


Surgical Approach for RSA has Little or no Influence on Scapular Inclination and Glenoid Baseplate Tilt Relative to the Horizontal

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Abstract

Purpose: Determine whether reverse shoulder arthroplasty (RSA) glenoid baseplate tilt is influenced by surgical approach and/or associated with functional scores.

Methods: In total, 501 shoulders (483 patients) who underwent RSA, by anterosuperior (AS, n = 88) or deltopectoral (DP, n = 413) approach. Preoperative and immediate postoperative anteroposterior and scapular Y-view radiographs were used to measure: Inclination of the supraspinatus fossa's floor relative to the horizontal (Sigma angle), inclination of the glenoid fossa line (or glenoid baseplate surface) relative to the horizontal (beta-h angle) or to the supraspinatus fossa's floor (beta-s angle).

Results: Sigma and beta-h were significantly greater for shoulders operated by DP approach, both preoperatively ($P < .001$, $P = .002$) and postoperatively ($P = .004$, $P < .001$), but net change was not significantly different ($P = .501$, $P = .742$). Conversely, beta-s was significantly greater for shoulders operated by DP approach, only postoperatively ($P = .042$), but there were no significant differences in either preoperative angles ($P = .580$) or net change thereof ($P = .528$).

Conclusion: Beta-s was slightly but significantly greater for shoulders operated by DP approach, while beta-h and sigma depended primarily on preoperative scapular inclination and glenoid tilt, rather than on surgical approach. At a minimum of 2 years following RSA, neither constant scores nor net improvements thereof were significantly associated with any of the angles.

Level of evidence: IV, case series

Keywords

reverse shoulder arthroplasty, angles, scapula, glenoid, baseplate, tilt, rotation

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Introduction

Glenoid baseplate positioning is of paramount importance for the success of reverse shoulder arthroplasty (RSA).^{1,2} Suboptimal glenoid baseplate tilt could lead to scapular notching, which may compromise range of motion (ROM) and clinical scores,^{3,4-5} and could also exacerbate shear forces at the bone-implant interface⁶ and eventually cause glenoid component loosening.^{2,7}

Numerous authors investigated whether outcomes of RSA are influenced by glenoid baseplate tilt (beta angle), relative to the scapula (beta-s angle) or to the horizontal (beta-h angle).^{8,9} Several in vitro studies demonstrated that inferior tilt tends to improve abduction and could thereby reduce scapular notching,^{10,11} and tends to improve internal and external rotation.¹² More recently, a large cohort study by Lignel et al³ revealed significantly higher rates of glenoid component loosening when the glenoid had superior tilt

(9.3%) compared to inferior tilt (0.4%), while another cohort study by Lopiz et al¹³ reported significantly more radiolucent lines when the glenoid had superior tilt (OR =

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6.78) but significantly less notching when the glenoid had neutral tilt (OR = 0.4) or inferior tilt (OR = 0.7).

Glenoid baseplate tilt can be influenced by preoperative scapular morphology and surgical approach. Lopiz et al¹³ found that risks of implanting the glenoid baseplate with superior tilt are significantly higher in shoulders operated for cuff tear arthropathy (OR = 3.83) or using the anterosuperior (AS) approach (OR = 2.52), whereas neutral or inferior tilt are more likely in shoulders operated for complex proximal humeral fractures (OR = 0.5), after a learning curve (OR = 0.88), or using the deltopectoral (DP) approach (OR = 0.39). Torrens et al⁹ confirmed that superior tilt is more likely when using the AS approach, while Aibinder et al⁸ found no differences in glenoid component tilt between the 2 approaches.

The purpose of this study was, therefore, to ascertain from a large cohort of RSA whether glenoid baseplate tilt is influenced by surgical approach, and to determine whether these have direct or indirect associations with functional scores. The hypotheses were that (1) superior tilt is more likely when using the AS approach compared to the DP approach and (2) inferior tilt grants better functional scores.

Methods

The authors retrospectively reviewed records of all RSAs performed between January 2015 and August 2017 by 16 experienced surgeons that participated in a large national society symposium (SoFEC). Inclusion criteria were primary RSA for treatment of primary osteoarthritis (OA) with or without rotator cuff (RC) tears, secondary OA due to RC tears, or massive RC tear (mRCT) with a minimum follow-up of 2 years. Exclusion criteria were patients operated on for rheumatoid arthritis or fractures, as well as shoulders with surgical antecedents, posttraumatic sequelae, or that had adjuvant latissimus dorsi tendon transfer. From an initial cohort of 743 shoulders (716 patients), 193 were lost to follow-up (25.7%), 33 were revised with implant exchange (4.4%), and 16 died (2.1%). This left a final cohort of 501 shoulders (483 patients) which were assessed at a mean follow-up of

3.2 ± 0.9 years (range, 2.0 to 5.5 years) (Figure 1). All patients provided informed consent for the analysis and use of their data, and the study was approved in advance by the institutional review board (IRB: COS-RGDS-2022-11-006-GODENECHÉ-A).

Surgical Technique

Ten surgeons used the DP approach exclusively (n = 518), while 5 surgeons used the AS approach exclusively (n = 172), and 1 surgeon used the DP approach in some (n = 22), but used the AS approach where preservation of the subscapularis was deemed beneficial (n = 31). In the 540 shoulders operated by DP approach, the subscapularis was detached in 504 (tenotomy, n = 425; peeling, n = 72; osteotomy, n = 7), and repaired after detachment in 479. In the 203 shoulders operated by AS approach, the subscapularis remained intact. On the glenoid side, surgeons had a choice of using additional bony increased offset (BIO) RSA which could be symmetric or asymmetric, depending on the extent of necessary glenoid lateralisation and/or bone defect compensation. On the humeral side, surgeons had the choice of using inlay or onlay stems, each with different neck shaft angles and implanted with or without cement. Following surgery, the shoulder was immobilized using a sling and passive ROM exercises were initiated on the first postoperative days. At 4 to 6 weeks following surgery, active ROM were started under supervision of a physiotherapist.

Radiographic Assessment

All patients had preoperative plain anteroposterior and scapular Y-view radiographs, and computed tomography or magnetic resonance imaging scans of their shoulders. Following surgery, radiographs were acquired for immediate postoperative assessment and at final follow-up, and were used to determine scapular notching according to the Sirveaux-Nérot classification,⁴ and any radiographic modifications.

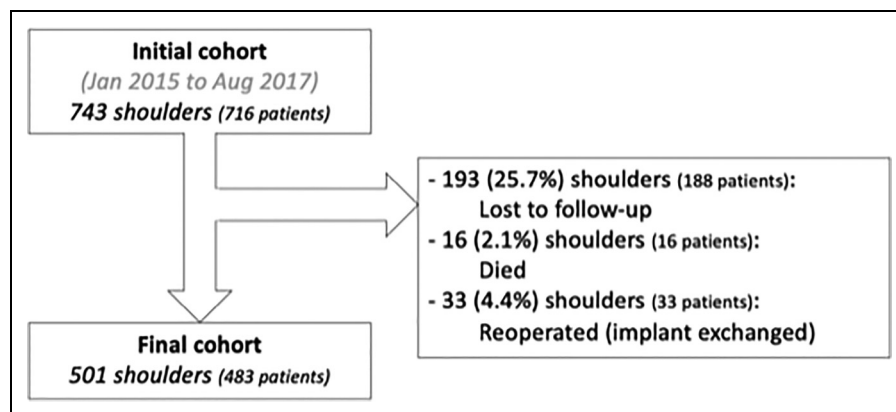


Figure 1. Flowchart of the study cohort.



Figure 2. Sigma angle.

Radiographic Angles

The radiographs that were acquired at preoperative assessment and at final follow-up were used to measure the following angles by 2 surgeons to calculate their repeatability on 48 X-rays:

- Sigma, defined as the inclination of the supraspinatus fossa's floor relative to the horizontal (ground).¹⁴ This angle represents scapular inferior inclination in the frontal plane (Figure 2).
- Beta-h, defined as the inclination of the glenoid fossa line (or glenoid baseplate surface) relative to the horizontal (ground).^{1,14} A positive value indicates glenoid inferior tilt, whereas a negative value indicates glenoid superior tilt (Figure 3).
- Beta-s, defined as the inclination of the glenoid fossa line (or glenoid baseplate surface) relative to the supraspinatus fossa's floor.¹⁴ A positive value indicates glenoid inferior tilt, whereas a negative value indicates glenoid superior tilt (Figure 4).

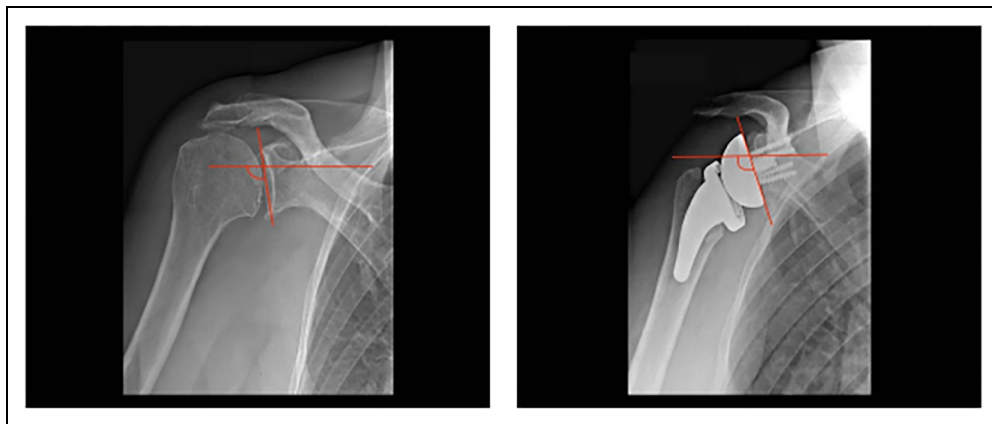


Figure 3. Beta-h angle.

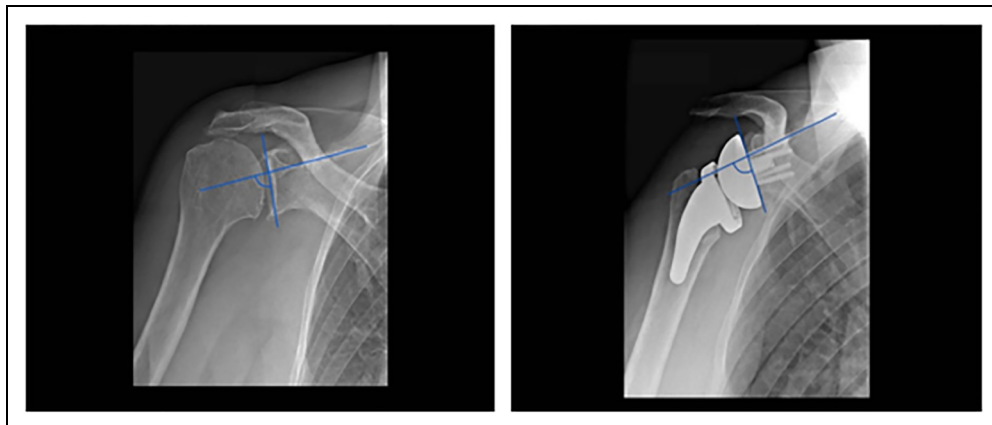


Figure 4. Beta-s angle.

Table 1. Demographics.

	Final cohort (n = 743)	
	Mean \pm SD	Range
Age at index surgery (years)	74.2 \pm 8.4	(46-99)
BMI	27.5 \pm 5.6	(16-54)
Female gender	502 (68%)	
Bilateral	54 (7%)	
Dominant arm	487 (66%)	
Etiology		
Primary OA without RC tears	119 (16%)	
Primary OA with RC tears	83 (11%)	
Secondary OA due to RC tear	390 (52%)	
Irreparable mRCT	132 (18%)	
missing	19 (3%)	
Surgical approach		
Anterosuperior	540 (73%)	
Deltopectoral	203 (27%)	

Abbreviations: OA, osteoarthritis; RC, rotator cuff; mRCT, massive rotator cuff tear; BMI, body mass index.

Table 2. Intraoperative and postoperative Complications Treated Conservatively or by Reoperation Without Implant Removal.

	Entire cohort (n = 501)	
	N	(%)
Intraop humeral fracture	10	(2%)
Intraop glenoid fracture	3	(1%)
Dislocation	1	(0%)
Subluxation	3	(1%)
Infection	1	(0%)
Glenoid loosening	4	(1%)
Humeral loosening	0	(0%)
Periprosthetic fracture	14	(3%)
Neurologic	7	(1%)
Other	4	(1%)
Any complication	47	(9%)
of which reoperated without implant removal	8	(2%)

Clinical and Functional Assessment

The authors noted demographic data, and measured preoperative and postoperative ROM, including active forward elevation, external rotation with the elbow on the side (ER1) and internal rotation with the hand at the back (IR1). The authors also assessed preoperative and postoperative Constant score and noted all complications (Table 2).

Statistical Analysis

Descriptive statistics were used to summarize the findings, and Shapiro–Wilk tests were used to assess the normality

Table 3. Preoperative and Postoperative Clinical and Functional Outcome.

	Entire cohort (n = 501)	
	Mean \pm SD	Range
Follow-up (years)	3.2 \pm 0.9	(2.0-5.5)
Constant score (0-100)		
Preoperative	27.4 \pm 12.2	(0-71)
Postoperative	66.3 \pm 15.2	(18-95)
Net improvement	39.9 \pm 16.5	(-3 to 81)
Active forward elevation (°)		
Preoperative	85.5 \pm 37.7	(0-180)
Postoperative	135.6 \pm 27.2	(20-180)
Net improvement	51.7 \pm 39.9	(-60 to 150)
External rotation (°)		
Preoperative	11.5 \pm 20.5	(-40 to 90)
Postoperative	28.5 \pm 20.0	(-40 to 90)
Net improvement	16.1 \pm 23.2	(-80 to 90)
Internal rotation		
Preoperative		
Functional (L3, T12, T7/T8)	138 (28%)	
Non functional (Sacrum, GT, buttock)	316 (63%)	
missing	47 (9%)	
Postoperative		
Functional (L3, T12, T7/T8)	322 (64%)	
Nonfunctional (Sacrum, GT, buttock)	176 (35%)	
missing	3 (1%)	

of data distributions. For normally distributed continuous data, differences between groups were evaluated using unpaired t-tests. For non-Gaussian continuous data, differences between groups were evaluated using Wilcoxon rank sum tests (Mann–Whitney *U* test). To assess the reliability of the sigma, beta-h, and beta-s angles, interobserver agreement between 2 surgeons was calculated using intraclass correlation coefficients, which can be interpreted as follows: < 0.40, poor; 0.41-0.59, fair; 0.60-0.74, good; 0.75-1.00, excellent.⁶ Statistical analyses were performed using R version 3.4.3 (R Foundation for Statistical Computing).

Results

A total of 501 shoulders (483 patients) met the inclusion criteria and comprised 337 women and 146 men, aged 73.7 \pm 7.8 years (range, 51-92 years) (Table 1). The indications for RSA were primary OA without RC tears in 97 shoulders (19%), primary OA with RC tears in 62 shoulders (12%), secondary OA due to RC tears in 255 shoulders (51%), and mRCT in 87 shoulders (17%). Of the 501 shoulders, 88 were operated through the AS approach (18%), while 413 were operated through the DP approach (82%). Of the final cohort at final follow-up, 47 (9.4%) had complications, 39 (7.8%) of which were treated conservatively, and 8 (1.6%) that required reoperations without implant removal (Tables 2 and 3).

Radiographic Results

The interobserver repeatability was excellent for all 3 angles (Table 4). Scapular inclination (sigma angle) was significantly greater for shoulders operated using the DP approach compared to the AS approach, both preoperatively ($19.5^\circ \pm 8.9^\circ$ vs $15.4^\circ \pm 9.3^\circ$; $P < .001$) and postoperatively ($19.7^\circ \pm 8.4^\circ$ vs $17.0^\circ \pm 9.2^\circ$; $P = .004$), but the net change was not significantly different ($0.3^\circ \pm 9.3^\circ$ vs $1.5^\circ \pm 11.2^\circ$; $P = .501$) (Table 5). Likewise, glenoid tilt relative to the horizontal (beta-h angle) was significantly greater for shoulders operated using the DP approach compared to the AS approach, both preoperatively ($94.4^\circ \pm 10.6^\circ$ vs $90.1^\circ \pm 10.1^\circ$; $P = .002$) and postoperatively ($101.2^\circ \pm 10.5^\circ$ vs $96.1^\circ \pm 11.6^\circ$; $P < .001^\circ$), but the net change was not significantly different ($6.6^\circ \pm 12.1^\circ$ vs $5.9^\circ \pm 13.5^\circ$; $P = .742$). Conversely, glenoid tilt relative to the scapula (beta-s angle) was significantly greater for shoulders operated using the DP approach compared to the AS approach only postoperatively ($83.8^\circ \pm 9.9^\circ$

vs $81.9^\circ \pm 11.7^\circ$; $P = .042$), but there were no significant differences in either the preoperative angles ($77.7^\circ \pm 11.3^\circ$ vs $77^\circ \pm 10.9^\circ$; $P = .580$) or the net change thereof ($5.6^\circ \pm 12.5^\circ$ vs $4.8^\circ \pm 14.8^\circ$; $P = .528$).

Comparing scapular inclination (sigma angle) preoperatively and postoperatively revealed that it remained within $\pm 5^\circ$ in 46% following the DP approach compared to 36% following the AS approach. Scapular inclination increased by 5° or more in 28% following the DP approach and 34% following the AS approach, and decreased by 5° or more in 26% following the DP approach and 30% following the AS approach ($P = .247$).

Univariable and Multivariable Analyses

Postoperative constant scores were not significantly associated with any of the angles measured preoperatively or postoperatively, but were significantly correlated with patient age ($P < .001$), sex ($P = .035$), etiology ($P < .01$), and surgical approach ($P < .001$) (Table 6). Likewise, net improvement in constant scores were not significantly associated with any of the angles measured preoperatively or postoperatively, but were significantly correlated with patient sex ($P = .042$), dominant side ($P = .035$), etiology ($P < .05$), surgical approach ($P < .001$), and the use of BIO RSA ($P = .004$) (Table 7).

Table 4. Interobserver Agreement (Intraclass Correlation Coefficients [ICC]) for Preoperative and Postoperative Radiographic Outcomes.

	Interobserver ICC		
	Mean	Range	P-values
Sigma ($^\circ$)			
Preoperative	0.93	(0.88-0.96)	<.001
Postoperative	0.86	(0.79-0.92)	<.001
Beta-h ($^\circ$)			
Preoperative	0.92	(0.87-0.95)	<.001
Postoperative	0.83	(0.74-0.89)	<.001
Beta-s ($^\circ$)			
Preoperative	0.73	(0.59-0.83)	<.001
Postoperative	0.83	(0.73-0.89)	<.001

Discussion

The most important finding of this study was that glenoid baseplate tilt relative to the scapula (beta-s angle) was slightly but significantly greater for shoulders operated by the DP approach compared to shoulders operated by AS approach. While the mean difference was only 1.9° , it supports the first hypothesis that superior tilt is more likely when using the AS approach compared to the DP approach.

Table 5. Preoperative and Postoperative Radiographic Outcomes With Subgroup Analysis by Surgical Approach.

	Entire cohort (n = 501)		Deltopectoral (n = 413)		Anterosuperior (n = 88)		P-values
	Mean \pm SD	Range	Mean \pm SD	Range	Mean \pm SD	Range	
Follow-up (years)	3.2 \pm 0.9	(2.0-5.5)	3.0 \pm 0.9	(2.0-5.3)	3.7 \pm 1.0	(2.0-5.5)	<.001
Sigma ($^\circ$)							
Preoperative	18.7 \pm 9.2	(-12 to 48)	19.5 \pm 8.9	(-10-40)	15.4 \pm 9.3	(-12 to 48)	<.001
Postoperative	19.2 \pm 8.6	(0-46)	19.7 \pm 8.4	(0-45)	17.0 \pm 9.2	(0-46)	.004
Net increase	0.6 \pm 9.7	(-29 to 43)	0.3 \pm 9.3	(-26 to 43)	1.5 \pm 11.2	(-29 to 32)	.501
Beta-h ($^\circ$)							
Preoperative	93.6 \pm 10.7	(62-130)	94.4 \pm 10.6	(63-130)	90.1 \pm 10.1	(62-120)	.002
Postoperative	100.3 \pm 10.9	(60-133)	101.2 \pm 10.5	(66-133)	96.1 \pm 11.6	(60-121)	<.001
Net increase	6.5 \pm 12.4	(-37 to 49)	6.6 \pm 12.1	(-28 to 49)	5.9 \pm 13.5	(-37 to 35)	.742
Beta-s ($^\circ$)							
Preoperative	77.6 \pm 11.2	(38-116)	77.7 \pm 11.3	(38-116)	77.0 \pm 10.9	(55-112)	.580
Postoperative	83.4 \pm 10.2	(57-120)	83.8 \pm 9.9	(57-114)	81.9 \pm 11.7	(58-120)	.042
Net increase	5.5 \pm 13.0	(-44 to 51)	5.6 \pm 12.5	(-44 to 51)	4.8 \pm 14.8	(-40 to 40)	.528

Table 6. Univariable and Multivariable Regression Analysis of Postoperative Constant Score.

Variable	n	β	Univariable	
			95% C.I.	P-value
Age at index operation (yrs)	501	-0.29	(-0.46 to 0.12)	<.001
BMI	501	0.09	(-0.15 to 0.33)	.460
Male sex	164	3.08	(0.22 to 5.94)	.035
Dominant arm	338	2.49	(-0.37 to 5.35)	.088
Etiology				
Primary OA without RC tears	97	REF		
Primary OA with RC tears	62	-7.64	(-12.41 to 2.86)	.002
Secondary OA due to RC tear	255	-9.63	(-13.14 to 6.13)	<.001
Irreparable mRCT	87	-9.03	(-13.35 to 4.71)	<.001
Surgical approach				
Deltpectoral	413	REF		
Anterosuperior	88	-6.72	(-10.19 to 3.25)	<.001
BIO RSA	196	1.62	(-1.14 to 4.38)	.249
Preoperative sigma	441	0.05	(-0.11 to 0.21)	.521
Preoperative beta-h	441	0.10	(-0.04 to 0.23)	.157
Preoperative beta-s	440	-0.06	(-0.19 to 0.07)	.369
Postoperative sigma	482	0.10	(-0.06 to 0.26)	.233
Postoperative beta-h	482	0.06	(-0.07 to 0.18)	.361
Postoperative beta-s	482	0.02	(-0.12 to 0.15)	.809

Abbreviations: yrs, years; C.I., confidence interval; REF, reference; BMI, body mass index; OA, osteoarthritis; RC, rotator cuff; BIO RSA, bony increased offset reverse shoulder arthroplasty; mRCT, massive rotator cuff tear.

Conversely, postoperative scapular inclination (sigma angle) and glenoid baseplate tilt relative to the horizontal (beta-h angle) depended primarily on preoperative scapular inclination and glenoid tilt, rather than surgical approach. Finally, univariable analyses revealed that neither postoperative Constant scores nor the net improvements thereof were significantly associated with any of the angles, which refutes the second hypothesis that inferior glenoid tilt grants better functional scores.

Glenoid baseplate positioning is important for the success of RSA.^{1,2} Superior glenoid tilt could lead to loosening of the glenoid component^{2,15} and scapular notching,^{2,3,5,13,16} as it increases the shear forces while reducing the compressive force component at the flat surface of the glenoid baseplate.^{6,17} It is worth noting that glenoid baseplate tilt could be influenced by surgical approach, because of a different exposure of the glenoid, but it could also be influenced by preoperative glenoid wear, as it is difficult to implant a glenosphere with inferior tilt in a glenoid that is superiorly tilted (Favard E3).^{4,18} Scapular notching is more frequent following RSA performed for cuff tear arthropathy, because of considerable glenoid erosion associated with this indication.^{1,15}

In this study, we found that glenoid baseplate tilt depends on primarily preoperative scapular morphology rather than on surgical approach. Several studies^{2,19} found that the AS

Table 7. Univariable and Multivariable Regression Analysis of Net Improvement in Constant Score.

Variable	n	β	Univariable	
			95% C.I.	P-value
Age at index operation (yrs)	501	-0.02	(-0.22 to 0.18)	.833
BMI	501	0.09	(-0.19 to 0.37)	.520
Male sex	164	3.38	(0.12 to 6.64)	.042
Dominant arm	338	3.48	(0.24 to 6.72)	.035
Etiology				
Primary OA without RC tears	97	REF		
Primary OA with RC tears	62	-6.26	(-11.68 to 0.84)	.024
Secondary OA due to RC tear	255	-10.32	(-14.31 to 6.33)	<.001
Irreparable mRCT	87	-9.40	(-14.35 to 4.45)	<.001
Surgical approach				
Deltpectoral	413	REF		
Anterosuperior	88	-10.39	(14.58 to 6.20)	<.001
BIO RSA	196	4.63	(1.51-7.75)	.004
Preoperative sigma	441	0.02	(-0.16 to 0.20)	.837
Preoperative beta-h	441	0.10	(-0.05 to 0.25)	.193
Preoperative beta-s	440	-0.02	(-0.17 to 0.12)	.780
Postoperative sigma	482	0.09	(-0.09 to 0.28)	.318
Postoperative beta-h	482	0.10	(-0.04 to 0.25)	.172
Postoperative beta-s	482	0.07	(-0.08 to 0.23)	.352

Abbreviations: yrs, years; C.I., confidence interval; REF, reference; BMI, body mass index; OA, osteoarthritis; RC, rotator cuff; BIO RSA, bony increased offset reverse shoulder arthroplasty; mRCT, massive rotator cuff tear.

approach is a suitable alternative, as it provides a straight exposure of the glenoid while preserving the subscapularis muscle, even though positioning the glenoid baseplate is more difficult.² On the other hand, Gadea et al²⁰ postulated that the DP approach is better at preserving the deltoid and at assessing humeral anatomy. As one of the drawbacks of the DP approach is the disinsertion of the subscapularis tendon, a new approach was introduced by Lädermann et al,²¹ an anterior approach that spares both the subscapularis and the deltoid muscles. Further studies are needed to investigate how glenoid tilt is influenced by this new approach.

There is no consensus in the literature on what angle is most reproducible to measure glenoid tilt. Maurer et al¹⁴ found that the inclination between the glenoid fossa line and the floor of the supraspinatus fossa (beta-s angle) was reproducible, and Lévine et al¹ reported difficulty in locating scapular landmarks and suggested to assess glenoid tilt independently of the scapula (beta-h angle). The present study found excellent interobserver repeatability for both beta-s and beta-h angles, though the latter may be easier to measure as it requires identification of fewer landmarks, as long as the patient is correctly aligned to the x-ray tube.

The present study investigated whether scapular inclination (sigma angle) changes following RSA performed by 2

different approaches, and found that it increased by 5° or more in 28% following the DP approach and 34% following the AS approach, and that it decreased by 5° or more in 26% following the DP approach and 30% following the AS approach. In another study, Kahn et al²² described the scapular rotation as the angle between the floor of the supraspinatus fossa and the vertical, and found that scapular rotation increased by 2° superiorly after RSA. Further studies might be necessary to investigate the influence of RSA on scapular position.

This study had several limitations that must be considered when interpreting the findings. First, in this large multicenter cohort, the data was collected retrospectively, and there are several significant differences in the baselines characteristics of patients operated by the different surgical approaches (eg, native scapular orientation, implant type, use of BIO RSA, inlay or onlay stem). Second, angles were measured by 16 different surgeons for their respective patients, and although interobserver repeatability was excellent for a sample of 48 x-rays remeasured by 2 different surgeons, differences in measurement methods and equipment could be a source of bias. Third, 25.7% of patients were lost to follow-up, and it is therefore likely that some patients with complications or poor outcomes were not represented; however, it is important to note that the outcomes of the present study were collected between 2020 and 2021, during which clinical assessment was difficult due to the coronavirus disease 2019 pandemic. Finally, the clinical and functional assessment was not blinded, and surgeons noted whether the patients had any surgical antecedents, but did not note what specific treatment they underwent.

Conclusion

Glenoid baseplate tilt relative to the scapula was slightly but significantly greater for shoulders operated by the DP approach compared to shoulders operated by AS approach, while postoperative scapular inclination and glenoid baseplate tilt relative to the horizontal depended primarily on preoperative scapular inclination and glenoid tilt, rather than surgical approach. At a minimum follow-up of 2 years, neither postoperative Constant scores nor the net improvements thereof were significantly associated with any of the angles.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethical Approval

The study was approved in advance by the Institutional Review Board.

Informed Consent

All patients provided informed consent for the analysis and use of their data.

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