Total Ankle Arthroplasty

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Abstract

Although ankle arthrodesis has been considered the gold standard for treatment of symptomatic end stage arthritis, recent improvements in arthroplasty designs and instrumentation have led to a resurgence in interest in ankle arthroplasty. While first generation arthroplasty systems had high failure rates due to cemented techniques or highly constrained designs, newer generations of ankle replacements have introduced more anatomic and press-fit techniques. Early results have been promising, with improved functional outcomes versus ankle arthrodesis. However, complication rates are still substantial, and the procedure should be restricted to properly indicated patients. Long-term follow-up studies are necessary, but total ankle arthroplasty has become a viable option for surgical treatment of ankle arthritis.

While most orthopaedic surgeons are well equipped to evaluate and treat patients with end-stage hip or knee arthritis, the management of patients with ankle arthritis represents a challenge to both general orthopaedists and to the foot and ankle surgeons to whom these patients are often referred. Although techniques for both hip and knee arthroplasty have evolved to provide long-term pain relief and functional improvement, neither ankle arthrodesis nor arthroplasty has demonstrated comparably favorable outcomes in long-term follow-up studies. Early ankle arthroplasty designs with highly constrained cemented components were abandoned due to unacceptably high failure rates and complications. While arthrodesis is still considered the “gold standard” for treatment of end-stage ankle arthritis, progression of adjacent joint arthrosis and diminished gait efficiency has led to a resurgence of interest in ankle arthroplasty.1,2

Anatomy and Biomechanics

The ankle, or tibiotalar joint, is primarily a rolling articulation with high congruence. Ankle stability is afforded by the bony anatomy, ligaments, joint capsule, and the muscles and tendons that cross the joint. Due to the obliquity of the ankle joint (the fibula lies posterior relative to the medial malleolus), the ankle externally rotates approximately 6° with dorsiflexion and internally rotates 1° with plantar flexion.3 In another cadaveric study, Kimizuka and colleagues4 found mean ankle range of motion to include 14.7° of dorsiflexion, 28.2° of plantar flexion, 13.8° of inversion, and 5.0° of eversion. Furthermore, the talus, which is wider anteriorly, allows for more rotatory motion when in a plantar-flexed position. With dorsiflexion, the anterior aspect of the talus is wedged within the mortise and results in a more stable configuration.

When compared to the other weightbearing joints of the lower extremity, the ankle has significantly less contact area than the hip or knee: 350 mm² versus 1100 mm² for the hip and 1200 mm² for the knee under 500N of load.5 While the knee is subjected to forces estimated at 3 times body weight,6 the ankle is subjected to 5.5 times body weight with normal ambulation.7 In contrast to the articular cartilage of the knee, which ranges from 1 mm to 6 mm,7 the ankle articular surface is uniformly thinner, ranging...
from 1 mm to 1.7 mm in thickness.7

Tibio-Talar Arthritis
Without injury to the articular cartilage of the tibial plafond or talus, alteration in mechanical alignment, or ligamentous instability, the human ankle is an efficient and resilient joint that is less frequently affected by degenerative changes when compared to the hip or knee.

Ankle arthritis is often described with respect to the Kellgren scale (Table 1), which is graded from I to IV. Grade I represents minor osteophytic lipping, while grade IV demonstrates end-stage changes, with severe joint space narrowing, sclerosis, and change in bony contour.

While the exact prevalence of ankle arthritis is difficult to quantify, approximately 6% to 13% of all cases of osteoarthritis (OA) involve the ankle.8 With respect to surgical treatment for end-stage arthritis, total knee arthroplasty is performed 24 times more frequently than ankle arthroplasty and arthrodesis combined.9

In a recent review of 639 patients with severe ankle arthritis,10 70% of cases were of posttraumatic etiology. Thirty-seven percent of these patients had sustained a rotational ankle fracture, 14.6% had recurrent ankle instability, and 13.7% had a single ankle sprain with continued pain. Less common causes were tibial plafond fracture (9.0%), tibial fractures (8.5%), talar fractures (8.3%), and talar osteochondritis dissecans lesions (4.7%).11 Rheumatoid arthritis (11.9%), primary OA (no other causes identified, 7.2%), and neuropathic (4.9%) arthritis accounted for most of the remaining patients. Of the 46 patients with “primary” ankle OA, 23 (50%) had significant concomitant hindfoot mal-alignment. Therefore, only 3.6% (23) of the 639 patients had true “primary” OA: a statistic that attests to the ankle joint’s ability to withstand many decades of mechanical stress.

In accord with previous estimates, 7.5% of patients evaluated over a 1-year period for Kellgren grade 3 or 4 had ankle involvement versus 66.4% for knee, and 26.1% for hip. Additionally, as testament to the younger age group affected, the mean age of patients with posttraumatic ankle arthritis was 51.5 years. In comparison, primary arthritis patients were 16 years older on average (67.2 years).

While the incidence of severe ankle arthritis is clearly less than either the hip or knee, the effects of symptomatic end-stage ankle arthritis on patient quality of life is significant. In a multi-center study comparing 130 patients with end-stage hip arthritis versus 130 patients with end-stage ankle arthritis, SF-36 scores for both groups were substantially lower than that for the population mean, by approximately two standard deviations. Both groups had equally profound impairment in physical and mental components of the SF-36. Most patients in this study had extreme difficulty walking 100 yards or navigating one flight of steps. The investigators note that while total hip arthroplasty has allowed for predictable relief for patients with hip arthritis, the optimal treatment for ankle arthritis, whether arthrodesis or arthroplasty, is still unclear.11

Management
In the early stages of ankle arthritis, nonoperative management can provide relief for patients. Non-steroidal anti-inflammatory drugs, corticosteroid injections, ankle-foot-orthoses, rocker-bottom shoes with solid ankle cushion heel (SACH), and a simple lace-up ankle support brace can all provide symptomatic relief. In addition, weight-loss and life-style modification may also benefit ankle arthritis patients.

Less invasive surgical techniques, including ankle arthroscopy and debridement and ankle distraction with an external fixator, can provide temporary relief.12-14 However, both modalities have limitations. Arthroscopic debridement is not recommended for patients with advanced arthritis, significant joint-space narrowing, marked fibrosis, or mechanical deformity.13,14 Articular distraction, a procedure involving gradual joint distraction of 5 mm following arthroscopic debridement and external fixation application for 6 to 12 weeks, has been shown to improve pain, function, and clinical results.12 Maximal clinical and radiographic improvement (up to 27% increase in joint space) took approximately 3 years. However, these positive results have not been replicated and the technique has not gained widespread acceptance.15

Short-term results from fresh osteochondral allograft ankle replacement have revealed good pain relief and maintenance of motion.16 However, issues with possible immune reactions and lack of long-term follow-up studies have limited the use of allograft arthroplasty in clinical use.

Ankle arthrodesis, widely considered the gold standard

Table 1 Kellgren-Lawrence Arthritis Grading Scale*

<table>
<thead>
<tr>
<th>Grade</th>
<th>Characteristics</th>
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<tbody>
<tr>
<td>I</td>
<td>Doubtful joint space narrowing, possible osteophytic lipping</td>
</tr>
<tr>
<td>II</td>
<td>Definite osteophytes, definite joint space narrowing</td>
</tr>
<tr>
<td>III</td>
<td>Moderate multiple osteophytes, definite joint space narrowing, some sclerosis and possible deformity of bone contour</td>
</tr>
<tr>
<td>IV</td>
<td>Large osteophytes, marked joint space narrowing, severe sclerosis and deformity of bone contour</td>
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treatment for ankle arthritis, is not without its drawbacks. Although it is a good pain-relieving option for a painful and stiff ankle, ankle arthrodesis negatively affects gait, with marked impairment in velocity. Waters and coworkers\(^2\) reported a 16% decrease in gait velocity, 3% increase in oxygen consumption, and 10% decrease in gait efficiency after ankle fusion. Furthermore, in order to accommodate for lack of motion at the ankle joint, increased motion at adjacent tarsal joints leads to progressive and predictable degeneration of these articulations. In a long-term follow-up study of 23 patients evaluated over an average of 22 years after tibiotalar arthrodesis, Coester and associates\(^1\) demonstrated progressive degenerative changes (Kellgren grade 4 or 5) of ipsilateral subtalar (91%), talonavicular (57%), and tarsometatarsal (41%) joints. The progressive arthritis in these joints led to ipsilateral foot pain and limitations in ambulation and activities of daily living.

Ankle arthroplasty has been advocated for patients with end-stage tibiotalar arthritis, although the specific indications are not clearly defined by present literature.\(^17\) While it seems the ideal candidate for ankle arthroplasty would be a thin, older individual with a painful ankle and preserved range of motion, a low-demand lifestyle, and possibly pre-existing hindfoot arthritis, there are no studies confirming better results in this theoretic cohort. As pre-operative range of motion best predicts postoperative range of motion, patients should be advised that the average increase in tibio-talar range of motion has been shown to be limited, approximately 5° in published studies.\(^16\) Therefore, patients with less than 10° of ankle range of motion may have more predictable results with arthrodesis.\(^18\)

The contraindications to total ankle arthroplasty have been more clearly delineated by literature documenting numerous clinical failures of previous and current total ankle designs. Absolute contraindications include active infection, vascular compromise, avascular necrosis of the talus, and significant peripheral neuropathy. Relative contraindications include previous infection, ligamentous instability, subluxation of the talus, and mechanical malalignment.\(^17\) A 2010 publication noted a 28% wound complication rate after total ankle replacement and isolated smoking, peripheral vascular disease, and cardiovascular disease as increasing this risk.\(^19\) The exact parameters regarding these contraindications are again, poorly supported by the literature and are left largely to the discretion of the surgeon.

### Ankle Arthroplasty: Historical Perspective

In 1970, the first total ankle arthroplasty reported in orthopaedic literature was performed by Lord in France.\(^20\) The cemented, highly constrained design with a long-stem tibial component led to 12/25 clinical failures at 10-years follow-up. The procedure was abandoned by this group in favor of ankle arthrodesis.\(^21\)

Since Lord’s initial report, more than 20 total ankle arthroplasty systems have been introduced. Many early designs had similar flaws; they required excessive tibial and talar bone resection, failed to appreciate the importance of intraoperative soft tissue balancing, and had inadequate instrumentation that led to poor implant positioning.\(^22\)

While many investigators reported early success with these first-generation implants, the results consistently deteriorated with extended follow-up. This trend is illustrated through review of the literature published regarding the Mayo Clinic Total Ankle. A 39-month follow-up study of 15 Mayo Clinic Total Ankle patients described seven excellent and eight good outcomes, as defined by the Boston Children’s Hospital ankle score system. This scoring system assigned a maximum of 50 points for pain relief, 40 for function, and 10 for ankle range of motion. However, in this same study, the investigators reported

### Table 2  FDA Approved Total Ankle Arthroplasty Systems*

<table>
<thead>
<tr>
<th>System and Manufacturer</th>
<th>Date of FDA Approval</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agility (DePuy, Warsaw, IN)</td>
<td>Dec 1992</td>
<td>Requires syndesmotic arthrodesis, semi-constrained talar component</td>
</tr>
<tr>
<td>INBONE™ (Wright Medical, Arlington, TN)</td>
<td>Nov 2005</td>
<td>Modular tibial stem, intramedullary instrumentation-alignment</td>
</tr>
<tr>
<td>Salto Talaris (Tornier, Saint Ismier, France)</td>
<td>Nov 2006</td>
<td>Conical talar component: medial radius of curvature greater than lateral</td>
</tr>
<tr>
<td>Eclipse (Integra Life-sciences, Plainsboro, NJ)</td>
<td>Nov 2006</td>
<td>Medial approach for insertion, cylindrical cuts for tibia-talus</td>
</tr>
<tr>
<td>STAR™ (Waldemar Link, Hamburg, Germany)</td>
<td>May 2009</td>
<td>Only approved 3-component system, tibial fixation with two 6.5 mm cylindrical bars</td>
</tr>
<tr>
<td>Mobility (DePuy International, Leeds, UK)</td>
<td>Pending</td>
<td>3-component design, anterior window for tibial stem, in clinical trials vs Agility</td>
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a 73% (11/15) rate of radiolucencies, a 40% (6/15) rate of component migration, and an 87% (13/15) rate of moderate to severe arthritic changes in adjacent tarsal joints.23 This same cohort of patients was followed by Unger and colleagues24 for an additional 3 years. While 83% of these patients had “satisfactory” clinical results (2 excellent, 7 good, 8 fair to poor), the radiographic results were uniformly poor. Ninety-three percent (14/15) of talar components demonstrated migration and settling, 93% (14/15) had radioloucencies adjacent to the tibial components, and 80% (12/15) of tibial components tilted postoperatively. Finally, in 1996, a study published at The Mayo Clinic described their 9-year follow-up study of 160 Mayo Clinic ankle arthroplasties.25 The vast majority of patients in their study had ankle arthritis from either rheumatoid arthritis (60%) or a posttraumatic etiology (35%). Fifty-seven of 160 arthroplasties (36%) resulted in clinical failures, defined as removal of the implant. Fifty ankles required subsequent fusion, with two patients requiring below the knee amputation. Of the 101 ankles with adequate radiographs, the most common cause of failure was talar component loosening, present in 57% (58/101) of ankles. In conclusion, they recommended against the use of total ankle arthroplasty with a constrained Mayo implant for rheumatoid arthritis or OA of the ankle.

**Current Ankle Arthroplasty Designs**

As a result of clinical failures of multiple cemented, highly constrained devices, implant design has evolved to allow for press-fit insertion, limited bone resection, as well as less constrained components. The second generation implants (Agility™, Salto-Talaris, INBONE™, Eclipse) are two-component systems with a polyethylene bearing surface incorporated into the talar or tibial component (Fig 1).

In contrast, the third-generation designs incorporate a third component: an independent polyethylene component, the mobile-bearing meniscus. The STAR™ (Scandinavian Total Ankle Replacement, Waldemar Link Hamburg, Germany) was recently approved by the Food and Drug Administration (FDA) as the first meniscal-bearing ankle for use in the United States, although it has been in clinical use throughout Europe since 1981 (Fig. 2).26

There are presently five arthroplasty designs that are FDA approved for implantation plus one system in final clinical trials in the USA. The INBONE™ Total Ankle System (Wright Medical Technologies, Arlington Tennessee), the Salto Talaris Anatomic Ankle (Tornier, Saint Ismier, France), and the Eclipse Total Ankle Replacement (Integra LifeSciences Corp., Plainsboro, New Jersey) have all been approved for less than 4 years. The Mobility Total Ankle System (DePuy International, Leeds, United Kingdom) is currently involved in a double-blind FDA study versus the Agility™ Total Ankle System. Due to the lack of published data supporting the survivorship and clinical outcomes for these four systems in the USA, it is difficult to determine their future significance. Each of the systems has unique characteristics which are summarized in Table 2.27

The Agility™ Total Ankle System, developed by Alvine, was first introduced in the USA in 1984.28 This two-
component system uses a cobalt-chrome, porous-coated talar component and a titanium-backed, polyethylene tibial component. Its most distinctive and clinically important characteristic is its dependence on syndesmotic arthrodesis to provide support and surface area for fixation of the tibial component. In addition, the talar component, which is undersized relative to the tibial component, allows for a semi-constrained design, whereby the talus is afforded medial-lateral motion beneath the polyethylene surface of the tibial component. The tibial component incorporates 22° of external rotation, replicating natural external rotation with dorsiflexion.

The INBONE™ total ankle replacement system was designed by Reiley and was approved by the FDA in November 2005. This implant is unique in that it utilizes intramedullary alignment-instrumentation and modular titanium tibial and talar stems. This theoretically facilitates better fixation in poor tibial bone, as well as talo-calcaneal fixation for revision cases (not approved in the USA).27

The Salto-Talaris total ankle is a modified fixed-bearing version of the three-component system used in Europe. Elimination of the mobile bearing polyethylene allowed for FDA approval in the USA; proper rotational positioning of the tibial-polyethylene component is instead achieved during trial reduction of the implant.27

The STAR™ was introduced by Hakon Kofoed in Copenhagen, Denmark in 1981. In contrast to the Agility™, the syndesmosis and fibula are maintained, and there is significantly less bone resection. The tibial and talar components are 100 µm hydroxyapatite coated cobalt-chromium alloy, and the unconstrained meniscal component is made of ultra-high-molecular weight polyethylene. It is believed that this additional rotational freedom may reduce joint reactive forces for the tibial and talar components. However, the mobile bearing design does introduce the possibility of meniscal subluxation or dislocation.26

Operative Technique

The vast majority of ankle arthroplasty systems utilize an anterior approach to the ankle, via the interval between tibialis anterior and extensor hallucis longus. The goal of surgery is to restore mechanical alignment to the ankle. Ultimately, this is achieved by alignment guides that allow for precise cuts of the tibia, talus, and in some systems the fibula. In addition, the recent iterations of total ankle arthroplasty systems have incorporated ligamentous balancing as a crucial part of the operative procedure. For example, pre-operative varus tilting of the talus may predict the need for lateral ligament reconstruction and potentially deltoid ligament release. In contrast, insufficiency of the deltoid ligament represents another relative contraindication for ankle arthroplasty, as a reliable technique for deltoid reconstruction has not been described.18 Gastrocnemius recession or percutaneous Achilles tendon release also can be performed to allow 5° of ankle dorsiflexion, thereby equalizing forces applied to the components in the sagittal plane. Distinguishing technical features of selected systems are briefly described below

For the Agility™ system, unique characteristics of the surgical technique include use of an external fixator to provide distraction and correction of alignment during implantation, as well as dependence upon syndesmotic arthrodesis for tibial component fixation.26 Implantation of this implant requires significant bone resection; approximately 5 to 6 mm of bone is resected from the distal tibia, as well as an additional 5 to 6 mm from the talar dome. The syndesmosis is addressed through a separate anterolateral incision. The syndesmotic ligaments are incised, and cortical surfaces are resected to allow for optimal fusion. Resected tibio-talar bone is placed as autograft to facilitate syndesmotic arthrodesis. The technique has evolved to use a one-third tubular plate to provide fixation, as Meyerson and coworkers29 demonstrated that plate fixation affords earlier consolidation, more predictable arthrodesis, and decreased radiolucency at 5 to 7 months postoperatively when compared to screw fixation. To allow for syndesmotic fusion, the patient is made non-weightbearing for 6 weeks.

The INBONE™ system is the only system that utilizes intramedullary alignment and instrumentation during the implantation of the components.27 A specially designed foot holder-targeting device allows for precise positioning of the components under radiographic imaging on anteroposterior and lateral views. The intramedullary canal of the tibia is reamed by inserting reamers onto the end of a driver that is passed retrograde through the calcaneus, talus, and tibia. The modular tibial stem components are assembled within the tibio-talar resection and the base-plate is captured via a Morse taper. A broad, flat cut is performed on the talus, and a modular stem of various lengths can be impacted onto the talar component. This modularity can accommodate revision situations, including concurrent subtalar fusion once the long-stem component is approved.27

As the only FDA approved third-generation implant, the STAR™ resurfaces the talar dome and hemi-resurfaces the medial and lateral facets of the talus and does not depend on syndesmotic arthrodesis for tibial component fixation. In addition, there is significantly less bony resection versus with the Agility™, and it uses a mobile bearing polyethylene “meniscus” between the tibial and talar components. Extra-medullary alignment is utilized, and chamfer cuts for the talar component allow for more surfaces for bony ingrowth, thereby adding theoretic fixation strength.30

Outcomes

Of the approved total ankle systems, only the Agility™ and STAR™ have published studies documenting mid to long-term outcome studies in the USA.

Agility™

In 1998, Alvine published his initial review of 100 consecutive total ankle arthroplasties performed between 1985 and
The majority of his patients (52%) had posttraumatic OA, while 22% were secondary to rheumatoid arthritis. Eighty-five ankles were followed for a mean follow-up of 4.8 years. Overall, the patients reported good relief of their ankle pain. Fifty-five percent had no pain, and an additional 28% had pain rated 1 to 3 on an analog scale. There was a statistically significant difference in pain relief depending on etiology: 76% of RA patients were pain free versus 40% for posttraumatic OA. The mean postoperative AOFAS hindfoot score was 85 for the study group. There was no observed progression of arthritis in the adjacent tarsal joints. Overall, there was a 5.9% rate of major revision during the study period.

Many of the reported complications were attributed to issues with the syndesmotic fusion. Twenty-nine percent of patients had delayed union (defined as more than 6 months), while 9% had nonunion of the syndesmosis. There was a direct association of tibial loosening with time to fusion for the syndesmosis, while none of the talar loosening was associated with syndesmotic nonunion. Fifty-six percent (5/9) of ankles that exhibited syndesmotic nonunion had tibial loosening, while 11% (3/28) of delayed-union patients had tibial loosening. In comparison, only 4 of 61 patients with successful syndesmotic fusion had tibial loosening. Alvine concluded that syndesmotic nonunion led to an 8.5-times increased risk of tibial component migration. Additionally, there was no relationship between age, weight, or pre-operative diagnosis to rates of osteolysis, lucency, or migration of the components; 79% of his patients were extremely satisfied, and 13% were satisfied with the results from total ankle arthroplasty.

In 2004, Alvine published continued follow-up of his initial 100 cases plus an additional 32 cases. At a mean follow-up of 7.2 years, there was an 11% rate of major revision and 24% rate of minor secondary operations. Of the 14 major revisions, seven resulted in arthrodesis, and seven underwent revision ankle arthroplasty.

With this extended follow-up, there was a 76% rate of lucency evident on radiographs and a 15% rate of expansile lysis. Problems with syndesmotic fusion were also significant: 41% with delayed union, 8% with nonunion. The average time to syndesmotic fusion was 10 months for all patients. There was a 19% rate of progressive subtalar arthrosis, and a 15% rate of talonavicular arthrosis. Despite these complications, patient-reported outcomes were consistently positive: 73% had no pain or only occasional pain, 94% had decreased pain, 92% were satisfied with the outcome, 94% would have the operation again, and 97% would recommend the operation to a friend.

Kofoed published his initial results with the STAR™ system in 2004. He followed 25 patients with cemented components as well as 33 patients with uncemented components for a mean of 9.4 years. He demonstrated significantly superior results in the uncemented group with respect to implant survivorship, clinical foot scores, and rate of radiographic lucency or subsidence. The Kofoed score, which consists of 100 possible points, assigns 50 points for pain relief, 30 for the ability to perform activities of daily living, and 20 points for mobility and absence of deformity. For the uncemented group, the mean Kofoed score was 91.9 when compared to 74.2 for the cemented group, and 12-year survival was 95.4% and 74.2%, respectively. Only one patient in the uncemented group had radiographic lucency or subsidence, compared to six in the cemented group. As a result of his findings, Kofoed recommended use of the STAR™ with a press-fit technique.

Schulte and Lowering published their experience with 49 uncemented STAR™ prostheses. They followed the patients for only 28 months, but there was a 33% peri-
operative complication rate, including alveolus fractures, neurapraxia of the peroneal nerve, and component malposition. In contrast to the published outcomes of Kofoid’s group, there was a significantly higher rate of both radiolucenty and osteolysis; 20% of tibial components and 4% of talar components for each outcome measured. Only 14 of 49 ankles had proper positioning without radiolucent lines. There were four clinical failures: two from infection and two from aseptic loosening, resulting in an 8% failure rate.

In determining specific parameters which might affect outcome with the STAR™ prosthesis, several groups have published their findings. Valderrabano and coworkers described 68 STAR™ procedures followed over a mean of 3.7 years. While again demonstrating impressive improvement in AOFAS hindfoot scores (24.7 to 84.3) and patient-reported satisfaction, 13% required revision surgery and an additional 21% required secondary procedures. However, of the 23 patients who required secondary procedures, 21 of 23 were posttraumatic OA patients. In comparison, only 1/11 rheumatoid patients and 0/9 primary OA patients required secondary procedures. The most common reason for re-operation was for significant periarticular heterotopic ossification that limited range of motion. Interestingly, 63% of all patients developed heterotopic ossification despite prophylactic treatment with indomethacin. The study also found a positive correlation between young patients with pre-existing hindfoot arthrodesis and postoperative tibial lysis or loosening. In general, age alone did not correlate with AOFAS hindfoot score, pain scores, range of motion, or rate of heterotopic ossification. When Kofoid and Lundberg-Jensen compared two groups, 30 patients younger than 50 versus 70 patients older than 50 years of age, they found no effect of age on clinical outcome. They also did not see variation in outcome with respect to gender or etiology.

With respect to pre-operative malalignment, two recent studies demonstrated inferior results with pre-operative coronal plane malalignment. Haskell and Mann compared 35 patients with greater than 10° of varus or valgus malalignment versus 51 with neutral alignment. Eleven of 35 patients with coronal plane deformity underwent intraoperative ligament balancing procedures and 8 of 35 developed progressive edge loading with half (4/8) requiring a secondary procedure. They determined that “patients with pre-operative incongruent joints are 10-times more likely to have progressive edge-loading develop than patients with congruent joints.” Wood and associates found that in their series of 200 consecutive STAR™ procedures, 15 of 39 ankles with greater than 15° of varus or valgus malalignment had complications. Six had aseptic loosening, two had medial malleolar fractures, and seven had progressive edge loading. While for the entire group of 200 ankles, the study demonstrated a 93.3% overall implant survival of 5 years and 80.3% survival at 10 years, the investigators noted that deformities greater than 15° were associated with early failure. Therefore, total ankle replacement was not recommended for these patients.

Both the Agility™ and STAR™ systems provide reliable pain relief, improvement of AOFAS hindfoot scores, and very high rates of patient satisfaction. However, they both have high rates of complications and requirement for secondary procedures. In published studies, the STAR™ demonstrates lower rates of radioluency and component migration, has lower failure rates at greater than 10-year follow-up, and avoids the complications related to syndesmotic arthrodesis.

### Arthroplasty Versus Arthrodesis

There are currently no published prospective randomized controlled clinical trials comparing ankle arthroplasty to tibiotalar arthrodesis. However, a 2009 study published in *Foot and Ankle International* showed non-inferiority of the STAR™ versus ankle fusion in a non-randomized multicenter design. This study, with minimum follow-up of 24 months, facilitated the final FDA approval for the STAR™ system. The initial Pivotal study compared 158 ankle replacements performed at 10 centers to 66 ankle fusion performed at five different centers. The Continued Access Group included 448 subsequent ankle replacements performed after enrollment had been completed for the Pivotal study. STAR™ patients demonstrated improved functional outcomes (measured via the Buechel-Pappas ankle score) versus arthrodesis, especially with deformity, function, and ability to stand without pain. However, the ankle replacement group also had a higher rate of complications, including nerve injury, fracture, and wound problems (20.9%). These complications were significantly reduced for the Continued Access Group when compared to the Pivotal study.

In a recent meta-analysis, aggregate results of 10 studies for arthroplasty were compared to 39 for arthrodesis. In order to meet inclusion criteria, studies needed at least 2 years of follow-up and included at least 10 subjects in the treatment group. Total ankle arthroplasty resulted in a 78% implant survival rate at 5 years and 77% survival rate at 10 years. There was a 7% revision rate, with loosening subsidence accounting for the majority (28%) of cases. In addition, 1% of patients ultimately underwent below the knee amputation. In comparison, arthrodesis resulted in a 10% nonunion rate with a 9% revision rate, the vast majority (65%) as a result of nonunion. Amputation rate for the arthrodesis group was 5%. The investigators concluded that both procedures yield satisfactory results, and the data suggest equivalence between the procedures.

### Discussion

Recent improvements in implant design and instrumentation have allowed for more reliable and predictable outcomes after total ankle arthroplasty. However, the complications associated with ankle replacement should not be taken lightly, and an honest conversation regarding risks, benefits,
alternatives, and expected outcomes should take place with every patient prior to ankle replacement.

The surgeon should critically assess his or her comfort level and familiarity with the procedure and specific implant system, as well as the individual characteristics of each patient. While there are no well-defined parameters for contraindications, our own personal exclusion criteria for ankle replacement include a young age (less than 50 years old), history of poor patient compliance, heavy industrial laborers, heavy smokers, uncontrolled diabetes with neuropathy, significant ankle instability, angular deformity greater than 10° to 15°, vascular insufficiency, obesity (greater than 250 lbs.), significant bone loss, avascular necrosis, and previous history of infection.

In order to avoid the biomechanical disadvantages of a tibio-talo-calcaneal fusion, individuals with pre-existing subtalar arthritis may benefit from ankle arthroplasty. For patients without previous tibial plafond fractures or bone quality issues, we prefer to implant the STAR™ due to the minimal bone resection and the mobile bearing polyethylene. However, for revisions and for patients with compromised tibial or talar bone stock, we prefer to utilize the INBONE™ system, with the added benefit of intramedullary tibial fixation and modular stem fixation for the talus. There is some concern regarding the possibility of difficulty revising or removing the tibial stem; this is an issue that could become problematic for a deep infection, potentially increasing the risk of below knee amputation.

Conclusion

Ankle arthroplasty has gained greater acceptance over the past 10 years due to encouraging clinical results; however, both surgeons and patients must continue to remember that it is a challenging procedure with significant complications. The ideal candidate is thought to be an older, low-demand patient with normal alignment, maintained range of motion, rheumatoid arthritis, and pre-existing subtalar arthritis, but to date the specific parameters remain unclear. Patients with pre-operative malalignment, limited range of motion, active infection, ligamentous instability, or possibly post-traumatic OA may be better served with arthrodesis. Further research regarding long-term outcomes, determination of the ideal patient, and comparisons between the various types of implant systems is needed.

Disclosure Statement

None of the authors have a financial or proprietary interest in the subject matter or materials discussed, including, but not limited to, employment, consultancies, stock ownership, honoraria, and paid expert testimony.

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