

Development of an Environmental Fatigue Method for Anatomic and Reverse Shoulder Prostheses

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INTRODUCTION: Primary and revision shoulder arthroplasty surgeries are expected to increase 322% by the year 2050 [1]. Currently, there is no ISO or ASTM standard to evaluate the environmental fatigue performance of total shoulder arthroplasty (TSA) implants. The purpose of this study was to develop a test method to evaluate the environmental fatigue performance of the AETOS™ shoulder system that allows for the conversion from an anatomic total shoulder arthroplasty (ATSA) construct to a reverse total shoulder arthroplasty (RTSA) construct.

METHODS: Prior to testing, finite element analysis (FEA) was performed to determine the worst-case construct. For the ATSA construct, the humeral stem was potted in polymethyl methacrylate (PMMA) cement at a worst-case potting depth and angle. The potting depth of approximately half the total stem length allowed most of the porous coating and all critical features of the stem to be unsupported. The selected angle of 45° inclination and rotation about the stem taper axis was intended to apply stress to all exposed features of interest above the potting level. A humeral head was assembled to the humeral stem using the constant rate assembly method outlined in ASTM F2009-20. The ATSA construct was submerged in a tank of saline solution and secured to the baseplate of a servo-hydraulic test frame. An acetal resin fixture with a flat end was secured to the test frame load cell above the humeral stem and head. A heating lamp and controller was used to maintain the solution temperature at 37°C during testing. The ATSA construct was loaded using a sinusoidal cyclic tapered waveform and a maximum load of 1x body weight (BW) using an R ratio of 0.1 at a rate of 10 Hz for 5 million cycles (Mcycles), which represents 10 years of simulated use. The chosen fatigue load of 1x BW is based on guidance from ASTM F1378-18^{el}. The solution was removed from the construct. After fatigue testing, the post-fatigue pull-off force of the humeral head and stem was evaluated per ASTM F2009, and all taper surfaces were evaluated using the Goldberg scoring system [2].

For the RTSA construct, four locking screws were inserted into a glenoid baseplate. The screws were inserted using the maximum allowable angulation for each screw in the direction of the baseplate post, thus offering the narrowest breadth of support as a worst-case. The glenoid assembly was potted with PMMA at a depth which allowed for baseplate and screw fixation while not submerging the porous coating on the baseplate perimeter to simulate proud seating. The glenosphere was assembled to the glenoid baseplate according to ASTM F2009. However, assembly utilized a bearing plate with freedom of movement normal to the load axis. The previously tested humeral stems from the ATSA construct were removed from the cement and potting fixture. The humeral stem was potted using PMMA at 25° from the loading axis and at the same potting depth as the ATSA construct. A humeral spacer was assembled to the humeral stem following ASTM F2009. A humeral liner was then assembled to the humeral spacer following ASTM F1820-22. The fixture containing the humeral portion of the RTSA construct was placed on the baseplate of a servo-hydraulic test frame. The fixture containing the glenoid portion of the reverse shoulder construct was secured to the load cell of the test frame. The components were surrounded by an acrylic cylinder filled with saline solution to fully submerge the components. The solution temperature was maintained at 37°C. The resulting position of the components on the test frame created a 60° angle between the glenoid baseplate face and the humeral stem axis. The RTSA construct was loaded using a sinusoidal tapered waveform and a maximum load of greater than 1x BW using an R ratio of 0.1 at a rate of 10 Hz for 5 Mcycles. A higher fatigue load was used to induce worst-case loading conditions for the RTSA construct. Post-fatigue disassembly forces were evaluated per ASTM F2009 for the glenosphere-glenoid baseplate assembly and the humeral spacer-stem assembly. All RTSA taper surfaces and screw interfaces were evaluated using the Goldberg scoring system [2].

The post-fatigue glenosphere pull-off loads were compared to those of a marketed RTSA system using Levene's test for equality of variances and Student's t-test for differences in means. The post-fatigue humeral spacer pull-off loads were compared to the pre-fatigue humeral liner push-out loads for the system using analysis of variance (ANOVA) and post-hoc Tukey test or Games-Howell test depending on the assumption of equality of variances between groups. The comparison of humeral spacer dissociation loads to humeral liner retention strength was considered appropriate since both components are on the same side of the shoulder joint and must withstand the same loads to prevent dissociation. A confidence level of 95% was used for all statistical analyses.

Goldberg scores for the humeral stem, humeral spacer, glenosphere and glenoid baseplate were compared to those of a marketed RTSA system after fatigue testing based on similar indications for use. Since Goldberg scores are semi-quantitative, the scores were compared by setting a proportion of the scores below 3 which is classified as "moderate" taper damage. For each data set, the proportion was defined as the number of tapers with scores equal to or less than 2 divided by the total number of evaluated tapers. The proportions were compared using a 2-sample proportion test with $\alpha = 0.05$.

RESULTS/DISCUSSION: The AETOS™ shoulder system completed 20 years of simulated use without fracture or failure (10 years of ATSA and 10 years of RTSA). All post-fatigue disassembly values for the AETOS™ shoulder system were greater than those of a marketed TSA system. The AETOS™ shoulder system showed similar or lower fretting and corrosion scores (2 or less) when compared to a marketed TSA system. This test method was also able to differentiate in dissociation as well as fretting and corrosion performance between ATSA and RTSA systems.

SIGNIFICANCE/CLINICAL RELEVANCE: Currently, there is no ISO or ASTM standard that evaluates the environmental fatigue performance of TSA systems. This study could be used as an input to the development of an environmental fatigue standard for TSA systems.

REFERENCES: [1] Goetti, P. *et al.* EFORT Open Rev 2021;6:918-931. DOI: 10.1302/2058-5241.6.210014 [2] Goldberg JR, *et al.* Clin Orthop Relat Res. 2002 Aug;(401):149-61.

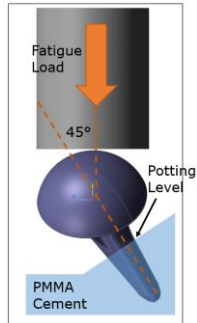


Figure 1: ATSA Construct

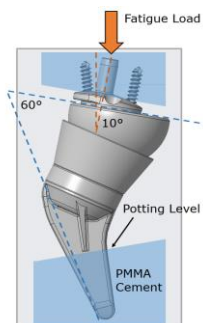


Figure 2: RTSA Construct