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A Comparison of a Second- and a Third-Generation Modular Cup Design

Is New Improved?

Cara C. Powers, MD,* Henry Ho, MS,* Sarah E. Beykirch, BS,*
Cathy Huynh, BS,* Robert H. Hopper Jr, PhD,*
C. Anderson Engh Jr, MD,*† and Charles A. Engh, MD*†

Abstract: The highly cross-linked polyethylene liners currently used with modular uncemented cups have substantially decreased wear and osteolysis at early follow-up. However, retroacetabular osteolysis has still been reported in some cases with DePuy Orthopaedic's (Warsaw, IN) second-generation Duraloc acetabular shell. DePuy's third-generation Pinnacle cup incorporates a different shell-liner locking mechanism. We compared the clinical outcome among a matched series of 42 Duraloc and 42 Pinnacle cups at a mean follow-up of 5.9 years. Although the Harris Hip Scores and wear rates were not statistically different between the 2 cup designs, retroacetabular osteolysis behind the central hole was absent among the Pinnacle cups but noted among 19% of the Duraloc cups. **Keywords:** total hip arthroplasty clinical outcome, hemispheric porous-coated modular cup locking mechanism, Marathon highly cross-linked polyethylene wear, computed tomography evaluation of osteolysis, DePuy Duraloc and Pinnacle acetabular components.

Background

New total hip arthroplasty (THA) component designs are introduced periodically with the anticipation of improved outcome. However, not all innovation proves to be progress. At our institution, we have used several different uncemented acetabular components over the past 25 years. Our experience dates back to 1982 when we implanted our first porous-coated cup, the AML TriSpike (DePuy, Warsaw, IN). This first-generation design featured a hemispheric shell with a beaded surface incorporating 3 spikes for initial fixation and a polyethylene liner that was preassembled in the shell by the manufacturer. Although the porous coating has demonstrated durable fixation, we have found a relatively high incidence of wear-related revisions and osteolysis at long-term follow-up [1,2]. In the later part of the 1980s, we began to use DePuy's ACS Triloc+ component, a first-generation modular porous-coated cup. Although the modular design afforded more intraoperative flexibility and the porous coating continued to demonstrate durable fixation, this cup had a relatively high incidence of polyethylene liner failure [3,4]. In the early 1990s, we began to use DePuy's Duraloc cup, a second-generation modular component. Like its predecessors, this design has demonstrated excellent fixation at intermediate follow-up [5]. During the late 1990s, Marathon liners cross-linked with 5 Mrad (50 kGy) of gamma irradiation and heat treated to eliminate free radicals were introduced. Although several clinical outcome studies have demonstrated that Marathon has substantially reduced both wear and osteolysis among Duraloc cups, computed tomography (CT) imaging demonstrates that pelvic osteolysis has not been completely eliminated [6-10].

In 2000, we began to use DePuy's Pinnacle cup, a third-generation modular component. The Pinnacle and Duraloc designs are both manufactured from the same titanium alloy and feature the same Porocoat porous coating achieved by sintering beads to a hemispheric shell. To implant both cup designs, we routinely under-reamed the acetabulum by 1 mm and impacted 100-

*From the *Anderson Orthopaedic Research Institute, Alexandria, Virginia; and †Inova Center for Joint Replacement at Mount Vernon Hospital, Alexandria, Virginia.*
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Reprint requests: Cara C. Powers, MD, Anderson Orthopaedic Research Institute, via postal service: PO Box 7088, Alexandria, VA 22307, via courier: 2501 Parker's Ln, Suite 200, Alexandria, VA 22306.

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series cups that feature only a single apex dome hole used for impaction and for visualization of component seating. During the past decade, we have routinely placed a threaded hole plug in the apex dome hole after impaction; but these plugs are not watertight. Initial fixation is achieved by press-fitting the cups without screws. The primary difference between the cup designs relates to the shell-liner locking mechanisms. The Duraloc incorporates a wire locking ring that engages a circumferential groove near the cup rim to prevent dissociation and small protrusions from the inner surface of the shell for rotational stability (Fig. 1). The Pinnacle cup features a 10° taper locking mechanism near the equator of the shell to prevent dissociation and a series of interlocking liner nubs and divots around the cup rim for rotational stability. The Pinnacle cup is also a full (180°) hemisphere, whereas the Duraloc is a subhemisphere of approximately 170° depending on the cup diameter. During the manufacturing process, the inner surface of the Duraloc shell is machined before the porous coating is sintered to the exterior of the shell, whereas the inner surface of the Pinnacle shell is machined after the Porocoat sintering process. The purpose of this study was to compare outcomes in a matched series of hips implanted with cross-linked Marathon polyethylene liners coupled with Duraloc 100 and Pinnacle 100 cups. We hypothesized that the Pinnacle cup would demonstrate a reduced incidence of retroacetabular osteolysis.

Methods and Material

Before compiling the study population, the number of cases required for 80% power was determined. In a previous report, we found that the incidence of pelvic osteolytic lesions with a volume of at least 1 mL on CT was 8% (3/36) among Duraloc cups with Marathon liners at a mean follow-up of 6.1 years with a minimum follow-up of 5 years [9]. Without a volume threshold used to classify defects, we found that the incidence of retroacetabular osteolysis in hips with Duraloc cups and Marathon liners was 17% (6/36). Because we did not plan to use a volume threshold for this study, our power analysis assumed that the incidence of pelvic osteolysis among the Duraloc group would be 17% and the Pinnacle cups would not demonstrate any osteolysis at minimum 5-year follow-up. Because zero could not be used for the power analysis, an incidence of 0.1% was used for computational purposes. A power analysis

Fig. 1. Although similar in many regards, the major difference between the Duraloc 100 (left) and Pinnacle 100 cup (right) relates to the shell-liner locking mechanism that can be seen on the interior of the shell near the rim. Other minor differences include a change in the sequence of manufacturing steps resulting in slightly different interior surface finishes and the use of a full hemispheric geometry for the Pinnacle cup compared with a 170° subhemisphere for the Duraloc cup. The "100" designates the presence of a single dome hole without any other cavitary screw holes.

Table 1. Study Demographics

Variable	Duraloc 100	Pinnacle 100	*P*	Test
No. of THAs [n (%)]	42 (50.0)	42 (50.0)	NA	
Cup diameter [mm; mean ± SD (range)]	55.5 ± 3.8 (48-66)	54.7 ± 3.1 (48-60)	.26	Student *t*
Sex [n (%)]			1.00	Fisher exact
Female	23 (54.8)	23 (54.8)		
Male	19 (45.2)	19 (45.2)		
Diagnosis [n (%)]			.80	Fisher exact
OA	31 (73.8)	33 (78.6)		(OA vs non-OA)
Hip dysplasia	6 (14.3)	5 (11.9)		
Fracture/trauma	3 (7.1)	1 (2.4)		
Avascular necrosis	2 (4.8)	3 (7.1)		
Activity level [n (%)]			.88	Mann-Whitney *U*
Heavy	8 (19.0)	10 (23.8)		
Moderate	26 (61.9)	20 (47.6)		
Light	4 (9.5)	10 (23.8)		
Semisedentary	2 (4.8)	2 (4.8)		
Sedentary	2 (4.8)	0 (0.0)		
Age at surgery [y; mean ± SD (range)]	58.1 ± 8.4 (40-73)	58.0 ± 8.4 (40-71)	.94	Student *t*
Weight [lb; mean ± SD (range)]	177 ± 48 (115-300)	181 ± 42 (105-300)	.69	Student *t*
BMI [mean ± SD (range)]	27.5 ± 5.5 (19.1-40.3)	28.0 ± 5.5 (20.5-44.3)	.66	Student *t*
Preop Harris Hip Score [median (range)]	50 (15-69)	54 (30-65)	.25	Mann-Whitney *U*

NA indicates not applicable; OA, osteoarthritis.

(SamplePower; SPSS Inc, Chicago, IL) indicated that 42 hips in each group would be necessary to achieve a power of 80% using a 2 × 2 independent-samples, 2-tailed χ^2 with an α of .05.

All data for this institutional review board–approved study were collected prospectively as part of routine care and were analyzed retrospectively. At our institution, patient outcomes are assessed at routine follow-up with standardized questionnaires that incorporate measures of pain and function as well as physician-assessed activity level, which is graded on a 5-point scale (1 = heavy, 2 = moderate, 3 = light, 4 = semisedentary, and 5 = sedentary). In addition to radiographs, for the past several years, we have routinely recommended CT scans to THA patients after 5-year follow-up. Surgical information, clinical outcome data, and digital CT scans are archived in our institutional database. The database was used to identify all primary THAs performed at our institution with Duraloc 100 or Pinnacle 100 cups, 4-mm lateralized Marathon liners, cobalt-chrome alloy heads, and extensively porous-coated femoral components that had a CT scan taken at least 5 years postoperatively. The apex holes of all implanted shells were filled with the same hole plugs that incorporated a positive stop to prevent over-insertion and postoperative advancement. One hundred thirteen THAs met these criteria. A computer algorithm was then used to identify all possible sex-matched pairs that had physician-assessed activity levels within 3 points of each other. A least squares method was subsequently used to find the 42 pairs that matched most closely on age at surgery (with a maximum 5-year age difference) and the length of follow-up at the time of the CT (with a maximum 0.6-year difference).

Helical CT scans had been taken at 140 kV (LightSpeed VCT; GE, Milwaukee, WI), and thin axial images (1.25 mm) were reconstructed from the raw data. To analyze the CT image, the DICOM-formatted image data were transferred to a personal computer for analysis using a computer-aided imaging program (Analyze 7.0; Biomedical Imaging Resource, Mayo Clinic, Rochester, MN). An automated segmentation algorithm based on a Hounsfield threshold was used to identify the implant. A single independent observer (CH) then traced the boundaries of acetabular osteolytic defects slice by slice. *Osteolytic lesions* were defined as any demarcated area adjacent to the acetabular component without trabecular bone that communicated with the effective joint space [11-13]. To ensure maximum specificity, the contralateral side was examined for the morphology of the fossa to ensure that areas of residual fossa were not classified as osteolysis. To ensure maximum sensitivity, no size threshold was used. The volume of pelvic osteolysis was computed by the software application based on a summation of the user-segmented regions.

Wear measurements were made by a second independent reviewer (SEB) using Martell's Hip Analysis Suite Version 8 that incorporates elliptical correction (University of Chicago Medical Center, Chicago, IL). All hips had at least 3 follow-up radiographs for the computation of a wear rate based on a linear regression [14]. A third independent reviewer (CCP) reviewed the anteroposterior (AP) pelvic radiographs for implant stability and femoral osteolysis [15-17]. Areas of femoral osteolysis on radiograph were measured using Martell's Hip Analysis Suite software that corrects for radiographic magnification. The same reviewer (CCP) also evaluated

Table 2. Functional Outcomes and Radiographic Wear at Latest Follow-Up

Variable	Duraloc 100	Pinnacle 100	*P*	Test
Satisfied with hip [n (%)]	41 (97.6)	42 (100)	1.00	Fisher exact
Decreased pain [n (%)]	41 (97.6)	42 (100)	1.00	Fisher exact
Pain severity [n (%)]			.35	Mann-Whitney *U*
None	29 (69.0)	26 (61.9)		
Slight	9 (21.4)	7 (16.7)		
Mild	1 (2.4)	4 (9.5)		
Moderate	3 (7.1)	4 (9.5)		
Severe	0 (0.0)	1 (2.4)		
Increased function [n (%)]	41(97.6)	42 (100)	1.00	Fisher exact
Walking distance [n (%)]			.89	Mann-Whitney *U*
Unlimited	32 (76.2)	32 (76.2)		
3-6 Blocks	7 (16.7)	4 (9.5)		
2-3 Blocks	1 (2.4)	4 (9.5)		
Indoors only	2 (4.8)	2 (4.8)		
Walking support [n (%)]			.36	Mann-Whitney *U*
No cane, no limp	21 (50.0)	26 (61.9)		
No cane, occasional limp	18 (42.9)	12 (28.6)		
1 Cane on long walks	0 (0.0)	2 (4.8)		
1 Cane most of the time	3 (7.1)	2 (4.8)		
Harris Hip Score [median (range)]	97 (57-100)	98 (53-100)	.72	Mann-Whitney *U*
Wear rate [mm/y; mean ± SD]	0.04 ± 0.08	0.03 ± 0.09	.81	Student *t*
Total volumetric wear [mm^3; mean ± SD]	160 ± 98	185 ± 132	.33	Student *t*

the AP pelvic and iliac oblique radiographs for the presence or absence of pelvic osteolysis on each film. Lesions located primarily in DeLee and Charnley zone 2 or appearing adjacent to the hole plug on either view were classified as *dome hole lesions*. Lesions in DeLee and Charnley zones 1 or 3 were classified as *rim lesions* [18]. Statistical analyses were performed with SPSS. Statistical tests were selected based on the nature of the data under consideration. A *P* value of .05 was used as the threshold for statistical significance.

Results

The computerized matching algorithm yielded very similar characteristics for the Duraloc and Pinnacle groups (Table 1). Twenty-three (54.8%) of the 42 cups in each group were implanted in women, and 19 cups (45.2%) in each group were implanted in men. The mean age of the patients at the time of surgery was 58.1 (range, 40-73) years in the Duraloc 100 group and 58.0 (range, 40-71) years in the Pinnacle 100 group ($P = .94$). Mean length of clinical and CT follow-up in the Duraloc 100 and Pinnacle 100 groups was 5.9 (range, 5.0-7.8) and 5.9 (range, 5.0-7.3) years, respectively ($P = .99$). No statistically significant differences were found in cup diameter (indicative of liner thickness), preoperative diagnosis, physician-assessed activity level, weight, or body mass index (BMI) between the 2 groups (Table 1).

Clinical outcome measures related to pain, function, and polyethylene wear were similar for the Duraloc and Pinnacle cups (Table 2). The median Harris Hip Score for both groups was excellent. The mean wear rate was 0.04 ± 0.08 mm/y for the Duraloc 100 cups and 0.03 ± 0.09 mm/y for the Pinnacle 100 cups ($P = .81$). The mean volumetric wear for the Duraloc and Pinnacle groups based on the 2-dimensional head penetrations were 160 ± 98 and 185 ± 132 mm^3, respectively ($P = .33$).

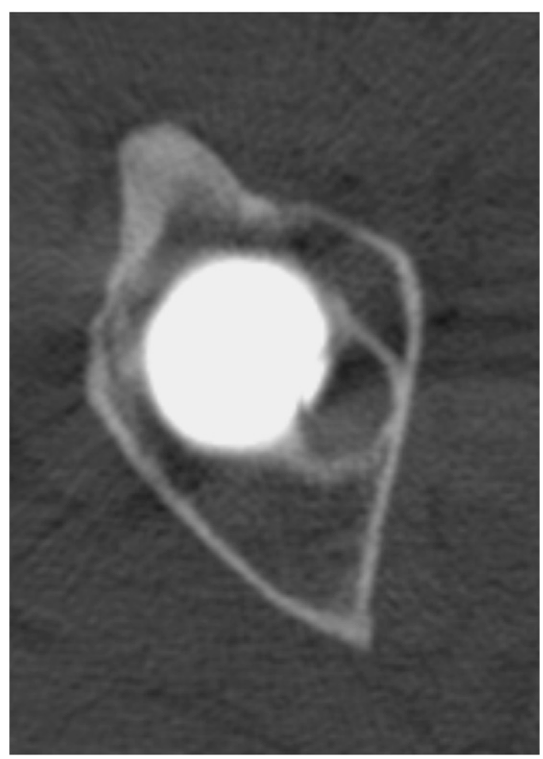

Fig. 2. An axial slice from a CT image taken 5.7 years postoperatively demonstrates a 1.1-cm^3 osteolytic lesion adjacent to the hole plug of a Duraloc 100 cup with a Marathon liner. No osteolytic lesions were seen on the CTs of the Pinnacle 100 cups.

Table 3. Comparison of Duraloc THAs With and Without Osteolysis

Variable	Lysis	No Lysis	*P*	Test
No. of THAs [n (%)]	8 (19.0)	34 (81.0)		
Cup diameter [mm; mean ± SD (range)]	55.7 ± 3.9 (50-62)	55.0 ± 3.7 (48-66)	.67	Student *t*
Sex [n (%)]			.71	Fisher exact
Female	5 (62.5)	18 (52.9)		
Male	3 (37.5)	16 (47.1)		
Diagnosis [n (%)]			.41	Fisher exact
OA	5 (62.5)	26 (76.5)		(OA vs non-OA)
Hip dysplasia	2 (23.0)	4 (11.8)		
Fracture/trauma	0	3 (8.8)		
Avascular necrosis	1 (2.9)	1 (2.9)		
Activity level [n (%)]			.94	Mann-Whitney *U*
Heavy	1 (12.5)	7 (20.6)		
Moderate	6 (75.0)	20 (58.8)		
Light	1 (12.5)	3 (8.8)		
Semisedentary	0	2 (5.9)		
Sedentary	0	2 (5.9)		
Age at surgery [y; mean ± SD (range)]	55.0 ± 10.2 (40-68)	58.8 ± 7.9 (42-73)	.25	Student *t*
Weight [lb; mean ± SD (range)]	148 ± 19 (116-172)	184 ± 50 (115-300)	.002*	Student *t*
BMI [mean ± SD (range)]	23.7 ± 3.1 (19.2-28.3)	28.4 ± 5.6 (19.1-40.3)	.03*	Student *t*
Satisfied with hip [n (%)]	8 (100.0)	33 (97.1)	1.00	Fisher exact
Decreased pain [n (%)]	8 (100.0)	33 (97.1)	1.00	Fisher exact
Pain severity [n (%)]			.19	Mann-Whitney *U*
None	7 (87.5)	22 (64.7)		
Slight	1 (12.5)	8 (23.5)		
Mild	0	1 (2.9)		
Moderate	0	3 (8.8)		
Severe	0	0		
Increased function [n (%)]	8 (100.0)	33 (97.1)	1.00	Fisher exact
Walking distance [n (%)]			.97	Mann-Whitney *U*
Unlimited	6 (75)	26 (76.5)		
3-6 Blocks	2 (25)	5 (14.7)		
2-3 Blocks	0	1 (2.9)		
Indoors only	0	2 (5.9)		
Walking support [n (%)]			.36	Mann-Whitney *U*
No cane, no limp	5 (62.5)	16 (47.1)		
No cane, occasional limp	3 (37.5)	15 (44.1)		
1 Cane on long walks	0	0		
1 Cane most of the time	0	3 (8.8)		
Harris Hip Score [median (range)]	99 (94-100)	97 (57-100)	.31	Mann-Whitney *U*
Wear rate [mm/y; mean ± SD]	0.05 ± 0.05	0.04 ± 0.09	.56	Student *t*
Total volumetric wear [mm^3; mean ± SD]	179 ± 83	156 ± 102	.55	Student *t*

*Statistically significant variables.

The only difference in outcome among the Duraloc and Pinnacle groups related to the incidence of pelvic osteolysis on CT. No defects meeting our definition of osteolysis were found on the CT scans of the Pinnacle 100 cups. However, in the Duraloc group, 9 osteolytic lesions in 8 hips were identified. Of the 8 dome hole lesions determined to be osteolysis, 1 measured 0.1 cm^3, 1 measured 0.2 cm^3, 3 measured 0.4 cm^3, 1 measured 0.7 cm^3, 1 measured 0.9 cm^3, and 1 measured 1.1 cm^3 (Fig. 2). One of the cups that had a 0.4-cm^3 lesion at the dome hole also had a 0.9-cm^3 lesion in the ischium. Thus, the overall incidence of dome hole osteolysis in the 42 hips with Duraloc 100 cups was 19.0% (8/42); and the incidence of pelvic osteolysis with a combined volume of at least 1.0 cm^3 was 4.8% (2/42). A statistically significant difference in the overall incidence of pelvic osteolysis between the 2 groups was found (P = .005, 2-tailed Fisher exact). Because the incidence of osteolysis was zero in the Pinnacle group, lesion sizes between groups could not be compared. Among the 42 THAs with Duraloc cups, patients with pelvic osteolysis tended to be lighter (P = .002) and had lower BMIs (P = .03). The hips with and without pelvic osteolysis did not differ significantly with regard to other patient demographics, physician-assessed activity level, clinical outcome, or implant wear (Table 3).

At a mean radiographic follow-up of 5.9 (range, 4.8-7.8) years for the Duraloc 100 cups and 5.8 (range, 4.7-7.1) years for the Pinnacle cups (P = .54), all stems in each group were found to be bone ingrown; and all of the cups were stable. One femoral osteolytic lesion was noted in each group. Both lesions were located in Gruen zone 1

[19]. The lesion in the Duraloc 100 group was 0.10 cm^2, whereas the lesion in the Pinnacle 100 group was 0.12 cm^2. No pelvic osteolysis was identified on plain radiographs in the Pinnacle 100 group. Although the radiograph reviewer identified 6 lesions adjacent to the dome hole in the Duraloc group, only 3 of the lesions were confirmed by CT scan. The CT scans revealed 6 pelvic lesions in 5 hips that were not identified by the radiograph reviewer, including both osteolytic defects in the hip with a rim lesion and a dome hole lesion. Using the CT findings as a criterion standard and including all 84 hips in our study population, the sensitivity and specificity of using the AP pelvic and iliac oblique radiographs to identify any pelvic osteolysis were 37.5% and 96.1%, respectively.

Discussion

Although the wear rates among the Pinnacle and Duraloc cups in this study were similarly low, the incidence of pelvic osteolysis on CT was significantly higher among the Duraloc cups. If osteolysis were entirely mediated by wear debris, then the reduced incidence of osteolysis communicating with the dome hole of the Pinnacle cups might have been associated with a higher incidence of rim or femoral osteolysis. However, both groups demonstrated the same incidence of femoral osteolysis. Other factors implicated in the pathogenesis of osteolysis include particle size and bioreactivity. Because the Pinnacle and Duraloc cups in this study featured the same cross-linked Marathon polyethylene liners coupled with cobalt-chrome alloy femoral heads, particle size and bioreactivity should have been the same among the groups.

Among THAs with low wear rates, fluid pressure is one hypothesis for the development of retroacetabular lysis [20]. Several studies have demonstrated that suboptimal conformity and shell-liner micromotion can lead to diaphragm and piston pumping mechanisms [21-23]. In vitro and in vivo studies have demonstrated that these mechanisms can induce cyclical increases in fluid pressure behind holes in the acetabular shell, leading to osteolysis [24-33]. The intrusion of synovial fluid into cancellous bone (the hydrodynamic theory) is also a leading theory of the pathophysiology of osteoarthritic cysts [34]. Among the Duraloc cups, the presence of mechanical forces acting behind the liner at the apex hole is evidenced by the advancement and separation of apex hole plugs previously reported by Walde et al [35]; and these same forces also may be contributing to retroacetabular osteolysis.

In view of the similarities among the Pinnacle and Duraloc groups in terms of age, sex, preoperative diagnosis, activity level, wear, and length of follow-up, it seems reasonable to attribute the reduced incidence of pelvic osteolysis in the Pinnacle group to differences between the cup designs. Although machining the interior surface of the Pinnacle shell after sintering the porous-coating could reduce the interior surface roughness and potentially reduce backside wear, we found no difference among the 2 groups in total radiographic wear, which represents the sum of articular surface and backside wear. Compared with the Duraloc cup with a 170° subhemisphere, the 180° hemisphere associated with the Pinnacle cup might influence fixation. However, because we found no difference in cup stability with all shells graded as radiographically stable at most recent follow-up, the difference between a 170° and 180° shell profile seems unlikely to influence the incidence of retroacetabular osteolysis. Although we cannot exclude potential contributions from other unquantified factors, differences among the locking mechanisms appear to be the most likely reason for the reduced incidence of retroacetabular osteolysis. Because of the full-hemisphere design and the taper lock mechanism, the Pinnacle design has more polyethylene-to-metal contact area than the Duraloc cup. The Duraloc liner is also less constrained radially than the Pinnacle liner. There is approximately 0.25 mm of clearance between the outer diameter of the Duraloc liner and the inner diameter of the shell in the locking region. Because the Pinnacle is a taper lock design, there is no radial clearance. The reduced incidence of osteolysis suggests that the combination of these design features has increased shell-liner conformity and constraint among the Pinnacle cups, reducing shell-liner micromotion and the associated fluid pressure gradients that can induce osteolysis.

The current study has both strengths and limitations. We used CT to diagnose pelvic osteolysis because it is very difficult to identify small osteolytic lesions at early follow-up on radiographs, as evidenced by the poor 37.5% radiographic sensitivity that we documented. To reliably diagnose osteolysis at early follow-up, we continue to recommend CT scans. Although we would have preferred to interpret femoral osteolysis on CT, we had to evaluate femoral osteolysis using conventional radiographs owing to the severe metal artifacts associated with the cobalt-chrome alloy used for our extensively porous-coated stems. Despite the fact that a prospective randomized study would have been preferable, the use of a computer algorithm to identify and match cases eliminated subjectivity in the selection process, resulting in 2 groups that were very similar.

Although the Duraloc cups in this study demonstrated a higher incidence of pelvic osteolysis, none of the osteolytic defects are currently of clinical concern. However, the potential for progression means that we will continue to monitor these patients. We are encouraged by the early results associated with the Pinnacle cup [36]. Based on the low wear and osteolysis coupled with the same durable porous-coated fixation surface used in prior-generation designs, we now preferentially use the Pinnacle cup design for most of our primary THAs, particularly among high-demand patients. The results of this study also underscore that osteolysis is a multifactorial problem that is unlikely to be eradicated by exclusively focusing on the bearing surface. Although many studies have demonstrated that bearing surface wear plays an important role, other patient, implant, and surgical factors likely contribute to the osteolytic process. In the context of the Pinnacle and Duraloc cup designs, the results of this study lend support to the theory that fluid pressure gradients contribute to the pathogenesis of osteolysis and indicate that improved locking mechanisms may further reduce the incidence of retroacetabular osteolysis when coupled with low-wear bearing surfaces. Although long-term follow-up will be required, improved bearing technology combined with better implant designs and surgical techniques holds the promise of reducing wear and osteolysis so that they do not become clinical problems during the lifetime of the patient.

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