



# Clinically significant outcome thresholds and rates of achievement by shoulder arthroplasty type and preoperative diagnosis

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**Background:** Clinically significant outcome (CSO) benchmarks have been previously established for shoulder arthroplasty by assimilating preoperative diagnoses and arthroplasty types. The purpose of this study was to establish unique CSO thresholds and compare the time-to-achievement of these for reverse shoulder arthroplasty (RSA) for osteoarthritis (GHOA), RSA for rotator cuff arthropathy (RCA), and total shoulder arthroplasty (TSA) for GHOA.

**Materials and Methods:** Consecutive patients who underwent elective RSA for GHOA, TSA for GHOA, or RSA for RCA between February 2015 and May 2020, with 2-year minimum follow-up, were retrospectively identified from a prospectively maintained single surgeon registry. The American Shoulder and Elbow Surgeons (ASES) score was administered preoperatively and postoperatively at 2-week, 6-week, 3-month, 6-month, 1-year, and 2-year timepoints. Satisfaction and subjective overall improvement anchor questionnaires were administered at the time of final follow-up. Distribution-based methods were used to calculate the Minimal Clinically Important Difference (MCID), and anchor-based methods were used to calculate the Substantial Clinical Benefit (SCB) and the Patient Acceptable Symptom State (PASS) for each patient group. Median time to achievement, individual incidence of achievement at each time point, and cumulative incidence of achievement calculated using Kaplan–Meier survival curve analysis with interval censoring were compared between groups for each CSO. Cox-regression analyses were also performed to determine which patient factors were significantly associated with early or delayed achievement of CSOs.

**Results:** There were 471 patients eligible for study analysis: 276 RSA for GHOA, 107 TSA for GHOA, and 88 RSA for RCA. The calculated MCID, SCB, and PASS scores differed for each group. There were no significant differences in median time to achievement of any CSO between groups. Log-rank testing revealed that cumulative achievements significantly differed between groups for MCID ( $P = .014$ ) but not for SCB ( $P = .053$ ) or PASS ( $P = .620$ ). On cox regression analysis, TSA patients had earlier achievement of SCB, whereas TSA and RSA for GHOA patients had earlier achievement of MCID. At 2-years, a significantly higher percentage of RSA for GHOA patients achieved MCID and SCB compared to RSA for RCA (MCID:100%, 95.5%,  $P = .003$ , SCB:94.6%, 86.4%,  $P = .036$ ).

**Conclusion:** Calculated CSO thresholds differ according to preoperative diagnosis and shoulder arthroplasty type. Patients undergoing TSA and RSA for GHOA achieve CSOs earlier than RSA for RCA patients, and a significantly higher percentage of RSA for GHOA patients achieve CSOs by 2 years compared to RSA for RCA patients.

This study received approval from the New England Baptist Hospital Institutional Review Board (Protocol #1702557).

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**Level of evidence:** Basic Science Study; Validation of Outcome Measures

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The volume of shoulder arthroplasty performed in the United States has dramatically increased in recent years, largely due to increased use of reverse total shoulder arthroplasty (RSA) for varying indications.<sup>2</sup> The RSA was initially introduced as a salvage option for patients with the destructive sequelae of rotator cuff dysfunction, termed rotator cuff arthropathy (RCA).<sup>3,14</sup> However, improvements in RSA techniques and implant design have resulted in its expanding indications, including primary glenohumeral osteoarthritis with an intact rotator cuff (GHOA).<sup>11,14,17,24,29</sup> Although early reports of RSA for patients with RCA demonstrated relatively modest functional results,<sup>3,4</sup> emerging evidence has shown that RSA affords substantially better outcomes in the setting of GHOA.<sup>8,24</sup> These findings, coupled with the comparatively higher cumulative revision rates after anatomic total shoulder arthroplasty (TSA), have solidified RSA as a reasonable alternative for the treatment of GHOA.<sup>11</sup>

The shoulder arthroplasty literature generally reports the functional success of a procedure in terms of patient-reported outcome measures (PROMs) at generally accepted postoperative time points when maximal improvement is thought to be achieved.<sup>13,15,21</sup> The rate of recovery and consistency of achieving these results are less often explored.<sup>5,13,19</sup> PROMs provide valuable insight to patient's pain and function, and may be readily compared in clinical studies.<sup>22</sup> However, the magnitude of improvement represented by changes in PROM scores is difficult to meaningfully conceptualize for patients and providers.<sup>10</sup> Reporting differences in PROMs over time or between groups in terms of statistical significance may also be misleading without additional clinically relevant insight to the magnitude of difference seen.<sup>10</sup> Clinically significant outcome (CSO) thresholds such as the minimal clinically important difference (MCID), substantial clinical benefit (SCB), and patient acceptable symptoms state (PASS) address these limitations. MCID and SCB represent changes in a PROM score that correlate to the smallest perceivable difference, and substantial or optimal subjective improvement, respectively.<sup>20,25,26,28,30</sup> PASS represents a PROM outcome score that is deemed satisfactory to the patient, irrespective of their preoperative state.<sup>28</sup> Appropriate derivation and application of these CSOs requires patients to have an identical diagnosis and procedure(s) performed.<sup>10</sup> MCID, SCB, and PASS previously established for RSA have conflated patients with the dissimilar diagnoses of RCA and GHOA.<sup>12</sup> The recent study by Drager et al applied such previously established CSOs to

their own patient cohort to compare TSA and RSA (single group containing patients with RCA or GHOA diagnoses), concluding that TSA patients achieved these CSOs more consistently and at faster rates compared to RSA patients.<sup>7</sup> Despite this conclusion, a diagnosis of GHOA was 1 of 2 variables significantly associated with earlier achievement of CSOs after RSA (Hazard Ratio (HR): 2.471, 2.696), and a diagnosis of RCA was 1 of 3 variables significantly associated with longer time to achievement (HR: 0.497).<sup>7</sup>

Delineating the outcome profiles of different, increasingly utilized shoulder arthroplasty types, and preoperative diagnoses in patient-centered and clinically-relevant terms is critical to guide patient expectations as well as for the surgeon to evaluate the quality of surgical intervention. The purpose of this study was to establish unique CSO thresholds and to compare the time-to-achievement of these for RSA for GHOA, RSA for RCA, and TSA for GHOA.

## Methods

This was a retrospective cohort study approved by our institutional review board (IRB) prior to its onset. Consecutive patients who underwent either a primary TSA for GHOA, RSA for GHOA, or RSA for RCA between 1/22/2015 and 11/1/2020 were identified from a prospectively maintained electronic registry (OBERD, Columbia, MO, USA). All procedures were performed by a single fellowship-trained shoulder surgeon. The American Shoulder Elbow Surgeons (ASES) score was administered preoperatively and postoperatively at 2 weeks, 6 weeks, 3 months, 6 months, 1 year, and 2 years after surgery. Patients also completed a subjective satisfaction and overall improvement questionnaire at 2-year minimum follow-up. Patients were excluded if they had a prior ipsilateral shoulder arthroplasty procedure, had a primary diagnosis for surgery other than GHOA or RCA, did not complete a preoperative and 2-year minimum follow-up ASES questionnaire, did not have available preoperative advanced imaging (computed tomography [CT] or magnetic resonance imaging [MRI]), or did not complete the subjective and overall improvement questionnaire at 2-year minimum follow-up.

The ASES questionnaire is routinely administered to all patients in our practice prior to surgery by a trained research assistant at the time of their preoperative office visit. The questionnaire is additionally administered to all patients at each postoperative time point and completed electronically. The questionnaire was available for completion 2 weeks prior to and 2 weeks after their specified postoperative time point. Patients were sent automatic e-mail reminders weekly to complete their questionnaires. The ASES questionnaire compliance rate for the entire cohort at each time point was as follows: 92.5% at 2 weeks, 94.5% at 6 weeks,

88.1% at 3 months, 43.1% at 6 months, 88.6% at 1 year, and 100% at 2 years. The overall subjective improvement questionnaire contained the following prompt, "Compared to preoperatively, how would you rate the overall pain and function of your shoulder now?". The answer choices were "much worse", "worse", "the same", "better", and "much better". The satisfaction questionnaire asked, "How satisfied are you currently with the outcome of your shoulder replacement surgery?" The answer choices were "very unsatisfied", "unsatisfied", "neutral", "satisfied", and "very satisfied". Preoperative MRI or CT as well as operative notes were reviewed to confirm rotator cuff status in the GHOA groups and to verify the preoperative diagnosis. Patients who had irreparable rotator cuff tears with or without superior glenoid erosion and acromiohumeral interval narrowing were determined to have a preoperative diagnosis of rotator cuff arthropathy, and exclusively had an RSA performed. Patients with intact rotator cuff tendons (tendinopathic or not) and osteoarthritis with an acromiohumeral interval distance within normal range received either TSA or RSA. The decision to receive TSA or RSA for these patients with GHOA was predicated on age, functional status, degree of glenoid deformity, and ultimately surgeon and patient preference after appropriate counseling. The following demographic and clinical variables were also extracted: age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) score, history of prior ipsilateral shoulder surgery, depression, and preoperative range-of-motion (forward flexion, external rotation).

The study groups were defined by their preoperative diagnosis and shoulder arthroplasty type: TSA, RSA for GHOA, and RSA for RCA. The MCID, SCB, and PASS values were established for each group using previously established anchor-based methods. For MCID development, the delta ASES scores (2-year score minus preoperative score) were used for patients who answered "the same" or "worse" on the subjective overall improvement questionnaire and compared to those who answered "better". For SCB development, the delta ASES scores for patients who answered "the same" or "worse" on the subjective overall improvement questionnaire was compared to those who answered "much better". For PASS development, 2-year postoperative ASES score among patients who answered "neutral" or "unsatisfied" on the satisfaction questionnaire was compared to those who answered, "satisfied" or "very satisfied". Nonparametric receiver operative characteristic (ROC) curves were developed for each patient group. The Youden Index was used to determine thresholds for each score that optimized the sensitivity and specificity for each MCID, SCB, and PASS value.<sup>23</sup> In order to evaluate the predictive power of the ROC curves, an area under the curve (AUC) analysis was performed for each. If the AUC was calculated to be 0.7 or greater, then the predictive power of that threshold was determined to be acceptable, and greater than 0.8 was deemed excellent. If the AUC analysis determined the predictive power of a ROC curve for a SCB or PASS value to be unacceptable, that CSO threshold value was not included for further analysis. For MCID specifically, if an unacceptable AUC was calculated, distribution-based methods were utilized by calculating one-half the standard deviation of the study population's mean delta (preoperative – 2 year postoperative) ASES score (which has been consistently demonstrated to equal the threshold of discrimination for change in a health outcome measure), as previously described.<sup>6,18,20</sup> Both methods for deriving MCID values have been demonstrated to be acceptable, and use of

multiple strategies has been suggested to enhance the interpretability of any particular instrument.<sup>9</sup>

Relevant demographic and clinical characteristics were compared across the 3 groups using chi-square or ANOVA testing, as indicated. Each patient's postoperative ASES score was subsequently reviewed to determine whether or not the group specific MCID/SCB/PASS thresholds were achieved at each postoperative time point. The median time required to achieve MCID/SCB/PASS was calculated as the earliest time-point at which each patient achieved an ASES score meeting the respective threshold. These times were compared across groups using a Kruskal–Wallis test. Next, chi-squared tests and posthoc Tukey testing was used to compare cumulative percentages of patients in each group that achieved MCID/SCB/PASS at each time-point. Kaplan–Meier survival curves with interval censoring were constructed (inverse curves with "survival" denoting failure to achieve the respective threshold) for each group to demonstrate the cumulative percentages of patients achieving MCID/SCB/PASS at each follow-up time point. Patients with missing ASES scores at a given time-point were included in the analysis but considered to be non-achievers of MCID/SCB/PASS at that specific time-point. Differences in survival curves between the 3 groups were assessed with log-rank tests. Cox-regression analyses were performed to determine which patient factors were significantly associated with early or delayed achievement of MCID/SCB. These factors included patient age, sex, BMI, patient group (TSA, RSA for GHOA, or RSA for RCA), history of depression, history of prior ipsilateral shoulder surgery, and preoperative ASES score. Results of these regression are presented as hazard ratios (HRs) with 95% confidence intervals (CIs). Statistical significance was denoted as a  $P < .05$ .

## Results

In total, there were 471 patients eligible for study analysis: 276 RSA for GHOA, 107 TSA for GHOA, 88 RSA for RCA. Patients in the TSA for GHOA group were significantly younger (60.8, 70.9, 70.8 years,  $P < .001$ ), more often male (60.7% 40.9%, 45.4%,  $P = .002$ ), and had better preoperative active forward elevation (101°, 93°, 89°,  $P = .016$ ) than the RSA for GHOA and RSA for RCA groups, and patients receiving RSA for RCA more often had previous ipsilateral shoulder surgery relative to RSA for GHOA and TSA for GHOA patients (58.1%, 17.3%, 33.0%,  $P < .001$ ). There were no significant differences among the 3 groups in BMI, ASA score, depression, preoperative external rotation, or preoperative ASES score (Table 1). There were 14 postoperative surgical complications overall. In the TSA for GHOA group there were 2 patients with postoperative rotator cuff tears, 1 patient with instability, and 1 patient with heterotopic ossification formation. In the RSA for GHOA group, there were 2 patients with acromial stress fractures, 1 patient with traumatic baseplate failure, and 1 patient sustained an ipsilateral clavicle fracture postoperatively. In the RSA for RCA group, there were 4 acromial stress fractures and 2 patients with instability.

**Table I** Baseline comparison of patient demographic and clinical characteristics

Parameter	TSA	RSA for GHOA	RSA for RCA	P value
Age at surgery, yr	60.8 (7.6)	70.9 (5.6)	70.8 (6.9)	<b>&lt;.001*</b>
Male sex	65 (60.7%)	113 (40.9%)	40 (45.4%)	<b>.002*</b>
BMI	29.9 (5.5)	30.3 (6.3)	29.5 (4.9)	.580
ASA >2	16 (15.8%)	67 (24.3%)	20 (22.7%)	.170
Depression	22 (20.6%)	69 (25.0%)	18 (20.5%)	.520
Prior ipsilateral shoulder surgery	32 (33.0%)	46 (17.3%)	50 (58.1%)	<b>&lt;.001*</b>
Preoperative ASES score	38.6 (18.6)	38.6 (17)	35.5 (18.3)	.320
Preoperative ROM				
Forward elevation	100.2 (23.8)	92.2 (30.8)	88.2 (33.2)	<b>.016*</b>
External rotation	28.8 (12.7)	27.6 (17.6)	27.5 (20.9)	.840

TSA, anatomic total shoulder arthroplasty; RSA, reverse shoulder arthroplasty; GHOA, glenohumeral osteoarthritis; RCA, rotator cuff arthropathy; BMI, body mass index; ASA, American Society of Anesthesiologists comorbidity score; ASES, American Shoulder and Elbow Surgeons score; ROM, active range of motion.

\* Represents statistical significance at  $\alpha = 0.05$ ;  $n$  (%) represents count and frequency for categorical variables, and averages with standard deviations for continuous variables.

The MCID thresholds for each group were initially calculated using anchor-based methods; however, the predictive power of each of these thresholds was deemed unacceptable (AUC = <70%), and thus distribution methods were employed to derive each MCID value. The MCID for TSA for GHOA, RSA for GHOA, and RSA for RCA were calculated as 11.2, 10.4, and 12.0, respectively (Table II). The calculated PASS values for the RSA for RCA group was deemed to have unacceptable predictive power (AUC = 0.69), and thus was not included for further analysis. However, the PASS values for TSA and RSA for GHOA were deemed acceptable; 67.5 (AUC = 0.91) and 69.1 (AUC = 0.95), respectively (Table II). The SCB thresholds for TSA for GHOA, RSA for GHOA, and RSA for RCA all had acceptable predictive power on AUC analysis and were calculated as 21.9 (AUC = 0.90), 28.3 (AUC = 0.92), and 23.1 (AUC = 0.81), respectively (Table II).

There were no significant differences in median time to achievement of any CSO between patients receiving TSA for GHOA, RSA for GHOA, and RSA for RCA (SCB: 3.0, 3.0, 3.0 months,  $P = .761$ ; MCID: 1.5, 1.5, 1.5 months,  $P = .063$ ; PASS: 1.5 and 1.5 months,  $P = .219$ ). However, Log-rank tests revealed that the survival curves for each group significantly differed for MCID ( $P = .014$ ) but did not significantly differ for SCB ( $P = .053$ ) or PASS ( $P = .615$ ) (Fig. 1). There were significant differences between the groups in the cumulative percentage of patients achieving SCB at 6 months ( $P < .001$ ) and MCID at 3 months ( $P = .022$ ) (Table II). Posthoc testing revealed a significantly higher cumulative percentage of patients in the RSA for GHOA group who reached SCB by 6 months (91.7%) compared to the TSA (80.4%,  $P = .002$ ) and RSA for RCA groups (72.7%,  $P < .001$ ). Additionally, after posthoc testing, a significantly higher percentage of RSA for GHOA patients cumulatively achieved MCID at

3 months compared to RSA for RCA (3 months: 89.9, 79.5,  $P = .011$ ) (Table III). There were no significant differences in the percentage of patients that achieved PASS at any time points between the RSA for GHOA and TSA patients. At 2-year follow-up, there were significant differences in the percentage of patients achieving MCID and SCB between groups; posthoc testing revealed a significantly higher percentage of RSA for GHOA patients achieved MCID and SCB compared to RSA for RCA (MCID: 100%, 95.5%,  $P = .003$ , SCB: 94.6%, 86.4%,  $P = .010$ ) (Table III).

On cox regression analysis, male sex (HR 1.27, 95% CI 1.04-1.55,  $P = .020$ ), TSA for GHOA (HR 1.54, 95% CI 1.10-2.18,  $P = .013$ ), and RSA for GHOA (HR 1.35, 95% CI 1.03-1.75,  $P = .027$ ) were significantly associated with earlier achievement of MCID, whereas prior ipsilateral shoulder surgery (HR 0.75, 95% CI 0.59-0.94,  $P = .012$ ) and higher preoperative ASES score (HR 0.97, 95% CI 0.96-0.98,  $P < .001$ ) were significantly associated with delayed achievement of MCID (Table IV). For SCB, male sex (HR 1.32, 95% CI 1.07-1.62,  $P = .009$ ), older age (HR 1.02, 95% CI 1.01-1.04,  $P = .009$ ), and TSA (HR 1.44, 95% CI 1.01-2.05,  $P = .047$ ) were significantly associated with earlier achievement, whereas prior ipsilateral shoulder surgery (HR 0.77, 95% CI 0.60-0.98,  $P = .036$ ), and higher preoperative ASES score (HR 0.97, 95% CI 0.96-0.97,  $P < .001$ ) were significantly associated with delayed achievement (Table V).

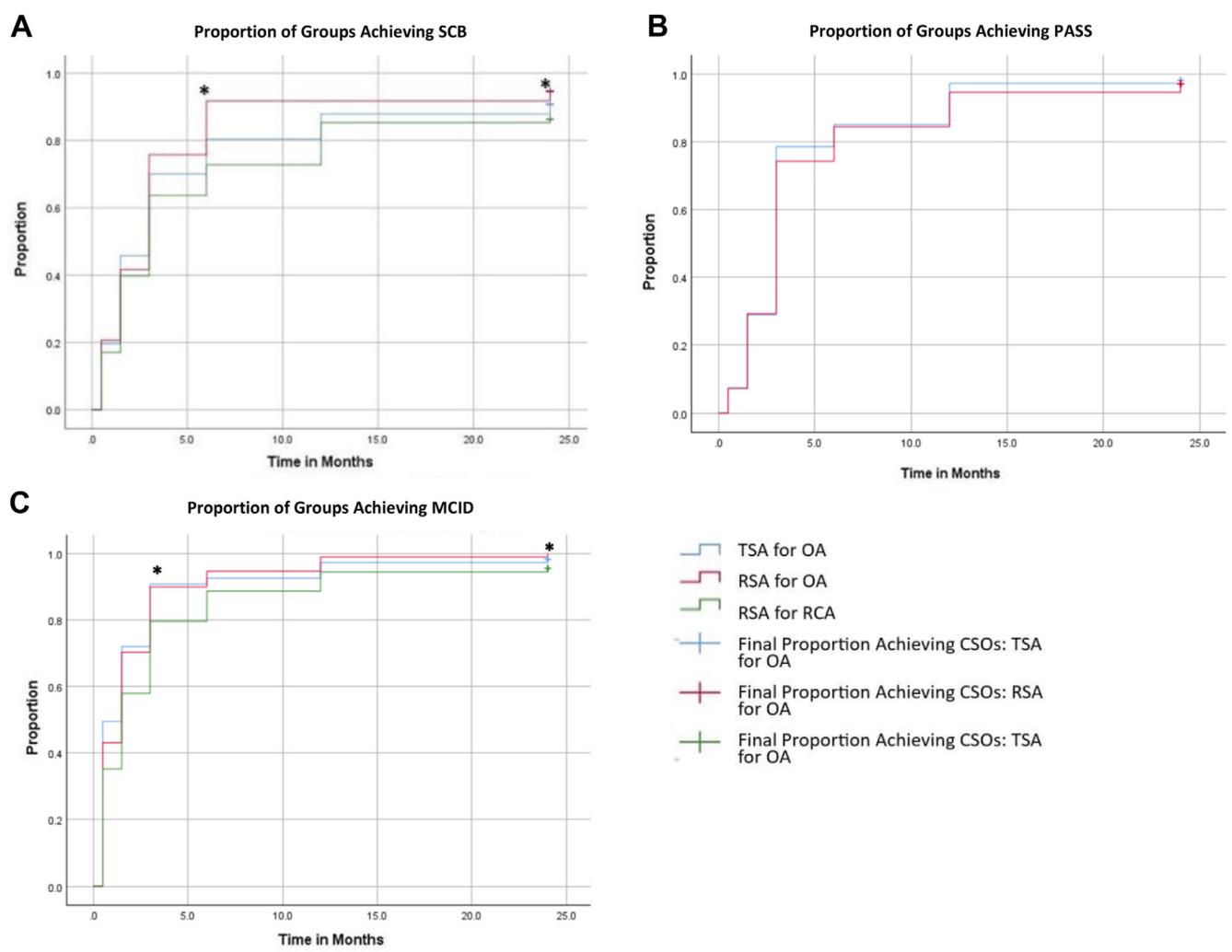
## Discussion

The results of this study establish distinct MCID, SCB, and PASS values for patients undergoing TSA for GHOA, RSA for GHOA, and RSA for RCA. Using these thresholds, it was found that patients undergoing TSA and RSA for



Table II CSO thresholds by group			
CSOs	TSA	RSA for GHOA	RSA for RCA
MCID	11.2	10.4	12.0
SCB (AUC/Sens/Spec)	21.9 (0.90/0.80/0.88)	28.3 (0.92/1.00/0.96)	23.1 (0.81/1.00/0.94)
PASS (AUC/Sens/Spec)	67.5 (0.91/1.00/0.94)	69.1 (0.95/0.71/0.87)	51.7 (0.69/0.94/0.67)

CSO, clinically significant outcome; TSA, anatomic total shoulder arthroplasty; RSA, reverse shoulder arthroplasty; GHOA, glenohumeral osteoarthritis; RCA, rotator cuff arthropathy; MCID, minimal clinically important difference; SCB, substantial clinical benefit; PASS, patient acceptable symptom state.



**Figure 1** Cumulative proportion of patients achieving (A) MCID (B) PASS and (C) SCB following RSA for GHOA, TSA for GHOA, and RSA for RCA. The population survival curves significantly differed by group for (A) MCID ( $P = .014$ ) but did not significantly differ for (B) PASS ( $P = .615$ ) or (C) SCB ( $P = .053$ ). (A) The cumulative percentage of patients achieving MCID significantly differed between groups at 3 months and 2 years. (B) The calculated PASS value for the RSA for RCA group was deemed to have unacceptable predictive power (AUC = 0.69), and thus was not included for analysis. There were no significant differences in the percentage of patients that achieved PASS at any time points between the RSA for GHOA and TSA patients. (C) The cumulative percentage of patients achieving SCB significantly differed between groups at 6 months and 2 years.

GHOA achieve CSOs earlier than RSA for RCA patients, and a significantly higher percentage of RSA for GHOA patients achieve CSOs by 2-years compared to RSA for RCA patients.

There were several notable limitations to this study. This study was designed to establish patient-centered CSOs and to compare the time to achievement among the identified groups. The goal was to create generalizable data for patient

**Table III** Between group comparisons of percentage of patients

Achieving CSO thresholds at each time-point

Parameter	TSA	RSA for GHOA	RSA for RCA	P value
2 weeks				
MCID (%)	49.5	42.1	35.2	.133
SCB (%)	19.6	20.7	17.0	.760
PASS (%)	7.5	7.2	-	.940
6 weeks				
MCID (%)	72.0	70.3	58.0	.063
SCB (%)	45.8	41.7	39.8	.670
PASS (%)	29.0	29.3	-	.940
3 mo				
MCID (%)	90.7	89.9	79.5	<b>.022*</b>
SCB (%)	70.1	75.7	63.6	.760
PASS (%)	78.5	74.3	-	.390
6 mo				
MCID (%)	92.5	94.6	88.6	.160
SCB (%)	80.4	91.7	72.7	<b>&lt;.001*</b>
PASS (%)	85.0	84.4	-	.880
1 yr				
MCID (%)	97.2	98.9	94.3	.056
SCB (%)	87.9	91.7	85.2	.180
PASS (%)	97.2	94.6	-	.280
2 yr				
MCID (%)	98.1	100	95.5	<b>.003*</b>
SCB (%)	90.7	94.6	86.4	<b>.036*</b>
PASS (%)	98.1	97.1	-	.440

TSA, anatomic total shoulder arthroplasty; RSA, reverse shoulder arthroplasty; GHOA, glenohumeral osteoarthritis; RCA, rotator cuff arthropathy; MCID, minimal clinically important difference; SCB, substantial clinical difference; PASS, patient acceptable symptom state; CSO, clinically significant outcome.

\* Represents statistical significance at  $\alpha = 0.05$ .

**Table IV** Cox regression analysis for factors associated with earlier

Achievement of MCID

Variable	HR	95% CI for HR		P value
		Lower	Upper	
Sex (male)	1.27	1.04	1.55	<b>.021*</b>
Age	1.02	1.00	1.03	.053
Depression	0.96	0.76	1.21	.731
BMI	0.99	0.98	1.01	.536
Prior shoulder surgery	0.75	0.59	0.94	<b>.012*</b>
Preop ASES score	0.97	0.96	0.98	<b>&lt;.001*</b>
TSA <sup>†</sup>	1.54	1.10	2.18	<b>.013*</b>
RSA for GHOA <sup>†</sup>	1.35	1.03	1.75	<b>.027*</b>

MCID, minimal clinically important difference; HR, hazard ratio; CI, confidence interval; BMI, body mass index; ASES, American Shoulder and Elbow Surgeons; TSA, anatomic total shoulder arthroplasty; RSA, reverse shoulder arthroplasty; GHOA, glenohumeral osteoarthritis.

\* Denotes statistical significance.

<sup>†</sup> Reference category set as RSA for rotator cuff arthropathy.

counseling and shared decision making. These data are not intended to guide the choice of surgical treatment (TSA vs. RSA) as the patient populations are not necessarily

comparable. As such, the patients were not matched which may confound the results of the group comparisons. Patients were evaluated based on surgical procedure and operative

**Table V** Cox regression analysis for factors associated with earlier

Achievement of SCB				
Variable	HR	95% CI for HR		P value
		Lower	Upper	
Sex (male)	1.32	1.07	1.62	.009*
Age	1.02	1.01	1.04	.009*
Depression	0.90	0.70	1.15	.390
BMI	1.00	0.98	1.02	.980
Prior shoulder surgery	0.77	0.60	0.98	.036*
Preop ASES score	0.97	0.96	0.97	<.001*
TSA†	1.44	1.01	2.05	.047*
RSA for GHOA	1.31	0.99	1.73	.060

SCB, substantial clinical benefit; HR, hazard ratio; CI, confidence interval; BMI, body mass index; ASES, American Shoulder and Elbow Surgeons; TSA, anatomic total shoulder arthroplasty; RSA, reverse shoulder arthroplasty; GHOA, glenohumeral osteoarthritis.

\* Denotes statistical significance at  $\alpha = 0.05$ .

† Reference category set as RSA for rotator cuff arthropathy.

indication rather than specific patient factors such as range of motion or degree of bony deformity. Additionally, the high-rate of noncompliance at the 6-month time point (RSA for OA: 55.1%, RSA for RCA: 53.4%, TSA: 64.5%,  $P = .19$ ) may have introduced a degree of measurement bias and is a limitation of our study. However, the significant finding at the 6-month time-point was regarding cumulative achievement up to that point. Thus, the nonresponders at 6-months were inconsequential if they had already achieved the outcome of interest (SCB) at prior time-points. Another limitation is that we did not use an adjusted  $P$  value to correct for multiple comparisons, as is done with the Bonferroni correction method. However, given that our study is retrospective without a-priori defined analyses and is purely exploratory rather than confirmatory for final decision making, we felt that it was not necessary to perform such corrections.<sup>1,27</sup> Doing so can increase the chance for type 2 errors and be diminutive to the power of an analysis.<sup>27</sup> Nonetheless, it remains possible that some of our significant results may be due to chance, and this exploratory work should serve as a pilot for future studies.

All surgeries in this study were performed by a single high-volume shoulder surgeon, which may limit the external validity of our results. Finally, we did not report postoperative imaging or objective range-of-motion measurements, which limits our ability to offer complete explanations of our results.

A multitude of prior studies have sought to establish CSO thresholds for shoulder arthroplasty procedures.<sup>12</sup> In a recent systematic review, Kolin et al identified several concerns regarding the substantial inconsistency and variability in how MCIDs were calculated and reported.<sup>12</sup> This review included 24 studies that calculated unique ASES MCID scores which varied widely from 6.3 to 29.5.<sup>12</sup> One of the most notable explanations for this variability were the different methodologies used to calculate the MCID.

Among the included studies, 37% used anchor-based methods, 26% used distribution-based methods, and 37% used alternative or arbitrary methods.<sup>12</sup> Distribution and anchor-based methods are both widely accepted modes of deriving CSOs, with the latter being limited when calculated for smaller populations.<sup>10,12</sup> For this reason, assessing the predictive power of CSO thresholds using AUC analysis is indicated whenever using anchor methods.<sup>6,10,20</sup> If the AUC is  $<0.7$ , the discriminative ability of the MCID threshold is unacceptable, and an alternative method should be used.<sup>6</sup> An additional explanation for the variability in reported MCID values is the conflation of TSA and RSA patients in 25% of the MCID calculations, and GHOA with RCA in all studies that reported MCIDs for RSA.<sup>12</sup> This limits each prior MCID calculation for TSA and RSA, since CSOs should be calculated separately for patient cohorts with different diagnoses and interventions. By avoiding these noted shortcomings of these prior studies, our study attempted to improve the internal and external validity of CSOs established for TSA and RSA.

There is increasing evidence suggesting that RSA affords vastly improved outcomes when performed in the setting of GHOA compared to RCA. Saini et al compared 198 RSA for GHOA to 113 RSA for RCA patients and found a  $>10$ -point difference in postoperative ASES scores, in favor of RSA for GHOA.<sup>24</sup> Additionally, a diagnosis of RCA was found to be the single largest predictor of postoperative ASES scores on multivariable analysis.<sup>24</sup> Similarly, the study by Forlizzi et al found that a diagnosis of GHOA was the strongest predictor of achieving an excellent outcome, whereas RCA was strongly predictive of having a poor outcome after RSA.<sup>8</sup> In a study by Matsen et al that evaluated 275 patients who received a shoulder arthroplasty procedure, they found that a humeral head not elevated on preoperative AP radiograph was independently predictive of a “better” outcome, defined as

an increase in the SST score of at least 30% of their maximal improvement based on preoperative SST scores.<sup>16</sup> The study by Lindbloom et al previously compared the outcomes among RSA patients according to preoperative diagnosis.<sup>14</sup> They found that compared to 221 RCA patients, the 129 with GHOA had 10-point greater improvement in ASES score from preoperative to 2-year postoperative. The reason for these notable differences in outcomes has been ascribed to improved force coupling and dynamic stability providing improvements in range of motion (ROM) with activity in patients with GHOA. Additionally, patients with RCA have a higher likelihood of sustaining postoperative acromial stress fractures, which is known to compromise postoperative outcomes. Despite this, complications such as acromial stress fractures were not significantly associated with time related achievement of CSOs in our study. This is likely due to these patients achieving CSOs at time points prior to developing an acromial stress fracture.

Prior studies comparing the time-related rate of recovery following TSA vs RSA have had mixed results. The study by Levy et al showed that RSA may result in less consistent and more variable postoperative recovery by comparing average PROM scores between groups at multiple consecutive postoperative time points.<sup>13</sup> These results were corroborated by Drager et al by comparing cumulative percentage of achievement of CSOs at multiple consecutive postoperative time points.<sup>7</sup> In contrast, Simovitch et al concluded that patients achieve improvements in PROMs and ROM that are, for the most part very similar, but with improvements in ROM favoring TSA.<sup>26</sup> However, their results suggest that Constant scores and forward elevation changes are greater after RSA, whereas improvements in external rotation were greater after TSA.<sup>26</sup> These inconsistencies may be attributed to the considerable differences in preoperative pain and function in patients with RCA, which are often much worse than in patients with GHOA.<sup>24</sup> Therefore, the improvements in PROMs and ROM reported by Levy et al should be interpreted within the context of their absolute postoperative score as well as their percentage of maximal improvement [ie, a patient with a preoperative ASES score of 10 and postoperative score of 40 (30 point improvement, ~33% maximum outcome improvement) compared to a preoperative score of 80 with a postoperative score of 90 (10 point improvement, 50% maximum outcome improvement)]. Notably, this study along with the 2 aforementioned studies by Drager et al and Levy et al pooled the diagnoses of GHOA and RCA in their RSA groups.<sup>7,13,26</sup>

## Conclusion

Calculated CSO thresholds differ according to preoperative diagnosis and shoulder arthroplasty type. Patients

undergoing TSA and RSA for GHOA achieve CSOs earlier than RSA for RCA patients, and a significantly higher percentage of RSA for GHOA patients achieve CSOs by 2 years after surgery compared to RSA for RCA patients.

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## References

1. Bender R, Lange S. Adjusting for multiple testing—when and how? *J Clin Epidemiol* 2001;54:343-9.
2. Best MJ, Aziz KT, Wilckens JH, McFarland EG, Srikumaran U. Increasing incidence of primary reverse and anatomic total shoulder arthroplasty in the United States. *J Shoulder Elbow Surg* 2021;30:1159-66. <https://doi.org/10.1016/j.jse.2020.08.010>
3. Boileau P, Gonzalez J-F, Chuinard C, Bicknell R, Walch G. Reverse total shoulder arthroplasty after failed rotator cuff surgery. *J Shoulder Elbow Surg* 2009;18:600-6. <https://doi.org/10.1016/j.jse.2009.03.011>
4. Boileau P, Watkinson D, Hatzidakis AM, Hovorka I. Neer Award 2005: the Grammont reverse shoulder prosthesis: results in cuff tear arthritis, fracture sequelae, and revision arthroplasty. *J Shoulder Elbow Surg* 2006;15:527-40. <https://doi.org/10.1016/j.jse.2006.01.003>
5. Cabarcas BC, Gowd AK, Liu JN, Cvetanovich GL, Erickson BJ, Romeo AA, et al. Establishing maximum medical improvement following reverse total shoulder arthroplasty for rotator cuff deficiency. *J Shoulder Elbow Surg* 2018;27:1721-31. <https://doi.org/10.1016/j.jse.2018.05.029>
6. Copay AG, Subach BR, Glassman SD, Polly DW, Schuler TC. Understanding the minimum clinically important difference: a review of concepts and methods. *Spine J* 2007;7:541-6. <https://doi.org/10.1016/j.spinee.2007.01.008>
7. Drager J, Polce EM, Fu M, Nemsick M, Huddleston HP, Forsythe B, et al. Patients undergoing anatomic total shoulder arthroplasty achieve clinically significant outcomes faster than those undergoing reverse shoulder arthroplasty. *J Shoulder Elbow Surg* 2021;30:2523-32. <https://doi.org/10.1016/j.jse.2021.02.015>
8. Forlizzi JM, Puzzitiello RN, Hart PA, Churchill R, Jawa A, Kirscht JM. Predictors of poor and excellent outcomes after reverse total shoulder



- arthroplasty. *J Shoulder Elbow Surg* 2022;31:294-301. <https://doi.org/10.1016/j.jse.2021.07.009>
9. Guyatt GH, Osoba D, Wu AW, Wyrwich KW, Norman GR. Methods to explain the clinical significance of health status measures. *Mayo Clin Proc* 2002;77:371-83. <https://doi.org/10.4065/77.4.371>
  10. Harris JD, Brand JC, Cote MP, Faucett SC, Dhawan A. Research pearls: the significance of statistics and perils of pooling. Part 1: clinical versus statistical significance. *Arthroscopy* 2017;33:1102-12. <https://doi.org/10.1016/j.arthro.2017.01.053>
  11. Kirsch JM, Puzzitiello RN, Swanson D, Le K, Hart PA, Churchill R, et al. Outcomes after anatomic and reverse shoulder arthroplasty for the treatment of glenohumeral osteoarthritis: a propensity score-matched analysis. *J Bone Joint Surg Am* 2022;104:1362-9. <https://doi.org/10.2106/jbjs.21.00982>
  12. Kolin DA, Moverman MA, Pagani NR, Puzzitiello RN, Dubin J, Menendez ME, et al. Substantial inconsistency and variability exists among minimum clinically important differences for shoulder arthroplasty outcomes: a systematic review. *Clin Orthop Relat Res* 2022;480:1371-83. <https://doi.org/10.1097/corr.0000000000002164>
  13. Levy JC, Everding NG, Gil CC, Stephens S, Giveans MR. Speed of recovery after shoulder arthroplasty: a comparison of reverse and anatomic total shoulder arthroplasty. *J Shoulder Elbow Surg* 2014;23:1872-81. <https://doi.org/10.1016/j.jse.2014.04.014>
  14. Lindbloom BJ, Christmas KN, Downes K, Simon P, McLendon PB, Hess AV 2nd, et al. Is there a relationship between preoperative diagnosis and clinical outcomes in reverse shoulder arthroplasty? An experience in 699 shoulders. *J Shoulder Elbow Surg* 2019;28:S110-7. <https://doi.org/10.1016/j.jse.2019.04.007>
  15. Mahendraraj KA, Carducci MP, Galvin JW, Golenbock SW, Grubhofer F, Jawa A. Reassessing the minimum two-year follow-up standard after total shoulder arthroplasty—is one year sufficient? *Shoulder Elbow* 2021;13:527-33. <https://doi.org/10.1177/1758573220922845>
  16. Matsen FA, Russ SM, Vu PT, Hsu JE, Lucas RM, Comstock BA. What factors are predictive of patient-reported outcomes? A prospective study of 337 shoulder arthroplasties. *Clin Orthop Relat Res* 2016;474:2496-510. <https://doi.org/10.1007/s11999-016-4990-1>
  17. Mizuno N, Denard PJ, Raiss P, Walch G. Reverse total shoulder arthroplasty for primary glenohumeral osteoarthritis in patients with a biconcave glenoid. *J Bone Joint Surg Am* 2013;95:1297-304. <https://doi.org/10.2106/jbjs.1.00820>
  18. Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. *Medical care* 2003;41:582-92. <https://doi.org/10.1097/01.mlr.0000062554.74615.4c>
  19. Puzzitiello RN, Agarwalla A, Liu JN, Cvetanovich GL, Romeo AA, Forsythe B, et al. Establishing maximal medical improvement after anatomic total shoulder arthroplasty. *J Shoulder Elbow Surg* 2018;27:1711-20. <https://doi.org/10.1016/j.jse.2018.03.007>
  20. Puzzitiello RN, Gowd AK, Liu JN, Agarwalla A, Verma NN, Forsythe B. Establishing minimal clinically important difference, substantial clinical benefit, and patient acceptable symptomatic state after biceps tenodesis. *J Shoulder Elbow Surg* 2019;28:639-47. <https://doi.org/10.1016/j.jse.2018.09.025>
  21. Razmjou H, Stratford P, Kennedy D, Holtby R. Pattern of recovery following total shoulder arthroplasty and humeral head replacement. *BMC Musculoskel Disord* 2014;15:306. <https://doi.org/10.1186/1471-2474-15-306>
  22. Ring D, Bozic KJ. Value-based healthcare: the value of considering patient preferences and circumstances in orthopaedic surgery. *Clin Orthop Relat Res* 2016;474:633-5. <https://doi.org/10.1007/s11999-015-4648-4>
  23. Ruopp MD, Perkins NJ, Whitcomb BW, Schisterman EF. Youden index and optimal cut-point estimated from observations affected by a lower limit of detection. *Biom J* 2008;50:419-30. <https://doi.org/10.1002/bimj.200710415>
  24. Saini SS, Pettit R, Puzzitiello RN, Hart PA, Shah SS, Jawa A, et al. Clinical outcomes after reverse total shoulder arthroplasty in patients with primary glenohumeral osteoarthritis compared with rotator cuff tear arthropathy: does preoperative diagnosis make a difference? *J Am Acad Orthop Surg* 2022;30:e415-22. <https://doi.org/10.5435/jaas-d-21-00797>
  25. Simovitch R, Flurin PH, Wright T, Zuckerman JD, Roche CP. Quantifying success after total shoulder arthroplasty: the minimal clinically important difference. *J Shoulder Elbow Surg* 2018;27:298-305. <https://doi.org/10.1016/j.jse.2017.09.013>
  26. Simovitch RW, Friedman RJ, Cheung EV, Flurin P-H, Wright T, Zuckerman JD, et al. Rate of improvement in clinical outcomes with anatomic and reverse total shoulder arthroplasty. *JBJS* 2017;99:1801-11. <https://doi.org/10.2106/jbjs.16.01387>
  27. Streiner DL. Best (but oft-forgotten) practices: the multiple problems of multiplicity—whether and how to correct for many statistical tests I. *Am J Clin Nutr* 2015;102:721-8. <https://doi.org/10.3945/ajcn.115.113548>
  28. Tashjian RZ, Hung M, Keener JD, Bowen RC, McAllister J, Chen W, et al. Determining the minimal clinically important difference for the American Shoulder and Elbow Surgeons score, Simple Shoulder Test, and Visual Analog Scale (VAS) measuring pain after shoulder arthroplasty. *J Shoulder Elbow Surg* 2017;26:144-8. <https://doi.org/10.1016/j.jse.2016.06.007>
  29. Waterman BR, Dean RS, Naylor AJ, Otte RS, Sumner-Parilla SA, Romeo AA, et al. Comparative clinical outcomes of reverse total shoulder arthroplasty for primary cuff tear arthropathy versus severe glenohumeral osteoarthritis with intact rotator cuff: a matched-cohort analysis. *J Am Acad Orthop Surg* 2020;28:e1042-8. <https://doi.org/10.5435/jaas-d-19-00493>
  30. Werner BC, Chang B, Nguyen JT, Dines DM, Gulotta LV. What change in American Shoulder and Elbow Surgeons score represents a clinically important change after shoulder arthroplasty? *Clin Orthop Relat Res* 2016;474:2672-81. <https://doi.org/10.1007/s11999-016-4968-z>