Author's response to reviews

Title: Biomechanical optimization of different fixation modes for a proximal femoral L-osteotomy

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Title: Biomechanical optimization of different fixation modes for a proximal femoral L-osteotomy

Dear Editor-in-Chief,

Thank you for your letter on June 10, July 23 and for the editorial work on the manuscript we submitted to *BMC Musculoskeletal Disorders*. The authors have read the comments and suggestions made by the reviewers with care. We have directly incorporated their suggestions or changed the text to address each of their concerns. All changes in the revised manuscript are highlighted in bold. Our responses to the referees’ comments are listed below, and we deal with each issue in a point-by-point manner. We hope that with these changes our manuscript will meet the criteria for publication in *BMC Musculoskeletal Disorders*. We thank you again and look forward to hearing from you soon.

**Response for editorial office:**

**Comment on letter from editorial office (July 23):**

Please clarify ethical approval. A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate

**Reply:**

A statement “This study was approved from the committee of National Science Council of the Republic of China (Contract Number: NSC92-2218-E-182A-001)” had been added in the “Method” section. *(Page 8, Line 3)*

**Response for reviewer #1:**

Thank you for your review. We have carefully read the comments and suggestions. Below we list your comments and deal with each issue in a point-by-point manner.

**Minor Essential Revisions:**

Figures 5 and 8 would be much clearer if a color image was provided.
Reply:
As per the reviewer’s suggestion, the original Figures 5 and 8 had been replaced with color images. (These two figures are shown as Figure 6 and 9 in the revised version)

Figure 7 needs to have a title on the graph itself.
Reply:
As per the reviewer’s suggestion, a title of “Vertical Displacement of Femoral Head” had been added in Figure 7. (This figure is shown as Figure 8 in the revised version)

It would be helpful if an image was included that shows the mesh used in the models.
Reply:
As per the reviewer’s suggestion, an additional figure (Figure 5) showing the FE mesh accompany with the loading configuration used for FE analysis had been added in the revised manuscript.

In the discussion section, first paragraph, second sentence the word ‘exist’ is repeated. “Many surgical procedures exist for treating these patients exists, but ….” Consider revising to “many surgical procedures exist for treating these patients, but ….”
Reply:
Thank you for your correction. This error had been corrected in the revised manuscript. (Page 15, Line 5)

In the finite element model the screw threads and tips are not modeled for simplicity sake. It would be very interesting to include those threads and determine if any changes would be seen in the stresses produced. This may not be necessary for publication, but some discussion of this in the paper would be a good inclusion.
Reply:
As per the reviewer’s comment, the following statement had been added in the “Discussion” section in the revised manuscript: In the finite element model, the screw threads and tips are not modeled because FE models with screw threads and tips will result in a large increase of element number and computation time. The simplified FE models without taking threads and tips into consideration may have an impact on the analytic results for local area close to the screw/bone interface. However, we believe these may not cause a global effect on the resultant FE analysis. (Page 17, Line 7)

Major Compulsory Revisions:
Model development: The models used are described as a solid model of the left and right femurs of a patient with hip dysplasia. It is unclear if both the cortical bone and trabecular bone structures of the femur were modeled (a figure would be very helpful to explain this). It seems from the description given in the text and in the material properties used that the femur was considered as a single solid material. This is not the case in vivo where the femur is a heterogeneous, anisotropic composite material. If indeed the models considered the femur as one homogenous isotropic material this is a serious limitation to the study. This needs to be clearly stated and discussion of what affect this may have on relating the results predicted by the current models to a clinical situation must be included in the manuscript.

If the model is not of a single solid material this should be made clear in the description of the model in the methods section. Again, a figure showing the mesh used would be very helpful here.

**Reply:**

1. In current study, both the cortical bone and trabecular bone structures of the femur were modeled. The material properties for cortical bone, cancellous bone and fixation devices were mentioned as follows:
   The Poisson ratios and moduli of elasticity used for the cortical bone, cancellous bone and fixation devices were set as 0.3, 0.22, 0.3 and 15.1 GPa, 445 MPa, and 190 GPa, respectively. (Page 11, Last Line)

2. To more clearly clarify this concern, the following description regarding the creation of solid models was added in the revised manuscript:
   The CT scan images of the intact femur were obtained at 1.25 mm intervals in the transverse planes starting from the femoral head using a GE Hi-speed scanner (General Electric, Milwaukee, WI, USA). The resolution for each of the CT scan image was 512 by 512 pixels, the field of view was 330 mm, and the pixel size was 0.625 mm/pixel. The cross-sectional image files of the femur were transferred to a custom-written automatic contouring program (Caotool) for the detection of the contours between the cortical bone and cancellous bone based on a dynamic density-thresholding algorithm. The parallel-stacked contours were then input into the Solidworks CAD software for the reconstruction of 3-D intact femur solid models. (The first paragraph in the “Method” section)

3. An additional figure (Figure 5) showing the FE mesh had been added in the revised manuscript.

Model validation: It is unclear from reading the text if the model is validated for the intact condition (without osteotomy) or for the osteotomy condition. This should be stated more clearly.
If the model was validated only for the intact condition what confidence to the authors have that the model is valid and relevant for use in investigating the osteotomy condition? This should be discussed as a limitation to the study and its potential effect on the results discussed.

Reply:
1. The authors are aware that the validation of our FE model should be conducted with osteotomy condition. However, as it is almost not possible to access the human cadaveric femur with residual deformities to perform an experiment with L-osteotomy, the validation of FE model is thus conducted using FE model created from the intact normal right femur of the same patient.

2. In order to validate the FE model, the results from previous experimental study (Shih et al., Clin Biomech, 1997) was used to compare with our FE analysis. In their experiment, the surface strains at the medial and lateral proximal femur under 2000 N vertical loading was recorded in fresh-cadaver compressive testing. To simulate this setting, an additional FE model was created from the intact normal right femur, and the surface strains at the medial and lateral proximal femur subjected to the same 2000 N vertical loading were also analyzed. The experimental and analytical results were compared for the validation of the FEA model. (Page 12, Last Paragraph)

3. Although the FE model was validated based on the intact condition without osteotomy, which may have an impact on the analytic results for the post-operative FE models with osteotomy. However, the boundary conditions including material properties (Poisson ratios and moduli of elasticity), element types (10-node, tetrahedral) and element length (4 mm) are identical for FE models with or without osteotomy, and we believe that our results provide useful information to orthopedic surgeons performing reconstruction of residual hip deformities with proximal femur L-osteotomy. (Page 17, Last Line)

4. The above statements had been added in the revised manuscript.

Response for reviewer #2:

Thank you for your review.
The authors would like to express our respect for your effort on the review of this manuscript. We have carefully read the comments and suggestions. Below we list your comments and deal with each issue in a point-by-point manner.

Reviewer's comments:
This study evaluates the biomechanical characteristics of a femur from a dysplastic patient who underwent an L-osteotomy surgical correction. This surgery aims to correct residual deformities by lengthening the femur and repositioning the greater trochanter. It is performed by sectioning the femur in two down from the trochanteric fossa and then re-securing in the desired position with a plate and bone screws. Two main variables are present in these surgeries: the number of fixations screws and osteotomy lengths. This study evaluated the impact of these two variables separately using finite element models (FEM). Using 3d reconstructions of CT data, simulated surgeries were performed. Finite element meshes of the bone and fixations were created and loaded with boundary conditions approximating single-legged stance, to obtain the von Mises stress distribution and femoral head displacement. No specific hypothesis was tested in terms of how variations of the L-osteotomy affect the biomechanics of the femur. Instead, a general hypothesis, that FEM can be used to understand the mechanical characteristics is proposed. The results provided meet this general goal. Overall, the methods were sufficiently described, but more could be included regarding the verification and validation of the models. Without this, the legitimacy of the FEM predictions is questionable, but it is most likely sufficient to evaluate trends between osteotomy variations. With N=1, no statistical analysis was performed on the results. Little was done to interpret the clinical significance of the obtained stresses and differences between screw placement and osteotomy length. The limitations of the work are clearly stated, and all previous work is appropriately acknowledged. The title and abstract accurately describe the findings of the study and overall, the writing is acceptable throughout the paper.

The following specific suggested revisions are labeled as follows:
(1) - Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)
(2) - Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
(3) - Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

Title Page: The title of the paper clearly describes the subject and purpose of the paper.
Abstract: No significant comments.
Background:
(1) The authors mention that 'the residual deformities compromise joint biomechanics and cause abnormal loading.' Could strengthen paragraph by explaining why abnormal loading and biomechanics is clinically relevant, i.e. What does it lead to, why should it be prevented long term through surgical correction?

Reply:
A statement “……and result in clinical symptoms: hip instability, limping gait, shortening of the extremity involved, limitation of range of motion in the hip and weakening of the hip abductors” had been added in the paragraph. (Page 4, Line 7)

(1) In paragraph 2, explaining the differences between Papavasiliiou's surgical approach versus the less successful previous methods.

Reply:
To clarify this concern, a statement “Although various procedures exist to treat patients with congenital hip dislocation or Perthes disease, residual deformities including leg length discrepancy, hip joint incongruity, proximal displacement of the greater trochanter, and poor joint biomechanics often persist that remain difficult to solve” had been added following the first sentence. (Page 4, Line 16)

(2) In the final paragraph, it is mention that the 'aim of this study [...] in subjects...'. Only one subject was evaluated in this study, so 'subject' should be used.

Reply:
We thank you for your correction; this error had been corrected in the revised manuscript. (Page 7, Line 6)

(1) Finally, the final paragraph could be strengthened by including why the finding of this study will increase postoperative longevity prior to mentioning it in the final sentence.

Reply:
The statement “These findings will be helpful to surgeons performing osteotomies and will also increase postoperative longevity.” had been revised as “These findings will provide preoperative planning to surgeons performing osteotomies and thus increase postoperative longevity” in the revised manuscript. (Page 7, Line 8)

Materials and Methods:
(2) Include CT scan information, like slice thickness, radiation parameters, etc.

Reply:
The following description regarding the CT information was added in the revised manuscript:
The CT scan images of the intact femur were obtained at 1.25 mm intervals in the transverse planes starting from the femoral head using a GE Hi-speed scanner (General Electric, Milwaukee, WI, USA). The resolution for each of the CT scan image was 512 by 512 pixels, the field of view was 330 mm, and the pixel size was 0.625 mm/pixel. The cross-sectional image files of the femur were transferred to a custom-written automatic contouring program (Caotool) for the detection of the contours between the cortical bone and cancellous bone based on a dynamic density-thresholding algorithm. The parallel-stacked contours were then input into the Solidworks CAD software for the reconstruction of 3-D intact femur solid models. (The first paragraph in the “Method” section)

(3) How was the femoral head center determined when the femoral head was not spherical?
Reply: The femoral head center was determined by fit circle method in Solidwork software. The fit circle method we used is the optimal circular approximations and optimizes the sphere that gives the best fit to the femoral head with minimum error.

(2) Why was the plate dimensions 'assumed' when they were obtained from the measurement of the actual plates? (Paragraph two of 'Generation of finite element model' section).
Reply:
Thank you for your correction. The statement had been revised as “A ten-hole plate fitting the bone contour of the lateral surface of the proximal femur was used for fragment fixation following L-osteotomy. The plate was in a width of 65 mm and a length of 150 mm obtained from the measurement of the actual plate (Synthes, Bettlach, Switzerland).” in the revised manuscript. (Page 10, Line 5)

(3) How might the simplification of modeling the fixation screws with no threads have affected model results? This simplification should at least be addressed in the discussion.
Reply:
As per the reviewer’s comment, the following statement had been added in the “Discussion” section in the revised manuscript:
In the finite element model, the screw threads and tips are not modeled because FE models with screw threads and tips will result in a large increase of element number and computation time. The simplified FE models without taking threads and tips into consideration may have an impact on the analytic results for local area close to the
screw/bone interface. However, we believe these may not cause a global effect on the resultant FE analysis. (Page 17, Line 7)

(1) Why was single-legged stance chosen over all other loading scenarios?

Reply:
In current study, the single-legged stance was chosen because it is convenient to adopt the loading conditions such as the location and angle of the applied forces from previous literatures. The concern only single-legged stance was simulated had been addressed in the limitation.

(3) A description of the location and angle of the applied forces should accompany the load values

Reply:
An additional figure (Figure 5) showing the location, angle and magnitude of the applied forces was added in the revised manuscript.

(2) How was the strength of the glue contact elements chosen?

Reply:
The value for the strength of the glue contact elements was adopted from previous literature. (Huang et al., Clin Biomech, 2003), this reference had been added in the list of reference. (Reference 17)

Results:
(3) A more detailed description of the verification and validation of the FEM should be described in the Methods section.

Reply:
As per the reviewer’s comment, a more detailed description of the verification and validation of the FEM had been added in the last paragraph in the Methods section. (Page 12, Line 3)

(2) For the verification of the model, it is unclear that a substantially refined mesh was achieved. While it is mentioned that the total strain energy predicted by four models were within 5% of each other, this does not blatantly state that enough elements were used for convergence, which could be done by including the percent difference between the most refined and second most refined meshes. What is the significance of 5% difference, clinically? Would this difference impact the results and how they may be interpreted?

Reply:
Results of convergence test demonstrated a less than 5% changes in the total strain energy among four models. The element numbers for four different models with average element lengths of 4, 5, 6, and 7 mm were 92749, 54634, 35031, and 28087, respectively. The total strain energies for each model were 4.131, 4.055, 4.006 and 3.952 J, respectively. The percent differences of the total strain energy compared with that of the finest mesh (element number: 92749) for each of the three models were 1.836%, 3.021%, 4.324% respectively. Although the results indicated that convergence was achieved, the geometry in the medial aspect of femoral neck for FE model with 5 mm element size were somewhat distorted. Therefore, the model with an average element size of 4 mm (element number: 92749) was chosen as the base model for the creation of post-operative models.

The above statement had been added in the “Results” section in the revised manuscript. (Page 13, First Paragraph)

(3) Was the interface behavior between the screws and bone validated? It seems that only the bony portions of these models were validated, but a validation of both the metal pieces and how they interact as a system was not been performed.

Reply:
1. The authors are aware that the validation of our FE model should be conducted with osteotomy condition. However, as it is almost not possible to access the human cadaveric femur with residual deformities to perform an experiment with L-osteotomy, the validation of FE model is thus conducted using FE model created from the intact normal right femur of the same patient.

2. In order to validate the FE model, the results from previous experimental study (Shih et al., Clin Biomech, 1997) was used to compare with our FE analysis. In their experiment, the surface strains at the medial and lateral proximal femur under 2000 N vertical loading was recorded in fresh-cadaver compressive testing. To simulate this setting, an additional FE model was created from the intact normal right femur, and the surface strains at the medial and lateral proximal femur subjected to the same 2000 N vertical loading were also analyzed. The experimental and analytical results were compared for the validation of the FEA model. (Page 12, Line 11)

3. Although the FE model was validated based on the intact condition without osteotomy, which may have an impact on the analytic results for the post-operative FE models with osteotomy. However, the boundary conditions including material properties (Poisson ratios and moduli of elasticity), element types (10-node, tetrahedral) and element length (4 mm) are identical for FE models with or without osteotomy, and we believe that our results provide useful
information to orthopedic surgeons performing reconstruction of residual hip deformities with proximal femur L-osteotomy. (Page 18, First Line)

4. The above statements had been added in the revised manuscript.

Discussion:
(2) The two paragraphs starting 'As computer technology...' and 'Finite element analysis…' seem better suited for the introduction.

Reply:
As per the reviewer’s suggestion, the paragraph “As computer technology...” had been moved to the “Background” section. (Page 5, Line 12)

(3) Why was the highest value of the von Mises stress in the screws important to evaluate? How close was the peak stress to failure of the material? Is it beneficial or detrimental to load the screws to the peak values seen? i.e. Is the concern of failure or uneven loading over the screws?

Reply:
As the authors’ consideration, it is of importance that a higher von Mises stress in the screws/bone interface might results in a higher risk for screw loosening or failure of the femoral construct. Therefore, it will be more beneficial for the postoperative femoral construct with a lower von Mises stress in the screws/bone interface.

(1) What is meant by 'the algorithm clearly indicates that no general rules can be applied to preoperative planning'? If 'the algorithm' refers to the FEM, it is the first time this terminology is used in the paper. Which results 'clearly indicate' the suggested observation? Better to briefly point the reader to specific results than make blanket statements.

Reply:
The statement “The algorithm clearly indicates that no general rules can be applied to preoperative planning of an L-osteotomy.” has been revised as “Therefore, the results from the FEA might not be regarded as general rules that can be applied to preoperative planning of an L-osteotomy.” (Page 17, Line 15)

(1) Ending the paper with the limitations of the study is weak. Reorganization of the discussion or ending with the future uses of this FE model after addressing the limitations would make the paper stronger.

Reply:
Thank you for your suggestions. An additional paragraph addressing the significance of our FE results and the importance of preoperative planning for L-osteotomy are added in the last paragraph in the revised manuscript.

We look forward to hearing from you soon. Thank you very much again.

Sincerely,

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