



EVALUATION OF A MOBILE BEARING TOTAL ANKLE REPLACEMENT IN SIMULATION AND CLINICAL RETRIEVAL

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INTRODUCTION

The use of total ankle replacements is increasing as an alternative to arthrodesis that allows patients to maintain both mobility and function concomitant with pain relief. Their success, however, remains mixed, mostly attributed to the interaction of design geometries and the complexity of ankle joint motion.⁶ This has been exemplified by failures of designs with excessive constraint or insufficient material durability leading to loosening and wear.^{7,10,15-17} The expectation of these failures makes paramount the evaluation of anticipated device performance, particularly long-term fatigue and wear characteristics, prior to widespread clinical use. The recent United States Food and Drug Administration (USFDA) clearance of the first mobile bearing total ankle replacement represents the culmination of extensive pre-clinical and clinical evaluations.

This exhibit describes the wear characteristics of a three-part mobile total ankle replacement during 10 to 20 years of simulated walking in a novel, multi-axial gait simulator (US Patent No. 7,493,828 B2) with comparison to clinical retrievals. These results are useful in demonstrating safety and effectiveness of this device and also present a pre-clinical evaluation methodology for future ankle designs.

THE DESIGN

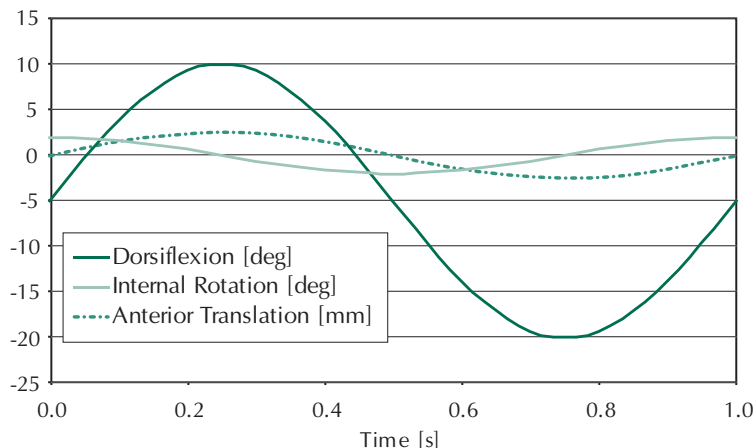
Testing was performed on the S.T.A.R.[®] mobile ankle device (Scandinavian Total Ankle Replacement, Small Bone Innovations, Inc., Morrisville, PA, USA). The S.T.A.R.[®] is a three-part ankle replacement consisting of an ultra-high molecular weight polyethylene (UHMWPE) mobile bearing positioned between highly polished cobalt chrome molybdenum (CoCrMo) talar and tibial components. The device relies on biological ingrowth for fixation and requires minimal bone resection. The mobile bearing is constrained to only dorsi and plantar flexion motion on the talar articulation, while allowing both translation and rotation to occur in a transverse plane on the tibial articulation. The indications for use are treatment of the painful arthritic ankle as an alternative to arthrodesis. This device has been implanted outside the United States since 1990 and received approval by the USFDA in 2009 based on both a clinical trial and the information presented in this simulator study.



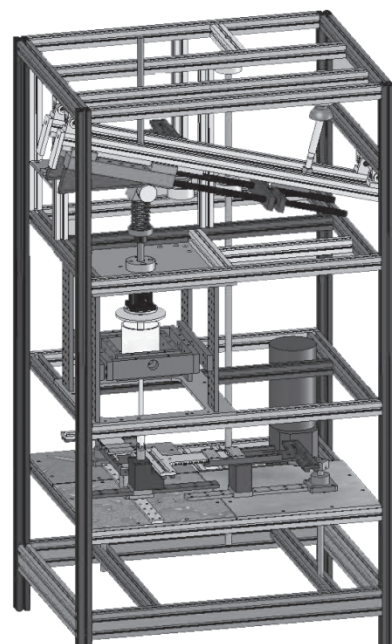
S.T.A.R.[®] Mobile Ankle Replacement

THE SIMULATION

Ankle motion simulation poses several technical difficulties including a limited knowledge of ankle loads and motions. Data from several researchers^{11,14} was synthesized into a walking profile. Specimens were aligned in 5 degrees of plantar flexion and loaded statically to 3000 N of joint compression. Under displacement control, the prosthesis was articulated through 15 degrees of fully reversing flexion ($R = -2$) and 2.0 degrees of fully reversing axial rotation ($R = -1$). In addition, the prosthesis was articulated 2.5 mm of fully reversing anterior translation ($R = -1$). All motions were sinusoidal at a rate of 1 Hz. Internal rotation was phase shifted -90 degrees with respect to dorsi/plantar flexion and anterior translation.



Ankle Simulator Wear Motion Profile



Multi-Axial Gait Simulator

Five specimens ($n=5$) were tested in a series of identical, custom, single-station motion simulators for 10 million motion cycles (Mc). All tests were conducted in bovine calf serum lubricant diluted to a total protein concentration of 20 grams per liter with phosphate buffered saline as specified in the ASTM guide F1714-96. Additionally, the lubricant contained 0.2% sodium azide and ethylene-diaminetetraacetic acid (EDTA) at a concentration of 20 mM.

Wear was determined by the gravimetric weight loss method described in ASTM F1714. Specimens were evaluated before testing, every 500,000 cycles for 1 million cycles, and every 1 million cycles thereafter. Individual components were weighed on a Sartorius ME235S analytical balance (Sartorius AG, Goettingen, Germany) with a resolution of 0.01 mg. At each of the test intervals fresh lubricant was replaced and the wear particles analyzed. The cumulative weight loss and wear rate were reported for each specimen at each interval after correcting for fluid absorption in two load soak controls ($n=2$).

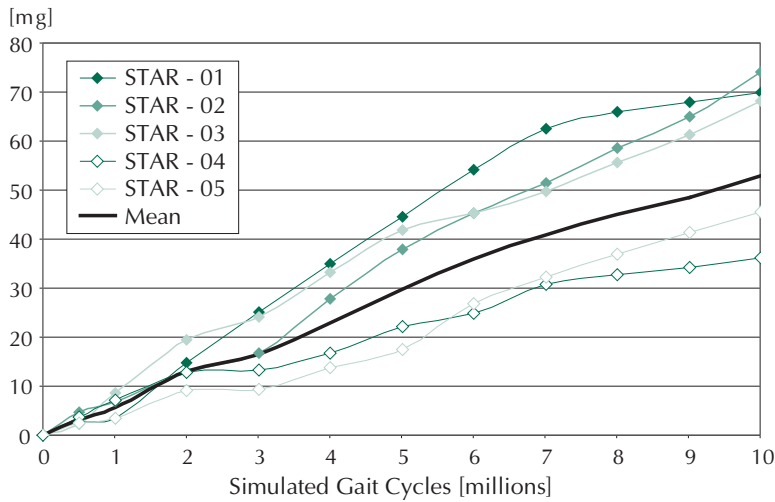
THE CLINICAL RETRIEVALS

Thirty-five retrieved UHMWPE cores from the S.T.A.R.[®] prosthesis were analyzed for wear damage based on the classification described by Hood et al.⁵ The damage modes were defined as burnishing, abrasion, pitting, surface deformation, delamination, scratching, debris capture, track scratching, biologic skiving, fracture and explantation. All surfaces underwent subjective grading with the ranking defined as single (less than 1%), trace (1% to 10%), minor (10% to 50%), major (50% to 90%) and uniform (greater than 90%) with particular attention to the central stabilizing trough/keel.

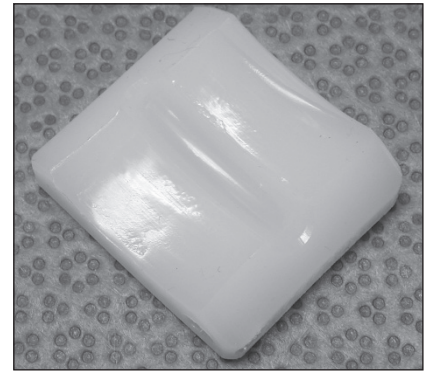
RESULTS

THE SIMULATION

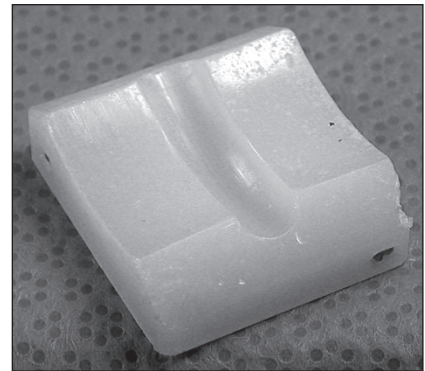
All five devices completed 10 million cycles without functional or mechanical failure. Abrasion of the UHMWPE cores was observed on all articulating interfaces with a mean volumetric wear rate of 5.7 mm³ per million cycles over the 10 million cycles. Average loss of height in the UHMWPE Core component was 0.19 mm on the talar articular surface and 0.18 mm on the tibial articular surface.



Cumulative Weight Loss - UHMWPE Core



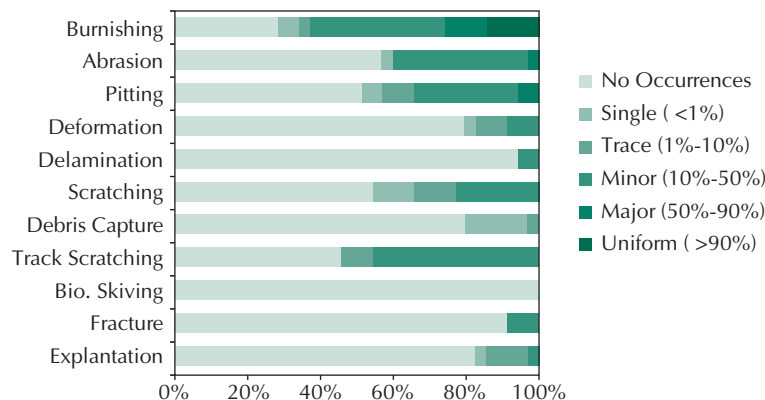
The inferior articular surface of the S.T.A.R.® UHMWPE Core component (STAR-04) after 10 million cycles demonstrating extensive abrasive polishing and minor pitting.



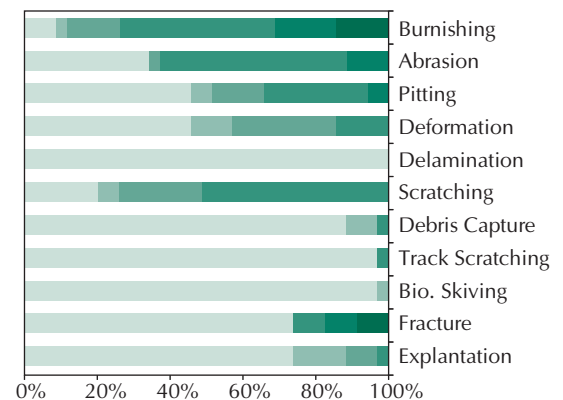
A S.T.A.R.® clinical retrieval with 4 years of in-vivo service displaying minor abrasion, pitting and track scratching, mimicking the damage patterns of the simulator components.

THE CLINICAL RETRIEVALS

The thirty-five clinical retrievals had implantation dates ranging from 0 to 6 years and all surfaces were graded to define the extent of damage for each defined mode. Burnishing was the most common mode of wear followed by scratching, pitting and abrasion. Three of the thirty-five (3/35) specimens presented with fractures that precluded reasonable function. Substantial damage to the trough/keel was observed on nine of the thirty-five (9/35) specimens. Further, bone contact was presumed to have caused significant loss of material on the edges of nine of the clinical retrievals. This data is presented graphically for both the talar and tibial surface in the following graphs.



S.T.A.R.® Core Retrieval Analysis
Damage Occurrence by Type on the Talar Surface



S.T.A.R.® Core Retrieval Analysis
Damage Occurrence by Type on the Tibial Surface

DISCUSSION

Trauma, most often, is the antecedent event giving rise to ankle degenerative joint disease (DJD) where impairment of the subtalar complex is not always appreciated. Early ankle designs provided excessive geometric constraint across the tibial-talar complex not fully accounting for the subtalar role in assisting ankle rotation. Fixation failure was all too common with failure rates ranging between 52% and 95% at 10 years.^{7,10,15-17} Mobile bearing ankle designs seek to accommodate rotation at the tibial-talar surface.^{3,13}

This study demonstrates that within a 10- to 20-year period of simulated function, the volumetric wear debris generated is substantially less than what has been reported in previous hip and knee simulator reports.^{2,4} Although variance in simulator and prosthetic design can account for data differences, the findings support a reduced UHMWPE particle load as well as a reduction in wear rate employing conventional UHMWPE.

Ankle replacement to-date has seen limited clinical use by comparison to arthrodesis. Its success is seen to be dependent not only on design, but on careful patient selection, precise technical placement, correction of deformity, and the ability to realize sound fixation over time.^{8,9,12} The relief of pain and return of function, as in any device, are the clinical endpoints. Mobility in total ankle design offers an appreciation of joint biomechanics and suggests that the above clinical goals are achievable.

CONCLUSION

The S.T.A.R.® mobile bearing ankle device represents a design which accommodates the need to achieve rotation at the tibial-talar articulation and overcomes the geometric constraint of earlier two-part ankle systems. The simulation suggests that the UHMWPE bearing exhibits durability over long-term dynamic function and offers reduction in both volumetric wear and wear rate by comparison to hip and knee simulator reports. The simulator mimicked damage modes observed in a majority of the clinical retrievals (21/35). Fourteen retrievals presented with unanticipated failures, some with multiple modes: edge wear (9/35), structural damage (9/35) and fracture (3/35) and may be associated with inadequate component placement.

These laboratory simulator evaluations assist an understanding of anticipated performance of total ankle designs particular to their material wear characteristics, and should be required of all future designs, both fixed and mobile, to assure their safety and effectiveness.

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