Reviewer's report

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

Version: 3 Date: 31 August 2011

Reviewer: Patrick Sussman

Reviewer's report:

Review

General Impression: Reject because scientifically unsound

1. Is the question posed by the authors well defined? No

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.

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. 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.

2. Are the methods appropriate and well described? No – they will need Major Compulsory Revisions

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.

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.

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 ....

3. Are the data sound? No

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.
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. 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.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
Yes

5. Are the discussion and conclusions well balanced and adequately supported by the data? No

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.

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.

The last paragraph on page 15 is an assumption and unnecessary. The assumption that good survivorship is related to excellent implant positioning. The authors did report implant position sufficiently to make this statement.

6. Are limitations of the work clearly stated? Yes

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.

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.

8. Do the title and abstract accurately convey what has been found? NO, see above.
9. Is the writing acceptable? Yes

**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