



Evaluating the Fixed Bearing Modular Stem Total Ankle Replacement: 8 Year Outcomes

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STATEMENT OF PURPOSE

While ankle joint replacement systems have a long history of complications, evolution in implant design continues to improve mid- to long-term outcomes and implant survivorship. The purpose of this study is to evaluate patient outcomes 8 years following total ankle replacement (TAR) with a two-part, modular stem, fixed-bearing ankle prosthesis.

PROCEDURE

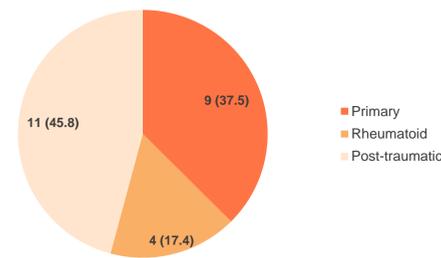
TAR was performed with intramedullary guidance according to the manufacturer's guidelines alone or in conjunction with tendo-achilles lengthening by one surgeon (SAB).

RESULTS

Patient Demographics

25 patients met the inclusion criteria; 1 patient was lost to follow-up 24 patients (63.0 ± 10.0 years) were included in the study

Arthritis



Complications

Minor Complications	
Intraoperative fracture	1 (4.2)
Stiffness	2 (8.3)
Superficial wound	2 (8.3)
Tibial loosening	-
TOTAL	5 (20.8%)
Major Complications	
Deep wound	2 (8.3)
Deep infection	1 (4.2)
Pulmonary embolism	2 (8.3)
Ectopic bone removal	1 (4.2)
Talar subsidence	1 (4.2)
TOTAL	7 (29.2)
TOTAL COMPLICATIONS	12 (50.0)

ANALYSIS & DISCUSSION

While ankle arthrodesis is still considered the "gold standard" for first line treatment of end-stage ankle arthritis, there continues to be advancements in the design of total ankle replacements, which has made them a viable surgical treatment option. This third generation total ankle replacement system with a modular stem fixed bearing construct has shown promising results. This study is a continuation of reported data 7 years following implantation. Our results show relatively low complication rates with significant improvements in patient reported outcomes.

For the 24 patients included in the outcomes analysis, there were significant improvements in pain in the morning, difficulty walking four blocks, and use of an ambulation device. In total, there were 4 (16.7%) wound complications. The two superficial wounds resolved with local wound treatment. Of the deep wounds, one had full thickness wound dehiscence with exposed tendon, which was treated with a local pedicle flap and healed without complication. The second wound was treated with a free flap. Pulmonary embolisms were anti-coagulated and recovered. The ectopic bone required surgical excision. Three patients (13.0%) required revision surgery during the study period. One patient demonstrated talar subsidence, requiring subtalar joint fusion. There is still a functioning prosthetic in the limb, and the patient is doing well. A revision surgery was also performed to treat the deep infection. One patient required a below the knee amputation following a motor vehicle accident.

The present study had several limitations, which have the potential to threaten the validity of our conclusions. A primary limitation was its retrospective design, which inherently increases the potential for bias. Additionally, our sample size was limited to 24 patients. This relatively small sample size may not give an accurate representation of the general population. We also lacked a control group due to the basic study design, which would have allowed us to make comparisons within our study population. Despite these limitations, we do believe that these results do show favorable outcomes of a modular stem fixed bearing total ankle replacement 8 years following implantation.

METHODOLOGY & HYPOTHESIS

Inclusion & Exclusion Criteria

Inclusion

- ≥18 years of age
- Underwent TAR with a modular stem fixed bearing total ankle prosthesis
- Procedure performed by one surgeon (S.A.B.) between 2008-2009

Exclusion Criteria

- No preoperative/postoperative data available

Outcomes

- Pain the morning visual analog scale [VAS]
- Difficulty walking 4 blocks (VAS)
- Use of an assistive device (VAS)
- Complications

Statistical Analyses

- Outcomes were compared across time using a paired samples t-test
- Statistical significance was set at the 5% level ($p \leq 0.05$)
- Data presented as mean ± standard error or count (%)

Hypothesis

Given the early success of this modular stem fixed bearing implant, we hypothesize that the modular stem fixed bearing TAR would improve patient reported outcomes.

LITERATURE REVIEW

End-stage ankle arthritis can be a debilitating condition for patients. Conservative treatments are often not sufficient to relieve pain and improve quality of life, and patients are left with the need for surgical intervention. Ankle arthrodesis and total ankle replacements are viable surgical solutions.

First generation ankle implants were wrought with complications and poor patient satisfaction, leading to their disuse. Second generation implants had much better outcomes, but patients still experienced complications such as subsidence and aseptic loosening (1-5). Ankle implants have continued to evolve in their design to create a more functional replacement (6-8) while preserving range of motion and restoring normal ankle joint kinematics (9,10).

A newer model of ankle replacement that consists of a modular stem fixed bearing total ankle replacement was approved by the Food and Drug Administration in 2005. The implant uses intramedullary alignment instrumentation to ensure an appropriate size for the individual patient anatomy (11). The early results of the INBONE prosthesis show improved patient-reported outcomes and increased range of motion (12,13).

Clinical Outcomes

(N = 21)



*Statistically significant at the 5% level
Three patients required revision surgery and were excluded from the outcomes analysis.

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