Reviewer's report

Title: Pedobarography as a clinical tool in the management of diabetic feet in New Zealand: a feasibility study

Version: 0 Date: 13 Apr 2017

Reviewer: Peter Lazzarini

Reviewer's report:

Thank you for the opportunity to review this interesting feasibility study investigating the practical use of plantar pressure measurement of people with diabetes in clinical practice in New Zealand. I congratulate the authors on undertaking what I believe to be a study that has the potential to deliver a very nice and useful paper; however, there are a few areas of this current manuscript that need major revision before I believe it is ready for publication. I would encourage the authors not to be disheartened by my major revision comments as I think they have a potential paper that will be very worthwhile to the general diabetes clinical and research community if they invest some time considering a few improvements. My major comments can be summarised as:

- Background was a pretty nice summary but could be shortened

- Methods needs a lot more detail around procedures used and definitions of variables. There are many variables that pop up in results that weren't mentioned in methods.

- Discussion should focus on the first 3 questions/aims which seem to me to be the unique part of this study and are nearly omitted in the discussion for a focus on the last 2 questions/aims instead. To my knowledge the last 2 questions/aims have been reasonably well studied previously in other nations and with much more robust methodologies than in this study while the first 3 aims haven't.

- Limitations need expanding as only one is mentioned and there are many more in my opinion. There are limitation in all studies just be sure to list them and be upfront with the reader
I would recommend the authors have a read of this excellent paper on what should be included and defined in the methods of diabetic foot studies and particularly if the authors are intending to do follow up studies in this field to this one:


Once the editors feel these points have been satisfactorily addressed I would be very happy to re-review this paper for publication in JFAR. Again I commend the authors for undertaking what I think is a unique study in many ways, however, I think this still needs to be drawn out and methods improved. I look forward to the authors improved paper being published in JFAR in future. Please see specific major, minor and discretionary revision comments below:

Major Revisions

1. Background: Paragraph 6. I'm not sure the authors are accurate, and should consider dampening this statement: "When compared to all other available foot screening techniques (including sensitivity tests, vibration perception threshold tests and clinical examination), pedobarography has the highest degree of specificity (and a moderate degree of sensitivity) in identifying those at risk of developing a foot ulcer.[31]". I'd suggest referring to this systematic review:


2. Methods: Post-pedobarography discussion with participants. It would be very useful for the authors to identify if their survey was based on any other similar survey, was customised or if they used any set methodology to devise it. It is fine if its completely self-made, but this should be added to the limitations of the paper. Also the authors should mention the available answers
to these questions were just dichotomous (yes/no), and thus, Likert scales typically used in these surveys were not used in this study. This should be added to limitations as well.

3. Methods: I'm not sure I saw any mention of clinical characteristics being captured, in particular DPN, previous foot ulcer, amputation etc. However, foot ulcer, amputation etc is mentioned in results. Please outline in methods how these were captured and defined. Additionally if DPN, PAD and foot deformity were not captured this needs to be mentioned in limitations considering DPN is one of the main justifications for performing such a test and probably should be the target patient population. Also how was either inshoe or platform plantar pressure measurements chosen as in Results it appears both were not done on each patient and the reader is left asking "why not?"

4. Methods: The authors need to provide a definition for "single condition" and "multiple conditions" which are referred to in the results.

5. Results Paragraph 6: I would strongly recommend the authors analyse the sub-groups of those undergoing inshoe and platform or both in terms of time to perform. This would answer their 2nd research question much better and be of particular interest for the overall purpose of this paper, ie how long do these tests take in clinical practice. Also I think the authors should add their definition of "time taken to perform" from Table 2 and put it in their methods.

6. Results: Participant experience. I think it would be incredibly useful for the authors to summarise the main reasons for the participants who did not give a positive response to the various questions here rather than in Additional Material. For example 5 (13%) patients "found aspects of the study annoying" why? This would be really interesting for someone trying to implement such a system in their clinic

7. Results: Footwear. I'm not sure footwear was mentioned in the methods. The methods used to define who footwear was captured and the definitions used of different footwear needs to be in
the authors methods. Additionally, please add to the methods if the in-shoe plantar pressure measures performed in the patients footwear or a standardised shoe

8. Discussion: Paragraph 1. I really think the authors have to discuss the findings of their original aims instead of stating "For the sake of brevity, our Discussion will focus on the last two of these aims". I personally think the findings for the first three questions/aims is what makes this potential paper unique and of interest to the reader, ie what are the practical implications for a clinician who wants to incorporate these historically research-based plantar pressure measures in their routine clinical practice. Whereas I think the last two aims have been answered by several other previous papers that the authors have already discussed and cited in their Background and now Discussion, ie what applications for plantar pressures are most useful and how should a researcher design a study to use these measures.

9. Discussion: Paragraph 5. Whilst I agree with the authors to an extent I think they need to be careful with such a sweeping statement based on their findings that "in the absence of evidence showing that early screening … it is premature and ill-advised to conduct such screening". I could think of a few uses for people without high risk feet (ie nil DPN and PAD) in terms of aiding orthoses effectiveness pre- and post, determining effective general callus debridement etc. Thus, it might be wiser for the authors to suggest the use of plantar pressure measurement needs further investigation in low risk patients as in practice this is happening in many athletic shoe stores all day every day without major incident to the reader's knowledge?

10. Discussion: Paragraph 7. This paragraph now contradicts the authors sweeping statement in my Point 1 above, ie "The authors observed only moderate sensitivity (59%) and specificity (69%) when the test was used only by itself; however, specificity improved somewhat (up to 78%) when the plantar pressure data were combined with the neuropathy disability score … ". I would suggest reflecting this more accurate discussion in the Background Paragraph 6. Additionally, I'd refer the authors to Mal Fernando's paper again for interpretation around the challenge of a plantar pressure threshold for developing foot ulcers:

Fernando ME, Crowther RG, Pappas E, Lazzarini PA, Cunningham M, Sangla KS, et al. Plantar pressure in diabetic peripheral neuropathy patients with active foot ulceration, previous

11. Discussion: Paragraph 9. The quote the authors have used from Bus et al seems to support my above Point 8 on the omission of not discussing the other aims of the study as the reader could have nearly determined "the efficacy of pedobarography in the reduction of diabetic foot morbidity in New Zealand deserves further examination via clinical trial in this context" already from previous larger more robust studies

12. Discussion: Paragraph 10. This paragraph focuses again on recommending further clinical trials to use plantar pressure measurement to inform offloading devices in high risk patients to prevent reulceration. However, they also discuss in detail how this has already been done in large RCTs by Owings et al and Bus et al and it also doesn't seem to actually reflect the authors findings. What does seem to reflect the authors findings were many of their patients that used plantar pressure measurement had foot ulcers and therefore should plantar pressure measurements be used to inform offloading devices in foot ulcer patients?.

13. Discussion: Limitations. The authors focus their limitations entirely on response rate which doesn't seem to be discussed in the Discussion. The authors really need to consider adding several other limitations I have suggested above in terms of their methods, definitions etc.

14. Conclusion: The authors should reconsider this summary of their findings and recommendations as per comments above

15. Abstract: After making the above changes make sure these changes are also then reflected in the new abstract
Minor Revisions

1. Background: Paragraph 7. Whilst this statement by the authors was till very recently true "The impact of pedobarography as a biofeedback tool remains entirely unexplored", a recent paper by Bijan Najafi has begun to look into this and I'd refer the authors to it, plus to potentially cite it:


2. Methods: Participants: Paragraph 1. I would suggest the authors just quickly tighten their definition of "Only patients who were able to walk were invited in to the study (e.g. those in wheelchairs were not included)." For example, typically this is described something more like "only patients who could walk unaided by mobility aides for at least 50 metres were included" or something like that

3. Methods: Pedobarography measurements. It would be worthwhile for the authors to cite their two different procedures for inshoe and platform measures here just so the reader knows it has been used and/or validated before. Although it's not the focus of this study, it would also be useful for the authors to define which plantar pressure outcomes they measured (e.g. mean peak plantar pressure, pressure-time integral etc) as this will help the reader understand which outcome the patient and clinicians were viewing. The authors give examples later, but it would be nice to know exactly which outcomes were used.

4. Discussion: Paragraph 2. I'm not sure the author's statement that they "provided real-time biofeedback regarding the efficacy of offloading" was reflected in their methods or results. It would be best to define how this was done in the methods and findings in results or perhaps dampen this statement as speculative
Discretionary Revisions


2. Background: Paragraph 2. Just be careful of the word "diabetics". I don't personally mind, but many nations now have position statements recommended not to label "people with diabetes" this way. Perhaps refer to this position statement: Diabetes Australia: Position statement on a new language for diabetes (2016): https://www.diabetesaustralia.com.au/position-statements

3. Background: Paragraph 3. This is up to the editors, but I'd recommend reference citations are in numerical order.

4. Background: Paragraph 3. There are quite a few old papers cited here to support increases in plantar pressure in people with diabetes and foot deformity from the pathophysiology of DPN. Although I'm biased may I suggest using some more contemporary papers from:


   b. Sicco Bus. I'd suggest this paper might be very useful: Barn R, Waaijman R, Nollet F, Woodburn J, Bus SA. Predictors of Barefoot Plantar Pressure during Walking in Patients
with Diabetes, Peripheral Neuropathy and a History of Ulceration. Plos One. 2015;10(2):e0117443

5. Background: Paragraph 5. There are 2 major papers in this field that have successfully used plantar pressure measurement to prevent reulceration which the authors summarise nicely in their later discussion but only summarise one of those papers here. The authors should consider doing the same succinctly here for the other paper also (which is current ref 41 in their paper) particularly as one uses a platform and the other inshoe which the authors investigate in their study:


6. Background: Paragraph 9. I'm not completely familiar with the multiple questions posed in the place of some tighter aims for this study, but if the editors are happy then I'm happy.

7. Methods: Participants: Paragraph 2: I personally prefer results to be in results, in this case "A total of 48 patients were invited to participate in the study by referring clinicians, of whom 39 agreed (response rate: 81% of those invited) ....". This is highlighted later on when the authors describe how the patients were recruited.

8. Results: Table 1 is currently formatted like a case series. I'm wondering if the authors can provide a more summarised table of characteristics here to help the reader quickly interpret their findings and make the current Table 1 an appendix.
9. References. There are a number of very old papers cited, some over 30 years and many of 20 years old. Just be careful that more recent literature hasn't made these papers outdated as I suspect there may be.

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