Thomas S. Roukis · Gregory C. Berlet
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Editors

Primary and Revision Total Ankle Replacement

Evidence-Based Surgical Management

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Mark A. Prissel, Content Editor

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Editors
Thomas S. Roukis, DPM, PhD
Orthopedic Center
Gundersen Health System
La Crosse, WI, USA

Christopher Bibbo, FACS, FAAOS, FACFAS
Department of Orthopaedic Surgery
Wisconsin Foot and Ankle Institute
Marshfield Clinic, Marshfield, WI, USA

Murray J. Penner, MD, B.Mech.Eng., FRCSC
Clinical Associate Professor
University of British Columbia
Vancouver, BC, Canada

Head, Department of Orthopedics
Vancouver Coastal Health Authority
and Providence Health Care
Vancouver, BC, Canada

Mark A. Prissel, DPM
Atlantic Foot & Ankle Center of Chesapeake
Chesapeake, VA, USA

Gregory C. Berlet, MD, FRCSC
Orthopedic Foot and Ankle Center
Westerville, OH, USA

Polaris Surgery Center, Westerville, OH, USA

Christopher F. Hyer, DPM, MS, FACFAS
Co-Director
Foot and Ankle Surgical Fellowship
Orthopedic Foot and Ankle Center
Westerville, OH, USA

Residency Program Director
Grant Medical Center
Podiatric Medicine and Surgical Residency
Columbus, OH, USA

Markus Wünschel, MD
Professor of Clinical Orthopedic Surgery
Foot and Ankle Center Karlsruhe
Karlsruhe, Germany

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Preface

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

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

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

La Crosse, WI, USA

Thomas S. Roukis, DPM, PhD

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Contributors

Orfan Arafah, MBBS, FRSC(C) Department of Orthopaedic (49), College of Medicine, King Khalid University Hospital/King Saud University, Riyadh, Saudi Arabia

Thanos Badekas, MD Department of Orthopedics, Hygeia Hospital, Attika, Greece

Jason T. Bariteau, MD Department of Orthopedic Surgery, Emory University, Atlanta, GA, USA
Department of Orthopedics, Emory University School of Medicine, Atlanta, GA, USA

Annette F.P. Bartel, DPM, MPH Gundersen Medical Foundation, La Crosse, WI, USA

Thomas C. Beideman, DPM Department of Foot and Ankle Surgery, Mercy Suburban Hospital, Norristown, PA, USA

Gregory C. Berlet, MD, FRCSC Orthopedic Foot and Ankle Center, Westerville, OH, USA

Jean-Luc Besse, MD, PhD Laboratoire de Biomécanique et Mécanique des Chocs, Université Lyon 1, IFSTTAR, LBMC UMR-T 9406, Bron, France
Service de Chirurgie, Orthopédique et Traumatologique, Hospices Civils de Lyon, Centre Hospitalier Lyon-Sud, Pierre-Bénite, France

Bernhard Devos Bevernage, MD Clinique du Parc Léopold, Foot and Ankle Institute, Brussels, Belgium

Christopher Bibbo, DO, DPM, FACS Department of Orthopaedic Surgery, Marshfield Clinic, Marshfield, WI, USA

Michel Bonnin, MD Department of Joint Replacement, Centre Orthopédique Santy, Lyon, France

Stephen A. Brigido, DPM, FACFAS Foot and Ankle Reconstruction, Coordinated Health System, Bethlehem, PA, USA

Frederick F. Buechel, MD Department of Surgery, St. Barnabas Medical Center, South Orange, NJ, USA

Bradly W. Bussewitz, DPM Steindler Orthopedic Clinic, Iowa City, IA, USA

Derek Butterwick, MD, FRSC Department of Orthopaedics, University of British Columbia, Vancouver, BC, Canada

Woo Jin Choi, MD, PhD Department of Orthopaedic Surgery, Severance Hospital, Seoul, South Korea

Jean Alain Colombier, MD Department of Foot and Ankle Surgery, Clinique de l'Union, Saint-Jean, France

James M. Cottom, DPM, FACFAS Fellowship Director, Coastal Orthopedics and Sports Medicine, Bradenton, FL, USA

Justin L. Daigre, MD Atlantic Foot & Ankle Center of Chesapeake, Chesapeake, VA, USA

Timothy R. Daniels, MD, FRCSC Department of Surgery, University of Toronto, St. Michael's Hospital, Toronto, ON, Canada

Paul André Deleu, MScPod Clinique du Parc Léopold, Foot and Ankle Institute, Brussels, Belgium

Sagar J. Desai, MD, MSc, FRCSC Department of Surgery, University of Toronto, St. Michael's Hospital, Toronto, ON, Canada

Jason George DeVries, DPM Department of Orthopedic Surgery, BayCare Clinic, Manitowoc, WI, USA

Lawrence A. DiDomenico, DPM Department of Surgery, St. Elizabeth Hospital, Youngstown, OH, USA

David A. Ehrlich, MD Department of Surgery, Thomas Jefferson University Hospital, Philadelphia, PA, USA

Andrew D. Elliott, DPM, JD Gundersen Medical Foundation, La Crosse, WI, USA

Norman Espinosa, MD Institute for Foot and Ankle Reconstruction Zurich, Zurich, Switzerland

Michel Fessy, MD, PhD Laboratoire de Biomécanique et Mécanique des Chocs, Université Lyon 1, IFSTTAR, LBMC UMR-T 9406, Bron, France

Service de Chirurgie, Orthopédique et Traumatologique, Hospices Civils de Lyon, Centre Hospitalier Lyon-Sud, Pierre-Bénite, France

Fabrice Gaudot, MD Department of Orthopedic Surgery, Raymond Poincaré University Hospital, Garches, France

Nikolaos Gougoulias, MD, PhD Department of Trauma and Orthopaedics, Frimley Park Hospital NHS Foundation Trust, Frimley Park Hospital, Camberley, UK

Jun Hashimoto, MD, PhD Department of Rheumatology and Allergology, NHO Osaka Minami Medical Center, Kawachinagano, Japan

Safet Hatic II, DO, MA Orthopedic Associates of SW Ohio, Centerville, OH, USA

Beat Hintermann, MD Clinic of Orthopaedic Surgery and Traumatology, Kantonsspital Baselland, Liestal, Switzerland

Makoto Hirao, MD, PhD Department of Orthopaedics, Osaka University Hospital, Osaka, Japan

Christopher F. Hyer, DPM, MS, FACFAS Orthopedic Foot and Ankle Center, Westerville, OH, USA

Grant Medical Center Podiatric Medicine and Surgical Residency, Columbus, OH, USA

Alexandre Di Iorio, MD, MSc Service de Chirurgie, Orthopédique et Traumatologique, Hospices Civils de Lyon, Centre Hospitalier Lyon-Sud, Pierre-Bénite, France

Keiji Iwamoto, MD, PhD Department of Orthopedic Surgery, National Hospital Organization Osaka National Hospital, Osaka, Japan

Thierry Judet, MD Department of Orthopedic Surgery, Raymond Poincaré University Hospital, Garches, France

Bom Soo Kim, MD Department of Orthopaedic Surgery, Inha University Hospital, Incheon, Republic of Korea

Markus Knupp, MD Clinic of Orthopaedic Surgery and Traumatology, Kantonsspital Baselland, Switzerland

Stephen J. Kovach, MD Division of Plastic Surgery, Department of Orthopaedic Surgery, Hospital of the University of Pennsylvania, Philadelphia, PA, USA

Division of Plastic Surgery, Perelman Center for Advanced Medicine, Philadelphia, PA, USA

Harish V. Kurup, MBBS, MS, MRCSEd, PG Cert, FRCS Department of Orthopaedics, Pilgrim Hospital, Boston, UK

Sameh A. Labib, MD Department of Orthopedic Surgery, Emory University, Atlanta, GA, USA

Jin Woo Lee, MD, PhD Department of Orthopaedic Surgery, Severance Hospital, Seoul, South Korea

Moses Lee, MD Department of Orthopaedic Surgery, Severance Hospital, Seoul, South Korea

Thibaut Leemrijse, MD Clinique du Parc Léopold, Foot and Ankle Institute, Brussels, Belgium

L. Scott Levin, MD, FACS Paul P. Magnuson Professor of Orthopedic Surgery, Raymond and Ruth Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, USA

Nicola Maffulli, MD, MS, PhD, FRCP, FRCS(Orth) Department of Musculoskeletal Disorders, Faculty of Medicine, University of Salerno, Salerno, Italy

Queen Mary University of London, Barts and The London School of Medicine and Dentistry, William Harvey Research Institute, Centre for Sports and Exercise Medicine, Mile End Hospital, London, UK

Jeffrey E. McAlister, DPM, AACFAS Department of Orthopedic, The CORE Institute, Sun City West, AZ, USA

Falk Mittag Department of Orthopedic Surgery, University Tuebingen, Tuebingen, Germany

Benjamin D. Overley Jr., DPM PMSI Division of Orthopedics, Department of Surgery, Pottstown Memorial Medical Center, Pottstown, PA, USA

Michael J. Pappas, PhD Department of Mechanical Engineering, New Jersey Institute of Technology, Newark, NJ, USA

Murray J. Penner, MD, BMechEng, FRCSC University of British Columbia, Vancouver, BC, Canada

Department of Orthopedics, Vancouver Coastal Health Authority and Providence Health Care, Vancouver, BC, Canada

Mark A. Prissel, DPM Atlantic Foot & Ankle Center of Chesapeake, Chesapeake, VA, USA

Thomas S. Roukis, DPM, PhD Orthopedic Center, Gundersen Health System, La Crosse, WI, USA

Ryan T. Scott, DPM, FACFAS Department of Orthopedics, The CORE Institute, Phoenix, AZ, USA

Devin C. Simonson, DPM Orthopedic Center, Gundersen Health System, La Crosse, WI, USA

W. Bret Smith, DO, MS, FAOAO Foot and Ankle Division, Department of Orthopedics, Providence Hospitals, Moore Center for Orthopedics, Lexington, SC, USA

Matthew D. Sorensen, DPM, FACFAS Weil Foot and Ankle Institute, Chicago, IL, USA

Foot and Ankle, Trauma and Sports Injury, Des Plaines, IL, USA

Kazuomi Sugamoto, MD, PhD Department of Orthopaedic Biomaterial Science, Osaka University Graduate School of Medicine, Osaka, Japan

Toru Suguro, MD, PhD Japan Research Institute of Artificial Joint, Tokyo, Japan

Tetsuya Tomita, MD, PhD Department of Orthopaedic Biomaterial Science, Osaka University Graduate School of Medicine, Osaka, Japan

Stephan Hermann Wirth, MD University Hospital Balgristof, Zurich, Switzerland

Markus Wünschel, MD Foot and Ankle Center Karlsruhe, Karlsruhe, Germany

Keitaro Yamamoto, PhD Department of Orthopaedic Surgery, TOHO University, Tokyo, Japan

Hideki Yoshikawa, MD, PhD Department of Orthopaedic Surgery, Osaka University Graduate School of Medicine, Osaka, Japan

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!

N. Gougoulias, MD, PhD (✉)
Department of Trauma and Orthopaedics, Frimley Health NHS Foundation Trust, Frimley Park Hospital, Portsmouth Road, Frimley GU16 7UJ, UK
e-mail: gougnik@yahoo.com

N. Maffulli, MD, MS, PhD, FRCP, FRCS(Orth)
Department of Musculoskeletal Disorders, Faculty of Medicine, University of Salerno, Salerno, Italy

Queen Mary University of London, Barts and The London School of Medicine and Dentistry, William Harvey Research Institute, Centre for Sports and Exercise Medicine, Mile End Hospital, 275 Bancroft Road, London E1 4DG, UK
e-mail: n.maffulli@qmul.ac.uk

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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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,

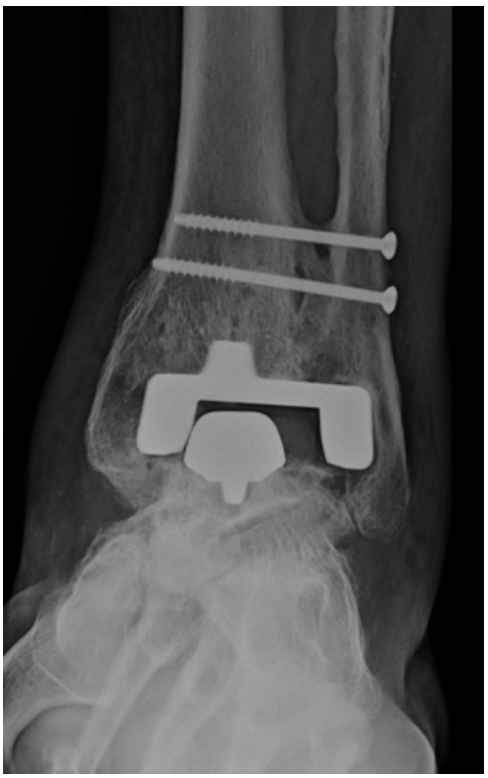

Fig. 1.1 The Agility is a semi-constrained, two-component, fixed-bearing prosthesis, requiring fusion of the syndesmosis. The iteration of the Agility allowed side-to-side "sliding" of the talus

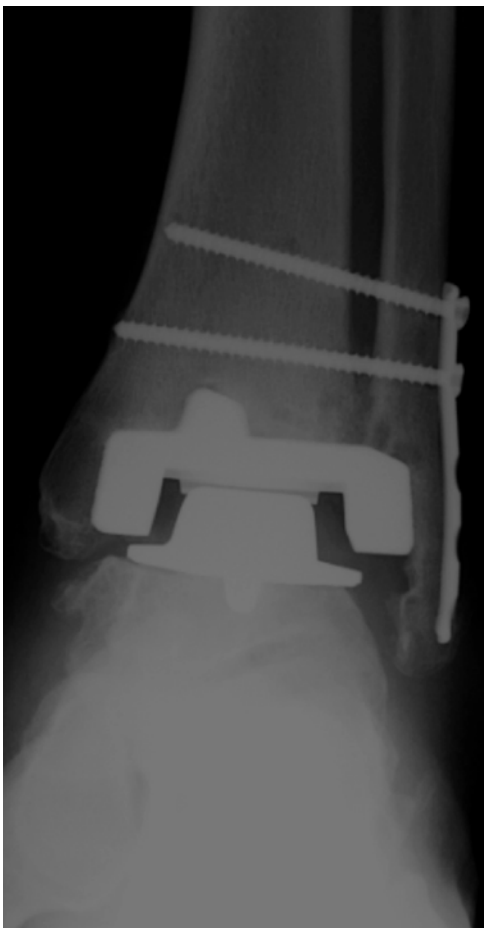

Fig. 1.2 The newer Agility LP prosthesis has a broad-based talar component

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.

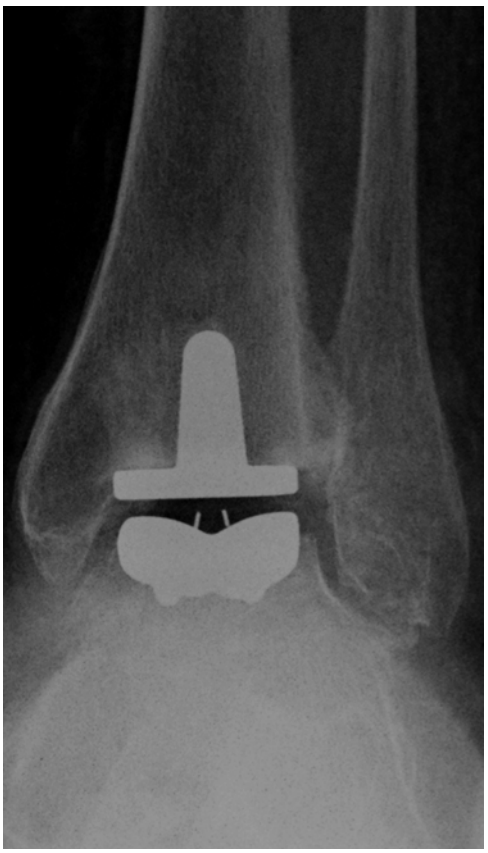

Fig. 1.3 The Mobility is a Buechel–Pappas-like prosthesis (three-component, mobile-bearing, tibial stem, for cementless implantation)

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].

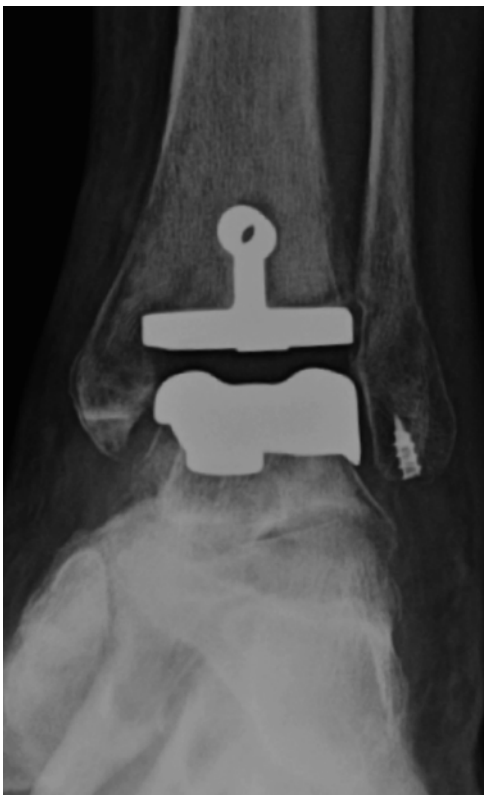

Fig. 1.4 The Salto Talaris ankle, two-component, fixed-bearing prosthesis

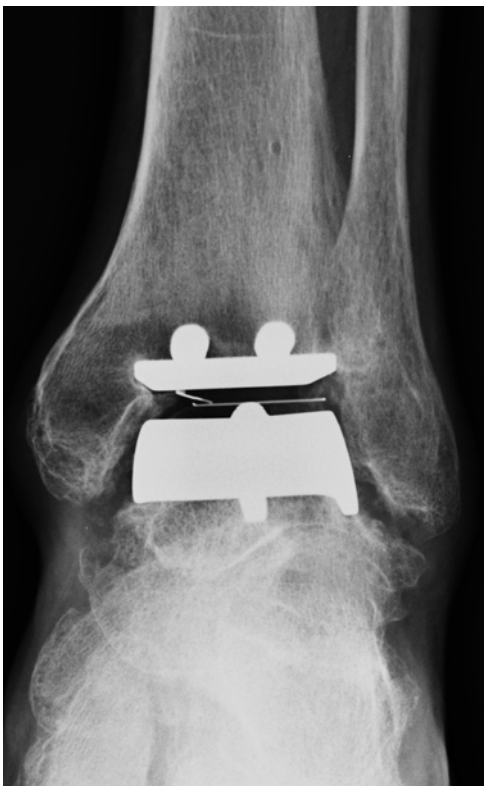

Fig. 1.5 The STAR is the only three-component cementless prosthesis approved by the FDA for use in the USA

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].

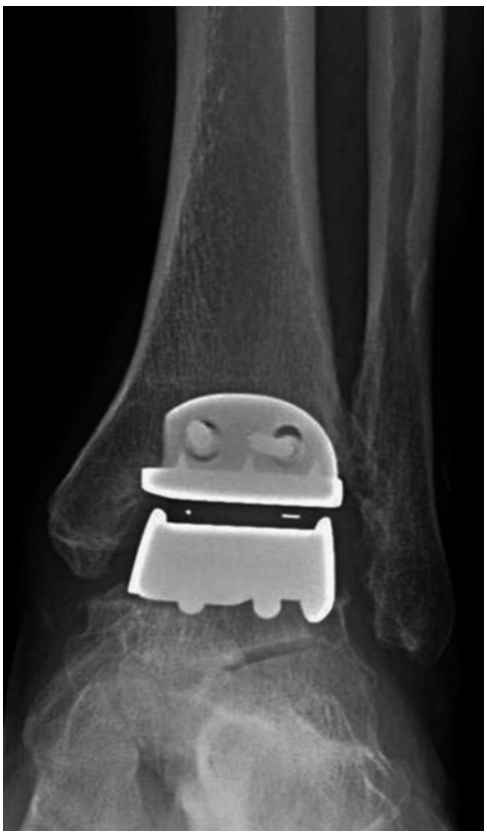

Fig. 1.6 The Hintegra ankle, three-component, cementless, mobile-bearing prosthesis

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

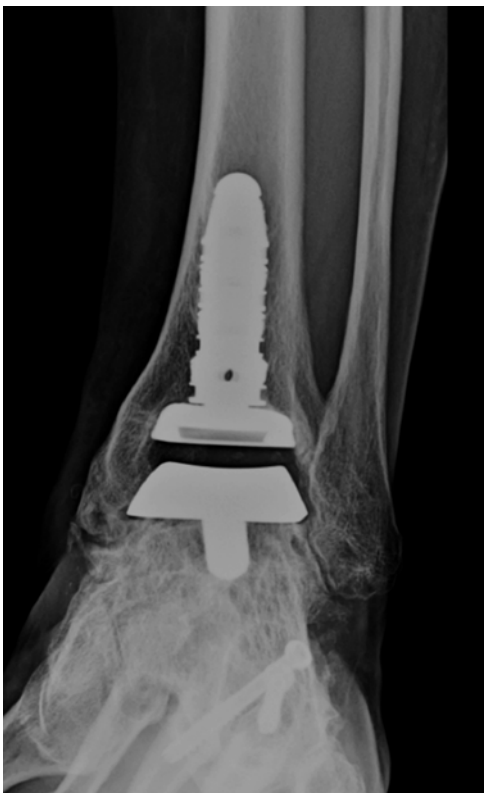

Fig. 1.7 The special feature of the INBONE prosthesis is the modular tibial stem. The INBONE I (early design) had a relatively flat talar component and was, therefore, unstable

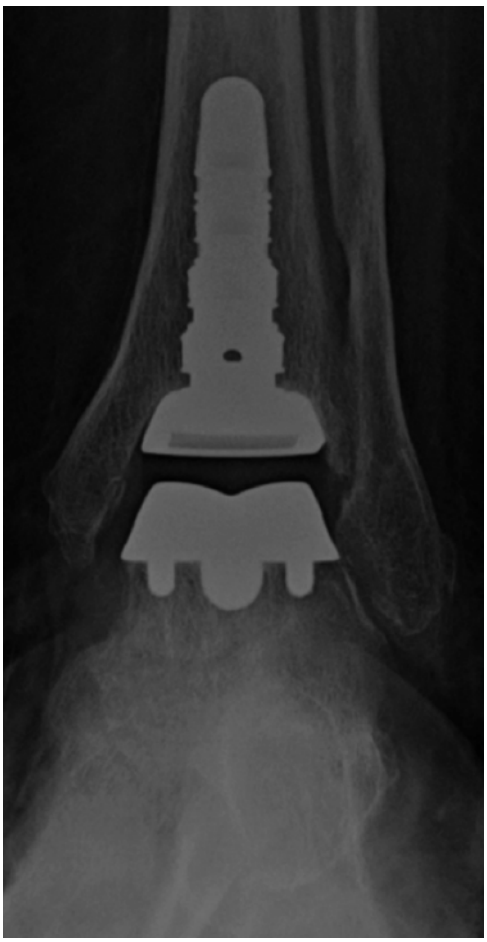

Fig. 1.8 The (modified) INBONE II prosthesis incorporated a talar sulcus to increase stability between the polyethylene and the talar component

(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].

T.S. Roukis, DPM, PhD (✉)
Orthopedic Center, Gundersen Health System,
1900 South Avenue, La Crosse, WI 54601, USA
e-mail: tsroukis@gundersenhealth.org

A.F.P. Bartel, DPM, MPH
Gundersen Medical Foundation, 1900 South Avenue,
La Crosse, WI 54601, USA
e-mail: afbartel@gundersenhealth.org

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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).

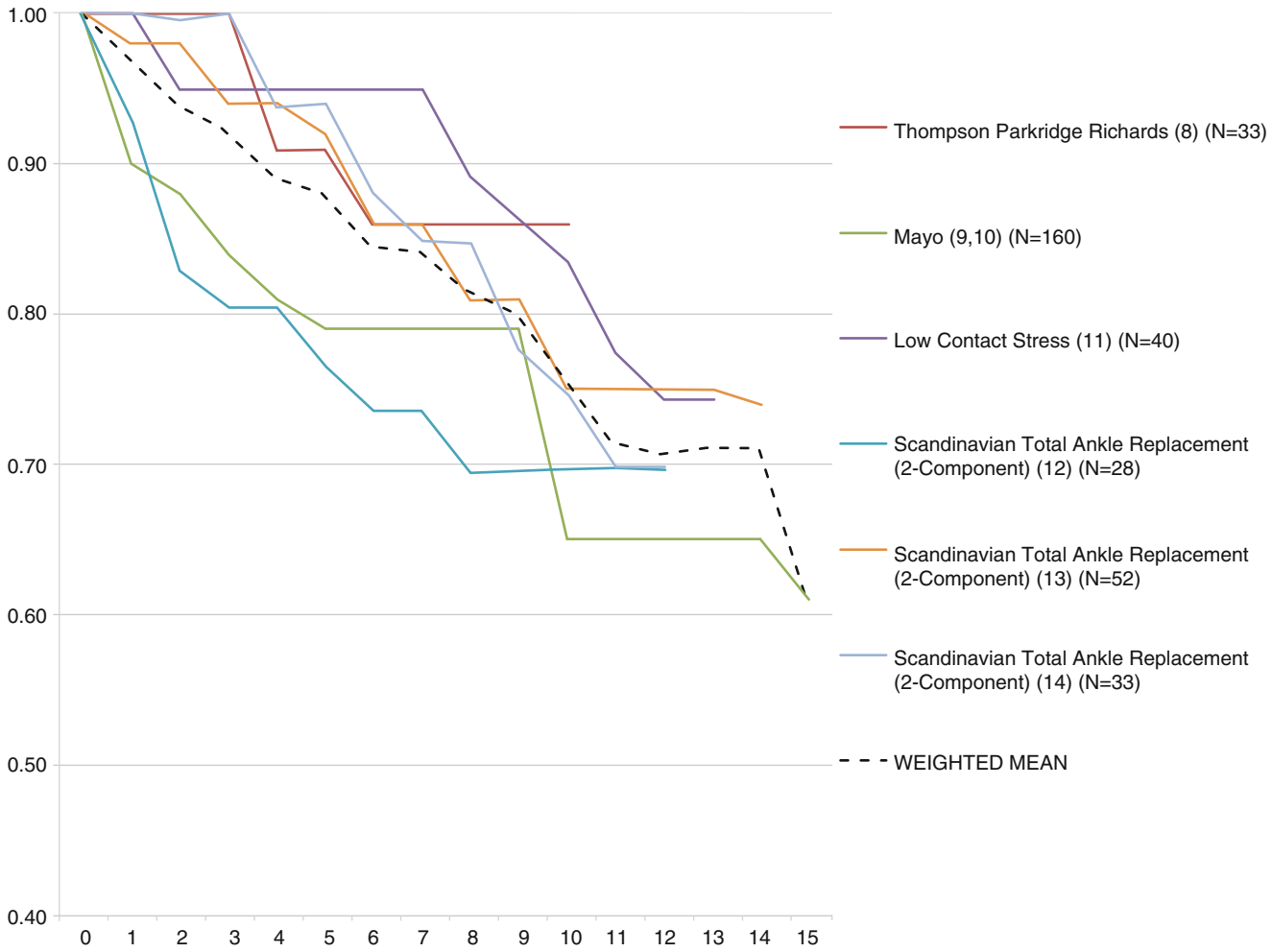

Fig. 2.1 Survival of total ankle replacements based on Kaplan–Meier estimators for first-generation prostheses censored over an 11–15-year follow-up period

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