Comparison Between Computer-Assisted-Navigation and Conventional Total Knee Arthroplasties in Patients Undergoing Simultaneous Bilateral Procedures

A Randomized Clinical Trial

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Background: Total knee arthroplasty has been increasingly used for young and active patients, and prosthesis durability is important in these patients. The accuracy of implant placement has been one of the major factors that determine the long-term survival of the prosthesis. The purpose of this study was to compare the accuracy of prosthetic alignment between computer-assisted-navigation and conventional total knee arthroplasties.

Methods: From March 2007 to June 2008, thirty-two patients with bilateral knee osteoarthritis underwent simultaneous bilateral total knee arthroplasty with the same type of implant in each knee. The subjects included seven men and twenty-five women, with an average age of sixty-three years. For each patient, the bilateral total knee arthroplasty was performed with computer-assisted navigation in one knee and a conventional technique in the other. The operative technique and the order of the surgical procedures were randomized. The patients and surgeons conducting the follow-up study and performing the imaging measurements were blinded to the type of surgical procedure.

Results: There was a significant difference between the two groups with regard to the alignment of the knee prosthesis in the coronal and sagittal planes. Nine knee implants (28%) in the conventional group, compared with no knee implants in the computer-navigation group, deviated >3° from the mechanical axis in the coronal plane. The coefficient variation of data in the conventional group was three times greater than that in the computer-navigation group. There was no significant difference in the rotational angle of the femoral component between the two groups. The Hospital for Special Surgery (HSS) scores at six months postoperatively were substantially increased compared with the preoperative scores in both groups.

Conclusions: Computer-assisted navigation consistently provided coronal plane alignment within 3° of the mechanical axis, which was significantly better than the alignment obtained with conventional total knee arthroplasty.

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

Disclosure: None of the authors received payments or services, either directly or indirectly (i.e., via his or her institution), from a third party in support of any aspect of this work. None of the authors, or their institution(s), have had any financial relationship, in the thirty-six months prior to submission of this work, with any entity in the biomedical arena that could be perceived to influence or have the potential to influence what is written in this work. Also, no author has had any other relationships, or has engaged in any other activities, that could be perceived to influence or have the potential to influence what is written in this work. The complete **Disclosures of Potential Conflicts of Interest** submitted by the authors of this work are available with the online version of this article at jbjs.org.

A commentary by Henry D. Clarke, MD, is linked to the online version of this article at jbjs.org.

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As more young patients undergo total knee arthroplasty, it is necessary to improve the long-term efficacy of this treatment. A wide array of factors may impact the long-term efficacy of total knee arthroplasty, including soft-tissue balance, the accuracy of the component alignment, postoperative complications, and the design of and processes for manufacturing the implants[1,2]. Among these factors, the accuracy of the component alignment is most directly related to operative technique. Several studies have demonstrated that total knee prostheses that are ≥3° from the mechanical axis of the lower limb in the coronal plane have a substantially higher long-term rate of loosening than those with <3° of deviation from the mechanical axis[2-4]. Jeffery et al. reported that, in a study of 115 knees, only 3% of those in which the alignment was within 3° of the mechanical axis developed implant loosening twelve years after surgery while 24% of those in which the alignment deviated by >3° developed loosening eight years postoperatively[2]. The association between prosthetic alignment and the long-term survival of total knee prostheses has been well established by previous studies, despite a recent paper challenging this correlation[5].

Improving the accuracy of the alignment of total knee arthroplasty components has been a subject of several investigations. The computer-assisted-navigation system was introduced to improve the accuracy of implant alignment in total knee arthroplasty and has been used clinically for at least ten years[6]. Many researchers believe that the navigation system improves the accuracy of bone cuts and implant positioning[7-10]. However, some studies suggest that there is no substantial difference in the accuracy of alignment between computer-assisted-navigation and conventional total knee arthroplasties and that use of this technology increases the operative time, with a potential increase in complications[11,12].

To evaluate if computer-assisted-navigation technology improves the accuracy of alignment in total knee arthroplasty, we compared that technique with conventional total knee arthroplasty in terms of the accuracy of implant alignment, the operative time, and improvement of knee function. The study

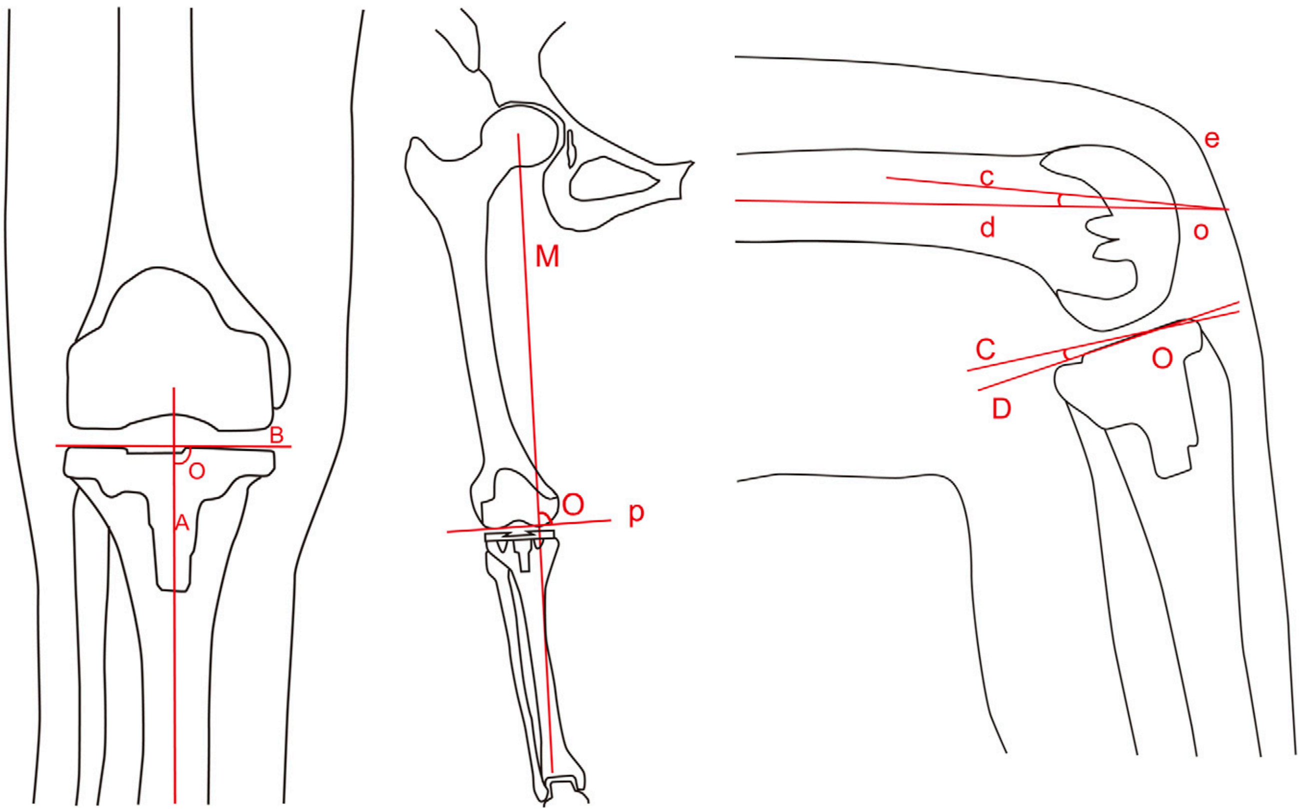

Fig. 1-A Fig. 1-B Fig. 1-C

Figs. 1-A, 1-B, and 1-C Measurement of various angles on anteroposterior and lateral radiographs after total knee arthroplasty. **Fig. 1-A** Varus/valgus angles of the tibial component in the coronal plane. AOB = the angle between the anatomical axis (A) and transverse axis (B) of the tibial component. **Fig. 1-B** MOP = the angle between the horizontal axis (P) of the prosthesis and a line (M) connecting the center of femoral head and the center of the ankle (that is, the degree to which the knee prosthesis deviated from the mechanical axis of the lower extremity). **Fig. 1-C** The posterior slope of the tibia in the sagittal plane is measured as the angle between the line (C) perpendicular to the anatomical axis of the tibia and the longitudinal axis of the tibial component (D) (angle COD). Flexion of the femoral component in the coronal plane is the angle between the mechanical axis (c) of the femur in sagittal plane and the line (d) vertical to the tangent of the distal portion of femoral component (e) (angle cod).

TABLE I Comparison Between the Computer-Assisted-Navigation and Conventional Total Knee Arthroplasty Groups (Paired t Test)

	Computer-Assisted-Navigation Group			Conventional Group				
Parameters*	Mean ± Stand. Dev. *(deg)*	95% Confidence Interval	Coefficient Variation	Mean ± Stand. Dev. *(deg)*	95% Confidence Interval	Coefficient Variation	T Value	P Value
MOP angle	90.341° ± 0.809°	90.05-90.63	0.89%	91.250° ± 2.383°	90.39-92.11	2.61%	2.044	0.0452
AOB angle	90.058° ± 0.647°	89.82-90.29	0.72%	90.842° ± 2.161°	90.06-91.62	2.4%	2.278	0.0252
COD angle	5.22° ± 0.716°	4.96-5.48	13.7%	4.26° ± 1.357°	3.77-4.75	31.9%	2.423	0.0221
cod angle	1.1° ± 2.04°	0.36-1.84	1.85%	2.41° ± 3.13°	1.28-3.54	1.30%	–2.299	0.0240
External rotation of femoral component	1.3° ± 3.27°	0.12-2.48	2.52%	0.7° ± 2.97°	–0.37-1.77	4.24%	0.891	0.3757
HSS scores†	47.6 ± 5.34 points	45.67-49.53	11.2%	45.4 ± 6.69 points	42.99-47.81	14.7%	1.685	0.0956
Operation time	90.043 ± 10.011 min	86.43-93.65	11.1%	58.391 ± 8.100 min	55.47-61.31	13.9%	11.788	0.0000

*The MOP angle is indicated in Figure 1-B, the AOB angle is indicated in Figure 1-A, and the COD and cod angles are indicated in Figure 1-C. †Differences between the preoperative and postoperative HSS scores.

was performed in a series of patients treated with simultaneous bilateral total knee arthroplasty, with each of the two different implantation techniques performed separately in each knee.

Materials and Methods

Study Design

This study was a prospective randomized controlled trial of patients who underwent simultaneous bilateral total knee arthroplasty with one knee treated with conventional total knee arthroplasty and the other treated with computer-assisted-navigation total knee arthroplasty. On the basis of our previous experience and a literature review[12,13], a power analysis was conducted to estimate the minimum sample size needed to assess a significant difference between the two groups. The type-I error was set at 0.05 ($\alpha < 0.05$) and the type-II error, at 0.2 (80% power). It was determined that a minimum sample size of thirty-two subjects (sixty-four knees) was required, and the operative technique for each knee and the order of the operations for the two knees of each participant were randomly selected.

Clinical Data and Techniques

Inclusion criteria included a need for bilateral total knee arthroplasty, with both knees suitable for replacement with a posterior cruciate-retaining total knee prosthesis. Three eligible patients refused to participate, leaving thirty-two patients who underwent simultaneous bilateral total knee arthroplasty between March 2007 and June 2008. The subjects included seven men and twenty-five women, with ages ranging from fifty-three to seventy-two years (average, sixty-three years). All had bilateral knee osteoarthritis.

Each of a patient's knee joints was randomly assigned to be treated with computer-assisted-navigation total knee arthroplasty or with conventional total knee arthroplasty. The mean flexion deformities (and standard deviation) in the two groups before surgery were 8.2° ± 2.9° and 8.3° ± 2.7°, respectively ($p = 0.882$). The varus deformities averaged 7.8° ± 2.6° and 7.6° ± 2.5°, respectively ($p = 0.766$). Gemini MK II knee implants (Link, Hamburg, Germany) were used for all knees. The VectorVision CT-free navigation system (BrainLab, Feldkirchen, Germany) was employed.

Written informed consent was obtained from all of the participants. This clinical trial was registered in the Chinese Clinical Trial Registry, and the registry number is ChiCTR-TRC-09000613.

Operative Techniques

An anterior midline incision and a medial parapatellar capsular incision were used in all knees.

All of the conventional total knee arthroplasties were performed with use of the principles of the measured resection technique. The tibia was cut orthogonal to the tibial anatomical axis (the line between the medial one-third of the tibial tubercle and a point 3 mm inward from the midpoint between the medial and lateral malleolus) by using an extramedullary guide. The tibial cut was made with a posterior slope of 5° and a resection height of 10 mm. Intramedullary instruments were used for femoral resection. The external rotation of the femur was based on the transepicondylar axis.

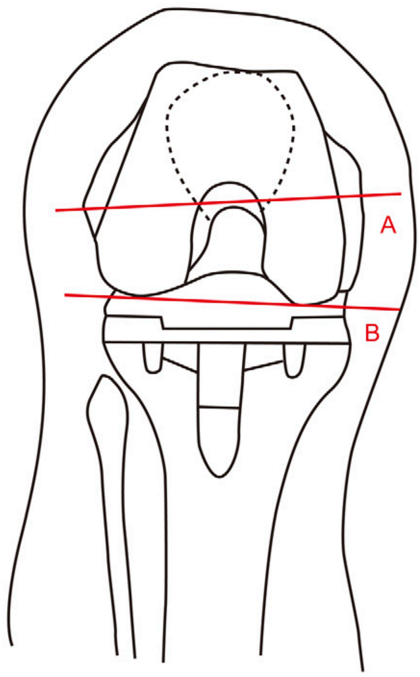

Fig. 2

Schematic diagram of the rotational angle of the femoral component relative to the transepicondylar axis on axial CT views. A = the transepicondylar axis. B = the line connecting the medial and lateral posterior condyles of the femoral component. The rotational angle of the femoral component relative to the transepicondylar axis is the angle between line A and line B.

TABLE II Deviation of the Knee Prosthesis from the Mechanical Line of the Lower Extremity and Deviation of the Tibial Component from the Anatomic Axis of the Tibia in the Coronal Plane in the Computer-Assisted-Navigation and Conventional Total Knee Arthroplasty Groups (Paired t Test)

	Tibial Component				Knee Prosthesis			
	<1°	≥1° and <2°	≥2° and <3°	≥3°	<1°	≥1° and <2°	≥2° and <3°	≥3°
Computer-assisted-navigation group	27	5	0	0	25	6	1	0
Conventional group	9	5	14	4	4	3	16	9

Before the computer-assisted-navigated total knee arthroplasties were performed, femoral and tibial infrared trackers were placed bicortically. The center of rotation for the femoral head, the related anatomical marks on the distal part of the femur and proximal part of the tibia, and the medial and lateral malleoli were then marked and registered. Bone resection was performed under the guidance of infrared tracking. As with the conventional procedures, the tibia was cut perpendicular to the tibial mechanical axis, the posterior slope was 5°, and the resection thickness was 10 mm. The distal femoral cutting was done orthogonal to the mechanical axis of the lower extremity. The external rotation of the femur was based on the transepicondylar axis. After bone resection, the resection planes were examined for accuracy by using an infrared tracker.

On completion of bone-cutting, soft-tissue balancing and prosthesis implantation were performed. Routine rehabilitation after total knee arthroplasty was performed postoperatively.

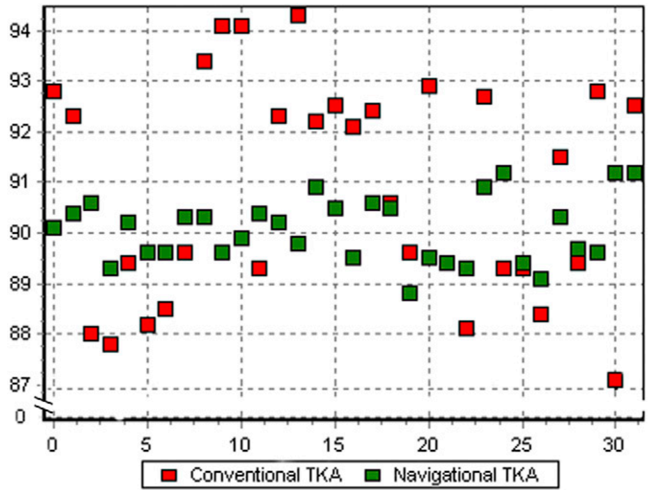

Fig. 3-A

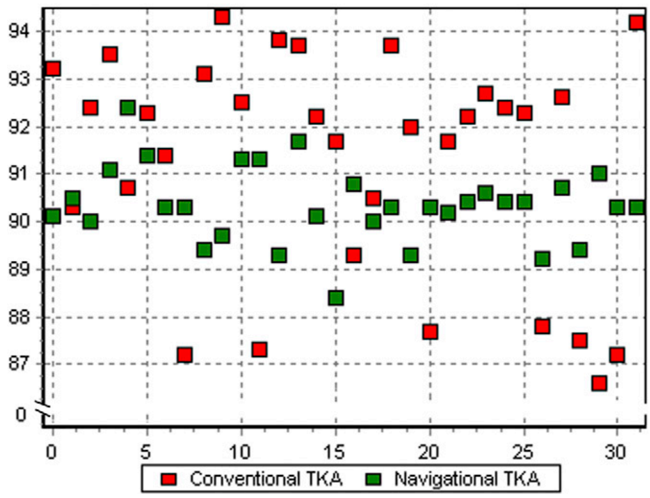

Fig. 3-B

Scatterplots of the degree that the knee prosthesis deviated from the lower limb mechanical axis (Fig. 3-A) and the tibial component deviated from the tibial mechanical axis (Fig. 3-B). The numbers on the y axis refer to the degrees of deviation, and the numbers on the x axis refer to patients (cases). TKA = total knee arthoplasty.

Postoperative Data Collection

In all cases, standing full-length radiographs of both lower extremities were obtained with use of a Siemens AXIOM syngo MultiModality Workplace (Siemens, Erlangen, Germany) and cross-sectional computed-tomography (CT) scans of the knee joints was performed (GE LightSpeed VCT; GE Healthcare, Milwaukee, Wisconsin). All image data were displayed, and measurements were completed via the picture archiving and communication system (PACS; Shanghai EBM Medical Information Systems, Shanghai, China). The image measurements included varus/valgus angles of the tibia and the angle between the horizontal axis of the prosthesis and a line connecting the center of the femoral head and the center of the ankle (Figs. 1-A and 1-B) in the coronal plane, the posterior slope of the tibial component in the sagittal plane (Fig. 1-C), the flexion of the femoral component (Fig. 1-C) in the sagittal plane, and the rotational angle of the femoral component relative to the transepicondylar axis on axial CT views (Fig. 2). The image measurement and data-recording were performed by one senior radiologist. The patients were followed for six months postoperatively by a surgeon who had not performed the operation, and knee function was evaluated with use of the Hospital for Special Surgery (HSS) scale. The radiologist, the surgeon who conducted the follow-up study, and the patients were all blinded with regard to the type of surgical procedure performed in each knee.

All of the data were statistically analyzed with use of a paired t test, and p values of <0.05 were considered significant.

Source of Funding

There was no external funding for this study.

Results

The postoperative image measurements were obtained for all of the subjects, and a six-month follow-up was completed for all.

There was a significant difference between the two groups with respect to the accuracy of the bone resection angles in the coronal and sagittal planes of the tibia and in the overall prosthetic alignment ($p < 0.05$) (Table I). The bone resection angle better approximated the normal mechanical axes of the lower extremities in the coronal and sagittal planes in the computer-navigation than in the conventional group. Moreover, the scatter of the data on the coronal plane in the computer-navigation group was smaller than that in the conventional group (Figs. 3-A and 3-B) and the coefficient variation of data in the conventional group was three times greater than that in the computer-navigation group (Table I). The axial alignment of the prostheses deviated >3° from the mechanical axis in nine knees (28%) in the conventional group compared with no knees in the computer-navigation group. No knee in the computer-navigation group and four knees (13%) in the conventional had >3° of deviation of the angle of the tibial tray from the anatomic axis of the tibia (Table II).

There were significant differences between the two groups with respect to the posterior slope of the tibia and the femoral flexion angle in the sagittal plane, but the actual differences and the coefficient variation were small (Table I). On the axial images, there was no significant difference in the position with regard to the transepicondylar axis (external or internal rotation) between the two groups (Figs. 4-A and 4-B).

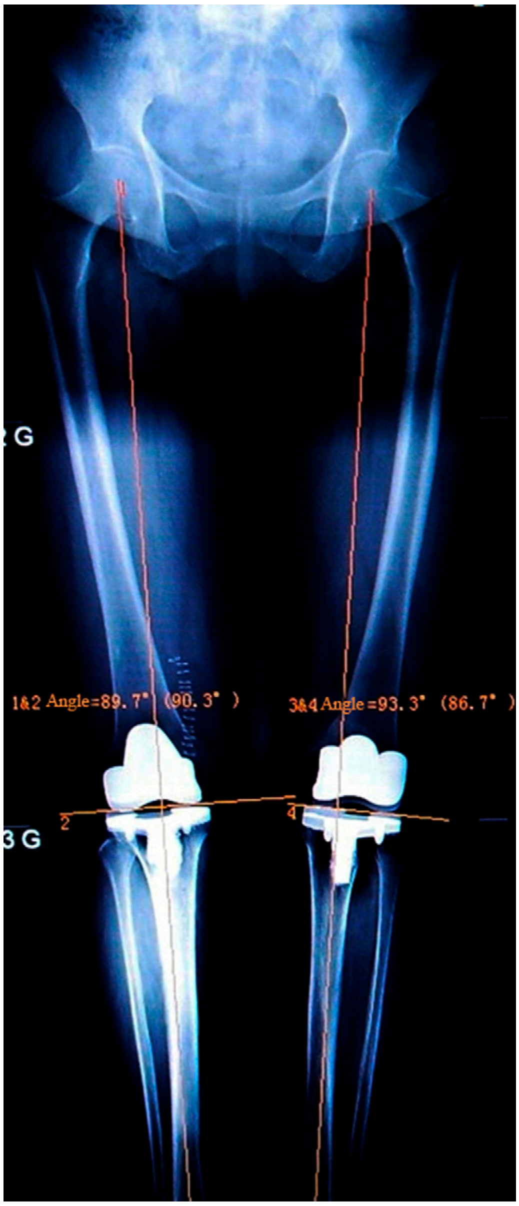

Fig. 4-A

Figs. 4-A and 4-B Radiographs and CT scan of a sixty-three-year-old women with bilateral osteoarthritis who had a conventional left knee replacement and computer-assisted-navigation right knee replacement. **Fig. 4-A** In the coronal plane, the angle between the transverse axis of the prosthesis and the mechanical axis of the lower limb was 93.3° in the left knee and 90.3° in the right knee.

At the six-month follow-up evaluation, the mean HSS score was substantially increased compared with the preoperative value, but there was no significant difference in the increase in the HSS scores between the two groups ($p = 0.0956$)[14]. No patient in the computer-navigation group had a fracture at a pin-track site or a pin-track infection.

The operative time in the computer-navigation group was an average of thirty minutes longer than that in the conventional group ($p < 0.01$).

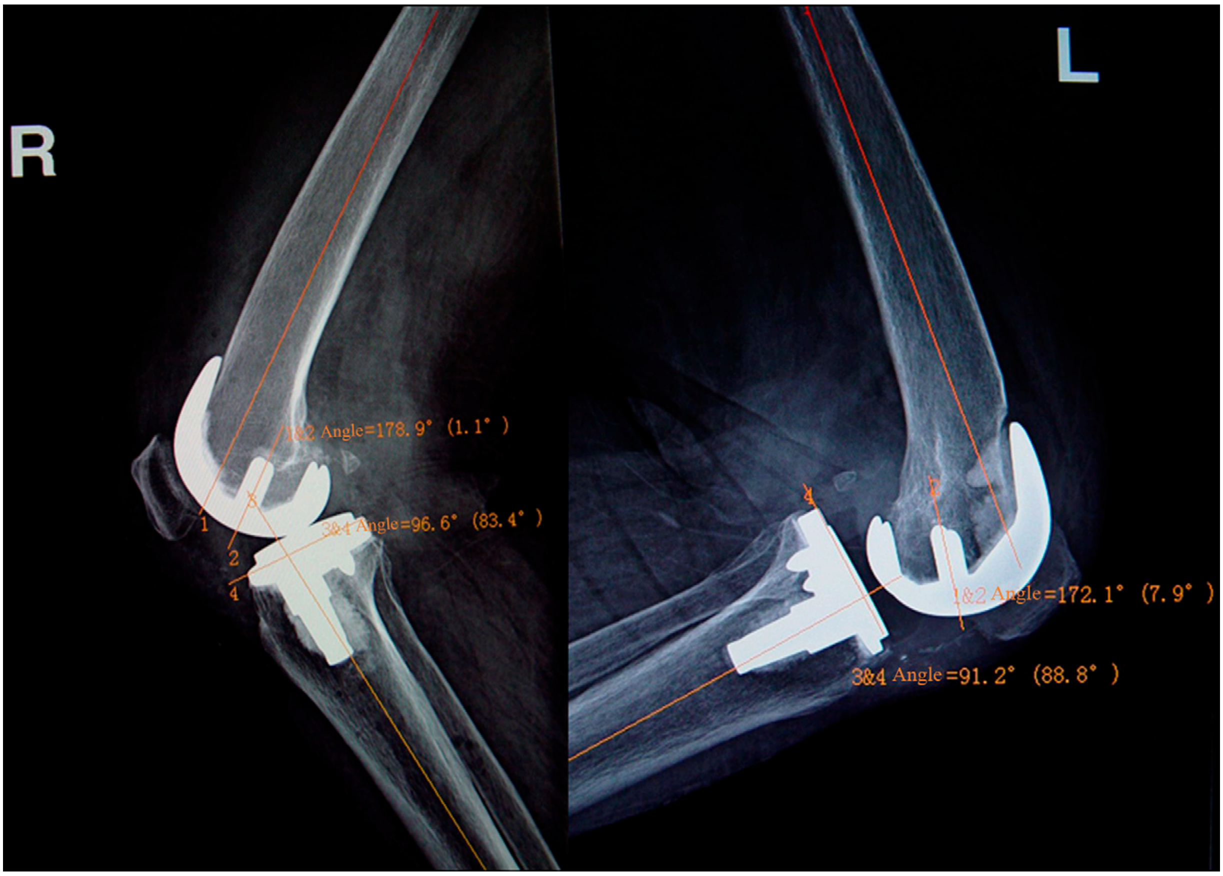

Fig. 4-B

The tibial posterior slope was 1.2° in the left knee and 6.6° in the right knee. The femoral flexion was 7.9° in the left knee and 1.1° in the right knee.

Discussion

Our study demonstrated that total knee replacement with computer-assisted navigation provided more accurate bone alignment in both the coronal and the sagittal planes than the conventional technique. There was no significant difference between the two groups in terms of femoral rotational alignment or early functional recovery.

Restoring the mechanical axis of lower extremities, especially in the coronal plane, is a major factor contributing to the mid-term and long-term outcomes of total knee arthroplasty[2]. Many researchers consider a deviation of ≥3° from the mechanical axis of the lower extremity as a threshold with which to assess patients at the time of mid-term and long-term follow-up after total knee arthroplasty[2-4,15]. In our series, the deviation of the mechanical axis of the prosthesis in the coronal plane was >3°in nine knees (28%) that had undergone conventional total knee arthroplasty and in no knee that had had computer-assisted navigation. No knee had >3° of deviation of the angle of the tibial tray from the anatomic axis of the tibia in the computer-navigation group whereas the angle in four knees exceeded 3° in the conventional group. In addition, the scatter plot and the coefficient variation of the data in the two groups showed that even when only knees with a deviation of <3° were considered, more knees in the conventional group had deviation close to 3° while in the computer-assisted group more knees had deviation approximating 0°.

In the sagittal plane, it is desirable to implant the femoral prosthesis along the mechanical axis whenever possible, as this facilitates knee extension while avoiding overextension of the prosthesis. With a posterior cruciate-substituting prosthesis, this can lessen the impingement between the post and the cam, minimizing polyethylene wear[16]. Although the deviation of the femoral prosthesis in the sagittal plane in our two groups was similar, our study showed that the computer-assisted operation tended to help reduce this deviation. One patient who had undergone a conventional total knee arthroplasty had notching of the anterior femoral cortex while no patient in the computer-navigation group did.

Currently, the computer-assisted-navigation system used in total knee arthroplasty is primarily based on infrared tracking technology. Bone resection is carried out on the basis of accurate real-time localization of the axes with regard to the previously registered anatomical marks of the femur and tibia. Because of variation of the medial and lateral femoral epicondyles used for femoral rotational alignment and difficulty with the accuracy of intraoperative marking of these anatomical structures, the computer-assisted-navigation technique cannot ensure the accuracy of bone resection with external rotation[17,18]. Our study confirmed the inability of computer-assisted navigation to attain higher accuracy in femoral rotation.

Computer-assisted navigation, as an aid, may be associated with complications. Authors of clinical studies have reported fracture at the pin-track site on the femur and tibia[19-21]. Major causes of fracture include a large pin diameter (4 to 5 mm), an improperly positioned pin, repeated drilling of pins, obesity, osteoporosis, and postoperative trauma. In our series, the pin diameter was 3.2 mm and was placed uneventfully in all knees.

This study was a prospective, self-controlled, randomized, single-blind trial. This protocol eliminated the bias of the patients and the evaluators. However, this study had limitations in that we failed to compare the difference in systemic complications caused by the two techniques. Moreover, since the same cruciate-retaining prosthesis was used in the two groups, caution should be exercised before extrapolating these results to other prostheses. Since the follow-up time in this study was relatively short, no conclusion concerning the long-term clinical efficacy of the technique can be reached and a longer follow-up is now under way. ■

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