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Longitudinal Validity and Minimal Important Change for the Modified Lower Extremity Functional Scale (LEFS) in Orthopedic Foot and Ankle Patients

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ABSTRACT

The lower extremity functional scale (LEFS) is a patient-reported outcome measure for lower extremity disorders. Aim of this study was to assess the longitudinal validity including responsiveness and test-retest reliability of the revised 15-item version, and to define the minimal important change (MIC) of the modified LEFS in a generic sample of orthopedic foot and ankle patients who underwent surgery. Responsiveness, effect size, and standardized response mean were measured by determining the score change between the baseline and 6 months administration of the LEFS from 156 patients. There was no significant difference between preoperative (median 78, interquartile range [IQR] 64.2-90.3) and postoperative (median 75.0, IQR 61.7-95.0) scores. Both effect size and standardized response mean were low (0.06 and 0.06, respectively). Test-retest reliability of the LEFS was satisfactory. Intraclass correlation coefficient was 0.85 (95% confidence interval 0.81-0.88). MIC value could not be estimated due to the lack of significant score change. The modified LEFS presented with relatively low longitudinal validity in a cohort of generic orthopedic foot and ankle patients. The findings of this study indicate that the modified LEFS might not be the optimal instrument in assessing the clinical change over time for these patients.

In recent years, use of patient-reported outcome measures (PROMs) has become more frequent in orthopedic surgery (1). PROMs are clinical assessment tools used for evaluating patients' direct subjective health outcomes such as function or health-related quality of life (HRQL) (2). PROMs should be chosen for use according to the validity, reliability, and repeatability of the instrument (3-5. There are at least 139 different instruments used in the literature for foot and ankle patient (2). While the majority of foot and ankle specialists utilize PROMs in their clinical work, there is a significant variation in the use of PROMs (2). Without a clear consensus on the preferable instrument, further research on measurement properties of foot and ankle PROMs is needed (6).

Lower extremity functional scale (LEFS) was developed by Binkley et al in 1999 for assessing lower extremity function including foot and ankle (7). It originally consisted of 20 items on a 0 to 4 scale, with a maximum score of 80 indicating no functional limitations. Prior studies have reported high reliability and internal consistency for the LEFS (8–10). Furthermore, test-retest reliability of the LEFS instrument has been reported as high (10,11). However, its convergent validity and distribution of scores in different patient groups have been criticized (12). Factor analyses have presented LEFS with loading on 2 or more factors (8,9,13,14). Several prior studies presented multidimensionality in Rasch analysis on the original 20-item LEFS (14-17). In a Rasch Model analysis, the Finnish version of the LEFS was modified to achieve unidimensionality by removing 5 items and reducing the response categories into 4 (15). The modified 15-item version of the LEFS showed improved structural validity. Nonetheless, the modified version of the LEFS lacks investigation on its longitudinal validity and minimal important change (MIC) for foot and ankle patients.

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Longitudinal validation refers to testing the ability of an instrument to detect change over time (18). It can be assessed with responsiveness to change and estimating measurement error. Responsiveness of the PROM stands for ability to detect real change in measurements (19). Two measurements of HRQL conducted over a short time with no real change in the clinical status should produce similar outcome scores for the score to be reproducible. This is also referred to as test-retest reliability (18).

MIC value is used for interpreting clinically significant change in the PROM scores (20). Change in clinical status over time can be used both in clinical and scientific work in assessing the effect of a treatment on patients or as an endpoint in scientific studies. PROM score changes larger than the MIC is considered as clinically significant change.

The current study aimed to assess the longitudinal validity of responsiveness and repeatability, and to define the MIC for the modified Finnish version of LEFS in orthopedic foot and ankle patients who undergo surgery.

Materials and Methods

Ethics Committee approval was granted from the Hospital District of Helsinki and Uusimaa. Patients were recruited at hospital visits on the day of surgery or mail before surgery from 4 hospitals providing surgical treatment for different orthopedic foot and ankle complaints. Patients completed the validated Finnish 15-item version of the LEFS (8). Written informed consent was obtained from the patients. Inclusion criteria were age at least 18 years, fluent in Finnish and planned foot and ankle surgery. Final analysis included patients that completed the LEFS on 3 different occasions: preoperatively, 6 months after the surgery, and at 6.5 months' follow-up.

Statistical Methods

The data are presented as means with standard deviations (SD) or as medians and interquartile ranges (IQR). Total scores for the LEFS in each administration were calculated by summing the scores of all items and dividing the result by the number of valid completed items. Lastly, the resulted score was multiplied by 100 to obtain the total score on a scale of 0 to 100. The patients that had more than 4 missing values were regarded as invalid and, thus, were excluded from the analysis.

Responsiveness

Responsiveness was measured by determining the score change between the baseline and at 6 months administrations of the LEFS as well as effect size (ES) and standardized response mean (SRM). Furthermore, differences in the pre- and postoperative scores were examined using Mann-Whitney U test for paired samples. ES was calculated as follows: ([mean postoperative score – mean preoperative score] / preoperative score SD) (21). The formula used in SRM calculation was: (mean score change / score change SD) (22). ES and SRM were interpreted according to criteria defined by Cohen with less than 0.2 meaning no change, 0.2 to 0.5 for small change, 0.5 to 0.8 for moderate change, and over 0.8 for large change (23).

MIC

Anchor question was used to define the patients whose foot had and had not improved after the surgery. The anchor question used was "Assess the current condition of your foot/ankle compared to the condition before the surgery." The response categories were on a 5-step Likert scale varying from "a lot better" to "a lot worse" with neutral midpoint. The patients that declared their foot/ankle was "a lot better" or "better" were counted as Improved and other patients were counted as Not improved.

Predictive MIC estimation method was applied in calculation of the MIC between the baseline LEFS score and the LEFS score of 6 months after the operation (24). Pretest probability of improvement was calculated by dividing the proportion of improved patients with the whole sample. The MIC value with 95% confidence intervals (CI) were calculated using logistic regression modeling with anchor question based reported change as a dependent variable and LEFS score change as an independent variable. Moreover, MIC values adjusted to the proportion of improved patients were calculated (25). In addition, to assess the capability of the LEFS to discriminate improved and not improved patients, receiver operating characteristic curves were drawn and area under curve was calculated.

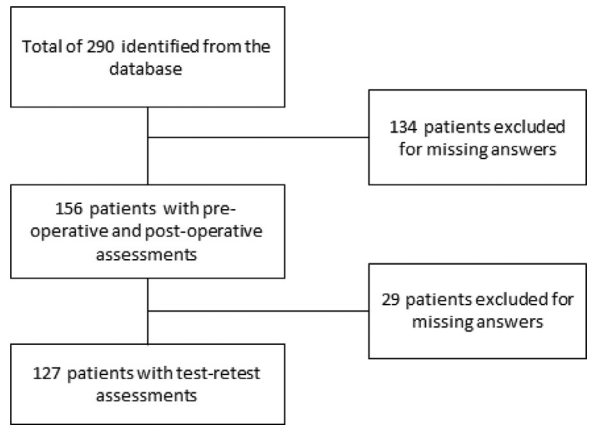

Fig. 1. Flow chart for patient selection.

Test-Retest-Reliability

Test-retest-reliability is a degree of which scores of two independent questionnaire administrations of the same patient correspond with each other. Test-retest-reliability was examined by calculating intraclass correlation coefficient between 6 and 6.5 months LEFS administration scores. In addition, dependent samples *t* test was performed to examine the difference in the LEFS total scores between the administrations. Lastly, standard error of the measurement (SEM) was estimated by calculating the square root of the ANOVA error variance of the two postoperative administrations.

Results

One-hundred and fifty-six patients provided sufficiently completed preoperative and postoperative LEFS questionnaires (Fig. 1). Seventy-

Table 1
Clinical and sociodemographic characteristics

Female, n (%)	120 (77)
Age (years), mean (SD, range)	55 (15, 18-80)
BMI, mean (SD, range)	27 (6.5, 18-77)
Education level, n (%)	
Comprehensive school	57 (37)
Upper secondary school, not graduated	4 (2.6)
Upper secondary school, graduated	16 (10)
Undergraduate degree, not graduated	3 (1.9)
Undergraduate degree, graduated	50 (32)
Graduate degree, not graduated	1 (0.6)
Graduate degree, graduated	16 (10)
Marital status, n (%)	
In a relationship	21 (13)
Married	81 (52)
Never been married	24 (15)
Divorced	15 (9.6)
Widow	13 (8.3)
	8 (10, 0-49)
Duration of symptoms (years), mean (SD, range)	
Patient-reported health state, n (%)	
Excellent	4 (2.6)
Very good	30 (19)
Good	85 (54)
Moderate	32 (21)
Poor	2 (1.3)
Previous operations, n (%)	66 (42)
Number of previous operations, mean (SD, range)	0.80 (1.3, 0-6)
Patient-reported comorbidities, n (%)	
Hypertension	38 (24)
Cardiovascular disease	26 (17)
Respiratory disease	22 (14)
Rheumatic disease	18 (12)
Diabetes	12 (7.7)
Cancer	11 (7.1)

Table 2
Diagnoses and procedures

Diagnosis	n (%)
Hallux valgus	25 (16)
Hallux rigidus	14 (9.0)
Digiti malleiformis	10 (6.4)
Other fractures of lower leg	6 (3.8)
Pseudarthrosis after fusion or arthrodesis	4 (2.6)
Metatarsalgia	4 (2.6)
Primary osteoarthritis of other joints	4 (2.6)
Pain in joint	3 (1.9)
Procedure	
Fusion of first tarsometatarsal joint	28 (18)
Internal fixation of fracture of ankle using wire, rod, cerclage or pin	8 (5.1)
Osteotomy or rotation osteotomy of first metatarsal or tarsal bone	8 (5.1)
Other operation on fascia, ganglion, synovial sheath or bursa of ankle or foot	7 (4.5)
Osteotomy or rotation osteotomy of II-V metatarsal or tarsal bone	7 (4.5)
Fusion of talocrural joint	4 (2.6)
Fusion between bones of ankle or ankle and foot	3 (1.9)
Tenodesis, shortening or lengthening of tendon of foot	3 (1.9)

eight percent of the patients were female. Mean age of the patients was 55 years (range 18-80 years). Patient characteristics are presented in more detail in Table 1 and Table 2. Forty-two percent of the patients had received prior operative treatment on foot or ankle. The top 3 indications for primary surgery were hallux valgus (16%), hallux rigidus (9%), and digiti malleiformis (6.4%).

Examination of the difference between the preoperative and postoperative scores revealed no significant difference (p = .61) as the preoperative score median was 78.3 (IQR 64.2-90.3) and postoperative median 75.0 (IQR 61.7-95.0). In accordance, both the ES and the SRM were low, 0.06 and 0.06, respectively, indicating no actual change in the scores when interpreted by means of Cohen criteria.

The classification of the patients into improved and not improved resulted in 127 improved patients giving the pretest probability of improvement of 0.81. The distributions of the score change in the improved and not-improved patients groups followed a similar pattern with mean score change of +1.6 (SD 19.0) in the improved subgroup and −1.0 (SD 22.4) in not-improved subgroups (Fig. 2). There was no significant difference between the subgroups (p = .56). Further, the absence of the difference in the score change between the subgroups complicated calculations of MIC. Logistic regression model of improvement probability by the LEFS score change is presented in Fig. 2. The estimated MIC value for the LEFS was +0.25 (95% CI -69.0 to 152.8) points at the pretest probability of improvement of 0.81. Adjusted MIC estimate was -2.4 points (Fig. 3). Although the scores did not differ between the improved and not-improved patients, when inspecting the LEFS score change distributions in each of the original 5-step anchor question subgroups, there was a slight pattern towards higher score change in the patients that reported better outcome with their foot or ankle (Fig. 4). However, the number of the patients that reported impairment of their foot was rather small. The receiver operating

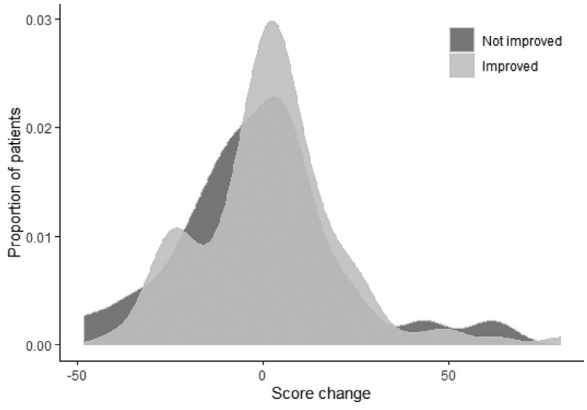

Fig. 2. Proportion of patients and their scores in groups where the foot and ankle situation improved (light gray) and did not improve (dark gray).

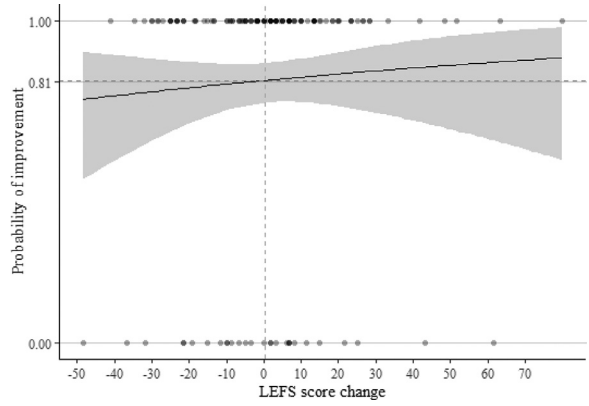

Fig. 3. Estimation of the minimal important change for the modified LEFS. The estimate is at the point where the lines cross (0.25). The gray area shows the 95% CI.

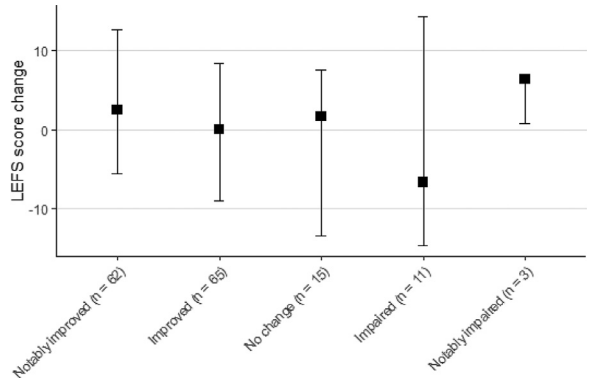

Fig. 4. The change in LEFS scores according to improvement or impairment of the foot or ankle situation after surgery.

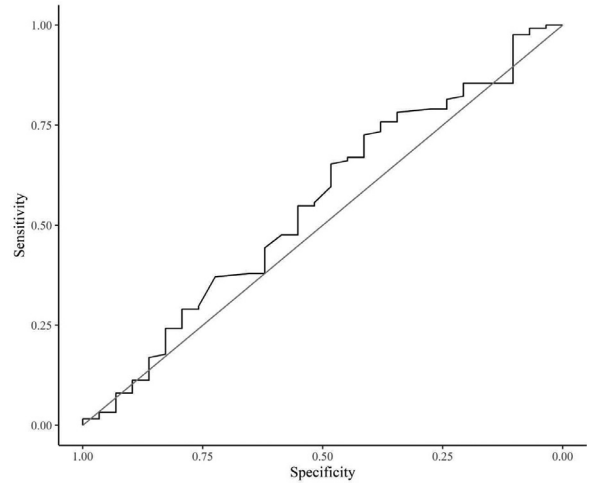

Fig. 5. The receiver operating characteristic curve and the area under curve value of 0.55 indicate poor discriminative properties of the LEFS.

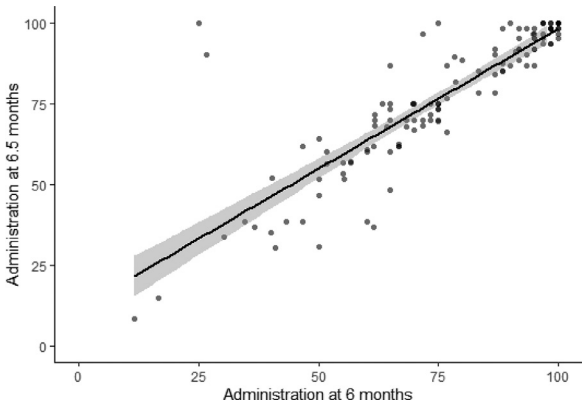

Fig. 6. Linearity of scores for the modified LEFS in the time points of 6 and 6.5 months after surgery.

characteristic curve and the area under curve value of 0.55 indicated poor discriminative properties of the LEFS (Fig. 5).

A total of 127 patients, that provided sufficient data on the LEFS at 6 months and 6.5 months administrations, were included into test-retest reliability analysis. There was no significant difference between the mean scores of the administrations (6 months 77.1 vs 6.5 months 76.9; $p = .92$). The ICC of the LEFS was 0.85 (95% CI 0.81-0.88, $p < .001$; Fig. 6). The SEM estimate for the LEFS was 7.9 (95% CI 6.7-9.1) indicating low variation in repeated measures scores.

Discussion

As patients completed the modified LEFS preoperatively and after surgery, change in the scores would have been expected. However, the difference in preoperative and postoperative LEFS scores did not reach statistical significance. The effect size and the standardized response mean values indicated no actual change in the LEFS scores in the preoperative and 6 months postoperative scores. The finding suggests that the modified LEFS was unable to detect change in the clinical status after operative treatment of foot and ankle pathologies. In addition, comparison of patients that reported improvement of the foot condition with those reporting no improvement showed no significant difference in the score distributions between the groups. These findings complicated the assessment of responsiveness and estimation of the MIC. In previous studies, MIC has been successfully determined after operative treatment for other outcome measures in similar patient samples (26–30). On the other hand, test-retest reliability was acceptable as the analysis presented no significant change in the score distributions of repeated measures and high ICC (0.85). SEM value indicated low variance caused by measurement error in the repeated measures.

Measurement properties and validity of a PROM may vary between differing patient samples, ie, diagnoses and type of treatment received. Few prior studies have analyzed LEFS on only foot and ankle patients (10,14,31–33). Alcock et al reported good responsiveness of the LEFS in athletes after ankle sprain (31) whereas Lin et al got parallel results in patients with ankle fractures in a short reassessment (32). In addition, the LEFS has been reported to be responsive in patients with general musculoskeletal conditions, total replacement of knee or hip and patients with osteoarthritis (10). However, in the current study, the patient sample consisted of patients that received operative treatment for a wide range of foot and ankle pathologies, which may explain the differences in the results of the current study and previous literature. Satisfactory function of a PROM in one patient group, for example, patients with total hip replacement, does not guarantee comparative results in other groups. This may partly be explained with different levels of disability due to the disease: osteoarthritis of the hip limits life significantly more than osteoarthritis of the first metatarsal. The similarity of the scores between the assessments in the current study suggests suboptimal responsiveness for the modified LEFS in generic orthopedic foot and ankle patients.

The Finnish validation study of the LEFS instrument revealed maximum scores in 17% in a sample of mostly injury-related foot and ankle patients (8). A study by Garrat et al found 80% of patients with full scores on 7 of the items of LEFS when compared to only one item in both OMAS and SEFAS in a sample of foot and ankle patients in a long-term follow-up (14). These are similar to the findings of the current study.

A study by Pinsker et al comparing 6 lower extremity PROMs including the LEFS in patients with ankle arthroplasty and arthrodesis found no significant differences between the measurement properties of the instruments and thus reported no superior instrument (33). According to their study, LEFS had satisfactory test-retest reliability and internal consistency. They reported relatively high minimum detectable changes for all the instruments (17.8 for LEFS, translating to almost 20% of the maximum score). This may indicate problems when evaluating the change over time. A study by Uimonen et al presented the modified LEFS with unsatisfactory convergent validity compared to 4 other foot and ankle PROMs (FAAM, FAOS, MOXFQ, VAS-FA) and to a general HRQL assessment using the EQ-5D (12). The authors hypothesized that the lack of general quality of life items in the LEFS leads to more function focused assessment. Foot and ankle pathologies requiring operative treatment may be too minor to lead to meaningful change in physical function and consequently LEFS assessment. The LEFS could potentially be used in the acute phase when assessing only lower extremity patient's momentary status or rehabilitation process. According to the findings of the current study, the modified LEFS might not be an ideal PROM for assessing long-term quality of life in foot and ankle patients. Based on general understanding, it is important to test the psychometric properties of PROMs in different patient groups to get an understanding of how the instrument functions in a specific pathology or anatomical region.

Strengths and Limitations

The current study was conducted on a patient sample with a wide range of foot and ankle diagnosis. Assessing longitudinal validity and MIC for a specific condition could have provided further insight of the measurement properties of the modified LEFS. However, the subgroup analysis was not possible due to small subgroups. The study investigated the modified LEFS for foot and ankle patients. The results of the current study cannot be generalized for general lower extremity patients or the original LEFS instrument.

In conclusion, the modified version of the LEFS instrument presented with suboptimal longitudinal validity on orthopedic foot and ankle patients who underwent operative treatment. Similarity between the preoperative and postoperative scores complicated the definition of the MIC. Further research on measurement properties is still needed for choosing the preferably foot and ankle PROM. Due to the findings of the current study, the modified LEFS seems not to be optimal as an assessment instrument of functionality for orthopedic foot and ankle patients.

Data Availability Statement

The data that support the findings in this study are available from the corresponding author, JR, upon reasonable request.

Declaration of Patient Consent

Informed consent was collected from the patients.

Author Contributions

AJS: data analysis, drafting of the manuscript, ASB: data analysis, drafting of the manuscript, JPR: original study idea, revision of the manuscript, HS: original study idea, revision of the manuscript, MMU: statistical analysis, drafting of the manuscript. All authors discussed the results and contributed to the final manuscript

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