We report the minimum five-year follow-up of 352 primary total hip replacements using the un cemented hydroxyapatite-coated ANCA-Fit femoral component with a modular neck and head. The series comprised 319 patients (212 men, 107 women) with a mean age at operation of 64.4 years (28 to 97). The principal diagnosis was osteoarthritis. A total of 18 patients (21 hips) died before their follow-up at five years, nine patients (11 hips) were lost to follow-up, and four (four hips) declined further follow-up. Patient-reported outcomes have been recorded for 288 patients (316 hips).

Their mean Oxford Hip Score improved significantly from 41 points (16 to 57) pre-operatively to 20 points (12 to 44) at five-year follow-up. Radiological assessment showed good bony stability in 98% of implants. There were two cases of aseptic loosening of the femoral component. There were no clinical or radiological complications related to modularity. In our series we did not see the high rate of intra-operative fracture previously reported for this implant.

This medium-term follow-up study demonstrates that the clinical outcome of the ANCA-Fit femoral component is, to date, comparable with that of other metaphyseal loading femoral components.

Modular femoral prostheses allow the surgeon to optimise femoral version at the time of total hip replacement (THR) by selecting separate head, neck and shaft components. Concerns have been expressed about corrosion and fretting at the modular junctions. We report the mid-term results of a modular cementless femoral component with emphasis on patient-reported outcome measures and assessment of radiological signs that may be considered complications of modularity.

**Patients and Methods**

Between 1998 and 2003, 352 primary cementless ANCA-Fit (Cremascoli, Milan, Italy) hip arthroplasties were performed in 319 patients (212 women, 107 men). The mean age of the patients at operation was 64.4 years (28 to 97). The pre-operative diagnosis was osteoarthritis in 278 hips in 248 patients (79%), and there was evidence of hip dysplasia in 68 hips, 65 patients (19%). In two patients the osteoarthritis was secondary to a slipped upper femoral epiphysis during childhood and two patients had rheumatoid arthritis. One operation was performed for the treatment of avascular necrosis of the femoral head, and one following a fractured neck of femur.

The surgery was performed at two hospitals. Operations were undertaken by five consultant orthopaedic surgeons or directly under their supervision. The hip was accessed via a posterior approach in 78% (274 hips) of cases, and through the anterolateral approach in 22% (77 hips).

A cementless ANCA-Fit femoral component was inserted in all patients. The prosthetic stem is anatomically shaped and produced in titanium 6A14V alloy, with hydroxyapatite (HA) coating on the proximal third, to which is added a modular neck system (Fig. 1). All but four femoral components were combined with cementless press-fitted acetabular components (Cremascoli) with or without supplementary screw fixation. One hemiarthroplasty was performed with the ANCA-Fit femoral component. Three patients had a cemented acetabular polyethylene component. Of the THRs undertaken, ceramic-on-ceramic bearings were used in 316 hips (90%). Metal-on-metal, metal-on-metal and ceramic-on-polyethylene bearings were used in 13, seven and 16 hips, respectively. A 28 mm head was used in 341 hips (97%). Metal-on-metal large-diameter heads were selected for young active men not suitable for hip resurfacing. Cemented
polyethylene acetabular components were used in three patients with poor bone density, where concern existed that an uncemented component would not be secure. Polyethylene acetabular bearings were also used as the surgeon’s preference in patients considered unlikely to require revision surgery during their lifetime. Selection of the modular femoral components was based on femoral anatomy, version, soft-tissue tension, stability of the joint and the estimated leg length.

Data were collected prospectively with Oxford Hip Scores (OHS) obtained pre-operatively, at six months, and annually thereafter. Serial anteroposterior radiographs of the pelvis and lateral radiographs of the hip were evaluated by two observers (CMB, LCB) working independently, neither involved in the clinical care of the patient. Stability of the femoral component was graded according to the method described by Engh, Massin and Suthers. Evidence of spot welding, pedestal formation and reactive lines was documented in each of the Gruen zones. A positive score was considered evidence of bony ingrowth. A score between 0 and -0 points was defined as stabilisation by fibrous fixation, and a score of less than -10 points as an unstable stem. Migration was determined from serial measurement of the vertical distance between the most proximal aspect of the implant within the greater trochanter and the apex of the greater trochanter itself. The radiographs were also inspected for evidence of heterotopic bone formation.

Survival analysis was performed using Graph Pad Prism statistical software version 5.0 for Windows (Graph Pad Software Inc., San Diego, California). The survival rate was calculated using Kaplan-Meier survival curves with 95% confidence intervals (CI).

Results
In all, 27 patients (30 hips) died during the follow-up period, nine of these (nine hips) had been followed for at
least five years before death and their outcomes are included in the results. No deaths were related to hip replacement surgery and all hips were stable in situ at the time of death. From the whole series, nine patients (11 hips) were lost to follow-up before the five-year review, and a further four (four hips) declined subsequent review. Patient-reported outcomes were recorded for 288 patients (316 hips) with a minimum of five years’ follow-up and a mean follow-up of 7.2 years (5 to 10).

Clinical and functional results in the group improved significantly. The mean OHS prior to surgery was 41 points (16 to 57). At five-year review the mean OHS was 20 points (12 to 44). The reduced (improved) score was maintained in those patients reaching the nine-year follow-up (Fig. 2).

A complete radiographic series was available for 226 hips (208 patients). The mean Engh score for fixation and stability was 12 (5 to 17.5) at final review, with 221 of 226 femoral components (98%) demonstrating good bony ingrowth on radiological analysis (Fig. 3). There was no radiographic evidence of osteolysis or subsidence (considered present if the component settled by ≥ 3 mm) in any hip. In all, 22 patients (24 hips) had radiological evidence of heterotopic ossification grade 2 or above.6

There were three intra-operative fractures of the calcar, all of which were secured with cerclage cables. All three showed complete healing and stability at radiological review. There were two documented superficial wound infections post-operatively treated with oral flucloxacillin, and three patients required treatment for pulmonary emboli. There were no complications such as disassembly or lysis relating to the modularity of the femoral component.

Revision surgery was required for 12 patients (12 hips). In five this was due to recurrent dislocation (Table I), of which two needed isolated acetabular revision. In three patients revision of the modular head and neck components in isolation was undertaken. In all cases of recurrent dislocation well-fixed femoral components were left in situ. Additionally, two acetabular components were revised following aseptic loosening at four and six years after the initial operation, respectively, in both, the head and necks were also exchanged. Revision of the acetabular liner due to incomplete seating was undertaken in one hip at two years, and in one hip revision of the femoral component was undertaken following late peri-prosthetic fracture at three years. The component was found to be loose at operation. One patient awaits conversion of a hemiarthroplasty to THR.

The femoral component was revised for aseptic loosening in two hips. Revision was undertaken after two years in a 60-year-old woman. Following primary surgery she continued to have discomfort. There was radiological evidence of loosening at ten months, with 4 mm of subsidence of the femoral component. Pain was thought to be the result of abductor dysfunction, secondary to shortening and increased offset. At exploration the femoral component was found to be loose, but no evidence of infection was found.

The second case, a 66-year-old man, was revised at one year. As with the first patient, pain was described over the buttock round to the greater trochanter following primary surgery. Therapeutic injections of 0.25% bupivacaine 20 ml and 60 mg depomedrone were given, but with no effect. The leg lengths were equal, but the patient had a Trendelenburg gait.7 At exploration the femoral component was found to be loose, but again no evidence of infection was found. The symptoms have not resolved following revision surgery and a further revision is planned.

Using aseptic loosening of the femoral component as the endpoint for failure, the survival rate of the component was 99% at five years (95% CI 98 to 100) (Fig. 4). Using revision for any reason, the total survival for this series was 97.5% (95% CI 95 to 99) at five years (Fig. 5).

Discussion

The use of a modular femoral component gives the surgeon greater control of limb length while restoring geometry. Control of both femoral offset and version is possible, and has been shown to improve outcome.8,9 When undertaking revision of the acetabular component or treating an unstable THR, a modular neck permits a good surgical exposure without removing of the femoral component, and allows the surgeon to adjust femoral neck length, offset and version.

There have been some concerns regarding the introduction of additional femoral modularity.1,2 Reports of dissociation of modular components are isolated, as are cases of component breakage.10,11 Experimental studies have demonstrated metallic particle release with cyclical loading.12

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Table I. Cases of recurrent dislocation

<table>
<thead>
<tr>
<th>Case</th>
<th>Age (yrs)</th>
<th>Gender</th>
<th>Pre-operative diagnosis</th>
<th>Date of primary surgery</th>
<th>Date of revision</th>
<th>Revision procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>54</td>
<td>F</td>
<td>Dysplasia</td>
<td>15/09/00</td>
<td>07/11/01</td>
<td>Neck exchange: short straight to short antverted 15°</td>
</tr>
<tr>
<td>2</td>
<td>73</td>
<td>M</td>
<td>OA</td>
<td>22/12/00</td>
<td>22/06/04</td>
<td>Acetabulum revised</td>
</tr>
<tr>
<td>3</td>
<td>80</td>
<td>F</td>
<td>OA</td>
<td>19/01/01</td>
<td>09/03/06</td>
<td>Acetabulum revised</td>
</tr>
<tr>
<td>4</td>
<td>61</td>
<td>F</td>
<td>Dysplasia</td>
<td>08/08/00</td>
<td>03/04/01</td>
<td>Neck exchange: short antverted 15° to long antverted 15°</td>
</tr>
<tr>
<td>5</td>
<td>68</td>
<td>F</td>
<td>OA</td>
<td>24/08/00</td>
<td>19/01/01</td>
<td>Neck exchange: short antverted 15° to short straight</td>
</tr>
</tbody>
</table>

*OA, osteoarthritis
This is especially abundant when there is poor fit at the modular interface, or where a mix of metals is used. The significance of this latter finding is not clear, as the femoral component and the head are often made of different metals. In our series 281 hips (88%) had ceramic-on-ceramic bearings. With other bearing combinations it has been suggested that the surface of a metal modular femoral head could be damaged by metal particles, leading to accelerated wear, and elsewhere it has been proposed that this could be damaged by metal particles, leading to accelerated wear, leading to osteolysis. The results of clinical outcome studies are important to establish the significance of experimental models of the fretting process. In our series, no adverse radiological findings occurred during the study period to suggest the theoretical sources of particle production were causing harm.

Gill and Edge reported an intraoperative fracture rate of 15% in their series comparing the ANCA-Fit stem with a JRI furlong stem. In contrast, only three peri-operative fractures of the calcar occurred in our series.

We experienced no clinical complications relating to modularity. Using aseptic loosening of the femoral component as the endpoint for failure, our series demonstrates 99% (95% CI 93 to 100) survival of the ANCA-Fit modular femoral component at five years. Mid-term survival is comparable to that of other proximally HA-coated components. This outcome complies with the targets set by the National Institute for Clinical Excellence and the Orthopaedic Data Evaluation Panel. Improvement in the OHS was consistent with expected levels after THR.

The mean Engh score represents an excellent level of implant stability. The additional modularity did not result in any supplementary expense, as the implant was priced at a comparable rate to standard cementless stems.

This series demonstrates excellent mid-term clinical and radiological results of a modular cementless femoral component for THR, with no detrimental effects resulting from the additional modular junction.

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References