**Anteroposterior laxity after bicruciate-retaining total knee arthroplasty is closer to the intact knee than ACL-resecting TKA: a biomechanical cadaver study**

**Running title**: Kinematics of ACL-retaining TKA

**Abstract**

The purpose of this study was to examine whether an ACL preserving TKA would yield anteroposterior (AP) laxity closer to the native knee than a conventional posterior cruciate ligament retaining (CR) TKA. A bi-cruciate retaining (BCR) TKA was designed, manufactured and tested using fresh-frozen cadaver specimens and compared versus CR TKA and the native knee. AP laxity with the CR TKA was greater than in the intact knee (P=0.014). The BCR TKA laxity did not differ significantly from the native knee (P=0.341). There were no significant differences in rotations between either of the prostheses or the native knee. BCR TKA was shown to be surgically feasible, reducing AP laxity versus CR TKA and may improve knee stability without using conforming geometry in the implant design.

**Keywords:** total knee arthroplasty; bicruciate prosthesis; ACL retaining TKA; stability; kinematics

**Introduction**

Although total knee arthroplasty (TKA) is a successful treatment for severe osteoarthritis (OA) of the knee, eliminating pain and typically with 8-year survivorship of 97% [1], as many as 25% of patients either feel neutral, dissatisfied or very dissatisfied about their TKA [2-4]. This disparity may be explained by the postoperative Knee Society Score function scores averaging only 71.7 (range 66.7 – 75.7) across three studies [5-7]. In addition, it has been demonstrated that function may be worse post-TKA in 24% of patients aged between 40-50 years old [8]. Thus a sizable minority of people are dissatisfied with their TKA. But why might this be the case - and what can be done about it?

TKA design might play a role in patient outcome. In 2012, the 10 most frequently implanted TKAs in England, Wales and Northern Ireland were of a wide variety of designs [9], yet all ten entailed sacrificing the anterior cruciate ligament (ACL) during implantation. The ACL and PCL control knee stability and tibiofemoral kinematics. The removal of the ACL for a posterior cruciate retaining (CR) prosthesis, or both ACL and PCL for a posterior stabilised/ substituting (PS) prosthesis, could be partially responsible for the loss of joint function that some TKA patients experience due to instability. There is in vivo evidence of a satisfaction and function gap between unicompartmental knee arthroplasty (UKA) and TKA patients [10, 11], and also that a bi-cruciate retaining (BCR) TKA (that keeps both the PCL and ACL) can improve replaced knee motion and corresponding patient satisfaction compared to conventional TKA [12-14]. However, these devices have only once been evaluated mechanically [15] and they have seldom been used clinically beyond their surgeon-inventors. One example of such is a new device, developed by Biomet (Warsaw, IN, USA), which is being used in clinical trials [16, 17].

The aim of this study was to assess the surgical feasibility and mechanical performance of a BCR TKA. Three phases of cadaveric experiments were performed to compare the kinematics and laxity of knees in 3 states: 1) native knee; 2) BCR TKA; and 3) CR TKA with resected ACL. Phases 1 and 2 were feasibility studies using two prototype designs of the device. The results and experiences from them were used to inform design modifications to the implant and instrumentation. The final version of the implant, instrumentation and surgical technique was used in Phase 3 and these are the results that are presented here. It was hypothesized that the kinematics with the BCR TKA would be closer to those of the intact knee than the CR TKA, particularly in the anteroposterior (AP) direction.

**Materials and Methods**

Level of evidence: basic science study

Type of study: repeated measures in vitro biomechanical study

Twenty fresh-frozen cadaver knee specimens (11 male, 9 female; mean age 76 years; median age 79 years; range 51-96 years) from consented donations were obtained from the International Institute for the Advancement of Medicine (Jessup, Pennsylvania, USA) and ethical permission for the study was granted by the National Research Ethics Service. None of the specimens exhibited any gross deformity or severe osteoarthritis. A previously developed test method and bespoke kinematics testing rig (Figure 1) were used [18, 19]. The rig allowed open-chain knee flexion-extension, with the femur fixed relative to the rig and in control of knee flexion and the tibia free to rotate internally and externally and to adduct and abduct. Soft tissue around the ends of the bones was removed and the bones were trimmed so that around 200 mm remained either side of the joint line. Intra-medullary rods were cemented into the femur and tibia and the knee mounted in the rig. Passive reflective optical tracking markers (Brainlab AG, Feldkirchen, Germany) were fixed to the femur and tibia and a Polaris camera (NDI, Waterloo, Canada) tracked and recorded their motion using the NDI Toolviewer software, giving 6 degrees of freedom (DoF) information with an accuracy of ±0.1 mm and ±0.4°. Bony landmarks on each bone were digitized prior to testing using a stylus with reflective markers. The intact knee was initially tested with only a 400 N central quadriceps load applied to the patella and then with the following loads applied in conjunction with this quadriceps load: (1) 135 N tibial anterior drawer force; (2) 135 N tibial posterior drawer force; (3) 7.5 Nm tibial internal rotation torque; (4) 7.5 Nm tibial external rotation torque; (5) 5 Nm varus moment and (6) 5 Nm valgus moment. Under each loading condition, the knee was moved manually over 3 cycles of knee flexion-extension to give neutral paths of translation and rotation and "envelopes of laxity" (AP, internal/external, varus/valgus) between 0° and 110° knee flexion. The loads and moments were applied to the tibia such that none of the 6 DoF of the knee joint was artificially constrained (Figure 1). When the intact measurements were complete, the test regime was repeated with the knee in 2 further states: BCR TKA and CR TKA.

Three separate phases of cadaveric experiment were conducted with 3 versions of a BCR TKA, as the design evolved. All 3 of the BCR TKA designs and the CR TKA used the same cobalt-chrome alloy femoral component (Unity Knee$^{TM}$, Corin Ltd, Cirencester, UK), but had different tibial trays and ultra-high molecular weight polyethylene (UHMWPE) bearings (Table 1). The first two phases represented the development stages for the device and instrumentation, the third produced the results which are discussed here.

***Phase 1:*** The first cadaver study used a prototype BCR TKA with a horseshoe-shaped tibial tray and adapted generic UKA instrumentation using 8 cadaver knees.

***Phase 2*****:** An updated tibial tray (implanted using the same instrumentation) was tested using a further 4 knees.

***Phase 3*****:** a 3rd design, using bespoke 3D-printed cutting guides for dual unicondylar tibial components and conventional TKA instrumentation for the femoral component, was tested using 8 knees. The surgical technique was carried out tibia first, with the 3D-printed guides which cut the tibia along the anatomic joint line in the coronal plane (approximately 87° to the long axis of the bone). The sagittal cuts were based on the most medial point of the ACL attachment point on the tibial plateau, in order to preserve as much of the ligament as possible. The femur was prepared based on anatomic alignment using the Unity Knee$^{TM}$ TKA instrumentation. The distal cutting block was positioned so that the thickness of the distal cuts (plus saw kerf) matched the thickness of the femoral component, which was equal on the two condyles. The specimens did not have erosive changes on the distal condyles, and so this led to the femoral component having an anatomic alignment, approximately 6 degrees valgus relative to the femoral axis. Once the BCR

TKA had been tested, the tibial components were removed and the ACL was resected. The CR TKA tibial cutting guide was then used to prepare the tibial plateau for the CR TKA tibial component.

The kinematics data were processed using Visual3D (C-Motion, MD, USA) and Excel (Microsoft, WA, USA). The intact knee at full extension was taken to be at 0° rotation and 0 mm translation in all directions; all other measurements were normalized to this point. Rotations and translations refer to tibial motion relative to the femur. Kinematics results are presented for the series of 8 knees used during Phase 3.

***Statistical Analysis***

A series of two-within-subject-factor repeated measures analysis of variance (ANOVA) with post-hoc pairwise comparisons with Bonferroni correction were run in SPSS (Version 21.0, IBM Corp., NY, USA) to compare the 6 DoF kinematic characteristics of the 2 TKAs to each other and to the intact knee for Phase 3. Significance was set at P=0.05. A power calculation based on 3 mm mean change in anteroposterior translation between the intact knee and a CR TKA in a prior study determined that a sample size of 8 was required to detect a significant change in translation with 80% power and 95% confidence.

**Results**

Six DoF data were collected during all 3 phases of the study, but these data are only presented here for the third and final phase, which used the final prototype device and instrumentation.

***Phases 1&2***: The surgical feasibility of implanting a BCR TKA with adapted generic UKA instrumentation for the tibial cuts was proven. However, with this first design of the BCR TKA, avulsion fracture of the remaining tibial spine was a recurring problem, particularly near full knee extension, with partial or complete fracture in 6 of 9 knees. Using an updated tibial tray in Phase 2, 1 avulsion fracture occurred during kinematic testing, an improvement on Phase 1, but not a complete elimination of the problem. In addition, concerns were raised about the fatigue strength of the horseshoe shaped tibial component and its ability to pass the ASTM F1800 pre-clinical fatigue testing requirement [20].

***Phase 3:*** The surgical feasibility of simultaneously implanting two tibial trays, on either side of the ACL and PCL attachments, using patient specific 3D-printed cutting guides was proven in this phase. No avulsion fractures were observed during testing with the BCR TKA in 8 cadaver knees. The 'neutral' path of motion (that is: without an AP drawer force) of the tibia in the intact knee consisted of a mean anterior translation of 4 mm in the first 60° of knee flexion and then a further 9 mm between 60° and 110° knee flexion giving a total femoral roll-back of 13 mm during knee flexion. The BCR TKA started with the tibia a mean of 4 mm posterior to the intact tibia (P=0.025) but by 65° flexion had moved back to a similar position as in the intact knee and no overall significant difference was found between the two in the ANOVA (Figure 3). With the CR TKA the tibia was a mean of 6 mm anterior to the intact position at full extension (P<0.02) and then it only translated a mean of 4 mm across 0 to 110° knee flexion: a loss of femoral roll-back in the absence of the ACL. Anterior laxity tended to be consistent across the whole range of knee flexion for the intact knee and the BCR TKA (2.9 mm ± 0.7 mm and 6.3 mm ± 1.0 mm, respectively). Thus, having started 4 mm posterior, the BCR TKA had an anterior drawer translation within 2.5 mm of the intact knee across 0-110° flexion (Figure 3). The CR TKA tended to exhibit greater anterior laxity beyond 35° than in early knee flexion and was found to have significantly more anterior laxity than the intact knee overall (10.1 mm ± 2.0 mm; P=0.005). No significant differences in anterior laxity were found between the intact knee and the BCR TKA. or between the BCR TKA and the CR TKA. Total AP laxity was significantly greater with the CR TKA than in the intact knee (P=0.006) and in comparison to the BCR TKA (P=0.039; Figure 4). The intact knee exhibited the "screw home" mechanism as the knee extended from 30° flexion, rotating externally by approximately 5° (P=0.001). Neither the BCR TKA nor the CR TKA displayed this behavior, but tended to rotate continuously internally as the knee flexed (Figure 5). However, total IE laxity was not found to be significantly different between implants or the intact knee. All three knee states behaved similarly in varus/valgus, although the CR TKA tended to have lower total varus/valgus laxity than the intact knee or the BCR TKA, but this was not found to be significantly different (Figure 6).

## Discussion

The bi-cruciate retaining (BCR) TKA demonstrated anterior drawer laxity, total AP laxity and neutral path of motion closer to the normal knee than the CR TKA, which was significantly different to the intact knee. The concept of a BCR TKA was shown to be a valid approach to reducing AP laxity in the knee compared to a CR TKA. However, during an initial phase of experiments, the BCR TKA frequently caused the remaining bony eminence on the tibia to avulse near full extension, possibly due to increased ACL forces caused by the insertion of the implant. After two iterations of the BCR TKA tibial component design, the avulsion fracture problem was eliminated in a series of 8 cadaver tests without appearing to compromise the added stability afforded by the retention of the ACL. Internal/external and valgus/varus rotational laxity did not differ between devices or the intact knee, although external rotation of the tibia as the knee approaches extension, observed in the intact knees, was not detected in either the BCR or CR TKAs.

As with all cadaveric experiments, the results of this study must be considered alongside some limitations, including the lack of hamstrings loading and the fact that the load used to simulate the quadriceps muscles acted only in one direction and remained constant over the arc of flexion. This loading was reduced from physiological to avoid patella fracture in the cadaver specimens. Open-chain knee flexion from 0° to 110° does not represent a full range of activities of daily living, which may produce different knee kinematics. In addition, none of the cadaver specimens showed signs of severe OA as would be expected in real TKA patients. However, comparing TKA kinematics to “normal” knees (as opposed to OA) is still relevant and avoids the problem of further specimen variability due to pathological changes. It was not possible to vary the order in which the TKAs were tested; the BCR TKA always had to be tested prior to the CR TKA. This may have affected the results due to changes in the material properties of the soft tissues over time and in response to repetitive testing. The loading parameters were chosen to minimize effects such as ‘stretching-out’ of ligaments and the length of the tests was kept to a minimum. Strengths of this study include: the repeated-measures protocol design, which should have minimized the inevitable effects of inter-specimen variability; the ability to apply forces and torques accurately; the accurate measurement of the knee kinematics with 3D optical tracking and the bespoke cutting guides for the tibial components, which should have ensured consistent sagittal and transverse cuts across all the specimens.

Although survivorship of TKAs is excellent, patient dissatisfaction with their function is commonplace. Abnormal knee kinematics relating to conventional TKA with resection of the ACL may be to blame for some of this functional dissatisfaction and patient reported instability problems and so an ACL-retaining TKA (a BCR TKA) appears logical. BCR TKA is not a new concept but it has not been widely used, making it difficult to conclude whether it improves patient function and satisfaction, although there is one study reporting patient preference [21]. Lack of surgeon enthusiasm for BCR TKA might be attributed to the perceived technical difficulty of the procedure. However, Jenny & Jenny found no significant difference in operation time between a BCR TKA and a CR TKA [22]. Another cause of apprehension relating to this type of device is the assumed lack of integrity of the ACL in OA patients, but it has been reported that the ACL is intact in 60 - 80% of TKA patients [23, 24]. If the ACL is deficient, a reconstruction could be incorporated with a BCR-TKA, as has been done with UKA [25]. The increase in AP laxity between the intact and “conventional” TKA knees that was found in this study has been observed in other studies [19, 26-28]. Lack of the screw-home mechanism post TKA has also been noted in other studies [19, 28, 29]; the fact that it was also eliminated in a TKA that retains the ACL perhaps confirms that this movement occurs due to a combination of the geometrical characteristics of the tibiofemoral joint [30] and the actions of the cruciate ligaments [31]. It has been previously demonstrated in-vitro that a BCR TKA has kinematics closer to the intact knee than an ACL sacrificing TKA, although stability was not examined in that study [15].

The experiment showed that it was important to preserve as much of the ACL bony attachment as possible to avoid avulsion fractures of the tibial eminence. The interaction of the femoral and tibial components led to the ACL being tensed by a cam mechanism in terminal knee extension. The first version of the tibial component had an anterior bridge directly between the two bearing trays and that led to fractures because of cutting into the tibia. The second version had the bridge formed as an archway over the bone, but that was still unusable, because it was shown by stress analysis that the bridge would not be strong enough to pass the ASTM F1800 fatigue tests for a partly-unsupported tibial plateau [20]. Therefore, the third version separated the tibial tray into two components akin to those used in UKA. Use of specimen-specific cutting guides allowed them to be aligned to each other and also spaced apart to enable the ACL attachment to retain sufficient strength.

BCR TKA could represent an addition to the orthopaedic surgeon’s armamentarium, bridging the gap between UKA and TKA, for the younger, more highly functioning patient with bi- or tri-compartmental OA and an intact ACL. It is surgically feasible and this study has shown that it provided post-operative knee laxity and kinematics closer to normal than a conventional CR TKA which excised the ACL. This mechanical improvement may then reduce the sense of instability some TKA patients’ experience [31]. Care must be taken to preserve as much of the ACL bony attachment as possible to avoid avulsion fractures of the tibial eminence.

**Funding and conflict of interest statement**

This project was funded by the National Institute for Health Research’s i4i Programme.

**Disclaimer**

This paper summarises independent research funded by the National Institute for Health Research (NIHR) under its i4i Programme (Grant Reference Number II-LS-0511-21003). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

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Figure 1
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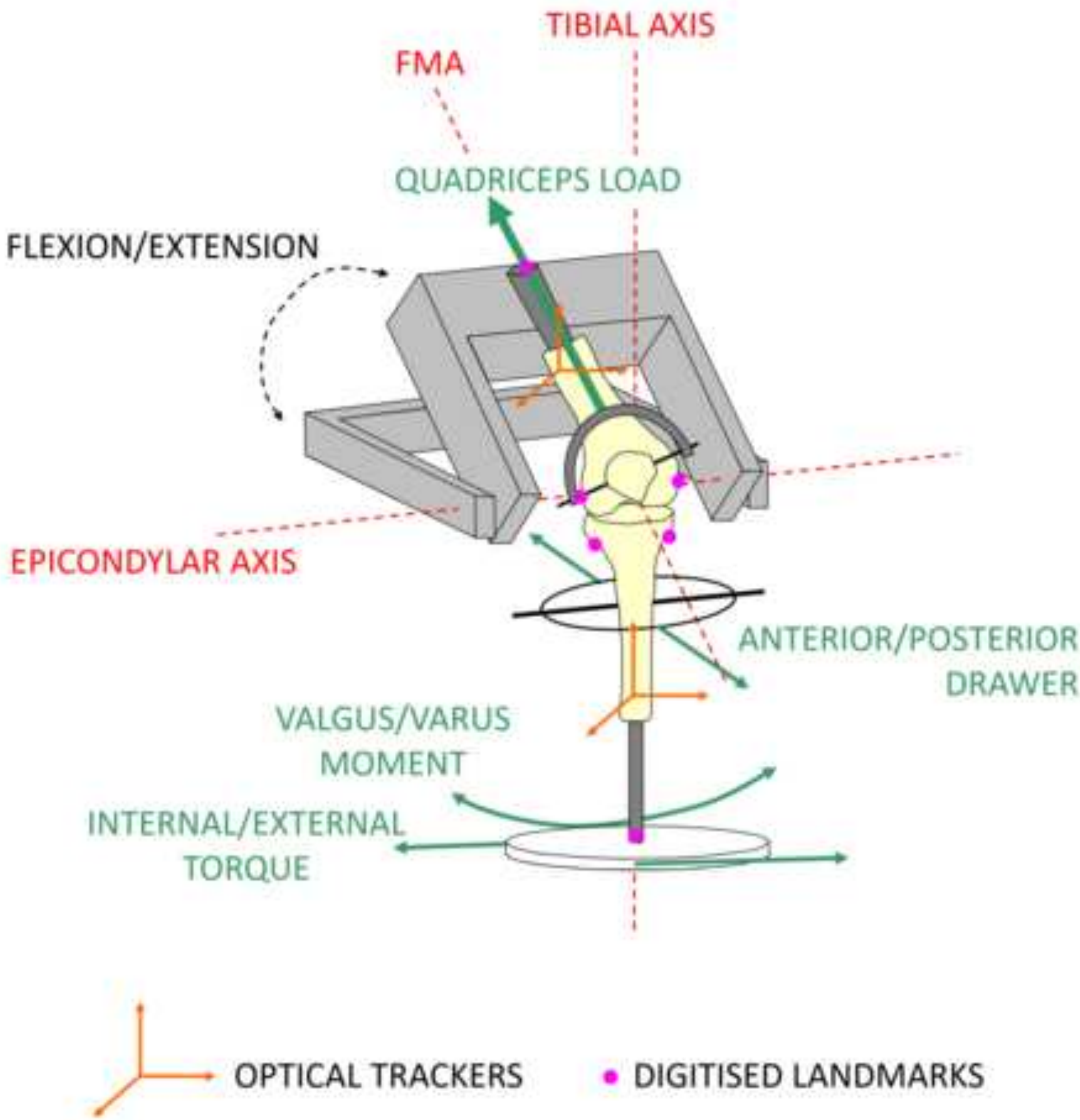

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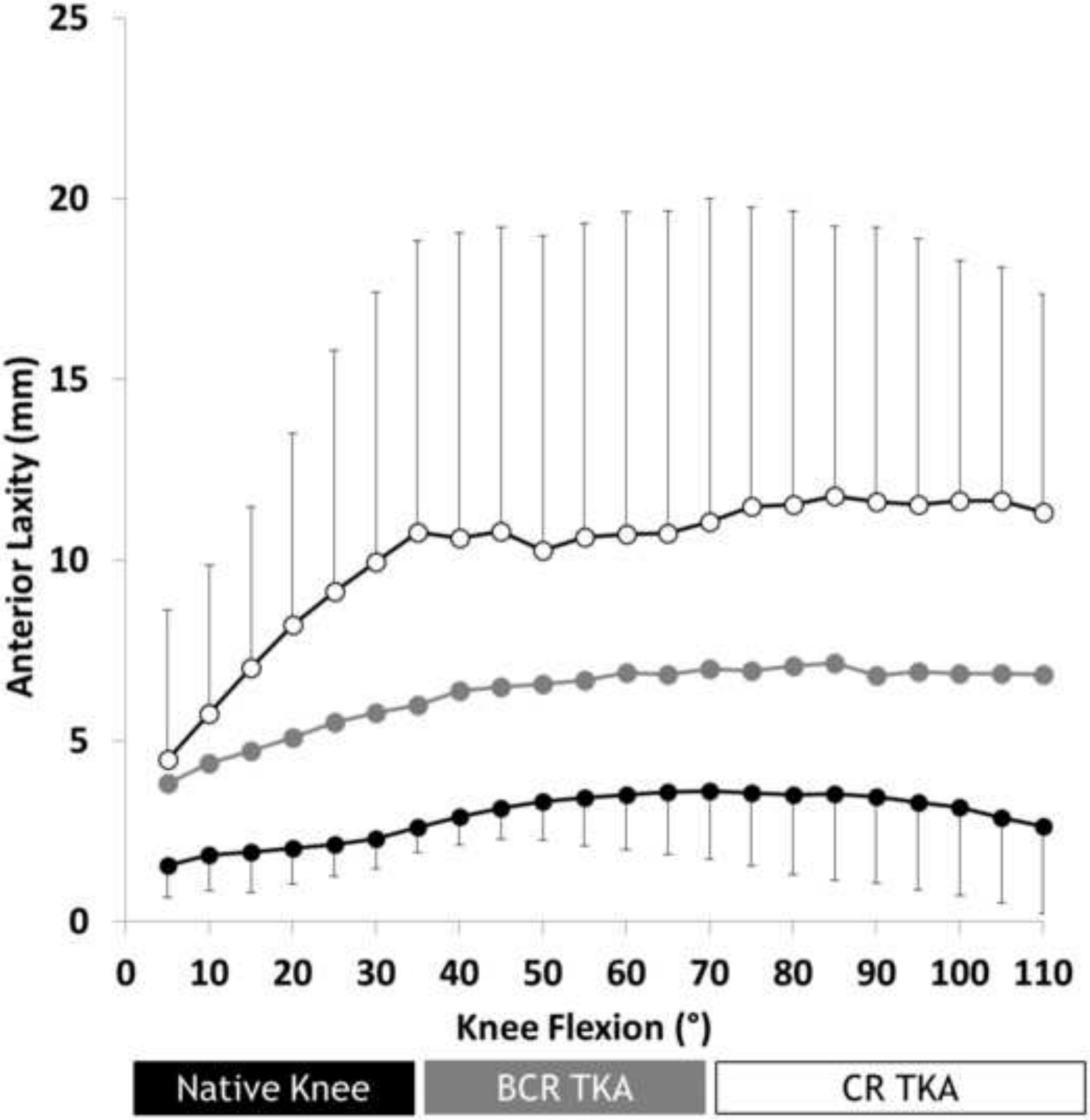

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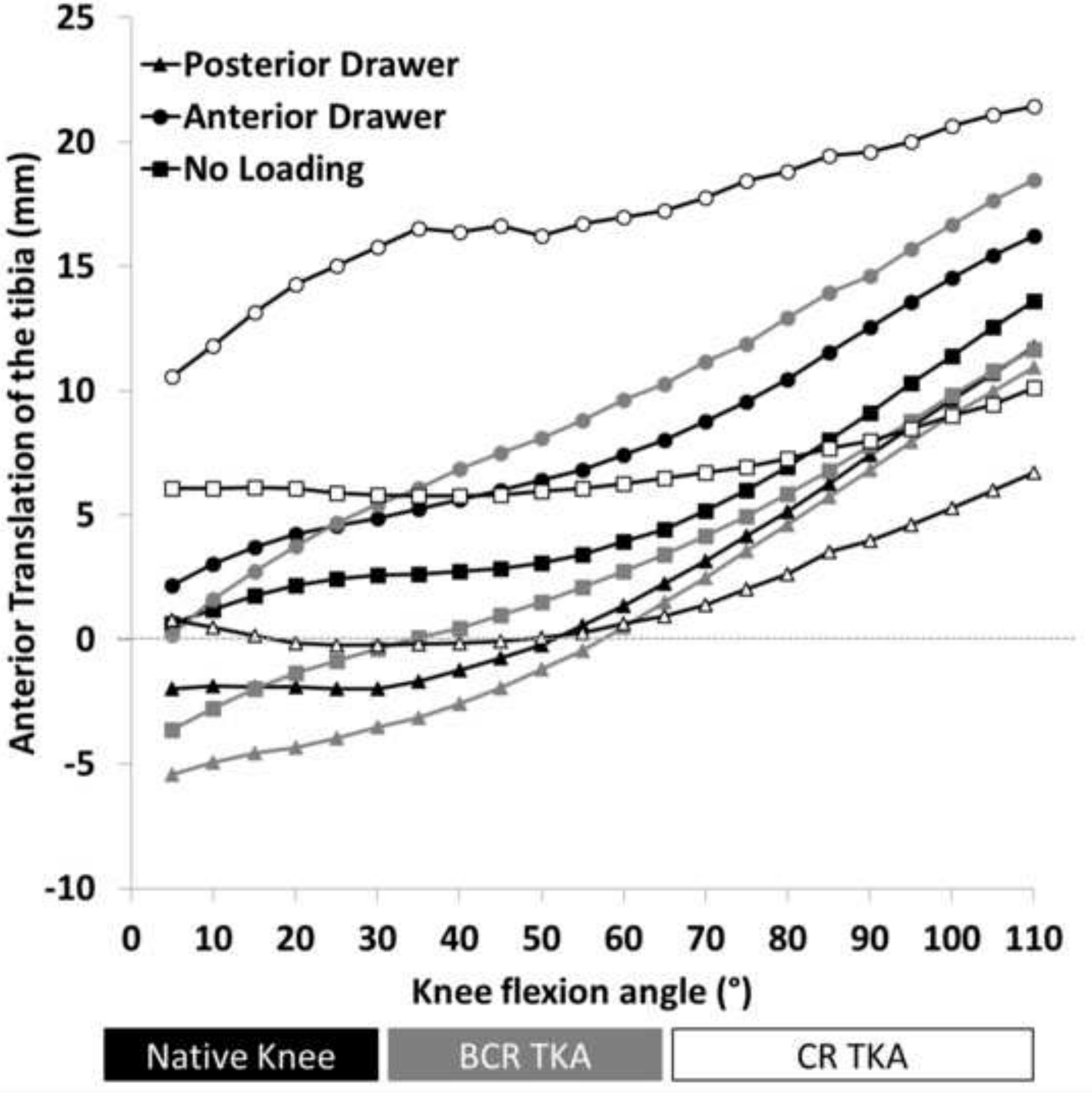

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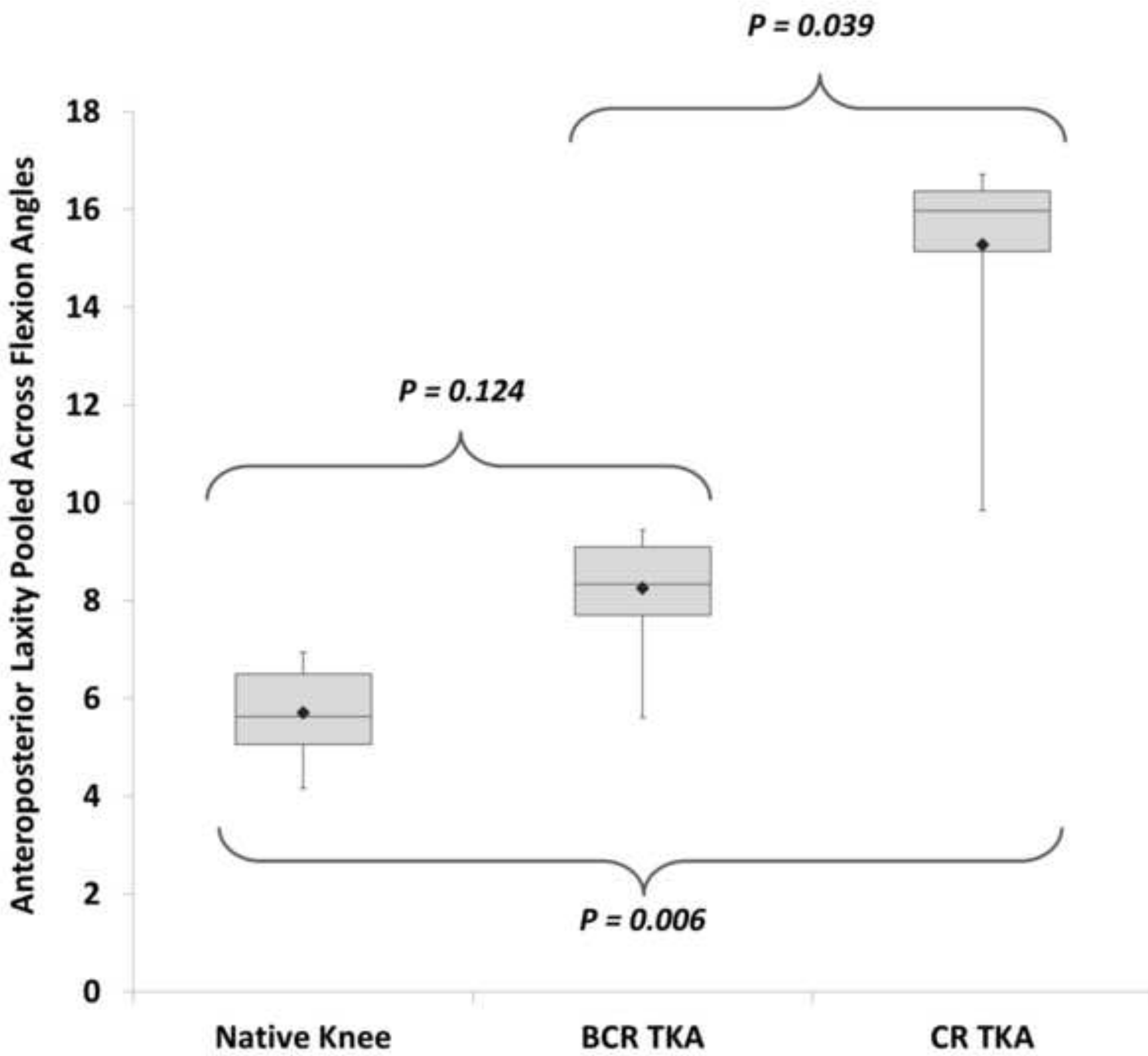

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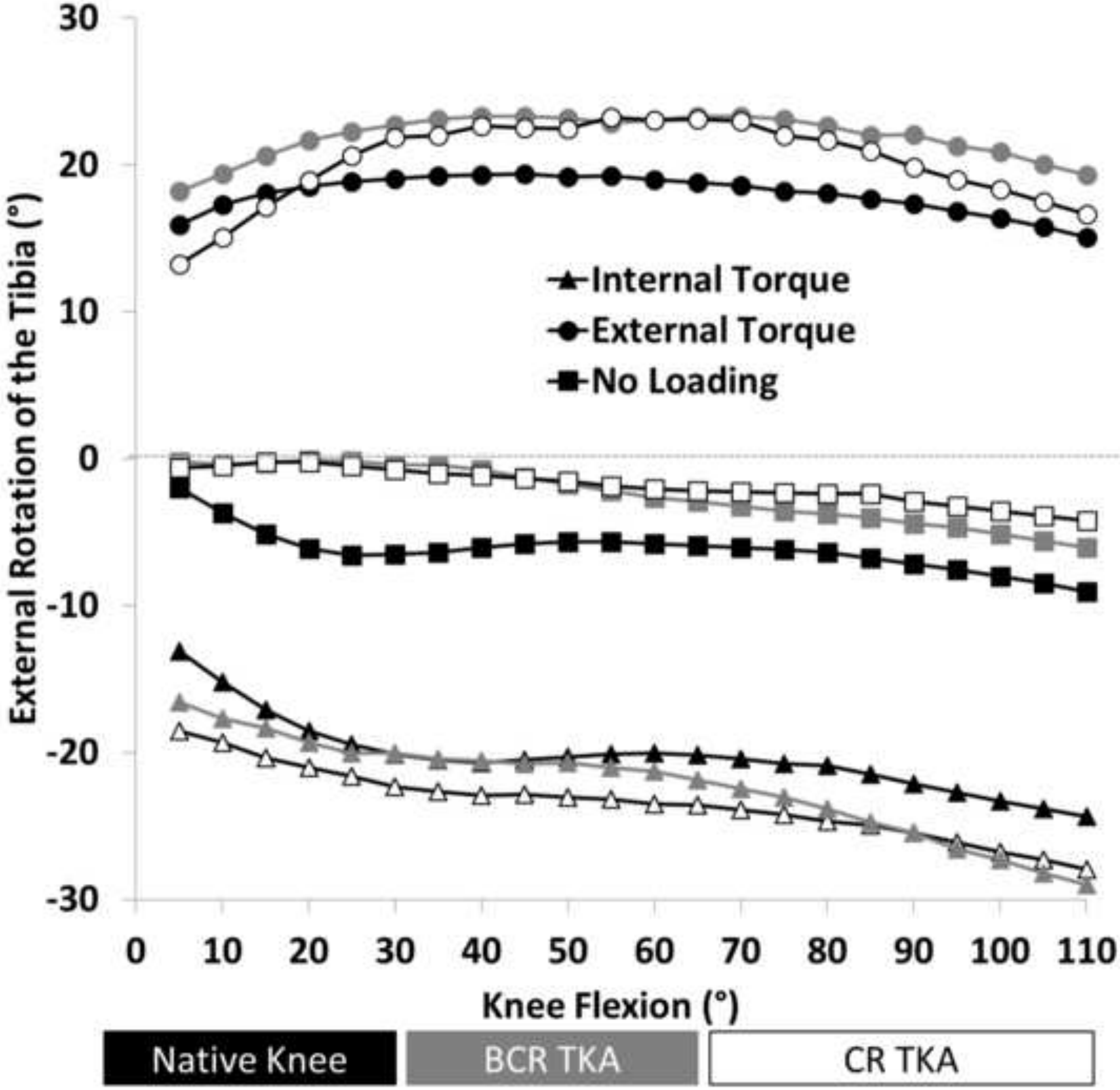

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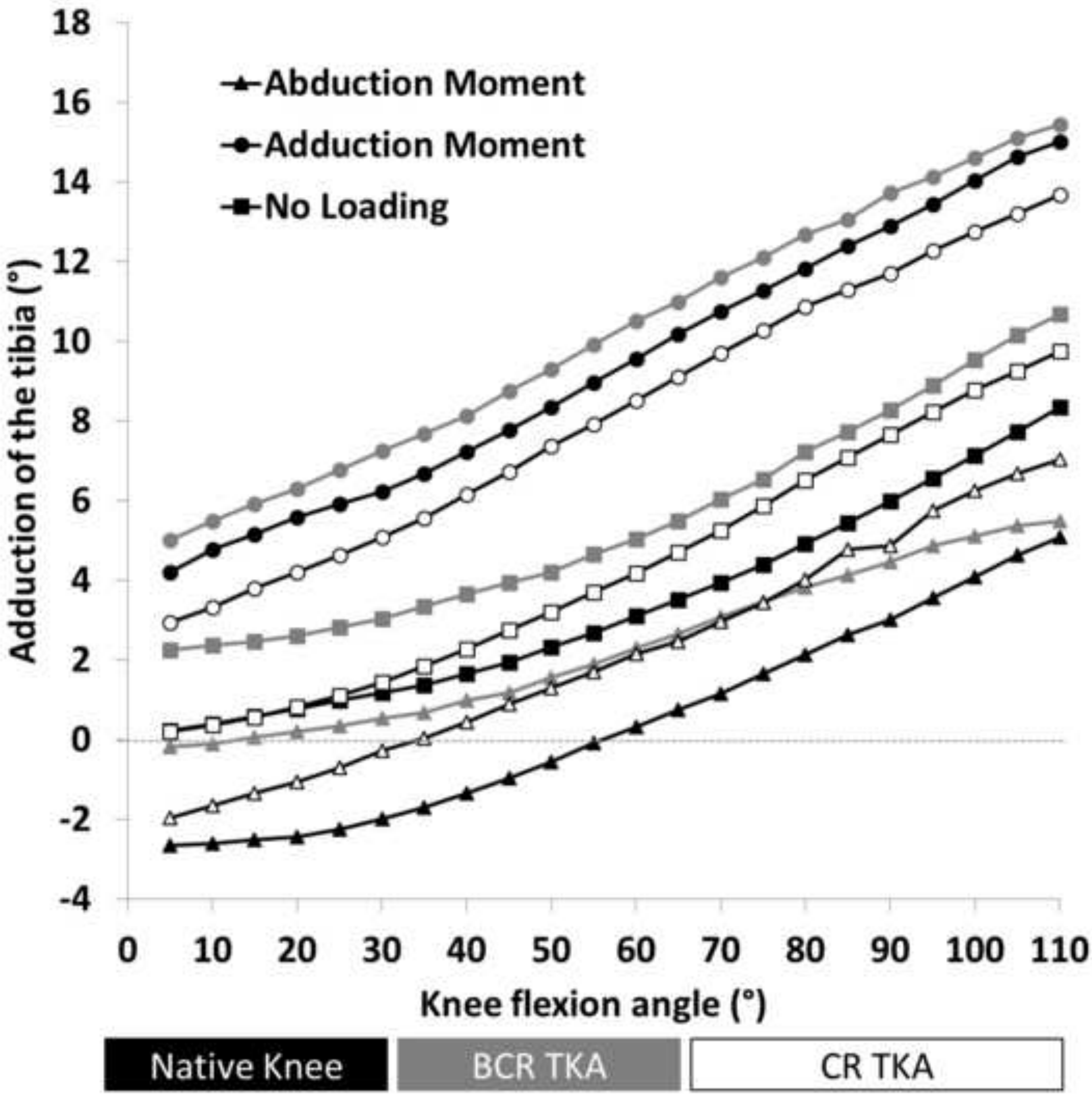

**Figure Captions**

Figure 1. A schematic of the kinematics testing rig.

Figure 2. Limits of anterior laxity for the 3 knee states. Mean values ± 1 standard deviation; n=8

Figure 3. Limits of anterior-posterior translation laxity for the 3 knee states, under three loading conditions: 400 N quadriceps tension only, quadriceps plus 135 N anterior drawer force and quadriceps plus 135 N posterior drawer force. Mean values; n = 8

Figure 4. Anteroposterior laxity pooled across all flexion angles for the 3 knee states. Mean values; n = 8

Figure 5. Limits of internal-external rotational laxity for the 3 knee states, under three loading conditions: 400 N quadriceps tension only, quadriceps plus 7.5 Nm internal torque, quadriceps plus 7.5 Nm external torque. Mean values; n = 8

Figure 6. Limits of varus-valgus rotational laxity for the 3 knee states, under three loading conditions: 400 N quadriceps tension only, quadriceps plus 5 Nm varus moment, quadriceps plus 5 Nm valgus moment. Mean values; n = 8.

**Tables (Number each one)**

**Table 1. Design details for the 3 phases of TKA**

| **Phase** | **Femur** | **Tibia** | **UHMWPE Bearing(s)** | **No. Knees** |
|---|---|---|---|---|
| 1 | Unity Knee™ | Single piece horseshoe | Single piece, semi-constrained | 8 |
| 2 | Unity Knee™ | Modified single piece horseshoe | Two pieces, semi-constrained | 4 |
| 3 | Unity Knee™ | Dual trays | Two pieces, non-constrained | 8 |

**Acknowledgements**

The authors would like to thank Thomas Luyckx, Steven Claes and Charles Willis-Owen for their technical and surgical assistance.