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KNEE ARTHROPLASTY

An accelerometer-based navigation did not improve the femoral component positioning compared to a modified conventional technique of pre-operatively planned placement of intramedullary rod in total knee arthroplasty

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Abstract

Introduction Although the most commonly used method of femoral component alignment in total knee arthroplasty (TKA) is intramedullary (IM) guides, this method demonstrated a limited degree of accuracy. Because of the femoral anterior bowing, the tip of the guide rod will impinge on the anterior cortex if a long rod is inserted. We hypothesized that the pre-operative planned insertion depth of the rod could increase the accuracy of the femoral component positioning in conventional TKA (modified conventional technique). Accelerometer-based, portable navigation device has been postulated to have better accuracy than conventional TKA in component positioning. The purpose of this study was to compare the post-operative femoral component alignment of TKA using the modified conventional technique with the accelerometer-based navigation.

Materials and methods Fifty-five knees underwent TKA using the modified conventional technique and femoral component positioning was compared with 55 knees performed using the accelerometer-based navigation device. The femoral component alignment was evaluated with a CT-based three-dimensional software.

Results The mean absolute deviation from targeted alignment in the sagittal plane was significantly less in the modified conventional cohort than in the accelerometer-based navigation cohort (1.1° vs 2.6°, $P<0.001$). In the modified conventional cohort, 96.4% had an alignment within 3° of a targeted angle in the coronal plane (vs 89.1% with the accelerometer-based navigation, $P=0.14$), and 96.4% in the sagittal plane (vs 74.5% with the accelerometer-based navigation, $P<0.001$).

Conclusion The modified conventional technique is a simple and equal to or more accurate method than the accelerometer-based navigation in positioning the femoral component in TKA at a mid-volume hospital.

Keywords Total knee arthroplasty · Accelerometer-based navigation · Three-dimensional planning · Intramedullary rod · Insertion depth

Introduction

Currently, an intramedullary (IM) distal femoral alignment guide is the most commonly used means of aligning the distal femoral cutting block in total knee arthroplasty (TKA). The human femur is described as having a sagittal bow with anterior apex [1–5]. Insertion of intramedullary guide rod beyond the bow will result in impingement of the tip on the anterior cortex and rod displacement in extension [6]. This would result in extension of cutting block. The distal femoral valgus resection angle is also influenced by femoral shaft bow in the coronal plane [7–9]. Insertion of intramedullary rod beyond the bow can cause the rod to impinge on the lateral cortex resulting in varus position of the cutting block. It was considered that the adjustment of the insertion depth to the pre-operatively planned length would provide the proper orientation as well as stability of the intramedullary cutting guide by the tip of the rod resting against the inner cortex at the anterior bow. Most surgeons use a fixed resection angle of 5°–7° for all patients. Several recent studies recommend

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pre-operatively planned valgus resection angle in view of great variation between mechanical axis and distal femur resection angle particularly in Asian population [7–9]. Inaccuracies with the intramedullary femoral guide arise from both an improperly positioned distal femoral entry site and poor centering of the rod within the canal proximally. Therefore, it is possible to assume that fixing the entry point at the center of the notch with the meticulous pre-operative planning can potentially reduce the outlier rate of the femoral component. It has been demonstrated that computer-assisted surgery (CAS) provides better alignment than conventional techniques in the coronal, sagittal and rotational alignments in TKA [10–12]. However, concerns regarding increased capital costs, longer operative times, extra pin sites and the learning curve required have limited its widespread acceptance. Recently, navigation systems have been developed using accelerometer electronic components. The KneeAlign 2 (OrthAlign Inc, Aliso Viejo, California) system for TKA is a hand-held accelerometer-based navigation device, which seeks to combine the accuracy of CAS techniques with the ease of use of conventional alignment methods [13]. We hypothesized that although the distal femur resection technique utilizing preplanned depth, distal entry point and distal resection angle based on CT reconstruction of the mechanical axis (modified conventional technique) would provide high accuracy, KneeAlign 2 system is still a more accurate method in obtaining the targeted post-operative alignment of the femur compared with the modified conventional technique. The purpose of this study was to compare the post-operative femoral component alignment of the modified conventional technique with KneeAlign 2 system.

Materials and methods

From April 2014 to October 2015, 49 patients (6 male, 43 female) received a TKA using the modified conventional technique to perform distal femoral resection (modified conventional TKA). Six patients underwent bilateral TKAs, for a total of 55 knees in modified conventional cohort. All surgeries in this cohort were performed by the senior author (T.T.) using Persona® CR knee system (Zimmer,Warsaw, Ind) with conventional manual instruments including an intramedullary femoral guide. During the same period, 48 patients (5 male, 43 female) received a TKA using an accelerometer-based, portable navigation device for TKA (KneeAlign 2 system; OrthAlign Inc, Aliso Viejo, California) to perform the distal femur resection. Seven patients underwent bilateral TKAs, for a total of 55 knees in the KneeAlign 2 cohort. In the KneeAlign 2 cohort, the surgery was performed by the two surgeons (44 knees by T.L. and 11 knees by Y.T.) using Vanguard® CR knee system (Biomet, Warsaw, Ind). Inclusion criteria were patients with a history of osteoarthritis or rheumatoid arthritis who received a primary TKA. Patients were excluded if they required the use of femoral stem extension.

The pre-operative knee alignment was assessed by the hip–knee–ankle angle (HKA angle; positive values indicate varus alignment) measured on a full-length weight-bearing X-ray in the standing position. All patients were subjected to CT scan of the entire lower extremity before surgery. Using the CT data, three-dimensional (3D) models of the bone were created with a 3D pre-operative planning software for TKA (ZedKnee, LEXI, Inc., Tokyo, Japan) and surgical simulations were performed. The mechanical axis of the femur was defined as a vector from the hip center to the knee center. The knee center was defined as the midpoint of the two epicondyles. First, the distal bone cut was made perpendicular to the mechanical axis in the coronal plane. The femoral component was positioned parallel to the anterior femoral cortex. The axis of the distal femoral anterior cortex was defined as the line along the cortex just proximal to the femoral anterior surface. Then the simulation of the IM rod insertion was performed. In the sagittal plane, the distal cut was made with femoral component parallel to the anterior cortex. This angle would depend on the morphology of the distal femur and not necessarily on a fix angle with respect to the mechanical axis. Therefore, the IM rod was positioned passing through the middle of the distal femur and parallel to the distal anterior cortex (Fig. 1b). The entry point of the IM rod was on the point of intersection between the coronal mechanical axis and the sagittal plane including the simulated IM rod (Fig. 1c). On the every 3D reconstruction images, we found that this point is always on the midpoint of the Whiteside line. The simulated IM rod length which will impinge on the anterior cortex of the femur was measured (Fig. 1d). The medial or lateral cortex impingement did not occur before the anterior cortex impingement in all pre-operative planning. The distal femoral valgus resection angle was determined by rounding the measured difference angle between the simulated IM rod and the mechanical axis of the femur down to the next integer (Fig. 1a). During the operation, pre-operative planned insertion depth was marked on an 8-mm-diameter IM femoral guide rod and the cutting block was attached at the position (Fig. 2). Then, the distal femoral osteotomy was performed in a standard fashion with the planned valgus angle.

The technique used for implementing the KneeAlign 2 system has been previously described [13, 14]. Targets for the distal femoral osteotomy were 0° in the coronal plane (perpendicular to the mechanical axis of the femur) and 3° of flexion in the sagittal plane. The resection depth was set, and the cutting block was pinned to the distal femur. The display console, sensor, and jig were removed, and the distal femoral osteotomy was performed through the cut block.

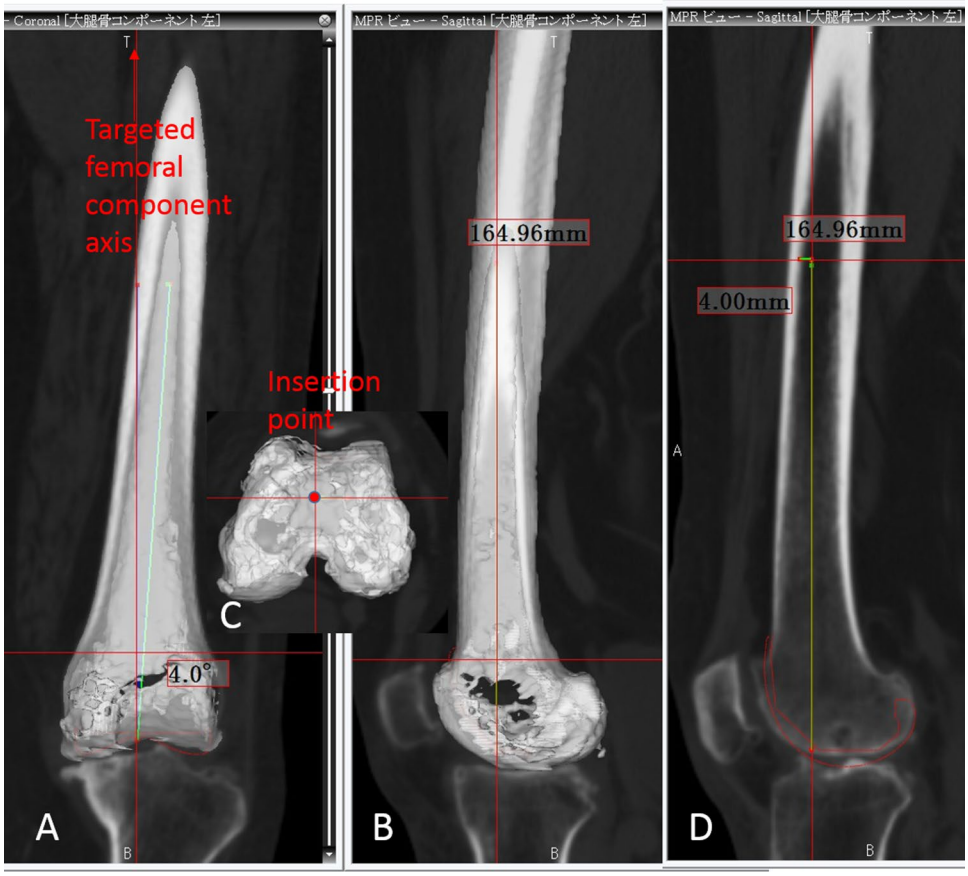

Fig. 1 Figures show how to plan the valgus resection angle (**a**) and the intramedullary rod insertion depth (**b, d**). The entry point of the simulated intramedullary rod was the midpoint of Whiteside's line (**c**)

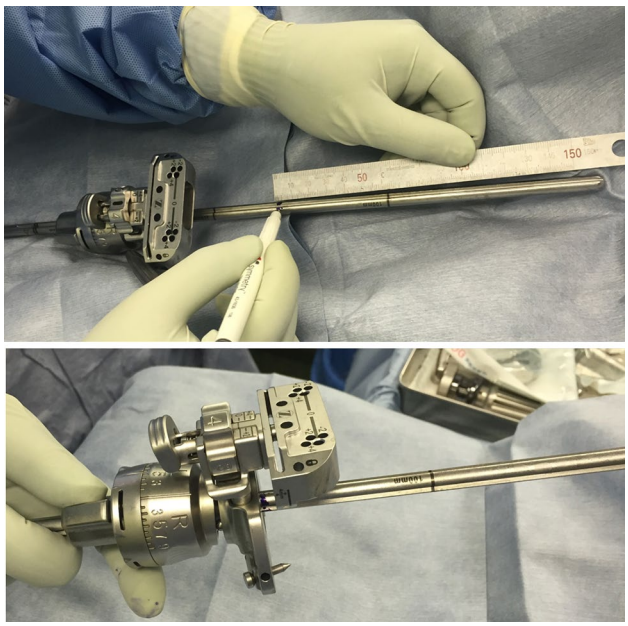

Fig. 2 Intraoperative photo shows how to set the intramedullary rod insertion depth

The post-operative CT was co-registered to the pre-operative CT by a surface-matching algorithm to overlap the pre- and post-operative femur at the same axis of coordinates by the post-operative alignment evaluation function of the pre-operative planning software (Fig. 3a). The femoral component positions were obtained using a CAD-model-based shape-matching technique and the deviation from the targeted femoral component position was measured (Fig. 3b–d). In Knee Align 2 cohort, the deviation from the targeted femoral component position (perpendicular to the mechanical axis in coronal and 3° of flexion relative to the mechanical axis in sagittal plane) was calculated in consideration of the difference between the definition of the knee center in the pre-operative planning software and Knee Align 2 (Fig. 4).

This retrospective study was approved by our Institutional Review Board.

Statistical analysis

Continuous data were summarized as means with standard deviations and ranges, and comparisons between the two cohorts were performed using a Student's *t* test (one tailed or two tailed). Fisher's exact test was used to analyze occurrence of outliers. A *p* value of less than 0.05 was considered

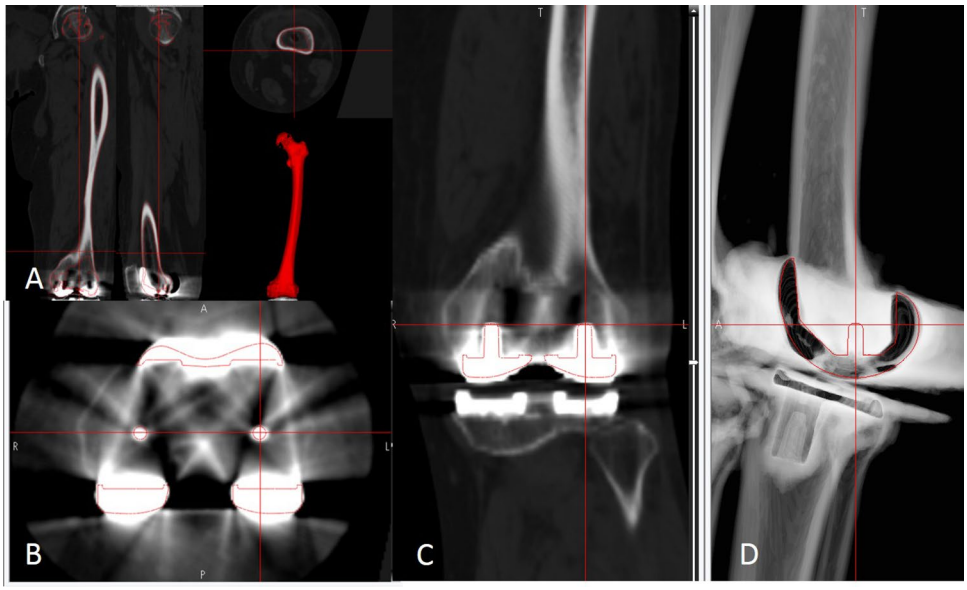

Fig. 3 Figures show post-operative femoral component positioning measurements. **a** The post-operative femur overlapped the pre-operative femur at the same axis of coordinates. Femoral rotation (**b**) and the coronal positioning (**c**) were determined by the two pegs as references. The digital reconstructed radiographs were used for the sagittal component positioning to reduce the effect of the halation of the implant (**d**)

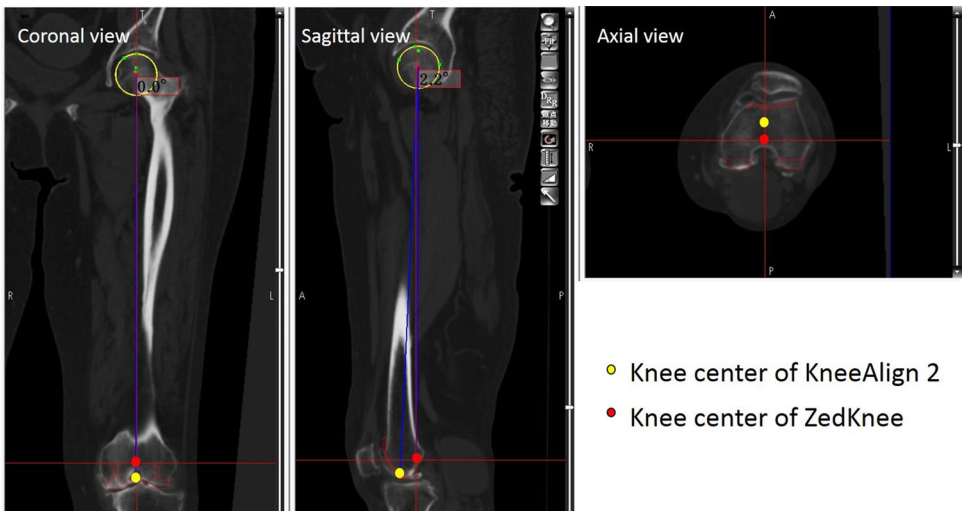

Fig. 4 Figure shows the difference between the definition of the knee center in the pre-operative planning software (ZedKnee) and Knee Align 2

significant. A priori sample size analysis with a one-tailed Student's *t* test determined that 51 knees were needed to detect a moderate effect size ($d=0.50$), with a power of 0.80 and an alpha of 0.05. Statcel 2 (OMS Inc. Japan) was used for all statistical analyses. G*Power 3 software (Heinrich Heine University, Dusseldorf, Germany) was used for power analyses. To test intra- and inter-observer reliability, each set of measurements was repeated three times on 30 randomly selected subjects by two of the authors (T.T.and K.Y.). The measurements were considered reliable if the interclass correlation coefficient (ICC) was calculated more than 0.80.

Results

Measurement reliability was excellent for the post-operative coronal femoral component alignment with a value of 0.985 for intra-rater and 0.948 for inter-rater reliability. The ICC for measurement of the post-operative sagittal femoral component alignment was good with a value of 0.872 for intra-rater and 0.904 for inter-rater reliability.

There were no statistical significant differences with regard to the pre-operative patient age, height, body mass

Table 1 Pre-operative demographics

	Modified conventional cohort	KneeAlign 2 cohort	*P* value
Age (years)	74.7 ± 7.8	73.5 ± 8.1	ns
Height (cm)	152.4 ± 6.2	150.6 ± 6.6	ns
BMI (kg/m^2)	27.4 ± 4.4	27.4 ± 4.3	ns
Pre-operative HKA angle (deg)	11.1 ± 6.6	8.8 ± 8.2	ns

All values presented as mean ± SD

BMI body mass index, *HKA* angle; hip–knee–ankle angle (positive value indicates varus)

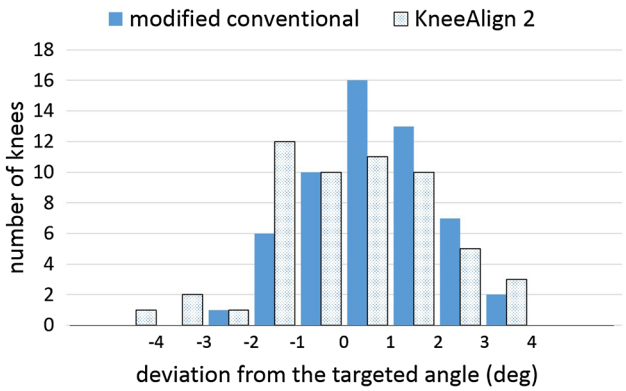

Fig. 5 Figure shows distribution of femoral coronal alignment

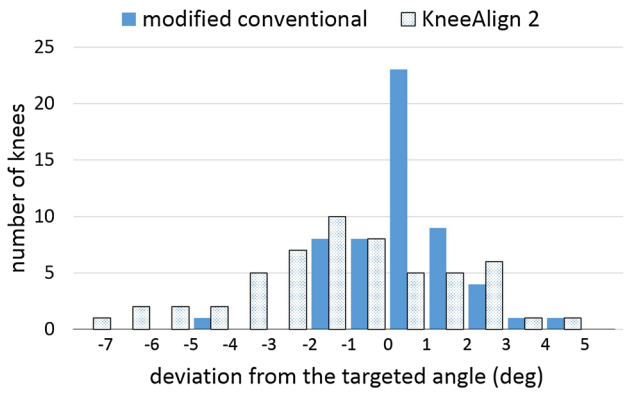

Fig. 6 Figure shows distribution of femoral sagittal alignment

index, and pre-operative alignment when comparing the modified conventional and KneeAlign 2 cohorts (Table 1).

The mean IM rod insertion depth was 182.9 mm ± 18.8 mm (mean ± SD). In the modified conventional cohort, the mean absolute deviation from the target alignment was 1.2° ± 0.9°, with 81.8% of knees having an alignment within 2° and 96.4% within 3° in the coronal plane (Fig. 5) and 1.1° ± 1.0°, with 90.9% within 2° and 96.4% within 3° in the sagittal plane (Fig. 6). In KneeAlign 2 cohort, the mean absolute deviation from the target alignment was 1.5° ± 1.1°, with 80.0% of knees having an alignment within 2° and 89.1% within 3° in the coronal plane (Fig. 5) and 2.6° ± 2.3°, with 56.4% within 2° and 74.5% within 3° in the sagittal plane (Fig. 6). There was no significant difference between the modified conventional and KneeAlign 2 cohort regarding the mean absolute deviation from the target alignment ($P = 0.14$) and outlier rate (Table 2) in the coronal plane. However, there was a significant difference between the modified conventional and KneeAlign 2 cohort regarding the mean absolute deviation from the target alignment ($P < 0.001$) and outlier rate in the sagittal plane (Table 2).

Discussion

The main finding of the present study was that the femoral sagittal malalignment of ± 3° and ± 2° were in favor of the modified conventional cohort than in the KneeAlign 2 cohort. Although encouraging evidence has been reported with the use of KneeAlign 2 in restoration of femoral component positioning, there was a wide range of outliers in the coronal plane (Table 2) [13–18]. Nam et al. [13, 14] and Gharaibeh et al. [18] reported excellent results with almost no outlier beyond 3°. The results in other studies [15–17] were similar to our findings. Technical issues during registration associated with hip adduction have been reported when using KneeAlign2 system. Fujimoto et al. [17] recommend small hip adduction motions during registration to avoid large femoral head movements during hip adduction to improve the accuracy of post-operative femoral component alignment. However, although the outlier rate was improved by this technique, the outlier rate still remained 8.2% and 26.2% at ± 3° and 2°, respectively, in their late group (Table 2). In regard to the sagittal femoral component alignment, there were few studies reporting the outlier rate of the femoral component after TKA using the KneeAling2. One of the reasons was that plain radiographs do not allow accurate assessment of component mechanical axis restoration in the sagittal plane. Gharaibeh et al. [18] used a post-operative CT imaging protocol for accurate alignment measurements. They reported an excellent post-operative component alignment in both coronal and sagittal planes with almost no outlier even in the conventional TKA group and concluded that KneeAlign did not significantly improve individual component alignment comparison with conventional IM guides. Fujimoto et al. [17] evaluated the post-operative component alignment by image-matching software which combined pre-operative CT images with post-operative radiographs. Their ICC for measurement of post-operative coronal and sagittal femoral component alignment were 0.842 and 0.751. This value was similar to our

Table 2 Studies reporting outlier rate of the femoral component in total knee arthroplasty (TKA) using KneeAlign 2 system

	Number of knees	Coronal outlier rate (%)		Sagittal outlier rate (%)	
		Beyond 2°	Beyond 3°	Beyond 2°	Beyond 3°
Nam [13]	48	4.2	0	NA	NA
Nam [14]	80	5.1	1.3	NA	NA
Huang [15]	53	39.6	13	NA	NA
Steinhaus [16]	49	28.6	8.1	NA	NA
Fujimoto [17]	48 (early group[a]) 61 (late group[b])	39.6 26.2	14.6 8.2	NA NA	22.9 11.5
Gharaibeh [18]	89 90 (conventional TKA)	9 12.2	1.1 5.6	3.4 5.6	0 2.2
This study	55 (KneeAlign 2) 55 (conventional TKA)	20.0 18.2	10.9 3.6	43.6 9.1	25.5 3.6

Early group[a]; large hip motion during registration, late group[b]; small hip motion during registration

NA not available, *ns* not statistically significant

measurement reliability. In the present study, we used the post-operative evaluation function of the pre-operative CT-based TKA planning software (ZedKnee®, LEXI, Tokyo, Japan) which makes the coordinates of the pre-operative femur match the coordinates of the post-operative femur. This type of image-matching software can gain more precise data than conventional measurement. The outlier rates in early group reported by Fujimoto were similar to our results in both coronal and sagittal planes. However, the outlier rates of the modified conventional technique in the current study were equal to or better than that of the modified registration technique group reported by Fujimoto. The IM rod insertion depth technique is a same technique as the conventional one except for the fixed insertion depth and the fixed entry point. Therefore, there is no learning curve.

Maderbacher et al. [19] reported that appropriate sagittal femoral component alignment cannot be ensured by an IM rod; a mean sagittal orientation of the cutting block was 4.4° of flexion in relation to the mechanical femoral axis. In their study, the entry point was determined by pre-operative radiological planning and they tried to insert the IM rod to the level of the isthmus. In our 3D pre-operative planning experience, the IM rod cannot be inserted to the level of the isthmus because of the anterior bowing of the femur. Furthermore, when 180-mm rod insertion depth was planned, 3° of deviation from the target angle needed 9.42 mm ($2\Pi \times 180\ \text{mm} \times 3°/360°$) of motion at the tip of the rod.

Loh et al. [20] reported a significant reduction in coronal femoral component outliers (> 3°) with 7% when hand-held navigation system Dash® using the infrared technology was applied, compared to 17% when the conventional techniques were used. This improved outlier rate was similar to our findings in KneeAlign 2 cohort (10.9%). Dash® has the disadvantage of increased capital cost and to decrease the cost to patient, it is recommended to be used in high-volume centers due to economies of scale [20].

The present study has several limitations. First, it was retrospective and includes a small number of subjects treated by different surgeons with different resection techniques and implants. However, patients were matched with similar baseline characteristics, and no clear learning curve effect was observed regarding the accuracy of implantation in the subanalysis in KneeAlign 2 cohort (Surgeon T.L.'s outlier rates beyond 3° in the first 22 knees and the next 22 knees were 90.9% and 86.4% in the coronal plane and 77.3% and 81.8% in the sagittal plane, respectively.). There was no statistically significant difference in regard to outlier rate between both KneeAlign 2 surgeons. Second, the cutting error has to be taken into consideration because KneeAlign 2 system just provides cutting block orientation. Therefore, our results performed by mid-volume surgeons (30–60 TKAs per year) might be difficult to directly extrapolate to TKA performed by high-volume TKA surgeons. Third, this study did not examine patient-reported outcomes, implant survivorship or cost data. However, the purpose of this study was to compare radiographic outcomes using IM rod insertion depth technique with KneeAlign 2 system. Fourth, CT-based 3D pre-operative planning software was used for the pre-operative planning. However, we believe that this technique can be performed by long hip/knee/ankle X-ray for mechanical axis for coronal alignment and a true lateral view for sagittal alignment. Further studies are needed to confirm whether the same accuracy as this study can be obtained by the pre-operative planning by the plane X-ray.

In conclusion, the accuracy of the modified conventional technique in femoral component positioning was better than KneeAlign 2 system in the sagittal plane and almost equal in the coronal plane. The modified conventional technique is a simple and highly accurate method in positioning the femoral component in TKA and could be recommended for non-high-volume surgeons.

Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interest.

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