Author's response to reviews

Title: A comparison of customised and prefabricated insoles to reduce risk factors for neuropathic diabetic foot ulceration: a participant-blinded randomised controlled trial.

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Author's response to reviews: see over
Dear Karl

Re: A comparison of customised and prefabricated insoles to reduce risk factors for neuropathic diabetic foot ulceration: a participant-blinded randomised controlled trial

# 1802018718533641

Thank you for reviewing our paper. We have addressed the issues raised, paying particular attention to your recommendations relating to our discussion section.

We thank you for your continued interest in our article and hope you find our revised interpretation of the trial findings appropriate for inclusion in the Journal of Foot and Ankle Research.

Yours sincerely

Joanne and colleagues

i) We are happy with the editorial changes you have made to the manuscript and agree it does not change the nature of the content.

ii) We are sorry about the large number of errors in our reference list that escaped our attention. We can confirm that the changes made are correct.

iii) We have addressed the comments made and attach the revised manuscript as requested.

1. The conclusion within the abstract has been revised to align with amendments made in the discussion section. The conclusion now only includes inferences relevant to our trial findings.

Conclusion

*Custom-made insoles are more expensive than prefabricated insoles and no better in reducing peak pressure. We recommend that where clinically appropriate the more cost effective prefabricated insole should be considered for use by patients with diabetes and neuropathy.*

2. After re-checking the name of the prefabricated insole we have amended the manuscript to read ‘First Line Full Length Orthotics’ (page 7).

3. The measurement mm has been corrected to read mm$^2$ (page11).

4. As suggested we have replaced the term perceived foot health with Bristol Foot Score and added the words Audit of Diabetes Dependent Quality of Life (page 11).

5. As requested we have revised the content of our discussion section to present a more balanced interpretation of results, without the undue emphasis on the significant finding pressure time integral. More specifically we condensed much of
the discussion about pressure time integral by 1) removing inappropriate speculation, 2) placing more focus upon the recent work of Waaijman and Bus and Keijers Stolwijk and Pataky to rationalise our findings (page 12).

Total peak pressure was selected as the traditional measure of the effect of footwear and insole efficacy to ease comparison of results between studies. Forefoot pressure time integral was selected to reflect the increased risk of ulceration over the forefoot. More recently it has been reported that peak pressure and pressure time integral are inter-dependent and that within clinical trials significant differences in patterns found between the two parameters are generally minimal [20,21]. Thus, there is little value in routinely reporting both measures of insole efficacy [20,21]. We acknowledge therefore that forefoot peak pressure would have been an equally suitable measure and accept that our findings are likely to have been the same if forefoot peak pressure had been selected [20,21].

No other randomised controlled trial has been identified to indicate that custom-made functional insoles are significantly more effective in reducing forefoot pressure time integral or forefoot peak pressure than prefabricated insoles when used to reduce ulcer risk in neuropathic diabetic feet.

6. The section on page 17 has been revised in light of the changes made earlier in the discussion and now reads;

There is no clear evidence that the custom-made functional or prefabricated insole is best practice for all diabetic neuropathic feet, however both are of value for reducing ulcer risk in people with diabetes and neuropathy. Both custom-made functional and prefabricated insoles were equally effective in reducing peak pressure therefore the less expensive prefabricated insole is likely to be most cost effective. Practitioners tasked with accessing the diabetic foot for insole provision should, where appropriate, consider prescribing the more cost effective prefabricated insole.

The custom-made functional insole was found slightly more effective than its cheaper counterpart in reducing forefoot pressure time integral. The clinical significance of reducing forefoot pressure time integral as a predictor of neuropathic foot ulceration remains undetermined. Further research is needed to determine; (i) which parameter is more important in predicting neuropathic foot ulceration, (ii) the
magnitude of reduction deemed clinically sufficient to produce a symptom change, and (iii) confirmation of costs over time.

7. The conclusion section on page 19 has been amended to reflect the changes to the discussion section.

The findings provide further evidence to suggest that insoles are of value and should form part of the plantar load reducing strategy for the diabetic neuropathic foot. Custom-made insoles are more expensive than prefabricated insoles and no better in reducing risk. We recommend that practitioners tasked with accessing the diabetic foot for insole provision should, where appropriate, consider prescribing the more cost effective prefabricated insole. Insole and footwear compliance remains an issue and must be improved to enable the diabetic neuropathic population to fully benefit from any treatment effect.

8. The order and numbering of references has been adjusted to take account of the changes made within the manuscript.

9. Table 2 has been reformatted as a standard word table.

   iv) Finally as requested we attached the completed CONSORT checklist.