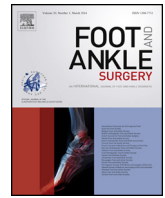




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EFAS Score –Validation of Persian Version by the Score Committee of the European Foot and Ankle Society (EFAS)



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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 nine European languages (English, German, French, Italian, Polish, Dutch, Swedish, Finnish, Turkish). From other languages under validation, the Persian version finished data acquisition and underwent further validation.

Methods: The Persian version of 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 Persian version (completed during initial validation study in nine 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 was confirmed in the Persian version (Cronbach's Alpha 0.82). The Standard Error of Measurement (SEM) was 0.38 and is similar to other language versions. Between baseline and follow-up, 97% of patients showed an improvement on their EFAS score, with excellent responsiveness (effect size 1.93).

Conclusions: The Persian 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.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 nine European languages (English, German, French, Italian, Polish, Dutch, Swedish, Finnish, Turkish) [1,2]. 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 [1,2]. The score contains six questions. 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 [1,2]. This issue is especially important for Europe, where numerous languages are spoken [1]. The most spoken mother tongues in Europe are German (18%), English (13%), Italian (13%), French (12%), Spanish (8%), Polish (8%), Romanian (5%) and Dutch (4%).¹⁰ In addition to all these native European languages, other languages, such as Persian and Arabic, are spoken as mother tongue by a growing number of immigrants.¹⁰ Therefore, 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 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 [2]. Data acquisition in Persian was recently completed, 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 Persian version

Data collection stage of the validation was performed in Iran. 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 (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 25, IBM, Armonk, NY, USA). The IRT modelling was performed in XCalibre 4 (Assessment Systems, Stillwater, MN, USA).

¹⁰ Wikipedia, March 16, 2021.

Table 1

Persian 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) |
|-----|-----------------|-----------|-------------------------|
| 100 | 41.28 ± 15.9 | 48.0 | 47.0/53.0/0 |

Table 2

Prevalence of primary diagnoses, in %, based on ICD-10 codes Persian data.

| Osteoarthritis (M19) | Deformities (M20–21, Q66) | Soft-tissue disorders (M60–79) | Other musculoskeletal (M) | Other diagnoses |
|----------------------|---------------------------|--------------------------------|---------------------------|-----------------|
| 20.0 | 26.0 | 10.0 | 30.0 | 14.0 |

Table 3

Responsiveness of the EFAS Score Persian version.

| | |
|--|-----------|
| Duration of follow up in days: mean (std) | 246 (122) |
| Distribution-based metrics | |
| Effect size | 1.93 |
| SEM (baseline) | 0.38 |
| % of patients improving > SEM | 97 |
| Anchor-based metric | |
| Pearson correlation between change in EFAS-PROM and patient-reported improvement | −0.04 |

2.6. 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

The internal consistency of the scale was excellent in both language versions. Cronbach’s Alpha was 0.82. Responsiveness of the EFAS Score is shown in Table 3 and Fig. 1. Effect sizes (ES) was 1.93. 97% of patients showed a minimally important difference following surgery. No patient answered 1 to the anchor question

(indicating minimal improvement), and only 1 patient answered 2 (moderate improvement). All other patients answered 3 or 4 (high or maximum improvement), with considerable variation in their EFAS scores. The change in EFAS Scores between baseline and follow-up was not significantly correlated with the patient-reported change in health status.

4. Discussion

The EFAS Score Committee initially planned clustered publication of more than one score version, and this was successfully executed with seven versions initially and two versions in a second publication [1,2]. 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. 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 38 million mother tongue speakers in Europe will inevitably result in more score users than, for example, the Estonian score version with 1.1 million mother tongue speakers.¹⁰ When examining the worldwide distribution of mother tongue speakers, this difference increases (Spanish, 480 million; Portuguese, 221 million; Estonian, 1.1 million).¹⁰ In this context, the validation in other than native European languages is a logical step to spread the score to, for example, Persian (70 million mother tongue speakers) or Arabic (310 million mother tongue speakers).¹⁰ Currently, complete data from Persian language were available, and the Committee decided to publish this without delay without waiting for completed data from other languages. Following the results of the present study, it can be concluded that the EFAS Score was successfully cross culturally validated in Persian. The internal consistency was high and comparable to other language versions [1,2]. The precision (SEM) was adequate and similar to other language versions. Between baseline and follow-up, 97% of patients showed an improvement on their EFAS score, which shows that the Persian EFAS score has excellent responsiveness. This is also reflected in the effect size which is the highest of all language versions so far. Ironically, because (almost) all patients showed strong improvement, the metrics for criterion-based responsiveness were poor – there is no significant association between the change in score from baseline to follow-up (Table 3), and the perceived improvement by patients on the one-item question. However, this probably results from a ceiling effect, since all patients improved markedly after their intervention, and it became impossible to distinguish

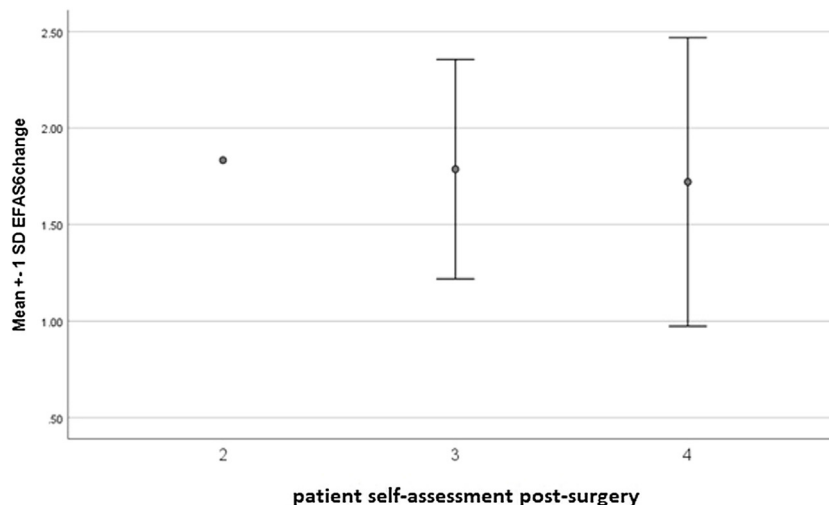


Fig. 1. Association between change in EFAS Score Persian version from pre- to post-surgery and patient self-reported improvement.

between different levels of improvement. Not all measurement properties of the EFAS Score have been established [1,2]. 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 [1,2]. 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 [1,2]. 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 [1,2]. This implies that the IRT modelling did not result in a unidimensional EFAS Sports Score [1,2]. Based on the findings of the IRT model, a 4-item EFAS Sports Score could be

considered, as this was the best-performing option [1,2]. 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 [1,2].

In conclusion, the Persian EFAS Score version was successfully validated in the orthopaedic ankle and foot surgery patients, including a wide variety of foot and ankle pathologies. The minimum score is 0 points and the maximum score 24 points. Missing answers count 0 points. All score versions are freely available at www.efas.co.

Conflict of interest

The work was supported and funded by the European Foot and Ankle Society.

Appendix A.

EUROPEAN FOOT AND ANKLE SOCIETY (EFAS)

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پرسشنامه EFAS

در زیر از شما 6 سوال در مورد مشکلات پا و/یا مچ پایتان پرسیده خواهد شد. لطفاً با توجه به وضعیت تان در هفته گذشته، مناسب ترین پاسخ را انتخاب نمایید. برای پاسخ به هر سوال شما میتوانی یک عدد را از صفر تا چهار، با توجه به توضیحات ارائه شده در بالای دو عدد انتخاب نمایی. اگر از بین سوالات، سوالی به وضعیت شما مرتبط نمی باشد، لطفاً گزینه "غیرمرتبط" را در ستون سمت راست علامت بزنید.

سوالات

| شماره | سوال | پاسخ |
|-------|--|---------------------------|
| 1 | آیا در حالت استراحت در پا و/یا مچ پایتان درد دارید؟ | همیشه 0 1 2 3 4 |
| 2 | چقدر میتوانی پیاده روی کنید قبل از اینکه پا و/یا مچ پایتان درد بگیرد؟ | غیرممکن 0 1 2 3 4 |
| 3 | چقدر شیوه راه رفتن شما بخاطر مشکلات پا و/یا مچ پایتان تغییر کرده است؟ | تغییرات شدید 0 1 2 3 4 |
| 4 | آیا پیاده روی روی سطوح ناهموار برای شما مشکل است؟ | همیشه 0 1 2 3 4 |
| 5 | آیا در حین پیاده روی در پا و/یا مچ پایتان درد دارید؟ | همیشه 0 1 2 3 4 |
| 6 | چند مدت یکبار در حین انجام فعالیت های بدنی در پا و/یا مچ پایتان درد دارید؟ | همیشه 0 1 2 3 4 |

سوالات ورزشی

لطفاً در صورتیکه بطور منظم در فعالیت های ورزشی شرکت میکنید، به سوالات زیر پاسخ دهید. اگر سوال خاصی به ورزش مورد نظر شما مرتبط نیست، گزینه "غیرمرتبط" را علامت بزنید.

| شماره | سوال | پاسخ |
|-------|---|----------------------|
| 1 | آیا میتوانی بدوید؟ | غیرممکن 0 1 2 3 4 |
| 2 | آیا میتوانی آرام بدوید؟ | غیرممکن 0 1 2 3 4 |
| 3 | آیا بعد از پریدن، در هنگام فرود آمدن درد دارید؟ | غیرممکن 0 1 2 3 4 |
| 4 | آیا قادر به اجرای ورزش با شیوه همیشگی خود، هستید؟ | غیرممکن 0 1 2 3 4 |

شما اکنون این پرسشنامه را به پایان رسانده اید. از همکاری شما بسیار سپاسگزاریم!

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