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Minimal clinically important differences after subpectoral biceps tenodesis: definition and retrospective assessment of predictive factors

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Background: Minimal clinically important differences (MCIDs) at 1 year after subpectoral biceps tenodesis are unknown for the American Shoulder and Elbow Surgeons (ASES) scale, Subjective Shoulder Value (SSV), and visual analog scale (VAS) for pain. Our objectives were to determine MCIDs for these measures at 1 year after biceps tenodesis and to identify preoperative factors that predict attainment of MCIDs.

Methods: We included 52 patients who underwent arthroscopic débridement, decompression, and mini-open biceps tenodesis from 2016–2018. We analyzed age, sex, body mass index value, arm dominance, diagnosis, range of shoulder motion, and preoperative and 1-year postoperative ASES, SSV, and VAS scores. MCIDs were calculated using a distribution-based method of one-half the standard deviation. Preoperative thresholds predictive of MCIDs were calculated with univariate logistic regression. Multiple logistic regression was used to determine factors that predict MCIDs. Significance was set at a 2-tailed P value of $<.05$.

Results: MCIDs for the ASES, SSV, and VAS were 13, 12, and 1.6 points, respectively. Preoperative ASES score <59 predicted MCID on the ASES ($P = .03$); VAS score >3 predicted MCID on the VAS ($P < .01$); external shoulder rotation $>40°$ predicted MCID on the SSV ($P = .02$); and age >41 years predicted MCID on the VAS ($P = .02$).

Conclusion: At 1 year after débridement, decompression, and biceps tenodesis, MCIDs were 13, 12, and 1.6 points for the ASES, SSV, and VAS, respectively. Patients most likely to attain MCIDs were those aged >41 years, those with the most preoperative pain, and those with the poorest preoperative shoulder function.

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

Keywords: American Shoulder and Elbow Surgeons score; biceps tenodesis; minimal clinically important difference; Subjective Shoulder Value; visual analog scale

As patient-reported outcomes (PROs) become a mainstay of evaluating clinical orthopedic practice, it is important to define what constitutes a clinically meaningful change in a given PRO.[3,4,12] The minimal clinically important difference (MCID), defined as "the smallest difference in the domain of interest which patients perceive as beneficial," allows physicians to determine whether changes in outcome scores are clinically relevant.[15] Although MCIDs have been defined for various outcome

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measures in several shoulder conditions and treatments,[30,35,38] little research has focused on determining MCIDs after biceps tenodesis[24] or preoperative factors associated with attaining such MCIDs.

Biceps tenodesis is an effective procedure for many patients with degenerative SLAP (superior labral anterior to posterior) tears or chronic bicipital tendonitis for whom nonoperative treatments have failed.[4,16] Biceps tenodesis is often combined with rotator interval débridement and subacromial decompression, which address commonly associated conditions.[6,10] Many patients experience statistically significant improvements after the procedure, but the clinical meaning of these improvements is unclear.[3,12,39] Recently, Puzzitiello et al[24] reported MCIDs after biceps tenodesis. The Single Assessment Numerical Evaluation and the American Shoulder and Elbow Surgeons (ASES) scores were reported, but there was no analysis of preoperative factors that predicted achieving MCIDs, and follow-up was limited to 6 months.

The ASES score, Subjective Shoulder Value (SSV), and visual analog scale (VAS) for pain are validated outcome measures used in many shoulder studies.[11,17,18,21,26,31,34,35] Therefore, our goals were (1) to define MCIDs for the ASES, SSV, and VAS for pain in patients undergoing débridement, decompression, and biceps tenodesis and (2) to determine which preoperative factors best predicted attainment of MCIDs in these outcome scores at 1 year postoperatively.

Methods

Patient selection

After obtaining institutional review board approval and waiver of consent, we retrospectively identified patients from our institution's electronic health records who underwent débridement, decompression, and biceps tenodesis (Current Procedural Terminology codes 29823, 29826, and 23430, respectively) performed by 1 fellowship-trained shoulder surgeon between January 1, 2016, and March 31, 2018. We included patients who had complete preoperative and 1-year postoperative PROs and shoulder range-of-motion assessments (forward elevation, abduction, and external rotation). We excluded those who underwent concomitant shoulder procedures, such as rotator cuff repair or labral repair. Shoulder conditions were initially diagnosed via clinical examination and magnetic resonance imaging (MRI), with final diagnosis made during surgery. Only those who had intraoperative confirmation of degenerative SLAP or biceps tendon tear or substantial synovitis surrounding the biceps tendon were included, limiting potential false-positive MRI findings for SLAP tears. Data on patient characteristics, PRO scores, and range of motion were extracted from patient records.

Patient characteristics

Fifty-two patients (26 women) met the inclusion criteria. Mean (± standard deviation) patient age was 47 ± 13 years (range, 19–77 years), and mean body mass index value was 28 ± 5.8 (Table I). Most patients (n = 28) underwent surgery on the dominant shoulder. The indications for surgery were biceps tendinitis/degeneration (n = 8), SLAP tear (n = 3), or both (n = 41).

Surgical technique

Diagnostic arthroscopy was used to confirm the diagnoses (Table I). Arthroscopic transection of the biceps tendon was performed at the superior tubercle, preserving the residual superior labral stump. Substantial rotator interval scarring was found in all cases, and extensive intra-articular débridement was performed. Subsequently, a subpectoral mini-open biceps tenodesis was performed. This remains our preferred approach because the tendon can be removed completely from the bicipital groove, and small anchors can be used with an on-lay technique, obviating the need for large holes in the proximal humerus. A meta-analysis has confirmed the biomechanical efficacy of this technique,[1] and several authors have supported the routine use of subpectoral mini-open tenodesis for the above reasons.[7,23,40]

Defining MCIDs

Two methods exist for determining MCIDs. One is a distribution-based approach, in which statistical modeling is used to calculate effect size and standard response mean, denoted as one-half the standard deviation.[5,20,25] The second method is an anchor-based approach, which relies on patients answering additional questions that gauge their overall satisfaction. These questions serve as the "anchor." Distribution-based MCIDs are easier to calculate because they require no additional questions, but they may not reflect the patient's perception of clinical importance. Anchor-based MCIDs may be more accurate but are more challenging to calculate. They are also limited by the quality of the anchor questions, which vary among studies and are not usually validated. No consensus or gold standard exists, although both methods are accepted. We chose distribution-based modeling, similar to the method that Wong et al[41] used to determine MCIDs after shoulder arthroplasty.

Statistical analysis

Univariate logistic regression was used to determine which variables were associated with achieving the MCID for each PRO measure. Continuous variables were dichotomized using the Youden Index to establish thresholds that best balanced sensitivity and specificity.[9] The area under the resulting receiver operating characteristic curve (AUC) was used to gauge the ability of the chosen variable to predict an MCID. An AUC of 0.5 indicates a predictive value no better than chance; an AUC >0.7 is considered a reasonable predictive model (70% likelihood of accurate prediction); and an AUC of >0.8 is considered excellent (80% likelihood of accurate prediction).[41] For the initial multivariate logistic regression model for MCID prediction, we included patient age, sex, arm dominance, and factors for which the P value was $<.2$ on univariate logistic regression analysis. The final multivariate model was calculated by excluding variables for which the P value was $\geq.2$ after each iteration.

Table I Characteristics of 52 patients who underwent biceps tenodesis by 1 surgeon between January 1, 2016, and March 31, 2018

Characteristic	Mean ± SD or n (%)
Age, yr	47 ± 13
Body mass index	28 ± 5.8
Female sex	26 (50)
Dominant arm injury	28 (54)
Diagnosis	
Biceps tendinitis/degeneration	8 (15)
SLAP tear	3 (6)
Both	41 (79)

SLAP, superior labral tear from anterior to posterior; *SD*, standard deviation.

Categorical variables are expressed as numbers and percentages and were compared using Fisher exact tests. Continuous variables are expressed as means and standard deviations and were analyzed using 2-sample *t* tests for parametric data and Mann-Whitney *U* tests for nonparametric data. Significance was set at a 2-tailed *P* value of <.05. Statistical analyses were performed using Stata, version 14, software (StataCorp LLC, College Station, TX, USA).

Results

MCIDs

MCID calculations were based on the following mean (± standard deviation) improvements in PRO scores from preoperatively to 1 year postoperatively: ASES, 48 ± 21 to 76 ± 22; SSV, 47 ± 21 to 76 ± 22; and VAS, 5.1 ± 2.7 to 2.4 ± 2.2 (all, $P < .01$; Table II). The MCIDs were as follows: ASES, 13; SSV, 12; and VAS for pain, 1.6.

Preoperative patient factors associated with MCIDs

Patient age at surgery, body mass index value, sex, arm dominance, and diagnosis were not associated with achieving an MCID on any PRO measure (Table III).

Preoperative PRO scores associated with MCIDs

Patients with preoperative ASES scores of <59 were significantly more likely than those with scores ≥59 to achieve an MCID on the ASES at 1 year postoperatively (AUC 69%, $P = .01$; Table IV). Patients with preoperative VAS scores for pain >3 were significantly more likely than those with scores ≤3 to achieve an MCID on the VAS at 1 year postoperatively (AUC 81%; $P < .01$). Preoperative SSV was not significantly associated with attaining an MCID on the SSV postoperatively.

Table II Preoperative and postoperative patient-reported outcomes after biceps tenodesis in 52 patients

Outcome measure	Preoperative, mean ± SD	Postoperative, mean ± SD	*P* value
ASES score	48 ± 21	76 ± 22	<.01
SSV	47 ± 21	76 ± 22	<.01
Pain VAS	5.1 ± 2.7	2.4 ± 2.2	<.01

ASES, American Shoulder and Elbow Surgeons; *SSV*, Subjective Shoulder Value; *VAS*, visual analog scale; *SD*, standard deviation.

Multivariate analysis of predictors of MCIDs

After controlling for patient age, sex, and arm dominance, preoperative ASES (AUC 73%; $P = .03$) and VAS (AUC 87%; $P < .01$) scores both predicted achieving an MCID postoperatively. Age >41 years predicted achieving an MCID on the VAS postoperatively ($P = .02$). Patients with preoperative external rotation >40° were significantly more likely to achieve an MCID on the SSV than those with preoperative external rotation ≤40° ($P = .02$). No other factors significantly predicted achieving an MCID postoperatively.

Discussion

In our cohort of patients undergoing débridement, decompression, biceps tenodesis, improvements of 13, 12, and 1.6 points represented MCIDs for the ASES, SSV, and VAS for pain, respectively. Worse preoperative PROs, older age, and preserved shoulder external rotation were predictive of achieving an MCID at 1 year after surgery.

These data expand the existing body of knowledge for MCIDs in various shoulder conditions. We believe ours is the first study to determine MCIDs for the SSV and VAS for pain after biceps tenodesis and to report factors correlated with achieving MCIDs. Puzzitiello et al[24] recently reported an MCID of 11 points for the ASES at 6 months after biceps tenodesis. Our clinical follow-up was 1 year, which may account for our slightly higher postoperative ASES score and larger calculated MCID. We chose this length of time as the benchmark established by several authors reporting MCIDs.[22,33] However, full recovery after biceps tenodesis might occur before 1 year.[14,24] The MCID for a 10-point VAS has been reported as ranging from 1.4 to 1.6 after nonoperative treatment of rotator cuff disease and after shoulder arthroplasty.[29,31,32] These values are consistent with our results, despite the differences in indications and surgical intervention. These similarities suggest that MCIDs for the VAS for pain vary little across conditions and treatments, at approximately 15% of the maximum

Table III Preoperative characteristics of 52 patients who underwent biceps tenodesis according to whether they experienced MCIDs in 3 outcome measures at 1 year postoperatively

Characteristic	ASES score			SSV			VAS for pain		
	MCID (n = 37)	No MCID (n = 15)	*P* value	MCID (n = 37)	No MCID (n = 15)	*P* value	MCID (n = 31)	No MCID (n = 21)	*P* value
Age, yr, mean ± SD	49 ± 12	42 ± 14	.08	49 ± 12	44 ± 15	.17	50 ± 12	44 ± 14	.11
BMI, mean ± SD	28 ± 6.1	26 ± 4.9	.23	28 ± 6.2	26 ± 4.6	.25	29 ± 5.8	26 ± 5.3	.05
Sex									
Male	20 (54)	6 (40)	.36	18 (49)	8 (53)	.76	15 (48)	11 (52)	.78
Female	17 (46)	9 (60)		19 (51)	7 (47)		16 (52)	10 (48)	
Dominant arm injury									
Yes	20 (54)	8 (53)	.96	21 (57)	7 (47)	.51	19 (61)	9 (43)	.19
No	17 (46)	7 (47)		16 (43)	8 (53)		12 (39)	12 (57)	
Diagnosis									
Biceps tendinitis	8 (22)	0 (0)	.15	7 (19)	1 (0)	.54	7 (23)	1 (4.8)	.20
SLAP tear	2 (5)	1 (6.7)		2 (5)	1 (7.1)		2 (6)	1 (4.8)	
Both	27 (73)	14 (93)		28 (76)	13 (93)		22 (71)	19 (90)	

MCID, minimal clinically important difference; *BMI*, body mass index; *SLAP*, superior labral tear from anterior to posterior; *ASES*, American Shoulder and Elbow Surgeons; *SSV*, Subjective Shoulder Value; *VAS*, visual analog scale.
Unless otherwise noted, values are n (%).

Table IV MCID and preoperative patient-reported outcome threshold values for predicting MCID after biceps tenodesis as determined by univariate analysis

Outcome measure	MCID	Cut-off	AUC, %	Sensitivity, %	Specificity, %	*P* value
ASES	13	<59	69	78	60	.01
SSV	12	<40	60	100	0	.12
Pain VAS	1.6	>3	81	90	71	<.01

MCID, minimal clinically important difference; *ASES*, American Shoulder and Elbow Surgeons; *SSV*, Subjective Shoulder Value; *VAS*, visual analog scale; *AUC*, area under the curve.

score. To our knowledge, no study has reported an MCID for the SSV. Future studies with larger cohorts are needed to confirm our findings.

We found that preoperative PROs independently predicted meaningful postoperative improvements. Patients with preoperative ASES scores <59 and VAS scores >3 were significantly more likely to achieve the greatest statistical improvement postoperatively. This concept of diminishing returns has been reported in shoulder arthroplasty. In a retrospective review of patients undergoing total or reverse shoulder arthroplasty, Wong et al[41] established certain thresholds for the ASES and the 12-Item Short-Form Health Survey, below which patients were most likely to achieve MCIDs. Similarly, Werner et al[38] showed that patients with higher preoperative ASES scores were significantly less likely to achieve MCIDs 2 years after shoulder arthroplasty compared with patients with lower preoperative scores. These findings corroborate the need for surgical intervention when nonoperative measures have failed. Patients who had the greatest pain and the lowest function experienced the most improvement after surgery. Whereas the determination of surgical eligibility has historically relied on subjective surgeon assessments of patient debilitation, our study provides objective criteria that may be considered when selecting candidates for débridement, decompression, and biceps tenodesis.

Patient age also independently predicted attaining an MCID after biceps tenodesis. Patients 41 years or older were significantly more likely to experience meaningful improvement in pain than were younger patients. Biceps tenodesis has historically produced better results than SLAP repairs in those older than 40 years.[8] The reason for this is unclear, although it is theorized that the superior labrum and biceps tendon are subject to more degenerative wear in older patients. It is also possible that bicipital tendonitis and groove synovitis account for a greater portion of their pain. The fact that patients younger than 41 years were less likely to achieve MCIDs suggests either a concomitant undiagnosed reason for pain or unrealistic patient expectations. It is possible that younger patients place greater demands on their shoulders, which are unmet

by biceps tenodesis. (Our sample was too small to determine associations of patients' diagnoses and preoperative levels of function with MCID.) This same principle has been reflected in nonoperative management of rotator cuff disease. Tashjian et al[31] reported greater improvements in pain in older patients, who were more likely to achieve MCIDs than were younger patients. The opposite was true in a retrospective analysis of patients who underwent shoulder arthroplasty; Tashjian et al[32] found greater improvements in younger patients. Clearly, the association between patient age and response to treatment varies according to the condition addressed. We believe ours is the first study to establish this age threshold for biceps tenodesis.

We also found that patients with preoperative external shoulder rotation >40° were significantly more likely to achieve an MCID on the SSV. This finding suggests that patients whose range of motion is preserved preoperatively can expect greater overall satisfaction after débridement, decompression, and biceps tenodesis. Those with range of motion <40° may have had a concomitant condition, such as stiffness or mild adhesive capsulitis, although no differences in forward elevation or internal rotation were found between groups. We are unaware of research suggesting that worse preoperative shoulder motion predicts worse outcomes after biceps tenodesis, but the correlation has been reported in studies of hip arthroplasty. Holtzman et al[13] showed that patients with impaired preoperative function, as measured by pain and ability to complete activities of daily living, had significantly greater functional impairments 1 year after hip arthroplasty than those with full function preoperatively. In a retrospective review of nearly 13,000 patients who underwent total hip arthroplasty, Röder et al[27] found that those with poor preoperative walking capacity and hip flexion were less likely to achieve optimal outcomes for walking and postoperative range of motion. Further research is needed to clarify the relationship between preoperative range of shoulder motion and outcomes after biceps tenodesis.

Our study has several limitations. All patients were treated by 1 surgeon, which does not account for variability in surgical technique; all cases were performed via a subpectoral mini-open approach. Furthermore, generalizability to other patient populations may be limited by our study's setting at a single academic institution. Duration of follow-up was limited to 1 year. Several studies have investigated clinical outcomes using similar follow-up,[19,28,36,37] and patients may achieve maximum improvement in less than 1 year after biceps tenodesis.[14] In addition, inherent diagnostic heterogeneity exists among patients undergoing biceps tenodesis. We attempted to isolate the pathology by excluding those who underwent rotator cuff repair or labral repair. Nonetheless, biceps tenodesis is routinely performed to address shoulder pain in a variety of conditions. Eleven patients had either biceps tendinitis/degeneration or SLAP tears, and 41 patients had both. We did not classify the degree of degeneration or the type of SLAP tear. Furthermore, the sample size was limited, increasing the likelihood of type II error. It is possible that we failed to identify additional correlations between preoperative factors and the likelihood of attaining an MCID, but sufficient power was established for the correlations we did find. Finally, we did not use an anchor-based method for determining MCIDs. For the reasons discussed above, a distribution-based approach was chosen. Previous studies have used this method.[2,22]

Conclusion

We determined that MCIDs at 1 year after biceps tenodesis are 13 points for the ASES score, 12 points for the SSV, and 1.6 points for the VAS for pain. We established preoperative PRO threshold values for the ASES (<59 points) and the VAS (>3 points) that predicted achieving MCIDs at 1 year postoperatively. Patient aged >41 years and preoperative external shoulder rotation of >40° independently predicted achieving an MCID on the VAS and SSV, respectively.

Disclaimer

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