

Transcultural adaptation and validation of the Spanish-French versions of the Self-reported Foot and Ankle Score (SEFAS)

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ABSTRACT

Objective: The study aim was to cross-culturally adapt the Self-reported Foot and Ankle Score (SEFAS) into Spanish and French-language versions, to validate them and to evaluate their psychometric properties.

Methods: The cross-cultural translation from the original SEFAS into French and Spanish was performed in accordance with the guidelines of the ISPOR. The participants were recruited from some private health-care institutions in France and Spain, from June to August 2019. The following inclusion criteria were applied: aged at least 18 years, with foot and/or ankle deformity, had a history of subtalar and/or ankle and/or talonavicular or hindfoot pain, did not make daily use of walking aids, and were able to achieve the normal range of motions in the ankle, subtalar and midtarsal joints. All patients gave signed informed consent and completed the SF-36 and SEFAS questionnaires in the Spanish or French version.

Results: The analysis was based on 319 participants. Internal consistency was excellent (Cronbach's alpha values of 0.94 for the Spanish version and 0.88 for the French version). No floor/ceiling effect was observed in any item, in either version.

Conclusion: The Spanish and French versions of SEFAS are valid, reliable instruments for evaluating foot and ankle pain and function.

IMPLICATIONS FOR REHABILITATION

- Self-report questionnaires specific to patients with rheumatoid arthritis are needed to assess the degree of pain, disability, and disability caused by foot problems.
- The Spanish and French versions of SEFAS show the necessary psychometric characteristics.

Each version provides a valid, reliable tool ensuring the correct evaluation of pain, function and limitation of function in the foot and/or ankle in the target population.

KEYWORDS

Ankle; foot; reliability; self-reported; validity

Introduction

The foot and ankle play an essential role in many activities of daily living and in sport [1]. Injuries to the foot and/or ankle and non-traumatic conditions such as metatarsalgia, hallux valgus, abnormal position of the toes, improper footwear and ankle sprain can produce sub-optimum biomechanics, limit physical activity, impair body function and structure and restrict participation in many activities [2]. In short, these problems may significantly prejudice the quality of life (QoL) [3]. Generic questionnaires such as the Short-Form Health Survey (SF-36) [4] and EuroQol 5-D [5] are useful for evaluating the patient's general health, but for the foot and/or ankle in particular, valid and reliable self-report questionnaires specific for this purpose are needed to assess the degree of pain, impairment and disability produced and the overall QoL. Such an instrument may be used to determine the effectiveness or efficiency of a treatment (surgical or otherwise) for a specific pathology, or as part of a clinical trial conducted to assess health care outcomes [6].

A recent systematic review has been made of the psychometric properties of specific foot and ankle questionnaires for persons with rheumatoid arthritis [7]. This review concluded that the Self-reported Foot and Ankle Score (SEFAS) best meets the criteria proposed by Terwee [8] and COSMIN [9]. However, to date the only validated translation of SEFAS is a German-language version [10].

SEFAS is a foot and ankle-specific questionnaire based on the New Zealand Total Ankle Replacement questionnaire [11], adapted by Cöster et al. [12]. This questionnaire contains 12 items with 5 response options, and addresses three constructs: pain, function and limitation of function, which are not reported separately in subscales.

The aim of the present study is to cross-culturally adapt and validate SEFAS into Spanish and French and to evaluate the resulting psychometric properties.

Material and methods

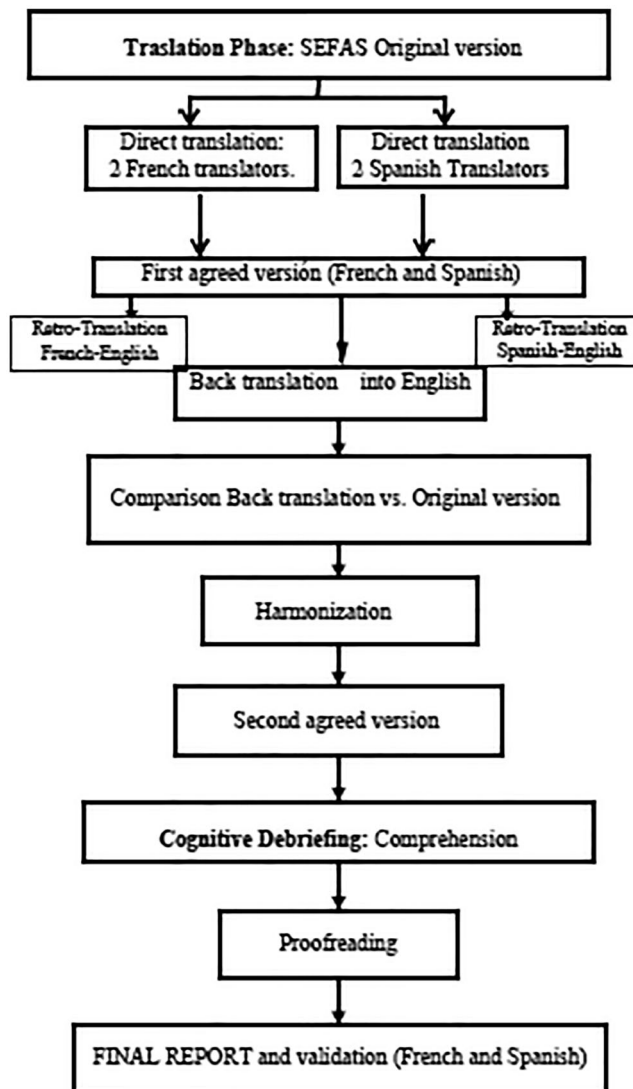
Ethical approval

This study was approved by the Ethical Committee of the University of Malaga (CEUMA 88-2019-H) and was performed in

accordance with the Declaration of Helsinki and all applicable legislation and regulations on ethical standards in human experimentation. Signed informed consent was obtained from all participants.

Translation and cross-cultural adaptation

Permission to translate SEFAS was obtained from the developer (Coster MC). The cross-cultural translation into French and Spanish was performed according to the guidelines of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the Patient-Reported Outcomes Measurement Information System (PROMIS) [13]. Forward translation was performed by two bilingual French translators, working independently, and by two bilingual Spanish translators, working independently. Final, reconciled versions in Spanish and in French were obtained after a consensus meeting of the four translators. These two consensus versions were then back-translated into English by two bilingual English translators, blinded to the original version. The project leader reviewed these two back-translations against the source to check for discrepancies. A consensus committee, comprised of the translators and a group of French and Spanish podiatrists, was then established to check that the translations were comprehensive and cross-culturally equivalent to the source, after which two final versions (in French and Spanish) were developed for field testing.



Cognitive debriefing

The final versions were pre-tested on five French and five Spanish patients (face to face interviews), who were Spanish or French residents and native speakers, met the inclusion criteria and had a low educational background without being illiterate. They were asked to confirm that they understood the questionnaire items and to identify any language problems encountered (to comment on any wording that was difficult to understand or to suggest alternative wording/phrasing for any wording that was difficult to understand).

Pilot testing review/review of cognitive debriefing results

To improve the performance of the translated questionnaire (Spanish or French), the pilot testing results were reviewed by the leader. At this stage, any item caused comprehensibility difficulties for the participants, and any modifications were incorporated to the final translated version (Spanish or French).

Proof-reading

In the final step, the project leader proofread the two documents to ensure there were no errors in either of the translated versions. Furthermore, the Flesh Reading Ease test and the Flesh Kincaid Grade Level were calculated for readability [14]. A flow diagram illustrating the procedure is shown in Figure 1.

Validation

The French participants were recruited at a single private health-care institution in Paris from June to August 2019. The Spanish participants were recruited at private podiatry clinics in Malaga and Granada (Spain) from June to September 2019. A total of 319 participants met the following inclusion criteria: aged at least 18 years, first language was French or Spanish, had a level educational background without being illiterate, with foot and/or ankle deformity [15], had a history of subtalar and/or ankle and/or talonavicular or hindfoot pain, did not make daily use of walking aids, and were able to achieve the normal range of motions in the ankle, subtalar and midtarsal joints [16]. Patients were excluded if they had undergone surgery to the foot and/or ankle or had received intra-articular infiltrations in the foot and/or ankle in the last three months.

Data collection

Prior to their inclusion, all patients were informed of the nature of the study and gave signed informed consent. All patients, in Spain and France, provided the necessary demographic data (age, gender, height and weight) *via* the French or Spanish Short-Form 36 Health Survey (SF-36) and the French or Spanish SEFAS.

The SF-36 questionnaire is a generic measure of health status. It includes eight domains: Physical Functioning (PF), Physical Role (PR), Bodily Pain (BP), General Health (GH), Vitality (Vt), Social Role (SR), Emotional Role (ER) and Mental Health (MH). The minimum score for each dimension is 0 points and the maximum, 100 points, on a scale on which the higher the score, the better the health status. From these results, two summary scales are calculated, one for physical health and one for mental health. The SF-36 has been translated into Spanish [4] and French [17], both of which have been validated (Licence No. QM052038).

The SEFAS questionnaire contains 12 items with 5 response options. The questionnaire constructs are not reported separately in subscales. Each of the 12 multiple-choice questions is scored from 0 to 4, such that a total sum of 0 points represents the most severe disability and one of 48 represents normal functioning. When the SEFAS questionnaire was not completed in full, the following approach was adopted: (1) when two or more questions were unanswered, the questionnaire was disregarded; (2) when one question was unanswered, the mean score for the remaining eleven questions was used; (3) when two answers were given for a single question, the less favourable outcome was recorded; (4) when a mark was made between two answers, the less favourable option was recorded [12].

All respondents described the items of the questionnaire as clear and understandable. Consequently, it was deemed that no items required modification due to misinterpretation or lack of understanding.

Statistical analysis

All statistical analyses were performed with IBM SPSS v.23.0. Descriptive statistics of the variables were obtained, and the normality of their distribution was confirmed by the Kolmogorov-Smirnov test. Bivariate analysis was performed using the chi-square test, Wilcoxon's test, and Pearson's or Spearman's correlations, according to the normality of the distribution. All calculations were performed assuming a 95% confidence interval (95%CI).

For the clinimetric validation, interobserver reliability and test-retest reliability were evaluated using Pearson's correlation coefficients and intraclass correlation coefficients (ICC). An ICC value >0.7 was classed as "excellent," $0.60-0.74$ as "good," $0.40-0.59$ as "fair" and <0.40 as "poor" [18]. Internal consistency was also assessed by Cronbach's alpha; in this case, values of 0.7, 0.8 and 0.9 were considered to represent a fair, good and excellent degree of internal consistency, respectively.

For construct validity, confirmatory factorial analysis was carried out. Convergent validity was assessed to test the relationship between the Spanish/French version of the SEFAS and the SF-36, which was measured by reference to the corresponding Pearson's correlations. Coefficients <0.30 , <0.60 and ≥ 0.60 were considered to indicate poor, moderate and strong correlations, respectively [18]. Ceiling/floor effects were analysed using descriptive statistics and considered to be present if $>15\%$ of respondents recorded the lowest or highest possible score [8].

Results

364 patients were initially recruited to the study. After reviewing the completed questionnaires, 319 were included in the final analysis. Of these participants, 30.7% were male and 69.3% female. The average age was 61.06 (19–88) years and the mean body mass index (BMI) was 26.32 kg/cm². There were 159 Spanish participants, with a mean age of 57.56 years, and 160 French participants, with a mean age of 64.56 years (Table 1).

	Spain (n¼159)	France (n¼160)
Gender	Women n¼97	Women n¼124
	Men n¼62	Men n¼36
Age	57.56 ± 13.36	64.56 ± 13.81
BIM	26.71 ± 4.06	26.01 ± 5.98

Cross-cultural adaptation

The SEFAS questionnaire was translated into Spanish and French and cross-culturally adapted to each language. The pilot testing phase revealed no discrepancies in meaning and the participants understood each of the questionnaire items without requiring any assistance with interpretation. Application of the Flesch Reading Ease test produced an overall mean result of 52.4, and a Flesch- Kincaid Grade Level of 7.7.

Table 2. Inter-item correlation matrix.

	Sefas_1	Sefas_2	Sefas_3	Sefas_5	Sefas_6	Sefas_7	Sefas_8	Sefas_9	Sefas_10	Sefas_11	Sefas_12
Spain											
Sefas_1	1.000										
Sefas_2	.391	1.000									
Sefas_3	.632	.569	1.000								
Sefas_5	.729	.488	.706	1.000							
Sefas_6	.733	.511	.667	.709	1.000						
Sefas_7	.474	.505	.685	.626	.509	1.000					
Sefas_8	.551	.432	.519	.706	.568	.573	1.000				
Sefas_9	.717	.583	.712	.864	.729	.652	.736	1.000			
Sefas_10	.580	.463	.636	.588	.558	.546	.616	.655	1.000		
Sefas_11	.612	.571	.593	.696	.624	.550	.666	.728	.642	1.000	
Sefas_12	.676	.531	.603	.723	.689	.568	.734	.753	.657	.730	1.000
France											
Sefas_1	1.000										
Sefas_2	.295	1.000									
Sefas_3	.408	.187	1.000								
Sefas_5	.585	.405	.462	1.000							
Sefas_6	.475	.369	.392	.485	1.000						
Sefas_7	.294	.434	.377	.400	.490	1.000					
Sefas_8	.416	.453	.325	.509	.525	.453	1.000				
Sefas_9	.574	.467	.481	.713	.614	.499	.627	1.000			
Sefas_10	.270	.245	.212	.336	.376	.405	.343	.417	1.000		
Sefas_11	.423	.440	.356	.476	.508	.497	.494	.564	.400	1.000	
Sefas_12	.354	.394	.190	.472	.435	.383	.524	.496	.383	.425	1.000

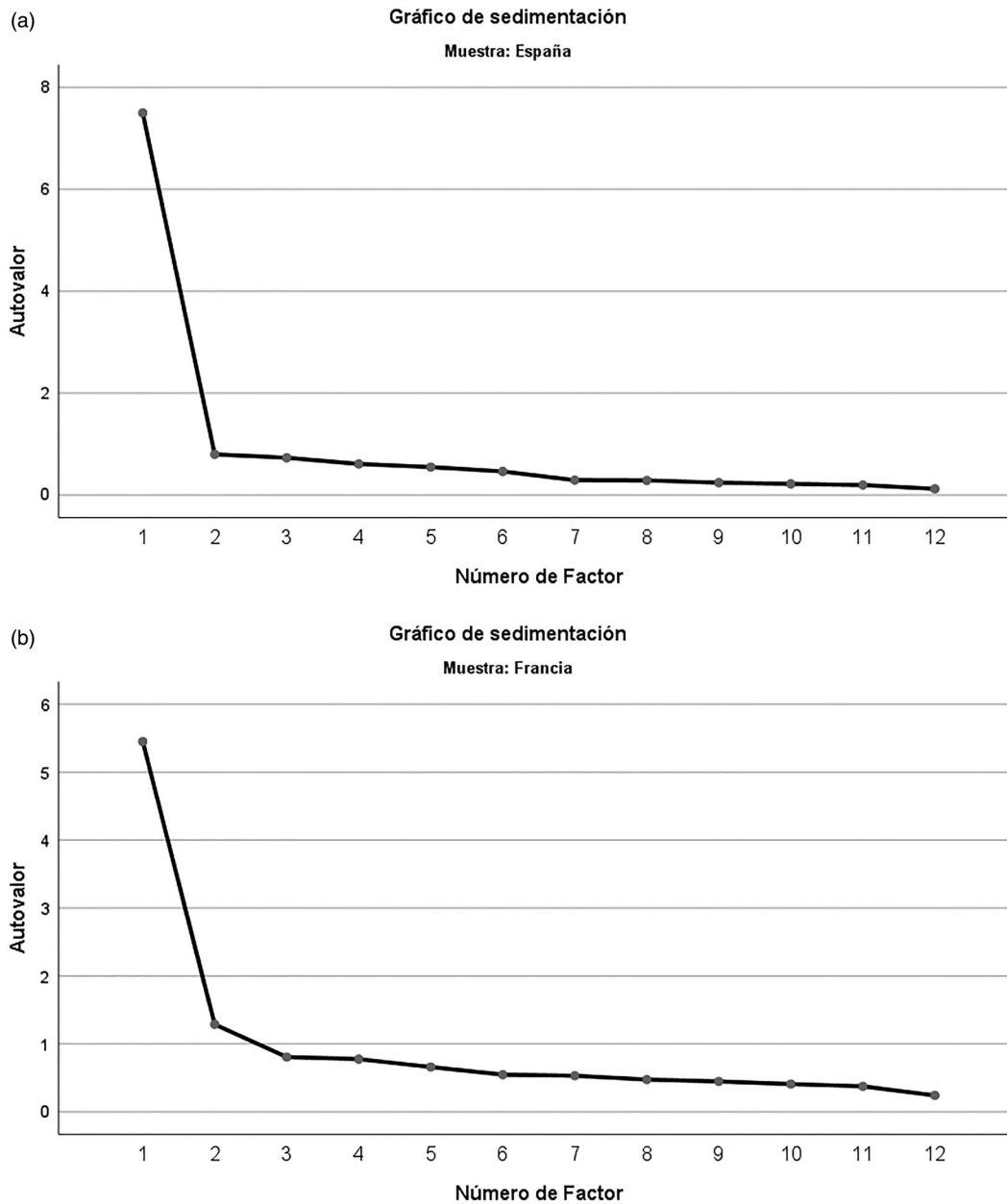


Figure 2. Scree Plot (Spain and French versión SEFAS).

Reliability

The internal consistency obtained for each questionnaire was excellent. The Cronbach's alpha values were 0.94 for the Spanish version and 0.88 for the French version. The inter-item correlation matrices are presented in [Table 2](#). The intra-class correlation coefficients (ICC) were 0.94 ($p < 0.000$) for the Spanish version and 0.87 ($p < 0.000$) for the French version. No floor/ceiling effects were observed for any item, in either the Spanish or the French versions. The SEFAS presented high test-retest reliability, with an overall ICC of 0.95 (95% CI: 0.93 to 0.98).

Construct validity

Factor analysis was performed using the Kaiser-Meyer-Olkin and Bartlett tests. According to the scree plot graph ([Figure 2](#)) and total variance analysis, both versions of the questionnaire had a single factorial structure; the single factor of the Spanish version

constituted 62.49% of total variance and that of the French version, 45.42%. These findings corroborate the existence of a single factorial structure.

Convergent validity

With respect to convergent validity, the Spanish version presented a strong correlation (0.717) with the physical health subscale of SF-36. This finding was statistically significant ($p < 0.001$).

Discussion

The aim of this study was to conduct a valid, reliable cross-cultural adaptation into Spanish and French of the SEFAS questionnaire, to provide clinicians working in these languages with a useful instrument for evaluating pathologies affecting the foot and/or ankle. Our results show that both of the versions obtained

are valid and sufficiently reliable to be used by clinicians in Spain and France.

The study populations in Spain and France were fairly homogeneous in terms of age and gender distribution, with a preponderance of female participants in both countries (61% and 77.5%, respectively). These population distributions are in line with prior adaptations of the SEFAS into German [10] (73.4% female participants) and Swedish [19] (54.81%). The reason for this gender imbalance is partly geographic, in that in the countries in question pathologies such as rheumatoid arthritis and osteoarthritis are common [20] and women tend to be more severely affected than men [21].

With respect to psychometric characteristics, our results corroborate the validity and reliability of both versions of the questionnaire. These results, moreover, are consistent with those obtained for the Swedish [19] and German [10] cross-cultural adaptations. In the exploratory factor analysis, a single factor explained 62.49% of the total variance in the Spanish version and 45.42% of that in the French version. These results are consistent with previous adaptations. These findings support the presence of construct validity and therefore the total score obtained can be used for purposes of evaluation in clinical practice. Strong internal consistency was observed, as reflected in the Cronbach's alpha score of 0.94 for the Spanish version and 0.88 for the French version. The corresponding scores for the Swedish [19] and German [10] versions were 0.84 and 0.89, respectively. No floor or ceiling effects were observed in either of the versions. The Spanish version presented good convergent validity between SEFAS and SF-36, with excellent correlation for the physical health subscale although not for the mental health subscale. The German version of SEFAS also correlated with SF-36, although in this case the physical health subscale presented only moderate correlation. The convergent validity couldn't be assessed in the French version.

The main limitation of the present study is that it was not possible to determine convergent validity between the French version of SEFAS and the SF-36 questionnaire, since the French weights were not available at that time and the version was different to the Spanish version SF-36 questionnaire. Another study limitation concerns the gender imbalance, which made it necessary to normalise the samples. Moreover, it was not possible to assess the responsiveness or the sensitivity to change of the Spanish and French versions of the questionnaire, due to the study design. In future research it would be useful to consider the responsiveness of the present questionnaires when applied to patients with other pathologies, such as the diabetic foot or undergoing surgery. In addition, the pre-testing stage, the sample size should be 30–40 participants for better understanding [22].

The main strength of this study is the methodology employed for both versions, which ensures the validity and reliability of the evaluation instrument obtained for use with Spanish and French-speaking populations. Recent systematic reviews have highlighted the need for valid, reliable self-administered questionnaires, available in Spanish or French, either for patients with foot or ankle diseases [1,23] or for specific pathologies, such as diabetes mellitus [24] or rheumatoid arthritis [7].

In conclusion, the Self-reported Foot and Ankle Score (SEFAS) is a specific, self-administered questionnaire for the evaluation of pain, function and limitation of function in the foot and/or ankle. The Spanish and French-language adaptations obtained present the necessary psychometric characteristics of validity and reliability for use with the target population even though future studies with a larger sample size are needed to assure consistent validity and reliability of the score.

Disclosure statement

All the authors declare that they have no conflict of interest derived from the outcomes of this study.

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