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The Usefulness of a Simplified Navigation-Based Instrumentation for a Novice Surgeon in Primary Total Knee Arthroplasty: A Retrospective Analysis of a Randomized Controlled Trial

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Background: A novel simplified navigation-based instrumentation system has been developed. It simplifies the existing navigation system and facilitates convenient bone cutting by positioning the tracker on an existing cutting block without additional pin fixation. This study aimed to compare the outcomes of this newly developed simplified navigation-based instrumentation system in primary total knee arthroplasty (TKA) performed by a novice surgeon with those of conventional surgical techniques.

Methods: From January 2020 to July 2020, 67 knees that underwent primary TKA using the ExactechGPS TKA Plus (group A) were compared to 68 knees that underwent primary TKA using a conventional technique (group B). All patients had a minimum follow-up of 24 months. The operative details such as tourniquet time were investigated. Postoperative hip-knee-ankle (HKA) angle and component position angles in the coronal and sagittal planes (α, β, γ, and δ angles) were evaluated. The outlier rates were compared between the groups as those lying outside ± 3°. Knee Injury and Osteoarthritis Outcome Score for Joint Replacement, the Western Ontario and McMaster Universities Osteoarthritis Index for pain and function, and range of motion were compared.

Results: There was no statistically significant difference in average tourniquet time between the groups (74.3 vs. 70.3 minutes, p = 0.061). Outlier rates for HKA angle (7.5% vs. 23.5%, p = 0.010) and β angle (1.5% vs. 22.1%, p < 0.001) in group A were significantly lower than those in group B. There were no significant differences in clinical outcomes between the groups.

Conclusions: Primary TKA performed by a novice surgeon using a simplified navigation-based instrumentation system did not significantly increase the operation time, and more accurate lower extremity mechanical alignment and tibial component alignment in the coronal plane could be obtained.

Keywords: *Total knee arthroplasty, Simplified navigation-based instrumentation system, Conventional technique, Outlier rate, Novice surgeon*

Many studies have reported that the optimal component positions in the coronal and sagittal planes and the mechanical axis within 3° after total knee arthroplasty (TKA) reduce implant wear and improve the survival rate of the prosthesis.[1-3)] To increase this accuracy, navigation-assisted TKA based on computer-assisted orthopedic surgery was introduced, and it has been steadily used for the past 20 years.[4-6)] A meta-analysis showed that navigation-assisted TKA could improve mechanical alignment and keep deviation from the target cut below 1°, thereby significantly reducing the outlier rate.[7)] Moreover, it has been reported that navigation-assisted TKA can be relatively reproducible and reduce the amount of bleeding and the risk of

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embolism because it does not use an intramedullary (IM) guide.[8,9)]

However, there has been controversy as to whether improvement in alignment and component positioning shows superior clinical outcomes compared to conventional surgical methods. Additionally, a change in the position of the tracker during surgery may reduce precision or cause operation errors, additional incisions are required to insert pins to fix the tracker, and stress fractures may occur depending on the position of the inserted pins.[10,11)] Variations or errors are likely to occur when setting anatomical landmarks such as the transepicondylar axis. Such additional instrumentation may extend the operation time and require the operating skill to cope with unexpected errors.[12)]

Recently, a novel simplified navigation-based instrumentation system was developed to facilitate bone cutting of the distal femur and proximal tibia by simplifying the previous navigation system and locating the tracker on the existing cutting block without additional pin fixation. This system was developed to provide real-time spatial tracking and allows for real-time computer registration and measurements while maintaining the conventional surgical technique. One study using the planned metrics knee model suggested that this system could reduce outlier rates (± 2°) and improve cut accuracy compared to the conventional method.[13)] Above all, this simplified cutting-aided device can reduce outliers and minimize complications such as prolonged operation time and pin-related problems in novice surgeons who start performing TKA independently.[13)] However, to our knowledge, there has been a paucity in literature regarding the clinical outcomes of TKA using this new system, and comparative studies with conventional surgical techniques are very limited.

Therefore, the purpose of this study was to compare the outcomes of a newly developed simplified navigation-based instrumentation system in primary TKA performed by a novice surgeon with those of conventional surgical techniques. We hypothesized that by using this new system, even novice surgeons could obtain more accurate radiographic outcomes, minimizing prolonged operation time or pin-related complications compared to conventional techniques.

METHODS

This study was approved by the Institutional Review Board of Yeungnam University Medical Center (No. YUMC 2022-03-003), and the requirement for informed consent was waived because of its retrospective design.

Patient Selection

Between January 2020 and July 2020, a total of 144 knees (78 patients) that underwent consecutive primary TKA were retrospectively reviewed. Inclusion criteria for this study were as follows: patients (1) with symptomatic progressed osteoarthritis (Kellgren-Lawrence grade ≥ III), (2) over 60 years of age, (3) with a minimum follow-up period of 24 months, and (4) with use of the navigation-based instrumentation system (ExactechGPS, TKA Plus) or a conventional technique. Four knees that underwent primary TKAs using a full-navigation option (3 with IM nails; 1 with extra-articular femoral deformity secondary to malunited femoral shaft fractures) were excluded.[14,15)] A computer randomization system was used to allocate the patients to either the navigation-based instrumentation system cohort (group A, n = 70) or the conventional cohort (group B, n = 70). During the study period, 5 knees were lost to follow-up (3 in group A, 2 in group B). Finally, 135 knees were enrolled in the current study and assigned to either group A (n = 67) or group B (n = 68) (Fig. 1).

All operations were performed by a novice surgeon (GBK) in a single institute using the same posterior-stabilized prosthesis (Truliant Knee System, Exactech). All prostheses were used with cement. The novice surgeon completed a 2-year fellowship for TKA, independently performed TKA within 1 year, and had no previous experience with navigation-assisted TKA alone.[16,17)]

Surgical Technique Using a Simplified Navigation-Based Instrumentation System

ExactechGPS TKA Plus is a novel hybrid system of cutting-aided device with minimal deviation from conventional surgical techniques based on the global positioning system (GPS) of navigation. This instrument facilitates cutting of the distal femur and proximal tibia and is different from the computer navigation system equipped with a full-option system that provides information on femoral component rotation and extension and flexion gaps.

A medial parapatellar arthrotomy with a midline incision was performed. All osteophytes were removed from the femur and tibia. The femur was first prepared in all cases. After entering the basic information, the femoral and tibial trackers were connected and calibrated. A distal femoral resection guide with adjusting knobs was combined with the distal femoral alignment guide of an existing implant. Then, while inserting the IM rod, the assembled device was seated on the distal femur and fixed with two threaded pins (Fig. 2A). After removal of the IM rod and distal femoral alignment guide, a femoral tracker was placed on the section guide to prepare the acquisition

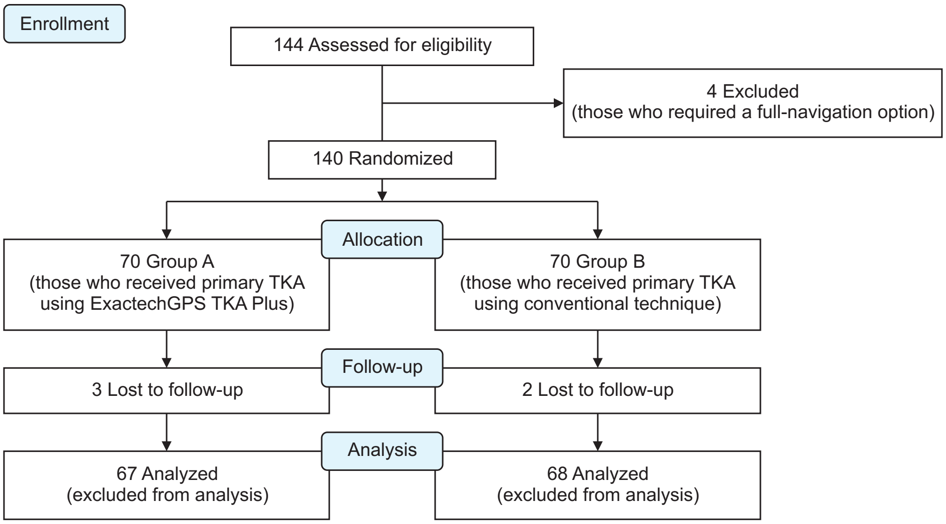

Fig. 1. Flow diagram for enrolled patients (numbers of knees). TKA: total knee arthroplasty.

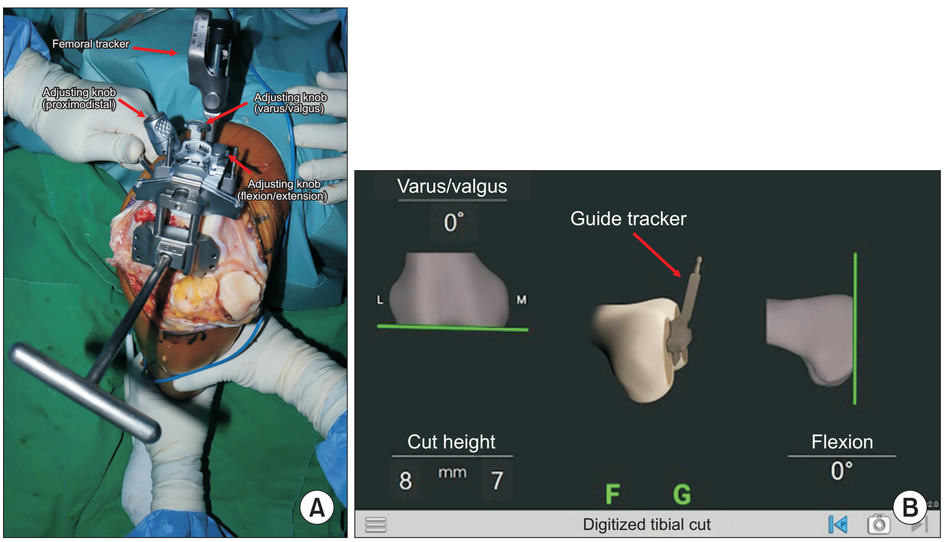

Fig. 2. Resection process of the distal femur using TKA Plus. (A) A distal femoral resection guide equiped with adjusting knobs was combined with the distal femoral alignment guide of the implant. After the intramedullary rod insertion, the assembled device was seated on the distal femur and fixed with two threaded pins. (B) The cutting accuracy was verified by placing a femoral resection tracker on the cutting surface.

of the femoral implant. For implant acquisition, the hip center, knee center, posterior femoral condyles, and distal femoral condyles were enrolled as tracker probes. While checking the degree of distal femoral cut on the screen, the surgeon controlled the adjusting knobs to modify the varus/valgus and flexion/extension of the distal femoral resection guide in units of 1°, enabling fine-tuning to desired cut parameters. In all cases, the degree of varus/valgus of the distal femur was set at 0°, and then bone resection was performed. Once the desired cut parameters were set, the resection guide was finally secured with a threaded pin to prevent movement. After distal femoral resection, the cutting accuracy was verified by placing a femoral resection tracker on the cutting surface (Fig. 2B).

The proximal tibial cut was performed using an extramedullary (EM) guide with adjusting knobs. After setting the rough cutting level with the tibial stylus, the tibial resection guide was secured with the first two threaded pins. Then, the tibial tracker was mounted on the resection guide (Fig. 3A). For implant acquisition, both malleoli, the center of the tibial spine, the direction of the sagittal plane, and both plateaus were enrolled as tracker probes. While checking the degree of proximal tibial cut on the screen, the surgeon controlled the adjusting knobs to modify varus/valgus and flexion/extension of the proximal tibial resection guide in units of 1°, which enabled fine-tuning to the desired cut parameters (Fig. 3B). As with the distal femur, after the degree of varus/valgus of the proximal tibia was set at 0°, bone resection was performed. Once the target cut parameters were decided, the resection guide was finally secured with a threaded pin to prevent movement. After proximal tibial resection, the cutting accuracy was

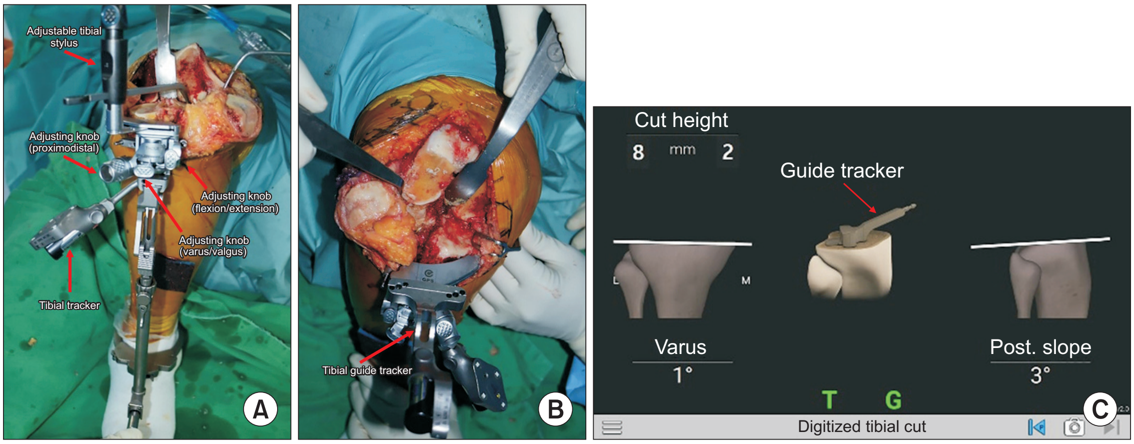

Fig. 3. Resection process of the proximal tibia using TKA Plus. (A) After setting the rough cutting level with the tibial stylus, the tibial resection guide was secured with the first two threaded pins. Then, the tibial tracker was mounted on the resection guide. (B) The surgeon could control the adjusting knobs to modify the degree of proximal tibial cutting in 1° increments, enabling fine tuning to the desired cut parameters. (C) The cutting accuracy was checked by placing a tibial resection tracker on the cutting surface.

checked by placing a tibial resection tracker on the cutting surface (Fig. 3C). Finally, the extension gap was checked by inserting a spacer block, and then all instruments were removed.

The remaining surgical procedures were performed using the modified gap-balancing technique, with which the extension gap could be balanced before the flexion gap[18] using the same posterior-stabilized femoral implant. Femoral component rotation was determined according to the balanced flexion gap.[19] Femur sizing was performed using an anterior reference system. The rotation of the tibial component was set by considering several reference points, including the medial one-third of the tibial tuberosity, anterior tibial cortex, and floating technique.[20] All prostheses were fixed with cement. Antioxidant polyethylene inserts were used in all cases. Patellar resurfacing was selectively performed in patients with intraoperatively identified International Cartilage Repair Society grade III or IV lesions.[21]

Conventional TKA Technique

The conventional technique was also implemented based on the modified-gap balance technique.[18] A medial parapatellar arthrotomy with a midline incision was performed. After removing all osteophytes from the femur and tibia, an IM alignment rod for distal femur cut was set with the goal of achieving 5°–6° valgus depending on alignment. A standard EM jig for the proximal tibia was used with the aim of cutting the bone perpendicular to the tibial axis. Femoral component rotation was determined according to the balanced flexion gap. Femur sizing was performed using an anterior reference system in all cases. All other procedures were performed in the same way as the surgical procedure using a navigation-based instrumentation system.

Postoperative Management

A single closed suction drain was maintained for 24 hours after surgery. All patients received an identical perioperative pain control protocol, including a multimodal drug regimen, postoperative patient-controlled analgesia, and intraoperative periarticular injection. The active dangling exercise was initiated on the day of surgery, and partial weight-bearing with a crutch was allowed on the first postoperative day. Full weight-bearing was permitted 3 weeks after surgery.

Outcome Assessments

The demographic characteristics were recorded before surgery. The operative details including tourniquet time and drainage amount were also investigated through medical records. Radiographic and clinical outcomes of each patient were assessed preoperatively, at 6, 12, and 24 months postoperatively, and annually thereafter. At each follow-up, the outcomes of group A and group B were compared.

Bilateral standing anteroposterior and lateral radiographs and scanograms were used to assess lower limb alignment and component position. The hip-knee-ankle (HKA) angle was defined as the angle between the femoral and tibial mechanical axes on scanograms (varus alignment indicated as a negative value).[22] The outliers were considered to be more than ± 3° of 0° (neutral mechanical alignment).[3] The position of components in the coronal and sagittal planes was evaluated using α, β, γ, and δ angles by the Knee Society radiological evaluation method.[23) The outliers of component positions were defined as those lying outside ± 3° of 6° (α angle), 90° (β angle), 0°–10° (γ angle), and 3° (δ angle).[3)

Radiologic measurements were performed twice at least 2 weeks apart by two independent observers (OJS and HGL) who had no clinical contact with the patients to evaluate intra- and interobserver reliability. Reliability for all radiographic parameters was analyzed using intraclass correlation coefficients and classified as little if any (correlation coefficient, ≤ 0.25), low (0.26–0.49), moderate (0.50–0.69), high (0.70–0.89), or very high (≥ 0.90).[24) All measurements were performed using a picture achieving and communication system (PiViewSTAR, Infinitt Co.).

For clinical assessments, Knee Injury and Osteoarthritis Outcome Score for Joint Replacement[25) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) for pain and function[26) were investigated. They were recorded by an independent researcher (HGL) in the outpatient clinic. Range of motion (ROM) of the knee joint including flexion contracture and further flexion angle was measured using a standardized manual goniometer with a 30-cm plastic movable long arm. The values at the final follow-up were compared with the preoperative values. The incidence of complications including infection and aseptic loosening was also investigated via chart review.

Statistical Analysis

Statistical evaluation was performed using IBM SPSS software ver. 25 (IBM Corp.) and continuous data were expressed as mean ± standard deviation or mean with range. All dependent variables were tested for normality of distribution and equality of variances using the Kolmogorov-Smirnov test and were analyzed using non-parametric tests because they showed non-normal distributions. Radiographic and clinical outcomes were compared between groups A and B using an independent samples *t*-test. The preoperative and postoperative radiographic and clinical outcomes were also compared using paired *t*-tests. The proportion of patients in each group was compared using the chi-square test. For all tests, a *p*-value < 0.05 was considered statistically significant. Moreover, a post-hoc power analysis was performed to evaluate whether the sample had sufficient power to detect significant differences using the significance set at an α of 0.05. A statistical power > 90% based on the enrolled sample size was considered to be sufficient, and all of the variables that were significantly different met this criterion.[27) Therefore, it was determined that our study was adequately powered.

RESULTS

Patient demographic characteristics and operative details are summarized in Tables 1 and 2, respectively. The average age at operation was 72.8 years (range, 62–88 years), and the average follow-up period was 26.8 months (range, 24.0–30.0 months). Demographic characteristics were not statistically significantly different between the two groups (Table 1). Although group A had a longer average tourniquet time, there was no statistically significant difference between the two groups ($p = 0.061$) (Table 2).

Radiographically, although the mean HKA angle was within the range of neutral alignment, group A showed a significantly greater valgus tendency in mean HKA angle after surgery ($p = 0.021$). The mean α, β, γ, and δ angles did not differ significantly between the two groups (Table 3). The percentage of outliers for HKA angle (7.5% vs. 23.5%, $p = 0.010$) and β angle (1.5% vs. 22.1%, $p < 0.001$) in group A was significantly lower than that in group B (Fig. 4).

Although clinical outcomes including KOO-JR, WOMAC, and ROM of the knee joint were significantly improved after surgery, there were no significant differences between the two groups (Table 4). No difference in the incidence of complications was observed between the groups (Table 5). Intraoperative agreement of the radiographic assessments showed very high intra- and interobserver reliabilities (Table 6).

DISCUSSION

The most notable finding of this study is that the incidence of outliers was significantly reduced for lower extremity mechanical alignment and tibial component alignment in the coronal plane after primary TKA using a simplified navigation-based instrumentation system performed by a novice surgeon. Moreover, there was no statistically significant increase in average tourniquet time.

ExactechGPS TKA Plus was developed to provide surgical accuracy based on navigation without modification of a surgical technique or additional installation of special instruments. This system could be seamlessly integrated with the same company's TKA implant, providing real-time guidance and data. Strictly, it is difficult to regard this device as a navigation system equipped with a full option that provides information on femoral component rotation and extension/flexion gaps. This is a novel hybrid system of cutting-aided device with minimal deviation from conventional surgical techniques based on navigation GPS.[13) Since the femoral and tibial trackers are positioned

Table 1. Patient Demographic Characteristics

Variable	Overall (n = 135)	Group A (n = 67)	Group B (n = 68)	*p*-value*
Age (yr)	72.8 (62.0–88.0)	72.3 (62.0–85.0)	73.3 (64.0–88.0)	0.493
Sex				0.761
Female	120 (88.9)	59 (88.1)	61 (89.7)	
Male	15 (11.1)	8 (11.9)	7 (10.3)	
BMI (kg/m^2)	26.4 (18.7–31.2)	26.2 (18.7–30.5)	26.6 (20.1–31.2)	0.812
Follow-up period (mo)	26.8 (24.0–30.0)	26.9 (24.0–30.0)	26.8 (24.0–30.0)	0.761
Side				0.929
Right	64 (47.4)	32 (47.8)	33 (48.5)	
Left	71 (52.6)	35 (52.2)	35 (51.2)	
ASA score				0.583
1	37 (27.4)	15 (22.4)	20 (29.4)	
2	87 (64.4)	47 (70.1)	42 (61.8)	
3	11 (8.1)	5 (7.5)	6 (8.8)	
Preoperative HKA angle (°)	–6.5 (–23 to 16.5)	–5.9 (–23 to 15.5)	–5.2 (–20 to 16.5)	0.605
Preoperative ROM (°)				
FC	10.0 (–5.0 to 30.0)	9.5 (–5.0 to 25.0)	9.5 (–5.0 to 30.0)	0.567
FF	120.5 (90.0 to 140.0)	119.5 (90.0 to 140.0)	122.5 (100.0 to 140.0)	0.409

Values are presented as mean (range) or number (%). Varus alignment was indicated as HKA angle less than 0°. Negative value of FC indicates hyperextension.
Group A: group that received primary total knee arthroplasty (TKA) using ExactechGPS TKA Plus, Group B: group that received primary TKA using a conventional technique, BMI: body mass index, ASA: American Society of Anesthesiologists, HKA: hip-knee-ankle, ROM: range of motion, FC: flexion contracture, FF: further flexion.
*The level of statistical significance was set at $p < 0.05$.

Table 2. Comparison of Operative Details between the Groups

Variable	Overall (n = 135)	Group A (n = 67)	Group B (n = 68)	*p*-value*
Tourniquet time (min)	72.8 (52.0–90.0)	74.3 (52.0–85.0)	70.3 (64.0–90.0)	0.061
Drainage amount (mL)	353.8 (187.0–431.0)	354.3 (187.0–390.0)	352.7 (205.0–431.0)	0.758
Need for blood transfusion	6 (4.4)	3 (4.5)	3 (4.4)	0.985

Values are presented as mean (range) or number (%). Transfusion criteria: 7.0 g/dL ≤ hemoglobin (Hb) ≤ 8.0 g/dL with symptomatic anemia or Hb <7.0 g/dL.
Group A: group that received primary total knee arthroplasty (TKA) using ExactechGPS TKA Plus, Group B: group that received primary TKA using a conventional technique.
*The level of statistical significance was set at $p < 0.05$.

on the existing cutting guides, there is no need to secure additional pins. Therefore, no additional skin incision is required and pin-related complications do not occur. Due to this, it is possible to minimize the prolonged operation time, which is a disadvantage of the full-option navigation system. In particular, for novice surgeons with no experience in navigation, problems such as stress fractures due to improper pin insertion may occur, and operation time may be extended due to additional procedures.[10,11] This study showed that the use of a simplified navigation-based

Table 3. Comparison of Radiographic Outcomes between the Groups

Variable	Overall (n = 135)	Group A (n = 67)	Group B (n = 68)	*p*-value*
Postoperative HKA angle (°)	–1.1 (–5.0 to 4.5)	1.3 (–1.5 to 4.0)	–2.4 (–5.0 to 4.5)	0.021†
Position of components (°)				
α Angle	94.9 ± 1.8	95.1 ± 1.6	94.8 ± 1.9	0.870
β Angle	90.4 ± 2.6	90.1 ± 1.1	91.2 ± 4.5	0.102
γ Angle	8.9 ± 2.6	8.8 ± 2.2	8.9 ± 2.8	0.792
δ Angle	86.9 ± 1.8	86.9 ± 1.6	86.8 ± 1.9	0.942

Values are presented as mean (range) or mean ± standard deviation.
Group A: group that received primary total knee arthroplasty (TKA) using ExactechGPS TKA Plus, Group B: group that received primary TKA using a conventional technique, HKA: hip-knee-ankle.
*The level of statistical significance was set at $p < 0.05$. †There was significant difference in HKA angle between the groups (independent sample *t*-test, $p < 0.05$). Varus alignment was indicated as HKA angle less than 0°.

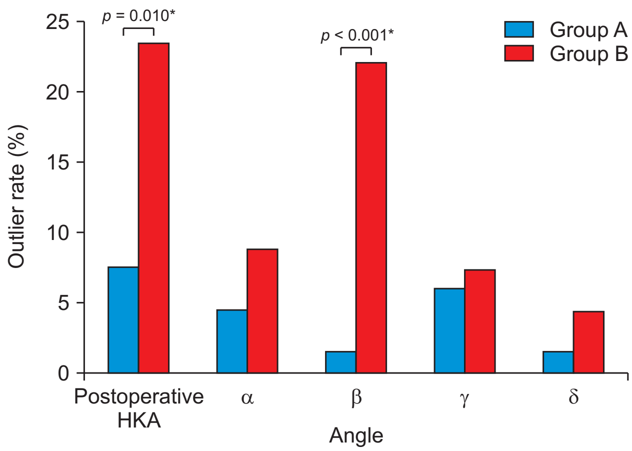

Fig. 4. Comparison of outlier rates between the two groups. The outlier rates for postoperative hip-knee-ankle (HKA) angle and β angle in group A were significantly lower than those in group B ($p = 0.010$, $p < 0.001$, respectively). Group A: group that received primary total knee arthroplasty (TKA) using ExactechGPS TKA Plus, Group B: group that received primary TKA using a conventional technique. *Chi-square test.

instrument aid by a novice surgeon did not lead to a statistically significant increase in tourniquet time.

Several studies comparing computer navigation and the conventional method have already reported that the conventional cohort by the EM alignment method has a higher outlier rate of tibial cutting.[4,7,28] Interestingly, a prospective randomized study of tibial alignment guides showed only 65% tibial cutting accuracy in the EM cohort.[29] This suggests that the use of conventional EM guides can lead to significant variability in the tibial component position even by an experienced surgeon. Furthermore, the tibial component outlier rate using the EM guide inevitably increases significantly in the novice surgeons who have performed TKA alone for a short period and have no previous experience with navigation TKA. In the present study, the simplified navigation-based instrumentation group showed an outlier rate of 1.5%, significantly lower than that of the conventional group, 21.4%. A study reported that the alignment of the tibial component plays an important role in the overall mechanical alignment obtained after TKA and that its malpositioning can be an independent risk factor for early aseptic failure.[30]

Meanwhile, since this simplified navigation-based cutting-aided device is fixed to the conventional cutting guide and then adjusted in 1° increments in the coronal and sagittal planes via an adjusting knob mounted on the cutting guide, it is convenient for surgeons to achieve their intraoperative goals for component positioning (Figs. 2 and 3). The learning curve barrier for this device was low even for a novice surgeon because it was possible to settle more stably than computer navigation based on the free-handed position of the previous generation. This could have contributed to the fact that although the operator of this study was a novice surgeon, there was no significant difference in tourniquet time.

Despite the encouraging results, this study has limitations meriting discussion. First, this study had a retrospective nature, the sample size was relatively small, and the follow-up period was short. Therefore, differences in significant outcomes may have been missed, and mid- to long-term outcomes were not assessed. Therefore, in the future, a randomized, prospective, well-designed study with a larger sample size and a longer follow-up period would be required to confirm that the simplified navigation-based instrumentation system can provide bet-

Table 4. Comparison of Clinical Outcomes between the Groups

Variable	Group A (n = 67)	Group B (n = 68)	*p*-value*
KOOS-JR score			
Preop	45.9 ± 13.4	46.2 ± 13.7	0.728
Postop at 6 months	64.8 ± 12.8	64.9 ± 12.1	0.589
Postop at 12 months	74.1 ± 15.1	73.8 ± 15.4	0.334
Postop at 24 months	74.2 ± 13.1	74.0 ± 14.4	0.739
WOMAC score			
WOMAC function			
Preop	46.6 ± 8.0	46.1 ± 7.3	0.613
Postop at 6 months	80.7 ± 7.8	81.0 ± 7.9	0.302
Postop at 12 months	86.9 ± 6.9	87.1 ± 7.5	0.747
Postop at 24 months	87.2 ± 3.9	87.4 ± 3.3	0.823
WOMAC pain			
Preop	45.1 ± 3.2	44.2 ± 4.4	0.289
Postop at 6 months	85.2 ± 5.1	85.1 ± 5.5	0.412
Postop at 12 months	89.1 ± 4.9	89.3 ± 4.8	0.682
Postop at 24 months	89.6 ± 5.2	89.8 ± 3.8	0.716
WOMAC stiffness			
Preop	42.2 ± 5.4	41.9 ± 5.2	0.725
Postop at 6 months	69.8 ± 6.0	69.2 ± 6.4	0.437
Postop at 12 months	81.0 ± 3.2	81.1 ± 2.9	0.898
Postop at 24 months	82.1 ± 5.2	83.1 ± 4.9	0.761
ROM of the knee joint			
FC (°)			
Preop	7.9 ± 3.2	9.2 ± 5.8	0.319
Last follow-up	1.5± 2.0	1.6 ± 2.2	0.723
p-value†	< 0.001	< 0.001	-
FF (°)			
Preop	118.9 ± 7.1	116.8 ± 6.8	0.419
Last follow-up	134.7 ± 2.1	135.1 ± 1.9	0.723
p-value†	< 0.001	< 0.001	-

Values are presented as mean ± standard deviation.
Group A: group that received primary total knee arthroplasty (TKA) using ExactechGPS TKA Plus, Group B: group that received primary TKA using a conventional technique, KOOS-JR: Knee Injury and Osteoarthritis Outcome Score for Joint Replacement, Preop: preoperative, Postop: postoperative, WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index, ROM: range of motion, FC: flexion contracture, FF: further flexion.
*There was no significant difference between the two groups (independent sample *t*-test, $p < 0.05$). †ROM was improved after the index operation (paired *t*-test, $p < 0.05$).

Table 5. The Incidence of Complications

Variable	Overall (n = 135)	Group A (n = 67)	Group B (n = 68)	*p*-value*
Venous thromboembolism				
PTE	-	-	-	-
DVT (proximal)	4 (3.0)	2 (3.0)	2 (2.9)	0.685
DVT (distal)	11 (8.1)	5 (7.5)	6 (8.8)	0.773
Infection	1 (0.7)	-	1 (1.5)†	0.504
Neurovascular injury	-	-	-	-
Periprosthetic fracture	-	-	-	-
Total	16 (11.9)	7 (10.4)	9 (13.2)	0.616

Values are presented as number (%).
Group A: group that received primary total knee arthroplasty (TKA) using ExactechGPS TKA Plus, Group B: group that received primary TKA using a conventional technique, PTE: pulmonary thromboembolism, DVT: deep vein thrombosis.
*There was no significant difference between the two groups (chi-square test, $p < 0.05$). †Acute hematogenous infection.

Table 6. Intra- and Interclass Correlation Coefficients of the Radiographic Measurements

Variable	Intraobserver	Interobserver
Postoperative HKA angle	0.93	0.91
α Angle	0.94	0.91
β Angle	0.93	0.92
γ Angle	0.91	0.90
δ Angle	0.93	0.91

Values are presented as absolute values. The data show almost perfect intra- and interobserver agreement for the measured parameters.[24]
HKA: hip-knee-ankle.

ter radiographic outcomes compared to the conventional technique. Second, this instrument is only a GPS-based instrument that aids in cutting the distal femur and proximal tibia and does not provide information on soft-tissue tension such as femoral component rotation or extension/flexion gaps, which have far more impact on the outcomes of TKA. Therefore, it is unreasonable to conclude that this instrument is superior to the existing computer-navigation system. This can be considered a novel hybrid system that minimizes deviation from conventional surgical techniques based on navigation GPS. Third, it is difficult to calculate the effect on the learning curve required to use the ExactechGPS TKA Plus device from this study. Studies on the learning curve of this device are needed in the future. Fourth, since this study was conducted with only an implant from a specific manufacturer, the outcomes of this study cannot be representative of all implants. In particular, clinical outcomes may vary for other implants or manufacturers with different kinematics. Lastly, a female predominance was observed in this study cohort. In general, knee osteoarthritis tends to be more frequent in women in most Asian countries. Therefore, the same outcomes may not be applicable to populations with different sex ratios.

Primary TKA performed by a novice surgeon using a simplified navigation-based instrumentation system did not significantly increase the operation time, and more accurate lower extremity mechanical alignment and tibial component alignment in the coronal plane could be obtained. Therefore, this hybrid system can be a useful device that can provide cutting accuracy to novice surgeons while minimizing deviations compared to conventional surgical techniques.

CONFLICT OF INTEREST

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

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