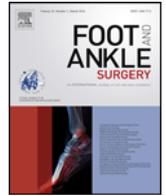


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EFAS Score – validation of Finnish and Turkish versions by the Score Committee of the European Foot and Ankle Society (EFAS)



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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.

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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 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.

2. 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].

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

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

2.2. 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].

2.3. 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].

2.4. 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].

2.5. 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 pre-operatively and at post-operative follow-up. Minimum post-operative 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]:

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

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

2.6. Ethics

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

3. Results

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

Table 1

Demographic data. *n* = sample size; F = female; L/R/B = left/right/both; N/A = not available.

	<i>n</i>	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)	Other diagnoses
Finnish	13.8	54.0	11.7	12.3	8.2
Turkish	10.7	46.9	5.5	28.7	8.2

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

3.1. 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 Fig. 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.

4. 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 to be changed during the process [1].

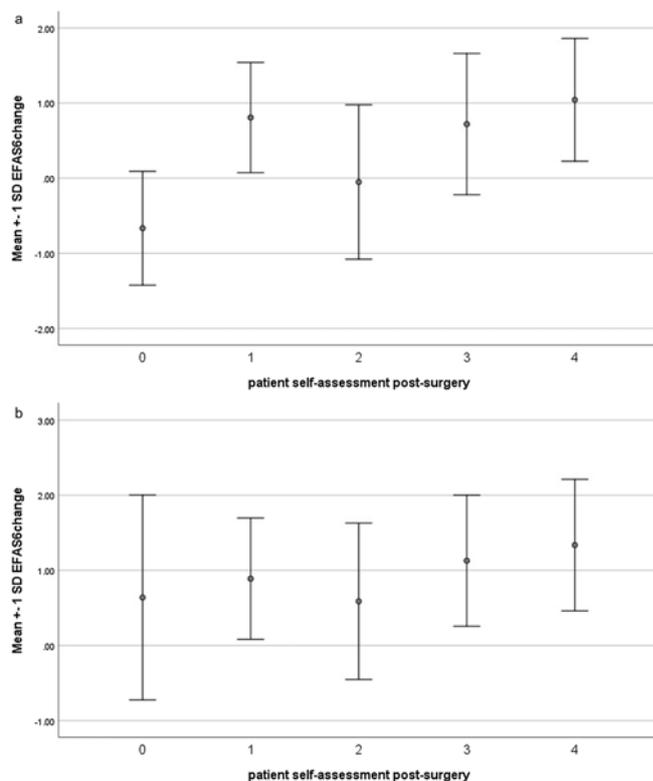


Fig. 1. (a and b) Association between change in EFAS Score from pre- to post-surgery and patient self-reported improvement (a, Finnish; b, Turkish).

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.

Acknowledgements

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Appendix

EUROOPAN JALKAKIRURGINEN YHDISTYS EUROPEAN FOOT AND ANKLE SOCIETY (EFAS)

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EFAS nilkan ja jalkaterän mittari

Alla on 6 kysymystä, jotka koskevat nilkkasi/jalkateräsi ongelmia.

Vastaa jokaiseen kysymykseen valitsemalla vaihtoehto, joka parhaiten kuvaa tilannettasi edellisen viikon aikana. Jokaiseen kysymykseen vastataan viisiportaisella asteikolla, jonka tarkemat kuvaukset on annettu kunkin kysymyksen yhteydessä.

Jos kysymys ei sovellu sinulle, merkitse rasti vasemmalla olevaan "Ei sovellu" -ruutuun.

KYSYMYKSET

Numero	Kysymys	Vastaus			
1	Onko sinulla kipua nilkassasi ja/tai jalkaterässasi levossa?	Aina	Ei koskaan		
() Ei sovellu		0	1	2	3 4
2	Kuinka pitkän matkan pystyt kävelemään ennen kuin nilkkasi ja/tai jalkateräsi kipeytyy?	Käveleminen mahdotonta	Rajattomasti		
() Ei sovellu		0	1	2	3 4
3	Kuinka paljon kävelysi (esim. kävelytyylisi) on muuttunut nilkka- ja/tai jalkateräongelmasi vuoksi?	Äärimmäisen suuri muutos	Ei muutosta		
() Ei sovellu		0	1	2	3 4
4	Onko sinulla vaikeuksia kävellä epätasaisella alustalla?	Aina	Ei koskaan		
() Ei sovellu		0	1	2	3 4
5	Onko sinulla kipua nilkassa ja/tai jalkaterässä kävellessäsi?	Aina	Ei koskaan		
() Ei sovellu		0	1	2	3 4
6	Kuinka usein sinulla on kipua nilkassasi ja/tai jalkaterässasi fyysisissä toiminnoissa?	Aina	Ei koskaan		
() Ei sovellu		0	1	2	3 4rrrr

LIIKUNTAKYSYMYKSET

Vastaa kysymyksiin ainoastaan, jos harrastat säännöllisesti jotakin liikuntalajia. Mikäli jokin kysymyksestä ei sovellu liikuntalajisi, valitse vasemmalta Ei sovellu -vaihtoehto.

Numero	Kysymys	Vastaus			
L1	Pystytkö juoksemaan?	Mahdotonta	Ei rajoituksia		
() Ei sovellu		0	1	2	3 4
L2	Pystytkö hölkkäämään?	Mahdotonta	Ei rajoituksia		
() Ei sovellu		0	1	2	3 4
L3	Onko sinulla vaikeuksia alustulossa hypyn jälkeen?	Mahdotonta	Ei rajoituksia		
() Ei sovellu		0	1	2	3 4
L4	Pystytkö suorittamaan liikuntalajiasi tavanomaisella tekniikallasi?	Mahdotonta	Ei rajoituksia		
() Ei sovellu		0	1	2	3 4

Olet nyt vastannut kaikkiin kysymyksiin. Kiitos yhteistyöstä!

EUROPEAN FOOT AND ANKLE SOCIETY (EFAS)

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AVRUPA AYAK VE AYAK BİLEĞİ CEMİYETİ EFAS Ölçütü

Aşağıda ayak ve / veya ayak bileği problemlerinize ilgili 6 soru bulacaksınız.

Lütfen son bir haftadaki durumunuzu dikkate alarak, sizi en iyi tanımlayan cevabı işaretleyerek her soruyu yanıtlayınız.

Ölçeği doldururken, ölçeğin her iki ucunda verilen ifadeler dikkate alınarak, her soruya 5 puanlık bir ölçekte cevap verilebilir.

Her hangi bir soru sizin için geçerli değilse, lütfen soldaki "U: Uygulanamaz" kutucuğunu işaretleyiniz.

SORULAR

No.	Sorular	Cevaplar			
1	İstirahat halinde iken ayak ve/veya ayak bileğinizde ağrı var mı?	Her zaman	Asla		
U		0	1	2	3 4
2	Ayak ve/veya ayak bileğinizde ağrı oluşmadan önce ne kadar yürüyebiliyorsunuz?	Hiç	Kısıtlılık olmaksızın		
U		0	1	2	3 4
3	Ayak ve/veya ayak bileğinizde yaşadığınız sorundan dolayı yürüyüşünüz ne kadar değişti?	Ciddi şekilde	Değişiklik		
U		0	1	2	3 4
4	Düzgün olmayan yüzeylerde yürürken herhangi bir zorluk yaşıyor musunuz?	Her zaman	Asla		
U		0	1	2	3 4
5	Yürürken ayak ve/veya ayak bileğinizde ağrınız var mı?	Her zaman	Asla		
U		0	1	2	3 4
6	Fiziksel aktivite esnasında ayak ve/veya ayak bileğinizde hangi sıklıkla ağrı hissediyorsunuz?	Her zaman	Asla		
U		0	1	2	3 4

SPOR İLİŞKİLİ SORULAR

Spor aktivitelerine düzenli olarak katılmanız durumunda, sadece aşağıdaki soruları yanıtlayınız. Eğer her hangi bir soru seçtiğiniz spor dalı için uygun değilse lütfen "U: Uygulanamaz" kutucuğunu işaretleyiniz.

No.	Sorular	Cevaplar			
S1	Hızlıca koşabiliyor musunuz?	Mümkün değil	Kısıtlılık olmaksızın		
U		0	1	2	3 4
S2	Yavaş koşu yapabiliyor musunuz?	Mümkün değil	Kısıtlılık olmaksızın		
U		0	1	2	3 4
S3	Zıpladıktan sonra yere temasta sorun yaşıyor musunuz?	Mümkün değil	Kısıtlılık olmaksızın		
U		0	1	2	3 4
S4	Her zamanki spor tekniğinizi eskisi gibi gerçekleştirebiliyor musunuz?	Mümkün değil	Kısıtlılık olmaksızın		
U		0	1	2	3 4

Ölçütü tamamladınız. İşbirliğiniz için teşekkür ederiz.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.fas.2020.03.004>.