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Anatomic total shoulder arthroplasty using a stem-free ellipsoid humeral implant in patients of all ages

Steven S. Goldberg, MD[a,*], Eric S. Baranek, MD[b], Kayla C. Korbel, BS[a], Theodore A. Blaine, MD[c], William N. Levine, MD[b]

[a]*Division of Orthopedic Surgery, Physicians Regional Medical Center, Naples, FL, USA*
[b]*Department of Orthopedic Surgery, New York Presbyterian–Columbia University Medical Center, New York, NY, USA*
[c]*Hospital for Special Surgery, Weill Cornell Medicine, New York, NY, USA*

Background: Stem-free shoulder arthroplasty has recently been shown to have comparable results to stemmed arthroplasty, though stemless designs are typically used in a younger patient population. Additionally, although the native humeral head is elliptical in shape, clinical results with ellipsoid implants in shoulder arthroplasty have not been reported on previously. This case series reports on the outcomes of a recently introduced anatomic total shoulder arthroplasty with an ellipsoid-shaped articular surface and unique multiplanar platform type of stemless fixation.

Methods: This retrospective case series examines the initial cohort of patients who received an anatomic total shoulder arthroplasty using an ellipsoid stem-free humeral prosthesis and an all-polyethylene glenoid component from the Catalyst CSR Total Shoulder System (Catalyst OrthoScience) over a 1-year period. Inclusion criteria were patients with a diagnosis of advanced glenohumeral joint arthritis with an intact rotator cuff, regardless of patient age. Clinical outcomes including shoulder range of motion and patient-reported outcome measures, as well as radiographs, were evaluated at multiple time points postoperatively, with minimum 2-year follow-up.

Results: Sixty-three shoulders in 57 patients with a mean age of 73.0 years (range 60-85 years) were included in the study with a mean follow-up period of 30.5 months (range 24-41 months). Forward elevation improved from 121° to 150° ($P < .0001$), external rotation improved from 28° to 48° ($P < .0001$), and internal rotation improved from L3 to L1 ($P < .001$). There were statistically significant improvements exceeding the minimal clinically important difference (MCID) in the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) score (37 to 94, $P < .001$), Single Assessment Numeric Evaluation (SANE) (40 to 93, $P < .001$), visual analog scale (6.3 to 0.4, $P < .001$), and Patient-Reported Outcomes Measurement Information System physical domain T score (44 to 57, $P < .001$). The improvement in the ASES score also exceeded the threshold for the substantial clinical benefit. Age, sex, and preoperative glenoid morphology did not appear to have an effect on the clinical outcome scores. There were no implant failures or evidence of radiographic loosening of the humerus component in any patients.

Conclusion: At 2-year minimum follow-up, this stem-free ellipsoid humerus total shoulder arthroplasty provides very good results with high patient satisfaction, clinical improvement in all outcome measures studied, and no signs of loosening.

This study was reviewed by the Western Institutional Review Board IRB Affairs Department (IRB no. 1-1231172-1) and it was found that this research met the requirements for a waiver of consent under 45 CFR § 46.104(d)(4).

*Reprint requests: Steven S. Goldberg, MD, Physicians Regional Healthcare System, 6101 Pine Ridge Road, 3rd Floor, Naples, FL 34119, USA.

E-mail address: drstevengoldberg@gmail.com (S.S. Goldberg).

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Keywords: Total shoulder arthroplasty; total shoulder replacement; ellipsoid humeral head; stemless shoulder; glenohumeral osteoarthritis; shoulder replacement; nonspherical humerus

Anatomic total shoulder arthroplasty (TSA) can provide lasting pain relief and improved range of motion for patients suffering from glenohumeral arthritis.[32,43,58] Multiple authors stress the importance of accurately restoring the anatomic relationship of the glenohumeral joint, and this is one of the major guiding principles in shoulder arthroplasty.[23,41,42,61] Nonanatomic positioning of components results in inferior outcomes and can result in complications such as subscapularis failure, stiffness, glenoid failure, and late tears of the supraspinatus.[16,22,28,44,57,60]

Two of the major variables to consider when attempting to restore the native anatomy of the proximal humerus are the shape of the humeral head articular surface and the position of the humeral head in space. With regard to the shape of the humeral head, though most currently available prosthetic humeral head components are spherical, the natural shape of the humeral head has actually been shown to be ellipsoid or ovoid.[21,23,25-27,38,59] However, biomechanical studies have shown that elliptical prosthetic humeral heads allow for more external rotation of the shoulder and decreased eccentric glenoid loading compared to spherical prostheses.[29,30] With regard to the position of the humeral head, stemless designs have the theoretical advantage of more accurate positioning without the constraint of a diaphyseal stem.[23,47] In addition, stemless implants may also be easier to remove in a revision setting.[8] However, these benefits have not been consistently demonstrated in clinical practice.[49,62]

Both traditional humerus resurfacing and more recently ''stemless'' designs have been used successfully for canal-sparing shoulder arthroplasty, though published series in the United States generally focus on a younger patient population.[13,15] Recently, a stemless design unique both for its backside geometry and its ellipsoid articular shape was developed but clinical results have yet to be reported. The implant backside has a 4-plane undersurface that rests on a platform of 4 precision osteotomies made in a similar shape to a hip roof on a house (Fig. 1). This technique has been demonstrated in cadaveric and radiographic studies to be highly accurate in replicating the preoperative anatomy.[3,18] The design was inspired by the femoral component in total knee arthroplasty, which rests on dense bone just below the subchondral surface and demonstrates excellent longevity in patients over a wide age range in numerous long-term studies.[2,36,45] In order to address potential challenges encountered with a more conservative bone resection, a glenoid component with angled anchoring pegs that can be inserted from an oblique angle, in the direction of a deltopectoral incision, was developed.

Figure 1 Four-plane undersurface of the humerus implant, which rests on 4 corresponding prepared bony surfaces, and after implantation.

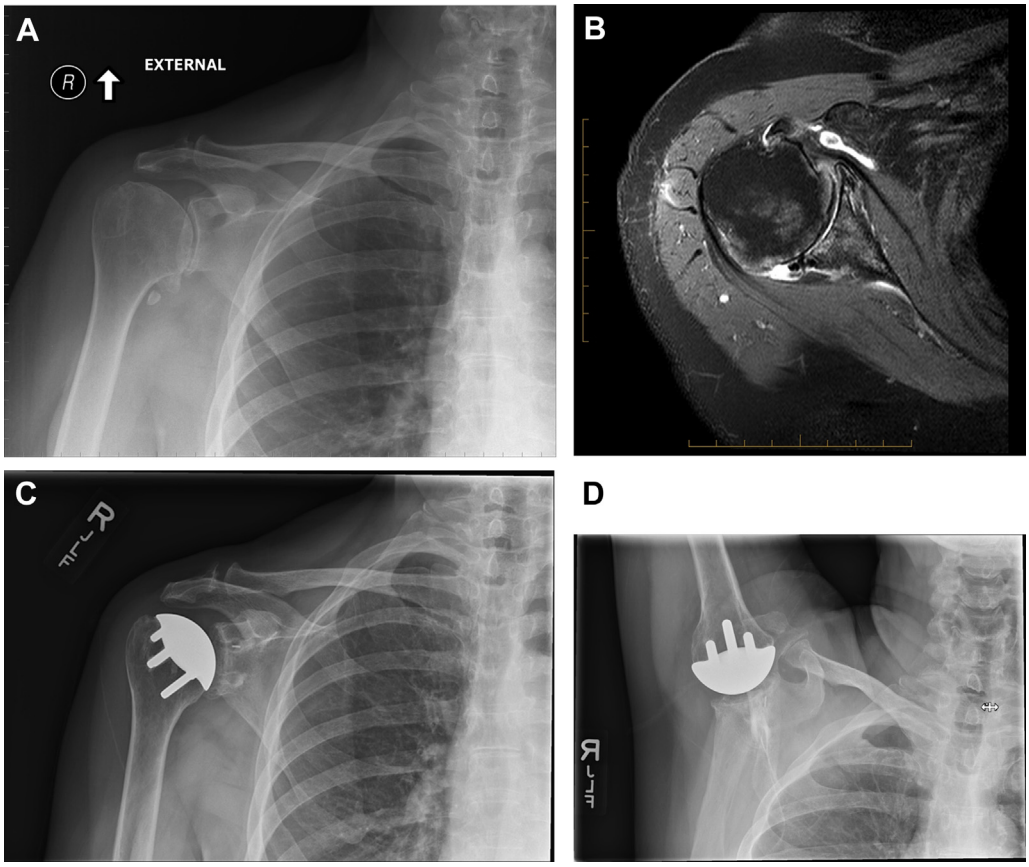

Figure 2 (**A** and **B**) Preoperative radiographs and magnetic resonance imaging (MRI) scan and (**C** and **D**) postoperative radiographs 28 months after arthroplasty in a study patient.

The purpose of this study was 2-fold: (1) to evaluate the early clinical outcomes of anatomic TSA with elliptical-shaped humeral implant and (2) to determine if a stemless device that rests on dense subchondral bone can be safely used in patients of more advanced age.

Materials and methods

This study was approved by our institutional review board. This is a retrospective case series of the initial cohort of 67 shoulders in 61 patients (6 bilateral) who underwent TSA using an ellipsoid stem-free humeral head and an all-polyethylene glenoid component between August 2016 and August 2017. Inclusion criteria were patients with moderate to severe glenohumeral joint osteoarthritis, inflammatory arthritis, or post-traumatic arthritis with an intact rotator cuff, regardless of patient age. Exclusion criteria were full-thickness rotator cuff tears diagnosed on MRI or marked posterior glenoid wear that, in the surgeon's opinion, required an augmented glenoid component or reverse shoulder arthroplasty. All anatomic TSA candidates in the practice, except those who met the exclusion criteria, over a 1-year period were treated in this manner.

Prior to surgery, all patients underwent nonoperative treatment for at least 3 months including activity modification, home exercises, and anti-inflammatory medication (unless contraindicated), and most patients underwent physical therapy and/or glenohumeral steroid injections.

The devices implanted at surgery were a CoCr ellipsoid humerus and all-polyethylene glenoid from the Catalyst CSR Total Shoulder System (Catalyst OrthoScience, Naples, FL, USA), which was approved for use in the United States by the FDA in 2016. The ellipsoid humeral head is a 1-piece CoCr humerus component with a radius of curvature in the anterior-posterior axis that is 93% of the radius of curvature in the superior-inferior axis, based on anatomic studies of the humeral articular surface, most notably by Iannotti[27] and other authors[21,23,38,59] (Fig. 2). The glenoid component is a 1-piece all-polyethylene implant with angled pegs that is inserted at 30° anterior to the glenoid articular surface. In contrast to traditional keeled and straight-pegged glenoid implants, which are inserted directly perpendicular to the normal glenoid articular surface, this new 30°-angled design allows for insertion with less posterior retraction of the humerus. Per the manufacturer's indications for use, both components were cemented in all cases. No procedures were aborted for bone quality or changed intraoperatively to stemmed anatomic or reverse arthroplasty.

Clinical analysis

Clinical evaluation included range of motion measurements performed using a goniometer to record active forward elevation,

external rotation with the arm adducted, and internal rotation measured to the vertebral spine level. Patient-reported outcome measures consisting of American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) score, Single Assessment Numeric Evaluation (SANE), visual analog scale (VAS), and Patient-Reported Outcomes Measurement Information System (PROMIS) physical and mental function[9] measures were recorded preoperatively and postoperatively at defined follow-up intervals. The ASES, SANE, and VAS scores were assessed at 1 and 6 weeks, and then at 3, 6, 12, and 24 months and at final follow-up. The PROMIS physical and mental function scores were assessed at 3, 6, 12, and 24 months and at final follow-up. Range of motion measurements and clinical outcome scores were also compared to the published references for the minimal clinically important difference (MCID) and substantial clinical benefit (SCB) in shoulder arthroplasty.[12,19,53,54,56]

Radiographic analysis

Preoperative radiographs were evaluated in all patients, and advanced imaging consisting of either computed tomography or magnetic resonance imaging was obtained in the majority of cases (n = 51). Per the modified Walch classification,[5] the glenoid morphology was graded as A1, A2, B1, B2, B3, C, or D.

Postoperatively, radiographs were obtained at 6 weeks and then annually. Radiographs were evaluated by a musculoskeletal radiologist for the presence of loosening, radiolucent lines, osteolysis, bone resorption, cortical thinning, adaptive changes, or change in position of any components. The Lazarus scale was used for evaluation of radiolucent lines on the glenoid.[33] The Lazarus scale was adapted for evaluation of the humerus to assess radiolucent lines around the pegs of the humeral component, a method previously used by other authors.[15] The humeral component was further evaluated by the method described by Habermeyer[20] and advocated by Denard[14] to evaluate for stress shielding under a stemless implant.

Surgical technique

Preoperatively, all patients received an interscalene block, general anesthesia, and a prophylactic intravenous antibiotic. Patients were positioned in a 60° beach-chair position, and a standard deltopectoral approach was used. A full subscapularis tenotomy was used in 63 cases, and a subscapularis-sparing partial subscapularis tenotomy as described by Savoie,[52] was used in 4 cases.

Surgical technique followed the manufacturer's technique guide. Once the humerus was exposed, osteophytes were removed, and a paper ruler was used to find the midpoint of the articular surface. A starting 3.2-mm guide pin was inserted at the midpoint using a pin guide, and using the circular reamer, 5-8 mm of proximal subchondral bone was removed, the thickness amount depending on the radius of curvature of the humeral anatomy. Next, the 4 planar undersurface cuts were made using an oscillating saw through the standard cut guides, and the 4 peg holes were drilled. Trials were placed onto the humerus, and the implant that best matched the size of the perimeter of the cut surfaces was selected. The trial implant was removed, a humeral cover was placed onto the cut surface to protect the humerus, and attention was then turned to glenoid preparation.

Glenoid exposure was obtained by placing the arm on a Mayo stand and was facilitated by placing the arm in neutral rotation. Retractors were placed posterior, anterior, and superior on the glenoid. The capsule was released from the glenoid anteriorly from 12-6 o'clock, and the anterior labrum was removed. In most cases, the posterior capsule was not released. A biceps tenotomy was performed in 28 cases, a soft tissue biceps tenodesis was performed in 11 cases, and the biceps tendon was left intact in 28 cases if glenoid access was straightforward and the biceps tendon had no visible pathology. Once adequate glenoid exposure was obtained, the glenoid was sized and the corresponding size reamer was used to smooth the glenoid articular surface. The glenoid reamer uses a ball-hex drive shaft that allows for polyaxial reaming from an angle requiring less posterior retraction of the humerus. In type A, B1, B3, and C glenoids, version correction was not performed, and emphasis was placed on preserving cortical bone stock.[15,28] The biconcave ridge in B2 glenoids was reamed until a single concave surface was achieved, essentially converting to a B3 shape without version correction. The chosen glenoid implant was inserted using third-generation cement technique.[4] After glenoid implantation, the humerus was washed with a pulse lavage and dried, and then cement was applied to the prepared surface of the humerus bone and to the underside of the implant. Excess cement was removed, the shoulder was reduced, and cement was allowed to harden. The subscapularis tenotomy was repaired with multiple No. 5 Ethibond figure-of-8 and Mason-Allen–type sutures. No additional local anesthesia was given at the operative site. No drains were used. Postoperatively, patients were placed in a standard sling. All procedures were performed by the lead author.

All patients were instructed to perform pendulum exercises starting on postoperative day 1. Patients were allowed to remove the sling while seated for eating and simple activities. On postoperative day 10, the staples were removed, and formal physical therapy was begun. The therapy protocol consisted of active-assisted range of motion exercises to 130° of forward elevation and 30° of external rotation for 4 weeks, then progressive active range of motion as tolerated. The sling was discontinued at 4 weeks.

Statistical analysis

Descriptive statistical analysis was performed, with categorical and continuous variables analyzed and reported using frequencies and means ± standard error, respectively. The Shapiro-Wilk test was used to assess data for normality and confirmed a normal distribution for all continuous variables. Paired and independent samples t tests were used to analyze normally distributed continuous variables. Fisher exact tests were used to analyze categorical variables. Statistical significance was set at $\alpha = 0.05$. A power analysis determined that the study was adequately powered to detect a difference in all reported values. In regard to the SANE, ASES, and PROMIS scores, the study was powered to 0.95 to detect the minimal clinically important difference. In regard to VAS score, the study was powered to 0.95 to detect a 3-point difference. In regard to range of motion measurements, the study was powered to 0.90 to detect a 20° improvement in forward elevation and a 17° improvement in external rotation. The study was powered to 0.80 to detect a 2–vertebral level change in internal rotation. All data were analyzed using SPSS Statistics Data Editor version 26 (IBM, Armonk, NY, USA).

Table I Patient demographics

Variable	Frequency	Percentage
Sex		
Female	34	54
Male	29	46
Laterality		
Left	32	50.80
Right	31	49.20
Age, yr		
≤70	25	39.70
>70	38	60.30
Prior surgery		
No	50	79.40
Yes	13	20.60
Glenoid morphology		
A1	20	39.20
A2	13	25.50
B1	3	5.90
B2	10	19.60
B3	3	5.90
C	2	3.90
D	0	0

Results

At the time of review, 2 patients were deceased, and 2 patients were lost to follow-up, leaving 63 shoulders in 57 patients who met inclusion criteria for final data analysis. The mean follow-up period was 30.5 ± 6.6 months (range of 24-41 months). There were 34 female shoulders (54%) and 29 male shoulders (46%). The mean age at surgery was 73.0 ± 5.9 years (range: 60-85 years). A total of 50 patients (79.4%) did not have any prior surgery on the ipsilateral shoulder examined in this study, 13 patients (20.6%) did have at least 1 prior surgical procedure. The diagnosis was osteoarthritis in 61 shoulders (96.8%), rheumatoid arthritis in 1 shoulder (1.6%), and post-traumatic arthritis in 1 shoulder (1.6%). Demographic data are summarized in Table I.

Range of motion

There were significant improvements in forward elevation, external rotation, and internal rotation (Table II). The mean preoperative forward elevation was 121° ± 27° and improved to 150° ± 17° ($P < .0001$) at final follow-up. The mean preoperative external rotation was 28° ± 20° and improved to 48° ± 10° ($P < .0001$) at final follow-up. The mean preoperative internal rotation was L3 and improved to L1 at final follow-up ($P < .001$). The average improvements of 28° in forward elevation and 20° in external rotation exceeded the threshold for MCID in anatomic shoulder arthroplasty (an improvement of 12° and 3°, respectively).[53]

Table II Range of motion

	Preoperative (mean ± SD)	Postoperative (mean ± SD)	*P* value
Forward elevation	121.3° ± 27.3°	149.5° ± 16.9°	<.001
External rotation	28.2° ± 19.6°	47.7° ± 9.7°	<.001
Internal rotation	L3 ± 3 vertebral levels	L1 ± 2 vertebral levels	<.001

Clinical outcome scores

There were both statistically significant and clinically meaningful improvements in all outcome score measures (ASES, SANE, VAS, PROMIS physical, and mental domain *T* scores) at 2 years postoperatively (Table III). The mean ASES score improved from 36.8 ± 20.1 preoperatively to 94.0 ± 11.7 at 24-month follow-up ($P < .001$). The mean SANE score improved from 39.8 ± 22.8 preoperatively to 93.0 ± 19.9 at 24-month follow-up ($P < .001$). The mean VAS score improved from 6.3 ± 2.8 preoperatively to 0.43 ± 1.6 at 24-month follow-up ($P < .001$). The mean PROMIS physical domain *T* score improved from 43.9 ± 5.5 preoperatively to 57.1 ± 8.5 at 24-month follow-up ($P < .001$). The mean PROMIS mental domain *T* score improved from 54.0 ± 7.5 preoperatively to 58.3 ± 7.6 at 24-month follow-up ($P = .026$).

There were significant improvements in ASES and SANE scores over preoperative scores at all time points. The improvements in ASES scores exceeded MCID and SCB criteria at 6 weeks postoperatively and at all time points thereafter (Fig. 3). The improvements in SANE scores exceeded MCID criteria at 6 weeks postoperatively and exceeded SCB criteria at 6 months and at all time points thereafter (Fig. 4). The improvements in VAS scores exceeded MCID criteria at 1 week postoperatively and exceeded SCB criteria at 6 weeks and at all time points thereafter (Fig. 5). There were statistically significant and clinically meaningful improvements exceeding MCID criteria in the PROMIS physical domain *T* score over preoperative scores at all time points. There was a statistically significant improvement in PROMIS mental domain *T* score over preoperative scores at 3, 6, 24, and 36 months. Improvements in PROMIS mental domain *T* score over preoperative scores exceeded MCID criteria at 12 and 24 months.

Complications

Complications were recorded in 3 patients. One patient ruptured his subscapularis doing pushups approximately 3 weeks postoperatively and underwent open subscapularis repair. One patient suffered a fall 5 months after surgery and had a periprosthetic glenoid fracture requiring removal of the glenoid component. Both of these patients continued to be followed in this study group for >2 years. One patient

Table III Clinical outcome scores

Outcome score	Preoperative score (mean ± SD)	Postoperative score (mean ± SD)							MCID	SCB
		1 week	6 weeks	3 mo	6 mo	12 mo	24 mo	36 mo		
ASES	35.7 ± 20.4	50 ± 12.6 *	74.4 ± 17.1*,†	85.0 ± 13.7*,†	89.1 ± 14.2*,†	91.8 ± 13.4*,†	94.0 ± 11.7*,†	93.9 ± 10.4*,†	21-point increase	37.6-point increase
SANE	39.4 ± 22.4	52.2 ± 28.6 *	69.6 ± 28.7*,‡	81.6 ± 23.8*,‡	90.0 ± 17.4*,†	92.7 ± 19.3*,†	93.0 ± 19.9*,†	96.9 ± 7.5*,†	28.8-point increase	50.2-point increase
VAS	6.4 ± 2.7	2.8± 3.0‡	1.3 ± 1.7*,†	0.88 ± 1.8*,†	0.67 ± 1.8*,†	0.42± 1.2*,†	0.43 ± 1.6*,†	0.55 ± 1.5*,†	1.4-point decrease	3.8-point decrease
PROMIS Physical Domain *T* score	43.5 ± 5.8			53.6 ± 8.4*,‡	54.9 ± 7.3*,‡	54.7 ± 6.2*,‡	57.1 ± 8.5*,‡	53.1 ± 7.8*,‡	4.0-point increase	n/a
PROMIS Mental Domain *T* score	53.6 ± 7.6			56.7 ± 9.0*	57.0 ± 7.5*	58.0 ± 6.7‡	58.3 ± 7.6*,‡	55.3 ± 9.0*	4.0-point increase	n/a

ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *SANE*, Single Assessment Numeric Evaluation; *VAS*, visual analog scale; *PROMIS*, Patient-Reported Outcomes Measurement Information System; *MCID*, minimal clinically important difference; *SCB*, substantial clinical benefit.

* Statistically significant difference from preoperative value ($P \leq .05$).

† Meets SCB difference from preoperative value.

‡ Meets MCID difference from preoperative value.

had late supraspinatus rupture and was revised to a reverse arthroplasty 1 year after surgery.

Radiographic results

Preoperative radiographs were obtained for all patients, and advanced imaging analysis for glenoid morphology was available for 51 of the 63 patients (80.1%) included in the final analysis. Glenoid morphology was characterized as A1 in 39.2%, A2 in 25.5%, B1 in 5.9%, B2 in 19.6%, B3 in 5.9%, and C in 3.9%. No patients were characterized as having type D glenoids.

Quality radiographs at final follow-up were available for analysis in 59 of 63 shoulders (93.7%). In evaluating the humerus implant using a modified Lazarus grading system[33] around the fixation pegs, 57 (96.6%) of humeral implants were grade zero (no lucency), 2 (3.4%) of humeral implants were grade 1 (incomplete radiolucency around 1 or 2 pegs), and zero implants showed grade 2, 3, 4, or 5 lucency.

Anteroposterior radiographs were further evaluated for stress shielding under the humerus implant per the zone method as described by Habermeyer.[20] One shoulder showed evidence of decreased density under the cranial part of the implant (zone A), and a second patient showed evidence of decreased density under the central portion (zone B). Both findings were seen on early and late radiographs and were not progressive. Both were in females with lower bone density, were not associated with radiolucent lines around the pegs, and had no impact on clinical outcome. No adaptive changes or bone resorption was seen along the medial calcar or the lateral cortex.

On the glenoid, 29 (49.2%) of glenoid implants were grade 0 (no lucency), 17 (28.8%) were grade 1 (incomplete radiolucency around 1 or 2 pegs), 12 (20.3%) showed grade 2 lucency (complete radiolucency around 1 peg), and 1 (1.7%) had a grade 3 lucency (complete radiolucency around both pegs <2 mm) per the Lazarus scale.[33] No glenoids were grade 4 (complete radiolucency around 2 pegs >2 mm) or grossly loose.

Secondary analysis was performed to assess if sex, age, history of prior surgery, or glenoid morphology had any association with postoperative range of motion, clinical outcome scores, or radiographic findings. With regard to sex, women had better postoperative internal rotation (T12 ± 2 vertebral levels), compared with men (L2 ± 2 vertebral levels) ($P = .001$) but no other significant differences in final outcomes. With regard to age, patients who were 70 years of age or younger achieved better postoperative forward elevation (156° ± 11° vs. 145° ± 19°, $P = .01$) and had higher PROMIS physical domain *T* scores (60.2 ± 7.2 vs. 54.9 ± 8.7, $P = .03$) and PROMIS mental domain *T* scores (61.9 ± 5.2 vs. 54.5 ± 9.0, $P = .004$) at 24-month follow-up, but no other significant difference in final outcomes. Glenoid morphology and prior shoulder surgery did not have any association with final range of motion, clinical

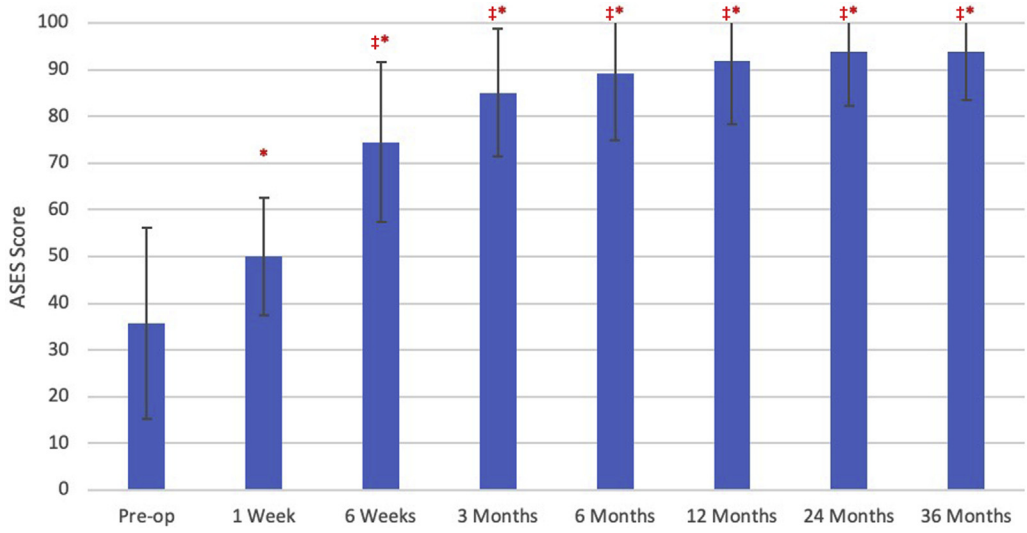

Figure 3 ASES scores. *Statistically significant difference from preoperative value ($P \leq .05$). ‡Meets SCB difference from preoperative value. *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *SCB*, substantial clinical benefit.

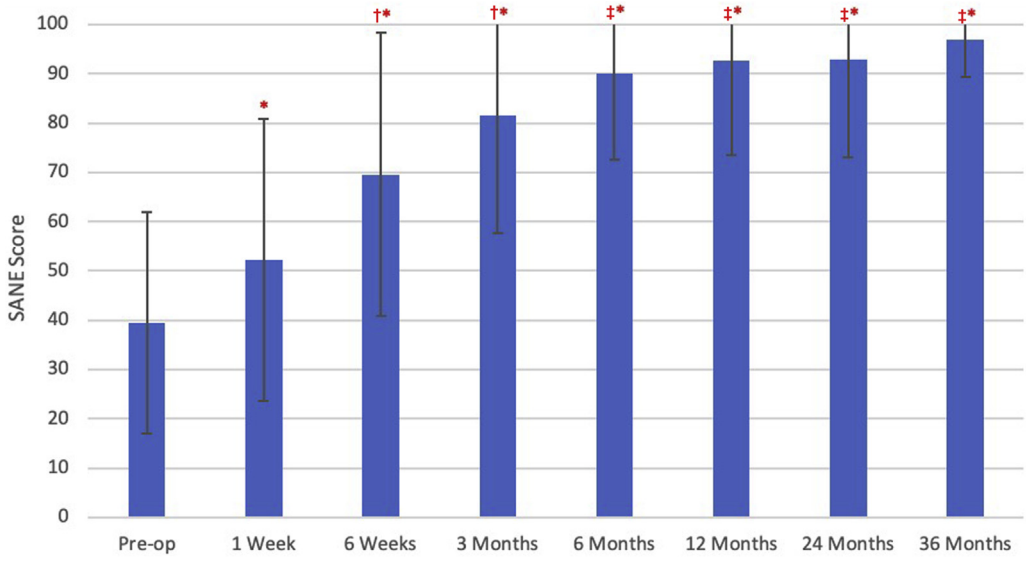

Figure 4 SANE scores. *Statistically significant difference from preoperative value ($P \leq .05$). †Meets MCID difference from preoperative value. ‡Meets SCB difference from preoperative value. *SANE*, Single Assessment Numeric Evaluation; *MCID*, minimal clinically important difference; *SCB*, substantial clinical benefit.

outcome scores, or evidence of radiographic loosening. There were no significant differences in postoperative clinical outcome score measures or range of motion in patients who had well-fixed glenoids (grade of 0) compared with patients who had glenoids with radiographic lucency around the pegs (grade 1, 2, or 3).

Discussion

The results of the current study demonstrate that a stem-free ellipsoid TSA can provide statistically significant and clinically meaningful improvements in range of motion and patient-reported outcomes in an older patient population than previously reported on, without signs of loosening, at minimum 2-year follow-up. Since the introduction of the original Neer prostheses,[41] the vast majority of anatomic shoulder arthroplasties have used a stemmed humeral implant with a spherical articulating surface. The persistence of this design is likely multifactorial. From a manufacturing standpoint, a spherical implant is easier to manufacture, and from a clinical standpoint, humeral implant survival has been predictable, with low rates of loosening.[7] Additionally, once third-generation stemmed humeral implants were developed,

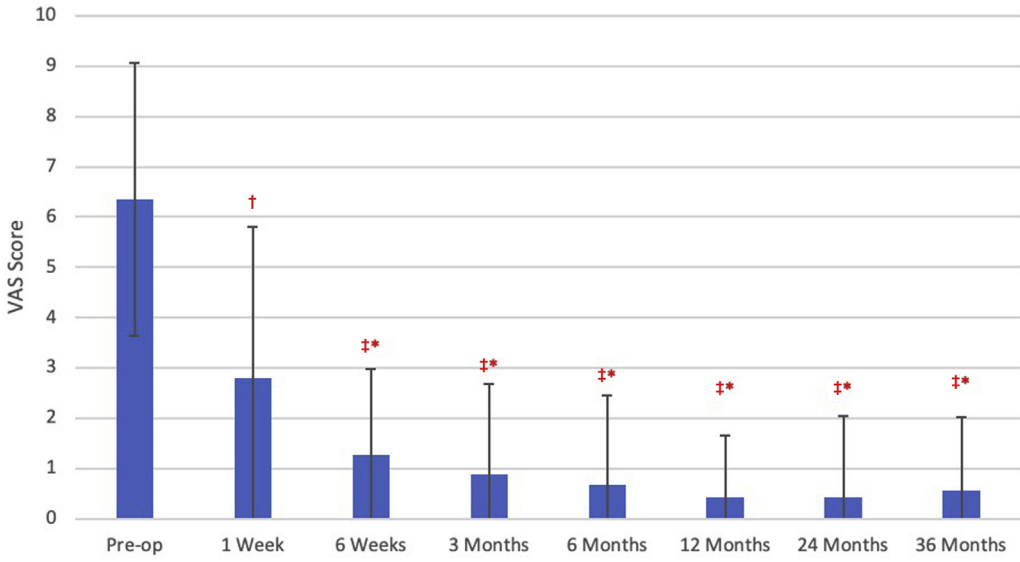

Figure 5 VAS scores. *Statistically significant difference from preoperative value ($P \leq .05$). †Meets MCID difference from preoperative value. ‡Meets SCB difference from preoperative value. *VAS*, visual analog scale; *MCID*, minimal clinically important difference; *SCB*, substantial clinical benefit.

a spherical head shape became a necessity to allow 360° rotation to position an offset-designed humeral head anatomically onto the morse taper of the stem.

Several anatomic studies have demonstrated that the true shape of the humeral articular surface is ellipsoid rather than spherical.[21,23,25-27,38,59] Subsequently, authors have reported highly accurate prosthetic fit in modeling studies using elliptical implants.[3,25] Additionally, studies have demonstrated improved range of motion in external rotation with decreased eccentric glenoid loading.[10,29,30] Therefore, there may be theoretical advantages to an ellipsoid-shaped humeral implant in TSA.

In the current study, patients treated with an elliptical humeral head implant had statistically significant and clinically meaningful improvements in their shoulder range of motion. The average improvement in forward elevation (28°) met the MCID of 12° and the average improvement in external rotation (20°) met the SCB of 12°.[53,54] We are unaware of any studies that have established an MCID or SCB threshold for internal rotation following anatomic shoulder arthroplasty, but the improvement in this patient cohort of 2 vertebral levels was statistically significant. These range of motion improvements are clinically comparable to findings seen at 2 years of follow-up with other modern stemless and stemmed shoulder arthroplasty systems.[6,13,15,35,55] However, without a direct comparison group, we cannot comment on if the elliptical humeral head component used in this patient cohort afforded any clinical benefit compared with other prosthetic designs.

Egger et al[15] reported a series of 31 shoulders that underwent TSA using a nonspherical, ovoid-shaped humerus resurfacing implant and an inlay glenoid in a single-surgeon series. Similar positive results were found. At a mean of 43 months, there were no revision surgeries or evidence of hardware failure of any components, with no difference between preoperative Walch type A and type B glenoid morphology.[15] The ovoid shape, resembling an egg, is very similar to an ellipsoid shape but it is not symmetric along its horizontal axis. The similarly reduced anteroposterior width of an ovoid implant allows for improved fit compared with spherical implants and may provide clinical benefits as well.[48]

There is significant heterogeneity in the clinical outcome scores used to evaluate function in the literature reporting on TSA. The average improvement in the ASES score of 57.2 in our cohort compares favorably to the average improvements (40.5, 53.2, 51) seen in comparable series and meta-analyses including both stemless and stemmed TSAs.[13,34,55] The improvement in VAS score in our cohort of 5.9 was comparable to that found in other similar series as well.[13,15,51]

Stemless implants have theoretical advantages of easier removal and do not require reaming or broaching of the humeral diaphysis. More accurate implant placement is also a potential advantage with stemless implants.[23,46] Resurfacing designs have also been found to be worse than standard stemmed implants in replicating the center of rotation, although this is controversial.[37,39] The surgical method in the current study uses instrumentation to match the height of bone resected to the implant thickness rather than relying on a freehand osteotomy. We previously reported on this technique as being reliable in replicating the preoperative anatomy and center of rotation in both a cadaveric specimen and in clinical practice.[3,17,18]

The mean patient age in this group was 73 years, which is older than the groups studied by Habermeyer, Egger, Churchill, and Berth, where the mean ages were

58, 59, 66, and 67 years, respectively.[6,13,15,20] In those studies, nonstemmed arthroplasty was shown to have very low rates of loosening over time. However, this low rate of loosening may be related to the improved bone quality in these younger cohorts of patients. The current study provides evidence that at short-term follow-up, this stem-free arthroplasty may safely be used in older patients with good clinical results. The multiplanar geometry of the undersurface of this prosthesis (Fig. 2) places the implant onto bone more proximally, which has been shown to have higher density and is recommended by other researchers as a preferred location for implant fixation.[1,31,50] Longer-term studies and continued surveillance of this group are necessary to validate this fixation strategy over time.

In the current short-term follow-up study, there was no evidence of humeral component loosening, and very few cases demonstrated evidence of radiographic changes. Because of the 4-pegged fixation elements, we chose to evaluate radiographs by the method proposed by Lazarus, which was intended for the glenoid side but has been adopted by others for the humerus.[15,33]

Because of the specific concerns for stress shielding in stemless implants, we additionally evaluated according to the method described by Habermeyer and advocated by Denard.[14,20] Only 2 patients demonstrated evidence of stress shielding, and it did not have an effect on clinical outcome. One potential explanation is that this prosthesis design allows the implant to rest on the entire cut surface of the humerus and partially load shares through the peripheral cortex as opposed to relying solely on metaphyseal fixation. The clinical significance of stress shielding under a stemless implant is unknown and could possibly be explained by a radiographic phenomenon rather than actual bone loss.[14,20,24,40] We did not include evaluation of axillary radiographs in this study as the majority were performed at one of several outside community radiology clinics and inconsistency in arm positioning did not allow for reliable grading with this method. This also limited our ability to evaluate ''recentering'' the glenohumeral joint.

Glenoid radiolucent lines were noted in 51.7% of patients, though no patients demonstrated clinically loose glenoids, and no additional surgery was performed for glenoid issues other than the patient who suffered a periprosthetic glenoid fracture. All-polyethylene glenoid components have shown variable rates of radiolucent lines as high as 90%, although the significance of nonprogressive lines is unknown.[11] Further surveillance of this glenoid implant in this cohort is ongoing.

The strengths of this study include the low rate of patients lost to follow-up, the use of multiple validated patient-reported outcome measures over multiple time intervals, and a standardized surgical technique and consistent postoperative protocol. We attempted to reduce selection bias by including all patients who were candidates for anatomic arthroplasty over a 1-year period in the practice regardless of age, except for those requiring an augmented glenoid component.

The limitations of this study include the relatively short duration of follow-up, lack of a comparison group or randomization, and a single-surgeon study design. Attempts were made to minimize interviewer bias: aside from range of motion measurements, all other outcome measures were patient-reported and collected directly into a tablet computer, and all radiographs were graded by an independent board-certified musculoskeletal radiologist. Despite those measures, however, bias may still exist. Another shortcoming was that our radiographic analysis included only anteroposterior radiographs, and no intra- or interobserver reliability measurements were calculated. Computed tomography could provide more information about potential glenoid loosening and recentering. Additional multicenter studies involving more surgeons are indicated to see if these outcomes can be reproduced.

Conclusions

At 2-year minimum follow-up, this stem-free ellipsoid humerus TSA provides statistically significant and clinically meaningful improvements in range of motion and patient-reported outcomes. The results of this study are encouraging evidence that this stemless design may be safely used in patients of more advanced age with glenohumeral arthritis. There was a low rate of complications and no implant failures in this study group. Although the early clinical results and the theoretical advantages of a more anatomic ellipsoid prosthesis are encouraging, large comparative studies with long-term follow-up are needed to corroborate these results.

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Disclaimer

Steven S. Goldberg has intellectual property related to the implants discussed in this article. Dr Goldberg is a paid consultant, owns stock in, and serves as Chief Medical Officer and a member of the Board of Directors of Catalyst OrthoScience.

Theodore A. Blaine owns stock and is a member of the Surgeon Advisory Board of Catalyst OrthoScience.

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