Author's response to reviews

Title: Anteroposterior glide versus rotating platform low contact stress (LCS) knee arthroplasty: a randomised controlled trial

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Author's response to reviews: see over
Dear Dr Le,

Re:: MS: 3980664461119066 'Anteroposterior glide versus rotating platform low contact stress (LCS) knee arthroplasty: a randomised controlled trial'

Thank you for your recent email, and for allowing us to revise the above manuscript.

We have carefully considered the comments and criticisms put forward by the reviewers. These have been implemented as follows, and changes/additions in the text are indicated in bold:

1. This is a prospective at least single blind randomized comparative study with multiple investigating sites.
   Answer: the study is not going to be carried out from multiple investigating sites. We have now spelled out that the patients are going to be recruited from the Orthopaedic Preoperative clinics held at the Orthopaedic Outpatient Department of the City General Hospital, Stoke on Trent, England. The operations will be performed in the operating theatres of the City General Hospital, Stoke on Trent, England. Assessment etc will be performed in the Bionics Laboratory, City General Hospital, Stoke on Trent, England.

2. The study is simple and direct. The primary endpoint is range of motion. The evaluators are blind.
   Answer: many thanks

3. The sample size calculation is OK.
   Answer: many thanks

4. However, the following points were not clearly addressed:
   A. The estimated difference of ROM is 20°. It is a little bit too large for a no-difference study clinically, when the standard deviation is as small as 20°.
   Answer: Our statistician and our clinicians advised that this difference of ROM of 20° would be both statistically and clinically relevant. When the study was sent for peer review (a necessary step required both by the Research and Development Department and by Ethics Committee in our setting), we received no adverse comments on this. Therefore, the application was approved by our Ethics Committee with this estimated difference of ROM of 20°. The study protocol has been registered with the ISRCTN number of 52943804.
2. How the FASTRAK system is used to measure the ROM should be addressed. Is there any potential bias? Answer: The following has been added to the text: ‘Fastrak has been developed by Polhemus (Colchester, VT, USA) in the early 1990 to monitor aircraft pilots and to be used in the animation industry. FASTRAK is a 3 dimensional tracking device based on emission of a low frequency magnetic field by a transmitter. Within this magnetic field, the position and orientation of up to four sensors and their spatial relationship can be recorded simultaneously. FASTRAK provides dynamic, real-time six degrees of freedom measurement. It computes the position (X, Y, Z Cartesian coordinates) and orientation (azimuth, elevation and roll) of the sensor through space relative to the source transmitter. Each sensor measures data in three different planes: a primary plane of movement and two secondary planes. The recording is performed digitally on a computer. The data can be represented as a real time graph or numerically as range of movement. To perform each Fastrak assessment, double-sided adhesive discs will be used to fix all sensors to the skin. The first sensor will be placed just above the lateral malleolus. The second sensor will be placed just lateral to the the anterior tibial tuberosity of the tibia. The third sensor will be placed over the lateral condyle of the femur. The wires connecting the sensors to the transmitter were secured with Micropore surgical tape (3M Healthcare Ltd. Loughborough, Leicestershire, UK) to avoid pull on the sensors.

Three flexion and extension movements will be performed consecutively without stopping so as to obtain three measurements. The Fastrak will be centred at 0º at full knee extension before movements begin. Each patient will perform a trial run to confirm that the patient satisfactorily understood the instructions. The average range of motion of the three trials will be used for analysis. A preliminary feasibility study showed a variability of 3° ± 1° in the measurements of range of flexion and extension of the knee performed using the Fastrak system in 25 patients on the waiting list for total knee arthroplasty. All measurements will be taken by the same researcher (AR) who is not involved in the clinical management of the patients.

3. Site variation should be considered, if any.

Answer: the study is not going to be carried out from multiple investigating sites. We apologise for the confusion engendered. We have now spelled out that the patients are going to be recruited from the Orthopaedic Pre-operative clinics held at the Orthopaedic Outpatient Department of the City General Hospital, Stoke on Trent, England. The operations will be performed in the operating theatres of the City General Hospital, Stoke on Trent, England. Assessment etc will be performed in the Bionics Laboratory, City General Hospital, Stoke on Trent, England.

4. The statistics should address how patient withdrawal is to be handled, or an ITT analysis.

Answer: we have spelled out that the analysis will be carried out using intention to treat criteria
5. Since PCL may play an important role of the knee proprioception. If there is difference in proprioception between the two groups, it would likely due to the presence of the PCL in the AP glide group rather than the prosthesis itself.
Answer: we do acknowledge that this is possible, but we shall only know after the study will have been carried out.

6. The measurement of proprioception in this study is carried out in the plane of flexion and extension. It will be interesting to study the proprioception in the rotating plane of the knee.

Answer: We agree with the reviewer that changes in other planes could be a consequence of the intervention performed. However, when reviewing the literature it emerged that normative data in this field are lacking, and that the criteria to measure this particular motion are ill-defined. Therefore, we decided not to undertake these measurements. This is reflected in the application to our Research and Development Department and Ethics Committee. The approved application (ISRCTN number 52943804) reflects this.

We thank the reviewer and the Editorial Board for the suggestions given. We hope that the changes implemented will have strengthened the manuscript, and made it suitable for acceptance in *Biomedcentral Musculoskeletal Disorders*.
With best regards

Nicola Maffulli