

Self-Reported Foot and Ankle Score: Italian Translation, Validation and Cross-Cultural Adaptation

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SUMMARY

Background. Nowadays the use of measurement instruments that evaluate the patient's condition is very common in the orthopedic field. We know that the most distal district of the lower limb, the osteoarticular complex of the ankle, is one of the most evaluated with rating scales; in fact, there are at least 76 different scoring systems for evaluating ankle problems. Furthermore, there is no measurement tool considered to be the absolute Gold Standard for evaluating problems affecting the ankle joint.

Objectives. The main aim of this study was to translate, culturally adapt, and validate in Italian language the Self-Reported Foot and Ankle Score (SEFAS).

Methods. The English version of the SEFAS has been translated according to international guidelines. The measurement properties (construct validity and reliability) have been tested according to COSMIN checklists. Cronbach's α was calculated to assess the internal consistency and the Intraclass Correlation Coefficient (ICC) was calculated to estimate the reliability. The Kaiser-Meier-Olkin (KMO), The Short-Form 36 (SF-36) and the EuroQol Health Questionnaire 5 Dimensions 5 Levels (EQ-5D-5L) were used to assess the construct validity and to verify sampling adequacy. A factorial analysis was used to confirm the mono-factorial nature of the scale.

Results. All the items were similar in meaning to the originals. Cronbach's α was 0,880 and the ICC was 0,869. The Pearson's Correlation Coefficient showed significant correlations ($p < 0.01$) between SEFAS and SF-36 and EQ-5D-5L items.

Conclusions. Based on the results obtained, we suggest the use of SEFAS in daily clinical practice, also promoting its continuation in the field of scientific research.

KEY WORDS

Ankle; assessment; foot; psychometrics; rehabilitation.

BACKGROUND

The need to develop assessment systems for the ankle is highlighted by the fact that injuries in this joint appears to be very frequent. In fact, scientific literature demonstrates that acute ankle sprain is one of the most common muscu-

loskeletal injuries. They have a particularly high incidence among physically active individuals (1) furthermore, acute ankle sprains have a high recurrence rate, which is associated with the development of chronic ankle instability (2, 3). It has been observed that an ankle or foot injury

is very frequent both in sports and in the workplace. In fact, in running, it has been seen that Achilles tendinopathy, plantar fasciopathy and ankle sprains are three of the most common types of injuries suffered during training (4). Furthermore, it has been observed that approximately 30% of running injuries affect the ankle joint complex (5). Lastly, the latest systematic reviews have highlighted that, one of the most common injuries in workplace concern the foot/ankle joint (6). Following a literature review, it was possible to deduce that there are a very high number of rating scales examining ankle pain and disability (7). Furthermore, there is no measurement tool considered to be the absolute Gold Standard for evaluating problems affecting the ankle joint. In any case, it has been found that the most used evaluation scales for dysfunctions of this joint are the AOFAS (American Orthopedic Foot and Ankle Score) and FFI (Foot Function Index) (7, 8). AOFAS is a frequently used tool to evaluate outcome after ankle and hindfoot injuries. On the other hand, FFI, was used to measure the impact of foot pathology on functionality in terms of pain, disability, and activity limitation. The Self-Reported Foot and Ankle Score (SEFAS) is a self-administered scale that was initially validated for osteoarthritis and inflammatory arthritis of the ankle. Subsequently we know that it has also been validated for other pathologies and deformities of the foot/ankle complex (9). It was developed by Maria Cöster *et al.* (2012) (10) and was based on the New Zealand Total Ankle Questionnaire (11) which was in turn derived from the Oxford-12 hip questionnaire (12). The SEFAS is made up of 12 items with five possible answers and each of them is assigned a score from 0 to 4, where 0, as a total score, represents the most severe disability and 48 represents normal function. The Self-Reported Foot and Ankle Score (SEFAS) has already been validated in: Spanish and French (Cronbach's alpha values of 0.94 for the Spanish version and 0.88 for the French version) (13), Danish (the intra-class correlation coefficient (ICC) level of the SEFAS-DK total score was 0.93 (95% confidence interval [CI]: 0.88-0.96). Cronbach's alpha (CA) for the SEFAS-DK was 0.93, while the floor and ceiling effect at week 6 post-injury was 22.4%) (14), German (the ICC values was 0.97. Cronbach's alpha (α) value was 0.89 demonstrated strong internal consistency. No floor or ceiling effects were observed. As hypothesized SEFAS correlated strongly with FAOS and SF-36 domains. It showed moderate (ES/SRM > 0.5) responsiveness between preoperative assessment and postoperative follow-up) (15), while it has not yet been validated in Italian. The aim of this study was to describe the translation and cross-cultural adaptation process of the English SEFAS version into Italian.

METHODS

Authors certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during this research. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all participants for being included in the study.

Translation and cultural adaptation

Once authorization for translation was requested and consent was obtained from the author, the original version of the SEFAS was subjected to a translation process based on the "Guidelines for the process of cross-cultural adaptation of self-report measures" by Beaton *et al.* (16) and "Principles of good practice for the translation and cultural adaptation process for patient reported outcomes (PRO) measures: report of the ISPOR Task Force for Translation and Cultural Adaptation" by Wild *et al.* (17). The first translation phase (Forward-Translation) was carried out independently by two Italian physiotherapists with a good command of the English language. In this phase, specific cultural adaptations were not necessary, as the scale contains questions conceptually applicable to different populations. Subsequently, the Back-Translation was carried out, so the Italian version, obtained from the combination of the two previous translations, was translated again into English by two bilingual translators. The original version and the back-translation were compared to verify that there were no discrepancies, resulting in overlap. Finally, the last version of the Italian SEFAS was reviewed by a Focus Group, made up of three physiotherapists with an excellent knowledge of English, so that the questionnaire was easily understandable and to correct any grammatical and/or spelling errors.

Study design and eligibility criteria

This is a translation and validation study. At the beginning the original SEFAS was translated and culturally adapted into Italian and afterwards tested for its validity and reliability in patients with: Achilles tendon problems, osteoarthritis, flat foot, cavus foot, hallux valgus, little finger varus and lateral ankle sprains. The study was conducted by a group of physiotherapists from the Sapienza University of Rome and professionals from the Aerospace Medicine Department of the Italian Air Force of the Diagnostic Therapeutic Center and Aero-Medical Rehabilitation, between August and October 2021. Following the "Consensus-Based Standards for the Selection of Health Status Measurement Instrument" (18) COSMIN checklist, the reliability and construct valid-

ity of the culturally adapted scale were assessed. Patients included in the study were suffering from at least one of the following conditions: Achilles tendon problems, osteoarthritis, flat Foot, cavus foot, hallux valgus, little finger varus, lateral ankle sprains. Exclusion criteria were the no eligibility for the survey completion, having undergone foot/ankle surgical therapy in the previous three months and having carried out infiltrations in the previous three months. In the period between the test and the retest, the study participants did not undertake any rehabilitation treatment.

Data collection

For the demographic and patient-reported outcomes (given the quarantine situation forced by the COVID-19 outbreak), the questionnaires were delivered as a Google Form questionnaire that were sent to individuals via social networks (WhatsApp) and emails. The retesting was repeated within 28 days using the same method. The form required around 10 minutes to complete as it was divided in more than one section. The first section included the consent for the use of personal data and a series of demographic questions (including name; surname; age; type; height; weight; affected foot; affected area of the foot; type of affection). The other sections of the form included patient reported outcome metrics (SEFAS, SF-36, EQ-5D-5L). The Google Form used for the retest only included the SEFAS questionnaire. The collected data, from the Google Forms, necessary for the statistical analysis, were cataloged in special tables, using an Excel file. SEFAS is made up of 12 items with five possible answers and each of them is assigned a score from 0 to 4, where 0, as a total score, represents the most severe disability and 48 represents normal function.

Other questionnaires

SF-36

The Short Form 36 (SF-36) is a very popular tool for assessing health-related quality of life, so much so that a PubMed search using the term “SF-36” found 9722 items. This measurement tool is composed of eight subscales: physical functioning (PF), role physical (RP), body pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE) and mental health (MH). Component analyzes showed that there are two distinct dimensions measured by the SF-36: a physical dimension, represented by the Physical Component Summary (PCS), and a mental dimension, represented by the Mental Component Summary (MCS). All scales contribute in different proportions to the score of both the PCS and MCS measures. The correct calculation of SF-36 scores requires the use of specific algorithms (19).

EQ-5D-5L

The EQ-5D is a generic tool for describing and evaluating health. It is based on a descriptive system that defines health in terms of 5 dimensions: Mobility; Self-care; Usual activities; Pain/Discomfort and Anxiety/Depression (20). Each dimension has five response categories corresponding to: “no problem”; “minor problems”; “moderate problems”; “strong problems”; “extreme problems”. The instrument is designed for self-completion and respondents also rate their general health on the day of the interview on a vertical visual analog scale (EQ-VAS) ranging from 0 to 100 marked by a 40 cm long ruler. The EQ-5D has been extensively tested and used in both general population and patient samples and has been translated into over 130 different language versions. The calculation of the total score of the EQ-5D-5L requires the use of specific algorithms that can return results from 0% to 100%, where 0% stands for the worst possible health and 100% stands for the best possible health (20).

Statistical analysis

Statistical analysis was performed to evaluate the internal consistency, reliability, and validity of the questionnaire. The Pearson's Correlation Coefficient evaluates the correlations between SEFAS and SF-36 and EQ-5D-5L following Cöster *et al.* (25). The significant level has been set for P-value less than or equal to 0.05. To determine the internal consistency of the scale the Cronbach's α coefficient was calculated. Intraclass correlation coefficients (ICCs) and their associated 95% confidence intervals (CIs) were selected to calculate the test-retest reliability of SEFAS. Following the COSMIN checklist, the Cronbach alpha, and the ICC values of >0.70 were considered acceptable.

All psychometric properties evaluated in this cultural adaptation was chosen following COSMIN (18) taxonomy and its domains of reliability and validity, and after a literature review of the other cultural adaptation of the questionnaire in order to compare psychometric properties obtained.

All statistical analysis was performed using IBM SPSS version 20.0.

RESULTS

Patients demographics

The study included a sample of 81 Italian patients. The group included 46 women and 35 men with an average age of 32.15 years, an average height of 171.10 cm and an average weight of 70.06 kg (**table I**). The answers showed that, the most common clinical presentation was lateral ankle sprain, found 48 times, followed by flat foot which affected 18 patients, followed by hallux valgus, found 13 times, and Achilles tendon problems, observed 9 times; rarer, however, are cavus

foot (4 patients) and little toe varus (2 patients). We have observed patients with more than one clinical presentation together (example: hallux valgus and sprains), for this reason the number of clinical presentations (n = 94) is greater than the total patients (n = 81). Following the COSMIN checklist, of those included only 29 completed re-test within 28 days.

Cross cultural adaptation and translation

Pre-definitive version obtained, following stages guidelines (16), was tested the on a sample of the Italian population included in the study, in order to verify its comprehensibility and the practical aspects of administration, as well as whether the compilation times fell within reasonable response limits. Final version of the questionnaire no needed variations in terms of cultural changes. No patient believed that the scale needed to be revised, resulting in it being understandable by

everyone. The definitive version of the Italian questionnaire was thus confirmed.

Reliability and internal consistency

The statistical analysis showed a good internal consistency of the SEFAS questionnaire since Cronbach's Alpha was equal to 0.880 (table II), therefore higher than 0.7. This shows that there is a good inter relation between all the items of the scale and therefore a good internal consistency. Furthermore, not all the items are relevant: if one of them were eliminated, the value of Cronbach's Alpha would tend to vary slightly, thus not reducing the internal consistency of the instrument (table III). In order to evaluate the reliability over a period of time the questionnaire was administrated two times, SEFAS test-retest reliability was also found to be good with an Intraclass Correlation Coefficient (ICC) of

Table I. Demographic characteristics: minimum and maximum value, mean, median, mode and standard deviation of the demographic characteristics of the 81 participants in the study.

	Age	Weight (Kg)	Height (cm)
Mean	32.15	70.06	171.10
Range	69	112	39
Minimum	16	45	154
Maximum	85	157	193

Table II. (A) Cronbach's alpha of the SEFAS; **(B)** Intraclass Correlation Coefficient (ICC).

(A)		(B)					
Cronbach's Alpha	Numbers of items	Intraclass correlation	95% Confidence Interval		F Test with True Value 0		
			Lower Bound	Upper Bound	Value	df1	
0.88	12	Avarage Measures	0.869 ^c	0.822	0.908	8.344	80

Table III. Internal consistency: Cronbach's Alpha, Mean and Variance if each item were eliminated.

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
ITEM 1	28.98	95.074	0.227	0.890
ITEM 2	28.42	79.922	0.754	0.859
ITEM 3	28.89	83.300	0.758	0.860
ITEM 4	28.19	101.928	-0.054	0.908
ITEM 5	29.19	84.603	0.785	0.860
ITEM 6	28.90	77.440	0.833	0.853
ITEM 7	28.53	80.527	0.827	0.855
ITEM 8	28.19	89.928	0.509	0.874
ITEM 9	28.91	86.130	0.652	0.866
ITEM 10	28.57	86.073	0.602	0.869
ITEM 11	28.28	86.181	0.767	0.862
ITEM 12	28.27	92.350	0.411	0.879

0.869 (table II). Even in this case the value is higher than 0.7 therefore demonstrating good reliability of the tool.

Validity

The feasibility was verified through the calculation of the KMO index and the Bartlett sphericity test. The KMO appears to have a value between 0.80 and 0.90, thus demonstrating good sampling adequacy (table IV).

In the absence of a gold standard, the validity in this study was expressed in terms of construct validity. During the first administration of the SEFAS, the participants also filled out the SF-36 and the EQ-5D-5L so that its construct validity, convergent validity precisely, could be calculated. The correlation between the scores of the SEFAS, the SF-36 and the EQ-5D-5L was possible thanks to the calculation of the Pearson’s Correlation Coefficient. The SEFAS has a strong correlation with the EQ-5D-5L, supported by the Pearson’s coefficient value of 0.609. Furthermore, the Italian version of the SEFAS also has a strong correlation with the physical activity subscale of the SF-36 with a Pearson’s coefficient of 0.775 (table V).

DISCUSSION

The aim of this study was to generate an Italian version of the “Self-Reported Foot and Ankle Score” (SEFAS) considering an optimal validity and reliability index. We found that SEFAS has good validity and reliability when evaluating patients with forefoot disorders and other foot/ankle disorders. The questionnaire - which has already been validated in patients with ankle OA and inflammatory disease in the ankle joint (24) and for the other conditions (25) - can now also be recommended as a valuable PROM when evaluating Italian patients with different disorders of the foot and ankle. The translation and cultural adaptation have led to a version consistent with the original as demonstrated by Cronbach’s alpha, the ICC and the Pearson Coefficient.

Internal consistency was assessed by calculating the value of Cronbach’s Alpha, which was equal to 0.880. In any case, the Italian version of the SEFAS has excellent levels of internal consistency, presenting an α value well above 0.700. Furthermore, the scale proved to be in line with the validations on which it was based, observing very similar internal consistency values (0.89 French, 0.88 German) (13, 15). The reproducibility of the test, concerning the 81 patients, appears to be excellent with an ICC of 0.869. Even in this case the value is higher than 0.700 demonstrating excellent stability of the instrument (21). Furthermore, the Italian version of the SEFAS proved, once again, in line with the respective validation in French, as they show very similar ICC values, of 0.869 and 0.87 respectively. While a small difference was observed in the German version, which differs slightly from the other two with a value of 0.97. The correlation between the SEFAS and the EQ-5D-5L appears to be strong, as the value of the Pearson coefficient is 0.609. The Italian version of the SEFAS also has a strong correlation with the physical activity subscale of the SF-36 with a Pearson coefficient of 0.775, in line with the Spanish validation, as the Pearson coefficients are 0.775 and 0.717 respectively. The KMO appears to have a good value as it is between 0.80 and 0.90 (22). It was not possible to evaluate the responsiveness of the questionnaire due to the study design. In future research, it would be useful to measure the responsiveness of the SEFAS questionnaire when applied to patients with other pathologies, such as diabetic foot.

In conclusion, the pathology most frequently reported among the participants was acute lateral ankle sprain, with 48 cases out of 81. This data suggests that the results obtained from this study could refer more to a population with acute lateral sprain (23). Therefore, to make the results more referable to different foot/ankle pathologies, future studies should therefore examine more heterogeneous patient populations, anyway the strength of this study still

Table IV. Validity: Pearson correlation coefficients between SEFAS, EQ-5D-5L and SF-36 (physical activity).

Kaiser-Meyer-Olkin and Bartlett’s test	
Kaiser-Meyer-Olkin Measure of Sampling Adequacy	Bartlett’s Test of Sphericity
	Approx. Chi-Square
0.885	577.813

Table V. Factor Analysis: KMO and Bartlett test.

		SEFAS	EQ-5D-5L	SF-36 (physical activity)
SEFAS	Pearson Correlation	1	0.609**	0.775**
EQ-5D-5L	Pearson Correlation	0.609**	1	0.565**
SF-36 (physical activity)	Pearson Correlation	0.775**	0.565**	1

was to validate a questionnaire capable of evaluating different clinical conditions of the foot and ankle as was done by Cöster *et al.* (24).

CONCLUSIONS

In conclusion, the “Self-Reported Foot and Ankle Score” (SEFAS) questionnaire is a specific self-administered questionnaire for the evaluation of pain, function, and limitation of the foot and/or ankle complex. Statistically significant results emerged from the analysis of the data collected, demonstrating that the Italian version of the SEFAS has excellent psychometric properties; this makes it a valid and reliable tool for assessing the level of disability in subjects suffering from different foot/ankle complex problems. Despite this, it is believed, as in the French and Spanish validation, that future studies with a larger sample size are necessary to ensure consistent validity and reliability of the score. The questionnaire proved to be short, schematic, easy

to understand and administer, representing a useful tool both in the field of research and clinical practice.

FUNDINGS

None

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

All authors contributed equally to this work.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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SUPPLEMENTS

Appendix 1. Italian Self Reported Foot and Ankle Score.

Vorremmo che rispondessi alle 12 domande sottostanti. Ogni domanda ha un punteggio da 0 a 4.

4= il più lieve o il meno problematico e 0= il più severo o il più problematico.

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Segna con una crocetta la casella che meglio descrive la tua condizione durante le ultime 4 settimane.

<p>1. Come descriveresti il dolore che hai di solito sul piede/caviglia in questione?</p> <p>4) Assente 3) Molto lieve 2) Lieve 1) Moderato 0) Severo</p>	<p>5. Quanto ha interferito il dolore nel piede/caviglia in questione sulle tue consuete attività, inclusi faccende domestiche e hobby?</p> <p>4) Per niente 3) Poco 2) Moderatamente 1) Molto 0) Completamente</p>
<p>2. Per quanto tempo riuscivi a camminare prima che il forte dolore si manifestasse nel piede/caviglia in questione?</p> <p>4) Niente dolore fino a 30 min. 3) 16-30 minuti 2) 5-15 minuti 1) Solo il giro dell'isolato 0) Incapace di camminare per il forte dolore</p>	<p>6. Quando camminavi zoppicavi a causa del piede/caviglia in questione?</p> <p>4) Nessun giorno 3) Solo uno o due giorni 2) Alcuni giorni 1) La maggior parte del tempo 0) Tutti i giorni</p>
<p>3. Riuscivi a camminare su un terreno irregolare?</p> <p>4) Sì, facilmente 3) Con poca difficoltà 2) Con difficoltà moderata 1) Con estrema difficoltà 0) No, impossibile</p>	<p>7. Riuscivi a salire una rampa di scale?</p> <p>4) Sì, facilmente 3) Con poca difficoltà 2) Con difficoltà moderata 1) Con estrema difficoltà 0) No, impossibile</p>
<p>4. Avevi necessità di utilizzare un'ortesi (plantare), supporti plantari per il tallone o scarpe particolari?</p> <p>4) Mai 3) Occasionalmente 2) Spesso 1) La maggior parte del tempo 0) Sempre</p>	<p>8. Sei stato disturbato di notte, al letto, dal dolore al piede/caviglia in questione?</p> <p>4) Nessuna notte 3) Solo uno o due notti 2) Alcune notti 1) La maggior parte delle notti 0) Tutti le notti</p>
<p>9. Quanto il dolore al piede/caviglia in questione ha influenzato le tue abituali attività ricreative?</p> <p>4) Per niente 3) Poco 2) Moderatamente 1) Molto 0) Completamente</p>	<p>11. Dopo un pasto (seduto al tavolo) quanto è stato doloroso alzarti dalla sedia a causa del dolore sul piede/caviglia in questione?</p> <p>4) Per niente doloroso 3) Lievemente doloroso 2) Moderatamente doloroso 1) Molto doloroso 0) Insopportabile</p>
<p>10. Hai avuto gonfiore al piede?</p> <p>4) Nemmeno un po' 3) Occasionalmente 2) Spesso 1) La maggior parte del tempo 0) Sempre</p>	<p>12. Hai avuto un grave improvviso dolore lancinante, puntorio o spasmi al piede/caviglia in questione?</p> <p>4) Nessun giorno 3) Solo uno o due giorni 2) Alcuni giorni 1) La maggior parte del tempo 0) Tutti i giorni</p>