Extreme Bending Fatigue Testing of a New Hybrid Anatomic Glenoid Implant

Thomas M. Vanasse, MS[1], Zachary L. Bryan, PhD[1], Sean Grey, MD[2], Stephen Brockmeier, MD[3], Joseph Zuckerman, MD[4], Thomas Wright, MD[5], Pierre-Henri Flurin, MD[6], Bradley Schoch, MD[7]

[1]Exactech, Inc., Gainesville, FL, [2]Orthopaedic Center of the Rockies, Ft Collins, CO, [3]UVA Dept of Orthopaedic Surgery, Charlottesville, VA, [4]NYU Langone Dept of Orthopedics, New York, NY, [5]University of FL Dept of Orthopaedics, Gainesville, FL, [6]Clinique du Sport, Merignac, France, [7]Mayo Clinic, Jacksonville, FL

Disclosures: T.M. Vanasse: 3A; Exactech, Inc. 4; Exactech, Inc. Z.L. Bryan: 3A; Exactech, Inc. S. Grey: 3B; Exactech, Inc. 7A; Exactech, Inc. S. Brockmeier: 3B; Exactech, Inc. 7A; Exactech, Inc. J. Zuckerman: 3B; Exactech, Inc. 7A; Exactech, Inc. T. Wright: 3B; Exactech, Inc. 7A; Exactech, Inc. P. Flurin: 3B; Exactech, Inc. 7A; Exactech, Inc. B. Schoch: 3B; Exactech, Inc.

INTRODUCTION: Current anatomic total shoulder arthroplasty (aTSA) glenoid implants largely include either cemented all-polyethylene implant components or hybrid implants, which include a polyethylene articular body and at least one titanium portion that promotes long-term biologic fixation. Hybrid glenoids have been shown to result in lower rates of loosening and radiographic lucencies at long-term follow-up when compared to all-poly pegged counterparts [1]. However, hybrid glenoids may be subject to a unique failure mode due to the necessary junction(s) between the polyethylene and metal. Significant progress has been made to improve hybrid glenoid designs in an attempt to increase their longevity; for example, the Equinoxe Laser Cage Glenoid utilizes a unique manufacturing process where the polyethylene body is direct compression molded to 3D printed peripheral pegs and central cage, which vastly increases the strength of the polyethylene/metal junctions. The relative strength of these junctions may be determined via mechanical testing, for which there are currently two standards for glenoid implants, ASTM F2028 [2] and ASTM F1829 [3]. However, neither of the current testing standards subjects the devices to extreme cyclic loading conditions to simulate an implant seated proud (i.e. the backside of the articular portion is partially or completely unsupported by the glenoid face), which in the case of a hybrid design, would put added stress on the metal/polyethylene junction increasing the risk for fatigue failure. The aim of this study is to propose a new method for fatigue testing of anatomic glenoid implants and to report on the results of this testing as performed with the Equinoxe Laser Cage Glenoid.

METHODS: Seven Laser Cage glenoids were tested using the newly designed loading condition, exceeding the ASTM F2028 minimum requirement of three specimens [2]. Each device was cemented with PMMA cement into a support fixture simulating a prepared glenoid, leaving a 5mm gap between the fixture surface and the glenoid backside (Figure 1). This 5mm gap constraint is beyond what would occur clinically and thus served as an extreme scenario intended to induce failure. The largest size Laser Cage Glenoid, the Extra Large 16° Posterior Augment, was utilized as this maximized the moments on the construct when loaded off-axis. ASTM F2028 Part I states that the resultant forces during the anatomic testing phase are expected to be 800-1000N and represent carrying a 5- to 8-kg object at the side or lifting a 2- to 4-kg load to shoulder height [2]. Previous testing of the Laser Cage Glenoid to ASTM F2028 Part I found that, with a 750N compressive force, the average superior-inferior subluxation force was 633N; resolving these two forces into a single vector resulted in a force of 981N at an angle of 49.8° with respect to the glenoid plane. Therefore, the applied load based on these test results was 1000N oriented at 50° relative to the glenoid plane. To accomplish this loading scenario, the glenoid support fixture was rigidly attached to the base of a load frame and oriented such that the loading axis was 50° relative to the glenoid plane. An indenter with a 38mm diameter curvature at the glenoid contact surface was rigidly attached to the load frame actuator and positioned such that it applied load at the inferior edge of the articular surface (Figure 1). The indenter diameter was limited to 0.5 in, significantly smaller than a humeral head, to create a worst-case condition that allowed rotation of the glenoid body during loading, as there was less contact between the indenter and glenoid. Cyclic loading was applied at a frequency of 2 Hz for 200,000 cycles (twice what is required by ASTM F2028). If the device completed 200,000 cycles at 1000N peak force, the peak force was increased in increments of 250N every 5,000 cycles until failure occurred.

RESULTS: Five Laser Cage Glenoids survived 200,000 cycles when loaded with a peak force of 1000N (Table 1). Two additional specimens failed prior to 200,000 cycles due to fixture failure, which prevented the continuation of the test for those specimens. Of the five specimens that survived 200,000 cycles, all but one was halted at a peak load of 1500N due to fixture failure. The remaining specimen failed at a peak load of 1750N due to separation between the peripheral peg and glenoid body. None of the metal pegs fractured or showed evidence of cracking.

DISCUSSION: The Equinoxe Laser Cage Glenoid was able to withstand a fatigue test that intentionally induced bending at the metal/polytheylene junctions via a completely unsupported construct with a 5-mm gap between the backside of the implant and the test fixture. The methodology utilized went well beyond the requirements of applicable standards for anatomic glenoid implant testing from a cycle count, load application, and fixation perspective. Future work could include additional testing to compare these results to those of other hybrid glenoid designs on the market. Furthermore, the overall test setup represents an extreme misuse scenario where the implant is left 5mm proud of the glenoid, so future work may focus on modifications to this method to increase clinical relevance or development of additional tests that mimic various other misuse scenarios (such as incomplete glenoid preparation, partial glenoid implant seating, excessive implant retroversion, etc.). Lastly, clinical data will need to be collected on the Laser Cage Glenoid to determine if the results of this fatigue testing are predictive of improved implant longevity as compared with previous hybrid glenoid designs.

SIGNIFICANCE/CLINICAL RELEVANCE: This study presents the methodology and initial results from an extreme cyclic test for anatomic glenoids. This novel test method, or a refinement thereof, could be used to develop new standards by which future anatomic glenoids could be more stringently evaluated prior to clinical use.

REFERENCES: [1] Friedman, et al. (2023, Feb 10-14). ORS annual meeting, Dallas, TX; [2] ASTM (2017) F2028-17; [3] ASTM (2017) F1829-17.

Table 1. Cycles to Failure Results for Laser Cage Glenoid

Specimen ID	Number of Cycles Achieved at Peak Force of:				Failure Mode
	1000N	1250N	1500N	1750N	
M1	200,000	5,000	3,342	-------	Fixture Failure
M2	200,000	5,000	5,000	555	Peg-Body Separation
M3	200,000	5,000	3,260	-------	Fixture Failure
M4	200,000	5,000	<10	-------	Fixture Failure
M5	52,288	-------	-------	-------	Fixture Failure
M6	100,603	-------	-------	-------	Fixture Failure
M7	200,000	5,000	5,000	<10	Fixture Failure

Figure 1. Fatigue Test Setup with 5-mm Gap