


Intraoperative Assessment of Gap Balancing in Total Knee Arthroplasty Using Navigation with Joint Stability Graphs

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Abstract

The purpose of this study was to assess continuous gaps in the replaced knee throughout the full range of motion (ROM) after total knee arthroplasty (TKA) using a joint stability graph, and to analyze the gap laxity in the mid-flexion range. Ninety-three TKAs were performed using imageless navigation with a joint stability graph. While positioning guides for each respective cut, the surgeon can safely preview the resection's impact for the resulting joint gaps and control the soft tissue balance at the knee flexion of 0° (extension) and 90° (flexion). The gaps between the femoral component and insert were evaluated throughout the full ROM using the joint stability graph. The mechanical axis (MA) and change of joint line height were radiographically evaluated. Posthoc power analyses using a significant α value of 0.05 were performed on the proportion of the mid-flexion instability as a primary outcome to determine whether the sample had sufficient power. The power was determined to be sufficient (100%). The flexion–extension gap differences in each medial and lateral compartment and the mediolateral gap differences in flexion and extension were all ≤ 3 mm. None of the knees had mid-flexion instability, which is defined by a peak mid-flexion gap that is 3 mm greater than the smaller value of flexion or extension gap. The average MA was well corrected from varus 11.4° to varus 1.0° postoperatively. The proportion of postoperative well-aligned knees ($MA \leq 3^\circ$) was 87.1%. The joint line height was well preserved (14.7 vs. 14.8 mm, $p = 0.751$). The joint stability graph in TKA using the navigation can effectively evaluate the continuous gap throughout the ROM, including the mid-flexion range. Mid-flexion instability was uncommon in primary TKAs with appropriate alignment and proper preservation of the joint line. The Level of evidence for the study is IV.

Keywords

- ▶ knee
- ▶ arthroplasty
- ▶ mid-flexion
- ▶ navigation
- ▶ gap

One of the major goals of total knee arthroplasty (TKA) is to balance the soft tissue,^{1–4} which means creating equal and rectangular gaps during knee range of motion (ROM). Meanwhile, the gap balancing has been mainly focused at knee positions of 0° and 90°,⁵ but there has been recent concern regarding balancing the knee in mid-flexion be-

tween 0° and 90°; one previous study reported that a significant proportion of patients with balanced extension–flexion gaps had mid-flexion instability.⁶ However, most previous studies measured the gaps discontinuously at the specific angle of knee flexion when evaluating the soft tissue balancing in the mid-flexion range.^{6–10}

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It is thought that continuous assessment of gap balancing throughout the whole ROM may help to detect mid-flexion or other instability more precisely, but no clinical studies have been performed with this method.⁵

Varying prosthetic alignments have direct implications for the surrounding soft tissue tension.³ Therefore, there must be optimal alignment prior to assessing flexion–extension or mediolateral gaps. The use of computer-assisted navigation can improve the accuracy and precision of alignment correction and component positions in TKA.¹¹ Further, a recent software program of imageless navigation for TKA, which is called a joint stability graph or balance in motion, provides the gap information on three-dimensional geometries. This program can also evaluate the gap throughout the full ROM prior to any resection and after any surgical

procedures (►Fig. 1). We suspected that the mid-flexion instability could be detected efficiently using recent navigation, because the gaps were measured throughout the full ROM and surgical errors can be minimized by displaying three-dimensional alignment, the amount of bone resection, and the expected joint gap on one screen (►Fig. 1A).

The purpose of the present study was to assess the continuous gaps in the replaced knee throughout the full ROM in TKA using navigation with a joint stability graph, and to analyze the gap laxity in the mid-flexion range. We hypothesized that the joint stability graph of TKA navigation can accurately detect the gap difference, including mid-flexion instability which would be uncommon in the primary TKA with appropriate alignment and proper preservation of the joint line.

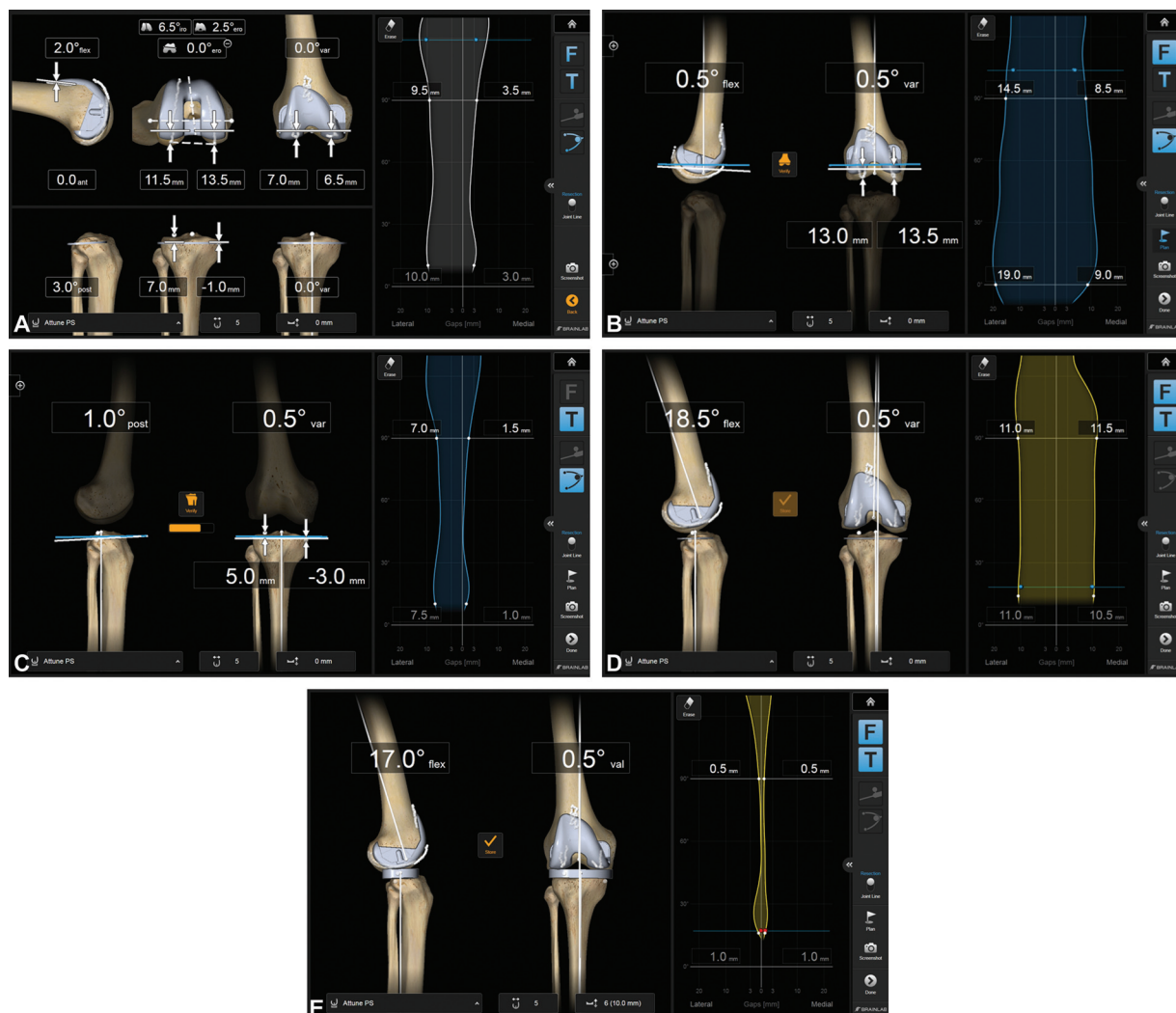


Fig. 1 Navigational workflow. (A) Planning bony resection and expected joint gap. An imageless navigation with a joint stability graph provides the gap information throughout the full ROM with three-dimensional alignments and the amount of bony resection prior to any resection. (B) Distal femoral resection and expected joint gap for the extension gap. The white line represents a target surface, and the blue line represents the current position of the cutting guide for the distal femoral resection. It can prevent elevation of the joint line and widening of the extension gap. (C) Tibial resection and expected joint gap for the flexion and extension gaps. Narrow flexion and extension medial gaps are expected prior to bony resection. Therefore, the amount of tibial resection must be adjusted. (D) Gap assessment with the trial components implanted after bony resection and initial soft tissue balancing. It can be measured from the tibial cut surface. (E) Secondary gap assessment with consideration of polyethylene thickness. It can be measured from the polyethylene insert surface with the appropriate trial insert thickness. ROM, range of motion.

Materials and Methods

Patients

The present study was conducted prospectively, and the data were reviewed retrospectively. Ninety-three TKAs using the Attune posterior stabilized prosthesis (Depuy Synthes, Warsaw, IN) were performed by a single surgeon under the guidance of an imageless navigation with a joint stability graph (Knee3 navigation, BrainLAB, Heimstetten, Germany) between October 2019 and March 2020.

The inclusion criterion was primary TKA due to Kellgren–Lawrence grade 4 degenerative osteoarthritis. The exclusion criteria were as follows: inflammatory arthritis; traumatic or infectious arthritis; a history of knee infection, fracture, dislocation, ligament injury; and reconstructive ligament surgery or high-tibial osteotomy. The preoperative demographics are presented in ►Table 1.

This study was approved by the Institutional Review Board. Informed consent was obtained from all patients before commencing the review.

Surgical Techniques

All TKA procedures were performed using a modified measured resection technique under navigation guidance. A tourniquet was applied. The medial parapatellar approach was adopted with a midline skin incision, and the patella was everted. The reference arrays were placed on the medial side of the distal femur and proximal tibia. The hip center was registered kinematically with hip circumduction. Other anatomical landmarks were registered with the point or surface referencing following the navigational workflow.

The coronal position of the femoral and tibial components was targeted to be mechanically aligned. The sagittal position of the femoral component was set 2° to flexion to avoid anterior femoral notching. The sagittal position of the tibial component was set to 3° of posterior slope (►Fig. 1A). The main reference of the femoral component rotation was the surgical transepicondylar axis; the rotational errors could be minimized by confirming the three-dimensional alignment and expected joint gap (►Fig. 1A). The rotational position of the tibial component was decided by considering the anteroposterior (AP) axis of the proximal tibia, ankle, and foot; this positioning was double-checked with the floating method to be matched to the rotation of the femoral component. While positioning the resection guides for each respec-

tive cut, the surgeon safely previewed the resection's impact on joint stability and thereby controlled the gap balancing (►Fig. 1B, C). The sizes of the femoral and tibial components were selected based on the size of the native femur and tibia under navigation guidance.

After bony resection, osteophyte removal, and initial gap balancing with release of the contracted soft tissue, the trial components were inserted and the gaps were evaluated on the navigation screen (►Fig. 1D). During the navigational gap assessment, one hand was supported on the thigh to align the knee in the sagittal plane. This positioning was used in an attempt to eliminate the external load on the knee during the full ROM with the implanted patella reduction. The medial-lateral gap balances at 0° (extension) and 90° (flexion) of knee position were achieved by ligament release or varus adjustment of the tibial cut surface until the mediolateral gap difference was ≤3 mm. The flexion–extension gap balance was achieved with modification of the tibial posterior slope, posterior capsular release, or additional distal femoral resection until the gap difference was ≤3 mm in both medial and lateral compartments. Next, the secondary gap assessment was performed using the joint stability graph throughout the full ROM considering the appropriate trial insert thickness (►Fig. 1E). The indicated gap at this time referred to the remaining gap between the trial femoral component and the selected trial insert.

All of the patellae were resurfaced. The patellofemoral articulation was carefully evaluated with the no-thumb technique. All components were implanted on cleaned and dried cut surfaces using a full cementation technique.

Shortly after surgery, the patients were instructed to begin isometric exercises involving the extensor and flexor muscles. The drain was removed on the second postoperative day, followed by active and assisted ROM exercises. Based on each patient's condition, full weight-bearing ambulation began 3 days after surgery.

Record of Gap Assessment throughout the ROM

Information regarding the postoperative gaps throughout the ROM was automatically stored in as image files with the joint stability graph. The gap sizes were recorded as numbers (mm) for 0° medial gap, 90° medial gap, 0° lateral gap, and 90° lateral gap (►Fig. 1E). The flexion–extension gap difference in the medial compartment was calculated as the 90° medial gap minus the 0° medial gap. The flexion–extension gap difference in the lateral compartment was also calculated using the same method. Positive values referred to a larger flexion gap rather than an extension gap. The mediolateral gap difference in extension was calculated as the 0° lateral gap minus the 0° medial gap. The mediolateral gap difference in flexion was calculated using the same method. Positive values refer to a larger lateral gap compared with the medial gap.

A peak mid-flexion gap between 0 and 90° was measured if the joint stability graph was convex shaped (►Fig. 2A, B). The mid-flexion gap difference was defined by subtracting the small value of flexion or extension gap from the peak mid-flexion gap. Mid-flexion instability was determined by a

Table 1 Demographic data

	Number of subjects or mean ± standard deviation
No. of knees (patients)	93 (63)
Age (y)	73.3 ± 5.6
Sex (female/male)	57/6
Body mass index (kg/m ²)	25.8 ± 2.9
Side (right/left)	48/45
Follow-up period (year)	1.2 ± 0.4

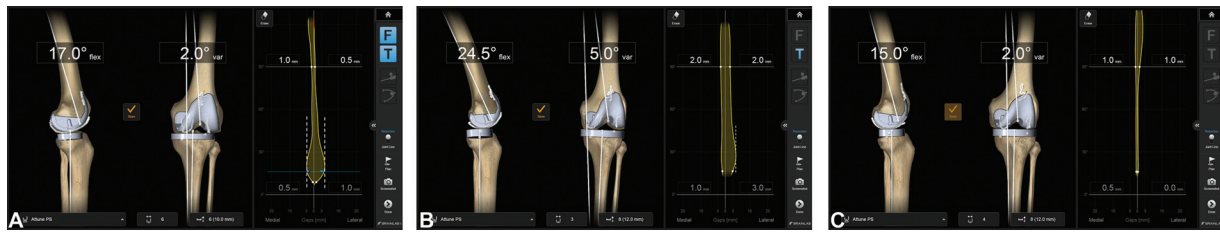


Fig. 2 Joint stability graph of convex, rectangular, and concave shapes. (A) Convex pattern in both compartments. (B) Convex pattern only in the lateral compartment. (C) Rectangular pattern in the medial compartment and concave pattern in the lateral compartment.

mid-flexion gap difference >3 mm according to previous studies.^{5,6} The peak mid-flexion gap, mid-flexion gap difference, and occurrence of mid-flexion instability were all evaluated in both medial and lateral compartments when there were convex-shaped graphs in both compartments (**► Fig. 2A**). These values were evaluated in one compartment when the convex-shaped graph was observed in only the medial or lateral compartment (**► Fig. 2B**). If the joint stability graphs showed a rectangular or concave pattern throughout the ROM, the peak mid-flexion gap and mid-flexion gap difference were not evaluated, and it was determined that there was no mid-flexion instability (**► Fig. 2C**).

Clinical Evaluation

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)¹² and ROM were recorded preoperatively and at 1 year postoperatively. The ROM was measured using a long-armed goniometer.

Radiographic Evaluation

The radiographic parameters were measured preoperatively and at 1 year postoperatively. The pre- and postoperative AP and lateral radiographs, as well as the orthoroentgenograms (full-length standing AP radiographs), were obtained under weight-bearing conditions. The quality of the radiographs was improved using a standardized radiographic protocol regarding the knee positioning and an identical distance between the X-ray beam and cassette.¹³ The true AP radiographs and orthoroentgenograms were taken with the patient standing with the knee fully extended and the feet slightly rotated to ensure forward placement of the knees. For the true lateral radiographs, an effort was made to superimpose the medial and lateral femoral condyles of the distal femur on the radiographs.

The pre- and postoperative mechanical axes were defined by the angle between the femoral and tibial mechanical axes on the orthoroentgenograms.¹⁴ The AP and lateral radiographs were closely analyzed to identify the α , β , γ , and δ angles according to the Knee Society radiological evaluation method.¹⁵ The joint line height was evaluated on the AP radiograph. This height was defined by the shortest distance between the fibular head and the lateral femoral condyle¹⁰ (**► Fig. 3**). The change in the joint line height was determined by the difference in height between the preoperative and 1-year postoperative values.

The images were transferred digitally to a picture archiving and communication system (PACS) (INFINITT, Seoul,

Korea). The radiographic magnification of all of the measurements was corrected using the PACS ruler. The assessment was performed on a 61-cm (24-inch) monitor (SyncMaster 2494HMN; Samsung, Seoul, South Korea) in the portrait mode using the PACS software. The minimum differences that the software could detect were 0.1° in angle and 0.1 mm in length.¹⁶

To minimize observation bias, two orthopaedic surgeons who did not participate in the surgeries repeatedly performed all the radiographic measurements at an interval of 2 weeks. The intra- and interobserver reliabilities of all measurements were assessed using the intraclass correlation coefficient (all values of which were >0.8). Therefore, the average values between the two investigators were used for the analysis.

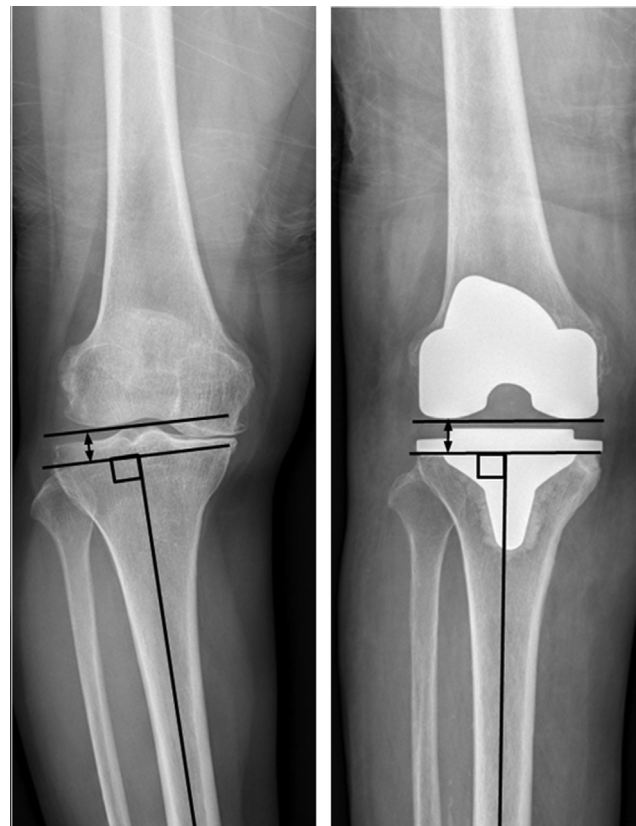


Fig. 3 Radiographic measurement of the joint line height from the fibular head. The preoperative and postoperative joint line heights were measured on the anteroposterior radiograph. It was defined as the shortest distance between the fibular head and the lateral femoral condyle.

Statistical Analysis

For the intraoperative gap assessment, a descriptive analysis was performed for the medial and lateral gaps at knee flexion and extension, the flexion–extension gap difference in the medial and lateral compartments, and the mediolateral gap difference in extension and flexion. In the cases with a convex-shaped joint stability graph, a description analysis was performed for the peak mid-flexion gap and mid-flexion gap difference. When there was the convex-shaped graph in both medial and lateral compartments, the peak mid-flexion gap and mid-flexion gap difference were compared between the compartments (paired *t*-test). The incidence of mid-flexion instability was also investigated.

The pre- and postoperative clinical and radiographic results were compared using the paired *t*-test. The proportions of well-aligned knees (postoperative mechanical axis [MA] $\leq \pm 3^\circ$) were investigated. The cut-off value of MA $\leq \pm 3^\circ$ was selected based on consideration of the measurement accuracy of the radiographs and the general trend of previous work.^{17–19} The preoperative and postoperative joint line heights were compared using a paired *t*-test. The correlation between the pre- and postoperative joint line heights was also analyzed. Statistical analyses were performed using SPSS version 18.0 (Chicago, IL). A *p*-value of <0.05 was considered statistically significant.

Posthoc power analyses using a significant α value of 0.05 were performed on the proportion of the mid-flexion instability as a primary outcome to determine whether the sample had sufficient power. A power $>80\%$ was considered to be sufficient. The results demonstrated that our study was adequately powered (100%) (**►Supplementary Material**, available in the online version only). The analysis was also performed on the secondary outcomes, and the powers for the secondary outcomes with statistical significances were also sufficient ($>99\%$) (**►Supplementary Material**, available in the online version only).

Results

The intraoperative medial and lateral gaps at knee flexion and extension are summarized in **►Table 2**. None of the knees had a flexion–extension gap difference of >3 mm in both compartments or mediolateral gap difference of >3 mm in extension and flexion.

There were 26 cases (27.9%) with convex joint stability graphs in the medial and lateral compartments (**►Fig. 2A**), and 22 cases (23.7%) with the convex graph in the lateral

compartment only (**►Fig. 2B**). The other 45 cases (48.4%) demonstrated rectangular or concave patterns in the joint stability graph (**►Fig. 2C**). In 26 cases with the convex graph in both compartments, the peak mid-flexion gap was 2.8 mm (standard deviation [SD]: 0.7 mm) in the medial compartment and 4.4 mm (SD: 0.7 mm) in the lateral compartment ($p < 0.001$). The mid-flexion difference was 1.1 mm (SD: 0.5 mm, range: 0.5–2.5 mm) in the medial compartment, and 2.0 mm (SD: 0.7 mm, 0.5–3 mm) in the lateral compartment in these 26 cases ($p < 0.001$). In the other 22 cases, the convex graph was only in the lateral compartment, with a peak mid-flexion gap of 3.9 mm (SD: 1.2 mm) and mid-flexion difference of 1.4 mm (SD: 0.8 mm, range: 0.5–3 mm). None of the knees had mid-flexion instability in cases with a convex stability graph in any compartment.

Clinically, the average WOMAC score increased from 66.0 to 15.7 at the final follow-up ($p < 0.001$), and the ROM averaged 120.8° preoperatively and 132.4° at the final follow-up ($p < 0.001$; **►Table 3**). Radiographically, the average preoperative MAs were 11.4° varus, while the average postoperative MA was 1.0° varus (**►Table 3**). The overall component positions were appropriate (**►Table 3**). Postoperatively, 87.1% of knees were well aligned (**►Fig. 4**). The joint line height was also well preserved (14.7 vs. 14.8 mm, $p = 0.751$) (**►Table 3**). There was a strong and significant correlation between the pre- and postoperative joint line height ($r = 0.760$, $p < 0.001$) (**►Fig. 5**).

Discussion

The most important finding of the present study was that continuous soft tissue balancing can be achieved in primary TKA (with a well-aligned and properly preserved joint line) when the femorotibial gap in the replaced knee is quantified throughout the ROM using navigation with a joint stability graph. Most surgeons apply various methods such as spatula, offset tension device, navigation, and wireless sensor to objectively assess the gap balancing with implant components and patellar reduction.^{6–10,20} However, prior work has only quantified the gap or tension at specific degrees of full extension, mid-flexion, and deep flexion rather than continuously throughout the full ROM.^{6,8–10,21} In a cadaveric study, Shalhoub et al⁵ applied robotic-assisted gap balancing in the full ROM; this group aimed for equal gaps at 0° and 90° of flexion, and produced equal gaps in knee extension and flexion with 2 to 4 mm larger gaps in mid-flexion. The

Table 2 Medial and lateral compartmental gaps

	Medial compartment	Lateral compartment	Medial–lateral gap difference
0° of knee flexion	1.2 ± 1.1	2.0 ± 1.4	0.8 ± 1.0 (range: -2.5 to 3)
90° of knee flexion	2.0 ± 1.1	2.4 ± 1.2	0.4 ± 1.1 (range: -2.5 to 3)
Flexion–extension gap difference	0.7 ± 1.2 (range: -2.5 to 3)	0.4 ± 1.4 (range: -2.5 to 3)	

Table 3 Clinical and radiographic results

	Preoperative	Postoperative	p-Value
Clinical results			
WOMAC score ^a	66.0 ± 4.9	15.7 ± 3.5	<0.001
Range of motion (°)	120.8 ± 19.7	132.4 ± 6.3	<0.001
Radiographic results			
Mechanical axis (°)	Varus 11.4 ± 5.2	Varus 1.0 ± 1.9	<0.001
Position of components (°)			
α angle		96.3 ± 1.6	
β angle		90.2 ± 1.1	
γ angle		1.4 ± 1.9	
δ angle		88.2 ± 1.5	
Joint line height (mm)	14.7 ± 3.8	14.8 ± 4.4	0.751

Abbreviation: WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

^aData are presented as mean ± SD.

current study assessed the gap of the replaced knee by applying imageless navigation with a joint stability graph throughout the ROM in clinical practice. We could not detect mid-flexion instability >3 mm in every knee, but could identify the mid-flexion laxity in which the mid-flexion gap difference was ≤3 mm in 48 knees (51.6%).

Mid-flexion instability is a term that came into existence after Martin and Whiteside⁸ found a considerable increase in laxity in the mid-flexion range by shifting the femoral component 5 mm proximal and 5 mm anterior in 10 cadav-

eric knees. This instability is thought to result from laxity in the mid-flexion range of the superficial medial collateral ligament (MCL), which otherwise behaves in a near isometric fashion.²² In a conceptual model with a 4 mm smaller femoral component in a 4 mm proximal position and a 4 mm thicker polyethylene insert (all compared with normal), the femoral insertion site of the superficial MCL no longer coincided with the center of rotation; therefore, the superficial MCL slackened in its mid-flexion range as the knee flexes around a new center of rotation.²¹

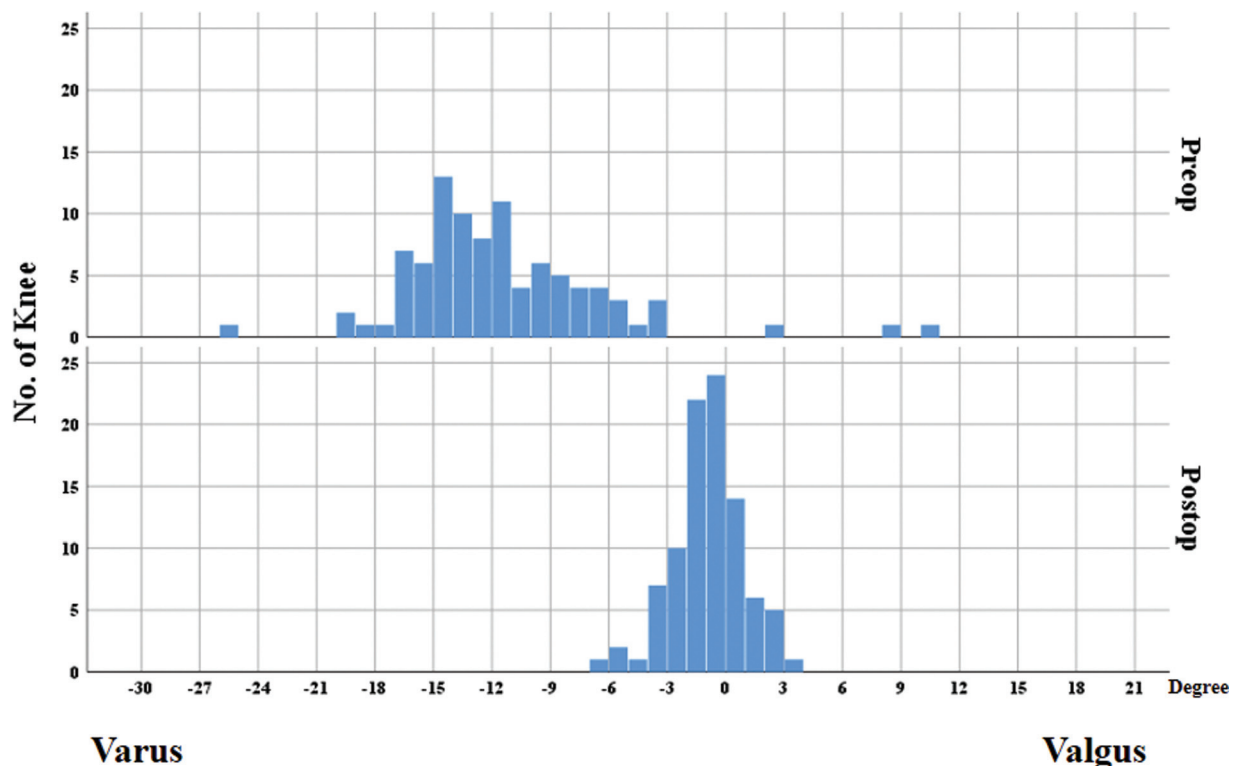


Fig. 4 Distribution of preoperative and postoperative alignments. Preoperatively, most patients had a varus deformity. The proportion of postoperatively well-aligned (postoperative mechanical axis ≤3°) joints was 87.1%.

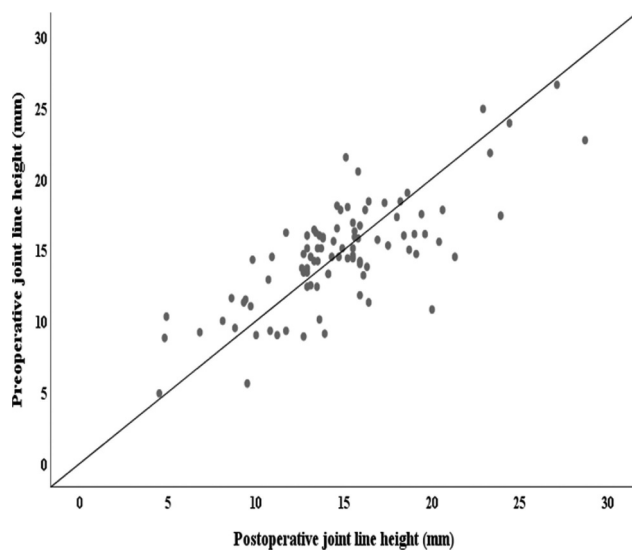


Fig. 5 Scattergram of preoperative and postoperative joint line heights. The pre- and postoperative joint line heights were well correlated ($r = 0.760$, $p < 0.001$).

However, in clinical practice, the proximal and anterior shift of the joint line by as much as 4 to 5 mm as described in cadaveric studies in primary TKA is uncommon.^{8,21} This shifting is even less common when TKA is performed using measured resection techniques and navigation displaying the three-dimensional alignment, amount of bone resection, and expected joint gap. A previous study reported that a 2-mm joint line elevation was not associated with mid-flexion instability in a simulated model using the trial femoral component with a 2-mm thinner distal and posterior condyle.⁹ In our study, the joint line height was well preserved (14.7 vs. 14.8 mm). Our low incidence of mid-flexion instability will be caused by proper joint line restoration with a measured resection technique using navigation. Although a previous study demonstrated that 28% of primary TKA had mid-flexion instability of >3 mm when the rectangular extension-flexion gap was achieved with navigation using the gap balancing technique,⁶ such a high incidence of mid-flexion instability has been attributed to their gap technique with an average joint line elevation of 2.8 mm.

Additionally, the appropriate size of the femoral component was based on the original AP size of the native femoral condyle under navigation guidance with surface registration in the present study. Furthermore, we used a prosthesis that has the following important characteristics: large conformity with a radius curve on the femoral component; an extensive range of sizes (for the femoral component); and an s-curve design in the cam and post for gradual femoral rollback and stability.^{23–26} These prosthetic features may have contributed to the low incidence of mid-flexion instability in this study.²⁷

Currently, there are no definitive diagnostic criteria for mid-flexion instability, and it is difficult to find exhaustive evidence on mid-flexion instability as an isolated entity.^{28,29} In particular, it is difficult to determine how much mid-

flexion instability is clinically meaningful when considering the mediolateral and flexion laxity in the physiologic kinematics of the native knee.⁵ In the present study, the mid-flexion instability was defined as the 3 mm greater difference between the peak mid-flexion gap and the smaller value of the flexion or extension gap.^{5,6} However, there were 48 knees with a convex-shaped joint stability graph in which the mid-flexion gap difference was ≤ 3 mm. The incidence of the mid-flexion instability would be increased if the cut-off value were less than 3 mm. It is necessary to conduct further research with different criteria for mid-flexion instability to analyze the incidence of mid-flexion laxity of the replaced knee, compare the clinical results, and determine its associated risk factors.

Interestingly, the peak mid-flexion gap and mid-flexion gap difference in the lateral compartment were greater than those in the medial compartment in 26 knees with convex-shaped stability graphs in both compartments. In addition, there were 22 knees with a convex graph in the lateral compartment only; none of the knees had a convex graph in the medial compartment alone. A previous radiographic study reported that the lateral collateral ligament complex has greater mobility in mid-flexion due to the rotational axis based in the medial side of the knee.³⁰ This mobility can induce mid-flexion laxity that is more prominent on the lateral side in the native knee than it is on the medial side.³⁰ Another study using a novel robotic tensiometer also identified a larger lateral gap than the medial gap in the mid-flexion range in both native and replaced cadaveric knees.⁵

This study has several limitations. First, the study had no control group. However, it is ethically impossible to use the previous version of the navigation without a joint stability graph, or to measure the gap with navigation after conventional bony resection. Therefore, this is an inherent limitation of clinical studies. Second, the intraoperative gap assessment in nonweight bearing and nondynamic conditions under anesthesia with an inflated tourniquet might be different to the postoperative gap, which is clinically more meaningful. However, this is a limitation in all studies of similar design. Third, we did not consider the possibility of differences in the incidence of mid-flexion instability according to methodological differences in gap assessment. As we described, the incidence of mid-flexion instability would be increased if the cut-off value of the mid-flexion gap difference was less than 3 mm. Finally, the TKA procedures were performed with the modified resection technique using a single prosthesis by an experienced surgeon. All of the included patients had degenerative osteoarthritis arthritis, and the majority of the patients were female. Therefore, caution must be taken when generalizing our findings to other patient populations.

Conclusion

The joint stability graph in TKA using navigation can effectively evaluate a continuous gap throughout the ROM, including the mid-flexion range. Mid-flexion instability was uncommon in the primary TKA with appropriate alignment and proper preservation of the joint line.

Conflict of Interest

None declared.

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