Preoperative Patient-Reported Outcomes Measurement Information System (PROMIS) scores predict postoperative outcome in total shoulder arthroplasty patients

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Background: The Patient-Reported Outcomes Measurement Information System (PROMIS) has recently been validated in orthopedic patients with upper-extremity disease. The purpose of this study was to describe preoperative and postoperative PROMIS scores in total shoulder arthroplasty (TSA) patients, compare PROMIS physical function (PF) scores with clinical functional measurements, and determine whether preoperative PROMIS scores could predict achievement of the minimal clinically important difference (MCID) postoperatively.

Methods: Preoperative and postoperative (>3 months) PROMIS scores in patients who underwent primary anatomic TSA were reviewed. Preoperative and postoperative shoulder forward flexion and external rotation were also collected. PROMIS PF, pain interference (PI), and depression scores were compared. Accuracy analyses determined whether preoperative PROMIS scores from each domain could predict postoperative achievement of the MCID in the same domain.

Results: The study included 62 patients. Significant improvements in PROMIS PF, PI, and depression scores, as well as forward flexion and external rotation, were found postoperatively ($P < .001$). The multivariate model demonstrated that preoperative PROMIS PF, PI, and depression scores were predictive of postoperative achievement of the MCID (area under the receiver operating characteristic curve, 0.70-0.87). Ninety percent cutoff scores showed that patients with a preoperative PF score lower than 31.7, PI score greater than 66.9, and depression score greater than 55.5 were more likely to achieve the MCID.

Conclusions: In TSA patients, preoperative PROMIS PF, depression, and PI scores demonstrated strong to excellent abilities to predict postoperative achievement of the MCID. PROMIS PF scores were responsive to the functional improvements observed clinically. The reported cutoff scores allow surgeons to identify patients with increased or decreased probabilities of achieving a clinically meaningful improvement after TSA.

There is a growing interest in measuring the success of orthopedic procedures through the use of patient-rated outcome measures (PROMs) as opposed to traditional clinician-based parameters. The Patient-Reported Outcomes Measurement Information System (PROMIS) is a high-throughput PROM that uses item response theory and computer adaptive testing to quickly capture patient responses electronically. PROMIS provides many advantages over legacy PROMs, including faster administration, a completely electronic platform, and automatic input of data into medical records and databases.[3,6,16,17] Many recent studies have shown PROMIS to be a valid patient-centered measurement tool for various orthopedic diseases, including shoulder pathology (glenohumeral arthritis, instability, rotator cuff tear).[1,2,4,6,21,23,24]

Total shoulder arthroplasty (TSA) has proved to be a very effective procedure in improving function and decreasing pain in patients with degenerative glenohumeral disease.[7,11,12] However, a subset of patients who have suboptimal outcomes remains.[10,14] Clinical factors such as sex, body mass index (BMI), and American Society of Anesthesiologists (ASA) score have been associated with outcomes after shoulder arthroplasty.[18,26-28] Identifying patients who are more likely to achieve poor outcomes early in the treatment phase is critical, as these patients can be given personalized treatment strategies to maximize their chances of achieving positive outcomes. PROMs provide a unique avenue to identify these at-risk patients. Wong et al[29] have recently shown that preoperative American Shoulder and Elbow Surgeons (ASES) pain and function scores, as well as Short Form Health Survey (SF-12) Mental Component Summary scores, were predictive of postoperative outcomes after shoulder arthroplasty. PROMIS has recently been validated in shoulder arthroplasty patients, and it is currently unknown whether preoperative PROMIS scores are predictive of postoperative outcomes in these patients.[8] PROMIS has the aforementioned advantages over the legacy PROMs (ASES and SF-12 scores), namely speed of administration, while also capturing function, pain, and mental health scores through 1 platform. Furthermore, PROMIS has shown the ability to predict postoperative outcomes in other orthopedic patient populations, such as foot and ankle patients.[15] Given this growing body of evidence, PROMIS has the potential to become a standard-of-care PROM throughout orthopedics, and its role in describing shoulder arthroplasty patients should be investigated.

The purpose of this study was to describe preoperative and postoperative PROMIS scores in patients who underwent anatomic TSA. The secondary purpose was to compare PROMIS physical function (PF) scores with clinical range-of-motion (ROM) findings. The final purpose was to determine whether preoperative PROMIS scores could predict achievement of the minimal clinically important difference (MCID) postoperatively. We hypothesized that all PROMIS domains would show the ability to predict postoperative outcomes and that PROMIS PF scores would show congruence with clinical ROM measurements.

Materials and methods

A review of PROMIS scores in patients who underwent primary TSA was performed based on protocols approved by our institution's Research Subjects Review Board before implementation. PROMIS scores were obtained from a prospectively collected database of shoulder and elbow clinic patients maintained at our institution. Patients who underwent TSA by 3 different fellowship-trained orthopedic surgery attending physicians between February 2015 and February 2017 were identified by Current Procedural Terminology code 23472. Two of the surgeons in this study used the Bigliani-Flatow Total Shoulder Arthroplasty System (Zimmer Biomet, Warsaw, IN, USA), whereas the third used the Global Shoulder Arthroplasty System (DePuy Synthes, Raynham, MA, USA). All patients underwent a similar postoperative physical therapy rehabilitation protocol, which included use of a sling for the first 4 weeks after surgery with a focus on passive ROM and active-assisted ROM for 3 weeks. Active ROM was initiated around 3 weeks postoperatively, progressive resistance exercises were added around 6 weeks postoperatively, and functional rehabilitation started around 8 weeks after surgery. A chart review of operative notes, clinic notes, and demographic data (age, sex, BMI, ASA score) of all identified patients was performed. ROM data (forward flexion [FF], external rotation [ER]) were collected in all patients. Patients were included if they underwent primary anatomic TSA and recording of PROMIS scores and ROM data from 2 time points: within 60 days before surgery and at a minimum of 3 months after surgery. Patients were excluded if they underwent a reverse total shoulder arthroplasty (RTSA) or if their procedure was a revision shoulder arthroplasty. No major complications after surgery were noted in this study population. PROMIS scores from within 60 days of the date of surgery were defined as the preoperative PROMIS scores. This time frame was selected to maximize the chance of capturing a patient's last preoperative visit before surgery. If a patient had more than 1 visit during this time frame, the scores from the date closest to surgery were used. PROMIS scores from 3 months or longer after the date of surgery were defined as the postoperative PROMIS scores. This time point was chosen to capture the early postoperative time frame when patients were pursuing a return to all functional activities, including age-appropriate sports (golf, tennis, swimming). Furthermore, in our practice, the 3-month postoperative visit signifies the earliest time frame in which a patient could potentially be instructed to follow up on an as-needed basis if he or she is recovering well after TSA. If a patient had more than 1 visit during

this time frame, the scores from the time point farthest from surgery were used. The 2 set of scores were compared to determine improvement in each PROMIS domain after operative intervention. Corresponding ROM data from both included visit dates were also compared.

Patients completed the PROMIS assessment on an iPad (Apple, Cupertino, CA, USA) during their clinic visits as standard of care. Clinic staff was available to provide technical support and to answer any questions during the completion process. Patients completed 3 PROMIS domains: PF, pain interference (PI), and depression. These domains have previously demonstrated concurrent validity with other legacy scales.[9,17,23] Custom software was used with the application program interface of the Assessment Center (www.assessmentcenter .net), which was run on the university servers behind the firewall, reducing data privacy concerns. Domains included PF (version 1.2), PI (version 1.1), and Depression (version 1.0). The PROMIS computer adaptive testing algorithm for each scale produced standardized T scores based on a normative US population. The mean score was 50, with a standard deviation of 10. Of note, higher PF scores indicated increased function, higher PI scores represented increased pain, and higher depression scores represented increased depression.

Statistics

To detect an improvement equivalent to the MCID (the value of 4 was used based on previous PROMIS MCID calculations) with a standard deviation of 8, it was determined that the study needed 50 patients with both preoperative and postoperative scores to achieve 80% power. All available data (N = 62) were used. Associations between preoperative and postoperative scores, as well as inter-domain associations, were quantified using the Pearson correlation coefficient. All PROMIS scores were assessed for discriminatory ability in predicting a postoperative improvement (of the same domain) that reached the threshold of the MCID, as defined by one-half of the standard deviation of the preoperative sample,[22,25,30] using receiver operating characteristic (ROC) curve analyses,[13] with overall accuracy summarized using the area under the ROC curve (AUC). The MCID was calculated as a postoperative increase in the PF score by 4.0, a postoperative decrease in the PI score by 3.2, and a postoperative decrease in the depression score by 4.3. Corresponding P values for testing the hypothesis that the AUC was 0.5 (no discriminatory ability) were also computed. AUC calculations were first performed with a univariate model using only presurgical scores in each PROMIS domain to predict postsurgical scores in that same domain. Next, a binary logistic regression multivariate model was used to predict the achievement of the MCID for each PROMIS

domain (PF, PI, and depression) while including presurgical patient age, sex, BMI, and ASA status, as well as PF, PI, and depression scores. By use of this model, AUC calculations were repeated to determine the ability of the model to predict corresponding postoperative scores. AUC values of 0.6-0.7 were defined as a moderate predictive model, values of 0.7-0.8 were defined as a strong predictive model, and values greater than 0.8 were defined as an excellent predictive model.[13] Finally, 90% specificity cutoff values for achieving and not achieving the MCID were calculated. All analyses used a significance level of 5%. SPSS software (IBM, Armonk, NY, USA) was used for all statistical analyses.

Results

Using Current Procedural Terminology code 23472, we identified 361 patients who underwent TSA. Of these patients, 62 met the inclusion criteria for the study. Of the excluded patients, 155 were excluded because they underwent RTSA surgery instead of an anatomic TSA procedure and 137 were excluded for having incomplete preoperative and/or postoperative PROMIS scores in the required time frames. We excluded 4 more patients because of lack of postoperative ROM data and 3 patients after their procedures were found to be revision shoulder arthroplasties.

The patients had a mean age of 67.6 years (standard deviation, 8.9 years). There were 34 male and 28 female patients. The mean preoperative date was 35 days (standard deviation, 17.6 days) before surgery. The mean postoperative date was 285 days (standard deviation, 201.9 days) after surgery.

Mean preoperative and postoperative PROMIS scores and the mean changes in the scores are presented in Table I. We found a significant increase in PROMIS PF scores (P = .001) and significant decreases in PROMIS PI scores (P < .001) and PROMIS depression scores (P < .001). Of the 62 patients, 28 (45%) met the MCID for PROMIS PF scores, 45 (73%) met the MCID for PROMIS PI scores, and 25 (40%) met the MCID for PROMIS depression scores. Preoperative and postoperative ROM data are presented in Table II. Patients showed significant improvements in FF and ER (both P < .001).

ROC analysis revealed that, using the univariate model, preoperative PROMIS PF, PI, and depression scores possessed a moderate ability to predict postoperative achievement of the MCID, with AUCs of 0.67, 0.69, and 0.67, respectively

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Table I PROMIS scores and cutoffs for TSA patients

PROMIS domain	PROMIS score, mean (SD)			90% MCID	90% no MCID
	Preoperative	Postoperative	Change in score*		
PF	40.4 (8.0)	44.1 (7.0)	+3.7 (6.1)	≤31.7	≥47.8
PI	61.2 (6.3)	52.6 (8.6)	−8.6 (8.0)	≥66.9	≤55.1
Depression	49.7 (8.6)	45.5 (8.8)	−4.2 (7.1)	≥55.5	≤41.0

PROMIS, Patient-Reported Outcomes Measurement Information System; *TSA*, total shoulder arthroplasty; *SD*, standard deviation; *MCID,* minimal clinically important difference*; PF*, physical function; *PI*, pain interference.
The "90% MCID" cutoff values represent T scores above or below which there is a 90% probability of achieving the MCID. The "90% no MCID" cutoff values represent T scores above or below which there is a 90% probability of failing to achieve the MCID.
 * Calculated by subtracting preoperative T score from postoperative T score.

Table II   Range-of-motion data for TSA patients

	Motion, mean (SD), °		
	Preoperative	Postoperative	Change*
FF	99 (24.2)	146 (24.5)	47 (30.1)
ER	26 (14.5)	54 (12.2)	28 (19.2)

TSA, total shoulder arthroplasty; *SD*, standard deviation; *FF*, forward flexion; *ER*, external rotation.
   * Calculated by subtracting preoperative measurement (FF or ER) from postoperative measurement (FF or ER).

Table III   Accuracy analysis of predictive abilities of preoperative PROMIS scores

PROMIS domain	Univariate analysis		Multivariate analysis	
	AUC	P value	AUC	P value
PF	0.67	<.001	0.70	.007
PI	0.69	<.001	0.87	<.001
Depression	0.67	<.001	0.71	.005

PROMIS, Patient-Reported Outcomes Measurement Information System; *AUC*, area under receiver operating characteristic curve; *PF*, physical function; *PI*, pain interference.
The multivariate analysis incorporated age; sex; body mass index; American Society of Anesthesiologists class; and PROMIS PF, PI, and depression scores.

(all $P < .001$). ROC analysis performed with the multivariate model including age, sex, BMI, and ASA class, as well as PF, PI, and depression scores, revealed that the model was a strong predictor of postoperative achievement of the MCID in both the PF and depression domains, with AUCs of 0.70 ($P = .007$) and 0.71 ($P = .005$), respectively. Furthermore, the multivariate model was an excellent predictor of postoperative achievement of the MCID in the PI domain, with an AUC of 0.87 ($P < .001$). The findings are summarized in Table III. Preoperative cutoff scores yielding a 90% chance of achieving the MCID ("90% MCID"), as well as scores yielding a 90% chance of failing to achieve the MCID ("90% no MCID"), for TSA are shown in Table I. As an example of how to use the calculated cutoff scores, for PROMIS PF, patients with a preoperative T score lower than 31.7 have a 90% probability of achieving the MCID postoperatively whereas patients with a preoperative T score greater than 47.8 have a 90% probability of not achieving the MCID. PROMIS T scores for all patients are plotted in Figures 1-3 along with MCID values and 90% cutoff scores.

Discussion

The objectives of this study were to describe perioperative PROMIS scores in patients who underwent shoulder arthroplasty, correlate PROMIS PF scores with clinical ROM findings, and determine whether preoperative PROMIS scores could predict postoperative outcomes. Preoperative and post-

operative PROMIS PF, PI, and depression scores are detailed in Table I, with significant improvements noted in all 3 domains after shoulder arthroplasty. PROMIS PF scores were responsive to patients' functional improvements seen in ROM data. At a mean follow-up time of 285 days, preoperative PROMIS PF, PI, and depression scores all showed strong abilities to predict postoperative achievement of the MCID.

To our knowledge, this is the first study to describe postoperative PROMIS scores after TSA. The patients in our study showed significant improvements in PROMIS PF (mean, +3.7), PI (mean, −8.6), and depression (mean, −4.2) scores. These subjective improvements in function, pain, and mental health status are consistent with prior studies that demonstrated similar improvements in all 3 domains using legacy PROMs.[5,19,20] Postoperative PROMIS PF scores showed that patients continued to have decreased PF (44.1) compared with the normalized US population, with 45% of patients meeting the PF MCID. These findings are likely attributable to the early follow-up period selected for this study. Furthermore, patients who undergo TSA are primarily more elderly and sedentary patients. A PROMIS PF score of 50 represents the normalized PF score of the US adult population, composed of individuals aged 18 years or older. Given differences in activity level depending on age, this normalized T score may not be representative of the elderly patient population. Therefore, it may be unrealistic to expect our older patient population to attain a PF score of 50 after TSA. Further investigations to determine baseline PROMIS PF scores for different age groups should be performed. Postoperative PROMIS PI scores showed that although PI declined dramatically, patients continued to have a slightly increased PI score (52.6) compared with the US population, with 73% of patients meeting the PI MCID. The large percentage of patients who achieved the PI MCID likely represents the fact that pain relief is one of the earliest areas of symptomatic improvement after TSA. Finally, postoperative PROMIS depression scores demonstrated that patients continued to have less mental health depression than the US population (the depression score improved from 49.7 to 45.5), with 40% of patients meeting the depression MCID. Prior studies in shoulder arthroplasty patients determined the achievement of the mental health MCID using legacy scales, such as the SF-12 Mental Component Summary, and found 25% attainment of the MCID. The greater number of patients who attained the mental health MCID in our study may signify that PROMIS depression is a more sensitive PROM to describe mental health status in TSA patients when compared with legacy scales.

Patients also demonstrated marked improvements in FF (from 99° to 146°) and ER (from 26° to 54°) after TSA. These findings are very similar to results reported in prior long-term follow-up studies.[19] For this study, these clinical measurements were used to determine whether PROMIS PF would show congruent findings when compared with clinical shoulder ROM data. Both PROMIS PF and ROM data exhibited significant improvements postoperatively. Therefore, PROMIS PF possesses the responsivity required to capture changes in shoulder function after TSA.
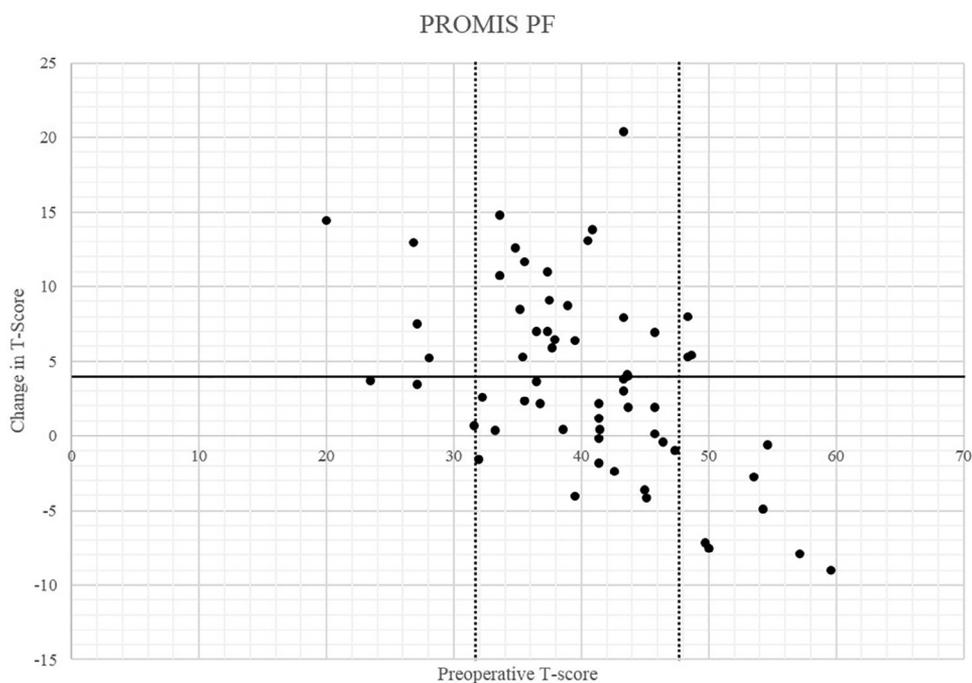
PROMIS PF

Figure 1   Preoperative Patient-Reported Outcomes Measurement Information System (*PROMIS*) physical function (*PF*) scores for all patients are plotted with the associated change in the T score (preoperative T score subtracted from postoperative T score). The minimal clinically important difference (MCID) was +4.0 (*horizontal solid line*). Data points above this line represent patients who achieved the MCID. Patients with a preoperative T score lower than 31.7 had a 90% chance of achieving the MCID; those with a score greater than 47.8 had a 90% chance of not achieving the MCID. These cutoff scores are illustrated as *vertical dotted lines*.
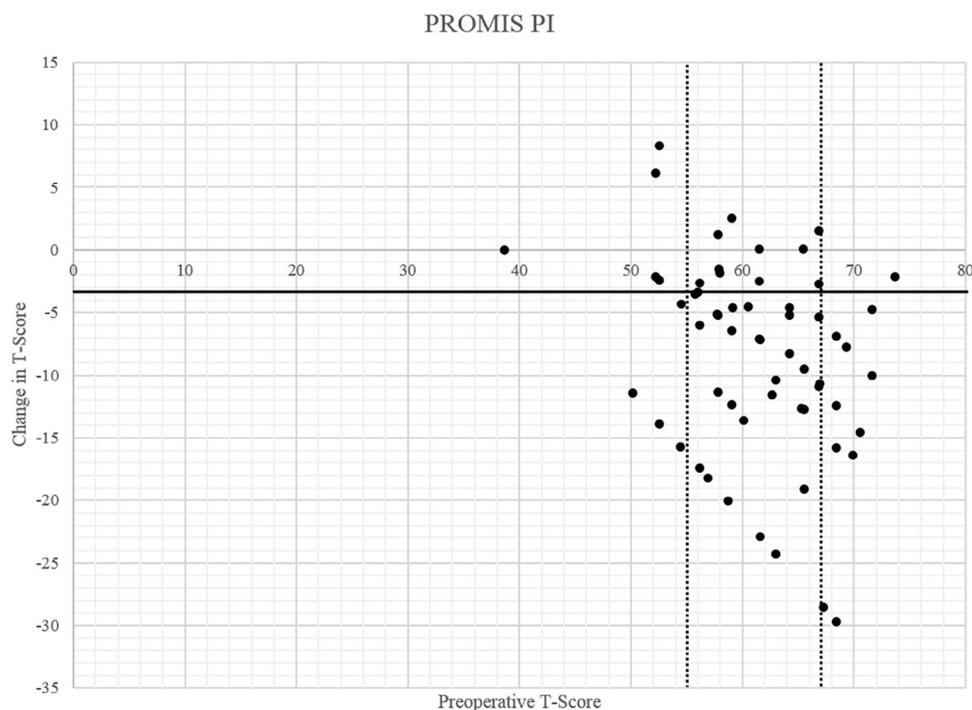
PROMIS PI

Figure 2   Preoperative Patient-Reported Outcomes Measurement Information System (*PROMIS*) pain interference (*PI*) scores for all patients are plotted with the associated change in the T score (preoperative T score subtracted from postoperative T score). The minimal clinically important difference (MCID) was −3.2 (*horizontal solid line*). Data points below this line represent patients who achieved the MCID. Patients with a preoperative T score greater than 66.9 had a 90% chance of achieving the MCID; those with a score lower than 55.1 had a 90% chance of not achieving the MCID. These cutoff scores are illustrated as *vertical dotted lines*.
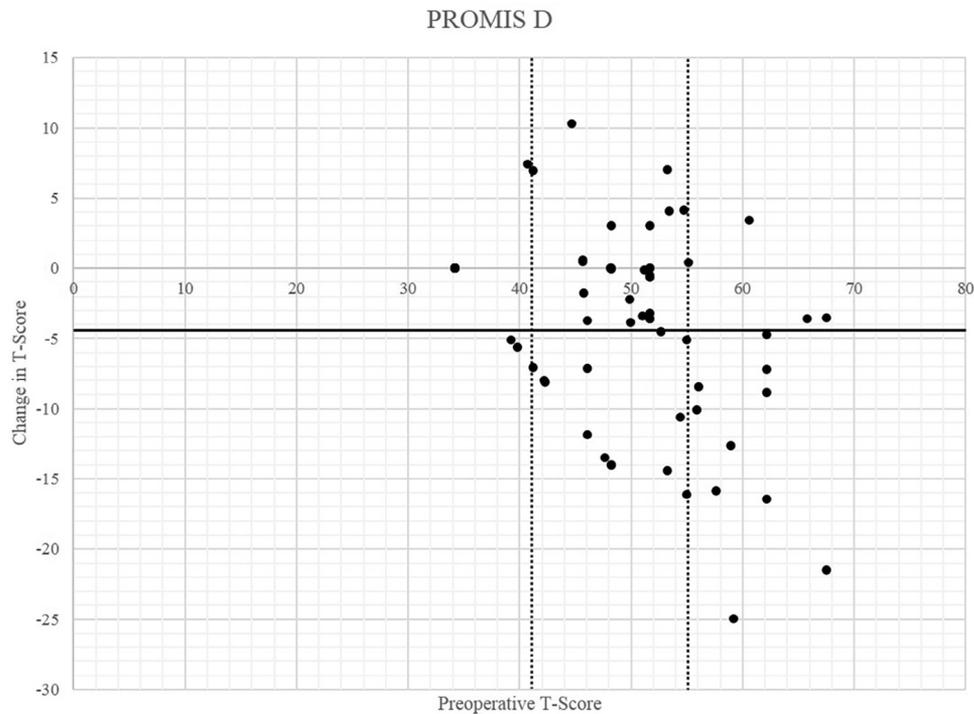
PROMIS D

Figure 3   Preoperative Patient-Reported Outcomes Measurement Information System (*PROMIS*) depression (*D*) scores for all patients are plotted with the associated change in the T score (preoperative T score subtracted from postoperative T score). The minimal clinically important difference (MCID) was −4.3 (*horizontal solid line*). Data points below this line represent patients who achieved the MCID. Patients with a preoperative T score greater than 55.5 had a 90% chance of achieving the MCID; those with a score lower than 41.0 had a 90% chance of not achieving the MCID. These cutoff scores are illustrated as *vertical dotted lines*.

The multivariate model demonstrated significant ability to predict which patients would achieve the MCID, with all PROMIS domains achieving AUCs of 0.70 or greater. The model showed the greatest predictive ability for PROMIS PI, with an AUC greater than 0.85. The ability of preoperative PROMIS scores to predict outcomes in TSA patients has not been previously described. Ho et al[15] investigated the predictive ability of preoperative PROMIS scores in the foot and ankle population, demonstrating that PROMIS PF and PI had predictive abilities, with AUCs of 0.73-0.83. Wong et al[29] investigated the predictive abilities of other PROMs (ASES pain and function scores, SF-12 mental and physical components) in the shoulder arthroplasty population. They found that preoperative scores on both the ASES questionnaire and SF-12 were able to predict postoperative outcomes, with AUCs of 0.79-0.90 and 0.74-0.85, respectively. It is important to note that the methodology of their study differed from that of our study, as they included all patients who underwent TSA or RTSA whereas we specifically included only anatomic TSA patients. Our study demonstrates that preoperative PROMIS PF, PI, and depression scores have a predictive power in the TSA patient population that matches the predictive ability of other legacy PROMs (ASES and SF-12 scores). Given the benefits of PROMIS compared with prior PROMs (speed of administration, all-electronic data capture), our findings provide further evidence that PROMIS can play a substantial role as a standard-of-care PROM in the shoulder patient population.

Using the 90% MCID cutoff values presented in Table I, surgeons are able to counsel patients on their likelihood of achieving satisfactory postoperative outcomes. For example, let us imagine a patient who presents to the office with severe pain and limited shoulder function in the setting of glenohumeral osteoarthritis with PROMIS scores of 35 for PF, 70 for PI, and 40 for depression. The patient inquires about his outcome after TSA surgery. On the basis of the data presented in Table I, a PF score of 35 falls between the 90% cutoff scores of 31.7 and 47.8. Therefore, it is difficult to predict whether the patient's PF will improve significantly after surgery. However, a PI score of 70 is greater than the 90% cutoff for achieving the MCID (66.9). Therefore, the patient has a very high likelihood of experiencing significant pain relief after surgery. Finally, a depression score of 40 falls below the 90% cutoff for failing to achieve the MCID (41.0). A depression score of 40 represents a patient with more positive mental health hygiene than the average patient, and the 90% cutoff value predicts that the patient is very unlikely to achieve a significant increase in this domain. Taken together, on the basis of the preoperative PROMIS scores, the patient has a high probability of achieving significant improvement in PI, an average chance of gaining significant improvements in PF, and a low probability of experiencing improvement in depression. For this patient, the preoperative discussion should emphasize that a TSA would provide him the greatest benefit in terms of pain relief and that he should not be expecting

any significant improvement in his mood after surgery. Given the patient's average chances of achieving significant improvements in PF, the patient could be offered a more extensive rehabilitation protocol postoperatively to maximize his functional gains. This example illustrates how preoperative PROMIS scores and our 90% cutoff values can be a powerful tool for surgeons to help predict postoperative outcomes after TSA. Our findings can assist clinicians with counseling patients in their decision-making process and provide patients with more accurate expectations after TSA surgery.

There are limitations to our study, including the retrospective nature of the investigation, potential selection bias, and early postoperative follow-up time frame. This study used a prospectively collected database to retrospectively review PROMIS scores in shoulder arthroplasty patients and therefore was limited by the factors inherent to retrospective studies. Next, selection bias was possible as patients were only included in this study if they returned to the clinic and continued to fill out PROMIS scores in the postoperative period. It is possible that patients who were doing well after surgery would be more inclined to miss follow-up appointments or opt out of filling out PROMIS questions. Therefore, our study may have selected patients who were doing worse postoperatively, as those patients would be more likely to return to the clinic and report their outcomes. Finally, this study focused on outcomes in the early postoperative period, as patients were included if they had the requisite data at a minimum of 3 months after surgery. As discussed previously, this time frame was chosen to capture the postoperative period when patients were beginning to pursue all functional activities after undergoing TSA. In our practice, if a patient is doing well after surgery, the 3-month postoperative visit can also represent the last scheduled clinic visit before we instruct the patient to follow up on an as-needed basis. Our mean follow-up time was 285 days, nearly 10 months after surgery. Furthermore, when the clinical ROM data from our study are compared with data from studies with longer follow-up times, the differences in FF and ER are minimal. Kiet et al[19] reported mean FF of 144° and ER of 53° at a 2-year follow-up time, and we reported FF of 145° and ER of 54°. Therefore, although our patient subset may show residual gains at longer follow-up times, it is likely that the time frame chosen for this study captures the large majority of the improvement expected in our patients after TSA. Ultimately, the findings of this study show that PROMIS is not only a strong descriptive PROM in the TSA population but also a predictive tool that can help guide surgeons to identify patients who are more or less likely to achieve positive outcomes after shoulder arthroplasty.

Conclusions

PROMIS has rapidly been adopted in multiple orthopedic clinical settings and has shown validity in the shoulder patient population, including in TSA patients. This study found that preoperative PROMIS PF, PI, and depression scores significantly improved in patients who underwent primary anatomic TSA. Furthermore, preoperative PROMIS PF, depression, and especially PI scores were strong predictors of postoperative outcomes after shoulder arthroplasty. The reported 90% PROMIS score cutoff values provide a valuable tool for surgeons to better counsel their patients on the expected outcomes after TSA surgery, furthering the patient-doctor relationship and maximizing patient satisfaction.

Disclaimer

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