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Establishing "Normal" Patient-Reported Outcomes Measurement Information System Physical Function and Pain Interference Scores: A True Reference Score According to Adults Free of Joint Pain and Disability

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Establishing "Normal" Patient-Reported Outcomes Measurement Information System Physical Function and Pain Interference Scores

A True Reference Score According to Adults Free of Joint Pain and Disability

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Background: Numerous recent studies have demonstrated the validity and efficiency of the National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS) forms in patients undergoing orthopaedic surgical procedures. It is assumed that a score of 50 in each domain represents the health state of a "reference" population, but this threshold has not been definitively proven. In order to truly assess whether a given orthopaedic intervention is successful, the comparative scores of healthy individuals must be known for any given health domain measured. Therefore, the purpose of this study was to determine baseline scores for the PROMIS general physical function (PROMIS-PF), pain interference (PROMIS-PI), and upper-extremity physical function (PROMIS-UE) domains in physically healthy, asymptomatic adult individuals. We hypothesized that, in individuals <40 years old, the mean PROMIS-PF and PROMIS-UE scores would be >50 and PROMIS-PI scores would be <50. We further hypothesized that these scores would be impacted by participant age.

Methods: Three PROMIS computer adaptive test (CAT) domains were administered (either in person or through email) to healthy adult volunteers. These domains included PROMIS-PF, PROMIS-UE, and PROMIS-PI. Individuals who reported joint pain or dysfunction were excluded.

Results: In total, 294 healthy volunteers with a mean age of 33.2 years (range, 18 to 83 years) completed all 3 PROMIS CAT forms. The mean (and standard deviation) PROMIS-UE, PROMIS-PF, and PROMIS-PI scores were 55.9 ± 6.6, 59.7 ± 8.0, and 43.6 ± 7.6, respectively, for individuals <40 years old and 51.2 ± 8.2, 52.9 ± 7.6, and 49.0 ± 8.0, respectively, for individuals ≥40 years old. Age correlated significantly with PROMIS-UE and PROMIS-PF in the older cohort.

Conclusions: For individuals <40 years old, baseline PROMIS-PF scores were significantly higher than 50 and PROMIS-PI scores were significantly lower. This difference was less pronounced in individuals ≥40 years old. When treating young patients, clinicians should be cognizant of these healthy baseline scores.

Clinical Relevance: In this study, reference range for asymptomatic musculoskeletal volunteers was determined across PROMIS CAT forms. These reference scores are important in treating and counseling patients with musculoskeletal conditions in order to determine relative impairment or functional capabilities.

The utilization of patient-reported outcome measures (PROMs) has rapidly grown in the field of orthopaedics, providing patient-centric assessments of clinical outcomes[1-6]. The National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS) has emerged as a valid and efficient PROM tool across numerous health domains, including physical function, pain, and mental health[7-11]. The use of computer adaptive tests (CATs) decreases time-to-completion and the number of total questions asked, which enhances the efficiency of administration compared with other "legacy" measures[1,4,12,13] in patients with orthopaedic conditions. These attributes have contributed to an increasing

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TABLE I PROMIS CAT Domain Scores by Age Group*

PROMIS Domain	<40 Years Old	≥40 Years Old	P Value
PROMIS-UE			
Mean	55.9 ± 6.6	51.2 ± 8.2	**<0.001**
Median	60.9 (52.7-61.0)	53.0 (46.2-55.9)	
Range	14.7-61.0	27.1-61.0	
PROMIS-PF			
Mean	59.7 ± 8.0	52.9 ± 7.6	**<0.001**
Median	61.0 (55.2-64.2)	51.9 (48.2-58.2)	
Range	14.7-75.6	37.2-75.6	
PROMIS-PI			
Mean	43.6 ± 7.6	49.0 ± 8.0	**<0.001**
Median	38.7 (38.7-50.1)	50.1 (38.7-54.3)	
Range	38.7-83.8	38.7-76.4	

*Values are given either as the mean ± standard deviation, the median with the interquartile range in parentheses, or the range. Bolding indicates a significant p value.

utilization of PROMIS measures as primary outcomes in patients undergoing orthopaedic treatment.

For any given PROMIS domain, a score of 50 represents the average of a reference population. This reference score allows clinicians to compare outcomes following orthopaedic intervention. However, to our knowledge, no study to date has defined reference scores for the PROMIS physical function (PROMIS-PF) and pain interference (PROMIS-PI; i.e., the impact of pain on patient quality of life) CAT domains in a healthy, asymptomatic patient population; thus, preoperative and postoperative scores are inaccurately judged against the average American rather than against a metric of unimpaired health. The initial validation study collected comorbidity and disease data and concluded that there was a correlation between worsening scores and comorbidities, the presence of generalized pain or disability in the extremities was not assessed[14]. Generalized pain or disability may be resultant of acute injury or joint stiffness that is not accounted for by the previous comorbidity analysis. Moreover, initial design and validation testing of PROMIS measures included a population with a much greater proportion of older individuals than seen in the general population. Out of 21,133 subjects, the initial design study cohort included 12% of subjects between the ages of 18 and 29 years old, 12% between 30 and 39 years old, 16% between 40 and 49 years old, 32% between 50 and 64 years old, and 28% ≥65 years old[15]. Therefore, the reference scores provided may be largely dependent on patient age. In order to establish an ideal comparative baseline score by which orthopaedic providers could judge efficacy of treatment, we evaluated physically healthy adults, with physical health defined in the present study as the absence of disability, pain, or limited functional ability in the upper or lower extremities.

The primary purpose of this study was to determine baseline PROMIS CAT scores for the PROMIS-PF, PROMIS-PI, and upper-extremity physical function (PROMIS-UE) domains in adults without generalized pain or disability in the upper or lower extremities. The secondary purpose of the study was to determine if responder age impacted these reference scores. We hypothesized that, in asymptomatic, young adults, mean PROMIS-PF and PROMIS-UE scores would be greater than the stated reference score of 50, and that PROMIS-PI scores would be <50.

Materials and Methods

The present study was approved by our institutional review board. Inclusion criteria were age ≥18 years without any stated symptoms of pain or disability in the upper or lower extremity, and completion of all 3 PROMIS CAT forms. Participants <18 years old and those with pain or disability in the lower or upper extremity were excluded. Participants who could not communicate in English were also excluded. Participants were recruited from numerous sources, such as in-person requests in public areas as well as email solicitation of peers, colleagues, and publicly available listservers. Questionnaires were emailed or administered on a tablet computer with use of REDCap (Vanderbilt University), a web-based data

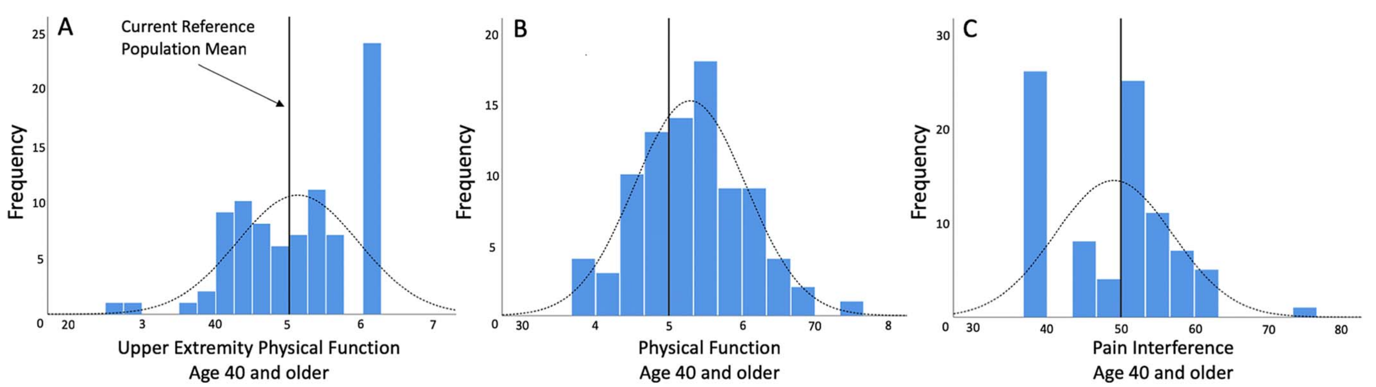

Fig. 1

Histograms showing PROMIS-UE (**Fig. 1-A**), PROMIS-PF (**Fig. 1-B**), and PROMIS-PI (**Fig. 1-C**) scores in individuals ≥40 years old. All 3 mean domain scores were similar to the reference value of 50 (black bar).

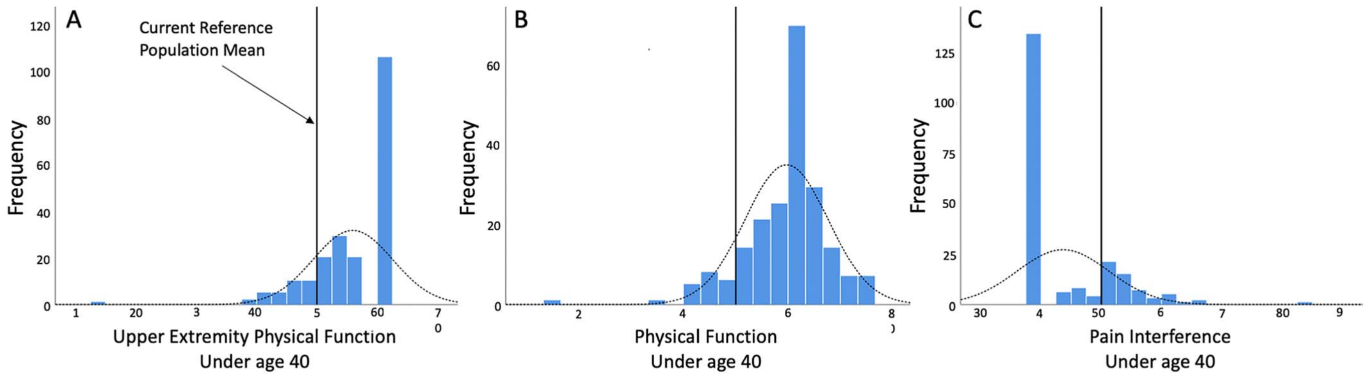

Fig. 2

Histograms showing PROMIS-UE (**Fig. 2-A**), PROMIS-PF (**Fig. 2-B**), and PROMIS-PI (**Fig. 2-C**) scores in individuals <40 years old. The PROMIS-PF and PROMIS-UE scores were higher and the PROMIS-PI scores were lower compared with the reference value of 50 (black bar).

management and collection application that is compliant with Health Insurance Portability and Accountability Act (HIPAA) regulations[16].

The study was conducted between August 6, 2018, and November 7, 2018. All participants indicated their age and then completed the 3 PROMIS CAT forms: PROMIS-UE version 2.0, PROMIS-PF version 2.0, and PROMIS-PI version 1.1. All PROMIS instruments are calibrated to a mean t-score of 50 with a standard deviation of 10, with greater scores indicating more of the health domain in question (i.e., higher PROMIS-PF and PROMIS-UE scores indicate greater function, whereas higher PROMIS-PI scores indicate that pain has a greater detriment on quality of life)[17].

Statistical Analysis

Descriptive statistics were used to report PROMIS scores. Secondarily, independent samples t tests were used to identify significant differences in PROMIS scores between 2 age groups, those <40 years old and those ≥40 years old. Significance was set at 0.05. Histograms were analyzed for floor and ceiling effects, which measure the ability of a questionnaire to differentiate between respondents at both extremes of the scale. For the present analysis, a ceiling or floor effect was considered present if >15% of participants achieved the highest or lowest possible score, respectively[18]. Kurtosis and skewness test statistics were also obtained and divided by the respective standard errors of measurement to determine normality with respect to each statistic. Values outside the range of −1.96 to 1.96 were considered non-normal. Lastly, Spearman correlations were used to evaluate the relationship between the 3 PROMIS domains and age. Correlation coefficients (r) were defined as high (>0.7), high-moderate (0.61 to 0.69), moderate (0.4 to 0.6), moderate-weak (0.31 to 0.39), or weak (≤0.3)[19]. All analyses were performed with use of SPSS (version 26.0; IBM).

Results

A total of 294 participants with a mean age of 33.2 years (range, 18 to 83 years) were included, of whom 207 were <40 years old (mean, 23.8 years old) and 87 were ≥40 years old (mean, 55.4 years old). The mean PROMIS-UE, PROMIS-PF, and PROMIS-PI scores (and standard deviations) were 55.9 ± 6.6, 59.7 ± 8.0, and 43.6 ± 7.6, respectively, for individuals <40 years old compared with 51.2 ± 8.2, 52.9 ± 7.6, and 49.0 ± 8.0, respectively, for individuals ≥40 years old (all comparisons $p < 0.001$) (Table I). Median scores and interquartile ranges can also be found in Table I.

Floor and ceiling effects and score distributions of each cohort were visualized on histograms (Figs. 1 and 2). PROMIS-UE showed significant ceiling effects in both age cohorts, whereas PROMIS-PI displayed strong floor effects, with both findings

TABLE II Distribution Analysis of PROMIS Domains by Age Group

	<40 Years Old		≥40 Years Old	
	Value	Normality	Value	Normality
PROMIS-UE				
Kurtosis*	5.87 ± 0.34	17.26	0.11 ± 0.51	0.22
Skewness*	−1.65 ± 0.17	−9.71	0.20 ± 0.26	0.77
Floor effect†	1 (0.5)		0 (0.0)	
Ceiling effect†	105 (**50.7**)		24 (**27.6**)	
PROMIS-PF				
Kurtosis*	9.29 ± 0.34	27.32	−0.20 ± 0.51	0.39
Skewness*	−0.24 ± 0.17	**−1.41**	−0.58 ± 0.26	**2.23**
Floor effect†	1 (0.5)		1 (0.5)	
Ceiling effect†	7 (3.4)		1 (1.1)	
PROMIS-PI				
Kurtosis*	4.78 ± 0.34	14.06	0.17 ± 0.51	0.33
Skewness*	1.92 ± 0.17	11.29	0.25 ± 0.26	0.96
Floor effect†	134 (**64.7**)		26 (**29.9**)	
Ceiling effect†	1 (0.5)		0 (0.0)	

*Values are given as the mean and standard error of the mean. Bolding indicates a nonideal distribution for normality. †Values are given as the number, with the percentage in parentheses. Bolding indicates a value >15% for floor and ceiling effects.

TABLE III Correlations of PROMIS Domains by Age Group*

	<40 Years Old			≥40 Years Old		
	R Value	P Value	Correlation Strength	R Value	P Value	Correlation Strength
PROMIS-UE						
PROMIS-PF	0.34	**<0.001**	Moderate-weak	0.62	**<0.001**	High-moderate
PROMIS-PI	−0.40	**<0.001**	Moderate	−0.59	**<0.001**	Moderate
Age	−0.08	0.252	Weak	−0.41	**<0.001**	Moderate
PROMIS-PF						
PROMIS-UE	0.34	**<0.001**	Moderate-weak	0.62	**<0.001**	High-moderate
PROMIS-PI	−0.29	**<0.001**	Weak	−0.53	**<0.001**	Moderate
Age	0.10	0.143	Weak	−0.33	**0.002**	Moderate-weak
PROMIS-PI						
PROMIS-UE	−0.40	**<0.001**	Moderate	−0.59	**<0.001**	Moderate
PROMIS-PF	−0.29	**<0.001**	Weak	−0.53	**<0.001**	Moderate
Age	0.07	0.323	Weak	−0.11	0.329	Weak

*Bolding indicates a significant p value.

more prominent among individuals <40 years old (50.7% and 64.7%, respectively) than individuals ≥40 years old (27.6% and 29.9%, respectively). Distribution analysis identified normality for PROMIS-UE and PROMIS-PI among individuals ≥40 years old when assessed by skewness and kurtosis (Table II). Among individuals <40 years old, PROMIS-UE and PROMIS-PF distributions were leptokurtic and PROMIS-UE was negatively skewed, whereas PROMIS-PI was positively skewed.

Among individuals <40 years old, there were moderate-weak correlations between PROMIS-UE and PROMIS-PF domains ($r = 0.34$) and moderate correlations between PROMIS-UE and PROMIS-PI ($r = -0.40$; $p < 0.001$ for both comparisons), and weak correlation between PROMIS-PF and PROMIS-PI ($r = -0.29$; $p < 0.001$). No significant correlations were found between age and any PROMIS domain among individuals <40 years old. Among individuals ≥40 years old, PROMIS-UE and PROMIS-PF displayed a high-moderate correlation ($r = 0.62$), PROMIS-UE and PROMIS-PI displayed a moderate correlation ($r = -0.59$), and PROMIS-PF and PROMIS-PI also displayed a moderate correlation ($r = -0.53$; $p < 0.001$ for all comparisons); additionally, age had a moderate correlation with PROMIS-UE ($r = -0.41$; $p < 0.001$) and a moderate-weak correlation with PROMIS-PF ($r = -0.33$; $p = 0.002$). There was no significant correlation between age and PROMIS-PI among individuals ≥40 years old ($p = 0.329$) (Table III).

Discussion

The results of the present study show that a reference score of 50 for the PROMIS-PF, PROMIS-UE, and PROMIS-PI CAT domains may not be applicable to patients under the age of 40 years. In individuals ≥40 years old, however, scores in these domains do approach the stated reference value of 50.

The principal finding of this study was that, in individuals <40 years old, the scores for PROMIS-UE (55.9) and PROMIS-PF (59.7) exceeded the reference score of 50 by over one-half of a standard deviation and 1 standard deviation difference, respectively. These values may be more accurate when assessing the efficacy of orthopaedic treatment in younger patients[20-23]. Among individuals ≥40 years old, the average PROMIS-PF and PROMIS-UE scores did approach 50. This would be consistent with the reported validation techniques used in the creation of the PROMIS measures, as older participants were selectively utilized in determining reference values[15]. Therefore, a score of 50 for physical function domains would be reasonable as a reference value in this patient age group.

Similarly, PROMIS-PI scores were significantly lower for individuals <40 years old (43.6) compared with those ≥40 years old (49.0; $p < 0.001$), indicating that a normal PROMIS-PI score is more than one-half of a standard deviation lower than the stated reference score of 50 for individuals <40 years old. As with physical function, for individuals ≥40 years old, a reference score of 50 may be reasonable for PROMIS-PI measures.

High ceiling effects were found for PROMIS-PF and PROMIS-UE, whereas high floor effects were found for PROMIS-PI. Given the asymptomatic nature of the study cohort, these findings were not surprising; however, the degree of ceiling and floor effects was found to be impacted by participant age, with less of an effect among individuals ≥40 years old. These findings again demonstrate the impact of age on PROMIS CAT scores in healthy participants. Most importantly, among individuals ≥40 years old, age correlated significantly with both PROMIS-PF and PROMIS-UE. Several studies have reported a similar impact of age on multiple PROMIS domains, but no study to our knowledge has reported these differences among asymptomatic adults[24,25]. If baseline function and pain scores decline as patients age, physicians must consider analyzing PROMIS values in a discriminatory fashion when assessing clinical improvement in the elderly. The

TABLE IV Postoperative PROMIS Scores in the Orthopaedic Literature*

Author (Year)	Anatomical Region	Mean Age *(yr)*	Postoperative Time *(mo)*	PROMIS-PF*	PROMIS-PI*
Chen et al. (2018)[30]	Knee	26.5	4.5	46.6 ± 7.0	47.3 ± 8.8
Papuga et al. (2014)[34]	Knee	29.5	12	55.0 ± 10.0	–
Bernholt et al. (2018)[39]†	Knee	53.3	1.5	43.4	55.5
Bernstein et al. (2018)[28]	Foot & ankle	–	14.4	42.3 ± 8.5	55.2 ± 8.6
Dean et al. (2017)[31]	Foot & ankle	52.7	75	51.9 ± 10.0	47.8 ± 8.5
Ho et al. (2016)[32]	Foot & ankle	53.2	9.9	42.6 ± 7.1	57.1 ± 8.5
Koltsov et al. (2017)[36]	Foot & ankle	53	6	47.8 ± 7.9	51.0 ± 8.3
Nixon et al. (2018)[33]	Foot & ankle	–	6.9	43.1 ± 7.4	54.5 ± 8.3
Raad et al. (2019)[35]	Spine	54	1.5	36.0 ± 8.8	65.0 ± 7.8
Rubery et al. (2019)[40]	Spine	40.1	2.9	44.1 ± 8.7	55.1 ± 9.8
Blank et al. (2018)[29]	Metastatic bone disease	–	3	45.7 ± 8.5	48.6 ± 3.0
Quispe et al. (2016)[37]	Shoulder	31.7	12	48.6 ± 7.4	–
Chen et al. (2019)[41]	Shoulder	67.6	9.5	44.1 ± 7.0	52.6 ± 8.6
Bozzio et al. (2016)[38]	Hip	47.5	19	66.4 ± 9.7	–

*Values are given as the mean and standard deviation. †Standard deviations not available.

present study also showed that PROMIS-PI was moderately correlated with PROMIS-PF and PROMIS-UE among individuals ≥40 years old, whereas the correlation was weak among those <40 years old for PROMIS-PF and moderate for PROMIS-UE. Thus, a reduction in pain would signify a positive overall increase in physical function, which is more prominent in an older population. Although multiple studies have already elucidated correlations between PROMIS domains[17,26,27], it is important to understand that these correlations are seen in non-disabled reference populations as well.

The present study is important because it documents true reference values for PROMIS CAT domains in physically healthy individuals. Although it is reasonable to hope that the functional health of a patient following an orthopaedic surgical procedure would approach that of a disability-free reference population, many studies have shown otherwise (Table IV)[28-41]. For example, although the young cohort in the study by Chen et al.[30] had a similar average age to that of the younger cohort in the present study, there were no similarities between the postoperative scores in that study and the reference values in the present study; however, this disparity may be attributable to the short follow-up period of 4.5 months in the study by Chen et al., as Papuga et al.[34] reported a mean postoperative PROMIS-PF score of 55.0 in a young cohort with 1 year of follow-up. A good understanding of healthy reference values for PROMIS CAT domains would improve the ability of the surgeon to properly counsel patients who are considering elective treatment. Physicians should utilize current literature on postoperative improvements in PROMIS scores in coordination with these revised reference scores so that patients may better understand both their physical health and the potential impact of a surgical procedure.

The present study does have notable limitations. Because of the study design, participants were primarily recruited from the local metropolitan area of the host institution, and demographic data, including previous injury or surgical history, were not queried in order to promote a greater response rate. Therefore, the study findings may not be generalizable to different geographic regions, and we were not able to provide a statistical analysis that isolated age as the sole contributor to domain score skewing; however, by nature, PROMIS CAT forms do not have different stratifications for scoring based on comorbidities or patient demographics. Interestingly, respondent data for both cohorts included scores for the lowest function and highest pain measurable, potentially contradicting the presence of no pain or disability. These outliers may be attributable to the respondent misunderstanding the forms, although these were very few samples and thus should not be alarming. Further, the PROMIS CAT domains were presented in English, thereby excluding individuals who were not able to communicate in English, which further limits the generalizability. To minimize these concerns, a wide age range was recruited without any selection for activity level or profession. Further studies may benefit from addressing these reference values in pain and disability-free athletes to better identify how these domains respond to levels of varying athletic involvement.

In conclusion, for individuals <40 years old, the stated reference score of 50 for PROMIS-PF, PROMIS-UE, and PROMIS-PI does not accurately represent physically healthy, asymptomatic individuals. Instead, scores of >50 for PROMIS-PF and PROMIS-UE and <50 for PROMIS-PI are more accurate measures of a non-disabled, asymptomatic young adult. In contrast, for individuals ≥40 years old, the reference score of 50 for these measures is relatively accurate. Identification of asymptomatic reference scores for these PROMIS CAT measures is important in assessing the true efficacy of orthopaedic interventions. ■

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