TECHNICAL BRIEF

Designing a Better Glenoid: Biomechanical Test Data Summary

Catalyst OrthoScience Research and Development

Loosening of the glenoid component is the most common mode of failure in total shoulder arthroplasty[1-3]. An inability to achieve long-lasting, secure fixation within the glenoid bone that can withstand the effects of repeated eccentric loading and glenohumeral translation leads to failure[4].

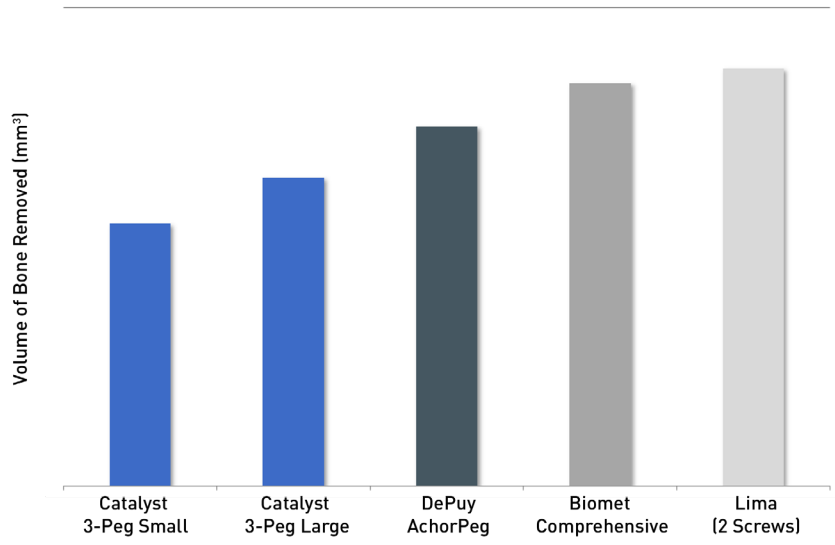
The following biomechanical data serves to demonstrate the effectiveness of the Catalyst 3-Peg Glenoid in maintaining strong initial and long term fixation while minimizing the amount of bone removed.

Glenoid Bone Removal

One of Catalyst OrthoScience's core principles involves the development of bone preserving technologies. The 3-Peg Glenoid implant maintains this philosophy as it utilizes the strongest, densest regions of the bone to maximize the fixation potential, while removing less bone than commonly used predicate systems. Each of the fixation pegs has direct contact with the native bone to create an interference fit that minimizes any free motion potential irrespective of the cement mantle. The design also preserves the central portion of the glenoid vault for potential revision procedures that typically rely on a central screw for primary fixation.

The Catalyst glenoids require **up to 35 percent less bone removal** from the native glenoid in preparation for implantation compared to competitors.

Glenoid Bone Removal



References

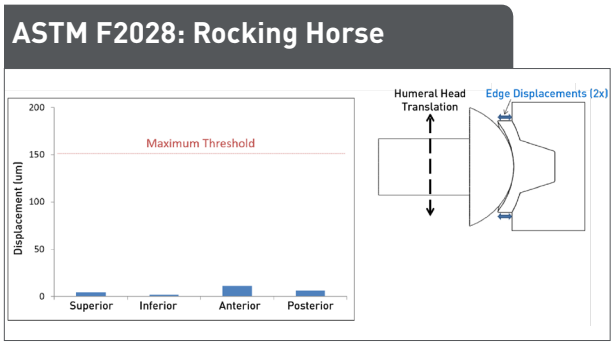
1. Wirth et al. Complications of total shoulder replacement arthroplasty. JBJS 1996: 603-16.
2. Franta et al. The complex characteristics of 282 unsatisfactory shoulder arthroplasties JSES 2007: 555-62.
3. Bohsali et al. Complications of total shoulder arthroplasty JBJS 2006: 2279-92.
4. Matsen et al. Glenoid component failure in total shoulder arthroplasty. JBJS 2008: 885-96.

ASTM F2028 - Rocking Horse

The rocking horse phenomenon is largely believed to be the primary reason for glenoid implant loosening in total shoulder arthroplasty. Eccentric loading of the humeral head onto the glenoid component, causes the opposing unloaded glenoid edge to want to lift off the bone. The ASTM F2028 test is designed to quantify the amount a glenoid implant rocks or pivots following cyclic displacement of the humeral head to the opposing glenoid rim. It is important for a glenoid component to demonstrate a high resistance to the rocking horse effect to ensure long term fixation.

Method: The humeral head is cycled in the AP and SI directions (separately) and then the resultant displacement is measured to determine how much the implant has rocked out of its native position.

Acceptance Criteria: 150 µm displacement threshold to promote ossesous integration and long term fixation into bone.



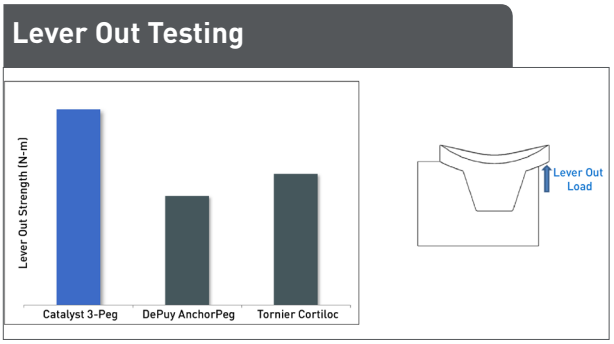
Lever Out Testing

To quantify the effectiveness of the initial interference fit fixation strength of the 3-Peg Glenoid, lever out testing was conducted against two commonly used predicate devices that were designed to specifically provide immediate stability through an interference fit design.

Method: A lever is placed under the edge of the implant and the load required to dislodge the cemented implant from the bone block is determined.

Results: Catalyst lever out is ~50 percent greater than Cortiloc and ~80 percent greater than AnchorPeg.

Note: The Catalyst 3-Peg Glenoid was pre-conditioned with 100,000 cycles of the ASTM F2028 rocking horse loading. The AchorPeg and Cortiloc implants were not pre-loaded. As such, these results could be even further magnified.

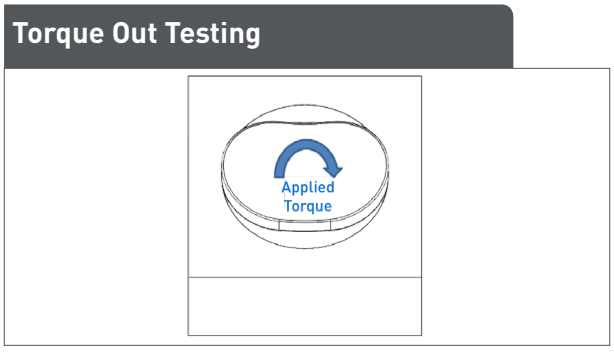


Tourque Out Testing

Torque testing was conducted on the 3-Peg Glenoid to ensure that any physiological moments across the glenohumeral joint would not contribute to any implant failures.

Method: With a bone block fixed in place, two pins were placed into the implant and then torqued until the implant failed.

Results: The Catalyst 3-Peg Glenoid is **nearly 3X greater t**han the maximum value reported in the literature [Bergmann, 2007] for the moment transferred across the glenohumeral joint due to friction.



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