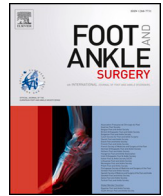




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Manchester oxford foot questionnaire in foot and ankle Spanish patients: Transcultural adaption and validation

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ABSTRACT

Background: Manchester–Oxford Foot Questionnaire (MOXFQ) has shown the best psychometric properties to evaluate patient-related outcomes in foot and ankle (F&A) surgeries. The aim is adapting and validating the MOXFQ for European-Spanish population, while assessing its psychometric properties.

Method: Translation and cross-cultural adaption (MOXFQ-EUROSpa) was performed from MOXFQ-English original test. Its psychometric properties (reliability, internal consistency, floor and ceiling effects, construct validity and responsiveness) were calculated in 102 patients operated of orthopaedic F&A surgery in a Spanish hospital between 2021 and 2022. It was applied MOXFQ-EUROSpa, VAS-pain and EURO-QoL questionnaires. Data analyzed with SPSS.13.0; p-value < 0.05

Results: MOXFQ-EUROSpa showed excellent reliability (ICC=0.94 MOXFQ-index) and strong internal consistency (Cronbach's alpha=0.95 MOXFQ-index). Strong correlation with EuroQoL and VAS-pain confirmed validity. Good to excellent responsiveness for all domains, except MOXFQ-social (moderate). Postoperative MOXFQ-social had a floor effect.

Conclusion: MOXFQ-EUROSpa demonstrated good psychometric properties therefore it should be considered to evaluate elective foot and ankle procedures results.

Level of evidence: II

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1. Background

Foot and ankle (F&A) procedures account for 15–20% of all orthopedic interventions [1]. Their main objective is to alleviate pain and provide comfortable footwear. However, there is a lack of reliable and standardized measurement methods to assess surgery outcomes [2]. Patient-reported outcome measures (PROMs) evaluate the subjective experience of the disease, unfortunately many PROMs

for F&A diseases have limited psychometric evidence which limits the interpretation of the results [2,3].

A recent review found inconsistencies between recommended lower extremity PROMs and those used in scientific journals [4]. The Foot Function Index (FFI) is the most commonly used, while the Manchester-Oxford-Foot-Questionnaire (MOXFQ) is the most reliable and valid instrument after a systematic review of 50 F&A instruments [3].

The MOXFQ was initially developed specifically for hallux valgus surgery [5] although its use in other F&A pathology has been established in successive studies.[1] Different translations have been validated in multiple languages [6–11], including Latin American Spanish [12]. Spanish is the second most spoken mother tongue globally, after Mandarin Chinese, and the fourth most spoken language overall, after English, Mandarin Chinese, and Hindi [13]. Cultural differences exist between Latin American Spanish [12] and Castilian Spanish, which may influence their transversal adaptation.

This study aim is to perform a transcultural adaptation and validation of the MOXFQ to Castilian Spanish (MOXFQ-EUROSpa) to

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Spanish population as well as assessing the measurement properties and its responsiveness to F&A pathology.

2. Material and methods

2.1. Translation procedure

The translation was carried out using a forward-backward method supervised by the University of Oxford, in adherence to International-Society-for-Pharmacoeconomics-and-Outcomes-Research (ISPOR) recommended standards [14], ensuring a cross-cultural adaptation from the original English test [1].

The process was carried out following these steps. Step 1: the original terms were accurately translated to avoid misunderstanding. Step 2: two native Spanish speakers, and fluent in English, translated the original MOXFQ to Spanish. Step 3: these translations were compared and a common version was agreed upon (MOXFQ-EUROSpa). Step 4: a native English speaker with no medical background, and unaware of the original MOXFQ, back-translated the MOXFQ-EUROSpa to English. Step 5: this version was reviewed by a committee designed by the original test developers. Step 6 (pilot testing): the provisional version was tested in 11 patients with hallux valgus to verify the test comprehension. Step 7: Final modifications were made based on feedback from a cognitive debriefing to create the final MOXFQ-EUROSpa version.

The main issue encountered during the creation of semantic equivalence was adapting the verbal tenses used in the source questionnaire. The present perfect tense in English, which refers to a past time, had to be translated into various past tenses in Spanish. Another challenge was finding a natural equivalent sentence in Spanish for the introductory phrase "this has happened to me," used in questions 1–14. As a result, it was decided in committee to omit this sentence. Additionally, there was difficulty in translating the word "foot." While the translators chose "pie/tobillo" (meaning foot/ankle), the committee ultimately decided to maintain only the word "pie" (meaning "foot"). The most changed question was 16, where the word "troubled by" was difficult to adapt conceptually. The word "molestar" was chosen as a replacement, and the sentence structure was changed from passive to active to improve clarity.

Committee of in-country investigators and developers [1] agreed on cognitive debriefing changes.

2.2. Patients

A prospective observational study was conducted. From February 2021 until March 2022, 102 successive patients were recruited in a Spanish public hospital. Inclusion criteria were Castillian Spanish speaking patients over 18 for elective orthopedic F&A surgery. Exclusions included patients with previous F&A surgery, chronic or acute trauma, infection, or inability to understand the questionnaire.

All patients completed the questionnaires before surgery and 12 months postoperatively (pre-post). Additionally, a test-retest was proposed on a volunteer basis, a total of 42 patients repeated the test after a week time span to assess reliability.

2.3. Questionnaires

The MOXFQ is a self-administered questionnaire with 16 items divided into 3 domains (walking standing, pain, and social interaction) plus a global index [1]. Each item is scored on a 5 item Likert scale. The scores for each domain range from 0 to 100, with 100 indicating the worst health condition [1,5,15–18].

The VAS-pain has been used in MOXFQ validations measures average foot pain over the previous 2 weeks using a line with no numbers. The position on the line corresponds to a score from 0 to

100, with zero representing no pain and 100 the worst imaginable pain [19].

The five-dimensional-EURO-QoL test (EURO-QoL 5D) Spanish version was used [20]. This test has also been utilized in MOXFQ validations [21], and it also possesses a highly sensitive test for detecting changes in F&A surgery.[22] It assesses the patient's quality-of-life across five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Responses were measured on a 5 item Likert scale (from "severe-problems" to "no-problems") and converted, using a normative value for Spanish population [23], to a single index score ranging from –1 (worse than dead) to 1 (best quality-of-life). A VAS ranging from 0 to 100 is also included, 100 representing the best state of health.

Transition item. The last question in the post-operative assessment ("anchor-question") is a 6 item Likert question to measure subjective change of the problems that motivated the surgical intervention (from "no-problems" to "much-worse").

Patients fulfilled these questionnaires without the intervention of any personnel.

2.4. Statistical analysis

The sample size was calculated following the requirement of 5–10 times as many observations as variables/items in the test [1]. In this case, 16 variables/items in MOXFQ requires a minimum sample of 80.

Descriptive analysis included mean, standard deviation of patient's demographic data and generic information from the surgery. Quantitative data was analyzed using mean and standard deviation and qualitative using percentages.

2.4.1. Reliability

Test-retest reliability of MOXFQ dimensions was assessed by calculating interclass correlation coefficient (ICC) using the test-retest. ICC ranges from 0 (no-reliability) to 1 (high-reliability). An ICC > 0.7 indicated good reproducibility.

2.4.2. Internal consistency

Cronbach's alpha determines the extent to which the questionnaire measures what it aims to [24]. It is calculated using the baseline values for all domains. It ranges from 0 (without-consistency) to 1 (high-consistency). An alpha score > 0.7 indicates high internal consistency [25].

2.4.3. Floor and ceiling effects

If over 15% of answers of any domain reaches minimum or maximum scores, a floor or ceiling effect was observed, affecting test accuracy [26,27].

2.4.4. Construct validity

Convergent and divergent validity were assessed using Spearman's correlation coefficient (r) to compare the results of MOXFQ with EURO-QoL and VAS-pain. The pain domain of MOXFQ and VAS-pain were expected to show high convergent validity ($r > 0.6$), for they were intended to measure the same (pain). Divergent validity was observed if dissimilar domains have a low correlation ($r < 0.5$).

2.4.5. Responsiveness

The questionnaire's responsiveness was defined by its ability to detect change over time.

The assessment values were obtained from the pre-postoperative data. It was expressed using the effect size (ES), which quantified the magnitude of change between preoperative and 1-year post-operative measurements on a scale of positive values [28]. ES values

Table-A
Sample demographic characteristics.

Age, years	n
Mean (SD)	58.4 (12.7)
Sex, n (%)	
Male	24 (23 %)
Female	78 (77 %)
BMI	
Mean (SD)	27.2 (4.7)
Main surgical indication, n (%)	
Forefoot	70 (68 %)
Midfoot	1 (1 %)
Hindfoot	6 (6 %)
Ankle	14 (14 %)
Soft tissue	11 (11 %)

of 0.2, 0.5, and 0.8 indicated small, moderate, and large effects, respectively [29].

The minimal detectable change (MDC) was defined as the minimum amount of change necessary to surpass the threshold of measurement error. It was expressed as a confidence level of 90% (MDC90). A true change requires a score higher than the MDC. To calculate MDC, the standard error of measurement (SEM) was essential.

The minimal clinically important change (MCIC) was determined by measuring the minimum change in a value that the patient perceived as a clinical improvement. The MCIC was calculated considering the mean change score of the patients that reported feeling "slightly better" in the postoperative questionnaire ("anchor-based" method) [16].

Data was analyzed with SPSS.13.0 (SPSS.Inc, Chicago, IL) and a p-value < 0.05 indicated statistical significance.

3. Results

3.1. Sample characteristics

102 patients undergoing elective surgery of the foot or ankle were consecutively recruited. Sample characteristics were described in Table-A. The most common diagnoses were hallux pathology and/or metatarsalgia (n = 70); cavovarus or planovalgus deformity (n = 7); ankle instability or impingement (n = 14) and plantar fasciitis (n = 11). Main pre-postoperative values were presented in Table-B.

3.2. Reliability

The MOXFQ questionnaire showed excellent test-retest reproducibility and strong internal consistency as shown in Table-C.

Table-B
Descriptive data of MOXFQ, EuroQoL and VAS-pain values for pre-postoperative group.

	Preoperative		12 months follow-up		p value
	n	Mean (SD)	n	Mean (SD)	
MOXFQ					
MOXFQ Pain	102	64.46 (25.5)	102	37.75 (29.5)	< 0.0001
MOXFQ Walking / Standing	102	69.51 (22.6)	102	40.83 (28.6)	< 0.0001
MOXFQ Social Interaction	102	45.47(28.7)	102	22.86 (25.0)	< 0.0001
MOXFQ Index	102	61.29 (23.0)	102	34.99 (26.7)	< 0.0001
EuroQoL					
EuroQoL index	102	0.59 (0.27)	102	0.73 (0.22)	0.0001
EuroQoL VAS	102	64.41 (20.8)	102	67.21 (22.0)	0.3514
PAIN VAS	102	61.38 (19.7)	102	30.79 (24.5)	< 0.0001

Descriptive data extracted from the pre-postoperative group.

Table-C
Internal consistency of MOXFQ-EUROSpa.

	ICC	Cronbach's alpha
MOXFQ		
MOXFQ Pain	0.95	0.89
MOXFQ Walking / Standing	0.88	0.93
MOXFQ Social Interaction	0.90	0.86
MOXFQ Index	0.94	0.95

Intraclass Correlation Coefficient (ICC) values were calculated using test-retest subgroup (n = 42) while Cronbach's alpha values were extracted from the baseline values of the pre-postoperative group (n = 102).

Table-D

Correlation between postoperative domains to express convergent and divergent validity.

	EuroQoL index	EuroQoL VAS	VAS Pain
Postoperative			
MOXFQ Pain	-0.674	-0.418 *	0.733
MOXFQ Walking / Standing	-0.719	-0.429 *	0.680
MOXFQ Social Interaction	-0.696	-0.388 *	0.501
MOXFQ Index	-0.731	-0.443 *	0.703

All p values were significant (p < 0.05). All of them were < 0.001 except correlations marked with asterisk (*) (p < 0.05 but > 0.001). Displayed in bold type were the values with strong correlation (r > 0.6).

3.3. Floor and ceiling effects

No preoperative and postoperative ceiling effects neither preoperative floor effects were observed in MOXFQ dimensions. However, only 35.3% (36/102) of patients achieved the minimum value (best possible status) in the MOXFQ-social domain considering a floor effect.

3.4. Construct validity

Convergent validity was confirmed with good correlation between all MOXFQ domains and EURO-QoL Index in the postoperative variables. Additionally, MOXFQ-Pain showed a strong correlation with VAS-pain. Nevertheless, MOXFQ-Social had a weak correlation with preoperative VAS-pain (r -0.354 p < 0.001) indicating divergent (Table-D).

3.5. Responsiveness

Table-E showed the responsiveness statistics of the MOXFQ. All MOXFQ domains showed excellent responsiveness (ES > 1) except for MOXFQ-Social domain, still presenting moderate-large ES. Moreover, significant improvements were observed in all MOXFQ domains, EQ index, and VAS scores (p < 0.001). The only exception was the EURO-QoL-VAS, which did not show statistically significant changes, moreover this variable had a low ES (0.13) suggesting it was not

Table-E
Responsiveness of the MOXFQ-EUROSpa.

	Mean change (SD)	p value	ES	SEM	MCD	MCIC
MOXFQ						
MOXFQ Pain	28.68 (27.30)	< 0.001	1.27	0.97	2.27	15.84
MOXFQ Walking / Standing	26.72 (28.83)	< 0.001	1.05	2.60	6.06	19.13
MOXFQ Social Interaction	22.61 (28.49)	< 0.001	0.79	1.43	3.35	11.96
MOXFQ Index	26.30 (25.18)	< 0.001	1.14	3.63	8.47	15.90

In bold typography was highlighted the value of minimal clinical important change (MCIC). ES: effect size; SEM (standard error of measurement); MCD (minimal detectable change).

responsive to pre-post changes in these patients. All the mean pre-postoperative changes of MOXFQ domains were higher than the MDC.

The anchor question to feel “slightly better” respect to the pre-operative status were responded by 23 patients and their results were used to calculate MCIC.

4. Discussion

This study successfully performed a transcultural adaptation of the MOXFQ into European Spanish and tested its psychometric values in a Spanish population ensuring its reliability, validity, and responsiveness. This new version adds up to other languages such as Italian, Dutch, Persian, Korean, Turkish, French, Chinese and German [6–11,30,31]. Although a version in Latin Spanish is already published [12], the MOXFQ-EUROSpa presented provides strong evidence for its use in the Spanish population, bridging the gap of the cultural and dialectal differences between Spain and Colombia.

Additionally, this study assessed psychometric values in an heterogeneous sample with 31.4% of patients having surgeries outside the forefoot, unlike others restricted to forefoot [1,6,8,9,11,31], expanding the scenarios for its validated use.

The psychometric properties obtained in our study matched evidence available in other languages [2,3,7]. Reliability ranged between 0.87 (Walking/Standing) and 0.95 (Pain), consistent with other European versions (English, Dutch, Italian and German) with ICC values around 0.9 [1,6–8,17].

The MOXFQ-EUROSpa showed high internal consistency, with Cronbach's alpha values ranging from 0.86 to 0.95, meaning that the subscales scores capture most the information contained in the 16 items. The results were similar to the original English (range 0.73–0.92), Dutch (range 0.74–0.86), Italian (range 0.72–0.83) and previous Latin American Spanish (range 0.65–0.9) versions. MOXFQ-Social, in all these studies, had the lowest Cronbach's alpha (<0.8), our version had 0.86. Although this difference could be due to improved accuracy in the translation and adaptation of the test, authors believe they were minimal differences to raise conclusions.

Correlations between PROMs indicate good construct validity. Convergent validity shows moderate and strong correlations between MOXFQ domains and EURO-QoL 5D Index, as well as MOXFQ-Pain and VAS-pain. Our hypothesis of divergent validity was supported by a low correlation between alike domains such as MOXFQ-Social and VAS-pain, maintaining the robust validity of our translated MOXFQ. Authors selected EURO-QoL 5D as an alternative SF-36 questionnaire (a widely utilized test in other similar studies) because it has been demonstrated EURO-QoL 5D to be a highly sensitive test for detecting changes in elective F&A surgery [22], being the SF-36 neither reliable nor responsive enough to detect real change after forefoot surgery [32].

Concerning the VAS for pain, it has been employed independently in a separate prior validation study [9]. Additionally, pain is a component domain of the MOXFQ, so the use of VAS-pain might be considered an important strengthen of the validation study regard to convergent validity assessment.

Responsiveness is missing in other cross-cultural adaptations of the MOXFQ. The effect size of all domains was mostly above 1.0, in line with previous reports [1,7], indicating high sensitivity in detecting real changes. However, MOXFQ-social domain presented the lowest ES (0.79). The authors believe that although the surgery can improve pain and walking, socialization was not limited by the patient's perception of improvement due to the surgery. Moreover, this can justify the heterogeneity of this domain even it must be considered as a consequence of the questionnaire construction more than its successive translations. In spite of all these reasons, 0.79 figure was considered almost a large effect size (<0.8).

The MDC90 value prevents random variation. Pre-postoperative changes in all domains were higher than the MDC, it means that all MOXFQ dimensions showed true changes that would not be explain by error measurements of the questionnaire.

Finally, the MCIC is fundamental in calculating sample size and interpreting results of MOXFQ-EUROSpa test as settles the numerical change that translates to a perceived clinical change. MCIC results for all MOXFQ domains were consistent with the original report by Dawson [16] as well as other languages [6–12,30,31].

5. Limitations

The small sample size was the main limitation of this study. Although sufficient (over the lesser limit, that is 5 times the amount of items), was smaller than other similar studies [7–12,30,31]. This leads to a small subgroup of patients when calculating the MCIC based on the anchor question. However, values were similar to those in the original version [16].

Although the sample include a wide range of F&A pathology and it could increase the applicability of the questionnaire, the majority part of patients (68%) had been operated on forefoot region. This sample heterogeneity could be a source of bias.

Also, the fact that only include elective pathology or patients over 18 years old limit the extrapolation of the results to trauma, non-elective surgery and pediatric population.

The clinical relevance of this study is twofold: firstly, it generalizes the MOXFQ in the Spanish population, bridging cultural differences with Latin Spanish. Secondly, it extends the usefulness of the MOXFQ in elective F&A surgery beyond the forefoot pathology, although a 32% of patients underwent surgery other than the forefoot.

6. Conclusion

The MOXFQ-EUROSpa demonstrated good psychometric properties similar to both the original test and successive translations. It should be considered as a reliable tool to evaluate results in European Spanish population requiring elective foot and ankle surgery.

Declaration of Competing Interest

There are no conflicts of interests.

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