Computer-assisted and conventional total knee replacement

A COMPARATIVE, PROSPECTIVE, RANDOMISED STUDY WITH RADIOLOGICAL AND CT EVALUATION

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After obtaining informed consent, 80 patients were randomised to undergo a navigated or conventional total knee replacement. All received a cemented, unconstrained, cruciate-retaining implant with a rotating platform. Full-length standing and lateral radiographs and CT scans of the hip, knee and ankle joint were carried out five to seven days after operation.

No notable differences were found between computer-assisted navigation and conventional implantation techniques as regards the rotational alignment of the femoral or tibial components. Although the deviation from the transepicondylar axis was relatively low, there was a considerable range of deviation for the tibial rotational alignment. There was no statistically significant difference regarding the occurrence pattern of outliers in mechanical malalignment but the number of outliers was reduced in the navigated group.

The outcome of total knee replacement (TKR) depends on a range of factors, including the alignment of the leg and the positioning of the implant. Less favourable clinical results with higher rates of revision are seen following malalignment in the frontal plane rotation.1-6

Biomechanical studies have demonstrated a change of load distribution with 3° of varus or valgus malalignment,7 and increased tibial cortical strain with 10° of rotational malalignment.8

The accuracy of computer-assisted navigation systems has been validated,9 they are claimed to improve the precision of positioning of the implant and hence the longevity of the arthroplasty. Several studies have demonstrated superior alignment of the components in the frontal plane in navigated compared with conventional implanted TKR, with fewer outliers outside a range of 3° varus or valgus.10-22 Other studies have not demonstrated a significant clinical difference between the two techniques23-30 and it is still not clear whether navigation can improve rotational alignment.31 Only two studies have demonstrated a difference from the conventional,32,33 both favouring navigation. Our study was designed to determine whether computer-assisted navigation can improve the rotational alignment in TKR.

Patients and Methods

The study was approved by the local independent ethics committee and the National Board for Radiation Protection. The patients included had primary or secondary osteoarthritis of the knee, no previous hemi- or total arthroplasty, a mechanical axis between 20° of varus and 5° of valgus, and no severe instability that could not be treated with an unconstrained, cruciate-retaining TKR. All the patients were operated on by two surgeons trained in navigated TKR (SK, JL).

A total of 104 patients met the inclusion criteria and were screened for enrolment in the study; 15 did not provide informed consent, two could not be randomised because of a clinical need for navigation (a post-traumatic arthritis with deformity of the distal femur where a conventional alignment rod could not be used), and seven were excluded because of a decision during the operation to use a posterior stabilised implant. After giving informed consent, 80 patients were randomised to undergo a navigated or conventional procedure. Randomisation was based on a permutation algorithm without stratification and administered by a certified medical biometrician (FK) by means of SAS software (release 12.0 for Windows; SAS Institute Inc., Cary, North California).

Study design. The patients were interviewed by a local study co-ordinator (CW) and their demographic data collected. The EuroQol questionnaire (release EQ-5D)34 was completed and the Knee Society score (KSS)35 was assessed one week before surgery.

Operative procedure. All the patients received a cemented, unconstrained, cruciate-retaining
TKR with a rotating platform (Scorpio PCS, Stryker Orthopaedics, Mahwah, New Jersey). No patellae were resurfaced. Osteophytes were trimmed from the patella and a parapatellar denervation was carried out. All operations were carried out with the use of a tourniquet and a single dose of 2 g of cefazolin was administered intravenously. A medial parapatellar approach was used and the femoral side was undertaken first.

The Stryker Navigation System, Knee Navigation Software V3.1 (Stryker Orthopaedics) was used for computer-assisted implantation. A bicortical femoral tracker was placed at the proximal end of the skin incision and one was placed through a separate incision distally on the tibia. The anatomical landmarks were registered and an initial kinematic analysis performed. Femoral alignment was aimed at a placement 90° to the mechanical axis in the frontal and sagittal planes and parallel to the transepicondylar axis for rotation. The epicondyles were identified by palpation. For the tibia, alignment was aimed at 90° to the mechanical axis in the frontal plane, 5° of posterior slope in the sagittal plane, and along a line from the lateral border of the medial third of the tibial tubercle to the centre of the tibial plateau for rotation. All the bone cuts, the kinematic analyses with the trial components and the final analyses were recorded by the navigation system as a PDF.

Conventional implantation was carried out using standard femoral intramedullary and tibial extramedullary guides. Femoral alignment in the frontal plane was determined relative to the angle between the anatomical and mechanical axes on the pre-operative radiograph, which could be adjusted in steps of 1°. Sagittal placement was parallel to the anterior femoral cortex and rotational alignment parallel to the transepicondylar axis. The epicondyles were identified by palpation. Tibial alignment used the same references as in the navigated arthroplasties, using an extramedullary alignment guide. For the rotation, the same bony landmarks were used as in the navigated procedures.

The operative details, including the time from skin incision to suture, the size of the implant and the name of the surgeon, were recorded for all patients.

**Radiological and CT evaluation.** A full-length standing and lateral radiograph as well as CT scans of the hip, knee and ankle joints were carried out five to seven days after operation. The digital images were evaluated using the software ID.PACS Release 3.6 (Image Devices, Idstein, Germany).

The mechanical axis was defined as the angle between a line from centre of the hip to the centre of the tibial tray, the fixation peg for the rotating platform, and a line from the latter position to the mid-point of the ankle joint, and was assessed on the full-length standing radiograph and the CT scan. The rotational alignment of the femoral and tibial components was evaluated on the CT scans. That of the femoral component was defined by a line through the centre of both femoral fixation pegs (Fig. 1a). The transepicondylar axis was measured from the sulcus of the medial epicondyle to the most prominent point of the lateral epicondyle. The angle between these two lines was assessed (Fig. 1b).
The rotational alignment of the tibial component was defined as a line along the posterior border of the tibial stem (Fig. 1c), from which a perpendicular line was drawn through the rotational centre of the tibial tray (Fig. 1d). The tibial tubercle was divided into three parts and a line was drawn from the lateral border of the medial third to the centre of the tibial tray. The angle between these two lines was measured and defined as rotation (Fig. 1e).

### Statistical analysis

The primary radiological endpoint of this investigation was the deviation of the tibial components from the medial third of the tibial tubercle, as described. Less than $SD \leq 10^\circ$ was considered as tolerable from a clinical perspective during the planning phase of the trial.

The study analysis was based on a two-sample Wilcoxon test at the 5% significance level to compare the distribution of the primary endpoint between the treatment samples. The results of this confirmatory test were summarised in terms of a p-value. The calculation of sample size originally applied a two-sample $t$-test analysis, but as soon as statistical outliers were observed in at least one of the treatment samples a Wilcoxon test was used instead.

The evaluation of the primary endpoint was based on the distribution of the medians and quartiles within the treatment samples as recorded on box plots. In order to allow comparison with graphical presentations of data in the literature, histograms of this data were also prepared.

All analyses were performed according to the intention-to-treat principle by FK, using SPSS software (release 12.0 for Windows; SPSS Inc., Chicago, Illinois).

### Sample size consideration

The investigation was designed to detect a minimum difference of $5^\circ$ in the primary radiological endpoint. A mean deviation of $10^\circ$ was expected after conventional surgery and of $5^\circ$ after a computer-assisted procedure. A common $SD = 7.5^\circ$ was assumed. To achieve a minimum power of 80% in detecting this difference by means of a two-sample $t$-test at the level of 5% significance, it was necessary to recruit a minimum of $2 \times 36$ patients. The assumption of a 10% drop-out rate in post-operative radiological assessment resulted in a net sample size of $2 \times 40$ patients.
Results

The patients in the computer-assisted and conventional study arms did not differ in their demographic data and pre-operative varus or valgus malalignment. The mean pre-operative KSS was higher in the conventional group, but this was not of statistical significance (Table I).

The operative time was significantly longer in the navigated group, with a median duration of 89 minutes (73 to 125) compared with 80 minutes (57 to 115) for the conventional technique (Wilcoxon test, \( p < 0.001 \), Table II).

The navigated group showed a median deviation from the mechanical axis of 1.5°, with a range between 5.9° of valgus and 4.6° of varus malalignment. The conventional group had a median deviation from the mechanical axis of 1.6°, with a range between 5.6° of valgus and 7.2° of varus malalignment. There were five navigated and seven conventional implanted arthroplasties outside the determined level of tolerance of 3° (Fig. 2). The conventional group had a tendency towards varus compared with the navigated group, but this was not statistically significant (Wilcoxon test, \( p = 0.195 \)).

The femoral component showed a median deviation from the transepicondylar axis of 1.7° (3.1° of external rotation to 4.4° of internal rotation) in the navigated group, and of 1.0° (2.4° of external rotation to 3.4° of internal rotation) in the conventional procedures (Wilcoxon test, \( p = 0.019 \)).

The femoral component showed a median deviation from the mechanical axis in the frontal plane of 0.8° (3.8° of valgus to 3.0° of varus) in the navigated group and of 1.0° (3.8° of valgus to 3.6° of varus) in the conventional procedures. The median deviation in the sagittal plane was 1.6° (3.2° of hyperextension to 3.6° of flexion) in the navigated group, compared with 1.8° (3.8° of hyperextension to 6.5° of flexion) in the conventional procedures.

The tibial component showed a median deviation from the tibial mechanical axis in the frontal plane of 1.2° (3.8° of valgus to 3.9° of varus) in the navigated patients and of 1.3° (3.5° valgus to 4.2° varus) in the conventional group. The median deviation from a desired posterior slope of 5° was 0.8° (0.3° to 6.8° of posterior slope) in the navigated group, and 1.1° (2.9° to 9.3° of posterior slope) in the conventional procedures.

The femoral component showed a median deviation from the transepicondylar axis of 1.7° (3.1° of external rotation to 4.4° of internal rotation) in the navigated group, and of 1.0° (2.4° of external rotation to 3.4° of internal rotation) in the conventional procedures (Wilcoxon test,
The tibial component showed a much greater range of rotational deviation from the medial third of the tuberosity, with a median of 6.0° (14.9° of external rotation to 26° of internal rotation) in the navigated group, and 4.8° (6.5° of external rotation to 23.8° of internal rotation) in the conventional group (Fig. 4).

The multivariate re-analysis of the primary endpoint revealed no additional information compared with the univariate analysis. Multiple logistic regression did not identify any clinical or radiological cofactors as significantly associated with the primary endpoints. Neither the assigned surgical treatment (p = 0.136), the pre-operative axis (p = 0.703), the KSS (p = 0.682) or the patients’ body mass index (p = 0.078) could be identified as having a significant association with the primary endpoints.

Deep-vein thrombosis was seen in seven patients, three in the navigated group and four in the conventional group. There was no deep infection and no delayed wound healing in any patients.

Discussion

Several studies have demonstrated that computer-assisted navigation leads to more accurate implantation of a TKR, but others have found no difference. A recent meta-analysis noted fewer outliers outside the critical ranges of 2° and 3° varus or valgus malalignment with navigated surgery. All except one of these studies used a post-operative full-length standing radiograph to measure the alignment of the leg and the implant. However, there may be inaccuracies in these radiographs owing to possible flexion and rotation of the leg, which may be a major limitation in the evaluation of the mechanical axis and the frontal and sagittal alignment of the femoral and tibial components. This is of particular significance in the early post-operative period when the patient may still have some pain and limited movement.

The radiographs in this study were taken before discharge from hospital, and possible inaccuracies may have influenced the analysis. If an accurate long-leg radiograph entails a third of the fibula being covered by the tibia, then only 56% of the films in this study were completely accurate.

Rotational alignment has also been investigated previously but only two studies demonstrated an improvement with computer-assisted navigation compared with conventional methods. However, these studies did not use the same landmarks for femoral rotation in the navigated and conventional study arms and are therefore of limited value. In the navigated arthroplasties both the transepicondylar line and Whiteside’s line were used as instructed by the navigation system. In conventional arthroplasties the posterior condylar line was used as the reference. The different landmarks used for the navigated arthroplasties may have resulted in improved rotational alignment.

It is widely accepted that the transepicondylar axis represents the functional flexion-extension axis of the knee. Therefore, we aimed to align the femoral component parallel to the transepicondylar axis in both study groups.

However, there is less agreement as to the most suitable landmark to determine the correct tibial rotation. Possible sites include the most prominent point, the medial third or the medial border of the tibial tubercle, but there is a greater level of inaccuracy with these points than with assessment of femoral rotational alignment. There is no consensus on how the rotational alignment of the tibial component can be measured accurately. Whereas aiming for the posterior cruciate ligament during surgery is relatively easy, this structure is difficult to determine on CT scans after implantation. Therefore, we used a line from the lateral border of the medial third of the tibial tubercle to the centre of the tibial tray as reference for rotational alignment. This is the site of the fixation peg of the rotating platform in the tibial component.

Our results did not demonstrate a notable difference between navigated and conventional implantation as regards the rotational alignment of the femoral or tibial components. Although the deviation from the transepicondylar axis was relatively low and most prostheses lay within a range of 3° of internal and external rotation, there was a considerable range of deviation in the rotational alignment of the implants, as shown in previous studies. This may be due to difficulties in defining the correct landmarks on the tibial tubercle during the operation, as well as during analysis of the images. The necessary use of very short axes for the measurement of tibial rotation leads to numerically greater angle deviations. For rotational alignment of both the components the surgeon needs to define bony landmarks. The epicondyles are suitable to determine the femoral rotation and the tibial tubercle for the tibial rotation. The process of rotational alignment is comparable in navigated and conventional TKR as long as the same landmarks are used. This may be the main reason why computer-assisted navigation did not improve the accuracy of the rotational alignment.

There was no significant difference in mechanical alignment between computer-assisted and conventional TKRs. Nevertheless, the absolute number of outliers was smaller in the navigated group. The rotational alignment of both components was comparable between the groups but tibial rotation showed a greater degree of variance within both groups.

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