Reverse Glenoid Rocking Horse Evaluation of the AETOS™ Reverse Shoulder System using ASTM F2028

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INTRODUCTION: Reverse total shoulder arthroplasty has increased in use and expanded its indications over the last 20 years. Such indications now include treatment of severe osteoarthritis, glenoid bone loss or deformity, proximal humeral fractures, rheumatoid arthritis, and failed arthroplasty. High failure rates were observed in early reverse total shoulder arthroplasty due to glenoid baseplate loosening [1]. The goal of this study was to investigate the resistance of a reverse shoulder glenoid baseplate (AETOS™ Reverse Shoulder System) to loosening as compared to competitive devices using a higher cycle count than the current relevant standard guidance. The AETOS™ System included an eccentric baseplate (AE) and a 15° augmented baseplate (A15A). The competitive devices included an augmented baseplate (AB) and a flat-backed baseplate (FBB). All devices were evaluated using a reverse glenoid rocking horse test as outlined in ASTM F2028.

METHODS: The testing protocol was established based on the recommendations of ASTM F2028-17 and guidance from the FDA [2]. Constructs consisted of a foam block, baseplate, screws, glenosphere, and a poly insert. A minimum of three constructs were tested for each design. Constructs were assembled following the recommended surgical technique of each manufacturer. To have a worst-case comparison between designs, the number, length, and orientation of the screws for each construct were chosen based on the minimum requirements outlined in each specific surgical technique. Pre-fatigue displacement measurements were collected by applying a shear load of 350 ± 15 N parallel to the glenoid plane as an axial compressive load of 430 ± 15 N was applied perpendicular to the glenoid plane, approximately through the center of rotation of the glenosphere (Figure 1). The shear and compressive loads were applied at different rates so that the target loads for each direction were achieved at approximately the same time. Using LVDTs, the initial pre-cyclic loading displacement of the glenoid construct was measured in the directions of both the applied shear and axial compressive load. The process was repeated for a total of three displacement measurement sets for each construct in each direction. Upon completion of the pre-fatigue displacement measurements, an axial compressive load of 750 ± 15 N was applied to the back of the humeral liner through the center of rotation (Figure 2). The glenoid construct was rotated ±22.5° about the humeral liner along the superior-inferior axis for 100,000 cycles at a rate of 1 Hz. Testing was conducted in air, at room temperature; surface lubricant was applied to the interface of the glenosphere and liner. An air-cooling jet was used to keep the humeral liner from overheating during the cyclic loading. Testing was terminated if the construct dislocated, disassociated, or failed in any way. The post-fatigue displacement measurements were performed following the same methods as the pre-fatigue measurements.

Eight total displacement measurements (average ± standard deviation) were reported for each construct design: horizontal (shear) and vertical displacement in the superior/inferior and anterior/posterior direction before and after fatigue testing. The three repeated static measurements were averaged for each construct. The three sample means were then averaged for each design. Construct displacement results were analyzed for variance using Levene's test for equality of variances, and a one-way ANOVA with a Tukey's post-hoc test for comparison of the means ($\alpha = 0.05$).

RESULTS: The pre- and post-fatigue displacement measurements are shown graphically in Figure 3. There were no statistically significant differences between the pre-fatigue displacement measurements for the AE and the A15A constructs as compared to the FBB constructs ($p > 0.05$); both AETOS™ constructs had lower average displacement values. There were statistically significant differences between three of the pre-fatigue displacement measurements for the AE and the A15A constructs as compared to the AB constructs ($p < 0.05$). There was a not statistically significant difference ($p > 0.05$) for the vertical AP displacement measurement. Both AETOS™ constructs had lower average displacement values as compared to the AB constructs for all four measurement groups. All tested constructs completed 100,000 cycles of fatigue testing with no signs of disassociation between the baseplate and the foam block, no signs of disassociation between the glenosphere and the baseplate, and no fracture of the baseplate or screws. There were no statistically significant differences between the post-fatigue displacement measurements of both AETOS™ constructs and the FBB constructs ($p > 0.05$). The post-fatigue displacement measurements of the AE and the A15A constructs were statistically significantly different from the AB constructs ($p < 0.05$); both AETOS™ constructs had lower average displacement values.

DISCUSSION: One difference between the method used in this study as compared to the ASTM standard was the cycle count. ASTM F2028 recommends the use of 10,000 cycles, whereas the FDA recommends a higher cycle count due to the current trends in the use of reverse shoulder arthroplasty [2]. The standard cycle count was considered justified as the test does not simulate prosthesis wear related failure modes, high-load activities are less likely with the reverse shoulder, and because the reverse glenoid component is uncemented. The higher 100,000 cycle endpoint could represent roughly 25 higher-load activities per day over a 10-year period; it resulted in a clear differentiation in displacement measurements in the reverse shoulder glenoid constructs used in this study.

SIGNIFICANCE/CLINICAL RELEVANCE: Early glenoid baseplate loosening is a known issue for reverse shoulder systems. The use of the AETOS™ Reverse Shoulder design has been demonstrated to resist glenoid baseplate loosening as compared to existing clinically available baseplate designs using a method intended to simulate physiological loading conditions typical of a reverse shoulder replacement.

REFERENCES: [1] Schell, *et al*. *J Shoulder Elbow Surg* (2023) 32, 1584-1593.
[2] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=41415 (last accessed August 2023)

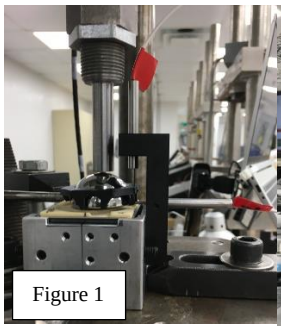

Figure 1

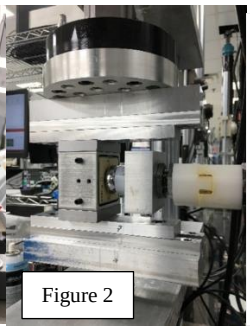

Figure 2