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Reliability and validity of the Finnish version of the Visual Analogue Scale Foot and Ankle (VAS-FA)

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Highlights

* Assessing patient-centered outcomes is essential to capture treatment effectiveness

* No validated foot and ankle-specific PROM has been available in Finnish

* The VAS-FA was translated and adapted into Finnish

* Validity and reliability of the Finnish version of the VAS-FA was good

ABSTRACT

Background: There have previously been no foot and ankle-specific patient-reported outcome measures in Finnish.

Methods: The Visual Analogue Scale Foot and Ankle (VAS-FA) was translated and adapted into Finnish. Thereafter, 165 patients who had undergone foot and ankle surgery completed a questionnaire set on two separate occasions. Analyses included testing of floor-ceiling effect, internal consistency, reproducibility, and validity.

Results: Minor linguistic differences emerged during the translation. Some structural adjustments were made. The mean (SD) total VAS-FA score was 74 (23). In the three subscales, maximum scores were noted in 2-5% of the responses, and internal consistency ranged from 0.81 to 0.94. Reproducibility was excellent (ICC, 0.97). The total VAS-FA score correlated significantly with the Lower Extremity Functional Scale (r = 0.84) and the 15D Mobility dimension (r = 0.79). The VAS-FA loaded on two factors (pain/movement and problems/limitations).

Conclusions: The Finnish version of the VAS-FA has high reliability and strong validity.

Keywords: reliability, validity, foot, ankle, VAS-FA

1. Introduction

Modern medical care increasingly measures what matters to the patient. Patient-centered treatment outcomes can be evaluated by using patient-reported outcome measures (PROMs). The PROMs can be divided into generic and disease-specific.

The foot and ankle region is a subtle entity. A wide range of instruments has previously been described for foot and ankle assessments [1]. Disease-specific PROMs may be required to accurately measure foot and ankle function. These instruments include the English version of the Visual Analogue Scale Foot and Ankle (VAS-FA) [2]. The VAS-FA has been further validated in Thai and Indian languages (Malayalam) [3,4].

Thus far there has been no validated foot and ankle-specific PROMs available in Finnish. The present study aimed to translate and adapt the VAS-FA instrument into Finnish and psychometrically test its reliability and validity among patients who had undergone foot and ankle surgery.

2. Materials and methods

2.1 Ethical considerations and participants

The study protocol was approved by the Ethics Committee of Helsinki and Uusimaa Hospital District, Finland. The study inclusion criteria were full understanding of written Finnish, age of at least 18 years, and previous foot or ankle surgery.

Participants provided signed informed consent according to the Declaration of Helsinki [5]. Participants were selected either from a database into which patients were prospectively entered before the electronic hospital database was established, or using Finnish National Institute for Health and Welfare procedure codes (NHJ10 Ankle fracture osteosynthesis; NHU20 Removal of implants from foot or ankle; NHG20 Tibiotalar joint fusion).

2.2 Translation and cross-cultural adaptation

Permission to use the VAS-FA was obtained from the copyright holder (Professor Martinus Richter). The translation and cross-cultural adaptation adhered to the International Society of Pharmacoeconomics and Outcome Research (ISPOR) guidelines [6].

Two native Finnish translators, fluent in English and experts in the field of rehabilitation, independently produced two forward-translations into Finnish. The Finnish versions were then synthesized into one by a steering group, and a written report was produced. An English translator produced a back-translation back into English. The translator has competence in translating PROMs, has no medical background and no (at the time of translation) previous knowledge of the translated instrument, is fluent in Finnish, and is familiar with Finnish culture. A back-translation panel consisting of all three translators reviewed the process, discussed any discrepancies, and produced a written report.

A committee of four physicians and the key in-country person reviewed all the phases on a separate occasion and produced a written report proposing a pre-final version.

The pre-final version was pretested according to the Beaton et al. guideline [7] among 20 Finnish patients who had undergone foot and ankle surgery during the previous month. Patients were then cognitively debriefed following the European Organisation for Research and Treatment of Cancer guidelines [8] to identify any offensive content, understandability, cultural relevance, problems in answering the items, and whether the patient would ask anything differently.

Finally, the expert committee reviewed the pretesting and cognitive debriefing outcomes. The committee proposed a final Finnish version of the VAS-FA, which was thereafter proofread by a linguistic professional of the Finnish Medical Society Duodecim finalizing the Finnish version of the VAS-FA (Supplement).

2.3. Reliability and validity testing

The authors included in the first questionnaire package a pre-information form, questions about the general health state, ankle pain and stiffness, the Finnish version of the VAS-FA, the Lower Extremity Functional Scale (LEFS), and the 15D generic health-related quality of life (HRQoL) instrument. Patients who did not return the first questionnaire compilation within a week received a reminder letter. After the participants had completed the first questionnaire, the authors mailed them the VAS-

FA instrument a second time along with a survey whose purpose was to ascertain whether the patients' health status had changed after completing the first round of questionnaires. Participants who completed the VAS-FA twice were included in the final analyses.

2.4 PROMs

2.4.1. Visual Analogue Scale Foot and Ankle

The VAS-FA is a validated foot and ankle-specific PROM for assessing a variety of musculoskeletal conditions [2,9]. It contains 20 items on a visual analog scale (0-100 mm, worst to best). The total score ranges between 0 and 100 points. The VAS-FA can be divided into three subscales: pain (4 items), function (11 items), and other complaints (5 items). The VAS-FA has a high intra-class correlation coefficient (ICC, 0.99) and internal consistency (Cronbach α, 0.99) [3]. The VAS-FA pain scale has shown significant correlation with the Hannover Scoring System (r = 0 .90) and the SF-36 (r = 0.70) [2]. The Hannover Scoring System is a 20-item questionnaire assessing symptom severity and functional capability [10]. The SF-36 is a general health survey based on 36 items [11] and is widely used internationally.

2.4.2. *Lower Extremity Functional Scale*

The LEFS is a 20-item lower extremity-specific PROM developed to assess lower extremity function [12]. The authors used the Finnish version of the LEFS [13]. The LEFS scores 20 individual activities on a five-point scale (0-4, worst to best). The total score ranges from 0 to 80 points, where higher scores indicate better function. The LEFS has proven reliable, responsive, and valid in assessing foot and ankle

function [12,13,14,15]. The psychometric properties of the LEFS have been reported to be superior to many widely used function-related foot and ankle instruments [1,16].

2.4.3. 15D instrument

The 15D is a valid generic HRQoL instrument [17]. It contains 15 dimensions: moving, seeing, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity [17]. Respondents elect one of the five levels in each dimension that best describes their current state of health (1-5, best to worst). The 15D produces both a HRQoL profile and a single index score representing the overall HRQoL. The reproducibility and the minimal important change of the 15D are estimated at 0.90 and 0.015, respectively [18,19].

2.4.4. Sociodemographic and clinical data questionnaire

Patients reported their general state of health during the previous week on a visual analogue scale (0-100 mm, worst to best). The scale also served as a single-item measure to capture subjective feelings concerning foot and ankle pain during activity and at rest.

In addition, the authors obtained information on patient age and sex, weight, height, smoking habits, occupation, and educational level. Clinical data consisted of information on the surgical procedure and duration of symptoms.

2.5 Statistics

The results are expressed as means with standard deviation (SD) or with 95% confidence intervals (95% CIs), as counts with percentages, or frequency distributions.

The "floor value" was defined as the worst possible value of the item or as the minimum total value of the scale. The "ceiling value" was the best possible value of the item or the maximum total value of the scale. The internal consistency was calculated using Cronbach's alpha [20]. The reproducibility of the total scale and the subscales were calculated using the ICC and coefficient of reproducibility (CR).

Construct validity was studied by using principal-component factor analysis with oblique rotations factor loadings. Correlation coefficients were calculated by the Pearson method. Sidak's adjustment was applied to correct levels of significance for multiple testing if appropriate. Bias-corrected bootstrapping (5000 replications) was used to obtain the confidence intervals for the mean changes and reproducibility.

Linear regression analyses were used to identify the appropriate predictors of the 15D age- and gender-standardized regression coefficients Beta (β). The β-value is a measure of how strongly each predictor variable influences the criterion (dependent) variable. The β was measured in units of standard deviation. Cohen's standard for β-

values above 0.10, 0.30, and 0.50 represent small, moderate, and strong correlations, respectively.

Statistical analyses were performed using SPSS 23.0 (SPSS Inc., Chicago, IL, USA) or STATA 14.0. (StataCorp LCC, Texas, USA). Predefined hypotheses are presented in Table 1. Reporting was done adhering to the COSMIN checklist [21].

3. Results

3.1. Translation and adaptation

The forward translations of the VAS-FA translated well into Finnish. The back-translation panel review found no major linguistic issues compared to the original English version. However, small changes were made to the Finnish VAS-FA to adhere to Finnish linguistics. In the original VAS-FA questionnaire, there are clarifications of some terms in the instructions. In the Finnish version, both the back-translation review panel and the steering group decided that they should be omitted, as adding examples in the actual items were considered more convenient. Thus the description of “physical rest” was thereafter described as “(e.g. laying and sitting)” in item 2. The phrase “physical activity” in item 4 was also modified to “(e.g. walking, exercising)”. In item 13, “one leg standing” was replaced with “standing on injured leg” for more accuracy. As the term “orthopedic shoe” may not be generally understood, an example “(e.g. elevated or wider shoe)” was added into item 18. Analyzing the results of the pretests and the cognitive debriefing gave no reason for change.

3.2. Reliability

Altogether 212 questionnaire booklets were returned and 165 participants (78%)

completed the VAS-FA twice (Table 2). The mean time between the start of symptoms and completing the questionnaires was approximately five years.

3.2.1. Floor and ceiling effect

In the total VAS-FA score or the three subscales (Function, Pain, Other complaints), no single participant received the lowest score (Table 3). Altogether 5%, 4%, and 2% of the participants scored the maximum points in the subscales of Pain, Function, and Other complaints, respectively. Several single items reached the ceiling effect (Table 3).

3.2.2. Internal consistency

Cronbach's alpha (CI 95%) was high in all subscales: Function 0.94 (0.93 to 0.96), Pain 0.91 (0.88 to 0.94) and Other complaints 0.81 (0.75 to 0.85).

3.2.3. Reproducibility

The mean (SD) VAS-FA score was 74 (23) in the first assessment. Between the first and the second completion of the VAS-FA, nine patients (5.4%) reported slightly worsened and eight patients (4.8%) improved health between the two assessments. Health state was stable for the remaining patients (89.8%). The mean change between the two assessments was 1.6 points. The total scale and its subscales all had good

reproducibility (Table 4). Absolute reliability of the total scale was good, as the CR was 16.

3.3. Validity

3.3.1. Factor analysis

In factor analysis, the VAS-FA loaded on two factors, explaining 70% of the total variance (Table 5). The first factor included items of pain and movement. The other factor consisted of items concerning foot and ankle problems and restrictions.

3.3.2. Convergent and criterion validity

The VAS-FA total score had strong correlation with the LEFS score (Figure 1). The 15D index and its dimensions of Mobility, Usual activities, Discomfort and symptoms, and Vitality correlated strongly with the VAS-FA total score and all of its three subscales (Figure 2). The total VAS-FA score and its subscales had significant correlation with general health, and pain during activity and at rest (Table 6). Patient weight (body mass index) and age had a moderate negative correlation with the Function subscale (Table 6).

4. Discussion

The VAS-FA was successfully translated and cross-culturally adapted into Finnish. Psychometric testing of the Finnish VAS-FA provided evidence of its validity and

reliability among patients who had undergone foot and ankle surgery.

4.1. Translation and adaptation

The authors used a rigorous translation protocol [6,7,8] to establish a linguistically valid Finnish version of the VAS-FA instrument. Using well-accepted international translation guidelines guaranteed conceptual equivalence to the original questionnaire. Accordingly, the translation can be considered culturally and linguistically appropriate for the target language. The authors' linguistic validation of the VAS-FA into Finnish found no cultural differences in health, disease, or operational environment in the adaptation process between the original and the translated version. Previously published translation and validation reports of the VAS-FA to another language have not specified if any linguistic or cultural changes were made in the translation process [3,4].

In the authors' translation and cross-cultural adaptation, several minor adjustments and clarifications were made. The final changes and adjustments were assessed by a group of health care professionals who are familiar with rehabilitation and with several medical specialties to guarantee the accuracy and necessity of the changes made.

4.2. Reliability

In floor-ceiling values, the hypothesized cut-off is at 15% [22]. In the Thai version, the authors noted no maximum or minimum scores [3]. The present study, with a

significantly larger study population, showed that the VAS-FA had no floor or ceiling effect in the total score or in its three subscales. However, several single items reached the ceiling, as over 15% of the participants achieved the maximum points. No clear relationship between the content of these items could be noted. Nonetheless, the items that reached the ceiling effect were associated with passive activities such as pain at rest, existence of callus, occupational limitations, driving a car, walking, daily activities, and footwear (Table 3).

Internal consistency of 0.8 or more is considered sufficiently high [23]. Angthong et al. reported an extremely high internal consistency of 0.99 for the total VAS-FA score in their psychometric analyses based on 42 patients with foot and ankle problems [3]. The original validation study by Richter et al. did not calculate the internal consistency [2]. Calculating the internal consistency of the three subscales using Cronbach's alpha provided insight into the correlation between different items of the VAS-FA. The authors estimated the internal consistency to be the following: Function 0.94, Pain 0.91, and Other complaints 0.81. These estimates represent good internal consistency for all subscales.

Angthong et al. reported an extremely high ICC of 0.995 for the FAS-VA [3]. No information on the time between the two tests was provided by the authors [3]. In the present study, the test-retest reliability was assessed after a 2-week interval. The 2-week time frame between the assessments has previously been estimated to be optimal in patients with stable health or symptoms [24]. The present study showed that the ICC was 0.97 for the total VAS-FA score. The ICC for the subscales ranged from 0.95 to 0.97. These results demonstrate the high relative reliability of the VAS-FA instrument.

The CR estimates the value of absolute difference between two test scores. The CR can be a more accurate estimation of absolute reliability than the standard error of measurement. The CI reported together with the CR value gives further precision to the assessment of absolute reliability. The authors estimated the absolute reliability of the total VAS-FA at 16 (CI, 13 to 21). Previous psychometric studies of the VAS-FA have not estimated the absolute reliability [2,3,4,9].

4.3. Validity

The VAS-FA has been divided into three subscales [2]. The authors hypothesized that factor analysis would support the construct of the three subscales. After trialing several different models, the VAS-FA factor loading was clear on two main themes: 1) pain and movement and 2) problems and restrictions. These factors explained 70% of the total variance. The factor has to explain at least 10% of the total variance to be accepted. Nonetheless, the authors decided to assess the psychometrics of the Finnish version of the VAS-FA for its original three subscales.

A study by Goldstein et al. claimed that one foot and ankle PROMs would be enough to capture the current foot and ankle state [25]. Richter et al. reported strong correlation between the VAS-FA total score and the Hannover score (r= 0.70) [2]. In the present study, the VAS-FA total score correlated significantly with the function-specific LEFS score (Figure 1). It would seem that both questionnaires primarily measure the same construct of function. The VAS-FA score also correlated significantly with the 15D Mobility dimension, supporting the construct validity of

the VAS-FA instrument for functional assessment. Nair et al. found a strong correlation between the VAS-FA and the American Orthopedic Foot & Ankle Society (AOFAS) score in their analysis of results in a cohort of 50 malleolar fracture patients [4]. Furthermore, Angthong et al. reported a significant correlation of the VAS-FA score and the SF-36 Physical Functioning scale (r= 0.55) [3].

The SF-36 is usually divided into two different component summaries or eight scaled scores [11]. Richter et al. used all eight SF-36 scaled scores and "standardized" them into a possible 100-point maximum for reference outcome in assessing the convergent validity of the VAS-FA [2]. The present study is not directly comparable to Richter et al., as the authors used a different generic PROM (15D). The authors assessed the correlation between the 15D index score and the VAS-FA total score. The correlation between these two instruments was 0.66. Richter et al. and Angthong et al. found a notable correlation between the VAS-FA and the generic SF-36 health survey “total score” (0.60 and 0.62, respectively) [2,3] supporting the findings of the present study. Furthermore, in the Thai study, moderate correlation with the SF-36 Vitality subscale (r= 0.22) was noted [3]. However, the present study found a strong correlation between the VAS-FA and 15D Vitality dimension (r= 0.54). The authors’ interpretation is that the more foot and ankle limitations, pain, or problems, the more impaired HRQoL the participants had.

The total VAS-FA score and its subscales had significant correlation with general health, pain during activity, and pain in rest (Table 6). Patient BMI and age had a

moderate negative correlation with the Function subscale. These results indicate that the higher the BMI or age, the lower the functional score will be.

4.4. Strengths and weaknesses

The authors recruited a representative population of foot and ankle patients that compared favorably with published reports of VAS-FA psychometrics [2,3,4]. The authors used two validated PROMs, of which the other was a well-recognized foot and ankle tool (LEFS) [12,13], to assess the convergent validity of the Finnish VAS-FA. Further, to the authors' knowledge, the present study is the first to assess the construct validity of the VAS-FA using factor analysis, giving more insight into the structural components of the VAS-FA instrument. A weakness of the present study was that time between the start of symptoms and completion of the questionnaires was in some cases relatively long. This may have had an impact on the maximum points in some items and the reproducibility values, as some of the patients may have fully rehabilitated after surgery. As most patients underwent operation after trauma and the defect located in the ankle in a significant proportion of patients, the results of this study should be interpreted with caution among the general population with foot and ankle problems.

5. Conclusions

The VAS-FA was successfully translated and cross-culturally adapted into Finnish. This study showed evidence of the validity and reliability of the Finnish version of the VAS-FA. The Finnish VAS-FA is available now for both clinical and research purposes when evaluating foot and ankle function.

Conflicts of interest:

JPR: None

EJT: None

RPR: None

HK: None

JL: None

OI: None

SJ: None

AH: None

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454 2010;31(12):1075-80.

455 Table 1. Predefined hypotheses for validation of the Finnish VAS-FA.

Feature	Hypothesis	Statistical Method	Result	Hypothesis Confirmed/Rejected
Reproducibility	ICC is ≥ 0.90	Two-way mixed model with absolute agreement	0.93	Confirmed
Internal consistency	Internal consistency is ≥ 0.90	Cronbach's alpha	0.96	Confirmed
Validity				
Content validity	Floor values ≤ 15%	Percentage of maximum or minimun scores	0%	Confirmed
	Ceiling values ≤ 15%		2-5%	Confirmed
Convergent validity				
	VAS-FA correlation with	Spearman		
	15D total index is strong		r = 0.66	Confirmed
	15D Mobility dimension is strong		r = 0.78	Confirmed
	VAS-FA correlation with LEFS is strong		r = 0.84	
Criterion validity	VAS-FA correlation with	Spearman		
	age is moderately negative		r = -0.16	Rejected
	BMI is moderately negative		r = -0.20	Confirmed
	general health is strong		R = -0.63	Confirmed
	foot and ankle pain at rest is strong		r = -0.70	Confirmed
	foot and ankle during activity is strong		r = -0.81	Confirmed
Construct validity				
	VAS-FA loads on three factors	Principal-component factor analysis with oblique rotations factor loadings	Two factors	Rejected

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459 Table 2. Participants' sociodemographic and clinical characteristics.

	N = 165
Female, n (%)	90 (54.5)
Age, years, mean (SD)	55.6 (16.1)
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)
In working life, n (%)	73 (44.2)
Smokers, n (%)	26 (15.8)
General health VAS, mean (SD)	24 (24)
Indication for surgery, n (%)	
Fracture	156 (94.6)
Soft tissue infection	6 (3.6)
Other	3 (1.8)
Defect location, n (%)	
Ankle	137 (83.0)
Foot	28 (17.0)
Time of symptoms (years), mean (SD)	4.9 (4.7)
Foot and ankle pain, VAS, mean (SD)	
At rest	8 (14)
During activity	16 (21)
Foot and ankle stiffness, VAS, mean (SD)	20 (23)
15D score, mean (SD)	0.90 (0.093)

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462 Table 3. Mean VAS-FA scores, response rate, floor and ceiling values.

Category	Mean (SD)	Response Rate (%)	Floor (%)	Ceiling (%)
Pain (Item)				
2	78 (30)	98	1	12
3	84 (22)	96	1	18
4	63 (35)	100	2	7
5	69 (31)	97	1	8
Total	73 (27)		0	5
Function (item)				
8	57 (36)	100	3	9
9	73 (30)	99	1	14
10	81 (27)	93	1	26
11	89 (20)	78	1	24
12	78 (27)	99	1	16
13	72 (33)	97	1	17
14	76 (28)	100	1	16
15	56 (39)	98	6	11
16	90 (19)	100	1	30
17	88 (24)	98	1	27
19	77 (30)	100	1	21
Total	76 (24)		0	4
Other Complaints (Item)				
1	72 (30)	100	1	8
6	59 (36)	99	1	8
7	82 (26)	98	1	17
18	77 (30)	99	1	21
20	77 (30)	100	1	22
Total	74 (23)		0	2

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Table 4. Reproducibility of the VAS-FA instrument.

Category	First measurement Mean (SD)	Change From First to Second Measurement Mean (95% CI)	ICC (95% CI)	CR* (95% CI)
Pain	73 (27)	2.1 (0.2 to 3.9)	0.95 (0.92 to 0.96)	24 (20 to 28)
Function	76 (24)	1.6 (0.2 to 3.0)	0.96 (0.95 to 0.97)	18 (14 to 26)
Other complaints	74 (23)	1.5 (-0.1 to 0.30)	0.95 (0.93 to 0.96)	20 (17 to 23)
Total	75 (23)	1.6 (0.4 to 2.9)	0.97 (0.95 to 0.98)	16 (13 to 21)

*Expresses the expected maximum size of 95% of the absolute differences between paired observations. 95% CI obtained by bias corrected bootstrapping.

ICC, intraclass correlation coefficient; CR, coefficient of repeatability.

469 Table 5. Factor analysis of the VAS-FA.

Item	Factor 1	Factor 2
1	0.53	
2	0.58	
3	0.61	
4	0.88	
5	0.88	
6	0.87	
7	0.70	
8	0.97	
9	0.62	
10		0.52
11		0.72
12	0.55	
13	0.56	
14		0.52
15	0.78	
16		0.85
17		0.96
18	0.58	
19	0.57	
20	0.52	

470 Explanatory factor analysis with oblique rotations factor loadings of the VAS-FA.

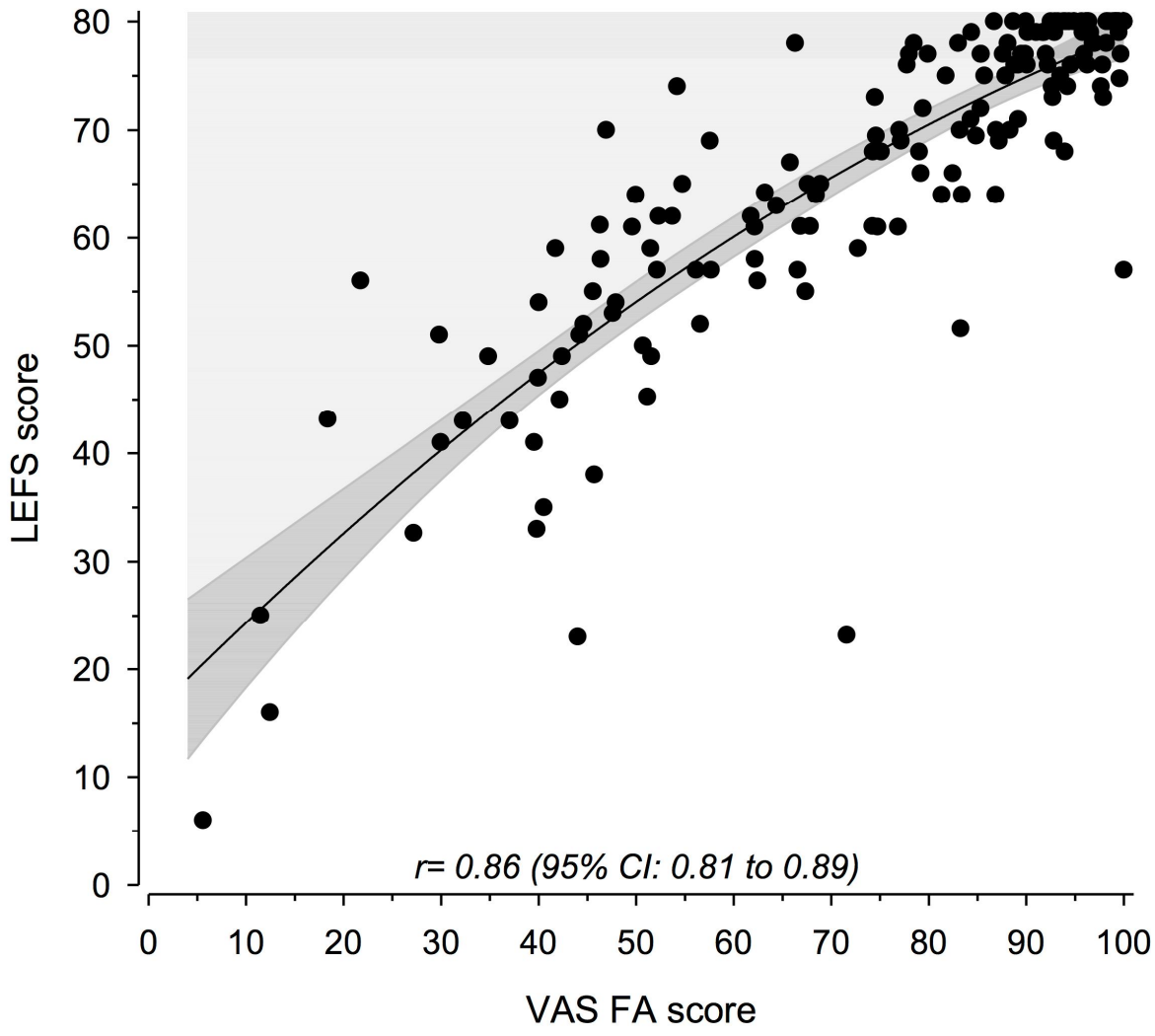
471 Coefficients with values <0.50 not shown. Factors explained 70% of the total

472 variance. Factor 1: pain/movement; Factor 2: problems/limitations.

473 Table 6. Correlation of the VAS-FA with sociodemographic and clinical parameters.

	Pain	Function	Other Complaints	Total
	r (95% CI)	*r* (95% CI)	*r* (95% CI)	*r* (95% CI)
Age	-0.05	-0.22*	-0.10	-0.16
	(-0.20 to 0.11)	(-0.36 to -0.06)	(-0.25 to 0.05)	(-0.30 to -0.01)
Gender	-0.01	-0.03	-0.07	-0.04
	(-0.15 to 0.15)	(-0.18 to 0.12)	(-0.22 to 0.08)	(-0.19 to 0.12)
BMI	-0.15	-0.21*	-0.18	-0.20
	(-0.30 to 0.01)	(-0.36 to -0.05)	(-0.33 to -0.02)	(-0.35 to -0.04)
Symptom duration	0.06	0.06	0.01	0.05
	(-0.10 to 0.21)	(-0.10 to 0.21)	(-0.15 to 0.16)	(-0.11 to 0.20)
General health	-0.54***	-0.64***	-0.55***	-0.63***
	(-0.64 to -0.42)	(-0.72 to -0.54)	(-0.65 to -0.43)	(-0.71 to -0.52)
Pain at rest	-0.71***	-0.71***	-0.63***	-0.70***
	(-0.78 to -0.63)	(-0.78 to -0.63)	(-0.72 to -0.53)	(-0.77 to -0.61)
Pain during activity	-0.75***	-0.80***	-0.72***	-0.81***
	(-0.81 to -0.68)	(-0.85 to -0.72)	(-0.78 to -0.63)	(-0.86 to -0.75)

474 Figure 1. Correlation of the VAS-FA with the LEFS instrument.



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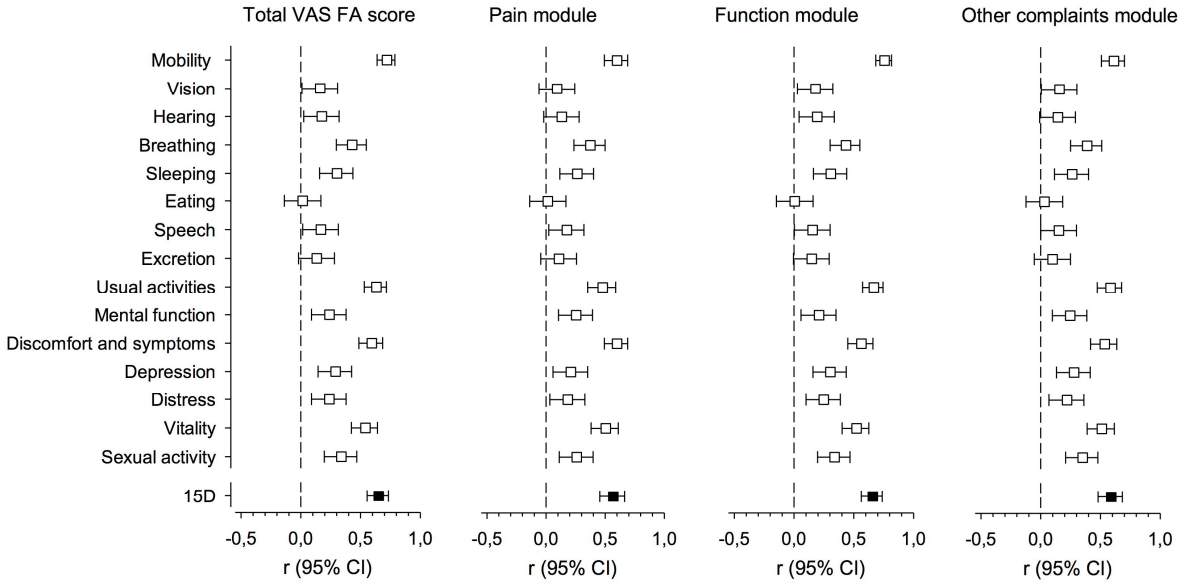
476 Figure 2. Correlation of the VAS-FA with the 15D and its dimensions.



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