A Preliminary Evaluation of a New Generation Fixed-Bearing TAR System

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STATEMENT OF PURPOSE

Total ankle replacement (TAR) aims to preserve motion and improve quality of life. Learning from areas of faulty implant design, mid- to long-term survivorship and functional outcomes have improved. The purpose of the present study was to report our preliminary results with a new generation fixed-bearing TAR system.

LITERATURE REVIEW

Total ankle replacement systems have evolved since they were first introduced in the 1970's as the kinematics of the ankle joint became more fully understood (1). First generation implants consisted of a polyethylene tibial component and a metal talar component. These implants had high failure rates due in large part to aseptic loosening and resulted in poor patient satisfaction. The implant designs necessitated a large amount of bone resection and the use of cement. Much of the failure occurred from loosening of the implant around the bone-cement interface (1). Second generation implants emerged in the 1980's, introducing semi-constrained implant designs that required less bone removal with the incorporation of a more anatomic design (1,4). In the late 1990's, third generation ankle replacement systems became available, which consisted of unconstrained, mobile bearing units. While fixed bearing constructs have only one articulating, partially conforming interface, mobile bearing implants have two separate, fully conforming articular surfaces (6).

Recently, a new generation implant has become available, which has increased tibial coverage to prevent subsidence, requires minimal talar resection, addresses sagittal plane alignment for patients with anterior or posterior ankle subluxation, and has anatomically-designed components based on a compilation of CT scans (7). This study provides the preliminary results following implantation of this new generation system in a small cohort of patients.

HYPOTHESIS

Given the increased tibial coverage and minimal talar resection, we anticipate encouraging preliminary results with this new generation fixed-bearing TAR system.

METHODOLOGY & RESULTS

Level of Evidence: IV

Study Design: Chart Review
- A retrospective chart review was performed to identify consecutive patients who underwent total ankle arthroplasty with a new generation fixed-bearing TAR system

Inclusion Criteria
- ≥18 years of age
- Underwent TAR with a new generation fixed-bearing prosthetic
- Procedure performed by one surgeon (S.A.B.)

Exclusion Criteria
- Revision surgery
- Postoperative acute traumatic injury interfering with wound healing

Outcomes
- Pain
- Return to activity
- Wound dehiscence

Procedure
- TARs were implanted through an anterior ankle approach

Statistical Analyses
- Pain was 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 deviation or count (%).

Figure 1. Concomitant Procedures

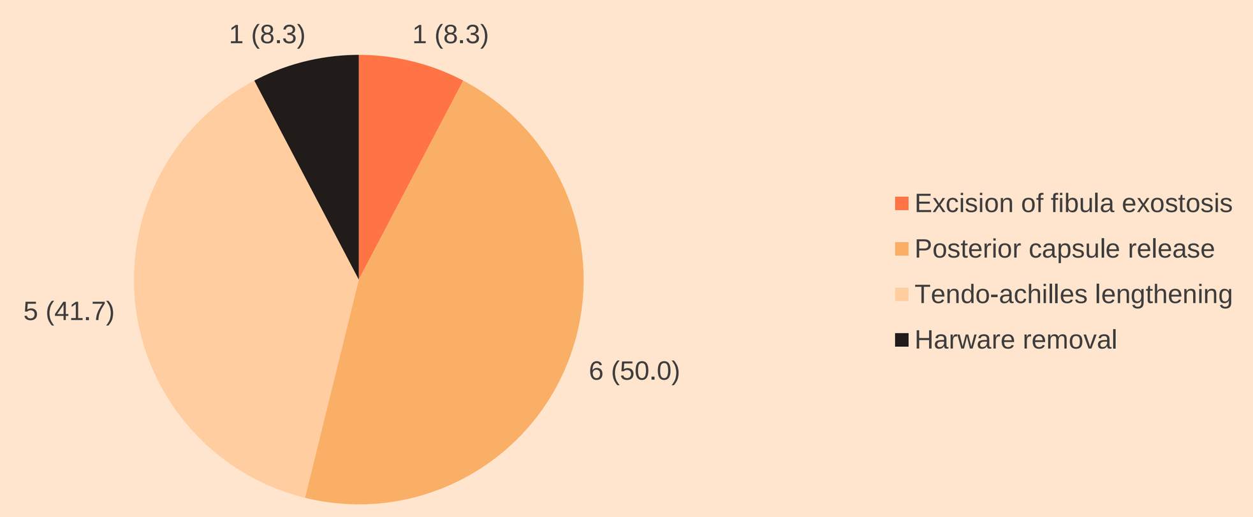


Table 1: Patient Demographics & Concomitant Procedures

Demographic	All Patients
Patients	12 (100.0)
Age (years)	66.3 ± 11.4
BMI (kg / m²)	31.0 ± 4.7
Gender	
Men	7 (58.3)
Women	5 (41.7)
Concomitant Procedures	
Yes	9 (75.0)
No	3 (25.0)

Table 2: Return to Activity

Outcome	All Patients
Duration of Non-weight Bearing Status (weeks)	2.9 ± 0.2
# Physical Therapy Visits	21.4 ± 13.2

Figure 2. Pain across Time

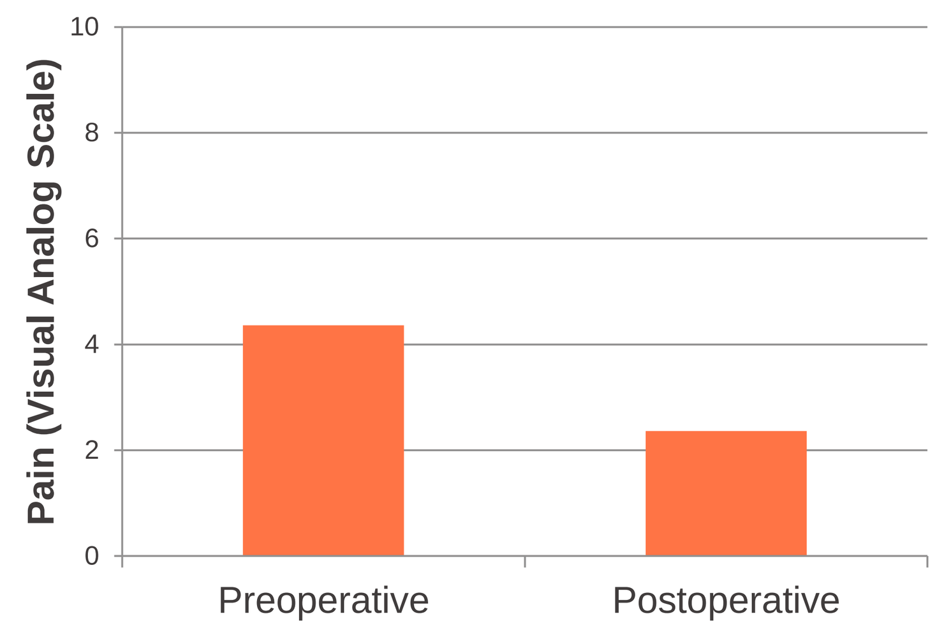
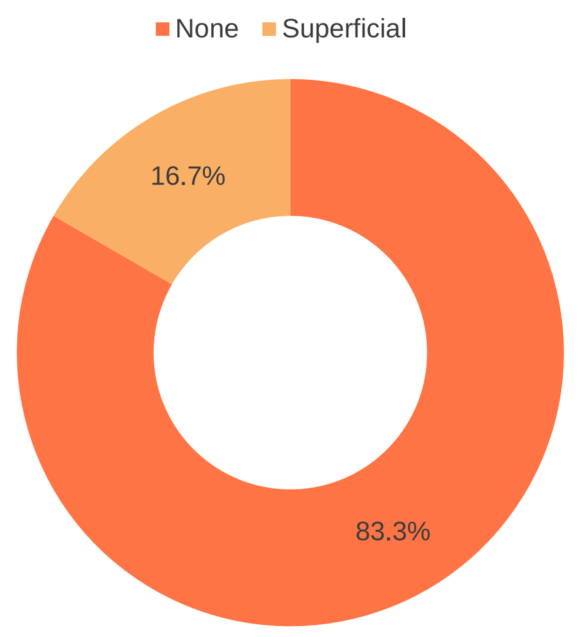


Figure 4. Wound Dehiscence



DISCUSSION

Ankle osteoarthritis is a painful and debilitating condition, which can alter a person's normal daily activities and lead to weight gain, medical problems, and a decreased quality of life. For end-stage ankle arthritis recalcitrant to conservative treatment, two main options for surgical treatment exist: ankle arthrodesis and total ankle replacement. Ankle arthrodesis is still considered the gold standard for surgical treatment of ankle arthritis, presumably due to the low success rate of first and second generation ankle joint replacement systems (8). As ankle joint replacement systems have evolved, research has demonstrated increased implant longevity with decreased complications, such as aseptic loosening and subsidence (9). The benefits of TAR over arthrodesis include maintenance of ankle joint motion, decreased risk of developing adjacent joint arthritis, and earlier weight bearing (8,9). In this study, we report the preliminary outcomes of a new generation TAR.

The present report examined changes in pain and return to activity following TAR in 12 patients. There was no significant difference in preoperative (4.4 ± 3.1, n = 11) and postoperative pain (2.4 ± 2.9, n = 11, P = 0.18). Following surgery, the average duration of non-weight bearing status was 2.9 ± 0.2 weeks with an average of 21.4 physical therapy visits. Wound dehiscence occurred in 2 (16.7%) patients and was successfully resolved with antibiotics and Epsom salt soaks.

There are several limitations to this study. First, these results are limited to a short follow up of 3 months, preventing any long-term complications from being reported. Second, with a small sample size of 12, our data are easily skewed and may not represent the outcomes expected from the general population. Third, this is a retrospective chart review, which lends itself to inherent bias. In some cases the subjective data from the patients was not suitable for extrapolation. In the future, a prospective study with a larger sample size and long-term follow up would provide a more accurate representation of the longevity of this implant. However, we do feel that even with our small sample size, this total ankle replacement system has promising short term outcomes.

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