



Determining minimal clinically important difference and patient-acceptable symptom state after arthroscopic isolated subscapularis repair



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Background: Minimal Clinically Important Difference (MCID) and Patient-Acceptable Symptomatic State (PASS) have emerged as patient-based treatment assessments. However, these have not been investigated in patients undergoing arthroscopic isolated subscapularis repair (AISR). The primary purpose of this study was to determine the MCID and PASS for commonly used patient-reported outcomes in individuals who underwent AISR. The secondary purpose was to assess potential associations between preoperative and intraoperative patient characteristics and the MCID and PASS.

Methods: A retrospective analysis was conducted on prospectively collected data for patients who underwent primary AISR between 2011 and 2021 at a single institution, with minimum 2-year post-operative follow-up. Functional outcomes were assessed using the American Shoulder and Elbow Surgeons (ASES) score, Subjective Shoulder Value (SSV), and Visual Analog Scale (VAS) pain scale. The MCID was determined using the distribution-based method, while PASS was evaluated using area under the curve analysis. To investigate the relationship between preoperative variables and the achievement of MCID and PASS thresholds, Pearson and Spearman coefficient analyses were employed for continuous and noncontinuous variables, respectively.

Results: A total of 77 patients with a mean follow-up of 58.1 months were included in the study. The calculated MCID values for VAS pain, ASES, and SSV were 1.2, 10.2, and 13.2, respectively. The PASS values for VAS pain, ASES, and SSV were 2.1, 68.8, and 68, respectively. There was no significant correlation between tear characteristics and the likelihood of achieving a MCID or PASS. Female sex, worker's compensation status, baseline VAS pain score, and baseline ASES score, exhibited weak negative correlations for achieving PASS for VAS pain and ASES.

Conclusion: This study defined the MCID and PASS values for commonly used outcome measures at short-term follow-up in patients undergoing AISR. Tear characteristics do not appear to impact the ability to achieve a MCID or PASS after AISR. Female sex, worker's compensation claim, and low baseline functional scores have weak negative correlations with the achievement of PASS for VAS pain and ASES scores.

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Approximately one-third of rotator cuff tears undergoing repair involve the subscapularis (SSC).^{7,8,15} Although SSC tears can occur in isolation, they are less common and comprise of 6.4% to 10% of all rotator cuff tears.^{1,17,24}

While multiple studies have evaluated the effectiveness of arthroscopic isolated SSC repair (AISR) in achieving statistically significant postoperative changes, there is limited understanding of what is considered a meaningful clinical change.^{31,35} Clinical significance can be determined by establishing the minimal clinically important difference (MCID) and patient-acceptable symptom state (PASS). MCID represents the minimum improvement in patient-reported outcomes (PROs) that is perceptible by patients, while PASS is the threshold of postoperative PROs necessary to reflect patient satisfaction. Previous studies have identified MCID and PASS values for arthroscopic rotator cuff repair (RCR), but these

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studies encompassed heterogeneous cuff tear patterns.^{6,13,19} There is no standardized criteria to determine the MCID and PASS for PROs specifically in the AISR patient population. Applying MCID and PASS estimates from previous studies extrapolated from combined posterolateral and SSC RCR to patients undergoing AISR is problematic, as these scores may not accurately represent this patient population.

The purpose of this study was to determine the MCID and PASS for frequently utilized PROs in patients who underwent AISR. A secondary purpose was to assess for associations between preoperative and intraoperative patient characteristics and the achievement of a MCID or PASS.

Methods

Study design

A retrospective study was conducted on prospectively collected data on patients who underwent AISR between 2011 and 2021 at a single institution. The inclusion criteria were primary repair, baseline PROs, and minimum 2-year follow-up. Patients were excluded if there was a history of previous surgery, concomitant posterolateral cuff repair and SSC tears, proximal humerus fracture or glenoid fracture, inaccessible magnetic resonance imaging scans or poor image quality, an incomplete physical examination record, or incomplete intraoperative documentation.

Study variables

Demographic variables including age, sex, tobacco use, worker's compensation and length of follow-up were collected. The Charlson Comorbidity Index, which includes 17 different comorbidities associated with mortality and assigns weights ranging from 1 to 6 points (0 to 29, respectively), was used to standardize comorbidities by dividing the patient's score by 29 (score received/29 = %).²⁰ The Goutallier classification was assessed and documented by one high-volume fellowship trained shoulder surgeon (PJD) preoperatively for each rotator cuff muscle on T1 sagittal magnetic resonance imaging scans using the most lateral image where the scapular spine connects with the body of the scapula.^{4,36} This classification system consists of 5 grades, scored from 0 to 4. Grade 0 indicates the absence of fat, grade 1 indicates the presence of some fatty streaks, grade 2 indicates a higher proportion of muscle compared to fat, grade 3 indicates an equal presence of fat and muscle, and grade 4 indicates a higher proportion of fat compared to muscle. The SSC was also divided into the upper and lower half for grading based on the division described by Collin et al.¹⁶

Surgical technique and arthroscopic findings

All procedures were performed by a single surgeon (PJD). Patients were positioned in the lateral decubitus position, and conventional portals were used (ie, posterior, anterosuperior and lateral). SSC tendon integrity was evaluated from the posterior viewing portal with both 30° and 70° arthroscopes. Intraoperatively, SSC tear type was documented according to the Lafosse classification^{17,27} (ie, type I to V) and SSC tear size was reported as a percentage (ie, % cephalad to caudal). In addition, long head biceps tendon integrity (ie, intact, subluxated, partial tear, or complete tear) was documented.^{17,27}

Following diagnostic arthroscopy, biceps tenodesis was performed on patients with compromised biceps sling or biceps pathology on physical examination or imaging. The width of the subcoracoid space was evaluated. Coracoplasty was performed if

there was a narrowed subcoracoid space (<7 mm) or if a coracoid spur was present. SSC repair was performed with a single-row or double-row technique based on the tear pattern and tendon mobility.

Postoperatively, patients were immobilized in a sling for 4 to 6 weeks to maintain neutral rotation and slight abduction. After sling discontinuation, patients were permitted to engage in passive external rotation and forward flexion. Strengthening exercises and passive internal rotation were initiated at 3 months postoperatively, with a full return to activity, including sport activities, at 6 months.

Patient-reported outcomes

The American Shoulder and Elbow Surgeons (ASES),²⁹ Subjective Shoulder Value (SSV),³⁰ Visual Analog Scale (VAS)¹¹ pain scores, and overall satisfaction levels were evaluated both preoperatively and at a minimum of 2 years postoperatively. The ASES score, ranging from 0 to 100, measures a patient's pain level and ability to perform activities of daily living.²⁹ The SSV score represents a subjective evaluation of shoulder function, expressed as a percentage of normal.³⁰ VAS estimates the level of pain on a scale from 0 (indicating no pain) to 10 (representing the worst pain).¹¹

Consistent with established literature, the MCID was calculated using the distribution-based method, involving half the standard deviation (SD) of the postoperative change for ASES, SSV, and VAS pain scores.^{21,25,26} This approach is based on a study by Norman et al.,²⁵ which revealed that the threshold for detecting changes in health-related quality of life is half a SD. To quantify the meaningful improvement in PROs, we compared the preoperative and postoperative scores and calculated one-half SD of the difference between them.

To assess the PASS for functional outcomes, patients were queried during their final follow-up regarding satisfaction with their current state while considering activities of daily living, level of pain, and functional impairment. The PASS was determined using receiver operating characteristic curve analysis, a statistical method commonly used to establish diagnostic thresholds.^{13,21,26} The threshold was determined with the Youden index.³⁴ An area under the curve greater than 0.7 was considered acceptably predictive of a patient achieving PASS, while an area under the curve greater than 0.8 was considered excellent.²¹

Statistical analysis

Continuous data were presented as mean \pm SD and compared using the student's t-test. Categorical data were expressed as frequencies and percentages and analyzed using the chi-squared test. Pearson correlation coefficients were computed for continuous variables, while Spearman correlation coefficients were used for noncontinuous variables. To ensure adequate statistical power, a priori power analysis was performed. The analysis aimed to detect a minimum "moderate" correlation ($r > 0.4$) with an α of 0.05 and 80% power, resulting in a required minimum sample size of 46 patients.²³ All statistical analyses were conducted using SPSS software (version 25; IBM Corp., Armonk, NY, USA) and MedCalc software (version 20; MedCalc Software Ltd, Flanders, Belgium). A threshold of 0.05 was used to denote statistical significance.

Results

A total 163 AISR were performed during the study period, of which 77 patients met the study criteria (Fig. 1). Baseline characteristics are summarized in Table I. There was a male predominance

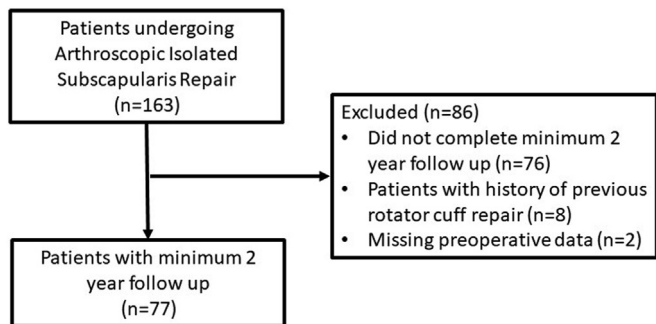


Figure 1 A total of 163 patients were identified from a registry of individuals who had undergone arthroscopic isolated subscapularis repair between 2011 and 2021 at a single institution. Out of those, 77 patients met the criteria for 2-year outcomes data.

(63.6%; n = 49) and the mean age was 57.3 ± 9.6 years. The mean follow-up time was 58.1 ± 3.3months.

Clinical outcomes are shown in Table II. The MCID and PASS values for VAS pain, ASES, and SSV are depicted in Table III and Figure 2.

There was no significant correlation observed between patients' demographic variables and the likelihood of achieving MCID. Baseline SSV (r = -0.281, P < .05) and baseline ASES (r = -0.357, P < .01) demonstrated weak negative correlations with achieving MCID for SSV and ASES, respectively. Additionally, the total number of anchors (r = -0.239, P < .05) used in the operation showed a negative correlation with achieving MCID for VAS pain (Table IV).

In achieving the PASS, no correlation was observed between baseline SSV and patient demographic data. However, sex (female, r = -0.293, P < .05), worker's compensation (r = -0.283, P < .05), baseline VAS (r = -0.291, P < .05), and baseline ASES (r = -0.281, P < .05) demonstrated weak negative correlations for achieving PASS for VAS pain. Additionally, worker's compensation (r = -0.317, P < .05) showed a weak negative correlation for achieving PASS for ASES (Table IV).

Discussion

The study's purpose was to establish values for MCID and PASS for VAS pain, ASES and SSV in patients who underwent AISR. The calculated MCID values for VAS pain, ASES, and SSV were 1.2, 10.2, and 13.2, respectively. The PASS values for VAS pain, ASES, and SSV were 2.1, 68.8, and 68, respectively. No correlation was observed between tear size or Goutallier classification and outcomes. Female sex, worker's compensation, baseline VAS, and baseline ASES demonstrated weak negative correlations in achieving PASS for VAS pain, and worker's compensation exhibited a weak negative correlation in achieving PASS for ASES. These study findings are informative in determining clinically meaningful and satisfactory improvements in patients undergoing AISR, providing valuable parameters for the design and interpretation of future clinical trials. Additionally, they offer guidance for preoperative counseling and can help in managing patient expectations before surgical intervention.

AISR has demonstrated beneficial clinical outcomes since its initial description by Burkhart in 2002.² In a study conducted by Hasler et al¹⁰ with 36 shoulders and 8.6-year follow-up, patients showed significant improvement in Constant score (61 ± 14 to 81 ± 8),_and SSV (40 ± 4 to 91 ± 12) (P < .01) after AISR. Similarly, in Liu et al's¹⁸ 10-year study, the Constant score improved from 55.1 to 75.4 (P < .01), with a postoperative SSV of 80.9, demonstrating sustained benefits over time. Our study results aligned with these

Table 1 Baseline characteristics of arthroscopic isolated subscapularis repair (n = 77).

Variable		
Patient demographics		
Age: y (mean, s.d.)	57.3	9.6
Sex: male (n, %)	49	63.6%
BMI (mean, s.d.)	29.3	5.4
Follow-up: mos (mean, s.d.)	58.1	3.3
Tobacco use: yes (n, %)	11	14.3%
Worker's compensation: yes (n, %)	10	13%
Charlson Comorbidity Index Score: % (mean, s.d.)	2.04%	3.11
Traumatic: yes (n, %)	46	59.7%
MRI findings		
Goutallier classification,		
Grade 0:1:2:3:4 (n)		
Supraspinatus atrophy (n)	60: 9: 8: 0: 0	
Infraspinatus atrophy (n)	54: 14: 9: 0: 0	
Subscapularis upper part atrophy (n)	33: 21: 14: 4: 5	
Subscapularis lower part atrophy (n)	65: 8: 1: 2: 1	
Intraoperative findings		
Size of the torn SSC tendon in the cephalad to caudal: % (mean, s.d.)	47.9%	25.6
Lafosse classification		
Type 1 (n, %)	33	44.2%
Type 2 (n, %)	24	29.9%
Type 3 (n, %)	13	16.9%
Type 4 (n, %)	7	9.1%
Type 5 (n, %)	0	0.0%
Long head biceps tendon		
Intact (n, %)	23	29.9%
Subluxated or dislocated (n, %)	14	18.2%
Partial tear (n, %)	32	41.6%
Complete or retracted tear (n, %)	8	10.4%
Concomitant procedures		
Biceps tenodesis (n, %)	69	89.6%
Biceps left intact (n, %)	6	7.8%
Acromioplasty (n, %)	67	87%
Coracoplasty (n, %)	19	24.7%
Fixation construct		
Single row (n, %)	54	70.1%
Double row (n, %)	23	29.9%
Number of anchors (median, min-max)	2	1-6

MRI, magnetic resonance imaging; SSC, subscapularis; BMI, body mass index; s.d., standard deviation.

findings, with the ASES score improving from 41.5 to 81.6, and the SSV improving from 38.2 to 80.5 (P < .01) at nearly 5-year follow-up and highlight the consistent and sustained outcomes following AISR.

When comparing outcomes of isolated SSC repair with combined RCR, there are inconsistencies in the literature. Some studies, such as Cigolotti et al³ and Toussaint et al,³³ reported better post-operative outcomes with higher Constant scores for patients with combined tears. In contrast, studies conducted by Jeong et al¹² and Monroe et al²² did not find significant differences in postoperative scores between patients with isolated tears and those with combined tears. Given the inconsistency in outcomes, establishing MCID specifically for isolated SSC repairs is beneficial for optimizing patient outcomes and aid in clinical decision-making. It can provide valuable guidance in determining meaningful improvements in functional outcomes and pain relief for patients undergoing AISR.

While Malavolta et al's¹⁹ study did not specifically include AISR patients, it included a cohort of 289 shoulders with arthroscopic RCR, 46.7% of whom had undergone concomitant SSC repair. The study estimated an MCID value of 10.3 for ASES score, which is consistent with the MCID observed in our study (10.2). This indicates that the level of clinical improvement considered meaningful for ASES scores is similar in both studies, despite the

Table II
Preoperative to postoperative changes.

	Preoperative		Postoperative		Improvement		P
	mean	Std. Dev.	mean	Std. Dev.	mean	95% CI	
PROs							
VAS pain	5.8	1.9	1.9	2.1	-3.8	(-4.4) to (-3.3)	<i>P</i> < .01
ASES	41.5	16.2	81.6	17.6	40.1	35.4-44.7	<i>P</i> < .01
SSV	38.2	19.9	80.5	19.9	42.4	36.4-48.4	<i>P</i> < .01
Status			% (n)				
Satisfaction			90.9% (70)				

PROs, patient-reported outcomes; ASES, American Shoulder and Elbow Surgeons; SSV, Subjective Shoulder Value; VAS, Visual Analog Scale; CI, confidence interval.

Table III
Threshold scores for MCID and PASS.

	MCID		PASS		SE/SP	AUC	95% CI
	value	% achieved	value	% achieved			
PROs							
VAS pain	1.2	97.4%	2.1	64.5%	71.4-100	0.888	0.795-0.948
ASES	10.2	88.3%	68.8	75.3%	82.9-100	0.947	0.871- 0.985
SSV	13.2	88.3%	68	77.2%	85.7-100	0.971	0.905- 0.996

PROs, patient-reported outcomes; ASES, American Shoulder and Elbow Surgeons; SSV, Subjective Shoulder Value; VAS, Visual Analog Scale; MCID, minimal clinically important difference; PASS, patient-acceptable symptom state; AUC, Area under the receiver operating characteristic curve For PASS, value; SE, sensitivity; SP, specificity; CI, confidence interval.

different patient populations. On the other hand, Cvetanovich et al's⁶ study assessed MCID and PASS values for ASES and SSV scores in a cohort of 288 patients who underwent RCR. Their findings yielded MCID values of 11.1 for ASES and 16.9 for SSV, while the PASS values for ASES and Single Assessment Numeric Evaluation were 86.7 and 82.5, respectively. Comparing these values to our study's results, we observed that the MCID value for ASES in our AISR (10.2) was slightly lower than the MCID value reported by Cvetanovich et al⁶ for RCR patients (11.1). Additionally, the PASS value for ASES in our study (68.8) was notably lower than the PASS value reported by Cvetanovich et al⁶ (86.7). These observed differences in MCID and PASS values between the two studies can be attributed to several factors. Firstly, as mentioned earlier, the patient population and the surgical procedures performed are different. SSCAISR is less common compared to RCR, and patient outcomes may differ based on the type of surgery and the extent of injury. Additionally, patient characteristics, such as age, comorbidities, and preoperative status, can influence the level of improvement and satisfaction following surgery, potentially contributing to the variation in MCID and PASS values.

Our analysis of potential associations between preoperative and intraoperative patient characteristics and the achievement of MCID and PASS values yielded interesting results. There was no significant correlation between patients' demographic variables and the likelihood of achieving the MCID. This suggests that patients with different demographic characteristics can achieve meaningful improvements in pain and function following AISR, and that the MCID values identified in this study are applicable across various patient groups. Regarding baseline SSV and its association with PASS, we observed no correlation between SSV and patient demographic data in achieving PASS. This implies that preoperative subjective evaluation of shoulder function, as measured by SSV, does not influence the likelihood of patients achieving an acceptable symptom state postoperatively. However, we identified several weak negative correlations between certain patient characteristics and the attainment of PASS for VAS pain and ASES. Specifically, sex, worker's compensation, baseline VAS,

and baseline ASES demonstrated weak negative correlations in achieving PASS for VAS pain, while worker's compensation exhibited a weak negative correlation in achieving PASS for ASES. The findings from this analysis are consistent with a study by Kim et al,¹³ which also explored factors influencing clinical symptom improvement in RCR patients. They reported that poor baseline scores, male sex, and biceps tenodesis were associated with higher odds ratios for clinical improvement, while poor preoperative scores, retear, large to massive tears, and older age were associated with lower odds ratios. These findings highlight the potential influence of these patient characteristics on the achievement of an acceptable symptom state after surgery and warrant further investigation.

Around 26% of patients within this cohort had SSC tears of 60% (types 3: 13; types 4: 7) or greater, and 29.9% had SSC muscle atrophy exceeding grade 2 or above. However, in our study, despite these advanced Goutallier grades and large tear sizes, we observed no correlation between tear size or Goutallier classification and achieving a MCID and PASS. While no existing literature specifically addresses MCID and PASS determination after isolated SSC repair, studies have been conducted following arthroscopic RCR.^{6,13,14,19,32} Tashjian et al³² evaluated ASES and the Simple Shoulder Test following arthroscopic RCR, revealing no significant correlation between tear size and MCID (*P* = .28, *P* = .24, respectively). Similarly, Kukkonen et al¹⁴ determined MCID for the Constant score, another frequently used PRO measure following arthroscopic RCR, demonstrating that tear size did not significantly impact MCID (*P* = .13). However, these studies did not address the relationship between Goutallier grade and MCID or PASS. These results suggest that despite the severity of SSC tears and muscle atrophy, there appears to be no direct connection between tear size or Goutallier grade and the attainment of meaningful clinical improvements or patient-perceived symptom resolution.

Although there is currently no universally accepted gold standard for calculating MCID, we adopted a distribution-based method, utilizing half the SD, which has been successfully employed in previous studies.^{9,21,25,28} Our choice of methodology was influenced by the limitations in the type of questioning used to assess patient satisfaction, which only allowed for binary responses of "satisfied" or "dissatisfied." For the analysis, 77 patients had both preoperative and postoperative measures, enabling the calculation of half a SD of the change in score averages over a 2-year period. The MCID values derived from this study contribute valuable insights to our understanding of clinical significance in patients undergoing AISR, complementing existing knowledge established for RCR patients at earlier time points.

This study has several limitations. First, the study's retrospective nature and reliance on prospectively collected data may introduce selection and information biases. Second, the distribution-based method was utilized to derive MCID values, while successful in previous studies, has been criticized for its "anchor-free" nature, potentially not fully representing the actual patient perspective.^{25,28} However, anchor-based methods can also be subjective and yield varying results based on the chosen anchor question.^{6,13} Due to this factor and the retrospective nature of our study, we opted for the distribution-based method. Third, the generalizability of our findings may be constrained since all surgeries were performed by a single experienced shoulder surgeon at a high patient volume institution, potentially limiting their applicability to outcomes. Finally, the extended follow-up time leaves the study susceptible to recall bias, as responses to anchor questions may be influenced by recent events or mood states, in addition to forgetfulness.⁵

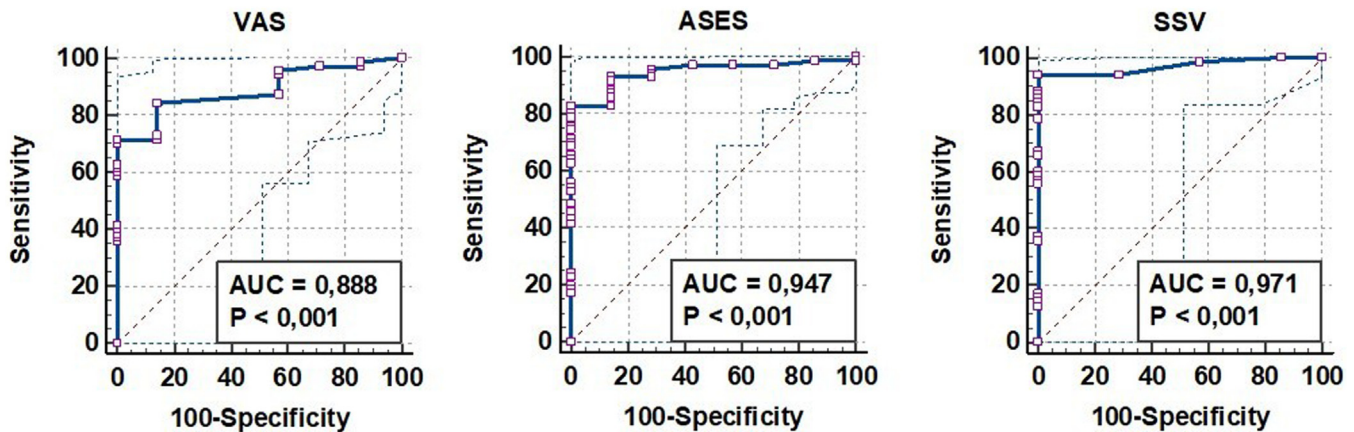


Figure 2 Receiver operating characteristic curve analysis for the threshold score required for achieving PASS in postoperative outcomes after arthroscopic isolated subscapularis repair. VAS, visual analog scale; ASES, American Shoulder and Elbow Surgeons; SSV, subjective shoulder value; AUC, area under the curve; PASS, patient acceptable symptom state.

Table IV
Correlation analysis of preoperative and intraoperative variables with MCID and PASS.

Variable	VAS pain		ASES		SSV	
	MCID r_s	PASS r_s	MCID r_s	PASS r_s	MCID r_s	PASS r_s
Patient demographics						
Age	-0.075	-0.015	-0.093	-0.016	-0.017	0.083
Sex (female)	-0.123	-0.293[†]	0.061	-0.194	-0.023	-0.154
BMI	-0.132	-0.069	-0.045	-0.138	-0.065	0.019
Tobacco use	0.067	-0.167	0.149	0.061	0.033	-0.045
Worker's compensation	0.063	-0.283[†]	-0.100	-0.317[†]	0.020	0.047
Charlson Comorbidity Index Score	0.130	-0.09	0.044	0.054	-0.054	-0.080
Traumatic	-0.134	0.007	-0.134	0.022	-0.051	0.043
Baseline PROs						
VAS pain	0.189	-0.291[†]	0.220	-0.198	-0.027	-0.114
ASES	0.002	0.281[†]	-0.357*	0.134	-0.047	0.080
SSV	0.192	0.196	-0.185	0.148	-0.281[†]	0.010
MRI findings						
Goutallier classification						
Supraspinatus	0.086	-0.078	-0.089	-0.052	-0.068	0.136
Infraspinatus	-0.103	-0.028	-0.099	-0.072	-0.099	0.027
Upper Subscapularis	-0.039	-0.053	-0.101	-0.150	-0.015	0.039
Lower Subscapularis	0.070	-0.072	0.156	-0.091	0.156	0.062
Intraoperative						
Lafosse Classification	-0.051	-0.189	-0.094	-0.149	-0.039	-0.160
Long head biceps tendon lesion	-0.029	0.024	-0.121	-0.078	0.038	0.025
Biceps tenodesis	-0.056	-0.163	-0.124	-0.099	-0.124	-0.139
Acromioplasty (n, %)	0.025	0.121	0.100	0.137	-0.020	0.173
Coracoplasty (n, %)	-0.096	-0.021	-0.167	-0.162	0.021	-0.111
Fixation construct	-0.104	-0.024	0.006	-0.030	0.058	-0.160
Total number of anchors (mead, s.d.)	-0.239 [†]	-0.061	-0.060	-0.123	-0.022	0.025

PROs, patient-reported outcomes; ASES, American Shoulder and Elbow Surgeons; SSV, Subjective Shoulder Value; VAS, Visual Analog Scale; MCID, minimal clinically important difference; PASS, patient-acceptable symptom state; MRI, magnetic resonance imaging; BMI, body mass index.

*Correlation is significant at the 0.01 level (2-tailed).

[†]Correlation is significant at the 0.05 level (2-tailed).

Conclusion

This study defined the MCID and PASS values for commonly used outcome measures at short-term follow-up in patients undergoing AISR. Tear characteristics do not appear to impact the ability to achieve a MCID or PASS after AISR. Female sex, worker's compensation claim, and low baseline functional scores have weak negative correlations with the achievement of PASS for VAS pain and ASES scores.

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