Reviewer's report

Title: Optimisation of rocker sole footwear for prevention of first plantar ulcer: comparison of group-optimised and individually-selected footwear designs

Version: 0 Date: 29 Mar 2017

Reviewer: Sobhan Sobhani

Reviewer's report:

General comments:

Thanks for giving me the opportunity to review this work. The idea has been simple, identifying the most optimum design of a rocker sole shoe (by manipulating rocker angle (RA) & apex position (AP)) with the aim that the so-called "best design" could sufficiently reduce diabetic forefoot pressure and thus be used as a prophylactic generic tool for those who at risk of foot ulcer. The idea is nice and worth considering. The problem, however, is that throughout the manuscript the authors feel free to analyze and talk about RA & AP sometimes together and sometimes separately. As far as I know, in a two-way ANOVA model your independent variables should each consist of two or more categorical, independent groups. RA & AP are neither independent neither categorical. The authors know better than me that these two features are not independent at all, on the contrary they are highly correlated. So in my opinion treating them as two independent factors is wrong in your statistical analysis. Reading your statistical section gives me the impression that you are not totally familiar with two-way ANOVA model. This is what you have stated in the method section: "Two-way ANOVA analysis was used to understand the relationship between shoe design features (apex position and rocker angle) and peak plantar pressures. If significant differences were found pairwise differences were investigated using a Bonferroni correction for multiple comparisons."

This is not correct. First of all, significant difference between what? Does ANOVA test the relationships? Suppose that you can run a two-way ANOVA, the first step should be checking the interaction between the two factors (RA & AP), and then if there was no interaction you could processed to check the main effects. It seems you have done the opposite! Here is my question: if these two features are independent, why having 8 separate designs (RA 52-AP 15, RA 57-AP 15, RA 62-AP 15, RA 67-AP 15, RA 52-AP 20 etc.) and not having 6 designs, RA 15, RA 20, AP 52, AP 57, AP 62 and AP 67? You have intentionally chosen these combinations based on previous findings, hoping that one of these 8 designs could be the best design. So this is what you need, having "shoe type (with certain AP and RA)" as an independent factor. I hope I have been clear here.
In some lines below that you state this: "An optimal apex position, corresponding to lowest pressures, was identified from the ANOVA data for each separate anatomical region."

This is not how ANOVA works! It only checks whether there is difference between repeated mean measures or not. It has nothing to do with the higher or lower values. You could see these values simply by looking at descriptive data. I suggest you consult a statistician on this matter as I am not one of them ;). It is likely that I am horribly wrong here. Please consider introducing you hypotheses and the inferential statistics to test null hypotheses.

The other issue is having the healthy controls. I don’t really understand why you decided to include a healthy group. If your target group is diabetic patients why should I care if their biomechanical response is different from the healthy population?! Let’s assume there were differences, what would you try to infer? We have two shoe designs that might work for diabetic people. That is great! Adding the information of NON-matched healthy group is only confuses the readers. Please be aware that there is a 10 kg differences between the two groups in terms of body weight. I believe pressure is related to force, isn’t it? What are we comparing here? Interestingly you have not mentioned a word about you healthy group in the discussion. So why did you bother at all? If you insists to have the healthy group, then I can argue that you have failed in matching them?

And the final point: in the legend of figure 1 you state the following: "Note that in order to simplify manufacturing, and to ensure all footwear was of similar weight, all footwear in our study had the same outsole thickness which was sufficient to accommodate a 20° rocker angle (panel C)."

With all due respect, I think this is not physically possible. The only way to keep RA constant while implementing various AP, is to increase the sole height (thickness). Please explain to me that how is it possible to fix RA at 20 degree and then go from a AP-57% to a 52-AP% without any change in thickness? Can you illustrate this in a picture or even better provide the pictures of these designs studied in your work? I am really eager to understand this.
Specific comments:

Introduction:

Please start you intro by some sentences about the risk of foot ulcer in diabetic patients, risk factors and some epidemiological facts, and then the role of footwear in treatment and prevention.

Methods:

I personally prefer to see the population characteristics at the beginning of the results as recommended by CONSORT. A simple reason for this would be the use of descriptive statistics to summarize population demographics. In your case, you also have used inferential statistics as well to compare weight, height etc between the two groups. This info does not belong to the method section then. You should mention the test you have used here by the way (an independent t-test I guess)!

Please provide the values of weight in "cm" not "m".

What is EVA? (sorry there was no page number so I could refer to the exact page/line, the line numbers were not continuous either)

You mention: " In-shoe plantar pressure was collected using Novel Pedar-X system (50Hz) whilst participants walked at 1m/s +/- 10% along a 20m walkway. Participants completed a familiarisation period of three-four minutes and a minimum of 25 steps was collected for each shoe (shoe order was randomised). Data was exported into Matlab for processing. "
Here are some questions:

1) Was the walking speed self-paced or controlled? How did you exactly check it?

2) How exactly did you randomize the shoe orders?

3) How much time was given as wash-out time between each trial?

4) Did you consider removing acceleration and deceleration steps during data analysis?

Unfortunately, as I did not completely understand your hypotheses and analysis, I cannot give further comments. I hope I can see a revised version of this nice work.

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