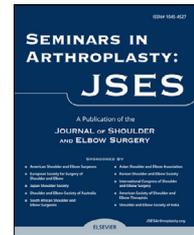


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Onlay versus inlay reverse total shoulder arthroplasty: a retrospective comparison of radiographic and clinical outcomes

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ABSTRACT

Introduction: Recent innovations in reverse shoulder arthroplasty (RSA) have presented 2 distinct humeral stem designs: an onlay system that rests above the anatomic neck and an inlay component that rests within the metaphysis. The purpose of this study is to compare clinical and radiographic outcomes between inlay and onlay-designed humeral stems in lateral center of rotation RSA implant systems.

Methods: A retrospective cohort study was performed on primary RSA patients treated by 2 surgeons at 2 separate hospitals with a minimum 2-year follow-up. Patients were categorized based on treatment with an onlay or inlay humeral design and matched 1:1 by indication and age. Patient-reported outcome measures (PROMs), including the Simple Shoulder Test, American Shoulder and Elbow Surgeons, and Visual Analog Score for pain, as well as active motion (forward elevation, internal rotation) were recorded at pre- and postoperative intervals. An Inlay-Onlay index assessed the degree of inset or offset of each particular implant referencing the anatomic neck. Radiographic analysis focused on scapular notching, bone resorption around the humeral stem, and acromion stress fractures.

Results: A total of 92 patients participated in the 1:1 matched analysis (46 each group). Cohorts were similar in age, gender, indication, follow-up length, and preoperative PROMs, with the exception of Simple Shoulder Test. At the most recent follow-up, there were no differences in all PROMs between groups. There were no differences in active internal rotation, but patients with an onlay-configuration demonstrated greater external rotation ($P < .001$) and forward flexion ($P < .001$). Greater tuberosity and calcar resorption occurred in 34 (74%) and 18 (39%) patients with an onlay-designed prosthesis, compared to 13 (28%) and 1 (2%) in the inlay group, respectively ($P < .0001$). Both groups had low rates of scapular notching ($P = 1.0$), while acromial fractures occurred in 6 patients with an onlay stem and in 4 patients with the inlay stem ($P = .73$).

Conclusion: There were no differences in clinical outcomes or incidence of acromial fractures following RSA with an onlay- or inlay-style humeral stem prosthesis. Bone resorption of the

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proximal humerus occurred more frequently in patients with an onlay prosthesis, suggesting that an inlay prosthesis may afford better prevention of humeral stress shielding.

Level Of Evidence: Level III; Retrospective Comparative Study

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Introduction

The reverse shoulder arthroplasty (RSA) has revolutionized the treatment of rotator cuff tears, providing significant functional and pain improvement for a variety of shoulder conditions [43]. As the indications and utilization of this procedure expand, different designs of reverse shoulder replacements have evolved. RSA implant systems with lateralization of the center of rotation (COR) and more varus neck-shaft angles have become popular as they have been shown to increase active motion while reducing the occurrence of scapular notching [10,20,24,29-31,47,56]. These lateralized systems use 2 different styles of humeral components: an onlay or inlay design. Theoretical implications of an inlay system are restoration of a more anatomic positioning, with the pivot point for motion approximating the COR of the humeral head, thereby, optimizing the impingement free arc of motion within the confines of the coracoacromial arch. In contrast, an onlay system may be more bone-preserving and facilitates modularity and convertibility; however, onlay systems result in additional humeral lateralization and lengthening [3]. Historically, Grammont-style RSA systems utilized inlay humeral designs, [18] but lateral COR reverse shoulder systems with inlay-style humeral components have yet to be compared to those with onlay-style humeral components.

Following RSA, there are known bony radiographic changes that occur on both the humerus and scapula. Scapular notching has long been associated with RSA, however, its incidence has been greatly reduced with the use of more lateralized COR glenospheres and more varus neck-shaft-angle humeral components [11,27,29,55,56]. Proximal humerus bone resorption has been associated with the use of press-fit humeral components, which may have implications in revision arthroplasty settings. [4,12,16,22,36,54]. In addition, acromion fractures remain one of the most common early complications after RSA and have been shown to negatively impact recovery and long-term functional outcomes [2,6,13,19,21,23,26,35,41,46,48,50]. While lateralized onlay humeral designs have been associated with increased incidence of acromial stress fractures and bone adaptations, [1,39] there has been no study that compares clinical and radiographic outcomes to inlay-designed counterparts.

The purpose of the study is to compare the clinical and radiographic results of RSA using inlay- or onlay-style RSA designs with lateral COR glenospheres. A secondary purpose is to utilize a comparative index for categorization of inlay and onlay humeral prostheses referenced to the anatomic neck. We hypothesized that there would be no differences in clinical outcomes based on the style of humeral prosthesis, but onlay-designed reverse shoulder prostheses would be associated with an increased incidence of humeral-sided bone changes.

Methods

A multicenter retrospective, comparative study was performed using a prospectively collected database, identifying all patients treated with a primary RSA between October 2015 and February 2018. Inclusion criteria consisted of patients treated with a press-fit RSA system for glenohumeral osteoarthritis with or without a rotator cuff tear with a minimum 2-year follow-up. Patients without preoperative data, those treated with revision RSA, and those treated with a cemented humeral stem were excluded. Two cohorts were evenly created based on treatment with either an onlay- or inlay-style humeral prosthesis and matched in the largest possible ratio (1:1) based on indication and age (± 3 years).

All procedures were performed by 2 shoulder fellowship-trained surgeons who perform high-volume shoulder arthroplasty at their respective institutions. Both surgeons completed the same fellowship and performed procedures with a similar technique and a standard deltopectoral approach. The surgeons differ in their use of either an onlay- (Reunion, Stryker, Kalamazoo, MI, USA) or inlay-designed (AltiVate Reverse, DJO Global, Austin, TX, USA) humeral prosthesis. Both implant systems use a more lateralized COR glenosphere and a 135-degree neck-shaft angle humeral stem. The glenoid baseplate, peripheral screws, and glenosphere were placed using the manufacturer's recommended surgical technique, and the humeral component was implanted through a press-fit technique [14]. All stems were proximally porous coated. The humerus was cut in 30° of retroversion in each instance and, in all situations, attempts were made to place the glenosphere in 10° of inferior tilt and neutral version. Soft tissue balancing and stability was achieved through the use of polyethylene humeral shells with thicknesses of neutral +0 millimeter (mm), +4 mm, or +8 mm, including both standard and semi-constrained options. The only notable difference in treatment is the surgeon preference for repair of the subscapularis tendon, which was routinely done in patients with an inlay-designed prosthesis but not for patients with an onlay-design prosthesis. All patients were treated with similar post-operative rehabilitation protocols, including a shoulder immobilizer and pendulum exercises for the first 4- 6 weeks, followed by progressive passive and active range of motion up to 3 months postoperatively.

Clinical Analysis

Baseline assessment on all patients was obtained preoperatively and postoperatively including the patient-reported outcome measures (PROMs) of American Shoulder and Elbow Surgeons (ASES) score, Simple Shoulder Test score, and Visual Analog Scale pain score. Active range of motion (ROM)

was reported preoperatively and at most recent follow-up through goniometer-based measurements of external rotation and forward flexion. Internal rotation was assessed by the patient through selection of a schematic picture representation of the highest midline segment of the back that can be reached.

Radiographic Analysis

Most recent follow-up radiographs were analyzed by each respective treating surgeon and compared for stress shielding, scapular notching, and acromial pathology. The degree of notching was classified with a grade of 0 to 4 according to Sirveaux et al [45]. Calcar and greater tuberosity resorption were graded according to the Inoue classification [25]. Acromion stress fractures were identified and characterized according to Levy et al [33]. An Inlay-Onlay Index was created to measure inset(-)/offset(+) of the glenohumeral articulation in reference to the anatomic neck, recognizing that not all inlay humeral stem cases were able to inset the articulation within the metaphysis. This measurement was taken for both implant systems using anterior-posterior radiographs and defined as the distance from the anatomic neck osteotomy to the most central tip of the glenosphere (Fig. 1).

Statistical Analysis

Based on existing literature on the biomechanics of inlay and onlay humeral stems, [3] a priori power analysis was performed with forward flexion as the variable of interest. With an effect size of 0.625 and alpha value of 0.05, a minimum of 42 patients per study group (84 total) was required to achieve 80% power. Data between cohorts were compared by an independent-samples *t* test for continuous variables and the Fisher exact test for categorical variables. These significant tests were 2-tailed, and significance was set at $P < .05$.

Results

A total of 92 patients were included in the study, with a 1:1 matched comparison of patients in each cohort differentiated by the inlay or onlay designs. Both groups were similar in

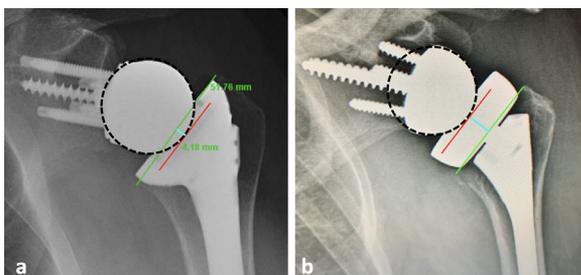


Figure 1 – Inlay-onlay index evaluation. AP view of a left shoulder after implant of a press-fit (a) inlay stem and (b) onlay stem. The inset/offset (blue) is measured from the center of the anatomic neck osteotomy (green) perpendicularly to the tip of the glenosphere (red).

Table 1 – Demographic data for reverse shoulder arthroplasty patients with either an onlay or inlay humeral prosthesis.

	Inlay (N = 46) mean ± SD or n (%)	Onlay (N=46) mean ± SD or n (%)	P value
Mean age, yr	73.2 ± 5.9	74.8 ± 3.6	.12
Mean follow-up (range), mo	31 (24-49)	29 (24-50)	.05
Gender distribution			
Male	18 (39)	22 (48)	
Female	28 (61)	24 (52)	
Indications			1.00
Rotator cuff tear arthropathy	43 (93)	43 (93)	
Osteoarthritis without cuff tear	3 (6.5)	3 (6.5)	
Glenohumeral Arthritis Classification			.26
Hamada 1	3 (6.5)	8 (17)	
Hamada 2	13 (28)	8 (17)	
Hamada 3	6 (13)	5 (11)	
Hamada 4A	5 (11)	7 (15)	
Hamada 4B	7 (15)	12 (26)	
Hamada 5	5 (11)	-	
Walch A1	1 (2.5)	1 (2.5)	
Walch B2	2 (4)	1 (2.5)	
Walch B3	-	4 (9)	
Walch D	4 (9)	-	
Pre-operative PROMs			
SST score	3.0 ± 2.3	4.1 ± 2.7	.04
ASES score	33.8 ± 13.8	37.1 ± 16.9	.30
VAS pain score	6.1 ± 2.5	6.9 ± 1.7	.06
(-)Inlay/(+)Onlay Index	0.4 ± 2.3	9.3 ± 2.7	<.001

age (inlay 73.2 years vs. onlay 74.8 years; $P = .12$) and in gender distribution ($P = .53$; Table 1). The mean follow-up was approximately 29 and 31 months for the inlay and onlay groups, respectively ($P = .50$). Indications for RSA included rotator cuff tear arthropathy resulting from a massive irreparable tear in 43 patients (93%) and osteoarthritis without a cuff tear in 3 patients (7%) for both cohorts. RSA was performed on selected patients with osteoarthritis and no cuff tear due to significant glenoid bone loss with type-B2 or type-B3 deformity [49]. The Inlay-Onlay Index confirmed the alignment differences between the humeral implant designs. Patients with an inlay-designed stem had a mean Inlay-Onlay Index of 0.43 mm (± 2.32 mm), while patients with an onlay-designed component had a mean of 9.26 mm (± 2.68 mm; $P < .0001$). There were no differences in preoperative PROMs (ASES and Visual Analog Scale pain scores), with the exception of patients in the onlay group having higher baseline Simple Shoulder Test function scores (4.09 vs. 2.96 inlay; $P = .04$).

At the most recent follow-up, there were no differences in all PROMs and active internal rotation between groups (Table 2). Patients with either humeral stem designs showed similar functional and pain improvements from preoperative to most recent postoperative interval. However, patients with an onlay-configuration demonstrated greater active external rotation ($P < .001$) and forward flexion ($P < .001$). Scapular notching occurred in 4 (8.7%) patients in each group ($P = 1.0$). Acromial fractures

Table 2 – Comparison of postoperative patient-reported outcome measures, mean improvements, range of motion, and radiographic findings.

	Inlay (N = 46) mean ± SD or n (%)	Onlay (N = 46) mean ± SD or n (%)	P value
Postoperative PROM			
SST score	8.3 ± 2.6	8.7 ± 2.9	.47
ASES score	80.1 ± 17.0	78.0 ± 21.0	.59
VAS pain score	1.0 ± 1.7	1.3 ± 1.7	.51
Mean improvement			
SST score	5.4 ± 3.0	4.7 ± 3.7	.38
ASES score	46.9 ± 20.5	40.8 ± 25.7	.22
VAS pain score	4.6 ± 2.7	5.6 ± 1.9	0.06
Active range of motion			
Forward flexion	129.8 ± 29.6	149.6 ± 20.4	<.001
External rotation	38.0 ± 18.5	49.1 ± 10.5	<.001
Internal rotation*	4.96 ± 2.69	5.74 ± 2.22	.13
Scapular notching			
Grade 1	2	1	
Grade 2	1	1	
Grade 3	0	2	
Grade 4	1	0	
Greater tuberosity resorption			
Grade 1	0	5	
Grade 2	6	2	
Grade 3	2	22	
Grade 4	5	5	
Calcar resorption			
Grade 1	1 (2.2%)	18 (39%)	<.001
Grade 2	0	6	
Grade 3	0	7	
Grade 4	1	0	
Acromial fracture			
	4 (8.7%)	6 (13%)	.73

PROM, patient-reported outcome measures; SST, Simple Shoulder Test; ASES, American Shoulder and Elbow Surgeons; VAS, visual analog scale.

* Internal Rotation conversion scale: Buttock to greater trochanter (2 points); sacrum to L4 (4 points); L3-L1 (6 points); T12-T8 (8 points); T7-T1 (10 points).

occurred postoperatively in 6 patients (13%) in the onlay group and in four patients (8.7%) in the inlay group ($P = .73$). In terms of stress shielding, patients with an onlay-style prosthesis had more instances of greater tuberosity ($P < .0001$) and calcar resorption ($P < .0001$). There were 34 (73.9%) onlay patients with bone resorption at the greater tuberosity, with 27 being Grade 3 or 4 (Fig. 2). In contrast, 13 inlay patients (28%) showed greater tuberosity resorption with only 7 classified as Grade 3 or 4. Calcar resorption occurred in 18 patients in the onlay group, with 6 Grade 1, 5 Grade 2, and 7 Grade 3. Only one patient with an inlay-designed prosthesis had calcar resorption, which was characterized as a Grade 4.

Discussion

This study compared clinical and radiographic outcomes in patients who underwent primary RSA using similar implant systems containing lateralized COR glenospheres and

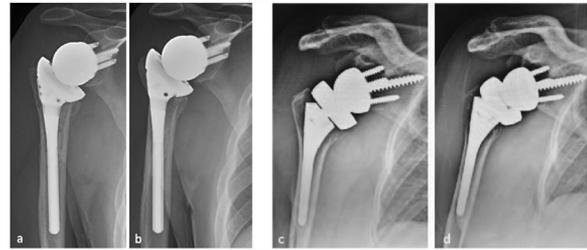


Figure 2 – Preoperative and most-recent postoperative AP radiographs demonstrating (a, b) greater tuberosity resorption in inlay-designed prosthesis and (c, d) both greater tuberosity and calcar resorption in onlay-designed humeral prosthesis.

identical neck-shaft-angle humeral components that differed primarily in the position of the humeral shell (inlay vs. onlay). Results of the study support the hypothesis, as patients in both groups predictably improved clinically with similar improvements in outcome scores. However, those treated with an onlay humeral design were found to have higher ROM in forward flexion and external rotation as well as a significantly higher rate of proximal humeral bone resorption. No differences in postoperative scapular notching or acromion fractures were observed.

The present study reports higher rates of both medial calcar (39.1% vs. 2%) and greater tuberosity (73.9% vs. 28.3%) resorption for onlay-style implants (Table 2). We speculate that the distribution of forces across the proximal humeral metaphysis is more evenly distributed with the rounded inlay prosthesis compared to the onlay prosthesis. Postoperative resorption of the proximal humerus following RSA is thought to be related to stress-shielding. Stress-shielding occurs when a bone adapts to changes in the distribution of stress, according to Wolff's law [39,52]. Stress-shielding of the proximal humerus has been described more commonly with press-fit stems in RSA [4,12,16,22,36,54]. Harmsen et al [22] reported the highest known incidence of stress shielding (97.4%) following RSA using diaphyseal press-fit fixation of a standard length stem. Raiss et al [42] found a 7-fold incidence in bone loss when the diaphyseal filling ratio of a short stem RSA was greater than 0.8. While the radiographic changes have yet to result in any demonstrated clinical impact, [12,22] bone loss along the proximal humerus can make revisions significantly more challenging. Proximal humeral bone loss has been associated with higher rates of instability, modular junction failures, and humeral sided failures [9,32]. Furthermore, reconstructive efforts in the setting of severe proximal humeral bone loss may necessitate the use of bulk allografts [5,8,44] or mega-prosthetic reconstructions with tumor prosthesis which have less predictable results [17,51].

Overall, patients treated with primary RSA in this study improved clinically and functionally irrespective of the humeral inlay or onlay design. This supports a host of literature using similar RSA designs with a lateralized COR and 135° neck-shaft angle humeral component [3,20,30,31,37,56]. One difference to note is that patients with an onlay-designed

prosthesis showed greater active motion, which has also been found in other studies [30,31,38]. Ladermann et al [30] reported that humeral offset and arm lengthening in an onlay-configuration had a strong linear regression with flexion and external rotation. Another explanation for the differences in motion could be related to repair of the subscapularis tendon as most patients in the onlay group were not repaired. As noted in the study by Friedman, [15] when the subscapularis was not repaired patients demonstrated significantly better abduction and passive external rotation. Finally, as would be expected from this type of RSA design, there was a similarly low rate of scapular notching for both cohorts of patients. The incidence of scapular notching has been greatly reduced with the use of lateralized offset COR reverse shoulder systems [11,27,29,55,56]. Nearly 9% of our patients developed scapular notching, similar to the reported values of up to 16% with lateralized systems [27].

The postoperative acromion fracture rate observed in this series is higher than what has been reported in prior studies [2,6,13,19,21,23,26,35,41,46,48,50]. The observed rate of postoperative acromial fractures was 8.6% for patients with an inlay prosthesis and 13% for patients with an onlay prosthesis. While one may speculate a higher rate of acromion fractures with use of an onlay prosthesis based on additional humeral lengthening, it is important to note that this study was not powered to detect a difference in acromion fracture rates given the low incidence following RSA. Ascione et al [1] reported an increased scapular spine fracture rate after RSA when a humeral onlay prosthetic design was utilized, whereas a low rate of scapular fractures was reported using a traditional Grammont-style RSA [40]. Wong et al suggested that lateralized COR RSA designs may result in higher acromion stress based upon finite element analysis,[53] however a more recent larger series of a lateralized COR RSA design [34] demonstrated similar acromion fracture rate (4%) as to what has been reported in several systematic reviews [7,28]. Further investigation using the Inlay-Onlay index with a larger population of patients will help clarify the impact of the onlay design feature on acromion fractures. There may be additional confounding factors which may have influenced the higher rate of acromion fractures in our series, including the dominance of older females with rotator cuff tear arthropathy in this series (Table 1) and the average age of each cohort being greater than 70 years. Osteoporosis is more prevalent in elderly females and has been implicated as a risk factor for developing postoperative acromial fractures after RSA [34].

This study introduces the Inlay-Onlay Index as a method for determining the position of the glenohumeral articulation in RSA designs, referencing the anatomic neck. This index is intended to quantify the degree of true humeral inset that is present, as even inlay RSA designs may be unable to position the glenohumeral articulation beneath the anatomic neck based on surgical technique or the thickness of the polyethylene insert. The index is calculated by measuring the distance from the anatomic neck to the lateral-most central edge of the glenosphere on an anterior-posterior radiograph (Fig. 1). Inlay implants that are implanted proud or utilize thicker polyethylene components, and all onlay implants will have a positive index value. While our data suggest that a more

positive Inlay-Onlay index is associated with increased proximal humeral resorption, this is more likely related to the differences in humeral stem design. The inset RSA design likely loads the proximal humerus more uniformly, whereas the onlay design results in more diaphyseal fixation. Use of the index to compare results of single implant designs is warranted to better understand the impact of surgical technique and thicker polyethylene on outcomes and complications.

The importance of repairing the subscapularis after RSA has been highly debated. In this series, the subscapularis was routinely repaired by the surgeon using the inlay design, and routinely excised by the surgeon using the onlay design. In a large multicenter study of an onlay design RSA (Equinox rTSA, Exactech, Gainesville, FL, USA), Friedman et al [15] demonstrated similar improvements of pain and function and complication rates, but differences in ROM, with better internal rotation in the repaired group and better passive external rotation and active abduction in the nonrepaired group. While repair of the subscapularis may be more difficult in an onlay RSA design given the additional lengthening of the humerus away from the subscapularis insertion, our study demonstrated no difference in outcome scores or acromial fractures. This study was not powered to determine if the differences in ROM were attributable to subscapularis repair or excision, and further research is needed to better clarify the role of subscapularis after RSA.

There are several limitations to our study. First, as mentioned previously, the study is likely underpowered to calculate differences in more rare complications such as postoperative acromion fractures. The study was powered based upon a clinical outcome of ROM, which is well-established in the literature, but there is much less literature available on detecting differences in acromial fracture incidence between inlay- and onlay-design humeral components [3]. Second, the study compared patients operated on by 2 surgeons. While both surgeons are shoulder fellowship-trained with multiple years of experience practicing a high volume of shoulder arthroplasty, subtle differences in surgical technique (subscapularis repair), and implant choice may exist creating variability. Finally, with a short-term follow-up, the long-term impact of proximal humeral bone resorption remains unclear and warrants further investigation similar to bone loss related to scapular notching on the glenoid neck following RSA.

Conclusion

There were no differences in clinical outcomes or incidence of acromial fractures following RSA with a more lateralized COR onlay- or inlay-style humeral prosthesis. Proximal humeral bone resorption occurred more frequently with the use of an onlay-style prosthesis, which suggests that an inlay-style prosthesis may afford better prevention of humeral stress shielding.

Disclaimer

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Location

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