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# Establishing minimal clinically important difference, substantial clinical benefit, and patient acceptable symptomatic state after biceps tenodesis

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**Background:** The purposes of this study were to establish thresholds for improvement in patient-reported outcome scores that signify the minimal clinically important difference (MCID), substantial clinical benefit (SCB), and patient acceptable symptomatic state (PASS) after biceps tenodesis (BT) and to assess patient variables that are associated with these clinically important outcomes.

**Methods:** A prospectively maintained institutional shoulder registry was queried for patients undergoing isolated BT between 2014 and 2017. Anchor-based and distribution-based approaches were used to calculate the MCID whereas an anchor-based method was used to calculate the SCB and PASS for the Constant-Murley score, Single Assessment Numerical Evaluation (SANE) score, and American Shoulder and Elbow Surgeons score.

**Results:** A total of 123 patients who underwent isolated BT were included for analysis. The MCID, SCB, and PASS calculated for the American Shoulder and Elbow Surgeons score were 11.0, 16.8, and 59.6, respectively. For the Constant-Murley score, the calculated MCID and PASS were 3.8 and 19.5, respectively. The MCID, SCB, and PASS calculated for the SANE score were 3.5, 5.8, and 65.5, respectively. The following patient variables were significantly associated with decreased odds of achieving the MCID: workers' compensation status, male sex, and higher preoperative SANE score. Patients with a history of ipsilateral shoulder surgery had significantly reduced odds of achieving SCB. The only factor significantly associated with failing to reach the PASS was workers' compensation status.

**Conclusion:** This study established values for the MCID, SCB, and PASS after BT without concomitant rotator cuff repair. Workers' compensation status, previous shoulder surgery, male sex, and higher preoperative patient-reported outcome measure scores are associated with lower odds of achieving clinically significant improvement after BT.

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



**Keywords:** Biceps tenodesis; clinical significance; minimal clinically important difference; substantial clinical benefit; patient acceptable symptomatic state; shoulder; value

The Rush University Medical Center Institutional Review Board approved this work.

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Pathology affecting the long head of the biceps tendon (LHB) is a common source of shoulder pain and dysfunction, for which several treatment modalities exist.[12,13,37] Patients in whom conservative treatment for LHB pathology fails and patients with concomitant pathology indicating other surgical treatment may receive a tenodesis or tenotomy of the LHB.[7,13] Biceps tenodesis (BT) is the preferred surgical management for many cases,[12] owing to the positive clinical outcomes reported,[5,19,42,51] maintenance of the length-tension relationship,[27] and prevention of cosmetic deformities.[27,42] Despite the evidence supporting this procedure, it remains difficult to clinically assess the effectiveness of BT as outcomes are often reported with concomitant procedures that result in significant and prolonged recovery, such as rotator cuff repair (RCR).[10,25,29,33,52] In addition, outcomes of BT have been previously reported in terms of statistical significance, which does not imply clinical relevance or patient benefit.

Patient-reported outcome measures (PROMs) are used in clinical research to provide snapshots of patients' levels of pain, function, or general quality of life.[40] Because the meaning of absolute changes in PROM scores is not readily obvious, there has been much recent interest in developing thresholds for changes in PROMs that have clinical relevance.[3,34,44,46,47,50] By developing such thresholds, conclusions regarding the clinical significance of a procedure can be made, allowing for better evaluation of the value of care provided. The current convention of comparing PROMs over time or between groups involves statistical analysis that quantifies the likelihood that changes in PROM scores after an intervention are due to chance or sampling error. The result of such analysis determines whether an outcome is statistically significant.[20] However, as the number of patients sampled increases, changes that are imperceptibly small in an individual patient may be determined to be statistically significant. Such analysis also generalizes outcomes into a dichotomous result of "significant" or "not significant" without giving meaning to the size of the changes achieved.

The minimal clinically important difference (MCID) is a threshold for change that is commonly used for determination of clinical significance.[23] The MCID is defined as the "smallest difference in score in the domain of interest which patients perceive as beneficial."[20,23] Because the MCID represents a minimum requirement or floor value for clinical improvement, additional psychometric values have been used to define thresholds for improvement that are perceived by patients to be substantial.[3,20] The substantial clinical benefit (SCB) is the change in PROM values for which patients demonstrate optimal improvement, and the patient acceptable symptomatic state (PASS) is the final PROM score that must be achieved for patients to be satisfied with their outcome.[3,46,50]

MCID, SCB, and PASS thresholds have been previously developed for shoulder-specific PROMs such as the American Shoulder and Elbow Surgeons (ASES) questionnaire, Constant-Murley score (CMS), and Single Assessment Numerical Evaluation (SANE) score; however, to our knowledge, there is no published literature regarding these psychometric values after isolated BT.[20] Therefore, the purposes of our study were to establish the MCID, SCB, and PASS for the ASES score, CMS, and SANE score in patients after BT and to assess patient variables that are associated with these clinically important outcomes.

## Materials and methods

### Study design

This was a retrospective outcome study of patients who were treated with BT and had their outcome measures prospectively collected. Our longitudinally maintained institutional shoulder registry was queried for all patients treated with BT without concomitant RCR or shoulder arthroplasty from April 2014 to March 2017. Data were collected from 123 patients treated by 1 of 7 fellowship-trained orthopedic surgeons. The inclusion criteria were suprapectoral or subpectoral BT for the indication of tendinitis, a superior labrum from anterior to posterior (SLAP) tear, partial tearing, or biceps instability and minimum 6-month follow-up. We chose 6 months' follow-up over a later time point because earlier time points have been previously shown to be more useful for calculating the MCID using the anchor-based method, whereas later time points may have a lower number of patients in the "no change" group, thus weakening the power of these calculations.[26] It has also been previously shown that patients who undergo isolated BT reach maximal medical improvement at 3 months[22]; extending follow-up beyond this point introduces additional confounders that are not reflective of medical improvement such as additional injuries and life events. The exclusion criteria were patients with full-thickness rotator cuff tears, patients receiving a concurrent RCR, patients receiving a concurrent shoulder arthroplasty, and patients with a history of ipsilateral BT.

### Patient assessment

All patients were assessed preoperatively and at 6 months' follow-up using the ASES score, SANE score, and subjective CMS. A physical examination was also performed preoperatively and at 6 months' follow-up to assess for range of motion. Furthermore, we collected the history and demographic variables including age; sex; body mass index; workers' compensation status; history of smoking, diabetes, hypertension, or thyroid disease; participation in athletic sports; handedness; duration of symptoms; history of surgery; concomitant procedures; and resulting complications.

At the 6-month follow-up visit, patients were asked 2 questions to evaluate overall improvement in pain and overall satisfaction:

1. Since your surgery, has there been any change in the pain in your shoulder?
2. 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 state is satisfactory?

Fifteen-item anchor responses developed by Juniper et al[24] made up the answer choices for the first question, and the second question required a binary response of yes or no from the patient.

## Determination of clinically significant thresholds

The MCID can be calculated using 3 accepted methods: distribution based, anchor based, or consensus based.[20] With the use of an anchor-based system to develop the MCID or SCB, anchor questions that aim to evaluate subjective improvement in global domains such as overall pain or function are compared against changes in PROMs.[49] The distribution-based method, which has only been validated for the development of the MCID, uses statistical analysis to ascertain minimal clinically significant changes that occur beyond expected variance or error.[32] To optimize the predictive power, distribution-based and anchor-based methods were both used for MCID analysis, and only an anchor-based method was used for SCB and PASS analysis.

A reliable distribution-based method can be performed by calculating 50% of the standard deviation for change between preoperative and postoperative scores for a given PROM within a population, as this value has been found to consistently represent a threshold for subjective discrimination of change.[4,32] Therefore, the mean ASES score, SANE score, and CMS were calculated for the preoperative time point and the time point of 6 months postoperatively. The mean difference and 50% standard deviation between these values were then calculated to determine the MCID for each PROM in this patient population.

A common procedure for anchor-based threshold calculation includes classifying patients' subjective feeling of improvement as no change, minimal change, or substantial change. The mean PROM score changes between classification groups are then compared to determine thresholds.[23] The anchor-based question for pain listed earlier (in the "Patient assessment" section) was used: Patients who responded that they were experiencing "no change" or being "almost the same, hardly any better/worse" were assigned a score from −1 to +1 and were categorized as having no change. Patients who responded that they were "a little better," "somewhat better," and "moderately better" were assigned a score of +2 to +4 and were classified as having experienced minimal improvement. Those who reported being "a good deal better," "a great deal better," and "a very great deal better" were assigned a score from +5 to +7 and were classified as having experienced a substantial change. The mean difference in the change in PROM scores between the no-change group and the substantial-change group was used to calculate each SCB, whereas the mean difference in the change in scores between the no-change and minimal-change groups was used to calculate each MCID. Calculation of the PASS was derived from identical analysis with the anchor question regarding satisfaction and the PROM score at 6 months. Threshold scores were determined by differentiating unsatisfied patients from satisfied patients.[9]

## Statistical analysis

Statistical analysis was performed using RStudio software (version 1.0.143; R Foundation for Statistical Computing, Vienna, Austria). To ensure that the study population was representative of the entire population, a 2-sample Student *t* test and $\chi^2$ test were used to compare continuous and categorical baseline demographic characteristics, respectively, between patients who had completed 6 months' follow-up and those who were not available for follow-up. A nonparametric receiver operating characteristic curve was developed for each outcome score, and by use of the Youden index, the optimal cutoff to maximize sensitivity and specificity for each outcome score was identified. An area under the curve (AUC) analysis was performed to evaluate the predictive power of each MCID, SCB, and PASS developed with the anchor method. If the AUC was calculated to be 0.7 or greater, then the predictive power of that outcome score was determined to be acceptable, whereas an AUC greater than 0.8 was considered excellent.[4] If an MCID had an AUC less than 0.7, the MCID that was calculated using the distribution method was assumed to be unreliable. All PROM scores were subsequently reviewed to determine which achieved the MCID, SCB, or PASS based on the threshold scores that were developed. A secondary analysis was also performed to assess whether individual patient variables were associated with achieving MCID, SCB, and PASS values for each PROM. A univariate logistic regression analysis was performed with respect to each patient variable, using the $\chi^2$ test for categorical variables or the Student *t* test for continuous variables. For variables that achieved $P < .20$, a subsequent multivariate logistic regression analysis was performed. The odds ratio (OR) and 95% confidence interval (CI) were calculated regarding reaching the MCID, SCB, or PASS for each variable included in the multivariate regression analysis. All variables with $P < .05$ were considered significant.

## Results

During the study period, a total of 342 consecutive patients fit the inclusion criteria, 123 of whom were available for 6 months' follow-up and answered the anchor questions. We found no statistically significant differences in demographic characteristics and baseline PROMs between patients who were available for follow-up and those who were not (Table I). The final study population comprised 70 male and 53 female patients, with an average age of 41.4 ± 12.4 years. The baseline ASES score, SANE score, and subjective CMS were 47.7 ± 18.4, 35.1 ± 21.6, and 12.9 ± 6.4, respectively. The ASES score, SANE score, and subjective CMS were not significantly different at 6 months versus 1 year of follow-up ($P = .399$, $P = .219$, and $P = .076$, respectively). A complete

**Table I** Comparison of demographic characteristics between compliant and noncompliant patients

| | Complete follow-up | Incomplete follow-up* | *P* value |
|---|---|---|---|
| n | 123 | 219 | |
| Mean age (SD), yr | 41.4 (12.4) | 42.9 | .286 |
| Sex, M:F | 70:53 | 150:69 | .032 |
| Mean baseline ASES score (SD) | 47.7 (18.4) | 49.7 (22.9) | .407 |
| Mean baseline SANE score (SD) | 35.1 (21.6) | 35.5 (23.9) | .878 |
| Mean baseline Constant-Murley score (SD) | 12.9 (6.4) | 11.8 (7.7) | .180 |

*SD*, standard deviation; *M*, male; *F*, female; *ASES*, American Shoulder and Elbow Surgeons; *SANE*, Single Assessment Numerical Evaluation.

* Patients met the inclusion criteria but did not complete the anchor questions, which precluded inclusion for minimal clinically important difference, substantial clinical benefit, and patient acceptable symptomatic state calculations.

**Table II** Preoperative demographic characteristics and concomitant procedures performed

| | Mean (SD) or % |
|---|---|
| BMI | 29.0 (5.7) |
| Workers' compensation status | 50.4 |
| Smoking | 13.8 |
| Diabetes | 4.1 |
| Hypertension | 13.8 |
| Interference screw | 42.3 |
| Suture anchor | 57.7 |

*SD*, standard deviation; *BMI*, body mass index.

list of patient demographic characteristics and concomitant surgical procedures can be found in Table II.

According to patient responses to the anchor question regarding change in pain, 8 patients (6.5%) reported no change, 40 patients (32.5%) reported a minimal change, and 47 patients (38.2%) reported a substantial change in pain. In addition, 25 patients (20.3%) reported worse outcomes for this anchor question and their data could not be used for anchor-based MCID or SCB calculation.

The MCID calculated for the anchor-based question examining improvement in pain was 16.3, 3.5, and 6.8 for the ASES score, SANE score, and subjective CMS, respectively. The AUC for the SANE score was acceptable (76.1%); however, the AUCs for the ASES score and subjective CMS were not (61.6% and 52.9%, respectively) (Table III). Thus, the MCIDs developed using the distribution method were preferable for these PROMs: 11.0 for ASES score and 3.8 for subjective CMS (Table III).

The thresholds determined for achieving SCB in pain were 16.8 for the ASES score, 5.8 for the SANE score, and 11.0 for the CMS. The ASES score (80.7%) and SANE score (85.0%) had excellent AUCs, but the AUC for subjective CMS was unacceptable (67.9%) (Table IV).

**Table III** MCID at 6 months after biceps tenodesis

| | MCID for anchor | Specificity, % | Sensitivity, % | AUC, %* | MCID for distribution |
|---|---|---|---|---|---|
| ASES score | 16.3 | 8.0 | 4.1 | 61.6 | 11.0 |
| SANE score | 3.5 | 80.0 | 83.3 | 76.1 | 15.2 |
| Constant-Murley score | 6.8 | 57.1 | 66.7 | 52.9 | 3.8 |

*MCID*, minimal clinically important difference; *AUC*, area under curve; *ASES*, American Shoulder and Elbow Surgeons; *SANE*, Single Assessment Numerical Evaluation.
* An AUC greater than 80% is required to be considered acceptable predictive power.

**Table IV** Substantial clinical benefit at 6 months after biceps tenodesis

| | SCB (anchor) | Specificity, % | Sensitivity, % | AUC, %* |
|---|---|---|---|---|
| ASES score | 16.8 | 80.0 | 82.5 | 87.0 |
| SANE score | 5.8 | 80.0 | 92.5 | 85.0 |
| Constant-Murley score | 11.0 | 85.7 | 56.2 | 67.9 |

*SCB*, substantial clinical benefit; *AUC*, area under curve; *ASES*, American Shoulder and Elbow Surgeons; *SANE*, Single Assessment Numerical Evaluation.
* An AUC greater than 80% is required to be considered acceptable predictive power.

**Table V** PASS at 1 year after biceps tenodesis

| | PASS (anchor) | Specificity, % | Sensitivity, % | AUC, % |
|---|---|---|---|---|
| ASES score | 59.6 | 61.7 | 96.6 | 86.2 |
| SANE score | 65.5 | 73.8 | 82.8 | 81.9 |
| Constant-Murley score | 19.5 | 84.8 | 84.1 | 79.6 |

*PASS*, patient acceptable symptomatic state; *AUC*, area under curve; *ASES*, American Shoulder and Elbow Surgeons; *SANE*, Single Assessment Numerical Evaluation.

At 6 months' follow-up, 60 patients answered yes when asked whether their final symptomatic state was satisfactory whereas 63 reported their outcome as unsatisfactory. This was not significantly different than the proportion of patients who reported satisfactory outcomes at 1 year ($P = .202$). The calculated threshold for the PASS was 59.6 for the ASES score, 65.5 for the SANE score, and 29.5 for the subjective CMS. The AUC for each of these values was excellent (Table V).

## Patient variables associated with achieving clinically significant outcomes

The MCID values calculated using acceptable threshold values were used to determine individual patient and surgical factors that were significantly associated with achieving clinically significant outcomes. In the event of unacceptable threshold scores, the distribution-based calculations were used. Logistic regression analysis identified patients with workers' compensation status to have significantly decreased odds of achieving the MCID for the ASES score (OR, 0.7; 95% CI, 0.1-0.8; $P = .017$). Male patients were associated with reduced odds of reaching the MCID for the subjective CMS (OR, 0.3; 95% CI, 0.1-0.9; $P = .04$). Higher preoperative scores were also associated with not reaching the MCID for the SANE score (OR, 0.9; 95% CI, 0.9-1.0; $P < .001$) and ASES score (OR, 0.9; 95% CI, 0.9-1.0; $P = .015$) (Table VI).

**Table VI** Logistic regression of variables associated with achieving MCID for ASES, SANE, and Constant-Murley scores

| | Univariate regression (*P* value) | Multivariate regression (*P* value) | OR (95% CI) |
|---|---|---|---|
| ASES score | | | |
| Preoperative ASES score | .147* | .015* | 0.9 (0.9-1.0)* |
| Workers' compensation status | .024* | .017* | 0.7 (0.1-0.8)* |
| Athlete | .140 | .278 | 2.6 (0.5-15.6) |
| Previous surgery | .121 | .123 | 0.5 (0.2-1.2) |
| Interference | .035 | .996 | NA |
| Onlay | .144 | .997 | NA |
| SLAP lesion repair | .064 | .992 | NA |
| Smoking | .053 | .992 | NA |
| SANE score | | | |
| Preoperative SANE score | <.001* | <.001* | 0.9 (0.9-1.0)* |
| Diabetes | .100 | .061 | 0.1 (0.0-1.1) |
| Interference | .095 | .131 | 2.0 (0.8-5.1) |
| SLAP lesion repair | .075 | .993 | NA |
| Smoking | .125 | .992 | NA |
| Constant-Murley score | | | |
| Sex | .057* | .040* | 0.3 (0.1-0.9)* |
| Acromioplasty | .198 | .996 | NA |
| SLAP lesion repair | .192 | .989 | NA |

*MCID*, minimal clinically important difference; *ASES*, American Shoulder and Elbow Surgeons; *SANE*, Single Assessment Numerical Evaluation; *OR*, odds ratio; *CI*, confidence interval; *SLAP*, superior labrum from anterior to posterior.
* Clinically significant.

**Table VII** Logistic regression of variables associated with achieving SCB for ASES and SANE scores

| | Univariate regression (*P* value) | Multivariate regression (*P* value) | OR (95% CI) |
|---|---|---|---|
| ASES score | | | |
| Dominant arm | .196 | .168 | 3.3 (0.1-17.6) |
| Previous surgery | .024* | .046* | 0.2 (0.1-0.9)* |
| Subpectoral | .128 | .063 | 1.4 (0.9-23.1) |
| Suprapectoral | .123 | NA | NA |
| Capsular release | .011 | .330 | 0.4 (0.1-2.4) |
| RC débridement | .194 | .991 | NA |
| SANE score | | | |
| Preoperative SANE score | .005* | .002* | 0.9 (0.9-1.0)* |
| HTN | .196 | .328 | 2.9 (0.3-23.9) |
| Interference | .112 | .111 | 2.6 (0.8-8.7) |
| BMI | .062 | .170 | 1.1 (1.0-1.2) |

*SCB*, substantial clinical benefit; *ASES*, American Shoulder and Elbow Surgeons; *SANE*, Single Assessment Numerical Evaluation; *OR*, odds ratio; *CI*, confidence interval; *BMI*, body mass index; *NA*, not applicable; *RC*, rotator cuff; *HTN*, hypertension.
* Clinically significant.

Patients who had a history of ipsilateral shoulder surgery had significantly reduced odds of achieving SCB for the subjective ASES score (OR, 0.2; 95% CI, 0.1-0.9; $P = .046$). A higher preoperative SANE score was also associated with failing to achieve SCB (OR, 0.9; 95% CI, 0.9-1.0; $P = .002$) (Table VII). Logistic regression analysis was not performed for the subjective CMS because the SCB value was not determined to be adequately predictive according to the AUC.

The only factor significantly associated with failing to reach the PASS was workers' compensation status (OR, 0.3; 95% CI, 0.1-0.8; $P = .020$). Higher preoperative subjective CMS values were significantly associated with reaching the PASS (OR, 1.2; 95% CI, 1.1-1.4; $P = .003$) (Table VIII).

## Discussion

The results of this study establish MCID, PASS, and SCB values for patients who undergo isolated BT with respect to the SANE score, ASES score, and CMS. Using these threshold values, we found that workers' compensation insurance status, history of ipsilateral shoulder surgery, male sex, and higher preoperative scores were associated with failure to achieve clinically significant outcomes. These values can provide physicians with insight regarding the level of improvement in PROM scores that must be obtained to have significant improvements that are detectable and satisfactory to the patient.

Currently, data on isolated BT are sparse, as this procedure is usually performed and reported in combination with concomitant procedures such as RCR.[10,25,29,31,33,52] Recent reports from the American Board of Orthopaedic Surgery Part II database have shown that from 2002 to 2011, the incidence of BT has increased significantly, more so than that of biceps tenotomy.[6] However, only a limited number of previous studies have reported on isolated BT, concluding it to be an effective treatment for SLAP lesions, partial tears, tendinitis,

**Table VIII** Logistic regression of variables associated with achieving PASS for ASES, SANE, and Constant-Murley scores

| | Univariate regression (*P* value) | Multivariate regression (*P* value) | OR (95% CI) |
|---|---|---|---|
| ASES score | | | |
| WC | .001 | .990 | NA |
| Athlete | .002 | .412 | 1.9 (0.4-8.8) |
| Dominant | .147 | .835 | 0.9 (0.4-2.3) |
| BMI | .036 | .058 | 1.1 (1.0-1.2) |
| SANE score | | | |
| Preoperative SANE score | .022 | .090 | 1.0 (0.9-1.0) |
| WC | .051* | .020* | 0.3 (0.1-0.8)* |
| Diabetes | .017 | .991 | NA |
| Dominant | .049 | .478 | 1.4 (0.5-3.8) |
| Previous surgery | .175 | .255 | 0.6 (0.2-1.5) |
| SLAP lesion repair | <.001 | .991 | NA |
| Constant-Murley score | | | |
| Preoperative Constant-Murley score | <.001* | .003* | 1.2 (1.1-1.4)* |
| WC | .096 | .987 | 0.9 (0.3-3.6) |
| Athlete | .003 | .994 | NA |
| Dominant | .150 | .769 | 1.2 (0.3-4.8) |
| DCE | .161 | .998 | NA |
| SLAP lesion repair | .124 | .320 | 3.5 (0.3-41.4) |

*PASS*, patient acceptable symptomatic state; *ASES*, American Shoulder and Elbow Surgeons; *SANE*, Single Assessment Numerical Evaluation; *OR*, odds ratio; *CI*, confidence interval; *BMI*, body mass index; *SLAP*, superior labrum from anterior to posterior; *WC*, Workers Compensation; *DCE*, Distal Clavicle Excision; *NA*, not applicable.
* Clinically significant.

instability, and biceps reflection pulley lesions.[16,17,22,36,39,48,51] However, these studies did not report their findings in terms of clinical relevance, so the clinical value of this procedure is relatively unknown.[41] Our study corroborates the findings of these previous studies that isolated BT is an effective treatment for LHB pathology. In addition, a unique strength of our study is that we present percentages of patients who show no change (6.5%), a minimal change (32.5%), a substantial benefit (38.2%), or worsening (20.3%) after isolated BT, rather than reporting statistically significant changes from baseline that may not necessarily be clinically relevant.

Several recent publications have elucidated the MCID, SCB, or PASS for common shoulder procedures such as RCR,[18,26,46] instability repair,[34] or shoulder arthroplasty.[43,47,50] To our knowledge, this is the first study that has established thresholds for clinically significant improvement after BT in the absence of a major concomitant procedure. Kukkonen et al[26] found the MCID for the Constant score in patients receiving concomitant BT and RCR; however, this value is not applicable to patients who receive BT without RCR, as patients with full-thickness rotator cuff tears frequently have severe functional limitations whereas the typical manifestation in patients with biceps pathology is isolated anterior shoulder pain with minimal functional deficits.[13] In addition, the time frame for maximal medical improvement after RCR is 1 year,[53] which is a considerably longer recovery period than is expected for BT.[38] This is supported by the lack of significant changes in PROMs at 6 months and 1 year postoperatively in our study, as well as the results of the study by Hufeland et al[22] of patients undergoing isolated BT that found no significant improvement in outcomes past 3 months. McCormick et al[28] concluded that BT provides clinically significant outcomes for revision surgery after SLAP tear repair, but their methodology included using thresholds for clinical significance that were previously developed based on patients undergoing conservative management for general shoulder dysfunction. Because these threshold values are specific to a given treatment or pathology, it is invalid to extrapolate these values to a population dissimilar to the population on which their development was based.[11] The values that were determined in our study represent a spectrum of effect sizes that can be used to assess the clinical benefit of BT and ultimately provide better evidence supporting the treatment of LHB pathology. Currently, there is a paucity of evidence to support treatment recommendations for LHB pathology in patients not otherwise indicated for surgery.[12,13] By excluding patients with concomitant RCR, we were able to determine thresholds for clinical significance that focus on BT, which may be applied in future efforts to determine the value of this procedure.

The use of an integrated system for determination of MCID, such as that used in our study, has been strongly advocated previously.[14] However, when using such a system, discrepancies in MCID values may arise that cannot be easily explained. Previous studies that have used both anchor and distribution methods found that the MCIDs calculated using the distribution method were lower than those obtained by the anchor method.[26,34] An exception to this occurred in the study by Kukkonen et al,[26] in which the MCIDs obtained using receiver operating characteristic analysis were considerably lower than those obtained using other methods. This observed discrepancy was also appreciated in our study, which may be attributed to the low predictive power of these values as shown by their unacceptable AUCs.[4] An exception to this is the MCID for the SANE score that we calculated using the anchor method (3.5), which showed an acceptable AUC. This value serves as a more sensible cutoff for minimal improvement over the distribution-derived MCID (11.0), given the fact that the threshold for substantial benefit was 5.8. By eliminating thresholds that have unacceptable AUCs, we were able to optimize the predictive power of these models, thus limiting potential bias.

Previous studies evaluating outcomes after BT have found factors that are associated with anatomic failure of BT, but limited studies have found factors significantly associated with clinically inferior outcomes. The study by Park et al[35] found that patients who received BT with interference screw fixation were more likely to experience anatomic failure than those

with suture anchor fixation, but differences in outcome scores were not statistically significant between the groups. Millett et al[30] did not find either technique to produce significantly different outcomes, but they did find a trend toward more persistent pain in the suture anchor fixation group. Our study supports the conclusion that the mode of fixation does not affect outcomes, as neither interference screws nor suture anchors were significantly associated with not reaching clinically significant outcomes. In addition, a multitude of previous studies have shown that workers' compensation status has a deleterious effect on several orthopedic procedures, including RCR and shoulder arthroplasty.[1,2,8,15,21,45] Logistic regression in our study also showed that workers' compensation status is an independent risk factor for failing to achieve clinically significant outcomes after isolated BT.

We acknowledge several limitations to this study. The largest limitation is the relative heterogeneity of the study group, because the included patients received various combinations of concomitant procedures. However, a large amount of the BT literature involves patients who received an RCR, which is a procedure that involves a longer recovery period than BT.[53] We contend that BT is rarely performed in isolation and that it is frequently accompanied by concomitant procedures such as subacromial decompression, tissue débridement, and distal clavicle excision. Furthermore, we believe that among the concomitant procedures included in this study, BT represents the rate-limiting procedure in terms of recovery period.

The follow-up period was only 6 months, and only 36% of the 342-patient cohort was compliant. It was crucial to keep the follow-up time point at which PROMs were assessed consistent, as these questionnaires are time sensitive. To reduce heterogeneity in the amount of recovery time that each patient had, patients who were unable to be seen in the office or to answer the anchor questions by other means within 1 month of their 6-month mark were considered noncompliant. Follow-up of 6 months was chosen over 1 year because we believe that patients are at maximal medical improvement from isolated BT at 6 months; extending follow-up beyond this point introduces additional confounders that are not reflective of medical improvement, such as additional injuries and life events. Earlier time points have also previously been shown to be more useful for calculating the MCID using the anchor-based method, as later time points may have a lower number of patients in the no-change group, thus weakening the power of these calculations.[26] Moreover, baseline demographic characteristics and PROM scores were compared with the noncompliant patient population to ensure that our patient group was representative of the entire cohort. In addition, although we did analyze for several patient and surgical factors, there are other variables we did not account for that may potentially impact a patient's odds of reaching a clinically significant outcome, such as patient expectations or the indication for BT. A final limitation is that we included all patients who received an isolated BT, regardless of indication. This wide inclusion may have increased the relative heterogeneity of our data, but we accounted for this by using multivariate regression analysis, which did not show any differences among the diagnoses included.

## Conclusion

This study established values for the MCID, SCB, and PASS after BT without concomitant RCR. Workers' compensation status, previous shoulder surgery, male sex, and higher preoperative PROM scores are associated with lower odds of achieving clinically significant improvement after BT.

## Disclaimer

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