Editor of BMC Musculoskeletal Disorders

Date: May 18, 2007

Dear Editor,

I have revised my manuscript based on the reviewers’ questions. I have addressed them all and in cases where I didn’t feel it was necessary to change the manuscript I have given an explanation to the reviewer’s question. For each questions, suggestion or concern I have given an answer and indicated how the manuscript has been revised. I hope you find the revised manuscript acceptable and up to standards but if you feel that I have not addressed the questions adequately I would be more than happy to revisit some of the questions. To answer some of the questions I did redo the analyses but didn’t include the new results in the manuscript but explained to the reviewer how the results were affected. If need be I can include these results in the manuscript as well and rewrite parts of the text.

For additional information please contact me at (919) 513-0220 or at harrysson@ncsu.edu.

Sincerely,

Ola L. A. Harrysson
Assistant Professor
Dear Jia Hua,

Thank you for reviewing my manuscript and thank you for your questions and suggestions to improve the manuscript. I have addressed all your questions, concerns and suggestions and each change is described below.

1. The main clinical problems for total knee replacements are the ligament balance during surgery and surface conformity between the femoral component and tibial tray, which can directly reduce stress concentration and wear, perhaps not from femoral implant-bone contact.

Answer: There are many problems and issues related to total knee arthroplasty and this work is only attempting to address a few of these problems. The two problems that we are attempting to address in this work is the bone remodeling due to the stress shielding and stress concentrations on the bone-implant interface and the change in the articulating surfaces of the condyles that will alter the gait when using generic implants.

2. In the FE study, the custom implant showed a more even stress distribution. However, is the implant stability (micromotion between femoral implant-bone interface) compromised?

Answer: This question is somewhat difficult to answer without conducting a clinical study. However, physical prototypes of both implants and knees were fabricated and the fit between the proposed implant and the knee was as good as the traditional design if not better. The proposed femoral component wrap around the condyles making it very stable.

3. From surgical point of view, is the anatomically shaped implant more difficult to insert accurately?

Answer: Based on the physical prototypes we conclude that the proposed femoral component would not be more difficult to insert and align accurately. The design was made to avoid any undercuts.

4. In FE model, a modulus of 10 GPa is far too stiff for cancellous bone which is normally in the range of 0.5-3.0 GPa.

Answer: We used 10GPa as the Young’s modulus for the cancellous bone based on the information in the following reference: “Jae Y. Rho, Richard B. Ashman, Charles H. Turner, Young’s modulus of trabecular and cortical bone material: Ultrasonic and microtensil measurements, Journal of Biomechanics, vol 26, issue 2, 111-119, 1993. They stated that the average young’s modulus for trabecular bone measured ultrasonically and mechanically were 14.8 GPa and 10.4GPa respectively. This reference has been added to the manuscript [17]. Based on your comment we went back to the literature and found the following reference: A Finite Element Model of the Human Knee Joint for the Study of Tibio-Femoral Contact, Tammy L. Haut Donahue et al., J. Biomechanical Eng., Vol 124, 273-280. According to their study the average
Young's modulus for trabecular bone was 0.4 GPa with a Poisson's ratio of 0.3 [18]. The same FEA simulations were performed using the new material properties for the cancellous bone. The stress distributions are very similar but the stress levels are slightly lower (0.5-1.0 MPa).

5. **The modulus of 110 GPa is for titanium alloy. Why use titanium alloy rather than CoCr which is the material actually used for femoral component in TKR due to its wear characteristics?**

**Answer:** According to our orthopedic collaborators both titanium and cobalt-chromium are used for knee implant components. The principle author is using an Electron Beam Melting (EBM) machine to fabricate custom designed implant components. At the time when the majority of the FEA work was conducted only titanium was available for the EBM process. Since then cobalt-chromium has become available for the EBM process as well. The main purpose of the FEA analysis was to analyze the stress distribution and not the level of stress. Since the stiffness of the titanium is an order of magnitude compared to the bone the authors felt that the stress distribution would not differ significantly by changing the modulus from 110 GPa to 220 GPa. To confirm the hypothesis a new set of FEA simulations were performed were the material properties of the implant was changed from 110 GPa to 220 GPa. The stress distribution was very similar in each case but the level of the stresses were slightly lower.

6. **The authors proposed that this custom knee should be used in more unusual deformed knees; however, the FE model for testing stress distribution is based on a rather normal geometry.**

**Answer:** This is a correct observation. At the time of the acquisition of the CT-data we had a hard time finding a CT-scan of a deformed knee joint since a CT-scan is not a standard procedure prior to TKA. At the time we could only get access to a CT scan of a relatively normal knee joint.
Dear Chris Sutcliffe,

Thank you for reviewing my paper and thank you for your valuable suggestions to improve the manuscript. I have addressed all your concerns, questions and suggestions and below are explanations for each question and how the manuscript has been improved.

3. Are the data sound and well controlled?
The data does seem to be sound although I would have like to see a better comparison of the FEA data recorded stresses from the literature. We need to know if the results are of the correct order and that the FEA study is properly converged.

**Answer:** A reference [18] has been added that shows similar results for the stress levels (0.4-6 MPa) at the bone interface. The Convergence of the equilibrium iterations were checked in ABAQUS based on several criteria. The maximum residual nodal force was required to be less than a user-defined fraction of a temporarily averaged force, which was set to 0.5% as a default at the loading step. The last iterative correction to the incremental nodal displacement was required to be less than 1% of the incremental nodal displacement. According to the ABAQUS output files all the analysis converged properly.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
Yes it does but It is overlong. I suggest that the manuscript is remodelled to be much shorter.

**Answer:** This is a valid suggestions but it would take a considerable amount of time to rewrite the manuscript as a shorter version. I have contacted the editor twice to ask about their preference when it comes to the length of the manuscript but they don’t seem to mind.

5. Are the discussion and conclusions well balanced and adequately supported by the data?
There is very little hard data presented and as such the discussions are brief and to the point. I don’t like the way in which the discussion and conclusions have been rolled into one.

**Answer:** The discussion and conclusion sections have been separated.

7. Is the writing acceptable?
Yes although I have some minor gripes detailed below
   1) I dont like (see Figure X) I prefer ,Figure X

**Answer:** Done

   2) Page 10 why does an STL file triangle need to be of equal size...they dont I can assure you
**Answer:** Mimics has a function where you can export the stl-mesh directly to ABAQUS and create the FEA mesh based off of it. The original stl-file has triangles of various sizes and shapes, which is not ideal for a FEA mesh. To get good results from the FEA the mesh should be consistent with a uniform mesh. ABAQUS will convert the triangles in the stl mesh into tetrahedral elements. The remesh module in Mimics is used to reshape and resize the triangles before being exported into an ABAQUS format. Local remeshing is available as well to create smaller triangles in areas of specific interest. The current limitation is that only tetrahedral elements can be created in ABAQUS using the mesh from the stl file.

3) Page 10 "significantly been reduced" should be "been significantly reduced"

**Answer:** Done

4) Page 10 Geomagic......Carolina Version 7.0 should be Geomagic Studio V7.0, Triangle part...

**Answer:** Done

5) Page 11 Paragraph 2 is a repeat of one earlier...remove or compress

**Answer:** This paragraph has been compressed to eliminate repeated information.

6) Page 12 I'm unsure if Uniformize is a word, I think not!

**Answer:** According to several online dictionaries “uniformize” is a word but it has been replaced by “even out”.

7) Discussion and conclusions need splitting.

**Answer:** Done