The Effect of Poly Sterilization on Wear, Osteolysis and Survivorship of a Press-fit Cup at 10-Year Followup

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Published online: 9 September 2011
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Abstract

Background During the mid-1990s when our institution was using a press-fit porous-coated cup without supplemental initial fixation for primary THA, the manufacturer transitioned from gamma irradiation to gas plasma for the terminal sterilization of their polyethylene liners.

Questions/purposes At minimum 10-year followup, we asked whether the fixation achieved by solely relying on a

press-fit would be durable and how different liner sterilization methods affected radiographic wear, osteolysis, and survivorship.

Patients and Methods We retrospectively reviewed 373 patients who underwent 398 primary THAs with a press-fit porous-coated cup between March 1995 and December 1996. Mean age at time of surgery was 61.5 ± 13.3 years and mean followup was 10.4 ± 3.7 years. We determined reasons for revision, survivorship, femoral head penetration, osteolysis, and wear-related complications.

Results Among 20 revisions involving any component, seven were associated with wear and osteolysis. Kaplan-Meier survivorship, using component revision for any reason as an end point, was 95.7% (95% confidence interval, 93.6%–97.9%) at 10 years. Noncrosslinked liners sterilized with gas plasma demonstrated a mean head penetration rate of 0.20 ± 0.09 mm/year compared with 0.13 ± 0.07 mm/year for liners sterilized with gamma irradiation in air and 0.09 ± 0.04 mm/year for liners sterilized with gamma-irradiation with barrier packaging without oxygen. THAs with increased volumetric wear tended to demonstrate larger osteolytic lesions ($r = 0.40$) and there tended to be less osteolysis among the liners sterilized with gamma-irradiation with barrier packaging without oxygen. However, there was no difference in survivorship among the sterilization groups and there has been no cup or stem loosening associated with osteolysis.

Conclusions Durable biologic fixation through 10-year followup can be achieved by solely relying on an initial press-fit. Noncrosslinking gas plasma for terminal sterilization of the polyethylene liners was associated with greater head penetration rate than gamma irradiation.

Level of Evidence Level IV, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Two authors (CAE, CAEJr) have received or may receive payments or benefits from a commercial entity (DePuy Orthopaedics, Inc, a Johnson and Johnson company, Warsaw, IN, USA) related to this work. Two authors (CAE, CAEJr) receive royalties from DePuy, one (CAEJr) serves as a DePuy consultant, and one (CAE) owns Johnson & Johnson stock. The institution (AORI) of the authors (CAE, CCP, HH, SEB, RHH, CAEJr) has received funding from Inova Health Services (Fairfax, VA, USA), Medtronic Sofamor Danek, Inc (Minneapolis, MN, USA), and a cooperative agreement awarded and administered by the US Army Medical Research & Materiel Command (USAMRMC) and the Telemedicine & Advanced Technology Research Center (TATRC) under Contract Number W81XWH-05-2-0079.

Each author certifies that his or her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research. This work was performed at Anderson Orthopaedic Research Institute and Inova Center for Joint Replacement at Mount Vernon Hospital.

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Introduction

Among THA components that rely on polymethylmethacrylate bone cement for implant fixation, implant failure is often attributed to mechanisms that involve the cement [17, 26, 43]. Cementless components were introduced with the ambition of achieving biologic implant fixation and eliminating cement-related failure modes [11]. To achieve biologic fixation via bone ingrowth or ongrowth, minimizing the relative motion between the implant surface and host bone is essential [12, 15]. Among first-generation hemispheric porous-coated cups that became available in the 1980s, intraoperative fixation with screws or spikes was often used to achieve initial stability [13]. However, holes for screws create potential pathways for osteolysis [4]. Screws can also break and their usage introduces the potential for other clinical complications such as vascular injury, nerve damage, and postoperative tendonitis [1, 30, 42]. Spikes can make it more difficult to seat the cup, potentially reducing the surface area of the shell in apposition to host bone and available for biologic fixation [13]. In the event that a cup needs to be revised, the presence of screws or spikes can complicate removal of the shell. With the ambition of eliminating the use of spikes and screws for initial fixation, we began to use press-fit Duraloc[®] cups (DePuy Orthopaedics Inc, Warsaw, IN, USA) without supplemental fixation in the early 1990s. These cups featured a rough porous surface for bone ingrowth that was achieved by sintered beads on the titanium-alloy shell. A modular polyethylene liner was locked into the shell by a removable wire locking ring that engaged opposing grooves machined into the liner and the inside of a metal shell. With the ambition of reducing volumetric wear during the period when these THAs were performed, we preferred to use a 28-mm femoral head. On the femoral side, our institutional preference was to use the DePuy Anatomic Medullary Locking (AML[®]) or Prodigy[®] femoral components. Both of these stem designs had a cylindrical distal geometry with a porous coating consisting of sintered beads over at least 2/3 of the stem length ("extensively coated").

Until the mid-1990s, gamma irradiation in air was a common method for terminally sterilizing implant components [18]. While gamma irradiation can result in increased polyethylene crosslinking, which reportedly decreases wear, it can also result in free radicals [32]. These free radicals are susceptible to oxidation either on the shelf or in vivo and the accumulation of oxidative degradation can lead to increased wear and failure of the polyethylene [31, 34]. With the ambition of mitigating the potential for oxidation, several implant manufacturers eliminated terminal sterilization with gamma irradiation in air during the mid-1990s, opting for gamma irradiation in

an oxygen-free environment or using a chemical surface treatment that would not create free radicals. Although gamma irradiation in an inert environment should eliminate the possibility of oxidation before implantation, in vivo oxidation of residual free radicals remains a possibility [33]. Chemical surface treatments such as gas plasma do not induce any polyethylene crosslinking or generate free radicals [5].

To determine the consequences of eliminating supplemental initial fixation and changing polyethylene sterilization techniques, we asked (1) whether the fixation achieved by solely relying on a press-fit would be durable; and (2) whether the newer liner sterilization methods decreased radiographic wear, reduced osteolysis and related complications, or improved survivorship.

Patients and Methods

We retrospectively reviewed 373 patients who had 398 primary THAs using Duraloc[®] 100 cups coupled with Prodigy[®] or AML[®] stems between March 1, 1995, and December 31, 1996. The components were sterilized using one of three methods: gamma irradiation in air (gamma-air), gamma irradiation with barrier packaging without oxygen (gamma-barrier), and gas plasma. This cohort represented 90% (398 of 440) of all primary THAs performed by two surgeons (CAE, CAEJr) at our institution during this time. The indications for these implants included the ability to restore the hip center and reconstruct hip biomechanics based on preoperative templating. Contraindications included an acetabulum outside the range of implants sizes available in the Duraloc[®] system, inability to obtain initial bone prosthesis stability without additional fixation, and inability to obtain a stable hip based on intraoperative ROM testing. The surgical technique involved preparing the acetabulum with reamers to a hemispheric shape undersized by 1 to 2 mm relative to the diameter of the cup. The cup was impacted into the acetabulum to achieve a press-fit without any supplemental fixation using a driving rod that threaded into a central dome hole. With the driving rod removed, seating of the shell against the acetabulum could be visualized through the dome hole. On the femoral side, initial fixation was achieved by press-fitting the stem so that a scratch fit was achieved between the inner diaphyseal cortices of the femur. For the entire cohort of 398 THAs, the mean ($\pm$ SD) patient age at the time of surgery was 61.5 ± 13.3 years (range, 22–88 years) and 74% of the patients had osteoarthritis as their primary diagnosis (Table 1).

All data used for this study were collected as part of routine care and reviewed retrospectively. For the patients included in this study, clinical evaluations with radiographs were recommended every 2 to 3 years as part of long-term

Table 1. Patient and implant characteristics

Variable	Value
Sex	
Male	200 (50%)
Female	198 (50%)
Age at surgery (years)*	61.5 ± 13.3 (22–88)
Body mass index*	27.4 ± 5.5 (18–52)
Diagnosis	
Osteoarthritis	296 (74%)
Hip dysplasia	34 (9%)
Avascular necrosis	33 (8%)
Fracture/trauma	21 (5%)
Inflammatory arthritis	14 (4%)
Surgeon	
Surgeon 1	284 (71%)
Surgeon 2	114 (29%)
Cup design	
Duraloc® 100	398 (100%)
Stem design	
Prodigy®	229 (58%)
AML®	169 (42%)
Liner material	
Conventional (Enduron™)	352 (88%)
Higher crystallinity (Hylamer™)	46 (12%)
Liner geometry	
4-mm lateralized	201 (51%)
Neutral	179 (45%)
10° lip	18 (5%)
Liner sterilization	
Gamma-air	188 (47%)
Gamma-barrier	70 (18%)
Gas plasma	130 (33%)
Unknown	10 (3%)
Femoral head material	
Cobalt-chrome alloy	298 (75%)
Ceramic	100 (25%)
Femoral head diameter	
22 mm	11 (3%)
26 mm	15 (4%)
28 mm	323 (81%)
32 mm	49 (12%)

* Values are expressed as mean ± SD, with range in parentheses; gamma-air = gamma irradiation in air; gamma-barrier = gamma irradiation with barrier packaging without oxygen.

followup. Patients who could not have clinical followup were contacted by telephone to inquire about any revision surgeries or other complications related to their THA. Of the 398 hips comprising the series for this report, 20 THAs among 19 patients have undergone a component revision and 81 patients with 85 unrevised THAs died with less than

10 years of followup. Minimum 10-year radiographs were available for 185 THAs with a mean followup of 12.3 ± 0.8 years (range, 10.1–14.4 years). Whether a revision had occurred at minimum 10-year followup was known for an additional 76 THAs with a mean followup of 12.5 ± 0.7 years (range, 10.9–13.9 years). Minimum 10-year followup of any type was not available for 32 THAs among 28 patients who were not known to be revised or deceased. The mean followup for these THAs was 3.3 ± 3.1 years (range, 0–9.3 years). The mean followup for all 398 THAs was 10.4 ± 3.7 years.

To evaluate fixation durability, we identified the reasons for component revision, calculated survivorship, assessed component stability radiographically, evaluated periprosthetic osteolysis, and recorded osteolysis-related complications. Assessments of wear and osteolysis were limited to the 185 THAs with minimum 10-year radiographs. Radiographs were analyzed by an independent reviewer (CCP) to evaluate implant stability, osteolysis, and other complications. Cups were classified as stable, fibrous fixed, or loose while stems were categorized as bone ingrown, fibrous fixed, or loose. In the absence of radiographic evidence of bone ingrowth, a component was considered fibrous fixed if it demonstrated a continuous radiolucent line at the bone-implant interface and loose if it demonstrated more than 2 mm or 5° of migration on the most recent followup radiograph relative to the immediate postoperative radiograph [14, 29]. Osteolytic lesions were defined as expansile regions of bone loss that did not exist on the immediate postoperative radiograph [16, 43]. Iliac oblique radiographs routinely obtained during followup were used to help interpret findings of osteolysis on the AP pelvic radiographs. The area of each lesion on the AP pelvic radiograph was measured using Martell's software (Fig. 1). Lesions measuring at least 1.5 cm² were considered clinically important and lesions with an area of 5 cm² were considered large. The locations of femoral osteolytic lesions were classified according to the zones described by Gruen et al. [17] and the pelvic locations were classified according to the regions defined by DeLee and Charnley [6]. Pelvic lesions in Zones 1 and 3 of DeLee and Charnley were considered rim lesions while those in Zone 2 were considered dome lesions. Femoral head penetration was measured by a single reviewer (SEB) from AP pelvic radiographs taken while the patients were supine with their legs internally rotated using Martell's Hip Analysis Suite Version 8 (University of Chicago Medical Center, Chicago, IL, USA) that incorporates elliptical correction [22, 28]. Using a paired-film analysis, the head penetration vector was determined by comparing the immediate postoperative radiograph with a minimum 10-year followup radiograph. A head penetration rate was computed by dividing the magnitude of the head penetration vector by the followup

Fig. 1A–B (A) Compared to the 6-week postoperative radiograph from a male patient who was 52 years of age at surgery, (B) an 11.9-year followup radiograph demonstrates three discrete regions of osteolysis demarcated by the white arrows. The pelvic osteolytic lesion has an area of 10.3 cm², which was the second largest acetabular defect in our series. On the femoral side, the greater trochanter has a 0.9-cm² osteolytic lesion and the calcar has a 0.4-cm² lesion. The total head penetration was 4.8 mm, corresponding to an annual rate of 0.41 mm/year.

duration. Total volumetric wear corresponding to the head penetration vector was computed by the software.

Kaplan-Meier survivorship [25] for the entire implant, cup, and stem was calculated using revision for any reason as an end point. Cup and stem survivorship were also calculated using revision for aseptic loosening as an end point. For these analyses, all 398 THAs were included and cases not known to be revised were censored at the time of their last followup. Kaplan-Meier survivorship for the different sterilization groups was also calculated using wear-related revision of any component as an end point and compared using a log-rank test. To check for differences among the sterilization groups for the 185 unrevised hips with minimum 10-year radiographic followup, we evaluated age at surgery and duration of radiographic followup using a Kruskal-Wallis test and sex using a Pearson chi square test. Differences in the incidence of osteolysis and osteolysis-related radiographic complications among the sterilization groups were evaluated using a Pearson chi square test. Differences in linear head penetration rates and volumetric wear were evaluated using a Kruskal-Wallis test. Among those hips with osteolysis, differences in lesion sizes were also evaluated using a Kruskal-Wallis test. All statistical analyses were performed using SPSS[®] (SPSS Inc, Chicago, IL, USA).

Results

We identified 20 THAs that had undergone component revisions (Table 2). None of the THAs with higher

crystallinity (HylamerTM) liners have been revised. Revisions for complications associated with wear and osteolysis began to occur 7.2 years after surgery and have included six liner exchanges and one cup revision performed at an outside institution. Implant survivorship, using component revision for any reason as an end point, was 97.9% (95% confidence interval [CI], 96.4%–99.3%) at 5 years and 95.7% (95% CI, 93.6%–97.9%) at 10 years (Fig. 2). Since 16 of the component revisions were limited to liner exchanges, cup survivorship was 99.2% (95% CI, 98.3%–100%) at 10 years using revision for any reason as an end point. Because only one femoral component was removed during a complete revision for infection, stem survivorship at 10 years using revision for any reason as an end point was 99.7% (95% CI, 99.2%–100%). Since no component has been revised for loosening and none of the primary THA components retained during a revision surgery subsequently loosened, cup and stem survivorship, using revision for aseptic loosening as an end point, were both 100% at 10 years. Among 185 unrevised THAs with minimum 10-year radiographs (mean, 12.3 ± 0.8 years; range, 10.1–14.4 years), none of the cups were graded as definitely loose or fibrous stable. Among the stems, 184 were bone ingrown and one was loose. Osteolysis was noted among 48% (89 of 185) of the THAs, and the mean combined size of the pelvic and femoral lesions in these hips was 2.9 ± 3.6 cm² (range, 0.04–15.1 cm²) (Table 3). Considered separately, the incidence of osteolysis was 31% (57 of 185) for the pelvis and 31% (58 of 185) for the femur. Pelvic osteolysis was confined to DeLee and Charnley Zone 2 behind the dome hole in 44% (25 of 57) of the THAs, limited to Zone 1 and/or Zone 3 around the rim in 12% (seven of 57), and involved the zones adjacent to both the dome and rim in 44% (25 of 57) of THAs. No fractures of the pelvis related to osteolysis were observed, but fractures of the greater trochanter associated with osteolytic lesions were noted among six THAs. Three of these six fractures were diagnosed acutely at 8.9, 9.1, and 12.8-year followup. The other three fractures were recognized on routine followup radiographs obtained at 12.5, 12.9, and 13.5-year followup, but the actual date of fracture is unknown.

The mean linear head penetration rate among unrevised THAs with minimum 10-year followup was 0.15 ± 0.08 mm/year (range, 0.01–0.41 mm/year). There were no differences in patient sex ($p = 0.48$) or age at surgery ($p = 0.70$) among the liners sterilized by different methods, but the radiographic followup was modestly longer ($p = 0.01$) for the gamma-barrier liners compared to the gamma-air and gas plasma liners. Although there were no differences in head penetration rates (0.16 ± 0.08 mm/year for higher crystallinity HylamerTM versus 0.14 ± 0.08 mm/year for conventional EnduronTM, $p = 0.36$) or

Table 2. Component revision summary

Component revised	Revision reason	Primary liner sterilization method	Postoperative years
All	Infection	Gamma-air	0.05
Cup	Recurrent dislocation	Gamma-air	0.2
Liner	Recurrent dislocation	Gamma-air	0.8
Liner	Recurrent dislocation	Unknown	1.1
Liner	Recurrent dislocation	Gas plasma	3.1
Cup	Recurrent dislocation with broken locking ring	Gamma-air	3.6
Liner	Recurrent dislocation	Gas plasma	3.7
Liner	Recurrent dislocation	Gas plasma	4.0
Liner	Recurrent dislocation	Gamma-air	5.7
Liner	Recurrent dislocation	Gamma-air	6.2
Liner	Recurrent dislocation	Gamma-barrier	7.1
Liner	Wear with broken locking ring*	Gamma-air	7.2
Liner	Osteolysis*	Gas plasma	8.5
Liner	Wear with late dislocation*	Gamma-air	9.2
Liner	Osteolysis with greater trochanter fracture*	Gamma-barrier	9.6
Liner	Osteolysis with greater trochanter fracture*	Gamma-air	10.4
Liner	Infection	Gamma-air	11.4
Cup	Osteolysis (performed outside our institution)*	Gamma-air	12.0
Liner	Osteolysis with greater trochanter fracture*	Gamma-air	12.7
Liner	Broken locking ring with liner dissociation	Gamma-air	13.6

* Denotes revisions associated with wear; gamma-air = gamma irradiation in air; gamma-barrier = gamma irradiation with barrier packaging without oxygen.

Fig. 2 Kaplan-Meier survivorship, using component revision for any reason as an end point, is $95.7\% \pm 2.1\%$ at 10-year followup. The thinner lines designate the 95% CIs.

volumetric wear ($0.97 \pm 0.57 \text{ cm}^3$ for Hylamer™ versus $0.88 \pm 0.61 \text{ cm}^3$ for Enduron™, $p = 0.33$) between the liner materials, there were differences in these measures of wear among all three sterilization methods (Table 3). Gas plasma liners, with a mean rate of $0.20 \pm 0.09 \text{ mm/year}$, had the highest penetration rates ($p < 0.001$). Among the radiation-sterilized liners, gamma-barrier components had

a lower ($p = 0.01$) head penetration rate than gamma-air components (0.09 ± 0.04 versus $0.13 \pm 0.07 \text{ mm/year}$). Although there was considerable variation in osteolytic lesion sizes among THAs with higher volumetric wear (Fig. 3), hips with gamma-barrier liners tended to have a reduced incidence of osteolysis and smaller lesion sizes compared to the other sterilization methods, but these differences were not significant with the numbers available (Table 3). Four of the osteolysis-related greater trochanteric fractures occurred among the hips with gamma-air liners, two among the hips with gas plasma liners, and none among the hips with gamma-barrier liners ($p = 0.47$). Survivorship among sterilization groups at 12-year followup using wear-related revision of any component as an end point was $96.9\% \pm 3.0\%$ for gamma-air, $98.1\% \pm 3.7\%$ for gamma-barrier, and $99.0 \pm 1.9\%$ for gas plasma ($p = 0.56$).

Discussion

During the mid-1990s when we were using a DePuy press-fit porous-coated cup without supplemental initial fixation combined with an extensively porous-coated stem for primary THA, the manufacturer transitioned from gamma

Table 3. Demographics, wear, and osteolysis in 185 unrevised THAs with minimum 10-year radiographic followup

Variable	Overall	Gamma-air	Gamma-barrier	Gas plasma	p Value for comparison among sterilization groups
Number of THAs	185	91	34	60	Not applicable
Age at surgery*	57.5 ± 11.6 [58.7] (22–83)	58.2 ± 11.5 [59.5] (31–83)	56.9 ± 12.3 [60.1] (22–74)	57.0 ± 11.5 [57.4] (31–80)	0.70
THAs among males	95 (51%)	50 (55%)	18 (53%)	27 (45%)	0.48
Years of radiographic followup*	12.3 ± 0.8 [12.3] (10.1–14.4)	12.3 ± 0.8 [12.3] (10.1–14.4)	12.7 ± 0.8 [12.6] (10.9–14.3)	12.2 ± 0.7 [12.1] (10.3–13.9)	0.01
Linear head penetration rate (mm/year)*	0.15 ± 0.08 [0.12] (0.01–0.41)	0.13 ± 0.07 [0.12] (0.01–0.34)	0.09 ± 0.04 [0.09] (0.03–0.18)	0.20 ± 0.09 [0.19] (0.02–0.41)	< 0.001
Volumetric wear (cm ³)*	0.89 ± 0.60 [0.72] (0.03–2.69)	0.80 ± 0.51 [0.68] (0.05–2.26)	0.48 ± 0.24 [0.45] (0.10–1.03)	1.28 ± 0.67 [1.24] (0.03–2.69)	< 0.001
Number of THAs with pelvic and/or femoral osteolysis	89 (48%)	42 (46%)	13 (38%)	34 (57%)	0.20
Average total osteolysis area (cm ²) when present*	2.9 ± 3.6 [1.2] (0.04–15.1)	3.3 ± 4.1 [1.6] (0.04–15.1)	1.1 ± 0.8 [0.9] (0.3–3.1)	3.0 ± 3.4 [1.4] (0.1–11.7)	0.40
Number of hips with total osteolysis					
1.5 to < 5.0 cm ²	23 (12%)	11 (12%)	3 (9%)	9 (15%)	
≥ 5.0 cm ²	19 (10%)	11 (12%)	0	8 (13%)	
Number of THAs with pelvic osteolysis	57 (31%)	26 (29%)	6 (18%)	25 (42%)	0.04
Average area of pelvic osteolysis (cm ²) when present*	3.1 ± 3.1 [1.8] (0.04–10.4)	3.8 ± 3.4 [2.5] (0.04–10.4)	1.4 ± 1.1 [0.9] (0.4–3.1)	2.7 ± 2.9 [1.6] (0.1–10.3)	0.16
Size of pelvic osteolysis					
1.5 to < 5.0 cm ²	22 (12%)	10 (11%)	2 (6%)	10 (17%)	
> 5.0 cm ²	12 (6%)	7 (8%)	0	5 (8%)	
Number of THAs with femoral osteolysis	58 (31%)	28 (31%)	9 (26%)	21 (35%)	0.68
Average area of femoral osteolysis (cm ²) when present*	1.4 ± 1.8 [0.6] (0.1–8.1)	1.5 ± 1.8 [0.8] (0.1–8.1)	0.7 ± 0.4 [0.6] (0.2–1.7)	1.6 ± 2.2 [0.5] (0.1–7.9)	0.62
Size of femoral osteolysis					
1.5 to < 5.0 cm ²	13 (7%)	7 (8%)	1 (3%)	5 (8%)	
> 5.0 cm ²	3 (2%)	1 (1%)	0	2 (3%)	
Osteolysis location in THAs with femoral osteolysis					
Zone 1 only	17 (9%)	11 (12%)	3 (9%)	3 (5%)	
Zone 7 only	24 (13%)	8 (9%)	4 (12%)	12 (20%)	
Both Zones 1 and 7	17 (9%)	9 (10%)	2 (6%)	6 (10%)	
Average area for THAs with Zone 1 osteolysis (cm ²)*	1.7 ± 1.7 [0.9] (0.1–7.0)	1.5 ± 1.5 [1.0] (0.1–6.0)	0.5 ± 0.1 [0.6] (0.3–0.7)	2.6 ± 2.4 [1.1] (0.3–7.0)	0.08
Average area for THAs with Zone 7 osteolysis (cm ²)*	0.6 ± 0.5 [0.4] (0.1–2.3)	0.6 ± 0.6 [0.4] (0.2–2.3)	0.6 ± 0.6 [0.4] (0.2–1.7)	0.6 ± 0.4 [0.5] (0.1–1.5)	0.90

* Values are expressed as mean ± SD, with median in brackets and range in parentheses; gamma-air = gamma irradiation in air; gamma-barrier = gamma irradiation with barrier packaging without oxygen.

irradiation to gas plasma for the terminal sterilization of their polyethylene liners. Although the elimination of gamma irradiation eliminated the generation of free

radicals during the sterilization process, it also eliminated a source for polyethylene crosslinking. As a consequence, we transitioned from using mildly crosslinked polyethylene

Fig. 3 Total osteolysis area is correlated with the volumetric wear ($r = 0.40$, $p < 0.001$, Pearson's correlation), but there are substantial variations in the amount of osteolysis among THAs with higher volumetric wear. The symbols in the legend designate the different terminal sterilization methods used for the polyethylene liners in our cohort.

with residual free radicals to using noncrosslinked polyethylene without any radiation-induced free radicals. At minimum 10-year followup, we asked whether the fixation achieved by solely relying on a press-fit would be durable and how the different liner sterilization methods affected radiographic wear, osteolysis, and survivorship.

This retrospective cohort study has several limitations. First, the two surgeons whose cases we reviewed did not treat all their patients with Duraloc® 100 cups combined with extensively porous-coated stems. The series we are reporting on represents 90% (398 of 440) of the primary THAs performed over a 22-month period. Second, whether or not a revision has been performed by 10-year followup is unknown for 8% (32 of 398) of the THAs in this series. These 32 THAs are included in our survivorship analyses and censored at the time of their last known followup so that they add to the uncertainty by increasing the magnitude of the 95% CIs. Third, radiographs were available for only 63% (185 of 293) of the unrevised THAs among living patients eligible for 10-year followup. Although our radiographic followup is incomplete, patient sex and age at surgery among the sterilization groups are not different (Table 3) so we believe comparisons among the groups are valid. We acknowledge the duration of followup was modestly longer for the gamma-barrier liners, but this group had the lowest incidence of osteolysis and wear-related complications. Fourth, the method used to sterilize the polyethylene liners was not explicitly randomized among the patients in our study population. However, we have no reason to suspect there was any surgeon preference for using liners with different sterilization methods since the physicians used the available inventory and did not select the sterilization method based on patient, implant, or surgical considerations.

Our results are consistent with previous reports describing the outcome of press-fit cups implanted without supplemental fixation [41]. With the exception of early radiographic outcome data from a single institution [39], the Duraloc® 100 cup has consistently demonstrated excellent fixation. Including the data from our study and three other clinical outcome series with 5- to 10-year followup, only one case of aseptic loosening has been reported among more than 700 Duraloc® 100 cups [2, 36, 38]. In our study, the absence of cup loosening, despite a 31% (57 of 185) incidence of pelvis osteolysis, may be explained by a previous finding that the surface area of the cup occupied by osteolysis plateaued at 40% despite progressively increasing lesions sizes [8]. As this prior research has demonstrated, when pelvic osteolytic lesions originate in DeLee and Charnley Zone 2 behind the dome hole, as they did among the majority of hips in our series, these lesions can expand into periacetabular trabecular bone without compromising the fixation achieved around the rim of the cup. Since other cementless cups that rely on bone ongrowth for fixation have demonstrated high rates of revision for osteolysis and loosening in conjunction with wear rates comparable to what we found in this study [10], we also attribute the durability of fixation in our series to the ingrowth achieved with the rough, three-dimensional porous-coated surface of the Duraloc® 100 cup. On the femoral side, our results are consistent with other studies demonstrating excellent fixation of the AML® and Prodigy® stems at minimum 10-year followup [16, 19]. Fracture of the greater trochanter associated with osteolysis was our most common femoral complication. Including the three fractures among the 20 revised THAs and the six fractures associated with lysis among the 185 THAs with minimum 10-year radiographs, the incidence was 4.4% (nine of 205) in our series, which is similar to the 4.3% rate reported in a previous study [3]. We presume these fractures may be due to the combination of osteolysis and the use of a straight-stemmed prosthesis that requires a larger entry hole through the greater trochanter.

Confirming studies with shorter followup [7, 21], we found the method of polyethylene sterilization can have a profound influence on wear. Noncrosslinked gas plasma liners had head penetration rates about twice those of liners moderately crosslinked by terminal sterilization with gamma irradiation. Among the irradiated liners, we also found gamma-barrier liners had lower head penetration rates than gamma-air liners [18, 20]. Consistent with other reports measuring wear and osteolysis, we found osteolytic lesion size was correlated with the amount of wear and the gamma-barrier liners with the lowest wear rates tended to have less osteolysis, but there can be considerable variation in the amount of osteolysis among individual patients with higher wear rates regardless of the polyethylene

sterilization method [9, 23, 24, 27, 35, 37]. Although the gas plasma liners had higher wear rates than the gamma-air liners, the incidence and size of the osteolytic lesions for both groups were similar (Table 3). With the trend toward reduced osteolysis associated with the gamma-barrier liners, we conclude the potential liability associated with oxidation of residual free radicals in vivo is outweighed by the decreased wear resulting from crosslinking associated with gamma irradiation, at least through 10-year followup.

Although we found a relatively high mean head penetration rate of 0.15 mm/year in this series, the combination of a press-fit Duraloc® 100 cup without supplemental fixation and an extensively porous-coated stem demonstrated durable implant fixation even in the presence of osteolysis [40] and a low revision rate with 95.7% survivorship at 10-year followup using component revision for any reason as an end point. We conclude supplemental initial fixation is not required with a press-fit porous-coated cup [36]. Despite a similar incidence of osteolysis in the pelvis and femur, pathologic fractures have only occurred on the femoral side. While we have not observed any osteolysis-related component loosening to date, continued followup will be required to assess the long-term effects of osteolysis on component fixation, particularly in view of the relatively high head penetration rates we observed. Longer followup will also be required to determine whether the differences in wear among the liner sterilization methods will eventually lead to differences in implant survivorship or the incidence of wear-related complications.

References

- Barrack RL, Butler RA. Avoidance and management of neurovascular injuries in total hip arthroplasty. *Instr Course Lect.* 2003;52:267–274.
- Chen CJ, Xenos JS, McAuley JP, Young A, Engh CA Sr. Second-generation porous-coated cementless total hip arthroplasties have high survival. *Clin Orthop Relat Res.* 2006;451:121–127.
- Claus AM, Hopper RH Jr, Engh CA. Fractures of the greater trochanter induced by osteolysis with the anatomic medullary locking prosthesis. *J Arthroplasty.* 2002;17:706–712.
- Claus AM, Sychterz CJ, Hopper RH Jr, Engh CA. Pattern of osteolysis around two different cementless metal-backed cups: retrospective, radiographic analysis at minimum 10-year follow-up. *J Arthroplasty.* 2001;16(8 Suppl 1):177–182.
- Costa L, Bracco P, Brach del Prever EM, Kurtz SM, Gallinaro P. Oxidation and oxidation potential in contemporary packaging for polyethylene total joint replacement components. *J Biomed Mater Res B Appl Biomater.* 2006;78:20–26.
- DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. *Clin Orthop Relat Res.* 1976;121:20–32.
- Digas G, Thanner J, Nivbrant B, Röhrh S, Ström H, Kärrholm J. Increase in early polyethylene wear after sterilization with ethylene oxide: radiostereometric analyses of 201 total hips. *Acta Orthop Scand.* 2003;74:531–541.
- Egawa H, Ho H, Hopper RH Jr, Engh CA Jr, Engh CA. Computed tomography assessment of pelvic osteolysis and cup-lesion interface involvement with a press-fit porous-coated acetabular cup. *J Arthroplasty.* 2009;24:233–239.
- Egawa H, Powers CC, Beykirch SE, Hopper RH Jr, Engh CA Jr, Engh CA. Can the volume of pelvic osteolysis be calculated without using computed tomography? *Clin Orthop Relat Res.* 2009;467:181–187.
- Emms NW, Stockley I, Hamer AJ, Wilkinson JM. Long-term outcome of a cementless, hemispherical, press-fit acetabular component: survivorship analysis and dose-response relationship to linear polyethylene wear. *J Bone Joint Surg Br.* 2010;92:856–861.
- Engh CA, Bobyn JD. Principles, techniques, results, and complications with a porous-coated sintered metal system. *Instr Course Lect.* 1986;35:169–183.
- Engh CA, Bobyn JD, Glassman AH. Porous-coated hip replacement: the factors governing bone ingrowth, stress shielding, and clinical results. *J Bone Joint Surg Br.* 1987;69:45–55.
- Engh CA, Hopper RH Jr, Engh CA Jr. Long-term porous-coated cup survivorship using spikes, screws, and press-fitting for initial fixation. *J Arthroplasty.* 2004;19(7 Suppl 2):54–60.
- Engh CA, Massin P, Suthers KE. Roentgenographic assessment of the biologic fixation of porous-coated femoral components. *Clin Orthop Relat Res.* 1990;257:107–128.
- Engh CA, O'Connor D, Jasty M, McGovern TF, Bobyn JD, Harris WH. Quantification of implant micromotion, strain shielding, and bone resorption with porous-coated anatomic medullary locking femoral prostheses. *Clin Orthop Relat Res.* 1992;285:13–29.
- Engh CA Jr, Culpepper WJ 2nd, Engh CA. Long-term results of use of the anatomic medullary locking prosthesis in total hip arthroplasty. *J Bone Joint Surg Am.* 1997;79:177–184.
- Gruen TA, McNeice GM, Amstutz HC. “Modes of failure” of cemented stem-type femoral components: a radiographic analysis of loosening. *Clin Orthop Relat Res.* 1979;141:17–27.
- Hamilton WG, Hopper RH Jr, Ginn SD, Hammell NP, Engh CA Jr, Engh CA. The effect of total hip arthroplasty cup design on polyethylene wear rate. *J Arthroplasty.* 2005;20(7 Suppl 3):63–72.
- Hennessy DW, Callaghan JJ, Liu SS. Second-generation extensively porous-coated THA stems at minimum 10-year followup. *Clin Orthop Relat Res.* 2009;467:2290–2296.
- Hopper RH Jr, Engh CA Jr, Fowlkes LB, Engh CA. The pros and cons of polyethylene sterilization with gamma irradiation. *Clin Orthop Relat Res.* 2004;429:54–62.
- Hopper RH Jr, Young AM, Orishimo KF, Engh CA Jr. Effect of terminal sterilization with gas plasma or gamma radiation on wear of polyethylene liners. *J Bone Joint Surg Am.* 2003;85:464–468.
- Hui AJ, McCalden RW, Martell JM, MacDonald SJ, Bourne RB, Rorabeck CH. Validation of two and three-dimensional radiographic techniques for measuring polyethylene wear after total hip arthroplasty. *J Bone Joint Surg Am.* 2003;85:505–511.
- Ise K, Kawanabe K, Matsusaki T, Shimizu M, Onishi E, Nakamura T. Patient sensitivity to polyethylene particles with cemented total hip arthroplasty. *J Arthroplasty.* 2007;22:966–973.
- Jialiang T, Zhongyou M, Fuxing P, Zongke Z, Bin S, Jing Y. Primary total hip arthroplasty with Duraloc cup in patients younger than 50 years: a 5- to 7-year follow-up study. *J Arthroplasty.* 2009;24:1184–1187.
- Kaplan EL, Meier P. Nonparametric estimation from incomplete observations. *J Am Stat Assoc.* 1958;53:457–81.
- Kay RM, Dorey FJ, Johnston-Jones K, Cracchiolo A 3rd, Amstutz HC, Finerman GA. Long-term durability of cemented

- primary total hip arthroplasty. *J Arthroplasty*. 1995;10(Suppl): S29–S38.
27. Kitamura N, Leung SB, Engh CA Sr. Characteristics of pelvic osteolysis on computed tomography after total hip arthroplasty. *Clin Orthop Relat Res*. 2005;441:291–297.
 28. Martell JM, Berdia S. Determination of polyethylene wear in total hip replacements with use of digital radiographs. *J Bone Joint Surg Am*. 1997;79:1635–1641.
 29. Massin P, Schmidt L, Engh CA. Evaluation of cementless acetabular migration: an experimental study. *J Arthroplasty*. 1989;4: 245–251.
 30. Mayne IP, Kosashvili Y, White LM, Backstein D. Iliopsoas tendonitis due to the protrusion of an acetabular component fixation screw after total hip arthroplasty. *J Arthroplasty*. 2010;25: 659.e5–8.
 31. McGovern TF, Ammeen DJ, Collier JP, Currier BH, Engh GA. Rapid polyethylene failure of unicondylar tibial components sterilized with gamma irradiation in air and implanted after a long shelf life. *J Bone Joint Surg Am*. 2002;84:901–906.
 32. McKellop H, Shen FW, Lu B, Campbell P, Salovey R. Effect of sterilization method and other modifications on the wear resistance of acetabular cups made of ultra-high molecular weight polyethylene: a hip-simulator study. *J Bone Joint Surg Am*. 2000;82:1708–1725.
 33. Medel FJ, Kurtz SM, Hozack WJ, Parvizi J, Purtill JJ, Sharkey PF, MacDonald D, Kraay MJ, Goldberg V, Rimnac CM. Gamma inert sterilization: a solution to polyethylene oxidation? *J Bone Joint Surg Am*. 2009;91:839–849.
 34. Muratoglu OK, Merrill EW, Bragdon CR, O'Connor D, Hoeffel D, Burroughs B, Jasty M, Harris WH. Effect of radiation, heat, and aging on in vitro wear resistance of polyethylene. *Clin Orthop Relat Res*. 2003;417:253–262.
 35. Puri L, Wixson RL, Stern SH, Kohli J, Hendrix RW, Stulberg SD. Use of helical computed tomography for the assessment of acetabular osteolysis after total hip arthroplasty. *J Bone Joint Surg Am*. 2002;84:609–614.
 36. Roth A, Winzer T, Sander K, Anders JO, Venbrocks RA. Press fit fixation of cementless cups: how much stability do we need indeed? *Arch Orthop Trauma Surg*. 2006;126:77–81.
 37. Shon WY, Gupta S, Biswal S, Han SH, Hong SJ, Moon JG. Pelvic osteolysis relationship to radiographs and polyethylene wear. *J Arthroplasty*. 2009;24:743–750.
 38. Stihsen C, Pabinger C, Radl R, Rehak P, Windhager R. Migration of the Duraloc cup after 5 years. *Int Orthop*. 2008;32:791–794.
 39. Stöckl B, Sandow M, Krismer M, Biedermann R, Wimmer C, Frischhut B. Migration of the Duraloc cup at two years. *J Bone Joint Surg Br*. 1999;81:51–53.
 40. Sychterz CJ, Claus AM, Engh CA. What we have learned about long-term cementless fixation from autopsy retrievals. *Clin Orthop Relat Res*. 2002;405:79–91.
 41. Udomkiat P, Dorr LD, Wan Z. Cementless hemispheric porous-coated sockets implanted with press-fit technique without screws: average ten-year follow-up. *J Bone Joint Surg Am*. 2002;84: 1195–1200.
 42. Wasielewski RC, Crossett LS, Rubash HE. Neural and vascular injury in total hip arthroplasty. *Orthop Clin North Am*. 1992;23: 219–235.
 43. Zicat B, Engh CA, Gokcen E. Patterns of osteolysis around total hip components inserted with and without cement. *J Bone Joint Surg Am*. 1995;77:432–439.