Author's response to reviews

Title: Foot pain and functional limitation in healthy adults with hallux valgus: a cross-sectional study

Authors:

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Author's response to reviews: see over
Dear Dr Shipley,

RE: Manuscript resubmission MS: 1215389179691967

“Foot pain and functional limitation in healthy adults with hallux valgus: a cross-sectional study”

We would like to thank the editor and reviewers for their attention to this manuscript. A point-by-point response to reviewers’ comments, including changes made to the manuscript, is outlined in the attached table. All changes made have also been highlighted in the revised Word document. Please note that Table 1 has been converted to a supplementary file (Additional File 1) as recommended by Reviewer 2.

Thank you once again for the opportunity to address the reviewers’ comments. The authors feel that this feedback has strengthened the paper, and therefore we believe that our manuscript will be of great interest to the readership of BMC Musculoskeletal Disorders.

Yours Sincerely,

Sheree Nix (on behalf of B. Vicenzino, and M. Smith)
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<th>Reviewer comment</th>
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<td><strong>Reviewer 1</strong></td>
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| 1 The manuscript title and introduction section refer to a case-control study. The abstract refers to a cross-sectional study. Although the study compares healthy adults with hallux valgus to "controls" without hallux valgus, it is not a case-control study as it examines cross-sectional associations rather than defining cases and controls by outcome and then looking back retrospectively for exposure. The manuscript title and introduction should be amended to describe a cross-sectional study. | We agree with the Reviewer’s suggestion to amend the title, which now reads:  
*Foot pain and functional limitation in healthy adults with hallux valgus: a cross-sectional study*  
In addition, the term “case control” has been replaced with “cross-sectional” in the Introduction (page 5). |
| 2 Methods (pg 5), Subjects: Control subjects without hallux valgus were matched for age, gender and BMI. What ranges for age and BMI were used to match eg for age +/-2 years, +/-5 years? | The range used to match subjects for age was ± 5 years and for BMI ± 5 kg/m². This information has now been added to the Methods (page 5).  
The mean absolute difference between matched subjects for age was 1.6 years and for BMI 1.7 kg/m². This information has been added to the Results (page 11) in place of p-values. |
| 3 Methods (pg 6), Measurement procedure: Intra-rater reliability obtained for this study are presented in table 1. The method for obtaining these data is not described. Were they obtained in this population of 60 people or were they derived from the published literature? If intra-rater reliability was assessed in this population then the method for doing so should be described and table 1 would be better signposted from the results section rather than the methods. What was the interval between the two assessments? | Pilot work was conducted to obtain intra-rater reliability data using a small sample of adults. The test-retest sessions were a minimum of seven days apart. As suggested by Reviewer 2 (see Comment #9), this data has now been presented as supplementary data (Additional file 1).  
Methods (page 6) now reads:  
*Intra-rater reliability for physical measures was determined from pilot work. Refer to Additional file 1 for intraclass correlation coefficients (ICC₃,1), standard error of measurement (SEM), and minimum detectable change at the 90% confidence limit.*  
Previously read:  
*Table 1 displays intra-rater reliability data obtained for this study, with intraclass correlation coefficients (ICC₃,1), standard error of measurement (SEM), and minimal detectable change at the 90% confidence limit (MDC₉₀)*. |
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| 4    | Methods (pg 7), General health and physical activity: Does the physical activity questionnaire have a name? Over what time-frame is physical activity assessed eg current, last week, last month etc? | The physical activity questionnaire used in our study is sometimes referred to as the Baecke Questionnaire, or the Habitual Physical Activity Questionnaire [1]. The questionnaire makes reference to “usual activity” and therefore a specific recall period is not defined [2].
To identify this questionnaire more clearly, the Methods text has been modified as follows. Now reads (page 7): Habitant physical activity levels were assessed using the Baecke Questionnaire [1] to calculate a work index, sport index, and leisure index. Originally read: Habitual physical activity level was assessed via questionnaire [1], and a work index, sport index, and leisure index were calculated. |
| 5    | Methods (pg 7), Self-reported foot pain and disability: Foot pain and disability scores were produced by summating responses to the Manchester Foot Pain and Disability Index. Use of such summated totals is problematical as it assumes that the scores are uni-dimensional and of an interval-level. Consideration should be given to use of Rasch-transformed scores or, at the very least, this issue acknowledged in the discussion. | The authors acknowledge that the Foot Pain and Disability Index (FPDI) and its subscales do not produce true continuous or interval level scores. Our FPDI data did not follow a normal distribution and no appropriate transformation was available. Therefore, non-parametric statistical analysis was performed using the Wilcoxon rank-sum test, as described on page 10: Differences between groups were then examined using independent t-tests for continuous variables or Wilcoxon rank-sum tests for ordinal variables and continuous variables for which no adequate transformation was available. As suggested by Reviewer 1, this issue has now been acknowledged in the Discussion by adding the following statements (page 18): Both foot-specific questionnaires (FHSQ, FPDI) produced significantly skewed data, and consequently non-parametric statistical tests were used. In particular the summed FPDI scores cannot be interpreted as a true interval scale unless a Rasch analysis is performed [3], which was not undertaken for the current study. |
| 6    | It is interesting that the sample size calculation is based on pain as the authors state in the introduction that concerns about appearance and difficulty with footwear in this population are the most novel aspects of the study. Nevertheless, it would be helpful if details were provided of the | The sample size calculation described on page 10 was based on preliminary analysis (n = 26) of the current study population. This has now been clarified under Methods – Sample size determination (page 10).
Now reads: Using standard deviations obtained from preliminary data analysis (n = 26), we |
pilot data on which the sample size calculation was based.

Previously read:
Using standard deviations obtained from pilot data, we determined that 29 subjects in each group would provide 80% power to detect a difference of 11 mm between groups...

Data are presented for the total FPDI and for the pain and function sub-scales. Although it would not be appropriate to present summated scores for the two items on the appearance sub-scale, as it is the findings related to appearance that are the most novel have the authors considered comparing responses to these to these two items between the groups (eg proportions answering none of the time, some days, most/every days)?

As suggested by Reviewer 1, responses to these two FPDI items have been compared between individuals with HV and control subjects. Results have been described as follows (page 12):

On the FPDI item which states “I feel self-conscious about my feet”, 19 participants with HV (63%) responded “on some days” or “on most/every day”, compared to five participants (17%) in the control group (Chi-squared p = 0.001). Similarly, 13 HV participants (43%) responded positively to the statement “I get self conscious about the shoes I have to wear”, compared to one participant (3%) in the control group (Chi-squared p = 0.001).

The Chi-squared test has now been included under Statistical Methods (page 10).

The abstract conclusion contains a potentially confusing double negative: “...negatively impacts on self reported... disability”. Negative impact on function might be better.

As suggested this minor revision has been made to the abstract conclusion.

This sentence now reads (page 3): “These findings show that HV negatively impacts on self-reported foot pain and function...”

As suggested by Reviewer 2, some paragraphs in the Methods and Results have been synthesized.

Table 1 (intra-rater reliability data) has now been presented as Additional File 1. Please also refer to authors’ response to Comment #3.

Sample size calculations were originally performed based on the Visual Analogue Scale (VAS) and Foot Health Status Questionnaire (FHSQ) subscales. The VAS and FHSQ were chosen for sample size determination because minimal clinically important difference has been reported in the literature [4]. The sample size calculations based on FHSQ subscales resulted in lower
parameters and did the authors only report that which resulted in the highest number of participants. numbers of participants (12 to 21 in each group); therefore, the sample size based on pain VAS (29 participants in each group) was reported on page 10 of the manuscript.

Please also refer to Comment #6 by Reviewer 1.

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<th>11</th>
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<th>The included population seems to be quiet heterogeneous with respect to the age. The authors should reflect on this in the discussion section.</th>
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|    |    | A minor revision has been made to Discussion paragraph 7 regarding sample characteristics. This section now reads (page 17):
|    |    | ...only ten males participated in this study, and the age range of study participants was relatively wide. Nevertheless, these sample characteristics were considered representative of a clinical population. Third, whilst our sample included participants with mild, moderate and severe HV, the sample size in the current study was not sufficient to examine subgroups according to HV severity. 
|    |    | Previously read:
|    |    | ...only ten males participated in this study, although the range of ages and severity of HV was considered representative of a clinical population. Third, the sample size in the current study was not sufficient to examine subgroups of mild, moderate, and severe HV. |

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<th>12</th>
<th>References</th>
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<td>The authors feel that the number of references is warranted given the scope of relevant background literature and the number of outcome measures used in the current study. However, if the editor wishes to restrict the number of references, we are willing to revisit this matter.</td>
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References