Author's response to reviews

Title: A novel approach to mapping load transfer from the plantar surface of the foot to the walls of the total contact cast

Authors:

Lindy Begg (lindybegg@bigpond.com)
Patrick McLaughlin (Patrick.Mclaughlin@vu.edu.au)
Leon Manning (leonmanning1985@hotmail.com)
Mauro Vicaretti (mvic3700@usyd.edu.au)
John Fletcher (johnf@med.usyd.edu.au)
Joshua Burns (JoshuaB2@chw.edu.au)

Version: 2 Date: 19 November 2012

Author's response to reviews: see over
Dear Prof Menz,

Ms. Ref. No.: 1772425852796473

Title: A novel approach to mapping load transfer from the plantar surface of the foot to the walls of the total contact cast: a proof of concept pilot study

We want to thank the Editor and Reviewers for their thorough feedback regarding our manuscript and for considering our pilot study for publication in the *Journal of Foot and Ankle Research*. We have modified the manuscript following careful consideration of the issues raised by the editorial team and reviewers.

We have provided our revised manuscript with the changes highlighted. In addition, we have provided a separate document listing the editorial and reviewer comments verbatim and our replies, point by point (with page numbers of any changes made).

We believe this revised manuscript is significantly improved in clarity and will be informative to the readership of *Journal of Foot and Ankle Research*.

Yours sincerely,

Lindy Begg

*on behalf of the co-authors*
**Editor's comment**

1. Remove line numbering

*Authors’ response: Removed.*

2. No need to use capital letters for Total Contact Cast

*Authors’ response: Amended.*

3. Page 7 – replace 1., 2., 3., with (i), (ii), (iii).

*Authors’ response: Replaced.*

4. There are several errors in the reference list. Please ensure references are correctly formatted using the JFAR style and journal titles are appropriately abbreviated. Citations in the reference list should include all named authors.

*Authors’ response: Amended.*

5. Figures need to be uploaded as separate files, not embedded in the main manuscript file.

*Authors’ response: Amended.*

6. Figure 1: merge into a single image rather than 1a, 1b, 1c, etc., but keep positions labels.

*Authors’ response: Amended.*

7. Tables need to be part of the main manuscript file, not additional files.

*Authors’ response: Amended.*
Reviewer’s report

Reviewer: Peter Anthony Lazzarini

Major Compulsory Revisions

1. Title: As the numbers of participant are limited (n=2) please ensure this is clear by either adding after the existing title. “A pilot methodological study” to align with your stated aims, or “A methodological case report” or something similar. Or clarifying in the abstract methods (see below point).

Authors’ response: Title modified.

2. Abstract: Methods: Please clarify your participants (i.e. n=2) here, it took this reviewer until halfway through the Main Manuscripts; Methods before it was clear to me that this study didn’t contain a much larger sample.

Authors’ response: Amended on page 2.

3. Abstract: Methods: Again to clarify for the reader it would be best to mention your statistical analysis (I’m presuming descriptive or similar) as the results look very impressive otherwise.

Authors’ response: Amended on page 2.

4. Background: Paragraph 2: Sentence 1. Please reference this statement or make it clear it is the anecdotal experience of the authors. It may seem obvious that this is true to the authors and reviewer, but not the lay reader.

Authors’ response: Amended on page 3.

5. Background: Paragraph 2 & 3. Again please reference the last sentence paragraph 2 and third sentence paragraph 3. Both sentences I’m presuming are citing reference 7 (Burns & Begg)

Authors’ response: Referenced.

6. Methods: Paragraph 1. Please state if the participant with a history of diabetes also had a history of plantar foot ulcers and/or peripheral neuropathy as this would seem to be your target population.

Authors’ response: Clarified on page 5.

7. Methods: Paragraph 5: Sentence 1. Was there a reason and/or reference for the specific walking speed chosen? This would assist others to repeat your methodology.

Authors’ response: Clarified on page 6.

8. Methods. Paragraph 6. I’m unsure how the canvas shoe aided “the rocker effect”, is this strategy cited? I understand the reason to reduce slipping etc.
9. Methods: A sentence or two on your statistical analysis, though descriptive, I think is necessary here as it’s not entirely clear what the denominator and numerator are to get the 23-34% result later.

Authors’ response: Amended on page 7.

10. Results: Table 1: The title of the table is a little confusing. Would it be clearer to say “Comparison of step data per participant, plantar foot and cast wall data methods: or similar? Also I’m still confused (it might be just me) as to how the 23% and 34% was determined (again it would be hands to include the numerator and denominator in the table to make this obvious).

Authors’ response: Amended.

11. Discussion: Paragraph 3: Sentence 5: The authors should probably clarify this statement as a number of papers have reported being able to measure shear in research settings (e.g. Yavuz & Davis. Yavuz et al 2008. Yavuz et al 2010) it is probably safer to say “At the present time, it is not possible to clinically measure shear….”

Authors’ response: Yes, we agree. Amended on page 10.

12. Conflict of interest: I would have thought as “PM is the Australian and New Zealand agent for novel gmbh” and that is what is used in this new method that this was a conflict that should be declared.

Authors’ response: Amended CoI on page 11.

Minor Essential Revisions

1. Abstract: Results: Last Sentence. As this sentence primarily compares the first sentences results to what has been reported in the literature to date, it would be preferable to move this sentence into the Abstract: Conclusion section.

Authors’ response: Results and conclusion of abstract have been rewritten to clarify our findings.

2. Methods Paragraph 1. It would be preferable to spell out there were only two participants here, plus, the reasoning you chose them.

Authors’ response: Amended page 5.

Discretionary revisions

1. Abstract: Background. Last sentence. To clarify that the aim of the study is about developing a new methodology to measure the cast wall load for the readers, perhaps it could be stated: “the aim of this pilot study was to determine the feasibility of a new method to directly measure the load between the cast wall and the lower leg...”

Authors’ response: Amended page 2.
2. Background: paragraph 2 Sentence 1. Do you need to state “in the tertiary hospital setting? TCC’s can also be applied in other settings.

Authors’ response: To provide our context we feel this is an important point.

3. Background: paragraph 4: Last sentence. Possibly change to past tense, e.g. “was in the vicinity of 30%” or even “appears to be similar and in the vicinity of 30%.

Authors’ response: Amended page 4.

4. Background: Last paragraph: Aims. The same point as Discretionary Revision 1 for aims here as well.

Authors’ response: Amended page 5.

5. Background: last paragraph: Aims. Also reading on, was one of the aims to determine if the methodology was safe as well since there was a healthy participant and a “target participant? This may add value to the manuscript?

Authors’ response: Our study design was not able to assess safety.

6. Methods: paragraph 1: It would be nice to define the setting here as well.

Authors’ response: Amended.

7. Results: Possibly consider moving the last paragraph to be the first paragraph.

Authors’ response: Amended on page 7.

8. Discussion: Paragraph 1: Sentence 2. It may be safer to dampen this statement by adding “These directly measured results appear to confirm previous…”

Authors’ response: Amended.

9. Discussion: paragraph 2. Sentence 2. Would it be useful to suggest that the new methodology also safely measured these two areas of (previously assumed) high risk areas for breakdown and potentially supports why we need to protect them.

Authors’ response: Our study design was not able to assess safety.

10. Discussion: paragraph 3: Sentence 3: Possibly qualify this statement, by adding “if time or resources are limited”. As it would appear, as you’ve stated in the last paragraph, that these two high load areas need a much larger sample in future studies to be confirmed as the two areas that should only be measured.

Authors’ response: We feel this section has been adequately explained.
Reviewer's report

Reviewer: Shan Bergin

1. I don’t believe a study with 2 participants comprises a ‘pilot study’. I believe what you have performed is more a ‘proof of concept study’ in that you have shown you have technology that is able to measure the load applied through the walls of a TCC.

Authors’ response: Amended to read ‘proof of concept’ study on page 1 and 2.

2. There is also no information included on where these participants were recruited from and how they were recruited. There is also no data on participant characteristics – were they the same height, weight etc. as all has the potential to influence data collected.

Authors’ response: Added to page 5.

3. From my understanding it would also appear that you have collected data from a series of different points along the cast wall only once at each point so again I am not convinced this is sufficient data to constitute a pilot study.

Authors’ response: Amended to read ‘proof of concept’ study on page 1 and 2.

4. The fact that the cast was bivalve and removed and re-applied several times is problematic. Firstly a true TCC and a bi-valved TCC are considered two different modalities so in effect you have not collected data on a TCC and I think it is perhaps misleading to state this. I have to wonder also whether the bi-valve and the constant removal of the cast has the potential to impact on the integrity of the cast and it’s ability to manage load. Whilst it is mentioned that this was necessary in terms of placing sensors it’s impact is not discussed.

Authors’ response: In order for testing of the cast walls to be performed the TCC had to be cut in some way to enable the safe and accurate placement of all sensors. After 20 minutes to allow for drying time, the TCC was bi-valved and testing commenced. The only activities undertaken by each participant were during data collection. The TCC was returned to a TCC with the use of Elastoplast i.e. snug fit. We believe that the resultant TCC used for data collection was not weakened by being bi-valved due to minimal activity incurred by each participant in the research setting. The fundamental difference between a bi-valved TCC vs. TCC is the issue of forced compliance in terms of wound healing. This study was focused upon the mapping load transfer of the TCC.

5. My biggest query with this study is whether it will have any impact on clinical practice. The reason behind ‘proving’ the ability to measure load along the cast wall in terms of future research or informing clinical practice is not discussed. We know that TCC off-loads the plantar area of the foot which is why it is used for wound healing but to what degree it off-loads…I am not sure that really matters?! To date the exact amount of pressure off-loading required to heal a foot wound has yet to be quantified and research indicates this exact measure is likely to differ significantly between individuals. For instance one person may only require a 20% reduction in load to obtain healing, whereas another may require 80%. The authors need to be more clear about why this study is important/necessary.
Authors’ response: As the reviewer points out this is a ‘proof of concept’ study and the clinical implications at this stage are limited. We discuss that our results support the concept of offloading modalities that extend proximal to the ankle due to the potential of load sharing from the plantar surface to the walls (page 8) and we have amended the point on page 9 that since this paper has reported the outcome from a proof of concept study; the methodology requires repeating in a larger sample of participants with plantar foot ulceration. Research of this type is necessary to develop a more comprehensive understanding of the TCC offloading mechanism in terms of pressure offloading and the healing of plantar foot ulceration.

6. The authors make the point that application of the TCC varies considerably yet it is not discussed what, if any, impact on findings a different method of application may have on the amount of pressure transferred to the cast walls. It would perhaps have been more informative to measure the degree of off-loading across a series of casts applied in different ways to assess whether one method was superior.

Authors’ response: We agree this approach would be interesting but was beyond the scope of our study.

7. Can I assume that once the cast was cut down and canvas cast shoes added further measurements were taken? This is not clear. If so what was the aim of the cut down version?

Authors’ response: The canvas cast shoe was added to the TCC and the shoe-cast to reduce the likelihood of slipping and to provide a slight rocker sole. Plantar pressure testing was repeated in the shoe-cast i.e. following removal of the cast walls. The decrease in plantar pressure in the TCC condition is attributed to load transfer to the cast walls. At the same time an increase in forefoot plantar pressure in the shoe-cast condition was apparent when the cast walls were removed.

Minor Essential Revisions

1. Please remove the italics from the text of the paper

Authors’ response: Amended.

2. I am not sure the description “load between the cast wall and the lower limb” is an accurate description as technically the space between the two is “dead space”. Perhaps something like the cast wall and leg “interface” would be more accurate. The TCC could be described as being a snug fit; a reduction of limb volume was not discernable after 20 minutes i.e. a “dead space” was not observed.

Authors’ response: Amended.