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17-Italian Foot Function Index with numerical rating scale: Development, reliability, and validity of a modified version of the original Foot Function Index

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ABSTRACT

Background: Clinical research quantifies symptoms and signs of pain.
Objective: To develop a brief outcome measure to assess foot and ankle conditions, the psychometric properties of a modified version of the original Foot Function Index (FFI) were examined.
Methods: Eighty-six subjects with musculoskeletal foot and ankle disorders were enrolled. The internal consistency and test–retest reliability were evaluated by using Cronbach's α and intraclass correlation coefficient (ICC). Criterion validity was tested by Pearson's correlation coefficient between 17 items of the Italian FFI (17-IFFI) and the Lower Extremity Functional Scale (LEFS). The responsiveness was calculated using the receiver operating characteristic curve (ROC).
Results: Cronbach's Alpha was 0.95 (95% CI: 0.92, 0.99). The intra-interviewer and inter-interviewer ICC values were, respectively, 0.92 (95% CI: 0.88–10 0.96) and 0.90 (95% CI: 0.89–0.94). Correlations between the 17-IFFI scores and the LEFS scores were −0.564 and −0.456 at the initial and at the end of the treatment, respectively. The ROC analysis revealed an area under the curve of 0.732 (95% CI: 0.61–0.82) for the 17-IFFI and 0.633 (95% CI: 0.52–0.71) for the LEFS score.
Conclusions: The 17-IFFI is a reliable and valid scale and we recommend its application to evaluate the effectiveness of a treatment in patients with musculoskeletal foot and ankle disorders.

1. Introduction

The painful foot and ankle conditions limit the activities of daily living and are the leading cause of immobility and disability [1–3]. They are secondary to traumatic and non-traumatic problems such as metatarsalgia, hallux valgus, abnormal position of toes, ankle sprain and arthritis, and they may also be attributed to improper footwear and/or abnormal biomechanics [4–7]. Foot pain prevalence is 24% for women and 20% for men aged 18–80 years [8].

Many outcome measures have been used to detect changes in a patient's health status in response to an intervention [7]. In Italy several generic measures have been applied to a variety of patients with lower-extremity musculoskeletal conditions, including the 36-Item Short-Form Health Survey (SF-36) [9], the Western Ontario and McMaster Universities (WOMAC) [10], Arthritis Impact Measurement Scales (AIMS2) [11] and Lower Extremity Functional Scale (LEFS) [12].

Foot Function Index [13] is a specific outcome measure of the impact of pathologies on foot and ankle function. At first it was used for patients with rheumatoid arthritis [14] but its reliability and validity were examined in several populations and the results

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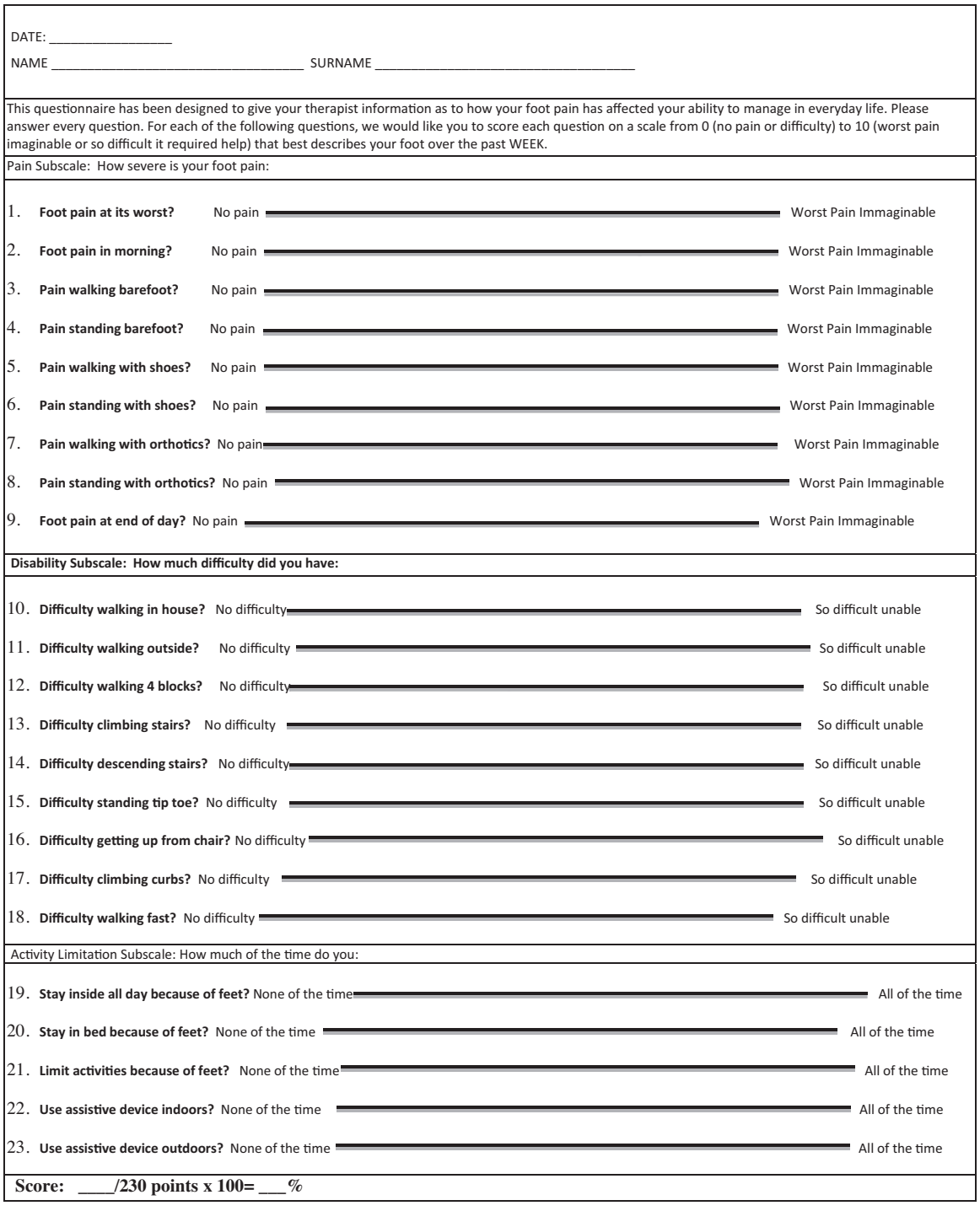

DATE: _____

NAME _____ SURNAME _____

This questionnaire has been designed to give your therapist information as to how your foot pain has affected your ability to manage in everyday life. Please answer every question. For each of the following questions, we would like you to score each question on a scale from 0 (no pain or difficulty) to 10 (worst pain imaginable or so difficult it required help) that best describes your foot over the past WEEK.

Pain Subscale: How severe is your foot pain:

1. **Foot pain at its worst?** No pain — Worst Pain Immaginable
2. **Foot pain in morning?** No pain — Worst Pain Immaginable
3. **Pain walking barefoot?** No pain — Worst Pain Immaginable
4. **Pain standing barefoot?** No pain — Worst Pain Immaginable
5. **Pain walking with shoes?** No pain — Worst Pain Immaginable
6. **Pain standing with shoes?** No pain — Worst Pain Immaginable
7. **Pain walking with orthotics?** No pain — Worst Pain Immaginable
8. **Pain standing with orthotics?** No pain — Worst Pain Immaginable
9. **Foot pain at end of day?** No pain — Worst Pain Immaginable

Disability Subscale: How much difficulty did you have:

10. **Difficulty walking in house?** No difficulty — So difficult unable
11. **Difficulty walking outside?** No difficulty — So difficult unable
12. **Difficulty walking 4 blocks?** No difficulty — So difficult unable
13. **Difficulty climbing stairs?** No difficulty — So difficult unable
14. **Difficulty descending stairs?** No difficulty — So difficult unable
15. **Difficulty standing tip toe?** No difficulty — So difficult unable
16. **Difficulty getting up from chair?** No difficulty — So difficult unable
17. **Difficulty climbing curbs?** No difficulty — So difficult unable
18. **Difficulty walking fast?** No difficulty — So difficult unable

Activity Limitation Subscale: How much of the time do you:

19. **Stay inside all day because of feet?** None of the time — All of the time
20. **Stay in bed because of feet?** None of the time — All of the time
21. **Limit activities because of feet?** None of the time — All of the time
22. **Use assistive device indoors?** None of the time — All of the time
23. **Use assistive device outdoors?** None of the time — All of the time

Score: ____/230 points x 100= ___%

Fig. 1. English version of Foot Function Index.

were satisfactory [15,16]. It consists of 23 items divided into three subscales: pain (9 items), disability (9 items), and activity limitation (5 items). The items are rated on a Visual Analogue Scale (VAS) consisting of horizontal line (10 cm). The poles are labeled "no pain" and "worst pain imaginable" (pain), "no difficulty" and "so difficult unable" (disability), and "none of the time" and "all of the time" (limitations). The patient is asked to mark the horizontal line at the spot that best corresponds to the effect of the foot complaints. Scores are added and divided by the maximum total possible (90 for both pain and disability subscale and 50 for activity limitation subscale). If a subject indicates as not applicable an item score, it is excluded from the total score. Decimal points were eliminated by multiplying the score by 100 (Fig. 1).

This scale has been translated and validated into several different languages [17,18], and most recently in Italian too [19]. Although the Italian version of the FFI showed satisfactory psychometric properties in patients with foot and ankle diseases, we adapted the original version of FFI as the basis for the creation of a new 17 Italian FFI, since the Italian FFI has not yet been widely used in clinical outcome research.

To address the need for a brief outcome measure to assess foot and ankle musculoskeletal conditions, the psychometric properties

of the modified version of the original Foot Function Index were examined.

2. Methods

Translation and cross-cultural adaptation of the FFI was performed according to international guidelines [20,21]. The original English version of the FFI [13] was independently translated into Italian by two bilingual translators, one of whom was a native English speaker and the second one was a physician whose native language was Italian. The two translations were analyzed by a health care committee (three physiatrists, one orthopedist, and one rheumatologist), which first ensured that the translations took Italian cultural characteristics into consideration. Then, they selected a consensus version of these translations (version A) that was translated back into English by two other non-medical professional translators whose native language was English. They were unaware of the concepts being investigated and had no medical background.

At the end of this phase, a new consensus version (version B) that was compared with the original FFI [13] to determine the equivalence was obtained. Version B was semantically and grammatically equivalent to the original FFI. A meeting was next held with the healthcare committee that confirmed the equivalence of the original FFI and the Italian version. Therefore, a pilot test on 20 patients with foot and ankle injuries (10 men and 10 women; mean age 52.4 years; range 18–70) to determine whether patients understood the questions was initiated.

Subsequently, according to cross cultural adaptation and validation of FFI in German speaking patients [18], we presented the Italian version of FFI to another 30 patients (who had the same problems as the previous subjects). Patients were asked to rate all items, and they were advised to respond NA (not applicable) if they were not involved in specific situations or did not perform an activity mentioned within the listed items.

We found a high ratio of non-applicable answers for 6 items. In the pain section of the original FFI [13], consideration was given to the difference between wearing shoes and being barefoot. Items 3 and 4 ("pain walking barefoot?" and "pain standing barefoot?") and 5 and 6 ("pain walking with shoes?" and "pain standing with shoes?") were, respectively, synthesized in 2 items, "when you walk?" and "when you stand?". In the same section items 7 and 8 ("pain walking with orthotics?" and "pain standing with orthotics?") were indicated as not applicable by 92% of patients. Therefore, we decided to remove them. In the activity limitation section the items 19 and 20 ("Stay inside all day because of feet?" and "Stay in bed all day because of feet?") were removed because they were rated "Never" by nearly all respondents. Moreover, we encountered some difficulties in translating the items of the scale. Indeed, the concept of block does not exist in Italy, so the equivalent of 500 m was substituted for a distance of roughly 4 blocks. As for the question relating to climbing curbs, we substituted the concept of "curb" with its respective height of 20 cm.

We substituted the original VAS with the Numerical Rating Scale (NRS) that is an 11-point scale consisting of integers from 0 to 10 (0 representing "No pain" and 10 representing "Worst imaginable pain"). The patients select the single number that best characterizes their pain intensity.

The final Italian version of FFI comprised 17 items (17-IFFI) separated in three subscales (Fig. 2): pain (5 items), disability (9 items), and limitation activity (3 items).

3. Subjects

Patients were randomly selected from a population of 195 subjects who had reported musculoskeletal lower limbs disorders.

Table 1
Baseline characteristics of patients.

Subjects, *N*	86
Injuries	39, Plantar fasciitis 21, Achilles Tendinopathy 12, Metatarsus fractures 14, Ankle sprain
Sex (male/female), *N*	44/42
Age (mean ± SD)	58 ± 10
BMI (mean ± SD)	28.10 ± 34

N, number; SD, standard deviation; BMI, body mass index.

Eighty-six patients (42 women and 44 men) with foot and ankle complaints lasting longer than 6 weeks were enrolled in our study. The data were collected from March 2011 to May 2012. Subjects ranged in age from 35 to 78 years, with a mean ± SD age of 58 ± 10.2 years (Table 1). Informed consent was obtained from all patients prior to their participation in the study.

4. Procedures

The diagnosis of foot disorders was established in all patients on the basis of clinical examinations and imaging (e.g. X-ray, ultrasound, computed tomography, or magnetic resonance imaging). The 17-IFFI was administered independently by two physicians–interviewers, physician 1 and physician 2 to estimate inter-interviewer reproducibility. Two days later, the scale was again administered by physician–interviewer 1 to examine intra-interviewer (test–retest) reproducibility. Patients did not receive any treatment during these two days of interval because we wanted to minimize the risk of short-term clinical change. Moreover, the 17-IFFI was administered again to patients at the end of rehabilitation treatment, which had a mean duration of 4 weeks.

In addition, the LEFS [22] was administered during the initial assessment and at the end of the treatment to provide a criterion specific comparison for the lower limb. This scale is used to qualitatively assess an individual's functional status during 20 specific functional tasks on a scale from 0 (unable to perform actively) to 4 (no difficulty). Total LEFS scores can vary from 0 to 80 points, with higher scores being associated with greater levels of functional status.

Subsequently, physician–interviewer 1 and the patients independently completed a seven-point global rating of change form at the end of the fourth week. "How is the patient today in comparison to his/her first visit?" "How are you today in comparison to your first visit?" were the questions which the physician and the patient answered, respectively. The patient and physician were unaware of each other's responses. The seven response options were: (1) very much worse, (2) much worse, (3) little worse, (4) no change, (5) little improved, (6) much improved, (7) and very much improved. The physician's and the patients' global rating of change scores were then averaged to give an overall change score, which was used in this study as the criterion standard of change. In the absence of a gold standard, the measure of change was used to evaluate responsiveness [23].

5. Statistical analysis

Statistical tests were conducted using SPSS Release 18 for Windows. We used the Kolmogorov–Smirnov test to verify the normal distribution of variables. Therefore, we could apply parametric tests. The change in values in 17-IFFI and LEFS at the end of the treatment in comparison with the baseline was assessed using a paired *t*-test.

One-way ANOVA was used to evaluate the education level (elementary, secondary, and university) as the between-subject factor,

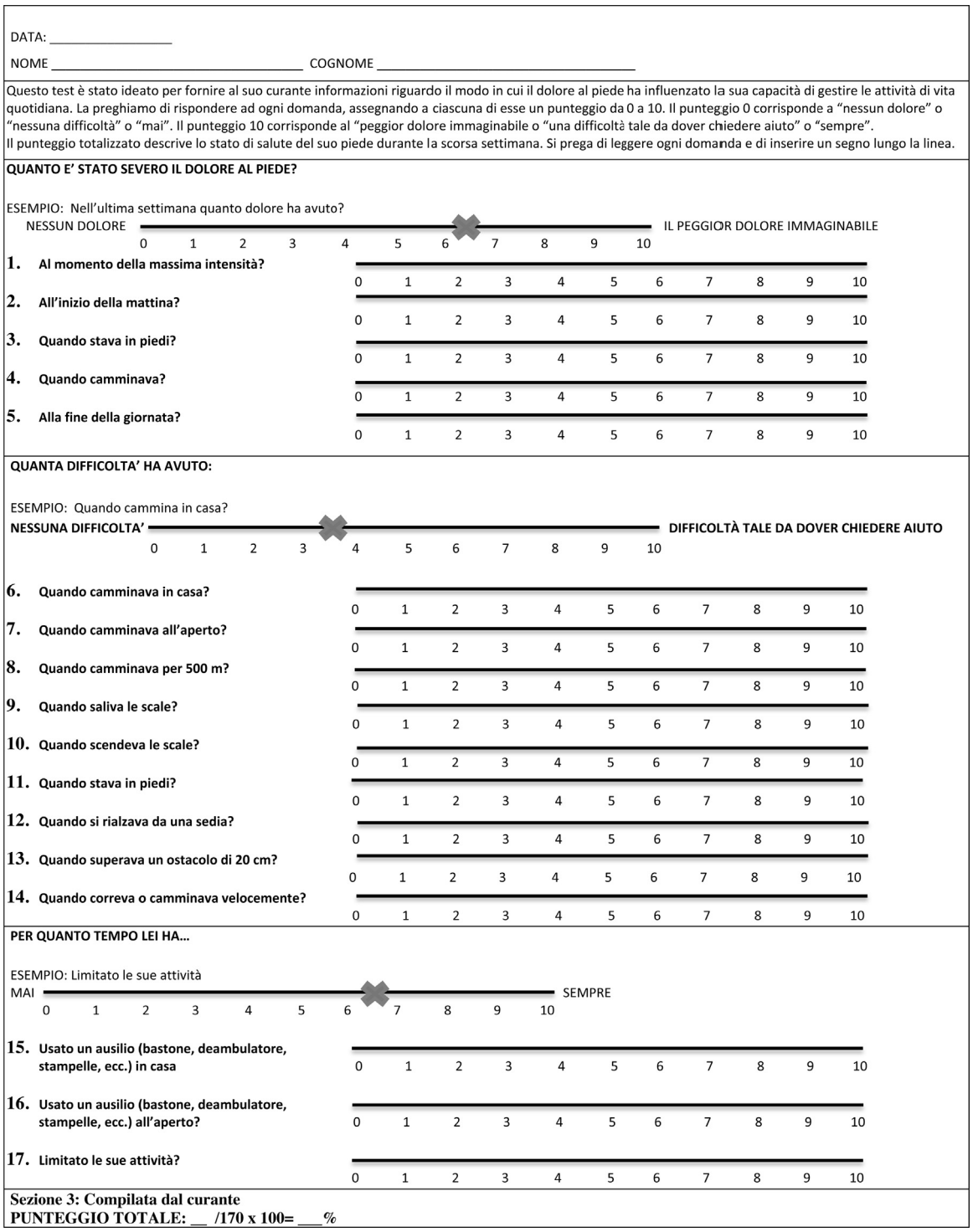

Fig. 2. 17 Italian version of Foot Function Index.

followed by a Tukey post hoc comparison when appropriate. The final step was a full assessment of the score level attributes: construct reliability, validity, and responsiveness.

The reliability of the 17-IFFI was assessed by test–retest reliability and quantified using the intraclass correlation coefficient (ICC), that is the most suitable statistical test to assess reliability [24,25]. ICC ranges from 0 (no agreement) to 1 (perfect agreement) and it was interpreted as follows: 0.00–0.25 = little, if any, correlation; 0.49 = low correlation; 0.50–0.69 = moderate correlation; 0.70–0.89 = high correlation; and 0.90–1 = very high correlation [12].

Internal consistency of 17-IFFI was evaluated by Cronbach's Alpha and 95% CI, using the data from the baseline questionnaire. Values can range from "0" (no internal consistency) to "1" (perfect internal consistency) and it is considered acceptable when Cronbach's Alpha exceeds 0.7 [12,26].

Cross-cultural adaptation ensures a consistency in the content and face validity between source and target version of a

Table 2
Internal consistency (Cronbach's α).

	Cronbach's α	IC (95% interval confidence)		p-Value
		Lower	Upper	
Activity limitation	0.92	0.86	0.96	<0.001
Pain	0.94	0.88	0.96	<0.001
Disability	0.96	0.91	0.98	<0.001
Total score	0.95	0.92	0.99	<0.001

Table 3
Differences in I-17FFI AND LEFS scores.

	Pre-treatment, Mean ± SD	Post-treatment, Mean ± SD	p-Value
17-IFFI	552 ± 196	372 ± 191	<0.001
LEFS	454 ± 154	567 ± 152	<0.001

SD, standard deviation.

questionnaire. The comparison between different outcome measures must be made against similar tests pre-formed using the original instrument [21]. According to the results from the concurrent and discriminant validation processes together, Trevethan et al. observed that the original FFI appears to be tapping a construct that reflects general problems with function of lower limb [27]. LEFS was created to evaluate functional impairment in patients with lower limb injuries and it can be used to monitor activity limitation in people with ankle fracture up to the short-term follow-up [22,28–30]. It is a valid, and responsive measure, with an excellent test–retest reliability.

Therefore, construct validity was evaluated by Pearson's correlation coefficient between scores of 17-IFFI and LEFS, that was interpreted as follows: 0.00–0.19 = very weak correlation; 0.20–0.39 = weak correlation; 0.40–0.69 = moderate correlation; 0.70–0.89 = strong correlation; and 0.90–1 = very strong correlation [31].

Responsiveness was calculated using the effect size (ES), the standardized response mean (SRM), and the receiver operating characteristic (ROC) curve. The effect size was calculated as the mean score difference between the baseline and follow-up values divided by the standard deviation from the initial measurement according to Kazis et al. [32]. The SRM was calculated as the mean change score divided by the standard deviation of the change score. Responsiveness (ES and SRM) was interpreted as follows: 0.2 = small, 0.5 = moderate, and 0.8 or greater = large [33]. The ROC curve, used in medicine to determine a cut-off value for a clinical test, is a graph of sensitivity (y-axis) vs. 1 − specificity (x-axis). We chose global change scores that were less than or equal to 4 to represent unimportant change and scores greater than 4 to represent important change. We calculated the area under the curve (AUC), which is interpreted as the probability of correctly identifying an improved patient from randomly selected pairs of patients who have and have not improved. An AUC of 10 indicates perfect discrimination between these two health conditions.

6. Results

Eighty-six patients underwent rehabilitation therapy with a mean duration of 4 weeks. They completed the 17-IFFI and LEFS. No individual scored the worst or best possible score (no floor/ceiling effects) for both scales. No differences were found between the 17-IFFI scores of subjects with different education levels ($F = 0.07$, $p = 0.993$).

6.1. Reliability

Reliability is the stability or consistency of scores over time or across raters. It indicates the homogeneity (internal consistency) of a scale and the reproducibility (test and retest reliability) of scores. Cronbach's Alpha of 17-item FFI was acceptable 0.95 (95% CI: 0.92, 0.99) ($n = 86$), while the values of pain subscale, disability subscale and activity limitation subscale were 0.92, 0.94 and 0.97, respectively (Table 2). The intra-interviewer test and retest reliability and inter-interviewer test and retest reliability, respectively, showed a very high and a high correlation. Indeed, the intra interviewer ICC and inter-interviewer ICC values were, respectively, 0.92 and 0.90.

6.2. Construct validity

To examine the construct validity of the 17-IFFI we chose the LEFS as the comparison scale. Indeed, the measurement properties of the LEFS are applicable to patients with foot problems. Criterion validity was tested by calculating Pearson's correlation coefficient. Correlations between the 17-IFFI scores and the LEFS scores were −0.564 and −0.456 at the initial and at the end of the treatment. There were statistically significant differences in 17-IFFI and LEFS scores between the patients at initial and at discharge assessments (Table 3).

6.3. Responsiveness

For the 86 subjects, the values of ES for FFI and LEFS were 0.9 and 0.74, respectively; the values of SRM for FFI and LEFS were 1.14 and 0.82, respectively. The ROC curve analysis revealed an AUC of 0.732 (95% CI: 0.61, 0.82) for the 17-IFFI and the 0.633 (95% CI: 0.52, 0.71) for the LEFS score with $p < 0.001$ (Fig. 3). The standard error values were 0.04 for 17-IFFI and 0.08 for LEFS.

7. Discussion

The scope of clinical research is to quantify symptoms and signs of pain. Rehabilitation is that field of medicine that requires specific instruments to measure pain, activity limitations, and functions to evaluate the effectiveness of treatments. However, the creation of satisfactory instruments is complex and time-consuming, and requires extended research effort and specialized knowledge.

FFI [13] is one of the most frequently used self-reported questionnaires that is used across national and international clinical and research communities. It is a valid instrument to monitor patient outcomes in foot and ankle disorders, with few items and easy to complete [16].

In this study we translated and modified the original FFI [13] in order to create a new and an alternative outcome measure. The new index was then tested for its reliability and validity in subjects with musculoskeletal foot and ankle disorders.

The original FFI underwent numerous changes [18,34,35]. The final version of 17-IFFI comprised 17 items (17-IFFI) separated in

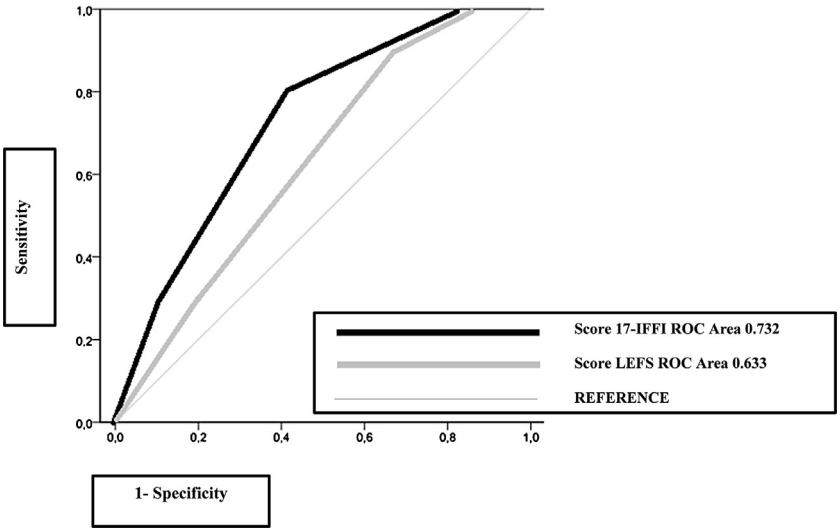

Fig. 3. Receiver operating characteristic (ROC) curves illustrating the relationship between sensitivity and complement of specificity (1 – Specificity) for the 17 IFFI and LEFS.

three subscales: pain (5 items), disability (9 items), and limitation activity (3 items). The measurement scale VAS was substituted with NRS since different respondents may place their marks at the same point on a VAS but intend somewhat different meaning. Recently, Trevethan *et al.* evaluated the original FFI in terms of the developmental procedures used to create it and they found that the VAS tends to have higher failure rates than the NRS. Moreover, the NRS has been shown to be at least as sensitive as the VAS and it is preferred over the VAS by patients and clinicians for its relative simplicity and ease of administration and scoring [27].

The previous Italian version of the scale [19] showed acceptable psychometric properties but it has not yet been widely used in clinical outcome research. The final version included 18 items separated into pain and disability subscales. The authors completely removed the activity limitation subscale because patients did not use assistive devices. This could represent a limitation, probably due to the low prevalence of serious diseases of their patients.

Cross cultural adaptation of 17-IFFI showed reliability and construct validity tests mostly comparable to previous studies, supporting the view that it is clinically applicable to foot and ankle disorders. In particular, the internal consistency, evaluated by Cronbach's Alpha, was acceptable for total scale (0.95) and for pain, disability, and activity limitation subscale. The ICC indicated satisfactory test–retest reliability.

We found a moderate correlation between 17-IFFI and LEFS scores at the beginning and at the end of the treatment. As for reproducibility, the intra-interviewer ICC of 17-IFFI (0.92) was slightly better than the inter-interviewer (0.90). Construct validity was established by the relationship between 17-IFFI and LEFS scores at the beginning and at the end of the treatment showing a moderate correlation of 0.564 and 0.456, respectively. ROC curve analysis revealed a large responsiveness for the 17-IFFI, whereas a moderate responsiveness for the LEFS.

Responsiveness, considered as part of the validity analysis, is the ability of the score to detect meaningful changes in a patient's condition over time. Although there is no consensus on the most suitable statistical analysis to assess responsiveness, we decided to calculate the effect size, the standardized response mean, and the receiver operating characteristic curve [36]. We found large ES (0.9) and SRM (1.14), with moderate AUC (0.732). All values were greater than those of LEFS.

Previous Italian FFI found a Cronbach's alpha value of 0.95 for both subscales and a good reproducibility with an ICC between 0.94 and 0.91 Moreover, the authors observed a strong correlation between the FFI and SF-36 and the VAS with related content. In particular, they observed in the areas of physical function and pain a good construct validity. The responsiveness was calculated only by ES (0.95 and 0.83 for pain and disability subscales, respectively) and SRM (0.74 and 0.72 for pain and disability subscales, respectively), without considering the receiver operating characteristic curve value [33].

There were some limitations in the present study. We used the LEFS as a specific comparison tool for the lower limb but we did not compare the 17-IFFI with a general health questionnaire. We included only subjects with chronic foot and ankle musculoskeletal disorders that indicated "as not applicable" a high ratio items.

In pain section, we synthesized the items "pain walking barefoot?" and "pain standing barefoot?" and "pain walking with shoes? and "pain standing with shoes?" in 2 items, "when you walk?" and "when you stand?", respectively. We decided to remove the items "pain walking with orthotics?" and "pain standing with orthotics?" because indicated as "not applicable" by 92% of patients. In the activity limitation section the items "stay inside all day because of feet?" and "stay in bed all day because of feet?" were removed because rated "Never" by nearly all respondents. Therefore, the results of the present study cannot be reliably applied to other diagnoses and a more diversified diagnosis should be tested.

8. Conclusions

The adapted 17 Italian Foot Function index is a reliable and valid outcome measure that showed more specific and sensitive properties than a generic questionnaire such as the LEFS. However, the cross cultural data have to be confirmed in future investigations. Two major changes have been adopted with respect to the original version of the scale. First of all, we shortened it permitting to reduce the time necessary for the questionnaire compilation. Moreover, we introduced the numerical rating scale.

Consequently, the 17 Italian Foot Function index could be used at a more general level and we suggest its application in clinical practice to evaluate the effect of the treatments in patients with musculoskeletal foot and ankle disorders.

Conflict of interest

None declared.

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