Defining Clinically Significant Outcomes Following Superior Capsular Reconstruction with Acellular Dermal Allograft

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Purpose: To define clinically significant outcomes (CSO) thresholds for minimal clinically important difference (MCID), substantial clinical benefit (SCB), and patient-acceptable symptomatic state (PASS) in patients undergoing superior capsular reconstruction (SCR) with an acellular dermal allograft. We also evaluated patient-specific variables predictive of achieving CSO thresholds. **Methods:** The American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), Single Assessment Numeric Evaluation (SANE), and subjective Constant-Murley (Constant) scores were collected preoperatively and at the most recent follow up for patients undergoing SCR from 2010 to 2019. A distribution-based approach was used to calculate MCID, and an anchor-based approach was used to calculate SCB and PASS. Logistic regression was used to determine factors associated with CSO achievement. **Results:** Fifty-eight patients were identified ($n = 39$ males; $n = 19$ females) with a mean age of 53.4 ± 14.1 years at surgery and an average follow-up of 23 months. The MCID, SCB, and PASS were 11.2, 18.02, and 68.82 for ASES, 14.5, 23.13, and 69.9 for SANE, and 3.6, 10, and 18 for Constant, respectively. Subscapularis tear, female sex, and workers compensation (WC) status reduced odds of achieving MCID. Reduced odds of achieving Constant SCB were associated with older age, female sex, and WC status, while concomitant distal clavicle excision during SCR and lower preoperative ASES increased odds of achieving ASES SCB. Reduced odds for achieving ASES PASS were associated with female sex and WC status, while reduced odds for achieving SANE PASS were associated with subscapularis tearing preoperatively. **Conclusion:** On the basis of calculated values for MCID, SCB, and PASS, subscapularis tearing, WC status, age, and sex are associated with failure to achieve clinically significant outcomes following SCR. Concomitant distal clavicle excision during SCR and lower preoperative ASES was predictive for achievement of MCID and SCB. By defining the thresholds and variables predictive of achieving CSOs following SCR, surgeons may better counsel patients prior to SCR. **Level of Evidence:** Level IV, case series.

Introduction

Injuries of the rotator cuff represent the most common source of shoulder pain and disability treated by orthopaedic surgeons.[1,2] Following failed nonoperative management, various surgical techniques are available for the surgical treatment of rotator cuff tears. However, the successful management of massive, irreparable rotator cuff tears (MIRCTs), defined by tendon retraction

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>5 cm or involvement of two or more tendons, remains challenging.[3,4] Irreparable tears, characterized as tears predicted to be irreparable on the basis of preoperative findings or tears predicted to have a poor outcome following rotator cuff surgery regardless of the extent of operative repair[5,6] have been reported in 12-15% of patients with massive rotator cuff tears.[7,8] For patients aged 70 and older with MIRCTs with associated glenohumeral osteoarthritis, reverse total shoulder arthroplasty (rTSA) has been shown to produce successful outcomes. However, concerns regarding implant longevity have made rTSA controversial in patients with MIRCTs aged 60 and younger.[5,9] Superior capsular reconstruction (SCR), initially described by Mihata et al.,[10,11] has gained increasing interest for the treatment of MIRCTs. By using autograft[12,13] or allograft [14,15] material, surgical reconstruction of the superior glenohumeral joint capsule restores joint stability and prevents superior migration of the humeral head while maintaining native glenohumeral station in cadavaric models and clinical settings.[1,3,10,11,16,17]

To date, both biomechanical[11,16] and clinical investigations[10,14,18] have demonstrated promising outcomes following SCR. Clinical series with fascia lata autograft and dermal allograft have shown significant improvements in American Shoulder and Elbow Surgeon (ASES) score, range of motion, and pain (based on visual analog score [VAS])[10,14] However, despite statistically significant differences, the clinically significant benefit of a procedure cannot be extrapolated on the basis of differences between preoperative and postoperative patient-reported outcome measures (PROMs).

In order to provide a more objective measure of patient satisfaction to optimize patient outcomes, increased attention has been placed on the evaluation of clinically significant outcomes by calculating the minimally clinically important difference (MCID), substantial clinical benefit (SCB), and patient-acceptable symptoms state (PASS) thresholds following surgery.[19-21]

These metrics represent tiers of health, where MCID establishes the improvement in outcome that results in the smallest clinical improvement after surgery, SCB demonstrates the improvement that a patient finds substantial postoperatively, and the PASS characterizes the degree of postoperative outcome score necessary for patient satisfaction. To date, the threshold values necessary to achieve these metrics have not been established.

The purpose of this investigation was to define clinically significant outcomes (CSO) thresholds for minimal clinically important difference (MCID), substantial clinical benefit (SCB) and patient acceptable symptomatic state (PASS) in patients undergoing superior capsular reconstruction (SCR) with an acellular dermal allograft. We also evaluated patient-specific variables predictive of achieving CSO thresholds. We hypothesize that that there are differences in the proportions of specific demographic, preoperative, radiographic, and intraoperative variables of patients achieving MCID, SCB, and PASS.

Materials and Methods

Patient Population

Institutional Review Board approval was obtained at Rush University Medical Center prior to the initiation of the study (ORA 20091103). A retrospective review of a prospectively collected database recording PROMs from a single-institution registry was queried for all patients who underwent SCR between 2010 and 2019. Inclusion criteria consisted of patients who underwent SCR for an irreparable rotator cuff tear with a minimum of 12-month follow-up. Exclusion criteria consisted of the following: 1) patients with evidence of anterior, posterior or inferior instability, 2) patients without preoperative PROMs, 3) patients without postoperative PROMs at a minimum of 12 months following SCR, 4) patients without completed anchor questions at a minimum of 12 months following SCR, 5) patients with significant rotator cuff arthropathy (defined as Hamada grade 4B and 5)[22], and 6) patients with a reduced acromiohumeral distance (AHD) on preoperative imaging that could not be effectively mobilized to a normal station with application of a downward force on the flexed elbow on radiographic evaluation.

Indications for SCR

Indications for SCR included patients with significant shoulder pain in the setting of a massive, irreparable rotator cuff tear and failed nonoperative or prior operative management. Patients possessed preserved passive range of motion, intact deltoid function, and limited evidence of rotator cuff arthropathy. Other relative indications were the presence of a supraspinatus or infraspinatus retraction to the glenoid and Goutallier grade $\geq$3 changes. Patients with milder retraction or Goutallier grades were indicated for SCR in the setting of poor cuff tissue quality or a history of multiple prior rotator cuff repairs failures.[23]

Surgical Technique

Several variations of the senior author's preferred technique have been previously described in the literature.[24-30] In brief, visualization of the glenohumeral joint is established using a standard posterior arthroscopic portal. Diagnostic arthroscopy is performed to assess the integrity of rotator cuff, concomitant pathologies and to confirm the operative plan. The biceps tendon is frequently absent because of prior surgery or traumatic rupture but, if present, we prefer a tenodesis,

as it is frequently diseased, and removal facilitates preparation of the superior glenoid surface. Next, a subacromial decompression and debridement of the superior labrum and rotator cuff footprint is performed. If feasible, repairs of any of the infraspinatus and subscapularis tears are performed, prior to performing SCR. In most cases, the senior author places 3-0 knotless anchors medially on the glenoid (1 at the base of the coracoid, 1 posteriorly at infraspinatus/teres junction, and 1 central, which is more medial) and 2 anchors slightly lateral to the humeral head articular margin at the medial edge of the rotator cuff footprint. A 40 mm × 70 mm × 3 mm acellular dermal allograft (Arthrex, Inc., Naples, FL) is cut to size using intraoperative measures. The measurements are taken by centering the humeral head, providing neutral rotation with 30-40° abduction and 15° forward flexion to maximize the acromio-humeral interval. Once prepared, the graft is passed through a canula and secured to the anchors using sutures along the glenoid and suture tapes to the humeral head, followed by placement of two lateral row anchors. Side-to-side sutures are then placed to close the interval between the graft and the infraspinatus and subscapularis, where possible. When marginal convergence with the subscapularis is performed, care is taken to suture in slight external rotation, so as not to overconstrain the construct. Glenohumeral abduction must also be limited to 10-30° to limit graft strain.

Data Collection

Demographics, preoperative, intraoperative, radiographic, and postoperative data were retrospectively collected in patients meeting inclusion/exclusion criteria. PROMs were collected preoperatively and postoperatively at 6 months, 12 months, and final follow up using an electronic data collection service (Outcome-Based Electronic Research Database; Universal Research Solutions, Columbia, MO). PROMs collected included ASES, subjective Constant-Murley (Constant) Score, and SANE. Demographic factors collected included patient sex, age, body mass index (BMI), smoking status, and workers compensation (WC) status. Preoperative data included shoulder laterality, type/number of prior ipsilateral shoulder surgeries, duration of symptoms, and shoulder range of motion.

Imaging measurements included acromio-humeral distance (AHD),[31] the presence of acromioclavicular joint (ACJ) arthritis (yes vs no), Hamada grade of glenohumeral osteoarthritis,[22] Goutallier stage of fatty infiltration[32] Thomazeau classifications,[33] supraspinatus, infraspinatus, and/or subscapularis tendon integrity (intact versus torn). All measurements were performed by an orthopedic surgery resident and a fellowship-trained sports medicine orthopaedic surgeon (D.K.) using a picture archiving and communications system (Opal-RAD PACS, Viztek, Garner, NC). Intraoperative data collection consisted of the presence of a subscapularis tear (intact vs torn) and performance of concomitant procedures (subscapularis repair, biceps tenodesis or tenotomy, distal clavicle excision). Postoperative data collected included the incidence of any complications related to the SCR procedure and conversion to rTSA.

Sample Size and Power Analysis

The differences in PROMs required to surpass the threshold to achieve a clinically significant benefit and patient satisfaction following SCR have not been established. Using the MCID previously reported for ASES following rotator cuff repair (RCR), the authors estimated that an improvement of 11.1 points would yield a MCID following SCR.[34] An a priori power analysis was then performed using a power of .80 and an error rate of 5%, a minimum of 16 pairwise comparisons was found to be sufficient to support the reliability of the study results.

Anchor Questions

Anchor questions were assessed at 12 months postoperatively. For calculation of SCB, patients provided a response to the anchor question: "Since your last surgery, has there been any change in the overall function of your shoulder?" For calculation of PASS, patients provided a response to the anchor question: "Taking into account all activities you have done during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is

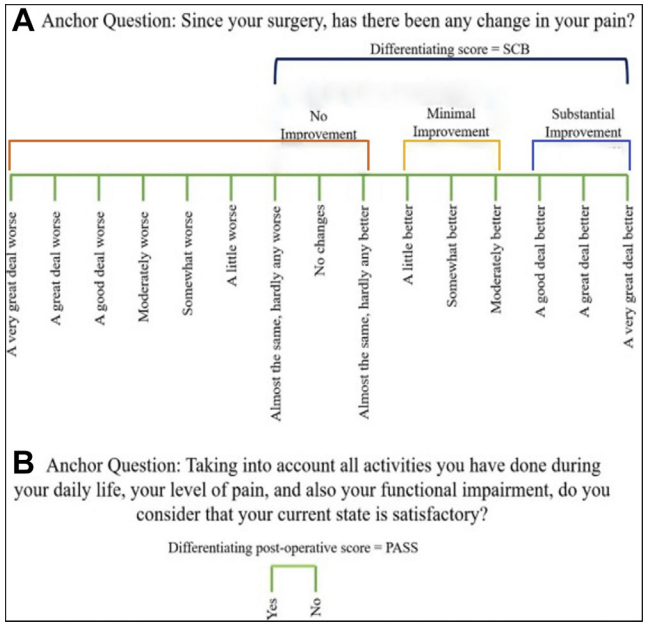

Fig 1. Anchor-based calculation of substantial clinical benefit (SCB; A), and patient acceptable symptom state (PASS; B).[34]

satisfactory?" Physical function questions are used because domain-specific questions have been previously shown to have high construct validity as anchors.[35] Responses to the anchor questions were based on data reported in previous investigations (Fig 1).[34,36-38]

Statistical Analysis

Several methods to calculate MCID, PASS, and SCB have been previously described, with distribution and anchor-based methods being the most common. In the distribution-based method, changes in the outcome represent the minimally significant change occurring beyond a variance of error. In previous studies half the standard deviation of outcome scores has been shown to reliably predict MCID. In the anchor-based method, "anchor" questions based on global function, pain, and satisfaction are used to determine patient-perceived improvement. [23,39,40] These outcomes are then used to determine values for MCID, PASS, or SCB. [23,39,40] In this study the MCID was calculated using a distribution-based method. An anchor-based approach was used to calculate SCB and PASS for ASES, SANE, Constant as described in previous studies.[23,39,40] Receiver operating characteristic (ROC) and area under the curve (AUC) analysis were used to identify optimal threshold values predictive of patient satisfaction. AUC values greater than .7 were considered to have adequate predictive value, while values greater than .8 were considered to have excellent predictive value.[41] The Youden index was used to maximize the sensitivity and specificity of threshold values. MCID, SCB, and PASS were calculated for ASES, SANE, and Constant. A stepwise logistic regression model was used to determine which patient factors were most predictive for achievement of MCID, SCB, and PASS. If a variable had a P value $<.05$ on univariate analysis, they were included in the multivariate logistic regression model along with age and sex. Weighted Cohen's κ was used to determine interobserver reliability for radiographic assessment for ordinal variables, and the intraclass correlation coefficient (ICC) was used to assess reliability for continuous variables. Odds ratios (ORs) were generated using cross-tabulation, and a 2-tailed Fisher exact probability test was conducted to determine statistical significance. Independent two-tailed Student's t-test was used to compare changes in preoperative and postoperative PROs. All statistical analyses were performed using Stata software v.16.1 (StataCorp, College Station, TX). Statistical significance was set at P value $<.05$.

Results

Demographics and Clinical Characteristics

Fifty-eight patients (mean age: 53.4 ± 13.9, range: 45 to 75 years) of a total of 75 patients (77%) who underwent SCR and completed a minimum 1-year follow-up were included in the study. Twenty-seven patients (mean age: 55.8 ± 6.6, range: 45 to 70 years) of a total of 75 patient did not complete the anchor questionnaire for MCID, SCB, and PASS calculation. Patients who completed the anchor questions were not statistically different from those who did not, based on demographic characteristics, with the exception of symptom duration, smoking status, and prior surgery (Appendix 1). Demographic characteristics are listed in Table 1. Fifty-seven percent ($n = 33/58$) of patients had a prior surgery on the ipsilateral shoulder prior to SCR, with 22% ($n = 13/58$) undergoing a prior biceps tenodesis.

Surgical Details and Concomitant Procedures

MRI diagnosis with an intraoperative confirmation of a supraspinatus tear was evident in all cases (100%); the infraspinatus was torn in 32 cases (55.2%); and the subscapularis was torn in 10 cases (17.2%). All subscapularis tears were repaired (100%). At the time of SCR, 36.2% ($n = 21/58$) of patients underwent a concomitant biceps tenodesis, 8.6% ($n = 5/58$) a distal clavicle excision, while 8.6% ($n = 5/58$) underwent both a biceps tenodesis and a distal clavicle excision.

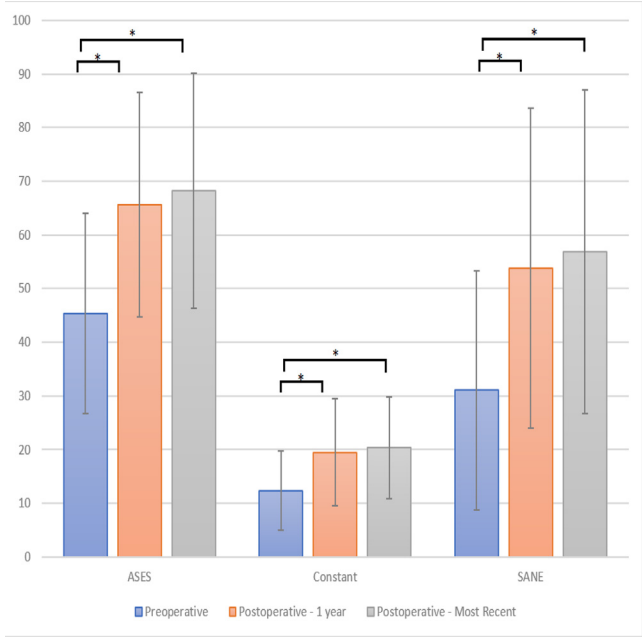

Fig 2. Preoperative and postoperative patient-reported outcome scores at 12 months and most recent. PROs shown include American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), Single Assessment Numeric Evaluation (SANE), subjective Constant-Murley (Constant) Score. There were no significant differences from 12 months to most recent (23 ± 11). *Designates statistically significant, $P < .05$.

Table 1. Demographic and Preoperative Clinical Characteristics*

Demographics	Overall ($n = 58$)
Age at surgery (yr)	53.4 ± 13.9
Sex	
Male	39 (67.2%)
Female	19 (32.8%)
Body Mass Index (kg/m^2)	30.5 ± 6.3
Laterality	
Right	31 (53.4%)
Left	27 (46.6%)
Smoking	
Never	33 (56.9%)
Yes	9 (15.5%)
Former	6 (10.3%)
Unknown	10 (17.2%)
Worker's Compensation claims	22 (37.9%)
Hypertension	19 (32.8%)
Diabetes	6 (10.3%)
Thyroid Dysfunction	4 (6.9%)
Symptom Duration (yr)	2.1 ± 2.5
Prior Surgery	33 (56.7%)
Preoperative forward flexion (°)	132.0 ± 39.5
Postoperative (°)	143.7 ± 36.6
Preoperative abduction (°)	97.1 ± 49.8
Postoperative (°)	104.1 ± 33.5
Preoperative external rotation (°)	46.9 ± 18.1
Postoperative (°)	48.1 ± 17.0
Preoperative internal rotation (°)	17.8 ± 12.3
Postoperative (°)	13.4 ± 2.8
Acromioclavicular joint arthritis	20 (34.5%)
Time to last follow up (months)	23 ± 11

*Continuous variables presented as means ± SD; binomial variables presented as frequencies (proportions).

Radiographic Outcomes

Preoperative imaging was available for assessment in all patients. Average AHD was 5.7 ± 2.8 mm. Evidence of AC joint arthritis was observed in 34.5% ($n = 20/58$) of patients. Glenohumeral osteoarthritis was present in 13.8% ($n = 8/58$) of patients, with 12.1% ($n = 7/58$) classified as possessing Hamada grade 3 and 1.7% ($n = 1/58$) classified as Hamada grade 4A. Moderate to severe fatty infiltration of the supraspinatus muscle, consisted with Goutallier classification grades 3 and 4, was present in 56.9% ($n = 33/58$) of patients. Moderate to severe supraspinatus muscle atrophy, graded as Thomazeau classification grades 2 and 3, was present in 63.8% ($n = 37/58$) of patients (Table 2). One hundred percent ($n = 58/58$) (100%) had tearing of the supraspinatus tendon, while 56.9% ($n = 33/58$) had associated tearing of the infraspinatus and 17.2% ($n = 10/58$) tearing of the subscapularis.

Clinical Outcomes

When compared to preoperative values, statistically significant improvement was noted in ASES (44.6 ± 19.2 to 65.5 ± 21.7; $P < .001$), Constant (12.4 ± 6.9 to 19.8 ± 9.6; $P < .001$), and SANE (31.1 ± 22.4 to 57.8 ± 30.4; $P < .001$) scores at final follow up following SCR.

Table 2. Preoperative Radiographic Characteristics Prior to Superior Capsular Reconstruction

Acromioclavicular Joint Arthritis	20 (34.5%)
Acromio-humeral distance (mm)	5.7 ± 2.8
Hamada Classification	
1	39 (67.2%)
2	9 (15.5%)
3	7 (12.1%)
4	1 (1.7%)
Insufficient preoperative radiographic imaging	2 (3.4%)
Goutallier Classification	
0	1 (1.7%)
1	7 (12.1%)
2	15 (25.9%)
3	18 (31.0%)
4	15 (25.9%)
Insufficient preoperative MRI imaging	2 (3.4%)
Thomazeau Classification	
1	19 (32.8%)
2	18 (31.0%)
3	19 (32.8%)
Insufficient preoperative MRI imaging	2 (3.4%)
Rotator Cuff Tear	58 (100%)
SSP	58 (100%)
ISP	33 (56.9%)
SSC	10 (17.2%)

ISP, Infraspinatus; MRI, magnetic resonance imaging; SSC, Subscapularis; SSP, Supraspinatus. *Continuous variables presented as means ± SD; binomial variables presented as frequencies (proportions).

Establishing MCID, SCB, and PASS

The MCID was calculated for individual PROMs using a distribution-based method as follows: ASES, 11.2; SANE, 14.5; and Constant, 3.6. The achievement rates of MCID for the respective PROMs was ASES (64.4%), SANE (60.9%), and Constant (75.8%) (Table 3).

The values for SCB and PASS were calculated for individual PROMs using the anchor-based method (Table 4). SCB values were the following: ASES 18.02, SANE 23.13, and Constant 10. The achievement rates of SCB were ASES (52.2%), SANE (43.5%), and Constant (42.4%).

PASS values were the following: ASES 68.82, SANE 69.9, and Constant 18. The achievement rates of PASS were ASES (40.0%), SANE (41.3%), and Constant (51.5%).

Table 3. Distribution-Based Method for Calculating MCIDs

	MCID	Achieved MCID, *n* (%)
ASES	11.2	29 (64.4%)
SANE	14.5	28 (60.9%)
Constant	3.6	25 (75.8%)

ASES, American Shoulder and Elbow Surgeons; MCID, minimal clinically important difference; SANE, single assessment numeric evaluation.

Table 4. Anchor-Based Method for Calculating Individual PROMs

	Threshold	Sensitivity	Specificity	AUC	Achieved SCB, *n* (%)
SCB					
ASES	18.02	92.3%	58.6%	69.1%	24 (52.2%)
SANE	23.13	80.0%	66.7%	71.4%	20 (43.5%)
Constant	10	84.6%	82.4%	83.3%	14 (42.4%)
PASS					
ASES	68.82	56.5%	66.7 %	61.4%	18 (40.0%)
SANE	69.9	66.7%	79.0%	72.1%	19 (41.3%)
Constant	18	77.8%	75%	76.7%	17 (51.5%)

ASES, American Shoulder and Elbow Surgeons; AUC, area under the curve; PASS, patient acceptable symptomatic state; PROMs, patient-reported outcome measures; SANE, single assessment numeric evaluation; SCB, substantial clinical benefit.

Logistic Regression

A statistically significant univariate factor associated with achieving ASES MCID was lower preoperative ASES scores. Achieving both Constant and SANE MCID was associated with absence of preoperative subscapularis tear (Appendix 2).

In univariate analysis for SCB lower preoperative ASES scores and female sex were the only significant factors associated with meeting ASES and Constant MCID, respectively. However, multivariate regression identified increased preoperative internal rotation (OR: .434; $P = .037$) as a significant independent factor associated with failure to achieve SCB for Constant (Appendix 3).

Females were less likely to achieve PASS (OR: .026; $P = .037$) for the Constant PROMs. (Appendix 4). Significant univariate factors for PASS include lower preoperative ASES and Constant scores, worker's compensation status, and decreased postoperative forward flexion. (Appendix 4). Reduced odds of achieving PASS for ASES was associated with worker's compensation status (OR: .124; $P = .032$), while subscapularis tearing (OR: .044; $P = .031$) was associated with failure to achieve PASS for SANE.

Discussion

Failure to achieve clinically significant outcomes following SCR with acellular dermal allograft was associated with subscapularis tearing, WC status, age, and sex. Concomitant distal clavicle excision during SCR and lower preoperative ASES was predictive for achievement of MCID and SCB. This study identifies threshold values for MCID, SCB, and PASS in patients undergoing SCR with respect to the ASES, SANE, and Constant scores at a minimum of 12 months patient follow-up. Values for MCID, SCB, and PASS were 11.2, 18.02, and 68.82 for ASES, 14.5, 23.13, and 69.9 for SANE, and 3.6, 10, and 18 for Constant, respectively. Variables associated with failing to achieve these clinically significant outcomes following SCR, including the presence of subscapularis tearing prior to surgery, WC status, older age, and female sex. These additional threshold values provide a spectrum of clinically meaningful outcomes that may be used to gauge operative efficacy.[34,42]

Recently, increasing interest in clinically significant outcomes following shoulder procedures has been reported. Cvetanovich et al. recently established MCID, SCB, and PASS thresholds for ASES, SANE, and Constant scores for RCR surgery with comparable results.[34] Specifically, the authors reported that MCID, SCB, and PASS were 11.1, 17.5, and 86.7 for ASES, and 16.9, 29.8, and 82.5 for the SANE score, and 4.6, 5.5, and 23.3 for the Constant score, respectively. However, the authors reported a largely heterogeneous cohort of patients with a variety of diagnoses and a combination of patients undergoing both operative and nonoperative treatments.[34] Establishing the threshold values to meet clinically significant outcomes following SCR provides surgeons with further evidence in helping counsel and guide expectations in patients with pathology of the shoulder prior to and following operative intervention.

Demonstration of greater external rotation following SCR was associated with an improvement in clinical symptoms and predictive of patients exceeding the threshold necessary to achieve MCID for ASES and SANE. In a systematic review by Catapano et al.,[43] the authors reported that in a total of 10 studies reporting on 350 shoulders undergoing SCR with a mean follow-up of 20.6 months, significant improvement in range of motion (forward flexion and external rotation) and PROs were reported in all studies, although statistical significance was not reached. Preserving range of motion after SCR may be of significance to patients due to maintenance of their activities of daily living (ADL).[44,45] In a study defining patient range of motion for ADLs, Namdari et al. evaluated healthy volunteers performing 10 activities of daily living (ADLs) and found that forward elevation of 121° and external rotation of 41.8° allowed completion of 10 of 10 and 9 of 10 ADLs, respectively.[44] Similarly, greater postoperative external rotation (47.9 ± 17.1) was associated with both a statistical and clinically significant improvement in our investigation, demonstrating the importance of preservation of motion to patient satisfaction following SCR. [6]

The presence of preoperative subscapularis tearing was found to be negatively associated with clinically significant outcome achievement for Constant and SANE MCID, as well as PASS for SANE. In a cohort of 54 patients with a mean follow-up of 24 months after SCR, Gilat et al. reported the presence of a subscapularis

tear on preoperative MRI to be associated with clinical failure as defined by 1) conversion to reverse total shoulder arthroplasty (RTSA), 2) a decrease in 12-month postoperative shoulder-specific PROs compared with preoperative scores, or 3) patient reporting at final follow-up that the shoulder was in a worse condition than before surgery following SCR.[23] These results were consistent with a prior study,[31] which correlated preoperative subscapularis atrophy with a higher rate of SCR graft tearing postoperatively.[46] As such, surgeons must counsel patients with subscapularis deficiency of the risks for not achieving a clinically significant outcome following SCR, while exercising caution in regard to proper patient selection.

Patients receiving WC benefits were also found to be less likely to achieve clinically significant outcomes, which is consistent with findings of prior studies evaluating treatment of work-related rotator cuff tears. A retrospective matched cohort study of 45 patients by Cvetanovich et al. reported that although WC and non-WC patients experienced significant clinical improvements following shoulder arthroplasty, WC patients were more likely to report inferior long-term outcomes, higher reoperation rate, and possess higher rates of pain compared to patients without a work-related injury.[47] Furthermore, multiple studies have reported inferior outcomes following shoulder surgery in WC patients despite patients experiencing pain relief and functional improvement postoperatively.[47-51] Another retrospective study by Henn et al.[17] assessing outcomes following rotator cuff repair in patients with WC claims reported worse outcomes after controlling for confounding factors, further demonstrating the predictive value of WC status in patients undergoing shoulder surgery.[49] Consequently, consideration of WC status should be taken into account when helping guide patient expectations following SCR.

Older age showed significantly lower ORs in SCB Constant alone, indicating that older patients may also be slow or even fail to recover. Female sex was also found to result in a lower OR in achieving several SCB and PASS items as well. Nonmodifiable risk factors, such as age and sex, have been shown to influence outcomes following arthroscopic surgery.[52-55] In a review of 38 Level 1 and Level 2 studies, increased age was reported to influence outcomes following RCR surgery with greater risk of retearing with increasing age, effectively doubling between the ages of 50 and 70 years.[56] Meanwhile, several studies[53,55] have reported women to experience greater pain and decreased shoulder function postoperatively compared with men, with one study[53] reporting increased pain in women in the initial 3 months after arthroscopic RCR, while no sex-based differences in patient-reported outcomes was appreciated by 12 months. Future studies are warranted to better understand the relationship between age and sex on patient-reported outcomes following SCR.

Limitations

This study was not without limitations. The authors anticipate a selection bias may have occurred, as 77% of patients with greater than 1-year follow-up also completed preoperative PROs for MCID, SCB, and PASS calculations. Moreover, patients who did not fill out PROs may have experienced poor outcomes, leading to follow-up failure or evaluation at an outside institution for further treatment or experienced significant symptomatic improvement after SCR without the need for further follow-up. In addition, several differences in demographic factors were appreciated between patients meeting inclusion criteria and those unable to complete preoperative and postoperative questionnaires. Another limitation was the use of the anchor-based method to calculate SCB and PASS and the distribution-based method to calculate MCID. Because the anchor-based method is more subjective, it may provide a less accurate assessment of the SCB and PASS scores. Moreover, the distribution method is more statistically centered and may less accurately assess the actual patient-perceived differences. Additionally, patients were predominantly male (67.2%), limiting the generalizability of our findings to female patients undergoing SCR. A total of 53.4% of patients underwent a concomitant procedure at the time of SCR, potentially confounding the direct contribution of the SCR procedure to achievement of a clinically significant outcome. Moreover, 56.7% of patients were found to have undergone a prior procedure, further potentially confounding our data due to differences in patient expectations.

It should also be noted that although commonly used shoulder-specific PROs have been used to assess clinical outcomes after SCR in several studies, no shoulder-specific PRO has been validated specifically for SCR. Further studies validating shoulder-specific PROs, such as WORC, OSS, and WOS, may further help understand the significance of clinical outcomes following SCR.

Conclusion

On the basis of calculated values for MCID, SCB, and PASS, subscapularis tearing, WC status, age, and sex are associated with failure to achieve clinically significant outcomes following SCR. Concomitant distal clavicle excision during SCR and lower preoperative ASES was predictive for achievement of MCID and SCB. By defining the thresholds and variables predictive of achieving CSOs following SCR, surgeons may better counsel patients prior to SCR.

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Appendix Table 1. Demographic and Clinical Characteristics for Patients Completing PROMs Questionnaires and Those Who Did not

	PROMs Completed	PROMs Incomplete	*P* Value
Age at surgery (yr)	55.9 ± 6.1	55.8 ± 6.6	.965
Sex (*n*, Male %)	35 (72.9%)	17 (54.8%)	.098
Body Mass Index (kg/m^2)	30.3 ± 6.9	30.2 ± 5.3	.927
Laterality (*n*, Right sided %)	25 (52.1%)	17 (54.8%)	.693
Smoking	8 (16.7%)	1 (3.2%)	.009*
Worker's Compensation claims	19 (39.6%)	8 (25.8%)	.301
Hypertension	15 (31.3%)	5 (16.1%)	.134
Diabetes	6 (12.5%)	2 (6.5%)	.393
Thyroid	4 (8.3%)	0 (0%)	.260
Handedness (*n*, right-handed %)	32 (66.7%)	26 (83.9%)	.427
Symptom Duration (yr)	2.1 ± 2.5	0.9 ± 0.1	.009*
Prior Surgery	29 (60%)	7 (22.6%)	.012*
Prior BT	12 (25%)	2 (6.5%)	.085

BT, biceps tenodesis; PROMs, patient-reported outcome measures.
*Denotes statistical significance $P < .05$.

Appendix Table 2. Logistic Regression for Factors Related to Achieving MCID

	P Value		
	Univariate Analysis	Multivariate Analysis	Odds Ratio (95% CI)
ASES			
Preoperative ASES Scores	.035*	.085	.933 (.862-1.010)
Postoperative ER	.102	.120	1.077 (0.981-1.182)
Sex	.061	.410	.340 (.026-4.431)
Age	.121	.058	1.105 (.997-1.224)
BMI	.116	.596	.957 (.815-1.125)
Prior BT	.107	.089	.081 (.005-1.471)
Constant			
Subscapularis MRI tear	.010*	.052	.122 (.015-1.022)
Postoperative FF	.072	.770	1.006 (.969-1.043)
SANE			
Sex	.104	.343	.304 (.026-3.554)
Subscapularis MRI tear	.014*	.194	.244 (0.029-2.046)
Hypertension	.062	.356	3.201 (.270-37.921)
Postop ER	.094	.057	1.058 (.998-1.121)

ASES, American Shoulder and Elbow Surgeons; BT, biceps tenodesis; CI, confidence interval; ER, external rotation; FF, forward flexion; MCID, minimal clinically important difference; MRI, magnetic resonance imaging; SANE, single assessment numeric evaluation.
*Denotes statistical significance $P < .05$.

Appendix Table 3. Logistic Regression for Factors Related to Achieving SCB

	P Value		
	Univariate Analysis	Multivariate Analysis	Odds Ratio (95% CI)
ASES			
Preoperative ASES Scores	.016*	.010*	.943 (.900-.986)
Age	.132	.072	1.094 (.992-1.206)
Sex	.136	.158	.313 (.062-1.573)
Constant			
Preoperative IR	.117	.037*	.434 (.198-.949)
Sex	.030*	.102	.013 (.000-2.378)
SANE			
Subscapularis MRI tear	.055	.057	.093 (.008-1.068)

ASES, American Shoulder and Elbow Surgeons; CI, confidence interval; IR, internal rotation; MRI, magnetic resonance imaging; SANE, single assessment numeric evaluation; SCB, substantial clinical benefit.
*Denotes statistical significance $P < .05$.

Appendix Table 4. Logistic Regression for Factors Related to Achieving PASS

	P Value		
	Univariate Analysis	Multivariate Analysis	Odds Ratio (95% CI)
ASES			
Preoperative ASES Scores	.014*	.272	1.027 (.979-1.078)
Prior BT	.092	.907	1.139 (.128-10.173)
Worker's Compensation	.010*	.032*	.124 (.018-.834)
Postop FF	.043*	.367	1.014 (.984-1.045)
Constant			
Preoperative Constant Scores	.009*	.205	1.192 (.909-1.564)
Sex	.026*	.037*	.026 (.001-.808)
Worker's Compensation	.027*	.465	.343 (.019-6.051)
Postoperative FF	.016*	.948	1.001 (.960-1.045)
SANE			
Subscapularis MRI Tear	.069	.031*	.044 (.003-.746)
Smoking	.106	.279	.418 (.086-2.028)
Worker's Compensation	.053	.062	.141 (.018-1.099)

ASES, American Shoulder and Elbow Surgeons; BT, biceps tenodesis; CI, confidence interval; FF, forward flexion; MRI, magnetic resonance imaging; PASS, patient acceptable symptomatic state; SANE, single assessment numeric evaluation.
*Denotes statistical significance, $P < .05$.