We reviewed 142 consecutive primary total hip replacements implanted into 123 patients between 1988 and 1993 using the Exeter Universal femoral stem. A total of 74 patients (88 hips) had survived for ten years or more and were reviewed at a mean of 12.7 years (10 to 17). There was no loss to follow-up.

The rate of revision of the femoral component for aseptic loosening and osteolysis was 1.1% (1 stem), that for revision for any cause was 2.2% (2 stems), and for re-operation for any cause was 21.6% (19 hips). Re-operation was because of failure of the acetabular component in all but two hips.

All but one femoral component subsided within the cement mantle to a mean of 1.52 mm (0 to 8.3) at the final follow-up. One further stem had subsided excessively (8 mm) and had lucent lines at the cement-stem and cement-bone interfaces. This was classified as a radiological failure and is awaiting revision. One stem was revised for deep infection and one for excessive peri-articular osteolysis. Defects of the cement mantle (Barrack grade C and D) were found in 28% of stems (25 hips), associated with increased subsidence (p = 0.01), but were not associated with endosteal lysis or failure.

Peri-articular osteolysis was significantly related to the degree of polyethylene wear (p < 0.001), which was in turn associated with a younger age (p = 0.01) and male gender (p < 0.001).

The use of the Exeter metal-backed acetabular component was a notable failure with 12 of 32 hips (37.5%) revised for loosening. The Harris-Galante components failed with excessive wear, osteolysis and dislocation with 15% revised (5 of 33 hips). Only one of 23 hips with a cemented Elite component (4%) was revised for loosening and osteolysis.

Our findings show that the Exeter Universal stem implanted outside the originating centre has excellent medium-term results.
Fowler et al.1 reviewed the older designs of femoral component implanted using first-generation cementing techniques and Williams et al.7 described the use of the third-generation Exeter Universal stem, but at a mean of only 8.9 years. The other Exeter series, unfortunately, described the use of a mixture of implants.8,9

Our aim was to establish whether published results for the Exeter Universal stem were reproducible in another centre and to identify the features associated with the survival of this prosthesis.

**Patients and Methods**

Between August 1988 and May 1993, 123 consecutive patients (142 hips) underwent a primary THR with the Exeter Universal stem and a variety of acetabular components. The size of the femoral head varied between 22 mm and 32 mm depending on the type and size of the acetabular component. Surgery was performed either by the senior author (GCB) or by trainees under his supervision. All the hips were implanted using the posterolateral approach. The insertions of gluteus maximus and psoas were left intact and the short external rotators were not repaired.

The femoral components were cemented using a second-generation cementing technique. The femoral canal was prepared by thorough curettage, non-pressurised lavage and drying. The intramedullary canal was occluded 16 cm distal to the tip of the greater trochanter using a Hardinge restrictor (Corin, Cirencester, United Kingdom). Palacos R bone cement with gentamicin (Schering-Plough Ltd, Welwyn Garden City, United Kingdom) was mixed in an open bowl and inserted prograde in dough form using a disposable cement syringe (Centerpulse Ltd, Zurich, Switzerland), a venting tube and proximal digital pressurisation.

The Exeter Universal stem was used in conjunction with the Exeter cemented metal-backed acetabular component in 32 hips (Howmedica International Ltd), the cemented Elite in 23 hips (De Puy International Ltd, Leeds, United Kingdom) or the uncemented Harris-Galante I acetabular component in 33 hips (Zimmer Ltd, Swindon, United Kingdom). The Exeter acetabular prosthesis had an inside diameter of 26 mm and was abandoned in March 1991 in favour of the Harris-Galante and Elite components because of poor instrumentation and a number of early dislocations.

The acetabulum for the cemented components was prepared with sequential hemispherical reamers without preserving the subchondral bone. Most of the earlier Exeter acetabular components in the series were undersized to allow for thick cement mantles. The uncemented Harris-Galante acetabular component was generally used in younger patients (< 65 years) and was fixed by two screws in the superior aspect of the ilium.

**Clinical assessment.** The patients and their records were reviewed and the clinical outcome was measured using the Oxford hip score.10

**Radiological assessment.** The radiological outcome was assessed using sequential, calibrated anteroposterior radiographs of the pelvis and lateral views of the affected hips by two authors (BJB, PJY).

**Radiological variables.** We used well-recognised assessment techniques to standardise the radiological and clinical evaluation to allow easier comparison with other prostheses as recommended by Johnston et al.11 The cementing technique as described by Barrack, Mulroy and Harris,12 was assessed in all the 14 zones of Gruen, McNeice and Amstutz13 (Fig. 2). Grade A is defined as complete filling of the medullary cavity by cement, grade B as the presence of slight radio-
lucency at the interface between the bone and cement, grade C as radiolucency involving 50% to 99% of the cement-bone interface, or a defective or incomplete mantle of cement of any size, with metal against bone, and grade D as radiolucency involving 100% of the cement-bone interface in any projection, or a failure to fill the canal with cement such that the distal tip of the prosthesis is not covered. The thickness of the cement mantle was also measured in all 14 zones of the femoral and the three zones of the acetabular components.14

Alignment and subsidence were measured directly from calibrated sequential films. The radiological landmarks used for measuring subsidence were the greater trochanter, the proximolateral cement mantle and the prosthesis.

Radiolucent lines at the cement-stem and cement-bone interface in the post-operative and ten-year radiographs were defined using the zones described by Gruen et al13 and extended by Johnston et al11 (Fig. 3). Proximomedial bone resorption was defined using the criteria described by Engh, Bobyn and Glassman.15 In the first grade only the most proximal medial edge of the cut femoral neck is rounded off slightly, in the second there is rounding off of the proximal medial femoral neck combined with the loss of medial cortical density to the level of the lesser trochanter, in the third there is resorption of both the medial and the anterior cortex at the level of the lesser trochanter as well as the medial cortex below the lesser trochanter and in the fourth the resorption extends into the diaphysis.

Cortical hypertrophy and fracture of the cement mantle were also measured.

Ectopic ossification was defined using the criteria of Brooker et al.16 In class I, islands of bone are present within the soft tissues about the hip, in class II, there are bone spurs from the pelvis or proximal end of the femur, leaving at least 1 cm between opposing bone surfaces, in class III, there is less than 1 cm between the bone spurs and in class IV, there is apparent bony ankylosis.

Filling of the canal was measured at the mid-point of the lesser trochanter and divided into metal (implant), total cement and cancellous bone.

Wear of the acetabular component was measured by the technique described by Latimer and Lachiewicz.17

Statistical analysis. Kaplan-Meier survival curves were produced, with 95% confidence intervals.18 A p-value of < 0.05 was considered to be statistically significant.

Results
Of the 123 patients, 49 (54 hips) (40%) had died at ten years, a typical mortality figure at ten years for these patients.7,19 Only two patients (two hips) were unable to attend for radiological review, but the clinical outcome was obtained by telephone interview. The fate of every stem is known. Therefore, the 74 patients with 88 THR's who survived for ten or more years were reviewed. Their clinical details and pre-operative diagnoses are given in Table I. The four patients who underwent revision before ten years were also included in the review.

Clinical assessment. The mean follow-up was 12.7 years (10 to 17). The mean Oxford hip score at follow-up was 24 (12 to 49), and increased with pain in the hip. Many with poor scores had impaired function as a result of other arthritic joints or medical conditions and found it difficult to complete the questionnaire accurately.

Revision. The rate of revision of the femoral component for aseptic loosening was 1.1% (1 stem), and that for revision for any cause was 2.2% (2 stems). A total of 19 acetabular components (21.6%) were revised, and in the...
process of gaining surgical access, five stems were removed and fresh prostheses implanted into the same cement mantle. Further, we intend to revise ten acetabular components in ten patients for migration and/or wear of the Exeter component. We also intend to revise one stem with excessive subsidence associated with pain in the thigh. A high proportion of Exeter acetabular components has been, or will be revised (37.5%; 12 of 32), along with 15% (5 of 33) of the Harris-Galante components. The deceased patients’ records were assessed for problems with their implants and, when possible, radiographs were analysed and subsidence measured. There were no revisions of the stem in these patients.

Radiological assessment. The radiological assessment of cementing on post-operative radiographs in all 14 zones showed that Barrack grade A was seen in 63 hips (72%), grade B in none, grade C in 21 hips (24%) and grade D in four hips (4%).

Alignment, subsidence and lucent lines. All stems were inserted within 5° of neutral in the anteroposterior plane. Only five were in between 3° and 5° of varus. Three stems had a change in alignment of more than 3° over ten years, two moved into valgus and one into varus. These were associated with a primary diagnosis of atrophic osteoarthritis and all had subsided more than the average distance to 3 mm, 4 mm and 10 mm, respectively. No stems had measurable migration at the cement-bone interface. The mean vertical subsidence at the stem-cement interface was 1.52 mm (0 to 8.3) over 12.7 years. The mean subsidence was 0.12 mm (0 to 0.65) per year, slowing from 0.5 mm (0 to 0.9) in the first year to 0.03 mm (0 to 0.9) per year after four years (Fig. 4). Subsidence was significantly related to the presence of defects in the cement mantle (p = 0.01). In grade-A hips, the mean rate of subsidence was 1.24 mm (0 to 5.26) over ten years, whereas in those with defects (grade C or grade D) the mean subsidence was 2.06 mm (0.42 to 8.0) over ten years.

Of the 88 stems followed for ten years, nine had radiolucent lines present at the cement-bone interface in one or more zones. Eight of these were progressive and one had stabilised by three years after operation. None of the lucent lines involved 50% or more of the cement-bone interface. Survivorship. Survivorship curves for revision for aseptic loosening, osteolysis and re-operation for any cause are shown in Figures 5 and 6. One further stem was considered to be a failure, but is yet to be revised. This was in a 41-year-old man with inflammatory arthritis whose stem had subsided by 8 mm over 12 years. Post-operatively, he had a defect of the cement mantle at the tip of the stem (Barrack grade D).

Proximal bone preservation. The results of resorptive bone remodelling in the region of the proximomedial cortex are shown in Table II. Zero or first-degree resorption was seen in 46 hips (52%), second-degree in 29 hips (33%) and third-degree in 12 hips (14%). Only one hip showed fourth-degree resorption (1%). This was not significantly related to the size of the stem (p = 0.32) or the thickness of the mantle at the calcar (p = 0.65)

Cortical hypertrophy and fractures of the cement mantle. Cortical hypertrophy was apparent in seven stems. It occurred exclusively in Gruen zones 3, 5 and 6, but was not related to excessive subsidence, loosening, thickness of the mantle, Barrack grade, fracture of the mantle, age or poor clinical outcome.

Fracture of the cement mantle was seen in five stems. This was associated with a mean excessive subsidence of 4.7 mm (2 to 8), defects of the mantle, male gender and poor bone quality (four had atrophic osteoarthritis, one avascular necrosis (AVN)).
Wear of the acetabular component and osteolysis. Wear of the acetabular component was significantly associated with osteolysis that was virtually entirely confined to the periarticular zones (Fig. 3). The mean wear in cases without significant lysis was 1.9 mm (0 to 6) and 3.6 mm (0.5 to 11) in the lytic group ($t$-test, $p < 0.001$). Other significant risk factors were young age (analysis of variance, $p = 0.01$) and male gender ($t$-test, $p < 0.001$). Significant localised endosteal bone lysis occurred in 22 hips (25%).

Discussion
This is the first series which has reported the results for the Exeter Universal stem with a minimum follow-up of more than ten years. Compared with the series reported from Exeter, our follow-up was more complete, longer and more detailed. Our revision rate for the femoral component was 1.1% (1 stem) for osteolysis and loosening, but our follow-up was a mean of four years longer. The femoral component had a very low incidence of lucent lines at the cement-bone interface, in both our study and that from Exeter. Thus our second-generation cementing technique with a longer follow-up was comparable with the third-generation cementing techniques at Exeter. Both techniques resulted in fewer lucent lines than with the first-generation technique reported by Fowler et al and the results of all three series were comparable with the best in the literature.

The Exeter stem migrates within the cement mantle without disrupting the cement-bone interface. Subsidence increased with Barrack grading both in our series and that from Exeter, indicating that cementing technique does have some influence on the behaviour of the stem. However, in this type of stem this increased subsidence is probably not important, indicating the forgiving nature of the stem to surgical technique, and supporting its applicability to general use.

Three of the stems changed alignment significantly over the ten-year period. These were associated with a primary diagnosis of atrophic osteoarthritis and all subsided much more than average. Although the study from Exeter failed to report this phenomenon, it has been described by Fowler et al (18% of stems changed alignment), by Ling and also by RSA studies. This characteristic does not seem to occur with other polished tapered stems even when there is significant distal migration. We feel that this phenomenon is due to the rounded shape of the implant at the shoulder (zone 1), which gives less resistance to the rotation of the stem around the calcar. We do not think that this change in alignment is an important problem in itself, but the associated excessive distal migration may be more of an issue, and suggestive of inadequate support of the construct. The rounded shape of the Exeter Universal stem also appears to reduce rotational stability when compared with squarer stems, which may be important in long-term survival as the stems move into retroversion. However, the magnitude and timescale of these changes suggest that these modifications of alignment and rotation are unlikely to have any impact on the clinical performance and survival of the implant.

Lucent lines at the cement-bone interface were present in nine hips, of which eight were progressive. They were not associated with poor cementing techniques or excessive subsidence, but six had occurred in what may be described as biologically and possibly structurally deficient bone (two AVN, four atrophic osteoarthritis). Other series have noted that both AVN and atrophic arthritis are risk factors for failure through loosening in both cemented and uncemented stems. The small numbers of cases involved in our series make it difficult to draw further conclusions.

The cement mantles in our series were extremely good. Using the most critical analytical method in all the 14 zones, Barrack grade C and grade D were not associated
with failure, unlike other types of stem, but osteolysis was significantly associated with thinner or absent cement at the greater trochanter (zone 1) \( p = 0.04 \), but not reduced thickness in zone 7. Significant, localised endosteal bone lysis occurred in 22 of our hips (2.5%) and in only 0.5% in the Exeter series.\(^7\) Most osteolysis in our series occurred in the peri-articular zones (Fig. 3) and was strongly associated with wear of polyethylene. On the basis of these findings we suggest that in the presence of wear particles, the Exeter stem reduces the likelihood of distal osteolysis by minimising access to the cement-bone interface with the polished surface and tapered stem. When there is inadequate cement at the greater trochanter, peri-articular osteolysis occurs frequently. Complete cement mantles prevent access of fluid and debris\(^{30} \) and hence late loosening at the cement-bone interface caused by migratory debris.\(^{31-33} \)

Incomplete cement mantles can occur from oversizing of the stems. Chiu et al\(^{34} \) from their experience with the Exeter stem in Chinese patients with small femora, showed that there was early loosening in a population in which oversizing of the stem was common, with a resultant incomplete cement mantle and high rates of failure. These incomplete mantles can be avoided by downsizing the implant from the last broach used as long as there are adequate smaller sizes available to allow this. Scherrlinck et al\(^{35} \) confirmed that cement mantles were less likely to be deficient when the stems were downsized from the broach, although they felt that support for the larger stems was good because of excellent penetration of the cancellous bone and the more secure support afforded by the cortical bone. We have previously shown that downsizing actually reduces subsidence of the stem with polished tapers,\(^{27} \) and now downsize most of our stems. However, we have also shown that adequate mantles can routinely be achieved with larger stems as long as care is taken to remove enough cancellous bone and to align the stem properly.\(^{36} \)

There was a low rate of fracture of the cement mantle (five cases) and cortical hypertrophy (seven cases) in our series in keeping with others using polished tapered stems. The hypertrophy was always minor and was not statistically significantly related to adverse outcome, poor mantles or excessive subsidence. Even in the presence of excessive load or poor mantles, this type of stem optimises bone loading through the even double taper and debonding. Hence, signs of over- and underload are unusual. The fractures on the other hand appeared to be related to poor supporting bone and poor mantles, leading to excessive subsidence. Nevertheless, even in this undesirable circumstance, the stems did not fail clinically. The access for wear debris which fractures of the mantle normally allow, was sealed off by the wedging effect of the polished taper, and distal osteolysis did not occur.

There was a noticeable number of hips with resorption of the medial calcar. This contrasts with the original series, but with a different system, in which Fowler et al\(^{1} \) noted that preservation of the cut proximal femoral neck appeared to be uniquely satisfactory. In the subsequent series with the Universal stem from Exeter, there was more calcar resorption, but it was still minimal.\(^7\) These findings are likely to be related to the increased rigidity of the Universal stem compared with the original design used in the series of Fowler et al.\(^{1} \) A narrower implant with a larger proximal cement mantle is logical and likely to reduce proximal stress. This did not reach statistical significance in this study, but did so in our other series using the similar collarless polished tapered stems \( p = 0.02 \).\(^{27} \)

The use of the Exeter cemented metal-backed acetabular component was unsatisfactory with 34% revised so far, and most of the others radiologically loose. Only one of the cemented Elite stems was revised for loosening, suggesting that the critical variable was the design of the component or the instrumentation and not the technique of cementing. This finding is consistent with that of other series using cemented metal-backed components reported in the literature.\(^{37} \) However, we are aware that the results of the Exeter metal-backed acetabular component were satisfactory in Exeter, although these findings have never specifically been reported in the literature. The cement mantles of non-flanged metal-backed cemented acetabular components have failed in our hands. The liners of uncemented components (Harris-Galante I) wear, but flanged cemented components without metal backing are the most reliable devices over the medium to long term.

One advantage of the use of the Exeter and other polished tapered stems with failure of the acetabular component is the ease of revision. If the component needs to be exchanged, then access can be dramatically improved by taking out the stem and then replacing the same stem, or a new one, into the original mantle.

The principal benefit of hip replacement is relief from pain. The Oxford hip score, like all composite hip scores, is biased by co-morbidity in the ageing population. Our mean follow-up was four years longer than that of the Exeter study.\(^7\) The clinical results were comparable, with respect to the Oxford hip score and rate of revision of the stem. Our mean Oxford hip score at follow-up was 24 (12 to 49) and in the series from Exeter it was 20.16 (12 to 48).\(^7\)

The Exeter Universal stem is performing at least as well as any published cemented implant, but unlike the results for the Charnley stem over ten years, the Universal stem is identical to the current Exeter stem within the cement mantle.\(^{3} \) It is relatively forgiving of the surgical technique and the results of polished tapered stems are comparable with those of first-, second- and third-generation cementing techniques. This suggests that the cemented collarless polished tapered stem is suitable for general use and represents a reference standard against which other femoral components should be compared.

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