



The long-term results of simultaneous fixed-bearing and mobile-bearing total knee replacements performed in the same patient

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We compared the results of 146 patients who received an anatomic modular knee fixed-bearing total knee replacement (TKR) in one knee and a low contact stress rotating platform mobile-bearing TKR in the other. There were 138 women and eight men with a mean age of 69.8 years (42 to 80). The mean follow-up was 13.2 years (11.0 to 14.5). The patients were assessed clinically and radiologically using the rating systems of the Hospital for Special Surgery and the Knee Society at three months, six months, one year, and annually thereafter.

The assessment scores of both rating systems pre-operatively and at the final review did not show any statistically significant differences between the two designs of implant. In the anatomic modular knee group, one knee was revised because of aseptic loosening of the tibial component and one because of infection. In addition, three knees were revised because of wear of the polyethylene tibial bearing. In the low contact stress group, two knees were revised because of instability requiring exchange of the polyethylene insert and one because of infection.

The radiological analysis found no statistical difference in the incidence of radiolucent lines at the final review (Student's *t*-test, $p = 0.08$), most of which occurred at tibial zone 1. The Kaplan-Meier survivorship for aseptic loosening of the anatomic modular knee and the low contact stress implants at 14.5 years was 99% and 100%, respectively, with a 95% confidence interval of 94% to 100% for both designs.

We found no evidence of the superiority of one design over the other at long-term follow-up.

Although well-designed, fixed-bearing total knee replacements (TKRs) have provided durable long-term results,^{1,2} wear of polyethylene and peri-prosthetic osteolysis have been reported.³⁻⁹ Mobile-bearing TKRs were introduced to reduce contact stresses in the polyethylene and potentially to decrease wear as well as to minimise cement-bone stress at the tibial surface.¹⁰⁻¹³ However, the theoretical advantages of mobile-bearing designs have not been proven.¹⁴⁻¹⁶

We questioned whether there is a difference between fixed-bearing and mobile-bearing TKRs in terms of clinical and radiological results and the prevalence of wear of polyethylene and peri-prosthetic osteolysis.

Patients and Methods

Between January 1992 and May 1995, the senior author (Y-HK) performed 320 primary TKRs in 160 consecutive patients. It is our practice to perform bilateral TKR as a one-stage procedure for bilateral end-stage arthritis

unless patients have pre-operative medical complications. During this period of study, over 95% of our patients had a one-stage bilateral TKR and the remainder a staged bilateral procedure. One-stage bilateral TKRs were performed during the same session of anaesthesia with one side treated immediately after the other, once the first knee had been completely closed and the dressing applied.

The study was approved by our institutional review board and all patients provided informed consent. Death unrelated to the knee surgery occurred in six patients (12 knees), and eight (16 knees) were lost to follow-up in the first two years after surgery. Therefore 292 knees in 146 patients were available for clinical evaluation at a mean of 13.2 years (11.0 to 14.5) after operation.

There were 138 women and eight men with a mean age at the time of TKR of 69.8 years (42 to 80). Their mean weight was 60.9 kg (48 to 85) and mean height 151.8 cm (148 to 185). The mean body mass index (BMI) was 27.5 kg/m²

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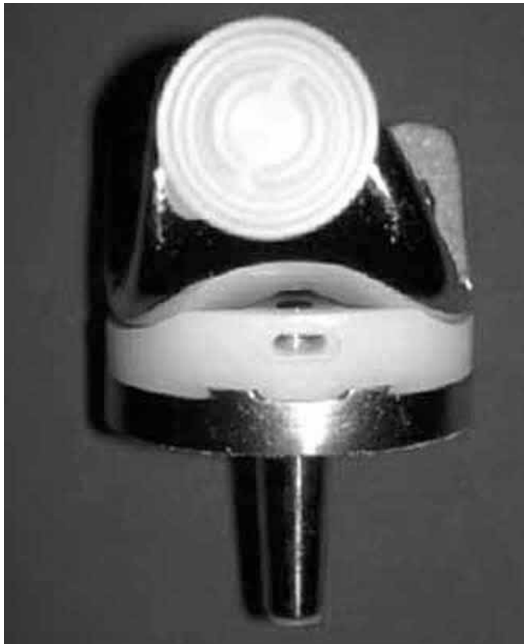


Fig. 1a



Fig. 1b

Photographs of the femoral, tibial and patellar components of a) the anatomic modular knee implant and b) the low contact stress implant.

(21 to 35). The diagnosis was primary osteoarthritis (OA) in 276 knees (94%), traumatic arthritis in eight (3%) and rheumatoid arthritis (RA) in eight (3%). Arthroscopic debridement had been undertaken previously in 28 knees (9.6%). The allocation of prostheses and which knee was replaced first was determined by a table of random numbers. A fixed-bearing anatomic modular knee total knee prosthesis (AMK; DePuy, Warsaw, Indiana) was implanted in 146 knees, 73 in the left and 73 in the right and a low contact stress mobile-bearing rotating-platform total knee prosthesis (LCS; DePuy) in the remaining 146 knees.

The AMK femoral component was curved in the coronal and sagittal planes and available in right and left knee orientations. It had a raised lateral flange and a 7° laterally-divergent patellofemoral groove. The modular tibial component had a symmetrical baseplate 4 mm thick. The tibial stem was 40 mm long.

The femoral and tibial components of the LCS mobile-bearing TKR were conforming, in the sagittal plane, from full extension to 30° of flexion to optimise the contact areas, and less conforming from 30° of flexion to full flexion to allow better mobility. The rotating-platform design allowed only rotation and had a relatively deep sagittal-plane conformity for posterior-cruciate-sacrificing procedures. The tibial polyethylene insert had a central post which related to a recess in the tibial tray in order to allow rotation but no translation.

The AMK prosthesis is designed for posterior-cruciate ligament (PCL) retention and the LCS rotating-platform for implantation with resection of the PCL. All the components (Fig. 1) were fixed by cement. In the AMK group, all the patellae were resurfaced by all-polyethylene patellar prostheses. In the LCS group, the patellae were resurfaced by metal-backed, rotating-bearing patellar prostheses. All the femoral components in both the AMK and LCS groups had a polished cobalt-chromium articular surface with a mean roughness of < 0.01 µm. The cobalt-chromium tibial baseplate in both groups had a polished superior surface with a mean roughness of < 0.01 µm. The tibial polyethylene inserts were curved in both groups. The mean thickness of the tibial polyethylene insert was 12 mm (10 to 14) in both groups. The same type of 412 resin was used in the manufacture of the polyethylene inserts in both groups which were machined to their final shape from a ram-extruded bar. All the polyethylene inserts were sterilised by gamma-irradiation in a vacuum. The mean shelf time of the insert between sterilisation and implantation was 0.8 years (0.5 to 1.0) in the AMK group and 0.9 years (0.6 to 1.2) in the LCS group.

Operative technique. The operation was performed using a midline skin incision 10 cm to 12 cm in length in extension with a subvastus approach. Ligamentous balancing was undertaken and an attempt was made to resect 10 mm of tibial bone to achieve a surface which was perpendicular to the shaft of the tibia in the coronal plane with 7° of

Table I. Results of the knee scores (range) for both designs of implant

	AMK*	LCS†	p-value‡
Hospital for Special Surgery score			
Pre-operative	50 (29 to 65)	49 (22 to 62)	0.92
Post-operative	89 (75 to 100)	87 (75 to 100)	0.26
Knee Society score			
Pre-operative	25 (17 to 39)	26 (19 to 41)	0.68
Post-operative	92 (62 to 100)	90 (55 to 100)	0.81
Knee Society functional score			
Pre-operative	31 (17 to 49)	29 (12 to 48)	0.42
Post-operative	81 (30 to 100)	83 (35 to 100)	0.17

* AMK, anatomic modular knee

† LCS, low contact stress

‡ Student's *t*-test

posterior slope in the sagittal plane. The distal part of the femur was resected with an attempt to achieve femorotibial alignment of 7° of valgus in the coronal plane. Distal and posterior femoral condylar resection was performed to remove a volume of bone which matched the size of the femoral component to be implanted. Care was taken to balance the flexion and extension gaps and to overcome any flexion contracture. The joint line was measured before and after implantation of all the components by measuring the distance between the adductor tubercle and the tibial tuberosity. The patellar thickness was measured before the resection which was performed to remove a volume of bone that was equal to or slightly more than that of the component to be implanted. All implants were inserted with cement after pulsed lavage, drying and pressurisation of cement.

A splint was applied with the knee in extension and retained for the first 24 hours after the operation. Subsequently, the knee was placed on a continuous passive motion machine and the settings were advanced incrementally until the knee reached 120° of flexion. All the patients began walking bearing full weight with crutches or a frame and began working on active and passive range of movement (ROM) exercises on the second day after the operation. The crutches or frame were used for six weeks followed by the use of a walking stick if needed.

Clinical evaluation. The patients were assessed by a physical examination and knee scoring pre-operatively, and at three and six months, at one year after surgery, and annually thereafter using the system of the Hospital for Special Surgery (HSS).¹⁷ Additionally, the Knee Society score¹⁸ was used to determine the knee and functional scores pre-operatively and at each follow-up. The level of activity was assessed further by using the Tegner and Lysholm scores.¹⁹ All the clinical data from the follow-up examinations were recorded and compiled by two observers (S-HY and another who was not an author) who were not part of the operating team and who had no knowledge of the radio-

logical findings. They were blinded to the type of prosthesis.

Radiological evaluation. Radiographs were obtained pre-operatively, at three and six months and at one year post-operatively and annually thereafter. Standing antero-posterior (AP) views including the femoral head and ankle as well as supine, lateral and skyline patellar views were taken under fluoroscopic control to allow initial examination of the interfaces. The radiographs were assessed by two observers (S-HY and another who was not an author) who were blinded to the type of prosthesis, the alignment of the limb, the position of the component and the presence and location of all radiolucent lines at the cement-bone interface, according to the recommendations of the Knee Society.¹⁸ The skyline patellar radiographs were examined for patellar tilt, subluxation or dislocation.

The joint line was determined on AP radiographs obtained before and after surgery with the patient supine, by measuring the distance between the tip of the fibular head and the distal margin of the lateral femoral condyle after correction of different magnification pre-operatively and the distal margin of the lateral femoral component post-operatively.

At the final follow-up examination, CT using a multi-slice scanner (General Electric Light Plus, Waukesha, Wisconsin) was performed to determine the rotational alignment of the components and osteolysis. The scan sequence was carried out from between 10 cm above the superior pole of the patella and 10 cm below the tibial tuberosity, using contiguous slices of 2.5 mm. Rotational alignment of the femoral component was determined by measuring the angle between the line joining the medial and lateral epicondyles of the femur and that joining the posterior margins of the femoral component. Rotational alignment of the tibial component was assessed by measuring the angle between the line connecting the tibial tuberosity anteriorly and the site of insertion of the PCL posteriorly and the AP

Table II. Radiological results (range) for both designs of implant

	AMK*	LCS†	p-value‡
Alignment			
Mean pre-operative (varus; °)	11.5 (0 to 20)	10.7 (-20 to 15)	0.15
Mean post-operative (valgus; °)	5.3 (0 to 7)	5.8 (0 to 8)	0.16
Femoral component orientation (°)			
Anteroposterior	94.5 (83 to 98)	95.6 (90 to 100)	0.14
Sagittal	7.2 (1 to 16)	9.7 (1 to 16)	0.10
Tibial component position (°)			
Anteroposterior	87.0 (82 to 95)	88.0 (82 to 93)	0.31
Sagittal	87.0 (80 to 93)	84.0 (80 to 90)	0.10
Patellar height (mm)	23.4 (19 to 25)	22.8 (20 to 26)	0.12
Joint line (mm)			
Pre-operative	16.3 (12 to 24)	16.7 (12 to 24)	0.70
Post-operative	13.9 (8 to 24)	14.0 (9 to 26)	0.88
Radiolucent line (overall) (knees) (%)			
Absence	102 (70)	110 (75)	0.16
Presence	44 (30)	36 (25)	0.08
Tibial radiolucent lines (knees) (%)			
Zone 1 (< 1 mm)	37 (25.3)	28 (19.1)	
Zone 1 and 2 (< 1 mm)	2 (1.4)	-	
Zone 4 (< 1 mm)	-	2 (1.4)	
All zones (> 1 mm)	1 (0.7)	-	
Femoral radiolucent lines (knees) (%)			
Zone 1 (< 1 mm)	4 (2.73)	6 (4.1)	
Lateral patellar tilt (knees) (%)	22 (15.1)	25 (17.1)	0.799
Wear of tibial polyethylene (knees) (%)	2 (1.4)	3 (2.1)	0.898
Mean external rotation of the components by CT (°)			
Femoral component	3.2 (3 to 4)	3.5 (3 to 5)	0.925
Tibial component	2.4 (2 to 3)	2.3 (2 to 4)	0.917
Osteolysis (knee) (%)	1 (0.7)		0.911

* AMK, anatomic modular knee

† LCS, low contact stress

‡ Student's *t*-test

line passing through the centre of the anterior and posterior margins of the tibial component.

Wear of the polyethylene tibial bearing was determined by asymmetry of the polyethylene joint-space shadow. Osteolysis was defined as any non-linear region of peri-prosthetic cancellous bone loss with delineable margins. Two authors (S-HY and J-SK) independently examined all the radiographs and CT scans. When the interpretation of the radiological and CT findings was different between these examiners, it was confirmed by review by a third (Y-HK).

Statistical analysis. A prospective and retrospective power analysis was performed and with power set at 0.8 and significance at $p < 0.05$, 85 knees were required in each group to determine if there was a significant difference in the clinical results. Fisher's exact test was used to compare the prevalence of polyethylene wear and osteolysis and the Wilcoxon rank-

sum test for comparisons of non-parametric ordinal data. Student's *t*-test was used to compare the knee scores.

The inter- and intra-observer reliabilities for the radiological measurements were assessed by calculation of the intraclass correlation coefficient. For angular measurements, the mean interobserver difference was 1.7° (0.9° to 2.5°) and the intraclass correlation coefficient was 0.97 (excellent reproducibility). For linear measurements, the mean interobserver difference was 1.6 mm (1.1 to 2.1) and the intraclass correlation coefficient was 0.98 (excellent reproducibility).

Survivorship analysis was performed to determine the cumulative rate of survival of the implant during the period of the study²⁰ and reported with 95% confidence intervals (CI). The end-point for the analysis was aseptic loosening and revision surgery for any reason or a recommendation

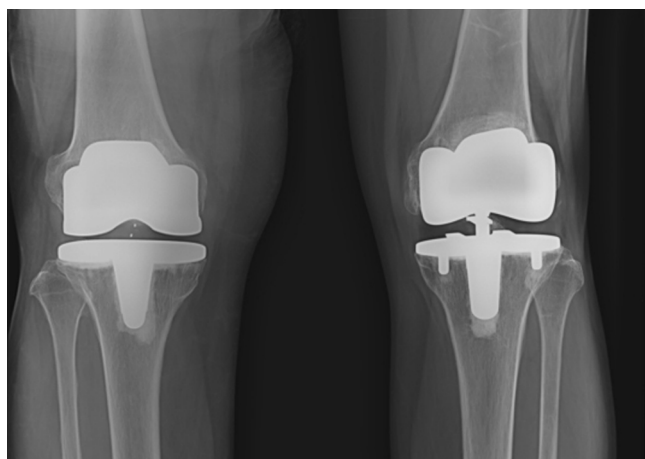


Fig. 2a

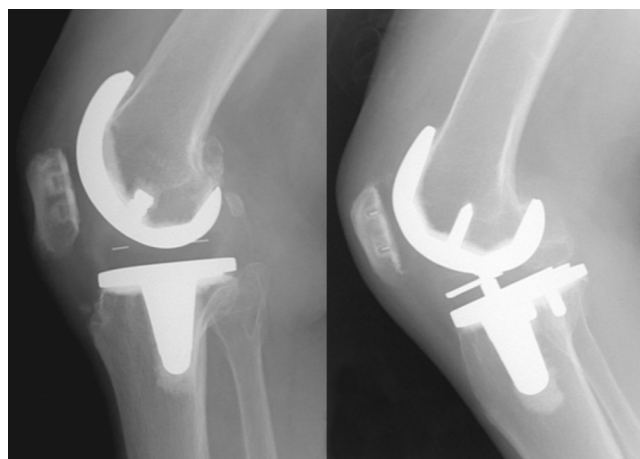


Fig. 2b

Anteroposterior and lateral radiographs of both knees of a 50-year-old woman with osteoarthritis. a) Anteroposterior view of both knees at 14 years after surgery showing that the anatomic modular knee (left) and the low contact stress (right) prostheses are fixed solidly. There are no radiolucent lines or osteolysis around the tibial components in either knee and no gross wear of the polyethylene tibial bearing in either knee. b) Lateral views of the same knees confirming the absence of radiolucent lines or osteolysis around the components in either knee.

for revision surgery by the senior author (Y-HK). Statistical significance was set at $p \leq 0.05$.

Results

Knee and functional scores. Comparison of the mean pre- and post-operative Hospital for Special Surgery scores showed no statistically significant difference between the AMK and LCS groups (Student's *t*-test, $p = 0.92$ and $p = 0.26$, respectively). Similarly, the mean pre- and post-operative Knee Society knee and functional scores showed no statistically significant difference in the groups (Student's *t*-test, $p = 0.68$, $p = 0.81$, $p = 0.42$ and $p = 0.17$ respectively; Table I).

The pre- and post-operative ranges of movement were not significantly different in both groups (Student's *t*-test, $p = 0.816$). For the AMK group, the mean pre-operative ROM was 126° (90° to 150°) and for the LCS group it was 125° (80° to 150°). Post-operatively, the mean ROM was 132° (95° to 150°) in the AMK group and 135° (90° to 150°) in the LCS group. In the AMK group, at the final review, 117 of 141 unrevised knees (83%) and 119 of 143 unrevised knees (83%) in the LCS group had a good or excellent functional score. The remaining unrevised 24 knees (16.4%) in each group did not have a good or excellent functional score and had associated medical conditions which limited function. However, the knee score, which determines the result for the knee independently of other potentially limiting conditions, was good or excellent in all 141 unrevised knees in the AMK group and 143 unrevised knees in the LCS group.

No preference was expressed by 124 patients (85%) for either knee in terms of function. In 12 patients (8%) the LCS mobile-bearing TKR was preferred and the remaining ten patients (7%) the AMK fixed-bearing TKR.

Activity score. The mean activity score of Tegner and Lysholm¹⁹ was 1.3 points (0 to 3) pre-operatively and 3.3 points (2 to 5) at the latest follow-up examination. This improvement reflected a change from sedentary work with limited walking on even ground to an occupation which involved light manual tasks (e.g. nursing) and competitive and recreational sports, which included swimming and hiking.

Radiological findings. These are summarised in Table II. All patients had complete radiological follow-up. In both groups, there were no significant statistical differences (Student's *t*-test, $p > 0.05$) in the following parameters: the alignment of the knee, the position of the femoral and tibial components in coronal and sagittal planes, the patellar angle, the tibial surface area covered by the implants, the pre- and post-operative joint line, and pre- and post-operative posterior condylar offset.

In the AMK group 102 knees (70%) and in the LCS group 110 knees (75%) had no evidence of radiolucent lines around any of the components (Fig. 2). Therefore, these were found in 44 knees (30%) in the AMK group and 36 (25%) in the LCS group. This difference was not statistically significant (Student's *t*-test, $p = 0.16$). The distribution of the radiolucent lines was principally in tibial zone 1 (Table II). One knee with the AMK prosthesis had a complete radiolucent line wider than 1 mm in all zones around the tibial component and was loose. On the femoral side radiolucent lines were rarely observed and those seen only occurred in zone 1 in both prostheses (Table II).

Lateral tilting of the patella was seen in similar numbers of each group (Table II). There were no cases of patellar dislocation, loosening or clunk syndrome. The CT scans

showed no statistically significant difference in the external rotation of the femoral or tibial components of either design (Table II) and revealed the presence of osteolysis in only one AMK knee.

Revision operations. In the AMK group five revisions (3%) were performed. One knee was revised because of infection and another for aseptic loosening of the tibial component. Wear of the polyethylene tibial bearing necessitated revision of three other knees (2%). In the LCS group three revisions (2%) were performed, in two (1.4%) because of instability of the knee caused by surgical error with inadequate thickness of the polyethylene tibial bearing, at one year and two years, respectively. The other was revised because of infection, five years after surgery.

Survivorship analysis. Kaplan-Meier survivorship²⁰ of 146 AMK implants and 146 LCS implants showed survival at 97% for the AMK prosthesis (95% CI, 94 to 100) and of 98% for the LCS prosthesis (95% CI, 96 to 100) with revision defined as the end-point at 14.5 years post-operatively. There was a survival rate of 99% with aseptic loosening as the end-point in the AMK group and of 100% in the LCS group (95% CI, 94 to 100 for both) at 14.5 years post-operatively.

Discussion

We found that there were no significant differences in the post-operative clinical and radiological results in the two groups or in the wear of polyethylene and peri-prosthetic osteolysis.

Failure because of wear of polyethylene or osteolysis has been reported at very low rates in clinical series of fixed- and mobile-bearing TKRs.^{14-16,21} Kim et al¹⁴ prospectively compared the results of AMK fixed-bearing and LCS meniscal-bearing TKRs in 116 patients (232 knees). At a mean follow-up of 7.4 years. No difference in the clinical outcome was identified in the two groups. This series comprises the majority of patients in the current report. Similar results have also been reported when comparing PFC Sigma fixed- and mobile-bearing prostheses with a shorter mean follow-up of 5.6 years.²² Woolson and Northrop²¹ compared the results of 45 NexGen fixed-bearing (Zimmer, Warsaw, Indiana) and 57 LCS rotating-platform (DePuy) implants at a mean follow-up of 41 months and found no difference clinically or radiologically. However, more patients with a mobile-bearing TKR required early revision for failure of rotating patellar or tibial polyethylene bearings. Price et al¹⁵ compared the results of AGC fixed-bearing (Biomet, Bridgend, United Kingdom) and TMK mobile-bearing (Biomet) TKRs in 40 patients (80 knees) who had bilateral simultaneous TKRs. At follow-up at one year they showed a small but significant clinical advantage for the mobile-bearing design. Wohlab et al¹⁶ compared the NexGen LPS mobile-bearing and fixed-bearing TKRs (Zimmer). They demonstrated no significant clinical advantages for the mobile-bearing TKR. In our study, the clinical outcome of the two groups was similar for all the param-

eters measured. No statistically significant clinical advantage could be demonstrated for either design.

Collier et al³ analysed the risk factors for osteolysis after a TKR. Men were 3.6 times more likely to have osteolysis than women. Knees in which the baseplate had a grit-blasted proximal surface were 2.6 times more likely to be affected by osteolysis than those treated by a polished-surface baseplate. Knees with an insert which had been gamma-irradiated in air were 4.0 times more likely to have osteolysis than those with an insert which had been gamma-irradiated in nitrogen. The risk of osteolysis increased by a factor of 1.5 with an increase of one year in the shelf age of the insert.

Our findings of a low incidence of osteolysis in both groups may be related to a preponderance of female patients, the use of a polished cobalt-chromium tibial baseplate to reduce backside wear of the insert, sufficient stiffness in the cobalt baseplate to maintain even load distribution for the polyethylene, a polyethylene insert sterilised by gamma irradiation in a vacuum and the short shelf life of the insert. It is possible that the follow-up was not sufficiently long to reveal osteolysis. The concept that a mobile-bearing TKR is associated with less wear and a low prevalence of osteolysis than a well-designed, fixed-bearing TKR remains to be proven in the longer-term follow-up. A fixed-bearing TKR cannot be fully conforming without being exceedingly constrained to axial rotation, transferring large rotational stresses to the cement-bone interface. A mobile-bearing TKR can overcome this conformity-axial constraint conflict by allowing unconstrained axial rotation with fully conforming articulations, reducing the axial stress to the cement-bone interface.^{23,24} Previous studies of fixed-bearing TKRs demonstrated that as conformity increased to minimise wear, theoretically more axial torque was applied to the cement-bone interface which was liable to loosen the prosthesis.²⁵ In our study, the prevalence of radiolucent lines around the tibial component was 30% (44 knees) in the AMK group and 25% (36 knees) in the LCS group. This difference was not statistically significant (Student's *t*-test, $p = 0.16$). There was one knee in the AMK group and none in the LCS group with a complete radiolucent line wider than 1 mm around the tibial component. Therefore, axial stress to the cement-bone interface of the tibial component appeared to be equivalent in both groups.

It has been emphasised that a good surgical technique is mandatory in a mobile-bearing TKR to avoid bearing dislocation or instability of the knee, especially balancing of flexion and extension gaps.²⁶⁻²⁸ In our series, instability occurred in two knees (1.4%) in the LCS group because of inadequate thickness of the polyethylene of the rotating platform. This necessitated replacement with a thicker polyethylene insert. There are some theoretical kinematic advantages associated with a mobile-bearing.²⁹

Many surgeons feel that the use of an unconstrained mobile-bearing TKR is contraindicated in cases of severe

varus and valgus deformity.²⁶⁻²⁸ This now has been challenged by Beverland³⁰ who stated that a mobile-bearing TKR can be used in virtually every primary TKR irrespective of deformity.

In our series, we were able to use a mobile-bearing TKR in every primary TKR selected by the process of randomisation irrespective of the range deformity, and with a low incidence of instability.

The main strengths of our study are the large number of patients and the relatively long follow-up. The main limitation was the dissimilarity of the prostheses in that they were different in the geometry of the femoral, tibial and patellar component⁸ in addition to the fixed- and mobile bearings.

In conclusion our study found no evidence to prove the superiority of the mobile-bearing over the fixed-bearing TKR. The clinical and radiological results of both types were encouraging over the long-term follow-up.

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