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Accuracy of Computed Tomography–Based Navigation-Assisted Total Knee Arthroplasty: Outlier Analysis

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ABSTRACT

Background: Achieving neutral limb alignment during total knee arthroplasty (TKA) has been identified as a potential factor in long-term prosthesis survival. This study aimed to analyze the accuracy of component orientation and postoperative alignment of the leg after computed tomography (CT)–based navigation-assisted TKA, compare these parameters with those of a conventional technique, and analyze differences in the data of outliers.

Methods: We retrospectively compared the alignment of 130 TKAs performed with a CT-based navigation system with that of 67 arthroplasties done with a conventional system. The knee joints were evaluated using radiographs.

Results: Mean hip–knee–ankle (HKA) angle, frontal femoral component angle, and frontal tibial component angle were 180.7°, 88.8°, and 90.6°, respectively, for the navigation-assisted arthroplasties and 181.1°, 88.7°, and 90.2°, respectively, for the conventional arthroplasties. All preoperative leg axes of 10 outliers in the navigation group were >193°, whereas the data of 17 outliers in the conventional group were scattered.

Conclusion: This study demonstrates significant improvements in component positioning with the CT-based navigation system. Furthermore, when analyzing cases with preoperative HKA angles ≤192°, no outliers were found in the navigation group, indicating high alignment accuracy. However, in cases with preoperative HKA angles ≥193°, outliers were found in both groups, and no significant difference between the groups was observed ($P = .08$). Detailed analysis of the outlier cases in the navigation group revealed that the femoral component was placed in the varus position. These findings indicate that the varus knee is an important factor influencing accurate positioning of the femoral component and the postoperative leg axis.

Total knee arthroplasty (TKA) has become one of the most successfully performed procedures in orthopedics with 15-year survival rates greater than 90% [1,2]. Long-term prosthesis survival may be influenced by the accuracy of component implantation and achievement of neutral mechanical axis of the affected limb [3-10]. In conventional implantation techniques, intramedullary or extramedullary alignment rods are used and positioned according to surgeon's judgment. It has been demonstrated that these techniques are associated with a substantially higher rate of inaccurate implantation [3,11-13]. Despite many studies [3-10] suggesting an association between achieving neutral limb alignment ±3° with improved long-term survivorship, it is currently an area that is being vigorously debated among some investigators [14,15], suggesting that this factor alone may not be as important as previously believed. Nevertheless, until biomechanical interrelations of components' orientation in coronal, sagittal, and axial planes are better understood, a neutral mechanical limb axis remains the golden standard [16].

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In previously reported studies, postoperative alignment of the limb exceeded the range of ±3° in up to 30% of cases. Jeffry et al [3] analyzed the TKA outcomes in 115 patients and found a 24% rate of loosening when the mechanical axis exceeded ±3° varus and/or valgus, whereas it was only 3% in the other cases. Mahaluxmivala et al [10] analyzed 673 TKAs. They found that more than ±3° varus and/or valgus alignment was present in 25% of cases, regardless of the surgeon's experience.

Navigation systems have been developed to improve the accuracy of prosthesis implantation in TKA. So far, only a few reports on the results of CT-based navigation-assisted TKAs have been published. In 3 prospective studies, radiological results after CT-based navigation-assisted TKA vs conventional insertion of components were analyzed, and significant differences were observed [17-19]. However, no detailed studies on outliers have been reported. We believed that by carrying out such a detailed study, the accuracy of the CT-based navigation might be further improved.

The aims of our study were to: (1) analyze the accuracy of component orientation and postoperative alignment of the leg after CT-based navigation-assisted TKA; (2) compare these parameters with those of a conventional surgical technique to extrapolate outliers in the CT-based navigation-assisted TKAs; and (3) perform detailed evaluation of the outlier data and evaluate whether outlier characteristics have any clinical importance.

Patients and Methods

We obtained institutional review board approval from our institution. We retrospectively analyzed the outcome data of patients with primary osteoarthritis who underwent TKA using either the CT-based navigation system or conventional technique. A total of 197 Asian patients who underwent primary TKA at our academic hospitals performed by a single surgeon from January 2007 to October 2013 were included in this retrospective cohort study: 130 were operated using a CT-based navigation system (the navigation group), and 67 patients underwent TKA using a conventional technique (the conventional group). Between January 2007 and December 2010, TKA was performed using navigation as a first choice in cases where it was possible to use navigation physically. All patients in whom CT-based navigation-assisted TKA for primary osteoarthritis was performed using 2 implants (PFC Sigma; DePuy Inc, Warsaw, IN, Vanguard; Biomet Inc, Warsaw, IN) in our academic hospital between January 2007 and December 2010 were selected. The conventional group was from the same hospital; the inclusion criterion was conventional manual implantation of the same prosthesis performed between May 2009 and October 2013. No exclusions were made regarding age and degree of leg axis deviation, and there was no significant difference between the 2 groups (Table 1). The same implants (PFC Sigma; DePuy Inc, Warsaw, IN; Vanguard; Biomet Inc., Warsaw, IN) were used in both groups.

Table 1
Preoperative Patient Data of the Navigation and Conventional Groups.

Parameter	Navigated Group (130 Knees)	Conventional Group (67 Knees)	*P* Value
Mean age at operation (y)[a]	74.1 ± 7.7 (48-90)	75.2 ± 9.0 (47-91)	.37
Gender			
Male	17	10	.72
Female	113	57	
Diagnosis			
Osteoarthritis	130	67	
Preoperative FTA (°)[a]	186.1 ± 7.8 (158-201)	184.5 ± 9.1 (167-205)	.19

FTA, femorotibial angle.
[a] Mean ± standard deviation (range).

The navigation group consisted of 113 female and 17 male patients with a mean age of 74 years (48-90 years). The mean preoperative mechanical axis of the leg was 192.2° (standard deviation [SD] 7.7°; range: 27° varus-17° valgus). In the conventional group, 57 female and 10 male patients were studied with an average age of 75 years (47-91 years). The mean preoperative mechanical axis of the leg was 190.3° (SD 8.8°; range: 30° varus-6° valgus).

Computer-Assisted Technique

In the navigation group, TKA was performed using a CT-based version of BrainLAB's VectorVision Knee 1.6. Following the standard protocol, CT scans of the leg were taken the day before surgery and included slices of the femoral head, knee, and ankle. Once computer models of the bones had been created, tibial and femoral components were orientated according to an automatically created treatment plan for neutral leg alignment, and bone resection plans were determined by the navigation system. If necessary, fine-tuning of resection planes and component orientation could be performed using either 3-dimensional (3D) surface images or the original CT scans.

At the start of the operation, a reference frame had to be attached to the distal femur or the proximal tibia with a bicortical pin. This was followed by surface matching, in which the surgeon had to digitize up to 20 freely chosen points on the bone surface of both the femur and the tibia. Femoral and tibia cutting blocks were orientated under real-time visualization on the navigation system display. The rotational alignment of the femoral component was adjusted to the surgical epicondyle axis, which was the line connecting the sulcus of the medial epicondyle and the most prominent point of the lateral epicondyle of the femur. For the proximal tibia resection plane, the resection level was set to 8 mm (PFC Sigma; DePuy Inc) or 10 mm (Vanguard; Biomet Inc) from the deepest point of the higher tibia plateau level. Rotational alignment of the tibial tray was orientated by reference to the medial third of the tibial tuberosity. After resection, all planes were checked using the verification tool of the navigation system.

Conventional Technique

The operations were performed using standard instrumentation. In all conventional cases, extramedullary instrumentation was used for the tibial component and intramedullary instrumentation for the femoral component. The femoral valgus angle for the intramedullary guide was determined on standardized, preoperative, long-leg, weight-bearing radiographs.

Radiological Measurements

The axis alignment of the limb and the orientation of the components were evaluated with standardized preoperative and postoperative, full-length, weight-bearing radiographs. For evaluation of the mechanical axis of the leg and frontal alignment, the following angles were measured: hip–knee–ankle (HKA) angle (=mechanical axis of the leg), frontal femoral component (FFC) angle, and frontal tibial component (FTC) angle. For sagittal plane evaluations, the lateral femoral component (LFC) angle and lateral tibial component (LTC) angle were measured. The LFC angle was measured between the anterior cortex of the distal femur and the shield of the femoral

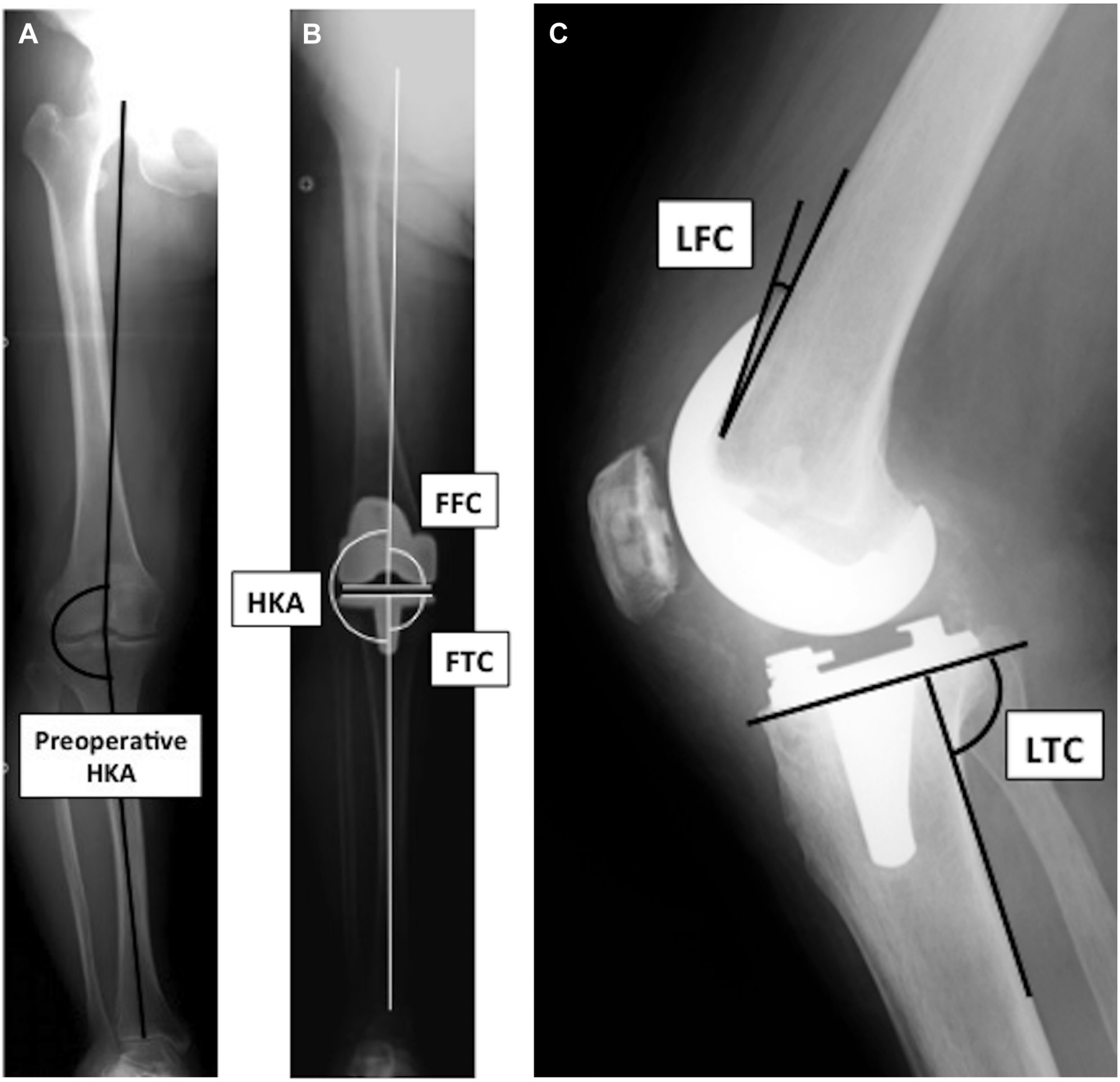

Fig. 1. Radiographic measurements of (A) preoperative hip–knee–ankle (HKA) angle (= mechanical axis of the leg), (B) the HKA angle (= mechanical axis of the leg), the frontal femoral component (FFC), and FTC angles, and (C) the lateral femoral component (LFC) and lateral tibial component (LTC) angles.

component. The LTC angle was measured in relation to the posterior tibia cortex (Fig. 1). The ideal HKA angle was defined as the angle within the range of 3°-180°.

Statistical Analysis

Statistical differences between the two groups were carried out with the following tests: gender was compared using a 2 × 2 chi-square test, and limb alignment was compared using an unpaired Student's *t*-test. A 2-tailed $P \leq .05$ was required for a statistically significant result. The Mann–Whitney *U* test was used to determine the statistically significant difference ($P < .001$) in the absolute HKA angle obtained from the target angles separately for the 2 groups. The 2 × 2 chi-square test was used to determine the statistically significant difference in the number of outliers between the 2 groups.

Results

Frontal Alignment

The mean postoperative leg axis was 0.7° varus (SD 1.7, range: 3° valgus-6° varus) in the navigation group and 1.1° varus (SD 2.8, range: 6° valgus-8° varus) in the conventional group (*t*-test, $P = .16$). A total of 120 patients (92.3%) in the navigation group and 50 patients (74.6%) in the conventional group had a leg axis within a range of ±3°. There were 10 outliers in the navigation group, and 9 of them were within a range of ±5° of leg alignment, whereas in the conventional group, 10 of 23 outliers exceeded the range of ±5°. A tendency for varus alignment was found in both groups. There was a significant difference in the absolute HKA angle value obtained from the target angles (Mann–Whitney *U* test, $P < .001$) between the 2 groups (Table 2).

Table 2
The Differences of Absolute Value Obtained From the Target Angles.

Parameter	Target Angle	Navigated Group	Conventional Group	*P* Value
Hip–knee–ankle angle (°, range)	180	1.4 (0-6)	2.3 (0-8)	<.001
Frontal femoral component angle (°, range)	90	1.4 (0-5)	1.7 (0-7)	.18
Frontal tibial component angle (°, range)	90	0.9 (0-3)	1.5 (0-6)	.001
Lateral femoral component angle (°, range)	0	2.3 (0-8)	4.1 (0-11)	<.001
Lateral tibial component angle (°, range)	90	0.9 (0-5)	3.3 (0-10)	<.001

In the navigation group, the mean FFC angle was 88.8° (SD: 1.3, 85°-93°), whereas it was 88.7° (SD: 1.8, 83°-93°) in the conventional group (*t*-test, $P = .53$). In the navigation group, the mean FTC angle was 90.6° (SD: 1.1, 87°-93°), whereas it was 90.2° (SD: 2.1, 86°-96°) in the conventional group (*t*-test, $P = .15$).

The ideal HKA, FFC, and FTC angles were obtained in 92.3% (120 knees), 96.2% (125 knees), and 100% (130 knees), respectively, in the navigation group, and in 74.6% (50 knees), 89.6% (60 knees), and 86.6% (58 knees), respectively, in the conventional group.

Sagittal Alignment

In the navigation group, the mean LFC angle was 1.0° (SD: 2.6, −6° to 8°), whereas in the conventional group, it was 3.7° (SD: 2.9, −5° to 11°; *t*-test, $P < .001$). The position of the tibia component with 0° posterior slope was planned, as recommended by the manufacturer. In the navigation group, the mean LTC angle was 89.9° (SD: 1.3, 85°-94°), whereas it was 87.0° (SD: 2.7, 80°-93°) in the conventional group (*t*-test, $P < .001$). Ideal sagittal femoral component and sagittal tibial component angles were obtained in 79.2% (103 knees) and 96.9% (126 knees), respectively, in the navigation group, and 41.8% (28 knees) and 56.7% (38 knees), respectively, in the conventional group.

Preoperative Leg Axis

In the navigation group, the mean preoperative leg axis was 192.2° (SD 7.7, range: 163°-207°), whereas in the conventional group, it was 190.3° (SD 8.8, range: 167°-210°). The mean preoperative leg axis of 10 outliers (7.7%) was 199.0° (SD 3.1, range: 193°-203°) in the navigation group, whereas the mean axis of the 17 (25.4%) outliers in the conventional group was 192.2° (SD 9.7, range: 177°-209°; Fig. 2).

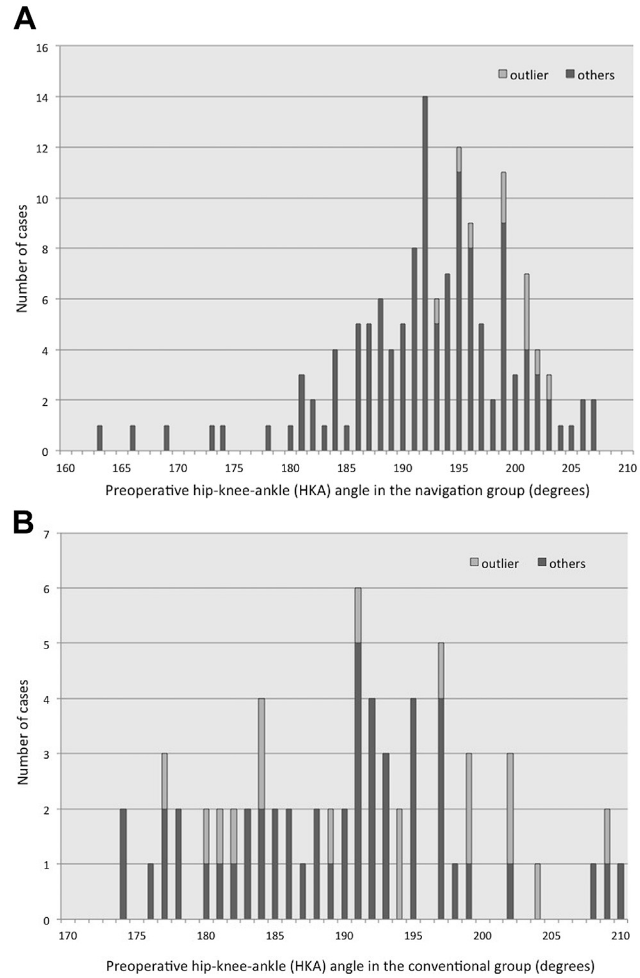

Fig. 2. Histogram showing the preoperative HKA angle between the postoperative HKA outliers and others in the navigation group (A) and convention group (B).

Discussion

In the present study, we compared the postoperative alignment after TKA performed with either the conventional method or CT-based navigation system. The alignment was assessed on preoperative and postoperative, full-length, weight-bearing radiographs based on measurements of HKA (=mechanical axis of the leg), FFC, FTC, LFC, and LTC angles for both the conventional and navigation-based procedures.

Numerous investigators have evaluated long-term outcomes of TKA and compared radiographic measurements of alignment [3-10]. An HKA angle exceeding ±3° (outliers) has been associated with worse functional outcomes and higher rates of implant failures. Therefore, achieving an alignment within the ±3° range is considered important for optimal TKA outcomes—more accurate alignment has been correlated with a longer service life of the implant and improved quality of life [20]. Some investigators [14,15] are suggesting that this factor alone may not be as important as previously believed. Parratte et al [14] concluded that until additional data can be generated to more accurately determine the ideal postoperative limb alignment in individual patients, a neutral mechanical axis remains a reasonable target and should be considered the actual golden standard [16].

In our study, the postoperative axis of the limb exceeded 3° of varus and/or valgus deviation in 25% of patients who were operated using the conventional technique. Our results were similar to those of Mahuluxmivala et al [10], who reported >3° varus and/or valgus deviation of the axis in 25% of patients postoperatively.

We found that the postoperative axis of the limb was significantly better in the computer navigation–assisted group. These findings were in agreement with the results of Bathis et al [21], who reported a tendency for better leg axis alignment when a navigation system (VectorVision CT-free knee; BrainLAB, Munich, Germany) was used. In their study, a mechanical axis of ±3° varus and/or valgus was achieved in 96% of patients using a navigation system and in 78% of patients in whom a conventional technique was used. In the same study, a significantly better orientation was reported in the computer navigation–assisted group for the femoral component in the frontal and sagittal planes and for the tibial component in the sagittal plane.

In a meta-analysis [22] that included a total of 3437 TKAs, a significantly better postoperative axis was achieved with computer-assisted surgery. In this study, 91% of patients attained an axis of ±3° varus and/or valgus alignment, whereas only 68% in the conventional group had a comparable result. In the same study, a significantly better orientation of ±3° varus and/or valgus alignment was reported in the computer-assisted group for the femoral and tibial components in the frontal planes.

By contrast, Yau et al found no significant differences in postoperative outcomes between computer-assisted TKA and conventional technique performed in a hospital with a lower volume total knee practice. In their evaluation, the mechanical axis of ±3° varus and/or valgus was achieved in 71% cases with the navigation system and in 75% cases with the conventional technique [23].

Some investigators [17-19] reported a tendency for better leg axis alignment when a CT-based navigation system (Vector Vision CT-based knee; BrainLAB Inc) was used. Mizu-uchi et al [18] reported that the mechanical axis of ±3° varus and/or valgus was achieved in 92% (34 of 37 operated knees) using a navigation system and in 72% (28 of 39 knees) with conventional surgery. In the same study, there were significant differences in the absolute values obtained from the target angle in the test for the HKA angle ($P < .01$). Mizu-uchi's findings in the 3D analysis [19] were similar to ours. We found better orientation of all components except for the FFC angle with the navigation-assisted technique, which might imply superiority of navigation over the conventional technique. However, further radiological and clinical data are needed to prove the validity of this assumption.

We also noticed that all preoperative leg axes values of the 10 outliers in the navigation group were >193°, whereas in the conventional group, the values of 17 outliers were scattered. This finding indicated that CT-based navigation was reliable and allowed high-precision alignment in patients with a preoperative leg axis ≤ 192°, whereas in patients with varus knees with a leg axis of >193°, no significant advantage of the CT-based navigation system was noted. On the other hand, all 10 outliers (15.4%) in the navigation group of 65 patients had a leg axis ≥193°, and there were 9 outliers (34.6%) of 26 patients in the conventional group with a leg axis >193° ($P = .08$).

Among mild cases of varus and/or valgus knees with relatively minimal bone loss and small bone spurs, segmentation was accurate, and preoperative planning was rather easy. However, correct segmentation was difficult for severe varus knees, especially those with large osteophytes and medial tightness (Fig. 3). This was also true for 10 outlier cases in the navigation group. All these cases were patients with varus knees, and there were 5 cases with FFC of 4° or more and 5 cases with varus FFC or FTC of less than 3° (Table 3). These findings implied that the varus knee is an important factor influencing accurate positioning of the femoral component and the postoperative leg axis. Our findings imply that specific usage of the CT-based navigation system in patients with severe varus and/or valgus knees needs to be reevaluated to

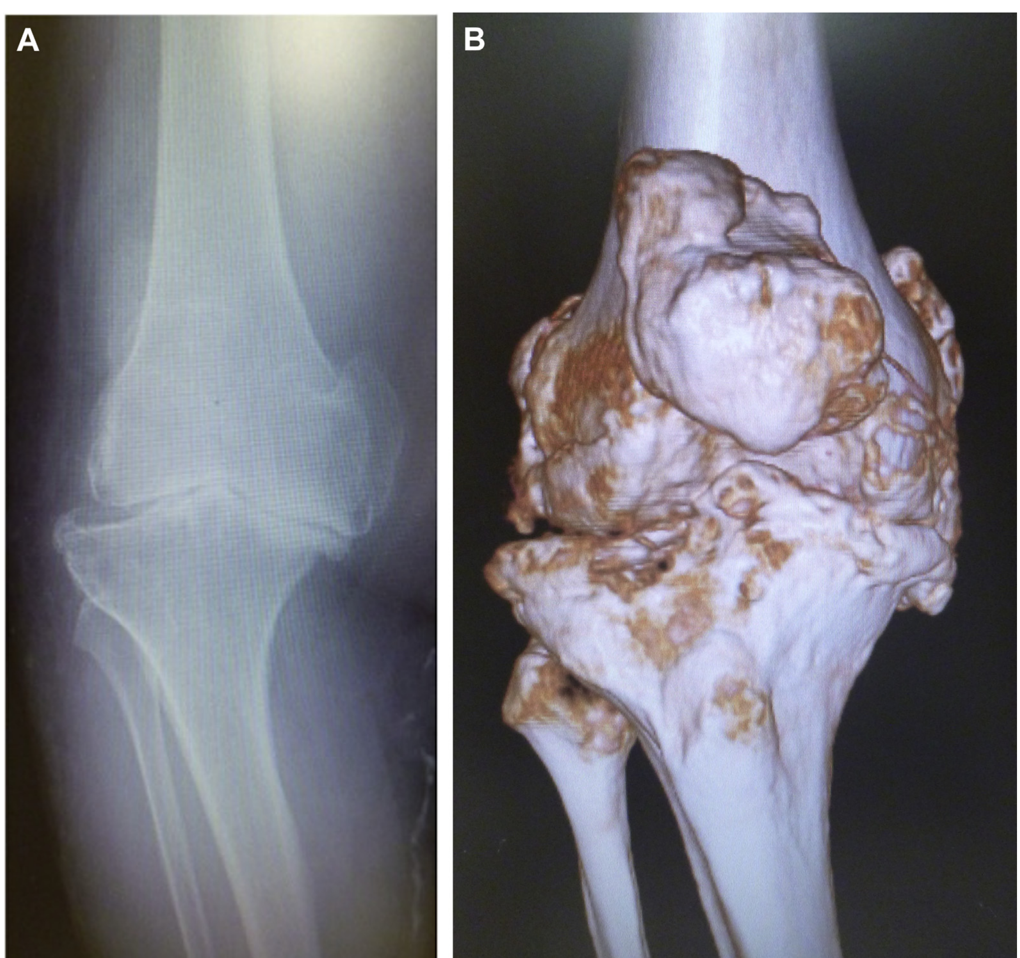

Fig. 3. Radiographs showing a knee with severe varus deformity and a big medial osteophyte (A) and a computed tomography (CT) image showing difficulty of segmentation (B).

Table 3
Ten Outliers in the Navigation Group.

No.	Postoperative HKA-180	FFC	FTC	Preoperative HKA
1	6	86	88	201
2	5	88	87	199
3	4	88	88	199
4	4	89	87	193
5	4	86	90	195
6	4	87	89	202
7	4	85	91	201
8	4	86	90	203
9	4	87	89	196
10	4	86	90	201
Ave.	4.3	86.8	88.9	199

HKA, hip–knee–ankle; FFC, frontal femoral component; FTC, frontal tibial component.

achieve the generally reported better accuracy of the system compared with the conventional technique.

Notwithstanding better component alignment parameters including the accuracy of the rotation installation [19], the CT-based navigation system for TKA has some disadvantages. Costs remain one of the most important, but possible reduction may be expected if significant improvements in prosthesis alignment and lower incidence of postoperative complications are proven to be obtainable. Additional preoperative CT scans and planning may be considered unnecessary by some patients and surgeons, but they may provide an important opportunity for selection of a more accurate operative strategy in some cases. In addition, the operative time is lengthened, and there are complications associated with pin insertion. Navigation systems are discussed in a broad sense, such as the inexpensive portable navigation and patient-matched instruments, which have been reported to have relatively good performance; on the other hand, there have been unfavorable reports with respect to component rotation [24,25]. Knacks and pitfalls are present with the use of any device. It is important that we have sufficient understanding of these devices and select the best device according to each case and the characteristics of each device.

Our study has some limitations. First, we did not evaluate the rotational alignment of the components. Second, the postoperative alignment was assessed only with 2-dimensional radiographs. Such an evaluation is usually affected by the positioning of the limb and by the scanning direction, despite the fact that preoperative planning and intraoperative procedures are performed in 3 dimensions. Consistent with this fact, Mizu-uchi et al [19] analyzed the 3D accuracy of TKA from preoperative and postoperative CT images and confirmed the importance of the postoperative 3D alignment. However, our evaluation was based only on postoperative lateral radiographs, and whole leg alignment of the tibial component was not examined because it was adjusted in relation to the lateral anatomical tibial slope. Third, it was a retrospective analysis, and further prospective research is necessary.

In our retrospective study, we studied the characteristics of the outliers and examined the accuracy of the CT-based navigation system using postoperative radiographs. Our results suggest the necessity for further improvements in the accuracy of CT-based navigation. These include more careful preoperative consideration of severe varus leg alignment and its possible correction by application of stress to widen the narrowed articular spaces on obtaining the preoperative scans of the varus and/or valgus knee joints.

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