A COLLARLESS COBALT-CHROME FEMORAL COMPONENT IN UNCEMENTED TOTAL HIP ARTHROPLASTY

FIVE- TO EIGHT-YEAR FOLLOW-UP

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We implanted 57 un cemented cobalt-chrome porous-coated collarless femoral components into 51 patients (mean age 49 years). At review, five to eight years postoperatively, good or excellent results were recorded in 70% by the Mayo Clinic hip evaluation and in 84% by the Harris hip score. Revision for aseptic loosening of the femoral stem was necessary in only one hip. Thigh pain diminished with time and was present in only two hips at the time of review. Endosteal bone formation was seen at the junction of the smooth and the porous segments of the stem in 94% of hips and in 60%, it continued after three years. In 90% of hips, proximal femoral atrophy did not progress after three years. Discontinuous radiolucent lines were seen around 30% of stems, most commonly in zones I, IV and VII. They were not progressive in 94% and their presence did not correlate with the clinical outcome.

Loosening rates of 30% to 50% at ten years were reported in the 1980s for the femoral components of hip arthroplasties which used first-generation cementing techniques (Stauffer 1982; Sutherland et al 1982). It seemed that aseptic loosening rather than polyethylene wear would be the primary reason for long-term failure of hip arthroplasty. Accordingly, alternative methods of prosthetic fixation using un cemented porous-surfaced components were investigated at several centres. Since that time, improved cementing methods have reduced the rate of stem loosening to between 3% and 7.7% (Mulroy and Harris 1990; Stauffer 1990), but un cemented components continue to be implanted in increasing numbers.

In 1981, a trial of porous-coated collarless cobalt-chrome straight-stemmed femoral components was begun at the University of Rochester. We now report the clinical and radiographic status of the first 57 implants at a minimum of five years after implantation.

PATIENTS AND METHODS

Patients with disabling hip disease who were thought to be at high risk of early failure of a cemented implant were selected for the study. As the long-term performance of un cemented hip prostheses was not known, informed consent was obtained from all patients under the auspices of our institution’s Human Investigations Review Board. Selection criteria included a high activity level, young age, and obesity. Good bone stock without known metabolic disease or a history of a previous operation on the femur were required so as to improve the chances of fixation by bony ingrowth.

From 1982 to 1984, 57 femoral components were implanted into 51 patients; the pre-operative modified Harris hip score was less than 50 in all of them. Their mean age was 49 years (35 to 65). The un cemented arthroplasty was the first procedure in 34 patients (66%), the remainder having previously undergone resurfacing arthroplasty, internal fracture fixation, or osteotomy. The diagnosis was primary osteoarthritis in 22 patients (42%), aseptic necrosis in eight (16%), post-traumatic osteoarthritis in seven (14%), rheumatoid arthritis in six (12%), slipped capital femoral epiphysis in four (8%), ankylosing spondylitis in two (4%), and chondrolysis and old septic arthritis in one patient each (2%).

We used a porous-coated cobalt-chrome femoral component (Tri-lock; DePuy, Warsaw, Indiana). The proximal five-eighths of the stem were coated circumferentially with sintered beads of average diameter 150 μm.
(100 to 250) to form an irregular porous surface with empty spaces ranging from 150 to 400 μm. The straight collarless stem was of cast cobalt-chromium-molybdenum alloy of the Müller type (DePuy, Warsaw, Indiana). The design allowed an interference fit with the medial and lateral endosteal cortices as viewed in the frontal plane. The thin flat lateral profile gave rotational stability and three-point fixation for the stem in the curved upper femur. We used a variety of acetabular components including 30 cemented metal-backed low-profile cups, 23 uncemented one-piece metal-backed porous-coated cups and four bipolar components, two of which were later revised to porous-coated fixed sockets. Although outcome data are available for each of these acetabular configurations, they do not come within the scope of this paper. A well-functioning acetabular component cannot improve the assessment score of a loose femoral stem and a symptomatically loose or worn cup can only diminish the score of a well-fixed femoral prosthesis. The state of the acetabulum has therefore only a negative bias, enhancing the value of a favourable clinical result.

No prophylaxis against heterotopic ossification was employed because we feared that irradiation or non-steroidal anti-inflammatory agents might impair bone ingrowth. Partial weight-bearing was maintained for 12 weeks postoperatively by the use of a walker or crutches. All patients were re-examined every three months for one year and annually thereafter.

For the purpose of this review, each patient completed a questionnaire, and was examined by an independent observer. In addition to the Harris hip score, functional activities were assessed on the basis of the Mayo Clinic questionnaire (Kavanagh and Fitzgerald 1985) which evaluates pain in the operated hip, maximum walking distance, limping, the use of supports and the ability to get in and out of a car, provide foot care and climb stairs. An excellent or good score was 80 to 100 points, a fair score 70 to 80, and a poor score less than 70.

Anteroposterior and lateral radiographs were used to assess bony ingrowth and component fixation. We measured subsidence, stem shift, prosthetic fit and four separate host-bone responses: endosteal bone formation, cortical hypertrophy (as measured by cortical index), tip sclerosis, and proximal femoral atrophy. Subsidence was measured by two methods, the first comparing the relative position of the medial flange of the implant with the lesser trochanter, and the second calculating the ratio of the length of the prosthesis to the distance between the tip of its stem and the greater trochanter (Swanson and Everts 1984, Fig. 1). The seven-zone system of Gruen, McNeice and Amstutz (1979) was used for radiographic analysis of the interfaces around the femoral component.

We used the Watson-Jones anterolateral approach without trochanteric osteotomy. The gluteus minimus tendon was cut, anterior capsulectomy was performed, and the short external rotators were divided. The size of the femoral component was predicted by pre-operative templating and finalised intra-operatively. The femoral canal was prepared with hand-driven broaches; no intramedullary reamers were used. After inserting the implant as a secure 'press-fit', the gluteus minimus tendon was repaired.

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**Diagram of the methods of radiographic measurement of component subsidence (a, b) and cortical hypertrophy (c, d).**

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Fig. 1

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The one femoral component that failed was examined by gross and microscopic methods, including a histological study of the bone–implant interface.

RESULTS

Of the 57 hips, 51 were available for review (21 women, 24 men). One patient died and five hips were lost to follow-up. The mean follow-up time was 6.5 years (5 to 8). Using the modified Harris hip score, 43 hips (84%) had good or excellent results, five (10%) fair, and three (6%) poor. According to the Mayo Clinic evaluation, which includes radiographic assessment, 36 hips (70%) were good or excellent, 11 (22%) were fair, and four (8%) were poor. Of the four poor results, three were in Charnley's functional class C pre-operatively, and their scores were reduced because of chronic obstructive pulmonary disease or disabling lumbar spinal stenosis. Three of the four poor results and six of the 11 fair results occurred in the 12 hips that had previously undergone major reconstructive procedures. Two of the hips with poor results had had a trochanteric osteotomy as part of a previous procedure. One hip failed from aseptic loosening and was revised for persistent pain. Of the six hips not available for review, the one patient who had died had a poor result. The five lost to follow-up had excellent clinical results when last examined two to three years postoperatively. Excluding hips with previous major operations, primary uncemented arthroplasty yielded 88% good to excellent results, 12% fair, and no poor results by the Mayo Clinic criteria.

Five patients complained of thigh pain during follow-up and specific enquiry revealed ten more who admitted to thigh pain at some time during the postoperative period. The pain was slight in ten patients, moderate in five and severe in none. No patient used medication to control thigh pain. All but one noted a decrease in the pain with time and four patients reported spontaneous resolution of pain within one year of operation. Only two had slight discomfort in the thigh at the time of the review. All patients who were in employment pre-operatively returned to work after the procedure. Thirty-five patients (78%) required no aids for walking and nine (20%) used a cane occasionally; one patient used a crutch.

One hip was revised in a 57-year-old farmer, who had undergone staged bilateral primary total hip replacement with a 10-month interval. He had mild discomfort for four months postoperatively, but became painfree and returned to dairy-farming. At two years he developed left thigh pain and the radiograph showed a complete lucent line around the femoral component. Serial films demonstrated subsidence of slightly more than 5 mm but no endosteal lytic lesions were seen. Aspiration arthrography was negative and a bone scan showed increased uptake at the tip of the prosthesis. At revision, 2.5 years after operation, the uncemented acetabular component was found to be securely fixed and the femoral component to be loose, surrounded by a proliferative pseudosynovial membrane in the femoral shaft. Histological examination of the membrane showed a foreign-body response with metal and refractile polyethylene particles in the histiocytes and the giant cells (Fig. 2). An uncemented collared stem was implanted with an excellent result which has been sustained at five years.

Subsidence of less than 5 mm, using both methods of measurement, was seen in two femoral components. Both had radiographic evidence of bony ingrowth and a good clinical result. The one component which subsided more than 5 mm was in the patient who required revision. Seventeen stems (34%) showed a shift of the distal tip of more than 1 mm, three shifting into valgus and 14 into varus. There was no correlation between stem shift and adverse clinical outcome, suggesting that positional stem changes may have been more apparent than real and due to differences in radiographic projection. Using the method of Callaghan, Dysart and Savory (1988) for determining fit, 12 (24%) were considered to have an excellent fit, 30 (58.3%) good, and nine (18%) poor. No femoral fractures occurred during the insertion of the femoral component.

Host–bone response, as assessed radiographically, was generally favourable. Endosteal bone accretion, defined as a continuous increase in density at the prosthesis–endosteal interface, appeared between 18 months and 24 months postoperatively and was present in 48 hips (94%). In 31 hips (60%) endosteal bone formation continued to progress after the third year and in 23 (45%) it progressed beyond five years. Characteristically, the endosteal bone was most dense adjacent to the
implant at the junction between the smooth and the porous-coated segments; 45 stems (88%) showed this pattern, five (10%) demonstrated ingrowth in zone I and seven (14%) in zone VII (Figs 3, 4). Patients with rheumatoid arthritis had less progressive endosteal bone formation despite excellent clinical outcomes. No focal endosteal lytic lesions were seen. Cortical hypertrophy occurred just distal to the junction between the smooth and the porous-coated segments of the implant, in zones III and V, in 13 hips (26%) (Fig. 5). Sclerosis at the tip of the prosthesis was seen in four hips (8%). Neither cortical hypertrophy nor tip sclerosis progressed after the third postoperative year.

Loss of bone density was the most common finding in the proximal zones of the femur. Cancellisation of the cortex in zone VII and rounding of the calcar, were seen in 46 hips (90%) but only 22 (44%) demonstrated cancellisation in zone I. Proximal cortical atrophy was closely associated with endosteal bone formation at the smooth-porous junction and with distal cortical hypertrophy. Atrophy was first apparent radiographically at six months and did not usually progress after three years (Fig. 6).

Radiolucent lines appeared between one and three years postoperatively in 15 hips (30%), but only three demonstrated progression beyond the third year. The only instance of a complete radiolucent line in all seven zones was in the hip that had undergone revision for aseptic loosening. The lines were most commonly seen in zone VII and, with decreasing frequency, in zones IV, I and III (Figs 7, 8). There was no correlation between incomplete radiolucent lines and clinical outcome.

Heterotopic bone formation was seen in 26 hips (52%), two were in Brooker class IV, seven in class III and 17 in classes I and II (Brooker et al 1973). There was limitation of motion in the Brooker class III and IV hips, with difficulty in foot care and putting on shoes and socks.

**DISCUSSION**

The five-to-eight-year follow-up of our patients is longer than that of previous reports of uncemented hip arthro-
Radiographs immediately after operation (a) and six years later (b) showing cortical hypertrophy at the junction of zones II and III and V and VI.

Radiographs immediately after operation (a), two years later (b), and at six years (c). Proximal femoral bone atrophy was seen at two years but did not progress thereafter.
plasty using implants with beaded surfaces (Engh, Bobyn and Glassman 1987; Callaghan et al 1988; Engh and Bobyn 1988; Lord et al 1988). The high-risk patients in this series were carefully selected to include only active individuals with a high likelihood of early failure of cemented arthroplasty but without metabolic bone disease which might prejudice bony ingrowth. The Harris hip score of good to excellent in 84%, compares favourably with the 75% satisfactory results of cemented arthroplasties in a similar age group reported by Dorr, Takei and Conaty (1983). Many authors have reported revision rates for cemented arthroplasty of 9% to 22% in similar groups of young patients (Chandler et al 1981; Dorr et al 1983; Collis 1984; Ranawat et al 1984; Sharp and Porter 1985; Cornell and Ranawat 1985; Jinnah et al 1986; Thomas, Salvati and Small 1986; Ritter and Campbell 1987; Sarmiento et al 1990). Using the Mayo Clinic grading system we had good to excellent results in 71%, consistent with the findings of Kavanagh and Fitzgerald (1985) who noted a difference of 11% in their study ratings when radiographic criteria were added.

Recent series of cemented arthroplasties in older patients have shown lower revision rates at a similar interval, although 15% of femoral stems had extensive radiolucent lines (Harris and McGann 1986; Russotti, Coventry and Stauffer 1988). In more recent reports of cemented arthroplasties in older patients, with a 10- or 12-year follow-up, the rates of stem loosening were from 3% to 7.7% (Mulroy and Harris 1990; Stauffer 1990). The 2% stem revision rate in our primary arthroplasties at five to eight years compares well with these results.

The radiographic assessment of uncemented prostheses is difficult. While the prognostic significance of radiolucent lines around cemented implants is well-known (Collis 1982; Kavanagh and Fitzgerald 1985), their predictive value in uncemented devices is uncertain. Our data suggest that neither radiolucent zones nor radiodense lines are absolute predictors of failure. Both have been reported in as many as 79% of asymptomatic uncemented femoral components at two years postoperatively (Callaghan et al 1988; Kaplan et al 1988). Nearly one-third of our cases had these changes but only three of them progressed, and only one went on to complete radiolucency heralding mechanical failure. Radiolucent zones and radiodense lines were not seen adjacent to the junction of the smooth and porous segments (zones II and VI). Engh et al (1987) have attributed these lines to micromotion and poor fixation by fibrous ingrowth. We attach significance to these appearances, however, only when they occur at the sites of expected bony ingrowth. Clearly, all radiolucent lines adjacent to uncemented surfaces do not have the same significance in terms of outcome prediction.

![Fig. 7](image1)

Diagrammatic representation of the incidence and site of radiolucent lines.

![Fig. 8](image2)

Typical radiolucent line in zone I in a patient with an excellent clinical result at eight years.

Subsidence of the uncemented femoral stem averaging 4 mm has been reported in 7% of asymptomatic hips at less than two years postoperatively (Kaplan et al 1988). In our series only three components subsided. In one patient subsidence was more than 5 mm and required revision; in the other two it was less than 5 mm and, although one patient had slight thigh pain, both had good or excellent results clinically. No bead shedding was observed radiographically, which is consistent with previous claims that the method of sintering used for this prosthesis is effective (Turner et al 1986; Manley et al...
1987). Stem fit was rated good or excellent in 82% of hips based on criteria previously established for a curved femoral stem (Callaghan et al. 1988). Although fit did not correlate with clinical outcome, seven of the nine stems with poor fit showed some distal stem shift. This, however, had no predictive value.

Thigh pain was revealed by direct questioning in three times as many patients as those volunteering the symptom which confirms the modest degree of the discomfort in most of these patients. All patients, except the one who eventually underwent revision for aseptic loosening, noted a decrease in pain over time. None took medication to control their symptoms and only two had symptoms in the thigh at the most recent follow-up examination. There was no correlation between any of the radiographic signs and the presence of thigh pain.

In animals, progressive bone growth into the interstices of porous-coated femoral components is indicated by a continuous increase in density between the prosthetic and endosteal surfaces (Richards et al. 1987). In our patients, endosteal bone formation appeared radiographically between the first and second postoperative years in 94% of hips, and was still progressing after the fifth year in nearly half of them. It occurred mainly at the junction of the smooth and the porous segments of the stem and was generally associated with an excellent clinical result. It was not seen in patients with rheumatoid arthritis, even in those with an excellent result. Progressive endosteal bone formation in the absence of proximal femoral atrophy was invariably associated with a good or excellent result.

Engh and Bobyn (1988) have shown that circumferential coating of more than half the femoral stem results in proximal bone atrophy, as was seen in 90% of the hips in our series. Of the five components without apparent proximal femoral resorption at five years, four were 10 mm in size or smaller. Conversely, all the five femora with progressive proximal bone loss beyond three years, had stem sizes of 12.5 mm or greater. These observations support the hypothesis that greater flexural rigidity, which is proportional to the fourth power of the radius of the implant, may increase proximal femoral atrophy. Proximal resorption did not correlate with poor clinical outcome; it was commonly associated with endosteal bone formation in zones II and VI and a good clinical result suggests that this degree of stress shielding is acceptable.

Cortical hypertrophy, seen in 26% of hips, was twice as common as previously reported with the same stem at less than two years postoperatively. It occurred at the junctions of zones II and III and V and VI rather than at the tip of the prosthesis (Kaplan et al. 1988). This is just distal to the junction of the smooth with the porous-coated surfaces of the stem and immediately distal to the site of preferential endosteal bone formation. Of hips with cortical hypertrophy at this site, 86% had a good to excellent clinical result. This observation together with the localisation of endosteal new bone at the junction of the porous and smooth surfaces of the stem confirms this region as the site of concentrated stress transmission. Moving this junction more proximally along the femoral stem should decrease bone atrophy of the calcar and trochanters. Tip sclerosis, reported in 36% to 44% of previous series, was infrequent in our study (Callaghan et al. 1988; Kaplan et al. 1988; Oswald et al. 1989). The four hips with tip sclerosis all had a good or excellent fit and showed no progression after four years. Tip sclerosis had no predictive value for clinical or radiological outcome.

Our experience suggests that uncemented porous-coated femoral components can achieve durable biological fixation by bony ingrowth in high-risk patients. Thigh pain was infrequent and decreased with time. No focal endosteal bone resorption was observed. We therefore recommend this type of implant for active patients less than 70 years old who have no metabolic bone disease. A longer follow-up will be needed, however, to determine the relative merits of uncemented and cemented implants at ten to 15 years.

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