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A cohort comparison of humeral implant designs in reverse shoulder arthroplasty: does implant design lead to lower rates of complications and revision?

R. Allen Gorman II, MD[a], Kaitlyn N. Christmas, BS, CRCC[a], Peter Simon, PhD[a,b], Mark A. Mighell, MD[c], Mark A. Frankle, MD[c,d,*]

[a]*Translational Research, Foundation for Orthopaedic Research and Education, Tampa, FL, USA*
[b]*Department of Medical Engineering, University of South Florida College of Engineering and Morsani College of Medicine, Tampa, FL, USA*
[c]*Florida Orthopaedic Institute, Tampa, FL, USA*
[d]*Department of Orthopaedics and Sports Medicine, University of South Florida Morsani College of Medicine, Tampa, FL, USA*

Introduction: The purpose of this study was to evaluate the outcomes, revisions, and complications between a first-generation cemented modular humeral implant and a second-generation monolithic, primarily uncemented humeral implant in reverse total shoulder arthroplasty with 135° neck-shaft angle and varying degrees of metallic glenosphere offsets.
Methods: We retrospectively evaluated patients undergoing reverse total shoulder arthroplasty from 2004 to 2014 with a first-generation cemented modular humeral implant (400 patients) or second-generation monolithic humeral stem (231 patients), who had at minimum 2-year clinical and radiographic follow-up.
Results: Both groups of patients had similar improvement of clinical outcomes (American Shoulder and Elbow Surgeons +30 points vs. +34 points, respectively) with improvements in all planes of motion (forward flexion +70° vs. +75°, abduction +61° vs. +71°, external rotation +23° vs. +22°, and internal rotation +1.6 vs. +1.5 level improvement, respectively). The incidence of humeral loosening for the cemented group was 3.6%, whereas in the uncemented group it was 0.4% ($P = .01$). A total of 28 shoulders treated with the cementing technique (4.0%) and 6 patients treated with the press-fit technique (1.5%) were revised ($P = .028$). The rate of postoperative acromial fractures within the first year was 3.4% in the cemented group and 1.8% in the uncemented group ($P = .177$).
Conclusions: Both the first-generation cemented modular humeral stem implant and the second-generation monolithic humeral stem implant had equivalent clinical outcomes. In addition, with the monolithic stem primarily using press-fit fixation, there was a significant reduction in the incidence of radiographic loosening and the need for revision compared with a cemented stem.
Level of evidence: Level III; Retrospective Cohort Comparison; Treatment Study

Keywords: Reverse shoulder arthroplasty; monoblock; modular; complications; advancement; uncemented

Investigation performed at Florida Orthopaedic Institute and Foundation for Orthopaedic Research and Education, Tampa, FL, USA.
This study was determined to be exempt from review by the Western Institutional Review Board.

*Reprint requests: Mark A. Frankle, MD, Florida Orthopaedic Institute, 13020 N Telecom Pkwy, Tampa, FL 33637, USA.
E-mail address: mfrankle@floridaortho.com (M.A. Frankle).

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The demand for shoulder arthroplasty has increased significantly over the past decade, with a 200% increase witnessed from 2011 to 2015.[8,15] This procedure is performed to manage a collection of end-stage degenerative, inflammatory, or traumatic pathologies of the shoulder. Reverse total shoulder arthroplasty (RSA) has demonstrated promising early, mid-, and long-term outcomes.[3,12,17,24] Subsequently, these results have led to RSA being used with great frequency and foreseeable stable growth.[8,13,16,20] Technological advancements in implant design and surgical technique have focused on diminishing complications and optimizing RSA performance for increased stability and sustained functional outcomes.

One implant design has used similar geometric reconstructive principles since its inception. The Reverse Shoulder Prosthesis (RSP) system (DJO Surgical, Austin, TX, USA) introduced an implant with a neck-shaft angle of 135° and varying degrees of lateral glenosphere offsets. Modifications of this design have been focused on the baseplate. Particularly, the introduction of larger peripheral locking screws and improvement of in-growth material on the backside of the component led to a decrease in baseplate failures.[7] Another more recent modification has been on the humeral implant.

The initial RSP humeral implant (Fig. 1) had a modular junction and was exclusively cemented. Concerns regarding modular junction failures (Fig. 2), dissociations, or component fractures, as well as the ability to achieve fixation without cement, prompted the second-generation design RSP Monoblock (DJO Surgical; Fig. 1).[6]

This study aimed to investigate the clinical and radiographic findings in a population of patients undergoing RSA performed by a single surgeon with either a first- or second-generation implant design. Our primary aim was to compare complications and revision rates between the 2 iterations of RSA designs: one that was cemented, the RSP modular implant, and the other more recent iteration, the RSP Monoblock, designed to allow for cemented or press-fit fixation. Our secondary aim was to report on the improvements in functional shoulder outcomes and range of motion (ROM) within the population stratified by the implant iteration and the use of cement for humeral component fixation. We hypothesized that technological modifications and changes in surgical technique would influence the complications and revision rate.

Figure 1 RSP (left) and RSP Monoblock (right) with proximal coating. Copyright DJO Global, Inc. 2020. *RSP*, Reverse Shoulder Prosthesis.

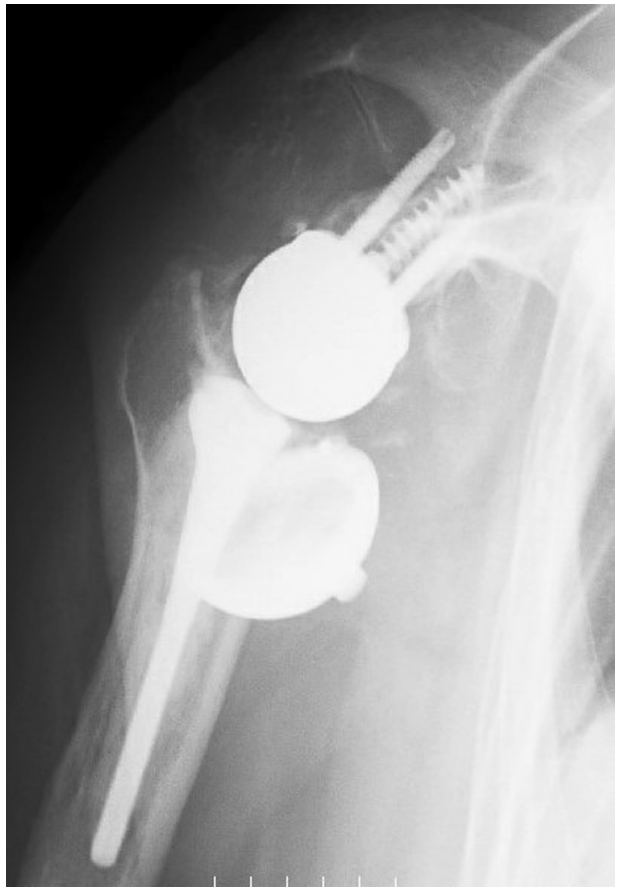

Figure 2 Postoperative radiograph of a patient who sustained a modular junction failure after being treated with the first-generation implant.

Methods

We performed a retrospective review of our institutional shoulder surgery registry to identify all patients treated with RSA between January 2004 and December 2014 (1525 patients) by a single fellowship-trained surgeon (MAF). This registry captures patient demographics, operative details, complications, reoperations, revisions, and clinical outcome scores of patients treated with shoulder arthroplasty. Patients were asked to follow-up postoperatively at 10 days, 6 weeks, 3 months, 6 months, 1 year, and annually thereafter. In addition, 2 upper extremity surgeons

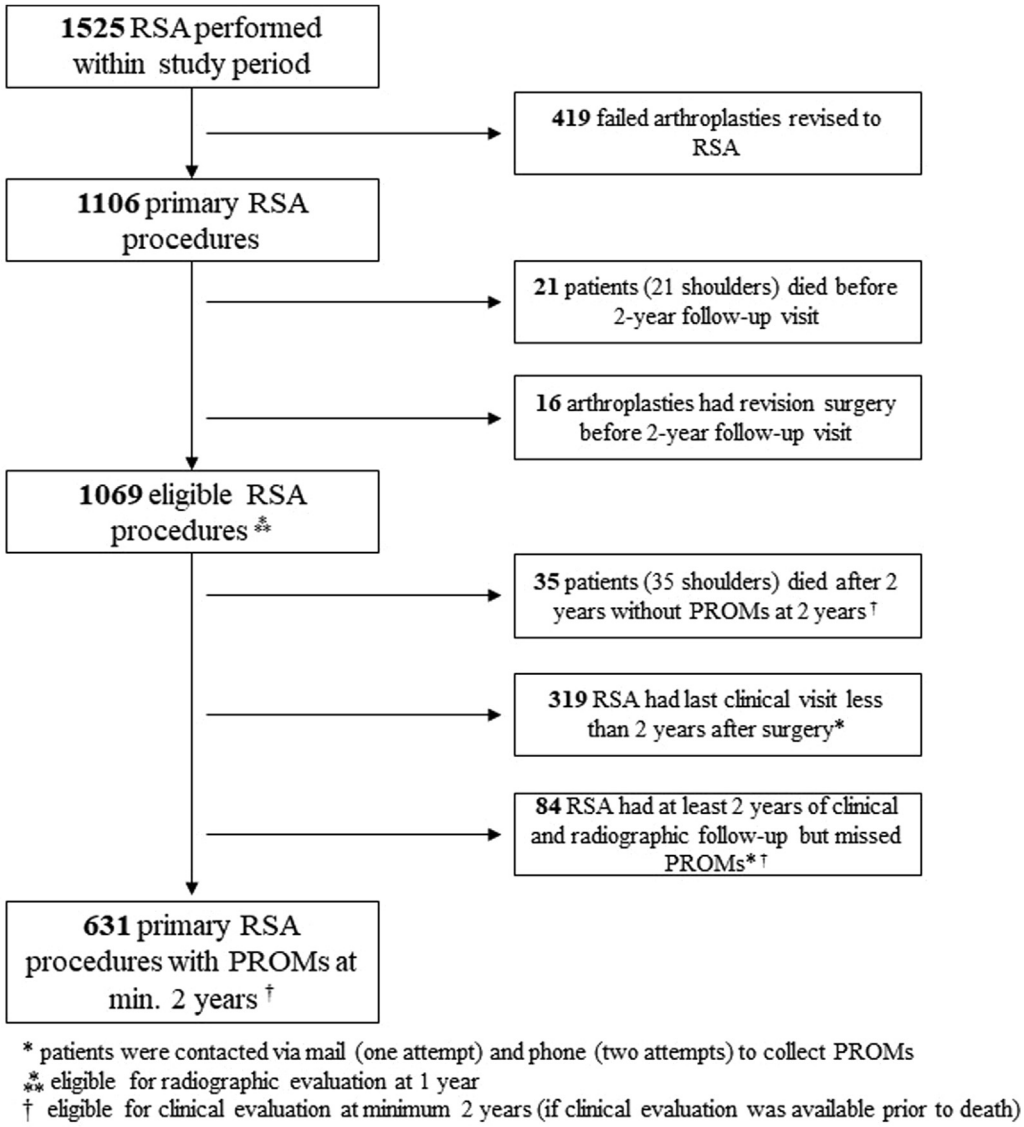

Figure 3 Flow diagram depicting patient inclusion and exclusion criteria due to lack of preoperative patient-reported outcome measure preoperatively and/or postoperatively at 2-years or greater. *RSA*, reverse total shoulder arthroplasty; *PROM*, patient-reported outcome measure.

performed radiographic evaluation on the study cohort throughout the treatment period. Exclusion criteria comprised patients who underwent RSA as a revision surgery (419 patients—failed index arthroplasties and tertiary referrals), patients who died before 2-year follow-up visit (n = 21), and patients who underwent revision before 2-year follow-up visit (n = 16). For our secondary aim, we excluded patients who had sufficient radiographic and clinical evaluation but failed to complete patient-reported outcome measures (PROMs) (n = 84), patients with less than 2 years of clinical follow-up (n = 319), and patients without sufficient clinical follow-up who died after reaching 2-year visit (n = 35) (Fig. 3).

Patient population and demographics

All surgeries were performed following the same technique through a deltopectoral approach. The surgical technique and postoperative protocol for this procedure have previously been described in detail.[10,11,17] Simple diaphyseal sounding and preparation of the metaphysis with hemispherical reamers to slightly smaller than the outer diameter of the implant was performed. Press-fit fixation was primarily assessed by the rim fit of the inset socket into the metaphysis. In addition, bone impaction was performed on all press-fit cases where the humeral head was morselized. Subscapularis repair and postoperative protocol were standardized during the study period. All patients received a subscapularis repair, even if not fully reparable (eg, loss of tendon). The postoperative protocol emphasized a physician-directed home therapy program and included the use of a shoulder immobilizer for 6 weeks with gentle pendulum exercises. This was then progressed to a light sling and active-assisted ROM in the supine position. As tolerated by the patient, they were then allowed to progress with a focus on strengthening and stretching exercises. At no point in time were the patients prescribed formal

physical therapy. The study population included 647 (61%) female and 422 (39%) male patients. The average age of the study population was 70.6 years (range, 22-91years): for female patients 71.6 years (range, 22-91years) and for male patients 69.1 years (range, 24-87 years). The majority of patients were diagnosed with cuff tear arthropathy (35%), followed by massive cuff tear without osteoarthritis (22%), osteoarthritis (17%), massive cuff tear with osteoarthritis (7%), malunion/nonunion (5%), inflammatory arthritis (4%), acute fracture (6%), infection (1%), and other (avascular necrosis, chronic dislocation, post-traumatic osteoarthritis, instability, congenital brachial plexus palsy; 4%). The study population included 681 cemented stems (64%) and 388 uncemented stems (36%). On the basis of the surgical note and postoperative radiographic confirmation, a group of 597 shoulders received the modular stem (group 1) and a group of 472 shoulders received the monolithic stem (group 2). There were a total of 681 cemented stems and 388 press-fit stems evaluated in this study (Table I). The decision was made preoperatively to cement the monolithic stem for all proximal humeral fractures, malunion/nonunion cases, and intraoperatively for any other cases based on the manual evaluation of the proximal diaphysis bone quality.

Radiographic evaluations

A total of 456 shoulders (group 1) and 285 shoulders (group 2) had routine preoperative and postoperative (at a minimum 2 years postoperatively) radiographs (anteroposterior [AP], Grashey, axillary lateral, and scapular Y) available for evaluation by 2 independent observers. For postoperative evaluation at a minimum of 1-year follow-up, there were 597 shoulders for group 1 and 472 shoulders for group 2 available. One year of radiographic follow-up has been reported as a sufficient period to capture the incidence of acromial fracture after RSA.[1,9,21,27] Humeral loosening was measured using the grading system described by Sperling et al.[25] Baseplate fixation was graded as stable (no evidence of radiolucency at the baseplate-bone interface or around any screw), at risk (>1 mm of circumferential radiolucency at the baseplate-bone interface or around any 1 screw), or loose (>1 mm of radiolucency around the baseplate-bone interface and around all screws, or the existence of a shift in the position of the baseplate). Radiographs were also evaluated for evidence of implant dislocation, acromial fractures,[18] and implant failure.

Revisions and complications

A chart review was conducted for all shoulders (597 shoulders in group 1 and 472 shoulders in group 2) to assess the incidence of revision surgeries (removal of any component), reoperations, and any reported complications in the period between the surgery and December 2019. All early revisions (16 early revisions before 2-year follow-up) were included in this analysis.

Clinical outcomes

Clinical outcomes included American Shoulder and Elbow Surgeons score and active ROM reported in 4 planes. A total of 400 shoulders treated with modular stems (group 1) and a total of 231 shoulders treated with monolithic stems (group 2) were evaluated. The average follow-up time for group 1 was 61 months (range, 24-146 months), and for group 2 it was 45 months (range, 24-93 months). Active ROM in forward flexion, abduction, and external rotation was collected with a video goniometer (Screen Protractor; Iconico, New York, NY, USA). Internal rotation was measured with the ability of the thumb to reach a posterior vertebral segment.

Statistical analysis

Continuous variables are reported as mean and standard deviations, or ranges and categorical variables are reported as frequencies and percentages. The Fisher exact test or the χ^2 test was

Table I Study group demographics and surgical indications

	Group 1 (n = 597)	Group 2 (n = 472)
Age (yr) (range)	70.4 (22-89)	70.9 (24-91)
Sex, n (%)		
Male	234 (40)	188 (40)
Female	363 (60)	284 (60)
Diagnosis, n (%)		
Cuff tear	241 (40)	135 (29)
Fracture	22 (4)	38 (8)
Infection	8 (1)	2 (0)
Inflammatory arthritis	21 (4)	17 (4)
Malunion/Nonunion	26 (4)	26 (6)
MCT with OA	58 (10)	17 (4)
MCT without OA	122 (20)	115 (24)
Osteoarthritis	75 (13)	105 (22)
Other	24 (4)	17 (4)
Cement use, n (%)		
Cemented	597 (100)	84 (18)
Press-fit	0 (0)	388 (82)

MCT, massive cuff tear; *OA*, osteoarthritis.

used to evaluate qualitative variables. Normality was tested using the Shapiro-Wilks test. For normally distributed continuous variables, we used a paired/independent *t*-test; for non-normally distributed variables, we used the Wilcoxon rank sum test/Mann-Whitney *U* test. Analyses were performed with SPSS 25 (IBM Corp., Armonk, NY, USA) with significance set at alpha = 0.05.

Results

Radiographic evaluation

The radiographically determined rate of humeral loosening for group 1 was 3.1% (14 of 456), whereas for group 2 it was 1.8% (5 of 285; $P = .343$). The rate of baseplate failure was found to be 1.1% (5 of 456) in group 1 and 0.4% (1 of 285) in group 2 ($P = .415$). The rate of postoperative acromial fractures within the first year was 3.1% (19 of 597; 6 type I, 8 type II, 5 type III) in the modular group and 2.3% (11 of 472; 5 type I, 6 type II) in the monolithic group ($P = .459$).

The radiographically determined rate of humeral loosening for the cemented group was 3.6% (18 of 502), whereas for the uncemented group it was 0.4% (1 of 239; $P = .01$). The rate of baseplate failure was found to be 1.0% (5 of 502) in the cemented group and 0.4% (1 of 239) in the uncemented group ($P = .67$). The rate of postoperative acromial fractures within the first year was 3.4% (23 of 681; 7 type I, 11 type II, and 5 type III) in the cemented group and 1.8% (7 of 388; 4 type I, and 3 type II) in the uncemented group ($P = .177$).

Revisions and complications

A total of 23 shoulders (10 shoulders were revised before 2-year follow-up) treated with the modular implant (23 of 607; 3.8%) and 11 shoulders (6 shoulders were revised before 2-year follow-up) treated with the monolithic implant (11 of 478; 2.3%) were revised ($P = .219$). In group 1, the causes for revision included recurrent instability (n = 7), infection (n = 7), humeral loosening (n = 4), periprosthetic fracture (n = 2), glenosphere dissociation (n = 1), baseplate failure (n = 1), and failure at the modular junction (n = 1). In group 2, the causes for revision included periprosthetic fracture (n = 3), baseplate failure (n = 3), recurrent instability (n = 2), humeral loosening (n = 1), infection (n = 1), and glenosphere dissociation (n = 1). The average time to revision in the modular group was 43 months (range, 1-161 months), and in the monolithic group it was 30 months (range, 1-87 months; $P = .318$).

A total of 28 shoulders treated with the cementation technique (4%) and 6 patients treated with press-fit (1.5%) were revised ($P = .028$). In the cemented group, the causes for revision included recurrent instability (n = 7), infection (n = 8), humeral loosening (n = 5), periprosthetic fracture (n = 5), glenosphere dissociation (n = 1), baseplate failure (n = 1), and failure at the modular junction (n = 1). In the press-fit group, the causes for revision included baseplate failure (n = 3), instability (n = 2), and glenosphere dissociation (n = 1). The average time to revision in the cemented group was 44 months (range, 1-161 months), and in the uncemented group it was 13.5 months (range, 1-38 months; $P = .005$).

Clinical outcomes

Both groups showed improvement from pre- to postoperative in every PROM collected ($P < .0001$). There were no statistically significant differences between mean improvement, except for abduction where the monolithic group showed slight superiority ($P = .032$) (Table II).

The cemented and press-fit groups demonstrated significant improvement from pre- to postoperative at each evaluated PROM. Furthermore, there were no statistically significant differences between mean improvement (Table III).

Discussion

In the present study, we compared complications and clinical outcomes in a consecutive series of the modular first-generation RSP (DJO Surgical) and second-generation RSP Monoblock (DJO Surgical) reverse shoulder arthroplasty followed for a minimum of 2 years. Both systems have a lateralized center of rotation by design; however, the second-generation humeral component uses a monolithic humeral stem design for press-fit into the metaphysis to avert torsional stress on the modular junction of the earlier design. Our study has shown significant clinical improvements in all planes of motion (forward flexion, abduction, external rotation, and internal rotation) in both groups even as we have expanded our indications for RSA with the second-generation implant.

This study demonstrates that uncemented humeral stems have equivalent clinical outcomes and lower rates of complications. Radiographically, the rate of humeral loosening for the cemented group was 3.6% (18 of 502), whereas in the uncemented group it was 0.4% (1 of 239; $P = .01$). In addition, the rate of revision was greater in the shoulders treated with cementation (4.0%) compared with patients treated with press-fit (1.5%; $P = .028$). The average time to revision in the cemented group was 44 months (range, 1-161 months), and in the uncemented group it was 13.5 months (range, 1-38 months; $P = .005$).

These results are consistent with Levy et al,[19] King et al,[16] and Phadnis et al.[22] In addition, Werthel et al[26] found that both types of fixation had a survival rate of >90% at 20 years. Our results further support the current

Table II Pre- and postoperative patient-reported outcome measures and range of motion measurements at 2+ years

Outcome	Mean preoperative score (± SD)	Mean postoperative score at 2+ yr (± SD)	*P* value	Mean improvement (2-tailed 95% CI)	*P* value (mean improvement RSP vs. Monoblock)
Group 1 (n = 400)					
ASES total	38.6 ± 17.9	69.2 ± 23.9	<.0001	30.6 (27.8-33.3)	
Forward elevation	69.7 ± 40.7	138.8 ± 42.3	<.0001	69.1 (63.2-75.1)	
Abduction	64.3 ± 37.2	125.3 ± 45.1	<.0001	60.9 (55.2-66.7)	
External rotation	24.0 ± 31.5	46.6 ± 38.7	<.0001	22.6 (17.2-28.1)	
Internal rotation	2.7 ± 2.0	4.4 ± 2.4	<.0001	1.6 (1.3-1.9)	
Group 2 (n = 231)					
ASES total	32.4 ± 18.2	66.4 ± 23.7	<.0001	34.0 (30.4-37.7)	.130
Forward elevation	62.0 ± 47.2	137.4 ± 39.5	<.0001	75.4 (67.9-82.9)	.195
Abduction	57.1 ± 44.4	128.4 ± 41.1	<.0001	71.2 (63.5-78.9)	.032
External rotation	23.2 ± 36.1	45.0 ± 35.4	<.0001	21.8 (15.2-28.3)	.838
Internal rotation	2.9 ± 2.5	4.4 ± 2.3	<.0001	1.5 (1.0-1.9)	.584

ASES, American Shoulder and Elbow Surgeons; *SD*, standard deviation; *CI*, confidence interval; *RSP*, Reverse Shoulder Prosthesis.

Table III Pre- and postoperative patient-reported outcome measures and range of motion measurements at 2+ years comparing the cemented and press-fit technique

Outcome	Mean preoperative score (± SD)	Mean postoperative score at 2+ yr (± SD)	*P* value	Mean improvement (2-tailed 95% CI)	*P* value (mean improvement cemented vs. press-fit)
Cemented (n = 450)					
ASES total	32.2 ± 18.3	66.5 ± 23.1	<.0001	30.9 (28.3-33.5)	
Forward elevation	64.7 ± 47.2	139.5 ± 40.0	<.0001	74.7 (64.8-75.8)	
Abduction	61.0 ± 44.4	130.3 ± 40.4	<.0001	63.2 (57.9-68.6)	
External rotation	25.1 ± 35.2	46.8 ± 34.1	<.0001	22.5 (17.5-27.5)	
Internal rotation	3.1 ± 2.5	4.3 ± 2.2	<.0001	1.7 (1.4-2.0)	
Press-fit (n = 181)					
ASES total	37.9 ± 17.9	68.8 ± 24.1	<.0001	34.4 (30.2-38.5)	.167
Forward elevation	67.4 ± 41.8	137.7 ± 41.7	<.0001	70.3 (65.9-83.5)	.39
Abduction	61.6 ± 38.5	124.9 ± 44.8	<.0001	69.3 (60.2-78.4)	.256
External rotation	22.9 ± 32.8	45.5 ± 38.8	<.0001	21.7 (14.1-29.4)	.854
Internal rotation	2.7 ± 2.1	4.4 ± 2.4	<.0001	1.2 (0.7-1.7)	.12

ASES, American Shoulder and Elbow Surgeons; *SD*, standard deviation; *CI*, confidence interval.

trend in the transition from a cemented to an uncemented technique for the RSA humeral component.

Shoulders treated with the modular implants were found to have a rate of acromial fracture of 3.1% within the first postoperative year, whereas those treated with the monolithic implant only had a rate of acromial fracture of 2.3% ($P = .459$) over the same interval. Because the geometric rationale for design between the 2 humeral components is identical, the lower incidence of humeral-sided complications and acromial fractures are likely confounded by surgeon experience, addition of proximal coating, and surface modifications as well as the surgical technique. Phadnis et al[22] compared the outcomes of cemented and uncemented fixation of the humeral stem in RSA and found a higher occurrence of acromial fractures in the cemented cases (31 of 1455, 2.1%) than the uncemented cases (0 of 329, 0%; $P = .004$). Similarly, we found a higher proportion of acromial fractures in our group of shoulders that underwent the cemented technique with a rate of 3.4%, whereas our press-fit group demonstrated a rate of 1.8% ($P = .177$).

There are several potential limitations in our study. First, 60% of patients were available for clinical review, and 70% had radiographic evaluation at a minimum 2 years of follow-up. There are many reasons for patients not following up, including a change of residence, scheduling

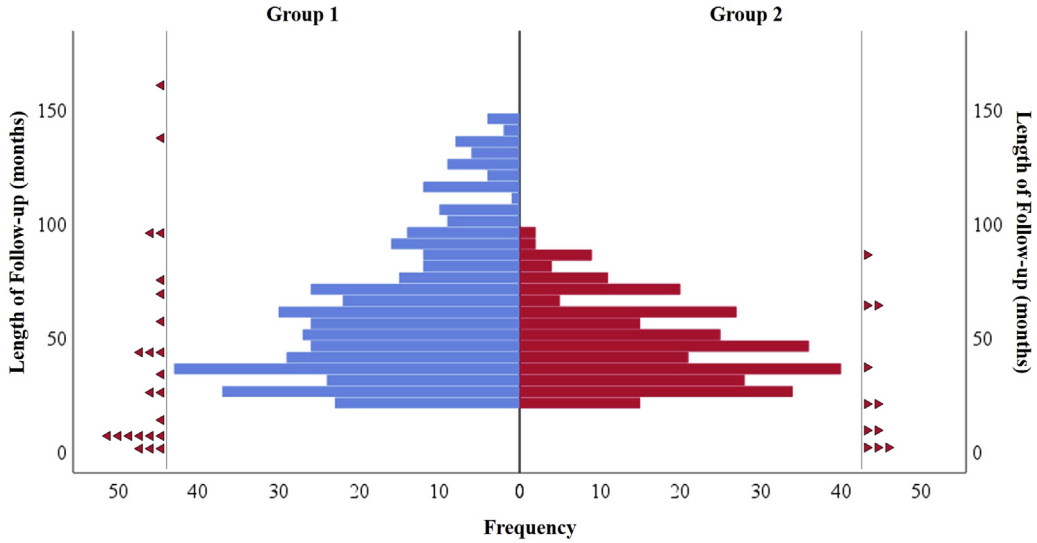

Figure 4 Distribution of the last follow-up visits for group 1 and group 2; secondary axes represent the distribution of the revision cases (▲, single revision) in the study period (left, revisions for group 1; right, revisions for group 2).

conflicts, difficulty traveling, older patients, death index, insurance status, patients with lower income, and patients with lower education level.[2,5,28] Although it is widely accepted that loss to follow-up is associated with the potential risk of bias,[23] several studies have demonstrated that there is no difference in functional clinical outcome scores and radiographic evaluations between the cohort of patients who follow up and those who do not.[4,14] Another limitation is our retrospective study design. As with any large database retrieval study, there is always concern that errors may be present in data entry or retrieval. In addition, observation bias may have been introduced during radiographic evaluation of pre- and postoperative radiographs as the senior author surgeon (M.A.F.) was used for final confirmation. Another limitation of this study is the difference in follow-up between the 2 groups. In the RSP group (group 1), it was 61 months, whereas in the RSP Monoblock group (group 2), it was 45 months. However, the revisions in both groups occurred at the same interval (Fig. 4; group 1: 70% of all revisions occurred before 48 months, and group 2: 73% of all revisions occurred before 48 months). Despite the success to date, the long-term survivorship of these patients' implants is not known.

The strength of this study is that it examined a large number of patients with a wide range of pathology. In addition, multiple steps were taken to avoid bias to make the collected data as objective as possible. With respect to measuring ROM, each patient was videotaped while performing a standardized protocol of active forward flexion, abduction, and external and internal rotation both preoperatively and at various points postoperatively. Three independent observers not involved in the treatment of the patients and blinded to the case information digitally measured the ROM on each video. The purpose of this was to eliminate measurement bias that can be seen when the operative surgeon measures and reports pre- and postoperative ROM. In obtaining our results, we used patient-reported outcomes recorded independently by the patient in the absence of the surgeon.

Conclusion

The RSP Monoblock prosthesis has a monolithic stem design, proximal coating with textured titanium surface, and option for press-fit implantation of the humeral component. It allowed for equivalent improvement in patient ROM and clinical outcomes. The improvement in component design that allowed for press-fit fixation reduced humeral-sided failure and radiographic loosening.

Disclaimer

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