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How can we define clinically important improvement in pain scores after biceps tenodesis?

Yining Lu, MD[a], Alexander Beletsky, BA[b], Jorge Chahla, MD, PhD[b], Bhavik H. Patel, MD[c], Nikhil N. Verma, MD[b], Brian J. Cole, MD, MBA[b], Brian Forsythe, MD[b,*]

[a]*Department of Orthopaedics and Sports Medicine, Mayo Clinic, Rochester, MN, USA*
[b]*Division of Sports Medicine, Midwest Orthopaedics at Rush, Rush University Medical Center, Chicago, IL, USA*
[c]*Department of Orthopaedics, University of Illinois College of Medicine, Chicago, IL, USA*

Background: Patient postoperative pain is an important consideration following biceps tenodesis. The visual analog scale (VAS) for pain is one of the most commonly used measures for perioperative pain assessment. Currently, there is limited understanding of clinically significant improvement in VAS pain.

Purpose: To define the substantial clinical benefit (SCB), patient acceptable symptomatic state (PASS), and minimal clinically important difference (MCID) for the VAS pain score in patients undergoing open subpectoral (OSPBT) or arthroscopic suprapectoral biceps tenodesis (ASPBT) at 1 year from surgery; and to identify preoperative predictors of achieving each outcome end point.

Methods: Data from consecutive patients who underwent isolated biceps tenodesis between January 2014 and March 2017 were collected and analyzed. Baseline data and postoperative patient-reported outcome (PRO) scores were recorded at 1 year postoperatively. In order to quantify the clinical significance of outcome achievement for the VAS pain score, the MCID, PASS, and SCB were calculated.

Results: A total of 165 patients were included in the final analysis. The VAS pain score threshold for achieving MCID was defined as a decrease of 12.9 (0-100). PASS was defined as achieving a 2-year postoperative score of 27.4 points (0-100), and SCB was defined as a decrease of 25.1 (0-100) at 1-year follow-up. The rates of achieving MCID, PASS, and SCB were 73.3%, 52.8%, and 45.9%, respectively. Multivariate regression analysis demonstrated that ASPBT ($P = .01$) and a lower preoperative Constant-Murley score were predictive of achieving the MCID ($P = .01$). In contrast, a lower preoperative score on the SF-12 Physical Component Summary ($P = .01$) and a higher score on the preoperative American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form ($P < .001$) were predictive of achieving the SCB and PASS, respectively. Preoperative duration of symptoms >6 months was predictive of a reduced likelihood to achieve PASS.

Conclusion: This study identified scores for VAS pain that can be used to define clinically significant outcome after biceps tenodesis. Specifically, a decrease in pain score of 12.9 was a clinically important improvement in VAS pain, whereas a decrease of 25.1 represented the upper threshold of VAS pain improvement. Additionally, there were both modifiable and nonmodifiable factors that predicted achieving clinically significant levels of postoperative pain improvement.

Level of evidence: Basic Science Study; Validation of Outcome Instruments

Keywords: Biceps tenodesis; VAS pain; MCID; PASS; SCB; shoulder; clinically significant outcomes

This study was approved by the Rush University Medical Center Institutional Review Board (FWA no. 00000482).

*Reprint requests: Brian Forsythe, MD, Midwest Orthopaedics at Rush, RUMC, Division of Sports Medicine, Orthopedic Surgery, Chicago, IL 60612, USA.

E-mail address: brian.forsythe@rushortho.com (B. Forsythe).

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The long head of the biceps tendon is a common source of shoulder pain, and treatment options for its pathology include both conservative measures and surgical interventions.[10,27] Biceps tenodesis (BT) using either an open subpectoral (OSPBT)[2] or arthroscopic suprapectoral (ASPBT)[18] approach is being performed with increasing frequency in the United States to treat bicipital tears, instability, and/or tenosynovitis.[54] Outcomes after BT have generally demonstrated significant benefits with respect to patient-reported outcome measures (PROMs).[22,29,51] However, examining the distribution of patient-reported outcome scores using statistical significance is limited because statistical differences may not be clinically significant.[23] Clinically significant outcome (CSO) metrics such as the minimal clinically important difference (MCID),[26] substantial clinical benefit (SCB),[35] and patient acceptable symptomatic state (PASS)[43,52] provide an important threshold to contextualize numerical changes in PROM score.

Threshold values for MCID, SCB, and PASS have only recently been established for isolated biceps tenodesis for the function-based PROMs including Constant-Murley score (CMS), Single Assessment Numerical Evaluation, and the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES).[1,43] However, clinical benefits after BT are more than functional in domain. Previous studies have demonstrated significant improvements with respect to health-related quality of life on the Short Form and EuroQoL instruments.[15,46] In addition, significant improvements on the visual analog scale (VAS) for pain have been reported for both the OSPBT[25,32] and the ASPBT.[28,56] Although CSOs with respect to the VAS pain instrument have been defined in rotator cuff disease[49] and low back pain,[41] threshold values for MCID, SCB, and PASS have not been established for VAS pain in biceps tenodesis. Despite the prominent role of anterior shoulder pain in the presentation and symptomology in biceps pathology and strong patient preferences and expectations regarding the resolution of this pain with surgical treatment, there has been a paucity of evidence in the literature on evaluating clinically meaningful improvements in pain following BT.[19]

Accordingly, the purpose of this study was to define threshold values for MCID, SCB, and PASS on the VAS pain measure in patients undergoing isolated BT. An important secondary aim was to identify important demographic and operative predictors of successful pain relief with respect to MCID, SCB, and PASS achievement. Our hypothesis was 4-fold: (1) the VAS pain measure and all functional PROMs would demonstrate significant postoperative improvements, (2) achievement rates of MCID would surpass those of SCB and PASS on VAS at 1 year, (3) no significant differences with respect to CSO achievement would exist between ASPBT and OSPBT, and (4) higher preoperative scores would significantly decrease the odds of MCID, SCB, and PASS achievement on the VAS pain score.

Methods

Cohort selection and patient-reported outcomes

This is a retrospective case cohort study of the aggregate patients of 3 surgeons at a tertiary center. Following institutional review board approval, a prospectively maintained institutional registry was queried for all patients receiving isolated biceps tenodesis between January 2014 and March 2017. Inclusion criteria included receipt of a primary biceps tenodesis using either an arthroscopic or open approach for the following indications: tenosynovitis, full or partial tendon tears, biceps instability, or superior labrum from anterior to posterior (SLAP) tears,[11] and a minimum follow-up of 1 year. Exclusion criteria included patients receiving revision surgery, those with concurrent rotator cuff tears, or recipients of significant concomitant surgeries (ie, shoulder arthroplasty, rotator cuff repair, and labral repair). Patients receiving concomitant acromioplasty were not excluded.[53]

PROMs collected preoperatively and at 1-year follow-up were inclusive of the VAS pain, measured on a 0-100 scale, with 0 described as "no pain at all" and 100 as "worst pain of your life," the ASES score, the Single Assessment Numerical Evaluation, CMS, 12-Item Short Form Health Survey (SF-12) Physical Component Summary (PCS) and Mental Component Summary (MCS), Veterans RAND 12-Item Health Survey (VR-12) PCS and MCS, and the Veterans RAND 6-Domain instruments.

After preoperative PROM collection, BT was performed by the senior authors (B.F., B.J.C., and N.N.V.) as previously described.[2,18] Demographic variables were collected, including age, gender, and worker's compensation status, and stored in the database. Similarly, intraoperative variables including tenodesis approach, fixation device (ie, screw and suture anchor), and long head of the biceps tendon findings on arthroscopy were collected and documented by trained research coordinators at the time of operation.

Statistical analysis

MCID, SCB, and PASS values for the VAS pain instrument in this study were calculated using receiver operating characteristic curve with area under the curve (AUC) analysis, using an anchor-based methodology relying on the global assessment scale.[9,35,36] Anchor-based approaches are the original method by which the concept of MCID was derived and demonstrate superior correlation with patient-perceived clinical changes compared to the distribution-based approach.[8] An AUC value exceeding 0.7 was determined to be sufficiently predictive of successful outcome achievement.[30] SCB was calculated using both a net change method and an absolute value threshold.[37] The specific anchor question and dichotomization of responses are provided in Fig. 1. Demographic variables collected were inclusive of age, sex, body

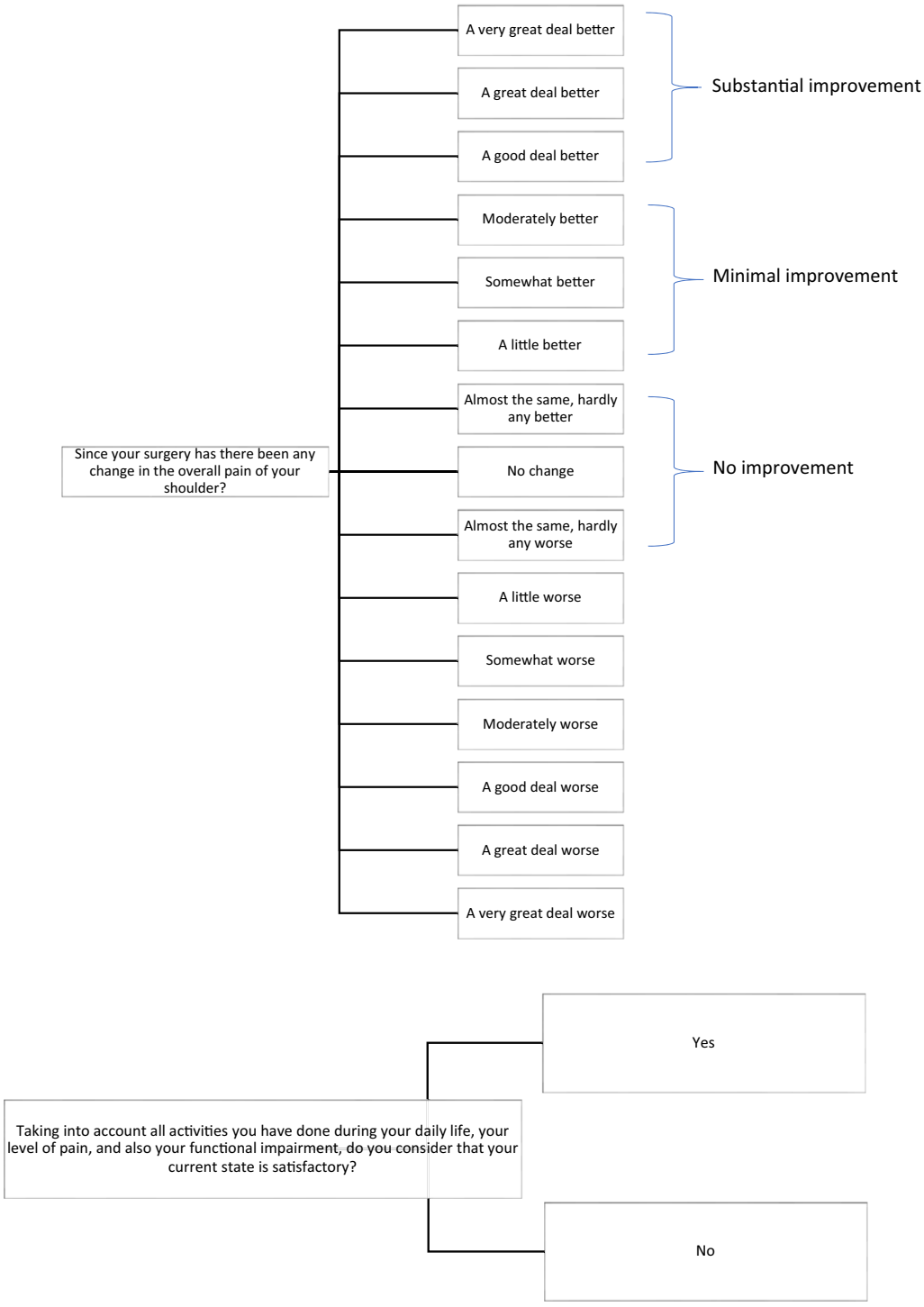

Figure 1 Anchor questions and dichotomization for determination of clinically significant outcome achievement.

mass index, worker's compensation (WC) status, preoperative narcotic use, and various operative variables (ie, tenodesis technique and fixation device). Preoperative and postoperative PRO scores were examined for normality using the Shapiro-Wilks tests. Given sufficiently normal score distributions, Student independent *t* tests were used to examine differences in the mean PRO scores between preoperative and postoperative time points at 1 year. Otherwise, a nonparametric Mann-Whitney *U* test was performed for non-normally distributed data.

Pearson coefficients were calculated to determine correlation between preoperative scores and postoperative outcomes at 1-year follow-up to identify covariates for regression. A stepwise multivariate logistic regression model was used to examine demographic and operative factors

Table I Demographic and clinical characteristics of study population

	Mean ± SD, or n (%)
Patients	161
Age, yr	50.04 ± 12.16
Male	99 (61.5)
WC	34 (21.1)
BMI	29.43 ± 6.92
Positive smoking history	52 (33.3)
Current smoker	20 (12.8)
Former smoker	32 (20.5)
Diabetes	5 (3.1)
Hypertension	30 (18.8)
Thyroid	10 (6.2)
History of anxiety/depression	18 (11.2)
Exercises regularly	94 (58.4)
Lives alone	24 (14.9)
Preoperative night pain	112 (93.3)
Preoperative narcotics use	31 (26.3)
Biceps pathology on arthroscopy	
No gross pathology	13 (8.1)
Complete tear	8 (5.0)
Partial tear	26 (16.1)
Tenosynovitis	114 (70.8)
Tenodesis technique	
Arthroscopic suprapectoral	42 (26.1)
Open subpectoral	119 (73.9)
Fixation device	
Tenodesis screw	56 (34.8)
Suture anchor	119 (73.9)

WC, worker's compensation; *SD*, Standard deviation.

predictive odds of MCID, SCB, and PASS achievement based on odds ratios.

Results

Demographics

A total of 161 eligible patients met inclusion criteria (76.7%). Patient demographic and intraoperative information are provided in Table I. There were 99 (61.5%) patients of male gender. The average age and body mass index were 50.0 ± 12.2 and 29.4 ± 6.9, respectively. The average preoperative symptom duration was 21.5 ± 35.4 months. The average length of follow-up was 14.2±8.6 months (range, 10-18 months). Of the BTs performed, 73.9% were OSPBTs and 26.1% were ASPBT.

Comparison of baseline and postoperative PROMs

Paired *t* tests performed to compare preoperative with postoperative PROM scores demonstrated significant improvements in score across all instruments, as well as on the VAS pain ($P < .001$-$.003$). There was a mean reduction of pain from 50.6 ± 22.8 at baseline to 27.7 ± 26.3 at 1-year follow-up. Average PROM scores at baseline and follow-up are provided in Table II.

VAS pain thresholds for MCID, PASS, and SCB

Values of Spearman rank correlation coefficients between the postoperative score on the VAS pain and PROMs investigated in the present study demonstrated moderate to high correlations. High correlations were found with the ASES ($r^2 = –0.93$, $P < .001$), Single Assessment Numerical Evaluation ($r^2 = –0.74$, $P < .001$), CMS ($r^2 = –0.75$, $P < .001$), SF-12 ($r^2 = –0.71$, $P < .001$), and VR-12 PCS ($r^2 = –0.71$, $P < .001$) and the Veterans RAND 6-Domain score ($r^2 = –0.75$, $P < .001$), whereas moderate correlations were observed with the SF-12 ($r^2 = –0.63$, $P < .001$) and VR-12 MCS ($r^2 = –0.63$, $P < .001$).

Threshold on the VAS pain representing the MCID was determined to be a decrease of 12.9 points (AUC 0.86, 95% CI 0.69-0.99), threshold representing the SCB was determined to be a net decrease of 25.1 points (AUC 0.84, 95% CI 0.72-0.96) or an absolute 1-year score of 28.9 points (AUC 0.93, 95% CI 0.82-0.99), and threshold representing PASS was determined to be an absolute 1-year score of 27.4 points (AUC 0.86, 95% CI 0.82-0.93). Achievement rates for each threshold were as follows: 73.3% of patients achieved the MCID, 45.9% of patients achieved the net SCB, 52.8% of patients achieved the absolute SCB, and 52.8% of patients achieved the PASS (Table III).

Factors predictive of achieving the MCID, SCB, and PASS

Univariate followed by a multivariate analysis identified the following factors to be significantly associated with the achievement of each CSO threshold (Table IV). Because of the similarity between values of the absolute VAS threshold for SCB and PASS, the net score change was selected to represent SCB achievement. OSPBT (OR 0.29, 95% CI 0.13-0.69, $P = .01$) and a higher preoperative CMS score (OR 0.89, 95% CI 0.82-0.97, $P = .01$) predicted a reduced likelihood of achieving MCID on the VAS pain score. Higher preoperative scores on the ASES (OR 0.96, 95% CI 0.94-0.98, $P < .001$), CMS (OR 0.87, 95% CI 0.80-0.95, $P < .001$), and the SF-12 PCS (OR 0.87, 95% CI 0.82-0.92, $P < .01$) were found to predict reduced likelihood of achieving the net SCB. A preoperative diagnosis of depression (OR 0.31, 95% CI 0.1-0.91, $P = .03$) and symptom duration >6 months (OR 0.01, 95% CI 0.01-0.64, $P < .001$) predicted reduced achievement of the PASS, whereas a higher preoperative ASES score (OR 1.10, 95% CI 1.06-1.14, $P = .006$) as well as a greater percentage change in ASES score (OR 1.88, 95% CI 1.06-3.34, $P = .03$) predicted increased achievement of PASS.

Table II Independent *t*-test analysis of preoperative and postoperative patient-reported outcome scores

	Preoperative	Postoperative	*P* value
ASES	46.77 ± 19.11	72.76 ± 24.56	**<.001**
SANE	32.93 ± 21.14	66.72 ± 29.47	**<.001**
Constant-Murley	12.44 ± 6.62	21.50 ± 9.59	**<.001**
SF-12 PCS	36.68 ± 8.89	40.81 ± 10.43	**<.001**
VR-12 PCS	38.43 ± 9.20	42.65 ± 10.61	**<.001**
SF-12 MCS	49.68 ± 10.82	51.52 ± 11.12	**.003**
VR-12 MCS	52.49 ± 10.90	54.97 ± 11.49	**<.001**
VR-6D	0.62 ± 0.12	0.68 ± 0.14	**<.001**
VAS pain	50.6 ± 22.8	27.7 ± 26.3	**<.001**

ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *SANE*, Single Assessment Numerical Evaluation; *SF-12*, 12-Item Short Form Health Survey; *PCS*, Physical Component Summary; *VR-12*, Veterans RAND 12-Item Health Survey; *MCS*, Mental Component Summary; *VR-6D*, Veterans RAND 6-Domain; *VAS*, visual analog scale.
Bold values denote statistical significance at $P < .05$.

Table III Calculated MCID, SCB, and PASS and cumulative probability of achievement at follow-up

CSO	Value	AUC	95% CI	Achievement, n (%)
MCID	12.9	0.86	0.69-0.99	118 (73.3)
SCB (net)	25.1	0.84	0.72-0.96	74 (45.9)
SCB (absolute)	28.9	0.93	0.82-0.99	85 (52.8)
PASS	27.4	0.86	0.82-0.93	85 (52.8)

MCID, minimal clinically important difference; *SCB*, substantial clinical benefit; *PASS*, patient acceptable symptomatic state; *CSO*, clinically significant outcome; *AUC*, area under the curve; *CI*, confidence interval.

Discussion

In the present study, the primary findings include definition of thresholds indicative of CSOs on the VAS pain score: the MCID was defined as a change of 12.9 points, PASS was defined as a 1-year absolute score of 27.4 points, and SCB was defined as a net decrease of 25.1 points or an absolute postoperative score of 28.9 points. Secondary findings included factors identified to significantly predict patient achievement of CSOs. These include the following: OSPBT and greater preoperative score on the CMS predicted a reduced likelihood to achieve the MCID; greater preoperative scores on the ASES, CMS, and SF-12 PCS predicted reduced likelihood to achieve the SCB; and preoperative diagnosis of depression and symptom duration >6 months predicted reduced likelihood to achieve PASS. Finally, higher preoperative ASES score predicted increased likelihood to achieve PASS. These established scores and risk factors are highly relevant to informing preoperative patient expectations and the modification of patient behavior to improve satisfaction with surgical treatment, leading to overall optimization of value-based care and delivery of patient-centered services.

Preoperative pain is one of the most common symptoms of biceps-labral pathology, and patients consider it significantly debilitating,[11,17] such that the presentation of anterior shoulder pain on clinical examination can offer significant diagnostic value to surgeons.[4,14,16,24,32,38,42,45,47] Although orthopedic research has established and validated extensive collection of legacy PROM instruments to evaluate function and quality of life in shoulder surgery,[12,39,40,43,50,55] there is less evidence for instruments of pain assessment. Furthermore, patients have traditionally reported subjective pain on an absolute scale, and an attempt to establish clinically meaningful changes in pain score may better quantify and contextualize postoperative improvements. With regard to the BT population, Puzzitiello et al[43] recently defined CSO threshold values for 3 different functional legacies; however, no studies have established CSO values for the VAS pain score in BT patients. The current investigation is the first to describe psychometric thresholds for patients undergoing biceps tenodesis and offers important insights for measuring postoperative patient-reported improvements in pain.

The current study found that 73.3%, 45.9%, and 52.8% of patients were able to achieve the MCID, the SCB, and PASS, respectively, on the VAS pain score 5 at 1-year follow-up. Although Puzzitiello et al did not provide the rate of CSO achievement for the PROMs evaluated, the authors reported that a combined 70.5% of respondents endorsed ''minimal'' or ''substantial'' improvements in function with their anchor question responses, with 32.5% in the first group and 38.2% in the latter group, at 6-month follow-up. Additionally, 48.7% endorsed a ''satisfactory'' state on the PASS anchor.[43] These values are consistent with the achievement rates on the VAS pain from the present investigation as additional patients are expected to achieve CSOs beyond 6 months, and suggests that most patients derive significant relative improvements with respect to both function and pain from BT. However, future studies should be performed to investigate any potential differences in domain-specific achievement rates of CSOs.

WC status was not significantly predictive of CSO achievement on multivariate analysis. Nevertheless, subgroup analysis by WC status demonstrated reduced achievement rates on the SCB and PASS in the WC cohort compared with non-WC patients (SCB: 36.1 vs. 57.9; PASS: 35.1 vs. 58.9), suggesting that a potential topic for future exploration could be to determine the impact of WC status on pain outcomes in this population.

Multivariate analysis found several predictors of CSO achievement. OSPBT was found to predict reduced achievement of the MCID for pain relative to ASPBT. Several previous case series and RCT have demonstrated satisfactory outcomes for both approaches with respect to both postoperative functional and pain PROM

Table IV Logistic regression analysis for CSO achievement

	Odds ratio	95% CI	*P* value
Predictors for achieving MCID			
Male gender	0.37	0.18-0.74	<.001
OSPBT	**0.29**	**0.13-0.69**	**.01**
Preoperative ASES score	0.96	0.94-0.98	.01
Preoperative Constant-Murley	**0.89**	**0.82-0.97**	**.01**
Preoperative SF-12 PCS	0.86	0.81-0.91	<.001
Preoperative VR-12 PCS	0.87	0.82-0.92	<.001
Preoperative VAS pain	1.44	1.17-1.76	<.001
Predictors for achieving SCB (Net)			
OSPBT	0.42	0.2-0.86	.02
Preoperative ASES score	**0.96**	**0.94-0.98**	**<.001**
Preoperative Constant-Murley	**0.87**	**0.8-0.95**	**<.001**
Preoperative SF-12 PCS	**0.87**	**0.82-0.92**	**.01**
Preoperative VR-12 PCS	0.89	0.84-0.93	<.001
Preoperative VAS pain	1.44	1.2-1.72	<.001
Predictors for achieving PASS			
WC	0.34	0.15-0.76	.01
Depression	**0.31**	**0.1-0.91**	**.03**
Preoperative narcotics use	0.14	0.05-0.38	.00
Arthroscopic Findings			
Tenosynovitis	3.33	0.87-12.75	<.001
Partial tear	7.50	1.61-34.83	.01
Complete tear	23.33	1.99-273.3	.01
Preoperative ASES score	**1.10**	**1.06-1.14**	**<.001**
Percent ΔASES score	**1.88**	**1.06-3.34**	**.01**
Preoperative SANE	1.03	1.01-1.04	.01
Percent ΔSANE	1.03	0.97-1.11	.02
Preoperative Constant-Murley	1.21	1.1-1.33	<.001
Preoperative SF-12 PCS	1.10	1.05-1.16	<.001
Preoperative VR-12 PCS	1.12	1.06-1.18	<.001
Percent ΔVR-12 MCS	0.92	0.83-1.01	.01
Preoperative VAS pain	0.49	0.38-0.64	<.001
Symptom duration > 6 months	**0.09**	**0.01-0.64**	**.006**

CSO, clinically significant outcome; *MCID*, minimal clinically important difference; *OSPBT*, open subpectoral biceps tenodesis; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *SF-12*, 12-Item Short Form Health Survey; *PCS*, Physical Component Summary; *VR-12*, Veterans RAND 12-Item Health Survey; *VAS*, visual analog scale; *SCB*, substantial clinical benefit; *PASS*, patient acceptable symptomatic state; *WC*, worker's compensation; *SANE*, Single Assessment Numerical Evaluation; *MCS*, Mental Component Summary; *CI*, confidence interval.
Variables in bold remained significantly predictive following stepwise multiple logistic regression.

scores.[15,20,21,56] Although none have evaluated differences with respect to CSO achievement. Several reasons could be responsible for this finding. Although it is possible that the arthroscopic approach may cause less pain compared to an open one in the short-term postoperative period, as demonstrated in several comparison studies,[31,33] it is more ambiguous whether such differences would persist at 1 year. In a multicentered study by Sperling et al[48] evaluating patient perceptions of open vs. arthroscopic shoulder surgery, 79% of patients endorsed the strong belief that arthroscopic surgery will produce less postoperative pain compared to an open alternative, despite little underpinning evidence in the literature.[5,6,21,59] As such, no conclusions can be drawn regarding a relationship between OSPBT and pain from the current evidence.

Preoperative depression as well as other psychiatric diagnoses have been linked to negative outcomes, both clinical and subjective, following shoulder surgery.[13,34,57] Dekker et al[13] stratified patients undergoing subacromial decompression by preoperative scores on the Hospital Anxiety and Depression scale and identified a strong negative correlation between the preoperative scores and postoperative pain. Additionally, Wong et al[58] demonstrated that patients with greater mental health scores preoperatively were more likely to achieve the MCID on multiple PROMs including the ASES function and pain components; the authors also found preoperative ASES score to predict achievement of the MCID. However, whether differences in outcomes are clinically significant is not always clear in the cited studies. The present

investigation is the first to define a significant relationship between a diagnosis of depression to reduced likelihood of achieving PASS. Curiously, there was no relationship between depression and achievement of either the MCID or the SCB, indicating that although these patients concede to clinically significant improvements with surgery, they struggle to achieve satisfaction with these outcomes. These insights may be useful in preoperative counseling of this population to manage expectations with surgical treatment.

Prolonged preoperative duration of symptoms has emerged as a significant predictor of negative outcomes in patients undergoing orthopedic surgery.[3,7,44] Chen et al[7] found in a prospective study of patients undergoing single-stage arthroscopy for concurrent rotator cuff tears and shoulder stiffness that those who experienced symptoms for greater than 6 months were 18.1 times as likely to experience an unsuccessful outcome, defined as a postoperative ASES score <80 points. Future studies should be undertaken to investigate the potential impact of durations of symptoms on postoperative outcomes, with regard to both function and pain, for shoulder arthroscopies in other indications.

There are several limitations that must be considered prior to interpretation of these results. Although precedent in the literature has shown CSO calculations in a similar manner,[55] limiting the sample to patients who were compliant with PROM data collection may introduce a risk of selection bias. Additionally, although multiple iterations of a stepwise regression were performed to find the most predictive model, confounding variables may be present that were not evaluated. Finally, patients constituting the cohort underwent isolated BT at a high-volume tertiary referral center, thus potentially limiting the generalizability of our findings.

Conclusion

This study identified scores for VAS pain that can be used to define CSO after biceps tenodesis. Specifically, a decrease in pain score of 12.9 was a clinically important improvement in VAS pain, whereas a decrease of 25.1 represented the upper threshold of VAS pain improvement. Additionally, there were both modifiable and nonmodifiable factors that predicted achieving clinically significant levels of postoperative pain improvement.

Disclaimer

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