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Preoperative PROMIS Physical Function Scores Predict Postoperative Outcomes Following Total Ankle Replacement

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Abstract

Background: Despite good evidence that supports significant improvements in pain and physical function following a total ankle replacement (TAR) for end-stage ankle arthritis, there is a subset of patients who do not significantly benefit from surgery. The purpose of this study was to perform a preliminary analysis to determine if preoperative Patient-Reported Outcome Measurement Information System (PROMIS) scores could be used to predict which patients were at risk of not meaningfully improving following a TAR.

Methods: Prospectively collected preoperative and $\geq$2-year postoperative PROMIS physical function, pain interference, pain intensity, and depression scores for 111 feet in 105 patients were included in the study. Significant postoperative improvement was defined using minimal clinically important differences (MCIDs). Logistic regression models and area under the curve (AUC) analyses were used to determine whether preoperative PROMIS scores were predictive of postoperative outcomes.

Results: Receiver operating characteristic curves found statistically significant AUCs for the PROMIS physical function (AUC = 0.728, $P = .004$), pain intensity (AUC = 0.720, $P = .018$), and depression (AUC = 0.761, $P < .001$) domains. The preoperative PROMIS pain interference domain did not achieve a statistically significant AUC.

Conclusion: Preoperative PROMIS physical function and pain intensity *t* scores may be used to predict postoperative improvement in patients following a fixed-bearing TAR; however, preoperative PROMIS pain interference scores were not good predictors. The results of this study may be used to guide research regarding patient-reported outcomes following TAR.

Level of Evidence: Level III, retrospective comparative series.

Keywords: ankle arthritis, total ankle replacement, patient-reported outcomes, PROMIS

Introduction

Patients with end-stage ankle arthritis are increasingly being treated with total ankle replacements (TARs).[20] Among foot and ankle disorders, end-stage ankle arthritis has been shown to be the most debilitating condition with patients preoperatively having the lowest physical function scores and most significant amount of pain.[14] There is good evidence that TARs result in significant improvement in pain and physical function at short-term, intermediate-term, and long-term follow-up; however, the results are not uniform and a small group of these patients does not achieve substantial gains following surgery.[4,7,8,10] Recent literature suggests that TAR patients have less pain relief and lower satisfaction rates for activities of daily living when compared to patients undergoing total hip or knee replacements.[21] Consequently, tools to preoperatively predict which patients are at risk of failure may help surgeons appropriately counsel patients. Factors such as ipsilateral hindfoot fusion, rheumatoid disease, poor

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mental health, and peripheral vascular disease have been associated with poor outcomes following TAR.[3,6,23,24]

Previous studies have demonstrated that patient-reported outcome measures (PROMs) may be useful in predicting who will achieve meaningful improvement after operative intervention for a variety of foot and ankle disorders.[2,11,18,25] PROMs may be employed preoperatively to evaluate the severity of patients' symptoms and counsel patients about the expected benefit of surgery. Recently, the Patient-Reported Outcome Measurement Information System (PROMIS) Physical Function Computerized Adaptive Test was endorsed by the American Orthopaedic Foot & Ankle Society (AOFAS) for the measurement of patient-reported outcomes.[16] The PROMIS pain interference and depression domains have also been used to study outcomes in foot and ankle surgery.[11,12,14,18] PROMIS is a symptom-specific and objective measurement of a patient's physical or mental health. Although not a substitute for clinical judgment, preoperative PROMIS thresholds may be helpful in appropriately setting patients' expectations prior to a TAR.

In addition to using PROMIS scores to predict who will benefit from a TAR, there is limited data proposing what amount of postoperative improvement on a PROMIS scale is clinically meaningful. Previously published minimal clinically important differences (MCIDs) in foot and ankle surgery have ranged from 3 to 30 points.[12] A recent study supported using disease-specific MCIDs in foot and ankle surgery and reported an MCID of 3.9 for the PROMIS physical function domain and an MCID of 4.65 for the PROMIS pain interference domain in patients with hallux valgus.[18] There is no literature describing MCIDs for PROMIS domains in patients with end-stage ankle arthritis.

The primary purpose of this study was to perform a preliminary analysis in a small sample of patients to determine if preoperative PROMIS physical function, pain interference, pain intensity, and depression *t* scores may be predictive of 2-year postoperative improvement as defined by a distribution-based MCID. We hypothesized that preoperative PROMIS physical function, pain interference, and pain intensity *t* scores would be useful in anticipating patients' 2-year postoperative improvement following a TAR. We believe that the results of this exploratory study may be used to guide future research in patient-reported outcomes after a TAR.

Materials and Methods

Inclusion and Exclusion Criteria

Patients were identified for this study using an institutional review board–approved Orthopaedic Foot and Ankle Registry following approval from the registry's steering committee. The registry includes prospectively collected data such as notes from patients' clinic visits and operations, imaging studies, patient-reported outcome measures, and demographic data. Patients were initially identified using *Current Procedural Terminology* codes for a TAR.

Patients were included in this study if they underwent a fixed-bearing TAR by 3 fellowship-trained foot and ankle orthopedic surgeons (J.T.D., C.A.D., S.J.E.) from a single academic institution for end-stage ankle arthritis between February 2016 and July 2018 and had preoperative and $\geq$2-year postoperative PROMIS physical function scores. Patients were excluded from this study if they had a history of infection prior to their primary TAR, if their primary surgery during the study period was a revision surgery, or if their 2-year postoperative PROMIS scores were within 3 months of a subsequent surgery on the ipsilateral foot. Because of restrictions immediately after surgery, it was felt that these patients may not be able to return to daily activities by 3 months postoperatively. Patients with complications and reoperations were included in the study if their 2-year postoperative PROMIS scores were obtained more than 3 months after the most recent surgery on their ipsilateral foot.

One hundred fifteen feet in 109 patients met the inclusion criteria. One patient was excluded because of a history of an ankle infection preoperatively. Three patients were excluded because they had surgery on the ipsilateral foot within 3 months of their 2-year PROMIS score follow-up. This left 111 feet in 105 patients who met all inclusion and exclusion criteria. The average follow-up was 24.5 months (range, 24-32.9 months). The mean age at the time of TAR was 64.8 years (range, 37.5-85.2 years). Table 1 demonstrates preoperative characteristics of the patient cohort.

Outcome Measures

Patient-reported outcome scores were available from the foot and ankle registry at the authors' institution. Scores are prospectively collected preoperatively and 1, 2, and 5 years after surgery. PROMIS physical function, pain interference, pain intensity, and depression were first administered in February 2016 at the authors' institution. The PROMIS scales incorporate computer adaptive testing, with each subsequent question being chosen depending on the patient's previous answer. This method has been shown to decrease response burden and avoid floor and ceiling effects.[13] Scores for each PROMIS domain are reported using a *t* score between 0 and 100 with 50 representing the mean of the US population. A difference of 10 points on a PROMIS scale is equal to 1 SD of the US population. Higher PROMIS *t* scores indicate that a patient reports a greater amount of that symptom or domain. For example, higher PROMIS physical function *t* scores demonstrate better physical function, but higher PROMIS pain interference, pain intensity, and depression demonstrate more severe pain or depression. The PROMIS pain intensity domain measures the severity of patient's pain, whereas the PROMIS pain interference domain measures the extent to which pain interferences with a patient's activities.

Table 1. Mean Age, Average Follow-up Time, Sex, and Etiology of Ankle Arthritis.

Characteristic	Mean (SD); Range or n (%)
Age, y, mean (SD); range	64.8 (8.7); 37.5-85.2
Follow-up time, mo, mean (SD); range	24.5 (0.1); 24.0-32.9
Sex, n (%)	
Females	44 (41.9)
Males	61 (58.1)
Etiology of end-stage ankle arthritis, n (%)	
Post-traumatic	57 (51.4)
Inflammatory arthritis	8 (7.2)
Adult-acquired flatfoot deformity	5 (4.5)
History of hindfoot arthrodesis	3 (2.7)
Cavovarus foot	2 (1.8)
Avascular necrosis of the talus	1 (0.9)
Idiopathic/not documented	35 (31.5)

Statistical Analysis

Patient characteristics are reported using the mean (SD) for continuous variables and count and percentage for categorical variables. Q-Q plots were evaluated to determine if the data approached the assumption of normality for each PROMIS scale. Because preoperative and postoperative PROMIS domains approached normal distributions on Q-Q plots, paired *t* tests were used to assess the change in PROMIS scores from preoperative to 2-year postoperative follow-up.

In order to determine meaningful change following a TAR, MCIDs were determined using a distribution-based method for each PROMIS domain, which has previously been shown to be a valid method of calculating the MCID.[18,19,25] The MCID was defined as one-half of the SD of the change in score from preoperatively to 2 years postoperatively.[18] To further validate our choice of MCIDs, MCIDs were calculated using one-half of the population SD estimate of 1000 bootstrapped resamples for the change in score from preoperatively to 2 years postoperatively. Because the MCIDs from the bootstrapped analysis were all within 0.1 of the estimates from the original sample, the MCIDs from the original sample were used in the analysis because this method has been used in previous studies.[5,18,19,25]

Logistic regression models controlling for age, gender, and body mass index (BMI) were then used to evaluate the predictive value of preoperative PROMIS scores in determining meaningful improvement after surgery based on the MCID. The area under the curve (AUC) was calculated in order to ascertain the ability of a PROMIS scale to differentiate between those patients who had meaningful improvement and met the MCID postoperatively and those who did not. An AUC closer to 1 suggested that the model had better accuracy using preoperative PROMIS scores in discriminating between patients meeting and not meeting the MCID. A logistic regression model with an AUC closer to 0.5 was no better than chance at predicting meaningful postoperative improvement. AUCs below 0.7 are considered not clinically significant, AUCs between 0.7 and 0.9 are considered to have moderate accuracy, AUCs greater than 0.9 are considered to have high accuracy.[9] An a priori sample size calculation was conducted using the "pROC" package in R (version 4.0.2; R Foundation for Statistical Computing, Vienna, Austria).[22] A previous study found that approximately 75% of patients with end-stage ankle arthritis achieved the MCID after either an ankle arthrodesis or TAR.[25] Therefore, assuming 75% of patients would achieve the MCID, a minimum AUC of 0.70, a significance level of 0.05, and a power of 0.80, a sample size calculation demonstrated that 80 patients would need to be included in the cohort for the study to be adequately powered.

For logistic regression models with statistically significant AUCs, 95% sensitivity and specificity thresholds were determined for patients who achieved the MCID. Likelihood ratios (LRs) were calculated for statistically significant AUCs in order to determine the implication of the 95% sensitivity and specificity thresholds. For the 95% sensitivity threshold, negative LRs were calculated so that the probability of a patient achieving meaningful improvement if they did not achieve the cutoff could be determined. In this case, we wanted to know that if the patient was too functional or had too little pain, what were the chances that the patient would still achieve the MCID? For the 95% specificity threshold, positive LRs were calculated so that the probability of a patient achieving meaningful improvement if they met the preoperative threshold could be quantified. Post-test probabilities were calculated for statistically significant LRs. Fisher exact tests were used because of low expected numbers to compare if patients with complications and reoperations were more likely to fail to meet the MCID compared to patients without complications or reoperations. Statistical significance was defined as *P* values of .05 or less. All statistical analyses were performed in SPSS, version 22.0 (IBM Corp, Armonk, NY).

Results

PROMIS Scores

The mean preoperative, 2-year positive, and change in PROMIS physical function, pain interference, pain intensity, and depression scores for patients undergoing a TAR are shown in Table 2. All PROMIS domains had statistically significant improvement (all *P* values < .001) (Table 2).

The MCID for the PROMIS physical function domain was 3.8, and 85.6% of patients in this cohort achieved the MCID at 2 years postoperatively. The MCIDs for the PROMIS pain interference and pain intensity subscales were 5.0 and 4.8 with 81.8% and 89.5% of patients, respectively,

Table 2. Mean Preoperative, Postoperative, and Change (SDs) in PROMIS Domains.

PROMIS Domain	Preoperative Mean (SD)	Postoperative Mean (SD)	Mean Preoperative to Postoperative Change (SD)	*P* Value[a] (Change)
Physical function	37.5 (5.5)	47.1 (6.2)	9.5 (7.5)	<.001
Pain interference	63.6 (5.7)	49.0 (9.2)	−14.5 (10.1)	<.001
Pain intensity	54.3 (6.2)	38.1 (7.8)	−16.2 (9.6)	<.001
Depression	48.7 (8.2)	45.5 (8.3)	−3.4 (7.5)	<.001

Abbreviation: PROMIS, Patient-Reported Outcome Measurement Information System.
[a]*P* values were obtained using Wilcoxon signed-rank tests.

achieving the MCID at 2 years postoperatively. Finally, the PROMIS depression subscale had an MCID of 3.8, but only 37.4% of patients achieved this MCID at 2 years postoperatively.

Logistic Regression Analyses

The results for the logistic regression analysis models for the PROMIS physical function, pain interference, pain intensity, and depression domains can be found in Table 3. The PROMIS physical function subscale demonstrated moderate accuracy and a statistically significant AUC (0.728, 95% confidence interval [CI] 0.578-0.878, $P = .004$). For the PROMIS physical function domain, a preoperative *t* score of 36.2 was identified as the 95% sensitivity threshold. The negative LR was 0.168 (95% CI 0.055-0.517), and the posttest probability of achieving meaningful improvement but having a preoperative PROMIS physical function *t* score greater than 36.2 was 50.0%. A preoperative *t* score of 26.4 was identified as the 95% specificity threshold, and the positive LR was 4.550 (95% CI 0.664-31.153), but was not statistically significant.

The logistic regression model for the PROMIS pain intensity domain also demonstrated moderate accuracy and a statistically significant AUC (0.720, 95% CI 0.547-0.892, $P = .018$). For the PROMIS pain intensity domain, a preoperative *t* score of 47.1 was identified as the 95% sensitivity threshold. The negative LR was 0.248 (95% CI 0.067-0.926). A preoperative *t* score of 63.5 was identified as the 95% specificity threshold, and the posttest probability of achieving meaningful improvement but having a preoperative PROMIS pain intensity *t* score less than 47.1 was 67.9%. The positive LR was 2.380 (95% CI 0.342-16.594), but was not statistically significant. The logistic regression model for the PROMIS pain interference domain resulted in an AUC of 0.629 ($P = .071$), which was not statistically significant. Therefore, 95% sensitivity and specificity thresholds could not be determined.

The logistic regression model for the PROMIS depression domain yielded a moderately accurate and statistically significant AUC of 0.761 (95% CI 0.667-0.855, $P < .001$). A preoperative PROMIS depression *t* score of 43.3 was identified as the 95% sensitivity threshold. The negative LR was 0.162 (95% CI 0.041-0.649), and the posttest probability of achieving the MCID with a preoperative PROMIS depression *t* score less than 43.3 was 8.8%. A preoperative PROMIS depression *t* score of 56.4 was found to be the threshold for the 95% specificity, and the positive LR was 5.840 (95% CI 2.023-16.848), which resulted in a posttest probability of achieving meaningful improvement but having a preoperative PROMIS depression *t* score greater than 56.4 was 77.7%.

Complications

There was a total of 6 complications and 6 reoperations in 11 patients in this cohort. The 6 complications included 2 patients who had revision TARs, 1 patient who required an irrigation and debridement with polyethylene liner exchange, and 2 patients had open reduction and internal fixation (ORIF) of postoperative periprosthetic fractures including an ORIF of a distal tibia fracture and an ORIF of a medial malleolus fracture. There were 6 reoperations in the cohort. Five patients required additional reconstructive procedures on the ipsilateral foot including a medializing calcaneal osteotomy and medial cuneiform osteotomy in 1 patient, subtalar arthrodeses in 2 additional patients, lateralizing calcaneal osteotomy in 1 patient, and a subsequent tibia and fibula osteotomy in 1 patient. One patient underwent irrigation and debridement 1 month after surgery and then required an ipsilateral subtalar fusion 1 year after his index TAR, and he was classified as having both a complication and reoperation.

Two of the 11 patients did not have meaningful clinical improvement in the PROMIS physical function domain 2 years after their TAR. Both patients underwent subsequent subtalar arthrodeses. Compared with patients without complications or reoperations, patients with complications or reoperations were not more likely to fail to meet the MCID for any of the PROMIS domains (all $P > .650$).

Discussion

Patient-reported outcome measures, especially PROMIS scores, are increasingly being used to preoperatively guide operative decision making and gauge postoperative success in foot and ankle surgery.[2,11,12,18] We performed a preliminary analysis in a small sample of patients, and our study suggests that preoperative PROMIS *t* scores may be

Table 3. Results From the Logistic Regression Models Including Area Under Curve (AUC), 95% Sensitivity and Specificity Thresholds, Negative and Positive Likelihood Ratios, and Posttest Probabilities for the PROMIS Physical Function, Pain Interference, Pain Intensity, and Depression Domains.[a]

PROMIS Domain	AUC (*P* Value)	Preoperative *t* Score 95% Sensitivity Threshold	95% Sensitivity LR− (95% CI)	95% Sensitivity Posttest Probability	Preoperative *t* Score 95% Specificity Threshold	95% Specificity LR+ (95% CI)	95% Specificity Posttest Probability
Physical function	0.728 (.004)	36.2	0.168 (0.055-0.517)	50.0%	26.4	4.550 (0.664-31.153)	–
Pain interference	0.629 (.071)	–	–	–	–	–	–
Pain intensity	0.720 (.018)	47.1	0.248 (0.067-0.926)	67.9%	63.5	2.380 (0.342-16.594)	–
Depression	0.761 (<.001)	43.3	0.162 (0.041-0.649)	8.8%	56.4	5.840 (2.023-16.848)	77.7%

Abbreviation: PROMIS, Patient-Reported Outcome Measurement Information System.
[a]For the PROMIS pain interference domain, no thresholds could be calculated because the AUC was not statistically significant. For the PROMIS physical function and pain intensity domains, the 95% specificity posttest probability could not be calculated because the positive likelihood ratios were not statistically significant.

predictive of which patients will meet the MCID postoperatively. From the logistic regression models, we were able to produce preliminary thresholds; however, these thresholds need further validation in larger sample sizes with a greater number of surgeons from multiple institutions before being employed clinically. These thresholds may be used to guide future studies using PROMIS scores to investigate clinical outcomes after a TAR.

Our study suggests that preoperative PROMIS physical function scores (AUC = 0.728, $P = .004$) and preoperative PROMIS pain intensity scores (AUC = 0.720, $P = .018$) were predictive of which patients would achieve meaningful clinical improvement following a TAR. However, in our data set, preoperative PROMIS pain interference scores (AUC = 0.629, $P = .071$) were not a good discriminator of who will and will not meet the MCID.

However, we did find meaningful change, based on the calculated MCIDs for each subscale, in the PROMIS physical function, pain interference, and pain intensity domains at 2 years postoperatively. Average change in these PROMIS domains was between 9.5 and 16.2 points, which represents a preoperative to postoperative change in PROMIS scores of between 1 and 1.5 SDs on the PROMIS scale and is higher than has been reported for other foot and ankle disorders.[2,11] Reoperations and complications did not seem to affect the overall success of a TAR.

Recently, several studies have found that preoperative PROMs are predictive of postoperative improvement in foot and ankle surgery.[11,18,25] Waly et al[25] retrospectively identified 427 patients with end-stage ankle arthritis who underwent either an ankle arthrodesis or TAR and had preoperative and ≥5-year postoperative PROMs including the Ankle Osteoarthritis Scale, Ankle Arthritis Score, and physical and mental components of the 36-Item Short Form Health Survey (SF-36). Using receiver operating characteristic curve analyses, they found that preoperative PROMs were predictive of postoperative outcomes and stated that patients with the worst preoperative baseline scores had the largest improvements in function and pain relief.[25] Despite their significance, the AUCs for these curves were low and all less than 0.7 except for the mental component of the SF-36, which had an AUC of 0.897, and they did not include any PROMIS computer adaptive tests (CATs) outcomes in their study.[25] A previous study that included 232 foot and ankle patients and 49 patients with ankle arthritis demonstrated that the PROMIS CATs performed better than legacy scales such as the SF-12 and Foot and Ankle Outcome Score (FAOS).[17] We found that patients with lower preoperative PROMIS physical function scores (ie, those who had worse preoperative physical function) were more likely to achieve meaningful improvement. Patients who had a preoperative PROMIS physical function *t* score above 36.2 were only 50% likely to achieve meaningful clinical improvement at 2 years following a TAR. For the entire cohort, 85.6% of patients met the MCID for the PROMIS physical function domain.

Another study using preoperative and ≥7-month postoperative PROMIS scores in patients undergoing a variety of elective foot and ankle surgeries also demonstrated that preoperative PROMIS physical function (AUC = 0.83), pain interference (AUC = 0.73), and depression (AUC = 0.74) scores were predictive of postoperative outcomes.[11] No patients with ankle arthritis were included in their cohort. They demonstrated that patients with a preoperative PROMIS physical function score less than 29.7 had an 83% chance of achieving the MCID after surgery, whereas patients with a preoperative PROMIS physical function score of greater than 42.0 had a 94% chance of failing to attain meaningful postoperative improvement.[11] A subsequent study by Anderson et al[2] endorsed similar preoperative PROMIS physical function thresholds of 28.0 with a 95% specificity for achieving the MCID and 41.6 with a 95% specificity for not achieving the MCID. However, the authors noted that a receiver operating characteristic curve analysis found that preoperative PROMIS pain interference (AUC = 0.57, $P = .33$) was a not good predictor of achieving MCID in their cohort.[2] This study included 5 patients with ankle arthritis, and none of these patients were treated with a TAR.

More recently, studies have looked at determining preoperative PROMIS thresholds for specific foot and ankle diseases.[18] In a study of 42 patients with hallux valgus and an average follow-up of 18.3 weeks after a chevron bunionectomy or first tarsometatarsal arthrodesis, MacDonald et al[18] identified a preoperative PROMIS physical function *t* score threshold of greater than 49.6 with 95% sensitivity. The negative likelihood ratio was 0.14 (95% CI 0.02-0.94), and the posttest probability of failing to achieve meaningful clinical improvement if a patient's preoperative PROMIS physical function *t* score was greater than 49.6 was 94.1%.[18] Similar to Anderson et al[2] and the results from our study, the authors found that the PROMIS pain interference domain was not a useful predictor of postoperative outcomes following bunionectomy.[18]

Our results suggest that preoperative PROMIS physical function and pain intensity scores may be useful to preoperatively counsel patients indicated for a TAR. Potentially, thresholds could be developed to help surgeons better counsel patients. For example, in our study, the 95% sensitivity *t* score threshold for the preoperative PROMIS physical function domain was 36.2 with a negative likelihood ratio of 0.168 (95% CI 0.055-0.517). However, the results of our study are investigational and should not be a substitute for clinical judgment when indicating patients for a TAR as many patients, including those who have high preoperative PROMIS physical function scores, may achieve meaningful improvement in other domains. Additional studies will be needed to validate these results.

Interestingly, when comparing PROMIS physical function thresholds for patients undergoing a bunionectomy[18] and TAR, the higher threshold (ie, the patients who are most physically functional preoperative and may still meet the MCID) is seen in the bunionectomy group. This may suggest that patients who are indicated for more complex procedures such as a TAR require more severe symptoms to benefit from surgery than those patients who undergo a bunionectomy. Therefore, disease-specific PROMIS thresholds are likely more helpful to counsel patients than more general PROMIS thresholds across all foot and ankle pathologies.

The PROMIS pain interference domain was not found to have a statistically significant AUC and, therefore, may not be a good preoperative predictor of who will benefit from a TAR at 2 years postoperatively. This finding is similar to those reported by MacDonald et al[18] in hallux valgus patients undergoing bunionectomy and Anderson et al[2] in a cohort composed of patients with a variety of foot and ankle disorders. Neither study could identify an association between preoperative PROMIS pain interference score and postoperative improvement. This may suggest that preoperative interference is not a good measure for predicting patients who will meaningfully benefit from surgery in these domains.

Our study used preoperative and 2-year postoperative PROMIS physical function, pain interference, pain intensity, and depression to define MCIDs. The MCIDs for the PROMIS physical function, pain interference, pain intensity, and depression domains were 3.8, 5.0, 4.8, and 3.8, respectively. These MCIDs represent a change of between one-quarter and one-half of the SD of the US population for each subscale and are consistent with previously reported values.[12,18] In a study of more than 1500 foot and ankle patients, Hung et al[12] used a distributed-based method to calculate the MCID for the PROMIS physical function and pain interference domains using one-third and one-half the SD of the change in PROMIS scores from preoperatively to postoperatively. They calculated the MCID to be between 3.0 and 4.5 for the PROMIS physical function domain and between 2.9 and 4.3 for the PROMIS pain interference domain.[12] Another study with a cohort of 61 patients with a variety of foot and ankle diagnoses reported an MCID of 4.2 for the PROMIS physical function domain, an MCID of 3.7 for the PROMIS pain interference domain, and an MCID of 5.3 for the PROMIS depression domain.[11] A follow-up study in a different foot and ankle patient population estimated an MCID of 5.8 for the PROMIS physical function domain.[2] However, a single MCID for all foot and ankle conditions likely does not exist. A systematic review looking at MCIDs in health-related quality of life after total hip and knee replacement concluded that different MCIDs exist for hip and knee osteoarthritis.[15] Recently, MacDonald et al[18] reported MCIDs of 3.9 and 4.65 for the PROMIS physical function and pain interference domains, respectively, in a cohort of patients with hallux valgus. In the present study, using a distribution-based method, we found that the MCID for the PROMIS physical function domain was 3.8 and for the pain interference domain was 5.0. For the PROMIS physical function domain, this was within the range reported by Hung et al[12] and very similar to the MCID found by

MacDonald et al.[18] For the PROMIS pain interference domain, however, this was considerably higher than that reported by Hung et al[12] and MacDonald et al.[18] We hypothesize that this might be due to higher variability in improvement in the PROMIS pain interference domain in patients who undergo a TAR, with some patients experiencing very substantial pain relief. For example, the maximum change in the PROMIS pain interference score in our study was –33.1, which is more than 3 SDs of pain relief. This may account for the higher MCID calculated for the PROMIS pain interference domain than what has been cited in other studies.

There are several substantial limitations of this study. First, this study included only patients with preoperative and >2-year postoperative PROMIS scores from a single institution. This may have introduced selection bias into the cohort. Additionally, 2-year follow-up may not be sufficient for obtaining maximal improvement after a TAR; however, a recent study suggested that maximal medical improvement following a TAR was at 1-year follow-up.[1] A larger sample size may have led to statistically significant AUCS for the PROMIS pain interference and pain intensity domains. Previous studies using similar analyses have used smaller sample sizes with less than one-hundred patients and have found statistically significant AUCs.[2,11,18] Additionally, because of the small number of complications and reoperations in the cohort, our study was likely underpowered to detect a difference in the proportion of patients who met the MCID in the complications and reoperations group compared with the larger cohort. It may be that these complications occurred early in the patients' treatment courses so that many of them were still able to have meaningful improvement by 2 years postoperatively. We also chose to use a distribution-based method rather than an anchor-based method to calculate the MCID. Anchor-based methods account for the patient's perspective of postoperative improvement by asking them if they notice significant improvement in their symptoms or physical function. Previous PROMIS physical function and pain interference MCIDs in foot and ankle surgery using an anchor-based method range from 13.2 to 22.8.[12] Future studies should confirm the MCIDs reported in this study for the end-stage ankle arthritis population. Further research may include larger sample sizes from multiple institutions stratified by demographic data, operative procedures, or preoperative deformity.

Conclusion

At 2 years postoperatively, patients who undergo a fixed-bearing TAR have meaningful improvement in the PROMIS physical function, pain interference, and pain intensity domains by an average of 1 to 1.5 SDs on the PROMIS scale compared with their baseline scores. In our data set, preoperative PROMIS physical function, pain intensity, and depression scores were predictive of postoperative improvement in patients indicated for a fixed-bearing TAR. The results of this study may be used to guide research regarding patient-reported outcomes following TAR.

Ethics Approval

Ethical approval for this study was provided by the Hospital for Special Surgery Foot & Ankle Steering Committee, as it met the criteria of a retrospective study.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. ICMJE forms for all authors are available online.

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