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Randomised controlled trials in hand surgery: a scoping review

Juuso Heikkinen ,[1] Soumen Das De,[2] Jarkko Jokihaara,[3] Kati Jaatinen,[4] Rachelle Buchbinder,[5] Teemu Karjalainen[6]

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[1]Orthopedic and Traumatology, Oulu University Hospital, Oulu, Finland
[2]Department of Hand & Reconstructive Microsurgery, National University Hospital, Singapore
[3]Department of Hand Surgery, Faculty of Medicine and Life Sciences, Tampere University Hospital, Tampere, Finland
[4]University of Jyväskylä, University of Jyväskylä, Jyvaskylä, Finland
[5]Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Victoria, Australia
[6]Unit of Hand Surgery, Department of Surgery, Central Finland Central Hospital, Jyvaskyla, Finland

Correspondence to
Dr Juuso Heikkinen;
juuso.heikkinen@fimnet.fi

ABSTRACT

Objectives To identify the evidence gaps that exist regarding the efficacy or effectiveness of hand surgery.

Setting A scoping review. We systematically searched MEDLINE, Embase and CENTRAL databases to identify all hand surgical randomised controlled trials from inception to 7 November 2020.

Results Of the 220 identified randomised controlled trials, none were fundamental efficacy trials, that is, compared surgery with placebo surgery. 172 (78%) trials compared the outcomes of different surgical techniques, and 143 (65%) trials were trauma related. We identified only 47 (21%) trials comparing surgery with non-operative care or injection.

Conclusion The evidence supporting use of surgery especially for chronic hand conditions is scarce. To determine optimal care for people with hand conditions, more resources should be aimed at placebo-controlled trials and pragmatic effectiveness trials comparing hand surgery with non-operative care.

PROSPERO registration number CRD42019122710.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The first strength is this is the first study of a systematic analysis looking at the evidence on efficacy and effectiveness of surgical operations in hand or wrist area.
⇒ The second strength is the study's methodological strengths including systematic search of all relevant databases and use of a published protocol and the analysis approach.
⇒ The third strength is the involvement of a professional research team comprised of content expertise in both clinical practice and methodology of clinical research.
⇒ The limitation of the study is that our search algorithm was based on anatomical area, while a search including all terms for a myriad of conditions of the hand might have been more sensitive.

INTRODUCTION

Treatment decisions in modern medicine should be mainly based on evidence from randomised controlled trials—but such evidence is relatively uncommon in hand surgery. While an in-depth understanding of hand biomechanics may provide viable hypotheses of what could work, only controlled clinical trials comparing surgery with not having surgery (placebo, no treatment or usual non-operative care) can determine whether surgery provides clinically relevant benefits that outweigh the potential risks. Unlike drugs, most surgical procedures were introduced into practice without these efficacy or comparative effectiveness trials. Most surgical trials compare the outcomes of two surgical treatments which do not provide information about their comparative effects over no treatment or non-operative treatment options. This has led to widespread adoption of surgical treatments in the absence of high-certainty evidence establishing their value.

To ensure that the available research resources are used properly, a thorough understanding of existing knowledge and evidence gaps in hand surgery is needed. Typically, research groups define key questions in their specific area of interests. However, it is uncommon for a whole research field to be assessed from a wider perspective to understand what is known and/or what is not known but needs to be known across a whole subspecialty. A broad perspective may help to identify research priorities across the whole field. The aim of this scoping review was to map the research evidence with respect to clinical effectiveness of surgical procedures for hand conditions and to identify any evidence gaps that exist.

METHODS

The protocol of this scoping review was published at PROSPERO database (ID: CRD42019122710). We adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[1]

Eligibility criteria for included studies

We included all published randomised controlled trials without language restriction that included human participants investigating a surgical intervention for any condition in the hand/wrist area irrespective of

the control arm/s. Surgery was defined as any procedure requiring general, regional or local anaesthesia and a skin incision. We excluded studies that included surgical treatment, but assessed other interventions related to surgery, such as different preoperative or postoperative protocols, anaesthesia or ex-vivo trials. We also excluded trials of injection therapies and trials that that did not exclusively include participants with a hand/wrist condition (eg, a nerve injury study if injuries in the lower extremities were also included).

Search methods

We searched the Cochrane Central Register of Controlled Trials, MEDLINE and Embase databases from their inception until 7 November 2020. The search strategies are listed in online supplemental file 1. There were no language exclusions. We removed duplicate entries before screening.

Two review authors independently screened the titles and abstracts for potentially eligible trials. We acquired full texts for all potentially eligible trials, and two authors independently read the full texts and identified eligible publications. When multiple papers had been published from the same trial, we included only the primary analysis. Discrepancies between the two assessors were resolved through discussion.

Data extraction

Two authors independently extracted data from included studies to pretested data extraction sheets, and discrepancies were settled through discussion.

Extracted data for this scoping review included: the first author, year of publication, trial design (number of centres, interventions, type of comparison), condition being studied, sample size, trial registration (if registered) and whether there was a published protocol.

Patient and public involvement

It was not appropriate or possible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

We identified 220 trials with 17 448 randomised participants (figure 1). For Lian *et al* (2016), we could only extract data from the English abstract. Included study references are presented in online supplemental file 2.

The trials were published between 1964 and 2020 (median 2011, IQR 11 years). The number of published trials per year broadly increased over time (figure 2).

One hundred ninety-one (87%) trials were conducted in a single centre and 29 (13%) in two or more centres. Only 41 (19%) trials were registered in publicly available trial registries and there was a published protocol for eight trials (4%). The median number of participants per trial was 31 (IQR 30).

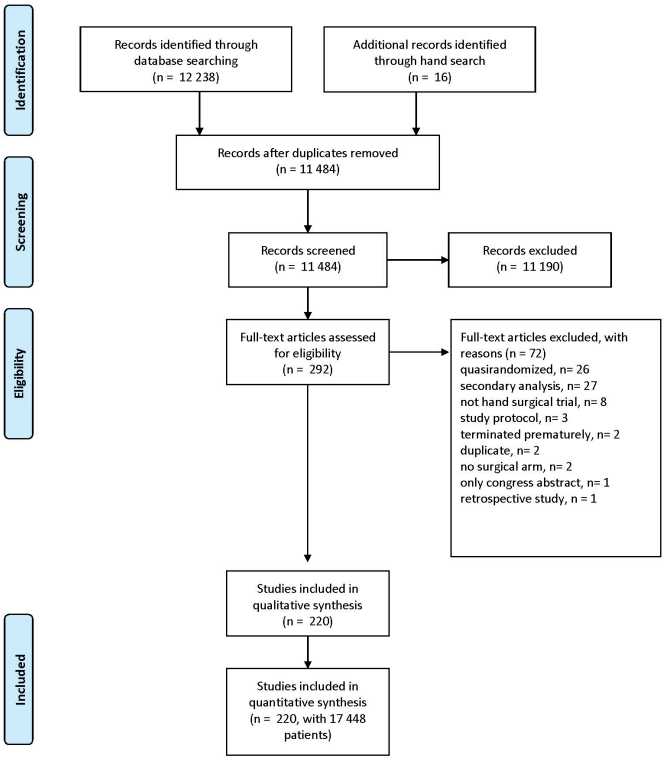

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.

One hundred forty-three (65%) trials were trauma related (figure 3). The most common trials evaluated the treatment of distal radius fracture (n=102, 46%). Of the 77 non-trauma-related trials, the most common evaluated surgical treatment of carpal tunnel syndrome (n=27, 35%) and hand osteoarthritis (n=21, 27%). Most trials included two arms (n=204, 93%), 15 trials (7%) included three arms and 1 trial was a four-armed parallel trial.

None of the trials included a sham or placebo surgery control. Over three-quarters (n=172, 78%) compared one type of surgery with another type of surgery. Surgery was compared with non-operative care or injection in 47 (21%) trials; and in one trial, surgery was compared with percutaneous procedure. There were 30 trauma-related trials that compared various internal or external fracture fixations with a non-operative control (distal radius fracture (n=22); scaphoid fracture (n=4); metacarpal and phalanx fracture (n=2) and mallet fingers (n=2)) (figure 3). We identified only 17 non-trauma-related trials in which surgery was compared with non-operative care or injection (figure 3).

DISCUSSION

Limited experimental data support the use of common elective hand surgery interventions. The benefits of surgery are largely assumed based on biomechanical considerations and observational data from before-and-after studies. We did not identify a single randomised controlled trial assessing the fundamental efficacy (ie, with placebo controls) of any surgical intervention of the

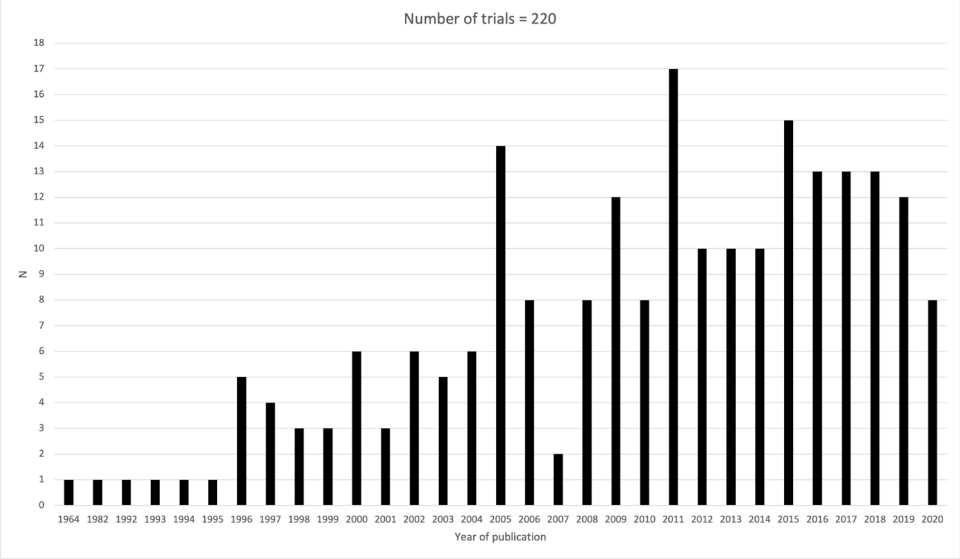

Figure 2 Published studies per year.

hand or wrist. There were also no trials that compared surgery with no treatment.

The efficacy of surgery is often assumed as self-evident, and the burden of proof is left to doubters. Hand surgery often involves individually tailored treatments for varying functional problems such as tendon or nerve transfers for a variety of traumatic conditions, and a requirement for efficacy data for all procedures is not feasible. Nevertheless, we could likely serve our patients better by subjecting the most common procedures to a comparison against placebo surgery or usual non-operative care instead of assuming efficacy based on a biologically plausible but unproven rationale.

We identified only 47 trials comparing surgery with non-operative care including injections. Comparing surgery with non-operative care is also useful: if surgery is no better than non-operative care, then we probably would recommend against surgical treatment most of the time as surgery has greater risks and costs. In these cases, if surgery is delivering no benefits in open-label trials, which tend to overestimate the benefits, a placebo-controlled trial may be redundant because such surgery is likely low-value care and placebo-controlled trial would probably show less benefit.

For some conditions where spontaneous improvement is biologically implausible (eg, Dupuytren's contracture

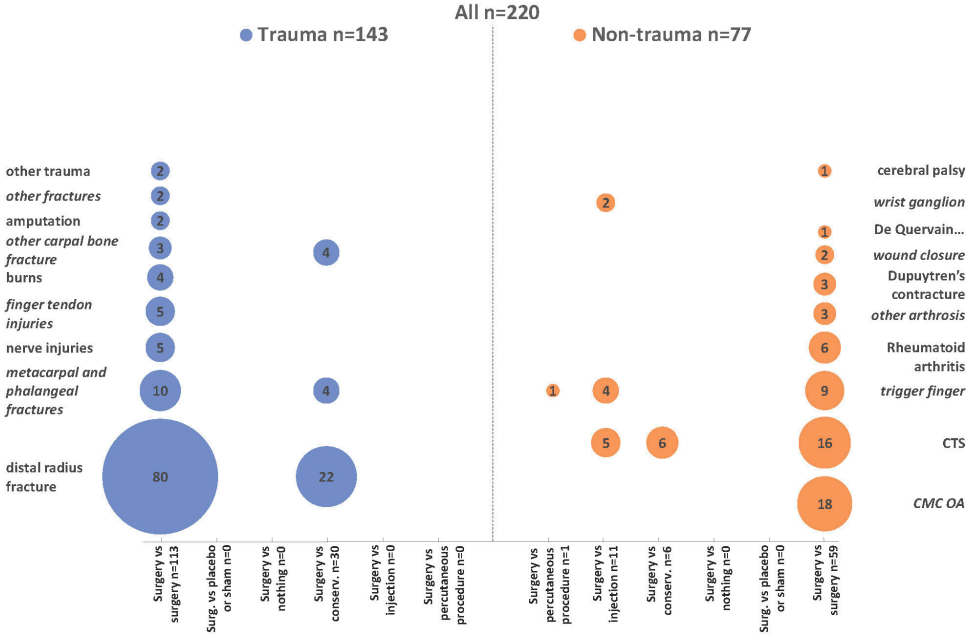

Figure 3 Hand surgical trials according to trauma or non-trauma-related conditions and control arms. CMC OA, carpometacarpal osteoarthritis; CTS, carpal tunnel syndrome.

or long-standing non-union of scaphoid fracture), it is reasonable to estimate efficacy based on a comparison with baseline status in a before–after study. But for conditions where the natural progression may include improvement, like osteoarthritis or wrist ganglia, any observed improvement after surgery needs to be interpreted with caution. Observed benefits are not necessarily attributable to the treatment and therefore we should avoid submitting to a common fallacy 'post hoc ergo propter hoc' (it follows therefore it is because of).

Biomechanical ex-vivo studies improve our understanding about the underlying pathomechanisms and thus provide useful hypotheses of what might work. However, a plausible theory about how a treatment might be effective is not enough—as has been seen with subacromial decompression surgery for shoulder impingement or arthroscopic partial meniscectomy for degenerative knee disease.[2–4] In a classic efficacy design, the intervention in question is compared with a placebo intervention and the trial includes participants who are most likely to benefit. Thus, an efficacy trial answers the question of whether an intervention works in ideal circumstances. If it does not, it likely does not work in usual clinical care due to large heterogeneity in the surgeons and in the population receiving the treatment. If surgery has been shown to be beneficial in an efficacy trial, pragmatic effectiveness studies are needed to determine whether or not the intervention works in daily clinical practice. In addition, the effectiveness of an intervention evaluated by the real-world scenario seems to show 20% smaller treatment effect than traditional rigorous trials.[5]

The extent of research was better in trauma care compared with elective hand surgery (figure 3). However, 102 trials were about distal radius fractures, and all the other fractures were studied rarely; only eight trials compared surgery with non-operative care for other than the distal radius. The lack of comparisons with non-operative care is partially understandable since some fractures (eg, complex unstable or open fractures) are not amenable to non-operative care.

Most (78%) of the identified trials compared two different surgical techniques, a study design that may help optimise operative treatment, but does not determine if surgery provides benefits compared with no treatment or non-operative care per se. If one surgery is better than another, this may be because one truly has benefits or one has less harms, but without a comparison against a treatment of known effects, it is not possible to distinguish between these possibilities.

We are not aware of a systematic analysis looking at the evidence on efficacy and effectiveness of surgical operations in hand or wrist area. One previous scoping review identified 78 studies specifically including hand fractures and joint injuries.[6] The authors concluded that the evidence is narrow in scope and utility is often low due to shortcomings in methods. Our review corroborates their findings and further extend it to cover any surgical operation of the hand/wrist.

We systematically searched all relevant databases to identify randomised controlled trials in the hand and wrist area, but the main limitation of this study is that our search algorithm was based on anatomical area, while a search including all terms for a myriad of conditions of the hand might have been more sensitive. However, it is unlikely that our search missed any published randomised controlled trials.

To conclude, most surgical interventions in the hand are based on observational or biomechanical evidence and efficacy data are scarce for most operations. Diverting resources to test common operations in rigorous efficacy and effectiveness trials would likely improve patient care, permit more efficient use of our resources and increase societal trust in hand surgery. Novel operations should be developed properly using IDEAL approach[7] and tested against placebo, usual care or no treatment instead of comparison with other unproven surgical techniques/with other surgical techniques, which also lack evidence. Until better evidence is available, hand surgeons need to make treatment decisions based on the highest certainty evidence currently available and acknowledge the decision's level of uncertainty. Surgeons and research funding bodies should actively contribute to filling the key knowledge gaps by enabling and participating in well-designed randomised controlled trials.

Twitter Juuso Heikkinen @JuusoHeikkinen2 and Teemu Karjalainen @TeemuVKarjalain

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ORCID iD
Juuso Heikkinen http://orcid.org/0000-0001-9137-788X

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