Author's response to reviews

Title: Changes in multi-segment foot biomechanics for a heat-mouldable semi-custom foot orthotic device.

Authors:

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Author's response to reviews: see over
We sincerely thank the reviewers and the Editor for taking the time to review our manuscript and provide very helpful comments and suggestions. We have addressed all points to the best of our ability and indicated all changes within the text in bold. The changes, in our opinion, have significantly improved the flow and substance of this manuscript and we look forward to hearing from you shortly regarding acceptance for publication in JFAR.

Editor's comment:
Could the authors please:
i: review the entire manuscript to replace 'et al., [ref]' with 'et al. [ref]' (eg: page 3, para 3)
This change has been made.

ii: review the manuscript and replace the wording 'subjects' with participants (eg: page 5, para 2).
This change has been made.

iii: review the first sentence of page 4. Should the word 'or' be 'of'? This change has been made. We apologise for this typographical error.

iv: consider adding a space between all values and their unit of measurement throughout manuscript (eg: page 4, para 2). Please spell out the word 'years' and replace 'deg' with the symbol for degrees. This change has been made.

v: clarify if one or both feet were measured from each participant. This change has been made and we have clarified that the right foot from each participant was measured.

vi: consider including a figure to illustrate the measurement of AHI? This change has been made.

vii: review page 6, para 3, where the word 'trail' should be 'trial'? This change has been made. We apologise for this typographical error.

viii: review page 6, para 4, and spell in full the word 'lab'. This change has been made.

ix: Data processing, page 7: should the final paragraph on this page be moved to the start of this section? This is a good suggestion to help improve overall flow of the manuscript. We moved this section to be the second paragraph after we introduce the specific markers used to calculate PFS and MLA.

x: Please do not abbreviate terms at the start of sentences (eg: page 7, para
2, where 'PFS' should be spelt in full at the start of the sentence).
This change has been made throughout the manuscript.

xi: Data analysis: the authors have used a ANOVA to compare for difference in their 3 groups. What post-hoc tests were used and was there any adjustment for family-wise type I error rate?
We added the following information to clarify our statistical approach: “Post-hoc tests were used to determine differences, if any, between the three conditions. With three conditions, and thus two degrees of freedom, a priori comparisons were planned between 1) SCO moulded and SCO non-moulded and between 2) SCO moulded and no-orthotic conditions. Finally, we calculated Cohen’s d effect sizes to better understand potential differences, if any, between orthoses conditions.”

Please consider adding 'measurement error' between the words 'condition' and 'experiment'.
This change has been made.

Can the authors please detail the statistics for the measurement error experiment? For example, average change in distance appears to have been calculated.
Correct. We calculated the average change in distance and this information has been added to the manuscript.

xii: Results: Can the authors please consider using sub-headings for the results to separate the 'measurement error study' from the major study.
This change has been made.

xiii: Results: Can the authors please consider including a table showing the mean (SD) for each of the measured variables across the three conditions and including p values for comparisons between groups? The text for the results could then be shortened and less confusing for the reader.
This change has been made. We have included a Table with means (SD), Effect sizes, and p-values. We have also removed this information form the Results section to improve its readability.

xiv: Please replace 'P' with lower case 'p'.
This change has been made.

xv: Could the authors please consider adding figures to show individual participant changes for all measured variables?
We have included temporal figures for MLA, RFEV, and TibRot as per the request of Reviewer 2. However, if the Editor would like to see similar Figures as Figure 5 showing individual changes we are happy to provide those either in addition or in replacement of the temporal graphs now included.
xvi: Discussion: are the authors referring to Cohen's d when they refer to effect size calculations? Please consider adding that this statistic was performed in the 'data analysis' section.
Yes, we are referring to Cohen's d and this has been added to the Analysis section.

xvii: page 11, para 2: are the authors referring to 'mean' differences when they say 'there were no differences in peak rearfoot eversion...'.
Yes we are and this change has been made.

xviii: page 12, para 1: Please consider deleting the word 'an'.
This change has been made.

xix: page 12, please consider including Landorf et al. (2006) to strengthen your argument.
This change has been made. Thank you for this reference.

xx: References: please review journal abbreviations (eg: refs 8, 18)
This change has been made.

xxi: Figure 3: Please consider deleting the word 'Percent' from the title as the title already shows '[%]'. Should the words 'molded' and 'unmolded' be 'moulded' and 'unmoulded'? Please replace the word 'subject' with 'participant'.
These changes have been made.
Reviewer: Thomas McPoil

Reviewer's report:

Major Compulsory Revisions:

1. **The authors selected a small sample of 20 healthy individuals who fell within the normal range for the AHI reported by Butler (ref 18). In reviewing the Butler, et al paper, the only information provided is the sitting and standing AHI values. Which did the authors use? Or, did the authors attempt to select their subjects based on the “change” in AHI between sitting and standing?**

   We have clarified that both the sitting and standing AHI values were used during our screening process. In effect, we selected our participants based on the “change” in arch deformation by ensuring that values were within both the sitting and standing AHI values.

2. **The change in AHI, which would provide a measure of foot mobility and was reported by Butler to be approx. 3 mm (with a standard deviation of approx. 0.6 mm) for both the left and right feet as well as for men and women. Assuming the authors selected their subjects based on a 3 mm change or the standing AHI mean value, if the authors only picked subjects who fell within the normal range of movement why would they expect a significant change in arch deformation during walking?**

   This is a very good question. As an initial investigation, we sought to understand how an orthotic device would reduce plantar fascia strain, if at all, for a group of normative subjects. We fully agree that future research involving a more pes planus population is necessary and this research is currently under way. We have added this information to the Limitations section in the Discussion.

3. **In light of the fact that the authors also performed their “standing” calibration in what appears to be “resting standing posture” and the subjects were within the normal range for the AHI, it would appear highly unlikely that the subject’s would undergo a significant amount of rearfoot or midfoot mobility during walking. Thus, the effect of the foot orthoses, molded or not molded, in comparison to the sock liner of the shoe would be minimal on midfoot and possibly rearfoot movement – which is what the authors found in their study. One could ask the clinical question – why would one expect a subject with a foot structure that most likely has minimal rearfoot or midfoot movement to demonstrate significant amounts of mobility during walking and thus benefit from the use of a foot orthoses?**

   We agree somewhat with this line of questioning. However, it appears to be a moot point considering significant differences in plantar fascia strain were measured between the sock liner of the shoe and the moulded orthoses condition. However, we speculate that with a more pes planus population, perhaps differences in rearfoot eversion and midfoot MLA angle would be
measured. Future research is necessary to answer this question. We have added these points to the Limitations section in the Discussion. Finally, we respectfully disagree that the population used in the current study would exhibit “minimal rearfoot or midfoot movement” since we screened them based on a normative standard (Butler et al. [18]). Thus, we would expect “typical rearfoot and midfoot movement” whereas a more pes cavus population would exhibit “minimal movement.”

4. It is unfortunate that the authors did not have a group of subjects (with or without pathology) with “excessively mobile” feet based on the AHI criteria as defined by Butler in comparison to a group of “healthy” subjects who fit the “normal range” for the AHI. The authors should discuss this issue (no mention of this important limitation) in their Discussion Section since it would appear to have a major impact on the results they are reporting.

We fully agree and this information has been added throughout the Discussion section.

5. The authors provide no information on the type of semi-custom device use in the study. Who is the manufacturer? What was the density of the orthotics device (classification based on Shore A gauge or other device)? How was the molding process conducted – in the shoe, outside the shoe, or other method? The reviewer is under the impression that one of the several types of SOLE Inc. foot orthoses devices was used in the study based on the Acknowledgement Section of the paper. But, the authors need to provide the reader with more detailed information on the foot orthoses used in their study based on the questions asked above.

This information has been added. We apologise for the oversight.

6. The fact that the PFS was significant but the MLA angles values were not is quite interesting. Since the change in position of the D1MT and MCAL markers were used to calculate the PFS and since PFS was significant (indicating a change in marker position) one must assume that the only reason the MLA angle was not significantly different amongst the three conditions studied was movement or lack of movement of the NAV marker. While the authors did discuss the issue of these three markers being removes and repositioned (page 8), the issue of skin movement for not only the NAV but also the D1MT and MCAL markers should be discussed more fully in the paper. While the Tranberg and Karlson paper (Clin Biomech 13:71, 1998) is over 10 years old, it still provides interesting information on the amount of marker movement that occurs in the foot during walking. The authors should include a discussion of this issue in their manuscript.

This is a very good point and we have included this information within the
Limitations section in the Discussion.

Minor Essential Revisions:
Page 4; Line 1 - the word “or” after efficacy I believe should be “of”. The authors should check this.
This change has been made. We apologise for this typographical error.

Page 4, Line 21 – the word “on” after “index (AHI) and were” does not seem to fit. The authors should check this.
This change has been made. We apologise for this typographical error.

Page 17, ref 18 – The pages provided for the Butler reference are incorrect – the pages should be listed as “102-106”
This change has been made.

Discretionary Revisions:
1. The authors note on Page 10, line 21 – that future research involving custom-made orthotic devices needs to be conducted. It would beneficial for the reader if the authors discussed the findings by Kogler GF, et al (Clin Biomechanics 11:243-252, 1996). In their study, they assessed five different foot orthoses and their effect on the strain of the plantar fascia in fresh frozen cadavers. While this is not a dynamic study, such as the one conducted by the authors, the results of the Kogler study substantiates the need for further dynamic motion research with other types of foot orthoses. This is a very good point and we have included this information within the Discussion.

2. The author’s note on Page 14, line 15 – that future research should include other types of experimental models, including finite element analysis and fluoroscopy. Again, it would beneficial for the authors to discuss the findings of Wearing SC, et al (Med Sci Sports Exerc 36:1761, 2004), as their findings are in agreement with the results of the authors study regarding the MLA angle. Wearing et al used digital fluoroscopy to obtain 2-D dynamic lateral radiographs during walking. Again, this would be beneficial for the reader and substantiate the point the authors have made in their manuscript.
This is a very good point and we have included this information within the Limitations section in the Discussion.
Reviewer: Douglas Powell
Reviewer's report:

General:
1.MER: The present study includes male and female participants; however, no tests were conducted to assess the effect of gender. Previous research has suggested that females (at least in a landing movement) exhibit a greater contribution from the ankle compared to the knee and hip (McLean 2006, Kernozek 2005). Perhaps a comparison of gender differences could explain some of the non-significant results. References included at end of review.

The purpose of this study was to assess the effect of an orthotic device on rearfoot and midfoot mechanics. While we did have a mixed group of male and female participants (9 males, 11 females) we did not assess the effect of gender. While the reviewer makes a good point, we chose not to conduct this analysis for two reasons. First, it was not the purpose of the study and second, our comparison would be under-powered based on a post-hoc power analysis we conducted. However, research is underway (abstract presented at 2010 iFAB conference) and we hope to submit this publication soon.

2.MER: Why did the current study select individuals with a 'normal' foot type to study orthotics? It seems that individuals with a normal foot type would have muted responses with the addition of an orthotic compared to a low-arched or flexible foot. Would you expect similar findings if this study was conducted with low-arched individuals? Perhaps this could be presented in the Discussion. Two potentially useful references pertaining to multi-segment foot motion in normal (Lundgren 2008) and low-arched individuals (Rattanaprasert 1999, Powell 2011) could be discussed.

This is a very good question and one also raised by Reviewer 1. As an initial investigation, we sought to understand how an orthotic device would reduce plantar fascia strain, if at all, for a group of normative subjects. We fully agree that future research involving a more pes planus population is necessary and this research is currently under way. We have added this information to the Limitations section in the Discussion.

3.MCR: A figure showing representative or ensemble curves of tibial internal rotation, rearfoot eversion and arch motion would aid in the presentation and interpretation of data.

This change has been made.

Introduction:
1.MER: The topic is well introduced. Perhaps some discussion of the kinematics and possibly kinetics addressed by the use of orthotics would be helpful in assessing the evidence this manuscript presents.
We feel that 1/3 of the Introduction does address the kinematics of the rearfoot and also provides sufficient justification for the purpose of the study. If the Reviewer could be more specific we would be happy to address this point further.

2.MER: Paragraph 3: top of page 4, “underlying mechanics underpinning the clinical efficacy or orthoses...”. Should be “of”. This change has been made. We apologise for this typographical error.

Methods:
1.MCR: It is unclear why the AHI was recorded in both sitting and standing positions as neither arch stiffness, relative arch deformity nor any other quasi-static measurement of the arch is not presented.
We have clarified that both the sitting and standing AHI values were used during our screening process. In effect, we selected our participants based on the “change” in arch deformation by ensuring that values were within both the sitting and standing AHI values.

2.MCR: More description of how the midfoot or forefoot was modeled would be helpful.
Aside from the paragraph in the Methods section describing location of the markers and how the variables of PFS and MLA are calculated, we are unclear how much more information the Reviewer is seeking. If the Reviewer could be more specific we would be happy to address this point further but overall we feel that sufficient information is provided allowing any reader to replicate the study.

3.MER: It could be made more clear that the subjects performed treadmill walking rather than over-ground. It is mentioned; however, it is not unmistakably clear.
This change has been made and we have clarified in several places throughout the Methods section.

4.MCR: It is unclear if the data processing occurred prior to temporal normalization (100 points) or after. If data were processed after being temporally normalized, some resolution could be lost.
This change has been made to clarify that data were normalized to 101 points prior to processing.

Discussion:
1.MCR: While the current study presents data in regard to walking, few people suffer overuse injuries while walking. How might these findings relate to running? Previous research (Powell 2011) has revealed greater differences in multi-segment foot biomechanics between high- and low-arched athletes in walking compared to running.
This is a good point and we have included this information within the Limitations section in the Discussion.
2. MER: It could also be noted more heavily that generally, the molded compared to unmolded orthotic was associated with greater reductions in PFS.
This is a good point and we have included this information throughout the Discussion.