Reviewer's report

**Title:** A Novel Device and Treatment Methodolgy for Reduced Pain and Improved Function in Knee Osteoarthritis: A Prospective Controlled Study

**Version:** 1  **Date:** 7 January 2010

**Reviewer:** Cindy Veenhof

**Reviewer's report:**

The manuscript describes an interesting study with very positive results of using a biomechanical device. In general, a large shortcoming of the study is that no data have been assessed after the intervention stopped. Therefore it is not known whether the intervention is only successful when the devices are used. I hope the authors are performing a long-term study at this moment. Some minor essential revision need to be made.

In my opinion the title does not reflect the intervention which was investigated. I would prefer something like: 'the effects of applying a biomechanical device to the feet of patients with knee OA' or 'applying a biomechanical device to the feet of patients with knee OA results in reduced pain and improved function'.

In the summary information is missing whether significant differences were found between control group and intervention group.

During the whole manuscript the references need to be checked.

**Interventions:**

It is not clear to me whether the control group felt the difference when using normal footwear or the foot worn platform. Was the foot worn platform also a kind of intervention? Did I understand it right that the control group also was advised to walk according to the same schedule as the intervention group?

I do not really understand the choice to stop the medication. Patients will use medication in future, therefore you should be interested in the supervalue of the device above the medication. I expected some discussion about this in the discussion section.

**Statistical analyses:**

were these performed according to intention-to-treat principle? This information should be written in this section. I have read that you did not perform ITT in results section. I do not understand why you did not perform ITT. Furthermore, this information need to be replaced to statistical analyses section.

I do not understand the 3rd hypothesis: I assume you mean: advantage in scale for the active group (instead of no advantage??)??

**Results:**
In the results section I miss information on the adherence to the protocol: How much did the intervention group walk during these 8 weeks: did they perform their schedule as was advised? And was there a difference in walking between intervention group and control group? The same for intake of medication.

Discussion:
I miss information on the clinical relevance and follow-up of this study. What needs to be done next?

I expected a discussion whether the device benefits more for a higher Kellgren en Lawrence score, or not...

Tables:
There are too many tables. I suggest to make a selection of the figures 3-5.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I do not have competing interests