

EFAS Score – Validation of Danish Version 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 13 languages. Currently, the Danish version completed data acquisition and underwent further validation.

Methods: 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 was confirmed in the Danish version (Cronbach's Alpha 0.88). The Standard Error of Measurement (SEM) was 0.31 and is similar to other language versions. Between baseline and follow-up, 77.2% of patients showed an improvement on their EFAS score, with adequate responsiveness (effect size 1.05).

Conclusions: The Danish EFAS Score version was successfully validated in patients with a wide variety of foot and ankle pathologies. All score versions are freely available at www.efas.net.

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1. Introduction

The Score Committee of the European Foot and Ankle Society (EFAS) developed, validated, and published the EFAS Score in 13 languages (English, German, French, Italian, Polish, Dutch, Swedish, Finnish, Turkish, Persian, Portuguese, Spanish, Estonian) [1–5]. The EFAS score covers pain and physical function, and is internally consistent, uni-dimensional 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) [1]. Language-specific cross-cultural validation of a given score is 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, where numerous languages are spoken [1]. The most widely spoken mother tongues in Europe are German (20%), English (15%), Italian (15%), French (14%), Spanish (9%), Polish (9%), Romanian (6%), Dutch (5%), Hungarian (3%) and Portuguese, Greek, Swedish, Czech and Bulgarian (2% each)[5]. Beyond Europe, Spanish (480 million), English (379 million) and Portuguese (221 million) are among the six most common mother tongues*. A need for different language-specific (validated) scores was planned at the very inception [1]. After having initially validated the EFAS Score in seven languages (English, German, French, Italian, Polish, Dutch, Swedish), the data acquisition in 14 other languages (Arabic, Cantonese, Catalan, Danish, Estonian, Finnish, Hungarian, Norwegian, Mandarin, Persian, Portuguese, Spanish, Turkish, Welsh) started at different timepoints. The Finnish and Turkish data acquisition, analysis and publication was completed in 2020, Persian in 2021, Portuguese in 2022, and Spanish and Estonian in 2023 [2–5]. Data acquisition in Danish (5.5 million mother tongue in Europe (0.7% from European mother tongues)) was currently completed, and the results of the validation process and the score are presented.

2. Methods [1]

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].

2.1. 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].

2.2. 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 I[1].

2.3. 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].

2.4. Confirmatory analysis and responsiveness Danish version

Data collection stage of the validation was performed in Denmark. Inclusion criteria for participants were being scheduled for 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. A minimum postoperative follow-up of 3 months and mean follow-up of 6 months were 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 (Spearman 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]:

$$SEM = SD \cdot \sqrt{1 - r} \quad (1)$$

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 28.0.1, IBM, Armonk, NY, USA). The IRT modelling was performed in XCalibre 4 (Assessment Systems, Stillwater, MN, USA).

2.5. Ethics

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

3. Results

Table 1 shows the language-specific demographic data and Table 2 diagnoses for the patient samples.

3.1. Confirmatory analyses and responsiveness (Table 3)

The internal consistency was confirmed in the Danish version (Cronbach's Alpha 0.88). The Standard Error of Measurement (SEM) was 0.31 and is similar to other language versions. Between baseline

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)
101	55.9 ± 15.9	65.7	42.6/51.5/5.9

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

Osteoarthritis (M19)	Deformities (M20–21, Q66)	Soft-tissue disorders (M60–79)	Other musculoskeletal (M)	Other diagnoses
33.3	41.6	5.0	2.0	17.8

Table 3
Responsiveness of the EFAS Score Danish version.

Duration of follow up in days: mean (std)	259 (98)
DISTRIBUTION-BASED METRICS	
Effect Size	1.05
SEM (baseline)	0.31
% of patients improving > SEM	77.2
ANCHOR-BASED METRIC	
Pearson correlation between change in EFAS-PROM and patient-reported improvement	0.52

SEM, Standard Error of Measurement

and follow-up, 77.2% of patients showed an improvement on their EFAS score, with adequate responsiveness (effect size 1.05).

4. Discussion

The EFAS Score Committee initially planned clustered publication of more than one score version, and this was successfully executed with seven versions together (English, German, French, Italian, Polish, Dutch, Swedish) initially, two versions together in two following publications (Finnish/Turkish, Spanish/Estonian) [1–3,5]. From the very beginning of this project, the data acquisition times differed markedly between countries, and the COVID crisis further delayed the data acquisition in some countries [5]. To allow for publication without delay caused by

waiting for other versions, Portuguese and Persian versions were published alone [3,4]. Currently, complete data from Danish version was available, and the EFAS Score Committee decided to publish this also without delay. Following the results of the present study, it can be concluded that the EFAS Score was successfully cross culturally validated in Danish. The internal consistency was high and comparable to other language versions [1–3]. The precision (SEM) was adequate and similar to other language versions. Between baseline and follow-up, 77% of patients showed an improvement on their EFAS score, which shows that the Danish EFAS score has adequate responsiveness. Not all measurement properties of the EFAS Score have been established [1–5]. 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 [1–5]. 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 [1–5]. If the test-retest reliability becomes available, this may lead to an adjustment in the SEM and therefore MID of the EFAS Score. Fig. 1.

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 [1–3]. This implies that the IRT modelling did not result in a unidimensional EFAS Sports Score [1–5]. Based on the findings of the IRT model, a 4-item EFAS Sports Score could be considered, as this was the best-performing option [1–5]. 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 [1–5].

In conclusion, the Danish EFAS Score version was 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.net.

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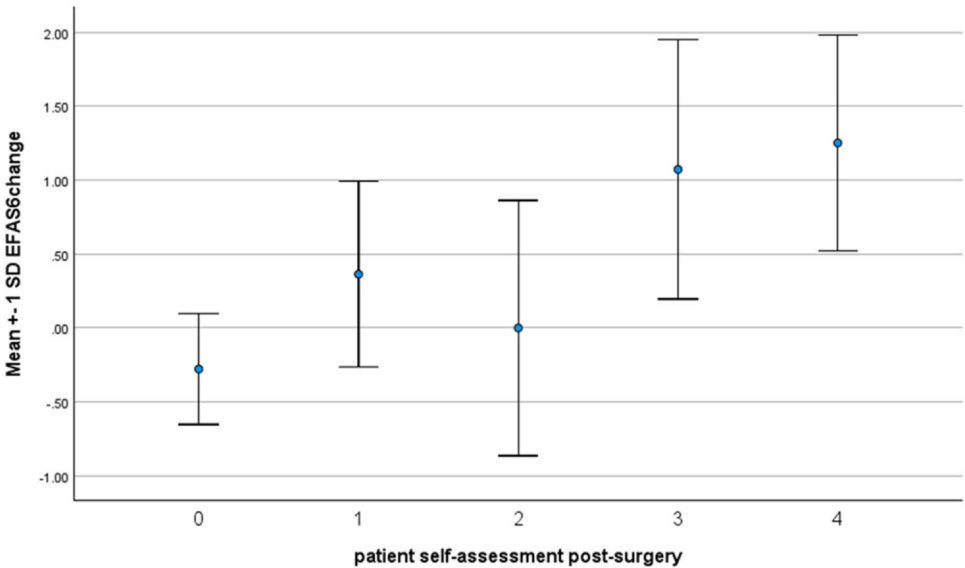


Fig. 1. Association between change in EFAS Score Danish version from pre- to post-surgery and patient self-reported improvement.

Appendix

Appendix 1, EFAS Score, Danish version.

EUROPEAN FOOT AND ANKLE SOCIETY (EFAS)

www.efas.co

EFAS Score

Nedenfor finder du 6 spørgsmål relateret til dit fod/ankel problem.

Vær venlig at besvar hvert enkelt spørgsmål ved at vælge det svar som bedst beskriver din situation inden for den sidste uge. Hvert spørgsmål kan besvares på en 5-point skala, med beskrivelser af hvert af skalaens to endepunkter.

Hvis et spørgsmål ikke er relevant for dig, afkryds da venligst I/R i boxen til venstre.

SPØRGSMÅL

Nr.	Spørgsmål	Svar
1 I/R <input type="radio"/>	Har du smerter i din fod/ankel når du holder dig i ro?	Altid 0 1 2 3 Aldrig 4
2 I/R <input type="radio"/>	Hvor langt kan du gå før du får ondt i din fod/ankel?	Umuligt 0 1 2 3 Ingen grænse 4
3 I/R <input type="radio"/>	Hvor meget har din gang (dvs. måden du går på) ændret sig på grund af dit fod og/eller ankel problem?	Ekstrem ændring i gangmønster 0 1 2 3 Ingen ændring 4
4 I/R <input type="radio"/>	Har du problemer med at gå på ujævne overflader?	Altid 0 1 2 3 Aldrig 4
5 I/R <input type="radio"/>	Har du smerter i din fod og/eller ankel når du går?	Altid 0 1 2 3 Aldrig 4
6 I/R <input type="radio"/>	Hvor ofte har du smerter i din fod og/eller ankel under fysisk aktivitet?	Altid 0 1 2 3 Aldrig 4

Du er nu færdig med spørgeskemaet. Mange tak for dit samarbejde!

SPORTS SPØRGSMÅL

Vær venlig kun at besvare disse spørgsmål hvis du jævnligt deltager i sports aktiviteter.
Hvis et bestemt spørgsmål ikke passer til din valgte sport, vær venlig at krydse af i I/R boksen.

Nr.	Spørgsmål	Svar
S1 I/R <input type="radio"/>	Kan du løbe?	Umuligt <div>01234</div> Ingen begrænsning
S2 I/R <input type="radio"/>	Kan du jogge?	Umuligt <div>01234</div> Ingen begrænsning
S3 I/R <input type="radio"/>	Har du problemer med landing efter hop?	Umuligt <div>01234</div> Ingen begrænsning
S4 I/R <input type="radio"/>	Er du i stand til at udføre din sport med din sædvanlige teknik?	Umuligt <div>01234</div> Ingen begrænsning

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