Author’s response to reviews

Title: Medical Grade Footwear: The impact of fit and comfort

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Author’s response to reviews:

Reviewer reports

Reviewer 1:

A clear opening to the abstract - minor amendment is in the results 'their' not 'the' perceived comfort Please also change the line about the medial border of the 1st metatarsal being statistically 'different' to 'higher or lower (p<0.05)'

We have now addressed this issue and have modified the text to reflect the comments.

P4

In the introduction, please change 'The forefoot has been highlighted as the most frequent area of pain related to footwear [1]. Forefoot pain is commonly associated with wearing ill-fitting footwear [2,3]; causing pressure over bony prominences on the dorsum of the lesser toes, the medial aspect of the first metatarsal head or the lateral aspect of the fifth metatarsal' to:

'The forefoot has been highlighted as the most frequent area of pain related to footwear [1] and is commonly associated with wearing ill-fitting footwear [2,3] with associated pressure over bony prominences on the dorsum of the lesser toes, the medial aspect of the first metatarsal head or the lateral aspect of the fifth metatarsal.'
We appreciate your comment. In our opinion the original sentence reads better than the suggested changes. If the editor/copy editor feel that the text should be amended, we will revisit this again.

Line 9 seems to relate to shoe length with assumption that footwear has led to lesser toe deformities - Coughlin's 1984 article postulates the reason for deformity and Menz' et al.'s footwear characteristics study describe common findings and is not a prospective study of the development of lesser toe deformities. Neither should really be used as a citation to imply without doubt that this is the way toes deform - be a little more speculative.

The wording related to the citations and outcomes of that work has been altered to suggest an association between footwear volume and toe deformities.

By contrast you are citing an experimental study in the line about shod feet being stiffer and downgrade this to 'shod feet are thought to be' when actually you could upgrade this by critiquing the study and noting the findings - how was stiffness measured, was it a large study etc.

We have had an opportunity to look at this comment. Given the nature of this manuscript and the associated limits, we have provided a succinct review of papers that we have cited rather than providing a detailed description.

Line 25 in the introduction needs to be reworded with some explanation of the 'recent studies' cited and avoid the word 'cramping' unless you mean muscle cramp rather than confinement of the toes in a small space.

Thank you, it is clear that to the journal audience cramping could be perceived as something different therefore this has now been changed to constriction.

Line 32 - avoid the use of 'it is thought' and 'transverse metatarsal arch' when referring to the spread of the distal parts of metatarsals (the transverse arch is at the proximal end). Instead cite the reasons that one might think this eg study findings.

These were the study findings and wordings used by the authors; therefore the text has not been altered.
Metatarsal splay is better described as horizontal splay not coronal splay when the foot is plantigrade.

This has now been altered

This line is supposition - Poorly fitting footwear compresses the digits and alters function, eventually leading to structural changes - please be less 'sure'! Try and postulate in the absence of prospective study or where cause and effect has been demonstrated in controlled trials.

Line 36 again is too black and white - try and add nuance eg: This subsequently subjects the toes to increased pressure from the upper of the shoe and, in some people, could lead to tissue breakdown/ulceration.

The context of the cited work has been altered to provide an open interpretation of the literature.

Line 36: ill-fitting footwear 'is' not 'are'

Alterations made here

Line 40 This is the real 'so what' line - the impact of why your study has value building on the findings of previous studies investigating the effects of footwear on foot ulceration rates. Rather than saying footwear is a 'major' cause of anything, be more specific. Please add more detail here eg a large, randomised controlled trial (or whatever is relevant here!) showed an x reduction in re-ulceration rates. Make your point with more analysis and you'll have a springboard for your study.

The details and references have been altered here to reflect the previous literature.

The same is needed in the penultimate line of the introduction - you are citing percentages which are not very meaningful until you cite the numbers in a study - if the study of robberies in a quiet street reported a 100% increase in a decade it would sound alarming until you realise that there was only 1 robbery last decade and 2 this. If you are citing percentages from studies add the numbers in brackets eg 25% (10 out of 40) to ensure the percentage is interpreted correctly.

Details on specific papers have been expanded.

Line 55: recommended by NICE not just recommended (as opposed to a Trust or charity etc - NICE is the gold standard so tell the reader who recommends it) Again, you are losing the significance of your argument saying 'studies suggest' in line 55. Which studies, how big, which patient group, what did the studies look at?

This has now been reworded

Overall, you need to add more critical depth to your literature review.
Although it is accepted that the introduction needs to be critical in its review of previous literature the purpose in an original article, in line with the journal specifications, is to justify and introduce the area of research being investigated in the manuscript. We have expanded on details of previous literature cited to give a broader view of the work in light of the comments made.

P5

Methods:

Line 21: add spaces between the = signs

This has been altered

Did you do a power calculation? If so please it here or add a reason why n=30 was your chosen sample size

In line with previous studies that have utilised pre and post intervention effect testing the sample of 30 subjects was achieved. This type of data outcome and method design presents a number of difficulties in calculating sample sizing. To derive compare means statistical testing avoiding errors a minimum of 20 data sets are required therefore it was felt that the achieved recruitment of 30 was sufficient to test for differences.

Line 24: NHS or private?

Line 25: which university ethics committee?

General note: the font is changing throughout - this should be uniform across the document Line 30: change pathologies to deformities Line 53: change pathologies to deformities

This has been revised and questions answered in the text

P6

More detail on the condition of the participants' own footwear would be useful to help compare the data eg age / condition, size, heel heights etc #

This is a valid point and although it was deemed as relevant also by the group it was difficult to tabulate the details of all shoes as there was such variability between the participants for the own
shoe condition. However the main aim of the study was to assess the impact of altering this shoe to the MGF shoe and therefore statistical analysis looked only at changes between conditions and not within the condition. Expansion on this in the text has been added.

Line 57: validated against what? Please add more in the literature review about how pressure is measured and how this system was validated rather than discussing the validity of a tool in the methodology

Depending on the style of the journal and restrictions for article type it is not always possible to complete full critique of previous work. All methods included are referenced with relevant validity work to support the use of the systems.

P7

Line 22: (IBM SPSS, Version 24, USA)

Please add what alpha was set at

This has been added

P8

Comfort scale values need absolutes - values of change eg 3 points on the VAS.

Line 17: name the statistical tests

This has been added

P9:

Line 28: add cycle after gait

This has been added

References need to be tidied and standardised - there are changes in font and odd parentheses by author initials

Reference are now in line with the journal style
Reviewer 2:

The paper describes an experimental study which quantifies inter-digital pressures walking in participants in own footwear and an alternative medical grade shoe. The paper is of interest to those who utilise medical grade footwear to reduce risk in patients, but some methodological choices in the paper should be clarified prior to publication and the results could be presented more clearly to the reader. The addition of pressure time integral may be of value to really fully address your research question.

Title:

Medical grade footwear: the importance of fit and comfort

Importance implies there are other aspects (aside from fit and comfort) measures undertaken within this research study and that these are identified as the most important within this work. Fit is also a very broad term when you are specifically talking about inter-digital pressures. I would consider reworking the title.

Thank you for your comment which highlights a very valid point. We have considered the implications of what the title means and how it could be mis-interpreted. “Importance” in this sense, is meant to imply significance therefore we have altered this to impact as this reflects the content of the study more accurately.

Introduction:

Introduction paragraph two could address comfort more so than the current emphasis on ulceration is reduced:

1. Participants in the study are not diabetic and ulceration is not necessarily a pronounced risk for the population

Although this is correct, the ultimate end result of wearing footwear that is too tight a fit at the forefoot is that tissue breaks down, whether you are at risk or not. Diabetic patients take a priority on risk assessment as the implication of ulceration can be devastating. The population studied in this research were a clinical population who regularly seek out intervention for foot pain, deformity and regular podiatry care. Therefore it is relevant to cover all aspects of complications of wearing footwear that is ill fitting as it can affect anyone. Similarly, the DR comfort range of footwear are marketed as a suitable alternative to the high street shoe for people who have painful feet related to corns and ulcerations.
2. The title of the research looks at comfort, research relating specific footwear features such as toe box comfort to shape/fit exists and may be relevant to include here. You reference your previous paper later, but more explicitly discussing this may be of value to the reader.

An additional comment has been added about forefoot shaping and pressure distribution.

Methodology:

Height of 5.4 metres for participants? Please convert to metres.

Thank you and this oversight has been addressed.

Footwear conditions:

The participants own shoe is the control: these need to be described broadly to justify their comparison to the medical grade footwear. The heel size, the upper material, the footwear style for each participant listed, even this is a descriptive sentence e.g. XX participants wore leather brogues, XX synthetic trainers.

Similarly, please describe the differences between the M and F Dr Comfort shoes.

Additional descriptions have been added to the text.

Also was the width fitting selected specifically to each individual?

Yes, the Dr comfort footwear was fitted to each participant ensuring the width fitting was appropriate for the Brannock measurements taken.

If the participants own shoe was not assessed for fit, how can you argue that participants were not just wearing the wrong sized footwear and that these would alter the inter-digital pressures (particularly in width, which does not have choice for many footwear brands) rather than being able to be specific that the MGF is causal?

It is very possible that the participants were wearing the wrong sized fit width and length in their personal selection of footwear. The reason for not standardising or measuring this was to create a true life scenario that demonstrated that own choice high street footwear that is worn day to day create more pressure than the Dr comfort M-GF. An additional comment relating to this has been added to the discussion.

Questionnaire:
Were all anchors asked from the scale? For example was medial-lateral control asked? Or were relevant ones chosen to the footwear styles you assessed. Please describe exactly how many VAS were completed in this section. It is alluded to with the total in the results, but would be clearer here. 

Was a baseline used as defined by Mundermann et al? This is not described. If not used then it should become a limitation of your work despite the randomisation.

The questionnaire was based on the work completed by Mundermann as referenced in the method. The wording for each VAS 150mm scale was modified to adopt features related to footwear comfort. This questionnaire has been used in our other work on footwear comfort [Branthwaite H, Chockalingam N, Greenhalgh A, Chatzistergos P. The impact of different footwear characteristics, of a ballet flat pump, on centre of pressure progression and perceived comfort. Foot(Edin) 2014;24(3):116-122.] To explain the detail further descriptions has been added to the method.

Statistical approach:

For comfort the non-parametric alternative to ANOVA was used (Kruskal-Wallis according to your results) please correct the methodology (where it states Wilcoxon) and state this is due to the data being non-parametric.

This has been addressed.

It appears that different statistical tests were used for different variables then presented together? e.g. that peak pressure may have been normally distributed in sensor 1 and not in sensor 2 and therefore paired samples t-test and Wilcoxon signed rank test were used respectively?

This is not denoted in the results and is a non-standard approach. The authors should consider transforming the data which is not normally distributed then running parametric stats on all-variables. Or running non-parametric tests on all data and stating the limitations of this for the reader to interpret.

The results table is not consistent, and not denoting the different statistical tests used is unclear.

We feel that is inappropriate to transform pressure data and have analysed the data in relation to the distribution and relevant statistical test. This has been completed in previous work and in our
opinion, this is the right approach and has been accepted as a valid approach to analysing data through the peer review process of our previous papers.

Results:

The authors should consider the justification for contact time, mean peak pressure and time to peak pressure as relevant variables to comfort and fit. Why has pressure-time integral been excluded particularly due to its relevance in ulceration and comfort literature?

We appreciate your comment. PTI is an important parameter and we are exploring ways of presenting this data in a non-linear fashion which is beyond the scope of the current manuscript. Given the clinical nature of this paper we would like to focus on the clinically relevant and simple parameters. To be specific, the PTI data has been held for future work that we are developing within our group. The results presented are still relevant to the context of this manuscript.

The numbers included in the parentheses in the results are unclear, e.g. sensor 6 (12.94, 24.07% increase). Does this mean a 12.94 kPa (24.07%) increase? Please clarify.

This has now been clarified

Are the bars on the figures standard deviations? If so this needs to be identified. Also, they are very large, and suggest that maybe mean and SD are not the most appropriate presentation of this data. This is supported by the non-parametric distribution of the data: the mean is not an appropriate presentation of the central tendency of the data set, please see notes above relating to your statistical approach.

As the reviewer would appreciate the pressure data has a large amount of variability between subjects. Our study is not different to all previous studies reporting this sort of data. Our results indicate the sort of variability which one would expect in reporting individual peak pressure values. This has been acknowledged in the discussion and highlighted as a limitation.

Referring to the data: “just missed” and “beginning to show” statistical significance is not appropriate terminology. Please amend.

This has now been altered.
To aid interpretation and coherence of your data please add further detail to all figures and tables captions to describe content fully, make number of decimal places consistent and consider the resolution and units of the measures/scales when presenting data.

The captions have been expanded and the presentation of data reviewed.

Discussion:

In your discussion relating to comfort perception being subjective it would be relevant for you to acknowledge the source of your participants as recruited from a podiatry clinic. It alludes them prioritising or at least thinking about their foot health more than others may. Therefore maybe prioritising comfort over appearance of shoes.

This has now been added.

Familiarisation periods are particularly important, particularly as one of the conditions is the participants own footwear. This could be emphasised in the limitations with relevant ref

This has already been referred to as a limitation.