Performance of PROMIS Global-10 Compared With Legacy Instruments for Rotator Cuff Disease

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Abstract

Background: The Patient-Reported Outcomes Measurement Information System (PROMIS) Global-10 was recently developed to assess physical and mental health and provide an estimated EuroQol-5 Dimension (EQ-5D) score. This instrument needs to be validated for specific patient cohorts such as those with rotator cuff pathology.

Hypothesis: There is moderate to high correlation between the PROMIS Global-10 and legacy patient-reported outcome measures; PROMIS Global-10 will not show ceiling effects; and estimated EQ-5D scores will show good correlation and low variance with actual EQ-5D scores.

Study Design: Cohort study (diagnosis); Level of evidence, 2.

Methods: A total of 323 patients with rotator cuff disease were prospectively enrolled before treatment. Each patient completed the PROMIS Global-10, EQ-5D, American Shoulder and Elbow Surgeons (ASES) shoulder assessment form, and Single Assessment Numeric Evaluation (SANE), and those with known rotator cuff tears completed the Western Ontario Rotator Cuff Index (WORC). Spearman correlations were calculated. Bland-Altman agreement tests were conducted between estimated EQ-5D scores from the PROMIS and actual EQ-5D scores. Ceiling and floor effects were assessed, defined as 15% respondents with highest or lowest possible score.

Results: Correlation between the PROMIS Global-10 and EQ-5D was excellent (0.70, $P <$ .0001). Correlation of the PROMIS physical scores was excellent-good with the ASES (0.62, $P <$ .0001), good with the WORC (0.47, $P <$ .0001), and good with the SANE (0.41, $P <$ .0005). Correlation between the PROMIS mental scores was poor with the ASES (0.34, $P <$ .0001), the WORC (0.32, $P =$ .0016), and the SANE (0.24, $P <$ .0001). No floor or ceiling effects were found. Agreement analysis showed substantial variance in individual scores, despite the overall similarity in mean scores between the estimated and actual EQ-5D scores, indicating poor agreement. Bland-Altman 95% limits of agreement for estimated EQ-5D scores ranged from 34% below to 31% above actual EQ-5D scores.

Conclusion: Physical function scores of the PROMIS Global-10 show high correlation with legacy patient-reported outcome instruments, suggesting that it is a reliable tool for outcome assessment in a population with rotator cuff pathology. The large variability in 95% limit of

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agreement suggested that the estimated EQ-5D scores from the PROMIS Global-10 cannot replace traditional EQ-5D scores.

Keywords

shoulder; rotator cuff; shoulder; general; clinical assessment/grading scales; economic and decision analysis

Patient-reported outcome (PRO) instruments allow patients to evaluate their health and measure change after surgical intervention based on their interpretation of the symptoms, distress, and function.[14-16,37] Since a primary treatment goal of orthopaedic surgery is to improve patients' quality of life, PROs have become essential tools in assessing patient's postoperative function and, arguably, the success and efficacy of orthopaedic interventions.[2,16,17,37]

Several well-validated PRO measures are used in orthopaedics and shoulder surgery. The 36-Item Short Form Health Survey (SF-36)[5] and EuroQol-5 Dimension (EQ-5D)[17] are broadly used in medicine to assess general health and quality of life, particularly for chronic conditions, and are not exclusive to orthopaedics.[30] The EQ-5D is often used to calculate quality-adjusted life years (QALYs): a combination of the utility value (range, 1 = full health to 0 = death) of a particular health state and time spent in that state.[36] QALYs are often used in health economic evaluations and for cost-utility analysis.[10,25] Limb- and disease-specific PROs have also been validated, including the American Shoulder and Elbow Surgeons (ASES) shoulder assessment form,[19,22] the Western Ontario Rotator Cuff Index (WORC),[20] and the Western Ontario Shoulder Instability Index (WOSI).[21,32]

There has been a recent emphasis to decrease patient response burden and improve compliance while improving measurement precision, owing to the often lengthy process of completing PROs.[18] The Patient-Reported Outcomes Measurement Information System (PROMIS) was created in 2004 by the National Institutes of Health (NIH) to develop and evaluate a set of publicly available efficient PROs for patients with various diseases and chronic conditions.[6] The PROMIS databank includes question sets covering multiple health domains. The questions were designed to utilize item response theory, which examines individual question responses and their relationships within question sets.[6] Recent studies validated the PROMIS physical function computer adaptive testing (PF CAT) and upper extremity instruments in comparison with traditional PROs for patients with meniscal injury and shoulder instability and those undergoing primary total shoulder arthroplasty.[1,9,12] These studies found the PROMIS PF CAT and upper extremity instruments to be comparable in accuracy to traditional PROs while providing low patient burden, high reliability, and no ceiling effects.

While the performance of these extremity-specific PROs was assessed in several orthopaedic cross-sectional studies, the performance of the PROMIS global health PRO (Appendix 1, available in the online version of this article) has not yet been studied for specific diseases and patient populations. The NIH PROMIS Global-10 is a PRO utilizing 10 items to measure overall physical function, fatigue, pain, emotional distress, and social health, instead of physical function isolated to a specific extremity.[2,14,29,32] This allows for

respondents to receive both a physical health score and a mental health score upon completion of the PROMIS Global-10, as well as an estimated EQ-5D score.[14,27,29,32] The PROMIS Global-10 includes fewer questions (n = 10) than the PROMIS upper extremity (n = 16) and WORC (n = 21) and, if reliable, could eliminate the need for patients to complete multiple legacy PROs during their office visit, resulting in decreased question burden, improved clinic flow, and possibly improved compliance.[2,14,29,32] Unlike extremity-specific PROs, the PROMIS Global-10 is broadly applicable and can be implemented to assess patient outcomes for various orthopaedic disorders as well as in nonorthopaedic specialties.

One such disorder that is commonly seen in upper extremity and general orthopaedic practices is rotator cuff disease and tears. In the United States, rotator cuff disease accounts for >4.5 million physician visits alone,[26] with degenerative rotator cuff tears being the most common upper limb condition among people >50 years old and with traumatic tears being common sequelae of acute and acute-on-chronic shoulder injuries.[7,26] Despite the high prevalence of rotator cuff disease and potentially debilitating consequences, the performance of the PROMIS Global-10 has not yet been studied among patients with rotator cuff disease.[1,9]

The purpose of this study is to validate the PROMIS Global-10 for rotator cuff disease to legacy general health, limb-, and disease-specific PROs. We hypothesize the following: (1) There is moderate to high correlation between the PROMIS Global-10 and the legacy PROs (ASES, EQ-5D, and WORC). (2) PROMIS instruments will not show ceiling effects. (3) PROMIS Global-10 will show a decreased question burden when compared with other PROs. (4) Estimated EQ-5D scores from the PROMIS Global-10 will show good correlation and low variance with actual EQ-5D scores.

METHODS

This investigation was approved by the Yale University Human Investigation Committee (protocol 1510016580) and was compliant with standard protocols of the Health Insurance Portability and Accountability Act. From January 2015 to September 2017, 323 new patients with rotator cuff disease had their PROs prospectively collected in the office of 2 fellowship-trained sports medicine surgeons (T.A.B., D.K.) before they received continued medical or surgical treatment. Patients were included in the study if they were clinically diagnosed as having shoulder impingement or a partial- or full-thickness tear of the posterosuperior rotator cuff, with all clinical diagnoses confirmed by magnetic resonance imaging findings.

Other inclusion criteria were defined as 18 years of age, English speaking, and having the ability to provide informed consent. Previous rotator cuff surgery was an exclusion factor. Patients with multiple rotator cuff pathologies were classified by the most severe pathology level. For instance, patients with both impingement and a partialthickness rotator cuff tear would be considered to have a partial-thickness rotator cuff tear for the purposes of analysis.

Patients prospectively completed the PROMIS Global-10, EQ-5D, Single Assessment Numeric Evaluation (SANE), ASES, and WORC instruments on a tablet computer during their office visit. Clinical examination and advanced imaging findings were used to confirm

that patients enrolled in the study who had completed the WORC had a diagnosed rotator cuff disorder. Patient's demographic information, such as age, sex, hand dominance, and operative side, were also prospectively collected with the tablet. Smoking status, medical comorbidities, and insurance status were obtained from chart reviews. Medical comorbidities were defined as having a documented diagnosis of diabetes, hypertension, depression, heart disease requiring previous heart surgery, chronic obstructive pulmonary disease, body mass index >35 kg/m^2, rheumatoid arthritis, or peripheral vascular disease. Study data were collected and managed with REDCap (Research Electronic Data Capture) hosted at our institution.[13]

PROMIS Global-10 results were used to calculate each patient's physical and mental health raw scores, T scores, and estimated EQ-5D scores. T scores are standardized and derived from raw scores such that a 50 represents the average (mean) for the US general population and the SD around that mean is 10 points. Estimated EQ-5D scores were generated from a linear combination of 8 Global-10 items as described by Revicki et al.[27] To assess construct validity, the correlation of PROMIS Global-10 physical and mental health scores with EQ-5D, SANE, ASES, and WORC instruments was calculated. While the EQ-5D, ASES, and WORC instruments are all legacy PROs that were validated for orthopaedic patients, the SANE has not yet been validated, and no minimal clinically significant difference has been reported.[32] Normality of variables was assessed with histograms and the Kolmogorov-Smirnov test.

The associations between the PROMIS Global-10 and the legacy PROs were defined with Spearman correlation coefficients. Correlations were defined as excellent (>0.7), excellent-good (0.61-0.70), good (0.4-0.6), or poor (<0.4).[31] Subgroup analysis of PRO scores and correlations were conducted for patients with a full-thickness rotator cuff tear, excluding those with a diagnosis of impingement or partial-thickness rotator cuff tear. A Bland-Altman analysis was conducted to assess the agreement between estimated and actual EQ-5D scores.[3,4] Simple linear regression analysis was used to assess the correlation between demographics and PROMIS physical or mental score.

The presence of floor and ceiling effects was assessed by calculating the percentage of participants with the highest and lowest possible scores. If >15% of participants scored in either extreme, a floor or ceiling effect was considered present.[23,33] Subgroup analysis for floor and ceiling effects was conducted for patients aged <40 years.

All statistical analyses were performed with SAS (v 9.4; SAS Institute). Statistical significance was set as $P < .05$ (2-sided).

RESULTS

A total of 323 patients met the eligibility criteria and were enrolled. Patient characteristics are summarized in Table 1. The median age of our patient population was 59 years (range, 18-89 years; 53.9% male, 46.1% female). Most patients had a diagnosis of full-thickness rotator cuff tear (44.6%) or impingement (43.7%), with only a small portion with a diagnosed partial tear (11.8%). Most patients had private insurance (54.4%), had never

smoked (49.8%), and had no medical comorbidities (61.3%). Patients with bilateral pathology tended to have bilateral shoulder impingement.

Mean scores for PRO instruments and PROMIS physical and mental health scores are shown in Table 2. The PROMIS mental T score was similar to that of the US general population (49.5 vs 50). The PROMIS physical T score was significantly lower than that of the US general population (42 vs 50, $P < .0001$), indicating that this study cohort with rotator cuff pathology has mental health similar to that of the general US population but a significantly lower physical function level.

Correlation between the PROMIS Global-10 and the EQ-5D was excellent, with a Spearman correlation of 0.70 ($P < .0001$). The mean difference between estimated EQ-5D scores from the PROMIS Global-10 and actual EQ-5D scores was −0.0128 (95% CI, −0.03 to 0.01; $P = .16$) on a scale of 0 to 1, indicating that the scores were similar overall. A Bland-Altman plot was created (Figure 1) to examine the difference between estimated and actual EQ-5D scores. Agreement analysis showed substantial variance in individual scores, despite the overall similarity in mean scores between the estimated and actual EQ-5D indicating poor agreement. On a scoring scale of 0 to 1, any individual estimated score could range from −0.34 below to 0.31 above the actual EQ-5D score, respectively. No consistent bias was identified for the estimated EQ-5D factors.

Correlations of the PROMIS physical and mental scores with the legacy PRO instruments are shown in Table 3 for the overall population and in Table 4 for the subgroups of full-thickness rotator cuff tears, partial-thickness rotator cuff tears, and impingement. Correlation coefficients between the PROMIS physical instruments and all legacy PROs were >0.4, indicating good correlation. Similar correlation results were found for the patient subsets diagnosed with full-thickness rotator cuff tears, partialthickness tears, and impingement as compared with the entire cohort and each other. Correlation coefficients between the PROMIS mental instruments and the other physical function PROs were all <0.4, indicating poor correlation.

Simple linear regressions were performed for patient demographics and the PROMIS physical and mental scores (Table 5). Age had a significant negative effect on PROMIS physical scores ($P = .001$) but not on PROMIS mental scores. Patients with impingement had significantly higher PROMIS physical health scores than patients with fullthickness rotator cuff tears ($P = .001$) and significantly higher mental scores ($P = .01$). Subgroup analysis of the correlation of the PROMIS Global-10 with the ASES, WORC, and SANE was performed for patients aged <40 years (n = 34) and >40 years, with similar correlation coefficients and results (Appendix 2, available online).

No floor or ceiling effects were found for the study cohort in terms of PROMIS physical or mental health scores (Table 6). Only 16 patients (5%) had the highest PROMIS mental score. Subgroup analysis of patients aged <40 years did not reveal floor or ceiling effects.

Average time to complete each PRO was recorded (Table 7). The ASES took the most time (1.84 minutes), whereas the EQ-5D took the least (0.47 minutes).

DISCUSSION

This study validated the PROMIS Global-10 among patients with rotator cuff disease. We found the following: (1) There was excellent correlation between the PROMIS Global-10 and EQ-5D, good to excellent correlation of the physical health score with legacy PROs (ASES, EQ-5D, and WORC), and poor correlation of the mental health score with legacy PROs. (2) PROMIS instruments did not show ceiling effects. (3) PROMIS Global-10 showed decreased question burden as compared with the WORC, similar question burden to the ASES, and more question burden than the EQ-5D and SANE. (4) Estimated EQ-5D scores from the PROMIS Global-10 had good correlation with actual EQ-5D scores but high variance. Considering the high prevalence of rotator cuff pathology found in orthopaedic practice, we believe a validated low-burden PRO tool such as the PROMIS Global-10 would be a significant advancement in how physicians can measure the success of their interventions in this patient population.

Beckmann et al[2] examined the PROMIS PF CAT among presurgical patients (N = 187) with rotator cuff disease and found moderate correlation with the ASES (0.581, $P < .001$) and the Simple Shoulder Test (0.635, $P < .001$). The Pearson product-moment coefficient between the PROMIS PF CAT and ASES was similar to the coefficient that we found for the PROMIS Global-10 physical T score to the ASES (0.61, $P < .0001$).

We learned that the PROMIS Global-10 had excellent correlation with the EQ-5D. However, when comparing the individual PROMIS-generated EQ-5D scores and the actual EQ-5D scores, we found that although the mean difference was small, Bland-Altman plots showed significant variance between the individual actual scores and estimated scores. The 95% limits of agreement for difference in scores ranged from –0.34 below to 0.31 above an EQ-5D score on a scale of 0 to 1. This is somewhat higher than the Bland-Altman 95% limits of agreement for estimated versus actual EQ-5D scores reported by Revicki et al[27] of –0.2 to 0.2. Thus, despite the excellent correlation between the PROMIS Global-10 items and the EQ-5D, the PROMIS-generated EQ-5D score may not be a sufficient substitute for the actual EQ-5D score of patients with rotator cuff pathology. This also indicates that PROMIS-estimated EQ-5D scores may not be an adequate substitute for EQ-5D-derived QALYs for economic and cost-effectiveness evaluations.

Although the PROMIS Global-10 is a general health PRO, it shows good correlation with legacy general wellness and extremity- and disease-specific PROs for assessment of rotator cuff pathology. The PROMIS Global-10 is similar in design to the 12-Item Short Form Health Survey (SF-12), another general health PRO measure that has been widely used in assessing patients with rotator cuff pathology and their response to treatment.[8,11,24,28,38] The SF-12 is a short-form version of the SF-36 and is similar to the PROMIS Global-10 in that it has both physical and mental component summaries, with high scores indicating better function and with a mean score of 50 for the US population (range, 0-100).[34,35] Ferreira et al[11] found significantly lower SF-12 physical component scores for patients with rotator cuff arthropathy as compared with matched controls and significantly poorer functional results according to the ASES. Corpus et al[8] used the SF-12 to measure response to treatment among patients with massive rotator cuff tears treated with an all-arthroscopic modified

rotator interval slide, finding a significant improvement in both postoperative ASES scores and SF-12 physical component scores. Similar to these 2 studies, our data showed decreased PROMIS Global-10 physical function scores among patients with rotator cuff pathology, whereas the PROMIS Global-10 mental function scores were similar to the US population average.

Although there are various general health PROs from which to choose, such as the SF-12, EQ-5D, and SF-36, the PROMIS instruments, including the PROMIS Global-10, are being increasingly adopted by medical institutions and need to be validated for specific pathologies. The PROMIS instruments were created by the NIH and, as such, are likely to remain in clinical practice until thoroughly vetted for specific disease pathologies, as done in this study. In fact, Wylie et al[38] conducted a review of PRO measurements after shoulder surgery, commenting that PROMIS PROs are likely to be increasingly reported in studies evaluating shoulder outcomes. At our institution, the PROMIS Global-10 is being adopted across orthopaedic subspecialties, including spine, shoulder, elbow, and sports medicine, as well as hip and knee joint arthroplasty, with plans on implementation and use for the entire department.

Traditional PROs can be both lengthy and timeconsuming, requiring completion of the entire questionnaire to ensure instrument validity. The high patient burden and time requirement can result in suboptimal office flow and lower patient compliance. We found that the PROMIS Global-10 has improved efficiency when compared with some other PRO measures. Only 10 questions must be completed as compared with the PROMIS upper extremity (16 questions), ASES (10 questions), and WORC (21 questions). The PROMIS PF CAT can range from 4 to 12 questions. The PROMIS Global-10 is, however, longer than the EQ-5D, which requires answering 6 questions. The ability to identify the same information with fewer questions can reduce patient burden and improve patient response rates and office flow.

Last, we found no floor or ceiling effects in our study cohort. This ensures that extremes of function can be measured, and it allows for continued measurements in response to treatment. Other recent articles validating various PROMIS instruments in shoulder instability, meniscal tears, and primary total shoulder arthroplasty also indicated no ceiling effects.[1,12] A number of articles cited a ceiling effect for the PROMIS upper extremity instrument, with 1 article recommending that it not be used among patients <21 years old. [1,15]

Limitations of this study include that we cannot compare the PROMIS Global-10 with the PROMIS PF CAT score. This study also required patients to complete multiple PRO tools, which may have introduced responder fatigue. This could be addressed by randomization of test administration order. Serial PRO measurements before and after surgery would be useful for validation of PROMIS responsiveness to treatment.

Given its correlation with general health PROs and legacy upper extremity PROs, our results suggest that the PROMIS Global-10 is valid for assessing patients with rotator cuff disease and may be a useful alternative. Given this broad applicability, the PROMIS Global-10 can

potentially be utilized by physicians in multispecialty groups. More important, while the PROMIS Global-10 provides estimated EQ-5D scores, we found that they may not be directly comparable with traditional EQ-5D scores, potentially limiting its ability to derive QALYs for economic and cost-effectiveness evaluations.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.
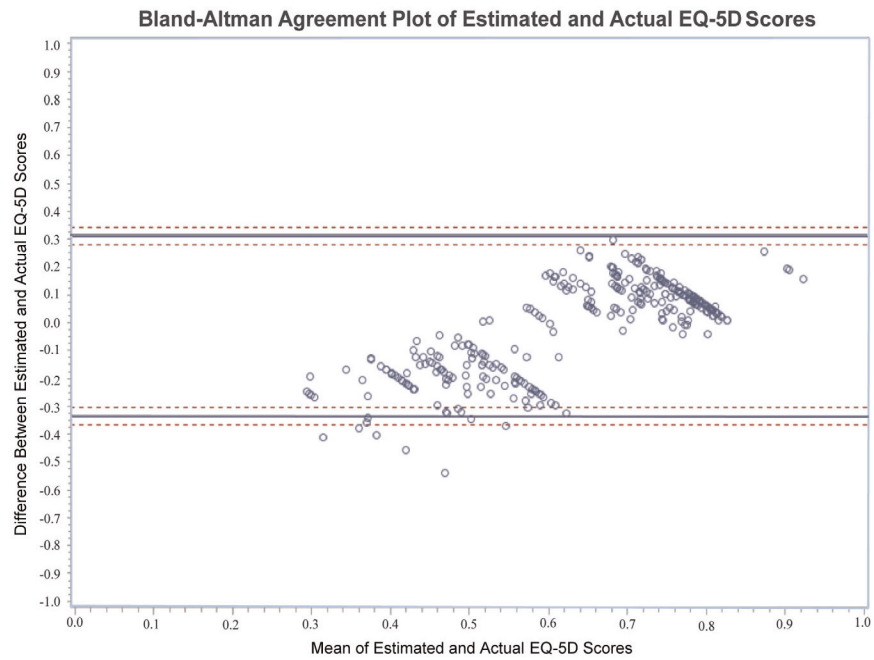
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Bland-Altman Agreement Plot of Estimated and Actual EQ-5D Scores

Figure 1.

Plot demonstrating the difference between the actual EQ-5D score and the estimated EQ-5D score from the PROMIS (vertical axis) and the average of the actual EQ-5D score and the estimated EQ-5D score (horizontal axis). Each dot represents 1 respondent. The solid lines are the lower and upper 95% limits of agreement, and the dashed lines are the lower and upper 95% CI for the lower and upper limits. EQ-5D, EuroQol-5 Dimension; PROMIS, Patient-Reported Outcomes Measurement Information System.

TABLE 1

Patient Characteristics

	Mean ± SD or n (%)
Age, y	57.7 ± 13.8
Body mass index, kg/m^2	29.4 ± 6.1
Sex	
Male	174 (53.9)
Female	149 (46.1)
Diagnosis	
Full-thickness tear	144 (44.6)
Impingement	141 (43.7)
Partial tear	38 (11.8)
Hand dominance	
Right	271 (83.9)
Left	37 (11.5)
Ambidextrous	15 (4.6)
Affected side	
Right	186 (57.6)
Left	128 (39.6)
Both	9 (2.8)
Comorbidity	
No	198 (61.3)
Yes	125 (38.7)
Insurance	
Private	176 (54.4)
Medicare	91 (28.2)
Medicaid	53 (16.4)
Workers' compensation	3 (1.0)
Smoking status	
Current smoker	49 (15.2)
Previous smoker	113 (35.0)
Never	161 (49.8)

TABLE 2

PRO Scores for Rotator Cuff Population[a]

Instrument	Scale	Mean ± SD	Median (Range)
PROMIS Global-10			
Physical health	4-20	12.7 ± 2.7	13.0 (6.0-18.0)
Mental health	4-20	14.3 ± 3.5	14.0 (4.0-20.0)
Physical T score	0-100	42.0 ± 7.3	42.3 (23.5-57.5)
Mental T score	0-100	49.5 ± 7.3	48.3 (21.2-67.6)
EQ-5D			
Actual	0-1	0.6 ± 0.2	0.8 (0.1-1.0)
PROMIS estimated	0-1	0.6 ± 0.1	0.7 (0.4-0.8)
ASES	0-100	43.8 ± 20.7	45.0 (0.0-100)
WORC	0-100	36.5 ± 9.2	13.0 (5.1-96.1)
SANE	0-100	43.9 ± 23.6	13.0 (0.0-96.0)

[a]ASES, American Shoulder and Elbow Surgeons; EQ-5D, Euro-Qol-5 Dimension; PRO, patient-reported outcome; PROMIS, Patient-Reported Outcomes Measurement Information System; SANE, Single Assessment Numeric Evaluation; SF-36, 36-Item Short Form Health Survey; WORC, Western Ontario Rotator Cuff Index.

TABLE 3

Correlation Coefficients Between the PROMIS Global-10 and Legacy Instruments: Entire Patient Cohort (N = 323)[a]

Instrument	r_s	P Value	Correlation Strength
PROMIS Global-10			
EQ-5D	0.70[b]	<.0001	Excellent
Global-10 physical health			
ASES	0.62	<.0001	Excellent-good
WORC	0.47	<.0001	Good
SANE	0.41	<.0005	Good
Global-10 mental health			
ASES	0.34	<.0001	Poor
WORC	0.32	.0016	Poor
SANE	0.24	<.0001	Poor

[a]ASES, American Shoulder and Elbow Surgeons; EQ-5D, Euro-Qol-5 Dimension; PROMIS, Patient-Reported Outcomes Measurement Information System; SANE, Single Assessment Numeric Evaluation; WORC, Western Ontario Rotator Cuff Index.

[b]$r_S = 0.704$.

TABLE 4

Rotator Cuff Disease Severity and Correlation Strength Between the PROMIS Global-10 and Legacy Instruments[a]

Subgroup: Instrument	r_s	P Value	Correlation Strength
Full-thickness tear (n = 144)			
EQ-5D	0.70[b]	<.0001	Excellent
Global-10 physical health			
ASES	0.60	<.0001	Good
WORC	0.46	.0003	Good
SANE	0.36	<.0001	Poor
Global-10 mental health			
ASES	0.27	.0013	Poor
WORC	0.39	.0031	Poor
SANE	0.14	.0864	Poor
Impingement (n = 141)			
EQ-5D	0.71	<.0001	Excellent
Global-10 physical health			
ASES	0.62	<.0001	Excellent-good
WORC	0.49	.005	Good
SANE	0.38	<.0001	Poor
Global-10 mental health			
ASES	0.33	.0013	Poor
WORC	0.09	.623	Poor
SANE	0.28	.001	Poor
Partial-thickness tear (n = 38)			
EQ-5D	0.67	<.0001	Excellent-good
Global-10 physical health			
ASES	0.53	.001	Good
WORC	0.00	.999	Poor
SANE	0.53	.001	Good
Global-10 mental health			
ASES	0.39	.019	Poor
WORC	0.10	.870	Poor
SANE	0.33	.042	Poor

[a]ASES, American Shoulder and Elbow Surgeons; EQ-5D, Euro-Qol-5 Dimension; PROMIS, Patient-Reported Outcomes Measurement Information System; SANE, Single Assessment Numeric Evaluation; WORC, Western Ontario Rotator Cuff Index.

[b]$r_s = 0.703$.

TABLE 5

Simple Linear Regression for PROMIS Global-10 Physical and Mental Scores[a]

Variable	PROMIS Global-10 Physical Score		PROMIS Global-10 Mental Score	
	Regression Coefficient (95% CI)[b]	P Value	Regression Coefficient (95% CI)[b]	P Value
Age	−0.10 (−0.16 to −0.05)	.001	−0.05 (−0.12 to 0.03)	.222
Sex				
Male	42.72 (41.64 to 43.80)	.053	49.42 (48.04 to 50.79)	.852
Female	41.15 (39.98 to 42.31)		49.61 (48.12 to 51.10)	
Affected side				
Left	41.57 (40.30 to 42.84)	.0696	49.08 (47.49 to 50.67)	.036
Right	42.28 (41.23 to 43.34)		49.42 (48.10 to 50.74)	
Ambidextrous	41.97 (37.18 to 46.75)		57.24 (51.24 to 63.25)	
Hand dominance				
Left	41.19 (38.84 to 43.55)	.575	49.07 (46.08 to 52.06)	.950
Right	42.17 (41.30 to 43.05)		49.58 (48.47 to 50.68)	
Ambidextrous	40.67 (36.96 to 44.37)		49.33 (44.64 to 54.03)	
Diagnosis				
Full tear	40.81 (39.64 to 41.98)	.001	48.29 (46.79 to 49.78)	.013
Partial tear	40.20 (37.92 to 43.68)		47.77 (44.86 to 50.68)	
Impingement	43.68 (42.50 to 44.87)		51.22 (49.70 to 52.73)	

[a] PROMIS, Patient-Reported Outcomes Measurement Information System.

[b] Regression coefficient for continuous variable or least squares means for categorical variables.

TABLE 6

Analysis of Floor and Ceiling Effects of the PROMIS Global-10: Patients Reaching Minimum or Maximum Score[a]

	Minimum Score	Maximum Score
Entire patient cohort (N = 323)		
Global-10 physical health	0 (0)	0 (0)
Global-10 mental health	1 (0.3)	16 (5.0)
Age <40 y (n = 34)		
Global-10 physical health	0 (0)	0 (0)
Global-10 mental health	0 (0)	2 (5.9)

[a]Data are given as No. (%) of patients. PROMIS, Patient-Reported Outcomes Measurement Information System.

TABLE 7

Average Time to Complete Each PRO Instrument[a]

	Minutes, Mean ± SD
PROMIS Global-10	1.72 ± 1.13
EQ-5D	0.47 ± 0.55
ASES	1.84 ± 1.34
SANE	1.59 ± 0.84

[a]ASES, American Shoulder and Elbow Surgeons; EQ-5D, Euro-Qol-5 Dimension; PRO, patient-reported outcome; PROMIS, Patient-Reported Outcomes Measurement Information System; SANE, Single Assessment Numeric Evaluation.