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Patient-Reported Outcomes Measurement Information System Physical Function Validation for Use in Anterior Cervical Discectomy and Fusion: A 2-Year Follow-up Study

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Objective: Our study aims to evaluate the correlation of Patient-Reported Outcomes Measurement Information System physical function (PROMIS PF) with legacy patient-reported outcome measures (PROMs) among patients undergoing anterior cervical discectomy and fusion (ACDF).
Methods: A prospectively maintained database was retrospectively reviewed for ACDF surgeries performed between May 2015 and September 2017. Inclusion criteria were primary elective, single- or multilevel ACDFs for degenerative spinal pathology. Patients lacking preoperative or 2-year PROMIS PF surveys were excluded. Mean scores were calculated for visual analogue scale (VAS) neck, VAS arm, Neck Disability Index (NDI), 12-Item Short Form Physical Component Score (SF-12 PCS), and PROMIS PF at preoperative and 6-week, 12-week, 6-month, 1-year, and 2-year postoperative timepoints. A t-test and Pearson correlation coefficient were utilized to evaluate score improvement and PROM relationships respectively.
Results: The 50 subject cohort was 60.0% male, 50% obese (body mass index ≥ 30 kg/m^2) and had an average age of 50.9 years. Significant improvements were demonstrated for VAS neck and NDI at all postoperative timepoints ($p < 0.001$) and for SF-12 and PROMIS PF at all timepoints except 6 weeks ($p \leq 0.025$). VAS arm improvement was seen up to 1 year ($p \leq 0.016$). PROMIS PF demonstrated strong correlations with NDI and SF-12 PCS at all evaluated timepoints and with VAS neck at all postoperative timepoints except 6 weeks (all $p < 0.01$).
Conclusion: PROMIS PF was strongly correlated with pain, disability, and physical function up to 2 years for patients undergoing ACDF. Our results support the long-term validity of PROMIS PF for measurement of patient-reported physical function among ACDF cohorts.

Keywords: Anterior cervical discectomy and fusion, Neck Disability Index, Patient-reported outcome, Patient-Reported Outcomes Measurement Information System, Visual analogue scale, Outcomes

INTRODUCTION

Anterior cervical discectomy and fusion (ACDF) is a common cervical spine procedure with an average of 137,000 ACDF performed per year from 2006–2013.[1,2] ACDF is a successful treatment for cervical spine pathologies such as herniated intervertebral discs, cervical radiculopathy, spondylosis, and myelopathy with low complication rates and minimal risk.[3,4] In recent years, the number of cervical spine surgeries has increased and are likely to rise as our population becomes older.[5,6]

Patient-reported outcome measures (PROMs) are an essential piece of the increased emphasis on cost effectiveness, quality of care, and in prioritizing the patient perspective as a part of the treatment plan.[7-9] Traditional or "legacy PROMs" of spinal surgery often fall into the following categories: general health questionnaires (e.g., Medical Outcomes Study Short Form [SF] or EuroQol Five Dimension), pain rating scales (e.g., Numeric Rating Scale or visual analogue scale [VAS]), and disease-specific questionnaires (e.g., Oswestry Disability Index [ODI], Roland Morris Disability Questionnaire, Neck Disability Index [NDI], Cervical Spine Outcomes Questionnaire, the Japanese Orthopaedic Association [JOA] myelopathy questionnaire, and the Myelopathy Disability Index).[10] Despite their widespread use, these legacy PROMs have known limitations. With additional surveys, they can increase patient burden, decrease measurement precision, and can deliver results that are challenging to compare. Many of these attributes can hinder interpretability.[9,11]

In order to address these shortcomings, a 2004 multicenter cooperative group initiative by the National Institute of Health developed the Patient-Reported Outcomes Measurement Information System (PROMIS). PROMIS is standardized across a broad range of medical conditions and patient populations.[12] The PROMIS system assesses numerous outcomes including physical function (PF), depression, anxiety, and pain interference.[13] Its use has demonstrated decreased patient burden, lessened ceiling/floor effects, increased precision and efficiency, and smaller sample size requirements.[11,14-17] As a response to these findings, there has been a substantial increase in correlational between PROMIS and legacy spine PROMs.[7]

With respect to cervical spine procedures, studies have since confirmed moderate-to-strong correlations of PROMIS with legacy PROMs such as NDI, modified JOA, ODI, SF-36/SF-12, and VAS ranging from 6 to 12 months of follow-up.[18-24] Among ACDF patients, PROMIS PF exhibits strong correlations with SF-12 and NDI at both preoperative and short-term postoperative time points.[20,25] However, among cervical spine patients the literature is lacking in studies which assess longitudinal correlations between PROMIS and legacy PROMs, which extend past one year. The purpose of this study is to evaluate the longitudinal correlations between PROMIS PF and legacy PROMs over a 2-year period among ACDF patients. Through this investigation, we intend to further evaluate the concurrent validity of PROMIS PF with legacy measures at follow-up time periods of up to 2 years.

MATERIALS AND METHODS

1. Study Population

Following Institutional Review Board approval of Rush University Medical Center Research Compliance Department (ORA-#14051301), a prospectively recorded single surgeon, single-institution surgical registry was retrospectively reviewed for eligible patients between May 2015 and September 2017 for elective ACDF surgeries. Inclusion criteria were primary, single or multilevel ACDFs for degenerative spinal pathology. Patients were excluded from our analysis if they had not completed PROMIS PF surveys at preoperative and 2-year timepoints. Patients were also excluded if surgery was indicated due to malignancy, trauma, or infection.

2. Data Collection

We collected cohort characteristics such as demographic, clinical, and operative variables. Demographic data included age, sex, body mass index (BMI), tobacco use, comorbidity burden as evaluated by Charlson Comorbidity Index, and insurance status. Following clinical and radiographic evaluation preoperative spinal pathology diagnosis was determined and recorded. Operative variables were recorded including number of levels fused, operative duration, estimated blood loss (EBL), and inpatient stay following surgery. Patients were administered SF-12 Physical Component Score (PCS), VAS neck/arm, PROMIS PF, and NDI surveys at both preoperative and postoperative time points (e.g., 6 weeks, 12 weeks, 6 months, 1 year, and 2 years).

3. Statistical Analyses

All computations were completed using Stata 16.0 (StataCorp LP, College Station, TX, USA). Descriptive statistics were performed for subject demographics, baseline pathologies, and perioperative characteristics. Average PROM scores were evaluated for VAS neck, VAS arm, NDI, SF-12 PCS, and PROMIS PF at both preoperative and postoperative timepoints (e.g., 6 weeks,

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12 weeks, 6 months, 1 year, and 2 years). Postoperative improvement in PROM scores from preoperative baseline was evaluated using a paired Student t-test. Pearson correlation coefficient was used to evaluate the relationship of PROMIS PF with VAS neck, VAS arm, SF-12 PCS, and NDI. Correlation strength was assessed according to Cohen standard with the following categories: $0.1 \leq |r| < 0.3$ = low; $0.3 \leq |r| < 0.5$ = moderate; $|r| \geq 0.5$ = strong.[26] Scatter plots visually represented PROMIS PF's relationship with NDI and SF-12 PCS at all evaluated timepoints. Statistical significance was determined using an alpha level of 0.05.

RESULTS

1. Patient Cohort

A total of 50 eligible patients underwent ACDF and were included in our analysis. The majority were male (60.0%). The cohort average age was 50.9 years, and 50% had a BMI ≥ 30 kg/m^2 (Table 1). The most common comorbid medical condition was hypertension (28.0%). The most common preoperative spinal pathology was herniated nucleus pulposus (78.0%). The majority of patients underwent 1 level (60.0%), followed by 2 levels (30.0%), 3 levels (8.0%), and 4 levels (2.0%) (Table 2). The mean operative time was 57.4 minutes, with an EBL of 30.5 mL, and inpatient stay of 12.5 hours.

2. Outcome Measures

Average (mean ± standard deviation) baseline preoperative VAS neck was 5.78 ± 2.39, VAS arm was 5.61 ± 2.33, NDI was 36.21 ± 16.86, SF-12 PCS was 35.56 ± 9.21, and PROMIS PF was 40.20 ± 6.38. VAS neck and NDI demonstrated significant postoperative improvement at all evaluated time points following ACDF when compared to baseline scores (all $p < 0.001$) (Table 3). PF instruments (SF-12 PCS, PROMIS PF) demonstrated significant postoperative improvement at 12 weeks, 6 months, 1 year, and 2 years (all $p \leq 0.025$) but failed to have a significant improvement at 6 weeks postoperatively. VAS arm had a significant postoperative improvement at 6 weeks to 1 year postoperatively (all $p \leq 0.016$) but had no difference at 2 years. All evaluated timepoints for NDI and SF-12 PCS revealed strong correlation with PROMIS PF as assessed with Pearson correlation coefficients (Table 4) (Fig. 1). VAS neck was found to have a strong correlation with PROMIS PF at all time points except for 6 weeks (moderate) and preoperatively (low). VAS arm only demonstrated statistically significant moderate correlation with PROMIS PF at 6 months and 2 years ($p \leq 0.028$).

Table 1. Patient demographics (n = 50)

Variable	Value
Age (yr)	50.9 ± 10.4
Sex	
Female	20 (40.0)
Male	30 (60.0)
Body mass index	
Nonobese (< 30 kg/m^2)	25 (50.0)
Obese (30 kg/m^2)	25 (50.0)
Smoking status	
Nonsmoker	45 (90.0)
Smoker	5 (10.0)
Insurance coverage	
Private	31 (62.0)
WC	18 (36.0)
Medicare/medicaid	1 (2.0)
CCI	1.56 ± 1.4
Preoperative diagnoses	
Diabetes	9 (18.0)
Hypertension	14 (28.0)
Arthritis	7 (14.0)
Malignancy	2 (4.0)
Spinal diagnoses	
Herniated nucleus pulposus	39 (78.0)
Degenerative disc disease	4 (8.0)
Foraminal stenosis	10 (20.0)

Values are presented as mean ± standard deviation or number (%).
CCI, Charlson Comorbidity Index; WC, workers compensation.

Table 2. Operative characteristics (n = 50)

Characteristic	Value
No. of levels fused	
1 Level	30 (60.0)
2 Levels	15 (30.0)
3 Levels	4 (8.0)
4 Levels	1 (2.0)
Operative time* (min)	57.4 ± 14.6
Estimated blood loss (mL)	30.5 ± 12.7
Length of hospital stay (hr)	12.5 ± 12.5

Values are presented as number (%) or mean ± standard deviation.
*Operative time was measured from skin incision to skin closure.

Table 3. Changes in PRO scores after ACDF

Variable	Score	Change	p-value†
VAS neck			
Preoperative	5.78 ± 2.39 (49)	-	-
6 Weeks	2.94 ± 2.59 (49)	-2.90 ± 2.83 (48)	< 0.001*
12 Weeks	2.66 ± 2.44 (48)	-3.06 ± 3.06 (47)	< 0.001*
6 Months	2.47 ± 2.60 (43)	-3.26 ± 2.70 (42)	< 0.001*
1 Year	2.98 ± 2.50 (32)	-2.44 ± 2.77 (31)	< 0.001*
2 Year	3.29 ± 2.75 (25)	-2.63 ± 2.84 (24)	< 0.001*
VAS arm			
Preoperative	5.61 ± 2.33 (49)	-	-
6 Weeks	2.51 ± 2.76 (49)	-3.14 ± 3.44 (48)	< 0.001*
12 Weeks	2.95 ± 3.11 (48)	-2.61 ± 3.84 (47)	< 0.001*
6 Months	2.51 ± 2.83 (42)	-2.92 ± 3.35 (41)	< 0.001*
1 Year	3.44 ± 3.42 (32)	-1.92 ± 4.17 (31)	0.016*
2 Years	5.27 ± 12.17 (25)	-0.10 ± 12.84 (24)	0.970
NDI			
Preoperative	36.21 ± 16.86 (48)	-	-
6 Weeks	27.07 ± 18.76 (49)	-8.79 ± 14.85 (47)	< 0.001*
12 Weeks	24.02 ± 19.96 (48)	-11.58 ± 17.38 (46)	< 0.001*
6 Months	18.52 ± 18.07 (42)	-16.59 ± 18.04 (41)	< 0.001*
1 Year	21.00 ± 19.04 (32)	-13.00 ± 17.31 (30)	< 0.001*
2 Years	22.64 ± 20.20 (25)	-16.08 ± 15.23 (23)	< 0.001*
SF-12 PCS			
Preoperative	35.56 ± 9.21 (44)	-	-
6 Weeks	35.89 ± 9.59 (43)	1.28 ± 8.34 (40)	0.336
12 Weeks	39.37 ± 10.75 (39)	3.31 ± 8.24 (34)	0.025*
6 Months	41.30 ± 10.50 (39)	5.73 ± 8.41 (34)	< 0.001*
1 Year	42.79 ± 10.71 (33)	6.21 ± 9.44 (28)	0.002*
2 Years	42.24 ± 11.99 (35)	6.50 ± 10.86 (32)	0.002*
PROMIS PF			
Preoperative	40.20 ± 6.38 (50)	-	-
6 Weeks	41.33 ± 7.82 (42)	1.52 ± 9.51 (42)	0.305
12 Weeks	46.76 ± 10.30 (38)	5.66 ± 9.23 (38)	0.001*
6 Months	48.45 ± 8.64 (35)	7.81 ± 7.33 (35)	< 0.001*
1 Year	48.49 ± 7.61 (33)	8.07 ± 7.11 (33)	< 0.001*
2 Years	47.37 ± 9.23 (50)	7.17 ± 8.15 (50)	< 0.001*

Values are presented as mean ± standard deviation (number).
PRO, patient-reported outcome; ACDF, anterior cervical discectomy and fusion; VAS, visual analogue scale; NDI, Neck Disability Index; SF-12 PCS, 12-Item Short Form Physical Component Score; PROMIS PF, Patient-Reported Outcomes Measurement Information System physical function.
*$p < 0.05$, statistically significant differences. †Calculated using a paired t-test to compare scores at each time point with preoperative scores.

Table 4. Association of PROMIS PF with VAS neck, VAS arm, NDI, SF-12 PCS

Variable	Pearson r	p-value†
VAS neck		
Preoperative	-0.116	0.429
6 Weeks	-0.411	0.007*
12 Weeks	-0.517	< 0.001*
6 Months	-0.685	< 0.001*
1 Year	-0.567	0.002*
2 Year	-0.535	0.006*
VAS arm		
Preoperative	-0.095	0.516
6 Weeks	-0.236	0.133
12 Weeks	-0.278	0.091
6 Months	-0.481	0.004*
1 Year	-0.072	0.715
2 Years	-0.440	0.028*
NDI		
Preoperative	-0.558	< 0.001*
6 Weeks	-0.586	< 0.001*
12 Weeks	-0.669	< 0.001*
6 Months	-0.772	< 0.001*
1 Year	-0.699	< 0.001*
2 Years	-0.646	< 0.001*
SF-12 PCS		
Preoperative	0.723	< 0.001*
6 Weeks	0.585	< 0.001*
12 Weeks	0.781	< 0.001*
6 Months	0.684	< 0.001*
1 Year	0.736	< 0.001*
2 Years	0.828	< 0.001*

PRO, patient-reported outcome; ACDF, anterior cervical discectomy and fusion; VAS, visual analogue scale; NDI, Neck Disability Index; SF-12 PCS, 12-Item Short Form Physical Component Score; PROMIS PF, Patient-Reported Outcomes Measurement Information System physical function.
*$p < 0.05$, statistically significant differences. †Strong correlation with PROMIS score as identified by the Pearson correlation coefficient.

DISCUSSION

PROMs often carry inherent bias, which makes it challenging to adequately gauge patient health.[10] To combat this, PROMIS was created to gather information about the state of a patient's health and their self-perception of PF and pain perception. By individualizing each patient's health, these metrics offer

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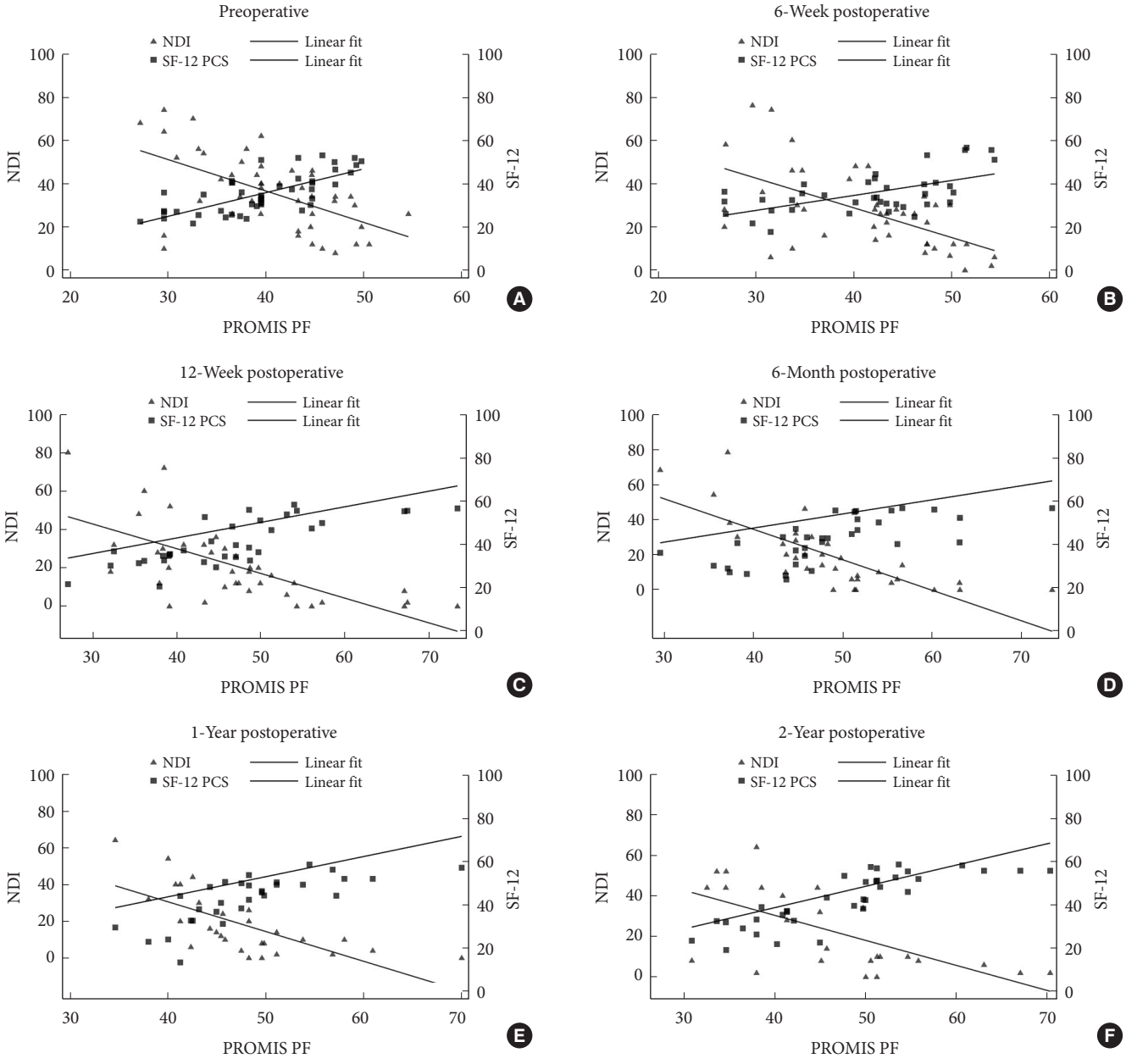

Fig. 1. Scatter plot of PROMIS PF scores against NDI and SF-12 PCS at pre- (A) and postoperative timepoints (6 weeks [B], 12 weeks [C], 6 months [D], 1 year [E], and 2 years [F]). PROMIS PF, Patient- Reported Outcomes Measurement Information System physical function; NDI, Neck Disability Index; SF-12 PCS, 12-Item Short Form Physical Component Score.

a way for physicians to prescribe more specific treatments.[10] PROMIS can be administered as a short form or as a computerized adaptive testing (CAT) that changes the course of the survey after the selection of each answer. This provides more detailed information to not only assist patients during recovery, but also decrease clinical burden and strengthen patient compliance.[12] PROMIS PF is most commonly used in spine surgery and is beneficial for understanding range of motion, mobility, and postoperative coordination.[20]

PROMIS PF has been increasingly used to psychometrically evaluate pre and postoperative outcomes of spinal surgery.[11,27] Multiple investigations of multilevel ACDFs have shown that PROMIS PF correlates with NDI and SF-12 during preoperative and short-term postoperative time points.[20] One study further highlighted that PROMIS PF can accurately compare patient improvement from preoperative scores out to 1 year postopera-

tively.[28] Vaishnav et al.[29] found significant associations between NDI and PROMIS PF, as well as between SF-12 PCS and PROMIS PF. Moreover, positive correlations between VAS neck and arm and PROMIS PF scores were reported preoperatively as well as postoperatively in patients undergoing surgery for cervical disc herniations.[18] It is important to note that neither study assessed these scores past the 1-year postoperative timepoint.

In our study, PROMIS PF was shown to be strongly correlated with NDI and SF-12 PCS in accordance with previous investigations in cervical spine surgery.[27,30] Both PF instruments (SF-12 PCS and PROMIS PF) demonstrated significant postoperative improvement from 12 weeks out to 2 years. However, we did not find significant improvements in the shortest time point of 6 weeks, which may be explained by the large portion of our cohort associated with a diagnosis of cervical myeloradiculopathy, which may take a longer timeframe to resolve. Moreover, previous studies validating the use of PROMIS PF in ACDF patients demonstrated a similar lack of postoperative improvement at 6 weeks for both PROMIS PF and SF-12.[20] Similarly, Khalifeh et al.[31] reported that PROMIS may be less attuned to measuring outcomes at short-term follow-up points than those at long-term follow-ups.

Our results demonstrated variable correlation strength between VAS arm and PROMIS throughout both the preoperative and postoperative time period. This result may be attributed to our patients being associated with a preoperative diagnosis of both herniated nucleus pulposus and foraminal stenosis with arm pain resolving at different rates than PF. Specifically, arm pain may resolve more immediately as peripheral radicular symptoms are relieved, compared to neck pain, disability, and overall PF which may take longer to resolve due to central compressive pathology, as well as recovery from the procedure itself. However, it should be noted that by the 2-year timepoint, VAS arm demonstrated significant correlations with PROMIS that were similar to those of other PROMs in our study and were in line with findings of previous research.[32]

Our findings support the convergent validity of PROMIS PF as a tool to evaluate patient health status. Unlike NDI, PROMIS is a general health measure that can be utilized among various patient populations and conditions.[29]

There are several limitations to our study. Because we conducted a retrospective review, selection biases are most likely present. Additionally, our study's exclusion criteria left outpatients who did not complete preoperative or 2-year follow-up PROMIS PF surveys. These patients are lost to postoperative follow-up and introduce an evident limitation of conducting analyses on PROM surveys, as well as decreasing the size of our cohort. Further encouragement and possible incentives of patients to fill out these surveys will be beneficial to future investigations. Furthermore, the ACDF procedures included in this study varied in terms of the number of vertebral levels fused and which levels were fused, which may introduce an element of bias to our results. However, restricting our analysis to only one level of the spine would have reduced the size of our cohort in a way that substantially limited our ability to observe meaningful trends in PRO improvement. Our study also included procedures performed by 1 surgeon at one institution; therefore, to produce more generalizable results, a multicenter and multisurgeon study design must be included in future investigations.

Another important aspect to consider is that the CAT questionnaire utilized by PROMIS includes a wide variety of items that are nearly universally applicable to patients across the globe (e.g., "Are you able to stand for an hour?"). However, some questionnaire items include references to activities or practices that may be less applicable to patients of some cultural backgrounds. For example, questions such as "Are you able to cut your food using eating utensils?" or "Are you able to open a new milk carton?" may not directly translate to the experiences of some patients living in Eastern nations. Fortunately, PROMIS includes a large "bank" of questions and the limited number of questions with such questionable cultural relevance could potentially be edited or excluded when the questionnaire is translated for use in other geographical regions. However, this highlights the importance of follow-up studies to validate the use of PROMIS for spine patients in other cultures and regions.

CONCLUSION

We observed strong correlations of PROMIS PF scores with pain (VAS neck), disability (NDI), and PF (SF-12 PCS) through both short-term and long-term (2 years) follow-ups for patients undergoing ACDF. The long-term validity of PROMIS PF provides evidence for its use as an instrument to evaluate PF among ACDF patients. Moreover, PROMIS PF could be used as a complimentary survey, or even as a primary instrument in place of legacy measures at time periods of up to at least 2 years.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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