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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)

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ABSTRACT

Background: A scientifically sound validated foot and ankle specific score validated ab initio for different languages is missing. The aim of a project of the European Foot and Ankle Society (EFAS) was to develop, validate, and publish a new score(the EFAS-Score) for different European languages.
Methods: The EFAS Score was developed and validated in three stages: (1) item (question) identification, (2) item reduction and scale exploration, (3) confirmatory analyses and responsiveness. The following score specifications were chosen: scale/subscale (Likert 0–4), questionnaire based, outcome measure, patient related outcome measurement. For stage 3, data were collected pre-operatively and 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 analyses from classical test theory and item response theory.

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Results: Stage 1 resulted in 31 general and 7 sports related questions. In stage 2, a 6-item general EFAS Score was constructed using English, German, French and Swedish language data. In stage 3, internal consistency of the scale was confirmed in seven languages: the original four languages, plus Dutch, Italian and Polish (Cronbach's Alpha >0.86 in all language versions). Responsiveness was good, with moderate to large effect sizes in all languages, and significant positive association between the EFAS Score and patient-reported improvement.
No sound EFAS Sports Score could be constructed.
Conclusions: The multi-language EFAS Score was 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.

1. Introduction

A scientifically sound validated foot and ankle specific outcome measure for different European languages is still missing. Indeed, language-specific cross cultural validation in other languages than English is largly absent [1,2]. Some outcome measures were validated for specific pathologies such as hallux valgus, ankle arthritis or flatfoot [3–6]. The European Foot and Ankle Society (EFAS) established in 2013 a Score Committee in order to develop, validate, and publish a new score, the "EFASScore" for different European languages which is not specific for single pathologies. The principal aim was to develop and validate the EFAS Score simultaneously for different European languages.

2. Methods

Previous scores were analysed and different types of scores were taken into consideration [1–31]. 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.

2.1. Type of score

We aimed to develop a questionnaire-based PROM, with one or more subscales depending on the results of the development process. After discussing different types of rating scales, a 5-point Likert scale (0–4) was chosen.

2.2. Questions — item identification

In the first stage, potentially relevant items from existing questionnaires were identified [1,2,4,6–30]. These items were combined into one pool of items that were taken forward into stage 2 of the development process. 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. Additionally, to ensure comparability of outcomes, it was decided to use 5-point Likert rating scales for all items in the patient data collections for stages 2 and 3 of the process, regardless of the original scoring method of the questionnaire from which the item had been mutated. In total, 31 general items and 7 sports-specific items were taken forward into the second phase of the project.

2.3. Item reduction and scale exploration

Through a process of forward and backward translation by bilingual translators, the original English pool of 38 items was translated into German, French and Swedish. These four language versions were then used for the stage 2 data collection. Participants were recruited from orthopaedic foot and ankle surgery departments. Inclusion criteria for participants were clinical and imaging indications for foot and ankle surgery and age ≥18 years. No exclusion criteria were used other than an inability to complete a written questionnaire. Data collection was performed in France, Germany, Sweden and Ireland. 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.

Following data collection, the following analytic steps were taken to reduce the item pool into one general EFAS Score and one EFAS Sports Score. All steps were performed separately for each language version and separately for the general and sports-specific items unless stated otherwise.

1. Items with a ceiling effect (i.e. already at the highest possible level for a large proportion of patients), low perceived relevance and a high proportion of missing values were noted and shortlisted for exclusion in subsequent steps.
2. Using all items, a principal component analysis (PCA) was performed. A PCA identifies clusters (principal components) of closely related items through a matrix of inter-item correlations. Principal components were retained into the next step if the eigenvalue >1 and if it was located left of the elbow of the screen plot. Then, items were excluded from further analysis if they showed no clear association with any of the retained principal components, or if they showed a high association (item load >0.40) on more than one principal component. Cronbach's Alpha was computed for each of the identified principal components to explore their reliability. Any item showing a detrimental effect on scale reliability (i.e., Cronbach's Alpha would improve if the item was removed) was then excluded from further analysis. Finally, any item showing an item-scale correlation of r <0.60 was excluded. At the end of this step, the remaining items in their respective principal components would provide optimal scale reliability according to classic test theory.
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. These analyses were performed combining available data from all language versions. Items were first excluded if they showed reverse thresholds. It is expected that for any valid item, the probability of providing a certain response is closely linked to the underlying level of the trait that is measured. The order in which each response is the most likely response is a logical sequence. Two examples are provided to illustrate this in Fig. 1a–b . Fig. 1a shows an item with no reverse thresholds: for each of the five responses to the item, a level of the underlying trait (on the x-axis) can be identified at which that response is the most likely response (as signified by the probability level on the y-axis) and the order in which the five responses are most likely is logically progressing from response 1 to response 5. In contrast, Fig. 1b shows an item for which only the two most extreme responses are ever the

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