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Original Research

Examining the Association Between Self-Reported Estimates of Function and Objective Measures of Gait and Physical Capacity in Lumbar Stenosis

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KEYWORDS	Abstract Objective: To evaluate the association of self-reported physical function with subjec-				
Exercise;	tive and objective measures as well as temporospatial gait features in lumbar spinal stenosis (LSS).				
Gait;	Design: Cross-sectional pilot study.				
Gait analysis;	Setting: Outpatient multispecialty clinic.				
Patient reported out-	Participants: Participants with LSS and matched controls without LSS (n=10 per group; N=20).				
come measures;	Interventions: Not applicable.				
Rehabilitation;	Main Outcome Measures: Self-reported physical function (36-Item Short Form Health Survey				
	[SF-36] physical functioning domain), Oswestry Disability Index, Swiss Spinal Stenosis				

List of Abbreviations: 40mFPWT, fast-paced 40-m walking test; IMU, inertia measurement unit; LSS, lumbar spinal stenosis; NCOS, Neurogenic Claudication Outcome Score; ODI, Oswestry Disability Index; PRO, patient-reported outcome; SF-36, 36-Item Short Form Health Survey; 6MWT, 6-minute walk test; SPWT, self-paced walking test; 3D, 3-dimensional.

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Spinal stenosis; Walking	Questionnaire, the Neurogenic Claudication Outcome Score, and inertia measurement unit (IMU)-derived temporospatial gait features
	<i>Results:</i> Higher self-reported physical function scores (SF-36 physical functioning) correlated with lower disability ratings, neurogenic claudication, and symptom severity ratings in patients with LSS (P <.05). Compared with controls without LSS, patients with LSS have lower scores on physical capacity measures (median total distance traveled on 6-minute walk test: controls 505 m vs LSS 316 m; median total distance traveled on self-paced walking test: controls 718 m vs LSS 174 m). Observed differences in IMU-derived gait features, physical capacity measures, disability ratings, and neurogenic claudication scores between populations with and without LSS were statistically significant.
	Conclusions: Further evaluation of the association of IMU-derived temporospatial gait with self-reported physical function, pain related-disability, neurogenic claudication, and spinal stenosis symptom severity score in LSS would help clarify their role in tracking LSS outcomes. © 2021 The Authors. Published by Elsevier Inc. on behalf of American Congress of Rehabilitation Medicine. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Lumbar spinal stenosis (LSS) is a major cause of mobility limitations and disability globally.^{1,2} LSS associated with neurogenic claudication frequently causes restrictions in mobility, which greatly affects physical activity, social functioning, and overall quality of life.³ Traditionally, clinical outcomes in LSS are evaluated through patient-reported outcomes (PROs).⁴⁻⁶ However, inconsistencies in PROs and the emergence of newer wearable-derived objective outcome measures have refueled interest in establishing links between legacy PROs vs objective measures.⁶⁻¹⁰ Advancements in wearable sensor technology with inertia measurement units (IMUs) such as foot-mounted sensors have provided new ways to fully evaluate temporospatial gait parameters in musculoskeletal conditions.¹¹⁻¹³

Although previous studies have examined correlation of self-reported physical function with clinical outcomes in musculoskeletal disorders, few studies have evaluated the association of legacy PROs, such as numeric pain rating score and Oswestry Disability Index (ODI), and objective sensorderived measures.¹⁴⁻¹⁶ Previous reports indicate that traditional PROs have floor and ceiling effects, which are affected by cognitive and emotional behavioral traits such as anxiety, low self-esteem, hypervigilance, catastrophizing, fear of pain, and attentional bias to pain.¹⁷⁻²⁰ Recent reports also suggest that some of the legacy PROs may be cumbersome to administer.^{4,8} Although newer PROs such as the Patient-Reported Outcomes Measurement Information System with computer adaptive testing overcome some of these shortcomings, they still inadequately capture important objective physical activity limitations in patients with chronic back pain.^{5-7,17,21}

Given these limitations, the convergence of subjective and objective measures of physical function and physical capacity with sensor-derived gait features is critical for effectively tracking outcomes in LSS. Yet, the association of self-reported measures with objective measures of capacity and temporospatial gait features in LSS have not been fully elucidated. Therefore, this study sought to evaluate the association of self-reported physical function and LSS-specific measures with objective tests of physical capacity and IMU-derived temporospatial gait features. An important consideration for this study is the fact that standards in the literature remain to be established regarding the minimal set of measures that are clinically sufficient to capture relevant outcomes in musculoskeletal spine conditions such as LSS. Moreover, there is broad variability in commercially available IMU tools.²² These tools differ in functionality including: body placement (hip, trunk, wrist, ankle, foot), number of sensors required (single, double, triple), number of sensor axes (uniaxial, biaxial, and triaxial accelerometer), sensor sampling rates, computed features, data epoch/window size, and quantity and quality of activity capture.^{22,23} In this context, this pilot study was necessary to explore capabilities of the Shimmer device sensor nodes for gait analysis in lumbar spine stenosis.²³ The Shimmer device was chosen because it allows comparison of data extraction algorithms with those validated in the literature using triaxial accelerometers and captures 3-dimensional (3D) spatial and temporal gait features for in-depth analysis.²⁴ Through this pilot study, the authors sought to identify candidate objective measures and gait features with enough discriminatory power to delineate differences in self-ratings of physical function and LSS-specific outcome measures (disability index, neurogenic claudication, spinal stenosis symptom severity). Given the authors' expertise with the Shimmer IMU device, and as work continues to ascertain standards for IMU-derived outcome measures, this study is important in exploring the role of foot mounted sensors in better understanding gait and activity limitations in musculoskeletal and spine disorders such as LSS.

Methods

This pilot study enrolled 20 participants recruited consecutively between October and December 2016 from the Stanford Medicine Outpatient Center, with equal distribution between disease group and controls (10 LSS and 10 controls). Control participants were volunteers without LSS who agreed to participate in the study and responded to study announcements advertised through the outpatient center bulletin. No records were maintained for potential participants who were approached and did not consent to the study. Considering that this was a pilot study, we did not perform power calculations prior to study commencement, and there were no issues of missingness because all relevant data were available. The inclusion criteria were age between 18-90 years and clinically documented diagnosis of LSS. Age- and sex-matched controls were recruited through the same outpatient center. Exclusion criteria for both groups were history of oxygen dependence, severe cardiac or pulmonary medical conditions, and neurologic or orthopedic condition resulting in immobilization or requiring assistive devices for mobility. The study was approved by the ethical committee for Human Subjects Research at Stanford University and was compliant with the Health Insurance Portability and Accountability Act of 1996. All patients who signed the written informed consents for study participation completed the data collection and were included in the analysis. Study participants completed the Stanford 7-Day Physical Activity Recall, the 36-Item Short Form Health Survey (SF-36), the Swiss Spinal Stenosis Questionnaire, the ODI, and the Neurogenic Claudication Outcome Score (NCOS).¹⁶ Objective physical capacity measurements included the self-paced walking test (SPWT), the 6-minute walk test (6MWT), and the fast-paced 40-m walking test (40mFPWT).²³ This study used the Shimmer3 wearable sensor^a platform for data collection.²³⁻²⁶ The sensor was placed on the dorsal surface of the study participant's right and left foot using shimmer straps. Each sensor has a 3D accelerometer, a 3D gyroscope, and a 3D magnetometer. Data were sampled at 102.4 Hz and hardware synced by control software. We used validated algorithms to extract gait parameters from the IMU sensors. Prior to processing, data were resampled to 200 Hz using linear interpolation to be consistent with previously validated algorithms.^{23,24,26} Gait cycles were detected based on the timing of 2 consecutive foot flats.^{24,26} Velocity and position of the foot were derived by the numerical integration of the gravity-corrected acceleration data and drift corrected using the Zero Velocity Updates method as previously described.14,25 Heel strike and liftoff angles were estimated based on the dedrifted angular velocity data.^{14,24-26} Maximum angular velocity of the foot and various temporal parameters were extracted from the angular velocity signals.^{14,25} Cycles with a turning angle between 2 foot flats <20 degrees were considered as straight walking cycles.14,24,25 Descriptions of IMUderived temporospatial gait features are listed in appendix 1. To reduce bias, the statistician was blinded to the index groups, and the staff involved in data collection did not contribute to data analysis. To minimize effect of unintentional coaching, all staff followed a standardized instructions script.

Statistical analysis

There were 3 buckets of data analyzed comparing participants with LSS vs controls without LSS: (1) self-reported measures; (2) physical capacity measures; and (3) IMU-derived temporospatial gait features. Data were analyzed via descriptive statistics, Spearman rank correlation coefficients, and 1-way analysis of variance (Kruskal-Wallis test inclusive of ODI and NCOS). ODI scores were also categorized as follows: 0 to minimal disability (0-20), moderate disability (21-40), severe disability (41-60), and crippled (61-80). There were no participants in the crippled category. NCOS data were also categorized into quartiles and differences in

gait feature of the groups compared by least square means with Tukey adjustments for multiple comparisons. All data processing and analysis were performed using SAS 9.4^{b} with statistical significance set at P<.05

Results

Participants' demographic characteristics and functional scores are presented in table 1. All participants who were initially found to be eligible at screening completed the assessments and were included in the analysis. There was no statistical difference between controls and LSS in age and body mass index. Controls, however, reported higher physical function and lower bodily pain scores than the LSS group (P<.001).

Self-reported measures: Spearman rank correlations

Spearman rank correlations are presented in table 2. The physical functioning and role physical subscales of the SF-36 showed the most consistent correlation with all other self-reported LSS-specific outcome measures (P<.0001). Subsequent analysis focused on the physical functioning domain of SF-36 because it outperformed the other SF-36 subscales because it pertains to correlation with spinal stenosis and back pain outcome measures.

Physical capacity measurements: LSS vs controls

Differences in physical capacity between LSS and controls were measured by 3 tests: the SPWT, the 6MWT, and the

Table 1 Baseline ch (N=20)	naracteristics of st	udy participants
Variable	Controls,	LSS,
	median (IQR)	median (IQR)
Age (y)	67.5 (56.0-73.0)	71.0 (55.0-86.0)
Male	5.0	7.0
Female	5.0	3.0
BMI	27.0 (25.0-31.0)	29.0 (24.0-31.0)
SF-36 Physical	90.0 (70.0-100)*	40.0 (30.0-60.0)
Function		
SF-36 Bodily Pain	77.5 (57.5-77.5)*	45.0 (22.0-55.0)
SF-36 General Health	85.0 (50.0-90.0)	62.5 (55.0-75.0)
Stanford Activity	2.0 (0.0-3.0)	1.0 (0.0-3.0)
Score (total)		
Stanford Activity	1.5 (0.0-3.0)	0.5 (0.0-3.0)
Stanford Leisure [†]	0.5 (0.0-3.0)	
		0.0 (0.0-3.0)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); IQR, interquartile range.

*P<.*001.

 † Reflects subscales of the Stanford 7-Day Physical Activity Recall.

F-36 Subscales	SSS-Physical Function*	SSS-Symptom Severity*	ODI	NCOS
Physical Functioning	-0.80^{\dagger}	- 0.80 [†]	-0.85 [†]	-0.71
Vitality	-0.59^{\dagger}	-0.58^{\dagger}	-0.57	-0.5
Mental Health	-0.55^{\dagger}	-0.55^{\dagger}	-0.63	-0.4
Social Functioning	-0.73^{\dagger}	-0.73	-0.77^{\dagger}	-0.6
Bodily Pain	-0.73^{\dagger}	-0.73^{\dagger}	-0.78	-0.6
General Health	-0.65^{\dagger}	-0.65^{\dagger}	-0.66^{\dagger}	-0.3
Role Emotional	-0.40	-0.39	-0.43	-0.3
Role Physical	-0.64^{\dagger}	-0.64^{\dagger}	-0.66^{\dagger}	-0.5

 Table 2
 Spearman rank correlation between self-reported domains of the SF-36 and LSS-specific self-reported measures

Abbreviation: SSS, Swiss Spinal Stenosis Score.

* Represents subscales of the SSS.

† *P*<.0001.

40mFPWT. Controls without LSS outperformed peers with LSS in the median total distance walked during the 6MWT and SPWT (P<.001) (table 3). Although controls had faster gait speed than the LSS group during the 40mFPWT, the differences were not statistically significant (see table 3).

IMU-derived temporospatial gait features and selfreported disability: LSS vs controls

The effect sizes of IMU-derived temporospatial gait features to distinguish reported disability in LSS vs controls are presented in fig 1A. Select candidate variables included liftoff angle, push ratio, minimal toe clearance, foot flat phase, gait speed, peak ankle angular velocity, double support phase, foot speed at toe clearance, and stance phase (see appendix 1 for detailed descriptions of parameters). When we adjusted for pain localization, between-group differences for minimal vs moderate disability ratings were best captured by liftoff angle (effect size=0.65, P<.001). Other IMU-derived features that were significantly different between the 2 groups as it pertains to disability ratings are presented in fig 1A. The details of the effect sizes of all IMU-derived temporospatial gait features and corresponding P values are presented in appendix 2.

IMU-derived temporospatial gait features and neurogenic claudication: LSS vs controls

Table 2 Tests of physical capacity in controls val CC

Self-reported neurogenic claudication ratings were categorized into quartiles, with 0 to minimum symptoms ranked in the top 75%-100% quartile (Q4). Figure 1B shows IMU-derived temporospatial gait features by mean differences in neurogenic claudication ratings. Group differences in claudication symptoms were most notable for peak angular velocity (98; 95% confidence interval, 64-189) between the top and bottom quartiles, respectively. Appendix 3 highlights details of the rest of the IMU-derived temporospatial gait features stratified by claudication symptoms.

Discussion

This study identified potential candidate IMU-derived features for assessing differences in gait, disability, and claudication ratings between controls without LSS and patients with LSS. After identifying select temporospatial gait features, their associations with self-reported estimates of physical functioning (SF-36 physical functioning domain) and specific measures of back pain outcomes in spinal stenosis (pain-related disability, neurogenic claudication, spinal stenosis symptom severity) were analyzed.

Some key findings included (1) correlation of physical functioning component of SF-36 with self-rated disability, neurogenic claudication, and symptom severity in spinal stenosis; (2) lower physical capacity measures in patients with LSS compared with controls; and (3) differentiating between self-ratings of disability and neurogenic claudication symptoms based on temporospatial gait features.

The observed cross-correlations of self-ratings of physical functioning with spinal stenosis—specific outcomes concurred with previous studies, which showed strong correlations among legacy PROs for pain and spine disorders.^{25,26,28,29} The findings also suggest that objective lower physical capacity scores in LSS vs controls may correspond with self-rated measures. This is interesting because objective markers and PROs have not always correlated, and PROs alone may be necessary but insufficient for complete functional assessments.^{7,8,13,29-32} Although measures like

Table 3 Tests of physical capacity in controls vs Ess						
Groups	6MWTTotal Distance (m)	40mFPWTGait Speed (m/s)	SPWTTotal Distance (m)			
Controls, median (IQR)	505 (446-538)*	1.6 (1.3-1.7)	718 (578-774)*			
LSS, median (IQR)	316 (285-386)	1.2 (0.9-1.4)	174 (109-207)			

Abbreviations: IQR, interquartile range.

P<.0001.



Fig 1 (A) Effect size of pain localized temporospatial gait features stratified differentiating categories of self-reported disability ratings (ODI). (B) Mean differences in temporospatial gait features stratified by quartiles of neurogenic claudication symptom ratings (NCOS). NOTE. Q1, NCOS 0%-25%; Q2, NCOS 25%-50%; Q3, NCOS 50%-75%; Q4, NCOS 75%-100%. Mean differences between Q3 vs Q4 were not statistically significant for all temporospatial gait features (see data in appendix 3). Abbreviation: MTC, minimum toe clearance. *P<.05. [†]Indicates temporospatial gait features that significantly differentiated between self-reported minimal vs severe disability, P<.05.

ODI and SF-36 may have overlapping information, the literature suggests that they provide unique and complementary data in the assessment of pain and spine outcomes. Adding objective indicators such as IMU gait features and physical capacity measures to subjective ratings could enhance evaluation of clinical outcomes in patients with LSS.

Our analysis provides preliminary data linking objective and subjective assessments of function in this population. The ability to detect signal changes in gait features that are sensitive enough to discriminate among subjective reports of function in a small study sample is encouraging. Followup studies with a larger population are warranted to confirm our study findings.

Given the inherent heterogeneity of lumbar stenosis symptoms, it will also be interesting to ascertain whether a larger cohort would yield similar findings in terms of objective physical capacity and gait features. This would add to previous reports assessing objective physical function in LSS.^{4-8,13,27,28} It would be instructive to explore whether the observed differences in physical capacity measures between LSS and controls are because of any underlying differences in gait features. Previously reported floor and ceiling effects of patient reported outcomes have prompted interest in developing more objective tools to overcome inherent limitations of subjective ratings.^{4,5,17} Consequently, validating the initial findings from this study will help establish whether objective gait features and physical capacity measures have enough discriminatory power to distinguish among legacy PROs in the population with LSS. This would expand the literature regarding utility of IMU-derived measures in identifying cases where legacy PROs fall short of delineating true disease risk.³³

From a clinical standpoint, validation of the results would be critical as gait features and physical capacity measures in LSS could serve as potential targets for rehabilitative interventions for patients with moderate self-reported neurogenic claudication symptoms and moderate to severe disability ratings. From this initial analysis, peak angular velocity and liftoff angle best delineated differences in neurogenic claudication symptoms and disability ratings, respectively (see fig 1). Further research exploring these gait features would enhance our understanding of altered gait patterns in patients with LSS with claudication symptoms.

Study limitations

The limitations of this study include small sample size and lack of generalizability. The observed effect sizes of gait features are small to moderate but significantly highlight detectable objective measures, which require further exploration. Larger studies may increase the discriminatory power of the identified gait features. The participants were all recruited at the Stanford Medicine Outpatient Center and were in the later stages of their disease. Additionally, although patients with a history of oxygen dependence or severe cardiac or pulmonary medical problems were excluded, other comorbidities that limit walking capacity may have affected the precision of these measures. Time and resource requirements to implement IMU in the clinical setting could pose challenges for implementation of objective measurements in some outpatient centers. This pilot study, however, demonstrates feasibility and successful implementation. Finally, several other important features of gait, such as gait variability, gait symmetry, and kinematics, were not considered in this study. 34,35

Conclusions

The study identifies objective candidate IMU-derived temporospatial gait features that correlate significantly with PROs and physical capacity measures. Further studies are needed to external validate the observed discriminatory function of IMU gait features to distinguish among disability ratings, neurogenic claudication symptoms, and other PROs in the population with LSS.

Suppliers

- a. Shimmer3 Wearable Sensor; Shimmer Research Ltd.
- b. SAS 9.4; SAS Institute Inc.

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