Author's response to reviews

Title: Subjective and objective outcome in congenital clubfoot; a comparative study of 204 children.

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Author's response to reviews: see over
Dear sir,

Further to your revision comments for our manuscript,

“Subjective and objective outcome in congenital talipes equinovarus; a comparative study of 204 children.”, we have made the following changes:

MS: 1439739927128742

We have made the following changes;

**Reviewer: Matthew B Dobbs**

1. change congenital talipes equinovarus to clubfoot in title.

The title has been changed.

2. Abstract: 1st line CTEV is used without defining it first. A suggestion for the entire manuscript is to use clubfoot. The authors can use congenital talipes equinovarus (clubfoot) initially and then refer to clubfoot throughout text.

The use of CTEV has been changed to clubfoot throughout the text.

3. Abstract: methods: list statistical methods

The statistics used are now detailed in the methods section of the abstract.

4. Background: 1st paragraph: the authors allude to the fact that an objective assessment looking at ankle motion and position would be good but those are not the objective measurements the authors use in the methods.

Range of movement at the ankle is indeed one of the objective measures evaluated in the paper, measured from photographs looking at maximum plantarflexion and maximum dorsiflexion. This method is explained in the patients and methods section of the manuscript.

5. Background, 2nd paragraph: The writing could be improved by “…….., calf circumference, gait, skinfold thickness, foot length, foot width, and shoe size.”

This has been incorporated into the manuscript.
6. Background, 3rd paragraph: Shouldn’t have one sentence for a paragraph. The authors state some have advocated the use of radiographs in evaluation of clubfeet. Certainly, many others don’t advocate it including the long-term follow-up out of the University of Iowa that found no correlation with radiographic outcome and clinical result.

The sentence regarding radiographs has been incorporated into the previous paragraph. The advantages or otherwise of radiographs in the assessment of clubfoot is discussed within the discussion section of the manuscript.

7. Patients and Methods: This section should be strengthened. There is no demographic information about the patient population. What is the age of the patients at follow-up? How were the clubfoot treated—surgically or with the Ponseti method, french method, etc? Age at diagnosis? Age at treatment? Number of surgeries? Number of complications? All of these factors can correlate with outcome as well.

Patient demographics and management information is now included within the initial paragraph of the patients and results section. The focus of the manuscript is a comparison of subjective and objective outcome, rather than a comparison of different management methods. Of course management will affect outcome, perhaps more so the subjective outcome, where some families may be unhappy with repeated hospital visits while others will be delighted to receive this dedicated care. Some of the limitations are now discussed in the discussion.

8. Patients and Methods: 3rd paragraph is only one sentence and should be included in paragraph 2. In the current paragraph the authors write “15” and “three”. Need to follow journal format on reporting numbers.

The manuscript has been corrected as suggested.

9. Patients and Methods: Authors current 4th paragraph: The authors need to justify why they chose the objective measures they did instead of strength, range of motion, etc.

A discussion concerning the objective measures used, and those not considered is now included in paragraph 4.

10. Patients and Methods: current 4th paragraph: The entire sentence starting with ‘Ideally…. “ can be deleted.

The sentence has been deleted as suggested.
11. Patients and Methods: The paragraph starting with “Twelve....” Should be part of the preceding paragraph.

This has been corrected.

12. Patients and Methods: The last paragraph should be separated and entitle statistical analysis. This needs to be more detailed as well and the authors need to note what p-value they considered significant for each test.

P values are quoted within the tables, including significance. The patients and methods description of the statistical analysis has been expanded as requested.

13. Results: We need to know who is answering the questionnaires. This comes back to my question as to what is the age of the patients?

The age of the patients at the time of study is included in the patients and methods section of the manuscript.

14. Results: Is there any information on the 46 families that are not included in the study. How were they doing at last follow-up? How many surgeries had they had? It would be important to know this cohort of patients is similar to those that responded.

As the object of the paper is to compare subjective and objective outcome, those who entered an incomplete response were excluded from further analysis. I have tried to stay away from an analysis of management and variation in outcome as this clouds the issue. Management will of course influence outcome but then raises questions about initial assessment and classification of CTEV.

15. Results: Objective assessment: 2nd paragraph, last sentence starting with, “Obviously....”. This sentence can be omitted. If it is obvious, don’t say it.

This section has been revised

16. Results: The authors refer to muscle wasting as being synonymous with decreased calf circumference. This is not necessarily true. Patients with clubfoot treated without surgery have been shown to have symmetric strength to the unaffected leg but still have smaller calf. This needs to be addressed throughout the text.

This issue concerning calf circumference as an indirect measure of muscle wasting in children has been expanded on in the discussion section of the manuscript.

17. Discussion: 2nd paragraph should be combined with 1st paragraph

Done.
18. Discussion: current 2nd paragraph: can be improved: ……ankle and foot, gait analysis,……sole of the foot, calf circumference, skinfold thickness, foot length, foot width, and shoe size.

This sentence has been rewritten accordingly.

19. Discussion: 3rd paragraph: “and there remains the risk of iatrogenic……patient.” This can be omitted.

Done.

20. Discussion: Paragraph that is one sentence: “In the present study…..” The authors should develop this paragraph.

This section has been revised. Each of the anthropometric measures shown to correlate with subjective outcome are discussed separately, with the different measures highlighted within the text.

21. Discussion: Does sex affect outcome? 1st sentence: “a greater proportion…” This should be in result section.

Management data has now been included within the results section of the manuscript.
Reviewer: Karl Landorf
Reviewer's report:

General
This manuscript presents results from an interesting study that attempts to correlate subjective outcomes with objective outcomes for congenital talipes equinovarus (the abbreviation ‘CTEV’ is used by the authors).
The results are from a large, national study of congenital talipes equinovarus. The investigators should be congratulated for such a significant undertaking.
The results of the study are on the whole very interesting, however I think the manuscript needs more focus (i.e. the results should be presented in a more focused fashion) and some more work needs to be done to make the manuscript easier to read. While I think the results are very worthwhile for improving knowledge about this condition, the manuscript doesn’t really present a main message. For example, if the reader read the ‘Conclusion’ of the ‘Abstract’ (arguably the most important component of a paper) they would be lead to believe that the main message was that “female patients and their parents are less happy with the results of management of CTEV”. Yet, nowhere in the ‘Results’ section of the ‘Abstract’ is there any mention of the differences between male and females; instead, the focus is on the correlation between subjective and objective measures.
The above highlights that the results and the conclusion of the manuscript need more work. I think the study is of interest and deserves publication, but the authors should be encouraged to re-write some sections, particularly the ‘Conclusion’ of the ‘Abstract’, the ‘Discussion’ section, and the final ‘Conclusion’ section so a more focused and appropriate main message can be portrayed. To reiterate my concern: if you focused on the ‘Conclusion’ of the ‘Abstract’, you would think that the study was set up purely to answer the question whether there were differences in males and females subjective assessment of their management of congenital talipes equinovarus. Whereas, from my understanding, the main thrust of the paper (i.e. primary focus) is the correlation between subjective and objective measures and that they can both be used to provide a better evaluation of the management of congenital talipes equinovarus. The difference between males and females appears to be a secondary question. Apologies if I have totally mis-read this, but this is how it appears to me. In addition to the above, there are a number of sections within the manuscript that are difficult to read. Most of these seem to relate to sentence structure and/or punctuation. The manuscript would be easier to read if the authors could address these sections.
Finally, I have concerns about the statistical analysis as outlined below in the revisions.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
Page 6, 1st line: I think “maximal plantarflexion” should be “maximal dorsiflexion”, and vice versa at the end of this sentence, “maximal dorsiflexion” should be
“maximal plantarflexion”. Can the authors check this carefully and change as necessary. Simply crouching down and standing on tip toes oneself should make this clear.

This has been corrected

Page 6, last paragraph: all statistical information should be included here, not in the ‘Results’ section. For example, the authors need to include details regarding the correlation coefficients here, not in the results section. 
Further to the point above: I’m unfamiliar with what a ‘Gamma correlation coefficient’ is. Is this simply a Pearson correlation coefficient, as a Pearson Correlation Coefficient should be used with continuous variables where the data is normally distributed as indicated? Or, is this a Spearman Rank Correlation Coefficient, which it probably should be given that the subjective outcomes are ordinal in nature, not continuous. The authors must clear this up so it is clear.

The Gamma correlation described by Goodman and Kruskal is popularly used by a number of medical specialities, including geneticists, epidemiologists and psychologists. It was the statistical test suggested by our statistical reviewer. The test was first described in the 1950’s, and is similar to the Pearson correlation coefficient (http://tolstoy.newcastle.edu.au/R/help/03a/2566.html)

Page 6, last sentence: Add ‘Statistical’ before the word “Significance” and add “and set at p<0.05.” at the end of the sentence.

Done.

Page 7, ‘Results’, ‘Objective Assessment’, 1st line: as indicated above, reposition the section discussing correlation coefficients in the Methods section where the statistical analysis is positioned. Further to the comment above: it appears that the investigators have used simple correlation coefficients to test for reproducibility (reliability). It is unclear if this means intra- or inter-tester reliability (or both)? In addition, did the investigators test for true differences in the data (i.e. agreement of measures)? For example, if testing for reliability of continuous measures, either a Pearson r and a t-test, or an ICC should be used. The authors need to provide more information regarding the statistical analysis as I cannot work out whether what they have done is correct.

The statistical analysis of the manuscript had been expanded.

Page 10, section relating to ‘Sex differences in outcome’: Remove the part of the 1st sentence where it is stated, “…, tested using the t-test for independent samples, …”. This should be included in the ‘Methods’ section where data handling and analysis is as discussed previously.

This has been changed.
Page 16, ‘Conclusion’, last sentence: This last sentence again strikes me as being an odd way to conclude because this question (i.e. the sex differences) was never articulated as being a primary question that the researchers wanted to answer. Even in the ‘Background’ section there is no mention that the investigators wanted to investigate sex differences, so to conclude with this (as has been done in the ‘Conclusion’ of the ‘Abstract’) does not seem right. As I stated previously, I think the authors should concentrate on their primary research questions (i.e. the correlation between subjective and objective outcomes) and keep that as the main message of the paper. If this were a randomised controlled trial, for example, the manuscript would most likely be rejected because it appears that the investigators are data mining (i.e. over analysing). I know that will seem harsh as the study is largely exploratory; however this highlights my concern about clearly defined, pre-specified research questions.

The abstract has been revised to include a clear statement of the purpose of the study. Sex differences, while interesting are not the primary focus of the manuscript, and the conclusion of the paper has been revised to make this clear. Sex differences are however an interesting finding which has not been previously been shown, although there is a perception among managing surgeons that girls have more severe disease than boys, and therefore have a worse outcome. Our manuscript shows this to be incorrect.

Pages 18 and 19, ‘References’: The references seem quite old, but this might be the nature of the topic area. There are, for example, only two references less than 6 years old. Are there any more recent references that the authors have not included that may be appropriate?

The CTEV literature is full of reports of small groups of patients, managed in different ways, assessed using different techniques and at variable times after their management. The papers quoted in the manuscript represent a number of the “classic texts” on the subject, and recent publications justifying the outcome measures we used. No where in the literature is subjective and objective outcome evaluated as we have done. This makes our paper unique. It is my impression that the CTEV literature has shifted from management to the genetic basis of the condition.

Page 20: Was there any validation of the questionnaire? Were, for example patients included in its development? Is it reliable?

A number of authors have used subjective ratings in the past, and have emphasized pain and function. The appearance of the foot has also been used by others. As far as I am aware however, there has been no validation of the questionnaire we used, however our study demonstrates a good correlation between subjective and objective outcome, suggesting that the questionnaire is indeed valid.
can be trusted to correct)

Page 2, ‘Abstract’, ‘Background’, 1st sentence, 3rd line: add a semi-colon after the quote to add a pause between the quote and “…a purely subjective assessment”.

Page 2, ‘Abstract’, ‘Background’, 1st sentence, 4th line: remove “cosmetic acceptability” as it is not only cosmesis that the patients are evaluating, they are evaluating health status issues as well.

Page 4, ‘Background’, 2nd paragraph: I suggest adding a colon after “include” in the first line and then a semi-colon after each cited article. It took me quite some time to work out the structure of this sentence because the current punctuation did not differentiate what section of the sentence should be grouped together. I assume the authors are attempting to group the outcomes used in each of the studies cited, therefore it would be appropriate to group these using semi-colons.

Page 4, ‘Background’, 3rd paragraph: Add this one sentence paragraph to the previous paragraph as it looks odd on its own.

Page 4, ‘Background’, 4th paragraph (beginning “Comparison of objective…”): I think it would be wise to begin this paragraph with, “As far as we are aware, …”.

Page 5, ‘Patients and Methods’, 3rd paragraph: Add this one sentence paragraph to the previous paragraph as it looks odd on its own.

Page 7, ‘Results’, 1st paragraph, 2nd line: add the percentage to the n value, i.e. “…leaving 158 (77%) complete subjective ratings…”

Page 7, ‘Results’, ‘Objective Assessment’, 2nd paragraph, 1st line (beginning “To compare children of different ages…”): add ‘as’ between ‘used’ and ‘a’, so it reads “…heights was used as a reference.”. Further, remove the following sentence as the first sentence makes the second sentence redundant.

Page 7, ‘Results’, 2nd last line: re-phrase “…foot length and width, and height…” as it’s not clear what correlates with what.

Page 8, ‘Results’, last line: “correlates” should read “correlated”. In most of the ‘Discussion’ the authors have used past tense, which seems appropriate, so for consistency this should read ‘correlated’. In line with this, the word “correlate” in the line above this (i.e. the second last line) should be changed to ‘correlated’ as well.

Page 11, last sentence: I suggest changing the phrase “Poorly mobile ankles…” to something like “Ankles with limited range of motion…”
Page 12, last line of 1st paragraph: remove the word “including” (i.e. “…by many authors including” as the references cited (i.e. [2,3,4,5,11]) imply this anyway.
Page 12, 2nd paragraph: similar to before, add a colon after ‘including’ and then semi-colons after each cited study so the reader can group each group of measures to the study cited. The authors may need to add further ‘commas’ or ‘ands’ to make it flow properly once the colon and semi-colons are added.
Page 16, ‘Conclusion’, 3rd sentence of 2nd paragraph: there are three ‘ands’ in this sentence: Can it be re-worded or written as two sentences?

These changes have been made as requested.

I hope you agree that these changes have improved the manuscript. I look forward to hearing from you in due course,

Sincerely,

David Chesney