Author's response to reviews

Title: A comparison of hallux valgus angles assessed with computerised plantar pressure measurements, clinical examination and radiography in diabetic patients

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Author's response to reviews: see over
Dear Dr. Piqué-Vidal, Dr. Roddy and Dr. Nix.

We would like to thank all the referees for the interest in our article and the helpful comments on our manuscript "A comparison of hallux valgus angles assessed with computerised plantar pressure measurements, clinical examination and radiography in diabetic patients".

We have considered the comments of the reviewers and we have changed the manuscript accordingly. Our reply to the issues the reviewers have raised together with the changes made in the manuscript are listed (numbered) below.

The changes made in the manuscript are highlighted. We hope that the revised manuscript is now acceptable for publication in Foot and Ankle research.

Comments reviewer: Carlos Piqué

1: “The authors should refer to radiographic examination you can observe details that are not visible on clinical examination whether visual, manual or baropodometric. Such as, for example, the state of the quality of the joint surfaces. And that the treatment decisions are based generally on the degree of pain and not on the degree of deviation”.

We agree with the comment and added these sentences in the method (radiographic measurement)-section and in the background section:

“An additional advantage of radiography is the possibility to evaluate more important information of the bony structures of the foot, especially preoperative. For example the quality of the joint surfaces and also other angles like the intermetatarsal angle, the distal metatarsal articular angle and the proximal phalangeal articular angle are relevant."[10]"
“Together with the degree of pain as the most important criterion for treatment decisions, the hallux deviation is also part of the selection criteria for conservative or operative treatment.”

2: “Regarding the radiographic measurement method certainly is a valid and accepted method. But it is accepted especially for comparative studies in pre- and postoperative conditions in that has carried out a displacement of the distal region of the first metatarsal. In research studies axis is taken as the first metatarsal diaphyseal shaft means. But as this study has made this a uniform form, and is also a valid way among the many that are, I believe that for this comparative study is valid this form of measurement”.

We added the following additional information about the measurement method in the ‘Radiographic measurement’ section: “... and is accepted especially for comparative studies in pre- and postoperative conditions.”

3: “The authors could make a positive assessment of the baro and goni, as these two techniques have their share of profit. For example are indicative and might be considered clinically useful for evolutionary studies to avoid repeated irradiations, once it has established a first radiographic study.”

We added the next sentence in the background section: “...and the additional benefit to avoid repeated irradiation during follow-up”.

And we added the next sentence in the conclusion: “As an additional indicative measurement it might be considered to use these methods for evolutionary studies, once a radiographic measurement is done.”
Comments reviewer: Edward Roddy

Major Compulsory Revisions:

1) Background: Quoted prevalence estimates for hallux valgus (HV) range from 3.5% in healthy adolescents to 23.9% in an older, high-risk diabetic population. The best reference for the prevalence of HV is the systematic review by Nix et al (JFAR 2010), in which the highest prevalence was found to be 35.7% in the over 65s, somewhat higher than the 23.9% quoted above.

We added the reference of Nix et al to the literature and changed the percentage of the highest prevalence to 35.7% in the background and the abstract.

2) Background: Pain is stated to arise from pressure between bunion and shoe. It would be helpful to provide a definition for bunion, to emphasise that hallux valgus and bunion are separate entities, in contrast to the lay use of the term bunion to equate with hallux valgus.

We added the following sentence in the background-section: “Hallux valgus and bunion are separate entities, in contrast to the lay use of the term bunion to equate with hallux valgus. We describe a bunion as the prominence at the medial side of the ball of the foot, which is formed by the protruding metatarsal head and in many cases by additional bone formation, swollen skin and sometimes a bursa.”

3) Background: Diabetic neuropathy and rheumatoid arthritis (RA) are given as examples of causes of insensate feet. Sensory loss is actually a rare manifestation of RA and I suggest removing RA as an example.

We agree with the reviewer and removed RA as an example.

4) Background: The authors state that they were unable to find information on the level of agreement of different methods for the assessment of the valgus deviation of the hallux but have overlooked validation of hallux valgus assessment with digital photographs (Nix J Orthop Sports Phys Ther 2012) and the Manchester scale (Menz Rheumatology 2005) against radiographs.

We looked especially to clinical goniometry and plantar pressure and also used these terms to search in literature and thereby we overlooked the study of Nix indeed. The other study of Menz we already added in the literature, but we did not described this study in the background.

We replaced the sentence “We couldn’t find other information on the level of agreement of different methods for the assessment of the valgus deviation of the hallux.” into “Nix et al. investigated the reliability and concurrent validity of photographic measurements of the hallux valgus angle compared to radiographs. They found an intraclass correlation coefficients greater than 0.96 [23]. Menz et al. investigated the correlation of a clinical assessment grading scale (the Manchester scale scores) with hallux valgus measurements obtained from radiographs. They found a high correlation (Spearman’s rho = 0.73, P<0.01) [16]. Garrow et al. found a kappa score of 0.86 for the interobserver repeatability for the Manchester scale [24]. Roddy et al. found a kappa score of 0.82 for the observer repeatability for a five-grade hallux valgus scale developed from a photograph of a normal foot [25].”

We also added the reference of Nix to the literature. We will thank you for these suggestions.

See also remark 1 of Sheree Nix.

5) Methods: the analysis essentially makes three two-way comparisons of the three methods of assessing the HV angle – radiographs vs goniometry, radiographs vs computerised plantar pressure measurement, goniometry versus computerised plantar pressure measurement. It is more customary in a validation study of this type to compare measurements against a clearly defined gold standard. The methods do not clearly state which of the three was considered to be the gold standard in the analysis although the background and discussion suggest that this would radiographic measurement. Certainly, radiographic measurement is the best established of the three measures and the stated clinical applicability of the study is to provide an alternative method of HV assessment for podiatrists who do not commonly have access to radiographs. I
therefore suggest clearly stating radiographs as the gold standard and focusing the analysis on the comparison of goniometry and computerised plantar pressure measurement against radiographs. I do not think that the assessment of direct correlation between goniometry and computerised plantar pressure measurement is needed or helpful if radiographs are considered to be the gold standard.

In the methods section (paragraph about Radiographic measurement) we have described explicitly that the radiographic measurement is the gold standard. In this study we analyse the level of agreement of 2 alternative measurement methods with radiographic measurement and thereby the possibility to use them as an alternative for the measurement of hallux valgus. For professionals who do not have facilities for radiography, like most podiatrists in European countries, it is important that they know the level of agreement between the alternative measurement methods what they use now and possibly will use in the future for evolutionary studies.

6) Methods, pg 6: the description of the technique if clinical goniometry does not mention the number of measurements taken although three measurements is mentioned earlier in the methods on page 4. Detail of this aspect of the methods should be added on page 6.

We agree with the reviewer to mention this detail to the description of the technique of clinical goniometry. So we mentioned it now on page 6 too.

7) Assessment of intra-rater and inter-rater reliability of the three measurement techniques does not appear to have been undertaken. This is a major limitation of the study. The limitation of not assessing inter-observer variation is mentioned in the discussion but lack of assessment of intra-observer is worthy of acknowledgement also.

We agree that this is a major limitation of the study. We made it more clear now in the limitations section that the lack of assessment of the intra-observer variation is just like the inter-observer variation a limitation of this study and a disability to analyse the influence of these variations on the level of agreement. We added the following sentence to the limitation section: “The data of this study were not appropriate for assessing the intra-observer variation. These limitations prevents to analyse the influence of the intra- en inter observer variation on the level of agreement.”

8) Results, pg 6/7: it would be helpful to the reader for a guide to interpreting ICCs to be added.

We described the definition with a guide to interpreting ICCs in the method section (statistical analyses). We added the sentence: “The ICC is the portion of the patient variance in relation to the total variance.” to the following description: “We used a two-way mixed model to calculate the ICC. An ICC close to 1 means that two measurement methods have a high level of agreement and an ICC close to 0 that there is a lot of variation between two methods and a low level of agreement.”

9) Discussion: Some mention should be made of the limitation of undertaking this study in a diabetic population and the implications for generalisability. A logical next step would be to examine this in a more general population without pre-selection for any particular conditions such as diabetes. This should be mentioned.

We added the next sentence to the limitation section: “Although literature showed no arguments to expect that the presence of diabetes in our study population has no significantly influenced on the study methods or results, a possible next step should be to examine these measurement methods in a more general population to exclude any suspicion of the influence of the presence of diabetes on the generalisability.”

10) Discussion: Could the authors comment upon the discrepancy between the mean range of the difference between the measures and the ICC? For example for the comparison of goniometry to radiographs, the mean range of the difference is 19 degrees which I agree suggests some imprecision yet the ICC was 0.81 which is very good.
The ICC is the portion of the patient variance in relation to the total variance i.e. the sum of the patients and the variance by measurement errors. The range of the difference in the Bland Altman plot is determined by the measurement variance. Our population is quite heterogeneous with a HVA range between 0 and 55 degrees which determines the patient variance. As the patient variance is much larger than the measurement variance, the ICC will be fairly/very good (despite the large value of the measurement variance).

11) In the background, the authors suggest that the main reasons for wanting a robust quantification of the hallux valgus angle are to estimate the severity of the hallux valgus, to evaluate progression in time, as selection criterion for conservative or operative treatment, and to evaluate the effect of an intervention. Whilst some of these indications would require a more precise measurement technique, are there some indications for which the degree of precision demonstrated in this study would be sufficient?

We think that the added sentence in the conclusion is an answer on this question. See remark 3 of reviewer Carlos Piqué.

12) Conclusion: there is some discrepancy between the abstract conclusion which appears to suggest that clinical goniometry has some validity whereas the main text conclusion states that neither computerised plantar pressure measurement or goniometry should be used as an alternative to radiographic assessment.

To prevent discrepancy between the abstract conclusion and the main text conclusion we changed the abstract conclusion as follows: “There is an unsatisfactory agreement of computerised plantar pressure measurement and clinical goniometry for HVA compared to radiographic measurement of HVA, although radiographic measurement of HVA and clinical goniometry for HVA yields better agreement than computerised plantar pressure measurement and radiographic measurement. The traditional measurement technique, through radiographic measurement is preferable as HVA indicator.”

Minor Compulsory Revisions:
1) Methods, pg 5: typo “trail” should be “trial”

We changed “trail” into “trial”.

2) In various places, common truncations of two words are eg “couldn’t” should be “could not”

We changed all truncations of two words accordingly.

Comments reviewer: Sheree Nix

Major Compulsory Revisions
1. Background - The authors have provided a sound rationale for their study regarding the prevalence of HV in diabetic feet and potential foot complications such as ulceration. The authors have also correctly identified that the literature surrounding their research question is very limited. However, please consider including the following points and relevant background literature:
   a) The potential for categorical grading scales to assess hallux valgus clinically should be identified (Garrow et al., 2001; Menz & Munteanu, 2005; Roddy et al., 2007).
   b) Digital photographs have been proposed as a valid method of HVA assessment (Nix et al., 2012).


We thank you for your suggestion and added the literature to the background section:

“Nix et al. investigated the reliability and concurrent validity of photographic measurements of the hallux valgus angle compared to radiographs. They found an intraclass correlation coefficient greater than 0.96 [23]. Menz et al. investigated the correlation of a clinical assessment grading scale (the Manchester scale scores) with hallux valgus measurements obtained from radiographs. They found a high correlation (Spearman’s ρ = 0.73, P<0.01) [16]. Garrow et al. found a kappa score of 0.86 for the interobserver repeatability for the Manchester scale [24]. Roddy et al. found a kappa score of 0.82 for the observer repeatability for a five-grade hallux valgus scale developed from a photograph of a normal foot [25].”

See also remark 4 of Edward Roddy.

2. Background para 4 – the authors have used the term “reliability” in the context of comparing three different measurement methods. As the current study did not investigate reliability, please ensure correct use of the terms “reliability” and “validity” throughout the manuscript.

You have right and we changed the terminology in the text accordingly.

3. Methods para 1 – could the authors please clarify how patients were “randomly” selected for this study?

We used the opaque envelope method and we added this randomisation process to the text.

4. Methods para 7 – Following the sentence “a custom-developed Windows-based program (Novel-Ortho-Geometry) was used to calculate foot angles including HVA”, the purpose of the references (33, 36) is unclear. These prior studies do not appear to have used the custom software. Can the authors provide more details regarding the “Novel-Ortho-Geometry” software (i.e. is it commercially available)?

This software is commercially available via Novel GmbH. This is a company in Munich Germany that develops commercially available Pedography systems. Novel-ortho is the package and geometry is an allocation.

We added the following information: “The Novel-Ortho-Geometry software calculates geometric parameters of the foot from the pressure distribution measurement.”

We also added 2 references that used the same Novel-ortho software:
Hayes A, Seitz P: The average pressure distribution of the diabetic foot: can it be used as a clinical diagnostic aid? Clin Biomech 1997, 12:3-4

5. Results para 1 – the means, SD and range data could be more clearly presented in table format.

We added a table (Table 1) to present the data more clearly as a supplement to the text.

6. Results para 2-4 – similarly, a table would be helpful to describe this data

We agree with your advice and added a table (Table 2) to the text.

7. Discussion Para 1 – Regarding the discrepancy between the correlation coefficient reported by Sanders et al. (Spearman’s ρ = 0.91, p = 0.041) and the current study (ICC = 0.59, p < 0.001), the large differences in sample size and different statistical methods used by Sanders (i.e. non parametric stats) should also be noted.

We noted in the discussion section: “The large difference in sample size and the different statistical method used by Sanders et al. could also contribute to the discrepancy between the findings of the two studies.”
8. Discussion Para 3 – the authors have discussed the impact of soft tissues interfering with the measurement of HVA using goniometric and footprinting methods. Another important point for discussion should be the large systematic difference between the footprint measurements and other methods. The authors should attempt to explain why plantar pressure footprints gave systematically smaller HVA’s than the other methods. These resulting smaller angles are possibly caused by a different alignment of the hallux during gait in compared with static weight bearing? Can the authors also justify why dynamic footprints were used for this study, rather than static footprint analysis?

We agree with this remark and we added the next sentence in the discussion section: “Furthermore, in this study we used a dynamic plantar pressure measurement. Computerised plantar pressure measurement gave systematically smaller HVA’s than the other methods. These resulting smaller angles are possibly caused by a different alignment of the hallux during gait in compared with static weight bearing.”

The reason for the use of dynamic plantar pressure measurements in this study is that the dynamic condition is the most regularly used measurement condition with, in many cases, the most valuable information for daily clinical decision making.

9. The Discussion should include reference to validated categorical rating scales that are available to grade HV clinically (Garrow et al., 2001, Roddy et al., 2007), especially given that the precision of goniometry and footprinting techniques was shown to be lacking. Please refer to Comment 1.

We did a suggestion at the end of the discussion for the use of validated categorical rating scales to grade HV: “To grade hallux valgus clinically for podiatrist who do not have facilities for radiography with validated categorical rating scales is possibly a better alternative than the use of clinical goniometry or computerized footprint to make an exact measurement of the hallux valgus deviation [16, 23-25].”

10. Discussion para 5 – the authors mention “reproducibility” of the 3 measurement techniques, but reliability (test-retest or inter-rater) was not investigated by the present study. If this statement was intended to refer to previous literature, please cite references accordingly.

Indeed, we intended to refer to previous literature. Now we have added the text “… as described in literature …” in the text of the paragraph about Limitations and added literature references.

11. Figures:
The data contained in Figures 4-6 could be provided in table format (i.e. numerical ICCs with confidence intervals), to reduce the number of figures. Please also refer to Comments 5-6.

We added a table with the ICC and 95% CI. See remark 5-6. Formerly given reviewer comments were more enthusiastic about these presented figures and we think that a visual presentation format will help the reader to understand the information. We therefor hesitate to change them in a table format. If the reviewers opinion is to reduce the number of figures and remove table 4-6 we will agree with the decision.

12. Figures 7-9 (Bland and Altman plots) are very informative; however, the axes should be clearly labelled as per Bland, J. M., & Altman, D. G. (1999). Measuring agreement in method comparison studies. Statistical Methods in Medical Research, 8(2), 135-160.

We labelled the axes clearly in figure 7-9.

Minor Essential Revisions
13. Methods para 3 – please be consistent regarding the use of either “dorsoplantar” or “anteroposterior” radiographs – at present both terms are used interchangeably.

We changed the text and used the term dorsoplantar radiograph.
Discretionary Revisions


We followed your suggestion and cited the reference by Kilmartin in this section.

15. Suggest combining Figures 1-3 into Figure 1a, b, c to reduce the overall number of figures. When designing the layout of this figure it would be helpful for the reader to clearly compare the 3 different methods side by side.

We combined the figures 1-3 into figure 1a, b, c in accordance with your suggestion.

We hope that we have corrected the deficiencies that you had mentioned and have provided adequate answers on your questions.

On behalf of all Co-authors

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