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Mobile-bearing versus fixed-bearing total knee implants. Results of a series of 100 randomised cases after 9 years follow-up☆

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ABSTRACT

Hypothesis: Mobile-bearing total knee arthroplasty (TKA) implants were developed as an alternative to fixed-bearing implants because of their theoretical advantages related to wear and range of motion. For all that, none of the short-term and medium-term studies published so far have reported a significant clinical improvement related to these mobile bearings. The goal of this study was to compare the outcomes of fixed and mobile bearings in the same type of TKA model after a longer follow-up.
Material and methods: This series initially comprised 100 patients with a mean age of 73 years who were operated by a single surgeon. The patients were randomised to receive either a fixed bearing TKA implant or a mobile one; their outcomes evaluated after a mean of 9 years (7.2–12.2) follow-up. Twenty-two patients died before the final review, 15 were lost to follow-up and 2 were excluded. This resulted in 30 patients with a mobile-bearing knee and 31 with a fixed-bearing knee being available for analysis.
Results: There were no significant clinical differences between the groups receiving a fixed or mobile bearing in terms of the range of motion, subjective outcomes or validated outcomes measured, such as the self-reported Oxford or the IKS. Conversely, there was a significantly higher rate of osteolysis in the fixed-bearing group, but it was not clinically relevant.
Conclusion: This study, which has the longest published follow-up, confirms the results found in the seven randomised studies published up to now: there are no significant differences in the clinical outcomes between fixed-bearing and mobile-bearing inserts of the same TKA model. Although the mobile bearing knees had a better radiographic appearance, this did not translate to better clinical outcomes. In practice, the superiority of mobile bearings is solely theoretical.
Level of evidence II: Prospective randomised study.

1. Introduction

During the 1980s, total knee arthroplasty (TKA) became a reliable, reproducible procedure with about 95% implant survival after 10 years [1]. However, longer-term data has revealed a higher rate of loosening and wear than the one reported for total hip arthroplasty implants. Loosening is related to the stresses at the bone fixation, whereas polyethylene wear is mainly due to lack of congruency during implant motion [2]. More recent TKA designs have sought to increase the congruency without increasing the stresses on the implant fixation.

Research on unicompartmental TKA implants by Goodfellow et al. [3] and Buechel and Papas [4] led to the emergence of the mobile-bearing concept. Because of its motion at the tibia-insert interface, greater tibiofemoral congruency can be achieved to reduce the wear of the polyethylene insert, without increasing the stresses at the bone-implant interface [5]. All the theoretical data from laboratory testing and computer modelling tend to show that mobile bearings actually help to minimise linear polyethylene wear by reducing delamination and fatigue fractures [6,7]. Despite several prospective, randomised studies having been performed, this is no clinical evidence supporting this superiority of mobile bearings relative to fixed bearing designs [8–13].

The goal of this study was to compare the clinical and radiological outcomes of fixed and mobile bearings in the same TKA model. This comparison was accomplished through a series of cases where

☆ Based on the Round Table: TKA revision.

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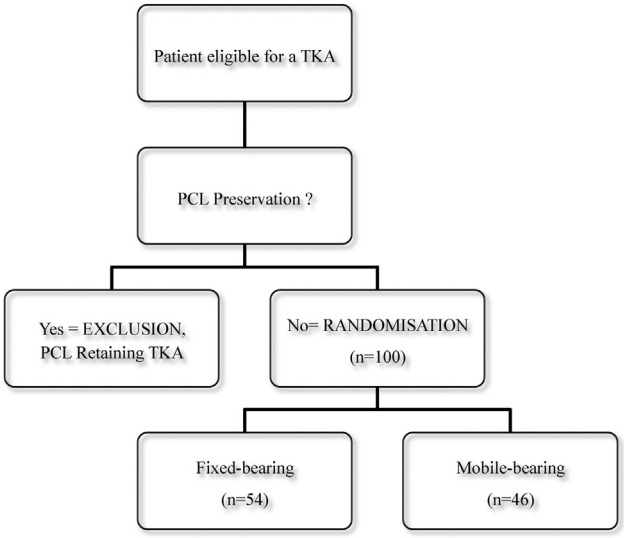

Fig. 1. Flow chart for patient inclusion. TKA: total knee arthroplasty; PCL: posterior cruciate ligament.

bearing allocation was randomised and at least 7 years follow-up was a available.

2. Material and methods

2.1. Patient population

Between January 2001 and December 2005, all eligible patients with a TKA indication were enrolled in the study and treated by a single surgeon at the same healthcare facility using the same perioperative protocol. This resulted in a series of 100 continuous patients being included, without exclusions. All patients provided written informed consent for this study, according to research ethics requirements. During the preoperative phase, all patients were examined by the primary surgeon to establish the Knee Society (IKS) score. All patients underwent a full radiographic assessment with standard weight bearing X-rays and angle measurements. The inclusion was confirmed during the intraoperative phase: only patients in whom the posterior cruciate ligament (PCL) could not be preserved received a posterior-stabilised TKA implant with fixed or mobile bearing according to a pre-established randomisation scheme (Fig. 1). The PCL had to be removed because it was either degenerated or overly taut in flexion. The surgeon decided on the need for implant cementing and patellar resurfacing on a case-by-case basis according to intraoperative findings. In all, 100 posterior-stabilised TKA cases were included, 54 with a fixed bearing and 46 with a mobile bearing. During the postoperative phase, all patients underwent the same rehabilitation protocol with mobilisation and immediate weight bearing.

2.2. Implants

All patients received the same implant model: Natural-Knee II with metal-backed tibial baseplate and ultracongruent Durasul® highly crosslinked polyethylene insert to provide posterior stabilisation (Zimmer®, Warsaw, Indiana, USA). In the patients receiving fixed-bearing inserts, the tibial component was cemented in four cases and fixed with a screw (without cement) in all the other cases (Fig. 2A and B). In the patients receiving mobile-bearing inserts, one with a central keel that allowed for rotation, the tibial baseplate was not cemented (Fig. 2C).

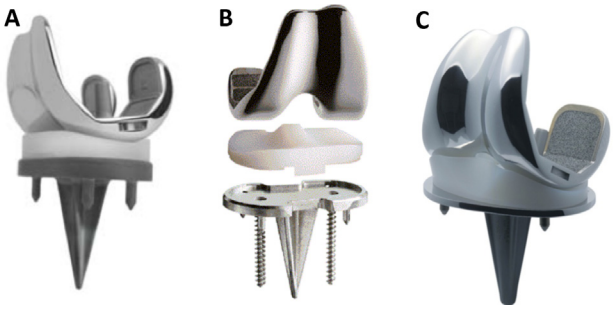

Fig. 2. Natural-Knee II (Zimmer®) with fixed bearing (A, B) and mobile bearing (C).

2.3. Follow-up

All the included patients were reviewed during 2013 by an independent observer and were assessed radiographically. The follow-up visit consisted of clinical examination with the scores described below and analysis of the radiographs.

2.4. Study variables

2.4.1. Clinical scores

Patient satisfaction was evaluated through the "forgotten knee" concept and by closed-ended question with three possible answers: very satisfied, satisfied, disappointed. The International Knee Society (IKS) score [14] was determined using the same procedure as the preoperative assessment. The French version [15] of the Oxford self-administered quality of life questionnaire [16] was given to the patients and the grading system initially described by ISIS was used.

2.4.2. Radiographic evaluation

All patients were evaluated with a goniometer and radiographs at the last follow-up to qualitatively determine signs of polyethylene wear, loosening or osteolysis (Fig. 3).

2.5. Statistical methods

The two groups were randomised before being included in the study according to a pre-established scheme, which ensured the groups were independent. This independence was verified using age, sex ratio, aetiology, preoperative ROM and IKS score criteria. The outcomes of these two groups were then compared using univariate analysis. Student's *t*-test was used with continuous variables and Fisher's exact test with quantitative variables. The risks of making an α or β error were set at the standard clinical levels of 5% and 20%, respectively. Quantitative results were expressed as mean and standard deviations values.

3. Results

3.1. Study population

The 100 TKA cases corresponded to 98 patients (2 bilateral procedures) having a mean age of 73 ± 6.5 years at the time of the procedure. Of the 98 patients who were initially included, 22 died before the final review, 15 were lost to follow-up and 2 were excluded because their knee could not be evaluated. Of the 61 remaining patients, 30 had undergone TKA with a mobile-bearing insert and 31 with a fixed-bearing inset. There were no significant differences in terms of the sex ratio, age, preoperative range of motion and IKS score between the two groups (Table 1).

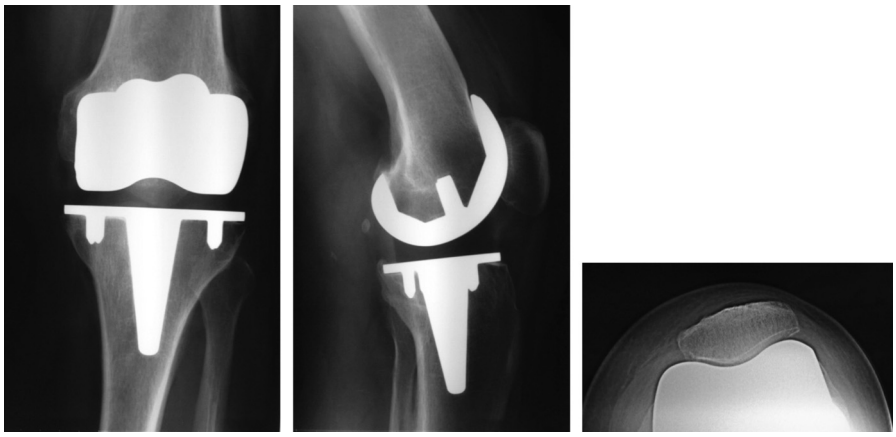

Fig. 3. Radiograph of mobile bearing implant after 10 years.

Table 1
Demographic data.

	Fixed bearing	Mobile bearing	*P*
n	31	30	
Male	13	14	1
Female	18	16	1
Age	72 ± 6	70 ± 6	0.29
Osteoarthritis	30	29	1
Osteonecrosis	1	1	1
Preoperative ROM	118° ± 11	117° ± 13	0.79
Preoperative IKS	51 ± 13	55 ± 13	0.21

ROM: range of motion.

3.2. Clinical results

Patients were reviewed after a mean of 9 ± 1.3 years and a minimum follow-up of 7 years. The patients' subjective evaluation indicated that 84% of those in the fixed bearing group and 96% of those in the mobile bearing group were satisfied or very satisfied with the outcome (Table 2). This difference between groups was not significant. In the fixed bearing group, 61% said they had "forgotten" about their knee, while 50% of the patients in the mobile bearing group stated the same ($P = 0.67$).

There were no significant differences between the two bearing types in terms of the range of motion: 118 ± 10° for the fixed bearing group and 117 ± 16° for the mobile bearing group. Nine years after the procedure, the ROM was identical to the preoperative value. The IKS revealed good outcomes after 9 years follow-up, with the results being slightly better, but not significantly, in the mobile bearing group. The Oxford functional evaluation did not reveal any significant differences between the fixed bearing and mobile bearing groups (Table 3, Fig. 4).

3.3. Radiography results

Analysis of the postoperative X-rays did not reveal any differences between groups. Similarly, at the last follow-up, neither group had more cases of loosening or joint space narrowing (Fig. 5). Conversely, the two groups differed significantly in terms of the appearance of tibial osteolysis at the last follow-up (Fig. 6). All eight cases of osteolysis occurred in patients who received fixed-bearing implants with non-cemented tibial components. Seven of these cases occurred with a screwed tibial baseplate. Overall, the risk was greater in the fixed-bearing group and resulted in three revisions procedures being performed because the osteolysis had breached the cortex (Table 4).

Table 2
Subjective results.

	Fixed bearing	Mobile bearing	*P*
Very satisfied	20	20	1
Satisfied	6	9	0.56
Disappointed	5	1	0.20
Forgotten Knee	19	15	0.67

Table 3
Objective results.

	Fixed bearing	Mobile bearing	*P*
ROM	118° ± 10	117° ± 16	0.69
Function score	77.1 ± 24.1	86.8 ± 18.3	0.09
Knee score	92.3 ± 11.7	91.1 ± 12.9	0.73
IKS	85.7 ± 15.0	88.9 ± 12.7	0.24
Change in IKS	35.2 ± 18.1	33.7 ± 14.3	0.34
Oxford score	19.4 ± 7.5	19.4 ± 7.2	0.98

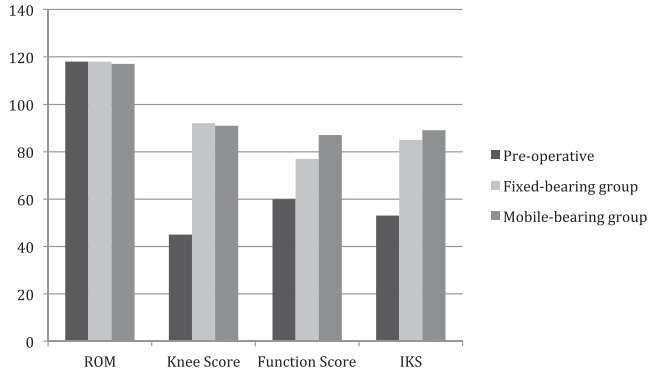

Fig. 4. Summary of objective data. ROM: range of motion; IKS: International Knee Society score.

Table 4
Radiographic results.

	Fixed bearing	Mobile bearing	*P*
Valgus	13	9	0.45
Varus	9	15	0.46
Average deviation	1.8° ± 1.4	2.0° ± 1.4	0.63
Joint space narrowing	4	0	0.11
Femoral loosening	0	0	1
Tibial loosening	0	0	1
Osteolysis	8	0	0.006

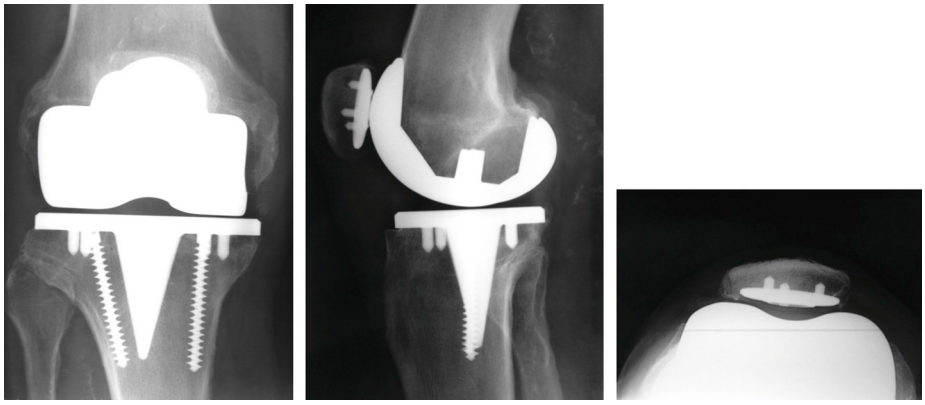

Fig. 5. Radiograph of fixed-bearing implant after 12 years showing joint space narrowing due to polyethylene wear.

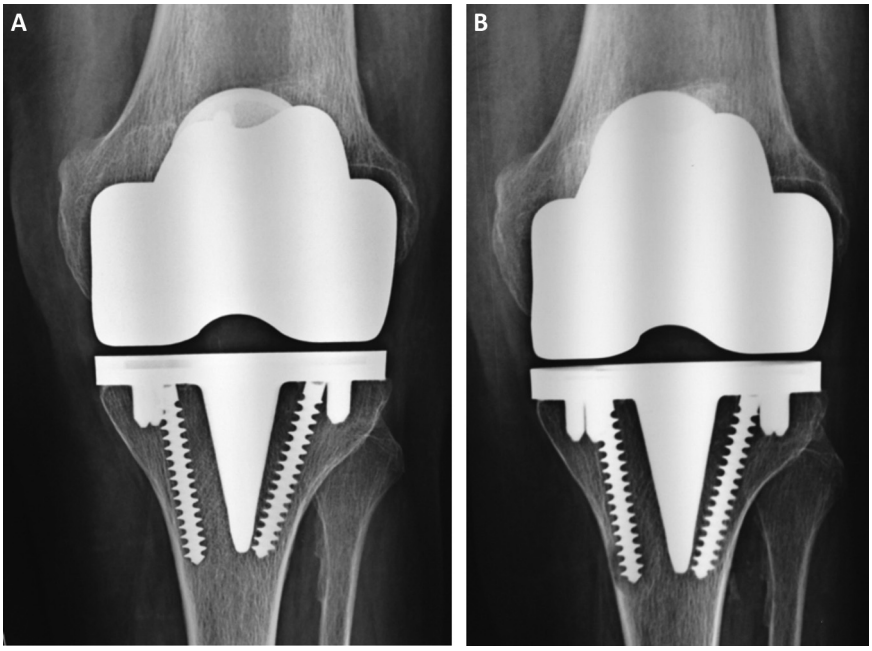

Fig. 6. Normal radiographic appearance after 7 years (A) and appearance of osteolysis along screw after 10 years (B).

3.4. Survival and complications

The overall osteolysis rate was 13%. Since only three cases had to be revised because of osteolysis, the overall implant survival was 95%. Although the three revisions occurred in the fixed-bearing group, this finding was not statistically significant ($P = 0.24$). No occurrence of spinout or dislocation of the mobile bearing was reported during the follow-up period.

4. Discussion

4.1. Summary of results

This randomised study comparing fixed and mobile bearings in the same TKA model sought to determine if a significant difference existed between bearings in terms of clinical scores (Oxford/IKS), wear or radiological signs of loosening. The greater movement resulting from mobile bearings was not apparent clinically, which is consistent with Callaghan's conclusions [17] that the results are comparable when a mobile bearing is inserted with the same accuracy as a fixed bearing. Nevertheless, from a radiology point of view, there was a significant difference ($P = 0.006$) in the osteolysis rate between groups. There were 25.8% more cases of osteolysis in the fixed bearing group, but this did not significantly affect survival after 9 years. This osteolysis problem is attributed to the polyethylene due to creep (Fig. 7) and diffusion of debris along the screws. But the screws are not solely responsible for this problem. Ferguson et al. [18] found no significant differences when groups of screwed and non-screwed tibial components were compared. In the current study, all the cases of osteolysis occurred in non-cemented implants with a fixed bearing; screws were used in all but one of these cases. Hence, this wear can probably be attributed to a type of backside wear that occurs on the underside of the insert where it contacts the baseplate's screw holes.

4.2. Comparison with published studies

Several other published studies exist on this topic, but all have a shorter follow-up than our study. The recent study by Breeman et al. [19], a randomised multicentre study comparing 539 patients with a 5-year follow-up, found no differences in the costs and OKS, SF-12, EuroQol, EQ-5D scores between the two types of bearings. In 2011, Ball et al. [9] published a randomised, prospective, multicentre study comparing two Stryker® implants in 69 patients

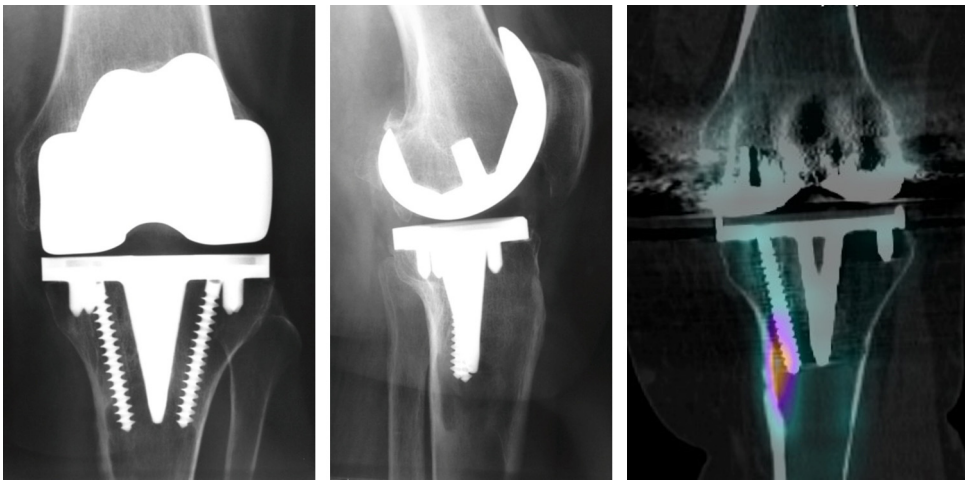

Fig. 7. Single-photon emission computed tomography (SPECT) showing osteolysis at tip of screw.

after 2 years. This study found no differences in the IKS/SF-12 score but found that the IKS Stairs score was significantly higher in the mobile bearing group (44.9 ± 8.7 versus 40.5 ± 11.3, $P = 0.04$). In a level I prospective, randomised study published by Gioe et al. [10], 312 knees were evaluated after 2 years of follow-up. They found no differences in terms of range of motion, survival, radiologic complications, or the IKS/WOMAC/SF-36 scores. Harrington et al. [11] also published a prospective, randomised study comparing 72 fixed bearing cases with 68 mobile bearing cases after 2 years of follow-up; they also found no significant differences on the X-rays and IKS/SF-36/Western Ontario scores. Lädermann et al. [12] conducted a prospective, randomised study comparing 52 fixed-bearing inserts to 52 mobile-bearing inserts. After 7 years of follow-up, they found no significant differences in the IKS/SF-12 scores or in the clinical and radiography outcomes. A prospective randomised study by Aglietti et al. [8] included 210 patients that were reviewed after 3 years. The only clinical difference found was a slight, but significantly greater flexion angle in the fixed-bearing group than in the mobile-bearing group (112° versus 108°, $P = 0.025$). They found no differences in the radiographs or IKS score. Pagnamo et al. [13] compared 80 mobile-bearing cases with 160 fixed-bearing cases (all-PE tibial component or with metal-backed baseplate), but found no differences in the range of motion or patella-related symptoms. In summary, the follow-up in other published randomised studies is equal to or less than 7 years and no noteworthy differences were found for either type of bearing. Comparative prospective studies are rare; only six are listed on the "ClinicalTrials.gov" website: three on going (NCT00435357, Université de Lyon; NCT01290640, University of Tennessee; NCT01361152, Ewha Womans University) and three completed (NCT00894361 [10]; NCT00289107 and NCT00289094, results awaiting publication).

In this study, we found that the postoperative range of motion was the same as the preoperative value. This validates the ability of preoperative flexion to predict the postoperative flexion [20]. The range of motion measured at the last follow-up ($119° \pm 12°$) includes slightly more flexion than that reported in similar published studies (110° to 116° [8–11]), likely because the High-Flex implant was used. Note that Evans et al. [21] retrospectively compared the range of motion of 100 patients with a fixed bearing to 113 knees with a mobile bearing. They found slightly more flexion in the fixed-bearing knees than the mobile-bearing knees ($116 \pm 15°$ versus $113 \pm 11°$) but this difference was not significant ($P = 0.08$). The IKS score in this study (87) was slightly lower than the one reported in other studies (92–95) [8–11], likely because the patients in our study were older than those in other studies. Our findings are consistent with the review of literature performed by Jacobs et al. using the Cochrane database [22], which found no evidence that one type of bearing (fixed or mobile) was better than the other in terms of range of motion or functional outcome, whether the TKA was performed because of arthroereisis (?) or osteoarthritis.

4.3. Strengths and limitations of this study

The large number of patients who died or were lost to follow-up reduced the statistical power of the study, but this seems to be unavoidable in a study where the mean age of patients was 71 years at the time of the procedure and 80 years at the final follow-up. Moreover, it is probable that the subjective outcomes scores used in this study (IKS score, Oxford) were not sensitive enough to detect the small differences expected in the outcomes.

One of this study's strengths is that all the procedures were performed by a single surgeon at a single facility. As a consequence, the sole experimental variable was the type of bearing. And more importantly, this was a Level II randomised study with a substantially long follow-up.

5. Conclusion

Despite the widely accepted success of TKA procedures, one out of five patients remains dissatisfied [23], which lends credence to the attempts to improve the implants. Despite its theoretical advantages, the mobile bearing design has no clinical advantages over the fixed bearing design. It seems well established that the expected benefit is not significant in the short term. In the longer term, its equivalence or even its superiority must still be demonstrated.

By providing a longer follow-up, this randomised, single-centre, single surgeon study validates this hypothesis and starts to reveals differences between fixed and mobile bearings, with some evidence of mobile bearings being better. We found a significantly greater risk of osteolysis after 9 years in the fixed bearing implants. But these cases of osteolysis occurred in patients with non-cemented tibial baseplates that have screw holes, which likely caused backside wear of the polyethylene insert. This difference between the two groups was not clinically meaningful. Similarly, evaluations of the range of motion, subject satisfaction, self-administered questionnaires (Oxford, International Knee Society score) found no significant differences between the fixed bearing and mobile bearing groups.

In all, mobile bearing implants seem to have a subtle advantage relative to fixed bearing implants, but this finding is tempered by the backside wear caused by the presence of screw holes in the fixed bearing implant model used in this study.

Disclosure of interest

N. Poirier and F. Dubrana have no conflict of interest to declare. P. Graf acts as a consultant for Zimmer® and receives royalties from Zimmer®.

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