Author's response to reviews

Title: Development and evaluation of a tool for the clinical assessment of footwear characteristics

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Author's response to reviews: see over
Development and evaluation of a tool for the assessment of footwear characteristics

Author response: 16th March 2009

Dear Editor

We would like to thank both Anita Williams and Tom McPoil for their review, critical appraisal and helpful suggestions related to this manuscript. We believe that addressing the feedback and suggestions they have provided the manuscript is now stronger for it. We hope we have addressed all issues raised to a satisfactory level and look forward to any further feedback/suggestions as part of the ‘Journal of Foot and Ankle Research’ editorial review process related to this manuscript.

Kind regards

Christian Barton, Daniel Bonanno and A/Prof Hylton Menz
Reviewer's report

Title: Development and evaluation of a tool for the clinical assessment of footwear characteristics

Version: 1 Date: 24 February 2009

Reviewer: Anita Williams

Reviewer's report:

Thank you for asking me to review this very interesting and detailed paper that deals with an important and timely issue. The standard of writing is, overall, acceptable but would benefit from several minor amendments to structure and some aspects of the wording in order to achieve clarity for the reader. These are as follows:

This is a very long paper – I wonder if this is in line with the recommended length for this journal?

Response: As JFAR is an online journal, there are no length restrictions. We believe that the current content of the manuscript is necessary to adequately explain the individual components of the assessment tool.

The title states a '...tool for clinical assessment' There appears to be more work needed in the development of this tool before it will be suitable for clinical assessment (see comments later) therefore I suggest that the word clinical is removed from the title

Response: This is a valid point and therefore the word ‘clinical’ has been removed.

Abstract- Background line 2 – replace the word multiple by many as the use of multiple in the context of the sentence implies that it is the individual that has numerous MSK conditions

Response: This has been completed.

Background – second paragraph move the last sentence ‘If choosing to implement…[17]’ to follow on from the sentence concluding with ‘…should be addressed first’

Response: This has been completed.

The last two sentences in the background are more ‘method’ and ‘result’ respectively. The background should end with the aim.

Response: These sentences have been moved to the first paragraph of the ‘Methods’ section.
Method – first paragraph – to reduce some of the words, after the first sentence add in brackets (see Additional Material File), remove the next sentence. After ‘An explanation of each (add of the six) items and (replace its with the) justification for inclusion is (now) outlined (add and measurement techniques described [see Additional Material file])

**Response:** Sentence modifications have been made as requested. However, the description of measurement techniques have been left in the body of the manuscript (i.e. not transferred to the Additional material file) as we believe the main this is necessary content to allow the manuscript to be a stand-alone document without the necessity of accessing the Additional material file.

Method - Sub headings add item number i.e Item 1 Fit

**Response:** Each item has been numbered as suggested.

Subheading under Fit rename Length, width and depth – saves repeating fit of Shoe

**Response:** Each item has been numbered as suggested.

Need a heading for Method and then Data collection procedure and statistical analysis become sub headings

**Response:** The authors feel this change is not necessary as there is already a level one ‘Methods’ heading at the beginning of the ‘Methods’ section.

Discussion
Line 6 replace ‘…able to be applied’ with applicable

**Response:** This has been changed as suggested.

The content is good and fairly well reasoned though there are some revisions that I recommend to ensure consistency of thought and clarity as to the purpose of the study.

Abstract- method – perhaps list the 6 items

**Response:** The six items have been listed as suggested.

Abstract and main body - You state that the aim of this study is to ‘develop …….. for use in a range of populations’. The outcome of the study is that you have developed a way of assessing footwear but that you now need to evaluate its use in a number of different populations. Perhaps say ‘potentially suitable for use in a range of populations’.

**Response:** Aim modified as requested in the ‘Abstract,’ final sentence of the ‘Background’ section, and line 6 of the ‘Discussion’ section.

Abstract and generally – need to be clear as to the difference between a scale and a tool. A scale implies some sort of ranking or score that results in a
meaning (particularly for clinicians)

**Response:** Throughout the manuscript all references to scale have been changed to tool with the exception of the ‘motion control properties sub-scale’ which is now termed the ‘motion control properties scale.’

In the abstract and main body (method) you mention clinical considerations/clinical experience – what was this and how did it influence the items?

**Response:** Qualifications and clinical experience of each of the researchers involved in the tool’s development are now outlined in the first paragraph of the methods section. The influence of considerations/clinical experience is already provided in the explanation of each included item (e.g. Why weight/length ratio is important).

**Method**
Under theme 2 General features – age of shoe, have you considered the difference between the age of the shoe and levels of usage ie a patient might have one pair that is 6 months old and worn for the majority of the day whereas another may have several pairs of shoes with which they alternate. Additionally ‘occupation’ may have an impact on wear i.e an office worker sat down all day compared to a shop worker who may be actively walking all day.

**Response:** These are important considerations. The following sentence has been added: ‘The therapist may consider this information in relation to other subjective examination information such as occupation or intended purpose of the footwear, and also frequency of wear.’ It is expected that clinicians using the footwear assessment tool will seek this information without the need for the inclusion of items in the tool relating to it.

Materials – have you considered linings? Some footwear may be leather but lined in synthetic material

**Response:** Prior to the tool’s development a number (i.e. around 15 – 20) of different types of footwear was looked at to assist item development and this combination was not identified. Although this is a valid suggestion, unfortunately with the study completed, changing this item without reliability evaluation is not possible.

Weight/length ratio – evidence to support this ‘sub item’ as a factor influencing gait efficiency or is this one of the observations from clinical experience – please clarify.

**Response:** An addition to this sentence to clarify this as on the clinical experience observations has been made.

Normalised Longitudinal profile is also known as shoe ‘pitch’ and this is a term commonly used in clinical practice by orthotists and footwear technicians – consider its use in this paper.
**Response:** The term ‘pitch’ has been added in brackets following this item’s title.

Rule of thumb uses the owners thumb – what if the patient cant bend down to reach the feet in order to carry this out?

**Response:** The palpation method uses the therapist’s thump (not the patient’s). This has been clarified in the text by adding the word ‘therapist’ before “palpation was used to categorise footwear.”

With regards the fixation of the upper to the sole- can you explain the 3 terms in relation to this as clinicians may not understand this.

**Response:** These terms have been described in the ‘Methods’ section.

I am not clear about the scoring system and its meaning for the subscale for motion control properties and particularly its meaning in clinical practice. Ie what does a score of 8 mean? This needs an explanation within the text.

**Response:** Sentences have been added to the Methods section stating the proposed meaning of higher and lower scores (i.e. theoretical changes in footwear motion control). As has already been outlined in the Discussion section the clinical validity of this scale and each component within it is yet to be determined and requires further research to do so – “However, despite good face validity, the scale and each item lack good quality research to support their clinical validity. Firstly, current motion control property items included in the scale are based on general consensus within the literature. Secondly, categories for subjective measures of heel counter stiffness, midfoot sole sagittal stability and midfoot sole torsional stability items are based on arbitrary ranges (i.e. 0 – 10º, 10 – 45º, and > 45º). Therefore, further research is needed to evaluate injury risk and treatment of various patient populations with footwear containing various characteristics from within the scale. This will allow the clinical validity of each item and the scale to be evaluated and modified if appropriate.”

I am not sure that clinicians will have access to penetrometers so what are you recommending for evaluation of sole hardness?

**Response:** For clinicians and/or researchers who do not have access to penetrometers it is recommended they use the palpation method which also had strong reliability results. The following sentence has been added at the end of the discussion section for Item 5: “Until this is achieved, clinicians and researchers that do not have access to a penotrometer may use subjective evaluation of cushioning properties with confidence that it is a reliable alternative.”

Discussion – first paragraph last sentence – you state that consideration has
been made on validity but I am not clear how this has been done (perhaps some recommendation for further work would be for clinicians in practice to use it and comment on its usefulness but in its entirety and for the specific items and sub items).

**Response:** Considerations for validity are made throughout the discussion. The wording of this sentence has been changed to clarify this: “Each item within the tool was evaluated for reliability, and this along side consideration of validity for further use clinically and in research will now be discussed.”

The following sentence was added in the conclusion to recommend some more qualitative research on the current tool: “Qualitative evaluation of the tool and each of its components during its application by a range of clinicians in different patient populations may provide guidance for future improvements to the tool.”

Do you have any comment to make on the time it takes to complete the assessment? It may be too long for a clinician to carry out?

**Response:** The following sentence has been added to the first paragraph of the discussion: “The tool when completed in its entirety takes around 10 minutes, although this time is shortened with experience or by omitting components the researcher or therapist may believe are irrelevant to their patient(s).”

Can you provide more clarity as to whether toe palpation or the straw method should be included or should be excluded until validity is carried out?

**Response:** The following sentence has been added at the end of the discussion of Item 1: “Until further research is conducted on the clinical validity of both methods, the ‘palpation’ method is recommended due to its comparative reliability combined with superior efficiency.”

Not sure if last shape is to be removed before further work / validation or included until this has been done? Likewise with midfoot stability

**Response:** These items demonstrated low kappa – high agreement statistics as outlined in the results – in this circumstance the percentage agreement is more valid and hence these items should be considered to possess high reliability. Therefore, at this stage they should be retained.

Under motion control properties - Not sure what you mean by ‘Therefore it is recommended that the scale be applied to at least 15-20…………research setting’ – does this mean training for the user.

**Response:** This sentence was clumsy and has been removed. Based on our analysis I don’t think we can make a recommendation on the level of training required to use the tool.

Motion control properties subscale page 20 what do you mean by cut points? Should it just be arbitrary points?
Response: This has been changed to arbitrary ranges.

Need consistency for the item Cushioning – there seems to be the use of shock absorbing and cushioning

Response: All references to shock absorbing have been converted to cushioning which is a more global term.

Conclusion –
You conclude that there is high reliability for all categorical items, is this so as some of the sub category items such as mid foot stability and last shape were considered as having poor reliability. However, you do go on to mention this. Can you clarify this in the conclusion as it is slightly unclear. Do you intend to take these items out?

Response: Again, these items possess high percentage agreements (i.e. high agreement – low kappa paradox) so can be considered to possess high reliability.

Are you planning on carrying out the clinical significance of each item and weighting and if so how do you plan to do this?

Response: The scale is currently been used as part of a clinical prediction rule study but in depth discussion of processes required to do this are beyond the scope of this study. The following sentence has been included: “Achievement of this will require application of the tool to footwear of participants during clinical prediction rule studies aimed at establishing etiological factors of various conditions and possible factors related to successful treatment outcomes.” The purpose of getting the current tool published and out there is so that multiple research groups are aware of its existence and can use it to assist in the clinical validation of some or all components in future research.

Do you think carrying out say for instance focus group work or interviews with clinicians and researchers in this area may have informed the study further at the outset in the formation of the items and sub categories rather than initially basing it on two ‘clinicians’ clinical experience and the available literature?

Response: The tool has been developed as part of a larger clinical prediction rule study for the efficacy of foot orthoses in the treatment of PFPS. Although focus groups and interviews are an excellent idea and may have proved very valuable, this process was thought to be beyond the scope of the purpose of this study. The three researchers involved in the scale’s development also have a diversity of both research and clinical experience which was considered adequate for the purpose of this study. The possible use of qualitative research in further development of the tool has now been alluded to in the ‘conclusion.’

An issue may be the time it takes to complete the assessment – can you comment on this
Response: This has now been commented on in the first paragraph of the ‘discussion’ section.

General – I am not sure what the resultant score would mean for a clinician – what would define a good shoe? Is this a tool for recoding specific information on footwear or achieving a value score – can you clarify this throughout?

Response: The term ‘scale’ has been replaced by ‘tool’ throughout which should clarify that the tool is designed at this stage to assist assessment and documentation of footwear information as opposed to achieving a value score (with the exception of the motion control properties scale).

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.
Reviewer's report

Title: Development and evaluation of a tool for the clinical assessment of footwear characteristics

Version: 1 Date: 24 February 2009

Reviewer: Thomas McPoil

Reviewer's report:

General Comments:

The authors should be congratulated for their work in the development of a reliable clinical tool to evaluated footwear. The reviewer enjoyed reading the manuscript and believes it would be of great interest to the readership of the Journal.

Major Compulsory Revisions:

NONE

Minor Essential Revisions:

Since one of the purposes of the study was to develop an efficient as well as reliable footwear assessment scale, the authors should consider providing the reader with the average time required for each of the two raters to complete the assessment scale. The reviewer would guess that the time required to complete the assessment scale would decrease with practice. Did the authors find this to be the case?

Response: No formal evaluation of time to complete the scale was carried out. However, the following sentence has been added to the first paragraph of the discussion (second last sentence): “The tool when completed in its entirety takes around 10 minutes, although this time is shortened with experience or by omitting components the researcher or therapist may believe are irrelevant to their patient(s).”

2. Page 8, Line 22, the authors describe the measurement of forefoot height. Under the heading FOREFOOT HIEGHT, the authors have in parentheses “measured at point of first metatarsophalangeal joint.” This is also written in the same manner on the actual Footwear Assessment Scale form. In the text that follows, however, the authors state that the forefoot height measurement was taken at BOTH the level of the 1st and 5th MTP joints with the average of both recorded. While the reviewer agrees with the authors that the measure of forefoot height should consist of the average of the 1st & 5th MTP joint heights – the wording at the start of this Section as well as on the actual scale “measured at point of first metatarsophalangeal joint” is misleading. The reviewer recommends that the authors clarify that the measure of forefoot is the average of the 1st & 5th MTP joint heights in both the Section title of the manuscript as well as on the actual Scale.
Response: As suggested, this has been clarified and the average of the 1\textsuperscript{st} and 5\textsuperscript{th} in both the manuscript and the tool.

3. Page 11, Line 19, the authors state that the title of this Section of the paper which is describing the components of the Scale is “Shock absorption” but in their Discussion Section as well as on the actual Footwear Assessment Scale they refer to this Section of the scale as “Cushioning.” The reviewer believes that “cushioning” is a more appropriate and global term and would recommend changing all references to this component of the scale to “cushioning.”

Response: All references to shock absorbing have now been changed to ‘cushioning.’

4. The authors should provide manufacturer details for the “penetrometer” that they describe on Page 12, under the section “Lateral midsole hardness.”

Response: This has been included as suggested.

5. Page 13, under sections titled “Upper” and “Midsole,” it would be very helpful if the authors could provide a picture to provide an example of what they are describing as “upper” and “midsole” wear patterns. The reviewer believes this would be very helpful for the clinician and ensure consistency with the assessment.

Response: Unfortunately (as stated in the manuscript) we did not test footwear with abnormal wear patterns and were therefore unable to produce example photographs of the different wear patterns as was originally intended. This weakness has now been outlined at the end of the discussion section relating to Item 6: “Unfortunately, the lack of abnormal wear patterns prevented the addition of pictorial guidance for future research and clinical use of the tool. This is an addition to the tool that is recommended if it is applied in future research investigating the relationship between abnormal wear patterns and pathology.”

Discretionary Revisions:
NONE

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests: I declare that I have no competing interests.