Development of a Total Ankle Wear Model

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INTRODUCTION: In recent years, total ankle arthroplasty has gained acceptance as a treatment option for ankle arthritis, and has been found to have comparable clinical results to ankle arthrodesis [1]. However, one of the primary reasons for revision of total ankle replacements is aseptic loosening [2-3], which may be attributed to osteolysis due to polyethylene (PE) wear [9]. Prior studies have reported ankle wear measurements in simulator testing but little is known regarding the clinical validity of these methods [4-5]. The purpose of this study was to develop an in-vitro simulation model for total ankle replacement systems and to compare the simulated PE wear damage to clinical retrievals of the same design. This in-vitro test methodology can provide us with a better understanding of contributing factors to clinically relevant PE wear mechanisms.

METHODS: A total of six (n=6) Total Ankle Arthroplasty (STAR, Stryker, Mahwah, NJ) UHMWPE mobile bearing inserts were evaluated in this study with all inserts of 6mm in thickness. Each PE insert articulated between cobalt chromium tibial (size US X-small) and talar (size US XX-small) components mounted on stainless steel fixtures using bone cement. The smallest possible sizing combination was used to simulate a worst case contact stress on the mobile bearing surfaces.

A knee joint simulator (MTS, Eden Prairie, MN) was used for testing. The tibial component was rotated (flexed) about a translatable axis with a specimen chamber containing a PE bearing surface insert and talar component on a base plate mounted below. The STAR system allows for decoupling of motions onto two articulating surfaces. dorsiflexion and plantarflexion took place on the curved talar surface. A groove in the PE bearing surface conforming to a crest on the talar component prevented sliding of the bearing component in the medial-lateral direction. Axial load and internal(+)/external(-) rotation were provided through the specimen chamber/talar assembly via an axial/torsional actuator. Plantarflexion(-)/dorsiflexion(+) and anterior(+)/posterior(-) translation were applied through the superiorly mounted tibial component (Figure 1).

The gait load and motion profiles were based on the existing work of Bischoff et al [4], as shown in Figure 2. These waveforms were adapted from the profiles of Bell et al. comparing the Buechel-Pappas and Mobility designs under walking conditions [5]. In diseased ankles, the joint loads are approximately 3x body weight, with similar values noted in replaced ankles [7]. Therefore a peak load of 3188 N (717 lb) was used representing an average weight multiplier of 3.8 for a total ankle arthroplasty patient [6].

Testing was conducted at a frequency of 1.0Hz. The lubricant used was Alpha Calf Fraction serum (Hyclone Labs, Logan, UT) diluted to 50% with a pH-balanced 20-mMole solution of deionized water and EDTA (protein level = 20 grams/liter) [8]. Bearing inserts were cleaned according to standard protocols every 0.5 million cycles for a total of 3.0 million cycles and serum was also changed at that interval. All test specimens were qualitatively inspected before and after simulator testing to determine the mode of wear and the extent of damage.

Images of PE inserts from patient retrievals (STAR, Stryker, Mahwah, NJ) were examined to compare against in-vitro wear samples.

RESULTS: As shown in Figure 3 and 4, visual inspection of PE bearing inserts for retrieved and simulated samples revealed wear scars in areas of load contact. Further inspection showed burnishing, striations and scratches which indicates net wear or deformation occurred. These findings were similar to retrieved components. No evidence of fracture or delamination of the material was observed on simulated samples.

DISCUSSION: Success in total ankle replacement is reliant on the understanding of the biomechanics involved at the tibio-talar articulation in the ankle. This study established a test method that generates similar wear as compared to retrieved components. This model may be utilized in the future to further understand and evaluate the tribological behavior of total ankle replacements. Future work may also include a test model to simulate polyethylene fracture in total ankle applications.

SIGNIFICANCE: Model may provide insight into total ankle replacement device design or material improvements.

Figure 3: Representative wear scars of STAR talar (left) and tibial (right) surface of bearing component from in-vitro testing.

Figure 4: Retrieval of STAR talar (left) and tibial (right) articulating surfaces of bearing component.