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Sex-related differences in stemless total shoulder arthroplasty

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Background: The use of stemless humeral implants for shoulder arthroplasty is becoming increasingly widespread. However, little is known about the difference in clinical, functional, and radiographic outcomes of stemless shoulder arthroplasty between men and women. Men and women do have reported differences in size, strength, and bone quality. As such, the purpose of this study was to evaluate sex-related differences in outcomes when using stemless humeral implants.

Methods: A retrospective review of 227 patients (men = 143 and women = 84) undergoing stemless shoulder arthroplasty was compared for sex-related differences. Clinical, functional, and radiographic outcomes were compared, including American Shoulder and Elbow Surgeons (ASES) scores, visual analog scale pain scores, range of motion, radiolucencies, operative data, implant data, and complications. Statistical analysis included descriptive statistics, t-tests, chi-square tests, and logistic regression.

Results: Preoperatively, men had a statistically significant greater range of motion of forward elevation ($P < .01$), external rotation (ER) at adduction ($P = .04$), ER at 90° abduction ($P = .03$), and baseline ASES scores ($P < .01$). At 2 years, there were no differences between men and women in ASES score ($P = .12$), visual analog scale pain score ($P = .74$), active ER ($P = .98$), implant migration, or radiolucencies ($P > .99$). Mean operating time was 9 minutes longer in male patients ($P < .01$). There was no significant difference in surgical complications, including dislocation, fracture, infection, or loosening. The three-year revision-free survival was 98.8% for women and 97.9% for men.

Conclusion: Patient sex is not predictive of postoperative functional outcomes after stemless shoulder arthroplasty. The operative time was significantly shorter in female patients, and there was no significant difference in surgical complications between men and women.

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Stemless implants for shoulder arthroplasty were first introduced in 2004 and have been growing in popularity since. The rationales for 'canal-sparing' implant designs are the preservation of bone stock, decreased risk of periprosthetic humeral fractures, and ease of revision.⁸ Stemless implants are associated with shorter operative times and decreased intraoperative blood loss when compared with conventional humeral stemmed implants.^{6,17,22} Because of these perceived benefits, stemless implants have been used in younger, active patients. Given these

implants are still relatively new, little is known about the effect of patient factors on clinical and functional outcomes of stemless components.

Anatomical differences between men and women may have implications when considering shoulder surgery. Male patients have significantly larger humeral heads than female patients.¹⁰ The cross-sectional area of the supraspinatus, infraspinatus, teres minor, and subscapularis is all significantly greater in men.¹ Volumetric measurements of the deltoid muscle are also significantly higher in men.¹⁹ With respect to bone morphology, the radius of curvature of the glenoid and humeral head is also significantly larger in men.¹⁰ These anatomical differences may affect implant sizing, as well as ease of surgical exposure. In addition, when utilizing stemless implants, the quality of proximal humeral bone may be important as it is required for implant fixation until bone

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on-growth or in-growth occurs. As it pertains to bone quality, the literature has reported that women >50 years old have a 4x higher rate of osteoporosis and a 2x higher rate of osteopenia than men.²

Gianakos et al examined the role of sex-specific analyses in orthopedic studies. The authors reported that in over one-third of orthopedic publications, that performed a sex-specific analysis, substantial differences in outcomes between male and female patients were identified.¹³ Baram et al investigated factors associated with revision after reverse shoulder arthroplasty from the Danish Shoulder Arthroplasty Registry.⁴ The authors reported that male sex was associated with a significantly higher 10-year cumulative reverse revision rate (6% for women and 13% for men). Presently, little literature exists on the analysis of sex-based differences in outcomes after stemless shoulder arthroplasty. As such, the purpose of this study was to evaluate preoperative and postoperative sex-based differences in patients undergoing stemless humeral implants during total shoulder arthroplasty.

Methods

A retrospective comparative study was performed utilizing prospectively collected data from 2 US Food and Drug Administration investigational device exemption studies (Biomet Comprehensive Nano and Zimmer Sidus Stem-Free Shoulder). The inclusion and exclusion criteria, operative procedures, and postop rehabilitation protocols were similar between the 2 investigational device exemption studies. A total of 227 stemless implants were recruited consecutively by 25 surgeons in 23 centers across the United States of America and Canada. A primary diagnosis of glenohumeral arthritis (Kellgren and Lawrence grade III or higher) was required for inclusion (see Table 1 for inclusion and exclusion criteria). Patients with acute trauma, infection, avascular necrosis, and previous reconstructive shoulder surgery were excluded. All patients were followed for a minimum of 2 years.

Surgical technique was performed as per the technical manual of the respective implants. All surgeons utilized a deltopectoral approach. Subscapularis management was conducted via subscapularis tenotomy (n = 111), peel (n = 65), or lesser tuberosity osteotomy (n = 50). One patient had incomplete data with respect to their subscapularis management. The humeral head was appropriately exposed and dislocated. The humeral head osteotomy was performed at the anatomic neck. The glenoid was prepared, and a cemented all-polyethylene glenoid component was inserted as per the implant technique guide. The proximal humeral metaphysis was subjectively evaluated to ensure the bone quality was amenable to stemless fixation. The metaphysis was prepared as per the technical manual, and a trial stemless implant was inserted. Trial humeral heads were sized for appropriate coverage of the humeral metaphysis and intraoperative stability after reduction. Final implants were confirmed and impacted in to position in a press fit manner. After the shoulder was reduced, subscapularis repair was performed and the incision was closed in layers. The patient was placed in a shoulder sling, and standardized postoperative rehabilitation was followed.

Patients were routinely followed up at 6 weeks, 3-6 months, 1 year, 2 years, and then annually. Clinical data collected at each visit include range of motion, American Shoulder and Elbow Surgeons (ASES) functional scores, visual analog scale (VAS) pain score, VAS instability score, and complications. The VAS instability score is a VAS where patients rate their subjective degree of shoulder stability, from 0 (very stable) to 10 (very unstable). Plain radiographs (anteroposterior and axillary views) were evaluated by 2 independent board-certified musculoskeletal radiologists. The radiographs were systematically analyzed for radiolucencies around the

Table 1
Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
22 years or older; skeletally mature	Avascular necrosis, shoulder infection, cuff tear arthropathy, chronic dislocation, massive rotator tear, severe instability
Able to provide informed consent	Previous shoulder surgery, contralateral shoulder replacement within 6 months
Glenohumeral arthritis with grade III or higher (as defined by Kellgren and Lawrence)	Prior ipsilateral shoulder fracture
Shoulder pain and/or loss of function for minimum of 6 months with a maximum ASES score of 40	Prisoner
Patients willing and able to comply with postoperative therapy as per protocol	Current alcohol and/or drug abuser
Patients willing and able to comply with follow-up schedule as per protocol	Inability to provide informed consent
	Sensitivity to implant materials
	Chronic renal impairment, vascular insufficiency
	Metaphyseal bony defect, insufficient glenoid or humeral bone stock inhibiting prosthesis fixation
	Pregnant

ASES, American Shoulder and Elbow Surgeons.

humeral and glenoid implants, implant migration or loosening, and joint subluxation.

Demographic data were analyzed using descriptive statistics. Sex-based comparisons were performed utilizing t-tests. Logistic regression models were run to evaluate intra-patient variability in outcome scores. Kaplan-Meier curves reported implant survivorship.

Results

Demographics

A total of 227 patients were enrolled (Table II). Eighty four (37%) were women, and 143 (63%) were men. The average age of the female cohort was 65 ± 10 years compared with 61 ± 9 years in the male cohort (P < .01). There was no difference in ethnicity, body mass index, hand dominance, or preoperative diagnosis between the male and female groups.

Clinical outcomes

ASES scores improved significantly in both men and women after surgery (Table III). The ASES score (P < .01) and VAS stability score (P = .03) were both significantly better after surgery. At 1-year follow-up, only the ASES score was significantly different between men (score = 92) and women (score = 88); however, at 2 years and onward, there were no longer any differences between sexes. The rate of improvement in ASES scores between men and women was similar at each time point. No differences were detected for VAS pain scores between men and women in either the preoperative or postoperative period.

Logistic regression models were run to assess possible factors influencing postoperative functional outcome scores. In a model featuring age, sex, and preoperative ASES scores as variables, only the preoperative ASES score was significantly associated with

Table II
Patient demographics.

Demographics	Female (n = 84)	Male (n = 143)	P value
Patient age	65 ± 10 (36-84)	61 ± 9 (33-85)	<.01*
BMI	31.8 ± 7.6 (18.1-53.8)	30.0 ± 5.3 (21.5-47.7)	.053
Hand dominance	Right: 76 (90.5%) Left: 12 (8.4%)	Right: 129 (90.2%) Left: 12 (8.4%)	>.99
Primary diagnosis	Ambidextrous: 1 (1.2%) Osteoarthritis: 82 (97.6%)	Ambidextrous: 2 (1.4%) Osteoarthritis: 138 (96.5%)	>.99
Ethnicity	Post-traumatic arthritis: 2 (2.4%) African American: 3 (3.6%) Asian: 1 (1.2%) Caucasian: 78 (92.9%) Undisclosed: 2 (2.4%)	Post-traumatic arthritis: 5 (3.5%) African American: 5 (3.5%) Asian: 1 (0.7%) Caucasian: 136 (95.1%) Latino: 1 (0.7%)	.40

BMI, body mass index.

Results for patient age, BMI, and hand dominance are reported as mean ± SD (range). Results for primary diagnosis and ethnicity are reported as n (percentage).

*denotes P values < 0.05.

Table III
Clinical and functional outcomes.

Outcome	Female (n = 84)	Male (n = 143)	P value
ASES score			
Pre-op	20.4 ± 11.2 (1.7-40.0)	24.8 ± 10.9 (0-40.0)	<.01*
1 yr	88.1 ± 14.6 (13.3-100.0)	92.4 ± 12.4 (20.3-100.0)	.02*
2 yrs	89.1 ± 15.0 (20.0-100.0)	92.3 ± 18.8 (25.0-100.0)	.12
VAS pain score			
Pre-op	8.1 ± 1.6 (4.0-10.0)	8.0 ± 1.4 (3.0-10.0)	.69
1 yr	0.6 ± 1.4 (0-9.0)	0.6 ± 1.3 (0-8.6)	.93
2 yrs	0.6 ± 1.5 (0-8.0)	0.7 ± 1.5 (0-8.0)	.74
VAS unstable score			
Pre-op	4.0 ± 3.9 (0-10.0)	5.0 ± 3.4 (0-10.0)	.03*
1 yr	0.3 ± 1.0 (0-7.0)	0.2 ± 0.7 (0-5.7)	.46
2 yrs	0.4 ± 1.5 (0-10.0)	0.6 ± 1.7 (0-10.0)	.42
Forward elevation (°)			
Pre-op	93 ± 29 (30-160)	108 ± 28 (45-180)	<.01*
1 yr	142 ± 26 (75-180)	153 ± 22 (80-180)	<.01*
2 yrs	146 ± 27 (60-180)	154 ± 22 (45-180)	.04*
ER, arm at side (°)			
Pre-op	20 ± 18 (-15-80)	25 ± 19 (-30-80)	.04*
1 yr	56 ± 18 (10-90)	58 ± 120 (10-118)	.36
2 yrs	58 ± 21 (0-169)	58 ± 21 (0-80)	.98
ER, arm at 90° of abduction (°)			
Pre-op	30 ± 28 (0-90)	39 ± 27 (10-90)	.03*
1 yr	73 ± 20 (0-100)	78 ± 16 (10-110)	.09
2 yrs	74 ± 21 (10-100)	77 ± 22 (0-175)	.35

VAS, visual analog scale; ER, external rotation; ASES, American Shoulder and Elbow Surgeons.

Results are reported as mean ± SD (range).

*indicates P values < 0.05.

improved postoperative ASES scores. In a logistic regression model with only age and sex as variables, neither was statistically significant.

Preoperatively, the male cohort reported greater range of motion than the female cohort (Table III). At baseline, active forward elevation (men 108° vs. women 93°; $P < .01$), active external rotation in adduction (men 25° vs. women 20°; $P = .04$), and active external rotation at 90° abduction (men 39° vs. women 30°; $P = .03$) were statistically significantly different. However, at 2 years' follow-up, all ranges of motion were similar between sexes, other than active forward elevation, which was significantly higher in men (men 154° vs. women 146°; $P = .04$).

Operative data and implants

The mean operating time for male patients was 104 minutes (range, 42-176 minutes), whereas the mean operating time for female patients was 95 minutes (range, 55-147 minutes). This was statistically significant ($P < .01$) (Table IV). There was no significant

difference in subscapularis management technique between men and women ($P = .20$). The mean implanted humeral head size for women was 44 mm (range, 40-50 mm) and for men was 50 mm (range, 42 to 58 mm). The most common glenoid polyethylene size for women was small (52%), followed by medium (47%). The most common glenoid component size in men was medium (55%), followed by large (44%). The larger glenoid sizes in men compared with women were statistically significant ($P < .01$). Because of differences in design, the metaphyseal component in the Sidus is smaller than the Comprehensive Nano. As such, statistical analysis comparing the humeral components between sexes was not performed.

Survivorship and complications

Kaplan-Meier survival curves were similar between men and women at 3 years. Three-year survival was 98.8% and 97.9% for women and men, respectively. Two cases were revised in female patients for postoperative rotator cuff tears (2.1% of women). There

Table IV
Operative and implant data.

Surgical data	Female (n = 84)	Male (n = 143)	P value
OR time	95.0 ± 20.6 mins	104.4 ± 27.3 mins	<.01*
Subscapularis management			
Tenotomy	43 (51.8%)	68 (47.6%)	.15
Peel	27 (32.5%)	38 (26.6%)	
LTO	13 (15.7%)	37 (25.9%)	
Subluxation			
1 yr	3 (3.8%)	4 (3.0%)	.71
2 yrs	2 (2.8%)	4 (3.2%)	>.99
Glenoid component size			
Large	1 (1.2%)	63 (44.1%)	<.01*
Medium	39 (47.0%)	78 (54.5%)	
Small	43 (51.8%)	2 (1.4%)	
Humeral head diameter (Sidus + Nano)			
(Sidus only) 40	2 (2.4%)	0	
42	32 (38.6%)	4 (2.8%)	
(Sidus only) 44	17 (20.5%)	4 (2.8%)	
46	28 (33.7%)	32 (22.4%)	
(Sidus only) 48	2 (2.4%)	9 (6.3%)	
50	2 (2.4%)	50 (35.0%)	
(Sidus only) 52	0	13 (9.1%)	
54	0	29 (20.3%)	
58	0	2 (1.4%)	
Humeral metaphyseal component diameter (Sidus + Nano)			
(Sidus) 24	8 (9.6%)	18 (12.6%)	
(Sidus) 28	27 (32.5%)	38 (26.6%)	
(Sidus + Nano) 32	14 (16.9%)	8 (5.6%)	
(Nano) 34	9 (10.8%)	22 (15.4%)	
(Nano) 36	12 (14.5%)	12 (14.5%)	
(Nano) 38	4 (4.8%)	31 (21.7%)	
(Nano) 40	0	26 (18.2%)	

LTO, lesser tuberosity osteotomy; OR, operating room.

Results are reported as n (percentage).

*denotes P values < 0.05.

Table V
Complications.

Complication	Female (n = 84)	Male (n = 143)	P value
Dislocation	2 (2.4%)	1 (0.7%)	.56
Fracture	1 (1.2%)	1 (0.7%)	.99
Infection	2 (2.4%)	4 (2.8%)	.99
Radiolucencies			
1 yr	1 (1.3%)	5 (3.7%)	.42
2 yrs	1 (1.4%)	3 (2.4%)	>.99
Subluxation			
1 yr	3 (3.8%)	4 (3.0%)	.71
2 yrs	2 (2.8%)	4 (3.2%)	>.99
Radiographic loosening (glenoid)	6 (7.1%)	2 (1.4%)	.054
Radiographic loosening (humerus)	0 (0%)	0 (0%)	-
Revision surgery	2 (2.1%)	3 (1.6%)	

Results are reported as n (percentage).

were 3 revision cases in men, including 2 for infection and one for subscapularis rupture (1.6% of men).

There was no significant difference in surgical complications between men and women (Table V). These included dislocation (P = .56), fracture (P = .99), and infection (P = .99). Plain radiographs did not reveal any difference in radiolucencies (P > .99) or subluxation (P > .99) at 2 years. Radiographic loosening of the all-polyethylene cemented glenoid component was higher in women than that in men, but this did not reach statistical significance (P = .054). There were zero reports of humeral stem loosening in both men and women.

Discussion

Stemless implants are becoming increasingly popular for their bone-sparing properties and relative ease of revision. As such, these

implants have been used for younger, more active patients who require shoulder arthroplasty. Short-term and mid-term studies for stemless implants show good outcomes that are comparable with stemmed implants.^{3,5,9,12,15,16,21,26} However, there is a paucity of literature as it pertains to sex-based difference in preoperative or postoperative outcomes for stemless implants.

Overall, our results showed no substantial differences in ASES scores between sexes. However, at 1 year, men did have significantly higher ASES functional scores than women. At 2 years of follow-up, however, the differences were no longer significant. Interestingly, the 1-year difference in ASES scores (6.3 higher in men) did not reach the minimal clinically important difference (MCID) threshold of 13.6, so this early difference is unlikely to be clinically important.²⁵ Men had significantly better active forward elevation at baseline (+15°), 1 year (+11°), and 2 years (+8°) postoperatively than women. These postoperative differences in

active forward elevation did not reach clinical significance (MCID = 12°).²⁵ Active external rotation only favored men at baseline, losing its significance at 1 year. This may suggest that women had improved gains in external rotation compared with men, but this was not statistically significant and was likely not clinically significant.

It is important to note that our male and female cohorts had significantly different preoperative scores. The mean ASES score in men was a mean of 4.4 points higher than that in women ($P < .01$); however, this difference was not clinically important. Logistic regression models were run to determine what preoperative factors influenced postoperative outcome scores. Models were run with baseline ASES scores, sex, and age as variables. Only baseline ASES scores were associated with improved outcome scores. Based on these models, the 1-year ASES scores favoring men are more likely to be attributable to the patients' baseline ASES scores, rather than patient sex or age. In addition, t-tests showed that the rate of improvement of ASES scores between men and women was similar ($P = .88$).

The total operating procedure times were significantly longer in men than those in women, taking a mean of 9 minutes longer ($P < .01$). Anecdotally, this may be explained by men generally having more muscular deltoids and pectoralis major muscles, resulting in longer exposure times for the humerus and the glenoid. In addition, men in general are larger than women and require slightly larger incisions, which can take longer to open and close. As one would expect, men in this study generally required larger-sized glenoid and humeral components. The Comprehensive Nano metaphyseal design is star-shaped with a highly porous coating. The Sidus metaphyseal design is a bone-sparing cross-shaped open fin design.

In our study, there was no significant difference in surgical complications between men and women. Okoroa et al suggested that men and women are prone to different types of complications after anatomic or reverse shoulder arthroplasty.²⁴ Their study noted women were likely to develop implant loosening and men were more likely to get a periprosthetic infection. In our study, there were zero reported cases of loosening of the stemless humeral component. This is especially important to mention, as in the general population, women do have a substantially higher rate of osteoporosis and osteopenia. Stemless implant time zero fixation has historically been a concern, and the present data show no difference in implant mid-term stability between men and women.

Previous studies have reported sex-based differences in stemmed anatomic total shoulder replacements and reverse shoulder replacements. In a retrospective study of stemmed anatomic implants, Matsen et al reported that preoperative shoulder function, physical function, mental health, and male gender were associated with better postoperative shoulder function.²³ Our study noted similar findings, but our logistic regression analysis revealed that sex was a confounding factor. Jawa et al evaluated gender-based differences in patient expectations in anatomic total shoulder arthroplasties.¹⁸ Although their male cohort was younger, the authors reported that men placed greater value on postoperative exercise and participation in sports than women. Women, on the other hand, reported that performing their daily routine and household chores as their top priority. Both sexes noted that the ability to sleep through the night as an important expectation.

A study by Friedman et al analyzed the rate of clinical improvement after reverse shoulder arthroplasty.¹¹ Women reported worse functional outcome scores (ASES, Simple Shoulder Test, and Constant) than men both preoperatively and postoperatively. The differences in the Constant score and SST score met the MCID threshold for a clinically important difference; however, the ASES score did not. There was no difference in the rate of

improvement between men and women. Men also had improved range of motion in abduction and passive external rotation compared with women. Wong et al also reported sex-based differences in the outcomes of reverse shoulder arthroplasty.²⁷ Although similar at baseline, men demonstrated better ASES functional scores after 2 years, but no difference in pain scores or range of motion. Length of hospital stay was similar between sexes.²⁷ A large, multicenter prospective study of both anatomic and reverse shoulder arthroplasty found that women had greater improvements in ASES and SST scores than men.²⁴ Although statistically significant, the difference was well below the MCID threshold and was not deemed clinically important.

The objective of our study was to evaluate sex-based differences in stemless shoulder arthroplasty. Our results are similar to previously published literature comparing men and women in stemmed total shoulder arthroplasty and reverse shoulder arthroplasty. In addition, the rate of improvement of functional outcome scores is similar between men and women. Overall, preoperative functional scores appear to be more relevant in predicting postoperative outcomes than patient sex.

A strength of this study is the large number of enrolled patients (227). Our 88% follow-up rate at 2 years postoperatively is excellent. Although it is a retrospective study, all data were collected prospectively. The multicountry, multicenter study design is a strength, as is the utilization of more than one stemless implant system. However, this study does have a number of potential limitations. A limitation is that the stemless implants were conducted by higher-volume arthroplasty surgeons, so the generalizability of this study may be limited. Another limitation is that our female and male cohorts were not equal. Our female cohort was older by a mean of 4 years, but our logistic regression analysis did not identify age as a predictor of postoperative outcome scores. This is in keeping with current literature, where women tend to be older at the time of primary shoulder arthroplasty surgery.¹⁴ At their preoperative baseline, our male group had a statistically significant, but not clinically important, higher mean ASES score. ASES scores are widely accepted as a reliable outcome test for various shoulder pathologies, including glenohumeral arthritis, rotator cuff disease, and shoulder instability.²⁰ In healthy adults, fortunately, age and gender have a negligible effect on baseline ASES scores.⁷

This study demonstrated that excellent clinical outcomes can be achieved with stemless implants, regardless of patient sex. Preoperative functional outcome scores are likely more predictive of postoperative function, rather than sex. Fortunately, there is no difference in complication rates using stemless implants between men and women.

Conclusion

This multicenter comparative study shows that patient sex is not predictive of postoperative functional or radiographic outcomes after stemless shoulder arthroplasty. Men and women may both benefit from stemless implants with an overall high survivorship with a low rate of migration or loosening. Women did have a significantly shorter operative time. In addition, there was no significant difference in surgical complications between men and women using stemless humeral implants.

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