Computer-assisted knee arthroplasty versus a conventional jig-based technique

A RANDOMISED, PROSPECTIVE TRIAL

S. K. Chauhan, R. G. Scott, W. Breidahl, R. J. Beaver

From the Royal Perth Hospital, Perth, Western Australia

We have compared a new technique of computer-assisted knee arthroplasty with the current conventional jig-based technique in 70 patients randomly allocated to receive either of the methods. Post-operative CT was performed according to the Perth CT Knee Arthroplasty protocol and pre- and post-operative Maquet views of the limb were taken. Intra-operative and peri-operative morbidity data were collected and blood loss measured. Post-operative CT showed a significant improvement in the alignment of the components using computer-assisted surgery in regard to femoral varus/valgus (p = 0.032), femoral rotation (p = 0.001), tibial varus/valgus (p = 0.047) tibial posterior slope (p = 0.0001), tibial rotation (p = 0.011) and femorotibial mismatch (p = 0.037). Standing alignment was also improved (p = 0.004) and blood loss was less (p = 0.0001). Computer-assisted surgery took longer with a mean increase of 13 minutes (p = 0.0001).

Correct alignment of the component and soft-tissue balancing have been cited as two of the most important aspects of successful knee arthroplasty. Alignment depends on many factors including accurate pre-operative planning, normal bone morphology to which standardised instruments are applied and accurate skilful placement of these instruments. Incorrect alignment caused by a variation of any of these factors can lead to abnormal wear, premature mechanical loosening of the components and patellofemoral problems.

Computer navigation systems, which are widely used in Europe and Australia, are now gaining popularity in the UK and North America. Their aim is to provide more accurate implantation by digital mapping based on standard anatomical landmarks and kinematic analysis. A number of studies have suggested that there is improved alignment when this technology is used. However, these studies have used standard radiography with isolated CT to measure alignment, which we believe is not sufficiently accurate. Our aim therefore was to assess the safety and accuracy of this new computerised technology, by comparing a group of patients operated on using computer-assisted total knee arthroplasty (CAKA) with a similar group using a conventional jig-based technique (JBKA). In this prospective, randomised, controlled trial, we employed a standardised CT protocol for seven measurements of outcome.

Patients and Methods

After the successful completion of a cadaver trial, 70 consecutive patients awaiting total knee arthroplasty were entered into this trial. The power number and level of significance were calculated from our cadaver study. All patients were provided with information sheets regarding the trial and, once they had agreed to participate, were allocated to one or other group at the pre-operative visit and consented to have surgery. The protocol was approved by the Institute’s Ethics Committee. The randomisation schedule, designed by an independent statistician, was in a blocking size of four. This ensured that during the period of enrolment, the ratio of the number of cases in the two groups remained approximately constant. The patients and paramedical staff were blinded as to the randomisation process. We excluded patients with active infection, malignancy or those deemed to be medically unfit for surgery. No patient refused to enter the trial.

All patients were seen before operation and their age, height, weight and body mass index (BMI) were recorded. A senior anaesthetist assessed all patients. Their pre-operative state was defined according to the American Society of Anaesthesiology classification (ASA grade).

All surgery was performed by one surgeon (SKC) who had carried out over 250 conventional knee replacements and 12 computer-assisted knee replacements before this trial.
The Duracon total knee prosthesis was used. No patellae were resurfaced. For the conventional jig-based JBKAs, the manufacturer’s recommended technique was followed. This involved intramedullary instrumentation for the femur and extramedullary instrumentation for the tibia. Standard cutting blocks were pinned into position with four pins.

CAKAs were performed using the Stryker Knee Navigation system. This is an imageless system, which uses anatomical mapping of the knee and kinematic analysis of the limb, to build-up a working model of the patient’s knee, as has been already described in a previous report. It uses an infrared camera array to track three fixed infrared emitters which are fixed to the anterior superior iliac spine, distal femur and proximal tibia by bicortical screws. The camera can also track the position of a pointer or attachment and relate their positions to the mapped anatomy. A process of registration is required whereby the anatomical landmarks of the limb are identified for the computer. This starts by kinematic identification of the centre of the femoral head, mapping of the lower femur, upper tibia and bony landmarks of the ankle. The mechanical axis of the limb and the transepicondylar axis of the femur, the morphology of the femoral condyles, the morphology of the tibial plateau and the long axis of the tibia are all identified and the image data stored. The algorithms used to determine the axial rotation of the femur average the readings of the transepicondylar axis and the anteroposterior axis known as Whiteside’s line. Tibial rotation is derived from the transmalleolar axis, the anteroposterior axis of the ankle and a line from the mid-part of tibial tubercle to the insertion of the posterior cruciate ligament. The relationships of the pointer or tool to the anatomy are shown in real time on the computer screen.

After surgery the blood loss was recorded for 24 hours. Any complications were noted and all patients underwent a standardised physiotherapy regime for the first five days. This consisted of continuous passive movement and active exercises, as soon as possible.

All patients had standard standing anteroposterior (AP) and lateral radiographs of the knee and long-leg views of the appropriate limb. These were used to determine the anatomical axis of the femur and set the position of the femoral jig during conventional surgery. The femorotibial angle was also determined and the distance of the mechanical axis from the centre of the knee. All measurements were performed by a single radiologist (RGS).

Before discharge from hospital, all patients had CT scans according to the Perth CT protocol, designed specifically to measure the alignment of the components with reference to defined AP and lateral mechanical and anatomical axes, as described. This allows measurement of varus/valgus of the femoral component, rotation and flexion/extension, together with varus/valgus of the tibial component, posterior slope and rotation. It also measures mismatch of the femoral and tibial components in extension. All scans were performed at a single radiology centre, reported by a single radiologist (WB) and checked by a second radiologist (RGS).

At follow-up at six weeks all patients had a further long-leg radiograph to determine the weight-bearing femorotibial angle and the position of the mechanical axis in relation to the centre of the knee. All radiographs were measured by a single radiologist (RGS), who was blinded as to the procedure and outcome variables.

Statistical analysis. All data were collected at the end of the trial and the patient groups blinded for further study. A statistician, independent of the surgical unit, analysed the
data using the SPSS database (SPSS Inc, Chicago, Illinois) and tests for normality and distribution were performed using the Kolmogorov-Smirnov test. Student t-test was used to analyse parametric data and the Mann-Whitney U test for non-parametric data. Box-and-whisker plots were produced for all CT variables. Outliers and extremes were identified and the appropriate source data verification (recheck CT output for any data transcription or measurement errors) was completed on any anomalous observations. Outliers were defined as values between 1.5 and 3 box lengths from the upper or lower edge of the box.

**Results**

Statistical analysis showed the gender, ASA grade, height, BMI and blood loss data to be parametric. All other data were non-parametric. The two groups of patients were matched for age ($p = 0.99$), height ($p = 0.47$), weight ($p = 0.5$), BMI ($p = 0.27$), ASA grade ($p = 0.49$) and pre-operative deformity of the limb ($p = 0.27$), as assessed on standing long-leg radiographs.

Assessment of post-operative CT alignment and varus/valgus ($p = 0.03$) and rotation of the femoral component ($p = 0.001$) showed a statistically significant improvement.
in the computer-assisted group compared with the conventional group (Figs 1 and 2). There was no difference in flexion of the femoral component (p = 0.425; Fig. 3). Varus/valgus of the tibial component (p = 0.047), tibial posterior slope (p = 0.001) and tibial rotation (p = 0.01) were all significantly improved in the computer-assisted group (Figs 4 to 6). Femorotibial mismatch (p = 0.037) was also significantly improved in the computer-assisted group (Fig. 7).

The cumulative error of alignment was based on the ideal values for each CT variable for each patient. The error from the ideal was then calculated and the sum of the seven variables measured (Fig. 8).

When assessing the post-operative long-leg radiographs (p = 0.004) the computer-assisted group was more likely to have a neutral femorotibial angle or be in slight valgus (Fig. 9). Also in this group the mean blood loss was 252 ml.
(25 to 620) whereas in the conventional group it was 446 ml (100 to 1100) (p = 0.001, Fig. 10).

Surgery took longer by a mean of 13 minutes in the computer-assisted group (mean 80 minutes; 60 to 120) compared with the conventional group (mean 67 minutes; 55 to 90) which was statistically significant (p = 0.001).

Complications in the computer-assisted group included one case each of deep-venous thrombosis (DVT), superficial infection, a stiff knee requiring manipulation under anaesthesia and an acute post-operative confusional state. In the conventional group there was one case of pulmonary embolus, two of DVT, two of superficial infection, one of transient ischaemia and ten of an acute post-operative confusional state. All patients recovered with no long-term morbidity. All superficial infections were treated successfully with oral antibiotics. There were no complications related to the computer software or tracker pins inserted into the pelvis, femur or tibia.

Discussion

The introduction of any new technology over an established method faces many difficulties and should follow good practice with extensive basic testing, a good cadaver trial and then a controlled randomised trial to prove its benefits. In this case, computer navigation produced better alignment in a laboratory setting before being used in routine clinical practice. The preliminary study allowed us to calculate the power for the clinical study which was 75 patients. It was decided to perform a blinded interim analysis on the first 58 patients and a further 12 patients were enrolled before the results of the interim analysis were available. These showed a statistical significance in a number of radiographic variables favouring computer navigation over the conventional technique. The trial was therefore stopped on ethical grounds with recruitment of 70 of the 75 patients.

Investigators of clinical trials are encouraged to use validated outcome scores when reporting results. However, this in itself raises a fundamental question regarding the radiographic measurement of the outcome variable of the alignment of total knee arthroplasty. It is already accepted that plain radiographs provide a poor indication of overall alignment. The literature suggests that coronal malignment of greater than 3° causes premature failure of knee replacement as does significant rotational malignment of the femur. Each of these angulations is measured separately in the coronal and axial planes, respectively. Any additive effect of coronal, sagittal and axial malalignment of components has not hitherto been assessed. In using a specific CT protocol, with measurements from defined mechanical and anatomical axes, we have been able accurately to define all the alignment characteristics of the femoral and tibial components and assess any cumulative error.

One goal of computer-navigated surgery is to implant components with greater accuracy, and reduce individual defects and their cumulative effect (Fig. 8). The statistically significant improvement in seven of the eight radiological parameters for alignment of the component using computer navigation over conventional surgery is clear from the results. Furthermore, the free-hand method avoids the need to penetrate the medullary canal with its associated morbidity. In our matched study, 28% of the conventional patients who had their femur instrumented, experienced confusion, which was attributed to transient hypoxia. No focus of infection, of cardiovascular or neurological event could be found and a clinical diagnosis of fat embolus was suspected. None of these patients, nor the single patient in this group who experienced a transient ischemic attack, suffered any long-term sequelae.

Almost as important as the improved accuracy is the reduction in the number of outliers for the various radiographic parameters. This incidence of surgical outliers is dependent on the skill of the surgeon, the volume of joint-replacement surgery performed and the familiarity with the implant. Despite the fact that the single surgeon operating had more experience and familiarity with conventional surgery than computer navigation, the reduction in outliers was greater in the navigation group.

We observed more loss of blood in the conventional group than in the computer-assisted group. We believe this to be due partly to non-penetration of the femoral medullary canal but also to care in soft-tissue management. During the registration process for the CAKA, we gain useful information about deformity of the knee both in terms of varus or valgus and fixed-flexion deformity. Once known, it is possible to stress the knee in the appropriate direction to determine how much of the deformity may be correctable. This can then be used to guide soft-tissue release of contracted structures.

It remains to be seen whether the individual and cumulative improvement in alignment will lead to better long-term results, but we believe that we have shown that computer-assisted knee arthroplasty is more accurate than jig-based knee arthroplasty and has a reduced morbidity in the short term.

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