THE DEVELOPMENT OF A TOTAL ANKLE ARTHROPLASTY PRE-CLINICAL TEST

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INTRODUCTION

Component loosening, migration, and subsidence are the biggest concerns to implant designers and orthopedic surgeons when faced with the challenge of providing adequate ankle joint replacements. It is commonly known in the biomaterials and orthopedics communities that excessive wear debris in orthopedic implants can lead to osteolysis, resulting in these adverse affects [1]. Many wear tests have been done on hip and knee replacements [2], however wear simulation has not been done on total ankle replacements (TAR). Various static and dynamic tests have been performed on TAR [3,4], however these were performed under a wide range of conditions and examined a variety of results. In reference to TAR Lewis [5] states, "Clearly, a simulator would be an invaluable resource in comparing the biomechanical performance of a series of designs and, therefore, selecting the one(s) that deserve additional attention…These tests should be done in the simulator under appropriate conditions: for example, the test ankle should be immersed in a biosimulating solution, such as bovine serum + 20 mmol/L EDTA and 30% distilled water, at 37°C; the test frequency should be 1 Hz (Stauffer et al reported that patients with total ankle replacements walked, 1 year postoperative, with a mean cadence of 48.2 strides per minute); and the test duration should be at least 2 million cycles."

The purpose of this project was to design a test that simulates the long-term mechanical loading of any TAR under standard, physiological loads and ranges of motion. The test should quantify component wear and strength, and allow for a direct comparison between various TARs. The focus of this project, however, will be the AGILITY Ankle by DePuy, Inc.

METHODS

The tibial and talar components of the AGILITY Ankle (Fig. 1) will first be potted or welded into their respective test fixtures. The fixed components will then be placed in an AMTI knee wear simulator. The testing environment will be a bovine serum at 37^{o} C.

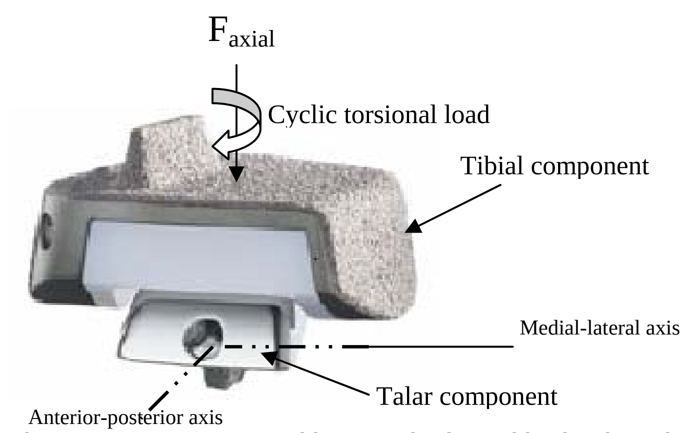

Figure 1: AGILITY Ankle prosthetic ankle implant by DePuy, Inc.

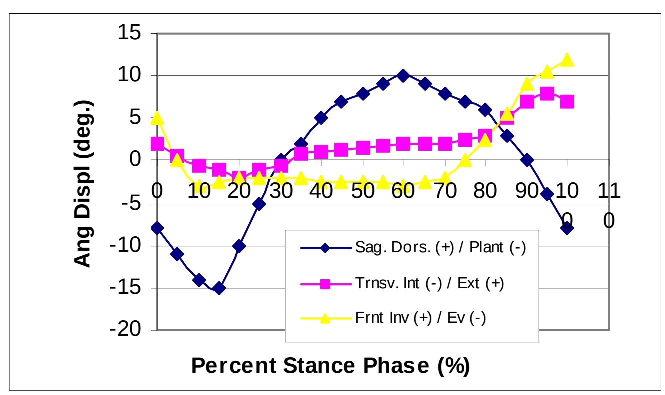

Figure 2: Talus Position in Sagittal, Transverse, and Frontal Planes over Stance Phase of Gait [6]

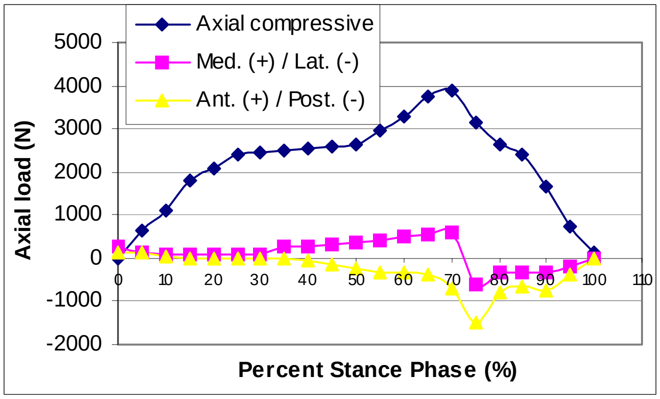

Figure 3: Axial Loads on Ankle Joint in 3 Directions Over Stance Phase of Gait Cycle [7]

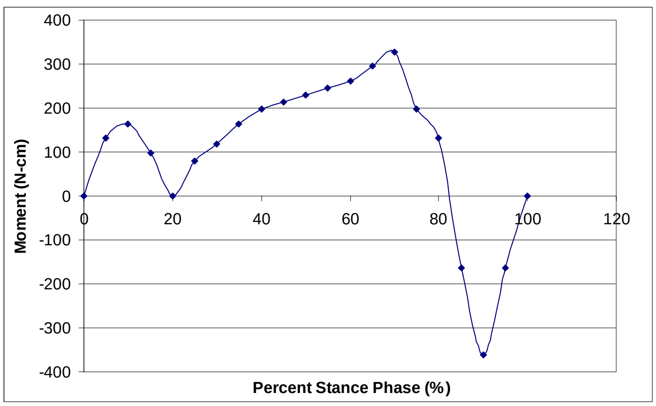

Figure 4: Torsional Load at Ankle Joint Over Stance Phase of Gait Cycle [8]

The inputs for the wear test will be physiological displacements (Fig.2) and loads (Figs. 3 & 4). This combination of loading and range of motion will closely simulate the physiological gait cycle. Load frequency, test duration, and Agility component size (1-6) will also be investigated according to physiological conditions, testing capabilities, and test duration.

Wear Test Input Validation

The mechanical wear test inputs will be validated by three methods: 1. By the comparison of wear patterns to those observed on clinical retrievals (Fig. 5), 2. By the comparison of specimen wear patterns to areas of high contact stress predicted by finite element (FE) models (Fig. 6), and 3. By comparing polyethylene wear particle shape and size to those obtained clinically [9]. The clinical retrievals were obtained from DePuy Orthopaedics, Inc., a J&J co., Warsaw, IN. In-vivo load conditions and number of cycles are unknown; however typical wear patterns can be seen. For the FE study, physiological forces and displacements were applied to the AGILITY components at every five percent of the stance phase of the gait cycle, resulting in 21 total models. A quasi-dynamic analysis of one movement through the stance phase of gait will result from the combination of these 21 models. It is expected that areas of high contact stress and large PE deformation on each of the 21 discreet computational models will combine to closely resemble the wear patterns found on the PE tibial insert clinical retrievals and in-vitro test specimens.

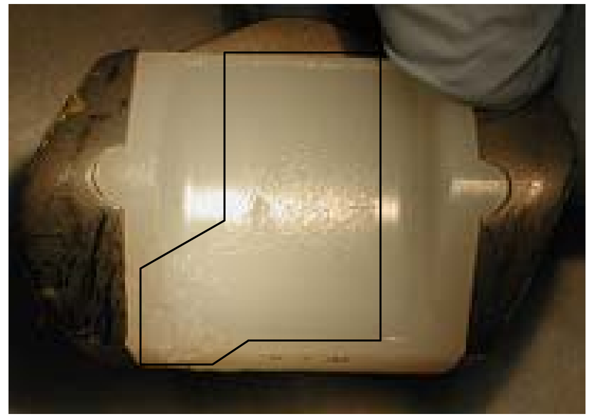

Figure 5: Typical wear pattern on an AGILITY clinical retrieval

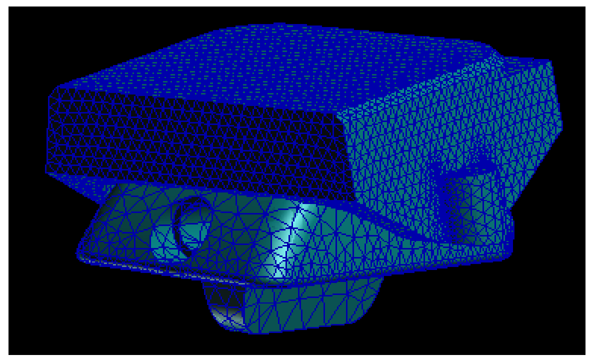

Figure 6: FE mesh of the AGILTY Ankle at 70% of the stance phase of gait: 8° dorsiflexion, 2° external rotation, 2° eversion

REFERENCES

1. Ratner, B. et al, 1996, "*Biomaterials Science: An Introduction to Materials in Medicine*", Academic Press.
2. Calonius, O., Saikko, V., 2002, "Analysis of Polyethylene Particles Produced in Different Wear Conditions In Vitro," Clinical Orthopedics, Vol. 399, pp. 219-230.
3. Greenwald, A. et al, 2000. (www.orlinc.com).
4. Valderrabano, V. et al, 2003, "Kinematic Changes After Fusion and Total Replacement of the Ankle," Foot and Ankle International, Vol. 24(12), 881-900.
5. Lewis, G., 2004, "Biomechanics of and Research Challenges in Total Ankle Replacement," Clinical Orthopaedics and Related Research, Num. 424, pp. 89-97.
6. Stauffer, R. et al., 1977, "Force and Motion Analysis of the Normal, Diseased, and Prosthetic Ankle Joint," Clinical Orthopedics, Vol. 127, pp. 189-196.
7. Seireg, A., Arvikar, 1975, "The Prediction of Muscular Load Sharing and Joint Forces in the Lower Extremities During Walking," Journal of Biomechanics, Vol. 8(2), pp. 89-102.
8. Dettwyler, M., et al, 2003, "Tibia Torsional Moments for Patients With a Total Ankle Arthroplasty of Unconstrained Type in Comparison With Healthy Adults During the Stance Phase of Walking," XIXth Congress of the ISB2003, Book of Abstracts p 89.
9. Kobayashi, A., 2004, "Ankle Arthroplasties Generate Wear Particles Similar to Knee Arthroplasties. CORR, Num. 424, pp. 69-72.