Management of displaced ankle fractures

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CRD summary
This review found no significant differences in adverse events or function for operative versus non-operative management, for biodegradable versus metal implants (including syndesmotic fixation), and for early versus late mobilisation. The authors concluded that further research is required. Given the methodological flaws of the review and the limited quality of the included studies, the reliability of the conclusions is unclear.

Authors' objectives
To review the evidence on the operative management of ankle fractures, in particular: non-operative versus operative management of displaced ankle fractures, biodegradable versus metal implants, syndesmotic fixation and post-operative rehabilitation protocols.

Searching
The Cochrane Database of Systematic Reviews (Issue 4, 2006), the Cochrane CENTRAL Register (Issue 4, 2006), PubMed (1966 to April 2006) and EMBASE (1980 to April 2006) were searched for eligible studies; the search terms were listed. In addition, the website of archived abstracts from the Orthopedic Trauma Association's annual meetings was searched (1996 to 2005), bibliographies of eligible articles were reviewed, and contents experts were consulted.

Study selection
Study designs of evaluations included in the review
The authors did not clearly specify the type of studies eligible for the review. Observational studies were excluded and all included studies were randomised controlled trials (RCTs). Studies with both parallel and crossover designs were included.

Specific interventions included in the review
Studies were eligible if they compared non-operative with operative management of displaced ankle fractures, or biodegradable with metal implants, or if they investigated syndesmotic fixation (bioabsorbable versus metal) or post-operative rehabilitation protocols (early versus late range of motion or weight-bearing).

Participants included in the review
To be eligible, studies needed to include patients with ankle fractures. The mean age of participants in the studies varied between 29 and 78 years.

Outcomes assessed in the review
The authors did not specify any inclusion criteria for the outcomes. The main outcomes reported were adverse events and functional score, which were not further defined.

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

Assessment of study quality
The authors did not state how the papers were assessed for validity, or how many reviewers performed the validity assessment. They did, however, comment on randomisation, allocation concealment, blinding, intention-to-treat analysis and sample size.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. Data on the mode of intervention, functional score and complications were extracted. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated for dichotomous data, while standard mean differences were
calculated for continuous data.

**Methods of synthesis**

**How were the studies combined?**
The studies were combined in a meta-analysis. Continuous data were combined using the fixed-effect inverse variance model. Dichotomous data were combined using a fixed-effect model and the Mantel-Haenszel risk ratio. If the data were heterogeneous, a random-effects model was used for both continuous and dichotomous data.

**How were differences between studies investigated?**
The studies were grouped according to the interventions assessed. The authors appear to have assessed statistical heterogeneity using the I-squared statistic.

**Results of the review**

Twenty-five RCTs (n=1,394) were included. Five investigated non-operative versus operative management (n=399), five investigated biodegradable versus metal implants (n=194), three investigated syndesmotic fixation (n=126) and twelve investigated post-operative rehabilitation protocols (n=665).

The quality of the included studies was limited. Some of the studies reported the method of randomisation, but none discussed allocation concealment. None of the studies discussed blinding and only two used a clear intention-to-treat analysis. The majority of the studies were underpowered.

**Effectiveness.**

Although the authors indicated trends, none of the comparisons showed significantly different results for adverse events or functional scores (range of p-values: 0.18 to 0.99). In two places the authors reported different numbers in the text and in the tables. The numbers in the tables are reported here.

**Operative versus non-operative treatment (2 RCTs).**

There was a non significant difference in favour of operative treatment for adverse events, OR 0.68 (95% CI: 0.39, 1.2, p=0.18; n=291), while for functional score the OR was 0.18 (95% CI: -32.65, 32.38, p=0.99; n=108). One study suggested that in the elderly (older than 65 years), non-operative management may give better functional results. Two studies suggested that at early follow-up (less than a year) results are in favour of operative management with respect to gait and range of motion, but that at later follow-up (up to 7 years) this difference was not significant.

**Biodegradable versus metal implants.**

There was a non significant benefit for metal implants: the OR for adverse events (n=224) was 2.63 (95% CI: 0.35, 19.63, p=0.35) for biodegradable versus metal implants. None of the studies found a significant functional difference between comparison groups at the final follow-up.

**Syndesmotic fixation.**

In the case of syndesmotic injury, there was a non significant advantage for bioabsorbable versus metal screws: the OR for adverse events (n=70) was 0.46 (95% CI: 0.08, 2.72, p=0.4), where removal of the implant was included in the assessment of adverse events. Two studies showed no significant subjective patient differences at the final follow-up.

**Post-operative rehabilitation.**

For post-operative rehabilitation, 8 studies compared early active range of motion with delayed range of motion, and 3 studies compared early cast protected weight-bearing with delayed weight-bearing; a non significant advantage was found for early versus late interventions. The effect size for the functional score (n=190) for early versus delayed intervention was 1.24 (95% CI: -1.32, 3.8, p=0.34), and the OR for adverse events (n=340) was 2.02 (95% CI: 0.49, 8.4, p=0.33). Two of 3 studies showed no significant difference for return to work with early or late range of motion or...
weight-bearing, while one found a significantly quicker return to work with early mobilisation (53.8 days versus 106.5 days, p=0.007).

There was significant heterogeneity for the results for functional score when comparing operative versus non-operative treatment, and for the results for adverse events when comparing biodegradable with metal implants and early range of motion or weight-bearing with late range of motion or weight-bearing during rehabilitation.

Authors’ conclusions
In view of the limitations of the studies examined, it is difficult to give recommendations for practice with respect to operative management of ankle fractures. Large RCTs using validated functional and clinical outcomes need to be conducted.

CRD commentary
This review had clearly stated inclusion criteria with respect to the participants, interventions and outcomes, but definition of the study design was unclear. The authors searched a number of relevant databases and efforts were made to identify supplemental information. It is unclear whether any language restrictions were employed and whether the authors sought unpublished studies, thus the potential for some relevant studies to have been omitted cannot be fully assessed. The study selection, validity assessment and data extraction processes were not reported, which means the potential for bias and error also cannot be assessed.

It is unclear whether a meta-analytic synthesis was appropriate since the study details and assessment of heterogeneity indicated significant clinical and statistical differences between the studies. It is also unclear how the results of crossover trials were incorporated into the statistical synthesis. The results of the meta-analysis were tabulated, and heterogeneity was present for some outcomes. The main outcomes reported in the meta-analysis were 'adverse events' and 'functional score', but it was not explained what these referred to in clinical terms. Follow-up times were not discussed and it is unclear what kind of time span the reported results referred to. The authors’ overall conclusion, that no clear conclusions could be drawn because of the limited quality of the data, was appropriately cautious, but is of unclear reliability in view of the methodological and reporting limitations outlined.

Implications of the review for practice and research
Practice: The authors stated that in view of the limitations of the data, they could not make any recommendations for practice with respect to operative management of ankle fractures.

Research: The authors stated that to help answer their questions, large RCTs using validated functional and clinical outcomes are needed.

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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.