EARLY FEMORAL LOOSENING IN ONE DESIGN OF CEMENTED HIP REPLACEMENT

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We have studied aseptic loosening of the femoral component in 76 patients with primary total hip replacement using the Capital prosthesis. The mean follow-up was 26 months (10 to 37).

Twelve femoral components (16%) were definitely and eight (10%) were possibly loose. They were characterised by a thin cement mantle (p < 0.001) and excessive residual cancellous bone in the proximomedial region (p < 0.01).

We recommend that the cement mantle around the prosthesis should be 2 to 3 mm and that further long-term studies are needed to evaluate the wear properties of titanium-nitride-coated titanium femoral heads.

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The Charnley total hip replacement has been the standard prosthesis used in our institution, but in 1991 we began to use the new Capital total hip replacement (3M Health Care Ltd, Loughborough, UK) in some of our patients because of perceived improvement and cost advantages. This prosthesis has an ultra-high-molecular-weight polyethylene acetabular component and a titanium-alloy femoral component with a modular head (cobalt-chrome or titanium-nitride-coated titanium). The stem is similar to that of the Charnley prosthesis with straight, flanged or round-back components. The neck-shaft angle is similar and the head is 22 mm in diameter. The theoretical advantages of this system are as follows:

1) The modular design allows final correction of soft-tissue tension and leg length after cementing of the femoral component.
2) The titanium femoral components, with a low modulus of elasticity and broader gradually tapering shoulders, give a more even distribution of stress.
3) The titanium-nitride-coated titanium modular head is reported to have excellent resistance to wear in vitro.\(^1\)
4) The femoral component has a methylmethacrylate insert at the tip designed to centre the component distally, hence avoiding malalignment.

PATIENTS AND METHODS

Between March 1991 and December 1993, we treated a total of 76 patients (84 hips) using the Capital total hip replacement. The indications for total hip replacement were osteoarthritis (64), dysplasia (4), injury (3), avascular necrosis (3) and rheumatoid arthritis (2). Eight patients (eight hips) were excluded from the study: one had a deep acetabular infection and had a revision two years later, one died, two failed to attend for review and four were too old or infirm to be assessed. Thus 68 patients (26 men and 42 women) were available for review, all by one observer (SNM).

Operative technique. All the operations were performed using the Hardinge approach\(^2\) but 11 patients also had an anterior trochanteric osteotomy.\(^3\) Femoral reaming used the Capital femoral reamers and rasps. Each size of femoral component has a corresponding rasp 2 mm larger to allow a cement mantle of 1 mm around the prosthesis. The size of the femoral component is indicated by the largest size of rasp that can be fully accommodated in the femoral canal.

Two types of standard viscosity cement, CMW (De Puy International Ltd, Blackpool, UK) and Palacos (Schering Plough Ltd, Welwyn Garden City, UK), were used according to the surgeon’s preference. The cementing technique was a ‘squirt-suck’ technique\(^4\) to clean the cancellous bone using hydrogen peroxide to improve the cleaning and secure better haemostasis.\(^5\) A polyethylene Hardinge cement restrictor was used routinely and the cement was introduced from a gun followed by digital pressurisation.

Clinical assessment. All the patients were assessed using

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the Merle D’Aubigné and Postel\cite{6} and the Harris\cite{7} hip function scores. Postoperative anteroposterior pelvic and true lateral radiographs were compared with those taken at follow-up.

A satisfactory clinical outcome was recorded when the patient had minimal or no pain (grade 5 or 6) on the Merle D’Aubigné and Postel score with function satisfactory to the patient (usually grade 5 or 6) and with the prosthesis in situ. An unsatisfactory outcome was recorded when the prosthesis had been revised or when grading for pain or function was 4 or less.\cite{8} Using the Harris hip score, a satisfactory result was recorded for scores of 80 or more (excellent and good results) and unsatisfactory for revisions and scores below 80 (fair and poor results).

The radiological criteria for acetabular loosening were a radiolucent zone more than 1 mm in thickness around the whole circumference of the acetabular component involving zones 1, 2 and 3,\cite{10} or tilting or migration of the acetabular component.\cite{11} For the femoral component radiological loosening was divided into two categories. Definite loosening was migration of the component\cite{12} as demonstrated by a change in alignment (Fig. 1) or more than 2 mm of subsidence\cite{13} (Fig. 2). Possible loosening was defined as the appearance of a radiolucent line of up to 2 mm at the cement-prosthesis interface that had not been present on the postoperative radiograph (Fig. 3).

The thickness of the proximomedial cement mantle, the thickness of the residual proximomedial medial cancellous bone and the canal-fill ratio (the ratio of the width of the component to the width of the femoral canal measured 7 cm distal to the collar of the component) were determined from postoperative radiographs to assess aseptic loosening (Fig. 4).\cite{14} The latest available follow-up radiographs were used to determine the extent of femoral osteolysis.\cite{13} We determined the relationship of aseptic loosening of the femoral component to the type of cement, the alignment of the prosthesis and the type of modular head.

RESULTS
At a mean follow-up of 26 months there was a 16% incidence of definite loosening and an additional 10% of possible loosening of the femoral component. Clinical outcome. Seven femoral components had been revised at the time of review. According to the Merle D’Aubigné and Postel assessment six patients had unsat-
isfactory results because of pain: three had definite loosening and three had no loosening. Sixteen patients had unsatisfactory walking ability: three had definite loosening, two had lucent lines (1 mm and 2 mm) and 11 had no radiological signs of loosening.

Using the Harris hip score all patients with unsatisfactory results on the Merle D’Aubigné and Postel system scored less than 80 and all with satisfactory results scored 80 or more.

Radiological outcome. The radiographs were assessed independently and then conjointly by two investigators (SNM and JBH). Five hips had a lucent line of less than 1 mm in the acetabular region, but none involved the whole acetabular circumference. No patient had tilting or migration of the cup.

Twelve patients had definite femoral loosening with evidence of migration. Seven had been revised by the time of follow-up. One patient with a definitely loose femoral component had a fracture of the femoral shaft in the region of the prosthesis after minor trauma before revision. Three patients with definite loosening had symptoms and were awaiting revision surgery while the other two were asymptomatic. Eight patients had possible loosening with a lucent line of 2 mm in four, of 1.5 mm in one and of 1 mm in three; none had symptoms.

Table I shows the relationship of the proximomedial cement thickness to loosening of the femoral component.

<table>
<thead>
<tr>
<th>Proximomedial cement</th>
<th>Loosening</th>
<th>No loosening</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;2</td>
<td>10</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>2 to &lt;5</td>
<td>8</td>
<td>19</td>
<td>27</td>
</tr>
<tr>
<td>5 to &lt;10</td>
<td>2</td>
<td>10</td>
<td>52</td>
</tr>
<tr>
<td>&gt;10</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>56</td>
<td>76</td>
</tr>
</tbody>
</table>

chi-squared test (<2 v >2) = 15.3, p < 0.001

Table II shows the thickness of the cancellous bone related to femoral loosening.

<table>
<thead>
<tr>
<th>Proximomedial cancellous bone</th>
<th>Loosening</th>
<th>No loosening</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>3</td>
<td>6</td>
<td>16</td>
</tr>
<tr>
<td>2 to &lt;5</td>
<td>4</td>
<td>14</td>
<td>28</td>
</tr>
<tr>
<td>&gt;5</td>
<td>10</td>
<td>7</td>
<td>17</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>56</td>
<td>76</td>
</tr>
</tbody>
</table>

chi-squared test = 8.02, p < 0.01

There was a significant increase in the incidence of loosening when the thickness of the cement mantle in the proximomedial area was less than 2 mm (chi-squared test, p < 0.001). Table II shows the thickness of the cancellous bone left in the proximomedial region as seen on the postoperative radiographs related to femoral loosening.
There was a significant increase in the incidence of loosening when this was more than 2 mm (chi-squared test, p < 0.01); this became more significant if the thickness was more than 5 mm.

The canal-fill ratio was more than 50% for all components. There was no significant increase in the incidence of loosening with varus, valgus or neutral alignments (Table III). Femoral osteolysis occurred in six of the definitely loose femoral components. Two were classified as mild (one in one Gruen zone and one in two zones) and four were classified as moderate (three in three zones and one involving four zones). Two patients with femoral osteolysis had titanium-nitride-coated titanium modular heads while four had cobalt-chrome modular heads. We found no association between femoral osteolysis and the type of modular head inserted.

Although loosening was more common with titanium-nitride-coated titanium modular heads than with cobalt-chrome modular heads, the difference was not statistically significant (Table IV). A higher incidence of loosening was associated with the use of CMW cement than with Palacos cement (Table V).

The initial indication of possible loosening was the appearance of a radiolucent line at the superolateral margin of the cement-prosthesis interface (Figs 5a and 5b). This was followed by progression to definite loosening with a progressive change in alignment or fracture of the cement mantle and subsidence (Fig. 5c). Femoral osteolysis followed in some of the definitely loose components (Fig. 5d).

At revision surgery, the acetabular components were not clinically loose and the polyethylene had no visible wear. The femoral components were grossly loose. Multiple cultures obtained during each procedure were all negative.

Samples retrieved at revision of four femoral components were analysed. Capsular tissue showed occasional polyethylene debris but was otherwise normal. There was a mixture of dense collagen with focal regions of chronic inflammation where cracks were present in the cement mantle. In two cases, both with cobalt-chrome modular heads, there was sufficient tissue to allow analysis of metal ions. In one of these, there was a high titanium ion concentration present in the membrane.

**DISCUSSION**

There is a high incidence of early aseptic loosening of the Capital femoral component which follows a similar pattern in all cases. Many factors are implicated in loosening at the cement-prosthesis interface including the thickness and cortical support to the cement mantle, the canal-fill ratio, the alignment of the prosthesis, the design of the component and the modulus of elasticity of the device.

The Capital cement mantle was thin because the rasps are designed to give a cement mantle of 1 mm. In the series of Ebramzadeh et al., a proximomedial cement thickness of 2 mm or less was associated with early loosening of the femoral component. A cement mantle of less than 2 to 3 mm carries a higher risk of cement fracture and a thin cement mantle produced higher stresses within the cement. Aiming for a cement mantle of 1 mm made it difficult to achieve a continuous layer of cement without contact between the component and bone, thus weakening the cement mantle.

The Capital rasp has a severe, proximally tapered profile which does not allow clearance of cancellous bone trabeculae. Cancellous bone of 2 mm or more in the calcar region was associated with early loosening. A decrease in the canal-fill ratio increases the stress in the cement mantle and if less than 50% there is a significant risk of progressive loosening. All Capital femoral components, however, had a canal-fill ratio of more than 50%. There was no association between the alignment of the component and early loosening in our series.

Capital femoral stems are made of low-modulus titanium alloy with a straight-stem and a collar. Straight-stem designs have a lower incidence of loosening than curved stems. Titanium alloy components, with functioning collars, create greater stress in the calcar bone (nearer their normal values) and less in the cement mantle especially at the tip of the component compared with high-modulus components.

Bone lysis around cemented femoral components may be caused by methylmethacrylate, polyethylene or metal debris. There have been some reports of failure of titanium-alloy femoral components due to wear debris from titanium-alloy femoral heads and from shot-blasted coarse-

| Table III. Relationship of the alignment of the prosthesis to loosening of the Capital femoral component |
|-----------------|----------------|------|------|
| Prosthesis alignment | Loosening | No loosening | Total |
| Neutral | 16 | 42 | 58 |
| Varus | 1 | 3 | 4 |
| Valgus | 3 | 11 | 14 |
| Total | 20 | 56 | 76 |

chi-squared test = 0.21, p > 0.1

| Table IV. Relationship of the type of modular head to loosening of the Capital femoral component |
|-----------------|----------------|------|------|
| Type of head | Loosening | No loosening | Total |
| Cobalt-chrome | 13 | 47 | 60 |
| Titanium-nitride | 7 | 9 | 16 |
| Total | 20 | 56 | 76 |

chi-squared test = 2.14, p > 0.1

| Table V. Relationship of the type of cement to loosening of the Capital femoral component |
|-----------------|----------------|------|------|
| Type of cement | Loosening | No loosening | Total |
| CMW | 15 | 21 | 36 |
| Palacos | 5 | 35 | 40 |
| Total | 20 | 56 | 76 |

chi-squared test = 6.88, p < 0.01
surface finish components, but not from smooth-surface finish components. Titanium-nitride-coated titanium modular heads are reported to have an excellent resistance to wear in vitro. In our series, the incidence of loosening with these was not significantly higher than with cobalt-chrome heads.

In the absence of acrylic or metallic abrasive particles, the wear properties of well-fixed titanium-alloy components are comparable with those of stainless-steel or cobalt-chrome components. None of the femoral components without apparent cement failure and subsidence, or change in alignment, had any femoral osteolysis. In our study, analysis of tissue obtained from four femoral revisions showed no aggressive proliferative soft-tissue reaction invading the cement-bone interface or giant cells and histiocytes filled with metallic debris. This, in addition to the finding that a high titanium-ion concentration was not
present consistently, suggests that the creation of titanium-wear debris did not precede but followed loosening and macromotion of the femoral component.

The explanation of the higher incidence of aseptic loosening of the femoral component associated with CMW cement is unclear. Titanium alloy is especially susceptible to abrasive wear by particles of acrylic cement.

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6. Hardinge K.

Conclusions. We recommend that rasps should be designed to provide a cement mantle around the prosthesis of 2 to 3 mm and should not taper severely in the proximomedial region. In addition, we believe that curettage of the cancellous bone at the calcar region is essential to allow adequate cement thickness in this area.

Further studies are needed to evaluate the wear properties of titanium-nitride-coated titanium femoral heads. Long-term radiological follow-up of titanium-alloy femoral components is recommended to detect the femoral osteolysis which appears to follow loosening of these components.

We strongly advise that any new prosthesis, even with an apparently minor design modification, should be released for general use only after a careful prospective trial against established successful prostheses.

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REFERENCES