Between 1985 and 1993, 146 patients (162 hips) had total hip replacement (THR) using a conservative uncemented femoral component. The mean age of the patients was 50.8 years and the mean follow-up was 6.2 years (2 to 13). One patient was lost to follow-up, one died within two years of surgery and one had a revision procedure after a fracture sustained in a road-traffic accident.

For the remaining 159, Kaplan-Meier survival analysis was calculated for the incidence of revision because of mechanical loosening or osteolysis. Survival without mechanical loosening at both five and ten years was 98.2%. Survival without osteolysis was 99% at five and 91% at ten years. The Harris hip score improved from a mean of 66.3 before to 90.4 at follow-up. Of particular note is the lack of thigh pain in this group. Radiological analysis showed that 139 stems (88%) had no measurable subsidence, 8 (5%) had less than 2 mm and 12 (7%) had more than 2 mm. Two of the eight and one of the 12 were revised for mechanical loosening. Nine hips were revised for late loosening associated with osteolysis. No reaming of the femoral canal was associated with statistically significant less blood loss compared with a comparable control group of uncemented implants ($p < 0.0001$).

Our study suggests that using a conservative femoral implant does not protect against wear debris but the reliable mechanical stability (98.2%) makes this an attractive design of implant particularly for young patients.

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The management of the young patient with severe osteoarthritis of the hip is controversial. A 'conservative', uncemented femoral implant with satisfactory proximal fixation is still being sought. In the early 1980s we developed a femoral device which differed in concept from the traditional design. A number of other types of uncemented proximally fixed femoral components have been developed, mainly in Europe. These allow resurfacing the head and the stabilisation of components within the neck with or without augmentation with a side plate. We describe our experience with a double-tapered device which, after FDA approval, has been termed the Mayo Conservative Hip (Zimmer International, Warsaw, Indiana).

The goals of joint replacement include relief of pain with immediate rigid fixation, long-term biocompatibility, favourable remodelling characteristics, a minimum of bone resection, reproducible results by different surgeons and ready revision should the implant fail.

A wedge-shaped device in both the anteroposterior and lateral planes should give immediate stability from multiple-point contact when inserted into an irregularly shaped cavity (Fig. 1).

In 1982 these features were incorporated into a short, 60 mm, double-tapered titanium alloy proximal femoral replacement with a modular head and neck. This basic design has not changed since it was first used in 1985 (Fig. 2). The mechanical rigidity of its fixation has been investigated in regard to torque and displacement. When compared with an uncemented revision implant used routinely, no statistical difference in displacement was observed. Both showed less than 10 µm, well below the threshold of 30 µm which is felt to be needed for bony incorporation.

Patients and Methods

Between April 1985 and February 1993, we inserted 162 conservative implants into 146 patients. This is a consecutive series and thus includes the 'learning curve' for this device. The selection criteria included age of less than 65 years with adequate quality of bone as determined by rigid fixation of the rasp, and a body-weight of less than 90 kg. There were 72 women with a mean age of 48.6 years (19 to
68) and 74 men with a mean age of 53.2 years (20 to 72). Their mean weight was 74.6 ± 15 kg, 65.2 kg in the women and 83.8 kg in the men. The underlying pathology was osteoarthritis (99, 61%), osteonecrosis (23, 14%), developmental dysplasia (14, 9%), rheumatoid arthritis (13, 8%), traumatic arthritis (7, 4%) and slipped epiphysis (5, 3%). One patient was lost to follow-up, one died within two years of surgery and one underwent revision because of fracture as a result of a road-traffic accident. This left 159 hips available for review.

Operative technique. We use an anterolateral approach with resection of the neck of the femur and preservation of the lateral aspect without involvement of the greater trochanter. The femoral rasp is initially inserted in varus (Fig. 3) and is impacted until no further advancement is possible. Three different designs of uncemented acetabular cup were used: in eight (1985 to 1986) Dual Geometry (Osteonics, Allenhurst, New Jersey); in 21 (1986 to 1988) the Harris/Galante I (Zimmer, Warsaw, Indiana); and in 131 (1988 to 1993) the Harris Galante II (Zimmer).
The patients were routinely contacted at 2, 5, 10 and 15 years after surgery. Complete clinical and radiological data were obtained at our institution in 83 (52%), by local physicians in 51 (32%), and by questionnaire or telephone surveillance with radiographs in 25 (16%). All radiographs were reviewed by the senior author (BFM). Clinical features such as pain, limp, the use of walking aids, walking distance and the Harris hip score, were assessed for each patient. Subjective satisfaction was also evaluated. Clinical data were available at a mean of 6.5 years after surgery (2 to 13) and radiological information at a mean of 6.2 years.

**Radiological analysis.** Five features were recorded, as follows: 1) the development of a neocortex or radiolucent line; 2) remodelling in the zones of Gruen, McNeice and Amstutz; 3) osteolysis at the femoral or acetabular interfaces; 4) acetabular wear measured according to the method of Livermore, Ilstrup and Morrey; and 5) subsidence determined by recording the relationship between the proximal aspect of the medial pad of the implant and the midline of the lesser trochanter measured on the radiograph taken three months after operation and on the most recent.

**Statistical analysis.** We used the Wilcoxon rank-sum test to test for significance between the study and control groups. Statistical significance was a p value of less than 0.05. Survivorship analysis was performed according to the method of Kaplan and Meier using the endpoint for the femoral component of revision for loosening.

<table>
<thead>
<tr>
<th>Zone</th>
<th>Neocortex</th>
<th>Lucency/lysis</th>
<th>Increased/density</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>127</td>
<td>145</td>
<td>104</td>
</tr>
<tr>
<td>1</td>
<td>27</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>2</td>
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<td>6</td>
<td>0</td>
<td>4</td>
<td>53</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

**Results**

Before operation 144 hips (91.2%) had moderate or severe pain. At follow-up there was no or only slight pain in 144 (91.2%). At one year, 106 of 111 (95%) had no or slight limp. At final assessment or before revision 149 of 159 (94%) had no or slight limp. No patient had significant thigh pain.

**Radiological changes.** These are summarised in Table I. Of the 159 hips, 127 showed no evidence of a neocortex or lucent line. In the remaining 32, most changes occurred in zones 1 and 2. Evidence of femoral remodelling was considered when there was an increase in bone density in at least one of the seven zones. This occurred in 55 implants, mostly in zone 6 but also in zone 3.

Both the neocortex and increased cortical density are

Radiographs at a) one and b) six years showing that the neocortex has matured in zone 1. Increased density and remodelling are observed in zones 3 and 6.

Fig. 4a

Fig. 4b
considered favourable since they indicate proximal femoral remodelling rather than stress shielding (Fig. 4).

Proximal femoral osteolysis was observed in 11 of the 159 hips (6%) and was circumferential in two. This was observed in both of the latter more than seven years after surgery and required revision. The process was almost exclusively proximal. Eight of the 11 had osteolysis in zones 1 or 2 and six in zones 6 and 7. Distal osteolysis was rare, occurring in only three patients, all with extensive acetabular wear.

Of the nine patients with acetabular osteolysis, this occurred in zone 1 in five, in zone 2 in four and in zone 3 in one. One patient had osteolysis in zones 1 and 2, but the cup had not changed position at six years. This radiological appearance was first detected after five years in two, after six years in three and after ten years in four.

We estimated wear using the technique of Livermore et al.\textsuperscript{10} In 120 hips (75%) no wear could be measured, in 30 (19%) 1 mm of wear was observed, in five 2 mm (3%) and in four (2%) more than 2 mm. In 37 of the 39 with measurable wear, this was first observed after five or more years. In the four cases of extensive wear this was observed at five years in one, and after ten years in two. In one the cup was quite vertical (55°) and the valgus deformity of the femur caused excessive wear at the superior margin of the cup at seven years.

In 141 hips (89%) no measurable subsidence was observed on the AP radiograph. Less than 2 mm of subsidence was seen in eight (5%) and more than 2 mm in 12 (7%).

Radiographs at a) three months and b) five years after operation in a patient with a type-IA fracture. There is increased density and remodelling.
Blood replacement. Low blood loss may be expected in view of the minimal preparation of the femoral canal and the short operating time. The first 117 consecutive procedures in our series were compared with 135 performed during the same period but using conventional uncemented designs. In the former 20.5% received no transfusion compared with 4.4% of the control group. The difference in the amount of transfused blood between the two groups was statistically significant (exact Wilcoxon rank-sum test, p<0.0001).

Harris hip score and survival data. The mean preoperative Harris hip score was 66.3, and at follow-up 90.4.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cup</td>
<td></td>
</tr>
<tr>
<td>Loose</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Unstable</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Wear</td>
<td>2 (4.2)</td>
</tr>
<tr>
<td>Total</td>
<td>4 (2.5)</td>
</tr>
<tr>
<td>Stem</td>
<td></td>
</tr>
<tr>
<td>Mechanically loose</td>
<td>3 (1.8)</td>
</tr>
<tr>
<td>Pain</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Trauma/fx femur</td>
<td>2 (4.2)</td>
</tr>
<tr>
<td>Total</td>
<td>6 (3.7)</td>
</tr>
<tr>
<td>Cup and stem</td>
<td></td>
</tr>
<tr>
<td>Wear/lysis</td>
<td>9 (5.6)</td>
</tr>
</tbody>
</table>

If those who had a component revised were removed, the mean Harris hip score was 92.5 at a mean of 6.4 years after operation. The Kaplan-Meier probability of survival without revision for mechanical loosening was 98.2% both at five and ten years (Fig. 5).

Complications. There were three complications not requiring further surgery, one haematoma and two pulmonary emboli.

There were 12 (7%) intraoperative complications. In ten, there was an undisplaced, type-IA, proximal femoral fracture which did not compromise the result and was not associated with subsidence or reoperation. Each was treated by cerclage wire (Fig. 6). In one patient palsy of the sciatic nerve was noted in the recovery room. The hip was immediately re-explored and a short-neck implant was inserted. There was complete recovery at two years.

Deep infection with Streptococcus viridens occurred two years after operation in one patient. Six years after debridement the patient was asymptomatic. Delayed complications requiring revision occurred in 19 hips (12%) (Table II). Problems with the cup alone accounted for four revision procedures (2.5%) (Fig. 7).

The stem alone was revised in six cases (3.8%), two for femoral fracture, one as a result of a road-traffic accident, and one because of a fall. Three cases of mechanical loosening occurred due to inadequate fixation (1.8%). In

Radiographs showing a) an extensively worn cup at seven years in a 35-year-old woman with b) a good result seven years after revision of the cup and bone grafting of the greater trochanter.
two the device subsided in the first three months after operation, and in one an initially stable implant at six months became loose when the patient jumped three feet from a step and landed on the operated limb. All three required revision. In nine (5.6%) delayed femoral osteolysis occurred in association with wearing of the cup and revision was required for both components. The mean time to revision was seven years (4 to 11).

Discussion

Although the reported rate of failure of cemented implants has decreased in recent years with improved cementing techniques, an un cemented, more ‘conservative’ option for the younger patient continues to be a desirable goal. The double-tapered contour and absence of a collar allow the implant to be inserted until it is firmly stabilised. Metaphyseal femoral loading independent of fixation with a ‘macrolock’ interference fit. Other surgeons have obtained fixation with a ‘macrolock’ interference fit. Our design features both elements: the multiple-point contact in both planes results in an immediate ‘macrolock’ and fibre metal pads give osseous integration with rigid fixation. The value of a tapered device in optimising bone remodelling in the lateral plane has recently been demonstrated by Kuiper and Huiskes.

The clinical results of this procedure seem acceptable in the young active population. The relative lack of thigh pain and proximal resorption which has been reported in other biologically fixed systems is encouraging. As increasing surveillance becomes available, the lucent line observed in zone 1 appears to become more dense, confirming that it represents remodelling and is not evidence of loosening. Pain, with progressive lucency, in this system as with others, is indicative of loosening and occurred in three cases. Subsidence of 2 mm or more was measured in three patients who have not been revised and who are asymptomatic. This may be explained by the macrolock nature of the tapered implant which provides increasing stability with increasing depth of insertion.

These data compare favourably with a multicentre Swedish study reporting migration greater than 5 mm in 22% of 539 PCA implants (Howmedica, Rutherford, New Jersey) and requiring 41 femoral revisions (8%). Furthermore, Mallory et al reported stress shielding in 6% of 150 patients with a mean follow-up of 6.3 years, and an incidence of thigh pain of 8%. The incidence of femoral fractures is also comparable with other series with un cemented implants, particularly during the time that these prostheses were being introduced. While fracture may not be as innocuous as once supposed, no patient in our series had measurable subidence or loosening associated with an intraoperative undisplaced fracture of the femoral neck.

The most important consideration which directly correlates with considerations of design is the incidence of initial rigid fixation. In our series, 156 of the 159 hips (98.2%) had pain-free initial stable fixation. In 20 (12%) there was subsidence without pain. Most of the revisions were associated with wear, as may be expected in a group of patients with a mean age of less than 52 years.

It should also be noted that these implants have a fibre metal pad which reflects the technology available at the time of design in 1982. In some designs the non-wrap-around pad has been associated with periprosthetic osteolysis. We did not see this often in our series, possibly because of the absence of a canal filling stem which reduces the chances of the development of a biologically active periprosthetic membrane and subsequent osteolysis. Nonetheless, since FDA approval was granted, a circumferential treatment by corundumisation has been used to 'seal' the proximal femur and shield the implant from wear debris.

The current technique also preserves the lateral neck of the femur, thus reducing the access of wear debris to the proximal femur. While the generation of wear particles remains an unsolved problem, the present design has shown that preservation of bone at the initial operation is possible and subsequent revisions may be achieved with conventional designs of primary implant.

The immediate outcome with this implant is comparable to that of many cemented and un cemented devices. Early mechanical loosening (1.8%) is greater than that observed with some designs. Nonetheless, the implant has attained most of the initial goals such as preservation of the lateral neck, simplified technique, reduced blood loss (p < 0.001), short operating time, avoidance of stress shielding, favourable proximal femoral remodelling, ease of revision using primary replacement stem designs, and a limited inventory. It appears to be an attractive choice for the young patient requiring hip replacement.

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


