Authors' objectives
To undertake a meta-analysis of the literature on the outcomes of Grade IIIB open tibial fractures treated by external fixation, compared with locked unreamed intramedullary nailing.

Searching
Handsearching was carried out from January 1985 to July 1995 on core orthopaedic trauma journals including Clinical Orthopaedics and Related Research, Journal of Bone and Joint Surgery (American and British versions), Journal of Orthopaedic Trauma and Journal of Trauma. MEDLINE and EMBASE were also searched using the MeSH 'tibial fracture'; this term was exploded for all subheadings. Additional studies were located by examining bibliographies of retrieved trials, by performing a weekly search of Current Contents, and through correspondence with active researchers in the field. No language restrictions are stated.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were included.

Specific interventions included in the review
The interventions studied include external fixation and locked intramedullary nailing. Concomitant treatment included wound care protocol with aggressive repeated debridement to a clean wound, definitive coverage within 10 days of injury, and administration of broad-spectrum antibiotics until wound coverage was complete.

Participants included in the review
The participants included patients who had sustained a Grade IIIB tibial fracture, defined as extensive soft tissue injury with periosteal stripping and bone exposure, often accompanied by major contamination. The patients were aged between 19 and 86 years and had sustained the injury as a result of motor vehicle accidents, as pedestrians or otherwise.

Outcomes assessed in the review
The main outcomes assessed were: time to union, defined as bridging callus and painless weight bearing or as complete radiographic consolidation; incidence of malunion; and rates of superficial and deep sepsis. Superficial sepsis was defined as local erythema or pin tract sepsis requiring control by local antibiotics, whilst deep sepsis was characterised by wound drainage with positive cultures, requiring debridement to the bone.

How were decisions on the relevance of primary studies made?
The author does not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
The author does not report the criteria used to assess quality, or how the quality assessment was performed.

Data extraction
The author does not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
The odds ratios (ORs) were combined using a fixed-effect model. For measured outcomes such as time to union, the weighted mean differences and 95% confidence intervals (CIs) were calculated.

How were differences between studies investigated?
Heterogeneity between the trials was tested using Cochran's Q statistic.

**Results of the review**

Two RCTs were used to assess the outcomes (N=55).

Time to union was defined differently and was substantially different for the 2 primary studies.

Time to union: weighted difference, with negative values favouring the intramedullary nailing group, -5.28 weeks (95% CI: -7.84, -2.72).

Superficial sepsis: the OR of sepsis in intramedullary nailing, compared with external fixation, was 0.29 (95% CI: 0.07, 1.20).

Deep sepsis: 2 deep infections were found in the intramedullary group, compared with 1 in the external fixator group.

Malunion: the OR of malunion in intramedullary nailing, compared with external fixation, was 0.37 (95% CI: 0.07, 2.73).

**Authors' conclusions**

Intramedullary nailing significantly shortened union time, whereas external fixation showed a trend towards a higher incidence of malunion and superficial sepsis. More well-designed randomised studies would add to this initial effort and yield more compelling evidence for either form of fixation. There is currently insufficient evidence to definitely recommend a specific method of skeletal fixation in the treatment of Grade IIIB open tibial fractures.

**CRD commentary**

This is a clearly-written review with a comprehensive search strategy that should have revealed most relevant studies. Unfortunately, despite the extensive search, only two small randomised studies were retrieved and this, as the authors acknowledge, limits the strength of the evidence offered. Details of the methodology used to select primary studies and extract data are lacking.

Inclusion criteria include the definition of a type IIIB tibial fracture, the definition of outcomes such as deep and superficial sepsis, and a minimum follow-up of one year, and suggest outcome assessment should be carried out by an independent investigator; it is unclear to what extent the included studies adhered to these ideals. More comprehensive details of the methodological criteria used to assess the quality of the primary studies would have been helpful, such as method of randomisation, baseline comparability of treatment groups, method of classification of the fracture type, assessment of outcomes, completeness of follow-up and comparability of surgeons experience. Heterogeneity was intended to be assessed statistically but no results of this are given. The differences between studies with respect to time to union are stated as being substantially different (not surprisingly given the different definitions used) yet the results are pooled to give a weighted mean difference. The variability, as assessed by the standard deviations of the time to union means, varies considerably between studies but this is not commented on or explored. The other outcomes assessed, i.e. sepsis and malunion, appear to have differing treatment effects reported in the primary studies, but no investigation is undertaken of factors which may explain this heterogeneity.

The small sample sizes of the studies give very small numbers (sometimes zero) of outcome events; this results in very wide CIs for the treatment effects, and a statistically non significant 95% CI for the calculated OR. The authors commence the discussion by stating that there is currently insufficient evidence to definitely recommend one method of skeletal fixation in Grade IIIB tibial fractures, yet the abstract introducing the review reports more definite conclusions for the evidence offered. Given the uncertainties discussed above, the conclusion that there is insufficient evidence to definitely recommend one method of treatment would seem to be supported.
Implications of the review for practice and research
More well-designed randomised studies, with adequate recording of all relevant information including assessment of patient functional ability, are required to evaluate the most cost-effective treatment for Grade IIIB tibial fractures.

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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.