Author's response to reviews

Title: Asian-Specific Total Knee System: 5-14 year Follow-up Study

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Author's response to reviews: see over
Dear Reviewers & Editor:

Thank you for your feedback on our manuscript. Please find our point-by-point response to each reviewer comment below. In addition, material that has been changed in the revised manuscript is red. We hope that we have addressed your queries and look forward to hearing from you.

Reviewer: Dr. John Cooper

[Major Compulsory Revisions]
1. p.10, statistical analysis
Response: We did not use the student t-test. Instead, we treated these data as non-parametric data. We deleted “and the paired student t-test for” from this section. (p. 10, line 1)

[Minor Compulsory Revisions]
1. p.5, 1st paragraph of Materials & Methods
Response: We changed the text to the following: “Of those, we investigated a consecutive series of 1055 knees in 595 patients (522 females and 73 males) surgically treated for OA who had undergone TKA at least 5 years earlier between July 1995 and December 2003. All study patients had a minimum of 5 years’ follow-up.” (p.5, line 11-15)

2. p. 5, line 3
Response: “implanted in 1801 patients with 3143 knees” was changed to “implanted in 3143 knees in 1801 patients”. (p. 5, line 10)

3. p. 5, line 9
Response: Procedures for TKA were performed by six surgeons. (p.5 line18-p.6, line 1)

4. p. 7, line 12
Response: “cement” was changed to “cemented”. (p. 8, line 3)
5. p. 7, line 14  
**Response:** Text was changed to “bone cuts were performed by…”. (p. 8, line 5)

6. p. 9, lines 1-2  
**Response:** “femoral tibia angle” was changed to “femorotibial angle”. (p. 9, lines 10-11)

7. p. 10, line 9  
**Response:** “Wilcoxon t-test” was changed to “Wilcoxon signed-rank test”. (p. 9, line 18)

8. p. 10, line 16  
**Response:** “followed” was changed to “follows”. (p. 11, lines 7, 8, 13, 14)

9. p. 11, line 6  
**Response:** “The angle of knees” was changed to “Range of motion”. (p. 11, line 15)

10. p. 12, line 6  
**Response:** “The incidence of radiolucent lines was noted in…” was changed to “Radiolucent lines were noted in...”. (p. 12, line 16)

11. p. 12, line 7: I don’t follow how the incidence of radiolucent lines is 5.6%. By my calculations, 93/817 = 11.4%. Please explain. (see also p. 16, line 1)  
**Response:** We apologize for this error. There were 826 patients who had two implants on the femoral and tibial side at least, respectively; thus, there were 1652 implants in total. Radiolucent lines were noted in 93 of 1652 implants (5.6%). (p. 12, line 17)

12. p. 13, line 2: please explain what is meant by “patellar lateralization”  
**Response:** ‘A patellar lateralization’ means that findings showed narrowing outside of the patellofemoral joint space on axial views in X-rays. We added this text to p. 13, line 14-15.

13. p. 13, line 11  
**Response:** “cumulative success rate” was changed to “cumulative survival rate”.(p.14 line8,16)
14. p. 13, line 12
Response: “95%, CI” was changed to “95% CI”. (p.14 line9)

15. p. 16, line 5: It’s unclear what the author means by “this model can also correspond to a severe transformation”
Response: We changed the text to: “This model can also be used for severe deformities and instability”. (p. 17, line 6)

16. p. 17: Conclusion line 1
Response: “Asiand” was changed to “Asians”. (p. 18 line 5)

17. p. 26. Gender should refer to “male and female” rather than “man and female”
Response: We changed “man” to “male”. (Table 1 (p 27))

18. p. 28.
Response: We changed “severe painful” into “severe pain” for item No. 2, and “recurrent hemarthrosis” into “recurrent hemarthroses” for item No. 7 in Table 3.(p. 29)

19. Figure 5: the Y-axis should be labeled.
Response: We labeled the y axis: “Value of ML/AP or H/AP”.

[Discretionary Revisions]
1. Line numbers
Response: We have changed the format accordingly.

2. Background:
Response: We added “Outcomes with these prostheses have not been previously reported” to p. 5, line 3-4.

3. p. 6, line 5-6
Response: We removed “The FNK provides high coverage of the Japanese distal femur”. (p. 6, line 12-13)

4. p. 6, line 8: “about 4mm”
Response: “about 4 mm” was changed to “3.5 mm”. (p. 6, line 15)
5. p. 7, line 6
   **Response:** “the lateral parapatellar point” was changed to “using a lateral, gently curved incision”. (p. 7, line 14-15)

6. p. 8, line 6
   **Response:** We removed “Patients were evaluated clinically and radiographically at our institution at 5-month to 1-year intervals”. (p. 8 line 14-15)

7. p. 8, last paragraph
   **Response:** We changed the text to: “Clinical evaluation was performed with use of the knee and function scores of the Knee Society clinical rating system [10]. Based on the scores, patient outcomes were classified as excellent (≥90), good (80-89), fair (70-79), and poor (<70). Range of motion (ROM) was measured preoperatively and at final follow-up by the surgeons using a standard goniometer”. (p. 9 line 3-9)

8. p. 11, radiographic evaluation, 2nd sentence
   **Response:** We changed the text to: “A neutral knee axis was defined as an FTA between 170-175°, a varus knee was defined as an FTA > 175°, and a valgus knee was defined as an FTA < 170°”. (p. 12 line 8-11)

9. p. 14, line 4
   **Response:** “The femoral distal size” was changed to “Distal femoral morphology”. (p. 15 line 2)

10. p. 16, line 6
    **Response:** “this implant” was changed to “this type of constrained implant”. (p. 17 line 6-7)
**Reviewer: Dr. Patrick Sussman**

1. This study includes a large number of patients, however the presented data does not show evidence that the FNK TKA system provides better results in an Asian patient population than does any other TKA system.  

**Response:** In this paper, we reported about a FNK designed for Japanese knees, but we could not compare this implant with Western implants for the outcome prospectively and retrospectively. However, this model had few revision cases and showed excellent mid- and long-term results. We added the following text to the limitations: “Further, the FNK implant should be compared directly and prospectively with Western implants in an Asian population”. (p. 18, line 2-3)

The authors point out that implant size and functional requirements, in particular deep flexion and squatting are especially important in an Asian patient population. Yet, there data lacks any information on how often over-sizing is seen with other type of implants.  

**Response:** We are sorry, but we do not know how often over-sizing is seen with other type of implants, because we did not examine this. However, according to Chaichankul and Cheng, it is expected that over-sizing may occur frequently. We added this text to the Background (p. 4, line 10) and included several references that show that femoral size of Asians differs from that of Caucasians (#1-8).

Also, the mean reported flexion especially in the CR type of implant (the majority of cases) was with 111.6# less than the preoperative 115.7#, and does not represent high flexion angles for tasks like squatting or sitting cross-legged as the authors propose in their discussion.  

**Response:** We removed the sentences about squatting or sitting cross-legged, as well as text stating that FNK shows a high flexion angle (p. 6 line 4, p. 15 line 8-10) and added the following text: “A movable range was extended in the CR as well as PS type, although the flexion angle of the CR type was not improved.”(p. 16 line 10-12)

2. Material and Methods: In the design section the authors state that the post of the FNK tibial insert is robust enough to bear stresses by potent constraint. This statement needs to be verified by biomechanical data and can not be made
without. Quote necessary.

Response: We added the following text: “The elasticity load limit from the rear side and lateral to the post is 490N and 580N, respectively (unpublished data)”. (p. 7, line 9)

Also, in the section for radiological assessment the authors should specify how the measured patella dislocation or subluxation and PE wear, which is part of their clinical results.

Response: We changed the text to: “Polyethylene wear over 2 mm was noted in 6 knees (0.7%); this was found in X-rays taken with patients standing and in the anteroposterior view”, “A patellar lateralization that showed narrowing outside of the patellofemoral joint space on axial views in X-rays…”, and “No knees had a subluxation or a dislocation, which is seen as a partial or a complete disappearance of adaptability of the patella and the femur on axial views in X-rays”. (p. 13, line 10-18)

Minor Essential Revisions

In the section on surgical technique there are spelling and grammar errors: … In most cases, we chose a cemented implant, … The bone cuts were performed

Response: “cement” was changed to “cemented”. (p. 8, line 3); “bone cut was” was changed to “bone cuts were”. (p. 8, line 5)

In the result section the authors point out that their mean ROM increased significantly, however in the CR group, which appears to be the majority of the cases the mean flexion angle is postoperatively reduced. However, the authors stated before that high flexion is at high demand in the Asian population.

Response: We removed the sentences about squatting or sitting cross-legged, as well as text stating that FNK shows a high flexion angle (p.6 line 4, p.15 line 8-10) and added the following text: “A movable range was extended in the CR as well as PS type, although the flexion angle of the CR type was not improved.”( p.16 line10-12)

Further when reporting radiolucent lines and loosening the authors report on 15 cemented and 17 cementless knees to have radiolucent lines. This makes a total of 32 knees and not 27 as the authors report before.

Response: We corrected this error. (p. 13, line 3)
There also is a discrepancy in the number of cases with progressive loosening. The authors report on one hand that there was one case of progressive loosening and in the next sentence state that loosening of the tibia was present in 3 cases. On the other hand the authors state in their discussion that all radiolucent lines where non-progressive and without clinical relevance. This discrepancy needs to be clarified.

**Response:** Loosening occurred in 3 cases. One case progressed from osteolysis at the tibia, and radiolucent lines were not seen. Two cases did not have osteolysis or radiolucent lines in X-ray. Cases with radiolucent lines did not worsen over time and no patient had any symptoms.

5. In the discussion the authors state the high demand for squatting, kneeling and sitting cross-legged; however the mean postoperative flexion angle of 111.6° hardly will allow for these tasks. These mean flexion angles should also be compared to other knee designs. Therefore the assumption on page 15 that for high-flexion, the femoral component has a small curvature radius that causes smooth rollback needs a study that shows this. Please quote literature.

**Response:** We removed the sentences about squatting or sitting cross-legged, as well as text stating that FNK shows a high flexion angle and add p.16 line10-12. We reconfirmed to see if a small curvature radius of the femoral component caused a smooth rollback, but findings were inconclusive. Thus, this text was removed. (p. 6, line 9-10; p. 15 line 18- p. 16 line 1) And we changed Fig.2.(p. 25 line 9-10)

In the next paragraph on page 15 the authors state that the implant reduces the need for allogenic bone graft. Allograft also in the other parts of the world is used infrequently in TKA.

**Response:** We removed “… which are used infrequently in Japan”. (p. 16, line 6)

The last paragraph on page 15 is an assumption and unnecessary.

**Response:** We removed “Excellent implant position …..”. (p. 16, line 17)

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? The authors do not give enough scientific evidence for the biomechanical and design based statements regarding the implant, which gives the impression of an advertisement.

**Response:** This is not an advertisement for an implant. This is merely a retrospective report of our findings using an implant designed for Asian subjects.
In the background section the authors should more detailed report on the background and results with other type of implants that led to the design of the FNK TKA system. There is the impression that sizing problems and limited function with other systems lead to the development of the FNK TKA system. The authors should give in this section more evidence on these points.

Response: Western implants do not fit an Asian population. We added a reference to Chaichankul and Chengs, which discusses the incidence of over-sizing, and included several references that show that femoral size of Asians differs from that of Caucasians (#1-8).

Statistical review:

Response: At this time, the manuscript has been proofread by one statistician.