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Assessment of the structural validity of three foot and ankle specific patient-reported outcome measures

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Highlights

- The Lower extremity functional scale (LEFS), the Visual analogue scale foot and ankle (VAS-FA), and the Western Ontario and McMaster Universities osteoarthritis index (WOMAC) have relatively similar psychometric properties.
- The LEFS had the least suitable properties of coverage and targeting for assessment of foot and ankle surgery.
- Considering coverage and targeting, the results suggests that the VAS-FA instrument has the most suitable measurement properties in this patient sample.

1. Introduction

The evaluation of the outcomes after surgical treatment with outcome rating scales has attracted more interest in recent years [1, 2]. Patient-reported outcome measures (PROMs) are frequently used tools in evaluating the outcomes of surgical interventions of the foot and ankle [2, 3]. PROMs

are useful to assess the quality and outcomes of different treatments in clinical trials, and they provide possibilities for benchmarking [4].

The Lower extremity functional scale (LEFS) [5], the Visual analogue scale foot and ankle (VAS-FA) [6], and the Western Ontario and McMaster Universities osteoarthritis index (WOMAC) [7, 8] have been used to evaluate the outcomes in foot or ankle surgery [9, 10]. The VAS-FA and the LEFS were originally developed to assess foot and ankle conditions, and they are both proven to be valid and reliable also in Finnish language [5, 6, 11, 12]. The WOMAC was first introduced for patients with osteoarthritis of the hip and knee [7, 8], yet it has been used in patients with foot and ankle specific problems [13-16]. A previous study by Pinsker et al. compared the LEFS, the WOMAC, the Foot Function Index (FFI), the Ankle Osteoarthritis Scale (AOS), Short Musculoskeletal Function Assessment (SMFA) and the patient-reported section of the American Orthopaedic Foot and Ankle Society Questionnaire (AOFAS) among patients with osteoarthritis of the ankle[15]. The study concluded that none of the PROMs captured patients' concerns properly, and there would be a further need for a valid instrument to assess foot and ankle specific problems [17].

At least 139 different assessment scales has been used in foot and ankle research [2]. Nonetheless, there have been a lack of consensus whether all used foot and ankle scales are valid and reliable [3]. The Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN) includes a checklist to evaluate the quality of validation process of PROMs to clarify the basic standards which a PROM should fulfill [18]. As there has not been a consensus on which are the most suitable instruments for the foot and ankle patients [2], it is essential to assess existing instruments before developing new ones.

Current literature does not provide studies comparing the LEFS, the VAS-FA and the WOMAC instruments in patients with foot or ankle specific problems. We aimed to measure and

compare the structural validity of these instruments in patients having undergone foot and/or ankle surgery.

2. Materials and Methods

The patients (n=212) were identified from a database into which patients had been prospectively entered, or from an electronic database using the National Institute for Health and Welfare procedure codes which are based on the Nordic Medico-Statistical Committee (NOMESCO) classification (NHJ10, Ankle fracture osteosynthesis; NHU20 Removal of Implants from foot or ankle; NHG20 Tibiotalar joint fusion). The inclusion criteria of the study were at least 18 years of age, history of foot and/or ankle surgery, and full understanding of written language. The Regional Ethics Committee reviewed and approved the study protocol.

The participants were asked to fill in the LEFS, the VAS-FA, the WOMAC, and the 15D generic health-related quality of life (HRQoL) instrument. Furthermore, patients completed questionnaires about sociodemographic and clinical details, general health state on a VAS scale, and physical activity (Kasari FIT index [19]).

2.1 Instruments

2.1.1 Lower extremity functional scale

The LEFS has been developed for assessment of function of the lower extremity [5]. It is a PROM consisting of 20 items with 5 response categories awarding points between 0 and 4. A higher score indicates better function of the foot and ankle [5].

The LEFS instrument has previously been validated for assessing the function of foot and ankle [5, 11, 20, 21]. The internal consistency (Cronbach alpha 0.96), the construct validity, and the sensitivity to chance have been found to be high [5].

2.1.2 Visual Analogue Scale Foot and Ankle

The VAS-FA is a 20-item PROM developed and validated for the assessment of function and pain, and other symptoms of foot and ankle [12, 22, 23]. The instrument consists of 20 VAS-scaled items in three subscales: Pain subscale of 4 items, Function subscale of 11 items, and Other complaints of 5 items [6]. Higher scores indicates better outcome [6]. The internal consistency of the subscales has been found high as the Cronbach alphas of the Function, Pain, and Other complaints subscales are 0.94, 0.91, and 0.81, respectively [12]. Relative reliability has also been found high as the intra-class correlation coefficient (ICC) for total score and for the subscales are 0.97 and 0.95-0.97, respectively [12].

2.1.3 Western Ontario and McMaster Universities Osteoarthritis Index

The WOMAC (version 3.0) is a VAS scaled 24-item PROM developed originally for measuring physical disability and symptoms in osteoarthritis of knee and hip [7, 8]. Afterwards, it has been validated with osteoarthritis of foot and ankle patients [17, 24]. It consists of three subscales: Pain subscale of five items, Stiffness subscale of two items, and Physical function subscale of 17 items with higher scores indicating higher amount of physical symptom and disability and vice versa [7, 8, 25]. The WOMAC has previously been validated using Rasch analysis, from which the findings indicated good fit of each subscale within the Rasch model. Factor analysis has also revealed a unidimensional construct of Pain and Physical subscales [25]. The internal consistency of Pain, Stiffness, and Physical function subscales are high as the Cronbach alphas of the subscales are 0.82,

0.80, and 0.95, respectively [25]. The WOMAC has previously been translated and validated in Finnish language [26].

2.2 Statistical Methods

Clinical, sosiodemographic and questionnaire data are presented as means with standard deviations (SD), medians with interquartile ranges (IQR), 95% confidence intervals (95% CI), as counts with percentages, or as ranges. When 15% of patients scored the minimum or maximum points, a floor or ceiling effect was considered to be confirmed [27]. The WOMAC index scaling was reversed, so that it would be more explicit to compare it with the other instruments. Patients with complete data were included.

The Spearman correlation coefficients of the instruments were calculated to assess convergent validity. The correlations were represented as follows [28]: 0.00-0.30 negligible, 0.30-0.50 low, 0.50-0.70 moderate, 0.70-0.90 high and 0.90-1.00 very high correlation. Linearity between the instruments was assessed.

Linear regression analyses were used to identify the appropriate predictors of the LEFS, the VAS-FA, and the WOMAC. Age-, gender- and BMI-standardized regression coefficients (beta β) indicate how strongly each predictor variable influences the criterion (dependent) variable. The β was measured in units of SD. Cohen reference values are 0.1 for small, 0.3 for moderate and 0.5 for strong correlations.

To conduct a regression analysis where all the reference outcome measures would be accounted, all the items of the 15D, the Kasari FIT -index and the VAS General health instruments were reduced to to factors using principal component (PC) analysis. A log transformation was applied to the continuous variables [29]. The PCs were chosen according to Kaiser criteria where a component was included if the eigenvalue was equal to 1 or higher [30]. Altogether four PCs fullfilled the Kaiser criteria. We analyzed the first PC as it explained the most (36.7%) of the total

variance. The PC was used to calculate how much variance the general health/function-related variables would explain as a whole. One PC was used to eliminate multilinearity bias. Rotation local regression together with the LOESS curve with 95% CIs was generated to illustrate the correlation of the PC with the LEFS, the VAS-FA, and the WOMAC instruments.

R (version 1.1.453) statistics software was used to perform the analyses. Results are interpreted and reported according to the COnsensus-based Standards for the selection of health status Measurement Instruments (COSMIN) [18] and Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [31].

3. Results

Altogether 165 (77.8%) of the recruited patients (n=212) provided valid questionnaires (**Table 1.**). The questionnaires were completed averagely 4 years (range from 1 month to 10 years) after the surgery. Indication for surgery had been trauma (n=156), infection (n=6), tumor (n=2) or osteoarthritis (n=1). Location of the surgery was ankle (n=133), hindfoot (n=16), midfoot (n=7), forefoot (n=3), or multiple anatomical locations (n=6). None of the three instruments had normally distributed scores (**Figures 1A-C**). The ceiling effect was confirmed for the LEFS, as 29 (17.6%) of the patients scored maximum points (**Table 1.**).

3.1 Correlations

Figure 2 A-C describes the linear correlations for the LEFS, the VAS-FA and the WOMAC instruments. High correlations (0.73-0.86; $P < 0.001$) indicated to linearity between all three instruments. The correlations between the LEFS, the VAS-FA and the WOMAC with the 15D dimensions are presented in the Table 2. There was a high correlation between the LEFS and the VAS-FA and the 15D Mobility dimension (0.74 and 0.70, respectively). The correlations with the foot and ankle instruments were moderate between the 15D total score (0.60 to 0.68), and the 15D

dimensions of Mobility (0.68 to 0.74), Usual Activities (0.50 to 0.61) and Discomfort (0.54 to 0.60), and the VAS General health instrument (-0.53 to -0.66). All correlations were statistically significant ($P < 0.001$).

The LEFS, the VAS-FA and the WOMAC scores were compared with four states of general health (**Figure 3.**). The scores showed a gradual increase where general health was higher. The results for all instruments were relatively comparable.

Relationships between the instruments and the HRQoL (15D) were evaluated (**Figure 4.**). The relationships were strong with the 15D total score and the dimensions of Mobility ($\beta = 0.68$-0.72; $P < 0.001$) and Usual activities ($\beta = 0.54 – 0.69$; $P < 0.001$). Relationships with the VAS-FA, the WOMAC and the dimension of Discomfort and symptoms ($\beta = 0.52 – 0.56$; $P < 0.001$) were strong, yet between LEFS and Discomfort and symptoms (15D) ($\beta = 0.47$; $P < 0.001$) moderate. The LEFS had a strong relationship with the dimension of Vitality (15D) ($\beta = 0.51$; $P < 0.001$), and the WOMAC and the VAS-FA scores had a moderate ($\beta = 0.35$-0.49; $p < 0.001$) relationship. Relationships between the reference instruments and the dimension of Breathing ($\beta = 0.35 – 0.49$; $P < 0.001$) were moderate.

Independent relationship of foot and ankle specific instruments were investigated against the principal component (**Figure 5A-C.**). Scattering of scores was relatively similar for the LEFS, the VAS-FA and the WOMAC. However, the LEFS instrument had the most variance.

4. Discussion

To the best of our knowledge, this is the first study comparing the psychometric, structural validity of the LEFS, the VAS-FA and the WOMAC instruments among patients having undergone foot or ankle surgery. Main findings of our study were that these three foot and ankle PROMs have relatively similar psychometric properties when evaluating the outcomes of foot and ankle surgery. However, the LEFS instrument had a notable ceiling effect, indicating that the LEFS had the least

properties of coverage and targeting for long-term outcome assessment of foot and ankle surgery. Considering coverage and targeting, the VAS-FA instrument seemed to have most suitable measurement properties in this patient sample.

Button et al. (2004) [3] published a meta-analysis on the PROMs used in the field of foot and ankle surgery. They concluded, that even though there are around 140 PROMs used among foot and ankle surgery, none of them were properly tested whether they fulfill the criteria for validity, reliability, and responsiveness, and being region-specific for foot and ankle [3]. According to their meta-analysis, the WOMAC was used in one study, and the LEFS was not used at all. Since their study, Richter (2006) [6] published a new instrument, the VAS-FA, to patch the lack of valid instruments in foot and ankle surgery. Nowadays, over twelve years after the meta-analysis, all three instruments have been validated properly [6, 25, 32]. Still, studies comparing all these three instruments have not been published.

In the present study, the correlations between the foot and ankle instruments and 15D dimensions did not show significant differences. All three foot and ankle instruments which were assessed in this study had a slightly higher correlation with the 15D dimensions related to physical function (Mobility, Usual activities and Discomfort and symptoms) than the other dimensions of the 15D instrument. When the scores of the foot and ankle instruments were compared with the four stages of general health, the instruments did not show significant differences. All the three foot and ankle instruments seem to evaluate the generic HRQoL of the patients quite similarly; yet they focus in physical functioning (Mobility, Usual activities, Discomfort and symptoms).

Pinsker et al. (2015) [17] compared six foot and ankle instruments, the LEFS, the WOMAC, the FFI, AOS, the AOFAS, and the SMFA, among patients with ankle arthritis. They concluded that all evaluated instruments were valid and reliable, and none of the foot and ankle specific scales offered advantages when comparing them to lower extremity instruments (the LEFS and the WOMAC). A new PROM called the EFAS score has recently been developed for foot and

ankle patients by the score committee of the European Foot and Ankle Society (EFAS) [33]. This new instrument may provide further possibilities is assessing the treatment of foot and ankle diseases as it has been developed to overcome the weaknesses of other foot and ankle specific instruments [33].

In the present study, the VAS-FA foot and ankle specific instrument was compared with two lower extremity specific instruments (the LEFS and the WOMAC) in foot and ankle surgery. Although there were some differences between the scales, there seemed to be no real advantages using the instrument specifically designed for foot and ankle patients according to correlations, abilities to explain the principal component when it was compared to the lower extremity specific scales. In fact, the correlation was lower between the two lower extremity instruments than between the lower extremity instruments and the VAS-FA. The results of this study are indicating that the lower extremity specific instruments (the LEFS and the WOMAC) were measuring the same constructs as the VAS-FA which has been developed solely for foot and ankle assessment.

The strengths of our study were the representative study population and the use of properly validated and popularly used foot and ankle specific PROMs. The recruited study population contained patients with various indications for surgery, such as trauma, infection and tumors. The lower extremity specific LEFS [32] and the WOMAC [25] have been previously validated using the Rasch analysis [34], which can be considered as one of the golden standards in psychometric validation [35]. The weakness of this study was the lack of testing the responsiveness of these instruments. Furthermore, as the duration between the surgery and fulfilling the instruments was long (averagely 4 years), patients had high points on physical function and low level of pain in the evaluated instruments. When evaluating the validity of the PROMs, responsiveness is also an important measurement property to assess [18]. However, that was beyond the scope of the present study.

5. Conclusions

As a conclusion, the LEFS, the VAS-FA and the WOMAC have relatively comparable psychometric properties when evaluating the outcomes of foot or ankle surgery. However, the LEFS instrument has a notably higher ceiling effect compared to the other two measures indicating that the LEFS had the least suitable properties of coverage and targeting for long-term outcome assessment of foot and ankle surgery. Considering coverage and targeting, the results suggests that the VAS-FA instrument has the most suitable measurement properties in this patient sample.

Table 1. Sociodemographic and clinical characteristics.

	N=165
Female, n (%)	90 (54.5)
Age, year, mean (SD)	54.6 (19.7)
BMI, mean (SD)	27.3 (4.9)
Education, n (%)	
Elementary school	3 (23.6)
Vocational school	36 (21.8)
High school	28 (23.0)
University	47 (28.5)
Working, n (%)	73 (44.2)
Smoking, n (%)	26 (15.8)
LEFS score, median (IQR)	70.5 (59.0; 78.0)
minimum score, n (%)	0 (0)
maximum score, n (%)	29 (176)

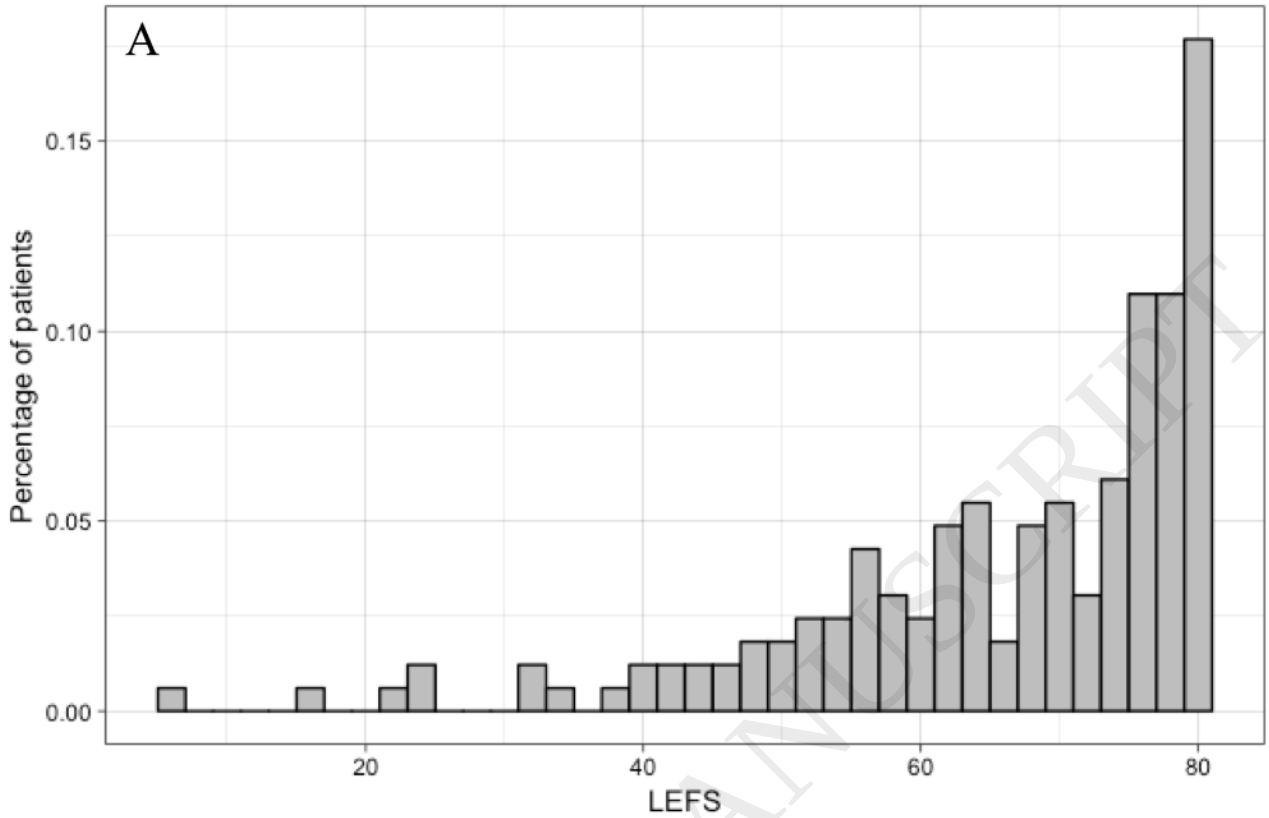
VAS-FA score, median (IQR)	83.2 (56.1; 93.8)
minimum score, n (%)	0 (0)
maximum score, n (%)	4 (2.4)
WOMAC score, median (IQR)	91.4 (75.4; 96.9)
minimum score, n (%)	0
maximum score, n (%)	4 (2.4)
15D mean score, median (IQR)	0.94 (0.87; 0.97)
Kasari FIT Index, mean (SD)	42.8 (21.9)
VAS General health, median (IQR)	14 (4.0; 38.0)

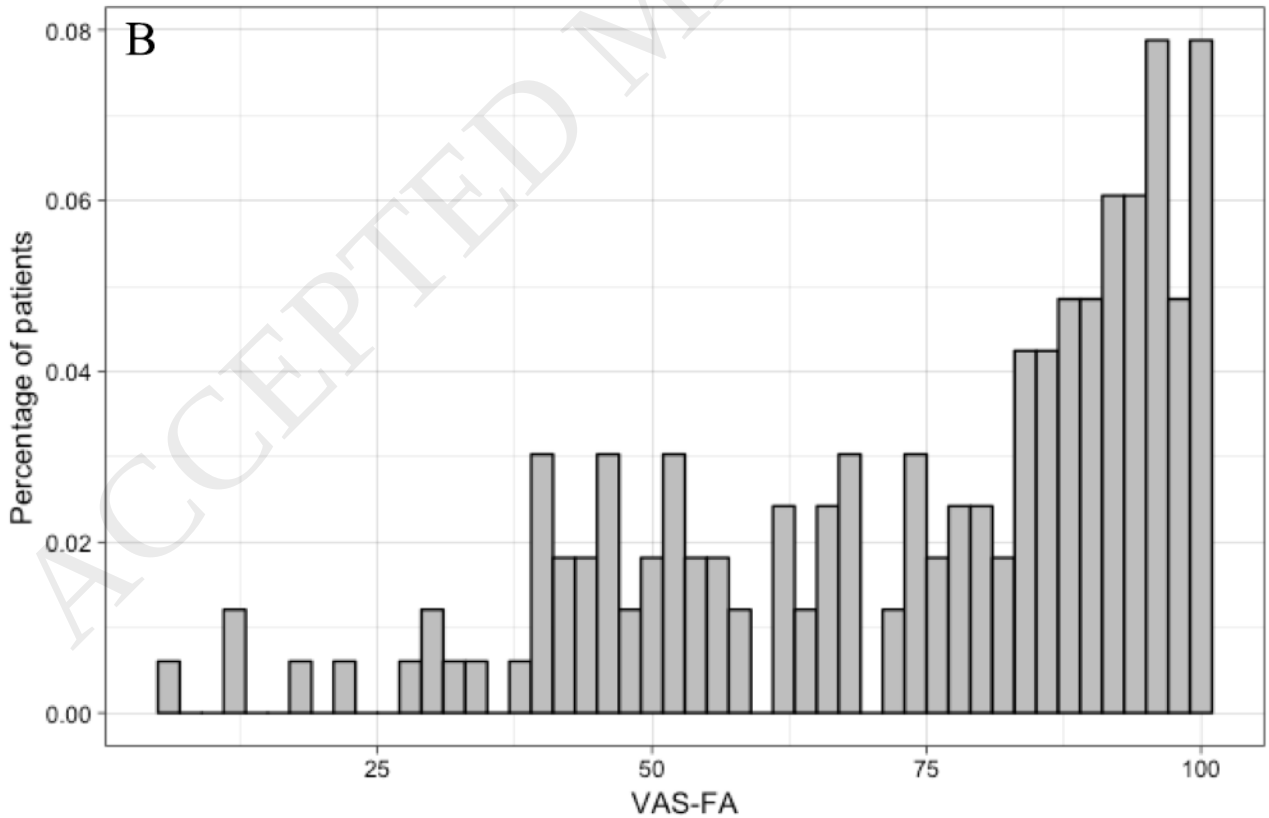
All correlations were statistically significant ($P < 0.001$)

Table 2. Correlations between the LEFS, the VAS-FA, the WOMAC, and the dimensions of the 15D. Eating dimension was removed, since all patients scored maximum points.

Variable	LEFS, r (95% CI)	VAS-FA, r (95% CI)	WOMAC, r (95% CI)
15D total score	0.67 (0.57 to 0.74)	0.68 (0.58 to 0.76)	0.60 (0.49 to 0.69)
15D dimensions			
Mobility	0.74 (0.66 to 0.81)	0.70 (0.60 to 0.77)	0.68 (0.58 to 0.75)
Vision	0.23 (0.09 to 0.36)	0.25 (0.12 to 0.38)	0.17 (0.04 to 0.31)
Hearing	0.26 (0.11 to 0.39)	0.22 (0.08 to 0.33)	0.20 (0.05 to 0.35)
Breathing	0.45 (0.32 to 0.56)	0.40 (0.27 to 0.52)	0.34 (0.20 to 0.48)
Sleeping	0.22 (0.07 to 0.36)	0.21 (0.05 to 0.35)	0.17 (0.02 to 0.32)
Eating	-	-	-
Speech	0.21 (0.11 to 0.32)	0.18 (0.07 to 0.28)	0.15 (0.06 to 0.24)
Excretion	0.23 (0.08 to 0.38)	0.18 (0.01 to 0.33)	0.11 (0.03 to 0.27)
Usual activities	0.61 (0.50 to 0.70)	0.55 (0.43 to 0.66)	0.50 (0.37 to 0.61)
Mental function	0.20 (0.05 to 0.35)	0.23 (0.07 to 0.39)	0.13 (0.03 to 0.29)
Discomfort	0.54 (0.41 to 0.64)	0.60 (0.49 to 0.69)	0.58 (0.46 to 0.68)
Depression	0.27 (0.11 to 0.44)	0.28 (0.12 to 0.42)	0.22 (0.07 to 0.36)
Distress	0.20 (0.05 to 0.35)	0.26 (0.11 to 0.39)	0.22 (0.07 to 0.36)
Vitality	0.49 (0.34 to 0.61)	0.49 (0.35 to 0.60)	0.41 (0.27 to 0.55)
Sexual activity	0.40 (0.26 to 0.52)	0.38 (0.23 to 0.51)	0.33 (0.19 to 0.46)
FIT index	0.44 (0.31 to 0.57)	0.35 (0.20 to 0.48)	0.31 (0.16 to 0.44)
VAS General health	-0.66 (-0.76 to -0.55)	-0.61 (-0.72 to -0.49)	-0.53 (-0.65 to -0.39)

All correlations were statistically significant ($P<0.001$)





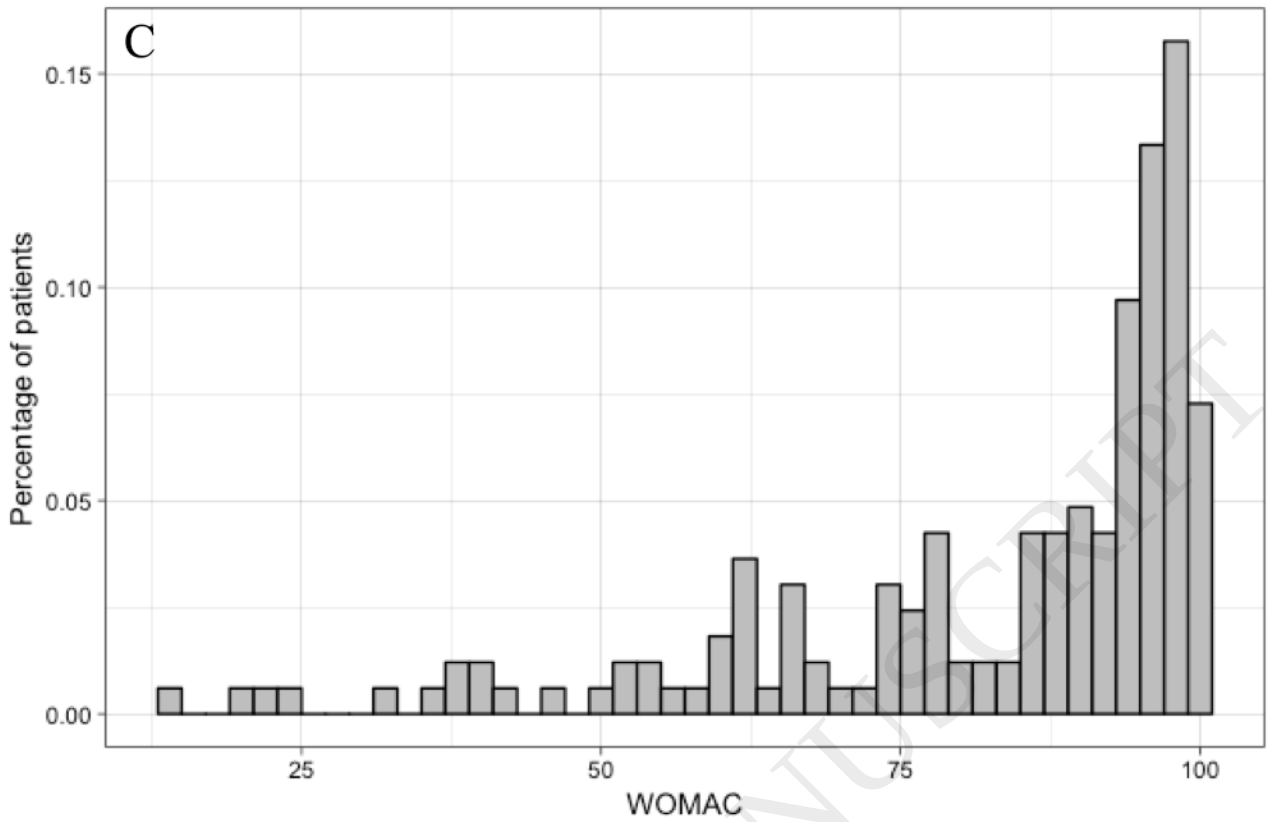


Figure 1A-C. Distribution of the LEFS, the VAS-FA and the WOMAC total scores.

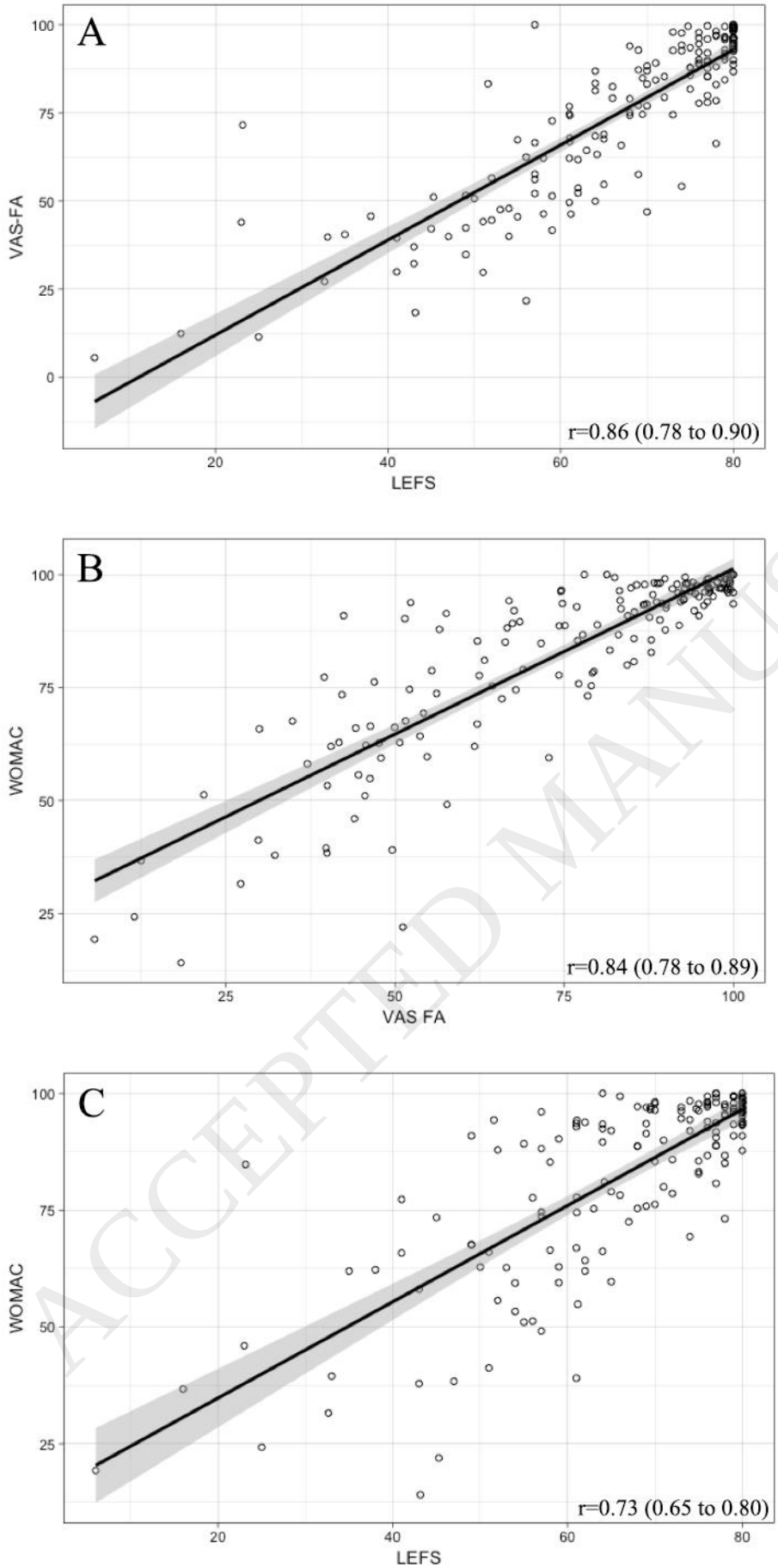


Figure 2A-C. The Spearman correlations between the LEFS, the VAS-FA, WOMAC instruments. All correlations were statistically significant ($P < 0.001$)

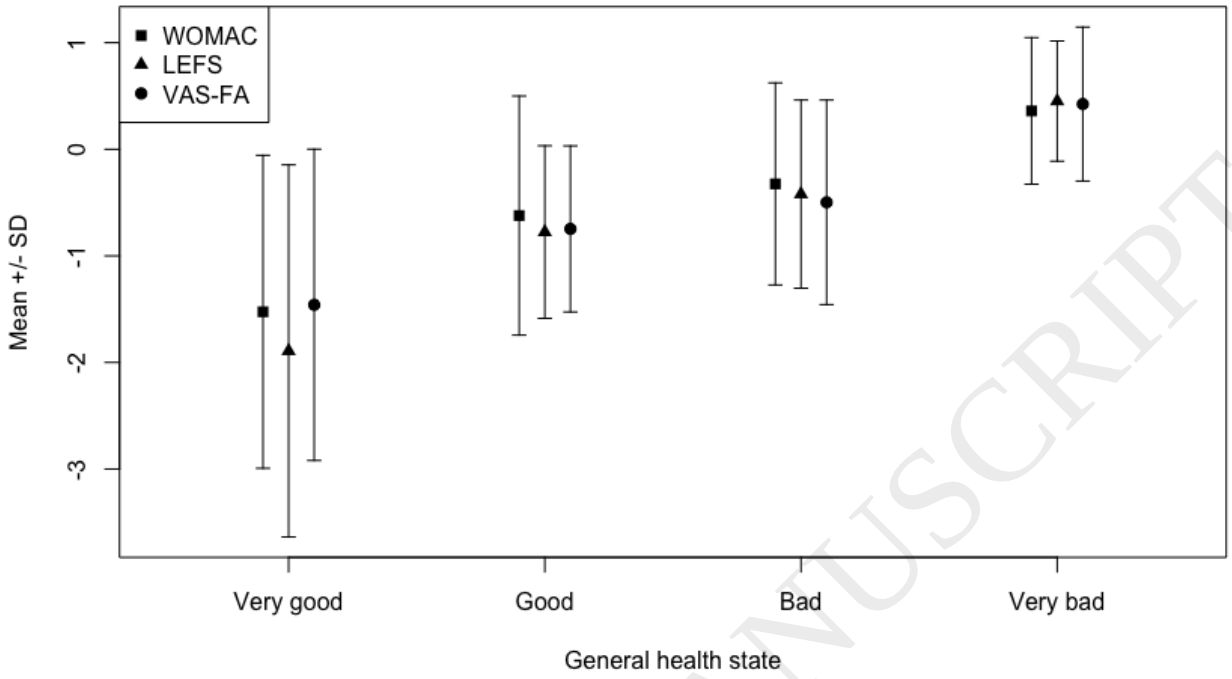


Figure 3. The LEFS, the VAS-FA and the WOMAC scores compared with four states of general health. The whiskers show the SD.

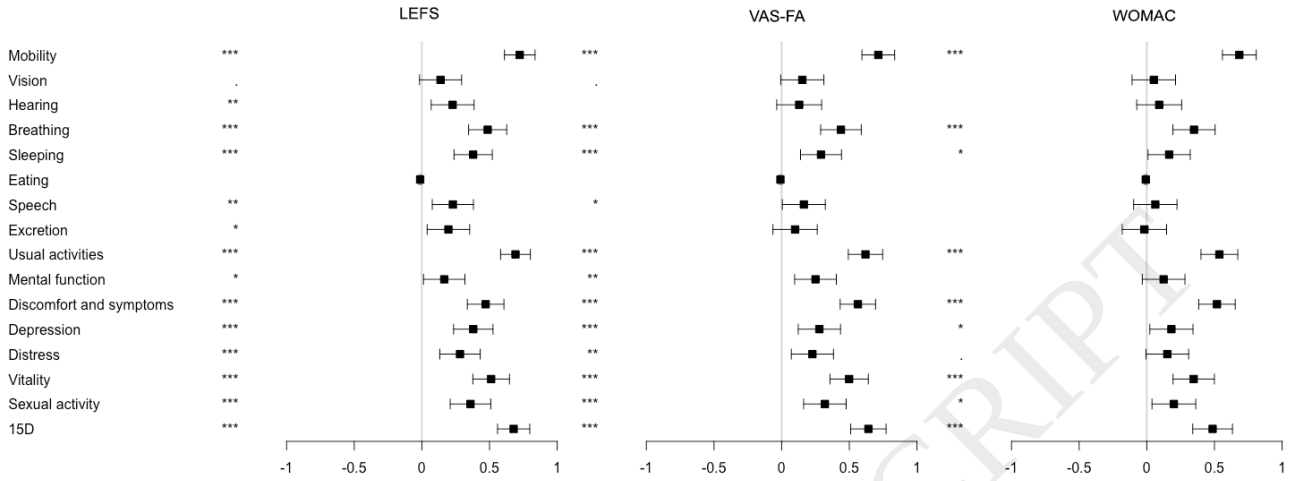
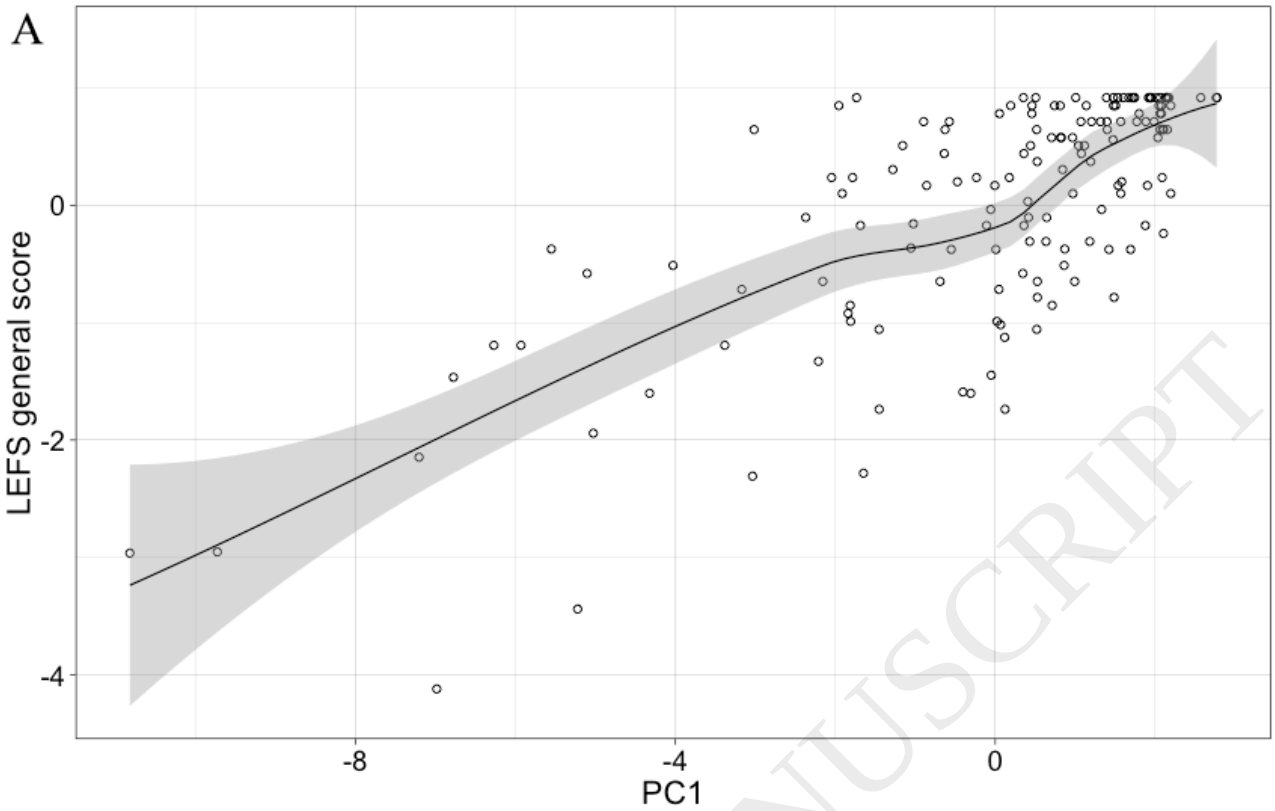
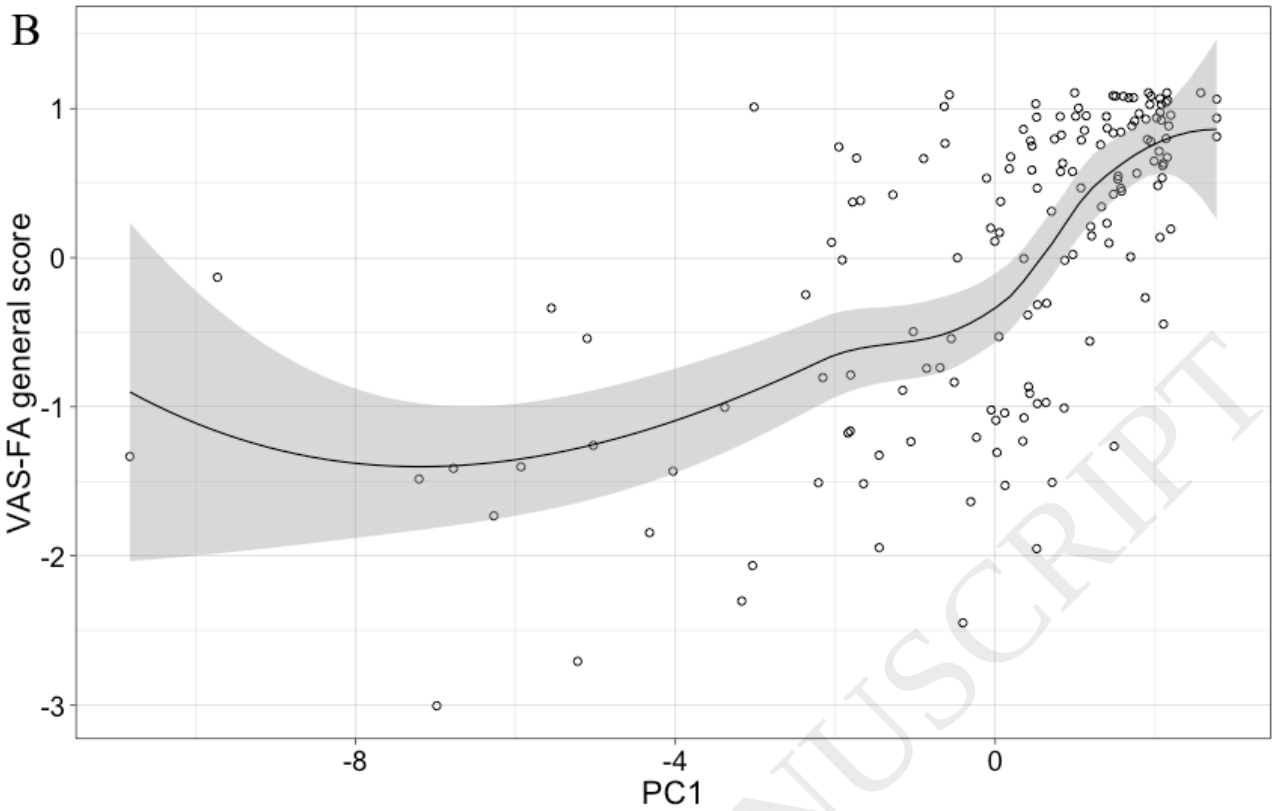


Figure 4. Relationships between the LEFS, the VAS-FA, the WOMAC and health related quality of life (15D dimensions and total score). Every patient scored the maximum score in Eating dimension, and therefore it did not have variance. Cohen's standard for β-values above 0.10, 0.30 and 0.50 represent small, moderate and large relationships, respectively. Boxes represent the mean scores (LEFS, VAS-FA, WOMAC). Whiskers show the 95% CIs. *** P< 0.001





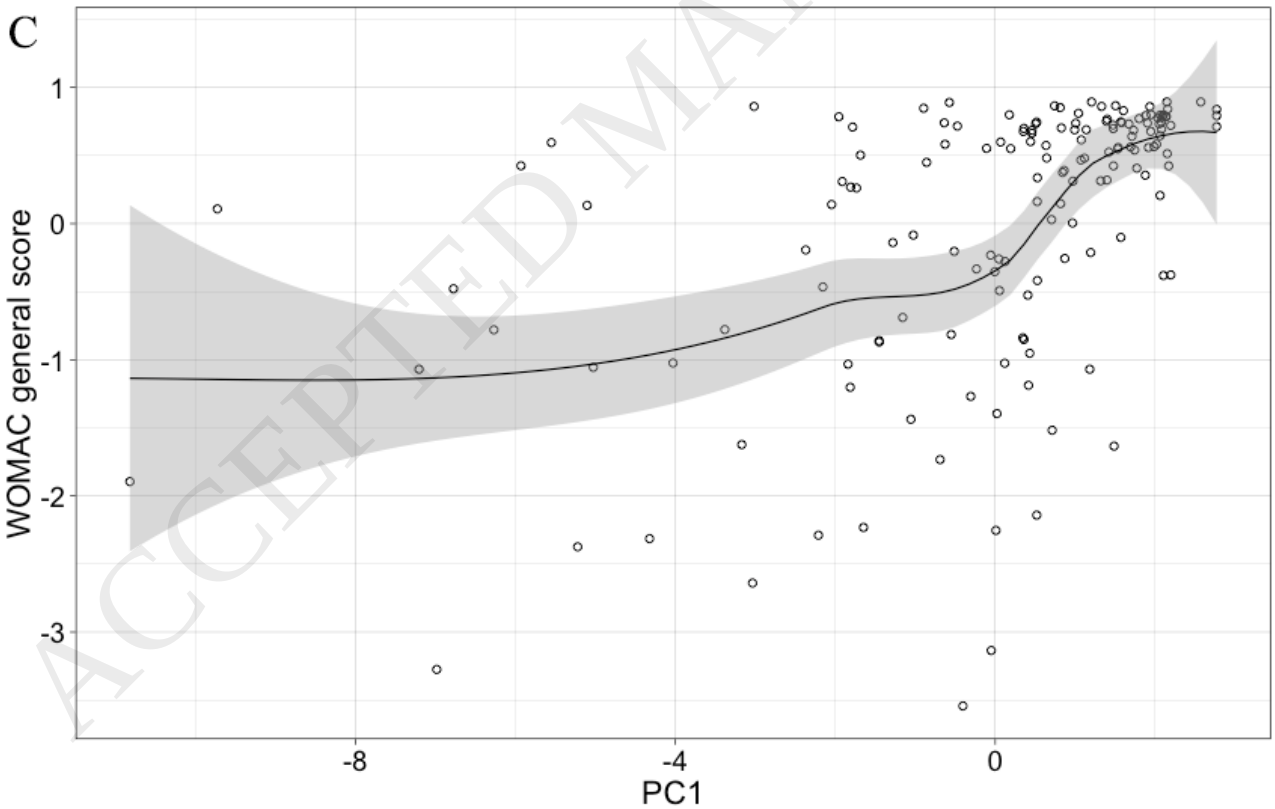


Figure 5A-C. Relationship of the LEFS, the VAS-FA, and the WOMAC scaled scores (general score) with the first principal component (PC1). The LOESS curve shows the deterministic part of the variation in the data. Gray area around the curve describes the 95% CIs.

Conflict of Interest Statement

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organization for the submitted work. This work did not receive any funding

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