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3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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ABSTRACT

Purpose:

To establish thresholds for improvement in patient-reported outcome scores that correspond with clinically significant outcomes (CSOs) including the minimal clinically important difference (MCID), substantial clinical benefit (SCB) and patient acceptable symptomatic state (PASS) for Patient-Reported Outcomes Measurement Information System (PROMIS) Upper Extremity (UE) Computer Adaptive Testing (CAT) and Pain Interference (PIF) CAT after biceps tenodesis (BT) and to assess patient variables that are associated with achieving these outcomes. **Methods:** After IRB approval, a prospectively maintained institutional database was queried for patients undergoing BT between December 2017 and August 2019. Patients undergoing isolated biceps tenodesis or biceps tenodesis in conjunction with rotator cuff debridement, superior labrum anterior posterior (SLAP) repair, subacromial decompression or distal clavicle excision were included in the analysis. Anchor-based and distribution-based methods were used to calculate the MCID whereas an anchor-based method was used to calculate the SCB and PASS for PROMIS UE CAT and PIF CAT.

Results:

A total of 112 patients (86.8% follow-up) who underwent BT were included for analysis. The MCID, net SCB, absolute SCB and PASS for PROMIS UE CAT were 4.02, 9.25, 43.4 and 41.1, respectively. The MCID, net SCB, absolute SCB and PASS for PROMIS PIF CAT were -4.12, -10.7, 52.4 and 52.4, respectively. Higher preoperative UE CAT and PIF CAT scores, preoperative opioid use, depression, and living alone were negative predictors of CSO achievement. Male gender and regular exercise were positive predictors of CSO achievement.

Conclusion:

Patients with higher preoperative UE scores were less likely to achieve MCID (OR: 0.84), while patients with higher preoperative PIF scores were less likely to achieve absolute SCB and PASS (OR: 0.83-0.89). The majority of patients achieved the MCID for PIF CAT (70.5%) and UE CAT (62.5%) at final follow-up. Male gender (OR: 4.38-9.15) and regular exercise (OR: 6.45-18.94) positively predicted CSO achievement while preoperative opioid use (OR: 0.06), depression (OR: 0.23) and living alone (OR: 0.90) were negative predictors of CSO achievement**.**

Level of evidence: IV, Case Series

INTRODUCTION

Biceps tenodesis is an increasingly common procedure used to treat pathology of the long head of the biceps tendon (LHBT)[1, 2]. The LHBT is implicated as a pain generator in a variety of conditions including biceps tenosynovitis, biceps instability, and superior labrum anterior posterior (SLAP) tears. While nonoperative management with activity modification, nonsteroidal anti-inflammatories, physical therapy, and corticosteroid injections are first-line treatment options, operative management is indicated in recalcitrant cases. Biceps tenodesis or tenotomy may be considered as surgical options, as both procedures produce reliable pain relief[3, 4]. Biceps tenodesis tends to be preferred in younger and active patients and has been associated with lower rates of muscle cramping and cosmetic deformity[4]. Patients undergoing biceps tenodesis have demonstrated high rates of good or excellent functional outcomes on a number of patient reported outcome measures (PROMs) including American Shoulder and Elbow Surgeons (ASES), Constant, and Oxford Shoulder scores[3].

Orthopaedic surgery is increasingly moving towards a value-based care model which places an emphasis on PROMs. However, traditional PROMs may be time consuming and burdensome for patients[5]. To address this, the NIH developed the Patient-Reported Outcomes Measurement Information System (PROMIS) as an instrument to efficiently collect PROMs[5]. Based on principles of Item Response Theory, PROMIS is a smart form that utilizes Computer Adaptive Testing (CAT) to tailor questions based on a participant's previous answers[6]. This dynamic testing allows more precise estimation of outcomes while reducing the questionnaire burden[6, 7]. Specifically, the Upper Extremity (UE) CAT was developed to assess functional outcomes of hand and upper extremity conditions, with higher scores indicating better functional status, and the pain interference (PIF) assesses the degree to which pain limits a patient's

physical, mental, and social activities, with higher scores indicating greater pain levels[8, 9]. As PROMIS continues to grow in popularity as an outcome measure, it is important to establish changes in scores that accurately reflect clinical improvement for patients.

While traditionally there has been a focus on statistical significance when assessing changes in PROMs, the orthopedic community is increasingly recognizing the importance of clinically significant outcome (CSO) values[10]. These quality measures may better reflect what a patient perceives as a positive or negative outcome. Specifically, the minimal clinically important difference (MCID), represents the smallest change in an outcome that the patient considers important[11]. The substantial clinical benefit (SCB) represents a change that the patient perceives as substantial[10]. The patient acceptable symptomatic state (PASS) is the threshold at which the patient is satisfied with his or her current health state. Two broad categories for calculating CSOs include anchor-based and distribution-based methods[12]. In the anchor-based method, patient-reported outcomes are paired or 'anchored' to another subjective subscale; changes in scores on the PROMs are compared with changes in the subjective subscale and are then used to calculate CSOs[12]. In the distribution-based approach, measures of variability in PROM scores such as the standard deviation or effect size are used to represent a CSO[12].

The objective of this investigation was to establish thresholds for improvement in patient-reported outcome scores that correspond with clinically significant outcomes (CSOs) including the minimal clinically important difference (MCID), substantial clinical benefit (SCB) and patient acceptable symptomatic state (PASS) for Patient-Reported Outcomes Measurement Information System (PROMIS) Upper Extremity (UE) Computer Adaptive Testing (CAT) and Pain Interference (PIF) CAT after biceps tenodesis (BT) and to assess patient variables that are associated with achieving these outcomes. We hypothesized that the MCID, SCB and PASS

79 could be reliably established utilizing anchor based and distribution-based methods, and that
80 patients with higher preoperative UE and PIF scores would be less likely to achieve these CSOs.
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METHODS

Study Design and Methods

After IRB approval, patients undergoing biceps tenodesis at a single institution were identified using a departmental registry between December 2017 and August 2019. Patients received their care and evaluation by one of the four senior authors, all of which are fellowship-trained orthopaedic sports medicine surgeons (ABY, BJC, NNV and BF). A retrospective review of prospectively collected PROMs completed by patients using an electronic data collection service (Outcome Based Electronic Research Database, Columbia, MO, USA) was conducted. The 6-month time point was selected as the minimum follow-up for assessing clinically significant outcomes (CSOs) as it has been identified as the point of maximal medical improvement for patients undergoing biceps tenodesis, after which no significant improvements in post-operative PROMs are expected[13-15]. In fact, extending follow-up significantly beyond this point allows for the introduction of other confounding variables such as additional injuries or life events that do not reflect the medical improvement after BT[15].

Patient selection

Patient medical records were reviewed retrospectively. Much of the existing literature on BT examines its outcomes when performed with more involved procedures such as rotator cuff repair, which requires a longer recovery than BT[15, 16]. Patients undergoing isolated biceps tenodesis or biceps tenodesis in conjunction with rotator cuff debridement, superior labrum anterior posterior (SLAP) repair, subacromial decompression or distal clavicle excision were included in the analysis. Thus, in all cases, BT remained the rate limiting procedure with respect to postoperative rehabilitation. Patients undergoing revision biceps tenodesis or biceps tenodesis in conjunction with rotator cuff repair or total shoulder arthroplasty were excluded[15]. In this

study, BT was performed concurrently with rotator cuff debridement, subacromial decompression and distal clavicle excision. However, All included patients underwent previously described surgical techniques of biceps tenodesis and corresponding rehabilitation protocols[15, 17, 18]. Patients identified as lost to follow-up were compared to included patients to assess for any selection bias in baseline demographics or outcome measures. Additional patient demographics, including age, gender, body mass index (BMI), smoking status, living situation, and comorbidities were collected from electronic medical records. Intraoperative variables were described by the operating surgeons (ABY, BJC, NNV and BF) and documented by trained research associates at the time of surgery.

Anchor questions

CSOs for PROMIS UE and PROMIS PIF were calculated via an anchor-based methodology. To determine PASS, patients were asked to respond “yes” or “no” to the following questions: “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 status is satisfactory?” MCID and SCB were determined by responses to the following anchor questions: “Since your surgery, has there been any change in the overall function of your shoulder?” and “Since your surgery, has there been any change in the overall pain in your shoulder?”. Patients could select one of the 15 possible responses to this question as shown in Figure 1. Respondents were categorized as experiencing no improvement, minimal improvement, or substantial improvement.

Statistical analysis

MCID was calculated using both an anchor-based and a distribution-based method, which has been reliably derived by calculating half of the standard deviation of all outcomes scores within a study population[19-24]. Receiver operating characteristic curves (ROC) and area under the curve (AUC) analysis was performed to evaluate CSOs using the aforementioned anchor questions and PROMIS scores. The ROC model reliability was acceptable if AUC was greater than 0.7 and considered excellent if the AUC was greater than 0.8, values that have been established and utilized in previous investigations[15, 25, 26]. SCB was calculated as both an absolute score and a net change in score at final follow-up. Cutoff analysis to define significant outcomes and threshold outcome scores in achieving clinically significant outcomes was performed through application of the Youden index[27], balancing maximum sensitivity and specificity of threshold values.

Both bivariate and multivariate logistic regression analysis was used to evaluate the association of baseline patient factors with achievement of CSOs. Variables that were found to be significant predictors on bivariate analysis were included in the final multivariate model, and significant predictors were selected through stepwise backwards elimination. All statistical analysis was performed using RStudio software version 1.2.5001 (Boston, MA).

RESULTS

Study population and demographics

Of the 129 patients identified as meeting the inclusion criteria, 112 patients (86.8%) completed preoperative and postoperative PROMIS UE and PIF and were included in the analysis. Seventeen patients were excluded from the study population because they did not complete pre or post-operative PROMs. The mean follow-up was 7.6 months (range 6.0-9.3 months). Patient demographics and comorbidities are reported in Table 1. Of the included patients, 79.5% were <55 years of age, 67% were male, 36.6% had BMI between 25-29, and 66.1% reported regular exercise. Intraoperative findings are reported in Table 2. Tenosynovitis represented the dominant biceps pathology identified at the time of surgery in 95.5% of patients. Biceps tenodesis was performed using an open, subpectoral approach in 92% of cases. Suture anchors and interference screws were employed as fixation constructs in 45.5% and 54.5% of cases, respectively.

Calculation of MCID, SCB and PASS

The MCID was determined using both anchor-based and distribution-based methods (Table 3). The AUC of the MCID ROC analysis (0.52 and 0.56 for PIF and UE, respectively) was inadequate; thus, calculation of MCID was completed using the distribution method as -4.12 for PIF and 4.02 for UE. The AUC of the net SCB ROC analysis was adequate for PIF (0.70) and UE (0.79). Values for net SCB were found to be -10.7 for PIF and 9.25 for UE. The AUC of the absolute SCB ROC analysis was excellent for PIF and UE (AUC of 0.90 for both measurements). Calculation of PASS yielded 52.4 for PIF and 41.4 for UE (AUC of 0.79 and 0.89, respectively). Patients demonstrated significant improvements on both PROMIS PIF

(60.15±6.98 vs. 51.78±9.41, *P*<.001) and PROMIS UE (34.70±9.45 vs. 42.31±9.98, *P*<.001) at final follow-up following biceps tenodesis (Figure 2).

Factors associated with achieving CSOs on PIF CAT

With respect to the PIF CAT, 70.5%, 27.7%, 38.4% and 38.4% of patients achieved MCID, net SCB, absolute SCB and PASS at final follow-up, respectively. Regular exercise was associated with achieving MCID on PIF CAT (OR: 6.45, 95% CI: 1.08-38.4, *P*=.04) (Table 4). Patients with higher preoperative UE CAT scores were less likely to achieve MCID on PIF CAT (OR: 0.84, 95% CI 0.72-0.97, *P*=.02). Male gender was associated with achieving net SCB (OR: 5.85, 95% CI: 1.7-20.11, *P*=.005), absolute SCB (OR: 9.15, 95% CI: 2.48-33.81, *P*<.001) and PASS (OR: 9.15, 95% CI: 2.48-33.81, *P*=.001). Patients with higher preoperative PIF CAT scores were less likely to achieve absolute SCB and PASS (OR: 0.83, 95% CI: 0.74-0.94, *P*=.002).

Factors associated with achieving CSOs on UE CAT

With respect to the UE CAT, 62.5%, 37.5%, 38.4% and 48.2% of patients achieved MCID, net SCB, absolute SCB and PASS on UE CAT at final follow-up, respectively. Regular exercise was associated with achieving MCID (OR: 4.04, 95% CI: 1.27-12.4, *P*=.01) and net SCB (OR: 18.94, 95% CI: 4.71-76.2, *P*=.009) (Table 5). Patients who used opioids preoperatively were significantly less likely to achieve MCID (OR: 0.03, 95% CI: 0-0.18, *P* <.001) or net SCB (OR: 0.06, 95% CI: 0.01-0.49, *P*=.009). Additionally, patients with depression were less likely to achieve net SCB (OR: 0.23, 95% CI: 0.04-1.27, *P*=.002). Patients with higher preoperative UE CAT scores were significantly less likely to achieve MCID (OR: 0.90, 95% CI: 0.84-0.96, *P*=.003) and more likely to achieve absolute SCB (OR: 1.08, 95% CI:

1.0-1.16, *P*=.04). Patients with higher preoperative PIF CAT scores were less likely to achieve absolute SCB (OR: 0.89, 95% CI: 0.8-0.99, *P*=.03) or PASS (OR: 0.85, 95% CI: 0.76-0.95, *P*=.005). Interestingly, male gender was predictive of achievement of PASS (OR: 4.38, 95% CI: 1.38-13.94, *P*=.01). Table 6 outlines preoperative PROMIS PIF and UE scores that were predictive of achieving MCID, absolute SCB and PASS.

DISCUSSION

The principal findings of this study were as follows: (1) the MCID, net SCB, absolute SCB and PASS values were determined for the UE (4.02, 9.25, 43.4 and 41.1, respectively) and the PIF (-4.12, -10.7, 52.4 and 52.4, respectively); (2) patients with higher preoperative UE scores were less likely to achieve MCID, while patients with higher preoperative PIF scores were less likely to achieve absolute SCB and PASS; (3) the majority of patients achieved the MCID for PIF CAT (70.5%) and UE CAT (62.5%) at final follow-up; (4) male gender and regular exercise were positive predictors of CSO achievement; and (5) preoperative opioid use, depression and living alone were negative predictors of CSO achievement.

We found that patients with higher preoperative UE scores were less likely to achieve MCID, while patients with higher preoperative PIF scores were less likely to achieve absolute SCB and PASS. This finding is fairly intuitive considering how MCID, absolute SCB and PASS are derived. MCID is a measurement of change in function that represents the minimum improvement (or worsening) reported by our patients. Absolute SCB represents the score at which patients report substantial benefit. PASS, on the other hand, represents what is acceptable to our patients, and is a calculation rooted in patient satisfaction rather than functional outcomes. While care should be taken not to conflate the two, absolute SCB and PASS are similar in that they represent absolute values of successful postoperative outcomes[28].

Therefore, it is logical that patients with higher preoperative UE functional scores are less likely to achieve a delta in their functional scores equivalent to the MCID, as they have less room for improvement after surgery. A similar finding was reported by Puzzitiello et al who found higher preoperative SANE scores to be associated with decreased odds of achieving the MCID amongst patients undergoing isolated BT[15]. On the other hand, patients who report higher

preoperative PIF scores are less likely to achieve absolute thresholds such as absolute SCB and PASS likely because they are starting from a lower functional baseline, and therefore require greater relative improvements to achieve these absolute thresholds.

We found preoperative opioid use (OR: 0.06) and depression (OR: 0.23) to be associated with decreased odds of achieving net SCB on PROMIS UE. This finding supports the work of previous studies, which have demonstrated the negative effects of preoperative opioid use on outcomes following common orthopaedic procedures such as rotator cuff repair (RCR), total shoulder arthroplasty (TSA), total knee arthroplasty (TKA) and spine surgery[29-38]. Depression, along with anxiety, stress and catastrophic thinking, have all been linked to inferior outcomes following elective shoulder surgery [39-43]. Of patients included in the analysis of this investigation, 20.5%, 22.3%, 2.7% and 4.5% of patients underwent concomitant distal clavicle excision, subacromial decompression, SLAP repair and rotator cuff debridement, respectively. Of note, undergoing any of these procedures was not associated with patients' ability to achieve CSOs on regression analysis.

Regular exercise was found to be associated with achievement of the MCID (OR: 6.45) on PROMIS PIF and MCID (OR: 4.04) and net SCB (OR: 18.94) on PROMIS UE. Male gender was associated with achievement of the net SCB (OR: 5.85), absolute SCB (OR: 9.15), PASS (OR: 9.15) on PROMIS PIF, and PASS (OR: 4.38) on PROMIS UE. Male gender has been shown to be associated with the achievement of CSOs following a variety of orthopaedic procedures, including rotator cuff repair [44-47]. Interestingly, Daniels et al demonstrated that women reported greater pain and decreased shoulder function during the initial 3 months following arthroscopic rotator cuff repair, but these differences were no longer significant at 1-

year follow up [47]. An appreciation of these risk factors may be useful to guide realistic patient and surgeon expectations in the preoperative setting.

Limitations

We acknowledge several limitations to this study. The first is that follow up was limited to a maximum of 9 months, rather than 1 year. Secondly, as the AUC value derived from anchor-based methods was insufficient, the MCID was calculated via a distribution method. While this method cannot incorporate patient responses, it is widely used and validated [19-24]. Lastly, patients included in this study received various combinations of concomitant procedures such as rotator cuff debridement, superior labrum anterior posterior (SLAP) repair, subacromial decompression or distal clavicle excision making the study population quite heterogeneous.

Conclusion:

Patients with higher preoperative UE scores were less likely to achieve MCID (OR: 0.84), while patients with higher preoperative PIF scores were less likely to achieve absolute SCB and PASS (OR: 0.83-0.89). The majority of patients achieved the MCID for PIF CAT (70.5%) and UE CAT (62.5%) at final follow-up. Male gender (OR: 4.38-9.15) and regular exercise (OR: 6.45-18.94) positively predicted CSO achievement while preoperative opioid use (OR: 0.06), depression (OR: 0.23) and living alone (OR: 0.90) were negative predictors of CSO achievement**.**

TABLE 1
Patient Demographics and Comorbidities

	N=112
Demographics	Mean ± SD/N (%)
Age	
75-85	1 (0.9)
65-74	3 (2.7)
55-64	19 (17.0)
30-55	65 (58.0)
18-29	24 (21.4)
Male gender	75 (67.0)
BMI	
18.5-25	27 (24.1)
25-29	41 (36.6)
30-39	29 (25.9)
>40	15 (13.4)
Lives alone	14 (12.5)
Regular exercise	74 (66.1)
Comorbidities	
Preoperative opioid use	12 (10.7)
Arthritis	5 (4.5)
Cancer	4 (3.6)
Depression	15 (13.4)
Diabetes	2 (1.8)
Fibromyalgia	1 (0.9)
Heart Disease	1 (0.9)
Hypertension	12 (10.7)
Thyroid dysfunction	9 (8.0)
Valvular heart disease	1 (0.9)
Alcohol abuse	6 (5.4)
Smoking history	
Current every day smoker	9 (8.6)
Current someday smoker	1 (1.0)
Former smoker	13 (12.4)
Never smoker	82 (78.1)

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TABLE 2
Intraoperative Variables

Biceps pathology	N (%)
Complete tear	2 (1.8)
Partial tear	3 (2.7)
Tenosynovitis	107 (95.5)
Tenodesis type	
Open, subpectoral	103 (92.0)
Arthroscopic, suprapectoral	9 (8.0)
Fixation device	
Suture Anchor	51 (45.5)
Tenodesis Screw	61 (54.5)
Concomitant procedures	
Distal clavicle excision	23 (20.5)
Subacromial decompression	25 (22.3)
SLAP repair	3 (2.7)
Rotator cuff debridement	5 (4.5)

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TABLE 3
Calculated MCID/SCB/PASS

Anchor	Value	AUC	Distribution
MCID			**MCID**
PIF	-5.57	0.52	-4.12
UE	10.33	0.56	4.02
Net SCB			
PIF	-10.7	**0.70**	-
UE	9.25	**0.79**	-
Absolute SCB			
PIF	52.4	**0.90**	-
UE	43.4	**0.90**	-
PASS			
PIF	52.4	**0.79**	-
UE	41.1	**0.89**	-

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TABLE 4
Predictors of Clinically Significant Outcomes on the PIF CAT

	Odds Ratio	**95% CI**	**P-Value**
MCID			
Regular exercise	6.45	1.08-38.4	0.04
Preoperative UE CAT	0.84	0.72-0.97	0.02
Net SCB			

Male gender	5.85	1.7-20.11	0.005
Absolute SCB			
Male gender	9.15	2.48-33.81	<0.001
Preoperative PIF CAT	0.83	0.74-0.94	0.002
PASS			
Male gender	9.15	2.48-33.81	<0.001
Preoperative PIF CAT	0.83	0.74-0.94	0.002

TABLE 5
Predictors of Clinically Significant Outcomes on the UE CAT

	Odds Ratio	95% CI	P-Value
MCID			
Regular exercise	4.04	1.27-12.8	0.01
Preoperative opioid use	0.03	0-0.18	<0.001
Preoperative UE CAT	0.90	0.84-0.96	0.003
Net SCB			
Lives alone	0.90	0.84-0.96	0.002
Regular exercise	18.94	4.71-76.2	0.009
Preoperative opioid use	0.06	0.01-0.49	0.009
Depression	0.23	0.04-1.27	0.002
Absolute SCB			
Preoperative UE CAT	1.08	1-1.16	0.04
Preoperative PIF CAT	0.89	0.8-0.99	0.03
PASS			
Male gender	4.38	1.38-13.94	0.01
Preoperative PIF CAT	0.85	0.76-0.95	0.005

TABLE 6
Preoperative Scores Predictive of CSO Achievement

	PIF Cutoff	AUC	UE Cutoff	AUC
MCID				
PIF	59.1	0.72	36.2	0.65
UE	64.1	0.54	29.1	0.64
Absolute SCB				
PIF	56.1	**0.76**	38.5	**0.74**
UE	61.0	**0.77**	34.3	**0.79**
PASS				
PIF	56.1	**0.76**	38.5	**0.74**
UE	61.0	**0.77**	34.3	**0.78**

Cutoff analysis for net SCB achievement did not reach AUC of acceptable predictive power

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290 **Figure 1.** Anchor questions administered postoperatively to assess function and satisfaction.

291 **Figure 2.** Patients demonstrated statistically significant improvements on both the PROMIS PIF

292 CAT (60.15±6.98 vs 51.78±9.41, P < 0.001) and the PROMIS UE CAT (34.70±9.45 vs

293 42.31±9.98, P < 0.001) at 6 months following biceps tenodesis.

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