## Research Article

Preoperative Patient-Reported Outcomes Measurement Information System Global Health Scores Predict Patients Achieving the Minimal Clinically Important Difference in the Early Postoperative Time Period After Total Knee Arthroplasty

Brian Darrith, MD Lafi S. Khalil, MD Sreten Franovic, MS Michael Bazydlo, MS Robb M. Weir, MD Trevor R. Banka, MD Jason J. Davis, MD

From the Department of Orthopaedics, Henry Ford Hospital, Detroit, Ml.

Correspondence to Dr. Davis: Jdavis7@hfhs.org

None of the following authors or any immediate family member has received anything of value from or has stock or stock options held in a commercial company or institution related directly or indirectly to the subject of this article: Darrith, Khalil, Franovic, Bazydlo, Weir, Banka, and Davis.

J Am Acad Orthop Surg 2021;00:1-10

DOI: 10.5435/JAAOS-D-20-01288

Copyright 2021 by the American Academy of Orthopaedic Surgeons.

#### ABSTRACT

**Introduction:** The patient-specific factors influencing postoperative improvement after total knee arthroplasty (TKA) are important considerations for the surgeon and patient. The primary purpose of this study was to determine which patient demographic factors influence the postoperative Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health (GH) scores. In addition, we aimed to compare the prognostic utility of preoperative PROMIS-GH scores and the Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS-JR) in predicting postoperative improvement.

**Methods:** This retrospective cohort study of a consecutive series of patients who underwent primary, unilateral TKA analyzed prospectively collected KOOS-JR and PROMIS-GH surveys. PROMIS-GH includes physical health (PH) and mental health scores. Patient demographic and presurgical characteristics were evaluated for prognostic capability in predicting postoperative improvement in the PROMIS scores and achievement of the minimal clinically important difference (MCID). Receiver operating characteristic curves were used to understand the prognostic thresholds of the preoperative PROMIS score and KOOS-JR for predicting MCID achievement.

**Results:** A total of 872 patients were included. Although unadjusted analyses showed associations between patient demographic factors and PROMIS-PH scores, multivariable regression analysis for predictors of MCID achievement demonstrated that PROMIS-PH was the only significant preoperative variable. Receiver operating characteristic analysis revealed that the area under the curve of

20wnloaded from http://journals.lww.com/jaaos by BhDMf5ePHKav1zEourn101N4a+.kLIhEZgbsHo4XMt0hCywCX1AWnYOp/IIQrHD3l3D00dRy/i7TvSFI4Cl3VC4/OAVpDDa8KKGKV0Ymy+78= on 08/30/2021

PROMIS-PH (0.70; 95% CI, 0.67 to 0.74) was less than that of the KOOS-JR (0.77; 95% CI, 0.73 to 0.81; P = 0.032). Sensitivity and specificity for achieving the MCID were maximized for preoperative PROMIS-PH scores of  $\leq$  38 (59% and 70%) and for preoperative KOOS-JR  $\leq$  51 (71% and 69%).

**Conclusions:** Preoperative KOOS-JR and PROMIS-PH scores predict clinically meaningful improvement after TKA. The KOOS-JR has greater prognostic utility in the early postoperative period.

Level of Evidence: Level III, Prognostic Study

otal knee arthroplasty (TKA) is a commonly performed orthopaedic procedure aimed to improve pain and function in appropriately selected patients. Although it is generally considered a successful intervention, the rate of unsatisfied patients after TKA has been noted to range from 5% to 40%.<sup>1</sup> Several studies have aimed to identify patients in whom TKA may produce unsatisfactory outcomes and a lower value of care.<sup>2-4</sup> The identification of preoperative prognostic factors for patients undergoing TKA has been conducted in various studies reporting heterogenous outcomes,<sup>5</sup> and certain patient demographic and comorbidity factors portend higher risks of surgical complication, readmission, or postoperative dissatisfaction.<sup>1,2,6</sup> The evaluation of these factors aids in the patient-centered discussion and management of expectations leading up to surgery.<sup>7</sup> In addition, patient-reported outcome measures (PROMs) allow the orthopaedic surgeon to gain insight into the patient's perception of the disease process. The potential interactions between patient demographic and comorbidity factors and preoperative PROM scores in predicting postoperative outcomes are a topic of recent interest.8

A difficulty in interpreting the PROMs in the literature is the heterogeneity in the various measures reported for specific diseases or anatomic locations, which inhibits the generalizability of outcomes.9 The Knee Injury and Osteoarthritis Outcome Score (KOOS) is a validated and responsive metric of knee pain and function as perceived by the patient,<sup>10</sup> and the KOOS for Joint Replacement (KOOS-JR) is a validated short form tailored to patients undergoing arthroplasty.11 Unlike KOOS, which is specific to the anatomic location of the knee, recent literature has evaluated the effect of knee surgery on patients' global health (GH) using the Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function outcome metrics.<sup>12,13</sup> PROMIS is a wellvalidated metric and has demonstrated responsiveness after knee surgery, similar to disease-specific measures.<sup>14-16</sup> In patients undergoing TKA specifically, PROMIS-Physical Health (PH) has recently been shown to demonstrate excellent responsiveness compared with

KOOS-JR at 1-year follow-up, which indicates that GH instruments may capture improvements attributed to disease-specific interventions.<sup>15</sup>

The incorporation of standardized preoperative PROMIS assessments during the presurgical discussion with patients has the potential to facilitate more realistic patient expectations regarding their postoperative course. The patient-specific demographic and preoperative factors influencing postoperative improvements in PROMIS-GH scales after TKA have yet to be elucidated. We hypothesize that patient-specific demographic and preoperative factors will not significantly influence postoperative changes in PROMIS-GH scales on the basis that these universal scales inherently account for contributing medical and social factors. In addition, preoperative PROMIS-GH scales are hypothesized to have prognostic utility in predicting meaningful postoperative improvement after TKA.

#### **Methods**

Approval through our institutional review board was obtained before this retrospective review of patient data that had been previously collected for routine clinical purposes. Patients undergoing primary unilateral TKA by one of three fellowship-trained arthroplasty surgeons (R.W., T.B., and J.D.), between December 2017 and April 2019, were included for analysis in this study. All patients underwent TKA at a suburban teaching hospital that is part of an academic tertiary referral center within a metropolitan health system. Patients who underwent staged bilateral TKAs without completion of the appropriate outcome measures between surgeries were excluded, as were revision knee arthroplasties. KOOS-JR and PROMIS-GH short forms were collected in clinic preoperatively and at 1-, 3-, 6-month, and 1-year follow-up visits. All PROMs were prospectively collected as part of the adult reconstruction division's protocol for perioperative PROM collection for all patients undergoing TKA. Both PROMIS and KOOS surveys were administered on a tablet computer (iPad; Apple) through Research Electronic Data Capture (REDCap; Vanderbilt

Table 1. Fatient De		
Variable	Values	Observations (n)
Age (yr) <sup>a</sup>	$67.5\pm9.2$	872
Height (in) <sup>a</sup>	66.0 ± 4.2	872
Weight (oz) <sup>a</sup>	3,259.2 ± 716.0	872
BMI (kg/m2) <sup>a</sup>	$32.7\pm6.2$	872
Hemoglobin (g/dL) <sup>a</sup>	13.5 ± 1.4	693
Albumin (g/dL) <sup>a</sup>	4.1 ± 0.3	407
Cholesterol (mg/dL) <sup>a</sup>	180.2 ± 42.9	191
Triglyceride (mg/dL) <sup>b</sup>	106.0 (74.8- 147.0)	188
Calcium (mg/dL) <sup>a</sup>	$9.5\pm0.5$	692
Creatinine (mg/dL) <sup>b</sup>	0.8 (0.7-1.0)	696
EBL (mL) <sup>b</sup>	100.0 (50.0- 150.0)	871
Hemoglobin A1c <sup>b</sup>	6.1 (5.8-6.6)	329
History of heart disease <sup>c</sup>	64 (7%)	871
History of liver disease <sup>c</sup>	24 (3%)	871
History of diabetes <sup>c</sup>	179 (21%)	871
History of hypertension <sup>c</sup>	542 (62%)	871
Current smoker <sup>c</sup>	13 (1%)	871
Anticoagulants <sup>c</sup>	22 (3%)	871

 Table 1. Patient Demographics and Clinical History

BMI, body mass index; EBL, estimated blood loss

<sup>a</sup>Values are expressed as mean  $\pm$  SD.

<sup>b</sup>Values are expressed as median (25th, 75th percentile).

<sup>c</sup>Values are expressed as count (%).

University), a secure and web-based application designed for data capture and storage. The PROMIS-GH is a 10question short form, which is separated into two domains for further analysis: PROMIS-PH and PROMIS-Mental Health components, of four questions each. The remaining two questions of the PROMIS-GH short form contains two general health questions not included in the aforementioned domains. For an example, forms may be viewed at www.healthmeasures.net/score-and-interpret/ calculate-scores. Exclusion criteria were as follows: patients undergoing secondary surgery before the first follow-up visit, patients undergoing revision surgery, or patients who were unable to adequately communicate in English. Patient demographics, comorbidities, and perioperative data such as age, body mass index, history of illnesses, laboratory values, and other intraoperative measures were collected through chart review of electronic medical records. All available laboratory data were

Table 2.	Associations Between Preoperative
PROMIS-P	H Score and Baseline Characteristics

Variable	Beta (95% CI)	Р
Age (5 yr)	0.18 (-0.02 to 0.38)	0.081
BMI (5 units)	−0.65 (−0.93 to −0.36)	<0.001
Hemoglobin	0.55 (0.30 to 0.80)	<0.001
Calcium	-0.14 (-0.81 to 0.54)	0.691
Creatinine	0.10 (-0.62 to 0.82)	0.785
History of heart disease	-1.47 (-2.68 to -0.26)	0.017
History of diabetes	-0.87 (-1.70 to -0.05)	0.037
History of hypertension	-0.65 (-1.39 to 0.09)	0.084

BMI, body mass index; PROMIS-PH, Patient-Reported Outcomes Measurement Information System Physical Health

included, but some patients did not have all preoperative laboratory values (Table 1).

The included KOOS-JR and PROMIS-GH PROMs were collected routinely by the adult reconstruction surgeons using REDCap software. However, the orthopaedic department implemented a new universal protocol for standardizing PROMIS short form collection across all orthopaedic subspecialties during the study period for this investigation, and this resulted in the cessation of PROMIS-GH collection. Therefore, patients in this study are limited to analysis of up to 12-month follow-up, as dictated by the available PROMIS-GH forms collected.

All statistical analyses were carried out by a trained biostatistician, using R (R Foundation for Statistical Computing). Alpha was set at 0.05 for all analyses, with a beta of 0.20. Minimal clinically important differences (MCIDs) were calculated for the KOOS-JR and PROMIS-PH using the distribution-based method (MCID = half the standard deviation of the change in outcome scores from preoperative to postoperative). Receiver operating characteristic (ROC) curves were used to compare the prognostic accuracy of preoperative PROMIS-PH score and KOOS-JR for predicting MCID achievement postoperatively and to establish threshold values for these preoperative scores. Multivariable ROC models were created to consider the influence of patient demographics such as age and body mass index. Regression analyses were conducted to identify associations between PROMIS-PH scores and patient baseline characteristics. Given the strong colinearity between PROMIS-PH scores and KOOS-JR, only

	1 Mont	1 Month		IS	6 Month	าร	1 Ye	ar
Variable	Beta (95% CI)	Р	Beta (95% CI)	Р	Beta (95% CI)	Р	Beta (95% Cl)	Р
Age (5-yr increments)	0.18 (-0.01 to 0.37)	0.067	0.17 (-0.26 to 0.61)	0.441	0.15 (-0.34 to 0.65)	0.551	-0.25 (-0.99 to 0.49)	0.508
BMI (5-unit increments)	-0.63 (-0.92 to -0.35)	<0.001	-0.72 (-1.31 to -0.13)	0.019	-0.90 (-1.63 to -0.17)	0.017	0.26 (-0.83 to 1.35)	0.642
Hemoglobin	0.44 (0.17 to 0.72)	0.001	-0.06 (-0.77 to 0.66)	0.874	0.28 (-0.37 to 0.93)	0.402	0.43 (-0.59 to 1.46)	0.413
Calcium	0.50 (-0.27 to 1.27)	0.206	-0.34 (-1.86 to 1.18)	0.665	-0.11 (-2.06 to 1.83)	0.908	-0.30 (-3.20 to 2.59)	0.840
Creatinine	-0.90 (-1.65 to -0.16)	0.018	0.86 (-2.70 to 4.42)	0.636	-4.34 (-9.04 to 0.36)	0.073	-1.44 (-4.04 to 1.17)	0.287
EBL (25 mL increment)	-0.02 (-0.15 to 0.11)	0.753	-0.37 (-0.74 to 0.01)	0.056	-0.17 (-0.59 to 0.25)	0.433	0.46 (-0.07 to 0.99)	0.096
History of heart disease	-1.73 (-3.05 to -0.42)	0.010	-1.01 (-3.94 to 1.93)	0.502	-0.54 (-4.20 to 3.13)	0.775	-3.99 (-8.23 to 0.25)	0.071
History of diabetes	-2.42 (-3.29 to -1.55)	<0.001	0.36 (-1.45 to 2.18)	0.694	-3.03 (-5.74 to -0.32)	0.030	-0.01 (-3.06 to 3.05)	0.997
History of hypertension	-0.76 (-1.47 to -0.04)	0.038	-0.79 (-2.37 to 0.79)	0.330	-0.05 (-1.91 to 1.81)	0.957	-1.11 (-3.68 to 1.45)	0.398
Surgery duration (30- min increment)	-0.17 (-0.59 to 0.26)	0.448	-0.70 (-1.76 to 0.37)	0.201	-1.21 (-2.39 to -0.03)	0.047	0.81 (-1.25 to 2.88)	0.444
Preoperative PROMIS-PH	0.48 (0.41 to 0.55)	<0.001	0.32 (0.15 to 0.48)	<0.001	0.55 (0.36 to 0.75)	<0.001	0.50 (0.26 to 0.74)	<0.001

	Table 3.	Associations Between Posto	perative PROMIS-PH S	Score and Baseline Ch	naracteristics–Bivariate Analysis	s
--	----------	----------------------------	----------------------	-----------------------	-----------------------------------	---

BMI, body mass index; EBL, estimated blood loss; PROMIS-PH, Patient-Reported Outcomes Measurement Information System Physical Health

one could be included in the multivariate analysis, and the PROMIS-PH was chosen as the main outcome of this study. The two general health questions present in the PROMIS-GH short form, which are components of neither PROMIS-PH nor PROMIS-Mental Health domains, were independently integrated into ROC analysis as well. For the bivariate analyses of preoperative laboratory values, patients whose pertinent laboratory value was missing were not included in that specific bivariate analysis.

#### Results

During the study period, 968 PROMIS-GH and KOOR-JR short forms were collected via REDCaps, which were

retrospectively reviewed. A total of 71 of these surveys were excluded because of subsequent bilateral surgeries or revision surgeries, 22 were excluded because of missing preoperative outcome scores, and three were excluded because of missing patient demographic information in the medical record. Final data analysis included 872 patients who underwent primary unilateral TKA procedures performed by one of three primary surgeons at the main institution during the study period. The average age was 67.5 years, and one-third were male (Table 1).

A number of demographic factors, patient comorbidities, and laboratory variables were significantly associated with both preoperative and postoperative PROMIS-PH scores on bivariate analyses (Tables 2 and 3). However, a multivariable regression analysis was

	1 Month (n =	517)	3 Months (n =	127)	6 Months (n =	103)	1 Year (n =	43)
Variable	Beta (95% CI)	P	Beta (95% CI)	P	Beta (95% CI)	P	Beta (95% CI)	P
Age (5 yr)	-0.06 (-0.28 to 0.15)	0.570	-0.15 (-0.70 to 0.41)	0.736	0.07 (-0.48 to 0.63)	0.894	-0.69 (-1.79 to 0.40)	0.724
BMI (5 units)	-0.10 (-0.41 to 0.20)	0.570	-0.43 (-1.18 to 0.32)	0.675	-0.10 (-0.99 to 0.79)	0.894	-0.11 (-1.51 to 1.28)	0.972
Hemoglobin	0.08 (-0.18 to 0.34)	0.570	-0.17 (-0.93 to 0.58)	0.736	0.04 (-0.62 to 0.70)	0.899	0.02 (-1.16 to 1.20)	0.972
Calcium	0.21 (-0.51 to 0.93)	0.570	-0.29 (-1.82 to 1.24)	0.736	-0.23 (-2.12 to 1.65)	0.894	0.17 (-2.82 to 3.16)	0.972
Creatinine	-0.67 (-1.35 to 0.01)	0.178	0.65 (-3.10 to 4.40)	0.736	-4.39 (-8.74 to -0.05)	0.323	-0.39 (-3.55 to 2.76)	0.972
History of heart disease	-0.75 (-1.98 to 0.47)	0.537	-1.00 (-4.70 to 2.70)	0.736	2.62 (-1.22 to 6.45)	0.528	-0.15 (-6.02 to 5.71)	0.972
History of diabetes	-1.16 (-2.03 to -0.29)	0.060	1.02 (-1.01 to 3.04)	0.709	-0.89 (-3.79 to 2.01)	0.796	2.97 (-0.95 to 6.90)	0.644
History of hypertension	0.45 (-0.31 to 1.21)	0.537	-0.37 (-2.36 to 1.63)	0.736	0.70 (-1.31 to 2.71)	0.796	0.53 (-2.95 to 4.00)	0.972
Estimated blood loss (25 mL increments)	0.15 (0.00 to 0.30)	0.178	-0.40 (-0.99 to 0.19)	0.613	-0.29 (-0.79 to 0.21)	0.528	0.62 (-0.06 to 1.31)	0.555
Surgery duration (30-min increments)	-0.26 (-0.77 to 0.26)	0.570	-0.49 (-1.71 to 0.73)	0.736	-0.87 (-2.21 to 0.47)	0.528	-0.80 (-3.57 to 1.97)	0.972
Preoperative PROMIS-PH	0.47 (0.39 to 0.54)	<0.001	0.18 (-0.03 to 0.40)	0.433	0.64 (0.40 to 0.87)	<0.001	0.65 (0.28 to 1.01)	0.020

Table 4	<ul> <li>Associations Between</li> </ul>	Postoperative PROMIS-PH	I Score and Baseline	Characteristics-Adjusted Analysis
---------	--	-------------------------	----------------------	-----------------------------------

BMI, body mass index; PROMIS-PH, Patient-Reported Outcomes Measurement Information System Physical Health.

performed on all of the associations showing significance when considered in isolation, and it demonstrated that they were not significantly associated with postoperative PROMIS-PH scores when considered in conjunction with the other baseline characteristics (Table 4). However, the preoperative PROMIS-PH score was found to be significantly associated with postoperative PROMIS-PH scores at 1, 6, and 12 months postoperatively on multivariable regression analysis (Table 4). Likewise, no patient demographic variables were significant in predicting a change in the PROMIS-PH score (Table 5). Moreover, the preoperative PROMIS-PH score was the only significant predictor of achievement of the MCID at each time point postoperatively (Table 6).

Using the distribution-based method, the MCID was calculated for the PROMIS-PH as a change of 2.3 and for the KOOS-JR as a change of 6.8, respectively. Of the 872 patients included, 473 achieved the PROMIS-PH MCID,

514 achieved the KOOS-JR MCID, and 383 patients achieved both MCIDs during at least one time point of the included postoperative follow-up period. ROC analyses revealed prognostic cutoffs for achieving the MCID for the preoperative PROMIS-PH (Figure 1) and preoperative KOOS-JR (Figure 2). The area under the curve (AUC) for the PROMIS-PH was lower than that of the AUC for the KOOS-JR, 0.70 (95% CI, 0.67 to 0.74) versus 0.77 (95% CI, 0.73 to 0.81; P = 0.032). Patients presenting with preoperative PROMIS-PH scores of  $\leq$  38 had an increased likelihood ratio (LR) of achieving the MCID (positive LR 2.0; sensitivity, 59%; specificity, 70%). Decreasing the cutoff to < 37increases the positive LR to 3.0 (sensitivity, 39%; specificity, 87%). However, increasing the cutoff to 43 yields high sensitivity (93%) and a low negative LR (0.28) but reduces specificity (25%). For preoperative KOOS-JR, a cutoff of  $\leq 51$  maximized sensitivity (71%) and specificity (69%) for a positive LR 2.3 and negative LR 0.42.

	1 Month (n = 518)		3 Months (n = 128)		6 Months (n = 103)		1 Year (n = 43)	
Variable	Beta (95% CI)	Р						
Age (5 yr)	−0.11 (−0.35 to 0.13)	0.378	-0.10 (-0.74 to 0.53)	0.746	-0.11 (-0.35 to 0.13)	0.378	-0.10 (-0.74 to 0.53)	0.746
BMI (5 units)	0.32 (-0.02 to 0.66)	0.069	0.08 (-0.78 to 0.95)	0.850	0.32 (-0.02 to 0.66)	0.069	0.08 (-0.78 to 0.95)	0.850
Hemoglobin	-0.18 (-0.48 to 0.11)	0.217	-0.80 (-1.72 to 0.11)	0.087	-0.18 (-0.48 to 0.11)	0.217	-0.80 (-1.72 to 0.11)	0.087
Creatinine	-0.68 (-1.45 to 0.10)	0.087	-1.00 (-5.58 to 3.57)	0.668	-0.68 (-1.45 to 0.10)	0.087	-1.00 (-5.58 to 3.57)	0.668
History of heart disease	0.27 (-1.14 to 1.68)	0.710	0.35 (-4.11 to 4.80)	0.879	0.27 (-1.14 to 1.68)	0.710	0.35 (-4.11 to 4.80)	0.879
History of diabetes	-0.43 (-1.42 to 0.56)	0.394	0.80 (-1.65 to 3.25)	0.521	-0.43 (-1.42 to 0.56)	0.394	0.80 (-1.65 to 3.25)	0.521

BMI, body mass index; PROMIS-PH, Patient-Reported Outcomes Information System Physical Health

Adjusting the predictive model to also incorporate the preoperative PROMIS-Mental Health along with preoperative the PROMIS-PH increased the AUC for achieving the postoperative PROMIS-PH MCID to 0.72 (95% CI, 0.68 to 0.76). Adjusting the model to incorporate additional demographic data (age and body mass index) and patient-specific data (the two additional general health questions from the PROMIS-GH short form) to the preoperative PROMIS-PH score or KOOS-JR resulted in marginal improvement of the predictive models for the PROMIS-PH achieving the MCID, AUC = 0.74 (95% CI, 0.70 to 0.78) and 0.79 (95% CI, 0.75 to 0.82), respectively (*P* = 0.100).

#### **Discussion**

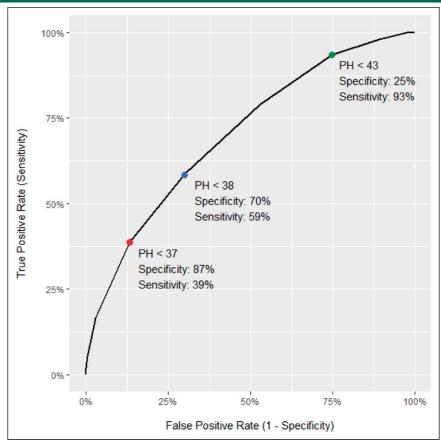
This study sought to investigate whether patient-specific demographic or preoperative characteristics influence postoperative changes or improvements in outcome scores and whether preoperative outcomes scores predict which patients may demonstrate clinically significant

	1 Month (n =	518)	3 Months (n =	= 128)	6 Months (n =	: 103)	1 Year (n :	= 43)
Variable	RR (95% CI)	Р	RR (95% CI)	Р	RR (95% CI)	Р	RR (95% CI)	Р
Age (5 yr)	1.00 (0.93- 1.08)	0.885	0.97 (0.86- 1.10)	0.378	1.00 (0.87- 1.16)	0.959	0.90 (0.69- 1.16)	0.082
BMI (5 units)	1.00 (0.91- 1.11)	0.938	1.01 (0.84- 1.21)	0.864	0.99 (0.79- 1.25)	0.917	1.07 (0.78- 1.47)	0.447
Hemoglobin	0.98 (0.90- 1.07)	0.408	1.04 (0.86- 1.26)	0.409	1.00 (0.85- 1.19)	0.971	0.99 (0.72- 1.36)	0.928
Creatinine	0.93 (0.73- 1.18)	0.325	0.81 (0.31- 2.12)	0.451	0.73 (0.23- 2.32)	0.356	1.08 (0.49- 2.42)	0.666
History of heart disease	0.81 (0.52- 1.25)	0.120	1.09 (0.45- 2.59)	0.776	1.06 (0.44- 2.58)	0.778	1.06 (0.24- 4.68)	0.859
History of diabetes	0.90 (0.67- 1.21)	0.255	0.87 (0.52- 1.45)	0.346	0.74 (0.33- 1.67)	0.260	0.78 (0.28- 2.16)	0.344
Preoperative PROMIS- PH	0.93 (0.90- 0.95)	<0.01	0.95 (0.90- 1.00)	<0.01	0.96 (0.90- 1.02)	0.022	0.93 (0.84- 1.02)	0.006

Table 6. Associations Between PROMIS-PH MCID Achievement and Baseline Characteristics

BMI, body mass index; MCID, minimal clinically important difference; PROMIS-PH, Patient-Reported Outcomes Measurement Information System Physical Health; RR, relative risk

### Figure 1



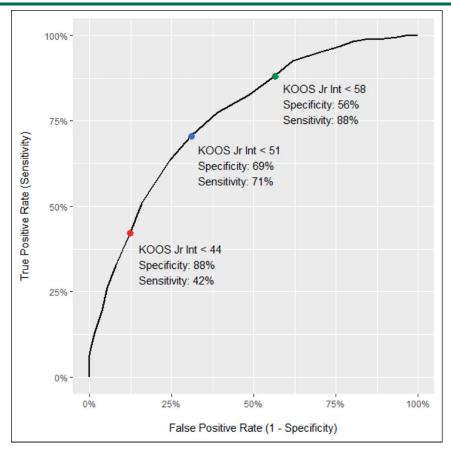
ROC curve for preoperative PROMIS-PH scores in predicting the MCID. The following receiver operating characteristic curves show the tradeoffs between sensitivity and specificity for various cut points of preoperative PROMIS-PH scores used to predict the likelihood of achieving the MCID after surgery. The blue point on the curves represents the cutoff that maximizes both sensitivity and specificity. The red points show the cutoff whose specificity value is closest to 90%, and the green point shows the cutoff whose sensitivity is closest to 90%. The area under the curve is 0.70. MCID, minimal clinically important difference; PROMIS-PH, Patient-Reported Outcomes Measurement Information System Physical Health

improvements postoperatively. The main findings demonstrate that with respect to PROMIS-GH outcome scales, patient-specific factors have no significant influence on the outcome scores reported by patients after undergoing TKA. More importantly, however, preoperative PROMs demonstrated prognostic utility in predicting which patients achieve clinically significant improvements after TKA.

The findings are in agreement with the basis of PROMIS-GH scales, inherently reflecting the universal—medical, functional, and psychosocial—well-being of the patient, as reported by the patient. Therefore, when analyzing patient factors in isolation, the present investigation found that patient demographics such as body mass index and comorbidities, such as diabetes and heart disease, were shown to affect postoperative outcome measures. However, when all preoperative variables were considered within one multivariate analysis, the preoperative PROMIS-PH score was the sole significant predictor of attainment of clinically significant improvement at all postoperative time points. Although the PROMIS-PH scale demonstrated capability in accounting for the influence of patient demographics and comorbidities, this investigation found that the KOOS-JR was even more predictive of postoperative improvement than the PROMIS-PH score. Previous studies have demonstrated the efficacy of both outcome metrics in detecting clinically significant improvement.<sup>15</sup> In addition, the prognostic utility of preoperative KOOS-JR has been demonstrated previously<sup>8</sup>; thus, the current study focuses on evaluating the prognostic capability of PROMIS-PH.

A utility of PROMIS scores is the quantification of patients' self-perceived function and pain that is normalized to the general cohort, with a mean set at 50 and a standard deviation of 10. However, the role of

#### Figure 2



ROC curve for preoperative KOOS interval scores in predicting the MCID. The following receiver operating characteristic curves show the tradeoffs between sensitivity and specificity for various cut points of preoperative PROMIS-PH scores used to predict the likelihood of achieving the MCID after surgery. The blue point on the curves represents the cutoff that maximizes both sensitivity and specificity. The red points show the cutoff whose specificity value is closest to 90%, and the green point shows the cutoff whose sensitivity is closest to 90%. The area under the curve is 0.77. KOOS, Knee Injury and Osteoarthritis Outcome Score; MCID, minimal clinically important difference; PROMIS-PH, Patient-Reported Outcomes Measurement Information System Physical Health

preoperative PROMIS scales in the shared decisionmaking process of deciding to undertake surgical intervention has not been established. Patients with preoperative PROMIS scales that are above average or top-quartile may represent those who have less to gain from surgery because their functional improvements may be marginal. The consideration of this association may influence the shared decision-making process, similarly to other patient-specific prognostic or risk factors. Sensible preoperative expectations must be discussed as they hold strong predictive value for utilization and outcomes after TKA.<sup>7</sup>

Several authors have discussed the use of PROMs in predicting postoperative outcomes after TKA,<sup>17-19</sup> total hip arthroplasty,<sup>17,20</sup> and a number of other orthopaedic procedures.<sup>21-23</sup> PROMs can be categorized broadly as either disease-specific or general metrics; the latter is universally applicable regardless of anatomic location or disease in question, whereas the former is specific to a certain diagnosis, procedure, or body part.<sup>15,17,24</sup> The results of the current study affirm previous work by Berliner et al,17 who found that preoperative scores from the 42-item KOOS predict achievement of MCID with a nearly identical AUC (0.76) as that of KOOS-JR in the current study (0.77). Their study also examined the SF-12 version 2 general health metric and found it to be significantly inferior to the KOOS in terms of AUC (0.65) and prognostic capability for MCID attainment,<sup>17</sup> and the current study supports the finding that a disease-specific metric has more prognostic utility than a general health PROM like the PROMIS-PH. The AUC of the PROMIS-PH is slightly higher than the previously reported SF-12 version 2 AUC (0.65), but without a direct comparison within the same patient cohort, it is impossible to draw conclusions about the superiority of one general health metric over another. The previous study sought to establish one threshold value for predicting MCID achievement and therefore reported the one value that maximized sensitivity and specificity, but in clinical practice, it is also important to know the thresholds that identify patients in the margins who are most likely or least likely to benefit from surgery. Although it is useful to divide continuous data points into distinct groups, it is important to remember that the prognostic inferences may be similar for two patients with preoperative PROM scores on either side of a given threshold.

This study expands on previous work by Fontana et al<sup>8</sup> using machine learning to identify predictors of achieving the MCID after hip and knee arthroplasty. Their study found that the preoperative KOOS-JR was the most important predictor (AUC = 0.69) for clinically significant improvement in knee function as assessed by the postoperative KOOS-JR, and the addition of all available patient-specific variables resulted in a significant but modest increase in the predictive power of their algorithm (AUC = 0.75).<sup>8</sup> Although they had a large sample of over 6,000 patients with knee arthroplasty, their patient cohort was much more heterogenous than the current one because they included primary and revision procedures as well as bilateral arthroplasties, and these cases were performed over a 6-year period.<sup>8</sup> The current cohort includes only primary, unilateral TKA, and this more homogenous sample likely accounts for the higher predictive ability of the preoperative KOOS-JR in the current results. Interestingly, in the findings by Fontana et al, the preoperative PROM with the highest AUC (0.88) was the mental health component of the SF-36. The current results and those of Berliner et al,<sup>17</sup> respectively, did not find the mental health components of the PROMIS-Mental Health or SF-12 version 2 general health measures to be independently predictive of postoperative achievement of MCID. However, both of these studies suggest that consideration of mental health scores can enhance the predictive ability of PH and disease-specific PROMs, and Berliner et al<sup>17</sup> specifically state that higher mental health scores resulted in higher preoperative thresholds for the studied PROMs. Given the importance of patient expectations and appropriate preoperative counseling,<sup>25,26</sup> surgeons should consider the results of mental health PROMs to effectively address patient expectations.

This study has several limitations. First, it is a retrospective cohort study from a single institution, which does enhance the internal validity but may limit the generalizability of the data. Second, a nonsurgical cohort

Brian Darrith. MD. et al

with the relevant PROMs to compare with the results of the current patients who elected to proceed with TKA does not exist. Although this study discusses patients who do or do not obtain meaningful clinical improvement after TKA, the ability to extrapolate guidelines for the decision to proceed with surgery is limited by the lack of a matched nonsurgical control group. Third, the data available are limited to the immediate postoperative period and lack sufficient power to draw conclusions regarding later postoperative periods. Follow-up periods exceeding 12 months could not be collected given the cessation of PROMIS-GH short forms and the implementation of new collection methods at the main institution. Unfortunately, validated methods for converting between the PROMIS-GH metrics used in this study and the alternate PROMIS short forms subsequently collected by the main institution are lacking. However, the postoperative improvement in PROMs is reported to occur within the initial 6 months of surgery<sup>27</sup>; therefore, longer follow-up may not change the significance of the current results. Finally, direct comparison with the literature is limited because of the differences in PROMs collected. To our knowledge, no previous studies report MCIDs for the PROMIS general health metric; therefore, external validation of the current results is warranted.

#### Conclusions

Although preoperative scores of both the KOOS-JR and PROMIS-PH measures predict clinically meaningful improvement after TKA, the KOOS-JR has greater prognostic utility in the early postoperative period. Further study is needed for external validation of these findings and to better understand the role of preoperative PROMs in patient counseling regarding appropriate postoperative expectations.

#### References

References printed in **bold type** are those published within the past 5 years.

1. Sakellariou VI, Poultsides LA, Ma Y, Bae J, Liu S, Sculco TP: Risk assessment for chronic pain and patient satisfaction after total knee arthroplasty. *Orthopedics* 2016;39:55-62.

2. Boraiah S, Joo L, Inneh IA, et al: Management of modifiable risk factors prior to primary hip and knee arthroplasty: A readmission risk assessment tool. *J Bone Joint Surg Am* 2015;97:1921-1928.

3. Kim KY, Anoushiravani AA, Chen KK, et al: Perioperative orthopedic surgical home: Optimizing total joint arthroplasty candidates and preventing readmission. *J Arthroplasty* 2019;34: S91-S96.

#### **PROMIS Scores Predict Improvement After TKA**

4. Kurtz SM, Lau EC, Ong KL, Adler EM, Kolisek FR, Manley MT: Which clinical and patient factors influence the national economic burden of hospital readmissions after total joint arthroplasty? *Clin Orthop Relat Res* 2017;475:2926-2937.

5. Harmelink KEM, Zeegers A, Hullegie W, Hoogeboom TJ, Nijhuisvan der Sanden MWG, Staal JB: Are there prognostic factors for oneyear outcome after total knee arthroplasty? A systematic review. *J Arthroplasty* 2017;32:3840-3853.e3841.

6. Abdel MP, Bonadurer GF III, Jennings MT, Hanssen AD: Increased aseptic tibial failures in patients with a BMI >35 and well-aligned total knee arthroplasties. *J Arthroplasty* 2015;30:2181-2184.

7. Riddle DL, Golladay GJ, Hayes A, Ghomrawi HM: Poor expectations of knee replacement benefit are associated with modifiable psychological factors and influence the decision to have surgery: A cross-sectional and longitudinal study of a community-based sample. *Knee* 2017;24:354-361.

8. Fontana MA, Lyman S, Sarker GK, Padgett DE, MacLean CH: Can machine learning algorithms predict which patients will achieve minimally clinically important differences from total joint arthroplasty? *Clin Orthop Relat Res* 2019;477:1267-1279.

9. Gagnier JJ, Mullins M, Huang H, et al: A systematic review of measurement properties of patient-reported outcome measures used in patients undergoing total knee arthroplasty. *J Arthroplasty* 2017; 32:1688-1697.

10. Roos EM, Lohmander LS: The knee injury and osteoarthritis outcome score (KOOS): From joint injury to osteoarthritis. *Health Qual Life Outcomes* 2003;1:64.

11. Lyman S, Lee YY, McLawhorn AS, Islam W, MacLean CH: What are the minimal and substantial improvements in the HOOS and KOOS and JR versions after total joint replacement? *Clin Orthop Relat Res* 2018;476:2432-2441.

12. Brodke DJ, Saltzman CL, Brodke DS: PROMIS for orthopaedic outcomes measurement. *J Am Acad Orthop Surg* 2016;24:744-749.

13. Fidai MS, Saltzman BM, Meta F, et al: Patient-reported outcomes measurement information System and legacy patient-reported outcome measures in the field of orthopaedics: A systematic review. *Arthroscopy* 2018;34:605-614.

14. Kenney RJ, Houck J, Giordano BD, Baumhauer JF, Herbert M, Maloney MD: Do patient reported outcome measurement information System (PROMIS) scales demonstrate responsiveness as well as disease-specific scales in patients undergoing knee arthroscopy? *Am J Sports Med* 2019;47:1396-1403.

15. Khalil LS, Darrith B, Franovic S, Davis JJ, Weir RM, Banka TR: Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health short forms demonstrate responsiveness in patients undergoing knee arthroplasty. *J Arthroplasty* 2020;35: 1540-1544.

16. Padilla JA, Rudy HL, Gabor JA, et al: Relationship between the patient-reported outcome measurement information system and traditional patient-reported outcomes for osteoarthritis. *J Arthroplasty* 2019;34:265-272.

17. Berliner JL, Brodke DJ, Chan V, SooHoo NF, Bozic KJ: Can preoperative patient-reported outcome measures be used to predict meaningful improvement in function after TKA? *Clin Orthop Relat Res* 2017;475:149-157.

18. Connelly JW, Galea VP, Rojanasopondist P, et al: Patient Acceptable symptom state at 1 and 3 years after total knee arthroplasty: Thresholds for the knee injury and osteoarthritis outcome score (KOOS). *J Bone Joint Surg Am* 2019;101: 995-1003.

19. Connelly JW, Galea VP, Rojanasopondist P, et al: Which preoperative factors are associated with not attaining acceptable levels of pain and function after TKA? Findings from an international multicenter study. *Clin Orthop Relat Res* 2020;478:1019-1028.

20. Rojanasopondist P, Galea VP, Connelly JW, et al: What preoperative factors are associated with not achieving a minimum clinically important difference after THA? Findings from an international multicenter study. *Clin Orthop Relat Res* 2019;477: 1301-1312.

21. Anderson MR, Houck JR, Saltzman CL, et al: Validation and generalizability of preoperative PROMIS scores to predict postoperative success in foot and ankle patients. *Foot Ankle Int* 2018; 39:763-770.

22. Chen RE, Papuga MO, Nicandri GT, Miller RJ, Voloshin I: Preoperative Patient-Reported Outcomes Measurement Information System (PROMIS) scores predict postoperative outcome in total shoulder arthroplasty patients. *J Shoulder Elbow Surg* 2019;28: 547-554.

# 23. Chen RE, Papuga MO, Voloshin I, et al: Preoperative PROMIS scores predict postoperative outcomes after primary ACL reconstruction. *Orthop J Sports Med* 2018;6:2325967118771286.

24. Berliner JL, Brodke DJ, Chan V, SooHoo NF, Bozic KJ: John charnley award: Preoperative patient-reported outcome measures predict clinically meaningful improvement in function after THA. *Clin Orthop Relat Res* 2016; 474:321-329.

25. Culliton SE, Bryant DM, Overend TJ, MacDonald SJ, Chesworth BM: The relationship between expectations and satisfaction in patients undergoing primary total knee arthroplasty. *J Arthroplasty* 2012;27: 490-492.

26. Husain A, Lee GC: Establishing realistic patient expectations following total knee arthroplasty. *J Am Acad Orthop Surg* 2015;23:707-713.

27. Canfield M, Savoy L, Cote MP, Halawi MJ: Patient-reported outcome measures in total joint arthroplasty: Defining the optimal collection window. *Arthroplast Today* 2020;6:62-67.