Clinical Policy Bulletin:
Total Ankle Arthroplasty

Number: 0645

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers total ankle arthroplasty (TAA) using a Food and Drug Administration-cleared implant (e.g., the Agility LP Total Ankle, the Eclipse Total Ankle, the INBONE Total Ankle, the STAR system, the Salto Talaris Total Ankle Prosthesis, and the Zimmer Trabecular Metal Total Ankle) medically necessary to replace an arthritic or severely degenerated ankle in skeletally mature persons with moderate or severe pain with loss of ankle mobility and function due to osteoarthritis (degenerative arthritis), post-traumatic arthritis and rheumatoid arthritis and who have failed at least 6 months of conservative management (including physical therapy, non-steroidal anti-inflammatory drugs, and orthoses as indicated), who have none of the contraindications to TAA listed below, and who have one of the following: arthritis in adjacent joints (i.e., subtalar or midfoot), inflammatory (e.g., rheumatoid) arthritis, arthrodesis of the contralateral ankle, or severe arthritis of the contralateral ankle.

Aetna considers revision TAA medically necessary for individuals with failed total ankle prosthesis.

Aetna considers TAA experimental and investigational for persons who have one or more of the following contraindications:

- Absence of the medial or lateral malleolus;
- Active or prior deep infection in the ankle joint or adjacent bones;
- Avascular necrosis of the talus;
- Charcot joint;
- Hindfoot or forefoot malalignment precluding plantigrade foot;
- Insufficient bone or musculature such that proper component positioning or alignment is not possible;
- Insufficient ligament support that cannot be repaired with soft tissue stabilization;
- Lower extremity vascular insufficiency;
- Neuromuscular disease resulting in lack of normal muscle function about the affected ankle;
- Osteonecrosis;
- Peripheral neuropathy (may lead to Charcot joint of the affected ankle);
- Poor skin and soft tissue quality about the surgical site;
- Prior arthrodesis (fusion) at the ankle joint;
- Prior surgery or injury that has adversely affected ankle bone quality;
- Psychiatric problems that hinder adequate cooperation during peri-operative period;
- Severe anatomic deformity in adjacent ankle structures, including hindfoot, forefoot and knee joint;
- Severe ankle deformity (e.g., severe varus or valgus deformity) that would not normally be eligible for ankle arthroplasty;
- Severe osteoporosis, osteopenia or other conditions resulting in poor bone quality, as this may result in inadequate bony fixation;
- Significant mal-alignment of the knee joint;
- Skeletal maturity not yet reached;
- Vascular insufficiency in the affected limb; or
- Weight greater than 250 lbs.

Aetna considers TAA experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.

Aetna considers the use of intra-operative fresh frozen section analysis to determine the presence of infection during TAA experimental and investigational because the effectiveness of this approach has not been established.

Background

Total ankle replacement is a procedure in which an injured ankle joint is replaced with a plastic and metal joint. The procedure has been used as an alternative to surgical fusion in patients with loss of ankle function and pain that is refractory to medications, especially because of rheumatoid arthritis. Arthritis from other causes is rarely a reason to do ankle replacement.

Examples of US Food and Drug Administration (FDA) approved total ankle replacement devices include, but may not be limited to: Agility LP total ankle system; Eclipse total ankle implant; INBONE total ankle system; Infinity total ankle replacement system; Salto Talaris total ankle prosthesis; Scandinavian total ankle replacement system (STAR); Topez total ankle replacement; and Zimmer Trabecular Metal total ankle.

Conservative management of ankle pain includes acetaminophen, aspirin, or other medication for pain and inflammation, limiting activity, wearing an ankle brace, shoe modifications, application of heat, and physical therapy.

When conservative measures of treatment fail to provide adequate pain relief, either an ankle fusion or total ankle replacement (ankle arthroplasty) may be considered. Ankle fusion has been the traditional method of treating arthritis of the ankle. In recent years, total ankle replacement has developed as another option. However there are limited long-term data on the effectiveness of total ankle replacement. Available data suggest that total ankle replacement has a relatively short lifespan. For this reason, ankle replacements are not usually recommended for people under the age of 50.

The surgery requires either one or two incisions in the ankle and displacement of the nerves, blood vessels and tendons allowing the surgeon entrance into the ankle joint capsule. Incisions are then made into the tibia, fibula and top of the talus allow for proper fitting of the implant components. A small amount of the tibia and fibula are removed to allow room for the prosthesis itself.

To stop motion between the tibia and fibula, which could cause the artificial ankle joint to loosen, screws are placed between the two bones and a bone graft to create a ligamentous fusion at the site. One component is attached to the tibia/fibula fusion site and the other is attached to the ankle bone.

The procedure is performed under general or spinal anesthesia. Patients are generally hospitalized for 1 to 4 days. A period of physical therapy is often required after ankle replacement. The patient is able to ambulate within a few weeks following the procedure. The most common complications include thrombophlebitis and pulmonary embolism. Swelling or pressure as a result of the procedure may injure the nerves in the ankle. The new joint can be dislocated rather easily. In addition, there is a risk of infection and hemorrhage.

Encouraged by the excellent results attained by total joint arthroplasty of the hip and knee, several
surgeon-engineer teams designed and developed total joint prostheses for the ankle. In the early and middle 1970's reports appeared of early success with these implants in 80 % to 85 % of patients. In 11 reports that included 346 arthroplasties, good or fair results were reported in 83 % and failures in 17 % at a mean follow-up of less than 5 years. A wave of enthusiasm developed for total ankle arthroplasty, and the indications for the procedure were expanded, often to include young people engaged in strenuous work or recreational activities. After further experience and longer periods of observation, reviews of most early series of total ankle arthroplasties revealed poor long-term results, especially in younger patients with isolated traumatic arthritis. In later reports in which the average follow-up was longer than 5 years, failure occurred in 35 % to 76 % of arthroplasties.

Comparison of long-term series of total ankle arthroplasty are difficult because of variability in diagnosis, patient age, length of follow-up, prosthesis design, and absence of a uniform scoring system.

Early implant designs had a high failure rate. However, the new designs introduced have shown improved results. One of the largest early series of total ankle arthroplasties is that of Kitaoka et al (1994, 1996), who reported their experience with 204 primary Mayo total ankle replacements. The overall cumulative rate of implant survival was 79 % at 5 years, 65 % at 10 years, and 61 % at 15 years. The probability of an implant being in place at 10 years was 42 % for patients 57 years of age or younger and who had previous operative treatment of the ipsilateral ankle or foot and 73 % for those older than 57 years of age who had no such previous operative treatment. Because of these poor long-term results, the investigators did not recommend the use of the Mayo total ankle arthroplasty, especially in younger patients who have had a previous operative procedure on the ipsilateral ankle or foot. In a series of 36 constrained Conaxial (Beck-Steffee) ankle replacements, Wynn and Wilde (1992) found that 27 % were loose at 2 years, 60 % at 5 years, and 90 % at 10 years; they recommend that this ankle prosthesis not be implanted.

Complications other than implant loosening were also found to be more frequent after total ankle arthroplasty using early designs than after total hip or knee replacement. Delayed wound healing had been reported to occur in as many as 40 % of patients, and most long-term early series cited rates of deep infection of 3 % to 5 %. Loosening had been reported in 6 % to 25 % of implants after 3 to 5 years; usually the talar component is involved. Demottaz et al (1979) reported radiolucent zones of 2 mm or more at the cement-bone interface in 88 % of prostheses at 1 year, and Unger et al (1988) reported talar subsidence in 14 of 15 arthroplasties and tibial component tilting in 12 of 15 at an average 6-year follow-up. Wynn and Wilde (1992) reported an overall complication rate of 60 %, including wound dehiscence (39 %), deep wound infection (6 %), fractures of the medial or lateral malleolus (22 %), and painful talofibular impingement (14 %).

In a review of total ankle arthroplasty, Saltzman (1999) concluded that despite efforts to develop a workable total ankle replacement the long-term results of most new designs are unknown. Saltzman concluded that prospective clinical trials are needed to determine which factors lead to successful and unsuccessful outcomes.

In 2003, the American Orthopaedic Foot and Ankle Society (AOFAS) published a position statement on total ankle arthroplasty that stated that ankle arthritis has many treatment options, both operative and non-operative. Operative treatment is available for patients with persistent symptoms. Surgical options include joint debridement, distraction arthroplasty, osteotomy, ankle arthrodesis and total ankle arthroplasty. The AOFAS concluded that total ankle arthroplasty is a viable option for the treatment of ankle arthritis; however, this position statement was not supported by a systematic evidence review.

In a review on total ankle replacement, Hintermann and Valderrabano (2003) stated that although the results of the different design approaches are encouraging in limited clinical series, there is still the need for careful, long-term analyses to estimate to what extent the current designs are mimicking the biomechanics of the ankle joint. More attention must be paid to more accurate implantation techniques that result in a well-balanced ligament and allow the ligaments to act together with the replaced
surfaces in a most physiological manner. Gill (2004) noted that there is a need for further basic science research in total ankle arthroplasty. The lessons learned from other arthroplasty should be considered in ankle arthroplasty design.

Spirt et al (2004) reported a relatively high rate of re-operation after total ankle arthroplasty with a second-generation total ankle replacement device -- the DePuy Agility Total Ankle System. Younger age was found to have a negative effect on the rates of re-operation and failure. Most prostheses could be salvaged; however, the functional outcome of this procedure is uncertain. Haskell and Mann (2004) tested the hypotheses that pre-operative coronal plane mal-alignment and incongruence of the ankle can be corrected and maintained for 2 years with total ankle replacement. These investigators found that patients with pre-operative incongruent joints are 10 times more likely to have progressive edge-loading develop than patients with congruent joints. They stated that surgeons must be attentive to coronal plane alignment during and after ankle replacement, and that longer follow-up is needed to assess the longevity of the correction and the impact of minor mal-alignment on implant wear.

Easley et al (2002) stated that four 2nd-generation total ankle arthroplasty designs have shown reasonable functional outcomes: (i) the Scandinavian Total Ankle Replacement (STAR), (ii) the Agility Ankle, (iii) the Buechel-Pappas Total Ankle Replacement, and (iv) the TNK ankle. They noted that intermediate results are promising but should be interpreted with care. Knecht et al (2004) stated that arthrodesis of the tibiofibular syndesmosis impacts the radiographical and clinical outcomes with the Agility total ankle replacement. The relatively low rates of radiographical hind-foot arthritis and revision procedures at an average of 9 years after the arthroplasty are encouraging. Agility total ankle replacement is a viable and durable option for the treatment of ankle arthritis in selected patients.

A cost-effectiveness analysis of total ankle arthroplasty by SooHoo and Kominski (2004) stated that the currently available literature has not yet shown that total ankle arthroplasty predictably results in levels of durability and function that make it cost-effective at this time. The authors reported, however, that the reference case of this analysis does demonstrate that total ankle arthroplasty has the potential to be a cost-effective alternative to ankle fusion. This reference case assumes that the difference between total ankle arthroplasty and ankle fusion will be borne out in future clinical studies. Performance of total ankle replacement will be better justified if these thresholds are met in published long-term clinical trials. A critique of the cost-effectiveness analysis by SooHoo and Kominski by the Centre for Reviews and Development (2005) noted that the authors made assumptions for the model based on the results in the literature, but that the authors did not state that they carried out a systematic review of that literature. The CRD stated that the authors made appropriate comparisons of their findings with those from other studies. In addition, sensitivity analyses were undertaken which helps validate the findings. The CRD noted that the authors of this cost-effectiveness analysis acknowledged a number of limitations in the study. For example, several variables in the model had unknown values, such as the durability of ankle prosthesis and the long-term utility of ankle fusion and replacement. However, sensitivity analyses performed on these variables did not change the results of the study. The CRD noted that the authors stated that the cost-effectiveness analysis of total ankle arthroplasty would benefit from empirical studies that more directly measure the long-term utility of ankle fusion and ankle replacement.

Some more recent reports of uncemented, unconstrained replacements have shown better short-term results. Stengel and associates (2005) performed a meta-analysis of studies exploring the effectiveness of 3-component total ankle prostheses for treating end-stage ankle arthritis of different origin. A total of 18 studies (n = 1,086) were included in the review, of which 6 had a prospective design (n = 497). The investigators found that the impact of the ankle prosthesis on range of motion (ROM) was small. Based on 7 studies, there was a statistically significant improvement in ROM after ankle replacement. However, the overall gain in ROM was small (weighted mean difference 6.3 degrees, 95 % confidence interval [CI]: 2.2 to 10.5). The authors reported that the results for STAR implants were similar to those for other types of prostheses used, and that the underlying cause of ankle arthritis had no significant impact on gains in ROM. The authors also found that prospective and retrospective studies produced similar results. Following ankle replacement, global scores improved
by a weighted average of 45.2 points on a 100-point scale (10 studies). This was mainly determined by pain ratings (28.6 points, 95% CI: 24.4 to 32.8). Functional subscales improved by a mean of 12.5 points (95% CI: 5.9 to 19.1). There appeared to be no association between the measure of ankle score used, type of implant, methodological issues, type of study design, or whether a publication was published in a peer-reviewed journal or not, and the results. The average scores increased with larger proportions of patients undergoing ankle replacement for osteoarthritis compared with patients suffering from rheumatoid arthritis. Pooled estimates for the rate of complications were as follows: superficial infections, 10.8% (95% CI: 7.0 to 14.7); deep infections, 1.6% (95% CI: 0.7 to 2.5); loosening, 5.4% (95% CI: 1.3 to 9.5); dislocation, 3.2% (95% CI: 2.1 to 4.4); fractures, 13.4% (95% CI: 6.2 to 20.7); revision surgery, 12.5% (95% CI: 5.6 to 19.4); impingement, 14.7% (95% CI: 0.0 to 33.5); arthrodesis, 6.3% (95% CI: 3.2 to 9.5). The authors found a nonsignificant trend towards lower rates of deep infections with STAR implants (1.0%, 95% CI: 0.2 to 1.8%) compared with all other prostheses (3.8%, 95% CI: 1.5 to 6.2). Retrospective studies found higher rates of superficial and deep infections (14.5% and 3.3%, respectively) than prospective studies (2.5% and 0.6%, respectively). Patients with rheumatoid arthritis tended towards higher risks of implant loosening and dislocation of components, and patients with post-traumatic conditions developed deep wound infections more often. The weighted survival probability after 1 year was 96.9% (95% CI: 94.9 to 98.8), and after 5 years 90.6% (95% CI: 84.1 to 97.1). These investigators concluded that ankle arthroplasty improves pain and joint mobility in end-stage ankle arthritis. Its performance in comparison to the current reference standard (i.e., ankle fusion) remains to be defined in a properly designed randomized trial. A critique of the systematic evidence review by Stengel et al by the CRD (2006) noted that the data included in the review appears to have come from uncontrolled pre-post comparisons, which have a higher risk of bias and are less likely to be reliable than data from controlled studies. The CRD stated that the methods used by Stengel et al for statistical analysis were unclear and might not have been appropriate. The CRD stated that Stengel et al's conclusion regarding the need for a trial is appropriate given the poor quality of the studies included in the review.

Murnaghan et al (2005) reported on short-term follow up of 22 STAR placements in 20 patients with a mean follow-up of 26 months. Of the 20 patients, 25% continued to have pain at the operative site with normal activities of daily living; 2 continued to have lateral discomfort, 2 had loading/start-up pain, and 1 had anterior impingement. One-quarter (5 of 20) subjects continued to need mobility aids (crutches or wheelchair), 2 directly due to difficulties at the ankle joint. Three of 20 subjects required secondary surgery at short-term follow-up, with 2 requiring revision of the prosthesis. Other adverse events including intra-operative fractures of the malleoli (5 subjects), radiographical lucency (6 subjects), and delayed wound healing (2 subjects).

Anderson et al (2004) reported that the risks of loosening and failure after total ankle replacement are higher than after total knee replacement or total hip replacement. The investigators reported on intermediate term results of 51 STAR placements. A total of 12 ankles had to be revised; 7 were revised because of loosening of at least one of the components; 2, because of fracture of the meniscus; and 3, for other reasons. A component was exchanged in 7 of the 12 revisions, whereas the ankle was successfully fused in the other 5. An additional 8 ankles had radiographic signs of loosening. The estimated 5-year survival rate, with revision for any reason as the end point, was 0.70. The median range of motion was approximately the same pre-operatively and post-operatively. Of the remaining 39 subjects whose ankles were not revised, 6 stated that they were not satisfied and 2 only partially satisfied with the result.

Tarasevicius et al (2004) also reported worse outcomes after total ankle replacement than has been reported after total knee replacement or total hip replacement. The investigators evaluated early clinical results of 18 patients (out of 23 operated patients), for whom total ankle replacement with an uncemented STAR prosthesis. Only 50% reported excellence or good results (9 of 18 subjects). Fair results were found in 6 cases, poor in 2 cases, and failure in 1 case. Complications occurred in most cases (11 cases, 61%) at early follow-up: 4 patients had neurological complaints in operated foot, delayed wound healing was observed in 2 cases, 3 patients had plantar flexion contracture, for 1 patient arthrodesis was done because of dislocation of meniscus component.
In a study comparing ankle replacement to ankle arthrodesis, Piriou et al (2008) found that ankle replacement resulted in improved symmetry (timing) with limp reduction, but in a significantly slower gait. The investigators compared before and after gait analyses of 12 patients who received ankle arthroplasty to 12 patients who received ankle arthrodesis. Patients with ankle arthrodesis demonstrated a faster gait and longer step length compared with ankle replacement. Ankle replacement patients showed restored ground reaction force pattern, greater symmetry in gait, and greater movement at the ankle than the arthrodesis group. The authors stated that longer term results are needed to determine whether the improved movement and force transmission persists with time and protects adjacent articulations.

Haddad et al (2007) examined if there are sufficient objective cumulative data in the literature to compare total ankle replacement and ankle fusion. A systematic review of the literature addressing the intermediate and long-term outcomes of interest in total ankle arthroplasty and ankle arthrodesis was performed. Two reviewers evaluated each study to determine whether it was eligible for inclusion and collected the data of interest. Meta-analytic pooling of group results across studies was performed for the 2 procedures. The analysis of the outcomes focused on second-generation ankle implants. The systematic review identified 49 primary studies, 10 of which evaluated total ankle arthroplasty in a total of 1,262 patients and 39 of which evaluated ankle arthrodesis in a total of 852 patients. The mean AOFAS Ankle-Hindfoot Scale score was 78.2 points (95 % CI: 71.9 to 84.5) for the patients treated with total ankle arthroplasty and 75.6 points (95 % CI: 71.6 to 79.6) for those treated with arthrodesis. Meta-analytic mean results showed 38 % of the patients treated with total ankle arthroplasty had an excellent result, 30.5 % had a good result, 5.5 % had a fair result, and 24 % had a poor result. In the arthrodesis group, the corresponding values were 31 %, 37 %, 13 %, and 13 %. The 5-year implant survival rate was 78 % (95 % CI: 69.0 % to 87.6 %) and the 10-year survival rate was 77 % (95 % CI: 63.3 % to 90.8 %). The revision rate following total ankle arthroplasty was 7 % (95 % CI: 3.5 % to 10.9 %) with the primary reason for the revisions being loosening and/or subsidence (28 %). The revision rate following ankle arthrodesis was 9 % (95 % CI: 5.5 % to 11.6 %), with the main reason for the revisions being non-union (65 %). One percent of the patients who had undergone total ankle arthroplasty required a below-the-knee amputation compared with 5 % in the ankle arthrodesis group. The authors concluded that on the basis of these findings, the intermediate outcome of total ankle arthroplasty appears to be similar to that of ankle arthrodesis; however, data were sparse. The authors stated that comparative studies are needed to strengthen this conclusion.

SooHoo et al (2007) compared the re-operation rates following ankle arthrodesis and ankle replacement on the basis of observational, population-based data from all inpatient admissions in California over a 10-year period. The hypothesis was that patients treated with ankle replacement would have a lower risk of undergoing subtalar fusion but a higher overall risk of undergoing major revision surgery. These researchers used California's hospital discharge database to identify patients who had undergone ankle replacement or ankle arthrodesis as inpatients in the years 1995 through 2004. Short-term outcomes, including rates of major revision surgery, pulmonary embolism, amputation, and infection, were examined. Long-term outcomes that were analyzed included the rates of major revision surgery and subtalar joint fusion. Logistic and proportional hazard regression models were used to estimate the impact of the choice of ankle replacement or ankle fusion on the rates of adverse outcomes, with adjustment for patient factors including age and comorbidity. A total of 4,705 ankle fusions and 480 ankle replacements were performed during the 10-year study period. Patients who had undergone ankle replacement had an increased risk of device-related infection and of having a major revision procedure. The rates of major revision surgery after ankle replacement were 9 % at 1 year and 23 % at 5 years compared with 5 % and 11 % following ankle arthrodesis. Patients treated with ankle arthrodesis had a higher rate of subtalar fusion at 5 years post-operatively (2.8 %) than did those treated with ankle replacement (0.7 %). Regression analysis confirmed a significant increase in the risk of major revision surgery (hazard ratio, 1.93 [95 % CI: 1.50 to 2.49]; p < 0.001) but a decreased risk of subtalar fusion (hazard ratio, 0.28 [95 % CI: 0.09 to 0.87]; p = 0.03) in patients treated with ankle replacement compared with those treated with ankle fusion. The authors concluded that this study
confirmed that, compared with ankle fusion, ankle replacement is associated with a higher risk of complications but also potential advantages in terms of a decreased risk of the patient requiring subtalar joint fusion. They stated that additional controlled trials are needed to clarify the appropriate indications for ankle arthrodesis and ankle replacement.

Vickerstaff et al (2007) stated that total ankle replacement was first attempted in the early 1970s, but poor early results lead to it being abandoned in favor of arthrodesis. Arthrodesis is not totally satisfactory, often causing further hindfoot arthritis and this has led to a resurgence of interest in joint replacement. New designs which more closely approximated the natural anatomy of the ankle and associated biomechanics have produced more encouraging results and led to renewed interest in total ankle replacement. Three prostheses dominate the market: the Agility, the Buechel-Pappas and the STAR System, and improving clinical results with these devices have led to more designs appearing on the market. Modern designs of prosthetic ankles almost exclusively consist of 3-part prostheses with a mobile bearing component, similar to the Buechel-Pappas and the STAR System. However, the authors stated that clinical results of these newer designs are limited and short-term and have often been carried out by the designers of the implants.

An assessment of total ankle arthroplasty by the Institute for Clinical Effectiveness and Health Policy (Pichon-Rivere et al, 2007) found that current evidence comes from observational studies, especially at short- and medium-term, and there is lack of information on the life, stability and rate of complications. The assessment stated that second generation non-cemented and mobile-bearing prostheses have shown promising short term results. "More evidence is required to state clear guidelines for the use of arthroplasty in the different clinical conditions resulting from controlled clinical trials and long term follow-up."

Guyer and Richardson (2008) stated that many orthopedic surgeons had abandoned the use of first and second generation total ankle replacement because of unacceptably high complication and failure rates as compared to arthrodesis. Recently, there has been renewed interest in ankle joint replacement as longer term outcome studies have become available. However, the authors noted that there continues to be much debate within the orthopedic community as to indications, patient selection, as well as optimal component design.

A review by Cracchiolo and DeOrio (2008) stated: "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." Cracchiolo and Deorio (2008) stated that 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 (2-component design) or mobile (3-component design) polyethylene bearing. Currently, 4 ankle replacements are approved by the United States Food and Drug Administration (FDA). These 4 -- Agility, INBONE, Salto-Talaris, and Eclipse -- are 2-component designs; the Scandinavian Total Ankle Replacement (STAR) is a 3-part mobile-bearing design. The authors concluded that, 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.

On May 27, 2009, the FDA approved the SBi Scandinavian Total Ankle Replacement (S.T.A.R. Ankle), for arthritic or deformed ankles that may preserve some range of motion in the joint. The new prosthesis is a mobile-bearing device, which relies on bearings that move across a surface of polyethylene, a flexible plastic. This mobile bearing is purported to allow motion with retained congruency. The reported disadvantages of mobile bearing include dislocation, 2-sided wear and tear, and fracture. As a condition for approval, the manufacturer is required to gather post-marketing data on the long-term durability of the implant.

The STAR System was approved by the FDA for use as a non-cemented implant to replace a painful
arthritic ankle joint due to osteoarthritis, post-traumatic arthritis or rheumatoid arthritis. According to the product labeling, the STAR System is contraindicated in the following:

- Active or prior deep infection in the ankle joint or adjacent bones
- Skeletal immaturity
- Bone stock inadequate to support the device including:
  - Severe osteoporotic or osteopenic condition or other conditions resulting in poor bone quality
  - Avascular necrosis of the talus
  - Prior surgery and/or injury that has adversely affected ankle bone quality
- Mal-alignment or severe deformity of involved or adjacent anatomic structures including:
  - Hindfoot or forefoot malalignment precluding plantigrade foot
  - Significant malalignment of the knee joint
- Insufficient ligament support that cannot be repaired with soft tissue stabilization
- Neuromuscular disease resulting in lack of normal muscle function about the affected ankle
- Lower extremity vascular insufficiency demonstrated by Doppler arterial pressure
- Charcot joint or peripheral neuropathy that may lead to Charcot joint of the affected ankle
- Prior arthrodesis at the ankle joint
- Poor skin and soft tissue quality about the surgical site.

The labeling states that the safety and efficacy of the STAR Ankle have not been studied in patients weighing more than 250 lbs. The labeling states that certain vigorous physical activities (e.g., basketball, football) and trauma to the joint replacement may cause early failure of the STAR Ankle.

As a condition of FDA approval, the company, Small Bone Innovations Inc. (Morrisville, PA), will evaluate the safety and effectiveness of the device during the 8 years following FDA approval. The FDA has already cleared several fixed-bearing ankle devices, which are also options to fusion surgery. In fixed-bearing ankle system, the articulating surface is molded, locked or attached to one of its metallic components.

Deorio and Easley (2008) stated that recent investigations support the belief that ankle replacement represents an attractive surgical alternative to arthrodesis for patients with advanced ankle arthritis. Although longer follow-up is needed for total ankle arthroplasty (TAA) to displace arthrodesis as the surgical "gold standard", intermediate-term results are encouraging. Indications for TAA include primarily post-traumatic and inflammatory arthritis. Contra-indications to TAA include unresectable osteonecrotic bone, peripheral vascular disease, neuropathy, active and/or recent ankle infection, non-reconstructible ankle ligaments, loss of lower leg muscular control, and severe osteopenia or osteoporosis. Young, active, high-demand patients with ankle arthritis may be better candidates for arthrodesis than for TAA. Rigorous patient selection is essential in the success of TAA, more than in other joint arthroplasty procedures. Total ankle prosthetic designs (the Agility, STAR, Hintegra, Salto, and Buechel-Pappas) with a minimum of published intermediate follow-up results, and several other innovative and biomechanically supported designs (the Mobility Total Ankle System, BOX, INBONE, and Salto-Talaris) were reviewed to demonstrate the recent evolution of TAA. Some TAA designs feature a non-constrained polyethylene meniscus (mobile bearing) that articulates between the porous-coated tibial and talar components. The concern for edge loading (when the polyethylene component comes in contact with a metal edge) has been addressed in more recent designs by reducing the superior polyethylene surface area, expanding the tibial component surface, and even offering a convex tibial component. More practical, effective, and safer instrumentation for implantation has also been developed and has been essential to the success of TAA. However, complications with TAA (such as inadequate wound healing and malleolar fractures) are more frequent when compared with total hip and knee arthroplasty, irrespective of the surgeon's training method. The authors stated that
adequate long-term follow-up and high levels of evidence are not available to support universal TAA over arthrodesis in the management of end-stage ankle arthritis. Furthermore, they noted that more research is needed to ascertain the cost-effectiveness of TAA and if conversion of ankle arthrodesis to arthroplasty is advisable.

Chou and associates (2008) stated that TAA was developed to reduce pain and retain motion of the ankle joint in patients with osteoarthritis. The ankle joint has unique, complex anatomic and biomechanical characteristics that must be considered in a successful TAA prosthesis. Initial designs from the 1960s to the 1970s had many failures. Current designs use 2 or 3 components, and recent reports on TAA show consistent good-to-excellent intermediate clinical results, with up to 90% decreased pain and high patient satisfaction. The follow-up time of these studies is limited, however, and long-term studies with 10- to 15-year follow-ups are needed. In addition, a wide variety of complications has been reported, including osteomyelitis and osteolysis. To limit the number of complications and improve clinical outcome of TAA, careful patient selection and surgeon experience are important.

Wood et al (2008) described the medium-term results of a prospective study of 200 total ankle replacement (TAR) at a single-center using the STAR system. A total of 24 ankles (12%) have been revised, 20 by fusion and 4 by further replacement and 27 patients (33 ankles) have died. All the surviving patients were seen at a minimum of 5 years after operation. The 5-year survival was 93.3% (95% CI: 89.8 to 96.8) and the 10-year survival 80.3% (95% CI: 71.0 to 89.6). Anterior subluxation of the talus, often seen on the lateral radiograph in osteoarthritic ankles, was corrected and, in most instances, the anatomical alignment was restored by TAR. The orientation of the tibial component, as seen on the lateral radiograph, also affects the position of the talus and if not correct can hold the talus in an abnormal anterior position. Subtalar arthritis may continue to progress after TAR. These findings are similar to those published previously.

Wood and colleagues (2009) found no significant difference in survivorship between the STAR implant and the Beuchel-Pappas (BP) ankle prosthesis in a randomized controlled clinical trial. The investigators reported continuing results of the previously described randomized, prospective study of 200 ankle replacements performed between March 2000 and July 2003 at a single center to compare the Beuchel-Pappas (BP) and the STAR implant with a minimum follow-up of 36 months. The 2 prostheses were similar in design consisting of 3 components with a meniscal polyethylene bearing, which was highly congruent on its planar tibial surface and on its curved talar surface. However, the designs were markedly different with respect to the geometry of the articular surface of the talus and its overall shape. A total of 16 ankles (18%) was revised, of which 12 were from the BP group and 4 of the STAR group. The 6-year survivorship of the BP design was 79% (95% CI: 63.4 to 88.5 and of the STAR 95% (95% CI: 87.2 to 98.1). The difference did not reach statistical significance (p = 0.09). However, varus or valgus deformity before surgery did have a significant effect (p = 0.02) on survivorship in both groups, with the likelihood of revision being directly proportional to the size of the angular deformity. The authors stated that these findings supported previous studies, which suggested that total ankle replacement should be undertaken with extreme caution in the presence of marked varus or valgus deformity.

Schutte and Louwerens (2008) reported on short-term results of 49 STAR placements in 47 patients followed for a mean of 28 months, reporting that 31 had radiological evidence of radiolucent lines, osteolysis, and malposition of components. Sixteen procedures were complicated by fractures or temporary neurological damage. Four of the ankle replacements had failed during the short-term follow-up period of this study.

Favang et al (2007) found their revision rate with the cementless STAR prosthesis and cemented TPR prosthesis to be comparable to other reports, but significantly higher than revision rates with total knee replacement and TAR. The investigators reported data on the use of TAR and the revision rate in the Norwegian population over a 12-year period, using the Norwegian Arthroplasty Register. There were 257 primary ankle replacements, 32 of which were cemented TPR prostheses and 212 of which were
cementless STAR prostheses. The overall 5-year and 10-year survival was 89% and 76%, respectively. The investigators reported that prosthesis survival was the same for the cementless STAR prosthesis and the cemented TPR prosthesis. The authors found no significant influence of age, sex, type of prosthesis, diagnosis, or year of operation on the risk of revision. The incidence of ankle replacements due to osteoarthritis, but not due to inflammatory arthritis, increased over the years.

Henricson et al (2007) found similar revision rates with the STAR prosthesis from an analysis of the Swedish Arthroplasty Register. The authors found that the overall survival rate at 5 years was 0.78 (95% CI: 0.74 to 0.82). For the 3 surgeons who had inserted the majority of the STAR ankles, the survival rates became significantly higher after the first 30 cases. The investigators found that younger patients had a higher risk of revision, whereas with no variation in risk of revision by gender or diagnosis. The authors concluded that the survival of the STAR prosthesis "is not comparable to that after hip or knee replacement."

Valderrabano et al (2004) reported on intermediate-term results of 68 TAR with the STAR prosthesis, stating that they encountered more complications and potential problems than previously reported. The 65 patients were assessed clinically and radiologically after a mean of 3.7 years. Almost half of subjects (46%) continued to have pain. Peri-articular hypertrophic bone formation was seen in almost 2/3 (63%, 42 subjects), associated with a decrease in dorsiflexion and plantar flexion. Three patients had a ballooning bone lysis on the tibial side. Fully 1/3 of subjects needed additional surgery by intermediate-term follow-up: 9 ankles had revision surgery because of problems with the components and 14 ankles had secondary or additional operations.

McGarvey et al (2004) found no substantial differences in rates of malleolar fracture after TAA with the STAR or Agility prostheses, the 2 most common ankle prostheses used in the United States. The investigators stated that prosthetic replacement of the ankle is associated with numerous complications including malleolar fracture. The investigators retrospectively compared the first 20 STAR with the first 25 Agility total ankle arthroplasties done by 2 surgeons. In the Agility group, 5 fractures occurred, all intra-operatively. Four involved the medial malleolus and 1 involved the lateral malleolus. All fractures were fixed as implant stability was compromised. In the STAR group, there were 4 fractures. Two lateral malleoli fractured intra-operatively and were fixed. Two medial malleoli fractures occurred post-operatively and were treated non-operatively. There was 1 medial malleolar nonunion in each group. The incidence of malleolar fracture was 20% in each group, comparable to results reported in relevant literature.

Benedetti et al (2008) stated that most clinical studies on TAR reported assessments based on traditional clinical scores or radiographical analysis. Only a few studies have used modern instrumentation for quantitative functional analysis during the execution of activities of daily living. The aim of this study was to use gait analysis to compare the functional performance of patients who underwent TAR versus a control population. A retrospective analysis was performed of 10 consecutive patients who had undergone meniscal-bearing TAR. Clinical and functional assessments were performed at a mean follow-up of 34 months with a modified Mazur scoring system and state-of-the-art gait analysis. Gait analysis assessment of TAR at medium-term follow-up showed satisfactory results for all patients, with adequate recovery of ROM. Because the literature reports unsatisfying long-term results, it is important to evaluate these patients over a longer follow-up period. The authors concluded that this study showed that TAR yielded satisfactory, but not outstanding, general functional results at nearly 3 years' follow-up. These gait analysis results highlight the importance of integrating in-vivo measurements with the standard clinical assessments of patients who underwent TAR while they perform activities of daily living. These results also emphasized the importance of evaluating the functional outcome of TAR over time.

In a case-series study, Naal et al (2009) evaluated the pre- and post-operative participation in sports and recreational activities of 101 patients at a mean of 3.7 years after TAA. Activity levels were determined with use of the University of California at Los Angeles (UCLA) activity scale. The International Physical Activity Questionnaire (IPAQ) was used to quantify habitual physical activity
levels and to calculate the proportion of patients meeting current guidelines for health-enhancing physical activity. The AOFAS hindfoot score was used as the clinical outcome measure. Radiographs were studied for tibial and talar radiolucencies, and any association between radiolucencies, activity levels, and sports participation was determined. Pre-operatively, 62.4 % of the patients were active in sports; 66.3 % were active after surgery (p = 0.56). Patients were active in 3.0 +/- 1.8 different sports and recreational activities pre-operatively and in 3.0 +/- 1.6 activities after surgery (p = 1.0). The sports frequency remained unchanged, with 2.0 +/- 1.6 sessions per week before TAA and 2.3 +/- 1.7 sessions per week post-operatively (p = 0.19). Overall, the patients were active in sports and recreation for 3.9 +/- 3.8 hours per week pre-operatively, and for 4.7 +/- 3.9 hours per week after surgery (p = 0.14). The most common disciplines after TAA were swimming, cycling, and fitness/weight training. Sixty-five percent of the patients stated that surgery had improved their sports ability.

The UCLA activity levels increased significantly from 4.3 +/- 2.2 to 6.2 +/- 1.6 (p < 0.001); AOFAS scores also improved significantly from 45.5 +/- 16.6 to 84.3 +/- 13.3 (p < 0.001). Patients suffering from post-traumatic ankle osteoarthritis were less satisfied with surgery than those with primary or inflammatory ankle osteoarthritis. A total of 79 % of the patients met the current guidelines for health-enhancing physical activity according to the IPAQ. Neither sports participation nor activity levels was associated with the presence of peri-prosthetic radiolucencies. The authors concluded that 2/3 of the patients were active in sports after TAA (but not different from pre-surgery), and the majority of the patients met current health-enhancing physical activity recommendations. The clinical outcome as determined by AOFAS scores and the patient satisfaction were favorable. The authors stated that the present study found no association between sports participation, increased physical activity levels, and the appearance of peri-prosthetic radiolucencies 3.7 years after TAA. However, these results have to be confirmed after longer follow-up, in particular of those patients regularly participating in sports with higher impact.

Karantana and associates (2010) noted that ankle arthroplasty is increasingly used to treat advanced ankle arthritis. Earlier prostheses have given way to second-generation implants, on which these researchers are accumulating medium-term data. Karantana et al (2010) retrospectively reviewed 45 patients (52 ankles) who had primary TAR using the STAR prosthesis, in order to assess survivorship. The minimum follow-up was 60 months (range of 60 to 110 months). Clinical outcome was determined using the AOFAS score. These investigators determined the rate of radiographical loosening and recorded complications and the need for further surgery. Survival was 90 % (95 % CI: 76.8 to 95.5) at 5 years and 84 % (95 % CI: 68.9 to 92.2) at 8 years. Six of 52 ankles (11 %) had component revision and 2 were converted to fusion. The mean post-operative AOFAS score was 78. The complication rate was 21 %. Subsequent surgery, excluding component revision, was performed in 9 of 52 (17 %) ankles.

In a manufacturer-funded study, Saltzman et al (2009) reported the results of 3 separate cohorts of patients: a group of STAR patients and a control group of ankle fusion patients (the Pivotal Study groups) and another group of STAR total ankle patients (the Continued Access group) whose surgery was performed following the completion of enrollment in the Pivotal Study. The Pivotal Study design was a non-inferiority study using ankle fusion as the control. A non-randomized multi-centered design with concurrent fusion controls was used. The initial peri-operative findings up to 24 months following surgery were reported. For an individual patient to be considered an overall success, all of the following criteria needed to be met: (i) a 40-point improvement in total Buechel-Pappas (BP) ankle score, (ii) no device failures, revisions, or removals, (iii) radiographical success, and (iv) no major complications. In the Pivotal Study, 158 ankle replacement and 66 arthodesis procedures were performed; more than 1/5 of Pivotal Study ankle fusion subjects did not have complete data at 24-month follow-up. In the Continued Access Study, 448 ankle replacements were performed, of which 416 were at minimum 24 months post-surgery at time of the database closure. Of these Continued Access patients, 25 % did not have a full set of BP scale data, and 1/3 did not have a complete set of safety data at the end of follow-up. The total number of reported adverse events at the operative site by 24-month follow-up in the Pivotal Study was more common in the arthroplasty group compared to the fusion group. Major complications and need for secondary surgical intervention were also more
common in the Pivotal Study arthroplasty group than the ankle fusion group. Although there was no significant difference in rates of major complications between Pivotal Study arthroplasty group and the Continued Access group, there were half as many secondary procedures performed in the Continued Access group compared with the Pivotal Study arthroplasty group. When the Pivotal groups were compared, the BP scores of pain relief, patient satisfaction, walking and limping were equivalent between fusion and replacement patients; stair climbing was marginally better ($p = 0.4$) in the Pivotal arthroplasty group; and other BP scores (deformity, function, standing, support, and range of motion) were higher for the Pivotal arthroplasty group. The authors concluded that the hypothesis of non-inferiority of ankle replacement was met for all areas of efficacy evaluated; however, non-inferiority of ankle replacement safety was not met with the initial analysis. The authors explained that a major strength of the study was its prospective design, but a disadvantage was its non-randomized design, such that arthroplasty and arthrodesis patients were enrolled in different centers, and the groups were somewhat dissimilar. Another weakness noted by the authors is that the BP criteria used as the primary endpoint is not a validated instrument, such that a clinical meaningful change in efficacy as measured by BP criteria is unknown. The BP assigns at 15% credit for ankle motion; thus, a prosthesis that maintains or restores motion is favored by the scale over fusion. The authors point out that, although a higher proportion of STAR patients (58.5%) than fusion patients (14.9%) were deemed a success based upon a 40-point change in the BP scale, one should not conclude that this defines the true success of surgery, as a similarly high proportion of arthroplasty and fusion patients (greater than or equal to 85%) were indeed pleased and satisfied, and the removal of motion as a criterion of success diminishes any differences seen in the relative efficacy rates. The authors stated that longer-term follow-up is needed to ascertain the durability and functional longevity of the STAR ankle replacement in this cohort. The authors explained that the long-term effects of ankle replacement, including sustained functional benefits, options for revision, and impact on incidence of secondary hindfoot arthritis, were not evaluated in this study.

Koivu et al (2009) noted that between 2002 and 2008, 130 consecutive ankles were replaced with an hydroxyapatite (HA) and titanium-HA-coated Ankle Evolutive System total ankle prosthesis. Plain radiographs were analyzed by 2 independent observers. Osteolytic lesions were classified by their size and location, with cavities greater than 10 mm in diameter considered to be "marked". Computed tomography scanning was undertaken in all patients with marked osteolysis observed on the plain radiographs. Osteolytic lesions were seen on the plain films in 48 (37%) and marked lesions in 27 (21%) ankles. The risk for osteolysis was found to be 3.1 (95% CI: 1.6 to 5.9) times higher with implants with Ti-HA porous coating. The authors concluded that care should be taken with ankle arthroplasty until more is known about the reasons for these severe osteolyses.

Yalamanchili et al (2009) stated that TAA is an evolving area of modern orthopedics that is gaining renewed interest after early failures. Implant design has improved with a greater understanding of the complex biomechanics of the ankle joint. Modern ankle prostheses consist of 3 components, including either a fixed or mobile polyethylene-bearing. Only a handful of implants are FDA-cleared for use in the United States, and the experience with some of these implants is limited. Although it is difficult to draw a consensus from the limited studies available, the trend has been towards lower complications and failures than with early implants. Also, multiple recent studies purport better gait and function with TAA. Equivalence with ankle arthrodesis has been suggested but has yet to be conclusively proven. Despite this renewed enthusiasm, surgeons should be aware that complications still exist and can be devastating even in experienced hands. Currently, ankle arthroplasty appears to be a viable alternative to ankle arthrodesis in selected patients. They also noted that although recent studies have been promising, there still is a need for long-term outcomes data and randomized controlled trials. The ultimate role for ankle arthroplasty has yet to be defined.

Bonnin et al (2009) evaluated function and return to sports after TAA. A total of 179 Salto TAA (170 patients) were implanted between 1997 and 2005. A self-administered questionnaire including the Foot Function Index (FFI) and Foot and Ankle Ability Measurement (FAAM) was sent to all patients. At last follow-up, 6 were deceased, 22 were not available for evaluation, and 6 questionnaires were incomplete. A total of 145 questionnaires were available. The mean age was 60.9 years and the
mean follow-up was 53.8 months. The main indications for TAA were osteoarthritis in 100 cases and rheumatoid arthritis in 40 cases. Overall, 15.2 % of the patients said that their operated ankle was "normal"; 60.7 % "nearly normal"; 20 % "abnormal" and 4.1 % "highly abnormal". The FFI scores were 13.7 +/- 17 for "activity limitations", 31.7 +/- 23 for "disability" and 16.9 +/- 19 for "pain". The FAAM scores were 74.9 +/- 18 for activities of daily living and 48.9 +/- 28 for sports activities. On a visual analog scale (0 to 100 where 100 is the "pre-pathology level") the mean rating was 70.2 +/- 19.6 for Activities of Daily Living and 53.7 +/- 28 for sport activities. In patients with osteoarthritis, 38 regularly rode bicycle, 21 perform recreational gymnastics, 58 swimming, 50 home gardening, 27 dancing, and 43 hiking. Seven patients regularly practice tennis, 9 cross-country skiing, 17 downhill skiing, and 6 regularly run more than 500 m. The authors concluded that these findings showed that TAA improved the quality of life and that return to recreational activities was generally possible; but the return to impact sport was rarely possible. This was a study with medium-term results; and approximately 20 % of patients were not available for evaluation, which could have biased the outcomes.

van den Heuvel and colleagues (2010) stated that the ankle joint has unique anatomical, biomechanical and cartilaginous structural characteristics that allow the joint to withstand the very high mechanical stresses and strains over years. Any minor changes to any of these features predispose the joint to osteoarthritis. Total ankle replacement is evolving as an alternative to ankle arthrodesis for the treatment of end-stage ankle osteoarthritis. Initial implant designs from the early 1970s had unacceptably high failure and complication rates. As a result many orthopedic surgeons have restricted the use of TAR in favor of ankle arthrodesis. Long-term follow-up studies following ankle arthrodesis show risks of developing adjacent joint osteoarthritis. Thus, research towards a successful ankle replacement continues. Newer designs and longer-term outcome studies have renewed the interest in ankle joint replacement.

Popelka et al (2010) presented their experience with the Ankle Evolutive System (AES) prosthesis and drew attention to some drawbacks of this surgical treatment. From September 2003 till June 2008, 51 AES ankle replacements were carried out in 51 patients (33 women and 18 men). Their average age at the time of surgery was 53.8 years. The youngest patient was 23 and the oldest was 88 years old. The indication for surgery was rheumatoid arthritis in 10, primary arthritis in 6, and post-traumatic ankle arthritis in 35 patients. Subjects were evaluated in 2008; and follow-up ranged from 4 months to 5 years. Subjects were examined for ankle joint mobility and pain. Radiographs were assessed for potential signs of component loosening. The results presented here were short-term ones. The pre-operative AOFAS score of 33.7 increased to 82.3 points post-operatively. The ROM was on average 20 degrees of plantar flexion and 5 to 10 degrees of dorsiflexion. A total of 35 patients (68.7 %) were free from pain, 11 (21.5 %) experienced slight pain while walking, and 5 (9.8 %) patients reported more intensive pain in the joint treated. Intra-operative complications included a fracture of the medial malleolus in 2 (3.9 %) patients subsequently treated with screw osteosynthesis. Post-operatively, 7 (13.7 %) patients experienced slow healing of the operative wound. One patient had dislocation of the polyethylene liner at 3 months after surgery. Revision surgery was carried out in 7 (13.7 %) patients. Two patients suffering from increasing pain around medial malleolus underwent revision and removal of ossifications. One patient developed necrosis of the talus at 1 year after surgery. She underwent extraction of the prosthesis and ankle arthrodesis with a retrograde locking nail inserted through the heel. A large bony effect arising due to extraction of the necrotic talus was repaired using bone graft. Three (5.8 %) patients developed post-operative instability of the ankle that required revision surgery. The radiographs of another 3 (5.8 %) patients showed bone cysts and signs of tibial component loosening. Of these, 1 patient underwent surgical revision with replacement of the polyethylene liner. Cavities were freed from granuloma induced by polyethylene wear debris, and filled with bone graft from the iliac crest. The authors stated that TAR is a complicated surgical procedure that may results in various technical difficulties and complications. These are inversely proportional to the surgeon's experience, as also shown by literature data. They concluded that the longevity of a TAR depends, much more than in other joint replacements, on an accurate implantation technique and correct indication.
Morgan et al (2010) presented the outcomes in 38 consecutive patients who had TAR using the AES prosthesis with a minimum follow-up of 4 years. Pain and function were assessed using the AOFAS score and regular standardized antero-posterior and lateral weight-bearing radiographs were obtained. Patient satisfaction and complications were recorded and the survival of the implants was demonstrated by the Kaplan-Meier method. The mean follow-up was for 57.8 months (range of 48 to 80). The cumulative survival rate at 6 years was 94.7 % (95 % CI: 80.3 to 98.7). The mean total AOFAS score was 88.1 (range of 53 to 100). The mean score for pain was 35.8 (range of 20 to 40).

Ten patients presented with edge-loading of whom 9 had corrective surgery. Two ankles were revised, 1 to an arthrodesis and the other to replace the tibial component. Nine patients showed radiological evidence of osteolysis. They had minimal non-progressive symptoms and further surgery was not undertaken. Nevertheless, the concerns about osteolysis led to the implant being withdrawn by the manufacturer. The medium-term results of the AES ankle replacement are satisfactory with high patient satisfaction, but the rate of osteolysis is of some concern. The long-term benefit of this procedure has yet to be determined.

A review by the Canadian Agency for Drugs and Technology in Health (Cimon and Cunningham, 2008) concluded that "outcomes for total ankle replacement were comparable to and, in some cases, superior to those for ankle arthrodesis. However, most authors stated that good quality, comparative trials are necessary to confirm their conclusions."

Slobogean et al (2010) found equal improvements in health state values, or utilities reported by a multi-center cohort of subjects with end-stage ankle arthritis treated with ankle arthrodesis or TAA. A total of 107 subjects with end-stage ankle arthritis were enrolled in a multi-center prospective cohort study. All subjects received either ankle arthrodesis or TAA. Participants completed baseline Short Form-36 (SF-36) outcome evaluations pre-operatively and at 1 year follow-up. Preference-based quality of life was assessed using health state values (HSVs) derived from the SF-36 (SF-6D transformation). The investigators reported similar mean baseline SF-6D health state value for the the TAA group and the arthrodesis group. The mean baseline SF-6D health state value for the TAA group was 0.67 (95 % CI: 0.64 to 0.69) and 0.66 (95 % CI: 0.63 to 0.68) for the arthrodesis group. At 1-year followup, the mean reported health state value was equivalent for the TAA group and the arthrodesis group. The mean health state value was 0.73 (95 % CI: 0.71 to 0.76) for the TAA group and 0.73 (95 % CI: 0.70 to 0.76) for the ankle arthrodesis group. The authors noted that these 1-year followup results approach age- and gender-matched population norms for the United States. The authors noted that these health state values poorly correlated with age; however, significant differences between genders were detected. The authors concluded that these data demonstrate improvements in preference-based quality of life following both ankle arthroplasty or arthrodesis.

Gougoulais et al (2010) reported on the results of a systematic evidence review of different types of ankle replacements (STAR, Agility, Buechel-Pappas, Hintegra, Salto, TNK and Mobility). Gougoulais et al (2010) stated that TAA provides an alternative to arthrodesis for management of ankle arthritis. These researchers conducted a systematic literature search of studies reporting on the outcome of TAA. They included peer-reviewed studies reporting on at least 20 TAAs with currently used implants, with a minimum follow-up of 2 years. The Coleman Methodology Score was used to evaluate the quality of the studies. A total of 13 level IV studies of overall good quality reporting on 1,105 TAAs (234 Agility, 344 STAR, 153 Buechel-Pappas, 152 HINETGRA(R)), 98 Salto, 70 TNK, 54 Mobility) were included. Residual pain was common (range of 27 % to 60 %), superficial wound complications occurred in 0 % to 14.7 %, deep infections occurred in 0 % to 4.6 % of ankles, and ankle function improved after TAA. The overall failure rate was approximately 10 % at 5 years with a wide range (0 % to 32%) between different centers.

The authors of the systematic evidence review (Gougoulais et al, 2010) found that "superiority of an implant design over another cannot be supported by the available data." Also, because of heterogeneity of study design and outcome measures, it was not possible to compare TAR with arthrodesis or other alternatives. The authors reported that residual pain after total ankle arthroplasty was relatively frequent (range of 27 % to 60 %), whereas "methodologic flaws in assessing
patients' satisfaction in the individual studies raises concerns regarding the high satisfaction rates reported. The authors found a wide range of rates of ankle failure among studies, with failure rates of up to 1/3 at 5 years having been reported (mean failure rate at 5 years of 10%). Rates of other complications also varied significantly among studies: superficial wound complications occurred in 0% to 14.7%, and deep infections occurred in 0% to 4.6% of ankles. The authors reported that improvement in ankle ROM with TAA was relatively small (0 degrees to 14 degrees). They stated that "patients therefore should be informed preoperatively, improvement in ankle motion is not one of the expected benefits from TAA."

The authors of this systematic evidence review (Gougoulais et al, 2010) noted "numerous limitations" in literature reviewed on TAR. The level of surgeons' experience and variability in patients' selection may have influenced results in the individual studies. Heterogeneity in study design and outcome measures "did not allow direct comparisons of much of the data." The length of follow-up varied among studies, thus reported outcomes are not directly comparable. Different scales and methodologies of assessment (patient recruitment, questionnaires, independent examiner or not) were used in different studies. Comparing functional outcomes of different implants requires caution because of the different methodologies used. The authors noted that "clinical outcome measures frequently were not validated, whereas some TAA implant designers have produced their own outcome scales"; results reported in the individual studies therefore could be biased. Patient satisfaction was not assessed using rigorous validated methods. Definitions of the radiographical variables used in the assessment were not identical in different studies, and the radiographical examinations were not always standardized. The authors noted that results from the prosthesis' inventors can be biased and may reflect the higher familiarity with the implant. In particular, surgeries performed by the designer of the Agility prosthesis reported a 95% survival rate at 6 years, whereas others achieved only 67%. Similarly, the designer of the STAR reported a 95% survivorship rate at 10 years, whereas an independent high-volume surgeon was reported to have a survivorship rate of 80% at 10 years. The designer of the Buechel-Pappas prosthesis reported a 92% survivorship rate at 12 years in 75 TAA with the newer, deep sulcus implant. These results were reproduced by an independent surgeon, however, in patients with rheumatoid arthritis (low demand). "Differences therefore may be symptomatic and reflect the surgeon's familiarity with the procedure, or selection of patients, rather than the effect of the intervention and the implant" (Gougoulais et al, 2010).

Raikin (2010) stated that the ideal candidate for TAA is a low-demand individual with a low body mass index (BMI) who has a good chance of out-living his or her replacement. Raikin stated that this is likely a 60-year old individual with a BMI less than 27 and weight less than 200 lbs whose occupation/lifestyle is relatively sedentary (e.g., no heavy lifting, excessive ladder climbing, or jumping). Raikin stated that the ideal candidate for TAA should have good limb alignment, adequate bone stock to support an arthroplasty, and a good soft tissue envelope around the ankle. Raikin (2010) stated that TAA has limited longevity, currently averaging approximately 80% 10-year survival. In particular, a TAA without ligament stability and appropriate alignment is prone to premature failure. However, the author explained, TAA provides improved biomechanics and diminished stress on other areas compared to ankle arthrodesis. Patients with concomitant subtalar joint arthritis (who would require a tibiotalarcalcaneal fusion) or contralateral ankle arthritis or fusion (who may end up with bilateral ankle fusions) are ideal candidates for TAA, as the morbidity of the fusion alternatives is significantly higher than an isolated ankle fusion.

Zhao et al (2011) provided cumulative data about the intermediate to long-term outcome of STAR in the literature and a summary of survival rate, implant failure rate and reasons. A comprehensive search for all relevant articles published in English and German from January 1995 to May 2011 was conducted. Two reviewers evaluated each study to determine whether it was eligible for inclusion and, if so, collected data of interest. The intermediate to long-term outcomes were determined. Evidence-based meta-analytic pooling of results across studies was performed to determine survival and failure rates. A total of 16 primary studies with 2,088 implants were identified. The mean AOFAS score was 77.8 points, and the mean Kofoed ankle score was 76.4 points. The pooled mean 5-year survival rate was 85.9% [95% CI: 80.9 to 90.3], and the pooled mean 10-year survival rate was 71.1% (95% CI:
Pooled failure rate was 11.1 % (95 % CI: 7.6 to 14.9), with a mean follow-up time of 52 months; 41 % failed within 1 year of initial operation. The first 3 reasons associated with implant failure were aseptic loosening (5.2 %), mal-alignment (1.7 %) and deep infection (1.0 %). The authors concluded that STAR prosthesis achieved encouraging results in terms of intermediate to long-term outcome. The 5- and 10-year survival rates were acceptable. However, the failure rate was still high. The major reasons for implant failure were aseptic loosening and mal-alignment. They stated that maybe the increase of surgeons’ experience and patient selection could improve outcomes and decrease failure rate.

Brunner et al (2013) reported poor long-term outcomes of the Scandanavian Total Ankle Replacement (STAR). From February 1996 to March 2000, 77 ankles in 72 patients (37 females and 35 males, with an average age of 56 years) underwent TAR using the STAR prosthesis with a single coating of hydroxyapatite. Two patients were lost to follow-up, and 12 patients with 13 ankle replacements died. The average duration of follow-up for the patients without revision was 12.4 years (range of 10.8 to 14.9). Sixty-two of the 77 ankles were available for final follow-up; 29 (38 %) of the 77 ankles had a revision of at least one of the metallic components. The probability of implant survival was 70.7 % at 10 years and 45.6 % at 14 years. The main reasons for revision were aseptic loosening, subsidence of the talar component, and progressive cyst formation. Polyethylene insert fractures were observed in 11 ankles. The investigators concluded that, while the short-term to mid-term results for patients managed with the STAR prosthesis have been encouraging at 3.7 years, the long-term survivorship of the same cohort was considerably inferior.

Summers and Bedi (2013) reported on a high rate of failure and reoperation after the Mobility total ankle arthroplasty. Sixty-two consecutive primary total ankle arthroplasties in 60 patients were performed with the use of the DePuy Mobility total ankle system between February 2006 and January 2009. Fifty-eight ankles in 56 patients were followed-up between 14 and 49 months (mean of 32). Eighteen ankles (31 %) underwent an initial reoperation at a mean time of 14 months after primary total ankle arthroplasty. Only 3 ankles (17 %) had improved symptoms after initial re-operation; 8 of these 18 ankles (44 %) underwent a second re-operation. A total of 7 ankles (12 %) had been revised. Overall, 67 % were satisfied, and 79 % stated that they would undergo the same operation again.

Criswell et al (2012) reported high rates of re-operation and revision with the Agility TAA. Investigators retrospectively reviewed 64 patients who had 65 TAAs between June 1999 and May 2001. Information was gathered through chart reviews, mailed-in questionnaires, and telephone interviews. Nine patients had died; data were available for 41 of the remaining 55 patients. Survival was based on revision as an end-point. The minimum follow-up was 0.5 years (median of 8 years; range of 0.5 to 11). Sixteen of the 41 patients (39 %) needed revisions. The average time to revision surgery was 4 years with 6 of the revisions (38 %) occurring within 1 year of the TAA. Of the 25 patients who retained their implants, 12 required secondary surgery for an overall re-operation rate of 28 of 41 (68 %) at an average of 8 years follow-up. The average VAS pain score was 4, the average FAAM sports subscale score was 33, and the average FAAM activities of daily living subscale score was 57. The authors concluded that TAA had high revision and re-operation rates, and patients who retained their implant had only moderate pain relief and function. The investigators stated that TAA must be approached with caution, and that more research is needed to elucidate the role of contemporary TAA.

Labek et al (2011) found that the outcome of TAA as reported in registries is significantly inferior to that reported in clinical trials. The authors conducted a structured literature review regarding sample-based clinical studies and national registry data. To allow for comparative analyses, registry data had to be available for the implants included. These were STAR Ankle, Büchel-Pappas, Hintegra, Mobility, Agility, and Ramses Total Ankle Arthroplasty. The revision rate was used as the main outcome parameter. The authors found that, on average, the revision rates published in sample-based clinical studies were about half the value found in registries. Implant developers represent a share of almost 50 % of the published content and are therefore over-represented in scientific publications. The inventors of STAR Ankle and BP total ankle implants published data which was statistically significantly superior to the outcome achieved in average patients as documented in registries. Irrespective of the
implant, the average revision rate to be expected according to the registry data available is 21.8 % after 5 years, and 43.5 % after 10 years. The authors concluded that the average revision rate published in peer-reviewed scientific articles was significantly lower than the outcome achieved according to national arthroplasty registry data, which reflect actual average patient care in the respective countries. Publications by some research groups, particularly by implant inventors, showed a deviation from the outcome published by other users and those shown in registry data.

Devries et al (2011) stated that the role of TAR is expanding in the United States. As the number of ankles implanted increases, undoubtedly the number of failures will increase. Several reports in the literature have dealt with salvage of the failed TAR through various methods. These researchers performed a retrospective chart and radiographical review on all patients who had conversion from a failed Agility TAR to an INBONE TAR at 2 centers and had been performed at least 12 months prior to the study. Exclusion criteria included any patient converted from a different type of TAR, primary TAR, patients followed less than 12 months, and surgical approach other than the standard anterior incision. Five patients met inclusion criteria. The average age was 65.6 +/- 13.6 years (range of 45 to 79). Complicating co-morbidities were found with 4 patients. The average follow-up was 17.2 +/- 6.6 months (range of 7 to 25). The cause of failure of the original Agility TAR was coronal plane deformity in 3 patients, and 1 patient each failed from extensive heterotopic ossification or infection. All patients presented with pain. In 4 cases, there was component subsidence at the talus, tibia, or both. All patients had adjunctive procedures at the time of the revision, including malleolar screw placement in 4 patients and hindfoot arthrodesis in 2 patients. All patients had either 4 or 5 tibial stem components placed. During the follow-up period, 3 patients required additional surgery, including 2 patients classified as failures (1 transtibial amputation and 1 tibiotalocalcaneal arthrodesis). The authors concluded that this salvage option is technically demanding. They cautioned against TAR revision by conversion in the place of previous infection and in ankle imbalance not amenable to reconstruction. In all cases the initial deformity was corrected. The early results, however, demonstrated high-risk of early failure and positional changes.

Hintermann et al (2011) noted that in the last 20 years TAR has become a viable alternative to arthrodesis for end-stage osteoarthritis of the ankle. Numerous ankle prosthesis designs have appeared on the market in the past and attracted by the encouraging intermediate results reported in the literature, many surgeons have started to perform this procedure. With increased availability on the market the indications for TAR have also increased in recent years. In particular, TAR may now be considered even in younger patients. Thus, despite progress in TAA the number of failures may increase. Up to now, arthrodesis was considered to be the gold standard for salvage of failed ankle prostheses. Because of extensive bone loss on the talar side, in most instances tibiocalcaneal fusion is the only reliable solution. An alternative to such extended hindfoot fusions would be revision arthroplasty. To date, however, there are no reported results of revision arthroplasty for salvage of a failed ankle replacement. Based on the authors’ experience, prosthetic components with a flat under-surface are most likely to be able to find solid support on remaining bone stock. The first 83 cases (79 patients, 46 males, 33 females, average age of 58.9 years, range of 30.6 to 80.7 years) with a average follow-up of 5.4 years (range of 2 to 11 years) showed good-to-excellent results in 69 cases (83 %), a satisfactory result in 12 cases (15 %) and a fair result in 2 cases (2 %) and 47 patients (56 %) were pain-free. Primary loosening was noted in 3 cases and of these 2 cases were successfully revised by another TAR and in 1 case with arthrodesis. Another case with hematogenous infection was also revised by arthrodesis. At the last follow-up control 2 components were considered to be loose and the overall loosening rate was thus 6 %. The authors concluded that this series has proven that revision arthroplasty can be a promising option for patients with failed total ankle prosthesis. The most challenging issue is the solid anchoring of available components on residual bone. More experience is needed, however, to better define the possibilities and limitations of revision arthroplasty.

Williams et al (2015) reported on a retrospective review of 35 cases of failed Agility TAA that were revised to an INBONE II TAA at 1 institution. Patient demographics, indications for revision, radiographs, and complications were reviewed. The average follow-up was 9.1 months (range of 0 to 28). All revisions were performed by 1 of 2 foot and ankle surgeons familiar with both prostheses. The
Agility TAA lasted a mean of 6.7 years prior to revision to an INBONE II TAA. Revision TAA was indicated due to mechanical loosening, osteolysis, periprosthetic fracture, and a dislocated prosthesis. Adjunctive procedures were performed in 31 of 35 cases. There were 6 intra-operative and 5 acute post-operative complications, leading to an overall 31.4% complication rate. There was 1 patient with continued pain post-operatively who underwent a second revision of the INBONE II 20 months post-operatively.

Ellington and colleagues (2014) reported on a retrospective review of 53 patients who underwent revision TAR and had been followed for a minimum of 2 years. Patients were assessed radiographically and with outcome scores. The rates of conversion to amputation or fusion were also assessed. The mean follow-up period was 49.1 months after the revision arthroplasty. The average time from primary TAR to revision was 51 months; 41 of the 53 patients (77%) were available for follow-up. The revision arthroplasty had been converted to an arthrodesis in 5 of the 41 patients, and 2 additional patients had undergone amputation. The most common indication for revision TAR was talar subsidence (63%; 26 of 41). Twenty-two patients (54%) had a subtalar arthrodesis performed at the time of the revision arthroplasty, with 19 of those having a custom-designed long-stem talar component placed simultaneously. The mean radiographic measurements of component position did not change significantly post-operatively. The mean post-operative scores for the 34 patients with a retained TAR were: 4.4 of 10 possible points on a visual analog pain scale (VAS), 65 of 100 possible points on the AOFAS hindfoot scale, 93.5 of 100 possible points on the Short-Form 12 (SF-12), 137.9 of 204 possible points on the Revised Foot Function Index (FFI-R), and 64 of 180 possible points on the Ankle Osteoarthritis Scale (AOS). The mean arc of motion radiographically was 18° pre-operatively and 23° post-operatively, with all improvement occurring in plantar flexion. A lesser amount of pre-operative talar subsidence was a significant predictor of a good outcome based on the AOFAS hindfoot score (p < 0.03) and the AOS (p < 0.01) score.

Hintermann et al (2013) reviewed a consecutive series of 117 cases (116 patients [56 female and 60 male]; mean age of 55.0 ± 12.0 years) in which a TAA failed after a mean of 4.3 years and was revised with use of the HINTEGRA 3-component total ankle prosthesis. The reason for revision involved the metallic components in 60 ankles (51%), the bone in 28 (24%), the soft tissues in 20 (17%), and infection in 9 (8%). The talar component was revised in 104 ankles (89%) and the tibial component, in 106 (91%). Early complications included a fracture of the malleoli in 2 ankles and a dislocation of the polyethylene insert in 1. Seventeen (15%) of the revision arthroplasties required further revision surgery, in most cases for loosening of 1 or 2 of the prosthetic components. The mean AOFAS hindfoot score for the remaining 100 ankles (85%) improved from 44 ± 18 pre-operatively to 72 ± 19 (p < 0.01) at the time of the latest follow-up (mean of 6.2 years). The estimated survival of the revision arthroplasties at 9 years, with loosening of components as the end-point, was 83%. The prevalence of component loosening was higher (p < 0.005) with the use of single-coated hydroxyapatite components (6 of 23 ankles, 26%) than with double-coated components (5 of 94 ankles, 5%). The correlation between the extent of bone loss at the resection surface and the prevalence of component failure was weak and not significant.

The Agility LP Total Ankle (DePuy Orthopaedics, Inc., Warsaw, IN) received 510(k) approval (K053569) from the FDA on March 31, 2006. The device was approved as a line extension to the Agility Total Ankle system components (cleared as DePuy Alvine Total Ankle Prosthesis under K920802, December 17, 1992). The device is intended for use in patients with end stage ankle disorders as an alternative to ankle fusions.

The Eclipse Total Ankle (Integra LifeSciences, Plainsboro, NJ) received 510(k) approval (K061749) from the FDA on November 22, 2006. The Eclipse Total Ankle replacement system is intended for prosthetic replacement of the tibio-talar joint in patients affected with degenerative arthritis, post-traumatic arthritis, or severe rheumatoid arthritis. It is also intended for revision of prior ankle surgery, and is intended for use with bone cement.

The INBONE Total Ankle (formerly Topez Total Ankle) (Wright Medical Technology, Inc., Arlington, TN)
received 510(k) approval (K103374) from the FDA on December 14, 2010. The device is indicated for patients with ankle joints damaged by degenerative arthritis, post-traumatic arthritis, or severe rheumatoid arthritis. The INBONE II Total Ankle received 510(k) approval (K100886) on August 26, 2010.

The Salto Talaris Total Ankle Prosthesis (Tornier, Inc., Bloomington, MN) received 510(k) approval (K060544) from the FDA on November 13, 2006. The device is indicated as a total ankle replacement device in primary or revision surgery for patients with ankle joints damaged by degenerative arthritis, post-traumatic arthritis, or severe rheumatoid arthritis.

The Zimmer Trabecular Metal Total Ankle (Zimmer, Inc., Warsaw, IN) received 510(k) approval (K120906) from the FDA on August 12, 2012. The device is intended to provide a patient with limited mobility by restoring alignment, reducing pain and preserving the flexion/extension movement within the ankle joint. It is indicated as a total ankle replacement in primary or revision surgery for patients with degenerative arthritis, post-traumatic arthritis, or severe rheumatoid arthritis. This device is intended for cemented use only.

Van Heiningen et al (2013) stated that while arthrodesis is the standard treatment of a severely arthritic ankle joint, TAA has become a popular alternative. This review provided clinical outcomes and complications of both interventions in patients with rheumatoid arthritis. Studies were obtained from PubMed, Embase and Web of Science (January 1980 to June 2011) and additional manual search. Inclusion criteria: original clinical study, greater than 5 rheumatoid arthritis (population), internal fixation arthrodesis or 3-component mobile bearing prosthesis (intervention), ankle scoring system (outcome).

The clinical outcome score, complication and failure rates were extracted and the methodological quality of the studies was analyzed. A total of 17 observational studies of 868 citations were included. The effect size concerning TAA ranged between 1.9 and 6.0, for arthrodesis the effect sizes were 4.0 and 4.7. Re-operation due to implant failure or re-operation due to nonunion, was 11 % and 12 % for TAA and arthrodesis, respectively. The methodological quality of the studies was low (mean 6.4 out of a maximum of 14 points) and was lower for arthrodesis (mean 4.8) as compared to arthroplasty (mean 7.8) (p = 0.04). The authors concluded that 17 observational and no (randomized) controlled clinical trials are published on the effectiveness of arthroplasty or arthrodesis of the ankle in rheumatoid arthritis. They stated that regardless of the methodological limitations it can be concluded that both interventions show clinical improvement and in line with current literature neither procedure is superior to the other.

In a prospective study, Daniels et al (2014) evaluated intermediate-term outcomes of ankle replacement and arthrodesis in a large cohort at multiple centers, with variability in ankle arthritis type, prosthesis type, surgeon, and surgical technique. These researchers hypothesized that patient-reported clinical outcomes would be similar for both procedures. Patients in the Canadian Orthopaedic Foot and Ankle Society (COFAS) Prospective Ankle Reconstruction Database were treated TAA (involving Agility, STAR, Mobility, or HINTEGRA prostheses) or ankle arthrodesis by 6 subspecialty-trained orthopedic surgeons at 4 centers between 2001 and 2007. Data collection included demographics, co-morbidities, and the Ankle Osteoarthritis Scale (AOS) and SF-36 scores. The pre-operative and latest follow-up scores for patients with at least four years of follow-up were analyzed. Sensitivity analyses excluded ankles that had undergone revision. A linear mixed-effects regression model compared scores between the groups, adjusting for age, sex, side, smoking status, BMI, inflammatory arthritis diagnosis, baseline score, and surgeon. Of the 388 ankles (281 in the TAA group and 107 in the arthrodesis group), 321 (83 %; 232 TAA and 89 arthrodoses) were reviewed at a mean follow-up of 5.5 ± 1.2 years. Patients treated with arthrodesis were younger, more likely to be diabetic, less likely to have inflammatory arthritis, and more likely to be smokers. Seven (7 %) of the arthrodoses and 48 (17 %) of the TAA underwent revision. The major complications rate was 7 % for arthrodesis and 19 % for TAA. The AOS total, pain, and disability scores and SF-36 physical component summary score improved between the pre-operative and final follow-up time-points in both groups. The mean AOS total score improved from 53.4 points pre-operatively to 33.6 points at the time of follow-up in the arthrodesis group and from 51.9 to 26.4 points in the TAA group. Differences in
AOS and SF-36 scores between the arthrodesis and TAA groups at follow-up were minimal after adjustment for baseline characteristics and surgeon. The authors concluded that intermediate-term clinical outcomes of TAA and ankle arthrodesis were comparable in a diverse cohort in which treatment was tailored to patient presentation; rates of re-operation and major complications were higher after TAA.

Gaudot et al (2014) noted that TAA is available with fixed-bearing (FB) or mobile-bearing (MB) versions, and there is little consensus on the benefits and drawbacks of each type. In a retrospective case-control study, these investigators compared clinical outcomes of statistically paired series of FB and MB versions of the same ankle prosthesis. The study was a multi-center retrospective comparison between 2 groups: (i) the FB group of 33 consecutive Talaris cases and (ii) the MB group of 33 "paired" Salto cases, selected from a database of 313 consecutive cases to statistically match etiology, age, and pre-operative AOFAS score. All patients were operated upon with the same operative technique and received identical pre- and post-operative clinical and radiographic assessments. The mean follow-up was 24 months for the FB group and 23 months for the MB group. There was no statistical difference between results of the 2 groups in terms of accuracy of positioning, clinical and radiographic mobility, and morbidity. The most recent post-operative AOFAS scores were higher for the FB group than for the MB group (p = 0.05). Radiolucent lines were observed in 4 FB patients versus 13 MB patients (p = 0.02). Subchondral cysts were noted in 1 FB patient and in 8 MB patients (p = 0.01). The authors concluded that there was no notable difference in clinical performance of the FB and MB implants with the numbers available. This short-term study demonstrated that FB ankle arthroplasty had results equivalent to, if not better than, MB ankle arthroplasty. Moreover, they stated that longer follow-up is needed to determine the success of this new generation of ankle arthroplasty.

Pugely et al (2014) noted that TAR has gained acceptance as an alternative to traditional ankle arthrodesis (AA) for end-stage ankle arthritis. Little is known about long-term trends in volume, utilization, and patient characteristics. These researchers used longitudinal data to examine temporal trends in TAR and AA. They identified all United States fee-for-service Medicare beneficiaries who underwent TAR and AA between 1991 and 2010 (n = 5,871 and 29,532, respectively). They examined changes in patient demographics and co-morbidity, nationwide and hospital volume, per capita utilization, and length of stay (LOS). Between 1991 and 2010, both TAR and AA patients had modest shifts in characteristics, with higher rates of diabetes and obesity. Overall, TAR Medicare volume increased by more than 1,000 % from 72 procedures in 1991 to 888 in 2010, while per-capita standardized utilization increased 670.8 % (p < 0.001). Ankle arthrodesis volume increased 35.8 % from 1,167 procedures in 1991 to 1,585 in 2010, while per-capita standardized utilization declined 15.6 % (p < 0.001). The percentage of all U.S. hospitals performing TAR increased nearly 4-fold from 3.1 % in 1991 to 12.6 % in 2010, while the proportion performing AA remained relatively unchanged. Length of stay decreased dramatically from 8.7 days in 1991 to 2.3 days in 2010 in TAR and from 5.5 days to 3.2 days in AA (p < 0.001). The authors concluded that between 1991 and 2010, Medicare beneficiaries undergoing either TAR or AA became more medically complex. Both volume and per-capita utilization of TAR increased dramatically but remained nearly constant for AA. At the same time, mean hospital volume for both procedures remained low.

Raikin et al (2014) used a nationwide database to compare epidemiologic profiles of TAR and ankle fusion (AF). Data collected for the Nationwide Inpatient Sample (NIS) from 2000 to 2010 were reviewed. Procedures were identified by searching for ICD-9-CM codes 81.11 (AF) and 81.56 (TAR). Patients' demographics and co-morbidities, geographic distribution, and cost of procedures were compared. The NIS analysis identified 2,666 TAR and 16,419 AF cases, which was extrapolated to 13,145 TAR and 80,426 AF nationwide. Spearman's ρ showed an increase in the number of AF per year while the number of TAR cases remained relatively flat per year until 2006, after which there was a steady increase in the number of TAR performed. Patients receiving a TAR tended to be older, female, and white. Patients who underwent AF were more likely to be obese or diabetic than TAR patients. Both TAR and AF were performed more frequently in private urban hospitals through 2007. However, in 2010, the number of TAR procedures was greater in academic centers compared to private urban hospitals. The authors concluded that despite recent increases in the number of TAR
implanted, AF was still performed more than 6 times more frequently for advanced ankle arthropathy. A trend was demonstrated toward an increasing number of TAR being implanted in academic centers, and in patients with more underlying co-morbidities than was previously seen.

**Fresh Frozen Section Analysis:**

Monaco and colleagues (2016) noted that the use of intra-operative fresh frozen section (FFS) analysis to determine the presence of infection has been well-reported in orthopedic studies. Specifically, the number of polymorphonuclear leukocytes per high-power field has been used to diagnose total joint arthroplasty-related infection. Less commonly, reconstructive surgeons have extended the use of FFS analysis for intra-operative evaluation when suspicion of deep infection with or without hardware is high. In a pilot study, these investigators retrospectively reviewed the data from 11 patients undergoing foot and ankle reconstruction in the setting of possible deep infection and determine the usefulness of FFS analysis. A retrospective review of the medical records of patients who had undergone reconstructive foot and ankle revision surgery with intra-operative FFS analysis and tissue/swab cultures available was performed. A positive FFS was defined as greater than 5 polymorphonuclear leukocytes per high-power field. A positive frozen section was associated with a positive tissue culture 4 of 7 times (57%). The sensitivity and specificity of FFS analysis for infection was 80% and 50%, respectively. The positive and negative predictive value of the FFS result was 57.1% and 75%, respectively. The authors concluded that FFS analysis and intra-operative cultures correlated only 57% of the time in the present series. This test had moderate sensitivity for detecting infection at 80%, but the specificity was poor (50%). They stated that more research is needed to further evaluate the role of FFS analysis in foot and ankle surgery.

**CPT Codes / HCPCS Codes / ICD-10 Codes**

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

**CPT codes covered if selection criteria are met:**
- 27702: Arthroplasty, ankle; with implant (total ankle)
- 27703: revision, total ankle

**CPT codes not covered for indications listed in the CPB:**
- 88331 - 88332: Pathology consultation during surgery

**Other CPT codes related to the CPB:**
- 27870: Arthrodesis, ankle, open

**Other HCPCS codes related to the CPB:**
- C1713: Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)
- C1776: Joint device (implantable)

**ICD-10 codes covered if selection criteria are met:**
- M05.071 - M05.079: Rheumatoid arthritis, ankle and foot
- M05.271 - M05.279
- M05.371 -
M05.379 - M05.479
M05.579
M05.679
M05.779
M05.879
M06.079
M06.279
M06.379
M06.679
M06.879
M08.079
M08.279
M08.479
M08.879
M08.979
M12.079
M12.579
M19.079
M19.179
M19.279
M97.8xx+
T81.89x+
T84.018+, T84.028+, T84.038+, T84.058+, T84.068+
T84.59x+
T84.81x+

M12.571 - Traumatic arthropathy, ankle and foot
M19.071 - Primary osteoarthritis, ankle and foot
M19.171 - Post-traumatic and secondary osteoarthritis, ankle and foot

Periprosthetic fracture around other internal prosthetic joint
Other complications of procedures, not elsewhere classified
Complications of internal orthopedic prosthetic devices, implants or grafts [joint]
Embolism due to internal orthopedic prosthetic devices, implants and grafts
<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>T84.86x+</td>
<td>Other specified complication of internal orthopedic prosthetic devices, implants and grafts</td>
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<td>T84.89x+</td>
<td>Infection and inflammatory reaction due to internal joint prosthesis</td>
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<tr>
<td>T84.50x+ - T84.59x+</td>
<td>Other specified complication of internal orthopedic prosthetic devices, implants and grafts</td>
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<tr>
<td>Z98.1</td>
<td>Arthrodesis status [covered for arthrodesis of the contralateral ankle]</td>
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</table>

**ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):**

- **A02.23** Salmonella arthritis
- **A39.83 - A39.84** Meningococcal and postmeningococcal arthritis
- **A48.0** Gas Gangrene
- **A51.46** Secondary syphilitic osteopathy
- **A52.11** Tabes dorsalis and charcot's arthropathy (tabetic)
- **A52.16**
- **A52.77** Syphilis of bone
- **A54.40 - A54.49** Gonococcal infection of musculoskeletal system
- **B06.82** Rubella arthritis
- **E66.01 - E66.9** Overweight and obesity
- **F01.50 - F99** Mental disorders [that hinder adequate cooperation during perioperative period]
- **G57.00 - G57.93** Mononeuritis of lower limb [resulting in lack of normal muscle function about the affected ankle]
- **G70.00 - G70.9** Myoneural disorders [resulting in lack of normal muscle function about the affected ankle]
- **I70.201 - I70.299** Atherosclerosis of native arteries of the extremities
- **I70.261 - I70.269** Atherosclerosis of extremities with gangrene, raynaud's syndrome with gangrene and gangrene
- **I70.361 - I70.369**
- **I70.461 - I70.469**
- **I70.561 - I70.569**
- **I70.661 - I70.669**
- **I70.761 - I70.769**
- **I73.01**
- **I96**
- **I70.301 - I70.799** Atherosclerosis of bypass graft of the extremities
- **I70.92** Chronic total occlusion of artery of the extremities
- **I73.00 - I73.9** Other peripheral vascular disease
- **I83.001 - I83.93** Varicose veins of lower extremities
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<th>Code Range</th>
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<td>Non-pressure chronic ulcer of ankle</td>
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<td>Infectious arthropathies ankle and foot</td>
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<td>M00.079</td>
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<td>M00.171 -</td>
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<td>M00.871 -</td>
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<td>M21.071 -</td>
<td>Acquired deformities of ankle and foot [precluding plantigrade foot]</td>
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<td>ICD Code</td>
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<td>M21.379</td>
<td>Other disorders of soft tissues [insufficient ligament support that cannot be repaired with soft tissue stabilization]</td>
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<td>Other joint derangement [ankle and foot] [that cannot be repaired with soft tissue stabilization]</td>
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M86.379
M86.471 -
M86.479
M86.571 -
M86.579
M86.671 -
M86.679
M86.8x7

M86.9 Unspecified osteomyelitis and periositis, ankle and foot

M87.071 -
M87.073
M87.171 -
M87.173
M87.271 -
M87.273
M87.371 -
M87.373
M87.871 -
M87.873

M89.671 -
M89.679

M89.671 - Osteopathy after poliomyelitis, ankle and foot
M89.679

M90.871 -
M90.879

M90.871 - Osteopathy in diseases classified elsewhere, ankle and foot
M90.879

Q66.0 - Q66.9 Congenital deformities of feet [precluding plantigrade foot]

Q68.2 Congenital deformity of knee (joint) (significant malalignment of the knee joint)

S75.001+
S75.299+
S85.001+ -
S85.999+

S81.001+ -
S81.859+
S91.001+ -
S91.059+

S82.301+ -
S82.309+
S82.391+ -
S82.399+
S82.51x+ -
S82.66x+
S82.841+ -
S82.856+
S82.871+ -
S82.899+
S89.101+ -
S89.199+
S89.301+ -
S89.399+
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<td>Sprains and strains of ankle and foot [that has adversely affected ankle bone quality]</td>
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<td>Numerous options Fracture of lower extremities, sequelae</td>
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<tr>
<td></td>
<td>Numerous options Sprain and strain of ankle, without mention of tendon injury, sequelae [that has adversely affected ankle bone quality]</td>
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<tr>
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<td>Numerous options Tendon injury, sequelae [that has adversely affected ankle bone quality]</td>
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<tr>
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<td>Numerous options Contusion of ankle, sequelae [that has adversely affected ankle bone quality]</td>
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<tr>
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<td>Numerous options Crushing injury of ankle, sequelae [that has adversely affected ankle bone quality]</td>
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<tr>
<td></td>
<td>Numerous options Burn of other extremities, sequelae [that has adversely affected ankle bone quality]</td>
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<td></td>
<td>Numerous options Burn of lower limb(s) [that has adversely affected ankle bone quality]</td>
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<tr>
<td>T33.011+</td>
<td>Superficial frostbite and frostbite with tissue necrosis [that has adversely affected ankle bone quality]</td>
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<td>Traumatic secondary and recurrent hemorrhage and seroma [that has adversely affected ankle bone quality]</td>
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<td>T79.2xx+</td>
<td>Disruption of wound</td>
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The above policy is based on the following references:


58. Schuberth JM, Patel S, Zarutsky E. Perioperative complications of the Agility total ankle replacement in 50 initial, consecutive cases. J Foot Ankle Surg. 2006;45(3):139-146.


78. Cimon K, Cunningham J. Total ankle replacements: Clinical effectiveness and a review of the guidelines. Health Technology Inquiry Service (HTIS). Ottawa, ON: Canadian Agency for Drugs and Technologies in Health (CADTH); October 20, 2008.


91. Naal FD, Impellizzeri FM, Rippstein PF. Which are the most frequently used outcome instruments in studies on total ankle arthroplasty? Clin Orthop Relat Res. 2010;468(3):815-826.


132. US Food and Drug Administration (FDA) Website. Summary and effectiveness data: Infinity total


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0645 Total Ankle Arthroplasty

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania

updated 01/12/2017