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KNEE ARTHROPLASTY

Knee kinematics are not different between asymmetrical and symmetrical tibial baseplates in total knee arthroplasty: A fluoroscopic analysis of step-up and lunge motions

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Abstract

Purpose: This clinical fluoroscopy study investigated knee kinematics of two different cemented fixed-bearing, posterior-stabilised (PS) total knee arthroplasty (TKA) designs: an asymmetric tibial component including an asymmetric insert designed to optimise personalised balance and fit and its precursor symmetrical design with symmetric insert.

Methods: A consecutive series of patients (16 TKAs from each treatment group) participating in a randomised controlled trial comparing TKA migration was included. The exclusion criterion was the use of walking aids. Flat-panel fluoroscopic recordings of step-up and lunge motions were acquired 1-year postoperatively. Medial and lateral contact points (CPs) were determined to calculate CP displacement, femoral axial rotation and pivot position. Using linear mixed-effects modelling techniques, kinematics between TKA designs were compared.

Results: During knee extension between 20° flexion and full extension, the CPs moved anteriorly combined with a small internal femoral rotation (a screw-home mechanism). Whereas CP movement was reversed: femoral rollback, external femoral rotation while flexing the knee between full extension and 20° knee flexion, At larger flexion angles, femoral axial rotation (FAR) occurred around a lateral pivot point both during step-up and lunge. The symmetric design had a 2.3° larger range of FAR compared to the asymmetric design during lunge (p = 0.02). All other kinematics were comparable.

Conclusion: Despite the differences in design, this study showed that the asymmetric and symmetric PS TKA designs had mostly comparable knee kinematics during step-up and lunge motions. It is therefore expected that the functionality of the successor TKA design is similar to that of its precursor design.

Abbreviations: AP, anteroposterior; ASA, American Society of Anaesthesiologists; BMI, body mass index; CAD, computer-aided design; CI, confidence interval; CP/CPs, contact point/contact points; FA, flexion angle; FAR, femoral axial rotation; HKA, hip knee ankle angle; LMM, linear mixed-effects modelling; LPS, legacy posterior-stabilised; n.s., not significant; PROM(s), patient-reported outcome measure(s); PS, posterior-stabilised; ROM, range-of-motion; RSA, radiostereometric analysis; SD, standard deviation; TKA, total knee arthroplasty.

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Level of Evidence: Level II, prospective comparative study.

KEYWORDS

fluoroscopic analysis, knee kinematics, NexGen, Persona, posterior-stabilised TKA, total knee arthroplasty

INTRODUCTION

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Well-performing total knee arthroplasty (TKA) designs show at least 95% survival 10 years postoperatively [29, 34, 36]. Although survival data is excellent, TKA function during daily activities and reduction of pain is of more importance and not fulfilled in a significant proportion of patients [27, 35]. Approximately 50% of failing prostheses are associated with poor knee biomechanics, which leads to instability and overload of the knee [11, 28]. Even more, 10%–20% of patients are dissatisfied with the outcome of their TKA [8, 19, 30], which is related to multiple reasons, such as preoperative pain level [27], unmet preoperative expectations [44], little preoperative osteoarthritis [23] and also failed restoration of joint mechanics [8, 27].

As the number of elective TKA performed showed an annual growth of 10% since 2008 [29], the number of dissatisfied patients also increased, underlining the importance of analyses on this. One possible way is improving knee kinematics by improving TKA design. Multiple asymmetric (anatomically shaped) tibial components with asymmetric inserts have been introduced, aiming for a better anatomical fit and closer to native knee kinematics. However, knee kinematic studies of anatomic TKA designs showed considerable heterogeneity in kinematics [6, 7, 40, 43]. It is, therefore, essential to use objective measurements to test new TKA designs not only for initial fixation using radiostereometric analysis (RSA) [33] but also for function and kinematics. At the time of conducting this study, no kinematic results of the specific anatomical TKA design, which was recently introduced, were known.

Therefore, the primary aim of this study was to investigate if knee kinematics, during step-up and lunge motions, differed between two cemented tibial component designs: an asymmetric component design with its asymmetric insert and its precursor symmetric design. The secondary aims were to compare the range-of-motion (ROM) of flexion–extension, ROM of femoral-tibial contact points (CPs), ROM of femoral axial rotation (FAR) and the pivot point location for FAR between the two TKA designs. The hypothesis was that the two designs had similar kinematics.

METHODS

Patients in this fluoroscopy study were consecutively included from a larger prospective randomised RSA trial investigating the migration of an asymmetric and a symmetric tibial component design of a TKA [26] until 16 TKAs for each design were included. Randomisation in the RSA trial was based on a 1:1 ratio using a randomisation list. The most important inclusion criteria of the RSA study were the following: age between 21 and 90 years and the need for a primary TKA due to end-stage osteo- or rheumatoid arthritis. Exclusion criteria for the kinematic study were the inability to walk over 500 m and the need for walking aids. All patients gave written informed consent specifically for fluoroscopy measurements. The study was approved by the Institutional Review Board (Protocol ID P13.277) and was registered in Clinical Trials (NCT02269254).

Patients either had the asymmetric Persona PS TKA design (Persona; intervention group) with 1 mm insert increment options or the symmetric NexGen Legacy posterior stabilised TKA design (NexGen; control group) with 2 mm insert increment options. Both are cemented, fixed-bearing, posterior-stabilised designs (Zimmer Biomet). Femoral condyle geometry is the same for both designs. Surgery was performed using standard bone-referenced and measured-resection balancing techniques aiming for neutral mechanical alignment. Full surgical details are provided in the previous RSA paper [26].

Fluoroscopic recordings

Fluoroscopic recordings for kinematic analysis were acquired 1-year postoperatively. A single-focus flat-panel fluoroscope (Ultimax-i Fluoroscope, Toshiba medical systems Nederland) was used to acquire sagittal recordings (10 Hz, full detector size [43 × 43 cm, 1536 × 1536 rows, columns], pulse width 2 ms, kV and mAs fixed with settings determined prerecording). An 18 cm height platform (60 × 90 cm, antislip surface) was positioned between the roentgen tube and the detector, and patients had their left knee closest to the detector. Patients were instructed to maintain an upright trunk position during motions. Patients familiarised with the step-up and lunge motions without shoes until able to perform the motions in a controlled manner at selfchosen speed. Patients were allowed to rest a hand on a support rail for balance but were asked not to lean onto the rail. Up to three recordings were acquired for each motion, and the recording with the largest flexion-extension ROM was included in the analysis. For both motions, the foot of the operated knee was positioned

on top of the platform, with the knee in front of the fluoroscopic detector. At the start of the step-up motion, most of the weight was on the nonoperated leg on the floor. The motion was finished when the patient stood upright on the platform with the nonoperated leg next to the operated leg (dual leg support). For the lunge motion, the toes of the nonoperated knee were on the edge of the platform at the start of the motion. The patient stepped back onto the floor with the nonoperated leg and continued to flex the operated knee until maximum comfortable flexion was reached.

Measurements

Fluoroscopic recordings were separated into single images. Images were loaded in Model-based RSA software (version 4.1, RSA*core*, Leiden University Medical Centre) for analysis. Fluoroscopic parameters were used to calibrate the images [21]. Computeraided design three-dimensional models were used to determine the position and orientation of the TKA components with submillimetre/degrees accuracy using shape-matching algorithms [38, 48].

For each image the femoral-tibial CP position (i.e. position where the distance between the femoral condyle and the tibial baseplate is shortest), on the medial and lateral side were determined [46]. Hereafter, CP measures (in mm) are always in the anteroposterior direction unless otherwise denoted. To compare CP movement between the Persona and NexGen designs, the CPs were expressed as relative CPs, where 0 was the most anterior point on the tibial baseplate, and 1 was the most posterior point on the lateral tibial condyle. The angle between the line connecting medial and lateral-CPs and the transverse axis of the tibial baseplate was calculated to assess FAR (in °, where 0° is neutral, positive is femoral internal rotation, negative is femoral external rotation) [13]. The knee flexion angle (FA°, where 0° is neutral [knee in extension], positive is flexion) was determined using projection angles [2]. Primary outcome variables were analysed per 5° of FA using the image with the FA closest to a multitude of 5° (0, 5, 10 etc.).

Secondary outcome variables were based on the minimum and maximum calculated CP positions and FAR for each patient for each motion included in the analysis. To determine the pivot point location, the change in the medial- and lateral-CP positions were used: medial-CP translation < lateral-CP translation = medial pivot, medial-CP translation > lateral-CP translation = lateral pivot [13].

Statistics

It was expected that about 50% of the 30 patients included in each group of the RSA part of the study

would be able and willing to participate in the fluoroscopy part of the study. Based on previous experience and experience of others [32, 37, 48] and limited by practical boundaries, including two groups of 16 patients would provide sufficient power to assess the primary objective of the study.

Statistical analyses were performed using SPSS (v25, IBM). Data were assessed for normality (Shapiro-Wilk test and visual inspection) and presented as mean (95% confidence interval [CI]). Linear mixedeffects modelling (LMM) [39] was applied to compare kinematic patterns during step-up and lunge motion. TKA design, knee flexion (per 5°) and their interaction were set as fixed effects, each knee was included as a random effect. The correlation structure was continuous autoregression-1 and residuals of the LMM were visually inspected for normality. A sensitivity analysis was performed using flexion angles $\geq 0^{\circ}$ and $\leq 60^{\circ}$ (step-up), or $\leq 90^{\circ}$ (lunge) to exclude the effect of some patients who reached larger flexion angles.

An independent-sample *t* test was applied to compare the ROM of the kinematic variables between the TKA designs. Significance was set at $p \le 0.05$.

RESULTS

Sixteen Persona and 16 NexGen TKAs were available for fluoroscopic analysis (Table 1). Regarding pre- and postoperative knee alignment, six long-leg X-rays were not made, either preoperative (four) or postoperative (two). From the 26 TKAs with pre- and postoperative long-leg X-rays, 15 TKAs had a postoperative neutral knee alignment, of which nine TKAs were preoperatively in varus, three in valgus and one in neutral alignment. From 10 varus TKAs postoperatively, nine TKAs had a preoperatively larger varus alignment and one had a neutral alignment. The one TKA with postoperative valgus alignment, had a preoperatively much larger valgus alignment.

At the end of the step-up motion, 10 TKA (six Persona/four NexGen) were not in full extension ($\geq 0^{\circ}$ knee flexion) and 21 TKA (12 Persona/nine NexGen) were not in full extension at the start of the lunge motion.

Step-up motion

None of the ROMs of the kinematic variables during the step-up motion was significantly different between the Persona and NexGen designs (Table 2). Mean (95% CI) flexion angle ROM during step-up were 62° (58.6–66.3°) and 66° (60.5–71.3°) for the Persona and NexGen designs, respectively (not significant [n.s.]).

The relative CP positions and FAR during step-up are shown in Figures 1 and 2. There was no effect of TKA design, nor an interaction effect of TKA design and

= 16)

NexGen (n = 16)

10 (63%)

	Persona (<i>n</i>
Gender, female (%)	8 (50%)
Height (m), mean (SD)	1.73 (0.09)

TABLE 1 Patient descriptives.

Height (m), mean (SD)	1.73 (0.09)	1.69 (0.11)
BMI, mean (SD)	29.4 (5.05)	28.7 (4.82)
Age (years), mean (SD)	61 (14.3)	68 (7.2)
Operated side, right (%)	5 (31%)	11 (69%)
Preopative HKA-angle (%)		
Neutral (≤−3°; ≥3°)	3 (18.75)	2 (12.5)
Varus (<-3°)	8 (50)	11 (50)
Valgus (>3°)	2 (12.5)	2 (12.5)
Missing	3 (18.75)	2 (6.25)
Postopative HKA-angle (%)		
Neutral (≤−3°; ≥3°)	10 (62.5)	7 (42.75)
Varus (<-3°)	3 (18.75)	8 (50)
Valgus (>3°)	2 (12.5)	N/A
Missing	1 (6.25)	1 (6.25)
ASA-score		
ASA 1	1 (6%)	1 (6%)
ASA 2	14 (88%)	12 (75%)
ASA 3	1 (6%)	3 (19%)
Osteoarthritis	15 (94%)	14 (88%)
Rheumatoid Arthritis	1 (6%)	2 (12%)

Abbreviations: ASA, American Society of Anaesthesiologists; BMI, body mass index; HKA, hip knee ankle angle; SD, standard deviation.

flexion angle on lateral and medial-CP positions (n.s) and FAR (n.s.).

At the start of the step-up, the lateral-CP position was more posterior compared to the medial-CP position. During step-up, both CPs moved posteriorly between 70° to around 20° flexion, reaching similar CP positions. During this part of the step-up, an internal rotation of the femur around a lateral pivot point occurred due to a larger posterior movement of the medial-CP compared to the lateral-CP (Figure 2). Between 20° flexion and full extension, the CPs moved anteriorly with limited FAR about a medial pivot point (Figure 2).

Lunge motion

The ROMs for the lunge motion are shown in Table 3. Mean (95% CI) flexion angle ROM was comparable between the Persona and the NexGen designs: Persona 82° (72.0–91.4°), NexGen 77° (67.9–86.9°) (n.s.). However, the FAR ROM was smaller for the Persona design than for the NexGen design with a mean difference (95% CI) of -2.3° (-4.3° to -0.5° , p = 0.02).

The position of the relative CPs and FAR during lunge are shown in Figures 3 and 4. There was no effect of TKA design, nor an interaction effect of TKA design and flexion angle on the lateral and medial-CPs positions during lunge (n.s.).

At the start of the lunge motion, both CPs were positioned on the posterior half of the tibial baseplate. Up to approximately 20° knee flexion, both CPs moved

TABLE 2 Range of motions for knee flexion (FA), femoral axial rotation (FAR), anteroposterior translation of relative medial contact point (rel_CP-med, AP), anteroposterior translation of relative lateral contact point (rel_CP-lat, AP), anteroposterior translation of medial contact point (CP-med, AP) and anteroposterior translation of lateral contact point (CP-lat, AP) during the step-up motion.

ROM		Persona	NexGen	95% CI difference	p Value
FA (°)	Mean (SD)	62.4 (7.2)	65.9 (10.1)	-9.8; 2.9	n.s.
	Min–Max	45.7–69.7	40.1–82.3		
FAR (°)	Mean (SD)	7.2 (2.5)	8.9 (2.5)	-3.4; 0.2	n.s.
	Min–Max	3.2–11.7	4.9–13.5		
Rel_CP-med, AP translation (%)	Mean (SD)	14.8 (5.0)	17.6 (4.6)	-0.1; 0.0	n.s.
	Min–Max	8.6–23.7	11.2–24.4		
Rel_CP-lat, AP translation (%)	Mean (SD)	13.1 (7.2)	15.7 (4.6)	-0.1; 0.0	n.s.
	Min–Max	2.8–27.7	10.0–25.9		
CP-med, AP translation (mm)	Mean (SD)	6.7 (2.2)	8.0 (2.0)	-2.8; 0.18	n.s.
	Min–Max	3.8–11.3	4.8–10.6		
CP-lat, AP translation (mm)	Mean (SD)	5.9 (3.2)	7.2 (2.1)	-3.2; 0.7	n.s.
	Min-Max	1.4–2.1	4.6–11.0		

Abbreviation: CI, confidence interval.



FIGURE 1 Projection of the mean relative contact point (CP) position onto the tibial insert during the step-up motion for the Persona (left) and NexGen (right) designs. Coloured lines indicate different knee flexion angles: light blue = 0° flexion angle; orange = 10° flexion angle; celeste = 20° flexion angle; purple = 30° flexion angle; green = 40° flexion angle; red = 50° flexion angle and blue = 60° flexion angle.

further posteriorly. The displacement of the lateral-CP was slightly larger than the medial-CP, resulting in a small femoral external rotation around a medial pivot point. From 20° to 90° flexion, both CPs moved anteriorly, with the medial-CP moving further anteriorly compared to the lateral-CP resulting in an external femoral rotation around a lateral pivot point. From 90° into deeper flexion, both CPs moved posteriorly again. Between approximately 60–95° flexion, the NexGen design rotated 2.5° more into external rotation compared to the Persona design (Figure 4, LMM p = 0.04).

For the lunge motion, there was no effect of the TKA design on FAR (n.s.).

The sensitivity analysis excluding all extreme flexion angles did not change the results of the analyses for either motion.

DISCUSSION

This fluoroscopy study showed that anteroposterior femoral-tibial CP displacements or FAR during step-up and lunge motions between cemented PS TKA designs with either an asymmetric or symmetric tibial component are not significantly different.

Regarding the secondary outcome parameters (ROM of flexion angles, ROM of FAR and ROM displacements of the CPs), only during lunge the FAR ROM of the NexGen was 2.3° larger (11.1° vs. 8.8°).

Implants are designed to mimic the kinematics of the native knee aiming for lateral femoral condyle rollback during initial flexion, femoral condylar rollback at larger knee flexion and internal rotation of the femoral component around a medial pivot point during the final 20° of extension, the screw-home mechanism [17]. This study showed that both TKA designs had similar femoral rollback (lunge) and femoral anterior displacement (roll forward, step-up) between full extension and 20° of flexion. This occurred simultaneously with a small external rotation (lunge) and small internal rotation (screw-home, step-up) of the femoral component: mimicking native knee kinematics in terms of directions, but not in magnitude. In native knees, the lateral-CP is reported to rollback during knee bending to around 20 mm and 16.5° FAR is reported [3, 24]. The FAR in this study occurred not only between extension and 20° flexion, but during full range of motion and mostly around a pivot point located in the lateral compartment of the knee. Although the location of the pivot point in the native and the TKA knee is frequently reported to be in the medial compartment [5, 16, 17, 24], there are also reports indicating a lateral pivot position in the native knee [20, 25].

The observed kinematics (femoral rollback/roll forward and FARs between extension and 20° flexion) in this study are comparable, although different in magnitude, to those reported by other studies assessing the kinematics of PS TKAs [10, 13, 40]. In this study, considerable paradoxical anterior and posterior medial-CP displacement were observed during lunge and step-up with knee flexion angles > 20°. In addition, the medial-CP ROM was larger than the lateral-CP ROM resulting in femoral rotations around a lateral pivot point. This is contrary to previous studies showing larger lateral-CP displacement compared to medial-CP displacement, resulting in FAR around a medial pivot point [6, 9, 40, 42]. Most studies, including this current study, showed comparable TKA kinematics between 0° and approximately 20-30° flexion. The kinematic differences appear to become more pronounced at

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FIGURE 2 Mean position of the relative medial-contact point (CP) position (top left), the relative lateral-CP position (top right) and the femoral axial rotation (bottom) at different flexion angles during the step-up motion (0% is the most anterior point, 100% is a most posterior point on the lateral tibial condyle). Patients move from large to small flexion angles. Error bars indicate 95% confidence interval. Coloured lines indicate different total knee arthroplasty (TKA) designs: blue = NexGen TKA and red is Persona TKA.

larger knee flexion, which could be due to the differences in motions studied, that is, sit to stand [42], the height of the riser platform [40] or the actual insert geometry varying not only between types [42] (medial-congruent, ultracongruent, PS etc.) but between manufacturers as well.

Several studies showed large variability of kinematic patterns between TKA designs, and if TKA kinematics were similar to those of the native knee, they were often smaller in magnitude [10, 14, 18]. Other studies showed variability in kinematics, including paradoxical femoral rollback and lateral pivot positions [4, 12, 14, 15]. PS TKA knees appear to have more medial-CP shift but less lateral-CP shift during deep knee bending compared to native knees. In this study, the anteroposterior ROM was around 8 mm for the medial-CP and around 6-7 mm for the lateral-CP. These values are in line with those reported for a cemented PS TKA design [10] but, as mentioned before, not of the same magnitude as that of the native knee [3]. As such, the TKA remains a compromise to nature.

Altered TKA kinematics may lead to a feeling of instability and may limit the mobility of patients [5]. Although not powered to detect differences in patientreported outcome measures (PROMs), 2-year TABLE 3 Range of motions for FA (flexion angle), FAR (femoral axial rotation), anteroposterior translation of relative medial contact point (rel CP-med, AP), anteroposterior translation of relative lateral contact point (rel CP-lat, AP), anteroposterior translation of medial contact point (CP-med, AP) and anteroposterior translation of lateral contact point (CP-lat, AP) during the lunge motion.

ROM		Persona	NexGen	95% CI difference	p Value
FA (°)	Mean (SD)	81.7 (18.2)	77.4 (17.8)	-8.7; 17.3	n.s.
	Min–Max	48.7–117.7	43.1–114.6		
FAR (°)	Mean (SD)	8.8 (2.9)	11.1 (2.4)	-4.3; -0.5	0.02*
	Min–Max	5.4–15.9	7.4–14.9		
Rel_CP-med, AP translation (%)	Mean (SD)	17.8 (5.6)	19.0 (3.5)	-0.05; -0.02	n.s.
	Min–Max	5.5–32.1	13.4–25.6		
Rel_CP-lat, AP translation (%)	Mean (SD)	12.8 (5.3)	12.0 (3.8)	-0.02; -0.04	n.s.
	Min–Max	4.0–20.7	6.2–20.3		
CP-med, AP translation (mm)	Mean (SD)	8.1 (2.3)	8.7 (1.8)	-2.1; 0.8	n.s.
	Min–Max	2.5–13.4	5.7–11.6		
CP-lat, AP translation (mm)	Mean (SD)	5.8 (2.5)	5.5 (1.8)	-1.2; 1.9	n.s.
	Min-Max	2.0–10.7	2.9–9.4		

Abbreviations: CI, confidence interval; SD, standard deviation.

*p < 0.05.



FIGURE 3 Projection of the mean relative contact point (CP) position onto the tibial insert during the lunge motion for the Persona (left) and NexGen (right) designs. Coloured lines indicate different knee flexion angels: light blue = 0° flexion angle; orange = 10° flexion angle; celeste = 20° flexion angle; purple = 30° flexion angle; green = 40° flexion angle; red = 50° flexion angle; blue = 60° flexion angle; pink = 70° flexion angle; light green = 80° flexion angle and lila = 90° flexion angle.

postoperative PROM scores and clinical performance of the patients in this study were good [26] without indication of increased instability. There is no consensus in the literature on whether nonnative TKA kinematics relate to poor PROM scores [10, 47]. Considering that most papers report good (long-term) clinical and PROM scores for TKA designs, variability in knee kinematics may not play a pivotal factor regarding patient satisfaction. Other factors such as preoperative

pain [27], unmet preoperative expectations [44] and the absence of severe radiological osteoarthritis [23] are likely to be stronger predictors of patient satisfaction.

Although studies showed that medial pivot designs do indeed result in medial pivot points during motion [40, 43], considerable variability was reported in lateral-CP displacement for medial pivot designs [43], and knee balancing was shown to be more important than insert geometry [45].

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FIGURE 4 Mean position of the relative medial-contact point (CP) position (top left), the relative lateral-CP position (top right) and the femoral axial rotation (bottom) at different flexion angles during the lunge motion (0% is the most anterior point, 100% is most posterior point on the lateral tibial condyle). Patients move from small to large flexion angles. Error bars indicate 95% confidence interval. Coloured lines indicate different total knee arthroplasty (TKA) designs: blue = NexGen TKA and red is Persona TKA.

A limitation was that intraoperative knee balancing related to insert thickness (possibility of 1 mm increments of the insert in asymmetric anatomical tibial plate design) was not recorded, although performed the same for both designs aiming for optimal balancing. Balancing of the knee is very important regarding function, as ligaments that are either too tight or too loose result in suboptimal stability and kinematics of the knee and hence function [41].

Another limitation was the performed motions. Although step-up and lunge motions are regularly used in fluoroscopic studies, they are not part of (complex) daily life motions. The platform height of 18 cm high was used in previous studies [22, 31]. This height, allowing 90° knee flexion in most patients, is sufficient to investigate differences in knee kinematics of TKA designs.

The included number of TKAs in this study was chosen based on previous fluoroscopic experience, but lacking a proper sample size calculation. Studies with a similar primary objective and with a sample size calculation, comparing the kinematics of two variations of the Persona TKA, included fewer TKAs per study group [1, 42]. Therefore, the results of this study are still of value.

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The observed smaller ROM in the FAR of the asymmetric design is not expected to be of clinical relevance. The difference between the two designs showed mostly at knee flexion over 60°, but at smaller knee flexion angles, kinematics were similar. In addition to the migration study showing no differences in component migration and PROMs [26], this study showed that regarding clinical functionality, the newer, asymmetric design generally performs similarly to its precursor symmetric design.

CONCLUSION

In conclusion, this study showed that TKA with the asymmetric tibial component with the asymmetric insert and the symmetric tibial component with the symmetric insert had comparable femoral-tibial kinematics during step-up and lunge motions. Both designs had a lateral pivot location during the majority of the step-up and lunge motions.

AUTHOR CONTRIBUTIONS

Lennard A. Koster: Wrote original draft; performed project administration; data curation; investigation; formal analysis; visualisation. Bart L. Kaptein: Reviewed and edited manuscript; performed conceptualisation; methodology funding acquisition; resources; formal analysis; software; validation. Enrike H. M. J. van der Linden-van der Zwaag: Reviewed and edited manuscript; performed surgery and clinical investigations. Rob G. H. H. Nelissen: Reviewed and edited manuscript; performed conceptualisation; methodology; funding acquisition.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

The trial was performed in compliance with the Declaration of Helsinki (2018) and Good Clinical

Practice guidelines. Institutional Medical Ethics Committee (MEC) approved the study (Protocol ID P13.277, ABR NL47243.058.13), and the study was registered in Clinical Trials (Clinical Trials.gov ID NCT02269254). All patients provided written informed consent.

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