Author's response to reviews

Title: A case-series study to explore the efficacy of foot orthoses in treating first metatarsophalangeal joint pain

Authors:

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Author's response to reviews: see over
Dear Hylton,

Re: A case-series study to explore the efficacy of foot orthoses in treating first metatarsophalangeal joint pain

Thank-you for your letter and we are delighted to provide revisions as requested by the reviewers. We have responded to each of the reviewer’s comments in the attached table, numbering each as they appeared in their reviews. We have found the reviewers’ comments in general to be highly constructive and believe that our paper is strengthened by the changes made at their suggestion.

Once again, thank-you for the opportunity to submit our revised manuscript.

Yours sincerely

Mr Brian Welsh
Dr Anne-Maree Keenan
Dr Anthony Redmond
Dr Nachiappan Chockalingam
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| 1.1 | The study is a case-series study. Is it possible for the authors to revise the title to include this? | We agree with the reviewer’s comments that the study design would be more accurately classified as case-series.  
*Action:*  
Text amended accordingly. |
| **Abstract** | | |
| 2.1 | Are the foot orthoses ‘functional’? Would it be less confusing if this word were omitted from the title to prevent confusion amongst readers? | We agree with the reviewer and have amended accordingly.  
*Action:*  
The word ‘functional’ has been omitted from the title. |
| 2.2 | Given that the aims of the study was to investigate the effects of foot orthoses on pain and function of the first MTPJ, the final sentence of the results section is out of place. Is it possible to omit this sentence? | We agree with the reviewer’s comments in that the inclusion of this sentence takes away from the main findings of the study.  
*Action:*  
The final sentence of the results section was omitted. |
| **Literature Review/Introduction/Background** | | |
| 3.1 | Can the authors spell out ‘MTP’ prior to abbreviating within the first sentence. | This is an oversight.  
*Action:*  
Metatarsophalangeal spelt out in first sentence of Background. |
| 3.2 | Can the authors reduce the frequency of the word ‘it’ | *Action:*  
We have reviewed the Background and have amended accordingly. |
| 3.3 | Page 5, paragraph 3: Is there ‘very little’ or ‘no’ evidence on those with painful 1st MTP joint? Also, please add the word ‘a’ between the words ‘painful and ‘1st MTP’ | *Action:*  
We have amended the sentence. |
| **Methods** | | |
| 4.1 | Page 6, paragraph 1: Can the authors add the word ‘foot’ prior to the word ‘orthoses’? Can the authors revise the final sentence to | The authors agree that for consistency, ‘foot’ is required before ‘orthoses’. The authors also feel that the final sentence can be improved and have amended accordingly. |
something along the lines ‘...to explore the mechanical effects of foot orthoses on 1st MTP joint and ankle/subtalar complex kinematics’?

**Action:**
We have added the word ‘foot’ before ‘orthoses’. The final sentence now been amended.

### Participants

5.1 The authors state the participants had ‘mechanically induced’ 1st MTP joint pain. How was this confirmed? Also, would it be more plausible to include the word ‘hypothetic’ if this wasn’t empirically proved?

This has now been clarified in the Background

**Action:**
Background amended accordingly.

5.2 Were participants with confounding foot pain excluded too?

The exclusion criteria are presented in the methods section, which does account for major causes of confounding foot pain. While we do not recall any participants with confounding foot pain that may have confused their responses, participants were advised to complete the pain questionnaires as they related to their 1st MTPJ pain. This has been clarified in the methods.

**Action:**
Instructions for pain questionnaire included in the methods.

### Foot orthoses

6.1 The word ‘functional’ is used in the title to describe the foot orthoses interventions, yet pre-fabricated foot orthoses were used. Can you please clarify this?

Please see reply 2.1

6.2 The assumption that excessive pronation is the cause of the mechanically induced first MTP joint pain is unlikely to be scientifically valid (Zammit et al., 2009). The authors need to highlight this within this section as well as the discussion. Perhaps the authors could argue that it is pragmatic however.

We are unclear of the publication that you are referring to – the only one we can find is the Zammit Cochrane protocol, which may eventually offer some interesting information when the full review is published. We would, as you rightly state, argue that as this is commonly undertaken in clinical practice, it is an appropriate clinical question to study.

6.3 Was any effort made to control for participant’s footwear, or determine if participants altered their footwear to accommodate the foot orthoses? Changing

The authors agree that a change in footwear may influence first MTP joint pain. We did not attempt to address this. The first paragraph of the ‘Clinical Protocol’ section on page 9 states:

“Orthoses were issued only if footwear was appropriate, determined by an assessment tool devised by Menz and Sherrington 1. This tool was modified to include ‘heel counter height’ which was considered an
footwear may influence first MTP joint pain. *important factor in the provision of foot orthoses*. The authors would also like to indicate that the discussion (second paragraph, page 15) states: "... participants wore their own footwear following assessment for suitability. There was however a level of variability amongst participants' footwear that may have influenced the therapeutic effect of the devices as there is a known orthotic effect of foot wear alone".

6.4 Can the authors provide any data concerning the FPI scores post-orthoses intervention (within the results)?

The FPI was stated incorrectly as an outcome measure when, in fact, it is used in the present study as an inclusion criteria. This was an oversight.

**Action:**
The FPI has been removed as an outcome measure.

**Gait analysis**

7.1 Page 10, paragraph 1: please specify that 'sagittal' plane motion of the 1st MTP joint was assessed.

Agreed.

**Action:**
Page 10, paragraph 1: the word "sagittal" has been included before "plane motion of the 1st MTP joint"

7.2 Can the authors provide any data or at least refer to any previous studies showing the reliability of the motion analysis system for there measurement?

We have now referred to Longworth et al (2006) which is a formal study of inherent error associated with the use of the electromagnetic motion tracking system and protocol used in this present study.

**Action:**
Reference added.

7.3 Page 10, paragraph 2: Was velocity of gait controlled for or measured?

Participants walked at a self-selected speed, which is stated clearly in the methods. The authors acknowledge that changes in temporal measurements may influence gait data. However, this was outside of the remit of this study.

**Data analysis**

8.1 Page 11, paragraph 3: The authors state ‘...relationships between variables were explored...’ Could the authors please specify the variables? Were p-values < 0.05 significant?

Relationships for all variables were explored graphically. The relevant findings are presented in the results section. Listing all variables at this point in the manuscript would seem unnecessary and laborious to the reader. If the editors feel strongly that such information is valuable, we would be happy to supply as supplementary information

**Results**

9.1 Page 12, paragraph 2: please add the word ‘significant’ between the word ‘no’

We have added the word significant as requested but would question the necessity of listing non-significant scores. We have now added all the r and p values.
and 'correlation'. Also, can the authors provide the exact r-values and p-values for each correlation?

9.2 The authors assessed maximum and total values of first MTP joint dorsiflexion and ankle complex (eversion and abduction). Can the authors also present data concerning total values of these parameters as it appears to be missing? Further, eversion of ankle/subtalar complex results are not reported. 

Action: Text added.

While total ROM has indeed explored, it did not contribute to the story and was not investigated in detail. Eversion of ankle/subtalar complex results are reported on Page 13, paragraph 1.

Action: The reference to total range of motion on page 10 is erroneous and has been removed.

### Discussion

10.1 Page 14, paragraph 2: A criticism of this work is the inclusion of participants with 'mechanically induced pain'. Theoretically, the pain was mechanical. However, I strongly feel that the authors need to acknowledge that the true diagnosis of their participants was unknown. Is it possible that participants showed reduced range of dorsiflexion as a result of pain (rather than reduced range of motion causing pain)?

We agree with the limitations of mechanically induced foot pain as a criteria and have attempted to clarify this – please see response to 5.1

As for the relationship between reduced ROM as a result of pain, this is also valid. However, we found no evidence of a relationship between pain and ROM in this cohort, albeit that we were unable to compare with those without pain.

10.2 Page 14, paragraph 4: I suggest that this paragraph be omitted for reasons stated previously in the results

Agreed. This was speculative.

Action: Paragraph removed.

10.3 Page 15 paragraph 1: The authors rightfully acknowledge the limitations of the study design. Can the authors provide some more detail concerning the possible ways in which participants might have improved (e.g. regression, placebo etc) given the lack of

We agree with the reviewer and have included such factors as suggested by the reviewer.

Action:

We have include in the discussion: “It is possible that the pain reduction gain by the participants could have been due to reasons other than the therapeutic effect of the foot orthoses such as the placebo effect, a change in footwear required for the accommodation of the foot orthoses, the participant incorrectly reporting lower pain levels to please the clinician or through natural resolution of symptoms.
control group. over time."

10.4 Page 15, paragraph 2: Can the authors state more clearly that participants may have changed footwear to accommodate for the foot orthoses and this may have contributed to the favourable effects of the intervention? Was this measured? We agree with the reviewer and have highlighted this point in the additional text in response 10.3. It was not measured, or documented, whether participants had to change their footwear to allow for the provision of foot orthoses though, in hindsight, it would have been interesting to have looked at this.

Action: See Action above (10.3)

Tables

11.1 Table 1: Please add data concerning the frequency of left versus right sides analysed and gender. Agreed.

Action:

Information is now included in the text.

11.2 Table 1 Please provide data concerning change in FPI scores post-intervention. Please see response 6.4.

11.3 Table 1 Please change the word ‘length’ to ‘duration’, and spell out ‘months’ Agreed.

Action:

Table 1 has been amended accordingly

11.4 Table 1 Please change the term ‘MTPJ1’ to be consistent with in-text abbreviation. Thank you reviewer for pointing this out.

Action:

Table 1 has been amended accordingly

Discretionary Revisions

12.1 The authors may wish to add that the positive effects of their foot orthoses were seen for the orthotics prescription protocol (which includes the orthoses used). Thank-you for your comment.

Reviewer Keith Rome

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(<10º) did however demonstrate a significantly higher degree of ankle/subtalar complex abduction after heel lift.” Has been omitted from the results section of the abstract.

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| **2.1** If the first MTP joint is often associated with osteoarthritis then I would assume this would be a criterion used in the current study. | The reviewer is correct. Some participants may have had mild OA changes. However, this study was exploring 1st MTP joint pain that was amenable to treatment and, therefore, participants with less than 40º 1st MTP joint dorsiflexion were excluded.  
*Action:* No action taken |
| **2.2** Reference 8 is rather out-dated and not peer reviewed and it is unclear how the absolute values can relate to current evidence. | Reference 8 is historical in that it is illustrating the first time in the literature that functional hallux limitus was defined. |
| **2.3** The aims are poorly written: there is a need to explain a significant difference in pain reduction rather than the effect of FOs. | The authors accept that the aims were worded in a way that suggested more emphasis on the functional impact of the foot orthoses rather than the main aim which is to influence pain levels.  
*Action:*  
The last paragraph of the background was amended to the following: “The main aim of this study was to investigate change in 1st MTP joint pain levels when foot orthoses are prescribed with the rationale of increasing 1st MTP joint dorsiflexion. Relationships between changes in 1st MTP joint pain levels and changes in the mechanical effects of foot orthoses on 1st MTP joint and ankle/subtalar complex kinematics were also explored.” |
| **2.4** Overall, the background is poor with limited information relating to the main aim of pain at the first MTP joint. | We trust that this has now been rectified in response to other comments. |

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<td><strong>3.1</strong> Inclusion criteria included a score of at least 40mm on a 100mm VAS. Reference to which VAS was used would be helpful.</td>
<td>Agreed. This has now been referenced.</td>
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| **3.2** Unclear of the reasons of using the Foot Posture Index as an inclusion criterion. | The authors accept the reviewers comments and have made amendments to clarify this point  
*Action:*  
Page 6, paragraph 4: The sentence concerning FPI requirements now reads “As the foot orthoses being tested in the study were to be modified to offer a tailored level of pronatory control, participants were required to demonstrate a Foot Posture Index (FPI-6) score of greater than. |
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| **3.3** | Unclear of the sample size calculation. What is ARE and if a power size was undertaken, then cross-reference to previous work is needed and the power and alpha level should be reported. | The ARE compares the efficiency of two competing test statistics. A sample size calculation was conducted and based on previous work\(^5\). A SD of 17.8 was taken from this study. A sample size calculation provided 80% power to detect a 10mm difference at an alpha level of 0.05.  
**Action:** The sentences regarding the sample size calculation has been amended to “The sample size was based on the Pitman’s Asymptotic Relative Efficiency (ARE)\(^6\). A calculation was performed using a standard deviation of 17.8, based on previous work that used the same outcome measure as this study (Redmond et al 2006). A sample size of 32 participants provided 80% power to detect a 10mm difference at an alpha level of 0.05. This was increased to 35 to allow for 10% drop-out (Landorf et al 2006).” |
| **3.4** | Reduction of 10mm on a VAS should be related to a foot-specific condition. | This has now been referenced to a foot-specific paper\(^7\). However, it should be pointed out that this paper had not been published at the time of planning and conducting our study. |
| **3.5** | There is a need to review minimal clinical differences to more current literature. | As for response 3.4 |
| **3.6** | How do references 21 and 22 differ from the current study? | They do not perform analysis on symptomatic subjects.  
**Action:** None required |
| **3.7** | Unclear if both or single feet analysed | The last paragraph of the ‘participants’ section, page 7, paragraph 1, states “Where participants reported bilateral 1st MTP joint pain, the joint which gave the most pain was selected for the purposes of the study”.  
**Action:** None required |
| **3.8** | The FOs criteria of using the Foot Posture Index requires further clarification as I am unclear of its merit | Please see response 3.2. |
| **3.9** | Secondary outcome using the Foot Posture Index is described but not analysed. | The reviewer is correct. The FPI was stated incorrectly as an outcome measure when, in fact, it is used in the present study as an inclusion criteria.  
**Action:** The FPI has been removed as an outcome measure. |
| **3.10** | EMT needs to be explained to the readership | This has now been addressed by referring to explanatory papers.\([23, 41]\) |
| 3.11 | Modifying a reliable tool needs clarification and adding ‘heel counter height’ requires further clarification and justification. | This has now been addressed. |
| | | **Action:** Page 9, paragraph 1, text has been changed “In addition to the footwear assessment tool, heel counter height was also assessed which was considered an important factor in the provision of foot orthoses.” |
| 3.12 | I assume that participants were familiar with completing the pain questionnaires over the time-frame | The authors agree. |
| | | **Action:** No action required. |

**Gait analysis**

<p>| 4.1 | Nine not ten participants were analysed | This has been addressed. |
| | | <strong>Action:</strong> Page 11, paragraph 2 now ends with “The original dataset of 10 was reduced to 9 due to technical problems”. |
| 4.2 | Need to justify why only 9 participants | See response 4.1 |
| 4.3 | Comparisons between those with and without pain relief was described but not explained in enough detail. | The authors have noted the reviewer’s concerns and the text has been changed accordingly. |
| | | <strong>Action:</strong> Page 9, paragraph 3 has been amended to end “The intention was to explore the relationship between change in pain and kinematic response for the indexed (or painful) foot.” |
| 4.4 | Page 10: three reps were undertaken and there is assumption that both feet were analysed. | Thank you for the reviewers comment. The authors would agree that some readers may indeed make this assumption. We have therefore changed the wording to make it clear that data was analysed for the study or index foot only. |
| | | <strong>Action:</strong> Page 11, paragraph 2: the following sentence was amended to include the text in brackets. “Data from the three trials (of the indexed limb), for each condition, was normalised and averaged.” |
| 4.5 | Unclear of why the data collection was randomised and needs further information about normalized and averaged. The reader will not understand the reasons. | This was to avoid systematic bias such as fatigue. |
| | | <strong>Action:</strong> Page 11, paragraph 2: Further information about normalized and averaged has been included. |</p>
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| **5.1** | Table 1: labels are missing and unclear of the data from the Foot Posture Index | Agreed.  
*Action:* We have amended the table accordingly. |
| **5.2** | No correlation between different variable….no correlation values reported | Page 11, paragraph 3. The analysis that this paragraph relates to was undertaken from observation of the scatter plots. It was clear from this analysis that no correlation existed and therefore no further statistical analysis was undertaken.  
*Action:* Page 12, paragraph 2: "The ‘r’ and ‘p’ values relating to baseline characteristics and pain have been included"? |
| **5.3** | Efficacy analysis: needs to be re-written as it is confusing. Rather than independent tests undertaken, should a non-parametric ANOVA have been used to prevent a type one statistical error. | As the primary outcome, specified *a priori*, was the single difference between pain at baseline and 24 weeks, it was appropriate to use Wilcoxon signed ranked test, the non parametric equivalent of independent t tests. By using a Kruskal Wallis test, the non parametric equivalent of an ANOVA to include the additional time points, the significance of the primary outcome may have been obscured by other relationships in the model. If the overall ANOVA model had failed to reach significance, doing post-hoc comparisons would be akin to data mining. We are confident that our approach is robust and appropriate. |
| **5.4** | Exploratory analysis: the results are poorly described. | In light of other comments, this has been re-written. |
| **5.5** | Although no statistical tests were used, the median scores were similar but the IQR were extremely high. | We agree: there is evidence of large variability in the data, as would be expected with such small numbers, as evidenced by the high IQRs. This is discussed on page 14, paragraph 32: “While large variation is expected with such a small sample size, this is a finding mirrored by a previous study that used intracortical pins to assess kinematic effects of foot orthoses 9, where a similar subject-specific and unsystematic effect was reported. Nester 9, from a review of recent dynamic cadaver and invasive kinematic research approaches, concluded that there was a similarly high and normal variation of foot kinematics between individuals.” |
| **5.6** | Page 13: second paragraph should be deleted as a further analysis of the secondary analysis was performed. | Agreed.  
*Action:* This is deleted. |

### Discussion

| 6.1 | Page 12-13; references [29,27,43,27,34] and The authors are not aware of any foot related studies that have assessed what level of pain |  |
| 6.2 | Reference 464 is a literature review rather than clinical study. | Thank you to the reviewer for this observation. Page 13, paragraph 2 did state ‘other studies that have explored’ one of which is indeed a review of the literature. Action: Page 13, paragraph 32 has been changed to ‘other authors who have explored’. |
| 6.3 | Link between pain reduction and kinematic analysis needs further explaining as I am unclear of what analysis was undertaken. | In light of previous comments, this section has been amended. |
| 6.4 | Too much emphasis on the kinematics and insufficient exploration of the main aims | In light of previous comments, this section has been deleted. |
| 6.5 | No cross-reference to previous similar studies | The authors accept this comment though would point out that the are no other studies that have looked at the effect of foot orthoses on 1st MTP joint pain with the aim of improving 1st MTP joint function other than of single case design. We were therefore not able to cross-reference to similar studies. |


