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The Clinical Outcome of Computer-Navigated Compared with Conventional Knee Arthroplasty in the Same Patients

A Prospective, Randomized, Double-Blind, Long-Term Study

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Background: The available comparative studies of computer navigation-assisted and conventional knee arthroplasties have short-term follow-up periods. Therefore, the clinical benefits after long-term follow-up are not clear. The purposes of the current long-term study were to compare clinical outcomes, alignment of the knee components, prevalence of aseptic loosening of the components, implant survival, and complications of total knee arthroplasties performed with and without computer navigation.

Methods: We prospectively compared the results of 162 consecutive patients (324 knees) with osteoarthritis. These patients had computer-navigated knee arthroplasty in 1 knee and knee arthroplasty without computer navigation in the other. Nine men and 153 women were enrolled in the study. At the time of the index arthroplasty, the mean age of these patients was 68.1 years (range, 49 to 81 years). The mean duration of follow-up was 12.3 years (range, 12 to 13 years). Clinical and radiographic follow-up examinations of the patients were performed at 3 months, 1 year after the operation, and every 2 or 3 years thereafter.

Results: The Knee Society knee score, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, and range of knee motion were not significantly different between the groups preoperatively or at 12.3 years of follow-up. Patient satisfaction at the final follow-up was not significantly different between the groups. There were no significant differences between the groups with respect to the position and loosening of the components at 12.3 years of follow-up. The Kaplan-Meier survivorship, with revision or loosening as the end point, was 100% (95% confidence interval [CI], 94% to 100%) at 12.3 years in both groups. The prevalence of anterior femoral notching was higher in the computer-navigated knee arthroplasty group (5%) than in the conventional knee arthroplasty group (0.6%).

Conclusions: Clinical function, position, and survivorship of the components were similar between the groups. The only effect of navigation was a negative one, anterior femoral notching. However, comparison of bilateral total knee arthroplasties may dampen the differentiation regarding pain outcomes. Further, the findings of this study are specific to a single navigation and total knee system.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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Although knee arthroplasty provides a durable long-term result, malalignment may lead to decreased survival of knee arthroplasty components¹. In an effort to reduce malalignment of total knee arthroplasty implants, computer-

navigated knee arthroplasty was introduced². Proponents of computer-navigated total knee arthroplasty have claimed that improved placement of the implants potentially leads to better long-term function and survival of the implants³. However,

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CONSORT FLOW DIAGRAM

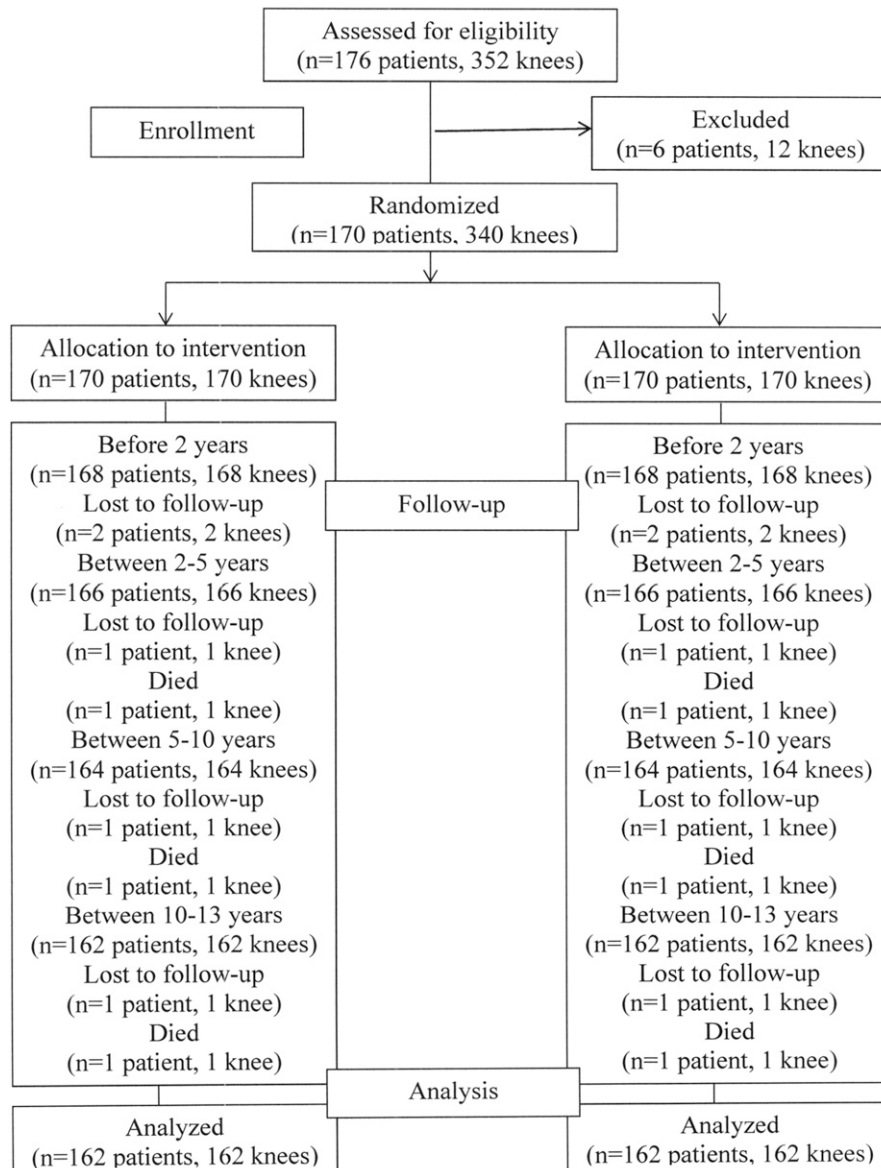


Fig. 1

CONSORT (Consolidated Standards of Reporting Trials) flow diagram. Three hundred and forty-knees in 170 patients having bilateral total knee arthroplasty were randomized to a NexGen CR-Flex prosthesis inserted with computer navigation on one side and a NexGen CR-Flex prosthesis inserted with the conventional, manual technique on the other. Both knees in 162 patients were followed for a minimum of 12 years.

there is a little evidence in the literature with regard to whether the improved alignment and position of the components from the use of computer navigation assistance improves the longevity of a total knee replacement and patient function⁴. Furthermore, many comparative studies of conventional and computer-navigated total knee arthroplasties have short-term follow-up⁵⁻¹⁰. Therefore, the clinical benefits after long-term follow-up on a larger scale are not clear.

The aims of the current study were to examine the same patients after long-term follow-up to determine whether the clinical results, radiographic results, patient satisfaction, and

survival rate of the components would be better after computer-navigated knee arthroplasty than after total knee arthroplasty without computer navigation assistance. Furthermore, we analyzed whether the complication rate would be lower for the patients who had computer-navigated knee arthroplasty than for those who had conventional total knee arthroplasty.

Materials and Methods

We performed 352 knee arthroplasties in 176 consecutive patients from January 2003 to March 2004. All of these patients were candidates for bilateral sequential knee arthroplasty under the same anesthetic for

TABLE I Demographic Data on the 162 Patients

Parameter	Value
Sex (M:F ratio)	9:153
Age* (yr)	68.1 ± 7.5 (49 to 81)
Height* (cm)	152.1 ± 5.8 (135 to 171)
Weight* (kg)	62.1 ± 8.7 (45 to 92)
Body mass index* (kg/m ²)	27 ± 3.3 (25 to 34.2)
Diagnosis of osteoarthritis (no. of patients [no. of knees])	162 (324)
Duration of follow-up† (yr)	12.3 (12 to 13)

*The values are given as the mean and the standard deviation, with the range in parentheses. †The value is given as the mean, with the range in parentheses.

the treatment of end-stage osteoarthritis of both knees. The design of the current study is similar to our previous report¹⁰, but the patient groups, as well as the types of implants, were different. The previous study¹⁰ involved posterior-stabilized high-flex prostheses, and the current study involved posterior cruciate-retaining high-flex prostheses. The study was registered in the ClinicalTrials.gov Protocol Registration System (NCT01520571). Our institu-

tional review board approved the study, and informed consent was obtained from all patients. The inclusion criterion was end stage of osteoarthritis of both knees that warranted knee arthroplasty. Patients with inflammatory arthritis, a foot or ankle disorder, dementia, or a history of stroke or hip disease were excluded.

Six patients declined to participate, and they were excluded. One hundred and seventy patients participated in the study. Five patients were lost to

TABLE II Clinical Results for 162 Patients (324 Knees) at Final Follow-up (12.3 Years)

Parameters	Preoperative*		Final Follow-up*		P Value	
	Computer-Navigated TKA	Standard TKA	Computer-Navigated TKA	Standard TKA	Preop.	Final Follow-up
Knee Society knee score† (points)						
Total knee score	27 (17 to 30) [21.1 to 35.9]	28 (22 to 30) [21.9 to 34.1]	93 (75 to 100) [88.1 to 98.1]	94 (75 to 100) [87.5 to 98.8]	0.364	0.445
Function score	55 (40 to 70) [48.9 to 63.9]	55 (40 to 70) [48.9 to 63.9]	75 (70 to 100) [65.1 to 98.8]	75 (70 to 100) [66.2 to 98.6]	1.000	1.000
Pain (no. of patients)						
None	–	–	120 (74%)	122 (75%)	–	–
Mild	–	–	40 (25%)	38 (24%)	–	–
Moderate	–	–	2 (1%)	2 (1%)	–	–
Severe	162 (100%)	162 (100%)	0 (0%)	0 (0%)	–	–
WOMAC score† (points)	61 (39 to 96) [59.6 to 69.3]	64 (43 to 96) [58.3 to 67.7]	16 (4 to 39) [14.5 to 17.1]	15 (4 to 38) [14.1 to 16.9]	0.857	0.993
Range of motion† (deg)	131 ± 10.8 (85 to 150)	133 ± 10.3 (90 to 150)	129 ± 9.9 (100 to 140)	128 ± 10.1 (100 to 140)	0.500	0.800
Satisfaction (no. of patients)						
Fully satisfied	–	–	81 (50%)	83 (51%)		
Satisfied	–	–	72 (44%)	69 (43%)		
Somewhat dissatisfied	–	–	9 (6%)	10 (6%)		
Fully dissatisfied	–	–	0 (0%)	0 (0%)		
UCLA activity score† (points)	1.8 (1 to 3)		5.8 (4 to 8)		–	–

*TKA = total knee arthroplasty. †The values are given as the mean, with the range in parentheses and the 95% CI in brackets.

follow-up, and 3 patients died, leaving 162 patients (324 knees) available for study (Fig. 1) (Table I). There were 9 male and 153 female patients, and their mean age (and standard deviation) was 68.1 ± 7.5 years (range, 49 to 81 years). The mean body mass index (BMI) was 27 ± 3.3 kg/m² (range, 25 to 34.2 kg/m²). The mean patient height was 152.1 ± 5.8 cm (range, 135 to 171 cm), and the mean patient weight was 62.1 ± 8.7 kg (range, 45 to 92 kg). All patients had osteoarthritis of both knees. The preoperative mechanical axes ranged from 23° of varus to 10° of valgus (mean, $10.3^\circ \pm 6.7^\circ$ of varus).

For the surgical approach, a medial parapatellar retinacular capsulotomy was performed after a 12 to 14-cm midline skin incision was made. All of the operations were carried out by the senior author (Y.-H.K.). A NexGen cruciate-retaining high-flex total knee prosthesis (CR-Flex; Zimmer) and an all-polyethylene patellar component were cemented in all knees. Randomization to computer-navigation assistance or conventional, manual, jig-based knee arthroplasty was done using a computer-generated study number in a sealed envelope, which was opened in the operating room before the skin incision was made. For each patient, navigation was randomized to either side (right or left). Assessors and patients were blind to the treatment assignment, to minimize confounding factors apart from the type of implant. The navigation system (VectorVision CT-free Knee; BrainLAB) had an optical tracking unit, which detected reflecting marker spheres with an infrared camera. In all conventional, manual, jig-based knee arthroplasties, the femoral component was implanted using intramedullary instrumentation, and the tibial component was inserted using extramedullary instrumentation.

Patients had a follow-up evaluation at 3 months postoperatively, at 1 year, and then every 2 or 3 years thereafter. The mean duration of follow-up was 12.3 years (range, 12 to 13 years). The Knee Society knee score¹¹ and Western Ontario and McMaster Universities Osteoarthritis Index¹² (WOMAC) score were obtained at subsequent examinations. In addition, the University of California at Los Angeles (UCLA) activity score¹³ was used to assess patient activity level. A

standard (60-cm) goniometer was used to measure the range of knee motion preoperatively and at each follow-up visit. A visual analog scale (VAS), ranging from 0 to 10, was used to assess patient satisfaction. The measurements were performed by an observer blinded to which knee received the navigation. The answers were categorized as ≤ 2 , indicating the patient was fully dissatisfied; 3, 4, or 5, somewhat dissatisfied; 6, 7, or 8, satisfied; or 9 or 10, fully satisfied. A research associate who was not part of the operative team recorded and compiled all clinical data.

At each follow-up visit, we assessed the alignment of the limb (the tibiofemoral angle), the position of the components, the joint line, the posterior femoral condylar offset, and the presence and location of radiolucent lines at the bone-cement or cement-implant interface in the anteroposterior hip-to-ankle radiographs (43.2×129.5 cm), as well as in the anteroposterior radiographs (43.2×43.2 cm) with the patient lying supine, lateral radiographs (43.2×43.2 cm), and skyline patellar radiographs, in accordance with the recommendation of the Knee Society¹¹. To control rotation of the knee, all radiographs were made under fluoroscopic guidance. A research associate who was not part of the operative team analyzed and recorded radiographic data at each follow-up. The observer was blinded as to which knee received the navigation.

At the final follow-up, to determine the rotational alignment of the component and osteolysis, a computed tomographic (CT) scan was performed for all patients with use of a multislice scanner (General Electric Light Speed Plus; GE Medical Systems). The scan was carried out from 10 cm proximal to the superior pole of the patella to 10 cm distal to the tibial tuberosity, with use of contiguous 2.5-mm slices. To determine rotational alignment of the femoral component, the angle was measured between the line joining the medial and lateral epicondyles of the femur and that along the posterior margin of the femoral component. To assess rotational alignment of the tibial component, the angle was measured between the line connecting the tibial tuberosity anteriorly and the site of insertion of the posterior cruciate ligament posteriorly and the

TABLE III Radiographic Results for 162 Patients at the Final Follow-up Evaluation (12.3 Years)

Parameters	Computer-Navigated TKA* (N = 162)	Standard TKA* (N = 162)	P Value†
Femorotibial angle (standing) (deg)			
Preop.‡	10.3 varus (23° varus to 10° valgus)	10.8 varus (21° varus to 8° valgus)	0.531
Final follow-up‡	5.6 valgus (4.9 to 6.9)	6.0 valgus (5.1 to 7.2)	0.729
Outliers§ (>3°)	19 (12)	22 (14)	
Femoral component position (deg)			
Anteroposterior‡	97.1 (95.9 to 98.1)	97.3 (96.1 to 97.9)	0.873
Outliers§ (>3°)	16 (10)	18 (11)	
Sagittal‡	2.5 (1.7 to 3.1)	2.5 (2.3 to 3.5)	0.419
Outliers§ (>3°)	13 (8)	16 (10)	
Tibial component position (deg)			
Anteroposterior‡	89.1 (86.3 to 89.8)	88.7 (87 to 89.1)	0.523
Outliers§ (>3°)	18 (11)	23 (14)	
Sagittal‡	84.3 (82.3 to 89.1)	84.5 (83 to 89.7)	0.231
Outliers§ (>3°)	21 (13)	24 (15)	
Joint line‡ (mm)			
Preop.	14.7 (13.1 to 15.6)	15.1 (14.1 to 16.4)	0.323
Final follow-up	14.5 (12.9 to 15.4)	14.8 (13.4 to 15.2)	0.234
Posterior condylar offset‡ (mm)			
Preop.	25.3 (24.4 to 26.1)	25.1 (24.1 to 25.9)	0.812
Final follow-up	25.8 (24.8 to 26.5)	26.1 (25 to 27.2)	0.213

*TKA = total knee arthroplasty. †T test. ‡The values are given as the mean, with the range in parentheses. §The values are given as the number of knees, with the percentage in parentheses.

anteroposterior line passing through the center of the anterior and posterior margins of the tibial component. Any nonlinear region of periprosthetic cancellous bone loss with delineable margins was defined as osteolysis. CT scans were examined by the senior author (Y.-H.K.), who was blinded to which knee received the navigation.

Kaplan-Meier survival analysis¹⁴ was performed to determine the cumulative survival rates of the implants during the study period, with 95% confidence intervals (CIs). The end points for analysis were aseptic loosening and revision surgery for any reason or recommendation for revision surgery by the senior author.

Statistical Analysis

To detect an effect size of 0.5, corresponding to an anticipated difference of 5 points in the Knee Society knee score and a standard deviation of 10.5 points, we calculated that 148 knees were required in each group. In anticipation of a 10% dropout rate, we recruited approximately 10% more patients. The Student paired t test and the Pearson nonparametric chi-square test were used to evaluate the differences between the groups with regard to the Knee Society knee and WOMAC scores. A 2-way repeated-measures analysis of variance was used to compare the range of knee motion between the groups. To compare complication rates and radiographic and CT data between the groups, nonparametric chi-square tests were used. The level of significance was set at $p < 0.05$.

Results

Either preoperatively or at a mean of 12.3 years of follow-up, there were no significant differences in the Knee Society knee and function scores between the groups. At the final follow-up, the mean knee score was 93 points (range, 75 to 100 points) in the group treated with the computer-navigated total knee arthroplasty and 94 points (range, 75

to 100 points) in the conventional knee arthroplasty group (Table II).

At the final follow-up, 120 (74%) of 162 knees in the computer-navigated total knee arthroplasty group had no pain, 40 (25%) had mild pain, and 2 (1%) had moderate pain after prolonged walking. In the conventional total knee arthroplasty group, 122 (75%) of 162 knees had no pain, 38 (24%) had mild pain, and 2 (1%) had moderate pain after prolonged walking (Table II). Compared with the preoperative score, the WOMAC score improved significantly ($p < 0.001$). No significant difference was detected between the groups with respect to the mean WOMAC scores (16 and 15 points) ($p = 0.993$) at the final follow-up (Table II). The range of knee motion in the groups was not significantly different either before ($p = 0.500$) or at a mean of 12.3 years after the operation ($p = 0.800$) (Table II). The mean UCLA activity score was 5.8 points (range, 4 to 8 points) at the final follow-up, and patient satisfaction was similar in both groups. One hundred and fifty-three patients (94%) who had computer-navigated knee arthroplasty and 152 patients (94%) who had conventional knee arthroplasty were satisfied with the clinical outcome of the procedure at the final follow-up.

The alignment of the limb (the femorotibial angle), positions of the femoral and tibial components, level of the joint line, and posterior condylar offset were not significantly different between the groups at the final follow-up (Table III). There was no aseptic loosening of the femoral, tibial, or patellar components in either group. Failure of the tibial polyethylene

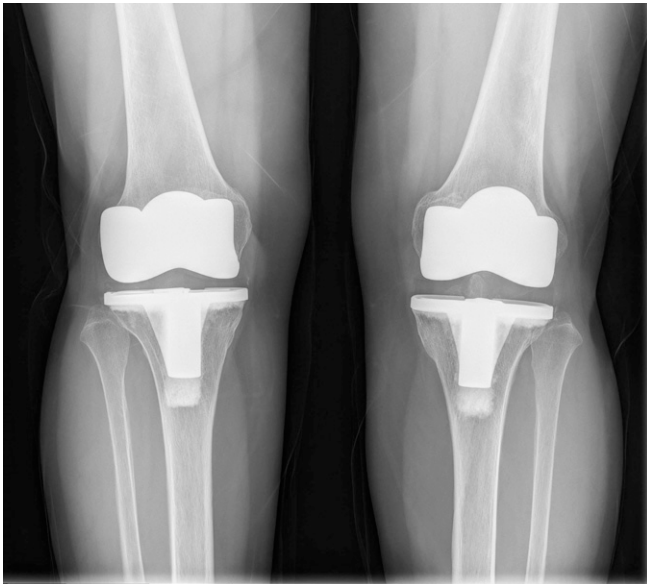


Fig. 2-A



Fig. 2-B

Figs. 2-A and 2-B Radiographs of both knees of a 62-year-old woman with end-stage osteoarthritis. **Fig. 2-A** Anteroposterior radiographs of both knees, made 13 years after surgery, revealed that the NexGen CR-Flex prosthesis implanted with the conventional technique (right knee, shown in the left image) and the NexGen CR-Flex prosthesis implanted with computer navigation (left knee, shown in the right image) are embedded solidly in a satisfactory position. No radiolucent lines or osteolysis are demonstrated adjacent to the tibial component in either knee. **Fig. 2-B** Lateral radiographs of the both knees show the absence of radiolucent lines and osteolysis around the femoral, tibial, and patellar components in both knees. Evidence of anterior femoral notching is visualized in the left knee (the radiograph of the left knee has been flipped to allow a better comparison).

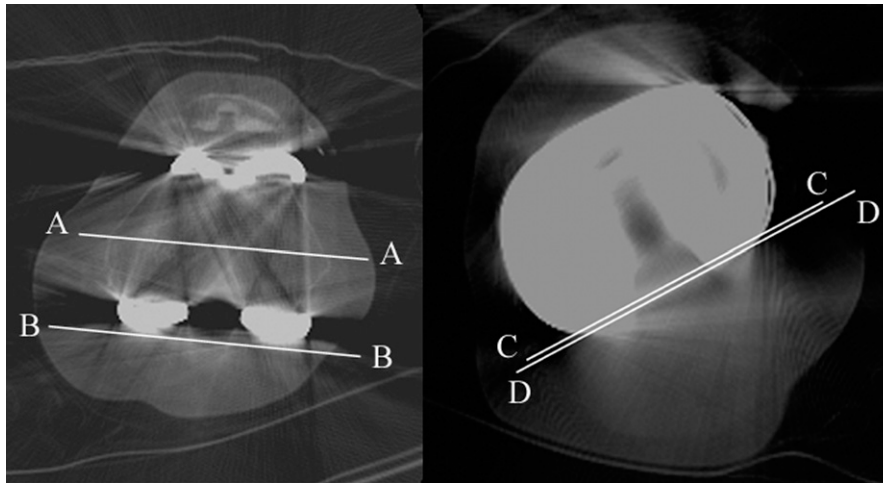


Fig. 3

CT scans show the measurement of the axial rotation of the femoral component in relation to the transepicondylar axis (A-A) and the posterior femoral condylar line (B-B). The CT scan on the right shows measurement of axial rotation of the tibial component in relation to the posterior margins of the tibial plateau (C-C) and the tibial bearing (D-D).

or evidence of osteolysis around the components was not found in either group at the final follow-up (Figs. 2-A and 2-B).

There were no significant differences between the groups with respect to the rotational alignment of the femoral or tibial components, and no tibial, femoral, or patellar osteolysis was visualized in the CT scans in either group at the final follow-up (Fig. 3).

Kaplan-Meier survivorship¹⁴ analysis, with revision or aseptic loosening defined as the end point, showed an implant survival rate for both groups of 100% (95% CI, 94% to 100%) at 13 years after the operation.

Eight knees (5%) in the computer-navigated knee arthroplasty group and 1 knee (0.6%) in the conventional knee arthroplasty group had anterior femoral notching. None of the patients with anterior femoral notching had a fracture or lower Knee Society function scores. Deep infection developed in 1 knee in each group. They were treated with open debridement and tibial polyethylene liner exchange, and intravenous antibiotics were administered for 6 weeks. There was no recurrence of infection in the 1 knee in the conventional knee arthroplasty group, but infection recurred in the 1 knee in the computer-navigated knee arthroplasty group. Two-stage revision surgery was required for this knee.

Discussion

Proponents of computer-navigated knee arthroplasty believe that improved positioning of the total knee components will provide better long-term function and survival of the implants³. However, there is little evidence in the literature with regard to whether the improved alignment and position of the components achieved with computer navigation improves the longevity of total knee arthroplasty implants and patient function. In addition, the available comparative studies of computer-navigated and conventional knee arthroplasties have short-term

follow-up periods and use different total knee prostheses. Therefore, the clinical benefits after long-term follow-up on a larger scale are not clear. We made 5 assessments in which we compared the results of computer-navigated and conventional knee arthroplasties with respect to the clinical results, radiographic results, patient satisfaction, survival rate of the components, and the complication rate. In the current study, clinical function, position and survivorship of the knee components, and complication rates were similar in both groups.

There are conflicting results for computer-navigated knee arthroplasty in the literature. One study has suggested that computer-navigated knee arthroplasty provided better knee function and better quality of life than that achieved with conventional total knee arthroplasty¹⁵. By contrast, other studies have found that knee function and quality of life were not different between the knees performed with or without computer navigation^{9,16-19}. Furthermore, in our 10.8-year follow-up study¹⁰, we found that clinical function and patient satisfaction were similar between the groups. The absence of severe malalignment ($\geq 6^\circ$) in the conventional knee arthroplasty group may have accounted for the similarity in the clinical results for that group and the computer-navigated knee arthroplasty group. The findings of the current study suggest that there were no significant differences between the groups at long-term follow-up with respect to the Knee Society knee and function scores, WOMAC scores, and patient satisfaction.

Bauwens et al.²⁰, Mielke et al.²¹, and Jenny and Boeri²² found no significant difference between knee arthroplasties performed with or without computer navigation with respect to the postoperative mechanical axis alignment of the limb. By contrast, other investigators have reported that computer-navigated knee arthroplasty produced more accurate alignment on radiographs than conventional knee arthroplasty did^{6,23}. However, Krackow et al.²⁴ suggested that the improvement in the

position of the knee components with computer-navigated knee arthroplasty is a few degrees, which is within the margin of error produced by projection-related errors in standing radiographs. In our previous study¹⁰, we found that the implant position and mechanical axis of the limb were similar between the groups that had knee arthroplasty with or without computer navigation. In the current study, we demonstrated that there were no differences between the groups in terms of femorotibial alignment, femoral and tibial component position, and posterior femoral condylar offset.

Baumbach et al.²⁵, in their 10-year follow-up study, found that 17% of the knees that had conventional knee arthroplasties and 9.8% of those that had computer-navigated knee arthroplasties had aseptic loosening. All of the knees that had aseptic loosening had presented with a femorotibial angle outside the optimal zone of $\pm 3^\circ$ around the neutral axis. Those authors concluded that their study demonstrated a clinically important advantage of the computer-navigation technique compared with the conventional procedure. On the other hand, our results were different from those of Baumbach et al.²⁵. At a mean follow-up of 12.3 years, no knee in either group had aseptic loosening or revision of the components, and the survival rate of the implants was 100% in both groups.

The reason for the higher rate of anterior femoral notching in the computer-navigated knee arthroplasty group (5%) than in the conventional group (0.6%) is not known. We speculate that there may have been errors in the navigation registration process.

There are some limitations of this study. First, at 12.3 years of follow-up, computer-navigated knee arthroplasty does not offer an advantage over conventional knee arthroplasty with regard to the position and survival rate of the knee components. However, these findings do not support an extrapolation past this time frame. Second, the present study did not have inter-

observer comparisons. Although intraobserver assessment was blinded to which knee received the navigation, intraobserver comparison could produce bias in interpreting the radiographic and CT results. Third, in our series, there were few obese and no morbidly obese patients, a group that may benefit from computer navigation, given their large body habitus and the difficulty of identifying normal anatomic landmarks for proper component position. However, even if navigation is shown to improve the implant alignment in obese patients, the question remains as to whether it affects the long-term clinical and radiographic outcomes.

In the present study, the clinical function, position and survivorship of the total knee components, and complication rates for the computer-navigated and conventional total knee arthroplasty groups were not significantly different. No effect of navigation was demonstrated, except a negative one of anterior femoral notching. However, comparison of bilateral total knee arthroplasties may have dampened differentiation with regard to pain and functional scoring. Further, the findings of this study are specific to a single computer navigation and total knee system. ■

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