

Soft Tissue Balance in Total Knee Arthroplasty

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1. Introduction

The primary goal of total knee arthroplasties (TKAs) is the achievement of stable tibiofemoral and patellofemoral (PF) joints, which relies on accurately aligning these joint components and balancing the soft tissues. In order to achieve these criteria, it is important to utilize appropriate surgical techniques and well-designed implants [1-3]. To this end, using the more traditional intra- and extra-medullary alignment devices, the proper alignment of each joint component further relies on performing accurate femoral and tibial osteotomies along ideal levels and angles. Recently, computer-assisted and robot-assisted surgeries have been developed and reported to improve the accuracy of osteotomies in TKA [4-7]. We similarly reported on a CT-free navigation system which significantly improved the accuracy of implantations in relation to the mechanical axis, and achieved an early and mid-term clinical outcome equivalent to that of a manual group [8-10].

In contrast, the management of soft tissue balance during surgery remains difficult, leaving much to the surgeon's subjective feel. TKA is a well-established procedure, which generally results in relief of pain, improved physical function, and a high level of patient satisfaction. However, knee instability after primary TKA is considered an important factor for early TKA failure. Fehring et al. studied 279 revision surgeries within 5 years of their index arthroplasty and reported 74 revision cases (27%) caused by instability [11]. In a retrospective study of revision surgery, Sharkey et al. reported instability in 21.2% of their early revision knee arthroplasty failures [12]. They concluded that the instability might be due to inadequate correction of soft tissue imbalances in both the sagittal and coronal planes. As a result, soft tissue balancing has been recognized as an essential surgical intervention for improving the outcomes of TKA.

2. Traditional soft tissue balance assessment

Although several methods and devices for assessing soft tissue balance such as manual distraction [13], traditional tensor [13], space block [14], and lamina spreaders [15] have been described in previous papers, assessment has not been quantitative and has mainly depended on the subjective feeling of the surgeons. The second generation of tensor devices which were quantitatively applied and objective with the measurement under fixed torque or load were commercially available [16-20] or individually developed or modified [21-24].

Asano et al. [25] used a commercially available tensor combined with their original measured torque-driver was and were able to measure the load at every 1 mm interval of gap distance. However, their method could only be used for measurement with an everted, and thereby unphysiological, patellar orientation, without the prosthesis, and only at extension or 90° of flexion.

D'Lima DD et al. developed a knee arthroplasty tibial tray with force transducers and a telemetry system to directly measure tibiofemoral compressive forces in vivo [26, 27]. From 1996, the study group spent time refining manufacturing techniques, improving durability, and safety testing and then reported the first electronic knee prosthesis implant in 2004. Recently, they summarized the design, development, and in vivo use of two generations of electronic knee prosthesis with activities of daily living, rehabilitation, exercise, and athletic activities from their many studies [28]. Although this device provides a lot of useful information on kinematics after TKA, it is too specialized and expensive for routine clinical use. The implantable tibial tray with force transducers and telemetry system is useful for research, but needs a bulky implant with an extension stem-like structure, and cannot be used with other TKA systems, limiting to the population used.

3. New soft tissue balance assessment with offset type tensor

3.1 Design and parameters

In order to permit soft tissue balancing under more physiological conditions, in a surgeon friendly manner, we developed a new third-generation tensor to obtain soft tissue balancing throughout the range of motion with reduced patella-femoral (PF) and aligned tibiofemoral joints [29]. The offset type tensor consists of three parts: an upper seesaw plate, a lower platform plate with a spike and an extra-articular main body (Fig 1). Both plates are placed at the center of the knee, and we apply one of two tensioning devices that are catered to appropriately fit either a cruciate-retaining (CR) or a posterior-stabilized (PS) TKA. The PS TKA tensor consists of a seesaw plate with a proximal post along the center that fits the inter-condylar space, as well as a cam for the femoral trial prosthesis. This post and cam mechanism controls the tibiofemoral position in both the coronal and sagittal planes. The CR TKA tensor consists of a seesaw plate with a proximal convex shaped centralizer that fits the inter-condylar space and controls coronal joint alignment. These mechanisms permit us to reproduce the joint constraint and alignment after implanting the prostheses. This device is ultimately designed to permit surgeons to measure the ligament balance in varus and joint center/joint component gap, while applying a constant joint distraction force. Joint distraction forces ranging from 30lb (13.6 kg) to 80lb (36.3 kg) can be exerted between the seesaw and platform plates through a specially made torque driver which can change the applied torque value. After sterilization, this torque driver is placed on a rack that contains a pinion mechanism along the extra-articular main body, and the appropriate torque is applied to generate the designated distraction force; in preliminary *in-vitro* experiments, we obtained an error for joint distraction within $\pm 3\%$. Once appropriately distracted, attention is focused on two scales that correspond to the tensor: the angle ($^{\circ}$, positive value in varus ligament balance) between the seesaw and platform plates, and the distance (mm) between the center midpoints of upper surface of the seesaw plate and the proximal tibial cut (mm, joint center/joint component gap). By measuring these angular deviations and distances under a constant joint distraction force, we are able to measure the ligament balance and joint center/joint component gaps, respectively.

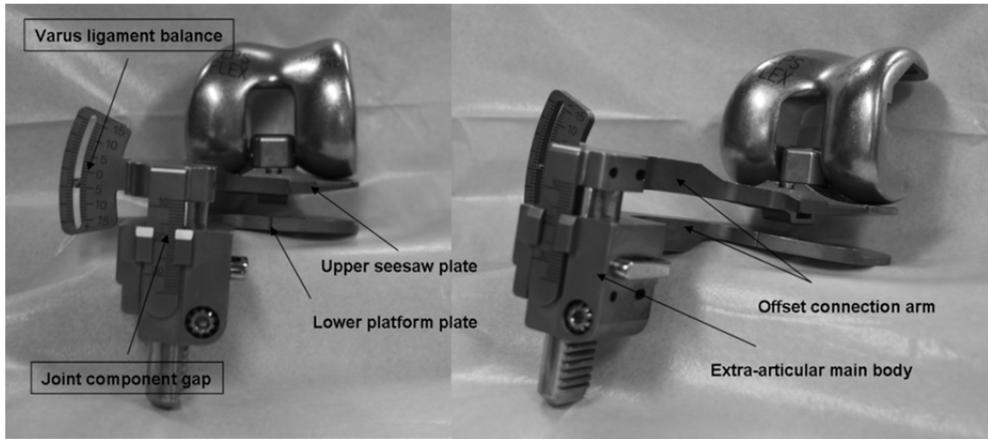


Fig. 1. Offset type tensor

The tensor consists of three parts: upper seesaw plate, lower platform plate and extra-articular main body. Two plates are connected to the extra-articular main body by the offset connection arm.

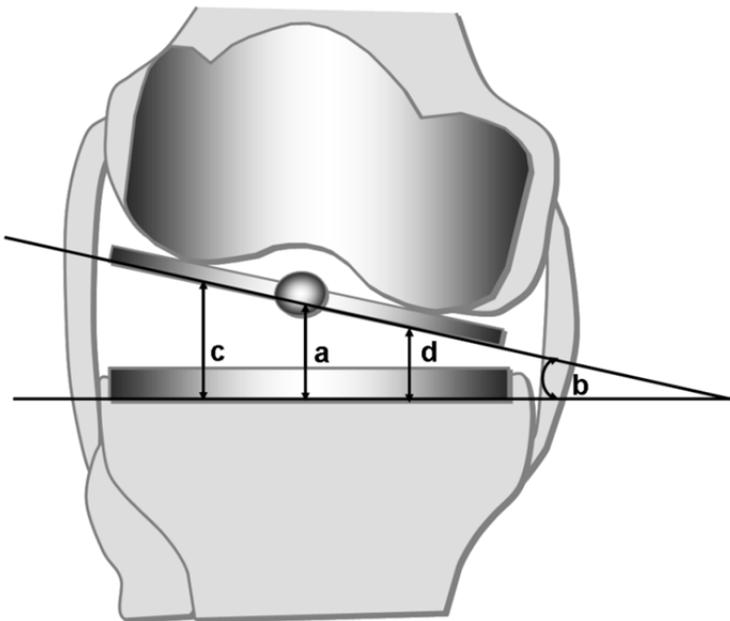


Fig. 2. Illustration showing parameters obtained and calculated.

- a. Joint center gap/ joint component gap.
- b. Varus ligament balance/ varus angle.
- c. Lateral compartment gap
- d. Medial compartment gap

Using the tensor, the following parameters can be calculated from the values: *joint component gap (joint center gap)* and *varus ligament balance (varus angle)* (Fig 2).

Joint looseness = "Component gap" - "Insert thickness"

Medial compartment gap = "Component gap" - 0.5× "Width between medial and lateral apex of femoral component representing the contact points to polyethylene insert" ×sin(varus angle)

Lateral compartment gap = "Component gap" + 0.5× "Width between medial and lateral apex of femoral component representing the contact points to polyethylene insert" ×sin(varus angle)

3.2 Soft tissue balance with reduced PF joint

We reported our experience using this device for intra-operative measurement with the PS TKA and further discussed the clinical relevance of this tensor [30-32]. First, we reported joint component gap kinematics in PS TKA with and without patellar eversion. The component gap showed an accelerated decrease during full knee extension. With the PF joint everted, the component gap increased throughout knee flexion. In contrast, the component gap with the PF joint reduced increased with knee flexion but decreased after 60° of flexion [30]. Secondly, we reported that intra-operative joint component gap kinematic assessment with reduced PF joint has the possibility to predict the post-operative flexion angle and thus allows evaluation of the surgical technique throughout the range of knee motion. Both an increased value during the extension to flexion gap and a decreased value during the flexion to deep flexion gap with PF joint reduced, not everted, showed an inverse correlation with the post-operative knee flexion angle, not pre-operative flexion angle [31]. Thirdly, we demonstrated that the correlations between the soft tissue balance assessed by the tensor and the navigation system were higher with reduced PF joint than everted PF joint, suggesting that surgeons should assess soft tissue balance during PS TKA with the PF joint reduced when using a navigation system [32]. In a series of intraoperative soft tissue balance assessments, we emphasized the importance of maintaining a reduced and anatomically oriented PF joint in order to obtain accurate and more physiologically-relevant soft tissue balancing.

Recent studies have emphasized the importance of the physiological post-operative knee condition in assessing soft tissue balance with PF joint reduction and femoral trial replacement in place [33-35]. Using our tensor with a 5-mm-long minute uniaxial foil strain gauge, Gejyo et al. reported a similar kinematic pattern of intra-operative joint component gap; when the patella was reduced, the joint gap was decreased at 90 and 135 degrees of flexion (by 1.9 mm and 5.5 mm, respectively) compared with the gap with the patella everted. Patellar tendon strain at 90 degrees of flexion, increasing with knee flexion, correlated with the joint gap difference with the patella in everted and reduced positions. Based on their study, they concluded the knee extensor mechanism might have an influence on the joint gap and be important in achieving the optimal joint gap balance during TKA [33]. With the use of an original tensor device which can measure the load of the spread joint gap, Yoshino et al. reported a significant difference between the loads in the patella everted position and the reset position in flexion, not in extension, in PS TKA. However, in CR-TKA, they reported no significant difference between the loads in patella everted position and in patella reset position at either extension or flexion. Therefore, they concluded that the load

in the flexion gap will increase in PS TKA or, in other words, the flexion gap distance will decrease by resetting [34]. With the use of an offset type tensor which has been developed based on our tensor, Kamei et al. reported a joint gap size and inclination measured intraoperatively on a knee in 90° flexion, with and without patellar eversion [35]. In the condition after tibial and distal femoral cut, they showed that the joint gap with patella in situ (17.0 ± 3.4 mm) was significantly greater than with patellar eversion (15.4 ± 3.0 mm), as was gap inclination at 90° flexion with the patella in situ ($4.9 \pm 3.1^\circ$) compared to with patellar eversion ($4.0 \pm 2.9^\circ$). Based on the results, they speculated that the steeper flexion gap inclination obtained without patellar eversion than with patellar eversion induced more externally rotated femoral positioning in the absence of patellar eversion. They emphasized that these results ought to be taken into account by surgeons considering switching from conventional to MIS-TKA.

3.3 Soft tissue balance with femoral component in place

The main concepts of measurement using the new tensor are, different from the conventional tensioning device, with femoral trial component in place as well as a reduced PF joint. As the next step, accordingly, we focused on the difference in soft tissue balancing between the femoral trial component in place and the conventional osteotomized condition. In the intraoperative assessment of soft tissue balance, the joint gap showed significant decrease at extension, not flexion, after femoral trial prosthesis placement, and varus ligament balances were significantly reduced at extension and increased at flexion after femoral trial placement [36]. These changes at extension might be caused by the tensed posterior structures of the knee with the posterior condyle of the externally rotated aligned femoral trial. At knee flexion, a medial tension in the extensor mechanisms might be increased after femoral trial placement with PF joint repaired, and increased ligament balance in varus. We measured the “joint component gap”, which is remarkably different from more conventional gap measurement. The joint component gap is measured with the femoral component in place, whereas the conventional gap measurement is made between the cutting surfaces of the femur and tibia. By keeping the femoral component in place, the knee is afforded a greater degree of extension because of its curving arc. In this arrangement, the posterior condyles of the component tighten the posterior capsule, resulting in a smaller joint gap at full extension. In addition, due to the 7 degree posterior slope of the tibia and a slight femoral anterior bowing, we can consider the “conventional extension gap” to be at about 10 degrees of the knee flexion angle. Mihalko et al. stated that the release of more posterior structures had a greater effect on the extension gap than on the flexion gap in explaining the importance of the relationship between posterior structures and the extension gap in a cadaver study [37]. Sugama et al. reported in their operative study that a bone cut from the posterior femoral condyles could change the tension of the posterior soft tissue structures and so alter the width and shape of the extension gap [38]. These previous reports support our hypothetical mechanism.

4. Soft tissue balance in CR and PS TKA

The Our above mentioned series of studies were only implemented with PS TKA. The long term results of CR and PS TKAs have shown an ability to relieve pain and improve function.

Nevertheless, the superiority of the CR or PS TKA remains a source of great controversy in the field of TKA. Proponents of the CR TKA advocate maintaining the PCL in order to increase stability, promote femoral rollback, and thereby enhance the patient's ability to climb stairs [39-43], while proponents of the PS TKA highlight studies in which patients with a resected PCL display a greater post-operative range of motion [43-45]. It is important to note in this debate, however, that investigators have been unable to show a difference in clinical outcome between both types of knees [41, 42, 46]. We have previously shown that among patients undergoing bilateral TKAs performed by the same surgeon, including a CR and PS TKA in alternate knees of the same patient, there was no difference in the post-operative knee score, yet the post-operative range of motion was significantly superior after resecting the PCL [47]. Accordingly, we extended our previous study and report on our experience with this device for the intra-operative soft tissue balance measurements of CR and PS TKAs, performed with both a reduced and everted patella.

While the joint component gap measurements with a reduced patella of PS TKA increased from extension to flexion, these values remained constant for CR TKA throughout the full range of motion. Additionally, the joint component gaps at deep knee flexion were significantly smaller for both types of prosthetic knees when the PF joint was reduced [48]. From our data, the CR TKA had stable joint kinematics from extension into deep flexion, while the joint kinematics for the PS TKA were more dynamic. Our data thereby supports prior studies indicating that the CR TKA affords patients greater stability. Our data further indicate that, compared to a CR TKA, a PS TKA with a reduced patella results in significantly larger gaps when the arc of motion ranges from mid- to deep flexion.

In the assessment of varus/vagus balance, while the measurements of varus ligament balance with a reduced patella in PS TKA slightly increased from extension to flexion, these values slightly decreased for CR TKA from extension to flexion [49]. The data showed that CR TKA produced constant soft-tissue tension from extension into deep flexion, whereas PS TKA produced soft-tissue tension that tended to be more in varus during flexion. The PCL in knees with osteoarthritis is considered relatively rigid and shortened, despite being relatively macroscopically intact. Our findings indicate that compared with CR TKA, PS TKA with the patella reduced results in a significantly larger varus angle when the arc of motion is between midrange and deep flexion. After performing the independent cut procedure, we applied 3 or 5° of external rotation in the series of studies when setting the femoral component, which may have caused a decreasing varus balance in flexion for those patients who underwent CR TKA. Some studies indicated that the flexion gap in healthy knees is not rectangular and that the lateral joint gap is significantly lax [50-53]. The use of both a traditional soft-tissue release and the measured resection technique for knees with osteoarthritis in varus produces a pattern of soft-tissue tension that may at least partly explain why PS TKA produces a better postoperative range of motion.

Taken together, the kinematic patterns of soft tissue balance differ between the patellae everted and reduced, as well as between PS and CR TKA (Fig. 3). In light of these findings, we should carefully select patients according to the condition of their PCL, set an appropriate angle of external rotation, or do both if we wish to obtain good outcomes in CR TKA.

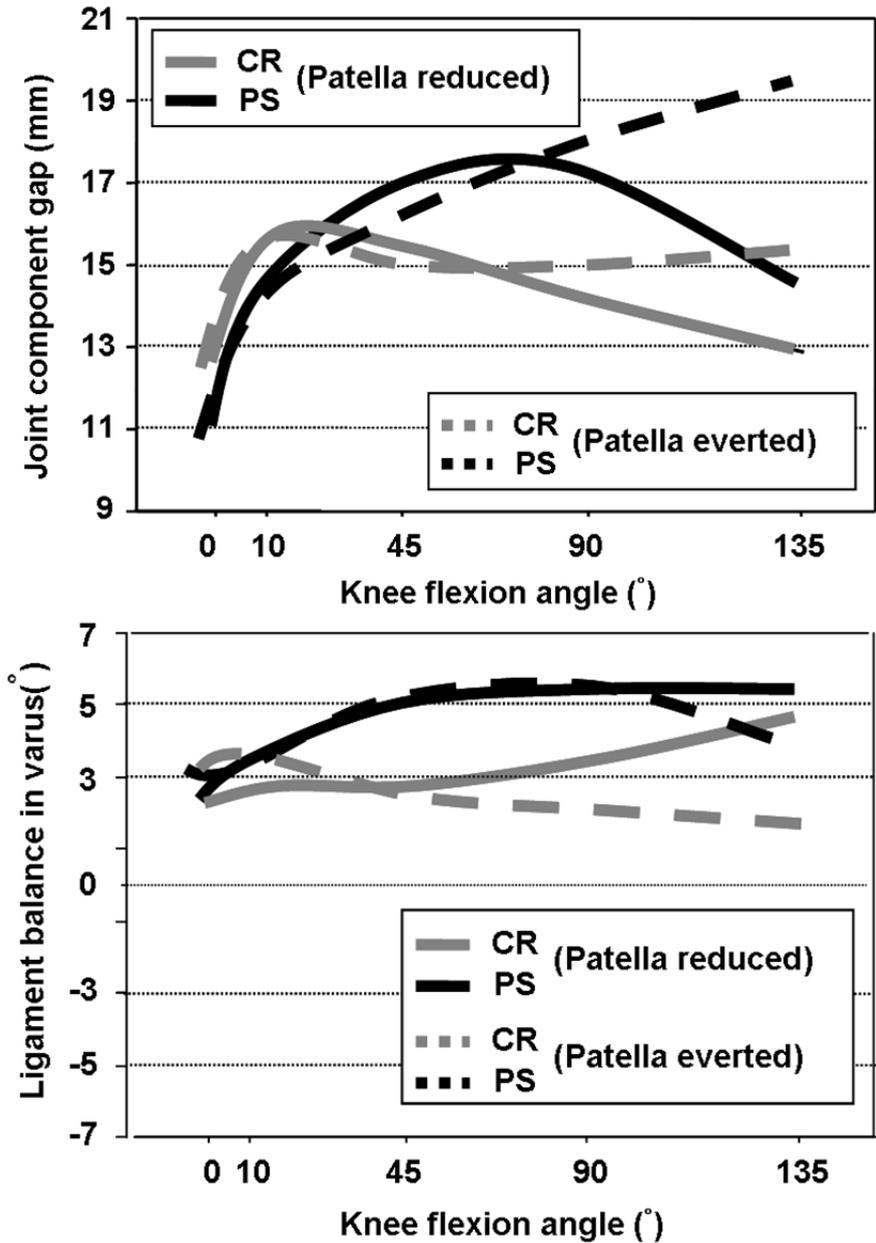


Fig. 3. Soft tissue balance in CR and PS TKA
 a. Joint component gap pattern throughout the range of motion differs between CR and PS TKA as well as between the everted and reduced PF joint condition.
 b. Varus ligament balance throughout the range of motion differs between CR and PS TKA as well as between the everted and reduced PF joint condition.

5. Soft tissue balance in MIS TKA

Recently, minimal incision surgery (MIS) TKA is widely promoted as a possible improvement over conventional TKA. The major advantages of MIS TKA over conventional TKA is the smaller skin incision required, and the avoidance of patellar eversion and quadriceps muscle splitting, leading to reduced blood loss, less perioperative pain, shorter length of hospital stay, and earlier return of knee function [54-61]. Although traditional TKA allow for excellent visualization, component orientation, and fixation, and have been associated with remarkable long-term implant survival, MIS TKA is attractive because of the small incision, and minimal or no pain and discomfort associated with surgery. However, while there is some evidence that these short-term benefits occur with MIS TKA [49-56], there is concern because of an increase in complications using the MIS technique, including vascular injury [62], patellar tendon injury [63, 64], condylar fracture [65], wound dehiscence and necrosis [65, 66], and component malalignment [54, 67-69]. In particular, the quadriceps-sparing (QS) approach has been developed as the least-invasive approach to the extensor mechanism by limiting medial parapatellar arthrotomy to the superior pole of the patella [70]. Although new surgical instrument designs enable surgeons to use this approach, this technique remains challenging to perform without causing damage to the vastus medialis obliquus (VMO) due to the limited working space [71, 72].

Accordingly, we compared intraoperative soft tissue balance measurements of MIS QS and conventional TKA, performed with the patella and femoral component in place. Whereas the joint component gap in MIS QS-TKA was significantly larger through the entire arc of flexion compared with conventional TKA, the pattern of joint looseness (joint component gap-polyethylene insert thickness) showed no difference between the two procedures. The varus ligament balance in MIS QS-TKA was significantly larger than that in conventional TKA at 0, 90, and 135 degrees of knee flexion [73]. The study suggested that MIS-TKA may lead to ligament imbalance due to the difficulties induced by a limited working space.

6. Influence of intra-operative soft tissue balance on post-operative flexion angle

Factors influencing the range of flexion after TKA can mainly be classified as intra-capsular or extra-capsular factors. Among extra-capsular factors the importance of pre-operative motion for post-operative results has been previously recognized [74-78]. Similarly, the pre-operative tightness of the extensor mechanism is an important factor influencing the post-operative knee flexion angle [79]. In contrast, intra-capsular factors, including implant design, ligament balancing, flexion-extension gap balance, height of the joint line, and patella resurfacing, have also been discussed by many authors [80-85]. Among such factors, although soft tissue balancing has been recognized as the essential surgical intervention for improving the outcome of TKA, the direct relationship between soft tissue balance and postoperative outcomes has never been clarified. As another concept of the joint condition, posterior condylar offset has recently been described as a determinant for flexion [86-88]. A mean reduction in flexion of 12° was reported to be found with every 2 mm decrease in offset [86]. Although posterior condylar offset is thought to be related to flexion gap, this relationship has not been discussed.

In the series of studies in PS TKA, joint gap change value (90-0°) with PF joint reduced, not everted, showed inverse correlation with post-operative knee flexion angle ($R=-0.484$,

$p=0.019$) and posterior condylar offset ($R=-0.62$, $p=0.002$) [31]. However, in another series of studies in CR TKA, the post-operative flexion angle was positively correlated with the joint gap change value ($90-0^\circ$). In either case, multivariate regression analysis among various values including various joint gap change values, ligament balance, and pre-operative knee flexion angle demonstrated the pre-operative knee flexion angle and the joint gap change value ($90-0^\circ$) had a significant independent result on post-operative knee flexion angle [89]. One of the reasons for this discrepancy may be the different patterns of soft tissue balance between PS and CR TKA [48, 49]. In that report, CR TKA showed significantly smaller gaps when the arc of movement ranged from mid- to deep flexion, compared to PS TKA [48]. The posterior cruciate ligament in osteoarthritic knee is considered relatively rigid and shortened despite being relatively macroscopically intact. When we consider flexion gap tightness, Ritter et al. reported that 30% of CR TKA required ligament balancing to obtain a smooth flexion arc [90]. If the PCL was too tight, excessive femoral rollback resulted in anterior lift-off of the tibial trial in flexion, leading to a limitation of flexion [91]. To make a better post-operative flexion angle, balancing the flexion gap can result in a satisfactory range of motion [92, 93]. In our series of studies in CR TKA, it was identified that 16% more flexion gap tightness (smaller flexion gap than extension gap) resulted in a smaller flexion angle. Similarly, using a commercially available knee balancer with the measurement under 80 N distraction force, Higuchi et al reported flexion medial/lateral gap tightness led to restriction of the flexion angle [94]. Therefore, in these cases, surgeons are advised to avoid flexion gap tightness by soft tissue release such as PCL [90, 91, 95].

7. Influence of preoperative deformity on intra-operative soft tissue balance

Pre-operative deformity of the knee differs from patient to patient. In the varus knee especially, many surgeons recognize that progressive shortening or contraction of soft tissue structures on the medial side may occur, whereas the lateral structures may become stretched [96-99]. Although severe intra-operative varus deformity needs substantial soft tissue release on the medial side during TKA, the ideal amount of medial release is still controversial; two strategies exist for soft tissue balancing in the varus knee. Some surgeons believe it is best to create equal medial and lateral gaps even in severely deformed knees [2, 100, 101]. Others accept some degree of lateral laxity is permissible, as long as proper alignment is maintained, based on evidence showing post-operative diminishment with time of lateral laxity after TKA [102, 103].

Accordingly, we compared intra-operative soft tissue balance measurements in various grades of preoperative varus deformity ($10^\circ < \text{varus deformity}$, $10^\circ < \text{varus deformity} < 20^\circ$, $\text{varus deformity} > 20^\circ$) during PS TKA, performed with a reduced patella. In the comparison of the changing pattern of joint component gap among the three different pre-operative deformity groups, we observed similar kinematic patterns showing an increase until 90° of knee flexion and a decrease towards deep knee flexion, and no difference among the groups throughout the flexion angle of the knee. In the comparison of medial-lateral ligamentous balance, on the other hand, the varus angle showed significant larger values in the varus alignment $> 20^\circ$ group compared to that of the other two groups throughout knee flexion in spite of similar patterns showing slight increases in the varus angle to 90° of knee flexion and constant balance after that. These results indicate that appropriate medial-lateral balancing is difficult in knees with severe pre-operative varus deformity, especially with varus alignment $> 20^\circ$ [104].

Even in normal knees, lateral ligamentous laxity and medial ligamentous laxity are not balanced and more lateral ligamentous laxity than medial ligamentous laxity has been observed [105-107]. To restore the joint line, we believe lateral laxity of less than 5 degrees is permissible in the varus alignment $< 20^\circ$ groups as long as proper alignment is maintained [102, 103, 108]. In such severely deformed varus knees, some surgeons may recommend the complete release of medial-sided structures including an MCL cut for achievement of a well-balanced knee [109]. However, we avoided this procedure due to the potential widening of the joint gap with elongation of the lower extremity, and subsequent patella baja as a result of joint line elevation due to a thicker polyethylene insert. Therefore, results in this series may be based on these operative procedures.

8. Soft tissue balance in gap technique

In the above mentioned study, soft tissue balance measurements were only performed in posterior-stabilized (PS) or cruciate-retaining (CR) TKAs using the measured resection technique. However, the best method of obtaining rotational alignment of the femoral component in flexion remains controversial. Some investigators favor a measured resection technique in which bony landmarks (femoral epicondyles, posterior femoral condyles, or the anteroposterior axis) are the primary determinants of femoral component rotation [110-115]. Others recommend a gap-balancing methodology in which the femoral component is positioned parallel to the resected proximal tibia with each collateral ligament equally tensioned [116-118]. Under such debate, several surgeons recently reported more consistent equalization of extension and flexion gaps with the use of computer-assisted gap balancing technique, compared with conventional measured resection technique [119, 120]. In contrast, in the comparison between the navigation-assisted measured resection and navigation-assisted gap balancing technique, some surgeons reported a better restoration of the joint line position in the navigation-assisted measured resection technique despite no differences in short-term clinical outcomes [120, 121].

Using the offset type tensor, which can be used in the gap technique [123], we performed soft tissue balance assessment during CR TKA using the tibia first gap technique with navigation system. With the tibia first gap technique, the kinematics of the component gap showed a similar pattern to the measured resection technique during CR TKA; following a significant increase during the initial 30° of knee flexion, the joint component gap showed a gradual decrease toward 120° of flexion [48, 89]. After that, soft tissue balance was assessed at extension and flexion between the basic value after tibial cut and the final value following femoral cut and with femoral component in place. The basic value of the joint gap before femoral osteotomy reflected the final value following femoral cut and with femoral component in place (unpublished data). Accordingly, the tibia first gap technique may have the advantage that surgeons can predict the final soft tissue balance from that before femoral osteotomies.

9. Summary

In the series of study using offset type tensor with PF joint reduced and femoral component in place, the kinematic pattern of intraoperative joint gap and ligament balance can be observed in TKA when they are performed while preserving a more physiological condition of the knee. Additionally, various factors influencing soft tissue balance such as patellar

orientation, PS/CR type of prosthesis design, MIS/conventional technique, grade of preoperative deformity, and operation procedures, measured resection or gap technique can be examined. We believe the information provided by the use of the offset type tensor is useful and essential for providing insight into true post-operative kinematics, and thus by maintaining a reduced patella for each intra-operative measurement, the surgeon will be able to adjust the soft tissue balance more accurately and thereby expect a better post-operative outcome.

10. References

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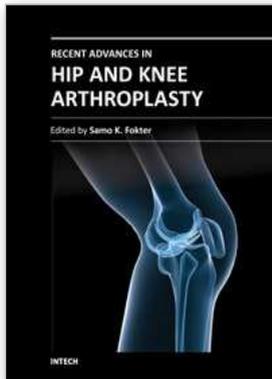
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The purpose of this book is to offer an exhaustive overview of the recent insights into the state-of-the-art in most performed arthroplasties of large joints of lower extremities. The treatment options in degenerative joint disease have evolved very quickly. Many surgical procedures are quite different today than they were only five years ago. In an effort to be comprehensive, this book addresses hip arthroplasty with special emphasis on evolving minimally invasive surgical techniques. Some challenging topics in hip arthroplasty are covered in an additional section. Particular attention is given to different designs of knee endoprostheses and soft tissue balance. Special situations in knee arthroplasty are covered in a special section. Recent advances in computer technology created the possibility for the routine use of navigation in knee arthroplasty and this remarkable success is covered in depth as well. Each chapter includes current philosophies, techniques, and an extensive review of the literature.

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