Successful Long-Term Fixation and Progression of Osteolysis Associated with First-Generation Cementless Acetabular Components Retrieved Post Mortem

Robert M. Urban, Deborah J. Hall, BS, Craig Della Valle, MD, Markus A. Wimmer, PhD,
Joshua J. Jacobs, MD, and Jorge O. Galante, MD, DMSc

Investigation performed at the Department of Orthopedic Surgery, Rush University Medical Center, Chicago, Illinois

Background: Primary cementless acetabular reconstruction has shown durable long-term fixation. Late failures secondary to aseptic loosening are rare but may occur in patients with previously well-fixed components. In the present study, the histopathological characteristics of postmortem specimens were correlated with wear damage and radiographic data in an attempt to better understand the long-term events in the periacetabular tissue around well-functioning devices.

Methods: Seventeen primary cementless Harris-Galante I acetabular components with adjacent tissues were harvested after a mean of eleven years (range, four to twenty-five years) from patients whose implants were well functioning at the time of death. Undecalcified and paraffin sections were used to quantify the extent of bone and soft tissues within the porous coating and at the interface between the coating and the surrounding bone. Wear particles were identified with use of polarized light microscopy and energy-dispersive x-ray analysis. Bearing-surface volumetric wear and backside wear damage of the polyethylene liner were assessed.

Results: All of the components were fixed by bone ingrowth (mean extent, $33\% \pm 21\%$). Particle-induced granulomas were present in the porous coating and along the interface and progressed through screw holes, ballooning into the retroacetabular bone in the longer-term specimens. Particles of femoral and acetabular origin were identified in the granulomas. Bearing-surface volumetric wear (mean, $41.6 \text{ mm}^3/\text{year}$) increased with duration and correlated with increasing extent of granuloma in the porous coating and the increasing size of pelvic granulomas. Radiolucencies on radiographs correlated with the extent of bone and fibrous tissue ingrowth. Of the six pelvic granulomas that were identified histologically, only one was apparent on routine radiographs.

Conclusions: Acetabular fixation by bone ingrowth can be successful into the third decade after implantation. Osteolysis and secondary replacement of bone with particle-induced granuloma are commonly seen in the presence of excellent clinical function. Strategies designed to minimize bearing-surface wear and backside damage are important to maintain long-term bone ingrowth fixation.

Clinical Relevance: There remains a large patient population with clinically successful implants at potential risk of late failure secondary to progressive osteolysis.

The use of cementless acetabular components for primary total hip arthroplasty has become routine, with numerous studies showing durable fixation through the second decade¹⁻⁴. Laboratory and clinical studies have confirmed the effectiveness of several different porous ma-

terials in allowing bone ingrowth and thus fixation of total joint prostheses⁵⁻⁹.

Recent registry reports, however, have indicated that, over long-term follow-up (up to twenty years), the risk of acetabular cup revision was significantly higher for bead and

Disclosure: One or more of the authors received payments or services, either directly or indirectly (i.e., via his or her institution), from a third party in support of an aspect of this work. In addition, one or more of the authors, or his or her institution, has had a financial relationship, in the thirty-six months prior to submission of this work, with an entity in the biomedical arena that could be perceived to influence or have the potential to influence what is written in this work. Also, one or more of the authors has had another relationship, or has engaged in another activity, that could be perceived to influence or have the potential to influence what is written in this work. The complete **Disclosures of Potential Conflicts of Interest** submitted by authors are always provided with the online version of the article.

hydroxyapatite-coated designs as compared with titanium wire mesh designs^{10,11}. In one clinical study of the Harris-Galante I acetabular prosthesis, a 96% rate of survivorship at twenty years was shown with component loosening as the end point in a relatively young patient population¹². However, with failure for any reason related to the acetabular component as the end point, the twenty-year Kaplan-Meier survivorship was 86%, and as many as 30% of the cups showed signs of osteolysis. As in the previously mentioned registry reports¹², most late-occurring reoperations and revisions were related to wear of the ultra-high molecular weight polyethylene insert. In addition to osteolysis, late loosening of the acetabulum surfaced as a long-term complication, with a low frequency (3%) after the second decade following implantation.

The Harris-Galante I acetabular prosthesis is modular, which introduces a second interface between the polyethylene

insert and the inner surface of the metal cup that is capable of generating wear debris and potentially contributing to osteolysis¹³⁻¹⁸. Most long-term studies rely on radiographs for the assessment of the implant-bone interface. The purpose of the present study was to quantify the extent of various interface tissues, including bone and wear particle-induced granulomas, associated with Harris-Galante I cementless acetabular components that were retrieved post mortem after four to twenty-five years and to relate these findings to measurements of bearing surface wear, liner backside wear damage, and the clinical and radiographic findings for these patients.

Materials and Methods

Seventeen primary acetabular components with adjacent bone and soft tissues were harvested post mortem after a mean duration of eleven years (range, four to twenty-five years) (Table I). Five components (Specimens 11, 12,

TABLE I Patient Data, Polyethylene Wear, and Pelvic Granulomas*

Specimen	Duration (yr)	Sex, Age at Implantation (yr)	Initial Diagnosis	Comorbidity	Harris Hip Score (points)	Bearing Surface Wear (mm ³)	Backside Wear Damage Score (points)	Pelvic Granuloma Maximum Dimension (mm)
1	24.7	F, 43	Osteonecrosis	Systemic lupus erythematosus	78	NA	9	57
2	21.1	M, 64	Osteoarthritis		89	1604	6	55
3	18.1	M, 81	Femoral neck fracture		81	291	6	0
4	16.9	M, 65	Osteoarthritis		98	433	6	0
5	14.0	M, 34	Revised hemiarthroplasty	Severe spinal stenosis, lumbosacral spondylosis	58	483	6	9
6	13.1	F, 87	Osteoarthritis		80	NA	NA	0
7	12.4	F, 41	Osteonecrosis	Neuroectodermal tumor of lumbosacral spine	73	716	6	7
8	9.0	F, 78	Osteoarthritis	Degenerative lumbar spine and knees	67	69	6	0
9	7.4	M, 51	Osteoarthritis		100	290	9	17
10	6.5	M, 48	Osteoarthritis		98	295	6	6
11	6.3	M, 33	Osteonecrosis	Renal transplant with pelvic fracture	52	309	7	0
12	6.0	F, 60	Congenital hip dysplasia		92	211	5	0
13	5.8	F, 63	Osteonecrosis		97	162	5	0
14	5.2	F, 56	Osteonecrosis		100	253	6	0
15	4.8	M, 66	Osteoarthritis		91	543	4	0
16	4.5	M, 67	Osteoarthritis		83	175	7	0
17	3.8	F, 82	Osteoarthritis		95	27	4	0

*NA = not available.

13, 16, and 17) were previously evaluated in part¹⁹ but were more extensively analyzed for inclusion in the present study.

The commercially pure titanium acetabular components (Harris-Galante I; Zimmer, Warsaw, Indiana) were hemispherical, had outer diameters ranging from 46 to 64 mm, and had eleven to nineteen screw holes. The convex surface was covered with a 1.65-mm-thick coating of titanium fiber metal with a mean pore size of approximately 400 μm for bone ingrowth^{9,11}. The components were inserted without impaction with use of a line-to-line technique (the acetabular component was the same size as the last reamer utilized) along with two to five titanium-alloy screws for fixation. Three peripheral tines secured the polyethylene liner. The modular liners were constructed of machined GUR 4150 ultra-high molecular weight polyethylene that had been gamma irradiated in air. Femoral reconstruction was performed with use of cementless titanium-alloy stems in twelve hips and cemented cobalt chromium-alloy stems in five.

The mean age at the time of the index arthroplasty was 59.9 ± 16.6 years. All procedures had been performed in our hospital between 1984 and 1988, and the patients were followed prospectively until death. Five patients subsequently underwent arthroplasty of the contralateral hip, but, to meet the assumption of independence needed for the statistical tests, the components on the contralateral side were not included. Clinical evaluation was performed with use of clinical notes and the Harris hip score (Table I). Scores were available for all patients at a mean of twenty-three months before death. The mean Harris hip score at the time of the latest follow-up was 84 points (range, 52 to 100 points). Five patients with substantial debilitating comorbidities affecting function had hip scores of <80 points (Table I). Three patients underwent revision surgery with exchange of the modular liner at seven to ten years postoperatively because of osteolysis (Specimen 1) or liner dislodgement (Specimen 6) or in the course of femoral component revision for the treatment of aseptic loosening (Specimen 5).

Methods of Analysis

The acetabular components with adjacent pelvic bone and joint capsule were harvested en bloc. The liner was removed, and the specimens were serially cut perpendicular to the opening of the cup from anterior to posterior with use of a custom water-cooled cutoff saw with a diamond-impregnated blade. Undecalcified, plastic-embedded sections of the acetabular components with adjoining bone were ground to approximately 100 μm in thickness and were surface-stained with basic fuchsin and toluidine blue^{11,19,20}. Routine paraffin sections of joint capsule, selected screw hole membranes, and pelvic lesions were stained with hematoxylin and eosin. Polyethylene particles were visualized with use of polarized light. The size and elemental composition of metallic particles were studied with use of backscattered electron imaging (model JSM-6490LV; JEOL, Peabody, Massachusetts) and energy-dispersive x-ray analysis (INCA Energy 350 Microanalysis System; Oxford Instruments, Concord, Massachusetts)²¹.

For each component, five undecalcified sections were analyzed with use of a rectangular grid in the eyepiece of a transmission light microscope to divide the porous surface into 1-mm fields. At 40 $\times$ total magnification, the type of tissue in each field and the location of that field were recorded as previously described^{11,19,20,22}. A field was categorized as positive for bone ingrowth if it contained any amount of tissue consistent with viable bone. Otherwise, a field was categorized either as primarily marrow, fibrous tissue, cartilage-like tissue, or particle-induced granuloma. This type of tissue was determined within the porous coating and separately at the implant-acetabular bone interface (the interface between the outer surface of the porous coating and the surrounding acetabular bone). The tissue distributions were analyzed over the entire cup, within 5 mm of the rim, and within 3 mm around holes with and without screws. The overall extent of each type of tissue was calculated as the number of 1-mm fields that were positive for that tissue divided by the total number of fields analyzed and was expressed as a percentage. The maximum dimension of pelvic granulomas was measured on the histological slides.

In three additional undecalcified, unstained sections, the volume fraction of bone ingrowth (the percentage of the void space occupied by miner-

alized bone) was determined from image analysis of backscattered electron micrographs as previously described^{17,20,22}. Bone ingrowth was defined as bone within the pores of the fiber-metal coating at any level deeper than the outer surface of porous metal composite.

Backside wear damage of the polyethylene liners was studied with use of a reflected-light stereo microscope at ten to fifty times magnification by two observers (R.M.U. and D.J.H.). The types of wear damage that were evaluated included scratching, burnishing (wear polishing), abrasion, and embedded third-body debris as defined by Hood et al.²³, Kurtz²⁴, McKellop²⁵, and Rostoker²⁶. The presence of other types of surface damage, including deformation, pitting, and delamination, was also recorded. The components were scored for the area of overall wear damage as 0 (none), 1 (<10%), 2 (10% to 50%), or 3 (>50%), according to the system of Hood et al.²³. This was done separately for the superior, medial, and inferior regions of the liner. An overall score for each liner was then calculated by adding the scores for the three regions to yield a maximum possible score of 9. The scores recorded by the two observers were highly correlated ($r = 0.913$, $p < 0.0001$).

Volumetric wear of the polyethylene bearing surface was determined for fifteen of the seventeen cups with use of a touch probe coordinate measuring system (SmartScope Flash 250; Optical Gaging Products, Rochester, New York) as previously described (Table I)^{27,28}. A total of 6750 points were measured on each retrieved component. An unworn area on each cup was identified and was used to reconstruct the original hemispherical bearing surface. Wear volume, which could include a small amount of creep, was then determined as the difference between the volume for the reconstructed cup and the volume calculated from the measured points on the retrieved component.

Serial clinical radiographs were reviewed to evaluate the status of the acetabular component with regard to stability and migration as well as radiolucencies and periacetabular osteolysis. These observations were compared with the histological findings. Standard radiographs included an antero-posterior view of the pelvis and anteroposterior and lateral views of the proximal part of the femur. A nonbiased observer (C.D.V.) who had not been involved in the implantation evaluated all radiographs according to previously reported methods, with use of the six-week postoperative radiographs as a baseline²⁹.

Statistical Analysis

SPSS 14.0 for Windows (SPSS, Chicago, Illinois) was used for data management. Because the data had statistically non-normal distributions, nonparametric statistical methods were used. Scatterplots and Spearman correlations were obtained to investigate associations between quantitative variables. The Friedman test was done to compare areas of bone and granuloma with respect to quantitative variables. All statistical tests were two-sided with a 0.05 significance level. The data are presented as the mean and the standard deviation.

Source of Funding

This study was funded by NIH Grant AR039310, Zimmer, and the Rush Arthritis and Orthopaedic Institute. The funds were used for salaries, supplies, and equipment maintenance.

Results

All of the acetabular components were fixed by bone ingrowth (Table II). The mean extent of bone ingrowth was $33\% \pm 21\%$, and the mean volume fraction of bone ingrowth was $13\% \pm 9\%$. These measures were significantly correlated ($r = 0.645$, $p = 0.005$). There was no particular regional preference for more bone ingrowth within 5 mm of the rim, within 3 mm of holes with or without screws, or at the dome. However, at the implant-acetabular bone interface, the extent of bone was greater around holes with screws ($54\% \pm 28\%$; $p = 0.046$) and was less around holes without screws ($30\% \pm 22\%$;

TABLE II Tissues within the Porous Coating and at the Implant-Bone Interface

Specimen	Volume Fraction of Bone Ingrowth (%)	Extent of Tissues in Porous Coating (%)				Extent of Tissues at the Implant-Bone Interface (%)			
		Bone	Marrow	Fibrous Tissue	Particle-Induced Granuloma	Bone	Marrow	Fibrous Tissue	Particle-Induced Granuloma
1	27.1	22.9	2.0	6.0	65.4	35.2	4.7	0.7	56.1
2	17.6	25.0	0.0	5.1	61.4	26.8	6.9	3.3	53.3
3	14.8	44.7	17.9	16.4	7.5	40.3	32.7	7.8	5.7
4	2.8	4.5	3.6	40.0	42.1	9.0	4.5	29.0	43.3
5	26.2	51.2	0.0	27.5	12.1	55.3	3.0	22.4	8.1
6	16.7	58.5	2.3	29.5	0.0	44.3	22.0	23.3	0.0
7	11.6	64.8	6.5	1.5	17.5	55.3	21.6	0.0	13.3
8	8.1	19.2	0.0	60.8	1.2	28.2	0.4	48.2	0.0
9	13.4	36.7	1.4	41.8	3.2	44.4	2.3	27.8	2.3
10	4.7	20.2	0.0	68.3	3.9	25.6	1.4	54.2	1.7
11	17.4	49.5	26.0	18.3	0.0	53.8	27.8	8.8	0.0
12	27.6	57.4	3.3	16.3	0.0	57.9	2.9	16.3	0.0
13	16.6	31.7	26.3	34.2	0.0	49.5	28.5	13.9	0.0
14	0.3	6.7	0.0	79.5	1.7	7.7	0.0	70.8	1.0
15	15.6	52.4	10.5	24.8	0.6	50.7	14.8	20.2	0.0
16	1.5	8.2	0.3	76.6	0.0	7.3	1.6	73.1	0.0
17	4.6	4.2	0.0	85.3	1.6	7.4	0.0	81.4	1.0

$p = 0.008$) and at the rim ($30\% \pm 27\%$; $p = 0.090$) compared with the rest of the component ($41\% \pm 22\%$). There was also notable condensation of the periprosthetic bone along the fixation screws in all of the specimens. Bone marrow, with an extent of $6\% \pm 9\%$, was also present in the porous coating adjacent to the sites of bone ingrowth. Holes, with or without screws, occupied $9\% \pm 3\%$ of the component surface.

Areas of the porous coating without bone ingrowth or marrow were occupied by fibrous tissue or particle-induced granuloma (Table II). The mean extent of fibrous tissue in the porous coating was $37\% \pm 27\%$. Chondroid metaplasia of fibrous tissue with areas of mineralization was also present, with a mean extent of $2\% \pm 3\%$.

Particle-induced granuloma was present in the porous coating in nine of the ten specimens that were retrieved after at least six and one half years of implantation and to a lesser extent in three of the seven shorter-term specimens (Table II). The mean extent of granuloma in the porous coating was $13\% \pm 22\%$ and increased significantly with duration of implantation ($r = 0.712$, $p = 0.001$) with a value of as high as 65% in one specimen at twenty-five years after implantation (Fig. 1). The extents of bone, fibrous tissue, and granuloma within the porous coating were strongly correlated with the extent of each of those tissues at the implant-acetabular bone interface ($r \geq 0.888$, $p = 0.000$) (Table II).

Granuloma penetrated into the porous coating in a patterned manner at the rim of the component, at holes with screws, and at holes without screws as compared with the other areas of the porous coating ($p \leq 0.034$). The granulomas were

composed of plump single and multinucleated macrophages laden with polyethylene particles and a lesser number of metallic particulates, except in Specimen 2, in which metal particles predominated. In most of the longer-term specimens, the granulomas were associated with resorption of the ingrown bone (Fig. 2). At some sites, granuloma completely filled the spaces between the titanium fibers that are normally occupied by bone, marrow, or fibrous tissue (Fig. 2).

Fig. 1
Graph showing the extent of granuloma in the porous coating and the maximum dimension of pelvic granulomas versus the time since arthroplasty.

Fig. 2

Plastic-embedded ground sections of Specimen 7 at 12.4 years, stained with basic fuchsin and toluidine blue (left, $\times 60$; right, $\times 300$). In most of the longer-term specimens, the granulomas in the porous coating appeared to be associated with resorption of the ingrown bone. *Left*: Particle-induced granulomas (asterisks) expanded into the retroacetabular bone and infiltrated the porous coating adjacent to screw holes. *Right*: Granulomas consisting of macrophages laden with polyethylene particles filled the spaces between the titanium fibers replacing bone (arrows), marrow, or fibrous tissue that normally occupied the pores. The central globular spaces are a result of residual lipids from previous marrow.

Particle-induced granulomas also ballooned out of holes with or without a screw into the periprosthetic bone, forming multiple pelvic lesions in the superior, medial, and inferior regions in six of the ten specimens harvested after a duration of ≥ 6.5 years and in none of the shorter-term specimens, in which granulomas were restricted to the screw holes and the adjacent porous coating (Table I). The three largest pelvic granulomas (Specimens 1, 2, and 9) were associated with inferior unfilled screw holes. The maximum size of pelvic granulomas increased with the duration of implantation ($r = 0.568$, $p = 0.017$), reaching >5 cm in the two longest-term specimens (Fig. 1). There was a positive correlation between the maximum dimensions of pelvic granulomas and the extent of granuloma in the coating ($r = 0.714$, $p = 0.001$). There was also a significant correlation between the size of the pelvic granulomas and decreasing age of the patient at the time of surgery ($r = -0.556$, $p = 0.020$). At the rim of the cup, infiltration of granuloma from the joint pseudocapsule into the pelvic bone appeared to be less pronounced than the ingress of granuloma at screw holes.

The pelvic granulomas were characterized by aggregates of single and multinucleated particle-laden macrophages, similar to those seen within the porous coating. The macrophages contained both polyethylene and metallic particulates in four of the six specimens with pelvic granulomas and polyethylene particles alone in two specimens (Specimens 5 and 9). The central areas of the two largest granulomas were filled with necrotic debris. The cellular characteristics at the margins were similar, regardless of the size of the granuloma or the duration of implantation. Single and clustered mac-

rophages advanced into the adjacent marrow, replacing the marrow elements and engulfing existing bone trabeculae without evidence of reactive bone or the formation of a sclerotic osseous shell. Inflammatory pseudotumors or perivascular chronic inflammation consisting of lymphocytes and plasma cells were not observed in the periprosthetic tissues any of the specimens³⁰.

Particles in the Tissues

Analysis with use of backscattered electron imaging with energy-dispersive x-ray analysis for metallic particles and polarized light microscopy for polyethylene particles indicated that the intracellular particles in granulomas at the screw holes, the rim, and within pelvic lesions originated from both acetabular and femoral sources. These particles included polyethylene, commercially pure titanium, titanium-aluminum-vanadium alloy, cobalt-chromium-molybdenum alloy, barium sulfate, chromium phosphate corrosion product, and stainless steel. The size of metallic particles that could be imaged in the scanning electron microscope ranged from 0.1 to 80 μm , with the majority of particles appearing to be in the submicrometer range. The range in size of polyethylene particles that could be seen with light microscopy appeared to be different at the rim and the joint capsule, where polyethylene particles ranged in size from 0.7 to 10 μm , as compared with the screw holes and pelvic granulomas, where intracellular particles ranged in size from 0.7 μm up to shred-like particles as large as 40 μm in length (Figs. 3-A, 3-B, and 3-C). The majority of the intracellular polyethylene particles were very likely below the resolution of the light microscope. Extracellular shreds of polyethylene up to

Fig. 3

Figs. 3-A, 3-B, and 3-C Decalcified paraffin sections stained with hematoxylin and eosin. **Fig. 3-A** Specimen 3 at eighteen years. Wear damage to the backside of the polyethylene liners was primarily abrasive in nature, resulting from contact with the relatively rough concave surface of the metal shell and the sharp edges of the screw holes (*). Scale bar = 1 mm. **Fig. 3-B** Specimen 14 at five years. Scratching of the backside of the polyethylene liner was among the dominant features of wear damage and often included third-body metal particles. Scale bar = 1 mm. **Fig. 3-C** Specimen 7 at 12.4 years. Abrasive wear mechanisms on the backside of the polyethylene liner produced shreds of polyethylene 5 to 40 μm long, which were observed intracellularly in screw hole and pelvic granulomas. Scale bar = 25 μm .

250 μm in length were also present in tissue adjacent to screw holes.

Backside Wear Damage

The principal types of wear damage observed on the convex surface of the polyethylene liners were indicative of an abrasive wear mechanism, including scratching (Fig. 3-B), abrasion, and third-body metal particles, and of adhesive wear, which was evident as burnishing or wear polishing. The mean score for backside wear damage was 6 ± 1 (range, 4 to 9) of a maximum possible score of 9 (Table I). The extent of backside wear damage did not appear to be different among the superior, medial, and inferior regions of the liners. Deformation consisted of impressions of the heads of fixation screws. Pitting or delamination was not observed in any of the components evaluated. Cups with higher scores for backside wear damage tended to have larger pelvic granulomas ($r = 0.482$, $p = 0.059$) (Table I).

Bearing Surface Volumetric Wear

Volumetric wear increased with duration ($r = 0.571$, $p = 0.026$) and ranged from 27 mm^3 in the shortest-term specimen at four years after implantation to 1604 mm^3 at twenty-one years (Table I). Volumetric wear was positively correlated with the extent of granuloma in the porous coating ($r = 0.623$, $p = 0.013$) and with the maximum size of pelvic granulomas ($r = 0.563$, $p = 0.029$) (Fig. 4). The mean rate of volumetric wear was 41.6 mm^3/year .

Radiographic Evaluation

All of the cups were stable on radiographs, without evidence of migration. Nonprogressive radiolucencies measuring <1 mm in thickness were observed in nine of the seventeen cups. Two components exhibited radiolucencies in one zone; two, in two zones; four, in three zones; and one, in all zones. The total

number of zones with a radiolucency was negatively correlated with the extent of bone at the implant-acetabular bone interface ($r = -0.506$, $p = 0.038$) and was positively correlated with the extent of fibrous tissue at that interface ($r = 0.689$, $p = 0.002$). The number of zones with a radiolucency was negatively correlated with the extent of bone in the porous coating ($r = -0.564$, $p = 0.018$) and was positively correlated with the extent of fibrous tissue in the porous coating ($r = 0.781$, $p = 0.000$). The pelvic granulomas that were identified histologically were not visualized on the radiographs of five of the six hips. In the sixth specimen, only a small osteolytic area was noted on the radiographs, greatly underestimating the actual size of the lesion (Fig. 5).

Fig. 4

Graph showing maximum dimension of pelvic granulomas versus backside wear damage score and volumetric wear of the polyethylene (PE) bearing surface.

Fig. 5

Pelvic granulomas that were identified histologically were not visualized on the radiographs of five of the six hips in which pelvic granulomas were present. In the sixth specimen (Specimen 5), a small osteolytic area was noted on the clinical radiographs, greatly underestimating the actual size of the lesion. *Left:* Contact radiograph of the cross-section of Specimen 5 at fourteen years, showing a retro-acetabular lesion due to a wear particle-induced granuloma. *Right:* The lesion was poorly visualized on this anteroposterior clinical radiograph of the same hip (Specimen 5), made one year before the patient's death.

Discussion

Bone growth into a porous surface is one of the key elements of a cementless device. In the present study, all of the implants were fixed by bone ingrowth and were clinically successful. The mean extent of bone ingrowth was 33% (range, 4% to 65%), and this finding was consistent with data reported by others with use of similar methods of analysis^{31,32}. All of the acetabular components had been inserted with use of a line-to-line technique without impaction, relying only on the screws to obtain the initial fixation. This is the same technique reported in the long-term clinical review of the Harris-Galante I component, recently published at a minimum of twenty years of follow-up, showing a 96% rate of survivorship with component loosening as the end point¹². Currently, a press-fit technique, in which the acetabulum is under-reamed and the component is impacted in place, is in wide clinical use. It is evident from the review noted above and corroborated by the findings of the present study that impaction is not a prerequisite for bone ingrowth or for long-term implant fixation.

Most retrieval studies have focused on bone ingrowth issues and less on the soft-tissue events that develop around the implants³³. The histological features of the soft tissues, and especially the presence, extent, and progression of granuloma, even in successful devices, are essential to understanding the potential mechanisms of late failure.

Our most dramatic finding was the presence, extent, and distribution of particle-induced granuloma in clinically successful implants. In our previous studies of shorter-term postmortem retrievals, we reported no granuloma formation or histological evidence of osteolysis¹⁹, whereas in the present

study of components retrieved after as long as twenty-five years, particle-induced granulomas were present in the porous coating as well as along the implant-acetabular bone interface and progressed through screw holes, ballooning into the retroacetabular bone in long-term specimens. At the rim of the cup, the granulomas progressed as well, but at a slower rate. Thus, screw holes with or without screws were the main pathway for extension of granulomas into both the porous coating and the retroacetabular bone.

Pelvic granulomas were identified in more than one-third of the cases and increased in size from a few millimeters at six years to ballooning massive lesions in the longest-term specimens. This represents a clinical dilemma because these lesions were poorly visualized or not visualized at all on radiographs. Pelvic granulomas were not present in any patient who was over the age of sixty-five years at the time of surgery, regardless of the length of implantation. Furthermore, there was a significant correlation between granuloma size and decreasing patient age. This influence of age is well known and clearly indicates the population at risk in need of long-term surveillance³⁴.

It should be noted that the data for granuloma within the porous coating represent a final status at the time of death rather than a continuous series of measurements. Nevertheless, the progressive nature of particle-induced osteolysis is well known³⁵. A progressive invasion of the porous coating and the interface by granuloma, replacing the preexisting bone, could eventually lead to loosening of the prosthesis. Although all of the implants in this series were successful, late loosening has been reported, with a slowly increasing incidence after the second decade following implantation¹².

There is considerable controversy with regard to the importance of backside wear in the generation of osteolysis in patients with first-generation cementless modular prostheses¹³⁻¹⁸. The size of pelvic granulomas in the present study was positively correlated with the volume of bearing surface wear. Furthermore, the polyethylene particles identified at the screw holes included 50 to 250- μ m shreds, which were not observed in the joint capsule, pointing to an additional wear mechanism operating at the convex surface of the cup. These larger polyethylene particles seen at screw holes were the result of abrasive wear damage caused by the sharp edges of the holes and the relatively rough concave surface of the metal shell. Adhesive wear, indicated by backside burnishing or wear polishing, is associated with micrometer-sized polyethylene particles that were abundant in the granulomas. These findings imply that, in these patients, polyethylene wear debris from both the bearing surface and the convex side of the liner played a role in the generation of osteolysis.

The particles that were identified within the granulomas were, for the most part, polyethylene, the majority of which were very likely below the resolution of the light microscope. Some of the titanium-alloy particles probably originated because of fretting of acetabular fixation screws. Other materials identified adjacent to screw holes and pelvic granulomas originated at the femoral side of the arthroplasty. Particles of these materials included barium sulfate from the bone-cement interface, cobalt chromium or titanium alloy from the femoral

stem, and stainless steel originating from wires used for trochanteric fixation. All of the ultra-high molecular weight polyethylene acetabular inserts in this study had been sterilized by means of gamma irradiation in air and therefore were more susceptible to oxidative degradation than the current generation of highly cross-linked, thermally stabilized polyethylenes. The introduction of newer methods of sterilization, and, more recently, of highly cross-linked ultra-high molecular weight polyethylenes and other wear-resistant couples point to a dramatic decrease in wear and potentially a solution to the problem of osteolysis^{36,37}. ■

NOTE: This study was funded through NIH Grant AR039310, by Zimmer, and by the Rush Arthritis and Orthopedics Institute. The authors are grateful to Susan Shott, PhD, for statistical consultation and review of this manuscript and to Michel Laurent, PhD, for conducting the volumetric wear analysis.

Robert M. Urban
Deborah J. Hall, BS
Craig Della Valle, MD
Markus A. Wimmer, PhD
Joshua J. Jacobs, MD
Jorge O. Galante, MD, DMSc
Department of Orthopedic Surgery,
Rush University Medical Center,
1653 West Congress Parkway,
Chicago, IL 60612

References

1. Anseth SD, Pulido PA, Adelson WS, Patil S, Sandwell JC, Colwell CW Jr. Fifteen-year to twenty-year results of cementless Harris-Galante porous femoral and Harris-Galante porous I and II acetabular components. *J Arthroplasty*. 2010 Aug;25(5):687-91. Epub 2009 Jul 29.
2. Hamilton WG, Calendine CL, Beykirch SE, Hopper RH Jr, Engh CA. Acetabular fixation options: first-generation modular cup curtain calls and caveats. *J Arthroplasty*. 2007 Jun;22(4 Suppl 1):75-81.
3. Mäkelä KT, Eskelinen A, Päävolainen P, Pulkkinen P, Remes V. Cementless total hip arthroplasty for primary osteoarthritis in patients aged 55 years and older. *Acta Orthop*. 2010 Feb;81(1):42-52.
4. Parvizi J, Sullivan T, Duffy G, Cabanela ME. Fifteen-year clinical survivorship of Harris-Galante total hip arthroplasty. *J Arthroplasty*. 2004 Sep;19(6):672-7.
5. Collier JP, Bauer TW, Bloebaum RD, Bobyn JD, Cook SD, Galante JO, Harris WH, Head WC, Jasty MJ, Mayor MB, et al. Results of implant retrieval from postmortem specimens in patients with well-functioning, long-term total hip replacement. *Clin Orthop Relat Res*. 1992 Jan;(274):97-112.
6. Bloebaum RD, Mihalopoulos NL, Jensen JW, Dorr LD. Postmortem analysis of bone growth into porous-coated acetabular components. *J Bone Joint Surg Am*. 1997 Jul;79(7):1013-22.
7. Moucha CS, Urban RM, Turner TM, Jacobs JJ, Sumner DR. Fixation of implants. In: Shanbhag A, Rubash HE, Jacobs JJ, editors. *Joint replacement and bone resorption: pathology, biomaterials, and clinical practice*. New York: Taylor and Francis; 2006. p 13-52.
8. Pilliar RM. Cementless implant fixation—toward improved reliability. *Orthop Clin North Am*. 2005 Jan;36(1):113-9.
9. Turner TM, Sumner DR, Urban RM, Rivero DP, Galante JO. A comparative study of porous coatings in a weight-bearing total hip-arthroplasty model. *J Bone Joint Surg Am*. 1986 Dec;68(9):1396-409.
10. Hallan G, Dybvik E, Furnes O, Havelin LI. Metal-backed acetabular components with conventional polyethylene: a review of 9113 primary components with a follow-up of 20 years. *J Bone Joint Surg Br*. 2010 Feb;92(2):196-201.
11. Howard JL, Kremers HM, Loechler YA, Schleck CD, Harmsen WS, Berry DJ, Cabanela ME, Hanssen AD, Pagnano MW, Trousdale RT, Lewallen DG. Comparative survival of uncemented acetabular components following primary total hip arthroplasty. *J Bone Joint Surg Am*. 2011 Sep 7;93(17):1597-604.
12. Della Valle CJ, Mesko NW, Quigley L, Rosenberg AG, Jacobs JJ, Galante JO. Primary total hip arthroplasty with a porous-coated acetabular component. A concise follow-up, at a minimum of twenty years, of previous reports. *J Bone Joint Surg Am*. 2009 May;91(5):1130-5.
13. Huk OL, Bansal M, Betts F, Rimnac CM, Lieberman JR, Huo MH, Salvati EA. Polyethylene and metal debris generated by non-articulating surfaces of modular acetabular components. *J Bone Joint Surg Br*. 1994 Jul;76(4):568-74.
14. Krieg AH, Speth BM, Ochsner PE. Backside volumetric change in the polyethylene of uncemented acetabular components. *J Bone Joint Surg Br*. 2009 Aug;91(8):1037-43.
15. Kurtz SM, Ochoa JA, White CV, Srivastav S, Cournoyer J. Backside nonconformity and locking restraints affect liner/shell load transfer mechanisms and relative motion in modular acetabular components for total hip replacement. *J Biomech*. 1998 May;31(5):431-7.
16. Lieberman JR, Kay RM, Hamlet WP, Park SH, Kabo JM. Wear of the polyethylene liner-metallic shell interface in modular acetabular components. An in vitro analysis. *J Arthroplasty*. 1996 Aug;11(5):602-8.
17. Shepard MF, Lieberman JR, Kabo JM. Ultra-high-molecular weight polyethylene wear: an in vitro comparison of acetabular metal types and polished surfaces. *J Arthroplasty*. 1999 Oct;14(7):860-6.
18. Young AM, Sychterz CJ, Hopper RH Jr, Engh CA. Effect of acetabular modularity on polyethylene wear and osteolysis in total hip arthroplasty. *J Bone Joint Surg Am*. 2002 Jan;84-A(1):58-63.
19. Pidhorz LE, Urban RM, Jacobs JJ, Sumner DR, Galante JO. A quantitative study of bone and soft tissues in cementless porous-coated acetabular components retrieved at autopsy. *J Arthroplasty*. 1993 Apr;8(2):213-25.
20. Urban RM, Jacobs JJ, Sumner DR, Peters CL, Voss FR, Galante JO. The bone-implant interface of femoral stems with non-circumferential porous coating. *J Bone Joint Surg Am*. 1996 Jul;78(7):1068-81.
21. Urban RM, Jacobs JJ, Tomlinson MJ, Gavrilovic J, Black J, Peoc'h M. Dissemination of wear particles to the liver, spleen, and abdominal lymph nodes of patients with hip or knee replacement. *J Bone Joint Surg Am*. 2000 Apr;82(4):457-76.
22. Sumner DR, Jasty M, Jacobs JJ, Urban RM, Bragdon CR, Harris WH, Galante JO. Histology of porous-coated acetabular components. 25 cementless cups retrieved after arthroplasty. *Acta Orthop Scand*. 1993 Dec;64(6):619-26.

- 23.** Hood RW, Wright TM, Burstein AH. Retrieval analysis of total knee prostheses: a method and its application to 48 total condylar prostheses. *J Biomed Mater Res.* 1983 Sep;17(5):829-42.
- 24.** Kurtz SM. The UHMWPE handbook: ultra-high molecular weight polyethylene in total joint replacement. San Diego, CA: Academic Press; 2004. The clinical performance of UHMWPE in knee replacements. p 151-88.
- 25.** McKellop HA. The lexicon of polyethylene wear in artificial joints. *Biomaterials.* 2007 Dec;28(34):5049-57. Epub 2007 Aug 16.
- 26.** Rostoker W. The appearances of wear on polyethylene—a comparison of in vivo and in vitro wear surfaces. *J Biomed Mater Res.* 1978 May;12(3):317-35.
- 27.** Salineros MJ, Crowninshield RD, Laurent M, Wimmer MA, Jacobs JJ. Analysis of retrieved acetabular components of three polyethylene types. *Clin Orthop Relat Res.* 2007 Dec;465:140-9.
- 28.** Pourzal R. Determination of polyethylene wear location in well functioning acetabular cups [Thesis]. Duisburg, Germany: University of Duisburg-Essen; 2006.
- 29.** Tompkins GS, Jacobs JJ, Kull LR, Rosenberg AG, Galante JO. Primary total hip arthroplasty with a porous-coated acetabular component. Seven-to-ten-year results. *J Bone Joint Surg Am.* 1997 Feb;79(2):169-76.
- 30.** Fujishiro T, Moojen DJ, Kobayashi N, Dhert WJ, Bauer TW. Perivascular and diffuse lymphocytic inflammation are not specific for failed metal-on-metal hip implants. *Clin Orthop Relat Res.* 2011 Apr;469(4):1127-33. Epub 2010 Oct 29.
- 31.** Engh CA, Zettl-Schaffer KF, Kukita Y, Sweet D, Jasty M, Bragdon C. Histological and radiographic assessment of well functioning porous-coated acetabular components. A human postmortem retrieval study. *J Bone Joint Surg Am.* 1993 Jun; 75(6):814-24.
- 32.** Sychterz CJ, Claus AM, Engh CA. What we have learned about long-term cementless fixation from autopsy retrievals. *Clin Orthop Relat Res.* 2002 Dec; (405):79-91.
- 33.** Huber M, Reinisch G, Zenz P, Zweymüller K, Lintner F. Postmortem study of femoral osteolysis associated with metal-on-metal articulation in total hip replacement: an analysis of nine cases. *J Bone Joint Surg Am.* 2010 Jul 21;92(8):1720-31.
- 34.** Wright TM, Goodman SB. Implant wear in total joint replacement: clinical and biological issues, material and design considerations. Rosemont, IL: American Academy of Orthopaedic Surgeons; 2001. What patient-related factors contribute to implant wear? p 13-9.
- 35.** Harris WH. Periprosthetic osteolysis around total hips and total knees. In: Shanbhag A, Rubash HE, Jacobs JJ, editors. *Joint replacement and bone resorption. pathology, biomaterials, and clinical practice.* New York: Informa Healthcare; 2006. p 1-11.
- 36.** Atienza C Jr, Maloney WJ. Highly cross-linked polyethylene bearing surfaces in total hip arthroplasty. *J Surg Orthop Adv.* 2008 Spring;17(1):27-33.
- 37.** Jacobs CA, Christensen CP, Greenwald AS, McKellop H. Clinical performance of highly cross-linked polyethylenes in total hip arthroplasty. *J Bone Joint Surg Am.* 2007 Dec;89(12):2779-86.