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The medial gap is a reliable indicator for intraoperative soft tissue balancing in posterior-stabilized total knee arthroplasty

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ABSTRACT

Background: Appropriate soft tissue balance and accurate alignment are important for successful total knee arthroplasty (TKA). However, the optimal technique for establishing and measuring soft tissue balancing remains unclear. The aim of this study was to analyze the intraoperative medial and lateral gap pattern using digital knee balancer in posterior-stabilized (PS) TKA.

Methods: This study involved 55 patients with medial osteoarthritis who underwent a primary TKA using an image-free navigation system. The extension gap and the flexion gap at 90° knee flexion were assessed using an offset seesaw-type digital balancer. Continuous joint distraction force from 10 lb to 60 lb was applied. Medial gap, lateral gap, and varus angle were measured.

Results: The medial bone gap difference between extension and flexion was constant regardless of the distraction force from 20 lb to 60 lb. The lateral bone gap was significantly greater than the medial bone gap in extension and flexion from 30 lb to 60 lb ($P < 0.05$). The varus angle changed depending on the distraction force, especially in flexion. The varus angle in flexion was significantly greater than that in extension from 40 lb to 60 lb ($P < 0.05$).

Conclusions: The medial bone gap is a reliable indicator unaffected by the distraction force during surgery and is useful for adjusting the medial gap in extension and flexion appropriately to ensure medial stability in PS-TKA. The digital knee balancer and navigation system support both precise gap assessment and surgery.

1. Introduction

Achievement of appropriate soft tissue balance and accurate alignment are important for successful total knee arthroplasty (TKA) [1–3]. Insall et al. initially recommended balancing the knee ligaments by creating equal and rectangular gaps in flexion and extension [4]. This recommendation has been generally accepted and the importance of this balancing technique has been reported in clinical studies and kinematic studies [5–9]. Many papers report that soft tissue imbalance causes poor clinical results with a limited range of motion [10–12]. Postoperative kinematic analysis obtained from clinically excellent and well-balanced cases show consistent pattern in motion such as knee bending and squatting [13,14]. The gap-balancing technique has been shown in the literature to be more accurate than the measured resection techniques to prevent imbalance of the knee [15–17]. It has been found that TKA cases with preoperative valgus knees treated with the balancing

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technique showed excellent clinical results and similar kinematics to those with preoperative varus knee [14]. Therefore, proper balancing of the soft tissue in both preoperative varus and valgus knee are the key to the success of TKA and hence clinical outcomes.

In posterior-stabilized (PS) TKA, flexion gap tends to become larger due to posterior cruciate ligament (PCL) resection [18], therefore appropriate control of the extension–flexion gap is extremely important to achieve. However, the optimal technique for establishing and measuring soft tissue balancing remains unclear [19,20]. In practice, accurate balancing and measurement of the gaps can be difficult in these maneuvers. To date, such feeling-based methods have been replaced with a quantitative method. To accurately measure the gaps and to achieve proper gap balancing, many tension devices and various intraoperative spreaders or distraction devices have been developed. These tension-measuring devices provide quantitative data of the balancing [21]. From these studies, lateral tibiofemoral articulation is reported to be lax compared with the medial articulation [22,23] and the balance is reported to change with joint distraction force [24]. Even with these pieces of information, the gap-balancing technique remains somewhat subjective and requires experience. It does not provide accurate objective data. This is partly because each surgeon measures at a certain different joint distraction force and with a different maneuver. In intraoperative gap measurement, the value changes depending on the joint distraction force. Furthermore, the optimal joint distraction force [25,26] may vary in individual cases and knee position such as extension and flexion. A reliable indicator unaffected by any factors is necessary to measure the intraoperative gap data. Thus far, to record the gap amount and varus angle obtained with continuously increasing force has not been possible. Understanding the precise relationship between applied force and gap obtained by various forces will provide important and suggestive information during knee replacement surgery. We adopted a digital balancer system together with a navigation system to perform accurate TKA.

The aim of this study was to precisely analyze the intraoperative medial gap, lateral gap and varus angle obtained by the consecutively applied joint distraction force using a digital knee balancer and to characterize the gap pattern in PS TKA.

2. Materials and methods

2.1. Patients

The present study involved 55 patients with medial osteoarthritis (Kellgren–Lawrence grade 4) who underwent a primary TKA between the period of June 2017 and December 2017. Lateral osteoarthritis (valgus knee deformity), rheumatoid arthritis, and revision TKA were excluded. The mean age at the time of operation was 73.5 ± 6.8 years (means ± standard deviation; SD), and there were 16 men and 39 women. The mean height was 153.1 ± 7.7 cm, the mean body weight was 64.1 ± 11.7 kg, and the mean body mass index (BMI) was 27.3 ± 4.4 kg/m^2. The average preoperative coronal plane alignment in varus was 11.4° ± 5.2°. Preoperative passive knee extension and flexion angles were – 10.1° ± 8.2° and 132.6° ± 14.9°, respectively. All the surgeries were performed in the author's institution by or under the supervision of one senior author (K.S.). Institutional review board approval was obtained as well as informed consent from all patients participating in this study.

2.2. Surgical procedure

All operations were performed using a midvastus approach, modified gap technique and the same PS type prosthesis (Scorpio NRG; Stryker Orthopedics, Mahwah, NJ, USA). The femoral component of this implant was single radius design. Distal and posterior thickness of the femoral component was 8 mm. In all cases, an image-free navigation system (Stryker Orthopedics, Mahwah, NJ, USA) was used for accurate bone cutting and implantation according to the manufacturer's instructions. The air tourniquet was inflated to 300 mmHg in all cases during surgery. The minimum medial soft tissue release was performed by femoral and tibial osteophyte removal and deep medial collateral ligament (MCL) release. Distal femoral resection was set on the navigation system perpendicular to the mechanical axis in the coronal plane. Although the level of distal femoral resection was adjusted to the implant thickness, resected bone thickness was increased by a few millimeters according to the flexion contracture. Proximal tibial resection was set on the navigation system perpendicular to the mechanical axis in the coronal plane. Tibial posterior inclination in the sagittal plane was set at 3°. Approximately 10 mm of bone was resected from the lateral tibial plateau. After excision of the menisci, the extension bone gap was assessed using digital balancer (details described below). Lateral laxity within 2° obtained by 40 lb of joint distraction force was allowed in this step. The complete removal of osteophyte and, if necessary, reduction osteotomy [27] of medial proximal tibia were performed in advance to release other soft tissues such as superficial MCL and pes anserine tendon. In no case did we need to release the superficial MCL and pes anserine tendon to obtain a proper gap in extension.

Subsequently, the flexion bone gap at 90° knee flexion was assessed to determine the amount of bone thickness to be resected from posterior condyle and axial rotation. Resection thickness of the posterior condyle was determined based on the difference between extension bone gap and flexion bone gap obtained by 40 lb of joint distraction force to match the flexion gap with the extension gap. Flexion gap was almost equalized to extension gap within 2 mm allowance at the most. Femoral rotational alignment was determined based on the varus angle at 90° knee flexion obtained by 40 lb of joint distraction force. After determining the posterior resection thickness and rotational alignment, femoral component size was selected avoiding anterior notching and overstuffing.

The patella was resurfaced to equalize the preoperative thickness in all patients, and a lateral retinaculum release was not performed in any patients. The tibial anterior–posterior (AP) axis of the tibial tray was placed parallel to Akagi's line [28], connecting the center of the PCL to the medial border of the patellar tendon attachment. Polyethylene insert thickness was determined based on the knee stability and joint component gap in extension. The average thickness of the polyethylene insert was 10.5 ± 1.5 mm.

2.3. Gap measurement

The extension bone gap and the flexion bone gap at 90° knee flexion were assessed using an offset seesaw-type digital balancer (DynAccurate, A&D, Tokyo) with the patellofemoral joint reduced by temporarily applying two stiches proximal and distal to the patella (Fig. 1). Within the balancer, a load cell, angle sensors, and gap sensors were applied in the selected part. The balancer has both a femoral side tray and a tibial side tray. Underneath the tibial tray of the balancer, the center peg was attached to engage the tibial peg hole and the rotational alignment to the tibia was adjusted. Continuous joint distraction force from 10 lb to 60 lb was applied. This balancer can measure three values (force, angle, gap) at the same time and automatically record the values. Medial bone gap, center bone gap, lateral bone gap, and varus angle were measured (Fig. 2). For determining the thickness of the posterior condyle to be resected, the difference between extension bone gap and flexion bone gap (extension bone gap – flexion bone gap) was calculated in order to match the flexion gap with the extension gap when implanting the femoral component.

After resection of the posterior condyle and other surfaces of femur, femoral and patellar trial component were inserted in anatomical position. Joint component gap in extension and flexion at 90° was assessed with the digital balancer on the tibial cut surface, and patellofemoral joint reduced by applying two temporary stitches. Joint flexion and extension angle were confirmed by navigation system.

2.4. Statistical analysis

Statistical analysis was carried out using Ekuseru–Toukei software (Social Survey Research Information Co. Ltd., Tokyo, Japan). Statistical comparisons were performed using the non-parametric Mann–Whitney *U*-test. Statistical evaluation of the bone gap difference between extension and flexion obtained by various joint distraction force performed using one-way analysis of variance (ANOVA) followed by Tukey's multiple comparison test. All differences were considered significant at a probability level of 95% ($P < 0.05$). Data are represented as means ± SD.

3. Results

In the coronal plane, there were no outliers over 3° determined on postoperative plain long film.

3.1. Analysis of the bone gap

At first, the extension and flexion bone gap in the medial and lateral compartments were analyzed, respectively. The extension and flexion bone gap in each compartment increased with joint distraction force. The lateral bone gap was significantly greater than the medial bone gap in extension and flexion from 30 lb to 60 lb (Fig. 3). Secondly, the medial and lateral bone gap in extension and flexion were analyzed, respectively. The medial bone gap pattern in extension and flexion was similar and changed in proportion to the joint distraction force (Fig. 4A). The difference in the medial bone gap between extension and flexion (extension bone gap - flexion bone gap in the medial compartment) was constant regardless of the joint distraction force from 20 lb to 60 lb (Fig. 4B, Table 1). The difference in the lateral bone gap between extension and flexion (extension bone gap - flexion bone gap in the lateral compartment) changed depending on the joint distraction force indicating the reduced stiffness of the lateral compartment in flexion (Fig. 4C and D; Table 1).

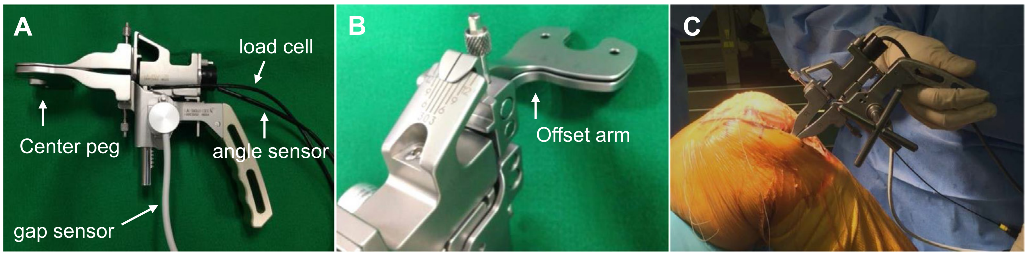

Fig. 1. (A, B) The digital knee balancer was manufactured by applying load cell, angle sensor, and gap sensor in the selected part within the offset seesaw type balancer. This balancer can measure three values (force, angle, gap). (C) Intraoperative gap measurement. The extension and flexion bone gap were assessed using this balancer with the patellofemoral joint reduced.

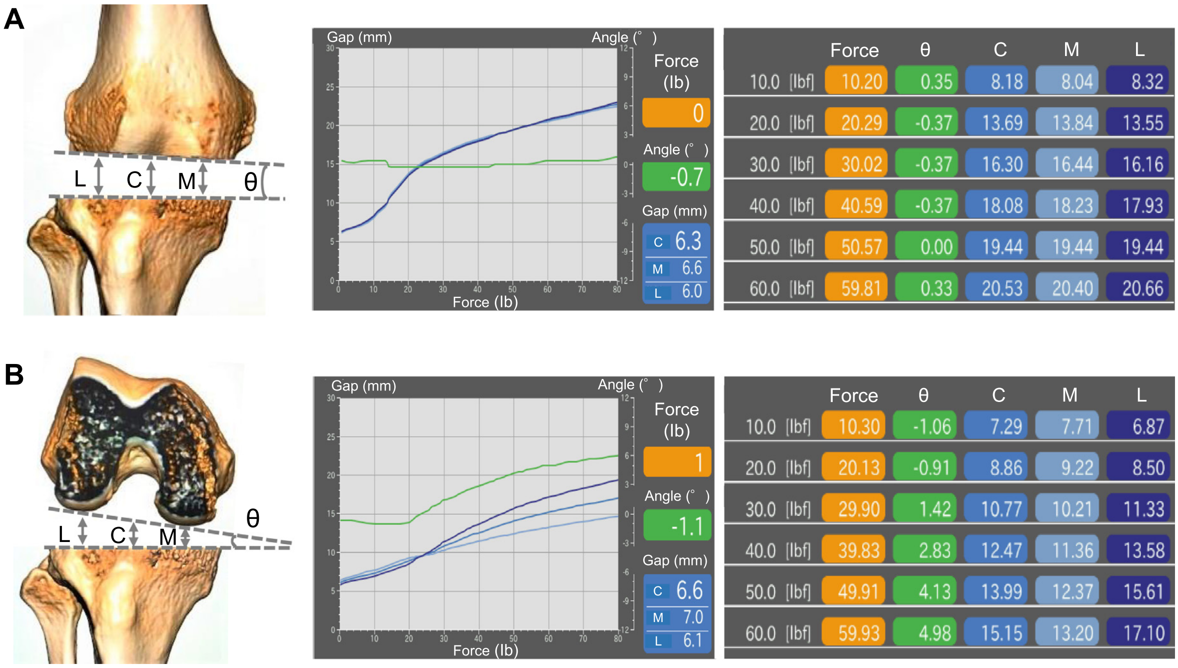

Fig. 2. (A) Extension gap measurement. (B) Flexion gap measurement. The digital balancer can measure three values (force, angle, gap) at the same time and automatically record the values. θ, varus angle (°); C, center gap length (mm); M, medial gap length (mm); L, lateral gap length (mm).

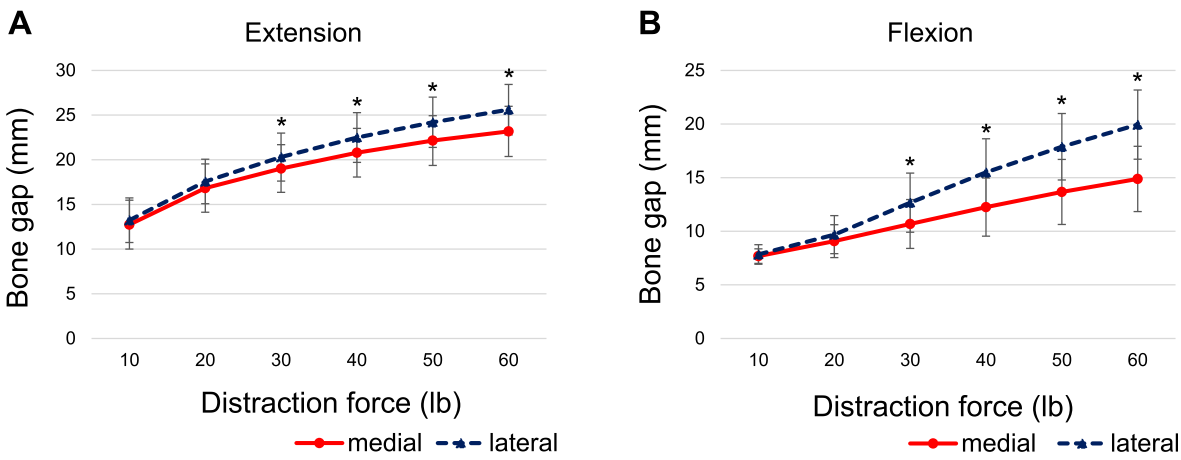

Fig. 3. (A) The extension bone gap in medial and lateral compartments. (B) The flexion bone gap in medial and lateral compartments. The lateral bone gap was significantly greater than the medial bone gap in extension and flexion from 30 lb to 60 lb (*$P < 0.05$).

3.2. Analysis of the varus angle

The varus angle also changed depending on the joint distraction force, especially in flexion (Fig. 5). The varus angle in flexion was significantly greater than that in extension from 40 lb to 60 lb. The mean varus angle in extension increased from 2.19 ° to 2.64 ° and 3.14 ° with increasing the force from 40 lb, to 50 lb and 60 lb, respectively. The mean varus angle in flexion is shown in Table 1.

3.3. Analysis of the joint component gap

Furthermore, joint component gap with the femoral component in place was analyzed. Lateral component gap was significantly greater than medial component gap from 40 lb to 60 lb in extension and flexion (Fig. 6). The mean gap difference between medial and lateral compartment (lateral component gap - medial component gap) in extension increased from

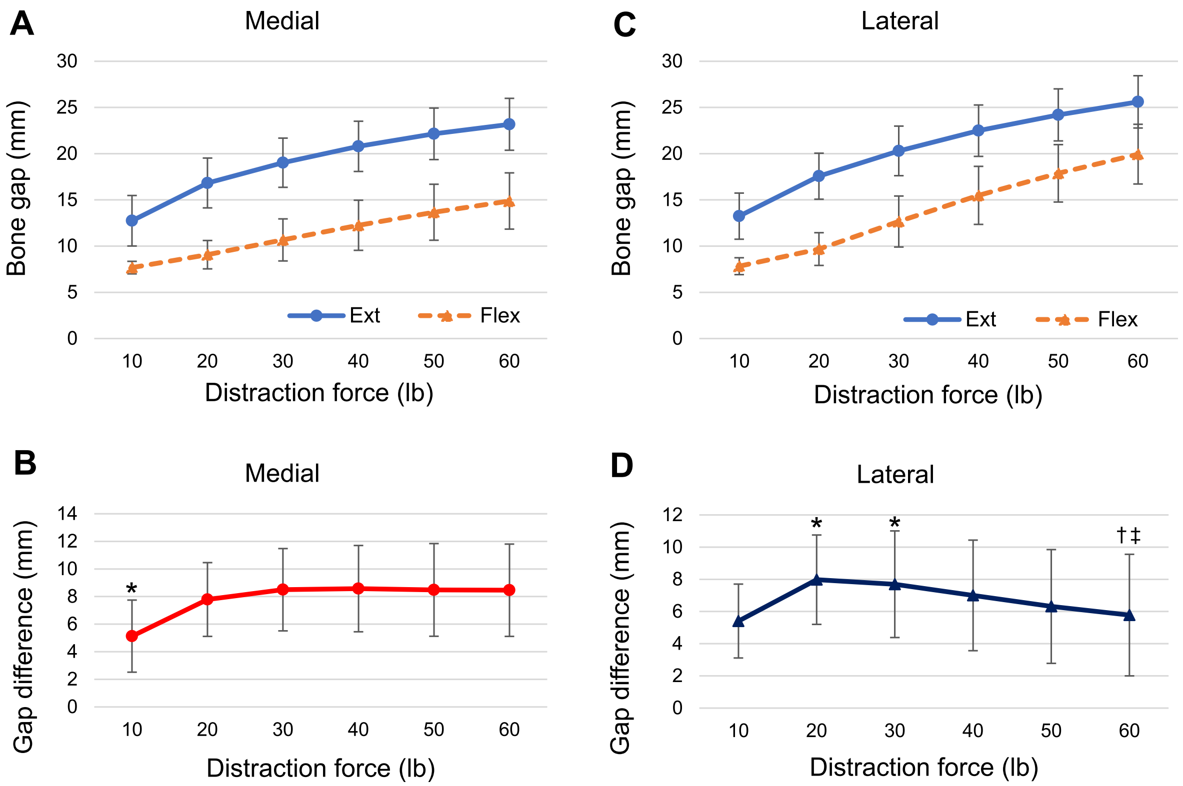

Fig. 4. (A) The medial bone gap in extension and flexion. (B) The bone gap difference (extension bone gap – flexion bone gap) in the medial compartment was constant regardless of the joint distraction force from 20 lb to 60 lb. There was a significant difference between 10 lb and 20–60 lb (*$P < 0.01$). There was no significant difference in the bone gap difference from 20 lb to 60 lb. (C) The lateral bone gap in extension and flexion. (D) The bone gap difference in the lateral compartment changed depending on the joint distraction force. * Significant difference compared with 10 lb (*$P < 0.01$); † significant difference compared with 20 lb (†$P < 0.01$); ‡ significant difference compared with 30 lb (‡$P < 0.05$).

Table 1
Details of gap difference and varus angle in flexion.

(lbs)	Medial GD (mm)	Lateral GD (mm)	Varus angle in flexion (°)
10	5.13 ± 2.61	5.40 ± 2.30	0.20 ± 1.59
20	7.79 ± 2.67	7.98 ± 2.78	0.78 ± 2.37
30	8.50 ± 2.98	7.69 ± 3.31	2.55 ± 3.29
40	8.57 ± 3.13	7.00 ± 3.43	4.14 ± 3.78
50	8.48 ± 3.36	6.31 ± 3.53	5.39 ± 4.09
60	8.46 ± 3.35	5.78 ± 3.77	6.49 ± 4.22

Data are represented as mean ± standard deviation. GD, gap difference (extension bone gap – flexion bone gap).

0.97 mm to 1.21 mm and 1.56 mm with increasing the force from 40 lb, to 50 lb and 60 lb, respectively. The mediolateral gap difference in extension was less than 2 mm through the whole joint distraction force (Fig. 6A). The mean gap difference between medial and lateral compartment in flexion increased from 1.14 mm to 2.02 mm and 2.74 mm with increasing the force from 40 lb, to 50 lb and 60 lb, respectively. The mediolateral gap difference in flexion was less than 3 mm through the whole joint distraction force (Fig. 6B).

The flexion component gap was significantly greater than the extension component gap from 50 lb to 60 lb in the medial compartment, and from 40 lb to 60 lb in the lateral compartment (Fig. 7). The mean gap difference between extension and flexion (flexion component gap – extension component gap) in the medial compartment increased from 1.22 mm to 1.38 mm with increasing the force from 50 lb to 60 lb, respectively. The gap difference between extension and flexion in the medial compartment was less than 2 mm through the whole joint distraction force (Fig. 7A). The mean gap difference between extension and flexion in the lateral compartment increased from 1.04 mm to 2.03 mm and 2.56 mm with increasing the force from 40 lb, to 50 lb and 60 lb, respectively. The gap difference between extension and flexion in the lateral compartment was less than 3 mm through the whole joint distraction force (Fig. 7B).

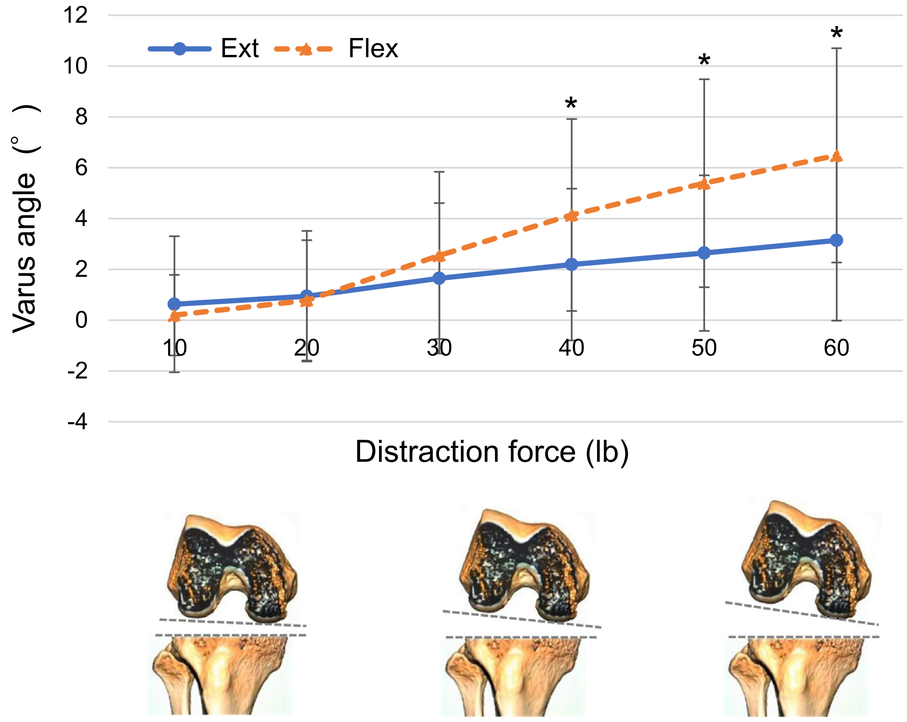

Fig. 5. The varus angle in extension and flexion. The varus angle changed depending on the joint distraction force, especially in flexion. The varus angle in flexion was significantly greater than that in extension from 40 lb to 60 lb (*$P < 0.05$). The illustration shows the varus angle in flexion by various joint distraction forces.

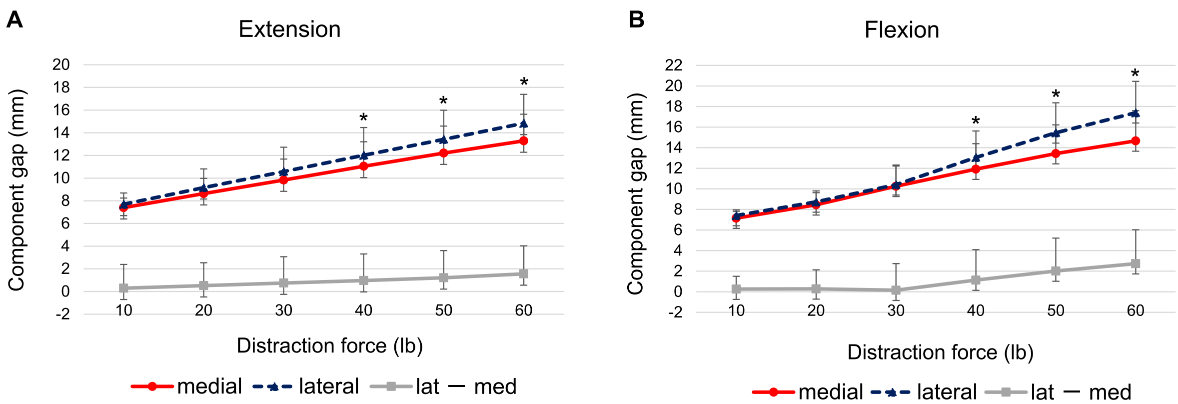

Fig. 6. (A) The extension component gap in medial and lateral compartments. (B) The flexion component gap in medial and lateral compartments. The lateral component gap was greater than the medial component gap from 40 lb to 60 lb in extension and flexion (*$P < 0.05$). The component gap difference between medial and lateral compartment (lateral component gap - medial component gap (lat - med)) was less than 2 mm in extension and 3 mm in flexion through the whole joint distraction force.

4. Discussion

Soft tissue balancing is important for successful TKA [2], however, the detail of this procedure has been unclear [20]. In intraoperative gap measurement, a reliable indicator unaffected by any factors is ideal. In this study, we reported gap patterns using a digital knee balance analyzer in vivo. Using an offset balancer, Nagai et al. reported a relationship between the joint distraction force and the soft tissue balance in TKA [24]. Our data shows a more precise and detailed relationship using a digital system. The digital balancer measures an applied force, gap length, and inclination angle simultaneously and shows on a computer output. The applied distraction force can be continuous, thus showing even a small change in the gap and any inclination produced by a small change in applied force. Reproducibility of each analysis in extension and flexion was maintained (Fig. 2). Using the device, gap length and varus angle are shown in a graph, which is visualized as curved line. We can

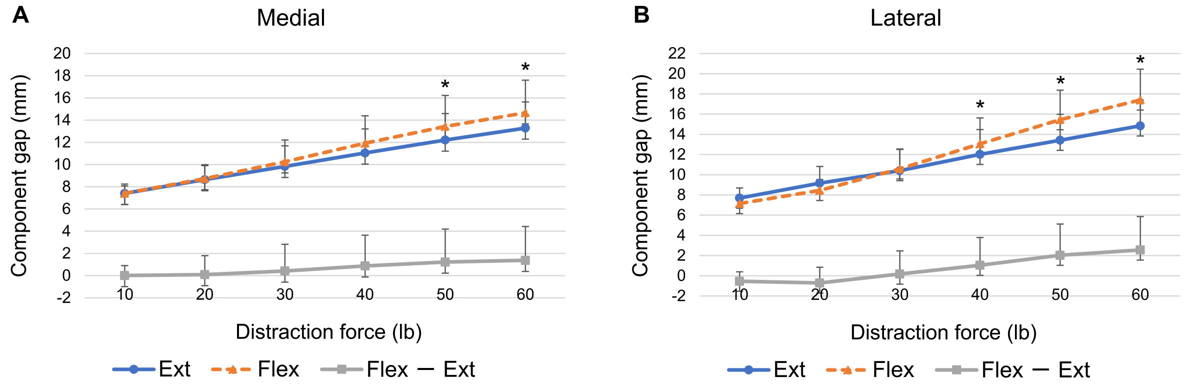

Fig. 7. (A) The medial component gap in extension and flexion. (B) The lateral component gap in extension and flexion. The flexion component gap was greater than the extension component gap from 50 lb to 60 lb in the medial compartment, and from 40 lb to 60 lb in the lateral compartment (*$P < 0.05$). The component gap difference between extension and flexion (flexion component gap – extension component gap (Flex – Ext)) was less than 2 mm in the medial and 3 mm in the lateral compartment through the whole joint distraction force.

measure the gap repeatedly and discard measurement data when the visualized curve contains a spike or an abrupt change. Therefore, the findings in this study are more reliable than the results obtained using a manual balancer which only shows point data with a specific joint distraction force.

In this study, the intraoperative medial gap, lateral gap, and varus angle obtained by the various joint distraction forces were analyzed in PS-TKA. The extension and flexion bone gap in each compartment increased corresponding with the joint distraction force, and the changes in the medial compartment were smaller than those in the lateral compartment. The medial bone gap pattern in extension and flexion was similar and increased in proportion to the joint distraction force. The increasing pattern in the medial bone gap was linear and the medial bone gap difference between extension and flexion was constant, regardless of the joint distraction force. This finding suggests that medial bone gap is a reliable indicator unaffected by the joint distraction force applied during surgery as long as the force is between 20 lb and 60 lb.

Okamoto et al. reported that lateral soft tissue was looser with greater varus deformity, and the contracture of the medial soft tissue did not exist even in severe varus knees [29]. The MCL length shows a nearly isometric pattern between extension and flexion [30]. Our results support these results consistently even though forces over 60 lb were not routinely applied in our study. Here we conclude that the difference in the medial bone gap between extension and flexion is constant regardless of the joint distraction force. In recent years, the importance of medial stability has been recognized in TKA. The medial stability is important for anterior–posterior stability [31], knee kinematics [32,33], and clinical outcomes such as patient satisfaction and knee function [34]. In addition, ingenious methods to keep the medial stability have also been reported [23,35,36]. Although the appropriate soft tissue balance is important, the extensive medial release to obtain a perfect rectangular gap in extension and flexion sometimes leads to irremediable medial instability, resulting in poor outcome [33,37]. The normal knee is medial tight and lateral lax [38,39] and the medial soft tissue length showed an isometric pattern [30]. Therefore, it is reasonable to maintain a constant medial gap throughout the whole arc of motion to keep the medial constraint and conformity. The findings of this study are useful to achieve the medial stabilizing procedure. The medial gap measurement is reliable during surgery and helpful for adjusting the medial gap in extension and flexion adequately to ensure medial stability.

Conversely, the difference in the lateral bone gap between extension and flexion increased depending on the joint distraction force indicating the reduced stiffness in flexion. At the same time, varus angle changed depending on the joint distraction force due to the laxity of lateral compartment, especially in flexion. The lateral compartment was stretched much more than the medial compartment. These observations are consistent with the fact that the normal knee joint is medial tight and lateral lax [38,39]. Our data supports the previous report [24] that the joint gap and lateral opening increases in accordance with increasing joint distraction force, indicating that the stiffness of the medial compartment is greater than the lateral compartment. Our new findings elucidate that an increased gap amount obtained with increased force is larger in flexion than in extension and lateral opening together with the varus ligament balance is observed more apparently in flexion than in extension. This is very important information for determining the femoral axial rotation and resection thickness of the posterior condyle to match the flexion gap with the extension gap.

Because the varus angle changes depending on the joint distraction force, we need to discuss the joint distraction force to be applied. Asano et al. [40] reported that the mean distraction force that created what felt like the proper tension to surgeons was 126 N (approximately 28.3 lb) in extension and 121 N (approximately 27.2 lb) in flexion on average. Heesterbeek et al. [41] considered 200 N (approximately 45 lb) in extension and 150 N (approximately 34 lb) in flexion to be applied, based on the surgeon's experience. Nowakowski et al. [26] reported that 100 N (approximately 22.5 lb) per compartment (a total force 200 N, approximately 45 lb) appeared to be adequate in their cadaveric study. Matsumoto et al. [25] established that 40 lb of joint distraction force corresponded most closely to the insert thickness in their preliminary clinical study. Forty pounds of joint distraction force has been used in many previous reports [8,23,29,31]. Considering these reports together, we usually determine the femoral rotational alignment based on the varus angle at 90° knee flexion obtained by 40 lb of joint distraction force. Femoral rotational alignment based on varus angle at 40 lb in flexion (4.14 ± 3.78 in this study) is within the range between surgical epicondylar axis (SEA) (external rotation from posterior condylar line averaged 3.23 ± 0.82° in this study) and clinical epicondylar axis (CEA) (external rotation from posterior condylar line averaged 6.88 ± 1.39° in this study). In individual cases, we can attain ligament balance in flexion by determining rotational alignment with unified force of 40 lb. However, in rare cases such as severe varus knees with thrust, varus angle can be large because lateral soft tissue is loose. In this situation, if the surgeon adopts the gap-balancing technique, femoral rotational alignment should be determined with minute attention. To prevent excessive external rotation surpassing CEA and to allow slight lateral laxity or give is of paramount importance. We are aiming to control the mediolateral imbalance within 2° in extension and 3° in flexion. The fact that the gap pattern of distance and the opening angle in extension and flexion differ mainly because the lateral side is more lax, especially in flexion is also extremely important for surgeons in deciding femoral rotational alignment.

The TKA cases performed in our method were well balanced. The component gap difference between medial and lateral compartments was less than 2 mm in extension and 3 mm in flexion with increasing the force from 10 lb to 60 lb. The lateral component gap was slightly greater than the medial component gap with applied force >40 lb (Fig. 6). At 40 lb, the component gap difference between medial and lateral compartments averaged 0.97 mm in extension and 1.13 mm in flexion. The component gap difference between extension and flexion was less than 2 mm in medial and 3 mm in lateral compartment with increasing the force from 10 lb to 60 lb. The flexion component gap was slightly greater than the extension component gap with applied force >50 lb in the medial compartment and >40 lb in the lateral compartment (Fig. 7). At 40 lb, the component gap difference between extension and flexion averaged 0.88 mm in medial and 1.04 mm in lateral compartment. In general, such a gap difference is acceptable.

Judging from the final component gap pattern, our surgical technique using a digital balancer seems to be preferable. After analyzing the bone gap pattern, we can determine the amount of bone thickness to be resected from the posterior condyle and the rotation of the femoral component; therefore, predicting the final component gap pattern is possible. Although we could create almost equal and rectangular gaps in extension and flexion with an applied force of 40 lb, the shape of the gap changes depending on the joint distraction force, thus we may need to state, e.g., that 'rectangular gap was obtained with applied force of 40 lb'. In the gap-balancing technique, ligament releases are performed before bone cuts to correct fixed deformities. The limb is brought into the approximate correct alignment after release, and then femoral component is placed parallel to the resected proximal tibia. What exactly controls the balance is the amount of posterior condylar bone resected and the rotation of the posterior cut surface of the femur relative to the tibial bone surface. Using a digital balancer with the updated knowledge that the medial compartment is a reliable indicator, we can obtain appropriate coronal stability in extension and flexion by resecting the posterior condyle properly.

This study has several limitations. Firstly, the patients were limited to those with varus-type osteoarthritis. It is of special interest to compare these data with patterns of valgus knees. We are now analyzing cases with valgus knee and arthritic knee. Secondly, the evaluation was limited to PCL sacrificed knees. We prefer PS knee implant to other types of knee implants. However, a different pattern might be observed with a different implant. The gap pattern of the cruciate-retaining knee should also be clarified. Finally, we have not clarified the clinical outcome of this technique, because the primary objective of this study was to clarify the precise gap pattern in varus knee and to get useful information when adjusting gap balance. However, we have previously reported a kinematic study of valgus knee using the same implant and same gap-balancing procedure with an offset seesaw-type balancer, which showed a medial pivot pattern followed by posterior roll back with clinically excellent results [14]. Large population studies are needed to clarify the detailed clinical outcome and to investigate the reproducibility and usefulness of our surgical strategy.

5. Conclusions

The medial bone gap can be a reliable and useful indicator for intraoperative soft tissue balance in PS-TKA. The digital knee balancer and navigation system support both precise gap assessment and surgery. Although further consideration is required, these findings will be valuable in developing the strategy to achieve the appropriate soft tissue balancing in PS-TKA.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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