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Stemless total shoulder arthroplasty using a novel multiplanar osteotomy and elliptical humeral head results in both improved early range of motion and radiographic center of rotation compared with standard total shoulder arthroplasty

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Background: Restoration of the native glenohumeral anatomy is an important consideration in obtaining optimal range of motion (ROM) after anatomic total shoulder arthroplasty (TSA). Recently, a new stemless TSA system has been developed that uses both a multiplanar osteotomy (MPO), to improve the surgeon's ability to restore humeral center of rotation (COR), and an elliptical humeral head to improve ROM. The purpose of our study was to compare the difference in early postoperative ROM and restoration of radiographic COR, between this stemless TSA and standard stemmed TSAs.

Methods: This was a retrospective review of 50 consecutive primary TSAs performed by a single surgeon for glenohumeral osteoarthritis. The initial cohort underwent TSA with a standard stemmed humeral component with a circular humeral head (n = 25), whereas the subsequent cohort underwent stemless TSA using an MPO and an elliptical humeral head (n = 25). Postoperative data collection included active shoulder ROM as measured by goniometer, complications or revision surgery, and measurements of radiographic COR. Patients were assessed at 6 weeks, 12 weeks, 6 months, and 12 months after surgery. Change in COR was determined on postoperative radiographs by 2 fellowship-trained surgeons on 2 separate occasions. Intra- and interrater reliability were computed using intraclass correlation coefficients.

Results: For both mean forward flexion (FF) and external rotation (ER), there was greater ROM in the MPO-elliptical group at all time points, which was statistically significant. Mean change in FF favored the MPO group at 6 and 12 weeks and was statistically significant and above the minimal clinically important difference (MCID): 6 weeks, standard −15.8° vs. MPO 8.4° ($P = .004$); 12 weeks, standard 6.4° vs. MPO 29.2° ($P = .001$). Mean change in ER favored the MPO group at 6 weeks and was statistically significant: standard 5.4° vs. MPO 14.0° ($P = .02$). There were no revision surgeries in either group. Average change in COR was 2.7 mm in the standard group and 1.8 mm in the MPO-elliptical group, which was statistically significant ($P < .001$). Number of patients with >3 mm of difference in COR was 10 (40%) in the standard group and 1 (5%) in the MPO-elliptical group, which was statistically significant ($P = .002$). Average intraclass correlation coefficient was 0.75, indicating good reliability within and between surgeon measurements.

Conclusion: The use of a multiplanar osteotomy and elliptical humeral head was associated with improved early range of motion and better reproduction of the radiographic COR compared with standard stemmed TSA.

This study was approved by the Kaiser Permanente Northwest Institutional Review Board (IRB 1581845-1).

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Restoration of a patient's native glenohumeral anatomy is an important consideration in anatomic total shoulder arthroplasty (TSA) as it can influence both postoperative range of motion (ROM) and patient outcomes.[11,16,21,28,35] One consideration in reproducing the native humeral head anatomy is the mismatch between the design of the prosthetic humeral head and the true anatomy of the proximal humerus. Although the majority of prosthetic humeral head designs are circular in nature, anatomic studies of the proximal humerus have shown that the humeral head is ellipsoid, with the anterior-posterior distance being approximately 2 mm less than the superior-inferior distance.[15,18-20] It has been postulated that a nonanatomic circular prosthetic humeral head has the potential to over-tension the soft tissue envelope of the shoulder, leading to decreased postoperative ROM.[22] This hypothesis is supported by recent biomechanical studies, which have shown that the use of elliptical humeral heads can lead to improved ROM compared with standard circular heads in TSA.[22,23] Currently, the use of elliptical humeral heads in the United States is limited to 2 implant systems, and there are no comparative clinical studies in the literature comparing these implants to systems using standard circular humeral heads.

Another consideration in attaining optimal ROM after TSA is the accurate reproduction of the native center of rotation (COR) of the humeral head.[10,34] In recent studies, restoration of the native COR of the humerus has been shown to influence ROM in TSA, with one study showing that significant outliers (>2.7 mm) in the radiographic measurement of humeral COR are associated with decreased ROM.[34] Reproducing the native humeral COR in anatomic TSA is predicated on performing an accurate humeral head cut and appropriately placing an implant that reproduces the humeral anatomy. Historically, this has been difficult for shoulder surgeons to achieve, with some studies showing poor surgeon accuracy with regard to the ability to re-create the normal humeral anatomy.[1,5,6,14] Implant type has also been shown to be a factor in reproducing the native humeral COR, with stemless implants in general having more variability in accurately restoring the COR compared with stemmed implants.[1,5,6,14] Additionally, a recent study demonstrated that even when using CT guidance, surgeons were frequently unable to restore the anatomic COR with stemless arthroplasty.[14] Although the clinical effect of reproduction of the COR is unclear, the variable ability of stemless implants to re-create humeral anatomy in vivo is well described.[1,5,6,14]

Recently, a new stemless TSA system was approved by the US Food and Drug Administration that uses both a multiplanar osteotomy (MPO), to improve the surgeon's ability to restore humeral COR, and an elliptical humeral head. Specifically, this implant uses a series of cutting jigs to create chamfer cuts in the subchondral bone of the humeral head, followed by an elliptical humeral head implant that replaces the bone resected from those cuts. This technique is similar to the femoral component cuts in a total knee arthroplasty. In cadaveric studies, this technique has been shown to be accurate in reproducing the preoperative anatomy,[12] and in clinical studies has shown excellent accuracy in reproducing the radiographic humeral COR.[2,5] An additional clinical study demonstrated good patient-reported outcomes and longevity of the implant at 2 years.[13] However, there are currently no comparative studies on this new implant to validate the potential clinical benefit of either an elliptical humeral head or a multiplanar osteotomy on postoperative ROM in TSA.

The purpose of our study was to compare both the radiographic difference in humeral COR and clinical difference in early postoperative ROM between a new stemless TSA using an MPO and elliptical humeral heads, and standard stemmed TSA using circular humeral heads. Our hypothesis was that a stemless TSA using the combination of elliptical humeral heads and MPO would lead to improvement in both the postoperative ROM and radiographic COR compared to stemmed TSA with circular humeral heads.

Materials and methods

This study was approved by our institutional review board (IRB: 1581845-2). This is a retrospective case series of 50 consecutive primary anatomic TSAs performed by a single surgeon for glenohumeral osteoarthritis from 2016 to 2019. The initial cohort underwent TSA with standard stemmed humeral components with a circular humeral head and a cemented all-polyethylene glenoid component (n = 25). Four separate implants were used at different intervals in the initial cohort, including the DePuy Global Advantage, Wright Medical Aequalis Ascend Flex, the Lima SMR, and the Biomet Comprehensive. The subsequent cohort underwent stemless TSA using an MPO and an elliptical humeral head TSA and a cemented all-polyethylene glenoid component—Catalyst CSR (n = 25). Inclusion criteria were patients aged >18 years with moderate to severe glenohumeral osteoarthritis, inflammatory arthritis, or post-traumatic arthritis who had failed at least 3 months of conservative management and who had

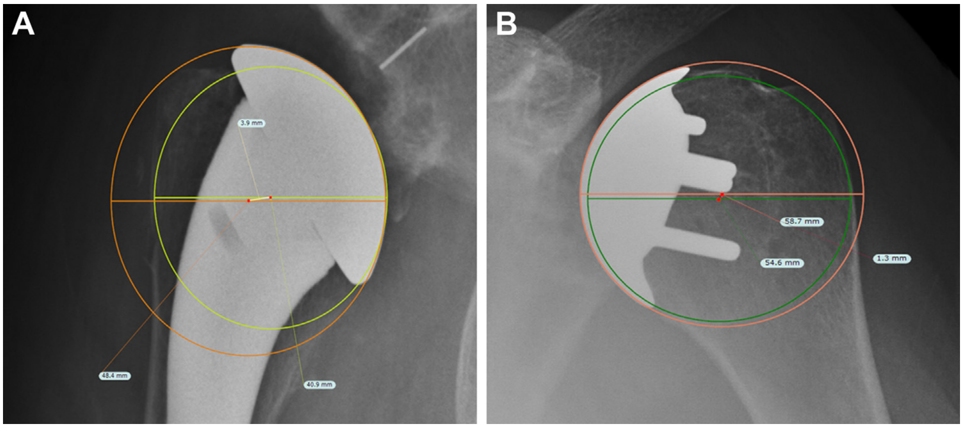

Figure 1 Measurement technique using a perfect fit circle technique. (**A**) Measurement of the ideal center of rotation (COR) in *yellow* and measurement of prosthetic COR in *orange*. The distance between the prosthetic and ideal COR was documented for all patients. (**B**) Measurement on the experimental (MPO-elliptical) group. *MPO*, multiplanar osteotomy.

undergone anatomic TSA. Exclusion criteria included patients with full-thickness rotator cuff tears or glenoid retroversion and posterior wear that would potentially require glenoid augmentation or reverse total shoulder arthroplasty, or patients with less than 12 months of follow-up.

At the time of surgery, all patients received general anesthesia with a single-shot interscalene nerve block. Surgery was performed via a deltopectoral approach. The subscapularis was managed either with a subscapularis peel followed by a double-row suture repair, or a lesser tuberosity osteotomy fixed with cerclage sutures depending on patient anatomy. In the postoperative period, all patients wore a sling and abduction pillow for 4 weeks when not performing physical therapy exercises. Physical therapy protocols were the same between the 2 cohorts of patients, and included immediate passive range of motion with limits for 4 weeks after initiation of active range of motion. Strengthening was allowed after 12 weeks.

Clinical analysis

Patients were assessed at 6 weeks, 12 weeks, 6 months, and 12 months after surgery. Clinical evaluation included active range of motion measurements performed using a standard 12-inch, double-armed, 360° goniometer. Patients were examined in the seated position for both forward flexion and external rotation, which has been shown to have good reliability for assessment of active ROM of the shoulder.[17] For evaluation of external rotation, the arm was held in adduction (0° abduction). Patients underwent belly press testing at 12 and 24 weeks after surgery, which was recorded as positive or negative. Patient charts were reviewed at the 12-month mark for postoperative complications or revision surgery.

Radiographic analysis

Change in COR was determined using the method of Youderian et al where a best-fit circle including the lateral cortex, medial calcar, and greater tuberosity insertion are used as a reference for the anatomic COR.[36] A circle is then drawn using the radius of curvature of the prosthetic humeral head, and the distance between the center of these 2 circles is the change in COR (Fig. 1). Overall change in COR from anatomic was recorded, and patients were subsequently subdivided into 2 groups based on change in COR, with $\geq$3 mm of change from anatomic considered an outlier.[1] The postoperative radiograph with the best-profile Grashey view of the humerus was chosen for the radiographic evaluation. Radiographs were reviewed by 2 fellowship-trained shoulder surgeons on 2 separate occasions.

Statistical analysis

Analyses were performed in Stata, version 15 (College Station, TX, USA). Continuous variables were explored through mean and standard deviation, whereas categorical variables were described through counts and percentage calculations. Comparisons between groups were made through 2-sample independent *t* tests for continuous variables and 2-sided Fisher exact tests for categorical variables. Analysis of variance was used for intragroup comparison among the radiographic measures of the 4 prosthetic types in the standard group. Intra- and inter-rater reliability were computed using intraclass correlation coefficients. Comparisons between groups were made through 2-sample independent *t* tests for continuous variables and 2-sided Fisher exact tests for categorical variables with statistical significance set at $P = .05$. An a priori power analysis was performed for the ROM measurements with a significance level (alpha) of .05 using a 2-sided 2-sample unequal-variance *t* test, indicating that a sample size of 25 per group was adequate to detect differences between groups consistent with published mean and standard deviation for minimal clinically important difference (MCID) in TSA.[31]

Results

Clinical results

There were no revision surgeries, complications, or losses to follow-up noted in either group. No patients in either group had a positive belly press test at 12 weeks or 6

Table I Demographic characteristics

	MPO	Standard	*P* value
Age, yr, mean ± SD	66.9 ± 8.9	68.3 ± 8.7	.58
Sex, n (%)			.15
Male	17 (68)	11 (44)	
Female	8 (32)	14 (56)	
Extremity, n (%)			>.99
Left	11 (44)	12 (48)	
Right	14 (56)	13 (52)	
ASA classification, mean ± SD	2.6 ± 0.6	2.5 ± 0.6	.65

SD, standard deviation; *ASA*, American Society of Anesthesiologists; *MPO*, multiplanar osteotomy.

Table II Forward flexion

	MPO	Standard	Difference	*P* value
Preoperation				
Mean FF	135°	130°	5°	.490
6 weeks				
Mean FF	143°	114°	29°*	**<.001**
Δ FF	+8°	−16°	24°*	**<.001**
12 weeks				
Mean FF	164°	137°	27°*	**<.001**
Δ FF	+29°	+6°	23°*	**<.001**
6 mo				
Mean FF	170°	157°	13°	**.005**
Δ FF	+35°	+27°	8°	.170
12 mo				
Mean FF	172°	160°	12°	**.004**
Δ FF	+34°	+32°	2°	.370

FF, forward flexion; *ΔFF*, change in forward flexion; *MPO*, multiplanar osteotomy.
Boldface indicates a *P* value with statistical significance.
* Indicates values above the minimal clinically important difference for anatomic total shoulder arthroplasty.

months. There were no statistically significant differences between the 2 cohorts in terms of age, sex, handedness, or American Society of Anesthesiologists score (Table I). Mean preoperative forward flexion (mFF) was 130.2° (± 25.1°) in the standard group and 134.8° (±21.1°) in the MPO group, which was not statistically significant ($P = .49$). Mean preoperative external rotation (mER) was 26.0° ± 11.2° in the standard group and 30.8° ± 12.6° in the MPO group, which was not statistically significant ($P = .16$).

Mean forward flexion was higher in the MPO group compared with the standard group at all time points, which was statistically significant (Table II). Mean FF was also above the MCID for anatomic TSA at 6 weeks and 12 weeks.[31] Mean change in forward flexion (ΔFF) was higher in the MPO group compared with the standard group at 6 and 12 weeks, which was statistically significant and above the MCID. Mean change in forward flexion was higher in the MPO group at 6 months and 12 months but did not reach statistical significance (Fig. 2). Mean external rotation was higher in the MPO group compared with the standard group at all time points, which was statistically significant. Mean change in ER (ΔER) between the 2 groups was statistically significant, favoring the MPO group at 6 weeks but not at other time points (Table III).

Post hoc power analysis of the ROM data indicated that we were likely underpowered to detect MCID with a sample size of 25 per group, this was due to the larger than expected standard deviation within the groups.

Radiographic results

In the standard group, there were no statistically significant differences in the radiographic measurements between the 4 prosthetic types ($P = .79$). Average change in COR from anatomic was 2.7 mm (±1.6 mm) in the standard group and 1.8 mm (±0.08 mm) in the MPO-elliptical group, which was statistically significant ($P < .001$). The number of patients with >3 mm of difference in COR was 10 (40%) in the standard group and 1 (5%) in the MPO-elliptical group which was statistically significant ($P = .002$). Average intraclass correlation coefficient was 0.75, indicating good reliability within and between surgeon measurements.

Discussion

The results of the current study demonstrate that stemless anatomic total shoulder arthroplasty using a multiplanar osteotomy and an elliptical humeral head results in both better ROM at 6 and 12 weeks and improved restoration of the radiographic center of rotation compared with standard stemmed TSA with a circular humeral head.

The clinical use of elliptical humeral heads is a relatively recent phenomenon in shoulder arthroplasty, with currently only 2 implant companies offering this as an option for TSA. There is, however, a significant body of research describing the potential benefits of elliptical humeral head design on the kinematics of shoulder function after shoulder arthroplasty.[4,22,23] Initial anatomic studies using cadaveric specimens described the native humeral head as ellipsoid, with an average humeral head diameter in the sagittal plane being 2 mm less than in the frontal plane.[18,20] Later computer modeling studies further confirmed that the radius of curvature of the humeral head was 1-2 mm smaller in the axial plane compared to the coronal plane.[15,19] Subsequent biomechanical studies have shown that the use of elliptical humeral heads can have a significant influence on glenohumeral joint kinematics. An initial cadaveric study by Jun et al[22] showed increased

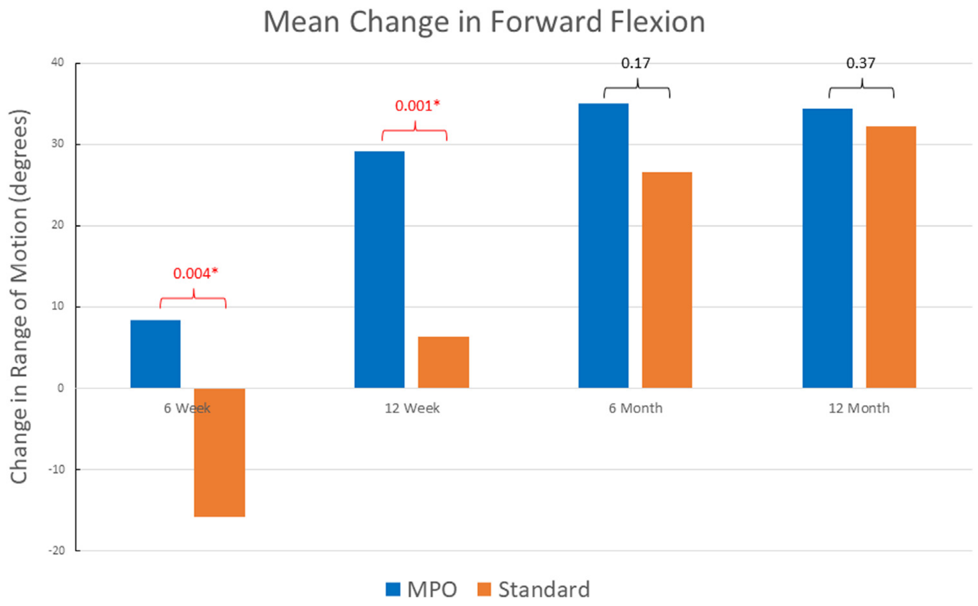

Figure 2 Mean change in forward flexion. *MPO*, multiplanar osteotomy. **P* value with statistical significance and above the minimal clinically important difference.

translation of spherical humeral heads compared to elliptical head and postulated that the use of spherical heads results in overstuffing of the joint with decreased range of motion and increased obligate translation of the humeral head. A subsequent study by this same group demonstrated that humeral head shape was a more significant determinate of glenohumeral kinematics than glenoid conformity.[23] An additional study by Buchler et al[4] demonstrated that the use of elliptical humeral heads limited eccentric loading and contact pressure on the glenoid compared to spherical humeral heads. However, a more recent study by Muench et al[27] failed to show a significant difference in terms of ROM between elliptical and circular humeral heads using a cadaveric model.

In addition to biomechanical studies, there have been 2 clinical studies using elliptical humeral head implants in TSA. Egger et al[8] demonstrated good patient-reported outcomes and function in a series of patients using elliptical humeral heads at an average of 42.6 months. An additional study from Goldberg et al[13] using elliptical humeral heads and a multiplanar osteotomy showed good outcomes and survival of an elliptical head implant at minimum 2-year follow-up. At this time, there are no published comparative clinical studies on circular vs. elliptical humeral head implants in the literature.

In addition to the use of elliptical humeral heads, the implant in the experimental group of this study uses a unique technique to position the humeral component. This technique involves the use of a central guide pin and a "plunge reamer" that sets the thickness of the humeral cut based on the diameter of the humeral head encountered by the reamer. In theory, this prevents the surgeon from overstuffing or undersizing the implant as the thickness of the implant is based on the diameter of the humeral head.[37] This is followed by a series of guided chamfer cuts on the humeral head similar to a total knee arthroplasty. The resultant MPO is then covered by an implant, which replaces only the amount of bone removed (Fig. 3). One of the theoretical benefits of this system is that because the surgeon is not making an approximation of the humeral neck cut, the ability to accurately reproduce the native humeral anatomy should be improved.[12] Additionally, because the reamer uses the humeral head diameter to

Table III External rotation

	MPO	Standard	Difference	*P* value
Preoperation				
Mean ER	31°	26°	5°	.060
6 weeks				
Mean ER	45°	31°	14°	**.001**
Δ ER	+14°	+5°	9°	**.020**
12 weeks				
Mean ER	58°	50°	8°	**.008**
Δ ER	+27°	+24°	3°	.260
6 mo				
Mean ER	61°	55°	6°	**.010**
Δ ER	+30°	+29°	1°	.360
12 mo				
Mean ER	62°	56°	6°	**.003**
Δ ER	+31°	+30°	1°	.370

ER, external rotation; *ΔER*, change in external rotation; *MPO*, multiplanar osteotomy.
Boldface indicates a *P* value with statistical significance.

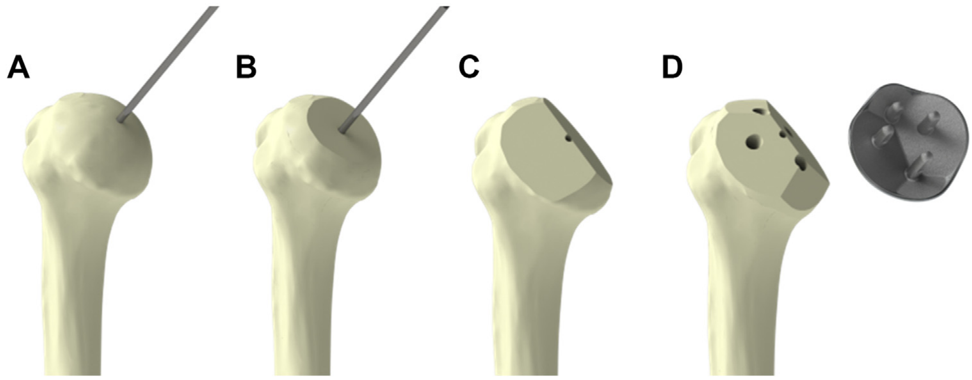

Figure 3 Diagram of the multiplanar osteotomy (MPO) technique. (**A**) Placement of central guide pin. (**B**) After the use of the plunge reamer to removal humeral bone. (**C**) After the use of the chamfer cutting guides. (**D**) Drill holes placed in the humeral head, and placement of the implant.

reproduce the native head height, this system can be used with moderately deformed and flattened humeral heads as long as the diameter of the humeral head is preserved.

Humeral component positioning has long been thought to correlate with outcomes in TSA,[11,16,21,28,29,32,35] and a variety of biomechanical and computer modeling studies have demonstrated that shifts in humeral head anatomy of only 2.5 mm can cause detrimental alterations in the humeral biomechanics.[3,9] This correlation has also been seen with larger size discrepancies between anatomic and final reconstruction, with some studies showing a 4-mm difference being detrimental,[16,35] and others a 5-mm difference.[29,32] Overall, a relatively small shift in the humeral head size or location from anatomic has been shown to be deleterious to postoperative shoulder function in TSA. Similarly, a surgeon's ability to reproduce the native humeral anatomy using stemless implants has been shown to be variable. Cox et al[6] demonstrated that restoration of anatomic parameters in TSA occurred significantly less with stemless implants compared with stemmed implants, concluding that a stemmed implant aids surgeons in reproducing humeral anatomy. Similarly, Grubhofer et al[14] studied if the addition of computerized 3D planning of the humeral head cut would improve restoration of the anatomic COR with stemless implants and demonstrated that even with CT guidance stemless implants had deviations >3 mm from anatomic 65% of the time. However, these results have not necessarily been seen in other studies of stemless implants.[24,30] A recent study involving the use of an MPO for placement of a stemless humeral implant has shown improved change in radiographic COR compared with stemmed implants, with the stemless group having an average change in COR of 1.7 mm vs. 2.8 mm in the stemmed group.[2] In this study, we found that 95% of the patients in the MPO group had a change in COR <3 mm, indicating that the MPO technique results in reliable reproduction of the humeral head COR, improving significantly on the results of stemless implants demonstrated in other recent studies.[6,14]

Improvement in the radiographic appearance of a TSA does not, however, equate to clinical improvement, and there are relatively few clinical studies specifically addressing the correlation between postoperative radiographic measurements and clinical outcome. Flurin et al[10] combined a variety of radiographic measurements after TSA into an Anatomic Reconstruction Index and demonstrated that an improved index results in better postoperative clinical outcomes in their case series. This is similar to Werner et al[34] who demonstrated that a change in prosthetic COR >2.7 mm from ideal was associated with worse patient outcomes and ROM after anatomic TSA. An additional study from Chalmers et al,[7] however, failed to find a correlation between change in COR from ideal and worse patient outcomes. In our study, patients in the MPO group had significantly less change in COR compared to the standard group as well as far fewer radiologic outliers, which was correlated with improved postoperative ROM at 6 and 12 weeks after surgery. However, we were unable to demonstrate a direct correlation between the millimeter change in COR and decreased ROM. This may be due to the relatively small number of patients included in this study or due to the effect of the elliptical humeral head on the postoperative range of motion. Given the implant in the study group used both an MPO and an elliptical head, determining which feature is the primary driver of improved range of motion is not possible in the current study design.

Strengths of our study include the inclusion of a standard stemmed control group, the use of multiple surgeons for the radiographic evaluation, and the interval assessment of ROM throughout the postoperative period. Additionally, this was a consecutive single-surgeon series of cases, which should limit sources of variability such as surgical technique or postoperative rehabilitation between the 2 groups.

Weaknesses of our study include a small nonrandomized sample size, short-term follow-up of 12 months, no reporting of patient-reported outcomes, inadequate power for ROM MCID evaluation, and no additional radiographic measurements other than change in COR. However, given that this study primarily focused on ROM and initial radiographic alignment, follow-up greater than 1 year may not be necessary.[26] Additionally, there was no direct evaluation of glenoid morphology, which can affect postoperative outcomes. However, all patients with glenoid wear that could not be managed with a standard glenoid implant were excluded, which should limit this as a confounding factor. Also, the use of goniometric measurement techniques for ROM assessment in this study can be associated with variability in intrarater reliability.[25,33] However, goniometric measurement may be more reliable than standard visual assessment of shoulder ROM, and we believe this technique is routinely used to assess patient ROM in the postoperative period.[33]

Conclusion

Stemless total shoulder arthroplasty using an MPO and an elliptical humeral head resulted in improved forward flexion at 6 and 12 weeks and improved external rotation at 6 weeks compared with standard stemmed TSA. However, these results are statistically equivalent between the groups at the 12-month follow-up. Use of a stemless TSA with an MPO and elliptical humeral head also improved restoration of the radiographic center of rotation compared with standard stemmed TSA with a circular humeral head.

Disclaimers:

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Conflicts of interest: Matthew D. Budge has a consultant agreement and has received stock from with Catalyst Orthoscience. Nathan Orvets has a consultant agreement with FH Ortho.

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