Design Features of Current Total Ankle Replacements: Implants and Instrumentation

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Abstract

Development of total ankle replacements began nearly 40 years ago. The initial devices were cemented and highly constrained, and they eventually failed. These were followed by second-generation cementless ankle implants with a fixed (two-component design) or mobile (three-component design) polyethylene bearing. Currently, four ankle replacements are approved by the US Food and Drug Administration. These four—Agility, INBONE, Salto-Talaris, and Eclipse—are two-component designs; the Scandinavian Total Ankle Replacement, a three-part mobile-bearing design, has been recommended for approval by the FDA. It is anticipated to arrive in the US market in late 2008. Although interest in total ankle replacements is increasing, midterm clinical results to date are few and often have not been validated by independent practitioners. In addition, no level I or II studies have been published. Therefore, the design rationale for these implants and instruments should be carefully evaluated.

The release of three total ankle replacement (TAR) implants in the United States during the past 3 years marks the beginning of the third phase in the quest to find a successful means of replacement for this small, complex joint. The first phase began in the mid 1970s and ended about 9 years later as a result of the inordinate failure rate of the highly constrained, cemented implants. The second phase started with the introduction in the United States of the Buechel-Pappas Total Ankle Replacement (Endotec, South Orange, NJ) in the early 1980s. During this same period, the Scandinavian Total Ankle Replacement (STAR; Waldemar Link, Hamburg, Germany) became available for use in Europe, although not in the United States. Shortly thereafter, in 1992, the Agility Total Ankle System prosthesis (DePuy, Warsaw, IN) was approved for use in the United States by the FDA.

The third phase began with approval by the FDA of three devices: the INBONE Total Ankle System in 2005 (formerly called Topez, then briefly the Berkeley Total Ankle; INBONE Technologies, Boulder, CO, acquired in March 2006 by Wright Medical Technology, Arlington, TN), the Salto Talaris Anatomic Ankle Prosthesis in 2006 (Tornier, Saint Ismier, France), and the Eclipse total ankle replacement in 2007 (Integra LifeSciences, Plainsboro, NJ). Follow-

ing a 7-year clinical trial, the FDA advisory panel in April 2007 recommended approval of the STAR device.[1] The STAR will be the first meniscal-bearing (ie, three-component) ankle to be made available in the United States outside the original FDA study. With this third phase has come the realization that soft-tissue balance, correction of deformity, patient education related to expectations, and salvage options all are equally important to the success of total ankle arthroplasty. It is hoped that the current phase will contribute to a continuum of improvement in total ankle arthroplasty, ultimately achieving results comparable to those seen with total hip and knee arthroplasties. Other ankle implants have been developed and are in clinical use in Europe and elsewhere, but long-term clinical results will not be known for several years.[2]

Ankle replacements have gained the attention and interest of patients, as well as of surgeons and manufacturers, particularly because gait studies affirm the intuitive belief that total ankle arthroplasty allows patients to approach a normal gait pattern.[3] Current popular ankle arthroplasties (Table 1) have two common features: all are porous-coated for bone ingrowth, and almost all components are made of a titanium alloy with a cobalt-chrome–polyethylene articulation. The sole exception is the TNK[4] (Takakura Nara Kyocera) ceramic component (Kyocera, Kyoto, Japan), used almost exclusively in Japan.

Table 1

Examples of Total Ankle Implants

Device (Manufacturer)	Components	Materials	Fixation
Agility (DePuy, Warsaw, IN)	Two	Tib = titanium Tal = Co-Cr	Central fins
INBONE (Wright Medical Technologies, Arlington, TN)	Two	Titanium Tal = Co-Cr	Tib = IM Stem
Salto Talaris (Tornier, Saint Ismier, France)	Two	Co-Cr	Tib = fin Topped by cylinder Tal = pegs, hollow stem
Eclipse (Integra LifeSciences, Plainsboro, NJ)	Two	Co-Cr	Tib = box Stem Tal = fin
STAR (Waldemar Link, Hamburg, Germany)	Three	Co-Cr	Tib = bars Tal = fin
Mobility (DePuy International, Leeds, UK)	Three	Co-Cr	Tib = stem
Buechel-Pappas (Endotec, South Orange, NJ)	Three	Titanium	Tal = fin
HINTEGRA (Integra LifeSciences)	Three	Co-Cr	Tib = screws Tal = fin
BOX (Finsbury Orthopaedics, Leatherhead, Surrey, UK)	Three	Co-Cr	Tib = bars Tal = pegs

Co-Cr = cobalt-chromium, IM = intramedullary, Tal = talar component, Tib = tibial component

Published Studies

Only a few studies published in the peer-reviewed literature describe the logic and testing that have gone into the design of total ankle prostheses. For this reason, some ankle implants can be described more extensively than others. It is important to understand the difference between fixed- and mobile-bearing ankle implants by explaining the concepts of constraint and conformity as they apply to the bearing surfaces of ankles. Constraint means to limit or restrict; conformity means to correspond in form or character. Two shallow surfaces that are mirror images of each other could have complete conformity with little constraint; these same surfaces, if made much deeper, could have complete conformity as well as great constraint. The optimal design for ankle bearing surfaces is "to maximize conformity and optimize constraint."[5] In other words, the surfaces require high conformity to avoid concentrated points of contact and subsequent wear, yet they must have sufficient constraint to give them stability without transferring the shear stresses to the prosthesis-bone interface. Most mobile-bearing ankle implants attempt to do this by offering two separate, fully conforming articular surfaces, one flat and one curved. Fixed-bearing ankle implants have only one articulating, partially conforming interface, with neither opposing surface fully replicating the normal ankle.

Lewis[6] recently discussed the gaps in the literature regarding what is

Table 2

Known Total Ankle Implants Worldwide*

Device (Manufacturer; Year of Origin)	
Two Components	Three Components
Agility (DePuy/Ace, Warsaw, IN; 1985)	STAR (Waldemar Link, Hamburg, Germany; 1978)
TNK (Kyocera, Kyoto, Japan; 1996)	Buechel-Pappas (Endotec, South Orange, NJ; 1989)
INBONE (Wright Medical Technologies, Arlington, TN; 2005)	Ramses (Fournitures Hospitalieres, Mulhouse, France; 1996)
Salto Talaris (Tornier, Saint Ismier, France; 2006)	Salto (Tornier, Saint Ismier, France; 1997)
Eclipse (Integra LifeSciences, Plainsboro, NJ; 2007)	Eska (Eska Implants GmbH, Lübeck, Germany; 1995)
	AES (Biomet, Dordrecht, The Netherlands, 1996)
	Albatros (Groupe Lepine, Lyon, France; 1995)
	HINTEGRA (Integra LifeSciences/ Newdeal, Lyon, France; 2002)
	Mobility (DePuy International, Leeds, UK; 2005)
	OSG (Corin, Cirencester, UK; 2005)
	BOX (Finsbury Orthopaedics, Leatherhead, Surrey, UK; 2005)
	Taric (Implant Cast, Buxtehude, Germany; 2006)
	Van Straten (Argomedical, Gifhorn, Germany; 2006)
	ARGE (Medizintechnik, Hannover, Germany; N/A)
	AlphaMed Ankle (AlphaMed Medizintech Fisch GmbH, Lassnitzhoehe, Austria; N/A)

* As of March 2008
N/A = not available

known of the design of newer ankle implants and noted the need for future research in several areas. For example, he cites the need for a valid ankle simulator and a set of standardized biomechanical tests. Gill[7] has described the theoretic challenges of designing a TAR and provides eight design goals; some of the goals are difficult to achieve, and others are contradictory. For example, Gill[7] espouses the need for a thick polyethylene liner while recommending minimal bone resection. Both authors[6,7] provide excellent descriptions of second-generation implants, as does Hintermann.[8] Ultimately, a good design requires limited bone resection and a cartilage-like spacer that does not wear out.

Worldwide, 20 TARs are either available or in the final stages of design (Table 2). For a TAR to be used in the United States, FDA approval is required and a 510(k) premarket notification submitted. This requirement dates to 1976, when the federal Food, Drug, and Cosmetic Act was modified and amended.[9] If a current ankle replacement is designed exactly like a TAR that was marketed before 1976, it is called a preamendments device and can be cleared through the 510(k) process as a class II device. (Class II devices require evaluations specific to the device, such as postmarket surveillance and patient registries.[10]) Because two-component, total ankle semiconstrained devices are already available, another device manufacturer could claim one of these as a predicate (ie, a device already on the market), supported by individual preclinical and perhaps clinical data to show that the TAR is safe and effective. Some of the data could rely on information from devices already on the market, extrapolated to the new device because of similarities in design and materials. An example of such an approved device is the DePuy Agility Total Ankle.

For mobile-bearing ankle implants, preamendments status does not apply. A mobile-bearing TAR is considered to be a nonconstrained prosthesis and is classified as a class III prosthesis. Class III devices typically require a randomized controlled clinical trial to be done under an FDA investigational device exemption (IDE), which can be lengthy and costly.

Nearly all TARs are identified in the federal regulations as being cemented prostheses; the sole exception is the STAR, the only ankle replacement recommended for approval without cement. Hence, in the United States, the use of all the other fixed-bearing designs without cement is considered to be an off-label (ie, unapproved) application. Although a physician may choose to use a product off-label with the best interests of the patient in mind, neither the physician nor the manufacturer/distributor can promote the off-label use of a product beyond the conditions of the FDA-approved product label. Custom devices can be used at the physician's discretion. However, it should be noted that a custom device is considered to be "one of a kind." When an exact copy is manu-

factured, the device ceases to fall under the custom devices category.

FDA-approved Ankles

Agility Total Ankle System

The Agility ankle has been extensively described in the literature.[11] Its design is well-known and depends on two unique surgical techniques. The first is an arthrodesis of the syndesmosis just above the ankle joint, which in theory improves the stability of the tibial component by allowing load sharing through the fibula. The second technique is the use of an external fixator for distraction.[12] Distraction is generally continued throughout the procedure until both the tibial and talar components are in place. At that point, the distractor may be removed, although some surgeons remove it earlier to avoid undue stress through the malleoli. The tibiofibular syndesmotic fusion is then prepared through the anterior incision by thorough decortication of the opposing surfaces of the tibia and fibula. Bone graft, obtained from the remnants of bone removed to allow insertion of the metal implants, is inserted into the syndesmosis.

Internal fixation for obtaining a bony tibiofibular synostosis has evolved to the use of a one-third semitubular plate on the fibula and two screws from the fibula through the tibia to provide greater stability.[13] However, the fibula-to-tibia syndesmosis, while increasing the surface area of the superior attachment surface of the ankle, also has led to failure when it does not fuse.[14] The tibial component is designed to be placed in approximately 22° of external rotation, allowing for the natural outward positioning of the transmalleolar axis. It is made from a titanium alloy; the medial and lateral walls sit flush against the cut surfaces of the malleoli. The talar component is semiconstrained, allowing medial and lateral shift beneath the tibial component and the polyethylene insert. The talus is slightly tapered in the medial-lateral direction posteriorly to facilitate insertion.

As with any joint arthroplasty used over a sufficient number of years, the Agility ankle has incorporated changes in design. These largely have affected the talar component, which is now offered with a much broader flared surfaced to capture the cut surface of the talus and resist subsidence. There is also an Agility revision talar component with increased height, as well as a custom talar component with a long calcaneal stem.

INBONE Total Ankle System

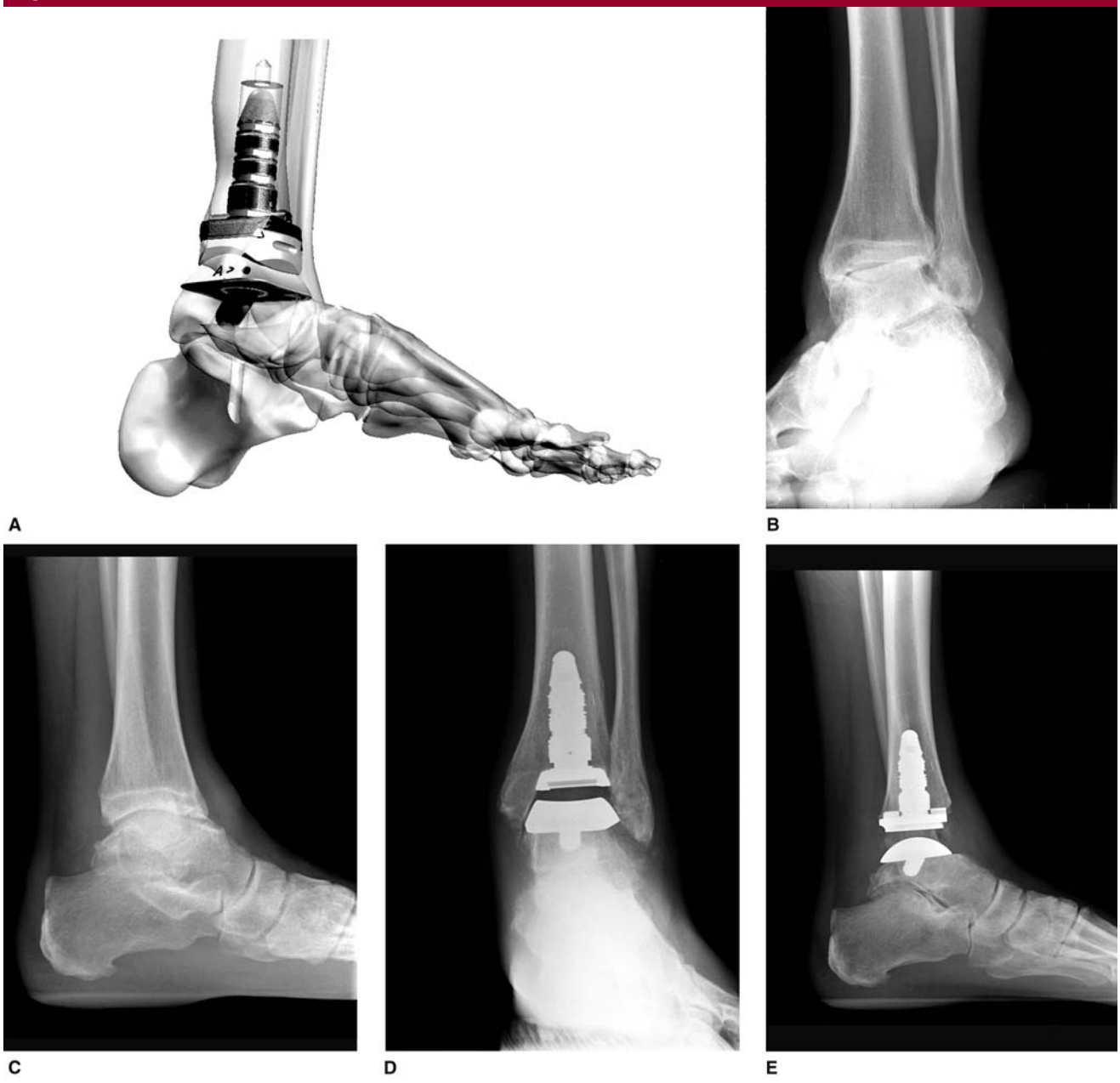
The INBONE Total Ankle System was released by the FDA in November 2005. The design and implantation are based on the developer's experience with total joint arthroplasty, especially total knee replacement.[15] The implant is unique, with a modular multipiece tibial stem (9 mm and 14 mm). Longer talar stems (48, 58, and 66 mm) are not currently FDA approved.[16] The shorter talar stems are used when the subtalar joint retains functional motion (Figure 1). The longer stems are designed for use when no subtalar motion exists, when the joint is already fused, when there has been substantial loss of the talar dome (eg, osteonecrosis, trauma, failed TAR), or when the joint is severely arthritic and a subtalar fusion is part of the planned surgery.

Intramedullary tibial reaming is necessary and is accomplished with the aid of a unique foot holder. This facilitates accurate alignment of guides, allowing plantar insertion of a drill into the calcaneus, which is driven up through the talus and into the tibia. Fluoroscopy is required for this procedure to provide accurate alignment of the drill guide. Only the INBONE Total Ankle System employs such instrumentation.

The tibial stem is composed of segments 12 to 18 mm in diameter, which are threaded together within the resected ankle joint and advanced following intramedullary reaming of the distal tibia. First, a conical top stem is threaded onto one of the middle stems and inserted into the tibia. A third component stem portion is then threaded into the first two. Then a thicker tibial base is screwed onto the first three, followed by the tibial tray, which is impacted onto the tibial stem via a Morse taper. The talar component is then inserted with the short (9-mm) stem. However, if the 14-mm stem or the long calcaneal stems are used (not yet FDA approved), they are inserted first; then the tibial tray is added and impacted onto the longer stem in situ. Finally, the polyethylene insert is inserted onto the tibial tray via an attached compression device.

The design concept is based on having the tibial and talar components supported by large stems, thereby removing load from the bearing components. The polyethylene comes in two thicknesses for each of the five component sizes available. The talar dome has a double saddle design and covers the entire surface of the resected talus. It has 1.5 to 2 times the talar surface of other FDA-approved ankles. Although no revision prostheses are available for the INBONE device, increased polyethylene heights have been provided for potential revisions. However, because of the large-stemmed tibial component, the INBONE provides a basis for the revision of other ankles to the INBONE prosthesis on the tibial side. Similarly, on the talar side, the flat cut of the talus, together with the use of the longer calcaneal stems, offers the possibility of revising other ankles to the INBONE without the need for custom components.

Figure 1

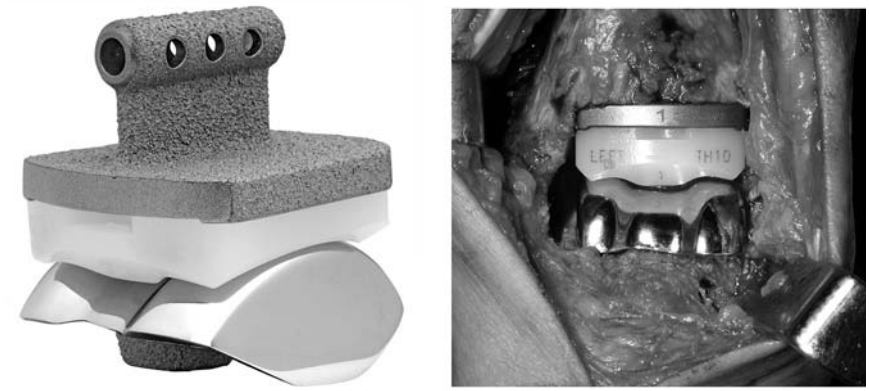


INBONE total ankle implant. **A,** The tibial stem is constructed using an upper conical stem of one or more pieces screwed together. A tibial tray is secured by a Morse taper. All are porous coated. The polyethylene tibial insert and talar dome and stem complete the ankle replacement. (A longer calcaneal stem is also available although not yet approved by the FDA.) Anteroposterior **(B)** and lateral **(C)** standing radiographs of an arthritic left ankle in a 60-year-old man. Anteroposterior **(D)** and lateral **(E)** postoperative standing radiographs after implantation of the INBONE ankle replacement. (Panels A-C courtesy of INBONE Technologies, Boulder, CO.)

Salto Talaris Ankle

The Salto Talaris Anatomic Ankle was approved for use by the FDA in November 2006 (Figure 2). The name is derived from the Italian *salto* ("to jump") and *talaria* ("winged sandals," such as those worn by Hermes, the Greek god of speed and good luck). Its design was based on that of the Salto Total Ankle Prosthesis (Tornier).[17,18] Despite good early results with the Salto, the developers decided to make a fixed-bearing ankle prosthesis. This decision was based on a postoperative radiographic evaluation of 20 Salto

Figure 2



A B

Salto Talaris anatomic ankle implant. **A,** The tibial component has a tapered fixation plug on top of a keel for tibial implantation. The talar component has two distinct radii of curvature (medial and lateral). Only the lateral side is resurfaced, and there is a small hollow fixation plug on the bottom. **B,** Salto Talaris prosthesis implanted at surgery. (Panel A courtesy of Tornier, Saint Ismier, France.)

Figure 3

Eclipse total ankle replacement, side view, demonstrating the upper tibial component with its fixed polyethylene surface. Surfaces are coated with titanium plasma spray. (Courtesy of Integra LifeSciences, Plainsboro, NJ.)

ankles that demonstrated, in 17 patients, no anterior-posterior motion between the polyethylene and the tibial component and, in 3 patients, approximately only 1 mm of motion.

In developing the Salto and the Salto Talaris ankle replacements, the developers improved the design characteristics of both the talar and tibial components by performing detailed three-dimensional measurements of 50 cadaveric ankles. These measurements led to designing the talar component with a conical talar surface with two different radii of curvature. The medial radius was made smaller than the lateral to mimic normal anatomy and to provide for equal tensioning of the collateral ligaments. Only the lateral facet of the talus was replaced. The developers also created a curved groove in the sagittal plane of the talar component, which forces the foot to travel from internal to external rotation with dorsiflexion. Additionally, 4° of rotation was allowed around the center of curvature in the area above the subtalar joint to allow for the usual stiffness of the subtalar joint. A central peg on the talar component is also present for stabilization.

On the tibial side of the Salto Talaris ankle, the design requires fixed insertion of the polyethylene bearing. The polyethylene is slid into the tibial component tray and is therefore replaceable. The tibial side is fixed in the tibia by a tapered pedestal on a thin shaft inserted through an anterior tibial cortical slot and drill hole in the bone. In theory, the instrumentation allows the trial tibial component to rotate into the correct position as determined by the talar component. In practice, the tibial component is sometimes confined so tightly by the malleoli that little if any rotation occurs. At this point, joint stability can be evaluated, and the final positioning of the tibial component determined and implanted. Therefore, the developers believe that, with the improvement in their instrumentation, and seeing little mobility in their mobile-bearing design, a fixed-bearing ankle would give good clinical results.

Eclipse Total Ankle Replacement

The Eclipse TAR was originally developed at Kinetikos Medical (Carlsbad, CA; now Integra LifeSciences). This TAR was approved by the FDA in November 2006 as a class II design[18] (Figure 3). The implant is inserted through either a medial or lateral approach; the medial approach is favored. Currently, only a few implants have been inserted. The bone cuts, guided by extramedullary instruments, are cylindrical and are thought to minimize bone resection while optimizing bone-to-implant interface. The developers of the Eclipse believe that by avoiding an anterior incision, which is required for nearly all TARs, they avoid crossing the angiosome of the anterior skin of the ankle and thereby hope to avoid postoperative skin complications.

Because the Eclipse ankle can be placed from either the medial or the lateral side, there is no need for a distractor. Six sizes are offered. The polyethylene bearing and the talar components are geometrically designed and thus are asymmetric for left and right versions. The components are partially modular, and three thicknesses of polyethylene are available. Potential problems include malleolar fixation, length of time to union, and possible delayed union or nonunion of the

Figure 4

STAR total ankle prosthesis, front view, demonstrating the cobalt-chromium talar component, with plasma spray, and the talar fin for stability. The polyethylene component features a groove to fit the matching talar crest. The flat tibial component has two cylindrical bars for initial fixation.

Figure 5

Mobility Total Ankle System. The (upper) tibial component features a short conical intramedullary stem. The polyethylene mobile bearing has an upper surface that is smaller than the flat tibial plate. The (lower) talar component has fins for fixation. (Courtesy of P. Rippstein, MD, Zurich, Switzerland.)

malleoli. Although the Eclipse has been approved for use by the FDA and inserted by a few surgeons, the date of release to all surgeons is unknown.

Scandinavian Total Ankle Replacement

The STAR device was originally a two-component, anatomic, unconstrained resurfacing ankle prosthesis; in 1986, it was redesigned as a three-component ankle (Figure 4). The polyethylene meniscus was added to minimize rotational stress forces at the implant-bone interface, thereby allowing only compressive forces and, it was hoped, a reduced rate of loosening. Since 1990, the STAR has been implanted with a porous-ingrowth titanium spray for cementless implantation. The current implant has been well-described in the literature.[2,19,20] In theory, the stability of the ankle is provided by its anatomic shape and the ankle ligaments.

Two anatomic factors influenced the implant design. First, the blood supply to the dome of the talus is most important because the pattern of the vessels is that they meet at the center of the talar body. Thus, a central talus fin was placed for fixation. Second, only the distal 1.5 cm of the tibia was considered to have sufficient bone strength to support an implant. To preserve this bone, the tibial component is fixed with two 6.5-mm cylindrical bars.

The talar component of the STAR is symmetrically cylindrically shaped, with medial and lateral wings to support the medial and lateral facets of the talus. However, if these metal sides impinge on the bone, then a smaller STAR talar component is necessary.[21] On the talar dome is a crest that corresponds to a groove in the polyethylene meniscus; this crest is used for medial and lateral stabilization and to keep the polyethylene from extruding anteriorly or posteriorly.

The tibial component is flat and is wider anteriorly than posteriorly. For fixation, its two parallel bars are inserted into solid subchondral bone in the distal tibia. Every effort is made to keep the distal tibial bone resection as minimal as possible. The surgical technique stresses that the tibial implant must rest on cortical bone both anteriorly and posteriorly. The polyethylene meniscus is congruent with both metal components. The meniscus is square and does not impinge on the malleoli during rotation against the tibial glide plate. Although the meniscus is allowed free rotation on the tibial glide plate, in practice, it rotates only a few degrees. Fortunately, the incidence of bearing luxation and fracture has been minimal.[22] The STAR was recommended for approval by the FDA advisory panel after a 7-year clinical trial but is still not available for general use.[23]

Mobility Ankle Replacement

The Mobility Total Ankle System (DePuy International, Leeds, UK) (Figure 5) is currently undergoing a double-blind clinical FDA study (Agility versus Mobility). Thus, DePuy (Warsaw, IN) and the members of the clinical evaluation team are prohibited from releasing any information about this ankle replacement. However, the implant has been used since November 2005 elsewhere throughout the world.

The Mobility tibial component has a flat plate that is sufficiently long to provide both posterior and anterior cortical support. It has a short conical intramedullary stem on the tibial component that requires creating an anterior cortical tibial window for insertion. The talar component is cylindrical. After resecting a minimal thickness of talar dome, it is press-fit into three prepared grooves on the talus. The meniscal-bearing insert has fully

congruent surfaces with the flat tibial plate and with a deep sulcus along the middle of the talar component, making it semiconstrained. The polyethylene is narrower superiorly to avoid contact with the edges of the tibial plate, thereby preventing edge loading and reducing wear. The instruments are designed to position the components so that the polyethylene moves minimally on the tibial plate; most of the motion occurs between the meniscus and the talar component.

The instrumentation depends on external alignment and has been developed to ensure accurate positioning of the tibial component over the talar component in the coronal and sagittal planes. The goal is to place the tibial stem in the center of the distal tibia, and then to prepare the talus to be aligned relative to the center of the tibial component and over the center of the talus. Bone grafts can be placed around the tibial stem if slight translation is required. The tibial stem aligns the component in the anterior-posterior direction; the talar component aligns the component in the medial-lateral direction.

Differences between the Mobility and Buechel-Pappas ankles include the fact that the Mobility has a smaller tibial stem. The Buechel-Pappas stems are larger with each successively larger size of tibial component. Also, the proximal part of the Mobility meniscus-bearing component tapers superiorly, and that of the Buechel-Pappas does not. Both ankles, however, carefully replace the resected anterior tibial cortical window that is removed for implanting the tibial stem. Although some believe that this weakens the anterior tibia, reports of fracture, malunion, or loosening are rare.

Other Ankles

Buechel-Pappas Total Ankle Replacement

The Buechel-Pappas Total Ankle Replacement was designed initially in 1989 and manufactured by Endotec. The current implant is a modification of the original mobile-bearing prosthesis.[2,5,8,24] The modification includes a deeper talar sulcus to contain the meniscal-bearing component, an additional talar fixation fin, and a thicker tibial component to avoid fracture. The tibial component is fixed by a central stem implanted through an anterior cortical window in the distal tibia. The tibial stems increase in size with the successively increasing size of the tibial component. The cortical bone is preserved and replaced following implanting of the tibial component.

The talar component is cylindrical and only resurfaces the dome of the talus; it does not resect the medial and lateral facets. This requires removal of minimal amounts of bone. The talar component is stabilized by two porous-coated fins. The polyethylene bearing is congruent to both surfaces. The upper surface is flat; the lower surface conforms to the talar dome, with a longitudinal central sulcus providing control of medial-lateral translation and preventing dislocation. The sulcus also provides some inversion and eversion without producing edge loading. The current status of the Buechel-Pappas Total Ankle Replacement is an incomplete FDA IDE application because of loss of follow-up data. Without the IDE application, the implant cannot proceed to market release.

The Salto Ankle

The Salto (Tornier) ankle prosthesis has been in clinical use in Europe since January 1997. As with most other European ankle devices, the design of the Salto was based on meniscal-bearing cementless implants.[17] The tibial component was designed to articulate with the superior flat surface of the mobile polyethylene bearing. The talar component replicated the anatomy of the talar surface, with the lateral side of the talus covered by the component, which can articulate against the lateral malleolus either directly or through a seldom-used resurfacing fibular component. The polyethylene mobile bearing articulates between the two metal components, maintaining full congruency with the talar component in flexion and extension and allowing as much as 4° of varus and valgus movement in the coronal plane. The tibial component that comes in contact with the tibia appears to be the same as that of the Salto Talaris ankle, having a keel with a tapered fixation plug. The Salto ankle continues to be used in France. Changes in implant design can be made only at certain times based on government regulations, and that period has not been reached.

HINTEGRA Ankle

The HINTEGRA Total Ankle Prosthesis (Figure 6) is manufactured by Newdeal (Lyon, France; now Integra LifeSciences). The ankle is a nonconstrained three-component implant that provides inversion-eversion stability. The axial rotation and flexion-extension movement are provided by a mobile-bearing polyethylene meniscus.[2,8,25]

The tibial component is flat, with a 4° posterior inclination angle approximating the normal distal tibial articulating surface. It has an anterior shield that allows for fixation by two screws (not commonly used) through oval holes placed to mitigate stress shielding. Thus, some settling of the component-bearing porous ingrowth is possible. Only 2 to 3 mm of subchondral bone needs to be resected. The anterior shield also may prevent adherence of scar tissue, which could restrict motion.

The talar component of the HINTEGRA ankle is conically shaped, like that of the Salto, with a smaller radius medially than laterally. An anterior metal shield also allows for placement of two screws for fixation, although these no longer are used by its designer. There are

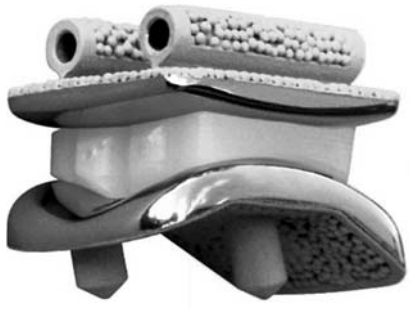
Figure 6

HINTEGRA total ankle prosthesis. The upper tibial component has pyramidal peaks on the flat surface and an anterior metal shield with two oval holes for screw fixation. The design features a mobile bearing insert, a talar component with medial and lateral wings, and 2.5-mm medial and lateral rims that stabilize the polyethylene insert. Two pegs stabilize the talar component (not shown). (Courtesy of Integra LifeSciences, Plainsboro, NJ.)

two wings, one medial and one lateral, with the inner, slightly curved surface of the wings allowing a press-fit into the talus. An additional feature of the talar component is 2.5-mm rims on both sides, which ensure stability while allowing anterior-posterior translation of the polyethylene on the talar surface.

The high-density mobile-bearing polyethylene component has a flat surface on the tibial side and a concave surface inferiorly, with full conformity to the talar surface. It is 5 to 9 mm thick, and the superior surface is smaller than the tibial surface to prevent impingement on either malleolus. It is restrained by the compressive actions of the collateral ligaments and adjacent tissue and by the medial and lateral rims. Since 2004, two short, posteriorly directed

Figure 7



BOX total ankle replacement. The upper tibial component has a slight convex surface and two bars for fixation. The mobile bearing polyethylene component features fully congruent surfaces. The lower talar component has two pegs for fixation. (Courtesy of Finsbury Orthopaedics, Leatherhead, Surrey, UK.)

porous-coated pegs have been added to facilitate insertion of the talar component, provide additional stability, and prevent the talar component from sliding too posteriorly while being press-fitted.

The BOX Total Ankle Replacement

BOX is an acronym for Bologna and Oxford, the two cities where the implant was developed (Figure 7). Although the tibial design of the BOX (Finsbury Orthopaedics, Leatherhead, Surrey, UK) at first appears to mimic that of the STAR, the talar component, instrumentation, and surgical technique differ sufficiently from those of other TARs that its design merits consideration. The surgical approach is also different, being anterolateral between the peroneus tertius and the extensor digitorum communis tendons. The dome of the talus is resected first, using external alignment guides. After resection of the dome of the talus, the alignment guide can internally tension the ankle.

The BOX is a three-component prosthesis developed after considerable biomechanical research.[2,26-30] It is designed to restore some subtalar motion, thus allowing physiologic rotation of the ankle complex in the transverse (internal-external rotation) and frontal (inversion-eversion) planes. Studies in unloaded conditions have shown that ankle motion occurs mostly in the sagittal plane, which has 1 degree of freedom, with very little motion at the subtalar joint. The models of the developers[27] suggest that physiologic motion is guided by the nearly isometric rotation of distinct fibers within the calcaneofibular ligament on the lateral side and fibers within the tibiocalcaneal part of the deltoid ligament. These fibers rotate isometrically about their origins and insertion, while other fibers of these ligaments are slack throughout the flexion arc, except at the extremes of dorsiflexion or plantar flexion. There is minimal constraint between the articular surfaces, thus enabling the soft tissues to control physiologic motion at the ankle. Therefore, the patient's ankle must have ligamentous stability or it must be achieved during ankle implantation.

The tibial component is different in that its surface is a slightly convex segment of a sphere rather than a flat surface, as is seen on all other three-component ankles. The radius of curvature for the arc in the sagittal plane is replicated for the arc in the frontal plane. The upper surface of the talar component is saddle-shaped, with a circular convex arc in the sagittal plane and a concave middle groove in the frontal plane. The radius of the talar arc is in the sagittal plane, but it is different from the radius of the arc of the tibial component and is calculated to be compatible with the isometric rotation of the ankle ligaments. The sagittal arc is slightly larger posteriorly because plantar flexion motion is expected to be greater than that of dorsiflexion. The component is narrower posteriorly than anteriorly. Fixation is achieved through two parallel cylindrical bars for the tibial component

and two pegs for the talar component.

The polyethylene meniscal-bearing component is designed with concave upper and lower surfaces that are fully congruent with the tibial and talar components, irrespective of joint position. The developers believe that, because fully congruent meniscal bearings have shown very low wear rates in the knee, a thick polyethylene meniscus is unnecessary. Therefore, the thickness of the central part of the component varies in 1-mm steps from 5 to 8 mm. The meniscus slides backward on the tibial component during plantar flexion and forward during dorsiflexion. It is stabilized by the biconvex shape of the tibial component and by the groove running anteroposterior across the dome of the talar component. The BOX designers[27] believe that this is the only three-component ankle implant that can allow natural joint movement to be replicated without significant distortion of the ligaments and capsule. At the same time, large contact areas are maintained throughout the arc of motion. The inventors believe that the fundamental difference between their design and other three-component ankles is that, with theirs, no constraints are imposed to reproduce the anatomic shapes of the natural articular surfaces. The minimum overall thickness of the prosthesis (11 to 12 mm in all three sizes) is within the range of the current three- and two-component ankles.

Discussion and Summary

In the history of TARS, a number of implants have been developed or are in development; some have never been used clinically.[30] The STAR and Buechel-Pappas ankles are widely used abroad, and the Mobility, Salto, and BOX, among others, are increasingly being distributed worldwide. All of these are three-component, meniscal-bearing ankle replacements. Although more than 600 STARs have been inserted in the United States by IDE investigators, the only ankle implants currently fully approved for use in this country are two-component designs. Clinical results at the midterm level and beyond are still too few in number for the TARs that have been used for a decade or more and often have not been validated by independent practitioners.[31]

Guidelines for determining whether to perform a TAR and for choosing a specific implant remain unsettled. The number of arthritic ankles is fewer compared with hips and knees and possibly even shoulders. Yet patients who are aware of the good results of hip and knee arthroplasty are seeking similar results with ankle arthroplasty: pain relief without sacrificing motion as a result of ankle fusion. Surgeons who perform TARs routinely do approximately 50 to 70 ankles annually. Therefore, it is unlikely that every foot and ankle specialist will have a sufficient patient load to become proficient at TAR. Furthermore, TAR has more stringent contraindications compared with the hip and knee, where arthrodesis is now rarely if ever performed. In addition, because of the infrequency of the procedure, TAR may not have been performed in many hospitals for several years, meaning that operating room personnel will need assistance in preparing for and assisting with these surgeries.

The process of selecting an ankle implant is likely similar to that which occurred in the early stages of hip and knee replacement. In time, one design may eventually dominate the others. However, few long- or even mid-term results exist to offer guidance. Those that are available are often written by the device designers, who have an inherent bias. All of this means that, in choosing an ankle replacement, one must consider the background and reputation of the device developers, the biomechanical principles and anatomic considerations of the ankle, and the short-term results published in the literature. Available support from the designers and manufacturers will be important. Furthermore, just as total hips and total knees require revision at an increasing rate,[32] consideration must be given to the revision capability of ankle replacements. Too few designs currently available have little more than an increased thickness of the polyethylene liner available for revision cases.

Finally, hospital-based value analysis committees are resistant to allowing TARs to be performed. Frequently these entities cite inadequate reimbursement as a reason. Also, insurance companies call the procedure "unproven technology" or "investigational." Nonetheless, in the United States, the two largest third-party payers, Medicare and Kaiser, do indeed reimburse for TAR. Therefore, despite unresolved issues, TAR likely is here to stay, and with design improvements, it is hoped that we will eventually have ankle replacements that rival those for hips and knees for longevity and excellence.

References

Evidence-based Medicine: There are no published level I or II studies. All of the references are level III, IV, or V.

Citation numbers printed in **bold type** indicate references published within the past 5 years.

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