

PERFORMANCE EVALUATION OF THE TRABECULAR METAL GLENOID

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Background

Total shoulder arthroplasty is successful in relieving pain and restoring function to the joint, but chronic loosening of the glenoid implant remains a common complication. The *Zimmer® Trabecular Metal™* Glenoid is an implant that is designed to achieve long-term fixation with biological ingrowth. The purpose of this paper is to describe the testing and analyses that were conducted to assess the performance of the implant under expected *in vivo* conditions.

Methods

The implant strength was evaluated using a novel fatigue test and subsequent static test method. Initial fixation of the implant was evaluated using the ASTM F 2028-05 standard. Initial fixation tests were performed on a cemented UHMWPE design for comparison. Finite element analyses were conducted to compare the contact stresses in the UHMWPE relative to a solid metal-backed design.

Results

The *Trabecular Metal* Glenoid successfully met the performance requirement. Displacement measurements from the initial fixation test were reduced (i.e. indicated less motion) compared to a cemented UHMWPE design. The contact stresses in the UHMWPE were reduced compared to a metal-backed design for functionally important loading conditions in which there is translation of the humeral head.

Conclusions

Through experimental and analytical testing, the *Trabecular Metal* Glenoid has been shown to withstand repetitive eccentric loading, provide initial fixation superior to a cemented UHMWPE design, and reduce the contact stresses in the UHMWPE compared to a metal-backed design.

Introduction

The most common complication in total shoulder arthroplasty is failure of the glenoid component. Failure of the glenoid component has been attributed to several different causative factors¹, including:

- Inadequate initial fixation
- Inability to fully seat the implant
- Inability to handle eccentric loading
- Poor quality bone stock

The *Trabecular Metal* Glenoid is a monoblock implant for reconstructive total shoulder arthroplasty. It consists of a *Trabecular Metal* base with a fully integrated, compression molded ultra-high molecular weight polyethylene (UHMWPE) articular surface. The base of the implant has five posts that provide fixation. The five post configuration provides initial fixation using a press-fit between the implant and the bone. Long-term fixation is provided by biological ingrowth into the *Trabecular Metal* material.



Figure 1 – The *Trabecular Metal* Glenoid

This paper is intended to describe the performance evaluation (strength and initial fixation testing) that was conducted in the development of the *Trabecular Metal* Glenoid.

Strength

Due to its large range of motion, the loads occurring at the glenohumeral joint are multi-directional and activity-dependent. The *Trabecular Metal* Glenoid base was engineered to withstand these loads while conserving as much bone as possible. The configuration of the posts provides support in the anterior, posterior, superior and inferior quadrants of the glenoid.



Figure 2 – The base of the *Trabecular Metal* Glenoid

The strength of the *Trabecular Metal* Glenoid was evaluated through mechanical testing, which consisted of the following steps:

1. Specimen preparation (Figure 3) – Blocks of rigid polyurethane foam were prepared to simulate a situation in which the glenoid implant is not fully seated, and a gap is present around the perimeter of the articular surface. The keel portion of the glenoid test specimens was rigidly fixed by PMMA bone cement in a cavity inside the foam block.
2. Fatigue testing – A dynamic test was performed, in which load was applied repeatedly to determine the implant’s resistance to fatigue fracture. Cyclic load was applied with humeral head translation alternating between the anterior and posterior rims of the articular surface.
3. Post-cyclic shear testing (Figure 4) – A destructive, load-to-failure test was conducted to determine the residual strength of the implant after completion of the fatigue test.

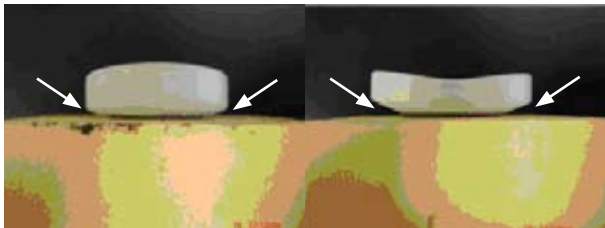


Figure 3 – Superior/Inferior and Anterior/Posterior view of fatigue test specimen (arrows indicate unsupported periphery)

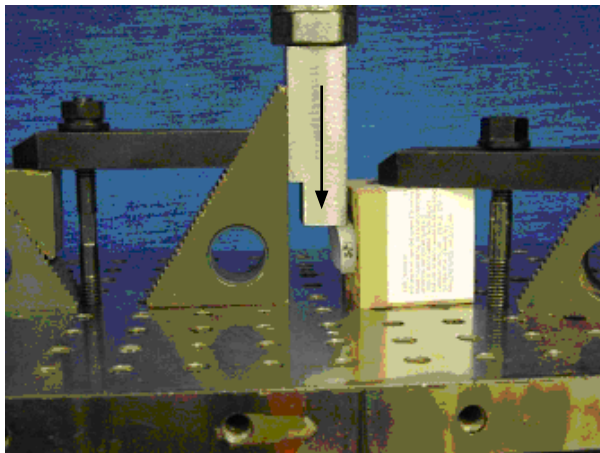


Figure 4 – Post-cyclic shear test setup

Results of the mechanical testing are shown in Figure 5. The post-cyclic shear strength was approximately 3.5x the performance requirement.

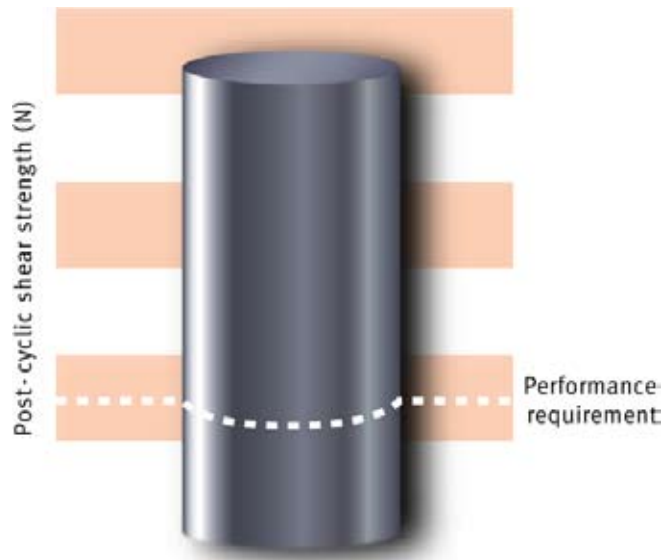


Figure 5 – Post-cyclic shear test results

Initial Fixation

Chronic loosening of cemented glenoid components is one of the primary causes of complication in total shoulder arthroplasty. This is believed to be related to the eccentric loading that is applied to the glenoid *in vivo*. Dynamic loosening testing was performed on the *Trabecular Metal* Glenoid to assess the initial fixation of the implant.

Dynamic loosening testing was conducted per the ASTM F 2028-05 standard. The *Trabecular Metal* Glenoid was tested in two different conditions; fully cemented and backside cemented. For comparison, the *Bigliani/Flatow*[®] polyethylene keeled glenoid was also tested in a fully cemented condition. The test setup is shown in Figure 6. All dynamic testing was performed in a deionized (DI) water bath held at $37^{\circ} \pm 2^{\circ}$ C. The test specimen was cyclically translated in the S-I axis under displacement control to 90% of the subluxation translation. Tests were conducted to 100,000 cycles at a frequency of 1.2 Hz. A peak compressive (vertical) load of 756 N (170 lb) was applied throughout the test.

Displacement measurements at the superior and inferior edges were taken continuously during the test. Initial, intermediate, and long-term displacement measurements were taken at 100, 4,000 and 100,000 cycles, respectively. 4,000 cycles was considered to be roughly equivalent to 16 weeks of predicted in-vivo use assuming 25 worst-case abductions per day to represent typical in-vivo loading.² Bone ingrowth into *Trabecular Metal* material has previously been shown to occur within this time frame in *Trabecular Metal* acetabular cups.³

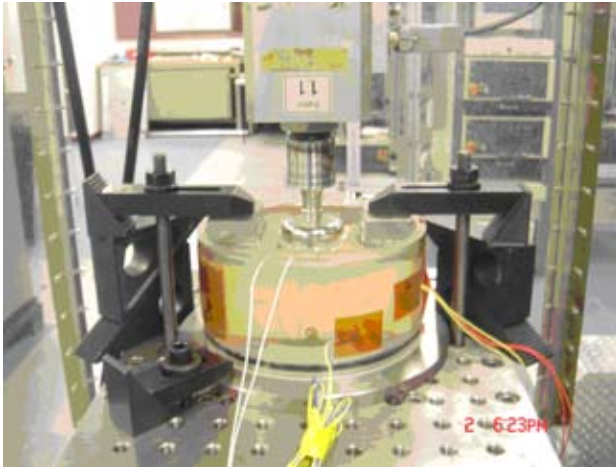


Figure 6 – Dynamic loosening test setup

The results from the dynamic loosening test are shown in Figure 7.

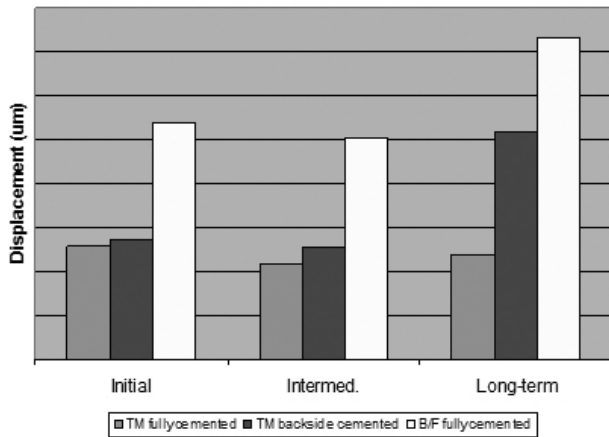


Figure 7 – Dynamic loosening test results

A comparison of the *Trabecular Metal* Glenoid with the *Bigliani/Flatow* keeled glenoid is summarized in Table 1. The results are expressed as a percentage of the motion measured for the cemented *Bigliani/Flatow* keeled glenoid (e.g. the long-term results of the backside cemented application reveal a reduction of 29.2%).

Condition	Displacement as a percentage of the <i>Bigliani/Flatow</i> glenoid		
	Initial	Intermediate	Long-term
Fully cemented	47.8%	42.7%	32.6%
Backside cemented	50.9%	50.7%	70.8%

Table 1 – *Trabecular Metal* Glenoid dynamic loosening test results

Joint Kinematics

Restoration of normal joint motion is one of the key goals in total shoulder arthroplasty. The *Trabecular Metal* Glenoid is designed to achieve this using the same articular surface as the *Bigliani/Flatow* design, with two distinct radii of curvature: an inner, perfectly congruent region extending into an outer, incongruent region or “translation zone”. Biomechanical studies have shown that this design allows for glenohumeral motion and contact area patterns similar to the natural joint.⁴

Articular Surface Integrity

Metal-backed glenoid designs have experienced complications due to polyethylene wear.⁵ The *Trabecular Metal* Glenoid is a monoblock design, in which the UHMWPE articular surface is fully integrated into the base of the implant. The monoblock nature of the design eliminates the backside of a UHMWPE modular articular surface as a potential source of wear debris.

A finite element analysis (FEA) study was performed to compare the *Trabecular Metal* Glenoid to a solid metal-backed design.⁶ Three different loading conditions were evaluated:

1. Axial compression with the humeral head centered on the glenoid
2. Compression with the humeral head translated in the A-P direction
3. Compression with the humeral head translated to a position simulating 90° abduction

Results of the FEA are shown in Figure 8. The *Trabecular Metal* Glenoid exhibited equivalent or lower contact stresses than the metal-backed design in all three loading conditions. Similar FEA studies of acetabular shell designs have reported that contact stresses in UHMWPE are lower in a compression molded, porous metal-backed component than in a modular, metal-backed component.⁷

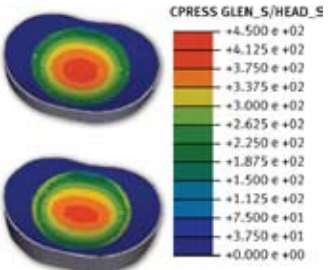
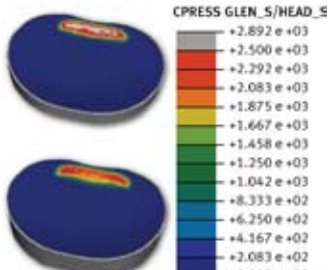
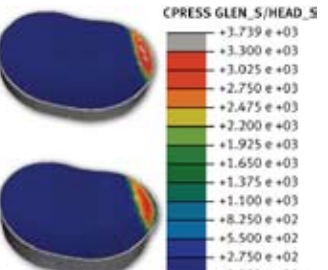
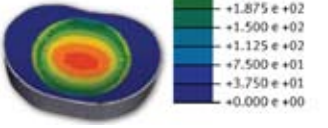
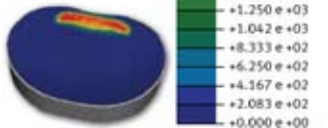
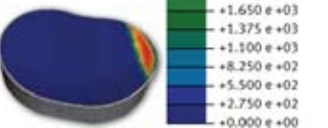
	Axial Compression	A-P Translation	90° Abduction
Solid metal-backed (Ti) design			
Trabecular Metal Glenoid design			
Difference	2.3%	-14.0%	-3.0%

Figure 8 – Finite element analysis results

Conclusions

Through experimental and analytical testing, the *Trabecular Metal* Glenoid has been shown to:

- Withstand repetitive eccentric loading
- Provide initial fixation superior to a cemented polyethylene design
- Restore more normal glenohumeral joint kinematics and contact area patterns
- Reduce contact stresses in the UHMWPE compared to a metal-backed design

References

1. Matsen FA, et al. Glenoid component failure in total shoulder arthroplasty. *J Bone Joint Surg* 2008; 90-A, 4: 885-896
2. Anglin C, Wyss UP and Pichora DR. Mechanical Testing of Shoulder Prostheses and Recommendations for Glenoid Design. *J. Shoulder Elbow Surg*, 2000, 9: 323-321
3. Stackpool GJ, Kay AB, Harvey EJ, Tanzer M, and Bobyn JD, "Characterization of Bone Ingrowth with a Unique Porous Tantalum Implant Material", 42nd Annual Meeting of the ORS, February 19-22, 1996, pp 524
4. Wang VM, et al. Biomechanical evaluation of a novel glenoid design in total shoulder arthroplasty. *J Shoulder Elbow Surg* 2005;14: 129S-140S
5. Martin SD, Zurakowski D, Thornhill TS. Uncemented glenoid component in total shoulder arthroplasty. Survivorship and outcomes. *J Bone Joint Surg Am.* 2005; 87: 1284-1292.
6. Data on file at Zimmer.
7. Fang Z, et al. The effect of poly thickness on contact stress in low stiffness porous metal-backed acetabular component: Is 4mm minimum thickness poly a gold standard? Poster No. 1770, 54th Annual Meeting of the Orthopaedic Research Society

