

POROUS-COATED HIP REPLACEMENT

THE FACTORS GOVERNING BONE INGROWTH, STRESS SHIELDING, AND CLINICAL RESULTS

C. A. ENGH, J. D. BOBYN, A. H. GLASSMAN

From the Anderson Orthopaedic Research Institute, Arlington and the Universities of Georgetown and Maryland

Total hip replacement using porous-coated cobalt-chrome femoral implants designed for biological fixation has been evaluated in 307 patients after two years and in 89 patients after five years. Histological study of 11 retrieved specimens showed bone ingrowth in nine and fibrous tissue fixation in two. Fixation by bone ingrowth occurred in 93% of the cases in which a press fit of the stem at the isthmus was achieved, but in only 69% of those without a press fit.

The clinical results at two years were excellent. The incidence of pain and limp was much lower when there was either a press fit of the stem or radiographic evidence of bone ingrowth. Factors such as age, sex, and the disease process did not influence the clinical results. Most cases showed only slight resorptive remodelling of the upper femur, but in a few cases with a larger, more rigid stem, more extensive bone loss occurred. The results after five years showed no deterioration with time. Fixation by the ingrowth of bone or of fibrous tissue both appeared to be stable, but bone ingrowth gave better clinical results.

The concept of fixing total hip prostheses by bony ingrowth rather than by cement, has evolved in an attempt to decrease the incidence of loosening (Judet et al. 1978; Lord, Hardy and Kummer 1979; Morscher 1984). The attractiveness of biological fixation lies in its potential for direct attachment of the implant to bone without an interposed fibrous tissue layer. It has been shown that the interface between implant and ingrowing bone can remodel with time and can maintain stability (Pilliar, Cameron and Macnab 1975; Spector et al. 1978; Bobyn et al. 1982; Hedley et al. 1982; Chen et al. 1983; Galante 1983; Harris et al. 1983; Spector et al. 1983).

Since 1977, cementless total hip replacement with porous-coated femoral prostheses has been performed routinely at the Anderson Clinic. The results have been very encouraging and we have sought to elucidate some of the factors of biological fixation which make for success.

We have studied the histological evidence for bony ingrowth, its frequency, radiographic appearance and clinical features. We have also assessed the importance of a press fit and of bone resorption and remodelling, and we have examined the long-term results.

MATERIALS

Implants. The femoral stem used in all cases was fabricated from cast cobalt-chrome alloy and coated with a powder-made, sintered porous surface (Pilliar et al. 1975; Pilliar 1983). Initially this surface had an average pore size of about 100 μm ; since 1979, this has been increased to about 250 μm . The implant was the straight-stemmed, collared, modified Moore design shown in Figure 1 (Engh 1983). Most stems had porous coating from under the collar to the tip of the stem; in more recent cases it was not applied to the distal two inches of the stem. With both types, the porous-coated part of the stem extended into the isthmus of the femur. In the earlier years only, the stem size was 10.5 mm in diameter; since 1981 diameters ranging from 9.0 to 18.0 mm in 1.5 mm increments have been available.

These uncemented femoral components were combined with either cemented, bipolar, porous-coated, or threaded acetabular components. Although clinical and radiographic data are available for each of these acetabular designs, the discussion of the acetabular side of the arthroplasty is not within the scope of this paper. **Histological specimens.** A total of 11 femoral specimens have been retrieved to date. In 10 of these the stem was obtained intact within the femur at autopsy and the specimen was processed whole. In one case the stem was removed during revision surgery for a failed acetabular component. In the longest term retrievals (6 years and 7 years), the porous coating had the smaller 100 μm pore size; in the other cases, the larger 250 μm size had been used. Details are given of each retrieval in Table I. In three cases the opposite femur also was obtained,

C. A. Engh, MD, Staff Orthopaedic Surgeon
J. D. Bobyn, PhD, Research Director
A. H. Glassman, MD, Staff Orthopaedic Surgeon
Anderson Clinic and Research Institute, 2465 Army Navy Drive,
Arlington, Virginia 22206, USA.

Requests for reprints should be sent to Dr C. A. Engh.

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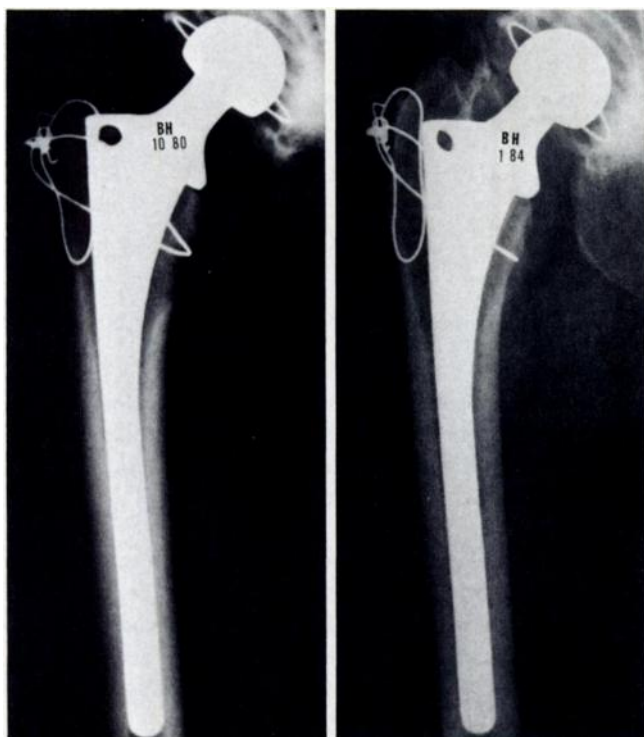


Fig. 1a

Fig. 1b

Radiographs of a 10.5 mm diameter fully porous-coated stem implanted into a 72-year-old woman with osteoarthritis. The immediate postoperative film (a) shows that the stem contacts the medial and lateral cortices with a press fit at the isthmus. Four years later (b) there is little change in the density and thickness of the bone around the implant except for the proximal medial aspect. The rounding of the cut edge of the medial femoral neck alone is classed as first degree stress shielding, but in this case, the additional loss of cortical density for about 2 cm distally resulted in classification as second degree stress shielding.

permitting a more detailed study of bone remodelling. **Patients.** The first 381 consecutive cases were operated upon at least two years before this assessment; 15 have been lost to follow-up, 9 have died, and 50 have not yet had their two-year examination. Thus, we have complete information about 307 cases from before operation to two years after. The pre-operative diagnosis was osteoarthritis in 218 cases, rheumatoid arthritis in 41, avascular necrosis in 40, and femoral neck fractures in eight. There were 176 women and 131 men with an average age of 56 years. In respect of Charnley's three classes of function, 135 patients were in Class A, having unilateral hip disease and no other problems, 92 were in Class B with bilateral hip disease and no other problems, and the 80 in Class C had other orthopaedic and/or medical problems which might reduce their scores regardless of the hip replacement (Charnley 1972, 1979). There were 182 fully coated and 125 partially coated prostheses in this series. In about two-thirds of the cases a small diameter (12.0 mm or less) stem was used and in the remainder the diameter was 13.5 mm or more.

Eighty-nine of the 307 patients have been followed up annually for at least five years. Forty-seven of these patients had osteoarthritis, 23 had rheumatoid arthritis, 18 had avascular necrosis, and one had had a femoral neck fracture. There were 57 women and 32 men with an average age of 53 years. Thirty-eight patients were of Charnley's Class A, 31 were Class B, and the remaining 20 were Class C. All 89 of the stems in this series were fully porous coated and all but four were of 10.5 mm diameter.

Table I. Specimens retrieved for histological examination

Specimen	Patient's age (years)	Sex	Diagnosis	Stem diameter (mm)	Extent of porous coating	Pore size (μm)	Interval before retrieval	Bone ingrowth	Opposite femur retrieved
1	78	M	Fracture	10.5	Full	250	4 weeks	Yes	No
2	87	F	Fracture	10.5	Full	250	6 weeks	Yes	No
3	82	M	Osteoarthritis	15.0	2/3	250	6 months	Yes	No
4	65	M	Osteoarthritis	16.5	2/3	250	7 months	Yes	Yes
5	84	F	Fracture	12.0	Full	250	1.5 years	Yes	Yes
6	75	M	Osteoarthritis	10.5	Full	250	2 years	Yes	No
7	73	M	Osteoarthritis	13.5	2/3	250	2 years	Yes	No
8	87	M	Fracture	10.5	Full	250	2.5 years	No - distally Yes - proximally	No
9	74	M	Osteoarthritis	10.5	Full	250	3 years	Yes	No
10	74	F	Rheumatoid arthritis	10.5	Full	100	6 years	No	Yes
11	58	M	Avascular necrosis	10.5	Full	100	7 years	Yes	No

METHODS

Histology. The specimens were dehydrated in ethanol, defatted in ether and acetone, embedded in polymethylmethacrylate, sectioned with a diamond-blade cut-off machine, and hand thinned on petrographic polishing wheels (Bobyne and Engh 1984; Engh and Bobyne 1985). Transverse sections were prepared along the length of each specimen, stained with Paragon, and examined by transmitted light. In each specimen the presence of bone or fibrous tissue ingrowth was noted and correlated with the radiographs, concentrating on the appearance of the bone-implant interface and signs of bone remodelling as compared with the contralateral femur.

Clinical evaluation. Before operation each patient was graded using the method advocated by Merle d'Aubigné and Postel (1954).

Each patient was also assigned a *bone quality score* based on an arbitrary 10-point scale derived from a pre-operative radiograph (Engh and Bobyne 1985): this scale includes a maximum of four points for the ratio of the diameter of the femur to that of the intramedullary canal at the isthmus, a maximum of three points for a simplified Singh index of the cancellous bone trabeculae in the intertrochanteric region, and one point each for a diagnosis other than rheumatoid arthritis, male sex, and

Table II. Number of patients evaluated two years and five years after operation

Interval since operation	Available for radiographic evaluation	In Charnley's Class C	Available for clinical evaluation	With complications
2 years	307	80	214/294*	13
5 years	89	20	60/80	9

* with and without Charnley Class C patients

age under 50 years. Patients were arbitrarily divided into groups scoring 1 to 5 (poor bone quality) and 6 to 10 (good bone quality).

Postoperative complications that might lower the clinical rating but were unassociated with the success of femoral stem fixation were also noted.

The yearly follow-up visits included both radiographic and clinical evaluation (see Table II) and the patients were again assessed according to Merle d'Aubigné and Postel's scale. Emphasis was placed on the presence or absence of a postoperative limp, and thigh pain which could be related to the implant. Patients with any discomfort were questioned as to the type of pain (start-up hesitancy or delayed onset of thigh discomfort) and the activity which caused the pain. From the series assessed at two years, 13 patients were eliminated

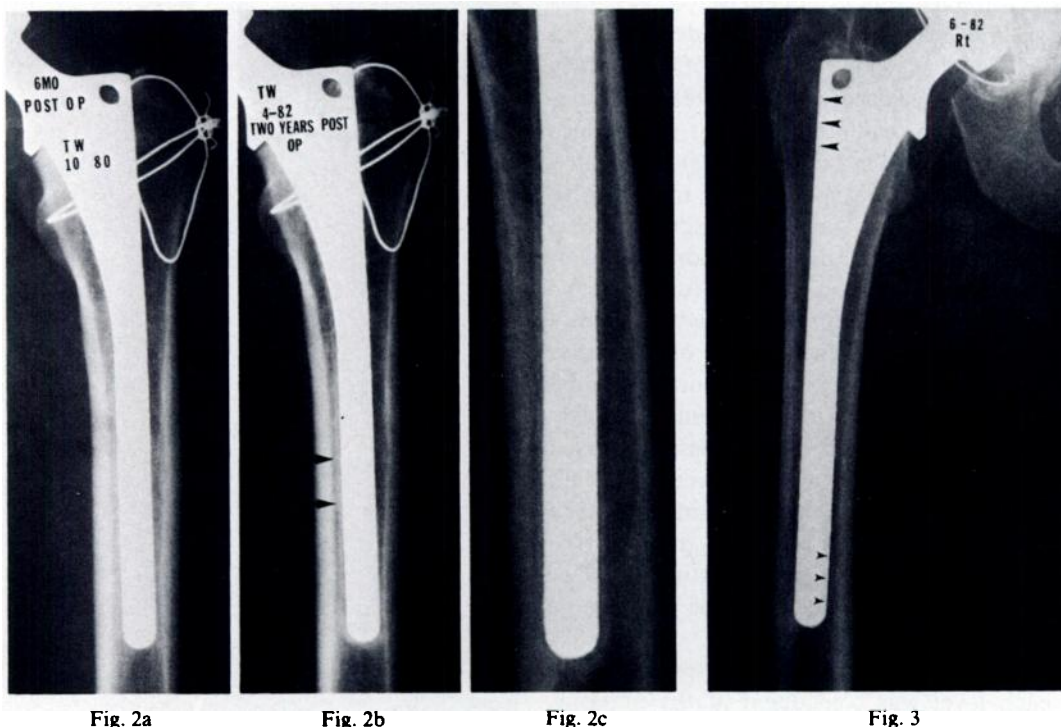


Figure 2 - Radiographs of a 30-year-old man at six months (a) and at two years (b), showing a 10.5 mm fully porous-coated stem which does not have a press fit at the isthmus. The two-year radiograph illustrates an apparent lateral shift in the position of the stem and the beginning of a radio-opaque line. At five years (c) a lateral radiograph shows complete encapsulation of the stem by a thin radio-opaque line. The stem is stable within the shell of new bone and this radiographic appearance has not changed. This appearance is typical of fibrous tissue fixation (see Fig. 10) as confirmed by histology in similar cases. Figure 3 - Radiograph of a 55-year-old woman with rheumatoid arthritis two years after operation. A 10.5 mm fully coated stem has been used and there is a large mismatch between the size of the implant and the medullary canal. Divergent radio-opaque lines are visible laterally in the intertrochanteric region and medially near the stem tip (arrowheads). Periosteal hypertrophy is present near the stem tip indicating high load transfer and lack of uniform stress distribution more proximally. This was classified as an unstable stem.

because of trochanteric non-union, loose acetabular components, heterotopic bone, and, in one case, a sciatic nerve palsy (Table II). From the five-year series, nine cases were eliminated. In both series the scores were computed both with and without Charnley's Class C patients (Table II). In this manner, the performance of the prostheses could be evaluated both with and without the influence of extraneous variables.

Radiographic evaluation. The technique and positioning for all radiographs were standardised and a magnification marker and aluminium step wedge were used on each film. The films were examined with respect to bone or fibrous tissue fixation and for bone remodelling.

Immediate postoperative anteroposterior radiographs were used to assess the press fit of the stem at the isthmus. The patients were divided into those with a good press fit, contacting both endosteal cortices at the same level at the isthmus (Fig. 1), and those without (Fig. 2).

We found that we were able, by radiographic inspection alone, to decide whether there was a high likelihood of stable fixation by bone ingrowth, stable fixation by fibrous tissue ingrowth, or an unstable prosthesis. *Fixation by bone ingrowth* was defined as an implant with no subsidence and minimal or no radio-opaque line formation around the stem; most of the bone-implant interface should appear stable (see Figs 1,5,6,7 and 8). *Stable fibrous ingrowth* was defined as an implant with no progressive migration (slight early migration may have once occurred) and extensive radio-opaque line formation around the stem: these lines surround the stem in parallel fashion and are separated from the stem by a radiolucent space up to 1 mm in width (Fig. 2); the femoral cortex shows no signs of local hypertrophy, suggesting that the surrounding shell of bone performs a uniform load-carrying function. An *unstable implant* was defined as one with definite evidence of either progressive subsidence or migration within the canal and is at least partially surrounded by divergent radio-opaque lines that are more widely separated from the stem at its extremities. Increased cortical density and thickening typically occur beneath the collar and at the end of the stem, indicating regions of local loading and lack of uniform stress transfer; the appearance is one of a very poorly-fitting implant (Fig. 3) although it may not necessarily be so unstable that revision is indicated.

Bone remodelling of the femur was assessed at four levels and each level was considered at the anterior, posterior, medial, and lateral quadrants, yielding a total of 16 inspection sites (Fig. 4). At each annual review the radiographic appearance of bone at each site was recorded as being thicker or thinner and lighter or darker relative to the femoral shaft below the tip of the stem. Typical changes included loss of bone density and thickness at the more proximal levels and increased density and thickening of the cortices at the lower levels.

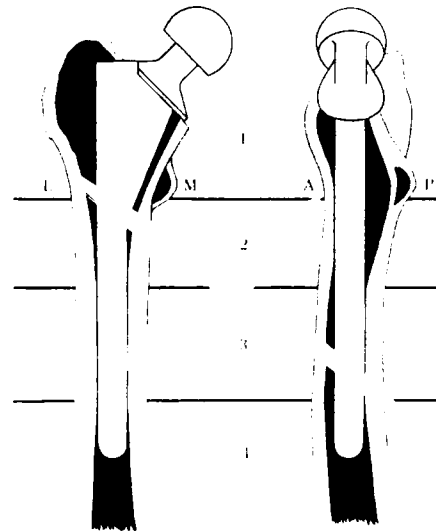


Fig. 4

Schematic division of the femur into four levels for studying bone remodelling. At each level, the medial, lateral, anterior, and posterior sites were examined for thickening or thinning and for radiographic lightening or darkening of the bone adjacent to the implant.

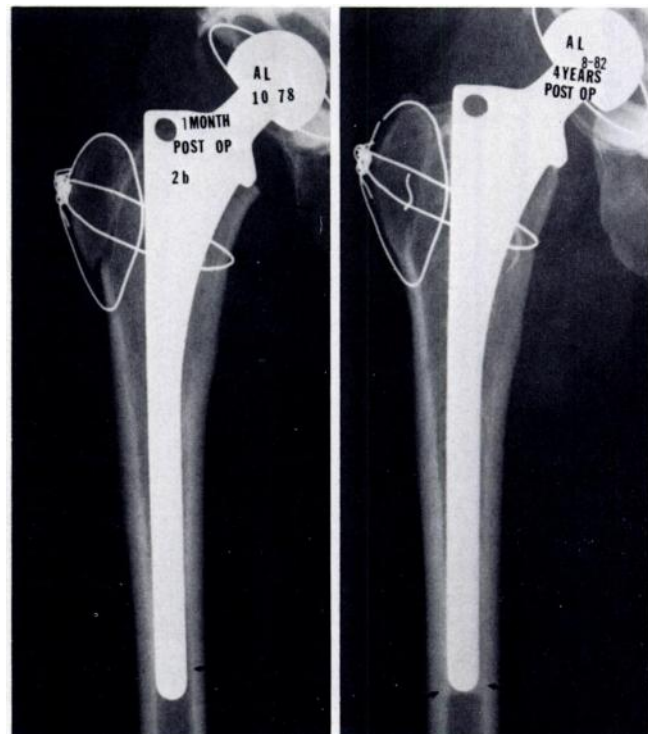


Fig. 5a

Fig. 5b

Radiographs of a 36-year-old woman with rheumatoid arthritis, showing a 10.5 mm diameter fully porous-coated stem, with a press fit at the isthmus in the early postoperative film (a). At four years the radiograph (b) shows third degree stress shielding. The proximal medial cortex has become osteoporotic down to the lesser trochanter and there is new endosteal bone formation near the tip of the stem. The entire bone-implant interface is stable and typical of those classified as having a high likelihood of bone ingrowth. This appearance has not changed up to seven years after operation.

The resorptive bone remodelling changes were attributed to *stress shielding* and categorised into degrees of severity: *first degree* – only the most proximal medial edge of the cut femoral neck was rounded off slightly (Fig. 1), which may have been partly due to disruption of blood supply at the osteotomy; *second degree* – rounding off of the proximal medial femoral neck was combined with loss of medial cortical density at level 1 as viewed on an anteroposterior film (Fig. 1); *third degree* – more extensive resorption of cortical bone typically involved both the medial and the anterior cortical regions at level 1 and the medial cortex at level 2 (Fig. 5); *fourth degree* – cortical resorption extended below levels 1 and 2 into the diaphysis, with the changes characteristically occurring in the medial and posterior cortices just above the level of the press fit where the cortex was most widely separated from the straight stem (Fig. 6).

RESULTS

Histology. The results of the histological analyses with respect to bone or fibrous tissue ingrowth are listed in Table I. Nine of the 11 prostheses were ingrown with bone and two with fibrous tissue. Some of these cases are detailed below.

A patient who died seven months after operation (Specimen 4 in Table I) is illustrated in Figure 7. Both femora were retrieved, and the postmortem radiographs show that the implant made little difference to the bone density. Transverse sections just proximal to the junction of porous and smooth implant surfaces are shown in Figures 7c and 7d. The implant-containing section shows the excellent press fit medially and laterally and apparent new bone formation in the form of discrete bridges between the porous coating and the endosteum anteriorly. It also appears that the cortex of the implant-containing section is more osteopenic than that of the normal femur. In two other cases (Specimens 5 and 10 in Table I), part of the contralateral femur was retrieved and the implant-containing sections again also showed a slight relative increase in cortical porosity.

Figure 8a shows the postmortem radiograph of a three-year retrieval (Specimen 9 in Table I) in which very little cortical osteopenia was observed either radiologically or histologically. Abundant new bone formation was evident along the stem (Fig. 8b) and bone ingrowth such as that illustrated in Figure 8c was common.

The seven-year retrieval (Specimen 11 in Table I) involved a case in which a small pore-sized implant was

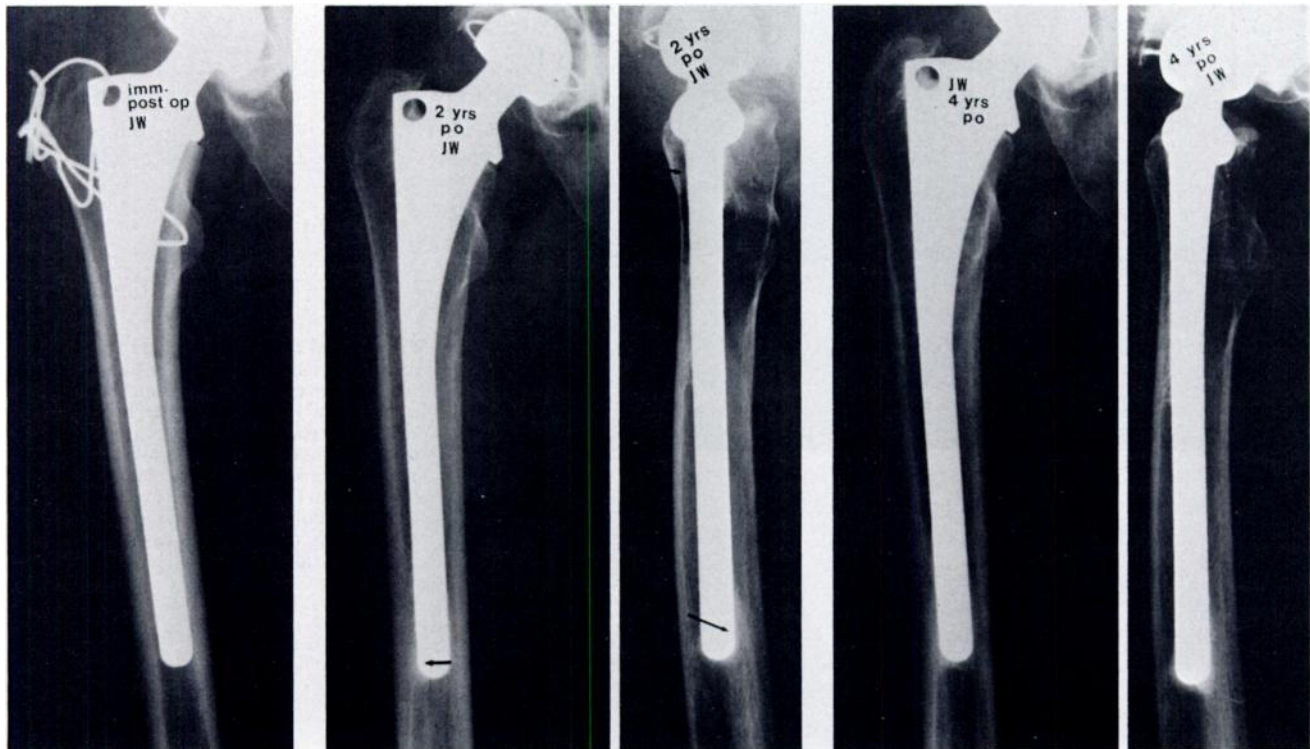


Fig. 6a

Fig. 6b

Fig. 6c

Fig. 6d

Fig. 6e

Radiographs of a 51-year-old woman with avascular necrosis. The postoperative film (a) shows implantation of a 10.5 mm fully coated stem. After two years (b) an anteroposterior radiograph shows marked loss of cortical density at levels 1 and 2 medially and laterally. This case is typical of those classified as showing fourth degree stress shielding. The distal tip of the stem appears to be fixed by new endosteal bone formation (arrow). The lateral radiograph at two years (c) shows good fixation of the stem anteriorly at level 2 and posteriorly at level 4 near the stem tip. The cancellous bone posterior to the stem has lost some density. The radiographs at four years (d and e) show no great progression of the severity of stress shielding. This was the only case in which a small diameter stem was associated with resorption typical of fourth degree stress shielding. The resorptive remodelling occurred unusually rapidly, being noted on six-month postoperative radiographs. Causalgia-like symptoms in the first postoperative year suggested a sympathetic dystrophy.

electively removed during an operation to revise the cup. The stem was well fixed and slender osteotomes were needed to divide the bone-implant interface before it could be forcefully extracted. Osseous tissue remained attached to the proximal regions of the stem. Sections showed the attached bone to be in apposition to the stem and within the surface porosities (Fig. 9).

Two of the 11 cases (Specimens 8 and 10 in Table I) showed evidence of fibrous tissue ingrowth. Specimen 8 had a prominent radio-opaque line, like that in Figure 2, around most of the implant length. Histologically, there was a thin shell of bone around the implant surface but separated from it. Specimen 10, a six-year retrieval, was a small pore-sized implant which showed a radio-opaque line around its distal portion, and in this region, the histological appearance was similar to that of Specimen 8 with fibrous tissue obliquely orientated within the space between the shell of bone and the porous surface (Fig. 10). More proximally in Specimen 10, there was no

visible radio-opaque line and bone was seen to be in direct apposition to the porous surface.

Radiography. The radiographic appearance of the bone-implant interface seen in Figures 1,5,6,7, and 8 is that of bone ingrowth at multiple points along the stem; this has been confirmed histologically. With such bony ingrowth there is no prosthetic subsidence, no radio-opaque lines around the porous-coated portion of the stem, and a pattern of bone remodelling which involves new endosteal bone in contact with the stem, increase of cortical density at points of contact, and proximal cortical atrophy in regions where the cortex is most distant from the stem. This corroborates findings in many canine porous-coated implants which have been studied both radiographically and histologically (Bobyne 1977, 1980; Bobyn et al. 1980, 1981, 1987). The appearance of a stem surrounded by an extensive radio-opaque line (Fig. 2) correlates histologically with the presence of a fibrous tissue layer between the porous surface and the surround-



Fig. 7a

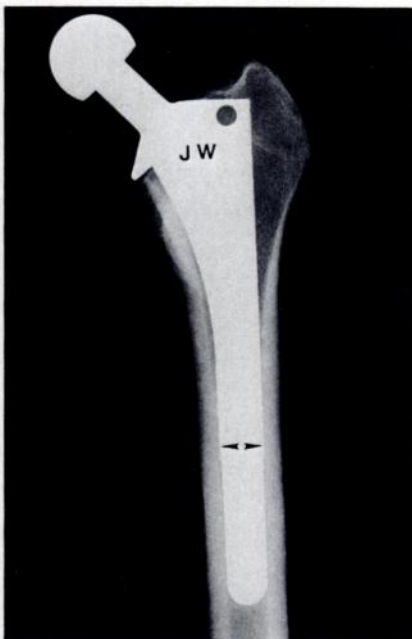


Fig. 7b



Fig. 7c

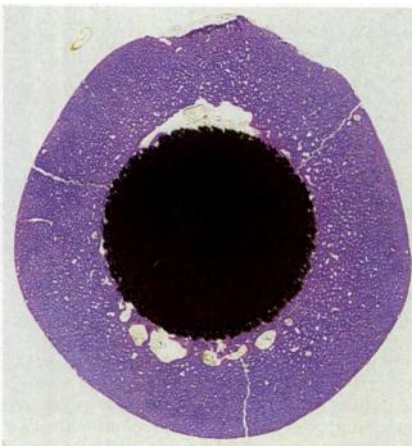


Fig. 7d

Postmortem radiographs (a and b) and histological sections (c and d) of a pair of femora retrieved seven months after operation (Specimen 4): The 16.5 mm stem had been implanted with a press fit. The cortical thickness and density of both femora is similar. The transverse sections were taken at the level marked by arrows in Figures 7a and 7b; the cracks are artefacts. Bone ingrowth fixation is evident and there is more cortical osteopenia on the implanted side.



Fig. 8a



Fig. 8b

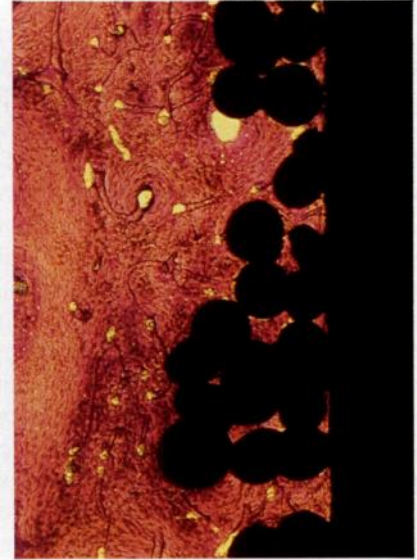


Fig. 8c

Postmortem radiograph (a) and histological sections of a femur retrieved three years after operation (Specimen 9). This case had been classified as showing first degree stress shielding. The transverse histological section (b) taken at about the level of the lesser trochanter shows abundant new bone filling the space between the implant and the endosteum. Cortical osteopenia is minimal. Higher magnification (c) shows the cortical-type bone ingrowth typically found in this specimen. Nutrient vessels and osteocyte lacunae are visible deep within the porosities.

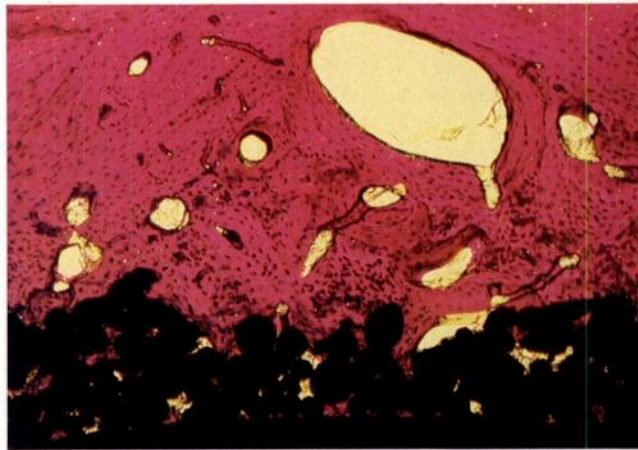


Fig. 9

Transverse section through the proximal region of a stem removed seven years after operation. Bony apposition and ingrowth down to the implant substrate are clearly evident. This is remarkable since the implant had a 100 μm pore size and the medullary canal was much larger than the stem diameter.

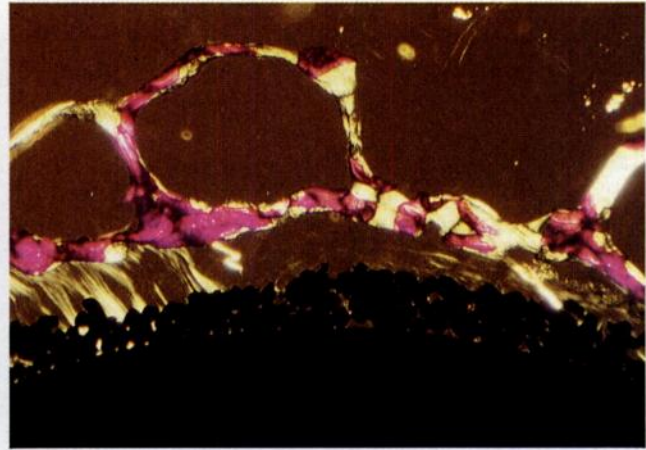


Fig. 10

Photomicrograph of the bone-implant interface of Specimen 10, retrieved after six years, viewed under polarised light. The radiographic appearance was of a radio-opaque line as shown in Figure 2. The surrounding shell of bone is separated from the implant by a space containing fibrous tissue.

ing bone (Fig. 10). Similar histological and radiographic appearances have also been reported in canine models by Pilliar et al. (1981).

Ten of our 307 cases had suspected early settling of the prosthesis amounting to less than 2 mm; seven had settling of between 2 and 5 mm. Radio-opaque lines surrounded the prosthesis in all these cases.

Clinical. Using Merle d'Aubigné and Postel's system the mean pre-operative scores for pain and walking were 2.9 and 3.6 respectively; those at the two-year follow-up were 5.9 and 5.8 respectively. This was without the Charnley Class C cases; their inclusion decreased the mean scores by only 0.05 to 0.1 points. These excellent scores could be misleading since they do not reveal the number of patients with a less than perfect result. When analysed in more detail, the incidences of pain and limp were 14% and 21%, respectively (including the Class C patients). In the great majority of cases the pain was occasional, was felt in the thigh at the level of the end of the stem, and was delayed in onset (usually after walking several blocks); the "start-up" hesitancy typical of a loose stem was rarely present. In the majority of patients this delayed onset "end of stem" pain was associated with a limp, but the converse was rarely true, as most patients with a mild limp denied having discomfort or weakness.

No correlation could be found between the pain and walking scores or the radiographic likelihood of bone ingrowth and the age, sex, or disease process. The bone quality index incorporates these factors together with the radiographic appearance of the cancellous and cortical bone in the femur. Two hundred and forty-three patients were considered to have good bone quality and 64 had poor bone quality; those with good bone quality had a significantly lower incidence of pain than the others (11% versus 26%). Bone quality did not have a statistically measurable influence on the incidence of limp or the radiographic likelihood of bone ingrowth.

There were no infections and no revisions for gross femoral stem loosening. Postoperative complications were no different from those occurring with cemented prostheses except that in 12 cases a femoral fracture occurred during impaction of the implant.

Bony ingrowth. Radiographic evaluation of the bone-implant interface showed that 259 cases (84%) had a high likelihood of bone ingrowth and 42 cases (13%) probably had stable ingrowth with fibrous tissue. Seven cases (2%) were judged to be unstable but none has yet required revision. These results might have been better but for the fact that many of the early cases were treated with a small (10.5 mm) diameter stem which was the only type available at the time. Table III lists the incidence of pain and limp for the cases with bone ingrowth and fibrous tissue ingrowth. There is about a three-fold lower incidence of both pain and limp in those with bony ingrowth and this is statistically significant ($p < 0.05$).

One hundred and ninety-five cases were classified as

Table III. Percentage incidence of pain and limp in patients with bone ingrowth and those with fibrous ingrowth at two years

	Bone ingrowth	Fibrous ingrowth	Significance of difference
Pain	10	28	$p < 0.05$
Limp	16	46	$p < 0.05$

having a *press fit* at the isthmus. Of these, 93% had a radiographic appearance suggestive of bone ingrowth and 7% had radio-opaque lines characteristic of fibrous tissue ingrowth (Table IV). Of the cases without a *press fit*, 69% were classified as having bone ingrowth, 24% as having stable fibrous tissue ingrowth, and 7% as being unstable. A chi-square test for the significance of the difference in proportions of cases with bone ingrowth with the two categories of fit yielded $p < 0.005$, indicating the strong influence of a *press fit* on bony ingrowth. Table V lists the incidence of pain and limp for the cases divided according to the category of stem fit. The lower incidences of both pain and limp for the *press fit* cases were statistically significant ($p < 0.05$).

Table IV. Relationship of type of fixation to stem fit

	Number of cases	Bone ingrowth (per cent)	Fibrous ingrowth (per cent)	Unstable (per cent)
Press fit	195	93	7	0
No press fit	112	69	24	7

Table V. Percentage incidence of pain and limp according to type of stem fit

	Press fit	No press fit	Significance of difference
Pain	9	23	$p < 0.05$
Limp	13	34	$p < 0.05$

Bone remodelling. With regard to stress shielding, 152 cases had none or only first degree resorption involving minor rounding of the proximal medial edge of the femoral neck; 119 cases had second degree stress shielding, 23 had third degree, and 13 had fourth degree. Thus, 36 cases (12%) had moderate or severe resorptive remodelling adjacent to the stem. Thirty-four of these 36 cases involved stems with a diameter of 13.5 mm or more, a *press fit*, and a radiographic appearance highly suggestive of bone ingrowth fixation. Stress shielding beyond the first degree occurred almost twice as often in cases with a *press fit* or bone ingrowth as compared with cases without a *press fit* or with fibrous tissue fixation ($p < 0.05$). The clinical ratings in terms of pain and limp

did not appear to be affected by the degree of severity of stress shielding.

Long-term results. The pain and walking scores for the 89 cases followed for up to five years did not change significantly from one year to the next (Table VI). As with the two-year series, the mean scores (including the Charnley Class C patients) decreased only slightly. When the cases were divided into those with bone and fibrous tissue fixation, no deterioration in the incidence

bone and therefore does not contribute to implant fixation.

Study of retrieved specimens with fibrous tissue fixation recall results in animals which demonstrated failure of bone ingrowth in the presence of excessive movement at the bone-implant interface (Cameron, Pilliar and Macnab 1973; Ducheyne, De Meester and Aernoudt 1977). The histological appearance of the radio-opaque line surrounding implants with an interposed fibrous tissue layer also is strikingly similar in humans and dogs. It has been postulated that in these cases the fibrous tissue transmits load from the implant to the surrounding bony shell, much as the periodontal ligament in the tooth acts as a buffer between one load-bearing structure and another.

Table VI. Mean scores for pain and walking (Merle d'Aubigné and Postel) in 80 cases from 1 to 5 years; excluding nine cases with known complications

	Year				
	1	2	3	4	5
Pain	5.8	5.8	5.8	5.8	5.8
Walking	5.6	5.6	5.7	5.7	5.6

Our results clearly indicate that, in order to achieve predictable fixation, it is best to implant the stem with a tight press fit at the isthmus; poorly fitting stems are less likely to become fixed by bone ingrowth. Pain and a limp also are less likely with a good press fit. Implants that fill the medullary canal poorly and/or have fibrous tissue ingrowth can be stable and remain so, but the clinical scores are significantly lower. It is surprising that age, sex, and the disease process all had no effect on the clinical scores. The bone quality index allows for some interaction of these factors and the incidence of pain in patients with good bone quality was lower. In general, it may be stated that if the stem fills the medullary canal, the prognosis for an excellent result with bone ingrowth is very good.

of pain and limp with either group was evident. Between one and two years, four cases initially classified as having bone ingrowth were reclassified into the fibrous tissue group. Conversely, one case in the fibrous ingrowth group was reclassified as having bony ingrowth. One case initially classified as fibrous ingrowth at one year appeared unstable at two years. Beyond two years, the number of cases in the three groups (bone ingrowth, fibrous ingrowth, and unstable) remained constant. In terms of stress shielding, the only noticeable progression based on radiographic examination occurred between one and two years; two cases initially in the group without stress shielding were reclassified as having mild or first degree stress shielding.

In terms of stress shielding, there is no doubt that bone resorption does occur with porous-coated femoral stems. Histologically, some cortical osteopenia was evident in the seven-month retrieval specimen depicted in Figure 7, where a direct comparison could be made between the implant-containing femur and the normal femur. Cortical osteopenia has also been described in a study of 12 cemented Müller-Charnley femoral prostheses retrieved one month to 10 years after operation (Kusswetter et al. 1984).

DISCUSSION

We are beginning to understand biological fixation of a femoral prosthesis and it is clear that bone ingrowth occurs in humans with a high degree of regularity as evidenced by histological studies (Bobyne and Engh 1984; Brooker and Collier 1984). The results from Specimen 11 are particularly interesting: bone ingrowth was documented seven years after operation in a case without a press fit and with an implant of only 100 μm pore size – a design later modified because of concern that the pore size was too small to support bone ingrowth. In general, it was observed that bone ingrowth was primarily cortical in nature, arising from regions where the implant was in contact with the endosteum or nearly so. In some cases, there was a remarkable degree of abundant new endosteal bone filling the space between the endosteum and the implant. In respect of filling of the porosity and new bone formation, the appearance of the bone-implant interface in humans is strongly reminiscent of that in dogs. Histological sections have shown that a large portion of the porous surface is not ingrown with

Radiographically, 88% (271/307) of the cases studied at two years showed little or no stress shielding. We postulate that the absence of more extensive stress shielding is related to the fact that most of the implants had a small stem diameter. None of the 89 cases followed for five years showed stress shielding beyond the first or second degree and all had small diameter stems. We believe that neither bone ingrowth nor fibrous ingrowth fixation of a fully porous-coated femoral stem of small diameter can be expected to cause serious bone loss in the short or long term. This is in contradiction to a recent report that progressive, marked proximal bone resorption occurred in several long-term cases (Brown and Ring 1985). The only major difference between the implants in that study and ours is that those evaluated by Brown and Ring had a high-density polyethylene femoral head bearing against a cobalt alloy acetabular

component, a combination which is poorer in terms of wear resistance of polyethylene. This raises the possibility that polyethylene wear debris may have elicited a histiocytic reaction leading to osteolysis in the proximal femur in a manner similar to that proposed by Willert and Semlitsch (1976) as causing late aseptic loosening with cemented implants. However, Brown and Ring reported no similar occurrences of osteolysis with identical non-porous-coated prostheses and it is thus difficult to explain the difference in results.

Larger diameter stems are expected to cause more pronounced bone loss by stress shielding. This is because the axial rigidity of the implant increases directly with the cross-sectional area or square of the stem diameter, and flexural rigidity increases directly with the area moment of inertia or fourth power of the stem diameter. Thus, a small increase in stem diameter can greatly increase its rigidity. Since, in a composite structure, load is preferentially carried by the more rigid material, the less rigid surrounding bone is relieved of stress to a greater degree with a larger stem.

Twenty-four of the 36 cases with more pronounced stress shielding occurred with implants whose diameter was 15.0 mm or more; that is, they had five to ten times the flexural rigidity of the smaller diameter stems. The femoral shaft is maximally relieved of stress by a stem that fills the canal; this explains why there is a higher incidence of stress shielding with a press fit. Preferential load-carrying by the more rigid material is enhanced if there is an integral bond between it and the less rigid material; this explains why there is a higher incidence of stress shielding after fixation by bone ingrowth.

The degree of stress shielding that is tolerable from a clinical standpoint is difficult to define. Stress-related bone loss does not influence the clinical results adversely and although it would be ideal to have no bone resorption at all, first and second degree stress shielding need cause little concern. Bone resorption as severe as that shown in Figure 6 is, however, more serious, especially as radiography underestimates the bone loss seen on histology. As a minimum objective it would be preferable to use implants that cause no more than second degree stress shielding. To achieve this goal, improvement in porous-coated femoral stem design should include reduction of the axial and flexural rigidity of the larger diameter implants (Morscher and Dick 1983).

To sum up, it is clear that the stability of fixation, the clinical scores, and the amount of stress shielding up to the five-year period are extremely encouraging. Sixteen patients have now reached a seven-year follow-up with no change in status. The cases with an appearance of bone ingrowth have the best overall clinical scores and beyond the first or second postoperative year, the radiographic appearance of the bone-implant interface has not changed. The cases with an appearance of fibrous tissue ingrowth have good clinical results but not as good or as predictable as those with

bone ingrowth; moreover, the fibrous tissue-implant interface has not shown any signs of late deterioration.

The loosening and revision rate in our series is much lower than that reported with uncemented smooth-surfaced stems of similar design (Anderson, Hamsa and Waring 1964; Harris 1966). The results also compare favourably with those of cemented hips. However, it must be emphasised that the implants evaluated had either complete or very extensive porous coating, so that the potential for tissue fixation was maximised. Similar results may not necessarily be obtained with less extensive porous coating. Biological fixation by bone ingrowth requires careful planning and meticulous technique, but our results support the conclusion that the addition of a porous surface to the femoral stem gives better results. The next five years will show whether the incidence of late aseptic loosening is reduced with this new approach to implant fixation in total hip arthroplasty.

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