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EFAS Score - Validation of Finnish and Turkish Versions by the Score Committee of the European Foot and Ankle Society (EFAS)

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Abstract

Background

The Score Committee of the European Foot and Ankle Society (EFAS) developed, validated, and published the EFAS Score in seven European languages (English, German, French, Italian, Polish, Dutch, Swedish). From other languages under validation, the Finnish and Turkish versions finished data acquisition and underwent further validation.

Methods

The EFAS Score was developed and validated in three stages: 1) item (question) identification (completed during initial validation study), 2) item reduction and scale exploration (completed during initial validation study), 3) confirmatory analyses and responsiveness of Finnish and Turkish version (completed during initial validation study in seven other languages). The data were collected pre-operatively and post-operatively at a minimum follow-up of 3 months and mean follow-up of 6 months. Item reduction, scale exploration, confirmatory analyses and responsiveness were executed using classical test theory and item response theory.

Results

The internal consistency of the scale was confirmed in the Finnish and Turkish versions (Cronbach's Alpha >0.8). Responsiveness was good, with moderate to large effect sizes in both languages, and evidence of a statistically significant positive association between the EFAS Score and patient-reported improvement.

Conclusions

The Finnish and Turkish EFAS Score versions were successfully validated in the orthopaedic ankle and foot surgery patients, including a wide variety of foot and ankle pathologies. All score versions are freely available at www.efas.co.

Keywords

Score; Foot; Ankle; Validation; PROM

Introduction

The Score Committee of the European Foot and Ankle Society (EFAS) developed, validated, and published the EFAS Score in seven European languages (English, German, French, Italian, Polish, Dutch, Swedish)[1]. The

score covers pain and physical function. The EFAS Score is internally consistent, unidimensional and responsive to change in samples of orthopaedic foot and ankle surgery patients[1]. The score contains six questions. The maximum score is 24 points (best possible), and the minimum 0 points (worst possible). The language-specific cross-cultural validation was necessary because simple translation of a validated score does not necessarily result in an instrument that provides valid scores in the target language[1]. This issue is especially important for Europe with numerous languages[1]. The most spoken mother tongues in Europe are German (16%), English (13%), Italian (13%), French (12%), Spanish (8%), Polish (8%), Romanian (5%) and Dutch (4%) (source Wikipedia, January 16, 2020). Therefore, a need for different language-specific (validated) scores, especially in Europe, is clear[1]. After having validated the EFAS Score in seven languages initially, the data acquisition in eight other languages (Arabic, Danish, Finnish, Hungarian, Norwegian, Portuguese, Spanish, Turkish) started. This data acquisition was finished in Finnish and Turkish so far and the results of the validation process and the results scores are presented.

Methods

The EFAS patient-reported outcome measure (PROM), the 'EFAS Score', was developed and validated in three stages: 1) item identification, 2) item reduction and scale exploration, 3) confirmatory analyses and responsiveness[1].

Type of score (initial score development)[1].

A questionnaire-based PROM, with a 5-point Likert scale (0-4) was chosen[1].

Questions - Item identification (initial score development)[1].

In the first stage of the initial validation, potentially relevant items from existing questionnaires were identified[1]. Given the low relevance of items related to sports activities for some diagnostic groups, it was decided at this point to develop two separate scores: a general item score and a sports-specific score[1]. In total, 31 general items and 7 sports-specific items were taken forward into the second phase of the project[1].

Item reduction and scale exploration (initial score development)[1].

Through a process of forward and backward translation performed by bilingual translators, the original English pool of 38 items was translated into German, French and Swedish[1]. These four language versions were then used for the Stage 2 data collection[1]. Participants were recruited from orthopaedic foot and ankle surgery departments[1]. Inclusion criteria for participants were clinical and imaging indications for foot and ankle surgery and age ≥ 18 years[1]. No exclusion criteria were used other than an inability to complete a written questionnaire[1]. Data collection was performed in France, Germany, Sweden and Ireland[1]. In addition to providing an answer to each item on a 5-point scale, all participants also rated the relevance of the item to their situation on a 5-point scale[1].

Following data collection, the following analytic steps were taken to reduce the item pool into one general PROM and one sports PROM[1].

1. Items with a ceiling effect, low perceived relevance and a high proportion of missing values were noted and shortlisted for exclusion in subsequent steps[1].

2. A principal component analysis (PCA) was performed[1]. At the end of this step, the remaining items in their respective principal components would provide optimal scale reliability according to classic test theory[1].
3. An Item-response theory (IRT) analysis was performed for each of the identified scales (i.e., principal components) to further reduce the number of items and optimize scale unidimensional[1].

Confirmatory analysis and responsiveness (initial score validation)[1]

Data collection for this final stage of the initial validation took place in the four original language versions, as well as Dutch, Italian and Polish[1].

Confirmatory analysis and responsiveness Finnish and Turkish versions

Data collection stage of the validation was performed in Finland and Turkey. Inclusion criteria for participants were scheduled foot and ankle surgery and age ≥ 18 years. No exclusion criteria were used other than an inability to complete a written questionnaire. Data were collected preoperatively and at postoperative follow-up. Minimum postoperative follow-up of 3 months and mean follow-up of 6 months planned, collecting at least 100 completed score sheets. To confirm the internal consistency for each language version, Cronbach's Alpha of the EFAS Score was computed for each language version separately[1]. To establish the responsiveness of the EFAS Scores, both distribution-based and criterion-based analyses were used[1]. Distribution-based measures of responsiveness included the effect size (ES) and minimal important difference (MID)[1]. The criterion-based measure of responsiveness used was the linear association (Pearson's correlation) between improvement on the EFAS Score and a 5-point Likert scale

anchor question: did the surgery improve the foot and/or ankle problem? (0= no, not at all; 4 = yes, very much)[1].

The ES was calculated as the difference between the baseline and three to six-month follow-up mean EFAS Score, divided by the standard deviation of the baseline EFAS Score[1].

The MID was considered to be equal to the standard error of measurement (SEM) of the baseline EFAS Score. The SEM was calculated as[1]:

$$SEM = SD * \sqrt{1 - r}$$ (Formula 1), where:

SD = standard deviation of the EFAS Score baseline score

r = value of Cronbach's Alpha for the EFAS Score at baseline.

To assess the responsiveness of the EFAS Score using the MID, the percentage of participants with an improvement in their EFAS Score between baseline and follow-up exceeding the MID was identified[1].

Statistical analyses were performed in SPSS (IBM SPSS Statistics 23, IBM, Armonk, NY, USA). The IRT modelling was performed in XCalibre 4 (Assessment Systems, Inc.)

Ethics

Approvals from the relevant ethical committees in different contributing countries were obtained, adhering to local legislation.

Results

Table 1 and 2 show the language-specific demographic data (Table 1) and diagnoses (Table 2) for the patient samples.

Confirmatory analyses and responsiveness

The internal consistency of the scale was excellent in both language versions. Cronbach's Alpha was 0.84 in Finnish and 0.81 in Turkish. Responsiveness of the EFAS Score is shown in Table 3 and Figures 1a and b. Large effect sizes (ES>0.8) were found in both language versions. A clear majority of patients showed a minimally important difference following surgery, 67.7% in Finnish and 79.4% in Turkish. The change in EFAS Scores between baseline and follow-up was significantly correlated with the patient-reported change in health status.

Discussion

The EFAS Score was successfully validated in Finnish and Turkish. Not all measurement properties of the EFAS Score have been established. In particular test-retest reliability, i.e. reproducibility of the score in a stable (pre-surgery) population, was not included in the initial validation and the present study[1]. The MID as reported in this and the initial validation study was based on the internal consistency of the scale (Cronbach's Alpha) rather than test-retest reliability[1]. In future, if the test-retest reliability becomes available, this may lead to an adjustment in the SEM and therefore MID of the EFAS Score.

The process to develop the EFAS Sports Score was ultimately unsuccessful during the initial validation study[1]. The questions related to sports activities were not relevant to a large proportion of the patient samples, and suffered from a high proportion of missing values[1]. This implies that the IRT modelling did not

result in a unidimensional EFAS Sports Score[1]. Based on the findings of the IRT model, a 4-item EFAS Sports Score could be considered, as this was the best-performing option[1]. The EFAS Sports Score was included in the data acquisition of all languages because this was part of the initially defined validation process that was decided not be changed during the process[1].

In conclusion, the Finnish and Turkish EFAS Score versions were successfully validated in the orthopaedic ankle and foot surgery patient population, including a wide variety of foot and ankle pathologies. All score versions are freely available at www.efas.co.

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Reference

1. Richter M, Agren PH, Besse JL, Coester M, Kofoed H, Maffulli N, Rosenbaum D, Steultjens M, Alvarez F, Boszczyk A, Buedts K, Guelfi M, Liszka H, Louwerens JW, Repo JP, Samaila E, Stephens M, Witteveen AGH. EFAS Score - Multilingual development and validation of a patient-reported

outcome measure (PROM) by the score committee of the European Foot and Ankle Society (EFAS). Foot Ankle Surg 2018; 24(3): 185-204.

Figure 1a and b. Association between change in EFAS Score from pre- to post-surgery and patient self-reported improvement (a, Finnish; b, Turkish)

Table 1 Demographic data. N = sample size; F = Female; L/R/B = Left/Right/Both; N/A = not available

	n	Age (mean±SD)	Sex (% F)	Affected side (% L/R/B)
Finnish	130	53.8±15.9	80.0	40.0/57.7/2.3
Turkish	131	46.9±14.7	70.0	40.8/42.1/17.1

Table 2. Prevalence of primary diagnoses, in %, based on ICD-10 codes

	Osteoarthritis (M19)	Deformities (M20-21, Q66)	Soft-tissue disorders (M60-79)	Other musculoskeletal (M)
Finnish	13.8	54.0	11.7	12.3
Turkish	10.7	46.9	5.5	28.7

Table 3. Responsiveness of the EFAS Score.

	Finnish	Turkish
Duration of follow up in days: mean (std)	206 (77)	187 (39)
DISTRIBUTION-BASED METRICS		
Effect Size	0.88	1.23

SEM (baseline)	0.323	0.403
% of patients improving > SEM	67.7	79.4
ANCHOR-BASED METRIC		
Pearson correlation between change in EFAS-PROM and patient-reported improvement	0.37	0.25

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213 **Appendices**

214 Appendix 1, EFAS Score, Finnish version

215 Appendix 2, EFAS Score, Turkish version