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Chapter 5

Differences in long-term fixation between mobile-bearing and fixed-bearing knee prostheses at ten to 12 years' follow-up: a single-blinded randomised controlled radiostereometric trial

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Abstract

This single-blinded randomised controlled trial investigated whether one design of mobile-bearing (MB) total knee replacement (TKR) has any advantage over a fixed-bearing (FB) design on long-term fixation as measured by radiostereometry. The amount of wear underneath the mobile bearing was also evaluated. A series of 42 knees was randomised to MB or FB tibial components with appropriate polyethylene inserts and followed for between ten and 12 years, or until the death of the patient. The polyethylene in the MB group was superior in that it was gamma-irradiated in inert gas and was calcium-stearate free; the polyethylene in the FB group was gamma-irradiated in air and contained calcium stearate. In theory this should be advantageous to the wear rate of the MB group. At final follow-up the overall mean migration was 0.75 mm (sd 0.76) in the MB group and 0.66 mm (sd 0.4) in the FB group, with the FB group demonstrating more posterior tilt and the MB group more internal rotation. In the FB group there was one revision for aseptic loosening, but none in the MB group. There were no significant differences in clinical or radiological scores.

For the MB group, the mean linear wear rate on the under-surface was 0.026 mm/year (sd 0.014). This was significantly smaller than the wear rate of 0.11 mm/year (sd 0.06) in the MB between femur and polyethylene ($p < 0.001$). Nevertheless, even in a best-case setting the mobile bearings of this TKR design had no apparent advantage in terms of fixation over the FB knee prosthesis at ten to 12 years. The wear underneath the mobile bearing was small and is unlikely to be clinically relevant.

Introduction

Mobile-bearing (MB) total knee replacements (TKRs) have greater conformity of the femorotibial articulation than fixed-bearing (FB) prostheses. This increase in femorotibial contact area should reduce contact stresses at both polyethylene (PE) surfaces and theoretically lead to less PE wear.[1,2] The mobility of the PE liner should at least partially transfer shear forces to the ligaments and other soft tissues,[3] which would tend to reduce the stress at the bone–cement interface, thereby reducing the likelihood of component loosening.[1,2]

However, the advantages described above remain strictly theoretical. Several recent meta-analyses could not demonstrate any clinical or radiological advantage for MB TKRs in short- to medium-term follow-up.[4-7] There are only a few randomised controlled trials with long-term -follow-up comparing MB with FB TKR.[8-10] Although the advantages of the MB TKR remain to be proved, reports on bearing dislocation in some designs and third-body wear underneath the mobile insert where it is in contact with the tibial base plate raise some concerns.[11]

In this study we evaluated the potential long-term advantages of MB TKRs using objective outcomes measures, including PE wear and migration measured by radiostereometric analysis (RSA). RSA is a radiological technique that can be used to accurately measure three-dimensional (3D) migration of the knee prosthesis relative to the bone, with resolutions of 0.2 mm.[12]

Methods

A total of 33 patients with 42 consecutive primary cemented TKRs were included in a randomised, controlled trial at the Leiden University Medical Center, which commenced in 1998. The intention was to compare MB and FB TKRs in terms of survival and wear, measured by RSA. All patients gave informed consent. We used the CONSORT guidelines and RSA guidelines for reporting of the ten- to 12-year results.[13,14] Patients were allocated based on a random number table to receive either an FB TKR (Interax PS; Stryker-Howmedica, Rutherford, New Jersey) or an MB TKR -(Interax Integrated Secure Asymmetric (ISA); Stryker-Howmedica). Bilateral cases were performed simultaneously, and randomisation always started with the right knee. The femoral components from both designs had identical geometric shapes. The MB design had a greater contact area than the FB design owing to higher congruency between the bearing surfaces, both between the PE surface and the tibia and between the PE and the femoral component.

Implant and surgical techniques were identical to those described in the two-year results.[15] The PE in the FB group was different from that in the MB group. This difference was previously unknown until the final evaluation of this study. By this time four liners in the FB group had failed at 1.6, 6.5, 8.2 and 11.6 years post-operatively, whereas none in the MB group had failed. As the liner failures did not require revision of the tibial or femoral components they remained in the migration analyses. The PE in the FB group was GUR 415 gamma sterilised in air and contained calcium stearate. It had a mean shelf-life (i.e., interval between time of manufacture (data provided by manufacturer) and implantation) of 3.0 years. The PE in the MB group was GUR 1050 gamma sterilised in inert gas and free of calcium stearate. The mean shelf-life of the MB inserts was 0.9 years. This randomised trial therefore compared a best-case (superior PE) MB design with a worst-case (inferior PE) FB design.

The study was a single-blinded design during the course of which patients remained blinded to the type of prosthesis they had received. Surgeons and observers were not blinded, as the type of bearing is obvious on radiographs. Inclusion criteria were primary TKR for end-stage osteoarthritis (OA) or rheumatoid arthritis (RA). Exclusion criteria were revision TKR and a deformity of > 20° in any plane. The two-year results of this trial have been previously reported.[15]

After randomisation there were 21 prostheses in each group. The groups were similar with regard to age, gender, diagnosis, body mass index (BMI), pre-operative limb alignment and function (Table 5.1).[16]

Table 5.1: Baseline pre-operative characteristics

	Mobile (N=21)	Fixed (N=21)
Age (yrs)	64 (SD 11)	66 (SD 14)
Female:Male	18:3	16:5
OA:RA	7:14	6:15
BMI	27 (SD 3.1)	27 (SD 5.4)
FTA angle* (degrees)	178 (SD 8.5)	175 (SD 9.2)
KSS (points)	20 (SD 15)	19 (SD 12)
KSS function (points)	24 (SD 19)	17 (SD 19)

* < 175 degrees is valgus, >175 degrees is varus; OA = Osteoarthritis; RA = Rheumatoid Arthritis; KSS = Knee Society Score

Patients were followed prospectively at three and six weeks, three and six months, and then annually for ten to 12 years post-operatively. During the course of the study eight patients (11 TKRs: three MB, eight FB) died of causes unrelated to surgery. For all patients who died it was known whether they had undergone a revision or not, and their follow-up has been used until time of death at a mean of 5.0 years (2.0 to 8.5). Details of the study flow are depicted according to the CONSORT guidelines in Figure 5.1.

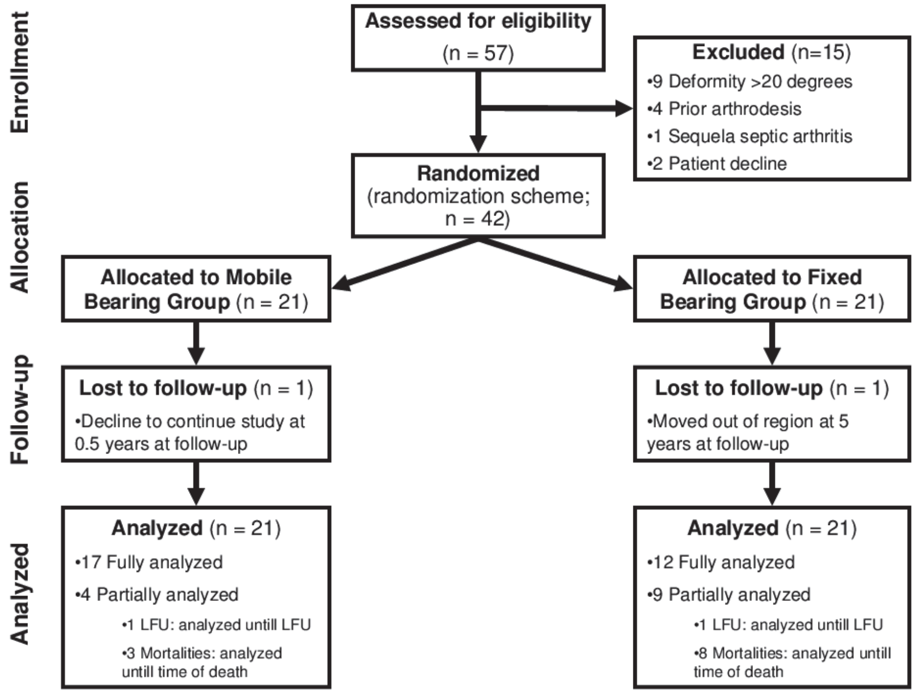

Figure 5.1: CONSORT flow chart of progression through the trial (LFU, lost to -follow-up).

Clinical and radiological evaluation

Clinical evaluation was performed according to the Knee Society score (KSS)[17] at each follow-up. In addition to the RSA radiographs, conventional weight-bearing radiographs were acquired at six weeks, five years and ten years and graded according to the Knee Society roentgenographic evaluation: femorotibial aligment (FTA) angle, as well as α (frontal angle of the femoral component), β (frontal angle of the tibial component) and δ angles (sagittal angle of the tibial component).[18]

Measurement of 3D migration

The first RSA radiograph served as a baseline reference for the measurement of migration, which was performed to a high degree of accuracy throughout the follow-up period.[14] It was determined whether the groups were different with regard to long-term migration expressed in maximal total point motion (MTPM), which is the length of the translation vector of the point on the prosthesis that has moved the most.[14] The three-dimensional migration (translations and rotations) of the tibial components along the *x*-, *y*- and *z*-axes was also assessed.

The RSA setup consists of two synchronised x-ray tubes angled 20° from the vertical and positioned 1.5 m above the x-ray sensor. The RSA was analysed using MBRSA 3.2 software (Medis Specials, Leiden, Netherlands). This enables determination of the relative 3D position of the markers of the prosthesis in relation to the bone markers. In situations where fewer than three markers could be detected in both images of the RSA radiograph, the Marker Configuration Model RSA technique was used to measure the position of a rigid body.[19] This technique was used in six TKRs (two FB and four MB) to save 23 extra follow-up events.

As determined by double examination analysis (n = 33), the bias in the system was very small for translations (*x*-axis -0.01 mm, *y*-axis 0.01 mm and *z*-axis 0.01 mm) and rotations (*x*-axis -0.07°, *y*-axis -0.03° and *z*-axis 0.00°). Accuracy at the 95% confidence level for translations was *x*-axis 0.14 mm, *y*-axis 0.12 mm and *z*-axis 0.28 mm. For rotations the accuracy was *x*-axis 0.50°, *y*-axis 0.46° and *z*-axis 0.12°. These values indicate a high level of precision for the measurement of migration of the tibial component relative to the bone and the absence of any systematic bias. In 2002 the calibration cage of our RSA unit was replaced, but this had no effect on the accuracy of the measurements (p = 0.72, linear regression).

Measurement of wear on the undersurface of the mobile bearings

The amount of wear on the under-surface of the mobile PE inserts at follow-up was measured using RSA. Wear was defined as a change in distance in the proximal–distal direction between tantalum markers in the PE insert and those in the tibial component. Markers (3) on the tibial component provide a reference for migration of the marker model of the PE insert in the proximal and distal directions. The markers were inserted from the periphery of the PE in order to prevent them becoming detached, a situation that could imitate wear. In order to allow reproducible insertion, the tantalum markers were inserted during surgery with drill guides at predefined angles and depths.[15]

Because the PE insert is designed to move only in the transverse plane and not proximally or distally, it is possible to define wear as the migration of the PE markers in the distal direction. In every case wear followed a linear pattern over time.

As the MB and FB groups were different regarding the quality of the PE, it is not possible to study whether the MB reduces PE wear more than the FB. For this reason it was decided that it was not appropriate to determine the linear wear rate in the FB group.

In the MB group the total linear wear of the PE insert was measured on conventional anteroposterior (AP) radiographs as described by Collier et al,[20] while using the size of the central stem to correct for the magnification caused by diverging X-ray beams. Hide et al[21] have shown that this method allows repeatable and precise measurement of insert thickness. The wear at the femorotibial articulation was defined as the total linear wear minus wear between the PE insert and the tibial surface.

Statistical analysis

Owing to the high degree of accuracy of RSA, 20 TKRs were required for each arm of the trial, as was standard for RSA studies at the time this study was designed.[22] The results were analysed according to the intention-to-treat principle. To take into account the repeated measures design of the study, bilateral cases (n = 9), any missing follow-up moments and variations in follow-up duration, a generalised linear mixed model (GLMM) was used, which is considered the analytical method of choice for this type of clinical study.[23] A p-value < 0.05 was considered statistically significant.

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Results

Clinical and radiological evaluation

The clinical results are presented in Table 5.2. Post-operatively there was a mean 68 points (63 to 74) increase in KSS compared with the pre-operative scores. There was no statistically significant or clinically relevant difference in the KSS knee score between the two groups (p = 0.85, GLMM). Death had no effect on KSS score (p = 0.24, GLMM). Post-operatively there was a mean 44 points (34 to 54) increase in KSS function score compared with pre-operatively. There was no statistically significant or clinically relevant difference in KSS function between the groups (p = 0.14, GLMM). There were also no significant differences in flexion between the groups.

Table 5.2: Clinical Results presented as means, standard deviation (SD) and 95% confidence interval [95%CI]

		Mobile Mean; SD; [95%CI]	Fixed Mean; SD; [95%CI]
KSS* (points)	5 yr	91; 5; [88-94]	85; 15; [76-94]
	10 yr	84; 13; [76-92]	90; 6; [86-95]
	Last FU^	81; 15; [74-88]	82; 17; [75-90]
KSS Function** (points)	5 yr	73; 30; [59-88]	55; 34; [36-75]
	10 yr	63; 28; [46-80]	63; 33; [39-86]
	Last FU^	52; 33; [36-67]	33; 36; [16-50]
Flexion Last FU^ (degrees)		110; 11; [104-115]	109; 14; [103-115]

* p = 0.85 GLMM
** p = 0.14 GLMM
^mean 8 years follow-up (range 6 months to 12 years)

The radiological results are presented in Table 5.3. There was no statistically significant or clinically relevant difference in FTA angle between the MB and FB groups (p = 0.94, GLMM), and no statistically significant or clinically relevant differences in α, β or δ angles. The groups were comparable with regard to the incidence of radiolucent lines at ten years' radiological follow-up. Two partial 2 mm radiolucent lines in the MB group, both at the lateral side of the tibial tray, were noted and one partial 2 mm radiolucent line in the FB group was observed at the medial side of the tibial tray.

Table 5.3: Radiological Results presented as means, standard deviation (SD) and 95% confidence interval [95%CI]

			Mobile Mean; SD; [95%CI]	Fixed Mean; SD; [95%CI]
FTA angle* (degrees)		PO	178; 2.7; [177-179]	178; 2.7; [177-179]
		5 yr	178; 2.0; [177-179]	179; 3.3 [177-181]
		10 yr	179; 2.7; [177-180]	181; 3.9; [179-184]
Alpha angle (degrees)	PO		94; 2.3; [93-95]	94; 2.8; [93-95]
Beta angle (degrees	PO		87; 2.9; [86-89]	87; 2.5; [86-88]
Delta angle (degrees)	PO		88; 2.2; [87-89]	88; 2.1; [87-89]

* p = 0.94GLMM; < 175 degrees is valgus, >175 degrees is varus
PO = post-operatively
FTA angle = Femoral-Tibial Aligment
Alpha angle = Frontal angle of the femoral component
Beta angle = Frontal angle of the tibial component
Delta angle = Saggital angle of the tibial component

3D migration

A total of 447 RSA analyses form the migration analysis. At ten years' follow-up the mean MTPM was 0.75 mm (sd 0.76) in the MB group and 0.66 mm (sd 0.4) in the FB group (p = 0.42, GLMM) (Figure 5.2). Throughout the follow-up the difference in MTPM between the two groups was neither statistically significant nor clinically relevant: MTPM MB – MTPM FB = 0.05 mm (95% confidence interval (CI) -0.07 to 0.17). When restricted to patients with OA the difference in MTPM was 0.02 mm (95% CI -0.13 to 0.16), and when restricted to RA patients the difference was 0.11 mm (95% CI -0.08 to 0.30). In the FB group there were two tibial components with continuous migration and none in the MB group. The rates of migration were not different in the group of patients who died. The mean translations and rotations are presented in Figure 5.3. The FB tibial components showed slightly more lateral translation, subsidence and posterior tilt, whereas the MB tibial components showed more internal rotation (p < 0.001 in all cases, GLMM).

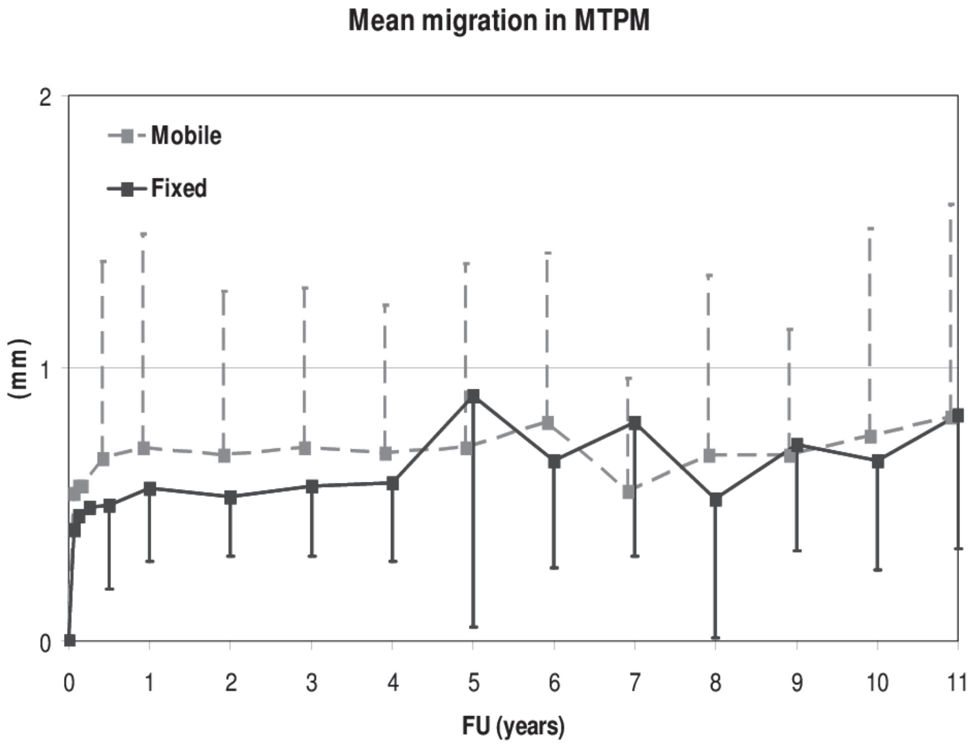

Figure 5.2. Graph showing the mean migration in maximum total point motion (MTPM) according to the duration of follow-up in the mobile- and fixed-bearing groups. The groups do not differ significantly in MTPM ($p = 0.42$, GLMM). The error bars represent the standard deviation.

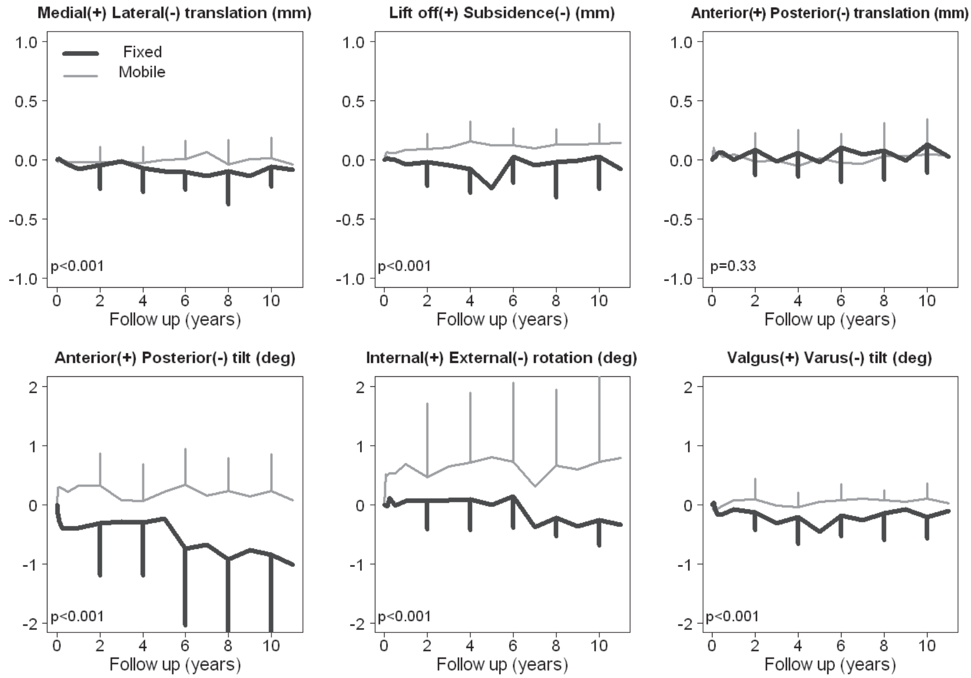

Figure 5.3. Graphs showing the mean translations (upper row) and rotations (lower row) according to the duration of follow-up in the mobile- (MB) and fixed-bearing (FB) groups. For reasons of clarity the standard deviation (vertical bars) is only presented for two, four, six, eight and ten years' follow-up. The FB tibial components showed statistically significantly more lateral translation, subsidence and posterior tilt. The MB tibial components showed statistically significantly more internal rotation. All analyses using generalised linear mixed model statistics.

Wear of the mobile bearings

The mean linear wear on the tibial bearing surface of the PE component for the MB group was 0.026 mm/year (0.019 to 0.033) (Fig. 5.4). The mean total linear wear rate was 0.14 mm/year in the MB group (0.11 to 0.17). The mean wear of the PE at the femoral bearing surface was 0.11 mm/year (0.08 to 0.14). The mean tibial surface PE wear rate of 0.026 mm/year was significantly smaller than the mean wear rate of 0.11 mm/year at the femoral bearing surface ($p < 0.001$).

Complications

In the MB group there was one case that required revision of all components because of septic loosening. None of the bearings dislocated. In the FB group there were two cases that required revision of all components, one for aseptic loosening and one for septic loosening. There were four cases in the FB group that required exchange of the PE insert. The reason was wear and subsequent instability in three cases and fracture of the posterior stabilising central post of the insert after a fall in one case. Including these four liner failures, there was a total of six revisions in the FB group during almost 12 years of follow-up, compared with one revision in the MB group.

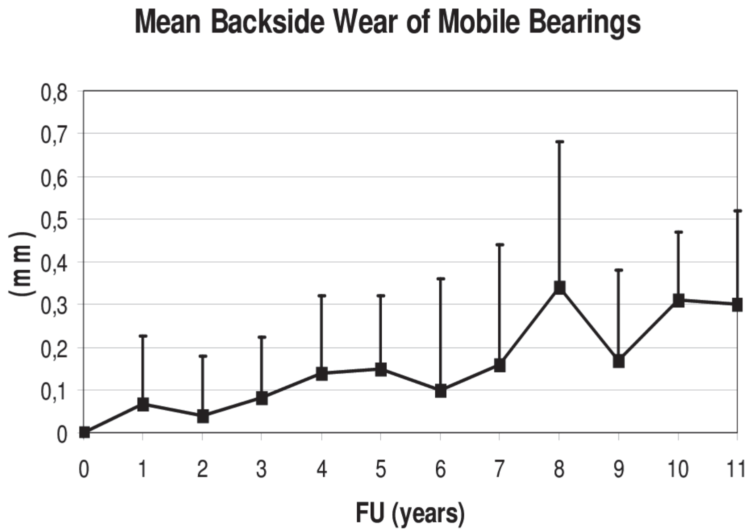

Figure 5.4. Graph showing the mean linear underside wear of the polyethylene mobile-bearing according to the duration of follow-up, measured with radio-stereometric analysis. The error bars represent the standard deviation

Discussion

The results of this randomised controlled trial using RSA show that the MB had comparable migration to the FB during ten to 12 years' follow-up. Therefore, even in a best-case scenario (superior PE in the MB group), the MB design did not yield any apparent advantages in terms of long-term fixation compared with the FB design with femoral components of the same geometrical shape. A mean difference in MTPM < 0.2 mm is not considered clinically relevant.[12,14] There are no studies with long-term RSA follow-up available in the literature for comparison. However, studies with two years' RSA follow-up by Hansson et al[24] and Henricson et al[25] also found no difference in MTPM between mobile and fixed bearings. In comparison to the previous report by Garling et al,[15] who presented the two-year results of this trial, there was higher variability in subsidence and AP tilting in the FB group. However, at that time no-one was aware of the confounding manufacturing and sterilisation differences in the PE, used in the two versions. Therefore the MB design was considered more predictable and forgiving with respect to migration of the tibial component. This conclusion can no longer be supported. In this updated study the FB group showed statistically more posterior tilting than the MB group, but the clinical relevance of this finding is unclear. One explanation might be the posterior-stabilised design of the FB insert compared with the MB insert. Strain on the post in the FB prosthesis due to contact with the femoral component during flexion may have caused posterior tilting.

In addition, there was statistically more internal rotation of the MB group relative to the bone, whereas there was little rotation in the FB group. This finding is surprising, considering that MB TKRs are designed to, and indeed have been shown to reduce strain on the proximal tibia.[26] However, not all MB designs are the same. This particular MB design accommodates only guided rotation through a curved slot on the underside of the liner with respect to the polished tibial tray, and not full freedom to rotate around a central or eccentric tibial tray post. Therefore, the seemingly paradoxical outwards rotation in this MB TKR might be due to the friction between the curved slot and the metal tibial pivot post.

The number of revisions in this series was small. These results are in accordance with other trials where no difference was found in revision rate at long-term follow-up.[8-10] With regard to medium-term follow-up, several meta--analyses could not demonstrate a difference in revision rates.[4-7] Therefore, additional trials of long-term follow-up are needed to investigate whether mobile bearings have any advantage over the fixed bearings regarding revision rates.

The additional articulating surface for MB TKRs may itself be a source of problems. In particular, Engh et al[27] found pitting, scratching and burnishing on the underside of the PE to be greater in mobile than in fixed bearings. However, *in vivo* we found only a small amount of wear under the mobile bearing of 0.3 mm at 11 years' follow-up, which corresponds to a rate of wear of 0.026 mm/year. This backside wear rate was significantly smaller than the wear rate of the PE between the mobile insert and the femur of 0.11 mm/year ($p < 0.001$), and is unlikely to be of clinical relevance.

Although this was a small series there were no differences between the MB and FB groups with regard to clinical outcomes and radiological parameters. These findings confirm the results of several meta-analyses.[4-7]

The strengths of this study are the randomised design, the objective outcome measures (RSA, linear wear), the long-term follow-up, blinding of the patients, and the fact that the femoral components of both the mobile- and the fixed-bearing group were identical in geometric shape. We were also able to demonstrate that even in a best-case scenario the MB knee prostheses have no apparent advantage for long-term fixation or wear over the FB prostheses.

This study has some limitations. Because the type of bearing is recognisable on radiographs the observers were not blinded during the RSA analysis. However, RSA is a standardised and objective method with low susceptibility to individual interpretation, so the risk of bias can be considered negligible.[14]

It should be accepted that although the study has sufficient power to delineate RSA differences, this is unlikely to be true for the clinical scores. The possibility that the results were affected by differences in migration between RA and OA patients should also be considered. A separate analysis on the difference in migration between MB and FB restricted to either RA or OA patients was carried out and no difference in migration rates between the two cohorts was demonstrable. Finally it is accepted there was a serious confounder as the MB inserts were produced in superior quality PE that was sterilised in inert gas, unlike the material used in the FB TKRs.

In conclusion, even in a best-case setting the AP sliding, rotating mobile bearings of the studied TKR have no clinically relevant advantage on long term fixation over the studied FB knee prosthesis. The backside wear underneath the mobile bearing was small and may not be of clinical relevance.

5

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