Mini-incision versus mini-incision and computer-assisted surgery in total knee replacement: A radiological prospective randomised study

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Abstract

The aim of this trial was to compare the radiological results of 74 patients undergoing a mini-invasive total knee replacement (TKR) using either a traditional alignment guide (MIS group) or a computer assisted alignment system (MICA group). All the patients were prospectively randomised to either group and the same implant was used for both groups. At 8 months post-operatively, the frontal femoral component angle (FFC), the frontal tibial component angle (FTC), the hip–knee–ankle angle (HKA) and the sagittal orientation of components (slopes) were evaluated respectively. The slopes of the femoral component and the FTC angle were statistically better aligned in the MICA group (p<0.001). The MICA group showed both a significant fewer number of outliers and a significant higher number of implants with all five radiological parameters ideally aligned. The operative time was statistically longer in the computer assisted group.

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1. Introduction

Minimally invasive joint replacement has become increasingly popular in the orthopaedic community. Proponents of this technique in total knee replacement (TKR) surgery claim benefits including faster recovery, reduced blood loss and lower costs [1–5,7]. Often less invasive surgery has been identified only as a shorter surgical approach to implant a traditional total knee arthroplasty performing the so called “key-hole surgery”. Likewise mal-alignment, avulsion fractures and wound problems are all potential dangers encountered when performing joint replacement surgery through small incisions [6–9].

Mal-alignment can adversely affect the longevity of the knee prostheses with early wear and implant loosening both linked to sub-optimal implant position [10,11]. Greater than 3° varus or valgus mal-alignment can result in higher failure rates whilst correct alignment has been associated with improved clinical outcome [10,11]. Berend et al. showed that alignment the relative hazard of failure after 2 years minimum follow-up was 17.2 times greater in a tibial component with >3° varus alignment [12].

Using traditional intra-medullary and extra-medullary TKR systems a number of studies have shown correct alignment was achieved in between 73 and 82% [13–15]. Computer-assisted joint replacement surgery has been introduced to aid implant alignment and hopefully improve on the traditional alignment systems. Recent studies using computer-aided alignment do appear to produce superior results compared to hand-guided techniques [16–21]. These computer-assisted systems have been shown to improve mechanical alignment in the frontal and sagittal femoral axis and the frontal tibial axis. Bathis et al. [17] and Sparrmann et al. [19] reported a post-operative mechanical alignment within 3° varus or valgus in 96% and 100% respectively in navigated implants. Obviously, computer assisted surgery should address the more difficult components position-ment in a correct alignment even with smaller surgical exposure.

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In 2005, Seon and Song [22] reported better functional results and patient satisfaction using computer navigation-assisted minimally invasive TKR compared to conventionally performed TKR. However, no comparison between minimally invasive TKR using traditional alignment guides and computer navigation systems has been documented in the literature. The aim of this prospective randomised trial was to compare the radiological results of two different groups of TKRs performed with a less invasive surgical approach using either a traditional hand guided technique or the assistance of a computer assisted alignment system.

2. Materials and methods

Following the local ethics committee approval since September 2004, 74 patients undergoing TKR have been enrolled in the study (Table 1). In all cases a Posterior Cruciate Retaining implant with a minimally invasive approach using dedicated tools (Genesis II, Smith and Nephew, Memphis, USA) was used.

Inclusion criteria included a body mass index less than 30, no combined ligamentous laxity, no flexion deformity and no previous open knee surgery. To avoid bias from the learning curve the first 10 cases in each group were previously excluded.

After an informed consent patients were randomly assigned to either the traditional or computer-assisted alignment group choosing one of two closed envelope by a nurse not involved in the study, just prior to the skin incision. All TKRs were performed by two of the Authors (N.C. and A.M.). In the MIS group (37 knees), a minimally invasive approach was performed using an intra-medullary femoral guide and an extra-medullary tibial guide. In the MICA group (37 knees), the implant was positioned using a CT-free computer assisted alignment system (Vector Vision, version 1.52, BrianLAB, Munich, Germany) [23] using the same minimally invasive surgical approach. In both groups a skin incision was pre-drawn over the mid patellar skin ranging in length from between 10 cm and 12.5 cm. A medial para-patellar arthrotomy extended proximally to the quadriceps tendon was performed in all cases with the patella retracted laterally. All prostheses were implanted using dedicated smaller instruments including cutting blocks specifically designed for minimally invasive surgery. The implants were cemented in all cases and the same pre- and post-operative rehabilitation protocols were used for both groups. Early weight bearing as tolerated was encouraged in all patients. The duration of surgery was documented in all cases.

Eight months after surgery each patient had long-leg standing anterior–posterior radiographs and lateral radiographs of the knee. Standing radiographs were obtained with the knee in maximum extension, the patella pointing forward and both hips and ankles visible on the film. The lateral radiographs were taken with the knee in 30° of flexion on a radiographic film 20×40 cm. All the

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Patient demographic and baseline data</th>
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<tr>
<td></td>
<td>MIS group (N=37)</td>
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<tr>
<td></td>
<td>Mean±SD (range)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>72.8±5.7 (64.8)</td>
</tr>
<tr>
<td>Gender</td>
<td>17 males</td>
</tr>
<tr>
<td></td>
<td>20 females</td>
</tr>
<tr>
<td>Pre-operative hip–knee–ankle angle (°)</td>
<td>172.5±5.7 (166–186)</td>
</tr>
<tr>
<td>Body mass index</td>
<td>27.0±1.7</td>
</tr>
<tr>
<td>MIS = traditional alignment system; MICA = computer-assisted alignment system; SD = standard deviation.</td>
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Fig. 1. Hip–knee–ankle (HKA) angle values distribution in the MIS and MICA groups.

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<table>
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<tr>
<th>Table 2</th>
<th>Comparison of the post-operative results in the two groups</th>
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<tr>
<td></td>
<td>MIS group (N=37)</td>
</tr>
<tr>
<td></td>
<td>Mean±SD (range)</td>
</tr>
<tr>
<td>Surgical time (min)</td>
<td>75.8±12.9 (48–106)</td>
</tr>
<tr>
<td>Post-operative HKA angle (°)</td>
<td>178.4±1.8 (175–182)</td>
</tr>
<tr>
<td>Post-operative FFC angle (°)</td>
<td>88.7±1.6 (86–91)</td>
</tr>
<tr>
<td>Post-operative FTC angle (°)</td>
<td>88.4±1.8 (84–91)</td>
</tr>
<tr>
<td>Femoral slope (°)</td>
<td>91.1±2.4 (87–96)</td>
</tr>
<tr>
<td>Tibial slope (°)</td>
<td>86.8±2.5 (82–93)</td>
</tr>
</tbody>
</table>

MIS = traditional alignment system; MICA = computer-assisted alignment system; SD = standard deviation; HKA = hip–knee–ankle; FFC = frontal femoral component; FTC = frontal tibial component.

Fig. 2. Frontal tibial component (FTC) angle values distribution in the MIS and MICA groups.
radiographs were always taken with a standardized protocol with the same magnification. We have painstakingly educated and communicated with our radiographers in obtaining consistent films before embarking on this trial. The radiographs were repeated if mal-rotation was detected.

The radiographs were assessed by an independent radiologist blinded to the original procedure to determine the mechanical axis of the limb (hip–knee–ankle angle: HKA) as primary outcome measure. Furthermore the frontal femoral component angle (FFC), the frontal tibial component angle (FTC) and the sagittal orientation (slope) of both femoral and tibial components were determined. The FFC was determined as the angle between the mechanical axis of the femur and the transverse axis of the femoral component. The FTC was determined as the angle between the mechanical axis of the tibia and the transverse axis of the tibial component. The slopes of the femoral and tibial component were evaluated by measuring the angle formed between a line drawn tangential to the baseplate (surface in contact with bone) of the respective components and the anterior femoral cortex or mechanical tibial axis. The desired prosthesis alignment for each parameter was determined prior to the study as a FFC angle of 90°, a FTC angle of 90°, an HKA angle of 180°, a femoral slope of 90° and a tibial slope of 87°.

The number and percentage of outliers for each parameter was determined. Outliners were defined as prostheses with any alignment parameter beyond 3° of the desired value. In addition the percentage of patients from each group with all five parameters within the desired range was calculated. Except the post-operative HKA angle, all the remaining values were considered as secondary outcome measures.

Statistical Analysis was carried out using SPSS for Windows Release 11.0 (SPSS Inc, Chicago, Ill, USA). Data were represented as a mean and standard deviation for continuous response variables and as percentages for discrete variables. Differences between the two groups were measured with an independent Student’s T test or Mann–Whitney non-parametric test depending on the data distribution of the continuous variables. Differences in the percentage of outliers for each parameter were tested using a Fisher exact test. The Pearson chi square test was used to compare the total sum of outliners and the percentage of patients in each group with all five parameters within the desired alignment. A p-value of less than 0.05 was considered statistically significant for all analyses.

According to the data reported in literature in post-operative mechanical alignment of the limb, we assumed a probability of outliners of 2% and of 26% for the MICA group and for the MIS group respectively according to the data.

**Table 3**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>MIS group (N=37)</th>
<th>MICA group (N=37)</th>
<th>Statistical p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outliners for HKA angle</td>
<td>6 (16.2)</td>
<td>0 (0.0)</td>
<td>0.025</td>
</tr>
<tr>
<td>Outliners for FFC angle</td>
<td>5 (13.5)</td>
<td>2 (5.4)</td>
<td>0.430</td>
</tr>
<tr>
<td>Outliners for FTC angle</td>
<td>6 (16.2)</td>
<td>0 (0.0)</td>
<td>0.025</td>
</tr>
<tr>
<td>Outliners for femoral slope</td>
<td>6 (16.2)</td>
<td>1 (2.7)</td>
<td>0.100</td>
</tr>
<tr>
<td>Outliners for tibial slope</td>
<td>4 (10.8)</td>
<td>1 (2.7)</td>
<td>0.360</td>
</tr>
<tr>
<td>Sum of all outliers</td>
<td>27 (73.0)</td>
<td>4 (10.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Implants with all 5 parameters ideally aligned</td>
<td>20 (54.1)</td>
<td>33 (89.2)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

MIS = traditional alignment system; MICA = computer-assisted alignment system; HKA = hip–knee–ankle; FFC = frontal femoral component; FTC = frontal tibial component.
3. Results

Analysis of the demographic data for both groups showed no statistically significant differences in age, body mass index and pre-operative deformity (Table 1). The mean surgical time was 89.4 min (range: 75–112) in the MICA group and 75.8 min (range: 48–106) in the MIS group. This difference was statistically significant ($p<0.001$) (Table 2). There were no intra-operative complications in either group.

The HKA angle was 179.1° (range: 177°–182°) and 178.4° (range: 175°–182°) in the MICA group and the MIS group, respectively. In the MICA group the FFC angle was 89.4° (range: 86°–92°) and in the MIS group 88.7° (range: 86°–91°). The FTC angle was 89.2° (range: 87°–91°) in the MICA group and 88.4° (range: 84°–91°) in the MIS group. The slope of the femoral component was 92.2° (range: 89°–94°) and 91.8° (range: 87°–96°) in the MICA group and the MIS group, respectively. The slope of the tibial component in the MICA group was 87.4° (range: 84°–91°) and in the MIS group 86.8° (range: 82°–93°).

The alignment of the femoral component as determined by the slope was significantly better in the MICA group ($p<0.001$). Comparison of the FTC angle showed a statistically better alignment in the MICA group ($p<0.029$). There were no statistically significant differences in HKA, FFC angles and in the slope of the tibial component between the two groups (Table 2).

The number of implants in each group aligned within 3° of the desired position was determined for all five radiological parameters. This showed all implants in the MICA group achieved HKA and FTC angles aligned within this range while only 31 implants (83.8%) in the MIS group achieved similar accuracy (Figs. 1 and 2). These differences in HKA and FTC angles were statistically significant ($p=0.025$). Thirty-six (97.3%) implants in the MICA group achieved a femoral slope aligned within 3 degrees of the desired position compared with 31 (83.8%) implants in the MIS group (Fig. 3). In the MICA group 36 implants (97.3%) achieved a tibial slope aligned within this range while only 31 implants (86.5%) in the MIS group achieved a similar result (Fig. 4).

4. Discussion

Correct axial alignment in TKR is a significant factor influencing the longevity of the implant. Mal-positioning of the prosthesis in any anatomical plane can cause significant complications. Varus or valgus mal-alignment, one of the commonest causes of early loosening and alterations in the joint line, can lead to limited movement [10,12–14,25]. Using traditional alignment systems Ritter et al. [11] reported that mal-alignment occurred in more than 10% of knee replacements. It is hoped that computer navigation can reduce the incidence of mal-alignment in TKR and recent comparisons between computer-aided and hand-guided alignment systems have suggested the former produces superior results [16–21].

Minimally invasive joint replacement has become increasingly popular driven both by the orthopaedic community and patient expectations. However, mal-alignment has been identified as a potential problem when performing joint replacement surgery through small incisions [6–9]. Minimally invasive techniques can make implant positioning more difficult by limiting visualisation of anatomical landmarks. Recently, after initial enthusiasm, authors have recommended caution when using mini-invasive techniques for total joint replacement [8,26–28]. Dalury and Dennis [9] pointed out that although total knee arthroplasty performed using a minimal incision may provide some early advantages, minimal incisions can impede a surgeon’s vision and may influence component alignment and possibly compromise long-term outcome.

In 2006, Chen et al. [29] demonstrated only peri-operative advantages with a quadriceps sparing approach over a standard para-patellar approach but with a lower accuracy in the radiological outcomes.

Computer-assisted surgery has the potential to address the difficulties of correct component positioning and alignment in minimally invasive knee replacement. The accuracy of computer navigation compared to traditional alignment systems has been demonstrated in the literature [16–21]. Recently a prospective randomised study comparing computer navigation-assisted minimally invasive TKR to conventional TKR reported a lower incidence of radiological outliers and better pain score in the computer navigation group [30].

In this prospective randomised study the authors compared 2 different TKR alignment systems using the same mini-incision approach and dedicated instruments. The same prostheses were implanted using either a traditional alignment guide (MIS group) or a computer assisted alignment system (MICA group). The inclusion criteria were very selective: ideal candidate for a
CR implant, no flexion deformity, neither obese nor previous open knee surgeries.

Comparison of the radiological results showed statistically significant differences between the 2 groups for component positioning both in the coronal plane and sagittal plane. The desired femoral slope and FTC angle were achieved in significantly more patients in the MICA group than the MIS group. Furthermore the results supported previous studies showing a statistically significant reduction in the number of outliers in the computer-assisted technique. In particular, the IKA angle in MICA group demonstrated significantly fewer outliers. The sum of all outliers for all the radiological parameters was statistically higher in the MIS group. In addition, the number of implants with all parameters aligned within desired values was statistically higher in the MICA group. No complications were seen in either group however the surgical time was statistically longer in the MICA group.

These early results suggest superior results for a number of radiological parameters and overall better alignment of implants using computer-assisted minimally invasive TKR.

Despite better radiological alignments using a computer assisted technique, Spencer et al. has recently pointed out how at 2 years follow-up the functional outcome between navigated and traditional groups of TKRs appears to be no different [31].

However, according to the short follow-up this study did not intend to demonstrate any correlation between the lower numbers of outliers and superior clinical outcome and implant survivorship in the computer navigation group. It is possible that improved alignment might decrease wear for the implant and improve the functional outcome in the long term, but this hypothesis needs further investigations and longer follow-ups.

References