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

Primary and Revision Total Ankle Replacement

Evidence-Based Surgical Management

Second Edition

Springer

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ISBN 978-3-030-69268-1 ISBN 978-3-030-69269-8 (eBook)
https://doi.org/10.1007/978-3-030-69269-8

This Springer imprint is published by the registered company Springer Nature Switzerland AG
The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

Preface

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

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

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

La Crosse, WI, USA

Thomas S. Roukis, DPM, PhD, FACFAS

Preface (for second edition)

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

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

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Part I

Introduction

History of Total Ankle Replacement in North America

1

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

Introduction

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

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First Generation

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

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

T. S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*, https://doi.org/10.1007/978-3-030-69269-8_1

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

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

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

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

Second Generation

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

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

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

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

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

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

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

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

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

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

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

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

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

Third and Fourth Generation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recent Trends

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

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

Conclusions

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

Table 1.1 Commonly used North American total ankle replacement systems

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

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Total Ankle Replacement Based on Worldwide Registry Data Trends

2

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Introduction

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

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

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

T. S. Roukis et al. (eds.), *Primary and Revision Total Ankle Replacement*, https://doi.org/10.1007/978-3-030-69269-8_2

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

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

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

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

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

Methods

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

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

Results: Worldwide Prosthesis Usage

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

Abandonment

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

Minimal Use

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

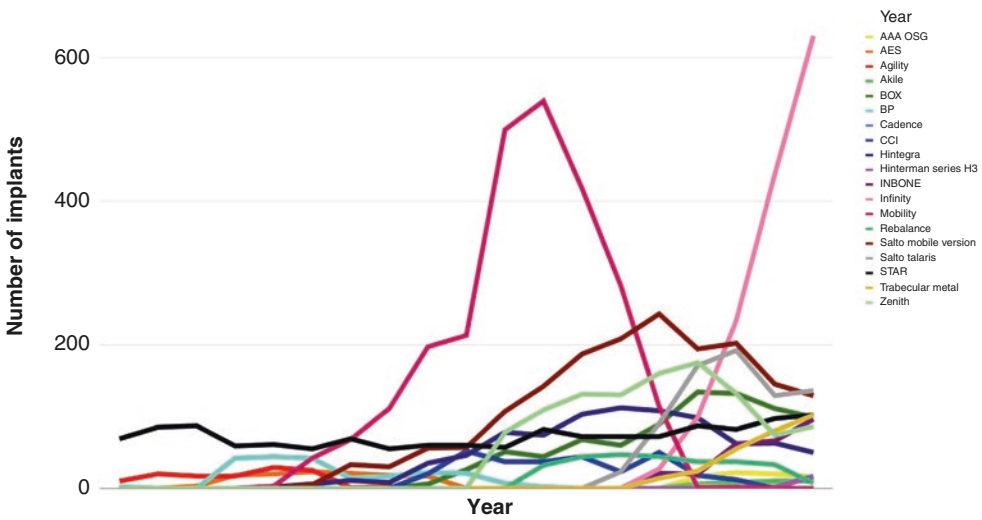

Fig. 2.1 Worldwide usage of primary total ankle replacement prostheses based on available national joint registries between 2000 and 2018

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

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

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

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

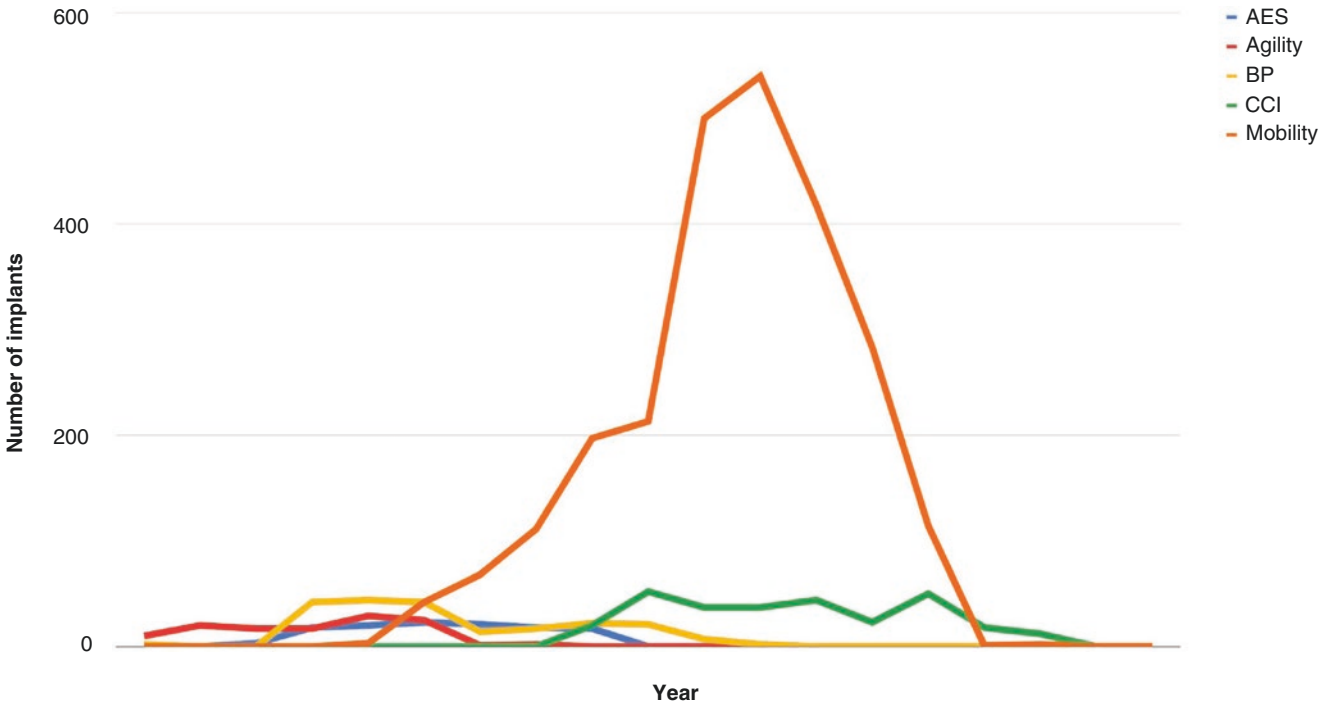

Fig. 2.2 Implants trending toward abandonment 2000–2018

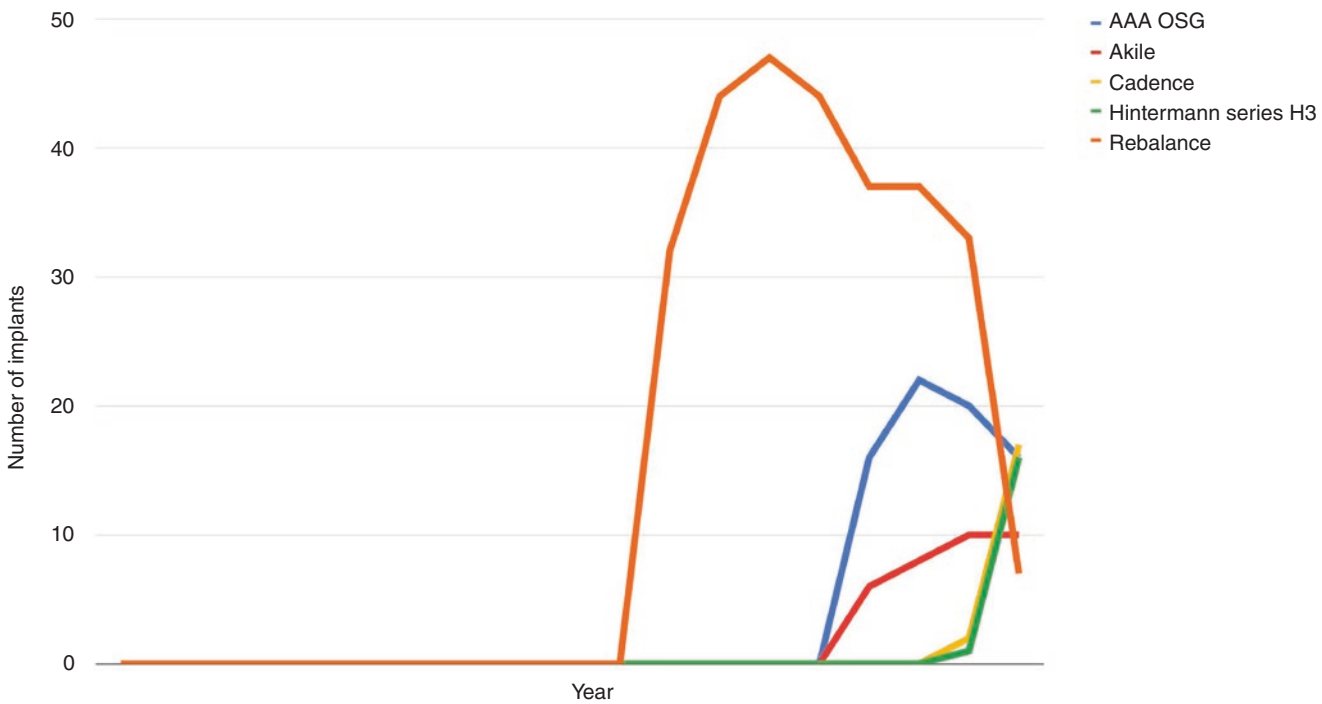

Fig. 2.3 Implants with minimal use 2000–2018

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