We describe the survivorship of the Medial Rotation total knee replacement (TKR) at ten years in 228 cemented primary replacements implanted between October 1994 and October 2006, with their clinical and radiological outcome. This implant has a highly congruent medial compartment, with the femoral component represented by a portion of a sphere which articulates with a matched concave surface on the medial side of the tibial insert.

There were 78 men (17 bilateral TKRs) and 111 women (22 bilateral TKRs) with a mean age of 67.9 years (28 to 90). All the patients were assessed clinically and radiologically using the American Knee Society scoring systems. The mean follow-up was for six years (1 to 13) with only two patients lost to follow-up and 34 dying during the period of study, one of whom had required revision for infection.

There were 11 revisions performed in total, three for aseptic loosening, six for infection, one for a periprosthetic fracture and one for a painful but well-fixed replacement performed at another centre.

With revision for any cause as the endpoint, the survival at ten years was 94.5% (95% CI 85.1 to 100), and with aseptic loosening as the endpoint 98.4% (95% CI 93 to 100). The mean American Knee Society score improved from 47.6 (0 to 88) to 72.2 (26 to 100) and for function from 45.1 (0 to 100) to 93.1 (45 to 100). Radiological review failed to detect migration in any of the surviving knees.

The clinical and radiological results of the Medial Rotation TKR are satisfactory at ten years. The increased congruence of the medial compartment has not led to an increased rate of loosening and continued use can be supported.

The Medial Rotation total knee replacement (TKR) (Finsbury Orthopaedics, Leatherhead, United Kingdom) is a development from the Freeman-Samuelson prosthesis (Zimmer-Centerpulse, Baar, Switzerland). The first condylar TKR to be implanted at the London Hospital in 1968 was the now obsolete Freeman-Swanson design. This comprised a cemented cobalt-chrome femoral roller articulating with a cemented, all-polyyethylene, tibial trough.¹ Certain elements of the original design have been maintained, in particular the attempt to minimise contact stresses in the polyethylene component.

The Medial Rotation design was initially known as the FS1000 in recognition of the increase of the articular contact area to slightly more than 1000 mm² throughout the range of flexion. In the Freeman-Samuelson design a load of five times body-weight (350 kg) exerted a contact stress of 6.8 MPa on the ultra-high-molecular-weight polyethylene (UHMWPE) insert.² However, the contact stress produced by the Medial Rotation TKR with the same load is 3.4 MPa throughout the range of flexion. This was achieved by increasing the radius of curvature of the medial femoral condyle from the 24 mm of the Freeman-Samuelson design to 25 mm and making this condyle a portion of a sphere. This produces lower stress at the highly congruent bearing surface. The medial aspect of the tibial polyethylene insert has a matching concavity with a maximum height from the lip of the tray to its deepest point of 11 mm which also confers enhanced stability.² The lateral femoral condyle remains cylindrical when viewed in the sagittal projection and retains the same radius of 24 mm as that of the Freeman-Samuelson design to allow rotation around the medial condyle. The lateral femoral condyle has been reduced in width thereby placing the trochlear groove more laterally to improve patellofemoral tracking.
We now describe the mid-term outcome and survival of the first 228 Medial Rotation TKRs implanted at our hospital.

**Patients and Methods**

Between October 1994 and October 2006, 228 consecutive cemented primary TKRs using the Medial Rotation prosthesis were implanted by the senior author (GS) or trainees under his supervision. There were 78 men, 17 with bilateral replacements (95 knees) and 111 women, 22 with bilateral replacements (133 knees). Their mean age was 67.9 years (28 to 90). The indication for surgery was osteoarthritis in 174 knees (76.3%), rheumatoid arthritis in 39 (17.1%) and post-traumatic and other causes in 15 (6.6%). All the information was gathered prospectively and entered onto a database.

**Operative technique.** Under general anaesthesia, often with supplementary regional anaesthesia, the patients were positioned supine with a foot bolster and a side support. A single dose of intravenous prophylactic antibiotic was given at induction. Additionally, in the latter part of the study, tranexamic acid at a dose of 10 mg/kg was given intravenously before inflation of the tourniquet.\(^3\) After preparation of the skin and excision of the soft tissues, a midline incision was made with a medial parapatellar approach. The osteophytes were excised and the soft tissues released as appropriate to restore normal alignment of the knee. The goal was to produce a knee approximating to 5° of valgus because a previous retrieval study of the Freeman-Samuelson design had shown that this produced the least amount of polyethylene wear.\(^4\) The tibial osteotomy was performed first, generally removing 8 mm to 10 mm of the proximal tibia, as measured from the more normal compartment in order to produce a flat surface parallel to the ground in a standing patient in both planes. The tibial cutting block was orientated using a manual extramedullary alignment rod. The femoral cuts were fashioned next using manual guides based on an intramedullary rod to produce balanced flexion and extension gaps. The finished gaps were checked with a tensor or trial components to confirm the thickness of the polyethylene insert and the alignment of the knee. The femoral component was available with an 80 mm stem initially, but from 1999 a pegged version was available, which then became the preferred option of the Bone and Joint Research unit at our institution. All the tibial components had central stems which were either 50 mm or 80 mm long depending on the size of the component required, and two laterally placed pegs. The definitive components were cemented with a single mix of CMW1 cement with added gentamicin (DePuy, Leeds, United Kingdom), but with cement applied only to the flat surfaces of the bone cuts and excluded from the intramedullary canals. The patella was routinely resurfaced with a saddle-shaped uncedmented polyethylene insert until 2000. After this, clinical experience suggested that a patellar component was not required to ensure engagement of the patella in the trochlear groove. When implanted the patellar component was uncedmented.\(^5\) Lateral soft-tissue releases were performed as required. Closure was performed in a standard fashion and a further dose of tranexamic acid (10 mg/kg) was given before deflation of the tourniquet. The patients were mobilised immediately bearing weight as tolerated and commencing active exercises under the supervision of a physiotherapist.

**Clinical outcome.** Post-operatively, all the patients were reviewed at six weeks, six months, and one year and annually thereafter by a variety of orthopaedic surgeons in the outpatient department. Information was recorded on a pro-forma to allow calculation of the American Knee Society score (AKSS).\(^6\) Additionally, the 177 patients (216 knees) who were not revised or lost to follow-up were categorised according to the AKSS system. There were 124 knees (57.4%) in category A with unilateral arthritis and with the other knee successfully replaced, 29 (13.4%) in category B with unilateral arthritis but with the other knee symptomatic, and 63 (29.2%) in category C with multiple arthritis or medical infirmity.

**Radiological assessment.** The extent of the arthritic change was assessed from pre-operative radiographs using the score of Kellgren and Lawrence,\(^7\) which has been shown to be reliable in defining the presence and estimating the severity of tibiofemoral osteoarthritis.\(^8\) Post-operatively, during the in-patient stay, at six months and at each subsequent review standardised anteroposterior (AP), lateral and skyline patellar radiographs were taken. Although the exposures were not aligned using an image intensifier, the radiographers were required to provide only exposures in which the beam was perpendicular to the cement-bone and cement-prosthesis interfaces.

The post-operative films were examined for the presence of radiolucent defects at the cement-implant or cement-bone interface parallel to the implant margins.\(^2\) In this group these were invariably ‘radiolucent lines with sclerosis’.\(^1\) Progression of these lines was recorded when there was an increase in width of 1 mm or more in any zone. Osteolytic defects were defined as expansive lesions with scalloped margins.\(^2\) The location of any such defect was defined using an adaptation of the distribution of the zones as described by the AKSS radiological assessment method (Fig. 1).\(^1\) Additionally, the pre- and post-operative alignment of the knee and prosthetic components was measured from the radiographs with a goniometer again using the AKSS system (Fig. 2). The components were also assessed for migration as identified by angular change, and anterior and proximal displacement, as described for the femoral component by Chockalingam and Scott.\(^1\) These criteria were also applied to the tibial component, with appropriate modification to assess for distal migration.

Reproducibility of the radiological assessment was undertaken using 20 sets of randomly selected radiographs. These were reviewed independently by each author one of whom (KM) reviewed the films again after an interval of one month. The intra- and interobserver
agreements were assessed using the plots of Bland and Altman, and the kappa statistics calculated with quadratic weighting.\textsuperscript{15}

**Survival analysis.** This was performed using the life-table method\textsuperscript{16} with revision for any reason as the first endpoint and revision for aseptic loosening as the second. The survivorship with 95% confidence intervals (CI) was calculated using the Wilson quadratic equation with Greenwood and Peto effective estimates of the size of the sample.\textsuperscript{16,17}

**Statistical analysis.** Fisher’s exact test was used for the analysis of the influence on survival of the presence or absence of a patellar component. The Wilcoxon signed-rank test was used to analyse the significance of improvement in the AKSS. Analysis of variance (ANOVA) was used to examine differences in the knee and function scores for the patient categories of the AKSS system. Statistical significance was set at a $p$-value $\leq 0.05$.

**Results**

The mean follow-up was for six years (1 to 13). Two patients were lost to follow-up. In total, 34 patients had died, six within the first year, which reduced the mean follow-up and minimum follow-up times. Only 18 patients (25 knees, 10.9%) reached the ten-year interval in the life table. Six patients (six knees, 2.6%) underwent revision for infection at which time well-fixed components were removed. Two patients sustained a periprosthetic fracture; one of these required a revision to allow internal fixation and in the other internal fixation was performed with retention of the prosthesis.

Three knees (1.3%) patients required revision for aseptic loosening, one within the first year and another at the end of the first year of follow-up. Both had inadequate initial cementation of the femoral component as evidenced by radiolucent lines between the cement of the component and the bone from the outset. Both were successfully revised. The third patient fell while climbing a ladder five years after operation, resulting in loosening of the tibial component.

One other patient, 18 months after the operation, underwent revision elsewhere for pain. Investigation using serological markers, serial radiography, scintigraphy, arthroscopy and biopsy had all failed to demonstrate a cause for his pain. After removal of the secure components and implantation of another design of TKR his symptoms remained unchanged. There were no other re-operations.

**Survival analysis.** With revision for any cause as the endpoint the survival at ten years was 94.5% (95% CI 85.1 to 100.0). This included the 11 revisions (Table I, Fig. 3a). When aseptic loosening alone was analysed as the endpoint for failure, the survival at ten years was 98.4% (95% CI 93.0 to 100.0) when 21 knees remained at risk (Table II, Fig. 3b).

With regard to patellar resurfacing, there was no statistically significant difference in survival, with revision for aseptic loosening as an endpoint, between those patients with or without a patellar component (Fisher’s exact test, $p = 0.16$).

**Radiological assessment.** The pre-operative Kellgren-Lawrence scores were grade II in one knee, grade III in 63 knees and grade IV in 136 knees. Pre-operative radiographs were not available for 28 knees. The mean pre-operative varus/valgus alignment was 6.4° of valgus (30° of valgus to 15° of varus), but for those knees with varus angulation the mean alignment was 3.7° (0° to 15°) while for valgus angulation it was 9.1° (1° to 30°).
The intraobserver correlation was 0.937 and interobserver correlation 0.877, both of which showed very good agreement.\textsuperscript{15} Bland-Altman plots showed means below 0.1 for intra- and interobserver analysis of angles and also for the assessment of radiolucent lines. These values again confirmed reliability.\textsuperscript{14} The mean post-operative alignment was 5.6° of valgus (3° of varus to 20° of valgus).

No migration was detected in any of the surviving knees. Excluding revised cases for any cause, 63 knees of 216 (29%) had radiolucent lines at the final follow-up. The most common sites for these were zones 1 (13 of 31) and 4 (17 of 31) for the tibia on the AP projection, zone 1 (14 of 16) for the tibia on the lateral projection and zone 1 (22 of 33) for the femur on the lateral projection (Fig. 4). Osteolysis was not identified in any of these patients.

Assessment of the positioning of the components and the post-operative alignment of the knee showed that acceptable results and consistency could be obtained with the instrumentation. The mean $\alpha$ angle was 96.9° (95% CI 96.5 to 97.3), the mean $\beta$ angle 89° (95% CI 88.7 to 89.4), the mean $\Omega$ angle 5.6° (95% CI 5.2 to 6.1), the mean $\gamma$ angle 3.4° (95% CI 1.8 to 5.0) and the mean $\sigma$ angle was 88.3° (95% CI 86.9 to 89.7) (Fig. 2).

Knee and function scores.

The mean AKSS for the knee improved from 47.6 (0 to 88) to 72.2 (26 to 100) and for function from 45.1 (0 to 100) to 93.1 (45 to 100). The mean pain scores improved from 15 to 48 points with 157 knees (69%) being free from pain and 55 (24%) having occasional or activity-related mild pain. The remainder consisted of those revised or lost to follow-up. As regards functional improvement, the walking distance score improved from a mean of 23.4 points (10 to 50) to a mean of 36.6 points (10 to 50). All the differences were significant (Wilcoxon matched-pairs signed-rank test, $p < 0.001$). When the differences by AKSS category were considered, there was a significant difference between the knee scores and the function scores. Application of the Wilcoxon matched-pairs signed-rank test showed that the improvement was significant in all groups for the knee score ($p < 0.001$) and for the function score in categories A and B ($p < 0.001$) and category C ($p = 0.017$).

\begin{table}[h]
\centering
\begin{tabular}{ccccccc}
\hline
Years since operation & Number at start & Failed & Died & Lost & At risk & Cumulative survival (%) & 95\% CI* \\
\hline
0 to 1 & 228 & 6 & 6 & 0 & 225 & 97.3 & 100.0 to 100.0 \\
1 to 2 & 216 & 2 & 8 & 0 & 212 & 96.4 & 95.4 to 99.2 \\
2 to 3 & 206 & 1 & 5 & 1 & 199 & 95.9 & 93.7 to 99.1 \\
3 to 4 & 191 & 0 & 7 & 0 & 175 & 94.5 & 93.3 to 98.6 \\
4 to 5 & 159 & 2 & 3 & 1 & 138 & 94.5 & 92.7 to 99.2 \\
5 to 6 & 115 & 0 & 3 & 0 & 102 & 94.5 & 90.5 to 98.7 \\
6 to 7 & 90 & 0 & 4 & 0 & 78 & 94.5 & 89.7 to 99.5 \\
7 to 8 & 66 & 0 & 4 & 0 & 52 & 94.5 & 88.7 to 100.0 \\
8 to 9 & 38 & 0 & 0 & 0 & 31 & 94.5 & 87.0 to 100.0 \\
9 to 10 & 25 & 0 & 0 & 0 & 21 & 94.5 & 85.1 to 100.0 \\
\hline
\end{tabular}
\caption{Survival table for the Medial Rotation total knee replacement with revision for any cause as the endpoint}
\end{table}

\* 95\% CI, 95\% confidence interval

Survivorship curves for the Medial Rotation total knee replacement showing revision a) for any cause as the endpoint and b) for aseptic loosening alone as the endpoint. The upper and lower lines represent the 95% confidence intervals (CI).

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The mean range of movement pre-operatively was 90° (15° to 125°) improving to 105° (40° to 125°) at the last follow-up. None of the patients reported instability.

Before TKR, 66 of the 189 patients (34.9%) used one stick and 25 (13.2%) two sticks, crutches or a walking frame to walk compared with 39 (20.6%) and 21 (11.1%), respectively, after operation. In all, 129 patients (68.3%) walked without any aids at the last follow-up.

**Discussion**

In our series survivorship of the Medial Rotation TKR at ten years with aseptic loosening as the endpoint was 98.4% (95% CI 93 to 100) which showed a modest improvement over the published results for the Freeman-Samuelson prosthesis of 96% (95% CI 90 to 100) and 93.4% (95% CI 85 to 100).  

Arora and Ogden observed radiolucent lines in 50% of their patients and osteolysis in 16% at a mean follow-up of 7.25 years. However, they only had access to the radiographs of 82 of a potential 125 knees because of a hospital policy of destroying the radiographs of deceased patients. By contrast, we had access to all the radiographs. In their series, as in ours, the radiographs were not aligned with an image intensifier, which is the preferred method of studying the interface. Vyskociil, Gerber and Bamert demonstrated that tilting the beam by only 2.3° when taking an AP radiograph of a tibial component 50 mm wide would obliterate a radiolucent line of a width of 2 mm. Therefore it was quite possible that the incidence of such lines was underestimated although our policy was to repeat exposures which did not demonstrate the interface clearly. Amin et al. found eight knees showing progressive radiolucent lines in an early assessment of 48 Medial Rotation prostheses. These patients were included in the current study and none has been revised nor have the lines progressed further. Smith et al. found that 15% of the TKRs with cemented tibial components and uncemented femoral implants in their series of 195 developed early radiolucent lines, without tibial osteolysis or loosening of the tibial component. They concluded that these were due to the failure to inject cement into sclerotic bone and that such lines did not progress. No migration was noted using a method shown to be reliable for identifying implants which were unlikely to fail.

The presence of osteolysis has been reported in previous studies and has been attributed to the design of the implant, especially the degree of conformity and contact area, the use of cement and the length of follow-up. The design of the Medial Rotation TKR currently uses cement for fixation, but this does not appear to be a problem because there have been no cases of osteolysis to date. It is assumed that wear will be reduced by adopting a spherical-on-spherical design such as in this implant. If both the medial and the lateral condyles were constrained sufficiently to limit rotation, this may have an adverse outcome in the younger or more athletic patient.

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**Table II. Survival table for the Medial Rotation total knee replacement with revision for aseptic loosening as the endpoint**

<table>
<thead>
<tr>
<th>Years since operation</th>
<th>Number at start</th>
<th>Failed</th>
<th>Died</th>
<th>Lost</th>
<th>At risk</th>
<th>Cumulative survival (%)</th>
<th>95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 1</td>
<td>228</td>
<td>2</td>
<td>6</td>
<td>0</td>
<td>224.0</td>
<td>99.1</td>
<td>100.0</td>
</tr>
<tr>
<td>1 to 2</td>
<td>218</td>
<td>8</td>
<td>8</td>
<td>0</td>
<td>213.5</td>
<td>99.1</td>
<td>99.1</td>
</tr>
<tr>
<td>2 to 3</td>
<td>209</td>
<td>0</td>
<td>5</td>
<td>1</td>
<td>195.0</td>
<td>99.1</td>
<td>99.1</td>
</tr>
<tr>
<td>3 to 4</td>
<td>182</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>167</td>
<td>99.1</td>
<td>97.2</td>
</tr>
<tr>
<td>4 to 5</td>
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<td>1</td>
<td>3</td>
<td>1</td>
<td>129.5</td>
<td>98.4</td>
<td>97.2</td>
</tr>
<tr>
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<td>106</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>92.5</td>
<td>98.4</td>
<td>95.7</td>
</tr>
<tr>
<td>6 to 7</td>
<td>79</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>68.5</td>
<td>98.4</td>
<td>95.7</td>
</tr>
<tr>
<td>7 to 8</td>
<td>58</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>47.0</td>
<td>98.4</td>
<td>95.1</td>
</tr>
<tr>
<td>8 to 9</td>
<td>36</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>29.5</td>
<td>98.4</td>
<td>94.1</td>
</tr>
<tr>
<td>9 to 10</td>
<td>23</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>10.9</td>
<td>98.4</td>
<td>93.0</td>
</tr>
</tbody>
</table>

* 95% CI, 95% confidence interval

---

**Fig. 4**

Bar chart showing the distribution of radiolucent lines. Tibia AP, tibia anteroposterior line, radiolucent line count on the tibial anteroposterior view; Tibia lat, radiolucent line count on the tibial lateral view; and Femur, radiolucent line count on the femoral lateral view. Other zones for the femoral radiographs included zones 2, 3 and 4 in similar proportions.
constrained. The increased constraint provided by the medial ball-and-socket geometry has been discussed previously.\textsuperscript{34} The deep medial dish provides enhanced stability without recourse to an intracollateral cam and post which have been reported to be a source of wear debris\textsuperscript{35-39} and breakage.\textsuperscript{40,41} In a series of 344 patients with bilateral TKRs of different types, Pritchett\textsuperscript{42} observed that patients have a preference for the knee with the greatest stability, whether it is obtained through the retention of both the cruciate ligaments or by substitution with a medial or lateral pivot prosthesis.

The geometry of the Medial Rotation TKR allows 763 mm\textsuperscript{2} of contact surface area for the medial compartment alone compared with a total contact area of 510 mm\textsuperscript{2} for the Freeman-Samuelson TKR, with contact pressures of 4.5 MPa throughout the range of flexion in the medial compartment. When the tibiofemoral articulation is considered as a whole the contact pressure is only 3.4 MPa.\textsuperscript{4} In a retrieval study of the Freeman-Samuelson TKR, Plante-Bordeneuve and Freeman\textsuperscript{4} showed that the tibiofemoral articulation yielded very low wear rates of the order of 0.025 mm per year, in a design in which the nominal contact stresses were 6.8 MPa, twice those of the Medial Rotation TKR.\textsuperscript{2}

When used the saddle-shaped patellar resurfacing component was implanted without cement to allow alignment with the trochlea and to reduce maltracking.\textsuperscript{19} However, although the discontinuation of the routine use of the patellar implant was not subjected to a randomised trial, our experience showed no difference in outcome whether or not the patella was resurfaced. This may be attributed to the lateralisation of the trochlear groove in the Medial Rotation TKR. Reproduction of an anatomical trochlear groove is considered to be desirable in the design of a TKR.\textsuperscript{43} Two independent studies\textsuperscript{23,44} found a higher rate of loosening in the patients in whom the patella had been resurfaced. The denervation technique performed as an alternative to patellar resurfacing produced results comparable with those of the contralateral resurfaced knee in a series of 52 patients with a TKR.\textsuperscript{44} A recent prospective, randomised trial has failed to demonstrate any difference in the outcome between TKR with or without patellar resurfacing.\textsuperscript{45}

The clinical and radiological results of the Medial Rotation TKR are satisfactory at ten years. The increased congruence of the medial compartment has not produced an increased loosening rate compared with Freeman-Samuelson prosthesis, and as predicted on the basis of the design has shown a slightly superior survival rate for aseptic loosening.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References


