Total Ankle Replacement Systems Available in the United States

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Abstract
Ankle replacement continues to be a viable option for treating patients with ankle arthritis. Over the past 10 years, there has been a significant increase in the number of ankle replacement systems available for use. Current controversy centers on whether fixed- or mobile-bearing devices are most advantageous. Most total ankle systems used outside the United States are mobile-bearing devices, whereas ankle replacement systems used in the United States are all essentially fixed-bearing devices.

Not all ankles with degenerative changes are amenable to replacement surgery, and several exclusion criteria are well documented. Ankle replacement is especially complicated because of the ankle’s proximity to the foot and the important role that the balance and alignment of the foot play in the success of the ankle replacement. Foot deformities should be treated before or at the time of ankle replacement surgery. Ignoring foot deformities can lead to failure of the ankle replacement.

It is also of paramount importance to consider the stability of the ankle ligaments. An unstable ankle with a varus or valgus deformity of more than 20° is probably not amenable to ankle replacement. There are currently no reliable options to predictably reconstruct the lateral or medial ligaments in these severe deformities.

It is important to be aware of the ankle replacement systems currently available in the United States and understand the key features of each design. Devices approved by the US Food and Drug Administration, a device that is awaiting approval, and a device that is being evaluated by the Food and Drug Administration in a prospective randomized clinical trial are discussed, along with an objective comparison of fixed- and mobile-bearing devices.


Ankle replacements are becoming a mainstream treatment option for patients with ankle arthritis. Currently, there are 23 different ankle replacement systems in existence worldwide; the proliferation of ankle replacement designs may result in even wider use in the future.

Conflicting reports exist regarding improved midterm and longer term outcomes of second-generation ankle implants compared with the first-generation ankle implants used in the 1970s. Recent studies also describe potential complications with total ankle replacement surgery. Orthopaedic surgeons should be knowledgeable about the various systems available, should be aware of the pitfalls of ankle replacement surgery, and should know how to treat challenging ankle disorders, especially those involving varus and valgus deformities. The greater the varus or valgus deformity, the more difficult is the ankle replacement procedure, and the less predictable is the outcome.

Range of Motion
Several important factors should be considered when discussing...
potential ankle replacement surgery with a patient. Generally, the eventual postoperative range of motion (ROM) is largely determined by the preoperative ROM. On average, there is only a 5° improvement in the preoperative ROM. This relatively small improvement is believed to result from the significant role that the soft-tissue envelope around the ankle has in ROM. For example, a patient with a severe pilon fracture treated with multiple surgeries will usually have a very stiff, rigid soft-tissue envelope compared with a patient with idiopathic degenerative joint disease and no prior surgeries.

**Foot Alignment**

A stable plantigrade foot is essential to successful ankle replacement. A cavus foot is common in patients with varus ankle deformities, and a planovalgus foot is common in those with valgus deformities. Chronic posterior tibial tendon dysfunction is common in patients with secondary foot deformities associated with a valgus ankle. In patients with varus ankles, the peroneal tendons may be compromised. Failure to treat these disorders will compromise the long-term outcome of the ankle replacement. Preoperative radiographs to diagnose cavovarus and planovalgus feet should include weight-bearing images. The lateral ankle view, in particular, should include the entire foot.

**Varus and Valgus Deformities**

As surgeons gain experience in total ankle arthroplasty, there is a tendency to attempt treatment of more complex deformities, including varus and valgus ankles. The difficulty in treating these deformities should never be underestimated. Occasionally, a varus or valgus deformity will result from pure bony erosion, but in many instances there will be an element of ligamentous imbalance and, often, elements of both erosion and imbalance. If the imbalance is not corrected at the time of surgery, the life span of the implant will be compromised.

**Varus Ankles**

As previously mentioned, both foot and ankle alignment should be treated before ankle replacement surgery. A supramalleolar deformity may be present; however, in some patients, hindfoot varus requires correction. After all the extra-articular deformities are treated, the surgeon can concentrate on the ankle. Not all varus ankles result from the same etiology. A varus deformity can result from bone erosion alone or a combination of bone erosion and lateral instability, or it may be caused primarily by ligamentous instability.

Alvine developed a useful classification system to quantify varus deformities, with stages ranging for those with minimal deformity (stage 1) to severe instability and secondary deformities (stage 3). A simple Broström ligament repair is never sufficient to correct instability as part of an ankle replacement procedure. Other treatment options include the use of a split or complete peroneus brevis tendon in an anatomic reconstruction, anatomic allograft reconstruction, or nonanatomic repair using allograft or peroneus brevis tendon. Stage 1 varus deformity can usually be corrected with a lateral ligament repair alone. Stage 3 deformities usually require subtalar fusion and other procedures prior to ankle replacement. Patients with stage 3 deformities are not candidates for routine ankle replacements.

In ankles with stage 2 varus deformity, the medial malleolus is often eroded, and there is shortening and contracture of the deltoid ligament, medial capsule, and tibialis posterior tendon sheath. There is often a large buildup of osteophytes in the lateral gutter, specifically the lateral side of the talus. Bone overgrowth in the gutters should be removed to allow rotation of the talus back into the mortise. The osteophytes are removed from the lateral talus and medial mortise. If it is still not possible to rotate the talus back into place, it can be assumed that the medial structures are tight. The deep deltoid is released from the talus by sliding an osteotome or knife down the medial border of the talus until the entire deep portion is released. It is advisable not to release the entire deltoid because it may leave the medial complex completely unstable.

An alternative to a deltoid release is a medial malleolar distal sliding osteotomy. Distal displacement of the medial malleolus creates functional lengthening of the deltoid without destabilizing the deltoid. Alternatively, the peristium above the deltoid can be lifted off the tibia and the entire deltoid peeled off the medial malleolus, thus leaving it intact as a continuous sleeve (similar to the technique used on the medial collateral ligament in a varus knee replacement).

After the ankle joint is mobile and passively correctable to neutral in the ankle mortise, hindfoot alignment is evaluated. If there is a tendency to a varus deformity below the ankle, a lateralizing or lateral closing wedge calcaneal osteotomy should be done to improve the mechanical axis of the ankle and subsequent lateral ligament repair. If there is a true calcaneus varus, a lateral
Valgus Instability

Ankles with valgus instability can be even more difficult to balance than varus ankles. In mild to moderate deformities, treatment can include a medializing calcaneal osteotomy, posterior tibial tendon repair and augmentation with flexor digitorum longus, and gastrocnemius slide and medial ray stabilization if indicated. Because there is no reliable local tissue to repair or reconstruct the deltoid ligament, reconstruction with nonnative tissue is needed. A double strand allograft deltoid reconstruction has been proposed as the best option.

Inclusion and Exclusion Criteria for Total Ankle Replacement

There are no uniform inclusion and exclusion criteria to determine if total ankle replacement is the most appropriate treatment. The choice is based on the patient's preference after receiving consultation and recommendations from the treating surgeon. Some guidelines can help the surgeon in making the appropriate treatment recommendations. Total ankle replacement is indicated in patients who are older than 50 years, have a body mass index less than 35, have advanced degenerative joint disease, or have advanced rheumatoid arthritis. Total ankle replacement is not recommended for patients with diabetes, especially insulin-dependent diabetes with no pulses; those with talar osteonecrosis that is not resectable at the time of arthroplasty; and patients with neurologic deficits resulting in motor loss of ankle muscles or sensory impairment of the foot and ankle. It also is contraindicated in patients with significant vascular insufficiency, inadequate skin or soft-tissue quality that would prevent reliable wound closure and healing, and those with ligamentous instability with more than 20° varus or valgus that could be difficult to correct.

Background on Implant Designs

For approximately 10 years, the two-piece, fixed-bearing, Agility Total Ankle (DePuy Orthopaedics, Warsaw, IN) was the only ankle approved by the Food and Drug Administration (FDA) for use in the United States. Outside this country, essentially all the ankle replacement systems are three-piece designs with no objective data to support the superiority of either type of device.

In addition to the Agility ankle prosthesis, there are other fixed-bearing devices that have FDA approval or that are seeking FDA approval for implantation in the United States (Table 1). The Scandinavian Total Ankle Replacement (STAR; Small Bone Innovations, Morrisville, PA) is a mobile-bearing ankle that is awaiting final approval from the FDA. The Mobility ankle (DePuy) is currently being used in an FDA prospective randomized clinical trial in an attempt to gain approval.

Two-Component Designs

Agility Total Ankle System

Two-component ankle prosthesis designs differ dramatically from each other (Figure 1). The Agility Total Ankle was designed by Alvine and has been in use longer (since 1984) than any other total ankle replacement system in the United States. The basic design includes six sizes of matching tibial and talar components. The titanium alloy tibial component has an ingrowth surface that simultaneously rests on the tibia and inner sides of the medial malleolus and fibula. Proper positioning requires resection of the...
articular surfaces of both malleoli to place the metal against cancellous bone. This procedure necessitates fusion of the syndesmosis, which has proven to be both an asset and a pitfall. The fusion allows a larger area of bone for ingrowth but also results in a possible complication (nonunion of the syndesmosis) that is unique to the Agility Ankle and can lead to a higher failure rate for the prosthesis. The largest study of the Agility Total Ankle included more than 300 ankles and showed a revision rate of 28% (for all reasons) and an overall 5-year implant survival rate of 80%.11

The dome of the talus is removed and replaced with a cobalt-chromium dome component. The redesigned (Agility LP) talar component provides a wider base that covers the entire cut surface of the talus to prevent subsidence of the talar component. The Agility LP has a front-loading insert instead of the previous bottom-loading system, which greatly simplifies exchange of the insert and also provides a better locking mechanism. Standard revision components are available for the talar and polyethylene components. The revision talus has a larger true rectangular base and a 2-mm greater vertical thickness. The new Agility LP talar component has largely replaced the older Agility revision talar component and is the preferred revision component for Agility Ankles. The Agility LP talar component can be used in only a limited number of ankle prostheses revision procedures because some prostheses require custom talar components.

The polyethylene component has half columns on the side; this allows replacement of the polyethylene without removing the tibial component. A thicker polyethylene revision component (2 mm) also is available. These components may be used to increase the total height of the revision prosthesis by 4 mm. More extensive revision components are available on a custom basis and include stemmed talar and tibial components. Motion is constrained by the implant’s articulating surfaces and the periankle ligaments.
tation between the components. The hole for the pedestal is then created. In practice, however, there is usually very little and sometimes no motion of the tibial component, which is wedged between the malleoli.

As previously mentioned, the reason for the change from a mobile-bearing to a fixed-bearing design was to permit an easier and more cost-effective introduction of the prosthesis into the US market. At present, there is no independent study that compares fixed- versus mobile-bearing ankle designs. A study by the manufacturer supported the two-component design over the three-component design after radiographic analysis showed that the free-floating polyethylene component moved only 1 mm in 3 of 20 ankle specimens. In the other 17 specimens, the polyethylene spacer was locked in place by heterotopic bone. The study did not provide information on how long it took for the polyethylene component to lock in place or if the initial motion of the polyethylene component was important in determining its final position. A more recent study comparing the translational and rotational motion between components of the Salto implant showed that the rotational motion played a more dominant role in the kinematics of the prosthesis.

It is possible that the mobile bearing is only mobile for a limited period of time until scarring occurs around the bearing. It is not clear how important this initial mobility is in obtaining the most suitable relationship of the tibial and talar components.

INBONE Total Ankle System
The INBONE total ankle system (Wright Medical Technologies, Arlington, TN) differs from the previously described ankle replacement systems (Figure 3). For implantation, the system requires immobilization of the leg in a holder with pin fixation. After correct positioning is assured with multiple fluoroscopic views, a hole (approximately 6 mm) is drilled in the plantar surface of the calcaneus, through the talus, and into the tibia. The tibia is reamed by a special reamer that is placed onto the rod inside the ankle and driven upward into the tibia. The talar stem hole is then drilled. The cylindrical tibial components (usually four components are used but more are needed if a longer stem is desired) are inserted one by one and screwed into each other, followed by the tibial tray, the stemmed talar component, and the polyethylene component.

The INBONE total ankle system does not resurface either side of the talus. A long calcaneal talar stem is available on a custom basis. At early follow-up, one of the authors and his coworkers at Duke University with extensive experience with the INBONE ankle reported a 5% rate of significant complications in more than 150 total ankle replacements. Significant complications included medial malleolar fractures (2%), serious wound problems requiring flaps in two ankles, and deep infection in three ankles (which required amputation in two patients). Minor wound problems also occurred in eight patients. (J DeOrio, MD, unpublished data).

Three-Component Mobile-Bearing Designs
The three-component ankle replacement systems with a mobile polyethylene component along with the names of their manufacturers are shown in Table 2. The ankle replacement systems share both similarities and differences. All incisions for ankle replacement surgery are made into the anterior aspect of the ankle, except for the ESKA Ankle, which is inserted from the lateral side and requires a fibular osteotomy, and the Eclipse, which can be inserted through either a medial or lateral approach. The choice of ankle replacement often depends on the surgeon's preference and experience.

Mobility Total Ankle System
The Mobility Total Ankle System was developed by a design team of surgeons in collaboration with the manufacturer (Figure 4). Although the Mobility Total Ankle was first implanted in September 2003 in Wrightington, England, it became commercially available in October.
Data from 200 cases with 1-year follow-up showed that pain, measured with a visual analog scale, ranged from a preoperative mean score of 8.1 to a postoperative mean score of 1.4 (PL Wood, P Rippstein, unpublished data presented at the EFORT meeting, Nice, France, 2008). Postoperative complications included two patients with delayed wound healing, one with deep infection (the patient underwent an arthroscopic débridement and had antibiotic therapy for 6 months with the prosthesis in place), two patients with stress fractures in the medial malleolus, and two with aseptic loosening of the tibial component at 6 months from an unknown cause.

### Scandinavian Total Ankle Replacement

The STAR is the prototypic, three-component, ankle replacement design (Figure 5). It was created by Kofod in 1981 as a smooth, two-component, cemented design. The design was changed over time and has evolved into a three-component, meniscal-bearing (mobile-bearing) ingrowth design. The tibial component is a trapezoidal tray (wider in the front) and has two cylinders with ridges to secure it to the bone. The talar component is a symmetric convex partial cylinder that is the average width of the medial malleolus, and two with aseptic loosening of the tibial component at 6 months from an unknown cause.

### Table 2

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<thead>
<tr>
<th>Implant</th>
<th>Manufacturer (Name and Location)</th>
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<tbody>
<tr>
<td>Scandinavian Total Ankle Replacement (STAR)</td>
<td>Small Bone Innovations (Morrisville, PA)</td>
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<tr>
<td>Buechel-Pappas Total Ankle System</td>
<td>Endotec (South Orange, NJ)</td>
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<tr>
<td>ESKA Ankle</td>
<td>ESKA Implants (Lübeck, Germany)</td>
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<tr>
<td>HINTEGRA Total Ankle Prosthesis</td>
<td>Newdeal France and International (Lyon, France)</td>
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<tr>
<td>Salto Total Ankle Prosthesis</td>
<td>Tornier (Stafford, TX)</td>
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<tr>
<td>BOX Total Ankle Replacement</td>
<td>Finsbury Orthopaedics (Leatherhead, England)</td>
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<tr>
<td>Mobility</td>
<td>DePuy Orthopaedics (Warsaw, IN)</td>
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<tr>
<td>Corin Ankle Replacement</td>
<td>Corin Group PLC (Cirencester, England)</td>
</tr>
<tr>
<td>Albatros</td>
<td>Groupe Lepine (Lyon, France)</td>
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<tr>
<td>Ramses</td>
<td>Maîtrise Orthopédiqute (Paris, France)</td>
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<tr>
<td>Ankle Evolution System</td>
<td>Biomet (Dordrecht, The Netherlands)</td>
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<tr>
<td>CCI Evolution</td>
<td>Van Straten Medical (Amsterdam, The Netherlands)</td>
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<tr>
<td>TARIC Ankle Joint Prosthesis</td>
<td>Implantcast (Buxtehude, Germany)</td>
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<tr>
<td>Alphamed Orthner</td>
<td>Alphamed Medizintechnik Fischer (Lassnitzhöhe, Austria)</td>
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<tr>
<td>German Ankle System</td>
<td>Arge Medizintechnik (Hannovera, Germany)</td>
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2004. Five hundred forty Mobility Total Ankle Systems were implanted in 2005, and 970 and 1,200 were implanted in 2006 and 2007, respectively. The device has been approved for general use in most of the world, including Europe, Australia, New Zealand, South Africa, and Canada. An FDA study for approval in the United States began in 2006. The Mobility is a three-component, cementless, unconstrained, mobile-bearing prosthesis. It features a short conical stem on the tibial component. It has a long plate that provides primary fixation to the tibia and allows rotational adjustment of the tibial component. The polyethylene insert has fully conforming congruent surfaces, and the talar component has a resurfacing three-plane contact area with the talus, a deep talar sulcus, and short and deep anterior talar fins. The metal that lies adjacent to the bone has a spray coating of titanium.
dial and lateral radii. The talar dome curves and has two sides that articulate with the malleoli. The talar component has a fin that inserts into the talus and a protruding central dorsal extension that fits into a high-density polyethylene congruent spacer. The spacer is concave on the bottom and articulates with the domed talar component. It is flat on the top and glides on the flat tibial component. The cobalt-chromium metal surfaces have a titanium spray coating for bony ingrowth. A hydroxyapatite coating also can be applied. The talus is available in five sizes, and the tibial component is available in 30- to 45-mm lengths (5-mm increments) with little change in the width. The polyethylene component is 6 to 10 mm thick (sized in 1-mm increments).

A stemmed revision component for the tibia is available, and thicker polyethylene revision components are available (11- to 15-mm thickness, 1-mm increments). Implantation of this system in 200 ankles with a mean follow-up of 46 months (range, 24 to 101 months) showed a 5-year implant survival rate of 93%. A second surgery (for any reason) was performed in 20 ankles.14

Summary

Direct comparison of the outcomes of ankle replacement systems is difficult, not only because of the relatively small number of cases but also because of the difficulty of doing prospective randomized studies with different ankle systems. A current ongoing FDA randomized clinical trial using the Agility Total Ankle and the Mobility Total Ankle system will provide an opportunity to compare mobile- and fixed-bearing designs.

Because of the long, steep learning curve required for all ankle replacement procedures, it is believed that few surgeons are willing or treat enough patients needing ankle replacement to warrant the use of multiple systems. There are unanswered questions regarding the need for resurfacing the sides of the talus, the use of fixed- versus mobile-bearing devices, the best surgical approach, the need for coating components to improve bone ingrowth, and the best revision options if the primary replacement fails.

Edge loading of the polyethylene is also a concern because it may cause wear, leading to osteolysis. Newer designs such as the Mobility Total Ankle system have an upward sloping polyethylene component to decrease the chance of polyethylene contact with the edge of the tibial component. A conforming two-component design has greater inherent stability; however, it is unknown if polyethylene wear or the mobile-bearing design more frequently leads to osteolysis.

The initial fixation of components is important because it allows ingrowth of bone into metal. Thus, components with increased metal-bone interface (for example, those with stemmed components) may be more stable and allow more rapid bony ingrowth than systems that have a lower metal-bone interface.

Ankle replacement procedures will never become as prevalent as hip and knee replacement procedures. Even though ankle replacement is a more complex procedure and fewer ankles require replacement, it is still important for orthopaedic surgeons to be aware of available total ankle replacement systems.

References


**Video Reference**

