# Safety of orthopedic implants: implant migration analysis a must

Hasan, S.

# Chapter VI

## Late stabilization after initial migration of patients undergoing cemented total knee arthroplasty

### A five-year follow-up paper of two randomized controlled trials using radiostereometric analysis

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# Abstract

## Background and purpose

In total knee arthroplasty (TKA), metal-backed (MBT) and all-polyethylene (APT) designs have shown comparable implant migration up to 2 years using radiostereometric analysis (RSA). However, studies comparing mid-term migration of both designs are lacking. Furthermore, continuously migrating TKAs up to 2 years may continue to migrate or stabilize hereafter. Therefore, we compared 5-year migration of MBT and APT using either cruciate-stabilizing (CS) or posterior-stabilizing (PS) designs and specifically assessed migration profiles of continuously migrating TKAs beyond 2 years.

## Patients and methods

The present study includes results from 2 randomized trials comparing migration of cemented MBT with APT of either CS (CS-study, n=59) or PS (PS-study, n=56) design. 2 surgeons performed all surgeries. We used a linear mixed model for the analyses.

## Results

The overall migration between MBT and APT TKAs was similar for either the CS- or PS-design over a 5-year period. In both studies combined, 9 implants showed continuous migration in the second postoperative year, of which 1 (APT-CS) was revised for instability, 4 (2 MBT-CS, MBT-PS, APT-PS) stabilized and 4 (2 MBT-CS, APT-CS, MBT-PS) missed 5-year data.

## Interpretation

Overall migration was similar between MBT and APT TKAs up to 5 years, for both the CS- and PS-design. 4 initially migrating TKAs stabilized between 2- and 5-year follow-up, stressing the need for longer-term follow-up to determine whether second-year continuous migration correctly predicts loosening.

## Introduction

Several total knee arthroplasty (TKA) design characteristics could influence migration. TKA designs include either metal-backed tibial (MBT) or all-polyethylene tibial (APT) components. MBT designs are currently the gold standard because of intra-operative flexibility and the possibility of applying a coating to increase bone ingrowth, but APT TKAs are gaining interest as these designs could reduce costs with approximately 40%.[1, 2]

Despite disappointing revision rates of APT designs in the early 1970s, contemporary studies showed comparable revision rates and clinical outcomes for MBT and APT TKAs.[3, 4] Also, studies comparing migration using radiostereometric analysis (RSA) between MBT and APT designs found comparable 2-year results for both designs.[5-10] However, mid-term results are needed to confirm whether migration is still comparable and, particularly for implants showing continuous migration in the first 2 years, to assess whether migration is progressive over time or stabilizes. These mid-term results are needed for both unconstrained TKA designs (e.g., cruciate-stabilizing (CS)) and posterior stabilizing (PS) designs as migration could differ between these designs due to the post-cam design of PS implants which could induce greater stress to the tibial component compared with unconstrained designs.[11]

Therefore, we (1) compared overall 5-year migration between MBT and APT using TKAs with either CS or PS design, and (2) evaluated continuously migrating TKAs in the second postoperative year in their migration profiles up to mid-term follow-up.

## Patients and methods

We describe 5-year results of 2 randomized controlled trials (RCTs) using RSA. The 2-year results as well as the patient selection and surgical procedures for these RCTs have been described in detail previously.[9, 10] Both RCTs were conducted in Hässleholm, Sweden and all patients in both studies were operated by 2 surgeons. study compared the MBT-cruciate stabilizing (CS) Triathlon Total Knee System with the APT-CS Triathlon, while the other study compared the MBT-posterior stabilizing (PS) Triathlon with the APT-PS (Stryker, Warsaw, NJ, USA). For the CS-study, 60 consecutive patients were included between June 2014 and November 2014. Another 60 patients were included between November 2014 and June 2015 in the PS-study. 1 patient in the CS-study and 4 patients in the PS-study were excluded before the first postoperative assessment [Fig. VI.I]. Thus, 115 patients were available for follow-up.

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### Outcome measures

The primary outcome measure was migration as measured with RSA over a 5-year period. RSA radiographs were taken 1-2 days postoperatively, and at 3 months, 1 year, 2 years and 5 years. Migration was expressed as transverse, longitudinal, and sagittal translation, and rotation as well as maximum total point motion (MTPM) which is the length of the translational vector of the marker with the greatest migration. TKAs migrating >0.2-millimeter (mm) MTPM between 1 year and 2 years were classified as continuously migrating.[12] Analyses and reporting were performed in concordance with the ISO 16087 Standard and the RSA guidelines.[13, 14] Precision of RSA measurements were assessed through double measurements and expressed as 2*SD of these measurements. The precision of the translation and rotation in the APT-CS study was ≤0.13 mm and ≤0.15°, respectively, and was ≤0.15 mm and ≤0.23° in the APT-PS study.[9, 10] A mean error of rigid body fitting <0.35 mm and a condition number <120 were set as cut-off points.[13] Marker-based migration was calculated using MB-RSA version 4.2014 (RSAcore, Leiden, the Netherlands). If <3 markers were visible on specific RSA radiographs (occurred in 13 patients), a marker-configuration model was used to migration and prevent loss of data.[15]

## Statistics

First, we assessed possible attrition bias by comparing baseline characteristics of patients with missing and available data at 5 years within each study group (i.e., MBT-CS, APT-CS, MBT-PS, APT-PS). Transverse, longitudinal, and sagittal translations and rotations, and MTPM were then compared using a linear mixed model per study. MTPM was log-transformed and presented MTPM values were back-transformed in the original scale. A mixed model was used as it takes the within-subject correlation into account and deals with missing values [16]. The model consisted of a group variable (i.e., CS-study: MBT-CS versus APT-CS or PS-study: MBT-PS versus APT-PS), a time variable (i.e., baseline, 3 months, 1 year, 2 years, 5 years), and an interaction term of group and time as fixed effects. Furthermore, operating surgeon was added as a fixed variable (i.e., surgeon 1, surgeon 2) as well as an interaction term of surgeon and time because the surgeon significantly influenced migration for the 2-year results and was unevenly distributed between groups in the CS-study.[9] The distribution of sex was also skewed in the CS-study, but was not included in the analysis as results at 2 years showed no influence of sex on migration.[9] An Autoregressive Order-1 covariance matrix was used to model remaining variability. Besides overall migration, the migration profiles beyond 2 years of continuously migrating TKAs at risk for aseptic loosening were examined. Means were reported with 95% confidence intervals without p-values.[17] We used SPSS version 25 (IBM SPSS Statistics 25.0; IBM Corp, Armonk, NY, USA) for all analyses.

## Ethics, registration, funding, and potential conflicts of interest

For both studies, approval of the Regional Review Board in Lund was obtained before recruitment (entry no. 2013/434; 2014/513) and were registered at the ISRCTN

Registry (ISRCTN04081530; ISRCTN10744502). The present study is reported in concordance with the CONSORT guidelines. Stryker funded both studies but did not take part in the design, conduct, analysis nor interpretations stated in this paper. The authors declare no other conflicts of interest.

Figure VI.I Consort Flowchart

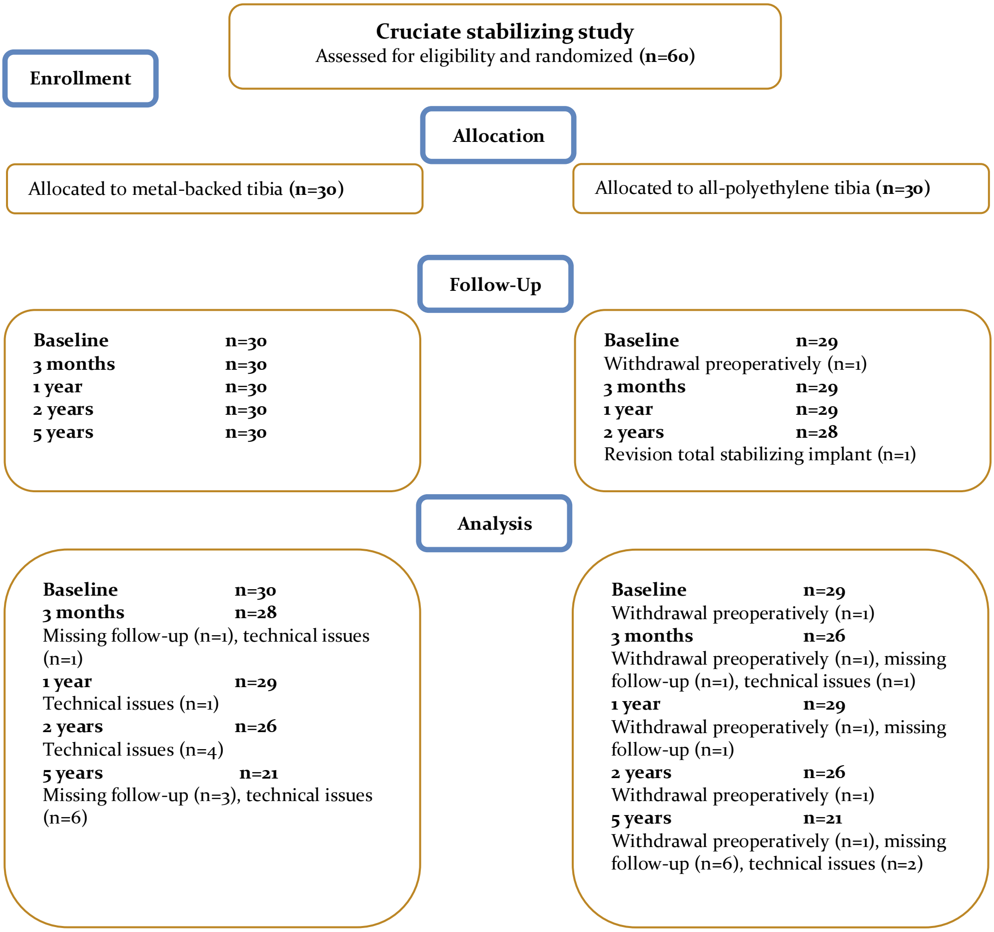

Figure VI.I Consort Flowchart (continued)

**Enrollment**

**Posterior stabilizing study**
Assessed for eligibility and randomized **(n=60)**

**Allocation**

Allocated to metal-backed tibia **(n=30)**

Allocated to all-polyethylene tibia **(n=30)**

**Follow-Up**

**Baseline** **n=29**
Insufficient tibial markers (n=1)
**3 months** **n=29**
**1 year** **n=28**
Death by gastric tumor (n=1)
**2 years** **n=26**
Patient withdrawal (n=2)
**5 years** **n=26**

**Baseline** **n=27**
Withdrawal preoperatively (n=1), death by myocardial infarction (n=1), mismatching images (n=1)
**3 months** **n=27**
**1 year** **n=27**
**2 years** **n=22**
Patient withdrawal (n=5)
**5 years** **n=22**

**Analysis**

**Baseline** **n=29**
Insufficient tibial markers (n=1)
**3 months** **n=27**
Insufficient tibial markers (n=1), technical issues (n=2)
**1 year** **n=27**
Insufficient tibial markers (n=1), technical issues (n=1), death by gastric tumor (n=1)
**2 years** **n=25**
Insufficient tibial markers (n=1), technical issues (n=1), death by gastric tumor (n=1), patient withdrawal (n=2)
**5 years** **n=12**
Insufficient tibial markers (n=1), technical issues (n=1), death by gastric tumor (n=1), patient withdrawal (n=2), missing follow-up (n=13)

**Baseline** **n=26**
Withdrawal preoperatively (n=1), death by myocardial infarction (n=1), mismatching images (n=1), technical issues (n=1)
**3 months** **n=26**
Same as baseline (n=4)
**1 year** **n=26**
Same as baseline (n=4)
**2 years** **n=21**
Same as baseline (n=4), patient withdrawal (n=5)
**5 years** **n=10**
Same as baseline (n=4), patient withdrawal (n=5), missing follow-up (n=11)

## Results

42 patients in the CS-study and 22 patients in the PS-study were analyzed at 5-year follow-up [Fig. VI.I, Table VI.I]. Patients in the PS-study missed their 5 years follow-up visit mainly due to the COVID-19 pandemic which prohibited patients to visit the hospital or resulted in patients refusing follow-up. No differences in baseline characteristics were found between patients with and without 5-year RSA data within study groups (data not shown). Given the reason for missing 5-year follow-up measurements, it seems likely that any loss-to-follow-up was random and therefore attrition bias was considered unlikely.

| | | Cruciate-stabilizing (CS) | | Posterior-stabilizing (PS) | |
|---|---|---|---|---|---|
| | | Metal-backed | All-polyethylene | Metal-backed | All-polyethylene |
| **Age, mean years (SD)** | | 68 (5) | 69 (5) | 68 (4) | 68 (4) |
| **BMI, mean (SD)** | | 29 (3) | 28 (4) | 28 (4) | 29 (3) |
| **Sex, N** | | | | | |
| | Female | 13 | 22 | 17 | 13 |
| | Male | 17 | 7 | 12 | 14 |
| **Surgeon, N** | | | | | |
| | #1 | 16 | 9 | 15 | 13 |
| | #2 | 14 | 20 | 14 | 14 |
| **Ahlbäck classification, N** | | | | | |
| | II | 10 | 6 | 5 | 4 |
| | III | 19 | 21 | 23 | 23 |
| | IV | 1 | 2 | 1 | 0 |
| **HKA postoperative, N** | | | | | |
| | Varus (<177°)z | 7 | 4 | 7 | 3 |
| | Neutral (177-183°) | 22 | 19 | 15 | 17 |
| | Valgus (>183° | 1 | 6 | 2 | 4 |
| | Missing[a] | 0 | 0 | 5 | 3 |
| **Size of femoral component, N** | | | | | |
| | 1-3/4/5/6/7-8 | 3/9/7/8/3 | 7/14/7/1/0 | 5/12/5/6/1 | 6/9/7/4/1 |
| **Size of tibial component, N** | | | | | |
| | 2-3/4/5/6/7-8 | 0/11/4/10/5 | 3/11/10/5/0 | 6/9/4/7/3 | 4/6/7/9/1 |
| **Thickness of polyethylene, N** | | | | | |
| | 9/11/13/16 mm | 2/18/10/0 | 1/17/9/2 | 5/18/6/0 | 11/9/7/0 |

Table VI.I Baseline characteristics

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## Migration up to 5 years of MBT and APT designs

No statistically significant differences in MTPM were found between MBT-CS and APT-CS TKAs nor between MBT-PS and APT-PS TKAs over a 5-year period [Fig. IV.II]. The operating surgeon, however, influenced migration significantly in the CS-study but not in the PS-study [Fig. VI.III]. Although differences were small, both MBT groups translated in positive direction along the longitudinal axis (i.e., lift-off) while both APT groups translated in negative direction along the longitudinal axis (i.e., subsidence; Fig. VI.IV). The APT-CS group tended to rotate more about the transverse axis in posterior direction (i.e., negatively) compared with MBT-CS TKAs [Supplementary data Table VI.II]. Also, a trend towards positive rotation about the longitudinal axis (i.e., internal rotation) was found for APT-PS implants while MBT-PS TKAs tended to rotate negatively about the longitudinal axis (i.e., external rotation; Supplementary data Table VI.II). No statistically significant differences were found in transverse or sagittal translation, nor in sagittal rotation [Supplementary data Table VI.II]. The operating surgeon had no influence on any of the translations or rations (data not shown).

Figure VI.II Mean maximum total point motion in milimeters per group. Error bars represent 95% confidence intervals. CS = cruciate stabilizing, PS = posterior stabilizing, mm = milimeters

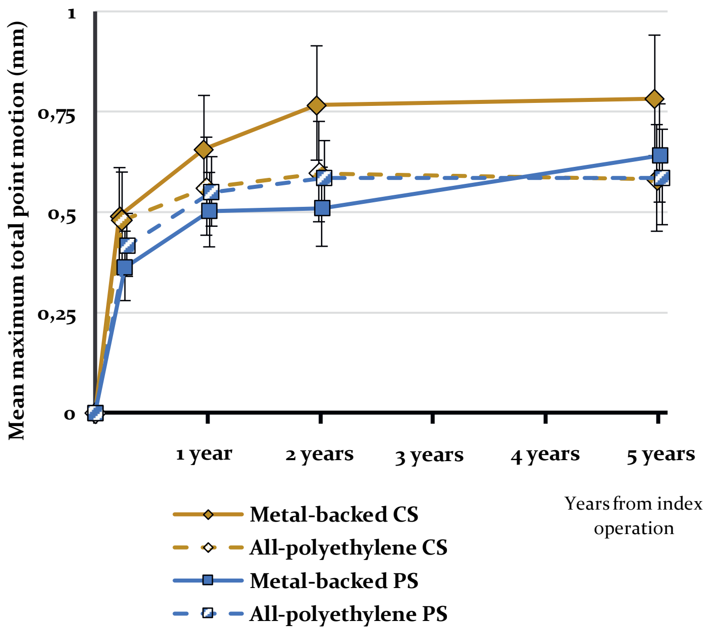
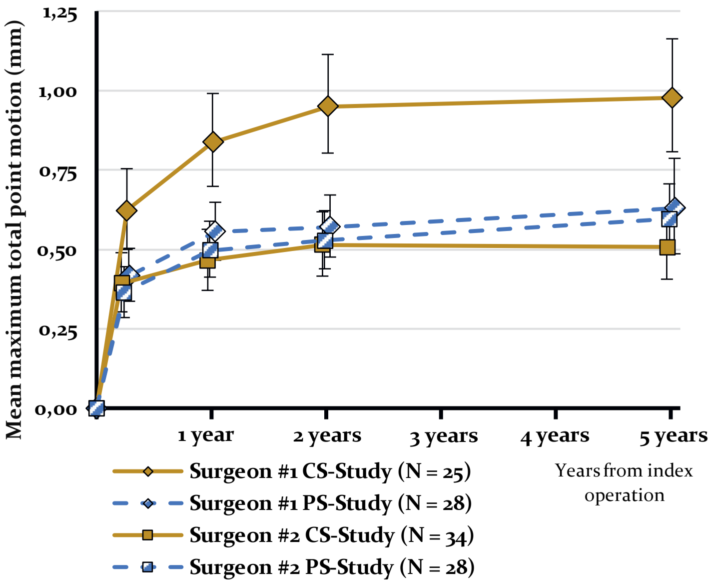


Figure VI.III Mean maximum total point motion (MTPM) stratified by surgeon at 3 months, 1 year, 2 years, and 5 years. Error bars represent 95% confidence intervals.

CS = Cruciate-stabilizing; PS = Posterior-stabilizing; mm = millimeters



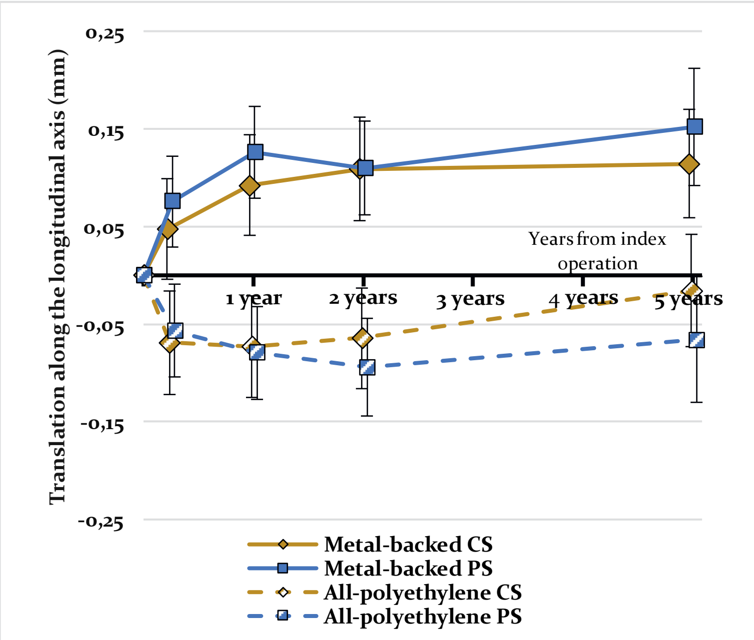




Figure VI.IV Mean translation along the longitudinal axis of the metal-backed tibial implant groups and the all-polyethylene tibial implant groups at 3 months, 1 year, 2 years, and 5 years. Error bars represent 95% confidence intervals. Positive values indicate lift-off of the tibial implant and negative values subsidence.

CS = Cruciate-stabilizing; PS = Posterior-stabilizing; mm = millimeters

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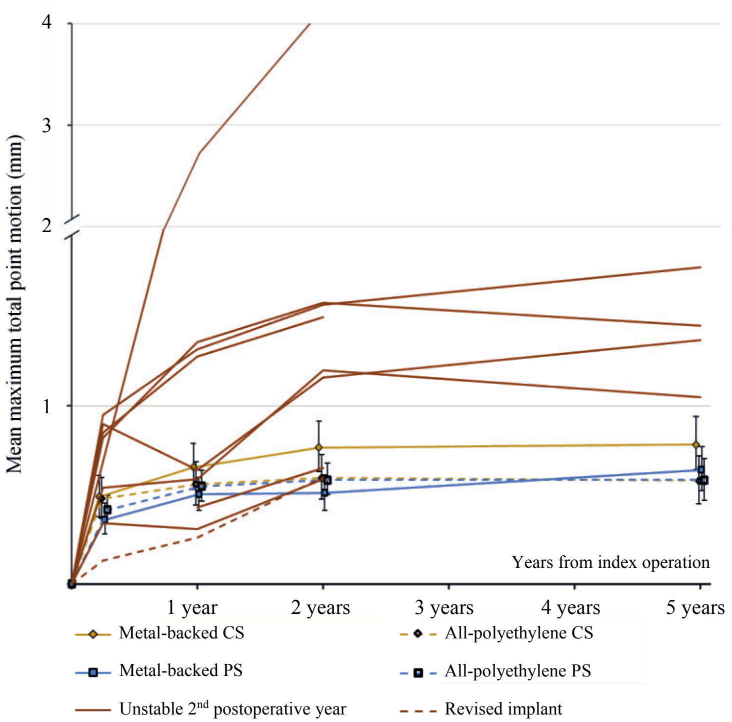
## Continuously migrating TKAs

In both studies combined, 9 tibial components showed continuous migration up to 2 years of which 4 (2 MBT-CS, MBT-PS, APT-PS) stabilized between 2 and 5 years, 1 (APT-CS) was revised for persistent pain and instability, 1 (MBT-CS) could not be analyzed due to a condition number >120 (i.e., technical issue), and 3 (MBT-CS, APT-CS, MBT-PS) were missing at 5 years [Fig. VI.V]. The latter 3 implants had a similar magnitude and slope of migration up to 2 years compared to implants with 5-year data available that stabilized. The other component (MBT-CS design) where 5-year RSA data could not be analyzed due to a condition number >120 had a different migration pattern with high migration at 1 year and 2 years (i.e., MTPM 2.7 mm and 4.2 mm respectively). This patient was a female of 67 years who had a BMI of 27. Walking distance at 2 and 5 years was unlimited, and she experienced no pain. Also, one of the continuous migrating implants was revised (ATP-CS). The MTPM of the revised patients increased >0.2 mm MTPM between 1-and 2-year follow-up and was therefore classified as continuously migrating. This revised patient was a female of 65 years with a BMI of 34. She was initially treated with an APT-CS design and was revised to a total-stabilizing TKA after 4 years to treat her complaints of persistent pain and instability [Fig. VI.V].

Figure VI.V Mean maximum total point motion (MTPM) of the continuously migrating (i.e. >0.2 mm MTPM between 1 and 2 years) implants at 3 months, 1 year, 2 years, and 5 years. Error bars represent 95% confidence intervals.

CS = Cruciate-stabilizing; PS = Posterior-stabilizing; mm = millimeters



## Discussion

This study is the first study comparing migration of MBT TKAs with APT TKAs up to 5 years and showed similar migration between MBT and APT TKAs for either the CS or the PS design. Consistent with the 2-year results, the operating surgeon still had a statistically significant effect on overall migration in the CS-study but not systematically on any of the translations or rotations. Even though overall migration was similar, MBT and APT designs tended to have a different migration direction, especially along the longitudinal axis where APT designs subsided while MBT implants showed lift-off. Moreover, mid-term results showed that 4 (3 MBT TKAs; 1 APT TKA) out of 9 continuously migrating TKAs up to 2 years showed late stabilization. That these implants stabilized after initial migration was unexpected as cement fixation mostly provides strong initial fixation which weakens over time (i.e., cement-debonding). It is unclear how this can be explained, which requires further research to unravel potential mechanisms provided that longer-term follow-up shows that these implants remain stable.

Both APT designs had comparable mid-term MTPM migration compared to their respective MBT designs in the present study. These results are in line with several short-term (i.e., 2-year) RSA studies as well as with clinical studies assessing survival and clinical outcomes between both designs and prior systematic reviews and meta-analyses.[3-8, 18-23] Beside clinical studies, a study using 10-year revision rates in the Swedish registry showed superior TKA survival when using revision for any reason as endpoint in favor of APT designs.[24] Despite these excellent results of modern APT designs, orthopedic surgeons are still hesitant to use these components which is reflected in national registries where APT designs account for less than 15% of all TKAs.[1, 25-27] As APT designs are less expensive than MBT designs, increasing the share of APT designs globally could reduce arthroplasty costs without risking patient safety.[2]

As we found earlier in our 2-year results, the CS-study showed a difference in migration up to 5-years between the 2 surgeons.[9] This difference in tibial migration between surgeons was absent in the PS-study. These findings suggest that migration might be influenced by the surgeon for specific designs e.g., a technically more demanding CS design due to surgeon skill or experience, although both orthopedic surgeons were experienced knee surgeons. However, other RSA studies have not reported such an effect of surgeon on tibial component migration. A difference between both surgeons was found for MTPM while no differences were found in translations or rotations. These findings suggest that minor differences in the direction of migration could result in an overall difference in migration between surgeons. Whether these differences could be due to unmeasured variables such as tibial undersizing or surgical technique should be explored in future studies. Also, future comparative RSA studies should take differences between surgeons across groups into account when designing and evaluating studies.



Although the MTPM was comparable between MBT and APT designs, we found several differences in translations and rotations. First, both APT designs tended to subside in contrast with the MBT designs which tended to show lift-off. This phenomenon has suggested to be due to a difference in tensile forces between the flexible APT and the rigid MBT TKA.[5] Second, all groups rotated posteriorly over a 5-year follow-up. Given the post-cam mechanism of PS-designs which engages in extension, posterior rotation was expected to be higher in the PS-designs, but this could not be confirmed in the present study. Unfortunately, comparison of translations and rotations with other RSA studies comparing MBT with APT designs was not possible as these studies reported unsigned values.[5, 6, 8] Also, the differences in translation along the longitudinal axis, and rotations about the transverse axis were mainly due to differences in the first 3 months. Therefore, it is quite uncertain whether these differences influence long-term migration which should be further investigated e.g. by assessing migration using certain feature points of the implant (e.g., medial border of the tibial component). However, minor changes in TKA design could have clinical effects as a recent study comparing revision rates of CR designs with PS designs in the Dutch arthroplasty registry found that PS designs had higher revision rates.[28]

A limitation of our study was that several patients missed their 5-year follow-up visit due to COVID-19 restrictions. These missing RSA examinations resulted in not being able to determine whether 4 continuously migrating TKAs up to 2 years continued to migrate or stabilized. As we did not have the resources to both reschedule these follow-up visits and continue regular follow-up for other running studies, we had to accept these missing follow-up visits. However, patients who have missed their 5-year follow-up visit due to COVID-19 restrictions are scheduled for regular follow-up at 7 years and 10 years, so that migration profiles of these implants (including possible stabilization) can at those time points. It seems promising that 3 of the 4 patients with missing data showed similar migration profiles up to 2 years compared to patients who stabilized.

In conclusion, we found similar overall 5-year migration between MBT and APT TKAs. Differences in tibial migration were present between the 2 operating surgeons in the CS study at mid-term follow-up, which may be due to the CS design being technically more challenging. In addition, we found that 4 continuously migrating MBT and APT TKAs up to 2 years showed late stabilization in the period hereafter. This highlights the need for mid- and long-term RSA studies to confirm predictions made at 2 years follow-up.

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**Supplementary data**; Table VI.II Mean translation along and rotation about the transverse, longitudinal, and sagittal axis with 95% confidence intervals. Statistically significant differences were highlighted in bold.

| | | **Mean (95% confidence interval)** *Signed values* | | | |
|---|---|---|---|---|---|
| | **Visit (months)** | **Metal-backed CS** | **All-polyethylene CS** | **Metal-backed PS** | **All-polyethylene PS** |
| **Transverse Translation** millimeters | **3** | 0.00 (-0.09; 0.10) | -0.04 (-0.14-0.06) | -0.04 (-0.14; 0.05) | -0.03 (-0.13; 0.06) |
| | **12** | -0.04 (-0.13; 0.06) | 0.01 (-0.08; 0.11) | -0.05 (-0.14; 0.05) | 0.01 (-0.08; 0.11) |
| | **24** | -0.08 (-0.18; 0.01) | 0.01 (-0.10; 0.11) | -0.08 (-0.18; 0.01) | 0.01 (-0.09; 0.11) |
| | **60** | -0.02 (-0.13; 0.08) | 0.05 (-0.06; 0.15) | -0.11 (-0.22; 0.01) | 0.01 (-0.11; 0.13) |
| **Longitudinal Translation** millimeters | **3** | **0.05 (0.00; 0.10)** | **-0.07 (-0.12; -0.02)** | **0.08 (0.03; 0.12)** | **-0.06 (-0.10; -0.01)** |
| | **12** | **0.09 (0.04; 0.14)** | **-0.07 (-0.13; -0.02)** | **0.13 (0.08; 0.17)** | **-0.08 (-0.13; -0.03)** |
| | **24** | **0.11 (0.06; 0.16)** | **-0.06 (-0.12; -0.01)** | **0.11 (0.06; 0.16)** | **-0.09 (-0.14; -0.04)** |
| | **60** | **0.11 (0.06; 0.17)** | **-0.02 (-0.07; 0.04)** | **0.15 (0.09; 0.21)** | **-0.07 (-0.13; 0.00)** |
| **Sagittal Translation** millimeters | **3** | -0.06 (-0.23; 0.10) | -0.10 (-0.26; 0.07) | -0.03 (-0.12; 0.05) | 0.04 (-0.05; 0.12) |
| | **12** | -0.01 (-0.17; 0.16) | -0.15 (-0.31; 0.02) | -0.07 (-0.16; 0.01) | 0.06 (-0.03; 0.14) |
| | **24** | 0.03 (-0.14; 0.19) | -0.16 (-0.33; 0.01) | -0.04 (-0.13; 0.05) | 0.07 (-0.02; 0.16) |
| | **60** | -0.03 (-0.20; 0.15) | -0.14 (-0.32; 0.03) | -0.01 (-0.11; 0.09) | 0.09 (-0.02; 0.19) |
| **Transverse Rotation** degrees | **3** | **-0.13 (-0.32; 0.06)** | **-0.33 (-0.53; -0.14)** | -0.12 (-0.26; 0.02) | -0.08 (-0.22; 0.07) |
| | **12** | **-0.13 (-0.32; 0.06)** | **-0.42 (-0.62; -0.22)** | -0.23 (-0.36; -0.09) | -0.11 (-0.25; 0.03) |
| | **24** | **-0.10 (-0.29; 0.10)** | **-0.47 (-0.67; -0.28)** | -0.24 (-0.38; -0.10) | -0.11 (-0.25; 0.04) |
| | **60** | **-0.19 (-0.39; 0.02)** | **-0.42 (-0.63; -0.21)** | -0.23 (-0.40; -0.06) | -0.14 (-0.32; 0.04) |
| **Longitudinal Rotation** degrees | **3** | -0.03 (-0.16; 0.09) | 0.13 (0.01; 0.26) | **-0.04 (-0.13; 0.05)** | **0.10 (0.01; 0.20)** |
| | **12** | -0.01 (-0.13; 0.12) | 0.14 (0.01; 0.27) | **-0.07 (-0.16; 0.02)** | **0.13 (0.03; 0.22)** |
| | **24** | -0.03 (-0.15; 0.10) | 0.12 (-0.01; 0.25) | **-0.05 (-0.14; 0.04)** | **z0.13 (0.03; 0.22)** |
| | **60** | 0.01 (-0.13; 0.14) | 0.08 (-0.06; 0.22) | **-0.12 (-0.23; -0.01)** | **0.15 (0.03; 0.27)** |
| **Sagittal Rotation** degrees | **3** | -0.06 (-0.20; 0.08) | 0.02 (-0.13; 0.16) | 0.11 (0.00; 0.21) | -0.01 (-0.12; 0.10) |
| | **12** | -0.04 (-0.18; 0.10) | -0.17 (-0.31; -0.03) | 0.09 (-0.02; 0.20) | -0.09 (-0.20; 0.02) |
| | **24** | -0.05 (-0.19; 0.10) | -0.20 (-0.33; -0.06) | 0.10 (-0.01; 0.20) | -0.10 (-0.22; 0.01) |
| | **60** | -0.06 (-0.21; 0.09) | -0.27 (-0.42; -0.12) | 0.18 (0.05; 0.31) | -0.09 (-0.22; 0.05) |