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PROMIS CAT forms demonstrate responsiveness in patients following reverse shoulder arthroplasty across numerous health domains: Responsiveness of PROMIS after RSA

Sreten Franovic

Kevin A. Taylor

Noah A. Kuhlmann

Fadi Aboona

Collin Schlosser

See next page for additional authors

Authors

Sreten Franovic, Kevin A. Taylor, Noah A. Kuhlmann, Fadi Aboona, Collin Schlosser, and Stephanie Muh

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PROMIS CAT forms demonstrate responsiveness in patients following reverse shoulder arthroplasty across numerous health domains

*Sreten Franovic, Kevin Taylor, Noah Kuhlmann, Fadi Aboona, Collin Schlosser, and Stephanie J. Muh**

Henry Ford Health System, Department of Orthopaedic Surgery, 2799 W Grand Blvd, Detroit, MI 48202, USA

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ABSTRACT

Background: To better optimize the administration and postoperative tracking of patients using PROM, the Patient-Reported Outcomes Measurement Information System (PROMIS) was established by the National Institutes of Health. PROMIS CAT domains have been since validated in multiple orthopedic interventions of the shoulder. However, no one to date has studied the responsiveness of PROMIS CAT domains in a cohort of patients undergoing reverse shoulder arthroplasty. The purpose of this study was to investigate the responsiveness of three PROMIS CAT domains in patients undergoing reverse shoulder arthroplasty.

Methods: Patients undergoing reverse shoulder arthroplasty by a board-certified shoulder and elbow surgeon were included in this study. PROMIS CAT Upper Extremity Physical Function ("PROMIS-UE"), Pain Interference ("PROMIS-PI"), and Depression ("PROMIS-D") scores were collected preoperatively and at five postoperative timepoints. Patient-centric demographic factors, range of motion, and clinical characteristics were also reviewed and analyzed for association with PROMIS scores.

Results: 104 patients undergoing primary reverse shoulder arthroplasty were included in this study. The patient cohort consisted of 52 males (50%), with an average age of 70.3 years (standard deviation, 11.2), and a BMI of 30.2 (standard deviation, 6.1). All three PROMIS domains showed significant improvement as early as 6 weeks after surgery, with values of 32.4 ± 6.6, 56.2 ± 7.5, and 44.6 ± 8.6, for PROMIS-UE, PROMIS-PI, and PROMIS-D, respectively. Significant improvements were noted for each postoperative timepoint thereafter, with 1-year follow-up values as follows: 42.1 ± 8.7, 52.5 ± 8.6, and 43.6 ± 9.5 for PROMIS-UE, PROMIS-PI, and PROMIS-D, respectively. Moderate correlations were identified with postoperative PROMIS-UE and abduction ($r = 0.439$, $p < 0.01$), as well as postoperative PROMIS-PI and PROMIS-D ($r = 0.502$, $p < 0.01$).

Conclusions: PROMIS CAT forms demonstrate responsiveness in patients undergoing reverse shoulder arthroplasty.

Level of Evidence: Level II; Retrospective Study

Approval for this study was received from the Henry Ford Health System Institutional Review Board Committee (no. 11,361).

*Corresponding author: Stephanie J Muh, MD, Division of Hand and Upper Extremity, Department of Orthopaedic Surgery, Henry Ford Health System, West Bloomfield, MI, USA

E-mail address: smuh1@hfhs.org (S.J. Muh).

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1. Introduction

Surgical management of end-stage glenohumeral joint arthritis, with or without rotator cuff arthropathy, has steadily increased in prevalence over the past decades [22]. For years, total shoulder arthroplasty (TSA) and hemiarthroplasty (HA) were the leading operative interventions for patients suffering from severe arthritis of the glenohumeral joint, but after FDA approval in 2003, reverse shoulder arthroplasty (RSA) became popularized in this patient cohort. RSA procedures have since increased in numbers, in accordance with large increases of total volume of shoulder arthroplasties, while both TSA and HA procedures have shown decreases in relative volume [5,25]. As such trends outline, orthopedic surgeons in recent years have been presented with multiple feasible options for treatment of cuff tear arthropathy. Several patient-reported outcome measures (PROM) have been established and validated in shoulder arthroplasties to better aid physicians and patients in the understanding of their postoperative outcomes [2,3,21,23]. However, the majority of PROM have been inconsistently used and reported in the literature and thus has challenged their optimization in orthopedic use.

To better optimize the administration and postoperative tracking of patients using PROM, the Patient-Reported Outcomes Measurement Information System (PROMIS) was established by the National Institutes of Health. PROMIS has emerged as a highly reliable and precise PROM that decreases the burden on both health care providers and patients [12,20]. Moreover, PROMIS computer adaptive testing (CAT) forms have demonstrated advantageous psychometric properties when compared to other traditional PROM [11,24]. With the use of item-response theory (IRT), PROMIS CAT forms ask patients fewer questions per survey, and thus result in less administration time in clinic [14]. Furthermore, each PROMIS CAT domain is standardized to a reference population, so that a score of 50 represents the mean and a change of 10 points represents 1 standard deviation.

PROMIS CAT domains have been validated in multiple orthopedic interventions of the shoulder [10,17]. PROMIS Upper Extremity (UE), PROMIS Pain Interference (PI), and PROMIS Depression (D), have shown external validity and responsiveness in patients undergoing rotator cuff repair [7,19]. Responsiveness is defined as the ability of PROM scores to change over time in line with postoperative recovery. In total shoulder arthroplasty patients, PROMIS CAT forms have also shown strong external validity when compared with other traditional shoulder measures, such as the American Shoulder and Elbow Surgeons (ASES), Marx Shoulder Activity Scale, Short Form-36 (SF-36pF), and the Western Ontario Osteoarthritis Shoulder (WOOS) index [4,9]. Furthermore, preoperative PROMIS scores have shown the ability to predict postoperative recovery of patients undergoing TSA [1]. One study investigated the functional workspace (FWS), a clinical measure of shoulder mobility, of patients undergoing TSA or RSA at different clinical time points and found significant correlation of these values with PROMIS-UE [18]. Flurin et al. previously elucidated key differences in outcome scores and range of motion for RSA patients, when compared to TSA patients, such as: lower active abduction, internal rotation, and active and passive external rotation. RSA patients also displayed significantly greater outcome improvements, but significantly less gain in ROM measures [8]. However, no one to date has studied the responsiveness of PROMIS CAT domains in a cohort of patients undergoing reverse shoulder arthroplasty for cuff tear arthropathy.

The purpose of this study was to investigate the responsiveness of multiple PROMIS CAT forms in patients undergoing reverse shoulder arthroplasty. We hypothesize that PROMIS-UE, PROMIS-PI, and PROMIS-D will all significantly improve after surgery.

2. Methods

Institutional review board approval was obtained prior to initiation of this retrospective study. 105 total patients with cuff tear arthropathy who underwent reverse shoulder arthroplasty by a board-certified shoulder and elbow surgeon, between December 2017 and August 2019, were included in this study. Patients were first identified by Current Procedural Terminology (CPT) code 23,472 and then a chart review was conducted to separate reverse shoulder arthroplasty patients from total shoulder arthroplasty patients (TSA). TSA patients were not included in the analysis for this study. Three PROMIS CAT forms were administered to patients at their clinical visit: Upper Extremity Physical Function v2.0, Pain Interference v1.1, and Depression v1.0. The surveys were completed on a tablet computer (iPad tablet; Apple Inc., Cupertino, CA, USA) through REDCap (Research Electronic Data Capture), a password-encrypted, web-based platform approved for storage and data capture. A larger score in each domain represents a greater amount of the item being measured. Thus, a higher PI score would represent a larger interference of pain on a patient's life, while a greater UE score would indicate greater upper extremity physical functioning.

Inclusion criteria were as follows: English-speaking patients undergoing reverse shoulder arthroplasty over the age of 18 that presented with cuff tear arthropathy. Exclusion criteria included patients undergoing revision, presence of infection at the surgical site, humeral fracture, or refusal to complete PROMIS CAT forms. Initially, 158 patients were identified using CPT code indexing as previously established. Of these patients, 28 were removed due to undergoing total shoulder arthroplasty and a further 25 patients were removed due to incomplete PROMIS CAT domains leaving 105 patients in our cohort.

Patients provided demographic information in conjunction with PROMIS scores. The following patient-centric factors were collected: age, sex, race, employment status, body mass index (BMI), tobacco use, and zip code. Zip code was used to estimate median household income (MHI), following a previously published methodology [7], using the United States Census Bureau website (https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml?src=bkmk).

Medical charts were reviewed to determine the following preoperative range of motion values: ABER (abduction with external rotation), ABIR (abduction with internal rotation), forward flexion, abduction, internal rotation, and external

rotation. Due to lack of consistent postoperative reporting, only Abduction and Forward Flexion were assessed at the latest clinical timepoint. Operative notes were gleaned for degree of glenoid version, prior to intervention, and patient ASA (American Society of Anesthesiologists) status.

3. Results

104 patients undergoing primary reverse shoulder arthroplasty were included in this study. The patient cohort consisted of 52 males (50%), with an average age of 70.3 years (standard deviation, 11.2), and a BMI of 30.2 (standard deviation, 6.1). All 104 implants showed intactness on postoperative radiological exams, at latest follow-up, and no revision surgeries were performed to date. Further patient demographics and clinical characteristics can be seen in Table 1.

Baseline preoperative PROMIS CAT scores were 29.3 ± 6.3, 63.8 ± 5.1, 49.6 ± 10.1, for PROMIS-UE, PROMIS-PI, and PROMIS-D, respectively. Only PROMIS-UE showed significant change (23.6 ± 5.6, $p < 0.05$) at the first clinical time point of 2-weeks after surgery. All three PROMIS domains showed significant improvement as early as 6 weeks after surgery, with values of 32.4 ± 6.6, 56.2 ± 7.5, and 44.6 ± 8.6, for PROMIS-UE, PROMIS-PI, and PROMIS-D, respectively. Significant improvements were noted for each postoperative timepoint thereafter, with 1-year follow-up values as follows: 42.1 ± 8.7, 52.5 ± 8.6, and 43.6 ± 9.5 for PROMIS-UE, PROMIS-PI, and PROMIS-D, respectively. Repeated measures ANOVA showed significant change across time for each PROMIS domain ($p < 0.05$). Values for each time point, along with ESI, can be seen in Fig. 1 and Table 2.

PCA analysis demonstrated that improvement of PROMIS-PI and PROMIS-D were significant factors correlated with improvement of PROMIS-UE ($p < 0.05$). Preoperative forward flexion and abduction were significant factors correlated with preoperative PROMIS-UE ($p < 0.05$). Therefore, preoperative PROMIS-UE t scores were grouped in buckets of <20.0, 20.0–30.0, and >30.0 to visualize the change in both PROMIS-UE and PROMIS-PI for patients with varying preoperative upper limb function Figs. 2 and 3.

External validity analysis revealed moderate correlations between preoperative PROMIS-UE and PROMIS-PI ($r = -0.585$, $p < 0.01$), PROMIS-UE and ABIR ($r = 0.441$, $p < 0.05$), and between PROMIS-PI and PROMIS-D ($r = 0.436$, $p < 0.01$). Postoperatively, moderate correlations were noted between PROMIS-UE and abduction ($r = 0.439$, $p < 0.01$) and between PROMIS-PI and PROMIS-D ($r = 0.502$, $p < 0.01$) Table 3.

Both PROMIS-UE and PROMIS-PI showed significantly different scores when compared across sex. Males displayed higher physical function (32.0 ± 6.2 vs 26.6 ± 5.1, $p < 0.05$) and lower pain interference (62.5 ± 4.8 vs 65.1 ± 5.1, $p < 0.05$). No differences were noted for PROMIS-D. No differences in any PROMIS domain were noted for employment, smoking status, or race.

3.1. Statistical analysis

All available data ($N = 105$) were analyzed. The primary outcome of interest in this study was the responsiveness of each PROMIS domain postoperatively. Power analysis revealed the study would require 50 patients with pre- and postoperative scores to achieve 80% power using an alpha value of 0.5. Repeated measures analysis of variance (ANOVA) was used to determine significant differences at postoperative time points. The Least Significant Difference (LSD) Post Hoc test was used to determine specific differences between each postoperative time point and the baseline (preoperative) score. Effect size indices (ESIs) were generated to determine the ability for each PROMIS domain to detect change, at each time point. The following guidelines were used for assessing ESI effect: <0.2, low effect; 0.2–0.8, moderate effect; >0.8, large effect [13,15]. Principal component analysis (PCA, Rotation Method: Varimax with Kaiser Normalization) was performed to isolate which group of preoperative factors could predict improvement of each PROMIS domain. External validity was assessed using Pearson and Spearman's correlation coefficients which identify interdomain correlation between PROMIS scores, as well as associations between preoperative PROMIS domains and preoperative range of motion. The correlation coefficients (r) were interpreted as follows: <0.19, very weak; 0.20–0.39, weak; 0.40–0.59, moderate; 0.60–0.79, strong; 0.80–1.00, very strong [6].

Table 1 – Patient characteristics.

Characteristic	Mean	Standard deviation
Age	70.3	11.2
Sex, n (%)		
Male	52 (50.0%)	
Female	52 (50.0%)	
BMI	30.2	6.1
MHI	$67,078	$23,628
Smoking Status		
Never	42 (40.4%)	
Former	56 (53.8%)	
Current	6 (5.8%)	
Race		
White/Caucasian	74 (71.2%)	
African-American	24 (23.1%)	
Asian/Middle Eastern	6 (6.7%)	
Preoperative ROM (degrees)		
ABER	73.5	13.9
ABIR	37.5	19.2
Abduction	96.0	44.3
Flexion	107.6	45.2
External Rotation	24.8	17.5
ASA Class		
1	4 (3.8%)	
2	39 (37.5%)	
3	59 (56.7%)	
4	2 (1.9%)	
Preoperative Glenoid Version (degrees)	−9.9	11.8

Abbreviations: Body Mass Index (BMI); Median Household Income (MHI); Range of Motion (ROM); Abduction and External Rotation (ABER); Abduction and Internal Rotation (ABIR); American Society of Anesthesiologists (ASA).

4. Discussion

The results of the present study suggest that PROMIS CAT domains are responsive in adult patients undergoing reverse shoulder arthroplasty. Furthermore, statistically significant

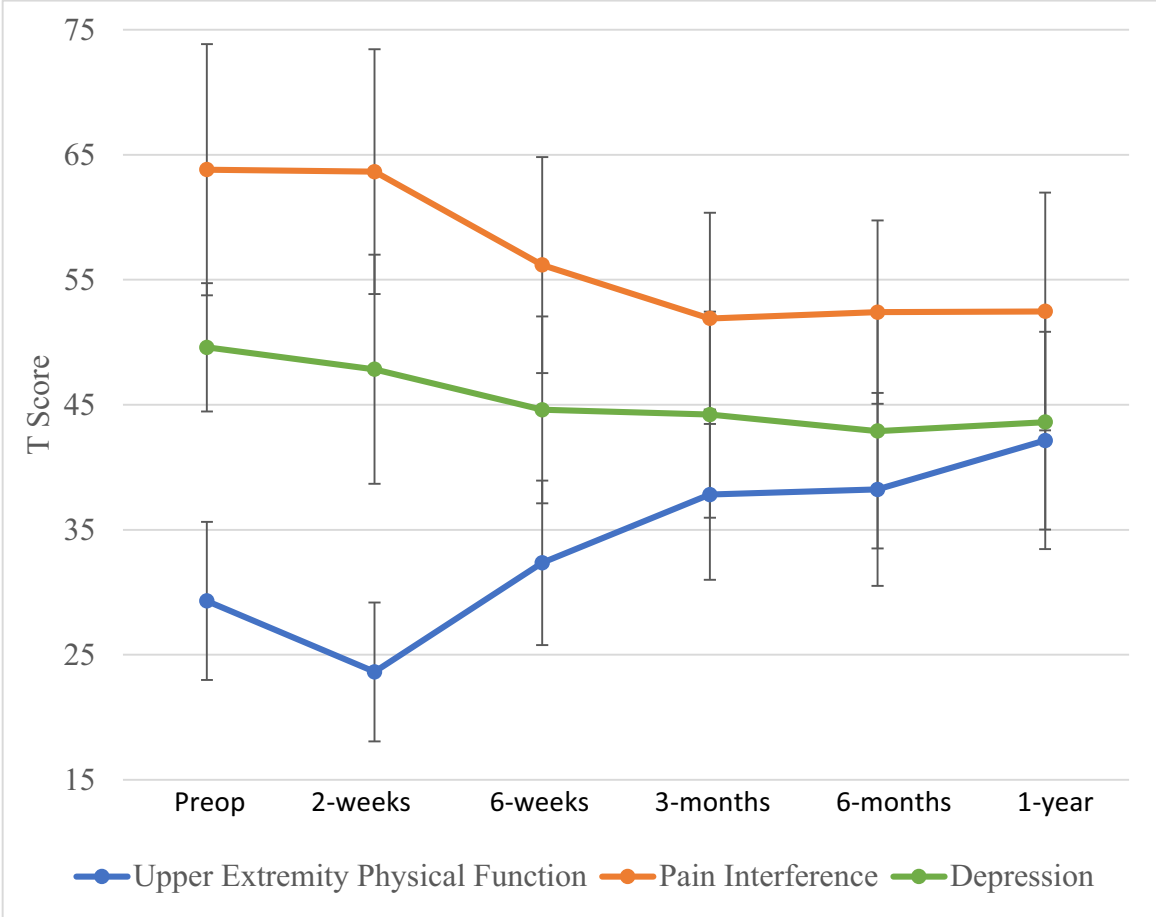

Fig. 1 – Responsiveness of PROMIS to intervention over time (Mean ± SD). Patients show improvement in all three PROMIS domains after reverse shoulder arthroplasty.

improvements can be seen as early as 6-weeks postoperatively in PROMIS-UE, PROMIS-PI, and PROMIS-D.

Many cross-sectional studies of PROMIS CAT domains outline the efficiency, validity, and responsiveness in patients with upper extremity pathology [7,10,16]. More specifically, PROMIS CAT domain studies have also been validated as responsive and useful measures for tracking total shoulder arthroplasty patients [1,18], but no study to date has demonstrated the responsiveness or efficacy of PROMIS CAT domains in measuring symptomatic states of reverse shoulder arthroplasty patients. The present study confirms our hypothesis that PROMIS-UE, PROMIS-PI, and PROMIS-D all demonstrate responsiveness to postoperative progression among reverse shoulder arthroplasty patients. Unlike other studies evaluating PROMIS effectiveness in shoulder arthroplasty cohorts, our study isolated reverse shoulder arthroplasties from total shoulder arthroplasty patients. Furthermore, as opposed to the cross-sectional nature of many previous studies, the present study longitudinally assessed patients before and after surgery and showed significant improvements in each PROMIS CAT domain at 1-year follow-up: 29.3–42.1 for PROMIS-UE, 63.8–52.5 for PROMIS-PI, and 49.6–43.6 for PROMIS-D.

Table 2 – Multiple comparisons of PROMIS scores between pre- and postoperative time points.

Measure	Baseline	2-Weeks	6-Weeks	3-Months	6-Months	1-Year
PROMIS-UE	29.3 ± 6.3	*23.6 ± 5.6	*32.4 ± 6.6	*37.8 ± 6.8	*38.2 ± 7.7	*42.1 ± 8.7
ESI		0.90	0.49	1.35	1.41	2.03
PROMIS-PI	63.8 ± 5.1	63.7 ± 9.2	*56.2 ± 7.5	*51.9 ± 8.2	*52.4 ± 9.4	*52.5 ± 8.6
ESI		0.02	1.49	2.33	2.24	2.22
PROMIS-D	49.6 ± 10.1	47.8 ± 9.8	*44.6 ± 8.6	*44.2 ± 8.5	*42.9 ± 7.3	*43.6 ± 9.5
ESI		0.18	0.50	0.53	0.66	0.59

Abbreviations: Patient-Reported Outcomes Measurement Information System (PROMIS); Upper Extremity (UE); Pain Interference (PI); Depression (D); Effect Size Index (ESI).

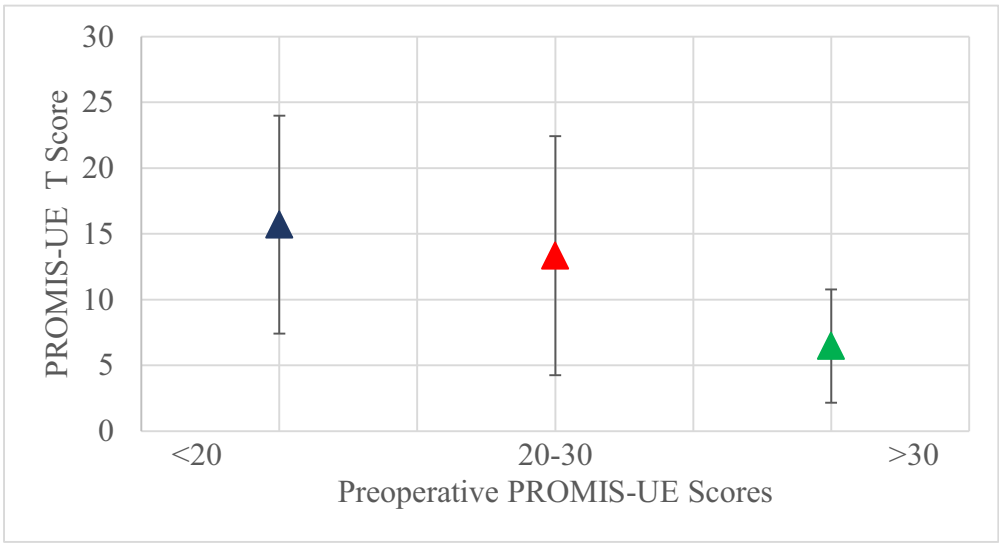

Fig. 2 – Change in PROMIS-UE scores grouped by preoperative PROMIS-UE buckets. Asterisks are used to denote statistically significant differences ($p < 0.05$). Abbreviations: Patient-Reported Outcomes Measurement Information System (PROMIS); Upper Extremity (UE).

Beyond the ability of PROMIS CAT domains to dynamically change relative to postoperative patient symptomatic states, we show extensive external validity of each domain by means of interdomain correlations. Significant correlations among upper extremity physical functioning scores and multiple range of motion measurements (ABER, ABIR, abduction, forward flexion) demonstrate the ability of PROMIS-UE to assess real clinical presentations. These results are not atypical, as previous studies have suggested such correlation among PROMIS domains in shoulder surgeries [1,7]. Fisk et al. evaluated similar correlations among PROMIS CAT domains in patients undergoing rotator cuff repair [7]. Unlike their results, we show no significant correlation in preoperative PROMIS-UE and PROMIS-D but echo their findings of significant correlations between PROMIS-UE and PROMIS-PI both pre- and postoperatively. These differences may be explained due to the degenerative, end-stage nature of shoulder injuries requiring reverse shoulder arthroplasties. Patients undergoing RSA may have learned to adapt to their disability and pain during the course of arthritic progression, and thus their depression scores may not reflect changes in functioning as clearly as rotator cuff repair patients' do.

While unique in its nature, this study does present with notable limitations. Primarily, all patients originated from an

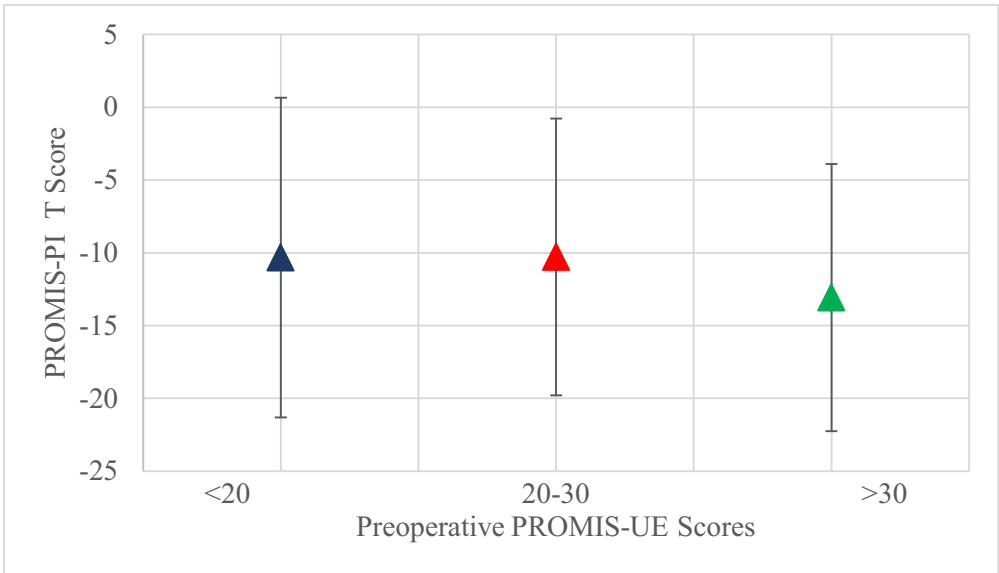

Fig. 3 – Change in PROMIS-PI scores grouped by preoperative PROMIS-UE buckets. Abbreviations: Patient-Reported Outcomes Measurement Information System (PROMIS); Upper Extremity (UE); Pain Interference (PI).

Table 3 – Correlation of PROMIS domains and ROM.

Domain	R^2	*P* value	Correlation strength
Preoperative			
PROMIS-UE and PI	−0.585	<**0.01**	Moderate
PROMIS-UE and D	−0.056	0.656	None
PROMIS-UE and ABER	0.373	**0.046**	Weak
PROMIS-UE and ABIR	0.441	**0.027**	Moderate
PROMIS-PI and D	0.436	<**0.01**	Moderate
Postoperative			
PROMIS-UE and PI	−0.392	<**0.01**	Weak
PROMIS-UE and D	−0.339	<**0.01**	Weak
PROMIS-UE and Ab	0.439	<**0.01**	Moderate
PROMIS-UE and FF	0.341	**0.025**	Weak
PROMIS-PI and D	0.502	<**0.01**	Moderate

Abbreviations: Patient-Reported Outcomes Measurement Information System (PROMIS); Range of Motion (ROM); Upper Extremity (UE); Pain Interference (PI); Depression (D); Abduction and External Rotation (ABER); Abduction and Internal Rotation (ABIR); Abduction (Ab); Forward Flexion (FF).

English-speaking metropolitan area, and thus these results may not be generalizable to other geographies, such as rural and remote patient populations. Furthermore, no other patient-reported outcome measures were utilized in this study for comparison against PROMIS domains. We acknowledge these limitations and note that a descriptive patient demographics section was included to display a wide range of MHIs and racial backgrounds to demonstrate the diverse socioeconomic status present in our cohort. Furthermore, by correlating preoperative ROM values to PROMIS domains, we provided a means to validate the PROMIS domains with clinical measures. While our function and depression results don't reach normative values provided by PROMIS, we can see that our pain values do near these values and overall the patient progression nearly follows previous shoulder studies [1,7]. These finidngs are also noted in elderly normative value cohorts from the literature [26]. To our knowledge, no literature suggests that these patients reach normative averages of physical functioning at any postoperative timepoint. Lastly, our study did not aim to identify further clinically relevant measure, such as minimal clinically important differences (MCID), thus limiting the analysis of improvement at our follow-up time periods. The only currently published work on MCID in shoulder arthroplasty patients defines an improvement of PROMIS-PF by 4.0, PROMIS-PI by 3.2, and PROMIS-D by 4.3. Using these values, our study shows achievement of MCID at 3-months for all three domains.

5. Conclusion

Reverse shoulder arthroplasty patients can be effectively measured postoperatively by use of three PROMIS CAT domains: PROMIS-UE, PROMIS-PI, and PROMIS-D. These three domains show responsiveness and significant improvement as early as 6-weeks postoperatively. No patient-centric factor, other than sex, influenced preoperative PROMIS CAT domains. Thus, clinicians should consider their current patient-reported outcome collection to include PROMIS CAT domains in shoulder arthroplasty patients.

Declaration of Competing Interest

None.

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