Lateral joint tightness in flexion following cementless mobile-bearing total knee arthroplasty decreases patient-reported outcome measures and postoperative range of motion

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ABSTRACT

Purpose: The purpose of this study was to clarify the association between clinical outcomes and the flexion joint gap following rotating concave-convex (Vanguard ROCC) total knee arthroplasty (TKA).

Methods: This consecutive retrospective series included 55 knees that underwent ROCC TKA. All the surgical procedures were performed using a spacer-based gap-balancing technique. To evaluate the medial and lateral flexion gaps, axial radiographs of the distal femur were obtained using the epicondylar view with a distraction force to the lower leg at 6 months postoperatively. Lateral joint tightness was defined as the lateral gap being greater than the medial gap. To evaluate clinical outcomes, patients were asked to complete patient-reported outcome measures (PROMs) questionnaires preoperatively and during at least 1 year of follow-up postoperatively.

Results: The median follow-up duration was 24.0 months. Overall, 16.0% of patients had postoperative lateral joint tightness in flexion. The postoperative range of motion and PROMs were lower in patients with lateral joint tightness than in those with a balanced flexion gap or lateral joint laxity. No serious complications, including bearing dislocations, occurred during the observation period.

Conclusion: Lateral joint tightness in flexion following ROCC TKA decreases PROMs and postoperative range of motion.

Level of evidence: 4.

What are the new findings

- Lateral joint tightness in flexion following rotating concave-convex (Vanguard ROCC) total knee arthroplasty (TKA) decreases patient-reported outcome measures (PROMs) and postoperative range of motion.
- Overall, 16.0% of patients had postoperative lateral joint tightness in flexion and 32.0% had postoperative lateral joint laxity in flexion.
- Even though patients with postoperative lateral joint tightness in flexion, improvement in PROMs exceeded the minimum clinically important difference (MCID).

1. Introduction

Mobile-bearing (MB) total knee arthroplasty (TKA) is known to improve implant conformity and minimize stresses transmitted to the prosthesis-bone interface, thereby reducing the risk of aseptic loosening and polyethylene insert wear [1,2]. It is also known that MB TKA is not inferior to fixed-bearing TKA in terms of revision rates and patient-reported outcome measures (PROMs) [2,3]. Similarly, a meta-analysis showed MB TKA to be superior to fixed-bearing TKA in terms of achieving a larger range of motion (ROM) and a lower deep infection rate [4]. Furthermore, registry data show that the frequency with which MB TKA was performed ranged from 2.9% to 33.8% in 2020, indicating that it is widely used [5].

Vanguard ROCC TKA (Zimmer Biomet, Valence, France) was recently introduced as MB TKA that sacrifices the cruciate ligaments [1,6]. The ROCC inserts have a distinctive saddle-like design and are expected to be very conformable. The trochlea design is also unique, with an anatomical structure that fits well with the native patella [6,7]. At least 5 years following the index surgery, favourable ROM has been reported, with an average flexion angle of 127° ± 15° [6].

Compared with the fixed-bearing mechanism, the MB implant is more sensitive to the optimal gap balance of flexion to avoid spinout
or dislocation of the MB insert \([4,8,9]\). Moreover, it has been reported that a postoperative flexion joint gap imbalance, especially medial laxity and lateral tight imbalance, adversely affects PROMs after fixed-bearing TKA \([10,11]\). However, it is unclear whether the flexion joint gap imbalance is associated with the clinical outcomes after MB TKA, which has a very conformable surface design, especially in ROCC. The currently proposed Forgotten Joint Score-12 (FJS-12) \([12]\), which is one of the PROMs, is associated with joint awareness \([13]\). The flexion joint gap imbalance may affect joint awareness postoperatively. Therefore, analysis of the flexion joint gap after MB TKA is critical.

The purpose of this study was to clarify the association between clinical outcomes, including the FJS-12 and flexion joint gap, following ROCC TKA. The hypothesis was that even in ROCC TKA, which is considered to have high conformity, medial joint laxity in flexion has a negative impact on clinical outcomes.

2. Materials and methods

2.1. Study design and participants

This consecutive retrospective series included 55 knees that underwent ROCC TKA at our institution between May 2018 and May 2021. All TKAs were performed in patients with a diagnosis of osteoarthritis, osteonecrosis or rheumatoid arthritis. The inclusion criteria were as follows: primary MB TKA using ROCC; femoral and tibial components used as a cementless press fit; no resurfacing of the patella; and PROMs evaluated preoperatively and during at least 1 year of postoperative follow-up. The following exclusion criteria were applied: cemented fixation of either the femoral or tibial components; incomplete PROMs data; and inadequate radiological data. After exclusion of five TKAs with inadequate radiological data, 50 ROCC TKAs were included in the analysis.

This study had a retrospective design and was approved by our hospital ethics committee (approval number 4952). Informed consent was obtained via an opt-out procedure.

2.2. Surgical technique and postoperative rehabilitation

All the surgical procedures were performed using a tourniquet via a sub-vastus approach by any of four specialist knee surgeons, all of whom were familiar with the implant and the implantation techniques used. In all cases, the anterior and posterior cruciate ligaments were resected and the cruciate ligament-sacrificing MB knee implant was used \([1]\) (Fig. 1). An initial tibial cut was made perpendicular to the mechanical axis with a 0° posterior slope in the sagittal plane using an extramedullary guide. A 10-mm half-spacer block was inserted after the tibial cut to confirm a balanced knee with flexion and extension gaps. A distal femoral osteotomy was performed perpendicular to the mechanical axis using an intramedullary valgus cutting guide. A spacer-based gap-balancing technique was used to determine the posterior femoral cut \([7,14]\). A 1–6-mm lateral spacer was inserted on the lateral side to adjust the external rotation in consideration of lateral flexion laxity (Fig. 2). The thickness of the lateral spacers (mm) used was also recorded. The decision to use the cemented component was made at the surgeon’s discretion based on the patient’s bone quality and primary stability in trials \([6]\). However, in this consecutive retrospective series, no femoral and tibial components were cemented. A drainage tube was not placed in all cases. Throughout the surgery, care was consistently taken to avoid excessive release of the soft tissue inside the knee joint. The superficial layer of the medial collateral ligament was not released in all cases.

Patients were permitted to ambulate with full weight-bearing as pain permitted from the first postoperative day and underwent rehabilitation without the restriction of ROM.

2.3. Radiological parameters and PROMs

The femorotibial angle (FTA) was measured preoperatively and postoperatively on plain radiographs. To evaluate the medial and lateral flexion gaps, axial radiographs of the distal femur were obtained using the epicondylar view at 6 months postoperatively \([10,11]\). A posterior–anterior radiograph of the knee in 80° of flexion was taken while a distraction force was applied to the lower leg using a 1.5-kg weight fastened at the ankle. The flexion gap angle was defined as the angle between the posterior condylar axis and the superior margin of the tibial tray \([10,15]\). The flexion gap angle was deemed to be positive if the lateral gap was greater than the medial gap (Fig. 3). According to the flexion gap angle, less than 0° was defined as the flexion lateral tight (FLT) group, 0°–4° as the flexion balanced (FB) group, and more than 4° as the flexion lateral loose (FLL) group. In addition, medial and lateral gaps were measured as the distance from the posterior edge of the femoral component to the proximal edge of the tibial insert (Fig. 3). The magnification of the radiographs was standardized by the width of the tibial tray on the radiographs and the actual width of the tibial tray used. Femoral component rotation was evaluated by the angle between the posterior condylar axis and the surgical transepicondylar axis on postoperative computed tomography images \([10]\), with external rotation about the posterior condylar axis taken as positive.

Intra-observer and inter-observer agreement for measurements was assessed using the intraclass correlation coefficient (ICC). To determine the intra-observer agreement regarding radiological parameters (postoperative FTA), measurements were repeated after more than a 2-week interval in 15 randomly selected subjects. For the inter-observer agreement, measurements were performed individually on 15 randomly selected subjects by two observers. The ICC values were evaluated as poor (<0.5), moderate (0.5–0.75), good (0.75–0.9), or excellent (>0.9), as in a previous study \([16]\).

Patient data, including age, gender, diagnosis, ROM, and preoperative body mass index, were collected from the medical records.

To evaluate PROMs, patients were asked by the attending surgeon to complete the Knee Society Score (KSS) \([17]\), Knee Injury and Osteoarthritis Outcome Score (KOOS) \([18]\), and FJS-12 \([12]\) questionnaires preoperatively and during at least 1 year of postoperative follow-up.
The MCID for preoperative and postoperative changes in the KSS subscale scores following TKA was as follows: symptoms, 1.9; satisfaction, 2.2; functional activities, 4.1 [19]. Similarly, the MCID in the KOOS subscale scores following TKA was as follows: pain, 18; symptoms, 7; activities of daily living, 16; quality of life, 17 [20]. For FJS-12, the MCID was considered to be 14 [21].

2.4. Complications

Complications occurring up to the last visit were retrospectively analysed using the patients’ medical data.

2.5. Statistical analysis

Descriptive statistics are reported as the median (range), the count (percentage), or the mean and standard deviation. The distribution of continuous variables was assessed for normality by visual inspection (histograms) and the Shapiro–Wilk test. The preoperative and postoperative PROMs values were compared using a paired t-test in order to evaluate improvement in terms of clinical outcomes. One-way analysis of variance and the Tukey–Kramer test were used for multiple comparisons of parametric data among three groups. For nonparametric data, the Kruskal–Wallis and Steel–Dwass tests were used for multiple comparisons among three groups. All statistical analyses were performed using JMP software version 16 (SAS Institute Inc., Cary, NC). A p-value < 0.05 was considered statistically significant.

A post hoc power analysis was conducted using G*Power (version 3.1.9.7). Based on the results of analysis of variance in the postoperative KSS total score, the effect size was calculated to be 0.52. With a sample size of 48 and an alpha error probability of 0.05 for three groups, it was calculated that a power of 0.88 would be needed. A total sample size of 50 was considered sufficient for this study.

Fig. 2. The spacer-based gap-balancing technique in the left knee. a. Intraoperative photograph showing a knee with the rotating concave-convex implant. b. A lateral spacer measuring 1–6 mm is inserted on the lateral side to adjust the external rotation in consideration of lateral flexion laxity.

Fig. 3. Axial radiograph of the distal femur in the epicondylar view. a. For measurement of the flexion gap angle, which is deemed to be positive if the lateral gap is greater than the medial gap. b. For measurement of the medial and lateral gaps. The gaps were measured as the distances from the distal edge of the femoral component to the lowermost portion of the proximal edge of the tibial insert.
3. Results

The patient demographics are shown in Table 1. The median follow-up duration was 24.0 months (17.5–27.3). No patients were lost to follow-up. There were no serious complications during the observation period, including no cases of deep infection, bearing dislocation, or fatal thromboembolism.

The ICC for intra-observer agreement regarding radiological FTA was 0.82 and that for inter-observer agreement was 0.86, both of which were considered good.

3.1. Radiological results

The radiological data are shown in Table 1. The mean flexion gap angle was 2.4° ± 2.9°. Overall, eight patients (16.0%) had postoperative lateral joint tightness in flexion and 16 (32.0%) patients had postoperative lateral joint laxity in flexion. There was no significant difference in medial flexion gap, external rotation, preoperative, and postoperative alignment (FTA), or thickness of the lateral spacer among the three groups (Table 2). The lateral gap was significantly less in the FLT group (0.7 mm [0.4–1.3]) than in the FB group (2.5 mm [0.9–3.7], p = 0.01) and FLL group (5.8 mm [4.6–7.5], p = 0.0003; Table 2). Although no difference in preoperative ROM was observed among the groups, the postoperative ROM was significantly less in the FLT group (120.6° ± 3.2°) than in the FLL group (131.8° ± 2.3°; p = 0.006, Table 2).

3.2. Clinical results

Significant improvements were observed in the KSS, FJS-12, and KOOS subscale scores following ROCC TKA. Only the KSS expectation score declined postoperatively. Improvement in PROMs exceeded the MCID in all three groups (Table 3). However, there was less improvement in PROMs in the FLT group than in the FLL and FB groups (Table 3). Significantly less improvement was observed in KSS satisfaction, KSS total, KOOS symptoms, and PROMs related to knee function, such as KSS function and KOOS activities of daily living.

4. Discussion

The most important finding in this study was that lateral tightness in flexion following ROCC TKA was associated with less improvement in PROMs and postoperative ROM. In knees with postoperative joint laxity in flexion, the medial joint gap was not too loose but the lateral gap was tight.

The postoperative knee flexion gap may be influenced by various factors, including surgical technique and intraoperative ligament balance [22]. In the present study, a spacer-based gap-balancing technique was used to obtain alignment of the femoral component and soft tissue balance. Nevertheless, the size of the lateral spacer depends mainly on the surgeon’s experience, which is considered a disadvantage [14]. In our study, there was no difference in the average lateral spacer thickness used among the three groups, but it is unclear whether the thickness was appropriate for the individual patient’s lateral laxity. Thus, the lateral gap was the smallest in the FLT group because the spacers placed on the lateral side may have been too thick. In this study, the medial joint gap was not too loose because the amount of bone resection from the posterior medial condyle was adjusted to a constant level by the ROCC surgical technique, whereby the reference point for the posterior reference technique is set at the posterior edge of the medial condyle. Although variation in lateral joint laxity was observed in the FLT group, no cases of bearing dislocation occurred during follow-up. Nevertheless, surgeons should be careful during surgery using ROCC to adjust the method of gap creation to avoid excessive flexion joint gap imbalance. To control the flexion gap, a modified gap technique using a tensor device [22] rather than a space-block would be suitable for ROCC TKA. Further research on this topic is needed.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Patient demographics and Radiological data.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at surgery, years, mean ± SD</td>
<td>72.9 ± 6.7</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>16 (32.0)</td>
</tr>
<tr>
<td>Body mass indexa, mean ± SD</td>
<td>26.6 ± 4.2</td>
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<tr>
<td>Operated side: right (%)</td>
<td>27 (54.0)</td>
</tr>
<tr>
<td>Diagnosis, n (%)</td>
<td>OA: 39 (78.0); RA: 5 (10.0)</td>
</tr>
<tr>
<td>ROM before surgery, (°), mean ± SD</td>
<td>116.1 ± 14.4</td>
</tr>
<tr>
<td>ROM after surgery, (°), mean ± SD</td>
<td>127.1 ± 9.9</td>
</tr>
<tr>
<td>Follow-up, months, median [range]</td>
<td>24.0 [17.5–27.3]</td>
</tr>
<tr>
<td>Flexion gap angle, (°), mean ± SD</td>
<td>2.4 ± 2.9</td>
</tr>
<tr>
<td>Group, n (%)</td>
<td>FLT: 8 (16.0); FB: 26 (52.0); FLL: 16 (32.0)</td>
</tr>
<tr>
<td>Medial gap, mm, median [range]</td>
<td>1.5 [0.8–2.4]</td>
</tr>
<tr>
<td>Lateral gap, mm, median [range]</td>
<td>3.3 [0.9–5.6]</td>
</tr>
<tr>
<td>External rotation, (°), mean ± SD</td>
<td>−0.5 ± 1.3</td>
</tr>
<tr>
<td>FTA before surgery, (°), mean ± SD</td>
<td>182.8 ± 7.1</td>
</tr>
<tr>
<td>FTA after surgery, (°), mean ± SD</td>
<td>174.9 ± 3.1</td>
</tr>
</tbody>
</table>

OA, osteoarthritis; ON, osteonecrosis; RA, rheumatoid arthritis; ROM, range of motion; SD, standard deviation.

* Calculated as kg/m²; FB, flexion balanced; FLL, flexion lateral loose; FLT, flexion lateral tight; FT, femorotibial angle.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Comparison of clinical data among the three groups.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>FLT (n = 8)</td>
</tr>
<tr>
<td>Flexion gap angle, (°), mean ± SD</td>
<td>−1.8 ± 1.4</td>
</tr>
<tr>
<td>Medial gap, mm, median [range]</td>
<td>1.7 [1.5–2.1]</td>
</tr>
<tr>
<td>Lateral gap, mm, median [range]</td>
<td>0.7 [0.4–1.3]</td>
</tr>
<tr>
<td>External rotation, (°), mean ± SD</td>
<td>−0.4 ± 1.3</td>
</tr>
<tr>
<td>FTA before surgery, (°), mean ± SD</td>
<td>182.0 ± 7.9</td>
</tr>
<tr>
<td>FTA after surgery, (°), mean ± SD</td>
<td>175.5 ± 2.6</td>
</tr>
<tr>
<td>ROM before surgery, (°), mean ± SD</td>
<td>109.3 ± 11.7</td>
</tr>
<tr>
<td>ROM after surgery, (°), mean ± SD</td>
<td>120.6 ± 6.7</td>
</tr>
<tr>
<td>Thickness of lateral spacer, mm, mean ± SD</td>
<td>3.0 ± 1.5</td>
</tr>
</tbody>
</table>

FB, flexion balanced; FLL, flexion lateral loose; FLT, flexion lateral tight; FT, femorotibial angle; ROM, range of motion; SD, standard deviation.

* Significant differences in each group.

b Significant difference between FLT and FLL.

Known predictors of postoperative ROM after TKA include preoperative ROM, patient gender and age, soft tissue balance, preoperative diagnosis, prosthetic design and prosthetic alignment [23]. In the present study, knees with lateral joint laxity in flexion had better postoperative ROM than those with lateral joint tightness in flexion. It has been reported that postoperative ROM is affected by lateral joint laxity in cruciate-retaining TKA [24]. Regarding MB TKA, better postoperative ROM has been reported with a rectangular flexion gap following low contact stress TKA (LCS: DePuy Inc, Warsaw, IN) [15]. To our knowledge, this is the first study to evaluate the effect of the flexion gap on ROM following ROCC TKA. We found no significant difference in the postoperative ROM between our FB group and our FLL group. Therefore, slight lateral laxity could be acceptable even in ROCC MB TKA. However, lateral tightness should be avoided to gain a good ROM with the ROCC, which has a relatively high-conformity surface design [6].
Although our FLT group showed the least improvement in PROMs, it was beyond the MCID. The MCID has long been a favoured method for assessing PROMs. According to Jacquet et al. [25], the MCID value can determine whether a procedure is effective. However, a challenge regarding MCID is that although its definition is clear, the choice of calculation method may lead to variation in the values estimated [20]. There are two main calculation methods: anchor-based and distribution-based [19,25]. Previous studies have shown that anchor-based methods can yield higher values than the distribution-based methods [26]. In our study, the MCIDs cited for KSS, FJS-12, and KOOS were all derived using anchor-based methods.

Patellar resurfacing during TKA remains controversial. O'Brien et al. [336] found that non-resurfacing of the patella did not adversely affect the outcome of LCS TKA after a minimum of 10 years of follow-up [27]. In their cohort, only 1.5% of knees underwent secondary resurfacing of the patella for anterior knee pain. Bercovy et al. [6] did not perform patellar resurfacing during ROCC TKA in the absence of clinical and intraoperative findings of patellofemoral osteoarthritis. In our study, none of the knees required secondary resurfacing of the patella during an observation period of 2 years.

This study has several limitations. First, the sample size was relatively small. Second, the follow-up period was relatively short. Therefore, future research should include longer-term follow-up. However, we believe that an average of 2 years of follow-up with a minimum of one year of follow-up was sufficient for the purposes of this research. Third, the study did not include adequate postoperative assessment of radiographic parameters without FTA or external rotation of the femoral component, such as malposition of the tibial component. Rotational alignment of the tibial tray may not affect the clinical outcomes in MB TKA, although the postoperative tibial slope may be associated with the postoperative ROM. However, there has been a suggestion that postoperative tibial slope should not be used as a predictor of ROM following MB TKA [23]. Finally, the soft tissue balance was not assessed intraoperatively. Evaluation using tensor devices is desirable in future studies.

5. Conclusion

Lateral joint tightness in flexion following ROCC TKA decreases PROMs and postoperative ROM.

Competing interests

The authors declare that they have no competing interests.

Funding

Not applicable.

Compliance with ethical standards

This study was approved by the institutional ethics committee of Tokyo Women’s Medical University (approval number: 4952).

Consent

Informed consent was obtained via an opt-out procedure.

Author contributions

Junya Itou: Conceptualization, Methodology, Writing - Original Draft, Investigation.
Masafumi Itoh: Investigation, Validation.
Umito Kuwashima: Investigation, formal analysis.
Ken Okazaki: Conceptualization, Supervision, Writing – review & editing.

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References


Table 3

<table>
<thead>
<tr>
<th>ΔPROMs, mean ± SD</th>
<th>FLT (n = 8)</th>
<th>FB (n = 26)</th>
<th>FLL (n = 16)</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td>ΔKSS (symptoms)</td>
<td>31.8 ± 3.6</td>
<td>15.4 ± 6.3</td>
<td>8.3 ± 6.7</td>
<td>0.09</td>
</tr>
<tr>
<td>ΔKSS (satisfaction)</td>
<td>3.4 ± 11.1</td>
<td>19.6 ± 8.3</td>
<td>11.6 ± 8.8</td>
<td>0.002*</td>
</tr>
<tr>
<td>ΔKSS (expectation)</td>
<td>5.0 ± 1.8</td>
<td>2.7 ± 3.3</td>
<td>−1.9 ± 3.9</td>
<td>0.12</td>
</tr>
<tr>
<td>ΔKSS (function)</td>
<td>4.4 ± 13.9</td>
<td>34.6 ± 17.7</td>
<td>33.1 ± 20.0</td>
<td>0.04*</td>
</tr>
<tr>
<td>ΔFJS-12</td>
<td>24.5 ± 13.3</td>
<td>27.3 ± 27.6</td>
<td>63.1 ± 30.9</td>
<td>0.004*</td>
</tr>
<tr>
<td>ΔKOAOS (pain)</td>
<td>24.5 ± 21.3</td>
<td>17.2 ± 20.3</td>
<td>52.3 ± 31.9</td>
<td>0.07</td>
</tr>
<tr>
<td>ΔKOAOS (symptoms)</td>
<td>16.1 ± 18.8</td>
<td>37.9 ± 18.7</td>
<td>37.3 ± 22.9</td>
<td>0.03*</td>
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<tr>
<td>ΔKOAOS (ADL)</td>
<td>6.9 ± 10.2</td>
<td>30.6 ± 15.9</td>
<td>36.0 ± 18.0</td>
<td>0.0004*</td>
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<tr>
<td>ΔKOAOS (sports)</td>
<td>31.2 ± 26.8</td>
<td>48.6 ± 25.2</td>
<td>40.3 ± 28.5</td>
<td>0.25</td>
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<tr>
<td>ΔKOAOS (QOL)</td>
<td>41.4 ± 36.1</td>
<td>54.1 ± 23.8</td>
<td>49.2 ± 21.0</td>
<td>0.45</td>
</tr>
</tbody>
</table>

Δ, postoperative change; ADL, activities of daily living; FJS-12, Forgotten Joint Score; FLL, flexion lateral loose; FLT, flexion lateral tight; FJF, flexion balanced; KOOS, Knee Injury and Osteoarthritis Outcome Score; KSS, Knee Society Score; QOL, quality of life. * Significant difference for comparison between FLT and other group. † Significant difference between FLT and FB.


