Author's response to reviews

Title: Comparison of theoretical xation stability of three devices employed in medial opening wedge high tibial osteotomy: a finite element analysis

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Author's response to reviews: see over
We would like to thank both reviewers at this stage for their valuable and detailed comments that helped us to improve the manuscript. In summary, we have reorganized the structure of the Results and Discussion sections to be consistent with the order of the outcomes (point 25 from the reviewer 2) and tried to focus on the most interesting findings. The vast majority of the proposed references as well as some new citations were now included in the manuscript. The Introduction and Discussion sections were accordingly adapted. Furthermore, the paper underwent a native speaker review to improve the language style and increase its readability. The paper also underwent all other changes proposed by the reviewers. They are mentioned individually in the point-by-point revision below. The amendments in the Results and Discussion section were not highlighted as these sections were reorganized and the vast majority of statements were reformulated. Also the stylistic and linguistic changes were not highlighted to maintain the readability of the revised version. But all the other amendments were highlighted in grey.

**Reviewer’s reports**

**Reviewer 1: Faik Türkmen**

Medial opening wedge high tibial osteotomy is a technique that still remains its popularity. This study contributes to understanding of the mechanical property of the technique. Especially the use (performing) of several different gaps increases the value of work. Opening a 22.5 mm gap may not be required because this amount of gap is not widely practiced considering the average width of the tibia but does not reduce (decrease?) the value of work. I think it is a well-designed study and will contribute to the literature.

Thank you. We mention now the limited clinical relevancy of the opening wedge of 22.5 mm in the Discussion and cite the study by Nelissen et al., which documented significantly higher overall complication rate for large wedge openings.

**Level of interest:** An article of importance in its field  
**Quality of written English:** Acceptable  
**Statistical review:** No, the manuscript does not need to be seen by a statistician.  
**Declaration of competing interests:** I declare that I have no competing interests.

**Reviewer 2: David Elson**

**Decision:** Accept with major compulsory revisions

General comments to authors:
I have enjoyed reading and reviewing this manuscript. It represents a significant body of work. I can appreciate how much effort the authors have contributed in creating this manuscript which I think on balance will represent a sound addition to our scientific knowledge. Knee osteotomy is an expanding area of high clinical interest as surgeons search for realistic options for patients in the treatment gap; symptomatic from varus medial compartment OA but too young or too active to be considered for arthroplasty.

Thank you.
There are however several deficiencies in the manuscript which would need to be addressed with major revisions prior to being acceptable for publication. These deficiencies relate to:

a) minor language objections which are likely to have occurred where English is not the first language of the authors.
   The manuscript was now edited by a native speaker.

b) A restructuring of the results section would significantly improve flow for the reader.
   The Results section was restructured to be consistent with the order of the studied outcomes (see also point 25 below). Also we reformulated the vast majority of the statements.

c) Repetition of the results prose in the discussion section.
   The repetition is omitted now.

d) A distinct lack of some specific relevant references to put this work in broader context.
   We used the references proposed by you and searched for further publication. The list of cited work was now extended. We greatly appreciate the list of proposed references and acknowledge our insufficient literature research prior to the submission of the first manuscript version.

e) A need for a generic explanation of finite element analysis and then a modification of conclusions because this study is based upon a theoretical model. The conclusions need to be adjusted to reflect this before making recommendations to clinical practice.
   We include now a generic explanation of the FEA in the abstract and in the introduction. We adjusted the conclusion to highlight the fact that the findings are based on a theoretical model.

I make further specific comments below in order to assist the authors with the revision process. I hope that the authors agree to complete these revisions because I believe that their work could make an excellent paper.

Thank you! The specific comments were very helpful.

Specific comments to authors:

TITLE

1) The study is a theoretical model and this fact actually needs to be brought to the front of the title. I would suggest changing to:
   “A finite element analysis comparing theoretical fixation stability for devices employed in medial opening wedge high tibial osteotomy.”
   We amended the title as proposed with some reformulation. The title is now the following “Comparison of theoretical fixation stability of three devices employed in medial opening wedge high tibial osteotomy: a finite element analysis”.

MOW HTO are the “buzz words” here alerting the reader that this manuscript relates to the surgical methods employed in the modern latter years of knee osteotomy.[1]
We use now MOWHTO as the abbreviation throughout the paper.

ABSTRACT
2) 1st sentence in abstract & background: “medial” opening wedge. Additionally change misaligned knees to varus “malalignment”.

Done.

3) Abstract, 2nd sentence: The statement that studies comparing fixation devices are “very rare” is factually incorrect. I suggest that this sentence is omitted and from the abstract. Subsequently the second paragraph of background should be re-written to include these references [2-8] which are all highly relevant.

The statement was corrected.

4) A sentence introducing finite element analysis is needed in abstract methods for the uninitiated. Something along the lines of “FEA is a mathematical simulation, a geometrical model which is broken down into linked equations, run many times until a stable solution is reached.” This is my understanding of it but ideally a sentence introducing FEA from a standard text such as ISBN 0750663200.

We include now a sentence introducing FEA in the abstract and in the Introduction section of the manuscript.

5) Abstract line 10: “screw failure, the stresses ..”

Done.

6) I cannot find where you derive the maximum allowable value of 1.2MPa. Perhaps I have missed this ....? but it needs to be clearly sourced because this value is used to draw conclusions about screw stability. This should be referenced at the end of the methods section.

We added explanations for this value including a literature reference.

7) Abstract conclusion is too strong. You can only conclude that screw tension exceeds the allowable limit in all devices in this FE study. Higher stability for TomoFix than Puddu - yes but this is not a clinical trial with real patients testing weight bearing status post op. So the conclusion must be tempered to reflect this (especially in the abstract which is all that a proportion of readers will access.)

We adjusted the conclusion to highlight the fact that the findings are based on a theoretical model.

BACKGROUND
8) Line 1: Introduce abbreviation (HTO) in line 1 instead of line 12. You could use MOW HTO

We use now the abbreviation MOWHTO throughout the paper.

9) Line 1: Remove “and frequently used” because this depends on geographical / training and political factors which influence surgeon preferences and varies widely in different countries / regions.

Done.

10) 1st Paragraph, 3rd Sentence: “In the last decade their has been a renaissance of MOW HTO catalysed by the use of fixed angle stability plates with locking head screws”. You should add some further modern context references [1, 9, 10] here.

Some recent references were added including all the proposed ones.
11) 2nd paragraph. As for the above comment there are several papers in the literature [2-8] which address this field which need to be read, considered and written into this paragraph with appropriate referencing. As a general rule if you are make the statement “nothing exists in the literature” .....check again. The Luo reference[2] is the most relevant of these papers because it also uses FE models and is already publised in BMC Musculoskeletal disorders - clearly inclusion are comprision to your manuscript is essential.

We re-wrote the introduction considering the proposed and other new references.

12) Line 15 - be wary of the statement “not yet been reported” - are you sure this will be true after you have included the references above...
The statement was removed.

13) Line 16: Suggest “The use of bone grafting to increase mechanical strength remains controversial, whilst it may increase mechanical strength some authors have suggested that opening wedges can be left unfilled [11] which avoids the risk associated with gap filling with inert substances [12].”

We use the proposed sentence now.

14) The last paragraph needs to be rephrased with a stated hypothesis. I don’t believe you can extrapolate the findings of this study to a recommendation on weight bearing status in clinical practice so it may be wise to change your hypothesis to: “Alternative fixation devices generating different stability profiles in a finite element model was the hypothesis of this study.” Your manuscript goes on to prove this hypothesis, which in itself is a laudable achievement.

If you choose to pursue the weight bearing theme the most you can do is “suggest” that this could be extrapolated to weight bearing recommendations as a discussion point. To do this would require citation of additional clinical references, specific to the weightbearing topic (there are several) and you MUST limit these recommendations because this is a theoretical manuscript not a clinical one. This should definitely not be your main conclusion.

We agree and use the proposed hypothesis now.

METHODS

15) Again revisit your chosen sentence introducing the science of FEA before giving details of the software used.

We include now general explanation for the FEA method including the citation of a relevant book describing the method.

16) 3rd sentence. “Four models of fixation were analysed: 1) first generation Puddu plate, 2) second generation Puddu plate, 3) TomoFix plate (includes LHS) without bone graft, 4) TomoFix plate (includes LHS) with bone graft.”

Use numbered device “generations” rather than “old” and “new” because if another Puddu plate is brought to market in future what will this be called? “the new new Puddu”. Accordingly is the model based upon the standard 1st generation TomoFix plate? The square distal end in figure 1c suggests to me that this is the case ...(the 2nd generation TomoFix NG “Next Geration” is rounded at its distal entent ) but this needs to be stated in the text.

I suggest a sentence describing the basic characteristics of the 2 devices with a reference for each. Find one for the Puddu and use Staubli[11] for TomoFix.

The proposed amendments including references were now implemented.
17) Line 9 “…cross-sections was based upon a computerised....”
Done.

18) line 10. State that he his knee was asymptomatic - if this was the case
Done.

19) line 11: “The tibial bone model ended 140mm below the joint line.
Done.

20) line 15: above mentioned - SPACE
Done.

21) line 21: Am I wrong in thinking that the cortical layer was modelled in the area
from level 0 up to 140mm?. If it truly was 120mm then what happens between 120 -
140mm?
The cortical layer with constant parameters was modelled effectively between the
level h1 and h4 (0-120 mm). The thickness of the cortical layer differed between h0
and h4 (between 5.0 and 1.0 mm). No cortical layer was modelled between h4 and
h5 (120 and 140 mm). This is due to the fact that the thickness of cortical layer is
decreasing between the tibia metaphysis and the tibia head. At the latter level we
assumed a cortical layer around or below 1 mm, which allowed us to ignore
modelling of the cortical layer at this height and model cancellous bone only. We
include now a statement in the methods and in the limitations paragraph.

22) Line 22: Can you give a reason or better still a reference for why the modulus of
elasticity and Poisson’s ratio were selected. Likewise a reference for your choice of
parameters for cancellous bone would be informative.
We added now some references in this paragraph, based on which the parameters
for the models were selected.

23) line 24: h0 was not prevously defined in line 12. Is this a typo? or can h0 to h1 be
redefined.
We distinguish between parameters for cortical and cancellous bones at those levels.
We have slightly changed the text now to make it clearer.

24) paragraph 7: This corresponds to a resultant force of 800N and resembles full
weight bearing.
Done.

25) Paragraph 9: “Outcome measures included: 1) stresses in bone, 2) displacement
magnitudes, 3) stresses in fixation devices, 4) stresses in the screw channels.”
We amended the sentences as proposed with some adjustments.

26) “Screw channel analysis was conducted along the x-axis (Fig. 2) considering the
upper and lower surfaces of the channels.”
We amended the sentence as proposed with some adjustments and shortened it
further (considering comments 25 and 26 just above here).
27) This is a good place to now state a reference for the allowable threshold 1.2MPa. The reader may want to know what occurs if this threshold is exceeded - do the screws pull out?

We include now at this place the explanation for our assumption with a citation of the study by Hearn et al. We assume the maximum screw extraction strengths resulting in a screw fixation failure to be 842 N (according to Hearn et al. 352-842 N) and a screw parameters 50 x 4.5 mm. The latter parameters allow calculating the screw surface. The formula is:

\[ \text{Force} / 2 \times \pi \times (\text{surface of the screw}) = 1.19 \text{ MPa}. \]

RESULTS
28) The results section is too long and should be abbreviate. Suggest ways to achieve this:

a) Reorganise into the sections outlined in point 25 above. This will focus the readers attention upon each table in turn with the text then drawing comparisons between devices, which after all is the purpose of this manuscript. Just reorganise it for each feature of your FEA. Sentences which are repeated many times “Similarly as in the case of the old Puddu plate” can now be dropped.

The Results section was now reorganised to be consistent with the order of the studied outcomes (according to the point 25 above).

b) Some thought needs to be applied to which are the most salient results in order to distill out a purer and simpler message. I would be tempted to report only the relative displacement in table 2 (a proxy for instability in larger wedge gaps). Clearly other parts of the manuscript would need to be adjusted when this is removed but I really think the message will be clearer for this simplicity...."Less is more".

We have reformulated this section and deleted some statements in order to focus on the most interesting and relevant findings.

29) As a surgeon and not an engineer I am struggling with the captions and headers for the tables which need greater explanation:

a) Table 1 suggest: The “extremes of stress occuring” because there are minimums in the table so this should not be billed as a maximum.

b) I presume that the maximums are compression forces and minimums are tensile forces? I am therefore unsure what the final column in table 1 “Miz” repesents can you define this abbreviation in the caption

c) Table 2: suggest reporting only relative displacement, perhaps as whole numbers 10^-6

d) Table 3: Can you define “Mis” column

All headers for the tables were adapted as proposed to simplify their interpretation for laymen. “Mis” is explained as the vor Mises stress (shear stress).

30) I have concerns that only Table 4 only describes 6 holes for the TomoFix device, the tomofix has 8 holes:


I assume that A-C are grouped together as hole 1 in the FEA of this study but this needs clarification and it would be better if the holes were defined in Table 4 and throughout the manuscript in the way that the manufacturer labels them in order to prevent future confusion.
It is absolutely correct that the TomoFix plate has 8 screw holes. For the modelling we considered only the 6 screw holes lying in the axis Z to assess only a symmetrical problem. We include now an according statement in the limitations.

DISCUSSION

31) Please start discussion with the sentence. “The main findings of this study were....” summarise in to 1 or 2 sentences then elaborate on this with reference to the literature.

There is considerable unnecessary duplication in the discussion (for example paragraph 1 is largely repeated from the introduction) and is not needed

We start now the Discussion section with description of the main findings and their interpretations as well as citations of the relevant literature.

32) Line 2-3: Some surgeons allow full weight bearing after HTO because they trust the stability of the Tomofix sufficiently. So don’t make the sweeping statement that all patients rehabilitate partially weight bearing with crutches as the reality is that this practice varies depending on the bravery of the surgeon.

We changed the discussion accordingly.

33) Line 10: Drop the Eastern Europe line Puddu and Tomofix are used in many different countries so your generalisability is more global.

We changed the discussion accordingly.

34) Paragraph 3: It seems counterintuitive that the larger wedge distance is more stable than the smaller one, so you need to hypothesize why this might have occurred - inaccuracies/assumptions within the model etc...

We include discussion of this issue in the paper now.

35) Paragraph 5: Further clarification of which holes 6/8 in the Tomofix Plate needed here- If the FEA was simplified from 8 to 6 holes here for analysis then you could discuss that here.

We include now an according statement in the limitations.

36) Paragraph 6: Beware of recommending bone graft without drawing attention to it’s potential clinical pitfalls. My understanding is that there are higher infection and non union rates[11, 12] where bone graft has been used, so readers must be alerted to these as caveats.

We have added an according statement on caution when using a bone graft and cite 2 references which reported complications while using a bone graft.

37) Paragraph 8: As previously stated some surgeons do allow full weight bearing in the post operative period. There is a Japanese series of simultaneous bilateral HTOs [13] who must have been fully weight bearing to get around. So please omit this sweeping statement “not prescribed”.

We have stepped back now from our previous argumentation on full weight bearing.

38) Avoid saying “forgotten”, again this is not true because many authors are aware of the evolution of knee osteotomies [1, 9] where Puddu plates feature as a key stage in development. Instead state: Device usage varies between countries. Puddu plate usage is higher in Eastern Europe where this study was conducted.

This sentence is omitted now.
39) The reference for your allowable limit at 1.2 MPa is essential to justify your conclusion. We explain the threshold in the methods and cite there a reference. See also above.

40) Move “Classic T shape” to earlier sentence introducing the Tomofix device. Done.

41) Soften the conclusion to the findings of this study in the context of FEA. Done.

Concluding comments to author's
I hope that you find this review constructive in terms of manuscript improvement and are not too disheartened by the number of recommended changes. There may be some minor language changes needed to a further revised submission but if you are prepared to spend the time making these major changes the paper will be far better. Thank you for such detailed and very helpful comments!

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Several language corrections required before being published
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests: I have no competing interests to declare with respect to the manuscript that I have reviewed.

References


