Robotic-assisted total knee arthroplasty improved component alignment in the coronal plane compared with navigation-assisted total knee arthroplasty: a comparative study

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Running head: Accuracy comparison of robotic-assisted TKA vs. navigation-assisted TKA

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Abstract

Background**:** The purpose of this study was to directly compare implant placement accuracy and postoperative limb alignment between robotic-assisted total knee arthroplasty and navigation-assisted total knee arthroplasty.

Methods**:** This retrospective case-control study included a consecutive series of 182 knees (robotic-assisted group, n=103 knees; navigation-assisted group, n=79). An image-free handheld robotic system (NAVIO) or an image-free navigation system (Precision N) was used. Component and limb alignment were evaluated on three-dimensional computed tomography scans and full-length standing anterior–posterior radiographs. We compared the errors between the final intraoperative plan and the postoperative coronal and sagittal alignment of the components and the hip-knee-ankle angle between the two groups.

Results**:** The orientation of the femoral and tibial components in the coronal plane were more accurate in the robotic-assisted group than in the navigation-assisted group ($p < 0.05$). There was no significant difference in the orientation of the femoral and tibial component in the sagittal plane between the two groups. There were fewer outliers in the tibial coronal plane in the robotic-assisted group ($p < 0.05$). There was also no significant difference in the frequency of outlying values for coronal or sagittal alignment of the femoral component or sagittal alignment of the tibial component or the hip-knee-ankle angle between the two groups.

Conclusion**:** Robotic-assisted total knee arthroplasty using a handheld image-free system improved component alignment in the coronal plane compared with total knee arthroplasty using an image-free navigation system. Robotic surgery is useful for accurate implantation and helps surgeons to achieve personalised alignment that may result in a better clinical outcome.

Keywords

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1. Introduction

Total knee arthroplasty (TKA) is a gold standard treatment for severe osteoarthritis of the knee. Accurate implant placement and lower limb alignment is important in TKA. Several studies have demonstrated that component errors greater than 3° from the mechanical axis of the lower limb in the coronal plane can lead to loosening, polyethylene wear and an increased probability of revision TKA [14, 23, 25]. Intramedullary or extramedullary rods are used in conventional TKA but have been associated with a higher proportion of knees with malalignment [11, 24, 29].

Several novel technologies have been used to obtain more accurate implant placement and limb alignment in TKA. The first report on use of a navigation system for TKA was published in 1999 [19]. In the 2000s, a patient-specific instrumentation system was developed for TKA [9]. In more recent years, robotic systems have been used in TKA (robotic-assisted TKA) [5, 26, 27, 33]. A robotic system can not only display the bone resection angle during surgery but also evaluate the soft tissue balance and control bone resection semi-automatically, enabling more accurate implant placement.

Previous studies have shown that robotic-assisted TKA is more accurate than conventional TKA [4, 5, 10, 17, 26]. However, to our knowledge, no study has directly compared the accuracy of implant placement between robotic-assisted surgery and navigation-assisted surgery. Given that robotic-assisted surgery is expected to become widespread in the future, we believe that it is important to compare the differences between robotic-assisted TKA and that performed using other technologies, such as a navigation system.

Our hypothesis was that robotic-assisted TKA can achieve higher implant placement accuracy and better lower limb alignment than navigation-assisted TKA. The purpose of this study was to directly compare the implant placement accuracy and postoperative alignment between robotic-assisted TKA and navigation-assisted TKA.

2. Materials and Methods

2.1 Participants and study design

This retrospective case-control study included a consecutive series of 117 knees in 96 patients which underwent TKA with an image-free handheld robotic system (NAVIO Surgical System; Smith & Nephew, Memphis, TN) at our hospital between January 2020 and December 2021. Patients who had secondary osteoarthritis of the knee, valgus knee (n=7), prior high tibial osteotomy (n=2), knee infection or fractures of the femur or tibia (n=2) were excluded. One patient was excluded because of missing data (n=1). After these exclusions, the robotic-assisted group included 103 knees in 89 patients. The control group included 79 knees in 68 patients which underwent image-free navigation-assisted TKA (Precision N; Stryker, Kalamazoo, MI) by the same surgical team between September 2017 and December 2019 (before introduction of the robotic system). A total knee component (Journey II BCS; bicruciate-stabilized type, Journey II XR; bicruciate-retaining (BCR) type; Smith & Nephew) was used in all cases. The indications for Journey II BCR were (a) intact anterior cruciate ligament (ACL) intraoperatively, (b) age <80 years, (c) varus deformity of ≤10°, (d) flexion contracture of ≤10°, (e) medial tibial posterior slope of ≤10°, (f) absence of osteoporosis, and (g) bone mass index ≤30 kg/m^2 [7]. For cases that did not meet the indication criteria for Journey II BCR, Journey II BCS was selected. The indications for BCR and BCS were the same in the robotic-assisted group and navigation-assisted group.

The study was approved by the institutional review board of the authors' institution and informed consent was obtained from all patients.

2.2 Surgical Technique

2.2.1 Robotic-assisted TKA

Robotic-assisted TKA was performed via a medial parapatellar approach. Accessible osteophytes were excised before surface registration. When using the BCS type of knee component, the ACL was resected, and the posterior cruciate ligament (PCL) was preserved during surface registration and resected before bone resection. When using the BCR type, the ACL and PCL were preserved. Bone pins were placed in the central tibia and distal femur to allow for tracking arrays. Next, the NAVIO Surgical System was set up. Patient landmarks were registered to identify the centres of the ankle, hip, and knee. Femoral and tibial surface mapping was performed by moving the point probe over the entire surface. The NAVIO Surgical System is image-free, and its software creates a realistic virtual three-dimensional model of the knee and proposes the initial implant size and position. We manipulated the implant position based on neutral mechanical alignment in the coronal plane. Femoral flexion was set to 3-5°, and tibial posterior slope was set to 3° in BCS TKA and natural slope in BCR TKA. Next, continuous varus and valgus stresses were applied to the collateral ligaments, and soft tissue balance data were collected throughout the range of motion. Based on these data, we further manipulated the implant position to minimise the medio-lateral gap imbalance if the ligament balance was not controlled appropriately. The orientation of each component was fine-tuned to within 2° in the coronal plane and a global alignment of neutral ± 3° was achieved. Rotational alignment and the anterior-posterior (AP) position of the femoral component was also fine-tuned to control the flexion gap. Rotational alignment of the tibial component was set parallel to Akagi's line. After the operator agreed on the final plan, a distal femoral cut was made using a high-speed 5-mm burr. In BCS TKA, a proximal tibial cut was made using a twin-peg cutting block under the control of the robotic-assisted system. If the twin-peg cutting block was not compatible because of medial tibial attrition, a conventional extra-medullary cutting guide was used under the control of the robotic-assisted system. The cut surface was then verified using the verification tool. If the cut was not performed according to the final plan, we fine-tuned the bone resection using a high-speed burr. At this point, the extension and flexion gap was confirmed using implant-specific spacer blocks. If a gap imbalance was expected, further manipulation of the AP position and rotation of the femoral component was added to the plan. In BCR TKA, a femoral chamfer cut was made using a cutting block after distal femoral resection, and the posterior tibial cut was made using a high-speed burr. After bone resection, the trial femoral and tibial components were set and the ligament balance was evaluated. If the planned ligament balance was not achieved, further modification was made using the robotic-assisted system. The rotational alignment of the tibial tray was modified by the range of motion technique [8]. After positioning was satisfactory, the implants were fixed with cement and the surgery was completed. An inlay-type patellar component was installed in all cases.

2.2.2 Navigation-assisted TKA

Knees in the control group underwent navigation-assisted TKA performed via a medial parapatellar approach. Registration was performed according to anatomical landmarks. The distal femur and proximal tibia were cut perpendicular to the mechanical axis in the coronal plane using cutting blocks and a saw blade. Femoral flexion was set to 3-5°, and tibial posterior slope was set to 3° in BCS TKA and natural slope in BCR TKA. After bone resection, we used the verification tool to check the bone resection angle. If the verification tool showed a major error from the target angle, we re-cut the bone resection and made adjustments. The extension and flexion gap was then evaluated using an implant-specific space block. In BCS TKA, to control the flexion gap, the rotational alignment and AP position of the femoral component was decided based on the gap measurement. Rotational alignment of the tibial component was manually set to be parallel Akagi's line. The implant was fixed with cement. An inlay-type patellar component was installed in all cases.

2.3 Three-dimensional measurements on preoperative and postoperative CT images and full-length standing AP radiographs

All patients underwent preoperative and postoperative computed tomography (CT) examinations that included the lower limbs. The postoperative CT scans were obtained 14 days after surgery. Implant planning software (ZedView, ZedKnee module; LEXI, Ltd., Tokyo, Japan) was used to import the CT images. Using the ZedView system, it is possible to determine the actual implant position by superimposing the postoperative CT images on the preoperative CT images. The error from the target angle in the intraoperative plan was also evaluated. The mechanical axes of the femur and tibia were set in the coordinate system; the mechanical axis of the femur was the line from the head of the femur to the intercondylar notch of the distal femur and that of the tibia was the line from the centre of the proximal tibia to the centre of the ankle. The axial alignment of the femur was set parallel to clinical transepicondylar axis and that of the tibia was set parallel to Akagi’s line [2]. Using the coordinate system, the mechanical axis could be determined accurately in the sagittal and coronal planes. Using ZedView to import the postoperative CT images, we also calculated the deviation of the implant position from the mechanical axis. The advantage of using this method was that the postoperative image could be evaluated in the same coordinate system as that used before the surgery (Figure 1).

We calculated the errors between the implant angle displayed by the robotic-assisted system or navigation-assisted system during surgery and the implant angle actually placed. We also investigated the errors in the coronal and sagittal alignment of the femoral and tibial components. Outliers were defined as values that deviated by more than 3° from the intraoperative plan.

A full-length standing AP hip-to-ankle radiograph was obtained 14 days after surgery for measurement of the hip-knee-ankle (HKA) angle. We also investigated the error between the planned HKA angle and measured HKA angle.

2.4 Statistical analysis

Based on previous reports [13, 30], a power analysis for outliers with a component alignment of more than ± 3° varus/valgus in the coronal plane and flexion/extension in the sagittal plane found that a sample size of 77 patients was needed in each cohort to provide appropriate power (beta = 0.80) with a significance level of 0.05. All measurements were performed twice by two independent observers, each of whom was blinded to the results reported by the other. The intraclass correlation coefficient (ICCs) were interpreted as follows: 0–0.40, poor; 0.41–0.60, moderate; 0.61–0.80, good; and 0.81–1.00, excellent. Differences between the two groups were examined using Student's *t*-test and Fisher's exact test. All statistical analyses were performed using SPSS version 27 (IBM Corp., Armonk, NY). A p-value < 0.05 was considered statistically significant.

3. Results

Table 1 shows a comparison of patient characteristics between the robotic-assisted group and the navigation-assisted group. Errors between the intraoperative plan and postoperative alignment are shown in Figure 2. In the robotic-assisted group, femoral coronal/sagittal errors were 0.2 ± 0.9 ° varus / 1.2 ± 1.4° flexion from the target, and tibial coronal/sagittal errors were 0.3 ± 1.2° varus / 0.2 ± 1.7° extension from the target angle. In the navigation-assisted group, the respective errors were 0.4 ± 1.1 ° valgus / 1.5 ± 1.8° flexion and 1.1 ± 1.2° varus / 0.1 ± 1.8° anterior slope.

Table 2 shows absolute errors between the intraoperative plan and postoperative alignment. Postoperative alignment of the femoral and tibial components in the coronal plane and of the femoral component in the sagittal plane was more accurate in the robotic-assisted group in the navigation-assisted group ($p < 0.05$). The postoperative alignment of the tibial component in the sagittal plane did not significantly differ between two groups. The HKA angle also did not significantly differ between the two groups.

Outlying values of component alignment are presented in Table 3. There were fewer outliers for the tibial component in the coronal plane in the robotic-assisted group ($p < 0.05$). There was no significant difference between the two groups in outlying values for the femoral component in the coronal and sagittal plane, the tibial component in the sagittal plane, or the HKA angle.

The ICCs for the inter-observer reliability of CT assessment in the coronal and sagittal planes were respectively 0.902 and 0.801 for the femur and 0.908 and 0.964 for the tibia. The ICCs for the intra-observer reliability in the coronal and sagittal planes were respectively 0.889 and 0.917 for the femur and 0.932 and 0.974 for the tibia. The ICC for the inter-observer reliability of radiographic assessment of the HKA angle was 0.862, and that for the intra-observer reliability was 0.962.

4. Discussion

The most important finding in this study was that robotic-assisted TKA improved component alignment compared with navigation-assisted TKA in terms of the coronal plane of the femur and tibia, and the sagittal plane of the femur.

Previous reports have suggested that robotic-assisted TKA is more accurate than manual TKA (Table 4) [10, 16, 17, 26, 28, 32]. It has also been reported that the absolute error of the implant placement angle in robotic-assisted TKA is within 1°-2°, which is consistent with our findings.

Another study found that conventional TKA had a 30% risk of outlying values for mechanical alignment (MA) [29]. Computer-assisted systems for TKA improved accuracy of component placement and MA outliers by 9% [22, 24]. In a recent report, 6% of MA values in robotic-assisted TKA were outliers [5]. In our study, despite the high accuracy of implant placement, the frequency of HKA angle outliers was higher than in previous studies. In addition, the frequency of HKA outliers was lower while tibial coronal outliers were higher in the navigation-assisted group than in the robotic-assisted group. The reason for this could be that the imaging conditions were different: CT images were taken in the supine position without varus/valgus stress. However, radiographs were taken in the standing position with some varus/valgus stress, which is thought to cause changes in global alignment between the supine and standing positions. Another reason may be that radiography itself is less accurate than CT imaging. Although we paid attention to the lower limb position in radiographs, it is difficult to eliminate minor positional error such as slight flexion contracture or incorrect rotational position that can result in inaccurate HKA. On the other hand, implant orientation measured on CT using well-established software is more accurate. Therefore, we believe the data on implant orientation is more accurate and reliable than the data on HKA.

To our knowledge, this is the first study to directly compare implant placement accuracy between robotic-assisted TKA and navigation-assisted TKA. In our study, implant placement accuracy was better and the percentage of malaligned components was lower with robotic-assisted TKA than with navigation-assisted TKA. Two network meta-analyses that indirectly compared robotic-assisted TKA with navigation-assisted TKA [6, 21] found that robotic-assisted TKA had a lower frequency of outlier values for lower limb alignment and position of the components compared with navigation-assisted TKA. Yau et al. suggested that saw blade deflection might occur when using a thin saw blade with a cutting guide [35]. In NAVIO TKA, bone cutting is performed accurately by using the handpiece with a semi-automatic burr. The difference in bone cutting achieved by the burr and that achieved by the thin bone saw may explain the difference in accuracy of implant placement between the two groups.

The two network meta-analyses reported that the frequency of outlying limb alignment and component position values was lower with robotic-assisted TKA than with navigation-assisted TKA but that there was no difference in postoperative clinical results between the two groups [6, 21]. A review of Australian Orthopaedic Association National Joint Replacement Registry data by Jorgensen et al. found a lower major aseptic revision rate with navigation-assisted TKA compared with conventional TKA [15]. The goal of postoperative lower limb alignment is controversial [1, 12, 14, 20] but it is important to achieve the goal of postoperative lower limb alignment. We set the target alignment as functional alignment in the robotic-assisted group and mechanical alignment in the navigation-assisted group, but recently the concept of personalised alignment has been proposed including kinematic alignment [12], restricted kinematic alignment [3], inverse kinematic alignment [34], and functional alignment [18]. Each concept differs from traditional mechanical alignment and requires highly accurate bone resection. The results of this study suggest that the angular differences between the two groups are minor and most likely not clinically relevant. However, in the recent trend toward personalised alignments rather than the traditional neutral alignment, robotic technology that can achieve target angles with greater accuracy will play important roles in achieving these personalised alignments.

Early studies have shown that several robotic systems can improve the accuracy and reproducibility of implant placement in TKA, including the NAVIO/CORI (Smith & Nephew), MAKO (Stryker), and ROSA (Zimmer-Biomet). For example, NAVIO is an image-free robotic system that uses a burr, MAKO is a CT-based robotic system that uses a robotic arm, and ROSA is an image-free robotic system that uses a robotic arm. In the future, it would be interesting to compare the implant placement accuracy and implant survival between such various systems.

This research has several strengths. First, it is the first to directly compare the accuracy of robotic-assisted TKA with that of navigation-assisted TKA and has demonstrated that installation is more accurate with robotic-assisted surgery. Second, we evaluated the accuracy of component placement on CT images. The accuracy of implant placement is better assessed on CT images than on radiographs [31]. Furthermore, three-dimensional CT measurements after TKA have been reported to have sufficient intraobserver and interobserver reliability [36].

There are also several limitations to this study. First, the robotic system was a closed platform (same manufacturer as the implant system); whereas the navigation system was an open/universal platform (different manufacturer from the implant system). As such, a universal platform may offer fewer options than a closed platform, such as evaluation of soft tissue balance. Also, the algorithm for setting up the coordinate system is not publicly available. We cannot rule out that differences between universal and closed platforms and differences in the coordinate systems might have affected our results. Second, the coordinate system of the NAVIO did not exactly match that of the ZedView software. In the ZedView system, the mechanical axis of the femur was set to the line from the femoral head to the intercondylar notch of the distal femur, and the mechanical axis of the tibia was set to the line from the centre of the proximal tibia to the centre of the ankle. Therefore, the difference between the two coordinate systems was considered to be extremely small. Third, there was no information on clinical outcomes. However, the aim of this study was to evaluate the accuracy of component placement and lower limb alignment and not to compare the clinical outcomes between the two groups. Fourth, assignment to the navigation-assisted and robotic-assisted groups in this study was not randomised, but sequential in nature. The possibility of improvement in the surgeons' skill cannot be ruled out. However, with regard to bone resection, intraoperative validation was performed after bone resection in both navigation-assisted TKA and robotic-assisted TKA. We believe that improvements in the skill of the surgeons had little impact on the accuracy results. Fifth, we could not evaluate the impact of the cement mantle on implant placement accuracy. Due to halation of the implants, we could not make reproducible measurements with our measurement tools. The potential impact of the cement mantle on the accuracy of implant placement would be an interesting subject of future research. Sixth, all the study participants had primary knee osteoarthritis with varus or neutral alignment. Therefore, its findings cannot be generalised to patients with other types of knee deformity. Seventh, we did not evaluate the accuracy of rotational alignment. In the navigation-assisted group, the rotational position of the femoral and tibial components was determined manually. Therefore, it is inappropriate to compare the accuracy of the rotational alignment between the robotic-assisted group and the navigation-assisted group.

5. Conclusions

This is the first study to directly compare the accuracy of robotic-assisted TKA with that of navigation-assisted TKA. Robotic-assisted TKA using a handheld image-free system improved component alignment in the coronal plane compared with TKA using an image-free navigation system. Robotic surgery is useful for accurate implantation and helps surgeons to achieve personalised alignment that may result in better clinical outcomes.

Abbreviations

ACL, anterior cruciate ligament; AP, anterior-posterior; BCS, bicruciate-stabilized; BCR, bicruciate-retaining; CT, computed tomography; HKA, hip-knee-ankle; MA, mechanical alignment; PCL, posterior cruciate ligament; TKA, total knee arthroplasty.

Declarations

Ethical approval

This study has been approved by the institutional review board of Tokushima University (approval no. 1627-3).

Informed consent

Informed consent was obtained from all patients to participate and to publish this study.

Conflicts of interest

DH received payment for lecture from Smith & Nephew.

Authors' contribution

YO: data curation, formal analysis, writing original draft. DH: conceptualization, methodology, supervision, writing review and editing. KW: formal analysis. YT, SS: data curation. KS: conceptualization, supervision. All authors have reviewed and approved the final manuscript.

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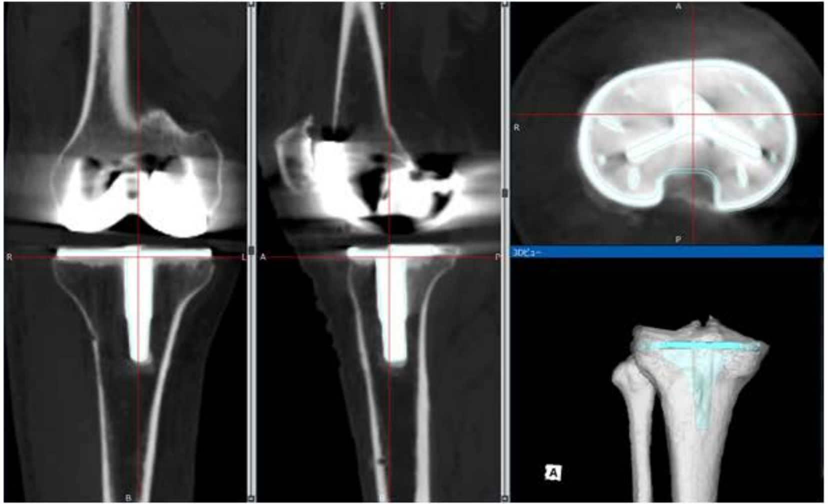
Figure Legends

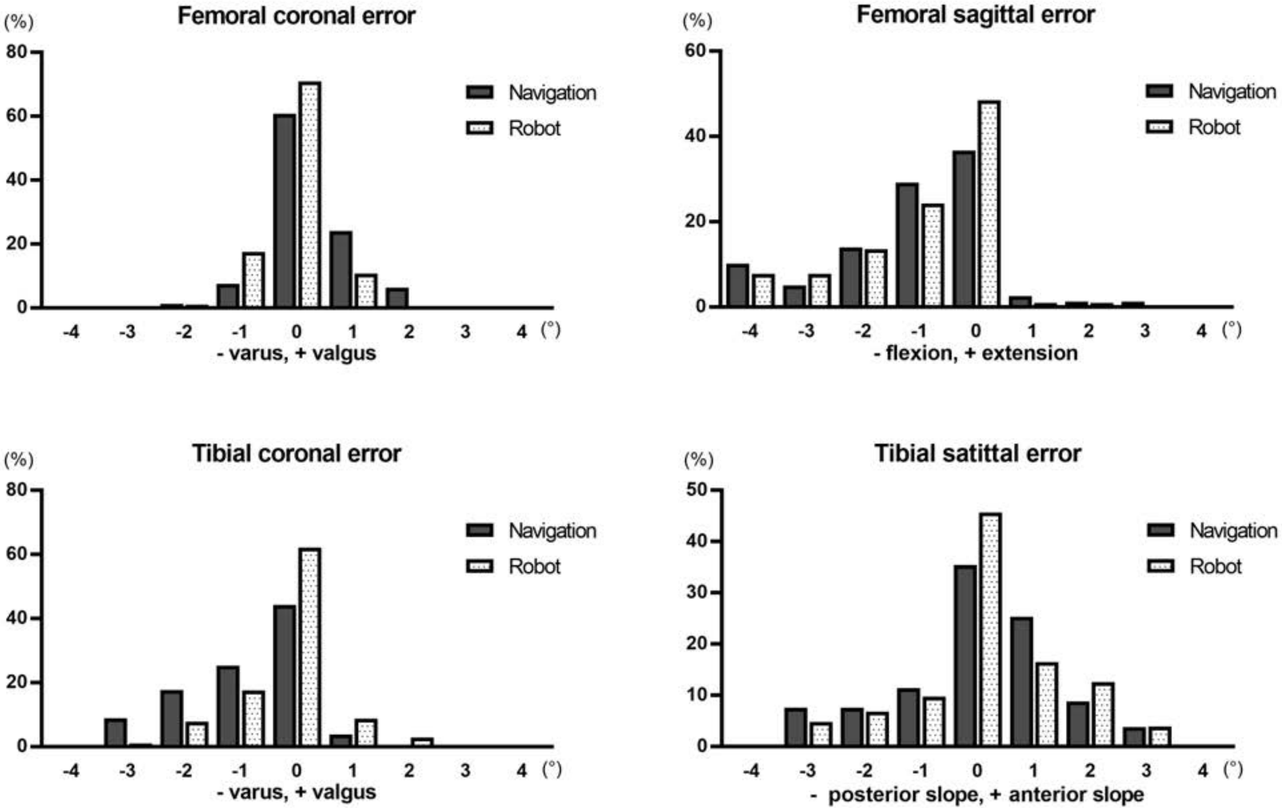
Fig. 1 Overlapping preoperative and postoperative computed tomography images. The three-dimensional implant model was accurately overlaid on the postoperative implant placement position. (a) Three-dimensional planes of the femur. (b) Three-dimensional planes of the tibia.

Fig. 2 Errors between the intraoperative plan and postoperative component alignment in each plane. (a) Femoral coronal error. (b) Femoral sagittal error. (c) Tibial coronal error. (d) Tibial sagittal error.

(a)



(b)



Femoral coronal error

Femoral sagittal error

Tibial coronal error

Tibial satittal error

Table 1 Comparison of patient characteristics between the robotic-assisted group and the navigation-assisted group

Variable	Robotic-assisted group	Navigation-assisted group	p-value
Knees, n	103	79	
Age, years	72.5 ± 8.7	72.3 ± 7.6	0.87
Body mass index*	26.9 ± 4.9	27.6 ± 4.1	0.26
Sex, %	Male 31.1 Female 68.9	Male 22.8 Female 77.2	0.21
Preoperative HKA angle, °	169.9 ± 6.3	169.5 ± 6.2	0.65

Data are presented as the mean standard deviation unless otherwise indicated.

*Calculated as kg/m^2. HKA, hip-knee-ankle (varus, <180°; valgus >180°)

Table 2 Absolute errors between the intraoperative plan and postoperative component alignment in each plane and the HKA angle

	Robotic-assisted group	Navigation-assisted group	p-value
Femoral component			
Coronal plane, °	0.7 ± 0.5 (0–2.7)	0.9 ± 0.7 (0–2.7)	0.007
Sagittal plane, °	1.4 ± 1.2 (0–5.0)	1.8 ± 1.5 (0–6.5)	0.049
Tibial component			
Coronal plane, °	0.9 ± 0.8 (0–3.9)	1.3 ± 1.0 (0–3.7)	0.007
Sagittal plane, °	1.3 ± 1.0 (0–3.5)	1.5 ± 1.0 (0–3.5)	0.41
HKA angle, °	1.8 ± 1.5 (0–9.5)	1.8 ± 1.4 (0–6.1)	0.85

Data are presented as the mean standard deviation unless otherwise indicated. HKA, hip-knee-ankle

Table 3 Outlying component alignment values in each plane and outlying HKA angles (outliers > 3°)

	Robotic-assisted group	Navigation-assisted group	p-value
Femoral component			
Coronal plane, n	0 (0%)	0 (0%)	n.s
Sagittal plane, n	12 (11.7%)	12 (15.2%)	0.51
Tibial component			
Coronal plane, n	1 (1.0%)	7 (8.9%)	0.02
Sagittal plane, n	9 (8.7%)	6 (7.5%)	1.00
HKA angle, n	18 (17.5%)	11 (13.9%)	0.55

Data are presented as the mean standard deviation unless otherwise indicated. HKA, hip-knee-ankle

Table 4 Comparative studies in the literature on accuracy of robotic-assisted TKA (with absolute errors)

Authors	n	Robotic system	Femoral coronal error, °	Femoral sagittal error, °	Tibial coronal error, °	Tibial sagittal error, °	Measurement
Our study	103	NAVIO	0.7 ± 0.5	1.4 ± 1.2	0.9 ± 0.8	1.3 ± 1.0	CT
Kaneko et al. (2021) [14]	41	NAVIO	1.4 ± 1.3	2.3 ± 2.0	1.3 ± 1.5	2.4 ± 1.9	CT
Vanlommel et al. (2021) [30]	90	ROSA	0.3 ± 0.3	0.5 ± 0.3	0.4 ± 0.3	0.9 ± 0.7	Radiography
Seidenstein et al. (2021) [24]	14 (cadavers)	ROSA	0.5 ± 0.4	1.3 ± 1.0	0.6 ± 0.4	0.6 ± 0.4	Radiography
Kayani et al. (2019) [15]	60	MAKO	1.0 ± 0.4	2.1 ± 0.7	1.0 ± 0.5	2.0 ± 0.6	Radiography
Sires et al. (2021) [26]	29	MAKO	1.2 ± 1.1	1.8 ± 1.1	1.0 ± 0.8	1.8 ± 1.2	CT
Hampp et al. (2019) [8]	6 (cadavers)	MAKO	0.6 ± 0.3	0.6 ± 0.5	0.9 ± 0.4	1.1 ± 1.6	CT

Data are presented as the mean standard deviation unless otherwise indicated. CT, computed tomography; TKA, total knee arthroplasty