Author's response to reviews

Title: Factors affecting aseptic loosening of 4750 total hip arthroplasties: multivariate survival analysis.

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Version: 2 Date: 23 March 2007

Author's response to reviews:

Dear Sir,

first of all I wish to thank you and the reviewers for the attention and for the professional help you are giving us.

Please find our answers to points raised by the two reviewers:

Reviewer's report

Title: Factors affecting aseptic loosening of 4750 total hip arthroplasties: multivariate survival analysis.

Version: 1 Date: 5 February 2007

Reviewer : Richie Gill

Reviewer's report:

General

Summary: The authors have analysed the survival of nearly five thousand primary total hip arthroplasties, and looked in particular for the differences between cemented and uncemented prostheses.

1. Is the question posed by the authors new and well defined?

In terms of looking at survival of prostheses, this is not a new question, but the authors address some limitations of previous studies and this is a very important question in orthopaedic management of patients.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?

Yes

3. Are the data sound and well controlled?

Difficult to assess.

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

The results need to be presented in a clearer manner, directing the reader to the most significant findings, at the moment this data is in various tables.

5. Are the discussion and conclusions well balanced and adequately supported by the data?
Relatively well written, will be easier to follow once results are re-written. Limitations need to be detailed.

6. Do the title and abstract accurately convey what has been found?

Title is descriptive of subject, not the result. Abstract is disjointed, the results reported in the abstract do not fully connect with the abstract discussion; it needs to be made clear that the uncemented components are higher cost but have lower risk of failure.

7. Is the writing acceptable?

Mostly, some typographical errors.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. Abstract

Need to make clear that uncemented devices are more expensive than cemented.

DONE

2. Results

Need to be presented in clearer and more complete manner, bring important factors to attention of the reader.

DONE

3. Discussion

A major limitation is that many conclusions are drawn from a relatively small number of failures; this limitation is not discussed. The stem failure rate is 1.8%, and that of the cups is 2.8%. There are a large number of different devices used, more than 20 types of stem and more than 14 types of cup. Failures were also associated with pathology and age; the use of various designs with particular pathology is not described. It may be that a higher proportion of a particular device was used for congenital dysplasia patients than for primary OA; and thus the failure incidence is related to the pathology not the device.

The statistical test applied (Cox multivariate analysis) guarantees, through the test for the validity of the model (-2 Log Likelihood), the correct application to the data; the independency of variables was verified as well.

The other point raised by the referee ..........’; and thus the failure incidence is related to the pathology not the device’ .......... is overcome by the statistical analysis we have applied, since Cox model is a semiparametric method for identifying multiple variables that relate to survival: In this model each variable is considered assuming all the other set at same level.

Therefore, in our hands, dysplasia represents a risk factor independent from type of cup/stem, and vice versa.

This point, that resulted unclear to the referee, has been clarified in the text.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
1. Abstract:

line 1. replace "in" with "with"

DONE

line 2. Spelling mistake "manly" should be "mainly"

DONE

line 3. Missing "The" before "present".

DONE


Last paragraph, "Four were the skilled surgeons." Sentence is not clear and has poor structure, does it mean that four skilled surgeons performed all surgeries, and some were performed by less skilled surgeons. If the intended meaning is that all surgeries were performed by four skilled surgeons, this should be clearly stated.

DONE

Poly is an abbreviation of polyethylene, the full term should be used.

DONE

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

My institution has received research funding from DuPuy, Stryker and Zimmer; products of these companies are included in the reviewed work.

Reviewer's report

Title: Factors affecting aseptic loosening of 4750 total hip arthroplasties: multivariate survival analysis.

Version: 1 Date: 5 February 2007

Reviewer: Andrew Roddam

Reviewer's report:

General
This manuscript describes the analysis of factors which could influence aseptic loosening of hip arthroplasties. To do this the authors make use of a consecutive series of arthroplasties between 1995 and 2000. This review concentrates mainly on the statistical and interpretational aspects of the manuscript - overall I think there are a number of problems which need to be addressed in a revised manuscript.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. I found the rather long and detailed description of the types of joint used and manufacturer presented in the text unnecessary and could be much more adequately summarised in a table.

DONE (data are now summarised in Tab 2 and 3)

2. There is a lack of a basic table summarising the main characteristics of the population - for example, sex, type of hip replacement, main reason, etc. To this end Tables 1 through 3 could be combined into a single table, which could be split according to those whose cup failed and those whose stem failed and those which did not.

Tables 1, 2 and 3 have been revised to adhere to the suggestions of both reviewers.

3. It is currently unclear whether or not there are any patients who suffered both a cup and stem failure. If so these should be treated separately from those who suffered either a stem or a cup failure. Is it true, as it is not stated, that if a patient suffered a cup failure their follow-up time would be censored at the date of this failure when analysing stem failures. This information needs to be given.

A sentence was added (in Materials and Method) to clarify:

Patient that suffered a cup failure their follow-up time would NOT be censored at the date of this failure when analysing stem failures.

Number of patients (46) having the failure at the same time of the cup and of the stem was added in result section

4. I find both the description and presentation of the results of the multivariable analysis almost impenetrable. It is not clear what the authors have done and this needs to be resolved. The authors need to state quite clearly what variables were included in the model - and c/f 2 describe these for all participants.

Variables included gender, age, diagnosis, Charnley score, right or left side, surgeon's skill, type of component, as stated both in the text (Materials and Method) and in Table 1. Also numbers contributing to each category have been presented in the revised Table 1.

Were these variables included all at once or was any sort of stepwise procedure used? My personal recommendation would be to include each variable individually and show these as unadjusted results, then I would include a fully adjusted analysis including all variables.

Suggestion has been welcome, as shown in the revised Tables 4 and 5

These two analyses can be shown in two columns and all relative risk estimates should be shown - not just
those which are not significant. When presenting results for categorical variables it is more usual for the first line to represent the reference group (and hence have a relative risk of 1.0) and then subsequent lines reflect each other level and shows their relative risk and CI. Also for categorical variables I would shown an n for each level to show the numbers contributing.

Reference groups (relative risk 1) have been more clearly emphasized in Tables 4 and 5

5. I was very surprised that the authors focused their interpretation so much on the cost aspects since it is not the price that influences the failure of item. Surely it is the more basic differences between the types of cup and stems which leads to failure?

Cost aspects can represent the basis for a future cost-efficacy analysis. That is the reason why we stressed on this aspect. Relative cost derives from design and technical properties of the devices.

6. This therefore leads to my next question - is it appropriate to include all cup/stem types in an analysis?

Should one be looking at failure within say cemented and non-cemented designs? Maybe there are more appropriate subgroups? One should investigate whether the patient/surgeon characteristics are the same in each of these subgroups - competing risks would be an appropriate analysis here.

We included all prostheses implanted in our Institute during a 6 years period. Subgroups were decided on the basis of a double criterion: cost and type of cup/stem. In the definition of type we considered not only the fixation (cemented/uncemented) but also the articular coupling in cup side (soft/hard) and the shape of the stem (anatomic).

Choice of Cox multivariate analysis was preferred due to the consideration that output of other International Registers of Hip and Knee prostheses (in Sweden, Norway, Denmark, Australia and more recently England) are usually done with this test.

Nevertheless the valuable suggestion of the reviewer is welcomed for our future approach to analogues problems.

After addressing the above points, the authors should review their text/interpretation of the results.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

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Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English Needs some language corrections before being published:

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests: I declare that I have no competing interests