Early to Mid-Term Results of Fixed-Bearing Total Ankle Arthroplasty with a Modular Intramedullary Tibial Component

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Background: There has been a continuing increase in the use of total ankle arthroplasty for the treatment of end-stage ankle arthritis. Our aim was to determine the clinical, radiographic, and functional outcomes of total ankle arthroplasties done with a prosthesis with a modular intramedullary stem and intramedullary referencing to align the tibia.

Methods: A consecutive series of patients who underwent total ankle arthroplasty with the INBONE Total Ankle Replacement from June 2007 to December 2010 were enrolled in this study. Pain and patient-reported function were assessed with use of a visual analog scale (VAS) for pain, the American Orthopaedic Foot & Ankle Society (AOFAS) ankle-hindfoot score, the Short Musculoskeletal Function Assessment (SMFA), and the Short Form-36 (SF-36) Health Survey. Objective function was measured with assessment of walking speed, the Timed Up and Go (TUG) test, the Sit-to-Stand (STS) test, and the Four Square Step Test (4SST). Standardized weight-bearing radiographs obtained preoperatively and after total ankle arthroplasty were evaluated. We analyzed clinical, functional, and radiographic measurements with a series of repeated-measures analyses of variance (ANOVAs) with post-hoc testing to assess differences between preoperative, one-year postoperative, and most recent follow-up data. On the basis of the number of statistical comparisons, a Bonferroni correction was completed (alpha < 0.003).

Results: We identified 194 primary INBONE total ankle arthroplasties with a mean duration of clinical follow-up of 3.7 years (range, 2.2 to 5.5 years). Patients demonstrated a significant improvement (p < 0.003) in VAS pain, AOFAS, SMFA, and SF-36 scores at the time of final follow-up, compared with preoperative values, and in walking speed, STS time, TUG time, and 4SST time at two years postoperatively, compared with preoperatively. The mean coronal tibiotalar angle for varus and valgus ankles significantly improved postoperatively and was maintained until the time of final follow-up. The prevalence of unstable subsidence leading to impending failure was 5%, and the prevalence of revision was 6%.

Conclusions: Patients who underwent total ankle arthroplasty with the INBONE Total Ankle Replacement demonstrated significant improvement in radiographic, functional, and patient-reported outcome scores at a mean of 3.7 years postoperatively. The overall implant survival rate was 89%.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

End-stage ankle arthritis has been reported to be equivalent to end-stage kidney disease and congestive heart failure in terms of the patient’s self-perceived quality of life and functional deficits. Traditionally, severe ankle arthritis was treated with ankle arthrodesis, but improvements in prosthetic design and surgical technique have renewed interest in

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total ankle arthroplasty. Total ankle arthroplasty provides pain relief that is equivalent to that following ankle arthrodesis. In addition, total ankle arthroplasty reduces the relative prevalence of adjacent joint degeneration. Both modern mobile and fixed-bearing total ankle arthroplasty designs have demonstrated encouraging short and medium-term results. The INBONE Total Ankle Replacement (Wright Medical Technology, Arlington, Tennessee) is a fixed-bearing prosthesis that was approved by the U.S. Food and Drug Administration (FDA) in 2005, but there have been no reports on the clinical outcomes to our knowledge. The purpose of this study was to present early to mid-term clinical, functional, and radiographic results associated with this prosthetic design.

Materials and Methods

Study Design

A retrospective review of data from our institutional registry (ClinicalTrials.gov NCT01986244) was performed for a consecutive series of patients who had received an INBONE Total Ankle Replacement in the period from June 2007 to December 2010. The tibial and talar components of the INBONE are made of cobalt-chromium with a titanium plasma-spray coating. There is a polyethylene meniscal bearing fixed to the tibial baseplate. The tibial stem is modular with a conical top, mid-stem pieces, and a slightly wider base-piece segment. The base-piece segment attaches to the tibial baseplate via a Morse taper. The prosthesis is FDA-approved for implantation with the use of cement. The INBONE II Total Ankle Replacement was FDA-approved in August 2010, but the components were not available at our institution during the study period.

All primary ankle replacements in this series were first-generation implants that were placed "off-label" without cement. All arthroplasties were performed by a fellowship-trained foot and ankle specialist who had performed more than 100 total ankle arthroplasties, including those with the INBONE prosthesis, prior to the start of the study. The indication for total ankle arthroplasty was symptomatic end-stage ankle arthritis without evidence of active infection at the tibiotalar joint, neuropathy, arterial insufficiency to the lower extremity, or poorly controlled diabetes mellitus. The decision to use this prosthesis was made by the attending surgeon. Patients who had undergone revision total ankle arthroplasty or takedown of an ankle fusion were excluded. The primary outcome measure was patient-reported outcome scores measured preoperatively and at regular intervals postoperatively. Secondary outcome measures included functional testing, radiographic assessment, implant survival, and complications. The study was approved by our hospital’s institutional review board, and all patients signed informed-consent forms prior to study enrollment.

Surgical Technique and Postoperative Protocol

With the patient supine, a standard anterior approach to the ankle was performed through the interval between the tibialis anterior and extensor hallucis longus tendons.

The ankle replacement was performed according to the manufacturer's published technique guide (http://www.wmt.com/footandankle/FA214-408.asp).

Patients returned to the clinic three weeks following surgery for cast removal, wound inspection, and suture removal. Depending on soft-tissue healing and other concomitant procedures performed, a short leg cast was applied or a removable below-the-knee controlled-ankle-motion (CAM) boot was used for an additional three weeks of non-weight-bearing. Patients were thus non-weight-bearing for six weeks. From six weeks to three months postoperatively, the patients initiated self-directed ankle-motion exercises and transitioned from a removable walking boot to a normal shoe with progression to full weight-bearing.

Clinical Assessment

Patient demographics, including the etiology of the ankle arthritis, previous surgical procedures, and comorbidities, were recorded. Surgical procedures performed concomitant with and/or subsequent to the total ankle arthroplasty were also documented, as were postoperative complications. When a complication was documented in the medical record, a research coordinator assigned to this study was notified and the complication was documented in the study database. Complications were categorized with use of a previously published total ankle arthroplasty complication classification system. Failure was defined as any revision total ankle arthroplasty or impending revision (i.e., prosthesis failure had been documented but the patient had not received revision surgery during the study period). In keeping with prior published total ankle arthroplasty studies, we defined revision as removal of either the tibial or the talar component and (1) reimplantation of a metal component or (2) conversion to tibiotalar arthrodesis. Pain and patient-reported function were assessed preoperatively, at six and twelve months postoperatively, and yearly thereafter.

Radiographic Assessment

Standardized weight-bearing anteroposterior, lateral, and mortise radiographs were obtained preoperatively, at six and twelve months postoperatively, and yearly thereafter. Coronal plane tibiotalar alignment was determined by timing the middle 5 m along a 10-m walkway during seven standardized functional tests, including the Timed Up and Go (TUG) test, the Sit-to-Stand (STS) test, the Four Square Step Test (4SST), and an assessment of average walking speed. They also completed a Foot and Ankle Ability Measure (FAAM) questionnaire, which has been validated for musculoskeletal disorders of the leg, ankle, and foot.

The TUG test is predictive of safe walking. It correlates well with gait speed and function, and has excellent reliability. The STS test is a good indicator of postural control, fall risk, lower-extremity strength, and proprioception, and it is a good measure of disability in older populations. The 4SST, for which faster times to completion are indicative of better balance and dynamic function, is a reliable and valid measure of multidirectional step stability for subjects with balance or vestibular disorders. It has been used previously for subjects recovering from a surgically treated ankle fracture.

In addition, the average walking speed, as measured by photocells, was determined by timing the middle 5 m along a 10-m walkway during seven trials. Gait speed correlates with disease processes, fitness level, activities of daily living, and emotional states. Velocity changes correlate with self-reports of improvement in global assessment. Gait speed is an imperative measure of safe and effective community ambulatory status and a reflective measure of function. The FAAM consists of twenty-six questions regarding activities of daily living. It measures pain and disability while walking on...
d i f f e r e n t s u r f a c e s a t v a r y i n g d i s t a n c e s , s l e e p i n g , a n d s t a n d i n g . T h e F A A M h a s d e m o n s t r a t e d a c c e p t a b l e r e l i a b i l i t y , c o n t e n t v a l i d i t y , a n d m o d e r a t e r e s p o n s i v e n e s s .

Statistical Methods

Repeated-measures analysis of variance (ANOVA) was used to determine significant differences among preoperative, one-year postoperative, two-year postoperative, and final follow-up time points for each continuous dependent variable. Tukey post-hoc testing was used to determine which time points were significantly different from one another. Descriptive statistics were employed to describe the number of concomitant procedures in patients with high-grade complications (deep infection, aseptic loosening, and implant failure). In addition, the number of patients with high-grade, medium-grade (subsidence and postoperative bone fracture), or low-grade complications (intraoperative bone fracture and wound-healing problems), as defined by Glazebrook et al., were reported. Because of the number of ANOVA assessments that were completed as part of the study, a Bonferroni correction was performed to adjust the alpha level. Following the Bonferroni correction, the alpha level was set at $p < 0.003$.

Source of Funding

This study was funded solely through institutional support. There was no outside grant or industry sponsorship.

Results

Patient Demographics

Two hundred and fourteen patients were treated with an INBONE Total Ankle Replacement during the study period. Eleven underwent revision total ankle arthroplasty with the INBONE system, and nine underwent takedown of an ankle arthrodesis and conversion to a total ankle arthroplasty. These twenty patients were excluded to ensure a homogeneous patient population. Therefore, the study population comprised 194 patients who had undergone primary total ankle arthroplasty and had been followed clinically for a mean of 3.7 years (range, 2.2 to 5.5 years). There were 135 men and fifty-nine women with a mean age of sixty-four years (range, twenty-three to eighty-eight years).

<table>
<thead>
<tr>
<th>Table I: Results of Patient-Reported Outcome Questionnaires</th>
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<tbody>
<tr>
<td><strong>Questionnaire</strong></td>
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<tr>
<td>VAS pain</td>
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<tr>
<td>AOFAS</td>
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<tr>
<td>Total</td>
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<tr>
<td>Pain</td>
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<td>Function</td>
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<td>Alignment</td>
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<td>SF-36</td>
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<td>Total</td>
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<tr>
<td>Physical</td>
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<tr>
<td>Mental</td>
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<tr>
<td>SMFA†</td>
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<tr>
<td>Function</td>
</tr>
<tr>
<td>Bother</td>
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*There was a significant difference between the preoperative and one-year evaluations and between the preoperative and final follow-up evaluations ($p < 0.003$). †With the SMFA, a lower value is a better score.

<table>
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<tr>
<th>Table II: Results of Functional Tests and FAAM</th>
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<tbody>
<tr>
<td><strong>Test</strong></td>
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<tr>
<td>Walking speed (m/s)</td>
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<tr>
<td>TUG (s)</td>
</tr>
<tr>
<td>STS (s)</td>
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<tr>
<td>4SST (s)</td>
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<tr>
<td>FAAM</td>
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</table>

*Significant ($p < 0.003$).
The etiologies of the ankle arthritis were posttraumatic (68%), osteoarthritis (22%), osteonecrosis (5%), rheumatoid arthritis (4%), and another diagnosis (1%). The median body mass index (BMI) was 29.7 kg/m² (range, 19.7 to 66.7 kg/m²), and seventy-nine patients (41%) were obese (BMI > 30 kg/m²). The most common comorbidities were coronary artery disease (14%), tobacco use (12%), and type-II diabetes mellitus (9%).

**Patient-Reported Outcomes**

All patient-reported outcome questionnaire scores demonstrated significant improvement from the preoperative baseline to the time of final follow-up, which was greater than two years for all patients (Table I). There was no difference in these patient-reported outcome scores between the one-year follow-up and any subsequent follow-up time point, including the two-year evaluation and the final follow-up (data not shown). Thus, all significant improvement in patient-reported outcomes occurred within the first year following the total ankle arthroplasty.

**Functional Assessment**

Walking speed; results of the TUG, STS, and 4SST assessments; and FAAM scores all demonstrated significant improvement from the preoperative baseline to the one-year follow-up evaluation and from the preoperative baseline to the two-year follow-up evaluation (Table II). Walking speed, STS results, and FAAM scores demonstrated significant improvement between the one and two-year evaluations (Table II), indicating some continued improvement in function beyond one year following total ankle arthroplasty.

**Radiographic Analysis**

Fifty-six patients (29%) had a preoperative coronal tibiotalar angle between 5.0° and 25.0° (neutral alignment). Seventy-five patients (39%) had a coronal tibiotalar angle of less than 5.0° (varus deformity), and sixty-three patients (32%) had a coronal tibiotalar angle of less than 25.0° (valgus deformity). Postoperatively, 96% of the patients had neutral alignment, 3% had persistent valgus alignment, and 1% had persistent varus alignment. The mean correction of the coronal tibiotalar angle (and standard deviation) was from 15.4° ± 7.0° to 1.0° ± 2.1° (p < 0.001) in patients with a preoperative varus deformity. In patients with a preoperative valgus deformity, the mean correction was from −14.5° ± 6.7° to −1.7° ± 2.6° (p < 0.001).

Twenty-five ankles (13%) had subsidence. Of these, ten (5% of the series) demonstrated subsidence that was considered stable at the time of the most recent follow-up. Another nine ankles (5%) demonstrated gross and progressive subsidence of the unstable talar component (Fig. 1). These nine ankles were considered impending failures, and revision arthroplasty was recommended but not accepted by the patients.

**TABLE III Prevalence of Procedures Concomitant to Total Ankle Arthroplasty**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Medial release</td>
<td>52</td>
</tr>
<tr>
<td>Gastrocnemius-soleus recession</td>
<td>35</td>
</tr>
<tr>
<td>Achilles triple hemisection</td>
<td>13</td>
</tr>
<tr>
<td>Hardware removal</td>
<td>29</td>
</tr>
<tr>
<td>Subtalar arthrodesis</td>
<td>23</td>
</tr>
<tr>
<td>Lateral ankle ligament reconstruction</td>
<td>13</td>
</tr>
<tr>
<td>Calcaneal osteotomy</td>
<td>12</td>
</tr>
<tr>
<td>First metatarsal osteotomy</td>
<td>9</td>
</tr>
<tr>
<td>Tibial osteotomy</td>
<td>8</td>
</tr>
<tr>
<td>Talonavicular arthrodesis</td>
<td>6</td>
</tr>
<tr>
<td>Fibular osteotomy</td>
<td>6</td>
</tr>
<tr>
<td>Tendon transfer</td>
<td>4</td>
</tr>
</tbody>
</table>

Fig. 1

**Figs. 1-A through Fig. 1-D** Lateral weight-bearing ankle radiographs made initially after total ankle arthroplasty (Fig. 1-A), at one year (Fig. 1-B), at three years (Fig. 1-C), and at five years (Fig. 1-D). The five-year radiograph demonstrates gross subsidence of the talar component and impending failure.
Six ankles with substantial subsidence of the talar component underwent conversion to a tibiotalocalcaneal arthrodesis, as discussed below.

Concomitant Procedures and Complications

At the time of the total ankle arthroplasty, 69% of the patients required at least one additional concomitant procedure (Table III). The most common concomitant procedures were a medial soft-tissue release to correct varus malalignment and a gastrocnemius-soleus complex recession for equinus contracture. Twelve patients (6%) had a high-grade complication, and eight of them had an average of 1.9 concomitant procedures. Of the remaining 182 patients in the cohort, 125 (69%) had an average of 2.0 concomitant surgical procedures.

Intraoperative complications included four medial malleolar fractures treated with internal fixation and one partial laceration of the posterior tibial tendon treated with primary repair reinforced with transfer of the flexor digitorum longus tendon to the navicular insertion of the posterior tibial tendon.

Twenty patients (10%) had a postoperative wound complication (Table IV). An additional six patients developed superficial peroneal neuritis, which was managed effectively with oral medication. Three patients developed a stress fracture along the medial aspect of the tibia after progression to weight-bearing. Treatment consisted of protected weight-bearing in a CAM boot for two and internal fixation in one. One patient developed a pulmonary embolism nine days after surgery and was treated with anticoagulation for six months.

Reoperation and Revision

Of the 194 patients, twenty-one (11%) required at least one nonrevision reoperation that was directly related to the total ankle arthroplasty, and an additional twenty-eight (14%) required at least one subsequent nonrevision procedure on the affected ankle and foot during the study (see Appendix). Twelve patients (6%) underwent revision or removal of the metallic components of the INBONE prosthesis, leaving 133 patients without subsequent surgery or revision.

The mean time from the operation to revision was 1.6 years (range, 0.2 to 3.2 years). Four of the twelve patients had revision total ankle arthroplasty: two patients underwent revision of the talar component, one underwent revision of the tibial component because of aseptic loosening, and one had revision because of a fracture of the tibial component at the junction of the baseplate and the stem. All who underwent a component revision also had a polyethylene exchange at the time of the surgery. Six patients had substantial subsidence of the talar component that precluded revision total ankle arthroplasty and underwent conversion to a tibiotalocalcaneal arthrodesis. Two of the twelve patients underwent revision because of deep infection.

Discussion

This study demonstrates that patients who undergo total ankle arthroplasty with a fixed-bearing implant with a modular intramedullary stem for end-stage ankle arthritis have significant improvement in alignment, pain scores, quality-of-life measures, and subjective function. The overall implant survival rate was 89%, when non-survival cases included revisions of one or more of the metal components and impending failures. Our implant survival rate at a mean of 3.7 years is comparable with that of other modern total ankle prostheses, for which survival rates of 70% to 98% were reported at three to nine years.

There was significant improvement in patient-reported outcomes validated for musculoskeletal and lower-extremity pathology. The significant improvements generally were gained in the first year after surgery, and while this improvement was maintained until the time of final follow-up, the outcome scores did not increase significantly after one year. The results also indicated improvements in overall function following total ankle arthroplasty. In contrast to the patient-reported outcomes, which did not demonstrate a significant change after one year, walking speed, STS time, and FAAM scores continued to improve significantly between one and two years following total ankle arthroplasty. The faster postoperative walking speeds and shorter completion times of the TUG, STS, and 4SST tests indicate overall improvement in patient function during activities of daily living. The improvement in 4SST performance suggests greater stability after total ankle arthroplasty. The mean walking
speed in this patient cohort increased by 41% at two years compared with the preoperative speed. Brodsky et al. reported a 32% increase in walking speed at forty-nine months in a cohort of patients treated with a Scandinavian Total Ankle Replacement (STAR).

The improvements in functional outcomes may be related to pain relief postoperatively. Previous literature has indicated that patients with ankle osteoarthritis and ankle pain tend to walk more slowly and have less postural stability and balance. Pain as determined by the VAS pain score and the AOFAS ankle-hindfoot pain subscore was significantly reduced.

In addition to a 6% revision rate for metallic components, 5% of the ankles had stable subsidence of the talar component, and 5% had unstable subsidence and impending failure of the prosthesis. We did not detect progressive radiolucent lines in these patients. This may represent an osteolytic process occurring in the intervals between our radiographic analyses, or it may represent avascular changes within the talar body. The introduction of instruments through the subtalar joint may risk injury to the extrasosseous and intraosseous talar vascular network. The artery of the sinus tarsi and the artery of the tarsal canal form an anastomosis on the plantar-posterior aspect of the talar neck. This complex arterial anastomotic network is at risk when the drill is passed through the sinus tarsi and into the talus. With the multiple potential factors leading to talar component subsidence and the small number of cases of talar component subsidence in our study, we cannot draw a conclusion about whether the 6-mm drill/reamer was the cause of the subsidence. Future studies with a larger number of failures and multiple prostheses are needed to adequately determine the association of these peritalar procedures and talar component subsidence.

There was a 10% prevalence of wound complications in the postoperative period. One-half of these complications were superficial and managed with immobilization, local wound care, and antibiotics. There was a 5% prevalence of wound complications leading to additional surgical procedures and sometimes failure of the implant. While patient comorbidities have a role in wound complications, we emphasize minimal skin trauma intraoperatively by initiating deep retraction as early as possible during the procedure. We routinely place a drain to prevent wound pressure from fluid collections and have patients use nasal cannula oxygen while they are in the hospital.

Although 25% of the patients subsequently required nonrevision procedures, a reoperation after a total ankle arthroplasty does not imply that the arthroplasty failed. Some additional procedures are planned in a staged fashion such as correction of an ankle deformity with a total ankle arthroplasty and subsequent correction of a foot deformity. Other additional procedures may not be planned but are important to relieve symptoms and improve function. In many of these instances, the etiologies of symptoms that occur after the total ankle arthroplasty are not evident during the operation or arise subsequently. We believe that additional procedures for relieving impingement, improving alignment, applying bone graft to cysts, and/or exchanging the polyethylene component can prolong metal implant survival.

There were several limitations to this study. First, all of the total ankle arthroplasties in this series were performed by surgeons experienced with performing total ankle arthroplasties and familiar with this prosthesis, so these results may not generally reflect those of surgeons with less experience with total ankle arthroplasty. The literature on total ankle arthroplasty outcomes suggests a period during which surgeons gain experience and expertise before they are proficient at performing the procedure, with several investigators directly studying this issue. Saltzman et al. suggested that this so-called learning curve exists irrespective of particular training in total ankle arthroplasty and showed, in a multicenter study, that with experience complication rates are essentially halved.

A second limitation of our study is that preoperative and postoperative ankle range of motion was not recorded. However, previous studies demonstrating pain relief and functional improvement after total ankle arthroplasty have demonstrated only marginal improvement in range of motion. A third limitation is that the AOFAS ankle-hindfoot score has not been validated. However, the score is a useful tool for comparison with previous studies, and the other validated outcomes measures demonstrated significant improvement. Finally, all implants used in this series were INBONE I prostheses. Currently, the INBONE II prosthesis is available for implantation.

In conclusion, early to mid-term outcomes with the INBONE Total Ankle Replacement are comparable with results of other total ankle arthroplasty systems after similar durations of follow-up. We identified significant improvements in alignment, pain, and function with a low revision rate. Continued follow-up of this cohort should prove useful.

### Appendix

| Table showing nonrevision reoperations directly related to the total ankle replacement and subsequent surgery on the affected ankle and foot is available with the online version of this article as a data supplement at jbjs.org. |

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