Reviewer’s report

Title: Lateral wedges with and without custom arch support for people with medial knee osteoarthritis and pronated feet: An exploratory randomized crossover study

Version: 0 Date: 16 Feb 2017

Reviewer: Justin Sullivan

Reviewer's report:

Dear Editor,

Thank you for the opportunity to review this manuscript, which focuses on a very interesting and important topic area. The trial investigates an important clinical question and is generally well presented with some interesting findings reported. I do, however, feel there are some significant concerns regarding the methodology. The most concerning surrounds the sample used, which could seriously threaten the extent to which the analysis validly answers the research question. Please find below my complete list of comments:

Background:

* The first paragraph contains comments concerning Osteoarthritis in general (with a comment that it commonly affects the knee). I think some more specific detail on the prevalence and impact of knee OA would be appropriate here.

* I think the paragraph establishing a connection between excessively pronated or flatter feet with OA is important and presents reasonably well. I do wonder, however, if the clinical issue at hand could be more clearly explained. For example, if people have knee OA and flatter feet, is it mainly that we may need to treat painful knees and painful feet in some patients, but is it also that we may need to consider the forces we are putting on an asymptomatic but flatter/more pronated foot when we use lateral wedging insoles for the knee. On a similar note, a comment is made that rearfoot eversion in gait is associated with KAM, although the direction of this association is not stated. This could be more explicitly stated, along with the rationale for lateral wedging, and perhaps this would start to suggest the potential conundrum of using an external pronatory force to offload the knee in patients whose feet are already flatter or excessively pronated.

* In the third paragraph of the background mention is made of pronated feet being treated with orthoses that maintain subtalar neutral. There is evidence that subtalar neutral is not a valid
marker to base foot function or foot orthoses prescription around and the authors should consider not using this explanation for practitioners choosing an orthoses type or design.

Methods:

* While 3/10 was sensibly used as a minimum pain level for the study, was there an upper limit for pain severity? Is it possible that people with very high levels of pain may not be most suitable for this intervention and require other forms or management?

* The biggest concern with the methodology surrounds the sample used and the definition of a flat foot. The authors have chosen a Foot Posture Index score of +4 or higher as flat foot. The published normative data have the mean FPI score at +4, with a standard deviation of over 2. This sample appears to have included those with a FPI score of 4, 5, and 6, who are people at or within one standard deviation of the mean. From table 1 it appears 6 is the 75th percentile, meaning only 25% of participants had a FPI of 7 or more. To me, this means that the sample includes mostly people with normal foot alignment and seriously threatens the validity of an analysis which is attempting to describe effects of interventions on people with flat/excessively pronated feet. The authors must respond to this issue and consider whether their data can validly answer the research question posed.

* The authors mention that not all participants completed the study, but more information is needed here. If 4 participants didn't complete the study (2 in the first phase), then this is a significant number in a sample of 26. The reasons for withdrawal should be stated and a justification for the decision on how to deal with the missing data should be provided. If the missing data is truly random then it may be only power that is affected, however, if these participants withdrew because they were doing poorly then the results of the analysis may be biased.

Results:

* Did the comparison of factors such as wear time, comfort include any statistics? If so, results of significance testing should be displayed.

* 16 reports of adverse events seems reasonably high, even if minor, out of a total of 46 interventions trialed. Were these all separate individuals or did some report multiple adverse events in the same treatment phase? Even so, there appears to be a somewhat high percentage of people having issues with the interventions and this probably deserves more discussion time as this would have clinical implications.
* Of interest, is there a cost difference between the 2 orthoses, as this may become important when considering cost-effectiveness

Discussion:

* In the first paragraph of the discussion there is a suggestion that the arch support insoles were more comfortable, however, this not in keeping with what is presented in the results regarding self-reported comfort. Similarly, comfort is provided as a reason that the arch support may be more effective (in the paragraph that discusses knee pain and external loads) which again is not consistent with the results section.

* The minimum clinically important difference for the WOMAC scale was referred to reporting the size of the treatment effect found in the study. Is there a MCID available for the FFI-R, and if so, do these changes represent an effect greater than this?

* Limitations are included, but the type of study design itself also has limitations and should be discussed as such. This doesn't mean that it's not appropriate to use a cross-over study with a small sample as a preliminary investigation, but the limitations of this design should be outlined. On this note, it is interesting that a glance at the figures seems to highlight that the second iteration is where the differences in interventions seem most apparent. Have the authors considered reasons for this being the case? This is something that should probably feature in the discussion.

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