Reviewer's report

Title: Optimisation of rocker sole footwear for prevention of first plantar ulcer: comparison of group-optimised and individually-selected footwear designs

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Reviewer: Anita Raspovic

Reviewer's report:

In my opinion the authors present a valuable concept which is worthy of publication. The paper would benefit however from further development first. Importantly, care is urged that the feasibility and generalisability of the concept are not over extended, given the early experimental stage of the work and the low to no risk population these research findings are based on.

My recommendations are as follows:

1. The paper should state very clearly up front (in the abstract) that the work was conducted on a low risk population. Arguably, many of the participants (without peripheral neuropathy) in this study would not require a pressure-reducing shoe in practice. Therefore, while this paper is of value for its proof of concept, it would be very beneficial for the study to be replicated on a true clinical population of whom this intervention is better targeted. This issue of external validity is reported but somewhat diluted in the limitations section, I recommend this approach be reconsidered. The assumption that the results would be similar in higher risk patients may not hold true and is therefore a risky one to make.

2. A clinically important loss of protective sensation was present in less than 20% of the participants with diabetes in this study (less than 10% of the sample overall), and no participants had significant foot deformity or a history of ulceration. In light of this, statements such as "we have been able to suggest a generic design for curved rocker footwear which could be provided to patients without the need for assessment of plantar pressures" overstates the study findings. There are several examples of this throughout the paper, which I strongly recommend be modified.
3. A statement identifying which related clinical groups the results of this paper are not intended to refer to may be of use. For example, people with significant diabetes-related foot deformity, amputation, charcots changes etc, where the alignment of the shoe is unlikey to match up to altered foot morphology.

4. The readability, flow and clarity of the paper would benefit from re-drafting in sections. In particular, the introduction and methods are difficult to follow in areas. As a suggestion, the past literature described in the methods would be well placed as background information in the introduction. In addition, the methodology described in the second half of the data analysis and statistics section may be better placed in a data collection section. Numerous different terms are used to describe the various footwear conditions and classifications (eg, group optimised, personal optimised, generic, personalised, etc) - operational definitions would assist clarify various meanings for those unfamiliar with the author's system of terminology. These terms get confusing.

5. The methods require more explanation and clarification. For example, the inclusion and exclusion criteria should be stated explicitly, including how they were operationalised. Regarding data collection, was the order of shoe condition pressure measurement randomised and what technique was used to ensure participants walked at the same speed? Was the control shoe the same as the intervention shoes apart from the rocker applied? The methods should be specific enough that they can be reproduced.

6. The paper lacked presentation of numerical data. Data, including key statistical data (descriptive statistics, inferential statistics, point estimates, 95% confidence intervals, etc) in tables are required. In addition, screening and reporting on any violations of statistical assumptions should be reported.
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