**Author’s response to reviews**

**Title:** Can an Insole for Obese Individuals Maintain the Arch of the Foot Against Repeated Hyper Loading?

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**Author’s response to reviews:**

We thank the reviewers for their careful consideration of our manuscript. We have revised the manuscript to address each point raised by the reviewers. These changes have been highlighted in “red” in the revised manuscript. Please find our responses to your comments below.

**Reviewer reports:**

John P Albright (Reviewer 1): This is a well done cadaver-based research project looking at the effects of silicone rubber shoe inserts with a medial longitudinal arch support in order to investigate the effects of insoles on time dependent changes in arch structure during a repeat repeated-loading simulation designed to represent 20,000 contiguous steps in individuals with BMI as of 30-40. The questions asked for 1) whether or not the insole can maintain the foot arch against repeated loading in the presence of obesity and 2) does the use of an insole affect the flexibility and energy absorption of the foot arch in obesity.

18 cadaver specimens were used with some of them being in the normal range and some obese. The tibia and fibula were fixed with Kirshner wires and embedded into methacrylate. The foot was placed on a force plate with a tibial shaft perpendicular to the plate and then fixed in a custom jig in the neutral position. Time dependent changes in arch height doing cyclical loading was monitored with a two-dimensional analyzer. Muscle activity during mid stance phase of gait was replicated by exerting traction on the posterior tibial tendon. The results indicated that the insole use could slow the progression of flatfoot in obese individuals however flexibility and energy absorption of the foot may be unsustainable against 10,000 cycles of load.
Author Response: We are grateful to Dr. Albright (Reviewer 1) for the positive remarks about our manuscript. We have revised the text based on each comment, and we hope that our modifications have improved the manuscript.

Limitations: The authors provide four different limitations which are well covered. This reviewer suggests an additional fifth limitation which is in the design of the project itself. The issue that is not covered here needs to be discussed since it is contained in some of the references provided. That is the dynamics of a gait pattern involves heel lift as the foot is going through a walking cycle. This push off phase is very dynamic and involves different biomechanical stresses which are not replicated in the current model. This does not mean that the study is invalid it merely means that this is a limited view of the dynamics of shoe insert and its function during the walking activity. A thorough discussion of the findings of these other studies involving heel lifts should be covered in reasonable detail.

Otherwise, I feel that this is a reasonable contribution to the literature done on limited but solid biomechanical basis. It represents an initial study on obesity from a group from which I would expect to also see subsequent work done.

Author Response: Thank you for your suggestion. We agree with your suggested limitation that the terminal stance phase, including the heel off and push off phase, involves different biomechanical stresses than the midstance phase, and it is important point to understand the effect of insole for flatfoot deformity. Accordingly, we have added the description as a second limitation in the Discussion section on page 11, lines 231–240.

Dustin Bruening, Ph.D. (Reviewer 2):

General comments

I understood the purpose of this paper to be an investigation into the time-dependent effects of insoles and increased weight on foot mechanical properties. Overall, I though the study was fairly well presented with detailed methodology and the conclusions were appropriate. I do see a number of areas where the writing quality and clarity can be improved (see specific comments).

Author Response: We sincerely thank Dr. Bruening (Reviewer 2) for the positive comments about our manuscript.
Specific Comments:

Abstract

Line 4-6: The second sentence of the Background (essentially the purpose statement) is awkward and should be re-phrased.

Author Response: Thank you for your comment. We have rephrased the statement as follows: “We aimed to investigate the effect of insole use on time-dependent changes in the foot arch during a repeated-loading simulation designed to represent 20,000 contiguous steps in individuals with a BMI in the range of 30–40 kg/m2”. Please see the Abstract section on page 2, lines 4–7.

Background

Line 32-34: The two clauses of this sentence are redundant.

Line 34-35: The last sentence of the paragraph is also redundant with the previous one.

Author Response: We have modified the sentences in lines 32–35, as follows: “Although the etiology of AAFD remains unclear, a high body mass index (BMI) value is believed to be a risk factor for AAFD in both men and women”. Furthermore, we have deleted the later sentence because, as you mentioned, that part is redundant. Please see the Background section on page 3, lines 32–34.

Line 37: Usability is unclear.

Author Response: Thank you for your comment. We have included a clear, detailed description of the advantages of conservative treatment. Please see the Background section on page 2, line 36.

Line 37-38: This sentence is awkward. You say the therapeutic and kinematic effects have been reported but are controversial. This is a very loaded statement that isn't fully explained. More information about the effects and why they are controversial are needed.

Author Response: Thank you for your comment. We have modified this paragraph with a description regarding the reason for the controversy about the effect of insole. Please see the Background section on page 3, lines 36–44.
Line 46-49: This overall purpose statement is too long and awkward. Consider breaking it up.

Author Response: Thank you for your suggestion. We have divided the purpose statement into two sentences. Please see the Background section on page 3, lines 45–48.

Methods

Line 58-60: You state 18 feet, but 14 were left and 5 right, which makes 19?

Author Response: Thank you for your observation. We have revised it to 14 left and 4 right feet. Please see the Methods section on page 4, line 59.

Line 62-63: I assume specimens were divided randomly into the three groups, but this should be explicitly stated here (and maybe in the abstract as well).

Author Response: Thank you for your suggestion. We have added information explaining that the specimens were randomly divided into three groups. Please see the Abstract section on page 2, line 8 as well as the Methods section on page 4, lines 61–62.

Line 124-127: The definitions of flexibility and energy absorption need additional clarification and/or supporting references as it may not be clear to readers where these come from. Flexibility appears to be defined as the inverse of material stiffness. Energy absorption also looks like it comes from strain energy of a linear elastic material. It's important to note that these definitions are borrowed from material science and may not perfectly apply to a complicated structure that includes joints and a variety of different tissues.

Author Response: Thank you for your comments. We have added a reference for the definitions of flexibility and energy absorption; we have also added a statement about how our calculated value may not perfectly apply to the foot and ankle structure because we did the calculation as an elastic and homogeneous body in limitation paragraph. Please see the Methods section on page 7, line 126 as well as the Discussion section on page 12, lines 247–250.

Line 129-141: For me, some additional reasoning on the statistical treatment would be beneficial. It's not immediately clear why non-parametric tests were chosen and what the statistical decision making process was. There is also some disconnect between this section and the results (see Results comments) and some additional clarity would be useful. Additionally, It doesn't look like
the insole group was tested without the insoles (e.g. at first load). Could this be added - it would help verify that both obese groups were the same at first load?

Author Response: Thank you for your comments. We have added a statement about the normality test. Please see the Statistical Analysis section on page 7, lines 138–140. As you have pointed out, the data for testing without the insole at first load to verify the equivalence of both the obese and insole groups would help verify that both the obese groups were comparable at first load; however, we did not record these data. These data may not be sufficient to provide some information regarding the equivalence of both the obese and insole groups. However, we have added the BAI data for non-weight bearing before the first load. Please see Additional Figure 1.

Results

Line 144-145: This is a poor single-sentence paragraph. It would be better to describe the time-dependent changes in BAI from Figure 3, rather than simply direct the reader's attention to the figure. Some description is needed for this figure.

Author Response: Thank you for your suggestion. We have added additional descriptions for figure 3. Please see the Results section on page 8, lines 152–156.

Line 146-147: Similarly, this first sentence is not needed. Consider removing and starting with the description that follows. The same goes for the next two paragraphs.

Author Response: Thank you for your suggestion. We have removed the first paragraph from each figure description.

Line 159: This is the first mention of calculating an inflection point. The rationale, appropriateness of the 3rd order fit, and meaning behind calculating an inflection point should probably be part of methods.

Author Response: Thank you for your comments. We have added a statement about the calculation of the inflection point and the method of model fit. We have used Akaike’s Information Criterion (AIC) for the estimated best-fit regression equation. Please see the detail description in the Methods section on page 7, lines 127–133.
Line 165: "Incremental changes" isn't clear. Is this simply the difference between 1 and 10,000 cycles?

Author Response: Thank you for your comments. I have changed all “Incremental changes” to the difference between 1 and 10,000 cycles. Please see the Abstract section on page 2, line 18; the Methods section on page 7, lines 141–142; the Results section on page 8–9, lines 173–174; and Figure Legend 7.

Discussion

Line 175-177: This first sentence appears overly assuming. The actual effect of midtarsal locking in general is controversial - treating it as a known explanation is a bit of a stretch. Consider re-doing this entire sentence, perhaps incorporating the references into specific explanations throughout the paragraph.

Author Response: Thank you for your comments. We have modified the sentence without using the midtarsal locking. We simply discussed that the increasing hind-foot eversion represents abnormal foot kinematics as per a previous report by Blackwood CB et al. Please see the Discussion section on page 9, lines 184–187.

Line 189: You mention restraints from medial column and plantar ligament, but what about plantar aponeurosis?

Author Response: Thank you for your suggestion. Of course, plantar aponeurosis was imposed tensile force during axial load; therefore, we have added the plantar aponeurosis. Please see the Discussion section on page 9–10, lines 198–199.