Background: Gap-balancing is an alignment method for total knee arthroplasty with the goal of creating uniform tension in the periarticular soft-tissue restraints and equal laxities throughout the arc of flexion. However, there is little evidence that achieving equal laxities prevents either overly tight or overly loose soft-tissue restraints after total knee arthroplasty. Accordingly, the purpose of the present study was to determine whether the laxities at 0°, 45°, and 90° of flexion are equal in the native knee.

Methods: Seven different laxities were measured at 0°, 45°, and 90° of flexion in ten fresh-frozen native cadaveric knees (with intact menisci, cartilage, and ligaments) by applying loads of ±5 N in varus-valgus rotation, ±3 Nm in internal-external rotation, 100 N in distraction, and ±45 N in anterior-posterior translation with use of a six-degrees-of-freedom load application system.

Results: The mean laxities (and standard deviations) at 45° of flexion were 1.7° ± 0.6° greater in varus, 0.9° ± 0.4° greater in valgus, 10.2° ± 2.7° greater in internal rotation, 10.1° ± 2.0° greater in external rotation, 1.7 ± 1.0 mm greater in distraction translation, and 3.3 ± 1.5 mm greater in anterior translation than those at 0° of flexion. The mean laxities at 90° of flexion were 2.5° ± 0.8° greater in varus, 1.0° ± 0.5° greater in valgus, 10.0° ± 4.6° greater in internal rotation, 10.1° ± 4.5° greater in external rotation, 1.8 ± 0.7 mm greater in distraction, and 1.6 ± 1.2 mm greater in anterior translation than those at 0° of flexion. The mean anterior translation at 90° of flexion was 1.7 ± 0.9 mm less than that at 45° of flexion.

Conclusions: Because five of the seven laxities were at least 1.7° or 1.6 mm greater at both 45° and 90° of flexion than those at 0° of flexion, the laxities of the native knee measured in this study are unequal at these flexion angles and therefore do not support the goal of gap-balancing in total knee arthroplasty.

Clinical Relevance: One possible disadvantage of changing the native laxities at 45° and 90° of flexion to match those at 0° of flexion in a total knee arthroplasty is the overly tight soft-tissue restraints relative to those of the native knee, which patients may perceive as pain, stiffness, and/or limited flexion.

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Complications associated with overly tight soft-tissue restraints are pain, stiffness, and a loss of flexion. Complications associated with overly loose soft-tissue restraints are instability.

It is important to achieve optimal tension in the periarticular soft-tissue restraints to restore optimum function and avoid related complications after total knee arthroplasty.
and accelerated polyethylene wear. Together, overly tight and overly loose soft-tissue restraints account for up to 54% of revision procedures.

Gap-balancing is an alignment method for total knee arthroplasty with a goal of creating uniform tension in the soft-tissue restraints around the arc of flexion. Although the tensions that should be achieved in the various soft-tissue restraints around the knee are unknown, gap-balancing strives to create rectangular gaps and equal laxities at 0° of flexion, 45° of flexion, and 90° of flexion. However, there is little evidence that achieving equal laxities prevents either overly tight or overly loose soft-tissue restraints after total knee arthroplasty.

If a preferred outcome of total knee arthroplasty is the restoration of native kinematics, then the laxities of the native knee should be used as a standard to determine whether the soft-tissue restraints after total knee arthroplasty are overly tight or overly loose. The soft-tissue restraints and the articular geometry interact to determine the passive kinematics of the knee. Consequently, a total knee arthroplasty with different laxities than those of the native knee will also have abnormal function of the soft-tissue restraints, causing abnormal kinematics. Therefore, restoring native knee kinematics in a total knee arthroplasty requires that the laxities at 0°, 45°, and 90° of flexion after total knee arthroplasty be similar to those of the native knee. Although many studies have measured the laxities of the native knee, to our knowledge, none has determined whether the laxities of the native knee are equal at 0°, 45°, and 90° of flexion. Accordingly, the purpose of the present study was to determine whether the laxities in varus-valgus rotation, internal-external rotation, distraction translation, and anterior-posterior translation of the native knee are equal at 0°, 45°, and 90° of flexion, and thus support the goal of gap-balancing total knee arthroplasty.

Materials and Methods

Thirty-seven fresh-frozen cadaveric knees were evaluated radiographically, and twelve were excluded because they had evidence of degenerative arthritis or chondrocalcinosis. The seven laxities in four degrees of freedom of three native cadaveric knee specimens were measured in a pilot study (method described below) to determine the greatest standard deviation of the three pairwise differences between the laxities at 0°, 45°, and 90° of flexion. For each laxity, a power analysis was performed to determine the minimum number of knee specimens required to detect a difference between flexion angles equal to the greatest standard deviation for the respective laxity measured in the pilot study. The standard deviations measured were 1.0° for varus rotation, 0.4° for valgus rotation, 3.0° for external and internal rotations, 0.7 mm for distraction translation, 1.0 mm for anterior translation, and 0.6 mm for posterior translation. A minimum of ten knee specimens was determined to be required, assuming a level of significance of 0.05 and a power of 0.80. The laxities were measured in the remaining twenty-five knee specimens and an arthrotonomy was performed on each knee specimen. Fifteen of the twenty-five knee specimens were excluded because cartilage wear was observed. The ten knee specimens comprising the study group were obtained from six men and four women, with an average height of 1.7 m (range, 1.6 to 1.9 m), an average weight of 60.3 kg (range, 44.0 to 86.3 kg), and an average age of sixty-nine years (range, fifty-two to ninety-three years) at the time of death.

Each knee specimen was thawed, dissected, aligned, and potted in preparation for laxity testing in a six-degrees-of-freedom load application system. The fibula was fixed to the tibia using a transverse screw placed 12 cm distal to the joint line to restore the stability of the proximal tibiofibular joint. The thigh was transected 20 cm proximal to, and the lower leg was transected 25 cm distal to, the joint line of the knee. Soft tissues between 15 cm proximal to and 12 cm distal to the joint line of the knee were retained. Dehydration of the soft tissues was prevented by wrapping the knee in a saline solution-soaked cloth. Intramedullary rods were cemented into the medullary canals of the femur and tibia using methyl methacrylate (COE Tray Plastic; GC America). These rods were attached to alignment fixtures that were connected to the load application system. Using a functional alignment procedure, the position and orientation of the femur and tibia were adjusted using the alignment fixtures until the flexion-extension and longitudinal fixation points of the fibial femoral joint were aligned with the flexion-extension and internal-external rotation axes of the load application system. The shafts of the femur and tibia were potted into aluminum square tubes with use of methyl methacrylate to rigidly fix the position and orientation of each bone to the load application system for subsequent testing (Fig. 1).

After dissection, alignment, and potting, each knee specimen was preconditioned with use of the following protocol. A compressive load of 45 N was applied, and the knee specimen was cycled five times between ±2.5 Nm in...
The position of the knee specimen under a 2.5-Nm extension moment defined 0° of flexion. The knee specimen was placed at a randomly selected flexion angle of 0°, 60°, or 120°. The compressive load of 45 N was again applied, and at the selected flexion angle, the knee specimen was cycled five times between the positive and negative load in each of the four degrees of freedom (i.e., varus-valgus rotation, internal-external rotation, compression-distraction translation, and anterior-posterior translation) in a random order. For each degree of freedom, the magnitude of the load was selected so that the soft-tissue restraints were loaded to the onset of the high stiffness region of their load-deformation curve. The magnitude of the load was ±5 Nm for varus-valgus rotation, ±3 Nm for internal-external rotation, ±100 Nm for compression-distraction translation, and ±45 Nm for anterior-posterior translation. The preconditioning protocol was repeated for the other two flexion angles in a random order.

After preconditioning, each of the seven laxities in the four degrees of freedom (excluding compression laxity) was measured with use of the previously described loads under the compressive load of 45 N at flexion angles of 0°, 45°, and 90° in a random order with use of the six-step loading cycle described in Figure 2.

**Statistical Analysis**

The mean and standard deviation were calculated for each laxity at 0°, 45°, and 90° of flexion. For each laxity, a one-way repeated-measures analysis of variance with the specimen as the repeated measure and a Tukey test were used to determine whether the mean laxities at 0°, 45°, and 90° of flexion were significantly different at a p value of <0.05. Statistical analyses were performed with JMP software (version 11.2.0; SAS Institute).

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**Results**

On the basis of the analyses of variance, the effect of flexion angle was highly significant for six of the seven laxities (p < 0.0001). Only for posterior laxity was the effect of flexion angle not significant (p = 0.75).

On the basis of the Tukey tests of the six laxities for which the effect of flexion angle was significant, all six laxities were significantly greater at 45° of flexion than those at 0° of flexion (Table I). The average varus laxity at 45° of flexion was 1.7° greater than that at 0° of flexion (p = 0.0001) (Fig. 3-A). The average valgus laxity at 45° of flexion was 0.9° greater than that at 0° of flexion.

<table>
<thead>
<tr>
<th>Laxity</th>
<th>0°</th>
<th>45°</th>
<th>90°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varus rotation (deg)</td>
<td>0.7 ± 0.3</td>
<td>2.4 ± 0.8</td>
<td>3.2 ± 1.0</td>
</tr>
<tr>
<td>Valgus rotation (deg)</td>
<td>-0.4 ± 0.2</td>
<td>-1.4 ± 0.5</td>
<td>-1.4 ± 0.6</td>
</tr>
<tr>
<td>Internal rotation (deg)</td>
<td>4.6 ± 1.4</td>
<td>14.8 ± 3.0</td>
<td>14.6 ± 5.5</td>
</tr>
<tr>
<td>External rotation (deg)</td>
<td>-4.4 ± 1.7</td>
<td>-14.4 ± 2.7</td>
<td>-14.5 ± 3.8</td>
</tr>
<tr>
<td>Distraction translation (mm)</td>
<td>-0.6 ± 0.1</td>
<td>-2.4 ± 1.0</td>
<td>-2.4 ± 0.8</td>
</tr>
<tr>
<td>Anterior translation (mm)</td>
<td>2.1 ± 0.5</td>
<td>5.4 ± 1.6</td>
<td>3.6 ± 1.3</td>
</tr>
<tr>
<td>Posterior translation (mm)</td>
<td>-2.4 ± 1.2</td>
<td>-2.8 ± 1.7</td>
<td>-2.4 ± 1.3</td>
</tr>
</tbody>
</table>

*The values are given as the mean and the standard deviation, with the 95% confidence interval in parentheses. The values in bold indicate a significant difference (p < 0.05). †P values for the difference in laxities between flexion angles were determined using a Tukey test. ‡Tukey tests were not performed for posterior laxity because the effect of flexion angle in the analysis of variance was not significant. NA = not applicable.

![Fig. 2](image-url)
Fig. 3
Box-and-whisker plots show the increase in each of the seven laxities at 45° of flexion relative to 0° of flexion (Fig. 3-A) and 90° of flexion relative to 0° of flexion (Fig. 3-B). The top and bottom of each box represent the 75th and 25th percentiles, respectively; the horizontal line inside each box represents the median; the upper and lower whiskers of each box extend either to the highest and lowest values (not including outliers), respectively, or to the 75th percentile + (1.5 × interquartile range) and the 25th percentile − (1.5 × interquartile range), respectively; the interquartile range is calculated as the difference between the 75th and 25th percentiles. If a point appears outside the whiskers, then it is an outlier. The p values for significant differences detected by the Tukey tests are denoted with asterisks. *P ≤ 0.02. **P ≤ 0.0002. ***P ≤ 0.0001.
0° of flexion (p = 0.0002). The average internal rotation laxity at 45° of flexion was 10.2° greater than that at 0° of flexion (p < 0.0001). The average external rotation laxity at 45° of flexion was 10.1° greater than that at 0° of flexion (p < 0.0001). The average distraction laxity at 45° of flexion was 1.7 mm greater than that at 0° of flexion (p < 0.0001). The average anterior laxity at 45° of flexion was 3.3 mm greater than that at 0° of flexion (p < 0.0001).

On the basis of the Tukey tests, all six laxities were significantly greater at 90° than those at 0° of flexion (Table I). The average varus laxity at 90° of flexion was 2.5° greater than that at 0° of flexion (p < 0.0001) (Fig. 3-B). The average valgus laxity at 90° of flexion was 1.0° greater than that at 0° of flexion (p = 0.0001). The average internal rotation laxity at 90° of flexion was 10.0° greater than that at 0° of flexion (p < 0.0001). The average external rotation laxity at 90° of flexion was 10.1° greater than that at 0° of flexion (p < 0.0001). The average distraction laxity at 90° of flexion was 1.8 mm greater than that at 0° of flexion (p < 0.0001). The average anterior laxity at 90° of flexion was 1.6 mm greater than that at 0° of flexion (p = 0.02).

On the basis of the Tukey tests, only the anterior laxity was significantly different between 45° and 90° of flexion (Table I). The average anterior laxity at 45° of flexion was 1.7 mm greater than that at 90° of flexion (p = 0.009).

Discussion

Overly tight and overly loose soft-tissue restraints are associated with poor function and numerous complications after total knee arthroplasty with the gap-balancing alignment method, in which the goal is to achieve equal laxities at 0°, 45°, and 90° of flexion. Because a preferred outcome in total knee arthroplasty is restoration of the laxities of the native knee to restore native kinematics, the purpose of the present study was to determine whether the laxities in varus-valgus rotation, internal-external rotation, distraction translation, and anterior-posterior translation of the native knee are equal at 0°, 45°, and 90° of flexion. The most important finding of the present study was that laxities in varus-valgus rotation, internal rotation, external rotation, distraction translation, and anterior translation were nearly two to nearly five times greater at 45° and 90° of flexion than those at 0° of flexion. Because gap-balancing strives to create equal laxities at 0°, 45°, and 90° of flexion, the results of the present study indicate that five of seven laxities of a gap-balanced total knee arthroplasty might be overly tight by at least 1.7° or 1.6 mm at both 45° and 90° of flexion compared with the native knee, which should be considered clinically important as justified below.

Laxity differences of 1.7° or 1.6 mm should be considered clinically important. An arthroplasty surgeon is likely to be able to recognize a total knee arthroplasty that is overly tight by 1 to 2 mm because several intraoperative corrections have been developed to avoid the associated adverse consequences. For example, the proximal-distal level of the distal femoral resection is fine-tuned in increments of 1 to 2 mm to correct an overly tight extension gap that limits extension26-29. The posterior slope of the tibial resection is fine-tuned in increments of 1° to 2° to correct anterior subluxation and limited internal-external rotation of the tibia caused by an overly tight gap at 90° of flexion27,30,31. Finally, the varus-valgus angle of the proximal tibial resection is fine-tuned in increments of 1° to 2° with use of a recut block to correct an overly tight or an overly loose compartment. Hence, laxities that are overly tight or overly loose by 1° to 2° or 1 to 2 mm after total knee arthroplasty should be considered clinically important because they are routinely recognized and corrected intraoperatively.

Before the results are discussed, three limitations should be mentioned. One limitation is that the present study did not determine the differences in the laxities between a native knee and a gap-balanced total knee arthroplasty. To our knowledge, whether the laxities are equal at 0°, 45°, and 90° of flexion in a gap-balanced total knee arthroplasty has not been reported in either a cadaveric or an in vivo study. It is likely that the laxities of a gap-balanced total knee arthroplasty will be different from those of the native knee because the anterior cruciate ligament and, in some cases, the posterior cruciate ligament are removed and because the size and shape of the articular surfaces do not match those of the native knee. However, knowing the laxities in a gap-balanced total knee arthroplasty might not change the conclusion of the present study. Meeting the goals of gap-balancing requires that the knee be stable at 0° of flexion and that the gaps at 0°, 45°, and 90° of flexion be equal, in which case the gaps at 45° and 90° of flexion will be overly tight by an average of 1.7 and 1.8 mm, respectively, in distraction (Table I). The overly tight gaps at 45° and 90° of flexion will in turn cause the soft-tissue restraints of the knee to be overly tight at these flexion angles. If the native differences in the laxities between 0° of flexion and 45° and 90° of flexion are important for allowing the native internal rotation, distraction, anterior-posterior translation, and flexion of the tibia on the femur, then a patient who had a gap-balanced total knee arthroplasty might perceive these overly tight soft-tissue restraints as pain, stiffness, and loss of flexion.

A second limitation is that this study was carried out in cadaveric knees rather than in vivo. If the laxities of a cadaveric knee are not representative of those in vivo, then these results would not be transferrable to clinical practice. However, several studies have shown that laxities measured in vitro using cadaveric knees are in fact representative of those measured in vivo32,33. Therefore, the findings of this study should be relevant to clinical practice.

A third limitation is that the laxities were measured in only ten knee specimens. If the sample size was increased, then it is likely that the range of the differences in each laxity among the three flexion angles would also increase. However, it is unlikely that a larger sample size would change the conclusions of the present study because only ten knee specimens were necessary to detect clinically important changes in laxity on the basis of the results of the previously described power analysis.

The finding that five of the seven laxities were at least 1.7° or 1.6 mm greater at both 45° and 90° of flexion than those at 0° of flexion has potentially important clinical implications for knee function. In the native knee, the medial contact point of
the femur on the tibia remains nearly fixed as the knee flexes, but the lateral contact point of the femur on the tibia translates posteriorly, \textsuperscript{34,35} often referred to as medial pivot. The difference between the motions of the contact points in the two compartments causes internal rotation of the tibia with flexion and posterior roll-back of the lateral femoral condyle on the tibia. When the laxities of a total knee arthroplasty at 45° and 90° of flexion equal those at 0° of flexion, the knee is overly tight at 45° and 90° of flexion and more so in the lateral compartment than the medial compartment because the varus laxity is greater than the valgus laxity at these two flexion angles in the native knee (Table I). Overly tight soft-tissue restraints at 45° and 90° of flexion, especially in the lateral compartment, might explain the paradoxical external tibial rotation with flexion (often referred to as lateral pivot) and anterior sliding of the lateral femoral condyle on the tibia in flexion observed after some total knee arthroplasties.\textsuperscript{36,37}

Also, because the laxities of the native knee are not equal at 0°, 45°, and 90° of flexion, a total knee arthroplasty aligned with the gap-balancing method requires selective release of the soft-tissue restraints at 0° of flexion to create equal laxities at 0°, 45°, and 90° of flexion.\textsuperscript{38} However, if the goal is to restore the laxities of the native knee, then these releases prevent the kinematics of the knee after total knee arthroplasty from being restored to those of the native knee.\textsuperscript{39,40} Limiting releases of soft-tissue restraints is important because releases of soft-tissue restraints made to balance one laxity often increase other laxities, leading to instabilities that are uncorrectable.\textsuperscript{39-44} Striving to restore the native laxities at 0°, 45°, and 90° of flexion might help the surgeon to avoid unnecessary releases.

Finally, the finding that laxities of the native knee are not equal at 0°, 45°, and 90° of flexion helps to explain the results of recent studies showing better outcomes after kinematically aligned total knee arthroplasty, which has the goal of restoring the laxities of the native knee rather than creating equal laxities at 0°, 45°, and 90° of flexion. A Level-I randomized controlled trial showed that kinematically aligned total knee arthroplasty provided better pain relief, function scores, and flexion than mechanically aligned total knee arthroplasty at two years.\textsuperscript{42} Another recent study showed that kinematically aligned total knee arthroplasty mimicked paradoxical kinematics during knee flexion.\textsuperscript{43} A national multicenter study analyzing patient dissatisfaction after total knee arthroplasty noted that patients were three times more likely to report their knee to feel “normal” after kinematically aligned total knee arthroplasty than after mechanically aligned total knee arthroplasty.\textsuperscript{44} These studies suggest that striving to restore the laxities of the native knee may contribute to improved function after total knee arthroplasty.

A proposed advantage of the gap-balancing method is that a total knee arthroplasty with equal laxities throughout flexion is associated with a lower prevalence of lift-off of a femoral condyle from the tibial liner during flexion.\textsuperscript{45} Adduction lift-off of the femur from the tibia in the lateral compartment is especially undesirable because it may be associated with an increased rate of polyethylene wear and tibial component loosening from medial overload.\textsuperscript{46}

Kinematically aligned total knee arthroplasty also limits lift-off in addition to restoring a more normal amount of coupled rotation during knee flexion than gap-balanced total knee arthroplasty. A study of sixty-nine consecutive subjects treated by three surgeons with two designs of a cruciate-retaining component showed that adduction lift-off with kneeling had a prevalence of only 4%, and the abnormal pattern of in vivo external or reverse rotation of the tibial component with knee flexion was minimal.\textsuperscript{47} These same subjects had an in vivo internal rotation of the tibia on the femur from 0° to 90° of flexion that averaged 6°, which is two times greater than the 3° average reported for the gap-balanced total knee arthroplasties and closer to the 17° of total internal-external rotation reported for native knees.\textsuperscript{48,49} Hence, lift-off can be minimized with either a method that creates equal laxities or a method that restores the native laxities at 0°, 45°, and 90° of flexion, but restoring the native laxities may help to better restore normal coupled rotation with knee flexion.

In summary, arthroplasty surgeons who prefer the gap-balancing alignment method should be aware that the total knee arthroplasty may be overly tight at 45° and 90° of flexion with respect to the native knee, which may be perceived by the patient as pain, stiffness, and/or limited flexion.

\textbf{References}


