Original Article
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Accuracy of Patient-Specific Instrument for Cylindrical Axis Implementation in Kinematically Aligned Total Knee Arthroplasty

Kwang-Kyoun Kim, MD*,†, Jaehwang Song, MD*

*Department of Orthopedic Surgery, Konyang University College of Medicine, Daejeon,
†Konyang University Myunggok Medical Research Institute, Daejeon, Korea

Background: In kinematically aligned total knee arthroplasty (KA-TKA), the cylindrical axis (CA) is very important in restoring the native joint line and kinematics of the pre-arthritic knee. This study aimed to determine the accuracy of patient-specific instrument (PSI) for restoring the CA for femoral bone resection in KA-TKA.

Methods: Thirty KA-TKAs were performed using a computed tomography (CT)-based PSI system. Data from preoperative CT were reconstructed into three-dimensional (3D) models using 3D-planning software. The CA was created by connecting the centers of each virtual sphere to the medial and lateral femoral condyles using computer software. Femoral bone resection of the distal and posterior condyles was performed parallel to the sagittal planes of the CA. The thickness of the CA-referenced bone resection was determined based on the thickness necessary for the respective regions of the femoral component. The PSI was manufactured to locate the guide pin for a conventional cutting block. The accuracy of PSI for KA-TKA was evaluated as the absolute error between the preoperatively predicted thickness and the intraoperative measurements in each of the four regions, as well as the difference in error between distal-medial (DM) and posterior-medial (PM) and between distal-lateral (DL) and posterior-lateral (PL).

Results: The differences in thickness of bone cut in the DM, DL, PM, and PL were 0.79 ± 0.39 mm (range, –1.20 to 1.50), 0.70 ± 0.42 mm (range, –1.50 to 1.50), 0.80 ± 0.46 mm (range, –0.80 to 1.50), and 0.75 ± 0.47 mm (range, –2.10 to 1.40), respectively. There was no significant difference in the thickness error between DM and PM ($p = 0.959$) and between DL and PL ($p = 0.812$).

Conclusions: In KA-TKA, PSI was effective for accurate femoral bone resection based on virtually planned thickness.

Keywords: *Total knee arthroplasty, Patient-specific instrument, Computer-assisted surgery, Kinematic alignment*

Mechanically aligned total knee arthroplasty (MA-TKA) aims for neutral alignment of the limb (0° hip-knee-ankle angle) and a varus-valgus angle of the tibial component perpendicular to the tibial mechanical axis in all patients. However, 20%–25% of the patients with well-aligned MA-TKA were dissatisfied.[1-3] Over recent years, kinematic alignment has gained interest because a few recent randomized trials and a nationwide multicenter investigation have shown that patients treated with kinematically aligned total knee arthroplasty (KA-TKA) reported significantly better pain relief, function, flexion, and a more normal-feeling knee than patients treated with mechanical alignment.[4-9] The goal of KA-TKA is to restore a patient's pre-arthritic anatomy and knee axes throughout the arc of motion. In terms of femoral component's alignment, the cylindrical axis (CA) or primary femoral axis is the most fundamental kinematic axis of the knee, passing through the center point of the best-fit circle of the medial and lateral femoral condyles.[10-13]

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Correspondence to: Kwang-Kyoun Kim, MD
Department of Orthopedic Surgery, Konyang University College of Medicine, 158 Gwanjeodong-ro, Seo-gu, Daejeon 35365, Korea
Tel: +82-42-600-9120
E-mail: kimajouos@gmail.com

Currently, there are two methods for performing KA-TKA: using either a generic instrument or a patient-specific instrument (PSI). Howell et al.[9] showed that calipered KA-TKA was well-implemented using a generic instrument specially developed for KA-TKA. However, the CA in the arthritic knee can be difficult to identify, especially for surgeons who are not familiar with KA-TKA. PSI for TKA was recently introduced as a new technology to address practical issues related to the navigation and the robotic system (such as complexities, costs, and a greater number of personnel required) and to improve surgical technique accuracy. It was mainly used for MA-TKA, and postoperative alignment following MA-TKA using PSI showed conflicting results.[14-17]

In KA-TKA, the CA is a very important axis in restoring the native joint line and kinematics of the pre-arthritic knee. Therefore, it is important to validate the accuracy of PSI in CA-referenced bone resection precisely. However, in measuring the precision of CA implementation, the method of measuring postoperative alignment is affected by cementing, final impaction, and bone resection on the tibia. Therefore, this study investigated the accuracy of PSI by measuring the thickness of resected bone intraoperatively with a caliper. We hypothesized that the PSI could reproduce accurate femoral bone resection for virtually planned CA in KA-TKA.

METHODS

Population

The Institutional Review Board of Konyang University Hospital approved this study (No. KYUH-2021-08-022), and informed consent was obtained from all patients. Between June 2019 and December 2019, 30 knees were analyzed from 21 enrolled patients treated with KA-TKA using PSI. The inclusion criteria were the diagnosis of primary osteoarthritis (Kellgren and Lawrence classification grades 3 and 4), loss of function, and disabling knee pain. The exclusion criteria were a history of infection in the knee, open knee procedures, osteotomy, and neurological disease with mobility impairment. The preoperative mechanical hip-knee-ankle angle was in 7.6° ± 4.7°. The patients' demographic data are shown in Table 1.

Table 1. Demographic Characteristics of the Patients

Variable	Value
No. of knees	30
No. of patients	21
Age (yr)	72.1 ± 7.5
Sex (knee)	
Male	5
Female	25
Height (cm)	157.5 ± 8.0
BMI (kg/m^2)	23.7 ± 5.2
Mechanical HKA (°)	7.6 ± 4.7

Values are presented as mean ± standard deviation.
BMI: body mass index, HKA: hip-knee-ankle angle.

Preoperative Planning for Manufacturing a PSI

All surgical plans were specifically made, modified, and approved by a single surgeon (KKK) before surgery. The PSI for KA-TKA was manufactured at the authors' institution and registered with the Korean Ministry of Food and Drug Safety.

Three-dimensional model reconstruction

Using 80-channel computed tomography (CT; Aquilion PRIME, Canon, Tokyo, Japan), 1-mm-thick axial CT images of the hip, knee, and ankle were obtained preoperatively in all patients. The Mimics software (version 19; Materialise, Leuven, Belgium) was used to generate a three-dimensional (3D) bone model of the lower extremity, including the femoral head, knee, and distal tibial plafond.

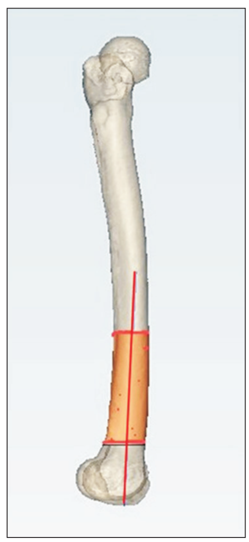

Fig. 1. From the upper margin of the distal one-third to the metaphyseal flare of the femur was registered with points by pen, which made a truncated cone. The distal femoral flexion axis passing the center of the truncated cone was obtained from the best-fit line. Reproduced from Kim et al. Yonsei Med J. 2020;61(3):201-9[18] with permission.

Preoperative determination of the distal femoral flexion axis

The femur was divided into three parts from the head to the distal femoral joint line. The portion from the upper margin to 5 cm proximal to the joint line of the distal one-third of the femur was manually registered with points using a pen (registration), creating a truncated cone. The distal femoral flexion axis was determined using the best-fit line passing through the center of the truncated cone (Fig. 1).[18]

Preoperative determination of the CA

The CA of the distal femur was simulated in the sagittal plane; the surfaces of the distal femoral condyles were marked from the distal femoral recess to the posterior end of the posterior condyles. The best-fit sphere was obtained from registered points, and the center of the putative positioning sphere was equidistant from the pre-arthritic articular surface. The CA was automatically created using a software program by connecting the centers of the two spheres (Fig. 2).[18]

Preoperative determination of the resection plane and thickness of the distal and posterior femoral condyles

Distal and posterior femoral resections were performed preoperatively using a virtual CA-referenced method at the same distance from the CA. The distal femoral resection plane was perpendicular to the distal femoral flexion axis and parallel to the CA. The posterior femoral resection plane was perpendicular to the distal femoral resection plane and equal to the distance from the CA to the distal femoral resection plane.

Preoperatively, the thickness of each of the four femoral bone cuts, namely distal-medial (DM), distal-lateral (DL), posterior-medial (PM), and posterior-lateral (PL), was predicted by the thickness of the respective regions of the femoral component and cartilage wear. In our study, all 30 cases were operated on with Lospa total knee system (Corentec, Korea) with a single radius design. The thicknesses of the distal and posterior condyles of the femoral component were 9 and 10 mm, respectively, and the thickness of unworn cartilage was considered 2.0 mm. When the radii of the medial and lateral condyles were different, their resection plane differed from the articular surface-based bone cut (Fig. 3).

Preoperative determination of PSI pin location for generic cutting block

The pin locations were virtually planned using the SolidWorks computer software (Chicago, IL, USA), taking into account pre-planned kinematic alignment, resection thickness, and conventional cutting guide (Fig. 4A). The PSI

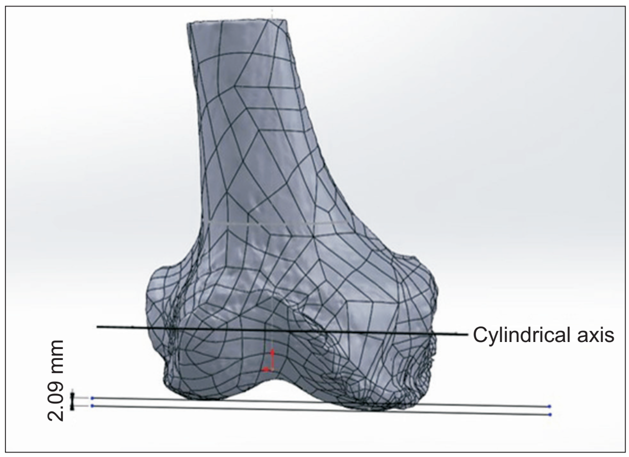

Fig. 3. The radii of the medial condyle and the lateral condyle were different. When the distal condyle was resected parallel to the cylindrical axis, resection thickness of the medial condyle was 2.09 mm larger than the lateral condyle.

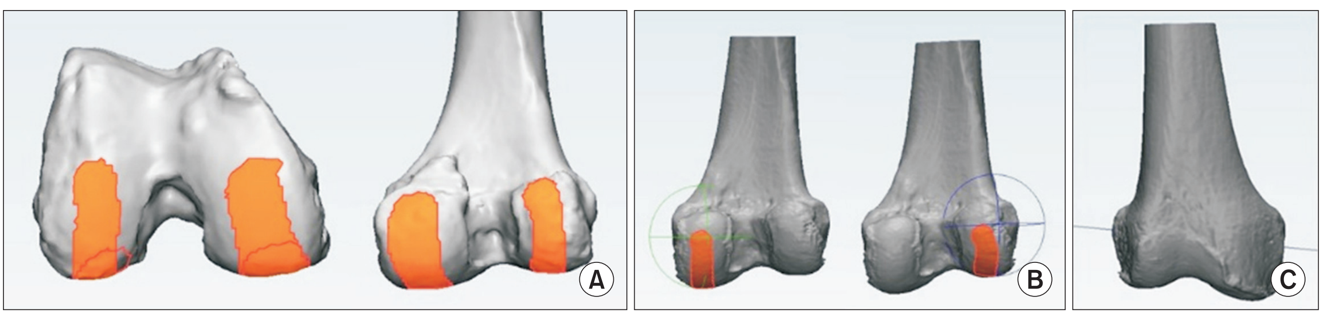

Fig. 2. (A) The surface of each distal femoral condyle was marked from the distal recess to the posterior end of the posterior condyle. (B) The best-fit sphere from each condyle was made from registered points, and the putative positioning sphere's center was equidistant from the pre-arthritic articular surface. (C) The cylindrical axis was made by connecting two sphere's centers. Reproduced from Kim et al. Yonsei Med J. 2020;61(3):201-9[18] with permission.

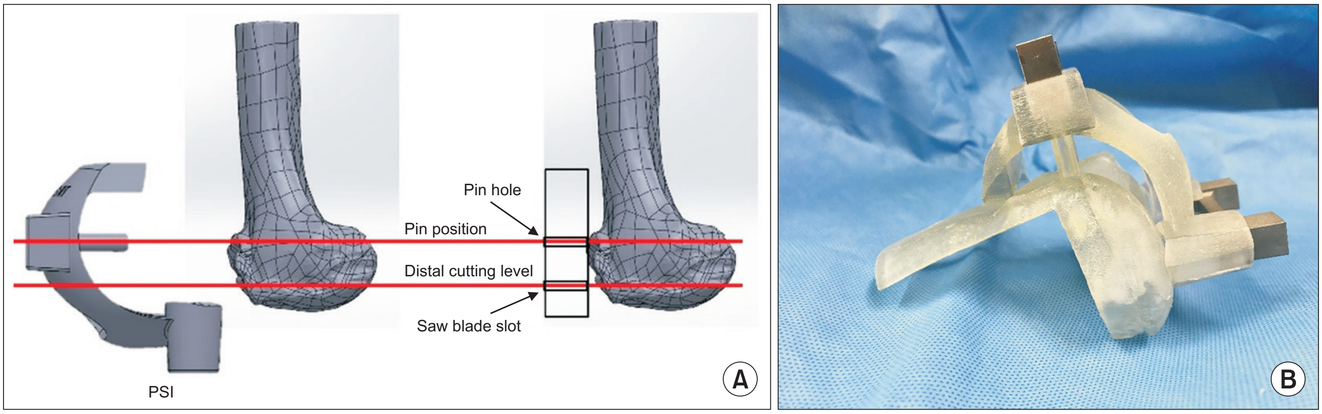

Fig. 4. (A) The patient-specific instrument (PSI) was manufactured by considering the distance between the pin hole and the saw slot location of the cutting block of the implant of total knee arthroplasty. (B) PSI was applied to the three-dimensional (3D) model of the patient's femur manufactured by a 3D printer.

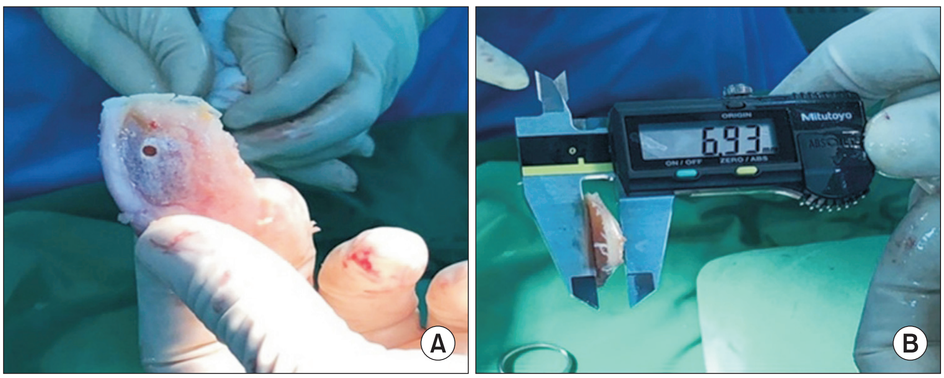

Fig. 5. (A) The medial femoral bone cut showed that the cartilage was worn out in a varus knee. (B) The resection thickness was 6.93 mm when measured by a digital caliper.

was designed to fit into the arthritic knee of each patient in one specific position to ensure accurate and secure fixation. The PSI for KA-TKA was 3D-printed (Objet Connex 500, Rehovot, Israel) following the manufacturer's instructions (Fig. 4B).

Surgical Procedure and Intraoperative Measurement of Femoral Resection Thickness

The PSI was seated and secured in its unique position on the anterior and distal surfaces of the femur. Since a CT-based PSI does not consider the thickness of the remaining cartilage of the worn area, the remaining cartilage must be completely removed from the footprint of the articular surface in contact with the PSI. After the PSI was removed, a distal and posterior cut was made through a conventional cutting guide, which was attached at two pin locations made by the PSI. Intraoperatively, the four femoral resection thicknesses (i.e., DM, DL, PM, and PL) were measured with a digital caliper (Scienceware Digi-Max, Seoul, Korea; range: 0 to 150 mm, accuracy: ± 0.1 mm) (Fig. 5).

Accuracy Assessment of PSI

First, the accuracy of the PSI for KA-TKA was evaluated as the absolute difference between the virtually planned thickness and intraoperative thickness in each of the four regions. Second, the differences in error between DM and PM and between DL and PL were evaluated. The preoperative accuracy of the 3D-planning software is approximately 1 mm; therefore, data were expressed to one decimal place (Mimics ver. 19; Materialise, Leuven, Belgium).

Statistical Analysis

The Shapiro-Wilk normality test was used to evaluate data distribution. The differences in resection thickness error between DM and PM and between DL and PL were evaluated using the Mann-Whitney *U*-test. The minimal sample size necessary for Mann-Whitney *U*-test analysis was 30 samples for each group based on effect size = 0.8, error probability = 0.05, power (1-error probability) = 0.80, and allocation ratio N2/N1 = 1 (using G-power 3.1 program). The level of significance was set at $p < 0.05$.

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Table 2. Data on Kinematically Aligned Total Knee Arthroplasties with Patient-Specific Instrument

Case	Resected bone thickness	DM	DL	PM	PL
1	Virtual (mm)	6.2	7.0	7.7	8.5
	Intraoperative (mm)	6.0	7.6	7.5	8.0
	Difference (±)	0.2	0.6	0.2	0.5
2	Virtual (mm)	5.6	6.1	7.0	8.9
	Intraoperative (mm)	6.0	7.3	7.6	9.0
	Difference (±)	0.4	1.2	0.6	0.1
3	Virtual (mm)	6.3	6.8	7.1	7.8
	Intraoperative (mm)	5.3	7.2	7.1	8.5
	Difference (±)	1.0	0.4	0.0	0.7
4	Virtual (mm)	6.7	4.8	7.3	9.0
	Intraoperative (mm)	6.0	5.6	7.9	8.8
	Difference (±)	0.7	0.8	0.6	0.2
5	Virtual (mm)	6.0	6.0	6.7	7.4
	Intraoperative (mm)	6.7	7.5	7.4	8.1
	Difference (±)	0.7	1.5	0.7	0.7
6	Virtual (mm)	6.0	6.7	7.0	7.9
	Intraoperative (mm)	5.5	7.0	6.3	9.0
	Difference (±)	0.5	0.3	0.7	1.1
7	Virtual (mm)	5.7	7.0	7.0	5.1
	Intraoperative (mm)	5.3	7.2	6.1	7.2
	Difference (±)	0.4	0.2	0.9	2.1
8	Virtual (mm)	5.6	5.1	7.3	7.2
	Intraoperative (mm)	6.8	6.2	6.2	8.2
	Difference (±)	1.2	1.1	1.1	1.0
9	Virtual (mm)	6.5	8.1	6.7	8.0
	Intraoperative (mm)	5.2	7.3	6.2	7.4
	Difference (±)	1.3	0.8	0.5	0.6
10	Virtual (mm)	6.1	6.0	7.0	9.0
	Intraoperative (mm)	4.6	5.2	5.5	8.2
	Difference (±)	1.5	0.8	1.5	0.8
11	Virtual (mm)	6.4	7.0	7.0	7.0
	Intraoperative (mm)	5.4	7.3	5.8	7.3
	Difference (±)	1.0	0.3	1.2	0.3

Table 2. Continued

Case	Resected bone thickness	DM	DL	PM	PL
12	Virtual (mm)	6.0	8.0	7.8	9.0
	Intraoperative (mm)	5.4	8.0	6.3	8.1
	Difference (±)	0.6	0.0	1.5	0.9
13	Virtual (mm)	6.0	7.2	7.5	8.5
	Intraoperative (mm)	5.2	7.0	8.3	8.0
	Difference (±)	0.8	0.2	0.8	0.5
14	Virtual (mm)	6.0	7.0	7.8	7.9
	Intraoperative (mm)	4.8	6.1	6.7	9.2
	Difference (±)	1.2	0.9	1.1	1.3
15	Virtual (mm)	6.0	7.8	7.0	8.0
	Intraoperative (mm)	6.2	8.0	6.5	8.2
	Difference (±)	0.2	0.2	0.5	0.2
16	Virtual (mm)	6.0	8.0	7.8	8.9
	Intraoperative (mm)	6.7	8.7	6.4	7.5
	Difference (±)	0.7	0.7	1.4	1.4
17	Virtual (mm)	6.4	7.0	8.0	8.9
	Intraoperative (mm)	5.2	6.1	7.0	8.0
	Difference (±)	1.2	0.9	1.0	0.9
18	Virtual (mm)	6.0	6.6	7.0	7.5
	Intraoperative (mm)	4.8	5.8	6.5	9.1
	Difference (±)	1.2	0.8	0.5	1.6
19	Virtual (mm)	5.5	6.0	7.0	7.8
	Intraoperative (mm)	6.1	5.8	5.5	6.5
	Difference (±)	0.6	0.2	1.5	1.3
20	Virtual (mm)	6.2	6.0	7.0	7.0
	Intraoperative (mm)	5.1	5.5	5.6	6.6
	Difference (±)	1.1	0.5	1.4	0.4
21	Virtual (mm)	7.0	7.8	7.8	7.9
	Intraoperative (mm)	7.8	6.7	8.2	8.8
	Difference (±)	0.8	1.1	0.4	0.9
22	Virtual (mm)	5.0	7.7	5.0	8.0
	Intraoperative (mm)	4.3	7.1	3.7	7.5
	Difference (±)	0.7	0.6	1.3	0.5

Table 2. Continued

Case	Resected bone thickness	DM	DL	PM	PL
23	Virtual (mm)	6.0	7.0	7.0	8.0
	Intraoperative (mm)	4.5	5.9	5.5	7.2
	Difference (±)	1.5	1.1	1.5	0.8
24	Virtual (mm)	6.0	6.0	7.0	7.0
	Intraoperative (mm)	6.5	4.9	7.2	6.1
	Difference (±)	0.5	1.1	0.2	0.9
25	Virtual (mm)	6.0	6.0	7.0	7.0
	Intraoperative (mm)	6.0	5.4	6.2	6.5
	Difference (±)	0.0	0.6	0.8	0.5
26	Virtual (mm)	5.7	6.0	6.0	7.0
	Intraoperative (mm)	6.3	6.0	5.2	7.3
	Difference (±)	0.6	0.0	0.8	0.3
27	Virtual (mm)	5.4	6.3	7.2	7.3
	Intraoperative (mm)	5.0	4.8	7.0	7.1
	Difference (±)	0.4	1.5	0.2	0.3
28	Virtual (mm)	6.2	6.6	7.5	8.2
	Intraoperative (mm)	5.0	5.4	7.0	7.2
	Difference (±)	1.2	1.2	0.5	1.0
29	Virtual (mm)	5.5	7.5	7.2	8.3
	Intraoperative (mm)	6.2	7.0	7.5	8.0
	Difference (±)	0.7	0.5	0.3	0.3
30	Virtual (mm)	5.7	7.3	7.5	8.2
	Intraoperative (mm)	5.0	6.5	7.1	8.5
	Difference (±)	0.7	0.8	0.4	0.3

Positive: more bone was resected intraoperatively than was virtually planned. Negative: less bone was resected intraoperatively than was virtually planned.
DM: distal-medial, DL: distal-lateral, PM: posterior-medial, PL: posterior-lateral.

RESULTS

The results on bone cut thickness in KA-TKAs with PSI in 30 cases are shown in Table 2. The absolute differences between virtually planned bone cut thickness and intraoperative bone cut thickness in the DM, DL, PM, and PL were 0.79 ± 0.39 mm (range, –1.20 to 1.50 mm), 0.70 ± 0.42 mm (range, –1.50 to 1.50 mm), 0.80 ± 0.46 mm (range, –0.80 to 1.50 mm), and 0.75 ± 0.47 mm (range, –2.10 to 1.40 mm), respectively (Fig. 6). There was no significant difference in the thickness error between the DM and PM ($p = 0.959$) and between the DL and PL ($p = 0.812$) (Table 3).

DISCUSSION

The most important finding of this study is that the CA implementation using PSI was accurate, with an average error of less than 1.0 mm between the virtually planned thickness and the intraoperative thickness. There was no significant difference in the distance from the CA to the

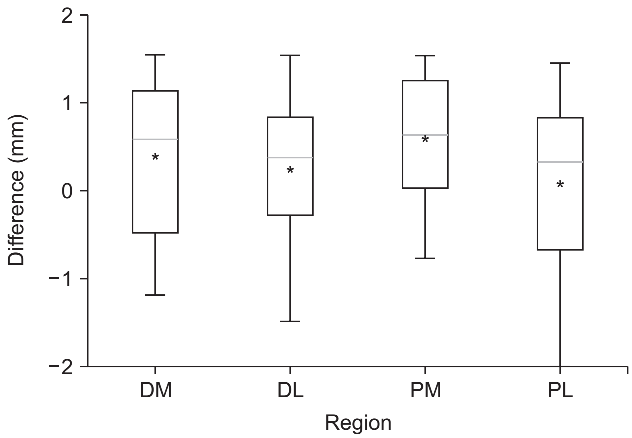

Fig. 6. Whisker plot depicting the range and distribution of difference between the virtually planned thickness and the intraoperatively measured thickness. A positive value means the virtually planned thickness was larger than the intraoperatively measured thickness. DM: distal-medial, DL: distal-lateral, PM: posterior-medial, PL: posterior-lateral. *Mean.

Table 3. Difference between Virtually Planned Thickness and Intra-Operatively Measured Thickness in Four Regions

Region	Error (mm)	*p*-value*
DM (n = 30)	0.79 ± 0.39	0.959
PM (n = 30)	0.80 ± 0.46	
DL (n = 30)	0.70 ± 0.42	0.812
PL (n = 30)	0.75 ± 0.47	

Values are presented as mean ± standard deviation.
DM: distal-medial, PM: posterior-medial, DL: distal-lateral, PL: posterior-lateral.
**p*-value shows difference in error between DM and PM and between DL and PL.

articular surface in both the medial and lateral condyles.

To perform KA-TKA successfully, the CA of the femur must be reproduced to restore the natural joint line and knee kinematics. The CA-referenced femoral bone cut adopted in this study is commonly used in PSI-guided KA-TKA. The CA of the femur was determined using a software program, and distal and posterior femoral bone cuttings were performed at the same distance from the CA. In the articular surface-based bone cut, the posterior reference plane for femoral bone cutting is established as a plane that includes a tangential line connecting the most posterior points of the medial and lateral femoral condyles. The distal reference plane was made parallel to the posterior plane, including a tangential line connecting the most distal points of the medial and lateral femoral condyles. Although the articular surface-based bone cut is commonly used in KA-TKA using generic instruments, it is also used in PSI-guided KA-TKA.[9,19] In calipered KA-TKA with generic instruments, the thickness of each of the four femoral resections should be equal to that of the corresponding region of the femoral component after correcting for saw-blade kerf and any potential wear on the articular surfaces. However, as shown in our study, when the radii of the medial and lateral condyles were different, the CA-referenced femoral bone cut resulted in a less valgus bone cut of the distal femur than the articular surface-based bone cut (Fig. 3). Regarding the clinical effect of the difference in radius between the medial and lateral condyles during calipered KA-TKA, Howell et al.[20] reported that the asymmetry between the radii of the medial and lateral femoral condyles in varus and valgus knees with end-stage osteoarthritis was ≤ 0.2 mm, which is small enough to be considered clinically unimportant when aligning a total knee. Nedopil et al.[21] reported that calipered KA-TKA with the use of serial verification checks restored the femoral component locations to within 2 mm, within 2° of the planned femoral joint lines in the contralateral native knee with a frequency of at least 91% and 83%. They also showed relatively high median Forgotten Joint Score and Oxford Knee Score without larger alignment deviations correlating with lower scores.[20] However, in a Japanese study, Niki et al.[22] reported that the mean cylindrical radii for medial and lateral femoral condyles were 17.4 ± 1.6 mm and 17.3 ± 1.4 mm, respectively. Of the 122 knees they analyzed, 46 exhibited a difference of > 1 mm between the condyles. Fifty-three and 22 knees exhibited > 2° of angular difference between the CA-referenced and the articular surface-referenced bone cuts in the coronal and axial planes, respectively, and concluded that a CA-referenced bone cut of the femur was preferable to an articular surface-referenced bone cut for reproducing functional flexion-extension axis in Japanese patients with osteoarthritis. However, the clinical effects of these angular differences were not reported. Although more research is needed on clinical results affected by the difference between CA-referenced and articular surface-referenced bone cutting, the CA position relative to the articular surface should be evaluated individually using data from preoperative CT, which could aid to recognize the actual CA during KA-TKA.

In KA-TKA, the CA is an important axis in restoring the native joint line and kinematics of the pre-arthritic knee. Therefore, precisely testing the accuracy of PSI in the CA-referenced bone cut is important.[10-12] In our study, the accuracy of intraoperative PSI of the femur was measured using a caliper to determine the thickness of the bone cut. Cementation and impaction of the final components can introduce a considerable alignment error, regardless of how accurately the resection planes are made.[23] There were reports of bone cut thickness being measured by postoperative long-standing alignment in KA-TKA using PSI.[14,24,25] Postoperative two-dimensional alignment is affected by cementing, implantation, tibial alignment, and ligament balancing.[25,26]

Some limitations of this study must be considered when interpreting its results. First, this study did not show clinical outcomes in KA-TKA. Second, tibial resection and soft-tissue balancing, as well as femoral resection, are important factors in the outcomes of KA-TKA. However, in this study, only the accuracy of femoral resection was evaluated. Third, the virtual CA-referenced bone cut was performed using CT data, and the bone cut on the CT could not precisely compensate for the thickness of the eroded cartilage. Several publications reported that magnetic resonance imaging (MRI)-based PSI showed smaller deviations in the coronal or sagittal plane than CT-based PSI.[24,27,28] However, Kang et al.[29] reported that MRI-based PSI system did not show better accuracy in predicting the thickness of bone resection than CT-based PSI. Moreover, there were no differences in radiographic and clinical outcomes between the two groups. The disadvantage of MRI-based PSI is that it takes more time than CT-based PSI in the manual segmentation process for image reconstruction, and patients with a metallic foreign body (metal sliver) in their eyes, pacemakers, defibrillators, other implanted electronic devices, or an aneurysm clip in their brain are not candidates for MRI.[30,31] Despites these limitations, PSI is an accurate tool for determining the femoral bone resection in KA-TKA.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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ORCID

Kwang-Kyoun Kim https://orcid.org/0000-0002-6844-5431
Jaehwang Song https://orcid.org/0000-0001-5192-4965

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