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Quantitative dynamic wearable motion-based metric compared to patient-reported outcomes as indicators of functional recovery after lumbar fusion surgery

Safdar Khan[a,b], Prasath Mageswaran[a], Guy Brock[c], Mariah Eisner[c], Sue A. Ferguson[a], William S. Marras[a,*]

[a] Spine Research Institute, The Ohio State University, Columbus, OH, USA
[b] Wexner Medical Center, The Ohio State University, Columbus, OH, USA
[c] Center for Biostatistics, Department of Biomedical Informatics, The Ohio State University, Columbus, OH, USA

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ABSTRACT

Background: Low back pain is a debilitating condition with poor patient outcomes despite the use of a wide variety of diagnostic and treatment modalities. A lack of objective metrics to support clinical decision-making may be a reason for these poor outcomes. This study aimed to compare patient recovery following lumbar fusion surgery using an objective motion-based metric (functional performance) and subjective patient-reported outcomes for pain, disability and kinesophobia.

Methods: A prospective observational study was conducted on 121 patients that received a lumbar fusion surgery. A wearable motion system was used to quantify three-dimensional multi-planar lumbar motion and benchmark each patient's lumbar function prior to surgery and post-operatively at follow-up time points for up to 2 years. Patient recovery profiles after surgery were evaluated using the acquired functional motion data and compared to patient-reported outcomes.

Findings: Our results found significant improvement after surgery in objective functional performance as well as patient-reported pain, disability, and kinesophobia. However, we found a delayed response in the objective metric, with meaningful improvement occurring only 6 months after fusion surgery. In contrast, we found significant improvement in all subjective scores as early as 6 weeks post-surgery.

Interpretation: Objective motion-based metric provides a unique perspective to assessing patient's functional recovery. While it is associated with dimensions of pain, disability and fear avoidance, it is also distinct and assesses a uniquely different dimension of functional health. This information can form the basis for the use of objective metrics to gauge patient recovery after lumbar fusion surgery.

1. Introduction

Low back pain is a debilitating condition that affects over 540 million people globally (Hartvigsen et al., 2018). The current estimate of incidence and prevalence are 245.9 million cases/year (~3.2%) and 577 million cases/year (7.6%) respectively, with age, sex and race serving as potential risk factors (Mattiuzzi et al., 2020; Waterman et al., 2012). Of particular concern is chronic low back pain (cLBP), which is often of unknown origin (non-specific). Despite an increase in medical costs of 300% over the past 20 years, treatment outcomes have not improved (Deyo et al., 2009; Dieleman et al., 2016). One reason for this discrepancy may be related to a lack of objective metrics available to healthcare providers to effectively gauge severity of impairment and accurately assess the impact of specific treatments on functional restoration over time. Patient-reported outcomes (PROs) such as pain scales, disability or quality of life measures are widely used in spine care to assess spine health. However, PROs are subjective and often influenced by the patient's perception of their condition. Furthermore, PROs only represent a fraction of the biopsychosocial picture. It is believed that the lack of objective metrics has contributed to the reliance on trial and error treatment approaches for cLBP. Thus, there is a critical need for objective metrics to facilitate quantitative assessment of disability,

* Corresponding author at: 1971 Neil Avenue, Room 520, Columbus, OH 43210, USA.
E-mail address: marras.1@osu.edu (W.S. Marras).

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monitor treatment effectiveness and enhance clinical decision-making to improve outcomes.

To address this problem, we developed a noninvasive, wearable, reliable, clinical motion assessment device that provides a direct objective measure of spine function (indicative of biomechanical function) (Ferguson et al., 2000; Ferguson et al., 2009; Ferguson et al., 2015; Ferguson et al., 2019; Marras et al., 1995; Marras et al., 1999; Marras et al., 2000; Marras et al., 2007). A wearable motion sensing system called the clinical lumbar motion monitor (cLMM) is used to capture a patient's unique motion signature while they perform a series of standardized multi-planer motion assessment. The system hardware (Fig. 1) is made up of two 9-axis inertial motion unit (IMU) sensors mounted on the upper back (thoracic region) and waist (pelvic region) using custom harnesses. The motion signature consists of three-dimensional (3D) lumbar range of motion (RoM) as well as dynamic features such as velocities and accelerations which have shown to be significantly more predictive and useful than RoM alone (Ferguson et al., 2009; Ferguson et al., 2015; Ferguson and Marras, 2013; Marras et al., 1999). Upon completion of the motion assessment, the motion data is compared to a normative motion database of healthy controls to generate a composite functional performance (probability of Normal or pN) score (Marras et al., 1995; Marras et al., 1999). This easy-to-interpret functional score ranges from 0 to 100%, where a score of <50% indicates the person has impaired functional performance for their age and gender and a score above 50% indicates healthy functional performance. The pN score yields sensitivity and specificity of 90 and 94% respectively for distinguishing between cLBP patients and healthy controls (Marras et al., 1995; Marras et al., 1999). Additionally, the cLMM assessment has shown excellent test reliability (intra-class correlation coefficients (ICC) > 0.9) (Marras et al., 1994; Marras et al., 1995). The development and validation of the pN score has been extensively published in peer-reviewed journals (Ferguson et al., 2000; Ferguson et al., 2003; Ferguson et al., 2009; Marras et al., 1995; Marras et al., 1999; Marras et al., 2000; Marras et al., 2007). Our prior research have demonstrated that dynamic motion features can serve as reliable biomarkers because of their excellent sensitivity and specificity to the effects of low back disorders (Ferguson et al., 2000; Ferguson et al., 2005; Ferguson and Marras, 2013; Marras et al., 1995; Marras et al., 1999; Marras et al., 2007) and, therefore, are excellent indicators of functional spine health. Thus, given the need for objective metrics in spine care, the clinical utility of this functional motion-based metric and its relationship to existing PROs needs to be further investigated in cLBP patient populations.

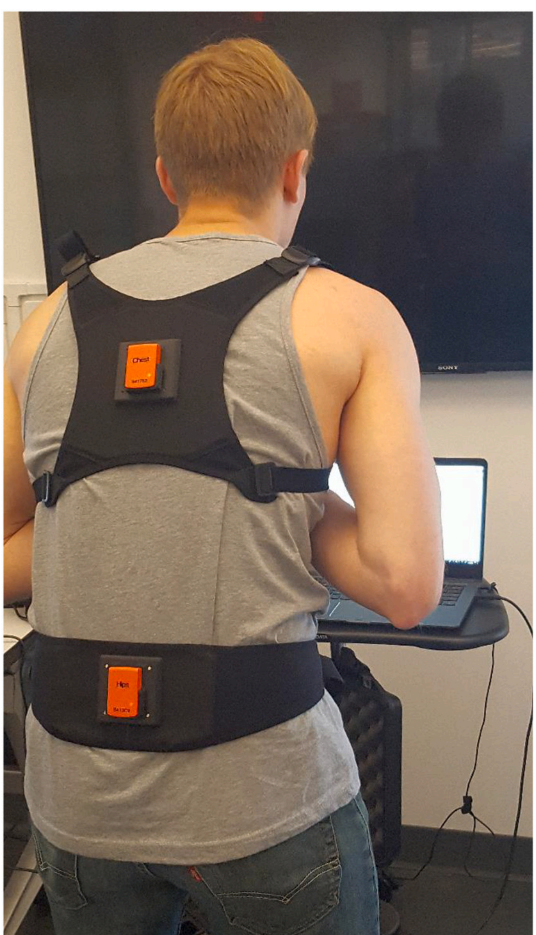

Fig. 1. Clinical Lumbar Motion Monitor uses wearable motion sensors mounted on chest and waist harnesses to quantify functional performance of patients in clinical settings.

The primary goal of our study was two-fold: (a) To longitudinally evaluate the recovery profiles of patients receiving a lumbar fusion surgery using the novel pN score and existing widely used PROs; and (b) to compare and document the relationship between pN and PROs over time.

2. Methods

2.1. Study design

We conducted a single-arm prospective observational study of cLBP patients ($n = 121$) receiving standard-of-care lumbar fusion surgery at the Ohio State University Wexner Medical Center (OSUWMC). Participants were recruited based on eligibility criteria and medical history. Prior to participant enrollment, a research team member explained the study in detail, confirmed eligibility per study protocol, and obtained informed consent. Clinical data were collected at baseline prior to treatment and at post-treatment follow-up periods over time. The study protocol was approved by the University's Institutional Review Board.

2.2. Patient sample

Our study participants were adults with cLBP and radicular symptoms that sought a surgical consult at OSUWMC. The inclusion criteria were (a) age of 18 years or older; (b) currently seeking surgical care for cLBP (defined as pain >3 months and at least 50% of the days during the past 6 months); (c) presence of neurogenic claudication or radicular symptoms; (d) ability to perform a motion test; and (e) failed conservative care. The exclusion criteria were: (a) neoplasia; (b) spinal deformity, (c) spinal fractures; (d) pregnancy; (e) spinal infection; and (f) cancer.

2.3. Outcome measures

PROs used in this effort included McGill Pain Questionnaire's 10-point visual analog scale (VAS) (Melzack, 1975) to assess back pain intensity; Oswestry Disability Index (ODI) which ranges from 0 to 100 points, with higher scores indicating severe functional disability (Fairbank and Pynsent, 2000; Frost et al., 2008); and the Fear-Avoidance Behavior Questionnaire (FABQ-PA) to assess kinesiophobia (Waddell et al., 1993). Finally, quality of life was assessed using short form (SF) 36 at baseline. The objective functional performance (pN or probability of Normal) was assessed via the cLMM (Ferguson et al., 2009; Marras et al., 1999; Marras et al., 2000; Marras et al., 2007). The pN score ranges from 0 to 100%, with scores >50% indicating a healthy function relative to the patient's age and gender. A change in pN score of 14% has been shown to be clinically meaningful (Ferguson et al., 2009). Outcome measures were collected at baseline on enrollment and longitudinally post-surgery at 6 weeks, 3 months, 6 months, 1 year and 2 year follow-up visits. Additional covariates collected at baseline included patient demographics; smoking status; medical history; and primary pre-operative diagnosis.

2.4. Procedure

Enrolled participants completed a series of PROs prior to performing a 15-min functional motion assessment administered using the cLMM. The system was placed on the participant's back and they were instructed to perform a series of predefined standardized dynamic motion tasks to the best of their ability without exacerbating any symptoms. The motion tasks included flexion-extension, lateral bending and axial rotation with data acquired for a minimum of 4 cycles for each motion task. All motions were practiced prior to data collection to ensure that patients were comfortable with performing the tasks. Participants were allowed to stop if they felt any exacerbation of pain symptoms or discomfort during testing. A trained team member helped oversee the 15-min motion test and ensure protocol adherence.

2.5. Statistical analysis

Data were described using frequency (percent) for categorical variables and mean (standard deviation) for continuous variables. Pearson correlation (r) was used to evaluate the association between outcome measures before and after fusion surgery. The strengths of these associations were interpreted as follows: $0.1 \leq r < 0.3$, $0.3 \leq r < 0.5$, and $r \geq 0.5$ indicated weak, moderate and strong correlations (Cohen, 2013; Haws et al., 2018). Paired *t*-tests were used to compare post-operative scores to pre-operative values at baseline and to compare PRO and pN scores between pre-operative diagnosis groups. Linear mixed-effect models were used to account for within-patient correlation while modeling trajectory of outcomes over time. These were fit with subject-level random intercepts and slopes. We presented contrast estimates from baseline to various time points using Bonferroni adjusted *p*-values. *p*-values < 0.05 were considered statistically significant. All statistical analyses were conducted using R 4.0 (R Core Team, Vienna, Austria).

3. Results

3.1. Demographic and baseline clinical characteristics

Our patient cohort comprised of 59 males and 62 females with a mean age of 55 ± 10 years prior to lumbar fusion surgery. The majority of the patients were married (65%) and non-smokers (87%). Most common pre-operative diagnoses were lumbar spondylolisthesis with stenosis (35%) and spinal stenosis only (55%). All patients underwent surgical decompression, prior to fusion. Single-level fusions were done on 47% of patients and the most operated levels were L4 – L5 (22%) and, L5 – S1 (21%).

Pre-operatively at baseline, mean (± Standard Deviation) pN score was 18% ± 23, which was well below healthy thresholds (scores >50% is considered functionally healthy). Similarly, mean scores for PROs were as follows: mean VAS was 6.5 ± 1.9; mean ODI was 46.3 ± 15.7, mean FABQ-PA was 16.7 ± 6.1, mean SF-36 (Physical) was 48.7 ± 5.1 and mean SF-36 (Mental) was 46.0 ± 5.0. Table 1 shows baseline patient parameters.

3.2. Patient recovery profiles

Out of the 121 patients undergoing a lumbar fusion surgery, 81 completed their 6 month follow-up, and 61 completed their 2 year follow-up. Our results showed significant long-term improvement in different dimensions (pain, disability, functional performance & fear avoidance) at 2 years post-surgery. However, we found that the recovery rates were different when assessed using an objective (pN) vs. subjective metrics (PROs). Fig. 2 reports the percent change from baseline of pN compared to PROs over time illustrating the varying recovery patterns as assessed by these different metrics. Using a linear mixed-effects regression model to estimate the contrast in pN from baseline to post-surgery time points, we found none to minimal functional improvement at 6 weeks (−52%, $p = 0.2$) and 3 month (3.0%, $p > 0.99$) post-surgery. It

Table 1
Baseline patient parameters.

Characteristic	Mean (Standard Deviation) or *n* (%)
Age, baseline	55 (10)
Gender	
Female	62 (51%)
Male	59 (49%)
Marital Status	
Single	9 (8.3%)
Married	71 (65%)
Divorced	22 (20%)
Separated	2 (1.8%)
Widowed	4 (3.7%)
Partnership	1 (0.9%)
Smoking status	
Smoking	14 (13%)
Non-smoking	107 (87%)
Pre-op Primary Diagnosis	
Stenosis only	62 (55%)
Spondylolisthesis	40 (35%)
Others e.g. Herniated disc	11 (9.7%)
Number of operated spinal levels	
1	62 (51%)
2	39 (32%)
3	14 (12%)
>4	6 (5%)
Baseline Motion-based metric	
pN	18 (23)
Baseline PRO scores	
VAS	6.5 (1.9)
ODI	46.3 (15.7)
FABQ PA	16.7 (6.1)
SF36 Physical Function	48.7 (5.1)
SF36 Mental Health	46.0 (5.0)

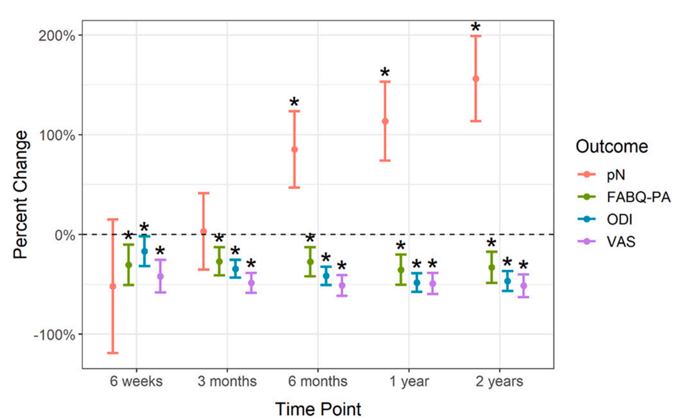

Fig. 2. Percent change from baseline with confidence limit for all measures; while VAS, ODI and FABQ-PA showed significant response as early as 6 weeks, pN showed a delayed response with significant improvement only occurring at 6 months that remained sustained at 1 year and 2 year time points. *indicates statistically significant change.

was not until 6 months after fusion surgery, that we observed a significant increase (meaningful improvement) in pN score of 85.2% ($p < 0.01$), with further sustained improvements at 1 year (113.7%, $p < 0.01$) and 2 year (156.3%, $p < 0.001$) time points. In contrast, we found significant improvement in ODI scores of 16.8% ($p = 0.02$) at 6 weeks, 34.5% ($p < 0.01$) at 3 months, 41.5% ($p < 0.01$) at 6 months, 48.3% ($p < 0.01$) at 1 year and 46.6% ($p < 0.01$) at 2 years. Similarly, post-operative VAS showed significant decrease in pain of 41.9% ($p < 0.01$) at 6 weeks, 48.6% ($p < 0.01$) at 3 months, 51.1% ($p < 0.01$) at 6 months, 49.3% ($p < 0.01$) at 1 year and 51.4% ($p < 0.001$) at 2 years. Finally, we found estimated percent change in FABQ-PA score from baseline were 30.4% ($p = 0.01$) at 6 weeks, 27.0% ($p < 0.01$) at 3 months, 27.3% ($p < 0.01$) at 6 months, 35.4% ($p < 0.01$) at 1 year and 33.0% ($p < 0.01$) at 2 years.

3.3. Functional performance by pre-operative diagnosis

In comparing functional scores by pre-operative diagnosis, we observed mean pN scores of 18% ± 23 (spondylolisthesis) and 19% ± 23 (spinal stenosis only) at baseline (Table 2). There was no significant difference ($p = 0.8$) between these two primary diagnoses. However, the recovery pattern assessed via pN trended much more slowly for patients with spinal stenosis than those with spondylolisthesis (Fig. 3). For PROs, only FABQ-PA trended towards significant difference between diagnoses at baseline while both VAS and ODI showed no significant differences in recovery patterns by diagnosis.

3.4. Concurrent validity – correlations between pN and PROs

In examining the association between pN and PROs pre-operatively, we found no significant correlation. However, post-surgery, pN showed moderate to strong negative correlations with PROs ($r = -0.40$ to -0.70) over follow-ups as shown in Table 3. Specifically, we found that pN scores were moderately-to-strongly correlated with VAS ($r = -0.42$ to -0.61) over time. Similarly, pN scores showed moderate to strong negative correlation with ODI ($r = -0.51$ to -0.70), with the strongest correlation at 2 years ($r = -0.70$). Finally, pN moderately correlated ($r = -0.41$ to -0.57) with FABQ-PA over time. Overall, we found that the association between pN and PROs was stronger further out in time (2 years) than prior time points.

4. Discussion

PROs are widely used to evaluate the effectiveness of treatments for patients with cLBP. However, these measures are subjective and sensitive to patient's perception of their condition, which can make it challenging for healthcare providers to accurately assess and track treatment response over time. In this study, we examined a novel motion-based metric, pN, in patients who underwent lumbar fusion surgery and its correlation with clinical PROs. Our findings demonstrate that pN can serve as an objective metric to monitor functional recovery and showed good correlation with PROs over time.

Our results indicate that patients showed a significant improvement in pN at 6 months, which remained sustained up to 2 years after lumbar fusion surgery. However, we did not observe significant changes in pN scores at 6 week and 3 month follow-ups compared to baseline. In contrast for PROs, we found significant improvements in all assessed outcomes (pain, disability, fear avoidance) as early as 6 weeks. This finding suggests that functional performance assessed via pN score might not be responsive to surgical intervention as PROs in the short term. This delayed response indicates that this motion-based metric is measuring a uniquely different domain and provides a more direct assessment of a patient's functional state compared to PROs. In addition, it also indicates that even though patients do achieve pain relief and improvement in disability rating after surgery, they may not be ready to return to normal activities until their functional state is within normal range. This objective functional assessment has the potential to help inform clinical decision-making on safe return to normal activities as patients may have to be appropriately counselled regarding their functional state and that meaningful improvements after lumbar fusion surgery might occur more slowly than improvements seen in subjective outcomes.

Studies in the literature have explored the relationship between lumbar spine kinematic variables and PROs (Nattrass et al., 1999; Poitras et al., 2000). Poitras et al. showed that individual kinematic variables were poor-to-moderately related to ODI in patients with subacute LBP (Poitras et al., 2000). A similar study by Nattrass et al. on cLBP patients found poor correlations between RoM and ODI (Nattrass et al., 1999). Our study is the first to investigate the utility of a composite metric derived from lumbar kinematics to evaluate functional recovery in a clinical setting. Our results showed that pre-operatively, weak or no correlation existed between pN and PRO scores. However, post-operatively, pN scores showed moderate-to-strong correlations at follow-ups. Specifically, we found that pN correlated better with ODI and least with FABQ-PA over time. Although, we found significant correlations between pN and PROs post-operatively, it is important to note that these results had <50% variance in common. The implication of both our pre-and post-operative results are that while pN score is associated with dimensions of pain, disability and fear avoidance, it is also distinct and assesses a uniquely different dimension of functional health compared to PROs. Thus, the integration of quantitative measures such as pN to augment PROs has the potential to enhance, clinical decision-making on surgical outcome and patient recovery assessment. However, further prospective studies are warranted to validate these relationships, evaluate clinical utility for spine care and determine whether these objective metrics can inform safe return to normal activities.

There are potential clinical implications from our results for post-operative clinical decision-making and management of patient care. The cLMM assessment provides a standardized, reliable, direct measurement of lumbar function, which can easily be administered in clinical settings to gauge a patient's functional recovery. Lumbar RoM is frequently used in clinical diagnosis of cLBP despite its questionable utility as an effective outcome and its poor ability to discriminate between healthy controls and cLBP patients (Lehman, 2004; Marras et al., 1995; Marras et al., 1999; Poitras et al., 2000; Zuberbier et al., 2001). A significant attribute of the pN score is that it is derived from dynamic features of lumbar spine kinematics (such as velocities and accelerations) which have been shown to be better functional indicators than RoM. While there are several other objective assessments in lumbar spine surgery such as five-repetition sit-to-stand test (5R-STS), timed up-and-go test (TUG), 6-min walk test (6MWT) and motorized treadmill test (MTT) (Gülbahar et al., 2006; Guyatt et al., 1985; Staartjes and Schroder, 2018; Stienen et al., 2019; Thome and Wolfla, 2016), these

Table 2
Comparing outcomes of patients with pre-operative diagnosis of stenosis only versus those with spondylolisthesis who received a fusion surgery.

Pre-operative diagnosis				
Characteristic		Spondylolisthesis	Stenosis	p-value
pN	Baseline	18(23)	19(23)	0.8
	6 months	42(36)	33(32)	0.3
	2 years	57(38)	37(35)	0.067
VAS	Baseline	6.7(2.1)	6.3(1.8)	0.4
	6 months	3.2(2.6)	3.0(2.7)	0.7
	2 years	2.3(2.7)	3.4(2.9)	0.2
ODI	Baseline	45.7(15.8)	47.4(14.7)	0.6
	6 months	25.8(21.9)	25.0(20.7)	0.9
	2 years	18.1(19.0)	26.8(22.6)	0.15
FABQ	Baseline	18.2(4.5)	15.7(7.1)	0.05
	6 months	13.0(8.0)	11.7(7.9)	0.6
	2 years	11.8(7.5)	9.9(8.8)	0.4

The table presents mean and standard deviations of outcomes and the p-values are based on t-tests.

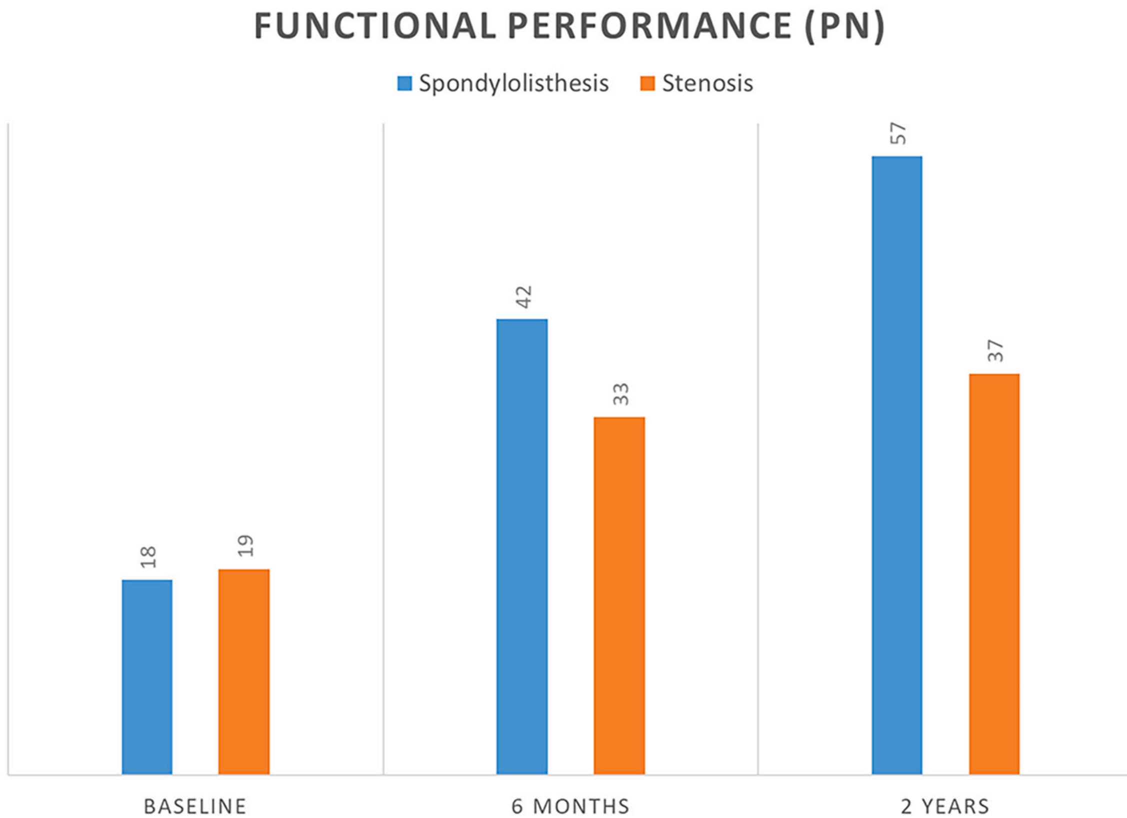

Fig. 3. Functional recovery assessed via pN indicates slower recovery for patients with stenosis compared to spondylolisthesis after fusion surgery.

Table 3
Pearson correlations (r) between pN and PROs (VAS, ODI and FABQ-PA) at baseline, 3 months, 6 months, 1 year and 2 years after lumbar fusion surgery.

	Baseline	3 months	6 months	1 year	2 years
pN vs VAS	−0.05	−0.42*	−0.58*	−0.53*	−0.61*
pN vs ODI	−0.13	−0.51*	−0.66*	−0.56*	−0.70*
pN vs FABQ-PA	−0.002	−0.41*	−0.51*	−0.54*	−0.57*
pN vs SF-36 (Physical Function)	−0.18				
pN vs SF-36 (Mental Health)	0.07				

pN – Overall functional performance (Motion-based metric);
VAS – Visual Analog Scale for pain intensity;
ODI – Oswestry Disability Index;
FABQ-PA – Fear Avoidance Behavior questionnaire for Physical Activities;
SF-36 – Short form 36 for Physical Function and Mental Health.
* $p < 0.001$.

tests don't specifically evaluate the lumbar spine, and can be easily influenced by other unrelated factors which can impact the results of the test. Therefore, within the context of an objective evaluation for the lumbar spine, the cLMM assessment is the only standardized lumbar spine-specific test that can be easily administered in a clinical setting and provides a unique functional outcome score.

This study has many strengths, namely the utilization and examination of a novel objective lumbar spine assessment, the use of standardized PROs that are widely used in spine care as well as prospective cohort design with 2 year follow-up. However, there are also various limitations that have to be acknowledged. First, our study population was a convenience sample of predominantly white, non-Hispanic patients presenting to one tertiary care center. Second, while unintentional, this study did not have older patients over the age of 70 years. Third, given that the study was conducted at a tertiary care center with a specific focus on fusion surgery, the findings may not be generalizable to larger population of spine patients receiving non-surgical treatments. Finally, there are also limitations due to loss to follow-up, which may impact generalizability of our results. Future prospective studies with larger sample sizes are needed to better investigate the relationship between motion-based measure, patient and treatment heterogeneity and clinical outcomes.

5. Conclusions

In conclusion, the quantitative motion-based metric is an easy-to-use test that provides an objective measure of a patient's functional state of their lumbar spine. It provides a unique perspective to assessing patient recovery and *measures something different from the patient's perception*. We found that there was a delayed response, with objective metric indicating return to normal much later than the subjective metrics. This information can form the basis of more objective clinical decision making on patient recovery after lumbar fusion surgery and safe return to normal daily activities.

Conflicts of interest

None.

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