Reviewer’s report

Title: A cohort study to explore the efficacy of functional foot orthoses in treating first metatarsophalangeal joint pain

Version: 1 Date: 16 November 2009

Reviewer: Shannon Munteanu

Reviewer’s report:

Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

Title:
The study is a case-series study. Is it possible for the authors to revise the title to include this?

Are the foot orthoses ‘functional’? Would it be less confusing if this word were omitted from the title to prevent confusion amongst readers?

Abstract:

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?

Literature review/Introduction/Background:
The literature review is well written and well structured. The rationale for the study is provided.

However, can the authors spell out ‘MTP’ prior to abbreviating within the first sentence?

Can the authors reduce the frequency of the word ‘It’?

Page 5, paragraph 2: 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’.

Methods:

Page 5, paragraph 4: Can the authors add the word ‘foot’ prior to the word ‘orthoses’? Can the authors revise the final sentence to something along the lines ‘…to explore the mechanical effects of foot orthoses on 1st MTP joint and ankle/subtalar complex kinematics’?

Participants:
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 ‘hypothetical’ if this wasn’t empirically proved?

Were participants with confounding foot pain excluded too?

Foot orthoses:
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?

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.

Was any effort made to control for participant’s footwear, or determine if participant’s altered their footwear to accommodate the foot orthoses? Changing footwear may influence first MTP joint pain.

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

Gait analysis:
Page 9, paragraph 1: please specify that ‘sagittal’ plane motion of the 1st MTP joint was assessed.

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

Page 10, paragraph 3: Was velocity of gait controlled for or measured?

Data analysis:
Page 11, paragraph 1: The authors state ‘…relationships between variables were explored…’. Could the authors please specify the variables? Were p-values < 0.05 significant?

Results:
Page 11, paragraph 2: please add the word ‘significant’ between the word ‘no’ and ‘correlation’. Also, can the authors provide the exact r-values and p-values for each correlation?

Page 12, paragraph 1:
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.
Discussion:

Page 13, paragraph 3:
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)?

Page 14, paragraph 2:
I suggest that this paragraph be omitted for reasons stated previously in the results.

Page 15, paragraph 2:
The authors rightfully acknowledge the limitations of the study design. Can the authors provide some more detail concerning the possible ways in which participants may have improved (e.g., regression, placebo etc) given the lack of control group?

Page 15, paragraph 3:
Can the authors state more clearly that participants may have changed footwear to accommodate for the foot orthoses and this may have contributed to favourable effects for the intervention? Was this measured?

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

Please provide data concerning change in FPI scores post-intervention.

Please change the word ‘length’ to ‘duration’, and spell-out ‘months’.

Please change the term ‘MTPJ1’ to be consistent with in-text abbreviation.

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

Page 15, paragraph 2:
The authors may wish to add that the positive effects of their foot orthoses were seen for the orthotic prescription protocol (which includes the orthoses used).

**Level of interest:** An article of importance in its field

**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