Injury 53 (2022) 2366–2372

Contents lists available at ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury

The use of patient-reported outcome measures in the literature on traumatic foot fractures: A systematic review

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ARTICLE INFO

Article history:
Accepted 22 March 2022

Keywords:
Evaluation
Function
Instrument
Overview
Trauma

ABSTRACT

Introduction: Adequate foot function is paramount in daily activities, yet the incidence of foot fractures shows a rising trend. Patient-reported outcome measures are increasingly used for research; however, the use of a wide variety of available instruments is undesirable. In the current study, an overview is provided of patient-reported outcome measures used in clinical research evaluating outcomes of foot fractures. Tools are provided to choose the most adequate instrument in future research.

Methods: To identify the instruments, a systematic review was performed using PubMed, Embase, and the Cochrane Library. Articles published since 2000, reporting on traumatic foot fractures and/or their posttraumatic sequelae, and using a minimum of one condition- or region-specific patient-reported outcome measure were included. Forty-nine instruments were identified, used 636 times collectively. These instruments were evaluated on frequency of use, bones or joints analyzed with the instruments, the type and amount of contained items, and existing literature on their psychometric properties.

Results: The American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Scale was used predominantly (AOFAS Ankle-Hindfoot Scale; n = 243, 38.2%), followed by the Maryland Foot Score (n = 90, 14.2%). Twenty-seven instruments were included for further analysis. The majority included questions on mobility (27/27) and pain (24/27). Tools to select an adequate instrument for new research are presented in the appendices.

Discussion: Controversy surrounds the AOFAS Ankle-Hindfoot Scale as other authors have found that its psychometric properties, indicating it measures what it is supposed to measure adequately, are flawed.

Conclusion: A multitude of specific patient-reported outcome measures concerning foot fractures exists. Furthermore, the predominantly used instrument is deemed insufficient regarding quality as found by other studies. A valid, reliable, and responsive patient-reported outcome measure for clinical research on foot fractures is necessary. The most adequate existing ones for future research on different topics can be found through the tools provided.

Introduction

The patient's voice as a treatment outcome measure is an increasingly popular endpoint in research [1,2]. Patient-reported outcome measures (PROMs) obtain the patient's perspective through self-completion of questionnaires querying their views on symptoms, functional status, and health-related quality of life [3]. These PROMs assure that, when correctly used in research, the means of obtaining subjective data is standardized and literature can be earnestly compared [2].

Particular relevance for PROMs arises when symptoms, functionality, and well-being are main areas of concern [4]. This is the case in trauma surgery since an individual's well-being is suddenly

Abbreviations: PROM, Patient-reported outcome measure; AOFAS, American Orthopaedic Foot and Ankle Society; VAS, Visual analogue scale.

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https://doi.org/10.1016/j.injury.2022.03.049

Table 1
Definitions.

Foot fractures	All fractures – including avulsion fractures and excluding pure ligamentous injury – distal of the talocrural joint.
PROM	An outcome instrument where half or more of the items are patient-completed.
Generic	A PROM designed to be used by any one individual to measure a general construct (e.g. (health-related) quality of life, satisfaction, or general pain score).
Specific	A PROM designed to be used within a specific domain, directed at specific conditions or diseases (*condition-specific*, also called *disease-specific*), pathology, or anatomical area (*region-specific*), and evaluating functional outcome.
Psychometrics	The study of psychological measurement.
Validity	Whether an instrument measures what it is intended to measure.
Reliability	Whether the instrument results are consistent while measuring an unaltered state at different times.
Responsiveness	Whether the instrument results adequately reflect a changed state.

altered by restricted functionality and often pain. Especially the foot is a notably interesting region, as patient's activities of daily living stand or fall depending on their foot function [5]. Traumatic injury of the foot is not uncommon; the incidence of foot fractures in the Netherlands was 226 per 100.000 inhabitants in 2012, and showed an increasing trend [6].

However, a major problem arises when exploring previous research on the optimal treatment of foot fractures from the past decennia. In 2004, Button et al determined which PROMs were used in the foot and ankle literature and attempted to identify those which were proven to be valid, reliable and responsive (Table 1)(7). Instead, they concluded that for none of the examined instruments this was the case and emphasized the need for a satisfactory one. Four similar studies concluded that a considerable variety of instruments is used in the foot and ankle literature [8–11]. This is undesirable, especially when the use of different instruments restricts adequate comparison of studies in reviews or meta-analyses [9,10]. However, four of the five studies only conducted searches in specific journals instead of using extensive search engines, and none provided practical tools to aid in the selection of optimal PROMs. Furthermore, an update is needed to determine whether new instruments have been developed in response to these studies.

Hence, this study aims to provide an updated overview of the PROMs used to evaluate traumatic foot fractures and their sequelae using an extensive search strategy. The overview includes frequency of use, item characteristics, and evaluation of the instrument's psychometric properties. Provided tools give an indication of the most adequate existing PROM for new research. These findings may aid the selection or development of a high-quality PROM that can be used in a standardized fashion – facilitating inter-study comparison and interpretation – for research on functional outcomes of traumatic foot fractures and/or their sequelae.

Methods

This review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines [12]. A published protocol for this review does not exist, however, a protocol was established prior to conducting the study. This is not a standard systematic review of interventions, more an observation of current research practice through a systematic search of available literature. Hence, Risk of Bias tools generally do not apply seamlessly. The ICROMS 'Integrated quality criteria for review of multiple study designs' was used to assess this study itself (Appendix I). Ethical committee approval was not necessary.

Search strategy and selection criteria

All consecutive original articles reporting on traumatic foot fractures and/or their posttraumatic sequelae and using a minimum of one PROM (Table 1) to assess functional outcomes were included. One reviewer (T.A.B.) searched PubMed, Embase and the Cochrane Library for articles published between January 1st, 2000 and December 31st, 2020. The search syntax including Boolean operators is provided in Appendix II. No filters were used. Articles were screened twice on two separate occasions by one reviewer (T.A.B.) on title and abstract. If available, potentially eligible articles were screened on full text if they were in English, Spanish, German, French, or Dutch. Study protocols, case reports, e-posters, and supplements of any language were included provided that the used instrument was specified clearly in the English abstract. Meta-analyses, reviews, and letters were excluded. Studies that combined foot fractures with ankle fractures were included. However, studies not aimed at foot fractures (i.e., an exceptionally broad domain or outcomes not directed at foot function) were not included. Articles only using generic or unclassifiable specific PROMs were excluded. Uncertainties were discussed with a second independent reviewer (D.P.J.S.).

Data extraction

The following data was extracted in a piloted data extraction form: identified PROMs (concerning relevant condition- or region-specific PROMs, and, where applicable, accompanying generic PROMs); publication year; which bones and joints of the foot were the subject of analysis (calcaneus, talus, os naviculare, os cuboid, ossa cuneiformia, ossa metatarsalia, phalanges, Lisfranc joint, Chopart joint, or, when unspecified: forefoot, midfoot, hindfoot and/or entire foot); and whether the ankle was also analyzed. Articles were not judged on further content, quality, or bias, as this was beyond the scope of our study. PROMs used for outcomes on subtalar fusions were categorized as analyzing the hindfoot and ankle. A Visual Analogue Scale (VAS) for pain was categorized as containing one single item if the authors had not reported its background and it concerned a scale of 0 or 1 (no pain) to 10 (worst pain) [13]. When it was unspecified which of the AOFAS scales was used, the scale was deduced by the bones and joints analyzed, if possible.

Subsequently, the extracted condition- or region-specific PROMs themselves were analyzed if they had been used more than once. Exclusion criteria were unpublished PROMs or unavailability of the instrument. All original articles initially presenting the instruments were located through reference screening. Data was recorded on publication year, population, validation, reporting individual (patient only or patient and physician), total number of items, and item themes. For data on validation, a separate search was conducted per PROM on January 13th, 2021. The search syntax format is available in Appendix II.

Definitions and analysis

Adopted definitions are reported in Table 1. Results are presented by descriptive statistics, tabular overviews, and a matrix. The PROM mode is presented. Numerical data are presented as frequencies with percentages. Analyses were performed using an automated setup with built-in data validations in Microsoft Excel 64-bits (16.0.13426.20352).

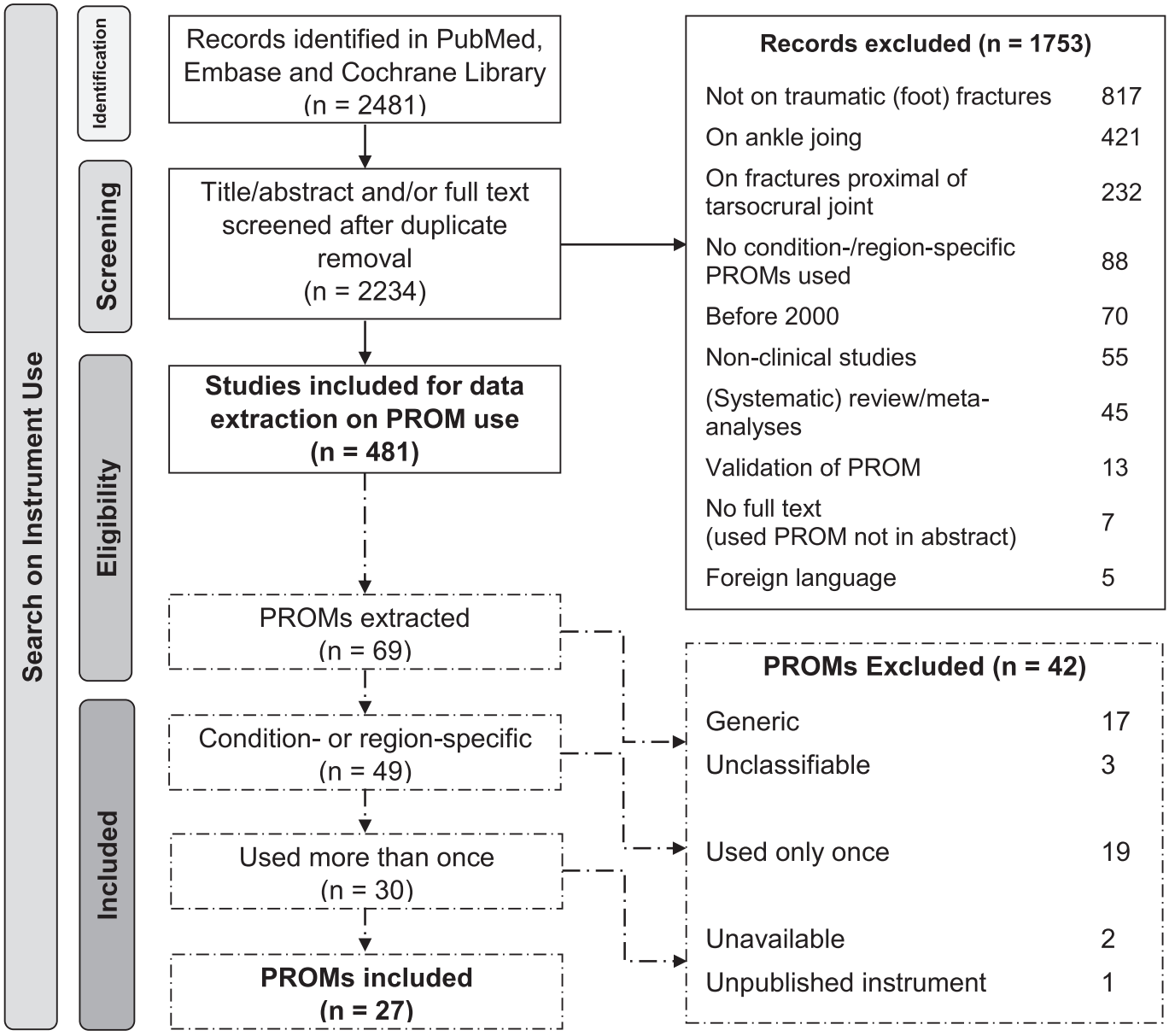

Fig. 1. Flowchart of the articles included for PROM extraction and, subsequently, PROMs included for further analysis. PROM = patient-reported outcome measure.

Results

Search

The search yielded 2481 results. After removal of duplicates, a total of 2234 articles were screened based on title and abstract or full text. Of these, 481 articles met the inclusion criteria and used at least one condition- or region-specific PROM (n = 282) or a specific and generic PROM simultaneously (n = 199). A flowchart is provided in Fig. 1.

Frequency of use

Collectively, a total of 49 unique condition- or region-specific PROMs or modifications were used. They were administered 636 times between the years 2000 and 2020, accompanied by generic PROMs in 199 cases. Of these specific instruments, 30 were used more than once. The Foot and Ankle Disability Index (FADI; used six times) is an unpublished precursor of the Foot and Ankle Ability Measure (FAAM) and was thus excluded. The Merle d'Aubigné Functional Score Foot Modification (used twice) and the Zhang Tieliang's Foot Score (used thrice) were unavailable. The 27 remaining included PROMs are provided in Appendix III.

The instrument used most often was the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale (n = 243, 38.2%), followed by the Maryland Foot Score (MFS; n = 90, 14.2%), the AOFAS Midfoot Scale (n = 82, 12.9%), and the Foot Function Index (FFI; n = 47, 7.4%) [14–16]. Combined, the two AOFAS scales were used in 53% of research in the last two years. The administration of PROMs in research on foot fractures and/or their post-traumatic sequelae shows an increasing trend (Fig. 2). The Olerud-Molander Score (publication in 1984), Lower Extremity Function Scale (publication in 1999), Foot and Ankle Outcome Score (FAOS; publication in 2001), FAAM (publication in 2005), three adapted FFI's, and the Manchester-Oxford Foot Questionnaire (MOXFQ, publication in 2006) were used solely during the past 8 years [17–21]. When plotted against the relative amount used per year, only the FFI, MOXFQ, FAOS, Visual Analogue Scale Foot and Ankle showed a

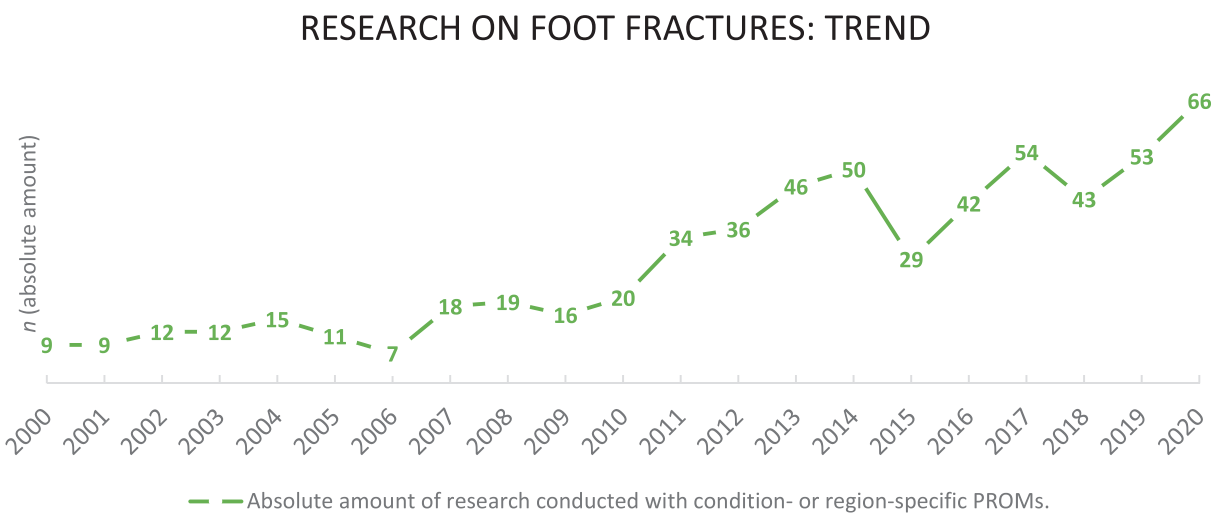

Fig. 2. Trend in time showing the amount of research conducted with condition- or region-specific PROMs (*n* shown in green). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

recent rising trend in terms of frequency of use out of all specific PROMs.

Bones and joints analyzed

Together, all 49 specific PROMS evaluated bones and joints of the foot 502 times. The calcaneus was analyzed most often (n = 282 articles, 58.6% of included research articles), followed by the talus (n = 64, 13.3%) and the Lisfranc joint (n = 63, 13.1%) (Fig. 3). The ossa cuneiformia and phalanges were not analyzed with specific PROMs. The ankle was included in the analysis in 27 articles (5.6%).

Instrument data

Of the 27 PROMs included for further analysis (Appendices II and III), 20 were completely patient-reported and five were both patient- and physician-reported. Two instruments cannot be categorized as such, as the initial publishing article did not specify the reporting individual for ambiguous items [15,22]. The amount of items each PROM contained ranged from four (AOFAS Ankle-Hindfoot Scale, Subjective component) to 116 (Musculoskeletal Function Assessment) [14,23]. All instruments included questions on mobility and the vast majority also included pain (24/27). An overview matrix presenting the types of questions for each instrument is provided in Appendix IV.

The systematic search for studies assessing psychometric properties or translations of the included PROMs yielded 7781 results; 255 studies were included. One additional article was found through reference screening and included. A summary is reported in Appendix III and a detailed overview is available in Appendix V.

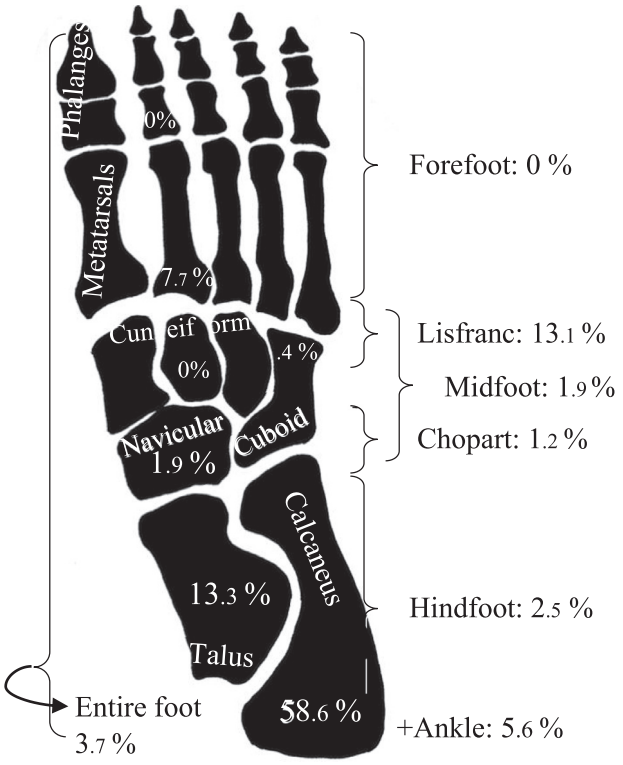

Fig. 3. Visualization of bones and joints analyzed (n = 502; the ankle was added in 27 cases) by the 49 specific PROMs extracted in this study as a percentage of the total research conducted on foot fractures (n = 481 included articles). Percentages may overlap due to articles reporting on multiple bones, joints, and/or regions. Analyses were only classified per region when bones and joints were unspecified in the article using the specific PROM.

PROM selection tools

The overview in Appendix V is accompanied by Fig. 4, a PROM selection flow diagram. Together, they can be used to select an adequate PROM for any foot fracture research. An example of how to use this framework is presented in the following paragraph.

A hypothetical study is set up in the Netherlands with the following aim: to compare long-term patient-reported outcomes of open surgical treatment for Lisfranc fractures and/or dislocations between two different surgical treatment options. Fig. 4 states that first all available PROMs must be identified. In this case, they are represented in Appendix V and no new PROMs have been published since then. The ones that have been evaluated on their psychometric properties are of interest. The current population is patients with acute Lisfranc injuries that are managed surgically. Since Appendix III shows that none of these instruments is specifically designed for this population, Appendix V is consulted to determine whether a later validation study was performed to include this population. This is not the case. Therefore, a broader population including that of the current study is considered: trauma

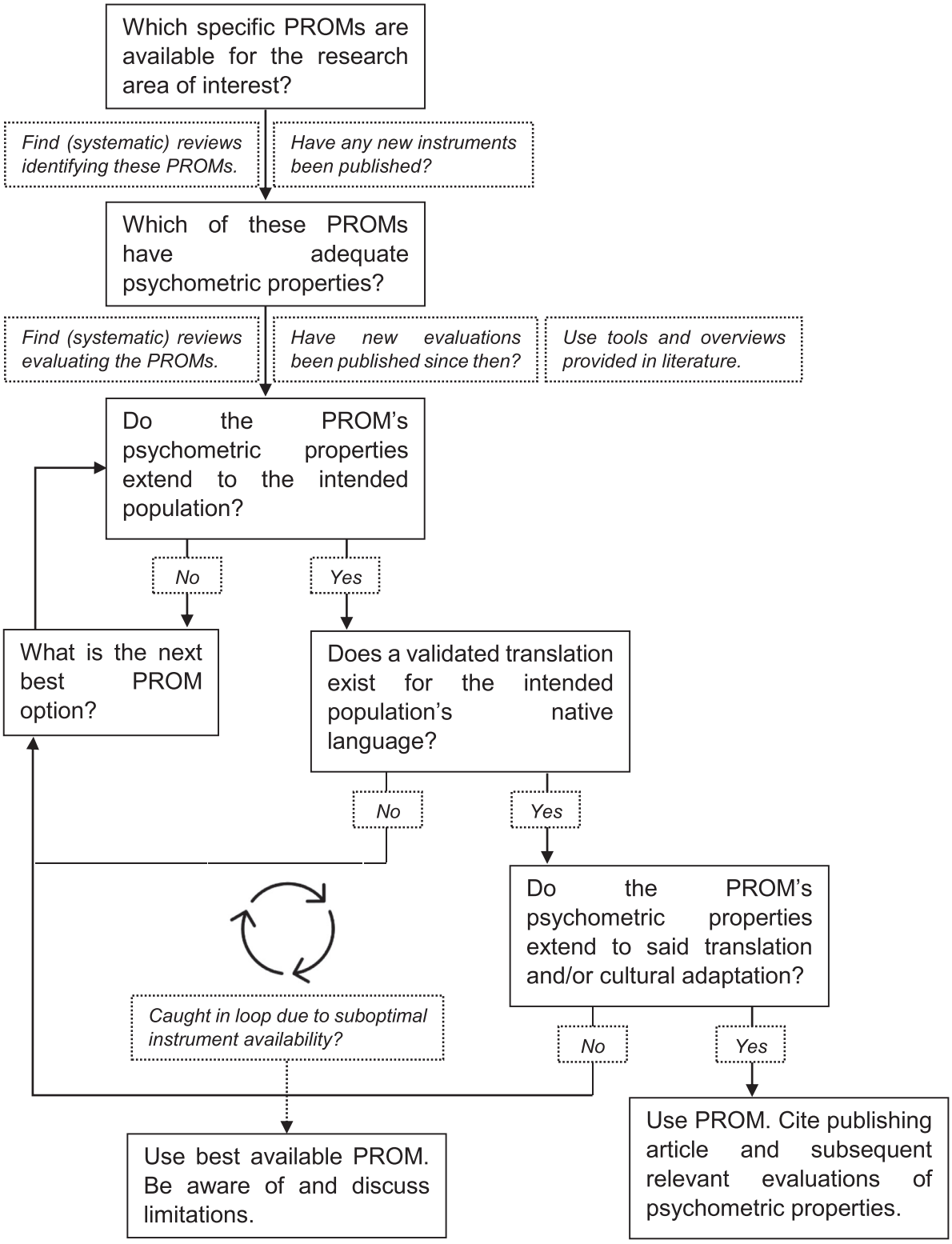

Fig. 4. PROM selection flow diagram. The use of suboptimal PROMs might result in the instrument not measuring the intended outcome. Note that for establishing the adequacy of eligible PROMs, Appendix IV of this review may be useful.

patients undergoing foot surgery. The options that have validated translations in Dutch are: LEFS, FAOS, FAAM, MOXFQ, and SMFA. The SMFA and LEFS are quite broad and have not been validated for foot trauma. Although the MOXFQ is validated for a variety of foot and ankle surgeries, this is not within a trauma population. The FAOS has a weak validation for posttraumatic ankle osteoarthritis, but has not been evaluated to be validated or reliable for foot fractures or surgery. It is, however, responsive in patients with hindfoot and ankle surgery. The FAAM has not been validated for foot fractures specifically, but it has been validated for their posttraumatic sequelae. Furthermore, it correlates with other measures in foot and ankle trauma. In this case the FAAM or FAOS

could be chosen and, since they are both not ideal, the limitations can be presented in the discussion.

Discussion

This study aimed to provide an overview of the PROMs used in clinical research evaluating PROs of traumatic foot fractures and/or their sequelae. Many different PROMs were utilized in the literature. The PROMs reported to be used most often were the AOFAS Ankle-Hindfoot Scale, MFS, AOFAS Midfoot Scale, and FFI, respectively. This research supports previous study outcomes stating that the AOFAS Ankle-Hindfoot Scale is the most popular PROM used in all foot and ankle literature to date [7–10]. Additionally, it confirms the same is true for literature on foot fractures specifically. Furthermore, the calcaneus, talus, Lisfranc joint, and the ossa metatarsalia were analyzed most often. Curiously, this does not directly reflect the incidence of these fractures [24]. It may, however, explain why the AOFAS Ankle-Hindfoot Scale is the most popular AOFAS scale.

Some inconsistencies between intention and practice were noted. Firstly, as the name suggests, a patient-reported outcome is a report of any aspect of a patient's health status that comes directly from the patient. However, literature upholds a broader definition, as the MFS and AOFAS scales are generally accepted as PROMs despite being partially physician-completed [7–10,14,15]. While this is debatable, it is reflected in the definition we adopted for this review. Secondly, articles that used PROMs in their research often neglected to cite the article publishing the PROM. Thirdly, at least two instruments (AOFAS Ankle-Hindfoot Scale and Olerud-Molander Score) were used multiple times to evaluate outcomes they were not designed and validated for. An example is an article on Lisfranc injuries where the AOFAS Ankle-Hindfoot was used [25]. This could raise the question whether a PROM designed for a wide array of indications or a larger region than solely the foot is useful for research on foot fractures. Fourthly, unpublished measures are being used and revised versions intended to replace the original are not. Confirmed by the first author (RobRoy L. Martin, PhD, PT, CSCS), this is the case for the FADI, the unpublished precursor of the FAAM. It is also the case for the FFI, which has been used 44 times since the publication of its revised version, which has only been used twice [26]. Lastly, although disputably not an inconsistency, scores are being used where the original article does not report on the development of the instrument, such as the MFS [15,22,27,28]. We showed an increase in research conducted on foot fractures and/or their sequelae. This means the choice in PROMs used is becoming exceedingly important.

The current study shows undesirable PROM trends both concerning quality and quantity. In a survey, many doctors perceived the frequently used AOFAS scales to be validated [29]. However, to date, they have not been proven to be adequately valid, reliable, and responsive [4,30]. This was concluded in a recent systematic review performed by Jia et al, who found that the studies evaluating these scales were of poor quality [30]. Guyton discussed the theoretical limitations of the instruments, for example how a minor change in response has a drastic effect on the total score [31]. Psychometric properties are considered crucial for PROMs as they reflect the instruments capacity to adequately measure what it is supposed to. The failure to do so has caused the scientific community to question these scales [10,31–35]. The AOFAS disclosed a position statement in 2018 regarding PROMs, stating that instruments should be chosen based on consistent evidence of good performance [2]. They declared not to endorse the use of AOFAS scales due to insufficient validity and reliability. Regrettably, it is still the most common instrument used since publication of the position statement. Concerning quantity, the current study found that 49 condition- and region-specific PROMs were used in the foot fracture literature over the last 21 years. Although research on various indications might call for the existence of various instruments, the current study only focused on traumatic foot fractures and/or their sequelae. Thus, it would not be expected to bring to light such a large collection. A universally used instrument would facilitate the comparison of different studies on treatment outcomes of foot fractures [2,9,10].

In the current study, most articles using PROMs only used a condition- or region-specific type. It was chosen to exclude generic PROMs, as the conceptual framework would not have been directed at any specific indication. Thus, the instrument might not be as sensitive to the condition's severity and will be affected more by other conditions [36]. However, this does not mean that generic PROMs should be omitted when studying functional outcomes. Kantz et al and Bombardier et al showed that simultaneous use of specific and generic PROMs has a complementary effect [36,37]. In our results, 199 studies indeed used both types. Van der Vliet suggested the use of an Olympic Model, where a specific PROM, generic PROM, injury factors, patient expectations, and physician's judgement are all combined for comprehensive outcome evaluation [38]. Outcomes are never determined by a single factor type, which should be reflected in a multifactorial outcome analysis. Thus, we favor the use of the Olympic Model, including a condition- or region-specific PROM containing all main item types mentioned in Appendix IV. This Olympic Model should not only be used in research, but also in clinical practice.

To our knowledge, this is the first systematic review investigating the use of PROMs in the foot fracture literature. Another strength is the overview of these PROMs provided and the PROM selection flow diagram (Fig. 4), which may aid future researchers in the selection of the instrument used in their studies. By including grey literature, e.g., protocols, e-posters, and supplements, publication bias was reduced. Limitations include a bias based on chronology, where recently developed instruments might have been undetected or excluded. A relatively new mode of administration that is emerging, the Computerized Adaptive Test, is an example of a potentially promising instrument type in this technology-based era that was not assessed in this review [39]. Secondly, when unspecified which of the AOFAS scales were used, the scale was deduced by the bones and joints analyzed, if possible, potentially categorizing the use of these scales unjustly. However, we do not expect this to have influenced the results significantly. Lastly, the frequency of PROM use was not corrected for the analysis frequency of a specific indication or anatomical region of the foot. The analysis was of a predominantly quantitative nature.

In conclusion, a vast variety of PROMs is being used for the evaluation of foot fractures and their postoperative sequelae, the most frequently used PROM being the deemed insufficient AOFAS Ankle-Hindfoot Scale. We argue that the AOFAS scales should not be used any longer in new research. To allow comparison between studies, it could exclusively be used alongside another specific PROM to bridge the coming years. We strongly advocate the consistent use of one or few valid, reliable, and responsive specific PROM(s) combined with a generic PROM, injury factors, patient expectations, and physician's judgment for clinical research on foot fractures, standardizing research and facilitating inter-study comparison. Future research should focus on finding this much-needed PROM, either through development or by continuing to test the validity, reliability, and responsiveness of the PROMs included for analysis in this study. To select the most appropriate existing PROM for new research, our tools and overviews can be used.

Funding statement

This research received no specific grant from any funding agency in the public, commercial, or non-profit sectors

Declarations of Competing Interest

No conflicts of interest related to this manuscript. Dr. Heng is a consultant for Zimmer-Biomet, Inc. serving on their Global Infection Advisory Board.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.injury.2022.03.049.

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