Author's response to reviews

Title: Correlates of foot pain severity in adults with hallux valgus: a cross-sectional study

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Author's response to reviews: see over
Prof Hylton Menz
Editor-in-Chief
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c/o BioMed Central
236 Gray’s Inn Road
London WC1X 8HB
United Kingdom

13 June 2014

Dear Hylton,

RE: Manuscript resubmission – 1553235631276348 “Determinants of foot pain severity in adults with hallux valgus: a cross-sectional study”
Sheree E Hurn, Bill T Vicenzino and Michelle D Smith

We would like to thank the Editor and Reviewers for their attention to this manuscript. We appreciate the feedback provided and the opportunity to address the Reviewers’ comments.

A point-by-point response to each concern raised is outlined in the attached table. Modified text has been highlighted in the revised manuscript.

We look forward to hearing from the editorial team regarding a decision on our manuscript.

Yours Sincerely,

Sheree Hurn (nee Nix)
(On behalf of Bill Vicenzino, and Michelle Smith)
### Reviewer 1 (JB)

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<td>A major limitation of the study is that the foot pain measures were not specific to the Hallux Valgus/1st MTP joint region. This has been acknowledged in the discussion on page 15 as well as the fact that some participants actually had pain in the arch and heel, and not the Hallux Valgus/1st MTP joint region at all. Do the authors think that this non-specific measure of Hallux Valgus pain as well as the likelihood of pain in other regions of the body (not reported) might explain the unusual findings, as well as some of the variance in the general health, education and occupational correlations?</td>
<td>As Reviewer 1 has noted, this consideration was acknowledged in our Discussion section on Page 16. However, at the planning stages we took the view that to ask only about great toe region pain and not to record other foot pain would bias our data. Since HV is a deformity affecting the entire forefoot, a specific measure of hallux/1st MTP joint pain could be too restrictive, given that pain in the lesser metatarsals or lesser toes is often associated with HV. Instead we asked about foot pain and then mapped it, as reported under “Foot pain locations.” It was apparent from our data that 67% of participants reported first MTP joint and/or hallux pain (60% 1st MTP joint, 12% hallux). We raised this issue as a potential limitation in order to alert readers that should they only ask about great toe pain that their enquiry might result in different outcomes to ours, though our data does not tend to support that possibility. In our discussion the reader will note that we included the pain localisation issue after and as part of a more critical issue related to the measurement of the complex and multidimensional nature of pain. Our recommendation for further research is mostly about addressing the more global issue of how to measure this pain construct, of which the specific localisation is likely a relatively small factor.</td>
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| With only 1 of 20 plantar pressure variables showing a significant association with foot pain, might the lack of standardised footwear during testing explain this finding? Using participant’s own footwear is more a measure of footwear pressure attenuation than an inherent foot pressure profile, especially considering the range of footwear people wear in any given week? | The lack of standardised footwear in our study is a limitation, which has now been acknowledged in our Discussion (see below). Nonetheless, since this study was investigating potential explanatory factors for pain intensity in HV (rather than foot biomechanics or pressure profiles associated with HV), we feel that pressure attenuation at the foot-shoe interface in participants’ own footwear is a very relevant measure. Our data indicate that participants with more painful feet may adopt a more cautious gait pattern (when wearing shoes) and spend less time loading the medial forefoot (indicated by lower force-time integrals). In order to clarify this point in our Discussion, the following modification has been made to the paragraph below (Page 15): *In-shoe plantar pressure analysis showed an inverse correlation between average foot pain and force-time integrals under the first and second metatarsal heads (Table 3). Given that the most common site of reported pain was the first MTP joint (60%), it is plausible that those with more painful feet might walk more cautiously and spend less time loading the medial forefoot when wearing shoes, although other studies have linked higher barefoot plantar pressures to pain in HV [1]. The lack of standardised footwear in our study is an important consideration, as the observed pressures could also reflect characteristics of the footwear. Further studies investigating barefoot versus in-shoe plantar pressures profiles in HV are warranted.* |
This section previously read:
Gait analysis showed an inverse correlation between average foot pain and force-time integrals under the first and second metatarsal heads (Table 3). Given that the most common site of reported pain was the first MTP joint (60%), it is plausible that those with painful HV might offload the medial forefoot during gait in order to avoid provoking pain, although other studies have linked higher plantar pressures to pain in HV [1].

| 3 | Sample size: Please provide further justification that n=57 and n=58 is large enough to perform the multivariate linear regression models shown in Table 4 (9 variables) and Table 5 (6 variables). | Our a priori sample size calculations (reported in the Methods, Page 9) showed that a sample size of 54 was determined to have 90% power in a model with 6 explanatory/independent variables. Our total sample size of 60 participants was intended to allow for some missing data.

Our multivariate analysis was a step-by-step approach using a series of multiple linear regression models. Variables were entered one at a time on the basis of the strength of their univariate associations with foot pain, and were retained in the model only if they made a significant contribution to the model. As such, no more than 5 explanatory variables were entered into a model at any one time. |

| 4 | The word ‘Determinants’ in the title suggests causality which is not possible to identify in a cross-sectional study. Please consider another terms like ‘Factors associated with’ or ‘Explanatory correlates’ | As suggested by Reviewer 1, the word “Correlates” has now been used rather than the word “Determinants” in the manuscript title. |

| 5 | Is the gender bias of the sample representative of the general population of those with painful Hallux Valgus? | It is clear from the literature that HV is approximately 2.3 times more common in females than males [2]. However, the gender bias in our study was more pronounced than this. Given that pain was not an inclusion criterion for our study, the authors believe it is more likely that women were simply more likely to respond to advertisements and/or be available to participate in our study.

The following has been added to our Discussion (Page 16):
...which may explain why our study did not find an association between foot pain and female sex. While HV is approximately 2.3 times more prevalent in females compared to males in the general population [2], the gender bias in our study was more pronounced, which may indicate that women were more likely to volunteer to participate. |
The foot pain locations section on page 13 seems out of place. Should this be used instead to describe the sample initially?  

As suggested by Reviewer 1, this section has been moved to the start of the Results section to improve flow of the manuscript.

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| 6               | The foot pain locations section on page 13 seems out of place. Should this be used instead to describe the sample initially?  
As suggested by Reviewer 1, this section has been moved to the start of the Results section to improve flow of the manuscript. |
| 7               | Was eligibility for the study based on radiographic classification of HV? It is interesting that one participant was scored a 0 on the Manchester Scale, when the rater would have known that the participant had HV. Can this be clarified?  

Initial screening was performed using the Manchester Scale, and potential participants then underwent x-rays to confirm eligibility. The participant in question was initially identified as having mild unilateral HV, based on the Manchester Scale (R = 0, L = 1). However, on radiographic examination the R foot measured as having a slightly greater HV angle, therefore this foot was used for all further analyses, as per Statistical Analysis Methods (Page 9).  

In order to clarify these study eligibility criteria, the following modification has been made on Page 5:  
**Participants with HV (defined as a radiographic HV angle greater than 15 degrees)...**  
A minor change has also been made to our Statistical Analysis section (Page 9):  
For variables measured bilaterally, only the right or left foot was chosen for analysis [3] based on the greater radiographic HV angle (28 right feet and 32 left feet). |
| 8               | Please provide a written summary of the results for the “Univariate associations with foot pain VAS”–what variables were significant (without replicating the values in the table).  

Thank you for this suggestion. The following paragraph has been added to our Results section (Page 12):  
**Lower educational attainment was associated with higher average foot pain VAS (p = 0.02), while poorer general health scores and higher work activity was associated with higher average and worst reported pain (p ≤ 0.05). Participants who wore shoes with a heel height > 25 mm to the examination session reported higher worst foot pain (p = 0.06), and those who failed the paper grip test reported higher average and worst foot pain (p < 0.05). An increased arch height difference between non weight-bearing and weight-bearing was associated with higher average and worst foot pain (p < 0.1), but interestingly lower Beighton scores, indicating less generalised joint hypermobility, were associated with higher average pain (p = 0.09).**  
**...The only in-shoe plantar pressure parameters that showed significant correlations with increasing foot pain were reduced force-time integrals under the first and second metatarsal heads (p < 0.1).** |
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| 9    | Is the SF-36 scored out of 100? Is so, please mention. | The following explanation has been added in parentheses in our Methods section (Page 6):  
General health was assessed using the SF-36v2 Health Survey general health subscale (score range 0 – 100, with higher scores indicating better general health). |
| 10   | What instructions were given for hallux abduction strength, was everyone able to complete the task? | This is an important question raised by Reviewer 2. In order to provide clarification, the following section has been added under Methods/Hallux plantarflexion and abduction strength (Pages 7-8):  
For hallux abduction, the load cell sensor was positioned so that it was just touching the medial aspect of the hallux in each participant’s resting position. Participants were then instructed to “spread their toes apart sideways.” All participants were able to produce some movement of the hallux given this instruction, although the amount of control to abduct the hallux towards the sensor varied greatly between participants, especially those with moderate to severe HV deformity. |
| 11   | Is there a maximal force that can be applied with the algometer? Did everyone reach a pain threshold? | The maximum amount of force specified by the manufacturer that can be applied using the pressure algometer is 2000 kPa. All participants in this study reported reaching their pressure-pain threshold before the maximum. |

**Editor**

12 Heading hierarchy: JFAR only accepts TWO levels of heading hierarchy. The first level should be indicated with bold Arial 16-point font, and the second level with bold Arial 11-point font (no italics). If you require a third level, this should be indicated by italics in the standard font used in the main text, followed by a colon and no carriage return.  
This amendment to the heading hierarchy has been made throughout the Methods section.
13 Reliability of measures: can the authors include (in parentheses) the statistical definitions/threshold values used to classify measurements as having "very good reliability", "good reliability", and "moderate reliability".

The following threshold values have been added (Page 9) in parentheses to define measurement reliability as:
Very good (ICCs ≥ 0.90)
Good (ICCs ≥ 0.75)
Moderate - an ICC of 0.73 is quoted, since this is specifically in reference to measurement of hallux abduction.

An additional reference for these threshold values has been added to the manuscript:

14 Page 11: please first spell out "MD" prior to first abbreviation.

This correction has been made (Results, page 11).

15 Multiple regression analysis: please consider specifying the direction of the relationship for those independent variables that explained the dependent variable. For example, is it failed paper grip test. Was it increased pressure beneath the second MTPJ etc

The following sentences have been added to the Results (Page 13):
As seen by the beta weights in Table 4, poorer general health, lower educational attainment, a higher work activity index, and lower second metatarsal force-time integrals were associated with increased average foot pain...

A failed paper grip test and higher work activity index were associated with increased worst foot pain.

16 Tables 4 and 5: please specify that a pass or fail for the paper grip test was the reference (consider parentheses beside the variable, eg: Paper grip test [fail])

In order to provide full explanation to help interpret standardised beta weights in Tables 4 and 5, the following information has been added in parentheses as suggested: (pass = 0, fail = 1)

**References**