Author's response to reviews

Title: Mid-term clinical results of primary total knee arthroplasty using metal block augmentation and stem extension in patients with rheumatoid arthritis

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The Editors
BMC Musculoskeletal Disorders

Manuscript # 1159488997162371
Title: “Mid-term clinical results of primary total knee arthroplasty using metal block augmentation and stem extension in patients with rheumatoid arthritis”

Dear Editors:

Thank you for your kind e-mail of 19-May-2015. We are most grateful to you and the referees for helpful comments on the original version of our manuscript. We tried to revise the manuscript as much as possible in line with the comments made by the referees.

Referee #1:

First of all it is hard to review articles with no line numbers.

According to the referee’s comment, line numbers have been added throughout the manuscript.

This is a nice article concerning the difficult task to solve severe rheumatoid knees with large bone defects. The limitation of having too few cases might be true, however it is probably not many centers that can report 26 knees of this kind. Using one particular prosthetic design is not a limitation in my mind, on the contrary it is a strength to have a design that works good for you.

Thank you very much for the comments.

“Finally, the results presented here were obtained using a single type of implant. Although strength of our study is that prostheses examined are still in current use, further studies with comparisons of different designs are also required.” has been changed to “However, compared to the literatures including various types of prostheses [14, 27], examination of currently used one particular prosthetic design could be a strength of our study.” (revised manuscript Page 17, Lines 262-264).

Major comments:

In Results -all the numbers in the second and third paragraphs would be much easier for the reader to follow if given in a table instead of running text.
According to the referee’s suggestion, “Table” (revised manuscript Page 25, Lines 374-378) and “(Table 1)” (revised manuscript Page 10, Lines 136, 155 and Page 25, Lines 374-378) have been added in the manuscript.

In the third paragraph the authors are stating "mean score was 1 point......) there is no explanation in the Methods section what kind of scoring this is. Please clarify.

“However, the mean score was 1 point (range, 0 to 4), and no knees had a score of 5 or above.” has been changed to “However, the mean sum of radiolucent lines beneath in all zones of the tibial side was 1 mm (range, 0 to 4), and no knees had 5 mm or above.” (revised manuscript Page 11, Lines 168-170).

Last paragraph (still in Results): even if the Kaplan-Meier analysis gives an estimated number of survival, I think it is a little bit too much to give a 10-year survival. The mean follow-up was 6 years and the 95%CI 71.7 to 97.8. This wide CI implies that there are very few cases left at 10 years making the figure 91.6% survival quite uncertain. A 5-6 year survival analysis would be more true, the 95% CI would then be less wide. By the way -I don’t understand the dotted line in figure 1, this line is said to be the CI and is at the 80% level, even if the lower limit of the CI is said to be 71.1%. This needs to be clarified.

According to the referee’s comments, we have re-estimated the cumulative probability of the revision TKA using the Kaplan-Meier product-limited method. However, a Kaplan-Meier analysis still identified a six-year survival rate of 91.6% (CI 71.7-97.9) with revision TKA as endpoint. As the referee pointed out, the dotted line in Figure 1 was a wrong line to point the lower limit of the CI. According to the referee #2’s suggestion, a Kaplan Maier curve (Figure 1) and one sentence in the abstract: “A Kaplan-Meier analysis identified a six-year survival rate of 91.6% (CI 71.7-97.9) with revision TKA as endpoint.” have been deleted. In the results, “a ten-year survival rate” has been changed to “a six-year survival rate” (Page 12, Line 189-Page 13, Line 190).

Minor comments:
In Discussion -third paragraph -there is no referral to any reference after Tsukada et al.

“[27]” has been added as referral (revised manuscript Page 15, Line 228).

References’ numbers have been changed accordingly.

Last paragraph -should be intermediate, not intermediated.
Referee #2:
The manuscript reports the results of 26 knees and 21 patients. I suggest to include only the first knee that underwent surgery. There is no sense in reporting on two knees in the same patient.

We would like to include cases with TKA in the contralateral knee because of the limited number of patients in this study. Previous studies did not necessarily confined to the first knee that underwent surgery. Besides, we consider that the inclusion of these cases does not fundamentally alter conclusions of this study. However, we have understood the referee’s kind advice for the elimination of inherent bias in this study and boldly described that we included cases with TKA in the contralateral knee in the limitation section.

Two sentences, “Finally, a cohort of patients included some cases with TKA in the contralateral knee. However, we believe that the inclusion of these cases does not fundamentally alter conclusions of this study.”, have been inserted in the limitation section (revised manuscript Page 17, Lines 266-268).

The number of patients/knees is rather limited regarding the midterm FU and there are larger studies published. Furthermore the patient pool is rather heterogeneous regarding defect size, FTA and metal augment.

To our best knowledge, few studies have reported outcomes of TKA with metal block and stem extension in severely degenerated RA knees at longer follow-up periods [14] (revised manuscript Page 6, Lines 73-74). Besides, compared to the previous reports including various types of prostheses [14, 27], examination of currently used one particular prosthetic design could be a strength of our study (revised manuscript Page 17, Lines 262-264). We consider that heterogeneous radiographic data including defect size, FTA, and metal augment could reflect actual clinical situations in severely degenerated RA knees replaced with metal block and stem extension.

It was stated in the introduction that the study was retrospective while the discussion starts with...."We performed a prospective study...". What was study design?

In the discussion, “a prospective” has been changed to “retrospective” (revised manuscript Page 13, Line 193).
Is there any further information regarding cementation technique (f.e. tourniquet use, type and viscosity of cement, vacuum mixing, pulsed lavage, hand packing etc.). If so, this must be added to the methods section, as a large number of radiolucencies was observed, which could be partially explained by cementing technique.

“using a pneumatic tourniquet” (revised manuscript Page 7, Line 98), “(Simplex P Bone cement: Stryker, Mahwah, New Jersey)”, “by finger-packing without vacuum mixing or pulsed lavage”, and “Axial compressive load was applied in knee extension with a trial insert until the cement cures.” (revised manuscript Page 8, Line 113-116) have been inserted in the Methods (revised manuscript Page 13, Lines 263-264).

“, Warsaw, Indiana” has also been inserted in the Methods. (revised manuscript Page 6, Lines 81)

How many patients were available at latest FU radiographic and clinical? Is there a difference in FU times? Any patients lost to FU? If so, this must be stated.

12 females (15 knees) and 3 males (3 knees) were available at latest follow-up. There is not any difference in follow-up times of radiographic and clinical evaluation. Six females (8 knees) are lost to follow-up after the two-year evaluation.

According to the reviewer’s suggestion, “Six females (8 knees) are lost to follow-up after the two-year evaluation.” has been inserted in the Methods (revised manuscript Page 7, Line 91).

The JOA knee score is rarely used to assess TKA function. I recommend to provide commonly applied scores like Knee Society Scores to allow comparison with other publications in the literature.

According to the referee’s suggestion, “the Japanese Orthopaedic Association Rheumatoid Knee Scoring System (JOA knee score) [19]” has been changed to “the Knee Society Clinical Rating System [19]” (revised manuscript Page 8, Line 120).

“The JOA knee score is a 100-point scale that comprises the subcategories of pain (0–40 points), ROM (0–12 points), ability to walk (0–20 points), ability to stair ascending and descending (0–8 points), and quadriceps strength (0–20 points) [19].” and “19. Obayashi O, Sasaki S, Katsube S, Uta S, Kaneko K, Yanagihara Y. The relationship between postoperative results and bone dynamics in RA patients who underwent cementless Ortholoc II TKA: histomorphometric study. Mod Rheumatol
In the Abstract, “Japanese Orthopaedic Association Rheumatoid Knee score from 45 to 75” has been changed to “Knee Society score (knee score/function score) from 35/18 to 90/64.” (revised manuscript Page 3, Lines 39-40).

“JOA knee scores” has been changed to “Knee Society Score (KSS; knee score/function score)” (revised manuscript Page 9, Line 129).

“JOA knee score was 45 points (range, 10 to 75)” has been changed to “KSS (knee score/function score) was 35 (range, 0 to 70)/15 (range, 0 to 60)” (revised manuscript Page 13, Line 147).

“JOA knee score was 75 (range, 49 to 97).” has been changed to “KSS (knee score/function score) was 90 (range, 76 to 100)/64 (range, 5 to 100).” (revised manuscript Page 11, Line 156).

“JOA knee score (p < 0.0001)” has been changed to “knee score (p < 0.0001), and function score (p < 0.0001)” (revised manuscript Page 11, Line 159).

“JOA score from 45 to 75” has been changed to “KSS (knee score/function score) from 35/18 to 90/64” (revised manuscript Page 14, Lines 213-214).

“JOA knee score: Japanese Orthopaedic Association Rheumatoid Knee Scoring System;” have been changed to “KSS: Knee Society Score;” (revised manuscript Page 18, Line 278).

Minor Essential Revisions:
One could argue if a Kaplan Maier curve is helpful with a small number of patients and only three patients being revised during FU.

According to the referee’s suggestion, a Kaplan Maier curve (Figure 1) and one sentence in the Abstract: “A Kaplan-Meier analysis identified a six-year survival rate of 91.6% (CI 71.7-97.9) with revision TKA as endpoint.” have been deleted.

EDITORIAL REQUESTS:
-Please include email addresses of all authors in the title page of your main manuscript.

E-mail addresses of all authors has been added in the title page.

-Requesting name of ethics committee: Please update your ethics statement to include the name of the ethics committee that approved your study.

“The study was carried out after obtaining approval from the institutional review
board (IRB #12-06).” has been changed to “The study was carried out after obtaining approval from medical ethics committee of National Hospital Organization Kyushu Medical Center (IRB #12-06).” (revised manuscript Page 6, Line 86- Page 7, Line 88).

-Acknowledgements: We strongly encourage you to include an Acknowledgements section between the Authors’ contributions section and Reference list. Please acknowledge anyone who contributed towards the study by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include their source(s) of funding. Please also acknowledge anyone who contributed materials essential for the study. Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements. Please list the source(s) of funding for the study, for each author, and for the manuscript preparation in the acknowledgements section. Authors must describe the role of the funding body, if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

1 According to the Editorial requests, “This study was supported by funds of Clinical research institute at National Hospital Organization Kyushu Medical Center. The funding sources had no role in study design; in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.” has been inserted in the manuscript (revised manuscript Page 18, Line 291- Page 19, Line 295).

1 “according to the extent of pain and general conditions of patients” has been inserted in the manuscript (revised manuscript Page 8, Line 118).

1 “11” and “9” have been changed to “Eleven” and “Nine”, respectively (revised manuscript Page 11, Lines 172 and 175).

We hope that our paper is now suitable for publication in BMC Musculoskeletal Disorders and we look forward to hearing from you at your earliest convenience.
Best regard,

Satoshi Hamai

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