INTRODUCTION:

A model was developed to evaluate the stability of acetabular liners within their respective shells. Liner stability is important because instability could lead to the liner dislodging from the shell, increased micromotion, and increased backside wear. Debris from backside wear may cause osteolysis and lead to implant loosening. Stability is measured as a function of micromotion and lever-out performance characteristics, both before and after extensive fatigue cycling. This test model assesses the stability of acetabular systems by measuring changes in micromotion and lever-out strength over time. The motivation for creating this model was to evaluate acetabular inserts made from the new highly cross-linked polyethylene (PE), Durasul™.

METHODS:

Micromotion: The stability of the locking mechanism is first assessed by measuring relative motion between the shell and liner (micromotion). This micromotion study is modeled after a previous study (Wentz et al 1996) and evaluates the stability of the liner and shell over a period of physiological fatigue cycling. The micromotion measurements are conducted in three stages.

Stage 1: The specimens are axially loaded from 1335-45 N (300-10 lb ≈ 2 X body weight) via a femoral head, while rotating the head 0-35° at 0.5 Hz in air at room temperature. Five spring-loaded LVDTs are arranged in a fixture to measure rim axial, rotational, and polar axial micromotion (Figure 1). The initial measurements are conducted on virgin specimens (1-10 fatigue cycles).

Figure 1: Motion Measurement Schematic:

Stage 2: A second set of micromotion measurements is conducted (as described in stage 1) on the specimens after a 1000 cycle break-in period (1001-1010 fatigue cycles).

Stage 3: The specimens are then fatigued for 10 million cycles submerged in Ringer’s solution at 37°C (98.6°F) under sinusoidal physiological loads (3336-334 N [750-75 lb]) and torque (2.5-0.25 N-m [22-2.2 in-lb]). A 40° inferior-superior load angle is incorporated. The acetabular assembly is placed into the fixture with the maximum screw hole density positioned in line with the load line, to create the maximum amount of unsupported PE. The torque is applied through a glued femoral head at 6 Hz. After 10 million cycles, the final micromotion measurements are conducted (as described in stage 1) at 1335-45 N axial load and rotated 0-35° at 0.5 Hz in air at room temperature (10,000,001-10,000,010 fatigue cycles).
Lever-out: Stability is also measured as a function of pre and post fatigue snaplock strength. (Figure 2). The pre-fatigue lever-out testing is conducted on six additional virgin liners (not fatigue tested) used as lever-out controls. Following fatigue and micromotion of the cycled specimens, a slot is machined into the inner diameter of the liners to accommodate a lever arm. The peak axial load required to lever the PE liner from its respective shell is recorded.

Figure 2: Lever-out Test Schematic

Post-Test Evaluation: After testing, each acetabular system is inspected under a microscope for gross creep, gross wear, and cracking, particularly at the liner’s rim where the PE is thin.

RESULTS:

A model for stability was defined and evaluated by testing six highly cross-linked Durasul Inter-Op™ liners (Sulzer Orthopedics) under physiological fatigue loads and torque. Micromotion and lever-out tests were conducted on the same specimens. All acetabular assemblies survived 10 million cycles with no adverse effects. All liners remained firmly attached to their respective shells during fatigue. There was no evidence of gross PE creep into the screwholes, or at any other location. No PE cracking was observed at the liner’s tabs, or in the liner’s body.

Micromotion: Figure 3 illustrates the average motion of the PE in the acetabular shell at each stage of testing. The results indicate a substantial decrease in motion over time. The decrease in micromotion was found to be statistically significant for the polar and rotational data using a student's t-t-test (p<0.05).

Figure 3: Change in Motion with Fatigue

Lever-out: The Durasul Inter-Op post fatigue lever-out strength (76.7±3.8 N-m [679±34 in-lb]) was statistically greater than the pre-fatigue lever-out strength (65.5±9.5 N-m [580±84 in-lb]) (p<0.05).

DISCUSSION:

The fatigue cycles experienced by the Durasul liners had a beneficial effect on the strength of the locking mechanism, relative to both the micromotion and lever-out performance characteristics.

CONCLUSION:

This test was successful in creating a stability model in the laboratory. The cyclic loads and torque did, in fact, effect snaplock stability. This effect was measured as a function of micromotion and snaplock strength, and found to be statistically significant.

REFERENCES: