

# A mobile-bearing total knee prosthesis compared with a fixed-bearing prosthesis

A MULTICENTRE SINGLE-BLIND RANDOMISED CONTROLLED TRIAL

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**B**efore proceeding to longer-term studies, we have studied the early clinical results of a new mobile-bearing total knee prosthesis in comparison with an established fixed-bearing device. Patients requiring bilateral knee replacement consented to have their operations under one anaesthetic using one of each prosthesis. They also agreed to accept the random choice of knee (right or left) and to remain ignorant as to which side had which implant. Outcomes were measured using the American Knee Society Score (AKSS), the Oxford Knee Score (OKS), and determination of the range of movement and pain scores before and at one year after operation.

Preoperatively, there was no systematic difference between the right and left knees. One patient died in the perioperative period and one mobile-bearing prosthesis required early revision for dislocation of the meniscal component.

At one year the mean AKSS, OKS and pain scores for the new device were slightly better ( $p < 0.025$ ) than those

for the fixed-bearing device. There was no difference in the range of movement.

We believe that this is the first controlled, blinded trial to compare early function of a new knee prosthesis with that of a standard implant. It demonstrates a small but significant clinical advantage for the mobile-bearing design.

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Mobile meniscal-bearing knee replacements have some theoretical advantages over fixed-bearing devices, but there are no published comparative trials which have shown any clinical benefits either in the short-term outcome or long-term survival.<sup>1</sup> Between 1996 and 1997, we carried out laboratory tests of a new design of mobile-bearing total knee prosthesis (Total Meniscal Knee (TMK); Biomet Merck, Bridgend, UK). The studies included mechanical tests of the strength of the components, simulated wear tests and cadaver studies to investigate patellar tracking and assessment of the risks of dislocation of the bearing.<sup>2</sup> We then decided to submit the new implant to a randomised, controlled clinical trial as part of its stepwise introduction. Our aim was to ensure that the device was at least as effective in early clinical outcome as a widely used current design of knee replacement, while putting as few patients as possible at risk should it prove to be unsatisfactory.

## Patients and Methods

**Prostheses.** The established fixed-bearing device studied was the posterior cruciate-retaining AGC knee (Biomet Merck) (Fig. 1) which has been used for many years in the centres involved in this study. There is good evidence of its clinical effectiveness and longevity.<sup>3-5</sup>

The mobile-bearing device (TMK) (Fig. 2) is for tricompartmental knee replacement. The femoral component has spherically convex condyles and a toroidally concave patellar groove. The relationship between the patellar groove and the condyles is closely similar to that of the normal anatomy. The non-articular surfaces are similar to those of the AGC knee and both metal-bearing surfaces are polished. The tibial component is the same as the AGC except that its

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Fig. 1a



Fig. 1b

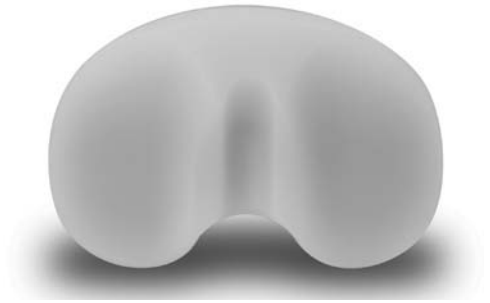


Fig. 1c

Photographs of the AGC knee showing a) the anterior and b) lateral views and c) the fixed-bearing surface.



Fig. 2a



Fig. 2b

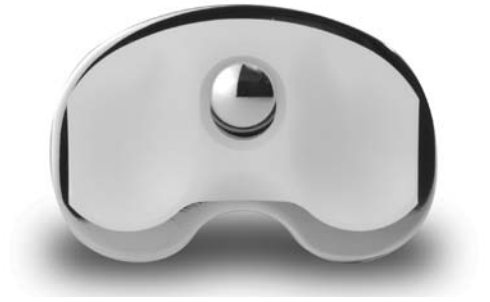


Fig. 2c

Photographs of the Total Meniscal Knee showing a) the anterior and b) the lateral views and c) the mobile-bearing surface.

articular surface is polished metal and flat. The articulation is completed by interposing a mobile polyethylene bearing, which is flat below and has two spherically concave sockets on its upper surface. The intercondylar region of the bearing is perforated by an oval slot fitting loosely over a cylindrical peg in the centre of the tibial articular surface (Fig. 2c). The peg-and-slot mechanism limits anteroposterior (AP) transla-

tion of the bearing to a distance of  $\pm 2$  mm (total 4 mm), but allows unrestricted rotation about an indeterminate axis. The mushroom-shaped top of the peg snap-fits through the slot and holds the bearing down on to the tibial plateau. The implant is designed to be used in knees which lack one or both cruciate ligaments. The anterior cruciate ligament is always sacrificed; if the posterior cruciate ligament is

**Table I.** Details of the 40 patients and the centres at which they underwent bilateral knee replacement

Centre	Mean age in years (range)	Male	Female	Number of patients
Nuffield Orthopaedic Centre, Oxford, England	73.6 (60.6 to 86.4)	7	13	20
Royal Orthopaedic Hospital, Birmingham, England	74.2 (54.8 to 86.1)	5	6	11
The Robert Jones and Agnes Hunt Orthopaedic Hospital, Oswestry, England	64.7 (62.8 and 66.6)	1	1	2
Royal Melbourne Hospital, Melbourne, Australia	72.4 (61.8 to 82.7)	3	4	7
Total	73.1 (54.8 to 86.4)	16	24	40

healthy it is usually retained. Since the non-articular surfaces of the two implants are similar, the AGC instruments were used for implanting both prostheses.

**Design of the trial.** Patients awaiting bilateral total knee replacement at the Nuffield Orthopaedic Centre were invited to have one knee replaced with the mobile-bearing knee and one with the AGC. Before deciding, the patients were given a full explanation of the potential risks and advantages of the new design, verbally and in writing. They were also asked to agree to random selection as to which knee would receive the new implant, and to be kept in ignorance as to which side had been chosen. Three other collaborating orthopaedic centres followed the same protocol. Randomisation was made within 24 hours of surgery and was carried out using a random number generator, at a distant centre, without knowledge of the patient. The surgeon was informed by telephone.

In the absence of any previous data to aid a calculation of sample size, it was decided to start the study and use the first six patients with follow-up of one year to base our final estimate of sample size. The outcome measurements based on the Oxford Knee Score were used in order to calculate the numbers required. In order to detect an effect size of 0.5, corresponding to an anticipated difference of 4 points and a standard deviation of 8 points, with a power of 85% and a significance level of 5%, we calculated that 38 participants were required. In anticipation of a small dropout rate, 40 patients were recruited.

All patients had already been recommended for primary bilateral total knee replacement for osteoarthritis. Previous patellectomy or high tibial osteotomy were considered to be contraindications to inclusion. Table I shows the contributions from each of the four hospitals and gives the basic clinical details of the patients.

**Operative technique.** It is the established practice of all the surgeons involved to undertake bilateral knee replacement sequentially under one anaesthetic and all the patients entered into the study were treated in this standardised way. All the surgeons were experienced in the use of the AGC knee and its instrumentation. None routinely replaced the patella during total knee arthroplasty (TKA). Intramedullary alignment was used for the femur and extramedullary alignment for the tibia, for both types of prosthesis. Some surgeons used tourniquets and some not. There were many other differences between the surgeons in regard to their preoperative, intraoperative and postoperative management of TKA but, because every patient had both knees treated similarly,

these differences were thought to be unlikely to affect the final outcome. The knees were randomised to the AGC or TMK and the decision was then made by the patient as to which knee, left or right, should be done first. At the end of the study the AGC prosthesis had been implanted first in 19 operations, the TMK in 21.

In 24 patients the same surgeon operated on both sides. In 16, different surgeons from the same team operated on each side and in 14 of these the consultants operated on the mobile-bearing side and senior trainees on the AGC side, under the supervision of the consultant.

**Assessment.** Clinical measurements were made preoperatively and at one year. This length of follow-up was chosen because after knee replacement, most improvement in function has occurred within the first year.<sup>6,7</sup> Outcome was assessed using the clinician-based American Knee Society Score (AKSS) (0 to 100)<sup>8</sup> and the patient-based Oxford Knee Score (OKS) (0 to 48).<sup>9</sup> A high score in each system signified a good outcome. The AKSS for both the knee and its function was recorded, but only that for the knee was used for the comparison. The range of flexion was also recorded. Pain was highlighted using the replies to the first question from the AKSS and OKS. For the AKSS the pain scale ranged from 50 (no pain) to 0 (severe pain). For the OKS it ranged from 4 (no pain) to 0 (severe pain).

At review at one year the patients were also asked if either knee 'clicked'. If clicking was reported, it was graded as problematic or non-problematic. The patients were also asked with which knee they were happiest. In 31 patients the clinical measurements at the follow-up at one year were made 'double-blind', in that neither the examiner nor the patient knew which knee contained which prosthesis. In the nine other patients, who all remained 'blind', an examiner who was potentially 'unblinded' made the assessments. Radiographs were taken in the immediate postoperative period and approximately 12 months later.

**Statistical analysis.** The TMK and AGC prostheses were compared using the OKS and AKSS outcomes and pain subsets, with the paired *t*-test applied to the postoperative scores at one year on an 'intention-to-treat' analysis. The proportion of patients reporting that a knee clicked was compared using the chi-squared test; the patients remained blinded as to which knee received which implant. In addition, a patient's preference for one or other type of prosthesis was compared using a sign test. All statistical tests were carried out using SPSS software (SPSS, Chicago, Illinois).

**Table II.** Summary statistics (mean, SD) for the TMK and AGC knees before operation and at follow-up at one year

		OKS		AKSS		Range of movement (degrees)
		Score	Pain	Score	Pain	
Before operation (n = 40)						
TMK		16.6 (6.40)	0.5 (0.60)	32.5 (16.24)	6.3 (8.07)	96.3 (21.27)
AGC		16.9 (6.26)	0.5 (0.68)	32.8 (17.87)	6.5 (9.49)	97.5 (19.71)
At one year follow-up (n = 39)						
TMK		39.3 (7.64)	3.4 (1.11)	90.4 (12.71)	46.4 (10.1)	105.3 (11.90)
AGC		37.6 (8.6)	2.9 (1.15)	84.6 (15.5)	41.5 (12.5)	105.3 (12.59)
Paired difference (TMK – AGC)	Mean	1.72	0.49	5.79	4.87	0.00
	95% confidence interval	0.39 to 3.05	0.13 to 0.84	0.77 to 10.82	0.98 to 8.76	-2.74 to 2.74
Paired <i>t</i> -test <i>p</i> value		0.013	0.009	0.025	0.015	1.0

**Table III.** The percentage of patients reporting scores for their knee prostheses at follow-up at one year

	OKS		AKSS		Range of movement
	Score	Pain	Score	Pain	
Higher score for TMK	44	36	41	31	23
No difference	36	54	26	62	46
Higher score for AGC	21	10	33	8	31

## Results

The bilateral study began in April 1998 and by May 2000, 40 patients (80 knees) had been recruited. One patient died in the immediate postoperative period from a pulmonary embolism. One knee had been revised two weeks after surgery for dislocation of the polyethylene mobile bearing. The operating surgeon had been concerned with regard to the stability of the bearing at the time of implantation. At reoperation, the bearing (6 mm thick) was found to have rotated through 90°. It was replaced with a 12 mm bearing and no further dislocation has occurred. The patient is included in the intention-to-treat analysis. By May 2001 all 39 patients who were still alive had been reviewed at one year. There were no further losses to follow-up.

Preoperatively, there were no obvious systematic differences in the OKS, the AKSS or the range of flexion between the patients' two knees (Table II). Table II shows that at the follow-up at one year, the mean scores for the mobile-bearing device (TMK) were better than those of the AGC, using the AKSS ( $p = 0.015$ ), the OKS ( $p = 0.013$ ) and both measurements of pain (AKSS,  $p = 0.015$ ; OKS,  $p = 0.009$ ). The differences were small, but statistically significant. For example, for the OKS score, the mean difference was 1.72 points (95% CI 0.39 to 3.05) on a scale up to 48. The sensation of clicking was experienced by 18 patients (46%) with the mobile-bearing knee and by nine (23%) with the AGC knee. This difference was statistically significant ( $p = 0.03$ ). In all knees, however, the clicking was considered not to be a problem by the patient.

The proportions of patients reporting their preferences for the two different prostheses are shown in Table III. Of

the 39 patients who were asked the question, 20 (51%) preferred the mobile-bearing device, nine (23%) preferred the fixed-bearing design and ten (26%) expressed no preference for either. Alternatively, two of three patients who expressed a preference (20 out of 29;  $p = 0.06$ ), cited the mobile-bearing knee as their favoured one. At review none of the implants showed radiological signs of loosening or subsidence. The patients' mean preoperative AKSS for function was 44.1 (SD 21.0) and at follow-up at one year was 77.9 (SD 24.7). Since this measurement does not distinguish between the two knees, it is not included in the comparison.

## Discussion

The trial shows that at one year after implantation, the new prosthesis functioned at least as well as the established implant. This was our minimum requirement to justify proceeding with further trials in a wider population to assess the range of suitability, rate of complications and, eventually, the medium and long-term survival of the new design. We believe that this is the first knee prosthesis to have been compared in a controlled study with an established prosthesis before allowing its wider use.

Lack of power in orthopaedic randomised controlled studies has been highlighted as a common flaw in the design of studies.<sup>10</sup> Comparison of the benefits of two different treatments in the same patient has the advantage that 'patient-dependent' prognostic factors are eliminated.

The particular strength of the trial design is that the statistical comparisons are within-patient (paired) and not between-patient as is more typical. The advantages are that fewer patients are required and that confounding factors are

controlled. These problems still occur in traditional parallel group trials despite every effort to minimise the potential for bias.

Fewer patients need bilateral than unilateral surgery and therefore recruitment in a bilateral study is more difficult. This potential problem was overcome by the use of a multi-centre study. The design allows data from four centres to be combined because any differences between their perioperative practices are controlled.

As with any controlled randomised trial of a new surgical procedure the relative experience of the surgeons with each operation is a potential source of bias.<sup>11,12</sup> In our study all the surgeons were highly experienced with the AGC prosthesis, but inexperienced with the new prosthesis. The surgical approach, instrumentation and ligament-balancing techniques are, however, the same for each device. All 16 patients, on whom different surgeons operated, were treated at the Nuffield Orthopaedic Centre. A previous study from this centre showed that the clinical outcome of patients after AGC arthroplasty, with pain as a criterion of failure, was independent of whether the consultant or the trainee had carried out the operation.<sup>3</sup> This suggests that no significant level of surgical bias was introduced by the use of different surgeons in the same team.

The standard methods of assessing general functional improvement after joint replacement depend upon bipedal activities (distance walked, use of a support, stair-climbing) and cannot be used to compare one leg with the other. We used established clinician- and patient-based outcome assessments of knee function. It would be expected that the paired differences would be normally distributed. There did, however, appear to be a disproportionate number of zero differences and therefore, as an aid to interpretation for each outcome, we also present the proportion of patients reporting a higher score for TMK, no difference between TMK and AGC, and a higher score for AGC. This clearly shows that for both OKS and AKSS outcomes, most patients either scored higher for the TMK knee, or could not separate the two prostheses. Nevertheless, it does emphasise that the TMK did not work better than the AGC for all patients.

The trial attempted to exclude 'observer-dependent' bias in clinician-based outcome (AKSS), with the examiner blinded to which implant was in which knee. Unfortunately, our study did not exploit all the theoretical advantages. In nine patients the protocol was broken, with some of the clinical measurements having been made by an examiner who could have known which implant was in which knee. In patient-based outcomes, such as the OKS, observer bias was not relevant since all patients remained blinded.

For every clinical measurement which we used, other than range of flexion, the mobile-bearing knee proved to be significantly better than the AGC. Despite their widespread use, no previous controlled comparison has shown any advantage for a mobile-bearing over a fixed-bearing total knee prosthesis either in clinical function or in longevity.<sup>13</sup> We believe any differences found are likely to be due to dif-

ferences in the design of the prosthesis but only indirectly related to the 'meniscal-bearing' form of the tibiofemoral articulation. That feature of the design may be expected to minimise wear of polyethylene<sup>14</sup> and confer longevity on the implant, but is unlikely to explain, for instance, the significantly better pain scores of the TMK knees at one year.

With any mobile-bearing knee replacement, dislocation is a potential complication.<sup>15-18</sup> In our study there was one dislocation (incidence 2.5%) requiring revision surgery to exchange the bearing implant to one of larger size. We believe that if there is any doubt about the stability of a mobile bearing at the time of surgery, the surgeon should revert to the fixed-bearing device. Continued surveillance of the device is required to confirm the rate of dislocation in the longer term. Clicking of the knee after mobile-bearing arthroplasty is another potential complication and may be expected when the excursion of a bearing is limited, as in the TMK, by a metal stop. Nearly half the patients experienced clicking in the TMK knee, but they stated that it presented no problem. Surprisingly, one in four had the same symptom in the AGC knee. The frequency of this symptom in fixed-bearing prostheses may have been previously underestimated because patients are not usually questioned about it.

The early benefit conferred by the new design may relate to improved kinematics and kinetics in the patellofemoral joint. Impingement of the meniscal bearing on the tibial peg diminishes the ill-effects of an absent anterior cruciate ligament by reducing (to 2 mm) the freedom of the femur to slide in the AP plane during flexion. In the absence of a functioning cruciate mechanism, paradoxical movement has been often observed both in mobile and fixed-bearing designs.<sup>19,20</sup> The length of the lever arm available to the quadriceps in flexion is diminished and causes abnormally high loads at the patellofemoral joint. Laboratory simulations suggest that compressive force at that joint may be increased by as much as one-third.<sup>21</sup> This is a possible cause of pain in the knee and weakness of extension after total arthroplasty; its avoidance may best explain why 20 of the 29 patients who expressed a preference, preferred the TMK.

Our study has shown that a bilateral randomised, clinical trial can reveal significant differences while putting at risk many fewer subjects than in a unilateral randomised clinical trial. We believe that this is the first controlled, single-blind trial to have shown a small, but significant early clinical advantage for a mobile-bearing over a fixed-bearing TKA.

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