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Clinical Study

# Validity and responsiveness of PROMIS in adult spinal deformity: The need for a self-image domain

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**Abstract**

**BACKGROUND CONTEXT:** Validity and responsiveness of the Patient-Reported Outcomes Measurement Information System (PROMIS) have been investigated in several orthopaedic subspecialties. PROMIS has shorter completion time and greater research flexibility for the heterogeneous adult spinal deformity (ASD) population versus the Oswestry Disability Index (ODI) and Scoliosis Research Society 22-item questionnaire (SRS-22r).

**PURPOSE:** Evaluate the validity and responsiveness of PROMIS in ASD surgery, during the early postoperative period.

**DESIGN:** Prospective, longitudinal study.

**PATIENT SAMPLE:** One hundred twenty-three patients with complete SRS-22r and PROMIS data.

**OUTCOME MEASURES:** Validity and responsiveness of PROMIS versus the ODI and SRS-22r.

**METHODS:** We identified patients who completed SRS-22r, ODI, and PROMIS questionnaires. Spearman's correlation was used to assess validity, paired-samples *t* tests to assess responsiveness, and Cohen's d to assess measure of effect. The authors report no conflicts of interests. No funding was received in support of this study.

**RESULTS:** One hundred twenty-three patients with SRS-22r and PROMIS data from the preoperative visit were included in the validity analysis. Seventy-six patients with preoperative and early postoperative (6-week to 3-month) data were included in the responsiveness analysis. The SRS-22r function, self-image, pain, and mental health scores were moderately to strongly correlated with the following PROMIS domains: physical function ($r = 0.53$), satisfaction with participation in social roles ($r = 0.51$), pain ($r = -0.60$), and anxiety ($r = -0.73$). All SRS-22r domains, PROMIS domains, and ODI scores changed significantly from preoperatively to postoperatively ($p < 0.05$). Compared with the SRS-22r, PROMIS showed superior responsiveness across all domains except self-image.

**CONCLUSIONS:** Our results indicate that PROMIS is a valid measure with comparable responsiveness to that of the SRS-22r and ODI during the early period after ASD surgery. However, a domain that reflects how ASD patients perceive their self-image should be developed and validated. 

*Keywords:* Adult spinal deformity; Effect size; Oswestry Disability Index; Patient-reported outcomes; Patient-Reported Outcomes Measurement Information System; Responsiveness; Scoliosis Research Society 22-item questionnaire; Validity.

FDA device/drug status: Not applicable.

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## Introduction

Adult spinal deformity (ASD) is a prevalent condition that reduces patients' quality of life [1,2]. Surgery is superior to nonoperative treatment of ASD [3,4], but comprehensive treatment also includes pain management, patient education, and physical therapy. Outcomes after surgery are variable and difficult to predict. Therefore, patient-reported outcome (PRO) measures are important for customizing treatment strategies on the basis of patient feedback. A number of validated tools are commonly used in the ASD population, including the Oswestry Disability Index (ODI), the Scoliosis Research Society 22-item questionnaire (SRS-22r), and the 36-Item Short-Form Health Survey [5–7]. However, these tools have limitations, which include inflexibility (ie, a rigid set of questions that are not adaptable for the heterogeneous ASD population [8]) and the administrative and patient burdens associated with completing surveys [9].

Recently, the Patient-Reported Outcomes Measurement Information System (PROMIS) was developed with support from the National Institutes of Health to overcome many of the shortcomings of PRO tools. PROMIS is a unique metric for use across various disease states and minimizes the number of questions the patient must answer without compromising reliability, flexibility, or precision [10]. Through computer-adaptive testing (CAT), PROMIS generates questions based on the patient's previous answers, greatly contributing to its flexibility. The reliability, responsiveness, and validity of PROMIS have been investigated in various diseases. PROMIS has been shown to be comparable or superior to disease-specific PRO tools in prostate cancer, human immunodeficiency virus, and degenerative spine surgery [11–13].

Outcomes during the early period after ASD surgery are important, because they have been shown to be predictive of long-term outcomes [14]. Given that the validity and responsiveness of PROMIS in the ASD population have not been reported, the aims of this study were to investigate (1) the validity of PROMIS in ASD surgery and its correlation with commonly used metrics and (2) the responsiveness of PROMIS and its ability to detect change in outcomes between the preoperative and early postoperative periods in ASD patients.

## Methods

Approval for this study was obtained from our institutional review board.

### *Data source and patient characteristics*

This was a prospective, longitudinal study. Patients aged 18 years or older who were treated operatively for ASD (major curve, >30°) and who presented to our clinic after March 2015 for a preoperative visit were invited to participate (our institution incorporated PROMIS as a PRO tool in March 2015). The aim of our responsiveness analysis was to assess the ability of PROMIS to detect changes from the preoperative to the postoperative period; thus, only patients with complete preoperative and postoperative data were included in the analysis. We investigated the validity of PROMIS compared with the ODI and SRS-22r by measuring the strength of their correlations at the preoperative visit. The early postoperative period was defined as 6 weeks to 3 months after ASD surgery.

## PROMIS

We investigated 4 PROMIS domains: anxiety, pain intensity, satisfaction with social roles, and activities (herein referred to as social satisfaction), and physical function. Each is scored on a scale of 0 to 100. Higher scores indicate worse anxiety and pain levels, whereas higher scores in the case of physical function and social satisfaction indicate more favorable outcomes. CAT selects only items that are able to sharpen the estimate of a patient's score on the basis of previous answers [15].

### *Validity*

Validity was defined as the correlation between the PROMIS domains of physical function, social satisfaction, pain, and anxiety with the SRS-22r domains of function, self-image, pain, and mental health, respectively. We also investigated correlations between the 4 PROMIS domains and the ODI. Spearman's correlation was used to assess the correlation between the PROMIS domains, ODI, and SRS-22r domains captured for every preoperative patient visit [16].

### *Responsiveness*

Pairwise Student *t* tests comparing the preoperative and early postoperative follow-up scores were used to assess the change in PROs. The standard estimates of effect size were made by measuring Cohen's d, in which a larger absolute value indicates greater responsiveness [17]. Effect size was classified as very small (<0.20), small (0.20–0.49), medium (0.50–0.79), large (0.80–1.19), very large (1.20–1.99), or huge (≥2.00) [17]. Statistical analyses were performed using Stata, version 15, software (StataCorp LP, College Station, TX, USA). Significance was assigned at $p < 0.01$.

## Results

### *Patient characteristics*

One hundred twenty-three patients with ASD had preoperative visits after March 2015. Of these patients, 76 had complete data for the early postoperative period (6 weeks–

Table 1
Correlations* (Spearman's rho) between PROMIS domain scores, SRS-22r scores, and ODI scores based on 96 preoperative patient visits in adult spinal deformity patients

| Measure | SRS-22r domain | | | | ODI |
|---|---|---|---|---|---|
| | Function | Self-image | Pain | Mental health | |
| PROMIS domain | | | | | |
| Anxiety | −0.49 | −0.53 | −0.33 | −0.73 | 0.52 |
| Pain | −0.61 | −0.57 | −0.60 | −0.54 | 0.77 |
| Physical function | 0.51 | 0.53 | 0.53 | 0.34 | 0.76 |
| Social satisfaction | 0.50 | 0.56 | 0.56 | 0.53 | −0.64 |
| ODI | −0.62 | −0.62 | −0.67 | −0.49 | |

ODI, Oswestry Disability Index; PROMIS, Patient-Reported Outcomes Measurement Information System; SRS-22r, Scoliosis Research Society 22-item questionnaire.
* All correlations, $p < .01$

3 months) after surgery and were included in the responsiveness analysis. Mean (± standard deviation) patient age was 58 ± 15 years. Seventy-three patients (59%) were older than 65 years. Eighty-nine patients (72%) were women. Patients who had missing postoperative data were not more likely to be older than 65 years (50% vs. 37%, $p = 0.15$). Patient sex was similarly distributed between the 2 groups ($p = 0.63$). However, patients who had missing data were significantly more likely to have been enrolled during the first 3 months of the study (26% vs. 7%, $p = 0.003$).

*Validity*

There were 123 patients with preoperative visits included in the validity analysis (Table 1). The PROMIS physical function domain was moderately correlated with the SRS-22r physical function domain ($r = 0.51$). However, it was correlated strongly with the ODI ($r = 0.76$). The PROMIS social satisfaction domain was moderately correlated with the SRS-22r self-image domain ($r = 0.56$). The PROMIS pain domain was strongly correlated with SRS-22r pain ($r = -0.60$) and function ($r = -0.61$) domains and the ODI ($r = 0.77$). The PROMIS anxiety domain was strongly correlated with the SRS-22r mental health domain ($r = -0.73$). Fig. 1 shows scatter plots with best-fit lines for the PROMIS and SRS-22r domains.

*Responsiveness*

Seventy-six patients with preoperative and complete early postoperative data were included in the analysis. All SRS-22r and PROMIS domains changed significantly from the preoperative to postoperative visit (all $p < 0.05$) (Table 2, Fig. 2). The ODI scores also changed significantly between the preoperative and postoperative visits (preoperative mean, 49 ± 18 vs. postoperative mean, 36 ± 18; $p < 0.001$).

Both the PROMIS and SRS-22r physical function domains demonstrated small effect sizes (−0.29 and −0.23, respectively). Similarly, the SRS-22r mental health domain and the PROMIS anxiety domain exhibited small effect sizes. However, the responsiveness of the pain domain was large in PROMIS ($d = 0.8$) and small in SRS-22r ($d = -0.41$). The SRS-22r self-image domain had a large effect size ($d = -1.25$), whereas the PROMIS social satisfaction domain had a small effect size ($d = -0.55$). The ODI showed a medium effect size of 0.67.

*Number of questions answered*

The number of questions in the ODI (10 items) and the SRS-22r (22 total; 5 each for self-image, pain, physical function, and mental health; and 2 for satisfaction and/or dissatisfaction with management) questionnaires is fixed and predetermined. As for the PROMIS domains, the mean numbers of questions answered in this study were as follows: pain, 3.9 (range: 1–12); physical function, 4.0 (range: 2–12); anxiety, 4.2 (range: 1–13); and social satisfaction, 4.3 (range: 2–13).

## Discussion

This is the first study to investigate the use of PROMIS in ASD surgery. PROMIS was moderately to strongly correlated with most SRS-22r domains in ASD patients. It had superior responsiveness to the SRS-22r domains except for self-image. Collection of PRO data using validated measures helps physicians customize treatments for individual patients in the clinical setting and assess and compare interventions in the research setting. Favorable characteristics of a PRO measure include a small number of items, short completion time, the ability to detect change (responsiveness), and the ability to predict the outcome of interest (validity).

Several studies have investigated the effectiveness of PROMIS as a PRO tool in the setting of orthopaedic specialties, including foot and ankle surgery [18,19] and upper extremity disorders [20,21]. In these settings, PROMIS was equivalent or superior to the "gold standard" tools being used in each subspecialty.

We showed that the SRS-22r function, self-image, pain, and mental health scores correlate moderately to strongly with the PROMIS physical function, social satisfaction, pain, and anxiety domains, respectively. Although the PROMIS physical function domain has been shown to be

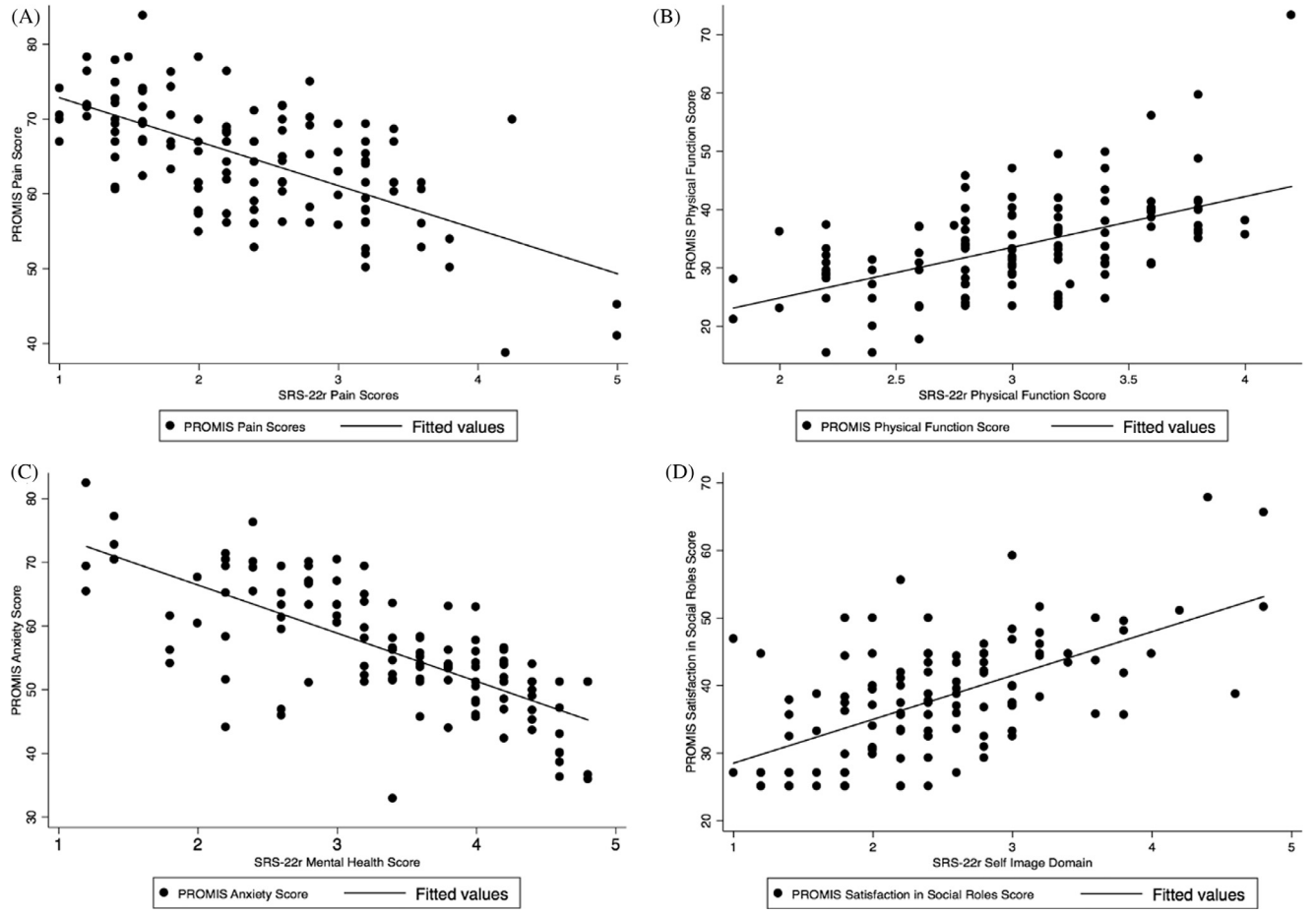


Fig. 1. Scatter plots for (A) Patient-Reported Outcomes Measurement Information System (PROMIS) pain domain versus Scoliosis Research Society 22-item questionnaire (SRS-22r) pain domain; (B) PROMIS physical function domain versus SRS-22r physical function domain; (C) PROMIS anxiety domain versus SRS-22r mental health domain; and (D) PROMIS social satisfaction domain versus SRS-22r self-image domain.

Table 2
Responsiveness of the PROMIS measure compared with traditional patient-reported outcome measures in adult spinal deformity surgery in 43 ASD patients

| Measure | Mean score (SD) | | p value* | Cohen's d (95% CI)† |
|---|---|---|---|---|
| | Preoperative | Postoperative | | |
| ODI | 49(18) | 36 (18) | <0.001 | 0.67 (0.30, 1.03) |
| SRS-22r domain | | | | |
| Function | 3.0 (0.50) | 3.1 (0.52) | 0.036 | −0.23 (−0.56, 0.09) |
| Mental health | 3.4 (0.95) | 3.7 (0.90) | <0.001 | −0.30 (−0.63, .04) |
| Pain | 2.3 (0.81) | 2.7 (0.88) | <0.001 | −0.41 (−0.7, −0.07) |
| Self-image | 2.4 (0.77) | 3.4 (0.83) | <0.001 | −1.25 (−1.6, −0.9) |
| PROMIS domain | | | | |
| Anxiety | 55 (10.3) | 50 (10.2) | <0.001 | 0.46 (0.13, 0.8) |
| Pain | 65 (7.8) | 58 (8.9) | <0.001 | 0.80 (0.45, 1.1) |
| Physical function | 34 (6.8) | 36 (8.8) | 0.018 | −0.29 (−0.62, −0.03) |
| Social satisfaction | 38 (8.9) | 44 (10.9) | <0.001 | −0.55 (−0.9, −0.22) |

CI, confidence interval; ODI, Oswestry Disability Index; PROMIS, Patient-Reported Outcomes Measurement Information System; SD, standard deviation; SRS-22r, Scoliosis Research Society 22-item questionnaire.

* From pairwise Student *t* tests.

† Effect size was classified as very small (<0.20), small (0.20−0.49), medium (0.50−0.79), large (0.80−1.19), very large (1.20−1.99), or huge (≥2.00).

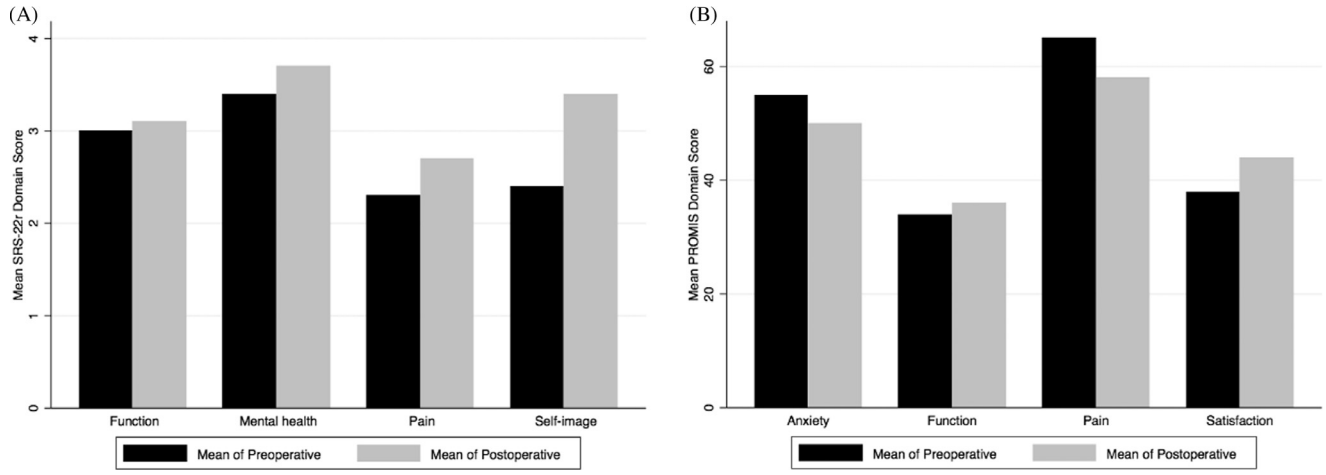


Fig. 2. Changes in (A) Scoliosis Research Society 22-item questionnaire scores and (B) Patient-Reported Outcomes Measurement Information System scores from the preoperative to the 3- to 6-month postoperative visit in 43 adult spinal deformity patients. (All domains except for the SRS-22r physical function domain were significantly different ($p < 0.05$).

highly correlated with ODI and Neck Disability Index scores in the setting of spinal surgery for low back pain [13,22], to our knowledge ours is the first study to investigate PROMIS in the ASD population. Similarly to previous studies in different patient populations [13,22], we found that the PROMIS physical function domain was strongly correlated with the ODI in ASD patients. All PRO tools used in this study were able to detect significant differences between the preoperative and postoperative visits, and our measurements of effect size indicate that PROMIS's responsiveness was comparable to that of the most commonly used PRO tools in the setting of ASD surgery, the SRS-22r and ODI.

The responsiveness of the physical function and mental health domains (anxiety domain in PROMIS) was small in our series. Those 2 SRS-22r domains have been previously shown not to change substantially between the preoperative and early postoperative period [14]. We compared the PROMIS social satisfaction domain with the SRS-22r self-image domain because of the known influence of self-image on social satisfaction [23] and lack of a more specific PROMIS domain. Although, the social satisfaction domain was moderately correlated with the SRS-22r self-image domain, it had lower responsiveness, indicating the possible need for a PROMIS domain that is both correlated with the SRS-22r self-image domain and that has equivalent responsiveness to change. Providers may be more likely to implement PROMIS in the future, given the rising interest in it. However, until a self-image domain is developed, we suggest supplementing PROMIS with the 5 questions of the SRS-22r that constitute its self-image domain. This is particularly important because self-image plays a major role in spinal deformity and has been shown to be an important determinant of outcomes and patient preferences [24]. Furthermore, our results also suggest that patient age and sex do not significantly affect the likelihood of completing PROMIS in the ASD population.

In addition to the advantages inherent in a dynamic PRO tool compared with a static one, Papuga et al. [22] showed that PROMIS, compared with the ODI and neck disability index, required fewer questions and less completion time. This could be helpful in the clinical setting, where time with patients is limited, and it could decrease the patient burden associated with completing surveys. The integration of CAT with PROMIS resulted in simplified data capture, as well as giving patients the option of completing the survey at home using email. Furthermore, the mean number of question was lower for each of the PROMIS domains compared with the SRS-22r domains and the ODI.

This study has several potential limitations. The number of patients with complete postoperative data was relatively low. Patients with missing data were significantly more likely to be enrolled during the first 3 months of the study when PROMIS had been recently introduced and effective data capturing procedures were still being implemented. The validity and responsiveness of PROMIS during the early postoperative period may not be reflective of longer-term follow-up. This is particularly true with regards to responsiveness because time is an important variable when it comes to improvement in PROs postoperatively. As such, responsiveness for some domains may be underestimated in our study. Nevertheless, it is important to understand the differences between the various PRO tools during this period because it constitutes a critical point in the postoperative care of ASD patients. We believe that with longer follow-up, the physical function domain may have a larger effect size because of the length of time required for ASD patients to experience improvement in physical function. We believe that this study is the first to investigate the potential role of PROMIS in ASD patients during a critical postoperative care period.

We found that PROMIS is a valid tool that has comparable responsiveness to the most commonly used questionnaires in ASD surgery. However, there might be a need to develop and

validate a PROMIS domain that can better detect change with respect to ASD patients' self-image before and after surgery. Furthermore, PROMIS may substantially decrease the administrative burden of collecting PRO data after ASD surgery.

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