Treatment of open fractures of the shaft of the tibia: a systematic overview and meta-analysis

Bhandari M, Guyatt G H, Swiontkowski M F, Schemitsch E H

Authors' objectives
To evaluate the clinical results of external fixation, and reamed and unreamed intramedullary (IM) nails, in the treatment of open tibial fractures.

Searching
MEDLINE (from 1969 to 1998), SciSearch, and the Cochrane Library were searched. Additional material was identified by handsearching major orthopaedic journals and orthopaedic proceedings, and by contacting experts in the field. Published and unpublished studies were eligible.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) and quasi-RCTs were eligible for inclusion.

Specific interventions included in the review
Studies of external fixation, plate fixation, and IM nails inserted with or without reaming, were eligible. The time to operating room ranged from immediate to 29 hours, and irrigation was immediate in all studies. The cointerventions included antibiotics given for 2 to 7 days, and bone grafting 6 to 8 weeks after the initial surgery.

Participants included in the review
Studies of patients with open fractures of the tibial diaphysis were eligible for inclusion. The participants were aged from 14 to 88 years and the mean age across studies ranged from 26 to 39 years. Stable and unstable fractures of various types (spiral, transverse, oblique and segmental) were included.

Outcomes assessed in the review
The primary outcome was reoperation, defined as any subsequent surgery. The secondary outcomes were bony union, rates of infection (deep and superficial), implant failure, and malunion.

How were decisions on the relevance of primary studies made?
The authors appear to have applied the inclusion criteria to the study titles. The number of reviewers involved was not stated. The weighted kappa for agreement was 0.82.

Assessment of study quality
Validity was assessed using the following criteria: randomisation (present and concealed); blinding of patients, clinicians, and those assessing outcomes; the proportion lost to follow-up; and the appropriateness of the statistical methods (sample size calculations, confidence intervals, appropriate tests). The validity was also scored using a 21-point scale (see Other Publications of Related Interest no.1). The overall quality score for each study was graded to a percentage. Three investigators independently graded validity.

Data extraction
Two authors (three stated in the abstract) extracted details on the population, intervention and outcome. A summary of the data extracted was sent to an author of each study with a request that they verify the accuracy of the data extraction. The overall agreement was good (kappa 0.68).
Methods of synthesis
How were the studies combined?
The pooled relative risks (RRs) and 95% confidence intervals (CIs) were calculated using the random-effects model of DerSimonian and Laird (see Other Publications of Related Interest no.2). An overall estimate for the RR of outcome for the indirect comparison of reamed IM nails and external fixators was calculated using the model described by Bucher et al. (see Other Publications of Related Interest no.3).

How were differences between studies investigated?
Statistical homogeneity was assessed using the Breslow and Day test (see Other Publications of Related Interest no.4). Potential sources of heterogeneity were explored; these included study quality, completeness of follow-up, the method of randomisation, and the presence of grade IIIB soft-tissue injury.

Results of the review
Four RCTs (268 patients) and 4 quasi-RCTs (316 patients) were included.

The validity scores for the studies ranged from 18 to 71%.

Plate fixation versus external rotation (1 quasi-RCT, 56 patients).
The use of external fixation was associated with a significantly reduced reoperation rate, compared with external fixation. The RR of reoperation was 0.13 (95% CI: 0.03, 0.54). External rotation did not significantly alter the rate of nonunion, deep infection, failure of fixation, or malunion.

Unreamed nails versus external fixators (5 RCTs, 396 patients).
The use of unreamed nails was associated with significantly lower rates of reoperation, malunion and superficial infection, compared with external fixation. The RR was 0.51 (95% CI: 0.37, 0.69) for reoperation, and 0.42 (95% CI: 0.25, 0.71) for malunion; no significant heterogeneity was found. The RR of superficial infection was 0.24 (95% CI: 0.08, 0.73) and significant heterogeneity was found (p=0.01). None of the postulated factors explained this heterogeneity.

There was no significant difference between the treatments with respect to the rates of nonunion or deep infection.

Reamed versus unreamed nails (2 RCTs, 132 patients).
No significant heterogeneity was found. There was no significant difference between the treatments regarding the rates of reoperation, nonunion and deep infection. The RR of reoperation was 0.75 (95% CI: 0.43, 1.32).

Implant failure was significantly less common with reamed nails, compared with unreamed nails; the RR was 0.32 (95% CI: 0.17, 0.89).

Reamed nails versus external fixators.
An indirect comparison showed significantly reduced rates of reoperation were obtained with the use of reamed nails, compared with external fixators. The RR was 0.43 (95% CI: 0.19, 0.95) and significant heterogeneity was found (p=0.04). There was no statistically-significant difference between the treatment groups in terms of the risk of nonunion or deep infection. Significant heterogeneity was found for all three outcomes (p=0.04, p=0.02 and p=0.04 for reoperation, nonunion and deep infection, respectively). None of the postulated factors explained this heterogeneity.

Authors’ conclusions
There was compelling evidence that unreamed nails reduce the incidence of reoperations, superficial infections and malunions, when compared with external fixators. The relative merits of reamed versus unreamed nails in the treatment of open tibial fractures remains uncertain.
CRD commentary
The aims were stated and the inclusion criteria were clearly defined in terms of the participants, study design, intervention and outcomes. Several relevant sources were searched, although the keywords used were not specified and it was not stated whether any language restrictions were applied. Published and unpublished material was eligible for inclusion in the review.

The included studies were restricted to randomised or quasi-randomised studies, and a formal validity assessment was undertaken. Relevant information on the primary studies was tabulated. The methods used to extract the data were described, and the agreement between the extractors was evaluated. The data were pooled, statistical heterogeneity was assessed, and possible sources of heterogeneity were investigated.

The evidence presented supports the authors' conclusions.

Implications of the review for practice and research
Practice: The authors state that the review provided strong enough evidence that IM nails offer benefit over external fixators in the treatment of open tibial fractures.

Research: The authors state that there is need for a large randomised trial of reamed versus unreamed IM nails in the treatment of open tibial fractures.

Bibliographic details

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
External Fixators; Fracture Fixation, Intramedullary; Fractures, Open /surgery; Fractures, Ununited /surgery; Postoperative Complications /surgery; Reoperation; Tibial Fractures /surgery; Treatment Outcome

AccessionNumber
12001000785

Date bibliographic record published
30/06/2002

Date abstract record published
30/06/2002

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on
the reliability of the review and the conclusions drawn.