

Reviewer's report

Title: Contoured, prefabricated foot orthoses demonstrate comparable mechanical properties to custom-made orthoses.

Version: 1 **Date:** 18 August 2008

Reviewer: Stephen Urry

Reviewer's report:

Contoured, prefabricated foot orthoses demonstrate comparable mechanical properties to custom-made orthoses.

General comments

The authors investigate an issue which is of interest to all prescribers of foot orthoses and the work is, therefore, useful and of interest. However, they present no rationale as to their selection and inclusion of the variables which are selected for analysis. This issue must be addressed. If the mechanical effects of orthoses are of interest, then perhaps measures of force are justified, whereas if the pressure relieving effects of orthoses are of interest (ulceration and diabetes) then measures of pressure are warranted? However, if the study is exploratory, as the authors state, then it is inappropriate to report on variables other than the fundamentals (force, pressure, area and time). Unless strong justification can be provided, derived variables (force-time-integral, pressure-time-integral and maximum mean pressure) should be removed. Furthermore, the inclusion of so many variables, clutters the results and detracts from the essential findings regarding the fundamentals - force, pressure, area and time. Confining the study to fundamental factors is even more important when the issues of effect size and subject numbers are considered, as discussed in the following paragraph.

The authors conclude (Page 2) that, "There was a similar change in loading with both the customised and the prefabricated orthoses when compared to the shoe alone condition. However, while customised devices offered minor gains over prefabricated orthoses in some variables, these were not statistically significant". Sample size calculations, however, were based on midfoot impulse values from a previous reference (13). The Force-Time-Integral (FTI) values in the cited reference are generally at odds with the literature and are approximately 10-fold greater than those found in the current study. Consequently, the mean difference (285Ns) used by the authors to calculate sample numbers is 4 times the mean value reported in the current study and results in a very large effect size. Given that the study was powered to find such a big effect size (>1), the likelihood of a Type II error is large and it is not surprising that few statistically significant differences between orthoses were found. With this in mind, the information in the paper needs to be presented most cautiously, and the following comments should be considered with this in mind.

Participants (page 4)

The validity and reliability of the Foot Posture Index and Rose's Valgus Index have been described... the authors could provide a very brief précis of the pertinent features and their relevance to this study. In addition, the authors have omitted reference to more recent studies which question the reliability of the Foot Posture Index. This oversight should be rectified and, if necessary, the relevant material should be discussed.

Data capture (page 5)

This section could mislead the reader into believing that evaluation of orthoses using pressure measuring insoles is a well developed, and therefore fully acceptable, procedure (...system has been described comprehensively... ..has been used in the evaluation of orthotic function...). This is not the case. As such the term comprehensively must be removed. Further, reasonable consideration to these issues must be given in the discussion section.

There is an indication that cadence and gait speed were standardised (...standardised cadence and gait speed for all measures page 5). However, no further information appears in the paper. Since speed is known to have an effect on pressure magnitudes, the authors must present their findings. The speed should be reported and the cadence would be useful. In addition, the duration of the stance phase along with indicators of variability are required.

Can the authors clarify whether the data that are presented only represent the stance phase of gait when the foot was bearing body weight and reassure the reader that any apparent loading within the shoe during swing phase (since this is an in-shoe method) has been excluded.

Analysis (page 6)

It would be useful if the mask regions were clearly defined (text page 5 and figure 1). This is commonly done in percentage terms.

Data for the lesser toes were variable... This should be re-phrased. What do the authors wish the reader to gain from this statement?

...patients in the shoe only (or control) condition... This is ambiguous. Delete or.

Results (page 6)

The authors should provide standard deviations wherever they indicate mean values. The omission of standard deviations must be rectified.

...control conditions for 11 of the 35 variable/mask combinations. This section is very difficult to follow. For the ease of the reader, the authors should provide a separate table indicating the 11 items.

...customised orthoses showed enhanced changes... Delete enhanced.

The results for the customised and prefabricated devices did not differ statistically however... In view of the effect size, this comment should be moderated, balanced, or simply removed.

...customised orthoses produced a moderate gain over prefabricated... Delete gain. It is reasonable to describe one as being larger or smaller than the other, but terms such as gain should be avoided so as not to lull the reader into a sense that one was “better” or more “preferable” than the other. Similarly with phrases such as ...were slightly better at increasing the contact area... The authors should refrain from this approach and simply describe the finding as “greater or lesser than...”.

The authors should include an additional results table for the foot as a whole, rather than simply the six selected sites or regions. Such information allows for a quick but broad comparison of these data with those in the published literature and gives added confidence that these data are reliable and representative.

Discussion (pages 8-10)

There are three important factors which must be considered with this discussion: 1) the sample size is small and the effect size large, and the possibilities of detecting statistical significance is therefore diminished, 2) the authors declare this to be an exploratory study (page 10, final para), and 3) the authors exhort the reader to extract meaning from the paper (...used by the reader to explore to their own satisfaction those differences... page 10, final para).

It is possible that many readers will not be empowered to adequately assess the statistical implications, therefore, the onus remains with the authors to ensure that the findings are presented with utmost clarity and simplicity and without any hint of preference (hence the need to remove all terms such as ...enhancement... benefits... limited...marginally beneficial... considerably... moderate...from the manuscript).

There is reference to clinical effects (devices clearly offered clinically similar mechanical... page 9; also ...clinical significance. Page 10, final para). This was not a clinical study and comments should be restricted to the mechanical findings. Readers should not be encouraged, even inadvertently, to interpret clinical relevance from these results.

The last paragraph of page 10 should be deleted, it is confusing and unhelpful. Rather than exhorting the reader to explore to their own satisfaction those differences that might be of more clinical significance, perhaps the authors should propose that researchers focus on parameters of potential interest and conduct further studies which incorporate clinical factors, while clinicians remain open minded until appropriate evidence regarding clinical interventions is available.

Conclusions

In this study both customised and prefabricated orthoses altered foot function. Page 11, para 1). This is an erroneous and misleading conclusion. This was not a study of foot function and the authors can only conclude that the characteristics of the loading profile of the sole of the foot are changed when an orthosis is worn.

Customised devices offered minor gains...Page 11, para 1. Inappropriate for reasons explained above. Remove.

These objective data question the role of custom orthoses over prefabricated orthoses...page 11, para 2. This conclusion is inappropriate and should be deleted. The authors might consider something such as, "While these data indicate that customised and prefabricated orthoses alter the loading profile at the skin-orthosis interface during walking, further research is required to ascertain whether one device affords a greater mechanical effect than the other".

Figures

The authors should arrange the images in the figures to match the order adopted for each table.

Title

The title could be re-phrased more appropriately as:

Custom-made and contoured, prefabricated foot orthoses demonstrate comparable mechanical properties

Summary

Major compulsory revisions

1. The rationale for the selection of variables.
2. Open acknowledgement and discussion of the potential impact of the large effect size
3. A conservative / cautious rewording of the paper in view of the issue of effect size
4. Explanation regarding the 10 fold difference in FTI between this study and that cited as reference 13
5. A results table for the foot as a whole, rather than just the site specific finding currently reported
6. Clarify the method regarding the loading of the pressure insole by the footwear (the influence of midfoot fixings – laces etc)
7. Provision of standard deviations in the results tables
8. The section concerning "11 of the 35 variable/mask combinations" must be re-worked to remove all ambiguity
9. All comments above regarding the Discussion and Conclusion sections to be addressed in full

Minor essential revisions

10. The broader literature regarding the Valgus Index and the Foot Posture Index, including those studies which question reliability
11. The inclusion of results regarding speed and cadence

Discretionary revisions

12. Re-word the title

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests