




Original Article

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Longitudinal Evaluation of Patient-Reported Outcomes Measurement Information System for Back and Leg Pain in Minimally Invasive Transforaminal Lumbar Interbody Fusion

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Objective: While visual analogue score (VAS) metrics are among the most universally adopted patient-reported outcome measures (PROMs), there is limited research on the influence of back and leg pain on the Patient-Reported Outcomes Measurement Information System (PROMIS) physical function (PF) scores. Here we assess the association of VAS back and VAS leg scores with PROMIS PF in the setting of minimally invasive transforaminal lumbar interbody fusion (MIS TLIF). Secondarily, we determine if PROMIS PF is more influenced by back or leg pain.

Methods: A prospective surgical registry was reviewed from May 2015 to November 2018. Inclusion criteria were primary, single-level MIS TLIFs. We excluded multilevel procedures and patients without preoperative PROMs. Pre- and postoperative PROMIS PF, VAS back, and VAS leg scores were recorded at 6 weeks, 12 weeks, 6 months, and 1 year. A Pearson correlation evaluated PROMIS PF association with VAS back and VAS leg scores. A Fisher z-test compared correlations. Linear regression evaluated PROMIS with VAS back and VAS leg scores.

Results: Our cohort was comprised of 146 subjects. 40.4% were female and the average age of 51 years. VAS back demonstrated a stronger correlation than VAS leg with PROMIS PF at all timepoints. PROMIS PF scores were negatively associated with both VAS back and VAS leg at all timepoints. Fisher z-test revealed VAS back to have a stronger correlation with PROMIS PF ($p = 0.025$) than VAS leg.

Conclusion: In the setting of MIS TLIF, physical function as evaluated by PROMIS PF, had a stronger correlation with VAS back than VAS leg at 6 months. This suggests that postoperative PROMIS PF scores may be more influenced by back pain than with leg pain.

Keywords: Patient-Reported Outcomes Measurement Information System, Visual analogue scale, Spine, Transforaminal lumbar interbody fusion, Minimally invasive surgery



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INTRODUCTION

While patient-reported outcome measures (PROMs) have overtaken the emphasis on advanced imaging, examining and

validating these metrics are important as they are increasingly relied upon to determine a patient's preoperative and postoperative state.^{1,2} PROMs enable clinicians to evaluate patient beliefs about health status by measuring different aspects of patient

health, such as mental health, physical health, pain, and disability.³⁻⁶ Within the perioperative setting of spine surgery, numerous PROMs have come into favor, all in an effort to evaluate the aforementioned health measures. These measurement tools, also known as legacy measures, have various advantages. For spine surgery patients, legacy PROMs are often utilized with proven validity, including visual analogue scale (VAS), the Oswestry Disability Index (ODI), and Neck Disability Index.^{7,8} The advantage of legacy measures is that clinicians are able to better understand patients' self-perspective with regard to state of health.⁸ However, legacy measures do have numerous disadvantages. Legacy measures cannot be customized based on patient needs or outcomes. Additionally, they can occupy a great deal of administration time for both the clinician and the patient. In these fast-paced settings where time is a precious commodity, the length and time-consuming nature of PROMs can sometimes be prohibitive.⁸

To address some of the disadvantages of legacy measures, the Patient-Reported Outcomes Measurement Information System (PROMIS) was created by the US National Institutes of Health in 2004.^{8,9} The major advantage of PROMIS is that it is standardized, resulting in less time expenditure and resource allocation. PROMIS can be administered by using individualized computer adaptive testing (CAT).^{8,9} CAT is a dynamic, ever-changing survey in which subsequent questions are based off of previous patient responses, which enables gathering of reliable information in a shorter time period than traditional legacy measures.⁸⁻¹⁰ PROMIS has many advantages and has gained recognition with an increasing volume of validation studies. Nonetheless, in the setting of minimally invasive transforaminal lumbar interbody fusion (MIS TLIF), the influence of pain severity and location requires further investigation.⁸

PROMs mark significant progress in placing the patient at the center of healthcare goals. PROMs help account for the disparity that occurs when a patient is in pain despite flawless radiologic evaluation. Furthermore, PROMs are now becoming tools that link a patient's responses directly to healthcare efficiency improvement measures, cost effectiveness, and ongoing research. Although the validity of PROMIS has been studied against a number of other PROMs, the relationship between VAS back and VAS leg in the setting of MIS TLIF remains unexplored. VAS metrics are one of the oldest, most straightforward, and universally adopted PROMs in healthcare.^{11,12} Having a better understanding of how back and/or pain presentations might impact overall physical function may assist counseling of patients and appropriately guiding expectations.

This study aims to fill the void in knowledge on the strength of association of PROMIS scores with back and leg pain in the setting of MIS TLIF. The purpose of this study is to better understand the association of PROMIS PF scores with VAS back and VAS leg scores in the perioperative setting of MIS TLIF. The secondary aim of this study is to compare the rigorously established legacy measures, VAS back and VAS leg scores, in order to determine if PROMIS PF is more influenced by pain originating from the back or lower extremities. While the terms PROMIS, PROMIS PF, and PROMIS PF CAT all have unique referents, throughout the rest of this manuscript, the term PROMIS will refer to the PROMIS PF CAT score.

MATERIALS AND METHODS

1. Patient Population

After Institutional Review Board approval (ORA #14051301), a prospectively maintained surgical patient registry was reviewed for eligible spine surgery cases between May 2015 and November 2018. All surgeries were performed by one surgeon at a single institution. The study inclusion criteria were patients 18 years of age or older undergoing primary, single-level MIS TLIF procedures for treatment of degenerative pathology. Exclusion criteria were multilevel (> 1 level) TLIF procedures, and patients that did not complete preoperative survey questionnaires for the PROMIS, VAS back, or VAS leg metrics. Patients were also excluded if they underwent surgery for traumatic, metastatic, or infectious pathologies.

2. Data Collection

Descriptive statistics were reported for baseline demographics including, body mass index, diagnosis, sex, smoking status, Charlson Comorbidity Index, and insurance coverage (Medicare/Medicaid or workers compensation/private). Diagnosed preoperative comorbid conditions were recorded, including hypertension, neurologic disease, arthritis, myocardial infarction, uncomplicated and complicated diabetes, etc. Preoperative spinal pathologies were recorded including degenerative or isthmic spondylolisthesis, degenerative disc disease, and herniated nucleus pulposus. Perioperative characteristics were reported including operative time (from skin incision to closure), estimated blood loss, length of inpatient stay, discharge day, and fusion rate. Fusion was evaluated during postoperative clinic visits by either radiograph or computed tomography (CT). PROMs such as PROMIS, VAS back, and VAS leg scores were reported at all time points (preoperative, 6 weeks, 12 weeks, 6 months, 1 year

postoperatively). VAS back and VAS leg assess pain in their respective anatomic regions on a scale of 0 (minimum pain) to 10 (maximum pain). PROMIS PF CAT surveys were administered using OBERED software (Universal Research Solutions, Columbia, MO, USA), with higher scores indicating greater physical function.

3. Statistical Analysis

Stata 16.0 (StataCorp LP, College Station, TX, USA) was utilized to evaluate baseline demographics and perioperative characteristics. To account for both normal and nonnormally distributed continuous variables, both mean with standard deviation and median with interquartile range were reported. Chi-square tests were used for categorical variables and Student t-tests were used for continuous variables. A paired t-test was used to evaluate improvement in score from preoperative baseline to all postoperative timepoints for all patient-reported outcomes (PROs). PROMIS scores were evaluated using Pearson strength of correlation values with VAS back and VAS leg scores at all time points. Strength of correlation coefficient r was defined as: weak $0.1 < |r| < 0.3$, moderate $0.3 \leq |r| < 0.5$, or strong $|r| \geq 0.5$. Linear regression was used to evaluate the relationship between PROMIS scores and VAS back and VAS leg at all preoperative and postoperative time points. Finally, the 2 Pearson correlation values at each timepoint were compared with a 2-sample Fisher z-test. This allowed for computation of a Fisher z-transformation with an associated p-value for each time point to quantify differences in the strength of correlation of PROMIS PF with VAS back and VAS leg, respectively. GraphPad Prism 8.0

for Mac (La Jolla, CA, USA) was utilized to plot PROMIS score values against VAS back and VAS leg and perform a linear regression to evaluate the relationship between metrics. Statistical significance was set at $p < 0.05$.

Table 1. Patient demographics (n = 146)

Variable	Value
Age (yr)	
Mean \pm SD	51.1 \pm 11.1
Median (IQR)	52.7 (42.2–61.2)
Sex	
Female	59 (40.4)
Male	87 (59.6)
Body mass index	
Nonobese ($< 30 \text{ kg/m}^2$)	76 (52.1)
Obese ($\geq 30 \text{ kg/m}^2$)	70 (47.9)
Smoking status	
Nonsmoker	129 (88.4)
Smoker	17 (11.6)
Insurance coverage	
Private or WC	141 (96.6)
Medicare/Medicaid	5 (3.4)
Ageless CCI	
Mean \pm SD	0.86 \pm 1.0
Median (IQR)	1.0 (0–1)
Preoperative diagnoses*	
Myocardial infarction	3 (2.1)
Uncomplicated diabetes	10 (6.9)
Complicated diabetes	2 (1.4)
Hypertension	40 (27.4)
Neurologic disease	2 (1.4)
Arthritis	27 (18.5)
Malignancy	13 (8.9)
Spinal pathologies	
Degenerative spondylolisthesis	84 (57.6)
Degenerative disc disease	82 (56.1)
Isthmic spondylolisthesis	33 (22.6)
Herniated nucleus pulposus	22 (15.1)

Values are presented as number (%) unless otherwise indicated. SD, standard deviation; IQR, interquartile range; WC, workers compensation; CCI, Charlson Comorbidity Index.

*There were no patients in our study with a recorded medical history of acquired immunodeficiency syndrome, paraplegia, congestive heart failure, peripheral vascular disease, metastatic disease, liver disease, renal failure, chronic obstructive pulmonary disease, or gastrointestinal bleeds.

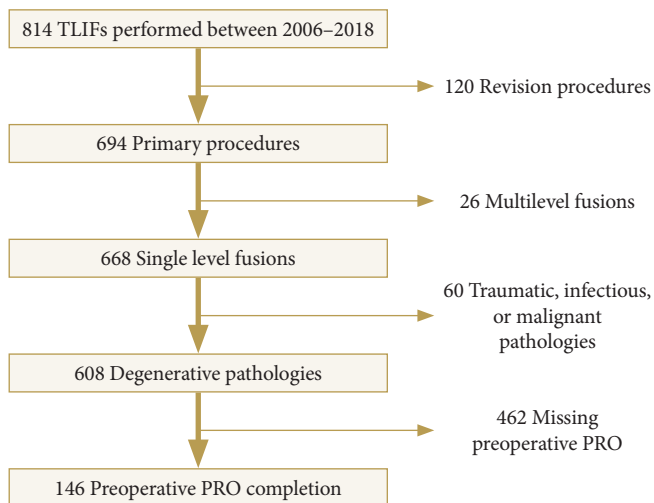


Fig. 1. Study enrollment flow chart. TLIF, transforaminal lumbar interbody fusion; PRO, patient-reported outcome.

RESULTS

From May 2015 to November 2018, a 146-subject cohort underwent a primary, single level, MIS TLIF (Fig. 1). The cohort was an average of 51 years of age. Over half of the cohort was composed of male, nonobese, nonsmoking patients (Table 1). The vast majority of the cohort had private insurance or workers compensation, while a slim minority had Medicare/Medicaid. The 3 most common preoperative diagnoses were hypertension, arthritis, and malignancy. The most common preoperative spinal pathology was degenerative spondylolisthesis (57.6%), followed by degenerative disc disease (56.1%). The majority of patients were discharged on postoperative day 1 or earlier (Table 2). With the exception of 1 patient who failed to fuse and 7 patients that did not have radiographic records available, we verified fusion of all other patients with follow-up radiographic x-ray or CT. The cohort PROMIS PF scores significantly improved from the preoperative score at all timepoints through 1 year (all $p < 0.034$) (Table 3). The average VAS pain levels for both back and leg pain significantly improved (numeric values decreased) from the preoperative mean to each timepoint through 1 year (all $p < 0.001$) (Table 3).

Pearson correlation coefficients of strength were assessed independently between VAS back and PROMIS PF as well as between VAS leg with PROMIS PF at all timepoints (Table 4).

VAS back correlations with PROMIS PF ranged from weak to strong negative correlations whereas the VAS leg correlation

Table 2. Operative characteristics (n = 146)

Value	Value
Operative time* (min)	
Mean ± SD	123.7 ± 22.8
Median (IQR)	121 (107–135)
Estimated blood loss (mL)	
Mean ± SD	53.4 ± 55.4
Median (IQR)	50 (25–50)
Length of hospital stay (hr)	
Mean ± SD	32 ± 20.0
Median (IQR)	28.4 (23.7–44.8)
Day of discharge	
POD 0	23 (15.9)
POD 1	85 (58.6)
POD 2	27 (18.6)
POD 3	6 (4.1)
POD 4	4 (2.8)
Fusion rate	138/139 (99.3)

Values are presented as number (%) unless otherwise indicated. SD, standard deviation; IQR, interquartile range; POD, postoperative day.

*Operative time was measured from skin incision to skin closure.

Table 3. Patient-reported outcome scores

Variable	PROMIS PF	p-value	VAS back	p-value	VAS leg	p-value
Preoperative						
Mean ± SD (n)	35.4 ± 6.2 (146)	-	6.6 ± 2.4 (146)	-	5.5 ± 3.0 (146)	-
Median (IQR)	35.6 (30.9–39.1)		7.1 (5.0–8.3)		6.0 (3.4–8.0)	
6 Weeks						
Mean ± SD (n)	36.8 ± 6.9 (112)	0.034	3.9 ± 2.6 (129)	< 0.001	2.9 ± 2.8 (129)	< 0.001
Median (IQR)	35.5 (32.1–42.6)		3.9 (2.0–5.9)		2.2 (0.0–5.1)	
12 Weeks						
Mean ± SD (n)	40.8 ± 7.0 (92)	< 0.001	3.6 ± 2.6 (122)	< 0.001	2.5 ± 2.6 (123)	< 0.001
Median (IQR)	42.6 (34.7–46.6)		3.1 (1.5–5.4)		1.7 (0.0–4.2)	
6 Months						
Mean ± SD (n)	43.5 ± 7.7 (93)	< 0.001	3.4 ± 2.7 (117)	< 0.001	2.2 ± 2.6 (117)	< 0.001
Median (IQR)	43.5 (37.5–49.8)		3.1 (1.1–5.4)		1.1 (0.0–4.0)	
1 Year						
Mean ± SD (n)	44.8 ± 9.0 (76)	< 0.001	2.8 ± 2.6 (71)	< 0.001	2.3 ± 2.8 (71)	< 0.001
Median (IQR)	45.7 (39.0–49.8)		2.0 (0.1–4.8)		1.0 (0.0–3.6)	

SD, standard deviation; IQR, interquartile range. p-value was calculated using Students t-test.

Table 4. Correlation of VAS back and VAS leg with PROMIS PF

Variable	VAS back	p-value [†]	Strength	VAS leg	p-value [†]	Strength	z-statistic	p-value
Preoperative	-0.176	0.034	Weak	-0.375	<0.001	Moderate	-1.837	0.066
6 Weeks	-0.470	<0.001	Moderate	-0.405	<0.001	Moderate	0.674	0.500
12 Weeks	-0.528	<0.001	Strong	-0.512	<0.001	Strong	0.179	0.858
6 Months	-0.659	<0.001	Strong	-0.483	<0.001	Moderate	2.237	0.025
1 Year	-0.641	<0.001	Strong	-0.514	<0.001	Strong	1.617	0.106

VAS, visual analogue scale; PROMIS PF, Patient-Reported Outcomes Measurement Information System physical function. [†]p-value was calculated using Pearson correlation; $0.1 < |r| < 0.3$ weak, $0.3 \leq |r| < 0.5$ moderate, $|r| \geq 0.5$ strong.

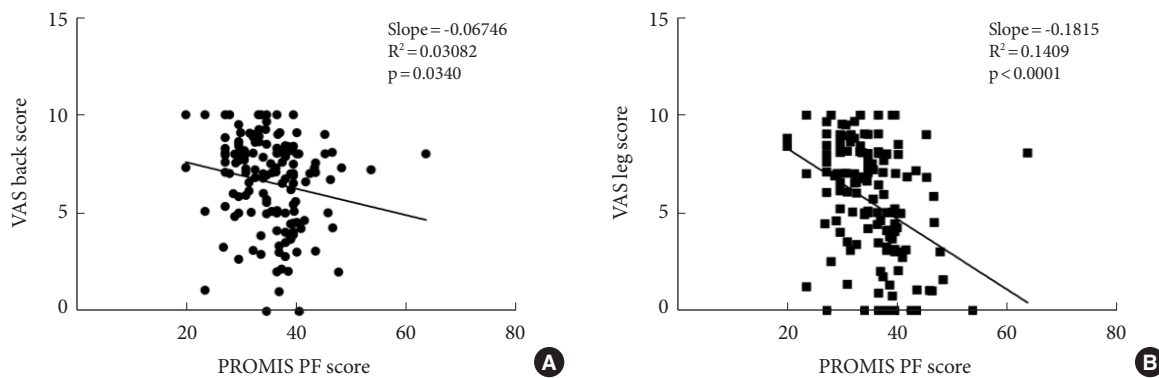


Fig. 2. Preoperative VAS back (A) and VAS leg (B) scores plotted against preoperative patient-reported outcomes measurement information system (PROMIS) physical function (PF) scores. VAS, visual analogue scale.

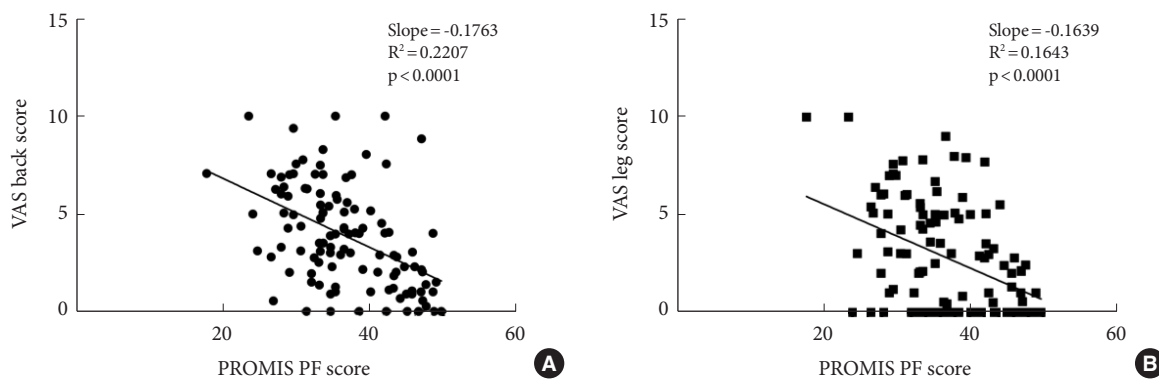


Fig. 3. Six weeks postoperative VAS back (A) and VAS leg (B) scores plotted against 6 weeks postoperative patient-reported outcomes measurement information system (PROMIS) physical function (PF) scores. VAS, visual analogue scale.

with PROMIS PF scores ranged from moderate to strong negative correlation. VAS back demonstrated stronger correlations with PROMIS PF scores than did VAS leg at all postoperative time points (Table 4). After linear regression, there was a significant negative association between PROMIS score and both VAS back and VAS leg at all time points (Figs. 2-6).

DISCUSSION

Although the VAS PROMs have among the most rigorously evaluated histories in nearly all medical specialties,^{11,12} this is the first study to focus on the influence of VAS back and VAS leg scores on PROMIS PF evaluations in the setting of MIS TLIF.^{8,13-15} While other studies have tangentially tabulated correlations with PROMIS and VAS scores,^{6,13,16-19} only one other

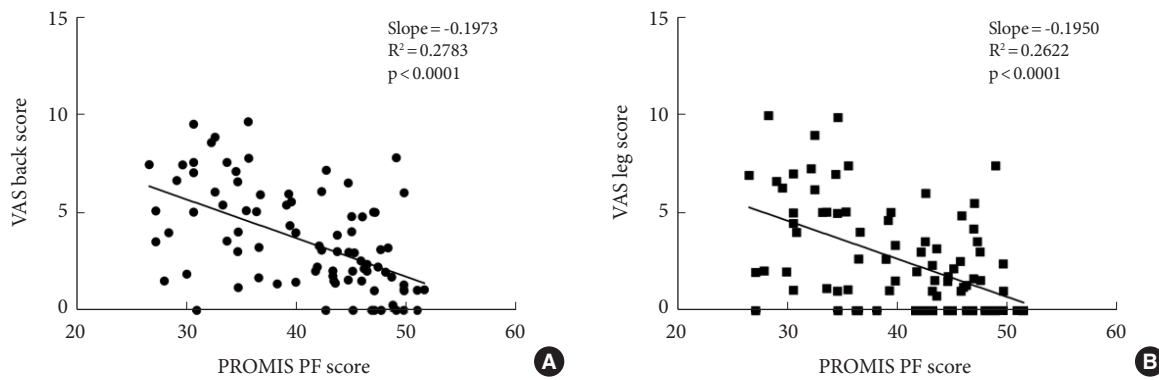


Fig. 4. Three-month postoperative VAS back (A) and VAS leg (B) scores plotted against 3-month postoperative patient-reported outcomes measurement information system (PROMIS) physical function (PF) scores. VAS, visual analogue scale.

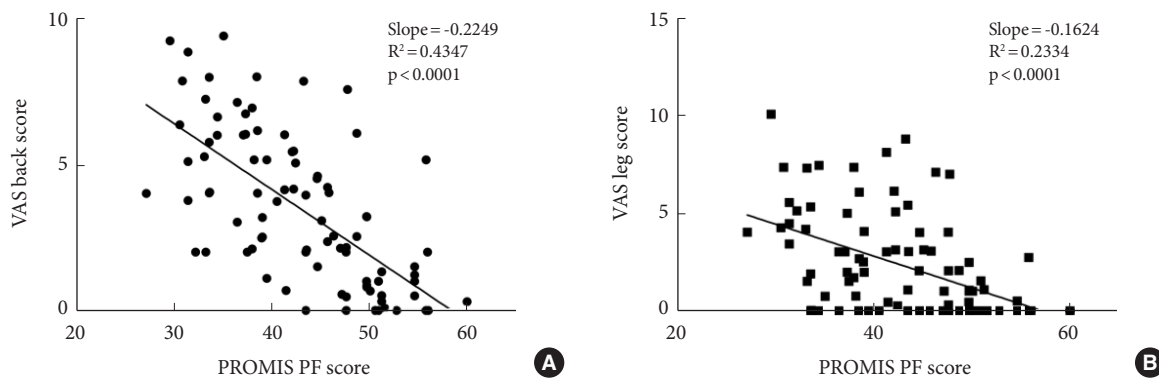


Fig. 5. Six-month postoperative VAS back (A) and VAS leg (B) scores plotted against 6-month postoperative patient-reported outcomes measurement information system (PROMIS) physical function (PF) scores. VAS, visual analogue scale.

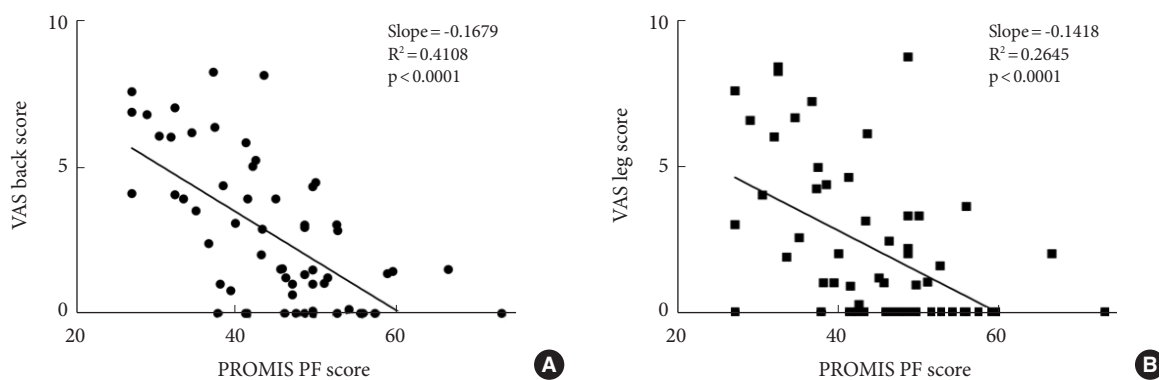


Fig. 6. One-year postoperative VAS back (A) and VAS leg (B) scores plotted against 1-year postoperative patient-reported outcomes measurement information system (PROMIS) physical function (PF) scores VAS, visual analogue scale.

study has done so with PROMIS PF scores. This current study adds to spine literature by focusing on PROMIS as a proxy for either VAS back or VAS leg and by utilizing a patient cohort that is twice the size as the largest cohort thus far. In a recent systematic review focusing on PROMIS score investigations, VAS was not even mentioned as a context in which PROMIS

has been assessed.⁸ Furthermore, no study has made a statistical comparison to investigate if physical function is more influenced by either VAS back or VAS leg.

This study is aligned with the only other investigation that has investigated perioperative PROMIS PF evaluations in conjunction with VAS back and VAS leg scores in the setting of

MIS TLIF. While both PROMs have been parenthetically explored with a sample size of 74 patients, the investigation did not discern if VAS back or VAS leg had a stronger correlation with PROMIS PF scores. Furthermore, our study nearly doubles the patient sample size with 145 participants.⁶ In comparison to previous investigations, this study is the first to demonstrate PROMIS PF score and VAS back scores have a statistically significant correlation during the preoperative evaluation. In comparison to previous studies, this investigation also demonstrated increased correlation values for VAS back at 6 weeks and 12 weeks. Additionally, this cohort demonstrated elevated VAS leg score values at the preoperative, 6-week, 12-week, and 6-month time points. This study also supports the findings of others that VAS back correlation values have a larger magnitude than VAS leg values for all postoperative time points. While our current study reports strong correlations for both VAS back and VAS leg scores with PROMIS PF scores at the 1-year evaluation, no comparison could be made with this finding and other literature as this is the first study to assess this time point correlation.

In comparison to others, we observed similar correlation strengths through the 6-month evaluation time period.⁶ Both this study and past investigations found that VAS back correlations were negative, and that they began as weak correlations, increasing in strength at 6 weeks and 12 weeks to moderate, and finally developing strong correlations at 6 months.⁶ Likewise, others have also observed VAS leg scores to be moderately correlated with PROMIS PF scores at preoperative, 6-week, and 6-month time periods, while demonstrating a strong correlation at 12 weeks.⁶

The final comparison this study conducted was between the 2 correlation values calculated at each time point. The Fisher z-

test revealed that, despite some variance between the VAS back and VAS leg scores, the 6-month VAS back score had a statistically significant stronger correlation than VAS leg score did with PROMIS PF scores. Interestingly, although the preoperative and 1-year correlation differences approached statistical significance, each favored different correlations. Beyond the numeric z-transformation statistical values, our interpretation is that the VAS leg scores may have been more correlated with PROMIS PF scores during the preoperative time period. However, VAS back scores were more associated with PROMIS PF at all postoperative timepoints, most significantly at 6 months and 1 year (Figs. 7, 8). It is likely that our findings might increase in significance at the preoperative and 1-year time point if observational power had been increased. This confirms the need for further research regarding PROMIS PF and VAS leg and VAS back validation in the setting of MIS TLIF.

Initially developed by the National Institute of Health, PROMIS was designed to be a health-focused measurement system that could not only evaluate a single disease, but also multiple comorbidities at once.⁹ An inherent limitation of global tests may be decreased performance in disease-specific PROs. Examples of poor correlations in other disease-specific PROs include the Marx Shoulder Activity Scale ($r=0.06$) for patients undergoing primary total shoulder arthroplasty,²⁰ the Single Assessment Numeric Evaluation ($r=0.23$) for patients experiencing shoulder arthritis,²¹ the American Shoulder and Elbow Surgeons shoulder assessment form ($r=0.34$) for patients with rotator cuff disease,²² and the Mayo Elbow Performance Score ($r=0.37$) for patients with lateral epicondylitis.²³

Additionally, the retrospective nature of this study might have introduced various biases, including selection biases. Part of

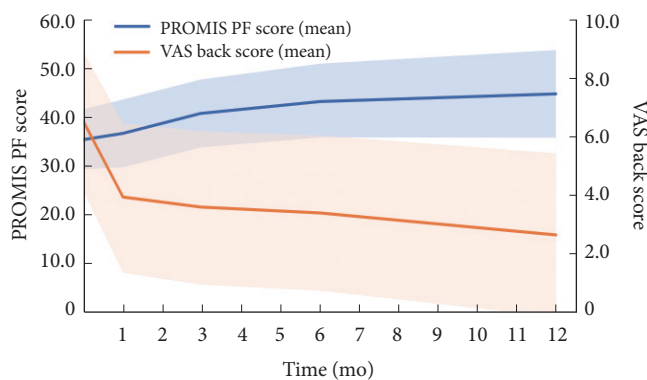


Fig. 7. Mean patient-reported outcomes measurement information system (PROMIS) physical function (PF) score versus mean VAS back score over 1-year observation. Shaded area represents one standard deviation. VAS, visual analogue scale.

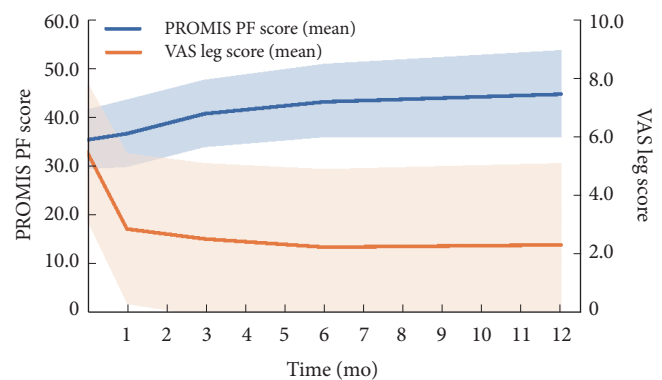


Fig. 8. Mean patient-reported outcomes measurement information system (PROMIS) physical function (PF) score versus mean VAS leg score over 1-year observation. Shaded area represents one standard deviation. VAS, visual analogue scale.

this selection bias may have been introduced due to the single surgeon, single-institution nature of this study. While this study attempted to use the largest consecutive patient cohort possible, this could limit the generalizability. The investigation of PROMs might also have had mixed effects on selection biases. Sick patients are typically considered more likely to return to the clinic in order to seek care for their illness. In opposition to this, severely disabled patients may have reached a disabled state that prevents them from returning to the clinic without proper assistance. Whatever the effect, this study observed a marked decrease in 1-year participant follow-up. While our patient follow-up at 1 year decreased for both PROMIS PF (n = 76) and VAS scores (n = 71), we did maintain enough power to determine statistically significant associations at these time points. Nonetheless, our loss to follow-up highlights the need for further research that investigates how to better encourage patient-reported outcome adherence.

An additional limitation arises due to our focus on our use of VAS back and VAS leg scores with PROMIS PF scores. In our current era of patient-centered healthcare for lumbar spine pathologies, we are confronted with numerous complexes, and very helpful, PROMs such as 12 Item Short Form, 36 Item Short Form, and ODI. Although we limited our focus to correlating VAS back and VAS leg scores with PROMIS PF scores, our study was designed to identify if either back or leg pain was more associated with PROMIS PF scores after MIS TLIF. A further limitation of our VAS leg instrument was its lack of differentiation between patients who experienced unilateral or bilateral leg pain. By pooling those patients together our study is unable to identify possible decreased physical ability in patients with bilateral leg symptoms. It should be considered that with the first postoperative visit being at 6 weeks, our study may not account for changes in PROs during the immediate recovery. One final limitation is related to our radiological imaging methods for evaluating postoperative fusion. This study determined a fusion rate, in many cases, via x-ray radiographs instead of computerized tomography scans. This could have led to underreporting cases of possible nonunion cases.

CONCLUSION

When assessing the postoperative period (6 weeks to 1 year) following MIS TLIF, patients that reported physical function, as evaluated by PROMIS PF, had a statistically significant stronger correlation with VAS back than VAS leg. This suggests that during the postoperative time period, PROMIS PF may be more

influenced by back pain than leg pain. Understanding how pain severity and origin impact physical function has an important role in the ability to appropriately guide patient expectations.

In focusing on patient-centered healthcare, it is important that all practitioners involved in the care of spinal pathology have a clear understanding of how pain severity and origin correlates with various outcome instruments. Knowing that back pain may be more associated with global physical function improvement than leg pain may allow clinicians to better anticipate overall physical function improvement.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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