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Fluoroscopic and radiostereometric analysis of a bicruciate-retaining versus a posterior cruciate-retaining total knee arthroplasty: a randomized controlled trial

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Aims
The aim of this study was to compare a bicruciate-retaining (BCR) total knee arthroplasty (TKA) with a posterior cruciate-retaining (CR) TKA design in terms of kinematics, measured using fluoroscopy and stability as micromotion using radiostereometric analysis (RSA).

Methods
A total of 40 patients with end-stage osteoarthritis were included in this randomized controlled trial. All patients performed a step-up and lunge task in front of a monoplane fluoroscope one year postoperatively. Femorotibial contact point (CP) locations were determined at every flexion angle and compared between the groups. RSA images were taken at baseline, six weeks, three, six, 12, and 24 months postoperatively. Clinical and functional outcomes were compared postoperatively for two years.

Results
The BCR-TKA demonstrated a kinematic pattern comparable to the natural knee's screw-home mechanism in the step-up task. In the lunge task, the medial CP of the BCR-TKA was more anterior in the early flexion phase, while laterally the CP was more posterior during the entire movement cycle. The BCR-TKA group showed higher tibial migration. No differences were found for the clinical and functional outcomes.

Conclusion
The BCR-TKA shows a different kinematic pattern in early flexion/late extension compared to the CR-TKA. The difference between both implants is mostly visible in the flexion phase in which the anterior cruciate ligament is effective; however, both designs fail to fully replicate the motion of a natural knee. The higher migration of the BCR-TKA was concerning and highlights the importance of longer follow-up.

Cite this article: ***Bone Joint J*** **2023;105-B(1):35–46.**

Introduction
As the average age of patients undergoing total knee arthroplasty (TKA) decreases,[1] the demands for improved knee function and restoration of normal joint kinematics increases.[2] Meeting patient expectations is important, as they are the strongest predictor of patient dissatisfaction after primary TKA, with up to 19% of patients being dissatisfied post primary TKA.[3] The design of bicruciate-retaining (BCR) TKAs may help meet patient expectations by conserving proprioception, stability, and natural feel of the knee.[4] The kinematics of the BCR-TKA are assumed to be closer to that of the natural knee compared to a cruciate-retaining (CR) TKA, bicruciate-substituting (BCS), or posterior-stabilized (PS) TKA where one or both cruciate ligaments are removed and their function is substituted by the design of the implant.[5] However, implantation of BCR-TKA is technically challenging,[6] as less space is available during surgery due to the intact cruciate ligaments. Despite some historical problems, BCR-TKAs

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doi:10.1302/0301-620X.105B1.
BJJ-2022-0465.R2 $2.00

Bone Joint J
2023;105-B(1):35–46.

Table I. Measurement error statistics (precision) of femoral and tibial components measured through double examinations.

Component	Mean translation, mm (SD)			Mean rotation, ° (SD)				
	Tx	Ty	Tz	TT	Rx	Ry	Rz	TR
Vanguard CR/XP Femur (36 doubles)	0.01 (0.07)	0.02 (0.05)	-0.06 (0.18)	0.17 (0.13)	0.03 (0.18)	-0.06 (0.19)	-0.03 (0.09)	0.25 (0.14)
Vanguard CR Tibia (20 doubles)	0.00 (0.06)	-0.01 (0.03)	0.06 (0.11)	0.12 (0.07)	0.08 (0.15)	-0.03 (0.21)	-0.00 (0.05)	0.24 (0.12)
Vanguard XP Tibia (16 doubles)	0.02 (0.04)	0.01 (0.03)	0.02 (0.08)	0.07 (0.06)	0.00 (0.08)	-0.01 (0.10)	-0.01 (0.06)	0.11 (0.08)

Values represent means (standard deviation) of the second image pair with regard to the first image pair, both taken at six weeks postoperatively. CR, cruciate-retaining; SD, standard deviation.

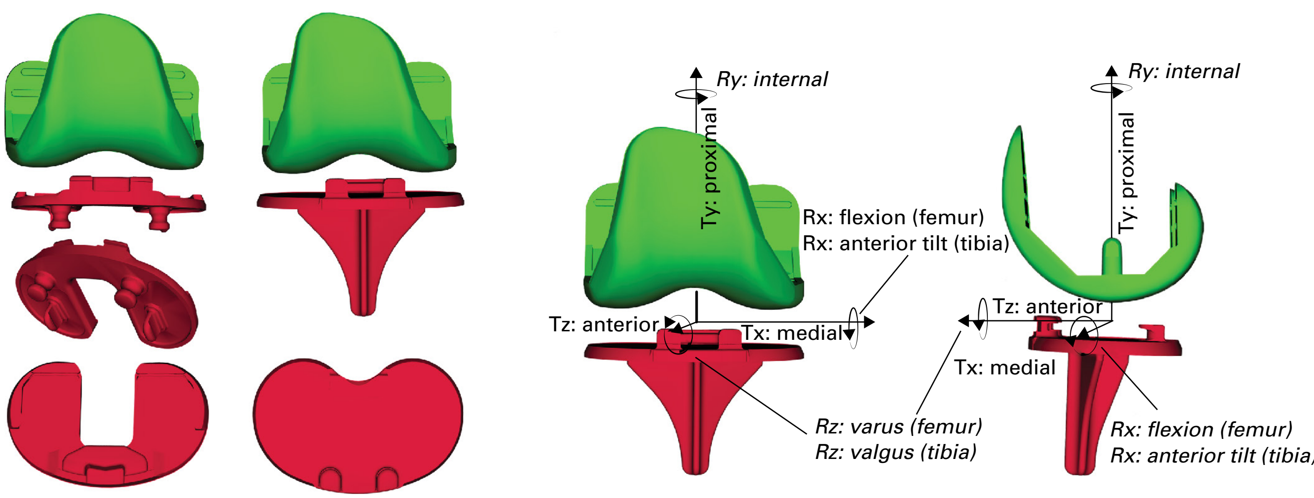

Fig. 1

Implant geometry of the a) Vanguard XP (bicruciate-retaining (BCR)) and b) Vanguard CR (cruciate-retaining (CR)). c) Frontal and d) sagittal orientation of the longitudinal, transverse, and sagittal axes and the directions of positive translation and rotation (in italics) for both the femur and tibia componenta.

have shown good results after 20 years concerning survival and function of the knee.[7,8]

In the natural knee, the medial femorotibial movement is described as a rolling movement with a 'rocking' movement at about 20° flexion.[9,10] Laterally, the femoral condyle moves posteriorly on the tibia plateau with increased flexion angles.[9,10] These two condylar motions combined cause femoral external rotation with knee flexion. Within the extension arc, a phenomenon called the 'screw-home mechanism' is observed: from 30° flexion to full extension, the femur rotates internally relative to the tibia, causing the tightening of the cruciate ligaments and locking of the joint.[11] The anterior cruciate ligament (ACL) plays an important role in this mechanism, as it is fully elongated at approximately 10° flexion.[11]

Earlier research using roentgen fluoroscopic analysis (RFA) to compare BCR-TKAs with CR-TKAs reported more natural knee kinematics when retaining the ACL.[12-14] However, Kwon et al[15] also showed differences in kinematics of BCR-TKAs compared to the contralateral knees during strenuous activities.

One of the previously highlighted problems of BCR-TKAs is suboptimal fixation of the tibia component.[6,16,17] Fixation of the implant in the bone can be influenced by design differences of the tibial component (i.e. smaller pegs in the BCR-TKA), and additionally the retention of two strong ligaments may have

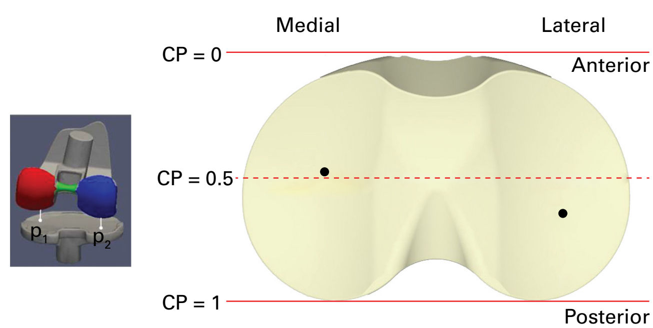

Fig. 2

Definition of femorotibial contact point (CP) was the minimal distance location between femur and tibia components. This CP is reported as a ratio from 0 to 1, representing respectively the most anterior and most posterior rims of the tibial inserts.

consequences for the fixation of both the femoral and tibial components. The pattern and magnitude of micromotion of an implant act as short-term predictors of long-term survival.[18,19] Radiostereometric analysis (RSA) is an established and high-precision method to assess implant migration and enables evaluation of the quality of the fixation before the loosening

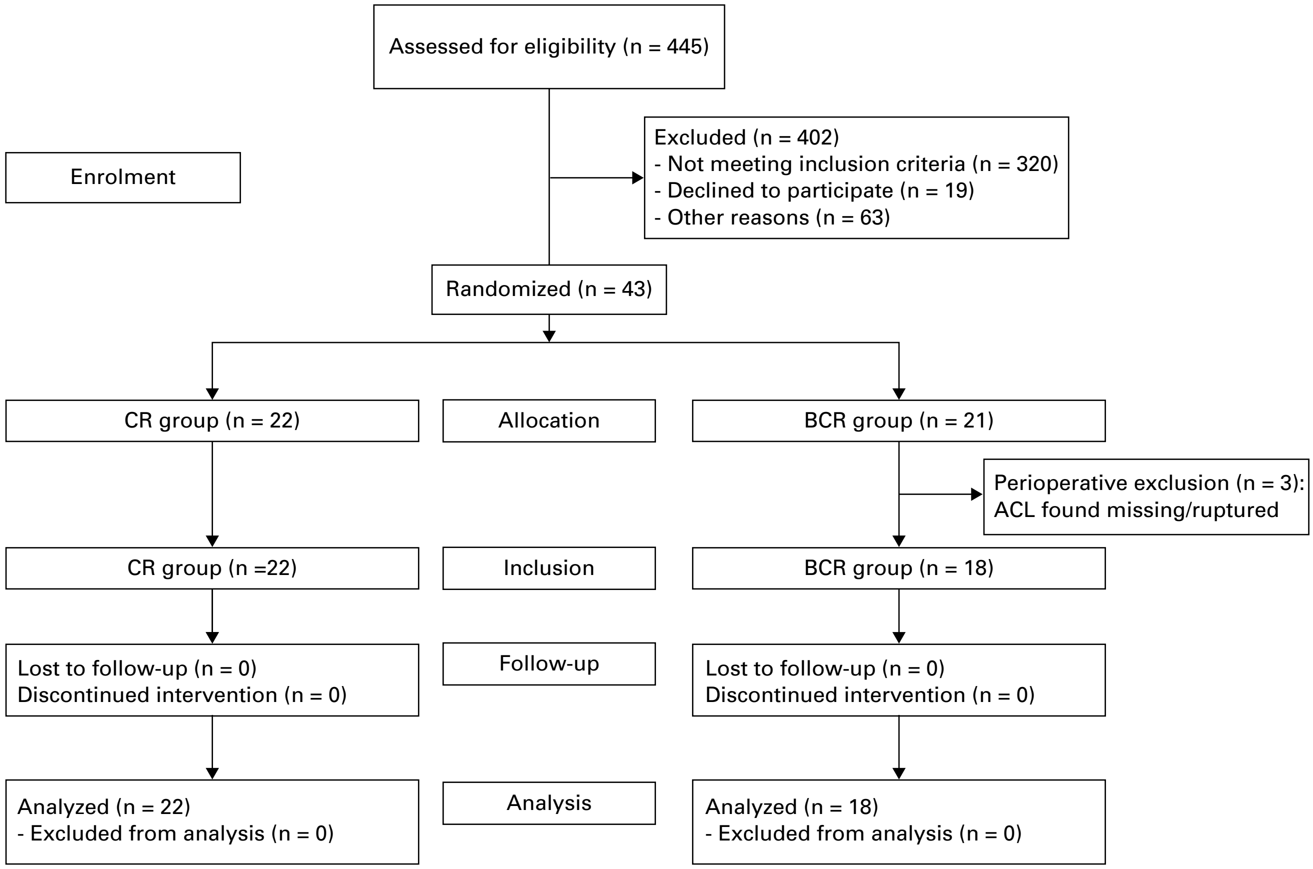

Fig. 3

Flowchart screening and selection of participants. ACL, anterior cruciate ligament; BCR, bicruciate-retaining; CR, cruciate-retaining.

becomes clinically apparent. The BCR-TKA we used (the Vanguard XP (Zimmer Biomet, USA)) has not been thoroughly studied in terms of fixation of both components.

The primary goal of this randomized controlled trial was to compare the in vivo kinematics using fluoroscopy between BCR- and CR-TKA during a step-up and lunge task. The secondary goal of this study was to compare the BCR- and CR-TKAs in terms of 3D implant micromotion. Our hypothesis was that BCR-TKA demonstrates different knee kinematics compared to CR-TKA and that micromotion of the tibial component is higher in the BCR-TKA than compared to CR-TKA. For the (nearly identical) femoral component we hypothesized equal low amounts of micromotion over the period of two years. Lastly, this study also assessed clinical and functional results, as a TKA that exhibits knee kinematics closer to a normal knee was also expected to show better outcomes.

Methods

This single-centre, patient-blinded, parallel-group randomized controlled trial (RCT; registered at Netherlands Trial Register: NTR5524) was conducted from November 2015 to April 2018 at Sint Maartenskliniek, Nijmegen, the Netherlands in accordance with the Declaration of Helsinki[20] and reported following the CONSORT guidelines,[21] ISO 16087:2013 for RSA, and RSA guidelines.[22] All patients were aged 40 to 75 years, had primary knee osteoarthritis (unilateral, or bilateral with a proper functioning contralateral knee), were scheduled to receive a primary cemented TKA, were in good general health, and had a fully correctable or < 10° fixed varus or valgus deformity of the knee. The exclusion criteria were inflammatory arthritis, BMI > 35 kg/m^2, previous surgery to the study knee, suspicion of anterior and/or posterior cruciate ligament rupture at clinical examination, knee flexion < 90°, fixed flexion deformity > 10°, and > 30° extension deficit (for a detailed description of inclusion and exclusion criteria see Supplementary Table i). In addition, patients without a functional ACL in the BCR group were excluded if this was found at surgery. All patients were recruited by a research nurse and the treating orthopaedic surgeon (ABW, GGvH, KCD). Patients were blinded for group allocation up until their last visit. Block randomization lists with a block size of 4 were computer-generated, with an allocation ratio of 1:1, prepared by an investigator not involved in the recruitment or surgical procedures (MRB). Ethical approval for this study was obtained from Medisch-ethische toetsingcommissie voor het Slotervaartziekenhuis en Reade (Dossier NL54336.048.15) and all patients provided written informed consent.

The indications for both implants are similar, with the exception that the BCR-TKA (Vanguard XP; Zimmer Biomet;

Table II. Patient characteristics.

Characteristic	BCR-TKA	CR-TKA
Sample size, n	18	22
Sex, M:F	8:10	11:11
Mean age at surgery, yrs (SD)	65.8 (6.3)	64.2 (6.2)
Mean body height, cm (SD)	175 (10.1)	173.7 (8.6)
Mean body weight, kg (SD)	83.2 (14.4)	82.8 (10.5)
Mean BMI, kg/m² (SD)	27.1 (3.9)	27.5 (3.6)
Mean physical activity (UCLA score) (SD)	6.4 (0.9)	6.1 (1.5)
Implant side (left/right), n	14/4	8/14

BCR, bicruciate-retaining; CR, cruciate-retaining; SD, standard deviation; TKA, total knee arthroplasty; UCLA, University of California, Los Angeles.

Figure 1) requires a functional ACL and is constrained by natural soft-tissue. The CR-TKA (Vanguard CR; Zimmer Biomet; Figure 1) requires the ACL to be sacrificed and is constrained by soft-tissue and the tibial bearing shape (a more concave design with 3° of built-in posterior slope). The surgical procedure used a bone-referenced technique with mechanical alignment.[23] The valgus angle of the distal femoral cutting guide was measured using long-leg radiographs with planning for a distal femur cut perpendicular to the mechanical axis. The femoral component rotation was set at 3° of external rotation, taking Whiteside's line as a reference combined with the epicondylar axis.[23] The femoral cutting guide was posterior-referenced. For the tibial side, an extramedullary tibia guide was used, planning for 9 mm resection of the unworn side. For the BCR, the bony island of the ACL and/or posterior cruciate ligament (PCL) was kept intact with protection of the insertion by using the Vanguard XP tibial island alignment guide. The tibial slope was planned to reproduce the natural tibial slope of the patient. After the BCR-TKA was implanted, a clinical assessment of the tibial insertion/bony island and ACL was performed, including testing of the anterior-posterior (AP) stability intraoperatively. After preparation of the bone and before placement of the implants, 1 mm tantalum beads for RSA were placed in the femur and tibia. All components in both groups were cemented separately (cement on bone and implant before implanting) with vacuum-mixed poly-methyl methacrylate (PMMA) bone cement (PALACOS *R* + G; Heraeus, Germany).

Outcome parameters: kinematics. To assess the kinematics during functional tests, monoplanar fluoroscopic images were captured using the Philips MultiDiagnost Eleva (MDE; Philips, the Netherlands) with a frame rate of 15 frames per second, a pulse width of 8 ms and a 1,024 × 1,024 image matrix. Patients performed a step-up and lunge test at one year postoperatively on an 18 cm platform-centred between the image detector and the focus of the fluoroscope positioning the knee in front of the image detector. These tasks were selected as both are functional weightbearing activities, with wide ranges of knee flexion. Previous research has demonstrated that the ACL plays a more important role in lower flexion angles; therefore, we decided not to include deep-lunge activities.[24] The step-up movement started with the operated leg on the platform and ended when the contralateral leg was on the platform. For the lunge test, subjects placed their foot on the platform and bended their knee to maximum comfortable flexion by stepping backwards. Data analysis was performed using the fluoroscopy module in model-based RSA (v. 4.2014; RSAcore, the Netherlands). Contours of both components were detected and virtually projected contours of their corresponding computer-aided design (CAD) models were aligned using contour-matching algorithms.[25,26] The position and orientation estimates of these models over time define the knee kinematics with sub-mm/° accuracy for in-plane translations and all rotations.[25,26] From these kinematics, for each frame, the medial and lateral minimal distance locations between the femur and tibia components are defined as the medial and lateral contact points (CP).[27] Each CP is reported as a ratio from 0 to 1, with 0 representing the most anterior point of the tibial insert and 1 the most posterior point (Figure 2).

The main outcome parameter was the AP CP during the step-up task from 30° to 0° flexion. Secondly, the AP CP during the lunge test from 0° to 70° flexion was assessed. Knee flexion, defined as the angle between the femur and tibia components, was calculated from the component orientations in the sagittal plane.

Outcome parameters: implant micromotion. Implant micromotion was measured with RSA using a uniplanar setup with one ceiling-mounted and one mobile X-ray tube. Patients were in supine position, with a standardized position for foot rotation. Micromotion of both components was expressed along and around three axes (Figure 1).

Model-based RSA measurements were performed with MBRSA software (MBRSA 4.2014 RSAcore). Micromotion of the femoral and tibial component was calculated with reference to the femoral and tibial bone markers, respectively. A cut-off level of < 120 was used for the condition number and in all analyses the same RSA markers were used. Total translation (TT) was calculated as:

$$TT = \sqrt{\left(Tx^2 + Ty^2 + Tz^2\right)}$$

Total rotation was calculated as:[28]

$$TR \approx \sqrt{\left(Rx^2 + Ry^2 + Rz^2\right)}$$

Precision was assessed through double examinations carried out for all subjects at six weeks postoperatively and was calculated as the 95% confidence interval (1.96 × standard deviation (SD)) around the mean migration between the two examinations (Table I). RSA analysis was performed postoperatively during hospitalization (post-weightbearing), six weeks, three months, six months, one year, and two years postoperatively.[28]

Clinical and functional outcomes. Clinical outcomes were assessed using clinician- and patient-reported outcome scores (CROMs/PROMs). The 12-item Forgotten Joint Score (FJS),[29] the Oxford Knee Score (OKS),[30] the OKS-Activities and Participation Questionnaire (APQ),[31,32] and the Knee injury and Osteoarthritis Outcome Score Physical Function Shortform (KOOS-PS)[33] were used to assess knee function. Pain and post-operative satisfaction were measured using a visual analogue scale (VAS; 0 to 100). Quality of life was measured with the EuroQol five-dimension questionnaire, three-level version (EQ-5D-3L).[34] Dutch validated versions were used when available. Serious device-related events were recorded.

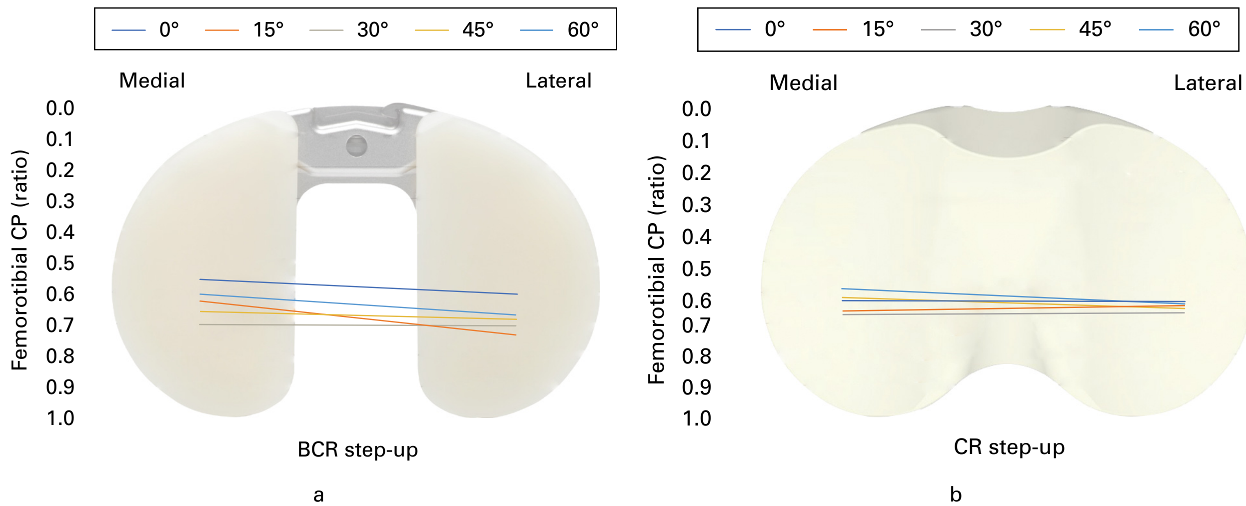

Fig. 4

a) Femorotibial contact points (CPs) projected on tibial insert during step-up task for bicruciate-retaining (BCR) total knee arthroplasty (TKA), displayed as a ratio from 0 (anterior) to 1 (posterior). b) Femorotibial contact points projected on tibial insert during step-up task for cruciate-retaining (CR) TKA, displayed as a ratio from 0 (anterior) to 1 (posterior).

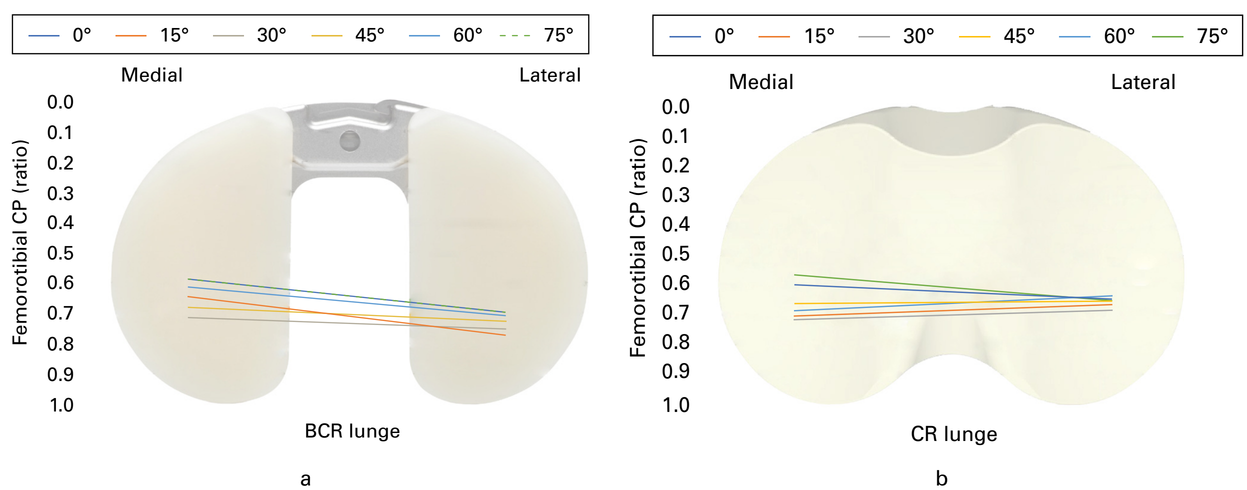

Fig. 5

a) Femorotibial contact points (CPs) projected on tibial insert during lunge task for bicruciate-retaining (BCR) total knee arthroplasty (TKA), displayed as a ratio from 0 (anterior) to 1 (posterior). The 0° line for the BCR group is overprojected by the 75° line. b) Femorotibial contact points projected on tibial insert during lunge task for cruciate-retaining (CR) TKA, displayed as a ratio from 0 (anterior) to 1 (posterior).

The AP laxity (in mm from anterior to posterior using a rolimeter (Aircast Europa, Germany)) of the knee in 20° and 90° flexion, and maximum knee flexion, were measured at all RSA follow-up moments.

The functional power output of the leg using the Leg Extensor Power Rig (Queens Medical Centre, UK)[35] was measured preoperatively and at six months, one year, and two years postoperatively. Five single leg extensions were recorded, and the highest recorded output was used for analysis.

Patients. A total of 40 patients were included; 18 patients received a BCR-TKA and 22 received a CR-TKA (Figure 3). Patient characteristics are displayed in Table II. The ACL was found ruptured intraoperatively in three patients. They were excluded from the study and replaced through randomization, which led to an unequal distribution between the groups.

Statistical analysis. The sample size calculation was based on the primary study parameter: the difference in AP CP in mm between the BCR and CR implant during the step-up task from 30° to 0° flexion. As the difference in AP CP between BCR and CR TKAs had never been assessed before, the estimation was based on previous research comparing PS with CR TKAs; where the posterior femoral rollback did not exceed 7.5 mm, which equals 10% of the plateau distance. Sample size calculation ($\alpha = 0.05$, power = 0.80 (G*Power, v3.1.7)) resulted in a sample size of 16. Because the difference between BCR and CR TKAs was expected to be smaller, we multiplied by 2, and to

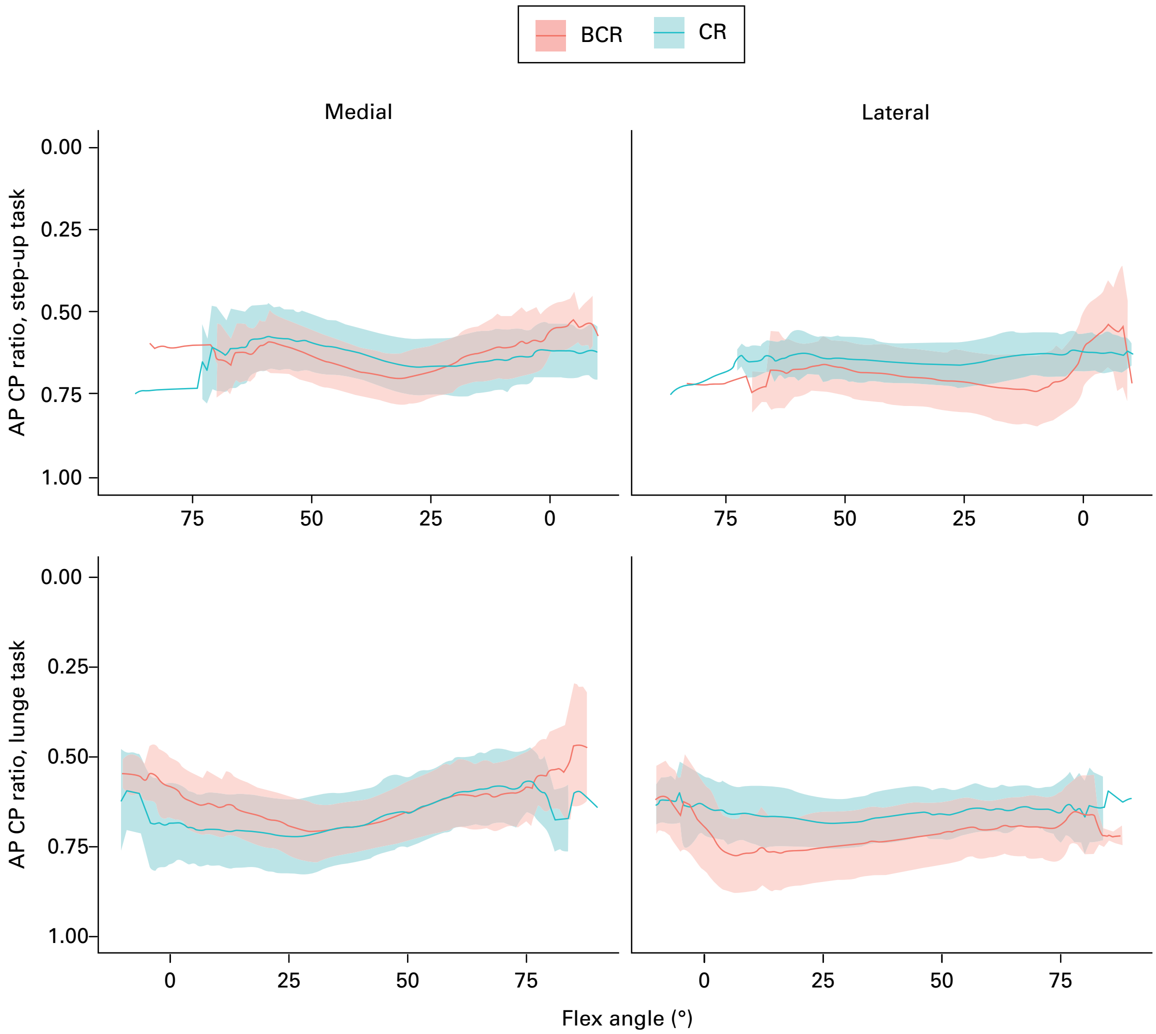

Fig. 6

Mean anteroposterior (AP) contact point (CP) ratios (0 anterior, 1 posterior) for the bicruciate-retaining (BCR) and cruciate-retaining (CR) groups per condyle by task. Shaded zones indicate one standard deviation.

account for loss to follow-up (10%) the sample size was set at 40 (20 patients per group).

The AP CP patterns for each patient extracted from the analyzed fluoroscopic images were first smoothed by averaging the samples over flexion angle zones of 0.5°. Subsequently, these data were linearly interpolated to have a CP at every degree of knee flexion within the movement range of the patient. Descriptive statistics were performed on the interpolated AP CP patterns for both groups. These patterns were compared between the groups for both condyles and both tasks, by using independent-samples *t*-tests to calculate the 95% confidence intervals (CIs) for the difference between the groups per degree of flexion angle. Results are reported as means and 95% CI. The groups were not compared when one of both groups contained less than three observations.

Multilevel regression analyses were used to study the effect of implant on migration of the femur and tibia components throughout follow-up. Differences between groups were assessed by estimating the mean treatment effect and the treatment × time interaction (only when time-varying mean differences were present). The model performance was tested with chi-squared tests based on the difference in log likelihood and the simplest models were presented. The fit of the model was assessed using residual plots. Sensitivity analyses showed that outliers did not influence the main analyses and were therefore not corrected. As advised in the literature,[18] the δ of maximal total point motion (MTPM) from six to 12 months, and from 12 to 24 months, was also calculated and compared between the groups. No interim analyses were carried out.

All other clinical and functional outcome scores were reported for at baseline and one and two years postoperatively and were compared between groups at one year postoperatively using Mann-Whitney U tests. The kinematics and mixed models analyses were performed with R v.3.6.2 (R Foundation for Statistical Programming, Austria) by a statistician. All other

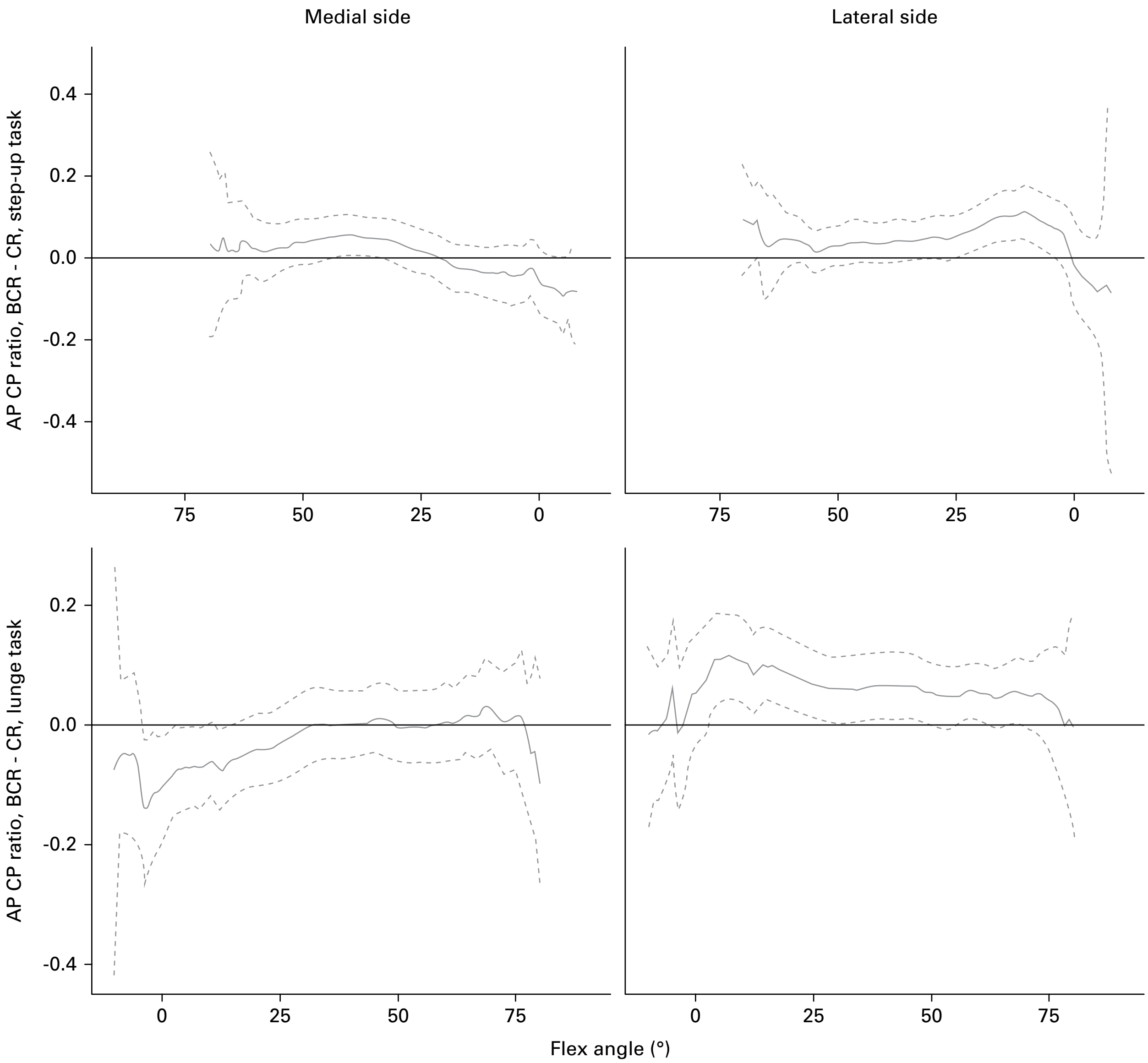

Fig. 7

Difference (bicruciate-retaining (BCR) – cruciate-retaining (CR)) in anteroposterior contact point (CP) ratio for each flexion angle per condyle by task. The dashed lines represent the corresponding 95% confidence intervals.

analyses were performed with STATA v.13.1 (StataCorp, USA), with a significance value $p < 0.05$.

Results

Kinematics. Figures 4 and 5 show the mean AP CPs at one year postoperatively, grouped in steps of 15° flexion. From 30° to 0° in the step-up task, the CR CP remains mostly fixed on the same position, while the BCR-TKA demonstrated tibial internal rotation from 30° to 15° and tibial external rotation in the final extension phase (Figure 4). In the lunge task, the BCR-TKA has more rollback up until 30° flexion, and overall the lateral CP is more posterior than the CR CP (Figure 5). From 30° there is some femorotibial forward sliding visible medially, in both groups.

Figure 6 shows the mean AP CP ratios during both tasks for both groups. The differences between the groups are small, but there are some clear distinctions. In order to compare both groups, Figure 7 shows the difference (BCR - CR) in CP ratio and the 95% CI of this difference. When 0 is outside of the 95% CI, the difference between the groups is statistically significant at a p-value < 0.05. A positive value for this difference means that the BCR CP is more posterior than the CR CP and vice versa. On the medial side from about 20° to 0° flexion during the step-up task, the CP for the BCR tends to be more anterior compared to the CR CP, although not significant. Laterally, the BCR CP is more posterior at these flexion angles. In the lunge task, there was a small amount of paradoxical forward sliding medially for both groups from about 30°

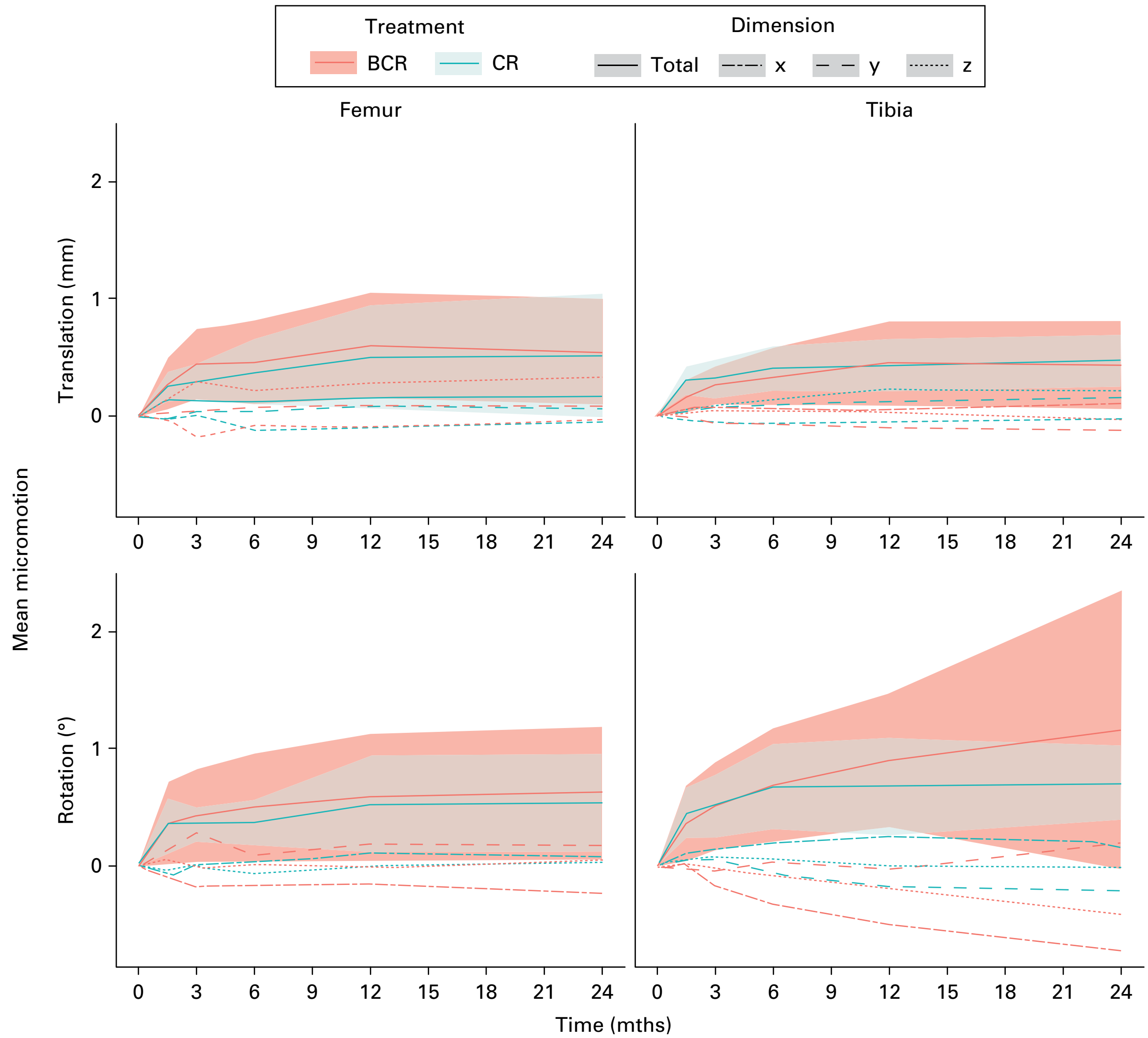

Fig. 8

Mean micromotion for the femur (left panels) and tibia component (right panels). The upper panels show translation, the lower panels rotation. Total translation and total rotation are visualized, as well as translation along and rotation around the three orthogonal axes. The shaded bands represent one standard deviation. BCR, bicruciate-retaining; CR, cruciate-retaining.

to 60° flexion (Figure 6). At full extension (0°), the BCR CP is more anteriorly located compared to the CR CP (Figure 7). This difference is reduced as the flexion angle increases, until the AP CP relation reaches an equilibrium at about 25° flexion. Laterally, the difference is more pronounced, with the BCR CP located more posterior for the entire movement cycle. The difference is highest around extension.

Implant micromotion. Two patients received no RSA beads, resulting in a total of 17 patients in the BCR group and 21 patients in the CR group for the RSA analysis.

Femur. Both the BCR- and CR-TKA show stabilizing patterns over time for both the mean translations and rotations (Figure 8, Supplementary Table ii). At one year, the median TT_{femur} and TR_{femur} were 0.44 mm (interquartile range (IQR) 0.29 to 0.81) and 0.48° (0.39° to 0.88°) for the BCR-TKA and 0.39 mm (0.25 to 0.95) and 0.50° (0.22° to 0.89°) for the CR-TKA (TT: z = -0.40; p = 0.689; TR: z = -0.18; p = 0.868, Mann-Whitney U test). Multilevel regression analyses showed a direct effect of group on rotation around the y-axis, and also through the interaction term group × time on rotation around the x- and z-axes and TR_{femur}, with BCR-TKA migrating more (Table III). The median MTPM at six months was 0.63 (0.42 to 0.93) for BCR and 0.61 (0.38 to 0.76) for CR TKA (z = -0.54; p = 0.588, Mann-Whitney U test). The δ MTPMs can be found in Table IV and show stable implants and no continuous migration on group level.

Tibia. Both implants show stabilizing patterns of translation over time (Figure 8, Supplementary Table iii). The rotational micromotion shows a slightly divergent pattern over time for the BCR-TKA. At one year, the median TTtibia and TRtibia were 0.31 mm (0.20 to 0.45) and 0.69° (0.54 to 1.01)° for the BCR-TKA and 0.28 mm (0.21 to 0.44) and 0.41° (0.29 to 0.68)

Table III. The best fitting models, found using multilevel regression analysis, are presented for all translations and rotations (x, y, and z) and total translation and total rotation, for both the femur and tibia components separately.

Component	Effect (95% CI)	p-value	Effect (95% CI)	p-value	Effect (95% CI)	p-value	Effect (95% CI)	p-value
Femur, translation	**Tx**		**Ty**		**Tz**		**TT**	
Intercept	-0.07 (-0.39 to 0.26)	0.683	0.03 (-0.10 to 0.17)	0.619	0.32 (-0.20 to 0.83)	0.229	0.35 (-0.06 to 0.76)	0.094
Group (1 = BCR; 2 = CR)	0.03 (-0.17 to 0.23)	0.770	-0.02 (-0.10 to 0.06)	0.647	-0.12 (-0.43 to 0.20)	0.459	-0.10 (-0.35 to 0.16)	0.455
Time	-0.02 (-0.03 to 0.00)	0.081	0.02 (0.01 to 0.03)	0.002	0.02 (-0.01 to 0.05)	0.193	0.08 (0.05 to 0.10)	< 0.000
Femur, rotation	**Rx**		**Ry**		**Rz**		**TR**	
Intercept	-0.11 (-0.70 to 0.47)	0.703	0.52 (0.07 to 0.98)	0.024	0.18 (-0.10 to 0.47)	0.209	0.39 (-0.08 to 0.86)	0.105
Group (1 = BCR; 2 = CR)	0.01 (-0.35 to 0.37)	0.961	-0.34 (-0.61 to -0.06)	0.018	-0.11 (-0.29 to 0.06)	0.200	-0.07 (-0.36 to 0.21)	0.617
Time	-0.08 (-0.18 to 0.02)	0.106	-0.04 (-0.12 to 0.04)	0.288	-0.05 (-0.09 to 0.00)	0.061	0.07 (0.04 to 0.09)	< 0.000
Group × Time	0.06 (0.00 to 0.13)	0.040	0.04 (-0.00 to 0.09)	0.066	0.03 (0.00 to 0.06)	0.048	Not in this model	
Tibia, translation	**Tx**		**Ty**		**Tz**		**TT**	
Intercept	0.22 (-0.00 to 0.45)	0.051	-0.01 (-0.33 to 0.31)	0.950	0.10 (-0.27 to 0.47)	0.588	-0.06 (-0.36 to 0.24)	0.695
Group (1 = BCR; 2 = CR)	-0.14 (-0.28 to -0.00)	0.049	0.02 (-0.18 to 0.22)	0.878	-0.05 (-0.28 to 0.18)	0.683	0.15 (-0.03 to 0.34)	0.107
Time	-0.01 (-0.05 to 0.03)	0.544	-0.07 (-0.12 to -0.03)	0.001	-0.06 (-0.11 to -0.01)	0.020	0.12 (0.07 to 0.17)	< 0.001
Group × Time	0.01 (-0.02 to 0.03)	0.497	0.05 (0.02 to 0.08)	< 0.001	0.05 (0.02 to 0.09)	0.001	-0.04 (-0.07 to -0.00)	0.026
Tibia, rotation	**Rx**		**Ry**		**Rz**		**TR**	
Intercept	0.24 (-0.57 to 1.00)	0.540	-0.37 (-0.91 to 0.17)	0.177	0.20 (-0.16 to 0.55)	0.273	-0.17 (-0.79 to 0.44)	0.577
Group (1 = BCR; 2 = CR)	-0.07 (-0.55 to 0.40)	0.766	0.28 (-0.06 to 0.62)	0.103	-0.04 (-0.26 to 0.18)	0.725	0.28 (-0.10 to 0.67)	0.144
Time	-0.35 (-0.47 to -0.23)	< 0.001	0.16 (0.07 to 0.24)	< 0.001	-0.16 (-0.23 to -0.10)	< 0.001	0.33 (0.21 to 0.44)	< 0.001
Group × Time	0.19 (0.12 to 0.27)	< 0.001	(-0.17 to -0.07)	< 0.001	0.07 (0.03 to 0.11)	0.001	-0.13 (-0.20 to -0.06)	< 0.001

All effects and corresponding 95% CIs are presented and the reported p-values were obtained from chi-squared tests to test the goodness of fit of the models. An example regression equation would be, for rotation around the x-axis, Rx = -0.11 + 0.01 Group – 0.08 × Time + 0.06 × (Group × Time).
BCR, bicruciate-retaining; CI, confidence interval.

Table IV. Change in maximal total point motion between six months and one year, and from one to two years postoperatively.

Median MTPM, mm (IQR)	BCR		CR	
	Femur	**Tibia**	**Femur**	**Tibia**
6 months to 1 year	0.16 (-0.08 to 0.29)	0.16 (0.07 to 0.23)*	0.11 (-0.05 to 0.54)	0.03 (-0.09 to 0.12)*
1 to 2 years	0.05 (-0.09 to 0.20)	0.06 (0.01 to 0.11)	0.01 (-0.14 to 0.17)	0.07 (-0.06 to 0.11)

*Represents a statistically significant difference between BCR and CR total knee arthroplasty (p = 0.010, Mann-Whitney U test).
BCR, bicruciate-retaining; CR, cruciate-retaining; MTPM, maximal total point motion.

for the CR-TKA (TT: z = -0.38; p = 0.702; TR: z = -2.29; p = 0.022, Mann-Whitney U test). Anatomically, the tibia component of the BCR-TKA showed more posterior and varus tilt compared to the (stable) CR-TKA. Multilevel regression analyses found statistically significantly more micromotion for the BCR-TKA compared to the CR-TKA. There is a significant direct effect of group on translation along the x-axis and through the interaction term of group × time along the y- and z-axes and TT (Table III), with the BCR-TKA showing higher micromotion. For rotation, the BCR-TKA showed statistically significantly more rotation around all axes and TR through the interaction term group × time (Table III). The median MTPM at six months was 0.49 (IQR 0.34 to 0.72) for BCR and 0.48 (IQR 0.33 to 0.85) for CR TKA (z = 0.21; p = 0.831, Mann-Whitney U test). The δ MTPMs can be found in Table IV and this change in MTPM from six months to one year was higher for the BCR-TKA (p = 0.010, Mann-Whitney U test), but remained < 0.2.

Clinical and functional outcomes. All clinical and functional outcome scores can be found in Table V, there were no differences between the groups at one year postoperatively (p = 0.092, Mann-Whitney U test). There were several minor/major adverse device-related events (Table VI). One patient had a revision TKA because of laxity; two had an insert exchange. All of these patients had a BCR-TKA.

Discussion

The main kinematic differences between the two TKA designs were found during final extension in the step-up task, where the BCR-TKA demonstrated a kinematic pattern more comparable to the natural knee's screw home mechanism.[11] In the lunge task, the main differences between the implants were observed in the early flexion phase. These differences observed for both tasks are in line with previous study results by Arauz et al[36] that investigated the same BCR-TKA. These differences were seen in the ACL-effective zone: in the native knee, the ACL is most active around extension, prohibiting the tibia from moving forward and away from the femur (anterior subluxation).[37]

Both implants have a different tibial insert design: the CR-TKA insert is deeper and more concave-shaped while the BCR-TKA insert is flatter to allow the cruciate ligaments to control the kinematics. This difference in tibial insert shape can explain that the CR-TKA CP remains mostly stable on the lateral condyle in terms of AP translation, while the BCR-TKA CP appears to be influenced by the ACL tension. However, there was a wide distribution for the BCR CP, indicating a large variation within this group. The authors believe this could indicate suboptimal ACL balancing in some of the BCR patients, however this was not investigated in the present study.

Table V. Clinical and functional outcome scores.

Outcome	BCR			CR			
	Baseline	1 yr	2 yrs	Baseline	1 yr	2 yrs	p-value 1 year*
Median CROMs and PROMs (IQR)							
OKS	26.5 (20.8 to 30.5)	42.5 (38.5 to 45.5)	44 (41 to 47)	24 (19 to 31)	41 (36 to 44)	44 (41 to 46)	0.533
OKS-APQ	12.5 (4.7 to 20.3)	68.8 (34.4 to 96.9)	79.7 (43.8 to 93.8)	10.9 (3.1 to 18.8)	79.7 (56.3 to 96.9)	90.6 (71.9 to 96.9)	0.468
KOOS-PS	44 (39.5 to 50.3)	26.2 (18.6 to 32.7)	22 (10.5 to 29.7)	42 (35.3 to 54.4)	29.7 (14.8 to 33.6)	22 (14.8 to 33.6)	0.722
EQ-5D score	0.775 (0.61 to 0.775)	0.897(0.775 to 1)	1 (0.807 to 1)	0.775 (0.651 to 0.775)	0.843 (0.807 to 1)	1.0 (0.843 to 1)	0.668
VAS	70 (59 to 85)	80 (72.5 to 87.5)	80 (78 to 86)	75 (60 to 85)	80 (75 to 90)	85 (70 to 90)	0.688
VAS Pain	50 (38 to 70)	4 (0 to 27)	6 (0 to 12)	52 (36 to 75)	4 (3 to 13)	3 (0 to 9)	0.788
VAS Satisfaction	N/A	94 (55 to 100)	97 (87 to 100)	N/A	89 (49 to 100)	95 (75 to 100)	0.380
Forgotten Joint Score	N/A	63.5 (43.2 to 77.1)	70.8 (62.5 to 89.6)	N/A	51.0 (14.6 to 75)	58.3 (20.8 to 93.6)	0.459
Median max. knee flexion (IQR)	120 (120 to 125)	120 (115 to 130)	120 (120 to 130)	120 (120 to 130)	120 (115 to 130)	120 (120 to 130)	0.379
Median laxity (IQR)							
20° anterior	2 (2 to 2.3)	2 (1.5 to 3)	3 (2 to 3)	2 (1 to 3)	2 (1 to 2)	2 (2 to 2)	0.484
20° posterior	2 (1 to 2.3)	2 (1.5 to 2)	3 (2 to 3)	2.3 (2 to 3)	2 (1 to 2)	2 (2 to 3)	0.641
90° anterior	2 (2 to 2.3)	2 (2 to 3)	3 (2 to 3)	2 (2 to 2)	2 (2 to 2)	2 (2 to 3)	0.228
90° posterior	2 (2 to 3)	2 (2 to 3)	2 (1 to 3)	2 (1.3 to 3)	2 (2 to 2.5)	2 (2 to 3)	0.352
Power output leg extension test							
Median max. wattage, W (IQR)	78 (51 to 108)	102.5 (79.5 to 135)	121 (98 to 185)	90 (67 to 102)	127 (111 to 171)	147 (105 to 182)	0.092
Median rel. power-body weight ratio, % (IQR)	0.89 (0.74 to 1.38)	1.49 (0.88 to 1.86)	1.69 (1.22 to 2.26)	1.05 (0.84 to 1.40)	1.58 (1.27 to 2.18)	1.55 (1.18 to 2.20)	0.232

*Comparison of XR vs CR one year postoperatively, tested with Mann-Whitney U test.
BCR, bicruciate-retaining; CR, cruciate-retaining; CROM, clinician-reported outcome measure; EQ-5D, EuroQol five-dimension index; IQR, interquartile range; KOOS-PS, Knee disability and Osteoarthritis Outcome Score-Physical Function Shortform; N/A, not available; OKS, Oxford Knee Score; OKS, OKS-Activity and Participation Questionnaire; PROM, patient-reported outcome measure; VAS, visual analogue scale.

Table VI. Overview of the reported (serious) adverse events up until two years postoperatively.

Diagnosis	Treatment	BCR	CR
Flexion limitation	Manipulation under anaesthesia	1*	2
Pain and mediolateral instability	Insert exchange and iliotibial band release	2	
Global laxity	Revision TKA	1	
Small intraoperative fracture of anterior bony island	Re-fixation with Ethibond (Ethicon, USA)	1*	
Persistent pain	Injection	1	2

*Same patient.
BCR, bicruciate-retaining; CR, cruciate-retaining; TKA, total knee arthroplasty.

In both groups, a paradoxical anterior translation of the CP was observed. Dennis et al[37] also found paradoxical forward sliding of the femur from mid to deep flexion in both healthy and ACL-deficient knees, but both the incidence and magnitude were higher in the ACL-deficient knee group. Heyse et al[38] compared the kinematics of this BCR-TKA design with a native knee and also found minor amounts of medial forward sliding of the CP. Komistek et al[39] even reported some minor anterior translation in the native knee in an order of magnitude comparable to our results, and attributed this to ligamentous tension. Therefore, we believe that the small amount of anterior translation in the present study may result from failure to restore PCL tension, as the PCL function is to prevent the tibia from sliding backwards with regard to the femur.[40]

The RSA results for the femoral component showed slightly higher rotation of the BCR-TKA compared to the CR-TKA, but these changes were small and have no clinical consequences. Migration results of the tibia, on the other hand, did show statistically significant differences between the BCR- and CR-TKA. The differences in rotation can be explained by a lack of built-in restraint in the prosthesis-bone interface due to the implant design (short pegs instead of a stem). This finding is in line with Robertsson et al,[41] who reported higher risk of loosening for a four-pegged design, compared with a stemmed design. Therefore, the differences in kinematics observed in this study, resulting from different forces exerted on the tibial baseplates, may possibly explain the differences observed. In contrast to our findings, Troelsen et al[42] found no difference in micromotion of the tibial components of the same system, for which we do not have an explanation.

There were no significant differences between the groups in clinical or functional outcomes, but the frequency of device-related complications with BCR-TKA was worrying. However, this study was underpowered to measure and assess these outcomes. Previous research including more modern BCR implants failed to reach consensus on a clinical advantage of the BCR-TKA, with one indicating few long-term revisions and a patient-preference for BCR-TKAs,[43] and another reporting higher frequency of reoperations with BCR-TKAs.[44] Longer-term studies in combination with registry data need to verify these results. The use of optimal surgical techniques to implant BCR-TKAs should be further investigated, such as robotic-assisted surgery, which may ensure highly precise implant placement, and makes use of algorithms for soft-tissue balancing. Thus, kinematic alignment (with or without robotic assistance) can also play a part in ensuring more natural knee kinematics by restoring the native anatomy of the patient's knee.

This study has some limitations. First, the absence of deeper flexion angles in the lunge task: the functional active arc of natural knee movement runs from 20° to 120° knee flexion,[10] while the motion cycles in this study only reached a maximum knee flexion at around 75°. Second, all patients received the same BCR- and CR-TKAs implants, so the results are not generalizable to other TKA designs. Third, we did not assess the postoperative leg alignment by radiographs. Malalignment can negatively influence micromotion. Finally, the relatively low sample size means the study was not sufficiently powered to draw conclusions about the clinical and functional outcomes. However, as the kinematics of both TKAs were assessed over the entire motion cycles for both tasks, this study does give more insight into subtle differences between the two groups and presents valuable RSA data that can be used for future referencing.

In conclusion, this RCT demonstrates that the BCR-TKA design showed a different kinematic pattern in early flexion/late extension compared to the CR-TKA. The small amount of paradoxical anterior translation of the CP in both groups, and the wide distribution in the kinematic data from the BCR group, suggest that care needs be taken to properly balance both the ACL and PCL during insertion of this BCR-TKA implant design to further improve kinematics. In addition, the tibial component of the BCR-TKA showed greater micromotion compared to the CR-TKA within the first two years after surgery. Whether this difference in tibial micromotion will have long-term clinical consequences remains unclear and requires further investigation. With short-term follow-up we found no clinical differences between both implants, but the combination of the higher migration and overall a higher complication rate does not support the routine use of this BCR-TKA implant.

Take home message

- While the bicruciate-retaining total knee arthroplasty (BCR-TKA) shows a different kinematic pattern compared to the cruciate-retaining TKA, the BCR-TKA also shows relatively high within-group variability.
- Furthermore, the BCR-TKA tibia component showed higher migration. Clinically, there were no noticeable differences between the groups.
- This combination of results does not support the routine use of this BCR-TKA at this stage.

Supplementary material

Full table of inclusion and exclusion criteria, and full radiostereometric migration results for femoral and tibial components.

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Funding statement:
The authors disclose receipt of the following financial or material support for the research, authorship, and/or publication of this article: the institution received funding from Zimmer Biomet to pay for staff and materials. Zimmer Biomet had no role in the design or conduct of the study, the collection, management, analyses, and interpretation of the data, or the preparation and review of the manuscript.

ICMJE COI statement:
K. C. Defoort reports royalties or licenses from Corin Medical, consulting fees and payment for honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events from Smith & Nephew, all unrelated to this study. P. J. C. Heesterbeek reports travel expenses from the International Society for Technology in Arthroplasty (unrelated to this study) and is an unpaid board member of the International RSA Society. G. G. van Hellemondt reports royalties from Smith & Nephew, consulting fees from Zimmer Biomet and Bodycad, and presentation and speaker bureau payments from Smith & Nephew, all unrelated to this study. A. B. Wymenga reports royalties or licenses from Smith & Nephew, unrelated to this study.

Acknowledgements:
The authors thank Saskia Susan for patient recruitment and study management and Jolanda Rubrech-van As for data management.
THE OXFORD KNEE SCORE – ACTIVITY AND PARTICIPATION QUESTIONNAIRE (OKS-APQ)

Ethical review statement:
Ethical approval for this study was obtained from Medisch-ethische toetsingcommissie voor het Slotervaartziekenhuis en Reade (Dossier NL54336.048.15) and all patients provided written informed consent.

Open access funding:
The authors confirm that the open access fee was covered by their study budget.

Trial registration number:
Netherlands Trial Register: NTR5524

This article was primary edited by D. Johnstone.