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The Knee

A prospective randomised study comparing rotating platform and fixed bearing total knee arthroplasty in a cruciate substituting design — Outcomes at two year follow-up

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ABSTRACT

Background: Fixed bearing (FB) total knee replacement is a well established technique against which new techniques must be compared. Mobile bearing (MB) prostheses, in theory, reduce polyethylene wear but the literature is yet to provide evidence that they are superior in terms of function or long-term survivorship. In addition there has been no comparison of patella resurfacing on the outcome of either design. The aims of this randomised prospective study were firstly to determine whether a mobile bearing prosthesis produced better clinical outcome and range of motion at two year follow-up and secondly to assess the effect of patella resurfacing on the outcomes of both types of bearing design.
Methods: Three hundred fifty-two patients were randomised into receiving either a PFC Sigma© cruciate sacrificing total knee arthroplasty either with a mobile bearing or a fixed bearing, with a sub-randomisation to either patella resurfacing or patella retention. All patients participated with standard clinical outcome measures and had their range of motion measured both pre-operatively and at follow-up.
Results: The mobile bearing TKR design had no impact on range of motion; Oxford Knee Score and American Knee Society knee and function scores when compared to its fixed bearing equivalent.
Conclusions: At two year follow-up there was no difference between the PFC Sigma© fixed and mobile bearing designs. With no clinical difference between the cohorts, we cannot recommend one design over the other. Long term benefits, particularly with regards to polyethylene wear, may yet be demonstrated.
Level of evidence — 1B.

1. Introduction

Fixed bearing (FB) total knee arthroplasty is well established with successful long term follow-up for patients with osteoarthritis [1,2] As the demographic of patients undergoing total knee arthroplasty changes to a younger more active population, newer designs have been developed with the aim of improving survivorship and clinical outcomes. In fact single component mobile bearing designs have been around for some time and were first introduced by Buechel and Pappas in 1979. Successful long term results have been published [1,3,4] but there are fewer studies comparing outcomes directly between fixed and mobile bearing designs.

Mobile bearings (MB) were developed to reduce the peak loading stresses and backside wear observed as a cause of aseptic loosening in FB designs [9]. To achieve this they have a more conforming articular design which, in theory, reduces the contact stresses [1,5–8]. In addition, a mobile bearing has the potential to correct any rotational mal-alignment of the femoral and tibial components by allowing the extensor mechanism to self-align throughout a range of motion; enhancing both patello-femoral and tibio-femoral mechanics. There have been concerns raised however about the risk of dislocation of a mobile bearing and some reports of early back-side wear [1,8,10].

Despite the theoretical advantages of mobile bearings, multiple randomised controlled trials have been published; the majority of which failed to demonstrate significant clinical advantage in both the short and the long term [1,6,7,11–25]. This has been underlined by three different meta-analyses which have all come to the same conclusion [26–28].

The aims of this prospective randomised study were to determine whether there was a difference in outcome and range of motion between a mobile and fixed bearing cruciate sacrificing total knee replacement and at the same time to assess the effect of patella resurfacing on both designs. We present the outcomes at two year follow-up, in what we believe is one of the largest studies reported.

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2. Methods

Three hundred fifty-two patients with osteoarthritis of the knee who required total knee arthroplasty were recruited and enrolled within this randomised prospective clinical trial (Fig. 1). Patients with an inflammatory arthropathy or significant co-morbidity such as history of previous malignancy were excluded from the study as were patients who had had previous surgery to their knee, excluding arthroscopy but including patellectomy. Those patients who required complex primary knee arthroplasty due significant bone loss were also excluded.

The study was subjected to full ethical approval through both the MREC (multisite research ethics committee) and LREC (local research ethics committee) routes. Full approval was granted. Informed consent was obtained from each patient following a full explanation and provision of all necessary patient information.

A single cemented cruciate sacrificing knee design was used in this study (PFC Sigma© Posterior Stabilised, DePuy, Warsaw, IN). The femoral component was constant for all patients with the tibial component being randomised into two main groups (mobile bearing vs. fixed bearing) using a third party computerised randomisation process.

The sample size was calculated to detect a 10 degree difference in the primary outcome measure of post-operative range of motion between the fixed and mobile bearing PFC Sigma© TKR with power of 90% with an α value of 0.05. The minimum number per group required to show a difference was calculated at 133, i.e. a total of 266 patients with 90% power. To account for an attrition rate of 20%, 352 patients were recruited. The study was suitably powered to detect a clinically significant difference of 5 points on the Oxford Knee Score between patellar resurfacing and retention. For 90% power at an α value of 0.05, 76 patients per group were required for this secondary outcome measure.

Table 1
Cohort demographics.

		Fixed bearing	Mobile bearing	P-value
Patients (n)		176	176	
Age	Mean (years)	69.8	70.2	P = 0.70[a]
	(SD)	(8.16)	(7.60)	
	Range	42–89	52–89	
Gender	Female (n)	94	93	P = 1.0[b]
	(%)	(53%)	(53%)	
	Male (n)	82	83	
	(%)	(47%)	(47%)	
ASA	I (n)	66	47	P = 0.03[c]
	(%)	(38%)	(27%)	
	II (n)	100	111	
	(%)	(57%)	(63%)	
	III (n)	9	18	
	(%)	(5%)	(10%)	
	No data (n)	1	0	
		(1%)		
BMI	Mean (kg/m^2)	29.7	31.1	P = 0.28[d]
	(SD)	(4.9)	(5.0)	

[a] P-value based on a two sample t-test with equal variance.
[b] P-value based on Fisher's Exact test.
[c] P-value based on Chi-squared test.
[d] P-value based on a Wilcoxon rank sum test.

The 352 patients were recruited at their pre-operative assessment appointment and randomised into receiving either a fixed modular tibial component (176 patients) or a rotating platform tibial component (176). There was no significant difference between the two groups [Table 1]. Further sub-randomisation was performed within each of

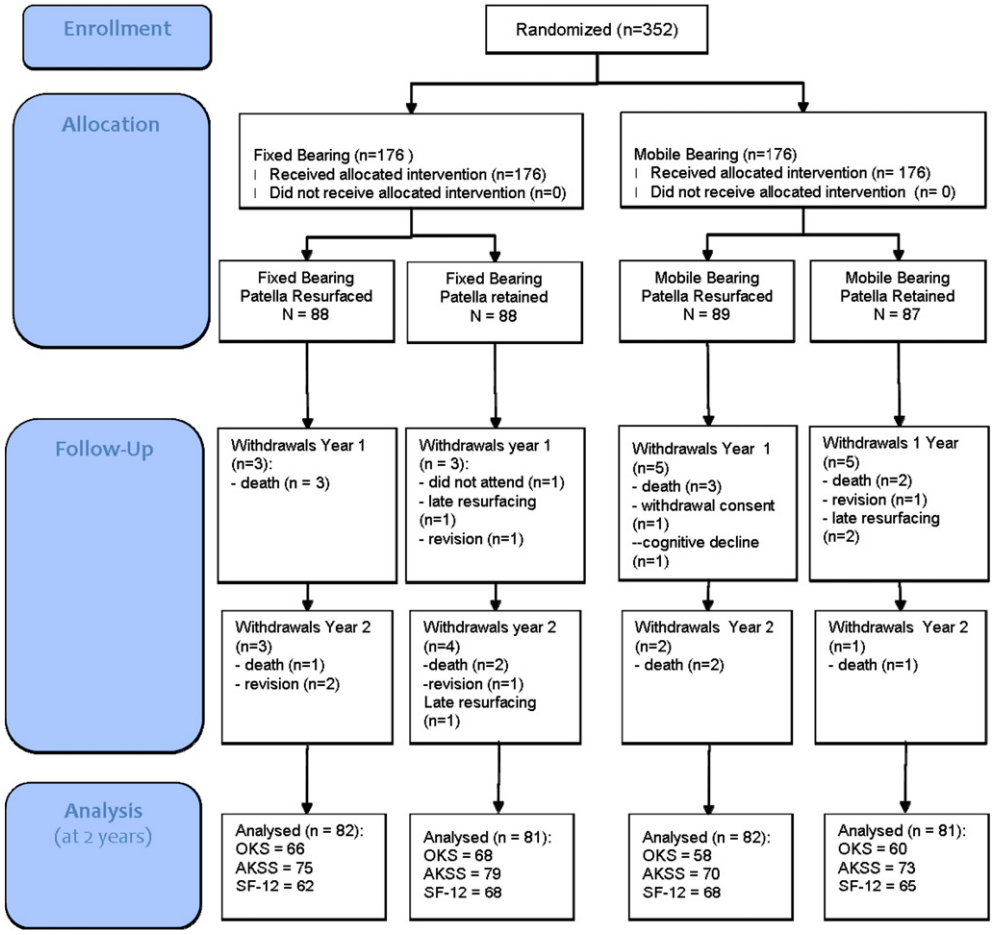

Fig. 1. Consort diagram.