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# Chapter 7

## Patient-reported outcome measures in hallux valgus surgery. A review of literature.

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## ABSTRACT

**Background:** Up to a third of patients may be dissatisfied with the outcome of hallux valgus surgery. This stresses the importance of uniform and relevant outcome measures. The purpose of the current systematic review is to identify and rate available patient-reported outcome measures (PROMs) in hallux valgus surgery.

**Methods:** We performed a systematic literature search for outcome measures directed at hallux valgus. We searched electronic databases for relevant content according to the PRISMA standard. Eligible articles were used to give an overview of available PROMs, with qualitative evaluation of their properties.

**Results:** Twenty-eight eligible studies were included. Most adapted general health assessment tools, in studies on hallux valgus surgery, were the EQ5D and the SF-36 score. The visual analogue scale (VAS) was most cited as pain score. Three disease-specific outcome scores were identified: the Manchester-Oxford foot questionnaire (MOXFQ), the foot and ankle outcome score (FAOS) and the self-reported foot and ankle score (SEFAS). The MOXFQ showed the best psychometric properties.

**Conclusions:** The MOXFQ scores best on positively rated qualities based on our criteria. The SEFAS may be a good alternative, however it contains less items which are regarded as important by patients with foot/ ankle complaints. A relative drawback of the MOXFQ consists of the copyright licence. The VAS is the best pain score and the SF36 the best general health assessment tool. Availability in native languages and future research should lead to uniformity in application of these tools.

## 1. INTRODUCTION

Hallux valgus has a prevalence of 23% in adults and this increases with age [1]. Although numerous articles have been published on hallux valgus surgery, there is no consensus on the optimal surgical technique or timing of surgery. Up to a third of treated patients may be dissatisfied with the outcome of surgery [2]. This is definitely not always reflected in outcome parameters in literature, due to a lack of uniform and relevant outcome measures in hallux valgus surgery [3–5].

Patients typically want a painless greater toe when wearing conventional shoes, and it is surprising that these expectations are only partly revealed by physician-based clinical outcome scores [6]. Current outcome measures tend not to use validated patient-reported outcome measures (PROMs), but rather physician-based outcome measurements [3–5]. Traditionally, these measurement tools have been developed for research purposes, not for quantifying patient-based outcome [7]. Standardized PROMs reflect the patients' rather than the clinicians' perspective and can provide useful information on patient satisfaction. Moreover, they are independent of the surgical team [6,8].

PROMs are classified into three general categories: general quality of life (QoL), pain scale and disease-specific outcome measures [9]. For various highly prevalent orthopaedic conditions, such as knee and hip osteo-arthritis, validated QoL, pain and disease specific PROMS are widely used for both research and clinical evaluation. Current literature shows the majority of scores in foot and ankle pathology have questionable validity, reliability, applicability and responsiveness [5,7,10]. The high incidence of hallux valgus surgery, the various treatment options, and the uncertainty regarding the optimal indication and timing of surgery warrant the need for consensus on outcome measurement. The purpose of current systematic review is to identify and rate available PROMs on hallux valgus surgery.

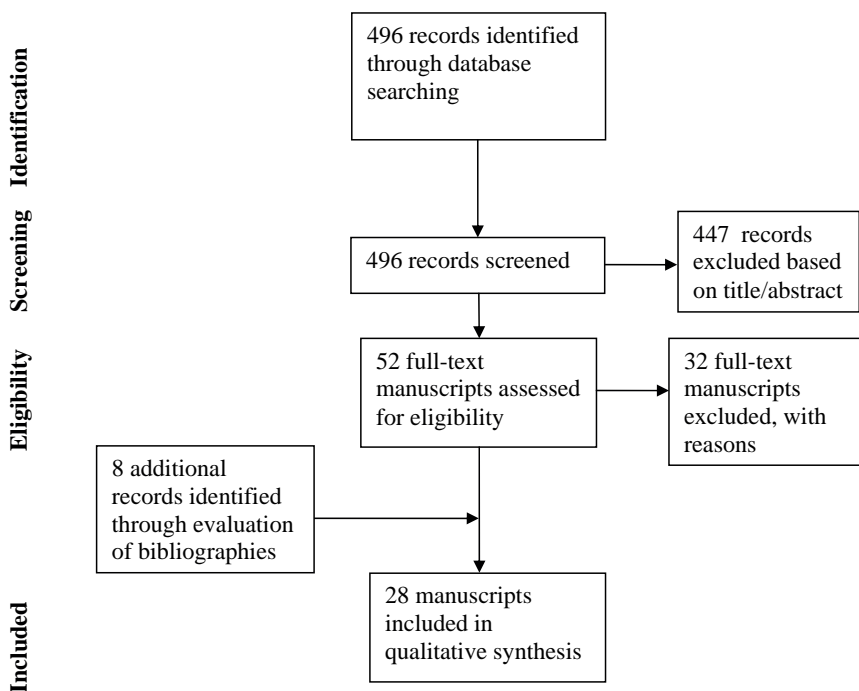
## 2. METHODS

The electronic databases Medline, Pubmed, Embase and Cochrane were searched systematically to identify relevant publications. Our systematic searches used the keywords “hallux valgus” OR “foot” OR “ankle”, “PROM” OR “questionnaire” OR “instrument” OR “outcome measure”, “validity” OR “reliability” OR “responsiveness”. Our search strategy was conducted applying the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) standard [11,12]. All references in the databases were included up to June 2014. Only manuscripts written in English were included. Bibliographies of relevant citations were screened for further manuscripts of relevance. Manuscripts and references were evaluated for relevant content, with PROMs of hallux valgus as main focus. The original manuscript, reporting the development and the psychometric properties of the relevant PROM, was included. We

excluded manuscripts that reported on physician based outcome scores and PROMs based on and accounting for foot-/ankle pathology, other than hallux valgus. The remaining manuscripts were systematically reviewed by two reviewers (JS and LP). All clinical patient-reported outcome scores, applied in selected manuscripts, were recorded. For evaluation PROMs were classified into three general categories: general quality of life outcome scores, pain outcome measures and disease-specific outcome measures [9].

Several manuscripts describe quality criteria for evaluation of outcome instruments [13–17]. Standardized evaluation of so-called psychometric properties of outcome instruments, promote scientific foundation of these tools. The psychometric properties of these instruments describe the relevance, quality and measurement properties. We adapted the checklist as described by Veenhof et al. and rated the included PROMs by following criteria: time to administer, ease of scoring, readability and comprehension, content validity, internal consistency, construct validity, floor/ceiling effect, reliability, agreement, responsiveness, interpretability and minimal clinically important difference (MCID) [14,16,18]. In our opinion this method covers clear outcome instrument evaluation best. All properties were rated as either “positive”, “doubtful”, “negative” or “unknown/unclear”. To give an overview we counted the number of all positive ratings for each tool.

Fig. 1. Preferred reporting items for systematic reviews and meta-analysis (PRISMA) flow diagram.



### 3. RESULTS

Initial search strategies yielded a total of 496 hits. Application of the search objective, inclusion/exclusion criteria and analysis of the bibliographies eventually resulted in 28 eligible manuscripts. These were included in this study and underwent quality assessment [Fig. 1].

Table 1 demonstrates the psychometric properties and quality of the included PROMs according to a checklist described in previous studies [14,16].

**Table 1** Summary of the quality assessment of PROMs directed at hallux valgus.

	SF-36	EQ5D	NRS	VAS	MOXFQ	FAOS	SEFAS
Patient-based	+	+	+	+	+	+	+
Time to administer	-	-	+	+	+	-	+
Ease of scoring	-	-	+	+	+	+	+
Readability and comprehension	-	+	+	+	+	-	+
Content validity	+	*	*	*	+	∅	+
Internal consistency	+	*	*	*	+	+	+
Construct validity	+	*	*	*	+	+	+
Floor/ceiling effect	*	*	*	*	+	-	+
Reliability	*	*	*	*	+	+	+
Agreement	+	*	*	*	+	*	+
Responsiveness	∅	*	*	*	+	∅	+
Interpretability	+	*	*	*	+	*	*
MCID	∅	*	*	*	+	*	*
Positively rated qualities, no.	6	2	4	4	13	5	11

Abbreviations: MCID: minimal clinically important difference; SF-36: medical outcome study short form (SF) questionnaire, NRS: numeric rating scale, VAS: visual analogue scale, MOXFQ: Manchester-Oxford foot questionnaire, FAOS: foot and ankle outcome score; SEFAS: self-reported foot and ankle score; + = positive; - = negative; ∅ = doubtful; \* = unknown/unclear.

#### 3.1. General quality of life outcome scores (QoL)

The Medical Outcome Study Short Form (SF) questionnaire (SF-36) is the most used general health outcome measure [9]. The SF-36 consists of thirty-six items, with eight subscales per item. The original questionnaire is quite extensive, possibly leading to reduced readability and comprehension. It is rather complex to calculate the total score to provide the single index value. In 1996 the SF-12 was developed, containing twelve items [19]. The SF form has been validated for various diseases, as for hallux valgus in specific (the SF-36) [20–23]. It has a good correlation with disease-specific measures [24]. The responsiveness among patients with hallux valgus seems rather questionable [Table 1] [5,23].

EQ5D is a standardized and validated questionnaire, with five subscales (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) [25–27]. It also contains a visual

analogue scale on general health status. It is complex to calculate the total score to provide the single index value. Although the questionnaire has been validated for multiple disorders, it has not been validated for hallux valgus surgery [28]. This also accounts for the reliability, responsiveness and MCID [29,30]. The responsiveness is higher when compared to the SF-36 [Table 1] [29–32].

### 3.2. Pain outcome measures

Pain and functional (dis)ability are the most important outcome factors for surgical treatment [1]. We found two pain scales used in hallux valgus surgery. It can be objectively measured by the numeric rating scale (NRS) or visual analogue scale (VAS).

The NRS is a 11-point numeric rating system, with zero representing “no pain” and 10 representing “the worst imaginable pain”. We could not retrieve any information regarding validity, responsiveness and reliability. Application of NRS for purposes of clinical research has shown variable effectiveness [Table 1] [33].

The VAS is the second most applied outcome tool in foot and ankle pathology (the American Orthopaedic Foot and Ankle Society (AOFAS) scales being the most popular) [4]. The VAS is virtually represented as a 10-cm horizontal line. The left terminus is designated “no pain”, the right terminus is designated “the worst imaginable pain.” The respondent marks the line at the site that characterizes the pain. The distance of the line from left terminus to the mark is measured, with centimetres representing the number of pain. The VAS is validated for various orthopaedic outcomes and has shown to be reliable [34–37]. Responsiveness has, amongst other things, been shown in a group of patients with osteoarthritis [38]. There are no specific psychometric data on hallux valgus [Table 1].

### 3.3. Disease-specific outcome measures

We found three disease specific outcome measures, the MOXFQ, the FAOS and the SEFAS. The Manchester-Oxford foot questionnaire (MOXFQ) is an instrument developed as an outcome measure for hallux valgus corrective surgery [23,39,40]. It consists of three domains (pain, walking/standing and social interaction) with 16 items, reported by patients. Each item is answered on a five-point Likert scale (0 to 4; ‘4’ assigned ‘most severe’; higher scores denoting higher severity). The score for each domain is calculated as the sum of each individual item score. This is expressed on a metric of 0 to 100 (100 times actual score, divided by the maximum possible domain score). The MOXFQ has already been configured to a summary score (MOXFQ-index) [41]. This score has been validated specifically for hallux valgus surgery, and has good reliability and responsiveness [3,23,31,32,41,42]. The MCID was demonstrated by Dawson et al., for each different domain [23]. These were 16, 12 and 24 for the walking/standing (seven items), pain (five items) and social interaction domains (four items), respectively. This score is more sensitive than general health measures for quantifying hallux valgus surgery. There were no floor and ceiling effects in patients undergoing foot

or ankle surgery (31.3% of this group underwent a non-specified method of hallux surgery) [Table 1] [42].

The foot and ankle outcome score (FAOS) consists of five subscales, with 42 items (pain, additional symptoms, daily activities, sports/recreational activities, foot/ankle-related QoL) [43]. The items are derived from the Knee injury and Osteoarthritis Outcome Score (KOOS) [44]. The questionnaire is quite extensive, possibly leading to reduced readability and comprehension. It has been validated in the original manuscript, on patients after ankle ligament reconstruction. Recently it has been validated for patients with hallux valgus, showing acceptable reliability and responsiveness [45,46]. However, the sports and recreation subscale of the FAOS showed little responsiveness to hallux valgus surgery. Ceiling effects were present for the ADL and sports subscale [45]. Data on MCID could not be traced [Table 1].

The self-reported foot and ankle score (SEFAS) originally was developed for assessing outcome after ankle replacement surgery, based on the New Zealand total ankle questionnaire [47]. It consists of 12 items, with 3 subscales (pain, function and additional symptoms) [48]. Eight questions are derived from the Oxford-12- hip questionnaire; 4 questions are focussed on foot/ankle pathology [39]. Recently its psychometric properties have been demonstrated among a population with foot and ankle disorders, including 91 patients with hallux disorders, who underwent surgical treatment [49]. This manuscript showed the SEFAS has good validity, reliability and responsiveness, when evaluating patients with hallux disorders. Data regarding MCID could not be found [Table 1].

Our evaluation of literature shows the American Orthopaedic Foot and Ankle Society Scales (AOFAS) are the most adapted outcome scales in foot and ankle surgery, however these scales are mostly physician-based, thus excluded from our review [4]. In addition, these scales have not been adequately validated [7,50]. Most other joint-specific PROMs (foot function index (FFI), American Academy of Orthopaedic Surgeons scale (AAOS), foot and ankle ability measure (FAAM), foot health status questionnaire (FHSQ)), directed at foot ankle pathology, are not validated for hallux valgus surgery and could therefore not be included in this review. These tools are not specifically designed for evaluation of hallux valgus surgery and lack factors that are of primary importance to the patient with a hallux valgus [51].

#### 4. DISCUSSION

Both the MOXFQ and SEFAS show good psychometric properties when used for the assessment of hallux valgus treatment. For the SEFAS, data on the minimal clinically important difference and interpretability are currently lacking. As a result, the MOXFQ scores best on positively rated qualities based on our criteria. This score has been specifically designed for patients with hallux valgus. The SEFAS, however, may still be a good alternative as it particularly uses fewer items. Both PROMs have shown to be versatile and are also validated



for other foot and ankle disorders [32]. A relative drawback of the MOXFQ consists of the copyright licence, which is required for any use of the score, with administration fees for any version [52]. Limited validated translations of both instruments have been developed until now [48,53].

The psychometric properties of the quality of life scores, demonstrate the SF-36 meets quality criteria best. It demonstrates, overall, the highest ratings in comparison to the EQ5D. There is limited evidence for the application of pain scores for rating patients with hallux valgus. The VAS has been cited most frequent in studies concerning patients with hallux valgus.

The importance of PROMs in evaluation of hallux valgus surgery is expressed by Baumhauer et al. They show outcome factors regarded by patients with foot/ankle complaints as important, differ from factors judged by physicians [7]. This suggests an inconsistency of expectations between the patient and physician. The study by Baumhauer et al. identifies 5 factors which are of critical importance to the patient (with variation between sexes and ages): limitations in walking, constant pain, activity-related pain, difficulty with prolonged standing, and inability to do a job or housework. Younger patients regarded the ability to play sports and to perform work responsibilities of additional importance. Women thought that fitting in a shoe was very important, this was not valued as much by men. The MOXFQ covers all these patient-relevant items. The SEFAS lacks items directed at prolonged standing, inability to perform work/sports and shoe fitting.

This current review has limitations. The conduct of our literature search may be incomplete, thereby excluding relevant instruments. Research focussing on evidence of outcome instruments is an ongoing process, implicating the actuality of our review may already be expired. In literature there is lack of uniformity in the use of quality criteria on systematically evaluation of outcome measurements [13–17,54–58]. The criteria we applied can be debated and no clear instructions exist how to apply these criteria [14,16]. The rating is mainly dependent on the availability of information and the quality of reporting of the specific measurement. Factors like responsiveness are often ill defined and not well assessed, making evaluation and comparison of specific scores rather difficult. We counted all positive ratings to an overall score, suggesting all different qualities are equally important. However, this is highly debatable.

An ideal PROM should be constructed as a disease-specific tool, with additional questions regarding general health/quality of life and pain [31]. It should encompass items that are relevant to the patient. The timing of obtaining a PROM depends, amongst other things, on factors like the end-stage after a specific treatment (when to perform the final PROM?). In the context of the high prevalence of hallux valgus surgery and the controversy regarding indication and timing of surgery, a well-defined and substantiated PROM is essential. This will improve the quality and comparability of scientific studies. Future research should focus on quality assessment of available PROMs, rather than development of new PROMs.

Based on available data, the MOXFQ and SEFAS are suitable PROMs for assessment of hallux valgus treatment. Which PROM will ultimately be most successful in daily clinical

practice, will depend on the availability in native languages and future research comparing the MOXFQ and the SEFAS for hallux valgus treatment.

**Conflict of interest statement**

There are no known conflicts of interest.

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