Alignment and orientation of the components in total knee replacement with and without navigation support

A PROSPECTIVE, RANDOMISED STUDY

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Bilateral sequential total knee replacement was carried out under one anaesthetic in 100 patients. One knee was replaced using a CT-free computer-assisted navigation system and the other conventionally without navigation. The two methods were compared for accuracy of orientation and alignment of the components. There were 85 women and 15 men with a mean age of 67.6 years (54 to 83). Radiological and CT imaging was carried out to determine the alignment of the components. The mean follow-up was 2.3 years (2 to 3).

The operating and tourniquet times were significantly longer in the navigation group ($p < 0.001$). There were no significant pre- or post-operative differences between the knee scores of the two groups ($p = 0.288$ and $p = 0.429$, respectively). The results of imaging and the number of outliers for all radiological parameters were not statistically different ($p = 0.109$ to $p = 0.920$).

In this series computer-assisted navigated total knee replacement did not result in more accurate orientation and alignment of the components than that achieved by conventional total knee replacement.

Restoration of the tibiofemoral angle to within 3° of normal during total knee replacement (TKR) is thought to be associated with a better outcome.¹⁻⁶ In previous studies, however, the post-operative tibiofemoral alignment has been found to exceed this in up to 30% of cases.⁷⁻⁹ Incorrect alignment can lead to abnormal wear,^{10,11} premature loosening^{1,12} and patellofemoral problems.^{13,14}

Recently, computer-assisted navigation systems have been developed to improve the accuracy of the alignment and orientation of the components in TKR. Some studies have indicated that there was no significant difference between computer-assisted navigated TKR and conventional TKR.^{9,15} Others found a clear tendency towards improved alignment of the limb with navigation.¹⁶⁻¹⁹

We carried out a prospective, randomised study to evaluate the accuracy of the orientation of the components and post-operative limb alignment in CT-free computer-assisted navigated TKR and to compare this with the results of conventional TKR in patients who were undergoing bilateral sequential TKR. Our hypothesis was that the navigation system would result in improved orientation and alignment of the components.

Patients and Methods

Bilateral sequential primary TKRs were carried out in 115 consecutive patients under the same anaesthetic by the senior author (Y-HK). A press-fit condylar Sigma mobile-bearing knee prosthesis (PFC Sigma, Depuy, Warsaw, Indiana) with an all-polyethylene patellar component was used in all the knees. Of the 115 patients, 15 with a varus deformity over 20° and a flexion contracture of more than 30° were excluded because they needed posterior-cruciate-substituting components and a medial tibial wedge to correct their deformity. Otherwise, a posterior cruciate-retaining design was used in all knees. The study was approved by our Institutional Review Board and all patients gave informed consent.

Randomisation was by means of a random number table. The side on which the navigation system was used alternated between successive patients.

There were 85 women and 15 men with a mean age of 67.6 years (54 to 83). The mean height of the patients was 152.2 cm (143 to 162), their mean weight was 62.8 kg (21 to 36) and their mean body mass index 27.1 kg/m^3 (21 to 36). General anaesthesia was given to ten patients and an epidural to 90. In all cases the diagnosis was osteoarthritis. A total of 25

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Fig. 1

Radiograph showing the mechanical axis in the coronal plane. The alignment of the femoral and tibial components was measured by the intersection of a line drawn across the base of each component and the mechanical axis (α , frontal femoral)

Fig. 2

Radiograph showing the measurement of flexion and extension of the femoral component and measurement of the posterior slope of the tibial component. A, sagittal femoral angle; B, sagittal tibial angle.

patients (25%) had undergone an arthroscopic debridement and the remaining 75 (75%) had no previous operation on their knees.

The procedure was carried out through a midline skin incision of 10 cm to 14 cm in length using a medial parapatellar approach. The incision was made as short as possible in all knees and there was no difference in the extent of soft-tissue dissection between the two groups. In all the conventional cases, extramedullary instrumentation was used for the tibial component and intramedullary for the femoral side. The femoral valgus angle for the intramedullary guide was determined pre-operatively on standardised long-leg weight-bearing radiographs. The anterior cruciate ligament was excised and the posterior cruciate ligament retained in all patients. Ligamentous balance was restored and 10 mm of tibial bone was resected to achieve a surface which was perpendicular to the shaft of the tibia in the coronal plane with a posterior slope of 3° in the sagittal plane. Resection of the distal femur (9 mm to 11 mm) and the posterior femoral condyles (9 mm to 11 mm) attempted to remove a thickness of bone which was equal to that of the femoral component to be implanted. Care was taken to balance the flexion and extension gaps and release any flexion contracture. During femoral and tibial resection the femur was prepared first in each group.

The navigation system which was used (Vector Vision CT-free knee; BrainLAB, Munich, Germany) had an optical tracking unit which detected reflecting marker spheres with an infrared camera. The system was controlled by a draped touch-screen monitor. Foot switches or additional cables were not necessary.

Two reference arrays with passive marker spheres were rigidly attached to the femur and tibia through our standard approach. Registration was performed and the centre of rotation of the hip defined as a pivot. The medial and lateral malleolus and specific landmarks on the knee were digitised using a navigation pointer. Bone-surface information from the proximal tibia and the distal femur was recorded by sliding the pointer over the tibial plateau and the femoral condyles. Based on these data, the system produced an adapted bone model of the knee and generated a planning proposal for the orientation of the components. In the frontal plane, this was determined as being perpendicular to the mechanical axis of the leg. In the sagittal plane, the femoral component was aligned to the anterior plane with additional flexion of 5°. The posterior slope of the tibial component was set at 3° as recommended by the manufacturer. As with conventional TKR, resection of 9 mm to 11 mm of the distal femur and posterior femoral condyles was carried out. Resection of 10 mm of tibial bone was performed to achieve a surface which was perpendicular to the shaft of the tibia in the coronal plane with a posterior slope of 3° in the sagittal plane. For comparative reasons, the posterior reference option with 3° of external rotation was used in all the patients.

Before resecting the bone, we rechecked and documented the axes of the leg and the stability of the knee throughout its range of movement. Resection started on the femoral side. The orientation of the cutting blocks and the definition of the cutting planes were determined using the navigation system. After making the bone cuts, the cutting

Fig. 3

CT showing measurement of axial rotation of the femoral component in relation to the transepicondylar axis (A-A) and posterior femoral condylar line (B-B).

Fig. 4

CT showing measurement of axial rotation of the tibial component in relation to the posterior margins of medial and lateral plateaux (A-A) and to the medial and lateral edges of the tibial component (B-B).

planes were checked and documented by the verification function of the system. The axis of the leg, the range of movement and the stability were checked again with the trial implants in place.

Clinical and radiological review was done at three months, and one year after the operation, and yearly thereafter. The duration of follow-up was 2.6 years (2 to 3). All the clinical data were recorded and compiled by two observers (JSK, SHY) who were not part of the operating team and who had no knowledge of the radiological findings. Pre-operative and post-operative scores were obtained for all patients using the Knee Society (KSS)¹⁸ and The Hospital for Special Surgery (HSS)¹⁹ systems.

Radiological measurements. All the radiographs were reviewed by one observer (SHY) who had no knowledge of the patients. The findings were recorded by a research assistant who knew the name of the patient. Full-length lying and standing anteroposterior (AP) radiographs, including the femoral head and ankle, and lateral and skyline patellar views were taken pre- and post-operatively and were assessed for alignment by the tibiofemoral angle, the mechanical axis, the distance between the centre of the knee and the mechanical axis (Fig. 1), the position of the components (Fig. 2), the orientation of the joint line, the posterior femoral condylar offset, the patellar angle, the tibial surface capping and the location of radiolucent lines at cement-bone interfaces as recommended by the Knee Society.¹⁸

Post-operative CT was carried out using a multislice scanner (General Electric Light Plus, Waukesha, Wisconsin) to determine the rotational alignment of the components. The scan sequence was started at the superior pole of the patella and ended at the tibial tuberosity, in contiguous slices of 2.5 mm. The rotation of the femoral component was determined in relation to the transepicondylar axis.¹⁴

An axial image of the distal femur was chosen which most clearly demonstrated the medial epicondylar sulcus, when present, or the central point of the medial epicondyle when no sulcus was found, and the lateral epicondylar prominence. A line was drawn between these two points, thereby establishing the surgical epicondylar axis. A second line was drawn across the posterior condyles of the femoral component. The angle between these represented the rotation of the component (Fig. 3). The rotation of the tibial component was determined relative to the posterior margin of the proximal tibia. A line was drawn between the posterior margins of the medial and lateral tibial plateaux. A second line was drawn between the medial and lateral edges of the peg of the tibial component. The angle between these represented the rotation of the component (Fig. 4).

Statistical analysis. The Kolmogorov-Smirnov²⁰ test was used to evaluate if the axial alignment followed a normal (Gaussian) distribution and Levene's²¹ test to assess the homogeneity of variance (constant variance).

Gender was compared between the groups using Fisher's exact test. The alignment of the limb and the duration of the operation were compared using an unpaired Student's *t*-test with the assumption of homogeneity of variance used as appropriate. The chance-corrected kappa coefficient was calculated to determine intra- and interobserver agreement with kappa values interpreted according to the recommendations of Landis and Koch²² as follows: slight, 0.00 to 0.20; fair, 0.21 to 0.40; good, 0.41 to 0.60; excellent, 0.61 to 0.80; almost perfect, 0.81 to 1.00.

Box-and-whisker plots were used to compare the post-operative alignment of the leg using median quartiles and interquartile ranges (IQR), and deviations were compared using the Mann-Whitney U test. For continuous variables and differences between two means, 95% confidence intervals (CI) were calculated. Two-tailed values of $p < 0.05$

Table I. Operating details in both groups

	Navigation	Conventional	p-value
Mean operating time in minutes (range)	97 (50 to 119)	82 (65 to 94)	< 0.001
Mean tourniquet time in minutes (range)	59 (53 to 81)	44 (32 to 56)	< 0.001
Mean length of incision (cm)			
Extension	22.2 (11 to 15)	11.8 (10 to 14)	0.052
Flexion	14.3 (13 to 17)	14.2 (13 to 16)	0.675
Mean intra-operative blood loss in ml (range)	277 (80 to 700)	264.7 (40 to 850)	0.714
Mean drainage in ml (range)	783.3 (52 to 1410)	750 (60 to 1440)	0.633
Mean drainage duration in days (range)	4.8 (3 to 7)	5.1 (3 to 7)	0.149
Mean volume of transfusion* in ml (range)	928.3 (250 to 2400)		

* this refers to the patient and therefore the same value applies to both groups

were considered to be statistically significant. Analysis of the data was performed using the SPSS statistical package version 11.5 (SPSS Inc., Chicago, Illinois).

Intraobserver reliability was almost perfect for both the computer-assisted navigated TKR and the conventional TKR ($p < 0.001$ in each case). In the computer-assisted group, the value of kappa was 0.96 for observer A and 0.97 for observer B. In the conventional group, it was 0.94 for observer A and 0.94 for observer B. The interobserver reliability was excellent for the computer-assisted ($\kappa = 0.97$) and conventional ($\kappa = 0.96$) TKR.

Power studies suggested that 60 patients were needed to determine whether there was a significant difference (power = 0.8 and $p < 0.05$) in the clinical and radiological findings between the groups.

Results

Clinical findings. The operating and tourniquet times were significantly longer in the navigation group ($p < 0.001$). The length of the incision, intraoperative blood loss, the duration and volume of drainage and the transfusion volume were not significantly different ($p > 0.05$) (Table I).

The clinical results of both groups are summarised in Table II. The pre-operative KSS and HSS scores were not statistically different between the two groups ($p = 0.288$ and 0.760 , respectively) and neither were the post-operative scores ($p = 0.456$ and $p = 0.433$, respectively).

The difference in the pain score of the KSS and HSS systems at the latest follow-up was not statistically significant ($p = 0.429$ and 0.184 , respectively).

The pre-operative range of movement in both groups was not statistically different ($p = 0.516$) nor was the range of movement at the final follow-up ($p = 0.939$).

Radiological findings. Every patient had complete radiological follow-up. There was no significant difference ($p > 0.05$) between the groups in regard to the alignment of the knee, the position of the femoral and tibial components in the coronal and sagittal planes, the patellar angles, the tibial surface area covered by the implant, and the orientation of the pre- and post-operative joint lines. No knee in either

group had to be revised, nor were there any patellar problems. The number of radiological outliers was not statistically different between the groups ($p > 0.05$; Table III). The post-operative limb alignment (tibiofemoral angle) exceeded 3° of varus/valgus deviation in 18% (18) of the patients operated on using the conventional technique, and in 21% (21) of the patients operated on by navigation.

Complications. There were six cases (6%) of anterior femoral notching in the navigation group and one (1%) in the conventional group. One knee (1%) in the navigation group had excessive resection of the tibia and required a tibial insert of 14 mm. The complication rate was not significantly different between the groups ($p = 0.058$).

Discussion

It is difficult for a patient who has undergone bilateral TKR to separate the function of each knee. Although this is a problem when assessing function after bilateral TKR, we believe that we were able to obtain fairly accurate information after careful assessment of the performance of each knee.

Proper alignment of the components is essential in TKR. In our study, post-operative limb alignment (the tibiofemoral angle) exceeded 3° of varus/valgus deviation in 18% of the patients operated on using the conventional technique. These results agree with those of Petersen and Engh⁷ and Mahaluxmivala et al,⁸ who found this in 26% and 25% of their patients, respectively.

In our study, the post-operative tibiofemoral angle was not significantly better in the navigation than in the conventional group. The post-operative tibiofemoral angle exceeded 3° of varus/valgus deviation in 21% of the patients operated on by navigation. This reflects the results of Mielke et al⁹ and Jenny and Boeri¹⁵ who found no significant difference between computer-assisted navigated TKR (Orthopilot; Aesculop, Tuttlinger, Germany) and conventional TKR. In the latter study, a tibiofemoral angle of $\pm 3^\circ$ varus/valgus was achieved in 83% of patients using a navigation system and in 78% using a conventional technique.

Table II. Clinical results (mean, range) in both groups

	Navigation		Conventional	
	Pre-operative	Final follow-up	Pre-operative	Final follow-up
Knee Society score (points)				
Total	29 (11 to 43)	93 (89 to 100)	28 (13 to 45)	94 (91 to 100)
Functional	25 (15 to 39)	85 (78 to 100)	26 (14 to 35)	84 (79 to 100)
Pain	0 (0)	44 (35 to 50)	0 (0)	46 (35 to 80)
Hospital for Special Surgery score (points)				
Total	61 (16 to 68)	90 (75 to 100)	60 (19 to 65)	89 (76 to 100)
Functional	15 (4 to 8)	15 (11 to 22)	6 (5 to 9)	17 (13 to 22)
Pain	5 (1 to 15)	25 (20 to 30)	5 (2 to 11)	25 (21 to 30)
Pain (%)				
None		78 (78)		70 (70)
Mild		21 (21)		30 (30)
Moderate		1 (1)	100 (100)	-
Severe	100 (100)	-	-	-
Range of movement (°)	128 (-4 to +132)	127 (0 to 127)	125 (-5 to +130)	126 (-1 to +127)
Walking distance* (%)				
< 1 block	-	34 (34)		34 (34)
1 to 5 blocks	11 (11)	33 (33)	11 (11)	33 (33)
5 to 10 blocks	47 (47)	23 (23)	47 (47)	23 (23)
Unlimited	42 (42)	10 (10)	42 (42)	10 (10)
Walking support* (%)				
None	90 (90)	83 (83)	90 (90)	83 (83)
1 cane	10 (10)	17 (17)	10 (10)	17 (17)
1 crutch	-	-	-	-
2 crutches	-	-	-	-
Stairs (%)				
Normal	-	30 (30)	-	30 (30)
With support	100 (100)	70 (70)	100 (100)	70 (70)

* these relate to the patient not to the knee. Therefore values will be the same for both knees irrespective of whether they are in the navigation or conventional groups

Table III. Prevalence of outliers between the groups

	Navigation (%)	Conventional (%)	p-value
Limb alignment (tibiofemoral angle) > $\pm 3^\circ$	21 (21)	18 (18)	0.141
Mechanical axis > $\pm 3^\circ$	28 (28)	35 (35)	0.512
Femoral angle > $\pm 3^\circ$			
Frontal	13 (13)	9 (9)	0.502
Sagittal	31 (31)	33 (33)	0.822
Tibial angle > $\pm 3^\circ$			
Frontal	16 (16)	7 (7)	0.188
Sagittal	25 (25)	9 (9)	0.1477
Joint line > ± 5 (mm)	29 (29)	33 (33)	0.649
Femoral rotation > $\pm 3^\circ$	29 (29)	15 (15)	0.109
Tibial rotation > $\pm 3^\circ$	54 (54)	49 (49)	0.659

By contrast, our findings were not in agreement with the results of Bthis et al,¹⁶ Jenny et al,¹⁷ and Chauhan et al.^{23,24} Bthis et al¹⁶ reported that the mechanical axis of the limb was significantly better in the computer-assisted group (96% within $\pm 3^\circ$ varus/valgus; VectorVision CT-free knee; Brain LAB, Munich, Germany)

compared with the conventional group (78% within $\pm 3^\circ$ varus/valgus). In a multicentre study¹⁷ involving 555 TKRs, a significantly better post-operative mechanical axis of the limb was achieved with computer-assisted navigation (Orthopilot). Chauhan et al^{23,24} reported that post-operative CT showed a significant improvement in the

alignment of the components using computer-assisted surgery in regard to femoral varus/valgus, femoral rotation, tibial varus/valgus, tibial posterior slope, tibial rotation and femorotibial mismatch.

Almost as important as the improved accuracy is the reduction in the number of outliers for the various radiological parameters. The incidence of surgical outliers is dependent on the skill of the surgeon, the number of TKRs performed and his familiarity with the implant.^{16,24} Despite the fact that the senior author has had more experience with conventional than navigated TKR, the reduction in outliers was greater in the navigation group in the first 50 patients. However, overall there was no significant difference in the number of radiological outliers between the groups. We believe that the use of navigation improved our surgical technique when performing conventional TKR, thereby reducing the number of radiological outliers after this procedure.

It has been claimed that anterior femoral notching is due to a mismatch between the anterior bow of the femur and its straight mechanical axis, which is judged by the computer to lie between the centre of the knee and the centre of rotation of the hip.¹⁶ It has been proposed that the distal femoral cut is flexed by 2° to 3° and that registration is slightly more proximal to avoid anterior femoral notching.¹⁶ In our series, anterior femoral notching occurred in six knees (6%) in the navigation group; this may have been caused by distal registration of the femur.

The possible reasons why our results differ from those reported previously are a poor navigation platform, improper patient recruitment for the elective use of the CT-free navigation system and inexperience with the navigation system.

We were not able to prove our hypothesis that computer-assisted navigated TKR give more accurate orientation and alignment than conventional TKR.

Supplementary Material

A table showing the clinical details of the patients in this study is available with the electronic version of this article on our website at www.jbjs.org.uk

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