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Total Ankle Replacement: Where Do We Stand?

David I. Pedowitz, MD, MS[1]
Keith L. Wapner, MD[1]

[1] Pennsylvania Orthopaedic Foot and Ankle Surgeons, Philadelphia, PA 19106

Total ankle replacement is a viable option for patients with disabling tibiotalar arthritis as an alternative to arthrodesis. There is cautious optimism that with meticulous attention to surgical technique, refined instrumentation, and continued scrutiny in the literature regarding mid and long-term follow up, ankle arthroplasty will enjoy the longevity as that seen with hip and knee replacement. This review examines the rationale for reconsidering this procedure in the United States after disappointing results in the 1970's and 80's.

With a nine-times lower incidence of symptomatic arthritis, the ankle joint enjoys a unique biologic resilience to the degenerative process that routinely plagues the hip and knee articulations[1-3].The reason for this discrepancy is not fully understood and seems counterintuitive, especially since when similar loads are applied, the ankle contact stresses (focused forces on one articular area) are much larger than those found in the hip and knee. Nonetheless, the tibiotalar joint is still susceptible to arthropathy, mostly in the form of post-traumatic arthritis.

Ankle fusion has historically been presumed to be the gold standard procedure for end stage symptomatic tibiotalar arthritis. Accordingly, ample evidence exists demonstrating that ankle arthrodesis provides reliable relief of pain and high degree of patient satisfaction[4-6]. On the other hand, early experience in the United States with total ankle replacement (TAR) was met with unacceptable failure and complication rates in the 1970's and 80's such that the procedure was largely abandoned. Consternation therefore exists within the general orthopedic community as to why ankle arthroplasty has seen a "new-found" interest within the past decade.

While it is difficult to pinpoint the exact etiology, the early failure of total ankle replacement in this country is thought to have resulted from the use of highly constrained cemented implants with poor sensitivity to managing the fragile soft tissue envelope around the ankle. Starting in the 1990's, two implant designs (Buechel-Pappas TAR, Endotec, South Orange, NJ and Agility TAR, DePuy Orthopedics, Warsaw IN) approved in the US demonstrated some encouraging early and midterm results. The steep learning curve with these implants and idiosyncratic instrumentation, however, still made ankle arthroplasty a technically difficult procedure with unproven long-term results.

Two occurrences over the past decade have changed the landscape for the treatment of ankle arthritis. The first is that more recent evaluations of the long term results following successful early ankle fusion have brought to light somewhat disappointing long-term satisfaction rates and the development of advanced symptomatic hindfoot arthritis in many patients[7-8]. Additionally, a recent meta-analysis brought into question the advisability of considering arthrodesis a "gold standard" procedure when there was a 9% revision and 5% below-the-knee amputation rate[9]. The second is the evolution of total ankle implant design to more bone sparing press-fit (non-cemented) components with extensive sizing options, refinement of surgical technique with the anterior approach, and the development of more accurate ankle instrumentation which appears to have facilitated more consistent and reproducible implantation.

Approximately twenty total ankle prostheses are currently in development or in use throughout the world with unique design parameters ranging from those requiring a medial or lateral approach, to those which are comprised of ceramic tibial and talar components[10]. Generally, most prostheses used today are implanted without cement and are either a two (fixed) or three piece (mobile-bearing) design. This general review will only address implants approved by the US Food and Drug Administration (FDA) for unrestricted use in the United States at the time of publication.

At the time of writing this manuscript, five novel designs are approved for use by the FDA: the Agility (DePuy, Warsaw IN), the Scandinavian Total Ankle Replacement, or STAR (Small Bone Innovations, Morrisville PA), In-Bone Ankle Replacement (Wright Medical Technology, Arlington TN), Salto-Tolaris Total Ankle (Tornier, Stafford TX), and the Eclipse Total Ankle (Integra Life Sciences, Plainsboro NJ). All of these five designs have two common features: their press fit surfaces are all porous-coated to enhance bony in-growth, and the components are made of a titanium alloy with a cobalt-chrome–polyethylene articulation[6]. A few other prostheses are being evaluated by the FDA and are currently being used by selected surgeons under a variety of investigational exemptions, but are not presently available for widespread

Corresponding Author:
David I. Pedowtiz, MD, MS
Pennsylvania Orthopaedic Foot and Ankle Surgeons
Farm Journal Building, 5th floor
230 W. Washington Square
Philadelphia, PA 19106
drpedowitz@yahoo.com

use (Mobility, DePuy, Warsaw IN; Hintegra, Newdeal, Lyon, France; and the Buechel-Pappas)[10].

The indications for TAR are still under investigation, since long term data on many implants remains pending. Nonetheless, relative indications include low-demand individuals with end-stage idiopathic, post traumatic, or inflammatory arthritis with minimal fixed deformity. Contraindications are still debated within the foot and ankle community but generally include Charcot neuropathy, current infection, severe fixed deformity, younger active patients, inadequate soft tissue envelope, marked ankle instability, and talar osteonecrosis. Smoking remains an absolute contraindication in some surgeons' practices due to its contribution to problems with wound healing and osteointegration at the bone implant interface.

Brief Results and Details

Agility

The Agility is the prosthesis which most American surgeons are most acquainted with and requires two unique technical aspects: it involves distraction of the ankle joint for insertion and relies on syndesmotic fusion for increased stability and load sharing. The Agility is a fixed bearing two-piece implant (Figure 1). Intermediate to long-term results suggest that this prosthesis facilitates decreased pain and patient satisfaction in over 90% of patients[11]. While the revision rate in this study was >10%, that parallels revision rates often seen following ankle fusion[5]. Long-term survivorship data for this specific implant design is difficult to interpret due to the numerous changes the implant and its instrumentation have undergone, such that earlier implants are no longer comparable to later ones. Nonetheless, the Agility appears to provide good pain relief and function in the hands of most surgeons.

STAR

The STAR is a three-piece uncemented mobile bearing prosthesis which was recently approved by the FDA for widespread use (Figure 2). It is the only three-piece design available in the US. The design rationale is that a mobile bearing dissipates translational, rotational and shear forces such that these biomechanical forces are assuaged at the bone-implant interface. There is extensive data supporting the use of the STAR from European centers but, until recently, no data from the US. A recent prospective non-randomized multi-centered study evaluated the safety and efficacy of the STAR compared to a control group of ankle fusion patients. This study was performed for FDA approval. By 24 months, ankles treated with STAR ankle replacement had superior function and equivalent pain relief as ankles treated with fusion[12]. Long-term results of survivorship have yet to be published but (via personal communication with authors) appear to be greater than 90% at 10 years.

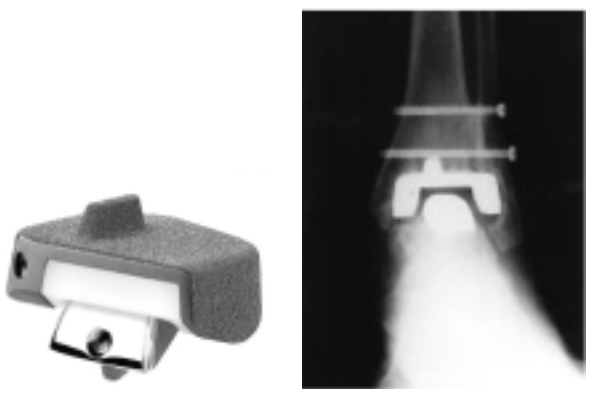

Figure 1. The Agility.

Figure 2. The STAR.

In-Bone

The In-Bone TAR is a modular prosthesis which has stems that extend from both the tibial and talar components into their respective bones (Figure 3). A longer talar stem exists for concomitant subtalar stabilization. Philosophically, the design concept is that large stems into the talus and tibia allow for more stress shielding of the subchondral bone and bearing surfaces themselves. Since no revision specific TARs exist, the In-Bone prosthesis is thought by many to be a very good option for other implants which have failed due to its modularity and the ability to use much larger polyethylene inserts when additional bony resection is required. While many surgeons report good personal results with this prosthesis, peer-reviewed published data on intermediate results is not available.

Salto-Tolaris

The Salto-Tolaris TAR is a two-piece implant based on the three-part Salto TAR developed in France (Figure 4). The Salto has an anatomic talar component with varying radii of curvature between the medial and lateral talar domes. The tibial component has a central peg to prevent rotation. With encouraging midterm results with the Salto, the prosthesis was brought to the United States in 2006 as a fixed-bearing device[13]. The reasons for this appear to be two-fold: firstly, radiographic evaluation suggests that only a little motion between the three components exists, and secondly, approval of a three-piece design would have required a lengthy prospective FDA trial[14]. The developers have instead added a step during implantation that attempts to find the center of rotation for the specific patient's ankle and then orients the tibial component based on this trialing. Since this implant has only been used since 2006, there is no available data on its performance.

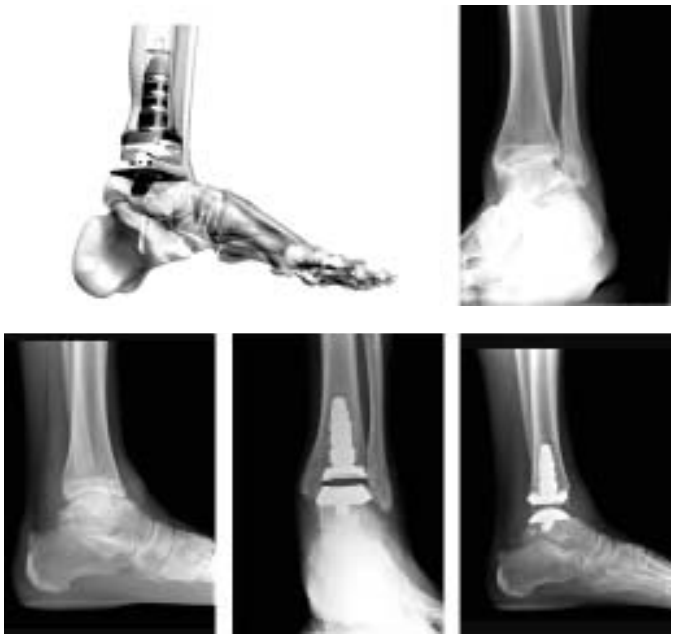

Figure 3. The In-Bone.

Figure 4. The Salto-Tolaris.

Eclipse

The Eclipse prosthesis is a two-piece design implanted from a medial or lateral approach (Figure 5). By avoiding the anterior approach, developers of this prosthesis suggest that one can implant a total ankle through a relatively safe angiosome resulting in much fewer devastating wound complications[10]. Drawbacks include the need for malleolar fixation and the limited experience with this implant in the United States. No published data on the Eclipse is available.

Conclusion

Total ankle replacement is a viable alternative to ankle fusion in many patients with disabling tibiotalar arthritis. It remains to be seen whether or not ankle arthroplasty will ever reach the widespread use and longevity that has been seen with hip and knee replacement. As more foot and ankle trained orthopedic surgeons collaborate and report mid- and long-term results with these newer designs, the orthopedic community will have more data on which to council patients on this new technology. Notwithstanding the lower prevalence of ankle arthritis in the US population, ankle fusion and arthroplasty remain reasonable options for many patients, but both have well-known limitations.

Figure 5. The Eclipse.

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