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AOFAS Position Statement Regarding Patient-Reported Outcome Measures

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Abstract

Outcome measures evaluate various aspects of patient health, and when appropriately utilized can provide valuable information in both clinical practice and research settings. The orthopedic community has placed increasing emphasis on patient-reported outcome measures, recognizing their value for understanding patients' perspectives of treatment outcomes. Patient-reported outcomes are information directly reported by patients regarding their perceptions of health, quality of life, or functional status without interpretation by healthcare providers. The American Orthopaedic Foot & Ankle Society (AOFAS) supports the use of validated patient-reported outcome (PRO) instruments to assess patient general health, functional status, and outcomes of treatment. It is not possible to recommend a single instrument to collect quality orthopedic data as the selection is dependent on the population being examined and the question being asked. We support the use of the PROMIS Physical Function Computerized Adaptive Test (PF CAT) or Lower Extremity Computerized Adaptive Test (LE CAT), which can be assessed with other domains such as Pain Interference. In addition, a disease-specific measure can be used when available.

Keywords: patient-reported outcomes, PRO, ankle, computer adaptive testing, PROMIS

Outcome instruments evaluate various aspects of patient health, and when appropriately used can provide valuable information in both clinical practice and research settings. In the past, there were few choices for evaluation of foot and ankle patients, and the widely used clinical scales were clinician-based outcome measures.[18] More recently, the orthopedic community has placed emphasis on patient-reported outcome (PRO) measures, recognizing their value for understanding patients' perspectives of treatment outcomes.[8,35,36] There has been substantial growth in the number of instruments available with 139 unique outcome scales identified in the foot and ankle literature over a 10-year period by a 2013 systematic review.[19] Patient-reported outcomes (PROs) are information directly reported by patients regarding their perceptions of health, quality of life, or functional status without interpretation by health care providers.[11] PROMs are valuable because they are able to measure otherwise unquantifiable data. There are various types of PROMs, including generic, utility, region- or system-specific (eg, lower extremity or musculoskeletal), disease-specific, and anatomic/joint-specific measures. They may focus on a single domain, such as pain and function, or assess multiple domains with overall scores and/or subscale scores. In a practical sense, PROMs are self-completed questionnaires, which can be administered electronically, in paper format, or over the telephone by a trained interviewer. Presently, there is variability in the use of PROMs and a lack of consensus as to which ones best describe the burden of a foot or ankle condition and evaluate the effects of intervention. Selection of the optimum outcome measure for a particular study is not always clear, complicated by the fact that the quality of PROMs varies, and many have been poorly or inadequately

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validated. Which is the most appropriate for a given situation? There is a need for health care providers to apply consistent instruments to evaluate patients with foot and ankle disorders in order to standardize outcome measurement.[1,18]

Previous investigators examined the measurement properties (eg, validity, reliability, responsiveness) of outcomes measures for the foot and ankle.[28,31] Some investigators reported the frequency of use of various outcome measures in the literature, and others assessed the methodological quality of studies reporting on the measurement properties of commonly used PROMs.[19] These studies demonstrated that not all PROMs have measurement properties that meet recommended quality criteria. The appropriate PROM should be chosen based on measurement property evidence with consistent findings of good performance from good quality studies.[34] Unfortunately, the measurement properties of some instruments have been extensively tested whereas others have not. PROMs with demonstrated measurement properties are available for evaluating outcomes of foot and ankle interventions. It is important to be familiar with the appropriate application of individual PROs, and understand concepts of validation and psychometric testing. The process of developing an outcome instrument is laborious, and the work of establishing their measurement properties even more so. Elements of sound outcomes instrument evaluation include (1) content validity: how well items accurately capture the complete spectrum of what patients experience relevant to the measurement aim or "target construct" of the instrument; (2) construct validity: whether items measure what they intend to measure (such as physical function), and scores of an instrument are consistent with predefined hypotheses (eg, regarding relationships with scores of other instruments or differences between meaningful groups); (3) criterion validity: assessment of how an instrument compares to a gold standard test (if available) or prespecified criterion or criteria; (4) reliability: measure of reproducibility or freedom from measurement error; (5) responsiveness: the ability to detect change over time in the target construct[5,6]; and (6) minimum clinically important difference: the smallest change in a treatment outcome that an individual patient would identify as important, which can provide meaningful interpretation of PRO scores.

Recommendations

PROMIS

The Patient-Reported Outcomes Measurement Information System (PROMIS)[3,32] was developed with support of the National Institutes of Health to improve PRO assessment and is administered with Computerized Adaptive Tests (CATs) using item response theory (IRT). The CAT draws items from an item bank relevant to a specific domain, such as physical function. The CAT targets the patient's ability so that a patient's response determines the next item asked, thereby reducing the number of questions required to assess outcome. This improves measurement precision and reduces floor/ceiling effects, administrative costs, and respondent burden.[16,21] Computer adaptive testing requires less than one-third of the time of legacy (original) clinical scales.[13,21] The PROMIS domain framework divides all of "self-reported health" into the domain groups: (1) general health; (2) physical health; (3) mental health; and (4) social health. Each domain represents a specific trait or conceptual area that is the target of assessment, such as a symptom or functional capability, which can also be divided into subdomains—further specifications of an aspect of health (www.promis.org[2,22]). PROMIS has developed domain-specific PROMs within each domain group, which can be used individually or together to assess the impact of intervention on several aspects of health, which is recommended. The general health and physical health domain groups are the most commonly used in orthopedics, with physical health consisting of domains, such as physical function, pain intensity, and pain interference, evaluating areas such as physical function, symptoms, social behavior, and treatment experience. They are available without charge (www.promis.org).

A domain is a "specific feeling, function, or perception being measured."[22] Patient-reported outcomes use domain-specific instruments such as physical function or pain interference. These domains do not necessarily overlap, and do not provide disease-specific data. The domain approach to patient outcome has the advantage of being useful for a broad array of disorders. However, domain instruments cannot entirely replace disease-specific outcome instruments that provide a level of detail that is important in characterizing specific aspects of disease; for example, an Achilles tendinopathy instrument (VISA-A questionnaire) asks how much pain occurs with 10 heel raises.[29] This information holds meaningful value in a specific patient population. The distinction of a domain instrument is its utility in assessing one specific aspect of health across multiple diseases. Describing patient outcomes with domain-based instruments can be combined with disease-specific validated measures whenever available.

The PROMIS Physical Function (PF) is available as a CAT and consists of 124 physical function items in 5 groups: upper extremity, lower extremity, axial, central, and instrumental activities of daily living. It was not designed for a specific disease or condition, but has been validated for a variety of foot and ankle conditions.[14,15,17] This assessment tool underwent further testing for validity, reliability, responsiveness, and efficiency compared with other clinical rating systems.[13] Assessment of the PROMIS PF CAT was performed by its developers and independent groups with similar results. Cohorts included patients who underwent treatment for hallux valgus, hallux rigidus, hammertoe,

ankle arthritis, flatfoot, talar dome lesions, ankle instability, and trauma[12,13,16,21,26,33]; however generalizability of results to specific populations has been raised as a concern. The PROMIS PF CAT is comparable or superior to legacy clinical scales, including the AOFAS Clinical Rating Scores, Foot Function Index (FFI), Foot and Ankle Ability Measure (FAAM), Foot and Ankle Outcome Score (FAOS), and Short Form-12 (SF-12) with regards to validity, reliability, and responsiveness.[13,21] Additionally, it may be useful in a clinical context to identify patients who may benefit from surgery.[11]

Lower Extremity Computerized Adaptive Test (LE CAT)

This PROM was developed using the 79 most relevant and psychometrically sound items of the PROMIS PF that pertain to lower extremity conditions.[15] It had improved validity and was more sensitive to foot and ankle and lower extremity conditions than the original 124 items of the PROMIS PF. It was found to be a valid, reliable, and feasible physical function tool for patients with lower extremity problems and retains all of the advantages associated with computerized adaptive testing.

The PROMIS PF CAT and LE CAT focus on the domain of physical function alone; consequently, additional domains should be assessed to capture other important outcomes, such as pain intensity, pain interference, general health, or ability to participate in social roles and activities. Though domain-specific measures have many advantages, "specific" measures (eg, disease-, region-, or joint-specific measures) are still valuable tools for measuring health aspects that are relevant or specific to a particular condition, region, or population of interest. Therefore, it is recommended that 1 or more domains should be considered for measurement of a foot or ankle intervention, and this can be combined with disease-specific validated measures whenever available.

Other Patient-Reported Outcome Measures

Use of validated anatomic/joint-specific, disease-specific, or system-specific measures is also recommended, such as the FAAM, the FAOS, the Musculoskeletal Function Assessment (MFA), and the Short Musculoskeletal Function Assessment (SMFA). The FAAM is composed of 21 items of activities of daily living and 8 items of sports subscales.[25] It was based on the Foot and Ankle Disability Index (FADI)[10,24] and found to be a reliable, responsive, and valid measure of physical function for individuals with a broad range of musculoskeletal disorders of the lower leg, foot, and ankle. The FAOS is a 42-item questionnaire of patient-relevant outcomes in 5 subscales (Pain, Other Symptoms, Activities of Daily Living, Sport and Recreation Function, Foot and Ankle–Related Quality of Life). It was validated for hallux valgus, sports injury, and adult acquired flatfoot disorder.[4,23,26,30] The MFA is a 101-item questionnaire for patients who have musculoskeletal disorders of the upper and lower extremities. It has been extensively tested and has well-established measurement properties.[7] The SMFA is a shorter version of the MFA, retaining 46 items.[34] It consists of two parts, the dysfunction index and the bother index, and was found to be reliable, valid, and responsive in patients who had a musculoskeletal disease or injury. Measurement evidence exists supporting its use for foot and ankle populations.[9,28] These specific PROMs are promising for evaluation of patients with foot and ankle conditions, but evidence supporting all measurement properties is not yet sufficient and should be taken into account when interpreting results in the clinical setting.[31] This list of "other" PROMs is not meant to be comprehensive, and may change over time.

AOFAS Clinical Rating Systems (1994)

These rating scales were reported by a subcommittee of the AOFAS Research Committee and remain widely used.[20] They are clinician-based outcome measures, which evaluate patients' pain, function, and alignment based on clinicians' observations. Subsequent studies demonstrated their limitations and the AOFAS does not endorse the scales because of insufficient reliability and validity.[27] Furthermore, the numeric threshold for a clinically significant difference remains unknown.[32] Use of the AOFAS Clinical Rating Systems as the sole instrument is discouraged.

Conclusions

It is not advisable to use a single instrument to collect quality orthopedic data as the selection is dependent on the population being examined and the question being asked. We support the use of the PROMIS Physical Function Computerized Adaptive Test (PF CAT) or Lower Extremity Computerized Adaptive Test (LE CAT), which can be assessed with other domains (eg, pain interference). In addition, a disease-specific measure can be used when available. Other PROMs supported for the foot and ankle are the FAAM and FAOS. Validated PROMs are important measures of outcome along with clinical measures, such as strength and range of motion. They are crucial for demonstrating whether health care interventions are effective in improving symptoms or function from the patient's perspective. They are useful for decision-making, encouraging patient-centered care, monitoring populations, and facilitating comparison of results across studies. PROMs such as PROMIS PF CAT and the LE CAT have been well-studied and have demonstrated measurement properties for multiple foot and ankle conditions. Foot/ankle-specific and

system-specific measures such as FAAM and FAOS are valid, reliable, and responsive PROMs for multiple foot and ankle pathologies. Clinicians and researchers should consider the appropriate PRO measure for their population based on the target domain(s) addressed by the PRO measure, and supplement with additional measures assessing domains of interest as recommended and "specific" health measures where appropriate. All PROMs should be appropriately referenced in manuscripts, including relevant studies about measurement properties, and the methods section should provide justification for the selection of the PROM(s) for the study's purpose, including discussion of validity, reliability, and responsiveness. The support of the use of these outcomes instruments are of interest to health care providers and researchers. Incorporating patient-reported outcome measures in daily practice will benefit patients and enable assessment of treatment. Looking to the future, we encourage patient-centered care, and improving the quality of measurement of outcomes for the foot and ankle.

Author Note

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