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Validation of the baseline severity stratification of objective functional impairment in lumbar degenerative disc disease

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OBJECTIVE The Timed Up and Go (TUG) test is a simple, objective, and standardized method to measure objective functional impairment (OFI) in patients with lumbar degenerative disc disease (DDD). The objective of the current work was to validate the OFI baseline severity stratification (BSS; with levels of "none," "mild," "moderate," and "severe").

METHODS Data were collected in a prospective IRB-approved 2-center study. Patients were assessed with a comprehensive panel of scales for measuring pain (visual analog scale [VAS] for back and leg pain), functional impairment (Roland-Morris Disability Index [RMDI] and Oswestry Disability Index [ODI]), and health-related quality of life (HRQOL; EQ-5D and SF-12). OFI BSS was determined using age- and sex-adjusted cutoff values.

RESULTS A total of 375 consecutive patients scheduled for lumbar spine surgery were included. Each 1-step increase on the OFI BSS corresponded to an increase of 0.53 in the back pain VAS score, 0.69 in the leg pain VAS score, 1.81 points in the RMDI, and 5.93 points in the ODI, as well as to a decrease in HRQOL of –0.073 in the EQ-5D, –1.99 in the SF-12 physical component summary (PCS), and –1.62 in the SF-12 mental component summary (MCS; all $p < 0.001$). Patients with mild, moderate, and severe OFI had increased leg pain by 0.90 ($p = 0.044$), 1.54 ($p < 0.001$), and 1.94 ($p < 0.001$); increased ODI by 7.99 ($p = 0.004$), 12.64 ($p < 0.001$), and 17.13 ($p < 0.001$); and decreased SF-12 PCS by –2.57 ($p = 0.049$), –3.63 ($p = 0.003$), and –6.23 ($p < 0.001$), respectively.

CONCLUSIONS The OFI BSS is a valid measure of functional impairment for use in daily clinical practice. The presence of OFI indicates the presence of significant functional impairment on subjective outcome measures.

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KEY WORDS Timed Up and Go test; objective functional impairment; degenerative disc disease; patient assessment; validation; spine surgery; lumbar spine

For patients with degenerative disc disease (DDD), accurate measurement of degree of pain, functional impairment, and health-related quality of life (HRQOL) is of paramount importance, as these are key decision-making determinants for surgical management.[5] A panel of reliable and valid scales, including the visual analog scale (VAS) for pain intensity, the Oswestry Disability Index (ODI) and the Roland-Morris Disability Index (RMDI) for functional impairment, and the SF-12 as well as the EQ-5D (Euro-QoL Group) for HRQOL, is available.[18] However, these scales are subjective and mostly nonstandardized.[1,20,26,28] Therefore, a simple, objective and standardized measure for the degree of functional impairment has recently been proposed: the Timed Up and Go (TUG) test.[10] A first report concluded that the TUG test was useful, easily applicable, and accurately reflected

ABBREVIATIONS ASA = American Society of Anesthesiologists; BMI = body mass index; BSS = baseline severity stratification; CCI = Charlson Comorbidity Index; DDD = degenerative disc disease; HRQOL = health-related quality of life; LDH = lumbar disc herniation; LSS = lumbar spinal stenosis; MCS = mental component summary; ODI = Oswestry Disability Index; OFI = objective functional impairment; PCS = physical component summary; RMDI = Roland-Morris Disability Index; TUG = Timed Up and Go; VAS = visual analog scale.

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disability in patients with DDD before and after surgery.[9] By gathering TUG data from 253 consecutive patients and comparing these to data obtained in the normal population, the concept of objective functional impairment (OFI) was introduced.[13] Briefly, a patient with lumbar DDD who scores a test time over 11.5 seconds (T-score > 123) can be considered functionally impaired. Mild, moderate, and severe OFI are defined as test times > 11.5 and < 13.4 seconds (T-score < 131.1), 13.4–18.4 seconds (T-score 131.1–152.0), and > 18.4 seconds (T-score > 152.0), respectively. Furthermore, cutoff values tailored to a patient's age and sex are available.[13] The minimum clinically important difference of the TUG test has been reported to be 3.4 seconds in patients undergoing surgical treatment for lumbar DDD, differentiating treatment responders from nonresponders.[16]

The use of OFI and its baseline severity stratification (BSS), with levels of "none," "mild," "moderate," and "severe," is new and thus has not been well elaborated yet. The purpose of this work was to validate the OFI BSS and demonstrate its relationship to commonly used subjective outcome measures.

Methods

This is a prospective 2-center observational study, approved by the local institutional review boards of each center. All patients gave written informed consent.

Patient Population

Consecutive patients with lumbar DDD scheduled for spine surgery were recruited between September 2013 and December 2015. Patients with the following diagnoses were included: 1) lumbar disc herniation (LDH), 2) lumbar spinal stenosis (LSS), and 3) degenerative disc disease (DDD) with or without instability requiring lumbar fusion surgery. Patients younger than 18 years and pregnant women as well as patients with known rheumatic disease or walking impairment (e.g. paraparesis, hemiparesis, hip/knee problems, dizziness, or vertigo) were excluded from study participation.

Data Collection

General patient data (e.g., age, sex, body mass index [BMI], smoking and working status, and comorbidities according to the Charlson Comorbidity Index [CCI][3] and American Society of Anesthesiologists [ASA] physical status classification[21]) as well as disease-specific parameters were collected. Lower back pain and irradiating leg pain were discriminated and graded on a VAS (score range 0–10). Functional impairment was measured with the validated disease-specific questionnaires RMDI (24 items, score range from 0 [no disability] to 24 [severe disability])[27] and ODI (10 items, score range from 0 [no disability] to 100 [severe disability]).[7] HRQOL was estimated using the standardized EQ-5D questionnaire (5 items, score range from 1 [best HRQOL] to −0.074 [worst HRQOL], using the European norms),[6] as well as the SF-12 (12 items, results standardized to a mean of 50) with its 2 composite scores, the physical component summary (PCS) and mental component summary (MCS) scores.

The TUG Test

The TUG test was performed in a standardized manner as described previously.[9,10,13] On "Go,"' patients got up and walked as fast as possible (no running) to a marked line on the floor at 3 meters' distance. At the line, they would turn around (180°) and return to the chair and sit down as quickly as possible. The time between getting up and sitting down again was recorded in seconds using a stopwatch.

Statistical Considerations

Raw TUG test times were transformed into T-scores, and the presence and severity of OFI was determined using age- and sex-adjusted norms.[13] Baseline tables were built according to the presence or absence of OFI in preoperative examinations. Demographic data were described using frequencies and percentage for categorical variables (Pearson chi-square tests) or group means and standard deviations for nominal variables (ANOVA). Validity refers to the ability of the OFI BSS to indicate which individuals have functional impairment and which do not. First, relationships between the OFI BSS (independent variable) and each of the subjective grading scales of pain, functional impairment, and HRQOL (dependent variables) were graphically visualized (Fig. 1 and Supplementary Fig. 1). Then a direct and an adjusted linear regression model were built to relate the independent to the dependent variables. Sensitivity analysis was performed to determine how each condition affected the overall result. The software used for the statistical analysis was Stata v14 (StataCorp LP).

Results

A total of 449 patients were screened for eligibility, of whom 378 (84.2%) were included in the study. Three patients (0.8%) were omitted from the final analysis because their data were incomplete. The final cohort comprised 375 patients of whom 189 (50.4%) were treated at participating Hospital 1 and 186 (49.6%) were treated at Hospital 2. OFI

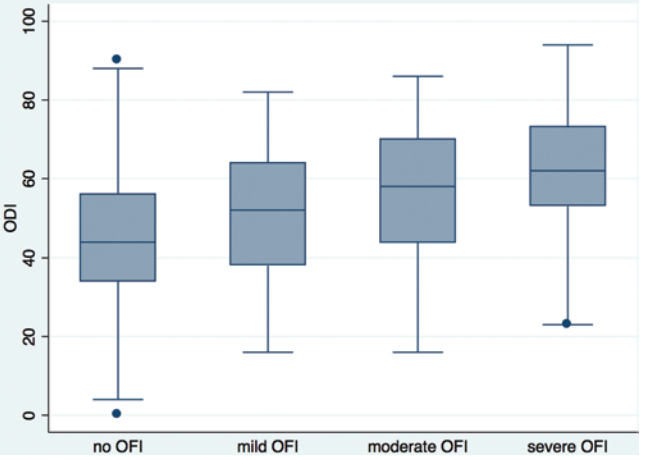

FIG. 1. Box plots demonstrating the group medians, interquartile range (*box*), and upper and lower adjacent values (*whiskers*) for the ODI in 203 patients without OFI, as well as in 49 with mild, 55 with moderate, and 41 with severe OFI BSS levels. The *solid circles* indicate outliers. Figure is available in color online only.

TABLE 1. Basic demographic data for patients with and without OFI

Characteristic	No OFI (n = 230)	Mild OFI (n = 49)	Moderate OFI (n = 55)	Severe OFI (n = 41)	p Value*
Age in yrs, mean (SD)	62.1 (14.7)	52.3 (16.0)	56.7 (15.5)	52.4 (16.1)	<0.001
Sex					0.392
Male	130 (56.5%)	25 (51.0%)	30 (54.6%)	28 (68.3%)	
Female	100 (43.5%)	24 (49.0%)	25 (45.4%)	13 (31.7%)	
Work status					<0.001
Not working	33 (14.4%)	11 (22.5%)	10 (18.2%)	8 (19.5%)	
Full/part time	77 (33.5%)	25 (51.0%)	26 (47.3%)	26 (63.4%)	
Retired	116 (50.4%)	10 (20.4%)	17 (30.9%)	6 (14.6%)	
Disabled	4 (1.7%)	3 (6.1%)	2 (2.6%)	1 (2.4%)	
BMI in kg/m^2, mean (SD)	26.9 (4.6)	27.4 (4.5)	27.9 (4.5)	26.9 (4.4)	0.475
Smoking					0.006
No	184 (80.0%)	36 (73.5%)	33 (60.0%)	26 (63.4%)	
Yes	46 (20.0%)	13 (26.5%)	22 (40.0%)	15 (36.6%)	
ASA					0.009
1	30 (13.0%)	10 (20.4%)	9 (16.4%)	14 (34.2%)	
2–3	200 (87.0%)	39 (79.6%)	46 (83.6%)	27 (65.8%)	
CCI					0.359
0–1	207 (90.0%)	46 (93.9%)	49 (89.1%)	40 (97.6%)	
≥2	23 (10.0%)	3 (6.1%)	6 (10.9%)	1 (2.4%)	

Data are presented as number of patients (%) unless otherwise indicated.
* For comparison of the 4 groups.

was present in 145 patients (38.7%); the degree of severity was mild in 49 (33.8%), moderate in 55 (37.9%), and severe in 41 (28.3%). Patients with OFI were compared with the remaining group of 230 patients without OFI.

Patients with OFI were younger, less often retired, and had lower ASA scores than the patients without OFI (Table 1). Sex and BMI were balanced between patients with and without OFI while patients with OFI smoked more often.

Patients with OFI were most frequently scheduled for lumbar microdiscectomy, whereas patients without OFI predominantly underwent lumbar decompression surgery (Table 2). Interventions affecting the lumbosacral

TABLE 2. Disease-specific data for patients with and without OFI

Variable	No OFI (n = 230)	Mild OFI (n = 49)	Moderate OFI (n = 55)	Severe OFI (n = 41)	p Value*
Type of surgery					<0.001
Microdiscectomy	93 (40.4%)	31 (63.3%)	33 (60.0%)	32 (78.0%)	
Decompression	100 (43.5%)	11 (22.4%)	17 (30.9%)	7 (17.1%)	
Fusion	37 (16.1%)	7 (14.3%)	5 (9.1%)	2 (4.9%)	
Level					0.143
1 level	191 (83.0%)	43 (87.8%)	51 (92.7%)	38 (92.7%)	
≥2 levels	39 (17.0%)	6 (12.2%)	4 (7.3%)	3 (7.3%)	
Segment†					0.006
L1–2	1 (0.4%)	1 (2.0%)	2 (3.6%)	— (0.0%)	
L2–3	15 (6.5%)	3 (6.1%)	3 (5.5%)	3 (7.3%)	
L3–4	55 (23.9%)	7 (14.3%)	7 (12.7%)	9 (21.9%)	
L4–5	118 (51.3%)	21 (42.9%)	22 (40.0%)	12 (29.3%)	
L5–S1	41 (17.9%)	17 (34.7%)	21 (38.2%)	17 (41.5%)	
Side					0.001
Right	90 (39.1%)	19 (38.8%)	17 (30.9%)	21 (51.2%)	
Left	72 (31.3%)	22 (44.9%)	32 (58.2%)	16 (39.0%)	
Bilateral	68 (29.6%)	8 (16.3%)	6 (10.9%)	4 (9.8%)	
Motor deficit					0.051
No	173 (75.2%)	40 (81.6%)	34 (61.8%)	26 (63.4%)	
Yes	57 (24.8%)	9 (18.4%)	21 (38.2%)	15 (36.6%)	

Data are presented as number of patients (%).
* For comparison of the 4 groups.
† The segment most affected is presented for multilevel surgeries.

level were more often performed in patients with OFI, and bilateral as well as multilevel procedures were more frequent in patients without OFI.

Table 3 shows the TUG T-scores, as well as pain, functional impairment, and HRQOL measures for patients with and without OFI. Note that the T-scores for mild, moderate, and severe OFI were 130.8, 147.8, and 221.3, respectively, with a broad value range and therefore relatively large standard deviations in the group with severe OFI. Patients with OFI had significantly more VAS back and leg pain and more functional disability as measured by the RMDI and ODI as well as lower HRQOL as measured by the EQ-5D and SF-12 PCS and MCS (Table 3). In fact, an almost linear increase on most subjective scales of pain, impairment, and decrease in HRQOL was noticed for the OFI BSS (Fig. 1; Supplementary Fig. 1).

Table 4 demonstrates the regression coefficients of the relationships between the OFI BSS and the subjective metrics. The regression coefficients are presented without and with correction for baseline group differences (as shown in Tables 1 and 2). For each increase in OFI BSS, disability on the disease-specific ODI increases by 5.57 points (95% CI 3.97–7.18, $p < 0.001$). In the adjusted model, this relationship became even stronger, with every 1-step increase of the OFI BSS corresponding to a 5.93 increase on the ODI (95% CI 4.23–7.64, $p < 0.001$). The relationships were highly significant for all other metrics as well (Table 4). When stratified for the specific degree of OFI, patients with mild, moderate, and severe OFI had increased disability, as measured by the ODI scores of 7.99 ($p = 0.004$), 12.64, and 17.13 ($p < 0.001$), respectively, compared with patients without OFI. Calculations for all other metrics are depicted in Table 4.

Sensitivity analysis revealed a stronger relationship between the OFI BSS and subjective measures in patients with LDH than in patients with LSS (Supplementary Table 1). Here, regression coefficients resembled those of the model for DDD in general (Table 4). In patients with LSS, the relationship with the RMDI and SF-12 PCS was even stronger than in patients with LDH (Supplementary Table 2). In patients scheduled for surgical fusion, the relationship between the OFI BSS and the SF-12 MCS tended to be particularly strong. Overall, the sensitivity analysis revealed that the final model of OFI BSS is valid and not affected by the inclusion of the 3 different diagnoses.

Discussion

This work analyzed data for 375 prospectively recruited patients with lumbar DDD who underwent a comprehensive multidimensional assessment including the TUG test to validate the OFI BSS. This work demonstrated that the OFI BSS is a valid measure of function. The most notable finding of this study was an arguably strong relationship between the key subjective measures of function in patients with low back pain, namely the RMDI and ODI. For every 1-step increase in OFI category, the RMDI showed an increase of 1.81 points and the ODI showed an increase 5.93 points. When stratified for OFI BSS, patients with mild, moderate, and severe OFI showed RMDI score increases of 3.30, 4.01, and 5.10 points in comparison to patients without OFI, and the corresponding increases in ODI scores were 7.99, 12.64, and 17.13 points (Table 4). This implies that the clinician can be confident using the OFI BSS presented here to accurately measure function in patients with DDD.

Besides validating the OFI BSS, the present report also highlights 3 interesting features that we noticed while exploring the utility of the TUG test in daily clinical practice. First, patients with OFI represent a distinct group of patients who are significantly more impaired in terms of every subjective outcome measure and more often require opioids than patients without OFI (Table 3). The concept of OFI has been developed by choosing the 99th percentile of the TUG test results in the normal population as the cutoff, thus implying a high threshold before a patient is considered to have OFI.[13] It should be appreciated that, even though patients with times on the TUG test that are between the upper limit of normal and the 33rd percentile are labeled to have "mild" OFI,[13] this already represents a considerable level of functional impairment. Discriminating between the presence and absence of OFI is—in fact—more important than determining the exact degree of OFI. Patients with OFI experience more back and leg pain

TABLE 3. Subjective and objective measures of pain, functional disability, and HRQOL in patients with and without OFI

Measure	No OFI (n = 230)	Mild OFI (n = 49)	Moderate OFI (n = 55)	Severe OFI (n = 41)	p Value*
TUG T-score	109.1 (8.2)	130.8 (5.0)	147.8 (9.0)	221.3 (158.0)	<0.001
VAS back pain	3.47 (2.66)	4.21 (2.69)	4.74 (2.77)	4.35 (2.99)	0.005
VAS leg pain	4.34 (2.76)	5.52 (2.99)	6.05 (2.41)	6.40 (2.47)	<0.001
RMDI	10.1 (4.9)	13.4 (4.9)	14.1 (4.9)	15.3 (4.4)	<0.001
ODI	45.1 (17.0)	52.0 (16.7)	56.9 (17.5)	61.1 (15.7)	<0.001
EQ-5D Index	0.566 (0.215)	0.446 (0.199)	0.451 (0.200)	0.326 (0.188)	<0.001
SF-12 PCS	32.2 (8.1)	30.1 (7.4)	28.9 (8.2)	26.5 (6.9)	<0.001
SF-12 MCS	44.3 (10.9)	39.8 (11.9)	40.8 (10.8)	37.0 (10.9)	<0.001
Opioid analgesic use, n (%)					<0.001
No	205 (89.1%)	37 (75.5%)	43 (87.2%)	20 (48.8%)	
Yes	25 (10.9%)	12 (24.5%)	12 (21.8%)	21 (51.2%)	

Data are presented as mean (SD) unless otherwise indicated.

* For comparison of the 4 groups.

TABLE 4. Linear regression model describing the relationship of OFI BSS to a panel of subjective measures of pain, functional impairment, and HRQOL in patients with lumbar DDD

Variable	Univariate Analysis			Multivariate Analysis		
	RC	95% CI	p Value	RC	95% CI	p Value
VAS back pain	0.42	0.16–0.68	0.002	0.53	0.26–0.80	<0.001
Mild OFI	0.75	−0.09 to 1.59	0.082	0.89	0.04–1.75	0.040
Moderate OFI	1.28	0.48 to 2.08	0.002	1.39	0.58–2.20	0.001
Severe OFI	0.89	−0.02 to 1.79	0.055	1.32	0.39–2.24	0.005
VAS leg pain	0.76	0.50–1.01	<0.001	0.69	0.42–0.96	<0.001
Mild OFI	1.18	0.34–2.02	0.006	0.90	0.03–1.77	0.044
Moderate OFI	1.71	0.90–2.51	<0.001	1.54	0.72–2.37	<0.001
Severe OFI	2.06	1.15–2.97	<0.001	1.94	0.99–2.88	<0.001
RMDI	1.89	1.43–2.36	<0.001	1.81	1.32–2.31	<0.001
Mild OFI	3.38	1.87–4.88	<0.001	3.30	1.72–4.88	<0.001
Moderate OFI	4.06	2.62–5.49	<0.001	4.01	2.52–5.49	<0.001
Severe OFI	5.29	3.67–6.91	<0.001	5.10	3.40–6.81	<0.001
ODI	5.57	3.97–7.18	<0.001	5.93	4.23–7.64	<0.001
Mild OFI	6.86	1.64–12.09	0.010	7.99	2.57–13.41	0.004
Moderate OFI	11.83	6.85–16.82	<0.001	12.64	7.52–17.76	<0.001
Severe OFI	16.03	10.40–21.66	<0.001	17.13	11.25–22.99	<0.001
EQ-5D Index	−0.074	−0.094 to −0.054	<0.001	−0.073	−0.094 to −0.052	<0.001
Mild OFI	−0.121	−0.185 to −0.056	<0.001	−0.113	−0.180 to −0.046	0.001
Moderate OFI	−0.115	−0.177 to −0.054	<0.001	−0.112	−0.175 to −0.049	0.001
Severe OFI	−0.241	−0.310 to −0.171	<0.001	−0.241	−0.313 to −0.168	<0.001
SF-12 PCS	−1.81	−2.57 to −1.06	<0.001	−1.99	−2.80 to −1.19	<0.001
Mild OFI	−2.12	−4.57 to −0.33	0.089	−2.57	−5.13 to −0.02	0.049
Moderate OFI	−3.32	−5.66 to −0.98	0.005	−3.63	−6.04 to −1.22	0.003
Severe OFI	−5.63	−8.27 to −2.99	<0.001	−6.23	−9.00 to −3.47	<0.001
SF-12 MCS	−2.28	−3.33 to −1.22	<0.001	−1.62	−2.73 to −0.50	0.005
Mild OFI	−4.52	−7.94 to −1.10	0.010	−2.92	−6.47 to 0.62	0.105
Moderate OFI	−3.49	−6.75 to −0.24	0.036	−2.12	−5.47 to 1.22	0.213
Severe OFI	−7.32	−11.00 to −3.64	<0.001	−5.61	−9.44 to −1.78	0.004

For each increase in the OFI BSS, the subjective measures of function RMDI and OFI increase by 1.89 and 5.57, respectively. In addition, regression coefficients (RCs) are presented for each specific degree of OFI BSS, compared to no OFI. Factors adjusted for in the multivariate analysis were age, surgical procedure, working status, smoking status, ASA score, and multilevel surgery.

(based on VAS scores), as well as more functional disability and lower HRQOL than patients without (Table 3). In clinical practice, patients identified to have (any degree of) OFI can be considered significantly impaired, regardless of the precise OFI BSS. With increasing OFI BSS, however, subjective scales of pain, functional impairment, and HRQOL also show a gradual increase in severity (Table 4), and patients can be categorized more accurately.

Second, the data once again confirm that OFI is a concept that measures a new dimension of disability and does not replace, but rather complements, the established patient-reported outcome measures.[2,17,23,24] On the one hand, the linear regression models show a highly significant relationship with each subjective grading scale (Table 4), indicating that OFI and subjective grading scales point toward a similar effect. On the other hand, however, the standard deviations of the dependent variables display an important spread of the data (Fig. 1; Supplementary Fig. 1). It is conceivable that certain patient characteristics, such as age, sex, BMI, medications taken, comorbidities, or degree of degeneration on MRI, factor into the TUG test results, which is why the impact of any of these parameters is analyzed separately at present.[4,11] Age and sex have both been previously identified as influencing the raw test results of the TUG,[11,14,15] which is why it is important to adjust for these factors by the use of OFI. OFI represents the degree of functional impairment independent from a patient's age, sex, and BMI.[32]

Third, the underlying diagnoses have some influence on the presence of OFI. Supplementary Fig. 2 illustrates that patients undergoing microdiscectomy for LDH have a mean TUG T-score of 134.4 ± 33.8 (SD), whereas those undergoing decompression for LSS (117.2 ± 19.5) or undergoing surgical fusion (118.8 ± 24.3) show less deviation from the normal. Probably, this relates to higher and more acute irradiating leg pain in the group of patients with LDH that is generally perceived as severely limiting even when walking short distances as required for the TUG test. In contrast, patients with LSS usually develop neurogenic claudication after a longer walking distance that usually exceeds the 2 × 3 meters tested by the TUG.[9,22,33] Other objective measures, such as the 6-minute walking test, for example,[8,31] could be of higher value in the evaluation of OFI in patients with LSS. Patients undergoing surgi-

cal fusion typically present with predominant axial lower back pain, with irradiating pain being more in the background.[29,34] Because patients with the 3 underlying diagnoses show different disability patterns, a sensitivity analysis was performed, pertaining in particular to the underlying diagnosis. It becomes evident from Supplementary Tables 1–3 that the relationship between the OFI BSS and the subjective measures is stronger in pathologies in which irradiating leg pain is the dominant part of the clinical picture.[9,12] In patients in whom this is less evident, the TUG test still measures OFI, but the OFI BSS does not align equally well with the subjective measures. Importantly, the sensitivity analysis confirmed that the main model of OFI BSS is stable, and none of the diagnosis-specific models differed significantly. More data on OFI in patients with different types of lumbar DDD will help to fully elucidate these relationships. Analyzing the relationship of the TUG test results and specific activities recorded by the ODI and the RMDI (e.g., sitting, standing, walking, lifting items, or putting on socks) could help shed more light on those aspects of lumbar DDD with the most influence.

Limitations should be mentioned and mostly relate to the inclusion of patients undergoing surgical treatment for 3 different diagnoses and procedure types that were combined for the analysis. From the beginning, it was the intention in this project to develop the TUG test as measure of OFI for a broad spectrum of patients suffering from lumbar DDD. To account for possible inaccuracies related to this, additional subgroup analyses were presented in supplementary tables. Second, 70 patients (18.7%) were taking opioids, and the influence of this medication on TUG test results is currently unknown. Third, the quality of a test is not only dependent on the validity; reliability also needs to be given. In healthy control subjects, the TUG test showed an intrarater reliability of 97% (standard error of the mean [SEM] 0.21) and interrater reliability of 99% (SEM 0.22).[13] In elderly patients (with longer TUG test times), intrarater and interrater reliability have mostly been reported as high (with intraclass correlation coefficients of 0.99,[25] 0.92–0.96,[19] and 0.98[30]), but current research is ongoing to determine the reliability of the TUG to measure OFI in patients with lumbar DDD. Fourth, a ceiling effect of the OFI BSS could prevent discriminating between patients with high and extremely high disability. In these cases, expressing a patient's OFI as a T-score (that is, as deviation from the normal population mean) is superior to using the BSS, a 4-tier categorical variable. Both measurements are provided by the smartphone "TUG" app, which we developed and which is available free of charge in multiple languages at the Apple App Store (https://itunes.apple.com/de/app/tug-app/id1119087707?mt=8) and Google Play (https://play.google.com/store/apps/details?id=ch.webgearing.tugapp).

Conclusions

The data demonstrate that the OFI BSS is valid for use in daily clinical practice. The presence of OFI indicates the presence of significant functional impairment on subjective outcome measures. With every increase in OFI BSS there is a gradual increase in subjective measures of pain and functional impairment and a gradual decrease in HRQOL.

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Stienen, Smoll, Gautschi. Acquisition of data: Stienen, Joswig, Corniola, Gautschi. Analysis and interpretation of data: Stienen, Smoll. Drafting the article: Stienen. Critically revising the article: Smoll, Joswig, Corniola, Schaller, Hildebrandt, Gautschi. Approved the final version of the manuscript on behalf of all authors: Stienen. Statistical analysis: Stienen. Administrative/technical/material support: Schaller, Hildebrandt, Gautschi. Study supervision: Schaller, Hildebrandt, Gautschi.

Supplemental Information

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