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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.

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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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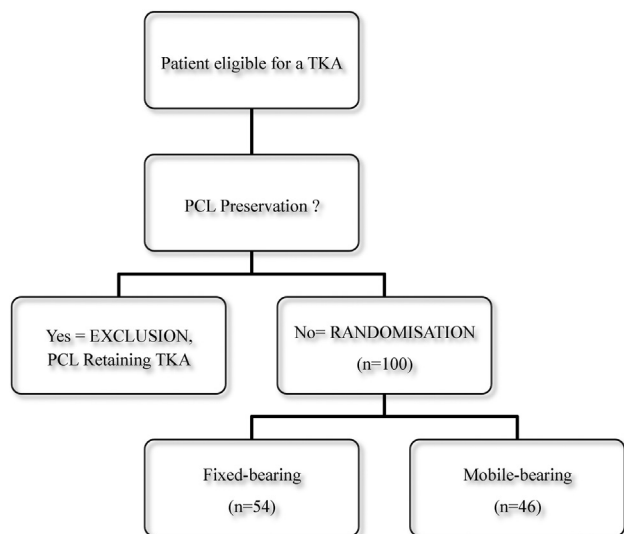


Fig. 1. Flow chart for patient inclusion. TKA: total knee arthroplasty; PCL: posterior cruciate ligament.

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

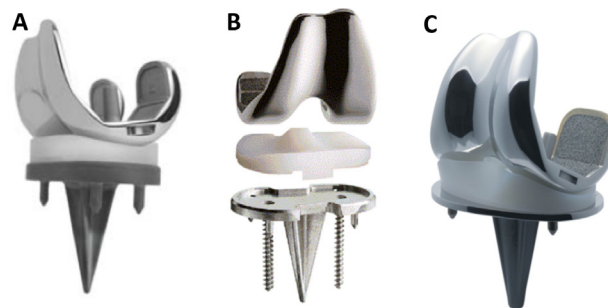


Fig. 2. Natural-Knee II (Zimmer®) with fixed bearing (A, B) and mobile bearing (C).

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 insert. 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).

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