Finite element analysis and physiologic testing of a novel, inset glenoid fixation technique

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Hypothesis: The success of shoulder arthroplasty surgery has been limited by one of the most common complications: glenoid implant loosening. Eccentric loading of the glenoid due to migration of the humeral head is considered to be the major cause of glenoid loosening and is referred to as the rocking-horse phenomenon. Glenoid implant loosening may cause pain, limitation of function, and the need for complicated revision surgery. Our hypothesis was that an inset fixation technique could offer increased fixation strength and minimize the effects of the rocking-horse phenomenon on glenoid loosening.

Materials and methods: Fixation strength and stress distribution were analyzed using two methods. First, mechanical simulation of physiologic in vivo cyclic loading was performed on 1 inset glenoid implant design and 2 standard onlay glenoid implant designs currently on the market. Second, 3-dimensional finite element analysis was performed to compare an inset glenoid implant and a standard onlay glenoid implant with a keel and a standard onlay pegged implant.

Results: After cyclic loading to 100,000 cycles, no glenoid implants demonstrated signs of loosening. Mechanical testing after cyclic loading demonstrated less distraction of the glenoid rim using an inset technique compared with an onlay technique. Finite element analysis results indicated that the inset technique achieved up to an 87% reduction in displacement.

Conclusions: Mechanical tests and finite element analysis support the concept of inset glenoid fixation in minimizing the risk of glenoid loosening.

Level of evidence: Basic Science Study, Biomechanical and Finite Element Analysis.

The success of shoulder arthroplasty surgery has been limited by one of the most common complications: glenoid implant loosening.13,21,43,47,49 Eccentric loading of glenoid implants due to migration of the humeral head is considered to be the major cause of glenoid loosening and is referred to...
as the rocking-horse phenomenon.\textsuperscript{7,8,12,15,22,24,42,47,49} Multiple clinical studies have shown a significant incidence of postoperative lucent lines around the backside of standard onlay implants and progression to glenoid implant loosening.\textsuperscript{43,46} Implant loosening may cause pain, functional limitation, stiffness, and the need for complicated revision surgery.\textsuperscript{18,47,49}

The strength of initial glenoid implant fixation is important in determining the potential for glenoid loosening.\textsuperscript{1,15,19} Glenoid implant fixation strength has been tested indirectly through micromotion measurements,\textsuperscript{14,31,39,46} finite element analysis (FEA),\textsuperscript{17,20,25,27,32,33,35,38,45} and nonphysiologic pull-out tests.\textsuperscript{18,31,40} The study by Anglin et al\textsuperscript{3} established a reproducible, physiologic protocol for evaluation of glenoid loosening by simulating rocking-horse translational forces. Using 6 different onlay glenoid implant designs, Anglin et al found that nonconforming, curved-back implants with a roughened backside surface withstood loosening in dynamic loading better than competitive implants. They also determined that distraction displacement of the inferior glenoid rim away from the foam block after superior rim loading was the best indicator of loosening.\textsuperscript{3}

Our study is a comparative scientific analysis of glenoid loosening using an inset glenoid fixation technique vs the standard onlay technique used with a keel or pegged implant. The analysis consists of two separate methods: First, physiologic in vivo cyclic loading of glenoid implants was simulated using the dynamic model described by Anglin et al and American Society for Testing and Materials (ASTM) F2028-08 Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation.\textsuperscript{3,6} Second, FEA was performed to estimate the glenohumeral joint stress and displacement for both standard onlay implants and an inset glenoid implant. Our hypothesis was that an inset fixation technique could offer increased glenoid implant fixation strength, which would minimize the effects of the rocking-horse phenomenon on glenoid loosening.

Materials and methods
Mechanical reproduction of in vivo loading

Materials and methods complied with the ASTM F2028-08 mechanical testing specifications.\textsuperscript{6} Test methods followed the protocol of Anglin et al\textsuperscript{3} to create directly comparable results. The specimens tested in our study were inset, circular glenoid implants with a 35-mm diameter with one 8-mm central, posterior peg (Shoulder Innovations LLC, Ada, MI, USA), standard size 40 onlay glenoid implants with a keel (DePuy, Warsaw, IN, USA), and standard size 40 anchor peg glenoid implants (DePuy, Warsaw, IN, USA; Table 1). We tested 12 specimens: 3 onlay keel and 3 onlay peg implants with their associate humeral heads, 3 inset specimens with a 38-mm humeral head, and 3 inset specimens with a 56-mm humeral head.

The inset glenoid implant (Shoulder Innovations, LLC) is an all polyethylene, circular implant designed for deficient glenoid bone. The 35-mm inset implant was chosen for testing instead of smaller sizes because it is the largest used in clinical practice by the senior author (S.B.G.). When coupled with the smallest humeral head implant currently in use (38 mm), this combination of head and glenoid sizes presents the largest potential for implant loosening because of the potential for edge loading.

A 20-pound per cubic foot block of cellular rigid polyurethane foam (Sawbones, Vashon, WA, USA) was used as a bone substitute in the fixture for the glenoid implants. According to the manufacturer’s specifications, the polyurethane has an ultimate compressive strength of 8.4 MPa and a modulus of 210 MPa. This bone substitute was chosen because it meets ASTM testing standards and replicates the Anglin et al\textsuperscript{3} protocol. This substitute represents average properties of cancellous bone and avoids the media inconsistencies of cadaveric bone.\textsuperscript{1,3,5}

The mechanical testing and sample preparation were performed at an independent laboratory (Knight Mechanical Testing, Fort Wayne, IN, USA). The implants were installed into the test blocks according to the manufacturers’ guidelines. For the inset implants, the polyurethane foam blocks were reamed with a flat back reamer to a 3-mm depth to replicate the cylindrical inset bone cavity created during the surgical procedure.\textsuperscript{23} The technique uses a central drill hole, followed by concentric reaming to create a precise cavity for the implant. Figure 1 is a representation of a glenoid implant partially inset within the glenoid cavity to provide increased fixation without allowing the humeral head component to contact the glenoid bone substitute.

Polymethylmethacrylate bone cement with a vacuum mixing system was applied to the inset cavity within the foam block and on the back of the implant. Each glenoid implant was manually compressed into the polyurethane block, and extruded peripheral cement was removed. The bone cement was allowed to cure in ambient conditions while the implant was gently compressed into the foam.

Holes (1 mm) were drilled in the superior and inferior edges of all the glenoid implants to allow for insertion of 1-mm stainless steel extension pins used during the testing to measure implant edge displacement. Holes were drilled parallel to the glenoid surface to avoid compromise of the implants. The DePuy glenoid implants were installed according to the manufacturer’s instructions for use. The manual dual-surface cement pressure technique with a vacuum mixing system used for the onlay implants was identical to that used for the inset implants.

Subluxation translation was determined for each of the implants according to the Anglin et al\textsuperscript{3} protocol. Subluxation translation is defined as the distance from the deepest point of the glenoid, located at the centroid, to the point corresponding to the peak shear load when the humeral head is subluxated from the glenoid.\textsuperscript{3,4} The subluxation translation for the onlay glenoid implants was determined by testing the size 40 glenoids with the size 40 humeral head implants, as suggested by the manufacturer. The articular surface of the inset implants was flat and nonconforming (56-mm radius of curvature). Therefore, we tested the smallest and largest humeral head sizes commercially available, which thus represent the extremes of conformity that could occur in a clinical setting. The contact point of the humeral head was located against the glenoid component within 0.5 mm of its center, and the 750-N compressive load was applied. The glenoid was translated superiorly and inferiorly at a rate of 50 mm/min while
shear force and horizontal displacement data were collected. Testing was conducted in ambient air.

Before dynamic testing, each specimen was conditioned with a static axial compressive load of 750 N with a superior/inferior translation stroke equivalent to the distance causing 90% of peak shear force (determined from the subluxation testing). Superior/inferior translation was 6.30 mm for the 56-mm head, 8.08 mm for the 38-mm head on the inset glenoid implants, and 2.8 mm for onlay glenoid implants due to the difference in radius of curvatures. Conditioning was conducted in ambient air at 0.25 Hz for 25 cycles. After conditioning, the stainless steel extension pins were inserted into the superior and inferior edges of the glenoid, and dial indicators were attached to the test-block housing fixture and oriented to indicate vertical displacement of the extension pins to the nearest 0.127 mm. The dial indicators were zeroed with no axial load on the glenoid. Readings were then taken with 750-N force applied to each glenoid via the humeral head centered and at the superior and inferior translation stroke distances (Fig. 2). Each reading was repeated once to verify the setup.

The testing apparatus was loaded into a water bath of 37°C to undergo 100,000 sinusoidal cycles at 1.5 Hz with an applied 750-N force. The cyclical load is equivalent to the load applied in predicate testing and represents 25 high-load glenohumeral activities a day for 10 years.2,3 To simulate rocking-horse loading, the superior and inferior sections of the glenoid implants were alternately loaded. Translation stroke was again defined as the translation that caused 90% of peak shear forces for each implant—humeral head pair as determined by subluxation testing. After dynamic testing, superior and inferior edge readings were again taken with the humeral head centered and at the inferior and superior translation stroke distances. After all testing and measurements were complete, implants were observed for signs of loosening. Statistical significance of the results was determined using a t test of the inset glenoid implants against the tested onlay implants.

**Finite element analysis**

A comparative 3-dimensional FEA was performed of inset vs onlay insertion techniques. The FEA characterized distributions of peak von Mises stresses and polymer displacement along the articulating surfaces of the glenoid implants and along the backside cement mantle. Stress and displacement were predicted based on humeral loads of 250, 500, and 750 N. Loading was determined based on ASTM F2028-08 loading requirements for testing of a glenoid implant.6 Device behavior was modeled with loads applied in 5 locations across the articular surface: position 1 is in

### Table 1 Glenoid prostheses features for finite element analysis and dynamic testing

<table>
<thead>
<tr>
<th>Features</th>
<th>Inset glenoids</th>
<th>Onlay glenoids</th>
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<tr>
<td></td>
<td>Inset 56</td>
<td>Inset 38</td>
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<tr>
<td>Humeral head diameter, mm</td>
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<td>38</td>
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Figure 1 Representation of a glenoid implant inset within the glenoid cavity and a cross section of the glenoid implant inset into the glenoid cavity.
the center of the articulating surface of the implant, positions 2 and 4 are half way between the center of the implant and the inferior and superior glenoid rims, respectively, and positions 3 and 5 are at the superior and inferior glenoid rims, respectively (Fig. 3).

Each implant was modeled as ultra-high-molecular-weight polyethylene, and the humeral head was modeled as chromium cobalt alloy. Respective material properties were again used to characterize the material (Table II). FEA was performed using ANSYS software (ANSYS, Inc. Canonsburg, PA USA), with mesh size ranging from the minimum element size of 0.0005 m to maximum element size of 0.003 m. Each glenoid was meshed in a similar manner, having approximately 32,000 elements and 6500 nodes.

Three types of glenoid implants were used: 1 representing a size 40 curved-back keeled implant currently used in total shoulder arthroplasty surgery, 1 representing a size 40 curved-back pegged implant also currently in use, and 1 representing an inset 35-mm-diameter circular implant with a flat backside surface and a single central posterior peg. Models were developed from measured dimensions of each implant. The circular implant design was analyzed using parameters simulating inset fixation of the implant in cortical bone. Implant fixation was modeled per boundary condition 2: the medial surface and 3 mm of the perimeter from the medial surface were constrained. The keeled implant design was analyzed as a standard onlay implant per boundary condition 1: only the medial surface was constrained, simulating standard bone cementing techniques (Fig. 4).

Physical tests were performed to more accurately determine actual load contact areas under the various applied loads. Using pressure sensitive films, we measured the actual contact areas between the humeral head and the glenoid articular surface under the applied loads. These contact surface areas were then used as loading areas in the FEA.

Results

Mechanical reproduction of in vivo loading

Subluxation testing determined that 90% of the peak shear force occurred 6.30 mm from the inset glenoid center when testing with a 56-mm humeral head, 8.08 mm from the inset glenoid center when testing with a 38-mm humeral head, and 2.8 mm from the onlay glenoid center when testing with a 40-mm humeral head. After up to 100,000 cycles of dynamic rocking testing, all inset and onlay glenoid specimens remained firmly anchored in the polyurethane foam blocks, with no indications of glenoid loosening.

Displacement results are reported as distraction, which indicates movement of the glenoid implant edge upward away from the polyurethane block. Distraction values were determined by the displacement at the glenoid edge opposite the loading, again using the location of that edge when the glenoid center is loaded to define zero displacement. Displacement of the glenoid implants in distraction, which was determined by Anglin et al3 to most accurately predict rocking-horse loosening effects, was more significant in both of the onlay implants than in the inset implants (Fig. 5). A standard t test showed statistically significant reductions in post-test distraction in the inset glenoid compared with the onlay keel implant (P < .0001 with 95% confidence) and with the inset glenoid vs the onlay pegged

<table>
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<th>Humeral heads</th>
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<td>Material</td>
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<td>Poisson’s ratio</td>
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UHWMP, ultra-high-molecular-weight polyethylene.
implant ($P < .0001$ with 95% confidence). Evaluation of inset glenoid loosening due to changes in glenohumeral conformity showed no statistically significant difference between post-test distraction performance of the 56-mm and 38-mm humeral heads.

**Finite element analysis**

Comparative data for both the onlay and inset fixation techniques included displacement of the polyethylene articular surface and the peak nodal von Mises stresses at the polymer-to-cement interface (backside surface) under rim loading conditions (Fig. 6). In the central zone (zone 1), which does not represent the rocking-horse phenomenon, the highest stress occurs in the pegged onlay implant (8.3 MPa), and there is less stress in this central region in the inset implant (3.27 MPa) and the keel implant (2.65 MPa). In the peripheral zones (zones 3 and 5), which represent the rocking-horse phenomenon, the highest stress occurs in the onlay implants (pegged onlay, 16.2 MPa; keel onlay implant, 7.85 MPa). The zones 3 and 5 stress in the inset implant is 3.26 MPa (Fig. 7).

Displacement of the polyethylene material in the central zone is highest in the onlay keel implant (0.048 mm). Zone 1 displacement of the inset glenoid implant (0.024 mm) and onlay pegged implant (0.027 mm) are less. Polyethylene displacement in the rocking-horse zone (zones 3 and 5) is highest in the onlay pegged implant (0.208 mm), second highest in the onlay keel implant (0.179 mm), and lowest in the inset glenoid implant (0.048 mm). This represents an 87% reduction in displacement of inset glenoid implant compared with the onlay pegged implant and a 73% reduction in displacement of the inset glenoid compared with the onlay keel implant (Fig. 8). Figure 7, a representation of these peak von Mises stresses, demonstrates that the onlay implant exhibits high stress at the implant edges, or a rocking-horse stress distribution, and shows that this rocking-horse stress distribution is not exhibited by the inset implant.

**Discussion**

The goal of this study was to evaluate the potential to minimize glenoid loosening using an inset fixation technique. The senior author (S.B.G.) has used this type of inset glenoid fixation previously. A case series of patients treated with this inset glenoid for severely deficient bone showed that the technique was safe and effective in a group of 7 patients with minimum 3-year follow-up. To our knowledge, there is no previously published mechanical data or finite element analysis of this type of glenoid fixation.

Mechanical testing can be helpful in predicting the clinical behavior of different implant designs and fixation techniques under simulated in vivo physiologic conditions. This study evaluated the potential for glenoid loosening by reproducing physiologic rocking-horse loading. This testing protocol differs from previous publications that have only indirectly evaluated the potential for glenoid loosening through micromotion measurements.

![Figure 4](image1.png)

**Figure 4** Glenoid boundary conditions for finite element analysis.

![Figure 5](image2.png)

**Figure 5** Distraction displacement of the glenoid edges after 100,000 superior—inferior cycles. See Table I for a description of glenoid types. The *error bars* show the standard error.
FEA,17,20,25,27,32,33,35,38,45 and nonphysiologic pull-out tests.18,31,40 The study by Anglin et al3 was the first scientific analysis to establish a reproducible, physiologic protocol for the evaluation of glenoid loosening while simulating superior rocking-horse forces. They tested 6 different standard onlay glenoid designs and concluded that the best indicator of glenoid loosening was the amount of tensile distraction in the contralateral (superior–inferior) glenoid rim after cyclic loading of the opposite rim. Interestingly, neither compression nor distraction before cyclic rocking predicted this post-rocking distraction. They also concluded from their testing that nonconforming, curved-back prostheses with roughened fixation surfaces14,46,27 exhibit the least amount of distraction and have the least potential for clinical loosening.3

In this current study, the Anglin et al protocol was replicated to reproduce rocking-horse effects on glenoid loosening. Glenoid implant testing in this study was performed using a translational stroke that caused 90% of the peak shear load on the glenoid so that glenoids of different articular profiles could be evaluated and compared. A fixed translational stroke was not appropriate for comparing glenoid implants of different conformity or curvature because higher shear loads were applied to more constrained glenoids or to glenoids with a smaller radius of curvature at a certain stroke than for less constrained implants or implants with a larger radius of curvature. Additionally, a fixed stroke does not account for the fact that translation distance of the humeral head may vary with glenoid implant size. The goal of this testing protocol was to isolate the effect of the rocking-horse shear forces on any polyethylene implant. By applying a translational stroke that loaded the glenoid to 90% of the peak shear load, rocking-horse loading was experienced in constrained and nonconstrained glenoid implants, regardless of size or curvature.

Anglin et al3 noted that humeral head translation in active loading of the glenoid is usually 1 to 2 mm, and patients with instability or rotator cuff tears may demonstrate translation of up to 4 mm.4,16,25,28,29,30,34 Therefore,
a stroke of 2.8 mm, as seen in the onlay glenoids, is aggressive but realistic. Translations of 6.30 and 8.08 mm for inset glenoids (paired with 56- and 38-mm humeral heads) are beyond the range of expected anatomic loading due to soft tissue restraints. Therefore, realistic translations and resultant rocking-horse loads on an inset glenoid would be lower than reported. Even though the inset translations may be overly aggressive and simulate an unrealistic in vivo condition, the testing results recorded at the independent laboratory showed statistically significant reductions in inset glenoid edge distraction after physiologic cyclic loading compared with standard onlay implants.

FEA was used to measure von Mises stresses at the backside surface of glenoid implants and also polyethylene articular surface displacement: First, the inset technique provided significant stress reduction on the polyethylene—cement interface.

Second, the data indicated that an inset technique resulted in a more uniform stress distribution at the cement—polymer interface and did not exhibit the characteristic rocking-horse distribution. Because this is one of the primary causes of glenoid loosening,27 the stress-shielding effect of insetting the glenoid may help to minimize clinical glenoid loosening.

Third, the data indicated that an inset technique demonstrated significantly less polyethylene edge displacement at the periphery of the implant compared with onlay glenoid implants for the same applied loads. Because stress and displacement of the polymer at the articular surface are considered indicators of potential articular surface wear, the inset glenoid implantation technique may result in decreased glenoid surface wear. Additional studies might be helpful to analyze these effects.

Increased resistance to loosening provided by an inset glenoid implantation technique may also allow total shoulder arthroplasty surgery to be performed in patients with deficient glenoid bone.23 Current onlay glenoid implantation techniques are contraindicated for some patients with deficient glenoid bone in which onlay implants can not be properly secured in the glenoid vault.9,10,11,26,36,37,41,43,44 Polymer fatigue failure, rigid cement constraints, and anatomic modeling were not investigated in this study because these factors are assumed to remain constant between an inset and onlay glenoid implantation technique. It may be helpful to evaluate these factors in future studies.

**Conclusion**

The mechanical testing in this study of the inset glenoid design and fixation technique showed a significant reduction in post-testing distraction after physiologic loading compared with standard onlay design and fixation. The results of the finite element analysis support the concept of inset glenoid fixation based on the significant reduction in stresses on the backside surface on the inset implant compared with the standard onlay implant. Also, the nodal displacement at the edges of the implants under rim loading conditions was significantly reduced for the inset implants, and there was more uniformity of stress distribution along the inset polyethylene surface. Our testing shows increased glenoid fixation strength using an inset technique, which may be beneficial in minimizing clinical glenoid loosening.

**Disclaimer**

Stephen B. Gunther, MD, and Desmond O’Farrell are partial owners of Shoulder Innovations, LLC, which owns some intellectual property related to the subject of this article. Shoulder Innovations, LLC is an early-stage company involved in the research, design, and development of novel shoulder implants but does not yet manufacture any commercially available products at this time. The other authors, their immediate families, and
References