

Editorial

Waiting for the evidence from ongoing trials: the role of surgery for treating clavicle fractures

Helen Handoll & Mario Lenza 12 June 2013



A new Cochrane Review looks at the evidence for surgical fixation of middle-third clavicle (collarbone) fractures.[1] Clavicle fractures account for up to 4% of all fractures and typically occur in young males engaged in sporting activities, such as cycling and skiing. Around 80% of these fractures occur in the middle-third section of the clavicle. This new review, which includes eight small and flawed trials, concludes that there is insufficient evidence to determine whether surgery gives better outcomes that matter to patients than conservative (non-surgical) treatment.

Three other recently published reviews making this key comparison for other fractures draw the same conclusion. Thus, currently there is insufficient evidence from randomised controlled trials to determine whether surgery gives superior results for ankle fractures,[2] calcaneal (heel bone) fractures,[3] or proximal humeral (shoulder) fractures.[4] Surgery generally involves open reduction, where the bone fragments are put back into position, and fixation of the fracture using various devices. Partial or total joint replacement (arthroplasty) may be an option for older people with severely displaced proximal humeral fractures because the blood supply to the humeral head is compromised, putting fracture healing at risk. Conservative treatment often comprises closed reduction, such as manipulation through the skin to re-align the

fractured bone or traction (when possible), and some form of immobilisation, such as an arm sling for clavicle and proximal humeral fractures, or a cast for ankle and heel fractures. Rehabilitation to restore mobility and function is generally required and is important in both treatment groups for these fractures.

For all four fracture localities, the severity of the fracture is one of the major determinants of type of treatment and outcome. Typically conservative treatment is advised for non-displaced or minimally displaced fractures, which are generally stable. At the other end of the fracture spectrum, especially where there is soft-tissue compromise as in major open fractures (fracture ends are exposed), surgery is needed. But for the majority of displaced (unstable) fractures in these four locations, it is uncertain whether the extra trauma involved and the risks of having surgery, in terms of anaesthesia, surgical complications (such as wound infection) and even mistakes,[5] are merited. The commonly perceived advantages of surgery are a better and retained restoration of anatomy, the potential for earlier rehabilitation, and, related to these, a quicker and better return of the patient to their former functioning and activities. The importance of deformity to function and the risk of post-traumatic arthritis vary considerably with the fracture type and locality. Later surgery for failed conservative treatment or major revision surgery for complications is usually technically more difficult and less successful.

Although the current findings of these reviews are disappointing, all four refer to ongoing trials that should provide better evidence to inform future practice. Furthermore, an assessment of the potential of this evidence to inform future practice and research has curbed a routine call for setting up good-quality well-conducted multi-centre randomised controlled trials as a priority. Instead, as suggested by the authors of the clavicle fracture review, an "appraisal of the need for further randomised trials should be deferred until it becomes clearer whether more are warranted as the evidence accumulates".[1]

The contrast between the currently available and pending evidence for these reviews is noteworthy in terms of sample size and study design. For example, the clavicle fracture review includes eight trials (555 participants), one of which was a multi-centre trial. The eight ongoing

studies, two of which are multicentre, should enrol a total of 1748 participants. The contrast is greater in the proximal humeral fracture review, where the six heterogeneous single-centre trials comparing surgical with conservative treatment involved 270 participants. Of the six ongoing trials, which should provide data for over 1000 participants, three are multicentre trials. The emphasis on multicentre trials is important as they are likely to increase the relevance and applicability of trial findings and, in turn, review findings. Moreover, these are likely to be pragmatic trials that reflect current practice and surgical expertise. Encouragingly, most recent trials are using validated patient-reported outcome measures to assess quality of life, function and pain, although none as yet are fully validated for the specific injuries covered here.

These trials are challenging to do. Some may not meet their recruitment target or may be abandoned, as happened with one multicentre calcaneal fracture trial.[2] However, there are notable advances in orthopaedic trauma, such as the UK National Institute for Health Research's substantial public funding for the AIM and ProFHER trials of ankle and proximal humeral fractures, respectively.[6,7] The citation of various versions of the Cochrane Review on proximal humeral fracture in justifications for new trials illustrates the use to which Cochrane Reviews can be put and the care that is needed in calling for more trials.

These four Cochrane Reviews illustrate the importance of looking at the results of a review in the context of the ongoing research. Trial registration and publication of trial protocols make the identification of ongoing trials easier and should raise the expectation of their completion and publication. A greater focus and discussion of the pending evidence can be viewed as an important adjunct to the task of updating Cochrane Reviews. We look forward to the time when there is much better evidence to inform the role of surgery for these fractures.

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Declarations of interest

The authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available upon request) and declare (1) no receipt of payment or support in kind for any aspect of the article; (2) no financial relationships with any entities that have an interest related to the submitted work; (3) that ML and HH are lead authors of Cochrane Reviews discussed in this editorial (references 1 and 4, respectively) and that HH is a member of the trial management team of the ProFHER trial, but there are no other relationships or activities that could be perceived as having influenced, or giving the appearance of potentially influencing, what was written in the submitted work.

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