



A New Paradigm in Foot and Ankle Outcomes?

Away From Radiographs and Toward Patient-Centered Outcomes

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KEYWORDS

- Reliability • Validity • Patient-reported outcome • Radiographic measures
- Patient-centered care

KEY POINTS

- Patient-centered care is becoming more valued.
- Patient-reported outcome measures (PROMs) are, therefore, becoming more common in clinical research.
- Reasonable outcome measures must have sound reliability, validity, efficacy, and responsiveness but lack the ceiling and floor effects.
- Provider-measured outcomes, such as radiographic measures, are becoming less valued because of the potential lack of reliability and correlation with PROMs.

INTRODUCTION

Research should bring us closer to the truth. Knowing the truth is the ultimate goal of science; nevertheless, this aim is unattainable, as we cannot possibly account for every variable in the universe. Therefore, we must settle for less-than-perfect research methodologies. However, this does not mean that research should be disregarded altogether; in fact, quite the opposite is true, as a well-controlled study will always improve our understanding of the world.

In many scientific disciplines, objective analysis of the matter at hand is essential. However, in medical research, subjective inputs from patients are also important, as the most important goal of medical research is to improve the well-being of the patients. In foot and ankle research, the quality of patients' lives, treatment efficacy,

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and procedure safety should improve through better understanding of the procedure, patients' bodies, and patients themselves. For years, foot and ankle research focused on the procedures and patients' bodies. However, the recent movement toward patient-centered care has shifted the focus toward patient-reported outcomes (PROs).¹ Instead of only reporting provider-measured outcomes (such as radiographic measurements), the trend is to capture outcomes from the patient's perspective. This shift in paradigm, and the advantages/disadvantages of this trend are discussed.

TYPES OF OUTCOME MEASURES COMMONLY USED IN FOOT AND ANKLE RESEARCH

Scientific reasoning requires the formulation of a hypothesis and the testing of that hypothesis. Outcome measures are needed to detect significant findings formulated in those hypotheses. Ideal outcome measures are free of errors and biases, they should be valid and reliable, and they should also be responsive to changes and not have floor or ceiling effects. From a practical standpoint, they should also be easy to use, reproducible, cost-effective for the investigators, and minimally cumbersome for the patients.

Error in measurement causes inaccurate results, and some outcome measures are more prone to measurement error than others. For example, measurements of Kite's angle in the dorsoplantar view of a plain radiograph of a foot can be subject to measurement error due to difficulty seeing the outlines of the talus and calcaneus and judging the axis of the corresponding osseous structures. On the other hand, measurements of the first intermetatarsal angle are much more straightforward, with more visible long bones. This type of disparity in measurement accuracy can cause inconsistency in study results, and one needs to be aware of this phenomenon.

An outcome measure also needs to be responsive to changes and free of floor or ceiling effects. Potentially, for example, a positive result, such as improved pain, can be lost when an investigator classifies pain into two broad dichotomized categories. Specifically, if preoperative and postoperative pain are measured as "yes" or "no," the broad spectrum of pain is lost in the dichotomized data. Similarly, the floor and ceiling effect of a measure can mask a potentially detectable difference between groups when the results are clustered in the maximum or minimum scores of the measure. For example, no difference can be detected among top students when an examination is too easy and when many students get 100% in the class. This ceiling effect does not prove that there is no difference between the top students, but rather makes the difference undetectable.

Validity refers to how well an outcome measure represents what is intended to be measured. For example, a patient's quality of life is often measured by scores obtained from surveys. How accurately the score represents patients' quality of life determines the validity of the survey instrument.

The validity of outcome measures is often overlooked in study design. A newly designed survey instrument must undergo vigorous validation processes to show relevance to the study question. The new instrument is said to be validated if the outcomes correlate well with previously validated instruments. Results obtained from unvalidated instruments may be inaccurate and may not answer the intended study question.

For the practicality of conducting research, cost-effectiveness and ease of use are also important. Often surgical outcome studies are conducted with patients filling out multiple surveys for PRO measures. This can take a great deal of time and create fatigue for patients, and the results can be inaccurate. From the perspective of patients

and the survey administrator, an ideal instrument should be short, easy to use or read, and free of cultural bias.

CLINICIAN-BASED VERSUS PROs

Outcome measures can be categorized into provider-based and patient-centered measures (Table 1). Provider-based measures are independent of patients' feelings, opinions, and perspectives. Examples of these in foot and ankle research include radiographic angles, nonunion rate, and gait analysis. On the other hand, patient-centered measures are reported by patients and are independent of provider-based measures. These include patient satisfaction, pain, and quality of life, all reported via survey.

RADIOGRAPHIC MEASUREMENTS

It is common to study surgical outcomes in terms of radiographic measurements, namely angles, distances, and presence or absence of nonunion. While these measures have been considered clinically significant by clinicians, providers, and surgeons, they are not a direct measure of patients' perceived clinical outcomes. In fact, many studies have failed to show a relationship between PROs and radiographic measurements.^{18,19} In such cases, one should question the importance of the radiographic measurements, as these measurements do not represent patients' perceived quality of medical/surgical treatments, and thus do not appear to impact patient outcomes.

Radiographic measurements can also be prone to measurement error. When the margin of error is greater than the detectable difference, the result is said to be

Table 1 Examples, pros, and cons of patient-reported outcomes versus provider-measured outcomes		
	Patient-Reported Outcomes	Provider-Measured Outcomes
Pros	<ul style="list-style-type: none"> • Outcomes are patient-centered • More accepted in today's clinical research and practice 	<ul style="list-style-type: none"> • More objective • Convenient for investigators
Cons	<ul style="list-style-type: none"> • More subjective • Often not specific enough • May be cumbersome for patients • May be costly 	<ul style="list-style-type: none"> • Do not incorporate patients' perspective • May not have any clinical significance
Examples	<ul style="list-style-type: none"> • Patient-Reported Outcomes Measure Instrument Systems (PROMIS)^{2,3} • Visual Analogue Score (VAS) for pain⁴ • 36-Item Short Form Health Survey (SF-36)⁵ • Foot and Ankle Ability Measure (FAAM) Score⁶ • Foot and Ankle Outcome Score (FAOS)⁷ • EuroQol EQ-5D⁸ • Foot Function Index (FFI)⁹ • Self-reported Foot and Ankle Score (SEFAS)¹⁰ • Western Ontario and McMaster (WOMAC) Osteoarthritis Index Score¹¹ • Short Musculoskeletal Function Assessment (SMFA) Questionnaire¹² • Ankle Osteoarthritis Scale (AOS)¹³ 	<ul style="list-style-type: none"> • Radiographic measures • Gait analysis • Manual muscle testing¹⁴ • Nonunion rate • Range of motion • American College of Foot and Ankle Surgeons (ACFAS) score¹⁵ • American Orthopaedic Foot and Ankle Society (AOFAS) score¹⁶ • Olerud-Molander Ankle Score • Japanese Society for Surgery of the Foot (JSSF)¹⁷

inaccurate. Measurement errors can stem from a measurement method, a rater's experience, the anatomical location at which the measure is taken, or the type of measurement, as detailed in the following sections.

Using manual instruments such as a ruler, caliper, tractograph, or goniometer on plain x-ray films was common in the past to measure the angles and distances. While the manual instruments themselves may be precise, an error can be introduced by the users of the instruments. These methods can be improved in terms of accuracy with computer measurement systems with or without additional software.^{20–22}

Even with accurate tools, there are issues with points of reference and the definitions of radiographic measurements.²³ Location, position, and type of structures being measured can also greatly affect the accuracy of the results.^{24,25} Reference points are often inconsistent between the observers and studies.^{26,27} For example, “bisection of long bone” can be determined by different methods, by different observers, and in different studies. Such variability is often more prevalent in smaller, shorter long bones than in more easily visible long bones. Even in the case of a well-visualized anatomical structure, reference points can be subject to inaccuracy due to parallax created by the radiographic projection angle and distance.^{28–30} Reduction of the 3-dimensional image into 2-dimensional measurements, therefore, can lead to discrepancy and inaccuracy.³¹ Three-dimensional CT scans and MRI measurements are often used to minimize this issue.^{32–34}

The experience of the raters can also affect the measurements. The variability between raters is often mitigated by training them to standardize their definitions and methods of taking particular measurements before a research project begins. Alternately, taking an average of measurements made by different raters can neutralize errors created among the raters. Without these quality measures and assurances that the measures are of high quality, the results obtained from radiographic measurements can be unreliable. To show a result's reliability, many investigators evaluate interrater and intrarater reliabilities.^{35,36} Analysis using measurements with poor inter-reliability and intrareliability should be questioned.

Another popular outcome measure in foot and ankle surgical research is the occurrence of nonunion. This, too, is not a direct measure of a clinical outcome from the patient's perspective, but it is more closely related to clinical symptoms, such as pain and satisfaction, than radiographic measures. It is, however, still prone to measurement error and inconsistency.³⁷ Many of the criteria within the definition of nonunion are subjective and prone to bias. Definitions of nonunion have different dimensions: It is a function of bone healing (often assessed by radiographs), time, and clinical symptoms.

Assessing nonunion on plain films can be subjective; poor-quality radiographs, an overlap of osseous structures, and soft-tissue edema often block the view and make judging key features such as cortical bridging challenging. While adjusting exposure and tone can improve visibility in a digital image, these improvements have their limits. Multiple views of plain radiographs are also used to minimize the aforementioned problem. Also, CT scan has been shown to be more reliable in identifying nonunions.

Time is a significant component in defining nonunions. Many studies define nonunion as a radiographically visible fusion/fracture site at the “final” visit, yet such studies may not have consistent follow-up times for all their subjects. This variability in follow-up length can bias the results: The shorter the follow-up, the more likely it is that “nonunion” is detected. For example, those with 10-year follow-up will more likely have union than those with only 3 months of follow-up.

Pain is often associated with nonunions; therefore, some use this symptom as part of the nonunion definition. However, it is often unclear in an article how authors dealt with contradicting results between the radiographic and the clinical signs. Often, conjunctions such as “AND” and “OR” in the definition of nonunion are not used correctly. If nonunion is defined by having the radiographic finding “AND” the clinical symptom, both these findings are needed to capture nonunion. If the radiographic finding “OR” the symptom is positive, only one of these findings is needed.

OTHER COMMONLY USED MEASURES IN FOOT AND ANKLE SURGERY

Biomechanical analysis (ie, range of motion and gait analysis) and time to return to work/activity are commonly used measures that are primarily based on providers' perspectives. These measures are also subject to measurement error. Averaging multiple attempts for a range of motion and gait analysis are common ways to minimize measurement errors. Return to work/activity, while important to many patients, is subject to the investigator's bias. If the investigator/surgeon has control over when the patient returns to a certain activity, the finding can be highly subjective and prone to bias. Further questions have been raised as to whether the measure is inherently biased.³⁸

While many studies evaluate multiple outcomes, including these provider-based outcomes and PROs, in the same cohort, the correlation between these provider-based measures and PROs is rarely studied. The assumption is that the more physiological the gait and range of motion are and the quicker the return to activity, the better the PROs. However, the association many times is not present or simply has not been evaluated.

PATIENT-REPORTED OUTCOME MEASURES

The movement towards patient-centered care has significantly increased the utility of patient-reported outcome measures (PROMs). In the research setting, the patient's perceptions of and satisfaction with treatment outcomes are recorded via a survey form and quantified with a validated scale. The survey often gives a “score,” and the number is used for statistical analysis. A broader categorization, for example, of satisfaction as “very satisfied,” “satisfied,” or “somewhat satisfied,” is becoming less popular, as these can be subject to floor and ceiling effects, unresponsiveness, and validation issues.

In contrast, however, more sophisticated scoring systems are time-consuming, expensive, and cumbersome for patients even though they can provide more reliable, responsive results. Especially when subjects fill out multiple long surveys, they can become fatigued and thus potentially provide inaccurate answers.

The PROMs can also be vague and not specific to the pathology or treatment of interest. General questions in some PROMs may not relate to foot and ankle-specific issues. This generalization might result in unresponsive scores, inaccuracy, and difficulty detecting significant results. In these cases, the lack of significant results should not be treated as an absence of proof; instead, they indicate that more specific instruments are needed.

Patient-reported outcomes measurement information systems (PROMIS) were created to solve many issues often associated with cumbersome survey instruments. The National Institute of Health developed the system to capture different dimensions of outcomes from patients' perspectives while keeping it user-friendly and relatively short and maintaining validity. It uses many validated, relevant questions to obtain information from patients. The survey is designed so that the set of questions changes

depending on the patient's response, minimizing the number of questions being asked.

The PROMIS has different versions for specific topics. It is available in multiple languages, each validated for cultural adaptation. It is also technologically easy to use and can be administered with minimum effort, for example, on a tablet while waiting for a provider.

The American Orthopaedic Foot and Ankle Society recommended that this instrument be used in foot and ankle research in their position statement in 2018.³⁹ Specifically, they support the use of the Physical Function Computerized Adaptive Test and Lower Extremity Computerized Adaptive Test. Along with PROMIS, they advocated for Foot and Ankle Ability Measure and Foot and Ankle Outcome Score (FAOS).

ASSOCIATION BETWEEN PROVIDER-BASED AND PATIENT-CENTERED OUTCOME MEASURES

Currently, in the practice of medicine, patient-centered measures are weighed more heavily than provider-based measures. However, in research, different study questions call for different measures. Therefore, both provider-based and patient-centered measures have their own scientific merits. Any foot and ankle procedure can be researched with either type of outcome measure. However, if the investigator is a clinician involved with a patient's medical/surgical care, identifying associations between provider-based and patient-centered measures should be of interest. For example, identifying an association between postoperative hallux valgus angle and PROs should be interesting for surgeons to judge the usefulness of the objective measure in future treatment and research.

Matthews and colleagues¹⁹ investigated the correlation between radiographic measurements and patient-centered outcomes in hallux valgus surgery. They tested the FAOS subscale scores against radiographic measurements such as postoperative hallux valgus angle, intermetatarsal angles, and metatarsal protrusion. They mostly did not find significant correlations between these measures. This finding is interesting, as this result leads us to infer that surgeons could have been focusing on surgically improving those radiographic measures, even though they did not matter to the patients. With this lack of correlation, the traditional focus in hallux valgus surgery might need to be re-evaluated.

Several reasons exist for the lack of association between provider-based outcomes and PROs. First, the relationship may, indeed, not exist. Improving the hallux valgus angle may not improve PROs, and surgeons may need to re-evaluate the paradigm altogether. Second, the method by which the relationship was assessed is not adequate. The inaccuracy of either type of measurement can mask associations. Alternatively, sometimes the relationship exists but is not necessarily a linear relationship; standard statistical tools may not detect it. While intermetatarsal angle as a continuous variable may not correlate with a PRO score, a range of values (ie, hallux valgus angle of <9 degrees) may. Third, other factors not accounted for in the study can influence the relationship of interest. For example, PROs may not be associated with nonunions in an arthrodesis study with many diabetic neuropathic patients, but the relationship may become apparent when the neuropathic patients are excluded.

On the other hand, there are many instances where PROs are associated with provider-based measurements. Shibuya and colleagues⁴⁰ showed a correlation between the modified ACFAS Rearfoot (Module 3) score and the 36-item short form version 2.0 (SF-36 v2). The ACFAS scale has multiple radiographic measures, while

the SF-36 measures patient-reported quality of life. The combination of the radiographic measure was associated with the patient's perceived quality of life in the study. Therefore, a surgeon may be able to improve a patient's quality of life by improving the components in the ACFAS scale.

Finding the association between provider-based measures and PROs will be essential in future medical research. Objective measures need to be evaluated against clinically relevant measures, including PROs.

SUMMARY

The Future

Patient-centered care will continue to grow, and medical research will focus more on patients' perspectives. For this reason, results and conclusions stemming from PROs will be valued and used in policymaking and by insurance companies more often in the future. At the same time, we cannot completely disregard provider-based measures because we need these measures to understand the science and to identify factors associated with improving PROs. At the same time, a lack of association between provider-based and patient-centered measures will more likely result in a re-evaluation of provider-perceived outcome measures than in that of patient-centered ones. On the other hand, identifying these associations would confirm the importance of the objective measures and enable the providers to better manage patients by improving these specific parameters.

PROs will be more widely incorporated not only in medical/surgical research but also in daily clinical practice. Patients will become accustomed to filling out short item-response surveys more often. The results of these surveys will be available for the physician as feedback and as a tool to communicate with the patients.

Provider-based measures should continue to be vetted for validity and reliability. Those provider-based measures strongly correlated with PROs are more likely to be refined and used further in medical research. Those measures with poor quality or association with PROs will become less popular, and studies using these measures will have a more challenging time being accepted by clinical journals.

CLINICS CARE POINTS

- Recognize that PROs are becoming the standard.
- Avoid focusing only on provider-based measures.
- Evaluate the relationships between PROs and provider-based measures.

POINTS OF INTEREST

- More medical/surgical journals will look for studies using outcome measures from the patient's perspective.
- When provider-based measures are used, many medical/surgical journals will expect to see the relationship of these objective measures to PROs.
- Health care systems and insurance companies will focus more on reviewing clinical studies tied to PROs for policymaking.

DISCLOSURE

The authors have nothing to disclose.

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