Peer Review File

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Reviewer A

Abstract: Background Line 34 you mean >15° side to side difference
Reply: Agree
Changes in the text: additional was changed by native (line 34). However, because another reviewer suggested to shorten the background, the complete sentence was deleted.
Line 40 facilitating rather than easing
Reply: agree
Changes in the text: done (line 40)
Line 42 anterior or posterior groin pain?
Reply: anterior
Changes in the text: anterior was added on line 42
Line 45 persistent hip pain?
Reply: agree
Changes in the text: the word hip (line 45 was added)
Line 46 endo rotation: do you mean increased femoral anteversion?
Reply: yes, we prefer the word 'endotorsion' or 'endorotation' for clinical description of the limb and 'anteversion' for imaging analysis (CT-scan).
Changes in the text: added 'CT-scan showed a side to side difference of 36° anteversion' on line 47-48 while deleting (36° on CT-scan) on line 46.
Use side to side difference of 36° (46° on operated side on CT scan and 10° on asymptomatic side)
Reply: Agree
Changes in the text: see suggestion above
Line 47 subtrochanteric femoral derotation osteotomy
Reply: Agree
Changes in the text: 'femoral' was added on line 48
Line 62 side to side difference
Reply: Agree
Changes in the text: added on line 63-64 (relative to the preoperative FAVA was deleted)
Line 89 and 90 againg endorotation: you mean increased femoral version, see above
Reply: yes, we prefer the word 'endotorsion' or 'endorotation' for clinical description of the limb and 'anteversion' for imaging analysis (CT-scan). However, we think that 'increased femoral version' can be appropriate here as well.
Changes in the text: 'increased femoral version' was added on line 96 (endo-rotation was deleted)
Line 108 exo rotation: you mean reduction of femoral anteversion?
you could say that the distal femur and the foot were rotated externally if this is what you mean

Reply: This is what we mean.
Changes in the text: ‘reduction in femoral anteversion’ was added on line 129-130 (distal exo-rotation deleted), ‘by external rotation of the distal femur’ was added on line 130 (in this case deleted)
Line 150 more recent references would be good.
Reply: Not sure what exactly needs support by references on this line.
Changes in the text: No changes so far
Line 150 please provide the total costs of this printing procedure
Reply: The cost for 3D guide ordering, material and printing was 150 euro.
Changes in the text: (150 euro) as added behind the guide manufacturing on line 186.
Line 158 side to side difference of femoral anteversion
Reply: agree, although another reviewer suggested to delete this sentence because not part of the conclusion
Changes in the text: First 2 sentences deleted as suggested by other reviewer.
Figure legends: please correct spelling errors (blue instead of bleu) in Figure 1.
Reply: agree
Changes in the text: corrected accordingly
Figure 3 figure legend: you mean 36° reduction of femoral anteversion?
external rotation of the distal femur and foot you mean?
Reply: Agree
Changes in the text: Figure 3 caption: ‘reduction of femoral anteversion’ was added. (external rotation was deleted).

Reviewer B

The article entitled "Patient-specific 3D printed guide for femoral derotation osteotomy: a novel case-based surgical technique" presents an interesting surgical technique taking advantage of customised 3D printing. However, it raises a number of issues that need to be clarified before publication:

- The authors explain that the vertex of the angle that serves as a reference for the correction is placed eccentrically and not in the centre of the bone. Could this mean a wrong correction at the moment of rotation? Please explain in the article.
Reply: The angle (vertex?) of both pins in the strict axial plane was 36° during planning and peroperatively (intended correction). One pin was placed more posteriorly (cortex) and the other more anteriorly (cortex), both eccentrically hereby not interfering with the nail. When correcting in the strict axial plane, it is irrelevant if the pins are placed towards the center or eccentrically. The amount of rotation needed before pins are parallel is the same. After derotation and the pins are placed in the center, it is true that they will also lay in the same sagittal plane while this is not true for pins placed eccentrically. However, an axial correction error can not be made either way.
Changes in the text: We added the following sentence in discussion line 177-178: ‘Either central or eccentrical placement of pins is irrelevant to the amount of rotation needed before pins become parallel.’

- After reading references 3 and 7 given by the authors, it seems that one of the differences is that these works have a guided cut. However, as described in the present article, here there is no a cutting guide: How do the authors control the direction of the cut? The fact of not making a guided cut could lead to the generation of a varus or valgus, how can this be avoided?

Reply: We do agree that a cutting slot was not provided in the guide while this was true for previous described 3D guides for derotation osteotomies. We think that a cutting slot or additional guidance pin can be implemented when performing another derotation case with this guide. For now, the authors performed a bone cut perpendicular to the femoral shaft between the placed pins after the guide was removed. However, we do not think a varus or valgus malalignment can be induced this way. The introduction of press fit nail and presence of the intramedullary rod will avoid this complication. Nevertheless, when a slight angulated cut relative to the perpendicular axis is performed, osteotomy fragment might not fit perfectly after derotation. Neither clinically nor radiologically, this was true in the current case.

Changes in the text: We added the cutting slot remark as technical downside of the guide in discussion (line 192-194)

- In relation to the previous point and the lack of a guided cut, it appears that this technique could only be used for pure axial deformities without varus and valgus. Please discuss this in the article.

Reply: The aim of correction was pure in the axial plane without the need for a varus or valgus correction of the femur in the coronal plane. We therefore recommend the current guide only for single plane derotation osteotomies.

Changes in the text: The authors think this doesn't need to be further explained in the manuscript since varus/valgus corrections are falling beyond the scope of this paper.

- Why do the authors place the guide in that specific position and not, for example, in a more distal location?

Reply: The authors hypothesized that placing the guide in the post-traumatic zone would increase the chances of exact placement due to additional bone landmarks on CT (callus). This is illustrated by the bony groove in figure 2a. Derotation osteotomies are described at several levels on the femur (supracondylar, diaphyseal and subtrochanteric) but plain bony surfaces should be avoided risking false guide placement.

Changes in the text: In caption of figure 2a a note was added about the bony groove that facilitates correct guide placement.

- As it is such a small guide, how do the authors manage to adapt it or fit it correctly to the surface of the bone and without it being able to move during the intervention?

Reply: Which was not mentioned in the manuscript was the additional 3D print of a phantom model of the subtrochanteric femoral area and the guide itself. The phantom was used perioperatively so guide placement could be copied. As mentioned above, the bony groove and callus formation determined corrected guide placement.

Changes in the text: Under the section of '3D planning and guide design' the following

sentence was added ‘In order to facilitate correct guide placement, a phantom of the subtrochanteric femoral area and the guide was 3D printed in non-medical resin for perioperative use.’ (line 133-135).

- Only two intracortical needles are used in this intervention. The fact that it is difficult to place them in the cortical bone due to its hardness could cause deviations in the placement of the needles and therefore in the correction.
Reply: The authors understand this comment. Therefore, before K-wire placement (2.0), the holes in the guide were predrilled with a new and sharp 2.5 drill bit which makes K-wire deviation unlikely to occur.
Changes in the text: the word ‘new’ was added before 2.5mm drill bits on line 143 (surgical technique section)

- The authors should add other control tests such as Rx or long leg radiographs to better show the final result.
Reply: Agree. Full leg Xray was not available but pre-derotation and post-derotation Xrays of the femur with nail in situ were added to the figures (Figure 6).
Changes in the text: Figure 6 was added in the figure file. ‘with central location of the nail distally’ was added on line 163-164.

- Please explain each image in figure 4 in the figure legend.
Reply: Agree.
Changes in the text: Figure 4 was subdivided into Figure 4a, 4b and 4c. Each accompanied by a specific text.

Reviewer C

This is a nice case report presenting a surgical technique which is based on a 3D printed cutting guides.

3D technology is a very strong tool for virtual preoperative planning and for the usage of printed patient specific instruments. It improves surgery accuracy and reduces operation time and complications. The surgical technique that the author’s kindly share with us is original and should be published. However , the paper should be revised before publication.

This is a simple case report and should be presented in a very straight forward manner

The introduction section is too long and should be shortened significantly. The main topic is the 3D new technology and not the mal-rotation deformity .

lines 55-76 should be summarized into few short sentences.
Reply: Agree
Changes in the text: The introduction was rewritten in a more balanced way although maybe not significantly reduced in length. However, since the journal has a broad scope on medicine,

we think that the length and info in the introduction is required for understanding the topic for the non orthopaedic readership of the journal as well.

I also warmly recommend on shortening the abstract background section (lines 32-40)
Reply: Agree
Changes in the text: The background section was reduced to 3 concise sentences. (line 33-40)

Line 98 : Figure 1a doesn't present the mirroring technique, moreover, for rotational deformity the axial view is usually used and not the coronal view.
Reply: Agree. The axial view of the CT scan was presented in figure 3. However, we think that during planning, the axial view is indeed more important to illustrate than coronal views.
Changes in the text: We added the axial views mirrored (anteversion) preoperatively, planned and postoperative segmentation (D) to Figure 1.
Figure 3 : Please Use the segmented axial view to present the FAVA angle and use the same slice level for before and after operation.
Reply: The axial segmented views of the planned and postoperative CT scan are illustrated in figure 1D. However we think that the CT slides on figure 3 are still useful to illustrate the difference between both limbs preoperatively.
Changes in the text: figure 1D and caption
Line 104 : Figure 1 c and figure 2 should be united
Reply: Agree.
Changes in the text: Figure 1c was added to Figure 2 (a-c) each with specific description.
Line 117 : " position was checked with fluoroscopy " , please explain what did you check in order to confirm that the 3D guide is in place ?
Reply: Correct guide positioning was confirmed in several ways. First, the clinical fit of the guide in the bony groove that was caused by callus formation in the fracture zone (figure 2b). Second, height placement of the guide was checked on fluoroscopy as showed by figure 4a. Third, which was not mentioned in the manuscript was the additional 3D print of a phantom model of the subtrochanteric femoral area and the guide itself. The phantom was used perioperatively so guide placement could be copied. Finally, guide placement was correct only when unicortical drilling through both guiding holes was successful.
Changes in the text: Under the section of '3D planning and guide design' the following sentence was added 'In order to facilitate correct guide placement, a phantom of the subtrochanteric femoral area and the guide was 3D printed in non-medical resin for perioperative use.' (line 133-135).

Line 117 : Figure 4 should positioned as Figure 3
Please give information about the printed guide (material, sterilization……) did you print it in house?
Reply: The 3D guide was a disposable Aluminum (AlSi10Mg) device printed externally and sterilized onsite in an autoclave with saturated steam at 134°C for 3.5 hours.
Changes in the text: This sentence was added at line 132-133.

Discussion :
Lines 138-148 should be shortened , you don't need to repeat on the surgical technique.
Reply: Agree. The primary section of discussion was reduced.
Changes in the text: Line 174-177 was deleted, 'eccentrical' was added on line 171.
Line 155-158 : not relevant , you present a surgical technique and not a review of post operative malalignment .
Reply: Agree.
Changes in the text: Line 196-199 in the new manuscript deleted.
In general the discussion section should be revised and focus on the advantages and innovation of 3D technology .
Reply: Agree, all advantages of 3D were listed in a paragraph from line 173-184, also followed by the downsides (line 185-195).
Changes in the text: See more focused discussion section.

Reviewer D

Abstract
Shortening is possible without losing relevant information.
Reply: Agree.
Changes in the text: The abstract background was shortened by two full sentences
Line 33: delete "surprisingly". Integrate the first sentence into the second.
Reply: Agree.
Changes in the text: 'surprisingly' was deleted on line 33. The second sentence of the abstract was deleted as suggested by another reviewer.
Line 36: Is it really necessary to wait for fracture consolidation? This procedure could be done early postoperatively, which would eliminate the need for an osteotomy.
Reply: No, in this case, the patient presented at 3 months after primary nail when the fracture was consolidated. An osteotomy was the only option. Overall, we think that axial malalignment after nailing is often discovered only after 4-6 week stage when the patient starts walking without support and subjective complains about groin pain and limping start. Unfortunately at this, most fractures are united. However when noticed early, a derotation over the non-united fracture is indicated without osteotomy.
Changes in the text: 'Once' was replaced by 'Supposing' (line 36)
Line 37: add that one main difficulty is the in situ lying nail.
Reply: Agree.
Changes in the text: 'despite in situ nail interference' was added (line 37)

Introduction
Well written. Find some specific comments below:
Line 58: maneuver
Reply: Agree.
Changes in the text: Changed accordingly (line 59)

Line 60: internal rotation instead of endo-torsion; to keep non-orthopaedics informed correctly, consider to state the normal range of femoral anteversion, which is approximately 15±10°.

Reply: Agree.

Changes in the text: endo-torsion was replaced by internal rotation (line 61), the normal value for FAVA were added behind the abbreviation line 62-63 with adding an additional reference (doi 10.1093/ptj/84.6.550)

Line 63/64: Valgus malalignment Relevant mechanical leg axis deviation might be expected in case of >20° maltorsion (https://pubmed.ncbi.nlm.nih.gov/35031820/) . However, increased femoral antetorsion results in increases femoropatellar contact pressure. Cite the following articles here: https://pubmed.ncbi.nlm.nih.gov/32785758/ and https://pubmed.ncbi.nlm.nih.gov/30269169/

Reply: Agree.

Changes in the text: Valgus malalignment was deleted. The suggested sentences were embedded in the manuscript together with the suggested citations. (line 63-67)

Line 69: this sentence is confusing. Not the excessive callus makes the maltorsion symptomatic. Rather altered gait is the problem. Either patients walk with the foot directed straight forwards (and rotate the hip joint in our outwards, resulting in malpositiong of the greater trochanter with impact on the abductor muscles) or with the foot pointed out or inwards (depending on the deformity). Therefore, correct this sentence and add this reference: https://pubmed.ncbi.nlm.nih.gov/35067083/

Reply: Agree. The sentences was corrected to 'However, most axial malrotations become symptomatic in the later phase of rehabilitation because of altered gait (toeing-in/-out or abductor muscle malfunction) when fracture consolidation is almost reached' + added suggested reference. (line 72-75)

Changes in the text: idem

Line 71: it should say: subtrochanteric OR diaphyseal

Reply: Agree.

Changes in the text: corrected on line 76

Line 72: Derotation osteotomies are indeed challenging procedures. However, it is also possible without PSI. Therefore, the reviewer suggests, for the sake of simplicity, to combine these two sentences as follows: Femoral derotation are technically demanding procedures which is why careful preoperative CT-based planning of FAVA correction is key to successful outcome.

Reply: Agree.

Changes in the text: Both sentences were merged. (line 77-79)

Line 74: Delete "However"

Reply: Agree

Changes in the text: Corrected on line 79

Line 78: use passive voice: delete the authors believe. Adapt as follows: …PSI can contribute to the improvement.

Reply: Agree.

Changes in the text: Sentence changed to 'With the increasing accessibility of preoperative 3-D planning and printing in orthopaedics nowadays, patient specific instrumentation (PSI)

can contribute to the improvement in performing femoral derotation osteotomies.' On line 82-84.

Line 81: it is not a novel technique, rather an alternative technique to previous reports (https://pubmed.ncbi.nlm.nih.gov/34217344/)

Reply: Agree.

Changes in the text: Novel was changed by alternative and the suggested citation was implemented.

Case presentation

ok

Line 89/90: international rotation of the foot instead of endo-rotation

Reply: Agree. The reviewer probably suggests 'internal rotation'. However, another reviewer suggested 'increased femoral version'. As such a detail, we think both terms are interchangeable and both appropriate and clear in the context.

Changes in the text: 'increased femoral version' was kept.

3D planning and guide design

Ok, but can be shortened substantially without losing information.

Reply: We think this section needs its length since focus is going to the technology and planning process.

Changes in the text: Additional details about the guide and the use of a phantom non-sterile model was added at the end of the section. This was suggested by other reviewers (line 118-121)

However, there are several aspects that are missing. As we use PSI for several years now at our clinic, I have the following questions: 1) which references (individual anatomical landmarks) were used to ensure correct placement of the cutting guide? Please state, if correct, that placement of the guide was allowed and facilitated thanks to the specific posttraumatic circumference of the femoral shaft.

Reply: Correct guide positioning was confirmed in several ways. First, the clinical fit of the guide in the bony groove that was caused by callus formation in the fracture zone (figure 2b). Second, height placement of the guide was checked on fluoroscopy as showed by figure 4a. Third, which was not mentioned in the manuscript was the additional 3D print of a phantom model of the subtrochanteric femoral area and the guide itself. The phantom was used perioperatively so guide placement could be copied. Finally, guide placement was correct only when unicortical drilling through both guiding holes was successful.

Changes in the text: Under the section of '3D planning and guide design' the following sentences were added 'Correct guide placement was facilitated by specific post-traumatic marks in the subtrochanteric zone (Figure 2A/B)' (line 124-126) and ''In order to facilitate correct guide placement, a phantom of the subtrochanteric femoral area and the guide was 3D printed in non-medical resin for perioperative use.' (line 133-135).

2) No integrated stabilizing arms in the guide design are shown (Figure 1 and 2). Was the cutting guide stable enough?

Reply: Yes, the guide positioning felt stable based upon the bony groove it was fitting in (Figure 2B). Correct eccentrical unicortical drill bit fixation confirmed the precise position of the guide and so the K-wire that were later introduced in the drill holes.

Changes in the text: No specific comments added to the text.

3) How was the osteotomy level determined? □ After careful preoperative 3D planning, the jig should guide the surgeon to the correct osteotomy level, allow easy placement and stable fixation.

Reply: We do agree that a cutting slot was not provided in the guide while this was true for previous described 3D guides for derotation osteotomies. We think that a cutting slot or additional guidance pin can be implemented when performing another derotation case with this guide. For now, the authors performed a bone cut perpendicular to the femoral shaft between the placed pins after the guide was removed.

Changes in the text: We added the cutting slot remark as technical downside of the guide in discussion that can further be optimized (line 192-194)

Line 97: use passive voice

Reply: Agree.

Changes in the text: Changed accordingly (line 103-104)

Line 108: external rotation instead of exo-rotation

Reply: Agree.

Changes in the text: Also suggested by another reviewer and changed accordingly (line 129-130).

Surgical technique

Shortening possible without losing information.

Reply: Agree.

Changes in the text: Your suggestions were implemented where possible.

Why did the authors use a new IM rod after removing the PFNA? Was reduction over the in situ lying PFNA nail not a considerable option?

Reply: With the nail in situ, it seems impossible to perform an osteotomy at the level of the medial cortex. After drill bit placement, the nail was removed and a IM rod was introduced which was in situ during the osteotomy. Major displacement between the proximal and distal part could be avoided this way. So the derotation itself was performed over the IM rod until both K-wires were parallel and fixed with hintermann retractor. A new IM nail was than introduced and locked (for sterility/infection prevention reasons).

Changes in the text: No changed needed.

Is there an explanation why the guide was fixed using 2.5mm drill bits instead of thicker K-wires or Schanz pins? If the 2.5mm drill bits are exchanged with 2mm K-wires, guide stability might be lost.

Reply: First new sharp drill bits were used to go easily to through the thick unicortical bone without deviation which you might expect if starting with K-wires. The difference of 0.5mm between drill bit and K-wire is a correct remark, although pin fixation felt stabile during surgery with minimal toggling. Overall it is more about pin stability (36° in the axial plane) than guide stability. Guide stability was primary determined by the phantom example and bony unevenness.

Changes in the text: No changed needed.

Why did the authors use a 1mm saw blade? This results in much more bone loss compared to a 0.8mm saw blade.

Reply: 1.0mm sawblade was only available in the OR. We think bone loss between 1.0 and 0.8mm saw is minimal when performing a straight perpendicular cut through the femur.
Changes in the text: No changed needed.

Line 111: Delete "Under general hypotensive anaesthesia and after administration of prophylactic IV antibiotics"
Reply: Agree.
Changes in the text: Deleted (line 137)

Line 112: delete "after disinfecting and sterile draping"
Reply: Agree.
Changes in the text: Deleted (line 138-139)

Line 114: add "corresponding to a direct lateral approach to the proximal femur"
Reply: Agree.
Changes in the text: Added (line 140-141).

Line 119: was introduced into the femoral canal
Reply: Agree.
Changes in the text: Added (line 147).

Line 127: this is the third time that the authors mentioning that the K-wires did not interfere with the new PFNA nail.
Reply: Agree.
Changes in the text: 'As the K-wires…' was deleted. 'easily' removed and 'with k-wires in situ added (line 158)

Line 134 ff: for which = linguistic error. Please edit.
Reply: Agree.
Changes in the text: Changed to 'so' (line 165)

Discussion

Overall, I would suggest to summarize the first paragraph into just 2-3 sentences.
Reply: Agree. Paragraph 1 counts 2 sentences now followed by the advantages of the technique.
Changes in the text: Line 168-172 adjusted.

There is too much repetition. My suggestion is to discuss the advantages, which are: 1) Placing K-wires without interfering with the nail that facilitate correction. 2) Especially low volume surgeons not familiar with rotational osteotomies might benefit from this technique.
Reply: Agree.
Changes in the text: Advantages outlined in line 173-184.

Line 138: please use passive voice "the here presented case-based surgical technique …"
Reply: Agree.
Changes in the text: Adjusted on line 168.

Line 139-141: facilitating surgical flow is not were scientific. Consider that surgeons with a high case load of subtrochanteric derotation osteotomies do not have to rely on cutting guides for surgical flow.

Reply: Agree.
Changes in the text: ‘especially for the unexperienced surgeon’ was added behind facilitating surgical flow (line 172).

Line 145: Compared to bulky guides, there might be less soft tissue damage … but probably at the cost of stability.
Reply: As mentioned above, stability of the guide was not an issue as long as the drill bits were placed correctly and stable. So we cannot admit to peroperative instability of the guide.
Changes in the text: None.

Line 149ff: In addition to downsides, please add thoughts and considerations how to improve this technique. Report the above-mentioned points: 1) reduction without nail exchange. 2) reduction without osteotomy before fracture consolidation occurs. 3) more stability versus less soft tissue damage. (+ adding a cutting slot)
Reply: (1) Reduction over the nails seems difficult for us, please explain how this is feasible for performing a complete osteotomy of the cortical bone. Further, IM nails are often tight in the femoral canal (reamed nailing) which makes rotation over an in situ nail not easy. (2) Agree, if discovered early, an osteotomy is not needed. (3) see remark above.
Changes in the text: the downsides were rewritten as suggested (line 185-195)

Line 155: This is not the conclusion of this case report. The conclusion is the new technique. Therefore, sentences of lines 155-158 should be deleted. Rather use the same conclusion as in the abstract. But without “facilitating the flow”.
Reply: Agree.
Changes in the text: Conclusion was adjusted accordingly. (line 199-204)

Figures
Good.

References
More recent articles needed. Therefore, cite suggested articles.
Reply: Agree
Changes in the text: The suggested articles are integrated in the text where appropriate. (see reply above).

Re-review comments
The authors have addressed most of the clarifications requested by this reviewer in a satisfactory manner. However, there is one point that they have yet to resolve.

The issue concerns the lack of a cutting guide. The authors indicate in the discussion that the addition of the cutting guide would guarantee a perpendicular cut of the femur. However, they have to specify that the cut has to be perpendicular to the mechanical axis and not to the diaphyseal axis, which is very difficult without a cutting guide.

Finally, it would be advisable to add an image of the 3D printed phantom.

A: In the discussion section, a perpendicular cut to the mechanical axis of the femur was added (line 161). An illustration of the phantom was added as ‘Figure 3D’ (line 113).