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No difference in range of motion in reverse total shoulder arthroplasty using standard or constrained liners: a matched cohort study

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Background: Prosthetic instability is one of the most common short-term complications following reverse total shoulder arthroplasty (RTSA). Numerous strategies exist to attempt to mitigate this complication, including utilization of constrained polyethylene humeral liners. A concern of constrained humeral liners is that they may come at the expense of restricted rotational range of motion (ROM). The purpose of the present study is to compare range of ROM and patient-reported outcomes (PROs), and satisfaction among matched cohorts using constrained vs. unconstrained liners after RTSA.

Methods: A multicenter shoulder arthroplasty registry was retrospectively reviewed to identify patients with two-year clinical follow-up after RTSA with constrained liners used at the surgeon's discretion. All patients had the same inlay humeral prosthesis with a 135° neck shaft angle. This study cohort was matched 1:2 to control patients who underwent RTSA with standard liners based on age, sex, total glenoid-sided lateralization, glenosphere diameter, and surgery performed on the dominant arm. Improvement in PROs and ROM was compared between groups.

Results: Twenty-two patients were identified who underwent RTSA with a constrained humeral liner; these were compared to 44 matched patients with standard liners. The groups were found to have no notable differences in demographics, baseline PROs and ROM. At two years postoperatively, both cohorts demonstrated improvements in all PROs without statistically significant differences between the two groups. There were no differences between groups in improvement in any ROM measure, including forward flexion (constrained: 54°, standard: 57°, $P = .771$), external rotation at the side (constrained: 42°, standard: 41°, $P = .906$) or internal rotation at 90° of abduction (constrained: 24°, standard: 20°, $P = .587$).

Conclusions: For an inlay humeral prosthesis with a 135° neck shaft angle, utilization of a constrained liner for RTSA demonstrates no significant difference in ROM or PROs compared to a well-matched cohort of patients who underwent RTSA with a standard polyethylene humeral liner. These are reassuring data for using constrained liners when there is intraoperative concern for prosthetic instability.

Reverse total shoulder arthroplasty (RTSA) continues to gain popularity as a versatile surgery that effectively manages many different shoulder pathologies including primary osteoarthritis, rotator cuff arthropathy, revision arthroplasty, malunion, nonunion, and four part proximal humerus fractures.[11] Expanding surgical indications does not happen without the risk of complications. Although improving with modern prosthesis designs and improved surgical techniques, complication rates for RTSA have historically been reported to be as high as 70% with increased complications noted in inexperienced surgeons.[14,18] The most common complications include scapular notching, periprosthetic infection, glenoid loosening, acromial fracture, deltoid weakness and fatigue, and periprosthetic instability.[5]

Periprosthetic instability is one of the most common early complications following RTSA, with an incidence up to 30% postoperatively.[4,19] There are several risk factors associated with instability including the indication for surgery, soft tissue

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tensioning, prosthesis design, bony deficiency, obesity, subscapularis integrity, and biomechanical factors such as bony impingement and implant positioning.[8,10] To combat these risk factors, implant design characteristics have been modified to improve stability.[3] One method for improving stability is by using a constrained or retentive polyethylene liner which increases the humeral cup depth with a higher peripheral rim providing more contact area around the circumference of the glenosphere.[3] Liner depth has proven to be one of the most important factors for stability in RTSA behind joint compressive force and can be a preferred method for increasing stability intraoperatively.[12]

Although increased prosthetic stability has clear benefits, the conceptual concern about using constrained liners is postoperative impingement and theoretical decrease in range of motion.[13] To date, there is limited literature investigating the clinical consequences of constrained liner usage. Accordingly, the purpose of the present study was to compare range of motion (ROM) and patient-reported outcomes (PROs) following RTSA using a constrained polyethylene liner to a matched cohort of patients who underwent RTSA with a standard polyethylene liner. We hypothesized that at two years postoperatively, ROM in forward flexion and internal/external rotation would be decreased in the constrained liner cohort but PROs would be comparable to the matched cohort using standard liners.

Materials and methods

Database and study patients

A prospective multi-institutional registry of patients undergoing RTSA was queried to retrospectively identify patients for inclusion in the present study. Approval from our institutional review board was obtained. Inclusion criteria for the study group were 1) RTSA with a constrained polyethylene liner, 2) baseline ROM measurements and PROs, and 3) minimum two-year postoperative PROs and ROM measurements. Exclusion criteria were as follows: 1) RTSA performed for an acute or chronic proximal humerus fracture, 2) RTSA performed as a revision, including revision of hemiarthroplasty, anatomic total shoulder arthroplasty or RTSA, or 3) worker's compensation. Additionally, patients with any glenoid bone grafting or that utilized an augmented baseplate were excluded. All constrained liner patients that met the inclusion and exclusion criteria were analyzed. Control patients meeting the same criteria, but implanted with a standard polyethylene humeral liner, were identified in the same database and matched 2:1 to study patients based on the following criteria: 1) age, 2) sex, 3) dominant arm surgery, 4) total glenoid lateralization, 5) glenosphere diameter, and 6) total humeral lateralization (combined polyethylene and humeral spacer thickness). 2:1 matching was utilized because additional matching cycles were found to not have sufficient potential control patients for a full additional matched cohort. In total, 317 patients at 11 sites undergoing RTSA were identified, of which 22 had constrained liners and met inclusion and exclusion criteria.

Baseline data

The database was queried for the following baseline and demographic data: age (years), sex, body mass index, arm dominance, tobacco use, and diabetes mellitus. The following important implant variables were also recorded, all of which were part of the matching algorithm: 1) total glenoid metallic lateralization, including the baseplate and glenosphere lateralization, 2) glenosphere diameter, and 3) total humeral lateralization (combined polyethylene and humeral spacer thickness).

All ROM data were obtained according to a prescribed study protocol at the individual sites utilizing a goniometer. The following baseline ROM data were obtained: active forward flexion (FF), active external rotation at side (ER0), active external rotation with 90 degrees of abduction (ER90), active internal rotation measured as a spinal level (IRspine), and active internal rotation at 90 degrees of abduction (IR90). The following baseline PRO data were queried for all patients: 1) visual analog scale (VAS) pain score, 2) Western Ontario Osteoarthritis of the Shoulder (WOOS) index score, 3) Veterans RAND 12 (VR-12) mental score, 4) American Shoulder and Elbow Surgeons (ASES) score, and 5) the Constant-Murley Score. Finally, the following baseline strength measurements were obtained using a manual muscle testing dynamometer in pounds, taking the average of three independent measurements: 1) Constant-Murley strength, 2) external rotation strength, and 3) modified belly press strength.

Surgical technique

Eleven surgeons contributed patients to this study, with slight variations in technique. Utilizing a deltopectoral approach, the biceps tendon was either tenodesed or tenotomized. The subscapularis was managed per the surgeon's preference (peel; $n = 16$ or tenotomy; $n = 6$) followed by a 135° humeral head cut. After appropriate glenoid exposure was obtained, the glenoid was prepared using sequential reaming steps per the manufacturer's recommended technique, and then a baseplate was implanted (Universal Baseplate or Modular Glenoid System; Arthrex, Inc., Naples, FL, USA). Baseplate lateralization, glenosphere lateralization, and glenosphere diameter were at the surgeon's preference, typically decided upon based on patient age, sex, preoperative planning, and glenoid coverage. After press-fitting the 135° inlay stemmed humeral component (Univers Revers or Revers Apex System, Arthrex Inc., Naples, FL, USA), subsequent increases in trial polyethylene humeral liners and metallic humeral spacers were added as needed. Utilization of a constrained or standard humeral liner was determined by the operative surgeon based on intraoperative stability testing. For this implant system, the constrained liner has an additional 2 mm of depth. The subscapularis was managed based on surgeon's preference, tendon mobility, and tissue quality.

Outcomes and statistical analysis

For patients in both the study and matched control cohorts, two-year ROM, PRO, and strength outcomes were collected. Comparisons of continuous variables (mean age, body mass index, PROs, ROM, and strength) were performed using Student's t tests. Comparisons of categorical variables (sex, dominant arm, tobacco use, diabetes mellitus, and diagnosis) were performed using chi-squared tests. All statistical analyses were performed using SPSS version 28 (IBM, Armonk, NY, USA). $P < .05$ was considered significant for all comparisons. A power analysis was performed to assess if the proposed study size, although a sample of opportunity, was sufficient. To detect a 10° difference in active external rotation between the two groups, assuming a standard deviation of 10°, 2:1 enrollment of controls: study patients and alpha = 0.05, 12 patients were needed in the study group and 24 patients in the control group to achieve a power of 80%.

Results

Baseline data

Twenty-two patients underwent RTSA with a constrained liner and met all the inclusion/exclusion criteria. These study patients

Table I
Baseline characteristics of patients.

Variable	Constrained liner (n = 22)		Matched unconstrained (n = 44)		*P* value
Patient demographics					
Age: years (mean, SD)	69.1	8.3	69.1	8.2	1.000
Sex: male (n, %)	7	31.8	14	31.8	1.000
BMI: kg/m^2 (mean, SD)	32.4	7.3	29.9	4.8	.100
Dominant arm: yes (n, %)	11	50.0	22	50.0	1.000
Tobacco use: yes (n, %)	1	4.5	2	4.5	1.000
Diabetes: yes (n, %)	2	9.1	2	4.5	.466
Surgical indications					
Rotator cuff tear arthropathy (n, %)	14	63.6	26	59.1	.722
Glenohumeral osteoarthritis (n, %)	4	18.2	10	22.7	.670
Irreparable rotator cuff tear (n, %)	4	18.2	8	18.2	1.000
Implant variables					
Glenosphere diameter					
33 mm (n, %)	7	31.8	14	31.8	1.000
36 mm (n, %)	6	27.3	12	27.3	1.000
39 mm (n, %)	6	27.3	12	27.3	1.000
42 mm (n, %)	3	13.6	6	13.6	1.000
Glenoid metallic lateralization					
0 mm (n, %)	2	9.1	4	9.1	1.000
2 mm (n, %)	0	0.0	0	0.0	1.000
4 mm (n, %)	11	50.0	22	50.0	1.000
6 mm (n, %)	4	18.2	8	18.2	1.000
8 mm (n, %)	5	22.7	10	22.7	1.000
	Mean	SD	Mean	SD	
Baseline PROs and ROM					
VAS pain	1.0	1.5	1.4	2.5	.493
ASES	78.7	14.4	82.2	20.5	.477
WOOS	81.4	19.0	84.1	21.3	.617
SANE	76.5	24.1	77.3	23.9	.899
VR-12 mental	46.7	11.2	54.5	8.3	.002
Constant	25.6	14.4	31.8	15.2	.117
Active FF (degrees)	81	41	92	36	.268
Active ER at Side (degrees)	23	19	30	21	.193
Active ER at 90 (degrees)	19	27	25	28	.410
Active IR (spinal level)	Sacrum	3	L5	2	.112
Active IR (at 90 abd)	18	22	21	23	.614
Baseline strength measures					
Constant-Murley (kg)	1.45	4.35	2.09	1.86	.409
External rotation strength (kg)	2.49	1.18	3.31	2.27	.119
Belly press strength (kg)	2.77	1.72	3.45	1.77	.142

BMI, body mass index; *PROs*, patient-reported outcomes; *ROM*, range of motion; *SD*, standard deviation; *VAS*, visual analog scale; *ASES*, American Shoulder and Elbow Surgeons; *WOOS*, Western Ontario Osteoarthris of the Shoulder; *SANE*, single assessment numeric evaluation; *FF*, forward flexion; *ER*, external rotation; *IR*, internal rotation.

were compared to 44 matched control patients who underwent RTSA with a standard liner. The mean age of patients in both groups was 69.1 years. Thirty-two percent of patients were male, 4.5% of patients were smokers, and dominant arm surgery was performed on 50% of the patients. There were no differences between the two groups in any of the baseline demographic or implant variables, indicating successful match (Table I).

Baseline ROM and PROs were similar between groups, with the exception of the VR-12 mental score, which was lower in the constrained liner cohort (46.7 ± 11.2) compared to controls (54.5 ± 8.3, $P = .002$). There were no differences in baseline strength measures between the two groups (Table I).

Range of motion

There were no differences in the final 2-year ROM measurements between groups (Table II). There were no differences between the two groups at two years postoperatively in improvement in active FF, active ER0, active ER90, active IRspine, and active IR90. (Table III)

Patient-reported outcomes

Overall, there were minimal differences between the two groups in final two-year PROs , with the exception of the VR-12 mental score, which was significantly higher in the control group ($P = .002$) (Table II). The change in VAS pain score from baseline was not different between groups (−4.0 ± 3.1 constrained; −4.5 ± 3.1 standard; $P = .548$). There were no differences in the improvement in any of the remaining assessed PROs from baseline between the two groups, including ASES ($P = .225$), WOOS ($P = .668$), SANE ($P = .990$), Constant ($P = .766$), and VR-12 Mental ($P = .416$). (Table III)

Strength

The final ER strength was higher in the control group compared to the constrained liner group (5.44 kgs vs. 3.99 kgs, $P = .002$) (Table II). There were no differences in the improvement of any of the three strength measures from baseline between study and control patients ($P > .05$ for all comparisons) (Table III).

Table II
Two-year clinical outcomes.

Variable	Constrained liner (n = 22)		Matched unconstrained (n = 44)		*P* value
	Mean	SD	Mean	SD	
DSB					
VAS pain	1.0	1.5	1.4	2.5	.493
ASES	78.7	14.4	82.2	20.5	.477
WOOS	81.4	19.0	84.1	21.3	.617
SANE	76.5	24.1	77.3	23.9	.899
VR-12 mental	46.7	11.2	54.5	8.3	.002
Constant	62.5	9.8	65.4	13.8	.382
Range of motion					
Active FF (degrees)	133	19	143	21	.065
Active ER at Side (degrees)	40	23	45	12	.249
Active ER at 90 (degrees)	56	22	64	27	.233
Active IR (spinal level)	L4	4	L4	3	1.000
Active IR (at 90 abd)	39	23	38	22	.864
Strength					
Constant-Murley (kg)	3.22	1.59	4.17	2.09	.064
External rotation strength (kg)	4	1.36	5.44	1.91	.002
Belly press strength (kg)	4	2.68	4.76	2.4	.241

SD, standard deviation; *VAS*, visual analog scale; *ASES*, American Shoulder and Elbow Surgeons; *WOOS*, Western Ontario Osteoarthris of the Shoulder; *SANE*, single assessment numeric evaluation; *FF*, forward flexion; *ER*, external rotation; *IR*, internal rotation.

Table III
Change in clinical outcomes from baseline.

Variable	Constrained liner (n = 22)		Matched standard (n = 44)		*P* value
	Mean	SD	Mean	SD	
Clinical outcome measures					
VAS pain	−4.0	3.1	−4.5	3.2	.548
ASES	38.0	22.0	45.7	25.0	.225
WOOS	48.1	23.0	51.0	27.0	.668
SANE	49.7	36.4	49.8	29.3	.990
VR-12 mental	1.6	14.4	4.2	10.9	.416
Constant	37.8	14.3	36.7	14.0	.766
Range of motion					
Active FF (degrees)	54	42	57	38	.771
Active ER at Side (degrees)	21	14	16	15	.197
Active ER at 90 abd (degrees)	42	29	41	34	.906
Active IR (spinal level)	−2	3	−2	3	1.000
Active IR at 90 abd (degrees)	24	30	20	27	.587
Strength					
Constant-Murley (kg)	2.86	1.81	2.40	2	.476
External rotation strength (kg)	1.63	1.45	2.49	2	.077
Belly press strength (kg)	1.27	2.22	1.81	2.63	.408

SD, standard deviation; *VAS*, visual analog scale; *ASES*, American Shoulder and Elbow Surgeons; *WOOS*, Western Ontario Osteoarthris of the Shoulder; *SANE*, single assessment numeric evaluation; *FF*, forward flexion; *ER*, external rotation; *IR*, internal rotation.

Complications

One patient in the constrained liner group had radiographic loosening of the glenoid component documented, but did not require revision surgery by the two-year postoperative time point. There was radiographic evidence of haloing around the peripheral screws but no baseplate failure or clinical evidence of infection. There were no complications in the control group. Specifically, there were no acromial stress fractures or postoperative instability events in either group.

Discussion

The present study demonstrates that RTSA with constrained liners achieve similar ROM, PROs, and strength at two years postoperatively to a matched cohort of patients who underwent RTSA with standard liners in a 135° inlay humeral system. While constrained liners are not frequently necessary, but when required for stability purposes, they do not appear to have a significant postoperative clinical impact.

A biomechanical study by Clouthier et al confirms that constrained polyethylene liners in RTSA offers enhanced prosthetic stability.[6] The theoretical disadvantage of constraint relates to a potentially decreased arc of motion for which the present study demonstrated no significant difference between the standard and constrained cohorts for active ROM in five different planes. These clinical data corroborate biomechanical data from a recent study by Abdulla et al, who evaluated six cadaveric shoulders with a custom RTSA implant with a 155° neck shaft angle and commercially available Depuy Delta XTEND humeral liners by testing joint kinematics, joint loads and range of motion using low (shallow), standard (normal), and constrained liners. The authors did not find any significant effect on total deltoid force required for active abduction and found no difference between the standard and constrained polyethylene with respect to passive and active external rotation and internal rotation. However, when comparing

the low-constraint option vs. the high-constraint option, there was noted to be significant difference in passive external rotation. The authors concluded that polyethylene constraint had limited effect on RTSA kinematics.[1] It should be noted, however, that biomechanical studies primarily evaluate glenohumeral motion, while clinically, motion after RTSA involves both glenohumeral and scapulothoracic motion, so these biomechanical findings may not translate directly to what is observed clinically.

The potential benefits of greater arc congruency and humeral socket depth must be weighed vs. the presumed risk of different contact profiles leading to potential osteolysis and ultimately implant failure.[7,16] Using an in vitro wear simulation model, Carpenter et al studied wear rates between constrained polyethylene liners and standard polyethylene liners in RTSA. They found that constrained or retentive liners experienced significantly greater total volume loss under cyclical load after 3.5 million cycles and form larger wear particles. The authors suggest that constrained liners offer a potential for increased wear and subsequent aseptic loosening which must be considered during intraoperative decision-making upon prosthesis stability.[2] While the present study found favorable 2-year postoperative outcomes and a very low complication rate, future studies will need to study the long-term complications associated with constrained liner use, as it would not be expected to see high rates of polyethylene wear at such an early time point.

Another concern with constrained polyethylene liners is scapular notching and impingement. A study by Kowalsky et al evaluated 88 patients who underwent RTSA with various prostheses with medialized center of rotation glenoid component design. The authors found that using a conventional liner vs. a retentive or constrained liner was not associated with significant increased risk of scapular notching.[15] Although, the present study did not include radiographic evaluations, the similar PROs suggest that if there is evidence of radiographic notching, this has not impacted patients clinically in the short-term. The implant system utilized for all patients in the present study also has a lateralized glenoid design and a 135° humeral neck shaft angle, both of which significantly reduce scapular notching, making this less of a concern.

There are several limitations that are important to discuss. This is a small sample size (66 patients total) with only 22 patients within the study group. This is likely because many surgeons will typically avoid using constrained liners in the primary arthroplasty setting, and all fractures and revisions were excluded. The most common indication currently is in the revision setting after a periprosthetic instability event and any of these cases were excluded from the present analysis. However, a power analysis did demonstrate sufficient patient numbers to examine the primary endpoint of active ER. There were also large standard deviations for many of the assessed outcomes, which is likely due to the small number of patients and variability in outcomes. Additionally, the present study includes only short-term follow-up. However, prior studies have concluded that most of the functional improvements following RTSA occur within the first 6 months postoperatively with little to no change in results with longer follow-up.[9,17] Another limitation is innate to database studies and multiple participating surgeons. There is inevitable variability regarding surgical technique, recovery, and postoperative rehabilitation between the institutions which introduces bias. We attempted to reduce this risk by utilizing a comprehensive matching algorithm, but there are likely still differences in patients owing to surgical technique and other patient variables which could influence the results of the study. An additional limitation is that included patients had either rotator cuff tear arthropathy or glenohumeral osteoarthritis as surgical indications. This resulted in patients being included with and without intact rotator cuffs, which could influence the postoperative range of motion and instability risk. Finally, the results are limited to the prosthetic design, and it is important to note that the vast majority of RTSAs in this series had at least 4 mm of glenoid-sided lateralization. Previous evaluation has demonstrated the IR specifically is improved with increasing lateralization. It is possible that the findings would be different with less glenoid-sided lateralization.

Conclusions

For an inlay humeral prosthesis with a 135° neck shaft angle, utilization of a constrained liner for RTSA demonstrates no significant difference in ROM or PROs compared to a well-matched cohort of patients who underwent RTSA with a standard polyethylene humeral liner. These are reassuring data for using constrained liners when there is intraoperative concern for prosthetic instability.

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