Author’s response to reviews

Title: The influence of computer-assisted surgery on rotational, coronal and sagittal alignment in revision total knee arthroplasty

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Author’s response to reviews: see over
Subject: Submission revised manuscript

Dear prof. dr. T. Shipley, 8 September, 2013

Thank you for the opportunity to submit a revision of our manuscript. We hope that this latest revision is to your satisfaction and that it enables publication of the paper in the BMC Musculoskeletal Disorders.

In the attachment, we have answered the reviewers’ questions and comments point-by-point.

We are looking forward to your reply.

Yours sincerely, on behalf of all co-authors,

M.F. Meijer
Regarding the manuscript “The influence of computer-assisted surgery on rotational, coronal and sagittal alignment in revision total knee arthroplasty”.

We would like to thank the editor and the reviewers again for the care with which they have read our manuscript and the valuable comments they have made to improve this manuscript. Their questions and comments will be answered below point-by-point and corrections in the manuscript are underlined.

Reviewer 1:

The authors described that a stem of a smaller diameter will be chosen, so that the components are placed according to the bone cut made using the navigation system instead of the stem. Could the authors show canal filling ratio of the stem?

When alignment of the components is influenced by the stem, a stem of a smaller diameter will be chosen. However, we cannot show the canal filling ratio of the stem as there isn’t a standard ratio. We may have to choose a stem that is 1 to 3 mm smaller than the original stem. The ratio is different when you go from a 16 mm to a 15 mm stem or from a 11 mm to a 10 mm stem. We will choose the stem of the highest diameter possible. Reviewer 2 suggested to use a cemented stem when a smaller stem has to be implanted and thus to enlarge the canal filling ratio. However, using a cemented stem complicates a potential re-revision and causes stress shielding of the metaphyseal bone. Cementing underneath the tibial tray and leaving the stem uncemented generally provides enough component stability. In the rare case of the components not being rotationally stable, the stem will be cemented.

In the methods / design section under the heading ‘Intervention group’, we added that the stem will be cemented when the components are not rotationally stable.
Reviewer 2:

Authors have adequately respond to the issues I raised in the initial review. Although it is better than the original submission, there still remain some minor concerns.

1. In the situation when authors have to choose a stem of smaller diameter, will authors also use a non-cemented stem? What do authors think of using a cemented stem to improve fixation stability?

It is a good suggestion to implant a cemented stem to improve fixation stability when we need to choose a stem of a smaller diameter. However, using a cemented stem has some disadvantages. First of all, in the case of a re-revision, a cemented stem will complicate this surgical procedure. Removing of cement in the medullary canal is very difficult and can result in increased peroperative bone loss. Secondly, a cemented stem causes more stress shielding of the proximal tibia, which can have a negative effect on component fixation. Cementing underneath the tibial tray and leaving the stem uncemented generally provides enough component stability. In the rare case of the components not being rotationally stable, the stem will be cemented.

In the methods / design section under the heading ‘Intervention group’, we added that the stem will be cemented when the components are not rotationally stable.

2. How will authors address the “interrater or intrarater reliability” issues regarding post operative CT or X-ray measurements?

We do not exactly understand what the reviewer exactly means with this remark. First of all it is strange to state “interrater or intrarater reliability”. As both inter- and intraobserver reliability are of relevance it is not the one or the other; both have to be considered.

With respect to rotational alignment of the femoral component the Berger CT protocol can be considered as the standard to be used. Rotational alignment of the femoral component as described by the Berger CT protocol is the angle measured between the epicondylar axis and the prosthetic posterior condylar axis. The epicondylar axis is widely accepted as a reference for femoral component rotation and most commonly used in clinical practice. Previous studies showed that inter- and intraobserver reliability of marking the epicondylar axis on CT scan is good. In a recent study by Konigsberg et al., an interobserver ICC for the femoral component of 0.386 and intraobserver ICC of 0.606 (good) were reported. A possible explanation for the low interobserver reliability can be the involvement of a less experienced surgeon in this reliability study. Leaving this surgeon out of the analyses resulted in an interobserver ICC of 0.681 (good) and an intraobserver ICC of 0.842 (excellent). Experience in measuring rotation is thus essential to provide reliable measurements.

For determining rotational alignment of the tibial component, no golden standard exists. Several anatomical landmarks can be used to measure rotational alignment of the tibial component and the tibial tubercle is mostly used. The Berger CT protocol, as described in this manuscript, uses the tip of the tibial tubercle to determine tibial rotation. Rotational alignment of the tibial component referenced on the tibial tubercle represents the most reliable method and interobserver and intraobserver reliability are respectively good (ICC of 0.670) and very good (ICC of 0.809) when measuring axial tibial component alignment according to the Berger CT protocol.

Until now no literature is available regarding the reliability of leg axis measurements using EOS when a knee prosthesis is in situ. Therefore, we performed a reliability study and the manuscript of this study will be submitted soon. Results of this study demonstrate excellent interobserver and intraobserver reliability when measuring mechanical axis of the leg using EOS. Reliability of other angles measured when determining knee prosthesis alignment using EOS has not been investigated yet. Reliability studies concerning EOS measurements of spine, hip and lower limb show good to excellent inter- and intraobserver reliability.

3. Regarding sample size, please explain why authors decide P1 and P2 as 0.90 and 0.75, respectively.

When reading the details regarding the sample size calculation, it appears that we did not state the correct P1 value in this manuscript. The P1 value has to be 0.95 instead of 0.90. This P1 value of 0.95 we also corresponded to the Medical Ethics Committee of the University Medical Center Groningen (UMCG). The P2 value of 0.75 is correct.
When using the conventional operation technique, around 25% of the knees is considered a radiological outlier.\textsuperscript{19,20} Therefore, we have chosen a P2 value of 0.75. Previous research has shown that the use of CAS in TKA decreases the proportion of patients with radiological outliers with 17-30\%.\textsuperscript{19,21,22} When a 20% decrease in outliers is expected in the CAS group compared to the control group, the P1 value will be 0.95.

The explanation of how we decided to use a P1 of 0.95 and a P2 of 0.75 is added and the P1 value is corrected in the manuscript in the methods / design section under the heading ‘Sample size’.

\section*{Bibliography}


10. Meijer MF, Boerboom AL, Stevens M, Bulstra SK, Reininga IHF. Reliability and concurrent validity of EOS for prosthesis alignment after revision TKA. (To be submitted)


