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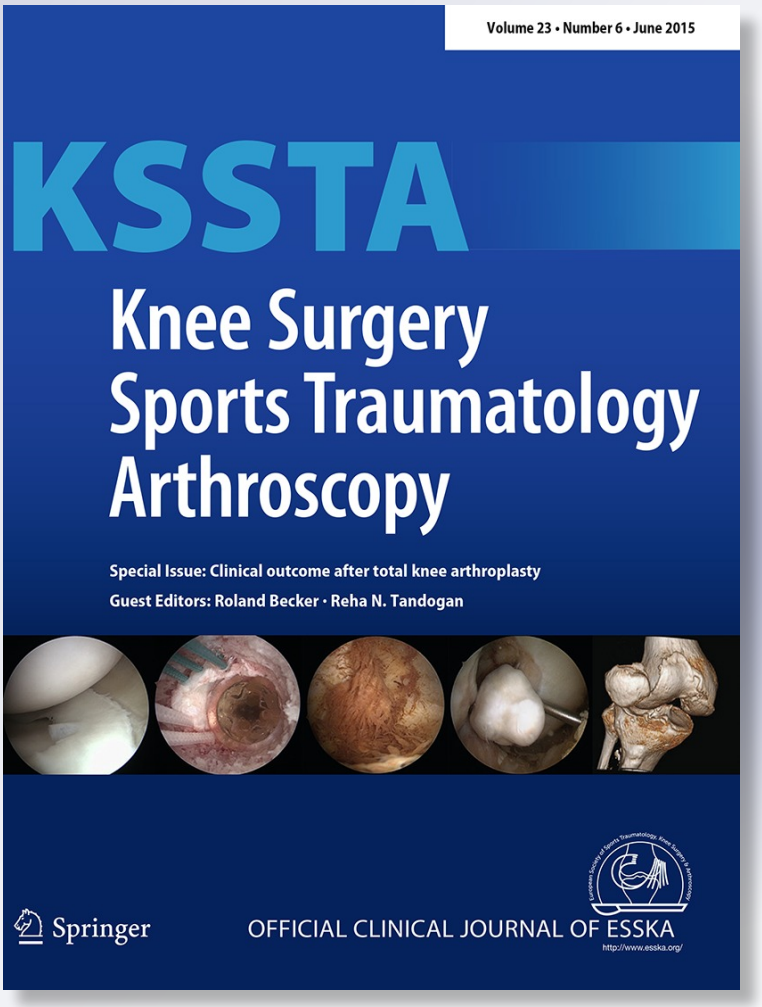

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Survivorship at minimum 10-year follow-up of a rotating-platform, mobile-bearing, posterior-stabilised total knee arthroplasty

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Abstract
Purpose To evaluate prospectively the long-term clinical and radiographic results and survivorship of a rotating-platform, posterior-stabilised knee prosthesis at minimum 10 years (mean 11.5 ± 1.41 years), and to test the hypothesis that this design would have a mechanical survivorship greater than 95 %.
Methods Between 2000 and 2002, 160 consecutive patients (166 knees) underwent total knee arthroplasty using a rotating-platform, posterior-stabilised prosthesis, and clinical and radiographic follow-up data were gathered prospectively.
Results One hundred and seven patients (112 knees) were available for final follow-up. Five patients (3 %) had undergone revision surgery, giving a Kaplan–Meier survival rate of 96.6 % for all causes of failure. No spin-out of the polyethylene insert was observed. The mean visual analogue scale, Knee Society and Oxford Knee Scores showed statistically significant improvements ($p < 0.001$). On radiographs, two cases (2.4 %) had radiolucent lines >2 mm, and no patient had osteolysis.
Conclusions The absence of osteolysis at minimum 10 years seems to support our hypothesis that this design may be able to reduce peri-prosthetic bone resorption in the long term. The survivorship was greater than 95 % and is comparable to the best results reported for this type of knee prosthesis in the literature. The clinical scores are reasonable, given the presence of various disabling concomitant pathologies and the relatively advanced mean age of the study population. This study is clinically relevant because it adds valuable information to the limited data regarding the long-term survivorship and performance of rotating-platform knee prostheses and, more specifically, of a single knee design.
Level of evidence IV.

Keywords Rotating-platform knee · Mobile bearing · Long-term outcome · Survivorship · Comorbidities

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Introduction

Although total knee arthroplasty (TKA) using fixed-bearing implants has provided excellent results even in the long term [32], there are still cases of premature failure for this kind of implant design, which are mainly caused by polyethylene wear and aseptic loosening [28]. The concept of mobile bearing was introduced in knee replacement with the aim of decreasing polyethylene consumption without increasing mechanical forces at the bone–prosthesis interface. Allowing movement between the two tibial components, mobile-bearing knees seemed finally to provide the solution to the well-known wear-conformity dilemma, significantly reducing both the stress at the bone–prosthesis interface and, thanks to the high conformity of the tibial insert, the polyethylene wear.

In-vivo fluoroscopic analyses have shown better kinematic behaviour in mobile-bearing knees when compared with fixed-bearing knees [11, 12, 16]. In addition, in vitro knee simulator studies have demonstrated decreased volumetric polyethylene wear with unidirectional mobile bearing in comparison with fixed-bearing knees [23].

Over the last few years, a purely rotating-platform design has emerged as the most clinically successful mobile-bearing design. However, fluoroscopic studies have shown erratic movements (e.g. paradoxical anterior sliding of the femur) during deep flexion in non-stabilised mobile-bearing designs, and in a significant percentage of low contact stress (LCS) rotating-platform implanted knees, the occurrence of subluxation or dislocation of the bearing (i.e. "spin-out") has been observed [16, 30]. The incidence of dislocation was higher with the cruciate-retaining meniscal-bearing prostheses than with the cruciate-sacrificing rotating-platform models [2, 7]. For these reasons, a post-and-cam mechanism was incorporated into the design, in order to obtain a consistent posterior rollback and a better flexion. The posterior-stabilised rotating-platform design promised the benefits of previous versions, reducing wear of the polyethylene surfaces and minimising unwanted roll-forward of the femur.

In spite of the favourable research data about mobile-bearing knees, limited information exists about long-term clinical results, survival rate and longevity of the rotating-platform posterior-stabilised design, and they are mainly related to the LCS rotating-platform knee (DePuy, Warsaw, Indiana), which shows a reported mechanical survival rate of 97 % at 10–12 years [17]. The data are slightly better than the 90–95 % survival rate reported for fixed-bearing designs [14, 32] and comparable to the best results reported in the literature for mobile-bearing prostheses [27]. The rotating-platform, posterior-stabilised knee design used in this study (press fit condylar—PFC Sigma, DePuy, Warsaw, Indiana) was conceived with the purpose to ameliorate the LCS design avoiding the reported polyethylene insert spin-out from the tibial tray and improving the range of motion [6, 8].

Therefore, the aim of this prospective study was to evaluate the long-term performance of this implant design and to test the hypothesis that it would show a sufficiently low rate of wear and osteolysis to guarantee a survivorship greater than 95 % at minimum 10 years. The clinical and radiographic results, and a Kaplan–Meier survival analysis at a minimum of 10-year follow-up, are presented.

Materials and methods

Between 2000 and 2002, a single surgeon implanted a mobile-bearing, rotating-platform, posterior-stabilised prosthesis in 160 consecutive patients (166 knees). The patella was not resurfaced. One hundred and thirty patients were female (81 %), and 30 were male (19 %). Six female patients were operated bilaterally. The diagnosis was primary arthritis in all patients. The mean age was 73 ± 6.4 (range 57.1–88.4) years. The mean BMI was 29 ± 5.2 (range 16.9–47.3) kg/m^2. Preoperative alignment of the limb was varus in 57 % of cases, valgus in 22 % and neutral in 20 %. All patients signed an informed consent prior to their participation in the study.

Assessments

Patients were prospectively monitored, and their data were stored electronically (Excel, Microsoft, Redmond, WA, USA). Follow-up visits were performed at 3 and 6 months, then at 1, 2 and 5 years and for this study, at a mean of 11.5 years. They were assessed by a single examiner, according to the Knee Society Score (KSS) [18] and the Oxford Knee Score (OKS, using the 0-48 scoring method) [9]. At final follow-up, patients unable to come to the hospital were visited at home to ascertain the status of the implant, functional KSS and OKS. In the case of patients who had died, members of the family or the patient's GP was contacted to obtain information regarding whether any revision surgery had been carried out on the operated knee. Active flexion was measured and recorded to the nearest degree pre-operatively and at all clinical follow-ups using a handheld goniometer, using skin markings to indicate the long axes of the tibia and femur, and the centre of axis on the lateral femoral epicondyle. Pain was measured on a 0–10 point visual analogue scale (VAS) and recorded to the nearest whole number.

Radiological assessment (weight-bearing anteroposterior, lateral and 30° tangential patellar views) was performed both pre-operatively and immediately post-operatively, and then at each subsequent follow-up visit. A detailed analysis was made of the radiographs at final follow-up, using Imagika software (View Tec, St-Maurice, France). Radiolucent lines (RLLs), loosening, osteolysis, component position and malalignment were evaluated according to the criteria defined by the Knee Society [13]. RLLs were recorded to the nearest tenth of a millimetre. The position of the patella was evaluated according to the Merchant technique [25] and the Insall–Salvati index [19].

Patients received an antibiotic prophylaxis of 2 gr. i.v. Cefazoline. Those patients who were allergic to penicillin and/or cephalosporines were given a prophylaxis of 500 mg i.v. of vancomycin. A daily subcutaneous anti-thrombotic prophylaxis of Enoxaparine 4000 UI was used for the first 35 days post-operatively.

All operations were performed by the same surgeon (M.U.), and in all cases, a cemented PFC Sigma rotating-platform posterior-stabilised prosthesis was implanted (DePuy, Warsaw, Indiana) (Fig. 1). Close attention was paid to the soft tissue balancing (medial release in 67.5 % of cases, and iliotibial tract release in 11.4 % of cases). Where necessary, posterior femoral osteophytes were resected, and the posterior joint capsule was detached. A

patelloplasty was performed if necessary, which included circumferential rim cautery for partial denervation, osteophyte removal and downsizing or contouring to the original anatomy. In 18.7 % of cases, a lateral release was carried out to establish a normal patellar tracking.

All patients were allowed to walk after 48 h with the aid of two crutches or a walker. Approval to perform the study was given by the ethical committee of the ASL of the Province of Monza and Brianza, Italy (Prot. ASLMB 3261).

Fig. 1 PFC Sigma rotating-platform posterior-stabilised implant

Statistical analysis

Two survivorship analyses were performed using the Kaplan–Meier method and the Peto method for confidence intervals (Stata statistical software, Statacorp Ltd, TX, USA). In the first analysis, the endpoint was the requirement for revision of the implant for any reason. The second survivorship considered the requirement for revision of the prosthesis for mechanical reasons as the endpoint. The Student's *T* test was used to measure statistical significance of the pre- and post-operative clinical scores. The sample size calculation showed that the KSS and VAS scores had at least 95 % power when a two-tailed alpha value of 0.05 was accepted to determine statistical significance, and an 89 % power for the OKS scores.

Results

The mean follow-up period was 11.5 ± 1.4 years. At final follow-up, the mean patient age was 82.1 ± 4.0 years. The details of follow-up and implant status are given in Fig. 2. Of the five patients (3 %) who had undergone revision of the implant, one implant was revised due to infection (in a patient who had died before 10-year follow-up), one for aseptic loosening, and two patients underwent subsequent patella resurfacing due to intractable patella pain. The fifth patient reported fracture and dislocation of the patella after trauma. During subsequent osteosynthesis and quadricipital tendon repair, the patella was also resurfaced. There were no cases reported of polyethylene insert spin-out.

At the minimum 10-year final follow-up, 83 patients (88 knees—53 %) were evaluated clinically and radiologically at our Institute, whilst 17 patients (10.2 %) underwent functional assessment during dedicated home visits. We also obtained information regarding the clinical status of the implant for seven subjects (4.2 %) who were unable to participate in the final follow-up stage of the study, and these data were used in the survivorship analysis. A variety of minor to severe concomitant diseases were reported at final follow-up (Fig. 3). Indeed, only 23 patients (21.5 %) were not suffering from any coexistent medical condition.

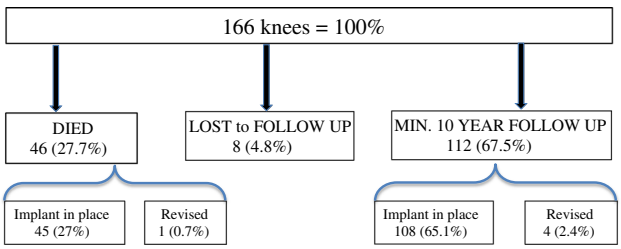

Fig. 2 Patients followed-up and implant status

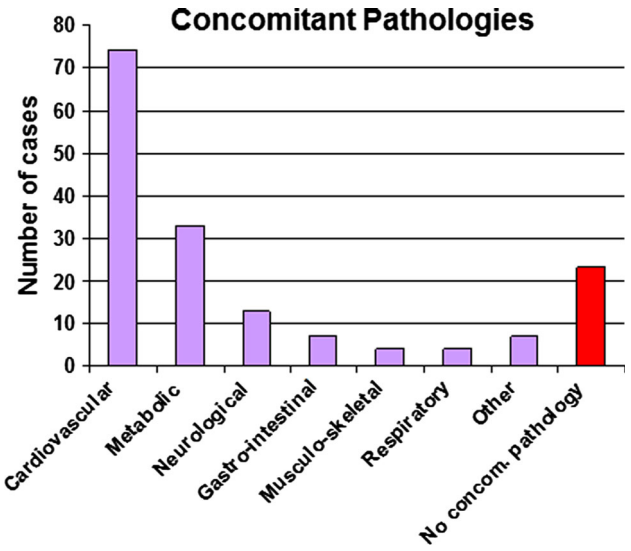

Fig. 3 *Cardiovascular* hypertension, cardiac and vascular insufficiency, stroke, atrial fibrillation, lymphangitis. *Metabolic* type II diabetes, hyperthyroidism, osteoporosis, dyslipidemia, gout, porphyria cutanea tarda. *Neurological* Alzheimer's disease, multiple sclerosis, epilepsy, sciatica, vascular Parkinsonism, cervical myelitis. *Gastro-intestinal* colon carcinoma, hiatus hernia, diverticulosis. *Musculo-skeletal* severe kyphosis, vertebral fracture, bilateral coxarthrosis. *Respiratory* chronic obstructive pulmonary disease, bronchial asthma. *Other* chronic renal insufficiency, prostatic hypertrophy

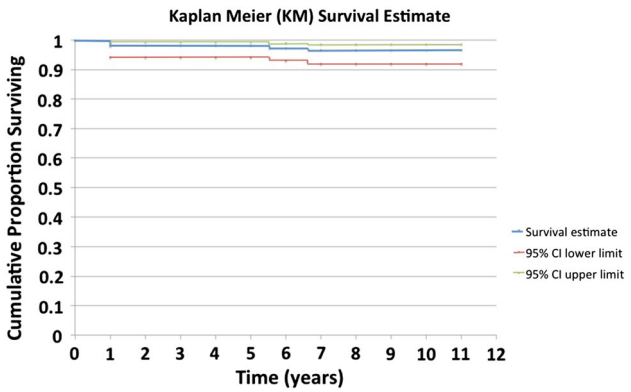

Fig. 4 Kaplan–Meier survivorship analysis with failure for any reason as endpoint

The Kaplan–Meier analysis showed 96.6 % survival (CI 92.0–98.6 %) at 11.5 years when we consider revision for any cause (Fig. 4), and a 100 % survival with mechanical failure as endpoint.

The pre- and post-operative OKS, KSS and functional KSS results are given in Table 1. In 20 of the patients (22.7 %) who were assessed for functional KSS, the concomitant diseases were severe, which negatively impacted on the score. If we exclude these 20 patients from the analysis, the mean score for functional KSS at final follow-up was 68.8 ± 21.2 points ($p < 0.001$).

Table 1 Average clinical scores, pre-operative and at final follow-up

	Pre-operative 166 knees, 160 patients	At final follow-up 105 knees, 100 patients	Significance
OKS	22.9 (range 8–45)	36 (range 12–48)	$p < 0.001$
KSS-F	56.4 (range 0–90)	58 (range 0–100)	(n.s.)
KSS	39.7 (range 10–85)	70.1 (range 26–92)[a]	$p < 0.001$

[a] Post-operatively, KSS was available for 88 knees, 83 patients

Table 2 Knee flexion, pre-operative and at final follow-up

	Pre-operative (166 knees)	Final follow-up (105 knees)
Mean flexion (°)	104.8° ± 11.6° (min. 40°, max. 130°)	106° ± 11.7° (min. 70°, max. 135°)
Flexion >110°	29.5 % (49 knees)	48.6 % (51 knees)
Flexion >120°	12.0 % (20 knees)	19.0 % (20 knees)
Flexion contracture	9.0 % (15 knees) (min. 3°, max. 35°)	4.8 % (5 knees) (min. 10°, max. 40°)

Table 3 Pain symptoms pre-operatively and at final follow-up

	Pre-operative 166 knees, 160 patients	At final follow-up 105 knees, 100 patients
VAS score	7.6 (range 2–10) points	1.4 (range 0–8) points
Pain at start of walking	150 cases (90.4 %)	32 cases (30.5 %)
Analgesics	154 patients (95.6 %)	45 patients (45 %)[a]

[a] All patients took <3 analgesics/day

Clinical data regarding flexion are given in Table 2. The improvement at final follow-up was not statistically significant ($p = 0.36$). The reduction in pain, as measured on the VAS 0–10 point scale, was significant at $p < 0.001$ (see Table 3).

The prevalence of anterior knee pain at final follow-up was 16.2 % (17 knees). Two patients (1.7 %) declared themselves dissatisfied with the result of their TKA, and one was doubtful about the result. The first patient had a severe flexion contracture (40°), but had not followed the rehabilitation protocol, and refused manipulation under anaesthesia. The second patient was suffering from multiple sclerosis and had severe muscular impairment.

It was possible to perform a radiological evaluation at final follow-up for 88 cases (83 % of the final cohort). RLLs were observed around 16 implants (19.2 %), but in only two cases (2.4 %) they were >2 mm. Six of the cases with a RLL related to the tibial component (range 0.6–2.4 mm), five of which were in Zone 1 and one in Zone 4. With regard to the femoral component, there were eight

cases with a RLL in Zone 1 (range 0.4–2.5 mm) and one case each with a RLL less than 0.8 mm in Zones 2 and 3. No osteolysis was detected on the radiographs.

The mean femoral angle and mean femoral flexion were 95.2° ± 3.8° (min. 86.0°, max. 103.0°) and 3.4° ± 1.7° (min. 0°, max. 6.5°), respectively. The mean tibial angle and mean tibial slope were 89° ± 2.4° (min. 83.9°, max. 93.0°) and 85.4° ± 3.4° (min. 77.6°, max. 96.0°), respectively. At final follow-up, according to the Insall–Salvati index [19], in 71.6 % of cases the patellar position was neutral; in 22.7 % it was high; and in 4.5 % it was low. In 35 cases (39.8 %), the patella was lateralised. One patient who had fractured and dislocated their patella was excluded from the radiographic analysis of the patellar alignment.

Discussion

The development of mobile-bearing systems has been one of the most significant recent advances in knee arthroplasty, because they offer possible solutions to the limitations of the fixed-bearing designs. Indeed, a significant decrease in polyethylene wear compared with that of fixed-bearing modular designs has been reported in studies employing simulator devices [3, 23, 26]. It is reasonable to suppose that this should increase mechanical survival rates. Furthermore, it was assumed that patients who had undergone mobile-bearing TKA would have experienced rotational kinematics similar to the normal knee and superior to fixed-bearing knees. In fact, fluoroscopic studies have shown better kinematics in mobile-bearing knees [12], although paradoxical movements have been observed with non-stabilised mobile-bearing designs [16].

In an attempt to improve these kinematic incongruencies and to avoid the risk of bearing spin-out reported in the Literature, mobile-bearing posterior-stabilised knee designs based on a cam-post system have been introduced. This should induce femoral rollback during flexion in the same way as in fixed-bearing posterior-stabilised designs, and indeed, mobile-bearing posterior-stabilised knee replacements have demonstrated greater and more natural internal rotation of the tibia during flexion than fixed-bearing posterior-stabilised designs [10].

In order to confirm these theoretical advantages, long-term studies investigating wear-related osteolysis and implant survival rates are necessary. As rotating-platform, posterior-stabilised implants have been developed relatively recently performance data are limited and relate to shorter follow-up periods [1, 15, 21, 22, 29]. The PFC Sigma rotating-platform posterior-stabilised prosthesis was introduced in 2000, and surprisingly, there is only one report concerning the performance and survival at least 10 years of this prosthesis [24]. Additionally, there are four studies that report results for the PFC Sigma rotating-platform posterior-stabilised prosthesis; however, they relate to short and medium term results, with minimum follow-up ranging from 13 months to 6.5 years [15, 21, 22, 29].

As said above, the only report that resembles ours in terms of follow-up and sample size is that published by Meftah et al. [24]. They reported the results at mean 10 years of a consecutive cohort of 117 patients (138 implants) with a mean age of 68.4 years, who underwent TKA using the PFC Sigma rotating-platform posterior-stabilised prosthesis. The survivorship was similar to that observed in this study with 100 % for mechanical failure and 97.7 % failure for any reason. There were statistically significant improvements in all the clinical measurements reported: mean KSS was 94.3 (44.1 pre-operatively); mean functional KSS was 90.2 (39.4 pre-operatively); and mean ROM improved from 111° to 119°. Although the mean age of the study group was significantly lower than in our cohort, the orthopaedic knee scores are clearly better than those we observed, particularly in terms of flexion and function.

However, as observed by Bremner-Smith et al. [4], it is important to take account of demographic and nosological variables when comparing functional outcomes after TKA, both when comparing scores between different study populations and when comparing different scoring systems within the same population. It has been shown that as patient age increases, and in the presence of concomitant pathologies, the orthopaedic scores—and particularly the functional component—tend to worsen [4, 5, 20]. Our study cohort, with a mean age of over 82 years at follow-up, suffered from a high level of minor to severe concomitant medical conditions, which we believe explains the difference between our results and those of Meftah et al. Furthermore, it is interesting to note that the mean OKS functional score of our cohort did show a statistically significant improvement post-operatively ($p < 0.001$), whilst the functional component of the KSS remained almost unchanged. It is reasonable to suppose that this incongruity is due to the fact that the OKS examines the ability to perform functional tasks with specific relevance to the operated knee, whereas functional KSS measures the overall ability of the patient to perform a functional task. Thus, a patient who has a good clinical result for their knee prosthesis, but with an invalidating coexistent medical condition, could conceivably score well on the knee-specific OKS, but much lower on the functional KSS.

In the three short-term follow-up reports, mean flexion remained largely unchanged at final follow-up at 120° [29] 109° [15] and 104° [1], respectively. In the two mid-term studies, mean flexion post-operatively was 120° [22] and

119° [21]. Although the mean flexion we observed of 106° is one of the lowest reported, we believe that the above-mentioned characteristics of this particular patient cohort may provide an explanation for this result.

Of the 17 cases with anterior knee pain at final follow-up, radiographs were available for 14 of these cases. In eight of them, the patella was lateralised, and there was one case where the patella was fractured and dislocated. All of these cases had a normal patella height according to the Insall–Salvati index [19]. During the follow-up period, two cases had required patella resurfacing for intractable pain at 2 and 5 years post-operatively, but at final follow-up they were without anterior knee pain. Meftah et al. [24] reported 7.5 % of cases with anterior knee pain. They also observed 9.4 % of cases with asymptomatic crepitation and 3.8 % of painful crepitation requiring scar excision. Neither of these complications was observed in this study. Maniar et al. [22] reported patello-femoral pain and crepitus in 5 % of knees. A relatively high number of lateral patellar releases were performed to correct maltracking. This may be a reflection of the large number of valgus knees (22 %), in a predominantly female cohort.

In the 88 cases that had radiographs for review at final follow-up, there were no signs of osteolysis. There were 16 non-progressive RLLs, of which two were greater than 2 mm (Fig. 5). These data favourably compare with the other reports concerning this implant design where no osteolysis or loosening was observed except in one asymptomatic case with RLLs >10 mm and clear signs of tibial loosening [21]. Small RLLs were also observed in two other studies at mid- and long-term follow-up: Maniar et al. [22] reported eight cases of non-progressive RLL lines, seven of which concerned the tibial plate, and Meftah et al. [24] reported three RLLs (two tibial and one femoral).

One of the more common complications of the LCS rotating-platform designs was spin-out of the polyethylene insert (up to 1 % of cases) [31]. However, with this specific posterior-stabilised design, spin-out seems to be less of a concern; in our series, there were no cases, and indeed, there has only been one case of spin-out reported in all the published studies to date [15]. This can be attributed to two factors: firstly, a proper surgical technique, with accurate flexion–extension gap balancing; and secondly, the bearing design with an adequate jump height (16 mm from the post-cam contact to the apex of the post).

Over the years, expectations of the duration of prosthesis life have steadily increased. When evaluating which prosthesis to implant, the surgeon needs to consider how it will perform in the long term, not just in the first 3–5 years. Therefore, long-term clinical studies are vital for assisting in the choice of implant. There are few studies with long-term results for rotating-platform prostheses, and our study is only the second to review the PFC Sigma design. It

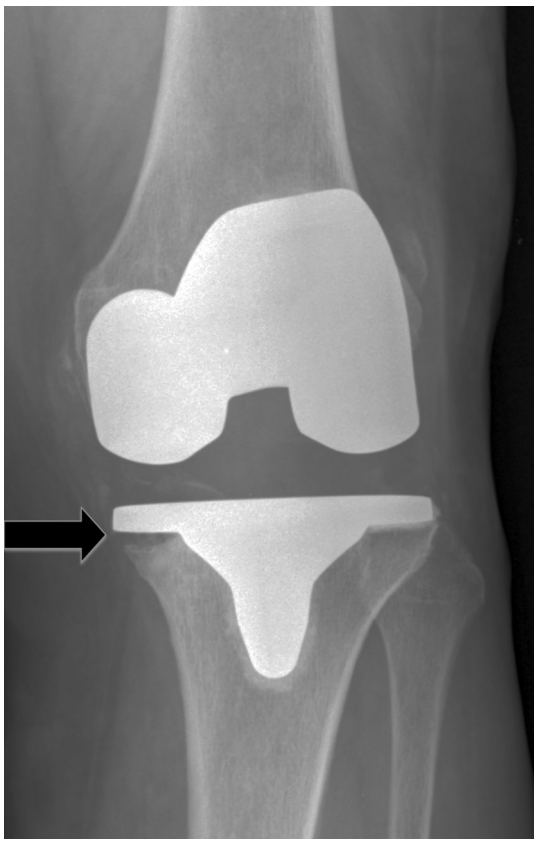

Fig. 5 Anteroposterior radiograph at 11.4 years post-operatively, showing a radiolucency in Zone 1 of the tibial implant >2 mm

confirms the findings of the one other study; this implant has a good long-term survivorship, even, as in this case, in a patient cohort with important concomitant medical conditions, which could conceivably affect the performance of the prosthesis. This study is limited by the lack of a control group implanted with a fixed-bearing prosthesis and by the number of patients who had either died or were lost to follow-up, which reduced the quantity of radiographical data at final follow-up. Although this is the second long-term follow-up study about the PFC Sigma rotating-platform posterior-stabilised knee implant, we believe that the specific characteristics of our cohort (relatively advanced age and remarkable comorbidities) differentiate this study from other reports previously published on the subject.

Conclusion

In this study, the use of the PFC Sigma rotating-platform posterior-stabilised implant produced a minimum 10-year survivorship greater than 95 %, comparable to the best survivorship rates reported for fixed-bearing TKA. The clinical scores are reasonable, taking into consideration the relatively advanced mean age of the study population and

the presence of various disabling concomitant pathologies. Nevertheless, further prospective studies with longer follow-up are required to validate our findings and to confirm the theoretical advantage of a mobile-bearing design in terms of wear and osteolysis.

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