Reviewer's report

Title: Bilaterality can be ignored when analysing the revision risk of knee prostheses: A frailty analysis of 55 298 knee prostheses on 44 590 patients in the national Swedish Knee Arthroplasty Register

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Reviewer: Birgitte Espehaug

Level of interest: A paper whose findings are important to those with closely related research interests

Advice on publication: Unable to decide on acceptance or rejection until the authors have responded to the compulsory revisions

Specific comments:

Few papers investigating knee replacements discuss or handle the issue of possible statistical dependencies introduced by bilateral operations. This is therefore an important paper. The national Swedish Knee Arthroplasty Register provides a uniquely large datamaterial with its information on knee replacements.

Compulsory revisions:

1. The Title may be unclear. In this article using a proportional hazards frailty model the authors find that there was no practical difference with the standard Cox proportional hazards model regarding the results of some explanatory variables, possibly due to a relatively low proportion of bilateral prostheses in the material.

2. In all the formulas for the hazards, the index for observation i is missing on the left side of the equal sign.

3. I would prefer to use another letter than b to indicate the random effect vector, since it is commonly used to indicate the estimate of the Greek letter beta. Another Greek letter may be more appropriate. Since the notation of P. Hougaard has been used for the individual frailty parameter Yi, I suggest that his notation and definitions be followed throughout the article. Yi should also be explicitly defined following its use.

4. Furthermore, while Y follows a gamma distribution b follows the log of a gamma distribution.

5. Is the interpretation of the frailty variance, as a measure for correlation (Kendall's tau), adequate in a situation where the estimation of the parameter is based primarily on patients with only one knee replacement?
6. Have the authors discussed possible effects of not having preset group sizes (since unilateral prostheses may become bilateral during follow-up)?

7. What was the estimation technique used to estimate the parameters in the frailty model? Was penalized partial likelihood used?

Orthographic corrections:
Abstract
- Background, line 2: ...one or both knees in a patient ...
- Background, line 3: Risk calculations are ... (delete 'such')
- Methods, line 4: ...which allows patients to ...
- The results paragraph was difficult to read.
- Conclusion, line 3: ...a relatively low proportion

Background
- page 1, lines 4-6: Unclear sentence.

Methods
- page 1, line 4: 1985-2000 (the abstract says 1985-1999)

Statistical methods
- page 2, line 1: Lifetimes of prostheses are often analysed ...
- page 2, line 5: ... and time t, common for all subjects i contributing ...
- page 2: We used the statistical software R ...
- page 3, line 1: The shared gamma frailty ... (delete 'For').

Results
- page 4, line 2: ...hazard ratio estimate of 1.98

Conclusions
- page 5, line 3: ...a relatively low proportion

References
- Reference 2: Author name is Hougaard, P.

Discretionary revisions:
1. Was the estimated frailty statistically significant different from zero?

Competing interests:
None declared.