

## Editorial

# About The Innovation...Inset Glenoid Technology: A Paradigm Shift in Shoulder Replacement Surgery

Stephen B Gunther, MD<sup>1</sup>, Joel A. Bervell, MS<sup>b</sup>

<sup>1</sup> Orthopedic Surgery, Sentara Martha Jefferson Hospital

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Shoulder arthroplasty surgery has progressively expanded and improved over the past 50 years, but long-term results are still limited by glenoid fixation failure and implant wear. Inset glenoid fixation technology offers a paradigm shift away from classic surface onlay implants to a new clinically proven, scientifically tested form of surgical fixation with excellent long-term results.

### INTRODUCTION:

Shoulder replacement surgery implants and techniques have advanced substantially over the past 50 years. Advanced imaging, better understanding of shoulder pathology, modular implants, more anatomic reconstruction of proximal humeral anatomy- all of these factors have advanced the field of shoulder surgery and have produced better patient outcomes. However, long-term clinical results with classic techniques are still limited by common complications including glenoid implant loosening, wear, and instability (Bohsali, Wirth, and Rockwood 2006; Iannotti and Norris 2003; Matsen et al. 2016). Humeral implant complications are rare, but glenoid implant complications are still relatively common (Denard et al. 2013; Matsen et al. 2008; Walch et al. 2012).

### CLASSIC SURGICAL TECHNIQUE:

The standard technique in shoulder arthroplasty surgery is an extensive deltopectoral interval dissection, anterior joint exposure through a subscapularis tendon incision, extensive anterior and inferior capsular excision with occasional posterior capsule incision, and biceps tenodesis. Bone preparation on the humeral side involves osteophyte excision followed by a humeral head osteotomy. A rigid humeral stem with fins is placed straight down the intramedullary canal with either press fit or cement fixation

technique, and then a metal humeral head is applied to the top of the stem. There have been multiple recent humeral side innovations from the previous standard of care including lesser tuberosity osteotomy, eccentric humeral heads, non-canal filling mini-stems, ovoid humeral heads, and stemless implants.

Glenoid implant preparation and fixation, on the other hand, has not changed much over the past 50 years. After extensive capsular excision has been performed, the entire labrum is excised. A central drill or pin guide is placed in the middle of the glenoid surface. Then, the entire glenoid is sequentially reamed with a large circular reamer, which usually extends past the anterior and posterior articular surface, in order to uniformly flatten the glenoid bone surface to match the backside surface of the new glenoid implant. Retractors must be pulled or twisted away from the glenoid during reaming since the reamer typically extends past the anterior and posterior articular surface. If there are any glenoid bone defects or irregularities from asymmetric bone loss, then the solution has been to either ream down the "high side" or fill the deficient side with either bone, cement, or polyethylene. The goal is to evenly place the new glenoid implant perfectly on top of the reamed glenoid articular surface while avoiding any wobble, shift, or twist of the implant on top of the bone which would create a defect that may predispose the implant to rocking horse loosening. Implant fixation involves the creation of a backside lever/counter-lever system to hold the implant on top of the glenoid bone. A keel may be attached to the backside

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<sup>a</sup> Dr. Stephen Gunther is the founder of Shoulder Innovations, LLC. He received his medical degree from Dartmouth Medical School and pursued residency training at the George Washington University Hospital. He completed a fellowship in Shoulder surgery at the Prince of Wales Hospital in Sydney, Australia, and he was a faculty member at UCSF-Stanford as Chief of the UCSF Shoulder Service. He lives in Charlottesville, Virginia and is affiliated with the Sentara Health System.

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of the implant or multiple pegs may be applied to the implant backside. The final glenoid implant is then pushed on to the glenoid bone surface while the backside fixation keel or pegs slide into the keel slot or holes in the glenoid surface with either press fit or cement technique. The goal is to cover most of the glenoid articular surface with the new implant while avoiding any surface defects behind the implant which would diminish the backside fixation. Also, any implant overhang over the bone edge must be avoided since it would create asymmetric torque stress in the polyethylene implant during humeral head translational motion.

### IMPETUS FOR INNOVATION:

After struggling through a complicated total shoulder revision case in the late 1990s during my teaching tenure at UCSF/Stanford Healthcare as a young faculty member, I decided that there was a need for innovation in glenoid fixation technology. Instead of relying on bone graft fixation and healing for large glenoid defects, there was a need for a better solution. In this particular case, a successful total shoulder replacement was performed 22 years previously by a renowned shoulder surgeon using posterior humeral head autograft to fill the glenoid defect. The bone was secured with 2 fixation screws. A Neer polyethylene glenoid implant with a backside keel was cemented on top of the native bone/bone graft hybrid surface through a cemented keel slot. The surgery was successful, and the patient regained good pain-free motion and function. Unfortunately, the patient came to see me at UCSF years later with severe pain, broken screws, resorbed bone graft, and a cavitory defect in the glenoid vault. The humeral implant was loose from osteolysis. After extensive patient counseling, I performed a 6-hour revision surgery. The first 4 hours involved exploration and retrieval of a broken screw fragment which was finally located inside the axillary sheath. I opened the axillary sheath, carefully removed the broken screw while protecting the axillary artery and vein, and then repaired the fibrous axillary sheath tissue. I also removed broken screw fragments from the deficient glenoid and removed the total shoulder implants and bone cement. At this point, there were huge, cavitory defects in both the glenoid vault and the proximal humerus. I treated the glenoid defect with impaction bone grafting. On the humeral side, I utilized the UCSF total hip impaction grafting instruments to cement a new humeral stem inside impacted allograft bone chips using the Ling technique (Ling 1997). The patient recovered well, and he regained the ability to elevate his arm slightly above shoulder level and rotate his arm adequately for daily functions. However, the 4-hour dissection of the axillary sheath to remove the broken screw, which was pushing on the axillary artery, left a permanent mark in my orthopedic memory bank.

### INNOVATION:

My initial response to this challenging problem of advanced shoulder arthritis with severely deficient glenoid bone was to develop a full examination of all variables. It struck me,

when I moved to northern California, on the border of wine country and lumber country, that I was evaluating a plethora of male, manual laborers such as truckers, millwrights, and loggers with deficient glenoid arthritis and severe bone loss. The bone loss was mostly posterior and medial, so I theorized that working overhead with resistance drives the humeral head posteriorly and medially creating asymmetric wear and bone loss in these patients. Unfortunately, asymmetric and volumetric bone loss both create many technical problems for glenoid replacement in shoulder arthroplasty surgery. First, the glenoid vault is often insufficient to support a large keel or multiple pegs. Second, the angle of articular surface deformity points the keel and pegs out the anterior cortical wall directly towards the axillary artery, vein, and brachial plexus. Third, there is insufficient bone remaining in the glenoid vault to allow the classic technique of "reaming down the high side" anterior bone to realign the articular surface back to neutral alignment. This would require reaming out the best hard, sclerotic, peripheral bone in order to expose an extremely small cancellous vault incapable of holding even the smallest keel or peg on the backside of a classic onlay glenoid implant on top of the deficient bone surface. I was already disinterested in the idea of bone grafting behind a polyethylene implant. In addition, bone graft healing to the native arthritic bone surface would require burring, drilling, or reaming through the tough, sclerotic articular surface bone in order to create a healthy, bleeding surface for healing of the bone graft to the native bone. However, this strong sclerotic surface bone that I repeatedly encountered in these challenging cases was the only remaining asset for long-term glenoid implant fixation. Years later, the depth of this strong, sclerotic surface bone would be quantified and measured for the first time and proven to be much thicker than the subchondral bone of non-arthritic glenoids (Burr and Galant 2012; Simon et al. 2015).

My innovation arose from the idea of utilizing the strongest remaining surface bone as an asset instead of a weakness. Why not use that extremely strong surface bone to support implant fixation instead of removing it? Could we eliminate the need for bone grafting? Is there a better method to restore anatomic version than removing more bone? My final question: could I use the mechanical advantage of this hardened surface bone to minimize the need for lengthy backside fixation inside a severely deficient glenoid vault?

These questions were answered as I drove to work one day. As I drove over a man-hole cover in the road, I realized that the geometry and inset nature of the man-hole cover allowed cars and trucks to drive over the top surface every day without loosening. The peripheral rim around the edge of the man-hole cover provides such strong support that it never loosens. In addition, the circular design offers the strongest geometric support system found in nature. This design feature is also found in the brilliance of ancient Roman architecture. When the Pantheon was built almost 2,000 years ago, a circular hole was designed in the top of the roof, which allows air and light to enter the building. The entire roof structure was constructed with an unrein-



**Figure 1: Photograph of Pantheon oculus by Dana M. Goldsmith**

forced concrete dome with an 8 meter circular hole termed the “oculus” in the middle of this heavy, concrete roof 142 feet above the floor of the temple. This structure remains intact today as an architectural masterpiece because all of the forces around the edge of the circle push on each other in an equal and opposite fashion. These geometric designs inspired a new form of glenoid implant fixation.

As I developed the concept of inset glenoid fixation, I designed a new type of glenoid implant. Following the man-hole cover concept and ancient Roman designs, I created a circular disc to press inside the surface of the strong, sclerotic surface bone. This allows several advantages over classic onlay glenoid fixation. First, the inset circular design and inset technique substantially increase fixation strength. Second, this technique allows the surgeon to asymmetrically inset the implant deeper into the “high side” of the articular surface in order to correct angular version deformities from asymmetric bone loss. Third, the strength of the peripheral, vertical wall of bone supporting the entire rim of the implant like an oculus eliminates the need for extensive backside fixation deep inside the glenoid vault. Thus, multiple long pegs were eliminated from the design. In fact, I created the first implant with only one single, central 8mm peg. I designed the peg with a mushroom shape in order to resist any pull-out forces. This was my initial design for severely deficient bone.

While I was still working in rural northern California, I was forced to innovate in order to treat these manual laborers with shoulder arthritis and severely deficient bone. The clinical solutions were extremely limited at that time. My preoperative discussion with patients included shoulder replacement surgery with current implants with backside keel and peg designs as well as bone grafting procedures. I also

discussed custom implants as an option for the worst cases with the worst prognosis. In these specific cases involving patients with severely deficient bone such that a standard implant was contraindicated because of insufficient glenoid vault bone depth, I discussed the option of creating a custom glenoid implant designed specifically for their shoulder. After a lengthy informed consent process was performed, I designed a custom implant to fit inside their specific deficient glenoid vault. The implants were made by a prominent orthopedic company and sent back to Howard Memorial Hospital for the surgical procedure. Prospective data was collected both before and after surgery.

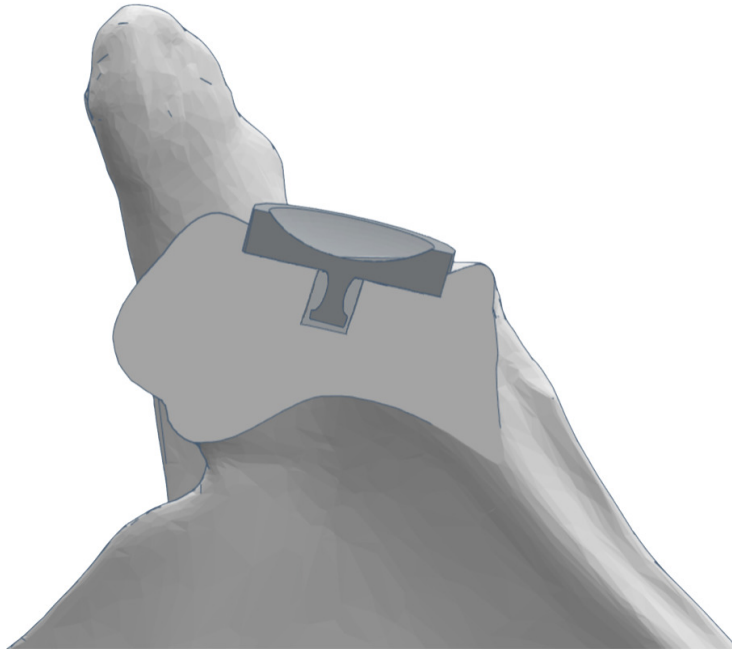
## SURGICAL TECHNIQUE:

My surgical technique for this procedure is an adaptation of classic Neer shoulder arthroplasty technique with the following modifications:

1. Anterior/inferior capsular incision instead of excision. I release the anterior capsule down to the anterior band of the inferior glenohumeral ligament complex. There is no incision of the posterior capsule. I avoid full excision of the anterior-inferior capsular ligaments in order to maintain joint stability. Instead, I excise scar and then perform an anterior capsule incision and full mobilization of the anterior/inferior glenohumeral ligament complex.
2. I leave any healthy peripheral labrum intact. Torn, degenerated labrum may be excised, but any healthy labrum is left intact in order to maintain physiologic conformity and containment of the shoulder joint.
3. A special guide is utilized followed by a circular reamer in order to create a circular inset pocket 2-3 mm into the glenoid articular surface bone. This allows the final implant to snap into the bone pocket like a puzzle piece.
4. The original cases were all custom implants created specifically for each individual patient using 3-D stereolithographic models from 3-D CT scan images.
5. Version abnormalities were corrected by asymmetrically inseting the implant deeper into the “high side” of the bone. Augmented polyethylene implants were also created for some of the worst deformity cases.

## RESULTS:

After I conceptualized the inset technique, developed the inset glenoid implants, and solidified my surgical method, I performed approximately 40 custom glenoid implants for individual patients with severe shoulder arthritis and severely deficient bone. The indications for surgery for each individual patient was advanced shoulder arthritis with severe destruction of glenoid vault architecture. Standard glenoid implants were contraindicated because there was less than 15mm of glenoid vault depth, which was the shortest backside fixation available on the market. Therefore, there was insufficient space in the glenoid vault to hold a standard keel or multiple pegs without broaching



**Figure 2: Image of a single peg inset glenoid fixation and circular containment retaining wall of peripheral bone.**



**Figure 3: Left - 3D SLA model of glenoid fossa of scapula. Middle - reamed glenoid fossa for inset fixation. Right - Surgical image of inset glenoid implant.**

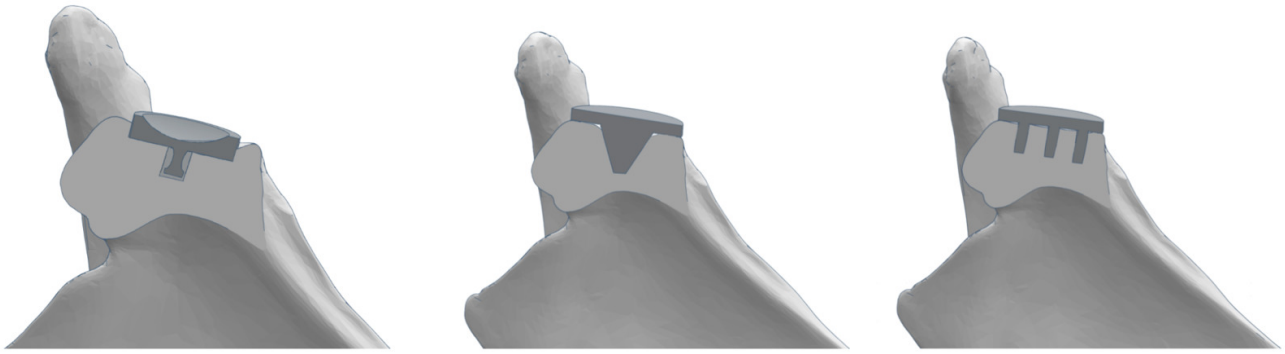
the glenoid vault and risking injury to neurovascular structures. Despite the complicated nature of these surgical procedures, there were no surgical complications in any of these cases. There have been no known loose glenoid implants and no revision surgeries. The first clinical paper on this patient population was published in 2012 (Gunther and Lynch 2012).

#### **JOURNAL OF SHOULDER AND ELBOW SURGERY 2012:**

This short-term clinical study is a retrospective review of seven consecutive patients with advanced arthritis and glenoid bone loss. Since standard implants were contraindicated because of the severe glenoid vault destruction, these patients were all treated with custom inset glenoid im-

plants. At the minimum 3 year clinical follow up, analysis was performed using the prospectively collected clinical data, XRs, and outcome study data. At the mean 4.3 year follow up, ASES scores improved an average of 68 points (pre-op 26 to final post-op 94). Range of motion improved with statistical significance in all directions. VAS pain scores improved from a mean of 6.9 to 0.1. There were no loose or “at risk” glenoids according to independent radiographic analysis. There were no surgical complications and no revision surgeries (Gunther and Lynch 2012).

The first scientific evaluation of inset glenoid fixation was also published in 2012. There were two separate methods of evaluation including mechanical testing with ASTM standard specifications and finite element analysis. Both of these analyses were performed at independent testing centers and are described below (Gunther et al. 2012)

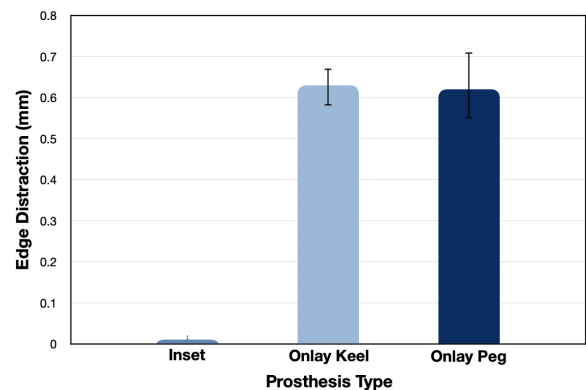


**Figure 4: Reproduced images of the original 1 peg inset glenoid implant that was tested against the onlay keel and onlay peg implants (Gunther et al. 2012) (from left to right). Images demonstrate coronal cross-sectional views.**

#### JOURNAL OF SHOULDER AND ELBOW SURGERY 2012:

This article evaluated the scientific basis of inset glenoid fixation. Since the prominent mechanism of glenoid implant loosening is asymmetric stress caused by humeral head translation causing a “rocking horse phenomenon”, these authors evaluated ASTM mechanical testing of inset glenoid implants and a comparison group of standard DePuy/J&J glenoid onlay implants. An independent lab was contracted to perform cyclic loading conditions to simulate in vivo physiologic loads on a glenoid implant. The Anglin et. al. protocol (Anglin, Wyss, and Pichora 2000), which provides standardized simulation testing of rocking horse stresses on glenoid implants, was utilized with 100,000 cycles of eccentric implant edge loading. Edge displacements were measured on the superior rim while 750N humeral head loads were applied to the inferior rim. The results showed statistically significant reductions in implant edge distraction in the inset glenoid implants as compared to a standard onlay keel implant and standard onlay anchor peg implant designs ( $P < .0001$  with 95% confidence). Finite element analysis (FEA) was performed at an independent lab that performs both independent FEA testing for private companies as well as extensive blast research for the US government. Comparative analysis of the inset glenoid implants versus the onlay implants showed 3 major advantages of inset fixation. First, there was an 87% reduction in edge displacement in the inset implants as compared to the onlay implants. Second, the inset technique provided significant stress reduction at the polyethylene implant-cement interface. Third, the inset technique created a more uniform von Mises stress pattern at the implant-cement interface in contrast to the onlay implant rocking horse stress distribution. In other words, the von Mises stress pattern demonstrated that the peripheral bone surrounding the edge of the inset glenoid implants provided a protective, stress shielding effect on the edge of the inset polyethylene implant and cement mantle (Gunther et al. 2012).

In 2016 & 2017, further clinical and scientific validation studies were published. The senior authors on both publi-



**Figure 5: Graph indicating the implant edge distraction of the various prosthesis types during mechanical ASTM testing (modified from the cumulative testing data in the 2012 JSES publication.) (Gunther et al. 2012)**

cations were previous presidents of the American Shoulder and Elbow Society (Davis et al. 2016; Gagliano et al. 2017).

#### JOURNAL OF SHOULDER AND ELBOW SURGERY 2016:

This is the second short-term clinical study to evaluate the results of inseting glenoid implants in severely deficient glenoid bone. In this series of seven patients (9 shoulder surgeries: 6 primary and 3 for revision surgery) with minimum 2 year follow-up (mean 34 months), there were statistically significant improvements in motion, function, and pain relief (8 points to 1 point). SANE scores improved from 31.7% to 89.4%. Mean patient satisfaction scores were 8.6 points on a 10-point scale. There were no surgical complications. The authors concluded that “our study results can be interpreted as comparable to those of Gunther and Lynch. Neither of the 2 studies had significant component loosening with early follow-up” (Davis et al. 2016).

## JOURNAL OF SHOULDER AND ELBOW SURGERY 2017:

This cadaveric study analyzed the strength of fixation and implant contact forces in inlay glenoid implants versus DJO onlay glenoid implants in a matched pair of 8 cadaver shoulders. Glenohumeral joint loading, contact forces, and fatigue stresses were all evaluated. Testing ended with evidence of gross glenoid loosening or at the end of 4,000 cycles. Surface contact forces were greater in the onlay implants than the inlay implants ( $p < .0001$ ). During fatigue testing, all onlay implants exhibited gross loosening at a mean of 1126 cycles (range 749-1838 cycles). None of the inlay implants loosened ( $p < .0001$ ). The authors conclude that "an inlay glenoid design resists loosening better than an onlay design, with statistical significance ( $p < .0001$ ). In addition, our biomechanical analysis revealed differences in the area, pressure, and force that occur at the implant articulations, supporting our observations (Gagliano et al. 2017).

In 2019, long-term results were published in the Journal of Shoulder and Elbow Surgery demonstrating excellent outcomes at a mean 8.7 years in these "worst case" examples of severe shoulder arthritis with glenoid vault destruction (Gunther and Tran 2019).

## JOURNAL OF SHOULDER AND ELBOW SURGERY 2019:

This article evaluates long-term results of inset glenoid fixation for severely deficient bone. A consecutive series of 24 patients were evaluated with final outcome scores, VAS pain scores, radiographs, and clinical measures. Most of the patients (21/ 24) were still alive and available for final follow up. Full clinical follow-ups and XRs were performed on 14 patients. Telephone interviews were performed for 7 patients who could not travel to the clinic. This enabled documentation of VAS pain scores, ASES outcome scores, and any history of any complications or revision surgery. Minimum follow-up was 6 years. At the mean follow-up of 8.7 years, there was statistically significant improvement ( $p < .0001$ ) in visual analog pain scores, ASES outcome scores, and range of motion. Final mean pain score was 0.1 (scale 0-10), and final mean ASES score was 95 (scale 0-100). There were no loose glenoid implants. There were no surgical complications. There was no revision surgery. This publication documented the long-term success of inset glenoid fixation in the most severe glenoid bone deficiency cases in which standard glenoid implants were contraindicated (Gunther and Tran 2019).

## COMMERCIALIZATION:

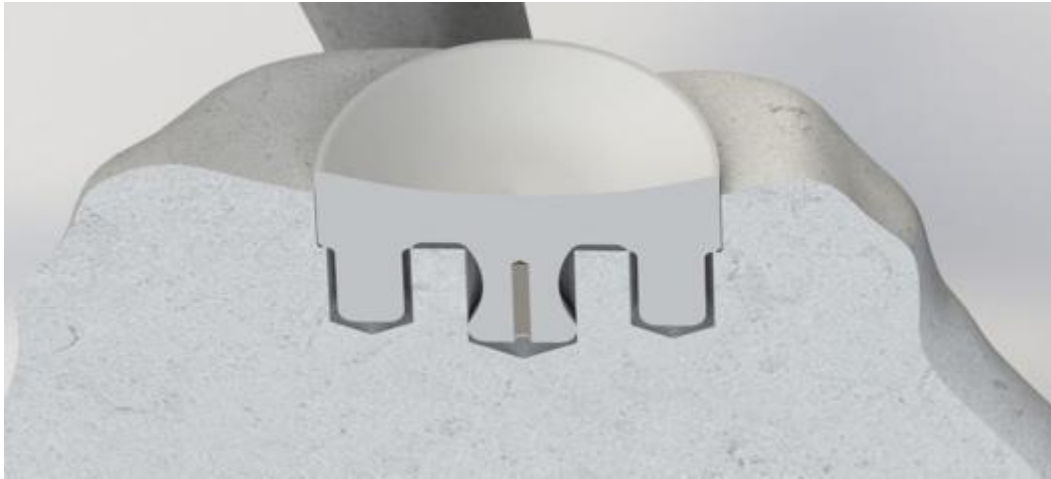
Shoulder Innovations partnered with Genesis Innovation Group in 2015 in order to bring this glenoid technology to the market. The SI inset glenoid, with 2 additional pegs, was produced in 2016 with regulatory clearance for a wide variety of shoulder arthritis cases. Shoulder Innovations,

Inc. is also currently developing a comprehensive portfolio of other novel, innovative shoulder replacement products. Over the past few years, more than 1,000 inset glenoid implants have been performed by more than 30 surgeons with excellent early results. The most significant early potential disadvantage expressed by new surgeons was the circular shape of the glenoid which may not cover the entire surface of an oval glenoid. However, many arthritic glenoids are more circular than oval. Also, the new technique provides peripheral cartilaginous soft tissue coverage from retained labrum. Lastly, the combination of retained labrum and capsule maintains anatomic, natural joint coverage and containment structures which can improve stability after shoulder replacement surgery. Multiple surgeons are currently collecting prospective data in order to demonstrate the success of this technology for a wide variety of different indications (including both standard primary cases and deficient bone cases).

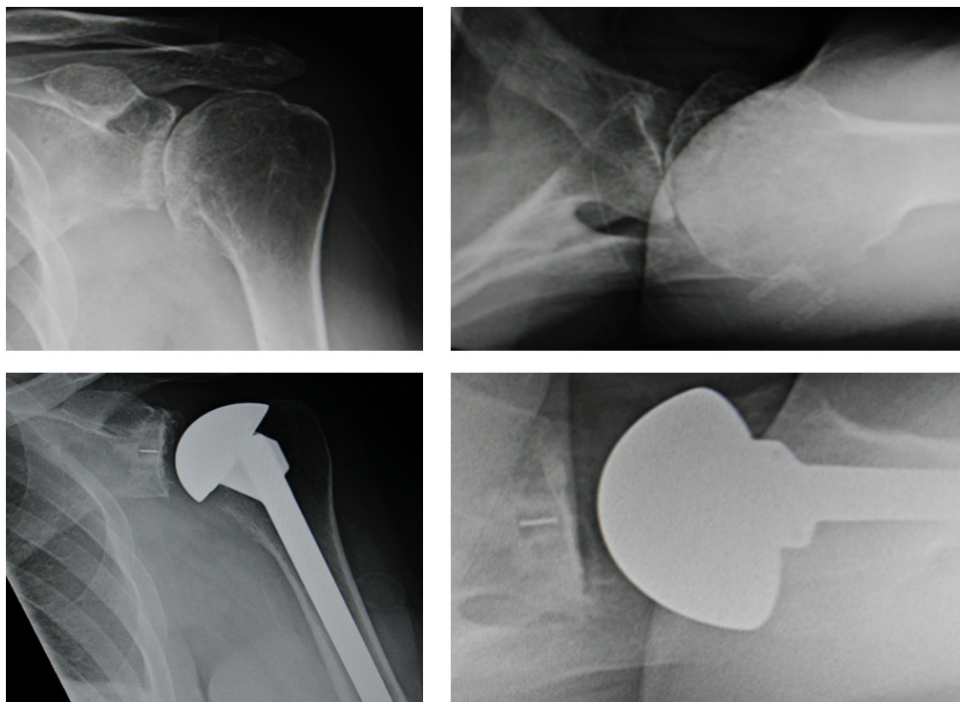
## DISCUSSION:

Shoulder arthroplasty surgery has progressed over the past 50 years with implant design innovations, advanced imaging techniques, better understanding of disease pathology, and new surgical techniques. However, glenoid implant fixation theory and technique have remained virtually unchanged. Most current glenoid implants still rely 100% on backside fixation with a keel or pegs in order to resist the substantial rocking horse translational forces applied on the glenoid by humeral head rotational, gliding, and translational forces. Unfortunately for surgeons and patients, glenoid loosening is still a common complication of primary shoulder arthroplasty surgery. Glenoid side complications, such as loosening and implant wear, continue to limit long term functional results in shoulder arthroplasty surgery (Bohsali, Wirth, and Rockwood 2006; Denard et al. 2013; Iannotti and Norris 2003; Matsen et al. 2008, 2016; Simon et al. 2015). These complications may also lead to painful, expensive revision surgery which is often plagued by significant bone loss.

Inset glenoid technology, on the other hand, offers a paradigm shift away from traditional onlay, backside glenoid fixation. Instead of laying the glenoid implant on top of the inherently unstable bone surface, inset fixation involves penetration of the hard, sclerotic arthritic surface bone in order to create a more secure support system for the implant. This allows a tight circumferential puzzle piece type of peripheral fit around the rim of the implant. This biomechanically proven solution provides a novel form of fixation which both increases fixation strength and avoids the need to ream away "high side" supportive bone. Instead of relying solely on backside pegs or keel, this new inset technology provides a peripheral rim of "containment" with a vertical retaining wall of bone to lock the implant in place. Once locked in place, the extremely strong, sclerotic, arthritic surface bone acts as an augmented form of peripheral bone fixation around the entire rim of the implant. Just as a manhole cover on the road is supported by a rim of metal, this new glenoid concept provides a simi-



**Figure 6: Image of the Shoulder Innovations inset glenoid implant. (Image courtesy of Shoulder Innovations, Inc.)**



**Figure 7: Preoperative (top images) and postoperative (bottom images) X-ray images of a patient with a B-2 glenoid configuration with posterior bone loss and subluxation. Joint subluxation and angulation were both corrected with the InSet Glenoid implant.**

lar peripheral containment system that creates enough mechanical strength to support much higher shear forces on the implant. Thus, this new type of inset glenoid implant fixation with vastly improved mechanical strength offers a paradigm shift away from the old technique of glenoid implant fixation on top of the bone surface.

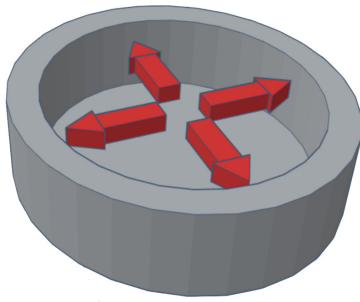
With traditional onlay glenoid fixation techniques, there is continued risk of implant loosening and polyethylene wear relating to multiple factors.

1. Incomplete backside contact between the implant and the bone. There is new data demonstrating po-

tential implant instability even with as little as a 5-10% backside defect (Verhaegen et al. 2020).

2. Implant overhang causing increased rocking horse leverage on the implant.
3. Increased edge loading of the glenoid implant with asymmetric humeral head motion and translation.
4. Incomplete seating of the implant, causing a backside defect, which causes increased stress on the cement mantle and increased risk of implant loosening.

The advantages of this novel inset glenoid fixation are numerous.



**Figure 8: Recreated image of peripheral rim of bony containment of the implant**

1. Increased mechanical fixation strength (ASTM testing).
2. No risk of implant overhang over the glenoid rim (inset technique).
3. 100% backside contact at the implant/bone surface in every case (inset technique).
4. Providing new, peripheral rim of bony “containment” of the implant that...
  - Protects the edges of the polyethylene implant from rim loading and therefore minimizes implant shear forces through stress shielding (FEA analysis).
  - Protects the implant/cement interface, minimizing the risk of implant loosening from rocking horse stresses (FEA analysis).
5. Allowing anatomic containment from retained labrum and capsule to provide natural, anatomic containment and coverage of the humeral head (surgical technique).

## CONCLUSION:

Inset glenoid fixation technology offers a paradigm shift away from traditional glenoid fixation techniques in shoulder arthroplasty surgery. Both the device and the related surgical technique offer a novel solution to the biggest problems in shoulder arthroplasty surgery including glenoid implant loosening, implant wear, and shoulder instability. The scientific basis for this technique has been proven with independent finite element analysis studies, independent mechanical ASTM studies, short-term clinical



**Video #1: Onlay Glenoid implant fixation**

URL: <https://www.youtube.com/embed/rj56wbMMTB8>



**Video #2: InSet Glenoid Fixation**

URL: <https://www.youtube.com/embed/dMTL-VrUNV4>

studies, and a long-term clinical study of patients with severely deficient bone. This technique allows successful treatment of advanced shoulder arthritis in patients with severe bone loss, and it precludes the need for bone grafts or salvage procedures such as reverse ball & socket arthroplasty surgery. Based upon the proven track record of excellent outcomes in these most challenging cases with severe bone loss, many surgeons are now shifting their preference to inset glenoid fixation for all of their standard primary cases.

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