Author's response to reviews

Title: Mid-term Results of Stryker Scorpio Plus Mobile Bearing Total Knee Arthroplasty

Authors:

Hideo Kobayashi (hi-deo@live.jp)
Naoto Mitsugi (nmitsugi@uraph.yokohama-cu.ac.jp)
Yuichi Mochida (U1Mochida@aol.com)
Naoya Taki (ntak@peach.plala.or.jp)
Yasushi Akamatsu (akamatsu@yokohama-cu.ac.jp)
Masato Aratake (aratake@cj9.so-net.ne.jp)
Hirohiko Ota (ota2000@sf6.so-net.ne.jp)
Katsushi Ishii (ishi69@yokohama-cu.ac.jp)
Kengo Harigane (harigane-ykh@umin.ac.jp)
Taichi Ideno (i-taichi@tulip.sanet.ne.jp)
Tomoyuki Saito (t_saito@med.yokohama-cu.ac.jp)

Version: 2 Date: 12 January 2012

Author's response to reviews: see over
January 12, 2012

Hideo Kobayashi, MD., Ph.D
Department of Orthopedic Surgery
Yokohama City University Medical Center
4-57 Urafune-cho, Minami, Yokohama
Kanagawa, Japan, 232-0024
Office: +81-45-261-5656
Fax: +81-45-252-7470
E-mail: hi-deo@live.jp

Editors
Sports Medicine Arthroscopy Rehabilitation Therapy Technology,
Department of Orthopaedic Surgery,
Kobe University Graduate School of Medicine,
7-5-1 Kusunoki-cho, Chuo-ku, Kobe 650-0017, Japan

Dear Drs. Masahiro Kurosaka and Kai- Ming Chan

Please find enclosed revised manuscript entitled: Mid- term Results of Stryker® Scorpio Plus Mobile Bearing Total Knee Arthroplasty”. We appreciate the reviewers’ comments and have modified the manuscript as indicated below. Changes are also highlighted in red in the text.

I confirm that all authors were fully involved in the study and preparation of the manuscript and that the material within has not been and will not be submitted for publication elsewhere.
All authors certify they have not signed any agreement with a commercial interest related to this study which would in any way limit publication of any and all data generated for the study or to delay publication for any reason.

We hope that our manuscript will now be suitable for publication.
Feel free to contact me if you have other questions or recommendations.

Sincerely yours,
Dear Editor.

This concerns our revised manuscript entitled; **Mid-term Results of Stryker® Scorpio Plus Mobile Bearing Total Knee Arthroplasty**.

We appreciate the reviewers comments and have modified the manuscript as indicated below. Changes are also highlighted in red in the text.

Reviewer Comments:

**Reviewer: 1**

Reviewer’s report:
*Level of interest: An article whose findings are important to those with closely related research interests*
*Quality of written English: Acceptable*
*Statistical review: No, the manuscript does not need to be seen by a statistician.*

Thank you very much for your comments.

**Reviewer: 2**

Reviewer’s report:
General
1. This study reported mid-term results of Scorpio plus mobile bearing total knee arthroplasty. This is the first study reported clinical results of this particular implant. However, the purposes of this study are not clear. Only reporting mid-term results of “new implant” will not give important information to the readers.

We completely agree with the reviewer’s comment.

Mechanism of rotation of this implant is quite different from other types
of mobile-bearing TKAs such as LCS and PFC. Figure 1 was added to show the design and mechanism of Scorpio mobile bearing TKA. We supposed that the differences of design, shape, and mechanism of rotation would bring different clinical and radiographic results. This is the reason why we reported the mid-term results of Scorpio mobile bearing TKA.

Introduction
2. **What is the difference of design between this implant and the other mobile bearing system? What did the authors expect this implant to perform based on the design characteristics?**

In response to the comment, the sentences have been added to describe the difference of design between mobile systems, as follows.

On the other hand, other types of mobile systems including the low contact stress prosthesis (LCS, DePuy) and press-fit condylar prosthesis (PFC, DePuy) utilize a central cone as part of the polyethylene insert which engages a matching conical cavity in the tibial tray. Thus, mechanism of rotation is quite different among the various manufacturers of mobile-bearing TKAs. Although many studies have been performed to investigate clinical results of mobile bearing TKAs and similar clinical outcomes have been reported between mobile bearing and fixed bearing TKAs [2, 3], the differences of design, shape, and mechanism of rotation might bring different clinical and radiographic results. (Page5, Line1 - Line10)

3. **Why did the author compare RA and OA? What did the authors make clear from this comparison?**

We appreciate this comment and have added the sentence as follows;

In addition, there are few reports assessing clinical result of mobile bearing TKAs in patients with RA [4]. Medial/ lateral laxity or
anteroposterior instability of patients with RA might result in worse clinical results compared with results of patients with OA. (Page5, Line13- Line16)

Patients
4. Thirty two patients were lost to follow-up. This is one of the limitations of this study. Please discuss the effect of decreasing a number of patients.

As the reviewer suggests, the follow up rate is not adequate. Some patients who were lost to follow-up might move or pass away. On the other hand, they may not visit our hospital simply because they do not have any complaints about their operated knees. It is hard to say the reason why they do not visit our hospital. Therefore, in the section of discussion, we have simply added the following sentences.

There are some limitations to this study. First, the follow up rate is not adequate for the mid-term results. Although improved follow-up rate might bring different clinical and radiographic results, the number of cases is supposed to be still adequate. (Page13, Line6- Line9)

5. Briefly describe the difference of background of RA and OA in the text.

As recommended, the following sentence has been added.

The mean age at the operation and the preoperative femora-tibial angle (FTA) were significant different between two groups. (Page6, Line12- Line13)

Surgical Technique
6. Line 7 What is the proper soft-tissue balance? Did the author use any device to evaluate soft tissue balance?

The soft tissue release was performed until the operator decided that
the proper soft tissue balances were obtained at both 0° extension and 90° flexion by using a balancer or a spacer block. However, we have not set any standard values for proper soft-tissue balance. Therefore, we have rephrased the sentences as follows (Page7, Line7-Line10):

After the initial bone cuts, the soft-tissue release was performed. A balancer or spacer block was used to evaluate soft-tissue balances between the distal femur and the proximal tibia or between the posterior femur and the proximal tibia at both 0° extension and 90° flexion.

Results

7. Please quote the figure and the table.

   We agree with the reviewer’s comment and quoted the figure and the table. (Page9)

8. Do not repeat results given in a table in a figure. Please describe important aspects of the data in the text.

   As recommended, we have summarized the section of results not to repeat results given in a table or in a figure.(Page9, Line1-Line17)

9. Which group had dislocation of the insert?

   As recommended, the sentence has been rephrased as follows, Spontaneous dislocation of a polyethylene insert occurred in one patient with osteonecrosis (Page9, Line8-Line9)

Discussion

10. Please discuss the effect of design characteristics of this implant on clinical
We appreciate this comment and have added the sentence as follows;

Mid-term clinical and radiographic results of the model were equivalent to results of other types of mobile-bearing TKAs described in literatures. Although a lowered posterior lip of the polyethylene insert was considered to allow deep flexion, the average postoperative flexion angle of the model was equivalent to those of other types of mobile bearing TKAs. (Page11, Line5- Line9)

11.3rd paragraph  How was the tension and alignment of the case with polyethylene dislocation?

We have previously reported a dislocation of the polyethylene insert in detail. The tension and alignment of the case was considered to be adequate. In our case, failure of the locking ring was the cause for the dislocation. Please refer to the case report (reference #15). We have added the sentence, as follows;

In our case, the tension and alignment was considered to be adequate. (Page12, Line5- Line6)

Reviewer: 3

Reviewer's report:
General comments:

The authors reported the mid-term results of Scorpio Plus Mobile Bearing TKA. The number of cases (66 patients) and a mean follow-up periods (5.8 years) are adequate.
However, the reviewer has some comments and concerns.
  - Major Compulsory Revisions
Introduction

1. I feel that the purpose of this study is not clearly described. What is the difference between Scorpio Plus and other mobile bearing total knee systems? Please elaborate the characteristics of this model using some figures, and then describe what the authors would like to know in this study.

We completely agree with the reviewer’s comment. Mechanism of rotation of this implant is quite different from other types of mobile-bearing TKAs such as LCS and PFC. Figure 1 was added to show the design and mechanism of Scorpio mobile bearing TKA. We supposed that the differences of design, shape, and mechanism of rotation would bring different clinical and radiographic results. This is the reason why we reported the mid-term results of Scorpio mobile bearing TKA.

In response to the comment, the sentences have been rephrased as follows; (Page5, Line1- Line10)

On the other hand, other types of mobile systems including the low contact stress prosthesis (LCS, DePuy) and press-fit condylar prosthesis (PFC, DePuy) utilize a central cone as part of the polyethylene insert which engages a matching conical cavity in the tibial tray. Thus, mechanism of rotation is quite different among the various manufacturers of mobile-bearing TKAs. Although many studies have been performed to investigate clinical results of mobile bearing TKAs and similar clinical outcomes have been reported between mobile bearing and fixed bearing TKAs [2, 3], the differences of design, shape, and mechanism of rotation might bring different clinical and radiographic results.

Methods

Patients

2. Follow-up rate (65.3%) is not adequate for the mid-term results. What is the cause of loss of 32 patients?
As the reviewer suggests, the follow-up rate is not adequate. Some patients who were lost to follow-up might move or pass away. On the other hand, they may not visit our hospital simply because they do not have any complaint about their operated knees. It is hard to say the reason why they do not visit the hospital. Therefore, in the section of discussion, we have simply added the following sentences.

There are some limitations to this study. First, the follow-up rate is not adequate for the mid-term results. Although improved follow-up rate might bring different clinical and radiographic results, the number of cases is supposed to be still adequate. (Page13, Line6- Line9)

Surgical technique

3. Why did the authors cut the distal end of the femur uniformly at 7°?

Our pre-operative planning is to cut the distal end of the femur perpendicular to the mechanical axis. Most of cases, the angle between the mechanical axis and femoral axis was 7 degrees. As the reviewer suggests, it is not always uniform angle. Therefore, we have rephrased the sentence as follows.

Briefly, the distal femoral osteotomy was perpendicular to the mechanical axis (Page7, Line4- Line5)

4. How did the authors determine the posterior slope of the tibia during the tibial cut?

We aimed to cut the sagittal proximal end of the tibia perpendicular to the tibial axis. We have rewritten the manuscript as follows.

the proximal tibial osteotomy was perpendicular to the tibial axis in the coronal and sagittal plane (Page7, Line5- Line6).
5. Did all the patients begin full weight-bearing from postoperative day 1?

Yes, all patients began full weight-bearing and range of motion exercises from postoperative day 1.

Clinical and radiographic evaluation
6. Please clarify the methods for the radiographic evaluation in the Methods section.

The methods for the radiographic evaluation are described in detail in reference 6. Please refer to reference #6.

Statistical analysis
7. T-test can be applied for metric variables. Because the JOA score uses discrete variables, the authors should use nonparametric statistics.

We agree with the reviewer’s comment. We used Mann-Whitney’s U test as a non-parametric test (Page8, Line9- Line13).

Discussion
8. Although the Scorpio Plus SuperFlex PS mobile bearing system has been designed to provide deep knee flexion, the average flexion angles of 116.8° in OA and 113.7° in RA are equivalent to those of other types of mobile bearing TKA. Please add discussion concerning to a discrepancy between the design concept and clinical results.

We agree with the reviewer’s comment. We have added the following sentences in the section of discussion (Page11, Line5- Line13).

Mid-term clinical and radiographic results of the model were equivalent to results of other types of mobile-bearing TKAs described in literatures. Although a lowered posterior lip of the polyethylene insert was considered to allow deep flexion, the
average postoperative flexion angle of the model was equivalent to those of other types of mobile bearing TKAs [2, 9, 13]. Postoperative flexion angle is supposed to have a good correlation with preoperative flexion angle. Additionally, it is influenced by a variety of factors, such as implant design and operative techniques. Therefore, it might be difficult to judge how much the model contributed to postoperative flexion angle.

9. **Why did failure of the locking system occur? Are there any structural defects in the tibial component? How can the authors prevent this problem?**

   We have previously reported a dislocation of the polyethylene insert in detail. In our case, failure of the locking system resulted in the dislocation of the insert. Please refer to reference #15.

Minor Essential Revisions
Results

10. **Please specify clearly table 2 and figure 1 in the manuscript.**

   We appreciate the comment and quoted the figure and the table in the manuscript (Page9).

We appreciate the thoughtful and helpful comments of the reviewer. They have certainly substantially improved our manuscript. We hope that our manuscript will now be suitable for publication.

Sincerely,