Author's response to reviews

Title: Pedobarographic and kinematic analysis in the functional evaluation of two post-operative forefoot offloading shoes

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Author's response to reviews: see over
REPLY to Reviewers’ comments

General reply to all reviewers

First of all we acknowledge the time the three reviewers have spent on revising this paper and we would like to thank them all for their detailed and sensible revisions. We hope they will appreciate that we have addressed, to the best of our knowledge, all their comments for a possible overall increased quality of the manuscript.

One of the recommended major revisions concerned with the statistical approach and the sample size. We do regret that, in our original submission, we had not chosen the most appropriate statistical test. In fact, the pedobarographic and kinematic data measured in this study are paired, thus Friedman’s test is certainly a better approach for the present comparisons between groups with non-Gaussian distributions.

Another criticism is about the limited sample size (n=10). This is generally accepted in the field of motion analysis science, accounted for to the nature of the data acquisition and processing, which involve extensive and simultaneous acquisitions of kinematic, kinetic, and plantar pressure measurements. The latter, due to their intrinsic nature, are indeed characterized by a relatively large inter-subject variability. This is only partially related to the accuracy of the instrumentation here utilized, which in our knowledge is top-of-the-market.

We have of course analysed the distribution of the kinematic and pedobarographic variables and we have found the peak of pressure as that one showing the largest variability. Therefore the power analysis was based on this variable, this also being one of the most relevant to this study’s results and conclusions. Ten samples was suffice to discriminate 15% difference in peak pressure under the whole foot to the control values with statistical power of 80% (alfa = 0.05). Although a definitive consensus has not been found on using Bonferroni correction to account for multiple comparisons, this is often invoked to decrease the chances of false-positive Type I errors. As correctly highlighted by one of the reviewers, a post-hoc Bonferroni correction would entail with a lower alfa thus increasing the required sample size. However, the authors are reasonably confident on the main outcome of the study as the regional pedobarographic results are “statistically” confirmed by different parameters (e.g. mean and peak pressure and/or mean and maximum force). These reviewers will concur on that the chances for this to happen across several variables is extremely low. In order to help the reader to make up his/her mind on the actual statistical differences found in the study, we have decided to report explicitly all the p values lower than 0.05 in the tables and text. This should improve the readers’ understanding of the results.

Summing up: the statistical approach has been changed to Friedman’s test and no Bonferroni correction has been applied. As a consequence, the outcome of some of the statistical comparisons between shoe groups has changed from the original submission, whereas the overall message of the study has only partially changed. In particular walking speed and stride length in the half-shoe have now been found significantly different from the control.

The results have now been streamlined and organized more rationally, as recommended. Focus has been given to the main pedobarographic variables: mean/max force, mean/max pressure, force- and pressure-time integrals. Figure 2 has now been moved to Supplementary material and replaced by a new figure with a graphical representation of
the statistical differences in the main pedobarographic data. These changes should help
the reader to grasp the main results more quickly and effectively.

Detailed answers to the reviewers’ specific comments follow.

Reviewer #1:
This is an interesting and relevant piece of work that warrants publication however there
are several recommendations that I believe should be addressed first.

Major Compulsory Revisions
1. Biomechanical studies commonly involve much data which can be difficult for the reader
to 1. orientate to and 2. appreciate the practical implications of. I recommend that the
authors consider re-formatting the results section so the data is presented in a systematic
way. This might be, for example, according to intervention type or by mechanical variable
or some other consistent convention. Sub-headings may assist. This would then set the
discussion up to follow in a way that provides more order to presenting the wide range of
variables, findings and practical implications.

This is a very sensible point, an issue in fact for many experimental research papers. The
present study particularly wants to integrate standard pedobarographic analysis of the
fore-foot offloading shoes with state-of-the-art gait analysis, which involves additional
complexity. The overall picture however provides a very relevant conclusion, i.e. forefoot
offloading, albeit lower than what achieved with a standard half-shoe, can be achieved
with a more kinematic-preserving shoe design. The reviewer however is right, the results
can be organized in a more clear way.
In order to address this reviewer’s very sensible comment, the pedobarographic section of
the Results has been fully reformatted. Sub-headings have been added to help readers to
find relevant information more quickly according to the pedobarographic variable. Moreover, a graphical representation of the statistical differences in the main
pedobarographic variables (maximum force, peak pressure, and pressure-time integral)
between shoes has been added (new Figure 2) as to replace Table 1. The latter has now
been moved to the supplementary materials.

2. Biomechanical studies of this nature also often involve multiple inferential tests, which
run the risk of an elevated type-1 error rate. I note that some of the post hoc testing utilised
a Bonferroni adjustment however it is still not clear to me how such a large number of tests
could conceivably be adjusted for without significantly compromising the power of the study
(which already has a low sample size of 10). Potentially the use of 95% confidence
intervals instead of inferential testing may be an approach worth considering alongside the
addition of effect sizes (as some of the significant differences appear quite small and
potentially not clinically important). As statistics is not my area of expertise I suggest that
full review by a statistician is conducted. Please note however that I believe the correct
non-parametric equivalent for a one-way ANOVA with repeated measures is a Freidmans
test, not a Kruskal-Wallis test which is for independent groups. Also consider reporting key
information showing that test assumptions are met.

We welcome this very appropriate comment. The reviewer is certainly aware that the
limited sample size is somehow dictated by the nature of the data acquired for this
experimental work which required the extensive simultaneous acquisition of synchronized force data (via 2 Kistler force plates), kinematic data (via 8 cameras for motion capture) and pedobarographic data via 2 pressure insoles. This is probably why such comprehensive evaluation of orthopaedic footwear has hardly been performed before.

In relation to the statistical test used, we do agree with the reviewer on that Friedman’s test is more appropriate for paired data. This test does not require any particular assumption on the data distribution (it is the non-parametric equivalent of ANOVA). We have therefore recalculated the statistics and, whenever different from the previous calculations, modified the relevant Results and Discussion sections. We have decided to limit the Type II error rate and in the post-hoc test we have opted not to apply a Bonferroni correction to account for multiple comparisons. In fact, a larger sample size would have been required to achieve at least 80% statistical power for some of the variables investigated. If required, a sentence may be added to the Discussion as a further limitation of the study.

See also “General reply to all reviewers”.

Minor Essential Revisions

3. Consider whether the data tables can be streamlined to show key information, important statistical data and perhaps omit tables where there were no (or minimal) statistically significant findings. This can just be reported in-text. For example, Tables 1a and 2a showing data for the contralateral side.

Table 1 has now been moved to the Supplementary material. The Results section has been fully reformatted and the original Figure 2 has been replaced by a new one to provide an easy-to-read graphical representation of the statistical based differences in pedobarographic parameters between shoe designs. Focus in the Results has been given to maximum force, peak pressure, and pressure-time integral. Sub-headings have been added to help the reader finding the relevant information according to the pedobarographic parameter of interest.

4. Please break the background, discussion and other sections of the paper up into paragraphs – this may just be a formatting issue with my version of the paper.

Yes, unfortunately it just looked like this; it is likely due to a formatting issue with your version of the paper. In our original version these sections are correctly divided in meaningful distinct paragraphs.

5. Please explain the rationale for the sample size, was a power analysis conducted?

A power-analysis had been indeed conducted by looking at the expected distribution of peak pressure, which is the pedobarographic parameter commonly with the largest variability. According to this power-analysis, 10 samples would suffice to discriminate 15% difference from the control mean with 80% power at 0.05 significance.

See also “General reply to all reviewers”.

6. I am not sure on the JFAR convention however the name of the specific ethics committee that gave approval, and the respective approval number, may need to be included.
The project was approved on July 26, 2010 by the Scientific Committee of Istituto Ortopedico Rizzoli with board resolution n° 362. The relevant sentence in the Methods has now been modified accordingly.

7. Please note whether the order of measuring each intervention was randomised.

Yes, the order of the tested shoes was randomised. This has now been added to the Methods. Unfortunately no blind experiment could be performed as the shoes had designs and lacing systems too distinctive not to reveal to the subject during the acquisition.

8. Consider adding details, or references, for the reliability and validity of the measurements used.

Sensible point. The instrumented insoles and relevant data analysis for baropodometry are state-of-the-art, and their high repeatability has been previously reported and now added to the Methods. The measurement technique for gait analysis was proposed and tested by some of the same authors, and the relevant supporting references have now been cited.

9. Please include reference to the marker set and model used for kinematic data.

This was cited in the sub-section ‘2.4 Kinematic and kinetic measurements’, citations 19 and 20; it is now more explicitly mentioned, and additional supporting papers reported (see above).

10. The results section does not include data (but refers to tables). I suggest that key data and statistics are reported directly in the results sections.

Self-explicative figures have been preferred over data in the Results to increase the readability. In order to address this reviewer’s suggestion, some key data have now been added to the Results, trying not to duplicate results already shown in the figures. Figure 2 has been replaced by a new one showing statistical differences in the pedobarographic parameters between shoe conditions. See also comments#1 and #3.

11. Note in the study limitations, that the findings of this research can not be directly generalized to older, frail or unwell populations as the sample who participated were young healthy females.

The reviewer is right, this was a misleading speculation. This has now been explicitly added to the Discussion as a limitation of the study.

12. The quality of the figures require improving, clearer labelling etc. This may just be an issue with the formatting in the version I have received.

Again, this is very unfortunate, in our version these are very clear; hopefully this will be sorted out in the final version of the paper.

Discretionary Revisions
13. Line 55 – do the terms comfort and functionality capture the intent of the study or is it more risk of negative effects versus functionality?
We welcome this reviewer’s suggestion. The use of the term “comfort” has been removed from the abstract and reduced throughout the manuscript.

The relevant sentence in the Abstract has now been changed as follows: “While these shoes are intended to be worn only for short periods, a compromise must be found between functionality and the risk of alterations in lower-limb kinematics.”

The term “comfort” was used just to cite the relevant literature on the assessment of forefoot offloading shoes. We acknowledge however that this variable was not directly assessed in this study and its frequent use may have been misleading thus its use has been reduced in the revised version.

14. Line 75 – should that say associated ‘with’ not ‘to’?
15. Line 88 – ‘designs’ not ‘design’
16. Line 96 – it is not clear what appropriate and inappropriate use refers to
17. Line 112 – should be due ‘to’ the particular shape, not due the particular shape
18. Line 119 – significantly increases hip adduction, not increase of hip adduction
19. Lines 123 & 124 are awkwardly worded – consider re-phrasing

All these recommendations have now been addressed, and the relevant text has been revised accordingly.
Reviewer #2:

The manuscript “pedobarographic and kinematic analysis in the functional evaluation of two post-operative forefoot offloading shoes” by Caravaggi and colleagues is a simple but elegant paper, describing in depth analyses of walking with two types of FOS in comparison with a control shoe. As the authors rightly point out, FOS are widely used, despite our lack of understanding with regard to kinetics and kinematics. As such, this study can be a useful addition to the literature. I would like to address various points for revision, to improve the quality of the manuscript.

We would like to thank the reviewer for the encouraging comments; this was in fact the main aim of our study. We hope the reviewer will now appreciate that all his sensible comments and recommendations have been addressed very carefully, thus helping to improve the overall quality of the manuscript and making it a more robust paper.

**Major Compulsory Revisions**

**Methodological:**
- I understand the choice of healthy volunteers in this type of study, but I have my doubts about the selection of ten young female participants only. Why were men not included? Why were only young people included? What is the rationale for including ten patients? The current participant selection is a major limitation with regard to generalizability of the findings. Authors acknowledge this a bit, using it to explain a lack of findings in lines 326-7. To me, this actually shows the current results should be questioned with regard to the translation to patients; I don’t know if the same results will be found in patients who actually use FOS. The study would greatly improve when healthy participants more similar to people using FOS are included as well (i.e. older people with some comorbidities), or (even better) when participants are included who have been using a FOS in the past. Such a group of participants would need to be added before the results warrant publication.

This is a very sensible comment, and the authors acknowledge it is a limitation. While 10 is a typical size for samples in gait analysis, the reviewer is certainly aware that the limited size is somehow dictated by the extensive nature of the data acquired for this type of experiments which required the simultaneous acquisition of synchronized force data (via 2 Kistler force plates), kinematic data (via 8 cameras for motion capture) and pedobarographic data via 2 pressure insoles. This is why such comprehensive evaluation of orthopaedic footwear was hardly conducted prior to this study.

In this study we preferred female participants because most of our relevant clinical population is female. These participants are somewhat younger than the typical patients, but it is reasonable to hypothesize very similar walking patterns in a very large spectrum of age for adults. By choosing a consistent cohort of healthy participants the authors aimed to reduce the amount of possible confounding factors due to the patients’ different clinical histories and biomechanical effects of the foot surgeries. It is worth mentioning that the preliminary results on patients undergoing hallux-valgus surgery are supporting these hypotheses. But the reviewer is very right; from the present results in this population we should not draw generalized conclusions on elderly. This is now made very clear in the manuscript.

- From the method section, it is not clear to me what a measurement consisted of. Authors describe that three steps from each subject in each shoe configuration were analysed for pedobarographic measurements.
In a single measurement trial, simultaneous acquisition of insole pressure data and gait analysis parameters was performed. Our laboratory settings allows about five full gait cycles to be acquired in a single walking trial (from start to stop) for each leg. However, because of the location of the force plates within the acquisition volume of the motion capture system, only the central cycle allows simultaneous acquisition of ground reaction forces and lower limb kinematics along with insole-pressure data. Three trials (for a total of about 15 gait cycles) were acquired for each participant, and the central 3 gait cycles, comprising of pressure, force and kinematic data, were recorded and used in the analysis. Walking speed was calculated from the gait analysis measurements by tracking the position of the rearfoot marker. Three repetitions are often used to analyse gait data. We have also found this data to be very consistent intra-subject in the present study. All this has now been made clearer in the revised Methods section.

Results:
- In the method section, both FOS are described as “two post-operative FOS” (line 141). In the results, only the full outsole FOS is described as FOS, whereas the other FOS is called “half-shoe” (Figure 1). This is confusing. The naming of the two devices should be critically looked at, and renamed consistently throughout the manuscript. Either both should be called FOS, or none.

The reviewer is right, that acronym and its use was unfortunate and misleading. ‘FOS’ has now been removed throughout the manuscript unless used to address both forefoot offloading shoe designs. The comparison is now between ‘half-shoe’ and ‘full-outsole shoe’.

- The results are rather lengthy, and continually describe differences: lower or higher, in rear-, mid- or forefoot, in three devices. As a reader, at some point I’m left guessing what the results mean. The figures and tables tell a great deal about the story, please rewrite the text of the results to guide the reader through the most important parts of the results. If the current version would be published, I’m afraid many readers will stop halfway through the results (with all other literature available as well) and the message of the paper will be lost.

We totally agree with the reviewer. In our original submission, the Results section was rather lengthy and unfocussed.

In order to address this reviewer’s very sensible comment, the pedobarographic section of the Results has been almost fully reformatted. Sub-headings have been added to help readers to find relevant information more quickly according to the pedobarographic variable. Moreover, a graphical representation of the statistical differences in the main pedobarographic variables (maximum force, peak pressure, and pressure-time integral) between shoes has been added to replace Figure 2 (now moved to the supplementary materials). Subheadings have been added also to the kinematic section of the Results to help the reader finding the relevant results more quickly.

Minor Essential Revisions:
- The English can be improved
This has been addressed with a thorough editing revision.

- No conflict of interest is stated, and no company is acknowledged. Were the three shoes provided by the company free of charge? If so, this should be stated.

  Yes, the shoes were provided by the company free of charge - this has now been added in the Acknowledgment section. However there was no direct involvement of the company in relation to the content of the study presented in this paper.

- In the abstract as well as the introduction, it is stated that comfort is an issue. However, comfort is not measured anywhere. Either remove this from abstract and introduction, or assess perceived comfort when more participants will be included.

  Comfort is of course an issue in the overall assessment of shoes. However, this was not addressed in the present population of healthy subjects, where the major interest was in objective measurements rather than in subjective impressions. The latter is also pretty obvious, the awkward design makes the half-shoe clearly less comfortable than any standard full-outsole shoe. Since comfort was not scored in this study, we have decided to address the reviewer’s request by removing “comfort” from the Abstract. The term “comfort” has also been limited in the Introduction, though we did not remove it completely when it was explicitly part of the relevant cited paper.
Reviewer #3:
I commend the authors on this paper which aimed to compare the effects on lower limb joint kinematics and kinetics of a full-outsole forefoot offloading shoe (FOS) with a traditional half-shoe, while a normal comfortable shoe was used as a control. I believe the authors are attempting to add to the body of evidence with respect to kinematic data in the presence of a lot of emphasis placed on plantar pressures in the literature. I believe the methods section can be further justified and needs to have some more clarity surrounding a few points I have raised below. The data seems to be sound, however more clear explanations of what was compared to what needs to be made within context of the below comments and their limitations. The figures supplement the work and to my knowledge, the standards of reporting have been consistent with requirements. I believe there are several grammatical errors within the paper however, which warrants review by an editor. The conclusions and discussion can be further supported by elaborating on the methodological limitations and additional factors of relevance in the study which have not been clearly justified as it currently stands.

The authors are grateful for the sensible review and have considered the comments and recommendations very carefully as a chance to improve the overall quality of the paper. The study aimed at a comprehensive biomechanical assessment, via gait analysis and pedobarography, of two common types of forefoot-offloading- shoes. In particular, measurements were taken to assess the shoes capability a) to effectively offload the forefoot, and b) to maintain a normal gait, the latter being very limitedly reported in the literature. The techniques and their justifications, the conclusions, and also the limitations should have now been expressed more clearly.

Major Compulsory revisions;
1. The authors state in the introduction that ‘In order for the results not to be affected by different clinical histories and treatments, the study was conducted on a population of healthy participants.’ I think the authors need to make a clearer justification of what this study adds to the literature and why studying a healthy female cohort is likely to assist in understanding how FOS work? This is especially important as the authors make several references in the discussion to the implications of the footwear in elderly people. Although the shoe might work effectively in healthy ‘female’ controls it could be argued that differences in kinematics and kinetics which occur due to pathology and in the case of surgery which occur post-surgery would affect these parameters. How can the current study be rationalised within the context of why the shoes are used for in the first place?

This point is relevant, and should in fact be discussed more carefully in the manuscript. The present interest was initially focussed on healthy participants as to isolate the biomechanical effects of the shoes on lower limb kinematics and kinetics. A pathological population may introduce confounding factors which would increase data variability and make more difficult the interpretation of the results. Moreover we chose female participants as these represent the majority of the patients undergoing forefoot surgery in our Institute. This should provide useful gender-matching functional data for future comparisons. Also, younger volunteers are easier to recruit and less critical in relation to ethical approval. Finally, it can be speculated that the alterations to the gait patterns can be even larger in the elderly, the present therefore being an underestimation of these critical effects. It is worth mentioning that our preliminary data on a pathological group are quite consistent with those reported here in the healthy group. However, we do agree that speculations on the translation of these results to patients may be questionable. This issue is now justified and discussed largely and more carefully.
2.1 Secondly, my opinion is that a more clear explanation of the control used needs to be made. I.e. I understand that the authors used an interventional shoe on one limb and a control shoe on the contralateral limb. However, I am not quite sure what was being compared to what. I.e. were comparisons made between left and right? If not why not? This needs to be made somewhat clearer.

We regret the explanation of the testing conditions did not result in a clear picture of what exactly was performed and the relevant scopes. This may also be due to an incongruence found in the description of the three footwear conditions between Abstract and Methods sections. This has now been amended.

The participants were required to wear always the control shoe on the LEFT side, and one of the three shoe designs on the RIGHT side: half-shoe, full-outsole shoe, and control. The comparisons shown in the text are between the three shoes worn on the RIGHT side (ipsilateral). This has been thought to be the best way to guarantee the same biomechanical conditions on the contralateral side for all three tested shoes. The control therefore was the kinematic and pedobarographic data recorded on the right side when the subject was wearing the control shoe on both sides.

The paragraphs titled “Contralateral limb” are showing the comparisons in kinematics and pedobarography between control shoes worn on the LEFT side (contralateral limb). This comparison helps to assess possible compensations affecting the contralateral side while wearing the two FOS on the right side.

2.2 Can the authors also specify the corrected alpha value to determine significance within the text? I think this would give the reader an idea of what the new p-value is for comparison as opposed to p<0.05. The corrected alpha value used in Bonferroni correction along with its limitations also needs to be stated and clarified to give context of significant differences in outcomes between comparisons here.

The reviewer is right and the whole statistical approach has now been extensively revised also following comments from Reviewer#1. Since the kinematic and pedobarographic data were paired, the Friedman’s test was surely more appropriate than the Kruskal-Wallis. We have decided to limit the Type II error rate and, in the post-hoc test we have opted not to apply a Bonferroni correction to account for multiple comparisons. In fact, more than 10 samples would have been required to achieve at least 80% statistical power for some of the variables investigated. If required, a sentence may be added to the Discussion as a further limitation of the study.

See also “General reply to all reviewers”.

3. Lastly, as the primary aim of this study is to add to the literature regarding kinematic parameters concerning the use of FOS, some justification of the marker placement issues at the foot needs to be given within the context of this being a major limitation of this study. So can the authors clarify how the reflective markers on the foot were placed during gait while wearing the shoe in the methods section? Perhaps some elaboration is needed here in regards to methods. I can see that some reference to it is made in the discussion but a small deviation in the lateral malleolus marker can have a profound impact on the kinematic chain and I believe warrants some elaboration. The same applies to the foot markers.
This is in fact another important point of the methods. The text now has been revised as follow: “...reflective markers [were] positioned on relevant lower limb anatomical landmarks according to the IORgait marker set [19, 20]” the citations addressing fully all requests for further details.

The issue of the interference of the markers with the shoes was largely addressed in a dedicated paragraph on limitations in Discussion. Nevertheless, more details and a deeper discussion is now provided in the same section. It is worth reporting here that because of the extensive experience of the authors with this gait analysis model, its definition and underlying algorithms, the solution identified to address this problem was towards the minimization of bias from measurement artifacts. As first precaution, the same relative location of the markers on the malleoli was maintained in all shoes. Secondly, because of the joint coordinate system convention (Grood&Suntay, 1983) adopted for the calculation of the joint rotations, a small translation of the markers on the distal shank would affect the anatomical reference frames for the shank and foot segments very limitedly.

Minor essential revisions;
4. Abstract line 53; should read ‘treatment.’
5. Results section line 70; should be ‘at the rearfoot’
6. Line 71; should read ‘highest’
7. Line 85; should read ‘lesser toe’ rather than ‘toes’
8. Line 96; not sure what ‘appropriate and ‘inappropriate use’ is, please define and make more clear

We would like to thank the reviewer for the suggested corrections. All these points have now been addressed in the text.

9. Line 110-112; the authors propose that the ‘FOS should work by having minimum kinematic and kinetic alterations which may cause discomfort while walking’ I would like some clarity about what the authors mean here, i.e. how do they propose the shoe works to reduce forefoot plantar pressure in this case for example without altering these characteristics?

In this study, the authors did not mean to offer ultimate solutions to forefoot offloading. Ideally, however, the authors believe FOS should perform their expected offloading actions but together with minimal alteration of gait, which may result in more energy expensive gait and take stability at risk. In this study, one of current FOS using a talus insole along with a full-outsole rocker shoe, is tested versus a traditional half-shoe. The authors believe that it is interesting to show whether acceptable offloading can be achieved also via novel FOS designs which would guarantee less kinematic alterations.

10. Line 125; should read as ‘a control.’

Ok.

11. Methods section; Can the authors justify why walking speed wasn’t controlled as a pathological condition was not being studied in this study? It could be argued that a more comfortable shoe vs. a less comfortable shoe is likely to alter Temporo-spatial parameters, although in the current study this does not seem to be the case. I think some clarity and justification about why walking speed wasn’t controlled might be useful in detailing the methods.
The walking speed was indeed measured – if this is what the reviewer meant with the term ‘controlled’ – and also reported in the Results. Walking speed could not be imposed on the participants, as this could have affected their natural walking patterns, and forced different and uncomfortable compensation mechanisms. Moreover, it is generally more important to measure the self-selected walking speed as it is known as the single spatio-temporal parameter that provides the most critical information on the major gait characteristics.

In our original submission it was reported that no difference was detected in walking speed between the three shoe groups. Because of the extensive revision of the statistical analysis, Friedman’s test has now been used to determine possible differences in the spatio-temporal, kinematic and pedobarographic parameters between these three groups. This has resulted in some modifications to the statistical outcome with respect to the original submission. It is now shown that half-shoe had the lowest walking speed and the shortest stride length. This has now been corrected in the present revised Results. Please refers to comment #1 for the rationale of using a healthy female population in this study.

12. Line 192; should read ‘Man-Whitney U test’

Ok, corrected.

13. Lines 208 and 214; should read to ‘the control’

Corrected.

14. Line 227; I understand the only significant pressure variable on the contralateral limb was an elevated PTI on the contralateral foot when using the half-shoe. Can the authors elaborate on the implications of this for patients for example?

Since these shoes are worn for a limited time (normally a maximum of 1 month in the post-op), we do not expect any major effect on the contralateral side of patients due to the increased PTI. This could only be somehow detrimental in case of pathologies also on the contralateral side.

15. Results section, kinetic data; I understand the authors state that they investigated kinetics of the lower limb. However, I do not see any reference to measure ground reaction force for example. Can authors clarify whether this data was measured and why it was not reported?

We apologise if this was not made clear in the original submission. Ground reaction forces were indeed measured by 2 Kistler force plates (see 2.4 in Methods). The relevant outcome from the force plate measurements have now been added into the first paragraph of the Results.

16. Line 265 should read ‘distal’ or ‘plantar’ depending on what the meaning the authors intend is an not anterior as anterior refers to the dorsal surface in this instance.

17. Line 283 should read ‘joint’ not ‘joints’

18. Line 291; should read ‘helped in shifting’

19. Line 292; should read ‘at the forefoot’

20. Line 295; should read ‘than the control’
All these sensible suggestions have been addressed carefully, and relevant adjustments to the manuscript introduced.

Discretionary Revisions;

21. In the discussion the authors make reference to the difference of height in the intervention shoe compared to the control shoe. I wonder whether any measurements concerning inherent limb length was performed to see whether the participant’s had any differences in limb length which was likely to influence results.

All participants were active, asymptomatic and perfectly healthy. While some small leg-length discrepancy is usually considered to be normal (within 20 mm), the authors do not believe this parameter has affected the present results. An estimation of the limb length could have been provided by a careful analysis of the position of the markers used in the kinematic analysis, but this can be considerably affected by other errors, such as marker misplacement etc.