Review

Patient-Reported Outcome Measures for Patients with Diabetes Mellitus Associated with Foot and Ankle Pathologies: A Systematic Review

Ana Belen Ortega-Avila 1,*,†, Pablo Cervera-Garvi 1,‡, Laura Ramos-Petersen 1, Esther Chicharro-Luna 2,* and Gabriel Gijon-Nogueron 1,3

1 Department of Nursing and Podiatry, Faculty of Health Sciences, University of Malaga, Arquitecto Francisco Penalosa 3, Ampliación de Campus de Teatinos, 29071 Malaga, Spain; pcervera@uma.es (P.C.-G.); lauraramos.94@hotmail.com (L.R.-P.); gagijon@uma.es (G.G.-N.)
2 Department of Behavioral Sciences and Health, Miguel Hernández University, San Juan de Alicante, 03550 Alicante, Spain; ec.luna@goumh.umh.es
3 Instituto de Investigación Biomédica de Málaga (IBIMA), 29010 Málaga, Spain
* Correspondence: anaortavi@uma.es; Tel.: +34-658-138-759
† These authors contributed equally to the study.

Received: 27 December 2018; Accepted: 24 January 2019; Published: 27 January 2019

Abstract: Background: Diabetes mellitus (DM) is a chronic and complex disease, which is a major cause of morbidity and mortality and affects all age groups. It commonly produces secondary effects on the foot, often making daily activities impossible. Patient-reported outcome measures (PROMs) provide a standardised method of obtaining patients’ outlooks on their functional status and wellbeing. Although many instruments have been proposed for obtaining data on persons with DM whose feet are affected by the disease, in many cases the psychometric properties of the instrument have yet to be established. The principal objective of our review was to identify PROMs specific for patients with DM affecting the foot and ankle and to evaluate the psychometric properties and methodological quality of these instruments. Methods: In this systematic review, we investigate studies (published in English or Spanish) based on the use of one or more PROMs specific to foot and ankle pathologies for patients with DM (type I or II). To do so, the databases PubMed, Scopus, CINAHL, PEDro and Google Scholar were searched for studies that analysed psychometric or clinimetric properties in this respect. These were assessed according to Terwee or COSMIN criteria. Results: Of the 1016 studies identified in the initial search, only 11 were finally included in the qualitative review. Analysis according to Terwee and COSMIN criteria showed that the Foot Health Status Questionnaire (FHSQ) presented the greatest number of positive values. Conclusions: The FHSQ is the highest-quality PROM currently available for the foot and ankle, for patients with DM.

Keywords: diabetes mellitus; foot; ankle; psychometrics; patient-reported outcome measures; systematic review

1. Introduction

In 2014, according to the World Health Organization (2018), 422 million adults suffered from DM worldwide, and its prevalence had almost doubled since 1980, rising from 4.7% to 8.5%. The disease, although non-communicable, is taking the form of a global epidemic and poses a growing threat to both affluent and non-affluent societies [1]. It is both chronic and complex [2], and is currently the world’s leading cause of morbidity and mortality, affecting all age groups [3].

DM is subdivided into several types, but Types I and II (TIDM and TIIDM) are the most prevalent [4]. During the course of the disease, patients may be significantly affected in terms of
reduced physical activity, psychological consequences and chronic clinical complications, requiring significant medical care [5]. In the majority of cases, its symptoms are associated with localised complications, especially in the foot, and approximately 15% of patients eventually develop a diabetic foot ulcer [6].

The diabetic foot syndrome (DFS) is characterized by the presence of infection and/or ulcer, and/or deep tissue destruction as a result of underlying neuropathy and different severity ischemia from peripheral vascular disease. Diabetic patients have up to a 25% lifetime risk of developing diabetic foot syndrome [7].

Symptomatic Peripheral Artery Disease (PAD) is about twice as common among patients with diabetes mellitus than in those without. In patients with diabetes, for every 1% increase in haemoglobin A1c level, there is a corresponding 26% risk increase for PAD. PAD is more aggressive in patients with diabetes, as compared with non-diabetics. Earlier large vessel involvement and more distal symmetrical neuropathy occur in PAD. The need for major amputation is five to ten times higher in patients with diabetes than in those without diabetes [8].

The International Diabetes Foundation has termed the disease a substantial threat to public health, affecting not only patients but also their families. Patients often lose sensitivity in the extremities, especially the feet, which may result in ulceration, difficulty in walking, amputation (the most devastating complication of DFS). It is estimated that 5% to 15% of patients with foot ulcers will require amputation, with major lower limb amputations accounting for 50% of these amputations. Over 50% of the amputees will undergo another amputation within five years, (of whom 50% will not survive the next five years) [7], prolonged hospital stays and recurrent ulcers, producing high treatment costs and causing major difficulties for public health systems. These factors may also make patients less able to work, provoke early retirement and lead to difficulty in performing the activities of daily life, generating feelings of helplessness, frustration, vulnerability and a poor body image [9].

Many outcome measures have been developed to assess the status of patients with DM, including the Diabetes Management Self-Efficacy Scale (DMSES) [10], the Patient-Perceived Difficulty in Diabetes Treatment Scale (PDDT) [11], Environmental Barriers to Diabetes-Regimen Adherence (EBAS) [12], the Diabetes Health Profile for DM Type II (DHP-18) [13], the Diabetes Distress Scale (DDS) [14], the Summary of Diabetes Self-Care Activities Measure (SDSCA) [15] and the Personal Diabetes Questionnaire (PDQ) [16].

In addition, various systematic reviews have been conducted on patient-reported outcome measures (PROMs) for DM, such as Corathers et al. (2017) for pyschosocial PROMs in children and adolescents with DM [9], and Breslow et al. (1987) on the psychometric properties and theoretical grounding of instruments for evaluating self-care in persons with TIIDM [17]. Other studies have addressed the question of PROMs for patients with ankle/foot pathologies, but not specifically related to DM [18]. However, to our knowledge no previous review has been made of PROMs for patients with DM with specific reference to its impact on the foot and ankle, despite this extremity being the most commonly affected by DM and subject to major complications.

In view of these considerations, the main aim of the present review is to identify PROMs that are specific for DM affecting the foot and ankle and to evaluate their psychometric properties and methodological quality.

2. Material and Methods

2.1. Design

A systematic review was carried out to evaluate PROMs specific to the foot and ankle for patients with DM. Review registration number: CDR42019115078.
2.2. Search Strategy

Studies were selected for analysis, in accordance with the PRISMA guidelines [19], from a search carried out on the following databases: PubMed, Scopus, CINAHL, PEDro and Google Scholar. No time limits were imposed on the search. The search was concluded in September 2018. The search strategy obtained all the psychometric properties described by Terwee et al. [20], including construct search (patient-reported outcomes specific to the foot and ankle), population search (diabetes mellitus), instrument search (questionnaires, scales, test), measurement properties and exclusion filters.

The following search terms were used, together with the operators “OR” and “AND”: diabetes mellitus, patient-reported outcomes, foot, feet, ankle, pain, disability, funct*. (Supplementary Materials).

2.3. Inclusion Criteria

- Types of participants: Patients with diabetes mellitus (TIDM or TIIDM), aged >18 years. The studies should be specifically focused on the foot and ankle.
- Types of studies: Psychometric validation studies on patient-reported outcome measures, published in English or Spanish.
- Types of outcomes: Psychometric or clinimetric properties based on criteria according to Terwee (content validity, internal consistency, criterion validity, construct validity, reproducibility, agreement, reliability, responsiveness, floor/ceiling effect and interpretability) or COSMIN (structural validity, internal consistency, reliability, measurement error, hypothesis testing for construct validity, cross cultural validity/measurement invariance, criterion validity and responsiveness).

2.4. Exclusion Criteria

- Types of studies: Studies using questionnaires without evidence supporting their validity or reliability.

2.5. Quality Appraisal

The updated COSMIN checklist was used to evaluate the methodological quality of the studies performed to investigate the measurement properties of a PROM [21]. This standard can be used either to assess the methodological quality of studies of PROMs [22] or to compare the measurement properties of several such instruments in a systematic review [23]. Measurement properties are considered with respect to three domains: reliability, validity and responsiveness. Each property contains various items, evaluated on a 4-point Likert scale as poor, fair, good or excellent. The “worst score counts” approach was applied to derive a final rating for the PROM [23].

In addition, the studies were assessed in terms of Terwee’s psychometric properties [24]: content validity, internal consistency, criterion validity, construct validity, reproducibility (agreement and reliability), responsiveness, floor/ceiling effects and interpretability. Each issue was rated as positive “+” (adequate description or value or measure or argument related to psychometric property), negative “−” (inadequate or values under the accepted standards in each psychometric property), indeterminate “?” (doubtful methods or measures or design) or absent “0” (no information available about a psychometric property), except for responsiveness, which was rated only as present/absent.

2.6. Study Selection

Two blinded reviewers (XXX) (XXX) evaluated the search results, and all the reference lists were independently reviewed to ensure that the inclusion criteria were met. Disagreements were resolved by discussion between the two evaluators, or if consensus was not possible, further opinion was sought (XXXX) (XXX).
2.7. Data Extraction

The following data were extracted from each study using a standardised template: full title, country, year of publication; dimensions and number of items; population used for the validation process; psychometric properties by Terwee’s criteria with a positive rating; cross-cultural adaptation into different languages of each questionnaire; methodological quality according to COSMIN.

3. Results

A potential 1016 studies were identified, but of these 319 were duplicates across the different databases. The remaining 697 were screened against the inclusion/exclusion criteria, using the titles, abstracts and keywords. This process led to 631 studies being discarded, in most cases because they were not psychometric validation studies of patient-reported outcomes or because they were not focused on the foot and ankle. Application of the quality appraisal filter led to the exclusion of a further 52 studies. After a detailed reading of the remaining 14 papers, three were excluded, and 11 were judged appropriate for the final qualitative review. Figure 1 shows the PRISMA flow diagram for the studies included in this review. The characteristics of each paper are summarised in Tables 1–5.

Figure 1. PRISMA flow diagram [19]. For more information, visit www.prisma-statement.org.
Table 1. Instrument included.

| Acronym | Full Title | Author | Country |
|---------|------------|--------|---------|
| NeuroQol | Neuropathy Quality of Life Instrument | Loretta Vileikyte et al. | UK and USA |
| DFS-SF | Diabetic Foot Ulcer Scale–Short Form | Carla M. Bann et al. | USA |
| CWIS | Cardiff Wound Impact Schedule | Patricia Price and Keith Harding | UK |
| AOFAS-DFQ | American Orthopaedic Foot and Ankle Society | Vibhu Dhawan et al. | USA |
| FAAM | Foot and Ankle Ability Measure | RobRoy L. Martin et al. | USA |
| Q-DFD | Questionnaire for Diabetes Related Foot Disease | Shan M Bergin et al. | Australia |
| DHPSC | Diabetes Health Promotion Self-Care Scale | Ruey-Hsia Wang et al. | Taiwan |
| FCBS | Foot Self-Care Behavior Scale | Yen-Fan Chin and Tzu-Ting Huang | Taiwan |
| DFSQ-UMA | Diabetic Foot Self-care Questionnaire of University of Malaga | Emmanuel Navarro et al. | Spain |
| HRQLQDFU | Health Related Quality of Life Questionnaire in Diabetic Foot Ulcer Patients | Ramya Kateel et al. | India |
| FHSQ | Foot Health Status Questionnaire | Patricia Palomo-López et al. | Spain |

Table 2. Characteristic of all instruments.

| Year | Dimensions and Number of Items | Population Used for Validation | Psychometric Properties | Cross-Cultural Adaptation |
|------|--------------------------------|--------------------------------|-------------------------|--------------------------|
| NeuroQol [25] | 6 dimensions: painful symptoms and paresthesia, symptoms of reduced/lost feeling in the feet, diffuse sensory motor symptoms, limitations in daily activities, interpersonal problems and emotional burden 28 items | 418 patients with diabetic peripheral neuropathy n: 296 male (70.8%) n: 122 female (29.2%) Mean age: 61.76 years | - Internal consistency: Cronbach’s alpha (0.86–0.95) | Spanish [26], Chinese [27], Brazilian [28] |
| DFS-SF [29] | 6 dimensions: leisure, physical health, dependence/daily life, negative emotions, worried about ulcers/feet, bothered by ulcer care 29 items | 218 (diabetic with foot ulcer) and 108 (placebo) patients: n: 241 male (74%) n: 85 female (26%) Age 27–87 years | - Internal consistency: Cronbach’s alpha (0.74–0.94) | Greek [30], Polish [31], Chinese [32] |
| CWIS [33] | 3 dimensions: physical symptoms and daily living, social life and well-being 26 items + overall and individual rating of HRQoL | 87 with leg ulceration and 48 with diabetic foot ulceration n: 74 male (55%) n: 61 female (45%) Mean age 65.9 years (43–85.5) | | Canadian [34], Chinese [34], French, German, English (US) [34], Sinhala [35], Swedish [36], Brazilian [34] |
### Table 2. Cont.

| Year | Dimensions and Number of Items | Population Used for Validation | Psychometric Properties | Cross-Cultural Adaptation |
|------|--------------------------------|--------------------------------|-------------------------|---------------------------|
| 2005 | 6 dimensions: general health, care, worry, sleep, emotion and physicality | 57 patients diagnosed with Charcot arthropathy <br> n: 25 male (37.8%) <br> n: 33 female (42.2%) <br> Mean age: 57.5 years (37.7–80.6) | Test-retest 0.77 | Dutch [38], German [39], Italian [40], Persian [41], Turkish [42] |
| 2009 | 2 dimensions: activities of daily living and sports 21 + 8 items | 83 patients with diabetes and foot and ankle problems <br> n: 45 male (54%) <br> n: 38 female (46%) <br> Mean age: 60.3 years (21–93) | - Internal consistency: Cronbach’s alpha 0.88 <br> - Reliability: ICC 0.94 <br> - Floor and ceiling effects: 4.59% | Brazilian [43], Chinese [44], Dutch [45], French [46], German [47], Italian [48], Japanese [49], Persian [50], Thai [51], Turkish [52], Spanish [53] |
| 2009 | 5 dimensions: peripheral neuropathy, peripheral vasculopathy, foot ulceration, amputation and foot deformity 12 items | 31 patients with diabetes <br> n: 15 male (48%) <br> n: 16 female (52%) <br> Mean age: 64 years (45–80) | | Spanish [54] |
| 2012 | 7 dimensions: interpersonal relationships, diet, blood glucose self-monitoring, personal health responsibility, exercise, adherence to the recommended regimens, and foot care 26 items | 489 patients with Type II diabetes <br> n: 243 male (49.7%) <br> n: 246 female (50.3%) <br> Mean age: 58.1 years | - Internal consistency: Cronbach’s alpha 0.88 <br> - Reliability: ICC 0.94 <br> - Floor and ceiling effects: 4.59% | |
| 2013 | 1 dimension 7 items | 295 patients with diabetes <br> n: 151 male (51.2%) <br> n: 144 female (48.8%) <br> Mean age: 66.93 years | - Internal consistency: Cronbach’s alpha 0.73 <br> - Reliability: test-retest 0.92 | Mexican [55] |
| 2015 | 3 dimensions: self-care, foot care, and footwear and socks 16 items | 209 with diabetes (48 type I and 161 type II) <br> n: 101 male (48%) <br> n: 108 female (52%) <br> Mean age: 57.78 years (male) and 64.66 years (female) | - Internal consistency: Cronbach’s alpha 0.89 <br> - Reliability: ICC 0.89–0.92 | |
| 2017 | 6 dimensions: physical health, daily activity, social, physical symptoms, emotional and financial 20 items | 10 patients with diabetic foot ulcers <br> n: 7 male (70%) <br> n: 3 female (30%) <br> Mean age: 65 years | - Internal consistency: Cronbach’s alpha 0.86 | |
| 2018 | 6 dimensions: foot pain, foot function, footwear, general foot health, general health, social capacity, physical activity, and vigour 17 items | 62 patients (31 type I and 31 type II) <br> n: 22 male (35.5%) <br> n: 40 females (64.5%) <br> Mean age: 59 years (30–86) | - Internal consistency: Cronbach’s alpha 0.89–0.95 <br> - Reliability: ICC 0.74–0.92 | Brazilian [60], Spanish [61] |

N: Number of subjects; ICC: Intraclass correlation coefficient.
Table 3. Summary of the assessment of the measurement properties of all questionnaires.

| Questionnaire       | Content Validity | Internal Consistency | Criterion Validity | Construct Validity | Reproduced bility Agreement | Reproduced bility Reliability | Responsiveness | Floor and Ceiling Effects | Interpretability | Final Assessment |
|---------------------|------------------|----------------------|--------------------|--------------------|----------------------------|-------------------------------|---------------|--------------------------|-----------------|------------------|
| NeuroQol            | +                | +                    | -                  | -                  | ?                          | ?                            | 0             | -                        | ?               | -                |
| DFS-SF              | +                | +                    | -                  | -                  | ?                          | ?                            | ?             | 0                        | 0               | 0                |
| CWIS                | +                | -                    | -                  | -                  | ?                          | ?                            | ?             | 0                        | 0               | ?                |
| AOFAS-DFQ           | +                | -                    | ?                  | ?                  | 0                          | +                            | ?             | ?                        | ?               | -                |
| FAAM                | +                | 0                    | -                  | 0                  | 0                          | 0                            | 0             | 0                        | 0               | ?                |
| Q-DFD               | +                | 0                    | 0                  | 0                  | ?                          | -                            | 0             | 0                        | 0               | ?                |
| DHPSC               | +                | +                    | -                  | -                  | 0                          | +                            | 0             | +                        | ?               | ?                |
| FCBS                | +                | +                    | -                  | -                  | 0                          | +                            | ?             | 0                        | ?               | -                |
| DFSQ-UMA            | +                | +                    | -                  | -                  | 0                          | +                            | 0             | 0                        | 0               | ?                |
| HRQLQDFU            | +                | 0                    | 0                  | 0                  | ?                          | ?                            | 0             | ?                        | ?               | -                |
| FHSQ                | +                | +                    | ?                  | 0                  | 0                          | +                            | 0             | 0                        | 0               | ?                |

Rating: + Positive rating; ? Indeterminate rating; - Negative rating; 0 No information available.

Table 4. Detailed COSMIN rating.

| Questionnaire       | Structural Validity | Internal Consistency | Reliability | Measurement Error | Hypothesis Testing for Construct Validity | Cross-cultural Validity | Criterion Validity | Responsiveness |
|---------------------|---------------------|----------------------|-------------|-------------------|------------------------------------------|------------------------|-------------------|-----------------|
| NeuroQol            | ?                   | +                    | ?           | ?                 | +                                        | -                      | -                 | +              |
| DFS-SF              | ?                   | +                    | -           | ?                 | +                                        | ?                      | -                 | +              |
| CWIS                | ?                   | +                    | ?           | ?                 | +                                        | ?                      | -                 | -              |
| AOFAS-DFQ           | ?                   | -                    | +           | ?                 | ?                                        | +                      | ?                 | ?              |
| FAAM                | -                   | ?                    | ?           | ?                 | +                                        | ?                      | ?                 | -              |
| Q-DFD               | ?                   | -                    | ?           | ?                 | ?                                        | ?                      | ?                 | -              |
| DHPSC               | ?                   | +                    | -           | ?                 | ?                                        | ?                      | -                 | ?              |
| FCBS                | -                   | +                    | +           | ?                 | +                                        | -                      | -                 | -              |
| DFSQ-UMA            | ?                   | +                    | +           | ?                 | ?                                        | -                      | -                 | -              |
| HRQLQDFU            | -                   | +                    | ?           | ?                 | ?                                        | ?                      | ?                 | ?              |
| FHSQ                | -                   | +                    | +           | ?                 | ?                                        | +                      | ?                 | -              |

Rating: “+”: Positive rating; “?”: Indeterminate rating; “-”: Negative rating.
Table 5. Methodological quality scores per patient-reported outcome measures (PROMs) on a measurement property.

|              | BOX A Internal Consistency | BOX B Reliability | BOX C Measurement Error | BOX D Content Validity | BOX E Structural Validity | BOX F Hypothesis Testing | BOX G Cross-cultural Validity | BOX H Criterion Validity | BOX I Responsiveness |
|--------------|-----------------------------|-------------------|-------------------------|------------------------|--------------------------|-------------------------|----------------------------|--------------------------|---------------------|
| DHPSC        | EXCELLENT                   | POOR              | EXCELLENT               | POOR                   | FAIR                     | -                       | POOR                       | POOR                     | POOR                |
| FCBS         | EXCELLENT                   | GOOD              | EXCELLENT               | POOR                   | FAIR                     | -                       | POOR                       | POOR                     | POOR                |
| FHSQ         | FAIR                        | POOR              | POOR                    | POOR                   | POOR                     | -                       | POOR                       | POOR                     | POOR                |

3.1. Population

The 11 studies considered included a total of 2007 participants, of whom 45.88% were male and 43.2% female, with a mean age of 61 years. Most of the participants had T1IDM (insulin-dependence).

3.2. Dimensions and Items

The PROMs included in the papers finally reviewed were fairly homogeneous with respect to the number of items and dimensions. The latter ranged from one in the Foot Self-Care Behavior Scale (FCBS) [58] to eight in the Foot Health Status Questionnaire (FHSQ) [5].

The areas addressed in the studies included self-care (diet, blood glucose, self-monitoring), pain, perceived health status and quality of life (quality of life, general foot health or foot health) or disability (activities of daily living, disability, limitation of function, activity restriction or sport and recreational function).

With respect to the number of items included, the PROMs ranged from long versions, with 29, for the Diabetic Foot Ulcer Scale-Short Form (DFS-SF) [29], to a mere seven items, in the Foot Self-Care Behavior Scale (FSCB) [58].

The most commonly used PROMs were the Cardiff Wound Impact Schedule (CWIS) [33] and the Foot and Ankle Ability Measures (FAAM) [43], which were similar in terms of dimensions and items, with three and two dimensions, and 26 and 29 items, respectively.

3.3. Psychometric Properties

The psychometric properties considered, in accordance with the Terwee criteria for each PROM, are summarised in Tables 2 and 3.

3.3.1. Content Validity

In all cases, the PROMs gave a clear description of the measurement aim and the target population and defined the criteria for item selection and exclusion. In addition, some (CWIS, DFS-SF, DFSQ-UMA) detailed the interpretability of the items, although this is not an essential characteristic for content validity.

3.3.2. Internal Consistency

Internal consistency was evaluated by Cronbach’s alpha, either for the entire instrument or for each sub-scale. Seven PROMs (NeuroQol, DFS-SF, DHPSC, FCBS, DFSQ-UMA, HRQLQDFU and FHSQ) obtained a positive rating, with values ranging from 0.7 to 0.95. Two (CWIS and AOFAS-DFQ)
had a negative rating, with values >0.95. No information was available in this respect for FAAM and Q-DFD, and so they were both rated zero.

3.3.3. Criterion Validity

None of the PROMs obtained a positive rating for this property, which required a strong correlation with the gold standard ≥0.7. Most of the PROMs (NeuroQol, DFS-SF, CWIS, FAAM, DHPSC FCBS and DFSQ-UMA) had a negative rating, with only weak correlation. Q-DFD, HRQLQDFU and FHSQ provided no information regarding the gold standard, and AOFAS-DFQ was deficient in its methodology in comparison with the gold standard.

3.3.4. Construct Validity

In this respect, none of the PROMs were rated positively. Either specific hypotheses were not formulated or less than 75% of the results obtained were in accordance with the study hypotheses, or this criterion was absent.

3.3.5. Reproducibility

**Agreement:** None of the PROMs had a positive rating for measurement error, either because the minimally important change (MIC) was not defined or because they did not refer exactly to the values. In most cases (AOFAS-DFQ, FAAM, DHPSC, FCBS, HRQLQDFU and FHSQ), the rating was 0 (no information available).

**Reliability:** AOFAS-DFQ, DHPSC, FCBS, DFSQ-UMA and FHSQ obtained a positive value for this property, with an intraclass correlation coefficient (ICC) greater than 0.7. The remaining PROMs presented lower values (ICC < 0.7), or were deficient in their design or provided no information in this respect.

3.3.6. Responsiveness

In this category, most of the PROMs (NeuroQol, FAAM, Q-DFD, DHPSC, DFSQ-UMA, HRQLQDFU and FHSA) had a value of 0, as they provided no information on the Smallest Detectable Change (SDC). The remaining measures did address this question, but either the methodology applied was doubtful or no evidence was provided of a clinically important change.

3.3.7. Floor/Ceiling Effect

Floor/ceiling effects were only described for DHPSC (4.59%). Another seven PROMs (DFS-SF, CWIS, FAAM, Q-DFD, FCBS, HRQLQDFU and FHSQ) provided no information in this respect. AOFAS-DFQ and DFSQ-UMA aroused doubts concerning the study design employed, while in NeuroQol the floor effect was only slight and there was little evidence of a ceiling effect.

3.3.8. Interpretability

Most of the PROMs considered failed to define MIC and were classed as ‘Indeterminate’.

3.4. Cross-Cultural Adaptation

In this respect, the PROMs varied widely, ranging from those providing no adaptation at all (DHPSC, DFSQ-UMA and HRQLQDFU) to the FAAM instrument, which has been adapted into 11 different languages (Brazilian, Chinese, Dutch, French, German, Italian, Japanese, Persian, Thai, Turkish and Spanish).

3.5. Methodological Quality

FHSQ obtained the best results in terms of methodological quality, according to the COSMIN criteria, see Table 4. This instrument scored positively for internal consistency, reliability, hypothesis
testing for construct validity, cross-cultural validity and responsiveness, indeterminate values in measurement error and criterion validity. The only negative value recorded was for structural validity.

The next-best-performing instruments in this regard were DHPSC and FCBS, which obtained positive values for four criteria.

3.5.1. Structural Validity

None of the PROMs obtained a positive value for this property. Most of them (NeuroQol, DFS-SF, CWIS, AOFAS-DFQ, DHPSC and DFSQ-UMA) were classed as 'Indeterminate', while FAAM, Q-DFD, FCBS, HRQLQDFU and FHSQ provided no information in this respect and were given a negative rating.

3.5.2. Internal Consistency

All of the PROMs except AOFAS-DFQ, FAAM and Q-DFD obtained a positive rating for internal consistency. The Cronbach’s alpha was $\geq 0.70$ for each subscale.

3.5.3. Reliability

For reliability, AOFAS-DFQ, DHPSC, FDBS, DFSQ-UMA and FHSQ obtained ICC $\geq 0.70$. The remaining PROMs were considered 'Indeterminate', with the exception of DFS-SF and Q-DFD, which provided no evidence in this regard and were rated negatively.

3.5.4. Measurement Error

In no case was the minimal important change (MIC) defined, and so all of the PROMs were classed as ‘Indeterminate’ for measurement error.

3.5.5. Hypothesis Testing for Construct Validity

For most of the PROMs (NeuroQol, DFS-SF, CWIS, FAAM, DHPSC, FCBS and FHSQ) a study hypothesis was defined and it was corroborated by the results obtained. Therefore, the instrument received a positive score.

3.5.6. Cross-Cultural Validity/Measurement Invariance

Only three PROMs (AOFAS-DFQ, FAAM and FHSQ) obtained a positive score for this property. Of the rest, DFS-SF, CWIS, Q-DFD, DHPSC, HRQLQDFU were scored as indeterminate and NeuroQol, FCBS and DFSQ-UMA were rated negatively because no important differences were found between group factors or by differential item functioning.

3.5.7. Criterion Validity

None of the PROMs scored positively in this respect, and most were given a negative rating due to lack of information or poor correlation.

3.5.8. Responsiveness

Seven PROMs were positively rated for responsiveness because the results obtained were consistent with the study hypothesis. Only AOFAS-DFQ, Q-DFD, DFSQ-UMA and HRQLQDFU scored negatively, with study results that were not in accordance with the hypothesis.

3.6. Methodological Quality Scores Per Study on A Measurement Property

The methodological quality scores obtained are summarised in Table 5. In this respect, only DHPSC, FCBS AND FHSQ obtained more positive than negative values and were eligible for evaluation. However, analysis of the methodological quality scores per study on a measurement property showed that none were of excellent quality; indeed, in most cases, this quality was very low.
The overall level of quality of the PROMs considered was low. FCBS obtained the best score, with an excellent rating for internal consistency and content validity, a good rating for reliability, a fair rating for hypothesis testing and a poor rating for measurement error, structural validity, criterion validity and responsiveness. None of the PROMs were evaluated for cross-cultural validity as the inclusion criteria applied limited the studies to the context of DM.

4. Discussion

The aim of this systematic review was to identify PROMs used to measure the effects of DM on the foot and ankle and to evaluate the methodological quality and psychometric properties of these PROMs.

Our literature search identified only 11 PROMs aimed at patients with DM, with reference to foot and ankle pathologies. Of these instruments, the Foot Health Status Questionnaire (FHSQ) provided the best overall psychometric properties, based on COSMIN, obtaining positive values for five properties: internal consistency, reliability, hypothesis test for construct validity, cross-cultural validity and responsiveness. The only negative value obtained was for structural validity, about which no information was provided, while measurement error and criterion validity were classed as indeterminate due to a lack of information regarding MIC and correlation with the gold standard, respectively.

The FHSQ is intended to be self-administered and was initially developed and validated to evaluate the effectiveness of surgical and conservative treatment for pathologies such as skin, nail, neurological, orthopaedic and musculoskeletal disorders [62–64]. This PROM has more dimensions than the others considered, examining the following eight areas: foot pain, foot function, footwear, general foot health, general health, social capacity, physical activity and vigour. However, in terms of applicability, it is merely average, with a total of 17 items. Each domain comprises a question-specific number, with four questions considering pain, four regarding function, three on footwear and two on general foot health. The possible scores range from 0 to 100, representing the worst and best states, respectively, of foot health imaginable.

Only two transcultural adaptations have been made of this questionnaire, into Brazilian-Portuguese [60] and Spanish [61]. In the first case, this adaptation was implemented with a population suffering from rheumatoid arthritis. The Spanish-language version was initially used with a healthy population and later adapted to evaluate the alterations to the quality of life and foot health among patients with type I or II DM [5].

The FAAM is the most commonly used PROM for foot and ankle pathologies, being available in 11 different languages, although not all of these adaptations are specifically intended for patients with DM. However, at the methodological level, this instrument presented positive values only for hypothesis testing for construct validity, cross-cultural validity and responsiveness. This finding suggests that very careful preparation is needed before performing transcultural adaptation into other languages or with respect to specific pathologies.

In line with the study goals, in this review, we identify and evaluate PROMs designed for patients with DM, with particular respect to foot and ankle pathologies. The methodological quality of each PROM is assessed. We observe that although reviews have been conducted previously on the impact of DM on the foot and ankle [16], sometimes narrowly focused on the rheumatoid foot [65], while others address the question more broadly [66] or are related to pain or dysfunction in particular [67], in every case they are deficient in the sense that appropriate methodological guidelines are not followed. In our opinion, the most up-to-date and rigorous methodological criteria for such reviews are those proposed by COSMIN. Further investigation in this field is needed to fill the research gaps observed in the PROMs analysed in this paper, perhaps focusing first on those scoring highest in our review and taking into account the COSMIN checklist for this purpose.

The application of PROMs in clinical practice is an important issue, and especially in the pathologies we discuss, because they often include screening and monitoring functions, as a means
of promoting patient-centered care, as a decision-making aid, in order to facilitate communication amongst multidisciplinary teams and to monitor the quality of patient care [68]. Evidence suggests that the use of PROMs in clinical practice helps detect HRQoL problems but has less impact on how clinicians manage patient problems or on subsequent patient outcomes. Despite the deficiencies observed, at present, the PROMs considered are the only instruments currently available for identifying and evaluating foot and ankle pathologies in all patients, irrespective of their geographic location.

5. Limitations

This study presents significant limitations. Firstly, very few PROMs have been designed for patients with DM, with particular respect to foot and ankle pathologies. Furthermore, many of the instruments analysed in our review lack important information in many respects: some fail to describe the type of diabetes, others do not report the proportions of patients with and without DM, while others present a statistical analysis that is not corroborated by the necessary data. Information in this respect was requested from the respective authors, but no response was obtained.

6. Clinical Implications

The present review offers useful information to researchers and clinicians regarding the PROMs that have been proposed for patients with DM and with foot and ankle pathologies. A detailed analysis is made of the methodological quality of each such PROM.

7. Conclusions

Noting the low overall methodological quality of the PROMs considered, with respect to foot and ankle pathologies in patients with DM, we conclude that the most appropriate questionnaire currently available is the Foot Health Status Questionnaire for diabetic patients.

Supplementary Materials: The following are available online at http://www.mdpi.com/2077-0383/8/2/146/s1, Searching strategy.

Author Contributions: Conceptualization, A.B.O.-A. and P.C.-G.; methodology, A.B.O.-A.; formal analysis, P.C.-G and L.R.-P.; writing—original draft preparation, P.C.-G; L.R.-P and E.C.-L.; writing—review and editing, G.G.-N.; visualization, P.C.-G.; supervision, A.B.O.-A.

Conflicts of Interest: All the authors declare that they have no conflict of interest derived from the outcomes of this study.

References
1. World Health Organization. Global Report on Diabetes; World Health Organization: Geneva, Switzerland, 2016; ISBN 9789241565257.
2. Almeida, P.H.R.F.; Silva, T.B.C.; de Assis Acurcio, F.; Guerra Júnior, A.A.; Araújo, V.E.; Diniz, L.M.; Godman, B.; Almeida, A.M.; Alvares, J. Quality of Life of Patients with Type 1 Diabetes Mellitus Using Insulin Analog Glargine Compared with NPH Insulin: A Systematic Review and Policy Implications. Patient 2018, 11, 377–389. [CrossRef] [PubMed]
3. Shaw, J.E.; Sicree, R.A.; Zimmet, P.Z. Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes Res. Clin. Pract. 2010, 87, 4–14. [CrossRef] [PubMed]
4. American Diabetes Association Diabetes Care. Standards of Medical Care in Diabetes—2018. Diabetes Care 2018, 41 (Suppl. 1), S1–S2. [CrossRef]
5. Palomo-López, P.; Losa-Iglesias, M.E.; Becerro-de-Bengoa-Vallejo, R.; López-López, D.; Rodríguez-Sanz, D.; Romero-Morales, C.; Calvo-Lobo, C. Specific foot health-related quality-of-life impairment in patients with type II versus type I diabetes. Int. Wound J. 2019, 16, 47–51. [CrossRef] [PubMed]
6. Bôas, N.C.R.V.; Salomé, G.M.; Ferreira, L.M. Frailty syndrome and functional disability among older adults with and without diabetes and foot ulcers. J. Wound Care 2018, 27, 409–416. [CrossRef] [PubMed]
7. Gebala-Prajsnar, K.; Stanek, A.; Pasek, J.; Prajsnar, G.; Berszakiewicz, A.; Sieron, A.; Cholewka, A. Selected physical medicine interventions in the treatment of diabetic foot syndrome. *Acta Angiol.* 2015, 21, 140–145. [CrossRef]

8. Olinic, D.M.; Spinu, M.; Olinic, M.; Homorodean, C.; Tataru, D.A.; Liew, A.; Scherntanher, G.H.; Stanek, A.; Fowkes, G.; Catalano, M. Epidemiology of peripheral artery disease in Europe: VAS educational paper. *Int. Angiol.* 2018, 37, 327–334. [CrossRef] [PubMed]

9. Lepántalo, M.; Apelqvist, J.; Setacci, C.; Riceo, J.B.; De Donato, G.; Becker, F.; Robert-Ebadi, H.; Cao, P.; Eckstein, H.H.; De Rango, P.; et al. Chapter V: Diabetic foot. *Eur. J. Vasc. Endovasc. Surg.* 2011, 42, S60–S74. [CrossRef]

10. Sturt, J.; Hearnshaw, H.; Wakelin, M. Validity and reliability of the DMSES UK: A measure of self-efficacy for type 2 diabetes self-management. *Prim. Heal. Care Res. Dev.* 2010, 11, 374–381. [CrossRef]

11. Tamir, O.; Wainstein, J.; Abadi-Korek, I.; Horowitz, E.; Shemer, J. The patient-perceived difficulty in diabetes treatment (PDDT) scale identifies barriers to care. *Diabetes Metab. Res. Rev.* 2012, 28, 246–251. [CrossRef]

12. Irvine, A.A.; Saunders, J.T.; Blank, M.B.; Carter, W.R. Validation of scale measuring environmental barriers to diabetes-regimen adherence. *Diabetes Care* 1990, 13, 705–711. [CrossRef] [PubMed]

13. Meadows, K.; Steen, N.; McColl, E.; Eccles, M.; Shiel, C.; Hewison, J.; Hutchinson, A. The Diabetes Health Profile (DHP): A new instrument for assessing the psychosocial profile of insulin requiring patients—Development and psychometric evaluation. *Qual. Life Res.* 1996, 5, 242–254. [CrossRef] [PubMed]

14. Polonsky, W.H.; Anderson, B.J.; Lohrer, P.A.; Welch, G.; Jacobson, A.M.; Aponte, J.E.; Schwartz, C.E. Assessment of diabetes-related distress. *Diabetes Care* 1995, 18, 754–760. [CrossRef] [PubMed]

15. Toobert, D.J.; Hampson, S.E.; Glasgow, R.E. The summary of diabetes self-care activities measure: Results from 7 studies and a revised scale. *Diabetes Care* 2000, 23, 943–950. [CrossRef] [PubMed]

16. Stetson, B.; Schlundt, D.; Rothschild, C.; Floyd, J.E.; Rogers, W.; Mokshagundam, S.P. Development and validation of The Personal Diabetes Questionnaire (PDQ): A measure of diabetes self-care behaviors, perceptions and barriers. *Diabetes Res. Clin. Pract.* 2011, 91, 321–332. [CrossRef] [PubMed]

17. Caro-Bautista, J.; Martín-Santos, F.J.; Morales-Asencio, J.M. Systematic review of the psychometric properties and theoretical grounding of instruments evaluating self-care in people with type 2 Diabetes Mellitus. *J. Adv. Nurs.* 2014, 70, 1209–1227. [CrossRef] [PubMed]

18. Jia, Y.; Huang, H.; Gagnier, J.J. A systematic review of measurement properties of patient-reported outcome measures for use in patients with foot or ankle diseases. *Qual. Life Res.* 2017, 26, 1969–2010. [CrossRef]

19. Liberati, A.; Altman, D.G.; Tetzlaff, J.; Mulrow, C.; Ioannidis, J.P.A.; Clarke, M.; Devereaux, P.J.; Marmur, D. Quality criteria were proposed for measurement properties of health status questionnaires. *Qual. Life Res.* 1998, 7, 321–332. [CrossRef] [PubMed]

20. Terwee, C.B.; Jansma, E.P.; Riphagen, I.I.; De Vet, H.C.W. Development of a methodological PubMed search filter for finding studies on measurement properties of measurement instruments. *Qual. Life Res.* 2009, 18, 1115–1123. [CrossRef]

21. Prinsen, C.A.C.; Mokkink, L.B.; Botter, L.M.; Alonso, J.; Patrick, D.L.; de Vet, H.C.W.; Terwee, C.B. COSMIN guideline for systematic reviews of patient-reported outcome measures. *Qual. Life Res.* 2018, 27, 1147–1157. [CrossRef]

22. Mokkink, L.B.; Terwee, C.B.; Patrick, D.L.; Alonso, J.; Stratford, P.W.; Knol, D.L.; Bouter, L.M.; De Vet, H.C.W. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: An international Delphi study. *Qual. Life Res.* 2010, 19, 539–549. [CrossRef] [PubMed]

23. Terwee, C.B.; Mokkink, L.B.; Knol, D.L.; Ostelo, R.W.J.G.; Bouter, L.M.; De Vet, H.C.W. Rating the methodological quality in systematic reviews of studies on measurement properties: A scoring system for the COSMIN checklist. *Qual. Life Res.* 2012, 21, 651–657. [CrossRef] [PubMed]

24. Terwee, C.B.; Bot, S.D.M.; de Boer, M.R.; van der Windt, D.A.W.M.; Knol, D.L.; Dekker, J.; Bouter, L.M.; de Vet, H.C.W. Quality criteria were proposed for measurement properties of health status questionnaires. *J. Clin. Epidemiol.* 2007, 60, 34–42. [CrossRef] [PubMed]

25. Vileikyte, L.; Peyrot, M.; Bundy, C.; Rubin, R.R.; Leventhal, H.; Mora, P.; Shaw, J.E.; Baker, P.; Boulton, A.J. The Development and Validation of a Neuropathy- and Foot Ulcer—Specific. *Diabetes Care* 2003, 26, 2549–2555. [CrossRef] [PubMed]
26. Victorson, D.; Cavazos, J.E.; Holmes, G.L.; Reder, A.T.; Wojna, V.; Nowinski, C.; Miller, D.; Buono, S.; Mueller, A.; Moy, C.; et al. Validity of the Neurology Quality-of-Life (Neuro-QoL) measurement system in adult epilepsy. *Epilepsy Behav.* 2015, 31, 77–84. [CrossRef] [PubMed]

27. Xie, G.; Chen, L.; Yang, S.; Tao, J.; Chan, C.C.H.; Heinemann, A.W.; Cella, D.; Lai, J.S.; Correia, H.; Wong, A.W.K. Simplified Chinese translation of 13 adult item banks from the Quality of Life in Neurological Disorders (Neuro-QoL). *BMC Health Serv. Res.* 2018, 18, 825. [CrossRef] [PubMed]

28. Xavier, A.T.; Foss, M.C.; Marques Junior, W.; dos Santos, C.B.; Onofre, P.T.B.N.; Pace, A.E. Cultural adaptation and validation of the Neuropathy- and Foot Ulcer—Specific Quality of Life instrument (NeuroQol) for Brazilian Portuguese—Phase 1. *Rev. Lat. Am. Enfermagem* 2011, 19, 1352–1361. [CrossRef] [PubMed]

29. Bann, C.M.; Fehnel, S.E.; Gagnon, D.D. Development and Validation of the Diabetic Foot Ulcer Scale-Short Form (DFS-SF). *Pharmacoeconomics* 2003, 21, 1277–1290. [CrossRef] [PubMed]

30. Kontodimopoulos, N.; Veniou, A.; Tentolouris, N.; Niakas, D. Validity and reliability of the Greek version of the Diabetic Foot Ulcer Scale—Short Form (DFS-SF). *Hormones* 2016, 15, 394–403. [CrossRef]

31. Macioch, T.; Sobol, E.; Krakowiecki, A.; Mrozikiewicz-Rakowska, B.; Kasprowicz, M.; Hermanowski, T. Health related quality of life in patients with diabetic foot ulceration—Translation and Polish adaptation of Diabetic Foot Ulcer Scale short form. *Diabetes Qual. Life Outcomes* 2017, 15, 1–8. [CrossRef]

32. Chin, Y.F.; Huang, T.T. Development and validation of a diabetes health self-care behavior scale. *J. Nurs. Res.* 2013, 21, 19–25. [CrossRef] [PubMed]

33. Price, P.; Harding, K. Cardiff wound impact schedule: The development of a condition-specific questionnaire to assess health-related quality of life in patients with chronic wounds of the lower limb. *Int. Wound J.* 2004, 1, 10–17. [CrossRef]

34. Jaksa, J.P.; Mahoney, L.J. Quality of life in patients with diabetic foot ulcers: Validation of the Cardiff Wound Impact Schedule in a Canadian population. *Int. Wound J.* 2010, 7, 502–507. [CrossRef] [PubMed]

35. Kateel, R.; Augustine, A.J.; Ullal, S.; Prabhhu, S.; Bhat, R.; Adhikari, P. Development and validation of health related quality of life questionnaire (Indian scenario) in diabetic foot ulcer patients. *Diabetes Metab. Syndr.* 2014, 8, 561–565. [CrossRef] [PubMed]

36. Fagerdahl, A.M.; Boström, L.; Ulfvarson, J.; Bergström, G.; Ottosson, C. Translation and validation of the wound-specific quality of life instrument Cardiff Wound Impact Schedule in a Swedish population. *Scand. J. Caring Sci.* 2014, 28, 398–404. [CrossRef] [PubMed]

37. Dhawan, V.; Spratt, K.F.; Pinzur, M.S.; Baumhauer, J.; Rudicel, S.; Saltzman, C.L. Reliability of AOFAS diabetic foot questionnaire in Charcot arthropathy: Stability, internal consistency, and measurable difference. *Foot Ankle Int.* 2005, 26, 717–731. [CrossRef] [PubMed]

38. Van Lieshout, E.M.M.; De Boer, A.S.; Meuffels, D.E.; Den Hoed, P.T.; Van Der Vlies, C.H.; Tuinebreijer, W.E.; Verhofstad, M.H.J. American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Score: A study protocol for the translation and validation of the Dutch language version. *BMJ Open* 2017, 7, e012884. [CrossRef] [PubMed]

39. Kateel, R.; Augustine, A.J.; Ullal, S.; Prabhhu, S.; Bhat, R.; Adhikari, P. Development and validation of health related quality of life questionnaire (Indian scenario) in diabetic foot ulcer patients. *Diabetes Metab. Syndr.* 2014, 8, 561–565. [CrossRef] [PubMed]

40. Rodrigues, R.C.; Masiero, D.; Mizusaki, J.M.; Imoto, A.M.; Peccin, M.S.; Cohen, M.; Alloza, J.F.M. Translation, Cultural Adaptation and Validation of the “American Orthopaedic Foot and Ankle Society’s (Aofas) Ankle-Hindfoot Scale”. *Acta Ortop. Bras.* 2008, 16, 107–111. [CrossRef]

41. Sayyed-Hosseimian, S.H.; Hassankhani, G.G.; Bagheri, F.; Alavi, N.; Shojaiie, B.; Mousavian, A. Validation of the Persian Version of the American Orthopedic Foot and Ankle Society Score (AOFAS) Questionnaire. *Arch. Bone Jt. Surg.* 2018, 233, 233–239.

42. Analay Akbaba, Y.; Celik, D.; Ogut, R.T. (Trans.) Cross-Cultural Adaptation, Reliability, and Validity of Turkish Version of the American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Scale. *J. Foot Ankle Surg.* 2016, 55, 139–142. [CrossRef] [PubMed]

43. Martin, R.L.; Hutt, D.M.; Wukich, D.K. Validity of the Foot and Ankle Ability Measure (FAAM) in Diabetes Mellitus. *Foot Ankle Int.* 2009, 30, 297–302. [CrossRef] [PubMed]
44. Moreira, T.S.; Magalhães, L.D.C.; Silva, R.D.; Martin, R.R.L.; Resende, M.A. Translation, cross-cultural adaptation and validity of the Brazilian version of the Foot and Ankle Ability Measure questionnaire. Disabil. Rehabil. 2016, 38, 2479–2490. [CrossRef] [PubMed]
45. González-Sánchez, M.; Li, G.Z.; Ruiz Muñoz, M.; Cuesta-Vargas, A.I. Foot and ankle ability measure to measure functional limitations in patients with foot and ankle disorders: A Chinese cross-cultural adaptation and validation. Disabil. Rehabil. 2017, 39, 2182–2189. [CrossRef] [PubMed]
46. Weel, H.; Zwiers, R.; Azim, D.; Sierveelt, I.N.; Haverkamp, D.; van Dijk, C.N.; Kerkhoffs, G.M.M.J. Validity and reliability of a Dutch version of the Foot and Ankle Ability Measure. Knee Surg. Sports Traumatol. Arthrosoc. 2016, 24, 1348–1354. [CrossRef] [PubMed]
47. Borloz, S.; Crevoisier, X.; Deriaz, O.; Ballaben, P.; Martin, R.L.; Luthi, F. Evidence for validity and reliability of a french version of the FAAM. BMC Musculoskelet. Disord. 2011, 12, 40. [CrossRef]
48. Bizjak, G. Report Information from ProQuest. Art Persuas. 2014. [CrossRef]
49. Sartorio, F.; Vercelli, S.; Bravini, E.; Bargeri, S.; Moroso, M.; Plebani, G.; Ferriero, G. Foot and ankle ability measure: Cross-cultural translation and validation of the Italian version of the ADL module (FAAM-I/ADL). Med. Lav. 2014, 105, 357–365.
50. Uematsu, D.; Suzuki, H.; Sasaki, S.; Nagano, Y.; Sunagawa, N.; Fukubayashi, T. Evidence of validity for the Japanese version of the foot and ankle ability measure. J. Athl. Train. 2015, 50, 65–70. [CrossRef]
51. Mazaheri, M.; Salavati, M.; Negahban, H.; Sohani, S.M.; Taghizadeh, F.; Feizi, A.; Karimi, A.; Parnianpour, M. Reliability and validity of the Persian version of Foot and Ankle Ability Measure (FAAM) to measure functional limitations in patients with foot and ankle disorders. Osteoarthr. Cartil. 2010, 18, 755–759. [CrossRef]
52. Arunakul, M.; Arunakul, P.; Suesiritumrong, C.; Angthong, C.; Chenchujit, B. Validity and Reliability of Thai Version of the Foot and Ankle Ability Measure (FAAM) Subjective Form. J. Med. Assoc. Thai. 2015, 98, 561–567. [PubMed]
53. Çelik, D.; Malkoç, M.; Martin, R.R. Evidence for reliability, validity and responsiveness of Turkish Foot and Ankle Ability Measure (FAAM), Rheumatol. Int. 2016, 36, 1469–1476. [CrossRef] [PubMed]
54. Cervera-Grvi, P.; Ortega-Avila, A.B.; Morales-Ascenso, J.M.; Cervera-Marin, J.A.; Martin, R.R.; Gijon-Nogueron, G. Cross-cultural adaptation and validation of Spanish version of The Foot and Ankle Ability Measures (FAAM-Sp). J. Foot Ankle Res. 2017, 10, 39. [CrossRef] [PubMed]
55. Bergin, S.M.; Brand, C.A.; Colman, P.G.; Campbell, D.A. A questionnaire for determining prevalence of diabetes related foot disease (Q-DFD): Construction and validation. J. Foot Ankle Res. 2009, 2, 1–10. [CrossRef] [PubMed]
56. Castillo-Tandazo, W.; Flores-Fortty, A.; Feraud, L.; Tettamanti, D. Spanish translation, cross-cultural adaptation, and validation of the Questionnaire for Diabetes-Related Foot Disease (Q-DFD). Vasc. Health Risk Manag. 2013, 9, 501–508. [CrossRef] [PubMed]
57. Wang, R.H.; Lin, L.Y.; Cheng, C.P.; Hsu, M.T.; Kao, C.C. The psychometric testing of the diabetes health promotion self-care scale. J. Nurs. Res. 2012, 20, 122–130. [CrossRef] [PubMed]
58. García-Inzunza, J.A.; Valles-Medina, A.M.; Muñoz, F.A.; Delgadillo-Ramos, G.; Compean-Ortiz, L.G. Validity of the Mexican version of the combined Foot Care Confidence/Foot-Care Behavior scale for diabetes. Rev. Panam. Salud Publ. 2015, 3838, 35–41.
59. Navarro-Flores, E.; Morales-Asencio, J.M.; Cervera-Marin, J.A.; Labajos-Manzanares, M.T.; Gijon-Nogueron, G. Development, validation and psychometric analysis of the diabetic foot self-care questionnaire of the University of Malaga, Spain (DFSQ-UMA). J. Tissue Viability 2015, 24, 24–34. [CrossRef] [PubMed]
60. Ferreira, A.F.B.; Laurindo, I.M.M.; Rodrigues, P.T.; Ferraz, M.B.; Kowalski, S.C.; Tanaka, C. Brazilian version of the foot health status questionnaire (FHSQ-BR): Cross-cultural adaptation and evaluation of measurement properties. Clinics 2008, 63, 595–600. [CrossRef] [PubMed]
61. Cuesta-Vargas, A.; Bennett, P.; Jimenez-Cebrian, A.M.; Labajos-Manzanares, M.T. The psychometric properties of the Spanish version of the Foot Health Status Questionnaire. Qual. Life Res. 2013, 22, 1739–1743. [CrossRef]
62. Bennett, P.; Patterson, C.; Wearing, S.; Baglioni, T. Development and validation of a questionnaire designed to measure foot-health status. J. Am. Podiatr. Med. Assoc. 1998, 88, 419–428. [CrossRef] [PubMed]
63. Landorf, K.B.; Keenan, A.M. An evaluation of two foot-specific, health-related quality-of-life measuring instruments. *Foot Ankle Int.* 2002, 23, 538–546. [CrossRef] [PubMed]

64. Bennett, P.J.; Patterson, C.; Dunne, M.P. Health-related quality of life following podiatric surgery. *J. Am. Podiatr. Med. Assoc.* 2001, 91, 164–173. [CrossRef] [PubMed]

65. Walmsley, S.; Williams, A.E.; Ravey, M.; Graham, A. The rheumatoid foot: A systematic literature review of patient-reported outcome measures. *J. Foot Ankle Res.* 2010, 3, 12. [CrossRef]

66. Sierevelt, I.N.; Zwiers, R.; Schats, W.; Haverkamp, D.; Terwee, C.B.; Nolte, P.A.; Kerkhoffs, G.M.M.J. Measurement properties of the most commonly used Foot- and Ankle-Specific Questionnaires: The FFI, FAOS and FAAM. A systematic review. *Knee Surg. Sport. Traumatol. Arthrosc.* 2018, 26, 2059–2073. [CrossRef] [PubMed]

67. Van Der Leeden, M.; Steultjens, M.P.M.; Terwee, C.B.; Rosenbaum, D.; Turner, D.; Woodburn, J.; Dekker, J. A systematic review of instruments measuring foot function, foot pain, and foot-related disability in patients with rheumatoid arthritis. *Arthritis Care Res.* 2008, 59, 1257–1269. [CrossRef] [PubMed]

68. Greenhalgh, J. The applications of PROs in clinical practice: What are they, do they work, and why? *Qual. Life Res.* 2009, 18, 115–123. [CrossRef]