Less wear in deep-dished mobile compared to fixed bearing total knee arthroplasty of the same design at 5-year follow-up: a randomised controlled model-based Roentgen stereophotogrammetric analysis trial

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Less wear in deep-dished mobile compared to fixed bearing total knee arthroplasty of the same design at 5-year follow-up: a randomised controlled model-based Roentgen stereophotogrammetric analysis trial

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Abstract

Purpose The aim of this prospective randomised controlled study was to compare wear characteristics and functional outcome between deep-dished mobile bearing (MB) and fixed bearing (FB) cemented total knee arthroplasty (TKA). We hypothesised that deep-dished MB reduces polyethylene wear and improves patient-reported outcome measures.

Methods A total of 50 patients were randomised to receive a MB or FB tibia component of the same cemented TKA design. Patients were evaluated over a 5-year follow-up period. Medial and lateral wear were assessed using model-based Roentgen Stereophotogrammetric Analysis (RSA) and compared with the direct postoperative minimal joint space measurement. Functional outcome was assessed by the clinician-derived KSS and OKS, WOMAC, LEAS, and FJS-12. All data were derived using a general linear mixed model.

Results At 5-year follow-up, decreased wear in the MB compared to the FB group was observed on the lateral side (0.07 ± 0.17 mm, $p = 0.026$), but not on the medial side (0.31 ± 0.055 mm, $p = 0.665$). Functional outcomes improved with a statistical significant effect over time, with no significant differences between groups (all $p > 0.17$).

Conclusion This model-based RSA study with 5-year follow-up showed that cemented deep-dished MB reduced lateral polyethylene wear as compared to FB in a single TKA system, whilst clinical outcomes were comparable. Longer follow-up is needed to establish clinical implications of these altered wear patterns and determine type of wear.

Level of evidence Level 1 randomised controlled trial.

Keywords Deep-dished mobile bearing · Cruciate-retaining TKA · Total knee arthroplasty · Model-based Roentgen stereophotogrammetric analysis · Wear caractheristics · Functional outcome · PROMs

Introduction

Deep-dished mobile bearing (MB) total knee arthroplasty (TKA) was introduced in the late 1970s with the goal to reduce long-term polyethylene wear and associated implant–bone interface stresses. The rationale behind MB design was that maximising the contact surface area of the femoral component during motion reduces bearing surface pressure [2, 14, 18, 25, 28]. If bearing surface pressure and friction could be reduced, wear could potentially decrease subsequently [14, 15, 18, 25]. Wear patterns of the articular surface of polyethylene inserts have been studied previously in a few retrieval studies and found that the fixed bearing (FB) polyethylene had a higher incidence of increased wear

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compared to ultra-congruent MB polyethylene designs [6, 14, 15, 18].

Although a estimation could be made about the type of wear based on these retrieval and retrospective studies, quantifying the amount of wear in these remains a challenge. The utilised techniques are also invasive, limited to retrospective or in vitro analysis and cross-sectional comparisons, leading up to heterogeneity in the patient groups, types of prostheses, and varying follow-up durations. As a solution to these shortcomings, recent model-based Roentgen stereophotogrammetric analysis (RSA) studies used three-dimensional (3D) prosthesis models that provide an accurate quantification of TKA polyethylene wear by measuring the minimal joint space width (mJSW) in weight-bearing conditions and in vivo [6, 7, 25, 30]. The main advantage of model-based RSA measurements as a complement to current retrieval studies is when repeated quantification of wear occurs, wear patterns can be determined and an early prognostic measurement of the wear can be calculated [16, 20]. Therefore, model-based RSA allows serial measurements of mJSW and allows us to overcome the main shortcomings of the current literature. To the best of our knowledge, no model-based RSA studies have been performed providing an insight in wear patterns in MB-TKA compared to conventional TKA.

We assessed wear patters between deep-dished MB and FB cemented TKA of this same design in a prospective randomised model-based RSA controlled trial over 5 years. Secondary objective of this study was to quantify differences in clinical outcomes between MB-TKA and FB-TKA at 5-year follow-up.

Materials and methods

Between October 2010 and December 2011, we conducted a prospective, single-centre, patient-blinded, randomised model-based RSA trial with 50 patients. Detailed information on baseline characteristics, surgical procedures, perioperative outcomes, postoperative protocols, and clinical outcomes is available in prior publications [25, 26]. All surgeries used the cruciate-retaining technique. Patients were allocated to either MB-TKA or FB-TKA groups using a computer random number generator (www.randomizer.org). Baseline demographics and loss to follow-up are shown in Table 1 and Fig. 1, respectively. Pre-randomisation, four patients withdrew consent (MB-TKA = 1, FB-TKA = 3). Notably, two patients received bilateral TKA, counting as individual cases, one receiving both implant types and the other receiving MB-TKA in both knees.

All the patients were operated by three experienced surgeons using the medial para-patellar approach with comparable instrumentation sets and surgical technique as described [26]. Patients were implanted the cemented deep-dished mobile bearing (MB-TKA) Vanguard TKA system (Zimmer Biomet, Warsaw, IN, USA), known as the Deep Dish Rotating Platform, or the cemented fixed bearing (FB-TKA) Vanguard TKA system. The femoral component was assessed first using intramedullary alignment

Table 1 Baseline demographics of the 5-year follow-up cohort, mean (± SD) and proportion (%), compared between the MB-TKA and FB-TKA

	MB-TKA (n = 20)	FB-TKA (n = 18)	p value
Age at surgery (years)	62.4 ± 7.0	63.8 ± 14.2	0.699
Body mass index (kg/m^2)	29.3 ± 4.4	29.7 ± 2.8	0.696
Sex female (%)	9 (45)	6 (40)	0.522
Insert thickness[a]	11,26 ± 0,6	11,62 ± 0,5	0.644

[a]This represents the mean bearing thickness at implantation. The possible bearing options which were used were size 10, 12 and 14

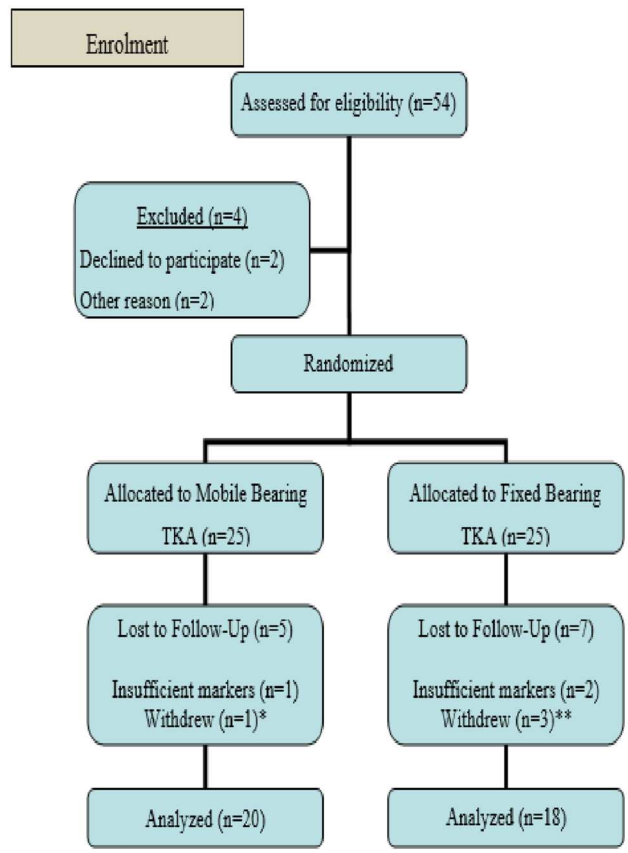

Fig. 1 Flowchart of the number of patients enrolled and analysed at 5 years of follow-up. *Patient withdrew consent after the 1-year follow-up due to family circumstances. **Patients withdrew consent: two patients did not wish to participate anymore, one patient experienced a rupture of the patella tendon in the contralateral (native) knee

instruments and was identical in both groups. The tibial component was implanted using extramedullary alignment instruments. In respect of the mechanical axis of femur and tibia, a 90° angle was aimed to perform the distal femoral cut and the proximal tibial cut. The standard CR bearing is characterised by a built-in posterior slope of 3 degrees and allowing for 15 degrees of internal/external rotation whilst the MB-TKA consists of a metal tray with an intramedullary spur in which limitless rotation of the polyethylene inlay around its longitudinal axis is possible. Soft tissue release was performed when deemed necessary. Patella resurfacing and ateral release were not routinely performed.

A three-dimensional (3D) model-based Roentgen stereophotogrammetric analysis (RSA) was conducted at multiple time points: at discharge, 6 weeks, 6 months, 12 months, 24 months, and 60 months post-surgery. The RSA radiographs taken at discharge served as the reference for all subsequent examinations [29]. During these assessments, patients assumed a weight-bearing position with fully extended legs in front of a uniplanar calibration box (Medis Carbon Box, Medis Specials bv., the Netherlands). Radiographic images were sent to RSA core in Leiden, the Netherlands, for analysis using model-based RSA software (Version 3.4 RSA-core) in a blinded setup, overseen by one of the authors (BK). The RSA setup and analysis method described by Garling et al. [29] were employed, and all measurements followed RSA guidelines (ISO 16087:2013). Intra-method agreement was confirmed 24 months post-surgery [29]. RSA reconstructed 3D models of both the femur and tibia components from the radiographs, allowing for the calculation of minimal joint space width (mJSW) by measuring the difference between the femoral condyles and the upper tibial component plane on both medial and lateral sides (Fig. 2).

This study presents medial and lateral wear at each follow-up moment. Liner wear was defined as change in mJSW as compared to direct post-op measurement (T0) (Fig. 2). Positive wear values indicate loss of polyethylene thickness, whilst negative wear values indicate contact loss or lift-off [23]. Validation of this technique shows that the estimated accuracy is 0.10 mm and precision is 0.20 mm [29]. The wear rate, calculated as amount of mJSW loss per timeframe, was reported as millimetres per year.

Preoperatively, and at each postoperative follow-up, three different patient-reported outcome measures (PROMs) were completed by the patient: the Oxford Knee Score [19, 25, 26] (OKS; 0–48, 48 being the best score), the Western Ontario and McMaster Universities Arthritis Index [25, 26] (WOMAC; 0–100, 100 being the highest score) and the Lower Extremity Activity Scale [25, 26] (LEAS; 1–18, 18 being the highest score). In addition, the clinician completed the Knee Society Score [25, 26] (KSS). At 36 and 60 months postoperatively, the

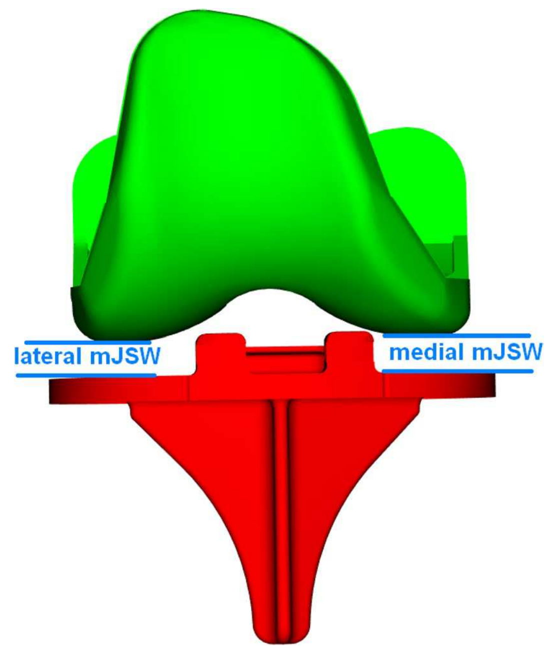

Fig. 2 The mJSW is defined as the minimum distance between the femoral condyles and the metal tibial baseplate. These distances and locations are calculated from the orientation and position of the femoral and tibial component

Forgotten Joint Score-12 [26] (FJS-12; 0–100, 100 being the highest score) was also completed by the patients. This trial was studied and approved by the local ethics committee (Atrium-Orbis Zuyd Heerlen, the Netherlands; Inr. 09-T-28).

Statistical analysis

A sample size calculation was performed for migration analyses by model-based RSA measurement as outcome after 2 years, and is described in detail in previous publications [25, 26]. A general linear mixed model (GLMM) was used to take into account the repeated-measures design of the study, to cope with any missing data being collected before and during each follow-up and to cope with the wide range of variation in relation to the time frame in which the data were collected [12]. The GLMM contained implant design, age, time, and the implant design × time interaction as fixed variables. Medial and lateral wear patterns were dependent variables. All statistical analyses were performed using SPSS for windows software version 26.0 (SPSS Inc., Chicago, USA). For all statistical comparisons, a threshold of $p \leq 0.05$ was considered statistically significant different. Results are presented as frequencies (%) or mean (range and/or SD).

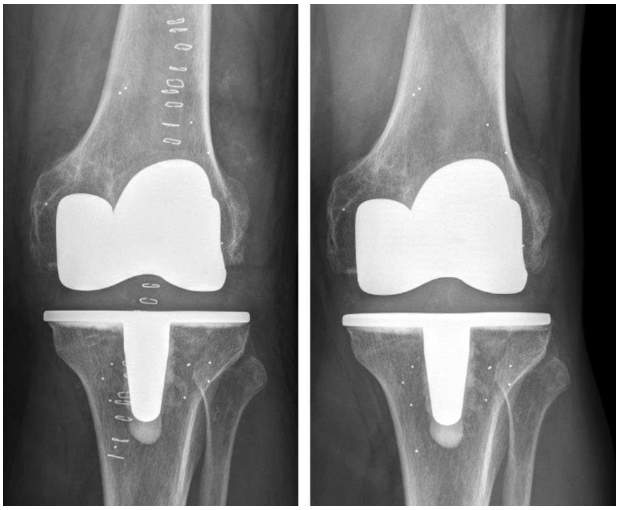

Fig. 3 Direct and 5-year postoperative X-ray of the MB-TKA with MB-RSA beads

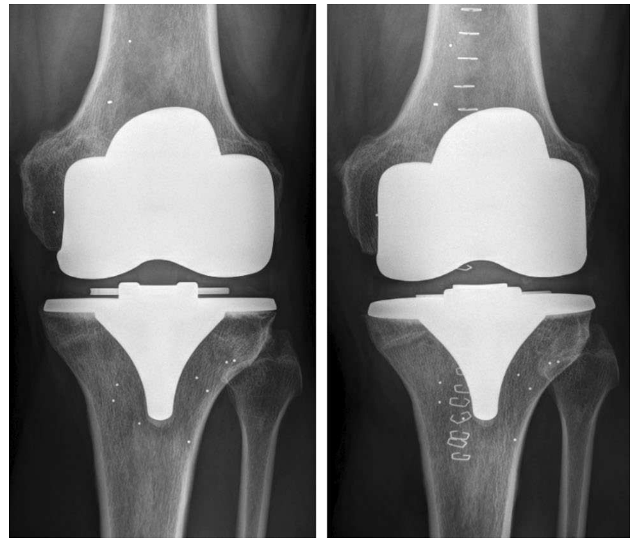

Fig. 4 Direct and 5-year postoperative X-ray of the FB-TKA with FB-RSA beads

Results

A patient attrition flow chart is presented in Fig. 1. At 5-year follow-up, no additional patients required revision surgery of one of the components (e.g. tibia, femur or bearing). Five patients (MB-TKA = 3, FB-TKA = 2) deceased due to causes unrelated to the surgery before the 5-year follow-up. Three patients were excluded from RSA follow-up because of insufficient markers in the bone (MB-TKA = 1, FB-TKA = 2). The total cohort analysed at 5-year follow-up consisted of 38 patients (MB-TKA = 20, FB-TKA = 18). The bearing sizes did not differ between both groups (Fig. 3). Baseline demographics (sex, age and BMI) were comparable between both groups (Table 1).

Over time, medial and lateral liner wear showed statistical significant wear progression after 6 and 24 months, respectively, for all patients (all $p < 0.001$). Between groups, lateral wear tended to be higher in FB-TKA as compared to MB-TKA at 2-year FU ($p = 0.057$) and became statistically significant after 5-year follow-up ($p = 0.026$). Progression of medial wear was comparable between groups (Fig. 4). The FB-TKA showed a wear rate of 0.16 mm/year for medial liner wear, and 0.07 mm/year for lateral wear in the first 2 years declining to a wear rate of 0.01 mm/year for medial liner wear and 0.03 mm/year for lateral liner wear between 2 and 5 years (Figs. 5, 6, 7 and Table 3). The MB-TKA showed a wear rate of 0.14 mm/year for medial liner wear and 0.03 mm/year for lateral liner wear in the first 2 years declining to a wear rate of 0.01 mm/year for medial liner wear and 0.01 mm/year for lateral liner wear between 2 and 5 years (Figs. 6, 7 and Table 3). Measurements for the medial liner wear were not normally distributed. The lateral liner wear showed normal distribution.

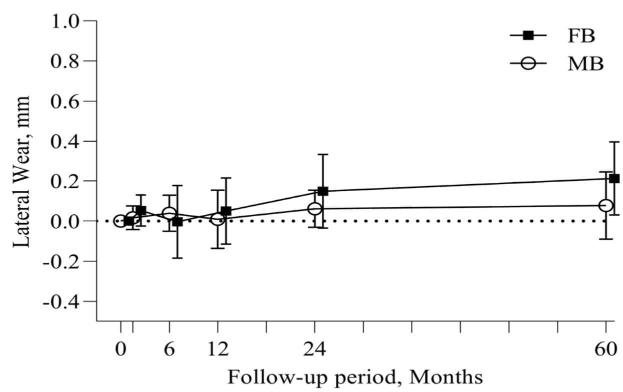

Fig. 5 Mean and SD lateral liner wear in the MB-TKA and FB-TKA at each follow-up moment

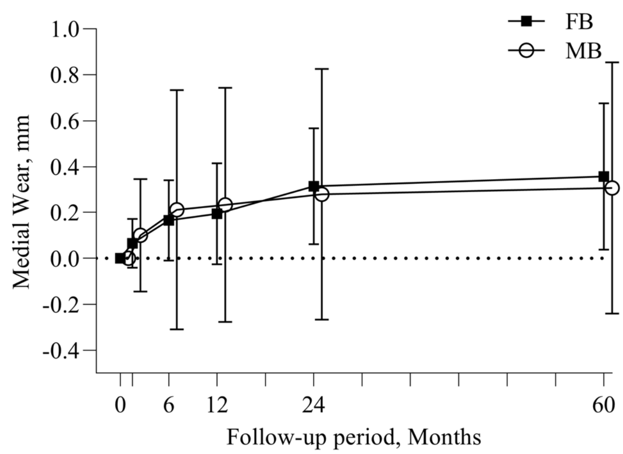

Fig. 6 Mean and SD lateral liner wear in the MB-TKA and FB-TKA at each follow-up moment

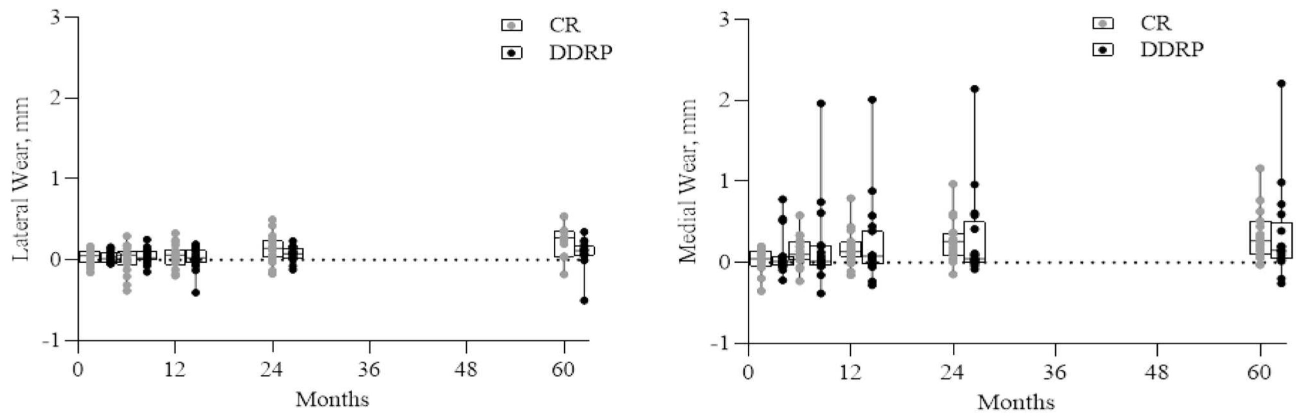

Fig. 7 Boxplot of normal distribution of lateral and medial wear in the MB-TKA and FB-TKA for each follow-up moment

Table 2 Mean and SD of the medial and lateral liner wear (mm) for the MB-TKA and FB-TKA 6 weeks, 6, 12, 24 and 60 months postoperatively

	MB-TKA ($n=20$)		FB-TKA ($n=18$)		p value
	Mean	SD	Mean	SD	
Medial wear, mm					
6 weeks	0.10	0.25	0.07	0.11	0.572
6 months	0.21	0.52	0.17	0.18	0.928
12 months	0.23	0.51	0.19	0.22	0.893
24-months	0.28	0.55	0.31	0.25	0.456
60-months	0.31	0.55	0.36	0.32	0.665
Lateral wear, mm					
6-weeks	0.02	0.06	0.05	0.08	0.441
6-months	0.04	0.09	0.00	0.18	0.342
12-months	0.01	0.15	0.05	0.16	0.396
24-months	0.06	0.09	0.15	0.18	0.057
60-months	0.07	0.17	0.21	0.18	0.026

Table 3 Wear rate measured during direct postoperative and 2-year follow-up, and 2-year and 5-year follow-up between MB-TKA and FB-TKA

	MB-TKA ($n=20$)		FB-TKA ($n=18$)		p value
	Mean	SD	Mean	SD	
Medial wear rate					0.851
0–2 years	0.14	0.27	0.16	0.13	
2–5 years	0.01	0.02	0.01	0.01	
Lateral wear rate					0.078
0–2 years	0.03	0.05	0.07	0.09	
2–5 years	0.01	0.01	0.03	0.03	

Detailed results of medial and lateral liner wear analysis are described in detail in Table 2. No knee arthroplasties were revised during the 5-year follow-up.

p values indicate the statistical significance of the group-difference in linear mixed model (Table 3). For both medial and lateral, wear rate declines significantly over time ($p<0.01$), without group × time interaction (medial: $p=0.779$, lateral: $p=0.122$).

The PROMs and the clinician-derived KSS significantly improved after surgery. Between groups, there was no statistically significant difference in KSS ($p=0.682$), WOMAC ($p=0.584$), OKS ($p=0.196$), LEAS ($p=0.153$), and FJS ($p=0.246$) (Table 4).

Discussion

The most important finding of this model-based RSA single-centre RCT was statistically significant less lateral liner wear for the deep-dished MB-TKA compared to the FB-TKA at 5-year follow-up. This improvement did not translate into improved PROMs and the clinician-derived KSS. These results contradict several meta-analyses and reviews, which had concluded that there were no statistically significant wear pattern differences between MB-TKA and FB-TKA designs, although these analyses often combined results from different prosthetic brands and types [13, 20, 22, 28]. In contrast, this study utilised a single cemented TKA system, eliminating such heterogeneity and providing a clearer assessment of the deep-dished MB-TKA vs. FB-TKA. The strength of this model-based RSA study lies in its enhanced reliability due to a more homogeneous study population, precise measurement techniques and a randomised TKA design [7, 30]. In addition, model-based RSA allows a reliable representation of a dynamic in vivo wear pattern at an early stage that can be quantified in a validated way [16, 20].

In this study, both medial and lateral wear rates for both bearings decreased between 2- and 5-year follow-up. Whilst medial wear rate between 2- and 5-year follow-up was

Table 4 Mean (SD) clinician-derived clinical outcome and PROMs measured pre-operative (Pre), 6 weeks, 6, 12, 24, and 60 months postoperative for both the MB-TKA and FB-TKA

	MB-TKA (n = 20)	FB-TKA (n = 18)	*p* value
KSS			
Pre	69.5 (15.6)	69.7 (13.0)	0.962
6 wks	71.5 (17.3)	72.2 (16.8)	0.739
6 mths	91.8 (10.2)	87.5 (14.8)	0.351
12 mths	95.0 (9.5)	93.1 (12.7)	0.677
24 mths	93.9 (11.5)	90.9 (21.4)	0.489
36 mths	92.0 (14.0)	93.1 (12.2)	0.979
60 mths	89.8 (16.9)	91.7 (11.0)	0.682
OKS			
Pre	24.9 (6.0)	24.5 (6.2)	0.825
6 wks	33.2 (7.3)	35.9 (5.2)	0.166
6 mths	42.5 (6.3)	41.9 (5.3)	0.756
12 mths	43.5 (5.6)	42.7 (5.1)	0.665
24 mths	44.2 (4.9)	44.0 (4.1)	0.985
36 mths	42.3 (5.6)	44.1 (3.6)	0.374
60 mths	43.1 (5.8)	42.1 (4.8)	0.584
WOMAC			
Pre	66.7 (9.8)	61.5 (10.5)	0.078
6 wks	83.8 (11.2)	88.0 (7.0)	0.163
6 mths	91.9 (9.0)	92.9 (6.8)	0.742
12 mths	94.1 (7.2)	93.6 (6.8)	0.869
24 mths	94.6 (7.0)	92.5 (6.0)	0.595
36 mths	91.8 (7.4)	92.4 (7.2)	0.927
60 mths	87.5 (12.3)	83.6 (11.8)	0.196
LEAS			
Pre	9.5 (2.2)	10.1 (3.2)	0.452
6 wks	8.7 (2.8)	8.8 (2.2)	0.821
6 mths	11.8 (2.3)	11.1 (3.0)	0.403
12 mths	12.8 (2.2)	12.4 (2.5)	0.638
24 mths	12.4 (2.4)	12.1 (2.2)	0.666
36 mths	11.9 (2.5)	12.6 (2.6)	0.432
60 mths	12.1 (2.6)	11.5 (2.4)	0.153
FJS			
36 mths	73.5 (32.7)	62.8 (29.7)	0.303
60 mths	73.4 (7.0)	62.8 (7.4)	0.246

KSS Knee Society Score, *OKS* Oxford Knee Score, *WOMAC* Western Ontario and McMaster University Index, *LEAS* Lower Extremity Activity Scale, *FJS* Forgotten Joint Score, *wks* weeks, *mths* months

similar for both groups (0.01 mm/year), the main difference occurred as lateral wear rate was found to be much lower in MB-TKA (0.01 mm/year) compared to FB-TKA (0.03 mm/year) leading up to a statistically significant difference in amount of wear at 5-year follow-up. The reason for the significantly reduced lateral wear was not retrieved in currently available literature. It can be hypothesised that lateral pivot moment forces in FB-TKA, especially if there is a rotational mismatch between femur and tibia, increases delaminating lateral liner wear. A key factor in wear rate patterns is reducing peak stresses by achieving optimal congruency of TKA components during gait which is set by optimal TKA implementation [27]. It is thought that whilst the FB-TKA is statically fixated at implementation by determining the rotation based on a few non-weight-bearing cycles of the knee, the MB-TKA will be given freedom of rotational movement for a longer period of time to find its specific equilibrium after a multitude of weight-bearing cycles. After this period in which the equilibrium for rotation is reached, characterised with retrieving optimal rotation interaction of liner and femoral component leading to minimization of delaminating wear, the deep-dished MB-TKA will also behave like a fixed bearing. A difference in activity level could also possibly affect these wear results but was not assessed as an outcome measurement. Recent kinematic studies comparing deep-dished MB-TKA and FB-TKA revealed statistically significant differences favouring deep-dished MB-TKA in tibial internal rotation and femoral component rollback [10, 11, 24, 36]. These advantages in articular conformity potentially explain lower polyethylene contact stresses in kinematic studies and reduced rate of liner wear in retrieval studies [9, 21]. These biomechanical benefits of deep-dished MB-TKA may underlie the reduced lateral polyethylene wear, possibly due to improved articulation or the implant ratio between femoral and tibial components. Since a statistically significant difference in amount of wear between both groups occurred at 5-year follow-up, no clear indication can be found that an equilibrium has been reached and the plateau phase in wear progression sets has yet to be observed. Therefore, continuous long-term monitoring is crucial to validate these findings. Additionally, the biomechanical advantages of MB-TKA may minimise implant-to-bone interface stresses, potentially lowering the risk of tibial component loosening. No revisions occurred during this study's follow-up, but longer term monitoring is essential, as aseptic loosening related to polyethylene wear manifests over time [3].

The clinician-derived outcome score (KSS) and PROMs (OKS, WOMAC, LEAS) significantly improved after surgery. The differences found in wear patterns did not translate into clinical superiority of one bearing design over the other. These results are in line with the majority of studies and meta-analyses which report no significant difference in clinical scores (KSS, OKS, WOMAC) and range of motion (ROM) between MB-TKA and FB-TKA after 5 years [1, 4, 5, 8, 17]. Only one meta-analysis reported better quality of life scores after MB-TKA [31], whilst other outcome scores were comparable. Therefore, based on these results, the theoretical greater ROM from MB-TKA was not of clinical importance as it does not lead to improved functional outcome at 5-year follow-up. Since wear differences, when reaching a certain threshold, only produce a discernible clinical effect on the long term, it is important to continue to monitor clinical data from these patient groups [17].

Strengths of this RCT include the design with both bearing designs containing the same femoral component, and that all the RSA examinations were acquired with the patient in a weight-bearing position. These RSA measurements provide a reliable prediction of wear characteristics and is also the most accurate way to measure wear and migration in in vivo TKA [25, 26, 30]. This results in reliable in vivo wear assessments in this TKA in a homogenous group of patients [7, 25, 30]. There are limitations to the present study. First, the study was powered to detect differences in migration between the groups, and thus may be underpowered for the presented analysis. This eviction is negated by the finding of a statistical significant difference in lateral wear. In the present study, the type of wear (delaminating, abrasive, etc.) was not examined and no distinction was made between conventional wear and any backside wear. To complement this study, the influence of the postoperative leg axis on the wear patterns should be further investigated.

Conclusion

This study showed that mid-term lateral polyethylene wear of cemented mobile bearing TKA is significantly lower than that of fixed bearing in a single TKA system with comparable clinical outcomes. Longer follow-up is needed to study and perhaps to confirm clinical implications of reduced wear on functional outcome and survival rate in deep-dished MB-TKA compared to FB-TKA.

Author contributions SK conceived, designed, coordinated the study, collected and analysed the data and drafted the manuscript. BVD, JM and BB critically reviewed the manuscript. PT participated in the design of the study and critically reviewed the manuscript. BK performed the data analysis. MS participated in the design of the study, co-ordinated the study and critically reviewed the manuscript. All authors have read and approved the final manuscript.

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Declarations

Conflict of interest The authors certify that they have no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licencing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Ethical approval Ethical approval by the local ethical committee was obtained for this study.

Informed consent Informed consent was obtained for each patient of this study.

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