J Shoulder Elbow Surg (2019) 28, 939–948

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

BASIC SCIENCE

Establishing clinically significant outcome after arthroscopic rotator cuff repair

Gregory L. Cvetanovich, MD[a], Anirudh K. Gowd, BS[b], Joseph N. Liu, MD[c], Benedict U. Nwachukwu, MD[b], Brandon C. Cabarcas, BS[b], Brian J. Cole, MD, MBA[b], Brian Forsythe, MD[b], Anthony A. Romeo, MD[d], Nikhil N. Verma, MD[b,*]

[a]*Department of Orthopedic Surgery, The Ohio State University, Columbus, OH, USA*
[b]*Department of Orthopedic Surgery, Rush University Medical Center, Chicago, IL, USA*
[c]*Department of Orthopaedic Surgery, Loma Linda University Medical Center, Loma Linda, CA, USA*
[d]*Department of Orthopedic Surgery, The Rothman Institute, New York, NY, USA*

Background: Outcomes reporting in rotator cuff repair (RCR) literature has been variable. The minimal clinical important difference (MCID), substantial clinical benefit (SCB), and patient acceptable symptomatic state (PASS) bridge the gap between statistical significance and clinical relevance.
Methods: The American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), Single Assessment Numeric Evaluation (SANE), and Constant-Murley (Constant) scores were collected preoperatively and 1 year postoperatively for patients undergoing RCR between 2014 and 2017. An anchor-based approach was used to calculate the MCID, SCB change, and PASS for the ASES questionnaire.
Results: The study included 288 patients who underwent RCR. The MCID, SCB, and PASS were, respectively, 11.1, 17.5, and 86.7 for ASES, 4.6, 5.5, and 23.3 for the Constant score, and 16.9, 29.8, and 82.5 for the SANE score. Factors associated with reduced odds of achieving MCID were current smoking for ASES (odds ratio, 0.056) and single-row repair for the Constant score (odds ratio, 0.310). Workers' compensation patients had reduced odds of achieving ASES SCB (odds ratio, 0.267) and were associated with reduced odds of achieving PASS by ASES (odds ratio, 0.244), SANE (OR, 0.452), and Constant (odds ratio, 0.313). Lower preoperative scores were associated with achieving MCID and SCB and higher preoperative Constant scores associated with PASS ($P < .001$).
Conclusion: This study establishes MCID, SCB, and PASS for ASES, Constant, and SANE scores in patients undergoing RCR. Factors associated with failing to achieve clinically significant values included current smoking, single-row repairs, high body mass index, and workers' compensation status.
Level of evidence: Basic Science Study; Development or Validation of Outcomes Instrument

Keywords: Rotator cuff repair; quality-based care; minimally clinically important difference; substantial clinical benefit; patient acceptable symptom state; patient-reported outcome measures

Outcome reporting in rotator cuff repair (RCR) is heavily reliant on patient-reported outcome measures (PROMs), and therefore, there is an increased need to establish clinical relevance within these measures.[8] Arthroscopic RCR leads to robust improvements in PROMs for most patients, with

The Rush University Medical Center Institutional Review Board approved this study (ORA No.: 14120505IRB01AM06).

*Reprint requests: Nikhil N. Verma, MD, Midwest Orthopedics at Rush University, Department of Orthopedics, 1611 W Harrison St., Ste 300, Chicago, IL 60612, USA.
E-mail address: nikhil.verma@rushortho.com (N.N. Verma).

1058-2746/$ - see front matter
https://doi.org/10.1016/j.jse.2018.10.013

significant changes occurring up to 1 year postoperatively.[22,33] Nevertheless, considerable variability exists in outcomes reporting for clinical studies of RCR, with a systematic review finding only 63% of studies documented range of motion measurements, 65% documented tendon integrity with imaging, and more than 20 functional outcome scores being reported.[16] Such variability makes establishment of practice guidelines from clinical studies difficult.

Clinically significant measures include the minimal clinically important difference (MCID), substantial clinical benefit (SCB), and patient acceptable symptom state (PASS). These established measures are able to reflect patient benefit and satisfaction after surgery.[11] The MCID establishes the change in outcome score that results in the smallest, appreciable clinical improvement after surgery, the SCB demonstrates further improvement that a patient finds to be considerable,[20] and the PASS represents the level of postoperative outcome score required to reflect patient satisfaction. These metrics represent tiers of health states, where achieving MCID represents minimal improvement from preoperative health, achieving SCB represents substantial improvement from preoperative health, and PASS represents satisfactory health status.[6,9,26]

These measures may be calculated through the distribution and anchor-based methods. The anchor-based method specifies patient perception of improvement based off of categories of pain or function. Questions that gauge patient feeling of improvement are tethered to PROM scores and analyzed to establish the change in score that best differentiates levels of improvement among patients. In doing so, this method may be more robust in determining clinical significance, because PROMs are "anchored" to a subjective patient evaluation of their improvement in pain.[7] These clinical measures are valuable to further research in regard to the rotator cuff so that we may find clinically significant evidence to support guidelines on operative technique and indications for management of rotator cuff pathology.[21]

This study was conducted to establish the MCID, SCB, and PASS for RCR with respect to 3 shoulder PROMS and to determine variables associated with achieving these values. The hypothesis of this study was that specific differences between preoperative and postoperative scores would be able to accurately predict patient perception of improvement and satisfaction as reflected by anchor-based questions.

Materials and methods

Study design

This was a retrospective analysis of shoulder PROMs. A longitudinally maintained institutional rotator cuff registry was queried for all patients undergoing RCRs between 2014 and 2017. PROMs were captured preoperatively and 1 year postoperatively by an electronic data collection service (Outcome Based Electronic Research Database; Universal Research Solutions, Columbia, MO, USA). On the day of surgery, trained research staff were present on-site to administer each outcome score for all included patients in the preoperative bay. At the 1-year follow-up, patients were contacted by e-mail every 5 days, for 1 month. After 1 month of reminders, the survey expired to not reflect improvement at a different time point. The 1-year follow-up was selected to measure improvement because recent evidence would suggest that little to no change occurs after the 1-year period,[33] and included patients were generally counseled to have reached improvement by 1 year. Extending follow-up beyond this point increases the likelihood of confounding variables and mechanisms related to repeat injury.

Outcome measures

All patients received shoulder-specific questionnaires: American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES),[18] subjective Constant-Murley (Constant) Score,[2] and Single Assessment Numeric Evaluation (SANE).[30] Patient-reported outcomes were collected preoperatively and at 1 year postoperatively.

Anchor questions

Patients received anchor questions once they were 1 year from their operation. These questions were used as anchors to determine clinically meaningful change in outcomes.[7] The satisfaction anchor question was phrased, "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 satisfactory?" Responses were binary. The anchor question for change in pain was phrased, "Since your surgery, has there been any change in the pain in your shoulder?" Responses were based on the previously used 15-point global scale that ranged from –7 ("a very great deal worse") to +7 ("a very great deal better").[9,10]

Patients who responded "almost the same, hardly any worse," "no change," or "almost the same, hardly any better" corresponded to a score of –1 to +1 and represented the no change group. Those responding "a little better," "somewhat better," and "moderately better" corresponded to a score of +2 to +4 and represented the minimal improvement group. Patients who responded "a good deal better," "a great deal better," and "a very great deal better" corresponded to a score of +5 to +7 and represented the substantial improvement group.

Differences between the no change (–1 to +1) and minimal change group (+2 to +4) were used to calculate the MCID using receiver operating characteristic (ROC)curve/area under the curve (AUC) analysis, and differences between the group with no change (–1 to +1) and substantial change (+5 to +7) were used to calculate the SCB change. The SCB was calculated only as a difference between preoperative and postoperative scores for ease of comparison with the MCID (Fig. 1, *A*). Differences in postoperative scores at 1 year after operation between satisfied and unsatisfied patients were used to calculate the PASS (Fig. 1, *B*). The distribution method was also used to calculate the MCID.[7]

Patient selection

After assessing the registry, an initial patient population of 355 was available that responded to all questionnaires. Patients lost to follow-up were compared with included patients to assess for any differences in age, sex, and baseline patient-reported outcomes that could produce selection bias. Available medical records were retrospectively

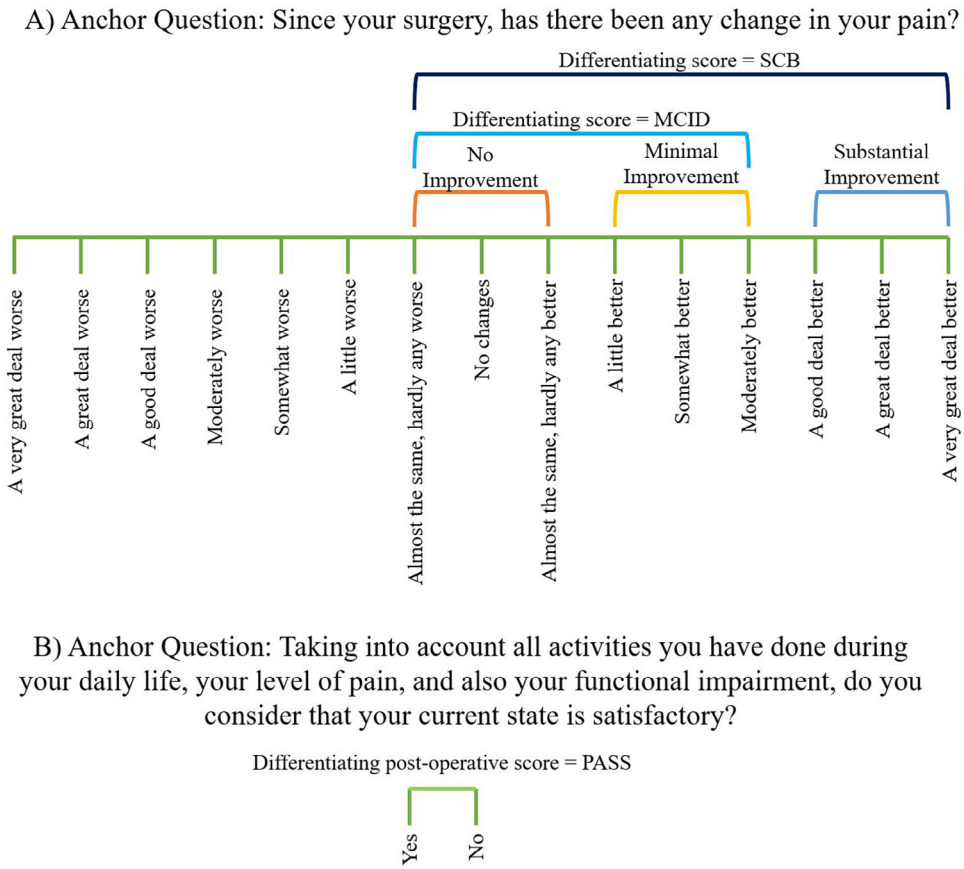

Figure 1 Anchor-based calculation of **(A)** minimally clinically important difference (*MCID*), substantial clinical benefit (*SCP*), and **(B)** patient acceptable symptom state (*PASS*).

reviewed to exclude patients who had undergone previous ipsilateral RCR or received any augmentation of repair with dermal allograft patch, platelet-rich plasma, or bone marrow aspirate concentrate.

Additional variables were retrospectively collected, such as demographics (age, sex, weight, body mass index [BMI]), medical history (smoking, comorbidities), tear characteristics (size, tendon involvement), and operative details (concomitant procedures, size of tear, single vs. double row, retraction). Tear size was considered small if between 0 and 1 cm, medium if between 1 and 3 cm, large if between 3 and 5 cm, and massive if >5 cm by any dimension. Tear size was not routinely measured during surgery. The Sports Medicine and Shoulder Service at our institution (Rush University Medical Center) consists of 6 surgeons, all of whom contributed to this registry.

Statistical analysis

Statistical analysis was performed using RStudio 1.0.143 software (Integrated Development for R; RStudio, Inc., Boston, MA, USA). Cutoff values for distribution method MCID were one-half of the standard deviation of all reported scores. Nonparametric ROC curves and AUC analysis were used to evaluate each outcome score to predict MCID, SCB change, and PASS based on the above anchor method calculation. The degree of association was acceptable if the AUC was greater than 0.7, and excellent if the AUC was greater than 0.8.[1] The Youden index was used to identify the optimal cutoff that maximizes sensitivity and specificity for each outcome score. These threshold scores were used to review all patient-reported scores to determine which achieved MCID, which achieved SCB change, and which achieved PASS.

Univariate analysis was performed with respect to each variable using χ^2 or the Student t test for categorical and continuous variables, respectively. Multivariate logistical regression analysis was performed on variables that achieved a P value of <.15 during univariate analysis. Variables were considered significant if the final P was <.05. Odds ratios were calculated for each variable with respect to achieving MCID, SCB, and PASS.

Results

Demographics

During the study period, 1,158 RCRs were performed, and 355 patients (229 men and 126 women) answered the anchor question at the 1-year postoperative assessment. The cohort was a mean age of 56.2 ± 10.1 years. The baseline ASES score was 44.7 ± 23.1, baseline SANE was 33.6 ± 20.4, and baseline subjective Constant was 12.2 ± 6.7. Patients who completed the anchor questions were not statistically different than those that did not based on age, sex, and baseline preoperative shoulder-specific outcome measures (Table I). Tear size was reported to be small in 30 shoulders, medium in 76, large in 32, massive in 60, and unmeasured in 90.

Table I Demographic characteristics

Variable	Completed anchors (n = 355)	Incomplete anchors (n = 802)	*P* value
Age, mean (SD), yr	56.2 (10.1)	56.1 (9.6)	.133
Sex			.379
Male, No. (%)	229 (64.5)	507 (63.2)	
Female, No	126	295	
Baseline scores			
ASES, mean (SD)	44.7 (23.1)	42.5 (20.3)	.129
SANE, mean (SD)	33.6 (20.4)	35.1 (24.3)	.322
Constant, mean (SD)	12.2 (6.7)	11.8 (6.8)	.379

SD, standard deviation; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form Score; *SANE*, Single American Numeric Evaluation; *Constant*, subjective Constant–Murley Score.

Table III Percentage of patients achieving clinically significant outcomes by score

Assessment	Achieved		
	MCID (%)	SCB (%)	PASS (%)
ASES	86.0*	80.6†	52.1†
SANE	80.6	66.0‡	51.9†
Constant	75.8*	75.8†	60.5†

MCID, minimally clinically important difference; *SCB*, substantial clinical benefit; *PASS*, patient acceptable symptom state; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form Score; *SANE*, Single Assessment Numeric Evaluation; *Constant*, subjective Constant-Murley Score.

† Found to have excellent area under the curve (AUC) from the receiver operating characteristic (ROC) curve/AUC analysis.

* Found to have acceptable AUC from ROC curve/AUC analysis.

‡ Found to have poor AUC from ROC curve/AUC analysis.

Establishing MCID, SCB, PASS

We excluded 67 patients because they received revision repair, superior capsular reconstruction, biologics in addition to repair, or graft augmentation, leaving 288 patients for analysis. From anchor-based questionnaire queries on patient improvement in pain, 18 patients reported "no change," 41 reported "minimal improvement," and 158 reported "substantial improvement." There were 71 patients that reported worse outcomes and could not be used to calculate MCID or SCB change. A further 218 patients reported the procedure was satisfactory, and 70 reported the procedures was unsatisfactory. The MCID calculated using the anchor method was 11.1 for ASES, 29.4 for SANE, and 5.5 for subjective Constant. ASES and subjective Constant had an acceptable AUC range of 76.2 and 71.0, respectively. The MCID calculated using the distribution method was 11.7 for ASES, 16.9 for SANE, and 4.6 for subjective Constant (Table II).

The calculated SCB change was 17.5 for ASES, 29.8 for SANE, and 5.5 for subjective Constant. ASES and subjective Constant had excellent an AUC range of 83.2 and 82.4, respectively. The SCB change calculation for SANE was not acceptable (Table II). PASS, calculated from satisfaction anchors and 1-year patient-reported outcomes, was 86.7 for ASES, 82.5 for SANE, and 23.3 for subjective Constant. The AUC was excellent for ASES, SANE, and subjective Constant at 87.5, 83.8, and 75.6, respectively (Table II). Using clinical thresholds for ASES, 86.0% achieved MCID, 80.6% achieved SCB, and 52.1% achieved PASS. With thresholds for SANE, 80.6% achieved MCID, 66.0% achieved SCB, and 51.9% achieved PASS. With thresholds for Constant, 75.8% achieved MCID, 75.8% achieved SCB, and 60.5% achieved PASS (Table III). From the pairwise comparison, a significant proportion of patients achieved SCB by ASES, but not

Table II Minimally clinically important difference, substantial clinical benefit, and patient acceptable symptom state at 1 year after rotator cuff repair

Assessment	MCID (anchor)	Specificity (%)	Sensitivity (%)	AUC (%)	MCID (distribution)
ASES	11.1	70.0	87.5	76.2	11.7
SANE	29.4	82.5	53.1	48.4	16.9
Constant	5.5	77.8	62.5	71.0	4.6
	SCB (anchor)	Specificity (%)	Sensitivity (%)	AUC (%)	
ASES	17.5	80.0	86.6	83.2	
SANE	29.8	62.5	71.6	65.4	
Constant	5.5	77.8	85.1	82.4	
	PASS (anchor)	Specificity (%)	Sensitivity (%)	AUC (%)	
ASES	86.7	94.8	69.6	87.5	
SANE	82.5	92.9	66.2	83.8	
Constant	23.3	84.5	77.8	86.8	

MCID, minimally clinically important difference; *AUC*, area under curve; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form Score; *SANE*, Single Assessment Numeric Evaluation; *Constant*, subjective Constant-Murley Score; *SCB*, substantial clinical benefit; *PASS*, patient acceptable symptom state.

from SANE ($P = .001$), and a significantly greater proportion achieved SCB by Constant score than from SANE ($P = .027$). An equivalent proportion of patients achieved PASS from all scores ($P > .05$), and an equivalent proportion achieved MCID from all scores ($P > .05$).

Variables associated with clinical significance

Logistical regression analysis to determine patient and surgical factors associated with clinical significance was performed using the anchor-based calculated scores for ASES and subjective Constant. The distribution-based scores were used for SANE because the ROC curve/AUC analysis suggested the anchor-based score was not reliable (Table IV). Univariate and subsequent multivariate analysis demonstrated that current smokers had significantly reduced odds of achieving MCID for the ASES score (odds ratio, 0.056; 95% confidence interval [CI], 0.005-0.697; $P = .025$). Single-row repair was associated with significantly reduced odds of achieving MCID for the Constant score (odds ratio, 0.011; 95% CI, 0.123-0.740; $P = .008$). Higher preoperative scores were also associated with reduced odds of achieving MCID for ASES (odds ratio, 0.950; 95% CI, 0.926-0.973; $P \leq .001$), Constant (odds ratio, 0.881; 95% CI, 0.832-0.933; $P < .001$), and SANE (odds ratio, 0.946; 95% CI, 0.900-0.993; $P < .001$).

Patients insured by workers' compensation had reduced odds of achieving SCB change for the ASES score (odds ratio, 0.267; 95% CI, 0.108-0.661; $P = .004$; Table V). Single-row repairs had reduced odds of achieving SCB change for the Constant score (odds ratio, 0.310; 95% CI, 0.15-0.768; $P = .011$). Multivariate analysis was not performed for SANE because this score was not found to be appropriately predictive of SCB change. Higher preoperative scores were associated with reduced odds of achieving SCB change for the ASES (odds ratio, 0.937; 95% CI, 0.916-0.959; $P \leq 0.001$) and Constant scores (odds ratio, 0.883; 95% CI, 0.834-0.934; $P < .001$).

Patients insured by workers' compensation were associated with reduced odds of achieving PASS by ASES (odds ratio, 0.244; 95% CI, 0.073-0.813; $P = .022$), SANE (odds ratio, 0.452; 95% CI, 0.221-0.924; $P = .030$), and Constant scores (odds ratio, 0.313; 95% CI, 0.139-0.703; $P = .005$). Patients with greater BMIs were also associated with reduced odds of achieving PASS by the Constant score (odds ratio, 0.947; 95% CI, 0.899-0.997; $P = .038$). Only a greater preoperative Constant score was associated with reduced odds of achieving PASS (odds ratio, 0.828; 95% CI, 0.777-0.882; $P \leq .001$; Table VI).

Preoperative scores were predictive of achieving MCID and SCB for all respective scores, but not PASS. Patients with a preoperative score of less than 58.3 for ASES (AUC = 72.1%), 51.6 for SANE (AUC = 76.7%), and 11.5 for Constant (AUC = 71.9%) had greater propensity to achieve MCID. Patients with a preoperative score of less than 46.6 for ASES (AUC = 75.3%), 50.1 for SANE (AUC = 81.8%),

Table IV Logistical regression of variables associated with achieving the minimally clinically important difference

Variable	Univariate regression (*P* value)	Multivariate regression (*P* value)	Odds ratio (95% CI)
ASES			
Pre-op ASES	**.001**	**<.001**	0.950 (0.926-0.973)
Smoking	.026	Current: **.025**	Current: 0.056 (0.005-0.697)
		Former: .979	Former: 0.965 (0.066-1.41)
		Never: .154	Never: 0.193 (0.020-1.86)
Biceps	.038	.119	0.432 (0.150-1.24)
Single-row repair	.134	.147	0.407 (0.121-1.37)
Age	.032	.154	0.968 (0.925-1.01)
Constant			
Pre-op Constant	**<.001**	**<.001**	0.881 (0.832-0.933)
Biceps	.076	.278	0.670 (0.325-1.38)
Single-row repair	**.011**	**.008**	0.302 (0.123-0.740)
Age	.091	.088	0.969 (0.934-1.00)
SANE			
Pre-op SANE	**<.001**	**.024**	0.946 (0.900-0.993)
Dominant side	.169	.155	0.177 (0.016-1.92)
DCE	.088	.995	N/A
Massive tear	.016	.753	1.46 (0.140-15.20)
Mobilization	.168	.236	0.150 (0.007-3.45)

CI, confidence interval; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form Score; *Constant*, subjective Constant-Murley Score; *SANE*, Single Assessment Numeric Evaluation; *DCE*, distal clavicle excision; N/A, not applicable.
Bold values are statistically significant ($P < .05$).

Table V Logistical regression of variables associated with achieving substantial clinical benefit on American Shoulder and Elbow Surgeons and Constant scores

Variable	Univariate regression (*P* value)	Multivariate regression (*P* value)	Odds ratio (95% CI)
ASES			
Pre-op ASES	**<.001**	**<.001**	0.937 (0.916-0.959)
WC	**.091**	**.004**	0.267 (0.108-0.661))
Biceps	.041	.175	0.556 (0.238-1.30)
Single-row repair	.068	.082	0.397 (0.140-1.12)
Age	.057	.288	0.978 (0.939-1.02)
Constant			
Pre-op Constant	**<.001**	**<.001**	0.883 (0.834-0.934)
Diabetes	.172	.597	0.886 (0.271-2.90)
Biceps	.080	.280	0.671 (0.325-1.38)
Single-row repair	**0012**	**.011**	0.310 (0.125-0.768)
Age	.091	.109	0.971 (0.936-1.01)

CI, confidence interval; *ASES,* American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form Score; *WC*, workers' compensation; *Constant*, subjective Constant-Murley Score.
Bold values are statistically significant ($P < .05$).

Table VI Logistical regression of variables associated with achieving the patient acceptable symptom state on outcome measures

Variable	Univariate regression (*P* value)	Multivariate regression (*P* value)	Odds ratio (95% CI)
ASES			
Pre-op ASES	.125	.784	0.996 (0.968-1.030)
WC	.006	.022	0.244 (0.073-0.813)
Comorbid HTN	.127	.574	0.465 (0.032-6.700)
Dominant Side	.051	.639	0.779 (0.274-2.210)
Age	.014	.361	0.967 (0.900-1.040)
Body mass index	.007	.483	0.968 (0.884-1.060)
SANE			
WC	.003	.030	0.452 (0.221-0.924)
Labral débridement	.036	.114	0.598 (0.317-1.130)
Body mass Inex	.090	.491	0.983 (0.938-1.030)
Constant			
Pre-op Constant	<.001	<.001	0.828 (0.777-0.882)
WC	<.001	.005	0.313 (0.139-0.703)
Bicep	.112	.184	0.638 (0.329-1.240)
DCE	.037	.950	1.030 (0.393-2.710)
Massive tear	.172	.675	1.160 (0.571-2.370)
Age	.135	.420	0.986 (0.952-1.020)
Body mass index	.018	.038	0.947 (0.899-0.997)

CI, confidence interval; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form Score; *WC*, workers' compensation; *HTN*, hypertension; *SANE*, Single Assessment Numeric Evaluation; *Constant*, subjective Constant-Murley Score; *DCE*, distal clavicle excision.

and 11.5 for Constant (AUC = 71.9%) had greater propensity to achieve SCB (Table VII).

Discussion

This study established values for the MCID, SCB change, and PASS for patients undergoing RCR with respect to the ASES, Constant, and SANE scores. We also found several factors associated with failing to achieve these clinically significant outcomes after RCR, including current smoking, single-row repairs, high BMI, and workers' compensation status. In addition, patient preoperative scores were highly predictive of achieving clinically significant outcomes because patients with lower preoperative scores were more likely to achieve MCID and SCB change, whereas those with higher preoperative Constant were more likely to reach PASS. These threshold values for metrics of clinically significant improvement and acceptable final outcome state after RCR for 3 commonly used outcome scores can be used to ensure that

Table VII Predictive value of preoperative scores toward achieving minimally clinically important difference, substantial clinical benefit, and patient acceptable symptom state for respective patient-reported outcome measures

Variable	Threshold	Sensitivity (%)	Specificity (%)	AUC
MCID				
ASES	58.3	62.1	79.2	72.1
SANE	51.6	57.5	87.3	76.7
Constant	11.5	78.8	60.1	71.9
SCB				
ASES	46.6	77.8	65.4	75.3
SANE	50.1	65.7	88.2	81.8
Constant	11.5	78.8	60.1	71.9
PASS				
ASES	35.7	48.7	73.6	61.9
SANE	17.4	77.7	25.9	47.7
Constant	8.3	75.3	32.3	49.1

AUC, area under the curve; *MCID,* minimally clinically important difference; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form Score; *SANE*, Single Assessment Numeric Evaluation; *Constant*, subjective Constant-Murley Score; *SCB*, substantial clinical benefit; *PASS*, patient acceptable symptom state.

significant improvements after surgery meet levels of improvement and final patient state that are significant and acceptable to the patient, beyond simple statistical significance. Moreover, factors associated with failing to achieve clinically significant improvements can be considered in preoperative counseling and surgical planning.

The literature contains several prior reports of clinically significant values for rotator cuff pathology, although generally for heterogeneous patient groups with a variety of diagnoses and mixture of operative and nonoperative treatments, as well as some reports with suboptimal methodology. For the Western Ontario Rotator Cuff Index (WORC), an early study reported a MCID of 245.26 points based on an anchor-based approach for a sample of 44 patients with diagnosis of chronic rotator cuff tendinosis without tear undergoing nonoperative treatment with subacromial cortisone injection with only 3 months of follow-up.[13] Another study of subacromial cortisone injections in 121 patients with rotator cuff disease (without specifying the percentage who had tear) undergoing subacromial cortisone treatment found a WORC MCID of 275 at 6 weeks of follow-up.[4]

The MCID for ASES and SST were evaluated by Tashjian et al[25] with an anchor-based approach in 81 patients with rotator cuff tendonitis or tear undergoing nonoperative treatment with 6 weeks of follow-up. This study found an MCID value of 2 for SST and 12 to 17 for ASES. Another study calculated the MCID using a distribution-based approach for ASES at 6.4 points in 63 patients with various causes of "shoulder dysfunction" treated with 4 weeks of physical therapy.[18]

It is difficult to compare the present study of patients undergoing RCR for rotator cuff tear with 1-year follow-up to these prior studies of patients with heterogenous shoulder pathology undergoing nonoperative treatment with 4 weeks to 3 months of follow-up. Clinically significant outcomes at 1 year are representative of maximal medical outcome, and therefore, establishing clinical improvement values for this time point holds greater relevance.[33]

The literature to date contains few studies evaluating MCID for patients with the specific diagnosis of rotator cuff tear undergoing RCR or nonoperative treatment. Kukkonen et al[14] reported the MCID for the Constant score using anchor-based and distribution-based methods with a 2-level question at 1 year after RCR in 781 patients. MCID estimates with various methods yielded an MCID estimate of 10.4 (range, 2 to 16).

Gagnier et al[5] recently reported 222 patients with full-thickness rotator cuff tear diagnosed by magnetic resonance imaging or ultrasound imaging and used both anchor-based and distribution-based methods to calculate the MCID for WORC and ASES. Operative RCR and nonoperative treatments were both included, and follow-up was 64 weeks. The MCID for ASES was 21.9 and 26.9 for anchor-based and distribution-based methods, respectively, and for WORC was –588.7 and –392.5, respectively. They found that the patient sex, age, Functional Comorbidity Index, and Charlson Comorbidity Index did not predict the MCID. Their study was limited by sample size, with only 18 patients total and only 5 patients who underwent surgical treatment with RCR reporting ASES and responding to anchor questions at 64 weeks of follow-up.

Our MCID for ASES (11.1 for anchor-based and 11.7 for distribution-based methods) was more similar to Kukkonen et al[14] than Gagnier et al,[5] which may reflect that both studies analyzed only patients undergoing operative treatment with RCR for patients with diagnosis of rotator cuff tear and had the same 1-year follow-up time point. In addition, the SANE score, as a single question survey, was not found to be an appropriate surrogate for lengthier questionnaires based on unacceptable AUC values (<70%) in predicting MCID and SCB. This discrepancy is in contrast to previous studies regarding the anterior cruciate ligament.[24,31] However, this questionnaire achieved high prediction of the PASS, which reflects its value in differentiating satisfactory and unsatisfactory results in patients.

Strengths of our study are that it expands upon this existing work by defining the MCID for the ASES, Constant, and SANE scores in a large series of patients with rotator cuff tears undergoing surgical treatment with RCR. We had significantly larger sample size with similar follow-up compared with Gagnier et al[5] (1 year vs. 64 weeks) and similarly used both anchor-based and distribution-based methods to calculate the MCID for the ASES. Kukkonen et al[14] had a larger series of patients undergoing RCR with similar 1-year follow-up, but they defined MCID only for the Constant score and used a 2-stage anchor question. The

use of a 2-stage question leaves no neutral zone for "unchanged," and our anchor question using a 15-item scale is a more robust method to account for nuanced outcomes with no or slight improvement.

Ours study is the first, to our knowledge, to report MCID, PASS, or SCB for the SANE score. Unlike prior studies to date, our study defines additional metrics of clinically significant results beyond MCID, namely SCB and PASS. These additional threshold values provide a spectrum of clinically meaningful outcomes that may be used to gauge operative value.[20] Providing these stratified levels of outcomes allows us to better support evidence for treatment guidelines in RCR.

Furthermore, we went beyond prior studies by detailed multivariate analysis of factors associated with failure to achieve clinically significant outcomes of RCR, finding that failure to achieve clinically significant outcomes was associated with current smokers, single-row repairs, workers' compensation patients, and high BMI. Previous systematic reviews and clinical studies have identified these factors as being associated with statistically inferior clinical outcomes and higher retear rates after RCR, although prior studies have not evaluated clinically significant outcomes.[12,17,19,23,28,32] For instance, in a cohort of 187 patients who had recurrent rotator cuff tears, workers' compensation was an independent predictor of poorer satisfaction and a lower ASES score,[12] which is directly corroborated by the association of workers' compensation to multiple inferior outcomes in the present study.

Our finding that single-row RCRs had multiple inferior outcomes on measurements of clinical significant results compared with double-row RCRs runs, contrary to the highest level of evidence, which generally suggests that double-row repairs may result in superior structural healing but without a difference in clinical outcomes. This discrepancy could be related to our retrospective study design and potential confounding variables that are not fully controlled for in our multivariate regression.

Lower preoperative scores were associated with increased odds of achieving MCID and SCB, whereas a higher preoperative Constant score was associated with achieving PASS. This suggests, similar to prior studies, that patients with worse preoperative function have more room to reach clinically significant improvement metrics like MCID and SCB but that patients with higher preoperative function are more likely to reach a threshold measuring acceptable state such as PASS.[3] Specific thresholds of preoperative score were found wherein lower scores had greater propensity in achieving MCID and SCB, but the same association was not found for PASS. This reflects the a greater prognostic ability for patients to improve when they subjectively feel at a lower health state, whereas the achievement of patient satisfaction (PASS) after surgery remains less predictable. Although not previously reported for RCR, 2 prior groups have reported factors associated with failure to reach ASES MCID have been reported for shoulder arthroplasty and include higher preoperative score, reverse as opposed to anatomic shoulder arthroplasty, diabetes, rotator cuff tear requiring repair at the time of shoulder arthroplasty, previous surgery, and diagnosis of rheumatoid arthritis.[15,29]

Findings of the present study are vital for clinicians to appropriately set patient expectations for recovery and identify factors that may be associated with achieving greater improvement. In addition, these metrics create benchmarks for recovery to evaluate outcomes. Future research may benefit from the use of these metrics in creating more robust power analyses and determining which operative variables may be associated with greater clinically significant outcomes. Future studies may also wish to control for variables noted to be associated with achievement of these outcome measures, such as preoperative score, single-row repair, smoking status, BMI, and workers' compensation.

Limitations of the present study include patient compliance at the 1-year evaluation. Maintaining a single follow-up time point was critical because patients with varying timelines would likely reflect differences in outcome scores. Baseline demographics and scores were compared with the noncompliant population to ensure our cohort is representative of all patients undergoing RCR. Similar methodology has been previously used to measure clinically significant outcomes[29]; however, it is important to note that this does not entirely account for selection bias of patients. Follow-up was also restricted to 1 year due to recent evidence of maximal improvement,[33] however, it may be possible that 2-year outcomes could show differing trends.

In addition, domain-specific anchor questions have been shown to hold greater construct validity over global anchor questions.[27] For this reason, pain was the domain of choice for constructing the MCID, SCB, and PASS and was selected based on our belief that this is the most relevant change within this population. Different anchor questions may influence the MCID, SCB, and PASS marginally.

These values are limited to only patients who underwent RCRs. Those with rotator cuff tears who elect to pursue nonoperative management or arthroscopic débridement are not related to the values established by the present study. Although numerous patient and surgical factors, including patient demographics, surgical technique with single-row vs. double-row repair, and tear characteristics, including tear size and retraction, were analyzed, there are other potentially important factors that were not considered, including Goutallier classification.

Analysis of tear size was limited because measurements were not routinely performed in all operations. Tear size may certainly be related to achievement of significant outcomes, but this was not found within the present study.

Finally, our retrospective analysis of collected data does not allow us to establish causation. For instance, the association of single-row repairs with several inferior outcomes could be related to confounding variables such as whether single-row repairs were preferentially performed in older patients with larger chronic tears and associated atrophy.

Conclusion

This study establishes the MCID, SCB, and PASS for ASES, Constant, and SANE scores in patients undergoing RCR. Factors associated with failing to achieve clinically significant values included current smoking, single-row repairs, high BMI, and workers' compensation status. Lower preoperative scores were predictive achieving MCID and SCB, whereas a higher preoperative Constant score was associated with achieving PASS.

Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

References

1. Berliner JL, Brodke DJ, Chan V, SooHoo NF, Bozic KJ. John Charnley Award: preoperative patient-reported outcome measures predict clinically meaningful improvement in function after THA. Clin Orthop Relat Res 2016;474:321-9. http://dx.doi.org/10.1007/s11999-015-4350-6
2. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res 1987;214:160-4.
3. Cvetanovich GL, Weber AE, Kuhns BD, Alter J, Harris JD, Mather RC, et al. Hip arthroscopic surgery for femoroacetabular impingement with capsular management: factors associated with achieving clinically significant outcomes. Am J Sports Med 2018;46:288-96. http://dx.doi.org/10.1177/0363546517739824
4. Ekeberg OM, Bautz-Holter E, Keller A, Tveitå EK, Juel NG, Brox JI. A questionnaire found disease-specific WORC index is not more responsive than SPADI and OSS in rotator cuff disease. J Clin Epidemiol 2010;63:575-84. http://dx.doi.org/10.1016/j.jclinepi.2009.07.012
5. Gagnier JJ, Robbins C, Bedi A, Carpenter JE, Miller BS. Establishing minimally important differences for the American Shoulder and Elbow Surgeons score and the Western Ontario Rotator Cuff Index in patients with full-thickness rotator cuff tears. J Shoulder Elbow Surg 2018;http://dx.doi.org/10.1016/j.jse.2017.10.042
6. Glassman SD, Copay AG, Berven SH, Polly DW, Subach BR, Carreon LY. Defining substantial clinical benefit following lumbar spine arthrodesis. J Bone Joint Surg Am 2008;90:1839-47. http://dx.doi.org/10.2106/JBJS.G.01095
7. Guyatt GH, Osoba D, Wu AW, Wyrwich KW, Norman GR, Clinical Significance Consensus Meeting Group. Methods to explain the clinical significance of health status measures. Mayo Clin Proc 2002;77:371-83. http://dx.doi.org/10.1016/S0025-6196(11)61793-X
8. 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. http://dx.doi.org/10.1016/j.arthro.2017.01.053
9. Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. Control Clin Trials 1989;10:407-15.
10. Juniper EF, Guyatt GH, Willan A, Griffith LE. Determining a minimal important change in a disease-specific quality of life questionnaire. J Clin Epidemiol 1994;47:81-7.
11. Katz NP, Paillard FC, Ekman E. Determining the clinical importance of treatment benefits for interventions for painful orthopedic conditions. J Orthop Surg Res 2015;10:24. http://dx.doi.org/10.1186/s13018-014-0144-x
12. Kim HM, Caldwell JM, Buza JA, Fink LA, Ahmad CS, Bigliani LU, et al. Factors affecting satisfaction and shoulder function in patients with a recurrent rotator cuff tear. J Bone Joint Surg Am 2014;96:106-12. http://dx.doi.org/10.2106/JBJS.L.01649
13. Kirkley A, Griffin S, Dainty K. Scoring systems for the functional assessment of the shoulder. Arthroscopy 2003;19:1109-20. http://dx.doi.org/10.1016/j.arthro.2003.10.030
14. Kukkonen J, Kauko T, Vahlberg T, Joukainen A, Äärimaa V. Investigating minimal clinically important difference for Constant score in patients undergoing rotator cuff surgery. J Shoulder Elbow Surg 2013;22:1650-5. http://dx.doi.org/10.1016/j.jse.2013.05.002
15. Mahony GT, Werner BC, Chang B, Grawe BM, Taylor SA, Craig EV, et al. Risk factors for failing to achieve improvement after anatomic total shoulder arthroplasty for glenohumeral osteoarthritis. J Shoulder Elbow Surg 2018;27:968-75. http://dx.doi.org/10.1016/j.jse.2017.12.018
16. Makhni EC, Steinhaus ME, Morrow ZS, Jobin CM, Verma NN, Cole BJ, et al. Outcomes assessment in rotator cuff pathology: what are we measuring? J Shoulder Elbow Surg 2015;24:2008-15. http://dx.doi.org/10.1016/j.jse.2015.08.007
17. Mascarenhas R, Chalmers PN, Sayegh ET, Bhandari M, Verma NN, Cole BJ, et al. Is double-row rotator cuff repair clinically superior to single-row rotator cuff repair: a systematic review of overlapping meta-analyses. Arthroscopy 2014;30:1156-65. http://dx.doi.org/10.1016/j.arthro.2014.03.015
18. Michener LA, McClure PW, Sennett BJ. American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form, patient self-report section: reliability, validity, and responsiveness. J Shoulder Elbow Surg 2002;11:587-94. http://dx.doi.org/10.1067/mse.2002.127096
19. Millett PJ, Warth RJ, Dornan GJ, Lee JT, Spiegl UJ. Clinical and structural outcomes after arthroscopic single-row versus double-row rotator cuff repair: a systematic review and meta-analysis of level I randomized clinical trials. J Shoulder Elbow Surg 2014;23:586-97. http://dx.doi.org/10.1016/j.jse.2013.10.006
20. Nwachukwu BU, Chang B, Fields K, Rebolledo BJ, Nawabi DH, Kelly BT, et al. Defining the "substantial clinical benefit" after arthroscopic treatment of femoroacetabular impingement. Am J Sports Med 2017;45:1297-303. http://dx.doi.org/10.1177/0363546516687541
21. Pedowitz RA, Yamaguchi K, Ahmad CS, Burks RT, Flatow EL, Green A, et al. American Academy of Orthopaedic Surgeons Clinical Practice Guideline on: optimizing the management of rotator cuff problems. J Bone Joint Surg Am 2012;94:163-7.
22. Russell RD, Knight JR, Mulligan E, Khazzam MS. Structural integrity after rotator cuff repair does not correlate with patient function and pain: a meta-analysis. J Bone Joint Surg Am 2014;96:265-71. http://dx.doi.org/10.2106/JBJS.M.00265
23. Santiago-Torres J, Flanigan DC, Butler RB, Bishop JY. The effect of smoking on rotator cuff and glenoid labrum surgery: a systematic review. Am J Sports Med 2015;43:745-51. http://dx.doi.org/10.1177/0363546514533776
24. Shelbourne KD, Barnes AF, Gray T. Correlation of a single assessment numeric evaluation (SANE) rating with modified Cincinnati Knee Rating System and IKDC subjective total scores for patients after ACL reconstruction or knee arthroscopy. Am J Sports Med 2012;40:2487-91. http://dx.doi.org/10.1177/0363546512458576
25. Tashjian RZ, Deloach J, Green A, Porucznik CA, Powell AP. Minimal clinically important differences in ASES and simple shoulder test scores after nonoperative treatment of rotator cuff disease. J Bone Joint Surg Am 2010;92:296-303. http://dx.doi.org/10.2106/JBJS.H.01296
26. Tubach F, Ravaud P, Baron G, Falissard B, Logeart I, Bellamy N, et al. Evaluation of clinically relevant states in patient reported outcomes in knee and hip osteoarthritis: the patient acceptable symptom state. Ann Rheum Dis 2005;64:34-7. http://dx.doi.org/10.1136/ard.2004.023028

27. Ward MM, Guthrie LC, Alba M. Domain-specific transition questions demonstrated higher validity than global transition questions as anchors for clinically important improvement. J Clin Epidemiol 2015;68:655-61. http://dx.doi.org/10.1016/j.jclinepi.2015.01.028
28. Warrender WJ, Brown OL, Abboud JA. Outcomes of arthroscopic rotator cuff repairs in obese patients. J Shoulder Elbow Surg 2011;20:961-7. http://dx.doi.org/10.1016/j.jse.2010.11.006
29. 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. http://dx.doi.org/10.1007/s11999-016-4968-z. Erratum in 2017;475:293.
30. Williams GN, Gangel TJ, Arciero RA, Uhorchak JM, Taylor DC. Comparison of the Single Assessment Numeric Evaluation method and two shoulder rating scales. Outcomes measures after shoulder surgery. Am J Sports Med 1999;27:214-21.
31. Winterstein AP, McGuine TA, Carr KE, Hetzel SJ. Comparison of IKDC and SANE outcome measures following knee injury in active female patients. Sports Health 2013;5:523-9. http://dx.doi.org/10.1177/1941738113499300
32. Xu C, Zhao J, Li D. Meta-analysis comparing single-row and double-row repair techniques in the arthroscopic treatment of rotator cuff tears. J Shoulder Elbow Surg 2014;23:182-8. http://dx.doi.org/10.1016/j.jse.2013.08.005
33. Zuke WA, Leroux TS, Gregory BP, Black A, Forsythe B, Romeo AA, et al. Establishing maximal medical improvement after arthroscopic rotator cuff repair. Am J Sports Med 2018;46:1000-7. http://dx.doi.org/10.1177/0363546517707963