# A randomized controlled trial comparing two-year postoperative femoral and tibial migration of a new and an established cementless rotating platform total knee arthroplasty

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## Aims

**The primary aim of this study was to compare the migration of the femoral and tibial components of the cementless rotating platform Attune and Low Contact Stress (LCS) total knee arthroplasty (TKA) designs, two years postoperatively, using radiostereometric analysis (RSA) in order to assess the risk of the development of aseptic loosening. A secondary aim was to compare clinical and patient-reported outcome measures (PROMs) between the designs.**

## Methods

**A total of 61 TKAs were analyzed in this randomized clinical RSA trial. RSA examinations were performed one day and three, six, 12, and 24 months postoperatively. The maximal total point motion (MPTM), translations, and rotations of the components were analyzed. PROMs and clinical data were collected preoperatively and at six weeks and three, six, 12, and 24 months postoperatively. Linear mixed effect modelling was used for statistical analyses.**

## Results

**The mean MTPM two years postoperatively (95% confidence interval (CI)) of the Attune femoral component (0.92 mm (0.75 to 1.11)) differed significantly from that of the LCS TKA (1.72 mm (1.47 to 2.00), $p < 0.001$). The Attune femoral component subsided, tilted (anteroposteriorly), and rotated (internal-external) significantly less. The mean tibial MTPM two years postoperatively did not differ significantly, being 1.11 mm (0.94 to 1.30) and 1.17 mm (0.99 to 1.36, $p = 0.447$) for the Attune and LCS components, respectively. The rate of migration in the second postoperative year was negligible for the femoral and tibial components of both designs. The mean pain-at-rest (numerical rating scale (NRS)-rest) in the Attune group was significantly less compared with that in the LCS group during the entire follow-up period. At three months postoperatively, the Knee injury and Osteoarthritis Outcome Physical Function Shortform score, the Oxford Knee Score, and the NRS-activity scores were significantly better in the Attune group.**

## Conclusion

**The mean MTPM of the femoral components of the cementless rotating platform Attune was significantly less compared with that of the LCS design. This was reflected mainly in significantly less subsidence, posterior tilting, and internal rotation. The mean tibial MTPMs were not significantly different. During the second postoperative year, the components of both designs stabilized and low risks for the development of aseptic loosening are expected.**



**Cite this article:** ***Bone Joint J*** **2023;105-B(2):148–157.**



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doi:10.1302/0301-620X.105B2.BJJ-2022-0414.R1 $2.00

*Bone Joint J*
2023;105-B(2):148–157.

a b

Fig. 1

a) The cementless cruciate-retaining rotating platform Attune total knee arthroplasty (TKA). b) The cementless cruciate-retaining rotating platform Low Contact Stress Complete TKA.

## Introduction

Approximately 20% of patients who undergo total knee arthroplasty (TKA) are dissatisfied after surgery,[1] and between 5% and 10% of patients have required revision surgery ten years postoperatively.[2,3] Instability, aseptic loosening, and pain are the most frequently cited indications for revision after primary TKA.[2,3]

Orthopaedic companies continue to adapt the designs of already successful prostheses with the aim of improving the long-term outcome. In order to investigate long-term survival of new designs in observational clinical studies, with revision as the endpoint, large numbers of patients and long follow-up are required.[4] The risk for aseptic loosening of an implant can be predicted by assessing its migration during the first two postoperative years using radiostereometric analysis (RSA), as shown for tibial components.[5-7] As RSA gives very accurate results, only small numbers of patients are needed to assess differences in migration between groups. However, knowledge about the relationship between the migration of the femoral component of uncemented TKAs and the incidence of long-term aseptic loosening is limited. One study reported that an annual change of 0.09 mm in maximal total point motion (MPTM) was associated with a good long-term clinical outcome.[8] One of the first RSA studies dealing with the femoral component of TKA, in 1995, showed comparable migration for cemented and cementless components.[9] Subsequently, few RSA studies involving the femoral component have been undertaken, mainly due to difficulties with the attachment of markers to the component and their appearance on RSA radiographs, and fewer problems with fixation of femoral compared with tibial components. Model-based RSA has overcome the difficulties with the attachment of markers to the component by using 3D surface models,[10] allowing analysis of the migration of the femoral component, resulting in several recent publications.[11-14]

The Attune cementless rotating platform TKA was introduced in 2016 and is the successor of the cementless Low Contact Stress (LCS) Complete rotating platform prosthesis (both DePuy Synthes, USA). The LCS TKA has a good clinical track record with rates of survival of > 95% five years postoperatively.[2,15] The Attune design aims to increase range of motion (ROM) and to improve mid-flexion stability of the TKA. The bone-implant interface of the Attune femoral component has fewer ridges, providing a larger contact area. The tibial baseplate has four radially positioned pegs next to the central peg, and reduced porous coating (Figure 1). The Attune TKA also has more and smaller sizing increments available.

To our knowledge, no clinical RSA or long-term survival data on the cementless Attune design are available. This RSA study was conducted as recommended for the stepwise introduction of new implants.[5,16] The primary aim was to compare the two-year postoperative migration of both the femoral and tibial components of the cementless Attune and LCS designs. A secondary aim was to compare clinical and patient-reported outcome measures (PROMs).

## Methods

A single-centre, single-blinded, noninferiority randomized controlled trial (RCT) was performed in a large general hospital. Between July 2017 and March 2019, consecutive patients aged between 21 and 90 years eligible for primary TKA for osteoarthritis (OA) were invited to participate in the study. Those in whom a posterior-stabilized TKA was contraindicated and those with insufficient understanding of the Dutch or English language were excluded. After providing written informed

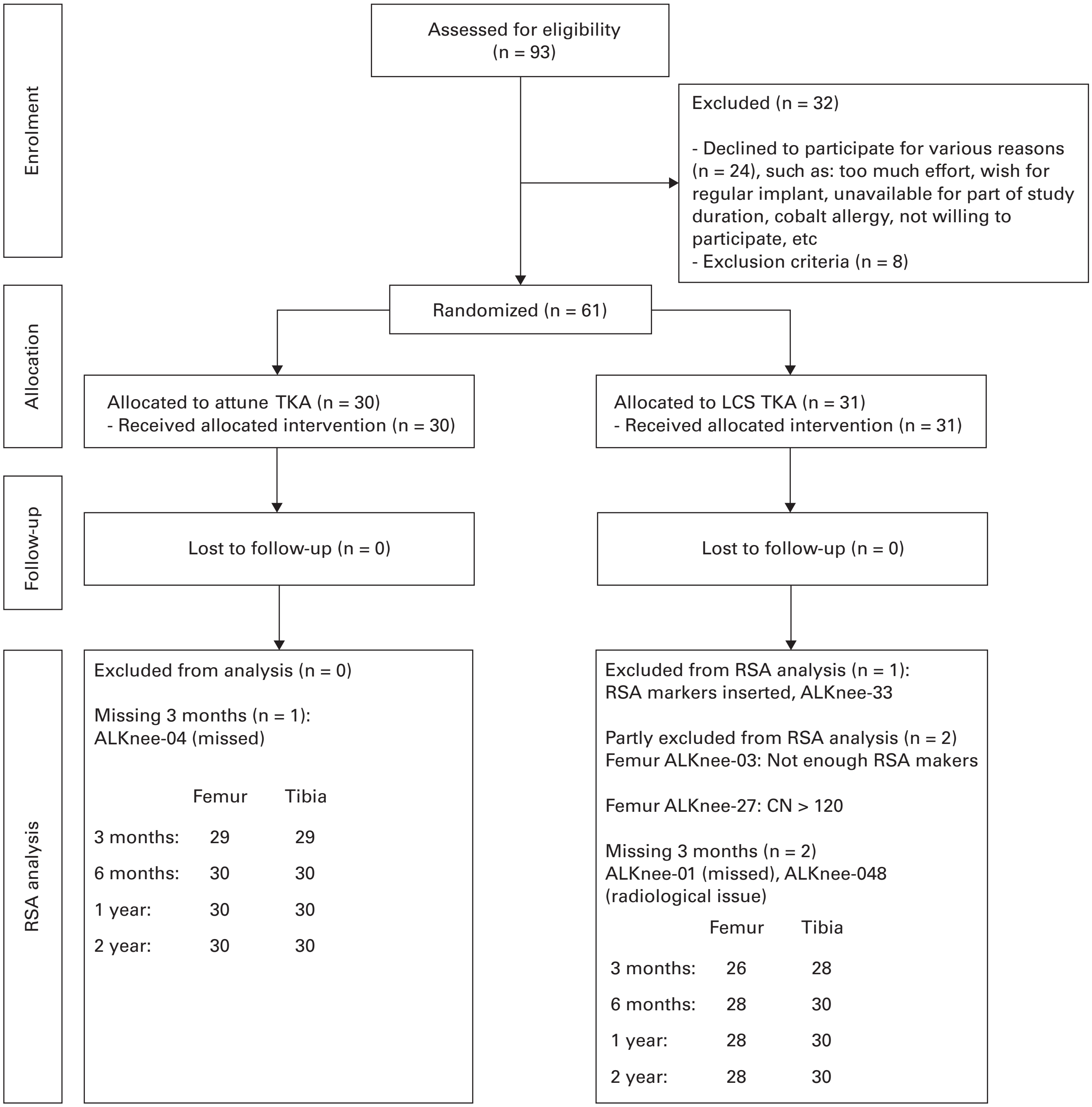


Fig. 2

Flow diagram of the patients through each stage. CN, condition number; LCS, Low Contact Stress; RSA, radiostereometric analysis; TKA, total knee arthroplasty.

consent, patients were enrolled and randomized to undergo surgery with either Attune or LCS components. Both are cementless rotating platform cruciate-sacrificing TKA systems (DePuy Synthes).

Randomization with variable block size was performed one week before surgery using a random number generator program (Research Manager, Netherlands). All three participating surgeons (PAN; see Acknowledgements for others), who were blinded for randomization until day of surgery, had extensive experience with the cementless LCS TKA, and were specifically trained to use the Attune system prior to the study. A medial parapatellar approach was used. Gap balancing (femoral sizing technique) was used, aiming for mechanical alignment. No patellar resurfacing was performed. In order to enable RSA analysis, at least five tantalum markers with a diameter of 1 mm were implanted into the bone around each component. Routine fast-track mobilization started between four and six hours postoperatively.

During enrolment, 84 patients (93 knees) were assessed for eligibility; 52 patients (61 knees) were included in the study and

**Table I.** Baseline demographic data of patients, based on individual total knee arthroplasty procedures.

| Variable | Attune (n = 30) | LCS (n = 31) |
|---|---|---|
| Mean age, yrs (SD) | 68.9 (7.7) | 68.4 (6.9) |
| Sex, female, n (%) | 16 (53.3) | 19 (61.3) |
| Operated side, left, n (%) | 16 (53) | 15 (48) |
| Mean BMI, kg/m$^2$ (SD) | 29.8 (5.0) | 28.6 (4.2) |
| Median duration of symptoms, mths (IQR) | 59 (11 to 96) | 52 (24 to 64) |
| **ASA grade at the time of surgery, n (%)** | | |
| I | 5 (16.7) | 6 (19.4) |
| II | 20 (66.7) | 20 (64.5) |
| III | 5 (16.7) | 5 (16.1) |
| **Kellgren-Lawrence grade, n (%)** | | |
| 2 | 4 (13.3) | 4 (12.9) |
| 3 | 18 (60.0) | 18 (58.1) |
| 4 | 8 (26.7) | 9 (29.0) |
| Mean operating time, mins (SD) | 57 (9.7) | 43 (13.2) |

ASA, American Society of Anesthesiologists; IQR, interquartile range; LCS, Low Contact Stress; N/A, not applicable; SD, standard deviation.

underwent surgery. Two patients underwent bilateral Attune TKA, one underwent bilateral LCS TKA, and six patients underwent bilateral TKA with one Attune and one LCS TKA. All patients were available for review two years postoperatively (Figure 2). One patient in the LCS group was excluded from the RSA follow-up due to there being fewer than five visible RSA markers in the postoperative radiographs, which was a secondary exclusion criterion.

The demographic data of the patients at baseline are shown in Table I. The mean operating time was significantly longer in the Attune group compared with the LCS group: 57 minutes (95% confidence interval (CI) 53.6 to 60.4) versus 43 (95% CI 38.2 to 47.8) ($p < 0.001$, independent-samples *t*-test).

Supine RSA radiographs were undertaken after weight-bearing on the first postoperative day (reference examination) and at three, six, 12 (twice to determine the precision of the measurements), and 24 months postoperatively using an acrylic biplanar cage (Baat Medical, Netherlands) to calibrate the radiographs.[17] DX radiology detectors (35 × 43 cm, Siemens Healthcare, Germany, and Carestream Health, USA) recorded the radiographs. Model-based RSA software (v. 4.2, RSAcore, Netherlands) was used to calculate the migration of the components, using computer-aided design models[18] according to the guidelines on RSA.[19,20]

The primary parameter of migration was the MTPM: the length (mm) of the translation vector of the point on the model of the component that moved the most. Secondary parameters were the translations (mm) and rotations (°) of the components. Positive translations along transverse (Tx), longitudinal Ty), and sagittal axes (Tz) represent the medial, proximal, and anterior translation. Rotations about these axes (Rx, Ry, Rz) are defined following the right-hand screw rule.[20]

The clinical precision of the RSA of the components is shown in Table II. Bone markers used for the analysis were well distributed: median condition numbers were 41.44 m$^{-1}$ (interquartile range (IQR) 35.21 to 54.32) and 45.58 m$^{-1}$ (IQR 37.34 to 55.49) for femoral and tibial markers. Median mean errors of rigid body fitting two years postoperatively were 0.25 mm (IQR 0.1679 to 0.2893) and 0.20 mm (IQR 0.1392 to 0.2714) for femoral and tibial markers.

PROM questionnaires (in print) were collected preoperatively and at three, six, 12, and 24 months postoperatively and included the Oxford Knee Score (OKS; 0 = worst; 48 = best),[21–24] Knee injury and Osteoarthritis Outcome Score Physical Function shortform (KOOS-PS; 0 = no problems; 100 = extreme problems),[25,26] EuroQol five-dimension three-level questionnaire (EQ-5D-3L; 0 = worst; 1 = best),[27] numerical rating scale for pain at rest (NRS-rest) and during activity (NRS-activity; 0 = no pain; 10 = worst pain imaginable), and two questions regarding change in knee function and pain since surgery (Likert scale 1 to 7). The Kellgren-Lawrence grade was assessed preoperatively to record the severity of OA.[28] ROM, stability and laxity of the knee, and the general presentation of the knee were evaluated by the treating physician during outpatient visits at six weeks, three, six, 12, and 24 months postoperatively. Serious adverse events were recorded.

**Statistical analysis.** Continuous baseline data are reported as means with standard deviations (SDs). Categorical baseline data are presented as numbers with proportions (%). A minimal clinically important difference (MCID) of 0.55 mm for the MTPM two years postoperatively between the Attune and LCS tibia components (primary objective) was considered important,[7] and set as the noninferiority margin. With a power of 80% (α 0.01, a SD of 0.6 mm), 26 TKAs per group were needed to confirm noninferiority with a one-sided independent-samples *t*-test. In order to accommodate for loss to follow-up, a minimum of 30 TKAs suitable for RSA analysis were included in each group.

A linear mixed-effects model (LMM)[29] was used to analyze repeated measurements. Figures and tables showing repeated measures of migration parameters are based on LMM. For all the parameters of migration and PROMs, the type of TKA, postoperative time, and their interaction were set as fixed effects. Each TKA was included as a random effect and (continuous) autoregression-1 (CorCAR[1]) was selected as the correlation structure. The LMM residuals were visually inspected to check the fit of the model using parametric modelling. MTPM was log-transformed during statistical modelling to obtain normal distribution, calculated as log(MTPM + 1). A sensitivity analysis was performed excluding the second TKA of patients who underwent bilateral surgery.

Statistical results are given as means with 95% CIs. Significance was set at the 5% level. The analysis was performed using R v. 1.4.1717 (R Foundation for Statistical Computing, Austria).

## Results

The MTPMs of the femoral components was significantly different ($p < 0.001$, LMM) between the groups from three months postoperatively (Figure 3a, Table III). At two years postoperatively, the mean Attune MTPM was 0.92 mm (95% CI 0.75 to 1.11) compared with 1.72 mm (95% CI 1.47 to 2.00) for LCS. The mean rates of migration in the second postoperative year were comparable ($p = 0.757$, LMM): 0.09 mm/yr (95%

**Table II.** The values for the precision of the radiostereometric analysis of the femoral and tibial components according to the design of the total knee arthroplasty based on double radiostereometric analysis examinations, which were undertaken 12 months postoperatively.

| Component | Mean Tx, mm (SD) | Mean Ty, mm (SD) | Mean Tz, mm (SD) | Mean Rx, ° (SD) | Mean Ry, ° (SD) | Mean Rz, ° (SD) | Mean MTPM, mm (SD) |
|---|---|---|---|---|---|---|---|
| **Femur** | | | | | | | |
| Attune (30 doubles) | 0.03 (0.15) | 0.00 (0.05) | -0.01 (0.09) | 0.08 (0.20) | -0.02 (0.15) | -0.02 (0.13) | 0.24 (0.20) |
| LCS (28 doubles) | 0.00 (0.08) | -0.01 (0.07) | 0.02 (0.11) | -0.03 (0.13) | 0.10 (0.27) | 0.02 (0.19) | 0.29 (0.29) |
| **Tibia** | | | | | | | |
| Attune (29 doubles) | -0.05 (0.17) | -0.02 (0.05) | 0.01 (0.07) | -0.02 (0.11) | 0.02 (0.23) | 0.07 (0.23) | 0.26 (0.26) |
| LCS (30 doubles) | -0.01 (0.05) | -0.01 (0.04) | 0.01 (0.06) | -0.05 (0.20) | -0.08 (0.37) | 0.01 (0.08) | 0.30 (0.14) |

Tx, Ty, Tz, translations along the orthogonal x-, y-, and z-axis; Rx, Ry, Rz, rotations about the orthogonal x-, y-, and z-axis.
LCS, Low Contact Stress; MPTM, maximal total point motion; SD, standard deviation.

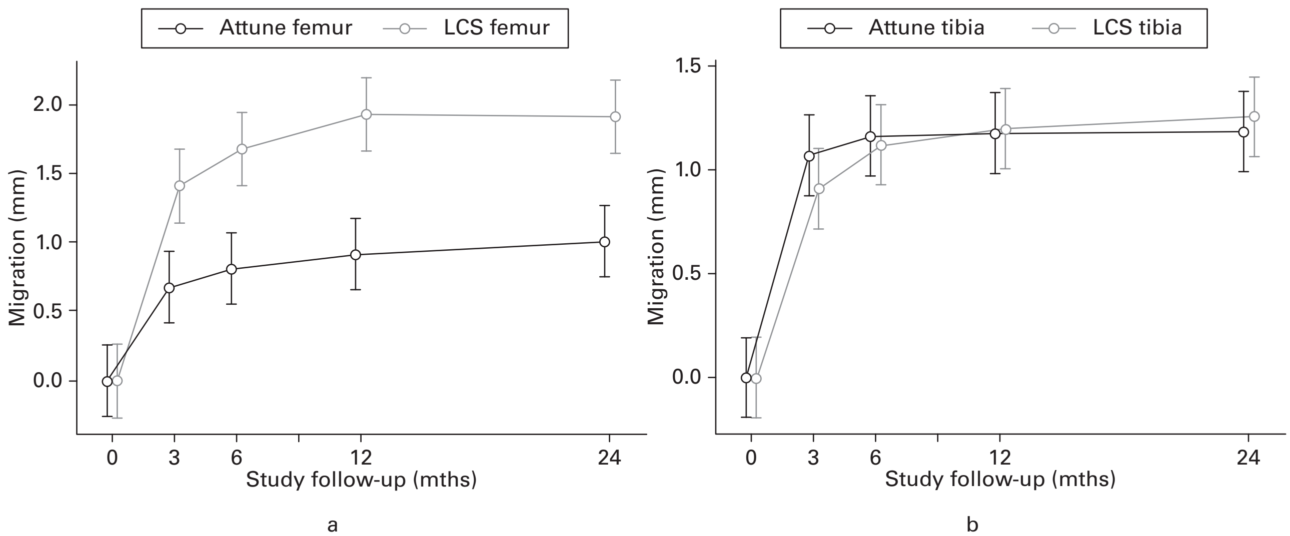


Fig. 3

The mean migration (maximal total point motion (MTPM)) during the first two postoperative years of a) the femoral components and b) the tibial components of the Attune and Low Contact Stress (LCS) total knee arthroplasties (TKAs). Error bars indicate 95% confidence intervals.

CI -0.01 to 0.19) for Attune and -0.02 mm/yr (95% CI -0.12 to 0.09) for LCS.

The MTPM of the tibial components were comparable (p = 0.447, LMM) (Figure 3b; Table IV). The mean MTPM in the Attune group two years postoperatively was 1.11 mm (95% CI 0.94 to 1.30) compared with 1.17 mm (95% CI 0.99 to 1.36) for the LCS group. The mean rates of migration in the second year were comparable (p = 0.257, LMM) between the groups: 0.01 mm/yr (95% CI -0.09 to 0.11) for Attune and 0.06 mm/yr (95% CI -0.04 to 0.15) for LCS.

The mean translations and rotations of the components during the two-year follow-up are shown in Table III and Table IV, and in Supplementary Figures a and b.

The femoral components of both designs moved into subsidence (positive Ty) and external rotation (negative Ry), with statistically less migration (Ty p < 0.001, LMM; Ry p = 0.010, LMM) for the Attune. The rates of migration of the femoral component (all migration parameters) in the second postoperative year were comparable between the Attune and LCS groups.

The subsidence of the tibial components (negative Ty) of both designs was comparable (Table IV). There was a significant group effect (p = 0.007, LMM) only with regard to anteroposterior translation (Tz). During the first six months postoperatively, the components of both designs tilted posteriorly (negative Rx) after which they tilted anteriorly again (Supplementary Figure b). The pattern of tilting during the entire follow-up period was comparable between the groups (p = 0.923, LMM). The rates of all parameters of migration in the second postoperative year were comparable for both designs.

**Clinical outcomes.** There were five serious adverse events (SAEs). One liner was replaced (Attune) due to spin-out in a patient with a slight preoperative valgus deformity. The other SAEs were not related to the study: cerebrovascular accident, electrical cardioversion for atrial fibrillation, admission for liver metastasis, and the removal of a Gamma nail from the contralateral hip.

There were no significant differences between the groups regarding ROM (Supplementary Figure c and Supplementary Table i), anteroposterior (AP) stability, and mediolateral (ML) stability (Supplementary Tables ii and iii).

All PROMs improved significantly in both groups (Supplementary Figures d to g and Tables iv to x). The largest improvement occurred in the first three months postoperatively at which

**Table III.** The mean migration of the femoral component at two years postoperatively and the rate of migration in the second postoperative year of the Attune (n = 30) and Low Contact Stress (n = 28) total knee arthroplasties.

| Femoral component | Attune | LCS |
|---|---|---|
| **Mean migration two yrs postoperatively (95% CI)** | | |
| Tx, mm | 0.05 (-0.04 to 0.14) | 0.03 (-0.07 to 0.12) |
| Ty, mm | 0.25 (0.15 to 0.34) | 0.72 (0.63 to 0.82)* |
| Tz, mm | 0.07 (-0.10 to 0.23) | 0.17 (0.00 to 0.34) |
| Rx, ° | 0.03 (-0.19 to 0.25) | -0.50 (-0.73 to -0.27)* |
| Ry, ° | -0.17 (-0.35 to 0.00) | -0.59 (-0.77 to -0.40)* |
| Rz, ° | 0.00 (-0.22 to 0.22) | 0.18 (-0.04 to 0.41) |
| MTPM, mm | 0.92 (0.75 to 1.11) | 1.72 (1.47 to 2.00)* |
| **Mean rate of migration in the second year (95% CI)** | | |
| Tx, mm/yr | -0.02 (-0.06 to 0.03) | 0.02 (-0.03 to 0.07) |
| Ty, mm/yr | 0.02 (-0.01 to 0.06) | 0.05 (0.01 to 0.08) |
| Tz, mm/yr | 0.00 (-0.05 to 0.06) | -0.02 (-0.07 to 0.04) |
| Rx, °/yr | 0.04 (-0.06 to 0.14) | -0.03 (-0.13 to 0.07) |
| Ry, °/yr | 0.03 (-0.07 to 0.12) | 0.03 (-0.07 to 0.13) |
| Rz, °/yr | -0.02 (-0.11 to 0.08) | 0.00 (-0.10 to 0.01) |
| MTPM, mm/yr | 0.09 (-0.01 to 0.19) | -0.02 (-0.12 to 0.09) |

Rx, Ry, Rz, rotations about the orthogonal x-, y-, and z-axis; Tx, T, Tz translations along the orthogonal x-, y-, and z-axis.
*Parameters that are different between the two designs ($p < 0.05$).
CI, confidence interval; LCS, Low Contact Stress; MTPM, maximal total point motion.

**Table IV.** The mean migration of the tibial component at two years postoperatively and the mean rate of migration in the second year of the Attune (n = 30) and Low Contact Stress (n = 30) total knee arthroplasties.

| Tibial component | Attune | LCS |
|---|---|---|
| **Mean migration two yrs postoperatively (95% CI)** | | |
| Tx, mm | -0.07 (-0.15 to 0.02) | -0.13 (-0.21 to -0.04) |
| Ty, mm | -0.30 (-0.43 to -0.18) | -0.25 (-0.38 to -0.13) |
| Tz, mm | 0.09 (-0.03 to 0.21) | -0.14 (-0.26 to -0.02)* |
| Rx, ° | -0.23 (-0.49 to 0.03) | -0.31 (-0.57 to -0.05) |
| Ry, ° | -0.03 (-0.20 to 0.13) | -0.17 (-0.34 to -0.01) |
| Rz, ° | -0.02 (-0.18 to 0.13) | -0.13 (-0.29 to 0.02) |
| MTPM, mm | 1.11 (0.94 to 1.30) | 1.17 (0.99 to 1.34) |
| **Mean rate of migration in the second year (95% CI)** | | |
| Tx, mm/yr | -0.02 (-0.06 to 0.01) | -0.01 (-0.05 to 0.02) |
| Ty, mm/yr | 0.02 (-0.02 to 0.05) | 0.00 (-0.04 to 0.03) |
| Tz, mm/yr | 0.00 (-0.03 to 0.05) | 0.00 (-0.04 to 0.05) |
| Rx, °/yr | 0.11 (-0.01 to 0.24) | 0.15 (0.03 to 0.28) |
| Ry, °/yr | -0.01 (-0.18 to 0.16) | -0.09 (-0.26 to 0.08) |
| Rz, °/yr | 0.01 (-0.09 to 0.1) | -0.08 (-0.17 to 0.01) |
| MTPM, mm/yr | 0.01 (-0.09 to 0.11) | 0.06 (-0.04 to 0.15) |

Rx, Ry, Rz, rotations about the orthogonal x-, y-, and z-axis; Tx, Ty, Tz, translations along the orthogonal x-, y-, and z-axis.
*Parameters that are different between the two designs ($p < 0.05$).
CI, confidence interval; LCS, Low Contact Stress; MTPM, maximal total point motion.

time the mean KOOS-PS, OKS, and NRS-activity scores for Attune were significantly better compared with LCS (Figures 4 to 6). This difference was not present at later follow-up.

The sensitivity analysis using 24 Attune and 28 LCS TKAs did not show an effect of bilaterality on any of the parameters.

## Discussion

This was the first clinical RSA study of the cementless Attune TKA, and we found that the overall migration (MTPM) of the femoral component of the Attune rotating platform TKA was significantly less than that of the LCS TKA. This difference was due to less subsidence, posterior tilting, and external rotation of the Attune component.

The tibial components of both designs had comparable migration throughout follow-up of two years. The mean rates of migration in the second year after surgery were comparable for the femoral and tibial components of both designs.

In 2017, Berahmani et al[30] performed a preclinical cadaveric study assessing the migration of the femoral component of cementless Attune and LCS TKAs using digital image correlation. They reported that the micromotions under different loading trials were significantly less for the Attune TKA, indicating better initial fixation. Although the femoral components in our study continued to migrate up to one year postoperatively, the Attune components migrated less. This could be due to better initial resistance to micromotion, as shown by Berahmani et al.[30]

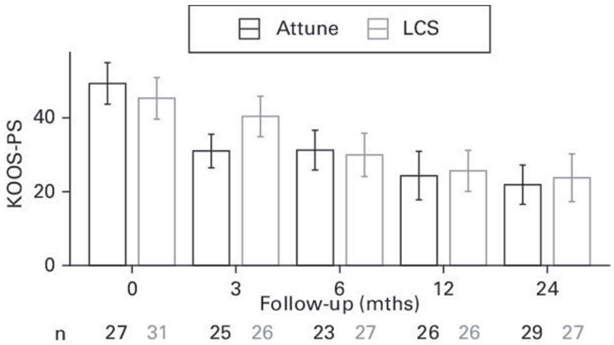


Fig. 4

Mean Knee injury and Osteoarthritis Outcome Physical Function Short form score (KOOS-PS) during the two-year follow-up of the Attune and Low Contact Stress (LCS). Error bars indicate 95% confidence intervals and n is the number of available patient-reported outcome measures for each period of follow-up.

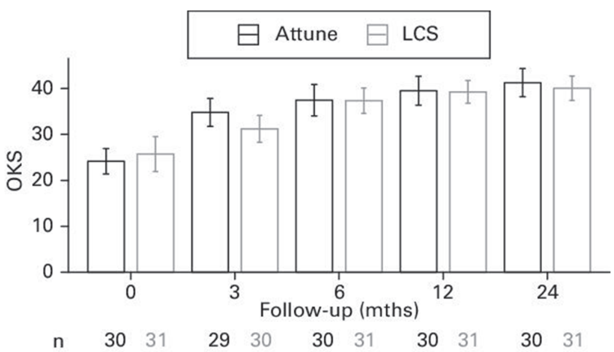


Fig. 5

The mean Oxford Knee Score (OKS) during the two-year follow-up of the Attune and Low Contact Stress (LCS). Error bars indicate 95% confidence intervals and n is the number of available patient-reported outcome measures for each period of follow-up.

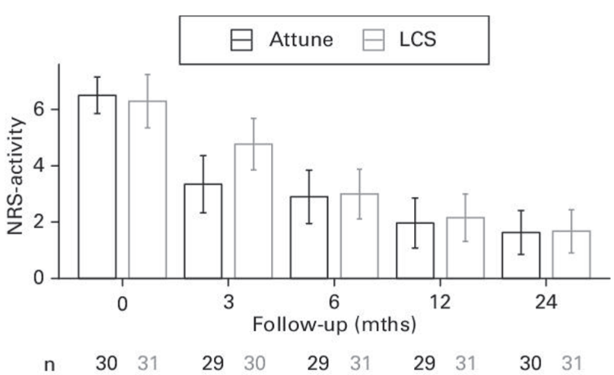


Fig. 6

The mean numerical rating scale (NRS)-activity scores during the two-year follow-up of the Attune and Low Contact Stress (LCS). Error bars indicate 95% confidence intervals and n is the number of available patient-reported outcome measures for each period of follow-up.

The mean MTPM of the Attune components was comparable in our study to those previously described in the few studies which have reported the migration of cementless femoral components using RSA. The mean MTPM of the LCS component was, however, larger.[9,31,32] The earlier studies showed that cementless femoral components had migration patterns which were similar to those of cemented components, with a median two-year postoperative MTPM of 0.87 mm for the cementless NexGen CR (Zimmer Biomet, USA)[31] and a mean of 0.89 mm for the cementless Miller-Galante I (Zimmer Biomet)[9] components. The rates of migration during the second postoperative year in these two studies were approximately 0.15 mm/year (based on medians) and 0.2 mm/year (based on means), deduced from figures in the original papers as the numbers were not provided. Recently Van Ooij et al,[33] Williams et al,[11] and Yilmaz et al[14] reported RSA measurements for cementless femoral components. Van Ooij et al[33] reported mean migrations of the femoral component of 1.16 mm and 1.30 mm two years postoperatively for cementless and hybrid fixation, respectively. Williams et al[11] investigated migration when using gap-balanced and measured resection techniques, and reported mean migrations of the femoral components of 0.62 mm and 0.89 mm, respectively, one year postoperatively. This difference was not statistically significant, and there was no significant change between six months and one year postoperatively. In the study by Yilmaz et al,[14] the mean femoral MTPM two years postoperatively was 0.96 mm. The rate of migration in the second year in the studies by Van Ooij et al[33] and Yilmaz et al[14] was 0.05 mm/year using both cementless and hybrid fixation, and 0.02 mm/year using cementless fixation, respectively. The rate of migration in our study was comparable to those in these studies. The rates of migration reported by Nilsson et al[9] and Gao et al[31] were larger, which may be due to a different surface-finish at the bone-implant interface. Henricson et al[8] assessed the ten-year postoperative migration of the patients in the study by Gao et al[31] and reported no significant difference in migration between cemented and cementless components at this time. They also reported that the annual changes in migration between two and ten years postoperatively for the approximately 50% of femoral components that did not stabilize were 0.10 mm and 0.09 mm for cemented and cementless components, respectively. They did not, however, describe how stabilization was defined. There were no revisions or clinical signs for loosening in either group, and the authors concluded that this annual change seemed to represent a good long-term performance.[8]

Based on our findings, it was not possible to identify whether the reduced migration of the Attune component was due to its design, the surgical technique, or other factors. We found that the initial migration of its femoral component was more in line with other designs of TKA, and that the LCS femoral components had more initial migration.

Recently, several authors have concluded that coated or highly porous tibial components have similar or even less migration after initial settling compared with cemented tibial components.[6,34–36] These authors also concluded that there was no increased risk of the development of aseptic loosening or an increased rate of revision for coated cementless TKA designs.

Based on a meta-analysis, Pijls et al[7] provided mean MTPM thresholds related to the long-term risk of aseptic loosening of tibial components. They also concluded that secondary stabilization seems to have occurred for components with a mean rate of migration between one and two years postoperatively of < 0.04 mm/year (0.02 to 0.06) (pooled mean and 95% CI). Based on these thresholds, the Attune and LCS tibial components in this study would be at risk. However, the rate of migration during the second year postoperatively of both components in this study was < 0.06 mm. This is within the 95% CI of the reported pooled rate of migration[7] and is similar to the rate reported for other cementless tibial components,[6,34–36] despite the differences in their design, such as pegs, coatings, and material. This, therefore, indicates that the tibial components become stable with a low risk of the development of aseptic loosening.

According to the Dutch Arthroplasty Register (LROI), the cementless LCS TKA has a ten-year rate of revision for any reason of 5.1%, and 2.8% for major revision of both femoral and tibial components, respectively, which is lower than the 5.8% and 3.3% for all cementless TKAs in the LROI.[2] The National Joint Registry in the UK reported a revision rate of 3.4% ten years postoperatively for the cementless LCS TKA.[3]

Despite the fact that the tibial component falls within the 'at-risk for long term aseptic loosening' category based on the mean migration in this study, a low long-term rate of revision may be expected. We have similar expectations for the cementless tibial component of the Attune TKA as the RSA results were comparable.

The clinical outcomes were similar for the two designs and are within the expected range. The improvements in PROMs were similar to those reported in the Dutch registry for all patients undergoing TKA.[2] Although this study was underpowered to detect differences in PROMs, an interesting finding was the better three-month postoperative scores for the Attune TKA in KOOS-PS, OKS, and NRS-activity. Though the differences were not present at later follow-up, the significant differences three months postoperatively were larger or equal to the MCID.[25,37,38] These findings may indicate a quicker improvement in knee function and pain for the Attune TKA. Perhaps the different design of the Attune femoral component causes less initial patellofemoral pain, as suggested by recent studies.[21,39] A large prospective study, The ATtune Knee Outcome Study (ATKOS; ClinicalTrials.gov identifier: NCT04247672), which evaluates the PROMs and functional and clinical outcomes, is ongoing.

This study has limitations, one of which is that it is underpowered to detect differences in PROMS. The clinical outcome as reflected by the PROMs therefore cannot be generalized and studies which are designed to detect differences in PROMs are required, such as the ongoing ATKOS-study (NCT04247672). Another limitation is the inclusion of patients who underwent bilateral TKA. However, a sensitivity analysis showed no difference in the results when those who underwent bilateral TKA were removed.

Another limitation is that three surgeons participated in the study, and that they assessed the clinical outcomes during follow-up themselves, being unblinded for the design. However, due to the randomized design of the study, each surgeon performed a similar number of Attune and LCS TKAs. A limitation in relation to the balancing of the knee was that intraoperative balancing was not recorded. Therefore, it was not possible to assess the effect of the balancing technique using Attune or LCS instrumentation on the outcomes. However, Williams et al[11] recently reported that the migration of components after TKA was not affected by the balancing techniques.

A final limitation was that pre- or postoperative long-leg radiographs were not available to allow measurement of the hip-knee-angle (HKA), making it impossible to relate migration to the HKA. However, Hasan et al[35] reported, in a meta-analysis involving ten RCTs that there was no significant relationship between the HKA and migration of the tibial component, two years postoperatively.

Our hospital is one of the few in the Netherlands in which cementless TKA is the default procedure. Thus, the surgeons in this study have extensive experience in this technique. The mean operating time for the Attune was 14 minutes longer compared with the LCS, due to many years of experience of both surgeon and team in using the LCS TKA system. The Attune balancing instrumentation in particular requires more time to prepare and use compared with the LCS instrumentation. This difference in operating time remained throughout the study and thus suggests that there was no learning curve for its use.

In conclusion, this model-based RSA study with two-year postoperative data showed that the migration of the tibial component was comparable between the two designs of TKA, and migration of the femoral component was less for the cementless cruciate-sacrificing rotating platform Attune than for the LCS TKA. The long-term risk for aseptic loosening of the Attune is thus expected to be similar to that of the well-functioning LCS, though longer-term evaluation is required as the migration of the Attune tibial component fell within the 'at-risk' range.

A TKA involves a femoral component and a tibial component with a liner, as one functional entity. Therefore, we believe that when assessing new designs of TKA it is not appropriate to only assess tibial migration. Femoral migration may affect pain and function shortly after surgery. Larger and long-term studies are required to investigate whether the reduced migration of the femoral component observed in this study leads to higher patient satisfaction and better clinical performance of the Attune TKA in the future.

## Take home message

- Apart from less migration of the Attune femoral component in the first postoperative year, resulting in lower migration values during entire follow-up, migration (patterns) of the Attune and Low Contact Stress (LCS) components are comparable and risk for aseptic loosening is expected to be equal for Attune and LCS components.
- Two years postoperatively, pain perception is similar, however patients with Attune components seem to experience a faster pain perception initially.

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## Supplementary material

ë Figures of femoral and tibial translations and rotations during two-year follow-up; mean patient-reported outcome measure values as measured during follow-up; and clinical scores (knee stability, range of motion) for all clinical follow-up moments.

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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 study was an investigator-initiated study for which DePuy Synthes provided funds in support of the costs associated with this radiostereometric analysis study. DePuy Synthes did not take part in the design, analysis, interpretation or writing of the manuscript.

**ICMJE COI statement:**
All authors' institutions have received funding from DePuy Synthes, during the study period. None of the authors, nor any member of their immediate families, have received funding or have commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript. DePuy Synthes also provided financial support to R. Rassir outside of the scope of this study (ATKOS; Clinicaltrial.gov identifier NCT04247672).

**Acknowledgements:**
Authors would like to thank MVR and DAV for performing surgery and clinical assessements.

**Ethical review statement:**
The trial was performed in compliance with the Declaration of Helsinki (2018) and Good Clinical Practice guidelines. The Committee for Medical Ethics (CME) of Leiden University Medical Center (LUMC) approved the study (Protocol ID P16.233, ABR NL58911.058.16) and the study was registered in Clinical Trials (ClinicalTrials.gov ID NCT03101007). Reporting of the trial is in accordance with the CONSORT statement. All patients provided Informed Consent.

This article was primary edited by J. Scott.