Reviewer's report

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

Version: 1 Date: 17 November 2009

Reviewer: Keith Rome

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Overall Comments
The study relates to the prescription of foot orthoses (FOs) relating to first MPTJ pain and would be of interest to both clinicians and researchers. However, the title is misleading as secondary analysis was undertaken that included kinematic analysis. There are a number of issues that need to be addressed. I have highlighted my concerns in the specific comment section.

Specific Comments

Abstract
The background is very generic and requires further reviewing. 35 patients were reported but only 32 were assessed with FOs. Measurements were undertaken at 0, 8, 12 and 24 weeks but not as reported in the abstract baseline and 24 weeks. The results are confusing in its present format and need reviewing. The secondary analysis is weak and the analysis of the secondary analysis requires further justification. The conclusion should state a significant decrease in pain rather than an improvement in pain and too much emphasis of the secondary analysis of only nine subjects.

Background
If the first MPTJ is often associated with osteoarthritis then I would assume this would be a criterion used in the current study. Reference 8 is rather out-dated and not peer-reviewed and it is unclear how the absolute values can relate to current evidence.

The aims are poorly written: there is a need to explain a significant difference in pain reduction rather than the effect of FOs and improving foot function.

Overall, the background is poor with limited information relating to the main aims of pain at first MPTJ.

Methods
Inclusion criteria included a score of at least 40mm on a 100mm VAS. Reference to which VAS was used would be helpful.

Unclear of the reasons of using the Foot Posture Index as an inclusion criterion.

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.
Reduction of 10mm on a VAS should be related to a foot-specific condition.
There is a need to review minimal clinical differences to more current literature.
How do references 21 and 22 differ from the current study?
Unclear if both or single feet were analysed.
The FOs criteria of using the Foot Posture Index require further clarification as I
am unclear of its merit.
Secondary outcome using the Foot Posture Index is described but not analysed.
EMT needs to be explained to the readership
Modifying a reliable tool needs clarification and adding ‘heel counter weight'
requires further clarification and justification.
I assume that participants were familiar with completing the pain questionnaire
over the time-frame.
Gait analysis: nine not ten participants were analysed.
Need to justify why only nine participants?
Comparison between those with and without pain relief was described but not
explained in enough detail.
Page 10: three reps were undertaken and there is assumption that both feet were
analysed.
Unclear of why the data collection was randomised and needs further information
about normalised and averaged. The read will not understand the reasons.

Results
Table 1: labels missing and unclear of the data from the Foot Posture Index for
its inclusion.
No correlation between different variable...no correlation values reported.
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?
Exploratory analysis: the results are poorly described. Although no statistical
tests were used the median scores were similar but the IQR were extremely high.
Page 11: second paragraph should be deleted as a further analysis of the
secondary analysis was performed.

Discussion
Page 12-13; references [29, 26, 41] are not foot related.
Reference 42 is a literature review rather than clinical study.
Link between pain reduction and kinematic analysis needs further explaining as I
am unclear of what analysis was undertaken.
Too much emphasis on the kinematics and insufficient exploration of the main
aims
No cross-reference to previous similar studies.

**Level of interest:** An article of limited interest

**Quality of written English:** Needs some language corrections before being published

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

**Declaration of competing interests:**
I declare that I have no competing interests