The Exeter Universal cemented femoral component at 15 to 17 years

AN UPDATE ON THE FIRST 325 HIPS


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The first 325 Exeter Universal stems (309 patients) implanted at the originating centre were inserted between March 1988 and February 1990 by a group of surgeons with differing experience. In this report we describe the clinical and radiological results at a mean of 15.7 years (14.7 to 17.3) after operation with no loss to follow-up. There were 97 patients (108 hips) with replacements still in situ and 31 (31 hips) who had undergone a further procedure. With an endpoint of revision for aseptic loosening, the survivorship at 17 years was 100% and 90.4% for the femoral and acetabular component, respectively. The mean Merle D'Aubigné and Postel scores at review were 5.4 (SD 0.97) for pain and 4.5 (SD 1.72) for function. The mean Oxford score was 38.4 (SD 9.8) (0 to 48 worst-to-best scale) and the mean combined Harris pain and function score was 73.2 (SD 16.9). Radiological review showed excellent preservation of bone stock in the proximal femur and no failures of the femoral component.

The Exeter Universal stem (Stryker Orthopaedics, Mahwah, New Jersey) was introduced in 1988 and, apart from a minor change to the neck and spigot, this polished, modular, double-tapered stem has remained unchanged (Fig. 1). In 2002 we described our experience with a consecutive series of the first 325 Exeter Universal stems at eight to 12 years.1 This highlighted the similarities in behaviour of the Exeter Universal stem and the original Exeter stem,2,3 with a predictable mean subsidence occurring at the stem-cement interface of 1.32 mm at eight to 12 years. We postulated that this subsidence was crucial to the load transmission and stability of the stem4-6 and that it was probably protective of the cement-bone interface. The 100% survivorship of the stem with aseptic loosening as the endpoint,1 and the generally benign radiological appearances seen in a broad spectrum of patients and the Barrack cement grades7 added credibility to this suggestion.

We now present an update of our series with results at a mean follow-up of 15.7 years (14.7 to 17.3) and with an emphasis on the clinical and radiological performance of the stem.

Patients and Methods

Between March 1988 and February 1990 we undertook 325 primary total hip replacements ( THRs) in 309 patients using the Exeter Universal stem. The material properties of the stem were described in our review at eight to 12 years.1

Of the 325 THRs, 133 (40.9%) were performed in men. The mean age of the patients at the time of operation was 67.6 years (24 to 87) with 31 patients (9.5%) under 50 years. The numbers of patients in each Charnley category8 are summarised in Table I. The case mix of diagnoses was presented in our original paper.1 Most patients had primary osteoarthritis, but three followed previous sepsis, 14 had a previous osteotomy or surgery for a fracture and two were conversions of a previous arthrodesis. A consultant orthopaedic surgeon carried out 48% (156) of the procedures, with a further 50.5% (164) performed by senior registrars, registrars and fellows, and 1.5% (five) by senior house officers. The data capture forms used at the time of surgery did not record details of the assistant surgeon and therefore it was not possible to determine from our database the degree of supervision during operations done by surgeons in training. However, in common with many other units at that time, after a suitable period of training, non-consultant surgeons were allowed to perform operations without direct consultant supervision.

The posterior approach was used in 248 hips and the transgluteal, or direct lateral, approach in 77,9,10 In all cases cemented polyethylene acetabular components were used; in 306 (94.2%) the acetabular components were...
metal-backed and in 19 (5.8%) they were all-polyethylene. A femoral head of 26 mm diameter was used in 316 (97.2%), a 30 mm head in seven with one each of 22 mm and 32 mm. Simplex RO cement (Stryker Orthopaedics) was used for fixation of both the acetabular and femoral components, following the general principles of exposure of strong cancellous bone, which was cleaned and dried and into which the cement was pressurised. In all cases the stem was inserted with a hollow distal polymethylmethacrylate (PMMA) centraliser, which helped to position the tip of the stem accurately, but more importantly provided a small void below the stem into which the latter could subside and therefore promoted the function of the stem as a polished taper.

All the clinical and operative data had been recorded prospectively using specially designed data-capture forms which were entered into our database. Pre- and post-operative clinical evaluation was carried out using the grading system of Merle D'Aubigné and Postel as modified by Charnley. In addition, the Harris\(^2\) and the Oxford\(^2\) hip scores were recorded at follow-up. The latter used the transformed 0 to 48 worst-to-best score as recommended by Murray et al.\(^2\) All the radiographs were digitised (Ortho-graphics Inc., Salt Lake City, Utah) before review, and were examined jointly by three surgeons (NCC, RJS, JRH) for evidence of migration of the stem at the stem-cement and cement-bone interfaces, changes in the femoral neck, diaphyseal hypertrophy, localised femoral lysis and luencies at the cement-bone interface of the stem. New radiographs were available for 88 patients (99 hips, 30%), the remaining patients being unable to attend for radiography because of infirmity. New radiographs of seven patients (seven hips) who had undergone revision of the acetabular component or re-operation for other reasons with the stem left undisturbed in the original cement mantle were also reviewed.

Subsidence at the stem-cement interface was assessed using the same technique, described by Fowler et al.,\(^2\) as in the previous review, in which the radiolucency cranialateral to the shoulder of the stem in zone 1 of Gruen, McNeice and Amstutz\(^14\) was measured. When this was not possible the reduction in distance from the tip of the stem to the bottom of the hollow centraliser was measured on the post-operative and review films. In two hips subsidence could not be measured by either method because the radiographs did not show the centraliser. Radiolucent lines were defined as linear radiolucencies adjacent to a sclerotic line, as described by Kobayashi et al.\(^15\) The acetabular components were also assessed for lucent lines at the cement-bone interface, lysis, fracture of the cement, debonding of the inferior part of the component from the cement, migration of the component and wear of the polyethylene using the method of Livermore, Illstrup and Morrey.\(^16\)

Survivorship analysis. This was performed using the life-table methods\(^17,18\) as advised by Murray, Carr and Bulstrode,\(^19\) using revision of the stem for aseptic loosening, revision of the acetabular component for aseptic loosening and revision for any reason, including periprosthetic fracture, as the endpoints. Confidence intervals (CIs) were calculated using the equations of Rothman\(^20\) (stem and acetabular loosening) and Peto et al.\(^21\) (all re-operations) as dictated by the data. Since no patient was lost to follow-up, construction of a worst-case curve was not necessary.

Results

Clinical. The patients were reviewed clinically and radiologically at a mean of 15.7 years (14.7 to 17.3) postoperatively. At the final review 181 patients (186 hips, 57.2%) had died with their replacement still in situ, at a mean of 8.3 years (0 to 16.6) from surgery. Revision or re-operation had been undertaken in 31 patients (31 hips, 9.5%), and 21 of these (21 hips) remain alive and continue to be studied prospectively, but their clinical scores were not included in this review. There remained 97 patients (108 hips, 33.2%) with their original hip in situ (Fig. 2). Of these, 14 (14 hips) were unable to attend the clinic for review either due to infirmity or because they had moved away, but Oxford and Harris hip scores were obtained by post or telephone in 12 and radiographs were acquired in five. In three there were no Oxford or Harris scores available, despite their attendance for review. The clinical scores at follow-up using the Charnley modification of the Merle D’Aubigné and Postel hip score are shown in Table I, and the Oxford and Harris hip scores in Table II. As expected, the Oxford and Harris scores are inversely related to the Charnley grade (Table II).
At the time of review 26 patients (26.8%) still undertook moderate manual labour or low-stress sport and this group had mean pain, function and movement scores of 5.5 (SD 0.89), 5.7 (SD 0.54) and 5.5 (SD 0.58) respectively, a mean combined Harris pain and function score of 82.1 (SD 20.87) (out of a possible 91) and a mean Oxford score of 43.5 (SD 7.2) (0 to 48 worst-to-best scale). A semi-sedentary level of activity was undertaken by 40 patients (41.2%), 21 (21.7%) were sedentary, and 10 (10.3%) required assisted care for a variety of reasons.

Radiological. Radiographs were available for 106 hips (Fig. 2). The mean subsidence of the stem at final follow-up, was 1.82 mm (0.4 to 3.4) and there was no migration at the cement-bone interface. Radiolucent lines were present in nine stems (8.5%, Table III) with no stems having lucent lines around more than 14% of the cement-bone interface. In another patient, previously identified in the review at eight to 12 years, there were areas of localised endosteal femoral lysis in Gruen zones 11, 12 and 13 on the lateral radiograph. These were not visible on the anteroposterior film. The lesion in zone 11 lay adjacent to the canal plug and currently measures $14.7 \text{ mm} \times 4.7 \text{ mm}$. Over the last three years there has been a reduction in the thickness of the adjacent posterior cortex from 6.5 mm to 5.2 mm. The patient has no symptoms and is being treated expectantly. The remaining 85 patients (96 hips) for whom radiographs were available had no evidence of radiolucencies at their cement-bone interfaces.

Loss of calcar height was seen in 26 hips (24.5%), but this measured 4 mm or more in only six (5.6%). Calcar round-off was defined as a slight rounding of the most proximal part of the medial cortex of the calcar but with preservation of its full height at the junction between cement and bone. This radiological appearance was seen in 72 hips (67.9%) (Fig. 3).
Migration of the acetabular component was noted in five hips (4.7%) and radiolucent lines affecting all three zones were observed in a further five. Focal pelvic osteolysis was noted in ten hips (9.4%) in which no obvious migration of the component had yet occurred. In all but one this was in DeLee and Charnley zone 1.22 Wear of the acetabular component was measured in 84 hips (79.2%); the mean total wear was 1.78 mm (0.5 to 3.6) with a mean rate of 0.11 mm/yr (0.03 to 0.23).

Survivorship. A total of 31 re-operations have been performed including revision procedures. There have been no revisions of the stem for aseptic loosening and none has fractured. The acetabular component has been revised for aseptic loosening in 13 hips (4%) and seven (2.1%) required a revision as a consequence of recurrent instability. The acetabular components revised for aseptic loosening and instability were metal-backed; none of the all-polyethylene components have been revised. There were four cases (1.2%) of periprosthetic femoral fracture, in three of which treatment was by fixation alone and in one by revision and fixation. The clinical details of these four cases are shown in Table V. Four hips were revised early because of deep sepsis and three patients have had re-operations for other reasons, two for removal of heterotopic bone and one for heterotopic cement.

The survivorship at 17 years with aseptic loosening of the stem as the endpoint was 100% (Rothman equation 95% CI 96.4 to 100) (Fig. 4). For aseptic loosening of the acetabular component, it was 90.4% (Rothman equation 95% CI 83.1 to 94.7), and with all reasons for re-operation including periprosthetic fracture as the endpoint, the survivorship was 81.1% (Peto equation, 95% CI 72.5 to 89.7), with 65 cases...
remaining at risk at 17 years (Fig. 4). As a result of the small numbers of all polyethylene acetabular components in our series it was not possible to compare their survivorship with that of the metal-backed design, although none of the 19 all-polyethylene components were revised.

Discussion
The original review of the Exeter Universal stem with results at 8 to 12 years showed its favourable behaviour with benign radiological appearances and 100% survivorship using aseptic loosening as an endpoint. With the improvements in the techniques of femoral cementing the mean subsidence was only 1.32 mm. These findings were associated with generally good or excellent clinical results. The mean age of the patients at the time of surgery was 68 years. These results were achieved by surgeons with a broad range of surgical expertise and with 52% of the operations performed by surgeons in training. There was a diverse mix of pathologies and the series included several patients who had a history of previous operations on the hip for sepsis, trauma and arthrodesis.

Approximately 10% of patients were under the age of 50, and good medium-term results have recently been reported in patients under the age of 40 using this stem.23

In the present review we have seen that the patients continue to return excellent scores for pain and function as measured using three scoring tools. Patients in Charnley group A, with only one hip affected, had a mean Merle D’Aubigné and Postel score of 5.5 (SD 0.90) for pain and 5.8 (SD 0.39) for function and their mean Oxford hip score was 43.9 (SD 8.0). We have compared the clinical scores described in our previous paper with a follow-up of eight to 12 years with those from the current review. There has been very little change in the clinical scores returned by these patients although they are now some years older. These observations were consistent for each of the Merle D’Aubigné, Oxford and Harris scores which were used to assess these patients, indicating that the good clinical results observed in our earlier paper have been maintained in the long term. Over a quarter of the patients in our series continue to undertake moderate manual labour or low stress sports, despite the fact that they are now 15 years older.

There have been no revisions for aseptic loosening of the stem and no stem is awaiting revision. These excellent results in an unselected series of patients operated on by numerous surgeons show that the polished tapered design provides an extremely reliable and durable mode of fixation. Our results agree with those from other centres.24-26

Of the nine hips which have required revision since our last report, six for aseptic loosening of the acetabular component, two for recurrent dislocation and one for a periprosthetic fracture, standard cement-in-cement revision27-29 was carried out on the femoral side in six. In two the stem was retained and the periprosthetic fracture required complete femoral revision. In the case in which the stem was retained, subsequent failure of an acetabular rim mesh, used during impaction grafting, has led to further revision including a cement-in-cement femoral exchange. The ability to perform this latter procedure is one of the major advantages of using this type of stem. With this technique, cement over the stem shoulder is cleared and the stem is then tapped out leaving the cement mantle behind. This allows full exposure of the acetabular component for revision and once this has been carried out a new stem is cemented into the old mantle. The technique therefore allows an easy exposure for revision without the potential complications inherent in removal of a well-fixed stem and cement mantle. The pristine nature of the cement-bone interface in these cases allows us to perform cement-in-cement revision more than ten years after implantation, giving further evidence of the protection that this interface is afforded by the stem.

There were four patients who required re-operation for periprosthetic fracture. Three were aged over 75 years at the time of fracture, which had been sustained in a low-energy fall. The fourth patient was a 58-year-old man who sustained the injury after a fall from his bicycle. Periprosthetic fracture is a rare but serious complication of THR. Data from the Swedish registry30 suggest that it occurs in approximately 0.4% of patients after a primary THR and in 2.1% after revision surgery. However, a recently published survivorship analysis of 6458 consecutive cemented THRs performed in Scotland31 showed an incidence at ten years of 3.6%. Our rate of 1.2% for re-operation following periprosthetic fracture after 15 years lies between these extremes. Hook et al32 described the results at ten years of 142 Exeter THRs performed in an independent centre and observed no periprosthetic fractures.

Several risk factors have been identified for periprosthetic fractures including age, the design of the stem,
previous fracture of the neck of the femur and fixation of the stem. Sarvilinna et al.33 compared 16 periprosthetic fractures with a control group of patients operated on for fracture of the neck of the femur. Within the study seven different designs of stem had been used and the authors compared the results for the Exeter component as one group with those of all the other designs combined as another. They found a higher incidence of periprosthetic fracture in the Exeter group and suggested that further studies were required to analyse this result. They had previously reviewed the results of the six most commonly used prostheses in the Finnish Arthroplasty Register of 33 154 primary THRs, which included 4798 Exeter stems. They found that the overall rate of periprosthetic fracture was low, with only 40 revisions (0.12%) for this. There were five Exeter stems (0.1%) revised for periprosthetic fracture. No association was observed between the design of the stem and the incidence of periprosthetic fracture.34

The table below provides clinical details of the four patients revised for periprosthetic fracture:

<table>
<thead>
<tr>
<th>Case</th>
<th>Gender</th>
<th>Age (yrs)</th>
<th>Indication for primary THR*</th>
<th>Time of fracture after THR (yrs)</th>
<th>Mechanism of fracture</th>
<th>Treatment</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1†</td>
<td>M</td>
<td>58</td>
<td>Osteoarthritis</td>
<td>5</td>
<td>Fall from bicycle</td>
<td>Cerclage wires and plate</td>
<td>Fracture healed. Presented ten years later with discharging sinus</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>79</td>
<td>Post-traumatic arthritis. Previous fracture dislocation of acetabulum</td>
<td>14</td>
<td>Fall at home</td>
<td>Uncemented component revision. Cement-in-cement femoral revision with long stem</td>
<td>Fracture healed. Perioperative myocardial infarction from which she recovered</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>86</td>
<td>Osteoarthritis</td>
<td>11</td>
<td>Fall in street</td>
<td>Cerclage cables and plate</td>
<td>Fracture healed. No complications</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>75</td>
<td>Post-traumatic arthritis. Previous fracture neck of femur and failure of internal fixation</td>
<td>4</td>
<td>Fall in garden</td>
<td>Cerclage wires</td>
<td>Fracture healed. No complications</td>
</tr>
</tbody>
</table>

* THR, total hip replacement
† poorly-controlled diabetic

Survivorship curves with revision as the endpoint for a) aseptic loosening of the stem, b) aseptic loosening of the acetabular component and c) any re-operation, including periprosthetic fractures.
results from the arthroplasty registers are conflicting. Lindahl et al.\textsuperscript{18} analysed 321 periprosthetic fractures from the Swedish National Hip Arthroplasty Register and found a higher rate of periprosthetic fracture for the Exeter and Charnley hip replacements compared with the Lubinus prosthesis. However, Mäkelä et al.\textsuperscript{15} have recently published the long-term results of the 12 most commonly used cemented hip replacements in the Finnish Arthroplasty Register. They noted that the Exeter Universal stem with an all-polyethylene acetabular component had the best long-term outcome.

Radiological assessment of the stem showed sustained excellent results at a mean of 15.7 years with radiolucent lines detected in only nine of 106 cases (8.5\%) reviewed. None of the stems had lucent lines around more than 14\% of the cement-bone interface, although in four the line was 2\ mm or wider. There was a single case of endosteal femoral lysis which had showed minimal change in appearance since the ten-year review.

We believe that a loss of calcar height after THR may be evidence of failure of the stem to load the proximal femur fully, according to Woolf's law. In our study, significant changes in appearance of the calcar were uncommon, although round-off was often present. In the six hips in which there was loss of calcar of 4\ mm or greater, two had undergone revision of the acetabular component for loosening, two further acetabular components were loose and migrating and another was probably loose. The sixth patient had no evidence of loosening. Preservation of calcar bone stock in most patients is evidence that this collarless, polished, tapered stem loads the proximal femur in a physiological manner.

Femoral cortical hypertrophy was seen in 11 hips (10.2\%) at a mean of 15.7 years, an appearance which may indicate that the stem is loading the femur distally. The mean subsidence in this group was 1.59 mm, compared with an overall mean subsidence of 1.82 mm. The larger size 3 stem was used in five of these 11 hips and stems of this size are rarely used in our current practice.

There was a slight increase in subsidence from a mean of 1.32 mm to 1.82 mm from ten to 15.7 years. There were only two hips in which measurement was not possible and these had Charnley pain scores of 6 and 4, the lower score occurring in a patient with rheumatoid arthritis. There were only two patients with subsidence greater than 3 mm and these both had Charnley pain scores of 6. Subsidence occurred at the stem-cement interface in all cases. We have already stressed the important role that subsidence plays in the stability of the stem.\textsuperscript{36} Roentgen stereoradiographic analysis studies have confirmed that the cement-bone interface is protected and that posterior migration of the head is minimal.\textsuperscript{37-39} This latter feature has been shown to be of greater predictive value in early failure of the stem, as borne out by the Oxford experience with the Elite Plus stem.\textsuperscript{40}

A total of 13 hips have been revised for aseptic loosening of the acetabular component and at the time of the review there were two further patients awaiting revision for this. Another eight hips have radiological evidence of loosening of the acetabular component, but revision is not planned at present. It must be remembered that 306 (94.2\%) of the THRs in our series were performed using an obsolete metal-backed acetabular component known for its propensity for failure. We discontinued its use in 1991 and it was superseded by an all-polyethylene component. Our series included 19 of this design, none of which have been revised so far. These experiences with the acetabular component have led to a number of advances in our surgical technique including the use of flanged components, iliac-bone suction\textsuperscript{41} and the development of a new instrument designed to improved cement pressurisation.\textsuperscript{42}

The excellent clinical and radiological results which were seen at eight to 12 years have been maintained in the longer term. In particular, the 100\% survivorship of the femoral component and the benign radiological appearances indicate that this type of stem achieved durable long-term fixation and transmits load in a manner which preserves bone stock in the proximal femur.

This paper could not have been written without the dedication of Professor R. Ling. As a surgeon, researcher, teacher and colleague he is an inspirational figure and we wish to express our profound sense of gratitude towards him. The completeness of this review is due in large part to the diligence of R. Sculpher, S. Wright and Z. Tippett for which we are extremely grateful. We also wish to thank Dr S. Whitehouse for her kind assistance with statistics and preparation of the manuscript.

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References
