A gap balancing technique for adjusting the component gap in total knee arthroplasty using a navigation system

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**Abstract**

**Introduction:** Recently, some studies showed assessment of the component gap is important for determination of the implant-inserted condition during total knee arthroplasty (TKA). We perform the modified gap technique with adjustment of the virtual gap which estimated by computer-aided design (CAD) using navigation system. The purpose of this study was to compare the virtual gap (CAD-gap) with the actual gap after inserting a femoral trial component (Trial-gap), and examine the usefulness of the surgical technique.

**Materials and methods:** The subjects were 35 patients who underwent primary TKA using a navigation system and posterior-stabilized type TKA. The surgical procedure was to produce an extension gap, confirm the flexed CAD-gap on the navigation screen based on CAD data, and plan osteotomy of the femur. After osteotomy, the femoral component was inserted and the gap balance was measured. A tensor was used to adjust and measure the gap balance. Initial alignment, rotation of the femoral component, soft tissue balance in extension, final alignment after fixing all components, and the CAD- and Trial-gaps in both extension and flexion were evaluated.

**Results:** The mean initial alignment angle, rotation angle of the femoral component, soft tissue balance angle and final alignment angle were 8.1 ± 4.2° varus, 3.5 ± 1.3° external rotation, 2.7 ± 2.5° varus and 0.4 ± 1.4° varus respectively. The mean medial and lateral CAD-gaps in extension were 10.8 ± 2.5 mm and 13.7 ± 2.5 mm, and the mean medial and lateral CAD-gaps in flexion were 12.2 ± 2.2 mm and 13.9 ± 2.7 mm. The equivalent Trial-gaps in extension and flexion were 10.2 ± 2.6 mm and 11.4 ± 3.1 mm, and 12.2 ± 2.5 mm and 14.4 ± 2.8 mm. The CAD- and Trial-gaps differed significantly only for lateral gaps in extension.

**Conclusion:** In comparing the CAD-gap and the Trial-gap, only small difference was found in the lateral gap of extension. The other gaps in both extension and flexion were well maintained. We concluded adjustment of the CAD-gap during surgery using a navigation system can be used to adjust the actual component gap especially in the medial side.

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component gap in TKA. Muratsu et al. assessed the bone and component gaps during surgery and found that the gap in extension was smaller with the femoral component, and that the medial soft tissue balance was smaller in extension and larger in flexion.\textsuperscript{13} Assessment of the component gap is important for determination of the implant-inserted condition. For example, in medial knee osteoarthritis (OA), medial instability due to excessive release of medial soft tissues worsens postoperative clinical outcomes.\textsuperscript{14} Therefore, treatment of medial knee OA requires appropriate tension in soft tissues.

In our TKA procedure, we use a navigation system that shows the component gap estimated by computer-aided design (CAD) during surgery (Fig. 1). We perform the modified gap technique with adjustment of this virtual gap, and particularly the medial virtual gap. In this study, we compared the virtual gap with the actual gap into which a femoral trial component was inserted. We hypothesized that the virtual gap shown by CAD would be equal to the actual gap, and that our technique allows adjustment of the gap during surgery. Therefore, the objective of the study was to compare the CAD virtual gap during surgery with the gap after insertion of a femoral trial component, and examine the usefulness of the surgical technique.

Materials and Methods

The subjects were 35 patients (35 knees, 5 male and 30 female) who underwent primary TKA at our hospital using a CT-free Navigation System (Brain Lab; Kick\textsuperscript{®}). The mean age was 74.3 ± 7.0 years old. All patients had medial knee OA. The mean preoperative knee extension was −10 ± 7.7\textdegree and knee flexion was 115.7 ± 17\textdegree. In the evaluation of preoperative X-ray, 4 knees were gradellii and 31 knees were grade IV by Kellgren-Lawrence classification, and the mean Hip-Knee Ankle angle (HKA) was 169.5 ± 5.1\textdegree. Patients with inflammatory disease, lateral knee OA and a history of knee surgery were excluded from the study. The implant used was the Attune knee system, posterior-stabilized type (DePuy, Warsaw, IN).

All patients underwent TKA by a single surgeon (the author). The patients carried out an operation using tourniquet by general anesthesia. After exposing the knee using para-patella approach, two passive optical reference arrays were attached on the distal femur and the proximal tibia. After approval of the center of the hip joint by circumduction, the required anatomical landmarks (femoral epicondyles, anterior femoral cortex, medial and lateral malleolus, tibial plateau magnitude and anterior tibial cortex) were acquired. Extension gap was first produced with mechanical alignment using the navigation system. Among the medial soft tissues, the deep medial collateral ligament (MCL), the attached semimembranosus, and pes anserinus were released in order. At this point, osteophytes of medial femoral condyle and posterior condyle were resected. The target for the soft tissue balance in extension was within 3\textdegree of varus with applying joint distraction forces with 30 lb of both medial and lateral joint gap using a tensor device. Consequently, data for the virtual component gap (CAD-gap) in the knee extension shown on the navigation screen were obtained (Fig. 2). Subsequently, the knee in flexion (90\textdegree flexion) was opened with a tensor (Fig. 3). After confirming the CAD-gap in the knee flexion on the screen, osteotomy was planned with adjustment of the size, the rotation angle and the anteroposterior position of the femur to reduce the difference between the medial CAD-gap in extension and the CAD-gap in flexion to <2 mm. Final osteotomy of the femur was then conducted (Fig. 4). After osteotomy, the femoral trial component was inserted and the extension and flexion component gaps (Trial-gaps) and the soft tissue balance were measured. In adjusting and measuring these parameters, the distraction forces were applied at 30 lb of both medial and lateral joint gap using a Knee Balancer (DePuy, Warsaw, IN) as a tensor device.

The initial alignment measured by the navigation system, the rotation angle of the femoral component from the posterior condyle axis, the soft tissue balance in knee extension under the condition using the tensor after medial soft tissue releasing, the final alignment after fixing all components, and the extension and flexion CAD- and Trial-gaps were determined, and the CAD- and Trial-gaps were compared. Statistical analysis was conducted using a two-tailed t-test and analysis of variance (ANOVA), with p < 0.05 taken to indicate a significant difference. We performed the power analysis and got the result was 0.996. The study was conducted after approval by the institutional ethics committee of our hospital.

![Fig. 1. The component gap in CAD during surgery shown continuously by the navigation system.](image)
**Results**

The mean angle of the initial alignment was $8.1 \pm 4.2^\circ$ of varus, the mean rotation angle of the femoral component was $3.5 \pm 1.3^\circ$ of varus, and the angle of the soft tissue balance in extension was $2.7 \pm 2.5^\circ$ of varus. The Range of this angle was from $-2^\circ$ to $6^\circ$. We adjusted the soft tissue balance by releasing deep MCL, semimembranosus and pes anserius, and removing all osteophytes. After doing everything, the case which didn’t reach a target was in the state. Twenty-nine cases were within $3^\circ$, remaining 6 cases were not within $3^\circ$. The final alignment after fixing all components was $0.4 \pm 1.4^\circ$ of varus. The mean medial and lateral CAD-gaps in extension were $10.8 \pm 2.5$ mm and $13.7 \pm 2.5$ mm, respectively. The mean medial and lateral CAD-gaps in flexion were $12.2 \pm 2.2$ mm and $13.9 \pm 2.7$ mm, respectively. The mean medial and lateral Trial-gaps in extension were $10.5 \pm 2.6$ mm and $11.4 \pm 3.1$ mm, respectively. The mean medial and lateral Trial-gaps in flexion were $12.2 \pm 2.5$ mm and $14.4 \pm 2.8$ mm, respectively. In comparison of the CAD- and Trial-gaps, the only significant difference was between the lateral gaps in extension (Fig. 5).

**Discussion**

In the gap balancing technique of adjusting the component gap using a navigation system, the medial CAD- and Trial-gaps in extension and flexion were maintained. Therefore, adjustment of the CAD-gaps in extension and flexion were considered to be equal to adjustment of the actual component gaps, which suggests that the surgical procedure is useful. This navigation system continually displays the CAD-gap on the screen, which allows the CAD-gap to be assessed and adjusted during surgery and the osteotomy plan to be implemented.

In the common gap balancing technique, the bone gap in extension and flexion and the soft tissue balance are assessed. Stability in the knee flexion is improved by a rectangular flexion gap. In normal knees, medial soft tissues have stability and lateral tissues have laxity. It was classically written in textbooks that the soft tissue is released until the extension gap is made rectangular, that is, $0^\circ$ varus and valgus. However, in TKA for medial knee OA, it is not necessary to make the extension gap rectangular, and we think that the medial tightness may remain. Therefore, in this technique, the target of soft tissue balance is within $3^\circ$ of varus. Tsubosaka et al. did not plan a rectangular flexion gap, but proposed the medial preservation gap technique to reproduce a trapezoid gap in extension and flexion for stability in medial soft tissues. Inui et al. also indicated that stability in medial side was important for TKA, as in normal knees. Several recent studies have shown the importance of assessment of the component gap during TKA. Muratsu et al. compared the gap with an inserted femoral component with the bone gap and showed that the component gap and the medial soft tissue balance were smaller in extension. Hananouchi et al. showed that the gap difference between extension and flexion after the femoral component was inserted was greater than that when the component was not inserted. Hayashi et al. also showed that the posterior joint capsule was tensed by the implant in the extended component gap and that this effect had an influence on the gap.
Based on these results, we hypothesized that postoperative stability may be improved by adjusting the medial component gap in extension and flexion during surgery. Therefore, we examined whether the CAD-gap in extension and flexion adjusted using the navigation system was equal to the Trial-gap after actually inserting a femoral trial component. The CAD-gap may differ from the Trial-gap due to differences in tension of the posterior joint capsule. However, our results showed a difference only for the lateral component gap in extension, with no other differences. As shown by Muratsu et al., the component gap was smaller in extension and the medial soft tissue balance was smaller in extension compare with the bone gap measurement. In this paper, the component gap was the central gap, and it wasn’t divided into the medial gap and the lateral gap. The lateral gap decreased more than the medial gap might be caused the decrease the medial soft tissue balance. Thus, decrease the central gap and medial soft tissue balance meant that the influence in which a component was inserted was bigger the lateral gap than the medial gap. We consider this to be consistent with our finding that only the lateral component gap in extension differed in comparison of the CAD- and Trial-gaps. And the adjustment of soft tissue balance in extension has an influence on this results. If we adjusted the soft tissue balance in extension more precisely, there was a possibility that the difference between lateral CAD-gap and Trial-gap would be small in extension. But the purpose of this surgical technique was to get the medial stability to medial knee OA, so we thought a soft tissue balance by the release carried out this study was enough from the results of stability of medial side. Consequently, our surgical procedure allows intraoperative adjustment of the medial component gap in extension and flexion.

The major limitation of this study is that our results were obtained from surgeries using a specific implant and tensor. The intraoperative gap has been shown to depend on the implant type, tensors used, and the applied distraction forces. Therefore, further studies are needed using different implant types and tensors. A second limitation is that we examined only intraoperative data without postoperative clinical outcomes. At present, it is unclear if our surgical procedure maintains stability of medial soft tissues at all knee flexion angles and contributes to improved clinical outcomes, and further studies of this issue are also necessary.

**Conclusion**

In comparing the CAD-gap and the Trial-gap, only small difference was found in the lateral gap of extension. The other gaps in both extension and flexion were well maintained. We concluded adjustment of the CAD-gap during surgery using a navigation system can be used to adjust the actual component gap especially in the medial side.

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Declaration of competing interest

Disclosure statement: The authors have nothing to disclose.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.asmart.2020.04.002.

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