Foot orthoses in lower limb overuse conditions: a systematic review and meta-analysis

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CRD summary
This review concluded that there is some evidence to support the use of foot orthoses in preventing lower limb overuse conditions, but little evidence to support their use in treating overuse conditions. Overall, the data appear to support the conclusions, but the generally poor quality of the included studies suggests a more cautious conclusion about preventive treatments may be more appropriate.

Authors' objectives
To evaluate the clinical efficacy and cost-effectiveness of foot orthoses for patients at risk of, or with, lower limb musculoskeletal overuse conditions.

Searching
MEDLINE, PubMed, EMBASE, CINAHL, PreCINAHL, PEDro, SPORTDiscus, Biological Abstracts, Web of Science, AMED and the Cochrane Library were searched to September 2005; the search terms were not reported. There were no restrictions on publication year, publication status or language. In addition, reference lists of included studies and relevant reviews were screened.

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

Specific interventions included in the review
Studies that evaluated foot orthoses were eligible for inclusion. The included studies evaluated foot orthoses for prevention and treatment. Studies compared foot orthoses with control, foot orthoses with a variety of other interventions (details were reported), and custom versus prefabricated orthoses.

Participants included in the review
Participants with, or at risk for, lower limb musculoskeletal overuse conditions, as specified by the American College of Foot and Ankle Orthopaedics and Medicine guidelines, were eligible for inclusion. All participants in the prevention studies were military populations undergoing regular military training; these included patients with lower limb pain, injury or problems, and lower limb stress fractures. Where stated, the mean age of these participants ranged from 18.74 to 28.5 years. Studies of treatment involved patients with a variety of conditions, including plantar fasciitis, anteromedial knee pain, metatarsalgia, heel pain, Morton's neuroma and myofascial pain syndrome of peroneus longus. The mean age of these participants ranged from 14.8 to 61.8 years.

Outcomes assessed in the review
Studies that assessed a clinically relevant outcome after a period of at least 1 week were eligible for inclusion. The review assessed injury incidence in prevention studies and patients-perceived treatment effect (PPE), pain visual analogue scale (VAS) and Foot Health Status Questionnaire in treatment studies. The outcomes were assessed over three time periods (up to 3, 6 and 12 months). Adverse effects were also assessed.

How were decisions on the relevance of primary studies made?
One reviewer conducted searches and screened reference lists. No other details of the methods used to select studies were reported.

Assessment of study quality
Two reviewers independently assessed validity using the following criteria based on a modification of the PEDro scale: eligibility criteria specified; random allocation; concealment of allocation; baseline similarity of treatment groups with respect to prognosis; blinding of the patients, therapists and assessors; follow-up greater than 85% for at least one key outcome; intention-to-treat analysis for at least one outcome; at least one between-group statistical analysis for a key
outcome; at least one point estimate and variability for a key outcome; justification of sample size; use of outcome measure with known validity and reliability; and adverse events/side-effects reported. The maximum possible validity score was 14 points. Any disagreements were resolved through discussion, with recourse to a third author if required.

**Data extraction**
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. Where possible, intention-to-treat data were extracted directly from the reports. Authors were contacted for missing data, where required. Relative risks (RRs) with 95% confidence intervals (CIs) were calculated for dichotomous data, and means and standard deviations for continuous data.

**Methods of synthesis**
How were the studies combined?
The studies were classified as prevention or treatment and grouped according to the type of foot orthoses, comparator and timing of the outcome assessment. Pooled RRs and standardised mean differences (SMDs) were calculated using a random-effects model. Clinically beneficial effects (for either intervention or control) were considered to be represented by an RR of greater than 1.5 or less than 0.7, and an SMD of 0.8 (large clinical effect), 0.5 (a moderate clinical effect) or 0.2 (a weak clinical effect). Studies not included in the meta-analyses were combined in a narrative.

How were differences between studies investigated?
The association between effect size and quality rating score was examined.

**Results of the review**
Twenty-three studies (reported in 22 papers) were included.

Modified PEDro scores ranged from 2 to 11 out of 14. Methodological flaws included lack of the following: eligibility criteria, reporting of allocation concealment, blinding, intention-to-treat analysis, justification of sample size, and reporting of adverse events. There was no significant correlation between quality score and RR (p=0.60) or SMD (p=0.10).

Prevention (8 studies).

Foot orthoses were associated with a significant and reasonably sized reduction in the risk of injury compared with controls (RR 1.49, 95% CI: 1.07, 2.08; based on 4 studies). The results were similar for a fifth study that did not provide sufficient data for meta-analysis.

One study reported a clinically significant reduction in the risk of injury with foot orthoses compared with simple insoles.

There was no significant difference in the risk of injury between custom and prefabricated foot orthoses (based on 2 studies in one publication).

Treatment (15 studies).

There was no significant difference between foot orthoses and control for PPE or VAS (based on pooled data from 2 studies).

Studies compared foot orthoses with a great variety of different interventions; one or at most 2 studies reported each comparison, thus pooling data was not possible.

Up to 3 months, there was no significant difference between custom and prefabricated foot orthoses (based on pooled data from 2 studies). One study reported no treatment effect of either type of orthosis at 6 and 12 months.

Adverse effects (8 studies).

The main adverse effect was discomfort; this was the main reason for discontinuation in 2 studies. One study reported
that 21% (30 out of 143) of patients discontinued use of foot orthoses in the first 14 days.

Cost information
On study reported that six patients would need to be treated with foot orthoses to prevent one injury at a cost of $122 (95% CI: 58, 1,103). One study reported significantly greater total mean cost per patient with prefabricated compared with cushioning insoles; the incremental cost per quality-adjusted life-year with prefabricated versus cushioned insoles was $3,210.

Authors' conclusions
There is support for the use of foot orthoses in the prevention of lower limb overuse conditions, but insufficient evidence to evaluate foot orthoses for treating overuse conditions. There is no difference between custom and prefabricated foot orthoses.

CRD commentary
The review addressed a clear question using a broad range of outcomes. Several relevant sources were searched and attempts were made to minimise publication and language bias. The review methods suggest that attempts were made to reduce the risk of reviewer error and bias, and the validity of the studies was assessed using specified criteria. The studies were appropriately grouped and only similar studies were pooled. However, it was not always clear which outcome measures were used to calculate summary statistics. Some studies had high drop-out rates which were not always similar between treatment groups; the potential effects of this do not appear to have been considered. Overall, the data tend to support the authors' conclusions, but the generally poor quality of the included studies and the high-dropout rates suggest that a more cautious conclusion about preventive treatments may be more appropriate.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated the need for higher-quality research to evaluate interventions of longer duration that use consistent and reliable outcome measures and more standardised definitions of foot orthoses. Future studies should follow the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

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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.