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Bony increased-offset reverse shoulder arthroplasty vs. metal augments in reverse shoulder arthroplasty: a prospective, randomized clinical trial with 2-year follow-up

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Background: Reverse shoulder arthroplasty (RSA) is rapidly being adopted as the standard procedure for a growing number of shoulder pathologies. Lateralization of the glenoid component is known to reduce the incidence of scapular notching and possibly improve postoperative range of motion. A number of methods are used for glenoid component lateralization, including bony increased-offset reverse shoulder arthroplasty (BIO-RSA) and porous metal-augmented baseplates. Presently, there exists little comparative literature on bone vs. metal lateralization. Therefore, the purpose of this study was to compare BIO-RSA to metal-augmented glenoid baseplates by assessing clinical outcomes and baseplate migration using model-based radiostereometric analysis.

Methods: A power analysis indicated 40 patients would be required for this radiostereometric study. Therefore, 41 shoulders were prospectively randomized to receive either glenoid bone grafting (BIO-RSA) or a porous metal-augmented wedge-shaped titanium baseplate for primary reverse shoulder arthroplasty. At the time of primary surgery, all patients also underwent implantation of 8 tantalum marker beads in the glenoid and coracoid. Following surgery, participants were imaged using a calibrated, stereo radiographic technique. Radiographs were acquired at 6 weeks (baseline), 3 months, 6 months, 1 year, and 2 years postoperatively. Migration of the prosthesis was compared between bone and metal lateralization groups at each time point using a mixed effects model with Bonferroni test for multiple comparisons. Outcome measures were acquired preoperatively and 2 years postoperatively.

Results: No significant differences were observed along any translation or rotation axis at any time point for either glenoid fixation group ($P \geq .175$). Mean total glenoid component translation ($\pm$ standard deviation) 2 years postoperatively was 0.4 ± 0.2 mm and 0.5 ± 0.3 mm for BIO-RSA and metal-augmented baseplates, respectively ($P = .784$). No significant differences were observed between groups in active range of motion; pain; American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form score; Simple Shoulder Test score; Disabilities of the Arm, Shoulder, and Hand score; Constant Shoulder score; or Subjective Shoulder Value ($P \geq .117$), with the exception of increased active external rotation in the BIO-RSA cohort ($P = .036$).

This study was approved by the Western University Health Sciences Research Ethics Board, Project ID 105908.

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Conclusion: This randomized clinical trial assessed reverse shoulder arthroplasty glenoid component migration using model-based radiostereometric analysis. At 2-year follow-up, our results indicate both BIO-RSA and porous metal wedge augmented baseplates provide stable initial fixation, which is maintained at 2 years' follow-up, with no substantial differences in clinical outcomes.

Level of evidence: Level I; Randomized Controlled Trial; Treatment Study

Keywords: Reverse shoulder arthroplasty; radiostereometric analysis; implant migration; BIO-RSA; augmented implant; patient-reported outcome measures

Reverse shoulder arthroplasty is being used as the standard surgical procedure for a rapidly growing number of shoulder pathologies.[10,18,27] Glenoid preparation and implantation remains a technical challenge, as different pathologies present varying glenoid wear patterns.[11] Excessive reaming, in an effort to optimize glenosphere baseplate seating, may lead to medialization of the glenohumeral joint's center of rotation and exacerbate scapular notching.[6,26,35] For this reason, glenoid lateralization has been recommended. Glenoid lateralization may be conducted by the addition of a structural bone autograft underneath the baseplate, a technique termed bony increased-offset reverse shoulder arthroplasty (BIO-RSA).[3,4] Although the short-term literature demonstrates good outcomes with BIO-RSA,[3-5] concerns are still raised for possible problems with bone graft healing, baseplate stability, increased operative time, and that the autograft technique is limited to primary surgeries.

Alternatively, metal-augmented baseplates have been engineered and marketed to address varying glenoid deficiencies, without relying on structural bone autograft.[13,31,36] Although metal augmentation provides a promising solution to scapular notching and improving impingement-free range of motion, there are concerns about lateralization of the joint's center of rotation and the introduction of bending moments at the bone-implant interface, compromising fixation and survivorship.[2,7,14,15]

Model-based radiostereometric analysis is a calibrated, dual-plane radiography technique capable of measuring submillimeter implant migration, and is currently the gold standard for such purposes.[32] The technique has been used extensively in studies of lower limb arthroplasty, where it has been shown that early implant migration, within the first 2 years postoperatively, is predictive of later loosening and failure.[21,22] To our knowledge, few to no studies have investigated glenoid component migration in reverse shoulder arthroplasty. The purpose of this prospective randomized clinical trial was to compare the migration between BIO-RSA and porous metal-augmented glenoid baseplates using model-based radiostereometric analysis in the first 2 years postoperatively. Secondary patient-reported outcome measures and incidence of scapular notching were also recorded. It was hypothesized that there would be no difference in migration between augmentation techniques and that patients would report comparable outcomes.

Materials and methods

Study design

This is a prospective, randomized clinical trial with 2×2 factorial design, investigating both glenoid and humeral stem fixation in reverse shoulder arthroplasty. This article presents the methods and results of the glenoid fixation study arm. At the time of study conception, and to our knowledge, few to no studies have evaluated glenoid component migration in reverse shoulder arthroplasty. Consequently, the study sample size was determined based on previously reported radiostereometric analysis results of humeral stem migration in anatomic shoulder arthroplasty,[24] and powered appropriately. Assuming a standard deviation of 0.3 mm within groups and 4 repeated measurements, differences in migration of 0.235 mm between cohorts can be detected with 80% power and an alpha value of 0.05. To account for 10% dropout, 20 patients were included in each group.

Patients were randomized into one of 4 RSA cohorts: BIO-RSA with either press-fit or cemented humeral stem and porous metal-augmented-wedge glenoid with either press-fit or cemented humeral stem. Block randomization was used to ensure a 1:1 allocation between the 4 groups. Five blocks of 8 were initially assigned, with an additional block of 4 added following the withdrawal of 2 patients from the study prior to radiographic assessment. This additional block resulted in the addition of 3 more participants for a total of 41 shoulders recruited for the study (the additional patient added because of randomization order, ensuring 20 patients in each glenoid cohort). Randomization sequence was generated using the online tool at sealedenvelope.com. Treatment allocations were printed, concealed, and sealed in an opaque envelope and then numbered sequentially. Envelopes were opened 3 weeks before surgery to ensure adequate time for preoperative templating and instrument availability.

Patient recruitment

Thirty-nine nonconsecutive patients (41 shoulders, 20 male) provided written, informed consent for prospective study enrollment and reverse shoulder arthroplasty. Procedures were completed between July 2017 and June 2019 by GSA, a fellowship-trained shoulder surgeon at St Joseph's Health Care, London, Canada. Inclusion criteria were shoulder arthrosis requiring reverse shoulder arthroplasty, a functional deltoid muscle, and the capacity to provide informed consent. Exclusion criteria included patients who were pregnant or planning to become pregnant, unable to read or write English, significant cognitive impairment, a gait or motor control disorder, and if their indication for surgery was humeral fracture, avascular necrosis, or revision surgery, or if they had insufficient bone stock for random treatment allocation.

Clinical and radiographic outcomes

Patient-reported outcomes were acquired preoperatively and 2 years postoperatively as secondary outcome measures. Active forward elevation, lateral abduction, and external rotation (at 0° abduction) were measured using a 30-cm handheld goniometer. Active internal rotation was measured as the highest point along the spine reached by the thumb pointing upward. Validated outcome measures include the Subjective Shoulder Value; the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; the Simple Shoulder Test; the Disabilities of the Arm, Shoulder, and Hand questionnaire; and the Constant Shoulder score. Pain was ranked from 0 to 10.

The most recent anteroposterior radiographs were assessed for evidence of scapular notching according to the grading by Sirveaux et al,[28] glenoid lucency, and specific to the BIO-RSA cohort, incorporation of bone graft.[4] Glenosphere inclination angle was also recorded, measured as the angle subtended by tracing the floor of the supraspinatus fossa with a line perpendicular to the back of the glenosphere.[17]

Surgical technique

All procedures were performed by a fellowship-trained shoulder surgeon (G.S.A.) and used the Aequalis Ascend Flex humeral component (Wright Medical-Tornier Group, Memphis, TN, USA). Prior to surgery, computed tomography scans of each patient's glenohumeral joint were assessed for glenoid deficiency and classified according to the Walch and Favard systems as appropriate (Table I).[16,34] Preoperative templating (BLUEPRINT; Wright Medical-Tornier Group) was completed for each patient to optimize implant size and positioning, though final sizes and placement were evaluated intraoperatively. The standard deltopectoral approach was used, with patients in the beach chair position. During surgery, 5 tantalum beads 1 mm in diameter (Halifax Biomedical Inc., Mabou, NS, Canada) were inserted into the glenoid vault, and 3 beads in the coracoid, before implanting the glenoid baseplate. Beads were spaced as far apart as possible to facilitate subsequent radiostereometric analysis.

For the BIO-RSA cohort, bone graft with a thickness of approximately 10 mm and diameter appropriate to the baseplate was harvested from the humeral head prior to head resection. The graft was then shaped to match each patient's glenoid deficiency, as described by Boileau et al,[5] and fixed using a long (25 mm) central post implant (Aequalis Reversed II; Wright Medical-Tornier Group), 2 compression, and 2 locking screws. A 36-mm glenosphere was used in 9 cases, a 39-mm glenosphere in 3 cases, and a 42-mm glenosphere in 8 cases.

For patients in the porous metal wedge cohort, the full wedge (15° slant) augment (Aequalis PerFORM+ Reversed, ADAPTIS integrated porous metal) was used, with a diameter of either 25 or 29 mm. The augmented baseplate was seated to the reamed glenoid and fixed using either a 6.5- or 9-mm-diameter central screw, 1 compression screw, and 3 locking screws. Eight 36-mm, three 39-mm, and ten 42-mm glenospheres were used. In 1 case (36 mm), a 15-mm-diameter central post was used, as insufficient purchase was achieved using the central screw. Radiographic differences between the 2 augmentation techniques are illustrated in Figure 1. In all cases, centered glenospheres were used.

Table I Patient demographic characteristics (mean ± SD)

	BIO-RSA (n = 20)	Augment (n = 21)	*P* value
Age, yr, mean ± SD	75 ± 9	70 ± 9	.096
Sex, male/female, n	11/9	11/10	.867
BMI, mean ± SD	30 ± 6	32 ± 7	.335
Walch classification			
A1	3	2	.985
A2	1	3	
B2	2	5	
B3	3	1	
Favard classification			
E0	6	8	.197
E2	2	2	
E3	3		
Indication			
OA	7	10	.535
CTA	9	6	
MRCT	2	4	
OA + RCT	1	1	
RA	1		

OA, osteoarthritis; *CTA*, cuff tear arthropathy; *MRCT*, massive rotator cuff tear; *RCT*, rotator cuff tear; *RA*, rheumatoid arthritis; *BIO-RSA*, bony increased-offset reverse shoulder arthroplasty.

Patients received either a cemented or press-fit stem, with either a 1.5-mm (n = 38) or 3.5-mm (n = 3) eccentric tray (Aequalis Ascend Flex; Wright Medical-Tornier Group). Trial reduction was completed prior to final polyethylene selection to ensure stability and mobility of the joint. Polyethylene diameter was matched to glenosphere diameter, with a ≥6-mm-thick polyethylene used in 35 cases and ≥9-mm used in 6 cases.

Radiostereometric analysis

Immediately following surgery, a graduated rehabilitation program was initiated. Six weeks postoperatively, the sling was removed. Baseline radiostereometric analysis examinations were taken at 6 weeks, with subsequent examinations taken at 3 months, 6 months, 1 year, and 2 years. Patients were imaged in a dedicated radiostereometric analysis suite using 2 ceiling-mounted x-ray units (Proteus XR/a; GE Medical Systems, Milwaukee, WI, USA). X-ray tubes were positioned parallel to the floor and 40° to one another, directed at the patient sitting in front of a uniplanar calibration cage (Cage 43, RSA Biomedical, Umea, Sweden), their arm at rest by their side. Images were acquired with 35.5 × 43.2-cm computed radiography imaging cassettes featuring 0.1-mm pixel spacing and 10-bit gray scale mapping (Capsula X CR; Fujifilm, Tokyo, Japan). Radiographs were taken at 90 kVp, with 6.3-16.0 mAs depending on patient size.

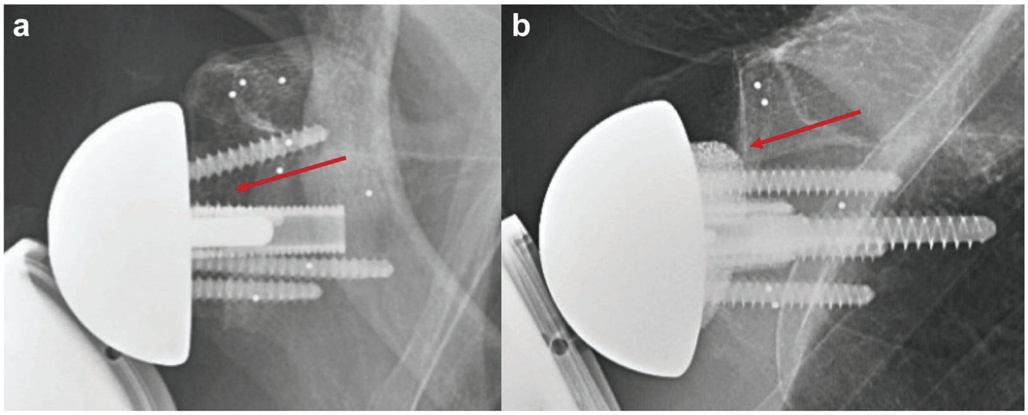

Figure 1 Anteroposterior radiographs of glenoid component augmentation (→) using (**a**) bony increased-offset reverse shoulder arthroplasty and (**b**) a porous metal full wedge augment. Tantalum beads are also visible in the glenoid vault and coracoid as small radiopaque circles.

Glenoid implant migration was measured in commercial model-based radiostereometric analysis software (RSACore, Leiden, the Netherlands). Linear translations were recorded along the medial (+)–lateral (–) *x* axis, superior (+)–inferior (–) *y* axis, and anterior (+)–posterior (–) *z* axis (Fig. 2, *a*). A 3-dimensional total translation vector was measured at each time point as well, calculated as the square root of the sum of squared translation components from each translation axis. Rotations of the glenoid implant were recorded about the anteversion (+)–retroversion (–) *x* axis, and declination (+)–inclination (–) *z* axis (Fig. 2, *b*). The glenosphere is symmetric about its *y* axis, and these measurements were consequently indeterminate. Note that rotations follow Euler rigid body kinematics and therefore are not in line with the model-based radiostereometric analysis global coordinate frame, as translations are.

Bias and repeatability of this technique using the same implant have previously been validated under ideal conditions, with a reported bias (mean absolute value ± 95% confidence interval) less than, and repeatability greater than, 0.08 ± 0.02 mm and 0.15 mm, and 0.3° ± 0.1° and 0.2° in translation and rotation, respectively.[33] The condition number, a value representative of the dispersion of the fiducial markers, was also recorded for each measurement. A well-conditioned marker cluster will be spread out in 3 dimensions, rather than colinearly, and will have a low condition number. It has been generally suggested that measurements with condition numbers less than 150 provide reliable results.[32] Because of the small glenoid and coracoid area within which tantalum beads could be placed, there is the potential for worse dispersion and higher condition numbers, and therefore this value has previously increased to 300 for the glenoid component of the shoulder.[29] In order to assess the clinical precision of model-based radiostereometric analysis, double exposures were taken 3 months postoperatively. Clinical precision is reported as 1.96 × SD of the measured migration values when no migration has taken place (ie, examinations taken a few minutes apart).[30] Clinical precision provides a lower limit for migration measurements recorded in the model-based radiostereometric analysis software, allowing the user to distinguish between meaningful migration values and noise. The threshold for rigid body error, measured as the absolute change in position of tantalum beads between exposures, was set at 0.350 mm.[32]

Statistical analysis

Glenosphere translations were measured along each orthogonal axis, in addition to a 3-dimensional "total translation" vector, and rotations were measured about the anteversion-retroversion and inclination-declination axes. Measurements were made relative to the 6-week baseline exams. Significant differences in migration between cohorts were assessed using a mixed effects model with Bonferroni test for multiple comparisons. Within-group effects were also assessed using Bonferroni test for multiple comparisons to determine if there were any significant differences in migration within cohorts between time points. Assessment of interaction between glenoid component migration and type of humeral stem fixation was performed using a 2-way analysis of variance.

Significant differences in continuous clinical outcomes were assessed using either an unpaired *t* test, if normally distributed, or the Mann-Whitney test if not. Categorical data was assessed using the χ^2 test. Normality was evaluated using the Pearson d'Agostino test. Analysis was performed in Prism 8 (GraphPad Prism, San Diego, CA, USA), with statistical significance set at $P < .05$.

Results

The mean age at time of surgery was 72 ± 9 years, with no difference in demographic characteristics between cohorts (Table I). Mean glenosphere inclination in the BIO-RSA cohort was 1° ± 3°, and 4° ± 5° in the metal augment cohort ($P = .055$). There was no significant difference in glenosphere size distribution (36, 39, or 42 mm) between cohorts ($P = .880$). A preoperative difference between groups was observed in forward elevation (mean difference = 18°, $P = .047$), though no other range of motion or outcome measures were significantly different (Table II). Postoperative patient-reported outcomes are also reported in Table II, along with the mean difference from baseline and comparative gain between cohorts. All outcomes for each cohort improved significantly 2 years

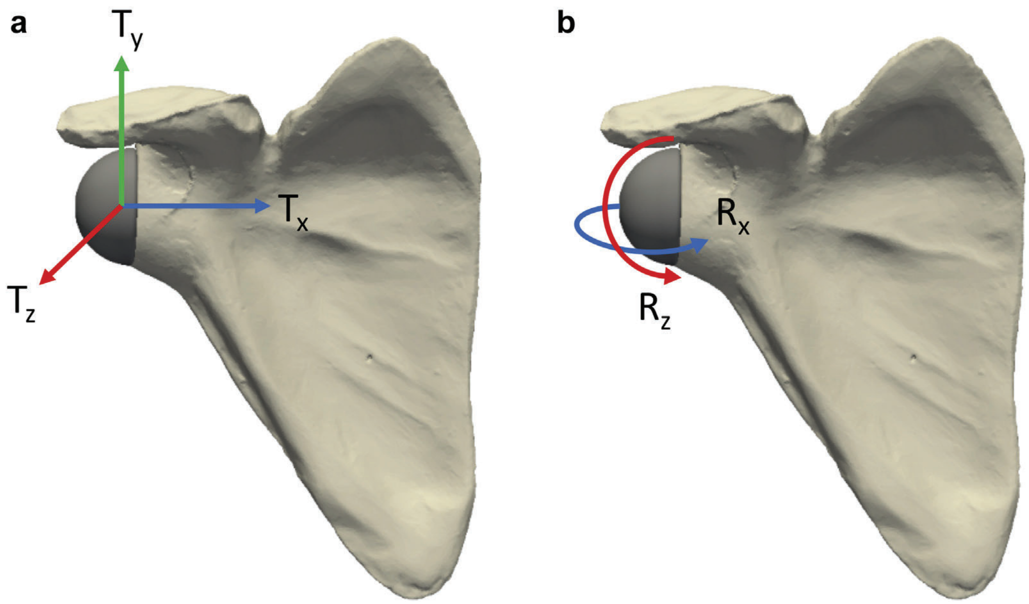

Figure 2 Right-handed coordinate system illustrating (**a**) translational axes and (**b**) rotational axes.

Table II Patient-reported outcome measures

	Preoperative			Postoperative (2 yr)			Difference from preoperative		
	BIO-RSA	Augment	*P* value	BIO-RSA	Augment	*P* value	BIO-RSA (*P* value)	Augment (*P* value)	Absolute difference in gain between cohorts
Forward elevation (°)	62 ± 31	80 ± 26	**.047**	125 ± 17	129 ± 18	.484	+63 (**<.001**)	+49 (**<.001**)	14
Lateral abduction (°)	56 ± 22	71 ± 26	.062	108 ± 22	113 ± 23	.489	+52 (**<.001**)	+42 (**<.001**)	10
External rotation (°)	24 ± 19	26 ± 23	.838	43 ± 15	32 ± 13	**.036**	+19 (**.003**)	+6 (.267)	13
Internal rotation (1-6)*	3 ± 1	3 ± 2	.281	4 ± 2	5 ± 1	.468	+1 (**.004**)	+2 (**.011**)	1
Pain (0-10)	7.0 ± 2.2	6.9 ± 2.4	.896	1.4 ± 1.5	1.1 ± 1.6	.324	−5.5 (**<.001**)	−5.8 (**<.001**)	0.3
SSV (0-100)	33 ± 21	29 ± 22	.715	90 ± 9	82 ± 19	.117	+57 (**<.001**)	+53 (**<.001**)	4
ASES (0-100)	34 ± 14	34 ± 19	.895	83 ± 14	84 ± 16	.724	+49 (**<.001**)	+50 (**<.001**)	1
SST (0-12)	2 ± 1	3 ± 2	.075	8 ± 3	9 ± 3	.852	+6 (**<.001**)	+6 (**<.001**)	0
DASH (0-100)	57 ± 15	52 ± 16	.322	20 ± 18	15 ± 17	.378	−37 (**<.001**)	−37 (**<.001**)	0
Constant (0-100)	23 ± 9	30 ± 15	.074	67 ± 9	70 ± 14	.259	+44 (**<.001**)	+40 (**<.001**)	4

SSV, Subjective Shoulder Value; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *SST*, Simple Shoulder Test; *DASH*, Disabilities of the Arm, Shoulder, and Hand; Constant, Constant Shoulder score; *BIO-RSA*, bony increased-offset reverse shoulder arthroplasty.
Values are mean ± standard deviation.
* Based on the landmarks from Constant Shoulder score: 1 = lateral thigh, 2 = buttock, 3 = lumbosacral junction, 4 = waist, 5 = T12, 6 = T7 or interscapular.
Bold values are statistically significant.

postoperatively, with the exception of external rotation in the porous metal augment cohort. Differences in external rotation were observed between groups 2 years postoperatively, with the BIO-RSA group showing increased range of motion (mean difference = 11°, P = .036). Adverse events include 1 revision due to dislocation in the augment cohort 9 months postoperatively, and 1 acromion fracture in the BIO-RSA cohort that healed without intervention. One patient in the BIO-RSA cohort passed away from unrelated causes prior to 2-year follow-up. Full study flow is illustrated in Figure 3. All bone grafts demonstrated structural integrity at the most recent follow-up, with no evidence of glenoid lucency. Grade I scapular notching was apparent in 3 cases, 2 of which were porous metal wedge patients. All 3 patients had a neutral or slightly superior glenoid inclination angle (range = 1°-4°).

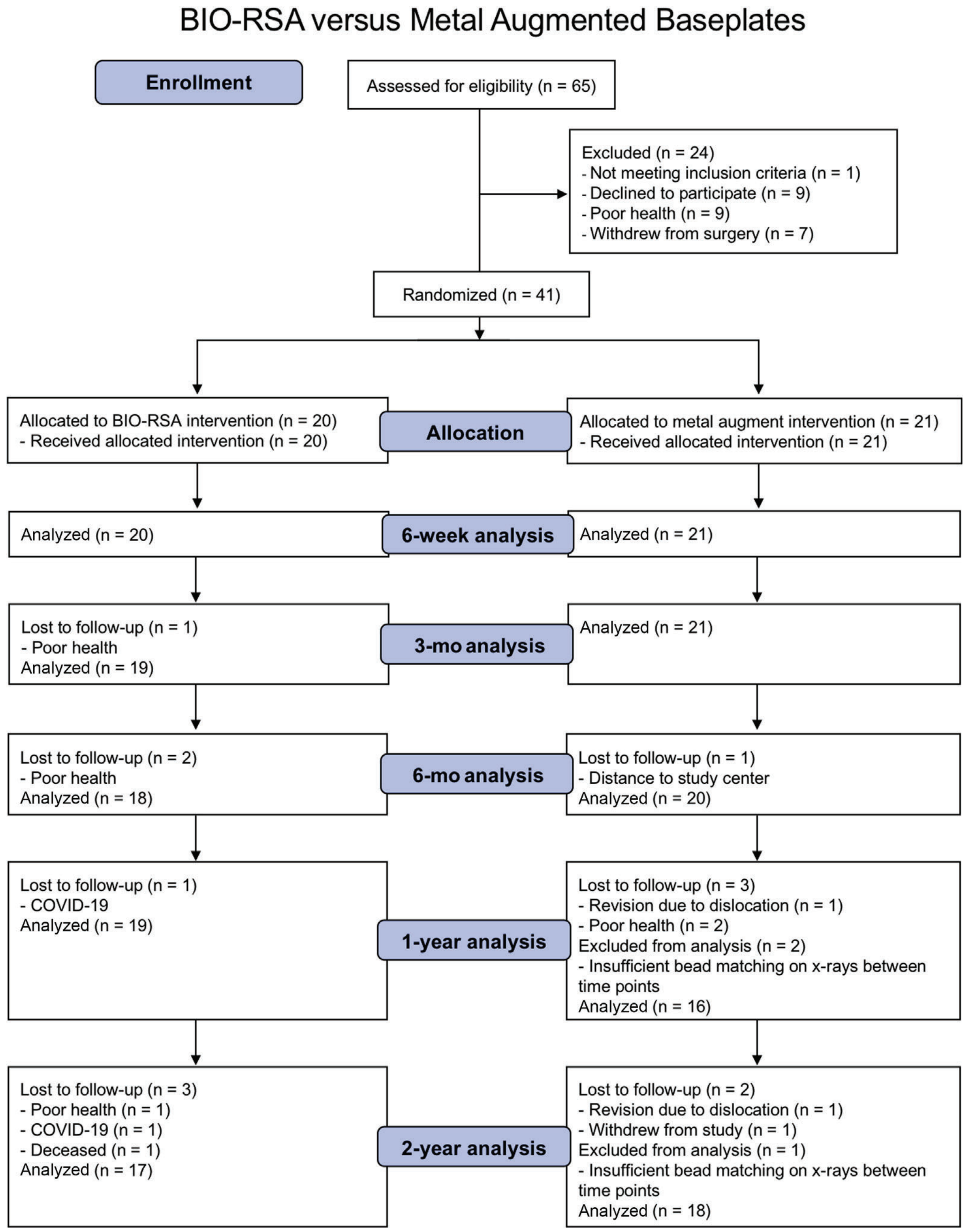

Figure 3 CONSORT study flow diagram. *BIO-RSA*, bony increased-offset reverse shoulder arthroplasty.

Clinical precision measured from double examinations is reported in Table III. Out-of-plane translations and rotations about the inclination-declination axis had the poorest precision. The glenosphere has one axis of rotational symmetry, and therefore measurements about this axis are indeterminate. Mean condition number for patients with BIO-RSA was 135 ± 66, and 127 ± 63 for patients with the metal augment.

There was no significant difference in total translation (mean difference = 0.1 mm, $P = .784$) between BIO-RSA and porous metal-augmented cohorts 2 years postoperatively (Fig. 4), or at any time point along any axis between glenoid lateralization groups (Table IV). Within cohorts, significant differences in total translation were observed from baseline through 3 months in both BIO-RSA (mean difference = 0.4 mm, $P < .001$) and metal augment (mean difference = 0.4 mm, $P < .001$) cohorts. No further differences were observed from 3 months to 6 months, 6 months to 1 year, or 1 year through 2 years in either cohort (all $P > .999$).

Assessing for interaction between glenoid implant migration and humeral stem fixation, there was no

Table III Precision (1.96 × SD), reported for translation (mm) and rotation (°)

	Medial (+)–lateral (–) (T_x)	Superior (+)–inferior (–) (T_y)	Anterior (+)–posterior (–) (T_z)	Total translation (T_r)	Anteversion (+)–retroversion (–) (R_x)	Declination (+)–inclination (–) (R_z)
BIO-RSA	0.4	0.4	0.5	0.3	1.0	1.1
Augment	0.4	0.4	0.7	0.4	1.0	1.9

SD, standard deviation; *BIO-RSA*, bony increased-offset reverse shoulder arthroplasty.

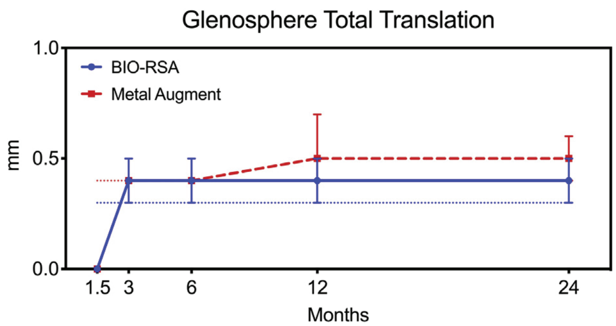

Figure 4 Mean ± 95% confidence intervals of total translation measurements for BIO-RSA (–) and porous metal wedge augment (---) glenoid lateralization techniques. Model-based radiostereometric analysis precision is illustrated as the ····· for BIO-RSA and the ····· for porous metal wedge augment. *BIO-RSA*, bony increased-offset reverse shoulder arthroplasty.

significant interaction between factors at any time point along any axis (P range = .112-.893), with the exception of the medial-lateral translation axis at 3 months ($P = .044$), where a mean difference in medial-lateral translation of <0.1 mm was reported between cohorts with press-fit and cemented stems.

Discussion

A handful of studies have investigated glenoid component migration in anatomic shoulder arthroplasty, with variable results. Unfortunately, the anatomic results are not transferable to the reverse shoulder glenoid component, as the reverse shoulder experiences different biomechanics and loading conditions.[9,19,20,23,25,29] Therefore, the purpose of this study was to compare implant migration in the first 2 years postoperatively between BIO-RSA and porous metal wedge augmentation techniques using model-based radiostereometric analysis. Patient retention at 2 years was 88% (36/41). No statistically significant differences in migration were observed along any translation or rotation axis at any time point between groups, supporting our hypothesis. Although it is likely that some minute migration occurred as the implant baseplates integrated with the reamed glenoid in the first few months postoperatively, the precision of the technique is poorer than the migration values observed, and therefore no distinguishable differences were observed between groups. Overall, it appears that immediate, stable fixation is achieved with both augmentation techniques.

Further, in assessing for interaction between glenoid implant migration and type of humeral stem fixation, the only instance of interaction between factors was at 3 months along the medial-lateral translation axis. The reported difference in glenoid implant migration between cohorts with cemented and press-fit stems was <0.1 mm, below the level of clinical precision for model-based radiostereometric analysis and clinically negligible. As a result, the authors conclude the type of humeral stem fixation had no effect on glenoid implant migration.

Both cohorts improved in all functional metrics 2 years postoperatively, with the exception of external rotation in the metal augment cohort. This limited improvement in external range of motion may be a result of the metal augment's geometry. A single geometry (15° full wedge, Aequalis PerFORM+ Reversed) was used for all patients in the metal-augmented cohort regardless of glenoid erosion pattern, whereas the bone graft for the BIO-RSA cohort was shaped to address patient-specific glenoid defects. This unique modification with BIO-RSA may have provided greater patient-specific benefit in our study. Practically speaking, a number of different porous metal augment geometries have come to market with the goal of managing different erosion patterns.[1,13] Presently, the Aequalis PerFORM+ Reversed full wedge is only offered in the 15° geometry. By choosing an appropriate augment for the suggested indication, this may provide superior patient outcomes. At this time, however, there were no differences in patient outcomes between BIO-RSA and porous metal-augmented glenospheres 2 years postoperatively, with the exception of external rotation. Additionally, it should be noted that this study was primarily powered for implant migration, and range of motion was a secondary outcome. As such, the difference in external rotation should be interpreted with caution and not overstated. Further, the immediate stability achieved with the 15° full wedge in this patient cohort may not be representative of all porous metal-augmented geometries, which vary in the volume of glenoid bone removal required for sufficient seating—the 15° full wedge requiring the least bone removal compared to the half wedge and standard nonaugmented designs.[1]

The incidence of scapular notching was minimal in both cohorts, supporting the use of both glenosphere lateralization techniques for impingement-free range of motion. The total

Table IV Translational (mm) and rotational (°) migration values

	BIO-RSA	Metal augment	*P* value
Medial-lateral (T_x)			
3 mo	0.0 ± 0.3	0.0 ± 0.2	>.999
6 mo	0.1 ± 0.3	0.0 ± 0.2	.625
1 yr	0.1 ± 0.2	0.1 ± 0.2	>.999
2 yr	0.1 ± 0.3	0.0 ± 0.3	>.999
Superior-inferior (T_y)			
3 mo	0.0 ± 0.2	−0.1 ± 0.3	>.999
6 mo	0.0 ± 0.2	0.1 ± 0.2	>.999
1 yr	0.0 ± 0.1	0.0 ± 0.3	>.999
2 yr	0.0 ± 0.2	0.0 ± 0.3	>.999
Anterior-posterior (T_z)			
3 mo	0.1 ± 0.4	0.0 ± 0.4	>.999
6 mo	0.0 ± 0.3	0.0 ± 0.4	>.999
1 yr	0.1 ± 0.3	0.0 ± 0.5	>.999
2 yr	−0.1 ± 0.3	−0.2 ± 0.4	>.999
Total translation (T_r)			
3 mo	0.4 ± 0.3	0.4 ± 0.3	>.999
6 mo	0.4 ± 0.2	0.4 ± 0.2	>.999
1 yr	0.4 ± 0.2	0.5 ± 0.3	.629
2 yr	0.4 ± 0.2	0.5 ± 0.3	.784
Anteversion-retroversion (R_x)			
3 mo	−0.1 ± 0.8	0.0 ± 0.7	>.999
6 mo	−0.1 ± 0.8	−0.3 ± 0.5	.885
1 yr	−0.2 ± 0.9	0.1 ± 0.5	.785
2 yr	−0.3 ± 0.8	0.0 ± 0.4	>.999
Declination-inclination (R_z)			
3 mo	0.1 ± 0.6	0.1 ± 0.6	>.999
6 mo	−0.2 ± 0.8	−0.3 ± 0.7	>.999
1 yr	−0.1 ± 0.7	0.4 ± 0.6	.175
2 yr	−0.2 ± 0.8	0.1 ± 0.9	.477

BIO-RSA, bony increased-offset reverse shoulder arthroplasty.
Values are mean ± standard deviation.

frequency of 7% (3/41) is lower than previously reported for BIO-RSA (40%),[3] and likely a result of combining glenosphere lateralization with a more acute humeral neck-shaft angle (145° vs. 155°), as used in this study.

This study has limitations. At the time of study conception and initiation, to our knowledge, few to no studies had been conducted investigating glenosphere migration in reverse total shoulder arthroplasty. Consequently, a priori power analysis was based on previously published mean and standard deviation results of humeral stem migration. The mean difference in glenosphere migration measurements between cohorts recorded for the present study were an order of magnitude smaller than the 0.235 mm used for power analysis. As a result, the current sample size at 2 years ($n = 35$ analyzed) is smaller than that required for power of 0.8 with alpha = 0.05. Despite this limitation, however, the authors believe the results are an accurate representation of the migration patterns of both BIO-RSA and porous metal wedge augmented glenosphere baseplates in reverse total shoulder arthroplasty. There were no incidences of observable migration in either cohort, and although a greater number of patients are required for adequately powering the glenosphere study arm, it is unlikely that any statistically significant difference in migration between cohorts would be clinically meaningful given the patterns observed in this study.

The present study relied on the use of the glenosphere CAD models as the implant surface model rather than a reverse-engineered model. One group recently, after our study had already started, evaluated the clinical precision of glenosphere migration measurements in the reverse shoulder using a reverse-engineered glenosphere model in the same model-based radiostereometric analysis software, with slightly improved results: $T_x = 0.22$ mm, $T_y = 0.13$ mm, $T_z = 0.25$ mm, $R_x = 0.36°$, $R_z = 0.69°$.[8] This study also changed the imaging position of the patients, having them lie supine, with the calibration cage rotated 90° from our sitting examinations. It has been shown that reverse-engineered models improve the clinical precision of model-based radiostereometric analysis compared to CAD models, and this is likely a source of their finer results.[12] Another limitation is that the glenosphere is symmetric about its *y* axis, and therefore rotations about this axis could not be measured.

The condition number for both BIO-RSA and metal augment cohorts was comparable, and within the acceptable range, at 135 ± 66 and 127 ± 63, respectively. Traditionally, the upper limit for condition numbers has been set at 150; however, this limit has been increased to 300 for the glenoid.[29] Tantalum beads were inserted into the coracoid in addition to the glenoid vault in order to improve the condition number, but as the results show, the limited surrounding bone volume is still a limitation of acquiring reliably small migration measurements in the glenoid.

Additionally, this study only examined BIO-RSA and glenoid baseplate augments as techniques for lateralization. Other techniques that are also effective, such as lateralized glenosphere implants, were not studied. Lastly, further long-term follow-up is required to relate implant longevity to these 2-year results and to determine the effect of any potential future bone graft resorption or glenoid lucency.

Conclusion

There are few to no randomized clinical trials comparing BIO-RSA to metal-augmented baseplates in reverse shoulder arthroplasty. The present study compared glenoid implant migration between bone and metal augments using model-based radiostereometric analysis. At 2-year follow-up, our results indicate both BIO-RSA and porous metal wedge augmented baseplates provide initial, stable fixation, with no substantial difference in clinical outcome measures.

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