

DESIGN OF A PRE-CLINICAL TEST FOR PROSTHETIC ANKLE IMPLANTS

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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 total ankle replacements (TAR). 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 effects (Ratner 1996). Many wear tests have been done on hip and knee replacements (Calonius 2002), however wear simulation has not been done on TAR's. Various static and dynamic tests have been performed on TAR components (Greenwald 2000 and Valderrabano 2003), however these were performed under a wide range of conditions and examined a variety of results. Therefore it would be prudent to examine TAR strength and wear characteristics under physiological loading.

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

METHODS

The development of the test design presented here began with research of current ankle testing being performed, results of those tests, and post-operative

performance of various TAR's (Pyeovich 1998). Clinical retrievals of TAR's were obtained from DePuy, photographed, and catalogued to serve as clinical validation of this test. A finite element analysis of the implanted Agility ankle (Galik 2002) was obtained to serve as computational validation.

The test will examine two loading regimes, that of the healthy person, referred to as normal, and that of the post-operative TAR recipient. The normal load scheme will be examined since the ultimate goal of orthopaedic manufacturers is to return normal function to TAR recipients. Post-operative loads and ranges of motion will also be examined in order to be able to compare these test results with the clinical retrievals.



Figure 1: AMTI knee wear simulator

The tibial and talar components of the AGILITY Ankle will first be fixed in a polyurethane bone substitute following actual surgical procedure. The components will then be mounted in an AMTI knee wear

simulator similar to the one shown in Figure 1. The testing environment will be a bovine serum at 37° C.

For the post-operative load cycle, a maximum axial load, F_{max} , of 3.3 times body weight (750 N), that is 2475 N, will be applied sinusoidally at a load ratio (F_{min}/F_{max}) of 0.1 to the tibial component by an axial actuator, which will simultaneously rotate to provide a cyclic torsional load from 40 kg-cm external down to -25 kg-cm internal torque. This loading will be synchronized with rotation of the talar component in the sagittal plane about the medial-lateral axis of the talar component. The range of motion will be 10 degrees of dorsiflexion and 14 degrees of plantarflexion (Stauffer 1977), and will be applied via an auxiliary rotary actuator. Also, a shear force of 0.4 times body weight, that is 300 N, will be applied in the anterior-posterior (a-p) direction via a horizontal actuator. The simulation of the normal load case will have the same load pattern as the post-operative case described above, with magnitudes of: F_{max} equal to 5.2 times body weight, that is 3900 N, torque from 49 kg-cm to -32 kg-cm, and a-p shear of 0.8 times body weight, that is 600 N (Seireg 1975).

This combination of loading and range of motion will closely simulate a normal and post-operative 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.

SUMMARY

A concept for a standardized test for prosthetic ankle implants has been developed. Normal and post-operative axial, torsional, and shear loads will be applied in physiological magnitudes and ranges of motion, mimicking a physiological gait cycle. This test will allow for direct

quantitative analysis of and comparison between various implants. Testing will be conducted in the summer of 2004 at DePuy, Inc. in Warsaw, IN.

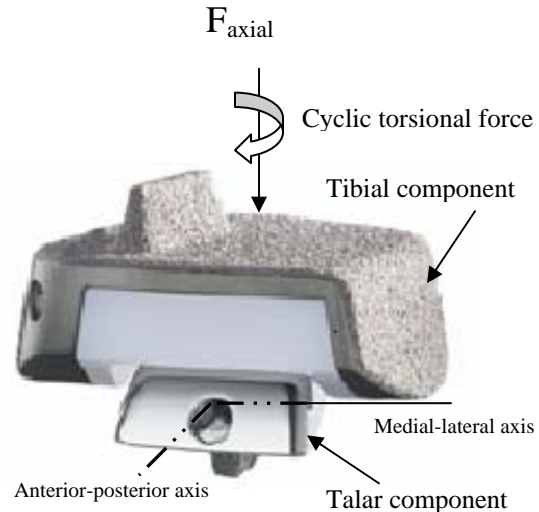


Figure 2: AGILITY Ankle prosthetic ankle implant by DePuy, Inc.

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