

Danish translation of the Foot and Ankle Outcome Score

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ABSTRACT

INTRODUCTION: The Foot and Ankle Outcome Score (FAOS) is a standardized instrument used to report on injury-specific clinical status following foot- and ankle-related problems. The primary aim of this study was to translate and conduct a cross-cultural adaptation of the FAOS into a Danish setting, including testing absolute agreement and the test-retest reliability of the questionnaire.

METHODS: Translation of the FAOS questionnaire was carried out according to the Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes Measures: report of the Society for Pharmacoeconomics and Outcomes Research Task Force for Translation and Cultural Adaptation.

RESULTS: No major disagreements were observed between the original and translated version of the FAOS questionnaire during the translation procedure and cognitive interview. A total of 51 patients were included in the reliability testing procedure. The test-retest reliability was high: pain interclass correlation coefficient (ICC) 0.88 (95% confidence interval (CI): 0.79-0.93), symptoms ICC 0.95 (95% CI: 0.91-0.97), activities of daily living ICC 0.95 (95% CI: 0.90-0.97), sport ICC 0.95 (95% CI: 0.90-0.97) and quality of life ICC 0.94 (95% CI: 0.90-0.97). The Bland-Altman plots showed good agreement between test and retest for all five subscales.

CONCLUSIONS: The translation of the FAOS questionnaire into Danish was done in accordance with best practice and has excellent repeatability in patients treated for ankle fractures.

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Fractures of the ankle are one of the most common bone injuries [1] with a reported incidence between 107 and 187 per 100,000 persons annually in Europe [2]. A bimodal distribution with increased likelihood of fracture in the adolescent and senior years is observed, with younger males and older females being more likely to fracture their ankles [3]. The management of ankle fractures includes immobilization in a cast, or surgical treatment with internal or external fixation of the fracture. The fracture and subsequent treatment increase the risk of ankle joint stiffness, pain and limitation in activity [4].

During the past decades, injury-specific evaluation methods, including patient-reported instruments, have

become popular following musculoskeletal injuries [5-7]. Injury-specific questionnaires may be more sensitive in capturing disability following musculoskeletal injuries than general health-related quality of life (HRQOL) questionnaires such as Eq5d or SF-36 [8].

However, the literature lacks injury-specific questionnaires capturing the patient-evaluated importance of disability following ankle fractures. This may limit the ability to capture the patient-perceived outcome. Currently, a single injury-specific questionnaire, the Olerud-Molander Ankle Score (OMAS) has been validated in patients treated for ankle fracture [9].

However, the OMAS score lacks complete evaluation of the patient-perceived importance of disability and impact on HRQOL. The Foot and Ankle Outcome Score (FAOS), the main focus of which is patient-perceived disability and its impact on HRQOL, may better capture this.

Moreover, the use of OMAS in elderly patients could be questioned because rather than fracture-related disability, it includes items like “jumping”, “running”, and “squatting”, which are all functions that might be difficult to perform because of advanced age.

The FAOS is a standardized instrument used to report on injury-specific clinical status following foot- and ankle-related problems [10]. The questionnaire includes 42 questions each scored 0-4. A total score of 0-100 is calculated for each of the following five subscales: Pain, Activity of daily living (ADL), Symptoms, Sport, and HRQOL. A total score of 100 indicates no symptoms and 0 indicates major symptoms [10].

The FAOS is commonly used in patients with lateral ankle instability, hallux valgus, osteoarthritis and plantar fasciitis [10, 11]. However, the FAOS had not as yet been translated into Danish or been validated in a Danish context.

The primary aim of this study was to translate and conduct a cross-cultural adaptation of the FAOS into a Danish setting including assessing the absolute agreement and the test-retest reliability of the questionnaire.

METHODS

This study was a translation, absolute agreement and test-retest reliability study.

ORIGINAL ARTICLE

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Ethical approval

The Ethics Committee for North Jutland, Denmark, stated that no approval was needed as the study included no patient intervention. The head of the Orthopaedic Department of Aalborg University Hospital approved the study. Informed consent was obtained from all patients before their inclusion. The study was approved by the Danish Data Protection Agency (R. no. 2008-58-0028). The study complied with the 1993 Declaration of Helsinki.

Procedure of translation

Translation of the FAOS questionnaire was carried out according to the guidelines published by Beaton et al [12] and the Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation [13].

The steps in translation procedure were as follows

1. Permission to translate the original Swedish FAOS questionnaires was obtained from the developer, Professor Ewa M. Roos, University of Southern Denmark, Odense, Denmark.

2. Forward translation. Two independent, bilingual Danish residents (T1 and T2), with Danish as their first language and Swedish as their second language, translated the original Swedish version of the FAOS questionnaire into Danish. T1 was a senior medical doctor (AMB), whereas T2 was not a healthcare professional, but a zoo-keeper.

3. Synthesis. Meetings with translators (T1, T2) to address discrepancies in the forward translation. Unresolved queries were cleared with the original developer, as needed.

4. Back translation: The final version of the forward-translated versions of the Danish questionnaire was translated back into Swedish by two Danish residents whose birth language was Swedish (BT1 and BT2). BT1 was a senior physiotherapist (ABI), and BT2 had no medical background, but was a technical engineer. BT1 and BT2 were both blinded to the original Swedish version of the FAOS questionnaire.

5. The back-translated versions were compared with the original FAOS version to ensure conceptual equivalence; discrepancies vis-à-vis the original FAOS version were resolved between BT1 and BT2.

6. The expert committee produced a pre-final version of the Danish version of the FAOS. The expert committee consisted of the back- and forward translators, a research physiotherapist, a senior orthopaedic surgeon, and a language-competent medical professional. All members of the expert committee approved the Danish version of the FAOS.

7. Cognitive interviews with six participants were conducted to test the pre-final version of the Danish FAOS. A research physiotherapist and a senior orthopaedic surgeon conducted the interviews. Two clinical physiotherapists (both skilled in treating ankle injuries following orthopaedic surgery), two orthopaedic surgeons (both skilled in treating ankle injuries), and two patients with a previous fracture of the ankle were interviewed. The interviews varied 10-20 min. Before the interview, each participant completed the questionnaire to establish how he or she had interpreted the items and responses.

8. The results of the cognitive interviews were reviewed, and a final translated version of the Danish FAOS was constructed. The final translated version was proofread and checked for errors of spelling and grammar; then the layout was finalized and approved by the expert committee.

Test-retest procedure of reliability Patients included in the test-retest procedure were recruited from the Orthopaedic Trauma Outpatients Clinic at Aalborg University Hospital, Denmark. Patients treated for a fracture of the ankle (AO type 43) were included [14]. Patients with multi-trauma, bilateral fractures and patients with pathological fractures were excluded. Patients who were unable to participate due to mental disabilities were also excluded. Basic characteristics regarding age and gender were obtained.

A group of 51 patients were included for the absolute agreement and test-retest reliability procedure of the FAOS. Patients treated for an ankle fracture (AO type 43) between 2011 and 2013 were identified in the hospital medical records system. Patients were asked by mail to complete the questionnaire and return it by mail. Two weeks later, all responders were asked to complete the questionnaire again. Non-responders of the second test were reminded by telephone after two weeks without a response. Patients who did not respond after the telephone call were excluded.

Statistics

Assuming a power of 0.80, an expected interclass correlation coefficient (ICC) of 0.90 and a significance level of 0.05, calculations showed that a sample of 49 patients was needed. To account for non-respondents, 51 patients were included in the test-retest procedure for reliability.

The assumption of a normal distribution in variables was checked visually by QQ plots. Continuous data were expressed as means and standard deviations (SD). Categorical data were expressed as frequencies.

The test-retest reliability was assessed by the calculation of ICC, and 95% confidence intervals (CI) are

given. ICC values were interpreted as follows: 0.0-0.3 low, 0.30-0.70 moderate, 0.70-1.0 high [15]. Bland-Altman plots were used to assess agreement and heteroscedasticity [16]. The statistical analysis was performed using SPSS (version 22).

Trail registration: not relevant.

RESULTS

Translation of the Foot and Ankle Outcome Score questionnaire

The forwarded translation showed only minor differences between T1 and T2. Differences were primarily related to the differences in the use of synonyms between Swedish and Danish. Moreover, minor differences were observed in the word order in the translation between T1 and T2.

The back translation was used as a quality control of the translation. No major differences were observed between BT1 and BT2 and the original version. Minor differences were observed, primarily related to the use of synonyms of the ankle between Danish and Swedish.

Cognitive interview

The cognitive interviews revealed minor difficulties in the medical groups. Differences were related primarily to cross-cultural adaptation; therefore, a few changes were made to the wording in four questions (S6, P2, A3, and Q4). No difficulties were observed related to the understanding and comprehension of the Danish FAOS version. The cognitive interviews revealed no difficulties in the non-medical patient group. The final Danish version of the FAOS was developed.

Reliability

A total of 51 patients took part in the reliability testing procedure. The study population consisted of 32 females and 19 males. The mean age was 57.8 years (SD = 17.5), ranging 18-94 years. All patients were asked by mail to complete the Danish version of the FAOS and return it by mail. Two weeks later all responders were asked to complete the questionnaire again.

Five dropouts were recorded between the first and the second request.

The mean FAOS scores for the five subscales were: pain 83.2 (95% CI: 78.6-87.8), symptoms 71.3 (95% CI: 65.1-77.6), ADL 85.3 (95% CI: 80.1-90.5), sport 68.8 (95% CI: 58.0-75.8) and QOL 63.7 (95% CI: 56.0-71.4).

The test-retest reliability was high: pain ICC 0.88 (95% CI: 0.79-0.93), symptoms ICC 0.95 (95% CI: 0.91-0.97), ADL ICC 0.95 (95% CI: 0.90-0.97), sport ICC 0.95 (95% CI: 0.90-0.97) and QOL ICC 0.94 (95% CI: 0.90-0.97).

The Bland-Altman plots showed good agreement

between test and retest for all the five subscales (Figure 1). No significant differences from test to retest in any of the five subscales were observed showing a mean difference below 2 FAOS points and $p > 0.31$.

DISCUSSION

Researchers should avoid creating new questionnaires if questionnaires measuring the construct of interest already exist in another language [17]. Rather than creating new questionnaires, translation and cross-cultural adaptation are recommended [17].

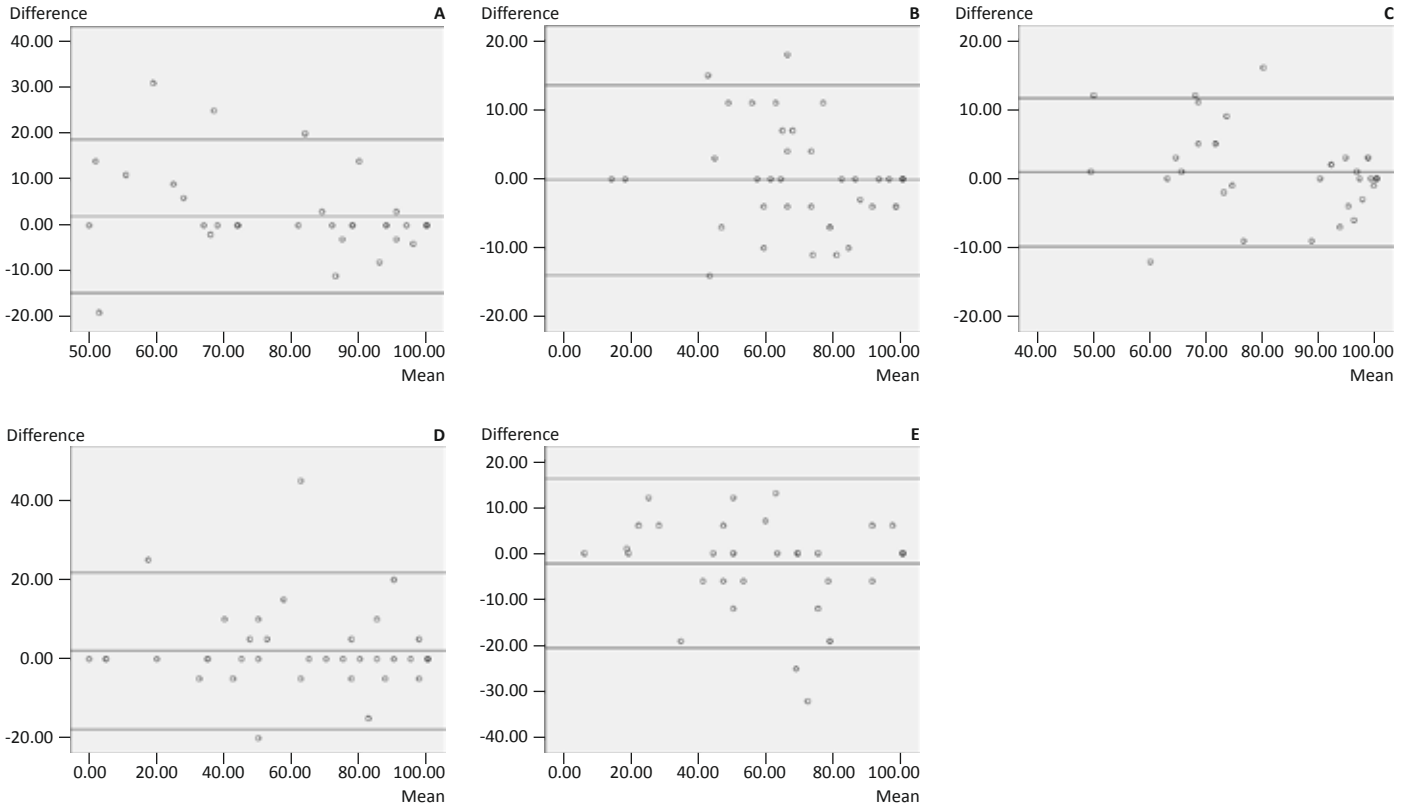
This study used a standardized and internationally recommended translation procedure to produce the Danish version of the FAOS. The rigorous method used in the translation procedure and further cross-cultural adaptation into a Danish context with cognitive interviews increase the validity of the Danish version of the FAOS. During the translation procedure, no major disagreements between the original Swedish version of the FAOS and the produced Danish version were observed. Moreover, the questionnaire was found to be highly reliable. In contrast, reporting the construct validity of the Dutch FAOS from a mixed group of ankle patients, van den Akker-Scheek et al [18] reported moderate-to-high correlations between FAOS and other questionnaires. However, the present study does not include validation or knowledge of responsiveness of the Danish FAOS, which need to be addressed in the future.

The FAOS is a structure-specific questionnaire originally developed to assess patient-reported outcome regarding a variety of foot- and ankle-related problems [10]. The FAOS questionnaire evaluates patient-perceived disability of the ankle which is in contrast to other ankle structure-specific questionnaires such as the Foot Function Index score and the Lower Extremity Functional Scale. The FAOS has already been used in many different patient groups such as lateral ankle instability, Achilles tendinosis, plantar fasciitis and ankle fractures [10, 11, 19]. Validity and/or reliability have been studied in patients following ankle ligament reconstructions, osteoarthritis of the ankle joint, in patients with hallux valgus [11] and in a group of patients with mixed foot/ankle problems [18]. To the author's knowledge, validity and reliability results for patients treated for an ankle fracture are missing in the literature. This study showed excellent absolute agreement and test-retest reliability in patients treated for an ankle fracture, indicating that the FAOS may be useful in the evaluation of patient-reported outcome following ankle fractures. However, Mani et al [20] concluded that the FAOS is a weak instrument for evaluation of ankle osteoarthritis. Ankle osteoarthritis constitutes a degenerative progressive disorder with a highly variable aetiology.

The use of structure-specific measuring tools in


 FIGURE 1

Bland-Altman plots showing the agreement between test and retest for all the five subscales of the Foot and Ankle Outcome Score. The plot depicts the differences against the mean including 95% confidence intervals (–). A. Pain. B. Symptoms. C. Activity of daily living. D. Sport. E. Health-related quality of life.



combination with generic health questionnaires such as the SF-36 and the Eq5d may improve the understanding of outcomes following ankle injuries. In other lower-extremity injuries, the use of structure-specific questionnaires has been recommended as it may be more sensitive in capturing structure-specific outcomes [8].

The strength of translation and culture-adaptation of internationally used questionnaires is that this approach enables comparison of health-research across different countries. Furthermore, the strength of publishing translated questionnaires such as the Danish version of the FAOS is that doing so should help to avoid multiple versions of the same measurement. Moreover, the high degree of transparency associated with the translation and cross-cultural adaptation procedure verifies that the current Danish version is of a high quality. The drop-out of five participants might render the study slightly underpowered, which represents a limitation. Furthermore, this study does not include a validation and knowledge of responsiveness of the FAOS, which is a limitation and needs to be addressed in future research.

CONCLUSIONS

The translation of the FAOS questionnaire into Danish was done in accordance with best practice and has excellent repeatability in patients treated for an ankle fracture.

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