We performed a prospective study of 54 patients (76 knees) who underwent Osteonics series 3000 cruciate-retaining cementless total knee arthroplasty between December 1990 and June 1993. Five patients (seven knees) were lost to follow-up (90.7% completion). One patient required revision at 10.5 years after operation.

The rate of survival was 100% at ten years and 96.7% at 13 years. The mean ten-year knee and function scores were 79 and 59 respectively. Both were significantly better than the pre-operative scores. The range of movement also improved. Although a radiolucent line around the tibial component enlarged in six knees (20.7%) at ten years, the clinical outcome was generally good. In a patient who died after 5.5 years, post-mortem examination of the knee showed no bony ingrowth into the tibial component. Despite poor bony ingrowth, press-fit fixation was satisfactory and good results can be obtained with this cementless, cruciate-retaining prosthesis.

Total knee arthroplasty (TKA) is an established procedure which greatly improves the quality of life of the patient. Factors which influence its longevity include the design of the components, the method of fixation (cemented or cementless) and the preservation or excision of the posterior cruciate ligament (PCL). Cementless fixation achieves a weaker early fixation but has the advantages of avoiding the toxic effects of cement on the body, retaining sufficient bone stock for revision and allowing earlier treatment of post-operative infections. PCL-retaining TKA has been shown to achieve an equivalent outcome to PCL-sacrificing TKA and to allow a near normal gait after surgery. However, there is no consensus on the relative merits and disadvantages of these procedures. There have been many reports of the long-term outcome of cemented TKA but few about the long-term outcome of cementless, cruciate-retaining (CR) TKA. Our aim was to assess prospectively the long-term outcome of cementless CR TKA performed with the Osteonics series 3000 TKA system (Omnifit, Osteonics, Allen- dale, New Jersey), and to report the histological fixation in one patient at autopsy who died 5.5 years after operation.

Patients and Methods
Between December 1990 and June 1993, 69 patients (96 knees) underwent TKA using this system. In the first 17 patients (20 knees) a metal-backed patellar component was used. These patients were excluded except for two who had bilateral TKAs, with a metal-backed patella only being used on one side. This left 54 patients (76 knees) in the study group. There were seven men (9 knees) and 47 women (67 knees). The pre-operative diagnosis was osteoarthritis (OA) in 44 patients (63 knees) of whom seven (9 knees) were men and 37 (54 knees) were women, and rheumatoid arthritis (RA) in ten patients (13 knees) all of whom were women.

The mean age at the time of surgery was 72.3 ± 5.9 (SD) years in the patients with OA and 65.7 ± 6.9 years in those with RA. This TKA has a single mediolateral radius (M-L radius) for the femorotibial articulation which is designed to increase the weight-bearing zone during flexion and extension. Both the femoral and tibial components are of cobalt-chromium alloy, and the under-surface is coated with CoCr beads in order to promote mechanical fixation. The patellar component is made of ultra-high-molecular weight polyethylene (UHMWPE) and is fixed with cement. One surgeon (SA) performed all the operations in the same manner. A midline, longitudinal skin incision was used and the joint opened through a medial parapatellar approach. The PCL was preserved in all patients. The bone cuts were made using an intramedullary guide on the
femoral side and an extramedullary guide on the tibial side by the tension-independent cutting method. Cancellous bone chips were used in order to fill any bony defects and the tibial component was fixed with two screws for initial stability.

**Survival analysis.** All the patients were followed up prospectively at intervals of six months for radiological and clinical assessment. Survival was assessed using life-table analysis and the end-point was defined as revision for any reason.31

**Clinical assessment.** The knee and the function scores from the Knee Society clinical rating system were used32 before surgery and at one, three, five and ten years after the procedure. The range of movement (ROM) was also assessed before surgery and ten years later.

**Radiological assessment.** Anteroposterior (AP) and lateral films were used in order to assess radiolucent lines. In accordance with the Knee Society system,33 lateral films of the femur were divided into three zones (Fig. 1a) and AP films of the tibia into two zones (Fig. 1b). The width of each radiolucent line was measured at one month and at one, five and ten years after operation.

**Statistical analysis.** The duration, scores, and data were expressed as the mean ± SD. Statistical analysis was performed with the paired and unpaired Student's t-test as appropriate and significance was set at p < 0.05.

**Results**

**Survival of the TKA.** Five patients (seven knees) were lost to follow-up which gave a follow-up of 90.7%. Fourteen

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**Table I.** Life-table survival analysis of the cementless Osteonics series 3000 TKA. Omnifit TKA using revision for all causes as the end-point

<table>
<thead>
<tr>
<th>Years after surgery</th>
<th>Number of knees</th>
<th>Withdrawn* (lost to follow-up)</th>
<th>Failures</th>
<th>Effective number at risk</th>
<th>Failure rate (%)</th>
<th>Cumulative survival (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 1</td>
<td>76</td>
<td>0</td>
<td>0</td>
<td>76.0</td>
<td>0.0</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>1 to 2</td>
<td>76</td>
<td>2</td>
<td>0</td>
<td>75.0</td>
<td>0.0</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>2 to 3</td>
<td>74</td>
<td>3 (1)</td>
<td>0</td>
<td>72.5</td>
<td>0.0</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>3 to 4</td>
<td>71</td>
<td>2 (2)</td>
<td>0</td>
<td>70.0</td>
<td>0.0</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>4 to 5</td>
<td>69</td>
<td>2 (2)</td>
<td>0</td>
<td>68.0</td>
<td>0.0</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>5 to 6</td>
<td>67</td>
<td>4 (2)</td>
<td>0</td>
<td>65.0</td>
<td>0.0</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>6 to 7</td>
<td>63</td>
<td>3</td>
<td>0</td>
<td>61.5</td>
<td>0.0</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>7 to 8</td>
<td>60</td>
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<td>0</td>
<td>56.0</td>
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<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>8 to 9</td>
<td>52</td>
<td>2</td>
<td>0</td>
<td>51.0</td>
<td>0.0</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>9 to 10</td>
<td>50</td>
<td>10</td>
<td>0</td>
<td>45.0</td>
<td>0.0</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>10 to 11</td>
<td>40</td>
<td>20</td>
<td>1</td>
<td>30.0</td>
<td>3.3</td>
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<tr>
<td>11 to 12</td>
<td>19</td>
<td>14</td>
<td>0</td>
<td>12.0</td>
<td>0.0</td>
<td>96.7</td>
<td>3.3</td>
</tr>
<tr>
<td>12 to 13</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>2.5</td>
<td>0.0</td>
<td>96.7</td>
<td>3.3</td>
</tr>
</tbody>
</table>

* includes patients who died

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Fig. 1a Fig. 1b

Radiographs showing the zones for recording radiolucent lines for a) the femoral and b) the tibial component.
The knee score (a) and function score (b) remained significantly higher for ten years after surgery compared with their pre-operative values (*p < 0.001).

Patients (22 knees) died during the follow-up period, 11 (16 knees) with OA and three (6 knees) with RA. The mean age at death was 76.5 ± 8.6 years at a mean of 7.8 ± 2.3 years after surgery. No death was related to the TKA. Revision was performed in one patient who had RA and in whom the tibial component failed 10.5 years after the operation. The cumulative rate of survival of the prosthesis was 100% at ten years and 96.7% at 13 years (Table I).

Clinical assessment. The mean knee score was 22.0 ± 13.3 before and 79.4 ± 24.0 ten years after operation (Fig. 2a). The mean function score was 27.3 ± 13.9 before and 58.6 ± 21.5 ten years after operation (Fig. 2b). Both scores showed a significant improvement throughout the follow-up period (p < 0.001). Before operation, the mean flexion contracture was 18.4 ± 14.1˚. The mean flexion was 111.7 ± 23.2˚ and the mean ROM 93.3 ± 31.4˚. Ten years after operation, the mean flexion contracture was 1.6 ± 4.9˚, the mean flexion 113.9 ± 24.0˚, and the mean ROM 112.4 ± 25.6˚. This represented a significant improvement (p < 0.01).

Radiological findings. For the femoral component, radiolucencies seen in zones 1 to 3 immediately after surgery became smaller with the passage of time and at ten years after surgery none had a radiolucent line with a width of ≥2 mm (Table II). By contrast, for the tibial component, a radiolucent line with a width of ≥2 mm was seen in zone 1 of two knees (6.9%) and zone 2 of one knee (3.4%) ten years after operation (Table III). For the 29 patients who had been followed up radiologically for ten years, the radiolucent line became smaller by 1 mm or more compared with its immediate post-operative size in zone 1 of one knee (3.4%), but it enlarged by 1 mm or more in four knees (13.8%). In zone 2, the radiolucent became smaller by 1 mm or more in two knees (6.9%) and enlarged by 1 mm or more in six knees (20.7%). The radiolucent enlarged in both zones 1 and 2 in four knees (13.8%). All those who showed an enlarged radiolucent still demonstrated a good clinical outcome, apart from the one which required revision.

Post-mortem case report. In June 1990, a 77-year-old woman with osteoarthritis underwent TKA. A metal-backed patellar component was used and she was thus excluded from the main study. She had post-operative knee and function scores of 103 and 80, respectively. However, she died from...
a cerebral haemorrhage 5.5 years after surgery. Plain radiographs taken five years after operation showed good alignment (Fig. 3). We examined the junction between the tibial component and the bone histologically. The specimen was mounted in a cold-curing plastic base and was embedded in methylmethacrylate for undecalcified histological examination. Coronal sections approximately 200 µm thick were cut and stained with basic fuchsin and toluidine blue after which the bone-implant interface was examined by light microscopy. Histological studies were not undertaken on the femoral component.

Akizuki, Takizana and Horiuchi\(^3\)\(^4\) also reported the histological findings of the implant-bone interface after cementless TKA. They reported that the bone-implant interface at an hydroxyapatite-tricalcium phosphate (HA-TCP) coated TKA was composed of 77.7% bone, 21.3% marrow and 1% fibrous tissue.\(^3\)\(^4\) By contrast we found that the beaded prosthetic coating was devoid of bone throughout the stained sections (Fig. 4) and was only filled with loose collagenous tissue. A fibrous membrane with areas of cartilage metaplasia was interposed between the coating and the proximal tibia. The screws were also surrounded by fibrous membranes. No bone ingrowth was seen.

**Discussion**

The ideal method of fixation and the handling of the PCL during TKA are still controversial. There have been several reports comparing cemented and cementless fixation.\(^3\)-\(^7\) Dodd et al\(^4\) reported that there was no difference in clinical outcome between cemented and cementless fixation at a mean of five years after operation.\(^4\) Collins et al\(^5\) reported similar results. This was supported by the findings of Khaw et al\(^7\) who performed a randomised, controlled trial of cemented and cementless fixation with a mean follow-up of 7.4 years and reported no difference in clinical outcome or patient satisfaction. There have been many reports on the long-term outcome of various types of cemented TKA. The ten-year survival of the Total Condylar Knee (Johnson & Johnson, Braintree, Massachusetts and Howmedica, Rutherford, New Jersey) has been reported to be 92%,\(^2\)\(^3\) 96.9%,\(^2\)\(^0\) and 99%.\(^1\)\(^9\) In addition, studies have shown the ten-year survival of the Kinematic Stabilizer (Howmedica) to be 95%,\(^2\)\(^1\) that for the Kinematic Condylar (Howmedica) to be 92.1%,\(^2\)\(^2\) and 96%,\(^2\)\(^5\) for the Insall-Burnstein II (Zimmer, Swindon, UK),\(^2\)\(^4\) to be 92.3% and for the Press-Fit Condylar (Johnson & Johnson) to be 95.5%.\(^2\)\(^6\) By contrast, there are very few reports on the long-term outcome of cementless TKA ten years or more after operation. Whiteside\(^1\)\(^2\) reported that the ten-year survival of the Ortholoc (Wright Medical Technology, Arlington, Tennessee) was 94% while Schroder et al\(^2\)\(^9\) found that the ten-year survival of the Anatomical Graduated prosthesis (Biomet, Warsaw, Indiana) which preserves the PCL was 97% after cementless fixation. Berger et al\(^3\)\(^0\) reported a lower rate of 83.6% for the Miller-Galante 1 (MG1; Zimmer).\(^4\) In our study, the ten-year survival of the Osteonic 3000 TKA was 100%, declining to 96.7% 13 years after operation. We consider this to be a very satisfactory result suggesting that
adequate longevity can be achieved after TKA without the use of cement. Cement has the disadvantages of toxicity, reduced bone stock at revision and difficulty in treating infections.

However, poor early fixation after cementless TKA has been highlighted as a problem when compared with cemented fixation. Cementless TKA components are coated with material which is designed to promote mechanical fixation by bony ingrowth. The Osteonics series 3000 is coated with cobalt-chromium beads. We consider that the radiolucent line seen immediately after surgery indicates the absence of bone ingrowth at that time. However, the width of this line on the femoral side became smaller ten years after operation and none of our patients had loosening after this period of time, suggesting that adequate fixation can be achieved from bony ingrowth.

On the tibial side, the initial radiolucent line did not become narrower and enlarged in some patients. Ranawat et al. have also reported the absence of histologically effective bone ingrowth. During the post-mortem examination of one TKA from our series we found that the gaps between the beads were filled with fibrous tissue and that there was little bony ingrowth. To resolve this problem, hydroxyapatite-tricalcium phosphate (HA-TCP) has recently been used on a trial basis in order to obtain better early fixation while preserving the merits of a cementless TKA. Soballe et al. have reported that fixation with HA-coated implants is three times stronger than with porous titanium alloy implants. Gejo et al. found that stronger fixation of the NexGen TKA (Zimmer) could be obtained with an HA-TCP coating and the initial gap was filled within one year of surgery. Akizuki et al. demonstrated long-term fixation.
with an HA-TCP-coated Miller-Galante II prosthesis (Zimmer) seven years after operation.

It has been reported that preservation of the PCL allows a near normal gait after TKA. However, it has also been found that there is no difference in the clinical outcome between PCL-sparing and PCL-sacrificing methods. We use a PCL-sparing arthroplasty since we have concerns about the possibility of postam wear in the longer term.

A prosthesis should only be judged on its long-term clinical outcome. The Osteonesics series 3000 Omnifit TKA was introduced more than ten years ago and this study reports excellent results.

We thank Dr Robert M. Urban of Rush University for preparation of the post-mortem findings.

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References