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, 

17 May, 2013

Thank you for your response and for the reviewers' valuable comments and constructive criticism which have enabled us to improve the quality of our manuscript. I hope these revisions are to your satisfaction and that they enable publication of this paper in BMC Musculoskeletal Disorders.

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

I am 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 for the care with which they have read our manuscript and the valuable comments they have made on the manuscript. Their questions and comments will be answered below point-by-point. Corrections in the manuscript are underlined.

**Reviewer 1:**

1. *Since tibial and femoral revision components are placed with press-fit stems, the alignment of the components may be influenced by the stem. Do surgeons place the components according to navigation system?*

   This is a good point which was also mentioned by the other reviewer. Additional information concerning this is added in the materials and methods / design section under the heading ‘Intervention group’ of the manuscript.

   When implanting a press-fit stem, it may be that alignment of the components are influenced by the stem. After removal of the primary prosthesis and preparation of the bone cuts, different provisional components are tried in order to determine the correct type and size of the components. In this way, and by checking the alignment of the components with the navigation system, the orthopaedic surgeon will know if the stem influences the component alignment. In the revision system we have the availability of straight stems and off-set stems to use the best position of the component in combination with the stem but not forced by the stem. When this is the case, 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.

   Besides, we do have had situations in the past (i.e. cases of pre-existing extra-articular deformity or cases with extreme narrow medulla) in which the femoral or tibal medullary canal was not able to address the proper position of a fixed stem to the component. In those situations the surgeon will have to improvise how to position the components. The use of CAS in these cases will be extra helpful as one may not be able to rely on the shaft canal.

   2. *The authors should add more detail description about ORTHOsoft Navitrack® navigation system. Do surgeons identify the anatomical landmarks after removing the implants? If so, how is limb alignment determined in the navigation system?*

   A more detailed description about the navigation system is added in the methods / design section under the heading ‘Intervention group’ in the manuscript.

   The anatomical landmarks will be identified before removal of the primary prosthesis. In this way, the anatomical model calculated by the navigation system is the most accurate. Any malpositioning of the primary components will be recognized and demonstrated by the navigation system; the surgeon has to address these facts and has to correct the alignment during the revision.

   3. *How do surgeons determine rotational alignment during operation? Do the authors consider that surgical epicondylar axis is identified in all knees?*

   A description about how surgeons determine rotational alignment of both femoral and tibial component is added to the methods / design section under the heading ‘Intervention group’ in the manuscript.

   Rotation of the femoral component is determined according to three reference lines:
   1. the epicondylar axis. This axis is calculated by marking the medial and lateral epicondyles.
   2. the posterior condyles line formed by the posterior facets of the primary knee component.
   3. Whiteside’s AP line of the trochlea as measured in the femoral component.

   The navigation system will show the position of the provisional component in reference to all three parameters, while the surgeon has to choose which parameter is most adequate in case the three parameters differ significantly from each other. In general, the first parameter, the epicondylar axis, is most reliable and combines with the most optimal patellofemoral articulation.
Rotation of the tibial component is determined according to the axis between the middle of the posterior cruciate ligament insertion and the medial third of the tibial tuberosity. This axis is generated through marking both anatomical landmarks by the orthopaedic surgeon. We consider that the surgical epicondylar axis can be identified in all knees, even in revision arthroplasty with severe bone loss.

4. It would be better to add clinical results in both groups.
We agree that it is very interesting to investigate whether the use of CAS during rTKA also improves clinical outcome. However, this is not the scope of the current study. The objective of the current study is to investigate if CAS during rTKA significantly improves the postoperative prosthesis alignment. It is our hypothesis that the use of CAS during rTKA leads to better postoperative prosthesis alignment. Malalignment of a knee prosthesis leads to worse survival because of a higher risk of aseptic loosening.\textsuperscript{1-3} The use of CAS during primary TKA leads to better prosthesis alignment and thus a decrease of aseptic loosening.\textsuperscript{4} For malalignment to cause aseptic loosening, this is a process of many years. Therefore, we don’t expect this advantage to be visible when functional outcome is compared at short- and midterm after primary CAS-TKA. Hoppe et al. found a better postoperative alignment after primary CAS-TKA, but no functional improvement 2 and 5 years postoperatively.\textsuperscript{5} This is in line with other studies.\textsuperscript{6}

It is expected that the advantage in terms of survival will also not be visible in the short- or midterm which will be the time span in this study. Bae et al.\textsuperscript{7} stated that the interval between rTKA and rerevision is 7.2 years. When stating this interval according to mode of failure of rTKA, rerevision due to aseptic loosening was performed after 8.0 years.

Concluding, since it can be hypothesised that primary CAS-TKA does not lead to improvement in clinical outcome in the short- and midterm, we also do not expect to find improvement in clinical outcome after revision CAS-TKA in the time span of the current study. Potential advantage of CAS during rTKA will be better prosthesis alignment, resulting in better survival. When this is the case, this potential advantage is expected to be seen in the long term. For that follow-up studies will be planned.
Reviewer 2:
Authors should be commended for planning a study regarding computer-assisted surgery (CAS) for revision total knee arthroplasty (rTKA) due to its technical difficulty, especially in a revision setting. The protocol of this study is to investigate the effect of CAS on rotational, coronal and sagittal alignment in rTKA. The authors hypothesized that CAS leads to better rotational, coronal and sagittal prosthetic alignment when used during rTKA. The publications regarding CAS of rTKA are very limited in number, so your research will be informative and educational. In addition, as the number of rTKA cases has increased, research regarding the accuracy of component alignment is well-timed. Even with the benefits of this study protocol, I would like to ask some questions regarding the background and study methods.

1. Minor Essential Revisions
Considering the use of an expensive system instead of no equipment, better results should be achieved. Other than the alignment issue, what is the benefit of such a system? The CAS system is expensive and requires a longer operation time (not to mention learning period), and longer operation time has an increased risk for potential complications, especially periprosthetic joint infection (PJI), a major cause of re-revision TKA. The authors’ hypothesis that “CAS system has better alignment than conventional TKR” is a good one. However, considering that information regarding CAS rTKA is very limited, if additional clinical parameters, such as patient’s quality of life measurements and knee score, in addition to better alignment and clinical parameters (operation time, blood loss, hospital stay, etc.), can be added to the study parameters, the value of this research will increase even more.

In primary CAS-TKA, it is known that the operation time is prolonged compared to the conventional technique. Mean extra time needed when CAS is used, is 12-15 minutes. Perlick et al. found a mean prolonged operation time of 15 minutes when CAS was used in rTKA, compared to the conventional technique. Although the use of CAS may increase operation time during rTKA, it may also save time during several steps. As we already have many years of experience in using CAS in primary TKA we have been using CAS in some rTKAs (pilot cases). Reconstruction of the joint with good alignment appeared to be easier with CAS than using conventional instruments. Thus, CAS also serves as a helpful tool for the orthopaedic surgeon during surgery. In both tibial and femoral preparation some steps are skipped or shortened as the navigation system tells us the overall alignment of the leg, the component alignment compared to the bone and the expected height of the joint by calculating the resection and defects. Therefore it is our expectation, that the use of CAS in rTKA will not take extra time. Since available literature regarding the use of CAS during rTKA is very limited, more data is needed to determine whether CAS actually prolongs operation time during rTKA as it does during primary TKA.

Reviewer 1 also suggested to add clinical parameters in this study and we think this is a good suggestion. However, we decided to not take this into account in this study. We agree that it is very interesting to investigate whether the use of CAS during rTKA also improves clinical outcome. However, this is not the scope of this study. The objective of this study is to investigate if CAS during rTKA significantly improves the postoperative prosthesis alignment. It is our hypothesis that the use of CAS during rTKA leads to better postoperative prosthesis alignment. Malalignment of a knee prosthesis leads to worse survival because of a higher risk of aseptic loosening. The use of CAS during primary TKA leads to better prosthesis alignment and thus a decrease of aseptic loosening. For malalignment to cause aseptic loosening, this is a process of many years. Therefore, we don’t expect this advantage to be visible when functional outcome is compared at short- and midterm after primary CAS-TKA. Hoppe et al. found a better postoperative alignment after primary CAS-TKA, but no functional improvement 2 and 5 years postoperatively. This is in line with other studies.

It is expected that the advantage in terms of survival will also not be visible in the short- or midterm which will be the time span in this study. Bae et al. stated that the interval between rTKA and rerevision is 7.2 years. When stating this interval according to mode of failure of rTKA, rerevision due to aseptic loosening was performed after 8.0 years.

Concluding, since primary CAS-TKA does not lead to improvement in clinical outcome in the short- and midterm, we expect not to find improvement in clinical outcome after revision CAS-TKA
in the time span of this study. Potential advantage of CAS during rTKA will be better prosthesis alignment, resulting in better survival. When this is the case, this potential advantage is expected to be seen in the long term. For that follow-up studies will be planned. Operation time, blood loss and length of hospital stay will also be recorded during this study as described under the methods / design section under the heading ‘Study procedures’. When the use of CAS during rTKA is proven to have more benefits besides improved alignment, this may outweigh additional costs and a possible prolonged operation time. However, more research has to be done to assess these potential advantages.

2. Background (Discretionary Revisions)

Aseptic loosening is the main reason for the use of CAS in primary TKA. Likewise, what is the main reason for use of CAS during rTKA? Technical issues such as distorted anatomical landmarks are important factors that should be included for consideration. Also, the causes of failure following revision TKA must be stated. In addition, PJI is actually the major cause of re-revision not the loosening that is stated in your paper. According to Dr. Parvizi’s report in 2011, loosening accounts for 4.9% of re-revisions and misalignment for 2.9%. Loosening and malalignment should be regarded as one of the factors to be prevented to assure implant survival rather than as the major cause of failure. It seems that the background of this study protocol is focused on the complications of conventional primary TKA and assumes that they will have the same impact on revision TKA. This may not be a legitimate assumption. I know that this project is focused only on component alignment during rTKA, and I agree that your background is sufficient. However, it will be beneficial for readers to provide more knowledge and information by way of including the above suggested information in the background section.

It is a good suggestion to state more background information about this and thus the reasons of rerevision are more clarified in the introduction section of the manuscript. The main reason for the use of CAS during rTKA is to help the orthopaedic surgeon to determine the right position of the components. Since anatomical landmarks have often disappeared during revision surgery, CAS may be a helpful tool. The technical issue of distorted anatomical landmarks is important, but is also the main reason why CAS may be very helpful in determining correct prosthesis position. Distorted anatomical landmarks make it also very difficult to determine prosthesis position with intra- and extramedullary guides. Using CAS may still not be perfect, but can still be easier than the conventional operation technique when it comes to determine saw cuts. We hypothesise that the use of CAS during rTKA also leads to better postoperative prosthesis alignment. This potential improvement in postoperative prosthesis alignment may result in less rerevisions because of aseptic loosening and thus increase survival. I agree that it is not aseptic loosening but infection that is the main reason for rerevision. However, there is a great variety concerning the indications for rerevision as stated in the literature. Mortazavi et al. found that 4.9% and 2.8% of the rerevisions were due to respectively aseptic loosening and malalignment. On the other hand, other studies report aseptic loosening to be the indication for rerevision in 19-30% of the cases. Concluding, infection may be the primary mode of failure after rTKA, malalignment and aseptic loosening are also important indications for rerevision.

3. Methods and Design (Major Compulsory Revisions)

Design
First of all, I think, for the most accurate study results, the authors should recruit a control and intervention group in the same time period. (Considering your reported revision of 21-30 revision surgeries per year, I think this is possible). However, if the authors decide to conduct the study over a different time period (10 years), the following concerns about the control and intervention groups must be explained.

The reviewer is right that the ideal situation would be to execute a Randomized Controlled Trial (RCT) in which an intervention and control group are recruited in the same time period. However we expect that the time period between September 2012 and September 2015 will be too short to execute an RCT. Based on earlier experience it is expected that an amount of patients will not be able to or are
not willing to cooperate in this study. Although our design with a historical group is methodological not that strong as a RCT, it is still a methodological acceptable design to compare the new technique with the conventional procedure.

We expect to include enough patients (n=44) between September 2012 and September 2015. However, we also expect that this time period will be too short to include patients for the control group. Recruiting patients for the historical control group will be done in reversed sequence from September 2012. We expect that the total time span for both the historical control group and intervention group will be a maximum of six years.

1. Surgeon factor: Will the same surgeon perform all of the surgeries? If not, how will the differences between surgeon’s experience be addressed?

All patients in both groups are operated by the same two surgeons (SKB or ALB).

2. Patient factor: Other than patient age, gender and other demographic features, we can assume that, 10 years ago, surgical indications were different than they are now (only in more severe patients maybe?).

Due to the limited time scope (max 6 yrs) we do not expect significant changes in surgical indications in both groups.

3. Device factor: Although the authors assume instrument similarity due to the use of the same company’s system, the system and assistant tool used during conventional rTKA must be changed and improved compared to that used ten years ago.

Instruments used during surgery will always be updated and improved over time, but the present revision system has not been changed for the last 5 years yet and according to the company’s expectation there will not be any major change in near future. Since we try to keep the time span as short as possible, we don’t expect this factor to significantly influence the outcome of this study.

Component rotation issue
In some cases, the medial and lateral epicondyles of the femur are missing or distorted. In this situation, 1) Is there a possibility of error during registration of anatomical landmarks and resultant erroneous computer information? 2) How will you measure and compare the femoral component between conventional rTKA and CAS rTKA?

In any system there is the possibility of error during registration, but the calculated model will be based on several landmarks. When one is missing the navigation system will even compute a model and will suggest the position of the knee. Then the surgeon has to approve the model before continuing. This means that the final decision about position and alignment will always be made by the surgeon with or without help of the navigation system. One has to consider the CAS as a helpful tool, not as a robotic arm which decides by itself.

In the case of severe bone loss with even missing the medial and lateral epicondyles we will assess the destruction according the AORI classification of bone loss. In the hypothetical case of type 3 bone defects with missing both epicondyles we will strongly take in mind that a revision with a rotating hinge knee prosthesis with augmentation may give inferior results compared to the use of a tumor prosthesis. When choosing the latter – which system is available on the shelf in our center as one of the four national orthopedic oncology centers – we will exclude the patient from the protocol of CAS-rTKA and we will continue with a tumor prosthesis.

Component coronal and sagittal alignment issue
Unlike CAS in primary TKA, during CAS rTKA, revision femoral and tibial components seem to also be dependent on the position of the extended stem within the femoral and tibial shaft canal. In particular, if each component has a fixed stem angle and a press-fit stem, positioning of the
components will likely be affected by stem-canal association, regardless of the femoral or tibial surface being resected by CAS. This issue will need to be addressed.

This is a good point which was also mentioned by the other reviewer. Additional information concerning this is added in the methods / design section under the heading ‘Intervention group’ of the manuscript.

When implanting a press-fit stem, it may be that alignment of the components are influenced by the stem. After removal of the primary prosthesis and preparation of the bone cuts, different provisional components are tried in order to determine the correct type and size of the components. In this way, and by checking the alignment of the components with the navigation system, the orthopaedic surgeon will know if the stem influences the component alignment. In the revision system we have the availability of straight stems and off-set stems to use the best position of the component in combination with the stem but not forced by the stem. When this is the case, 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.

Besides, we do have had situations in the past (i.e. cases of pre-existing extra-articular deformity or cases with extreme narrow medulla) in which the femoral or tibial medullary canal was not able to address the proper position of a fixed stem to the component. In those situations the surgeon will have to improvise how to position the components. The use of CAS in these cases will be extra helpful as one may not be able to rely on the shaft canal.

**Measurement:**
The coronal angle of the femoral component seems to be missing (for femur, mL DFA only; for tibia, mMPTA and aPPTA).

In the methods / design section under the heading ‘Radiographic evaluation’, the postoperative radiographic evaluation is added, including mL DFA, mMPTA and aPPTA.

**4. Conclusion (Discretionary Revisions)**
Your conclusion is good, but adding other clinical parameters will increase its strength.

We agree that it is very interesting to investigate whether the use of CAS during rTKA also improves clinical outcome. However, this is not the scope of this study. A detailed description of why we have chosen not to include other clinical parameters is described under point 4.

**Bibliography**


