Effectiveness of insoles used for the prevention of ulceration in the neuropathic diabetic foot: a systematic review
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CRD summary
The authors concluded that there was limited evidence to suggest that insoles may prevent ulcers in patients with neuropathic diabetic foot. Further research was required to confirm the specification of insole. This cautious conclusion appears justified given the poor methodological quality of the included studies and their varied study characteristics.

Authors’ objectives
To assess the effectiveness of insoles for the prevention of ulceration in patients with neuropathic diabetic foot.

Searching
MEDLINE and CINAHL were searched from inception to 2008 for published studies; search terms were reported. Grey literature (including government documents and a thesis database) were searched for further studies. Reference lists of retrieved studies and reviews were screened for further data.

Study selection
Randomised controlled trials (RCTs) and non-randomised studies (including follow-up studies) that assessed the effectiveness of insoles for the prevention of diabetic foot in patients free from ulceration were eligible for inclusion in the review. Eligible participants had to present with type 1 or type 2 diabetes and neuropathy. The primary outcome measure of interest was time to ulceration. Eligible studies had to include one or more of the outcomes: ulceration, cost, pressure measurement and patient-based response.

The included studies assessed different custom-made insoles that included plastazote-based casted insoles, magnetic insoles, ethylene-vinyl acetate (EVA) and polyethylene foam insole and ridged (TL-2100 graphite) casted insole. Where reported, included participants were recruited from university/teaching hospitals, an orthotics laboratory and private practices. Specific patient characteristics varied between the studies with respect to level of detail reported, type of diabetes and risk of ulceration; further details were reported in the review. Patient age ranged from 59.6 to 68.9 years. Duration of diabetes ranged from 11.6 to 7.5 years. Inclusion criteria for the studies varied. Studies were carried out in USA, Italy and Germany. Reported outcomes included ulcer relapse rate, reduction in peak pressure, reduction in neuropathic pain, contact surface area and quality of life.

Two reviewers independently assessed the studies for inclusion. Discrepancies were resolved through discussion (the rate of agreement was 97%).

Assessment of study quality
Study validity was assessed independently by two reviewers using published criteria (Downs and Black) for quality of reporting, internal validity (bias and confounding) and external validity. Each study was awarded an overall score.

Data extraction
Two reviewers independently extracted study data that reported effect sizes confidence intervals and measures of statistical significance, where available.

Methods of synthesis
Studies were summarised using a narrative synthesis.

Results of the review
Two RCTs (n=444 participants), two case-control studies (n=97) and one follow-up study (n=8) were included. Only one study was reported to be of good quality and the others were assessed as poor quality. Study follow-up ranged from three to 12 months. Sample size ranged from eight to 375.
A significant reduction in ulceration at one year was reported by one RCT that compared insoles with therapeutic shoes versus patients’ own non-therapeutic shoes (p=0.009). Two studies reported a reduction in peak pressure that favoured insole interventions after one month compared to no insole (p=0.001) and after one year compared to conventional footwear (p value not reported).

One study that compared two different types of insoles found no difference in peak pressure after three months (p value not reported). One RCT that compared magnetic insoles with placebo reported a significant difference in neuropathic symptoms (p<0.05) that favoured the insole group, with no evidence of ulceration in either group at four months.

**Authors’ conclusions**
There was limited evidence to suggest that insoles may prevent ulcers in patients with neuropathic diabetic foot. Further research was required to confirm the specification of insole.

**CRD commentary**
This review answered a well-defined research question using a broad range of study designs. Searches for relevant data cover a number of resources including electronic databases and grey literature sources; however there may be a risk of publication bias as only published studies appear to have been included. The risk of language bias is unclear. Attempts were made to reduce the risk of reviewer error and bias during study selection, data extraction and appraisal of methodological quality of the studies. It appeared that methodological quality was assessed using appropriate criteria that reflected the different included study designs. The authors reported that only one study was of good quality. Studies varied with respect to patient characteristics, outcomes and interventions. Use of a narrative synthesis appeared appropriate given the level of heterogeneity between studies.

The authors’ cautious conclusion appears justified given the poor methodological quality of the studies and varying study characteristics. The authors appear justified in recommending further research to confirm their findings.

**Implications of the review for practice and research**

**Practice**: The authors stated that insoles should be considered within a prevention strategy for diabetic neuropathic foot, but no recommendations could be made regarding the specific type and specification of insole.

**Research**: The authors stated that further large well-designed RCTs that compared the clinical and cost-effectiveness of different types of insole commonly used for the prevention of ulceration in the diabetic neuropathic foot were required. Such studies should include outcome measures that assess patient perceptions of the clinical/cost-effectiveness in addition to compliance and adverse effects of different insoles.

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