INTRODUCTION:

Acetabular Wedge Augments are used as an alternative to structural allograft in cases of superior and superior/posterior acetabular deficiencies. They are used to aid in initial stability and ultimately long term fixation of an acetabular shell achieved through osseointegration into the shell in situations where the bone stock is deficient. Augments are attached, via bone cement, to un cemented shells or fully cemented cups in revision or difficult primary surgeries.

Currently there are no international standards or FDA guidance documents addressing acetabular augment strength. The purpose of this test method is to verify that the fatigue strength of the augment (Restoration Acetabular Wedge Augments, Stryker Orthopaedics, Mahwah, NJ) and shell construct is strong enough to support physiologic acetabular loads until long term fixation of the shell is achieved. Also it characterizes the design performance throughout the full implanted life-time of the device since this device is not explanted.

METHODS:

This test verifies that the fatigue strength of the augment and shell construct is strong enough to support physiologic acetabular loads. Since loads transmitted through the hip implant are reacted at the femoral head interface/acetabular component assembly, the minimum acceptable hip implant neck strength values may be applicable to the augment/shell construct. ASTM F2068-03 [1] recommends minimum neck fatigue strength of 5340 N (1200 lbf) for hip implants and thus this test utilizes 5340 N as the applied load value.

The total number of cycles run replicates full weight bearing until long term biologic fixation of the shell is achieved. Shell fixation is typically achieved in acetabular revision cases within 6 months for un cemented shells [2]. This would equate to 0.5x10^6 cycles [3], but 1x10^6 cycles is used in this model as a factor of safety of 2. Thus the augment/shell construct must be able to sustain load for the full 1x10^6 cycles at a loading rate of 15 Hz. Finally to characterize the design performance throughout the full implanted life-time of the device the test is run out up to an additional to 9x10^6 cycles for a total of 10x10^6 cycles per ASTM F2068 [1].

RESULTS:

The design performance was characterized out to 10 million cycles of each size construct were evaluated. Thus, both sizes were determined to be the worst case and were tested in this model. The augment design tested is made out of metal foam (Stryker Orthopaedics, Mahwah, NJ) and shell construct is strong enough to support physiologic acetabular loads until long term fixation of the shell is achieved and throughout the full implanted life-time of the device.

DISCUSSION:

Although there are no international standards or FDA guidance documents addressing acetabular augment strength this test method demonstrated that it could verify that the fatigue strength of the augment/shell construct is strong enough to support physiologic acetabular loads until long term fixation of the shell is achieved and throughout the full implanted life-time of the device.

REFERENCES:
