

ORIGINAL ARTICLE

Kinematic Navigation in Total Knee Replacement — Experience from the First 50 Cases

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Background/Purpose: Proper alignment of the prosthesis is critical in total knee replacement (TKR) to minimize long-term wear, risk of osteolysis, and loosening of the prosthesis. This study examined the accuracy of lower limb alignment obtained using a kinematic navigation system for TKR, and the extra time needed to adopt this system.

Methods: From August 2002 to April 2003, 71 patients with knee osteoarthritis underwent 79 primary TKR operations by the same surgical team. Fifty of these operations were performed with the aid of the CT-free kinematic navigation system, and the remaining 29 were performed with conventional manual methods. Results, including operation time, radiographic alignment of the prosthesis and complications, for the two groups were compared.

Results: Patients in the kinematic navigation group achieved better accuracy in the coronal plane than the conventional group in terms of postoperative mechanical axis ($1.89 \pm 0.63^\circ$ vs. $3.38 \pm 1.07^\circ$). Less variation was noted in the navigation group (femur: SD 1.88° vs. 7.12° ; tibia: SD 1.54° vs. 2.99°), although the difference in the mean values was not significant ($p = 0.475$ and 0.55 , respectively). The operation time (from skin to skin) in the navigation group (100.6 ± 4.3 minutes) was longer than that in the conventional group (92.7 ± 5.1 minutes; $p = 0.027$). Two perioperative fractures occurred in the navigation group, both of which were attributed to patient factors as opposed to operation procedures. No major complications such as infection or pulmonary embolism occurred during this study.

Conclusion: Use of a kinematic navigation system in TKR provides better accuracy than conventional manual methods. The technique is easy to use, has a short learning curve, and requires an additional operation time of less than 10 minutes. Precise alignment can be achieved with the aid of navigation in most cases. [*J Formos Med Assoc* 2006;105(6):468–474]

Key Words: kinematic navigation system, mechanical axis, total knee replacement

Accurate alignment of knee implants is essential for the success of total knee replacement (TKR). Jeffery et al reported a 3% loosening rate over 8 years when the knee was correctly aligned, whereas insufficient alignment led to loosening in 24%.¹ Recently, computer-aided instrumentation systems have become available, and preliminary results in small patient series showed more accurate and consistent installation of knee

implants. Clinical data on the use of this technique for our patient population are still lacking. We introduced the CT-free kinematic navigation system for TKR in August 2002. The purpose of this prospective study was to assess the accuracy of computer integrated instrumentation for knee alignment by radiographic measurement, and determine the extra time needed for using this system.

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Received: July 4, 2005

Revised: September 7, 2005

Accepted: December 6, 2005

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Methods

Between 2002 August and 2003 April, 79 primary TKR operations (71 patients) were performed by the same surgical team. Among them, 50 operations were performed with the aid of the navigation system and the others with classical TKR. No patient was excluded on the basis of gender, age or deformity. Clinical evaluations including history review, physical examination, and radiographic studies were performed.

In the navigation group, there were eight males and 35 females with a mean age of 68.3 years (range, 49–79 years), and a mean preoperative mechanical axis deviation of the lower extremity of 13.38° (varus 25° to valgus 10°). In the conventional group, there were four males and 25 females with a mean age of 70 years (range, 55–79 years) and a mean axis deviation of 12.08° (varus 12° to valgus 1°). There were no significant differences between the groups with regard to age and preoperative deformity ($p = 0.176$ and 0.327 , respectively).

Classical midline incision was undertaken and subvastus arthrotomy was used to preserve the integrity of the extension mechanism in all patients, and the same implants (Search Evolution; Aesculap, Tuttlingen, Germany) were used in both

groups. The patella was resurfaced in all patients. In the conventional group, extramedullary-guided instrumentation was performed for the tibial component and intramedullary-guided instrumentation for the femoral component.

Computer-assisted technique

The CT-free kinematic navigation system (Ortho-pilot; Aesculap) is a computer-controlled image supported alignment system that does not require data from computed tomography or magnetic resonance imaging. Therefore, preoperative or intraoperative data matching are not required. A three-dimensional optotrack camera localizes infrared diodes which are located on the transmitters. With the use of light emitting diode (LED)-equipped alignment instruments, the femoral and tibial resection planes are determined. In this study, after performing the same arthrotomy of the knee, the transmitters were attached to the distal femur and proximal tibia with bicortical screws. A registration process was performed and the centers of the hip, knee and ankle joints were defined by intraoperative kinematic analysis (Figure). Various additional landmarks of the knee and ankle joints were digitized by a navigation pointer to determine the suggested plane of bone cutting and sizing of components. After each step of bone resection or

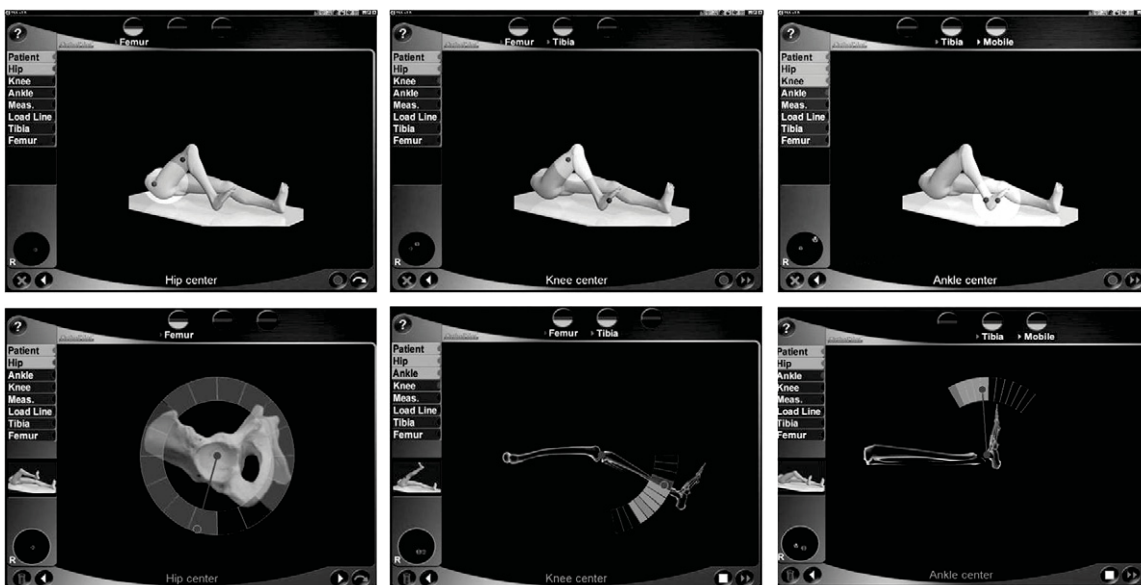


Figure. Procedures used to determine the joint centers of the lower extremity with kinematic analysis.

implanting, the surgeon could check and document the cutting plane or alignment via the verification function using real-time data shown on the screen.

Radiologic measurement

Preoperative radiographs of the knee joint, including the standing anteroposterior (AP), lateral and scanograms were taken for comparison with those taken 3 months after operation regarding the positions of components and the mechanical axes. All radiographs were taken using the conventional methods. Scanogram and standing AP were taken in the weight bearing standing position with both knees in full (or maximal) extension with the patella facing forward. Standing lateral views were taken with the knee at 30° flexion and weight bearing. The results of implantation were using a previously recommended method.² To assess coronal plane alignment, the following angles were measured: mechanical axis of the leg, the frontal femoral component angle and the frontal tibial component angle. To assess sagittal alignment, the lateral femoral component angle and the lateral tibial angle were measured. The mechanical axis of the lower limb was measured using long-leg (3 feet) scanograms in the AP projection. All radiologic measurements were performed by the same observer who was blinded to all other clinical information. Two cases in the navigation group were excluded from the analysis due to perioperative fractures.

Statistical analysis

Differences in gender of the two groups were compared using Fisher's exact test. The duration of operation was compared between the two groups

using two-sample *t* test. The axes deviation and positions of components were compared between the two groups using the Mann-Whitney rank sum test. Two-tailed values of $p < 0.05$ were considered to be statistically significant. Analysis of the data was performed using SigmaStat version 3.1 (SYSTAT Software Inc, Point Richmond, CA, USA).

Results

The preoperative characteristics of all 79 patients are shown in Table 1, while the comparison of operation time, alignment and positioning angles between the conventional and navigation groups are shown in Table 2.

Clinical results

Knee function was evaluated pre- and postoperatively using the Oxford Knee Score (OKS). Before operation, the score was 40.5 ± 2.5 for the navigation group, and 43.7 ± 2.8 for the conventional group ($p = 0.065$). Six months after operation, the score was 20.9 ± 1.1 for the navigation group and 22.1 ± 2.8 for the conventional group ($p = 0.663$). The improvement in OKS was 19.6 ± 2.6 and 21.5 ± 3.4 , respectively ($p = 0.251$).

Mechanical axis of the leg

The deviation in postoperative mechanical axis of the leg was $1.89 \pm 0.63^\circ$ (SD 2.19°) in the navigation group, based on absolute value; which was closer to the normal axis than that of the conventional group ($3.38 \pm 1.07^\circ$; SD 2.93°) ($p = 0.012$). In the navigation group, 39 cases (81.3%)

Table 1. Preoperative characteristics of patients

	Conventional ($n = 29$)	Navigation ($n = 50$)	<i>p</i>
Mean age (yr)	70.0 ± 2.2	68.3 ± 1.7	0.176
Gender (M/F)	4/25	8/35	1.000
Diagnosis	OA (28)/RA (1)	OA (48)/RA (2)	–
Mean body weight (kg)	62.4 ± 4.9	63.6 ± 2.39	–
Height (cm)	152.2 ± 3.43	154.0 ± 2.38	–

OA = osteoarthritis; RA = rheumatoid arthritis.

Table 2. Comparison of operation time, alignment and positioning angles between the conventional and navigation groups

	Conventional (n = 29)	Navigation (n = 50)	p
Operation time (min)	92.7 ± 5.09	100.6 ± 4.33	0.027
Preop mechanical axis deviation (°)	12.08 ± 2.11	13.38 ± 1.44	0.327
Postop mechanical axis deviation (°)	3.38 ± 1.07	1.89 ± 0.63	0.012
Coronal femoral component angle (°)	88.50 ± 0.69	89.54 ± 0.70	0.01
Sagittal femoral component angle (°)	83.61 ± 2.64	86.82 ± 0.89	0.475
Coronal tibial component angle (°)	88.28 ± 0.97	89.61 ± 0.47	0.029
Sagittal tibial component angle (°)	89.50 ± 1.11	90.17 ± 0.44	0.55

achieved the optimal alignment, defined as within the range from 177° to 183°. In the conventional group, there were 17 cases (58.6%) with an optimal mechanical axis.

Positions of the components

Alignment in the coronal plane

The frontal femoral component angle was 89.54 ± 0.70° (range, 81–94°; SD 2.41°) in the navigation group and 88.50 ± 0.69° (range, 84–91°; SD 1.88°) in the conventional group. On the femoral side, 44 cases (91.8%) in the navigation group and 24 cases (83%) in the manual group achieved the optimal femoral component range between 87° and 93°.

As to the tibial component, the coronal angle was 89.61 ± 0.47° (range, 85–94°; SD 1.64°) in the navigation group and 88.28 ± 0.97° (range, 82–93°; SD 2.67°) in the conventional group. Only three cases (6.25%) in the navigation group failed to achieve optimal positioning of the tibial component. In the manual group, six cases (20.7%) had outlying data, defined as component deviation of more than 3°.

In terms of prosthetic positions in the coronal plane, the navigation group achieved significantly better results than the manual group for the femoral ($p = 0.01$) and tibial component ($p = 0.029$).

Alignment in the sagittal plane

In the navigation group, the sagittal femoral component angle was 86.82 ± 0.89° (range, 84–90°; SD 1.88°), and in the manual group was 83.61 ± 2.64° (range, 68–92°; SD 7.12°). There were 17 cases (58.6%) in the manual group and 24 cases

(50%) in the navigation group with a more flexed (< 87°) position of the femoral component.

The sagittal tibial component angle was 90.17 ± 0.44° (range, 86–93°; SD 1.54°) in the navigation group and 89.50 ± 1.11° (range, 82–94°; SD 2.99°) in the manual group. Most cases in the navigation group (44 cases, 91.7%) and the manual group (25 cases, 86.2%) achieved optimal alignment.

In the sagittal plane, the differences in either component positions between the two groups were not significant ($p = 0.475$ for the femoral component and 0.55 for the tibial component, respectively). However, the positions of the tibial component in both the navigation and manual groups were more accurate than those of the femoral component ($p < 0.05$).

Operation time

The mean operation time (from skin to skin) in the navigation group (100.6 minutes; range, 65–145 minutes) was longer than in the conventional group (92.7 minutes; range, 66–134 minutes; t test, $p = 0.027$). In addition, the mean duration of operation in the first 25 cases in the navigation group was significantly longer (105.5 minutes; range, 65–145 minutes; SD 17.0) than the next 25 cases (95.7 minutes; range, 70–120 minutes; SD 12.5; $p = 0.024$).

Complications

Two intraoperative fractures occurred in the navigation group. One was a femoral fracture adjacent to the prosthesis and the other was a splitting fracture of the proximal tibia along the tibial com-

ponent. Notching of the anterior femoral cortex was noted more often in the navigation group (12 cases, 25%) than in the manual group (4 cases, 13.8%, $p = 0.414$). No major complications such as infection, deep vein thrombosis or pulmonary embolism were found in either group.

Discussion

In this study, similar improvement in OKS was found between patients who received TKR using a kinematic navigation system or conventional manual methods.

The accurate alignment of knee prostheses and ligament balance are essential for the success of TKR. A mechanical axis within a range of $\pm 3^\circ$ varus/valgus is thought to be associated with a better outcome. However, in previous studies, postoperative alignment exceeded a range of $\pm 3^\circ$ in up to 25–30% of cases with various guides.^{3,4} The development of a CT-free navigation system provides a reliable tool for real-time guidance of bone cutting and verification.

In this study, postoperative mechanical axes were significantly better ($p = 0.012$) in the navigation group. These findings are comparable with the results of Mielke et al, who reported a better femorotibial axis using the same navigation system.⁵ Jenny and Boeri also noted a similar result with postoperative mechanical axis $\pm 3^\circ$ achieved in 83% of patients using a navigation system.² Better coronal alignment of individual components was achieved using navigated TKR in this study, a finding which is comparable with most previous studies.

To avoid interobserver error, all radiographic measurements were done by the same researcher in this study. However, some issues should still be considered in interpreting the results. First, if the position was not adequate, the combination of limb rotation and knee flexion might introduce a larger error in the measurement of the accentuation effect on angulation. Second, the length of cassette also determines the accuracy of the measurement. Bonnici and Allen reported that long-leg

views are more precise (2°) than short-leg views (5°).⁶ Short-leg views had greater errors including 1.6–1.9° oblique errors,^{7,8} and rotational errors. Therefore, the long-leg view with true lateral projection is recommended to evaluate the sagittal position of the femoral component with greater accuracy. It was not possible, however, to obtain a sagittal radiograph of the whole leg in all cases, especially in obese patients. In this study, the less ideal sagittal position of femoral components compared to other studies might have been due to problems with imaging quality and intraobserver errors in measurement. Moreover, only short-leg lateral views of the knee joint in slight flexion were available for evaluation of the sagittal alignment of femoral components in all patients.

On the femoral side, the performance of osteotomies according to different methods/reference lines determines the different positions of components. The conventional intramedullary method only permits detection of the anatomic axis of the femur. Thus, different degrees of anatomic variations of the femur, like distal femur anterior bowing, wide or deformed shape, osteophytes, etc. often cause inconsistencies and errors in femoral reference osteotomy. In addition, the surgeon's subjective perceptions of the landmarks also play a role in determining the entry point of intramedullary rods. Olcott and Scott reported that a variation of as much as 8.3° could be made by an inappropriate choice of the insertion point.⁹ Consistent and reproducible results can be achieved by using the mechanical axis of the femur as the guide, which can be calculated intraoperatively using the kinematic analysis of the navigation system. In this study, despite the lack of significant difference in the position of the femoral component ($p = 0.581$), less variation was noted in the navigation group.

Anterior bowing of the distal femur is a problem for the implantation of the femoral component.¹⁰ Increased flexion of the femoral component should occur without notching of the anterior cortex using the conventional methods. However, anterior notching was common in the navigation group using the different femoral osteotomy ex-

tramedullary-guided by the mechanical axis without taking the antecurvature into consideration.¹¹ In this study, anterior notching was noted in 25% navigated TKRs. To alleviate this problem, a femoral component with more open flange design was suggested by Haaker et al.¹² Matsumoto et al also reported the possible problem of component oversizing by the navigation system in cases of anterior bowing.¹³ Correct sizing of prosthetic components in TKR is an important factor in optimizing both function and long-term results.¹⁴ Although some authors claimed that no additional costs are incurred by additional imaging procedures or preoperative trial measurements of the implant with most real-time navigation systems, detailed preoperative surgical plans including radiographic sizing and the use of consecutive procedures of implantation are recommended to avoid possible anterior notching and component oversizing.

In this study, the difference in the sagittal alignment of the tibial component between the navigation and conventional groups was not significant, and the accurate position of the tibial component was always achieved in both groups. The unique anatomic characteristics of the tibia, including less soft tissue coverage and more identical, prominent bony landmarks facilitated an accurate tibia cut and implantation of the tibial components. Similar findings were reported by some studies.^{12,15}

The alignment and position of components in the coronal plane can be measured, displayed and verified in a real-time mode. The rotational position of the femoral components can be measured and displayed relative to the posterior condylar line in a similar method while setting the cutting block with a transmitter; however, the final rotational position should be determined by the surgeon. The rotational position of the tibial component is also important; however, it could not be displayed in the system used in this study.

In this study, in spite of previously reported accuracy of the navigation system, some outlying data were still found in our navigated TKRs. The possible causes include the accuracy of the diodes, software algorithm, insecure fixation of transmitters, cutting error¹⁶ and cementing tech.¹⁷ Haaker

et al considered the learning curve as the main factor responsible for such data.¹² In our navigated TKRs, three of the first 25 and one of the subsequent 25 cases failed to achieve the optimal range of the mechanical axis.

As occurs with the introduction of any new method or concept, it took time for the surgeons to become familiar with the different procedures and associated instruments. Our data suggest that it only took about 25 cases to become familiar with this system. The difference in operation time between the first 25 and the subsequent 25 cases in the same navigated group indicated that the additional time required for the procedure decreased with increasing operator experience. After an initial learning curve, a mean extended duration in the range of 10–14 minutes was reported.^{12,18} An additional time of less than 10 minutes was considered to be acceptable in clinical practice to avoid creating significant disadvantages such as tourniquet pain or increased infection rate.

There were two perioperative fractures in the navigation group. The first femoral fracture occurred intraoperatively when setting the femoral component with pressure, and a short-oblique fracture over the medial femoral condyle resulted. The other femoral fracture occurred during the immediate postoperative period due to a slipping episode in the bathroom. A spiral femoral shaft fracture 3.2 cm lateral to the fixing screw was noted. Neither of these fractures was considered to be related to the navigation system. A review of the preoperative radiographs showed osteoporotic bone in both patients.

Using the navigation system, all bone cutting procedures were performed extra-medullary. Compared with the conventional intramedullary-guided techniques, the reduced violation of the medullary canal could theoretically decrease the risk of fat embolism.

Precise alignment is a key factor for better clinical results in the long-term.¹⁹ Although the kinematic navigation system provided more precise position and alignment in this study, the actual impact on long-term clinical outcomes remains unclear.

In conclusion, this study found that more precise coronal alignments of the prosthesis and mechanical axis of total knee arthroplasty can be achieved with the aid of a navigation system. The additional time required to use this method was less than 10 minutes. Long-term clinical results are needed to verify the significance of the impact of the introduction of this newly-developed navigation system for precise alignment and component positions.

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