In a prospective study, 93 unselected consecutive uncemented hip arthroplasties were performed in 80 patients using the titanium-coated RM acetabular component and the CLS femoral component. The mean age of the patients at operation was 52 years (28 to 81). None were lost to follow-up. In the 23 patients who had died (26 hips) only one acetabular component had been revised. In the 57 living patients (67 hips), 13 such revisions had been performed. Of the 14 revisions, seven were for osteolysis, five for loosening and two for infection.

Survival analysis of this implant showed a total probability of survival of 83% (95% confidence interval 73 to 90), with all revisions as the endpoint, and a probability of 94% (95% confidence interval 87 to 98) with revision for aseptic loosening as the endpoint, indicating reliable long-term fixation of the titanium-coated RM acetabular component.

The main challenges in providing a durable total hip replacement (THR) relate to acetabular fixation and the bearing surface. Uncemented acetabular components were developed in the hope of improving fixation. Key factors for their long-term survival are their immediate stability and surface properties which promote secondary stability by bony ingrowth. Some porous-coated, threaded and press-fit designs have been developed, as have hemispherical versions and shells with supplementary screw fixation. Long-term results of more than 15 years are available for only a limited number of such implants. Some series have to be interpreted with care, as many designs were modified during the period of study or too many patients were lost to follow-up.

We have used the titanium-coated RM acetabular component in combination with the CLS femoral component for over 20 years. We report the long-term survival of this system in a consecutive cohort of 80 patients.

Patients and Methods
In this prospective study we included 93 consecutive uncemented primary THRs performed in 80 patients between January 1986 and July 1989 (Table I). Altogether, 498 THRs using the RM acetabular component were carried out during this time, mainly in combination with a cemented Müller femoral component (405 cases) generally in older patients.
Clinical evaluation included a pre-operative assessment of pain, mobility and walking ability according to Merle d’Aubigné and Postel.\textsuperscript{9} Also, the Harris Hip score (HHS)\textsuperscript{10} was calculated at the latest follow-up. In patients with bilateral procedures each hip was assessed separately. The potential dependence resulting from the use of bilateral procedures was not considered to introduce substantial bias, and therefore the paired structure of bilateral cases was ignored with respect to statistical analysis.

The radiographs were examined by two of the authors (MI, SM) and an independent, experienced orthopaedic surgeon for evidence of acetabular migration according to the criteria of Massin, Schmidt and Engh\textsuperscript{11} and for radiolucent lines or osteolysis according to the definition proposed by Engh et al\textsuperscript{12} in the zones described by DeLee and Charnley.\textsuperscript{13} The most recent radiograph was compared with its immediate post-operative counterpart and any interim films. In the hips which were revised, the status of the components was assessed on the pre-operative radiograph before revision. The acetabular component was considered to be radiologically loose if it had migrated > 3 mm, or tilted > 8°, or if the radiographs demonstrated circumferential radiolucent lines > 2 mm in width.\textsuperscript{14} Heterotopic ossification was graded according to Brooker et al.\textsuperscript{15}

**Statistical analysis.** The probabilities of survival were estimated by the Kaplan-Meier method.\textsuperscript{16} Failure was defined as revision for aseptic loosening or any other reason. The revision operations were differentiated into three groups, namely aseptic loosening, isolated acetabular osteolysis and infection. There was no case of recurrent dislocation. The time to revision was between the dates of implantation and revision. Patients without revision were censored at the date of the last follow-up or at death. Cox’s proportional hazards model\textsuperscript{17} was used to examine the survival rates for different risk factors for acetabular component revision which were age, the material of the femoral head, gender, the body mass index, the surgical approach, indication and the size of the acetabular component. To account for within-patient correlation, robust variances were estimated based on the marginal approach of Wei, Lin and Weissfeld.\textsuperscript{18} These robust sandwich estimates were about 2% to 13% larger than ignoring correlation.

<table>
<thead>
<tr>
<th>Table I. Demographic characteristics at operation</th>
</tr>
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<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Number of hips</td>
</tr>
<tr>
<td>Number of patients</td>
</tr>
<tr>
<td>Mean age (yrs)</td>
</tr>
<tr>
<td>Mean body mass index (kg/m²)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial diagnosis (number of hips)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoarthritis</td>
</tr>
<tr>
<td>Avascular necrosis</td>
</tr>
<tr>
<td>Developmental dysplasia</td>
</tr>
<tr>
<td>Femoral neck fracture</td>
</tr>
<tr>
<td>Post-traumatic osteoarthritis</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
</tr>
</tbody>
</table>
The model assumptions were checked graphically by comparing log-log survival curve plots (parallel lines over time) and by a formal correlation test based on the Schoenfeld residuals. Risk ratios and 95% confidence intervals (CI) are presented. Scores were compared in a non-parametric manner by the Wilcoxon's signed ranks test for paired observations, with the level of significance set at \( \alpha = 0.05 \) two-sided.

For statistical analysis SAS software version 9.1.3 was used (SAS Institute, Cary, North Carolina).

**Results**

Intra-operatively, longitudinal fractures or fissures of the femur were observed in 18 hips (19.4%). Eight healed uneventfully after cerclage wiring, five after screw fixation, and five without fixation. None showed loosening or needed revision at the latest follow-up. Three hips had an intra-operative fracture of the greater trochanter which was treated by screw fixation.

During the early post-operative period there were four haematomas, three wound dehiscences, two dislocations and two infections, one of which was superficial and was successfully treated by wound revision and antibiotic therapy. The other was a deep infection requiring revision of both components. No nerve damage was reported.

At the last follow-up 23 patients (26 hips) had died. Two of them had been revised, one of both components for infection, and one of the femoral components for aseptic loosening. The mean age of the deceased at the time of operation was 56.2 years (37 to 81), and at the last clinical and radiological follow-up before death there were no signs of radiological loosening or clinical failure in the unrevised cases.

Of the 57 patients (67 hips) who are still alive, 13 (15 hips) underwent revision. In nine hips the acetabular component, in two hips the femoral component and in four hips both components were revised (Fig. 2). The two acetabular components corresponding to the isolated revised femoral components were stable intra-operatively and showed no radiographic signs of loosening or osteolysis at the latest follow-up.

Of the 54 unrevised acetabular components, 49 were available for follow-up. Three could not be examined because of poor health, and two no longer had the original combination after revision of the femoral component. The remaining 44 unrevised patients (49 hips) had a mean follow-up of 19.3 years (17.4 to 20.9). Their mean age at the initial operation was 51.2 years (28 to 65) and at latest follow-up was 71.3 years (46 to 85).

The HHS for these 49 hips was a mean of 87.5 points (54 to 100); 27 hips (55.1%) were graded excellent, 12 (24.5%) good, five (10.2%) fair and five (10.2%) poor. Musculoskeletal comorbidities had a considerable influence on these results. A total of 14 cases without comorbidity had a mean HHS of 95.5 (88 to 100), whereas 35 cases with comorbidity had a mean HHS of 84.3 (54 to 100). Hip pain was considerably relieved after surgery. At the latest follow-up 35 hips (71.4%) were pain free, ten (20.4%) had occasional mild pain not affecting daily activities, and four (8.2%) had significant pain, but considered it severe enough to warrant revision surgery. Thigh pain was not reported.

The Merle d'Aubigné score showed significant improvements in all three parameters for the 49 unrevised hips (Table II).

Of the 54 acetabular components which had not undergone revision, three radiographs could not be obtained because the patients were in nursing care, and three patients refused examination, leaving 48 complete series of radiographs for evaluation.

According to the criteria of Engh et al, only one acetabular component was radiologically loose, probably because of a fall. A radiolucent line adjacent to the acetabular component was seen in zone 1 (DeLee and Charnley) on two
radiographs, and in zone 3 on one. None had continuous radiolucencies in all three zones. Osteolysis was seen as a sharply demarcated radiolucent space on eight radiographs, six in zone 3, one in zone 2 and one in zone 1. At the latest follow-up these components did not show any clinical signs of loosening and none are awaiting revision.

Grade 4 heterotopic ossification was found in two hips, grade 3 in two, grade 2 in nine and grade 1 in 12. There was no heterotopic bone in 23 hips.

The 14 acetabular component revisions were carried out after a mean of 12.3 years (0.5 to 20) from the initial operation. Two patients had bilateral revisions. The 12 cases had a mean age of 49.2 years (32 to 57) at revision. Detailed information on the acetabular revisions is shown in Table III. The reasons for revision and the timing thereof are shown in Figure 3. The mean HHS in the follow-up of the 13 revised hips in 11 living patients was 78.9 points (53 to 97).

In ten acetabular component revisions sufficient bone substance was available for the insertion of an equally sized or slightly larger uncemented RM component. Seven acetabular components, which were stable in spite of the osteolysis, were removed after being broken apart without additional bone loss. A reinforcement ring was needed owing to extensive bone defects, in four cases.

The Kaplan-Meier survival rate, with acetabular revision for aseptic loosening as the endpoint, was 96.2% at 15 years and 94.4% at 19.8 years (95% CI 87 to 98, Fig. 4). As rates based on samples < 20 are questionable,20 we focused on the rates at 19.8 years, and did not place much emphasis on the estimated survival rate beyond 20 years when the number of patients remaining at risk fell below 20. With any acetabular

### Table II. Merle d’Aubigné score

<table>
<thead>
<tr>
<th></th>
<th>Pre-operative</th>
<th>Current</th>
<th>Wilcoxon’s signed ranks test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Range</td>
</tr>
<tr>
<td>Pain</td>
<td>2.2</td>
<td>0.65</td>
<td>1 to 3</td>
</tr>
<tr>
<td>Mobility</td>
<td>4.5</td>
<td>0.92</td>
<td>3 to 6</td>
</tr>
<tr>
<td>Ability to walk</td>
<td>3.0</td>
<td>0.77</td>
<td>2 to 4</td>
</tr>
</tbody>
</table>

### Table III. Acetabular component revisions in chronological order

<table>
<thead>
<tr>
<th>Case</th>
<th>Gender</th>
<th>Diagnosis*</th>
<th>Age at operation</th>
<th>Time to revision</th>
<th>Reason</th>
<th>Osteolysis</th>
<th>Migration</th>
<th>Femoral head</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>AN</td>
<td>48.3</td>
<td>0.5</td>
<td>Infection</td>
<td>-</td>
<td>-</td>
<td>Metal</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>OA</td>
<td>44.9</td>
<td>4.3</td>
<td>AL†</td>
<td>Zone 1</td>
<td>Yes</td>
<td>Ceramic</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>OA</td>
<td>57.0</td>
<td>4.9</td>
<td>Infection</td>
<td>-</td>
<td>-</td>
<td>Ceramic</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>OA</td>
<td>45.2</td>
<td>8.2</td>
<td>AL</td>
<td>Zone 1+2</td>
<td>Yes</td>
<td>Metal</td>
</tr>
<tr>
<td>5 (a)</td>
<td>M</td>
<td>AN</td>
<td>40.5</td>
<td>14.0</td>
<td>Osteolysis</td>
<td>Zone 1</td>
<td>Yes</td>
<td>Metal</td>
</tr>
<tr>
<td>6 (a)</td>
<td>M</td>
<td>RA</td>
<td>42.8</td>
<td>14.0</td>
<td>Osteolysis</td>
<td>Zone 1</td>
<td>-</td>
<td>Ceramic</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>AN</td>
<td>32.6</td>
<td>14.2</td>
<td>Osteolysis</td>
<td>Zone 1</td>
<td>-</td>
<td>Ceramic</td>
</tr>
<tr>
<td>8</td>
<td>M</td>
<td>AN</td>
<td>49.0</td>
<td>14.4</td>
<td>Osteolysis</td>
<td>Zone 1</td>
<td>-</td>
<td>Ceramic</td>
</tr>
<tr>
<td>9</td>
<td>M</td>
<td>NF</td>
<td>46.3</td>
<td>14.7</td>
<td>AL</td>
<td>-</td>
<td>Yes</td>
<td>Metal</td>
</tr>
<tr>
<td>10</td>
<td>F</td>
<td>OA</td>
<td>56.2</td>
<td>15.4</td>
<td>Osteolysis</td>
<td>Zone 1</td>
<td>-</td>
<td>Ceramic</td>
</tr>
<tr>
<td>6 (b)</td>
<td>M</td>
<td>AN</td>
<td>39.8</td>
<td>15.7</td>
<td>Osteolysis</td>
<td>Zone 1+2</td>
<td>-</td>
<td>Ceramic</td>
</tr>
<tr>
<td>11</td>
<td>F</td>
<td>OA</td>
<td>54.3</td>
<td>17.6</td>
<td>AL</td>
<td>-</td>
<td>Yes</td>
<td>Ceramic</td>
</tr>
<tr>
<td>12</td>
<td>F</td>
<td>OA</td>
<td>48.6</td>
<td>20.0</td>
<td>AL</td>
<td>Zone 1</td>
<td>Yes</td>
<td>Metal</td>
</tr>
</tbody>
</table>

* AN, avascular necrosis; OA, osteoarthritis; RA, rheumatoid arthritis; NF, femoral neck fracture
† AL, aseptic loosening

The Kaplan-Meier survival rate, with acetabular revision for aseptic loosening as the endpoint, was 96.2% at 15 years and 94.4% at 19.8 years (95% CI 87 to 98, Fig. 4). As rates based on samples < 20 are questionable, we focused on the rates at 19.8 years, and did not place much emphasis on the estimated survival rate beyond 20 years when the number of patients remaining at risk fell below 20. With any acetabular

Graph showing time course of revisions of the acetabular component.
revision as the endpoint, the survival rate was 87.2% at 15 years and 82.7% at 19.8 years (95% CI 73 to 90). The cumulative probability of survival of both components at 19.8 years was 79.7% (95% CI 70 to 88) with any revision as the endpoint, and 90.7% (95% CI 83 to 96) with revision for aseptic loosening as the endpoint.

The Cox regression analysis showed that younger patients had a fourfold risk of acetabular revision compared to older patients (Fig. 5, Risk Ratio (RR) = 4.0, 95% CI 1.2 to 13.8). The main factor was the material of the head with metal heads having an eight times greater risk of acetabular revision than with ceramic heads (RR = 8.0, 95% CI 2.4 to 26.5). The effect of the size and inclination of the component were not significant (Wald chi-square p = 0.99 and 0.85, respectively) and were not included in the final model. Neither age nor gender violated the assumption of proportional hazards over time (correlations between Schoenfeld residuals and follow-up time were not significant; p > 0.85, Pearson correlation test following the approach outlined by Ng’andu). The other variables in the model, namely gender, surgical approach and body mass index respectively, did not appear to directly affect survival of the acetabular component, but were retained to account for potential confounding.

The effect of the primary diagnosis appeared to be substantial, but could not be evaluated with the Cox model owing to scarcity of data. In particular, patients with dysplasia appeared to have a more favourable prognosis, as none needed revision (log-rank test dysplasia versus remaining indications, p = 0.027).

**Discussion**

Long-term follow-up is necessary in order to evaluate the survival of any primary THR. The strength of this study is the minimum follow-up of 17 years with complete records, the combination of only two components and the absence of any significant design changes to either component. The low rate of aseptic loosening demonstrates the fixation potential of the acetabular component. Survival rates after ten years of 98%, as calculated by Flückiger and Bamert and 99.1% by Diks et al., confirm good anchorage. The coating of pure titanium particles produces excellent osseointegration and osseoconduction. In contrast to metal-backed modular systems, the structural behaviour of the polyethylene is not affected. Direct contact between uncoated polyethylene components and bone has shown comparatively poor results, with a loosening rate of 9% after seven, 17% after eight and 28% after nine years. The RM concept of a monoblock acetabular component is unique. It provides minimal relative movement at the bone-implant interface, along with optimal osseointegration. Backside wear, which occurs between a hard metal shell and the polyethylene liner, can be avoided. The design has remained unchanged and the material properties have been altered only slightly, gamma sterilisation is done under nitrogen and the polyethylene is stearate free.

Complete information was available on the deceased or revised patients and all the patients were reviewed regularly. With smaller cohorts even a few cases lost to follow-up reduce the reliability of the results. A cohort restricted to a fixed combination of components minimises the influence of different implant designs. All revisions were considered for the calculation of the survival curves.

Long-term results beyond 15 years are available for only a few uncemented systems. The Zweymüller threaded component demonstrated a survival rate of 94% with revision for aseptic loosening (respectively a rate of 85% for all acetabular revisions) after 15 years, and the AML
acetabular component, a non-modular press-fit system, gave a rate of 95.3%. The survival rates of uncemented modular components with all revisions as the endpoint have been reported for the PCA acetabular component as 79% after 20 years in young patients (mean age 48 years) and 86% after 15 years for older patients (mean 58 years). For the Harris-Galante I acetabular component, Della Valle et al reported a rate of 82% after 18 years for the past decade, with Dorr et al reporting a marked reduction of various types of femoral component must be considered. In many studies, however, bias due to incomplete follow-up, exclusion of liner exchange from the revision rate, or the use of various types of femoral component must be considered.

In order to reduce wear and particulate debris, highly cross-linked polyethylene has been used in THR over the past decade, with Dorr et al reporting a marked reduction of penetration of the metal femoral head at five years and Bragdon et al confirming low rates of wear at six years. With our current understanding of the complex biological process through which particulate debris leads to peri-prosthetic osteolysis, a marked reduction of wear using a contemporary bearing surface may lead to a marked reduction in osteolysis.

The CLS femoral component is frequently used in Europe, and good long-term fixation has been reported. A revision rate of 4.3% due to aseptic loosening after 20 years in our study confirms this experience. The high rate of femoral fractures, occurring mainly in the first two years, reflects the learning curve after the introduction of the new design of cementless femoral component in our hospital in 1985. Our current rate of femoral component fracture and fissures in cementless THR is 3%.

The limitations of this study are the relatively small number of patients and the fact that it is a single centre study. Initially, the indications for completely uncemented THR were strictly defined. Furthermore, the Merle d’Aubigné score, used initially, shows less differentiation than the HHS.

Because of the relatively young age of the patients in this study almost half of the cases had developmental dysplasia of the hip, avascular necrosis or post-traumatic osteoarthritis as the diagnosis leading to THR. These diagnoses commonly reflected some deficiency in bone stock, particularly in the acetabulum. Along with their presumed greater levels of activity, caution was advised in the treatment of these young patients. Considering the high failure rates reported with a variety of cemented acetabular components, it was hoped that uncemented acetabular components would be more durable in younger patients. Therefore, we decided to use a completely uncemented combination for young patients and this later became common practice.

In this overall young cohort Cox regression analysis revealed an approximately fourfold higher risk for acetabular component revision in the under 52-year-old group, compared to the older patients. Metal heads had approximately eight times greater risk for acetabular component revision than ceramic heads. Patients with dysplastic hips (19%) showed a significantly better outcome, with none needing revision. Although we can offer no definite explanation for this finding, some patients may be less active, and metal heads were inserted in only two cases. Furthermore, this acetabular component does not require circumferential bone contact, and half of them were implanted without complete cover in order to achieve a good inclination angle. The outcome strongly suggests that the anchoring principle and component design are suitable for these cases.

Between 13.7 and 15.7 years after the initial operation there was a notable number of revisions due to osteolysis, probably due to polyethylene wear. We evaluated these cases separately (Fig. 3). In spite of good anchorage, as seen in a low number of revisions because of aseptic loosening, the total survival rate is negatively biased owing to the influence of stable components revised for isolated acetabular osteolysis. Therefore, reduction in wear is a future challenge for uncemented hip prostheses.

Supplementary material
A further figure and two additional tables are available with the electronic version of this article on our website at www.jbjs.org.uk

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References