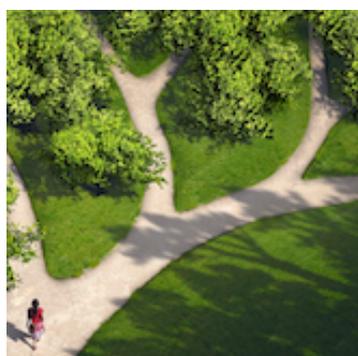


## Editorial

# Not quite what was planned: accommodating the reality of clinical practice in Cochrane Reviews

Helen HG Handoll

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Two new and very different Cochrane Reviews illustrate some key pragmatic decisions taken to enhance the relevance of review findings to clinical practice. Both reviews required reconsideration of their scope. The adjustments related to the participants (in the case of a review of the management of children with ankle fractures) and the study design and control intervention (for a review of interventions for treating anterior cruciate ligament (ACL) injuries).[1,2]

Patterns of injury differ between children and adults, in part reflecting the different vulnerabilities of bone and soft tissues. A twist of the ankle that would commonly result in an ankle sprain in an adult is more likely to result in an ankle fracture in a child. Typically, these fractures involve growth plates, which are the last part of the bone to harden during development. A badly damaged growth plate may result in long-term leg deformity.

All three trials contributing evidence to the Cochrane Review of interventions for treating ankle fracture in children involved children with a diagnosis of a 'low-risk' fracture involving the distal fibula.[1] Diagnosis is primarily based on clinical findings as the undisplaced growth plate fracture is usually not evident on plain X-rays. These less serious fractures have a low risk for impairing growth. The three trials compared early mobilization (comprising ankle brace or bandage) with cast immobilization. In reports of two of the trials, the authors raised the possibility that some of injuries were not fractures. The third trial reported ultrasound examination conducted after randomization, the authors concluding that 19 of 34 followed-up children had "definite evidence of growth-plate injury".[3] As noted in the Cochrane Review, recent evidence from magnetic resonance imaging (MRI) studies of the main category of injury (Salter-Harris type I growth plate fractures of the distal fibula) examined in the three trials strongly suggests that most of the injuries in these trials were sprains or bone bruises.[4,5] An editorial accompanying one of the MRI studies observed that these results debunk the commonly held belief that "children don't get sprains".[6] This new evidence could be disconcerting for authors of

a review on ankle fractures. However, the review authors argue that the key characteristic of the injuries included in the trials is that they heal without deformity and thus "accurate diagnosis of this group of low-risk ankle injuries may be academic".

The role of surgery is the focus of many Cochrane Reviews of musculoskeletal trauma, including ACL rupture. For more serious musculoskeletal injuries, surgery promises better restoration of anatomy, better stability while healing takes place and in the long term, and the prospect of earlier mobilization and return to function. However, these aims may not be achieved, and surgery comes at the risk of surgery-related complications, such as infection and iatrogenic injury. Conducting randomized trials comparing surgical with non-surgical (conservative) treatment is especially challenging, with strong treatment preferences of both clinicians and patients being major barriers to recruitment, adherence to treatment allocation and ultimately to trial success.

ACL injuries are common sports-related knee injuries. Definitive treatment is either non-surgical, primarily a structured exercise programme, or surgical, typically ACL reconstruction followed by a structured exercise programme. ACL reconstruction, which has superseded surgical repair of the ACL, involves the replacement of the ACL by a tendon graft that is often extracted from the patient's leg. In 2006, about 130,000 ACL reconstructions were carried out in the USA alone, and trends show increasing surgery, particularly in adolescents.[7] In contrast to the relatively abundant literature on different approaches to ACL reconstruction, a new Cochrane Review found just one trial comparing ACL reconstruction plus rehabilitation versus rehabilitation alone.[2] This reported the results of 121 young adults with acute ACL injuries. Many of the participants had other knee injuries (e.g. meniscal tears) that were treated surgically.[8] The need for surgery (concurrent or separate) for these concomitant injuries in both groups is the first lapse from a pure surgery versus non-surgery study design. However, the main deviation, built into the study design, was a formal option for subsequent (delayed) ACL reconstruction in the non-surgical group if chosen by the participant and provided prespecified criteria relating to knee instability were met. This can be considered as a formal recognition of a potential clinical sequel of failed conservative treatment; ACL reconstruction is often performed for chronic knee instability related to 'ACL insufficiency'.

A related qualitative study examining the preferences of 34 trial participants indicates the tactic of deferred surgery facilitated recruitment of patients with a strong preference for surgery.[9] These participants saw the trial as a means to circumvent waiting lists, which are a common feature of publicly funded healthcare systems. As noted in this study and reported elsewhere, trial participation often occurs in the absence of participant equipoise as well as misunderstanding by clinicians of equipoise.[10] Although opting for surgery in those participants allocated surgery could be strongly influenced by their prior preference for surgery, the trial results showed no difference between the treatment groups in patient-reported outcomes of knee function. This may indicate, as shown in a trial comparing surgery versus conservative treatment for shoulder fractures, that participant preferences may not have importantly affected patient-reported outcome assessment despite the unavoidable lack of blinding.[11]

Both the reviews described here shifted away from the more exacting inclusion criteria initially implied in their scopes. This resulted in a change in the classification of injury in the first review and a move away from a strict interpretation of a surgery versus not-surgery comparison in the second review. Both changes reflect clinical reality and thus increase the applicability of the review findings.

## Author information

Helen HG Handoll

Senior Research Fellow, Health and Social Care Institute, Teesside University, Middlesbrough, UK; Co-ordinating Editor, Cochrane Bone, Joint, and Muscle Trauma Group; [h.handoll@tees.ac.uk](mailto:h.handoll@tees.ac.uk)

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## Declarations of interest

The author has completed the **ICMJE form for disclosure of potential conflicts of interest** (form available upon request) and declares that she is a co-applicant of the PROFHER trial (reference 11).

## Provenance and peer review

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Denise E Yeung, Xueli Jia, Clare A Miller, Simon L Barker

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