Author's response to reviews

Title: Exeter total hip replacements 654 primary prostheses, with a maximum follow-up of 20 years

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PDF covering letter
Response to reviewers comments and suggestions

Dr Søren Overgaard

Discretionary revisions
1. Complication rates. Specify which complications are reported.
Comment
This is specified in table 2.
Action
Minor revision of text.

2. Could any of the patients have been revised in other countries?
Comment
No patients have moved abroad and we find it highly unlikely that a patient would travel abroad for revision, as he would have to pay for it himself.

3. Age and gender are important parameters in the prognosis of THR. It would be of interest to categorize into age groups and gender although the number of THR included is low.
Comment
We find that there is no significant statistical difference for gender and we feel that the material isn’t sufficiently large to stratify for age.
Action
Addition to results section regarding gender.

4. Wound infection. The definition is not strict for infection. Every wound will have a positive culture if secretion.
Comment
Samples were taken from all wounds suspected being infected. Those requiring antibiotic treatment were classified as infected.
Action
Text in methods section clarified.

5. How was pulmonary embolism diagnosed?
Comment
Clinically and by chest x-ray. Scintigraphy was not available at the time.
Action
Text in methods section clarified.

6. Explain why very few urinary tract infections were diagnosed.
Comment
Early withdrawal of urinary catheter post-operatively and the use of ampicillin (in addition to cloxacillin) as antibiotic prophylaxis for all patients who got a urinary catheter.
Action
Text in results section clarified.
Compulsory revisions
1. Include only primary procedures.
Comment
   We agree.
Action
   Changed.

2. The methods should include: Which kind of Exeter components used, cementing technique, kind of theatres, prophylaxis with antibiotics, prophylaxis against thrombo-embolic episodes, kind of anaesthesia, number of surgeons, cement type, approach. Most of these parameters appear in the discussion paragraph.
Comment
   We agree.
Action
   This information was moved from the discussion section to the methods section and further clarified.

3. Are there any statistical significant difference between the to survival curves in fig. 1 and 2?
Comment
   We found no significant difference in the revision rate (1-survival) between patients operated on during 1982-1990 and patients operated on during 1991-2000 (using Wilcoxon test and Cox regression). We have added this information to the results section. Unfortunately both the EPS pictures submitted with the article were drawn with the Y-axis (number of years) having the same length although the pictures reflected periods of different length (i.e. 10 years and 16 years). This makes the difference between the pictures appear bigger than it actually is.
Action
   The new figures we supply have comparable time periods.

4. The first paragraph of the conclusion belongs to the discussion.
Comment
   We agree.
Action
   Corrected.

Dr Stein Atle Lie

Compulsory revisions
1. The subtitle is misleading. Of the 744 prosthesis, there are only 654 primary prostheses which are followed until revision. The subtitle: "654 primary prostheses, with a maximum follow-up of 20 years", may be more appropriate.
Comment
   We agree.
Action
   Corrected.
2. This study both gives results for the protheses (time to revision) and for the patients (complications and deaths). The structure of the article should be strengthened by dividing these two issues into separate paragraphs.

Comment
We agree.

Action
Changed.

3. There has been a change in the design of the Exeter prosthesis during the years of the study. This may explain changes in revision rates, there have, however, also been a decrease in hospitalisation, and a change to vacuum mixing, during the same period. The argument that there has been a change in revision rates should be based on a measure for statistical significance (e.g. a p-value from a log-rank test or results from a regression analysis. A Cox-regression would be simple to perform since this method is present in the SPSS-software).

Comment
We agree with Dr. Lie in that there could be several different reasons for an observed change in revision rate. However, in the article we never argued that there had been significant changes in the revision rate. We only reported that when the whole period (1982-1999) was analyzed the CRR was 6% at 10 years while it was less than 5% for the period after 1990. Using Wilcoxon test and Cox regression, we found no significant difference between patients operated on during 1982-1990 and patients operated on during 1991-2000 (independent of if the end-point was loosening or all revisions). As this information was not stated in the paper, we have added it to the result section.

Action
Results section clarified.

4. It should be stated in the "Methods" section that all prostheses were cemented with Palacos containing gentamycin.

Comment
We agree.

Action
Changed.

5. In survival studies of prostheses, the observation of the prosthesis is lost to follow-up when the patient dies. The observational time for the prosthesis is, hence, censored at the time of death for the patient. Thus, a complete follow-up for the patients (with only administrative censoring at the end of study) don’t necessarily mean a complete follow-up for the prostheses. This should be clarified in the article.

Comment
The survival statistics methods used in this article are not at all controversial (they are those used by major arthroplasty registers) nor are the results. We therefore do not find it necessary to go into methodological descriptions of survival statistics. However, we have clarified the follow-up time of our patients in the method section.

Action
Methods section clarified.
6. There are 591 patients with 744 prostheses. What were the number of patients for the 654 primary prostheses?
Comment
548 patients.
Action
Results section clarified and changed to include only primary THR.

7. Are only prosthesis which was primary operated at Akureyri included? Were revisions from any hospital in Iceland connected to these primary operations? If so how where comparison of revision rates with other hospitals performed, which are stated as the primary purpose of the study (last sentence in the background section)?
Comment
Our material includes only those patients that have had their primary hip arthroplasty done in Akureyri. As of now only the hip arthroplasties done in Akureyri are registered in detail. Register for operations in other hospital in Iceland exists, but includes only the diagnosis and the time and type of operation. Thus we were able to search for all our patients that might have undergone a revision at another hospital, but we are not able to compare our material with results from other hospitals in Iceland. The purpose is therefore to compare our results with those previously published, primarily in Scandinavia.
Action
None (we feel that this is stated clearly in the text).

8. Figure 1 and Figure 2 should have the same axis. Thus, the X-axis in Figure 2 should also go from 0 years to 17 years.
Comment
We agree.
Action
New figures.

9. Total revision rates should be provided, and not only curves for aseptic loosening, since dislocations is common for Exeter prostheses. It would, furthermore, be interesting to see a table with the different designs of the Exeter prosthesis (matt vs. polished stem and metal backed vs. all polyethylene acetabulum) and the reasons for revision (such as for the 28 aseptic loosening, the 7 dislocations etc.). Preferably figures for the total revision rates, which are commonly presented in the literature, should be presented, in addition to the curves for aseptic loosening.
Comment
Reports often include graphs describing revision rates for loosening only. The reason for this is probably space consideration as well as that these are the most common failures and those most often believed to be affected by cement/implant properties. However, we agree that the total revision rate is of importance. Therefore we submit an additional CRR curve for the whole period 1982-2000 while we take out the curve for the period 1990-2000. The difference between the periods is instead described in the text.
Regarding the requested table showing the combinations of matt/polished stems and metal-backed/all-poly cups and the number of failures we do not have exact information on the combinations and it would be very labor intensive for us to acquire that information. As the follow-up time is so different, a table with a count of complications cannot be used as a
measure of the risk for a combination of sustaining a complication. To estimate differences in risk between the combinations, survival statistics would have to be used. As a course estimate of differences in risk between the major combinations we can use an analysis of the 2 time periods instead and as we stated above we found no significant difference in the CRR between the periods.

**Action**
Text in results section revised.

10. It may also be that prostheses lost to follow-up due to patient death have a higher risk for revision than those not lost to follow-up. Some of this difference might be explained by differences in age, since old patients have a high mortality and may have a low revision rate. This paragraph should be moved from the conclusion section to the discussion.

**Comment**
It is a common knowledge that in general survival statistics assume that the risk of revision is the same in the censored group (lost to follow-up and dead) as in the uncensored one (available for follow-up). However, in countries without socialized healthcare and where tracking of patients is difficult (USA) it is quite possible and even likely that patients lost to follow-up at one center have moved elsewhere, just because they are dissatisfied and in need of revision. This, among other things makes it considered to be quite important that lost cases are kept to a minimum.

The reviewer speculates that patients that become censored due to death may have a higher risk for revision (have had a higher rate of revision if the had lived??). We see no sensible way to prove or disprove this hypothesis.
Regarding the content of the conclusion section it has now been rewritten and some content moved to the discussion.

**Action**
Parts of conclusion section moved to discussion and conclusion section rewritten.

11. The conclusion section does not summarize the findings in the study and should hence be rewritten.

**Comment**
We agree.

**Action**
Conclusion section rewritten.

12. Is Table 2 for the early postoperative period? If so, state the number of days in the table heading, that these numbers account for.

**Comment**
Table 2 accounts for all complications registered during the postoperative hospital stay and for all complications that occurred later and required re-admission of the patient.

**Action**
Table heading clarified.

**Orthographic corrections**
1. In the results section of the paragraph change the last sentence to "... within the end of year 2001.".
Comment
   We assume that Dr. Lie refers to the results section of the abstract.
Action
   Text revised.

2. In the first sentence of the background section erase the word "there".
Comment
   We agree.
Action
   Changed.

3. Rewrite the first sentence of the second paragraph in the background section to: "In Iceland, as in the other Scandinavian countries, ..." (Two commas and the word "the" added).
Comment
   We agree.
Action
   Changed.

4. Rewrite the third sentence of the second paragraph in the background section. It is difficult to understand.
Comment
   We agree.
Action
   Clarified.

Discretionary revisions
1. State the version of the SPSS-software used for the statistical analyses.
Comment
   We agree.
Action
   Changed.

2. Figure 1 and Figure 2 is obviously not plotted in SPSS. State the software used to calculate the confidence limits and to create the figures.
Comment
   SPSS tables were exported to Excel in which the corrected confidence intervals were calculated and the figures were drawn (the scripts used were those used by the Swedish Knee Register).
Action
   Text in methods section clarified.