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Can a functional difference be detected in reverse arthroplasty with 135° versus 155° prosthesis for the treatment of rotator cuff arthropathy: a prospective randomized study

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Background: The purpose of this randomized controlled trial was to compare humeral inclinations of 135° and 155° in patients undergoing primary reverse shoulder arthroplasty (RSA). Our hypothesis was that forward flexion would be higher in the 155° group but be associated with a higher rate of scapular notching.
Methods: A randomized controlled trial was conducted on 100 primary RSAs performed with a humeral inclination of either 135° or 155°. The prostheses were otherwise identical and a neutral glenosphere was used in all cases. Functional outcome, forward flexion, external rotation, and scapular notching were assessed at a minimum of 2 years postoperatively.
Results: There was no difference in range of motion or functional outcome scores between the 2 groups. In the 155° group, forward flexion improved from 76° to 135° ($P < .001$) and external rotation remained unchanged (29° vs. 30°; $P = .835$). In the 135° group, postoperative forward flexion improved from 78° to 132° ($P < .001$) and external rotation was unchanged (28° vs. 29°; $P = .814$). Scapular notching was observed in 58% of cases with a 155° inclination compared with 21% with a 135° inclination ($P = .009$).
Conclusion: With a neutral glenosphere there was no difference in postoperative forward flexion or external rotation after an RSA with a humeral inclination of 135° compared with 155°. Scapular notching was reduced with the use of 135° design compared with a 155° design but persists at a rate of 21% at 2-year follow-up in the absence of a lateralized glenosphere.
Level of evidence: Level 1; Randomized Controlled Trial; Treatment Study

Keywords: Reverse shoulder arthroplasty; forward flexion; humeral inclination; scapular notching; randomized controlled trial; 135°; 155°

The University Hospitals Institutional Review Board has approved this study (UHCMC IRB number: 12-13-21).

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Reverse shoulder arthroplasty (RSA) has revolutionized the treatment of several conditions, most notably irreparable rotator cuff tears and rotator cuff arthropathy. The initial Grammont design used a neutral glenosphere and a humeral prosthesis with an inclination of 155°, which medialized the center of rotation and lengthened the arm to increase the function of the deltoid and compensate for a deficient rotator cuff. This design provides reliable improvements in function and decreases pain in the short to midterm. However, this nonanatomic humeral inclination leads to scapular notching in 50% to 96% of cases.[2]

In an effort to decrease the rate of scapular notching, some authors have advocated for a more anatomic or vertical humeral inclination with or without a lateralized glenosphere. Gutiérrez et al[6] demonstrated that among implant factors, humeral inclination has the single biggest effect on scapular notching. Cuff et al[3] reported 5-year follow-up of a prosthesis with a humeral inclination of 135° and reported a notching rate of only 9%. At the same time, it was suggested that a humeral inclination of 155° leads to improved forward flexion (FF) as compared with 135°. One of the problems in evaluating the differences between these 2 inclinations is that most prostheses are only available in 1 fixed humeral inclination. Moreover, there is high variability between designs that can affect range of motion (ROM) and notching including offset of the glenoid baseplate or glenosphere and inlay or onlay humeral designs.

A recently introduced RSA prosthesis (Univers Revers; Arthrex, Inc., Naples, FL, USA) has an adaptable inlay humeral cup that can be locked at either 135° or 155° before placement. This prosthesis allows a unique opportunity to clinically evaluate the effect of humeral inclination on clinical outcomes. The purpose of this randomized controlled trial was therefore to compare humeral inclinations of 135° and 155° in patients undergoing primary RSA. Our hypothesis was that FF would be higher in the 155° group but be associated with a higher rate of scapular notching.

Methods

A randomized controlled trial was conducted of patients who underwent RSA between August 2013 and July 2014 at a single institution. Randomization based on even and odd numbers (1-10) was performed using a random number generator, placing our patients in 2 treatment groups (135° [even] vs. 155° [odd]). Institutional review board approval was obtained before beginning the study. Inclusion criteria included a primary RSA performed for an irreparable rotator cuff tear and/or severe glenohumeral joint osteoarthritis. Exclusion criteria included previous arthroplasty, preoperative infection, and preoperative fracture. The minimum follow-up was 2 years.

A power analysis was performed before beginning the study. Based on an anticipated difference of 10° of FF with a standard deviation of 10°, it was determined that 32 patients were required to have an 80% power to detect a statistical difference. To account for dropout, we elected to enroll 100 patients. Twenty patients refused to participate in the study.

Surgical technique

All surgical procedures were performed by the same shoulder fellowship-trained surgeon who implanted an RSA system with a humeral component that can be placed with either 135° or 155° of humeral inclination. A deltopectoral approach was used to access the shoulder. The biceps was tenotomized and subsequently tenodesed at the conclusion of the case with a soft-tissue repair. The subscapularis was released off the lesser tuberosity with a peel technique, followed by a 3-sided release. Before surgery the patients were consented and immediately randomized to either a 135° or 155° humeral inclination. Based on this randomization, an intramedullary cutting guide was used to perform a humeral head cut at either 135° or 155°. The humeral head cut was performed in anatomic retroversion or 20° if adequate landmarks were not available. A metaphyseal protector was placed and attention was turned to the glenoid.

After excision of the remaining biceps and labrum, the capsule was released. An oval baseplate was then selected based on the patient's anatomy and placed at the inferior aspect of the glenoid with neutral tilt. The baseplate in the system used is available in 3 sizes (small, medium, and large) and has a central post and screw and 2 peripheral polyaxial locking screws (Univers Revers; Arthrex, Inc.). A glenosphere was then impacted. The glenosphere in the system used is available in diameters of 36, 39, or 42 mm with neutral or 4 mm of lateral offset; a neutral offset glenosphere was used in all cases. Baseplate size and glenosphere diameter were based on patient anatomy and surgeon preference.

Attention was returned to the humerus, and the humeral canal was prepared to accept an inlay humeral stem. Trial components were then placed to determine stability and polyethylene thickness. Before placing the final component, drill holes were created in the proximal metaphysis and 2 No. 2 FiberWire sutures (Arthrex, Inc.) were placed and passed around the stem. Although the humeral stem design allows for a press-fit technique, all stems were cemented distally with antibiotic-impregnated cement based on a previous study demonstrating a decreased rate of infection with this technique.[8] The glenohumeral joint was reduced and the subscapularis was repaired. A hemovac drain was placed and then removed on the first postoperative day. Any intraoperative complications were recorded at the time of surgery.

The same postoperative rehabilitation protocol was used for all patients. Patients remained in the sling for 1 week with active hand, wrist, and elbow ROM only. The sling was removed immediately for daily activities and was used for comfort up to 1 additional week. At 1 week postoperatively, full passive ROM was allowed in the supine position. At 2 weeks postoperatively, active ROM was allowed. No specific strengthening was advised.

Clinical evaluation

The patients were evaluated preoperatively and postoperatively at 6 weeks, 3 months, 1 year, and 2 years. Functional outcome

Table I 135° vs. 155° demographics, average follow-up, baseline range of motion, and outcome scores

	Total (range)	135°	155°	*P* value
N	68	37	31	
Age	73 (43-94)	71	73	.385
% Male	34	38	29	.139
Months FU	38 (29-45)			
Baseline FF		78° ± 47°	76° ± 50°	.878
Baseline ER		28° ± 14°	29° ± 15°	.852
Baseline VAS		6.3 ± 2.9	6.6 ± 2.1	.562
Baseline ASES		36.9 ± 22.6	36.7 ± 18.8	.889
Baseline SANE		31.5 ± 19.6	35.9 ± 20.5	.366

ASES, American Shoulder and Elbow Surgeons; ER, external rotation; FF, forward flexion; FU, follow-up; SANE, single assessment numeric evaluation; VAS, visual analog scale.

included a visual analog pain scale (VAS), the American Shoulder and Elbow Surgeons (ASES) score, the single assessment numeric evaluation (SANE) score, and the Simple Shoulder Test (SST). ROM included FF in the plane of the scapula and external rotation (ER) with the arm at the side, which were assessed with a digital goniometer by the research fellow (Physio2Go, iOS app, Gerard Vehof Physiotherapy, 2015).

Clinical measurements

Radiographic evaluation included an anteroposterior view of the glenoid and an axillary lateral view taken preoperatively and postoperatively at 6 weeks, 3 months, 1 year, and 2 years postoperatively. All radiographs were assessed for gross humeral loosening, component malposition (defined as >10° of varus/valgus of the humeral stem or >10° superior tilt of the glenoid component), acromial stress fracture, and scapular notching graded at 0 to 4 according to the Nerot-Sirveaux criteria.[9]

Statistical analysis

Statistical analysis was conducted using SPSS 17.0 (SPSS, Armonk, NY, USA). Measured scores were analyzed by an *F* test of equality of variance and then compared using *t* tests for independent variables using a *P* value of .05 to determine significance. Nonlinear variables were compared with a χ^2 test. The data were recorded as mean ± standard deviation for all continuous variables.

Results

Study group

A total of 37 patients (74%) in the 135° group and 31 patients (62%) in the 155° group had a minimum follow-up of 2 years. The mean follow-up was 38 months (range, 29-45 months). Thirty-four percent of patients were males, and the average age at the time of surgery was 73 years (range, 43-94 years). There was no difference in baseline demographic data or function between the 2 groups (Table I).

In the 135° group, there were 4 small baseplates, 17 medium baseplates, and 16 large baseplates. Glenosphere size was 36 mm in 4 cases, 39 mm in 20 cases, and 42 mm in 13 cases. Five patients required revision (1 infection, 1 dislocation, 2 periprosthetic fractures, 1 baseplate loosening) before the final follow-up and were excluded from the analysis. Among the remaining 37 patients, there were statistically significant improvements in all functional parameters. VAS pain improved from 6 preoperatively to 2 postoperatively ($P < .001$), the ASES score improved from 37 to 74 ($P < .001$), the SANE score improved from 32 to 74 ($P < .001$), and the SST score improved from 3 to 8 ($P < .001$). FF improved from 78° preoperatively to 132° postoperatively ($P < .001$). ER was 28° preoperatively, compared with 29° postoperatively ($P = .814$) (Table II).

Table II 135° cohort: preoperative and postoperative range of motion and outcome scores

	Preoperative	Postoperative	*P* value
FF	78° ± 47°	132° ± 19°	<.001
ER	28° ± 14°	29° ± 10°	.814
VAS	6 ± 2.9	2 ± 2.9	<.001
ASES	37 ± 22.6	74 ± 24.6	<.001
SANE	32 ± 19.6	74 ± 25.4	<.001
SST	3 ± 2.8	8 ± 3.0	<.001

ASES, American Shoulder and Elbow Surgeons; ER, external rotation; FF, forward flexion; SST, Simple Shoulder Test; SANE, single assessment numeric evaluation; VAS, visual analog scale.

Table III 155° cohort: preoperative and postoperative range of motion and outcome scores

	Preoperative	Postoperative	*P* value
FF	76° ± 50°	135° ± 17°	<.001
ER	29° ± 15°	30° ± 14°	.835
VAS	7 ± 2.1	1 ± 1.8	<.001
ASES	37 ± 18.8	78 ± 15.1	<.001
SANE	36 ± 20.5	76 ± 16.8	<.001
SST	23 ± 2.7	7 ± 2.2	<.001

ASES, American Shoulder and Elbow Surgeons; ER, external rotation; FF, forward flexion; SST, Simple Shoulder Test; SANE, single assessment numeric evaluation; VAS, visual analog scale.

In the 155° group, there were 2 small baseplates, 25 medium baseplates, and 4 large baseplates. Glenosphere size was 36 mm in 2 cases, 39 mm in 26 cases, and 42 mm in 3 cases. Four patients required revision (2 dislocations, 1 infection, 1 baseplate broken screw) before 1-year follow-up for subjective scores (VAS, ASES, SST) and were excluded from the analysis. Among the remaining 31 patients, there were statistically significant improvements in all functional parameters. VAS pain improved from 7 preoperatively to 1 postoperatively ($P < .001$), the ASES score improved from 37 to 78 ($P < .001$), the SANE score improved from 36 to 78 ($P < .001$), and the SST score improved from 3 to 7 ($P < .001$). FF improved from 76° preoperatively to 135° postoperatively ($P < .001$). ER was 29° preoperatively, compared with 30° postoperatively ($P = .835$) (Table III).

135° Versus 155°

There was no statistically significant difference in functional outcome or ROM between the 2 groups postoperatively (Table IV). Scapular notching (Table V) occurred in 21% of the 135° group (Fig. 1) compared with 59% in the 155° group (Fig. 2) ($P = .009$).

Complications

One patient had a postoperative stress fracture, 4 patients had component malposition (2) and component loosening (2), and 25 patients had scapular notching. Six (9%) required revision surgery that included 2 arthroscopic explorations, 3 fracture and hardware revisions, and 1 hematoma drainage. There was no significant difference in complications between the 2 groups ($P > .05$) (Table VI).

Table IV Comparison of outcomes and range of motion between the 135° and 155° groups

	135°	155°	*P* value
FF	132° ± 19°	135° ± 17°	.321
ER	29° ± 10°	30° ± 14°	.416
VAS	2 ± 2.9	1 ± 1.8	.267
ASES	74 ± 24.6	78 ± 15.1	.446
SANE	74 ± 25.4	76 ± 16.8	.482
SST	8 ± 3.0	7 ± 2.2	.598

ASES, American Shoulder and Elbow Surgeons; ER, external rotation; FF, forward flexion; SST, Simple Shoulder Test; SANE, single assessment numeric evaluation; VAS, visual analog scale.

Discussion

The major findings of this study are that there is no apparent difference in postoperative FF or ER after RSA using a humeral inclination of 135° or 155° with a neutral glenosphere, but that scapular notching is higher with an inclination of 155°. These findings contradict our hypothesis that FF would be higher in the 155° group. On the other hand, the results support our hypothesis that notching is higher with a 155° design.

Traditionally, RSA was performed with a prosthesis using a humeral inclination of 155°. The goal of the initial design was to medialize the center of rotation and lengthen the arm to improve the mechanical advantage of the deltoid. Wall et al[10] reviewed 191 RSAs at a mean follow-up of over 3 years. Overall FF improved from 86° to 137°. However, ER (8° vs. 6°) and internal rotation (L5 vs. L4) did not improve from preoperative to postoperative and 51% of patients had evidence of scapular notching. The outcomes of the 155° group in the current study are remarkably similar to findings of Wall et al. FF improved from 76° to 135°, ER remained unchanged (29° vs. 30°), and scapular notching was observed in 58% of cases. The lack of improvement in rotation as well as the high incidence of scapular notching with a 155° design led to the development of prostheses with a more anatomic humeral inclination such as 135°.

Several computer modeling studies have evaluated bony impingement with different RSA configurations. Gutiérrez et al[6] evaluated different configurations with an inlay humeral prosthesis and concluded that the single biggest factor in reducing adduction deficit (and thus scapular notching) is humeral inclination. Similarly, Lädermann et al[7] compared an inlay 155° prosthesis to onlay prostheses with 135°, 145°, or 155° of humeral inclination and reported that the 135° design improved adduction by 28° compared with the traditional 155°. Interestingly, there was no difference between 135°, 145°, and 155° designs in FF, but ER at the side was approximately 15° higher with the 135° compared with the 155° configuration. However, these modeling studies do not account for soft-tissue tension or the mechanical advantage of the deltoid with different degrees of arm lengthening. For instance, initially there was concern that FF would be reduced with a 135° prosthesis because of decreased arm lengthening.

Cuff et al[3] reported minimum 5-year follow-up of RSAs using a 135° humeral stem. FF improved from 64° to 144°, ER improved from 15° to 51°, and scapular notching was

Table V Scapular notching rate in the 135° and 155° groups

Notching grade	135°	155°	*P* value
1	3	5	
2	3	10	
3	1	1	
4	1	2	
Percentage	21	58	.009

only observed in 9% of cases. Erickson et al[5] compared outcomes of 135° and 155° in a systematic review of over 2000 RSAs using a variety of prosthetic designs. They reported no difference in FF between the designs, but noted improved ER with a 135° design (33° vs. 23°). At first glance, these studies suggest that a humeral inclination of 135° leads to similar improvement in FF, with greater ER, and lower scapular notching than a 155° prosthesis. On the other hand, the differences are not related to humeral inclination alone; rather, they are also related to other implant variables such as glenosphere offset. In the Cuff et al[4] study, the average glenosphere offset was 6.4 mm. In addition, most of the patients in the systematic review of Erickson et al had a lateralized glenosphere. Conversely, all patients in our study had a neutral glenosphere. Interestingly, with a 135° prosthesis and a neutral glenosphere postoperative, FF improved from 78° to 132°, but in contrast to previous studies with a 135° prosthesis, ER was unchanged (28° vs. 29°) and scapular notching remained relatively high at 21%. The lack of improvement in ER and

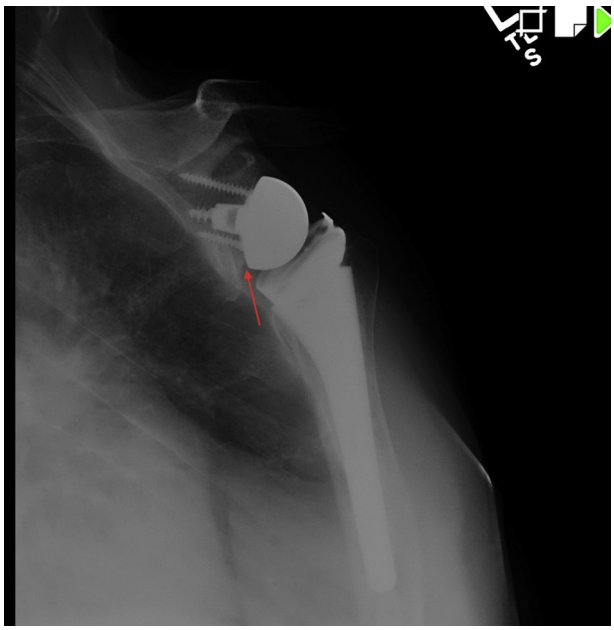

Figure 1 Postoperative radiograph of a 78-year-old patient with a 135° prosthesis demonstrates grade 1 scapular notching (*red arrow*).

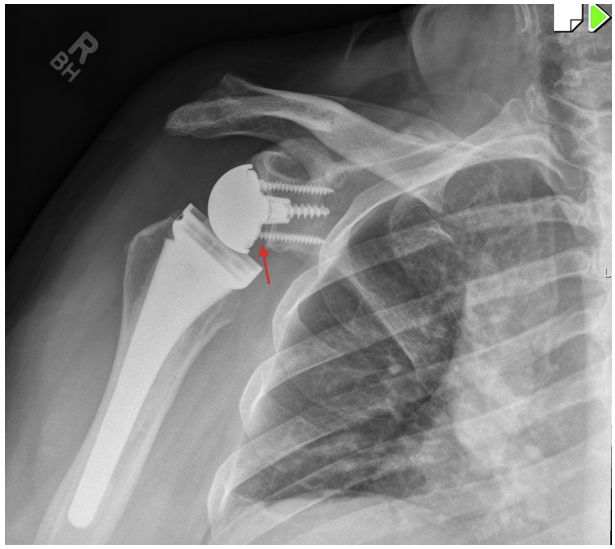

Figure 2 Postoperative radiograph of a 67-year-old patient with a 155° prosthesis demonstrates grade 4 scapular notching. Note that the notching (*red arrow*) extends to the inferior screw.

high rate of scapular notching in our 135° group may therefore be explained by our use of a neutral glenosphere lacking lateral offset. On the basis of this, the authors currently use a lateralized glenosphere in most cases with a 135° prosthesis.

The strengths of this study include the randomized design and minimization of implant factors by using a prosthesis with a consistent design other than humeral inclination. The latter limited implant variables such as glenosphere offset and inlay or onlay humeral design, allowing the comparison to be limited to humeral inclination. However, there are several weaknesses to our study. First, several patients were lost to follow-up. Second, baseline ER was high in both groups at baseline, which may have led to the lack of difference in this ROM parameter between the groups. Third, we did not evaluate different glenosphere offsets. A previous study has suggested that a lateralized glenosphere may improve rotation.[6] Fourth, we did not evaluate the influence of retroversion. However, our goal was to place the stems in anatomic retroversion that has been shown to decrease

Table VI Complications reported in the 135° and 155° groups

	Total	135°	155°	*P* value
Stress fractures	1	0	1	.151
Other fracture	4	2	2	.831
Notching	25	8	17	.009
Component loosening or malposition	4	3	1	.414
Revisions	6	2	4	.210

notching.[1] Finally, the findings are limited by the short-term follow-up. Further study is needed to examine the long-term survival rates and change in function in both groups.

Conclusion

With a neutral glenosphere there was no difference in postoperative FF or ER after an RSA with a humeral inclination of 135° compared with 155°. Scapular notching is reduced with the use of a 135° design compared with a 155° design, but persists at a rate of 21% at 2-year follow-up in the absence of a lateralized glenosphere.

Disclaimer

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