The early results with the Harris-Galante femoral stem were poor because of high rates of subsidence and femoral osteolysis [1–6]. The present study prospectively followed the clinical and radiographic performance of a consecutive series of Harris-Galante implants over the first decade to assess the magnitude and progression of the problems.

Materials and Methods

Eighty-eight primary total hip replacements in 80 patients performed between March 1984 and December 1987 by the senior author (W. H. H.) using the Harris-Galante femoral component were studied prospectively. Because during this time period hybrid total hip replacements were also being done [7,8], this uncemented femoral stem was generally used in patients younger than 65 years old who had normal proximal femoral bone stock and did not have a stovepipe configuration of the proximal femur. Thus, the series did not comprise consecutive patients and was biased against the Harris-Galante femoral component by selection of the younger patients.

Five patients (7 hips) died before the 7-year minimum follow-up. One patient (1 hip) was lost to follow-up. Two patients (2 hips) refused to obtain current radiographs but provided clinical data. One patient had a resection arthroplasty at another institution for infection at 115 months. All femoral components in these 11 hips (9 patients) had been well fixed at last follow-up, and there were no reoperations or revisions among these hips except the resection arthroplasty.
Thus, 77 hips (72 patients) comprised the present study. The average follow-up was 128 months (range, 84–155 months). There were 52 men and 20 women. The mean age at operation was 54 years (range, 30–70 years). The mean weight of the patients was 77 kg (range, 45–109 kg). The initial diagnosis was osteoarthritis in 50 hips, congenital dysplasia in 12, osteonecrosis in 6, post-traumatic arthritis in 3, rheumatoid arthritis in 2, childhood sepsis in 2, and multiple epiphyseal dysplasia in 2. Titanium hemispheric Harris-Galante porous acetabular components (HGP-1 in 74 hips and HGP-2 in 3 hips) fixed with screws were used for all hips. The diameter of the femoral head was 28 mm in 42 hips, 26 mm in 26 hips, 22 mm in 7 hips, and 32 mm in 2 hips.

The Harris Hip Score [9] was determined preoperatively and at final follow-up. Twenty-eight patients (30 hips) were evaluated by a direct interview. Forty-four patients (47 hips) were evaluated by questionnaire. All patients had current radiographs.

Femoral lysis was defined as focal areas of endosteal or intracortical loss of bone that had a scalloped contour with the appearance of bone destruction. Thin (≤2 mm) radiolucent lines between the prosthesis and the femoral cortex not causing focal erosion or scalloping were not considered lysis. The dimensions and the location of lysis were recorded according to the zones of Gruen et al. [10] on both the anteroposterior and the lateral radiographs. The severity of the osteolysis was described as extensive if the lesions occupied at least 6 zones or had an area of more than 10 cm²; intermediate, if the lesions occupied 3, 4, or 5 zones or had an area of 2.5 to 10 cm²; and mild, if the lesions occupied 1 or 2 zones or had an area of less than 2.5 cm² [5]. Smaller radiolucent areas (<2.0 mm thick) that were limited to the proximal 2 cm of the most proximal Gruen zones (so-called la, 7a, 8a, and 14a) were not considered to be osteolysis. Fixation was assessed using the radiographic evidence of bone opposition to the porous pads, radiolucent zones against porous pads, changes in position or subsidence of the stem, and changes in the particular bone pattern in the areas of the porous pads.

All patients had Harris-Galante porous acetabular components. The acetabular reconstruction is not the subject of this report. We have published a prior, matched-pair study of cemented precoated femoral stems versus this Harris-Galante porous femoral stem in which all patients had Harris-Galante porous acetabular components [1]. The group with Harris-Galante porous femoral components in that study were taken from the cases in the current report. In that study, there was no effect of the acetabular component (eg, differences in wear, polyethylene thickness, acetabular reoperations), but there was a striking and statistically significant increase in the femoral lysis in the Harris-Galante porous group compared with the cemented group. The previous study supports the concept that the major factors relating to the femoral lysis in the current series are centered around the specifics of the femoral component, not the acetabular component. Kaplan-Meier survivorship analysis [11] was used to assess the life span of the femoral component, with failure defined as revision of the femoral component.

**Results**

Fifteen stems (19%) in 14 patients were revised, 12 (16%) for aseptic loosening and femoral osteolysis. One was revised for major osteolysis around a well-fixed stem, and 1 well-fixed femoral component was revised elsewhere for recurrent dislocation. An additional femoral component was revised elsewhere for a periprosthetic femur fracture through an area of lysis. These 15 femoral revision procedures were performed at an average 69 months (range, 20–131 months).

For the 62 unrevised hips, the average Harris Hip Score was 89 points (range, 35–100 points). Of the 4 patients (5 hips) with a poor clinical result, 1 had a loose femoral stem. The remaining 3 patients with 4 hips had other factors contributing to the low Harris Hip Score. Pain was not present in 32 (52%) hips, and 28 (45%) hips had slight, occasional, or mild pain. Fifty-five patients could walk 6 or more blocks, and 52 patients had no limp or only a slight limp. Fifty-seven of the 60 patients were satisfied with the result of the surgery.

In the 62 unrevised hips, 7 (11%) of the components were loose, and 32 (52%) had lysis. Sixteen lesions were classified as mild, 15 as intermediate, and 1 as extensive. Kaplan-Meier survivorship analysis [11] revealed an 82% chance of survival at 120 months (95% confidence interval, 0.72–0.90) with failure defined as revision of the femoral component. No correlation could be made between preoperative diagnosis and the incidence of lysis in this series or with Charnley classification. This lack of correlation was probably a reflection of the small numbers of cases in each diagnostic category. Data on activity levels were inadequate for analysis.

**Discussion**

When we presented the first instance of lysis in a cementless total hip replacement [3], the incidence
of femoral lysis in the Harris-Galante femoral component was 3%. We report now the first 10-year results of that component. Nearly 20% required revision, an additional 11% (7 of 62) were loose, and the overall incidence of femoral lysis was 60% (46 of 77).

These data also show the important progression of lysis since the prior report [5] at 53 months. Our observations extend similar data by others over shorter-term follow-up [2–4]. Because the lysis is commonly asymptomatic, these and similar patients [12] should be followed regularly both radiographically and clinically.

The high prevalence of femoral osteolysis associated with this cementless femoral stem appears to be related to the noncircumferential proximal porous coating [3,5,6,12,13]. Smooth surfaces on the stem can serve as channels for particulate debris migration [13–15]. Maloney et al. [16] reinforced the importance of this in a report on a matched-pair series comparing the results of 47 cementless Harris-Galante femoral stems with 47 cementless MultiLock (Zimmer, Warsaw, IN) stems (a similar titanium alloy stem but with circumferential proximal porous coating). The patch porous-coated Harris-Galante stem had a 51% prevalence of femoral osteolysis with 4 of these components being revised. In contrast, the circumferential porous-coated MultiLock stems had no associated diaphyseal femoral osteolysis, and none were revised.

References