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Randomised trial of custom orthoses and footwear on foot pain and plantar pressure in diabetic peripheral arterial disease

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Objective: Custom-made foot orthoses have been shown to reduce plantar pressure, ulceration and amputation in patients with diabetes mellitus. There is limited evidence of their effect on foot pain. In a randomised, single-blind, sham-controlled trial, the efficacy of custom orthoses on foot pain and plantar pressure in diabetic peripheral arterial disease was investigated. **Research Design and Methods:** 61 participants were randomly assigned to either custom foot orthoses ($n=30$) or sham insoles ($n=31$). Both groups also received standardised walking footwear. Outcomes included foot pain and function, mean pressure, toe-brachial index, average daily steps, disability, comfort, quality of life, adherence and adverse events. A multivariate predictive model was constructed to explore factors contributing to pain relief during the trial. Trial registered with the Australian New Zealand Clinical Trials Registry [ACTRN12606000481572]. **Results:** At 8-weeks, 95% of participants provided follow-up data, adherence was high and there were few adverse events. Foot pain and function scores significantly improved at 8-weeks with both custom orthoses and the sham, but there was no significant difference between groups. Custom orthoses reduced pressure significantly more than the sham. There were no significant differences between groups for toe-brachial index, daily steps, disability, comfort or quality of life. Regression modelling identified inappropriate pre-trial footwear as the strongest predictor of foot pain relief during the trial. **Conclusion:** Custom foot orthoses significantly reduced plantar pressure compared to the sham, but there were no significant differences between groups for pain or function. The high-quality walking footwear provided to both groups may explain this finding. Footwear should have greater emphasis as the clinical intervention.