Histology of porous-coated acetabular components

25 cementless cups retrieved after arthroplasty

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25 hemispherical acetabular components retrieved from patients who had a total hip arthroplasty (THA) were studied histologically. All of the components had titanium fiber metal porous coatings and were implanted with adjuvant screw fixation, 18 in primary THA and 7 in revision THA. None of the cups had been removed because of infection or failure of fixation. The components had been in place an average of 30 (1–140) weeks. 18 cups had bone ingrowth into the porous coating. Up to one third of the available void space within the porous coating was occupied by bone, while the maximal proportion of the area of the bone-implant interface with bone ingrowth was over 80 percent. Bone ingrowth was more often observed at the dome and in the vicinity of sites of screw fixation than elsewhere. Peripherally, bone ingrowth was less consistent, and in isolated areas fibrocartilage and mineralized fibrocartilage were occasionally observed. The longer-term cases had more bone ingrowth than the shorter-term cases. Apparent metallic debris was observed within histiocytes adjacent to screw holes, and the amount of this material increased with duration of implantation.

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Histologic evidence of bone ingrowth was observed in 46 of 109 retrieved cementless acetabular components (Collier et al. 1988, Cook 1991, Zettl-Schaffer et al. 1992). The relationship between bone ingrowth, duration of implantation and the type of surgery (primary as opposed to revision) has not been well characterized. We report the type of tissue found within porous-coated acetabular components of one design retrieved for reasons other than loosening or infection.

Material and methods

The porous-coated acetabular cups were hemispherical in design with a commercially pure titanium fiber metal surface sintered to a commercially pure titanium backing (Harris/Galante, Zimmer-U.S.A.). Holes through the backing and porous coating permitted initial stabilization of the component into the skeleton with titanium alloy (Ti6A14V) screws. A removable ultra-high molecular weight polyethylene liner served as the bearing surface. The fiber-metal surface layer was made from 250 micrometer thick sintered titanium wires. The surface layer had a porosity of 50 percent and was 1.7 mm thick.

Of the first 35 components consecutively received, 7 were excluded because of documented infection and 3 had the porous surface disrupted during removal or processing, leaving 25 components available for analysis (Table 1). The original diagnoses included osteoarthrosis (14), osteonecrosis (2), non-union of femoral fracture (1), rheumatoid arthritis (1), and failed total hip arthroplasty (7). 13 of the components had been implanted by surgeons from or trained at our 2 centers and 12 were submitted from elsewhere. All of the cups had been implanted with adjuvant screw fixation.

Operative reports were available on 20 of the 22 cases retrieved at revision surgery. On the basis of these reports, all of the components were considered to be well-fixed at the time of revision, with the exception of the component removed 1 week postoperatively (Case 1 of Table 1) and of 1 of the revision components (Case 23). However, these 2 components were not removed because of loosening. For the 3 autopsy cases, the stability of the component was not recorded. To our knowledge, only Case 2 was treated with corticosteroids. Neither of the 2 major centers which contributed cases to this study routinely uses non-steroidal anti-inflammatory agents in the immediate post-operative period.

Table 1. Clinical and histologic data for the 25 cases

A	B	C	D	E	F	G	H	I	J
1	65	M	P	1	1	0.0	0.0	a	not well-fixed at revision
2	38	M	P	5	1	0.9	0.0	2	corticosteroid treatment for lupus erythematosus, renal failure
3	65	M	P	6	1	2.2	0.2	a	
4	59	F	P	6	1	20	2.6	1	acetabuli protrusio/autogenous bone graft to medial wall
5	55	M	P	7	2	0.0	0.0	3	
6	61	M	P	8	1	3.6	0.3	4	autogenous bone graft to medial wall
7	81	M	P	8	3	0.4	0.0	1	Paget's with extensive cysts, fx femur at 4 weeks, non-ambulatory
8	62	M	P	14	1	3.1	0.4	3	previous bipolar hemiarthroplasty
9	50	F	P	28	3	24	3.7	2	autogenous bone graft to haversian notch
10	74	F	P	28	1	3.8	0.3	3	
11	56	M	P	30	3	3.1	0.4	5	death due to disseminated neoplasm
12	57	F	P	34	1	0.0	0.0	4	extremely difficult to remove
13	71	F	P	36	1	17	3.6	a	
14	71	M	P	45	1	28	6.0	3	autogenous bone graft used
15	69	M	P	46	4	7.0	1.0	4	
16	47	M	P	66	1	33	5.2	0	
17	67	M	P	68	5	85	24.7	0	
18	56	M	P	140	6	73	35.2	2	
19	32	F	R	4	1	2.4	0.4	1	
20	63	M	R	6	1	5.6	0.4	a	
21	73	F	R	8	1	1.6	0.2	b	residual bone cement present in 4 of 5 zones at time of implantation
22	90	M	R	13	1	0.0	0.0	a	
23	70	F	R	32	1	18	1.2	4	not well-fixed at revision
24	69	M	R	42	1	0.0	0.0	5	extensive morsalized allograft used
25	34	F	R	56	1	49	8.3	1	

A Case number
B Age
C Sex
D Type of surgery
  P primary
  R revision
E Duration of implantation, weeks
F Reason for removal
  1 malposition/dislocation
  2 leg length discrepancy
  3 autopsy
  4 unexplained pain
  5 femoral stem loosening
  6 loose polyethylene liner
G Extent of bone ingrowth, percent
H Volume fraction of bone ingrowth, percent
I Number of radiolucent zones
  a suitable radiograph unavailable
  b analysis not performed because of presence of residual bone cement
J Comment

In 7 of the 22 components retrieved at revision surgery, substantial amounts of acetabular bone were removed along with the component. There was no adverse tissue response or granuloma formation on gross examination. Upon retrieval, the components were fixed in formalin, examined grossly, and photographed. The implants were prepared for undecalcified histological examination by dehydrating in a graded series of alcohols, clearing with xylene, embedding in methylmethacrylate and serial sectioning with a diamond-tipped blade mounted on a modified industrial surface grinder. Typically, 25–30 1.0-mm thick sections were cut from each implant. The sections were attached to slides, ground to a nominal thickness of 100 micrometers and surface-stained with basic fuchsin and toluidine blue. These sections were examined by light microscopy, with the slide resting on a plate of ground glass to characterize the type and location of tissue ingrowth. With this technique, one can only focus the top surface of the slide and the cellular detail is good. In addition, selected sections were microradiographed and examined with a scanning electron microscope, as described elsewhere (Sumner et al. 1990).

2 quantitative measurements of bone ingrowth were made from the histologic sections: volume fraction and extent (Figure 1). All of the measurements were performed in the laboratory of the senior author. The volume fraction of bone ingrowth represents the fraction of available pore space within the porous coating filled by bone tissue and is designed to provide a stereologically meaningful description of the quantity of bone present within the porous coating. The extent of bone ingrowth provides an indication of the topographic distribution of bone ingrowth over the surface of the component.

For these measurements, every third section was analyzed so that the entire implant was systematically sampled. The sections were evaluated at a magnification of 50 times with a light microscope. An 11 by 11 grid was placed in the eyepiece of the microscope and superimposed on the porous surface with the outer line of the grid parallel to the superficial surface of the porous coating and positioned one-half of a fiber diameter

Figure 1. Measurements of bone ingrowth.The extent measurement provides information on the topographic distribution, while the volume fraction measurement conveys how much of the void space of the porous coating is occupied by bone ingrowth. These 2 measurements of bone ingrowth are not necessarily correlated.

Measurements of extent of bone ingrowth.
No. of fields with bone ingrowth = 4
Total no. of fields = 7
Extent of bone ingrowth = 57%

Measurements of volume fraction of bone ingrowth.
Area of bone = 0.7
Void area = 2.7
Volume fraction of bone ingrowth = 26%

deep to the outermost aspect of the fiber metal. In this way, the entire depth of the porous coating was included. To measure the volume fraction of bone ingrowth, each grid intersection was scored as overlying bone, soft tissue or metal. The volume fraction of bone ingrowth (BI) in the entire component was calculated as

$$BI = (I_B/(I_T–I_M))\ 100,$$

where I_B is number of intersections overlying bone, I_T total number of intersections and I_M number of intersections overlying the fiber metal. The data were collected from the entire section, using adjacent fields, which were 2 x 2 mm in size. Approximately 20,000 points per implant were scored. This method has been shown to be comparable to automated analyses of backscatter scanning electron microscopic images (Sumner et al. 1990). The extent of bone ingrowth (EX) in the entire component was calculated as

$$EX = (F_B/F_T)\ 100,$$

where F_B is the number of 2 x 2 mm fields with at least 1 intersection overlying bone and F_T the total number of fields. On average, 185 fields per implant were evaluated.

The presence and relative amount of apparent metallic particulate matter was recorded. Sections were scored as positive for the presence of this material only when the particles could be demonstrated to be intracellular. This criterion was used so that debris generated during cutting and grinding of the sections would not be confused with particulate matter generated during in vivo service of the implant. If none or only 1 of the sections had debris, a score of 0 was assigned. Scores of 1, 2, and 3 were assigned to cases with less than half, more than half, and every section, respectively, having this material.

A detailed analysis was also performed on radiographs obtained prior to component removal. For 20 of the 25 cases, adequate anteroposterior films were available. In these 20 cases, the following were recorded: acetabular component inclination angle (component abduction), the number and condition of the stabilizing screws, and the location of the hip center relative to the tear drop (see h and v of Figure 2). The bone/prosthesis interface was divided into 5 zones modified after DeLee and Charnley's (1976) 3 zones to permit a more detailed analysis (Figure 2). The presence and width of radiolucencies, sclerotic lines and bony condensation were assessed in each zone in an attempt to define radiographic features of bone ingrowth.

Descriptive statistics were calculated and analyses of variance and correlation procedures were used. The

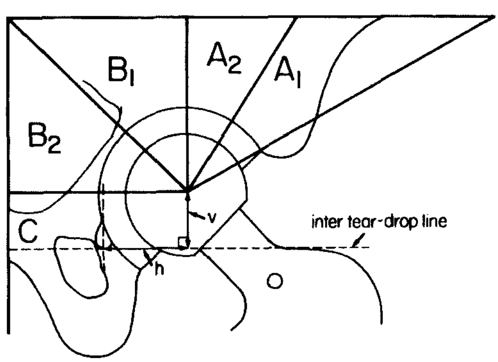
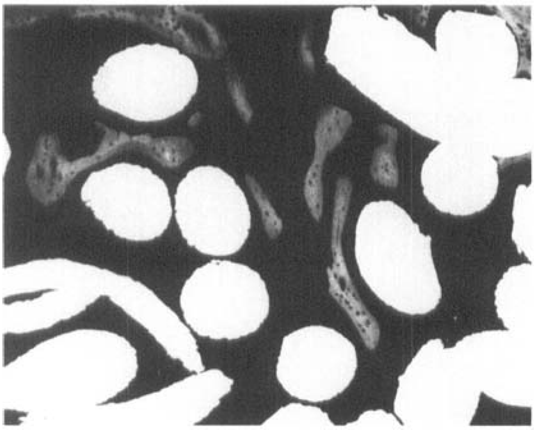


Figure 2. Radiographic zones (modified from DeLee and Charnley 1976). Note that 2 of DeLee and Charnley's zones were subdivided, thereby providing a more detailed description of the interface. The variables h and v were used to locate the center of the reconstructed joint.

Figure 3. Backscatter scanning electron micrographs from Case 4. The component had been implanted in a 59-year-old woman in a primary surgery and was removed 6 weeks after implantation because of recurrent dislocation. Note that woven bone was present within the void spaces of the porous coating.



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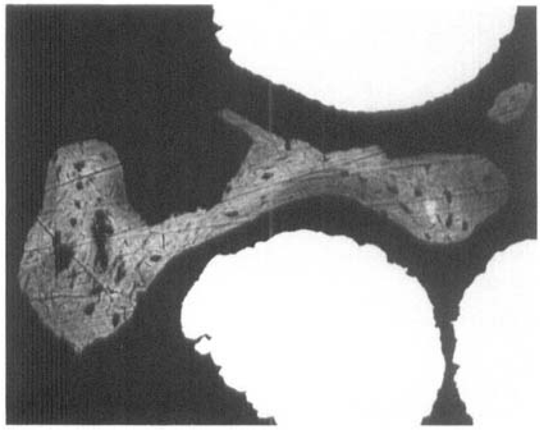

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analyses of variance were performed with the extent of bone ingrowth and the volume fraction of bone ingrowth as dependent variables, and the duration of implantation (arbitrarily set at less or more than 14 weeks), type of surgery (primary or revision), and the patient's sex as the independent variables. The patient's age was included as a covariate. Pearson product moment correlation coefficients (r) were calculated for continuous data (such as duration of implantation and the amount of bone ingrowth) and Spearman rank order correlation coefficients (r_S) were calculated for interval level data (such as number of radiolucencies or the metal debris score), following standard statistical procedures (Snedecor and Cochran 1967). The radiographic-histologic correlations were based on the entire implant rather than on a zone-by-zone basis because the position of the components in service was not always known.

Results

Discoloration of the tissue surrounding the joint, suggestive of metallic debris, was noted in 5 hips (Cases 9, 17, 18, 24, and 25). In Case 9, apparent metallic debris was noted adjacent to the Ti alloy screws, in Case 17 the femoral component was loose with metallosis, in Case 18 there had been wear between the femoral head and the metallic acetabular component because of a dissociated polyethylene liner, and in Cases 24 and 25 the femoral stem impinged on the acetabular cup.

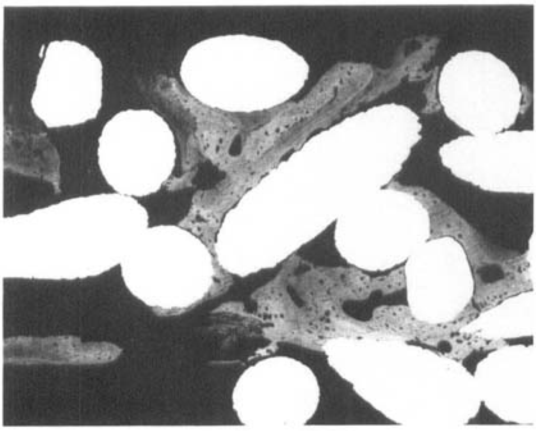
Histology

Overall, 13 of the 18 primary retrievals and 5 of the 7 revision retrievals had bone ingrowth, using the criterion of the extent being > 1.0 percent. At the early time periods (14 or less weeks), bone ingrowth took the form of small immature trabeculae which penetrated up to four fifths of the depth of the porous coating (Figure 3). Implants which had been in place for more than 14 weeks tended to have lamellar bone ingrowth (Figure 4) near the dome and, in particular, adjacent to screw holes. The 3 primary cases retrieved after 1 year had considerable areas of bone ingrowth (Cases 16, 17, and 18). The bone penetrated from one third to nearly the full depth of the porous coating (Figure 5). The 1 revision case retrieved after 1 year had many areas of bone ingrowth (Case 25, Table 1).

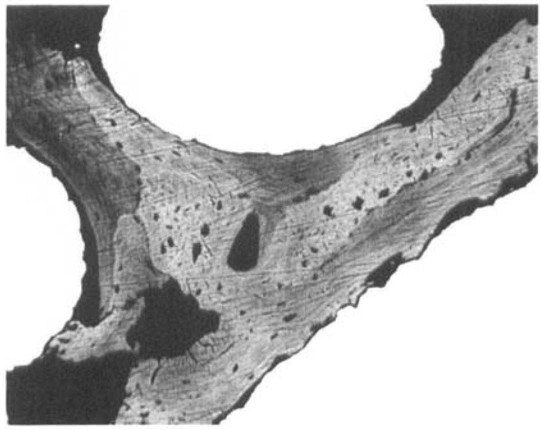
In 1 of the components retrieved at autopsy, autogenous particulate bone graft had been placed at the haversian notch (Case 9). While some of the bone graft had been incorporated into the host bone, only fibrous tissue grew into the porous coating in this region. Autogenous bone graft was also used in Cases 4, 6, and 14, but because these were not autopsy retrievals it was not possible to correlate the location of the graft with specific areas of the component. In addition, extensive morsalized allograft was used in 1 of the revision cases (Case 24), but no bone ingrowth was found.

No fibrocartilaginous tissue was observed in either the primary or the revision cases removed 14 or fewer weeks after implantation. However, in implants in place longer than 14 weeks, fibrocartilage was

Figure 4. Backscatter scanning electron micrographs from Case 14. The component had been implanted in a 71-year-old man in a primary surgery and was removed 45 weeks after implantation because of recurrent dislocation. Note that lamellar bone had formed on a core of woven bone.



Low power, ×54.



Higher power of the same region, ×150.

observed in isolated areas in 6 of the 10 primary implants. 2 of these 6 cases also had areas of mineralized fibrocartilage. None of the 3 revision implants retrieved more than 14 weeks postoperatively had fibrocartilaginous tissue at the interface.

In all of the cases, most of the pore space not occupied by bone ingrowth was occupied by a well-vascularized loose connective tissue. 12 of the 18 primary and 4 of the 7 revision implants had occasional areas of increased cellularity characterized by foci of lymphocytes. These foci were most commonly observed in the shorter-term implants.

Many areas adjacent to screw holes had fine intracellular particulate matter, which may represent small metallic particles created by fretting between the screws and metal backing. 3 of the components were assigned a debris score of 0, 7 a score of 1, 8 a score of 2, and 7 a score of 3. This material was associated with a mild localized histiocytic response. The amount of this material appeared to be somewhat greater in the longer-term cases compared with the shorter-term cases and there was a positive correlation between the length of implantation and the metal debris score (r_S 0.40, $P < 0.05$).

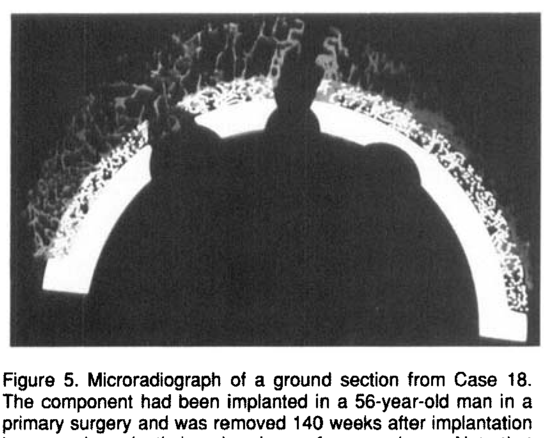


Figure 5. Microradiograph of a ground section from Case 18. The component had been implanted in a 56-year-old man in a primary surgery and was removed 140 weeks after implantation because the polyethylene bearing surface was loose. Note that bone ingrowth was found throughout the porous coating and was particularly dense in areas adjacent to the screw holes.

Quantitative analyses

For the total population the mean extent of bone ingrowth was 15 percent and the mean volume fraction was 3.8 percent (Table 2). Of the factors examined statistically (duration of implantation, primary vs. revision surgery, sex, age), only the duration of implantation had an effect on the amount of bone ingrowth ($P < 0.05$). In particular, the shorter-term primary and revision cases had less bone within the porous coating, whether assessed as the extent or as the volume fraction (Table 2). Thus, there was a significant linear correlation between duration of implantation and the volume fraction (r 0.86, $P < 0.001$) and the extent (r 0.80, $P < 0.001$) of bone ingrowth.

Radiographic analyses

The number of radiolucent zones ranged from 0 to 5. Typically, these radiolucencies were less than 1 mm in width. There was an inverse relationship between the number of radiolucencies and the extent (r_S –0.47, $P < 0.05$) and the volume fraction (r_S –0 43, P 0.069) of bone ingrowth. In agreement with these correlations, it

Table 2. Summary of statistics for the bone ingrowth data, broken down by duration of implantation and shown separately for the primary and revision cases

	< 14 weeks			> 14 weeks			Total		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
Extent of bone ingrowth									
Primary cases	8	3.8	6.7	10	27	30	18	17	25
Revision cases	4	2.4	2.4	3	22	25	7	11	18
All cases	12	3.3	5.5	13	26 [a]	28	25	15	23
Volume fraction of bone ingrowth									
Primary cases	8	0.4	0.9	10	8.0	12	18	4.6	10
Revision cases	4	0.3	0.2	3	3.2	4.5	7	1.5	3
All cases	12	0.4	0.7	13	6.9 [a]	11	25	3.8	8

[a] Difference from the implants in place for < 14 weeks, $P < 0.05$.

was found that the average extent of bone ingrowth was 32 (± 31) percent for the 9 components with radiolucencies in 2 or less of the 5 zones, while the average extent of bone ingrowth was 6.7 (±9.1) percent for the 10 components with radiolucencies in 3 or more zones ($P < (0.05)$. No correlations were observed between the volume fraction or extent of bone ingrowth and the acetabular inclination angle or number of stabilizing screws. No significant correlations were found between the variables describing the position of the reconstructed hip center and the amount of bone ingrowth in the total sample or when the correlation was restricted to primary cases.

Discussion

Studies of retrieved porous-coated acetabular components have been reported by 3 other laboratories. Bone ingrowth was observed in 9 of 58 cases by Collier et al. (1988), 28 of 42 cases by Cook (1991), 9 of 9 cases by Zettl-Schaffer et al. (1992), and in 18 of 25 cases in the present study. Cook (1991) reported no cases with more than 10 percent of the void space within the porous coating occupied by bone, whereas Zettl-Schaffer et al. (1992) reported a maximum value of 36 percent. The 2 cases from our series which had more than 10 percent volume fraction of bone ingrowth had values comparable to those observed in some canine models of porous-coated acetabular components (25–35 percent; Harris and Jasty 1985, Kang et al. 1991), although the average for all of the longer-term cases was only 7 percent. Most importantly, there was considerable variability in the data, certainly more than observed experimentally. Many factors can affect bone ingrowth (Sumner and Galante 1990) and some of these factors, presumably, contributed to the variability observed in this and other retrieval studies.

The presence of bone ingrowth within most of the components of the present study, although often limited in scope, suggests that the initial stability of the device was adequate for differentiation of interface tissue along an osteogenic pathway. However, bone ingrowth and focal areas of fibrocartilage and mineralized fibrocartilage were occasionally observed in some of the longer-term cases, suggesting that motion was present at the interface in some of the cases. The presence of bone ingrowth and fibrocartilage at the interface in the same component indicates that the amount of interface motion can vary within one component. Support for this possibility can be found in a finite element analysis of metal-backed cementless acetabular components which indicated that different regions of the interface experience different amounts of motion between the bone and implant (Rapperport et al. 1987).

The duration of implantation was the only factor which correlated with the amount of bone ingrowth. The role of this variable should be interpreted cautiously as it is possible that the longer-term implants had substantial amounts of bone ingrowth soon after implantation, and that the shorter-term implants, most of which were removed for malpositioning and recurrent dislocation, may never have been loaded normally, a factor known to be associated with limited amounts of bone ingrowth in animal experiments (Chen et al. 1983). Certainly, bone ingrowth is multifactorial and cannot be determined solely on the basis of duration of implantation. Analysis of well-functioning implants retrieved at autopsy should permit a more detailed examination of the time-course of bone ingrowth in humans.

In 5 of the hips, discoloration of the tissue surrounding the joint cavity suggestive of metallic debris, was observed grossly. In 4 of these cases, the cause of the metallosis was ascribable to loosening of the femoral component, dissociation of the polyethylene liner, or impingement of the femoral component on the cup, while in 1 case metallic debris was noted grossly in the region of the screws. Microscopically, apparent metallic debris was present to some degree in 22 of the 25 specimens in this study. Thus, in many specimens there was microscopically apparent metallic debris which was not appreciated upon gross examination. As observed microscopically, this material was most often noted in the vicinity of the screw holes and was more prevalent in the longer-term implants, suggesting that fretting between the screws and the acetabular component may have been the source of this material. This is a source of concern when considering long-term periods of implantation because of the potential influence of metal particles on bone resorption (Pizzoferrato et al. 1991, Amstutz et al. 1992, DiCarlo and Bullough 1992, Jacobs et al. 1992, Shanbhag et al. 1992, Glant et al. 1993).

Another current concern is the effect of polyethylene-wear debris on interface tissues, particularly in the light of the effects of this material on bone resorption (Willert et al. 1990, Amstutz et al. 1992, DiCarlo and Bullough 1992, Jacobs et al. 1992). Polyethylene debris could gain access to the interface from the periphery or via the screw holes. Unfortunately, the use of relatively thick methylmethacrylate sections (which were needed to process these metal-containing samples) makes it difficult, at best, to identify polyethylene. Thus, our data do not allow us to comment on the presence of polyethylene at the interface and its influence on the tissues in this series.

A radiographic follow-up study at an average postoperative evaluation period of 6 (5–7) years has found no evidence of osteolytic lesions in the vicinity of the screws or elsewhere adjacent to the acetabular component of the HGP prosthesis (Martell et al. 1993). Thus, the potential negative effects of particulate debris on biological fixation have not been recognized in the intermediate term with this device, despite the microscopic evidence of metallic debris at sites of screw fixation. Given that osteolytic lesions have been observed adjacent to cementless femoral components, including the HGP (Maloney et al. 1990, Martell et al. 1993), one can only presume that, in the intermediate term, the particulate burden adjacent to the acetabular component remains insufficient to cause osteolysis or that other factors, such as interface motion, must also be present to engender an osteolytic response.

Lymphocytes were observed in some cases, most often in the shorter-term implants near the periphery of the component. The presence of lymphocytes at the bone-implant interface in cementless arthroplasty has been noted by other authors (Cook 1991), although its significance is currently not known.

While it was not possible to correlate the histology and radiographic data on a zone-by-zone basis, there was an inverse correlation between the amount of bone ingrowth and the number of radiolucent zones at the interface, suggesting that clinical radiographs of this type of prosthesis are of use in evaluating implant fixation. In particular, the presence of radiolucencies is a sign of the lack of bone ingrowth.

Two goals of histologic studies of human implants are to have some estimates of tissue ingrowth into well-functioning components and, eventually, to understand the relationship between the histological characteristics of the interface and clinical performance. As the majority of all of the components in the present study were said to be well-fixed by the revising surgeon, the presence of so much variability in the amount of bone ingrowth raises two interesting questions, for which we have no answers currently: (1) how much bone ingrowth is needed to provide adequate short-term fixation of acetabular components which have supplemental screw fixation, and (2) does long-term fixation depend upon bone ingrowth?

Analysis of retrieved components represents a first step in answering these questions. The data in our series indicate that bone ingrowth does occur clinically in load-bearing implants, incorporating as much as 85 percent of the bone-implant interface and 35 percent of the void space of the porous coating. The need to obtain this degree of bone ingrowth for long-term fixation is currently a matter under investigation. The high degree of variability in the histology of the interface observed in this series may be a reflection of the situation in clinical practice or it may be related to the inclusion of a disproportionate number of short-term implants, an inherent shortcoming of retrieval studies. As additional autopsy cases become available, it will be possible to extrapolate with more confidence to patients with well-functioning implants and to increase our understanding of the natural history of biologic fixation.

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