Polish Cross-cultural Adaptation of the Lower Limb Functional Index (LLFI) demonstrates a Valid Outcome Measure for the Lower Limb Region and Joints

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Abstract

Background: Patient reported outcome measures (PROMs) are recommended to enable the standardization of collected data and provide accurate representation of the patients' subjective opinions of their functional capabilities. The purpose of this study was to perform linguistic and cross-cultural adaptation to establish a Polish version of the Lower Limb Functional Index (LLFI), and to evaluate the psychometric properties of internal consistency, reliability, error score, validity, and factor structure with standardized criteria PROMs in a population with lower limb problems.

Methods: Linguistic and cultural adaptation complied with the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines to produce the Lower Limb Functional Index - Polish version (LLFI-PL). This was a two-stage, cross-sectional study with repeated measures on two variables during retest examination. The study recruited n=125 subjects (age

=52.86±19.53 years, range 20-87, 56% female, injury duration

=17.69±18.39 weeks, range 5-71). Baseline reliability and construct validity included the LLFI-PL, Western Ontario and McMaster University Osteoarthritis Index (WOMAC), Euroqol Health Questionnaire 5-Dimensions (EQ-5D-5L), and an 11-point pain Numerical Rating Scale (NRS), with retest at 3-7 days. Practicality for readability was considered within the face and content validity. Completion and scoring time were also calculated.

Results: Statistical analysis showed high internal consistency (α=0.94) that is below the 0.95 threshold limit, and excellent test-retest reliability ($ICC_{2.1}$=0.96). The error score found the SEM=4.85% with MDC_{90}=11.3%. Validity analysis showed strong correlations between the LLFI-PL with the WOMAC (r=-0.81) and moderate with the EQ-5D-5L (r=-0.63). Exploratory factor analysis confirmed a single-factor structure. Times for completion (172±33 seconds) and scoring (20±9 seconds) were determined.

Conclusions: The LLFI-PL is a psychometrically sound questionnaire for Polish-speaking patients with lower limb musculoskeletal conditions. The results support the findings of previous original-English, Spanish, and Turkish versions for internal consistency, validity, reliability, error score, and factor structure.

Background

Lower limb problems and dysfunctions are an increasing concern in society, regardless of age. Problems, including pain on movement and at rest, plus impaired functions limiting activities of daily living (ADL) and participation in social life, lead to decreased quality of life [1]. Patients' opinions about their own health and functional status may differ from objective evaluations provided by different professionals. Consequently, patient reported outcome measures (PROMs) are recommended to enable standardization of the data collected and provide accurate representation of the patients' subjective opinions of their functional capabilities. It is increasingly emphasized that the overall assessment of health status should include the subjective consideration of functional status, particularly the use of PROMs, together with

objective testing [2].F These PROMs enable detailed planning of treatment and rehabilitation programs as well as the determination of the effectiveness of medical or rehabilitation interventions [3]. However, the measurements made are only as good as the tools that are used and the clinimetric considerations of both the psychometric and practical properties must both be fully investigated using the international guidelines such as Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN) [4].

In English-speaking countries, many PROMs have been created that can be used to assess the functional status of specific joints, conditions or region-specific conditions [5-7]. However, in Poland, only a limited number of questionnaires are available to assess the function of the lower limbs. Foreign language PROMs must be adapted according to the methodology available in the scientific literature in order to be used. This requires a translation, cross-cultural adaptation and subsequent validation. Examples of such available PROMs include the Knee Injury and Osteoarthritis Outcome Score (KOOS), which has been comprehensively validated in Polish on patients with anterior cruciate ligament (ACL) injury, and osteoarthritis undergoing total knee replacement (TKR) [8,9]. Similarly, the Polish version of the Knee Outcome Survey Activities of Daily Living Scale (KOS-ADLS) demonstrates good reliability, validity, and responsiveness for use in patients at the end-stage of knee osteoarthritis who have undergone TKR [10]. The Lysholm's scale and International Knee Documentation Committee (IKDC) have both been validated in Polish in patients who underwent arthroscopic reconstruction of the ACL. However, the authors only evaluated internal consistency [11].

Recently, in Poland, comprehensive validation of two versions of the Hip disability and Osteoarthritis Outcome Score (HOOS) have been carried out in patients with osteoarthritis [12], and in those with osteoarthritis who underwent total hip arthroplasty [13]. The Western Ontario and MacMaster Universities Osteoarthritis Index (WOMAC) is validated to assess function with degenerative changes in the hip and knee. Initially developed in 1982, the WOMAC has undergone multiple revisions (most recent version 3.1). The WOMAC version 3.1 is available from the authors' website (http://www.auscan.org/womac) in > 80 languages, including Polish, and has been validated in 14 language translations [14,15].

However, none of these PROMs are applicable to the whole lower limb as a single kinetic chain enabling the use of a single tool for all joints and conditions. Only the Lower Extremity Functional Scale (LEFS) [16] and, more recently, the Lower Limb Functional Index (LLFI) [17] are validated for regional use, but neither are available in the Polish language.

The LLFI was developed to assess function within the domains based on the World Health Organization (WHO) International Classification of Functioning, Disability and Health (ICF). The items in the questionnaire contain statements that include body functions or structures, and activities or participation in family or social life, which may be affected by problems related to the lower limbs [17,18]. This item selection is detailed in-depth within the e-appendices of the publication [17]. The original English version has demonstrated strong clinimetric properties. These include the psychometric characteristics for internal consistency, reliability, error measurement, validity, and responsiveness. From the perspective of

practical characteristics, the LLFI demonstrated brevity, ready transferability to a 100-point scale, ease and rapidity of completion and scoring, low missing responses, and suitable readability, all of which were preferable to the LEFS [17]. These clinimetric properties were reinforced with the scale's adaptation to Spanish [19] and Turkish [20].

The purpose of this study was to perform a translation and cross-cultural adaptation of the LLFI to establish a Polish version (LLFI-PL), and to evaluate its psychometric properties.

Methods

Material

Patients were recruited during all visits made with a specialist rehabilitation physician or orthopedic surgeon at the Specialist Hospital in Rudna Mała, Poland from January to May in 2018. All patients were diagnosed by a specialist based on: the results of an interview, physical examination, and imaging studies (depending on the needs: USG, MRI, CT, X-ray).

People with a variety of lower limb conditions were included, provided they met the following inclusion criteria: age >18 years, native speaker of Polish, informed consent to participate in the study was provided, diseases/injuries located in any part of the lower limb - osteoarthritis, arthroplasty due to osteoarthritis, conditions after injury (of muscles, nerves, ligaments, menisci, bones, joints, as well as contusion/hematoma), patellar chondromalacia, joint deformations, and symptoms, provided the duration was >4 weeks.

Exclusion criteria were coexisting neurological disease, failure to provide written consent, and an inability to read Polish.

Design

This was a two-stage, cross-sectional study with repeated measures on two variables during re-test examination.

Stage 1 involved translation and cross-cultural adaptation of the LLFI. This was completed in accordance with the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines and is approved by regulatory agencies such as the Food and Drug Administration and the European Medicines Agency [21].

It consisted of nine steps, each of which was documented with a written report **(Figure 1)**.

Figure 1: Flow chart of the translation and cultural adaptation process of the Lower Limb Functional Index from English to Polish

Step 1. Two forward translations were performed by two independent translators whose native language is Polish. This process allows Polish language equivalents to be introduced in place of terms that are

otherwise difficult to translate.

Step 2. Reconciliation meeting between the two forward translators and the authors of the Polish adaptation (experts in health/physiotherapy, expert with experience in instrument development and translation) - to create a common version of the two forward translations.

The team analyzed the individual items, the sets of answers to questions, the instructions for questionnaire completion and score calculation.

Step 3. Back translation by an independent English native speaker, fluent in Polish, who was not familiar with the original version or different language versions of the LLFI to create a back translation version.

Step 4. Back translation review. The English back translation version was compared to the original English version by the author of the original LLFI, the “back” translator, and authors of the Polish adaptation.

Step 5. Review by clinicians working in the relevant medical field who were bilingual. The received version of the questionnaire was assessed by a three-person expert panel: an orthopedic surgeon, one physician - a specialist in rehabilitation medicine and a physiotherapist/expert with experience in instrument development and translation. They qualitatively assessed compliance with a 5-0 scale (5=full compliance to 0=non-compliance) of each question in the source version with the relevant question in the Polish version, i.e. whether both questions measured the same symptom/problem.

Step 6. Cognitive debriefing. In this stage the resulting version was pilot-tested on a group of five symptomatic patients (two women, three men) with lower extremity problems that were present > three months (ACL injury, knee osteoarthritis, knee joint arthroplasty, hip osteoarthritis, and patellar chondromalacia) to assess face and content validity through the accuracy of questions and clarity of the wording. The group assessed whether a given position of the scale was fully understood or raised doubts using a three-point (2,1,0) scale where: 2=completely understood, 1=partially understood and 0=completely incomprehensible. In the event that the question was incomprehensible to the respondent, they were asked to indicate the reason for the lack of understanding.

Step 7. Review of cognitive debriefing results and finalization to create a final Polish version of the LLFI (the LLFI-PL).

Step 8. Proof reading. In this stage, a Polish language teacher checked the LLFI-PL for any minor errors (spelling, grammatical or other), which could have occurred during the translation process.

Step 9. Final report. The final report provided a description of all translations and cultural adaptation decisions and was sent to the author of the original version of the LLFI.

Stage 2 involved a prospective evaluation of the essential psychometric properties of the LLFI-PL. The subjects were evaluated twice with an initial baseline examination that consisted of completing the

Polish versions of all questionnaires by the respondents: the LLFI-PL, the WOMAC, the EuroQol 5-Dimensions, five-level version questionnaire (EQ-5D-5L), and the Pain Numerical Rating Scale (NRS). During the second examination (re-test), patients completed the LLFI-PL and the Pain NRS. This second visit took place three to seven days (average=six days) after the first examination, during a period of non-treatment, which is considered adequate and reasonable [4,22]. Patients completed the Pain NRS (to eliminate unstable participants from reliability analysis for whom the pain difference between baseline and retest was more than +/-1 point on the 11-point NRS). There is a low probability of changes in symptoms in this period, and the recollection of original responses is reduced [22].

Research tools

The LLFI assesses the impact of any lower limb problem on everyday activities. It is a 25-item regional PROM with a three-point response option of 'Yes' (points=1), 'Partly' (points=1/2) and 'No' (points=0) with a raw score range of 0-25 points. The final score is calculated by simple addition of the responses from the 25 items. The sum is multiplied by four and then subtracted from 100 to generate a 0-100% score (100%=no disability). Up to two missing responses are permitted[17].

The WOMAC index v. 3.1 was used to subjectively assess the functional status of patients. It includes 24 questions on a five-point (0-4) scale that determines symptom intensity in three domains: pain (five items), stiffness (two items) and function (17 items). The final score is obtained by summing all items (0-96) where the higher the score, the worse the functional status suspected. The data could be standardized to a range of values from 0-100 on a percentage scale, where 0 represents the worst health status and 100 the best health status. The WOMAC has been adapted into multiple languages including Polish [14,23,24].

The EQ-5D-5L consists of two parts. The initial part's questions are grouped into five life-domains: movement, self-service, everyday activities, pain/discomfort, and emotional state (anxiety/despondency). Each question is assessed on five levels, from 1=minimum (no problems/no pain) to 5=maximum (impossible to perform/max pain). The second part consists of a 0-100 point visual analogue scale (VAS) where 0=minimum (worst self-rated health status) to 100=maximum (best self-rated health status). A basic subdivision can be made according to the structure of the EQ-5D-5L: presenting results from the EQ-index value (1-5, the higher the score, the worse the condition) and presenting results of the EQ-VAS as a measure of overall self-rated health status (0-100, the higher the score, the better health status). The questionnaire has been adapted to a Polish version [25,26].

The 11-point Pain NRS was used, where 0=minimum (no pain) and 10=maximum (the highest imaginable intensity). The recall period was 'last week', and during the re-assessment it was specified that it concerned the period between test and re-test [27].

Statistical analysis

All statistical analyses were conducted using SPSS Statistics software version 24. The level of statistical significance was assumed at $p<0.05$. Normal distribution of the results of this study was verified using the Shapiro-Wilk test.

Sample size

Internal consistency

The internal consistency was determined using Cronbach`s alpha (α) coefficient, where α should be between 0.70 and $\leq$0.95 [22,30]. Data from the first examination, at baseline, were included in the analysis (n=125).

Reliability

The intra class correlation ($ICC_{2.1}$, CI=95%) was used to assess test-retest reliability in patients whose completed the LLFI-PL twice and for whom the difference on the Pain NRS between baseline and retest was +/- 1 point (n=94). In addition, the Pearson's correlation coefficient (PCC) was also estimated between two LLFI-PL measurements. Fisher's F test was used to assess statistical significance of the PCC. Reliability was good when the ICC$\geq$0.70 and the PCC was $r^3$0.70 [31].

Measurement Error

To assess error *the* Standard Error of Measurement (*SEM) and* Minimal Detectable Change at the 90% level (MDC_{90}) the sample was all participants who completed the LLFI-PL at baseline and reassessment and for whom the difference on the Pain NRS between baseline and retest was +/-1 point (n=94).

The SEM was calculated using the formula: $SEM=SD\sqrt{(1-R)}$, where SD is the standard deviation of measurements repeated from the test and retest and R - the reliability parameter ($ICC_{2.1}$) [32].

The MDC is the minimum change in a patient's score that ensures the change is not the result of measurement error. The MDC_{90} was calculated using the formula: $MDC=SEMx1.645x\sqrt{2}$, where 1.645 reflects the 90% Confidence Interval (CI) of no change, and $\sqrt{2}$ indicates two measurements assessing change [33].

Construct Validity

In order to evaluate the LLFI-PL *construct validity* the PCC was calculated between the LLFI-PL, the WOMAC (total, pain, stiffness, function), the EQ-5D-5L index value, the EQ-5D-5L-VAS, and the Pain NRS (n=125). Consequently, the LLFI-PL should correlate highly with the WOMAC, which is also used to assess the function of the joints of the lower extremities. It should correlate moderately with the EQ-5D-5L index value because the generic questionnaire was designed to measure both the functional state, pain, and the emotional state. The LLFI-PL should correlate moderately with the EQ-5D-5L VAS, because this part of the

questionnaire assesses the overall sense of health. The LLFI-PL should also correlate moderately with the Pain NRS, as it assesses only the severity of pain.

Therefore, the *a-priori* hypotheses were proposed as follows:

1a-d. The LLFI-PL should correlate highly with the WOMAC total; and with each domain (pain, function, and stiffness);

2. The LLFI-PL should correlate moderately with the EQ-5D-5L index value;
3. The LLFI-PL should correlate moderately with the EQ-5D-5L VAS.
4. The LLFI-PL should correlate moderately with the Pain NRS.

If fewer than (25 %) of the hypotheses were rejected, construct validity of the LLFI-PL was considered high, and for moderate validity 25–50 % and for low validity, more than 50% should be rejected [22,34]. The indications for PCC r strength for validity were <0.30=low, 0.30-0.70=moderate and ³0.70=high [31].

Factor Structure

Exploratory factor analysis (EFA) was used with maximum likelihood extraction (MLE) and Varimax rotation. The Kaiser-Meyer-Olkin measure of sampling adequacy (KMO) was set at 0.80-1.0 to indicate adequate sampling and the Barlett Test of Sphericity significance level was $p<0.001$ indicating that the EFA could be used for the data analysis. A single-factor structure was indicated if extraction requirements satisfied all three *a-priori* criteria: 1) 'Screeplot' inflection at the second point, 2) Eigenvalue >1.0 and 3) Variance >10% for a population >100 [35]. The item loading was also calculated for the one-factor solution using the maximum likelihood extraction (MLE) method.

Practical Characteristics

Readability was performed qualitatively as part of the face and content validity. The completion and scoring times were calculated from the average of three separate measures of n=15 participants performed by n=15 therapists.

Results

Stage 1: LLFI translation and cross-cultural adaptation

As a result of the translation and cross-cultural adaptation of the LLFI to the Polish version, changes were introduced at several stages of this process.

Step 2. Reconciliation meeting. There were some acceptable differences between the two forward translations, resulting from the many Polish language equivalents, which could be used by the translators.

Step 4. Back translation review. Change was made to one item (#24). A minor problem was with the phrase "unaccustomed footwear" and matching its best meaning in Polish to the concept of the questionnaire item which approximated to „shoes that I am not used to”.

Step 5. Review by clinicians working in the relevant medical field who were bilingual.

Based on the panel’s results, four questions were distinguished (#1, 5, 11 and 15) with minor comments, and subsequent corrections were made.

Step 6. Cognitive debriefing. Analyzing the obtained answers from the five respondents (symptomatic patients) gave an average=2.0 out of 2.0, indicating patient cognitive acceptance. Consequently, no corrections were made.

Step 7. Review of cognitive debriefing results and finalization. At this stage, no changes to the received version of the LLFI-PL were introduced by the Polish research team. The final version of the LLFI-PL was approved.

Step 8. Proof reading. There were no errors (spelling, grammatical or other in Polish) reported.

The LLFI translation and cross-cultural adaptation process produced the LLFI Polish version (LLFI-PL).

Table 1: Clinical characteristics of the patients

Subregion	[a] Diagnosis	*N* (%)
HIP		**42 (33.6)**
	Osteoarthritis	38 (90.5)
	Total hip arthroplasty	4 (9.5)
UPPER LEG		**7 (5.6)**
	Muscle strain:	7 (100)
	Biceps femoris	2 (28.6)
	Quadriceps femoris	3 (42.9)
	Adductors	2 (28.6)
KNEE		**53 (42.4)**
	Osteoarthritis	27 (50.9)
	Ligament injury: ACL	5 (9.4)
	MCL	5 (9.4)
	Patellar chondromalacia	2 (3.8)
	Meniscus repair	4 (7.5)
	Knee arthroplasty	10 (18.9)
LOWER LEG		**11 (8.8)**
	Muscle strain:	7 (63.6)
	Triceps surae	5 (45.5)
	Tibialis anterior	1 (9.1)
	Achilles tendon	1 (9.1)
	Injury (contusion/hematoma)	4 (34.4)
ANKLE		**12 (9.6)**
	Injury of ligaments	11 (91.7)
	Osteoarthritis	1 (8.3)
FOOT		**4 (3.2)**
	A joint	2 (50.0)
	Hallux	2 (50.0)
WHOLE LIMB		**5 (4.0)**
	Neurological reasons	5 (100.0)
Multiple areas	Diagnoses were included above	**9 (7.2)**
Pain characteristic		
	Acute 4 - 6 weeks	40 (32.0)
	Subacute 6 – 12 weeks	13 (10.4)
	Chronic ≥ 12 weeks	72 (57.6)

N=number, *%*=percent. [a] Subregion and percentage values of diagnoses include individuals with multiple (2 or more) affected subregions. Consequently, totals are greater than 100%.

Stage 2: Psychometric Investigation

A total patient sample of n=125, i.e. 69% of patients contacted, (age =52.9±19.6 years, range 20-87, 56% female, symptoms duration =17.7±18.4 weeks, range 5-71 weeks) qualified for the study.

The characteristics of problems, history, diagnosis and area affected are presented in **Table 1** above.

The PROMs absolute values are presented in **Table 2.**

Table 2: The absolute values of all scores

Questionnaire	±SD	Me	Range
LLFI -PL I (0-100)	60.7±25.1	66.0	6.0-100.0
LLFI-PL II (0-100)	66.4±24.4	72	6.0-100.0
NRS I (0-10)	5.2±1.8	5	2-9
NRS II (0-10)	4.6±1.75	4	1-9
WOMAC I (0-100)	61.7±21.6	61.0	16.0-95.0
EQ-5D-5L Index value I (1-5)	1.7±1.17	1.8	1.1-2.0
EQ-5D-5L – VAS I (0-100)	60.2±19.8	60.0	15.0-95.0

(mean), *SD* (standard deviation), *Me (*median), *LLFI-PL* (Lower Limb Functional Index – Polish version), *I* (test examination), *II* (retest examination), *WOMAC* (Western Ontario and McMaster Osteoarthritis Index), *EQ-5D-5L* (Euro–Quality of Life Questionnaire), *NRS* (Numerical Rating Scale, for pain)

Internal consistency

The LLFI-PL internal consistency was within the recognized acceptable range with Cronbach`s α=0.936 (n=125) **(Table 3).** Cronbach's α values' after removal of a given item from the questionnaire ranged from 0.931-0.937, and had no effect on the overall α value.

Reliability and measurement error

The value of $ICC_{2.1}$ was very high (0.962, CI ranged from 0.941-0.975) with SEM=4.83% and MDC 90%CI=11.3% **(Table 3).** In addition, the correlations (PCC) between two LLFI-PL measurements were also high r=0.843 (p <0.0001, Fisher's F test), which also indicated good test reliability. The re-test assessment using the LLFI-PL was performed three to seven days after the initial test assessment (average=six days).

Table 3: Psychometric properties of the LLFI-PL

Questionnaire	Internal Consistency N=125	Test-Retest Reliability N=94			Error Score (Max=100%) N=94	
	Cronbach's Alpha	($ICC_{2.1}$)	95% CI Lower Bound	Upper Bound	SEM	90%CI MDC
LLFI-PL	0.936	0.962	0.941	0.975	4.83	11.3

LLFI-PL (Lower Limb Functional Index – Polish version), *I* (test examination), *II* (retest examination), *WOMAC* (Western Ontario and McMaster Osteoarthritis Index), *EQ-5D-5L* (Euro–Quality of Life Questionnaire), *NRS* (Numerical Rating Scale, for pain)

Construct Validity

Table 4 shows the construct validity using the PCC, for the LLFI-PL and the reference questionnaires. The LLFI-PL correlated strongly with the WOMAC (r=0.81), the WOMAC pain (r=0.77), the WOMAC function (r=0.81) and moderately with the WOMAC stiffness (r=0.45), the EQ-5D-5L (Index value) (r=-0.63), the EQ-5D-5L-VAS (r=0.57), and with the Pain NRS (r=-0.39).

Table 4: PCC between the LLFI-PL and the WOMAC, the EQ-5D-5L, and the Pain NRS

Questionnaire	LLFI-PL (N=125)
	PCC
WOMAC Total	r=0.81, p<0,001 *
WOMAC Pain	r=0.77, p<0,001 *
WOMAC Stiffness	r=0.45, p<0,001 *
WOMAC Function	r=0.81, p<0,001 *
EQ-5D-5L Index value	r=-0.63, p<0,001 *
EQ-5D-5L - VAS	r=0.57, p<0,001 *
NRS Pain	r=-0.39, r=p<0,001 *

LLFI-PL (Lower Limb Functional Index – Polish version), *I* (test examination), *II* (retest examination), *WOMAC* (Western Ontario and McMaster Osteoarthritis Index), *EQ-5D-5L* (Euro–Quality of Life Questionnaire), *NRS* (Numerical Rating Scale, for pain)

Factor Structure

The EFA was conducted to assess factor structure and indicate construct validity. Initially, the factor analysis was performed without the single-factor extraction option. The KMO test was adequate

(0.88) and Bartlett's Test of Sphericity was significant (p<0.0001).

A total of five factors were extracted from the raw data analysis with Eigenvalues>1 (**Figure 2**, horizontal line indicates Eigenvalue=1). However, only the single-factor solution fit all three *a-priori* assumptions

which complied with the *a-priori* requirements for a single-factor structure (**Table 5**).

The item loading for the one-factor solution for the MLE method is shown in **Table 6.** Items 22, 23, 9, 19, and 20 were the least embedded in the determined single factor.

Figure 2: Scree Plot with a horizontal line at Eigenvalue=1.0

Table 5: Sums of load squares after isolation (analysis without one factor option enforced)

Factor	Total	% of Variance	Cumulative %
1	9.919	39.676	39.676
2	2.034	8.136	47.812
3	0.930	3.722	51.534
4	0.960	3.842	55.375
5	0.784	3.136	58.512

Table 6: Factor loadings of all items for one factor solution

LLFI-PL Items	Factor 1
LLFI-PL_7	0,825
LLFI-PL_25	0,799
LLFI-PL_4	0,795
LLFI-PL_16	0,785
LLFI-PL_1	0,782
LLFI-PL_11	0,769
LLFI-PL_18	0,759
LLFI-PL_6	0,729
LLFI-PL_10	0,727
LLFI-PL_13	0,724
LLFI-PL_15	0,721
LLFI-PL _5	0,680
LLFI-PL_24	0,661
LLFI-PL_3	0,631
LLFI-PL_17	0,579
LLFI-PL_14	0,501
LLFI-PL_2	0,496
LLFI-PL_21	0,478
LLFI-PL_12	0,475
LLFI-PL_8	0,424
LLFI-PL_19	0,374
LLFI-PL_20	0,371
LLFI-PL_9	0,366
LLFI-PL_23	0,327
LLFI-PL_22	0,298

LLFI-PL (Lower Limb Functional Index – Polish version)

Practical Considerations

The time to complete the questionnaire was 172±33 seconds, and scoring was 20±9 seconds. Missing responses were minimal with items 3, 5, 11, and 18 missed once in four separate responses. Respondents did not indicate these items were missed due to issues with understanding the question or item comprehension. Consequently, no further corrections to the LLFI-PL were necessary.

Discussion

The United States FDA defines PROMs as "*any report of the patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else*" [36]. A comprehensive assessment of patient health status should, consequently, combine objective clinical and biological data with the patient's subjective opinion. The PROMs allow clinically focused health professionals to reliably assess the impact of interventions and effectively select optimal therapy solutions and interventions [37,38].

Most of the proposed hypothesis were proven. The LLFI-PL had high but suitable and not excessive internal consistency, and test-retest reliability. The correlation was stronger between the LLFI-PL and the WOMAC than between the LLFI-PL and the generic EQ-5D-5L or the Pain NRS. Only one hypothesis was rejected because the WOMAC stiffness moderately correlated with the LLFI-PL; however, according to the adopted criteria [22,34], the LLFI-PL can be considered as a questionnaire with high construct validity. The EFA of the LLFI-PL confirmed a single-factor structure, though the inflection at point-2 in the scree plot is at an Eigenvalue >1.0 which suggests the potential that a modification to the questionnaire could be made, such as shortening to remove items and consolidate the factor structure. This would support the internal consistency value findings of 0.936 approaching the upper threshold of $\alpha \leq 0.95$, though still within acceptabe limits. This is consistent with the recommendations of previous authors [17,19,20].

The cultural and linguistic adaptation that produced the LLFI-PL complied with recognized standards [21] and ensured the linguistic proportionality of the concepts used and accounted for the slight discrepancies from a number of synonyms for individual words. The process confirmed the strong psychometric properties of the original-English, Spanish, and Turkish versions. The decision to complete this study was justified as it provided a regional lower limb PROM in the Polish language that could be applied to a wide range of patients with various functional problems in the lower limbs of varying severity and duration.

This study's results demonstrated the LLFI-PL has comparable psychometric properties to the original-English, Spanish, and Turkish versions [17,19,20]. The internal consistency ($\alpha=0.94$) is slightly higher than the original and Spanish versions ($\alpha=0.91$) [17,19] and notably more than the Turkish ($\alpha=0.82$) [20].

The test-retest reliability ($ICC_{2.1}=0.96$, at 6-days average) is identical to the Spanish version ($ICC_{2.1}=0.96$, at 7-days) [19] and comparable to both the original and Turkish versions (at three-days, $ICC_{2.1}=0.97$) [17,20].

The LLFI-PL error scores (SEM=4.8%, MDC_{90}=11.3%) are slightly higher than the three published versions, the original English (SEM=2.8%, MDC_{90}=6.6%) [17], Turkish (SEM=3.2%, MDC_{90}=5.8%) [20], and Spanish (SEM=3.1%, MDC_{90}=7.1%) [19]. This finding suggests that changes obtained at the level >6-11% can be interpreted as real change in functional status.

The construct validity, assessed with the PCC, was higher with the joint and condition specific WOMAC total (r=0.81) than the generic EQ-5D-5L (r=-0.63), the EQ-5D-5L-VAS (r=0.57), and the Pain NRS (r=0.39). These correlation differences were expected with the higher level due to the greater relevance and specificity of a joint/condition-related PROM compared to a general health and quality of life PROM or 11-point Pain NRS. These are mildly higher than the Spanish findings for the WOMAC (PCC, r=0.77), EQ-5D-3L (r=0.62), and EQ-5D-3L-VAS (r=0.58) [19] and similar to the Turkish findings where the SF-36 subscales were used and with a high-moderate finding for the physical dimensions (from r=0.43 to r=0.76) but moderate-low (from r=0.20 to r=0.66) for the mental dimension [20].

The finding in versions of the LLFI (English, Spanish, and Turkish) recommend a preferred single-factor structure. This was achieved consistently with the recommended MLE and Varimax rotation format [17,19,20]. The EFA of the LLFI-PL confirmed a single-factor structure, though the presence of the inflection at point-2 in the scree plot, where point #2 at an E=2.034 exceeds the arbitrary Eigenvalue 1.0 cutoff. However, at 8.14% this remains as counting for <10% variance, the recognized required minimum to contribute to an additional factor under the EFA *a-priori* determination. This finding suggests that a modification to the questionnaire may be possible to improve the practicality, such as shortening to remove potential redundant items. This is consistent with the recommendations of previous authors [17,19,20]; however, recent work [39, Gabel et al 2020 under review], suggests that the use of a dual-factor uni-dimensional model may also be present when both Classical Test Theory (CTT - EFA, CFA) and Modern Test Theory (MTT - Rasch Analysis) are considered in tandem. This is particularly so when CFA suggests a dual-factor structure while the more simplistic EFA suggests a single-factor structure is present, as is the case with the LLFI-PL and each of the other versions.

From the perspective of parsimony this confirms that the questionnaire items do measure the construct of lower limb functional status as a single kinetic chain and can be calculated with a single-summated score. However, each previous study also found multiple factor structures were potentially possible from the raw data analysis. This suggests a shortened version is a possible option and a ten-item [40] and an eight-item option preference being recommended and currently under journal review [Gabel et al. 2020, 'A Shortened ten-item and eight-item versions of the LLFI retain the psychometric properties while improving factor structure and practicality'].

The LLFI-PL questionnaire is easy and quick to complete and score. The questions are simple and clearly defined, so the patient and therapist burden is minimized. The times to complete (172±33 seconds) and score (20±9 seconds) are marginally longer than determined by the original study (131±23 and 17±5 seconds respectively) [17].

Limitations and Strengths

The current study limitations include a lack of assessment of responsiveness of the LLFI-PL. Further, the test-re-test period of three to seven days may have been too long for the acute participants who were within the latter stage of the acute phase being at four to six weeks only (32.0%). Changes in the condition in these patients may occur more dynamically than in patients in the subacute and chronic phases, though this is minimized by the use of the final third of the acute phase period. The procedures used in the study were employed to exclude data from unstable patients through the verification and use of the test-retest analyzes; however, this is possible as any participant at 4-6 weeks post injury is considered acute, and could have affected the increase in the change scores level of reliability. However, the high $ICC_{2.1}$ value reflects that of previous versions and, consequently, this difference may not have greatly affected the psychometric properties. Ideally, a regional criterion such as the LEFS [16] should be used but, as there is none available in Polish, this was not possible. The substitution of the WOMAC was not ideal but provided a regional indication.

The study strengths include the use of standardized methods for both cross-cultural adaptation and assessment of the psychometric properties. Further strengths are the prospective nature and diversity of conditions affecting each lower limb sub-region with varied degrees of severity and duration.

Future Considerations

The lack of determination of the responsiveness suggests that future studies need to consider the ability of the LLFI-PL to detect change in the construct measured over a period of time longer than two weeks. Also, that a larger study population (~1000) or data pooling be used to definitively clarify the factor structure through the use of confirmatory factor analysis (CFA) [41]. This has already been completed with the ideal shortened version being considered at ten-items [40], and an eight-item option also being investigated [Gabel et al. 2020, ‘A Shortened ten-item and eight-item version of the LLFI retain the psychometric properties while improving factor structure and practicality’, under review].

Conclusions

The LLFI-PL is a reliable and valid questionnaire for Polish-speaking patients with lower limb musculoskeletal disorders. The psychometric properties are comparable with the original English version and the published Spanish and Turkish linguistic and cultural adaptations. It can be used in clinical practice and scientific research projects on patients with various lower limb functional problems, variable levels of severity and symptom duration. Further research is required to clarify the factor structure, the relevance of a shortened 10-item and eight-item versions and the level of responsiveness.

List Of Abbreviations

CFA: Confirmatory Factor Analysis

CI: Confidence Interval

COSMIN: Consensus-based Standards for the selection of health status Measurement Instruments

E: Eigenvalue

EFA: Exploratory factor analysis

EQ-5D-5L: The EuroQol 5-Dimensions, 5-level version questionnaire

ICC: Intra class correlation

ICF: International Classification of Functioning, Disability and Health

IKDC: International Knee Documentation Committee

ISPOR: International Society for Pharmacoeconomics and Outcomes Research

KMO: Kaiser-Meyer-Olkin measure

KOOS: Knee Injury and Osteoarthritis Outcome Score

KOS-ADLS: Knee Outcome Survey Activities of Daily Living Scale

LEFS: Lower Extremity Functional Scale

LLFI: Lower Limb Functional Index

LLFI-PL: Lower Limb Functional Index - Polish version

MCID: Minimal Clinically Important Differences

MDC: Minimal Detectable Change

MLE: maximum likelihood extraction

NRS: Numerical Rating Scale

PCC: Pearson's correlation coefficient

PROM: Patient reported outcome measures

SEM: Standard Error of Measurement

VAS: Visual analogue scale

WHO: World Health Organization

WOMAC: Western Ontario and MacMaster Universities Osteoarthritis Index

Declarations

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The Bioethical Commission of the Faculty of Medicine, the University of Rzeszów granted permission to conduct research (No 2017/06/31b).

Written informed consent was obtained from all individual participants included in the study.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

AB conceptualized and designed the study, overall study coordination. AB, AP, SK, MM, PM, EDJ participated in the data collection process, analysed data and drafted the manuscript. MM revised the manuscript. CPG contributed to the design of the study, advised on the analytical approach, contributed to the discussion of results and revised the manuscript. All authors read and approved the submitted version.

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Lysholm Knee Scoring Scale, Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner Activity Score (TAS). Arthritis Care Res 2011;63(011):S208–S228.

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Figures

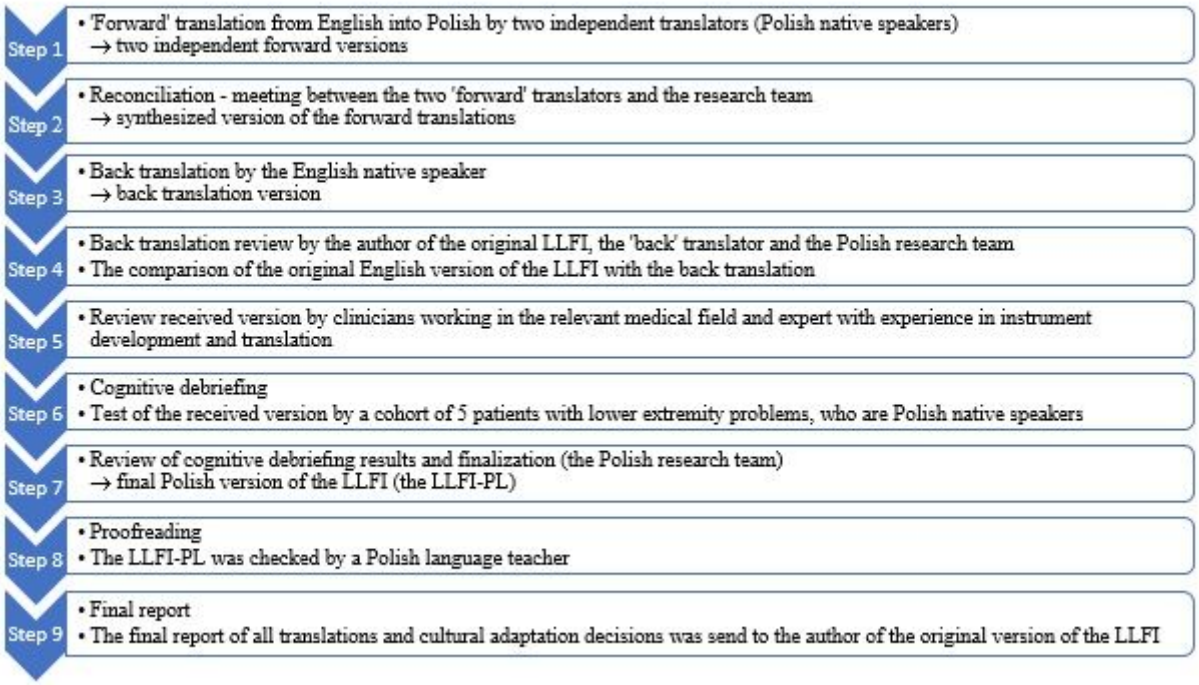

Figure 1

Flow chart of the translation and cultural adaptation process of the Lower Limb Functional Index from English to Polish

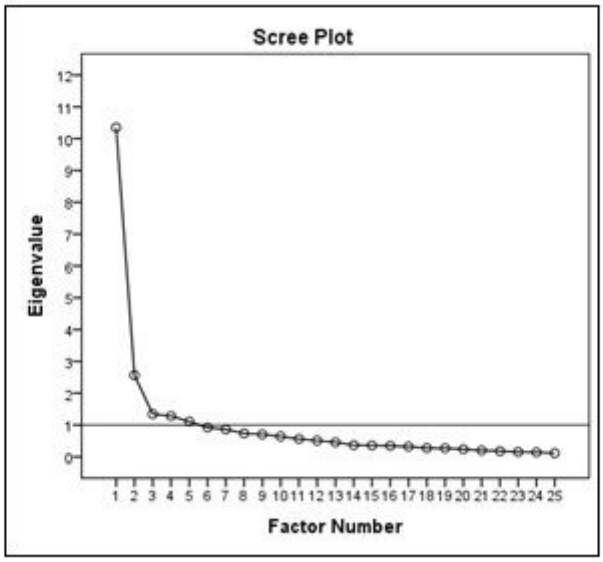

Figure 2

A Scree Plot with a horizontal line marked = 1 stands for own value