

# Minimally important change was estimated for the Manchester–Oxford Foot Questionnaire after foot/ankle surgery

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## Abstract

**Objectives:** To ascertain the smallest amounts of change for the three Manchester–Oxford Foot Questionnaire (MOXFQ) domains that are likely to be clinically meaningful and beyond measurement error for conditions affecting the foot/ankle. Estimates were compared with those from the Short-Form 36 (SF-36).

**Study Design and Setting:** A prospective observational study of 671 consecutive patients undergoing foot or ankle surgery at an orthopedic hospital. Before and 9 months after surgery, patients completed the MOXFQ and SF-36; transition items (anchor) asked about perceived changes in foot/ankle pain or problems since the surgery.

**Results:** Four hundred ninety-one patients completed pre- and postoperative questionnaires. Anchor-based minimal clinically important change (MCIC) values were ~13 points for each of the MOXFQ Walking/standing (W/S), Pain, and Social Interaction (S-I) domains [and greater than the standard error of measurement (SEM)]. MCIC values for all SF-36 domains fell within the SEM. Between-group MCIDs for the MOXFQ were W/S, 16.2; Pain, 9.9; S-I, 9.3. Distribution-based minimal detectable change (MDC<sub>90</sub>) values for the MOXFQ were ~11, ~12, and ~16 score points for the W/S, Pain, and S-I scales, respectively.

**Conclusion:** This article provides information for aiding the interpretability of MOXFQ outcomes data and for planning future studies. The SF-36 is not recommended as a primary outcome for foot/ankle surgery. © 2014 Elsevier Inc. All rights reserved.

**Keywords:** Foot and ankle; MOXFQ; SF-36; Surgery; Outcomes; Minimally important

## 1. Introduction

Patient-reported outcome measures (PROMs) represent outcomes of greatest relevance to patients and are increasingly being used to evaluate orthopedic surgery in a variety of contexts [1–4]. Recognition of their increasing usage, but also of their variable quality, has led to guidelines being

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published by the US Food and Drug Administration (FDA) on appropriate methods for their development and application [5]. These guidelines state that in addition to involving patients in their development, PROMs need to be validated for the population and context in which they are to be used [5]. Although a number of questionnaires have been produced with the intention of measuring patients' subjective experiences of foot or ankle problems, these have generally not been developed with appropriate, if any, patient input [6–10], as is recommended [5,11], casting doubt on their content validity.

The Manchester–Oxford Foot Questionnaire (MOXFQ 2011; Isis Innovation Ltd., Oxford, UK) [12,13] is a PROM for foot and ankle surgery. In line with FDA recommendations, MOXFQ item content was informed by interviews with patients [12], and the questionnaire's measurement properties have now been extensively evaluated (validated) in two key studies. The first involved patients undergoing surgery for hallux valgus, in which the questionnaire was found to have a meaningful factor structure, and exhibited

### What is new?

#### Key findings

- A number of anchor- and distribution-based estimates of minimally important change/difference have been presented for the patient-reported Manchester–Oxford Foot Questionnaire (MOXFQ) in the context of a large prospective study of patients undergoing foot or ankle surgery. This includes estimates for specific regions of the foot/ankle: hallux, lesser toes, and ankle/hindfoot.

#### What this adds to what was known?

- These estimates update previously presented values that were based on a smaller study, involving mainly female patients undergoing hallux valgus surgery.

#### What is the implication and what should change now?

- The MOXFQ is increasingly being used as a primary outcome measure in studies, as well as for routinely assessing individual patients undergoing a wide range of foot or ankle procedures. These estimates will assist the interpretation of MOXFQ outcomes, and researchers wishing to use this instrument as a study end point should use these estimates to more precisely plan their studies.

good reliability, validity, and responsiveness [12,13]. A second study, involving 671 patients undergoing surgery for a wide range of foot and ankle conditions, provided comprehensive evidence concerning the acceptability, reliability, concurrent validity [14], and responsiveness [15] of the MOXFQ within different subgroups of patients representing different regions of the foot/ankle receiving surgery.

In prospective outcome studies, the responsiveness of an outcome measure—its ability to detect change when a change has occurred [16,17]—is an essential characteristic of the validity of the measure [18–20]. In addition, however, it is also important that PROM scores are interpretable, that is, that qualitative meaning can be assigned to a particular quantitative score (or to a change in the score) [21]. Determining whether score changes or differences are clinically (and/or subjectively) meaningful or important is essential for performing sample size calculations, for judging the efficacy of interventions in clinical trials, and also for interpreting score changes in longitudinal cohorts, clinical trials, or clinical practice, in individual patients.

There are a number of different estimates of minimal change (and difference), and terms and definitions used in this area are frequently confusing [22,23]. The choice of which estimate to use may relate to context. For instance,

although the terms “change” and “difference” are often used interchangeably (especially in relation to cohort studies), in certain contexts, a distinction can exist between the concepts [24]: When the intension is to measure improvement (or deterioration) in health status over time (in a single patient or within a group/cohort), then a value representing the minimal important “change” (MIC) is generally most appropriate. Alternatively, if the aim is to compare two independent groups of patients (such as in a randomized controlled trial), then a value representing the minimal important “difference” (MID), that is, the difference in the outcome score “between” the two groups, is used. This should be a value representing the relative change from baseline.

There are two main approaches to estimate the smallest amount of change on a measure that is likely to be meaningful or important [25]. The first approach is distribution based, that is, based on the statistical characteristics of the sample under study. Examples include the effect size (ES), the standard error of measurement (SEM), and the minimal detectable change (MDC) [26,27]. This approach strives to provide the smallest change—for an individual—that is likely to be beyond the measurement error of the instrument and therefore to represent a true change. However, such statistical approaches, although meaningful in a statistical sense, do not necessarily indicate whether these changes are subjectively meaningful or clinically relevant [22].

The second approach uses anchor-based methods, in which an external criterion (rated or set by patients, clinicians, or another stakeholder) is used to provide an indication of the minimal change that is subjectively meaningful. Because anchor-based estimates of MIC make reference to a clinical criterion, they are also commonly (and appropriately) referred to as the minimal “clinically” important change (MCIC). Unfortunately, the term MCID is occasionally wrongly applied to distribution-based methods.

The aim of this article was to ascertain the smallest amounts of change in the three MOXFQ domain scales that are likely to be clinically meaningful and beyond measurement error for conditions affecting the foot/ankle. These were compared with equivalent values for the Short-Form 36 (SF-36) generic health status questionnaire.

## 2. Materials and methods

NHS Research Ethics Committee approval was obtained (ref 08/H0604/68). All subjects consented to participate in the study.

Full details concerning recruitment procedures, subjects, assessments, and sample size calculations have been reported elsewhere [14,15].

### 2.1. Assessments

Within 3 months before surgery, patients completed the MOXFQ [12–15], for each foot to be operated on, together

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