Total Shoulder Arthroplasty

Biomechanical Testing of the Fixation of a New Glenoid Design

*By Susan G. Capps, Ph.D.**
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Abstract

The Comprehensive® Shoulder Solutions' Modular Hybrid Glenoid from Biomet is a revolutionary design for replacement of the glenoid in total shoulder arthroplasty. It provides three outer pegs and three central peg options for surgical implantation. *In vitro* testing of the Modular Hybrid Glenoid resulted in mean axial pull-out peak loads ranging from 209 to 303 lbf, mean inferior/superior shear peak loads from 383 to 460 lbf and mean anterior/posterior shear peak loads from 483 to 636 lbf.[1] Based on the clinically proven design of the Bio-Modular® Glenoid, the Modular Hybrid Glenoid provides for enhanced fixation. Theoretically, solid initial fixation leads to fewer radiolucencies and thus fewer clinically loose components. The Modular Hybrid Glenoid offers a solution to the growing needs of an expanding total shoulder arthroplasty population.

Introduction

In total shoulder arthroplasty, glenoid components are replacements for the glenoid portion of the gleno-humeral joint. As with most total joint replacements, surgical technique and implant design are the major factors that influence glenoid implant fixation. Radiolucent lines and component loosening are the best indicators of instability *in vivo* and are presently the most concerning clinical issue relative to glenoid component fixation.[2–5,7–11]

Glenoid components, both keeled and pegged designs, are usually either all-polyethylene or metal-backed-screw-fixed with a polyethylene tray. Preliminary results indicate that metal-backed-screw-fixed glenoid implants are associated with lower short-term rates of radiolucent lines and loosening than all-polyethylene components.[4]

Radiolucencies are sometimes indicators of poor implant fixation at the cement-bone interface, and the frequency of radiolucencies increases with length of follow-up (reported frequencies range from 30 percent to 90 percent).[3] Some studies report a direct relationship between radiolucencies and component loosening, while other authors regard radiolucent lines about the glenoid component to be unrelated to future loosening.[3,8,10] The revision rate of glenoid components due to loosening has been reasonably low at 2 percent (range, 0 percent to 8 percent).[2]

Glenoid fixation is clearly an issue worth addressing. Shown below in Figure 1, the Modular Hybrid Glenoid (Biomet, Inc., Warsaw, Indiana) is an evolution of the clinically proven Bio-Modular® design. As with the Bio-Modular® glenoid, the Modular Hybrid Glenoid's outer three pegs are intended to be implanted with bone cement. The optional Regenerex™ Porous Titanium peg is inserted without bone cement. The optional polyethylene peg is indicated for use with bone cement.

Figure 1
Modular hybrid glenoid

Poor initial fixation of orthopedic implants contributes to component loosening long-term. Therefore, *in vitro* mechanical testing of axial pull-out, inferior-superior shear and anterior-posterior shear were performed to determine the strength of initial attachment mechanisms. The axial pull-out test determines the baseline strength of the glenoid fixation. The shear tests measure a more physiologically accurate loading condition on the glenoid. *In vivo,* the friction of the humeral head sliding over the face of the glenoid causes shear forces on the glenoid.

Materials and Methods

Prosthesis

In an effort to address glenoid component fixation, the Modular Hybrid Glenoid was developed with three outer pegs for cemented fixation and a central boss that can remain empty or accept a central peg (Figure 2). There are two central peg options: Regenerex™ Porous Titanium for press-fit biologic fixation and polyethylene for cemented use (Figure 3).

Figure 2
Outer pegs and central boss

Figure 3
Regenerex™ Porous Titanium and polyethylene central peg options

Regenerex™ Porous Titanium Construct is manufactured from titanium, allowing for vascularized direct osteogenesis.[6] Recent animal model testing has shown bony integration and vascularization two weeks after insertion.[1,12]

Testing Protocol

Mechanical *in vitro* testing was performed to determine the initial stability via release strength of the Modular Hybrid Glenoid in both axial pull-out and shear/lever-out configurations. These *in vitro* mechanical tests do not simulate clinical use of the device. All tests were conducted using a hydraulic testing machine: MTS® Renew Controller, Smtec 1S Testframe, a 2000 pound load cell and Testworks® software. Basic statistical analysis included mean, standard deviation and median values.

Test Samples

Boneblock is a synthetic material created to simulate human bone during *in vitro* mechanical testing (Figure 4). In this study, boneblocks were machined to accept Modular Hybrid Glenoid prostheses. Actual Modular Hybrid Glenoid components were altered to facilitate test fixturing, and the articulating surface was replaced with a much thicker polyethylene component. This alteration was not expected to influence test results. The three outer pegs of each prosthesis were cemented into a prepared boneblock using Cobalt™ HV Bone Cement, and 15 pounds of force was applied until the cement had cured. Separate load testing determined that 15 pounds of force most closely mimics the thumb-force used during surgical cement fixation of glenoid components.[1]

Figure 4
Test sample preparation

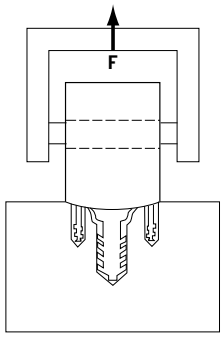
A: Machined boneblock

B: Boneblock with cement for the three outer pegs

C: Weight application during cement curing

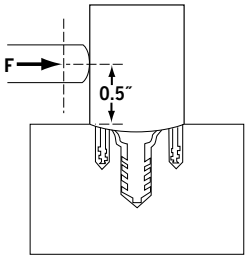
Axial Pull-out Testing
Test samples were mounted into the hydraulic testing machine using a custom test fixture, and the top of the component was pinned using a through-hole (Figure 5). Next, an axial load was applied until either release or component failure occurred. Load versus deflection results were plotted, and ultimate strength was recorded.

Figure 5
Axial pull-out testing



Shear/Lever-out Testing
As with axial pull-out tests, test samples were mounted into the hydraulic testing machine using custom test fixtures (Figure 6). Force was applied to the inferior aspect of the glenoid half an inch from the simulated glenoid/bone interface. This distance was chosen to mimic the shear force of a humeral head sliding across the glenoid. Shear force was applied until release or component failure occurred. Again, load versus deflection results were plotted, and ultimate strength was recorded.

Figure 6
Shear testing

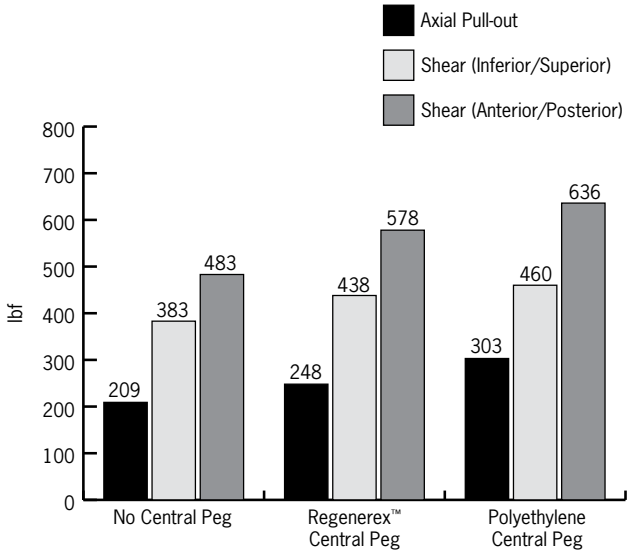


Results
The test results most closely approximate glenoid component fixation during the post-operative period. Bone ingrowth into the Regenerex™ Porous Titanium central peg will enhance the potential for long-term fixation.

The Modular Hybrid Glenoid with a polyethylene central peg has the highest mean axial pull-out value—303 lbf (Figure 7). As expected, the Modular Hybrid Glenoid without a central peg has the lowest mean axial pull-out, as it presents the smallest attached surface area.

Although the axial pull-out testing does not constitute physiologic loading, it is a good indicator of shear testing results for the Modular Hybrid Glenoid. In each of the shear test configurations, the Modular Hybrid Glenoid with a central polyethylene peg had the highest mean strength inferior/superior shear—460 lbf (Figure 7) and anterior/posterior shear—636 lbf (Figure 7). Again, the Modular Hybrid Glenoid without a central peg had the lowest mean shear peak load values.

Figure 7
Mean peak load



Discussion
In total joint arthroplasty, initial fixation is an indicator of long-term loosening and implant revision. In other words, an implant that starts out loose will not improve with time or physiologic loading. Therefore, it is logical that the evolution of implant fixation will continue for all implants, even those that are performing well clinically. Also, as the total joint replacement population expands to include younger, more active patients, all fixation improvements are deemed beneficial. The Modular Hybrid Glenoid represents the newest design evolution of the total shoulder arthroplasty glenoid component.

A detailed literature search revealed a single source with *in vitro* testing results of pegged glenoid component fixation design features. Nyffeler *et al.* conducted an *in vitro* pull-out strength study of peg design (macrostructure and surface finish) and cement mantle thickness using cadaveric bone samples.[9] Three macrostructures were compared: cylindrical, notched on one side and threaded; as well as two surface finishes: smooth and rough-blasted. The diameter of the insertion hole was enlarged to compare cement mantle thickness, with the larger diameter hole corresponding to a thicker cement mantle. Cylindrical pegs with smooth surfaces fixed in a thin cement mantle had the lowest

average pull-out strength of 4.5 ± 1.1 lbf.[9] The highest average pull-out strength resulted from threaded pegs fixed in a thick cement mantle (95.5 ± 1.6 lbf).[9] Threaded pegs had significantly higher pull-out strength than notched pegs ($p<0.008$), and notched pegs were significantly stronger than cylindrical pegs ($p<0.006$). Rough-blasting improved the pull-out strength for cylindrical and notched pegs; however, it slightly decreased the pull-out strength for threaded pegs because the threads became rounded. While increasing hole diameter improved pull-out strength for all designs, the most obvious improvement was for rough-blasted cylindrical pegs ($p<0.0001$).[9] For this study, the primary mode of failure was at the cement-peg interface.

The test results from Nyffeler *et al.* are not easily compared to those presented here for the Modular Hybrid Glenoid. Nyffeler *et al.* used cadaveric bone and conducted pull-out tests on single pegs only with the goal of comparing peg design and cement mantle thickness. The Modular Hybrid Glenoid *in vitro* testing used bone-block (a material with consistent properties for all test samples unlike cadaveric bone) and conducted axial pull-out plus two shear tests with the goal of determining baseline *in vitro* values for the entire glenoid component. However, some of the conclusions reached by Nyffeler *et al.* are applicable to evaluating design aspects of the Modular Hybrid Glenoid. The Modular Hybrid Glenoid incorporates grooved outer pegs without surface modifications, analogous to the best design option of the threaded pegs without rough blasting in Nyffeler *et al*.

The Modular Hybrid Glenoid, which evolved from the clinically successful Bio-Modular® all-polyethylene glenoid implants, performed as expected. *In vitro* testing of the Bio-Modular® three-peg and keeled designs, using the same protocol outlined above, resulted in mean axial pull-out peak load of 227 lbf (3-peg) and 245 lbf (keeled), mean inferior/superior shear peak load of 289 lbf and 330 lbf and mean anterior/posterior shear peak load of 313 lbf and 234 lbf. The Modular Hybrid Glenoid presents three central peg options, and test results range from 209 to 303 lbf mean axial pull-out, from 383 to 460 lbf mean inferior/superior shear and from 483 to 636 lbf mean anterior/posterior shear.[1]

Conclusions

Initial fixation of cemented orthopedic implants is critical to lessening the development of future loosening. Based on the clinically proven Bio-Modular® glenoid, the Modular Hybrid Glenoid provides for optimal initial fixation. Solid initial fixation means fewer radiolucencies are anticipated. Decreased radiolucent lines may allow for fewer loose glenoid components and reduced implant failure rates.

The Modular Hybrid Glenoid also offers the orthopedic surgeon multiple central peg options, allowing the glenoid implant to be more specifically tailored to the patient's needs and anatomy. The Modular Hybrid Glenoid offers a revolutionary option for the needs of an expanding total shoulder replacement patient population.

References

1. Data on file at Biomet. Bench test results not necessarily indicative of clinical performance.
2. Bauer, G.S. *et al.* Fixation for the millennium: the shoulder. *Journal of Arthroplasty*. 17(4 Suppl 1): 9–10, 2002.
3. Boileau, P. *et al.* Arthroplasty of the shoulder. *Journal of Bone and Joint Surgery* (British). 88-B(5): 562–75, 2006.
4. Bohsali, K.I. *et al.* Complications of total shoulder arthroplasty. *Journal of Bone and Joint Surgery*. 88-A(10): 2279–92, 2006.
5. Gartsman, G.M. and Hasan, S.S. What's new in shoulder and elbow surgery. *Journal of Bone and Joint Surgery*. 87-A(1): 226–40, 2005.
6. Karageorgiou, V. and Kaplan, D. Porosity of 3-D biomaterial scaffolds and osteogenesis. *Biomaterials*. 26(27): 5474–91, 2005.
7. Lazarus, M.D. *et al.* The radiographic evaluation of keeled and pegged glenoid component insertion. *Journal of Bone and Joint Surgery*. 84-A(7): 1174–82, 2002.
8. Martin, S.D. *et al.* Uncemented glenoid component in total shoulder arthroplasty: survivorship and outcomes. *Journal of Bone and Joint Surgery*. 87-A(6): 1284–92, 2005.
9. Nyffeler, R.W. *et al.* Influence of peg design and cement mantle thickness on pull-out strength of glenoid component pegs. *Journal of Bone and Joint Surgery* (British). 88-B(5): 748–52, 2003.
10. Wallace, A.L. *et al.* Resurfacing of a glenoid in total shoulder arthroplasty. A comparison, at a mean of five years, of prostheses inserted with and without cement. *Journal of Bone and Joint Surgery*. 81-A(4): 510–18, 1999.
11. Yian, E.H. *et al.* Radiographic and computed tomographic analysis of cemented pegged polyethylene glenoid components in total shoulder replacement. *Journal of Bone and Joint Surgery*. 87-A(9): 1928–36, 2005.
12. Testing done on animal models.

* Dr. Capps, President of BENSOL, is an independent outsource for research, analysis and communication services to the orthopedic device industry and orthopedic surgeons. She has written white papers and journal articles for various clients on topics including orthobiologics, FDA regulations, surgical instruments/trays and total joint arthroplasty.

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