2:00 – 3:00 pm
SESSION 6:
ANKLE ARTHROPLASTY

Moderators:
Steven L. Haddad, MD
(Glenview, Illinois)

John S. Reach, Jr, M.Sc., MD
(New Haven, Connecticut)
There was a time in the not too distant past where correcting varus and valgus deformities with available US total ankle prostheses was fraught with complication and failure. Even adhering to fundamental principles of ligament and structural balance resulted in recurrence of deformity due to the inadequacy of the ankle prosthesis itself to provide inherent stability. Our own study (Kadakia, Haddad, 2007) found that arthritic ankles with a greater than 20 degree pre-operative varus deformity, and a 15 degree preoperative valgus deformity, had respectable initial correction (immediately following surgery), which failed 75% of the time over a 2 year interval.

Interestingly, there is no definition of failure in total ankle arthroplasty. In total knee literature, failure is defined as postoperative coronal plane incongruence of greater than 3 degrees. Authors in the ankle replacement literature have chosen 5 degrees of tilt to define failure, though there is nothing to support whether that specific number leads to increased risk of osteolysis or component subsidence. Of course, though there is no literature to define an absolute number, the surgeon strives for a perfect coronal plane alignment to minimize any risk of late-term failure of the prosthesis. Those surgeons who perform any volume of total ankle arthroplasties recognize that any methodology that minimizes component failure and subsequent need for challenging revision surgery is a welcome addition to this endeavor.

To answer the primary question, I would strongly suggest that pre-existing varus and valgus matters much less than it did in the past given the host of more intrinsically stable prostheses we now have at our disposal. Over the past 17 years of modern total ankle replacement arthroplasty, we have learned both extra-articular techniques to minimize prosthetic tilt, and attempts at prosthetic placement to minimize said tilt. Some of these methods worked well, others did not work at all, and some are in evolution.

Personally, I have learned that challenging deformities are best corrected through a staged procedure. There are, however, a number of experienced and extremely competent ankle replacement surgeons who debate this point. Both camps agree that a perfect prosthetic balance, as well as a perfect extra-articular balance, must be achieved at the conclusion of the procedure(s). One stage prosthetic reconstruction certainly has advantages for the patient, including a shorter recovery time and shorter anesthetic risk. However, I would argue that, for challenging deformities, two stage procedures allow the surgeon to ensure that the extra-articular components are in perfect balance, making the second stage (prosthesis implantation) as simple as any non-deformity ankle replacement procedure. In addition, I have learned that there are contrasting surgical principles which intrinsically make less sense with one-stage ankle reconstruction in challenging deformities. For instance, our post-operative goal with any fusion operation is some form of extended immobilization to allow successful fusion. In contrast, our post-operative goal with any ankle replacement operation is early motion to prevent disappointing post-operative stiffness. Despite this prejudice, I would agree with the “one-stage camp”
that inherent stability of modern ankle joint prostheses allow greater latitude in deformity correction within the index operation.

For major deformities, the type that was previously uncorrectable by ankle replacement, a few of the “envelope pushers” have learned the power of prostheses to assist in a mobile ankle joint. This becomes particularly important for those patients with prior (or current) hindfoot fusions, as extension to pantalar fusion leads to a much less desirable outcome. These are real issues that do need tackling, as symptomatic adjacent joint arthritis is a phenomenon that leads to great patient dissatisfaction following joint fusion. Thus, techniques to tackle these deformities with joint replacement become pivotal to increasing patient satisfaction through dissipation of joint contact stresses on these adjacent joints.

To achieve major deformity correction, I begin by correcting the ankle deformity by releasing contracture preventing reduction, then pinning the ankle in neutral (with fluoroscopic confirmation) in both the coronal and sagittal planes (critical point). The bone work is then done beneath the ankle joint to ensure the hindfoot and forefoot is plantigrade. This is followed by the ligament work, lateral and medial, which, in major deformity correction, generally requires allograft tendon reconstruction for the longstanding deficient ligaments. I then fill the gap in the ankle joint (either medial or lateral erosion) with liquid methylmethacrylate, allowing it to harden completely before withdrawing the pin that traverses the ankle joint. Now, the ankle is in neutral, and the foot beneath it is plantigrade. This ankle is casted non-weight bearing for 6wks, followed by full weight bearing in a CAM boot. By twelve weeks post-operative, the patient can stand independently, and I can make a thorough assessment of any residual deformity that may require correction at the time of total ankle replacement. Note that such additions are often minor, from a calcaneal osteotomy to a Cotton osteotomy, which does not add significantly to the ankle replacement second stage. I have the patient bear full weight to both ensure the patient is satisfied with the corrected alignment, and to minimize disuse osteopenia that can compromise prosthesis fixation in the second stage.

The second stage occurs anywhere from 3.5 months to 4 months postoperatively. The ankle replacement is now routine and straightforward, regardless of the prosthesis chosen. Stability is assessed, but with ample time for ligament healing, does not require supplementation. Gutter debridement can be aggressive at this time to allow good prosthesis motion, as the stable bone alignment prevents deformity recurrence.

References:


Causes of total ankle failure
1) Prosthesis failure
   a) Poly wear
   b) Implant fracture

2) Osteolysis / Bone Loss
   a) Wear particles
   b) Infection
   c) Loose prosthesis

3) Infection
   a) Superficial infection
   b) Deep Infection

4) Loosening
   a) Mal-positioning
   b) Mal-Adherence (non-compliance)

Solutions
1) Non-Operative (Brace, Meds, etc)

2) Bone graft
   a) Impaction grafting
   b) Bulk / Structural
   c) Vascularized

3) Replace total ankle parts
   a) Polyethylene
   b) Tibia
   c) Talus

4) Replace whole total ankle
   a) Same implant
   b) Different Primary Implant
   c) Custom / Revision Implant

5) Fuse ankle
   a) Internal fixation
b) External fixation

6) Staged Reconstruction
   a. Removal All Non-viable material/ tissue
   b. Biopsy tissue and obtain accurate Culture and Sensitivity
   c. Maintain Anatomy (Spacer)
   d. Eliminate infection (with Infectious Disease consultation)
   e. Re-Biopsy (ensure infection obliterated)
   f. Achieve Soft-tissue Coverage
   g. Reconstruct functional anatomy

7) Amputation
SESSION 6: ANKLE ARTHROPLASTY

Moderators:
Steven L. Haddad, MD (Glenview, Illinois)  
John S. Reach, Jr, MD (New Haven, Connecticut)

SESSION 6: 2:30 pm

Prospective Randomized Trial Comparing the Agility™ LP versus Mobility™ Total Ankle Replacement Systems
Presenting:
J. Chris Coetzee, MD (Edina, Minnesota)
Mark S. Myerson, MD; Patrick B. Ebeling, MD; Rebecca Stone, MS, ATC; Mary Panozzo, CCRA; Jeffrey A. Murphy, MS

Introduction
There is ongoing controversy between fixed versus mobile bearing devices as the best option in ankle replacements. Up to now no study looked at two ankle replacements systems in a true prospective randomized fashion. All previous reports were either a longitudinal case study looking at one device, or some form of comparison to other devices in a non-randomized fashion. This is therefore the first ever prospective randomized trial, not only comparing two ankle replacements systems, but also a fixed versus a mobile bearing system.

Methods
Appropriate IRB and FDA approval was obtained to collect data from multiple centers. Appropriate inclusion and exclusion criteria were followed and patients who chose to enroll were randomized into either an Agility LP or Mobility group.
111 patients (57 Mobility, 54 Agility LP) were recruited into the study, of which 91 (46 Mobility, 45 Agility LP) have more than two year follow-up. Weightbearing X-rays and AOFAS outcomes forms were completed pre-operatively, and at 3, 6, 12, 24 and 36 months post-operatively. (listed in table below)

Results
The average age in the Mobility group was 65 (50-79) and 63.1 (47-79) in the Agility LP group. BMI was 28.3 (20-35) in the Mobility and 28.8 (21-36) in the Agility LP group. In the Mobility group 58% had osteoarthritis, 35% post traumatic and 7% Rheumatoid. In the Agility LP group 43% had osteoarthritis, 50% post traumatic and 7% Rheumatoid arthritis.

<table>
<thead>
<tr>
<th>Interval</th>
<th>Mobility</th>
<th>Agility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AOFAS Ankle Hind</td>
<td>Foot Total Score</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
</tr>
<tr>
<td>Pre-Op</td>
<td>50</td>
<td>39.2</td>
</tr>
<tr>
<td>3 Month</td>
<td>51</td>
<td>77.9</td>
</tr>
<tr>
<td>6 Month</td>
<td>53</td>
<td>82.2</td>
</tr>
<tr>
<td>12 Month</td>
<td>55</td>
<td>82.3</td>
</tr>
<tr>
<td>24 Month</td>
<td>46</td>
<td>88.2</td>
</tr>
</tbody>
</table>
There was no statistical difference in the AOFAS ankle and hindfoot score at any interval, except 48 months where the 92.9 average score for the Mobility ankles was significantly higher (p-value = 0.023) than the average 79.0 Agility ankle scores. (The p-value was 0.416 at 2 years).

Range of motion was not statistically different between the two groups at any time interval.

Two-Year Post-Operative Scores

<table>
<thead>
<tr>
<th></th>
<th>Mobility (n=46)</th>
<th>Agility (n=45)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two-Year TTJ DF</td>
<td>12.7 +/- 6.7</td>
<td>12.1 +/- 8.5</td>
<td>0.747</td>
</tr>
<tr>
<td>Two-Year TTJ PF</td>
<td>13.3 +/- 9.0</td>
<td>12.4 +/- 8.6</td>
<td>0.673</td>
</tr>
<tr>
<td>Two-Year ankle/Foot DF</td>
<td>23.2 +/- 8.3</td>
<td>24.2 +/- 9.2</td>
<td>0.639</td>
</tr>
<tr>
<td>Two-Year ankle/Foot PF</td>
<td>40.1 +/- 8.5</td>
<td>38.1 +/- 11.5</td>
<td>0.412</td>
</tr>
</tbody>
</table>

Total foot/ankle ROM for the Mobility group was 63 degrees at two years, while 62 degrees in the Agility group.

Over the term of the study 5 of the 111 patients were withdrawn. One for inability to continue with follow-up, one did not meet the inclusion criteria, and 3 required revisions. (2 Agility LP, 1 Mobility).

Intra-operative malleolar fractures occurred in 7/54 Agility LP cases (13.0%) and 2/57 Mobility (3.5%) A further four Agility cases developed malleolar fractures postoperatively. Two Mobility patients developed medial malleolar stress fractures one year postoperatively. There were wound problems in 5 Agility LP and 3 Mobility patients, one of which (Agility LP) was serious and needed a skin graft for coverage. Three Agility LP and two Mobility patients had objective complaints of impingement after 6
months. There were signs of device-related loosening of components in 3 Agility LP and 5 Mobility ankles.
One Mobility patient was revised after a year due to anterior subluxation of the talus as a result of a surgical error. One out of each group was converted to an arthrodesis due to early failure of the replacement. There were a total of 7 revisions, 3 Mobility and 4 Agility. Syndesmosis non-unions occurred in 6% of the Agility cases.

Discussion
There are complications inherent to the Agility LP replacement including the syndesmosis non-union and a higher incidence of malleolar fractures. Other than that there were no statistical differences in range of motion, or outcome scores at minimum two year follow-up. The Mobility Ankle is not available in the USA and the FDA trial enrollment was terminated in 2009.
SESSION 6: 2:35 pm

A Retrospective Comparison of Total Ankle Arthroplasty versus Arthroscopically Assisted Ankle Fusion for End Stage Ankle Arthritis

Presenting:
Joan Ryan Williams, MD (Chicago, Illinois)
Jamie L. Lynch, MD; Steven A. Kodros, MD; Armen S. Kelikian, MD; Brian E. Abell, MD

Introduction:
The use of noncemented anatomic total ankle prostheses are gaining widespread use in the United States. However, ankle fusion remains the gold standard procedure for end stage ankle arthritis. The goal of our study was to perform a retrospective evaluation of the safety and efficacy of a noncemented prosthesis to treat end stage ankle arthritis and compare the outcomes to arthroscopically assisted ankle fusion. We evaluated both cohorts based on the following outcomes: 1 - postoperative complications, 2-visual analogue pain scale, 3-SF-36 outcome scores, and 4-AOFAS scores. All data was collected at a minimum of 6 months postoperatively.

Method:
Patients undergoing total ankle arthroplasty or arthroscopically assisted ankle fusions were asked to fill out AOFAS, SF-36, and VAS both pre-operatively and post-operatively. They also all underwent and full radiographic assessment with AP, lateral, dorsiflexion, and plantarflexion views of the operative ankle at least 6 months after surgery. These radiographs were assessed for adjacent joint changes and measurements of component placement, dorsiflexion and plantarflexion. Charts were reviewed to obtain any post-operative complications. The improvement in either group in SF-36, AOFAS, and VAS scores were analyzed using a two-sample paired Student t test. All procedures were performed by the senior authors and all of the total ankle arthroplasties were done using the same prosthesis.

Results:
The charts of patients undergoing arthroscopic ankle fusions and total ankle arthroplasty performed by the senior authors between 2006 and 2011 were reviewed. In total there were 14 fusions and 35 total ankle replacements who had full sets of data. In the total ankle group there were 5 reported complications, which included varus malalignment, wound dehiscence, subtalar changes, and posterior tibial tendonitis. In the fusion group, there were 7 complications, which included primarily subtalar arthritis and nonunions requiring revision. The average time of follow-up was 17 months for the total ankle group and 30.5 months for the ankle fusion group. There was a statistically significant improvement in the physical component of the SF-36 score for patients undergoing both total ankle replacement (P<0.0001) and ankle fusion (P= 0.0184), however, the changes in the mental component of the SF-36 were not statistically significant in either group. Both groups showed improvement in their AOFAS scores post-operatively, which was statistically significant for both the fusion group(P = 0.0001) and the total ankle group (P<0.0001). VAS scores were also improved and statistically significant in both groups (P<0.0001). The average mechanical axis was 90.1 degrees in both groups.
Conclusion:
Although our study is limited due to the small size of the arthroscopically assisted fusion group, we found that noncemented total ankle prostheses performed comparably to arthroscopically assisted ankle fusions in patients of similar ages with end stage arthritis. In addition, the total ankle group had fewer complications requiring secondary procedures. While both procedures can be associated with subtalar degenerative joint changes, total ankle arthroplasty is a safe and effective alternative to ankle fusion in patients with end stage arthritis.
Salto Talaris Precision-Bearing Total Ankle Replacement: Early Outcomes, Complications

Presenting:
Richard M. Marks, MD (Milwaukee, Wisconsin)
Jamie Silkey, PA-C; Jason T. Long, PhD

Summary
The Salto Talaris anatomic precision-bearing design is associated with high satisfaction, restoration of function and gait, and a low peri-operative complication rate. Careful patient selection, proper technique and improvements in ankle design result in greater outcomes and diminished complications for early-term results compared to prior reports. It is a safe intervention for treatment of end-stage ankle arthritis.

Introduction
Total ankle replacement (TAR) has gained a resurgence in the treatment of end-stage ankle arthritis. Ankle fusion has been considered the gold standard, however, newer generation total ankle systems may provide a viable alternative to ankle fusion, due to improvement in anatomic design, instrumentation and technique. This study evaluates one center’s early experience with the Salto Talaris total ankle replacement, including outcomes, radiographic and gait analysis, and review of complications.

Methods
This prospective, IRB approved study evaluated the first 39 consecutive patients who underwent 40 Salto Talaris total ankle replacements performed at a single center between January, 2007 and November, 2010. Pre- and postoperative clinical and radiographic evaluation was performed for all patients at regular intervals. Complications data is reported for all procedures. Outcomes data is reported for patients with > 2 yr follow-up. Pre- and post-operative gait analysis was performed on 12 patients, with 1 and 2 year follow-up. Significance was set at p< 0.05.

Results
From January, 2007 - November, 2010 39 pt.s (20 M, 19 F) with a mean age 64.2 (range 52-80) underwent Salto Talaris TAR. Average follow-up was 16.3 mo (range 1-36). 18 patients have > 2 yr f.u. (mean 30 mo.). No patients were lost to follow-up. Additional surgeries performed at time of index procedure include subtalar fusion (2), removal of hardware (2), peroneal debridement(1). Secondary procedures include 1 subtalar fusion, 1 Dwyer calcaneal osteotomy. There were no cases of tendon or nerve injury. Two patients had an intraoperative medial malleolar fracture. Postoperatively, there was 1 DVT, 1 minor wound dehiscence. No components experienced subsidence, loosening or failure. No revisions were performed/planned. 2(6.7%) patients had mild anterior placement of the talar component ; both with good clinical outcomes > 2 years. Gait analysis showed normalized stride length, walking speed, stance duration and cadence at 2 yr.s . AOFAS scores significantly improved from 43.1 to 84.4 at 1 yr, and 91.3 at 2 yr. SF36 scores showed significant improvement for physical function, role-physical, bodily pain and vitality scores. There was a strong trend towards normalization in the general health scale. All parameters remained significantly improved at 2 yr. Arc of motion significantly improved from 23.9 deg. → 36.5 deg. post-operatively.
Conclusion
The Salto Talaris anatomic precision-bearing design is associated with high satisfaction, restoration of function and gait, and a low peri-operative complication rate. Careful patient selection, proper technique and improvements in ankle design result in greater outcomes and diminished complications for early-term results compared to prior reports. It is a safe intervention for treatment of end-stage ankle arthritis.
Prospective Clinical Results of the INBONE Total Ankle Replacement

Presenting:

Thomas Moore, Jr., MD (Atlanta, Georgia)
Sameh A. Labib, MD; Marie Johanson, PT, PhD, OCS; Sam Borrelli, BS; claude Pierre-Jerone, MD

Summary:
An option for operative treatment of end stage ankle arthritis is total ankle replacement. Ankle fusion is considered the gold standard operative treatment, but it has been shown in previous studies that adjacent joint degeneration and an altered gait pattern can occur in these patients. This study gives the short term clinical outcome data of an alternative to ankle fusion with the use of the Inbone total ankle replacement.

Introduction:
We present an early experience with the Inbone total ankle replacement with prospectively collected data from 2007 to 2010.

Methods:
Twenty-one consecutive patients who underwent total ankle arthroplasty with the Inbone prosthesis by a single surgeon were prospectively followed. Pre and post operative AOFAS-hindfoot scores, as well as visual analog score (VAS) for pain and function were recorded. Clinical and radiographic analysis of the Inbone total ankle replacement were independently reviewed. The average post operative follow up was 21 months, range 6-39 months, in this study.

Results:
The average pre operative AOFAS-hindfoot score was 26.7, and the average AOFAS score after Inbone total ankle arthroplasty was 80.9. 62% of the patients (13 of 21) had a good or excellent result, 33% (7 of 21) had a fair result, and one patient, 5%, had a poor result. Average VAS pain scores went from 8.6 preoperatively to 2.7 at last follow up. VAS function scores went from 3.2 to 6.8 after ankle replacement. There were two (10%) minor complications which were superficial wound infections requiring oral antibiotics, and there were 3 (14%) major complications which required reoperation. One patient had a deep infection which occurred 3 years post operatively and was treated with implant removal and salvage ankle fusion. One patient underwent revision of the talar component for loosening. The other reoperation occurred in a rheumatoid arthritis patient who required a subtalar fusion two years after initial ankle replacement. Potential risk factors for fair outcome were talar bone deficiency, concomitant fusion, and deformity correction.

Conclusion:
The Inbone total ankle arthroplasty offers patients with end stage ankle arthritis significantly better scores on the AOFAS hindfoot scale and significantly better pain and function on the visual analog scale at a short follow up period. Risk factors are identified and discussed.