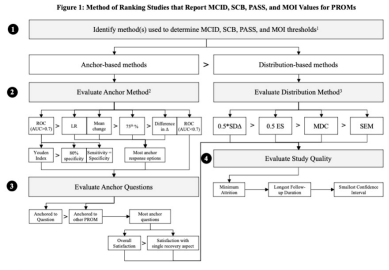
A Novel Methodology for Establishing Best Values for Minimal Clinically Important Difference (MCID), Substantial Clinical Benefit (SCB), and Patient Acceptable Symptom State (PASS) Thresholds following Rotator Cuff Repair

Alexander Lee, Joshua Chiang, Radhika Gupta, John D Kelly, Robert L. Parisien[1]
[1]Mount Sinai

INTRODUCTION:
Increased use of patient reported outcome measures (PROMs) after rotator cuff repair has led to a proliferation of studies reporting minimal clinically important difference (MCID), substantial clinical benefit (SCB), and patient acceptable symptom state (PASS) thresholds. The heterogeneity of values frustrates efforts to standardize measures and make meaningful comparisons. This systematic review identifies publications reporting threshold values and proposes a means of ranking them based on their methodology. We then present recommended threshold values for the *Constant-Murley* (CMS), *American Shoulder and Elbow Surgeons* (ASES), *Visual Analog Scale for Pain* (P-VAS), *Single Assessment Numeric Evaluation* (SANE), and *University of California at Los Angeles shoulder* (UCLA) scores.
METHODS:
All studies reporting MCID, SCB, and PASS following rotator cuff repair between January 1, 2000 and May 31, 2022 were extracted via systematic review. We evaluated each study's design (retrospective vs. prospective data collection), follow-up duration, and participant attrition. We also recorded quantities relevant to their threshold values, including area under the curve (AUC) values for receiver operator characteristic (ROC) analyses and confidence intervals (CI) for other methods. We then present recommended MCID, SCB, and PASS threshold values, based on a novel methodology of analyzing the quality of included studies.
RESULTS:
Of the 41 unique studies identified in the systematic review, 37 (90%), 11 (27%), and 16 (39%) reported MCID, SCB, and PASS thresholds, respectively. Twelve studies calculated thresholds through anchor-based methods and 6 calculated values through distribution-based techniques. We recommend thresholds from 3 studies: Kim 2020, Xu 2019, and Cvetanovich 2019. Their threshold values and derivation methods are presented in Table 1. For MCID thresholds, we recommend an ASES of 21, P-VAS of 1.5, SANE of 12, and UCLA of 6 from Kim, as well as a CMS of 6.7 presented by Xu. For SCB thresholds we recommend an ASES of 26, SANE of 20, both from Kim, and CMS of 5.5 from Cvetanovich. For PASS thresholds, we recommend an ASES of 78, P-VAS of 1.7, and SANE of 71 from Kim, as well as a CMS of 23.3 from Cvetanovich.
DISCUSSION AND CONCLUSION:
We recommend values calculated using anchor-based methods, as they are more reliable than those using distribution-based methods. For studies using anchor-based methods, we select values from studies using ROC analysis over those utilizing mean change or linear regression, as these methods risk over-estimating values. The exception to this rule was the CMS MCID value reported by Xu 2019, calculated through linear regression, as the alternative values had high rates of attrition (70.3% lost to follow up) or had insufficient follow up. When multiple MCID, SCB, or PASS thresholds were reported using ROC analysis for the same PROM, the study with less patient attrition and a greater number of anchor responses was chosen.

FIGURE 1.
Predetermined hierarchy used to rank studies. Anchor methods are superior to distribution methods.
(A) For anchor-based methods, those using ROC (with AUC>0.7) to calculate thresholds were preferred. Thresholds determined by maximizing the Youden Index (YI) were superior to those that did not. If studies used linear regression (LR) or mean change, they were evaluated by the number of anchor responses. If studies used the same anchor method, those with multiple anchors were superior. Finally, prioritized studies with the least attrition.
(B) For distribution-based methods, we favored those using 0.5 times standard deviation change. Finally, prioritized studies with the least attrition.



[1]Excludes studies with less than 12 months follow-up
[2]ROC=receiver operator characteristic; AUC=under area curve; LR=linear regression; Δ difference=change difference
[3]SDΔ=standard deviation change; ES=effect size; MDC=minimal detectable change; SEM=standard error of measurement

TABLE 1
Recommended threshold values and their associated studies. Table presents the number of studies that report a particular PROM, the range of values encountered in systematic review, and our recommended threshold. Reports the study that threshold was established in, its derivation method, and the area under curve (AUC) or confidence interval (CI).

MCID				*Recommendation*			
Score	**# Studies**	**Measurement Range**	**Range of MCID**	**Value**	**Study**	**Method**	**95% CI / AUC**
CMS	17	0 - 100	2.0 - 44.5	6.7	Xu (2019)	LR	4.5–8.9
ASES	26	0 - 100	6.1 - 39	21	Kim (2020)	ROC	0.85
P-VAS	9	0 - 10	1.4 - 6.5	1.5			0.86
SANE	6	0 - 100	12.0 - 29.4	12			0.82
UCLA	5	0 - 35	2.5 - 9.3	6			0.96

SCB				*Recommendation*			
Score	**# Studies**	**Measurement Range**	**Range of MCID**	**Value**	**Study**	**Method**	**AUC**
CMS	4	0 - 100	5.5	5.5	Cvetanovich (2019)	ROC	0.82
ASES	9	0 - 100	16.8 - 27.9	26	Kim (2020)	ROC	0.88
SANE	4	0 - 100	20.0 - 32.8	20			0.90

PASS				*Recommendation*			
Score	**# Studies**	**Measurement Range**	**Range of MCID**	**Value**	**Study**	**Method**	**AUC**
CMS	5	0 - 100	23.3 - 44.0	23.3	Cvetanovich (2019)	ROC	0.87
ASES	13	0 - 100	78.0 - 93.5	78	Kim (2020)	ROC	0.82
P-VAS	5	0 - 10	0.5 - 1.7	1.7			0.85
SANE	6	0 - 100	71.0 - 82.5	71			0.88

TABLE 2
Recommended values for commonly used MCID, SCB, and PASS thresholds. The studies included in this table include: Kim (2020), Xu (2019), and Cvetanovich (2019). ROC = receiver operating characteristic; SD = standard deviation.

		Methods and Follow-up					
Study	**Patients**	**Follow-up (mo)**	**% Lost to Follow-up**	**Study Design**	**Metric**	**Score**	**Method**
Kukkonen (2013)	781	3, 12	3%	Basic Science Study - Validation of Outcomes Instrument	MCID	CMS	ROC - Youden Index Positive Anchor Mean Change Effect Size
Gagnier (2018)	19	15	0%	Basic Science Study - Validation of Outcomes Instrument	MCID	ASES, WORC	Positive Anchor Mean Change
Cvetanovich (2019)	268	12	9%	Basic Science Study - Validation of Outcomes Instrument	MCID, SCB, PASS	ASES, SANE, SANE	ROC - Youden Index Effect Size
Gowd (2019)	89	12	0%	Cohort Study - Level of Evidence 3	MCID, SCB, PASS	ASES, CMS	ROC - Youden Index
Xu (2019)	306 222	12 24	34%	Retrospective-Prospective Study - Level of Evidence 3	MCID	CMS, OSS, UCLA	Linear Regression
Haunschild (2020)	101 105	12 12	17%	Cohort Study (Diagnostic) - Level of Evidence 3	SCB, PASS MCID	PROMIS-UE	ROC - Youden Index Effect Size
Kim (2020)	82	12	12%	Cohort Study (Diagnostic) - Level of Evidence 2	MCID, SCB, PASS MCID, SCB	ASES, pain-VAS, SANE, UCLA	ROC - Youden Index Positive Anchor Mean Change
Tashjian (2020)	202	12	9%	Basic Science Study - Validation of Outcomes Instrument	MCID	ASES, pain-VAS, SST	Positive Anchor Mean Change
Marka (2021)	148	12	9%	Prospective Cohort Study - Level of Evidence 2	MCID	EQ-5D-5L	ROC - Youden Index Positive Anchor Mean Change Effect Size
Pogan-Conesa (2021)	110	12	20%	Prospective Therapeutic Study - Level of Evidence 3	MCID	CMS, pain-VAS	Mean Change Score 0.5 * SD Change
Malevitis (2022)	289	12	4%	Basic Science Study - Validation of Outcomes Instrument	MCID	ASES, UCLA	ROC - Youden Index Effect Size
Kim (2022)	201	24	18%	Case-Control Study - Level of Evidence 3	PASS	ASES, pain-VAS, SANE	ROC - Youden Index
Tramer (2022)	168	18	9%	Retrospective Cohort Study (Prognostic) - Level of Evidence 3	MCID, SCB	PROMIS - D, PROMIS - PI, PROMIS-UE	ROC - Youden Index