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The Use of Patient-Reported Outcomes Measurement Information System in Spine: A Systematic Review

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ABSTRACT

Background: The Patient-Reported Outcomes Measurement Information System (PROMIS) was developed to provide an easily administered patient-outcome questionnaire that was adaptable to a variety of medical and surgical subspecialties. Numerous authors have examined the effectiveness of PROMIS in various areas of spine surgery. Our goal was to systematically review PROMIS scores compared with legacy patient-reported outcomes measures (PROMs) in spinal surgery and spine pathology.

Methods: A systematic search of the PubMed, EMBASE, and Cochrane databases using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines was performed, yielding 254 unique studies reporting on "PROMIS" in "spine." Each study was independently reviewed. A total of 16 studies were selected for inclusion.

Results: The pooled sample size yielded a total of 4268 patients. In the cervical population, PROMIS physical function (PF; $|\mathbf{r}| = .47-.87$, pain intensity (PIn; $|\mathbf{r}| = .61-.74$), pain interference (PIf; $|\mathbf{r}| = .65-.88$), and pain behavior (PB; $|\mathbf{r}| = .59-.74$) correlated with the Neck Disability Index (NDI). PROMIS PF also strongly correlated with the modified Japanese Orthopaedic Association scale (mJOA; $|\mathbf{r}| = .61-.72$). Among patients with lumbar pathology and adult spinal deformities, PROMIS PF ($|\mathbf{r}| = .53-.85$), PIn ($|\mathbf{r}| = .73-.78$), PIf ($|\mathbf{r}| = .59-.89$), and PB ($|\mathbf{r}| = .58-.82$) strongly correlated with the Oswestry Disability Index (ODI). PF ($|\mathbf{r}| = .51-.78$), PIf ($|\mathbf{r}| = .60-.70$), and anxiety ($|\mathbf{r}| = .73$) also strongly correlated with the Scoliosis Research Society (SRS)-22 and SRS-30. When comparing measures of global health, PROMIS PF was strongly correlated with the Short Form (SF)-12 and SF-36 ($|\mathbf{r}| = .50-.85$). On average, all PROMIS domains required less time to complete (49.6–56 seconds) than the ODI (176 seconds), NDI (190.3 seconds), SF-12 (214 seconds), and SF-36 physical function domains (99 seconds). The responsiveness of the PROMIS PF, PIf, and PB was comparable to that of legacy measures ODI, NDI, and SF-12.

Conclusions: The PROMIS PF, PIn, PIf, and PB demonstrated moderate to strong correlations with NDI, mJOA, ODI, SRS, and SF-12 measures in various populations of spine patients. All PROMIS domains had decreased time to completion and similar responsiveness compared with legacy measures.

Level of Evidence: 2.

Clinical Relevance: These results highlight the potential of PROMIS as a valid and reliable tool to assess patientreported outcomes in spinal surgery patients and support more widespread use of PROMIS in spine.

Other & Special Categories

Keywords: patient-reported outcome measures (PROMs), PROMIS, spine

INTRODUCTION

As the focus on evidence-based medicine and value-driven health care has grown over the past several decades, patient-reported outcomes measures (PROMs) have gained in popularity and importance in orthopedics.^{1,2} The current approach to PROMs focuses on a group of "legacy outcome measures" that measure outcomes in specific disease states and/or anatomical locations.^{3,4} This disease-specific approach, however, is fragmented by its

nature and makes it difficult to compare patient health and response with treatment across different pathologies and interventions. Furthermore, current PROMs are burdensome and require significant time to complete.⁵

To remedy these challenges, in 2004 the National Institute of Health developed the Patient-Reported Outcomes Measurement Information System (PROMIS) to provide a widely reliable and valid tool to measure patient outcomes across medicine.⁴ PROMIS questionnaires offer a set short-form

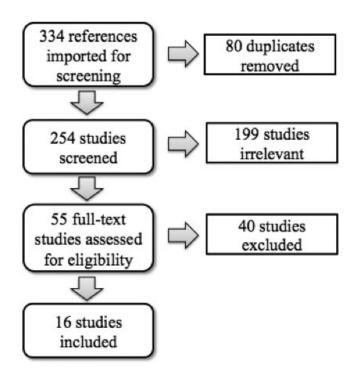


Figure. Flow diagram representing search process used in the study. A total of 334 references were identified from the initial search terms. Ultimately, 55 references underwent full text review and 16 studies were selected for final inclusion.

version with a fixed set of 4–10 questions or a computer adaptive test version of 4–12 questions tailored to individuals and the severity of their symptoms.⁶ Since its development, there has been a substantial increase in attention surrounding the validity, responsiveness, and ease of using PROMIS in spine patients.

The goal of this study was to systematically review PROMIS scores compared with legacy PROMs in spinal surgery. We hypothesize that PROMIS scores will be highly correlated with the various legacy PROMs in spinal surgery and be less burdensome to patients, requiring less time to complete.

METHODS

A systematic search of 3 databases, MEDLINE via PubMed, EMBASE, and the Cochrane Library, was performed to identify all relevant literature published between database inception and November 2018. The search strategy was created in collaboration with a professional medical librarian. Search terms included a combination of MeSH terms and keywords related to PROMIS and spine. The search was completed on November 20, 2018. The complete search strategy is available in the Appendix.

Inclusion criteria were any orthopedic-related article with level of evidence 1-4 and reporting use of PROMIS in spine pathology. Articles not related to spine, non-English articles, unpublished studies, studies with level 5 evidence, letters to the editor, editorials, basic science articles, and conference abstracts were excluded. Covidence (Melbourne, Australia) software was used for the screening process. The search yielded 254 unique studies reporting on "PROMIS" in "spine." Each study was independently reviewed. Ultimately, 55 studies were selected for full-text review, and 16 studies were selected for final inclusion (see Figure). Study characteristics (eg, study population, level of evidence, number of included patients, mean age) were recorded. The reported outcome instruments were noted and correlations between PROMIS domains and legacy measures were documented for each study. Correlations were reported as weak ($0 \le |\mathbf{r}| \le$ 3), moderate $(3 \le |\mathbf{r}| \le 5)$, or strong $(|\mathbf{r}| \ge 5)$. Responsiveness of the instrument and time to completion were also noted when available.

RESULTS

The characteristics of the included studies are shown in Table 1. The pooled sample size from the 16 studies yielded a total of 4268 patients. Of the 16 studies, one was level 1; nine were level 2; four were level 3; and two were level 4. The mean number of patients in each study was 267 (range, 41–1607).

Cervical Spine and Neck Pain

Of the 16 studies included, 7 reported on cervical pathology and the respective legacy measures (Table 2). In this population, PROMIS physical function (PF; $|\mathbf{r}| = .47-.87$, pain intensity (PIn; $|\mathbf{r}| = .61-.74$), pain interference (PIf; $|\mathbf{r}| = .65-.88$), and pain behavior (PB; $|\mathbf{r}| = .59-.74$) all moderately to strongly correlated with the Neck Disability Index (NDI). In Table 2, correlations may be reported as negative, given that higher PROMIS PF scores indicating an improvement in physical functioning would correlate with lower disability scores such as the NDI. Owen et al¹⁶ also showed PROMIS physical function strongly correlated with the mJOA (|r| = .61-.72). In a population of nonsurgical patients, Moses et al¹⁵ demonstrated a strong correlation between PROMIS PF and the NDI (|r|

Study	Population	Level of Evidence	n	Mean age, y	PROMIS	Legacy Measure
Bernstein et al ⁷	Adult spinal deformity	3	163	48	Physical function Pain interference Depression	SRS-30
Bhatt et al ⁸	Lumbar discectomy	2	78	41.6	Physical function Pain intensity Pain behavior	ODI SF-12
Boody et al ⁹	Cervical spine surgery	1	59	55.7	Physical function Pain intensity Pain behavior	NDI SF-12
Brodke et al ¹⁰	Back/leg pain	2	1607	54.2	Physical function	SF-36 PFD ODI
Haws et al ¹¹	MIS TLIF	2	74	53.9	Physical function	ODI
Hung et al ¹²	Spine clinic	3	316	57	Anxiety Depression	mZDI
Hung et al ¹³	Spinal disorders	2	763	58.28	Physical function Pain interference	ODI NDI
Khechen et al ¹⁴	MIS Lumbar Microdiscectomy	4	41	50.3	Physical function	ODI VAS Back VAS Leg
Moses et al ¹⁵	Neck pain	3	130	45–55	Physical function Pain intensity Pain interference	NDI VAS Back VAS Neck VAS Arm VAS Leg
Owen et al ¹⁶	Cervical myelopathy surgery	3	60	60	Pain intensity Anxiety Depression	NDI mJOA GAD-7 PHQ-8
Papuga et al ¹⁷	Spine clinic	4	283	55.2	Physical function Pain interference Pain behavior	ODI NDI
Patel et al ¹⁸	Lumbar stenosis surgery	2	98	61.9	Physical function Pain interference Pain behavior	ODI ZCQ SF-12
Purvis et al ¹⁹	Anterior cervical spine surgery	2	148	53	Physical function Pain intensity Anxiety Depression	NDI GAD-7 PHQ-8
Purvis et al ²⁰	Lumbar disc degeneration decompression	2	231	59	Physical function Pain intensity Anxiety Depression	ODI SF-12 BPI Pain BPI Back BPI Leg GAD-7 PHQ-8
Raad et al ²¹	Adult spinal deformity	2	123	58	Physical function Pain interference Anxiety	ODI SRS-22r
Sharma et al ²²	Cervical/Lumbar surgery	2	94	49	Physical function	ODI NDI

 Table 1.
 Characteristics of the studies included in this systematic review.

Abbreviations: BPI, Brief Pain Inventory; GAD-7, General Anxiety Disorder-7; MIS, minimally invasive surgery; TLIF, transforaminal lumbar interbody fusion; mJOA, modified Japanese Orthopaedic Association scale; mZDI, modified Zung Depression Index; NDI, Neck DISABILITY INDEX; ODI, Oswestry Disability Index; PHQ-8, Patient Health Questionnaire; SF-12, Short Form 12; SF-36 PFD, Short Form 36 physical function domains; VAS, visual analog scale; SRS-22r, Scoliosis Research Society questionnaire; ZCQ, Zurich Claudication Questionnaire.

= .771) but only moderate correlations with the visual analog scale (VAS) instruments ($|\mathbf{r}| = .302$ -.428).

Lumbar Spine and Adult Spinal Deformity

There were 11 studies that reported on patients with lumbar pathology or adult spinal deformity. In this population, the most common legacy measures included the Oswestry Disability Index (ODI), Scoliosis Research Society (SRS)-30 and SRS-22r, and VAS Back/Leg (Table 3). Among these patients, PROMIS PF ($|\mathbf{r}| = .53-.85$), PIn ($|\mathbf{r}| = .73-.78$), PIf ($|\mathbf{r}| = .59-.89$), and PB ($|\mathbf{r}| = .58-.82$) all strongly correlated with the ODI. The PROMIS PF ($|\mathbf{r}| = .51-.78$) and PIf ($|\mathbf{r}| = .60-.70$) also strongly correlated with the SRS-22 and SRS-30, whereas PROMIS PF demonstrated a wide range of correlations with VAS Back ($|\mathbf{r}| = .09-.69$) and with VAS Leg ($|\mathbf{r}| = .33-.64$).

Study	Population	n	PROMIS	Legacy	Correlation	Responsiveness	
Surgical Studies							
Boody et al ⁹	Cervical spine	59	PF	NDI	81		
2	Ĩ		PIn	NDI	.61		
			PB	NDI	.59		
Hung et al ¹³	Spinal disorders	763	PF	NDI Pre-op	66	PF SRM = 1.31	
C	1			NDI 3 mo	76	PIf SRM $= 1.16$	
				NDI 6 mo	80	NDI SRM = 1.18	
			PIf	NDI Pre-op	.71		
				NDI 3 mo	.81		
				NDI 6 mo	.74		
Papuga et al ¹⁷	Spine clinic	283 ^a	PF	NDI Pre-op	.8334		
	*			NDI Post-op	.871		
			PIf	NDI Pre-op	.6544		
				NDI Post-op	.8875		
			PB	NDI Pre-op	.7367		
Purvis et al ¹⁹	Anterior cervical spine	148	PF	NDI	47	PF ES = 0.35	
	ŕ		PIn	NDI	.74	PIn ES $= 0.86$	
Owen et al ¹⁶	Cervical myelopathy	60	PF	NDI Pre-op	69		
				NDI 6 mo	76		
				mJOA Pre-op	.61		
				mJOA 6 mo	.72		
Sharma et al ²²	Cervical surgery	42	PF	NDI Pre-op	603	PF SRM = 0.98	
				NDI 3 mo	703	NDI SRM = 0.58	
Nonsurgical Studies							
Moses et al ¹⁵	Neck pain	130	PF	NDI	771		
	*			VAS Neck	428		
				VAS Back	337		
				VAS Arm	333		
				VAS Leg	302		

Table 2. Correlations of various PROMIS domains with cervical spine legacy measures.

Abbreviations: ES, effect size; mJOA, modified Japanese Orthopaedic Association scale; NDI, Neck Disability Index; PB, pain behavior; PF, physical function; PIf, pain interference; PIn, pain intensity; Post-op, postoperative; Pre-op, preoperative; SRM, standard response mean; VAS, visual analog scale. ^aPapuga et al reported a total of 283 patients, but did not specify the number of cervical patients vs. lumbar patients.

In addition, when comparing PROMIS measures with ODI measures at different follow-up time points, PROMIS PF and PIf showed greater correlation as follow-up time increased. PROMIS PF demonstrated increasing correlation with ODI, from baseline or preoperative scores ($|\mathbf{r}| = .53-.76$) to 3-month postoperative scores ($|\mathbf{r}| = .74-.85$) to 6month postoperative scores ($|\mathbf{r}| = .80-.84$). PROMIS PIf demonstrated a similar pattern of increasing correlation with ODI with greater follow-up time, from baseline or preoperative scores ($|\mathbf{r}| = .59-.61$) to 3-month postoperative scores ($|\mathbf{r}| = .79$) to 6month postoperative scores ($|\mathbf{r}| = .83$).

Global Health and Mental Health

When comparing PROMIS with legacy measures of global health (Table 4), PROMIS PF was moderately to strongly correlated with the Short Form (SF)-12 ($|\mathbf{r}| = .50-.85$) and strongly correlated with the SF-36 physical function domains (PFD; $|\mathbf{r}|$ = .807), whereas the SF-12 moderately strongly correlated with PROMIS PIn ($|\mathbf{r}| = .34-.67$) and PB ($|\mathbf{r}| = .44-.47$). Three studies reported on PROMIS anxiety and depression scores compared with legacy mental health scores General Anxiety Disorder (GAD)-7, Patient Health Questionnaire (PHQ)-8, and modified Zung Depression Index (mZDI; Table 5). PROMIS depression scores strongly correlated with depression risk assessments PHQ-8 ($|\mathbf{r}| = .74-.79$) and mZDI ($|\mathbf{r}| = .67$), whereas PROMIS anxiety scores strongly correlated with the GAD-7 ($|\mathbf{r}| = .71-.76$).

Time to Completion

All studies that have reported on the time needed to complete PROM questionnaires in spine patients have shown that PROMIS requires significantly less time to complete than legacy measures (Table 6).^{8–10,17,18} On average, individual PROMIS domains required less time to complete (49.7–56 seconds) than ODI (176 seconds), NDI (190.3 seconds), SF-12 (214 seconds), and SF-36 PFD (99 seconds).

Responsiveness

The responsiveness of the PROMIS PF (effect size [ES] = 0.35-1.42, standard response mean

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Study	Population	n	PROMIS	Legacy	Correlation	Responsiveness
Surgical Studies						
Bhatt et al ⁸	Lumbar discectomy	78	PF	ODI	78	PF ES $= 1.42$
			PIn	ODI	.78	PIn ES = 1.6
			PB	ODI	.58	PB ES = 1.09
Haws et al ¹¹	MIS TLIF	74	PF	ODI Pre-op	525	
				ODI 3 mo	738	
				ODI 6 mo	831	
				VAS Back Pre-op	091	
				VAS Back 3 mo	446	
				VAS Back 6 mo	693	
				VAS Leg Pre-op	333	
				VAS Leg 3 mo	397	
				VAS Leg 6 mo	452	
Khechen et al ¹⁴	MIS Lumbar Microdiscectomy	41	PF	ODI Pre-op	.5735	
	j			ODI 3 mo	.8543	
				VAS Back 3 mo	.6522	
				VAS Leg Pre-op	.3964	
				VAS Leg 3 mo	.6412	
Papuga et al ¹⁷	Spine clinic	283 ^a	PF	ODI Pre-op	.7604	
i upugu vi ui	Spille enline	200		ODI Post-op	.8468	
			PIf	ODI Pre-op	.6133	
				ODI Post-op	.8907	
			PB	ODI Pre-op	.7226	
			I D	ODI Post-op	.8273	
Patel et al ¹⁸	Lumbar stenosis	98	PF	ODI I OST OP ODI	58	PF ES = 0.96
i atei et ai	Editodi Steliosis	20	11	ZCQ	61	PIf ES = 0.88
			PIf	ODI	.73	PB ES = 0.30
			1 11	ZCQ	.66	ODI ES = 0.96
			PB	ODI	.60	ZCQ ES = 0.41
			I D	ZCO	.59	200 ES = 0.41
Purvis et al ²⁰	Lymbor disa deconcration	231	PF	ODI	74	
Purvis et al	Lumbar disc degeneration	231	ГГ	BPI Pain If	74 51	
					31	
			DI.	BPI BP		
			PIn	ODI DDI Doin If	.73	
				BPI Pain If BPI BP	.61	
Sharma et al ²²	T 1	50	DE		.33	DE CDM 0.04
Sharma et al-	Lumbar surgery	52	PF	ODI Pre-op	753	PF SRM - 0.84
M. 1 M 10/ 1				ODI 3 mo	773	ODI SRM – 0.70
Mixed or Nonsurgical Studies		1(2	DE	CDC 20	70	
Bernstein et al ⁷	Adult spinal deformity	163	PF	SRS-30	.78	
			PIf	SRS-30	70	
D 11 110		1.00	D	SRS-30	80	
Brodke et al ¹⁰	Back/leg pain	1607	PF	ODI ODI II	81	
Hung et al ¹³	Spinal disorders	763	PF	ODI Baseline	66	PF SRM - 0.97–1.31
				ODI 3 mo	76	PIf SRM - 0.94–1.16
				ODI 6 mo	80	ODI SRM - 1.16–1.3
			PIf	ODI Pre-op	.59	PF ES – 0.98–1.11
				ODI 3 mo	.79	PIf ES – 1.29–1.39
			_	ODI 6 mo	.83	ODI ES – 1.03–1.08
Raad et al ²¹	Adult spinal deformity	123	PF	ODI	.76 ^b	PF ES – –0.29
				SRS-22r	.51 ^b	PIf $ES - 0.80$
			PIf	ODI	.77 ^b	Ax ES – 0.46
				SRS-22	.60 ^b	ODI ES – 0.67
			Ax	ODI	.52 ^b	SRS ES – –0.23
				SRS-22r	.73 ^b	

Table 3. Correlations of various PROMIS domains with lumbar spine and spinal deformity legacy measures.

Abbreviations: Ax, Anxiety; BPI BP, Brief Pain Inventory Back Pain; BPI Pain If, Brief Pain Inventory Pain Interference; D, depression; MIS, minimally invasive surgical; TLIF, transforaminal lumbar interbody fusion; ODI, Oswestry disability index; PB, pain behavior; PF, physical function; PIf, pain interference; PIn, pain intensity; Post-op, postoperative; Pre-op, preoperative; VAS, Visual analog scale; SRS-22r, Scoliosis research society questionnaire; ZCQ, Zurich claudication questionnaire; ES, effect size; SRM, standard response mean.

^aPapuga et al reported a total of 283 patients but did not specify the number of cervical patients vs lumbar patients.

^bReported as Spearman correlations; all other correlations reported as Pearson correlations.

[SRM] = 0.31-1.31), PIf (ES = 0.8-1.39, SRM = 0.78-1.16), and PB (ES = 0.7-1.09) was comparable to that of legacy measures ODI (ES = 0.96-1.03, SRM = 0.7-1.33), NDI (ES = 074-0.76, SRM = 0.58-1.18) and SF-12 (ES = 0.675).^{8,13,18,19,21,22}

Floor and Ceiling Effects of PROMIS

Multiple included studies reported on floor and ceiling effects of various PROMIS domains. Reported floor effects for PROMIS PF (0.0%-3.86%),^{9,10,18,23} PIf (0.0%-0.44%),^{7,15,18} and PB

Table 4.	Correlations of various	PROMIS domains	with global health	legacy measures.
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Study	Population	n	PROMIS	Legacy	Correlation	Responsiveness	
Surgical Studies							
Bhatt et al ⁸	Lumbar discectomy	78	PF	SF-12	.61		
			PIn	SF-12	47		
			PB	SF-12	47		
Boody et al ⁹	Cervical spine	59	PF	SF-12	.57		
	*		PIn	SF-12	34		
			PB	SF-12	44		
Haws et al ¹¹	MIS TLIF	74	PF	SF-12 Pre-op	.65		
				SF-12 3 mo	.786		
				SF-12 6 mo	.854		
Patel et al ¹⁸	Lumbar stenosis	98	PF	SF-12	.50	PF ES = 0.96	
						SF-12 ES = 0.6	
Purvis et al ²⁰	Lumbar disc degeneration	231	PF	SF-12	.68		
	0		PIn	SF-12	67		
Nonsurgical Studies							
Brodke et al ¹⁰	Back/Leg pain	1607	PF	SF-36 PFD	.807		

Abbreviations: ES, effect size; MIS, minimally invasive surgical; TLIF, transforaminal lumbar interbody fusion; PB, pain behavior; PF, physical function; PIn, pain intensity; SF-12, Short Form 12; SF-36 PFD, Short Form 36 physical function domains.

 $(0.0\%-1.0\%)^{9,18}$ were comparable or less than those reported for SF-36 PFD (23.65%),¹⁰ ODI (0%– 44.24%),^{9,10,18} NDI (7.10%),¹⁵ SF-12 (0.0%),^{9,18} and SRS-22r (0.88%–1.32%).⁷ Similarly, ceiling effects were relatively low for PROMIS PF (0.0%– 1.7%),^{9,10,18,23} PIf (0.0%–0.88%),^{7,15,18} and PB (0.0%).^{9,18}

DISCUSSION

As health care becomes more reliant on PROMs to evaluate treatments, numerous general and disease-specific measures have been put forth as means to assess the impact of various interventions across orthopedic pathologies. Nevertheless, these instruments are often cumbersome to complete and/ or lack the ability to compare across populations and pathologies. PROMIS is promoted as a fast, simple instrument with broad applicability, and it has become increasingly used in research and to assess clinical outcomes in orthopedics.^{2,4} The goal of this study was to systematically review the

literature available comparing the psychometric properties of **PROMIS** and legacy measures in spinal populations.

Across all populations included in this review, we found PROMIS to have strong correlation with legacy outcome measures. In the cervical population, PROMIS PF, PIn, PIf, and PB all moderately to strongly correlated with the NDI ($|\mathbf{r}| = .47-.88$) and PF strongly correlated with the mJOA ($|\mathbf{r}| =$.61–.72). Among patients with lumbar pathology and adult spinal deformity, the PROMIS PF, PIn, PIf, and PB all strongly correlated with the ODI (|r|= .70–.76), and PROMIS PF and PIf also strongly correlated with the SRS-22 and SRS-30 (average $|\mathbf{r}|$ = .65). Similarly, PROMIS measures correlated strongly with measures of global health (SF-12 and SF-36), as well as those assessing depression and anxiety, such as the PHQ-8, GAD-7, and mZDI.

It is important for the providers and reseachers in spine to be able to coordinate the use of PROMs in

Study	Population	n	PROMIS	Legacy	Correlation	Responsiveness
Surgical Studies						
Purvis et al ¹⁹	Anterior cervical spine	148	Anxiety	GAD-7	.76	Anxiety $ES = -0.55$
	_			PHQ-8	.73	Depression $ES = -0.24$
			Depression	GAD-7	.63	^
			*	PHO-8	.74	
Purvis et al ²⁰	Lumbar disc degeneration	231	Anxiety	GAD-7	.71	
	8		2	PHO-8	.73	
			Depression	GAD-7	.64	
			1	PHO-8	.79	
Nonsurgical Studies						
Hung et al ¹²	Spine clinic	316	Anxiety	mZDI	.712	
	··· I		Depression	mZDI	.667	

Table 5. Correlations of PROMIS anxiety and depression scores with mental health legacy measures.

Abbreviations: GAD-7, General Anxiety Disorder-7; mZDI, modified Zung Depression Index; PHQ-8, Patient Health Questionnaire.

Table 6.	Time in seconds needed to complete each patient-reported outcome measure.	
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Study	Population	n	PF	PIn	PB	ODI	NDI	SF-36 PFD	SF-12
Bhatt et al ⁸	Lumbar discectomy	78	48	36	54	162			180
Boody et al ⁹	Cervical spine	59	66	72	54		204		246
Brodke et al ¹⁰	Spine	1607	44			169		99	
Owen et al ¹⁶	Cervical myelopathy	60	56						
Papuga et al ¹⁷	Spine	283	36	48		187	180		
Patel et al ¹⁸	Lumbar stenosis	98	48		60	186	187		216
Average time, s			49.7	52	56	176	190.3	99	214

Abbreviations: NDI, Neck Disability Index; ODI, Oswestry Disability Index; PB, pain behavior; PF, physical function; PIn, pain intensity; SF-12, Short Form 12; SF-36 PFD, Short Form 36 physical function domains.

outcome research so that results can be compared between different studies. Guzman et al⁵ reported in 2016 that the top 6 most frequently used PROMs in spine practices were the VAS, ODI, SF-36, mJOA, NDI, and SRS-22, highlighting that the use of these different disease-specific legacy measures resulted in inconsistencies and author-dependent modifications that could not be standardized.5 Similarly, Winebrake et al²⁴ evaluated outcome reporting in the setting of fusion for lumbar spinal stenosis, noting substantial variability across the literature and recommending efforts to standardize reporting of outcomes to facilitate comparison across surgical interventions and pathologies. The high variability in PROMs used in research led the National Institute of health to develop PROMIS. The findings in this study support the use of PROMIS in diverse spine populations and anatomic locations.

In addition to standardized use and broad applicability, another important factor in determining the effectiveness and utility of PROMs is the burden of the instrument to the patient. Because most of these PROMs forms are administered during clinic visits, ease of use and time to completion are critical components of their success. On average, the PROMIS PF required 49.7 seconds to complete, PROMIS PIn required 52 seconds, and PROMIS PB required 56 seconds. Comparatively, legacy measures ODI (176 seconds), NDI (190.3 seconds), SF-12 (214 seconds), and SF-36 PFD (99 seconds) required more time to complete. The findings in this study demonstrate the possible reduced burden of administration of the PROMIS domains, highlighting this key advantage over legacy measures. However, investigators may want to administer multiple questionnaires to assess different domains of health and should be aware of the additive time of multiple questionnaires.

With these findings in mind, we believe that PROMIS has several advantages over other instruments. Including PROMIS data consistently in

spine outcomes will allow practitioners and researchers to easily review literature and compare outcomes across interventions and pathologies.²⁵ As seen in this review, the PROMIS domains focused on physical function and pain were the most commonly studied because these address symptoms often primarily targeted in spine patients. However, if investigators wish to study other domains such as global or mental health, they may still be able to compare results across the different domains because the PROMIS scoring system is a T-score metric with a score of 50 being the mean for a reference population and a 10-point standard deviation in either direction. PROMIS can be administered using the short form or computer adaptive testing, allowing practitioners to use technology to easily distribute questionnaires, increase response rates, and further reduce the administrative burden in their clinics.

There are several limitations of our study. As a systematic review, our study is limited by the quality of the underlying studies that were analyzed. Several studies that were examined included heterogeneous populations undergoing widely varied treatments, limiting the applicability to any 1 pathology or intervention. Nevertheless, the goal of this study was to examine the use of PROMIS in the spine literature, comparing its use with legacy outcome measures generally, and where possible we attempted to provide study details and organize by pathology and type of intervention (eg, surgical vs nonsurgical). Furthermore, there are multiple studies included in this review that were published by the same group of authors, raising the possibility of observer bias among these studies. Last, given that PROMIS was developed relatively recently, there are a limited number of studies providing direct comparisons of PROMIS to legacy measures. Therefore, although this review covers a range of different spinal pathologies, numerous diagnoses are not included. Future studies reporting PROMIS

are needed to provide a more comprehensive review of the spine literature.

CONCLUSIONS

PROMIS PF, PIn, PIf, and PB demonstrated strong correlations with disease-specific legacy measures NDI, mJOA, ODI, and SRS-22 and global health measures SF-12 and SF-36 in cervical, lumbar, and spinal deformity patients. The decreased time to completion and comparable responsiveness of PROMIS domains support more widespread use of PROMIS in spine outcome research.

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APPENDIX. SEARCH STRATEGIES FOR RESPECTIVE ACADEMIC DATABASES

PubMed Strategy

("Promis"[tw] OR "Patient-Reported Outcomes Measurement Information System"[tw] OR "Patient-Reported Outcome Measurement Information System"[tw]) AND ("Spine" [Mesh] OR "Spinal Diseases"[mesh] OR "Back Pain"[mesh] OR "neck"[mesh] OR "Spine"[tw] OR "Spinal"[tw] OR "lumbar"[tw])

EMBASE Strategy

(promis:ti,ab,de,tn,kw OR 'patient-reported outcomes measurement information system':ti,ab, de,tn,kw OR 'patient-reported outcome measurement information system':ti,ab,de,tn,kw OR 'patient reported outcomes measurement information system'/exp OR 'patient reported outcome measurement information system'/exp) AND ('spine'/exp OR 'spinal disease'/exp OR 'backache'/exp OR 'neck'/exp OR spine:ti,ab, de,tn,kw OR spinal:-ti,ab,de,tn,kw OR lumbar: ti,ab,de,tn,kw)

Cochrane Library Strategy

(Promis:ti,ab,kw OR "Patient-Reported Outcomes Measurement Information System": ti,ab,kw OR "Patient-Reported Outcome Measurement Information System":ti,ab,kw) AND ([mh Spine] OR [mh "Spinal Diseases"] OR [mh "Back Pain"] OR [mh neck] OR Spine: ti,ab,kw OR Spinal:ti,ab,kw OR lumbar: ti,ab,kw)

Resources for Selecting PROMIS Forms

A full list of PROMIS adult measures can be found here:

http://www.healthmeasures.net/exploremeasurement-systems/promis/intro-to-promis/ list-of-adult-measures

A manual for the PROMIS physical function instruments including characteristics of the short form, computer adaptive tests, and scoring guide can be found here:

http://www.healthmeasures.net/images/ PROMIS/manuals/PROMIS_Physical_ Function_Scoring_Manual.pdf

A manual for the PROMIS pain interference instruments including characteristics of the short form, computer adaptive tests, and scoring guide can be found here:

http://www.healthmeasures.net/images/ PROMIS/manuals/PROMIS_Pain_Interference_ Scoring_Manual.pdf