

Validity of the Hispanic version of the American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes Questionnaire in patients with traumatic foot and ankle injuries

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Abstract

Background: Hispanics represent the largest minority group in the United States and are projected to represent 29% of the US population by 2060. Enrolling Hispanic patients in clinical outcome trials is critical to study a representative sample of the general population. Lack of translated and validated survey tools has been identified as a major barrier to enrolling Spanish speaking patients. The purpose of this validation study was to study the correlation between the Spanish translation of the American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes questionnaire (AAOS-FAOQ) and the Spanish versions of the Foot Function Index (FFI) and the Foot Health Status Questionnaire (FHSQ) in Hispanics from Mexican lineage with traumatic foot and ankle injuries.

Methods: A cross-sectional validation study in 36 Hispanic patients from Mexican lineage with foot and ankle injuries was performed. The Hispanic version of the AAOS-FAOQ and the Spanish translations of the FAOQ, FHSQ, FFI, and the Short-Form 36 questionnaire (SF-36) were distributed among all patients. Subsequent statistical analysis correlating the Hispanic version of the AAOS-FAOQ to the FFI, FHSQ, and SF-36 was performed. Additional analysis on the Hispanic AAOS-FAOQ included test-retest reliability and internal consistency.

Results: The Hispanic AAOS-FAOQ Global Foot and Ankle subscale showed statistically significant ($P < .05$) correlations with 5 of 8 subscales of the FHSQ, the FFI, and the Physical Component Summary subscale of the SF-36. The AAOS-FAOQ Global Foot & Ankle Scale also demonstrated a test-retest reliability of 0.736 and a strong internal consistency.

Conclusions: This study further validates AAOS-FAOQ in Mexican Hispanics by showing strong correlations with the validated Spanish versions of the FFI and FHSQ.

Keywords: foot, Hispanic, outcome measure, validation

1. Introduction

United States census reports from 2014 demonstrate that 17.2% (55.4 million) of people residing in the United States are Hispanic.^[1] Hispanics represented the largest minority group in the US population in 2014 and are projected to represent 29% of the US population by 2060. This growth accounts for 65% of the total projected US population growth over the same period.

Additional census analysis shows that 64% of the Hispanic population in the United States are of Mexican lineage.^[2]

This data emphasizes the large representation of Mexican Hispanics within the US population. To accurately represent the US population, clinical investigators should ideally be enrolling a corresponding proportion of Mexican Hispanics in their studies. Recent investigations however have shown that the patient populations enrolled in randomized clinical trials do not match the distribution of race and ethnicity that is found in the actual US population.^[3] Specifically, a lack of minority inclusion in orthopaedic research trials has been identified. One potential barrier to enrolling minority patients into clinical trials is the lack of translated and validated survey tools.

González-Sánchez et al^[4] validated a Spanish translation of the American Academy of Orthopaedic Surgeons Foot and Ankle Outcomes questionnaire (AAOS-FAOQ) in podiatric patients from Spain.^[4] The authors observed significant correlations with the Spanish versions of the Foot Function Index (FFI)^[5] and the Foot Health Status Questionnaire (FHSQ)^[6]. However, these investigators also emphasized the importance of an ongoing validation process that not only includes Spanish patients, but also in Hispanic/Latinos.^[4] Thus, in a recently published study, the AAOS-FAOQ was translated, cross-culturally adapted, and validated for use in Mexican Hispanics.^[7] However, this most recent study did not examine the correlation of the Hispanic

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version of the AAOS-FAOQ with other validated foot and ankle outcome measures, which seems to be an important part of the ongoing validation process. Therefore, the specific goal of this study is to further validate the Hispanic version of the AAOS-FAOQ by examining the correlations with the FFI and the FHSQ.

2. Materials and methods

2.1. Design

This study was approved by the Institutional Review board at UT Health San Antonio (Protocol #HSC 2013016H) and was performed at an urban level-1 trauma center. Patients were identified by their treating physician in the outpatient orthopaedic trauma follow-up clinic. Thirty-six patients, 18 males and 18 females, with a mean age of 40.8 years of age were enrolled. The primary foot and ankle injury included 22 ankle fractures, 5 pilon fracture, 1 Lisfranc fracture, 1 calcaneus fracture, and 7 forefoot fractures. Of these patients, 32 had closed-fractures, 4 had open fractures. A total of 11 patients had been managed non-operatively while the remaining 25 patients had received surgical treatment of their injury.

The following inclusion criteria were considered for enrollment into the study:

1. Age 18 years and older
2. Hispanic from Mexican lineage
3. Spanish as mother language
4. Follow-up after unilateral fracture of foot and ankle region (OTA/AO regions 43, 44, and 8)^[8]
5. Weight bearing as tolerated at the time of follow-up
6. Wearing regular shoe wear at the time of follow-up
7. Willing to provide informed consent.

The following exclusion criteria were used while enrolling patients for the study:

1. Less than 18 years of age
2. Unable to read and write in the Spanish language
3. Bilateral injuries to foot and ankle region
4. Nontraumatic foot and ankle problems
5. Injuries resulting in below knee amputation
6. Mentally and/or intellectually challenged
7. Prisoners
8. Unwilling to participate in study.

2.2. Data collection

From April 6, 2016, to November 30, 2016, 36 enrolled patients were given a first set of questionnaires which included the Hispanic version of the AAOS-FAOQ^[7] and the validated Spanish version of the SF-36.^[9,10] Patients were instructed to complete these questionnaires during their clinic visit or at home. Patients who preferred to complete the questionnaires at home were given a labeled and stamped envelope to return their completed questionnaires. A second set of questionnaires consisting of the Hispanic versions of the AAOS-FAOQ and the SF-36, FFI, and FHSQ in Spanish was mailed to patients 1 week later. Patients were given a labeled and stamped envelope to return the questionnaires upon completion. Upon receipt of the second set of questionnaires, patients were given a \$40 gift card for study participation.

The AAOS-FAOQ is a self-administered validated questionnaire that has been released by the American Academy of Orthopaedic Surgeons (AAOS) for use by individuals and

organizations without copyright restrictions. The questionnaire and electronic scoring system were accessed through the AAOS website (www.aaos.org). In this study, we used the Hispanic version of the AAOS-FAOQ, which has undergone a rigorous translation, cross-cultural adaptation, and validation process.^[7] The *Global Foot and Ankle Scale* portion of the AAOS-FAOQ questionnaire surveys 20 items and highlights areas regarding pain, function, swelling and other components related to foot and ankle wellbeing. Standardized scores for the *Global and Foot Ankle* questionnaire range from 0 to 100; “0” representing total disability and “100” signifying the least disability. The *Shoe Comfort Scale* consists of an additional 5 questions addressing the patient’s comfort regarding different shoe types and has a standardized range of 0 to 100; “0” representing total discomfort and “100” signifying total satisfaction. The General population mean scores for *The Global Foot and Ankle Scale* and *The Shoe Comfort Scale* are 93.19 (± 12.33) and 73.87 (± 29.51), respectively.^[11]

The SF-36 is a standardized scoring system to assess general health-related quality of life.^[12] It has been widely used in clinical trials and has a documented Spanish translation that has been validated in the literature.^[9,10] The SF-36 consists of 36 questions and allows for 8 subscale calculations including physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. The SF-36 also allows for calculation of 2 summary measures, the Physical Component Summary (PCS) and the Mental Component Summary.

The foot function index (FFI) consists of 23 questions.^[13,14] Each question is answered on a visual analog scale ranging from 0 to 9. A percentage score is calculated and the final score ranges from 0 to 100. A Spanish translation, cross-cultural adaptation, and validation has been published by Paez-Moguer et al.^[5]

The FHSQ is a validated outcome measure consisting of 19 questions on foot health.^[15,16] It is designed to assess quality of life related to overall foot health. The domains pain, function, general health, and footwear are reported on a numerical scale from 0 (worst health status) to 100 (best health status). The score is reported for 8 subscales including foot pain, foot function, footwear, general foot health, general health, physical activity, social capacity, and vigor. The English version of this outcome measure has undergone a rigorous validation process.^[15,16] Recently, a validated Spanish translation has been published, which was used in this study.^[6]

2.3. Data analysis

The SF-36 was scored using licensed software purchased from OptumInsight Life Sciences Inc. The AAOS-FAOQ was scored using spreadsheets obtained from the AAOS website (www.aaos.org). The FHSQ was scored using proprietary software purchased from Care Quest Pty. Ltd. The FFI was scored manually according to instructions included with the survey. Statistical analyses were performed using IBM SPSS Statistics version 20 (IBM Corp, New York, NY). The 8 subscales of FHSQ were used for analyses rather than a total summative score. Additionally, the *Global Foot and Ankle Scale* and the *Shoe Comfort Scale* of the AAOS-FAOQ were analyzed individually. The FFI was considered as a summative score. The summary measures of the SF-36, the Mental Component Summary, and PCS, were used for statistical analysis. The parametric Pearson Correlation Coefficient was calculated between scales/scores when the following assumptions were met: a linear relationship

Table 1**Correlation of the Spanish AAOS-FAOQ with the SF-36v2, FHSQ, and FFI.**

	SF-36v2		FHSQ							FFI	
	PCS	MCS	FP	FF	FW	GFH	GH	PA	SC	VI	FFI
AAOS-FAOQ Global Foot and Ankle Scale											
Correlation	0.718*	0.130†	0.558*	0.689*	0.193*	0.533†	0.243*	0.652*	0.469*	0.216†	-0.649*
P	<.0001	.565	.007	<.0001	.390	.011	.275	.001	.028	.335	.001

FF=foot function, FP=foot pain, FW=footwear, GFH=general foot health, GH=general health, MCS=mental component summary, PA=physical activity, SA=social capacity, SF-36v2=Short Form 36 version 2, VI, vigor.

*Spearman's Rho.

†Pearson correlation.

existed between the 2 variables, no significant outliers were present, data were approximately normally distributed, and homoscedasticity was observed.

Linear relationships, outliers, and homoscedasticity were assessed with scatterplots, box plots, and other visual representations of the data. A normal distribution was calculated using the Shapiro–Wilk Test. If the Shapiro–Wilk *P*-value is < .05 then the data cannot be assumed to follow a normal distribution. When this occurred, a nonparametric Spearman's Rho/Rank Correlation test was performed. Significant skewness and kurtosis values as well as the presence of outliers can also signify that a nonparametric test is preferable to a parametric one. Skewness values should fall between -1 and 1 and kurtosis values should fall between -2 and 2 to avoid potentially distorted data.

Correlation analysis was performed as outlined above to examine the test–retest reliability of the AAOS-FAOQ. Cronbach's alpha coefficient was also calculated to determine the reliability of the Global Foot and Ankle Scale and the Shoe Comfort Scale.

3. Results

Of the 36 patients enrolled, 20 returned both sets of questionnaires and 2 patients returned one set of questionnaires. These 22 patients were used for our data analysis.

The Global Foot & Ankle Scale of the Hispanic AAOS-FAOQ showed a significant correlation with the PCS of the SF-36 (Table 1). In addition, it correlated significantly with 6 of the 8 subscales of the FHSQ. Moreover, there was a significant correlation between the Global Foot & Ankle Scale of the Hispanic AAOS-FAOQ and the FFI. In contrast, the Shoe Comfort Scale of the Hispanic AAOS-FAOQ was only significantly correlated with 1 subscale of the FHSQ, but did not show any significant correlation with any of the remaining scoring systems.

Twenty patients returned both sets of questionnaires and which allowed for calculating the test–retest reliability. The Hispanic AAOS-FAOQ Global Foot & Ankle Scale showed a strong test–retest reliability ($r=0.736$, $P<.0001$). The Hispanic AAOS-FAOQ Shoe Comfort Scale also showed a strong test–retest reliability ($r=0.875$, $P<.0001$). A Spearman's Rho/Rank Correlation coefficient was calculated for these data.

Each set of the AAOS-FAOQ Global Foot & Ankle Scale produced high Cronbach's alpha values (0.928 and 0.919). The internal consistency of a scale increases as Cronbach's alpha approaches 1.00. Therefore, values of 0.928 and 0.919 show strong reliability. Each set of the AAOS-FAOQ Shoe Comfort Scale produced low Cronbach's alpha values (0.437 and 0.264).

Any value below 0.5 is generally unacceptable, as values between 0.65 and 0.8 are typically considered the minimum necessary for a reliable scale.

4. Discussion

With the growing proportion of Hispanics in the US population, it is necessary for research scientists and clinicians to include more Mexican-Hispanic individuals in clinical trials to adequately represent the US population.^[1,2] However, lack of validated outcome measures in Spanish continues to represent a potential barrier for inclusion.^[3] The AAOS-FAOQ has been shown to be a valid survey tool in different languages and cultures.^[4,7,17–19] A recently published study offered an appropriate translation, cross-cultural adaptation, and validation in Mexican Hispanics.^[7] The purpose of the current project was to further evaluate the validity of the Hispanic AAOS-FAOQ by examining correlations with other foot and ankle scoring systems that are available in Spanish, such as the FFI and the FHSQ. Similar to prior studies, our study found strong correlations between the Hispanic AAOS-FAOQ and the SF-36. Additionally, we found strong correlations between the Hispanic AAOS-FAOQ and the FFI and FHSQ. In addition, we identified a strong test–retest reliability as well as a strong internal consistency of the Hispanic AAOS-FAOQ Global Foot and Ankle Scale. These findings support the validity and use of the Hispanic AAOS-FAOQ.

We also acknowledge that our study has its limitations. Our validation is based on strong correlations with multiple independently validated foot and ankle outcome measures. Other measures of validation such as minimum detectable difference and minimum clinically important difference were not analyzed in this instance. To the best of our knowledge, these data measures are not available for the AAOS-FAOQ in any language including English. We would also like to emphasize that our study was specifically performed in Mexican Hispanics with traumatic foot and ankle injuries. We are therefore unable to make any statements on the validity of this outcome measure among other populations. Our study was performed in a relatively small sample size as compared to previous publications. However, we would like to emphasize that the strong correlations that were identified in our patient population dispute the need of further testing in larger populations.

We find that the psychometric variables measured in this study are in line with available reports from the literature on the AAOS-FAOQ. González-Sánchez et al^[4] examined a Spanish translation of the AAOS-FAOQ in podiatric patients in Spain. They found a correlation of 0.799 ($P\leq.001$) between the FFI and the AAOS-FAOQ Global Foot and Ankle Scale. They also found significant correlations with the subscales of the FHSQ. Test–retest

reliability has been described by a study on the English version of the AAOS-FAOQ which found a reliability of 0.79 and 0.87 for the Global Foot & Ankle Scale and Shoe Comfort Scale, respectively.^[20] One study examining the validity of the Korean translation of the AAOS-FAOQ in 181 patients found a test-retest reliability as high as 0.999; however, the retest interval was only 24 hours.^[18] In contrast, our study used a one-week interval which we feel is appropriate. Similar, to previous investigations, we did not find significant correlations between the Shoe Comfort Scale and the other outcome measures used in this study. This suggests the Shoe Comfort Scale to be a very specific outcome measure with a strong focus on foot wear problems rather than an outcome measure to assess the general foot function.

5. Conclusions

In summary, this study further validates the Hispanic version of the AAOS-FAOQ by showing a strong correlation with the FFI and FHSQ. The use of this outcome measure allows Mexican Hispanics to be included in clinical studies related to foot and ankle injuries.

6. Conflict of interest statement

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CFA and NAMG declare that they have no conflict of interest.

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