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Clinical, functional and radiographic outcomes of inverted-bearing reverse shoulder arthroplasty at minimum two year follow-up

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A R T I C L E I N F O

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Heterotopic ossification
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Scapular notching
Impingement
Polyethylene
Cuff tear arthropathy

Level of evidence: Level IV; Case Series; Treatment Study

Background: Inverted-Bearing Reverse Shoulder Arthroplasty (IB-RSA) is an alternative reverse bearing construct characterized by an ultrahigh molecular weight polyethylene glenosphere combined with a cobalt-chromium metallic humeral liner. This concept was designed both to minimize bearing wear as well as reduce the potential for scapular notching (SN) seen with more traditional-bearing RSA systems. This study reports on clinical outcomes, functional scores, pain scores, and radiographic incidence of SN in a series of IB-RSA at a minimum of two-year follow-up.

Methods: A retrospective study was conducted on patients who underwent an IB-RSA between 2016 and 2019, with a minimum follow-up period of two years. Patients were evaluated clinically for disabilities of the arm, shoulder and hand (DASH) score, American Shoulder and Elbow Surgeons score (ASES), EQ-5D Health Questionnaire, Global Rating of Change score (GRC), Single Assessment Numeric Evaluation score (SANE) and range of motion (ROM). Presence and grade of radiographic SN was assessed using the classification of Sirveaux at 6, 12, 24 months and at the last x-ray available.

Results: 61 consecutive patients were assessed at a mean postoperative follow-up of 37 months (range, 24-72 months). IB-RSA exhibited high overall outcome scores including DASH (38.3 +/−5), ASES (83 +/−6), GRC (4 +/−0.6), and SANE (83 +/−11). ROM was assessed in 41 patients with 135 ± 21 of elevation, 23 ± 12 of external rotation, and 5 ± 2 for internal rotation. SN was radiographically present in 23 (38%) patients (twenty grade 1, three grade 2) in the final follow-up, with all cases showing evidence of mechanical notching while no grade 3 or 4 cases were observed. The SN did not progress in most of the patients after the first year ($P > .05$). The presence of SN did not influence on clinical outcome scores as DASH, ASES, EQ-5D Health Questionnaire, GRC, SANE ($P > .05$), or active ROM ($P > .05$).

Conclusion: IB-RSA demonstrates high patient-reported and functional outcome scores at a minimum of two years follow-up. We report only low-grade SN with little progression after the first year. There was no correlation between SN and clinical outcomes.

Scapular notching (SN) in reverse shoulder arthroplasty (RSA) is a common problem ranging between 4.6 and 50.8%.[13] SN was initially described to happen in adduction and internal rotation when the medial aspect of the polyethylene contacted the lateral aspect of the inferior glenoid. [13,31,22] This impingement-induced wear is exacerbated by the constant stress on the inferior part of the polyethylene, leading to increased wear and debris that can cause bone loss, baseplate loosening, and RSA failure.[23,14,27]

While some studies have shown no significant impact on clinical outcomes,[1,4] others suggests a potential negative effect of scapular nothing that could lead to glenoid side failure. [30,17,25] Consequently, there has been increasing interest in developing new designs and techniques to reduce SN. Several strategies have been developed to address this including reducing the humeral neck/shaft angle from 155 to 135,[10,11], using a larger glenosphere with an inferior overhang,[34] positioning the glenosphere as low as possible and as inferiorly tilted as possible.[12,15,19] In addition, lateralization of the center of rotation using bone (bony increased offset-reversed shoulder arthroplasty),[4,9] metal augments,[2] or a lateralized glenosphere [12] are common options used to reduce the SN.

The inverted-Bearing Reverse Shoulder Arthroplasty (IB-RSA) was created as an alternative to decrease the SN by reducing debris formation created when using a traditional RSA bearing. This new

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design is characterized by an ultrahigh molecular weight polyethylene glenosphere combined with a cobalt-chromium (CoCr) metallic humeral liner. This study reports on clinical outcomes, functional scores, pain scores, and radiographic incidence and progression of SN in a series of IB-RSA.

Methods

A retrospective study was conducted on patients who underwent an IB-RSA between 2016 and 2019, with a minimum follow-up period of two years. All patients who received an IB-RSA during this period were included, while those with less than two years of follow-up or lacking X-rays at 6-12 and 24 months were excluded.

Prosthesis design

A curved metalback baseplate with a central post and 2 screw fixation is available in 4 sizes (small-R, small, standard, and large). Two sizes of polyethylene glenosphere (40 and 44 mm) and three metal reverse liners (short, medium, and large) for each glenosphere are available in this system. The modular humeral stem can be fixed in either by a press fit or cemented design. Additional design features to reduce mechanical notching include an eccentric glenosphere that covers the inferior aspect of the glenoid and an ultrahigh molecular weight polyethylene glenosphere combined with a CoCr metallic humeral liner. Overall, these results in glenoid-sided lateralization of 14.2 mm ie, increased by 1 mm when using the glenosphere size 44 mm option.

Surgical technique

Under general anesthesia and interscalene block, the patient was placed in a beach chair position. A deltopectoral approach and a biceps tenodesis to the pectoralis major tendon was done in all cases if the biceps was still present. The subscapularis tendon was then peeled of the lesser tuberosity and the inferior osteophytes were resected in the inferior part of the head and neck. A free hand osteotomy was done matching the neck shaft angle of the implant in approximately 10-20 degrees of retroversion. Residual remnants of the supraspinatus tendon (if present) were resected from the greater tuberosity. After a standardized glenoid exposure was undertaken, a central guidewire was placed in the desired position for the implant, and the glenoid surface was reamed removing the remanent cartilage and the subchondral bone. Drilling for the central post was followed by insertion of the final baseplate of the modular shoulder replacement (SMR) RSA (LimaCorporate S.p.A, Udine, Italy) and secured with 2 6.5mm screws. The definitive SMR high profile glenosphere (LimaCorporate S.p.A, Udine, Italy), was then introduced taking care to cover the inferior aspect of the glenoid with the polyethylene inferior overhang. The glenosphere size was calculated according to patient size varying between 40 mm and 44 mm. The humeral stem was then prepared using progressive fluted impaction stem achieving best fit in the endosteal cancellous bone of the upper humeral diaphysis. After a trial stem and liner was tested and the definitive implant was selected, the definitive modular SMR stem with a CoCr metallic humeral liner (LimaCorporate S.p.A, Udine, Italy) was prepared in the back table and impacted. Once the RSA was reduced, the subscapularis/capsular remnant tissue (if available) was reattached in a more inferior/medial position with 2 nonabsorbable braided transosseous sutures. Before closure, 1 gram of vancomycin powder was distributed in two layers (deep and subdermal). All surgeries were done by the senior author of this study.

Clinical evaluation

Patient-reported outcomes measures (PROMs) included disabilities of the arm, shoulder and hand score, American Shoulder and Elbow Surgeons score (ASES), EQ-5D Health Questionnaire, Global Rating of Change score and the Single Assessment Numeric Evaluation score. This clinical evaluation was done in person or by telemedicine depending on the patient's preference. When assessed in person, range of motion (ROM) was recorded by one of the study authors (JM) who is not involved directly in the patients care. Internal rotation was quantified using a scale ranging from 2 for buttocks, 4 for the sacroiliac joint, 6 for the posterior waist, and 8 for the T12 region, to 10 between the shoulder blades.

Radiographic evaluation

The 6, 12, and 24 months and last true anteroposterior x-ray available were assessed in all the patients by two specialized shoulder fellows, using the Sirveaux classification for SN.[31] If ossification was present in the inferior aspect of the glenoid, this was recorded and measured. Whenever this area of ossification was larger than 5 mm, this was considered as a SN grade 1. In case of disagreement, the case was discussed with the senior author (DD) and a consensus was reached. At the 6 months x-ray, RSA angle was measured as described by Boileau et al[3] (Fig. 1); lateralization shoulder angle and distalization shoulder angle were measured as described by Boutsiadis et al.[5] At the last x-ray available, humeral radiolucent lines, loosening and greater tuberosity, or calcar reabsorption was assessed according to Melis et al, [24] and glenoid side radiolucent lines or loosening was assessed according to Castagna et al.[7]

Statistical analysis

We present a descriptive table with means, medians, and ranges. A correlation study was done between the SN, the inferior ossification, and the PROMs and ROM using SPSS (IBM Corp., Armonk, NY, USA).

Results

Patient demographics

Between July 2016 and July 2019, 55 patients (61 shoulders) met our inclusion criteria with a minimum of 2 years (average 37 months). Six patients received a bilateral IB-RSA during this time. The mean age at surgery was 67 years (47-80 years) with 64% being male. The preoperative diagnosis included cuff tear arthropathy in 39 patients (63.9%), osteoarthritis in 19 (31.1%), posttraumatic in 2 (3.3%), and failed hemiarthroplasty in 1 (1.6%). Fourteen (23%) patients had a previous surgery, including rotator cuff repair in 12 (19, 7%), 1 instability procedure and 1 hemiarthroplasty.

Clinical scores

The mean disabilities of the arm, shoulder and hand score was 12 ± 5, ASES of 83 ± 6, Global Rating of Change score of 4 ± 0.6, EQ5D of 77 ± 6 and Single Assessment Numeric Evaluation score of 83 ± 11. ROM was recorded in 41 patients with a mean of 135 ± 21 of elevation, 23 ± 12 of external rotation and 5.2 ± 2.4 of internal rotation (Table I).

Radiographic findings

At 6 months, 12 patients (12%) had SN grade 1 and 2; at 12 months, SN was grade 1 in 19 patients (31) and grade 2 in 2

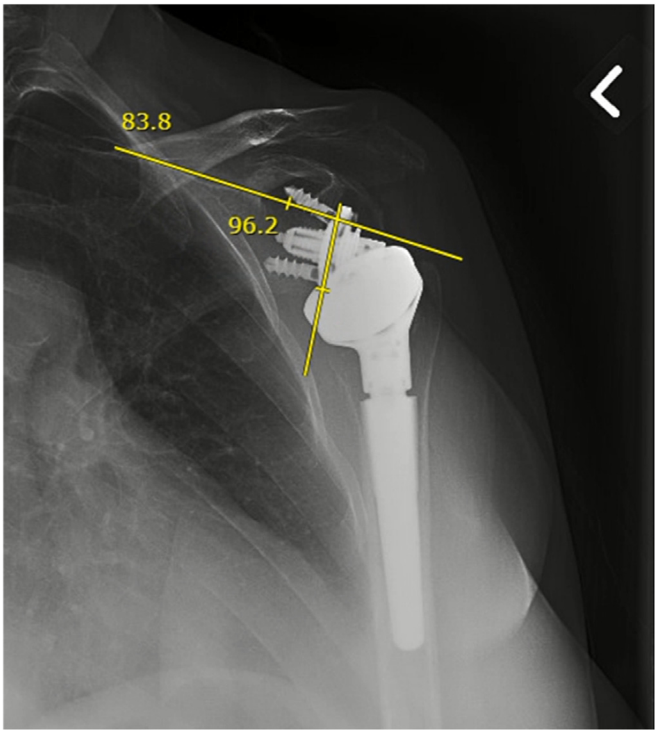

Figure 1 Reverse shoulder angle measured at the 6 months x-ray.

patients, and at the 24 months x-ray, the SN was grade 1 in 21 patients (34%) and grade 2 in 2 patients. At the last x-ray available with a mean of 3.8 years (2-6 years), there was 20 grades 1 (31%) and 3 grade 2. No grade 3 or 4 cases were observed during this follow-up. A summary of radiographic findings is shown in graphic 1. There was no correlation between the Sirveaux classification and the PROM or ROM at any month ($P \geq .05$). Also, minimal progression was found in both the rate and grade of SN after the 12-month X-ray ($P > .05$).

A heterotopic ossification (HO) in the medial aspect of the glenosphere was present in 26 shoulders (42%) in the last x-ray with a mean size of 7.8 mm (3-18 mm). There was no correlation between the presence and size of HO and PROM or ROM ($P > .05$). At final follow-up, 17 cases of HO were classified as SN grade 1.

At the 6 months x-ray, the average lateralization shoulder angle and distalization shoulder angle were 81.6 ° 6.9 and 47° ± 9.1, respectively. The average RSA angle was 7 ° (±5.5) with no correlation between angulation and SN or PROM or ROM ($P \geq .05$).

On the last x-ray assessment, which was done at an average of 37 months (range, 24-72 months), there was 5 patients (8%) with partial reabsorption of the greater tuberosity. Partial reabsorption of the calcar occurred in 23% of shoulders without associated stem loosening. There were no radiolucency lines in the glenoid side or signs of loosening during the follow-up of this study.

Complications

We report 6 complications (9.8%) including 2 distal clavicle fractures secondary to a trauma, 2 acromion fractures without trauma, 1 complex regional pain syndrome and 1 nerve injury in a patient with preexisting radiculopathy. No revision was performed and there was no infection or loosening to report during this follow-up. One patient died of causes no related to surgery after 4 years of follow-up.

Table I
Patients PROM and ROM after IB-RSA.

	Min	Max	Mean	SD
Age	47	80	67	7.4
FU	2	6	3.85	
DASH	4.17	38.3	12.4	51.4
ASES	55	93	83.2	6.0
EQ5D	60	90	77.1	6.2
GRC	2	5	4.0	0.66
SANE	25	95	83.3	11.4
Forward elevation	90	160	135	21
External rotation	0	50	23	12
Internal rotation	2	10	5.2	2

SD, Standard deviation; *FU*, follow-up; *DS*, DASH score; *ASES*, American Shoulder and Elbow Surgeons score; *EQ-5D*, EQ-5D Health Questionnaire; *GRC*, Global Rating of Change score; *SANE*, Single Assessment Numeric Evaluation score; *PROM*, Patient-reported outcomes measure; *DASH*, disabilities of the arm, shoulder and hand; *IB-RSA*, inverted-bearing reverse shoulder arthroplasty.

Discussion

The aim of this study is to present a clinical and radiologic evolution after an IB-RSA. Our study shows a good result in clinical shoulder function with a SN rate of 38% with only low-grade notching observed after an average follow-up of 3.8 years. The presence of SN did not influence on the clinical outcome scores or ROM. Notably, the SN remained relatively stable on x-rays after the first year. The rate of complication was 9.8% with 3.2% of acromion stress fracture and 3.2% of distal clavicle fracture secondary to trauma. These findings demonstrate that IB-RSA is a safe and effective procedure without specific implant-associated complications in the short-term follow-up.

The key design of IB-RSA intends to reduce induced osteolysis by using a polyethylene glenosphere and a metal (cobalt chrome) socket. In traditional RSA, polyethylene wear can occur due to repetitive joint motion and contact between the metal ball and the polyethylene cup.[22,31] This process can generate debris, leading to inflammation and osteolysis that might compromise the long-term success of the implant.[27] The inferomedial aspect of the polyethylene bears the majority of the load in traditional RSA [23] and leads to changes in the loading areas, generating more debris and increased SN rate and grade.[14,32,26] In a previous study, Jones et al compared metal and PE glenosphere, showing that SN was lower in the PE glenosphere group, with 11.1% vs. 25% at a minimum 2 years follow-up.[18] SN in IB-RSA has been reported to be between 20.5% and 27% with no high grade notching observed for this types of implants.[6,16,21] Irlenbush et al conducted a prospective multicenter study involving 113 patients with IB-RSA using the Affinis Inverse (Mathys Ltd., Bettlach, Switzerland) and reported an average ASES score of 77.4 at a mean follow-up of 27 months,[16] with 20.5% of low grade SN and no advanced grades. These results were maintained over time with only 4% of grade 3 SN at a mean follow-up of 86 months.[21] The different design used in our study with a 14.2 mm of glenoid lateralization, eccentric glenosphere and an inferior glenoid coverage could explain some of the higher functional outcomes.[6,35] Despite that glenoid lateralization should decrease the SN,[2,4,9,12] our study had a similar rate of SN compared to the one reported with a more medialized polyethylene glenosphere.[16,21] However, in our study 17 patients (28%) were included as SN grade 1 due to HO, increasing our SN incidence. This was done due to the difficulty to differentiate between SN and HO type 2 described by Ko et al.[20] Upon exclusion of these patients, prevalence decreased to 8% at the last available x-ray, showing no correlation with PROM or ROM ($P > .05$). Compared to regular RSA

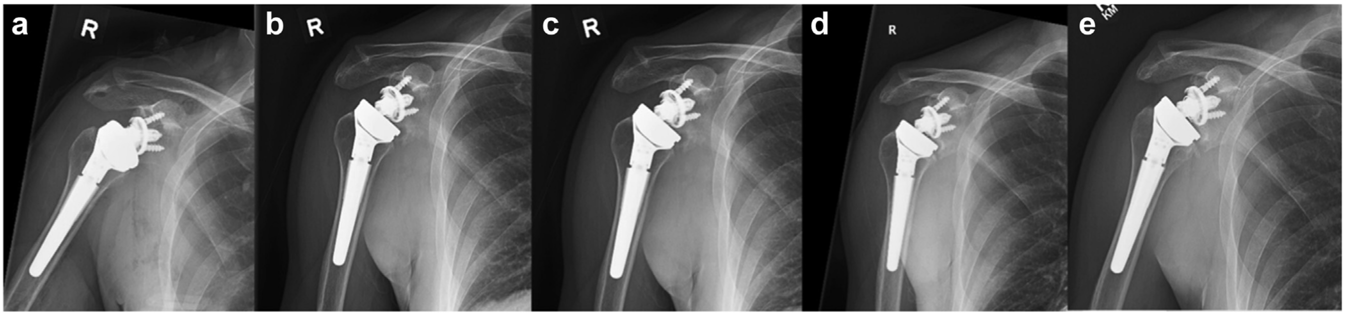

Figure 2 Anteroposterior view of a right shoulder showing the inferior heterotopic ossification growing around the PE glenosphere **a**) 1 month after the surgery **b**) 6 months after the surgery **c**) 1 year after the surgery **d**) 2 years after the surgery **e**) 7 years after the surgery. *PE*, polyethelene.

where SN has shown to increase over time,[29] IB-RSA have shown to remain stable over the years in our study which was also found by Jones et al .[18]

Inferior glenoid HO has been described previously with IB-RSA by Castagna et at using the same implant.[6] However, they don't report on size and correlation with clinical outcomes. Using regular RSA, Verhofste et al reported a 29.5% incidence of HO around the long head of the triceps, which was associated with worse clinical outcomes but showed no correlation with SN.[33] Similar results were found by Ko et al who reported a 61.6% of HO with a decreased forward elevation and external rotation in the HO group.[20] In our study we observed HO in the inferior aspect of the glenoid in 26 shoulders (42%) in the last x-ray with a mean size of 7.8 mm (3-18 mm). The exact origin of this ossification is not fully understood; yet it does not appear to be related to any complications, SN or inferior clinical results in our study ($P > .05$). HO started to appear at the 6 months x-ray and generally progressed over time increasing in size around the medial border of the PE glenosphere as seen in Fig. 2.

SN has been described to be influenced by the glenoid position and angulation.[3,12,15,19] In our study the average glenoid inclination was 7 degrees (−7 degrees to 26 degrees). The baseplate angulation did not have any correlation with the SN nor the clinical outcomes ($P > .05$). This more "anatomic" position of the baseplate is possible due to the eccentric polyethylene glenosphere and the inferior overhang over the inferior glenoid. This design has been shown to increase adduction in previous biomechanical studies but did not result in a lower SN rate.[8,28] Moreover, we believe that this more anatomical position of the baseplate decreases the need of asymmetric reaming, increasing the bone stock in case of revisions.

There are several limitations in our study. First, the absence of a control group hinders our ability to attribute the observed outcomes to changes in the bearing surfaces. Second, the lack of preoperative scores impedes a comprehensive assessment of the magnitude of improvement observed. Third, the exclusive performance of surgeries by a single, experienced surgeon may introduce a degree of selection bias and raises questions about the broader applicability of our results. Finally, the relatively short follow-up period of a minimum of two years may not capture potential late complications associated with shoulder arthroplasty.

Conclusion

IB-RSA demonstrates high patient-reported and functional outcome scores at a minimum of two years follow-up. We report only low-grade SN with little progression after the first year. There was no correlation between SN or HO in the inferior aspect of the glenoid and clinical outcomes.

Disclaimers:

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Conflicts of interest: Darren Drosdowech is a paid consultant from Lima. All the other authors, their immediate family, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jseint.2024.10.003.

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