Reviewer's report

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

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Reviewer: Reinoud W. Brouwer

Reviewer's report:

In this manuscript the effect of a novel biomechanical foot/shoe device has been studied during a follow-up of 8 weeks in a controlled clinical trial.

This device has the capability to change the location of the centre of pressure during walking and generates perturbation during movement that challenges neuromuscular control. I do not understand in what way this device changes the location of pressure in the knee and in what way generates perturbation, which challenges neuromuscular control?

The study was designed to be prospective, double blind study although without an adequate randomisation. I do not understand why the researchers did not go for a RCT, which is nowadays the state of the art.

I am not a statistician and a power analyses has been performed including two sided testing, but the number of the patients in each group for a new device seems to be too low. Moreover, the follow-up was only 8 weeks which is relatively short for a chronic disease like knee osteoarthritis.

Background:

The background is much too long and some parts have to be transferred to the methods part.

Has this new device been tested in the laboratory with e.g. gait analyses?

Methods:

There is no method of randomisation performed and the senior orthopaedic surgeon included the patients. When was the study performed and during which period were the patients included?

The inclusion criteria are not accurately defined. What was the reason to include only patients with bilateral medial knee oa? How do we know which knee has been scored? Was the oa grade of both knees the same? And if not which knee has been scored? What was the alignment of the leg, because most patients with medial knee oa have a varus alignment? How do we know that this device unloaded the medial compartment? Moreover, the degree of varus influences the adduction moment.
Where the patients blinded?

Were the devices for both the intervention as the control group optically identical?

What was the compliance of the allocated treatment?

Why did the authors not perform an ITT analysis?

The authors describe, “the consumption of acetaminophen and other medication was monitored”. How was this monitored and why are the results not presented.

Results:

It is remarkable the control group showed no effect. Normally there is some placebo effect.

The effect of the new device is outstanding high, which is unusual in treatment of medial compartment OA. These effects have not been shown in RCT studying other devices like unloading insoles or braces.

The side effects of both treatments have not been scored.

Tables and figures:

Table 1: leg alignment outcomes are missing.

Table 2 is too extensive and has to be summarized.

Are the p values presented between group differences or pre-post analysis?

Figure 2: a photograph of the device probably will give more information

1. Is the question posed by the authors well defined? yes
2. Are the methods appropriate and well described? no
3. Are the data sound? no
4. Does the manuscript adhere to the relevant standards for reporting and data deposition? no
5. Are the discussion and conclusions well balanced and adequately supported by the data? yes
6. Are limitations of the work clearly stated? no
7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? yes
8. Do the title and abstract accurately convey what has been found? yes
9. Is the writing acceptable? yes

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

'I declare that I have no competing interests’