Measurement and assessment in modern hand surgery research

Alexia Karantana, Jeremy Rodrigues, Tim Davis

The outcome of hand surgery has traditionally been objectively assessed with measures such as sensory thresholds, grip strength and range of thumb, finger or wrist movement. Cut-off thresholds for each of these measures are often broadly categorised as "excellent", "good", "fair" or "poor"; or "good" or "bad". In Dupuytren’s disease it is stated that surgery is indicated if there is a 30° or more flexion deformity of a joint, regardless of whether the contracture is causing inconvenience or loss of function.

Additionally, a 20-30° increase in the flexion deformity following surgery is categorised as "recurrence" and thus a "poor" outcome. This again is regardless of whether there is loss of function or disability, or whether it requires revision surgery. However, angular deformity does not correlate well with loss of function in Dupuytren’s disease, and does not reflect the impact of surgical complications such as digital artery and nerve damage, or loss of finger flexion.

Hand surgery outcomes may also be assessed radiographically. This may be acceptable if the x-ray measurement is a reasonably good surrogate for the clinical outcome, as, for example, is the case for union/non-union of a scaphoid fracture. However, the assessment of outcome according to x-ray features which do not correlate well, or at all, with the clinical outcome are unsatisfactory. Similarly, dorsal tilt, radial angle and shortening of a united distal radius fracture have not been shown to reliably correlate with function, despite a plethora of studies. They may predict the cosmetic outcome but this is more readily assessed by actually looking at the wrist or, best of all, by asking the patient what they think of the appearance of their wrist – a PROM (patient reported outcome).
PROMs assess variables that cannot be measured directly, such as “hand function”, “health status” or “health-related quality of life”. Improving these is the aim of treatment in non-terminal conditions that are usually encountered in hand surgery. Such PROMs are more pragmatic than many objective outcomes. For example, it is probably more important to establish whether or not patients’ function improves as a result of treatment, rather than whether they achieve an arbitrary improvement in grip strength yet still require social care for activities of daily living. PROMs typically involve questionnaires completed by the patient and, if well-designed and validated, can provide a patient-centred perspective on treatment effect. Increasingly, robust science underpins the design and validation of high-quality PROMs, and their use in research and clinical practice.

PROMs can be used to assess the outcome of both hand trauma and elective surgery. There are many PROMs available for use in hand surgery. They range from those that assess general health status or health-related quality of life, through domain-specific PROMs to assess the hand or upper limb as a functional entity, to disease-specific measures that assess a particular condition. Often, the most popular PROMs are domain-specific to the hand, wrist or upper arm. These include the Disabilities of the Arm, Shoulder and Hand (DASH), the Patient Evaluation Measure (PEM), the Michigan Hand Questionnaire (MHQ) and the Patient Rated Wrist Evaluation (PRWE). At present no specific upper limb PROMs are superior in terms of their reliability, validity and responsiveness.

In contrast, disease-specific PROMs, such as the Unité Rhumatologique des Affections de la Main (URAM) scale for Dupuytren’s disease, may be more sensitive when working within a condition, for example, comparing two operations for Dupuytren’s disease. However, they do not compare different hand conditions. While most of the PROMs currently used in hand surgery have good points, they have limitations. Most have not been developed using contemporary methods and do not perform ideally when subjected to rigorous modern psychometric assessments of validity, reliability, responsiveness and interpretability. In the future, it is likely that existing PROMs will be refined, and new PROMs will be introduced. PROMs should be seriously considered for use as the primary outcome in most hand surgery studies, whilst acknowledging their limitations.

Unfortunately, there is little consensus on which PROM is best for any clinical setting.

Outcome assessment with a PROM may show that treatment ‘A’ produces good results in 85% of cases while treatment ‘B’ only produces good results in 70% of patients. In this case, should all patients receive treatment ‘A’? This could be the case if treatment ‘A’ costs no more than treatment ‘B’. However, if treatment ‘A’ is more expensive, is it not reasonable that those paying for the treatment should be involved in the decision? Cost and, more specifically, the concept of “value for money” is an increasingly important factor in decision making for the modern NHS.

In general, a new treatment is considered clinically effective if, in day-to-day clinical practice, it results in an overall benefit to health. It is considered cost-effective if these health benefits are greater than the costs required to fund it, in the context of limited NHS resources. In other words, the general consequences for the wider group of patients in the NHS are considered alongside the effects for those patients who directly benefit from the new treatment. For example, is the benefit of a renal transplant greater than that of using the same resources for carpal tunnel surgery or newer technologies such as collagenase in Dupuytren’s?

The National Institute for Clinical Excellence (NICE) was established in 1999 to address geographic variations in prescribing (‘postcode lottery’) by providing national-level guidance on the clinical and cost-effectiveness of health technologies in the NHS. As part of its process of technology appraisal, NICE has adopted a ‘reference-case’ approach, specifying methods and outcomes used to assess the cost-effectiveness of treatments.

Cost-effectiveness analysis (CEA) from the perspective of the NHS does not take into account personal or societal costs. Costs borne by patients, such as loss of income or personal expenses, are included only when reimbursed by the NHS or Personal Social Services. Wider costs to society do not feature in this setting. The health system does not benefit from returning someone to work earlier, as the purchaser pays the provider the same, whether the person is off work for one day or one year.

Health benefits are measured in terms of Quality of Life (QoL) using generic outcome instruments, such as the EQ-5D or SF-36. These are designed to...
cover the more common, core dimensions of health and, unlike clinical PROMs, allow direct comparisons across different conditions and treatments in healthcare. On the other hand, they can be less sensitive to change than clinically focused patient-reported outcome measures for a particular treatment. They also require a potentially larger sample size. The EQ-5D is the required measure of QoL in the NICE reference case (Guide to the methods of technology appraisal, 2013). NICE also use Quality Adjusted Life Years (QALYs) as a measure of cost-effectiveness. It considers that a QALY cost of £20,000-£30,000 represents good value for money in terms of cost-effectiveness.

Alongside clinical appraisal, CEA is now a requirement for NIHR comparative studies, such as multicentre randomised controlled trials of interventions. The NICE reference case has been set to specify the methods and outcomes “considered by the institute (NICE) to be appropriate for the Appraisal Committee’s purpose and consistent with the NHS objective of maximising health gain from limited resources”6. Nevertheless, the methodology of economic evaluation in healthcare, and in particular CEA, is fraught with areas of uncertainty and controversy. In addition, the concept of cost-effectiveness has yet to be fully grasped by surgeons and users of the NHS alike.

Alexia Karantana is Clinical Associate Professor in Hand Surgery at the University of Nottingham and Honorary Consultant Hand Surgeon at Nottingham University Hospitals NHS Trust. She is Deputy Director of the Centre for Evidence-Based Hand Surgery, which aims to facilitate high quality patient-centred studies on common hand conditions, addressing clinically important areas of uncertainty relevant to patients and the NHS.

Jeremy Rodrigues is an NIHR Academic Clinical Fellow registrar in plastic surgery at the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS) of the University of Oxford, an Honorary Research Fellow at Warwick Evidence, and a Fellow at the National Institute for Health and Care Excellence (NICE). His MSc dissertation, PhD thesis and ongoing research focus on outcome measurement in hand surgery.

Tim Davis is a Consultant Hand Surgeon at Nottingham University Hospitals and an Honorary Professor at Nottingham University. He is interested in clinical research on common hand conditions and injuries.

Correspondence
Email: Alexia.Karantana@nottingham.ac.uk
Email: j.n.rodrigues@doctors.org.uk
Email: Tim.Davis@nuh.nhs.uk

References
References can be found online at www.boa.ac.uk/publications/JTO or by scanning the QR Code.

---

Remember them fondly
It is with great sadness that we report the passing of Neil Bradley. Our thoughts are with his family and friends at this time.

Thinking of the future
The work you do is incredibly important and affects the lives of so many people suffering from musculoskeletal disorders throughout the UK. You selected orthopaedics over any other specialty which means you believe in helping and advancing this field of medicine.

We have shifted our focus from funding multiple pump-priming grants to funding one targeted, larger grant with the BOSRC, which we believe will have an even bigger impact, by successfully multiplying available research funds. By doing this, we hope to achieve a step change in research – with more trials, at more centres, looking at treatments for more orthopaedic conditions. This change means that we need your support more than ever.

To continue this valuable work and to benefit future generations, please consider leaving a legacy in your Will to the Orthopaedic Research Appeal of the BOA. You can make a difference.

For more information visit www.boa.ac.uk/research/leaving-a-legacy.

Festive Fun Answers
Solve the Puzzle answer: Thank you to all of our members for a successful year
Festive Quiz answers:
1. Holiday Inn;
2. Ladies dancing;
3. Christmas cracker;
4. Mexico;
5. The Nightmare before Christmas;
6. Dr Seuss;
7. Canada;
8. George V (in 1932);
9. Clarence (Odbody);
10. Robert Burns
References