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Less femoral lift-off and better femoral alignment in TKA using computer-assisted surgery

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Abstract

Purpose A comparison has been made between navigation-assisted and conventional measured resection total knee arthroplasty (TKA), under the hypothesis that navigation assistance would improve the precision and consistency of component alignment and femoral component rotation.

Methods The following radiographic parameters were measured: mechanical femorotibial angle, coronal and sagittal component angle, and femoral component rotation. Femoral condylar lift-off was checked by axial radiographs, and thresholds for outliers were set at 1.0 mm.

Results Clinical results obtained using Knee Society and Hospital for Special Surgery systems were not statistically different. The mean mechanical femorotibial angle was 2.2° (SD: 0.9) in the conventional group and 1.7° (SD: 0.7) in navigation group ($p = 0.001$). The mean coronal femoral component angle was 89.2° (SD: 2.2) in conventional group and 90.4° (SD: 1.8) in navigation group ($p = 0.006$). The mean transepicondylar-posterior condylar axis angle was 1.7° (SD: 0.9) in conventional group and 1.2° (SD: 0.5) in navigation group ($p = 0.008$). Femoral condylar lift-off greater than 1 mm occurred more frequently ($p = 0.000$) in conventional group.

Conclusion Coronal plane stability and precision of femoral component rotation were impacted by navigation system. The use of a navigation system with measured resection TKA can help optimize coronal stability and parallel component position.

Level of evidence Retrospective case control study, Level IV.

Keywords Total knee arthroplasty · Navigation · Measured resection · Femoral component rotation

Introduction

A successful knee arthroplasty requires the correct alignment of the components, including femoral rotation and soft tissue balancing [11, 15]. Incorrect alignment can lead to abnormal prosthesis wear, along with premature mechanical loosening of the components and patellofemoral problems [9, 10, 20, 29, 31, 32]. Rotational alignment of the femoral component in total knee arthroplasty (TKA) is particularly crucial for patellofemoral and femorotibial kinematics and the balancing and stabilizing of the replaced joint [9–11, 15].

Optimal axial limb alignment represents a key factor for the satisfactory outcome of TKA in the long term [13, 32]. Various ranges of tolerable limb alignment have been reported [12, 14], but a range of ±3° varus/valgus in the mechanical axis has been suggested for better success [9, 10, 12–14, 20, 29, 31, 32]. Many conventional TKA studies indicate that a post-operative limb alignment exceeds ±3° varus/valgus in up to 30 % of cases [2, 8–10, 12–14, 22, 28]. Although alignment guides can improve the precision in conventional TKA, limitations of this technique have been widely reported [25, 26].

Navigation offers more precise implantation based on anatomical landmarks and kinematic analysis, improving

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the precision and consistency of component alignment. Many comparative studies have described better alignment in navigation-assisted TKA compared to conventional TKA [2–4, 16]. With regard to femoral component rotation, however, the debate continues over whether navigation systems provide a more reliable tool for establishing precise femoral rotational alignment than conventional techniques [19].

A number of studies have evaluated the precision and consistency of conventional TKA and TKA using the navigation-assisted gap technique [2–10, 12–14, 18, 19, 22, 25, 26, 28, 29, 32], but few comparisons have been made of a navigation-assisted measured resection TKA and a conventional TKA using a measured resection technique.

The primary purpose of this study was to compare navigation-assisted measured resection TKA and conventional measured resection TKA using 3° external rotation relative to posterior condylar axis [1, 21, 23, 30].

It is hypothesized that a navigation-assisted measured resection technique would provide better precision and consistency for component alignment and femoral component rotation in TKA than the conventional measured resection technique.

Materials and methods

This was a retrospective case control, clinical study of patients who had TKAs between 2008 and 2009 with a minimum 2-year follow-up (range from 24 to 36 months). Of the 91 patients who had primary TKAs (Columbus®, Aesculap, Tuttlingen, Germany), 73 consecutive cases involved the OrthoPilot navigation system (Aesculap), and 38 consecutive cases involved conventional instrumentation. The navigation-assisted group included 57 unilateral and 8 bilateral TKAs in 55 female and 10 male patients, with an average age of 67.3 ± 5.9 years and an average preoperative mechanical axis deviation of 8.0° varus (67 varus to 6 valgus cases). The 38 conventional cases (12 patients bilaterally, 14 patients unilaterally) were performed in the same centre by the same surgeon. The conventional group included 20 female and 6 male patients with an average age of 70.5 ± 4.6 years and an average preoperative mechanical axis deviation of 6.3° varus (38 varus cases). The exclusion criteria were as follows: cases with bone graft due to severe deformity or bone defect, revision surgery, and BMI over 30. We also excluded patients who had a fixed flexion contracture of more than 30° because that deformity could influence the zero setting of the navigation system.

Pre-operative and post-operative scores were obtained for all patients using the Knee Society (KSS) and Hospital for Special Surgery (HSS) systems.

Surgical technique

All arthroplasties were performed using a standard mid-vastus approach with patellar subluxation. The Orthopilot (version 4.2, Aesculap, Tuttlingen, Germany) navigation system was used for navigation-assisted TKAs. A minimum medial release was performed to correct varus deformity, guided by real-time feedback from the navigation system. The posterior cruciate ligaments were sacrificed in all patients. Coronal alignment was accepted within 0°–2° of varus. The distal femoral cut was performed prior to femoral rotational alignment. Femoral jig rotation was recorded after alignment to Whiteside's line by the navigation system. This femoral component rotational angle was the angle of the AP axis relative to the posterior condylar axis [1, 21, 23, 30]. After the antero-posterior (AP) cut was completed using a femoral cutting block guide, the flexion gap was measured. If the flexion gap was larger than the extension gap, the femoral block was set 2 mm posterior to its initial position under navigational monitoring.

The flexion gap from the medial posterior femoral cutting surface to the medial tibial plateau was measured with using a metal ruler. We tried not to loosen the flexion gap by more than 2 mm relative to the extension gap. We accepted medial and lateral flexion gap differences of less than 3 mm (rectangular flexion gap).

If the femoral rotational angles did not result in an acceptable rectangular flexion gap, we adjusted the femoral rotational angles under a real-time navigation feedback. The tibial cut was performed perpendicular to the tibial mechanical axis using navigational instrumentation. After all bone cutting was performed and femoral and tibial trials were inserted, we verified that the valgus and varus angles once more under real-time navigation feedback to evaluate collateral ligament balancing and prostheses were implanted with cement subsequently. Patellar tracking was confirmed by the towel clip method.

In the conventional TKAs, the surgical approach was performed in the same method as described above. Orientation of the resection guides was performed under the surgeon's control, with intramedullary femoral and extramedullary tibial guide rods. The femoral rotational angle was set to 3° external rotation relative to a posterior condylar axis. The distal and posterior femoral cutting thickness was determined according to the selected size of implants before the resection in the usual way.

Radiographic analysis

The axial limb and component alignment in the coronal plane were evaluated on standardized full-length weight-bearing radiographs by two independent observers. The

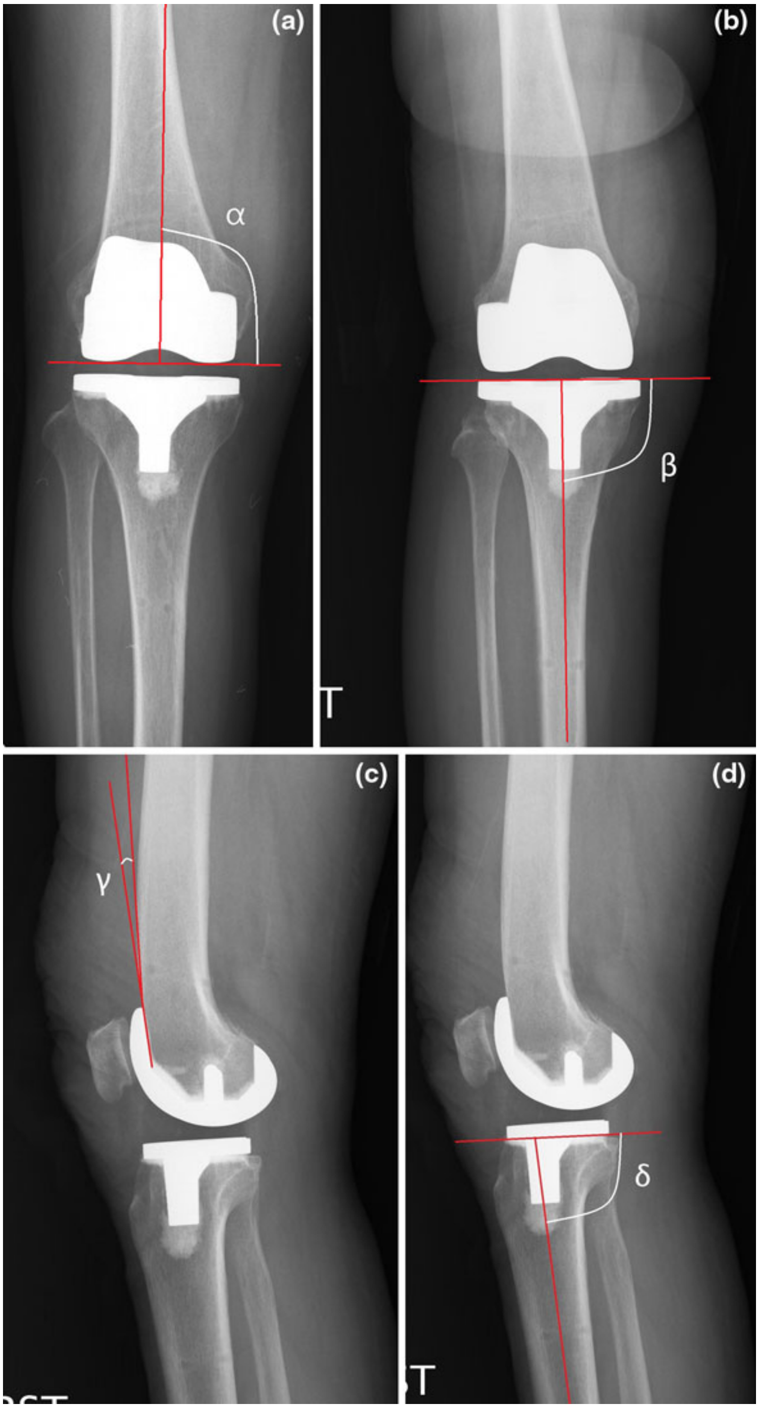

Fig. 1 **a** The coronal femoral component angle (α) is the angle between the mechanical axis of the femur and the lower margin of the femoral component. **b** The coronal tibial component angle (β) is the angle between the mechanical axis of the tibia and the upper margin of the tibial component. **c** The sagittal femoral component angle (γ) was measured between the anterior cortex of the femur and the shield of the femoral component. **d** The sagittal tibial component angle (δ) was measured between the anatomical axis of the tibia and the lower margin of the tibial component

following angles were included: mechanical femorotibial angle (mechanical axis deviation, MAD), coronal femoral component angle (α), and coronal tibial component angle (β). The mechanical femorotibial angle (MAD) was measured between the mechanical axis of the femur and the tibia. The coronal femoral component angle (α) was defined as the medial angle between the mechanical axis of the femur and the lower margin of the femoral component (Fig. 1a). The coronal tibial component angle (β) was defined as the medial angle between the mechanical axis of the tibia and the upper margin of the tibial component (Fig. 1b). Sagittal alignment was measured on lateral knee radiographs by analysing the sagittal femoral component angle (γ) and the sagittal tibial component angle (δ). The sagittal femoral component angle (γ) was measured between the anterior cortex of the femur and the shield of the femoral component for the prosthesis (Fig. 1c). The sagittal tibial component angle (δ) was measured between

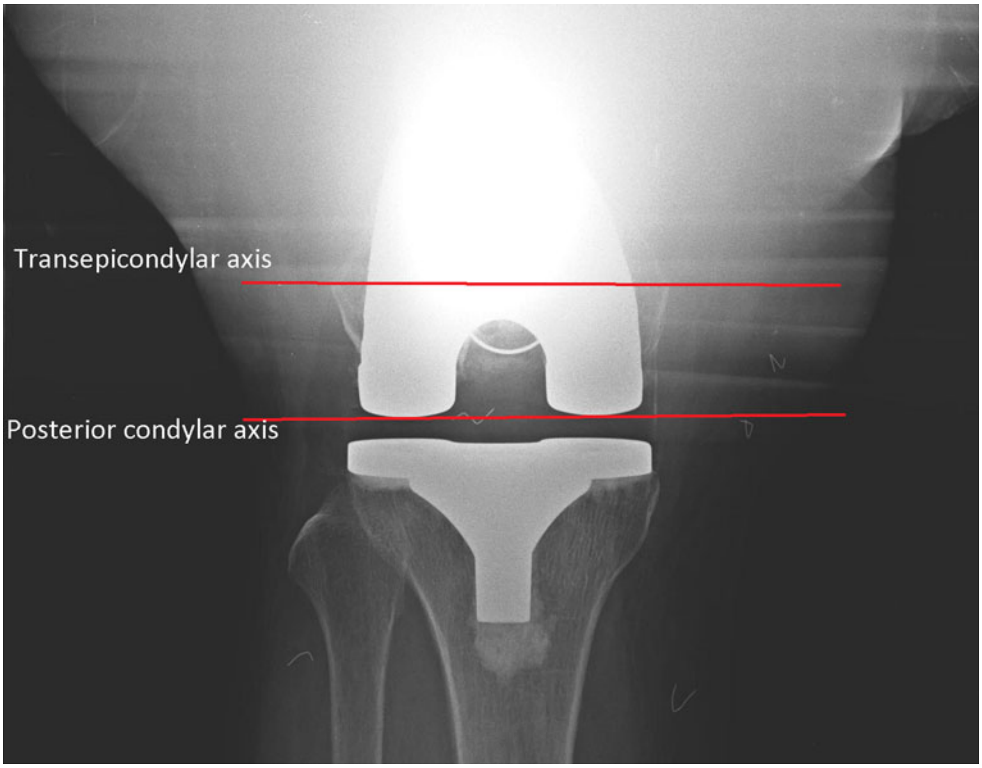

Fig. 2 Axial radiograph showing the transepicondylar axis and posterior condylar axis. The two femoral rotation axes should be parallel and measuring the angle between two *orthogonal lines* was drawn

the anatomical axis of the tibia and the lower margin of the tibial component (Fig. 1d). The ideal range for each angle and outliers were defined based on the range of ±3° varus/valgus and ±3° flexion/extension. The mean deviation (±SD) and number of outliers were evaluated for each angle.

Postoperative evaluation of the femoral component rotation was performed using axial radiographs. Patients sat on a wooden table with their knees in 90° of flexion with neutral rotation. The central ray of the radiograph beam was directed to the centre of the patella at a 10° upward angle to minimize the effect of soft tissue. The distance between the radiograph tube and the film cassette was set at 100 cm [18]. The posterior condylar axis and transepicondylar axis were drawn on the axial radiographs, and the femoral component rotation between two orthogonal lines was measured. The acceptable range of outliers was defined as ±1° (Fig. 2).

Differences in mediolateral femoral condylar lift-off were checked by axial radiographs to evaluate the rectangular flexion gap and coronal plane instability by performing digital measurements of the distances from the medial and lateral femoral condyles to the tibial tray (Fig. 3) [6, 7]. Dennis et al. [6, 7] used 3D reconstruction models to measure the lift-off value, but we used simple X-ray films to measure the true AP in each flexion angle (full extension, 45°, 90° flexion). The incidence of femoral condylar lift-off greater than 1 mm that occurred at any of the flexion values was compared. Lastly, the mean and maximum magnitude of femoral condylar lift-off at any flexion increment was recorded and compared.

All measurements were performed on a PACS (Picture Archiving and Communications System; General Electric, Chicago, IL, USA) monitor using a mouse point cursor and an automated computer calculation.

Statistical analysis

Two orthopaedic surgeons performed the measurements on the radiographs, and the mean value for each parameter was used for the statistical analysis. The primary outcome measurement of the study was to find the differences of mean with postoperative mechanical axis. The allocation ratio was set at 2:1 and the sample size calculation was based on a pilot study of 10 patients in each group. The standard deviation in a pilot study was 1.01 in the navigation group and 0.72 in conventional group. We accepted a two-sided α error of 5 % and β error of 20 % to detect any significant difference. Based on these calculations, the required study size was 73 in navigation group and 36 in conventional group. For comparison of mean values, the groups were analysed for normality using the Shapiro-

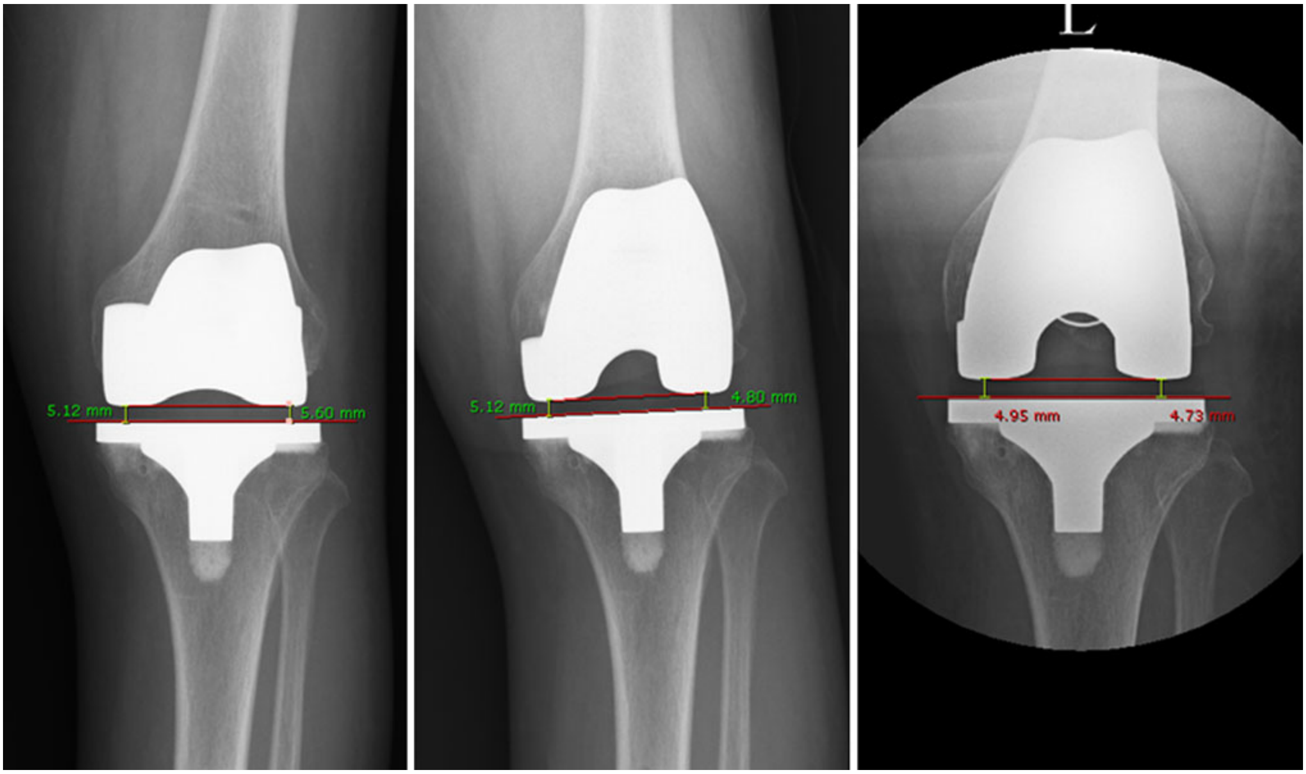

Fig. 3 Measure the distances from the medial and lateral femoral condyles to the tibial tray at each flexion angles. The given values with two decimal were automatically calculated, round off the numbers to two decimal places

Wilks test first, and all values revealed over $p < 0.05$ except femoral condylar lift-off values, comparable for normal distribution.

Radiologic alignment angles between the groups were compared using an independent t test. Chi-square analysis was used to determine the difference of the rates of angles over outliers and the differences in the incidence of femoral lift-off greater than 1.0 mm between the groups. Because of femoral condylar lift-off mean values did not show normal distribution, the groups were analysed by Mann–Whitney test. Statistical significance was set at $p < 0.05$. The reliability of measurements was assessed by examining the inter-observer agreement and determined using the intraclass correlation coefficient (ICC), which quantifies the proportion of the variance due to the variability between measurements. A test–retest for intra-observer reliability was performed with each orthopeadic surgeon after 4 weeks from first measurement. The test–retest reliability was calculated by Spearman's correlation coefficient for femoral condylar lift-off measurement and Pearson's correlation coefficient for other measurement. Statistical analysis was performed using a software package (SPSS for Windows Release 17.0, Chicago, Illinois) and SAS software, version 9.1 (SAS Institute, Inc., Cary, NC, USA).

Results

The clinical results of both groups are summarized in Table 1. Neither pre-operative KSS and HSS scores nor postoperative scores were statistically different between the two groups (n.s, respectively). The difference in pain score of the KSS and HSS systems at the latest follow-up was not statistically significant (n.s, respectively). Neither the pre-operative range of movement nor the range of movement at final follow-up was statistically different between groups (n.s, respectively).

Radiologic differences in limb alignment and lift-off value

The mean mechanical femorotibial angle (MAD) and the mean coronal femoral component angle (α) were statistically different in both groups, but others were not statistically different. The outliers of MAD, α, γ angle were statistically different in both groups, whereas others were not. The mean value and outliers of transepicondyle-posterior condyle axis angle were statistically different in both groups (Table 2).

A femoral condylar lift-off greater than 1 mm occurred more frequently ($p = 0.000$) in the conventional group

Table 1 Clinical results in both groups (mean)

	Navigation		Conventional	
	Pre-operative	Final follow-up	Pre-operative	Final follow-up
Knee society score (SD)				
Total	31 (SD: 8.2)	92 (SD: 4.3)	30 (SD: 7.9)	93 (SD: 4.8)
Functional	27 (SD: 7.4)	87 (SD: 3.9)	26 (SD: 6.4)	85 (SD: 4.2)
Pain	0 (0)	44 (SD: 5.2)	0 (0)	46 (SD: 4.9)
Hospital for special surgery score (SD)				
Total	60 (SD: 8.5)	90 (SD: 3.3)	60 (SD: 6.8)	89 (SD: 3.1)
Functional	5 (SD: 0.9)	16 (SD: 2.7)	6 (SD: 0.8)	18 (SD: 2.5)
Pain	4 (SD: 0.9)	25 (SD: 2.3)	5 (SD: 1.0)	26 (SD: 2.1)
Pain (%)				
None		60 (82)		34 (90)
Mild		13 (18)		4 (10)
Moderate	7 (9)	–	4 (10)	–
Severe	66 (91)	–	34 (90)	–
Range of movement (°)	121 (0 to +127)	125 (0 to +130)	122 (−5 to 130)	127 (−1 to +129)

SD standard deviation

Table 2 Overall angle of lower limb alignments and transepicondylar-posterior condylar axis

	Measured angle		*p* value	Outliers >3°		*p* value
	Navigation	Convention		Navigation	Convention	
Mechanical femorotibial angle (MAD)	1.7° (SD:0.7)	2.2° (SD:0.9)	0.001	10 (14 %)	12 (33 %)	0.005
Coronal femoral component angle (α)	90.4° (SD:1.8)	89.2° (SD:2.2)	0.006	2 (3 %)	8 (22 %)	0.001
Coronal tibial component angle (β)	90.2° (SD:1.7)	90.7° (SD: 1.5)	n.s	0 (0 %)	0 (0 %)	NA
Sagittal femoral component angle (γ)	2.0° (SD: 1.4)	2.1° (SD: 1.4)	n.s	11 (15 %)	18 (48 %)	0.005
Sagittal tibial component angle (δ)	85.2° (SD: 1.6)	85.1° (SD: 1.8)	n.s	15 (20 %)	9 (25 %)	n.s
Transepicondylar-posterior condylar axis angle	1.2° (SD: 0.5)	1.7° (SD: 0.9)	0.008	14 (17 %)†	16 (42 %)†	0.01

† Outliers >1°; *NA* not applicable, *SD* standard deviation

than in the navigation group. There were no statistical differences in the mean values. The maximum magnitude of femoral condylar lift-off observed at any flexion was similar between the conventional and navigation group (Table 3).

The ICC for inter-observer reliability was greater than 0.8, ranging from 0.82 to 0.96, for all measurements, indicating that all measurements had good inter-observer reliability. The Pearson's and Spearman's correlation coefficient for test–retest reliability ranged from 0.89 to 0.93, indicating that all measurements had significant correlation.

Table 3 Frequency and mean measured value of femoral lift-off

	Measured values		*p* value
	Navigation	Convention	
Femoral lift-off >1.0 mm	18 % (40/219)	45 % (52/114)	0.000
Mean femoral lift-off	0.7 mm	0.7 mm	n.s
Maximal femoral lift-off	3.6 mm	3.6 mm	n.s

Discussion

The most important finding of the present study was that axial limb and component alignment was more precise and consistent in the navigation-assisted measured resection TKAs relative to conventional TKAs, except for tibial component alignment. Taken together with the transepicondylar-posterior condylar axis angle and femoral condylar lift-off value, femoral component rotation and coronal stability were also more precise and consistent in navigation-assisted measured resection TKAs than conventional measured resection TKAs. Moreover, measured resection technique based on navigation system could help to prevent the catastrophic results in alignment and clinical calamity and to help achieve more reproducible results with a step-by-step real-time feedback.

In this study, the navigation group had better consistency and precision in the α angle, but the β angle was not significantly different between the two groups. The mean γ angle was similar between the two groups, but there were more outliers in the conventional group (48 %) than in the navigation group (15 %). The δ angle, like the β angle, was not significantly different between the two groups. The consistency and precision of the β and δ angles in the conventional group were comparable to those of the navigation group, probably due to technical and instrument improvements for tibia cutting and the use of the same anatomical references in both groups [25–27]. As in the most previous studies, we also assessed prosthesis component alignment on postoperative radiographs [4, 9, 10, 18, 19, 24, 29, 32] along with femoral condylar lift-off [6, 7] and the transepicondylar axis [18] to evaluate femoral component rotation and stability. The consistency of alignment in each radiological parameter was assessed by setting outliers. For the MAD angle, the mean value was closer to a perpendicular angle in the navigation group, with 33 and 14 % of patients as outliers in the conventional and navigation groups, respectively, demonstrating remarkable improvement in consistency and accuracy with the navigation group.

For the transepicondylar-posterior condylar axis, the mean value was closer to a parallel angle in the navigation group. The navigation group also had better consistency, with 17 % of patients as outliers compared to 42 % in the conventional group. There were no complications after TKA including fracture, infection or any other findings.

Jennings et al. [17] studied the effect of femoral condylar lift-off on the wear of ultra high molecular weight polyethylene in both fixed bearing and rotating platform TKA using a physiologic knee simulator, supported the relationship between the wear and both femoral condylar lift-off value and coronal stability. In our study, more conventional group patients exceeded the 1.0 mm outlier value (45 %) than navigation group patients (18 %).

Dennis et al. [6, 7] demonstrated that rotation of the femoral component using a gap balancing technique resulted in better coronal stability than the measured resection technique. In that study, however, TKA was performed using conventional techniques without navigation. Our findings show that a navigation-assisted measured resection could play a meaningful role in assuring proper rotation of the femoral component. Both gap balancing and measured resection software has independent advantages, allowing surgeons to choose based on personal preference. Navigation-assisted TKAs still have outliers, although less than conventional TKAs, making it important to have the surgeon check the surgical steps briefly. Navigation-assisted surgery provides information that can be used to guide surgical procedure selection, but it cannot replace a surgeon's judgment. However, taken together with the results of this study and a previous study, navigation-assisted measured resection TKA could help to obtain precise coronal alignment and stability, especially in femoral component placement, and to accomplish more safe procedure with step-by-step sequence.

This study has a number of limitations. The selected patients were not consecutive or randomized, and the sample size was not the same in both groups. In addition, we only used a measured resection technique, and the results may not be applicable to other systems and surgical procedures. On the other hand, one surgeon performed all of the TKAs using the same technique, allowing us to isolate the attributes of navigation. It seems that the small changes of improved precision with navigation-assisted TKA may be within the range of measurement errors of standing radiographs, but the meaningful findings of this study were that the outliers in the conventional group occurred more frequently with regard to MAD angle, transepicondylar-posterior condylar axis and condylar lift-off. Moreover, validation might be needed with the plain radiograph and 3D models in femoral condylar lift-off measurement. And lastly, long-term follow-up should be planned to evaluate that differences of outliers in both groups, especially femoral lift-off and rotation, which could affect the survival rate from a wearing and loosening point of view.

Conclusion

In conclusion, navigation-assisted TKAs were more precise and consistent in an alignment and component position. Also, coronal plane stability and precision of the femoral component rotation were impacted by the navigation system. The use of a navigation system with a measured resection programme can help optimize coronal stability and parallel femoral component position with step-by-step feedback in daily working.

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