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ORIGINAL ARTICLE

In vitro biomechanical evaluation of tri-condylar total knee arthroplasty with posterior release for restoration of full extension

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Summary *Background/Objective:* The continuous improvement of knee function during deep flexion remains a challenge in total knee arthroplasty. Tri-condylar total knee arthroplasty has been designed to achieve this goal. However, the introduction of a third nonanatomic spherical condyle might prevent the joint from reaching full extension due to posterior soft tissue tightening. This study aimed to address these issues related to soft tissue tightening and full extension limitation.
Methods: Biomechanical tests were performed on six cadaveric specimens of the entire lower extremities. The tri-condylar design was compared with a posterior cruciate sacrificing design of the same shape without the ball structure. Knee joint kinematics was measured, including the extension and flexion angles, the extension balance, and the extension gap. The test was repeated after release of the medial and lateral posterior intercondylar soft tissues at a safe distance from the popliteal artery and nerves.
Results: Both designs resulted in a knee flexion angle up to $\sim 130°$. The tri-condylar design showed an extension angle of $-11.2 \pm 5.4°$, which was a significantly greater limitation than that obtained with the cruciate sacrificing design ($-3.8 \pm 4.7°$; $p = 0.047$). Moreover, the extension angle of the tri-condylar design was significantly improved after the release of posterior intercondylar soft tissues ($-0.1 \pm 6.7°$; $p = 0.028$).

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Conclusion: The tri-condylar design efficiently allowed the full extension by the release of posterior intercondylar soft tissues at a safe distance from the popliteal artery and nerves.

Introduction

One of the most challenging tasks when designing total knee arthroplasty (TKA) is the continuous improvement of knee function at deep flexion. This is particularly important for patients performing activities requiring deep flexion such as squatting, kneeling, or cross-leg sitting, notably in the Japanese and Arabian populations [1]. The traditional TKA methods, including posterior cruciate retaining and posterior cruciate sacrificing (CS) TKA, present some issues regarding femoral component geometry which lead to anterior slide of the femur in deep flexion at the time of condylar lift-off, especially in case of CS TKA [2–6]. This may lead to abnormal contact outside of the implant contact surface in deep flexion. The posterior stabilizing (PS) design TKA introduces a polyethylene surface with a post, to adequately constrain the anterior femoral slide with more posterior femoral rollback in deep flexion. However, the PS TKA raises post-related issues such as post-wear, post-fractures, or patellar clunk syndrome [7–9].

Tri-condylar TKA is another solution for improving knee function in deep flexion [10–16]. The primary feature of this design is the introduction of a third nonanatomic spherical condyle in the posterior groove and a socket surface on the tibial component, thus providing a contact between the femoral and tibial components in deep flexion. The ball-socket articulation not only prevents anterior sliding of the femoral component when reaching up to 130° flexion, but also offers joint contact in deep flexion with more stability and smoother contact force than the PS design [1,17,18]. In addition, the ball-socket articulation allows a smooth internal rotation, which is essential for achieving activities requiring deep flexion like kneeling or cross-leg sitting [16].

The tri-condylar TKA has been clinically launched in Japan and France, showing its design advantage of high flexion [14,16]. However, it has been noted that full extension is occasionally limited by posterior soft tissue tightening owing to the additional ball structure on the femoral component [19]. It has been suggested that a posterior release should be performed during this procedure [19]. To date, the posterior portions and tissues that should be released remain unclear. Also, since the popliteal space is the site of the popliteal artery, femoral nerve, and other critical structures, the posterior release may add collateral risks to the operation.

The purpose of the study was to experimentally address the following questions associated with the soft tissue tightening and the full extension limitation of the tri-condylar design *in vitro*: (1) what is the knee range of motion of the tri-condylar design? (2) how much does the range of motion improve after the posterior release of soft tissues? and (3) which anatomical sites are safe to perform a posterior release? The CS design was also examined and analysed for comparison.

Materials and methods

The experiment was performed on the entire left lower extremity of six female cadaveric specimens (5 Caucasians and 1 African American; mean age, 79.0 ± 7.5 years). No visible deformities, such as osteoarthritis, were noticed in all extremities. The proximal femur was fixed on a specifically designed multi-angle jig (Paock, Niigata, Japan). Each specimen was examined so that they had a full range of knee motion prior to the experiment. The standard arthroplasty procedure was then performed. After the resection of the bony spur around the distal femur and the removal of the anterior and posterior cruciate ligaments, the distal end of the femur was resected perpendicularly to the mechanical axis, since each valgus angle was measured, and the proximal tibia plateau was resected according to the tibial shaft. The femoral rotation was then set in parallel with each trans-epicondylar axis. The chamfer cut was performed in a regular way, and the preparation for the femoral trial was then completed. The thickness of the distal resection was 8.5 mm.

The tri-condylar design (Kyocera Medical, Osaka, Japan) was examined comparatively with the CS design of the same shape without the ball structure. To ensure consistency between the experimental conditions, the test employed plastic trials for each design which were made using a computer software (Solid Edge, ST3, Siemens PLM Software Inc., Plano, TX, USA) and a three-dimensional printer (VeroWhite FullCure, Objet Geometries Ltd., Rehovot, Israel; Figure 1). Each trial had exact bony interface geometry to fix into the femoral osteotomy via a stainless plate and neodymium magnets. The stainless plate

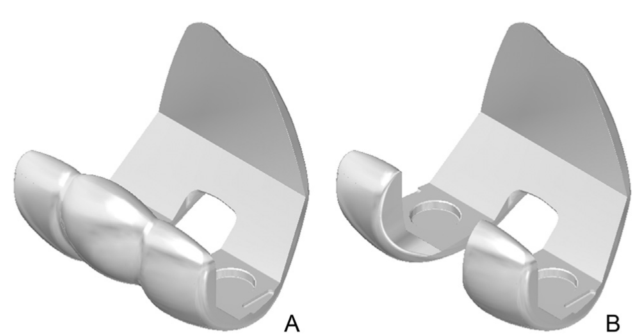

Figure 1 Templates of tested femoral components: (A) the tri-condylar design and (B) cruciate sacrificing (CS) design.

and magnet combination allowed the component to be attached and detached freely so that the two designs could be tested on the same specimen.

The test was first performed on the tri-condylar design, followed by the CS design. With the proximal femur immobilized on the jig, the testing specimen was moved from extension to flexion by manually moving the distal end of tibia and fibula, as shown in Figure 2. Kinematics was measured, including the extension angle and flexion angles, the extension gap, and the extension balance. Angles were formed by the femur midline and the tibia midline, each midline being marked by two metal pins, and measured by a digital goniometer (Digiangle, Crosswork, Osaka, Japan). The extension gap was measured by a tensor/balancer (VT-tensor Biomet Inc., Warsaw, IN, USA) as the space between the femur and the tibia in the frontal plane at full knee extension. The frontal plane was the one constructed by two lines on the femur: the trans-epicondylar axis and a line connecting the femoral head centre and the midpoint of the trans-epicondylar axis. Extension balance was the tilting angle between the femur and the tibia indicated by the tensor/balancer with a compressive force in the frontal plane at the knee extension [20,21]. The tensor/balancer could apply variable extraction force (0—200 N) between the two plates (one was fixed and the other was a tilting plate) and measure the extension gap ranging from 6 mm to 30 mm, the tilt ranging from -12° to 12° with an accuracy of 0.5 mm and 0.5°.

The posterior release was then performed on the posterior intercondylar soft tissues. As it was important to balance the knee joint gap medially and laterally, the release was achieved in a medial to lateral order with scissors (Figure 3). The resection included the residual posterior cruciate ligament (PCL), joint capsule, and Wrisberg ligament medially and the residual anterior cruciate ligament (ACL), joint capsule, and a part of oblique popliteal ligament laterally. The complete release was confirmed by finger touching the most distal end metaphysis of the posterior aspect of the femur. After medial and lateral releases, the kinematic tests were repeated with both designs. The distance between the most posterior

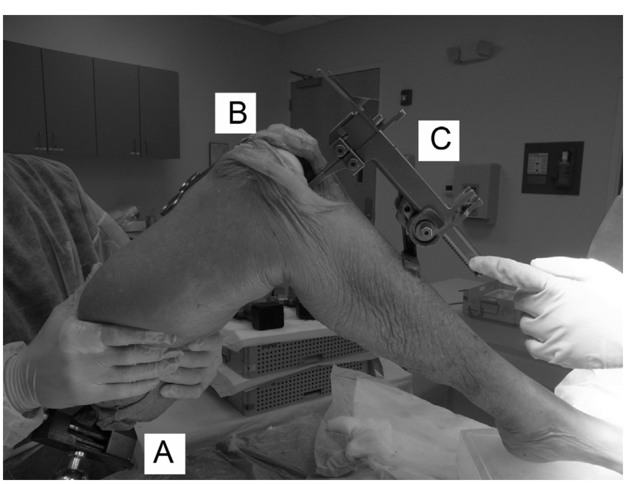

Figure 2 The experimental setup with: (A) the multi-angle jig, (B) the insertion of plastic trials, and (C) the tensor/balancer.

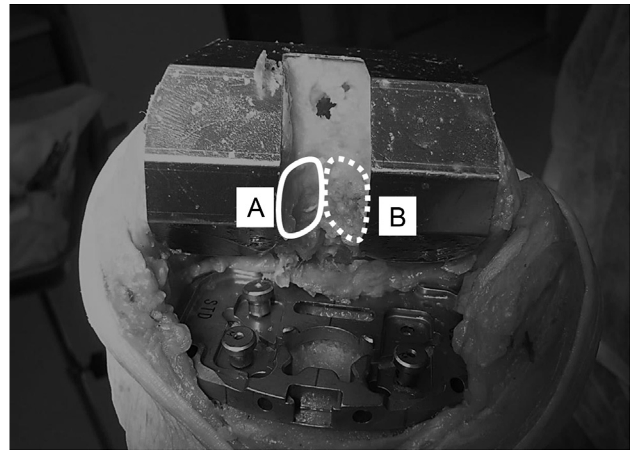

Figure 3 The sites of posterior release: (A) medial and (B) lateral.

roof of the intercondylar notch and the release end point, as well as the distance between the popliteal artery and the release end point, were measured by a digital caliper of 0.1 mm resolution (Shinwasokutei Co. Ltd., Nigata, Japan).

The mean and standard deviation in each group were calculated. Statistical analysis was performed with two-sample *t* test to detect the difference between tri-condylar design and CS design. The data were further analysed by analysis of variance with *post hoc* Tukey test to detect the difference among groups. The significant level was set at $p < 0.05$.

Results

The tri-condylar design resulted in a reduced extension angle compared with the CS design ($-11.2 \pm 5.4^\circ$ vs. $-3.8 \pm 4.7^\circ$, respectively; $p = 0.047$). Also, the extension gap was smaller with the tri-condylar than the CS design (10.1 ± 1.6 mm vs. 15.0 ± 2.7 mm, respectively; $p = 0.006$). The extension balance was similar between the tri-condylar and CS designs ($0.6 \pm 0.8^\circ$ and $0.3 \pm 1.8^\circ$, respectively; $p = 0.770$). Moreover, no significant difference was found in the knee flexion angle between the tri-condylar and CS designs ($129.6 \pm 9.7^\circ$ and $133.8 \pm 13.3^\circ$, respectively; $p = 0.580$; Figure 4).

The extension angle of the tri-condylar design significantly increased after posterior medial and lateral release ($-0.1 \pm 6.7^\circ$) but not after posterior medial release alone ($-9.0 \pm 5.8^\circ$; $p = 0.028$). By contrast, no difference was found in the CS extension angle after both types of release ($-0.1 \pm 6.7^\circ$ and $-0.9 \pm 5.8^\circ$, respectively; $p = 0.426$; Figure 5). Similarly, the extension gap significantly increased after both types of release (13.4 ± 1.4 mm and 15.0 ± 1.9 mm, respectively) with the tri-condylar design ($p < 0.001$),but remained unchanged (16.1 ± 2.1 mm and 15.8 ± 2.1 mm, respectively) with the CS design ($p = 0.727$; Figure 6). The extension balance remained similar after both types of release with the tri-condylar design ($0.1 \pm 3.3^\circ$ and $0.4 \pm 1.6^\circ$, respectively; $p = 0.922$) and with the CS design ($0.8 \pm 2.0^\circ$ and $0.8 \pm 1.8^\circ$, respectively; $p = 0.876$; Figure 7). The release site was at a safe distance from the popliteal artery and the nerve structures (10.8 ± 3.8 mm). The distance between the most posterior

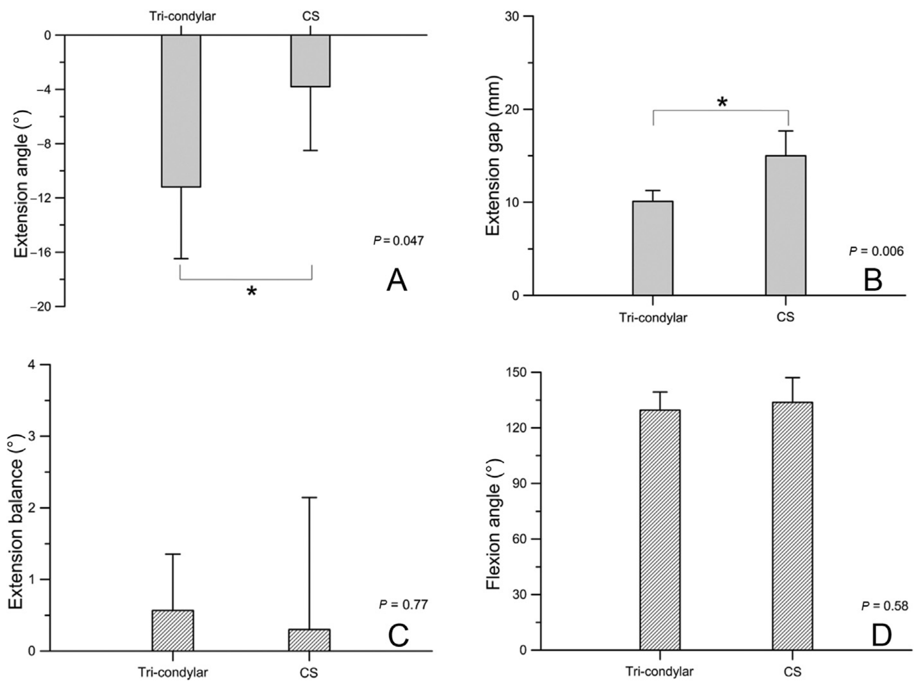

Figure 4 (A) extension angle, (B) extension gap, (C) extension balance, and (D) flexion angle of the tri-condylar and cruciate sacrificing (CS) designs.

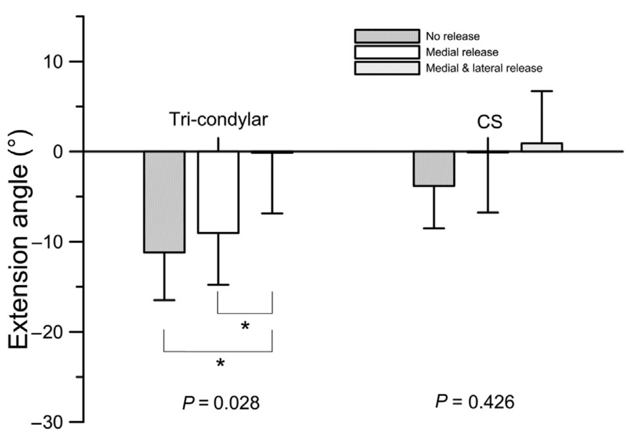

Figure 5 Extension angle before and after posterior release.

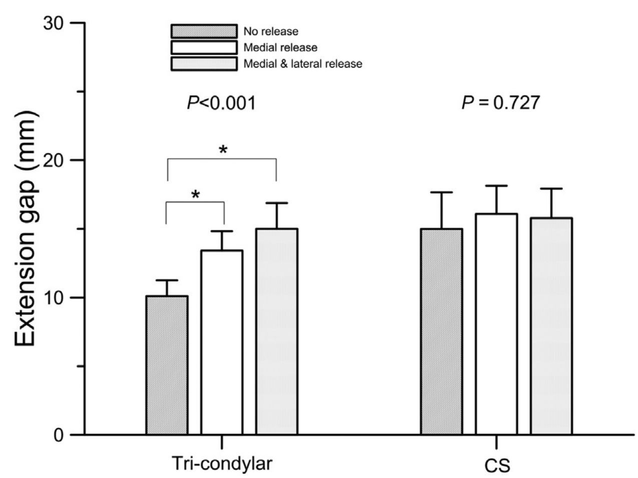

Figure 6 Extension gap before and after posterior release.

roof of the intercondylar notch and the release site was 15.3 $\pm$ 2.9 mm.

Discussion

This study demonstrated that the tri-condylar design prevented the knee from full extension with an extension angle of $-11.2°$. When the posterior release was performed, the full extension was achieved with a consistent extension gap among the specimens. Since the difference between the two designs only lied in the ball structure, this outcome indicates that the extension limitation was caused by posterior soft tissue tightening, an assumption previously proposed by Maeda et al [19].

By comparison, the extension gap did not increase after posterior release with the CS design, indicating that posterior release did not affect the extension gap of the femoral component without posterior intercondylar structure. In other words, posterior release is a useful technique for the femoral component with posterior intercondylar structure, such as the ball structure or the cam in the PS design. This result suggests that one may control the extension gap according to the component design, and the posterior release only restored the extension gap decreased by the femoral component placement.

This study showed the usefulness of posterior release techniques for actual surgery: (1) posterior release procedure is feasible if peeling off along the femur at a safe distance from the popliteal space where artery and nerves are located; and (2) the extent of posterior release is sufficient for the clearance of posterior intercondylar structure.

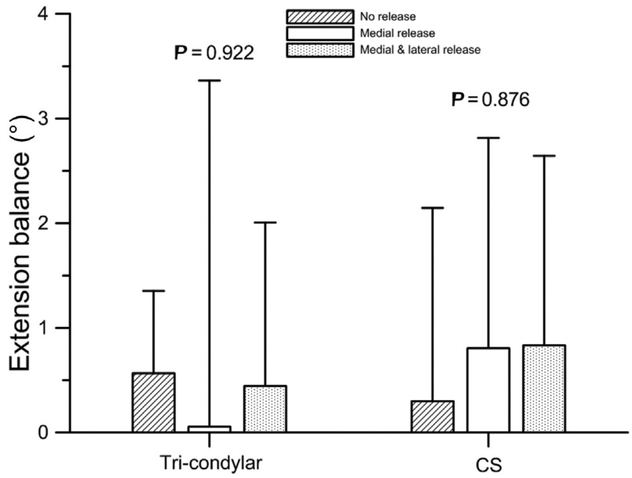

Figure 7 Extension balance before and after posterior release.

The advantage of the tri-condylar design over the PS design is joint stability during deep flexion [22]. The PS design allows for deep flexion with the post and cam mechanism, while the tri-condylar design is based on the third ball socket articulation. However, this functional improvement is at the cost of a decreased extension angle. The present biomechanical *in vitro* study illustrated this shortcoming with a posterior release solution.

To our knowledge, this biomechanical analysis of the tri-condylar design aiming at addressing the restoration of the full extension has not been reported in English journals. Nevertheless, biomechanical analyses of various designs have been extensively studied, thus offering a valuable database for the critical evaluation of our experiment [1,17—26]. Clinical studies on CS design reported a broad range of deep knee flexion from 102° to 127° [24,26—30]. Kinematics of the tri-condylar TKA *in vivo* has been recently reported [1,17,18], with a maximum knee flexion reaching 139.6° under a weight bearing knee bend.

Limitations of this study should also be acknowledged. Gap and flexion measurements were mainly based on the standard instruments used in surgery, in an attempt to simulate the operational measurement. The pitfall of these instruments is their accuracy, which may be resolved with more accurate kinematic measurements [31]. In addition, as the trial was only made of one medium size of the left knee, the cadaveric specimens were limited to left knees falling into this size. Therefore, these findings might not represent those obtained in the general population, especially in size-sensitive measurements, such as the extension gap. Furthermore, the CS design had the same geometry as the tri-condylar design, excluding the ball socket structure, and this design was not used clinically. The commercial CS design was not employed in this study in order to minimize confounding factors related to other design features.

Conclusion

Posterior intercondylar release at a safe distance from the popliteal artery and nerves could be an elective procedure to gain more extension gap and allow for a full knee extension in tri-condylar TKA.

Conflicts of interest

The authors have no conflicts of interest relevant to this article.

Acknowledgements

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