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Laxity Profiles in the Native and Replaced Knee – Application to Robotic-Assisted Gap-Balancing TKA

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Abstract:

Background: The traditional goal of the gap-balancing method in total knee arthroplasty is to create equal and symmetric knee laxity throughout the arc of flexion. The purpose of this study was to 1) quantify the laxity in the native and the replaced knee throughout the range of flexion in gap-balancing TKA, and 2) quantify the precision in achieving a targeted gap profile throughout flexion using a robotic assisted technique.

Methods: Robotic-assisted, gap-balancing TKA was performed in fourteen cadaver specimens. The proximal tibia was resected, and the native tibiofemoral gaps were measured using a robotic tensioner that dynamically tensioned the soft-tissue envelope throughout the arc of flexion. The femoral implant was then aligned to balance the gaps at 0° and 90° of flexion. The post-operative gaps were then measured during final trialing with the robotic tensioner and compared to the planned gaps.

Results: The native gaps increased by 3.4±1.7mm medially and 3.7±2.1mm laterally from full extension to 20° of flexion (p<0.001), and then remained consistent through the remaining arc of flexion. Gap balancing after TKA produced equal gaps at 0° and 90° of flexion, but the gap in mid-flexion was 2-4mm more lax than at 0° and 90° (p<0.001). The root mean square error between the planned gaps and actual measured post-operative gaps was 1.6mm medially and 1.7mm laterally throughout the ROM.

Conclusion: Aiming for equal gaps at 0° and 90° of flexion produced equal gaps in extension and flexion with larger gaps in mid-flexion. Consistent soft-tissue balance to a planned gap profile could be achieved by using controlled ligament tensioning in robotic-assisted TKA.

Keywords: Laxity, Gap balancing, Robotics, total knee replacement, Gaps
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Introduction

Knee stability and implant alignment are crucial to the short and long-term success of total knee arthroplasty (TKA) [1]. Gap-balancing is a technique used in TKA to obtain correct alignment and soft tissue balance. The goal of gap-balancing is to create equal and symmetric gaps in flexion and extension through bone cuts or ligament releases [2-5]. Gap-balancing techniques have been shown to produce equal and symmetric gaps at 0° and 90° of flexion; however, one study reported 36% of patients with balanced flexion-extension gaps had high mid-flexion laxity [6]. The increase in knee laxity in mid-flexion using the gap balance technique may be due to the technique not accounting for soft-tissue balance throughout the range of motion [4]. Assessing and balancing knee gaps and stability throughout the entire range of flexion may lead to improved patient outcomes and satisfaction [7].

While gap balancing in TKA aims for equal and symmetric gaps in flexion and in extension, laxity in the native knee has been shown to be neither equal nor symmetric, leading some clinicians to question the goals of traditional gap balancing methods [8, 9]. The native knee has been shown to be tighter on the medial side throughout the flexion range [8, 9]. In addition, laxity in the native knee has been shown to increase significantly from full extension to mid flexion, but then remain constant or increase only slightly at 90° of flexion. Although these studies provide information on the native gap profile, they only provide gap information at discrete flexion angles such as 0°, 30° or 45°, and 90°. Quantifying the native gap continuously throughout the range of motion may aid in understanding the variation in the tibiofemoral gap profile and in determining the flexion range where the most prominent changes in the tibiofemoral gaps occur.
Measuring and balancing the tibiofemoral gap throughout the range of motion in the operating room is challenging using conventional instrumentation. Advances in technologies have allowed for the development of new tools in TKA, such as navigation and robotic devices, that can measure tibiofemoral gaps in real-time. These devices have been shown to improve implant alignment accuracy and surgical outcomes [10-14]. In the tibial cut first gap-balancing technique, the native gap at full extension and flexion is acquired after resecting the tibia. The data is combined with the implant geometry and used to plan the femoral cuts in order to achieve a balanced gap in extension and flexion [5, 15, 16]. Most algorithms only provide data points at 0° and 90° however, which does not allow for gap planning in mid-flexion. A planning method that allows for visualization of the post-operative gaps throughout the range of motion, based on the native gaps and a planned component position, may provide a better understanding of the effects of implant alignment on joint laxity in mid-flexion as well as in extension and flexion, prior to performing bone resections. This may aid in determining optimal patient-specific balance targets, which may reduce the frequency and the extent of soft tissue releases required to achieve balance and achieve more consistent outcomes in TKA [17].

The objective of this study was to quantify the tibiofemoral gap throughout the arc of flexion for the native knee and the replaced knee implanted with a gap balancing technique. A secondary objective of this study was to evaluate the virtual gap algorithm used to predict the post-operative tibiofemoral gap profile as a function of the measured pre-operative gap and the virtual femoral component plan.

Materials and Methods

Fourteen cadaveric knees (10 male, mean age: 73±13, BMI: 26.8±7.6) were used in this study. All knees were exposed with a standard midline skin incision and a traditional medial
parapatellar arthrotomy. The medial aspect of the patellar fat pad, the anterior aspect of the tibial meniscus and the anterior cruciate ligament were excised. Minimal subperiosteal dissection of the medial collateral ligament was performed to obtain sufficient exposure of the knee joint. A tibial tracking array was rigidly fixed to the tibia remote to the incision with two threaded bone pins. A femoral tracking array was rigidly fixed to the femur within the incision with two cancellous bone screws. The base of the femoral tracker also serves as the mounting base for the robotic femoral cutting guide and was attached to the medial side of the distal femur, anterior to the medial collateral ligament (MCL) insertion area so that it did not interfere with the ligament tension and the knee gap measurements throughout the range of motion (ROM). Tracking arrays were rigidly attached onto the femoral and tibial bone. Anatomical landmarks on the femur and the tibia were digitized and used to establish a three-axis orthogonal coordinate system to describe the tibiofemoral kinematics [18]. An image-free bone morphing algorithm was used to create 3D models of the femoral and the tibial bone based on the registered femoral and tibial surface [19]. The bone morphing process consists of gliding a tracked point probe with a spherical tip over the exposed surfaces of the bone, continuously capturing a cloud of points on the bone surface to which a 3D statistical shape model is deformed. The final accuracy of the registration was verified to be within 1mm in all digitized areas using the robotic system point probe.

The tibia was then resected perpendicular to the mechanical axis in the frontal plane with 4° posterior slope. A navigated adjustable cutting block was used to guide the resection and the final cut surface was validated with the system planar probe [20, 21]. Collateral and posterior cruciate ligament (PCL) retractors were sequentially positioned to protect the ligaments and surrounding soft tissues during the resection. The PCL was retained in each specimen. Following
the tibial resection, a novel robotic-assisted ligament tensioning tool (OMNIBotics Active Spacer™, OMNI, Raynham, MA) was inserted into the joint space to measure the native tibiofemoral gaps (Fig 1). The Active Spacer consists of two independent motorized actuators with integrated force sensors. A tibial baseplate that matches the size and profile of the selected tibial tray size and two upper arms are attached to the Active Spacer. The OMNIBotics system is used to independently control the Active Spacer actuators in either force or position mode to measure gap distance under controlled ligament tension or to measure medial and lateral loads for a controlled gap height, respectively. After performing the tibial resection, the size of the tibial baseplate was selected to provide appropriate anatomical coverage on the tibial resection and was attached to the Active Spacer. With the Active Spacer inserted in the knee joint, the gap profiles were measured using the navigation system as the limb was manually taken through a range of flexion with the patella reduced. The system applied 80-100 Newtons of tension equally to each of the medial and lateral sides from 0 to 25° of flexion (Fig. 2A). The applied force was then decreased linearly from 25° to 75° of flexion to a target load of 50-80N per side then held constant throughout the remaining arc of flexion. Applying a lower force in flexion was based on prior studies and the surgical goal of leaving the knee in slightly less tension in flexion than in extension to replicate normal ligament tensions [8, 22]. The native gap was defined as the distance between the tibial resection and the closest point on the articulating surface of the native femoral bone model on the medial and lateral sides at each degree of flexion [23]. The tibiofemoral kinematics measured during the native gaps were used in a virtual gap algorithm to predict the post-operative gap profile for the planned implant alignment (Fig. 2B). The design of knee system used in this study (OMNI Apex™ CR, OMNI, Raynham, MA) incorporates highly conforming articulating surfaces in the frontal and sagittal planes, with one-
to-one femoral to tibial insert implant size matching and a multi-radius femoral component design in the sagittal plane to provide stability throughout the range of motion and in mid-flexion. The femoral component size, and coronal and sagittal alignment was planned such that the virtual post-operative gaps were as close to equal as possible in extension and flexion while respecting the following limits for anatomic placement of the implant on the bone: 3° varus or valgus; 0-8° external rotation relative to the posterior condyles. The AP size and the flexion of the femoral component was planned such that the flexion gaps equaled the extension gap without notching or overstuffing the anterior aspect of the femur. The iBlock robotic cutting-guide was used to perform the femoral cuts based on the planned implant position and size (Fig. 2B) [24]. The iBlock is a miniature bone mounted robot that attaches onto the medial side of the femur via the femoral tracker fixation base, and automatically positions a single saw-capture to the five cutting plane locations determined during the femoral implant planning step. After performing the resections, the distal and anterior femoral resections were validated using the system cut controller and the femoral trial component was inserted. Separate medial and lateral inserts that mimic the tibial insert and that match the femoral implant were attached to the Active Spacer. The Active Spacer was then reinserted into the joint and the same loading profile used for the native gap acquisition was repeated with the patella reduced. The Active Spacer was positioned on the tibial resection in AP and in rotation to reflect the desired final tibial implant position, ie to achieve appropriate anatomical coverage on the tibia and to minimize rotational mismatch with the femoral component in extension. The implant gap was measured as the distance from the tibial resection to the closest point on the femoral trial (Fig. 2C).

The native and implants gaps were normalized in order to standardize the measurements across specimens. The native gaps for each specimen were normalized by subtracting the amount
of tibial bone resected from the medial and lateral side while the implants gaps were normalized relative to the insert thickness [23]. The difference between the measured post-operative gap and the predictive gap at each flexion angle was used to calculate the prediction error and quantify the algorithm predictive capabilities. The mean and standard deviation of the native gaps, implant gaps, and prediction error were calculated across the fourteen specimens. The root mean square (RMS) error between the predicted implant gaps and the measured post-operative implant gaps was calculated over the arc of flexion on the medial and lateral sides. Paired t-tests were used to identify significant differences in the native gaps between 0°, 10°, 20°, 45° and 90° of flexion, the difference between the overall medial and lateral native gap, and the difference between the predicted and post-operative gaps. The false discovery rate method was then used to correct for multiple comparison and reduce type I error in the statistical analysis [25].

Results

The native medial and lateral gaps were tightest in extension at 1.3±2.5mm and 2.2±2.9mm, respectively (Fig 3A). The gaps increased significantly by 3-4mm (p<0.001) as the knee was flexed from 0° to 20° of flexion, and then plateaued with no significant changes throughout the remaining arc of motion (Table 1). The lateral native gap was on average 1.3mm±0.2mm larger than the medial gap throughout the range of flexion (p<0.0001).

The post-operative medial femoral gaps were similar to the lateral femoral gaps throughout the entire flexion range (Fig. 3B). The post-operative femoral gaps were smallest at full extension and 90° flexion (approximately 0mm). As the knee went into flexion the gaps started to open up until reaching a maximum mean laxity of 1.9mm medially and 3.7mm laterally at approximately 30° of flexion (Fig. 3B). Beyond 30°, the gaps gradually decreased until 90° flexion.
The RMS error between the predicted and post-operative gaps was 1.6mm medially and 1.7mm laterally over the range of flexion. The mean error was approximately 1mm in full extension and early flexion, where the algorithm predicted slightly larger gaps than the post-operative gaps (Fig. 4). Differences between the predicted and the measured post-op gaps on the medial or the lateral side were not statistically significant for all flexion angles (p>0.6).

Discussion

The tibiofemoral gap prior to resecting the femur in a tibial-cut first TKA technique were assessed in the study, the gaps increased significantly in the first 20° of flexion then remained consistent through the remaining arc of flexion. Planning the femoral component alignment to produce equal gaps at 0° and 90° of flexion resulted in an increase in mid-flexion gap laxity compare to 0° and 90°. In addition, the root means square error of the post-operative gap prediction algorithm used in the study was determined to be 1.7mm.

The native knee laxity was smallest at full extension, then increased significantly until reaching 30° of flexion at which point the gap remained consistent for the remaining arc of flexion. The medial gap was approximately 1mm smaller than the lateral gap throughout the flexion range. Similar results have been previously reported, however, prior studies quantified laxity only at specific degrees of full extension, mid-flexion, deep flexion and not continuously throughout the arc of flexion [8, 9, 23]. While discrete laxity measurements provide some insight into knee laxity profile patterns, these prior studies are limited in their ability to identify where the most significant changes in laxity occur. Our results show that the most significant changes in knee laxity occur in extension to early mid-flexion (0-30°), with the laxity staying consistent past 30°. The contributor to the change in knee laxity throughout the range of motion is the contribution of the soft tissue. The collateral ligaments are tightest at full extension; however, as
the knee starts to flex the distance between the attachment points of the collateral ligaments gets smaller reducing the force applied by these ligaments on the knee joint [26, 27]. The reduction in collateral ligament load and posterior capsule tension, as well as the knee screw home effect, cause the knee laxity to increase up to 30° flexion [26, 28]. The significant increase in the native knee laxity from 0° to 30° of flexion observed in this and in other studies [8, 9, 23] is an under-recognized phenomenon in gap balancing approaches and may imply an anatomic cause for mid-flexion laxity post TKA.

The alignment of the femoral component was varied during the planning phase by either flexing or shifting the femoral component posteriorly to balance the flexion and extension gaps. This technique produced balanced gaps at 0° and 90°, a result well supported in the literature [29-31]. Planning for a zero-millimeter residual gap (i.e. equal gaps) at 0° and 90° resulted in the implanted gaps being tightest at these flexion angles and loosest in mid-flexion. The native gap is shifted to produce equal gaps at 0° and 90° which causes a change in the shape of the laxity profile if no ligament releases are performed (Fig. 5). The result is a TKA laxity profile that is smallest at 0° and 90° and largest at approximately 30° flexion (Fig. 3B). While the mid-flexion laxity we measured in the replaced knee was smaller than in the native knee, by approximately 2-3mm, the relative increase in the laxity profile with flexion may be observed clinically as mid-flexion laxity or instability when evaluating the replaced knee in the operating room [32, 33]. While studies have suggested an elevated joint line, multi-radii femoral component design and MCL laxity may cause mid-flexion laxity [34], our data suggest that the increase in TKA laxity from 0° to 30° may primarily be an anatomic phenomenon driven by the native soft tissue stabilizers. Planning for a zero gap at 5 or 10 instead of 0 degrees of flexion or planning for a flexion gap that is slightly looser than the extension gap in patients with large differences in their
native flexion/extension gaps may reduce the laxity in mid-flexion, at the risk of overtightening the extension gap and creating a flexion contracture, or over-loosening the flexion gap and creating an instability in flexion. Although this may produce gap profiles that are comparable to that of the native knee [22], future studies are needed to evaluate the effect of changing the extension planning angle and the targeted laxity profile on outcomes.

The gap planning algorithm was capable of predicting post-operative laxity with a maximum mean error of 2mm, with the largest error occurring in early flexion. Specifically, the extension gap was on average approximately 1mm tighter than predicted (Fig. 4). The tighter extension gap may be due to multiple factors. To reduce flexion gap laxity the femoral component was either shifted or flexed posteriorly, which increased the posterior condylar offset by 1.3mm medially and 4.1mm laterally [35]. This may have caused some additional tensioning of the posterior capsule when the knee is brought into full extension. Secondly, the design of the knee system used in this study has a relatively conforming tibiofemoral articulation in full extension and small variations in the rotation of the tibial insert may have affected the extension gap measurement. Despite these minor discrepancies the gap information provided during the femoral planning phase proved to be valuable tool overall for predicting knee balance and laxity throughout the range of motion. Surgeons can utilize the prediction algorithm to visualize the effect of various femoral cuts on the post-operative gaps and develop a femoral alignment plan that addresses the laxity throughout the range motion and can achieve the desired gap.

Several limitations should be taken into consideration when interpreting the results of this study. The tibiofemoral gaps were measured in cadaveric specimen which may have variations in soft tissue properties compared to living patients. Additionally, the anterior cruciate ligament (ACL) was excised during the initial exposure, so the gaps measured prior to femoral resection
are representative of the ACL deficient knee. However, the ACL is usually resected in TKA (or is often absent in the arthritic knee) so these gaps are representative of the intra-operative situation which must be managed in TKA to achieve balanced gaps post-operatively. The shape of the tibial insert influences the anterior-posterior translation of the femur which could affect the tibiofemoral gaps. Finally, the laxity profiles reported on in our study were measured in the PCL intact knee and thus may not be directly translatable to PCL substituting TKA. The PCL is known to be a stabilizer in flexion and had we resected the PCL we would expect the native flexion gap to be approximately 2mm larger, according to prior studies [23]. This may have resulted in a different implant plan with less bone resection posteriorly on the femur to achieve balanced gaps. Further studies are required to determine how PCL resection affects the laxity profiles in gap balancing TKA [36].

Aiming for equal gaps in flexion and extension using a gap-balancing technique resulted in a balanced knee in flexion and extension with approximately 2-4mm of residual laxity in mid-flexion. The gaps prior to femoral resection exhibited the greatest change from 0 to 30 degrees of flexion, with little change thereafter, suggesting an anatomic cause for increased laxity in mid-flexion. Computer and robotic-assisted surgical methods that can predict knee implant laxity prior to making femoral resections provide a useful tool for achieving an optimal tradeoff between implant position, alignment and soft-tissue balance. The results from this study provide insight into the native and implant tibiofemoral gaps throughout the flexion range. The study also validates an algorithm that can be used to predict the post-operative gaps for a specific implant alignment plan before making any femoral resections. Understanding the relationships between native knee laxity, implant alignment and post-operative knee laxity may lead to improved surgical outcomes and increased patient satisfaction in gap-balancing TKA. Future studies are
required to establish the accuracy and repeatability of the gap prediction method \textit{in vivo}, and to associate target gap profiles with clinical outcomes and patient satisfaction in TKA.

\textbf{Acknowledgment}

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References


Tables:

Table 1: Average differences in the native gaps between 0°, 10°, 20°, and 90° for the medial and lateral sides. * P<0.001

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<th>Flexion</th>
<th>10°</th>
<th>20°</th>
<th>90°</th>
<th>10°</th>
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<td>0.9±1.0</td>
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<td>0.1±1.2</td>
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Figures:

Figure 1: Model of the Active Spacer
Figure 2: Screenshots from the OMNIBotics system and the cadaveric experiment showing (A) native gap balancing collection, (B) femoral planning and resection, and (C) implants gap acquisition.
Figure 3: Average (A) native and (B) implant medial (left) and lateral (right) gaps throughout the flexion range. The shaded areas represent ±1 standard deviation.

Figure 4: Average prediction error (blue line) between the predicted and the post-operative gap. The shaded areas represent ±1 standard deviation.
Figure 5: Illustration of the change in the gap profile from native to implant when reducing the flexion gap.
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