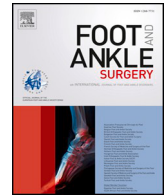


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EFAS Score—Validation of Spanish and Estonian Versions by the Score Committee of the European Foot and Ankle Society (EFAS)

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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 11 languages (Dutch, English, German, Finnish, French, Italian, Polish, Portuguese, Persian, Swedish, Turkish). From other languages under validation, the Spanish and Estonian versions completed data acquisition and underwent further validation.

Methods: The EFAS Score was developed and validated in three stages: 1) item (question) identification (completed during the initial validation study), 2) item reduction and scale exploration (completed during the initial validation study), 3) confirmatory analyses and responsiveness of the Spanish and Estonian versions (completed during the 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 Spanish and Estonian 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 Spanish and Estonian EFAS Score versions were successfully validated in orthopaedic ankle and foot surgery 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 eleven languages (Dutch, English, German, Finnish, French, Italian, Polish, Portuguese, Persian, Swedish, Turkish) [1–4]. The EFAS score covers pain and physical function, and is internally consistent, unidimensional and responsive to change in samples of orthopaedic foot and ankle surgery patients. The score contains six questions with 5 possible answers (0–4 points). Unanswered questions count 0 points. The maximum score is 24 points (best possible), and the minimum 0 points (worst possible). 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 [1–4]. This issue is especially important for Europe, where numerous languages are spoken [1]. The most widely spoken mother tongues in Europe are Russian (14.1%), German (12.9%), French (10.8%), Italian (8.7%) and English (8.4%) (Table 1).⁵ When considering the total number of speakers of European languages worldwide (mother tongue and secondary languages), English (1452 million), Spanish (548 million), French (274 million), Russian (258 million), and Portuguese (221 million) are among the ten most common (Table 1).⁶ 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 ten other languages (Arabic, Danish, Estonian, Finnish, Hungarian, Norwegian, Persian, Portuguese, Spanish, Turkish) started at different timepoints. The Finnish and Turkish data acquisition, analysis and publication was completed in 2020, Persian in 2021, and Portuguese in 2022 [2–4]. Data acquisition in Spanish and Estonian was recently completed, and the results of the validation process and the validated 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 score and one sports score [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].

Table 1
Mother tongues in Europe and total speakers worldwide.

Language	Mother tongue Europe (Million)	Mother tongue Europe (%)	Total speakers worldwide (Million)
Russian	106.0	14.1	258.2
German	97.0	12.9	185.0
French	81.0	10.8	274.1
Italian	65.0	8.7	67.9
English	63.0	8.4	1452.0
Spanish	47.0	6.3	548.3
Polish	38.5	5.1	40.6
Ukrainian	32.6	4.3	45.0
Romanian	24.0	3.2	24.0
Dutch	22.0	2.9	30.0
Greek	13.5	1.8	13.5
Hungarian	13.0	1.7	13.0
Turkish	12.0	1.6	88.1
Swedish	11.1	1.5	11.1
Czech	10.6	1.4	10.6
Portuguese	10.0	1.3	257.7
Serbian	9.0	1.2	9.0
Bulgarian	7.8	1.0	7.8
Croatian	5.6	0.7	5.6
Danish	5.5	0.7	5.5
Finnish	5.4	0.7	5.4
Albanian	5.4	0.7	5.4
Norwegian	5.2	0.7	5.2
Slovak	5.2	0.7	5.2
Arabic	5.0	0.7	274.0
Lithuanian	3.0	0.4	3.0
Bosnian	2.5	0.3	2.5
Slovenian	2.1	0.3	2.1
Estonian	1.2	0.2	1.2
Chinese	0.3	0.0	1376.6
Persian	0.3	0.0	110
Hindi	0.0	0.0	602.2
Japanese	0.0	0.0	125.0
Korean	0.0	0.0	82.0

Languages with validated EFAS Score in bold.

⁵ Wikipedia, January 1, 2023

⁶ Wikipedia, January 1, 2023

2.5. Confirmatory analysis and responsiveness Spanish and Estonian versions

Data collection stage of the validation was performed in Spain and Estonia. The language specific score versions were created by the standardized process of forward and backward translation performed by bilingual translators. 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).

2.6. Ethics

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

3. Results

Table 2 shows the language-specific demographic data and Table 3 diagnoses for the patient samples.

3.1. Confirmatory analyses and responsiveness (Table 4)

The internal consistency of the scale was excellent in both language versions. Cronbach's Alpha was 0.81 in Spanish and 0.87 in Estonian. Responsiveness of the EFAS Score is shown in Table 4 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, 91% in Spanish and 87% in Estonian. The change in EFAS Scores between baseline and follow-up was significantly correlated with the patient-reported change in health status.

Table 2
Demographic data. N = sample size; F = Female; L/R/B = Left/Right/Bilateral.

	n	Age (mean \pm SD)	Sex (% F)	Affected side (% L/R/B)
Spanish	100	59.3 \pm 11.2	84.0	41.0/59.0/0.0
Estonian	101	52.7 \pm 13.9	81.2	44.6/55.4/0.0

Table 3
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
Spanish	2.0	91.0	7.0	0.0	0.0
Estonian	15.7	68.7	4.9	4.9	4.0

Table 4
Responsiveness of the EFAS Score.

	Spanish	Estonian
Duration of follow up in days: mean (std)	213 (19)	213 (19)
DISTRIBUTION-BASED METRICS		
Effect Size	1.40	1.10
SEM (baseline)	0.37	0.37
% of patients improving > SEM	82.0	68.0
ANCHOR-BASED METRIC		
Pearson correlation between change in EFAS Score and patient-reported improvement	0.375	0.430

std, standard deviation; SEM, standard error of measurement

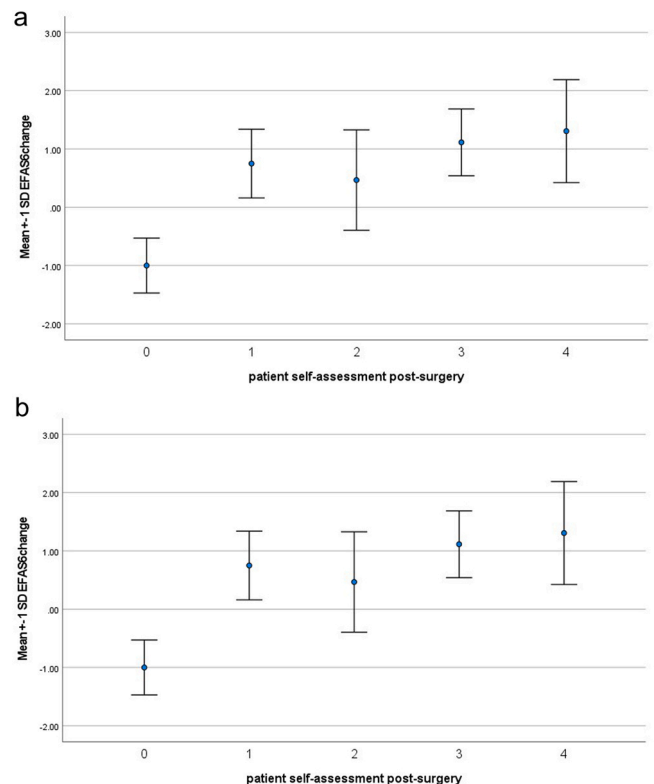


Fig. 1. a and b. Association between change in EFAS Score from pre- to post-surgery and patient self-reported improvement (a, Spanish; b, Estonian).

4. Discussion

The EFAS Score Committee planned ab initio clustered publication of more than one score version, and this was successfully executed with seven versions initially, and two versions (Finnish and

Turkish) in a second publication [1,2]. Then, Persian and Portuguese EFAS Score versions were published alone sequentially based on the different times of data acquisition completion [3,4]. From the very beginning of this project, it was realised and acknowledged that the data acquisition times would have differed markedly between countries, and the COVID crisis further delayed the data acquisition in some countries. There are no more or less important languages. However, the number of mother tongue speakers differ, and the validation of the Spanish score version with 47.0 million mother tongue speakers in Europe inevitably result in more score users than, for example, the Estonian score version with 1.16 million mother tongue speakers.⁷ When examining the worldwide distribution of mother tongue speakers, this difference increases (Spanish, 480 million; Estonian, 1.16 million).⁸ Finally, when considering the total number of speakers worldwide, Spanish is the fifth common spoken language with 548.3 million speakers (mother tongue and secondary language) (Estonian 1.16 million).⁹ In this context, the validation of the Spanish version was given high priority from the inception [3]. Currently, complete data from Spanish and Estonian language became available. Following the results of the present study, it can be concluded that the EFAS Score was successfully cross culturally validated in Spanish and Estonian. The internal consistency was high, and comparable to other language versions [1–4]. The precision (SEM) was adequate and similar to other language versions. Between baseline and follow-up, 91/87% (Spanish/Estonian) of patients showed an improvement on their EFAS score, which shows that the Spanish and Estonian EFAS Scores have adequate responsiveness. Not all measurement properties of the EFAS Score have been established [1–4]. 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 studies [1–4]. 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 [1–4]. 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 [1–3]. This implies that the IRT modelling did not result in a unidimensional EFAS Sports Score [1–3]. Based on the findings of the IRT model, a 4-item EFAS Sports Score could be considered, as this was the best-performing option [1–3]. 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 [1–3].

In conclusion, the Spanish and Estonian 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.net.

Acknowledgements

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⁷ Wikipedia, January 1, 2023

⁸ Wikipedia, January 1, 2023

⁹ Wikipedia, January 1, 2023

Appendix 1. EFAS Score, Spanish version

EUROPEAN FOOT AND ANKLE SOCIETY (EFAS)

www.efas.net

Puntuación EFAS

A continuación encontrará 6 preguntas relacionadas con su problema de pie y/o tobillo.

Por favor, conteste cada pregunta escogiendo la respuesta que describe mejor su situación en la última semana. Cada pregunta se responde en una escala de 5 puntos, proporcionándose una descripción en los extremos de la escala.

Si una pregunta no es aplicable a usted, por favor indíquelo marcando la casilla N/A a la izquierda.

PREGUNTAS

No.	Pregunta	Respuesta
1 N/A <input type="radio"/>	¿Le duele el pie y/o el tobillo cuando está en reposo?	Siempre 0 1 2 3 Nunca 4
2 N/A <input type="radio"/>	¿Cuanto puede caminar antes de que le duela el pie y/o el tobillo?	Imposible 0 1 2 3 Sin limitación 4
3 N/A <input type="radio"/>	¿Cuanto ha cambiado su marcha (es decir, su manera de caminar) debido a su problema del pie y/o tobillo?	Un cambio extremo 0 1 2 3 No ha cambiado 4
4 N/A <input type="radio"/>	¿Tiene usted dificultad para caminar en superficies irregulares?	Siempre 0 1 2 3 Nunca 4
5 N/A <input type="radio"/>	¿Le duele el pie y/o el tobillo cuando está caminando?	Siempre 0 1 2 3 Nunca 4
6 N/A <input type="radio"/>	¿Con qué frecuencia le duele el pie y/o tobillo durante la actividad física?	Siempre 0 1 2 3 Nunca 4

Usted ha terminado esta encuesta. Muchas gracias por su colaboración.

PREGUNTAS SOBRE DEPORTE

Por favor, sólo responda estas preguntas si usted practica regularmente actividades deportivas. Si una pregunta específica no se aplica a su deporte de elección, por favor marque la casilla N/A.

No.	Pregunta	Respuesta
S1 N/A <input type="radio"/>	¿Puede usted correr?	Imposible 0 1 2 3 Sin limitación 4
S2 N/A <input type="radio"/>	¿Puede usted trotar?	Imposible 0 1 2 3 Sin limitación 4
S3 N/A <input type="radio"/>	¿Tiene usted problemas al caer después de saltar?	Imposible 0 1 2 3 Sin limitación 4
S4 N/A <input type="radio"/>	¿Es usted capaz de practicar sus deportes con su técnica habitual?	Imposible 0 1 2 3 Sin limitación 4

Usted ha terminado esta encuesta. Muchas gracias por su colaboración.

Appendix 2. EFAS Score, Estonian version

EUROPEAN FOOT AND ANKLE SOCIETY (EFAS)

www.efas.co

EFASe skoor

Altpoolt leiate 6 küsimust Teie labajala- ja/või hüppeliigeseprobleemi kohta.

Palun valige igale küsimusele üks vastus, mis kirjeldab Teie seisundit viimase nädala jooksul kõige paremini. Igale küsimusele saab vastata 5-punktilisel skaalal, lähtudes kirjeldustest skaala kummaski otsas.

Kui küsimus Teie kohta ei käi, palun märkige linnuke “N/A” kasti küsimusest vasakul.

KÜSIMUSED

Nr	Küsimus	Vastus
1 N/A <input type="radio"/>	Kas Teil on labajalas ja/või hüppeliigeses rahuolekus valu?	Alati 0 1 2 3 Mitte kunagi 4
2 N/A <input type="radio"/>	Kui kaugelt saate kõndida enne valu tekkimist labajalga ja/või hüppeliigesesse?	Võimatu 0 1 2 3 Piiranguta 4
3 N/A <input type="radio"/>	Kui palju on Teie kõnnak (s.o viis, kuidas kõnnite) Teie labajala- ja/või hüppeliigeseprobleemi tõttu muutunud?	Äärmuslik kõnnaku muutus 0 1 2 3 Muutuseta 4
4 N/A <input type="radio"/>	Kas ebatasasel pinnal kõndimine on Teie jaoks raske?	Alati 0 1 2 3 Mitte kunagi 4
5 N/A <input type="radio"/>	Kas Teil on kõndides valu labajalas ja/või hüppeliigeses?	Alati 0 1 2 3 Mitte kunagi 4
6 N/A <input type="radio"/>	Kui sageli esineb Teil kehalisel koormusel valu labajalas ja/või hüppeliigeses?	Alati 0 1 2 3 Mitte kunagi 4

Olete nüüd selle küsimustiku täitmise lõpetanud. Täname Teid väga koostöö eest!

SPORDIKÜSIMUSED

Palun vastake nendele küsimustele ainult siis, kui Te tegelete regulaarselt spordiga. Kui mõni küsimus ei käi Teie valitud spordiala kohta, tehke linnuke kasti “N/A”.

Nr	Küsimus	Vastus
S1 N/A <input type="radio"/>	Kas Te suudate joosta?	Võimatu 0 1 2 3 Piiranguta 4
S2 N/A <input type="radio"/>	Kas Te suudate sõrkida?	Võimatu 0 1 2 3 Piiranguta 4
S3 N/A <input type="radio"/>	Kas Teil on raskusi maandumisel pärast hüppamist?	Võimatu 0 1 2 3 Piiranguta 4
S4 N/A <input type="radio"/>	Kas Te suudate oma spordialaga tegeleda, kasutades enda jaoks tavapärasest tehnikat?	Võimatu 0 1 2 3 Piiranguta 4

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