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CHAPTER 1

Evidence-Based Medicine in Hand Surgery

Jeffrey Stepan, MD, MSc • Ryan Calfee, MD, MSc

Introduction

In the last 5–10 years, patient-reported outcomes (PROs) have become increasingly emphasized in hand surgery and health care overall. The changing landscape of health care has placed an emphasis on value and patient's perspectives, with value defined as cost/outcome. Historically, outcomes were solely determined by objective measurements, such as range of motion or strength. There is now greater importance placed on the patient's perspective. Thus, PROs are used to understand clinical outcomes and quantify the value of care according to the patient.[1,2] Some medical and orthopedic specialties have one or two primary PROs that are heavily relied on, while hand surgery has multiple PROs. The multitude of PROs gives hand surgeons flexibility as each provides slightly different information, but the number of options can present a daunting task when choosing which to use. The options include general outcome instruments to assess overall health and function, while some focus on specific body regions and conditions. Several review articles examine the traditional PROs used by hand and upper-extremity surgeons.[1,3,4] This chapter will review the most recent trends and future directions of hand surgical outcome assessment.

Shortcomings and Challenges

Outcome measurements in hand surgery are not without limitations and challenges. The use of PROs always requires resources. Whether putting in time or money with programing and technological resources to deliver digital surveys, or printing and scanning paper surveys into records, an investment from the investigator is needed. Then, given the range of options and lack of a consensus outcome measure for most conditions, it is likely that any outcome measure used universally in a practice is going to perform imperfectly. Finally, most practices are still trying to find the best way to incorporate outcome assessments in real-time during care delivery and to collect such data at regular intervals when patients stop needing clinic follow-up visits.

New Developments and Current Concepts

Patient-Reported Outcome Measurement Information System (PROMIS)

PROMIS is quickly becoming one of the most used PRO measures in hand and upper-extremity surgery.[5] It represents the latest generation of PROs, which leverages computer adaptive testing. The National Institutes of Health (NIH) funded the development of PROMIS, which includes a comprehensive set of health instruments based on the biopsychosocial model that are not disease specific.[6] This allows comparison across specialties of medicine with evaluations of physical, mental, and social health. While any domain can be collected, the domains that seem most relevant to hand surgeons are physical function (PF), upper-extremity (UE) function, pain interference (PI), depression, and anxiety. A guide to the implementation and use of PROMIS for the hand surgeon is available online.[7] The PROMIS administration information is available at healthmeasures.net.

Although it can be administered in a paper format, PROMIS is typically administered using the item response theory (IRT) and a computer adaptive test (CAT).[8–10] Question banks have been developed for each domain. The IRT gives a series of questions from the item bank that are calibrated based on the probability that a person will respond in a particular way and can discriminate one patient from the next. The CAT allows the instrument to be administered on a computer (tablet) and uses an algorithm to select questions based on the answer to the previous question. This typically produces scores after 4–6 questions taking about 1 minute per domain.[10,11] This reduces the number of questions asked while maintaining precision health estimates.

The PROMIS scoring is designed to follow a normal distribution with a mean T-score of 50 and a standard deviation of 10.[6,12,13] Higher scores always indicate more of a domain. Thus, higher PROMIS PF and UE scores indicate better physical function, or upper-extremity function, while lower PROMIS PI, anxiety, and depression scores indicate better pain coping and less anxiety or depression symptoms, respectively. With a standard deviation of 10, 90% of the population should score between 40 and 60 and 95% of the population between 30 and 70. While possible to score lower or higher than this, it is uncommon, and ceiling and floor effects do exist, meaning the instruments can have difficulty discerning levels of function at the extremes. Recently, the PROMIS UE was updated to address known ceiling effects by adding 31 items to create PROMIS UE v2.0.[10,14,15] While this new version has improved psychometric properties, studies have shown that PROMIS UE v2.0 still exhibits a ceiling effect which may make it difficult to differentiate between high-functioning patients with minor disability doing specialized and demanding upper-extremity tasks or healthy patients with average upper extremity use without upper-extremity disability or disease.

Multiple authors have reported a strong correlation between PROMIS and various legacy instruments, including Disabilities of the Arm, Shoulder, and Hand outcome measure (DASH), Patient-Rated Wrist and Hand Evaluation (PRWHE), Michigan Hand Outcomes Questionnaire (MHQ), Boston Carpal Tunnel Questionnaire (BCTQ), and Thumb Disability Index (TDI) for various conditions.[10,16–20] In over 1000 patients presenting with non-traumatic hand conditions, PROMIS PF successfully demonstrated differential functional impairment between specific conditions. When compared with QuickDASH surveys in a subset of these patients, PROMIS PF indicated similar relative impairment with a strong correlation between QuickDASH and PROMIS PF scores.[21]

Single Assessment Numeric Evaluation (SANE)

Recognizing the responder burden of lengthy surveys, there has been motivation to validate shorter assessments. Brevity both reduces the time for completion and potentially improves responders' attention to questions. Hand surgeons have seen the development and the growing popularity of the QuickDASH and the brief MHQ. Most recently, researchers have sought to validate the SANE which comprises a single question and is unique in allowing a patient to rate their body part without any constraint or direction as to why, or how, to choose a score. Originally published as a shoulder assessment, the SANE asked, "How would you rate your shoulder today as a percentage of normal (0%–100% scale, with 100% being normal)?"[22] The modified SANE question used by Gire et al modified this by querying, "For the problem that you are seeking treatment for today, out of 100% (100% being normal), how would you rate the function of your right/left wrist/hand/finger/elbow today?"[23] Among 214 patients undergoing common hand surgeries, the SANE was concluded to be a reasonable measure of global function with psychometric properties comparable to the QuickDASH and PROMIS UE.

Patient-Specific Function Scale (PSFS)

The PSFS is a PRO that also crosses over into a realm of patient-centered outcome measures (PCOMs). The idea is that an outcome measure can be used that aligns with the values of that particular patient and measures disease status and treatment effect relative to the patient's individual goals. For the PSFS, patients identify 3–5 activities with which they have difficulty because of their condition and rate them on a scale from 1 (unable to perform activity) to 10 (able to perform activity at the same level as before injury or problem). Scores are averaged, resulting in a score from 1 to 10 (1 indicating extreme disability and 10 indicating no disability).[24]

In a study of hand surgical patients, 77% preferred the PSFS over the QuickDASH.[24]

Content analysis revealed that the preferences were driven by the instrument simplicity, the personalized assessment, the instrument being goal directed, and the basis on distinct items. This type of assessment may best allow patients and treating providers to see if treatment is meeting expectations for that individual. The drawback is that having each patient scored based on differential functions prohibits comparisons between populations and across conditions, whereas standardized patient-rated outcome measures may better compare across populations. The suggestion by Shapiro et al was that it may be ideal to incorporate both a standardized patient-rated outcome measure and a patient-specific measure to assess outcomes.[24]

Legacy Questionnaires

Despite recent trends for shorter and computer-adaptive questionnaires, upper extremity and disease-specific questionnaires are still widely used in hand surgery research. General hand questionnaires such as the DASH, MHQ, and PRWHE and their shorter versions the QuickDASH and Brief MHQ are some of the most commonly used measures. Several investigators have shown good correlation between PROMIS UE and PF questionnaires[17–21] with existing patient-reported upper-extremity outcome measures. For a list of commonly used patient-rated outcome measures, see Table 1.[25]

Disease-specific questionnaires such as the BCTQ and Cold Intolerance Severity Scale may continue to be important in analyzing how patients respond after treatment to specific diseases. The BCTQ is more responsive after treatment for carpal tunnel syndrome than PROMIS UE, PROMIS PI, or MHQ and thus is better able to distinguish how patients improve after treatment.[26,27] The Cold Intolerance Severity Scale is another specialized survey which is more symptom specific as opposed to disease specific.

Questionnaire Delivery and Uses

PROs can be implemented and delivered in a variety of ways. Traditionally, many of the patient-rated outcome measures have been used for research. More recently, however, there is increasing utilization of questionnaires for patient care in real time and in value-based and -shared decision-making models. This requires differing delivery models to obtain results that can be viewed at the point of care. The overall purpose, number of resources, and funding will drive the type of delivery method of PROs.

Most legacy questionnaires as well as PROMIS short form questionnaires can be delivered via paper forms that require manual calculation of scores and either manual input or scanning of completed forms into records. The logistics of collecting, scoring, and scanning/inputting paper form questionnaires limits the usefulness of real-time point-of-care use but is often the cheapest mode of PRO delivery.

For research purposes within academic settings, REDCap can collect PRO's measures and store them outside of the medical record. REDCap is an online, secure data collection tool often used in clinical research available at most academic institutions, typically free of charge. Forms are delivered either via a tablet or desktop computer through a program or web browser. REDCap has the capability to deliver both standard and computer adaptive PROs that will automatically score measures once they are completed by the patient. Given that REDCap scoring and data collection occur outside of the medical record, it limits the use of PROMIS at the point of care.

The availability of PROs delivered through various electronic medical record (EMR) systems continues to expand. As use of questionnaires becomes more widespread, many EMRs have built-in functions to allow PROMIS and many legacy questionnaires to be collected directly through the patient portal. For example, in EPIC, PROMIS can be delivered using *my chart* or through in-office kiosks or tablet computers associated with the EPIC *Welcome* app system. Alternatively, institutions or groups may pay to use the web-based assessment center, an Assessment Center Application Programming Interface (API), or Outcomes-Based Electronic Research Database (OBERD) enterprise software to deliver PROMIS and then integrate scores into the medical record. Depending on the EMR or third party used to collect PROs, this option may be the most cost prohibitive. However, these delivery methods may be the most efficient for

Table 1. Widely referenced patient-rated outcome measures for the hand and wrist.

Scale	Anatomic Region	Measures	Scores	Number of Questions	Populations Tested
Boston Carpal Tunnel Questionnaire (Levine and Katz)	Hand	Pain, sensibility, weakness, and function	Symptom severity, functional status	19 q	Carpal tunnel syndrome Also applied to cubital tunnel syndrome
Michigan Hand Questionnaire	Hand	Hand function, daily activities, work activity, pain, appearance, satisfaction	Total, activities of daily living, work, pain, aesthetics, satisfaction for right and left	71 q	General hand and wrist disorders
Brief MHQ	Hand	Hand function, daily activities, work activity, pain, appearance, satisfaction	Total	12 q	General hand and wrist disorders
Patient Rated Wrist/Hand Evaluation	Hand	Pain, daily activities, recreation, and work activities	Total, pain, function	15 q	General hand and wrist disorders
DASH	Upper extremity	Composite bilateral function	Total	38 q	General upper-extremity diagnoses
QuickDASH	Upper extremity	Composite bilateral function	Total	11 q	General upper-extremity diagnoses
Cold Intolerance Severity Scale	Hand	Cold intolerance frequency, duration, alleviating measures, impact on activity	Total	6 q	Patient with cold intolerance
PROMIS Physical Function	General physical function	Overall function including upper and lower extremities	Total	Typically 4–8 questions using computer adaptive testing	Any patient
PROMIS Upper-Extremity Function	Upper extremity	Overall upper-extremity function	Total	Typically 4–8 questions using computer adaptive testing	General upper-extremity diagnoses

Adapted from Calfee and Adams.[25]

both the patient and the provider, especially in offices without access to REDCap. This real-time collection of PROs with integration into the EMR also allows the use of PROs within a patient's office visit to inform the care discussion.

Future Directions

Point of Care

The importance of PROs in evaluating and assessing patient function is of vital importance in determining the success of various treatments. These assessments

have mostly been performed on a population level; however, there is increasing interest in utilizing PROs to inform patient decision making at the point of care. As our ability to collect PROs in real time at or prior to an office visit becomes less burdensome, these data will be available both to the surgeon and the patient during an office visit. There is still much controversy in the best way to utilize this information in real-time discussions with patients. A recent study from the Hand Surgery Quality Consortium[28] attempted to reach consensus on "the importance, feasibility, usability, and scientific acceptability of validating candidate process guidelines on how to routinely collect and communicate PRO's at the point of care in hand surgery." Unfortunately, lack of evidence and agreement precluded the formation of guidelines on the use of PROs at point of care in hand surgery.

It is easy to imagine how PROs can be useful in point-of-care tracking of patients in measuring the improvement after treatment. Future directions, however, may involve utilizing the information obtained from PROs to move toward personalized shared decision making,[29] potentially providing quantifiable estimates of improvement in function or pain after a certain treatment as well as estimating risks based on demographics, disease status, and psychosocial and function scores. Although we may not yet be at the point of true personalized shared decision making with use of PROs in hand surgery, there is mounting evidence of the usefulness in simply sharing and discussing results of these outcome measures with patients.

Registries

When assessing outcomes, retrospective reviews of medical records are fraught with limitations. Meanwhile, the necessary limited focus and exclusion criteria associated with prospective trials can limit the ability to generalize findings to clinical practice. Hand surgical registries may serve a role moving forward to document value of care delivered and treatment outcomes in a rigorous manner while still reflecting typical practices.[30] Registries can be within institutions, collaborative efforts between centers, or national programs.[30–33] While cost and infrastructure remain major challenges for most registry efforts, such prospectively designed and purposefully collected data may provide a largely untapped method to provide evidence to guide future hand care.

Qualitative Research

Qualitative research methodologies are also emerging as an increasingly popular way to understand patient experiences.[34–36] Using standardized interviews followed by coding and thematic analytics, this approach delves deep into the impressions of limited number of patients. As opposed to producing scores for statistical analysis, these patient interviews are assessed to determine common feelings, concerns, and impressions from patients' personal health journey.

Future Directions

Outcome assessments for hand surgery have evolved substantially in the past decade. Without question, the value of care delivered is now being judged from the patient's perspective more than ever. Most research is incorporating standardized PRO assessments. The sophistication of validated PRO instruments is ever increasing and making large-scale data collection feasible. Moving forward, we expect that such tools will contribute to the delivery of truly patient-centered care. In the next 10 years, we expect more qualitative research and for registries incorporating PROs to guide our delivery of evidence-based medicine.

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