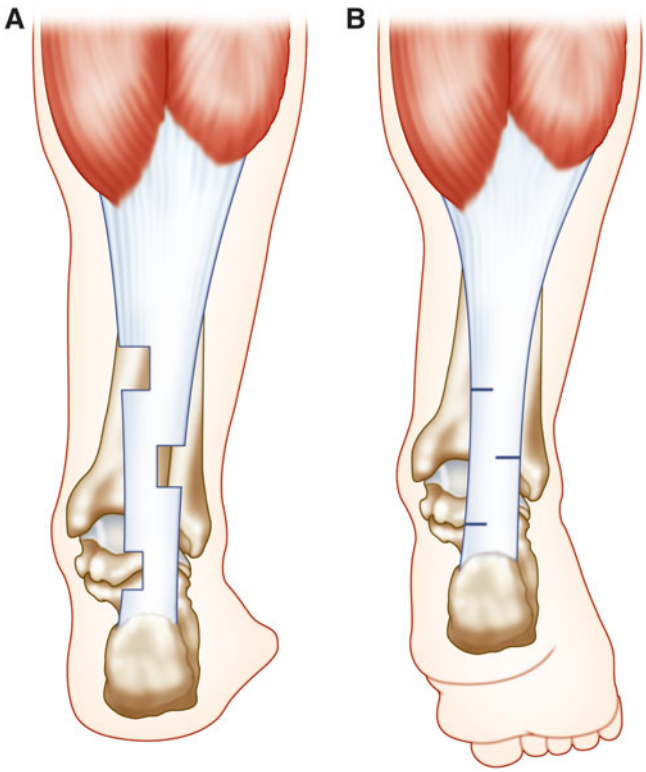

Fig. 21.12 Heel cord lengthening

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. 21.12). 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.

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 transmalleolar 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 showed 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 showed 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

22

Beat Hintermann and Markus Knupp

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. 22.1a–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 deformities 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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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_22

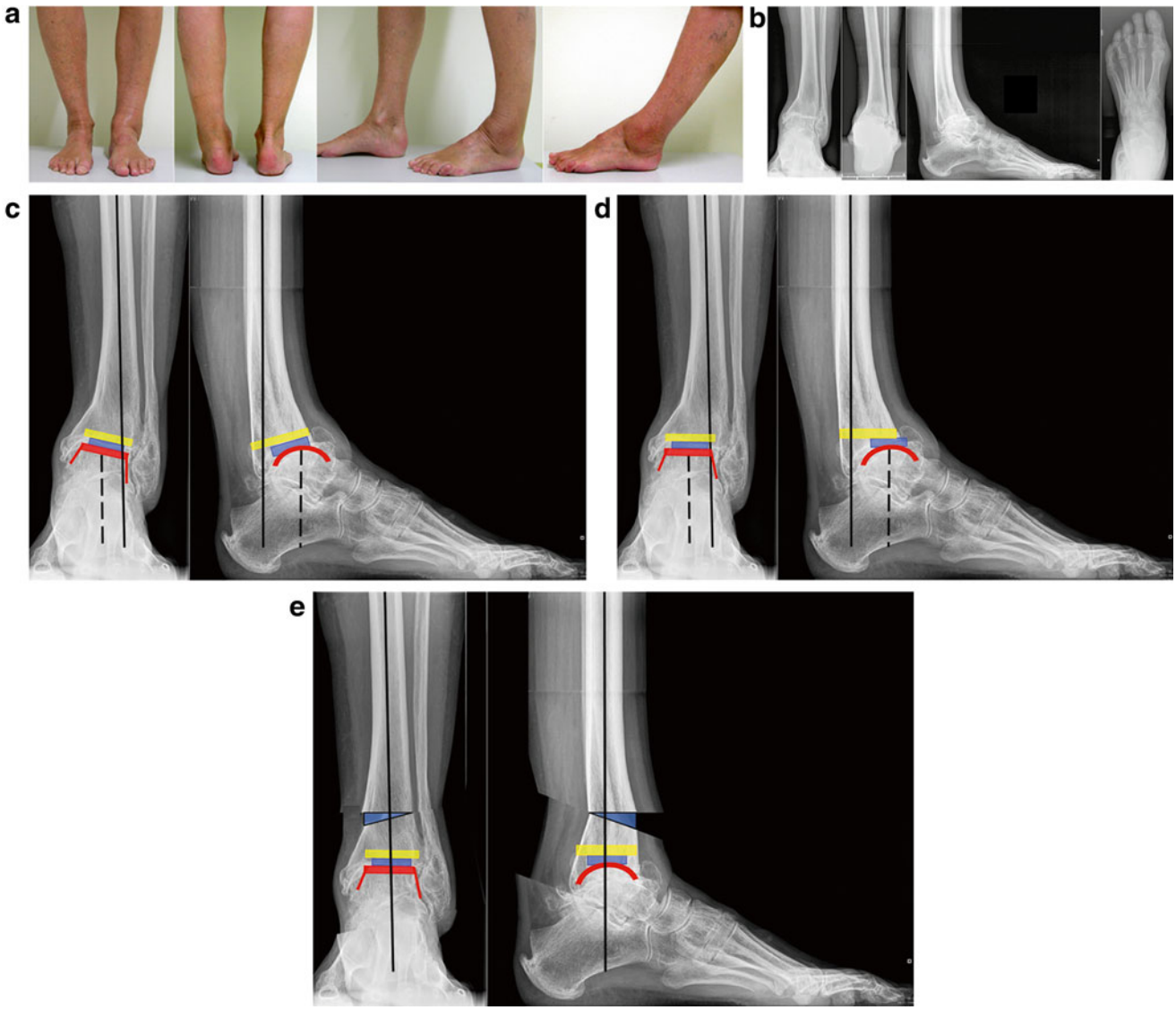

Fig. 22.1 A 58-year-old female patient with posttraumatic ankle osteoarthritis subsequent to a malunited distal tibial fracture 32 years ago. Marked varus and recurvatum deformity as seen clinically (**a**) and radiographically: AP, Saltzman, and lateral view of the ankle as well as a foot AP (**b**). 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*) plane: 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. 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

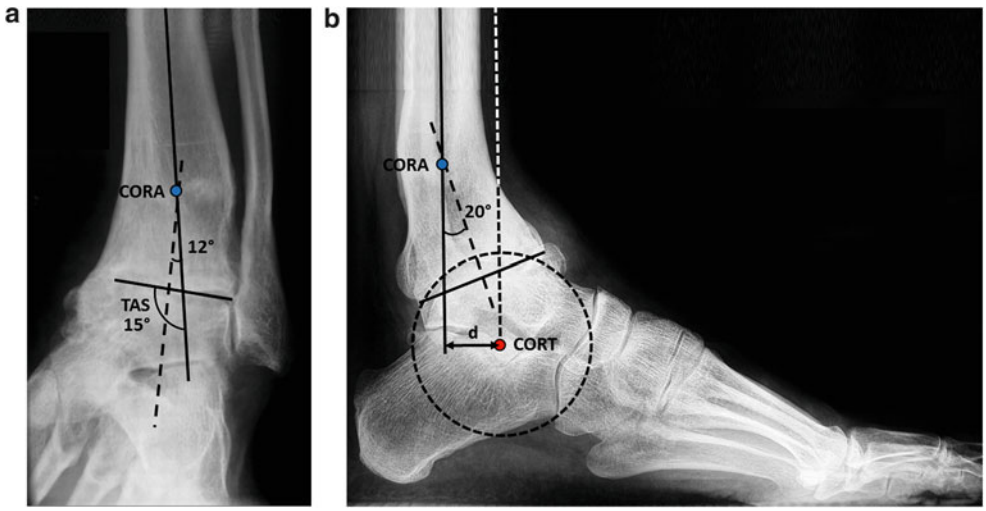

Fig. 22.2 Assessment of the deformity with the aid of the center of rotation of angulation (CORA), the distance "d," representing the deviation of the joint loading axis to the center of rotation of the talus (CORT) and the tibial articular surface (TAS) angle. (**a**) Coronal plane; (**b**) sagittal plane

angulation (CORA), and to measure the amount of angulation in the coronal plane (Fig. 22.2a) [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. 22.2b). The Saltzman view is used to assess overall alignment of the hindfoot.

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. 22.3a–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. 22.4a, 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. 22.5a, 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. 22.6a–e) [12, 24].

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. 22.7a–d).

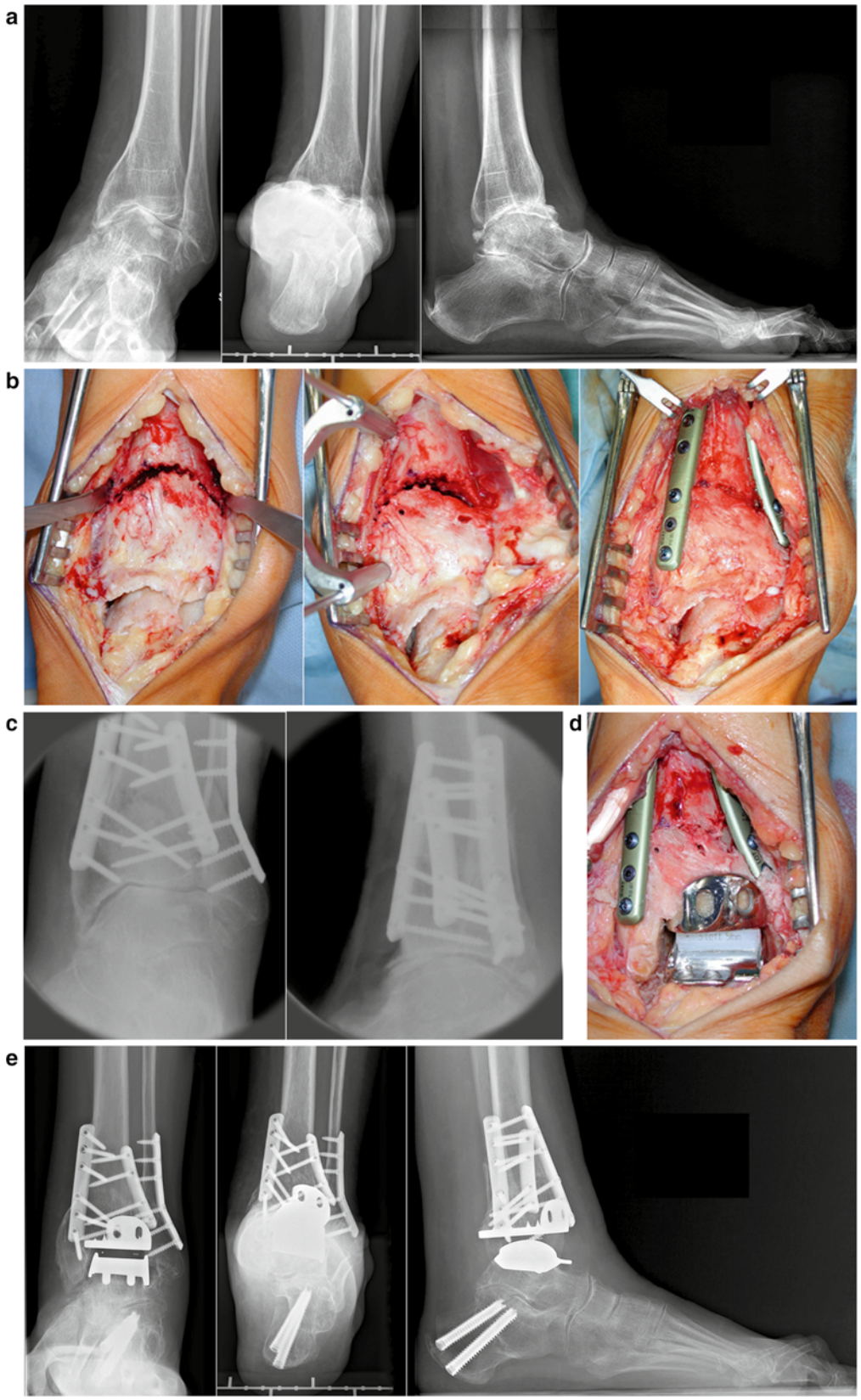

Fig. 22.3 A 61-year-old male patient with end-stage osteoarthritis with a marked varus deformity of the distal tibia after an ankle fracture with injury to the epiphysis at the age of 12 years. (**a**) AP view, Saltzman view, and lateral view of the ankle. Radiographic assessment evidences a talar tilt 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

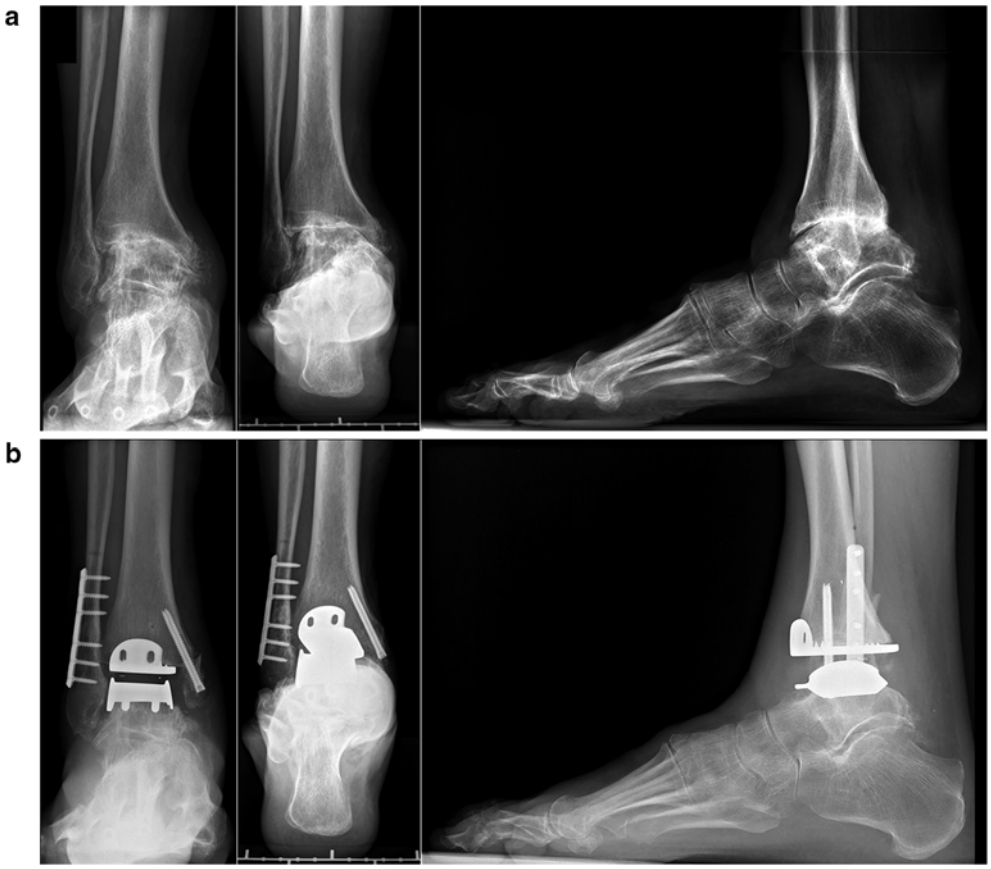

Fig. 22.4 A 48-year-old female patient with end-stage ankle osteoarthritis subsequent to an ankle fracture 24 years earlier. (**a**) AP view, Saltzman view, and lateral view of the ankle. The radiographic assessment reveals a distinct varus deformity of the distal tibia and a malunited fibula that is 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

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. 22.8a–c).

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.

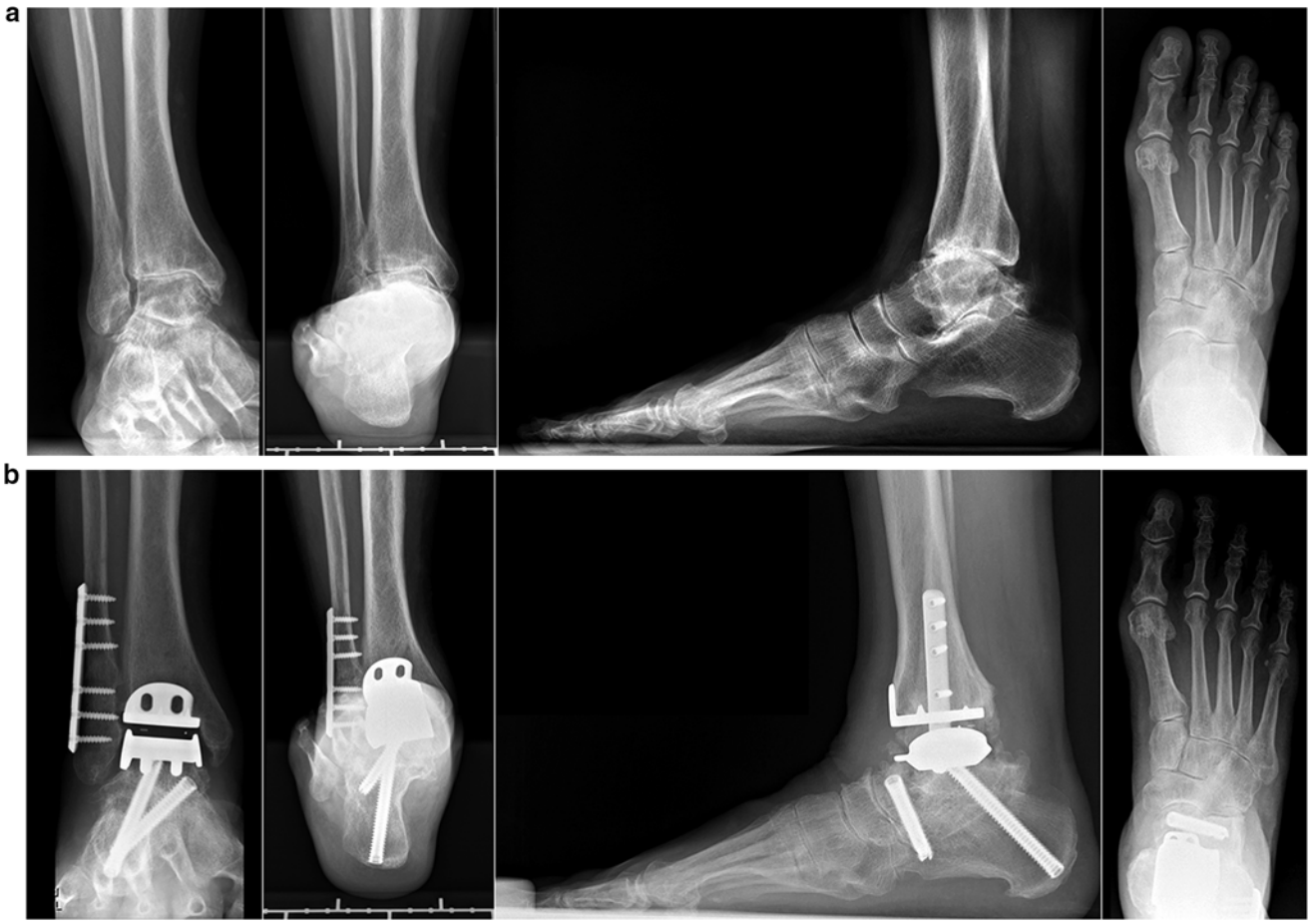

Fig. 22.5 A 54-year-old female patient with end-stage ankle osteoarthritis subsequent to an ankle fracture 18 years earlier. (**a**) AP view, Saltzman view, and lateral view of the ankle and foot AP. The preoperative radiographic assessment reveals a recurvatum malunion of the distal fibula that forces 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

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, 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. 22.9a). While an opening wedge osteotomy is considered for minor corrections (Fig. 22.9b), 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 correction (Fig. 22.3). 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. 22.9c). Plate fixation should be done such as not to interfere with the

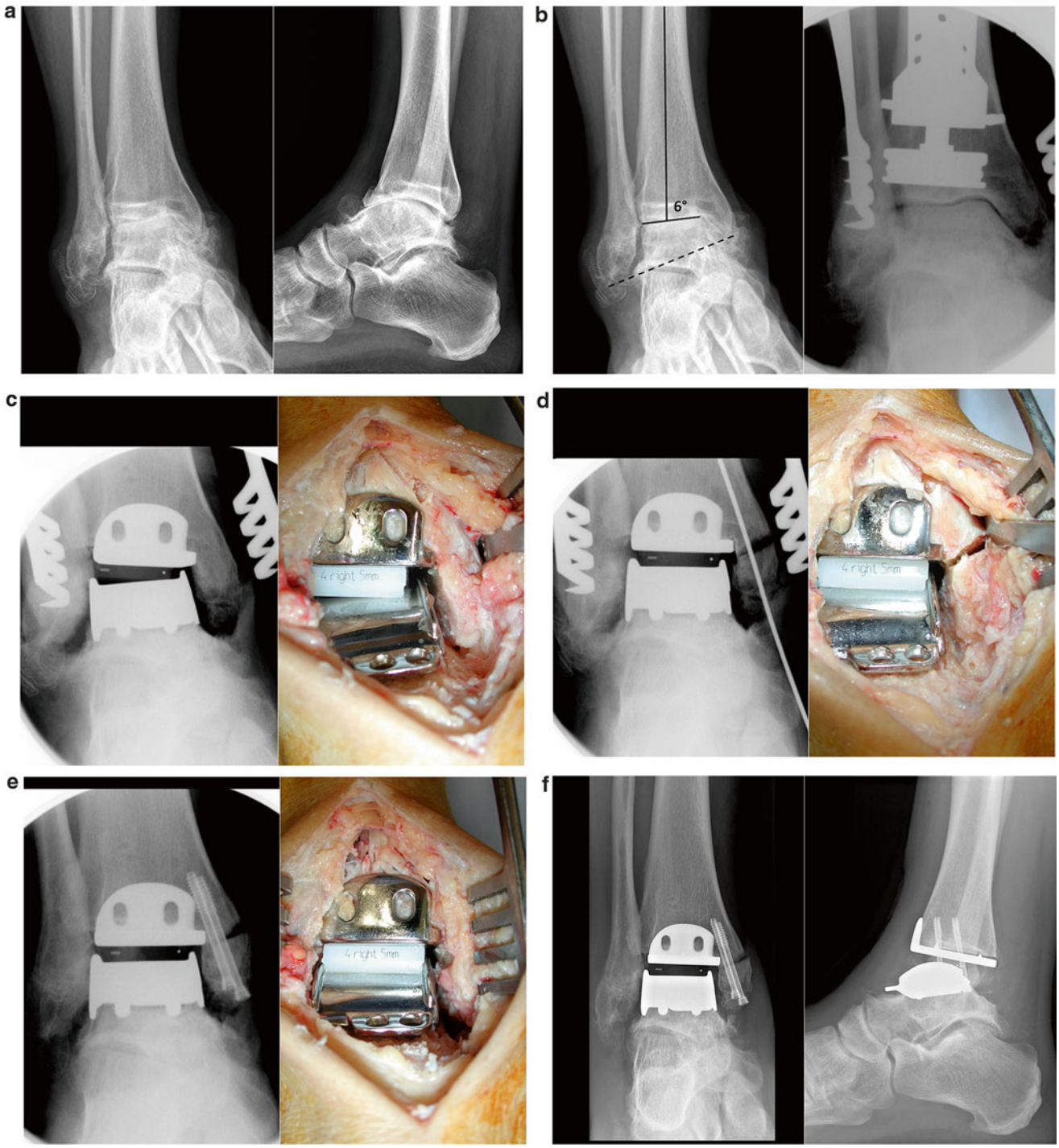

Fig. 22.6 A 51-year-old male, former soccer player, with end-stage ankle osteoarthritis subsequent to recurrent ankle sprains. (**a**) AP view and lateral view of the ankle. The preoperative radiographic assessment reveals a varus deformity of the distal tibia with a moderate varus tilt of the talus 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

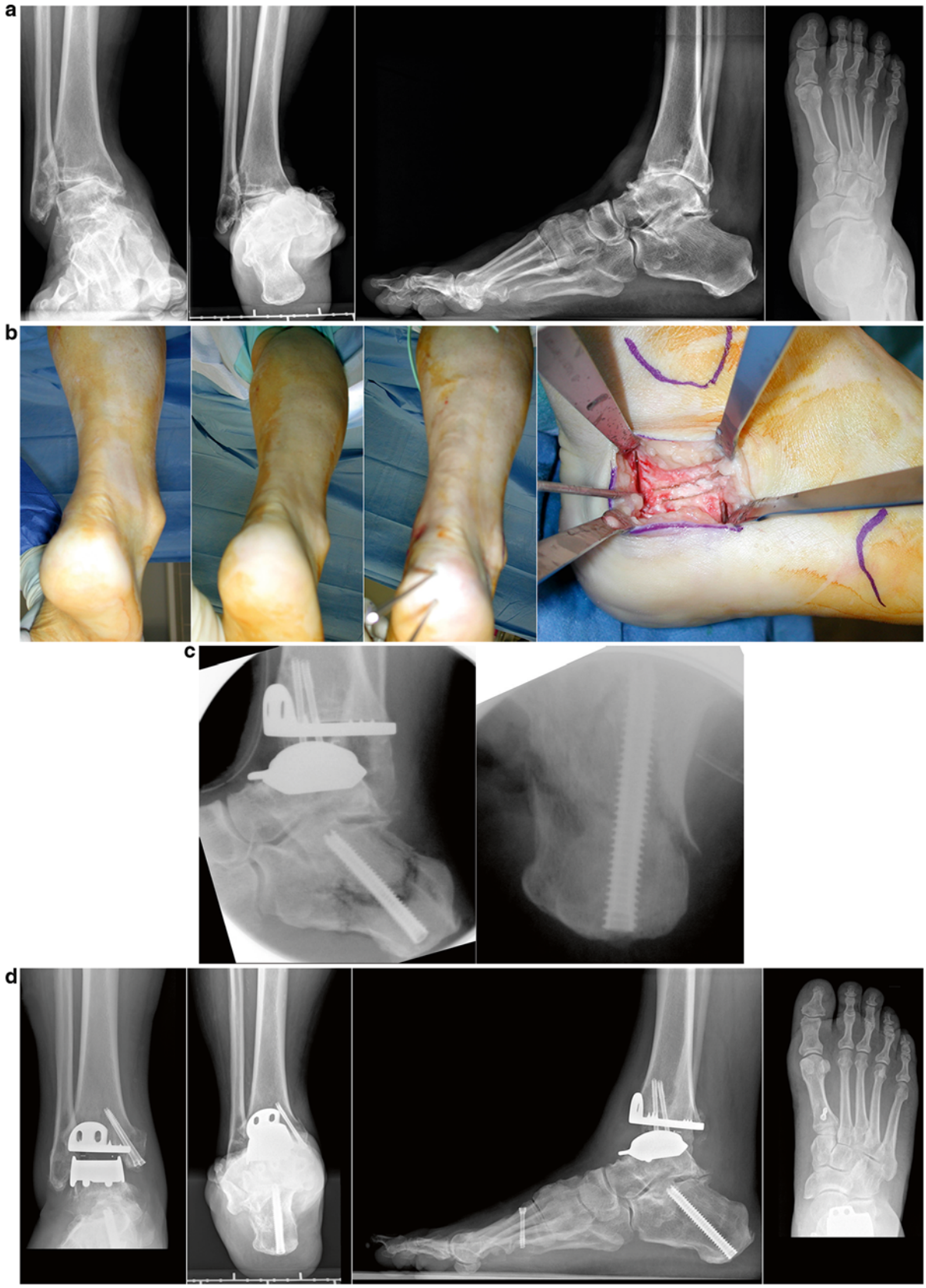

Fig. 22.7 A 56-year-old male patient with end-stage osteoarthritis associated with a severe varus deformity. (**a**) AP view, Saltzman view, and lateral view of the ankle as well as a foot AP. Radiographic assessment reveals a purely inframalleolar deformity associated with a significant incompetence 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

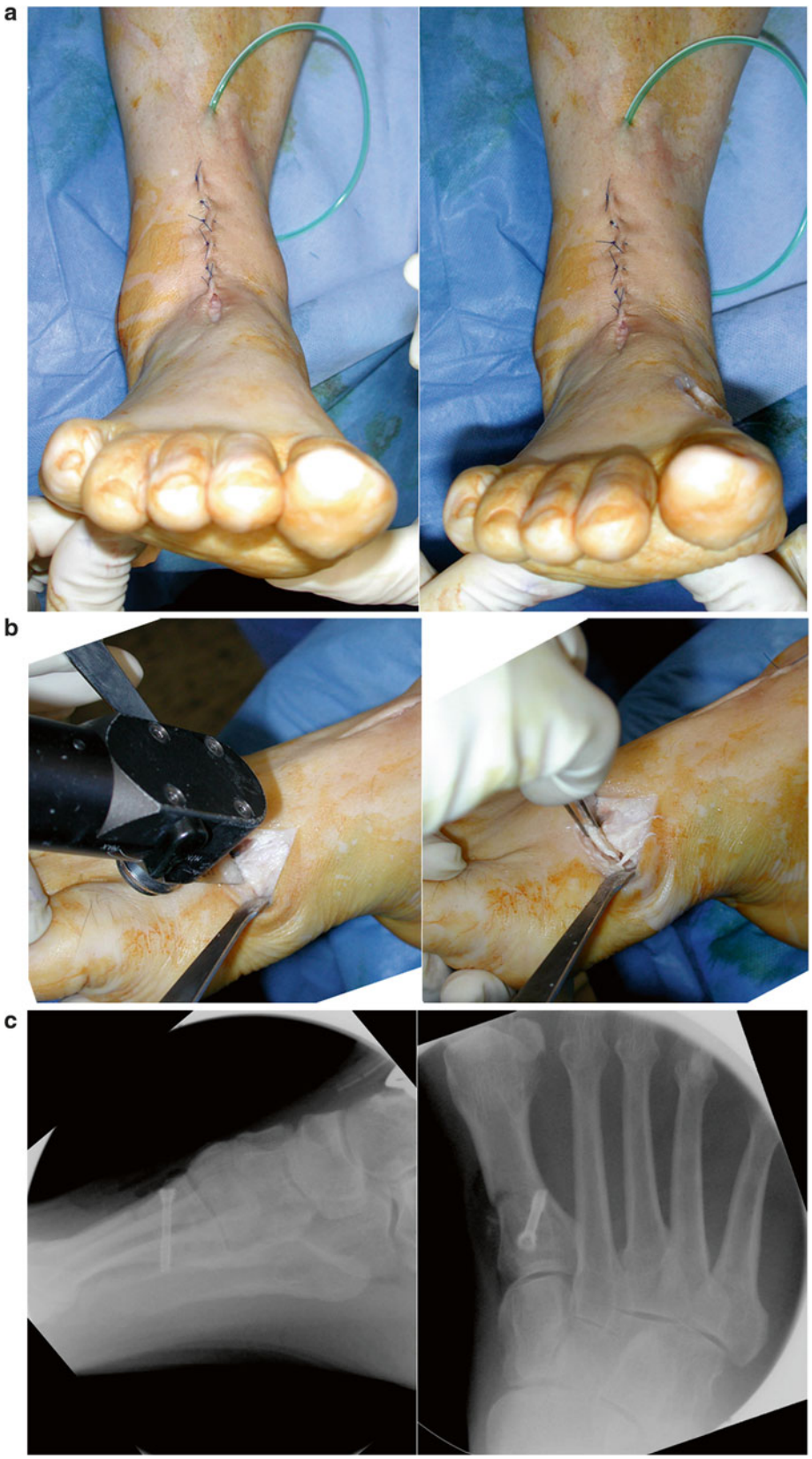

Fig. 22.8 After having finished the reconstruction of the ankle joint complex, the forefoot is meticulously assessed with regard to the remaining deformity. (**a**) While the foot is held in neutral position, the lateral forefoot is supported with one hand and the first metatarsal head with the other hand, showing a plantarflexed first ray in this patient (same patient as Fig. 22.7): 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

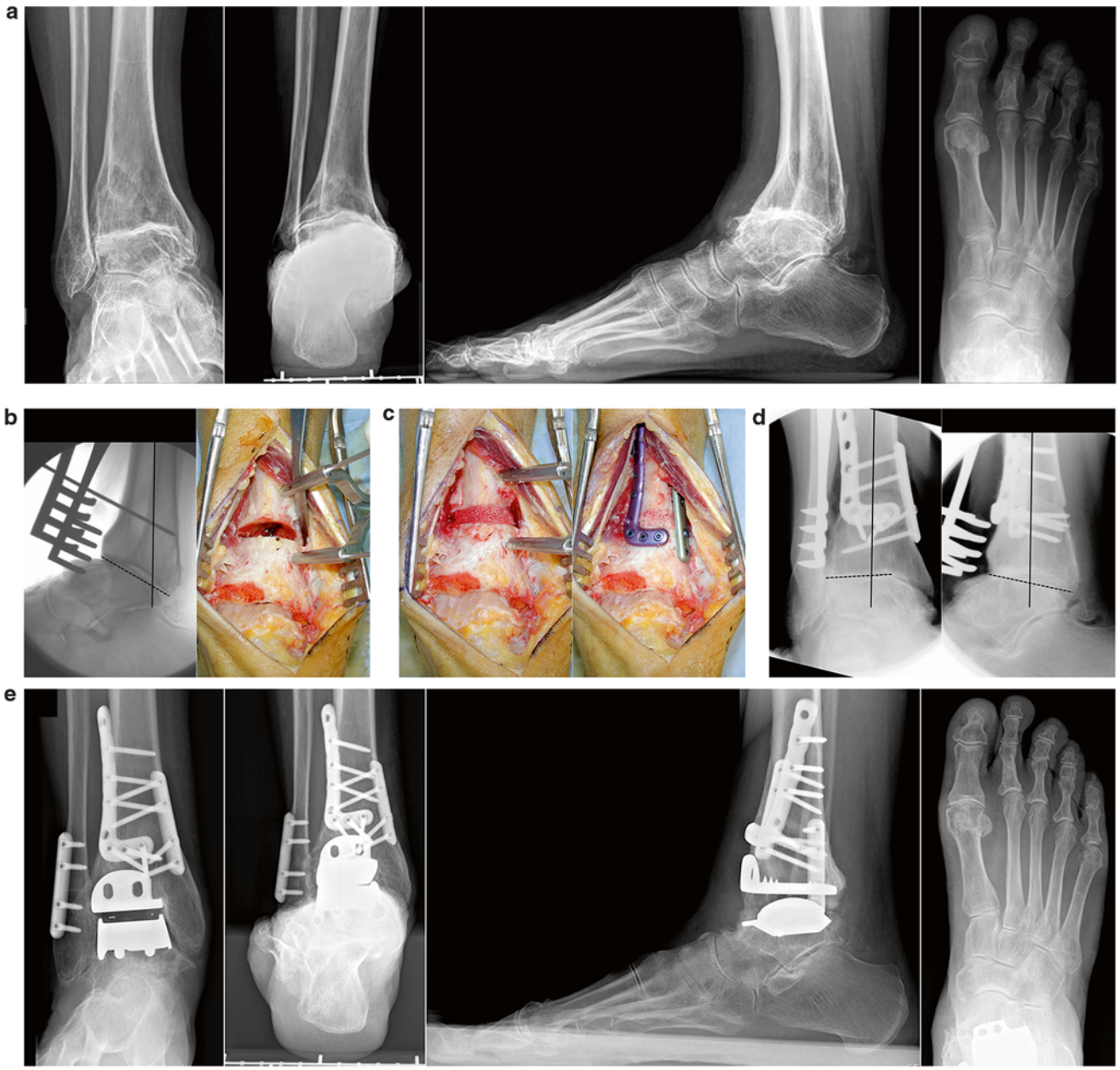

Fig. 22.9 A 60-year-old female patient with end-stage ankle osteoarthritis subsequent to a pilon tibial fracture 26 years earlier. (**a**) AP view, Saltzman view, and lateral view of the ankle as well as a foot AP. Radiographic assessment reveals a triplane deformity, e.g., a varus deformity combined 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 plane. 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

subsequent total ankle replacement (Fig. 22.9c, 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. 22.9d).

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. 22.9d). 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. 22.4). 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. 22.6). 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. 22.4).

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 it 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. 22.7) [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. 22.8).

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. 22.10a–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. 22.11a–c).

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. 22.12a, 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.

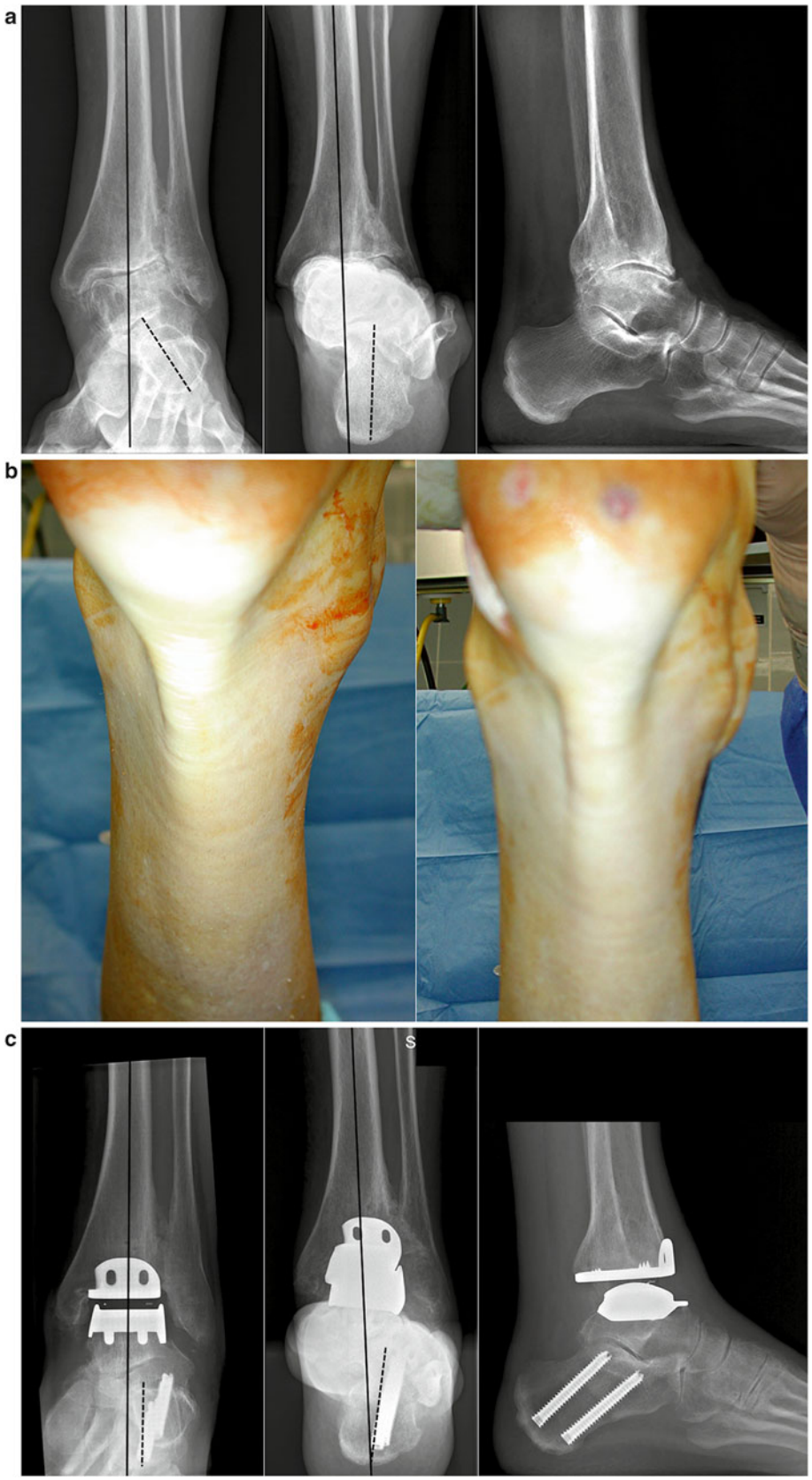

Fig. 22.10 A 62-year-old female patient with posttraumatic ankle osteoarthritis subsequent to an external-pronation fracture 3.5 years earlier and a progressive valgus deformity. (**a**) AP view, Saltzman view, and lateral view of the ankle. Preoperative radiographic assessment reveals a severe valgus 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

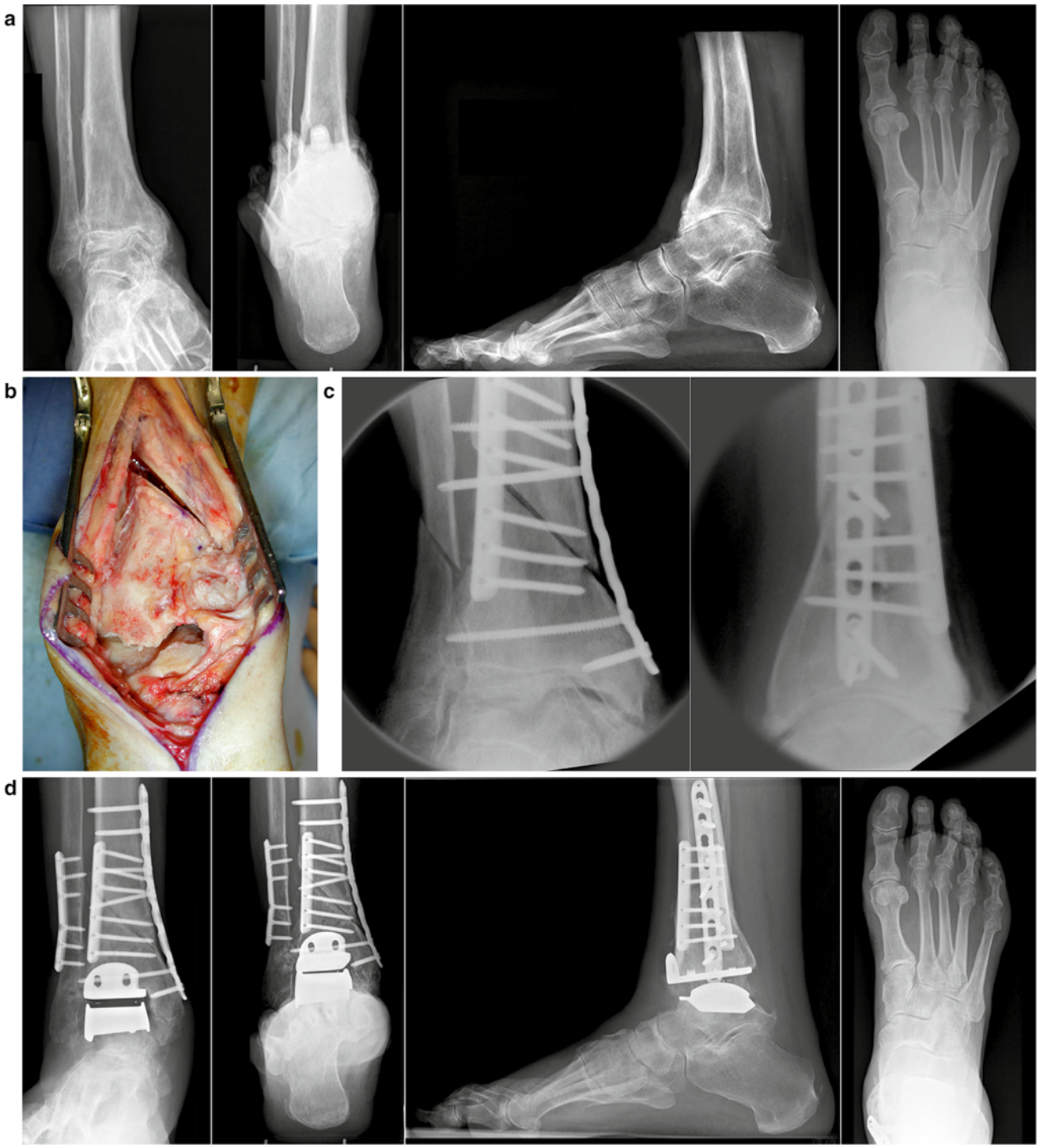

Fig. 22.11 A 68-year-old male patient with posttraumatic ankle osteoarthritis subsequent to an oblique fracture 37 years earlier that was treated conservatively. (**a**) AP view, Saltzman view, and lateral view of the ankle as well as a foot AP. Preoperative radiographic assessment reveals a combined 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

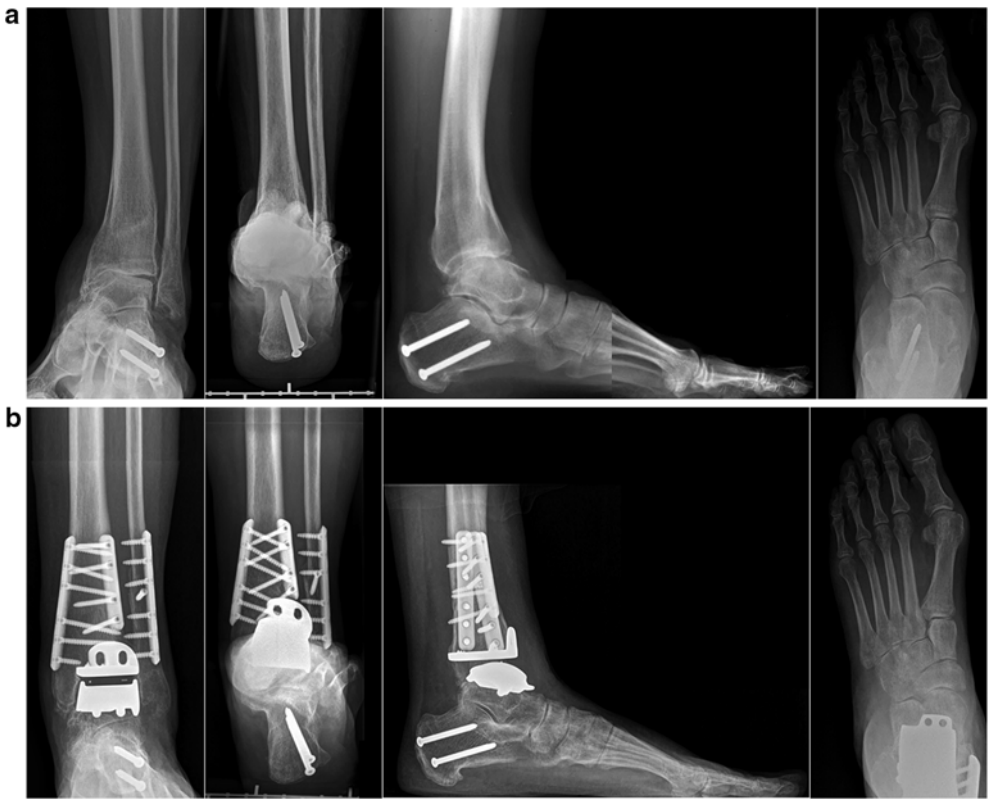

Fig. 22.12 A 64-year-old female patient with posttraumatic ankle osteoarthritis, subsequent to an oblique fracture of the distal tibia, 28 years earlier that was treated conservatively. She was treated elsewhere with a lateralizing osteotomy of the calcaneus that resulted in increased pain at the medial 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

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 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.

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

Failure and Success of Current Total Ankle Replacements Used in the United States

23

Frederick F. Buechel and Michael J. Pappas

Introduction

Although there is much recent interest in total ankle replacement for the treatment of severe ankle degenerative pathology, ankle arthrodesis remains the current "Gold Standard" for such treatment. Still, it seems clear that a well-functioning, reliable and durable total ankle replacement is preferable to arthrodesis due to improved function, if for no other reason.

Unfortunately, most total ankle replacement prostheses have been unsatisfactory [1–6] and thus, ankle arthrodesis remains the procedure of choice for most foot and ankle surgeons. There are, however, problems with ankle arthrodesis [7–9] and, thus, there has been considerable effort attempting to develop and market a satisfactory total ankle replacement. Currently there are several total ankle replacement devices generally available and in use in the USA. Most of these are two-part devices with one a tibial component with a polyethylene bearing affixed to it and the other a talar component. The Food and Drug Administration (FDA) cleared these devices under a flawed "grandfather" rule (510 k) as being substantially equivalent to devices available before July 1976. It should be noted that the devices on which the FDA determined, in 1982, the classification of allowable devices [10] were all failures and where withdrawn from the market [11]. The currently available two part devices cleared by the FDA were found to be "substantially equivalent" to those failed devices. Three-part devices, where the polyethylene bearing is mobile with respect to the tibial and talar components have, on the other hand, been more successful. One such device is available in the USA, the Scandinavian Total Ankle Replacement (Stryker, Mahwah, NJ) that has been approved for general use by the FDA after an extensive non-inferiority clinical trial comparing it with ankle arthrodesis and ongoing monitoring of these enrolled patients [12]. Unfortunately, this clinical trial is relatively short-term. Fortunately, medium-term and long-term data suggest that this and other three-part devices from European trials have shown very promising results [13–17].

Evaluation Methodology

The evaluation of an orthopaedic implant and, thus, its risks requires knowledge of the motion and stability of the joint involved, the forces on the joint, and the modes of failure possible for the device. In addition one needs to know the device characteristics and its clinical performance.

Motion and Stability of the Ankle Joint

Ankle movement is a complex three-dimensional motion [18], with infinity of instant axes of tibiotalar rotation, as is the case in all condylar joints. Fortunately, for purposes of analysis and design the complex motion degrees can be approximated by a planar plantar–dorsiflexion [19], axial (internal–external) rotation, and inversion–eversion [19].

The five degrees of freedom associated with the tibiotalar joint are illustrated in Fig. 23.1.

The normal plantar–dorsiflexion range in level walking is typically between 25° and 35°. If limited, it adversely affects ankle function and can produce undesirable loading on the total ankle prosthesis, ligaments, and bone fixation interfaces.

Normal axial rotation is between +5° and −3° during walking. Other activities can produce a maximum rotation of about 16° [20–22]. Any restriction of this motion is also undesirable as it produces undesirable torque on the total ankle prosthesis and bone fixation interface.

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_23

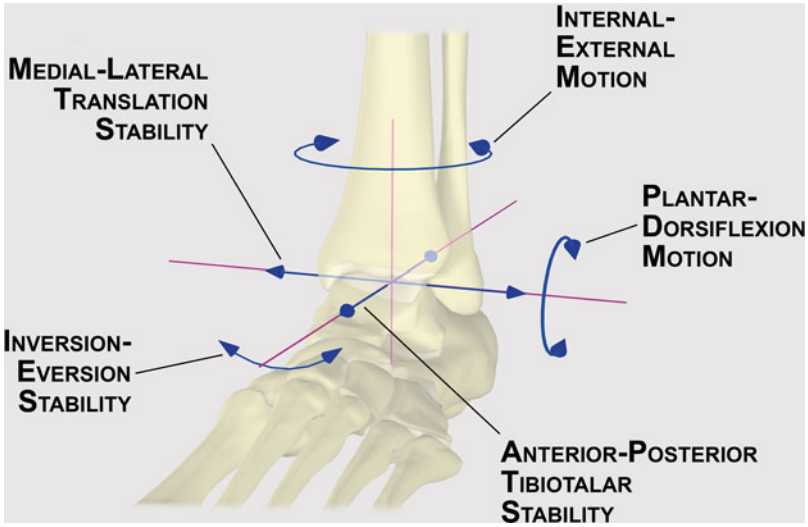

Fig. 23.1 Degrees of freedom of ankle motion and modes of ankle stability

The tibiotalar joint is stable and, thus, is constrained against significant anterior–posterior, medial–lateral and inversion–eversion motion. There are two types of stability: intrinsic stability provided by the shape of the articulating surfaces and extrinsic stability provided by soft tissues.

Normal inversion–eversion is between +10° and −2° during walking although most of this motion is in the subtalar joint [20–22]. Inversion–eversion stability is provided by the tibiotalar ligaments and the width of the tibiotalar articulating surface.

Anterior–posterior stability is primarily extrinsic and is provided by the ankle ligaments. Some intrinsic stability is also present.

Medial–lateral stability is almost entirely intrinsic and is provided by the ankle mortise. There is, however, about 2 mm of medial–lateral motion in the normal ankle [20, 21].

Forces

Tibiotalar compressive forces have been estimated to exceed four times body weight during normal walking. The posterior shearing forces are about 80 % of body weight [20].

The joint compression force is carried primarily by the tibiotalar articulating surfaces and partially by the talofibular joint. The anterior–posterior shearing force is carried by these surfaces and the ligaments. The medial–lateral shearing forces are carried by the malleolar articulation and inversion–eversion torques by the articulating surfaces and ligaments. The combination of the axial compression and shearing forces produces a peak resultant force vector on the tibiotalar joint which is posteriorly inclined relative to the tibial axis as is the tibial articulation surface.

Failure Modes

The safety and reliability of orthopaedic implant systems is of obvious critical importance. Thus, it is essential to understand the modes and processes of failure and degradation of the elements of such systems and to determine the cause of failure when it occurs.

A thorough understanding of mechanical failure involves an understanding of the field of stress analysis [23] and corrosion and wear [24]. A thorough understanding of stress analysis involves an understanding of material properties and the "Theory of Elasticity" [25]. Modern techniques for predicting the behavior of materials under loading allow reasonable prediction of such behavior if used in light of knowledge of material properties and elasticity theory.

An understanding of the risks of biological failure is also essential. Such failure may occur in the absence of any damage to the implants by the release of toxic material from an implant by leaching or corrosion [26]. Biological failure, however, is often associated with mechanical problems such as loosening due to bone necrosis resulting from wear or mechanical subluxation due to component subsidence.

Finally complications can result from the surgical intervention. It is important, therefore, to understand such complications and methods to avoid them.

Stress Analysis

Stress analysis involves the prediction of stress and strain in a body under loading or thermal effects. Only the effects of loading will be discussed here.

Finite element analysis (FEA) was first introduced in 1943 by Courant using the Ritz numerical method and variational calculus to develop approximate solutions to a class of vibration problems, which in 1956, Turner et al. [27] expanded to include the deflection of complex structures. Work over the last half century has greatly expanded the application of FEA and greatly simplified its use. Linear FEA stress analysis of mechanical parts is now an integral part of most high-end computer aided design (CAD) software packages. FEA may be used to analyze a mechanical part by creating a digital three-dimensional solid, computer model of the part and then defining a mesh used to approximate the behavior of the part under the expected loading conditions.

To perform the analysis an appropriate mesh is first generated with regions of expected high stress and stress concentration using a greater node density. Rigid body or elastic constraints are placed on the motion of those nodes where the part is attached to simulate its attachment boundary conditions and forces are placed on appropriate nodes to simulate the expected loading.

A set of simultaneous differential equations is then formulated and solved computing the approximate stress, and if desired strain, or deformation, at each node. The results are then presented usually in graphical form to allow easy location of the largest stress and their values. This methodology is in common use by orthopaedic implant designers.

Mechanical Testing

The approximations used in analysis during design verification often make mechanical and clinical testing a requirement of validation studies. Mechanical test methodology is well defined by a number of "American Society for Testing Materials" (ASTM) testing protocols developed by industry and the society. Thus, it is usual to use these methods during the mechanical testing phases of verification and validation. Often mechanical testing using these methods is required by regulatory authorities before approval of a device for general orthopaedic use.

As the result of the sophisticated FEA stress analysis methods used and the development and use of standardized testing procedures a high degree of reliability against fracture of the nonplastic components can usually be assumed.

Wear

The most serious mechanical complication is wear rather than fracture or deformation of the metallic elements of a device. An example of serious wear may be seen in Fig. 23.2 that shows the effects of various wear modes.

Polyethylene wear has received much attention due to catastrophic problems with metal-backed patellar [28, 29] and tibial prostheses [30, 31]. Such wear has been recognized by scientific investigators and clinicians as a major problem for some time [32–37]. Wear related problems involve wear-through, break-up, and the physiological effects of wear debris [38, 39].

To better understand the wear phenomena and what can be done to reduce wear, and its undesirable effects, one needs to examine abrasive, adhesive, three body, and fatigue related wear; contact pressures and stresses; and the relationship between design and wear.

Abrasive wear results from direct contact between the metal and plastic components. Even polished surfaces are microscopically rough. If the metal is allowed direct contact with the plastic peaks (asperities) on the metal surface it will slowly gouge (abrade) away the plastic as the metal surface moves over the plastic surface, much as very fine sandpaper abrades away a wooden surface. The rate of abrasion is a function of the smoothness of the metal surface, the rate declining as the height of the asperities decline (the metal becomes smoother) [40].

Human joint motion is characterized by a predominance of boundary and the more destructive dry lubrication. Boundary lubrication is improved, and the period of dry lubrication is reduced, if the wettability of the surfaces is increased.

Adhesive wear results from localized welding and tearing, rather than gouging, of the contacting surfaces. When opposing asperities contact each other the greatly localized nature of the contact produces such high stresses that the two materials in contact will become welded or adherent. Translation of one with respect to the other will then produce tearing or rupture of one or both of the asperities

The wear rate under adhesive conditions is much higher than that associated with smooth surface abrasive wear. Such wear can apparently be minimized with ceramic ultra-high molecular weight polyethylene (UHMWPE) articulations [41].

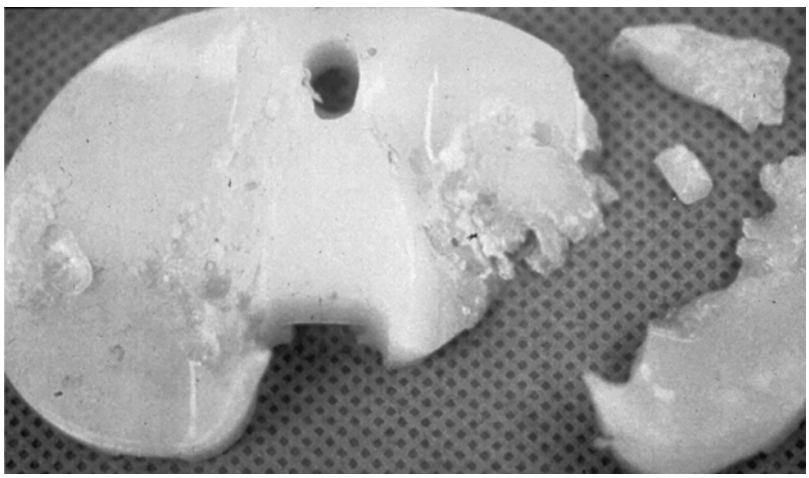

Fig. 23.2 Wear failure of a knee replacement bearing

The presence of contaminants such as polymethylmethacrylate cement, bone debris, and loose metallic beads, as well as the wear debris of the articulating couple, also contributes to wear. This contribution is called "three-body wear."

Typically the harder bodies become embedded in the soft bearing. These bodies then can rapidly abrade the metal surface increasing abrasive and adhesive wear. The much harder ceramic surfaces are more resistant to the effects of such contaminants.

Surface Fatigue

The dominant wear (perhaps better called "fatigue failure") mode in total knee replacements is fatigue related due to breakup under excessive fluctuating stress. Incongruent bodies in contact under load will deform and produce an area of contact, or a contact patch. The highest damaging, or Von-Mises, stress will be about 1 mm below the surface of the UHMWPE near the center of the patch as illustrated in Fig. 23.3.

As the metal component slides and rolls over the surface of the weaker plastic surface the point of peak stress will move under the surfaces of the plastic. If the stress is high enough cracks will initiate below the surface. The cracks may then coalesce to produce pitting, delamination, and by propagation through the part, catastrophic failure as illustrated in Fig. 23.4. This is a classic mode of surface failure in rolling contact [42]. Such catastrophic wear is seen in Fig. 23.2.

Contact Stress

Ordinary FEA boundary conditions cannot be used to compute incongruent contact stresses since the deformation patch is not known and thus one does not know where to apply node forces or what these forces are. Specialized software is needed which can handle incongruent contact. Such software, although generally available, is expensive and is not part of generalized mechanical CAD packages. Fortunately, equations, sufficient for use in incongruent knee prostheses, for the computation of the contact stress of two bodies in contact were developed in the 1930s using elasticity methods [42]. Computations can readily be carried out by a computational program. A study using a 2200 N load employing the above equations yielded the results shown in Fig. 23.5. It seems clear from the typically excessive stresses found in most ankle and knee designs that most designers are either unaware of such equations, or disregard their teaching. It may be seen that only the contact stresses in the "area" (mobile-bearing) type are within the recommended limit of 10 MPa [43, 44]. The other types (fixed-bearings) have stresses greatly exceeding acceptable limits, even approaching, or exceeding, the compressive yield stress of UHMWPE which is approximately 30 MPa [45]. Pappas et al. [45] found that the average wear of the fixed-bearing knees tested was six times greater than the mobile-bearing knee tested

Misconceptions

Several misconceptions are prevalent on the effects of congruency and incongruency. These are:

1. Incongruent surfaces become more congruent with use.
2. Mobile-bearings have greater wear since they have wear on two articulating surfaces.
3. If a UHMWPE bearing is at least 6-mm thick it is acceptable.
4. Mobile-bearing ankles are less intrinsically stable.
5. Extrusion of the bearing is a significant complication.

We consider all of these unrealistic and untrue [46]. With respect to items 4 and 5, at least with respect to the Buechel-Pappas Total Ankle Replacement (Endotec, South Orange, NJ) prosthesis, this device is more stable than most fixed-bearing devices and bearing extrusion is rare and was always the secondary result of talar component subsidence.

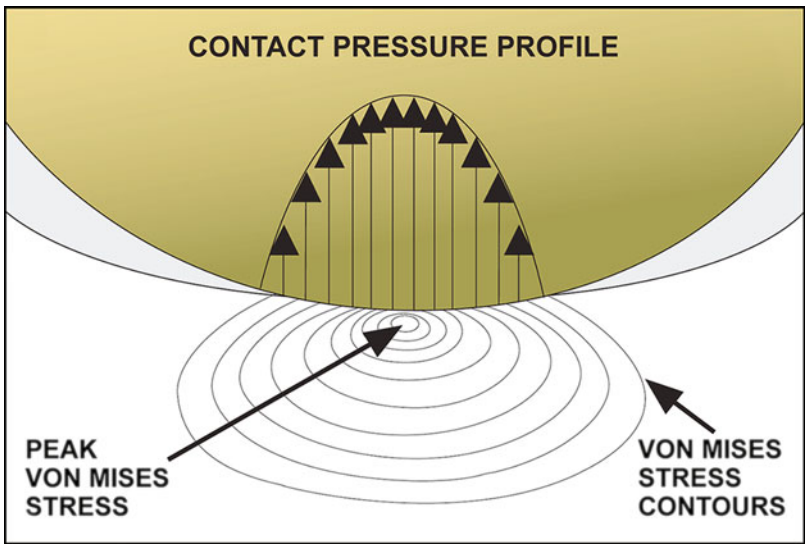

Fig. 23.3 Stress contours for incongruent contact

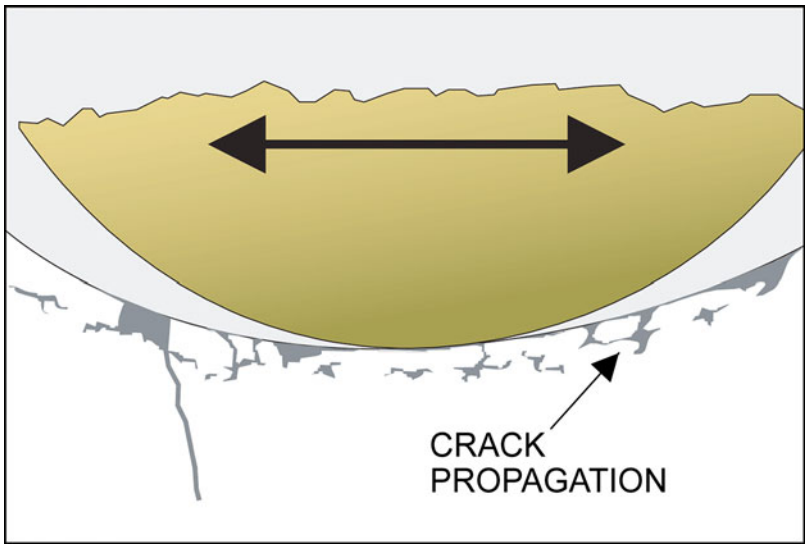

Fig. 23.4 Crack formation and propagation

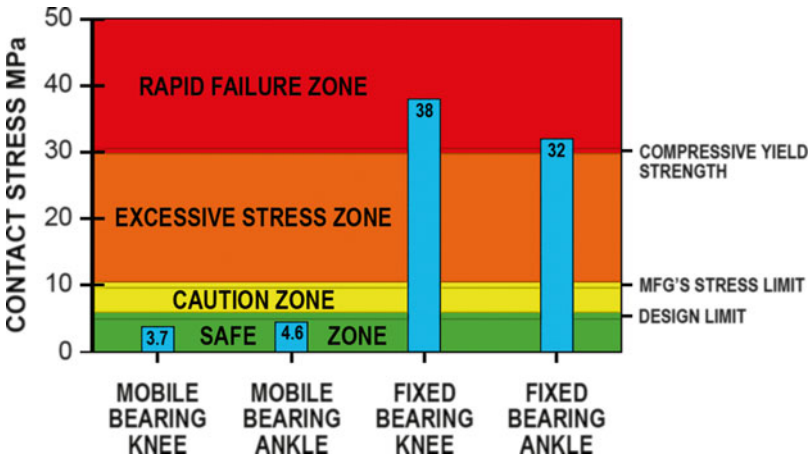

Fig. 23.5 Contact stresses in the B-P ankle and knee and typical fixed-bearing devices

Other Wear Related Design Considerations

It is a simple matter to produce a fully congruent design. Congruency, by itself however, is not sufficient. This is evidenced by the early Geomedic-Geometric designs that fail to provide adequate provision for axial rotation [47]. Mobility is needed along with congruity.

Inversion of the ankle occurs during the swing phase of the walking cycle, and during other normal activities. Although loads during the swing phase are relatively low they are still significant. To minimize wear the articulating surfaces must accommodate inversion–eversion.

Biological Failure

Just as mechanical failure leads to poor function, biological failure of an artificial joint replacement can lead to significantly worse complications or even death. The most commonly encountered biological failure modes are infection, aseptic osteolysis, progressive osteoporosis, avascular necrosis, peri-prosthetic fracture, and tumor formation.

Septic joint replacements occur in 1–2 % of cases overall [48]. The gram positive organisms of *Staphylococcus aureus* and *Staphylococcus epidermidis* are most common and generally thought to occur at the time of initial surgery or shortly afterwards if the skin incision fails to heal in a timely fashion.

Small (submicron) polyethylene or metallic wear particles initiate an inflammatory process, whereby macrophages and giant cells phagocytose the particles and attempt to digest them with lyzozymes and proteolytic enzymes. Unfortunately, the wear particles persist in the cytoplasm of these cells and continue to stimulate digestive enzyme production, which spills over into the surrounding bone and begins to digest this host bone. Once enough bone is lost in this osteolytic process, a cystic cavity filled with these macrophages and giant cells replaces the normal bone and begins to expand if the threshold for particle volume is exceeded.

If the osteolytic cysts become too large, then fixation failure of the implant can occur, requiring revision, curettage, and bone grafting of these defects to regain stability and function.

Disuse atrophy of the bone, also known as progressive osteoporosis, occurs when the patient fails to load the bone sufficiently to maintain its strength and integrity. Regardless of the reason, such as a cerebral vascular accident for example, the host bone atrophies around the joint replacement and the device may loosen or the surrounding bone may fracture due to its weakened condition.

Vascular compromise to supporting bone causes bone cell death, known as avascular necrosis or osteonecrosis. If the region of bone is in the talus, an ankle replacement will fail due to collapse of the talar component into avascular bone [49].

Such necrosis can be reduced by minimizing the interruption of the blood supply in the talus, as is commonly done by the resection of the talus in fitting the talar component.

Although there is a mechanical component to fractures surrounding joint replacement implants, it is a failure of the bone that creates instability and can even be life-threatening if sufficient fat emboli compromise cardiovascular function.

Pseudotumors or malignant tumors can compromise a well-functioning joint arthroplasty. Pseudotumors generally form from wear debris particles that accumulate [50]. Malignant tumors are rarely associated with joint replacement, but have been reported to erode the bony fixation of implants, making them essentially non-reconstructable.

Fixation

Component subsidence, particularly of the talar component, is a major complication of total ankle replacement. The surgical influence of talar preparation has recently been quantified by Tennent et al. [51]. Thus, a properly designed device should require minimum bone removal since the bone with the greatest load bearing capacity is adjacent to the articulating surfaces and minimal resection results in minimal disruption of the blood supply to the load bearing regions. It would appear that a talar onlay component that does not resect the medial or lateral malleolar surfaces or interfere with the artery of the tarsal canal would be ideal.

Clinical Results

The considerations given above are useful in evaluating total ankle replacement devices but the best evidence of prosthesis longevity and function is their clinical performance. Buechel et al. [52] formulated the simple, necessary, but not sufficient, conditions for orthopaedic implant acceptability. These are:

1. There is reliable clinical evidence of 90 % survivorship at 10 years.
2. The peak articulating surface contact stresses must be below 10 MPa during normal walking.

In addition one needs to analyze the surgical procedure and instruments used to attempt to reduce the incidence of surgically introduced complications.

Ankle Arthrodesis

Due to the historically generally poor performance of total ankle replacement ankle arthrodesis remains the procedure of choice for most foot and ankle surgeons for ankle reconstruction. There seems, however, to be little literature on the long-term outcome of such a procedure. The data of Coester et al. [9] is unreliable, except to show a major loss of functionality in the arthrodesis joint due to the high lost to follow-up rate of 64 % (range: 41 % of 64 %). Buchner and Sabo [53] in their average 9-year study of 48 patients found substantial pain relief, but a significant number (21 %) of patients still had severe to moderate pain after ankle arthrodesis. Further, their study found a failure rate defined as the need for reoperation of 19 %.

These clinical studies clearly demonstrate that ankle arthrodesis is much less successful than total hip or knee replacement where a 90 % success rate can reasonably be expected with appropriate designs.

First Generation Fixed-Bearing Total Ankle Replacements

Clinical Outcomes

On Friday, July 2, 1982, in the Federal Register, Vol. 47, No. 128, the FDA published the proposed Rules for 888.3110; Docket No. 78 N-3060; Ankle joint metal/polymer semi-constrained prosthesis [10]. The Orthopaedic Device Classification Panel's recommendations found that there was sufficient scientific evidence to support a Class II designation. (See Sect. XI. Regulatory History: *Regulatory History of the ankle joint metal/polymer non-constrained prosthesis*.) The Panel based its recommendation on four oral presentations based upon four semi-constrained ankles presented by their developers.

The FDA agreed with the panel's recommendations and sought additional data and information on the safety and effectiveness of these devices. The FDA cited the following studies on three additional devices. These are those of Stauffer [54], Scholz [55], and Waugh [56].

The decisions of the panel and the FDA to designate semi-constrained ankles as class II were founded on these relatively short-term encouraging results of early ankle designs based on presentations and publications of the developers of these ankles. Such a designation, particularly in light of what is known today, is unreasonable since these references and presentations cannot be considered reasonable proof of

Table 23.1 Long-term results of typical early fixed-bearing ankle replacement [11]

Authors	Device*	Number of cases	Diagnosis (number)	Average follow-up (years)	Survival rate (%)
Jensen and Kroner [1]	TPR	148	RA (21), OA (2), RA (125)	4.9	48
Kitaoka et al. [3]	Mayo	79	SA (65), OA (14)	5, 10, 15	79, 65, 61
Kitaoka and Patzer [2]	Mayo	168	RA (96), SA (64), OA (8)	9	64
Wynn and Wilde [4]	Beck-Steffee	30	RA (18), SA (12)	2, 5, 10	73, 40, 10
Helm and Stevens [5]	ICLH	19	RA (19)	4.5	83
Bolton-Maggs et al. [6]	ICLH	62	RA (34), OA (13), SA (15)	5.5	47
Unger et al. [57]	Mayo	23	RA (23)	5.6	65
Takakura et al. [58]	Takakura Cemented	33	OA (20), RA (11), SA (2)	8.8 (metal), 6.7 (ceramic)	15
Kofoed [59]	Cylindrical 2-piece Cemented	28	RA (13), OA (1)	12	70

device safety and efficacy. Longer-term studies, furthermore, clearly demonstrate that these ankle prostheses were failures. The performance of such total ankle replacement systems is illustrated in Table 23.1.

None of the total ankle replacements considered by the FDA in their ankle classification were successful and all have been abandoned.

Analysis

Early ankle replacement failures were primarily the result of excessive constraint, abetted by excessive contact stresses, and excessive bone removal resulting in component loosening and subsidence.

Neufeld and Lee [60] state, "After early successes, the longer-term results bred failure." Lachiewicz et al. [61] presented data on 15 patients, with one of the most widely used prostheses, the Mayo ankle, with a mean follow-up of 3.3 years and excellent results. When Unger and coworkers [57] reported on the same 15 patients with a longer follow-up of 6.2 years, deterioration in their clinical scores and radiographs was apparent.

Neufeld and Lee also state "Several reasons for the long-term failure of the early prostheses have been suggested. First, many original designs required excessive bone resections and relied on cement fixation onto soft cancellous bone. Constrained prostheses placed excessive stress on the cement-cancellous bone interface. Subsequently the main reason for their failure was aseptic loosening. Unconstrained prostheses failed due to malleolar and soft-tissue impingement. Therefore, the failure of early designs may have been caused by the lack of respect for the anatomy, kinematics, alignment and stability of the ankle joint." Furthermore they state, "They (early constrained total ankle replacement designs) have failed to incorporate the biomechanical characteristics of the ankle joint. The design of the implant should permit effective transfer of joint loads, be inherently stable, allow ease of surgical implantation/removal with minimum bone loss, and have resistance to wear, creep, fatigue failure and compressive shear loading."

Therefore, despite encouraging early results, long-term studies proved that these total ankle replacement prostheses were not viable and were subsequently abandoned by the orthopaedic community in favor of ankle arthrodesis.

First Generation Mobile-Bearing Total Ankle Replacements

From Tables 23.2 and 23.3 it may be seen that both the early LCS (B-P) and STAR ankle performance, although not equal to the acceptance standard for hips and knees, are superior in performance to ankle arthrodesis and therefore could be considered acceptable devices.

Analysis

STAR

Of the first generation mobile-bearing designs the STAR has the best clinical performance. Further, this device provides essentially normal gait [59]. This good performance is further evidenced by the approval of the Pre-Market Approval,

Table 23.2 Long-term results of the LCS and B-P ankles [11]

	Buechel [17]	Buechel [62]	Keblish [63]	Doets [14]	Doets [64]	San *Giovanni* [16] 9180 Giovanni [16]
Number of cases	40 (*38 patients*) patients	23	237	58	30 (*28 patients*) patients	21
M/F	Male = 20 Female = 20	Male = 12 Female = 11			Male = 2 Female = 26	
Age (mean)	55	56	57	55	56	–
Diagnosis	PTA = 21 (52.5 %) OA = 7 (17.5 %) RA = 9 (22 %) Arthrodesis = 3 (7.5 %)	PTA = 10 (43.5 %) OA = 4 (17.4 %) RA = 6 (26.1 %) AVN = 2 (8.7 %) arthrodesis = 1 (4.3 %)	PTA, OA, RA	RA, JCA, PA	RA = 25 (88 %) JCA = 1 (4 %) PA = 1 (4 %) OA = 1 (4 %)	RA
Follow-up	Mean 10 years (2–20 years)	Mean 35 months (24–64 months)	Mean 45 months (18–72 months)	Mean 6 years (2–13 years)	Mean 6 years (3–9 years)	Mean 5.5 years (3.3–9 years)
Delayed wound healing	9 (23 %)	4 (19 %)	2 (1 %)	0 (0 %)	3 (10 %)	–
Talar subsidence	6 (15 %)	0 (0 %)	3 (2 %)	0 (0 %)	0 (0 %)	2 (10 %)
Bearing *wear*	4 (10 %)	1 (5 %)	11 (5 %)	0 (0 %)	3 (10 %)	0 (0 %)
Severe bearing *wear*	4 (10 %)	0 (0 %)	17 (7 %)	2 (3 %)	0 (0 %)	1 (5 %)
Malleolar fracture	3 (8 %)	1 (5 %)	6 (11 %)	–	5 (17 %)	–
Infection	2 (5 %)	1 (5 %)	9 (4 %)	1 (2 %)	1 (3 %)	2 (10 %)
Reflex *sympatric dystrophy*	2 (5 %)	2 (10 %)	1 (1 %)	0 (0 %)	0 (0 %)	–
Varus/valgus deformity	–	–	–	6 (10 %)	–	–
Tibial loosening	0 (0 %)	0 (0 %)	6 (3 %)	3 (5 %)	1 (3 %)	1 (5 %)
Survivorship (percentage)	74.2 (Kaplan-Meier) Revision for any reason at 20 years	100 (Kaplan-Meier) Revision for any reason at 5 years	90.7 (Kaplan-Meier) Revision for any reason at 6 years	–	–	–
Average overall clinical score (percentage)	70 (NJOHAEF)	83.7 (NJOHAEF)	81.5 (NJOHAEF)	74 (NJOHAEF)	84 (NJOHAEF)	87 (AOFAS)

based on a non-inferiority clinical trial comparing it with ankle arthrodesis, by the FDA allowing, for the first time, the sale of a mobile-bearing total ankle replacement in the USA [68]. However, the primary fault of the STAR is that it loses congruity in the event of inversion or eversion. Therefore, alignment and stability are mandatory, a concept shared by Queen et al. [69].

The B-P Mark I (LCS)

The LCS design, although performing well in the short-term, experienced degradation in performance with time. The most frequent cause of failure is related to talar subsidence. This subsidence was due to several causes. The long fin allowed distal fixation to occur leading the stress protection of the proximal talus. This contributed to atrophy and collapse of the talus leading to talar component subsidence and bearing extrusion and wear.

In examining the blood supply to the talus [70] it was concluded that the relatively long central fin might be disrupting blood supply excessively further contributing to talar necrosis and collapse. This and other evaluations lead to the development of the Mark III B-P ankle.

Total Ankle Replacement Systems Available in the USA

FDA "Cleared" Fixed-Bearing Devices

Devices, such as the INBONE I and INBONE II and INFINITY Total Ankle Replacements (Wright Medical Technology, Memphis, TN); Salto Talaris Anatomic Ankle Prosthesis and Salto Talaris XT Revision Ankle Prosthesis (Tornier, Inc., Bloomington, MN); and Agility and Agility LP Total Ankle Replacement systems (DePuy Synthes, Warsaw, IN) ankles have been "cleared" (not approved) for sale in the USA since they were found to be the substantial

Table 23.3 Long-term results of the Scandinavian (STAR) Ankle [11]

Study	Valderrabano [13]	Schernburg [65]	Kofoed [66]	Kofoed [67]
Device	STAR Mobile-Bearing TAR	STAR Mobile-Bearing TAR	STAR Mobile-Bearing TAR	STAR Mobile-Bearing TAR
Number of cases	68 (65 Patients)	131	Cemented = 33	76
			Cementless = 25	
			Total 58	
M/F	Male = 31 (48 %)		Male Cemented = 14	Male = 35 (46 %)
			Female Cemented = 19	
	Female =34 (52 %)		Male Cementless = 16	Female =41 (54 %)
			Female Cementless = 9	
Age (mean)	56	–	Cemented = 60	56
			Cementless = 58	
Diagnosis	PTA = 48 (71 %)	OA, RA	Cemented RA = 13	OA = 44 (58 %)
	RA = 11 (16 %)		Cemented OA = 20	RA = 22 (29 %)
	OA = 9 (13 %)		Cementless RA = 3	PA = 4 (6 %)
			Cementless OA = 22	AVN = 4 (6 %)
				Failed Arthrodesis = 1 (1 %)
Follow-up	Mean 3.7 years (2.4–6.2 years)	6 years	Cemented = 9.3 ± 2.7 years	10 years
			Cementless = 9.5 ± 1.7 years	
Delayed wound *healing*	–	–	–	–
Talar subsidence	1 (4 %)	–	–	–
Bearing *subluxation*	1 (4 %)	–	–	–
Severe bearing wear	3 (13 %)	–	Cementless 1 (2 %)	–
Malleolar fracture	0 (0 %)	–	–	–
Infection	0 (0 %)	–	–	–
Reflex sympathetic *dystrophy*	1 (6 %)	–	Cemented 1 (2 %)	–
Tibial component *loosening*	2 (9 %)	–	Cemented 6 (10 %)	–
			Cementless 1 (2 %)	
Survivorship (%)	87 (After component related revision) at 6 years	87.3 (Kofoed, 1986) at 6 years	70 Cemented 95 Cementless (Revision/Removal for any reason) at 9 years	86.7 (Kofoed, 1986) (Revision for any reason) at 10 years
Average Clinical Score Overall (Percentage)	85 (AOFAS)	85 (Kofoed, 1986)	Cemented = 74.2 ± 19.3 years	–
			Cementless = 91.9 ± 7.4 years	

equivalent of those devices used by the FDA to establish the classification for such clearance. Unfortunately, in the case of total ankle replacement prostheses, such a designation provides only a negative connotation since all of the devices used for this purpose were later found to be failures and were withdrawn from the market although most were satisfactory in the short-term. Thus, the fact that they can be sold does not imply that it is safe to do so, but since they are substantially equivalent to failed devices a more reasonable inference is that they are not safe. The comments of Neufield and Lee [60] apply to these devices as well as those used for the FDA classification. Further, all of these devices suffer from a serious, fundamental design defect, excessive contact stresses and/or constraints.

The INBONE I and II Total Ankle Replacement systems and Salto Talaris Anatomic Ankle Prosthesis and Salto Talaris XT Revision Ankle Prosthesis have little published clinical data and no long-term survivorship data. The data on the Agility Total Ankle Replacement System is extensive but generally negative [11]. Thus, none of these devices seem appropriate as an alternative to ankle arthrodesis since they are unproven devices of a failed type with serious design flaws.

The INBONE designs have several weaknesses in addition to the general defect of fixed-bearing devices, i.e., excessive constraint and/or contact pressures. These are:

1. Excessive bone resection. As seen in Fig. 23.6, the entire dome of the talus is resected, weakening it materially. Further, the large diameter talar component fixation peg substantially interferes with the talar blood supply.
2. The complex tibial stem is unnecessary [17, 62]. The INBONE stem increases cost, complicates implantation, and introduces the possibility of micromotion between the assembled elements and, thus, reactive metallic wear particles. The argument made [71] that ankles suffer from

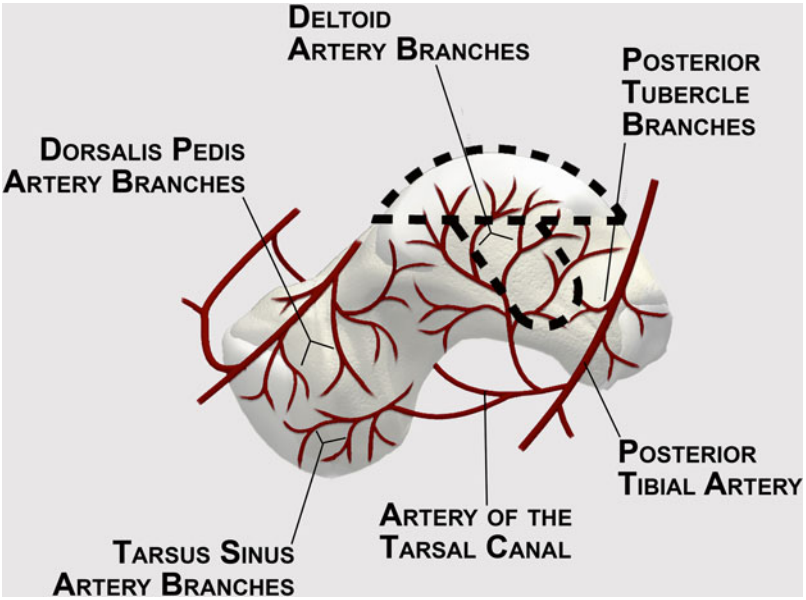

Fig. 23.6 Excessive talar resection and blood supply disruption

problems of tibial fixation due to lack of long stems and tibial windows [67] is not supported by any evidence and is, in any event, untrue in light of the successful use of windows and short stems by the B-P ankle. Talar fixation is the most significant complication, not tibial fixation [14, 64].

3. The argument that precision of implantation can overcome all the problems of over constraint and excessive contact stress is invalid.

A fixed-bearing variant of the successful European Salto mobile-bearing total ankle has been introduced in the USA and has shown to have early (2.8 years) success. Schweitzer et al. [72] indicate these devices are comparable to the STAR in the short-term (2-year follow-up). Queen et al. [73] show there is little functional differences between fixed-bearing and mobile-bearing devices in the short-term. Such success must, however, be cautiously evaluated over a 10-year period to have significance, since early results of fixed-bearings have been disappointing in the long-term. Here again one sees unnecessary resection and interruption of the talar blood supply, although not to the extent in the INBONE Total Ankle Replacement systems and, thus, talar collapse is to be expected in longer-term use.

The Agility Total Ankle Replacement is now nearly three decades old. Due to its poor performance [11] a series of modifications have been made to attempt to overcome various design defects. The latest iteration, the Agility LP Total Ankle Replacement, does seem to offer some improvement but the fundamental problems of excessive bone resection, over constraint and excessive contact stress remain. This design is so new and use of this prosthesis limited such that no useful clinical data on its performance is available and likely not forthcoming.

FDA "Approved" Mobile-Bearing Ankle Replacement

The only approved ankle device is the STAR that was finally approved in 2009 after a 2-year "non-inferiority" comparison study with ankle arthrodesis [74]. Saltzman et al. [68] give the results of this study of 158 patients from ten centers performing ankle replacement and 66 patients in five different centers performing fusion. In addition they report on the results of a 435 patient FDA monitored continued access study of the STAR prosthesis.

It seems clear from these studies, particularly the continued access study where improved instrumentation was used, that, at least in the short-term, STAR at least as good as if not superior to ankle arthrodesis. Coupled with the results of the STAR given in Table 23.3 which show superiority to ankle arthrodesis in the mid- and long-term the STAR seems preferable to ankle arthrodesis.

The Future

The STAR, although superior to ankle arthrodesis, does not approach the performance of well-designed hip, knee, or even other total ankle replacement prostheses. Fortunately, the evolution of the B-P ankle design has advanced to the point where a device comparable in performance to the hip and knee is possible [17, 75]. Although the clinical results of the

latest B-P ankle meet the acceptance criteria for hips and knees described in Sect. 2.7, an unexpected problem of cyst formation leading to talar and even tibial component subsidence has been observed [50, 76]. Although wear in the bearing is extremely low, even minor wear can produce such cysts.

A solution involving better polishing of the talar component and more wear resistant highly cross-linked UHMWPE is now under trial with initially promising results. Hopefully, total ankle replacements comparable to well-designed hip and knee replacements will become available in the near future in the USA.

Conclusions

FDA clearance of a total ankle replacement device does not imply safety since the FDA classification of class II for total ankle replacement finds that such ankles are "Substantially Equivalent" to the devices that have been found to be failures. All of the FDA-cleared fixed-bearing devices can, therefore, not be considered acceptable. All such devices available in the USA fail to satisfy reasonable design criteria since they all have serious design defects. Further, none has acceptable, published clinical long-term (>10 years) performance data. Thus, these designs should not be considered for clinical use.

Only the STAR, which has reasonable mid- and long-term results and FDA approval, seems preferable to ankle arthrodesis and acceptable for total ankle replacement. Still better devices are on the horizon.

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24 Revision of Aseptic Osteolysis With and Without Component Subsidence After Total Ankle Replacement

Norman Espinosa and Stephan Hermann Wirth

Introduction

During the last two decades total ankle replacement (TAR) has seen major improvement in terms of design and biomechanical behavior [1]. Current designs better replicate normal ankle joint range of motions. While the overall results, compared to TAR designs of the first and second generation, have improved, the longevity of current TAR still remains inferior or unknown when compared with contemporary hip and knee arthroplasties [2].

Advances in TAR prosthesis design have renewed interest in revision TAR as an alternative to ankle arthrodesis or below-knee amputation in the management of a failed TAR. In addition, increasing experience among foot and ankle surgeons and the availability of modern TAR prostheses has led to an increasing number of TAR implantations worldwide. However, this enthusiasm must be tempered to avoid the tendency of performing TAR with stretched indications (e.g., younger aged patients or severe deformities). As a result the risk of premature failure is potentially increased.

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. Recent scientific data showed that the results of salvage arthrodesis are inferior to those of primary ankle arthrodesis [3].

Exchange of TAR components require 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. 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 [5]. 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 [6, 7]. 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 [8]. 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) [9, 10]. In order to prevent premature wear of the UHMWPE insert it should have an optimal thickness and resistance to compressive and shearing forces [11]. Premature wear has been recognized as potential factor for TAR failure and depends on strength (ultrastructure), geometry, and alignment of TAR components [9, 11]. Currently, the optimal thickness of UHMWPE insert is unknown. The best UHMWPE insert should be thin, strong, and positioned at the original joint-line level. A “perfect” TAR replicates the ankle joint anatomically and biomechanically.

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_24

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 [12–15].

Contemporary TAR designs offer better anatomical and biomechanical behavior and emply biological integration of the metallic components into bone [16, 17]. 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 [18].

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 take 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 [8, 19–21].

Total Ankle Replacement Revision

Failure of TAR encompasses several factors including improper patient selection, prosthesis specific characteristics, surgical technique, and surgeon errors [22]. 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. 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, that 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 [23, 24].

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. 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 [25–27].

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 [28–30].

Surgical Management

Selection of treatment depends on whether the loose TAR can be salvaged or not. If this is the case, the authors utilize a TAR system that offers readily available revision components such as the Hintegra Ankle prosthesis (Newdeal, Lyon, France) or Salto Talaris XT Revision Ankle Prosthesis (Tornier, Inc., Bloomington, MN).

Hintermann and colleagues published an algorithm, which has been based on the size of osseous defect at either the tibial or talar side (Fig. 24.1) [23]. 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 [8].

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 author usually tries 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 laterally. The preparation is continued until the underlying tibia, talus, and implant surfaces are encountered.

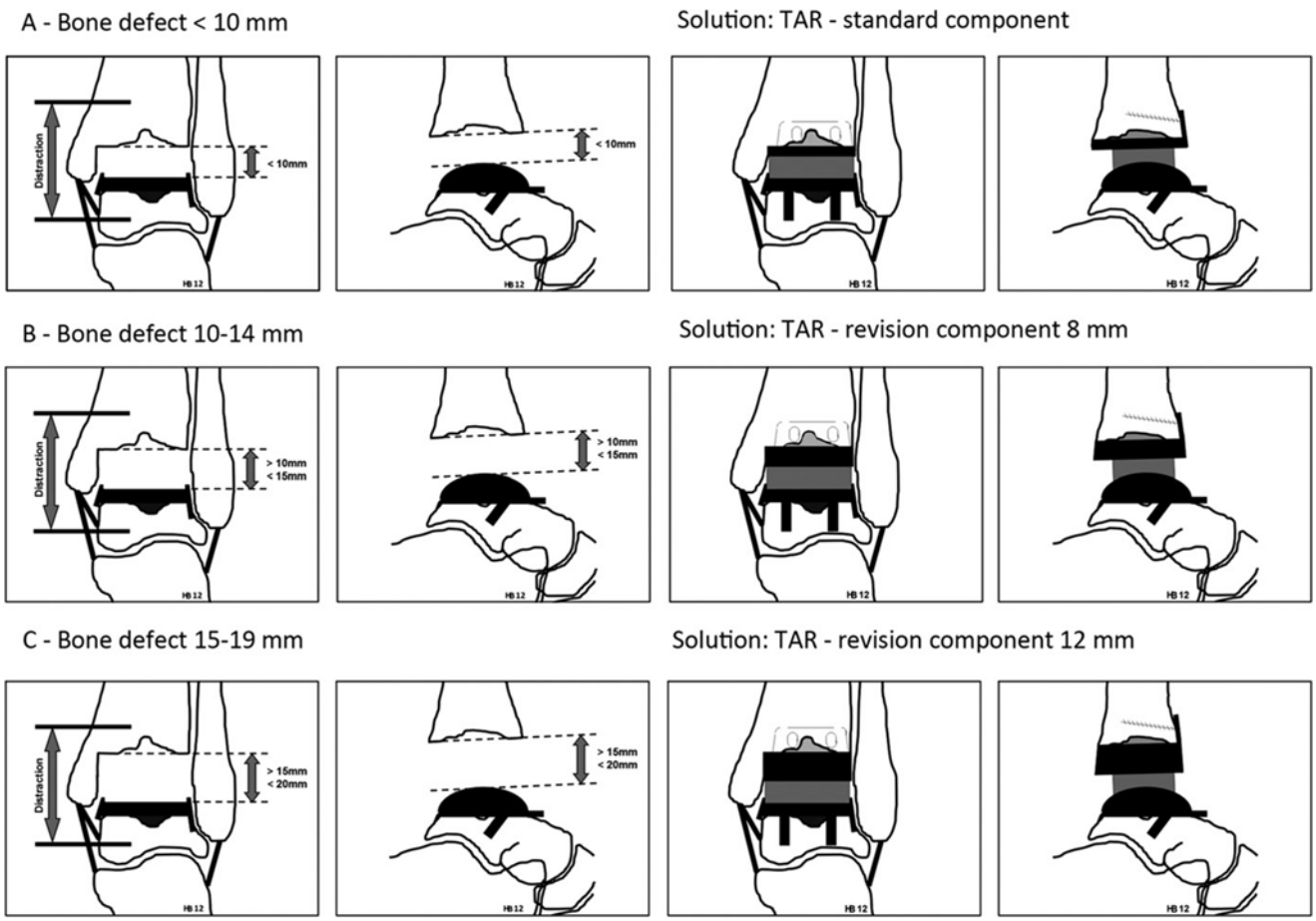

Fig. 24.1 Classification of tibial bone defects according to Hintermann et al. [23]. From Hintermann B, Zwicky L, Knupp M, Henninger HB, Barg A. HINTEGRA revision arthroplasty for failed total ankle prostheses. J Bone Joint Surg Am. 2013;95:1166-1174

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 [22]. 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 surfaces 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 (Fig. 27.1) [2, 18, 31]. In general, the authors try to achieve a flat and perfectly aligned surface in order to re-implant 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. 24.2) [32].

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 [23].

Absence of Tibial Component Subsidence

After removal of the implant the medial and lateral gutters of the ankle are débrided. 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. 24.3). 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. 24.4).

Cysts of different sizes can be filled with autograft that is harvested from the ipsilateral, proximal or distal tibia or iliac crest [37]. 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 débrided 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 [22]. 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 [33–35]. However, there is no meaningful evidence to guide the surgeon so far.

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.

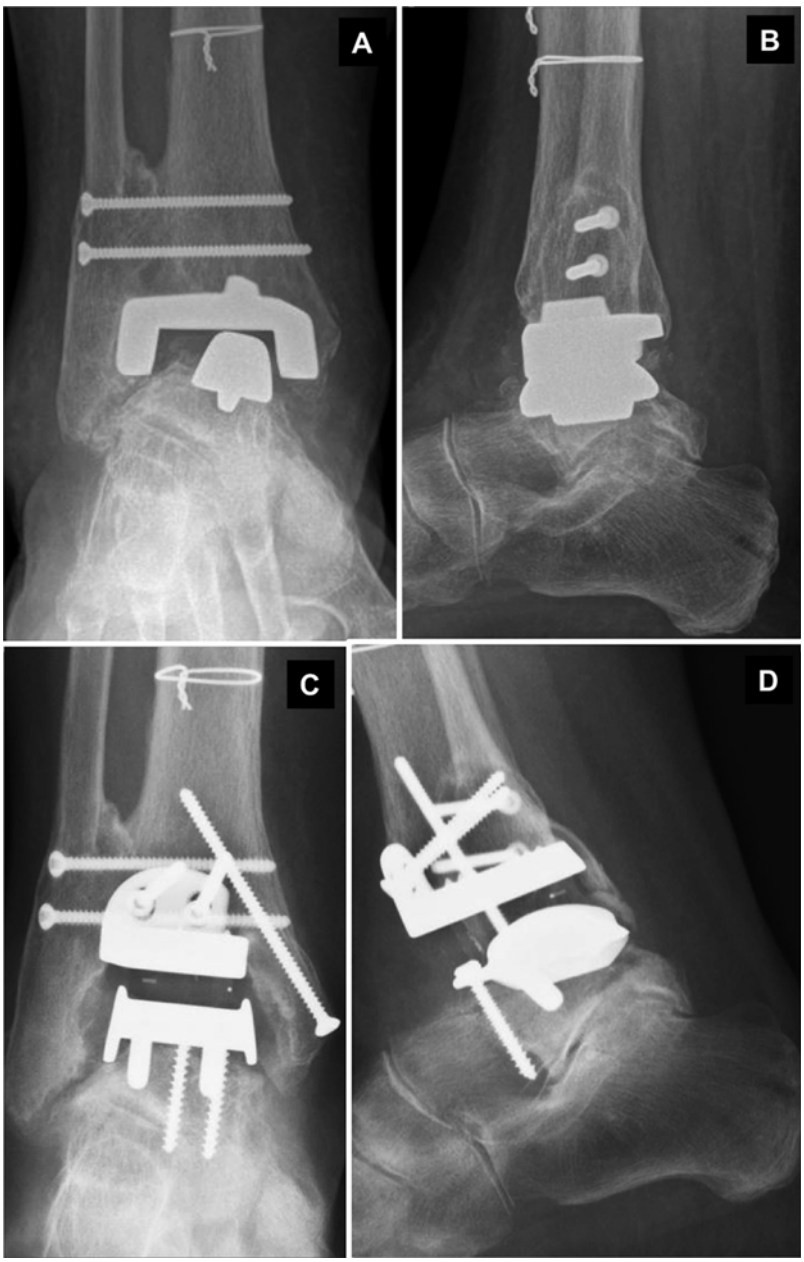

Fig. 24.2 Weightbearing anterior–posterior (**a**) and lateral (**b**) radiographs of an ankle in a 79-year-old female patient who received an Agility total ankle replacement 6 years prior due to symptomatic posttraumatic end-stage arthritis. She complained about severe pain in the hindfoot and functional deficit. The images demonstrate the thin medial malleolus, 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 were 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 to secure the graft onto the remnants of the talus

Malalignment can be corrected or improved using the TAR specific cutting jigs (Fig. 24.4). 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 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

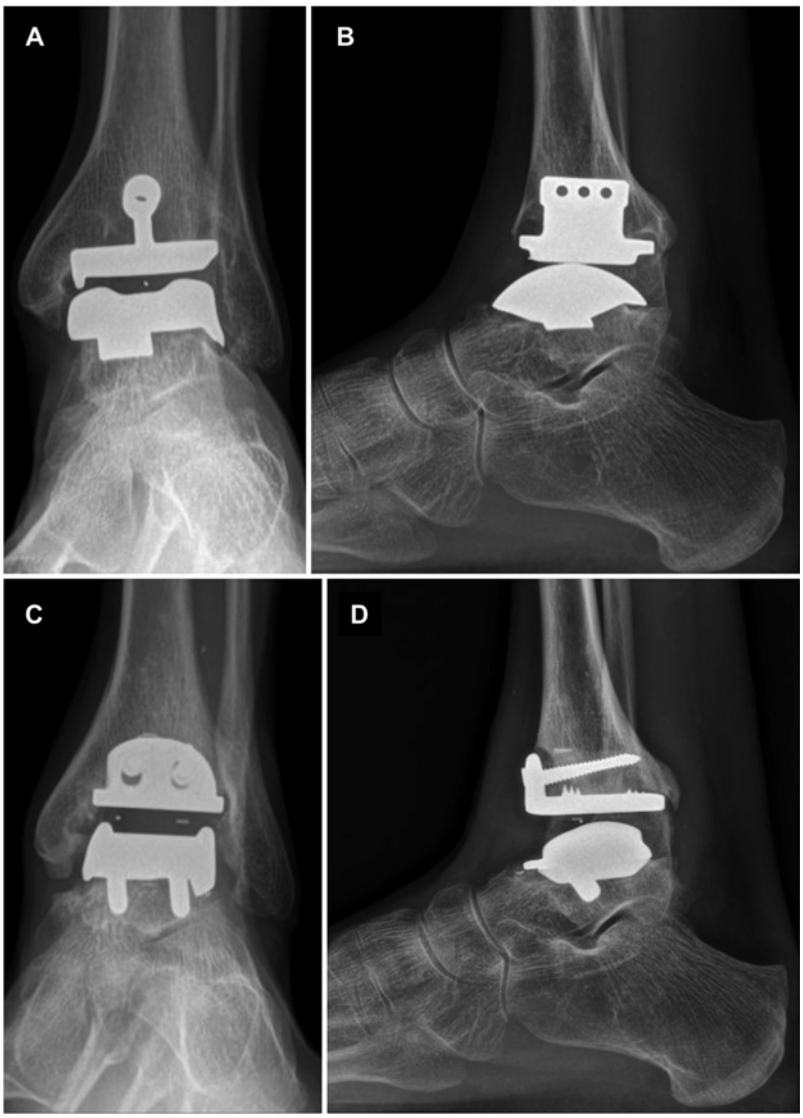

Fig. 24.3 Weightbearing anterior–posterior (**a**) and lateral (**b**) ankle radiographs in a patient who underwent a Salto Mobile Ankle Prosthesis (Tornier, Inc., Amsterdam, The Netherlands) 3 years prior. The patient suffered from aseptic loosening associated with a severe hindfoot valgus deformity. In addition, the talus was not well centered under the tibia. Note the tibial cysts in the anterior half of the distal tibia. Postoperative weightbearing 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

estimated using the technique as described by Ellington and Myerson for the Agility total ankle replacement system [31]. 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 grade 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 [22].

All cysts that are present should be filled using an impaction bone grafting technique [22, 27, 36]. Otherwise, if loosely impacted, there is a high chance that the bone will resorb over time.

Hintermann et al. [23] proposed another classification (Fig. 24.5) 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

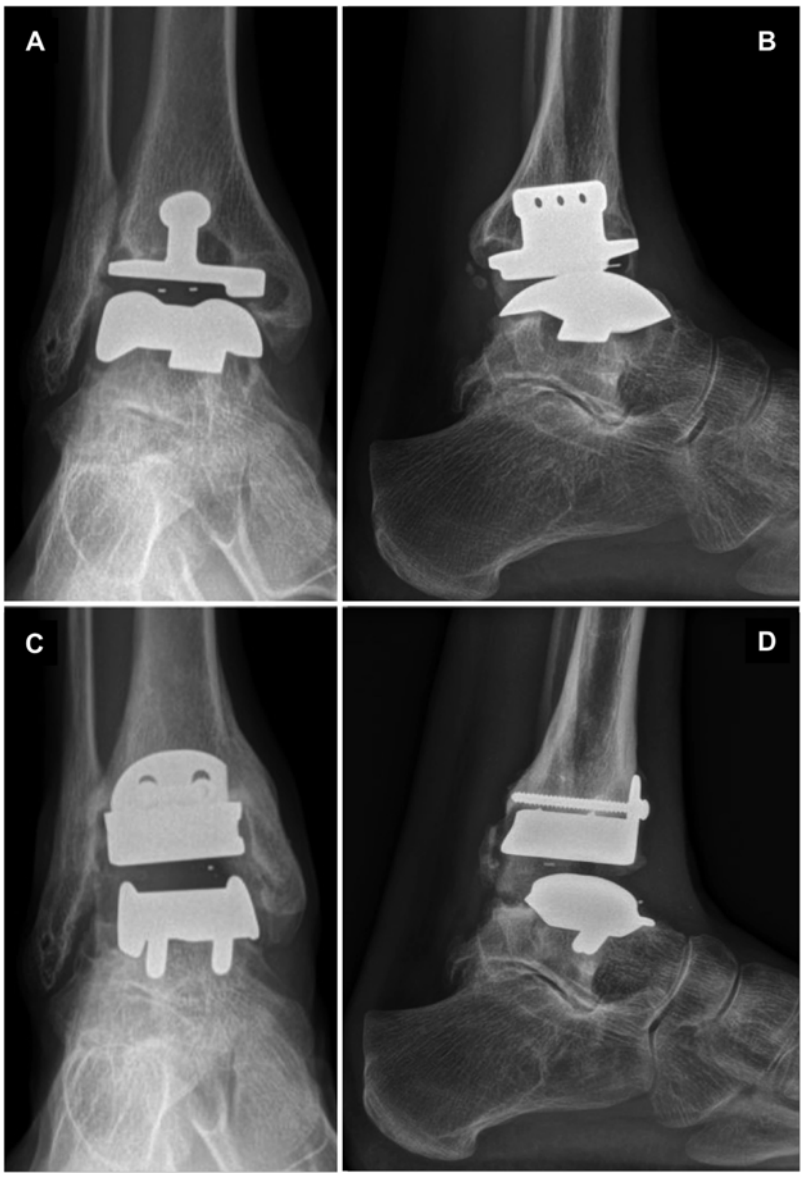

Fig. 24.4 Weightbearing anterior–posterior (**a**) and lateral (**b**) radiographs demonstrating advanced aseptic loosening of a Salto Mobile Ankle Prosthesis. Note the extensive cysts, which are found around the talar and tibial components. In addition, the tibial component is tilted in dorsiflexion. Weightbearing anterior–posterior (**c**) and lateral (**d**) radiographs demonstrating revision Hintegra tibial and talar components, as well as cyst débridement 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

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 different 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. The Hintegra 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 is similar in concept with a flat undersurface and cylindrical stem press-fit into the talar bone (Fig. 24.6). Other prostheses, as for example the Inbone II TAR system (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. 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.

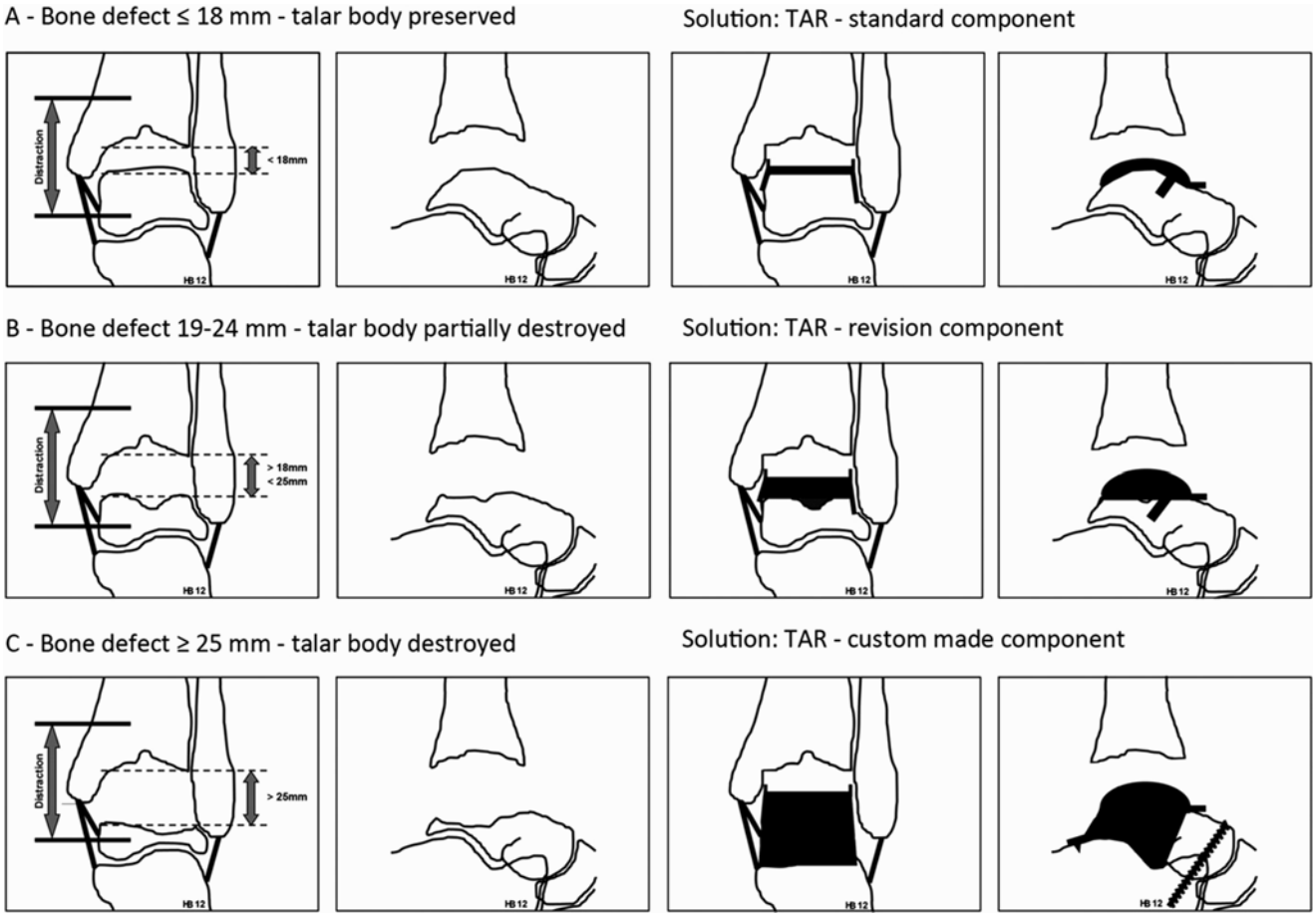

Fig. 24.5 Classification of the talar bone defects and decision-making regarding treatment. From Hintermann B, Zwicky L, Knupp M, Henninger HB, Barg A. HINTEGRA revision arthroplasty for failed total ankle prostheses. J Bone Joint Surg Am. 2013;95:1166-1174

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 [5, 11]. 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) [24, 38–41]. It is up to surgeon's preference whether to perform the osteotomies during a single-stage 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 [42, 43]. In case of anterior-lateral ankle instability a peroneus longus to brevis tendon transfer is an effective tool to address the problem [44]. 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 [24].

Postoperative Management

Postoperatively the patient is put in a short-leg splint with the foot in neutral position. The authors use an indwelling suction drain, which is removed 24 h postoperatively. 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-weightbearing except those who have undergone

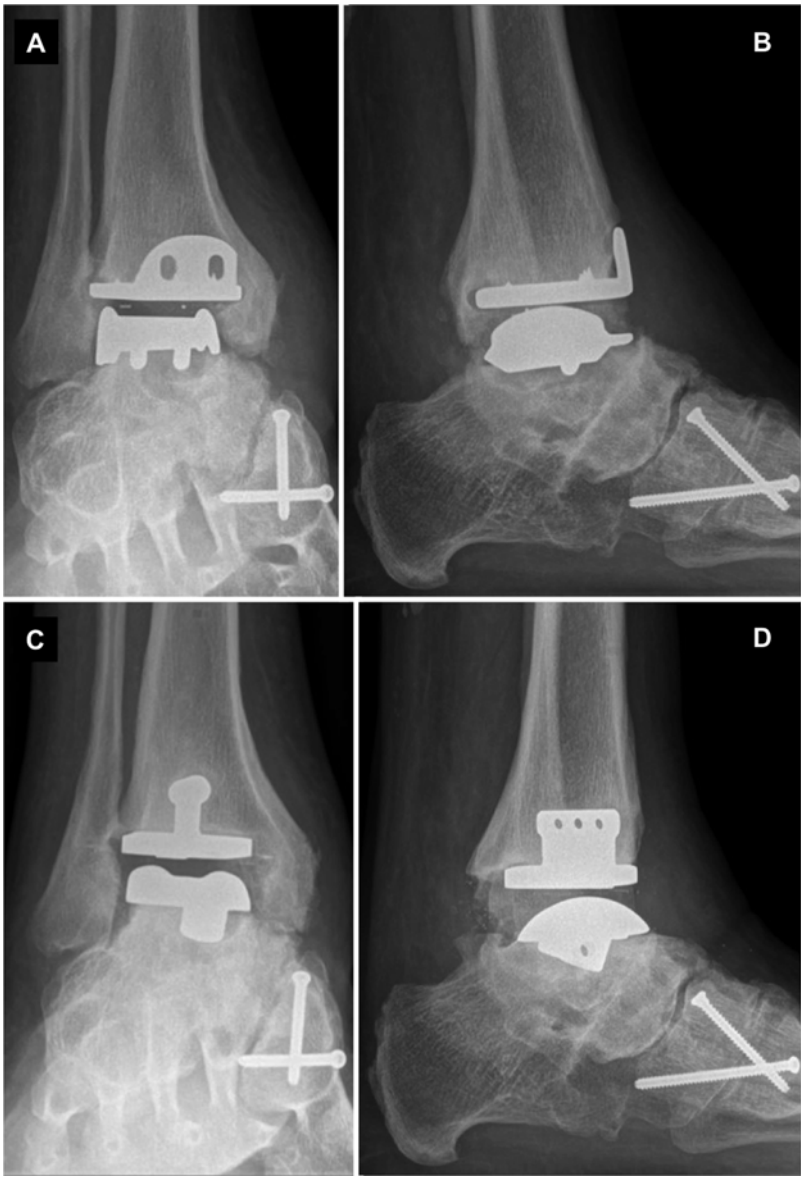

Fig. 24.6 Weightbearing anterior–posterior (**a**) and lateral (**b**) radiographs of a failed Salto Mobile total ankle replacement in a 54-year-old male patient. The patient has had a long history of residual clubfoot deformity and corrective pedal arthrodeses. The talar component subsided and caused 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). Weightbearing 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

additional foot surgery. Those patients should follow a partial or non-weightbearing regimen. Two weeks postoperatively (after removal of the sutures) a structured rehabilitation program is commenced with active and passive mobilization of the ankle joint.

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 [23] and American [20] literature. In their first evidence-based medicine level-IV study 83 revision TAR surgeries in 79 patients were performed. Fifty-three percent of cases revealed aseptic loosening, 41 % suffered from painful dysfunction, and 6 % from a septic loosening of the TAR. Five years postoperatively 83 % of 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 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 [20]. 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. [23] concluded that the medium-term results of revision arthroplasty after failed TAR were similar to those after primary TAR.

Williams et al. [32] performed a single-center retrospective study and focused on complications during revision surgery of a failed TAR. A total of 35 failed Agility TAR System 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 [32].

Salvage Arthrodesis

In case revision TAR is not be feasible, salvage arthrodesis remains a viable limb-salvage option [2–4, 32, 35, 45–49]. 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. Débridement 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 [50]. 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. Afterwards, 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 double 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.

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 is no high-level evidence-based medicine studies available. Zwipp and Grass [51] 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 [52] described tibiotalar fusion without bone grafting with the drawback of significant leg shortening. Hopgood et al. [53] 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 [53]. In a study by Culpan et al. [54] 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 tri-cortical autogenous iliac crest grafts. All patients but one achieved solid union and no complications were reported. More recently, Berkowitz et al. [49] 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 [49]. 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 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 % [55]. 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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Management of the Infected Total Ankle Replacement

25

Christopher Bibbo and Steven 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. 25.1) 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 surmises 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, 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 to 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.

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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.

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].

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_25

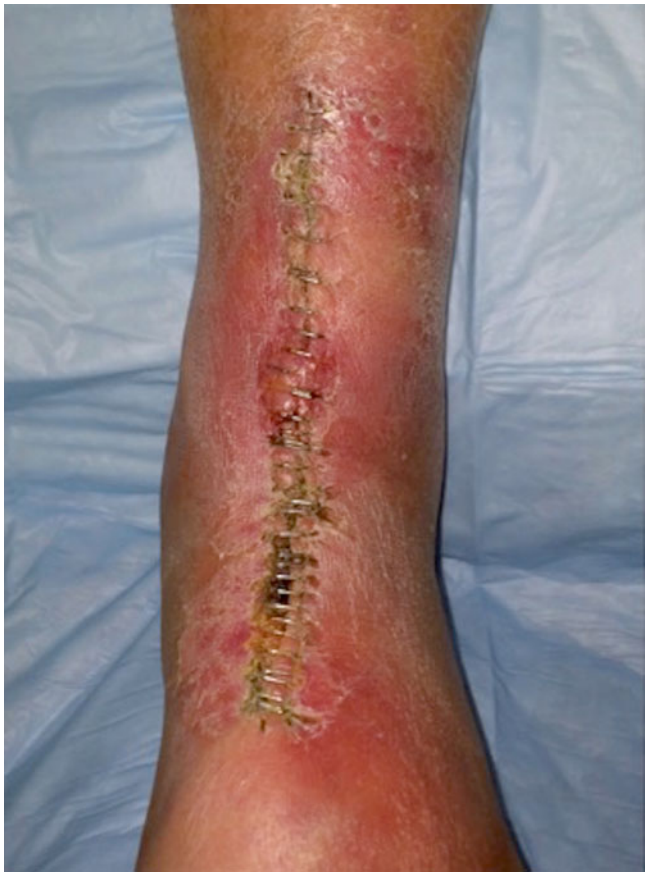

Fig. 25.1 Cellulitis 3 weeks after primary total ankle replacement. Antibiotics should be started targeting skin flora or resistant organisms in high-risk/institutionalized patients and a work-up for deep periprosthetic infection initiated

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 does 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 has 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 authors typically admits the febrile patient with an obvious diagnosis of infected TAR and starts 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 is performed in the obvious infection and is 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. 25.2a, 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, is 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

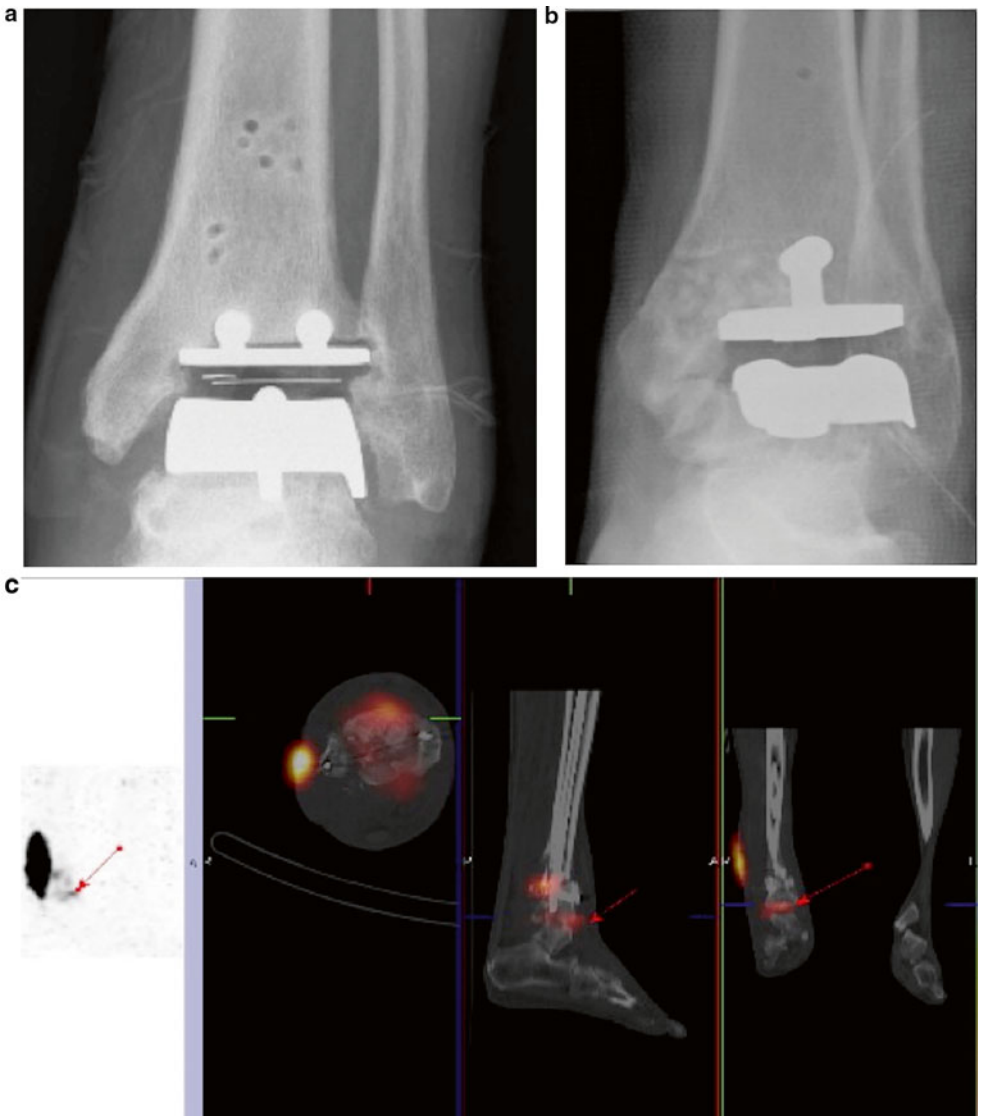

Fig. 25.2 Radiograph of infected total ankle replacement with minimal changes on radiographs (**a**). Radiograph of total ankle replacement with changes within the medial malleolus suspicious for infection or avascular osteonecrosis. Indium-111 scan can assist in differentiating an infectious etiology (**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 well infection 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 utilizes 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. 25.2c), 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 polymethylmethacrylate (PMMA) cement spacers or beads are utilized (Fig. 25.3a). After prosthetic

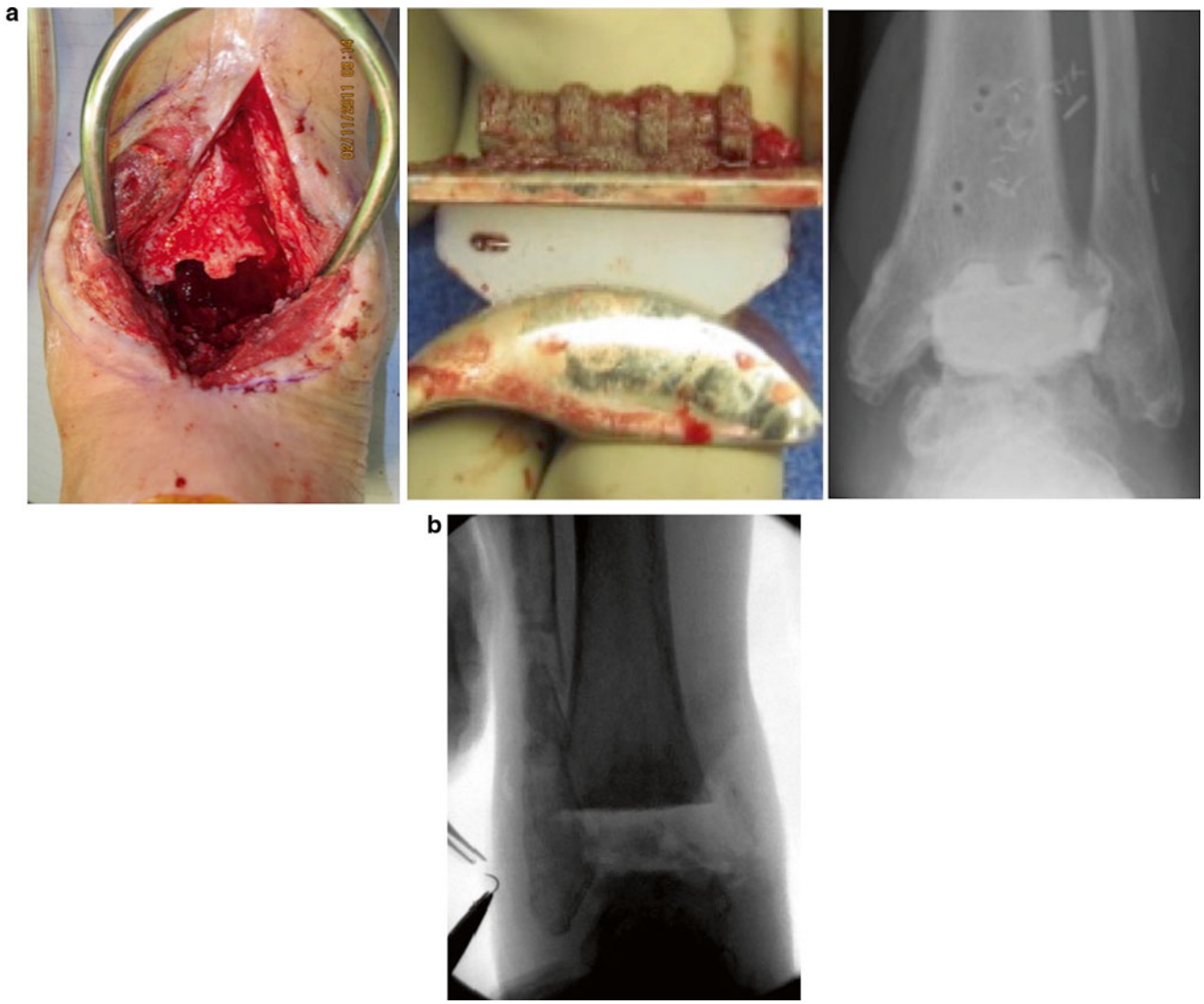

Fig. 25.3 Infected total ankle replacement (*left panel*) that is easily explanted (*center panel*) and the residual osseous defect is filled with antibiotic-loaded polymethylmethacrylate cement spacer (*right panel*) (**a**). Bone resection should be kept to the minimum needed if replantation is planned. 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

component removal, bone is debrided judiciously. It is a fine line between retaining infected bone versus performing an overzealous resection of bone (Figs. 25.3b and 25.4); 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 25.1 and 25.2.

Since 2005, the primary authors has 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 25.3). The authors has 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

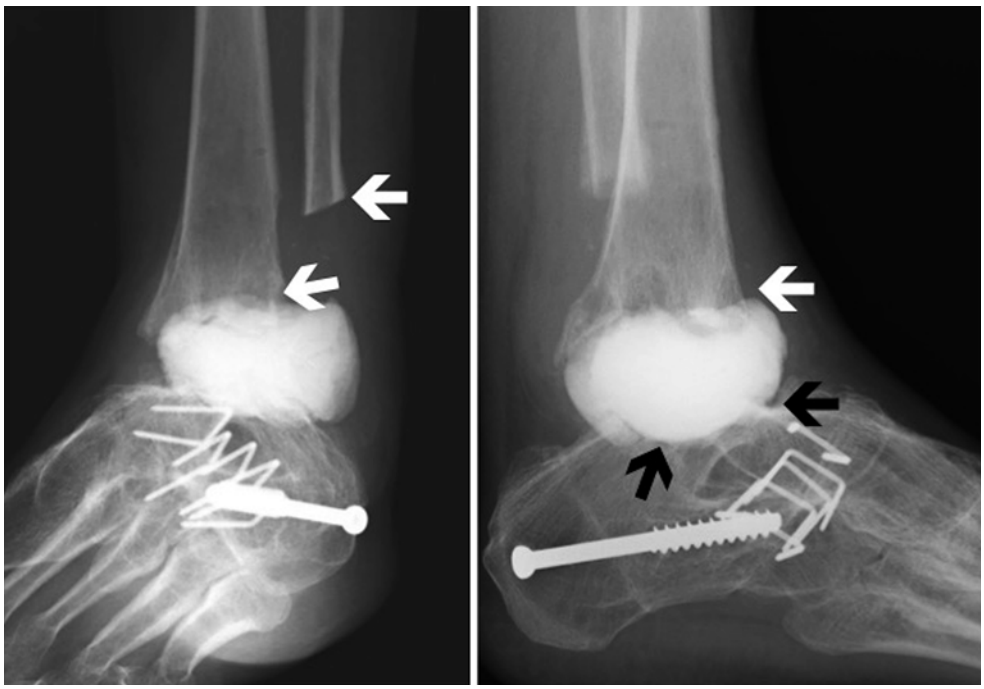

Fig. 25.4 Antibiotic-loaded polymethylmethacrylate cement spacer after explant of infected total ankle replacement. Note the bone loss on both the tibia and fibula (*white arrows*) and the near total loss on the talar side (*black arrows*). This setting mandates a fusion with reconstitution of the bone that has been resected to maintain functional limb length

Table 25.1 Antibiotics (Abx) compatibility with polymethylmethacrylate (PMMA)

Abx mixable w/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:
Amoxicilli			1. Hand mix
Ampicillin			2. No vacuum
Amphoteracin-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 25.2 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†
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†
Cefamandole (Mandol®)	NR	Quadruple standard dose†
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†
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†
*Potentially heat unstable!	MDR *Acinetobacter* two million units/day (k.)	MDR *Acinetobacter*: add rifampin (Osteoset) and doxycycline (Osteoset)
Daptomycin	NR	Quadruple standard dose†
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†
Methicillin	NR	Quadruple standard dose†
Novobiocin	NR	Quadruple standard dose†
Oxacillin	NR	Quadruple standard dose†
Polymyxin B	NR	Quadruple standard dose†
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)

† Osteoset and is Wright Medical Technologies, Inc., Arlington, TN

direct cultures. If all fluid and tissue is 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].

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 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.

Table 25.3 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)

Requisites to be fulfilled include eradication of the infection from soft tissues and bone, adequate residual bone stock of good quality, and the 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 believes that some benefit may be derived from antibiotic-loaded PMMA cement. However, the antibiotic 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. 25.2) 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 considers 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. 25.5), the protocol described by Bibbo et al. [23] should be followed.

When bone loss is present and structural bone is required for a late reconstruction, several options exist. The authors prefers to utilize fine-wire circular external fixation and autologous bone grafting (Fig. 25.6). 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. 25.7). Patients at extreme high risk for nonunion may require vascularized bone graft procedures, such as vascularized free fibula or free iliac crest (Fig. 25.8) or free fibula (Fig. 25.9) [24]. The authors' preferred fixation technique in conjunction with free

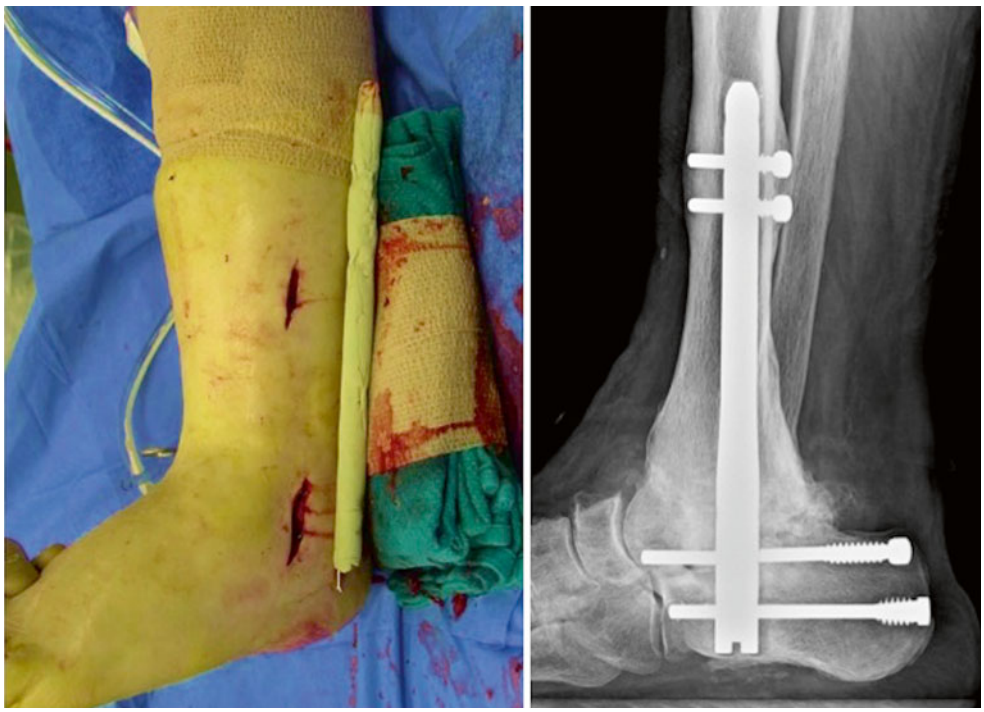

Fig. 25.5 Extended ankle fusion with retrograde intramedullary nail (*right panel*) after surgical cultures was negative following serial debridements, culture-specific systemic antibiotics, and exchanges of the antibiotic-loaded polymethylmethacrylate cement impregnated nail (*left panel*)

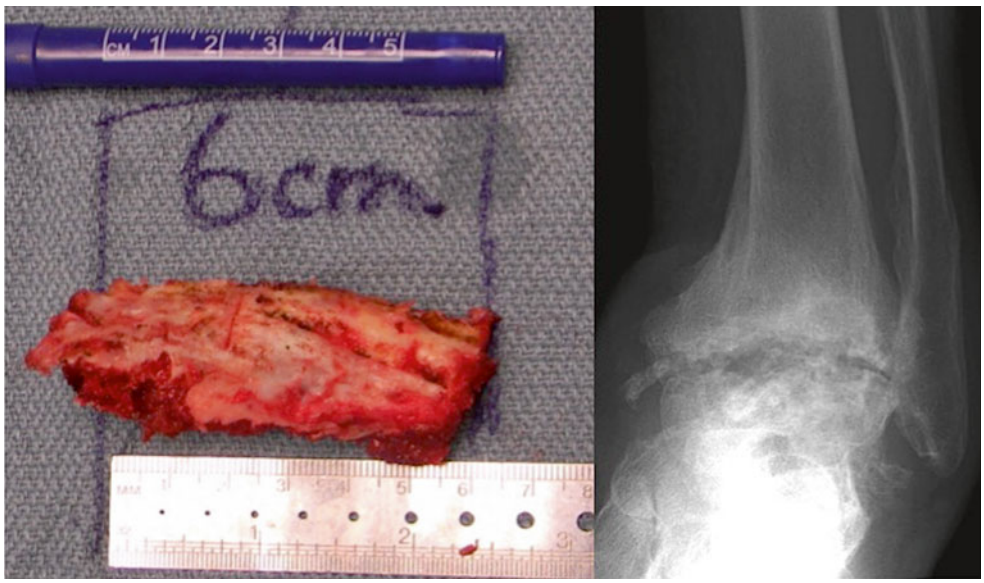

Fig. 25.6 Intraoperative photograph of a 6-cm autologous iliac crest bone graft. Typically, a single 6-cm graft combined with banked bone and rhBMP-2 will suffice for the ankle radiograph shown on the *right* that demonstrates both talar and tibial plafond bone loss. For massive local bone loss, the authors has used non-vascularized grafts as large as 9 cm from each iliac crest to salvage to the ankle after deep periprosthetic infection

vascularized bone graft remains fine-wire circular external fixation; internal fixation may be used but not in the face of residual infection.

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 are 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

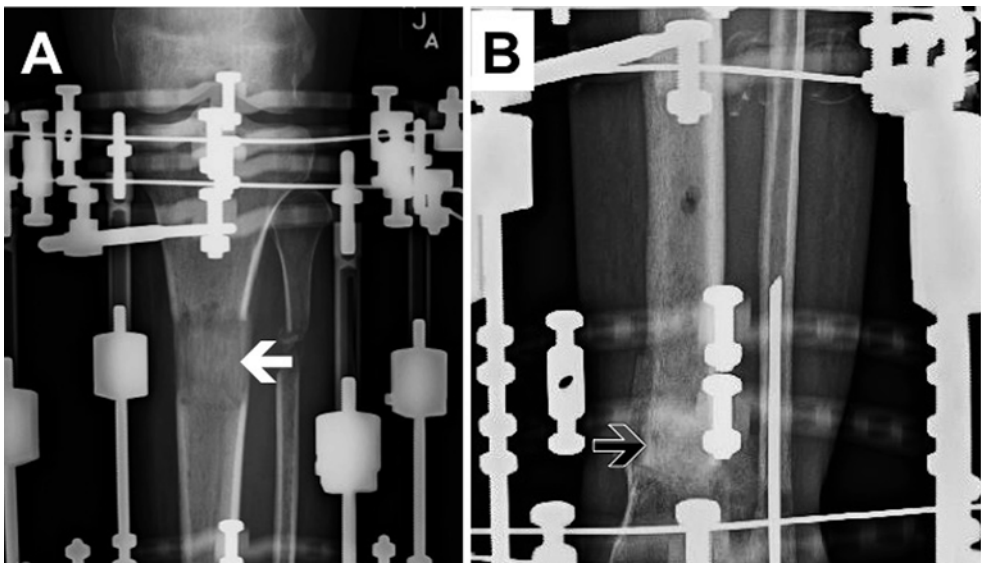

Fig. 25.7 Radiograph of bifocal Ilizarov technique (*white arrow*) for 4-cm bone loss. Proximal distraction osteogenesis is carried out (**a**, *white arrow*) at the same time as distal compression osteogenesis (**b**, *black arrow*)

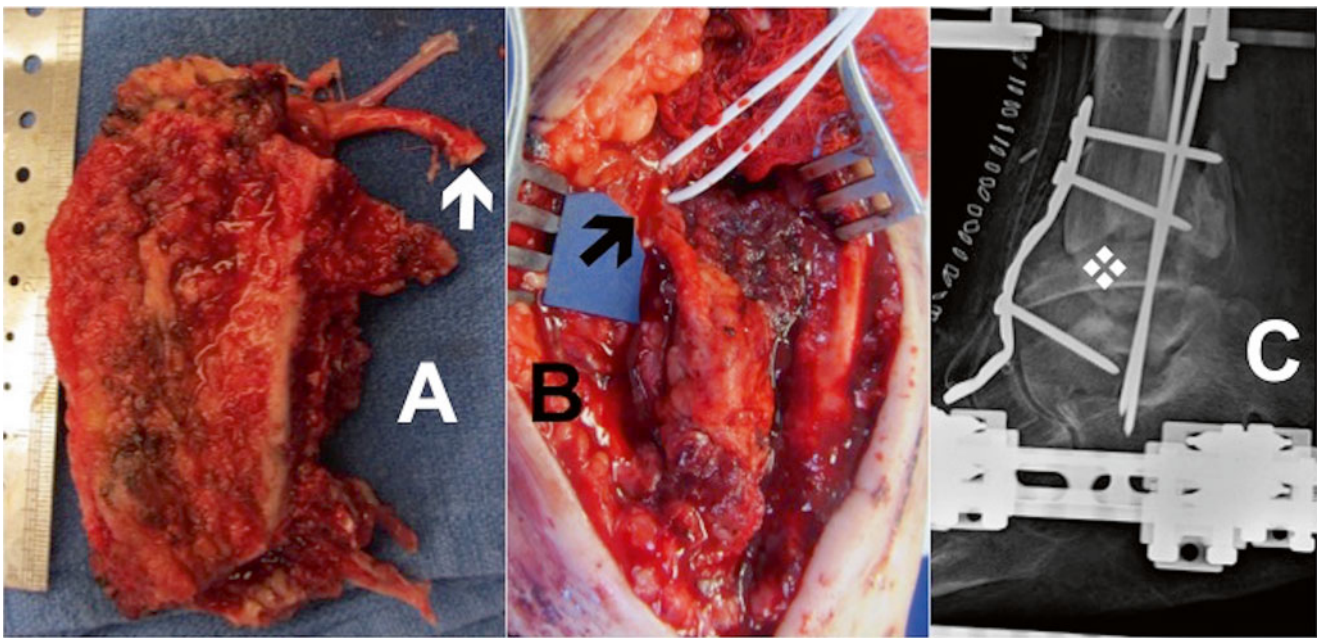

Fig. 25.8 Free vascularized iliac crest bone flap to treat a recalcitrant nonunion for limb salvage after explanted total ankle replacement. Free flap with pedicle (**a**, *arrow*); inset of bone free flap with anastomosis to tibialis anterior vessels (**b**, *arrow*); radiograph of free bone flap (**c**)

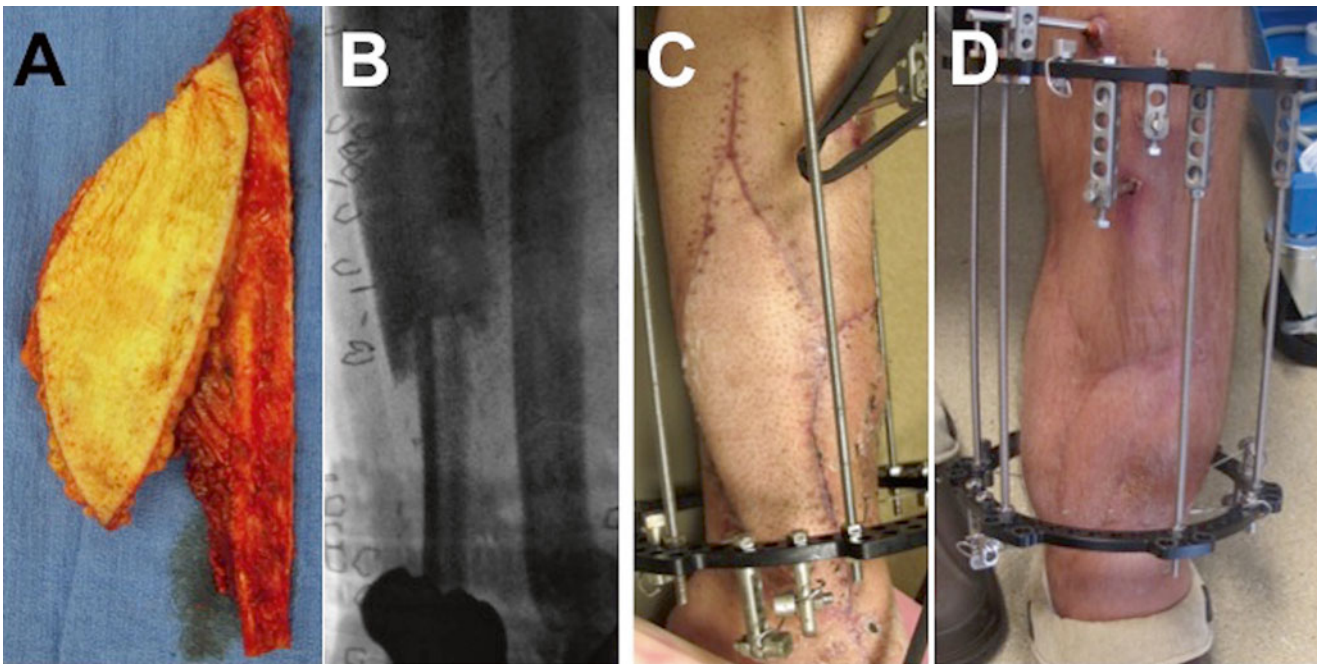

Fig. 25.9 Free fibula osteocutaneous flap for limb salvage after severe distal tibial bone loss and anterior/medial soft-tissue loss after an infected total ankle replacement with massive wound complications. Intraoperative photograph of the harvested fibula osteocutaneous flap (**a**). Intraoperative 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

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 is essential to a successful outcome.

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Primary and Revision Total Ankle Arthroplasty in Japan

26

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Introduction

Clinical use of total ankle replacement (TAR) started in the 1970s and myriad different TAR prostheses have been developed worldwide. From the point of pain relief, TAR can provide an acceptable result; however, serious problems still occur. The ankle joint is much smaller in comparison to other joints in the lower extremity, such as the hip and knee joints. As a result, the ankle joint must bear large compressive and shear forces during weight-bearing ambulation. Thus, the TAR prosthesis is placed in a highly stressful environment [1] that makes it difficult to achieve consistently good long-term clinical outcomes. Aseptic osteolysis, metallic component loosening, and subsidence in the early postoperative period following TAR are unfortunately common. Based upon these problems, the standard treatment for end-stage arthritis of ankle joint has been arthrodesis. TAR is not popular for end-stage ankle arthritis in Japan where only 300 cases of TAR were performed during 2010 [2].

In our institute, joint reconstructive surgeries for inflammatory arthritis have achieved consistently good outcomes. We have identified a high incidence of subtalar degenerative joint disease in patients with end-stage ankle arthritis [3]. As with ankle arthritis, arthrodesis has long been performed for subtalar joint pain, deformity, and/or instability [4]. Fusion of both the ankle and subtalar joint may result in significant functional gait abnormalities, especially on inclines, uneven ground, and stairs [5]. As a result, we consider TAR indicated for rheumatoid patients and those with arthritis of both the ankle and subtalar joints. At our institute [6], we used the TNK ankle prosthesis (Kyocera, Kyoto, Japan) from 1984 until 2003 and reported our outcomes of 32 ankles with rheumatoid arthritis [7]. Patient satisfaction was relatively good with the majority of patients stating they were better than prior to TAR. However, we experienced a high incidence of tibial component migration and talus component subsidence secondary to osteonecrosis of the talus. In the last 30 years, TAR prosthesis design, variations in the size of the prosthesis, accurate surgical instruments, and improved understanding of soft-tissue balancing techniques have become recognized as critical for TAR survivorship. The prosthesis design can be roughly classified into two types: the two-component fixed-bearing TAR prosthesis, which consists of a talar component and a tibial component with a polyethylene insert affixed to it, and the three-component mobile-bearing TAR prosthesis, which consists of a talar component, a tibial component, and an polyethylene insert that can move relative to both metallic components [8–12]. The mobile-bearing

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_26

polyethylene insert mechanism allows anterior–posterior translational and rotational motions during dorsiflexion and plantar flexion [13, 14]. The TNK ankle prosthesis is a two-component fixed-bearing prosthesis which we stopped using in 2003. Since 2003, we have used the FINE Total Ankle Arthroplasty (Teijin Nakashima Medical Co., Ltd., Okayama, Japan) three-component mobile-bearing TAR prosthesis.

Prosthesis Design Concept of the FINE Total Ankle Arthroplasty

The theoretical advantages of a three-component mobile-bearing TAR prosthesis are the large contact area with low-contact stresses between the metallic components and polyethylene insert that allows anterior–posterior translational and rotational motions and also a self-alignment effect, through which the ankle alignment is automatically corrected by the mobile polyethylene insert [15]. Various three-component mobile-bearing TAR prostheses have been developed worldwide [8, 16–22]. However, none of these prostheses have been approved by PMDA in Japan due to the fact that three-component TAR prostheses have been designed for Caucasian people and there is an expected mismatch for Japanese joint anatomy and alignment considerations.

Accordingly, a Japanese three-component mobile-bearing TAR prosthesis concept has been developed. Specifically, the FINE Total Ankle Arthroplasty (Fig. 26.1) is based on a Japanese-specific design for stress dispersion and durability. The FINE Total Ankle Arthroplasty prosthesis is a three-component prosthesis secured with polymethylmethacrylate cement. The talar and tibia components are made from a cobalt chrome alloy (Co–Cr–Mo); the polyethylene insert is manufactured from GUR1020 (Ticona GmbH, Kelsterbach, Germany) ultrahigh-molecular-weight polyethylene (UHMWPE) powder, machined from compression molding, and sterilized using ethylene oxide gas. The contour and size variations of the prosthesis compared to the osteotomy surface were optimized based on extensive dissections of Japanese cadavers.

Clinical Experience with the FINE Total Ankle Arthroplasty

Between July 2003 and August 2014, a total of 44 FINE Total Ankle Arthroplasty prostheses in 35 patients were performed at our institute. Four ankles in 4 patients had osteoarthritis (1 man, 3 women) and 40 ankles in 31 patients had rheumatoid arthritis (4 men, 27 women). One patient (1 ankle) died for cardiovascular disease at 68 months postoperatively. Eight patients (10 ankles) were lost to follow-up at the time of review allowing the remaining 34 ankles (77.3 %) of the original cohort to be evaluated. The mean age at the time of operation was 62.5 years (range, 47–78 years). The mean follow-up was 71.2 months (range, 4–140 months).

Surgical Technique for the FINE Total Ankle Arthroplasty

A longitudinal incision was made between the tibialis anterior tendon and the extensor hallucis longus tendon and the dorsalis pedis artery and deep peroneal nerve were mobilized laterally. In rheumatoid arthritis cases, synovectomy of the

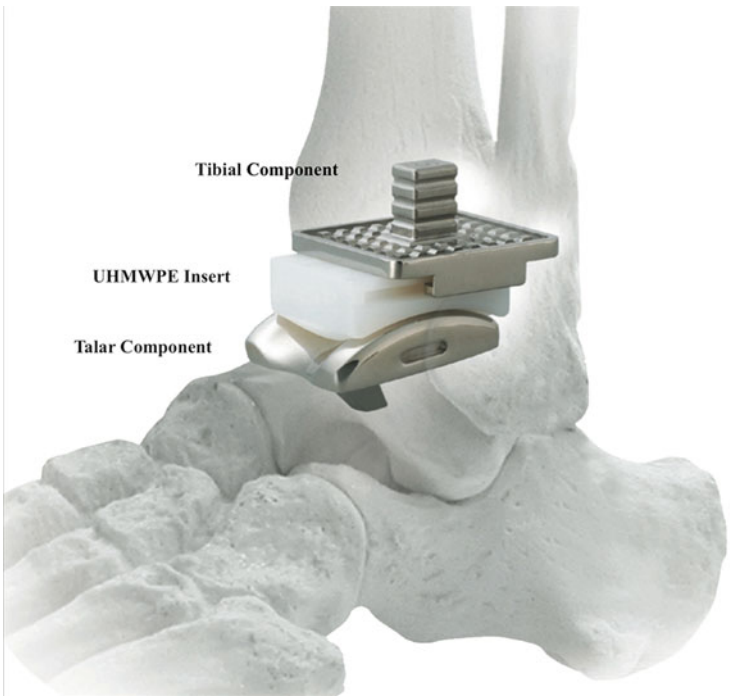

Fig. 26.1 Foot and ankle model viewed from anterior–lateral demonstrating the three-component mobile-bearing FINE Total Ankle System

extensor tendon sheath and ankle joint was performed. Using the osteotomy guide, osteotomy of the tibia and talus was performed. Then using trials, the motion and tension (joint gap) were checked and finally the definitive prosthesis components were fixed using polymethylmethacrylate cement. Usually it is difficult to adjust the joint gap to manage soft-tissue varus contractures during TAR. Since 2006 a sliding medial malleolar osteotomy was added after talus preparation was completed to balance the medial and lateral soft tissues (Fig. 26.2) [22]. In cases with severe bone loss, hydroxyapatite augmentation was used with tibial preparation especially patients with rheumatoid arthritis. In our series presented here, sliding medial malleolar osteotomy was employed in 8 ankles (24.2 %) and hydroxyapatite augmentation was used in 16 ankles (48.5 %). Since 2008, all FINE Total Ankle Arthroplasty prostheses were prepared using dedicated patient-matched instrument for the tibial and talar joint resection osteotomies [23]. These patient-matched instruments were developed from DICOM data obtained from their preoperative CT scan, thereby allowing three-dimensional preoperative planning and precise joint resection (Fig. 26.3).

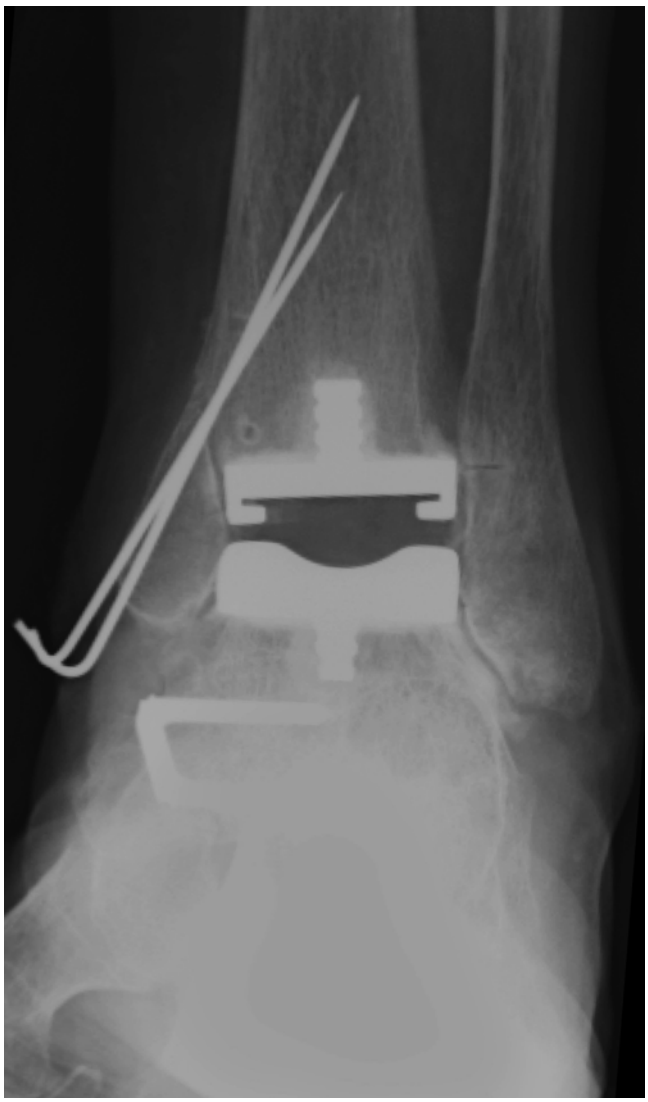

Fig. 26.2 Non-weight-bearing anterior–posterior radiograph demonstrating medial malleolar osteotomy stabilized with Kirschner wire fixation. The osteotomy is performed after talar preparation is completed when the balance between the medial and lateral soft-tissue ligaments is not acceptable using the trial spacer block

Clinical Results following FINE Total Ankle Arthroplasty

We previously reported the clinical results of our recent TAR experiences performed in Japanese patients [24]. From 2003 to 2010, a total of 33 TAR were performed. From this initial series, 27 ankles (21 patients) were clinically evaluated except the lost-to-follow-up cases and one early revision case. Clinical results were evaluated by the Japanese Society for Surgery of the Foot (JSSF) ankle–hindfoot scale, which is a validated functional scale (for Japanese people) consisting of 40 points for pain, 50 points for function, and 10 points for alignment (100 points total) [25]. According to JSSF ankle–hindfoot scale, the mean ± standard deviation postoperative score was 82.1 ± 5.3 (range, 76–92) points at the time of follow-up examination. Formerly we reported the in vivo kinematics of TAR in 10 patients (13 ankles) with rheumatoid arthritis in whom plain film radiographs did not demonstrate any signs of loosening. Clinically we measured the sagittal plane ankle range of motion which averaged 4.2° ± 4.7° of dorsiflexion and 19.2° ± 8.2° of plantar flexion preoperatively and 5.9° ± 4.9° and 20° ± 9.5° postoperatively, respectively. There were no significant differences between preoperative and postoperative range of motion at final follow-up.

Failure Cases following FINE Total Ankle Arthroplasty

At a mean follow-up of 71.2 months, we experienced one case of aseptic loosening involving both the tibial and talar component at 7 years postoperative, one septic loosening at 2 years postoperative, and one talar component subsidence at 29 months postoperative. The remaining 30 ankles demonstrated the presence of nonprogressive radiolucent lines around the tibial component in ten cases (33.3 %) and talar component subsidence in four cases (13.3 %) (Fig. 26.4). TAR revision was performed for the one case with both tibial and talar component loosening using long-stem components (Fig. 26.5). The other case involving aseptic loosening of both the tibial and talar components was treated with arthrodesis using autogenous bone graft (Fig. 26.6). The one septic loosening case was treated with prosthetic

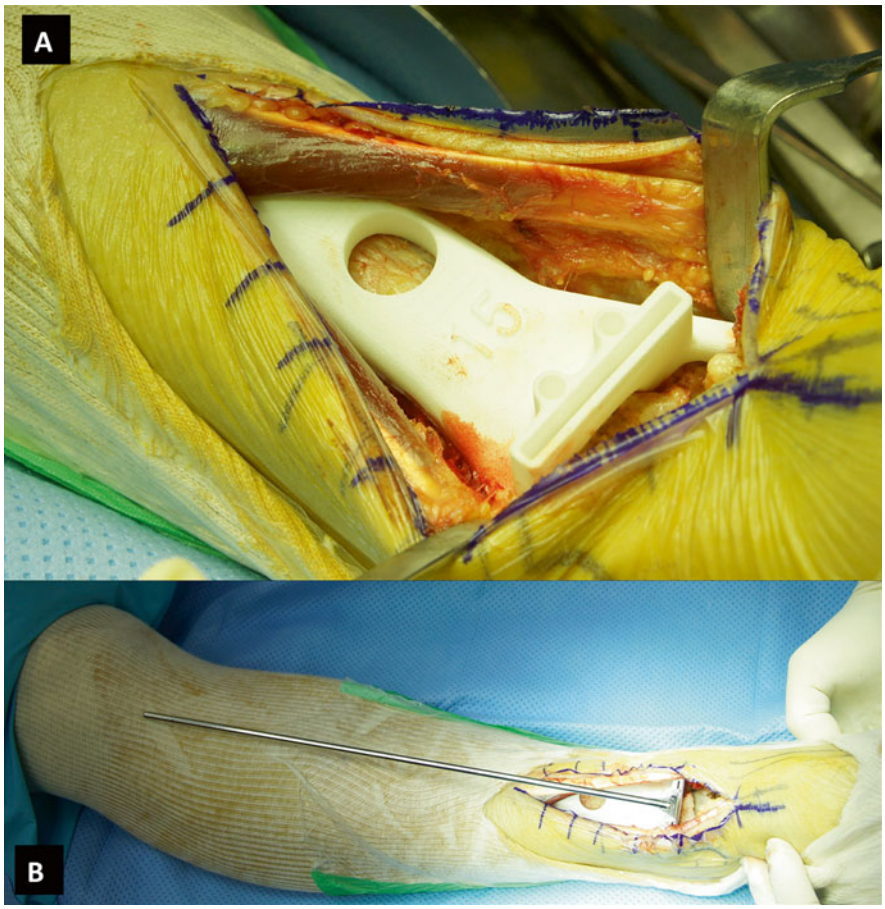

Fig. 26.3 Patient-matched instrumentation demonstrated on the anterior tibia at the ankle joint line for the FINE Total Ankle Arthroplasty system fabricated based on preoperative computed tomography DICOM data (**a**). An extramedullary rod articulates with the patient-matched instrumentation and is employed for alignment verification (**b**)

component explantation alone. We experienced one medial malleolar fracture at 8 years postoperative. In this case, arthrodesis was also performed with autogenous bone graft (Fig. 26.7).

In Vivo Kinematics of the FINE Total Ankle Arthroplasty

It is important to evaluate the in vivo kinematics following TAR. The third-generation three-component mobile-bearing TAR prostheses are expected to function more naturally in vivo compared with second-generation two-component fixed-bearing TAR systems. We evaluated the in vivo kinematics of the FINE Total Ankle Arthroplasty prosthesis in patients with osteoarthritis during gait (Fig. 26.8a, b). The stance phase during gait was analyzed from heel strike to toe-off during the gait cycle. Successive ankle movements were recorded as serial digital radiograph images (Fig. 26.8c). We evaluated the range of motion of the ankle joint, dorsiflexion, and plantar flexion, as well as calculated the relative position of the talar component to the tibial component on the serial digital radiograph images obtained by fluoroscopy during the stance phase of gait. Ankle motion during the stance phase of gait with full weight bearing was 3.4° of dorsiflexion and 4° of plantar flexion with a total sagittal plane arc of 7.4°. The kinematic pattern from heel strike to toe-off was slightly plantar flexed toward foot flat, then gradually dorsiflexed toward heel off, and finally plantar flexed toward toe-off (Fig. 26.9). The range of motion is limited compared to the normal ankle; however, the kinematic pattern mimics normal ankle kinematics [26].

Conclusion

Ankle arthrodesis is still performed more frequently than total ankle replacement for treatment of painful degenerative changes about the ankle joint. However, total ankle replacement has advanced during the last few decades and the clinical results have been improved substantially. Prosthesis design, preoperative planning, operative techniques to balance the joint, and postoperative evaluation of outcomes have made progress and have allowed surgeons to achieve good clinical results reliably. Since 2003, we started to use the three-component total ankle prosthesis with a mobile-

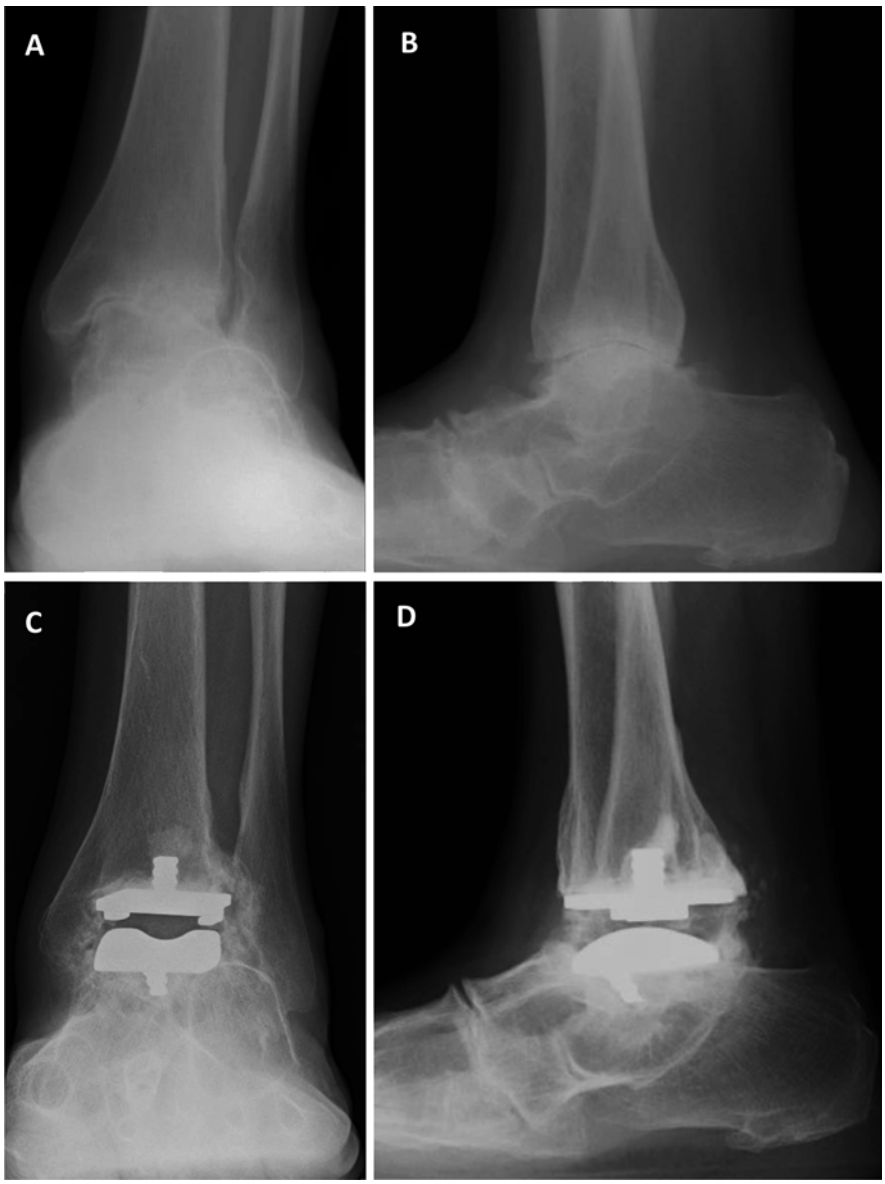

Fig. 26.4 Weight-bearing anterior–posterior (**a**) and lateral (**b**) preoperative radiographs of a 49-year-old woman with rheumatoid arthritis demonstrating degenerative joint disease of the ankle and hindfoot. Weight-bearing anterior–posterior (**c**) and lateral (**d**) 11-year postoperative radiographs following implantation of a FINE Total Ankle Arthroplasty that remains well seated and functions well

bearing polyethylene insert. As a result, the FINE Total Ankle System is the most frequently employed ankle prosthesis in Japan today. It was designed to allow not only dorsiflexion and plantar flexion but also ±10° of internal and external rotation and ±3-mm anterior–posterior sliding along the mobile-bearing mechanism. We have investigated the in vivo kinematics of this three-component total ankle replacement. The preliminary results are promising and the prosthesis mimics the normal ankle kinematics during gait. Since 2006, the sliding medial malleolar osteotomy technique to balance varus malalignment, the use of a preoperative three-dimensional preoperative bone model based upon DICOM data obtained from a preoperative computed tomography scan, and dedicated patient-specific surgical instruments have played important roles in total ankle replacement surgery precision. However, we previously have limited the indication for total ankle replacement to only inflammatory arthritis due to low-demand physical activities, but more recently, we started expanding our indications to include osteoarthritis patients with higher daily activities. Even with the limited clinical experiences, the midterm results may be promising.

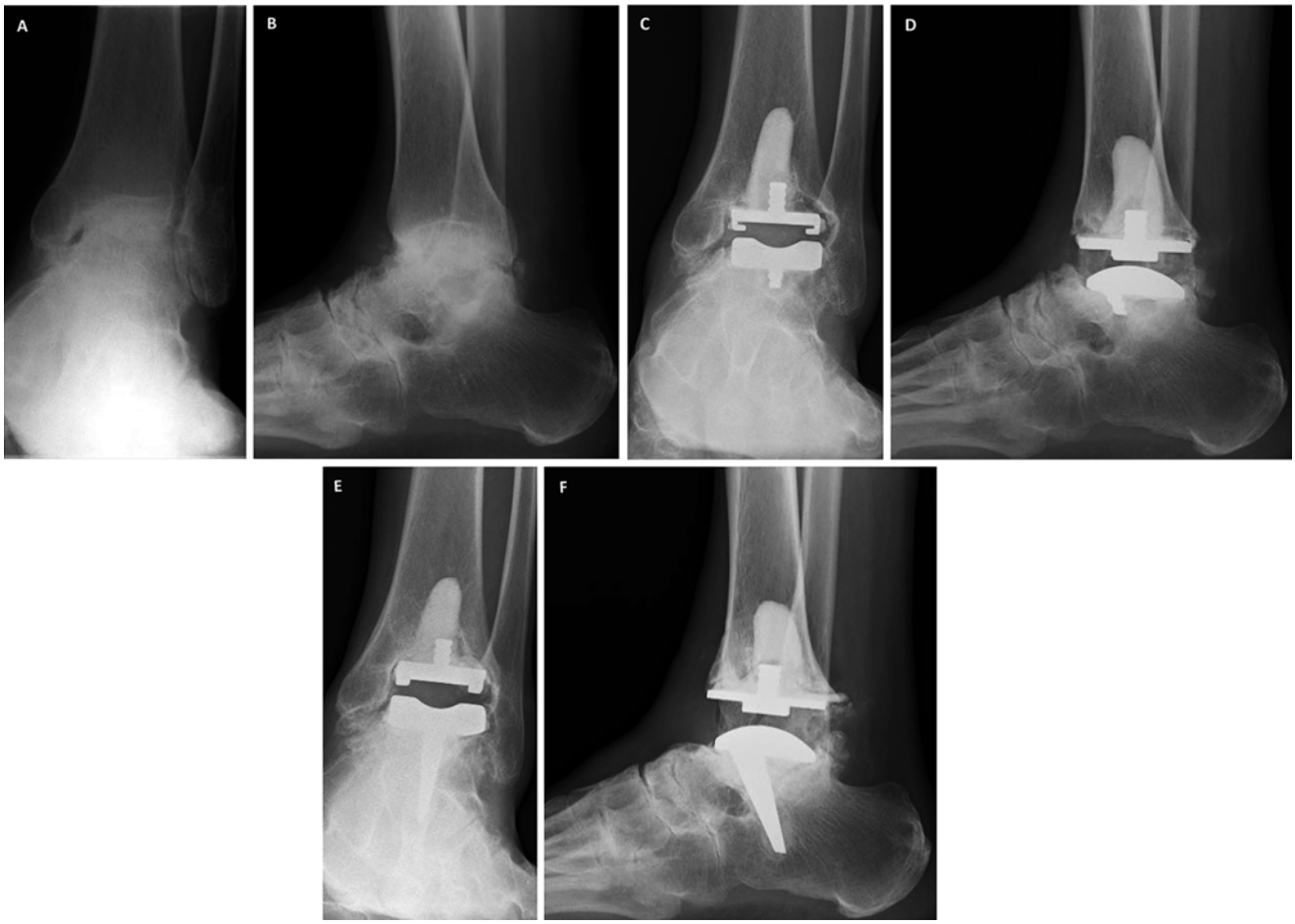

Fig. 26.5 Weight-bearing preoperative anterior–posterior (**a**) and lateral (**b**) radiographs of a 47-year-old man with rheumatoid arthritis. Weight-bearing postoperative anterior–posterior (**c**) and lateral (**d**) radiographs demonstrating the FINE Total Ankle Arthroplasty at 29 months which demonstrates subsidence of the talar component and osteolytic changes around tibial component. Revision total ankle replacement was performed with explantation of the original FINE Total Ankle Arthroplasty and conversion to long-stem talar component as shown on these anterior–posterior (**e**) and lateral (**f**) weight-bearing radiographs

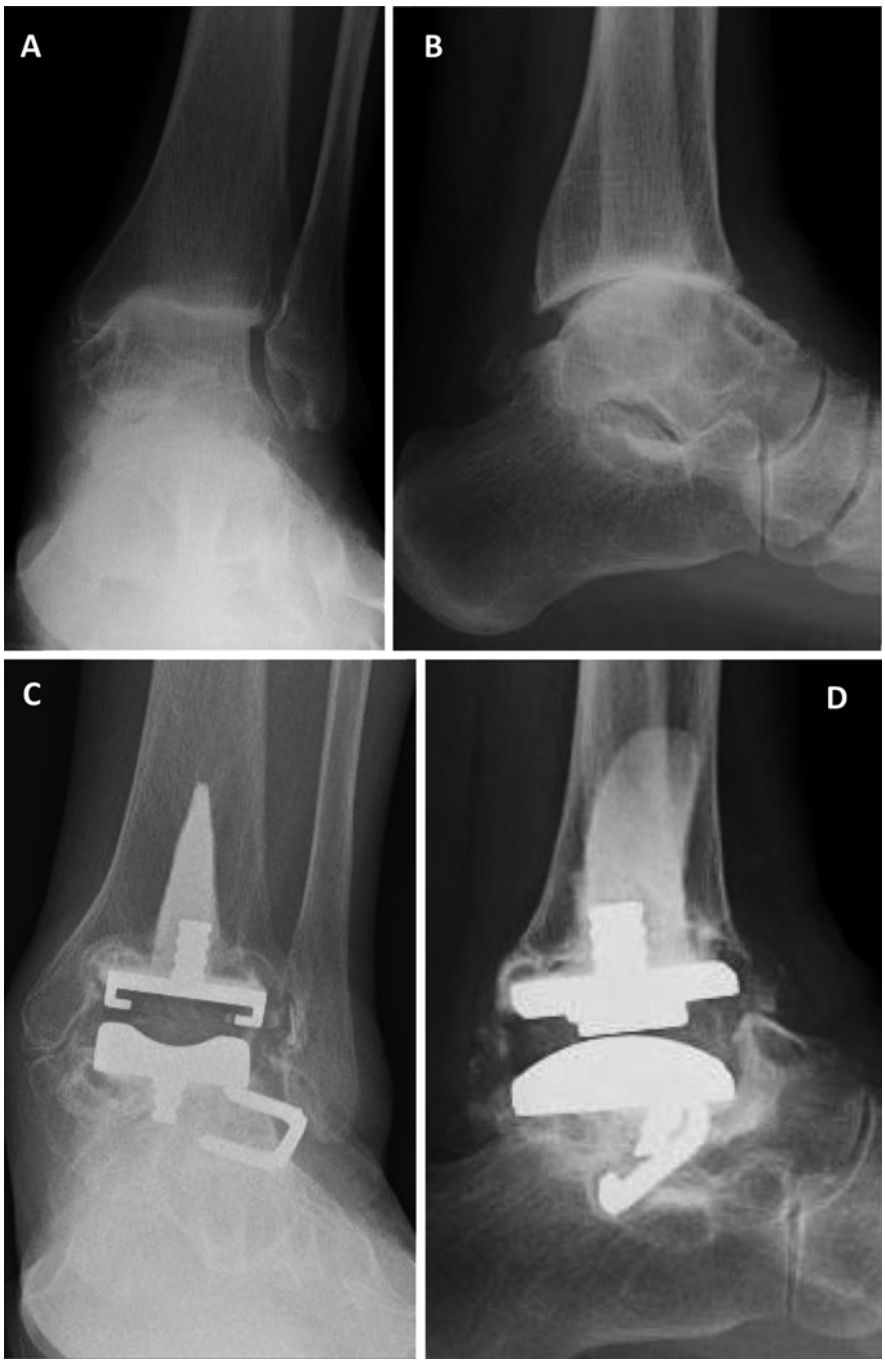

Fig. 26.6 Weight-bearing anterior–posterior (**a**) and lateral (**b**) radiographs of a 69-year-old woman with osteoarthritis. Weight-bearing anterior–posterior (**c**) and lateral (**d**) radiographs 8 years following implantation of a FINE Total Ankle Arthroplasty demonstrated subsidence of the talar component and osteolytic changes around tibial component. Salvage was performed with a tibio-talo-calcaneal arthrodesis using autograft and retrograde intramedullary nail fixation

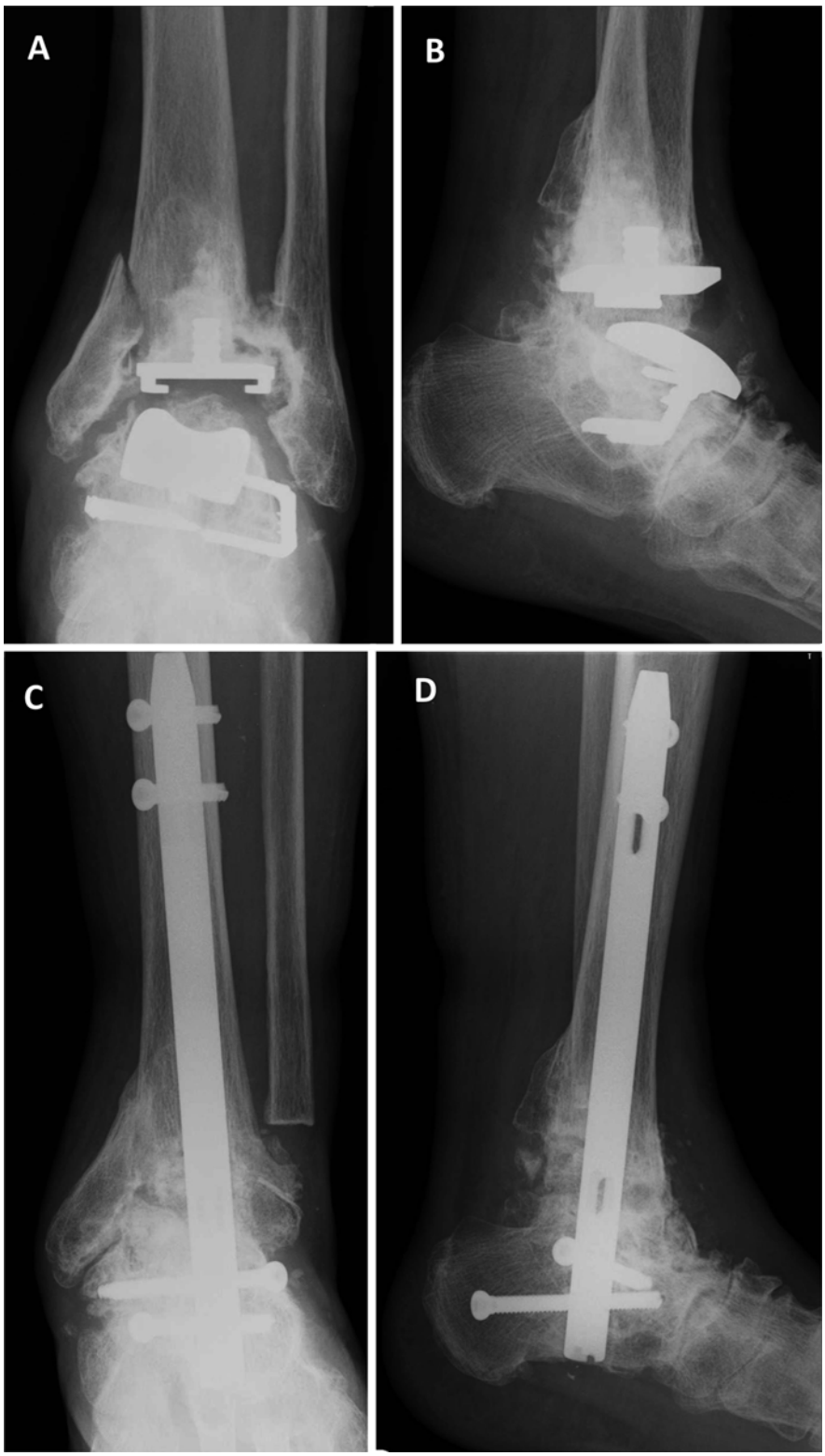

Fig. 26.7 Weight-bearing anterior–posterior (**a**) and lateral (**b**) preoperative radiographs of a 61-year-old woman with rheumatoid arthritis. Weight-bearing anterior–posterior (**c**) and lateral (**d**) radiographs obtained 8 years following implantation of a FINE Total Ankle Arthroplasty following a fall while shopping which resulted in fractures of her medial malleolus treated with tibio-talo-calcaneal arthrodesis using autograft and retrograde intramedullary nail fixation

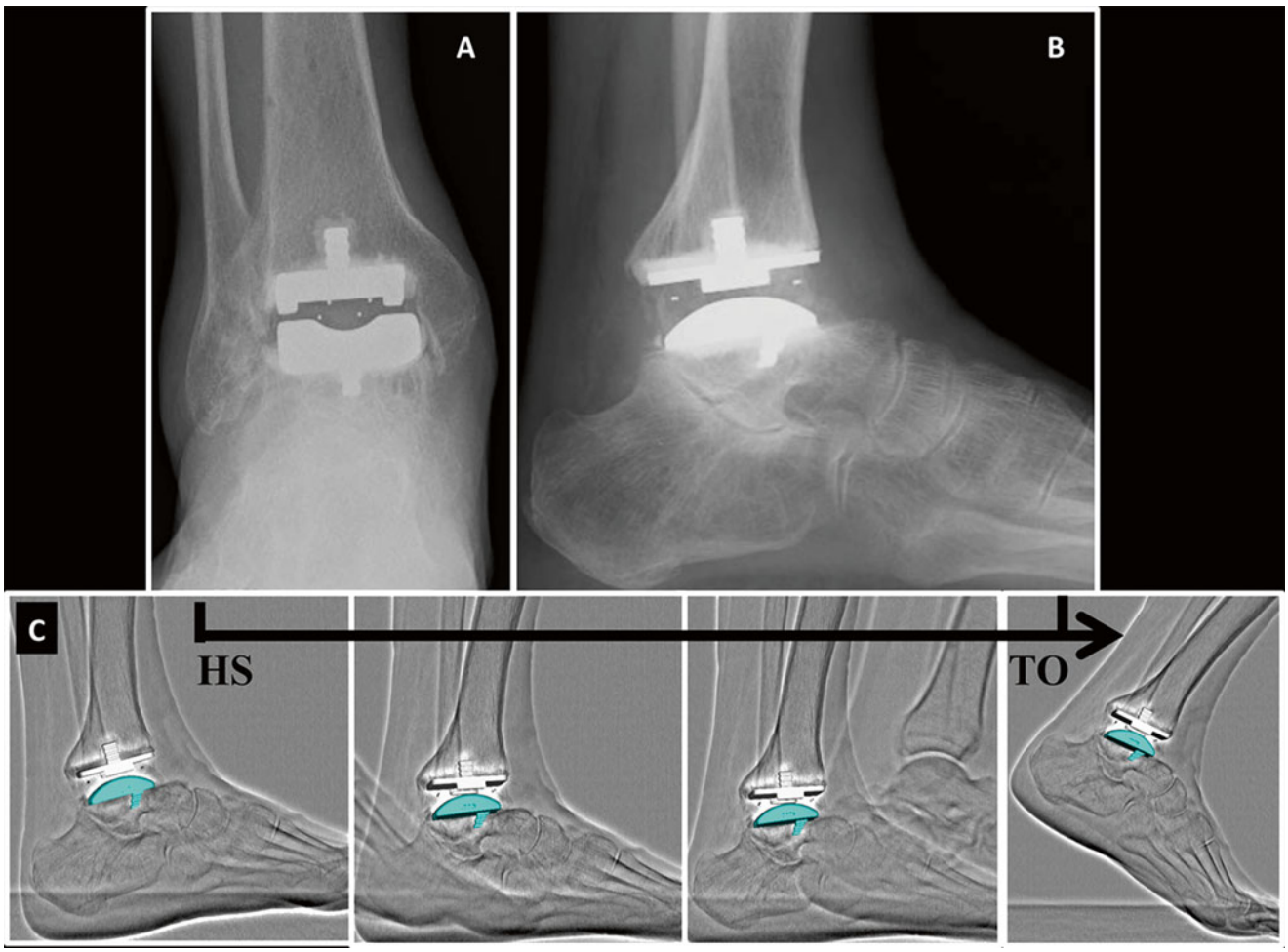

Fig. 26.8 Weight-bearing anterior–posterior (**a**) and lateral (**b**) radiographs obtained 6 years following implantation of a FINE Total Ankle Arthroplasty in a 58-year-old man with osteoarthritis. (**c**) Consecutive images of the FINE Total Ankle Arthroplasty during gait where the prosthesis images are computer-aided design model overlay after pose estimation. *HS* heel strike, *TO* toe-off

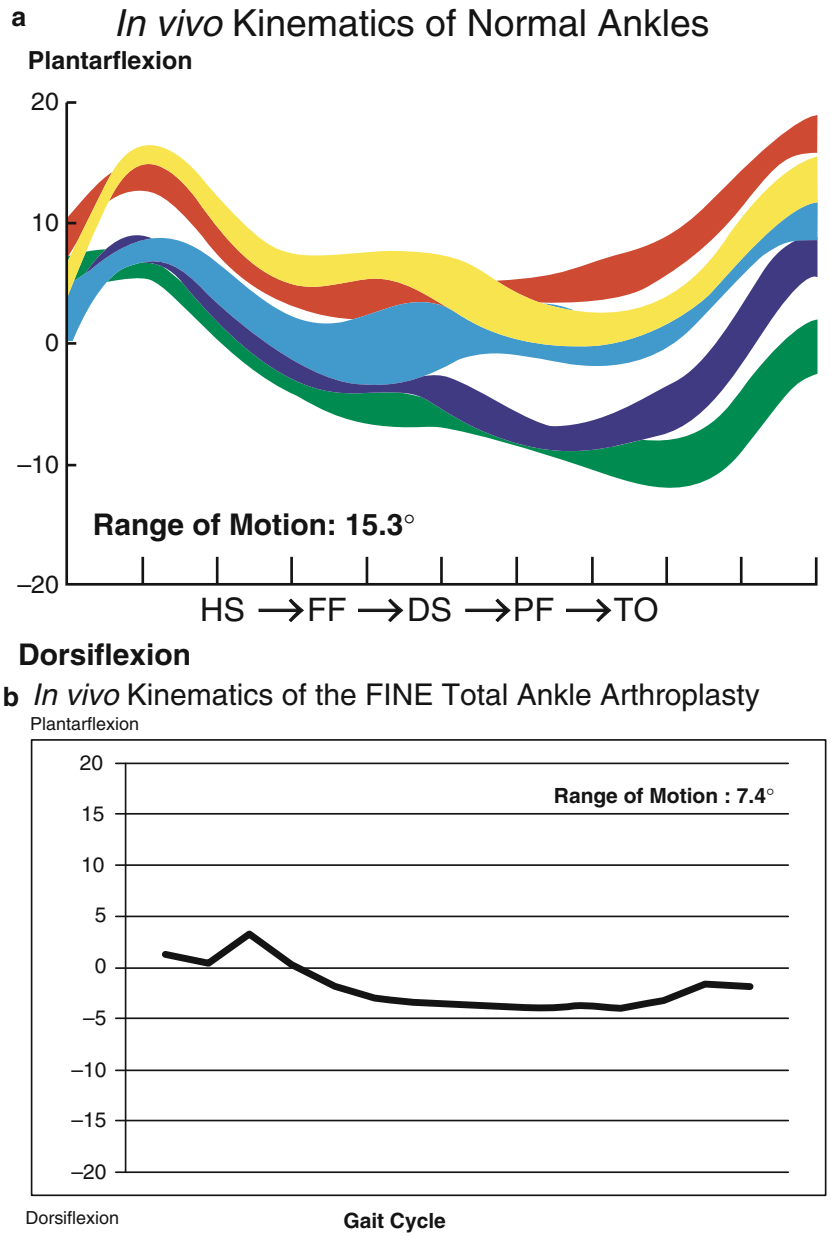

Fig. 26.9 In vivo kinematics of implanted ankle during the stance phase of gait was investigated using 2D/3D registration technique specific for normal ankle kinematics (**a**) [26] and the FINE Total Ankle Arthroplasty kinematics (**b**)

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Alternate Incision Approaches to Revision Total Ankle Replacement

27

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. 27.1). 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 a 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 skin perforating vessels and the interconnecting subdermal network between the skin perforators (Fig. 27.1). 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. 27.2 and 27.3), 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

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_27

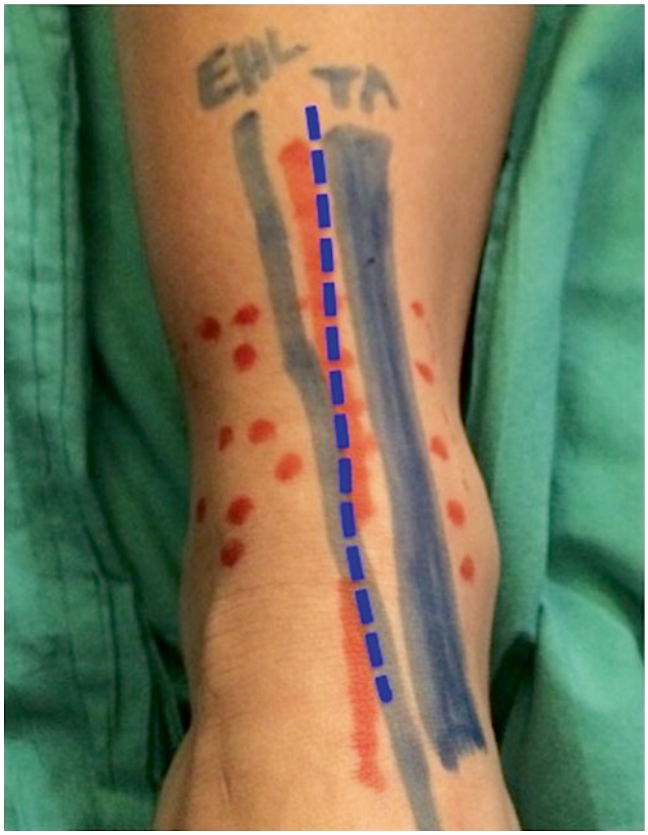

Fig. 27.1 Standard anterior incision for an anterior approach for TAR (*blue dashed line*). The incision is generally centered between the extensor hallucis longus and the tibialis anterior tendons. The anterior tibial neurovascular bundle is usually situated between the extensor hallucis longus and tibialis anterior tendons. The *red dots* depict local potential skin perforators

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 form 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. 27.3). Tension on the skin from below can be relieved by

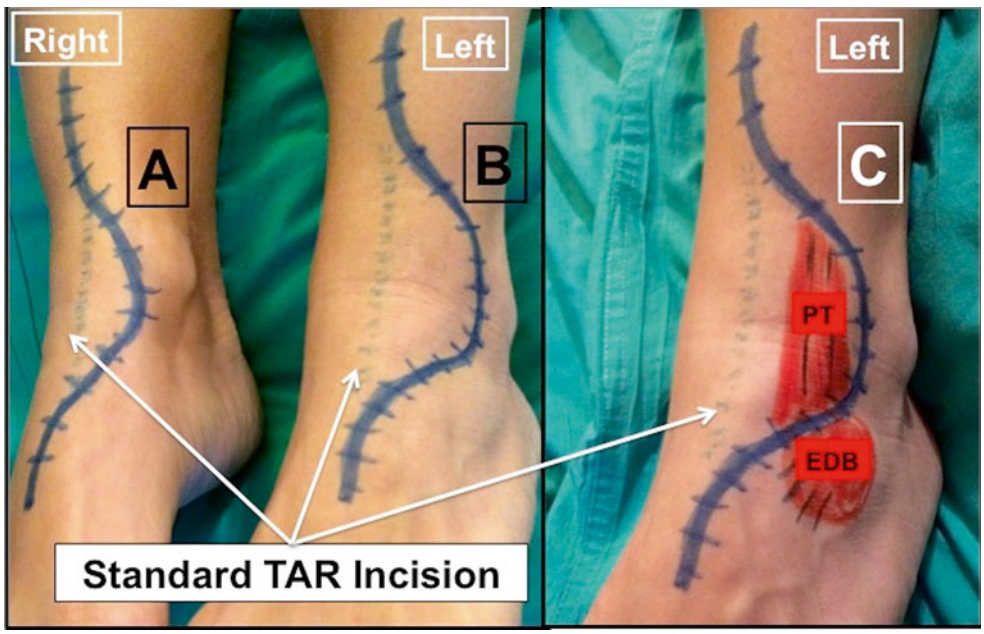

Fig. 27.2 Alternate anterior incisions to the ankle. Raising a large medial flap (**a**) may spare the area that breaks down along the tibialis anterior tendon. A large lateral flap (**b**) will allow access to the peroneus tertius muscle belly (**c**), as well as access to the extensor digitorum brevis muscle, which can also be an extremely useful source of local vascularized tissue

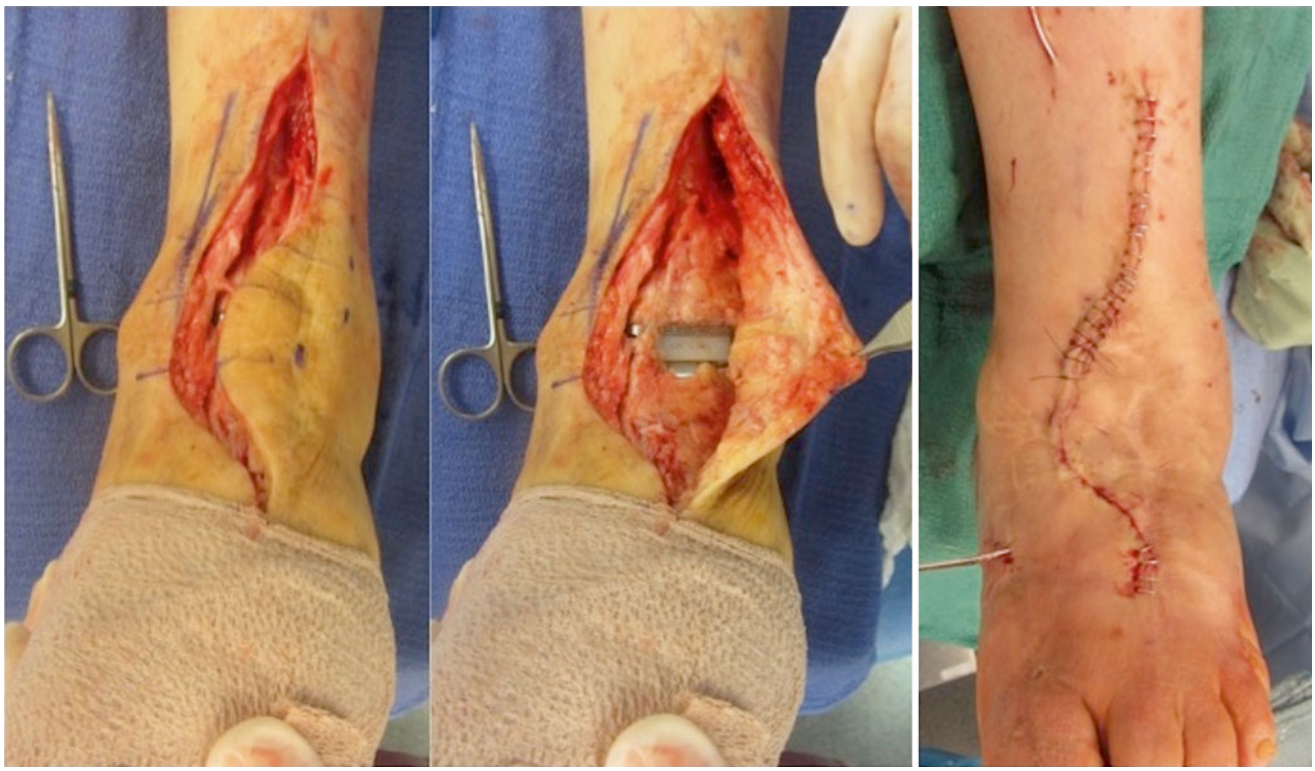

Fig. 27.3 Intraoperative photograph of lateral-based large skin flap incision for revision total ankle replacement in a patient with a poor anterior soft-tissue envelope

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 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. 27.2).

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–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, tibio-talocalcaneal 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. 27.4). 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. 27.5). 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. 27.5). Variations to the posterior approach include medial and lateral paramedian incisions (Fig. 27.6). 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 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. 27.7). 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. 27.8) 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

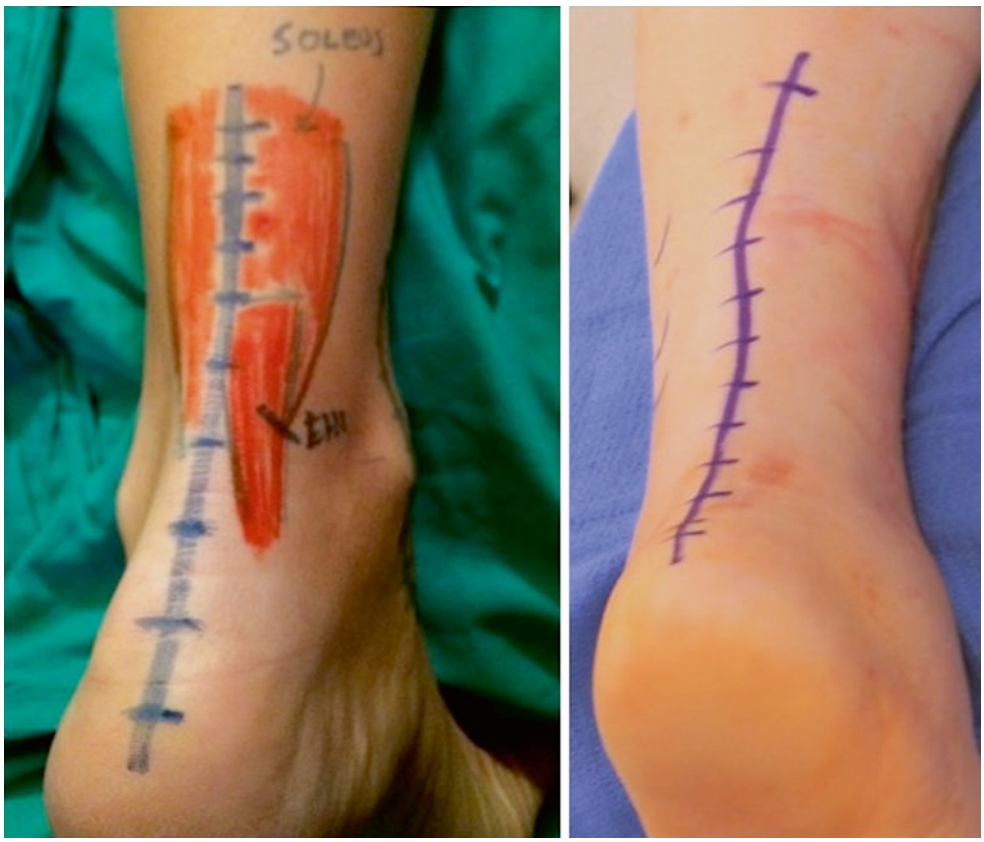

Fig. 27.4 Posterior midline approach for primary and revision total ankle replacement

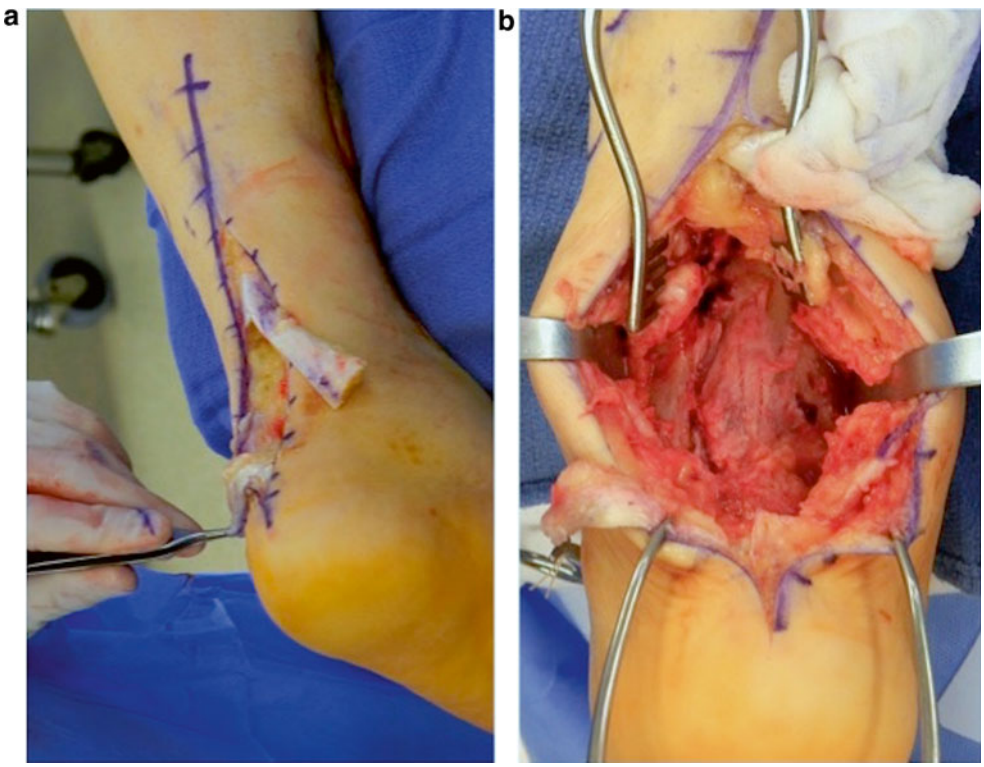

Fig. 27.5 After the posterior skin incision, the Achilles tendon is split in a "Z" fashion and retracted (**a**). Deep dissection continues with retraction of the posterior compartment muscles and tendons, exposing direct access to the posterior ankle and subtalar joints (**b**)

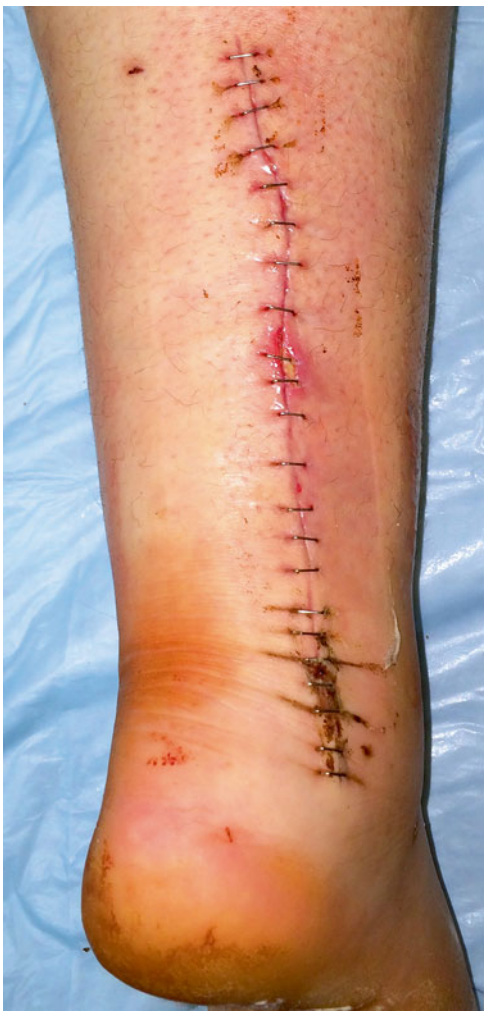

Fig. 27.6 The paramedian lateral variation of the posterior approach to the ankle is just slightly off the direct posterior midline; the same concept for incision placement holds for the paramedian medial incision, but a more medial approach puts the neurovascular bundle at greater risk for injury

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. Alternatively, a gastrocnemius recession may be performed. If the Achilles tendon was split, it is repaired by the surgeons' preferred technique, but 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, 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.

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 are 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.

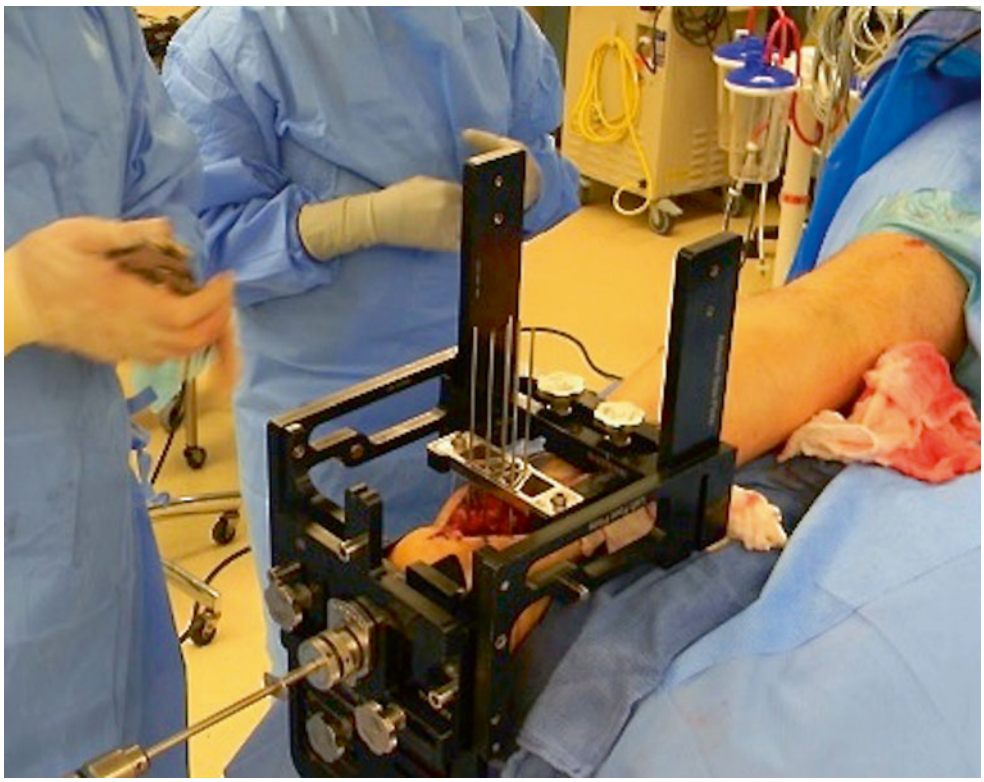

Fig. 27.7 Modified use of instrumentation is required for the posterior approach. This also necessitates more intraoperative C-arm image intensification to ascertain appropriate bone cuts and proper seating of the total ankle replacement components

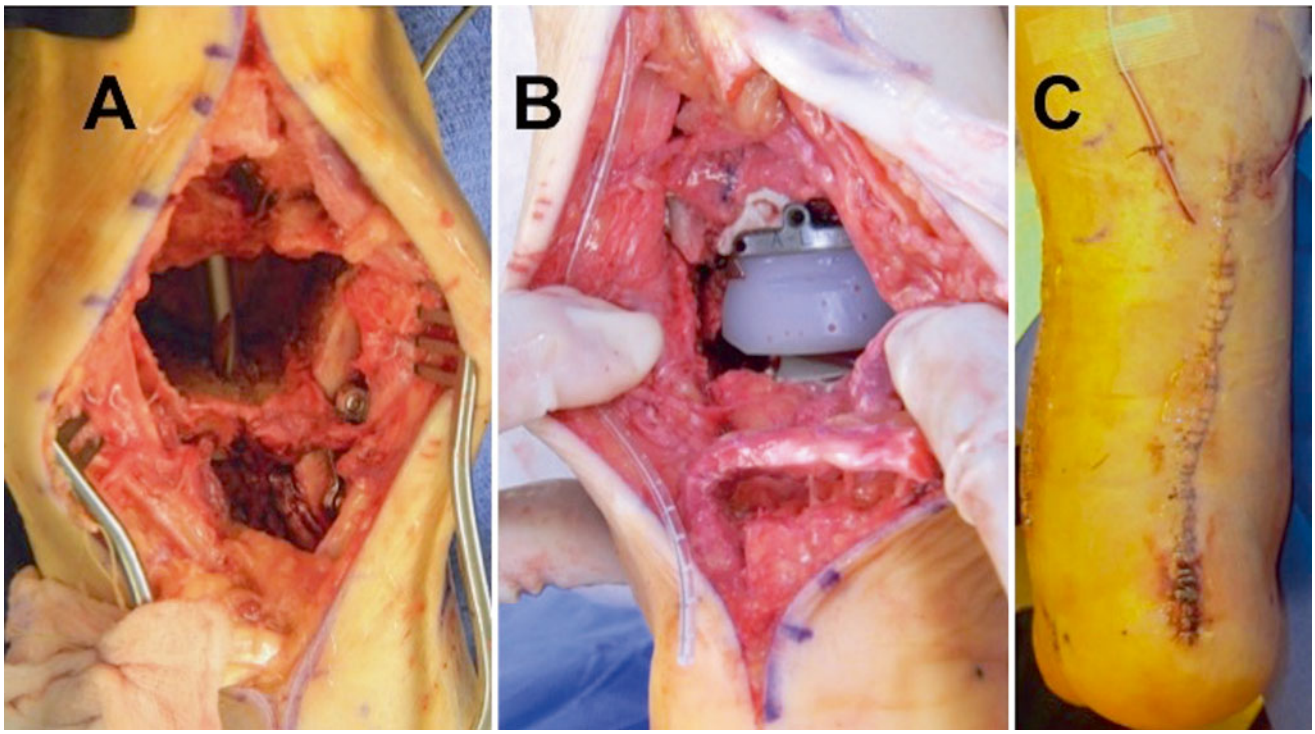

Fig. 27.8 Intraoperative photographs demonstrating the posterior approach for bone resection (**a**), final seating of the INBONE Total Ankle System prosthetic components implanted (**b**), and incision closure over drains (**c**)

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The Learning Curve Associated with Revision Total Ankle Replacement

28

Devin C. Simonson and Thomas S. Roukis

Introduction

The emergence, initial failure, and subsequent resurgence of total ankle replacement (TAR) as a viable alternative to ankle arthrodesis for the treatment of end-stage ankle arthritis are well documented [1–8]. Improved surgeon training and usage of current generation TAR systems have allowed for better patient outcomes, and as a result, foot and ankle surgeons competent in primary TAR have now achieved outcomes comparable to if not superior to ankle arthrodesis [1–13]. Without truth to these statements, the premise for this entire textbook would be lost; that being said, as with all new technologies and procedures, there certainly is a learning curve for surgeons during their initial use of various TAR systems [1–10, 12]. In the orthopedic realm alone, learning curves exist for nearly every procedure performed, with the closest comparison likely being found with total hip and knee arthroplasty. For these major joint replacements, the surgeon learning curve has been robustly studied. As we continue to embark further into the reality of primary TAR becoming commonplace, the same level of definition of the surgeon learning curve period for TAR is desired. Furthermore, with the growth of primary TAR comes a paralleled development of the need for surgeons proficient in revision TAR. In some instances, a foot and ankle surgeon may first encounter revision TAR as part of their practice, well before they ever implant their first primary prosthesis. Such a trend is not difficult to imagine as we are currently seeing the failures of previous generation prostheses present to the foot and ankle surgeon, and with these patients comes a reasonable yet often challenging goal of improving their lives. While it may seem reasonable to assume that the majority of complications leading to revision, re-revision, or prosthesis failure will occur during the surgeons' learning curve period, the lack of current literature defining this period warrants further discussion of this topic and is the purpose of this chapter.

The Learning Curve

First, we will begin with a word on the surgeon learning curve in general. As physicians and surgeons, we are constantly seeking to improve the lives of our patients through the procedures we perform. Specifically as it relates to TAR, we must navigate the often murky waters of new technology, as this entails new prosthesis designs and systems, improved imaging approaches, and a variety of ancillary procedures than can be performed in conjunction with TAR. There is little doubt that newer technologies regarding TAR may benefit patients; however, the effectiveness and safety of any new prosthetic system or approach are related at least in part to the surgeon's experience and training in using any particular new technology. Any novel surgical technique introduced will pose new challenges to even the most skilled surgeon. Therein may reside an ethical dilemma: does a surgeon need to disclose to the patient where he or she is on the learning curve for a particular prosthesis system or even TAR in general? Is it relevant to a patient's decision whether they are the first to undergo TAR by a surgeon or the hundredth? *Primum non nocere* is the Latin phrase depicting our primary obligation to our patients: first, do no harm. As part of this obligation, we must disclose all relevant risks to our patients, and certainly these can be numerous, even when excluding the inherent risks of new technology. In addition to the universal risks come those of the surgeon learning curve—the incremental risk of applying a new technique or prosthesis prior to becoming entirely facile with the new procedure. All surgeons are subject to the learning curve

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_28

when they attempt a new procedure or use an unfamiliar product. While many avenues exist to blunt the learning curve related to TAR, such as in-depth technique guides and training videos, educational courses—both those sponsored by various prosthesis manufacturers and those put forth by numerous medical associations—and dry and cadaver-based labs alike, there is no way to completely avoid the unique challenges and obstacles every surgeon must face when performing a new technique in the operating room. Unfortunately, there is no universal definition for how long it takes to emerge from the learning curve for a new technique—is it the first 10 cases, 25, 50, or more? Furthermore, will surgeons continue to improve without limit, or is there a natural plateau after the first 50 cases? Is there less risk to the 200th patient than that of the 100th? The answers to these questions most definitely depend on factors such as the complexity of the new technique or prosthesis system, the tolerance of the prosthesis to accommodate malalignment, as well as the individual surgeon's experience with similar procedures. Regardless, all surgeons performing TAR encounter complications in their learning curve period, and our duty as physicians is to ensure that our patients are actively aware of the risks for these complications. Furthermore, we must be our patients' greatest advocate by allaying fears derived from undesirable personal outcomes found on the Internet and dispelling marketing propaganda which may promise unrealistic patient outcomes in public advertisements. Quality patient care goes beyond disclosure of the risks of being within a surgeon's learning curve, as it includes taking concrete steps to reduce the patient's risks during this trial and error period. This is particularly true of surgeons in the beginning of their career, as those with less experience are more apt to make mistakes and have more complications. This notion applies to virtually all areas of life, not just to surgeons. In the book *Outliers: The Story of Success*, author Malcolm Gladwell suggests that making the transition from novice to expert may require in excess of 10,000 h of dedicated effort [14]. Suffice it to say, because the surgeon learning curve for TAR cannot be avoided, one must accept it and make every effort to navigate this period with precision so as to reduce the risk of complications for our patients.

Learning Curve Associated with Primary Total Ankle Replacement

Now that we have discussed the learning curve in general, we can analyze how it applies to TAR. The primary concern with a surgeon being in their learning curve would involve a potential for a higher incidence of complications associated with the procedure. Thus, if we could analyze the incidence of complications during a surgeon's learning curve for TAR, then we could compare this incidence with that of an established surgeon who is beyond the learning curve. This type of comparison would then offer insight into patient safety during the surgeon learning curve. If perhaps there was a significant, unacceptably high difference between surgeons either in or beyond their learning curve for TAR (or any particular procedure for that matter), then one could determine that further steps need to be taken to minimize the surgeon learning curve before it could be considered safe for the patient. Such measures could include having the supervision of a more experienced surgeon for the first *X* number of cases. If on the other hand, one found no significant difference or an acceptably low variance between surgeon groups, then it may suggest current measures in place to blunt the learning curve are sufficient.

At the time of publication of this textbook, the authors of this chapter had performed and submitted a systematic review of the world literature to determine the incidence of complications encountered during the surgeon learning curve period for their initial performance of primary TAR, regardless of specific prosthesis system employed. The search for potentially eligible information for inclusion in the systematic review yielded a total of 25 studies involving 2453 TARs (2414 patients) and 12 different TAR systems (Table 28.1) [1, 2, 4–13, 15–27]. Of the studies that included gender, there were 1142 (51.6 %) women and 1070 (48.4 %) men. The weighted mean age of the patients was 59.8 years (range, 18–89 years), and the weighted mean follow-up was 29.3 months (range, 1.5–240 months). The reported indication for primary TAR was most commonly posttraumatic arthritis (50.9 %) followed by primary end-stage arthritis (25.6 %), rheumatoid arthritis (16.5 %), and "other" (5.8 %), which included various inflammatory arthritides and pseudarthrosis, following attempted arthrodesis and hemochromatosis. The indication was not specified in 1.2 % of cases. Five complications consisted of deep vein thrombosis (DVT), which were excluded because this complication is germane to all surgery. Taking this into account, we then identified a total of 1085 complications reported during the surgeon learning curve period. This yields an overall incidence of complications of 44.2 % (1085/2453). Unfortunately, this covers a rather heterogeneous population, given the numerous studies with varied systems and techniques employed and included surgeons with significant experience with TAR who were trying a new system, as well as those entirely new to TAR altogether. To account for this concern, the authors further extrapolated the data to make it more meaningful. When broken down per specific TAR system employed, the incidence of complications was as follows: 60.8 % (141/232) for the Agility Total Ankle Replacement System (DePuy Synthes Orthopaedics, Warsaw, IN); 51.9 % (82/158) for the Hintegra Total Ankle Prosthesis (Integra, Saint Priest, France); 47.9 % (650/1356) for the Scandinavian Total Ankle Replacement System (STAR, Waldemar Link, Hamburg,

Table 28.1 Study data included in systematic review of primary TAR during the surgeon learning curve

Author	Year (EBM)	No. of patients	No. of ankles	TAR system (No.)	Total number of complications included	Designated early and late groups?
Myerson and Mroczek [4]	2003 (IV)	50	50	Agility	39	Y
Natens et al. [5].	2003 (IV)	25	27	STAR	10	
Saltzman et al. [15].	2003 (IV)	90	90	Agility	41	
Wood and Deakin [16]	2003 (IV)	200	200	STAR	90	
Buechel et al. [17]	2004 (IV)	112	115	BP	59	
Haskell and Mann [18]	2004 (IV)	187	187	STAR	79	Y
Murnaghan et al. [6]	2005 (IV)	20	22	STAR	9	
Schuberth et al. [7]	2006 (IV)	48	50	Agility	51	
Harris et al. [19]	2007 (IV)	138	138	AES	41	
Kumar and Dhar [8]	2007 (IV)	43	50	STAR	27	Y
Álvarez-Goenaga [20]	2008 (IV)	25	25	Hintegra	18	
Lee et al. [21]	2008 (III)	50	50	Hintegra	32	Y
Saltzman et al. [2]	2009 (II)	593	593	STAR	353	Y
Bai et al. [22]	2010 (III)	65	67	Hintegra	26	
Reuver et al. [9]	2010 (IV)	55	60	Salto	14	
Criswell et al. [23]	2012 (IV)	41	42	Agility	10	
Pinar et al. [24]	2012 (IV)	179	183	Salto (91), Hintegra (39), AES (20), Coppélia (17), STAR (11), Ramses (4), Akilé CLL (1)	52	
Bleazey et al. [10]	2013 (IV)	57	58	INBONE	14	
Brunner et al. [25]	2013 (IV)	72	77	STAR	12	
Clement et al. [1]	2013 (IV)	24	26	STAR (14), Salto Talaris (11), INBONE (1)	9	
Lee et al. [26]	2013 (III)	60	60	Mobility	13	Y
Noelle et al. [11]	2013 (IV)	97	100	STAR	22	
Schimmel et al. [12]	2013 (IV)	100	100	STAR	48	
Schweitzer et al. [27]	2013 (IV)	67	67	Salto Talaris	10	
Willegger et al. [13]	2013 (IV)	16	16	Hintegra	6	
Total	–	2414	2453	–	1085	6

Agility Total Ankle Replacement (DePuy/Synthes Orthopaedics, Inc, Warsaw, IN), Akilé CLL (Unknown Manufacturer, France), *AES* Ankle Evolutive System (Transysteme-JMT Implants, Nimes, France), *BP* Buechel-Pappas (Endotec, South Orange, NJ), *EBM* evidence-based medicine, Hintegra (Integra, Saint Priest, France), Coppélia (Unknown Manufacturer, France), INBONE total ankle replacement (Wright Medical Technology, Inc., Memphis, TN), Mobility (DePuy UK, Leeds, England), *No.* number, Ramses (Laboratoire Fournitures Hospitalières Industrie, Heimsbrunn, France), Salto Mobile Version Ankle Prosthesis (Tornier, Saint-Martin, France), Salto Talaris Total Ankle Prosthesis (Wright Medical Technology, Inc., Memphis, TN), Scandinavian Total Ankle Replacement (LINK STAR, Waldemar Link, Hamburg, Germany/Stryker Orthopaedics, Mahwah, NJ), *Y* yes

Germany/Stryker Orthopaedics, Mahwah, NJ); 29.7 % (41/138) for the Ankle Evolutive System (AES, Transystème-JMT Implants, Nimes, France); 24.1 % (14/58) for the INBONE I Total Ankle Replacement (Wright Medical Technology, Inc., Memphis, TN); 23.3 % (14/60) for the Salto Mobile Version Prosthesis (Tornier NV, Amsterdam, The Netherlands); 21.7 % (13/60) for the Mobility Total Ankle System (DePuy UK, Leeds, England); and 14.9 % (10/67) for the Salto Talaris Total Ankle Prostheses (Wright Medical Technology, Inc., Memphis, TN). The incidence of complications for the remaining 209 prostheses was 29.2 % (61/209) but could not be separated out by the specific TAR systems. An important designation among included studies lies within the separation of reported data into two patient cohorts: early and late. Studies that provide such a separation afford their audience a clear analysis of the assumed trend toward minimizing complications as the surgeon progresses through the natural learning curve period. Unfortunately, very few of the identified studies provided such a separation, with only 24 % (6/25) of the publications, involving 990 TAR prostheses, which designated the complications as occurring either early or late. For these studies alone, the incidence of complications was 54.9 % (543/990).

As previously stated, our review identified 1085 reported complications, yielding an incidence of complications encountered during the surgeon learning curve period for primary TAR of 44.2 %. This incidence as a whole is not necessarily appropriate to quote to patients during the preoperative discussion of potential risks involved in the procedure. Among the motley complications, there is a high degree of variable as

to severity and long-term consequence, as well as the array of specific TAR systems employed, all of which greatly devalues the discovered incidence. Because of this, further extrapolation of the data was performed so as to provide a more useful incidence of complications to both patients considering and surgeons performing primary TAR.

The most beneficial means of dividing the incidence of complications would be according to a classification system. In 2009, Glazebrook et al. [28] proposed a classification system based on the rate of failure for a given complication encountered during primary TAR published in the literature. While they admit the clinical significance of their classification system is questionable because the reliability had yet to be investigated at the time of publication, they found three categories of complications correlating with the likelihood of the complication leading to failure of primary TAR. These categories are low, medium, and high grade, which were described, respectively, as being very unlikely to cause TAR failure, lead to failure <50 % of the time, or lead to failure ≥50 % of the time. Low-grade complications included intraoperative bone fracture and wound healing problems; medium-grade complications included technical error, subsidence, and postoperative bone fracture; and high-grade complications included deep infection, aseptic loosening, and prosthesis failure. Most would agree that the rate of a complication progressing to failure carries more clinical importance than the general incidence of any complication because it better serves as an indicator of the severity of a particular complication.

Based on the collection of reported data above, nearly all complications could be categorized as described by Glazebrook et al. [28]. Out of the reported 1085 complications, 112 (10.3 %) were considered high grade, 209 (19.3 %) were medium grade, 588 (54.2 %) were low grade, and 176 (16.2 %) were unclassified. The unclassified complications included nerve and tendon injuries and could certainly be considered "technical error," thus classifying them as medium-grade complications; however, these specific injuries are not explicitly defined in their manuscript. With these separate incidences, based on the number of complications encountered from the entire cohort included in the data of our systematic review, a foot and ankle surgeon new to primary TAR could reasonably expect the overall incidence of high-, medium-, and low-grade complications encountered during their initial learning curve period for primary TAR to be 4.6 % (112/2453), 8.5 % (209/2453), and 24 % (588/2453), respectively, and the incidence of encountering an unclassified complication (specifically nerve or tendon injury) to be 7.1 % (176/2453).

As is the case with most meaningful classification systems, another group sought to investigate the reliability of the literature-based classification system proposed by Glazebrook et al. [28]. In 2014, Gadd et al. [29] did so based on their tertiary referral center in the UK. Their published data of 212 primary TARs revealed an incidence of revision of 17 % ($n=36$). However, as opposed to Glazebrook et al. [28], Gadd et al. [29] found that every complication aside from intraoperative bone fracture and wound healing problems led to prosthesis failure ≥50 % of the time. Based on their data, they proposed a simplification of the Glazebrook et al. [28] classification system, reducing the number of grades of complications to two: high and low. The low-grade complications are the same as the original system, with both intraoperative bone fracture and wound healing problems being considered unlikely to lead to implant failure. The remaining possible complications would then be classified as high grade, as they were found to lead to implant failure in ≥50 % of cases. Turning our attention one last time to our review of the world literature, based on the revised classification system proposed by Gadd et al. [29], out of the same reported 1085 complications identified above, 321 (29.6 %) were considered high grade, 576 (54.2 %) were low grade, and 176 (16.2 %) were unclassified, which again included nerve and tendon injuries. Utilizing the two-tiered system proposed by Gadd et al. [29] would suggest a nearly threefold increase in the incidence of complications leading to prosthesis failure as compared with the results when categorized using the three-tiered system by Glazebrook et al. [28]. While Gadd et al. [29] agreed that a validated classification system would improve consistency in reporting primary TAR complications, they found the proposed three-tiered system by Glazebrook et al. [28] to be unreliable. The authors of this chapter certainly agree that timely recognition and treatment of all complications are imperative, and regardless of the varied classification systems of Glazebrook et al. [28] and Gadd et al. [29], prompt recognition of these concerns will reduce the likelihood of primary TAR failure and poor clinical outcome.

An attempt to summarize our review data suggests an overall incidence of complications during the surgeon learning curve period for primary TAR is roughly between 45 and 55 %, with an increase up to 60 % depending on the specific prosthesis utilized. However, when deciphering the significance of these complications, there are two classification systems that are proposed to identify those complications that are likely to lead to failure of the prosthesis (i.e., high-grade complications). Based on these systems, the incidence of encountering a high-grade complication during primary TAR is somewhere between 10 and 30 %, depending on the classification system used to delineate high-, medium- and low-grade complications.

Learning Curve Associated with Revision Total Ankle Replacement

Thus far, we have discussed the incidence of complications associated with primary TAR during the surgeon learning curve. However, it is equally if not more important to discuss how it pertains to revision TAR, given revision surgery, regardless of location in the body, universally proves more involved and often caries higher risk. As already stated, with rising frequency in which foot and ankle surgeons are performing primary TAR, revision TAR will likely become more commonplace. Such a pattern has already been clearly shown over time in the Norwegian Arthroplasty Register [30]. Accordingly, it is imperative that we establish a standard by which we can measure the safety of revision TAR as determined by the incidence of complications encountered. Currently, the world literature is significantly void of studies assessing the incidence of complications during the surgeon learning curve period for revision TAR.

As of the time of publication of this text, the US public can receive only one of nine metal-backed fixed-bearing cemented TAR devices that are 510(k) cleared and one three-component mobile-bearing uncemented device approved by the US Food and Drug Administration (FDA) for general use. The seven metal-backed fixed-bearing cemented TAR devices that have been FDA cleared for use are (1) Agility and Agility LP Total Ankle Replacement Systems (DePuy Synthes Joint Reconstruction, Warsaw, IN); (2) INBONE I, INBONE II, and INFINITY Total Ankle Replacement Systems (Wright Medical Technology, Inc., Arlington, TN); (3) Eclipse (Integra LifeSciences, Plainsboro, NJ); (4) Salto Talaris Anatomic Ankle Prosthesis and Salto Talaris XT Revision Ankle Prosthesis (Wright Medical Technology, Inc., Arlington, TN); and (5) Zimmer Trabecular Metal Total Ankle (Zimmer, Inc., Warsaw, IN). Additionally, one three-component mobile-bearing uncemented TAR has received FDA pre-market approval for use: the Scandinavian Total Ankle Replacement System (STAR System, Stryker Orthopaedics, Mahwah, NJ).

The Agility Total Ankle Replacement System was the only US FDA-cleared ankle replacement readily available in the USA until 2007 [31]. As a result, the Agility Total Ankle Replacement System was the most widely implanted ankle replacement in the USA for over a decade. It is now common knowledge that the Agility Total Ankle Replacement System was unforgiving as a primary prosthesis. As previously discussed, a review of publications specific to the complication rate associated with primary implantation of the Agility Total Ankle Replacement System during the surgeon learning curve period reveals an incidence of complications of 60.8 % (141/232) [4, 7, 15, 23]. Looking back to the aforementioned classification systems proposed by both Glazebrook et al. [28] and Gadd et al. [29], categorical division of these complications associated with the Agility Total Ankle Replacement System reveals that 14.2 % of the complications were considered high grade, 29.1 % were medium grade, and 50.3 % were low grade according to Glazebrook et al. [28], while according to Gadd et al. [29], 43.3 % were considered high grade and 50.3 % were low grade. Both classification systems found an incidence of unclassified complications of 6.4 %, and these consisted of nerve and tendon injuries.

We should take a moment to acknowledge that the above-mentioned classification systems [28, 29] were initially designed to categorize complications associated with primary TAR and to assess the likelihood of prosthesis failure. Furthermore, they are both yet to be validated classification systems. This could lead one to question our application of these systems to the realm of revision TAR; however, these are the only available classification systems of their kind, and in general, the risks of complications for both primary and revision TAR are quite similar, regardless of the specific prosthetic components employed. Another noteworthy mention is that although Glazebrook et al.'s [28] classification system involved a large portion of Agility Total Ankle Replacement Systems, Gladd et al.'s [29] classification system did not. Taking this all into account, the prognostic value of these classification systems on predicting future failure of the revised Agility and Agility LP Total Ankle Replacement Systems remains unanswered.

Because there is a paucity of data available in the current world literature that would be useful in determining the incidence of complications in the perioperative period during the surgeon learning curve period with revision TAR, the authors performed an observational case series at our institution to shed some light on the matter. Our series involved a retrospective review of prospectively collected data of the first 32 consecutive revision procedures performed by the senior author of this chapter for the management of failed primary Agility and Agility LP Total Ankle Replacement Systems at our facility between October 2010 and August 2014. The senior author currently serves as the director of the TAR surveillance program at our facility, and he inherited a practice that involved 192 primary implantations of the Agility or Agility LP Total Ankle Replacement Systems. These TARs included 68 (35.4 %) original, 70 (36.5 %) posterior augmented, 38 (19.8 %) LP, and 16 (8.3 %) revision (used for primary TAR) talar components. Of note, one replacement was performed by a surgeon at an outside healthcare center, while the remaining 191 primary replacements were performed by a single surgeon at our facility prior to retiring. It should be noted that none of the primary Agility or Agility LP Total Ankle Replacement Systems had polymethylmethacrylate (PMMA) cement fixation, despite this being included in the surgeon technique guides [32, 33].

While the severity of pathology and/or persistent pain indicative of implant failure varied among our patient population, all were found to be at significant risk for impending catastrophic consequences if TAR revision was postponed or avoided altogether. Comparison of serial weightbearing radiographs over time during the preoperative evaluation revealed that 18 of the 32 (56.3 %) patients demonstrated progressive aseptic osteolysis ≥5 mm of the tibia, fibula, or talus [34]. When found in the tibia, it predominantly involved the medial malleolus or syndesmosis. For those with aseptic osteolysis of the fibula, it generally involved the lateral sidewall of the tibial component, and with those involving osteolysis of the talus, this was usually found in the neck, adjacent to the site of the half pin placed during external fixation application. Six of 18 patients with osteolysis were considered massive osteolysis, meaning there was ≥15 mm, and also involved a cortical breach of the adjacent bone. Eight patients exhibited ≥5° progressive varus or valgus component malalignment. We found clinically significant lateral ankle instability which was uncontrolled by prescription brace therapy in three patients. Deep periprosthetic infection was present in two patients. Syndesmosis nonunion was found in two patients. A single patient presented with multiple periprosthetic midfoot fractures following a traumatic injury. At the time of TAR revision, 29 (90.6 %) patients had documented talar component loosening with eight (27.6 %) of these patients also exhibiting loosening of the tibial component. Twenty-three patients (71.9 %) underwent component revision of the ultrahigh molecular weight polyethylene (UHMWPE) insert and talar component to either an LP or revision design using the Agility Total Ankle Replacement Systems. Eight (25 %) patients with massive osteolysis and/or severe ≥15° varus deformity underwent explantation of the Agility Total Ankle Replacement System and conversion to the INBONE II Total Ankle Replacement System. A single patient (3.2 %) underwent explantation of the Agility Total Ankle Replacement System and conversion to the Salto Talaris XT Revision Ankle Prosthesis. Table 28.2 highlights the details specific to each of these revision TAR procedures.

Patient demographics of the 32 revision Agility or Agility LP Total Ankle Replacement System procedures are as follows: 20 left ankles, 12 right ankles; 21 men, 11 women; mean age at the time of revision was 64.6 years (range 44–81 years); and mean follow-up was 13.6 months (range 0.2–38.4 months) (Table 28.2). There were no patients lost to follow-up.

Table 28.2 Case Series patient population data for revision TAR (n = 32 ankles in 32 patients)

Case No.	Index TAR specifics (tibia/talar component; UHMWPE insert)	Revision TAR specifics (tibia/talar component; UHMWPE insert)	Additional procedures [35–39]	Age at index TAR (years)	Age at revision TAR (years)	Laterality (L/R)	Gender (M/F)	Complications
1	LP; 0 mm	No UHMWPE		78	81	L	M	
2	LP; 0 mm	Custom stemmed LP talar; 0 mm		72	77	R	M	
3	Revision; +2 mm	Custom stemmed LP talar; +2 mm		36	44	R	F	
4	Original; 0 mm	Custom stemmed LP talar; custom stemmed augmented tibial; +1 mm	Evans PB lateral ankle stabilization [35]	57	70	R	M	
5	LP; 0 mm	Custom stemmed LP talar; +2 mm	Evans PB lateral ankle stabilization [35]	53	55	L	F	
6	Original; 0 mm	Conversion to INBONE II	Intraoperative ORIF medial malleolus, fibula, and talus Fx	61	78	R	F	Intraoperative Fx; nonhealing incision with 2°BKA
7	Original; +2 mm	Conversion to INBONE II	Metal-reinforced PMMA augmentation tibia [36] and talus [37]	45	52	L	M	
8	Posterior augmented; 0 mm	Conversion to INBONE II	Intraoperative ORIF medial malleolus and fibula Fx	59	68	R	M	Intraoperative Fx; dorsal foot neuritis
9	Posterior augmented; 0 mm	Revision; 1/2 column 0 mm	ORIF traumatic navicular Fx, cuneiform Fx, and cuboid Fx	60	68	L	F	
10	Revision; 0 mm	Conversion to INBONE II	Metal-reinforced PMMA [36, 37]; superficial peroneal neurectomy with muscle implantation	43	49	L	M	
11	Posterior augmented; 0 mm	Revision; +2 mm	Metal-reinforced PMMA tibia [36]; PMMA cement talus	70	80	L	M	

(continued)

Table 28.2 (continued)

Case No.	Index TAR specifics (tibia/talar component; UHMWPE insert)	Revision TAR specifics (tibia/talar component; UHMWPE insert)	Additional procedures [35–39]	Age at index TAR (years)	Age at revision TAR (years)	Laterality (L/R)	Gender (M/F)	Complications
12	LP; 0 mm	Revision; 0 mm	Metal-reinforced PMMA [36, 37] syndesmosis; PB to PL transfer	66	69	L	M	
13	Posterior augmented; 0 mm	Revision; 1/2 column 0 mm	Metal-reinforced PMMA tibia [36] and talus [37]; PT recession [38]; deltoid release	66	75	R	M	
14	Posterior augmented; 0 mm	Conversion to INBONE II	Metal-reinforced PMMA tibia [36] and talus [37]; intraoperative ORIF medial malleolus Fx	47	55	L	M	Intraoperative Fx
15	LP; 0 mm	Revision; mismatch	Metal-reinforced PMMA tibia [36]; Evans PB lateral ankle stabilization [35]; PT recession [38]	67	73	R	M	Delayed incision healing
16	LP; 0 mm	Revision; +1 mm	Metal-reinforced PMMA tibia [36] and syndesmosis; PB to PL transfer	61	64	L	M	
17	Posterior augmented; 0 mm	LP; +2 mm	Metal-reinforced PMMA tibia [36] and syndesmosis; Evans PB lateral ankle stabilization [35]	58	67	R	M	
18	Revision; 0 mm	LP; +2 mm	Metal-reinforced PMMA tibia [36]	66	76	R	M	
19	Original; 0 mm	LP; +2 mm		32	46	L	F	
20	LP custom stemmed posterior augmented talar; +2 mm	Conversion to INBONE II	Reverse Evans PB deltoid reconstruction [39]	36	46	L	F	
21	Posterior augmented; 0 mm	Revision; +2 mm	Metal-reinforced PMMA talus [37]	63	74	L	M	
22	Posterior augmented; 0 mm	LP; +2 mm	Metal-reinforced PMMA fibula and talus [37]; Evans PB lateral ankle stabilization [35]; PL to PB tendon transfer; PTT recession [38]; deltoid release	56	63	L	M	
23	LP; 0 mm	LP; mismatch	Metal-reinforced PMMA talus [37]	68	73	L	M	
24	Posterior augmented; 0 mm	LP; +2 mm	Metal-reinforced PMMA talus [37]	62	72	R	F	
25	LP; mismatch	Revision; 0 mm		62	66	R	F	Delayed incision healing
26	LP; 0 mm	LP; +2 mm	Evans PB lateral ankle stabilization [35]	39	48	L	F	
27	LP; 0 mm	LP; +1 mm	Metal-reinforced PMMA tibia [33]	42	48	R	F	
28	LP; 0 mm	LP; 0 mm	Metal-reinforced PMMA tibia [36]	51	56	L	M	
29	LP; 0 mm	Conversion to INBONE II	PTT recession [38]; deltoid release; tarsal tunnel release; PB Evans lateral ankle stabilization [35]; TAL	56	61	L	M	
30	LP; 0 mm	Conversion to INBONE II	Intraoperative ORIF medial malleolus Fx	52	57	L	M	Intraoperative Fx
31	LP; 0 mm	LP; mismatch	Metal-reinforced PMMA syndesmosis; reverse Evans PB deltoid reconstruction [39]; 1st MTPJ arthrodesis	73	79	L	M	
32	Posterior augmented; 0 mm	Conversion to Salto Talaris XT	Metal-reinforced PMMA tibia [36]/fibula; deltoid release; TAL	69	78	L	F	

Agility Total Ankle Replacement (DePuy Synthes Joint Reconstruction, Warsaw, IN), *BKA* below-knee amputation, *DOS* date of surgery, *F* female, *Fx* fracture, *INBONE II* Total Ankle Replacement (Wright Medical Technology, Inc., Memphis, TN), *L* left, *LP* low profile, *M* male, *mm* millimeter, *MTPJ* metatarsophalangeal joint, *NCJ* naviculocuneiform joint, *No.* number, *ORIF* open reduction internal fixation, *PB* peroneus brevis, *PL* peroneus longus, *PMMA* antibiotic-impregnated polymethylmethacrylate cement, *PTT* posterior tibialis tendon, *R* right, Salto Talaris XT Revision Ankle Prosthesis (Wright Medical Technology, Inc., Memphis, TN), *TA* tibialis anterior, *TAR* total ankle replacement, *TAL* percutaneous tendo-achilles lengthening, *UHMWPE* ultrahigh molecular weight polyethylene insert

While unrelated to the revision Agility or Agility LP Total Ankle Replacement, one patient died at 30 months postoperative; however, because regular surveillance through 2 years postoperative revealed no complications of the revision surgery, we deemed it appropriate to include this patient in our review. We encountered a total of eight complications (25 %), which are highlighted in Table 28.2. As we did above in our review of the complications associated with primary TAR, we categorically divided our complications based on both the classification system proposed by Glazebrook et al. [28] and the simplified system proposed by Gadd et al. [29]. Our findings were consistent with both systems, in that seven of the eight complications (87.5 %) were classified as low grade, which correlates with being very unlikely to cause subsequent TAR failure [28, 29]. The lone remaining complication (12.5 %) was unclassified and involved unresolved dorsal foot neuritic symptoms. We would like to highlight that no complications were considered high or medium grade, which again would correlate with a likelihood of leading to failure of the implant ≥50 % of the time or <50 % of the time, respectively [28, 29]. As we have discussed previously, there are inherent flaws in utilizing these classification systems for revision TAR; however, because both systems yielded the same number and category of complications for our data, we utilized these systems as a means of classifying our complications associated with revision of failed primary Agility and Agility LP Total Ankle Replacement Systems.

An important designation to be made when studying the learning curve includes comparison of the early and late groups of patients, so one can hopefully identify a trend toward minimizing complications over time. For our data, we compared the results of the first 16 patients (early group) with the next 16 (late group). Six of the eight complications (75 %) occurred in the early group, while only two (25 %) occurred in the late group, both of which consisted of minor wound healing problems that eventually healed conservatively. This downward trend with regard to complications over time revealed an overall incidence of complications 37.5 % (6/16) in the early group and 12.5 % (2/16) in the late group.

Coming back to our earlier discussion of both the Glazebrook et al. [28] and Gadd et al. [29] classification systems, our data revealed an incidence of low-grade complications according to both systems of 21.9 %. The incidence of unclassified complications (i.e., nerve damage) was 3.1 %. We did not encounter any high- or medium-grade complications in our series. For the sake of comparing our data with revision Agility or Agility LP Total Ankle Replacement to that of our previously discussed review of primary Agility Total Ankle Replacement System, the overall incidence of complications for our data was 25 % (8/32), while the incidence of complications during primary implantation of the Agility Total Ankle Replacement System was 60.8 % (141/232) [4, 7, 15, 23]. Although our complications were either low grade or unclassified according to both Glazebrook et al. [28] and Gadd et al. [29], those in the review of the literature for primary procedures revealed that 14.2 % of the complications were considered high grade, 29.1 % were medium grade, and 50.3 % were low grade under the Glazebrook et al. [28] system and 43.3 % were high grade while 50.3 % were low grade under the Gadd et al. [29] system. According to each classification system, 6.4 % of complications were unclassified. When compared to the incidence of complications encountered for primary implantation of the Agility Total Ankle Replacement System encountered during the surgeon learning curve period, our results during a single surgeon's learning curve period for revision Agility and Agility LP Total Ankle Replacement Systems were highly favorable and may suggest that these revision procedures can be accomplished safely when performed meticulously by a qualified foot and ankle surgeon.

Continuing our discussion of revision TAR, we will look elsewhere in the literature. Out of an original pool of 53 TAR patients with failed primary Agility Total Ankle Replacement System, Ellington and Myerson [40] were able to evaluate 41 patients following revision at a mean follow-up of 49.1 months (range 25.9–77.8 months). The authors reported that revision consisted of talar component replacement only in 36.6 % (15/41) and both tibial and talar component replacement in 63.4 % (26/41). Out of their cohort of 41 patients, two (4.9 %) underwent custom-design stemmed tibial component replacement, while 19 (41.5 %) underwent custom-design stemmed talar component replacement with concomitant subtalar joint arthrodesis. Ellington and Myerson [40] provided a grading system consisting of grades 1–3 in order to define the severity of talar component subsidence as well as predict outcome following revision TAR. They defined the grades as follows: Grade 1, minimal subsidence of the talar component; Grade 2, talar component subsidence into the talar body without violation of the subtalar joint; and Grade 3, migration of the talar component onto or through the subtalar joint. Using a multivariable linear regression analysis, they found that preoperative talar subsidence was a significant predictor of a good outcome following revision. Based on these results, McCollum and Myerson [41] concluded that for Grade 1 and early Grade 2 talar component subsidence involving the Agility Total Ankle Replacement System, revision may be achieved with the use of LP or revision talar components; however, for cases of severe subsidence associated with late Grade 2 and Grade 3 or with anticipated inability of the talus to support an LP or revision talar component, one should use a custom-design stemmed talar component [40, 41]. In our patient cohort, we had four patients who underwent conversion to custom-design stemmed LP talar components and concomitant subtalar joint arthrodesis with one of these including a custom-design

stemmed tibial component. Three of the four of these patients have done well clinically, and none of these had complications intraoperative or postoperative. One of the custom-stemmed talar components underwent progressive component migration over time and subsequently required explantation with conversion to an INBONE II Total Ankle Replacement System. Unfortunately, custom-design stemmed talar components for the Agility or Agility LP Total Ankle Replacement System are no longer available for clinical use due to FDA regulation, and the availability of this in the future remains uncertain [32]. We would like to acknowledge that the complexity of revision Agility Total Ankle Replacement is borne out by the fact that Ellington and Myerson [40], who were experienced with primary implantation of the Agility and Agility LP Total Ankle Replacement Systems, reported further revision in the form of tibio-talo-calcaneal arthrodesis with bulk allograft in five of their 41 (12.2 %) revision TAR patients due to progressive component migration with subsidence. Furthermore, two of their patients (4.9 %) required below-knee amputation as a complication of deep periprosthetic infection during revision TAR surgery. We did not encounter a failure of our revision surgery performed in our series; however, our results cannot be directly compared with those of Ellington and Myerson [40] because we focused on the incidence of complications encountered with revision of failed primary Agility and Agility LP Total Ankle Replacement Systems during the perioperative period and not clinical outcomes over time. Lastly, Myerson et al. [42] reported an incidence of deep periprosthetic infection following primary Agility and Agility LP Total Ankle Replacement Systems of 3.2 % (14/433) compared with 0.7 % (1/139) following primary Salto Talaris Total Ankle Prosthesis implantation. While we did not encounter the development of a deep periprosthetic infection after revision TAR, it is apparent that this remains a major concern for both primary and revision Agility and Agility LP Total Ankle Replacement, and efforts to minimize infection should be diligently followed.

The last form of revision TAR we will discuss is explantation of the failed Agility and Agility LP Total Ankle Replacement Systems with conversion to the INBONE II Total Ankle Replacement System, which has been reported previously and is considered a limb salvage procedure. DeVries et al. [43] reported an overall incidence of complications during their conversions of 64.3 % (9/14), with 13 performed through an anterior incision and one through a posterior incision. The mean age at time of revision was 65.2 years (range 45–79 years) for the eight men and six women included. The Agility Total Ankle Replacement System had been in place a mean of 7.8 years (range 3.5–23 years). As we have done with previous data, we were able to categorize the reported nine complications according to both the Glazebrook et al. [28] and Gadd et al. [29] classification systems. According to Glazebrook et al. [28], two of the nine complications (22.2 %) were high grade, and both involved deep infection, one (11.1 %) was medium grade consisting of malposition necessitating secondary alignment procedures and one (11.1 %) was low grade involving minor wounding. Five complications (55.6 %) were unclassified and involved the need for secondary neurolysis, minor asymptomatic subsidence, and "residual pain." The same complications were categorized according to Gadd et al. [29], revealing three high-grade (33.3 %), one low-grade (11.1 %), and five unclassified (55.6 %) complications. Our results compare favorably to those of DeVries et al. [43] as we had no incidence of high- or medium-grade complications, as well as fewer unclassified complications. Another study by Meeker et al. [44] reported an overall incidence of complications of 27.7 % (5/18) for 18 conversions performed through an anterior incision. The original Agility Total Ankle Replacement System had been in place a mean of 12.8 years (range 1.6–13.4 years). As with the previously discussed manuscript, we categorized each of the five complications reported by Meeker et al. [41] according to both the Glazebrook et al. [28] and Gadd et al. [29] classification systems, respectively. The Glazebrook et al. [28] system revealed that one of the five complications (20 %) was medium grade, which involved postoperative dislocation of the prosthesis, three (60 %) were low grade and all consisted of intraoperative fractures, and one (20 %) was unclassified and involved tibial nerve compression that required neurolysis. The only difference according to Gadd et al. [29] is that the postoperative prosthetic dislocation would be classified as high grade (20 %), while the three intraoperative fractures would remain classified as low grade (60 %), and the nerve compression would remain unclassified. Our results are more comparable with those of Meeker et al. [44] than DeVries [43]; however, once again, we report no high-grade complications according to either classification system. In yet another report of revision TAR involving conversion to the INBONE II Total Ankle Replacement System, Williams et al. [45] reported an overall incidence of complications of 31.4 % (11/35). All conversions were performed through the original anterior incision. The mean age at time of revision was 61.2 years (range 29–83 years) for the 20 women and 14 men included. The Agility Total Ankle Replacement System had been in place a mean of 4.1 years (range 0.6–9.4 years). According to both classification systems [28, 29], eight of the 11 complications (72.7 %) were low grade and involved six intraoperative fractures and two wound dehiscence problems. The authors do mention that the intraoperative fractures ultimately had no effect on outcome as reported. Of note, while the two patients with wounds were the only patients to have associated comorbidities (rheumatoid and diabetes mellitus), one ultimately required flap coverage by a plastic surgeon, while the other elected for a below-knee

amputation at 16-month post-revision. The remaining three complications (27.3 %) were unclassified, two of which involved tibial nerve compression and deep peroneal neuroma, which were treated with neurolysis and excision, respectively, while the third involved prosthesis dislocation noted at 6-week follow-up and required open reduction with medial and lateral osteotomies as well as a polyethylene exchange for a thicker component.

Conclusions

While extremely heterogeneous, the above discussions suggest a comparable incidence of complications encountered during revision TAR as to that of primary TAR, both during the surgeon learning curve period. Compilation of the above reviewed studies, including our own, suggests an incidence of complications during the surgeon learning curve period for revision TAR of roughly 35 %, which is a fair degree lower than what review of the world literature reveals for primary TAR, which is between 45 and 55 %. Perhaps of more significance than simply the data revealed above is the highlighted need for further research in this area so we can more clearly define the learning curve period for both primary and revision TAR and furthermore to analyze the incidence of complications for both periods. Moreover, a validated classification system for complications encountered during TAR regardless of prosthetic design is needed to allow for more standardized reporting of complications, irrespective of whether they are primary or revision TAR. Further still, more case series reporting on revision TAR complications during the initial learning surgeon learning curve period with separation of patient cohorts into early and late groups would then allow for systematic review and more homogenous analysis for a clinically significant incidence of complications during the revision TAR surgeon learning curve period.

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Revision of Failed Primary Agility and Agility LP Total Ankle Replacements

29

Thomas S. Roukis

Introduction

The Agility Total Ankle Replacement System (DePuy Synthes Orthopaedics, Warsaw, IN) was invented by Frank G. Alvine, MD, based on three specific areas of study: (1) CAD–CAM computer analysis of 100 normal ankle radiographs; (2) modes of failure of previous-generation total ankle replacement (TAR) systems, specifically component subsidence, impingement, and malalignment; and (3) surgical approach including accuracy of insertion and instrumentation including an external fixation device to tension the ligamentous structures [1, 2]. The design process started in 1978 and it was first implanted in a patient in 1985. It was subsequently marketed in 1992 as the "DePuy Alvine Total Ankle Prosthesis" [3]. Between 1985 and 2007, the implant went through a total of four generations and seven phases of implant improvement [1, 2, 4]. Of note, it was FDA 510(k) cleared only for use with polymethylmethacrylate (PMMA) cement fixation.

Between 1985 and 1998, several early phases of improvement occurred included thickening the tibial titanium component, augmenting the posterior dimensions of the tibial component, changing the metallurgy of the talus from titanium to cobalt–chrome, increasing the sizes from three to six, developing a rectangular "revision" talar component, and adding revision ultrahigh molecular weight polyethylene (UHMWPE) with an additional 2-mm thickness, as well as a half-column design for the 0-mm UHMWPE insert to make revision insertion of the bottom-loaded insert easier [4]. These changes were based on the continued effort of the inventor to refine the prosthesis and improve his patient's outcomes, as well as the release of the prosthesis to a select group of orthopedic surgeons in the USA in 1993 and their ongoing feedback. Following these changes, the prosthesis was made widely available to orthopedic surgeons starting in 1998 who completed a company-sponsored surgical skills course at the *American Academy of Orthopaedic Surgeons* Learning Center in Rosemont, Illinois. The Agility Total Ankle Replacement System was the only FDA 510(k)-cleared TAR readily available in the USA until 2007. As a result, the Agility Total Ankle Replacement System was the most widely implanted TAR in the USA for over a decade, and accordingly, complications began to surface predominantly involving three modes of failure: (1) syndesmosis nonunion and subsequent tibial component malalignment or loosening, (2) talar component subsidence, and (3) aseptic osteolysis [2, 4–17]. The last two modes of failure usually coincide. As a result, the next changes to the Agility Total Ankle Replacement System occurred in 2002 with alterations to the talar component making it 18 % wider and shortening the length of the fin, as well as adding the ability to create a custom-design long-stemmed talar component to replace lost height due to subsidence and cystic changes and perform concomitant arthrodesis of the subtalar joint [2, 18]. This was followed in 2003 by the ability to create a custom-design long-stemmed total talar replacement [2] and in 2004 with the use of a plate and screw construct to enhance syndesmosis union [19]. The final changes occurred in 2007 after surgeons and engineers developed the Agility LP Total Ankle Replacement System which included three major modifications: (1) the development of a broad-based "winged" and 2-mm-thicker talar component to reduce the incidence of subsidence with primary implantation, as well as allow for the ability to revise previously inserted talar components and corresponding shortening or "lowering the profile" of the tibial component side walls by 2 mm to accommodate the talar wings; (2) the ability to mismatch component sizes by upsizing one talar component relative to the tibial component thereby allowing for more precise insertion and revision capabilities since the tibial component

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_29

from an earlier generation can be left in situ and an LP talar component inserted with a bottom-loaded full-column +2-mm UHMWPE insert; and (3) the development of a front-loaded polyethylene locking mechanism with 0-mm (i.e., neutral) and +1-mm thickness making subsequent replacement easier [3, 20, 21].

Unfortunately, despite four generations and seven phases of implant modifications, the Agility and Agility LP Total Ankle Replacement Systems have essentially no modularity built in, and accordingly revision options are limited. As a result, since the introduction of other TAR systems into the US market, the Agility Total Ankle Replacement System has fallen into disuse. The Agility LP Total Ankle Replacement System does not appear to have gained any traction. The bulk of the volume of primary Agility Total Ankle Replacement Systems were implanted in the USA between 1999 and 2007 and the Agility LP Total Ankle Replacement System between 2007 and 2010 (Fig. 29.1). Therefore, it is reasonable to assume that surgeons unfamiliar with primary implantation of the Agility and Agility LP Total Ankle Replacement Systems will encounter patients with failure of these prostheses that would benefit from revision. Additionally, the Agility LP Tibial Tray is no longer being manufactured and foretells the end of the LP version as a primary TAR, as well as complicates revision options.

Complications Associated with the Agility and Agility LP Total Ankle Replacement Systems

It is well established that the Agility Total Ankle Replacement System was unforgiving as a primary TAR prosthesis. Although not definitive, the incidence of revision, defined as component replacement, ankle or tibio-talo-calcaneal arthrodesis with or without bulk allograft, or below-knee amputation (BKA) [22] after primary implantation of the Agility Total Ankle Replacement System, has been determined to be 10.2 % (240 revisions/2353 primary implants). In this detailed systematic review (updated in November 2013), 78.6 % of the revisions consisted of implant component replacement followed by arthrodesis (18.7 % of revisions) and BKA (4.7 % of revisions) [23, 24]. It should be noted that all studies included in this systematic review involved uncemented Agility Total Ankle Replacement System that is against the US FDA requirements for the 510(k) cleared use of this prosthesis. Further the prosthesis evaluated was the version available for use between 1998 and 2007, but the exact version of the talar component implanted (i.e., original, posterior augmented, revision) could not be determined. Data pertaining to the Agility LP Total Ankle Replacement System that became available for use in 2007 has not been published; however, a US FDA clinical trial [25] completed in November 2012

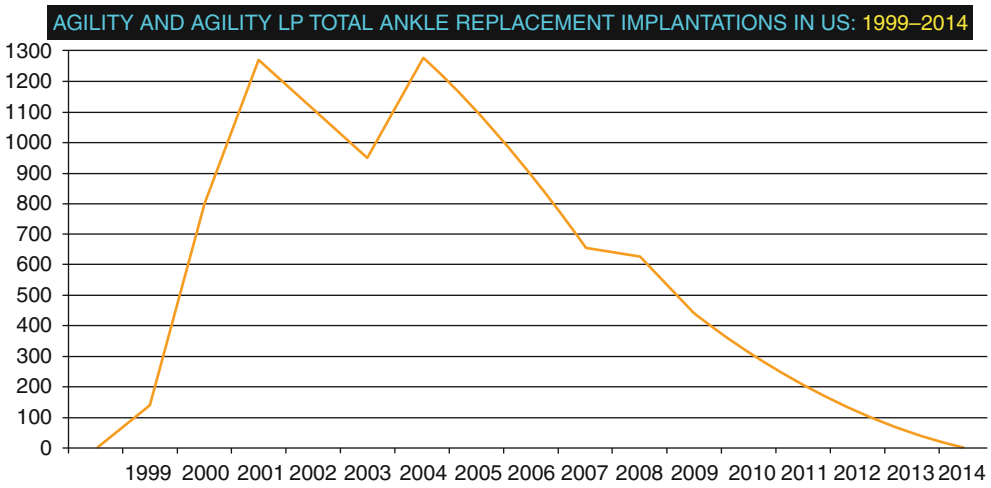


Fig. 29.1 Graph demonstrating the number of prostheses implanted per year between 1999 and 2014 for the Agility and Agility LP Total Ankle Replacement Systems. The total volume implantations are over 10,000 during this 15-year period of time. The nearly vertical rise in use between 1999 and 2001 corresponds with the release of the Agility Total Ankle Replacement System to orthopedic surgeons other than the inventors and paid consultants who attended a mandatory corporate training course. The reciprocal sharp drop in prosthesis use between 2001 and 2003 is likely due to appreciation of the unforgiving prosthesis design and associated complications encountered. Additionally, it was during this period that the type of surgeon (i.e., foot and ankle surgeon, total joint surgeon, general orthopedic surgeon, etc.) who would best perform TAR and the learning curve for TAR was being defined. The reciprocal sharp rise in use between 2003 and 2004 corresponds with the opening of the mandatory corporate training courses to podiatric foot and ankle surgeons in 2003. The slight flattening of the curve between 2006 and 2007 corresponds with the release of the Agility LP Total Ankle Replacement System. At present the only prosthesis components available are the bottom-loaded 0-mm and +2-mm UHMWPE inserts and revision talar components for the Agility Total Ankle Replacement System and the front-loaded 0-mm and +1-mm and mismatch UHMWPE and LP talar components for the Agility LP Total Ankle Replacement System. Accordingly, primary implantation of either system is no longer possible, and the available prosthesis components exist only as a legacy product intended for partial revision situations

determined an incidence of revision of 6 % (3/50) at a mean follow-up of 24 months. These authors noted radiographic findings of talar subsidence at final follow-up in 10 (20 %), both talar and tibial subsidence in 5 (10 %) and tibial subsidence in 1 (2 %). Since metallic component subsidence is a known potential precursor to revision, the overall incidence of metallic component subsidence of 32 % (16/50) is a cause for concern, and it would be beneficial for these authors to publish their medium- and long-term follow-up of these patients.

The development of aseptic osteolysis following primary implantation of the Agility and Agility LP Total Ankle Replacement Systems is the major cause of failure, increases with time, and results in loss of fixation of the prosthesis [2, 5, 7, 15, 17, 24, 25, 27–30]. In brief, this process involves a macrophage-mediated osteolytic destruction of periprosthetic bone secondary to phagocytosable UHMWPE wear debris [30–32] usually as a result of component malposition [33–37] or motion between the metallic components and bone [38] (Fig. 29.2). Specific to the Agility and Agility LP Total Ankle Replacement Systems, aseptic osteolysis about the tibial tray involves subsidence with or without component loosening [27–29, 39]. Aseptic osteolysis involving the talar component nearly universally involves subsidence and component loosening [27–29, 40]. The resultant bone loss can be quite extensive. The author has identified three general patterns of osteolysis that are encountered during revision of the Agility and Agility LP Total Ankle Replacement Systems (Figs. 29.3, 29.4, and 29.5).

A consistent finding during revision of the uncemented Agility and Agility LP Total Ankle Replacement Systems is the limited osseous ongrowth to the talar components regardless of design and the rather robust osseous ongrowth about the tibial tray keel for both designs (Fig. 29.6). Specific to talar component subsidence with the Agility Total Ankle Replacement Systems, Ellington et al. [41] provided a grading system from 1 to 3 to define the severity of talar component subsidence and predict outcome following revision. In Grade 1, there is minimal subsidence of the talar component. In Grade 2, the talar component has subsided into the talar body but has not violated the subtalar joint. Grade 3 is where the talar component has migrated onto or through the subtalar joint. Using a multivariable linear regression analysis, preoperative talar subsidence was a significant predictor of a good outcome following revision. Based on these results, McCollum and Myerson [29] concluded that the revision options for Grade 1 and early Grade 2 talar component subsidence involving the Agility Total Ankle Replacement System are to use the revision or LP talar components. For severe subsidence associated with late Grade 2 and Grade 3 or with anticipated inability of the talus to support a revision or LP talar component, the use of a custom-design long-stemmed talar component was determined to be effective [42–45]. Based upon surveillance of a large number of Agility and Agility LP Total Ankle Replacement Systems implanted, the author has further modified the Ellington et al. [41] talar component subsidence classification (Fig. 29.7). Specifically, Grade 3 has been divided into A where the talar component has migrated onto or through the subtalar joint and B where the talus is fractured and the talar component has migrated onto or through the subtalar joint. Additionally, frontal plane considerations have been added and include Valgus-A where the primary implant was inserted in valgus and Valgus-B where the distal tibiofibular syndesmosis fusion has gone on to nonunion and the tibial component has subsided into valgus. Finally, varus has been added where Varus-A where the primary implant was inserted in varus, Varus-B where the lateral ankle ligaments and/or peroneal tendons are incompetent and lateral ankle instability is appreciated, and Varus-C involves talar component subsidence into varus. The prognostic value of these additional subcategories has not been established, and accordingly, except for research purposes, their value remains a matter for conjecture.

General Considerations for Revision of the Agility or Agility LP Total Ankle Replacement Systems

At present there are no "standard principles" associated with revision of the Agility and Agility LP Total Ankle Replacement Systems, and instead this is very much a concept in evolution [2, 4, 8, 11, 12, 15–18, 27–29, 39–49]. What is clear is that the current approaches are technically very complex and fraught with complications, and no one approach represents the only answer.

Metallic Prosthetic Component Exchange Using the Agility or Agility LP Total Ankle Replacement System Components

The concept of tibial and/or talar metallic component exchange for revision of failed primary Agility Total Ankle Replacement System is an established approach reserved for situations where one of the metallic components is well bonded to the adjacent bone and well aligned while the other is loose, subsided, and malaligned or otherwise requires removal and revision replacement. Unfortunately, little information exists for the outcomes following metallic prosthetic component exchange with the Agility Total Ankle Replacement System. Gould [11] evaluated 27 talar and/or tibial implant component replacements of which 20 (74 %) were considered to have had "good" or "excellent" outcomes at 24 months postoperatively. Ellington et al. [41] were able

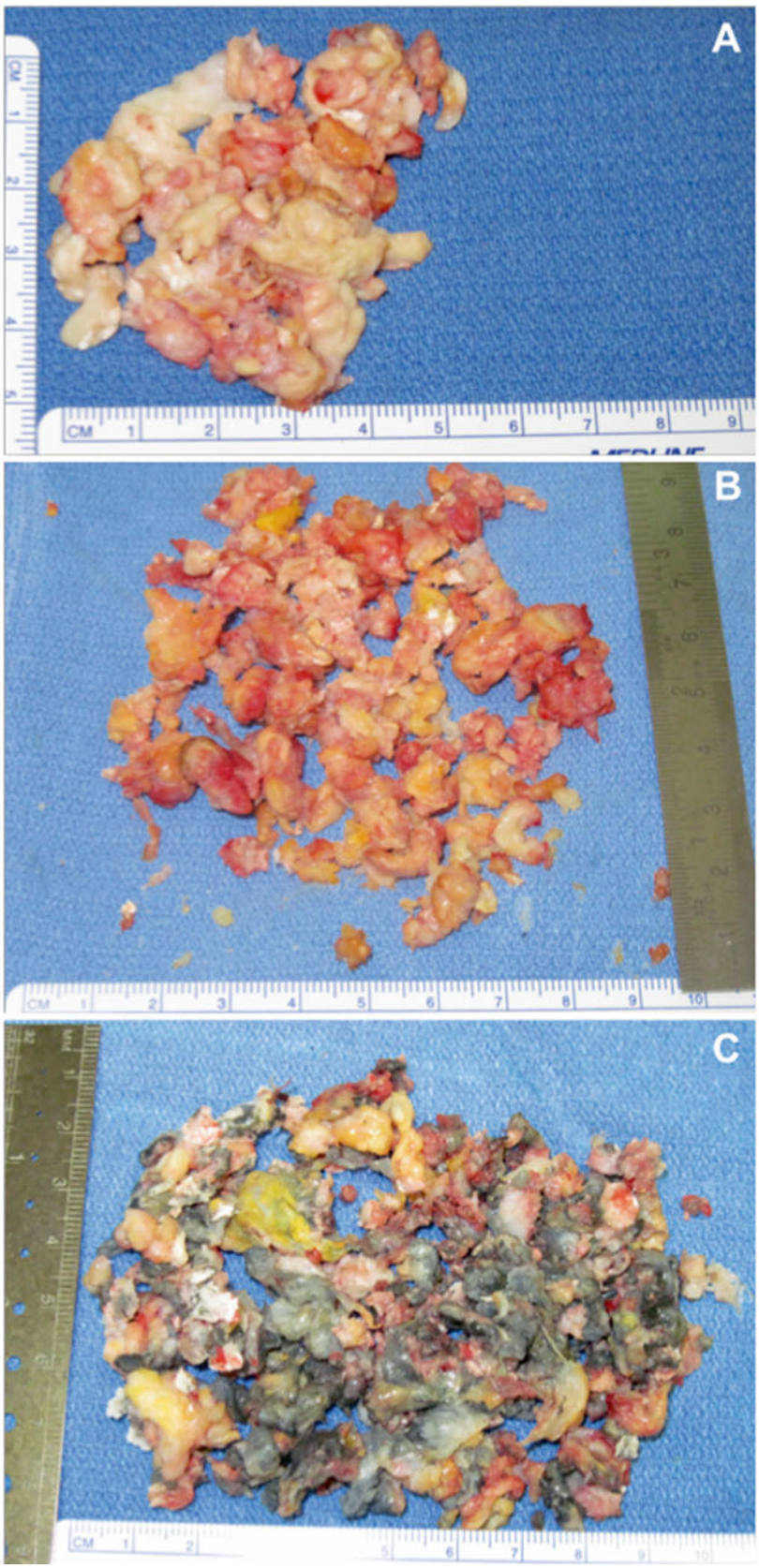


Fig. 29.2 Intraoperative photographs demonstrating three general patterns of osteolysis are encountered during revision of the Agility and Agility LP Total Ankle Replacement Systems. The first is associated with primarily prosthesis subsidence (**a**). Histopathologic analysis consistently reveals *pink-white* to *pink-purple* dense fibrous connective tissue scarring with foreign body reaction. The second is associated with osteolysis due to component loosening and UHMWPE insert wear associated cystic changes (**b**). Histopathologic analysis consistently reveals *golden-yellow* to pale *brown-gray* dense fibrous tissue with chronic inflammation and abundant granular histiocytes. The third is associated with osteolysis due to component loosening and wear of the titanium coating leading to extensive metallic debris, as well as UHMWPE insert wear associated cystic changes (**c**). Histopathologic analysis consistently reveals *pink-white* and *gray-black* fibromembranous tissue with foreign body giant cell reaction and fibrinous degeneration

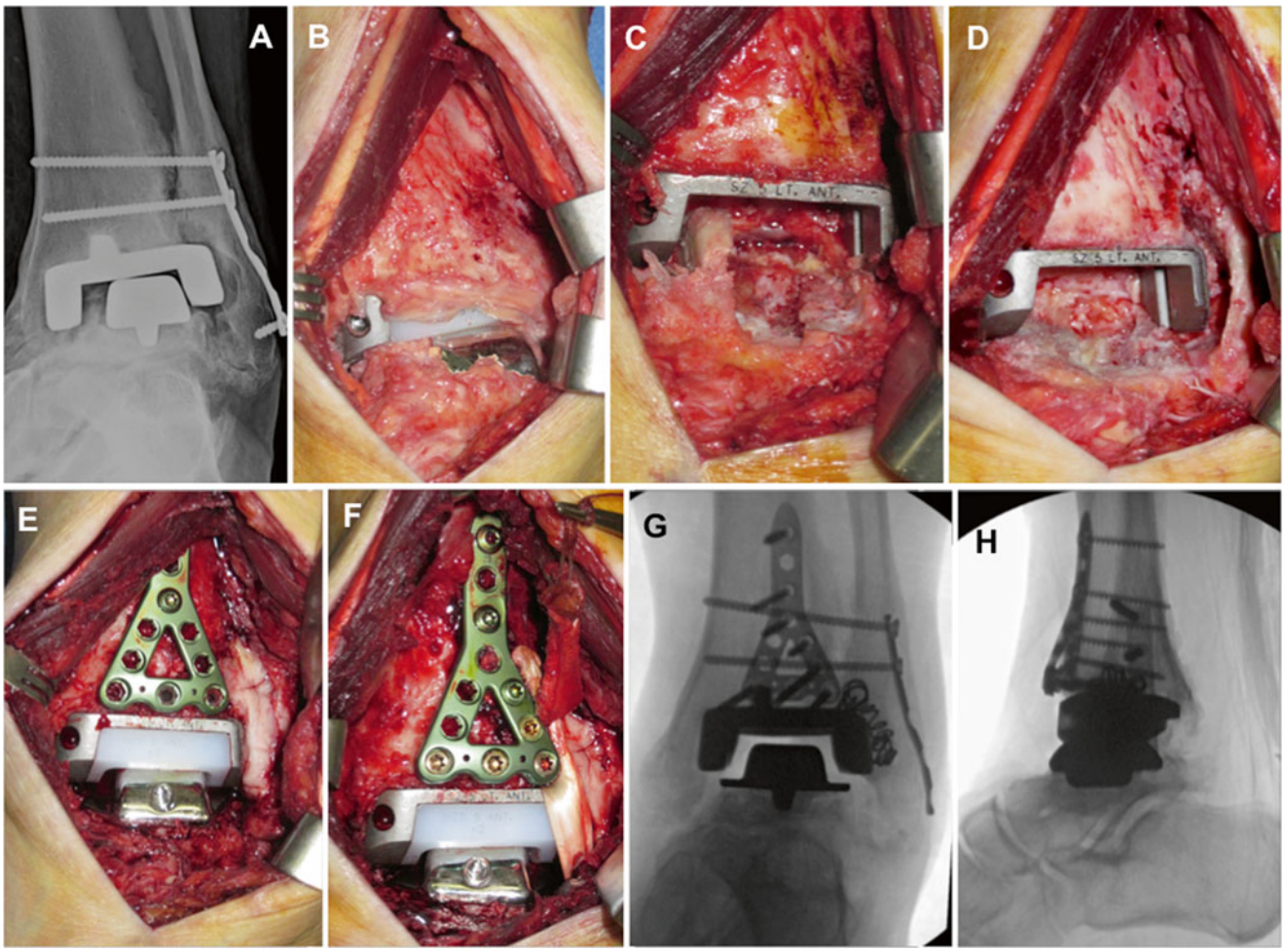


Fig. 29.3 Example of primary talar prosthesis subsidence. Mortise weight-bearing ankle radiograph (**a**) and intraoperative photograph (**b**) demonstrating posterior augmented talar component subsidence with lateral translation and varus malalignment, as well as tibial tray subsidence with valgus malalignment. Intraoperative photograph immediately following removal of the talar component and UHMWPE insert demonstrating the severe subsidence into the talus (**c**). Following sequential debridement, enough talar body remains anterior–posterior and medial–lateral to support conversion to an LP talar component (**d**). Intraoperative photograph following PMMA cement augmentation of the LP talar component, bottom-loaded full-column +2-mm UHMWPE insert, evacuation of the distal tibiofibular syndesmosis nonunion/osteolysis, and filling the residual osseous defect with metal-reinforced PMMA cement augmentation (**e**). Note the use of an anterior distal tibia plate and screw construct to both support the tibial tray realignment and anchor the modified Evans peroneus longus tendon transfer for lateral ankle stabilization (**f**). A deltoid release and posterior tibial tendon recession were also performed to provide medial soft-tissue release prior to lateral ankle stabilization. Anterior–posterior (**g**) and lateral (**h**) intraoperative image intensification views demonstrating well-aligned tibial tray and talar component with neutral frontal plane alignment

to evaluate 41 patients, out of an original pool of 53 patients with failed primary Agility Total Ankle Replacement System, following revision consisting of talar component replacement only in 36.6 % (15/41) and both tibial and talar component replacement in 63.4 % (26/41). Unfortunately, 46.3 % (19/41) of these revisions consisted of custom-made talar components, but the specific prosthesis survivorship was not provided. At a mean follow-up of 49.1 months, further revision in the form of tibio-bulk allograft-talo-calcaneal arthrodesis was required in 12.2 % (5/41) for progressive component migration with subsidence and BKA in 4.9 % (2/41) as a complication of deep periprosthetic infection.

Few TAR systems have readily available revision tibial and/or talar components. Compared to the original or posterior augmented talar components, the revision talar component for the Agility Total Ankle Replacement System is rectangular in shape with wide medial and lateral flanges, has a fin that is 1 mm less in height and length, and is between 1.5 and 2.8 mm thicker. Unfortunately, no published outcome data exists specific to this revision component despite unpublished finite element modeling supporting the design concept to limit talar subsidence [50].

The options for revision of the talar component depend on whether the failed system was an Agility or Agility LP Total

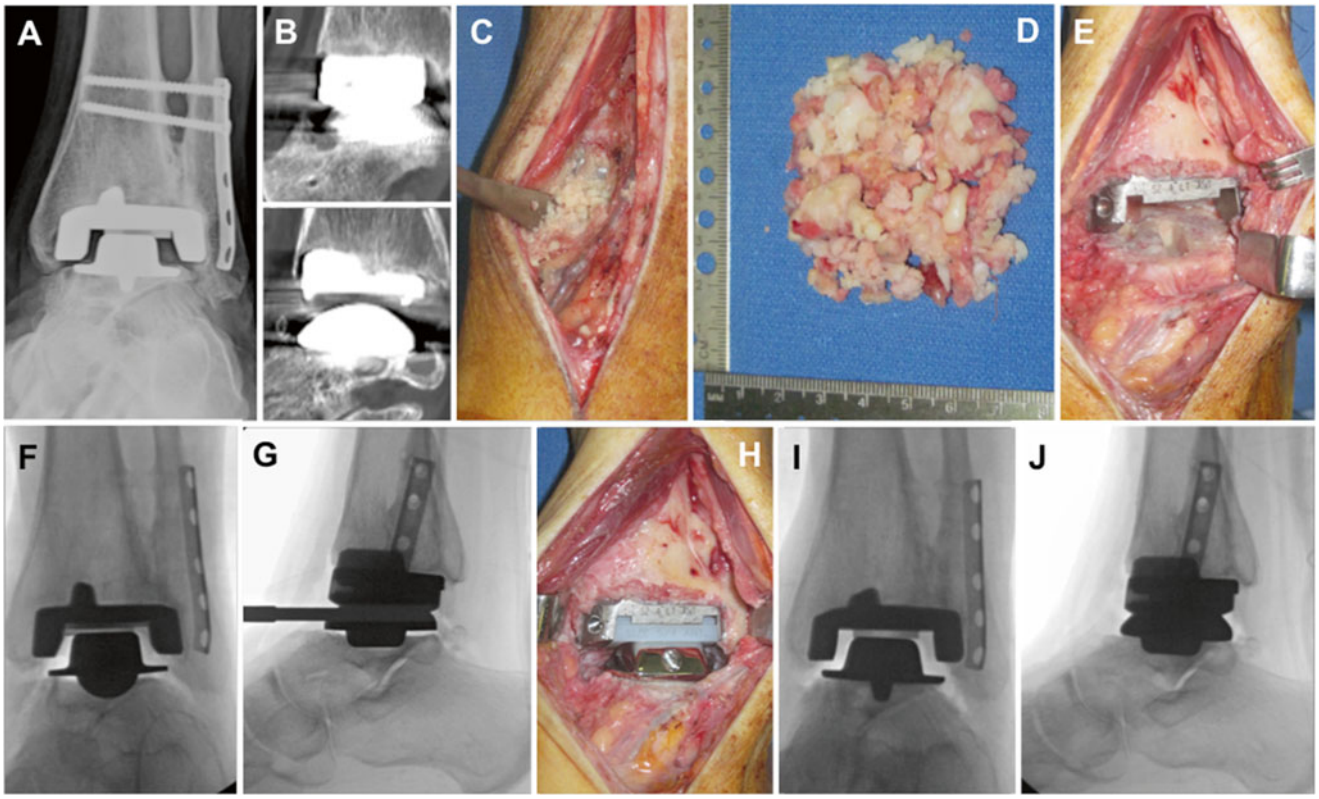


Fig. 29.4 Example of osteolysis due to component loosening and UHMWPE insert wear associated cystic changes. Anterior–posterior weight-bearing ankle radiograph (**a**) and sagittal computed tomography images (**b**) demonstrating size 4 LP talar component subsidence and talar osteolysis secondary to UHMWPE debris as encountered upon entering the ankle joint (**c**). Photograph of the extensive amount of UHMWPE debris that was resected (**d**). Intraoperative photographs following (**e**) removal of the talar component and UHMWPE insert demonstrating sufficient preserved medial and lateral talar body to support conversion to an upsized LP talar component as noted on anterior–posterior (**f**) and lateral (**g**) image intensification views with the trial size 5 LP talar component and front-loaded mismatch 5/4 UHMWPE insert. Intraoperative photograph (**h**) as well as anterior–posterior (**i**) and lateral (**j**) image intensification views demonstrating good talar component support following conversion to the upsized LP talar component and mismatch UHMWPE insert

Ankle Replacement System. The original and posterior augmented talar components are no longer available for use. It should be noted that the LP talar component has the same height and the same size as the original and posterior augmented talar components. However, the articulating top surface of the LP talar component is broader than these other designs and results in comparably less frontal and transverse plane motion [51]. Finally, several UHMWPE insert options exist depending on the specific version of the Agility or Agility LP Total Ankle Replacement System undergoing revision (Fig. 29.8). Specifically, if the failed system is an Agility Total Ankle Replacement System, then the revision options include (1) same-size revision talar component with bottom-loaded full- or half-column 0-mm UHMWPE insert (Fig. 29.9), (2) same-size revision talar component with bottom-loaded full-column +2-mm UHMWPE insert, or (3) same-size LP talar component with bottom-loaded full-column +2-mm UHMWPE insert (Fig. 29.10).

If the failed system is an Agility LP Total Ankle Replacement System, then the revision options include (1) same-size revision talar component with front-loaded 0-mm UHMWPE insert; (2) same-size revision talar component with front-loaded +1-mm UHMWPE insert (Fig. 29.11); (3) same-size LP talar component with front-loaded 0-mm UHMWPE insert (Note: this is only possible if the talar component subsidence is corrected back to its original state with the use of PMMA cement augmentation; otherwise, an unstable joint will result); (4) same-size LP talar component with front-loaded +1-mm UHMWPE insert; (5) one size larger revision talar component with front-loaded mismatch UHMWPE insert (i.e., retained size 4 LP tibial tray with size 5 revision talar component and size 5/4 mismatch UHMWPE

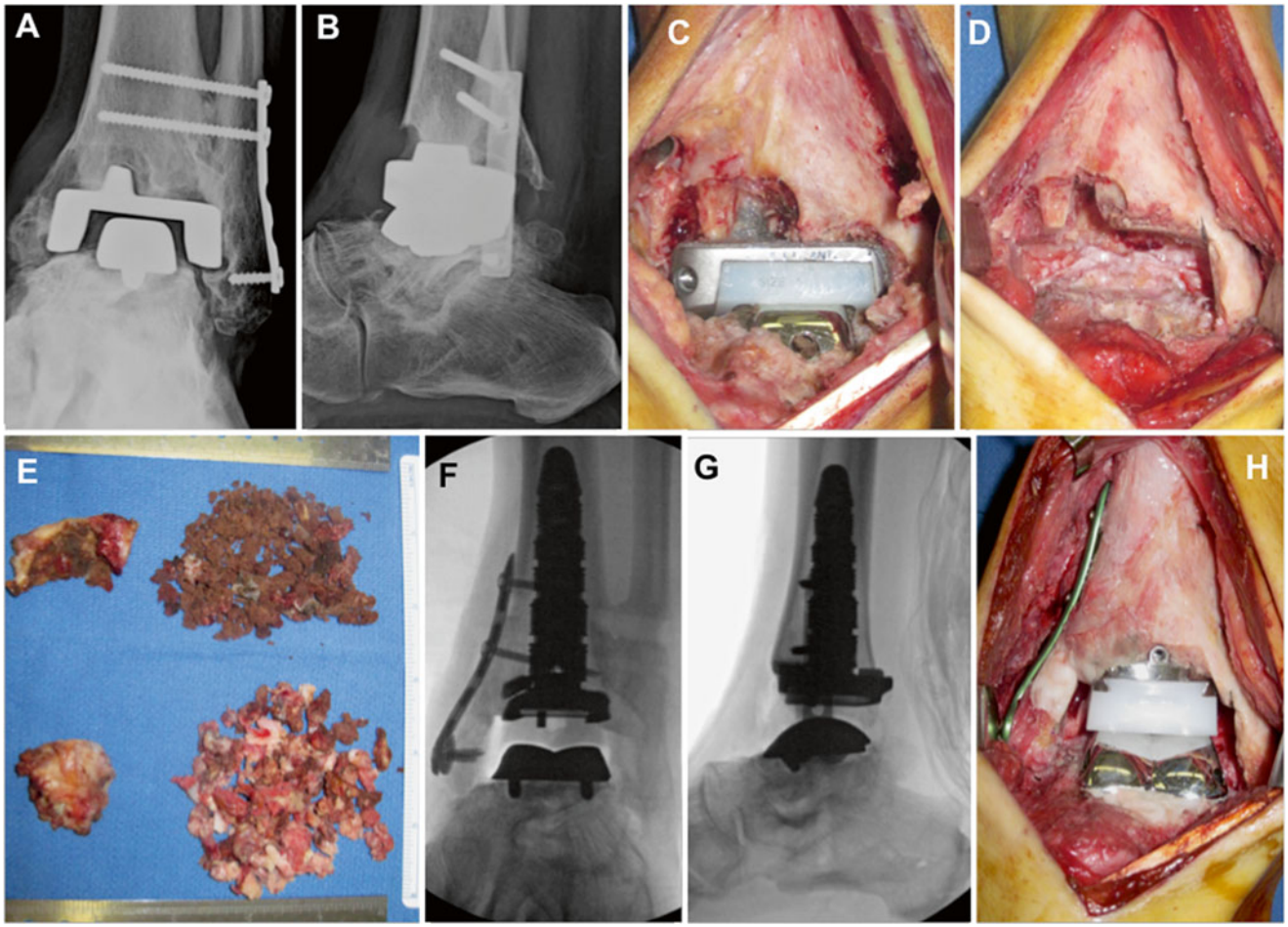


Fig. 29.5 Example of osteolysis due to component loosening and wear of the titanium coating leading to extensive metallic debris, as well as UHMWPE insert wear associated cystic changes. Anterior–posterior (**a**) and lateral (**b**) weight-bearing ankle radiographs, as well as intraoperative photograph (**c**) demonstrating posterior augmented talar component subsidence with massive cystic changes within the entire talus and distal medial–anterior tibia. Gross tibial and talar loosening was appreciated and upon removal revealed significant osseous defect (**d**) secondary to severe aseptic osteolysis caused by violent reaction to the UHMWPE debris (**e**). The talar material removed is at the bottom and the tibial material removed at the top of Figure E. Anterior–posterior (**f**), lateral (**g**) intraoperative image intensification views, and intraoperative photograph (**h**) following PMMA cement packing of the tibial and talar cysts and conversion to an INBONE II Total Ankle Replacement System. Note the use of a spanning plate about the medial malleolus to support the resection performed and lack of a talar stem due to the diminutive residual talar body

insert); and (6) one size larger LP talar component with front-loaded mismatch UHMWPE insert. It should be noted that the mismatch UHMWPE insert does not independently add any additional height. It is important to achieve proper talar height such that the medial and lateral ankle ligaments are properly tensioned [52] and the mechanical axis of the ankle joint is restored.

Viewed as a whole, it appears that approximately 75 % of Agility Total Ankle Replacement System requiring revision can be treated with metallic component exchange and 75 % of these will not require revision in the short term.

Metallic Prosthetic Component Exchange with Conversion to Agility LP Total Ankle Replacement System Custom-Design Long-Stemmed Components

One alternative component revision strategy is long-stemmed tibial and/or talar components [4, 18, 28–30, 42–46] that allow augmentation of segmental bone loss and spanning fixation into the calcaneus and/or tibial metaphysis. None of the commercially available TAR systems currently in use

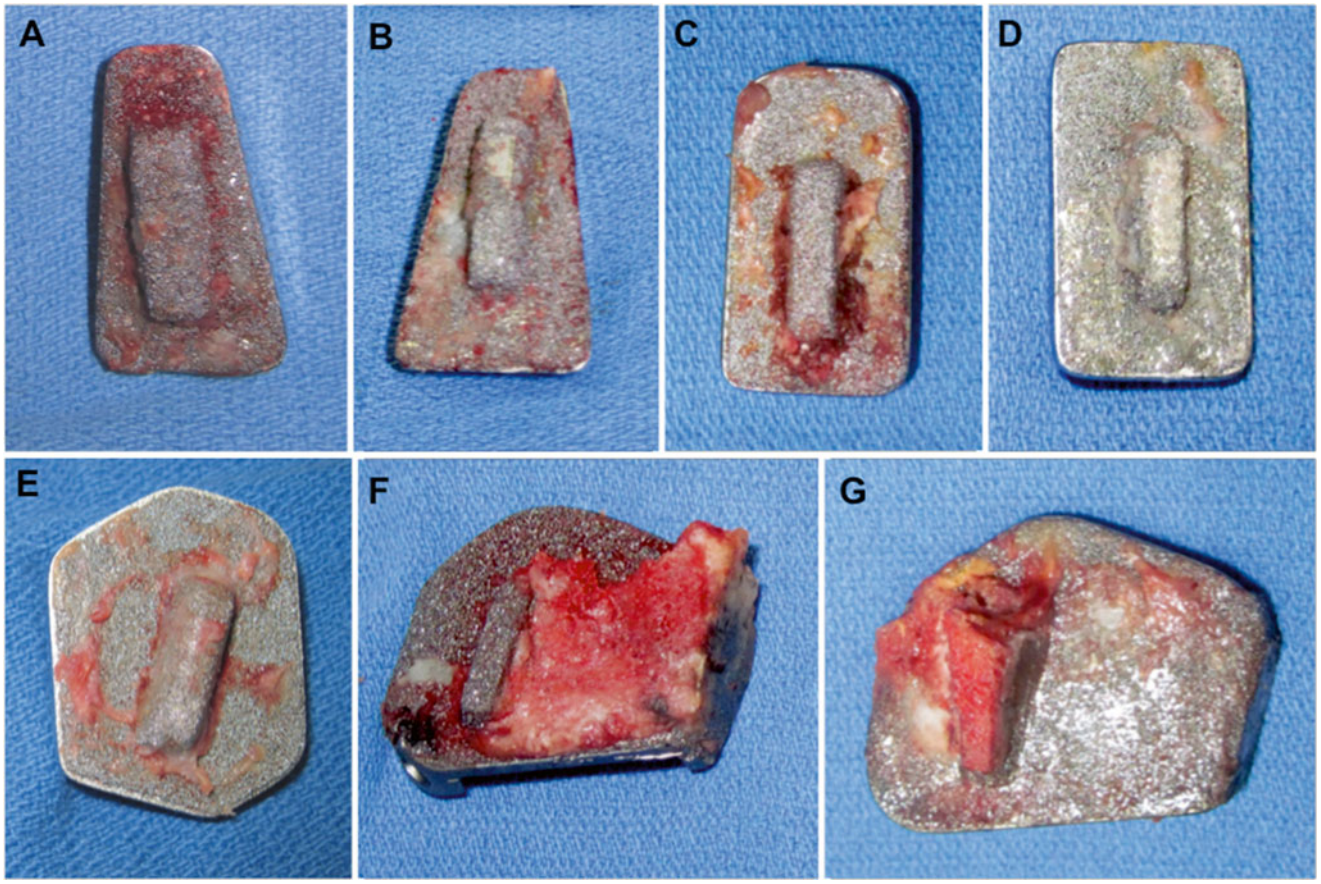


Fig. 29.6 Intraoperative photographs of the inferior surfaces of the original talar component for the "DePuy Alvine Total Ankle Prosthesis" (**a**); the original (**b**), posterior augmented (**c**), and revision (**d**) talar components for the Agility Total Ankle Replacement System, as well as the LP (**e**) talar component for the Agility LP Total Ankle Replacement System. A consistent finding during removal of these uncemented components is the lack of firm osseous ongrowth and instead limited "spot welds" of fibrous tissues between the components and underlying bone. Intraoperative photographs of the tibial tray superior surface for the Agility Total Ankle Replacement System (**f**, **g**). A consistent finding during removal of these uncemented components is the presence of very robust osseous ongrowth about the tibial keel requiring use of a power saw to safely separate the bone from the component

offer one-piece off-the-shelf long-stemmed tibial or talar components. Another option is the development of custom-design long-stemmed tibial and talar components based on specific individual patient needs. Alvine [4] described the use of a custom-design long-stemmed talar component in 2002 and a custom-design long-stemmed total talar replacement in 2003 for salvage of the failed Agility Total Ankle Replacement System. Alvine et al. [42] presented the use of custom-design long-stemmed talar components for 26 patients with complicated primary TAR or revision of failed Agility Total Ankle Replacement Systems and four patients with talar osteonecrosis. At a mean follow-up of 16 months, two ankles remained painful, one stem fractured, one chronic infection developed, and one BKA occurred. Similarly, Noriega et al. [44] described the use of custom-design long-stemmed talar components for 12 patients with takedown of prior ankle arthrodesis, complicated primary TAR, or revision of failed Agility Total Ankle Replacement Systems. Unfortunately neither Alvine et al. [42] nor Noriega et al. [44] provided separated data specific to those patients undergoing revision of failed Agility Total Ankle Replacement Systems, and accordingly the outcomes remain unknown. Out of an original pool of 53 patients with failed primary Agility Total Ankle Replacement System, Ellington et al. [41] were able to evaluate 41 patients following revision at a mean follow-up of 49.1 months. Out of the entire cohort, 4.9 % (2/41) underwent custom-design long-stemmed tibial component replacement, and 41.5 % (19/41) underwent custom-design long-stemmed talar component replacement. Further revision in the form of tibio-bulk allograft-talo-calcaneal arthrodesis was required in 12.2 % (5/41) for progressive talar component migration with subsidence and

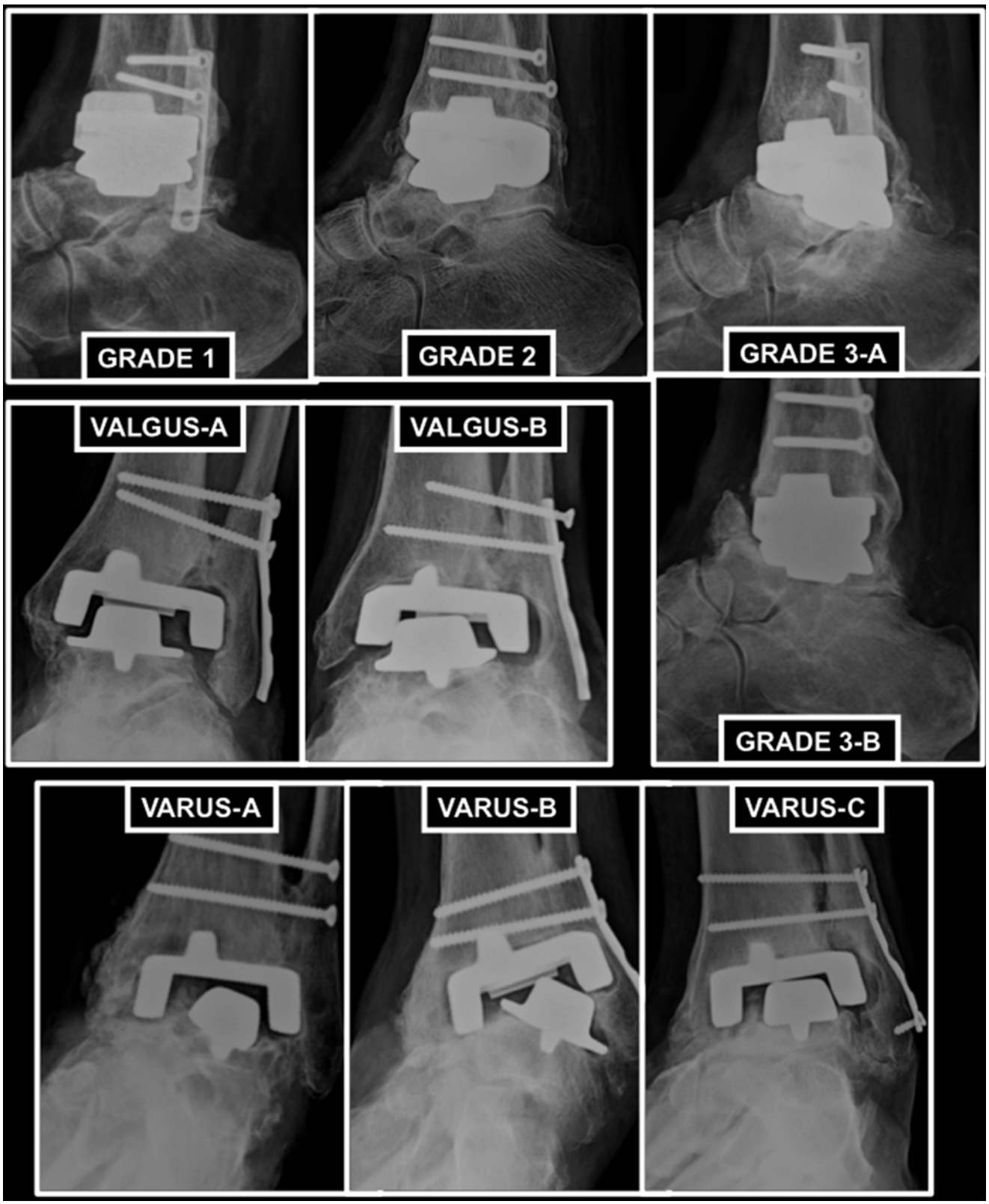


Fig. 29.7 Modified Ellington et al. [41] talar subsidence classification system. Lateral weight-bearing radiographs demonstrating (**a**) Grade 1 (no or minimal subsidence) and (**b**) Grade 2 (subsidence but not to the level of the subtalar joint) remain unchanged. Grade 3 includes A (talar component migration onto or through the subtalar joint) and B (talus is fractured with talar component migration onto or through the subtalar joint) subtypes. Frontal plane varus and valgus considerations have been added. These include Valgus-A (implant was inserted in valgus) and Valgus-B (distal tibiofibular syndesmosis arthrodesis nonunion with valgus migration of the tibial component), as well as Varus-A (primary implant was inserted in varus), Varus-B (lateral ankle ligaments and/or peroneal tendons are incompetent and lateral ankle instability is present), and Varus-C (talar component subsidence into varus)

UHMWPE Insert				LP Talar	Revision Talar
Size	0-mm	+1-mm	Mismatch		
1	3.7-mm	4.7-mm	3.7-mm	11.8-mm	13.3-mm
2	3.7-mm	4.7-mm	3.7-mm	12.3-mm	14.1-mm
3	3.9-mm	4.9-mm	3.9-mm	12.8-mm	14.9-mm
4	3.9-mm	4.9-mm	3.9-mm	13.1-mm	15.7-mm
5	3.9-mm	4.9-mm	3.9-mm	14.1-mm	16.9-mm
6	4.6-mm	5.7-mm	3.9-mm	15.6-mm	17.8-mm

Fig. 29.8 Specific height dimensions for the revision and LP talar components for the Agility and Agility LP Total Ankle Replacement Systems. Note that the original Agility Total Ankle Replacement System talar component and posterior augmented component have the same height specifics as the Agility LP talar component

BKA in 4.9 % (2/41) [41]. Unfortunately, as of December 8, 2011, any custom-design long-stemmed talar component is no longer available for clinical use in the USA due to FDA regulation, and the availability of this in the future remains uncertain [53]. However, based on available published data, custom-design long-stemmed tibial (Fig. 29.12) and/or talar (Fig. 29.13) components clearly represented viable options and should also be relevant in the future once the FDA loosens the current restrictions.

Metallic Prosthetic Component Exchange with Conversion from an Agility or Agility LP Total Ankle Replacement System to an Alternative Total Ankle Replacement System

Explantation of the Agility or Agility LP Total Ankle Replacement Systems and conversion to an alternative TAR system are warranted when the same system component exchange is not feasible and the osseous defect is massive such that even tibio-talo-calcaneal arthrodesis with bulk intercalary allograft would be challenging. The options available in the USA for explantation of the Agility or Agility LP Total Ankle Replacement Systems and conversion to an alternative TAR are limited to the prosthesis available for use in the USA. At the present, besides the Agility and Agility LP Total Ankle Replacement Systems, the US public can receive only one of seven metal-backed fixed-bearing cemented TAR devices that are 510(k) cleared and one three-component mobile-bearing cementless device approved by the US FDA for general use. The metal-backed fixed-bearing cemented TAR devices that have been FDA cleared are (1) INBONE I, INBONE II, and INFINITY Total Ankle Replacement Systems (Wright Medical Technology, Inc., Arlington, TN); (2) Eclipse (Integra LifeSciences, Plainsboro, NJ); (3) Salto Talaris Anatomic Ankle Prosthesis and Salto Talaris XT Revision Ankle Prosthesis (Tornier, Bloomington, MN/Wright Medical Technology, Inc., Arlington, TN); and (4) Zimmer Trabecular Metal Total Ankle (Zimmer, Inc., Warsaw, IN). Additionally, the one three-component mobile-bearing cementless TAR FDA approved for use is the Scandinavian Total Ankle Replacement system (STAR System, Stryker Orthopaedics, Mahwah, NJ). Comparing the tibial (Fig. 29.14) and talar (Fig. 29.15) medial–lateral width and anterior–posterior length between these TAR systems reveals that only the INBONE I or II Total Ankle Replacement Systems and Salto Talaris XT Revision Ankle Prosthesis represent viable options.

Explantation of failed Agility or Agility LP Total Ankle Replacement Systems with conversion to the INBONE I or II Total Ankle Replacement Systems has recently been proposed [54–56]. Three scenarios involving bone loss management with conversion to the INBONE II Total Ankle Replacement System exist: (1) the tibial tray is press fit against the distal tibia with standard UHMPE insert use (Fig. 29.16); (2) the tibial tray is press fit against the distal tibia with revision UHMWPE insert use (Fig. 29.17); and (3)

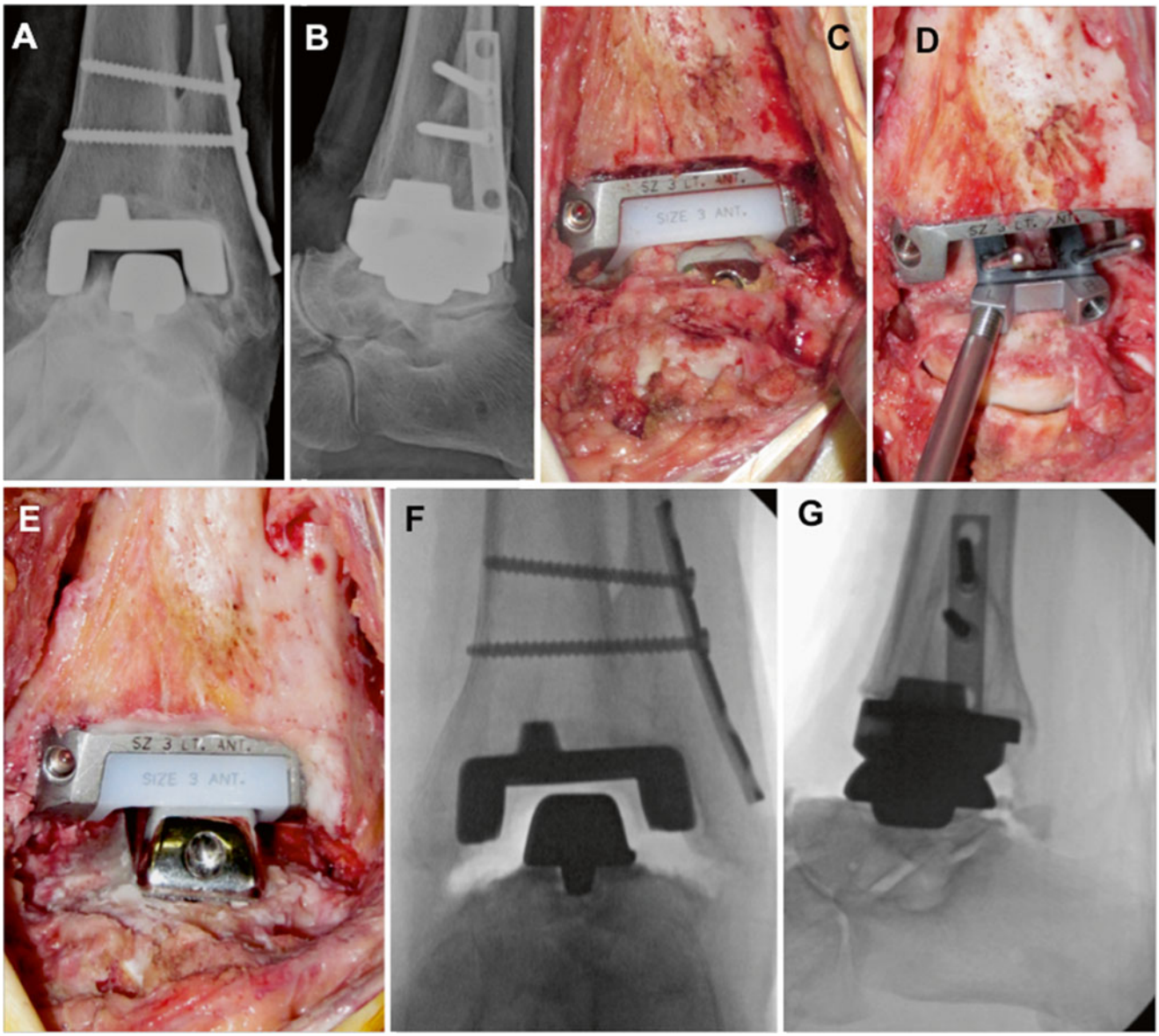


Fig. 29.9 Anterior–posterior (**a**) and lateral (**b**) weight-bearing ankle radiographs, as well as intraoperative photograph (**c**) demonstrating original talar component posterior subsidence with lateral translation and extensive cystic changes within the talar body, neck, and head. Intraoperative photograph demonstrating utilization of the talar cutting guide to recut the talar fin in a corrected position (**d**). Intraoperative photograph (**e**) and anterior–posterior (**f**) and lateral (**g**) intraoperative image intensification views following packing the talar cystic lesions with PMMA cement to support conversion to a revision talar component and bottom-loaded half-column 0-mm UHMWPE insert. Note the good talar component support anteriorly and posteriorly following conversion to the revision talar component

the tibial tray is supported on broad intramedullary stem components, and the defect between native tibia and metallic component is filled with structural corticocancellous bone graft or metal-reinforced PMMA cement (Fig. 29.18).

DeVries et al. [54] reported an incidence of complications of 64.3 % (9/14) with Agility Total Ankle Replacement System explantation and conversion to the INBONE I Total Ankle Replacement System. Meeker et al. [55] reported an incidence of complications of 27.7 % (5/18) with Agility Total Ankle Replacement System explantation and conversion to the INBONE II Total Ankle Replacement System. Williams et al. [56] from the same institution as Meeker et al. [55] reported an overall incidence of complications of 31.4 % (11/35) with Agility Total Ankle Replacement System

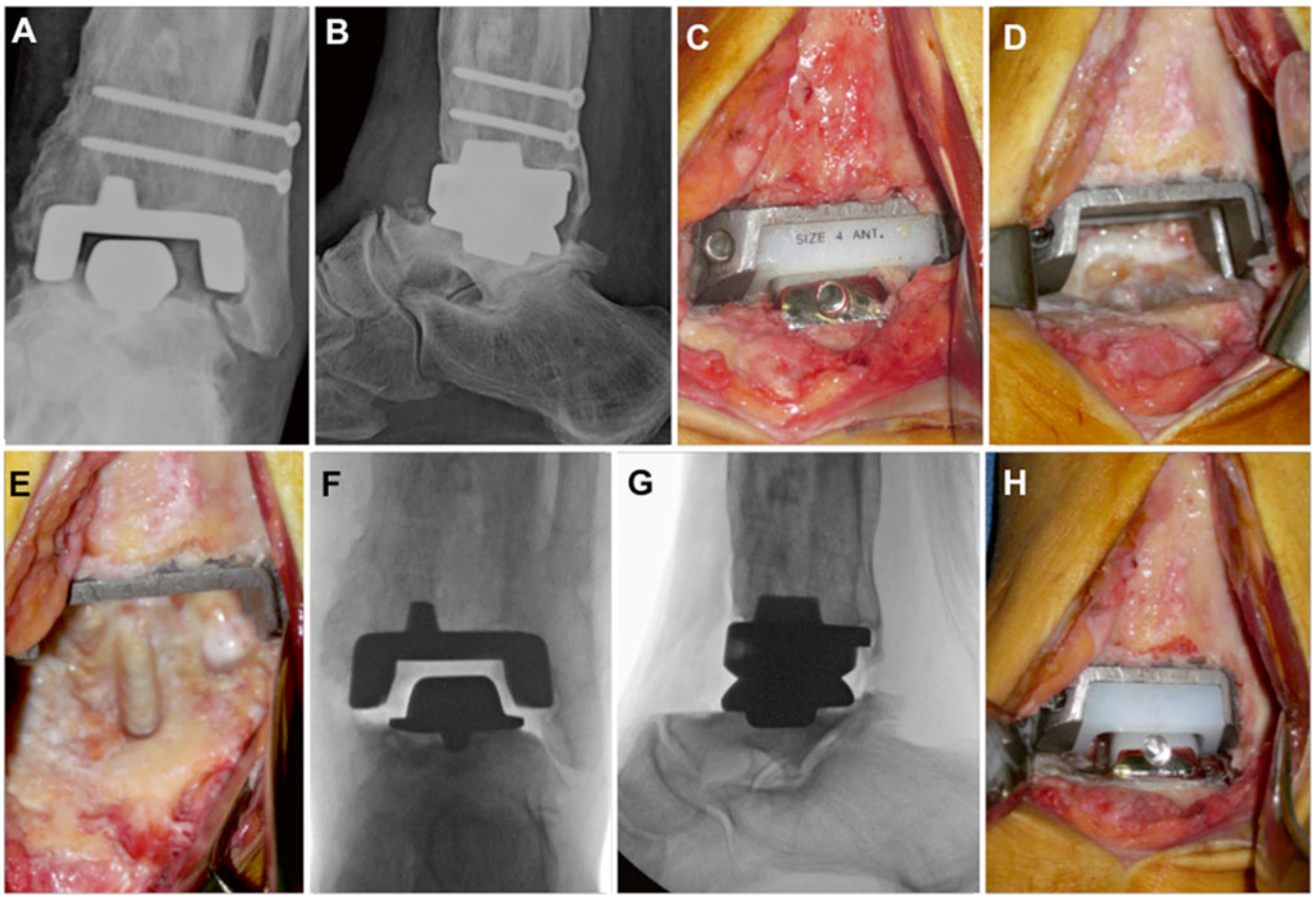


Fig. 29.10 Anterior–posterior (**a**) and lateral (**b**) weight-bearing ankle radiographs demonstrating original talar component posterior subsidence. Intraoperative photographs prior to (**c**) and following (**d**) removal of the talar component and UHMWPE insert demonstrating sufficient preserved medial and lateral talar body (**e**) to support conversion to an LP talar component secured with PMMA cement and bottom-loaded full-column +2-mm polyethylene insert (**f**, **g**). Note the good talar component support following conversion to the LP talar component (**h**)

explantation and conversion to the INBONE II Total Ankle Replacement System.

While it is obviously beneficial to have a TAR system capable of revising the massive osseous defects created with explantation of the Agility Total Ankle Replacement System, the incidence of complications utilizing the INBONE I or INBONE II Total Ankle Replacement Systems is a cause for concern. Another option is the Salto Talaris XT Revision Ankle prosthesis (Fig. 29.19) that was developed to specifically revise failed Salto Talaris Anatomic Ankle prosthesis. Compared with the Salto Talaris Anatomic Ankle prosthesis talar height of 5.5-mm, the Salto Talaris XT Revision Ankle prosthesis talar component has greater height between 10.5-mm and 11.9-mm. The undersurface of the talar component is flat, and primary stability involves a 70°-posterior-angled 10.2-mm-deep 12-mm-outer-diameter medially offset hollow fixation peg with a stabilizing posterior blade. However, until thicker UHMWPE inserts, wider tibial base plates, long-stemmed talar, and augmented height tibial and talar components are readily available, the Salto Talaris XT Revision Ankle Prosthesis remains underpowered for universal revision of failed Agility Total Ankle Replacement Systems.

Explantation of failed Agility Total Ankle Replacement Systems with conversion to alternative TAR systems is associated with myriad intraoperative and perioperative complications that can negatively affect outcome. Therefore, the surgeon and patient should expect a high incidence of

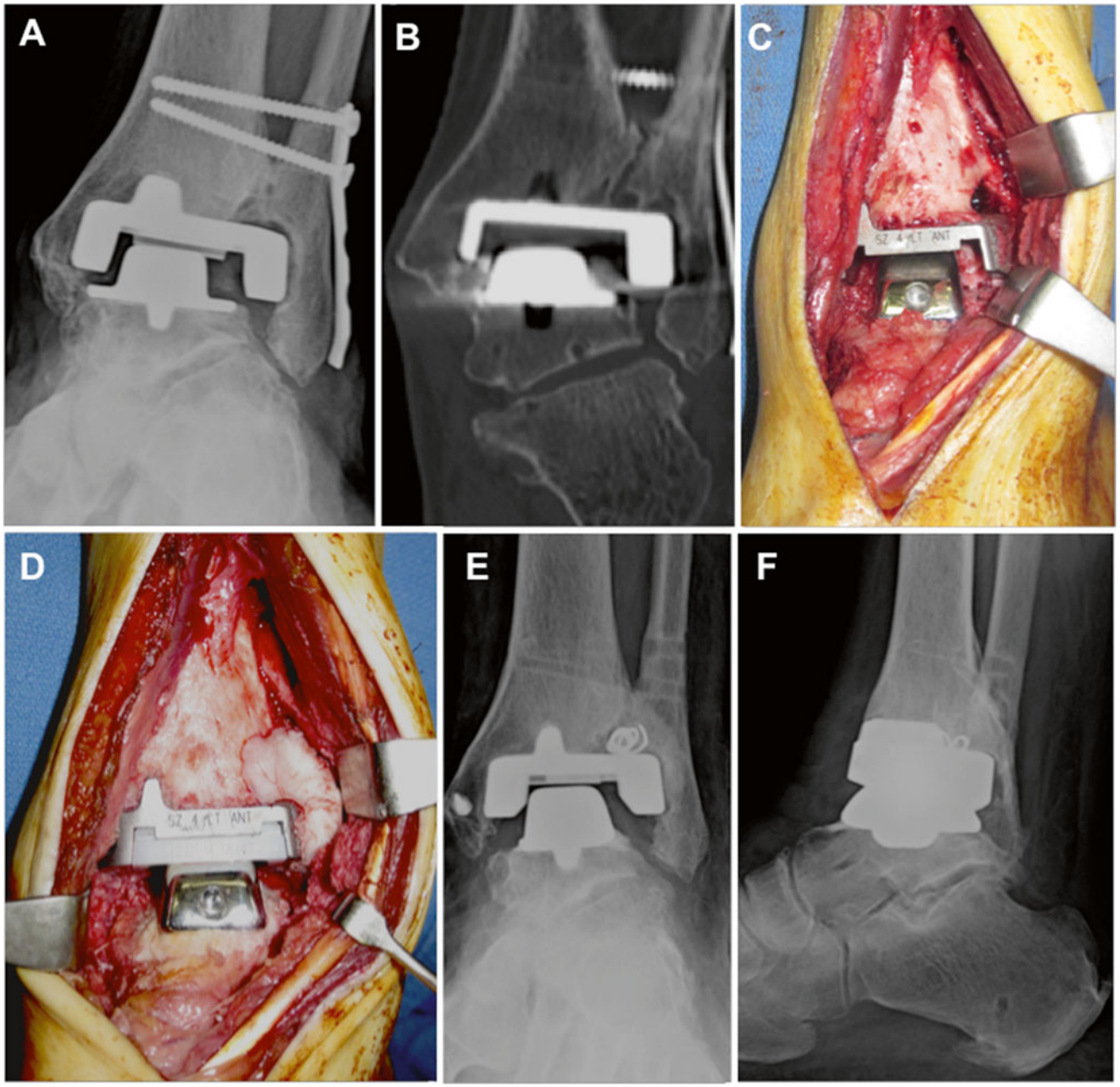


Fig. 29.11 Weight-bearing oblique ankle radiograph (**a**) and frontal plane CT scan (**b**) following primary insertion of an Agility LP Total Ankle Replacement System with nonunion of the distal tibiofibular syndesmosis arthrodesis that was secured with a side plate and fibula-protibia compression screw fixation. Intraoperative photograph following resection of the syndesmosis nonunion and osteolysis about the fibula demonstrating the residual osseous defect (**c**). Intraoperative photograph (**d**) and weight-bearing oblique (**e**) and lateral (**f**) radiographs following implantation of a coiled 0.062-in. Kirschner wire within the osseous defect and PMMA cement filling the void. Note that the LP talar component has been replaced with a revision talar component secured with PMMA cement after recutting the talus to correct the valgus malalignment, front-loaded +1-mm UHMWPE insert, and deltoid reefing with metallic suture anchor reinforcement following lateral ligament complex release off the distal fibula to balance the joint

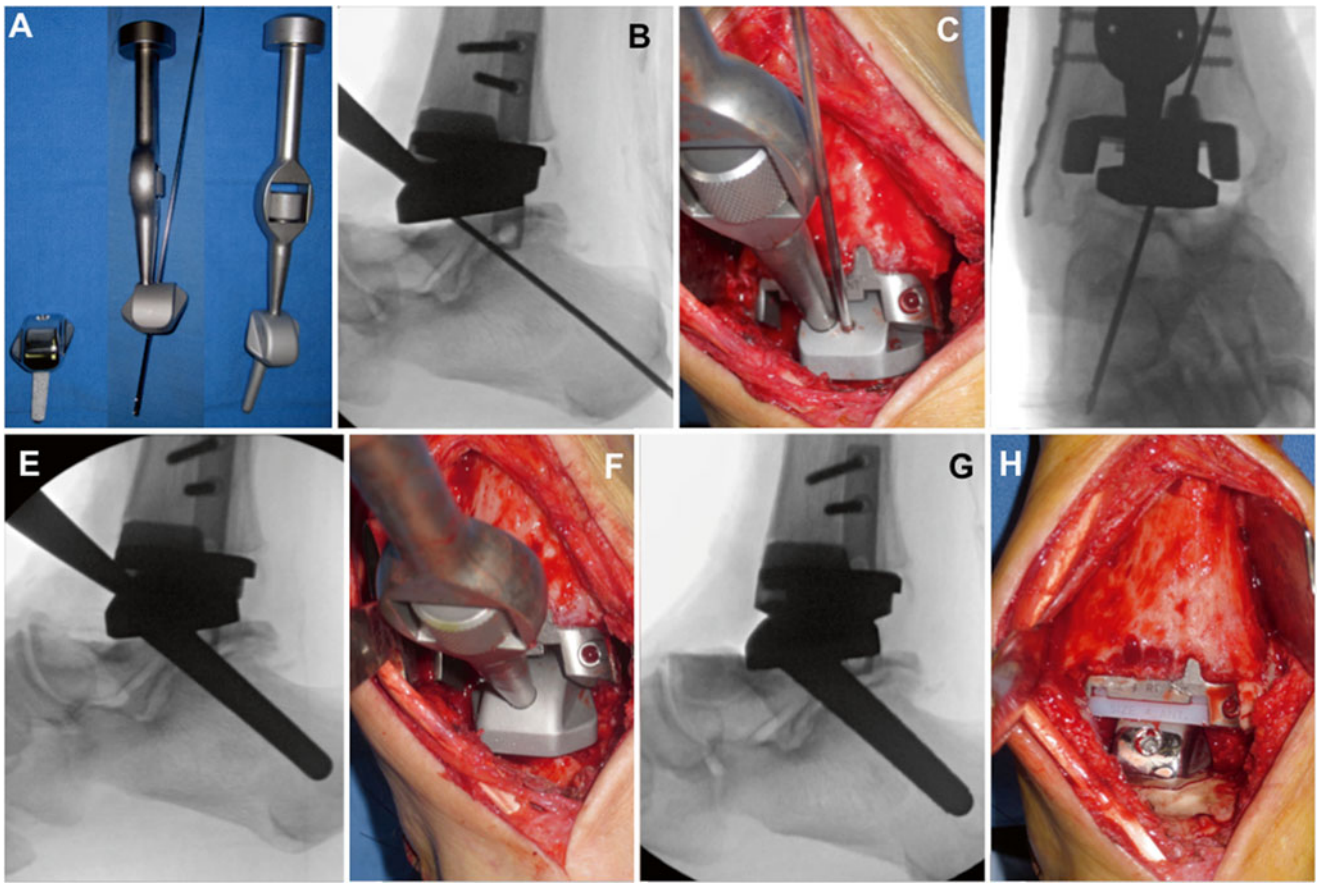


Fig. 29.12 Intraoperative photograph demonstrating, from left to right, custom-design long-stemmed LP talar component, custom LP talar guide secured to insertion handle with guide wire, and custom-stemmed LP talar component trial component secured to insertion handle (**a**). Lateral intraoperative radiograph (**b**) and photograph (**c**) demonstrating alignment of the custom LP talar guide and guide-wire placement into the calcaneus. Lateral intraoperative image intensification radiograph following removal of the talar drill guide demonstrating the use of the cannulated reamers to dilate the calcaneal stem path in the talus and calcaneus (**d**). Lateral intraoperative image intensification view (**e**) and intraoperative photograph (**f**) following insertion of the custom-design long-stemmed LP talar trial component. Lateral intraoperative image intensification view (**g**) and intraoperative photograph (**h**) following insertion of the final custom-design long-stemmed LP talar component. Note the use of PMMA cement augmentation of the talar body, neck, and head cystic changes in addition to arthrodesis of the posterior subtalar joint facet

complications to occur with this approach that should be reserved for situations where alternative revision strategies are not possible and tibio-bulk allograft-talo-calcaneal arthrodesis is undesirable. This will remain a matter for conjecture until peer-reviewed published data is available for review.

Additional Procedures during Revision of Failed Agility or Agility LP Total Ankle Replacement Systems

The use of an anterior distal tibia plate abutting the superior portion of the tibial tray can be invaluable to support or buttress the tibial tray realignment [16] and also can be employed as a fixation point for various tendon transfers (Fig. 29.20) [58, 59]. Although a variety of specialty plates are available, the use of a standard T-shaped plate is very effective for this purpose. Intraoperative fractures require stabilization, and this is best achieved with either direct medial or lateral standard 1/3 tubular plate and screw fixation or anteriorly about the malleoli using mini-fragment plate and screw fixation (Fig. 29.21). Finally, it is frequently necessary to perform soft-tissue procedures to properly balance the TAR in the frontal plane. It is the author's preference to employ posterior tibial tendon recession [57] over deltoid release in addition to lateral ankle stabilization with a modified Evans peroneus brevis tendon transfer secured to the distal tibia or fibula whenever possible [58]. The use of a reverse Evans peroneus brevis tendon transfer secured to the distal tibia or fibula is helpful in performing medial ankle stabilization with mild to moderate deltoid insufficiency [59].

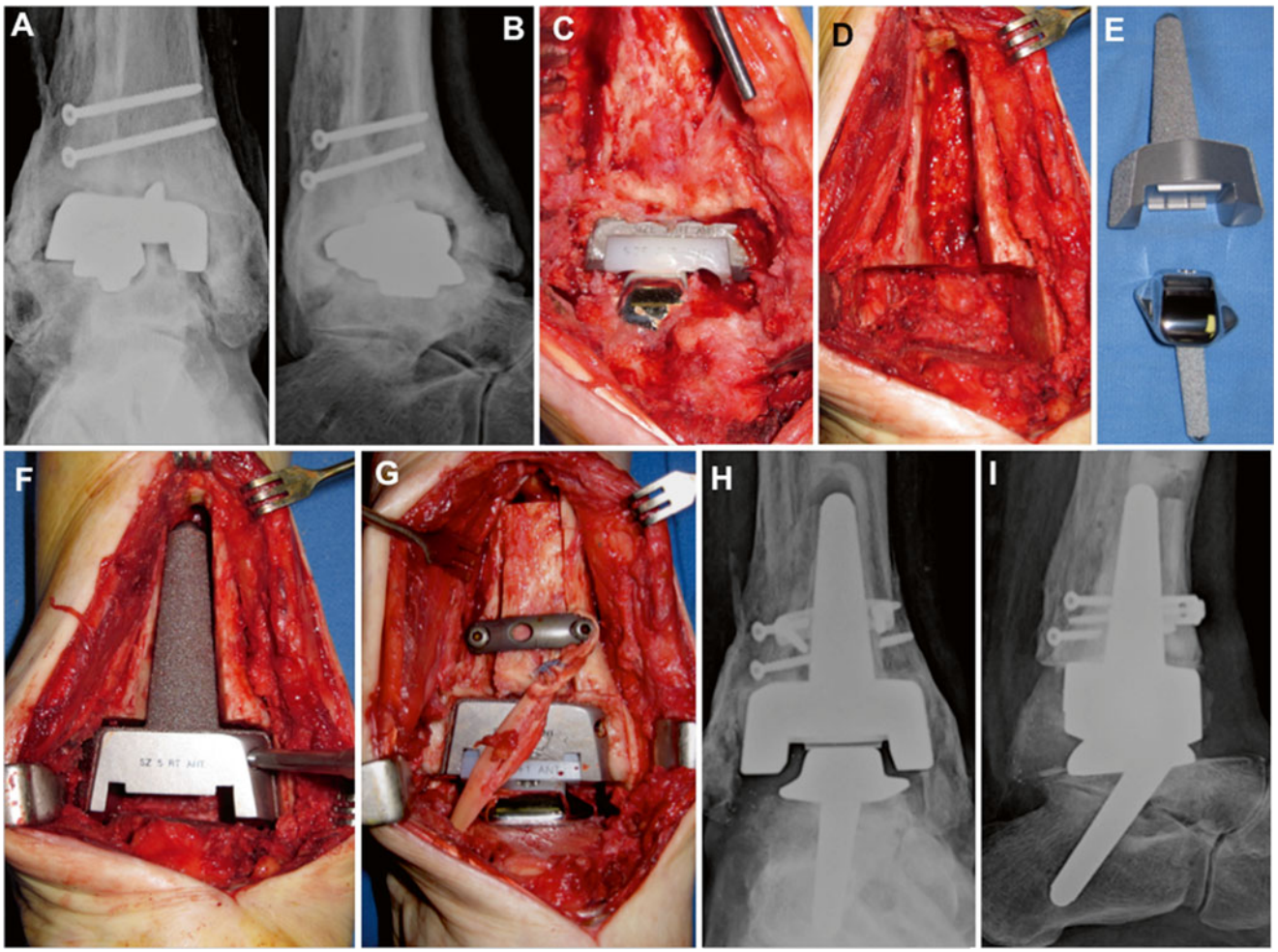


Fig. 29.13 Weight-bearing anterior–posterior (**a**) and lateral (**b**) radiographs demonstrating extensive syndesmosis arthrodesis, aseptic osteolysis, and gross loosening of the tibial and talar components with severe subsidence of the tibial component into the distal tibial metaphysis following primary implantation of an original "DePuy Alvine Total Ankle Prosthesis." Intraoperative photograph (**c**) demonstrating initial presentation following resection of the anterior tibial bone engulfing the implant. Intraoperative photograph following planar resection of the talar dome to correct varus malalignment deformity and resection of the distal tibia to accept the custom-design long-stemmed tibial component (**d**). It was necessary to cut through the screws used to perform the syndesmosis arthrodesis as they had been completely overgrown with bone and could not otherwise be removed. Photograph of the custom-design long-stemmed tibial (top) and talar (bottom) implants with porous coating on the stems, tibial external sidewalls, superior tibial component, and inferior talar component (**e**). The custom-stemmed tibial component has been inserted following PMMA cement stabilization, the previously resected anterior tibial cortical window replaced, the custom-stemmed talar component inserted following PMMA cement stabilization, and a front-loaded +1-mm UHMPE insert placed (**f**). Note the peroneus brevis tendon transfer to the anterior–medial distal tibia underneath the three-hole plate and screw construct used to stabilize the anterior tibial cortical window (**g**). Weight-bearing anterior–posterior and lateral ankle radiographs demonstrating maintained alignment of the custom-design long-stemmed tibial and talar components (**h**, **i**)

Alternative Revision Techniques for Salvage of Failed Agility or Agility LP Total Ankle Replacement Systems

Revision TAR with conversion to tibio-talo-calcaneal arthrodesis utilizing bulk intercalary femoral head allograft (Fig. 29.22) [60], autogenous circular fibular pillar graft [61], or trabecular metal spacers [62] should be reserved for select non-reconstructable cases when one of the previously mentioned options is not possible. A systematic review of tibio-talo-calcaneal arthrodesis and tibio-bulk allograft-talo-calcaneal arthrodesis for failed TAR revealed complications in 62.3 % including nonunion rate of 24.2 % [60]. Revision TAR with the tibial and/or talar components supported by multiple metal-reinforced triangular rods/large diameter

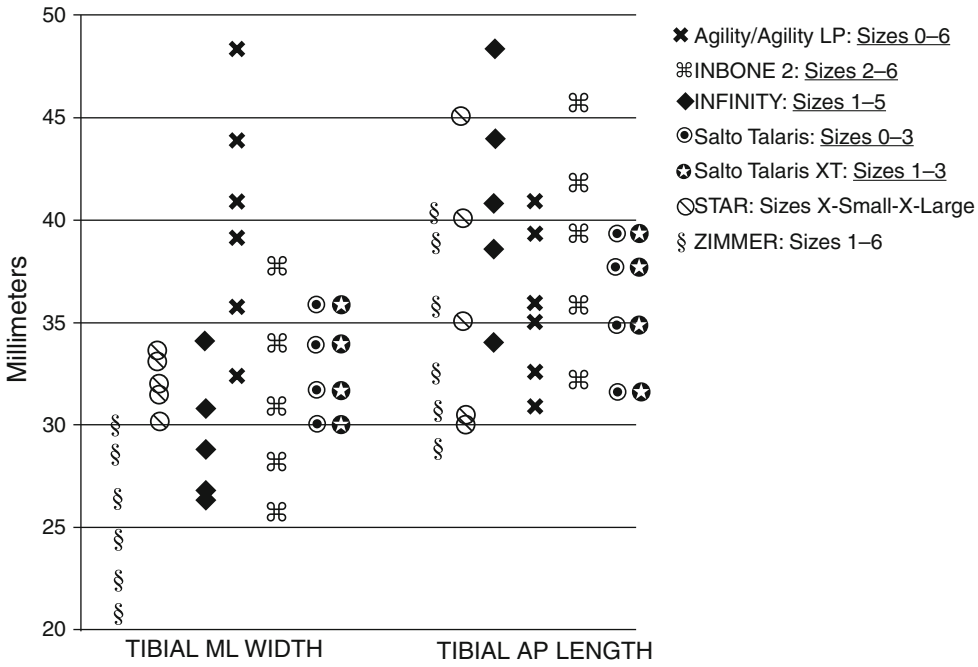


Fig. 29.14 Scatter plot of the tibial tray medial–lateral width and anterior–posterior length for the FDA-cleared/approved TAR systems available in the USA relative to the Agility and Agility LP Total Ankle Replacement Systems

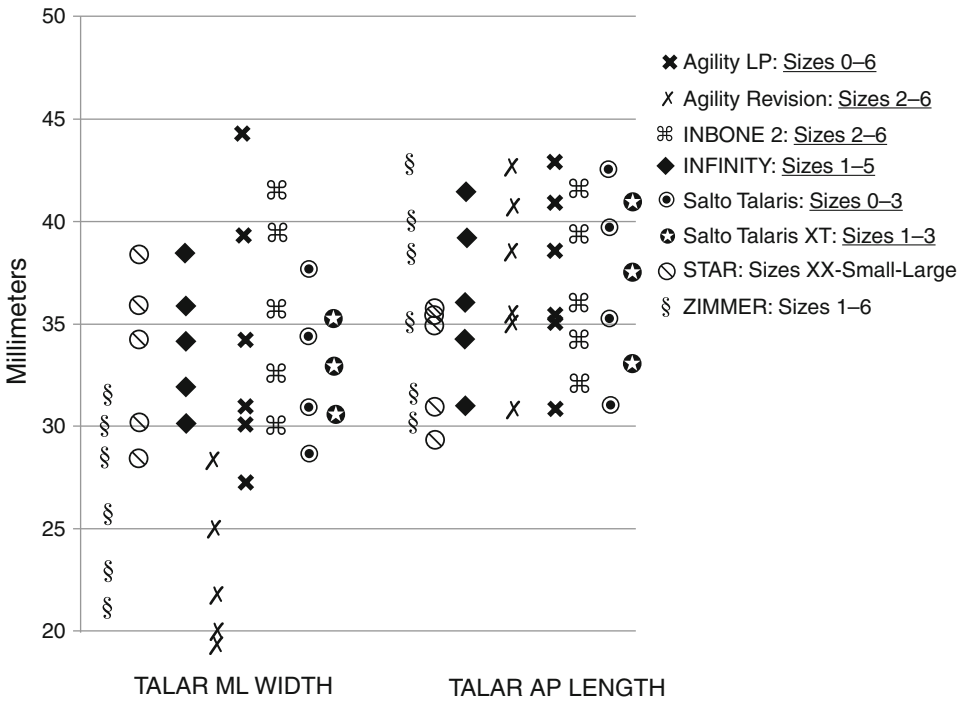


Fig. 29.15 Scatter plot of the talar component medial–lateral width and anterior–posterior length for the FDA-cleared/approved TAR systems available in the USA relative to the Agility Revision and Agility LP talar components

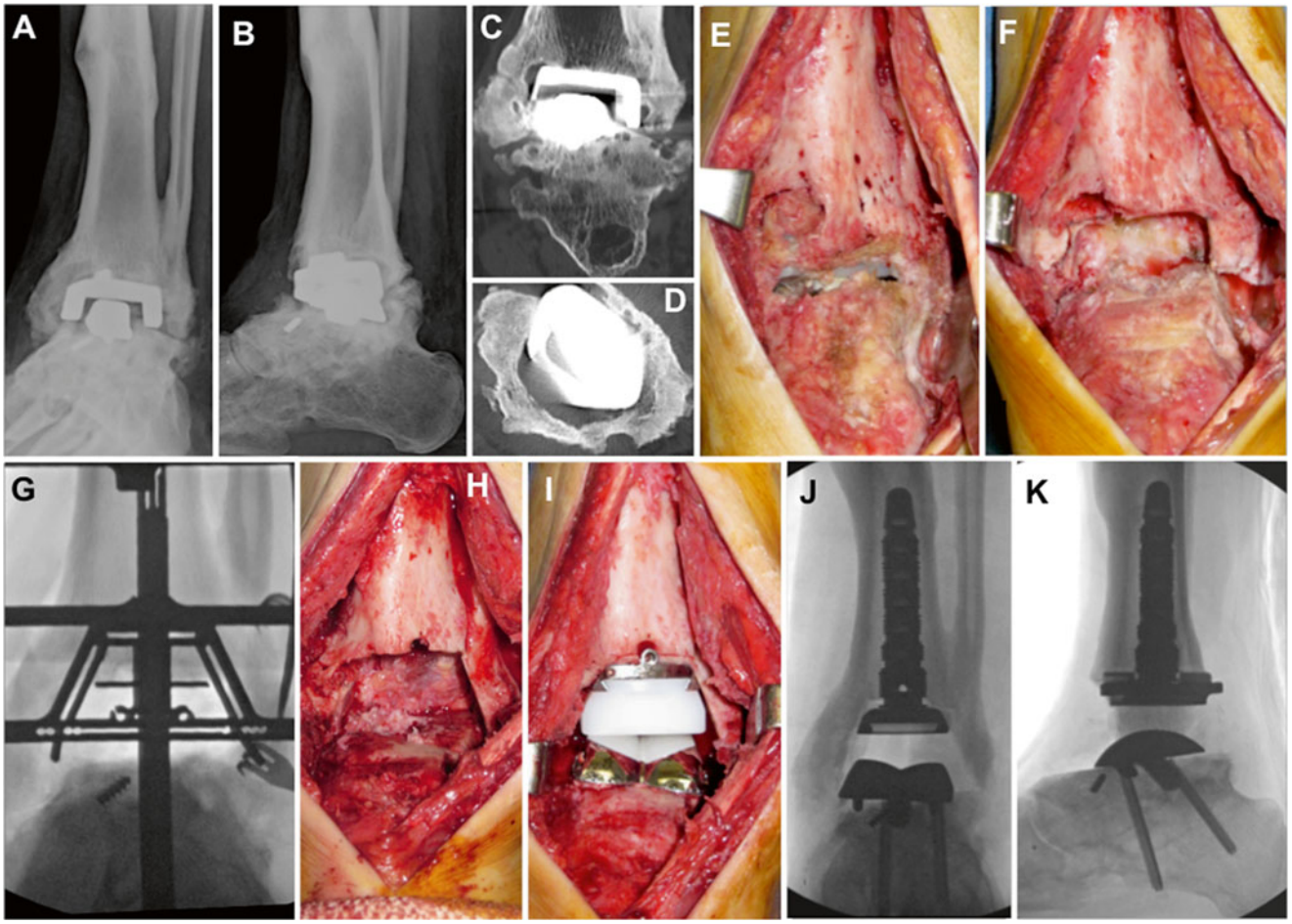
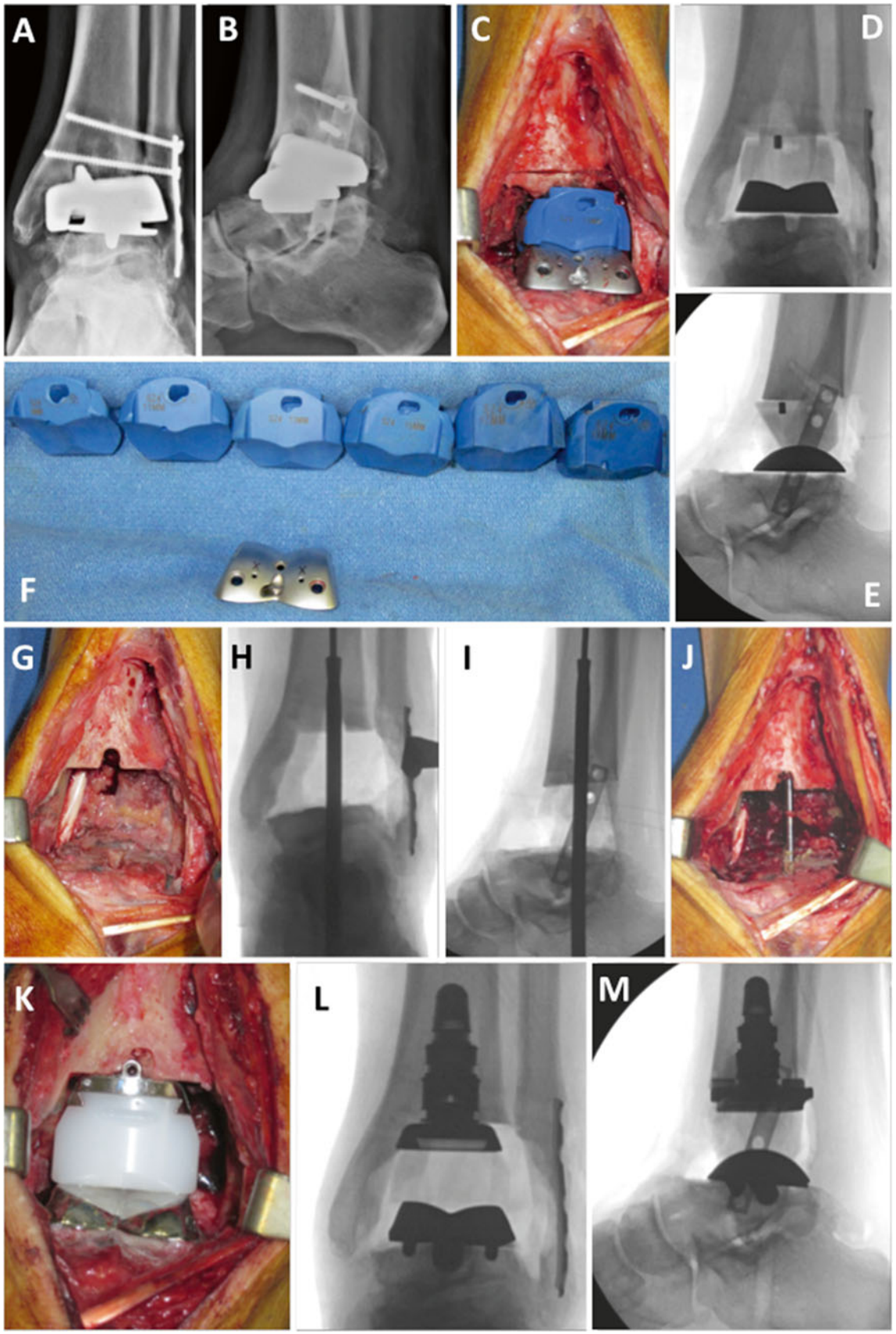


Fig. 29.16 Mortise (**a**) and lateral (**b**) weight-bearing radiographs, as well as frontal (**c**) and transverse (**d**) plane computerized tomography images of a patient with a painful pantalar arthrodesis and ankle arthrodesis takedown with conversion to an Agility Total Ankle Replacement System. Tibial and talar subsidence are appreciated. Intraoperative photograph prior to (**e**) and following (**f**) explantation of the failed Agility Total Ankle Replacement System. Intraoperative image intensification view demonstrating planned resection level in the tibia to recreate a lateral malleolus (**g**). Intraoperative photograph following tibial resection (**h**) and implantation of the INBONE II Total Ankle Replacement System with the tibial tray being in direct contact with the native tibia (**i**). Anterior–posterior (**j**) and lateral (**k**) intraoperative image intensification views following explantation of the failed Agility Total Ankle Replacement System with conversion to an INBONE II Total Ankle Replacement System. Note that the talar component is further supported but triangular metallic fusion rods to limit potential for subsidence of the talar component

screws [63] or coiled metallic wires [39, 40] affixed within PMMA cement are feasible in situations where the defects are contained to the medial malleolus (Fig. 29.23), fibula (Fig. 29.24), or talus (Fig. 29.25). Additionally, the use of metal-reinforced PMMA cement augmentation represents a viable alternative when other revision options or conversion to tibio-talo-calcaneal arthrodesis or tibio-bulk allograft-talo-calcaneal arthrodesis is not possible (Fig. 29.26). Explantation of the failed Agility or Agility LP Total Ankle Replacement System and implantation of a permanent PMMA cement spacer [64–66] or BKA [67] should be reserved for non-reconstructable talar body destruction, non-reconstructable soft-tissue defects, unremitting pain with joint stiffness, uncontrollable infection, or in situations where the patient does not desire or is medically unable to undergo other types of revision surgery.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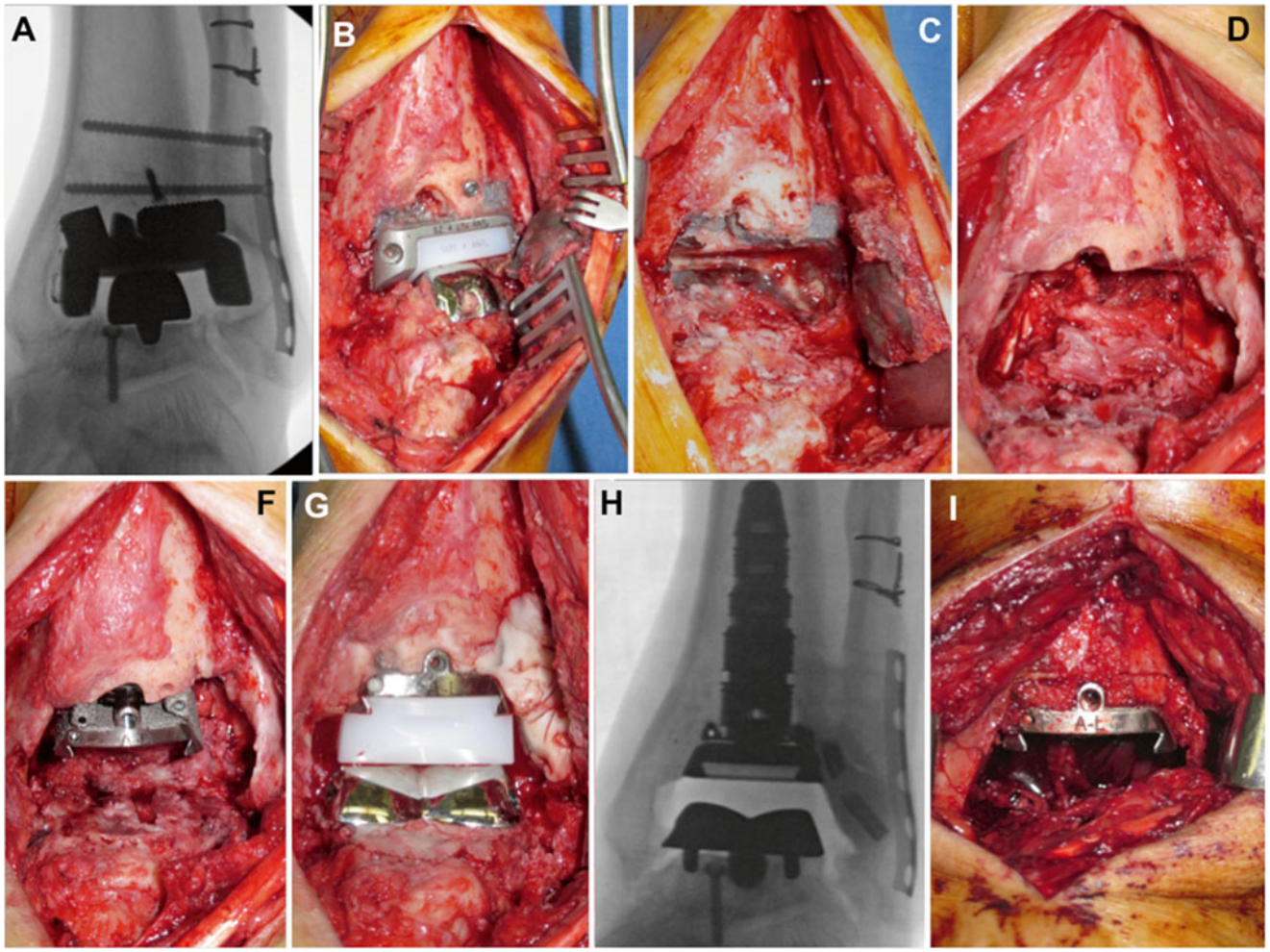

Fig. 29.18 Mortise image intensification view (**a**) and photograph (**b**) demonstrating a failed Agility Total Ankle Replacement System that had developed anterior tibial subsidence and underwent metal reinforcement between the anterior tibial tray and distal tibia. Intraoperative photograph (**c**) revealing severe metallosis imbedded within the bone and soft tissues prior to debridement. Intraoperative photograph (**d**) following resection of the tibia and talus to accept conversion to an INBONE II Total Ankle Replacement System. Intraoperative photograph (**e**) demonstrating the tibial tray supported solely by the intramedullary stems due to the deficient bone distally. Intraoperative photograph (**f**) and anterior–posterior image intensification view (**g**) following metal-reinforced PMMA cement augmentation of the tibial tray and talar component completing the conversion. Intraoperative photograph (different patient) demonstrating an alternative approach to bridge the defect between the native tibia and tibial tray employing structural corticocancellous allograft and impaction bone grafting (**h**)

Fig. 29.17 Mortise (**a**) and lateral (**b**) radiographs of a failed Agility LP Total Ankle Replacement System demonstrating extensive tibial osteolysis, as well as anterior and lateral tibial component subsidence. Intraoperative photograph (**c**) demonstrating the use of the talar trial and revision poly trial to determine the level of tibial resection since the external alignment jig could not be secured with the joint under appropriate tension. Anterior–posterior (**d**) and lateral (**e**) image intensification views following resection of the distal tibia and talus to accept the INBONE II Total Ankle Replacement System. The full complement of poly trial implants for the prosthesis employed based on the specific tibial tray employed (**f**). In this instance the sizes are for a size 4 standard tibial tray, and from left to right, the thicknesses of the poly trial implants are 9-mm, 11-mm, 13-mm, 15-mm, 17-mm, and 19-mm mm. Alternate prosthesis sizing for a size 3 long tibial tray would have allowed for 10-mm, 12-mm, 14-mm, 16-mm-, 18-mm, or 20-mm-thick poly trial implants. Accordingly it is critical to determine the tibial component length (standard or long) since there is a difference in thicknesses of the poly trial implants that may be more important than talar coverage. Intraoperative photograph following tibia and talar preparation demonstrating massive osseous defect (**g**). Anterior–posterior (**h**) and lateral (**i**) image intensification views, as well as intraoperative photograph (**j**) following initial freehand guide-wire placement and subsequent cannulated drill use from a 6.5/8.0-mm screw set to create the intramedullary tibia channel. Reaming the tibial canal as per standard technique followed this. Intraoperative photograph (**k**), as well as anterior–posterior (**l**) and lateral (**m**) image intensification views following explantation of the failed Agility Total Ankle Replacement System with conversion to an INBONE II Total Ankle Replacement System. Note the direct contact between the tibial tray and the native tibia with use of revision UHMWPE insert to maintain the ankle joint near the native joint line

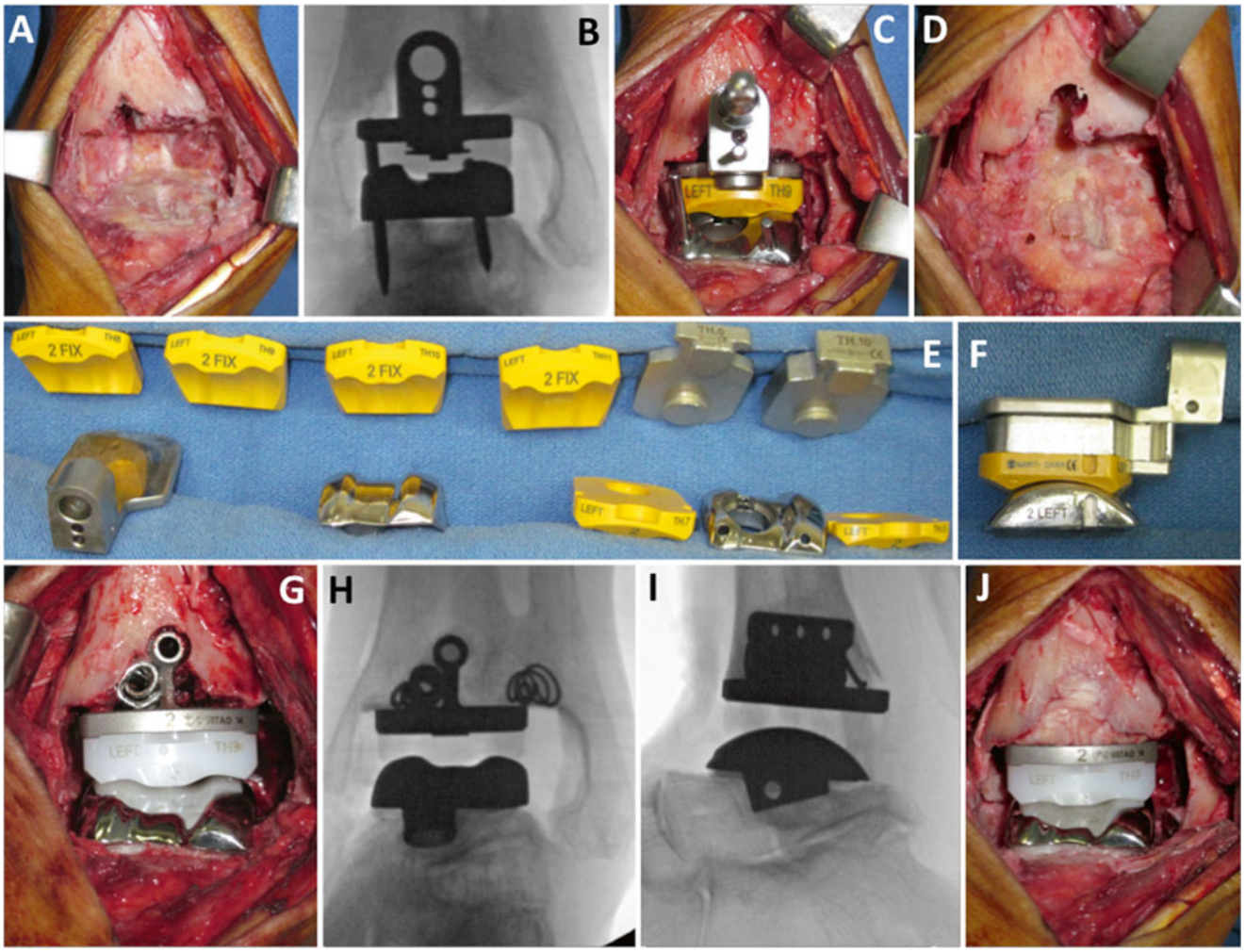

Fig. 29.19 Intraoperative photograph following removal of a failed Agility Total Ankle Replacement System demonstrating the significant osseous void created (**a**). Intraoperative mortise image intensification view (**b**) following insertion of the Salto Talaris XT Revision Ankle Prosthesis tibial assembly and pinning of the talar trial component demonstrating proper component alignment. Intraoperative photograph demonstrating fixation of the tibial trial component with a distal pin and proximal drill and talar component with two offset pins (**c**). Note that despite the massive osseous defect created following removal of the failed Agility Total Ankle Replacement System, it was not necessary to use a thicker revision poly to achieve proper ligamentous tension. In this case a 5-mm poly trial is employed which when combined with the 4-mm-thick tibial trial results in a 9-mm-thick tibial assembly (Th 9 noted on the yellow trial poly). Intraoperative photographs demonstrating the location of the Agility Total Ankle Replacement System tibial keel relative to the Salto Talaris XT Revision Ankle prosthesis tibial keel and plug (**d**). For the standard UHMWPE sizes 4, 5, 6, and 7 mm, the tibial trial base and standard poly trial insert are clipped together, and the selected talar trial implant is then implanted as a unit. If the thicker poly trial 10-mm, 12-mm, and 14-mm inserts are required, then a metallic spacer needs to be interposed between the tibial trial base and poly trial insert. Specifically, there are two thicknesses of metallic spacers, 3-mm and 7-mm, in addition to the 3-mm thickness of the trial tibial component base plate. There are also two thicknesses of trial poly inserts: 5-mm and 7-mm. These trial components would be assembled with a 3-mm metallic spacer and 7-mm poly trial insert to create 10-mm, 7-mm metallic spacer and 5-mm poly trial insert to create 12-mm, and 7-mm metallic spacer and 7-mm poly trial insert to create 14-mm definitive thicknesses (**e**). It should be noted that the thicknesses above are only for the poly thickness, and an additional 4-mm needs to be added to account for the thickness of the tibial tray. Lateral view of the assembled trial tibial tray, metallic spacer, poly trial insert, and XT talar trial (**f**). Intraoperative photograph following implantation of the final Salto Talaris XT Revision Ankle Prosthesis demonstrating metal reinforcement within the medial distal tibial osseous defect adjacent to the keel of the tibial component (**g**). Mortise (**h**) and lateral (**i**) ankle image intensification views, as well as intraoperative photograph (**j**) following PMMA cement augmentation. Note that there is complete talar body coverage but only partial tibial coverage due to the specific dimensions of the osseous defect created by explantation of the Agility Total Ankle Replacement System and the presence of a very thin residual medial malleolus

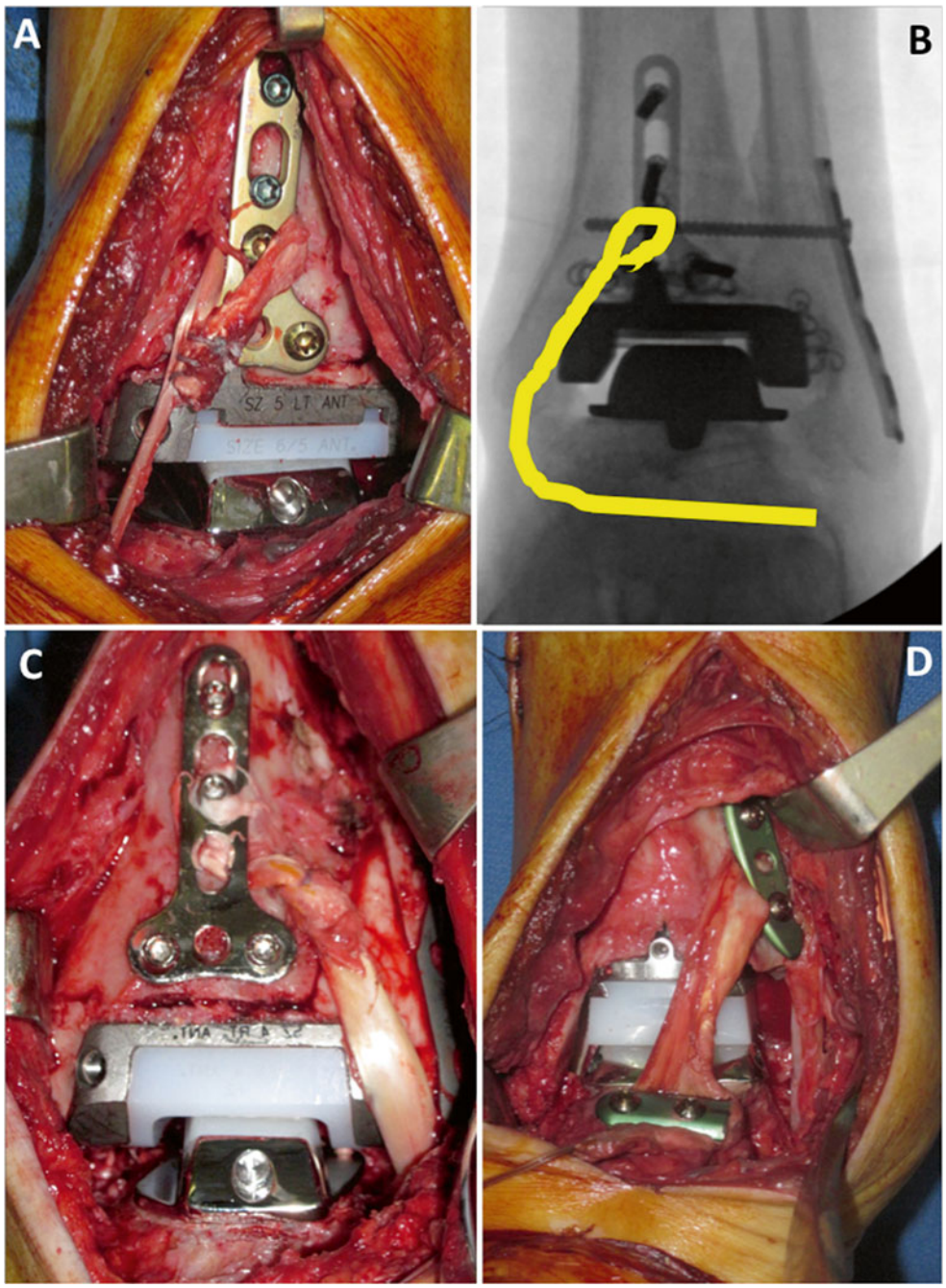

Fig. 29.20 Intraoperative photograph demonstrating the reverse Evans peroneus brevis tendon medial ankle stabilization with the tendon oriented along the anterior–medial aspect of the tibial component sidewall, secured between the plate and distal tibia and sewn back on itself (**a**). Mortise ankle image intensification view (**b**) demonstrating the orientation of the peroneus brevis autograft (*yellow outline*) shown in (**a**). Intraoperative photograph following modified Evans peroneus brevis lateral ankle stabilization with the tendon being anchored between the T-shaped plate and anterior–lateral distal tibia (**c**). In the presence of persistent anterior drawer, the redundant peroneus brevis tendon can be secured to the talar neck with a small plate and screw construct that improves lateral ankle stabilization (**d**)

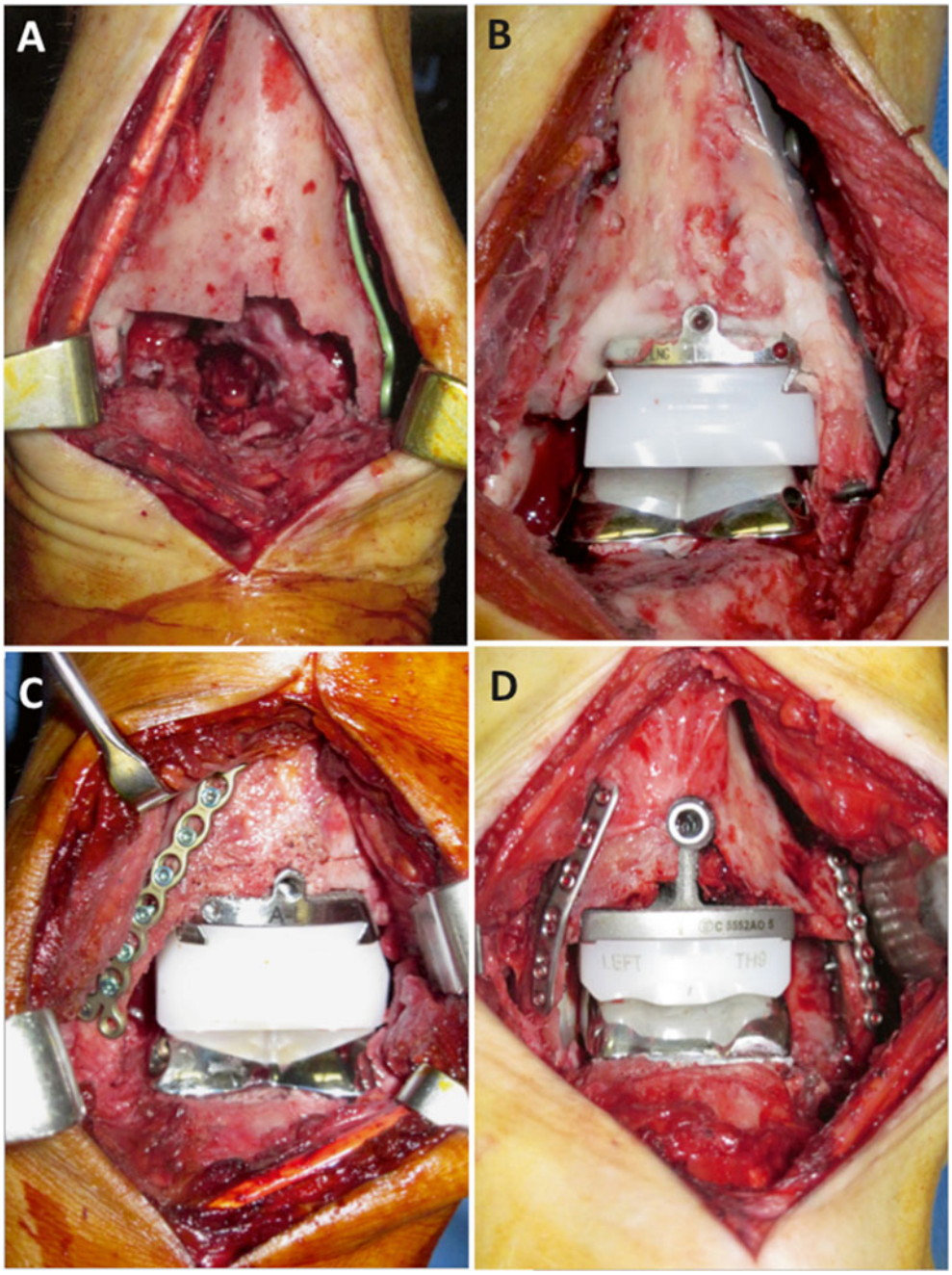

Fig. 29.21 Intraoperative photograph demonstrating various metallic fixative constructs for malleolar fracture fixation including anatomic plate (**a**), contoured 1/3 tubular plate (**b**), and mini-fragment plate (**c**, **d**) fixation

Conclusions

At present, failure of the Agility and Agility LP Total Ankle Replacement Systems leading to revision involves aseptic osteolysis of the tibial and/or talar components with or without secondary component subsidence. Depending on the alignment and integration of the components and size of the osseous defect, multiple revision possibilities exist such that approximately 80 % of the failed systems can be revised. The revision possibilities include the use of revision or LP talar components and corresponding UHMWPE exchange,

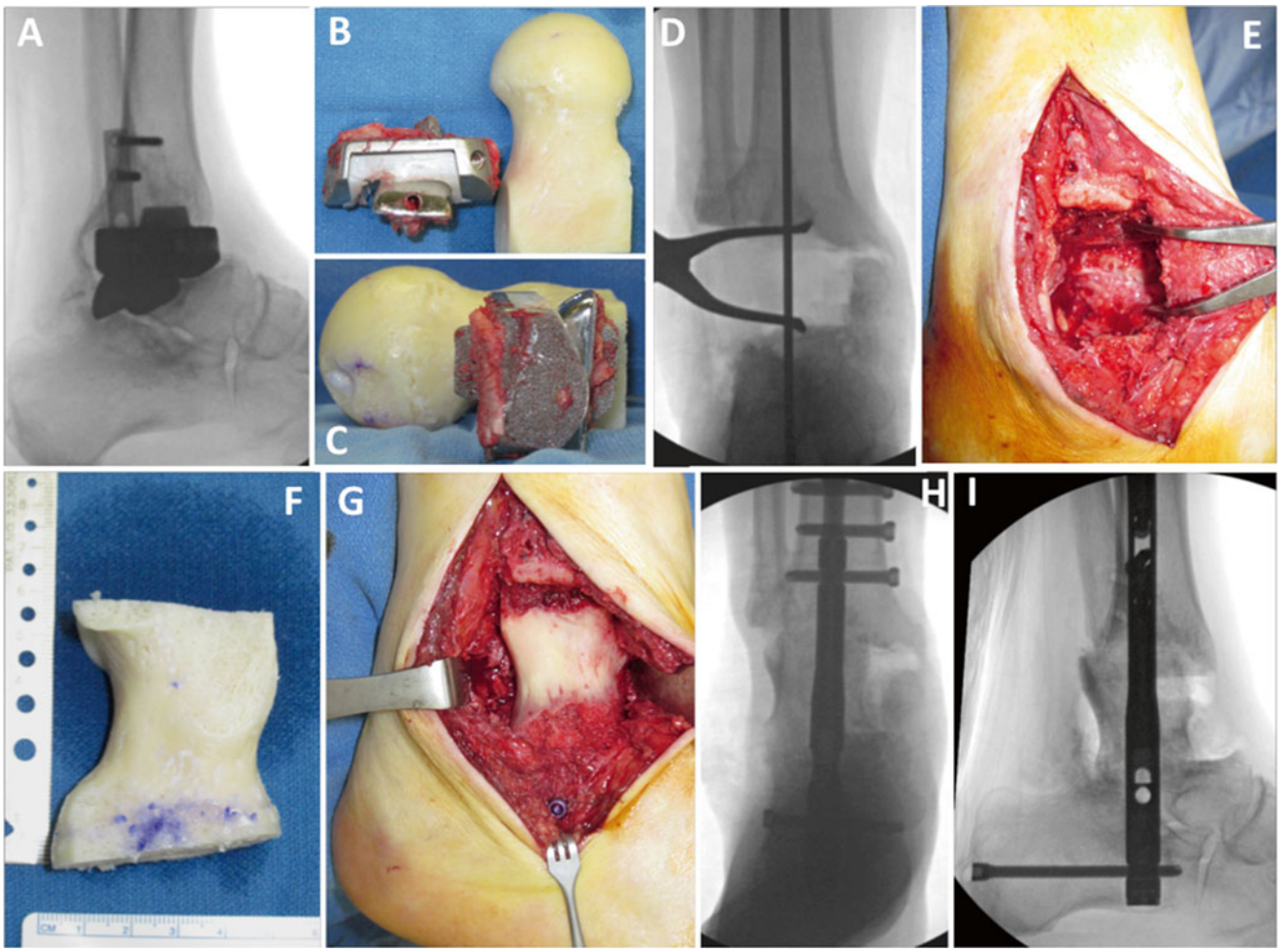

Fig. 29.22 Lateral image intensification view of a failed Agility Total Ankle Replacement System demonstrating severe subsidence of the posterior augmented talar component into the calcaneus (**a**). Anterior (**b**) and lateral (**c**) views of the explanted Agility Total Ankle Replacement System and bulk femoral head allograft. Explantation and resection of all devitalized bone until a healthy cancellous bone substrate is obtained resulted in a massive osseous defect over 65-mm in height as demonstrated on anterior–posterior image intensification (**d**) and intraoperative photograph (**e**). Intraoperative photograph of the contoured bulk femoral head allograft (**f**). Intraoperative photograph (**g**) as well as anterior–posterior (**h**) and lateral (**i**) ankle image intensification views following insertion of the contoured bulk femoral head allograft stabilized with a locked compression retrograde intramedullary arthrodesis nail

as well as conversion to the INBONE I or II Total Ankle Replacement Systems or Salto Talaris XT Revision Ankle prosthesis. Although no longer available for use in the USA, custom-made long-stemmed tibial and/or talar components represented viable options and should also be relevant in the future once the FDA loosens the current restrictions and the full complement of the Salto Talaris XT Revision Ankle prosthesis is cleared for use. Reinforcement of the osseous

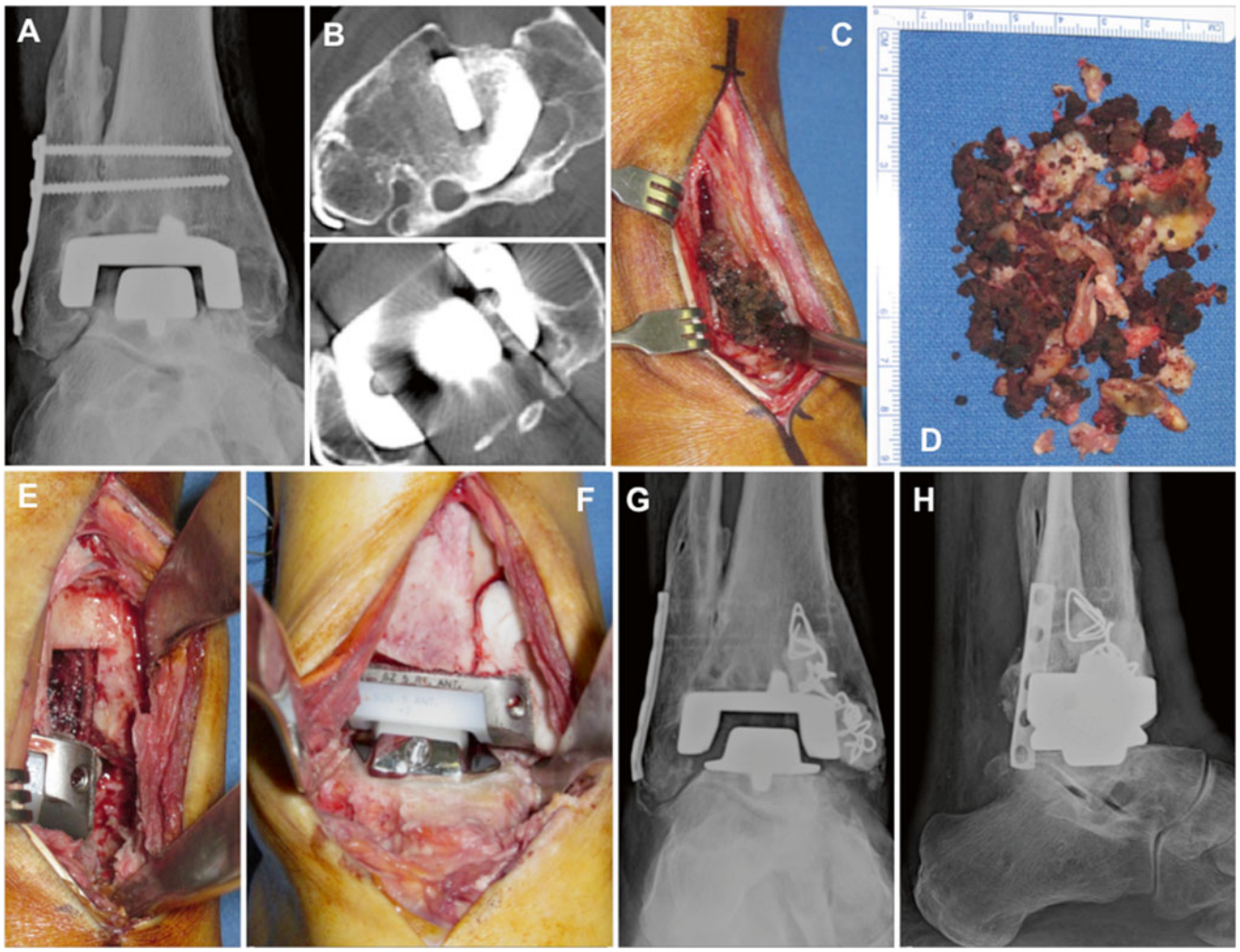

Fig. 29.23 Mortise weight-bearing ankle radiograph (**a**) and transverse computed tomography images (**b**) demonstrating extensive osteolysis about the medial malleolus and anterior aspect of the distal tibia. Intraoperative photograph upon entry into the medial joint space (**c**) demonstrating extensive darkly pigmented UHMWPE and metallic wear debris (**d**). Intraoperative photograph following cortical window to allow for complete evacuation of the osteolysis demonstrating nearly absent medial malleolus (**e**) but otherwise stable and well-aligned tibial component. Intraoperative photograph (**f**) as well as weight-bearing mortise (**g**) and lateral (**h**) radiographs following insertion of multiple-coiled 0.062-in. Kirschner wires within the osseous defect and PMMA cement filling of the osseous void. Note that the posterior augmented talar component has been converted to an LP talar component secured with PMMA cement and bottom-loaded full-column +2-mm UHMWPE insert

defects utilizing PMMA cement with or without geometric metal augmentation should be reserved for select contained defects when formal explantation and conversion is not appropriate. Tibio-talo-calcaneal arthrodesis and tibio-bulk allograft-talo-calcaneal arthrodesis should be reserved for non-reconstructable talar body destruction. BKA should be reserved for select non-reconstructable cases or situations where the patient does not desire or is medically unable to undergo formal revision surgery. Given the anticipated volume of patients with retained Agility and Agility LP Total Ankle Replacement Systems in the USA, there is a real need for long-term survivorship following revision of these prostheses and future efforts ought to be directed in this area.

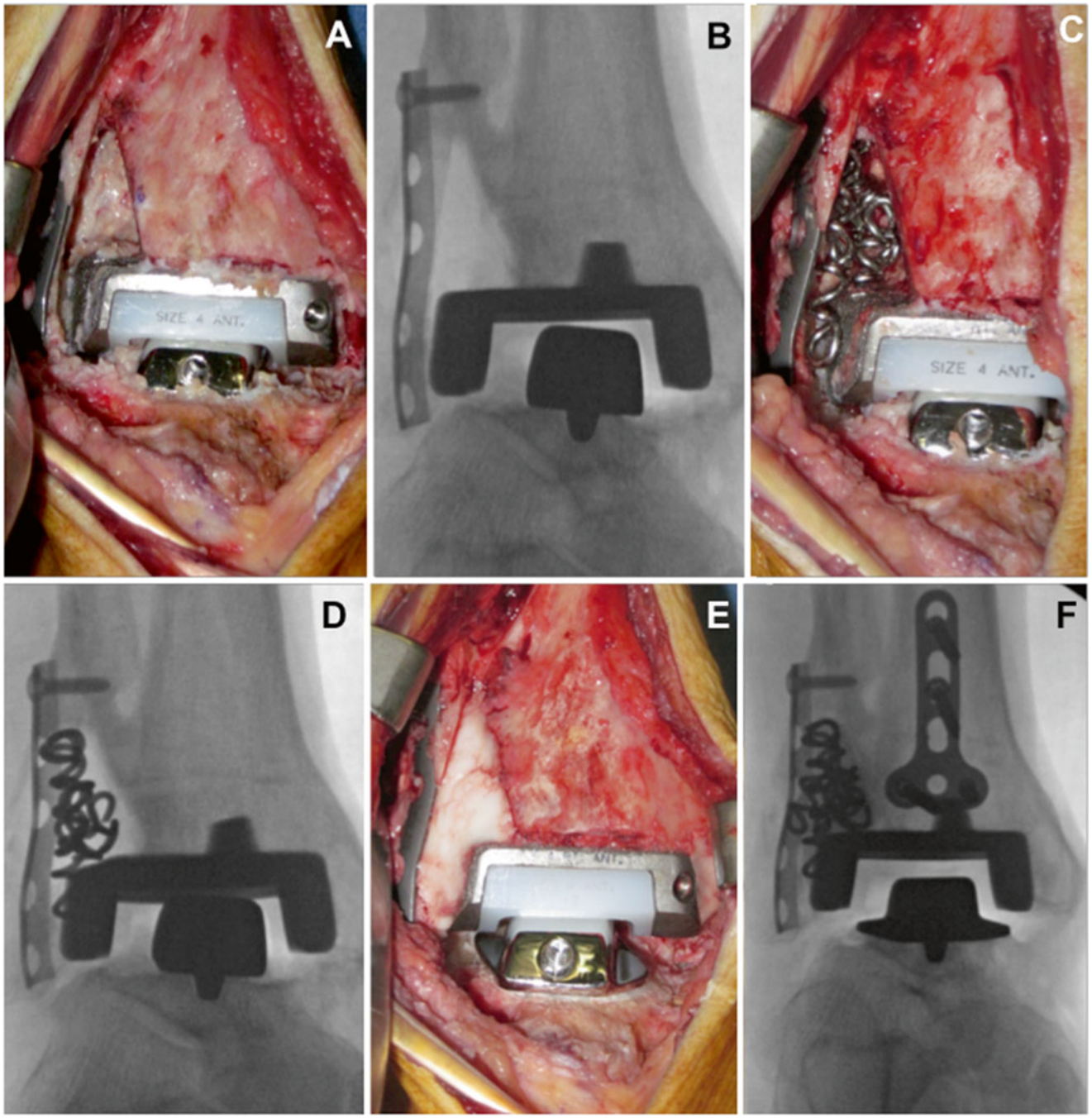

Fig. 29.24 Intraoperative photograph (**a**) and image intensification mortise view (**b**) demonstrating massive distal tibiofibular defect following resection of the nonunion but otherwise stable and well-aligned tibial component. Intraoperative photograph (**c**) and image intensification anterior–posterior view (**d**) following implantation of multiple-coiled 0.062-in. Kirschner wires within the osseous defect. Intraoperative photograph (**e**) and image intensification mortise ankle view (**f**) following insertion of PMMA cement within the osseous defect where it intermixes and bonds with the metal reinforcement. Note the conversion of the posterior augmented talar component and bottom-loaded 0-mm UHMWPE insert for an LP talar component and bottom-loaded +2-mm UHMWPE insert, as well as the use of a T-plate to secure the peroneus brevis lateral ankle stabilization

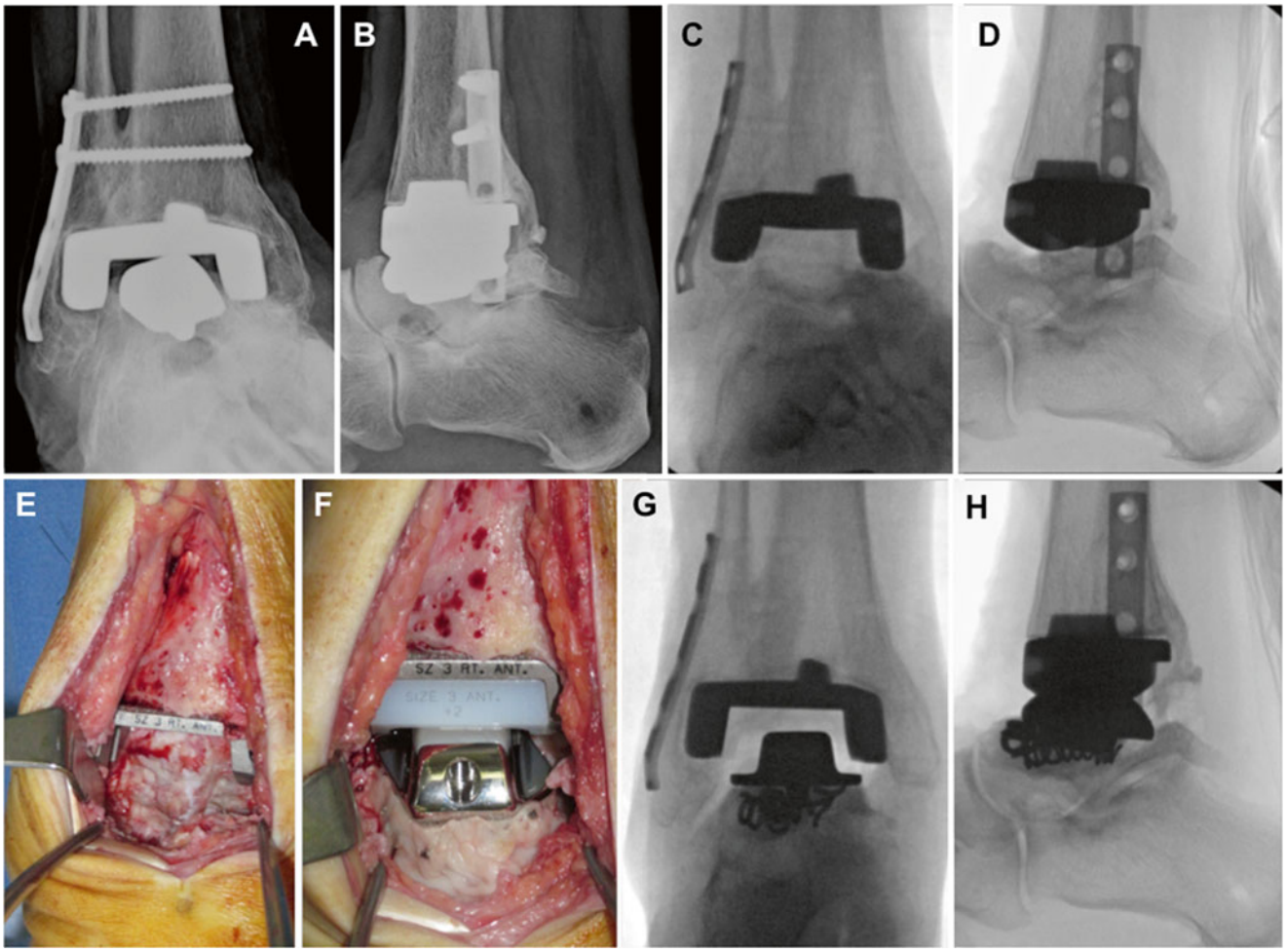

Fig. 29.25 Mortise (**a**) and lateral (**b**) weight-bearing radiographs demonstrating a failed Agility Total Ankle Replacement System with severe varus subsidence of the posterior augmented talar component. Intraoperative image intensification mortise (**c**) and lateral (**d**) radiographs, as well as intraoperative photograph (**e**) demonstrating extensive loss of the lateral 2/3 of the talar body and neck. Intraoperative photograph (**f**) as well as oblique (**g**) and lateral (**h**) image intensification views following filling of the talar body and neck osseous defect with multiple-coiled 0.062-in. Kirschner wires and PMMA cement to support the talar component. Note the use of an LP talar component and bottom-loaded +2-mm UHMWPE insert

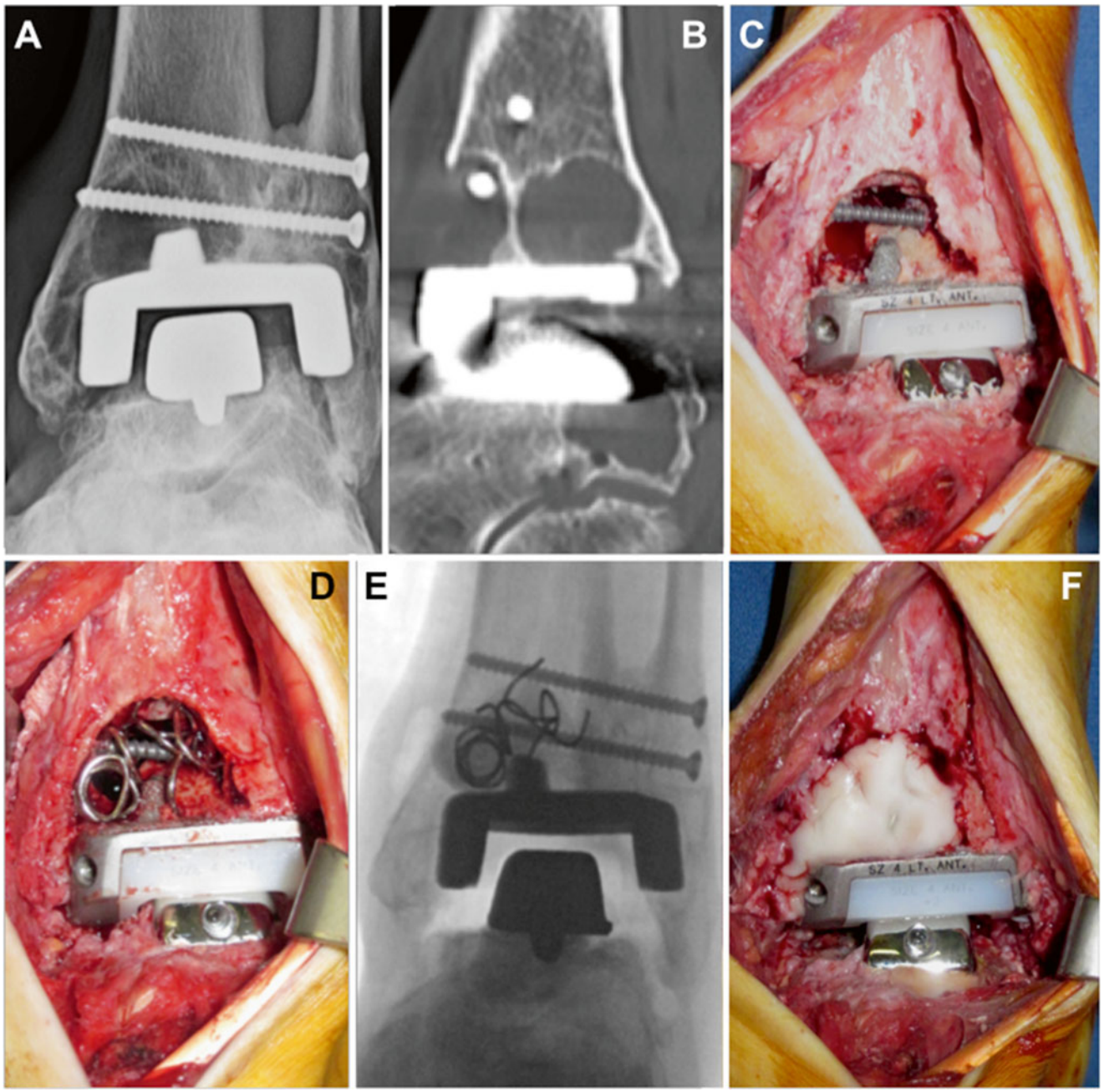

Fig. 29.26 Anterior–posterior weight-bearing ankle radiograph (**a**), sagittal computed tomography image (**b**), and intraoperative photograph (**c**) demonstrating massive osteolysis about the entire medial and central aspect of the tibial tray but otherwise stable and well-aligned tibial component. Intraoperative photograph (**d**) following evacuation of the osteolysis and filling the residual osseous defect with multiple-coiled 0.062-in. Kirschner wires. Intraoperative image intensification anterior–posterior view (**e**) and photograph (**f**) following insertion of PMMA cement within the osseous defect filling the void. Note that the posterior augmented talar component has been converted to a revision talar component secured with PMMA cement and bottom-loaded full-column +2-mm UHMWPE insert

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Revision of the Failed INBONE Total Ankle Systems

30

Sameh A. Labib and Jason T. Bariteau

Introduction

Ankle arthritis is a painful condition with disabling effect on life quality measures similar to end-stage hip arthritis [1]. The ankle joint carries more weight than the hip or knee and subsequently is under increased mechanical loads during gait. The cartilage of the ankle appears to be more resistant to degeneration, and ankle arthritis is estimated to be nine-fold less common than knee arthritis [2]. Most cases of ankle arthritis are the result of trauma especially a rotational injury [3]. The surgical treatment of ankle arthritis has been evolving with multiple techniques available to preserve the joint. [4] As for end-stage arthritis, ankle arthrodesis is still considered the "gold standard" with total ankle replacement (TAR) enjoying a recent resurgence due to better designs and techniques [5].

First-generation ankle replacements were fixed with polymethylmethacrylate cement, constrained, and consisted of two-piece systems without modularity. During the 1970s, TAR was essentially abandoned [6]. However, the development of second- and third-generation TAR with multiple components, improved fixation options, and instrumentation has lead to resurgence in TAR. The INBONE and INBONE II Total Ankle Systems (Wright Medical Technology, Inc., Arlington, TN) are fixed-bearing two-component prostheses originally design by Mark Reiley, MD, and first Food and Drug Administration 510-k cleared for clinical use in the United States in 2005 [6]. The INBONE and INBONE II Total Ankle Systems are the only TAR system that allow for intramedullary referencing for tibial component placement. The design theoretically provides more precision in implantation and a versatile TAR option in patients with significant deformity or as a revision option. Recently, the use of custom patient-specific cutting guides (PROPHECY, Wright Medical Technology, Inc., Arlington, TN) has become available based on preoperative computed tomography scans for placement of the INBONE and INBONE II Total Ankle Systems.

A systemic review of outcomes of TAR from 2003 to 2008 was recently published [7]. All available studies were level IV evidence that demonstrated posttraumatic arthritis as the leading indication for primary TAR at 34 %. There were many complications with superficial infection at 14.7 %, deep infection at 4.6 %, and residual pain as high as 60 %. Clinical failure rate was 10 % at 5 years with 62 % of failures undergoing revision TAR. Adjacent joint arthritis was also common at 15–19 % of ankles demonstrating talonavicular and subtalar arthritis.

Further work by Haddad et al. [5] compared the intermediate outcomes of TAR and ankle arthrodesis utilizing a systemic review of literature. They showed that approximately 70 % of patients had good or excellent results following primary TAR, with the most common cause for revision being loosening or subsidence of the metallic components. A recent analysis of administrative data for primary TAR demonstrated decreased rate of blood transfusion, increased rate of short-term nursing facility placement, and overall complication rate when compared to ankle arthrodesis [8]. However, no difference was seen in most common medical complications queried. Further, no difference in length of stay was observed.

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_30

INBONE and INBONE II Total Ankle Systems

The INBONE and INBONE II Total Ankle Systems are fixed-bearing TAR prostheses with either a saddle-shaped or sulcus-shaped design talar component, as well as a modular intramedullary tibial stem component. To date there has been a paucity of clinical data supporting the use of these devices. Recently, Adams et al. [9] reported on midterm results (mean follow-up of 3.7 years) of 194 INBONE Total Ankle System prostheses from one major academic foot and ankle center [9]. They demonstrated significant improvement in visual analog scale (VAS) for pain, Short Form-36, and AOFAS hindfoot–ankle scoring scale. Gait analysis also showed significant improvement from preoperative baseline in assessment of walking speed, the Timed Up and Go (TUG) test, the sit-to-stand (STS) test, and the Four Square Step Test (4SST). Radiographic parameters demonstrated significant improvement for those ankles with clinically relevant varus or valgus malalignment preoperatively. Twenty patients in this series suffered from some type of postoperative wound complication. Ten patients had either local wound healing problems or superficial infections. Five patients suffered from deep periprosthetic infection with two undergoing irrigation and debridement, polyethylene insert exchange, and retention of the metallic prosthetic components. The other three patients required explantation with one having reimplantation, one going on to tibio-talocalcaneal arthrodesis, and one requiring below-knee amputation. Five patients suffered from full-thickness skin loss, two were treated with rotation flaps, and three were treated with free tissue transfer coverage. There were five intraoperative complications: four medial malleolar fractures and one posterior tibial tendon laceration. All fractures were successfully treated with internal fixation, and the tendon laceration was treated with primary repair and flexor digitorum longus transfer. Forty-nine additional procedures were required in the postoperative analysis. Twenty-one of these were deemed directly related to the TAR. Four patients in the series underwent revision TAR, two had revision for talar component loosening, one for tibial stem loosening, and one for tibial component fracture at junction of base plate and stem. An additional six patients underwent tibio-talocalcaneal arthrodesis for talar component subsidence that was believed not to be amenable to revision TAR surgery. However, subsidence was also seen in additional 19 patients who did not have additional surgery. Ten of these were believed to be stable at last follow-up, while the other nine were significantly subsided, felt to be impending failure, and offered TAR revision but was refused by the patients.

Outcomes comparing the INBONE and INBONE II Total Ankle Systems have only recently been published. Lewis Jr. et al. [10] 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 [11] reported improved patient-reported outcomes with increased ankle range of motion at a minimum of 2-year 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.

Etiology of Failure

Understanding the etiology of the failure is paramount when deciding on the most appropriate management. Glazebrook et al. [12] have defined complications based on three categories: high grade, medium grade, and low grade. High-grade complications include implant failure, aseptic loosening, and deep infection. Medium-grade complications include technical error, subsidence, and fracture. Low-grade complications are not consistently associated with failure but include wound healing problems and intraoperative fracture.

Another recent systemic review of literature of complications following various modern design TARs has demonstrated a 12.4 % failure rate over 64-month average follow-up period [13]. Wound healing problems and intraoperative and postoperative fractures were found to be low-grade complications and are unlikely to lead to TAR revision. Aseptic loosening, deep infection, and component subsidence were more than likely to lead to TAR failure and revision.

Complications can also be defined based on the anatomy that has failed. Haddad [12] has published a very good synopsis of these anatomic failures based on his expert opinion. These include early and late fractures of the malleoli, syndesmotic nonunion specific to the Agility Total Ankle Replacement Systems (DePuy Synthes, Warsaw, IN), subsidence of the tibial or talar components, ligamentous failure, scarring of the extensor tendons with associated decreased plantarflexion, anterior wound complications, infection, and osteomyelitis. Ultimately, failure is inevitable once an angular deformity or instability develops as this leads to edge loading, osteolysis, and subsidence.

Preoperative coronal plane deformity >10–15° is a risk factor for failure. The thought being that edge loading of the prosthesis will lead to early failure [14, 15].

Datir and Labib [16] retrospectively analyzed radiographic measurements in 30 consecutive INBONE Total Ankle Systems. Out of 30 patients, 23 had a successful clinical outcome with intact prosthesis at a 2-year follow-up. The only variables with significant correlation ($p<0.05$) to the postsurgical outcome were the lateral talar component angle ($p=0.002$) and the mean difference between preoperative and postoperative tibial slope ($p=0.001$). The coronal deformity had significant mean difference between preoperative and postoperative values ($p<0.001$); however, it lacked a significant correlation to the final surgical outcome. None of the categorical variables had a significant correlation with postsurgical outcome.

Adjacent joint arthritis is also associated with failure. In the patient with talonavicular or subtalar joint arthritis, persistent pain may necessitate arthrodesis, which in turn may lead to excessive implant stresses and early failure. Recently, Lee et al. [17] performed a prospective study of 80 ankles after primary TAR. They found a 10 % incidence of symptomatic heterotopic ossification, generally occurring in the posterior ankle.

Osteolysis is critical problem that can occur following TAR and is thought to occur due to numerous factors with particulate debris being most common [18, 19]. Particulate debris is thought to lead to stimulation of RANK-L pathway leading to accumulation of osteoclasts at the bone–prosthesis interface [20]. This association is not as clear as in total hip arthroplasty where metal ions are thought to actively stimulate this pathway. In TAR, few ions are identified and more commonly necrotic tissue surrounded by a synovial-like membrane is seen in conjunction with staining associated with cells of the RANK-L pathway. The elucidation of the pathway of osteolysis in TAR is currently an active area of research, but surgeon awareness of this problem is critical. Another factor that may play a role in the development of osteolysis with TAR is significantly high intra-articular joint pressures leading to necrosis of the bone–prosthesis interface.

Failure Mechanisms Related to the INBONE and INBONE II Total Ankle Systems

The INBONE and INBONE II Total Ankle Systems have possible peculiar failure mechanisms. For either system, the instrumentation is complex, and they have a steep learning curve that may contribute to longer time in surgery, higher radiation exposure, and a possible higher incidence of soft-tissue complications and/or deep periprosthetic infection. The INBONE Total Ankle System bulky talus component and a flat talus cut are also concerning for talus bone compromise and a higher talus component failure. While intramedullary referencing and reaming may allow more accurate tibial component placement, it certainly violates the subtalar joint and its blood supply in the tarsal canal. A recent cadaveric study by Amendola et al. [21] showed a high incidence of talar blood supply interruption with the INBONE Total Ankle System as compared to three other TAR systems. The injury to the blood supply was related to the intramedullary drilling guide and may explain the catastrophic talus subsidence that the authors have experienced in their series [16], which is also similar to the recent reported series involving the INBONE and INBONE II Total Ankle Systems [9–11].

Clinical History and Diagnostic Workup

Kotnis et al. [22] published a helpful review of their experience with revision TAR. They found that patients with a failed TAR frequently present with persistent pain; however, the clinician should press the patient for any symptoms worrisome for deep periprosthetic infection. Initial evaluation should include weight-bearing anterior–posterior, lateral, and mortise radiographic views of the ankle, as well as the foot if there is pain in adjacent joints. Radiographs should be examined thoroughly for radiolucent lines around the components and any subsidence. Diagnostic injections under sterile conditions can be used to elucidate the source

of joint pain. All patients should have basic labs including cell count and differential, erythrocyte sedimentation rate, and C-reactive protein. If these are equivocal, a fluoroscopically guided aspiration and tissue biopsy can be performed. A computed tomography scan can provide invaluable information regarding loosening, cyst formation, or talar component collapse.

Management

Periprosthetic fractures, bone cysts, gutter impingement, and arthrofibrosis may lead to continued pain and disability in the early postoperative period. Periprosthetic fractures may pose a challenge as the available surface area for healing and bone quality may be poor. Nonoperative management can be accomplished with casting and prolonged non-weight bearing at the risk of losing sagittal plane range of motion. Open reduction internal fixation is the treatment of choice. Bone cysts can be related to arthritis and should be addressed at the index TAR procedure. Delayed bone cysts are usually related to polyethylene debris-induced foreign body reaction and should be addressed with curettage and impaction bone grafting. Gutter impingement and arthrofibrosis can be improved with arthroscopic arthrolysis.

Failed TAR patients without deep periprosthetic infection should be counseled regarding revision TAR versus ankle arthrodesis. The decision to proceed with revision TAR should be based on bone quality, bone loss, the soft-tissue envelope, patient comorbidities, and most importantly the needs of the patient. On the tibia side, bone loss salvage is often possible with the use of stemmed prosthetic components. However, bone loss by itself may be a contraindication to revision especially on the talar side. The clinician should be vigilant for any signs of talar avascular necrosis and adjacent arthritis as these would preclude a successful revision. The use of stemmed talar implants with or without subtalar fusion is a controversial option that merits further study.

Deep Periprosthetic Infection

The infected TAR should generally be treated with a two-stage revision, a below-knee amputation, or arthrodesis. In knee and hip arthroplasty surgery, single-stage revision can be considered in the acute (< 4 weeks) infection; to this author's knowledge, no studies have validated this as a surgical option in TAR. In the study by Kotnis et al. [22], they recommend thorough debridement and placement of an antibiotic-loaded polymethylmethacrylate cement spacer with bacteria-specific antibiotics at the discretion of the infectious disease specialist for a minimum of 6 weeks. Infection markers should be followed to confirm that the patient has responded to therapy. Then, removal of the spacer and salvage ankle or tibio-talocalcaneal arthrodesis can be performed. However, if the patient fails to respond to these therapies, a below-knee amputation should be considered.

J. Chris Coetzee, MD (unpublished data), has developed a treatment algorithm that the authors adopt with few modifications and use as a guide for management of failed TAR (Fig. 30.1). As illustrated in Fig. 30.1, the presence of deep periprosthetic TAR sepsis is treated with two-stage salvage. The authors routinely use the existing anterior approach if the soft tissue is intact but resorted to an Achilles tendon splitting approach in cases where anterior soft tissue is compromised. A tibio-talocalcaneal arthrodesis with a retrograde intramedullary nail is the preferred method of salvage. If sepsis is not a limiting factor, revision TAR is possible except in severe talus collapse or avascular osteonecrosis (Fig. 30.2a). With adequate talar bone stock, revision TAR surgery is often successful with the use of a larger talar component and thicker polyethylene liner with or without cyst impaction bone grafting (Fig. 30.2b). TAR systems with long tibia or talar stems may be employed to obtain secure fixation and help achieve soft-tissue balancing.

Case Examples

Case 1

An otherwise healthy 62-year-old man with severe ankle arthritis with hindfoot valgus and anterior talar subluxation (Fig. 30.3a) was treated with an INBONE Total Ankle System and significant soft-tissue balancing at the time of index TAR procedure (Fig. 30.3b). Follow-up radiographs showed progressive talar component subsidence (Fig. 30.3c, d) and the patient presented with worsening pain. Talar component revision was performed with impaction bone grafting subtalar arthrodesis performed through a lateral sinus tarsi approach. The talar avascular osteonecrosis and collapse was curetted (Fig. 30.4a) and packed with autogenous bone graft in addition to a strut fibula graft placed laterally and fixed to the medial talus (Fig. 30.4b). Pain improved and the patient is ambulating well with no support 3 years post-revision (Fig. 30.4c, d).

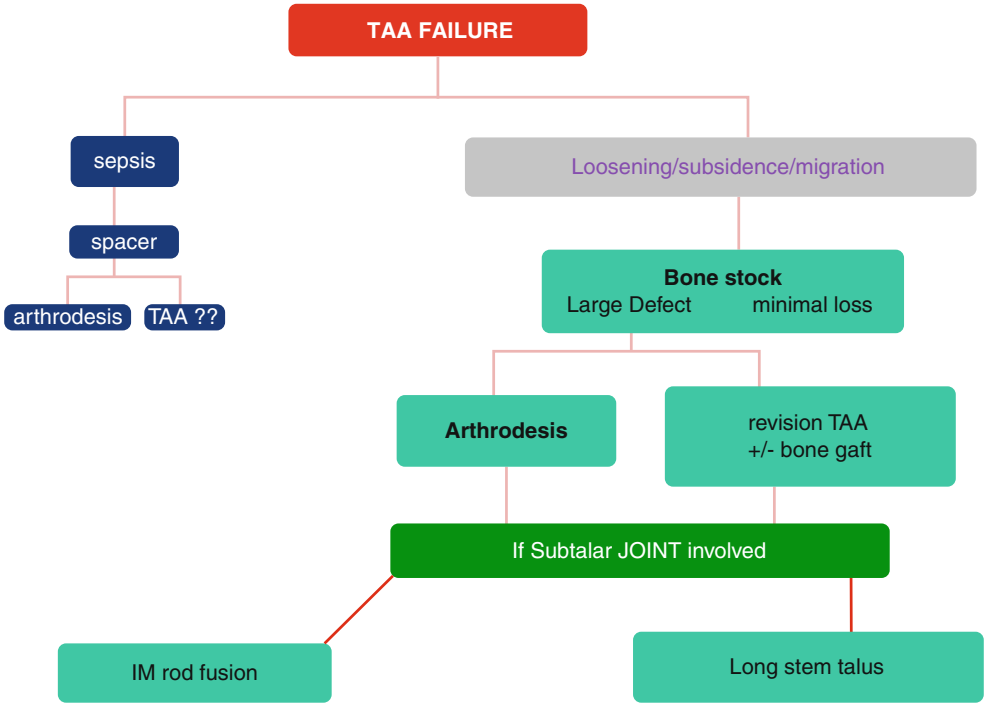

Fig. 30.1 Total ankle replacement failure treatment algorithm

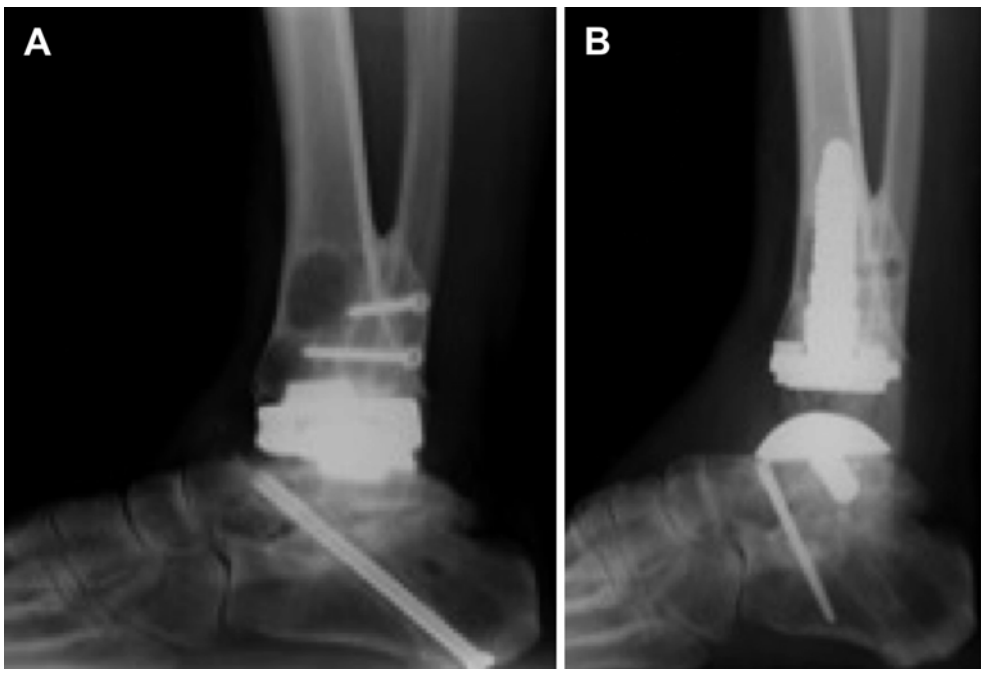

Fig. 30.2 Weight-bearing lateral radiograph of a failed Agility Total Ankle Replacement System with concomitant subtalar arthrodesis nonunion and adequate talar bone stock (**a**). Weight-bearing lateral radiograph following revision with the INBONE Total Ankle System and revision subtalar joint arthrodesis (**b**)

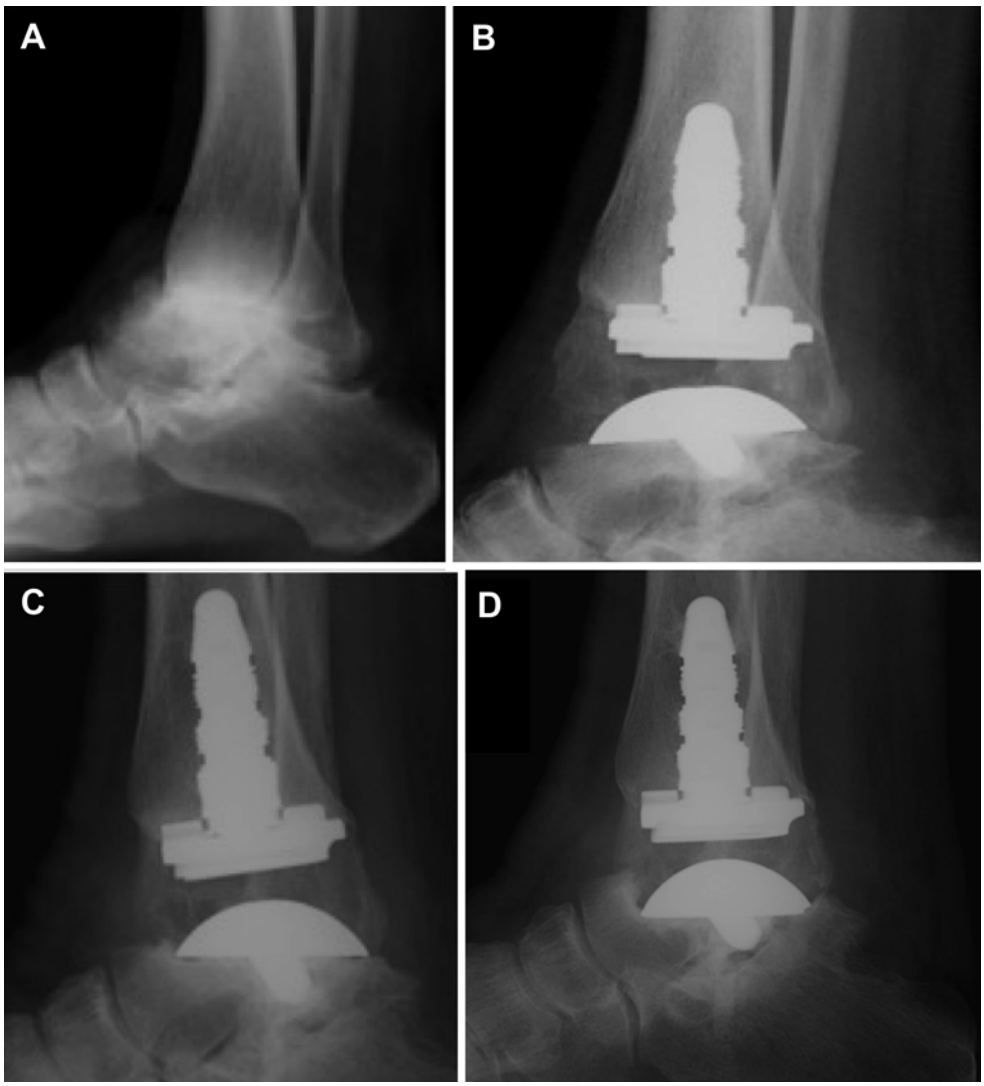

Fig. 30.3 Preoperative weight-bearing lateral radiograph showing severe right ankle arthritis and anterior talar subluxation (**a**). Early postoperative (**b**), 6-month follow-up (**c**), and 1-year follow-up (**d**) weight-bearing lateral radiographs following INBONE Total Ankle System implantation

Case 2

An otherwise healthy 78-year-old woman presented 2-year status-post INBONE Total Ankle System implantation and subtalar arthrodesis complicated with talar bone collapse and component subsidence. The patient had known osteoporosis and a revision TAR was deemed impossible due to talar bone deficiency (Fig. 30.5a). She underwent a salvage hindfoot arthrodesis with an interpositional bulk femoral head allograft performed through a lateral approach (Fig. 30.5b). At 1-year follow-up, the patient has significant pain relief and ambulates without support.

Conclusions

TAR is just beginning to have surgical series with mid- and long-term results, and there is currently a paucity of evidence about the role of revision for TAR. TAR demonstrates reliable improved clinical function and enhances gait parameters in patients with end-stage ankle arthritis. There is also a significant number of patients, however, who will require revision surgery and/or salvage arthrodesis for prosthesis failure and patient-related complications. The result of those procedures to date is limited to a few small surgical series. Kotnis et al. [22]

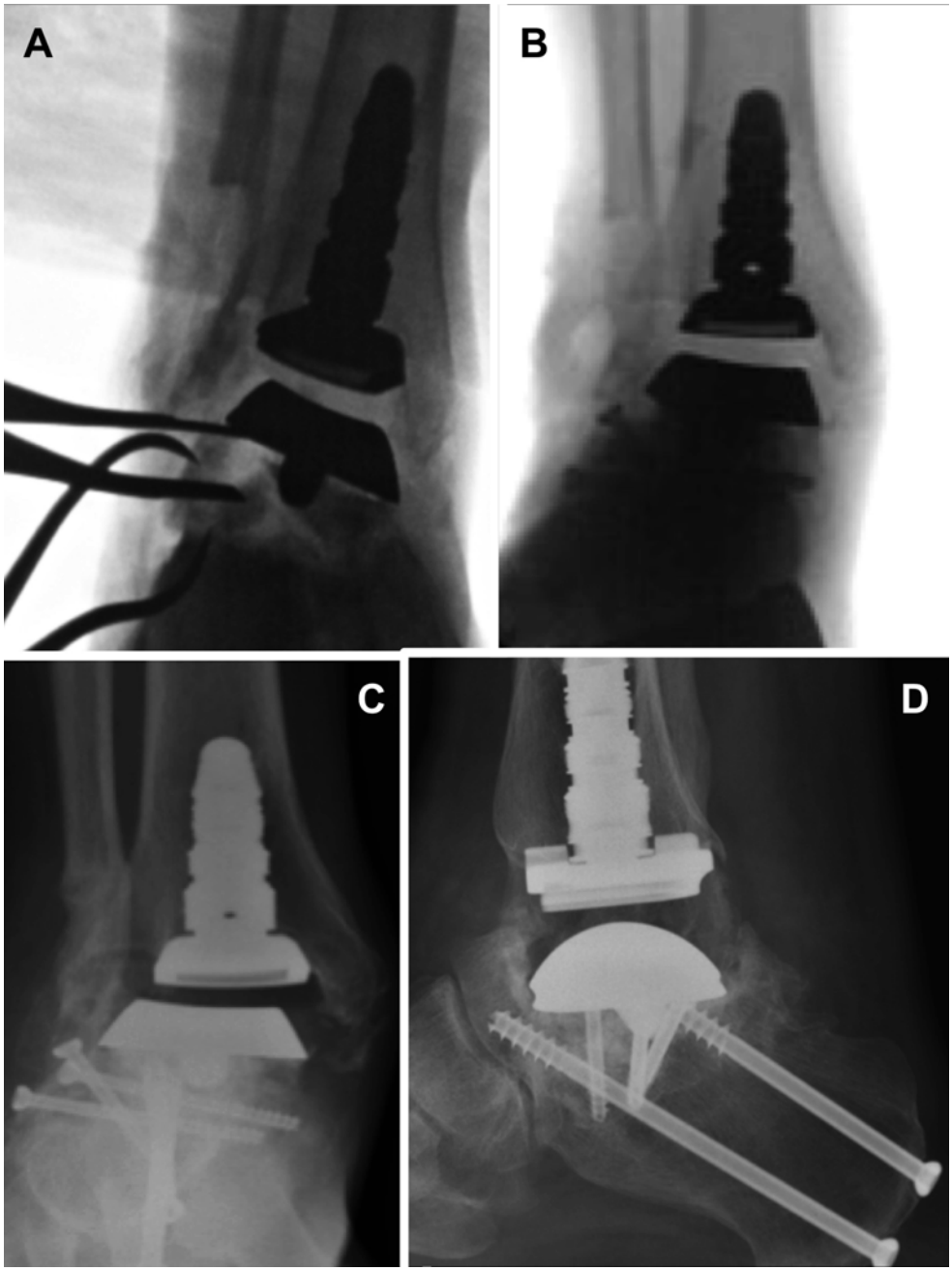

Fig. 30.4 Salvage of the failed INBONE Total Ankle System shown in Fig. 30.3. Anterior–posterior intraoperative C-arm image intensification view prior to (**a**) and following (**b**) talar component revision with impaction bone grafting to achieve subtalar arthrodesis and structural support to the talar component with an onlay fibular strut. Weight-bearing anterior–posterior (**c**) and lateral (**d**) radiographs at 3-year follow-up demonstrating stable alignment and no further talar component subsidence despite loss of talar component height

reported that three of five patients undergoing revision TAR had persistent pain, while only two of ten patients who had salvage arthrodesis demonstrated long-term pain. However, salvage arthrodesis is not without its own associated morbidities, including limb shortening and abnormal gait. Our results are similar; of the last four revisions performed, two have been converted to retrograde intramedullary nail, while the other two are doing well with significant improvement in clinical outcome scores and moderate improvement in pain relief. Future work is needed to define the appropriate role of revision TAR. There is need for enhanced instrumentation and dedicated revision prostheses to better deal with challenges of bone loss and malalignment that the revision setting presents. However, INBONE and INBONE II Total Ankle Systems are important tools for the foot and ankle specialist to consider when planning revision TAR.

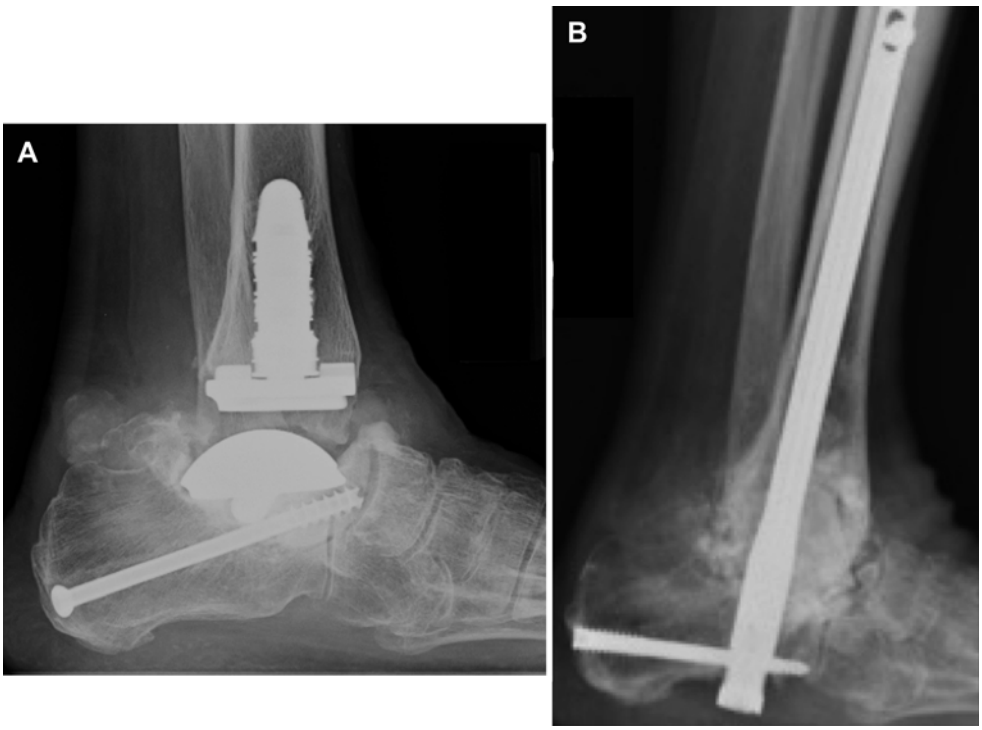

Fig. 30.5 Weight-bearing lateral radiograph demonstrating a failed INBONE Total Ankle System due to severe talar component subsidence and bone collapse (**a**). Weight-bearing lateral radiograph 1 year following explantation of the failed total ankle replacement and salvage tibiofemoral head allograft–calcaneal arthrodesis stabilized by retrograde intramedullary nail fixation (**b**)

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The Salto Talaris XT Revision Total Ankle Replacement System

31

Fabrice Gaudot, Thierry Judet, Jean Alain Colombier, and Michel Bonnin

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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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_31

(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 polymethylmethacrylate 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. 31.1). 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. 31.2). The primary and revision TAR prostheses are

Fig. 31.1 Lateral view of the assembled Salto Talaris XT revision total ankle replacement with the revision tibial component and short-stem flat-cut talar component

therefore perfectly compatible, with the exception of the size "zero" primary size range, which is not available in the revision size range.

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 bladelike 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.

Fig. 31.2 Angled view of a sloped-cut long-stem talar component demonstrating the features of the articular surface

Salto Talaris XT Talar Component

The talar component is available in three models (Fig. 31.3) and all have identical articular geometries:

1. The "flat-cut short-stem" revision talar component (Fig. 31.3a) features a flat cut (Fig. 31.4a) and a keel slightly deeper than that of the primary talar component (Fig. 31.4b, 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 anteroposterior, 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. 31.3b) 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. 31.3c) 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.

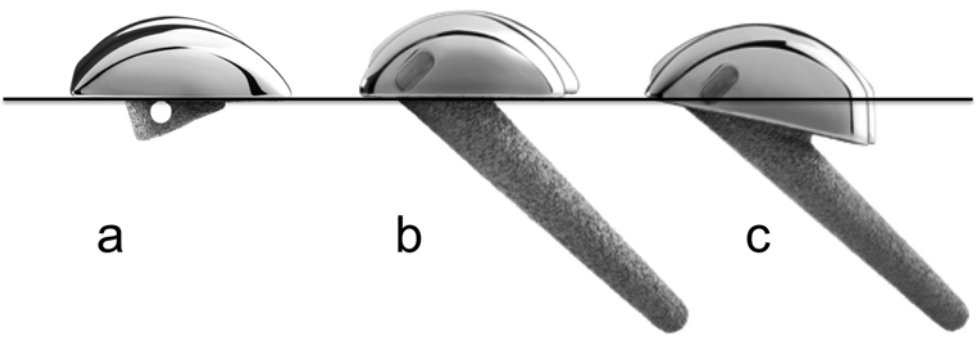

Fig. 31.3 Salto Talaris XT revision talar component, lateral view: flat cut, short stem (**a**); flat cut, long stem (**b**); and slopped cut, long stem (**c**)

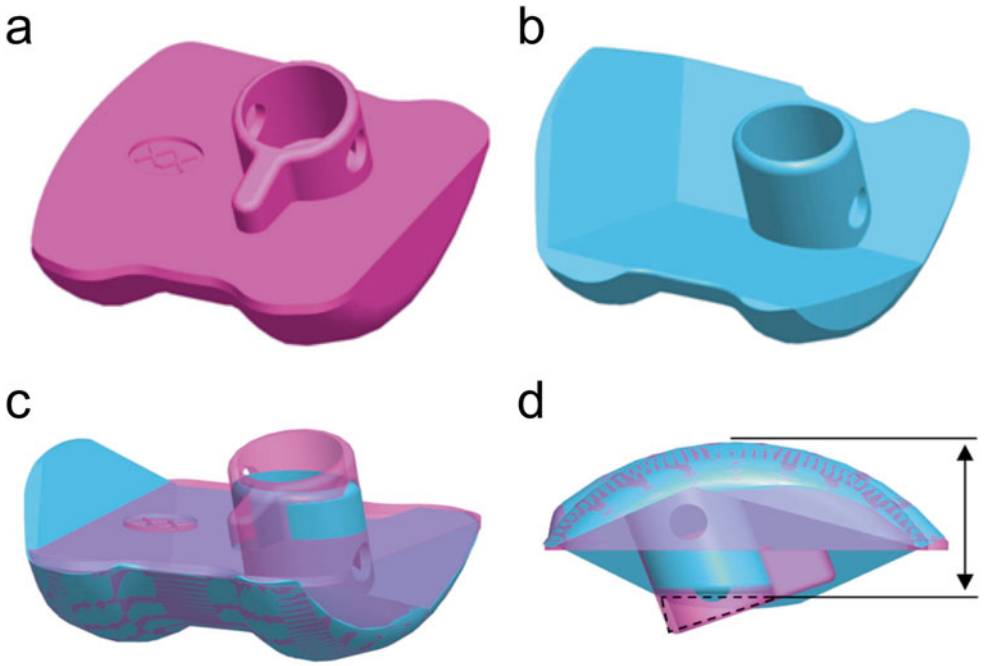

Fig. 31.4 Difference between the talar stem for the Salto Talaris XT revision flat-cut short-stem (*pink*) and Salto Talaris (*blue*) talar components. Flat cut, short stem, inferior view (**a**); Talaris talus, inferior view (**b**); overlapping of both talar components, inferior view (**c**); and overlapping of both talar components, lateral view (**d**)

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.
- 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. 31.5). 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. 31.6). 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. 31.7), 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. 31.8). 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. 31.7 and 31.9). 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. 31.10). 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 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.

Fig. 31.5 Tibial extramedullary alignment guide

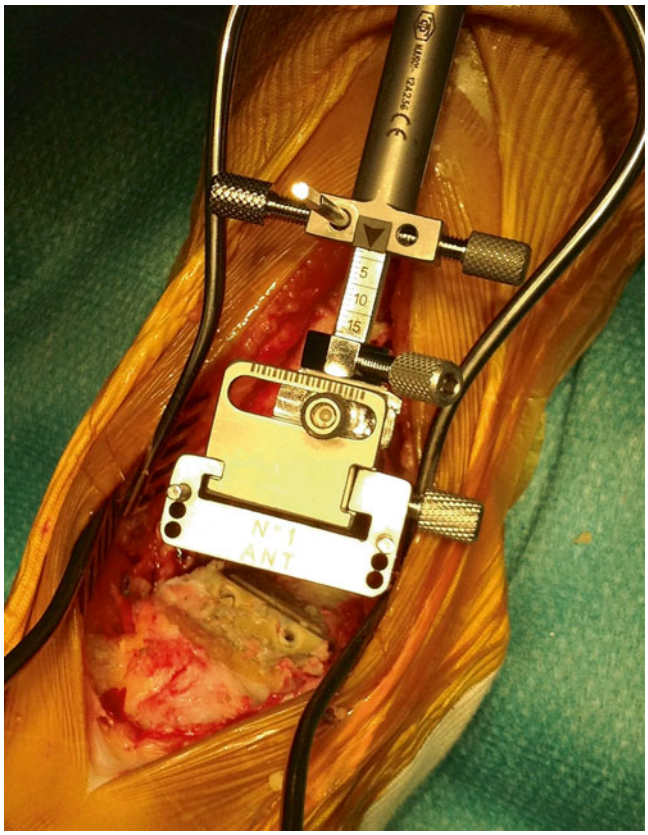

Fig. 31.6 Tibial cutting block, perioperative view

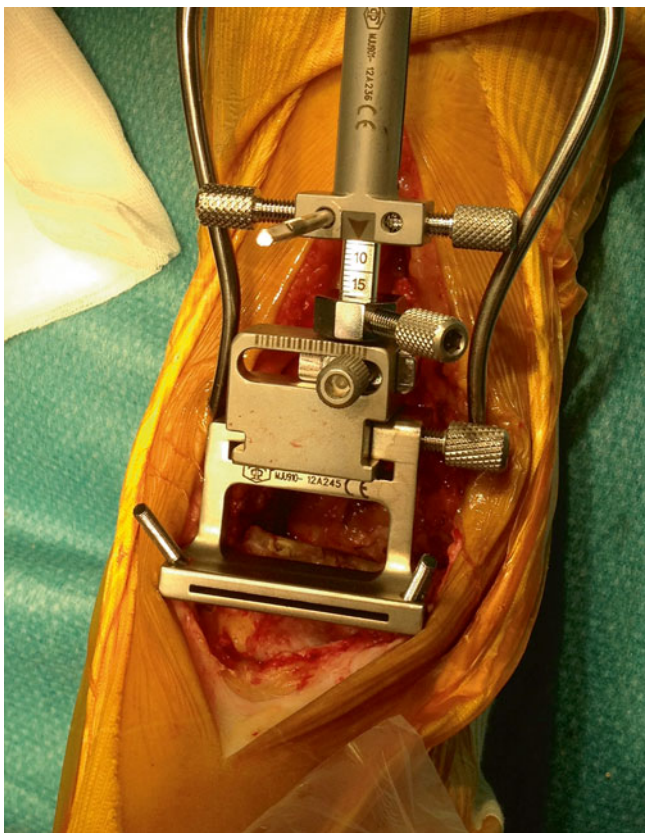

Fig. 31.7 Talar cutting block, intraoperative view

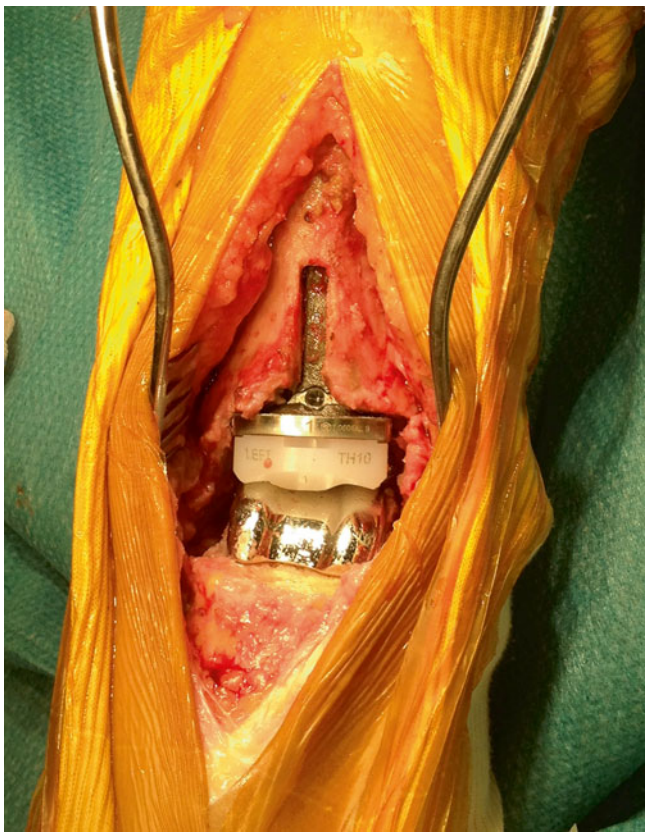

Fig. 31.8 Salto Talaris XT revision tibial and short-stem flat-top talar components, definitive components, intraoperative view

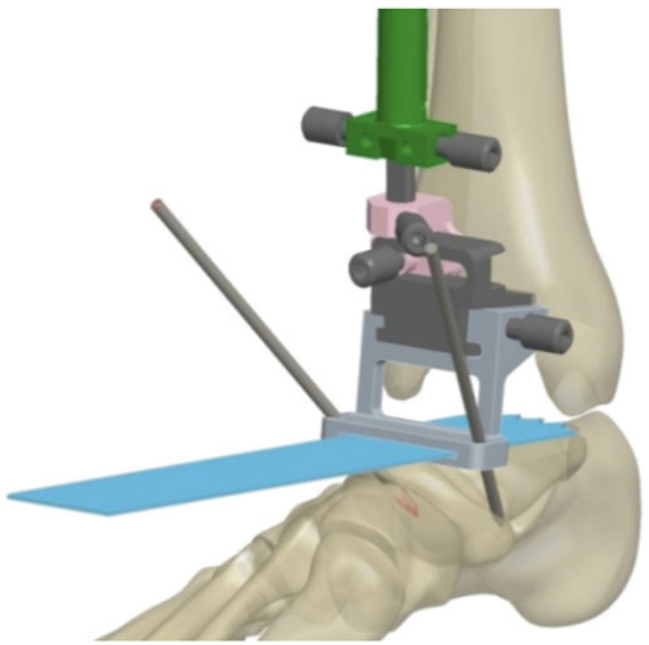

Fig. 31.9 Talar cutting block, schematic drawing of the flat-top talar preparation

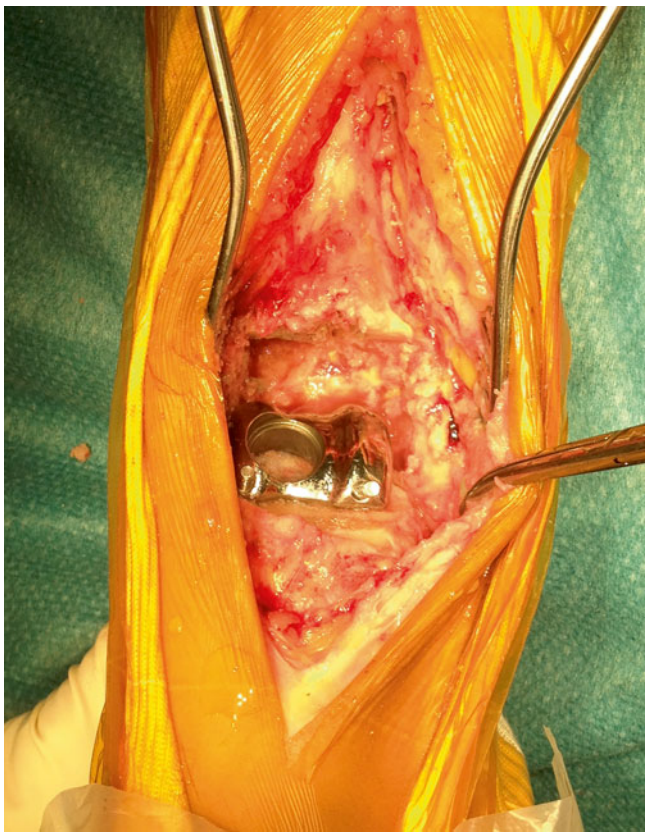

Fig. 31.10 Setting of trial talar component, intraoperative view

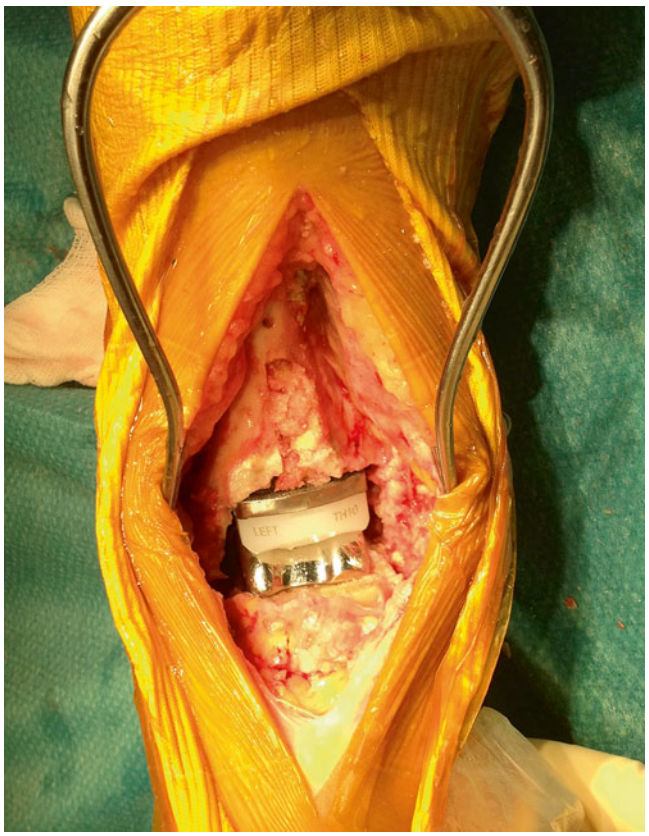

Fig. 31.11 Impaction bone grafting of the tibial window, intraoperative view

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. 31.11). 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

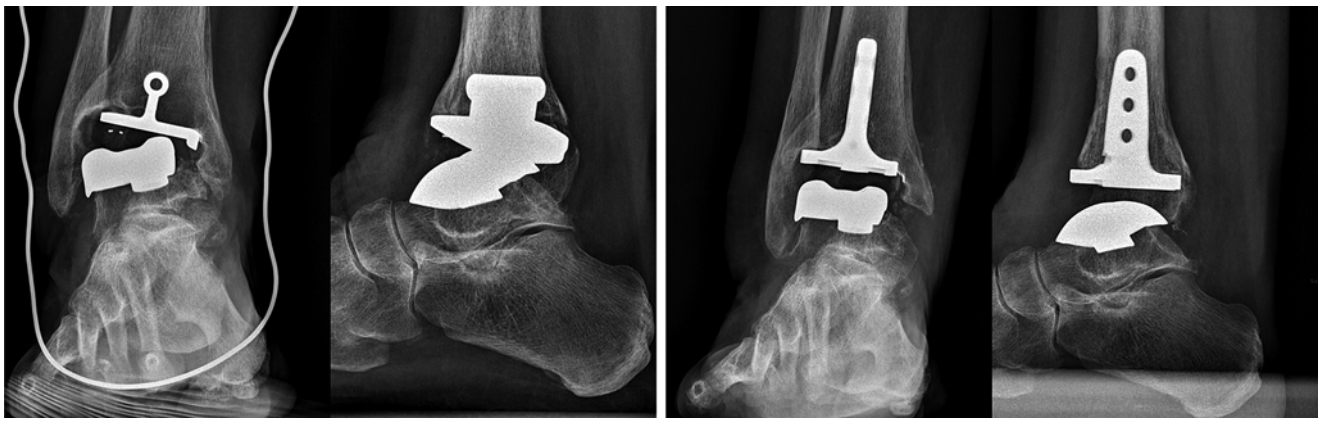

Fig. 31.12 Unipolar tibial revision procedure for subluxation of a mobile-bearing total ankle replacement. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating persistent lateral ankle instability following implantation of a Salto Mobile Prosthesis. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating removal of the index tibial component and conversion to a Salto Talaris XT revision tibial component demonstrating anatomic alignment

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. 31.12). 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 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. 31.13); one "flat cut, long stem" (Fig. 31.14); and three "sloped cut, long stem" (Fig. 31.15). 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. 31.15). 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 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

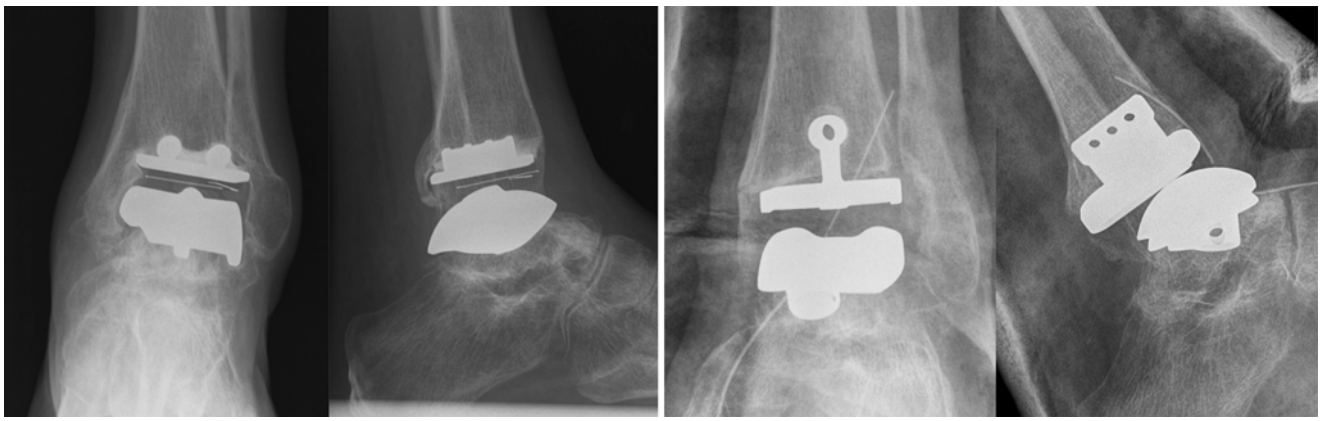

Fig. 31.13 Case of bipolar revision for talar migration. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating persistent lateral ankle instability following implantation of a STAR Prosthesis. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating explantation of 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

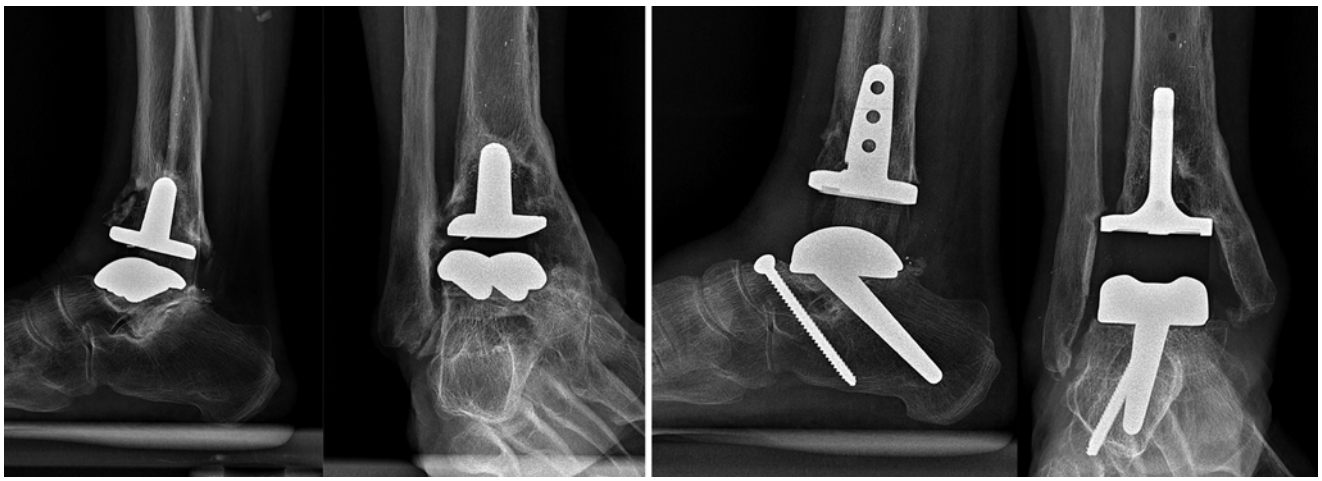

Fig. 31.14 Case of bipolar revision for tibial bone cyst formation. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating persistent lateral ankle instability following implantation of an AES total ankle replacement. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating explantation and conversion to a Salto Talaris XT revision tibial component and long-stem flat-cut talar component and arthrodesis of the subtalar joint

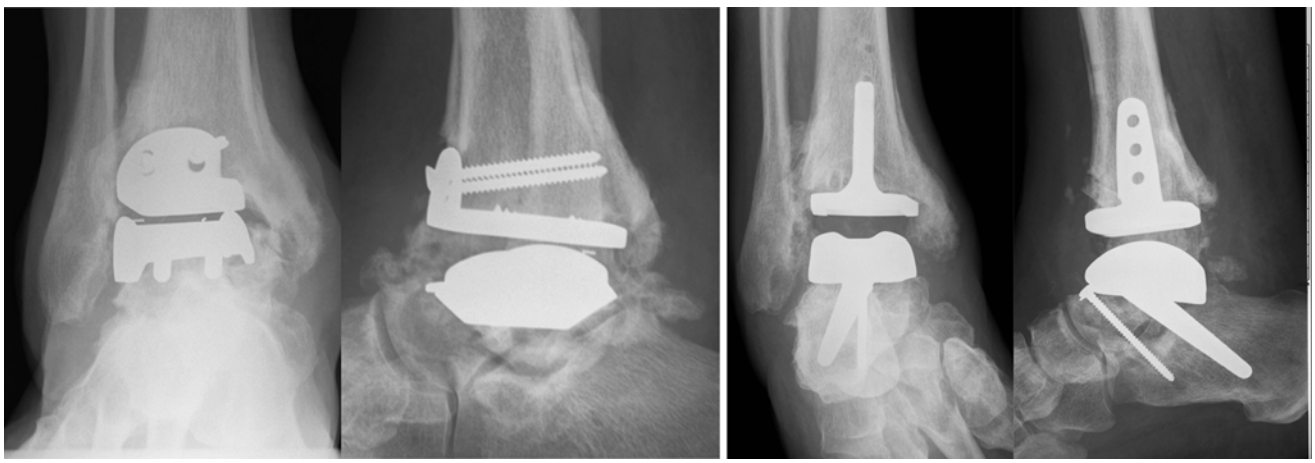

Fig.31.15 Case of bipolar revision for talar subsidence. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating persistent lateral ankle instability following implantation of an HINTEGRA total ankle replacement prosthesis. Anteroposterior (*left*) and lateral (*right*) radiographs demonstrating 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

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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Revision of the Failed STAR Total Ankle Replacement

32

Timothy R. Daniels, Sagar J. Desai, and Murray J. Penner

Introduction

The Scandinavian Total Ankle Replacement (STAR; Waldemar LINK, Hamburg, Germany; now distributed by Stryker Orthopaedics, Inc., Kalamazoo, MI) is one of the most commonly implanted total ankle replacements (TARs) globally. Hakon Kofoed, MD, has introduced four different versions of the prosthesis since the initial design in 1981. The current prosthesis is a three-component, mobile-bearing TAR with metal tibial and talar components and a polyethylene liner. The STAR has been in clinical use in Europe since 1981. In the United States, investigational use began in 1998, and it has been approved for clinical use since 2009. Short- and intermediate-term clinical data of the STAR prosthesis have demonstrated excellent survivorship in some studies; however, reports of high revision rates and poor implant survivorship have questioned its efficacy [1].

This chapter describes the history of the implant, the clinical outcomes to date pertaining to each version of the STAR prosthesis, and the potential flaws of the prosthesis.

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History

Hakon Kofoed, MD, from Copenhagen, Denmark, designed the first STAR implant in 1978. The first prosthesis was implanted in 1981. This implant was a two-component, anatomic, unconstrained design that consisted of a metal talar component and a polyethylene tibial component [2]. The talar component had medial and lateral talar wings to cover the medial and lateral surfaces of the talus. Both the talar and tibial components were fixed with polymethylmethacrylate cement.

In 1986, the STAR was revised to a three-component prosthesis, which included metal tibial and talar components and a meniscal-type liner made of ultrahigh molecular weight polyethylene. This version of the prosthesis included two cylindrical bars on the tibial platform to enhance fixation into the solid subchondral bone of the distal tibia. The inferior surface of the tibia was flat and polished. The metal talar component had a longitudinal ridge in the midline, congruent with the undersurface of the mobile polyethylene component to mimic the semi-constrained nature of the native ankle joint. At the talar-polyethylene articulation, dorsiflexion and plantarflexion were enabled, but talar tilt was not permitted.

In 1990, a significant additional modification was introduced. A bioactive surface coating was added to allow cementless implantation. This included a titanium plasma spray porous coating and a hydroxyapatite coating on both the tibial and talar components. Two cylindrical fins secured the component on the tibial side, and a single fin secured the component on the talar side.

In 1999, double coated hydroxyapatite was introduced to both the talar and tibial components. In 2000, in the fifth version of the prosthesis that is currently still in use, the coating was once again modified to provide only a titanium plasma spray porous coating.

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_32

Implant Use

After its introduction in 1981, the STAR prosthesis became one of the most utilized TARs worldwide for a number of reasons. The STAR had a more anatomic design consisting of three components with a polyethylene meniscus; it allowed for cementless fixation, and it required limited tibial bone resection.

Kofoed developed the STAR prosthesis with great respect for the anatomy and kinematics of the ankle joint. The talar component was designed to avoid potential disruption of the delicate talar blood supply. The talus derives its blood supply from four primary sources [3], and the confluence of vessels meets at the center of the talar body. Kofoed placed the talar fin in this region to avoid vascular disruption. Additionally, the STAR talar component had a more anatomic design, as the surface shape resembled the native talus and wings replaced the medial and lateral talar facets [2].

The three-component design of the STAR was also a novel development in ankle arthroplasty. The Buechel–Pappas prosthesis [4] and the STAR prosthesis were the first to introduce the principle of a meniscal-type polyethylene component in the 1980s [5]. This modification was introduced to minimize the rotational stress at the bone–implant interface. It allowed only compressive forces, which was hoped would reduce the prevalence of implant loosening. The three-part design, with two joint surfaces, was theorized by the designer to provide better ankle kinematics [2].

The limited bone resection required for implantation was another attractive feature of the STAR implant. The tibial component consists of two cylindrical bars which are designed to insert into solid subchondral bone. The more proximal bone in the distal tibia is largely loose spongious bone [3], which provides a less stable platform for the tibial component. The STAR design requires minimal bone resection, as only the anterior and posterior lips of the distal tibia require resection [2]. This allows for greater bone stock in the event of prosthesis failure, thus easing the conversion to either ankle arthrodesis or another TAR.

Outcomes

Kofoed published his data on 28 TARs performed with this prosthesis from 1981 to 1985 [6]. Seven failures occurred, and the cumulative survival was 70 % for the prosthesis at 12 years [6]. Kofoed and Lundberg-Jensen [7] reported on use of this prosthesis in a prospective series comparing two groups of patients: 30 ankles in patients younger than 50 years of age (median age 46 years) and 70 ankles in patients older than 50 years of age (median age 63 years). Scores for pain, function, and mobility improved significantly in both groups. Survivorship was 75 % in the younger group and 81 % in the older group, which were statistically similar. Kofoed and Sorensen [5] reported the results of 52 TARs performed between 1981 and 1989 in patients with either osteoarthritis or rheumatoid arthritis. Pain, function, and mobility were significantly improved in both groups. There were no differences between the osteoarthritis and rheumatoid arthritis groups in survival rates at 14 years, which were 73 % and 76 %, respectively. This study used the initial STAR design until 1986 and the next-generation, three-component, meniscal-bearing implant from 1986 to 1989. The results before and after this change were not reported individually.

In 1990, a hydroxyapatite surface coating was introduced for cementless implantation. Kofoed [2] compared 33 patients treated between 1986 and 1989 with the cemented prosthesis to 25 patients treated between 1990 and 1995 with the cementless prosthesis. At a mean follow-up of 9.4 years, 9 of 33 (27 %) patients in the cemented group had undergone revision surgery, whereas only 1 of 25 (4 %) patients in the uncemented group had undergone revision. Prosthesis survival was 70 % in the cemented group and 95 % in the uncemented group [2]. Based on these results, the author (and designer) of the prosthesis suggested an unconstrained, three-component, cementless ankle prosthesis should be used.

Wood and Deakin [8] reported on 200 TARs they performed using the STAR prosthesis between 1993 and 2000. All implants were uncemented and included either the single or dual layer of hydroxyapatite coating. Fourteen (7 %) ankles failed and underwent either revision or fusion. Eight patients underwent reoperation for various reasons, including fracture at the time of or after surgery, edge loading, and pain and stiffness. The survival rate was 93 % at 5 years, with revision or conversion to fusion as the end point. Wood et al. [9] reported the midterm results of 200 STAR implants in 184 patients. Twenty-four ankles (12 %) underwent revision, including 20 converted to arthrodesis and four converted to arthroplasty with a different prosthesis. The 5- and 10-year survival rates were 93 % and 80 %, respectively. Karantana et al. [10] reported the results of 45 patients (52 ankles) who underwent TAR with the STAR prosthesis and had a minimum of 60-month follow-up. The survival rates were 90 % and 84 % at 5 and 8 years, respectively. Six ankles (12 %) underwent revision and two (4 %) were converted to ankle fusion. The average time to revision was 44 months. Reoperation, excluding component revision, occurred in nine patients (17 %).

In 2011, Zhao et al. [11] published a systematic review of the uncemented STAR. Sixteen studies, including 2088 implants, were included in the analysis. The mean time to follow-up was 52 months. The 5- and 10-year survival rates were 86 % and 71 %, respectively. Seven studies included in the systematic review reported time to failure. These studies included 34 failures in 357 TARs for a pooled failure rate of

11 % with a mean follow-up of 52 months. Implant failure was most commonly due to aseptic loosening, malalignment, and deep infection. They found that 41 % of failures occurred within 1 year of implantation. The authors suggested surgeon experience was an important factor, since failure rate decreased significantly if first-year failures were eliminated from the analysis.

The early studies supporting outcomes with the STAR implant were criticized, since they were predominately published by the developers of the implant. Prissel and Roukis [12] recently performed a systematic review and found an 18 % rate of revision in various ankle registries, compared to a 2 % rate of revision reported by the inventor and 6 % rate reported by paid consultants and/or faculty.

Other studies have also revealed inferior results for the STAR prosthesis. Anderson et al. [13] reported on 51 patients who underwent uncemented fixation with the STAR prosthesis between 1993 and 1999. In their series, 12 (24 %) patients underwent revision, performed for prosthesis loosening (seven ankles), fracture of the polyethylene liner (two ankles), or other reasons (three ankles). In addition to these 12 patients, 8 other patients had radiographic signs of loosening. The 5-year survival was 70 %. Brunner et al. [1] reported on the long-term outcomes of TAR using the single coated hydroxyapatite STAR prosthesis in 77 ankles. Seventeen (22 %) ankles had chronic pain. Polyethylene fractures occurred in eleven (14 %) ankles. Revision of at least one of the metal components was performed in 29 (38 %) ankles, of which one was converted to ankle arthrodesis, 25 underwent revision of both the talar and tibial components, and three underwent revision of the talar component alone. The average time to revision was 7.4 years. The survival rate, using revision of any component as the end point, was 71 % at 10 years and 46 % at 14 years. The authors reported that the majority (25/29) of the revisions were from failures at the bone–prosthesis interface. They hypothesized that this may have been a result of the single hydroxyapatite coating and warned against its use in a three-component system.

North American outcome studies of the STAR implant are limited to four primary studies, all using the current version of the prosthesis [14–17]. A fifth non-inferiority study focused on comparison of the STAR implant to ankle arthrodesis at 24-month follow-up [18].

Mann et al. [14] reported excellent long-term results in 84 TAR in 80 patients using the STAR prosthesis. Significant improvements were found in both pain and function subscores of the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle–Hindfoot Scale. Prosthesis survival at an average of 9.1-year follow-up was 91 %. The probability of implant survival at 5 and 10 years was 96 % and 90 %, respectively. However, high-grade complications occurred in nine (12 %) patients, including two ankles with aseptic loosening, three deep infections, and four implant failures. Fourteen of these patients underwent additional procedures.

Nunley et al. [15] reported intermediate- to long-term outcomes of the STAR implant using various outcome measures in 82 patients who were followed for an average of 61 months. Significant improvements were found in all outcome categories, including the AOFAS Ankle–Hindfoot Scale pain, function, alignment, and summary scores, the Short Form-36 (SF-36) Standard Health Survey physical component summary and mental component summary scores, visual analog scale (VAS) pain scores, Buechel–Pappas scores, and ankle range of motion. Five patients (6 %) required removal of the tibial and/or talar components. With the end point being revision of any component, the survival rate at a mean of 5 years was 94 %.

Jastifer and Coughlin [16] reported on 18 patients who underwent TAR with a STAR prosthesis between 1998 and 2003, during the investigational period of the prosthesis in the United States. At a minimum of 10-year follow-up, implant survival was 94 %. Seven of eighteen (39 %) patients required additional surgical procedures, most of which were performed more than 9 years after the TAR. Patient satisfaction, function, and pain relief were all high.

Daniels et al. [17] recently reported the intermediate- to long-term outcomes of 111 total ankle replacements with the STAR prosthesis in 98 patients with a variety of primary diagnoses, including posttraumatic osteoarthritis, rheumatoid arthritis, primary osteoarthritis, and osteoarthritis due to deformity. Thirteen (12 %) ankles required metal component revision at a mean of 4.3 years following TAR, with a projected 10-year survival rate of 88 %. Twenty (18 %) ankles underwent polyethylene bearing exchange at a mean of 5.7 years postoperative, mostly due to fracture. Clinical outcomes showed large improvements in Ankle Osteoarthritis Scale pain and disability scores and SF-36 physical component summary scales at a mean of 7.6 years following surgery.

To date, only one study has directly compared the STAR to another prosthesis. From 2000 to 2003, Wood et al. [19] performed a prospective, randomized study of 200 TARs and compared the STAR prosthesis to the Buechel–Pappas prosthesis. Both implants are three-component designs with a meniscal-type polyethylene. The main difference is in the markedly different shape and geometry of the talus [19]. The Buechel–Pappas prosthesis is more anatomic, with a sagittal groove mimicking the normal talar anatomy, whereas the version of the STAR prosthesis used was mainly cylindrical with a central peg. The minimum duration of follow-up was 3 years. A total of 16 (8 %) ankles were revised, including 12 from the Buechel–Pappas group and four from the STAR group. Although there was a trend toward a higher failure rate with the Buechel–Pappas, this did not reach statistical significance. The survivorship at 6 years was 79 % for the Buechel–Pappas and 95 % for the STAR, which was not significantly different.

Failure of the STAR Prosthesis

TAR may ultimately fail due to many factors. Common modes of failure for TAR include infection, malleolar fracture, and pain and stiffness. The STAR prosthesis has specific failure characteristics that can potentially be attributed to the prosthesis itself. These factors include polyethylene bearing failure with premature wear or fracture, cystic (Fig. 32.1), aseptic loosening, and subsidence (Fig. 32.2) [20].

There are three main modes of failure for any arthroplasty. In the first scenario, the implant is inserted in the optimal position, but in a suboptimal situation. In the second scenario, the implant is inserted in the optimal patient or situation, but has been inserted in a suboptimal fashion. These modes of failure are referred to as *implementation-related failures*, suggesting that surgeon error is responsible and a contributing factor. Finally, *design-related failures* occur even when the implant has been placed in an appropriate patient and in a technically optimal manner, suggesting that the failure can be attributed to the implant itself, rather than to patient or surgeon factors [20].

Evaluation of the specific failure characteristics of the STAR prosthesis suggests that both implementation-related failures and design-related failures have contributed. The implant may have been placed in an optimal manner, but in a suboptimal situation. Many suboptimal situations may lead to implant failure, regardless of the specific prosthesis used. For example, poor bone quality, bone loss, ligamentous laxity, non-correctable deformity, and infection can all potentially compromise the outcome following any total ankle replacement. Defining which of these specific characteristics is most important in the failure of the STAR prosthesis is challenging. In 2012, Laflamme et al. [21] examined patient characteristics leading to polyethylene bearing failure when using the STAR implant and determined that male gender, increased body mass index (BMI), and better postoperative functional level led to an increased risk of early polyethylene failure. Additionally, larger talar implant size was also associated with polyethylene bearing fracture [20]. To our knowledge, there is no similar literature on other prostheses used in TAR. It is not known if these failures can be attributed specifically to the STAR prosthesis or to all ankle prosthesis designs in general.

The second mode of failure, implementation-related failures, is related to the implant being placed suboptimally in the optimal situation. There is evidence that TAR has a high learning curve, regardless of prosthesis [17, 22–25]. Specific to the STAR implant, Haskell et al. [22] reported 3.1 times higher rates of complications in the first five TARs performed compared to subsequent cases. Daniels et al. [17] also reported a higher rate of metal component revision and polyethylene bearing exchange for the first 20 ankle replacements using the STAR prosthesis. However, they noted that the first 20 cases had nearly 2 years longer follow-up and suggested the improved survivorship seen with subsequent patients may not be sustained with longer follow-up. Certain characteristics of the STAR prosthesis implantation may be especially challenging in the hands of an inexperienced surgeon. The STAR instrumentation involves placement of an extramedullary tibial guide that utilizes fluoroscopy for confirmation of position. The use of the medial corner of the tibial plafond and the second metatarsal as references relies heavily on the surgeon's visualization. The reproducibility of this process is unknown. Other ankle prostheses rely on a similar process for correct placement.

Another surgeon-related factor is the correction of underlying deformity prior to TAR placement. Regardless of the prosthesis, appropriate correction of the coronal deformity and appropriate balancing of soft tissues is paramount to the long-term outcome of a TAR [10, 17, 26]. Some authors have suggested that the STAR prosthesis geometry is particularly intolerant to postoperative ankle instability or misalignment [20].

The third mode of failure, design-related failure, implies that a failure has occurred even when the implant has been placed in an appropriate patient and in a technically optimal manner. The main modes of failure that may be attributed to the design of the STAR prosthesis are aseptic loosening, polyethylene bearing failure, and osteolysis [1]. The STAR prosthesis consists of a mobile-bearing polyethylene insert, which articulates between a flat tibial component and a metal talar component that has a longitudinal ridge in the midline. The relationship between with tibial surface and the polyethylene insert allows for unconstrained motion in both anterior–posterior and mediolateral translation, as well as in axial planes. However, this articulation is unable to accommodate any coronal plane motion, which results in lift-off of one edge and edge loading of the other [20]. At the talar end of the polyethylene bearing, only sagittal plane rotation (flexion and extension) is allowed. The talar component is constrained against mediolateral translation by the sagittal ridge at the center of the talar component. However, there is no constraint to coronal plane motion, which can also cause edge loading. This lack of tolerance for coronal plane motion makes coronal balancing critical for the surgeon. Any imbalance in coronal plane motion throughout the range of motion will result in lift-off and edge loading of the polyethylene insert.

Another factor in the design of the STAR implant that may play a role in polyethylene edge loading is the shape of the talar component. The talar cylindrical design was meant to mimic the native articular surface of the talus. However, the STAR component has the same radius of curvature both medially and laterally, which does not precisely mimic the native talus, which is conical and has a larger radius of

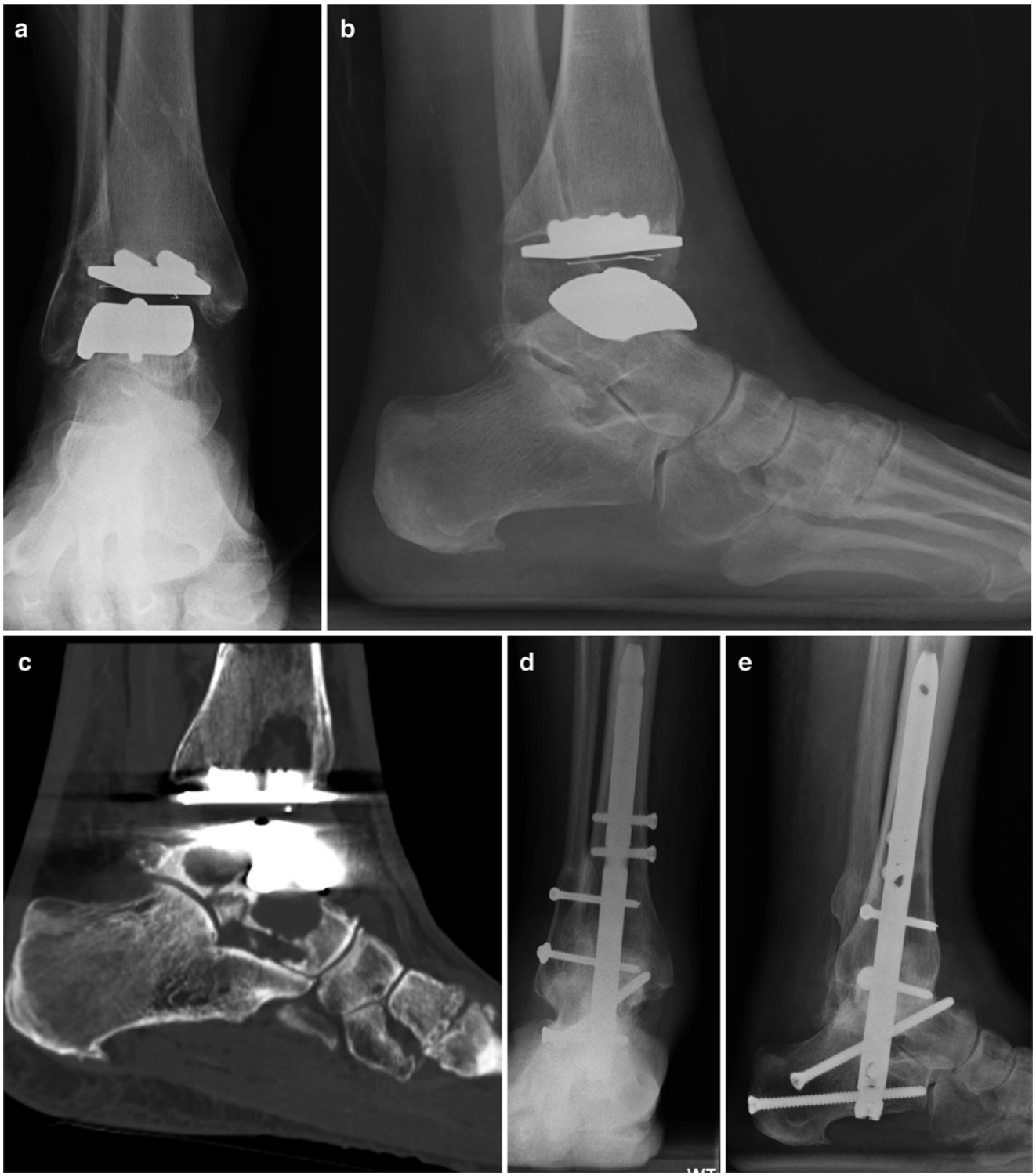

Fig. 32.1 Female patient diagnosed with posttraumatic osteoarthritis due to a history of severe sprain underwent total ankle replacement of right ankle with a STAR prosthesis at age 70 years; see radiographs at 5 years postoperatively, anterior–posterior (**a**) and lateral (**b**) views. Computed tomography (CT) scan (**c**) 10 years after ankle replacement, when patient presented with sudden onset of pain. Note the large talar cyst with a fracture into the posterior facet of the subtalar joint and possible osteonecrosis of the posterior third of the talus (fractured fragment). The patient underwent tibio-talocalcaneal fusion; see anterior–posterior (**d**) and lateral (**e**) radiographs at 1 year postoperative

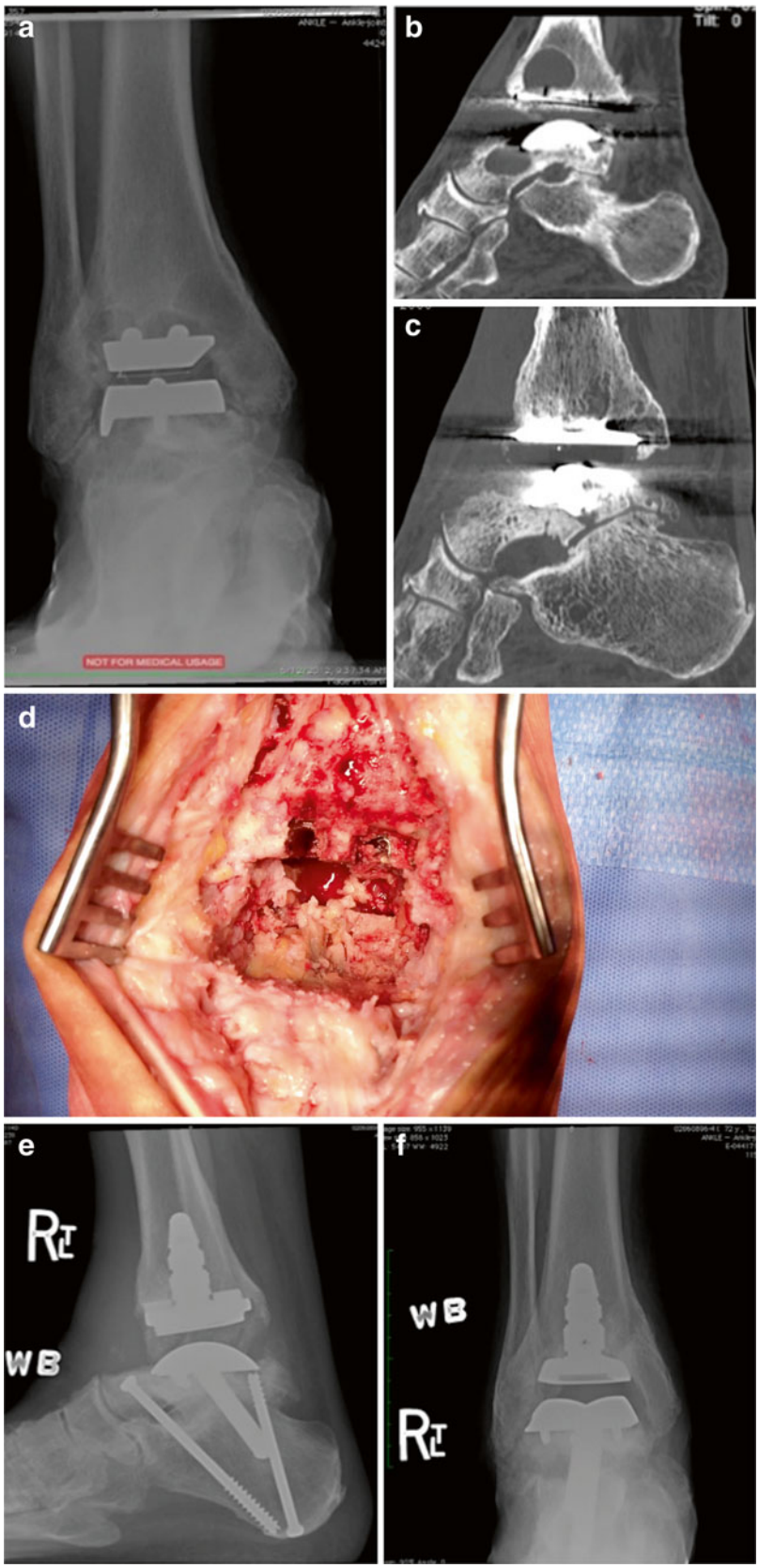

Fig. 32.2 Male patient with ankle arthritis underwent total ankle replacement of his right ankle with a STAR prosthesis at age 70 years. Ten years later, large cystic osteolysis was observed in the tibia and talus on radiograph (**a**) and computed tomography (CT) scan (**b**). The patient underwent bone grafting of cysts. Six months later (**c**), the CT scan showed talar subsidence and fracture, and the patient reported worsening pain. Intraoperative photograph (**d**) showing large talar defect during revision to an INBONE II total ankle replacement. Lateral (**e**) and anterior–posterior (**f**) radiographs at 1 year following revision surgery

curvature laterally. Penner [20] suggests that this results in a dynamic ligament imbalance laterally. The lateral curvature of the articular surface after insertion will be smaller than the normal radius. If the ankle is well balanced in neutral dorsiflexion, a parallel "dorsiflexion gap" is created. As the ankle is plantarflexed, the smaller radius laterally will lead to less filling of the lateral joint space than expected with the normal talus. This creates a nonparallel "plantarflexion gap" that is wider laterally than medially. Thus, the STAR prosthesis' cylindrical talar geometry obligates a mismatch between the "dorsiflexion gap" and the "plantarflexion gap" [20]. Regardless of how well the ankle is balanced, a mild degree of ligament imbalance is inevitable and would result in some degree of polyethylene bearing edge loading. Laflamme et al. demonstrated maximal edge loading in the posterior–medial aspect of the polyethylene bearing in all 16 fractured bearings from STAR prostheses in their study [20]. These findings are consistent with the above theory. Due to the wider lateral "plantarflexion gap" and the inherently shorter medial side (due to a greater prevalence of varus deformity and relatively strong deltoid ligament), edge loading is expected on the medial side. Additionally, the posterior–medial corner is typically the most constrained part of the ankle joint due to the deltoid ligament and flexor tendon sheaths [20].

The size of the component used must also be considered. As the size of the anatomic talus increases, so does the radius of curvature. However, the STAR prosthesis has a single radius of curvature across all sizes; the use of larger talar sizes in presumably larger and heavier individuals exacerbates the imbalance described above. Additionally, the talar component becomes wider as the size increases, but the polyethylene insert does not, resulting in an increased lever arm of the talar component relative to the polyethylene bearing. Larger patients will impart greater forces on the TAR, have larger coronal plane lever arms, and have increased lateral plantarflexion imbalance [20]. This combination of factors could lead to increased edge loading and overloading of the polyethylene bearing. This is consistent with the findings of Laflamme et al. [21], who found a higher risk of polyethylene bearing fracture in males, patients with higher body mass index, and better functional outcomes (i.e., postoperative activity) [21].

Osteolytic cysts are another area of concern with respect to failure of the STAR prosthesis. There is still debate as to what exactly causes osteolytic cysts in TAR. In total knee arthroplasty and total hip arthroplasty, it is well established that osteolysis occurs secondary to polyethylene wear. Authors have assumed this to also be true in osteolysis around TAR. However, Koivu et al. [27] found minimal debris due to polyethylene wear in samples taken from failed Ankle Evolution System prostheses. These authors suggest that osteolysis around TAR implants is caused by RANKL-driven chronic foreign body inflammation directed against necrotic autologous tissues, rather than implant-derived particles [27]. This finding has not been replicated, so it cannot be considered definitive evidence. However, in the senior authors' experience with the STAR prosthesis, osteolytic cysts form early, often in the first 2 years postoperatively. This would suggest that the process is potentially mediated by something other than polyethylene wear, which usually occurs many years after implantation. During implantation of the STAR prosthesis, the talus requires five bone cuts and a central fin cutout, which may cause thermal necrosis leading to the RANKL-driven process suggested by Koivu [27].

In summary, clinical outcomes following TAR with the STAR prosthesis are generally good, but implant survivorship typically averages around 71 % at 9–10 years postoperative. Failure of the STAR prosthesis can be implementation related or design related. Various aspects of the STAR design may contribute to overloading and fracture of the polyethylene bearing. Osteolytic cysts in TAR require further research, but the implantation process for the STAR prosthesis may contribute to the presence of cysts. These factors may all contribute to the eventual failure of the STAR prosthesis and the poor results reported in some studies.

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33 Ankle and Tibio-talo-calcaneal Arthrodesis After Failed Total Ankle Replacement

Falk Mittag and Markus Wünschel

Introduction

Total ankle replacement (TAR) is an alternative for arthrodesis with promising mid- and long-term results [1–3]. On the other hand, complication rates are still higher compared with total hip or knee arthroplasty. Aseptic loosening und infections are the main causes for failure in TAR [2]. Other causes are polyethylene fracture, peri-prosthetic soft-tissue problems, peri-prosthetic heterotopic ossifications, peri-prosthetic fractures, mal-alignment of components, or peri-prosthetic aseptic osteolysis.

Patients with failed TAR usually report about newly developed increasing pain, swelling in the ankle area, and often decreased range of motion of the ankle joint. Symptoms occur when walking, later also at rest.

Radiographs of the ankle and lower leg need to be performed to evaluate a possible loosening or wear of components, osseous defects, and cysts. A long leg view could reveal deviations of the leg axis. A computed tomography (CT) scan of the ankle joint is often necessary to determine the size of peri-prosthetic bone defect.

A potential infection of the prosthesis should be ruled out before revision surgery. Immunosuppressive medications or diseases like diabetes mellitus, renal failure, rheumatoid arthritis, and neoplasms lead to higher infection rates [4, 5]. If blood tests and clinical examination indicate suspicion of an infection, an aspiration of the ankle joint should be performed. Through this the causative agent could be cultured with long incubation period, leading to a specific antibiotic therapy. A high leukocyte count in the aspiration sample could also confirm a suspicion of infection. In the case of an acute infection after TAR, there are good chances of preserving the implant [6]. In chronic infections, the implant usually needs to be removed.

If revision after TAR becomes necessary, surgeons have to face considerable challenges due to extensive bone loss and poor soft-tissue conditions in the ankle area. Especially as a result of the scarce bone stock of the talus and its diminished perfusion, revision arthroplasty cannot be performed in all cases. In these settings, ankle or tibio-talo-calcaneal arthrodesis (TTC arthrodesis) with auto- or allografting of bone remains the procedures of choice in lieu of permanent bracing or below-knee amputation.

Indications

The main indication for ankle or TTC arthrodesis is a loose TAR with extensive loss of bone stock with no option of revision arthroplasty. Condition after removal of the implant due to infection also leads to an arthrodesis in most cases. Ankle arthrodesis could be performed if there is enough bone left for screw or plate fixation within the talus in which the subtalar joint must be free of pain and arthritis. Otherwise, TTC arthrodesis should be preferred.

Rare indications for ankle or TTC arthrodesis are otherwise non-treatable peri-prosthetic soft-tissue problems and severe peri-prosthetic heterotopic ossifications.

Contraindications

In case of fulminant or chronic infections of TAR, ankle or TTC arthrodesis should not be performed primarily. Infection must be treated with effective antibiotics and in most cases removal of the implant including debridement of the joint.

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© Springer International Publishing Switzerland 2016
T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_33

Poor soft-tissue conditions and vascular diseases with reduced blood flow are relative contraindications for ankle or TTC arthrodesis. The risks of wound complications, infections, and failed bony union should not be underestimated in those cases. Comorbidities such as diabetes mellitus and rheumatoid arthritis or immunosuppressive medications increase the risk of infection or failed bony union.

On the other hand, ankle or TTC arthrodesis is often the last chance for the patient prior to below-knee amputation.

Surgical Technique

Preoperative Considerations

Once the decision is made that revision surgery is necessary after failed TAR, the next step is to determine if the implant can be maintained and revised. This depends on several factors including patient comorbidities as described above, quality and amount of bone stock, and available revision implants for the specific TAR model. Due to the specific anatomy of the ankle joint, the most solid way to help the patient frequently is to remove the implant and perform a TTC arthrodesis [7]. 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. The most obvious advantage of this procedure is that by involving the calcaneus, a well perfused, healthy bone can be utilized as stable basis for reconstructing leg length with bone grafts of various sizes and origins. Another positive aspect is the possibility to anchor the osteosynthesis material safely no matter if it is a retrograde intramedullary nail, screws, or blades of all variations which mostly allows a straight forward postoperative management.

Preoperative Planning

To consider the bony situation, a weightbearing radiograph of the ankle and the lower leg is mandatory (Fig. 33.1). If clinically relevant, a long leg view is also helpful. Here, one can locate deviations of the axis and bony defects and measure the exact size and length of the revision implant.

If there are large bone defects, a CT scan of the ankle joint is also very useful to determine the amount of bone necessary to fill the gap (Fig. 33.2). This needs to be done sufficiently in advance since in some cases iliac crest won't be enough and allogenic bone has to be preordered, preferably femoral head bulk allograft.

Preoperative workup needs to include a thorough history-taking and clinical evaluation. Since we are in a revision situation, the condition of the skin and the formerly used surgical approach is an important factor. An adequate blood flow needs to be verified otherwise major complications may occur including the need for transplantation of vascularized skin flaps or below-knee amputation in the worst case, not to speak of delayed union or frank nonunion.

If there is suspicion an infection might exist, a puncture of the joint with aspiration of joint fluid needs to be performed. Only if the microbiological examination with a long incubation period of 6 weeks to rule out slow-growing bacteria like *Brucella* species is negative, one should

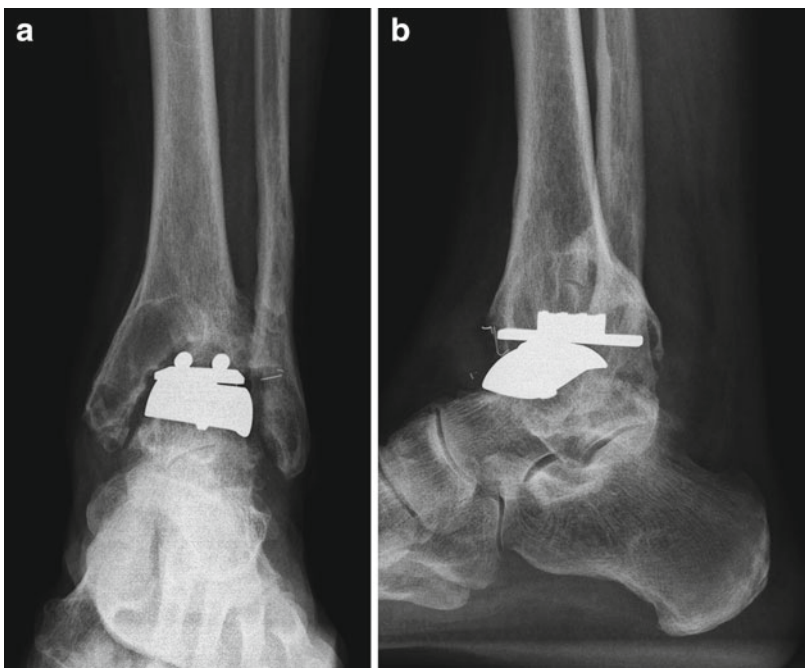

Fig. 33.1 Anterior-posterior (**a**) and lateral (**b**) weightbearing radiographs of the ankle joint with lower leg of a 70-year-old male patient for preoperative planning 10 years after primary total ankle replacement. The radiographs reveal an obvious loosening of the total ankle replacement with large cysts and incongruity of the talar and the tibial component. The destruction and position of the radiopaque mark of the inlay is a clear indicator of profound wear of the polyethylene

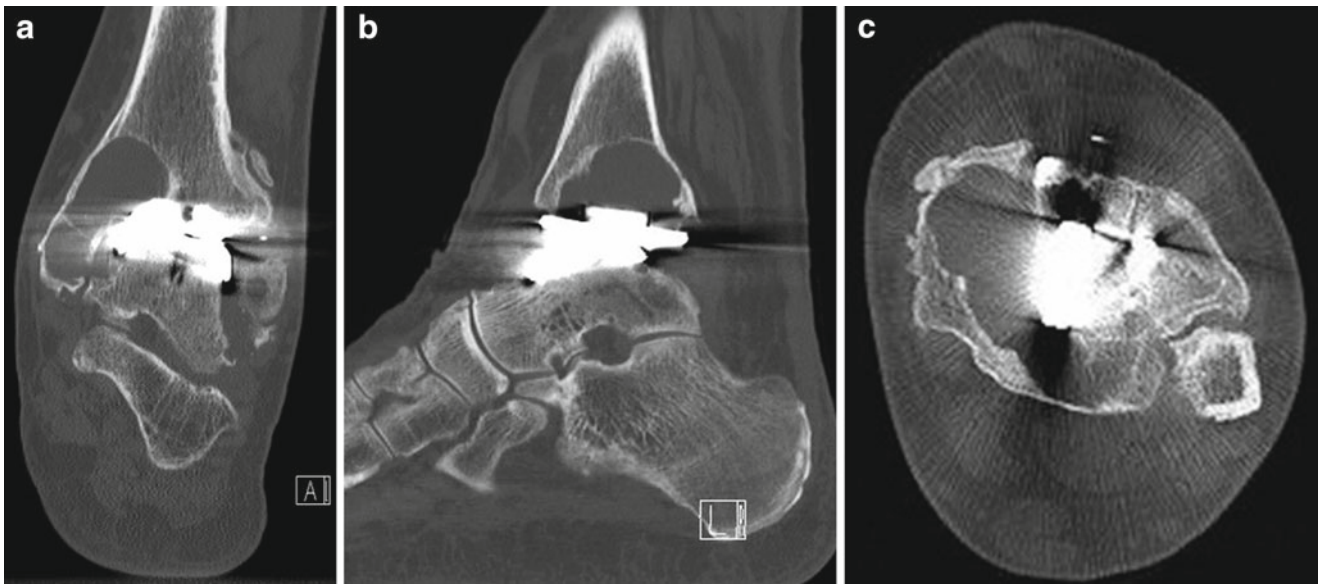

Fig. 33.2 Preoperative computed tomography scans (**a**–**c**) of the same patient shown in Fig. 33.1 displaying the dimension of the cysts in the tibia and talus. Especially in the medial aspect of the distal tibia, there is only a thin bone shell intact

proceed with a primary fusion using intramedullary implants. In case of infection, a different course of action is proposed as described later.

Before surgery the patient needs to be consented about autologous or autogenic bone transplantation, possible adjacent joint degeneration, leg length discrepancy, postoperative treatment scheme, and general surgical risks such as bleeding, blood transfusion, infection, bruising, nerve damage, nonunion, fracture, implant failure, and revision surgery.

Surgical Procedure

Since our preferred fusion technique for revising a failed TAR is the use of an intramedullary nail, this technique is described in detail subsequently. Alternative techniques are mentioned in the corresponding subsection afterward.

We like to have the patient positioned supine since this is the standard position for foot and ankle procedures which allows optimal visual control for axis correction. Ultimately, the position of the patient is determined by the implant utilized (i.e., nailing system). The opposite leg may also be prepped to have an optimal control of leg length discrepancy although this can usually be palpated well through the draping.

The iliac crest should be reachable during surgery depending on the planned bone graft harvesting site which regularly is necessary. The ipsilateral pelvis is raised by a pillow for better access to the lateral portion of the ankle if this is—as in our case—the applied surgical approach.

The foot needs to overhang the operating table by about 15–20 cm. This is necessary to use the target device of the nailing system. For optimal intraoperative C-arm usage, the contralateral leg is lowered a few centimeters.

A decision needs to be made whether to use a tourniquet or not. In more complicated cases with expected duration of surgery exceeding 120 min, either no tourniquet is used at all or it needs to be deflated in the midst of surgery which has a number of disadvantages. So in most cases the tourniquet is applied only to be inflated in case of emergency.

An antibiotic (e.g., second-generation cephalosporin) is administered during anesthesiologic preparation of the patient approximately half an hour before surgery starts. In case of a long-lasting procedure, a repeated dose may be administered later usually after 3 or 4 h of open air time. While draping the leg up to the thigh, the patella needs to be clearly visible during surgery. This is of importance because it helps the surgeon to align the foot and ankle properly.

Our standard approach is an anterior-lateral incision from about 8 to 10 cm above the tip of the lateral malleolus going straight down slightly behind the fibula to the posterior facet of the subtalar joint and then turning distally ending at the sinus tarsi. This approach can be varied depending on the individual situation and allows sufficient access to the fibula, ankle joint, and subtalar joint area.

The incision is cautiously taken down to bone with special focus on the sural nerve which occasionally appears in the field and needs to be protected. The focus is then brought to the distal fibula which must be osteotomized in order to access the ankle joint. There are different ways to proceed; in case of using an intramedullary nail, the fibula does not necessarily have to be reattached to increase stability and therefore can be used as bone graft. The fibula is osteotomized

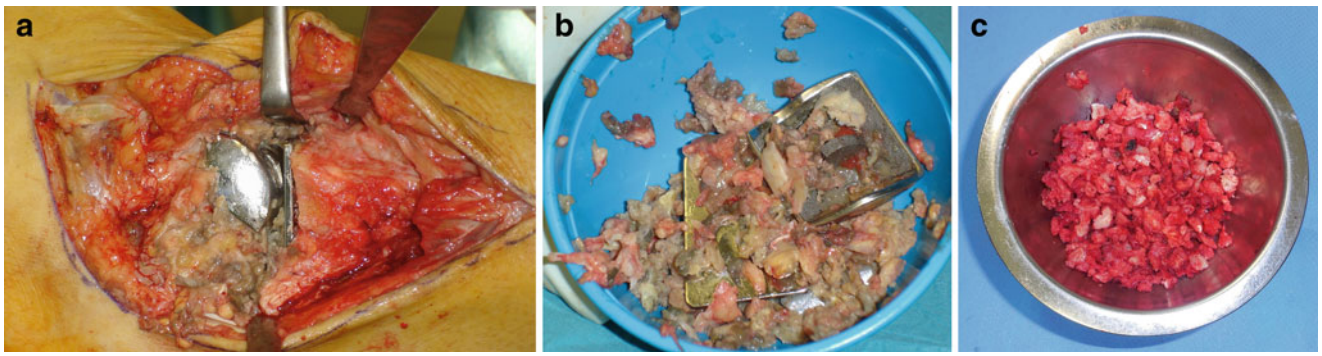

Fig. 33.3 Intraoperative situation after entry into the ankle joint. Note the *grayish-yellow* debris that is caused by the polyethylene wear. There is no inlay visible. Note the gap between the medial part of the tibia and the tibial component (**a**). Explanted prosthesis components and vast amount of debris removed (**b**). Note that there is practically no polyethylene inlay leftover. Parts of the fibula and the iliac crest allografts have been morselized and prepared for later impaction in the ankle and subtalar joints (**c**)

approximately 6 cm above the joint line; the soft tissues including the syndesmosis and the lateral ligaments are removed and the bone is then stored on the instrument table in a moistened surgical sponge to be used later during the procedure.

Now the implant or the remnants of it come into sight (Fig. 33.3a). If it hasn't already been procured, intraoperative cultures of the deep tissues need to be taken to rule out an infection. One should take several cultures from parts of the implant as well as from the debris and the peri-prosthetic membrane to increase the yield of bacterial growth if bacteria are present.

To have better access to the joint, usually at first the inlay is removed with a chisel and a forceps. Now the talar and tibial components are carefully removed with a chisel. This is a very sensitive part of the procedure since one can destroy good healthy bone or cause fractures if one proceeds to quickly; this especially applies to the talus with its scarce bone stock that has already been weakened during the primary TAR. In situations where the CT scan revealed large bone defects and cysts with thinned out cortical bone, extreme caution is advised.

After finally removing the implant, the surgeon needs to debride the joint thoroughly and remove the scar tissue which quite often has a grayish color due to metal friction (Fig. 33.3b). After synovectomy and irrigation using a pulsed lavage system, the necrotic bone is then removed and the exposed bone surfaces of the now remaining talus and tibia are perforated with a drill or small chisel depending on the amount of bone available.

Now the subtalar joint needs to be addressed. After opening up the joint laterally, a laminar spreader is used to improve visualization of the joint surfaces. The cartilage and sclerotic bone are removed with chisels and a rongeur (Fig. 33.4a). Now that the joints are prepared, one needs to decide how to perform the bone grafting and which graft is to be used. Oftentimes the osteotomized fibula is sufficient. It is cut into bicortical pieces of the adequate length. The actual insertion into the joint will be completed later in the procedure. If the distance to bridge is too long or a tricortical bone graft is favored, the bone graft should be harvested from the iliac crest or an allograft femoral head can be utilized.

We subsequently prepare the nail insertion by marking the ideal entry point using an intraoperative C-arm image intensifier and a radiopaque metal rod. A lateral and axial image of the ankle allows an accurate labeling of the ideal entry point of the nail with a pen. This is a crucial step. By determining the entry point, the orientation of the nail is set and can only be varied within a narrow window. So it is very important to have the ankle in a reduced position when applying the rod and using the C-arm image intensification. It is mandatory to check for the position of the proximal end of the rod, especially if a longer nail is to be used.

The skin is incised longitudinally at the two intersecting lines extending about 2 cm in each direction. We continue with blunt dissection to the bone, usually the plantar fascia has to be divided. After inserting the guide sleeve to shield the soft tissues and neurovascular bundle medially, a guide wire is driven from the calcaneus through the talus into the tibial shaft. The position is then checked by intraoperative C-arm image intensification in both planes, again taking into account the importance of this step. If the position is satisfactory, the bone is reamed in steps of 0.5 mm up to the diameter of the preplanned nail. An over-reaming of at least 1 mm is recommended for easier nail insertion.

The intramedullary nail is then mounted on the target device and introduced. Since most of the available retrograde nails for TTC arthrodesis have an anatomic design with a built-in 5–7° of valgus, not only the depth of insertion but also the exact rotation is crucial for a satisfying result. All this needs to be monitored by intraoperative C-arm image intensification. Now the locking screws can be placed. This part strongly depends on the type of implant used [8]; in our case it is the T2 ankle arthrodesis nail system (Stryker Trauma, Schönkirchen, Germany).

After inserting the talar locking screw in the slot hole and the two proximal tibial screws, the harvested and customized

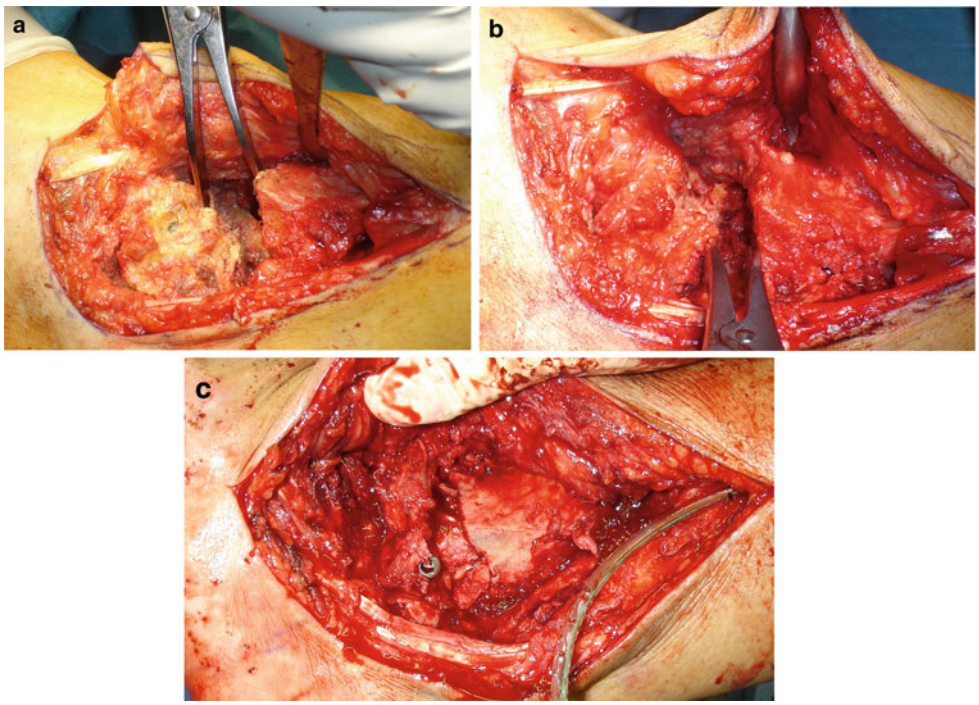

Fig. 33.4 After removal and thorough debridement of the joint, the talus and tibia as well as the subtalar joint have been worked on with a chisel and drill to break through the sclerosis zone (**a**). Note the large gap to be filled with autograft. After harvesting a tricortical graft and cancellous bone from the iliac crest, parts of the morselized graft have been filled in the gap and can be identified in the depth of the joint (**b**). The tricortical graft will be inserted after the nail has been placed. The nail has been locked (note the talar locking screw) and the gap was filled with the formerly harvested tricortical autograft (**c**)

bone grafts are filled in the gap of the ankle around the nail. The bi- or tricortical bone grafts are used to bridge the gap of the lacking implant and enhance stability. Additionally bone chips are used to fill up the remaining smaller cavities (Fig. 33.4b, c). At this point, leg length should be compared to the contralateral side. Now the so-called compression screw which has been put in the nail from its distal opening is rotated clockwise to generate a tibiotalar compression. This is achieved by slowly pushing the talar screw toward the tibia in its slot hole.

One needs to take care not to cut through the talus or fracture it. Once it has reached its position, the compression screw remains in the nail. After that, subtalar compression can be induced, and subsequently, two calcaneal locking screws are placed. Now the target device can be removed and an end cap is inserted. A final intraoperative C-arm image intensification is performed. The ankle should now be locked very stable in a perfect 90° angle. The correct insertion of the bone grafts that now should be compressed in the talus and tibia is inspected and final adjustments are made. Then the wound is thoroughly irrigated and 1 or 2 suction drains are inserted and the wound is closed in layers. After that we apply a sterile compression dressing. A lower leg plaster posterior splint is applied in the operating room.

Postoperative Treatment

The patient is immobilized with bed rest for 2 days. At this time, the drains are removed, and the first dressing change is made. After that the patient is mobilized with crutches and partial weightbearing of 20–30 lbs. Usually the patient can leave the hospital 5–7 days after surgery. The sutures are removed 14–21 days after surgery. Depending on the compliance of the patient, this is a good time to apply a circular cast; alternatively the plaster splint is continued.

After 6 weeks of partial weightbearing, radiographs are taken. Depending on the degree of consolidation the patient is allowed to bear weight as tolerated with a new cast/plaster splint. As long as the cast/splint is used, deep venous thrombosis prophylaxis is indicated. Dynamization of the nail is only performed in cases with radiological signs of delayed union. After a total of 12 weeks postoperatively when the patient should be able to fully weightbear, another radiograph is obtained and the patient is allowed to discontinue the cast/splint (Fig. 33.5a, b). Hardware removal is rarely performed and only advisable for young patients or when symptoms exist, at least 1 year after the surgery after complete arthrodesis has been proven radiologically. If required, the patient may wear modified or orthopedic shoeware with a rocker sole.

Special Situations and Alternative Techniques

In case of an infected implant, there are several ways to proceed [9–11]. The first goal always should be to eradicate the bacteria from the joint. Therefore it is absolutely necessary to gain microbiological detection of the underlaying agent in order to treat the patient with a potent and effective antibiotic. Once the TAR has been removed and the joint has been accurately debrided and irrigated, a septic fusion can be

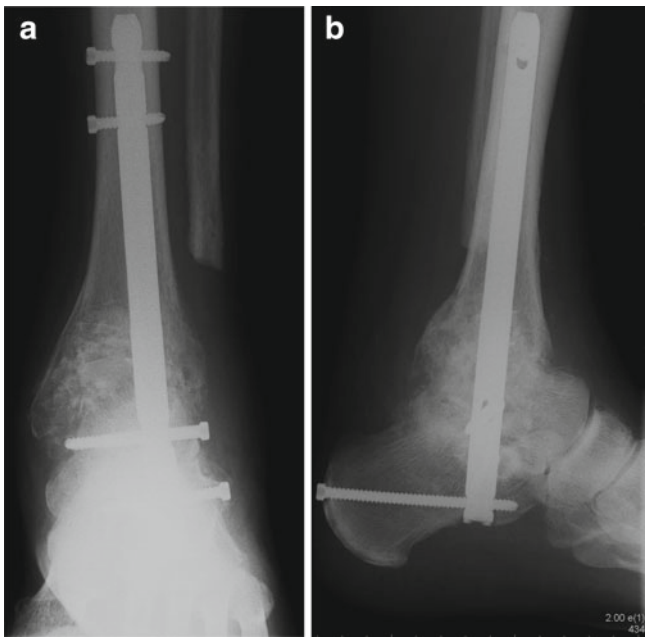

Fig. 33.5 Anterior-posterior (**a**) and lateral (**b**) weightbearing radiographs of the patient shown in the preceding figures 3 months postoperatively demonstrating a solid tibio-talo-calcaneal arthrodesis. One can still identify the morselized as well as the tricortical autograft. The height of the ankle has been restored

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 many disadvantages. In most cases it is better to initiate a negative pressure wound therapy system and repeated debridements 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.

Since specialized retrograde nailing systems for the TTC arthrodesis have only been established a couple of years ago, in former times the surgeon needed to come back to different techniques including screws and different blades or a combination of those [12]. As mentioned above it will be a rare occasion that a simple ankle fusion can be performed after removing the implant. In this context, special focus also needs to be addressed to the subtalar joint. If there are signs of degeneration, a TTC arthrodesis should be considered.

When performing an ankle arthrodesis in a revision situation, the following topics need to be taken into account: The fibula should be preserved and attached laterally at the talus and tibia for higher primary stability; parts of it can be used as bone graft. If possible the periosteal blood supply should not be destroyed; thus the fibula needs to be left in situ throughout the procedure. We prefer to use 7.0-mm cannulated self-tapping self-drilling screws sometimes in combination with a (locking) blade, especially if there is a large gap to be filled. At present there are a number of specific plates available on the market.

As mentioned above, in our opinion the most stable implant remains the retrograde intramedullary compression nail which primarily should be used for TTC arthrodesis. TTC arthrodesis may also be performed by using plates (e.g., blade plates, L-shaped, or T-shaped plates). There have been a number of publications reporting good results [13, 14].

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 [15].
- 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.
- Refixation of the distal fibula can improve stability especially in ankle arthrodesis. Parts of it could also be used as bone graft.

Pitfalls

- Correct entry point of the nail insertion into the plantar aspect of the calcaneus is 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.
- Correct ankle rotation has to be verified before inserting the locking screws of the nail.
- In case of ankle arthrodesis with self-drilling partially threaded screws, it is necessary that the thread is placed beyond the area of arthrodesis to reach sufficient compression.
- Poor soft-tissue management will lead to higher complication rates. If possible the former approach to the ankle joint should be used.

Review of the Literature

Anatomic Considerations, Complications, and Techniques Utilizing Retrograde Nails

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. [16] 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 [17] 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. [18] 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. [19] recommend a more lateral entry point at the lateral column of the calcaneus to protect the neurovascular bundle. Rausch et al. [20] 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 [20].

Common complications after TTC arthrodesis by an intramedullary nail include nonunion, prominent implant material, chronic regional pain syndromes, peri-prosthetic fractures, deep infection, and below-knee amputation [21]. Different methods have been described to restore hindfoot height by materials other than bone, thus reducing the harvesting-associated complications. While some authors had good results with fusions in low sample series [22–25], Carlsson [26] describes the unsuccessful use of a titanium mesh cage.

Rammelt et al. [27] report that 24 % of their patients treated with TTC arthrodesis for mixed indications had at least one complication; the nonunion rate was 16 % [27]. The risk of an amputation after TTC arthrodesis has been shown to be associated with diabetes, revision surgery, preoperative ulceration, and age in a retrospective study presented by DeVries et al. [28]. 11.8 % of their cohort of 179 patients (including various different indications) had to be treated with a major amputation after salvage TTC arthrodesis.

Tibi-talo-calcaneal Arthrodesis by Retrograde Intramedullary Nail

In the recent years different retrograde nailing systems to correct hindfoot problems have been developed. Starting with nails constructed for other localizations [29, 30], surgeons now widely use these specialized implants if difficult anatomic situations exist [7, 8, 31–37].

Only a few articles have been published focusing on TTC arthrodesis with a nail after failed TAR. Among those, Thomason and Eyres [38] describe a small series of three patients using femoral head allografts with excellent results at a follow-up of 32 months.

Schill et al. [29] treated 15 patients by TTC arthrodesis with a 93 % fusion rate; the average American Orthopaedic Foot and Ankle Society (AOFAS) Hindfoot-Ankle Score was 58 [29]. Henricson and Rydholm [23] even reached a 100 % fusion rate in 13 patients combining metal cages and allografts.

Pelton et al. [39] report their results after TTC arthrodesis utilizing an intramedullary nail and had an 88 % fusion rate after an average time of 3.7 months. Donnenwerth and Roukis [40] performed a systematic literature review on TTC arthrodesis by retrograde intramedullary nail for failed TAR and included six articles that met the inclusion criteria with a total number of 62 treated ankles. They conclude that due to a nonunion rate of 24.2 % and an overall complication rate of 62.3 %, TTC arthrodesis by nail should only be performed by experienced surgeons although a modified AOFAS Hindfoot-Ankle Score of 67.6 on a 100 point scale was satisfactory given the alternatives.

Alternative Techniques

When revising a failed TAR in selected cases, an ankle arthrodesis or a TTC arthrodesis utilizing screws and plates or even external fixation is possible and many different techniques have been described [12, 15, 41–45].

Culpan et al. [46] treated 15 out of 16 patients successfully with an ankle fusion after failed TAR using screws/bridging plates. AOFAS Hindfoot-Ankle Score increased from 31 to 70 with good patient satisfaction; the authors recommend use of a nail only in patients with rheumatoid arthritis.

Hopgood et al. [47] had 17 unions in 23 patients treated either by screw fixation (tibiotalar and TTC) or by an intramedullary nail (TTC). They advise using a nail in patients with rheumatoid arthritis and discourage from using screws to fixate a TTC arthrodesis.

Doets et al. [14] analyzed 18 patients (15 with inflammatory joint disease (IJD)) and found that IJD led to a significantly

higher nonunion rate. Blade plate fixation was used for ankle arthrodesis and led to a 100 % fusion rate in seven patients. Berkowitz et al. [48] compared two groups of tibiotalar and TTC arthrodesis after failed TAR. They identified subtalar nonunion as a primary risk when performing a TTC arthrodesis. The AOFAS Hindfoot-Ankle Score improved significantly for both techniques.

In a study published by Deleu et al. [13], 17 patients after failed TAR were treated by ankle arthrodesis ($n=5$) or TTC arthrodesis ($n=12$). The overall fusion rate was 76.5 % with a 100 % union in the ankle arthrodesis subgroup utilizing screws and blades. Zarutsky et al. [49] in contrast treated 43 cases of salvage ankle arthrodesis with a circular wire external fixation. Although 80.5 % of the patients had a fusion and 68.3 % showed a good clinical result, major complications occurred in 51.2 %.

Conclusions

Due to excessive loss of bone stock, revision TAR is often impossible or involves substantial risks. Therefore TTC arthrodesis with bone autograft or allograft is the salvage procedures of choice. Relatively few publications exist for this technique but those that do report overall good results. Since TTC arthrodesis by retrograde intramedullary nail is a challenging procedure, it should only be performed by experienced surgeons.

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Ankle Arthrodesis and Malunion Takedown to Total Ankle Replacement

34

Jason George DeVries, Christopher F. Hyer, and Gregory C. Berlet

Introduction

End-stage ankle joint arthritis 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 are not indicated, they are faced with either an ankle arthrodesis (AA) or total ankle replacement (TAR). AA has been the historical "gold standard" for ankle joint arthritis in North America. AA offers a predictable operation that can be accomplished in almost any case of ankle joint 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 [2–5]. A key concept to remember is that even a well-executed AA with good positioning and successful bone healing will not provide satisfactory outcome for all patients. In general AA has its largest detriment to normal gait mechanics in speed, stride length, and symmetry when compared to TAR [6]. In some patients, the functional cost of a stiff ankle outweighs the pain relief benefit of a solid AA. In other patients, a once well-tolerated AA may become painful again as the adjacent joints develop arthritis from the mechanical demands amplified by the AA or from post-traumatic arthritis related to the index injury. It is in these patients that the consideration can be made for an AA takedown and conversion to TAR prosthesis. In addition, there may be cases of attempted AA that resulted in nonunion or positional malunion that may also be candidates for conversion to TAR.

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Ankle Arthrodesis Takedown to Total Ankle Replacement

As surgeons and patients move toward further acceptance of primary TAR, the concept of an AA being taken down and converted to a TAR has been developed. 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 undergoing AA 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 arthrodesis or ankylosis takedown to a total joint replacement. Multiple studies have shown that previously fused or immobile hips [7, 8] and knees [9, 10] 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 arthrodesis takedown based on other joints, the difficulty and complications with AA revision, and the known benefits of joint motion preservation, AA taken down to TAR is a natural progression.

Indications for AA takedown to TAR are based on a limited set of peer-reviewed literature. Generally, it is agreed that a well-positioned, well-functioning, non-painful AA 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 AA in hopes of preventing some future complication or simply to improve patient function and gait.

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_34

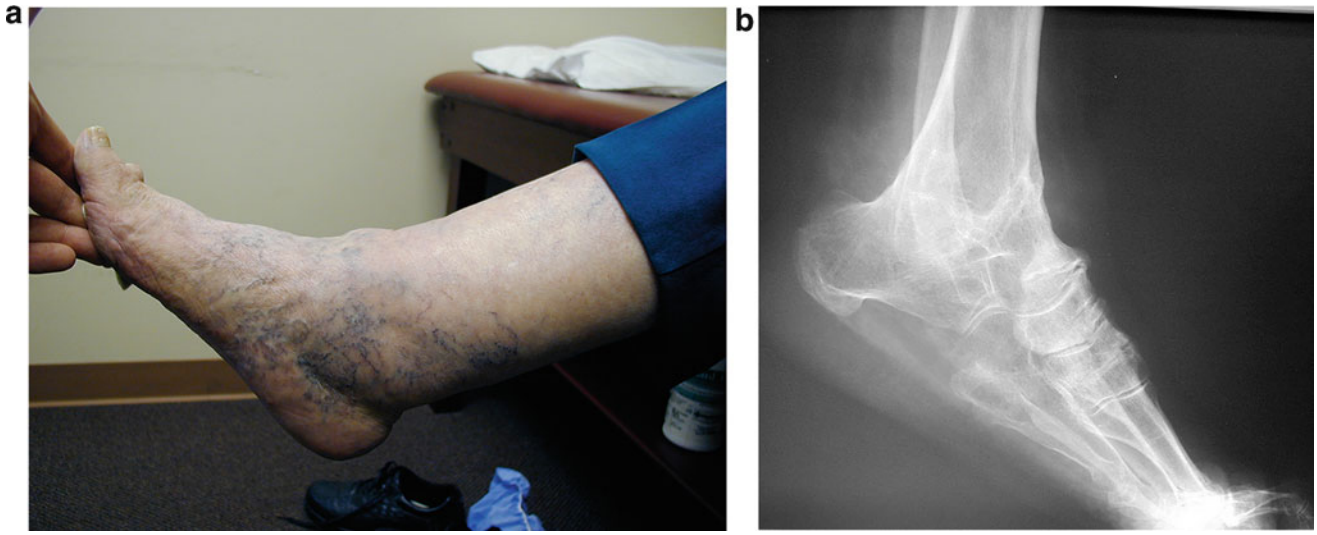

Fig. 34.1 Clinical photograph of a plantar flexion malunion of ankle and subtalar joint demonstrating significant ankle edema and fixed equinus deformity (**a**). Lateral demonstrating solid malunion of the ankle and subtalar joints in severe plantar flexion with significant adjacent joint arthritis is demonstrated at the talonavicular joint (**b**)

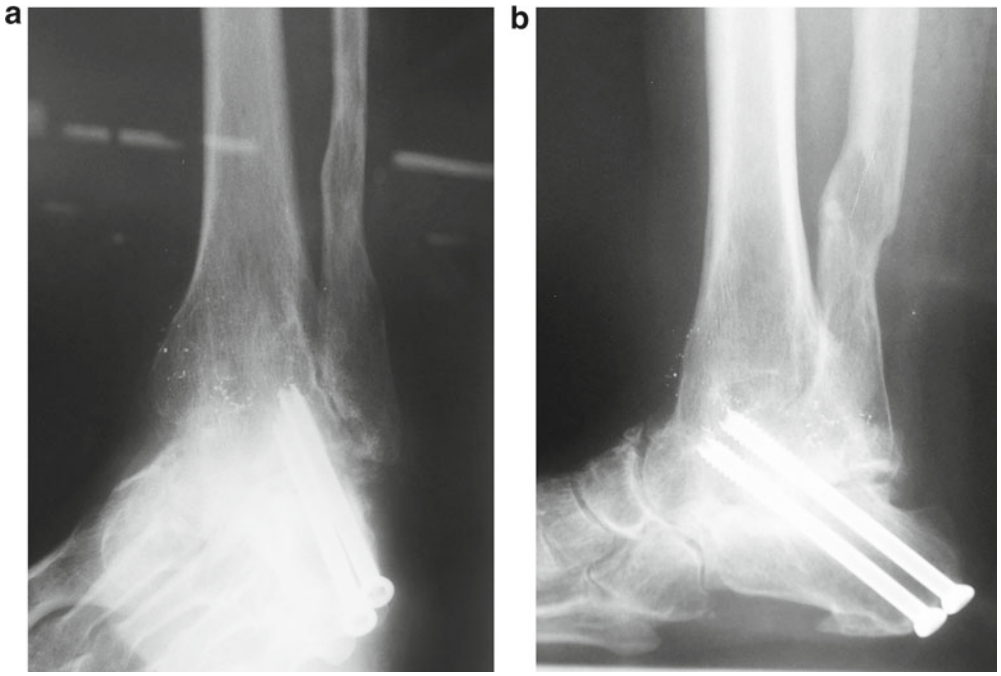

Fig. 34.2 Mortise (**a**) and lateral (**b**) weight-bearing radiographs demonstrating subtalar nonunion after previous ankle arthrodesis. Overall good positioning is noted with good bone stock, preservation of both malleoli, and maintenance of the lateral gutter. Revision subtalar arthrodesis and takedown of ankle arthrodesis to total ankle replacement was undertaken to decrease stress across the subtalar joint

However, in patients that have identifiable pain after AA, 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. 34.1); and nonunion of the AA. Additional indications may include subtalar nonunion under an AA because the increase stresses placed on the subtalar joint after AA may continue to decrease arthrodesis rate. Restoration of motion at the ankle joint is thought to offload these stresses and may enhance arthrodesis rates and pain relief (Fig. 34.2). Finally, tibial or fibular stress fractures due to malalignment of the hindfoot after AA have been proposed as an indication for AA takedown and conversion to TAR [11–14].

Contraindications largely fall into line with the contraindications for primary TAR. Severe malalignment that cannot be corrected, uncorrectable soft-tissue instability, peripheral vascular disease and/or neuropathy, Charcot neuroarthropathy, deep infection and osteomyelitis, and chronic pain are contraindications. High physical demands and avascular necrosis may also preclude TAR. Specifically, takedown to TAR is contraindicated if previous interventions have left soft-tissue compromise (such as anterior flap placement) that prevents the necessary approach or have resulted in significant limb length discrepancy. In addition, several unique relative contraindications for TAR that apply only to previous AA have been described. The most important of these is a lack of a distal fibula due to previous fibulectomy at the time of arthrodesis (Fig. 34.3). 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 [11–14].

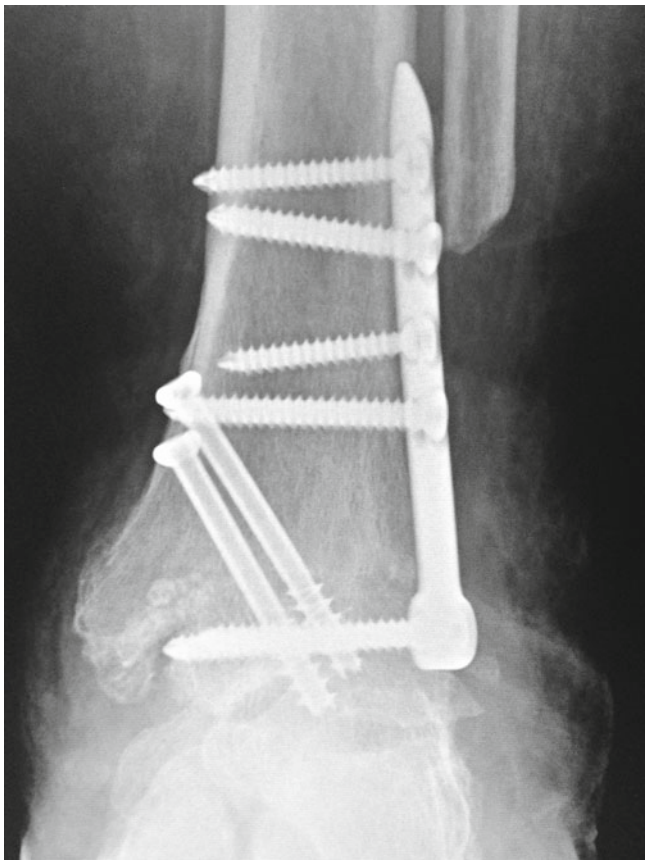

Fig. 34.3 Anterior–posterior radiograph of the ankle demonstrating previous ankle arthrodesis with complete fibulectomy and lateral plate. This is a contraindication to ankle arthrodesis takedown to total ankle replacement

Careful and thorough preoperative planning and considerations are absolutely 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 incision approach. Range of motion across the hindfoot is assessed, and in the case of AA nonunion, any range of motion across this joint is noted, as well as location and extent of previous internal fixation constructs. Clinical appearance of frontal, sagittal, and transverse plane deformities needs to be assessed and will be compared to the radiographs. Diagnostic anesthetic injections can be performed to determine where any pain is being generated. Finally, limb length discrepancy should be assessed.

After clinical evaluation of the patient, radiographs need to be obtained. At minimum, this should include weight-bearing images of the affected foot and ankle, as well as a long leg calcaneal alignment, or Saltzman, view [15]. The presence of surrounding joint degeneration and arthritis in the hindfoot can be evaluated via these radiographic studies. Remaining osseous anatomy is evaluated for the presence of available anatomic landmarks. The presence or absence of a fibular is of paramount importance. The ankle joint level is assessed for remaining anatomic landmarks, particularly the medial and lateral gutters (Fig. 34.4). Comparison to contralateral weight-bearing ankle radiographs can also be helpful. This can help determine the level and location of the joint previously and is very helpful for proper prosthesis positioning. Other radiographs 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 arthrodesis site, particularly important in the nonunion or partial union. It also gives accurate imaging of the remaining hindfoot bones (Fig. 34.5). 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 hardware can be removed prior to MRI. Other imaging that can be used includes technetium-99 bone scans and single-photon emission computed tomography (SPECT) scan. The latter in particular has been advocated to give the most accurate assessment of surrounding joint arthropathy.

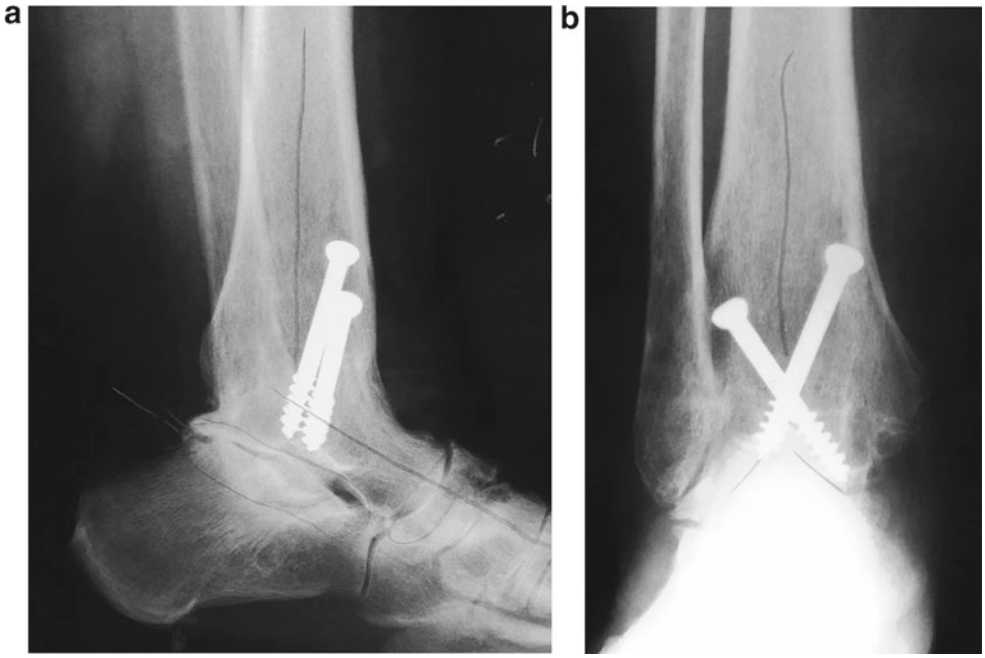

Fig. 34.4 Lateral (**a**) and AP (**b**) image of an ankle arthrodesis prior to takedown. This shows solid fusion of the ankle joint, preservation of the malleoli, and maintenance of the lateral gutter. The ankle is fused in plantar flexion, and there is evidence of arthritis in the posterior facet of the subtalar joint, as well as previous avulsion fracture of the dorsal aspect of the navicular with preservation of the joint

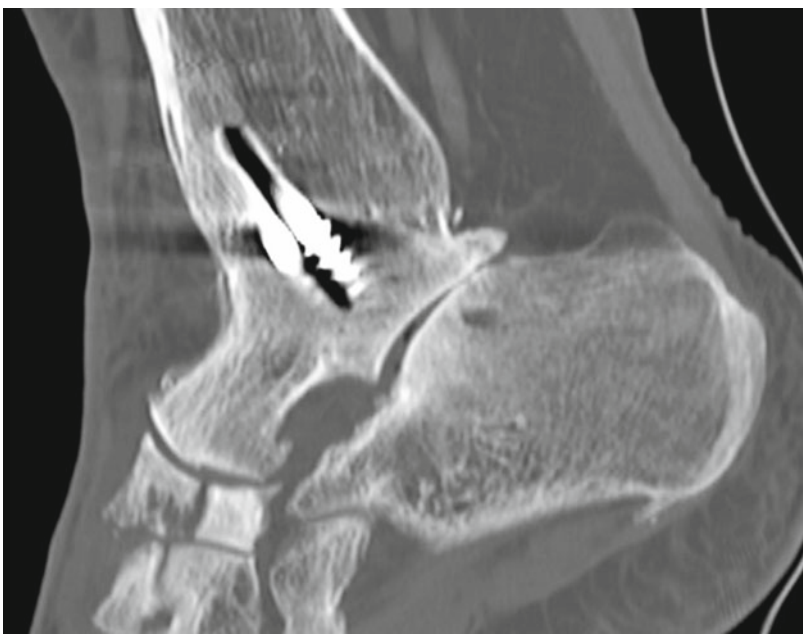

Fig. 34.5 Computed tomographic sagittal image that clearly demonstrates solid union across the ankle joint with good trabeculation. This also shows arthritis in the posterior aspect of the subtalar joint with sclerosis and fracture through the navicular bone with preserved joint space

Literature Review

The published, peer-reviewed literature evaluating the results of the takedown of painful ankle malunion or nonunion is sparse and comes from two centers in the world: The Dr. Sigvard T. Hansen Jr. Foot and Ankle Institute in Seattle, WA, and the Department of Orthopaedics, Cantonal Hospital in Liestal, Switzerland. Overall four articles encompassing a total of 53 patients represent all previous published results. Despite a relative dearth of published, peer-reviewed case series, these procedures are being undertaken at many sites.

Published in 2004, Griesberg et al. [11] provided a retrospective analysis on a consecutive series on the first patients to undergo AA takedown and conversion to TAR using the Agility Total Ankle Replacement System (DePuy Synthes, Warsaw, IN). Initially, this involved 23 ankles (22 patients), but four were lost to follow-up leaving 19 ankles (18 patients) for review. The mean follow-up time was over 3 years, but was as short as 7 months in at least one patient. The authors divided patients into groups with a clear source of pain (i.e., nonunion, adjacent joint arthritis, malunion) and those that had less clear sources of pain in joints that otherwise appeared to be successful AA.

Though this early report is an important reference, it used this older TAR prosthesis that has some specific issues related to it. The tibial component is wide and extends into the fibula, which no longer is relevant in current generation TAR systems and can increase the potential for malleolar fracture. It also requires the use of an external fixator to apply distraction across the joint during the implantation procedure. This also can potentially lead to malleolar fracture if the joint is over distracted. The authors noted that four ankles had lateral malleolar fractures, three patients had medial malleolar fractures, and three had bi-malleolar ankle fractures, leading to an overall rate of 52.6 % (10/19 ankles) that sustained malleolar fractures. Additional procedures were performed in 12 of the 19 patients (63.2 %) and included Achilles tendon lengthening, subtalar arthrodesis, flatfoot reconstructions, and other tendon transfers. The authors noted that intraoperative range of motion was a total of 28°.

The results showed a high rate of additional procedures post-conversion AA to TAR. In total, 10 of the 19 ankles (52.6 %) had an average of 1.5 additional procedures, including five ankles (26.3 %) that had a formal revision TAR. Of these five patients, one patient was eventually revised back to an AA and one patient proceeded on to a below-knee amputation (BKA). There were five patients that had excessively thin or resected fibulas at the time of conversion to TAR, and all of these patients had complicated postoperative courses; ultimately, three patients (15.8 % of all patients, 60 % of previous fibulectomies) went on to BKA, and this included the patient that underwent formal revision of the TAR prior to BKA. The authors demonstrated that the mean American Orthopaedic Foot & Ankle Society (AOFAS) Hindfoot-Ankle Scale improved from 42 preoperatively to 68 postoperatively, excluding the patients undergoing BKA. When stratified into groups, the authors found that those patients that had a clearly definable source of pain preoperatively averaged an AOFAS Hindfoot-Ankle Scales of 74 points after conversion and those that did not averaged 54 points and that this was a statistically significant difference ($p = 0.006$). Overall, 15 of 18 patients (78.9 %) were satisfied and would have the procedure again, and this included one patient that eventually went on to BKA. The mean range of motion maintained was 26° at a mean of 39 months at the final follow-up. The authors acknowledge that the revision and failure rates of an AA takedown to TAR are higher than in primary TAR and caution use in patients with previous removal of the fibula and those without a clear source of pain. They do however state that this is a viable option for these difficult situations.

Hintermann et al. [12] published results of AA conversion to TAR in 2009 and then followed with a formal technical report and a short update, both in 2010 [13, 14]. This report included 30 ankles (28 patients) that were followed in a prospective fashion for a mean of 55.6 months, with a minimum of 3 years. The authors utilized the Hintegra (Integra, Saint Priest, France) that is a three-component, mobile-bearing, cementless TAR with a wide talar base and does not require fixation into the fibula. All patients had a clear causation for pain and included malunion with or without adjacent joint arthritis in >90 % of cases. Nonunion of the ankle or subtalar joint and tibial stress fracture were also listed as indications for conversion to TAR.

Patients underwent conversion to TAR at a mean of 13.2 years after the primary AA in those that fused and an average of 4.5 years after an attempted AA in patients that had a nonunion. The longest time from AA conversion to TAR conversion was 57 years. Patients had undergone an average of 3.3 additional procedures after the AA prior to conversion to TAR. This patient population underwent only 5 intraoperative malleolar fractures (16.7 %, including 3 medial malleolar, 1 lateral malleolar, and 1 bi-malleolar fracture), and one patient had intraoperative transection of the flexor hallucis longus.

The mean preoperative AOFAS Hindfoot-Ankle Scale was 34.1 and improved to 70.6 points postoperatively, with patients >60 years fairing slightly better than those younger. Patient outcomes also suffered somewhat in those patients that had undergone greater than four previous operations. No patients underwent BKA, one patient had revision for talar component subsidence, and only one patient underwent a revision to tibio-talo-calcaneal arthrodesis. Clinically, 5 ankles (17.2 %) were pain-free, and 21 ankles (72.4 %) were still moderately painful, leaving 3 ankles (10.3 %) that had significant pain with an average of 5.2 points on the visual analog scale. Twenty-four patients (85.7 %) were satisfied or very satisfied with the outcome. Clinical range of motion after conversion to TAR was 24.3°, which was approximately half the range of motion of the contralateral, non-operated on ankle. An update published the next year that used some of the same patients (the 2009 report had patients from August 1999 to December 2004; the 2010 report had patients from May 2000 to January 2009) included 33 ankles (31 patients). AOFAS Hindfoot-Ankle Scale improved similarly from 36.2 to 72.3 points and achieved 27.3° clinical range of motion [13].

Several important points can be drawn from these studies. AA takedown and conversion to TAR is a viable option for the painful malunion or nonunion of the ankle joint, especially in the face of adjacent joint arthritis. Patients with chronic pain syndromes or no definable source of pain should be approached with caution. Alignment is of the utmost importance, and any steps needed to ensure that the TAR is balanced to the foot and leg must be taken. Postoperative range of motion averages between 24° and 27° and can be maintained thereafter [16]. One of the most important aspects to successful conversion of the failed AA to TAR is the existing anatomy. Incision approach, preservation of the malleoli, and final position allowing for recreation of the ankle joint all have a significant impact on outcomes. In particular,

a previous fibulectomy is a unique problem in AA takedown, and even though Hintermann et al. [13] have reported a method for fibula reconstruction, this still has dire consequences on the ability and complexity of AA takedown conversion to TAR.

A pertinent point of discussion related to AA takedown and conversion to TAR is the method of AA that 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 TAR. As long as there is a skin bridge of at least 4 cm, it has been suggested that a standard approach can be undertaken [12–14]. If an anterior incision is to be used for the primary AA, 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. AA approached anteriorly, medially, or posteriorly typically facilitates little or no violation of the fibula. 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 an AA takedown to TAR.

Ankle Arthrodesis Takedown Conversion to Total Ankle Replacement 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 preexisting vascular disease in the intended limb should be carefully evaluated as a potential contraindication for surgery.

Contralateral weight-bearing radiographs for comparison are 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.

Approach

It is the experience of the authors to use an anterior approach for AA conversion to TAR 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 be taken into consideration in respect to the location of the future intramedullary stem (Fig. 34.6). These points need to be considered with central keeled tibial prostheses as well. A vertically oriented intramedullary screw similarly protects the fibula with the start point at the tip of the malleolus. Fully threaded screws can be used in both applications, typically 4.0-mm cannulated.

Defining the Joint Line

The ankle joint line is defined carefully using the contralateral limb for guidance. Intraoperative image intensification is compared to preoperative imaging. Often there is an indent in the healed bone segment that can aid the surgeon in identifying the ankle 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 arthrodesis, the distal extent of each gutter is still visible. Guide wires are placed in an anterior–posterior direction through the estimated horizontal and vertical joint lines, and a careful intraoperative image intensification evaluation is performed (Fig. 34.7). It is helpful to use multiple wires to determine the horizontal joint line. Once position is established, care-

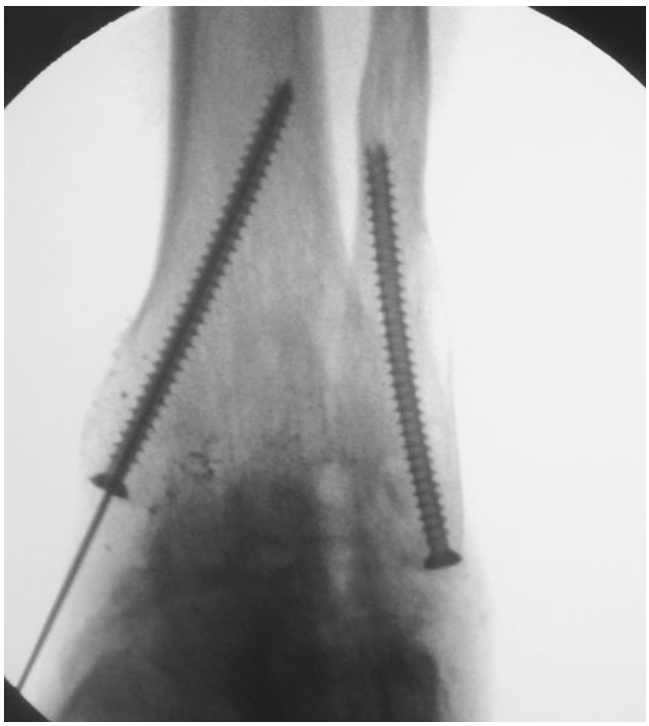

Fig. 34.6 Intraoperative image intensification views demonstrating prophylactic pinning of the malleoli using fully threaded 4.0-mm cannulated screws. Trajectory of the screws must be taken into account later in the placement of the prosthesis, particularly important when using a stemmed tibial prosthesis. Care must be taken not to impinge on the prosthesis

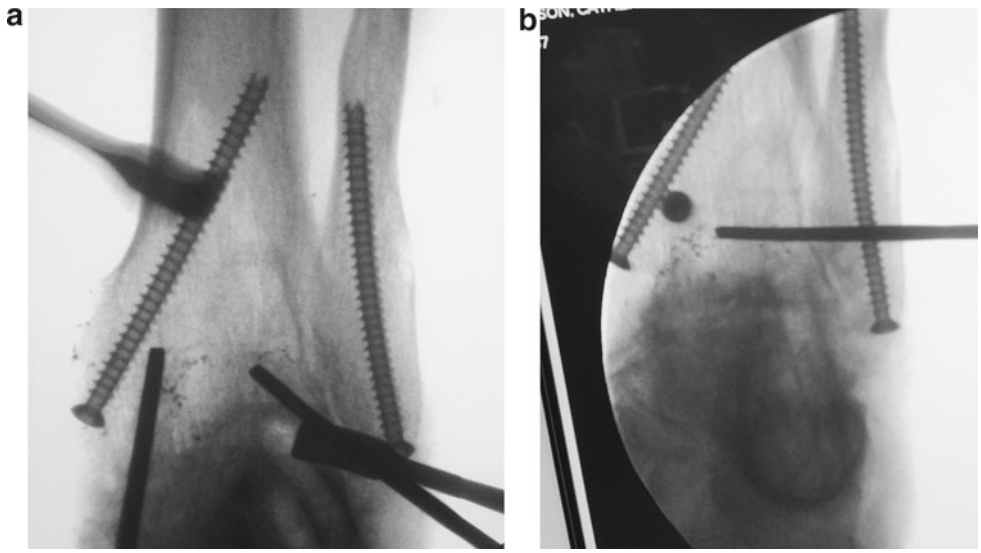

Fig. 34.7 Intraoperative image intensification views using guide wires to define and plan for the ankle joint line and medial and lateral gutters. Vertical (**a**) and horizontal (**b**) joint lines need to be defined

fully scrutinize the alignment between the wires if the plan is to use the wires as cut guides (Fig. 34.8). Particular attention to the anterior–posterior flexion angle of the wires should be taken.

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

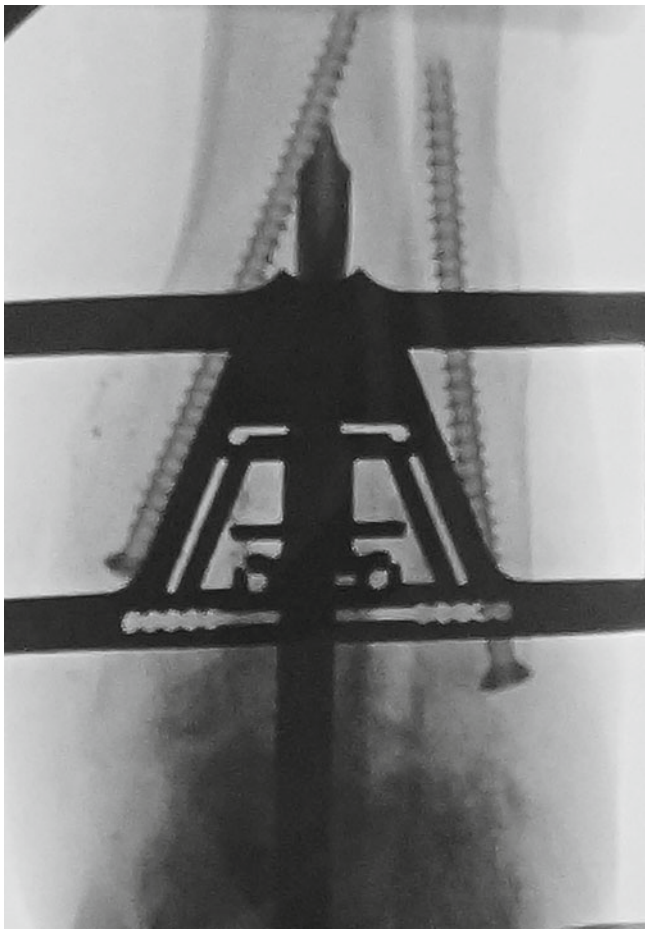

Fig. 34.8 Intraoperative image intensification views assessing the planned bone cut(s) for the prosthesis. Care is taken to ensure that the malleoli are preserved and that flexion of the ankle is correct. Guide wires marking the joint line and gutters can be used to assess proper positioning

its own advantages and disadvantages. One technique may fit the particular case better than the other, so consider both options carefully.

For the first technique, mobilize the tibia from the talus prior to placement of the cut guides. This would be performed freehand using a power saw and osteotomes using the wires as cut guides. Angular deformities can be corrected through these cuts with careful planning. The advantage of this technique is that it allows for free movement of the tibia with respect to the talus that markedly decreases the risk for intraoperative fractures. Also, once the joint is re-created 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 tendo Achilles lengthening is performed. The disadvantage is that the freehand cuts are performed prior to placement of the cut guides. There may be greater chance for error using freehand cuts in establishing both the new joint line and its alignment or potential for injury to the malleoli through the cut. We recommend using 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.

The second technique involves placement of cut guides followed by removal of the resection segment and then mobilization of the tibia and talus. The advantage of this technique is that it 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. The disadvantage is that 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 pinned. The remainder of the cuts to the gutters will need to be done freehand once the bone segments are removed. We recommend using this technique in solid AA 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 image intensification visualization.

Bone Cut Technique

The soft tissues may be adherent to the posterior aspect of the tibia including the flexor hallucis longus and neurovascular bundle. A pec 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 tendon will need to be lengthened in nearly all cases. The posterior tibial tendon

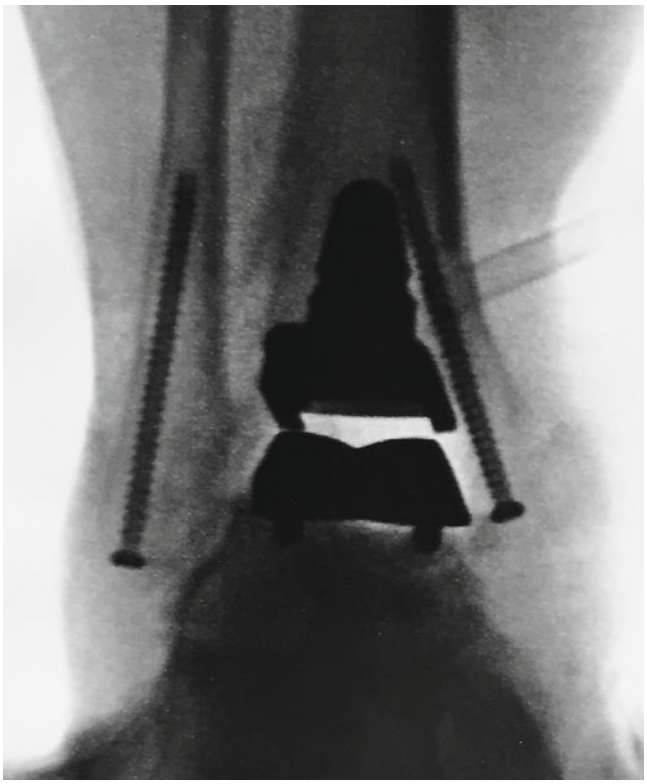

Fig. 34.9 Intraoperative image intensification view after final implantation of the prosthesis and screws in the malleoli. Final inspection is undertaken to ensure that the implant is properly seated, the components are congruent to each other, the gutters are open and decompressed, and the screws do not impinge on the implant

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 prosthesis is in place and evaluate surrounding soft-tissue contractures again.

Final Imaging

Confirm position of the prosthesis 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. 34.9). In some cases screws in the malleoli may be removed if necessary (Fig. 34.10). It is recommended to take dorsiflexion and plantar flexion views intraoperatively to confirm range of motion that was achieved after implantation (Fig. 34.11).

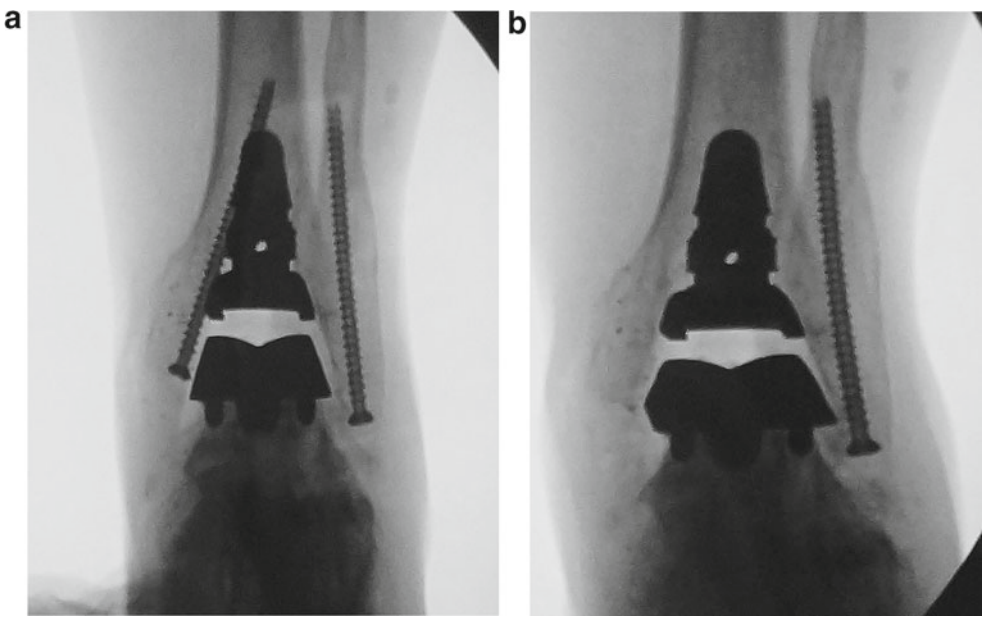

Fig. 34.10 Final intraoperative image intensification views ensuring proper placement of the final prosthetic components (**a**). In this case, the medial malleolar screw was determined to be too close to the final prosthesis and was subsequently removed (**b**). This was possible because of good medial bone structure with excellent prosthesis placement and alignment

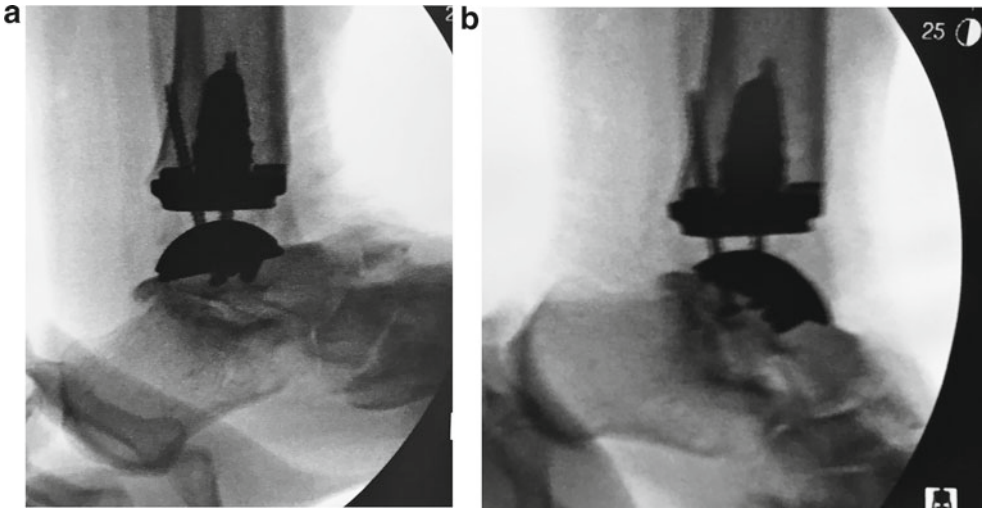

Fig. 34.11 Intraoperative lateral image intensification views taken in maximal dorsiflexion (**a**) and plantar flexion (**b**) to confirm range of motion achieved after the takedown of the ankle arthrodesis with conversion to total ankle replacement

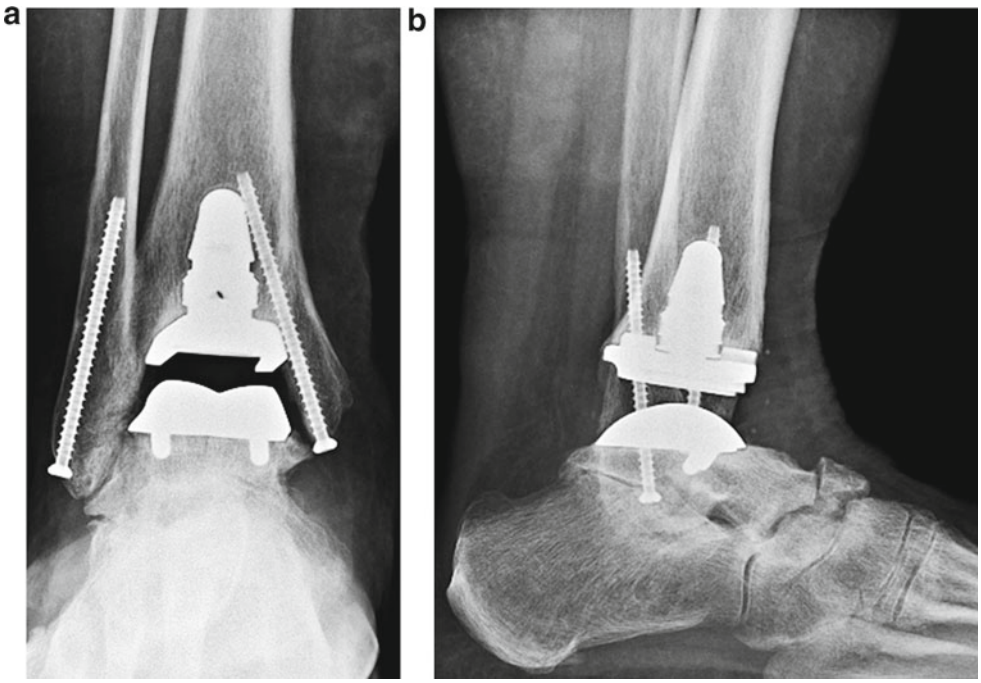

Fig. 34.12 Anterior–posterior (**a**) and lateral (**b**) weight-bearing radiographs taken at 1 year postoperatively after ankle arthrodesis takedown and conversion to total ankle replacement. Range of motion is preserved and takes stress off of the adjacent joints providing for pain relief and a return to activity

Letting Down the Tourniquet

It is the author's recommendation that the tourniquet be let down prior to closure. It is a known risk of TAR to have vascular and neurologic compromise of the tibial nerve and artery. These risks are higher with a conversion of an AA to TAR. Excessive bleeding from the posterior medial corner should be investigated for vascular compromise to the tibial artery.

Closure

Normal layered closure for a TAR is completed. Drains are not routinely used although incision-negative pressure wound therapy 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 demonstrates the viability of this option (Fig. 34.12). 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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Limb Salvage Techniques Following Failed Total Ankle Replacement

35

Christopher Bibbo, Stephen J. Kovach, and L. Scott Levin

Introduction

Catastrophic complications after total ankle replacement (TAR) is fortunately uncommon, but efforts to maintain limb length over higher-level amputations (i.e., below-knee or above-knee amputations) are indicated so that biomechanical performance is improved, prosthetic usage more compliant, and patient body image perception enhanced. Techniques for limb salvage include the use of ankle-level amputations, Ilizarov external circular ring fixation techniques, as well as local and free tissue transfers.

Regional Amputations to Maintain Limb Length

Catastrophic complications after TAR may unfortunately result in amputation of the limb as a final salvage outcome. The reasons are many and include a lack of solutions to provide other forms of functional limb salvage or the patients' desire to end further reconstruction efforts and proceed with an amputation. The below-knee amputation (BKA) is a common procedure, but the authors believe other viable options exist regarding pedal amputations. Most amputations result after complete loss of the hindfoot and ankle region. The desired goal of preserving limb length during amputation will require sacrifice of the foot. Each limb length sparing amputation is dependent upon what volume of hindfoot bone remains.

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Limb Salvage with Ankle-Level Amputations: The Pirogoff, Boyd, and Syme Amputations and Modifications Thereof

Amputations at the ankle level are valuable to preserve limb length and may provide long-term durable limb use. It has been the authors' observation that in comparison a BKA, especially in the elderly, prosthetic use is easier and compliance greater and in middle-aged patients, the range of activities in which the patient may participate in is greater, body image is enhanced, and social integration is improved. When amputation is deemed necessary, efforts should be made to maintain the amputation at the level of the ankle. Among amputations at the ankle level, the Pirogoff, Boyd, and Syme amputations as classically described or modified as needed are excellent choices to maintain the distant extremity and spare the patient from a BKA [1].

The Pirogoff amputation involves sacrificing the foot, keeping the calcaneus only, at the TAR explant level. Very simply, after removal of the foot and the remainder of the talus, the anterior edge of the calcaneus is transected; the remaining body of the calcaneus is rotated 90° in the sagittal plane, placing the cut surface of the anterior calcaneus up against the remaining tibial plafond. In doing so, the posterior calcaneus then becomes the plantar weight-bearing surface of the limb (Fig. 35.1). If a large anterior soft-tissue defect exists, the plantar skin of the foot can be used as a flap and rotated anteriorly, using the "fillet of foot" flap

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
DOI 10.1007/978-3-319-24415-0_35

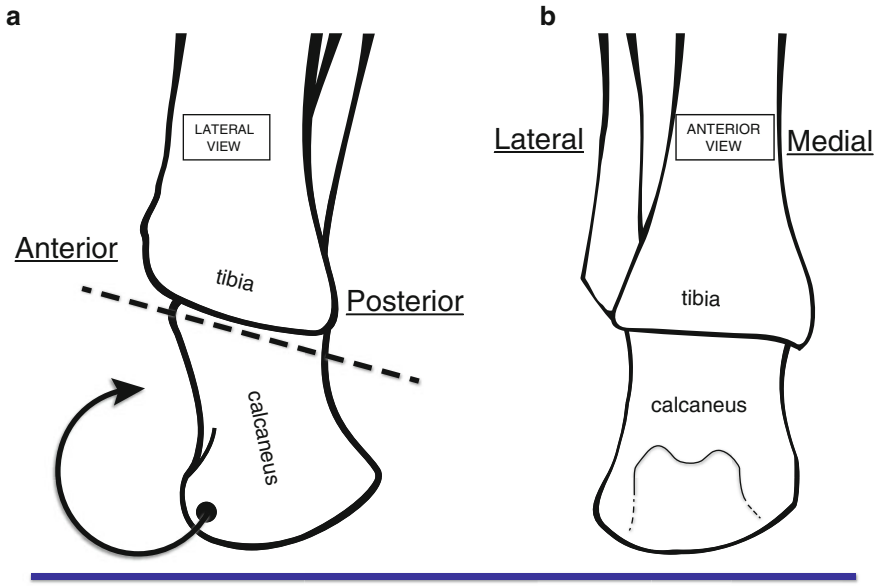

Fig. 35.1 Lateral (**a**) and anterior views (**b**) of Pirogoff amputation. The calcaneus is resected through its anterior distal portion (*dashed line*) to meet the contour of the tibial plafond and then rotated in the sagittal plane approximately 90° (*arrow*). The posterior aspect of the calcaneal tuber bears weight against the ground (*blue solid line*)

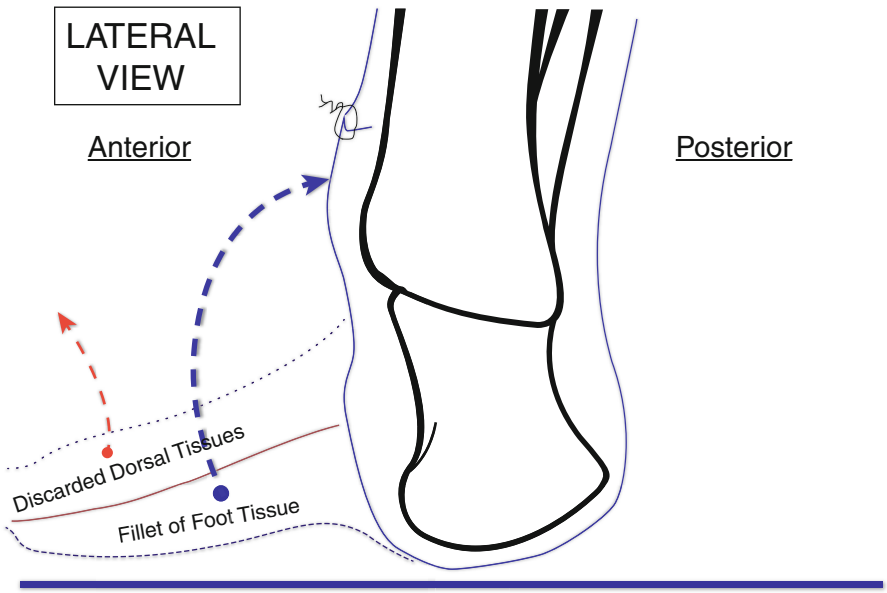

Fig. 35.2 Lateral view of fillet of foot to cover anterior soft-tissue defects. All bones of the foot are removed; the dorsal skin and structures are discarded; the plantar surface of the foot, supplied by the medial and lateral plantar arteries, is rotated and tailored to fit the soft-tissue defect

technique (Fig. 35.2). If limb length is lost from the tibia and maintenance of limb length is required, the explanted TAR site may be bone grafted with autologous bone, banked bone, or free vascularized bone. The primary author avoids the use of frozen allografts, as recurrent infection is not infrequent. Recombinant bone morphogenetic protein (rhBMP-2) may be used to augment healing in difficult cases [2–6]. Advances in "stem cell" biologic grafts (Trinity Evolution, OrthoFix, McKinney, TX) have also been demonstrated to be of value in obtaining osseous healing in local hostile environments [7]. Modification of the Pirogoff amputation (i.e., Lefort-Neff modification) maintains the calcaneus in its anatomical position, but requires resection of the superior surface of the calcaneus and fusion to the remaining tibial plafond, followed by trimming the malleoli to debulk medial/lateral prominences. Obviously, the more of the calcaneus that is resected, the more grafting will need to be preformed, or proximal distraction osteogenesis may provide needed limb length (Fig. 35.3).

The Boyd amputation is a variation of the Pirogoff amputation, shifting the calcaneus posteriorly. If the calcaneus is shifted anteriorly, for forward weight transmittal during gait, it is termed the Camilleri modification of the Boyd amputation.

These above amputation techniques act to preserve distal limb length at the expense of increased shear forces of the

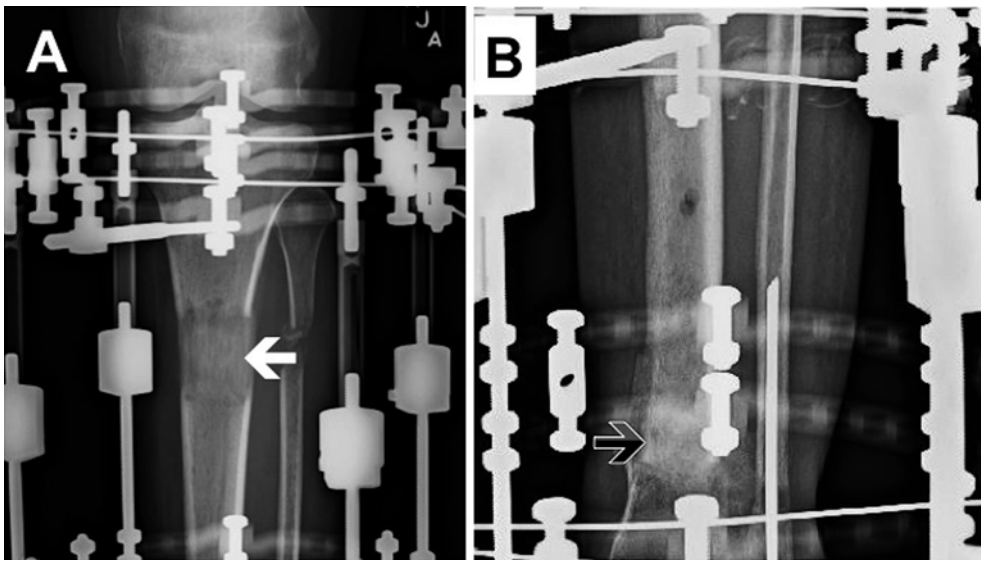

Fig. 35.3 Radiograph of bifocal Ilizarov external circular wire fixation technique (*white arrow*) for 4-cm bone loss. Proximal distraction osteogenesis is carried out (**a**, *white arrow*) at the same time as distal compression osteogenesis (**b**, *black arrow*)

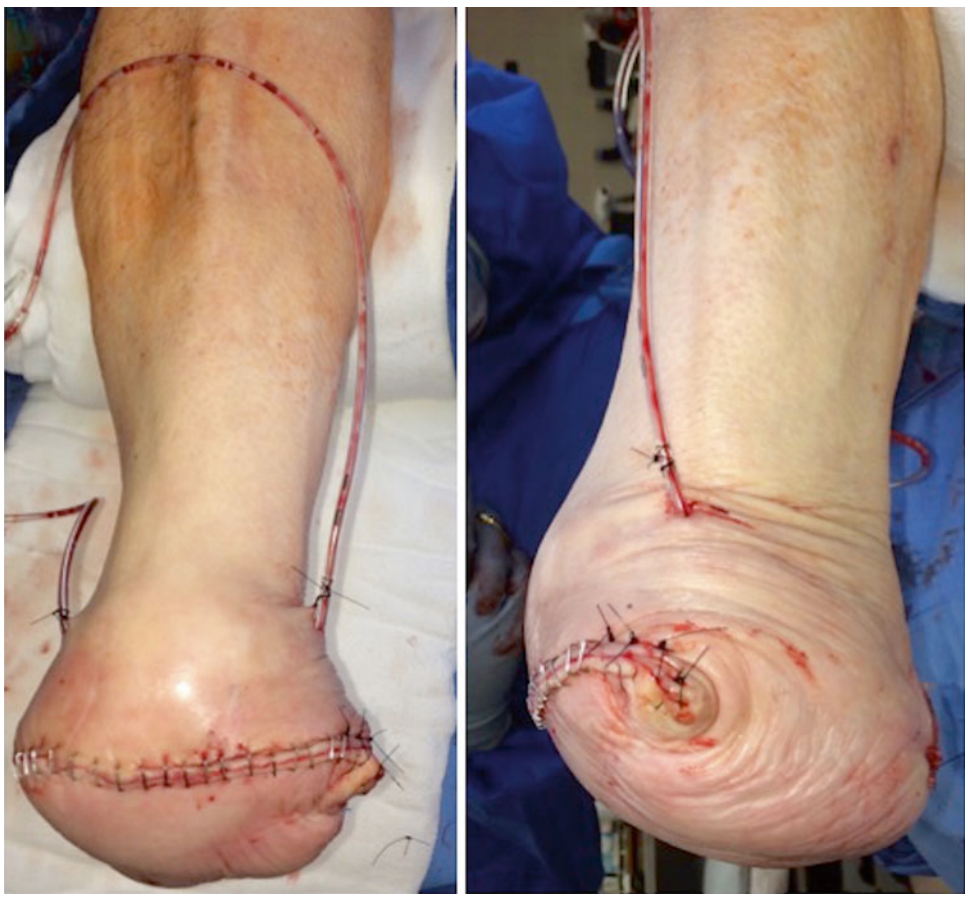

Fig. 35.4 Anterior and lateral clinical photos of a Syme amputation. Note the plantar heel pad acts as the near total plantar weight-bearing surface of the amputation site

amputation; breakdown may occur without appropriate orthotic control, with perhaps the Pirogoff, where the durable heel skin is bearing weight. Additionally, foot clearance may be an issue in some patients, as residual length is created, because no articulating joint is present distally, foot clearance may be impeded slightly. The surgeon may choose to create a mild limb length discrepancy of 1–2 cm to allow for enhanced foot clearance during ambulation.

The Syme amputation is an ankle disarticulation amputation that discards the foot in its entirety except for the terminal insertion of the Achilles tendon and heel pad (Fig. 35.4), better known as an amputation in diabetic patients with

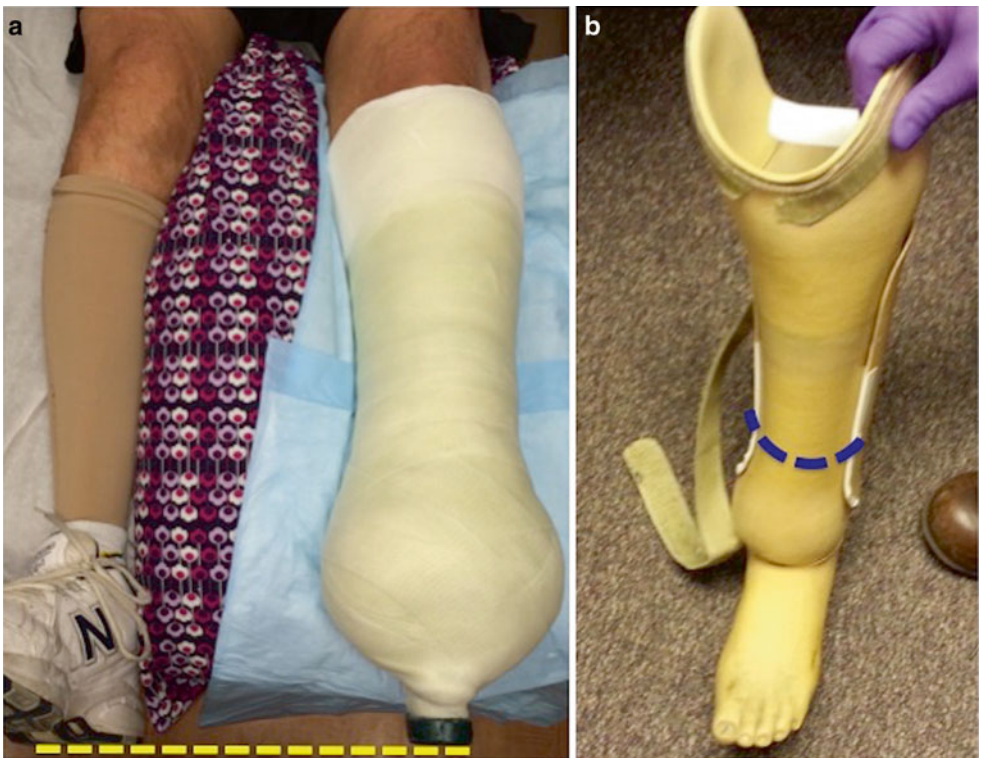

Fig. 35.5 Postoperative Syme amputation walking cast (**a**). Note that limb lengths are equalized (*dashed line*). Off-loading style Syme amputation prosthesis for morbidly obese patient (**b**). The prosthesis may be as low as the distal tibial flare (*dashed line*) in patients with normalized body weight

infection or Charcot neuroarthropathy. The Syme-level amputation provides for a good swing phase during gait and relies on an intact heel pad to cover the entire distal limb; thus, an intact heel pad is mandatory to perform a Syme amputation. The Syme amputation is well suited to immediate weight bearing after drain removal with a simple patellar-tendon-bearing cast that is well padded and designed to match limb lengths prior to prosthetic fabrication (Fig. 35.5). The Syme prosthesis incorporates a simple padded socket incorporated onto a prosthetic shoe filler. The Syme prosthesis may be as low as the distal tibial flair or higher, to help off-load moribund patients (Fig. 35.5). The primary author has known patients to ambulate approximately 50 % of the time in their home bare legged being without their prosthesis, without undo consequences. However, in patients with weak lateral leg musculature, tibial varum, or a varus knee thrust during gait, late varus heel pad migration can occur. This late varus heel pad migration can be mitigated by incorporating the peroneal tendons into the lateral heel pad, the so-called Bibbo modification of the Syme amputation [8].

In cases where massive soft-tissue loss will challenge the standard hindfoot/ankle-level amputation, the use of free tissue transfers may help retain a distal level of amputation. In this setting, composite tissue free flaps, comprised of skin, subcutaneous fat, fascia, and even muscle, are the most desirable of the free flaps (Fig. 35.6). Providing all soft-tissue components in one composite flap greatly fills the needs of tissue fill and resurfacing and lends for a remarkably more stable long-term soft-tissue envelope over the amputation site. The technique of using free tissue transfers may also be applied to catastrophic complications in places in which the limb is in jeopardy of an above-knee amputation (i.e., free tissue transfers to resurface a BKA level can salvage the BKA and knee function, preventing it from becoming the biomechanically inferior above-knee amputation) [1].

Critical Length Bone Loss

Bone loss considerations must be thought of as on the "talar side" and the "tibial side." Complete talar loss implies the need for a tibio-calcaneal or tibio-bulk allograft-calcaneal arthrodesis; loss of additional tibial bone presents the need for replacement of critical bone stock. Loss of the calcaneus with the talus is an extreme challenge that may ultimately require "borrowing" the foot and placing it against or under the tibia or a higher-level amputation (BKA), discussed in the amputation section of this chapter.

Bone loss of up to 2 cm is easily accommodated with an in-shoe lift. Due to bone loss resulting in ≥4-cm limb length discrepancy, to maintain proper limb length balance even with a shoe-based lift is usually difficult. The goal of all limb salvage techniques is to prevent a higher-level amputation and preserve the foot.

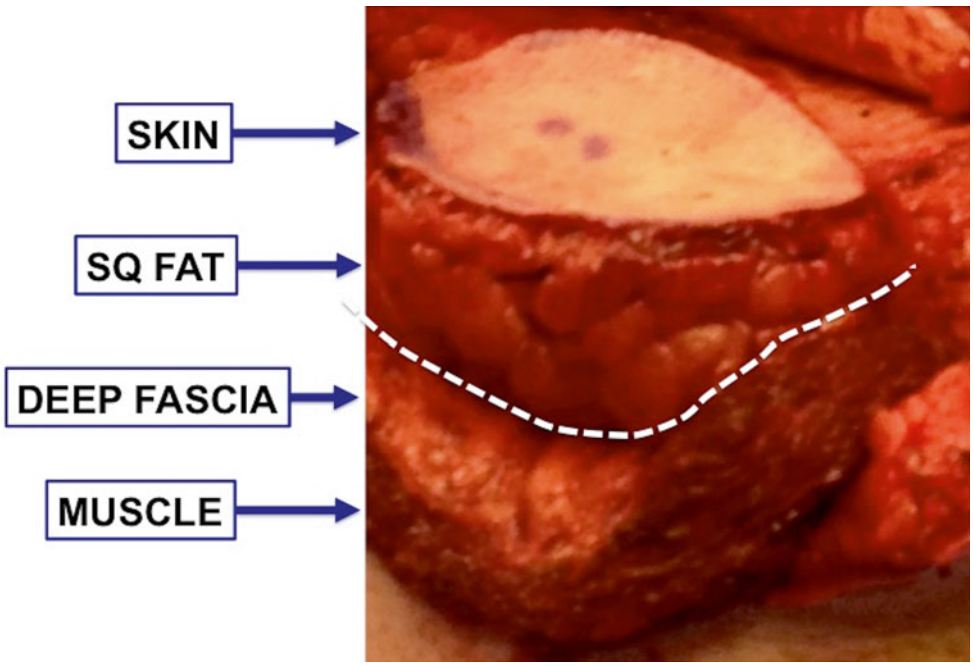

Fig. 35.6 Intraoperative photograph of a composite skin perforator-based free flap (anterolateral thigh flap depicted). All tissue layers or just a few may be harvested. Dashed line demarks a "skin perforator flap" (skin and subcutaneous [SQ] fat)

Bone loss can be reconstructed with a combination of autologous and banked bone (2–4 cm), massive autologous bone graft (4–6 cm) with bilateral iliac crest grafts, free vascularized bone graft, or a combination of Ilizarov external circular ring fixation techniques: either distraction osteogenesis with distal docking or a bifocal technique with acute distal compression and proximal distraction osteogenesis (Fig. 35.3). The primary author has found the latter to be more reproducible and more reliable [9]. Complications resulting in bone defects of ≥6 cm of the tibia will generally require a free vascularized fibula to salvage the limb. Distraction osteogenesis of ≥8 cm can be performed with the "Weber cable technique," but is technically challenging (Fig. 35.7).

Critical-Size Soft-Tissue Loss

A thorough discussion of soft-tissue techniques to manage wound issues after TAR is presented elsewhere in this textbook. Still, soft-tissue defects are a prime determinant of whether functional limb salvage is an option. In general, in the setting of attempted limb salvage after catastrophic TAR complications, large wounds may be covered by either a local flap or a soft-tissue free flap. When salvage is the main concern, local soft tissue may provide all the elements to achieve a stable soft-tissue envelope about the salvaged limb. Fillet of foot flaps can provide non-weight-bearing coverage as well as weight-bearing skin quality for end-bearing prosthesis.

Critical-Size Bone and Soft-Tissue Loss

Massive compound limb defects after catastrophic complications of TAR are those that require both soft tissue and bone to maintain a functional limb. In this setting, there are two options to avoid a higher-level amputation (i.e., BKA). The use of computerized fine-wire circular fixation may provide assisted wound closure by closing down soft-tissue defects via volume reduction techniques and/or bone defects while performing distraction osteogenesis at a distant site on the tibia [10].

This technically complex variant of the bifocal Ilizarov technique requires substantial knowledge and experience with computer-assisted deformity correction programs. The other option is a free osteocutaneous free flap, namely, a free osteocutaneous fibula, performed in conjunction with the application of a simple external fixation device ("delta frame" or mono-lateral design). If residual deformity correction is needed, simple external fixation is later converted to a computerized fine-wire circular external fixation device, and ambulation of the external fixator permitted based on free flap incorporation.

Conclusions

Catastrophic complications after total ankle replacement (TAR) is fortunately uncommon, but efforts to maintain limb length over higher-level amputations (i.e., below-knee or above-knee amputations) are indicated so that biomechanical

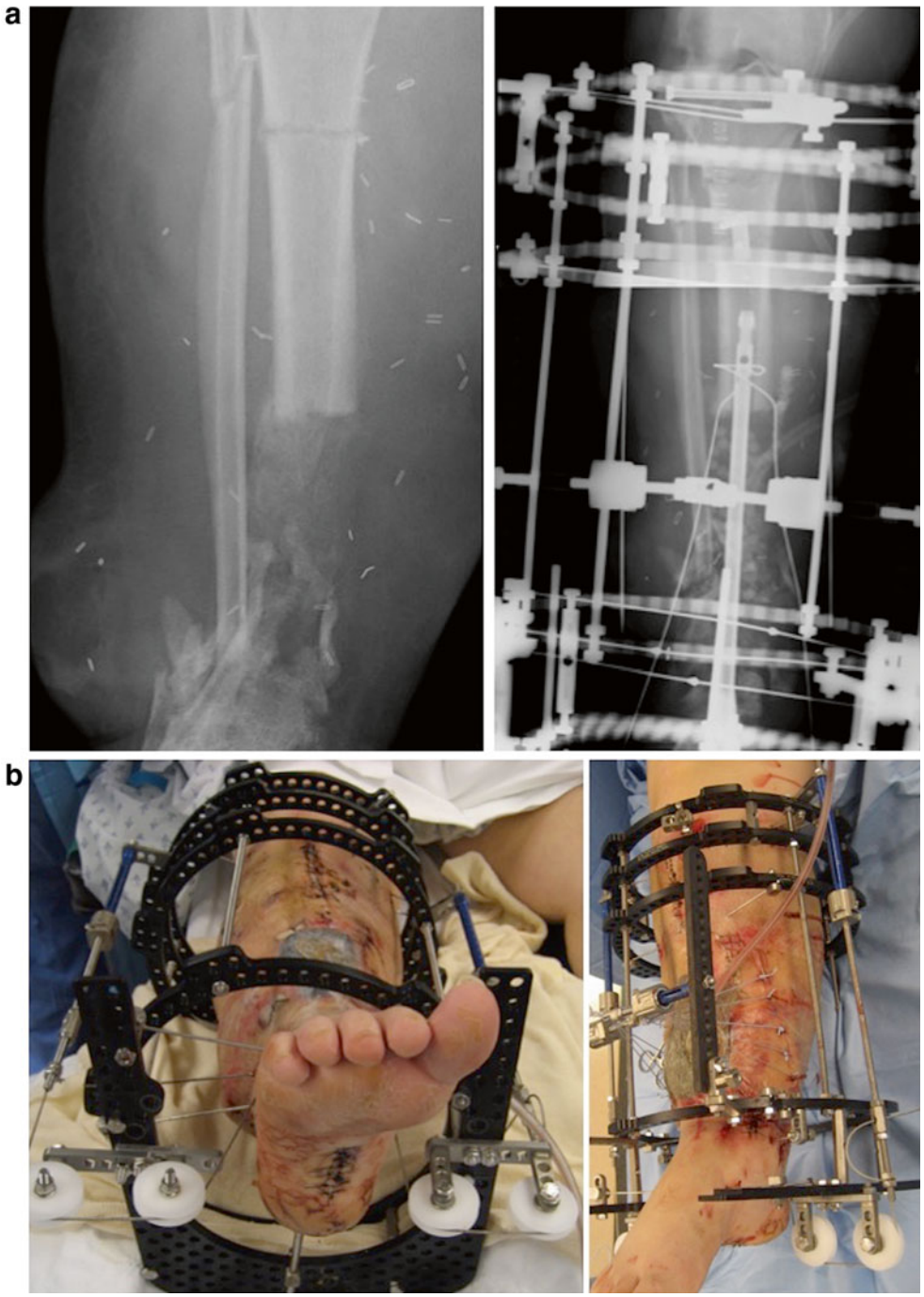

Fig. 35.7 Radiographs (**a**) and clinical photographs (**b**) of Weber cable-pulley technique for distraction osteogenesis transport of long tibial bone segment for massive bone loss (12 cm in this patient) for limb salvage after methicillin-resistant *Staphylococcus aureus* tibia infection

performance is improved, prosthetic usage more compliant, and patient body image perception enhanced. Techniques for limb salvage include the use of ankle-level amputations, Ilizarov external circular ring fixation techniques, as well as local and free tissue transfers. Management of the failed total ankle replacement, especially those requiring soft-tissue coverage and limb salvage efforts, should only be performed by experienced surgeons and ideally in units where multidisciplinary support is available.

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T.S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*,
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