Scandinavian Total Ankle Replacement: 15-Year Follow-up

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Abstract

Background: Over the past decade, total ankle arthroplasty (TAA) has become a mainstay in the treatment of end-stage ankle arthritis. Currently in its fourth generation, the Scandinavian Total Ankle Replacement (STAR) is the only 3-piece mobile bearing ankle prosthesis available in the United States. Our current study reports implant survivorship at 15 years and patient outcomes for a subset of these survivors available for study.

Methods: Eighty-four TAA were performed between 1998 and 2000. Metal component survivorship at 15 years was calculated with a Kaplan-Meier curve. Twenty-four (29%) of 84 patients were available for participation with a minimum 15-year follow-up. Any radiographic changes were documented. All additional procedures and complications were recorded. Clinical findings, self-reported performance and pain evaluations, and AOFAS ankle/hindfoot scores were noted.

Results: Metal implant survival was 73% at 15 years. Of the 24 patients available for clinical evaluation, 18 of 24 patients (70.7%) had no change in prosthesis alignment from the immediate postoperative radiograph. Only 1 subtalar fusion was required for symptomatic adjacent joint arthritis. Three patients sustained a broken polyethylene component. AOFAS scores improved from an average of 39.6 points preoperatively, to an average of 71.6. More than half (52.4%) of patients with retained implants required an additional surgical procedure; 3 required 2 additional procedures. The average time to subsequent procedure was 10.2 years.

Conclusion: Our small cohort demonstrated STAR ankles with retention at 9 years were highly likely to survive to 15 years, and patients continued to have significant improvement in pain relief and minimal decrease in function. At 15 years from TAA, metal survivorship was 73%. As with all ankle replacements, supplementary procedures were common.

Level of Evidence: Level IV, case series.

Keywords: arthritis, arthroplasty, ankle, outcome studies.

Introduction

Total ankle arthroplasty (TAA) is now a widely accepted alternative to ankle arthrodesis in the treatment of end-stage ankle arthritis. Historically, tibiotalar arthrodesis had been the only surgical option for treatment of disabling ankle arthritis. However, since 2006, there has been a steadily increasing trend in the number of TAA performed, and an abundance of literature now shows promising intermediate results of TAA. Of the total ankle prostheses available in the United States, the STAR ankle is the only 3-piece mobile bearing design. Literature has shown survivorship of the STAR ankle to be 89% to 94% at 9-12 years in the United States and Canada. However, the question remains as to patient outcomes beyond 10 years.

Literature regarding implant survivorship of the STAR ankle is confusing given the different generations of the prosthesis available at different time points worldwide. The STAR is currently in its fourth generation. The prosthesis was initially designed by Hakon Kofoid in Denmark in 1978, as a cemented fixed-bearing device. In 1986, it was converted to a mobile bearing design. As technology improved, it was revised to a press-fit design with a single hydroxyapatite (HA) layer on a smooth metal surface in 1989. One European study found this variation of the STAR prosthesis to have a 70.7% survival at 7 years and 45.6% at 14 years. The single HA layer did not allow for long-term

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bone ingrowth, and in 1999 the coating was revised to include a titanium porous grit spray.

None of the hydroxyapatite-coated prostheses ever entered the US market. The fourth generation of the STAR, the only one ever utilized in the United States, is a cobalt-chrome prosthesis that is grit-blasted with a titanium porous spray to provide greater ingrowth. This is the version that received FDA approval in 2009. We reported the first intermediate-term outcomes of the fourth generation STAR in 2011, showing 90% survivorship at 9 years, and multiple other studies using the fourth-generation prosthesis showed analogous results. This current report is a follow-up to our previous study, now with a minimum of 15-year follow-up.

Methods

The study protocol was submitted and approved by the IRB and all patients provided informed consent for the use of the STAR ankle as a custom device (Figure 1). Eighty-four total ankle replacements were performed on 80 patients (4 bilateral) between February 1998 and September 2000. Operative technique, postoperative care, and radiographic parameters were the same as noted in our previous publication. After 10 years, patients were instructed to follow-up biannually, barring any interval change, and again at the 15-year mark.

Follow-up evaluations were sought in all patients. Attempts were made to contact all patients in the initial study. Of the 84 ankles in the original study, 9-year follow-up, 5 patients had died, 7 had metal component failures resulting in fusion or revision, and 4 patients (2 bilateral) were lost to follow-up. Of these 66 remaining ankles, at minimum 15-year follow-up, 10 patients were confirmed deceased (2 bilateral), 7 declined to participate, 4 reported subsequent metal revision or fusion by another surgeon, and 17 were unreachable, leaving 24 ankles available for the clinical study (Figure 2). All patients had radiographic evaluations, and of the patients with retained implants at 15 years, 14 patients were evaluated in the clinic, and 10 had an extensive telephone follow-up interview.

The 2 primary objectives of our study were as follows: to determine metal component survivorship at 15 years and to characterize overall long-term function of patients with an ankle replacement in place for at least 15 years. Survivorship was based on all data available for all 84 patients and calculated with a Kaplan-Meier survival curve. Overall functional status was based on the 24 patients available for the clinical study. To achieve this objective, a subjective analysis was performed that included questions about pain and function, the use of assistive devices, and maximal walking distance. AOFAS ankle/hindfoot scores were recorded as this was the scoring system used in previous evaluations. Patients reported pain in the ankle as “no pain, slight pain, mild pain, moderate pain, or severe pain.” Any shoe modifications or use of an ankle brace or orthotics were noted. For the patients evaluated in the office, physical measurements were recorded, including ankle range of motion and alignment. For patients only available by telephone, the applicable pain and function aspects of the AOFAS ankle/hindfoot score were recorded.

Another main objective of the study was to evaluate radiographic changes involving the ankle joint replacement over a 15-year time span. Weight-bearing AP, oblique and lateral ankle radiographs were performed for all patients. All analog preoperative, postoperative, and any outside films were digitized for valid comparisons. Radiographs were reviewed by 2 fellowship foot and ankle–trained orthopedic surgeons. Radiographic evaluation was performed by the protocol detailed in our previous study. Any change in prosthetic position, coronal plane alignment, osteolysis, heterotopic ossification, or adjacent joint arthritis was reported. Heterotopic ossification (HO) was defined as any new bone formation from immediate postoperative radiograph and was graded by the modified Brooker classification. Any required resection due to symptomatology was noted. Progression of arthritis of the subtalar, talonavicular, and calcaneocuboid joints was recorded and graded on the Kellgren-Lawrence scale. The nature of and time interval to any additional surgical procedures were documented.

Statistical Methodology

Descriptive statistics for patient demographics, clinical variables, outcome-scoring instruments, and survivorship are reported as mean or mean ± standard deviation. The data were censored separately according to a primary failure, which was defined as a complete explant, including either conversion to an arthrodesis or revision of metal prosthetic components. A Kaplan-Meier survivorship curve
The probability of survival for at least 15 years was 73% (95% CI: 69, 76) (Figure 3).

**Objective Outcomes Analysis**

Twenty-four patients were included in the clinical study, with an average follow-up of 15.7 years (15.0-17.7). Average age was 73.7 years (range 51.3-92.9). Three of the 24 patients (12.5%) had failure of the metal components and were not included in the subjective or objective follow-up and scoring but were included in the overall survivorship analysis.

Of the 21 patients surveyed, 15 (71.4%) ambulated without the need of an assistive device. Three (14.2%) required an ankle-foot orthosis for walking support and comfort. Overall, 41% had no limitations in walking distance, 24% could walk farther than 6 blocks, 11% could walk 4 to 6 blocks, and 24% could walk 2 to 3 blocks. In addition, 38% reported no pain related to the ankle, 24% had slight pain, 19% had mild pain, and 19% had moderate pain.

The AOFAS ankle/hindfoot score improved from an average of 39.6 points preoperatively, to an average of 71.6 points (range 42-89) at the most recent visit. The average AOFAS score at 9 years was 78.6 in the same cohort. The pain component decreased on average by 3.2 points and the function component decreased by 5.3 points from the 9- to the 15-year assessment. Overall, 41% of patients had improvement, 18% had no change, and 41% had a decrease in pain score. Only 1 had a decrease in pain score greater than 10 points.

Fourteen patients were available for physical examination. The average range of motion of the ankle joint was 17 degrees (range: 5-30 degrees). The average dorsiflexion was 2.5 degrees (range: −10 to 15) and plantarflexion was 14.3 degrees (range: −7 to 30).

**Radiographic Evaluation**

*Component alignment.* Eighteen of 24 patients had no change in prosthetic alignment. Three patients had component migration and required metal revision, which is reported on in a different section. Of the remaining 21 patients, 2 patients had talar subsidence <5 mm and 1 patient had talar subsidence of >5 mm. These were all observed and reported in the 9-year study and were stable from 9 to 15 years. No patient had change in alignment of the tibial tray (Figure 4).

*Coronal plane alignment.* One patient (4.7%) had a persisting coronal plane deformity at 15-year follow-up. On immediate postoperative radiograph, the patient had a residual incongruent varus joint measuring 5 degrees, from a preoperative varus deformity of 15 degrees. The patient was reoperated 7.8 years later with a calcaneal osteotomy to a
residual 1.5 degrees of varus incongruency, which persisted at most recent radiographs. Overall, 6 of the 24 patients had a preoperative incongruent joint deformity greater than 5 degrees; in the remaining 5 the deformity was fully corrected at the time of TAA and there was no recurrence.

Adjacent joint arthritis. Overall, only 1 patient had symptoms and required subsequent surgery as a result of adjacent joint arthritis. Progression in arthritis was seen in 9 of 62 joints, or 14.3%. In regard to the subtalar joint, 18 had no progression, 2 had an increase of 1 grade, and 1 had an increase of 3 grades on the Kellgren-Lawrence scale. The latter was symptomatic and went on to subtalar fusion. At the talonavicular joint, 2 joints demonstrated an increase of 1 grade and 2 had an increase of 2 grades. There was an increase of 1 grade in one calcaneocuboid joint and of 2 grades in one other. None of these were symptomatic.

Heterotopic ossification. Eight patients had no HO or bone spur formation. Thirteen (61.9%) patients had some degree of heterotopic ossification compared to immediate postoperative radiographs. Three of the patients had Grade III HO, or bony ankylosis, though these were not painful (Figure 5). Two patients required surgical intervention for removal of symptomatic, painful exostoses. This occurred at 11.8 and 12.7 years postoperation.

Osteolysis. Fifteen patients (71.4%) had no radiographic evidence of osteolysis around the tibial or talar components at 15 years following TAA. Three patients (14.3%) required primary bone graft procedures for symptomatic or progressive bony cysts, at an average of 12.3 years postoperatively. One symptomatic cyst was in the medial malleolus, and the other 2 patients had cyst formation underneath the talar component as well as around the tibial barrel holes. Two patients had grafting of asymptomatic bony cysts in the tibia at the time of replacement of a broken polyethylene component in the setting of stable metal implants.

Complications

Metal component failure. Of the original 84 patients, 14 patients had metal component failure (16.7%). Seven failed prior to the 9-year follow-up, and 7 between the 9- and 15-year time marks. Of the 24 patients who were available for the clinical study, 3 had metal component failure. Two patients had revision of all components for aseptic loosening, 1 at 11 and 1 at 12 years postoperation. The other patient was converted to a tibiotalocalcaneal fusion at 11 years postoperation owing to avascular necrosis of the talus (Table 1). Polyethylene fracture. Three of the 21 polyethylenes components fractured, which is a survival rate of 85.7% at an average of 15.7-year follow-up. None of these patients had metal component loosening, and none needed revision of the metal components.

Hindfoot malalignment. Of the 14 patients evaluated clinically, 2 patients developed a progressive calcaneovalgus deformity after the time of TAA, likely secondary to failure of the posterior tibial tendon. One patient also had subtalar arthritis, and underwent correction with a subtalar fusion at 13.8 years from TAA. The other underwent correction with a calcaneal osteotomy at 11 years from TAA. Both had correction but not full improvement of the hindfoot valgus at latest follow-up.

Subsequent procedures. Eleven of 21 patients with metal component survivorship required an additional surgical procedure, 3 of whom required 2 additional procedures. The majority (78.6%) of these occurred between the 9- and
15-year follow-up (Table 2). Two patients underwent polyethylene exchange for a broken polyethylene component, one of whom later had a calcaneal osteotomy for a persistent coronal plane deformity, and one of whom previously underwent ORIF for a medial malleolar stress fracture. Another patient had a polyethylene fracture at greater than 15-year follow-up, but the replacement surgery had not been performed at the time of this study. One other patient had a calcaneal osteotomy for hindfoot malalignment. Three patients had bone grafting for osteolysis, one of whom went on to later have a subtalar fusion for symptomatic subtalar arthritis, and one who concurrently had a tendo-Achilles lengthening (TAL). Two patients had removal of bone spurs, one of whom concurrently had a TAL. The average time to any subsequent procedure was 10.2 years. Three of the subsequent procedures occurred before the 9-year mark and were previously reported upon.19 It should be noted that if a patient underwent an anterior ankle arthrotenomy for any subsequent procedure, the polyethylene component was routinely exchanged, which occurred in 3 patients.

Discussion

Total ankle arthroplasty is a widely used alternative to ankle arthrodesis in the treatment of end-stage ankle arthritis.26,27 Advantages of total ankle arthroplasty include preserved ankle range of motion and reduction of adjacent joint arthritis.29 Of the commercial total ankle prostheses available in the US market, the STAR is the only 3-piece mobile-bearing design, and the only with FDA approval for uncemented use.

Similar to the evolution of total knee and hip replacements, total ankle replacements have undergone revisions and improvements.1,3,17 The STAR is currently in its fourth generation. The current version of the STAR, the only ever used in the United States, is a cobalt-chrome prosthesis, grit blasted with a titanium porous spray. European studies often report on older versions of the STAR with hydroxyapatite coatings.25,26,28 A frequently cited article is that of Brunner et al, which reported prosthetic survival rates of 70.7% and 45.6% at 10 years and 14 years, respectively.4 This article included the third-generation STAR, which had a hydroxyapatite coating on smooth metal and significant problems with ongrowth. Conversely, Jastifer and Coughlin showed 94.4% survivorship at 9- to 12-year follow-up.14 Daniels et al reported 88% survivorship at 9-year follow-up.5 Nunley et al showed a 93.9% survivorship at an average of 60.1 months.22 Our previous study showed 90% survivorship at 9 years.19 Although we had significant drop-off of patient follow-up, our current study shows 73% survivorship at 15 years. Mercer et al reported on inconsistency in the literature in reporting adverse outcomes in total ankle arthroplasty, and proposed specific guidelines to improve uniformity.19 We agree with the authors that need for polyethylene exchange should not be included in the overall survivorship of the implant, but rather as a secondary procedure, given the minimal recovery time and the common practice of routine polyethylene exchange during unrelated procedures.

The clinical arm of our current study includes 21 patients who demonstrated metal component survivorship at 15 years. Overall, these patients had good results. Greater than 70% ambulated unassisted, and AOFAS scores remained improved by greater than 30 points from preoperative scores. Between the 9- and 15-year follow-up studies, the pain component of the AOFAS score stayed relatively constant. The function component decreased by 5.3 points. Average age of the patients at the time of this study was 73.7 years, 7 over the age of 80, and may partly contribute to the decrease in functional status.

Multiple studies have investigated adjacent joint arthritis after ankle arthroplasty. Coester et al in 2001 showed that at 22-year follow-up, 21 of 23 subtalar joints of fused ankles had moderate or severe arthritis.7 Ling et al in 2015 performed a systematic review that found after ankle arthrodesis, the prevalence of subtalar joint arthritis ranged from 24% to 100%.18 In our study, only 1 adjacent joint was symptomatic and required fusion (1.6%), with asymptomatic radiographic progression of arthritis in 14.3% of joints. Our data support that ankle replacement with a mobile-bearing device reduces the incidence of adjacent joint arthritis compared with arthrodesis. Conversely, Chao et al reported a rate of 43.5% of progressive subtalar joint arthritis at 3-year follow-up, 17.4% requiring a fusion, with the fixed bearing Salto Talaris ankle.5 Further research is required to determine if there is a difference in occurrence of adjacent joint arthritis between fixed- and mobile-bearing ankle designs.

Previous intermediate follow-up data have shown that subsequent procedures are common after TAA. Nunley et al
Table 1. STAR Failures of 84 Original Total Ankle Arthroscopies at 15-Year Follow-up.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Mode of Failure</th>
<th>Time From Index Procedure, y</th>
<th>Revision or Fusion?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zero- to 9-year follow-up</td>
<td>1 Aseptic loosening</td>
<td>3</td>
<td>Fusion</td>
</tr>
<tr>
<td>(included in the 9-year study)</td>
<td>2 Osteolysis with implant stability</td>
<td>5</td>
<td>Revision</td>
</tr>
<tr>
<td></td>
<td>3 Implant subsidence</td>
<td>6</td>
<td>Fusion</td>
</tr>
<tr>
<td></td>
<td>4 Implant subsidence</td>
<td>6</td>
<td>Fusion</td>
</tr>
<tr>
<td></td>
<td>5 Unstable talar component</td>
<td>7</td>
<td>Fusion</td>
</tr>
<tr>
<td></td>
<td>6 Osteolysis with implant stability</td>
<td>7</td>
<td>Revision</td>
</tr>
<tr>
<td></td>
<td>7 Implant subsidence</td>
<td>8</td>
<td>Fusion</td>
</tr>
<tr>
<td></td>
<td>8 Aseptic loosening</td>
<td>8</td>
<td>Fusion</td>
</tr>
<tr>
<td>Nine- to 15-year follow-up</td>
<td>9 Aseptic loosening</td>
<td>11</td>
<td>Revision</td>
</tr>
<tr>
<td></td>
<td>10 Talar AVN</td>
<td>11</td>
<td>Fusion</td>
</tr>
<tr>
<td></td>
<td>11 Aseptic loosening</td>
<td>12</td>
<td>Revision</td>
</tr>
<tr>
<td></td>
<td>12 Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td></td>
<td>13 Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td></td>
<td>14 Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td></td>
<td>15 Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

Abbreviation: AVN, avascular necrosis.

Table 2. Summary of All Subsequent Surgical Interventions After Index Total Ankle Arthroplasty.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Complication</th>
<th>Intervention</th>
<th>Time From Index TAA to Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Equinus contracture and heterotopic ossification</td>
<td>Removal of bone spurs and TAL</td>
<td>11.8 y</td>
</tr>
<tr>
<td>2</td>
<td>Osteolysis</td>
<td>Bone grafting to the tibia and talus, routine polyethylene exchange</td>
<td>10.8 y</td>
</tr>
<tr>
<td></td>
<td>Adjacent joint arthritis</td>
<td>Subtalar fusion</td>
<td>13.7 y</td>
</tr>
<tr>
<td>3</td>
<td>Polyethylene</td>
<td>Polyethylene replacement and bone grafting of the tibia</td>
<td>5.5 y</td>
</tr>
<tr>
<td></td>
<td>Hindfoot malalignment</td>
<td>Calcaneal osteotomy</td>
<td>7.8 y</td>
</tr>
<tr>
<td>4</td>
<td>Coronal plane deformity</td>
<td>Calcaneal osteotomy</td>
<td>11.0 y</td>
</tr>
<tr>
<td>5</td>
<td>Osteolysis</td>
<td>Bone grafting of the tibia, routine polyethylene exchange</td>
<td>11.6 y</td>
</tr>
<tr>
<td>6</td>
<td>Heterotopic ossification</td>
<td>Removal of the medial malleolar exostosis</td>
<td>12.7 y</td>
</tr>
<tr>
<td>7</td>
<td>Medial malleolar stress fracture</td>
<td>ORIF</td>
<td>44 d</td>
</tr>
<tr>
<td></td>
<td>Polyethylene fracture</td>
<td>Polyethylene replacement and bone grafting of the tibia</td>
<td>15.2 y</td>
</tr>
<tr>
<td>8</td>
<td>Osteolysis</td>
<td>Bone grafting of the tibia and talus with routine polyethylene exchange and TAL</td>
<td>11.6 y</td>
</tr>
<tr>
<td>9</td>
<td>Polyethylene fracture</td>
<td>Pending polyethylene replacement</td>
<td>15.6 y</td>
</tr>
</tbody>
</table>

Abbreviations: ORIF, open reduction internal fixation; TAA, total ankle arthroplasty; TAL, tendo-Achilles lengthening.

reported that at an average of 5 years after TAA, 17% of patients required additional procedures. Jasti and Coughlin showed that 39% of TAA patients needed a subsequent surgery at 10-year follow-up. In our study, at 15 years, 52.4% of patients required additional procedures. The additional procedures were quite diverse, including correction of hindfoot deformity, removal of symptomatic bone spurs, replacement of broken polyethylene components, or grafting of symptomatic bony cysts.

Of the 21 patients with metal component retention available for clinical evaluation, none had changes in prosthetic alignment between the 9- and 15-year follow-ups. Only 1 had a coronal plane deformity at 15-year follow-up. This patient had a preoperative coronal plane deformity of 15
degrees of varus incongruency, which was corrected to 5 degrees with the TAA. The patient was revised 7.8 years later with a calcaneal osteotomy to a residual 1.5 degrees. Five patients had preoperative coronal plane deformities, none of which occurred 15 years after TAA. This is similar to the findings of Trajkovski et al in 2013, who showed good results with TAA for severe coronal plane deformity, although patients may have higher rates of subsequent procedures.  

As in other studies, the majority of our patients developed some degree of HO. Angthong et al in 2014 reported that 97.8% of TAA at 3-year average follow-up had presence of HO, though only 3.3% were symptomatic. 2 Choi and Lee in 2011 reported on 112 HINGE GRA ankles, of which 34.4% showed HO, though all were located posterior to the tibial component, and there was no significant association with HO and clinical outcome. 6 In our study, 61.9% showed evidence of HO, and overall 9.5% of patients required bone spur removal or gutter debridement, at an average of 12.3 years postoperation.  

At 15 years, we found bony cysts in 6 of the 21 patients (28.6%) available for clinical study. This was determined by plain radiographs and not computed tomographic (CT) evaluation and, therefore, likely underestimates the true occurrence of cyst formation. Three of these patients were symptomatic and required intervention (14.3%). In our experience, the tibial tray tends to remain fixed in the presence of bony cysts, as long as the radiographic signs of ingrowth are present. Talar cysts show a higher propensity to progressively enlarge and risk implant stability, and therefore should be evaluated with a CT scan whenever identified or suspected. 12 We grafted symptomatic, painful cysts, or any tibial or talar cysts that compromised the integrity of the component positioning as confirmed by CT scan.  

The primary limitation of this study was patient participation. Of the 66 patients from the original study, 10 were confirmed deceased (14 ankles), which is a statistical expectation for a 15-year follow-up study with an average age of the participants of 61 years initially. We were disappointed that 17 patients did not stay in contact with us as had been requested, and an additional 11 patients declined to participate in the study (7 with known implant survival and 4 with known revision or fusion). Of those who declined to participate, most cited inconvenience of travel and other health ailments not related to the ankle. Furthermore, we used the AOFAS scoring system, which is not validated, but was a widely used instrument when this cohort commenced. We elected to continue to use the AOFAS scoring system because it allowed longitudinal comparison to our previous studies.  

Although our patient cohort is somewhat small, we were able to make the following conclusions. Our cohort showed an overall 73% metal component survivorship of the STAR at 15-year follow-up. Furthermore, implants with retention at 9 years are likely to survive to 15 years, and patients continued to have significant improvement in pain relief and minimal depreciation in function, and implant migration was very rare. As with all ankle replacements, supplementary procedures were common.  

Declaration of Conflicting Interests  
The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Ariel Palanca, MD, and Andrew Haskell, MD, report personal fees from Stryker, outside the submitted work. Roger A. Mann, MD, reports personal fees from Stryker during the conduct of the study. ICMJE forms for all authors are available online.  

Funding  
The author(s) declared receipt of the following financial support for the research, authorship, and/or publication of this article: Roger A. Mann, MD received a grant for this study from Small Bone Innovations.  

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