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OPEN Research Article

Impact of Spinal Deformity Characteristics on Patient-reported Outcome Measurement Information System Scores in Patients With Idiopathic Scoliosis Undergoing Posterior Spinal Fusion

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ABSTRACT

Introduction: The impact of posterior spinal fusion (PSF) on physical function and pain and mental health in pediatric patients as quantified by the Patient-Reported Outcomes Measurement Information System (PROMIS), developed by the National Institute of Health, is largely unknown. The purpose of this study is to report the changes of PROMIS scores for upper extremity (UE), pain interference (PI), mobility (MOB), and peer relationships (PR) after PSF in patients with idiopathic scoliosis (IS), compare postoperative changes in PROMIS PI and Scoliosis Research Society-30 pain scores, and evaluate associations between curve characteristics and PROMIS scores.

Methods: A retrospective cohort of 122 patients (<18 years old) who underwent PSF for IS was identified through electronic medical record search. PROMIS scores were obtained preoperatively and 6 weeks, 6 months, 1 years, 2 years, and 3 years postoperatively.

Results: The mean age of the cohort was 14.2 ± 1.6 years, and the mean Cobb angle was 62.9 ± 13.8° at surgery. Eighty patients had preoperative PROMIS data. UE and MOB scores were statistically lower at 6 weeks and 6 months postoperatively and returned to baseline with a longer follow-up. PI scores were significantly lower at 1 and 2 years postoperatively. PR was unchanged up to 2 years postoperatively and then showed significant improvement. There was a statistically significant negative relationships between lowest instrumented vertebra and PROMIS UE and MOB scores at 6 weeks and 1 year postoperatively, but not at a longer follow-up. There were no significant differences noted in PI and PR PROMIS scores and lowest instrumented vertebra. PROMIS scores were not statistically

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associated with the Lenke Classification, number of vertebral levels fused, or percentage coronal correction.

Discussion: Changes in PROMIS functional domains (UE and MOB) postoperatively normalize at longer follow-ups. Changes in PI and PR demonstrated improvements over preoperative values at 1 to 2 years postoperatively. Preoperative coronal and sagittal measures, and the percentage correction did not correlate with any PROMIS scores.

Patient-reported outcomes (PROs) have become a major tool to measure the impact of disease on patient health and function and the effectiveness of disease treatment and are showing increased significance as payment methods moved to more outcome-based systems. As a part of its Health Roadmap initiative, the National Institute of Health developed the Patient-Reported Outcomes Measurement Information System (PROMIS), a general health PRO system that is independent of diagnosis. PROMIS aims to make the administration and completion of PRO instruments easier by using item response theory to develop validated, item banks for adult and pediatric populations with Computer Adaptive Testing (CAT) to dynamically present 4 to 7 relevant items to patients for their assessment. This combined item response theory and CAT system helps to decrease the number of questions completed at each encounter, thus reducing patient burnout and increasing the reliability when compared with static questionnaires.[1,2] Various adult PROMIS item banks have been validated among many adult populations, but there is little documented evidence on the pediatric domains in the orthopaedic population.[3]

Idiopathic scoliosis (IS) is the most common diagnosed spinal deformity in children. Treatment is mainly based on the magnitude of the deformity and the amount of remaining spinal growth. Most patients with IS have a low magnitude deformity and generally do not require treatment beyond observation. However, larger deformities are associated with decreased spinal flexibility and mobility (MOB), pain, and body asymmetry, and these patients are at risk of suffering from decreased pulmonary function, back pain, and psychosocial concerns.[4] Posterior spinal fusion (PSF) is the most commonly used surgical intervention for idiopathic IS and is commonly indicated in patients with curve magnitudes greater than 45°.[5] Outcomes of surgical treatment have typically been radiographic measures of spinal deformity and disease-specific validated PRO instruments such as the Scoliosis Research Society's Scoliosis Research Society (SRS)-30, the Oswestry Disability Index (ODI), and the general health assessment Short Form-36 (SF-36). The aims of this study were to (1) report the changes in PROMIS scores following PSF for IS; (2) compare the changes in the PROMIS Pain Interference (PI) domain with the SRS-30 questionnaire pain subscore; and (3) measure the impact of curve characteristics on PI, upper extremity (UE), MOB, and peer relationship (PR) PROMIS scores.

Methods

This investigation was a retrospective cohort study involving multiple surgeons at a single surgical center. After an institutional review board approval was obtained, 138 consecutive patients were identified as having a PSF for IS between January 2015 and June 2018. Patients were excluded from the study if they were older than 18 years of age at time of surgery, had PROMIS scores for less than two time points, or had nonfusion surgeries (including growing rod or growth modulation constructs). Sixteen patients were excluded from analysis because of having less than two PROMIS scores for analysis, leaving 122 patients for study analysis. Patient demographics, surgical data, radiographic assessments, and PROMIS and SRS-30 scores were reviewed at preoperative, initial postoperative, intermediate postoperative, 1-, 2-, and 3-year follow-up encounters. Radiographic measurements were made using standing posteroanterior views. During this study, physician follow-up schedules varied; therefore, time points were categorized based on a range: initial, 4 to 10 weeks; intermediate, 4 to 10 months; 1 year, 11 to 17 months; 2 years, 17 to 26 months; and 3 years, 26 to 38 months. Over the 3-year period, PROMIS measures were collected from the PI (88 items), PR (83 items), function—UE (86 items), and function—MOB (87 items) item banks.[6-9] Assessments were administered using a CAT delivery system on an iPad (Apple). PROMIS assessments are scored by the CAT, and scores are reported as T scores ranging from 0 to 100 with a mean of 50 and a standard deviation of 10. For PROMIS measures with negative connotation, such as PI, a higher score represents impairment. In measures

Table 1. Preoperative and Postoperative Radiographic Measurements

Factor	Preoperative	Postoperative
Cobb angle (%)	62.9 (±13.8)	22.5 (±9.11)
Cobb angle correction (measured)	—	40.4 (±12.9)
No. vertebral levels fused	—	11.9 (±2.01)
T5-T12 kyphosis (%)	31.1 (±13.5)	28.3 (±9.24)
T5-T12 kyphosis correction (measured)	—	2.8 (±1.24)

with a positive connotation, such as PR and function, a lower score represents impairment. SRS-30 scores were collected using written questionnaires. Both outcome measures were completed before being seen by a physician during the patient encounter.

Study data were extracted from the electronic medical record and entered into REDcap, a secure online, Health Insurance Portability and Accountability Act-compliant database. Preoperative and postoperative PROMIS T scores were compared using a T test assuming unequal variance. PROMIS PI T scores were compared with the SRS-30 pain domain using the Pearson correlation coefficient. Strength of correlations were categorized as follows: very high, $0.9 < r < 1.0$; high, $0.7 < 0.9$; moderate, $0.5 < r < 0.7$; low, $0.3 < r < 0.5$; and negligible, $0 < r < 0.3$.[10] PROMIS T scores for PI, UE, MOB, and PR were compared with the Lenke Classification, spinal fusion length, upper instrumented vertebra (UIV), lowest instrumented vertebra (LIV), and curve correction using the Pearson correlation coefficient. Spinal fusion length was determined by counting the number of fused vertebrae. UIV and LIV were defined as the most superior and inferior fused vertebrae, respectively. The curve correction was defined as the computed difference between preoperative curve and postoperative curve magnitude. Significance was determined at the $P < 0.05$ level. As this was an exploratory study, no correction for multiple comparisons was made.

Results

Over the 3-year period, 122 patients were identified, which satisfied inclusion criteria. There were 101 female patients (83%) with a mean age of 14.2 years (range 9 to 17 years). The mean body mass index was 23.1 (range 14.7 to 45) at the time of surgery. Patients were classified by the Lenke Classification, with the highest prevalence of type I (46 patients, 38%) and type III (36 patients, 30%) curve patterns. After surgical correction, the mean coronal curve magnitude improved from 62.9° to 22.5°, a 64% improvement ($P < 0.01$) (Table 1). Sagittal T5–T12 was 31.1° preoperatively, which minimally decreased to 28.3° (−9%) ($P = 0.06$). On average, patients completed their initial follow-up at 6.7 weeks after surgery (SD = 1.7 weeks), intermediate at 6.6 months (SD = 1.2 months), 1 year at 12.6 months (SD = 1.3 month), 2 years at 24.3 months (SD 2.7 months), and 3 years at 35.3 months (SD 2.6 months). Because of the change in PROMIS administration, the number of participants completing each PROMIS domain declined with a longer follow-up: 80 patients had at least one PROMIS score in one domain preoperatively, 82 at the initial postoperative encounter, 88 at the intermediate follow-up, 65 at 1-year follow-up, 32 at 2-year follow-up, and 11 at 3-year follow-up.

PROMIS measures for both physical function domains (UE and MOB) initially decreased significantly postoperatively, with a decline of 10.3 points ($P < 0.01$) in the UE domain and 10.2 points ($P < 0.01$) in MOB at the initial postoperative encounter (Table 2, Figure 1). At the intermediate encounter (6 months), both domains remained significantly lower, a 3.9-point decline ($P < 0.01$) in UE and 3.8-point decline ($P < 0.01$) in MOB. MOB scores showed only a 2.4-point improvement at 1 year, 2.9-point improvement at 2 years, and 1.2-point improvement at 3 years. These increases in MOB scores were not significant (1 year, $P = 0.2$; 2 years, $P = 0.155$; 3 years, $P = .70$). UE scores also returned to normal at 1 year postoperatively ($P = 0.80$) and showed a nonsignificant increase of 1.7 points at 2 years ($P = 0.08$) and 2 points at 3 years ($P = 0.252$).

PROMIS PI measures were not different from preoperative values at the initial postoperative encounter ($P = 0.52$) and the intermediate encounter ($P = 0.45$) (Figure 2). Significant changes were not seen until 1 year postoperatively, when PI scores decreased by 6 points ($P < 0.01$) and 4.1 points ($P < 0.05$) at the 2-year follow-up from preoperative values. At the 3-year follow-up, PI scores showed a nonsignificant decrease of 4.9 points ($P = 0.136$), likely because of the low patient numbers at this time point.

PROMIS PR scores were not different at the initial postoperative encounter ($P = 0.66$), the intermediate encounter ($P = 0.56$), and the 1-year encounter ($P = 0.149$). PR scores improved significantly from preoperative values at the 2-year encounter, with an increase of 7.2 points ($P < 0.05$), and continued to improve at the 3-year encounter, 8.8 points ($P < 0.01$) (Figure 3).

Table 2. **Evaluation of Patient-Reported Outcomes Measurement Information System Scores in AIS Patient Population After Posterior Spinal Fusion Surgery**

Event Name	Mean (SD) / N = Sample Size	Pain Interference	Upper Extremity	Mobility	Peer Relationships
Preoperative		49.7 (9.89)	52.5 (7.66)	49.0 (9.15)	53.8 (8.67)
		N = 80	N = 79	N = 79	N = 76
Initial		52.6 (8.91)	42.2 (7.71)[a]	38.8 (6.77)[a]	53.1 (9.99)
		N = 81	N = 80	N = 81	N = 69
Intermediate		48.3 (11.0)	48.6 (7.79)[a]	45.2 (8.62)[a]	54.6 (8.57)
		N = 88	N = 86	N = 87	N = 83
1 yr		43.7 (9.88)[a]	52.1 (6.51)	51.4 (9.08)	56.0 (9.33)
		N = 65	N = 64	N = 63	N = 64
2 yr		45.6 (10.9)[a]	54.2 (5.67)	51.9 (9.65)	58.1 (9.33)[a]
		N = 61	N = 30	N = 30	N = 30
3 yr		44.8 (9.52)	54.5 (4.77)	50.2 (9.10)	62.6 (5.77)[a]
		N = 11	N = 10	N = 10	N = 10

[a]$P < 0.05$.

All encounters, where both a PROMIS PI assessment and SRS-30 questionnaire were completed, regardless of the time point, were used to determine the correlation between PROMIS PI T scores and the pain domain of the SRS-30. A moderate negative correlation was present between the two outcomes (r = −0.546, $P < 0.01$), demonstrating that as PROMIS PI T scores increase, SRS-30 pain scores decrease. This moderate negative correlation was present at all patient encounter time points (Table 3).

At the initial postoperative encounter, LIV was correlated with a moderate decrease in both physical function domain scores (MOB: r = −0.268, $P < 0.05$; UE: r = −0.262, $P < 0.05$). A moderate negative correlation was also observed at the 1-year encounter for both MOB (r = −0.269, $P < 0.05$) and UE (r = −0.264, $P < 0.05$) scores. PROMIS MOB and UE domain scores were not different relative to LIV at the intermediate, 2-year, and 3-year encounters. LIV had no significant impact on PI or PR scores at any patient encounter. UIV, Lenke classification, number of vertebrae fused, and curve correction had no impact on PROMIS domain scores at any patient encounter.

Discussion

PROs have become a major tool to measure the impact of disease on patient health. As a part of its Health

Figure 1

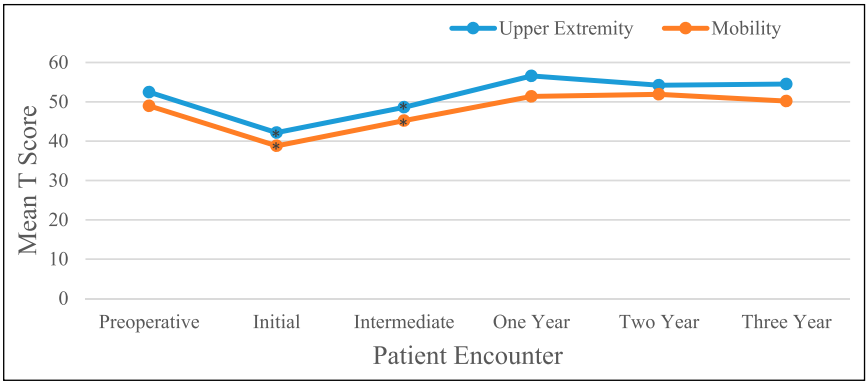

Chart showing PROMIS function scores over time. PROMIS = Patient-Reported Outcome Measurement Information System

Figure 2

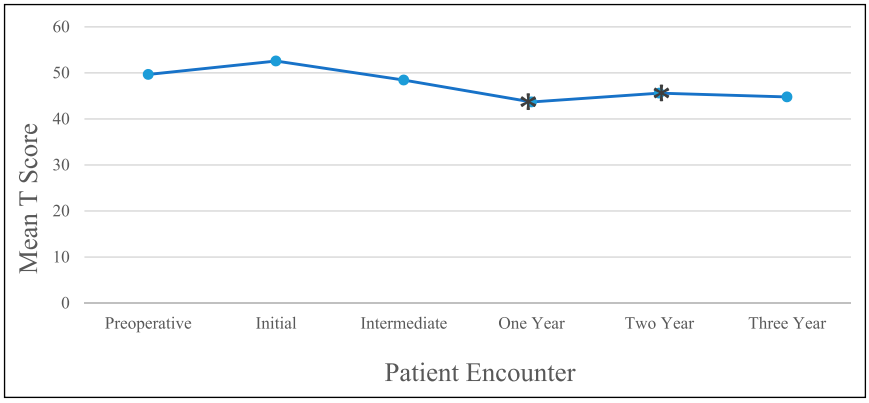

Chart showing PROMIS pain interference scores over time. PROMIS = Patient-Reported Outcome Measurement Information System

Roadmap initiative, the National Institute of Health developed the PROMIS, a general health PRO system that is independent of diagnosis. IS is the most commonly diagnosed spinal deformity in children, with most patients having a low magnitude deformity and generally not requiring treatment beyond observation. However, larger deformities are associated with decreased spinal flexibility and MOB, pain, and body asymmetry, and these patients are at risk to suffer from decreased pulmonary function, back pain, and psychosocial concerns.[4] PSF is the most commonly used surgical intervention for IS and is commonly indicated in patients with curve magnitudes greater than 45°.[5] Outcomes of surgical treatment have typically been radiographic measures of spinal deformity and disease-specific validated PRO instruments such as SRS-30 and ODI and the general health assessment SF-36, but there are little data on the use of PROMIS in IS. A 2019 study compared PROMIS and SRS scores in AIS patients, both surgical and nonoperative, and found that the PROMIS PI, MOB, and peer relations were all significantly correlated with SRS pain, function, and mental health domains, respectively.[11] Similarly, Bernstein et al[12] evaluated PROMIS and SRS data in adult and pediatric patients with spinal deformity and found that in the pediatric population PROMIS appropriately correlated with SRS in domains evaluating pain, function, and mental health. Our study expounds on these earlier studies, examining the use of PROMIS in the postoperative course of AIS patients.

Functional restrictions are common practice after spinal fusion for IS; however, no consensus is available on when patients should be allowed to resume normal physical activity such as lifting and running, or participating in athletics. Rubery and Bradford[13] surveyed SRS members and documented highly variable recommendations and procedures among the 261 physicians. Physical education class was permitted by 53% at 6 months, whereas 63% also allowed returning to noncontact sport at the same time. By 1 year, both physical education and noncontact sport participation increased to 97%. A 2015 study looked more closely at the recommendations of 23 spinal deformity surgeons using pedicle screw constructs and reported that 80% of physicians released patients for both physical education and noncontact sport at 6 months and 100% released for participation in both at 1 year.[14] Sarwahi et al[15] reported that 75% of patients returned to physical education by 6 months postoperatively and 54% returned to noncontact sport in that same period. By 1 year, 98% of the patients had returned to physical education, and 90% to noncontact sport. Sarwahi demonstrated that despite conservative recommendations, patients may be able to return to baseline activity earlier than those recommendations. Because there is no unanimous return to activity protocol by spinal surgeons, it is often difficult to distinguish whether patient-reported functional outcomes are due to activity restrictions or true functional limitations. Despite this phenomenon, the timing of functional improvements in our study is comparable with those found in the previous literature. At our institution, the surgeons have slight variations in their postoperative activity limitations, with most releasing patients back to full activities at 6 months postoperatively. Hence, it is not surprising, based on our postoperative instructions, that the PROMIS function measure (UE and MOB) domains were decreased immediately postoperatively and at 6 months postoperatively and then improved

Figure 3

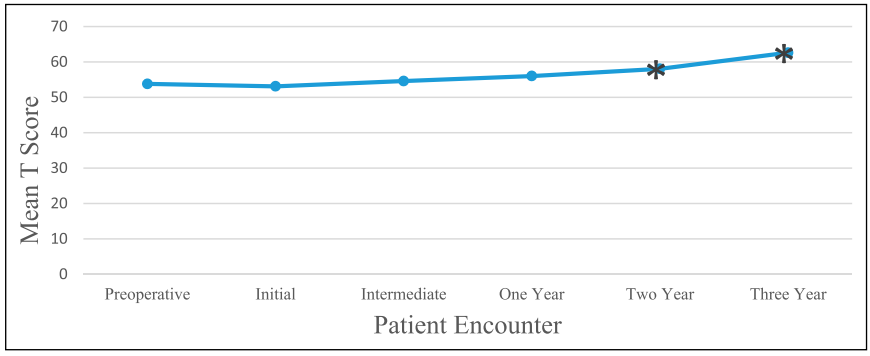

Chart showing PROMIS peer relationships over time. PROMIS = Patient-Reported Outcome Measurement Information System

back to preoperative baseline at 1 year after they had been cleared by their surgeon to return to all activities. Thereafter, this difference disappeared and was similar to baseline.

The PROMIS PR domain was constructed as a measure of social health in the pediatric population, as determined by a patient's social roles and functioning within their peer group.[8] When compared with legacy measures, results from the mental health and self-image domains of SRS questionnaires align most closely with the aims of this domain. Earlier studies demonstrated that of the five domains among SRS, self-image shows the most significant improvement at 2 years.[16] Mental health, on the other hand, demonstrates inconsistent findings throughout the literature.[17-21] These inconsistencies suggest the need for more thorough examination into the long-term effects of surgical management of IS on patients' mental health and social interactions. Because the PROMIS PR domain combines the aspects of mental health and self-image with specific information regarding social interaction with peers, older assessments may not sufficiently assess the aims of this domain. This study documented no change from baseline preoperative PR until the 2- and 3-year postoperative time points. The complexity of the PR domain makes it difficult to explain these findings. Improvement in the physical body appearance, resolution of back pain, and resumption of athletic activities at their preoperative levels could all contribute to the improved PR postoperatively.

This study demonstrated no significant differences in the PI domain at the preoperative, initial postoperative, and intermediate postoperative encounters. In a 2010 study using the SRS-30, 35% of patients with IS reported of moderate to severe pain within the month before surgery.[22] Of these patients, over 50% (54%) reported pain improvements at 1 year postoperatively and maintained these improvements over 5 years. Similarly, this study documented improvements in PI at 1 year and 2 years postoperatively, with PROMIS PI T scores from 4 to 6 points. Although patients reported pain improvements at the 1-year time point, the lack of change in pain initially was not surprising. The literature demonstrates that 38% of patients have pain at 2 to 3 months postoperatively. However, few additional studies compare these short-term postoperative measurements with preoperative values. The lack of short-term change postoperatively may be attributed to the low levels of preoperative pain seen in our patient population and the expected postsurgical pain. Various studies have indicated a strong correlation between preoperative and postoperative pain in spinal fusion surgeries.[23-25] Sanders et al[26] demonstrated that patients with Lenke class 3 and 6 curves are associated with higher preoperative and long-term postoperative pain measurements. Watanabe et al[27] reported that the amount of surgical correction is a more significant factor for postoperative pain than the presurgical curvature itself. This study did

Table 3. Patient-Reported Outcomes Measurement Information System Pain Interference Versus Scoliosis Research Society-30 Pain

Factor	r	N
Time point	—	—
Preoperative	−0.742[a]	48
Initial	−0.657[a]	27
Intermediate	−0.512[a]	55
1 yr	−0.601[a]	51
2 yr	−0.531[a]	30
3 yr	−0.546[a]	7

[a]$P < 0.05$.

not find the Lenke Classification or amount of correction to have a significant impact on any PROMIS domain. In a 2018 study on 100 adolescent patients with IS, Akgül et al[28] reported that PSF involving L3 is associated with decreased pelvic tilt and sacral slope. Although this study did not evaluate pelvic tilt and sacral slope, LIV was found to have been negatively correlated with PROMIS MOB and UE scores for up to 1 year. No significant associations were found between UIV and number of vertebrae fused and PROMIS scores.

The introduction of new PROs to the lexicon of clinical care creates a wrinkle in our ability to integrate them into the framework of existing legacy PROs. The applicability of general health PROs within the specific context of IS and their correlation with accepted disease-specific PROs need to be proven before their use clinically and in research applications. This study demonstrates that PROMIS PI and SRS-30 pain subdomain showed a significant negative correlation in the IS population. This indicates that as PROMIS PI Mean T scores increase, representing an increase in PI, SRS-30 pain domain scores decrease. The SRS questionnaires have been proven reliable and valid in assessing the effects of scoliosis and its treatment on patient satisfaction and outcomes. Our study is the first to compare the PROMIS measurement with more frequently used outcome measures within the pediatric spine population. Other studies, however, have demonstrated the success of the system within the adult population. Papuga et al[29] also examined the relationship between the PROMIS PI domain and the ODI and Neck Disability Index in adult spine patients. Strong correlations were demonstrated between PROMIS PI scores and both the ODI and Neck Disability Index measurements. Similarly, a study analyzing the validity of various PROMIS domains in pediatric chronic pain patients found that the PI domain exhibited strong correlations with legacy measures commonly used in practice.[30] These correlations provide early insights into the use of the PROMIS measurement as a valid instrument for patient outcomes in relation to pain within the pediatric spine population.

Using the CAT-administered PROMIS instrument may be preferable in clinical practice because of its ease and decreased time to complete for patients. This results in decreased patient burden while still maintaining the validity of the instrument.[5] Scores are computed and stored automatically by the CAT system, therefore saving clinicians and researchers time normally spent manually in calculating scores and decreasing the chance for error. PROMIS domains are general measures of health, allowing for comparison with other adolescent orthopaedic and nonorthopaedic conditions as well.

A limitation of this study is the recent implementation of PROMIS assessments at our institution. PROMIS assessments were implemented 9 months after the start of the 3-year study; therefore, only a portion of the total population had measures from preoperative to 3 years. The number of participants with data declined with a longer follow-up: 80 patients had at least one PROMIS score in one domain preoperatively, 82 at the initial postoperative encounter, 88 at the intermediate follow-up, 65 at 1-year follow-up, 32 at 2-year follow-up, and 11 at 3-year follow-up. In addition, because this was a retrospective study, not all patients had PROMIS assessments at each visit; however, completion rates for PROMIS at our institution are 98% of outpatient visits.

In conclusion, this study demonstrated the early trends in pediatric PROMIS measures following PSF for IS. In the short term, IS patients undergoing spinal deformity correction surgery can be expected to have decreased function (PROMIS MOB and UE) for up to 1 year, improved pain at 1 year (PROMIS PI), and improvements in PR (PROMIS PR) after 2 years. The significant correlation between SRS-30 pain domain and PROMIS PI scores demonstrates its utility for use in patients with IS. In addition, IS patients who have PSF with a more caudal LIV may have decreased MOB and UE function during the early postoperative period. Further study with a longer follow-up and larger patient cohort is necessary to validate these early findings in AIS patients.

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