

INITIAL FIXATION OF THE TRABECULAR METAL REVERSE SHOULDER GLENOID BASE PLATE IMPLANT

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Background

Reverse total shoulder arthroplasty is an increasingly utilized treatment option for glenohumeral arthritis with massive, irreparable rotator cuff disruption associated with loss of glenohumeral stability and function. Several reverse shoulder implant designs from different manufacturers have been introduced to the market in recent years. Fixation of the glenoid base plate has been shown to be sensitive to the implant geometry and clinical complications related to the glenoid implant have been reported. The *Zimmer® Trabecular Metal™* Reverse Shoulder prosthesis is designed to achieve both initial and long-term stability of the glenoid base plate implant through a unique combination of screw fixation and biological ingrowth. The purpose of this paper is to report on the testing that was conducted to quantitatively assess the effect of bone quality on the initial fixation of the *Trabecular Metal* Reverse Shoulder glenoid base plate implant.

Methods

Displacement of the glenoid base plate implant relative to a rigid polyurethane foam (bone analog) was measured while cyclic physiologic load was applied. Tests were performed in three different foam densities with mechanical properties covering the entire reported range for glenoid bone to represent the spectrum of bone quality from poor to excellent. Specimens were tested with and without locking caps to evaluate the effect of captured vs. uncaptured screw fixation.

Results

The foam density had a statistically significant effect on the measured displacement. There was no significant difference in the displacement between the samples with and without locking caps in any of the foam densities tested.

Conclusions

The *Trabecular Metal* Reverse Shoulder prosthesis provides initial stability necessary to achieve biological ingrowth enabling long-term fixation over a wide range of bone properties.

Introduction

Reverse shoulder arthroplasty is a treatment for glenohumeral arthritis with massive, irreparable rotator cuff disruption associated with loss of glenohumeral stability and function. The procedure is based on the concept introduced by Grammont, in which the geometry of the implant reverses the normal relationship between scapular and humeral components, allowing the deltoid muscle to compensate for rotator cuff deficiency.³

The success of reverse shoulder arthroplasty is based on a fundamental alteration of the biomechanics of the normal shoulder. Medialization of the center of rotation is achieved by placement of a fixed hemispherical component on the glenoid, increasing the moment arm and thus creating a mechanical advantage for the deltoid muscle.^{12,41} Several clinical studies have demonstrated the effectiveness of this procedure, but have also shed light on the complications that can occur, summarized in Table I. A ten-year survivorship of 84% has been reported with glenoid loosening as the end point.¹⁷

The most common complication in reverse shoulder arthroplasty is impingement of the medial aspect of the humeral component on the inferior neck of the scapula, commonly referred to as scapular notching. *In vitro* experimental studies have shown that the position of the glenoid component³¹ and the lateralization of the center of rotation¹⁹ can influence the range of motion, and hence the incidence of scapular notching. Increased lateralization of the humerus from the glenoid is a design concept intended to reduce the incidence of scapular notching, but comes at the expense of glenoid implant stability due to an increased distance from the center of rotation to the glenoid face, as glenoid loosening or mechanical failure of the glenoid implant have also been reported.¹⁶ Hence, there is an inherent tradeoff between implant stability and scapular notching when considering the design of the glenoid implant used in reverse shoulder surgery.

The fixation of the glenoid implant in a reverse shoulder arthroplasty is typically achieved through a combination of a central post or coarse-threaded screw and auxiliary screws. Previous studies have been performed using both finite element analysis and experimental testing to investigate the stability of the glenoid implant in a reverse shoulder arthroplasty.^{1,7,8,18,20,21,30,33,43} These studies have shown that the fixation of the glenoid base plate implant is sensitive to several factors, including the positioning and the amount of lateralization relative to the glenoid face, the presence of a cavitory defect, the purchase of individual screws, and the direction of the applied load. In the majority of these previous studies, a single bone analog material with mechanical properties equivalent to excellent bone stock was used to simulate the glenoid bone. A limited number of studies have investigated the effect of bone density. Chebli et al used materials representative of normal and osteopenic bone to evaluate the effect of bone quality in a static test model.⁷ Roche et al also reported results for two different polyurethane bone substitute densities; however, their motion measurements quantifying the implant stability were limited to pre and post-cyclic loading.³³ To our knowledge, no attempt has been made to determine the effect of diminished bone quality on the fixation of the glenoid base plate implant as it is subjected to dynamic loading. Thus, the goal of this study was to quantitatively assess the effect of bone quality on the initial fixation of a cementless reverse shoulder glenoid base plate component.

Table I – Clinical studies reporting glenoid implant complications in reverse shoulder arthroplasty

Author	Year	N	Mean follow-up (months)	Glenoid-side complications			
				Radiolucencies	Scapular notching	Loosening	Mechanical Failure*
Levy ²⁸	2007	19	42	0%	0%	10.5% (2/19)	0%
Levy ²⁷	2007	29	35	10.3% (3/29)	0%	0%	3.4% (1/29)
Seebauer ³⁵	2006	56	39	0%	80.4% (45/56)	3.6% (2/56)	1.8% (1/56)
Boileau ⁴	2006	45	40	44.7% (17/38)	68.4% (26/38)	0%	0%
Guery ¹⁷	2006	80	69.6	NA	NA	7.5% (6/80)	3.8% (3/80)
De Wilde ¹³	2005	4	38	0%	0%	0%	0%
Frankle ¹⁶	2005	60	33	5.0% (3/60)	0%	1.7% (1/60)	11.7% (7/60)
Werner ⁴⁴	2005	58	38	10.4% (5/48)	95.8% (46/48)	5.2% (3/58)	0%
Paladini ³²	2005	7	30	0%	14.3% (1/7)	0%	0%
Seebauer ³⁶	2005	57	18.2	0%	24.6% (14/57)	0%	1.8% (1/57)
Seitz ³⁷	2005	12	12	0%	0%	0%	0%
Katzer ²⁵	2004	21	24	0%	9.5% (2/21)	0%	0%
Sirveaux ³⁸	2004	80	44.5	25% (20/80)	63.6% (49/77)	6.3% (5/80)	8.8% (7/80)
Vanhove ⁴²	2004	32	31	0%	50% (12/24)	3.1% (1/32)	0%
Woodruff ⁴⁵	2003	17	87	38.5% (5/13)	NA	15.4% (2/13)	0%
Boulahia ⁵	2002	18	35	0%	62.5% (10/16)	6.3% (1/16)	0%
Delloye ¹⁴	2002	5	81	NA	NA	40% (2/5)	20% (1/5)
De Wilde ¹¹	2002	6	12	0%	0%	0%	0%
Rittmeister ³⁴	2001	8	54.3	NA	NA	37.5% (3/8)	12.5% (1/8)
De Wilde ¹⁰	2001	5	30.2	0%	60% (3/5)	0%	0%
Valenti ⁴⁰	2001	39	84	NA	56.4% (22/39)	2.6% (1/39)	7.7% (3/39)
Favard ¹⁵	2001	80	45.4	NA	62.5% (50/80)	3.8% (3/80)	5.0% (4/80)
Jacobs ²²	2001	7	26	0%	0%	0%	0%
De Buttet ⁹	1997	71	24.7	0%	0%	0%	4.2% (3/71)
Brostrom ⁶	1992	23	87	100% (23/23)	0%	13% (3/23)	8.7% (2/23)

* includes fracture of baseplate implant, screw(s), or disassociation of glenoid head from base plate

Materials

The *Zimmer Trabecular Metal Reverse Shoulder* is a prosthetic design that employs modular humeral and glenoid components to restore function to patients with rotator-cuff deficient pathologies (Figure 1). Numerous humeral components allow for independent control of the stem offset and deltoid tension. The system offers two different glenosphere sizes and numerous UHMWPE liners to allow for optimum joint stability.

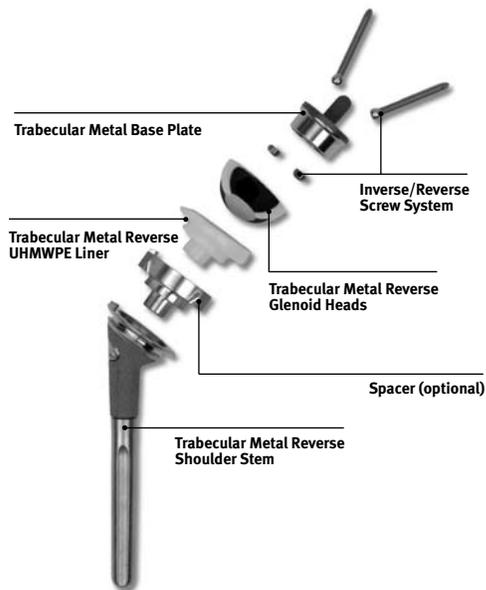


Figure 1 – *Zimmer Trabecular Metal Reverse Shoulder*

The subject of this study was the *Zimmer Trabecular Metal Reverse Shoulder* glenoid implant. The *Zimmer* system uses two (2) screws for initial fixation, as opposed to four (4) screws in other manufacturers' designs. In this study, five (5) production quality glenoid constructs were tested. The glenoid construct consisted of a *Trabecular Metal* base plate component (Ti-6Al-4V *Titanium*[®] alloy with diffusion bonded *Trabecular Metal* material), two 4.5mm, 30mm length screws and locking caps (Ti-6Al-4V *Protasul*[®] alloy), and a 40mm glenosphere component (CoCrMo *Zimaloy*[®] alloy), as shown in Figure 2.

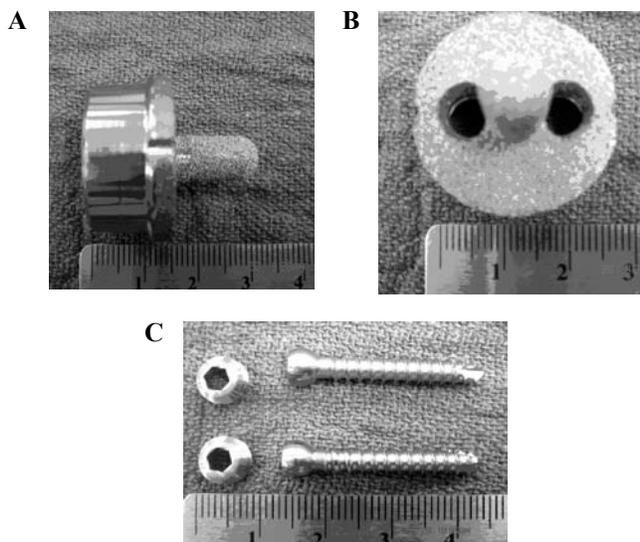


Figure 2 – A) Base plate component (side view); B) base plate component (bottom view); C) locking screws and caps

Methods

Rigid polyurethane foam (Sawbones, Vashon, WA) was used as a bone substitute material. Foam densities of 0.48, 0.32 and 0.24 grams per cubic centimeter (g/cc) were selected to represent a broad range of bone quality. The compressive strength of glenoid cancellous bone has been reported to range from 6.7 to 17 MPa.² The foam densities chosen for testing covered the entire reported range and were considered to represent the spectrum of bone quality from poor (0.24 g/cc) to excellent (0.48 g/cc). Mechanical properties of the foam as provided by the manufacturer are given in Table II.

Table II – Mechanical properties of polyurethane foam (bone analog)

Density (g/cc)	Compressive		Tensile		Shear	
	Strength (MPa)	Modulus (MPa)	Strength (MPa)	Modulus (MPa)	Strength (MPa)	Modulus (MPa)
0.24	4.9	153	3.9	143	2.8	44
0.32	8.8	260	5.9	267	4.5	67
0.48	18.9	520	12.2	427	9.7	146

Individual foam blocks (65mm x 60mm x 40mm) were cut from bulk sheets and were prepared to accept the glenoid implant components per the prescribed surgical technique. A pilot hole was created at the center of the block using a 6mm drill. The pilot hole was then increased in diameter using a 7.5mm drill and drill guide. The base plate component was then seated into the block by applying several impacts to an inserter instrument. Once fully seated, pilot holes were drilled for the screws using a drill guide and 2.5mm drill. The screws were then driven into the prepared block by hand using a hex driver until the head of the screw was firmly secured within the hole of the base plate. The locking caps were then inserted into the threaded holes and secured using a torque-limited hex driver. Specimens were tested with and without the locking caps to evaluate the effect of captured vs. uncaptured screw fixation. Finally, the glenosphere component was seated onto the base plate component via a locking taper connection by striking the glenosphere with a surgical mallet.

The locking screws, locking caps, and glenosphere component were re-used throughout the testing. The base plate components were re-used, and were tested a total of 6 times (3 foam densities, with and without locking caps). Every base plate component was cleaned after each test and measured with a digital micrometer to ensure that the diameter of the *Trabecular Metal* post was not changed.

Specimens were rigidly fixed to a linear biaxial servohydraulic test machine with custom software used to run the tests in force control. A 756 N compressive force was applied while a fully reversed, cyclic transverse (shear) force of ± 756 N was applied in the superior-inferior (S-I) direction for a duration of 1,000 cycles at a frequency of 0.05 Hz. A single gage-type differential variable reluctance transducer (DVRT, Model MG-DVRT, Microstrain, Burlington, VT) was placed in contact with the base plate component at the *Trabecular Metal* material/foam interface and aligned with the S-I axis of the implant to measure displacement (micromotion) of the base plate component relative to the foam block (Figure 3). The DVRT was spring-loaded and

thus was always in contact with the base plate component, allowing for measurement of micromotion in both directions. The force, displacement and DVRT peak/valley data were acquired every 10 cycles, and full cycle data was collected every 100 cycles. All testing was performed in air at ambient laboratory temperature.

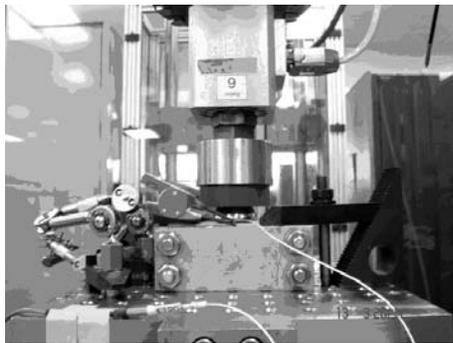
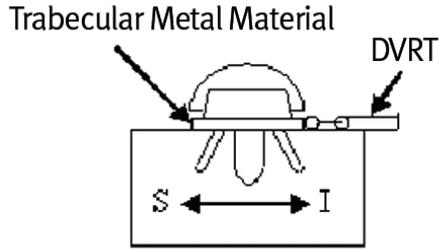


Figure 3 – Schematic diagram (top) and actual experimental test setup

Each data set was analyzed to determine the superior and the inferior displacement of the base plate component, corresponding to the change in the position of the DVRT between the neutral position (0 N) and the maximum superior force (756 N), and the neutral position and the maximum inferior force (-756 N), respectively. A representative plot of shear force and DVRT output is shown in Figure 4. Motion was defined as the average of the superior and inferior displacement of the base plate component. Comparisons of the different test groups were made using the final data set (~1000 cycles) for each specimen. A Student's t-test was performed to determine differences between foam densities and to compare specimens with and without locking caps in the same foam density.

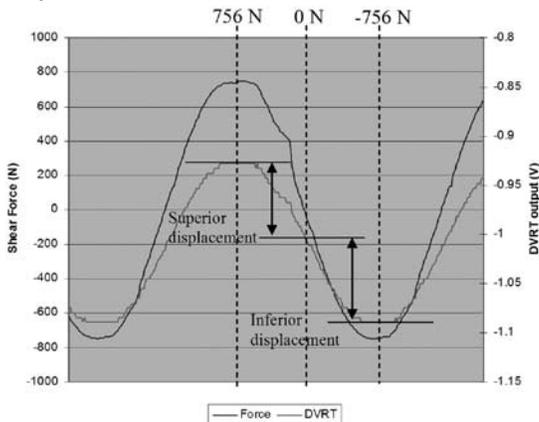


Figure 4 – Representative data plot of shear force and DVRT output

Results

Displacement measurements for all foam densities with and without locking caps are shown in Figures 5 and 6, respectively. The displacement measurements remained fairly constant, only varying by 0% to 9% over the course of the test in any of the specimen groups. Displacement as a function of foam density is shown in Figure 7. The foam density had a significant effect on the measured displacement. There was a statistically significant difference ($P < 0.05$) in the displacement between the 0.48 g/cc and the 0.32 g/cc foam and between the 0.32 g/cc and 0.24 g/cc foam. There was no significant difference in the displacement between the samples with and without locking caps in any of the foam densities tested.

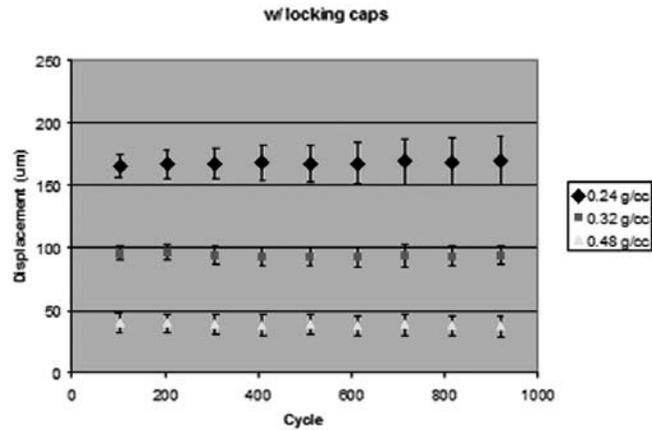


Figure 5 – Glenoid base plate implant displacement measurements with locking caps.

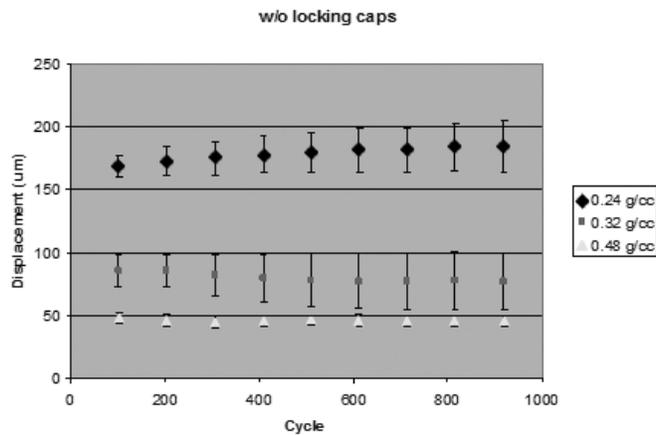


Figure 6 – Glenoid base plate implant displacement measurements without locking caps.

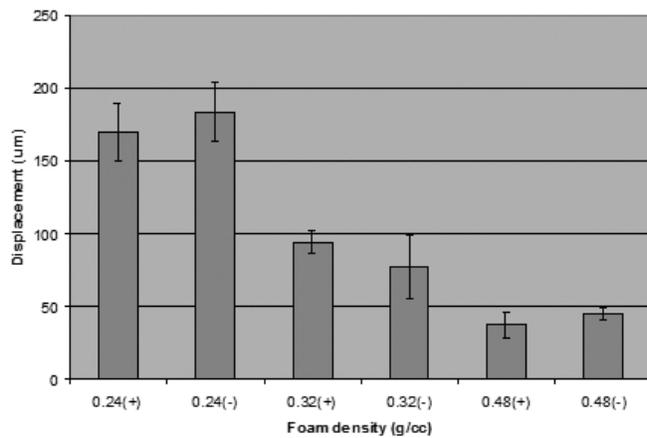


Figure 7 – Glenoid base plate implant displacement as a function of foam density. (+) indicates locking caps were used, (-) indicates no locking caps were used.

A comparison of the results from this study to published values for commercially available 4-screw designs is shown in Figure 8.

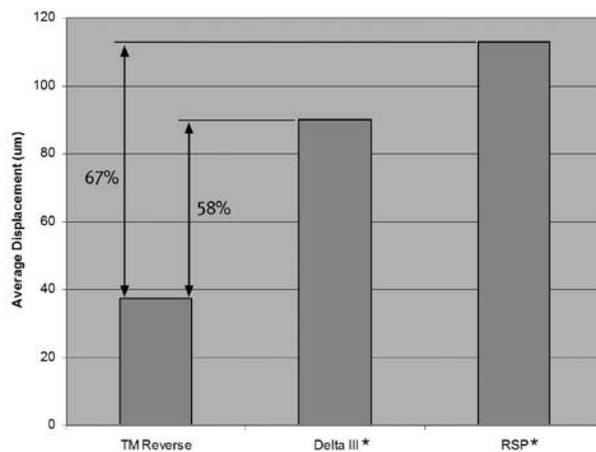


Figure 8 – Comparison of test results for implant designs (*Data from Harman et al²⁰).

Discussion

The load applied to the glenoid construct in this testing was approximately 1.0 times body weight (BW), consistent with previous study of glenoid base plate implant micromotion under cyclic displacement.²⁰ This load magnitude, and therefore the reported displacement values, is likely conservative, as studies on reverse shoulder biomechanics have predicted joint reaction forces of approximately 0.5 x BW for activities of daily living.^{24,26,29,39} The joint reaction force magnitude would be expected to be reduced in a reverse shoulder, as the missing rotator cuff muscles would no longer exert compressive force on the glenoid as they would in a normal, healthy shoulder.

The glenoid base plate component tested in this study achieves fixation through several means. Initial stability is afforded by a combination of interference fit of the central post and the compression provided by the locking screws. Long-term fixation is achieved through biological ingrowth into the *Trabecular Metal* material on the post

and the underside of the baseplate. The inability of the rigid polyurethane foam material to simulate ingrowth is one of the limitations of this study. An additional limitation was the homogeneous nature of the material used to simulate the bone, as it does not provide a means of simulating screw purchase in a targeted area of the scapula, such as the pillar with the inferior screw. In addition, the applied load was in the superior-inferior direction, aligned with the screw fixation. Further study is needed to determine the effects of anterior-posterior directed shear forces.

Studies of the initial stability of glenoid base plate designs with four peripheral screws have been conducted^{20,43}. The results of those studies indicated that the magnitude of the relative motion of the implant is dependent on the lateral offset and the type of peripheral screw used (captured or uncaptured). These implant designs were only evaluated in a material representative of excellent bone quality; therefore, only the results of specimens tested in the 0.48 g/cc foam in the current study can be directly compared (see Figure 8). The results of the current study compare favorably to the published values for 4-screw implant designs, using the same bone analog material (0.48 g/cc density) and test methods. These results indicate that the use of 2 locking screws and a *Trabecular Metal* post has an equal or superior amount of initial fixation to commercially available 4 screw constructs.

The results from this study did not reveal a significant difference in the magnitude of the implant motion when locking caps were not used to secure the screws. The locking cap is intended to secure the screw at a desired orientation with respect to the glenoid base plate implant. The lack of a significant difference may have been due to the homogeneous nature of the foam material, as the screws were uniformly surrounded by material with consistent mechanical properties. The *in vivo* environment would likely have mechanical properties that vary regionally through the glenoid bone stock, making security of the screw orientation more important. It is important to note that the surgical technique for the implant system evaluated in this study explicitly indicates the use of the locking caps, and it should not be inferred from the results from this study that the use of locking caps is unnecessary.

The *in vivo* response of trabecular bone to porous-coated implant surfaces has been shown to be sensitive to induced motions at the implant-bone interface.²³ Ingrowth has been demonstrated to occur with up to as much as 150 µm of motion. In the material representative of excellent to average bone quality (0.48 and 0.32 g/cc), the magnitude of the displacement was below the generally accepted threshold of 150 µm for biological ingrowth to occur. The results in the 0.24 g/cc foam, representing poor bone quality, exceeded this value by approximately 10-20%. Thus, the 0.24 g/cc foam represents the lower bound of mechanical properties that would be expected to achieve biological ingrowth. In this study, the assumed bone quality, and hence the mechanical properties of the foam bone analog material, was found to have a significant effect on the relative motion of the glenoid base plate implant under physiological load. However, the magnitude of the displacement was at or below the generally accepted threshold for biological ingrowth to occur, even in material with properties representative of poor quality bone. Clinical outcomes studies with this device are needed to determine if the experimental results from this study translate to successful biological fixation *in vivo*.

Conclusions

The results from this study show that the fixation of the glenoid base plate implant is sensitive to the quality of the bone. Based on generally accepted limits of induced motion at the implant-bone interface, the *Trabecular Metal* Reverse Shoulder prosthesis provides initial stability necessary to achieve biological ingrowth enabling long-term fixation over a wide range of bone properties.

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