Increase in early polyethylene wear after sterilization with ethylene oxide

Radiostereometric analyses of 201 total hips

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ABSTRACT We evaluated polyethylene wear by measuring femoral head penetration in 201 THA (median age 62 (31–81) years, 117 women) extracted from 5 randomized studies aimed to assess various fixation principles. There were 30 cemented all-polyethylene Lubinus cups sterilized by gamma irradiation in a reduced oxygen environment, 65 porous-coated Trilogy cups with liners gamma-sterilized in inert gas. Moreover, 37 cemented cups were sterilized with ethylene oxide (Reflection all-poly) and 69 porous-coated cups had liners sterilized in ethylene oxide (Reflection). 28 mm femoral heads were used in all cups. The patients were followed with repeated radiostereometric measurements (RSA) up to 2 years. The activity level of the patients was evaluated by a questionnaire.

After 2 years, cups with polyethylene sterilized in EtO had almost twice the proximal and 3D penetration rates, as compared with gamma-sterilized polyethylene. The penetration did not differ between the gamma-irradiated designs. Using stepwise linear regression analysis, we found that the type of sterilization, age and weight were the most important predictors and that they determined the direction of the proximal penetration rate. Activity score, male gender and proximal migration of the cup had little effect. The accelerated wear observed with the EtO-sterilized polyethylene causes concerns about long-term problems and especially in younger patients.

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The wear rate of polyethylene in total hip arthroplasty is multifactorial (Schmalzried and Callaghan 1999). Young age and high activity scores seem to be the most important patient-related factors (Schmalzried et al. 1998, Feller et al. 1994). During the past decade, high penetration rates have been related to variations in polyethylene quality and sterilization techniques (Sutula et al. 1995, Collier et al. 1996b, Ries et al. 1996, Bargmann et al. 1999).

Gamma irradiation of polyethylene in air breaks polymer chains and frees radicals, which may recombine, cross-link or react with oxygen (Premnath et al. 1996). Cross-linking leads to an interconnection between polyethylene chains and improves the wear characteristics of the material (Grobbelaar et al. 1978, Muratoglou et al. 1999, Wroblewski et al. 1999). The molecular mechanism and material properties responsible for this improvement in wear resistance are still not well understood. Crosslinking may cause the polyethylene to become softer, weaker and change its elasticity. Such changes in the material, however, have been regarded as less important for the tribological properties than an increase in cross-link density (Muratoglou et al. 1999).

When polyethylene is irradiated in air some of the free radicals react with the oxygen and cause scission of the molecules, which reduces resistance to wear and results in delamination and fracture

Figure 1. Acetabular implants from right to left: Reflection all-poly (Smith Nephew, USA), Lubinus (Waldemar Link, Germany), Reflection ± HA, ± screws or pegs (Smith Nephew, USA) and Trilogy with 70% HA and 30% TCP ± screws (Zimmer Inc., Warsaw, USA).

(Sutula et al. 1995, Premnath et al. 1996). Irradiation in inert environments, sterilization with ethylene oxide or gas plasma have been used to reduce this problem. Gamma irradiation in an inert or vacuum environment impedes oxidative reactions until the package is opened. After implantation, the polyethylene is exposed to oxygen in the surrounding tissues. Oxidative degradation of polyethylene can also occur from exposure to synovial fluids, which contain peroxides and may increase due to cyclic loading (Eyerer and Ke 1984, Jahan et al. 1991).

Gas plasma and ethylene oxide sterilization do not generate free radicals in the polyethylene. In this way, oxidative degradation that causes changes in the mechanical properties is avoided. However, these methods do not induce cross-linking and do not improve the wear resistance (Denpsey 1989).

To our knowledge, no clinical studies, have compared the wear of polyethylene cups gamma sterilized in an inert atmosphere with ethylene oxide sterilization. We designed such a study to assess 4 types of implants. These patients had been operated on with cemented whole polyethylene cups or uncemented sockets with polyethylene liners. In both the cemented and uncemented cases, sterilization of the polyethylene had been done with gamma irradiation in a reduced oxygen environment or ethylene oxide. Repeated radiostereometric examinations were done up to 2 years after the operation.

Patients and methods

We first selected one or more groups of cemented or uncemented implants from 5 prospective, randomized studies. Only 4 basic designs were included (cemented Lubinus and Reflection cups, uncemented Trilogy and Reflection cups, Figure 1). In the cemented cases, only cups fixed with Palacos cement (Schering-Plough, Belgium) were included. In total 237 (hips) patients were available. 30 of these had to be omitted because too few tantalum markers were visible on the postoperative or 2 year-follow-up examination. 6 patients had bilateral operations, but only the hip that was first operated on was included. Therefore, in total, 201 total hip arthroplasties in 201 patients (117 women) were studied. Their median age and weight were 62 (31–81) years and 75 (38–115) kg (Table 1).

The Lubinus cups and the liners for the Trilogy cups had been sterilized with gamma irradiation (2.5 Mrad). The Lubinus cup (Link, Germany, n = 30) is fixed with cement. This all-polyethylene socket is manufactured by a compression-molded technique and sterilized with gamma irradiation in reduced oxygen environment. The Trilogy liners (Zimmer, Inc, Warsaw, IN; n = 65) were also manufactured with compression-molded technique, and sterilized in an inert nitrogen environment. The metallic shell of this design is made of a titanium-aluminum-vanadium alloy (Tivanium, Zimmer, Inc, Warsaw, IN) with a fiber mesh of pure titanium attached to it. The mesh is plasma-sprayed with 40-μm coating, consisting of 70% hydroxyapatite and 30% tricalcium phosphate. 21 cups had no holes for screws. In the remaining 44, 1–3 screws had been inserted in the 3 screw holes available.

The 2 remaining groups had been polyethylene sterilized with ethylene oxide (EtO). 37 were cemented all-polyethylene (Reflection all-poly,

Table 1. Cup specifications and patient-related data. Median (range)

	Lubinus cemented n = 30	Trilogy uncemented n = 65	Reflection cemented n = 37	Reflection uncemented n = 69	P-value [a]	P-value [b]
Resin type	Chirulen 1020	GUR 1050	GUR 1050	GUR 1050		
Method of manufacture	Compression molded	Compression molded	Ram extrusion	Ram extrusion		
Sterilization	γ–irrad. in vac. 2.5 Mrad	γ–irrad. in N_2 2.5 Mrad	EtO	EtO		
Male/female	13/17	25/40	10/27	36/33	0.08	0.6
Age	68 (53–78)	60 (32–81)	72 (31–78)	56 (34–66)	<0.001	0.3
Weight (kg)	77 (53–100)	75 (38–111)	70 (49–115)	78 (54–106)	0.1	0.8
Activity	19 (13–25)	20 (10–28)	18 (9–32)	22 (12–30)	<0.001	0.1
Primary/sec. arthrosis	29/1	44/21	26/11	53/16	0.02	0.7
Cup size (mm)	52 (46–56)	52 (48–62)	52 (46–61)	58 (50–62)	<0.001	<0.001
Inclination	49 (26–67)°	40 (27–56)°	44 (33–55)°	50 (30–66)°	<0.001	<0.001

[a] 4 groups (Kruskal-Wallis test)
[b] Gamma irradiation vs. EtO-sterilized polyethylene (2 groups, Mann Whitney test)

Smith&Nephew, USA) and 69 were uncemented porous-coated press-fit cups (Reflection, Smith & Nephew USA). Both designs were manufactured using a ram-extrusion technique (Table 1). The uncemented Reflection cup is made of titanium-aluminum-vanadium alloy and has a porous coating made of commercially pure titanium beads. On the basis of a randomization protocol designed for this subpopulation, 15 of these cups had additional screw fixation and 19 were supplied with pegs. 35 had no additional fixation, but 18 of these were coated with a 45 μm thin layer of pure hydroxyapatite (Table 6). The thickness of the Trilogy liners ranged between 6.3 and 11.3 mm and that of the Reflection liners between 7 and 12 mm.

In the groups with uncemented press-fit cups, the acetabulum was underreamed 1–2 mm. All femoral heads had a diameter of 28 mm. The Lubinus, Trilogy and cemented Reflection cups were inserted with femoral heads made of cobalt-chromium alloy. 55 of the 69 uncemented Reflection cups articulated against a ceramic head made of zirconium oxide. The remaining 14 cases had femoral heads made of cobalt-chromium alloy.

During the operation, tantalum markers were inserted into the periacetabular bone and into the polyethylene, except those with a Lubinus design, in which the manufacturer had inserted the polyethylene markers. Various stems were used in the four groups of patients (Table 2).

Radiostereometric examinations were done within 7 days of the operation and after 6, 12, and 24 months. The translation of the head's center, using the polyethylene markers as a fixed reference segment, corresponded to the penetration of the femoral head. The precision (99% detection limit) of the measurements of wear varied between 0.05 and 0.20 mm, concerning the most precise (proximal-distal), and between 0.15 and 0.4 mm, the most imprecise directions (3-D penetration), depending on the method of measurement (digital or manual). We determined the migration of the cups along the horizontal, longitudinal, and sagittal axes on the basis of the signed values.

Conventional radiographic examinations included anteroposterior (AP), lateral, and pelvic views centered on the symphysis. The inclination of the cup was measured on the postoperative radiographs of the pelvis.

The activity level was evaluated by a questionnaire, which was sent to the patients 2–7 years (median 3 years and 9 months) after the operation. Each question was rated with an increasing number of points (3–5/question) corresponding to an increase in the patient's activity. This rating resulted in a total sum between 9 and 39 points. 179 of the 201 patients answered the questionnaire. 7 of the remaining 22 patients had died when the activity rating was done and 15 could not or declined to answer. The repeatability of the questionnaire was studied in 20 patients who agreed

Table 2. Distribution of acetabular, femoral components and material of femoral head

Stem design	Cup design									
	Lubinus ± flange		Reflection cemented	Trilogy ± screws		Reflection uncemented				Total
	+	–		+	–	Press-fit	pegs	screws	HA	
Cemented										
Lubinus SP II	17	13								30
Spectron			37	25	0	15 [b]	14 [b]	12 [b]	14 [b]	117
Anatomic-option				9	8					17
Uncemented										
Epoch				3	3					6
Anatomic				7	10					17
Cone						0	1 [a]	1 [a]	1 [a]	3
Bimetric						2 [a]	4 [a]	2[a]	3 [a]	11
Total	17 [a]	13 [a]	37 [a]	44 [a]	21 [a]	17	19	15	18	201

[a] CoCr (Cobalt chromium)
[b] Zr (Zirconium)

Table 3. Repeatability of the questionnaire in 20 patients

Activity-related item	Levels	Difference between 1 and 2 [a]	Kendall's tau [b]	No. who changed their reply
Walking	5	0 (–1–1)	0.84	3
Less demanding physical activity	5	0 (–2–0)	0.87	3
Biking/swimming	5	0 (–1–1)	0.68	4
Running/dancing	5	0 (–1–2)	0.76	4
Demanding physical activity	4	0 (0–1)	0.72	1
Very hard work	4	0 (0–0)	1.0	0
Use of cane or cratch	3	0 (0–2)	0.75	2
Climbing stairs	3	0 (–1–1)	0.71	3
Self-estimated degree of activity	5	0 (–1–0)	0.81	4

[a] Time between replies 1 and 2: 2 weeks. Median difference (range)
[b] 1 means perfect agreement between the two examinations

to answer a second time at an interval of 15 days (Table 3).

Statistics

The Kruskal-Wallis and Mann-Whitney tests were used to evaluate the differences in wear between the 4 groups. The same tests were used to assess the effect of the material used in the femoral head, additional fixation devices and presence or not of hydroxyapatite in the group with uncemented Reflection sockets. The Mann-Whitney test was used to evaluate the effect of additional screw fixation in the Trilogy group, and stepwise linear regression analysis to determine whether various factors affected the penetration rate in the total material. The variables included the type of sterilization, age, gender, side, weight, diagnosis (primary or secondary arthrosis), type of fixation (cemented or uncemented), socket size, inclination of the cup, activity score, medial/lateral, proximal/distal, anterior/posterior and total (three-dimensional) migration of the cup 0–2 years after the operation.

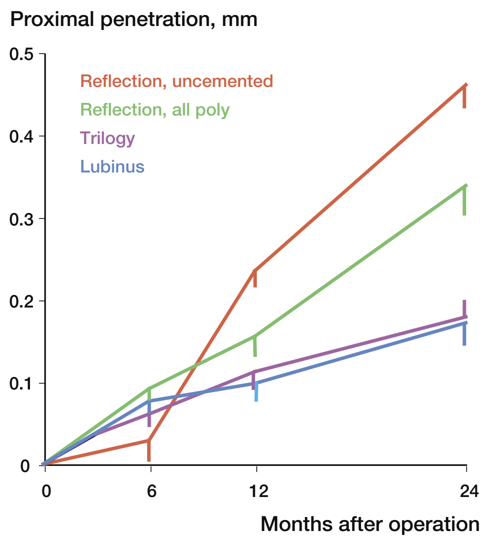

Figure 2. Proximal penetration of the femoral head. Mean (SE).

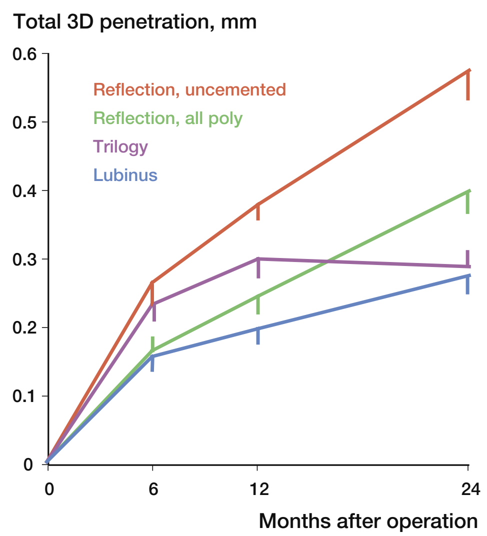

Figure 3. The total or three-dimensional vector length of femoral head penetration. Mean (SE).

Results

The repeatability of the questions at the activity rating varied between fairly well to full agreement between the answers given on the two occasions (Kendall's tau = 0.7–1.0; Table 3).

Penetration—signed values

At 2 years, the mean proximal penetration was less than 0.2 mm by the Lubinus and Trilogy cups and more than 0.3 and 0.4 mm by the cemented and uncemented Reflection cups, respectively ($p < 0.001$, Kruskal-Wallis test, Figure 2, Table 4). The mean medial/lateral and anterior/posterior wear were less than 0.1 mm in all 4 designs ($p = 0.3$ and 0.1). At 2 years, the mean total or three-dimensional wear of the 2 designs with gamma sterilized polyethylene (Lubinus/Trilogy = 0.27/0.29 mm), was about the same, but more (0.40/0.57 mm) in the cemented and uncemented Reflection designs ($p < 0.001$; Figure 3, Table 4).

Penetration—absolute values

The absolute values of mean medial/lateral wear of about 0.1 mm were slightly higher, using the uncemented Reflection cups ($p = 0.003$). The corresponding values for penetration in the proximal/distal directions were about the same as the signed values, because the wear was in a proximal direction ($p < 0.001$). The absolute values of anterior/posterior wear ranged between 0.13 and 0.22 mm, without any obvious differences ($p= 0.4$; Table 5).

Regression analysis

The stepwise linear regression analysis showed that the proximal penetration increased with the use of EtO-sterilized cups ($p < 0.001$, adjusted $r^2 = 0.37$), younger age at operation ($p < 0.001$, increase of r^2 to 0.46), male gender ($p = 0.003$, increase of r^2 to 0.49), increase in activity score ($p = 0.007$, increase of r^2 to 0.51), and proximal migration of the cup ($p = 0.05$, increase of r^2 to 0.52). The total or three-dimensional penetration increased with the use of EtO-sterilized polyethylene ($p < 0.001$, adjusted $r^2 = 0.17$), greater body weight ($p < 0.001$, increase of r^2 to 0.25) and lower age ($p = 0.004$, increase of r^2 to 0.28). The remaining variables (diagnosis, socket size, cement-no cement, inclination of the cup, side, medial/lateral, anterior/posterior and three-dimensional migration of the cup) had no effect on the penetration rate. We found a weak correlation between the activity score and age ($r = 0.18$, $p = 0.05$, Pearson correlation; Figure 4).

The distribution of stem fixation (cemented/uncemented) and head material (cobalt chronium/zirconium) in the various types of polyethylene did not permit a satisfactory statistical evaluation of the effect of stem fixation in the total material. In the subgroup of Trilogy cups, 42 cases had

Table 4. Wear at the 2-year follow-up (signed values, mm)

	n	Mean	95% confidence limit of the mean	Range	P-value [a]
Medial(+)/lateral(–)					0.3
Lubinus	30	–0.02	–0.06 to 0.02	–0.21–0.3	
Trilogy	65	–0.03	–0.06 to 0.00	–0.41–0.52	
Reflection cemented	37	–0.002	–0.03 to 0.02	–0.15–0.20	
Reflection uncemented	69	0.006	–0.04 to 0.05	–0.31–0.83	
Proximal(+)/distal(–)					<0.001
Lubinus	30	0.17	0.12 to 0.23	–0.09–0.53	
Trilogy	65	0.18	0.14 to 0.22	–0.18–0.67	
Reflection cemented	37	0.34	0.27 to 0.41	–0.09–0.92	
Reflection uncemented	69	0.46	0.42 to 0.50	0.19–0.95	
Anterior(+)/posterior(–)					0.1
Lubinus	30	–0.07	–0.12 to –0.02	–0.33–0.35	
Trilogy	65	0.02	–0.03 to 0.07	–0.41–0.75	
Reflection cemented	37	–0.04	–0.09 to 0.01	0.48–0.23	
Reflection uncemented	69	0.04	–0.06 to 0.14	–0.55–2.69	
Total translation [b]					<0.001
Lubinus	30	0.27	0.23 to 0.31	0.07–0.55	
Trilogy	65	0.29	0.25 to 0.33	0.05–0.95	
Reflection cemented	37	0.40	0.34 to 0.46	0.11–0.93	
Reflection uncemented	69	0.57	0.49 to 0.65	0.30–2.97	

a Kruskal-Wallis test
[b] Three-dimensional translation

Table 5. Wear at the 2-year follow-up (absolute values, mm)

	n	Mean	95% confidence limit of the mean	Range	P-value [a]
Medial(+)/lateral(–)					0.003
Lubinus	30	0.09	0.07–0.11	0.00–0.25	
Trilogy	65	0.09	0.07–0.11	0.00–0.52	
Reflection cemented	37	0.06	0.05–0.08	0.00–0.20	
Reflection uncemented	69	0.13	0.10–0.15	0.00–0.83	
Proximal(+)/distal(–)					<0.001
Lubinus	30	0.18	0.13–0.23	0.00–0.53	
Trilogy	65	0.19	0.16–0.22	0.00–0.67	
Reflection cemented	37	0.34	0.28–0.41	0.02–0.92	
Reflection uncemented	69	0.46	0.43–0.50	0.19–0.95	
Anterior(+)/posterior(–)					0.4
Lubinus	30	0.13	0.09–0.16	0.01–0.35	
Trilogy	65	0.16	0.13–0.20	0.00–0.75	
Reflection cemented	37	0.13	0.09–0.16	0.00–0.48	
Reflection uncemented	69	0.22	0.13–0.30	0.00–2.69	

[a] Kruskal-Wallis test

cemented and 23 hips uncemented fixation of the stem. The uncemented stems showed an increase in proximal and three-dimensional wear, but this difference disappeared, when it was adjusted for confounding factors in a regression analysis.

In the uncemented Reflection group, several methods of fixation (press-fit with or without HA, pegs and screws) were used. Fixation with pressfit and HA had the highest proximal and three-dimensional penetration rate (0.55 and 0.76 mm). Press-

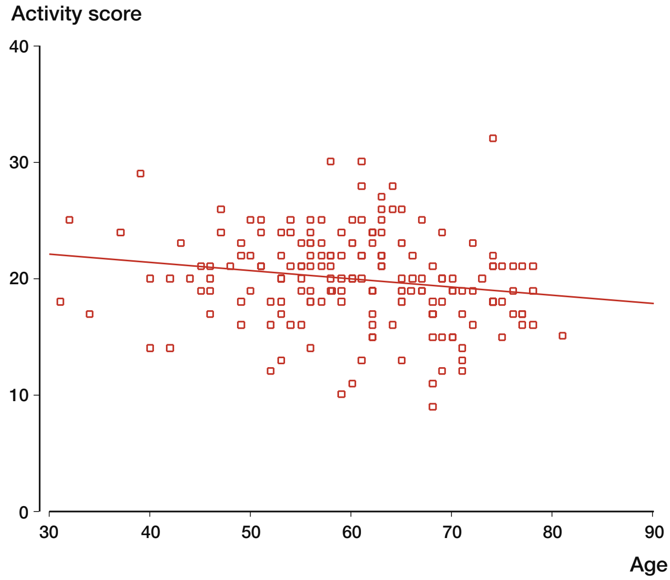

Figure 4. Scatterplot of age versus activity score.

fit with screws had the lowest rate (0.40 and 0.47 mm; p = 0.07 and p = 0.007, Kruskal Wallis test; Table 6).

14 of the patients with uncemented Reflection cups (2 press-fit—no HA, 4 press-fit with HA, 3 with screws, 5 with pegs) had femoral heads made of cobalt-chromium alloy and 55 (15 press-fit— no HA, 14 press-fit with HA, 12 with screws, 14 with pegs) had heads made of zirconium oxide. The median proximal and three-dimensional penetration rates were 0.54 and 0.62 mm in the first and 0.41 and 0.50 mm in the second group, respectively (p = 0.2 and p = 0.02). 44 of the patients with a Trilogy cup had additional fixation of the cup with screws. In the remaining 21 patients, only press-fit fixation was used. The mean proximal and three-dimensional penetration rates were 0.17 and 0.26 mm in the first group and 0.20 and 0.34 mm in the second group, respectively (p = 0.2 and p = 0.03; Table 6).

Discussion

Several authors (Griffith et al. 1978, Kim and Kim 1993, Nashed et al. 1995, Shih et al. 1997, Sychterz et al. 1997) have reported a statistically significant relationship between the patient's age and excessive wear. Goldsmith et al. (2001) found that implant and patient-related factors could partly explain the reported differences in wear. They measured patient activity, using a pedometer, and noted that it varied at least 25-fold between patients. They found a weak correlation between age and activity, in data similar to ours (Figure 4). Moreover, it seems unlikely, on the basis of their findings, that activity level, using pedometer data, is the main factor affecting the wide variation in penetration values measured clinically. Our finding that both age and activity should be considered in the regression analysis probably mirrors the weakness of the correlation between these two variables. Contrary to common belief, patient activity is neither the only nor the most important variable affecting penetration. Indeed, other age-dependent factors, such as step length and walking speed or choice of physical activities, may affect wear.

We evaluated the activity score almost 4 years after the operation, and the penetration rate 2 years after surgery. Therefore, the activity score may have been higher, especially in the elderly patients, when the penetration rate was evaluated.

Nonrandomized studies should be controlled for several factors if meaningful conclusions are to be drawn. Each variable must be present in all groups in a sufficiently high frequency. Our material suffers from some problems in this respect, but we

Table 6. Proximal and total penetration of uncemented cups, using various fixation techniques (signed values, mm), 2 years after surgery

Penetration	n	Mean	95% confidence limit of the mean	Range	P-value [a]
Trilogy					
Proximal					
Press-fit [c]	21	0.20	0.12–0.26	–0.18–0.44	0.2 [b]
Press-fit and screws	44	0.17	0.13–0.21	–0.09–0.67	
Total					
Press-fit [c]	21	0.34	0.27–0.41	0.06–0.75	0.03 [b]
Press-fit and screws	44	0.26	0.21–0.31	0.05–0.95	
Reflection uncemented					
Proximal					
Press-fit without HA [c]	17	0.42	0.35–0.50	0.19–0.71	0.07 [a]
Press-fit with pegs	19	0.47	0.41–0.54	0.24–0.78	
Press-fit with screws	15	0.40	0.33–0.48	0.26–0.74	
Press-fit with HA	18	0.55	0.46–0.63	0.28–0.95	
Total					
Press-fit without HA [c]	17	0.51	0.43–0.58	0.32–0.78	0.007 [a]
Press-fit with pegs	19	0.54	0.50–0.59	0.34–0.78	
Press-fit with screws	15	0.47	0.38–0.56	0.30–0.88	
Press-fit with HA	18	0.76	0.48–1.04	0.37–2.97	

[a] Kruskal Wallis test
[b] Mann-Whitney test
[c] no additional fixation

do not believe that these problems jeopardize the overall conclusions.

Some factors could not be addressed in the regression analysis. One of these is a possible influence of the type of resin, since all Lubinus cups were made of Chirulen 1020, but the polyethylene in the 3 other groups was made of GUR1050. The early proximal penetration in the Lubinus group was similar to that observed in the Trilogy group suggesting that this factor was of minor importance. To our knowledge, there is no information from previous clinical studies on this issue.

Another factor, which could not be completely evaluated in our study, is the use of zirconium heads in the uncemented Reflection group. Zirconium ceramics have been developed as an alternative to aluminum ceramics, because it is stronger and provides a greater margin of safety. The hardness and wettability of zirconium are better than those of cobalt-chromium (Piconi and Maccauro 1999). A comparison of the wear of zirconium on polyethylene shows that it is 2–3 times less than that of cobalt-chromium on polyethylene bearings (McKellop and Lu 1992, Derbyshire et al. 1994). The use of a zirconium head in most of the cases with porous-coated Reflection cups showed that it slightly reduced the early penetration rate. If all these cases had had heads of cobalt-chromium, the wear rate would have been even higher.

Our study only included a follow-up of 2 years after surgery. With time, gamma sterilized polyethylene may change because of oxidation. In addition third bodies in terms of degraded cement and metal particles may enter the joint. Both the Reflection and Trilogy designs represent the second generation of liner locking mechanisms and are polished inside the metallic shell. Nonetheless, fixation failure of the liner with time cannot be excluded. This would increase the production of particles and of penetration with time.

Bone cement and thicker polyethylene may absorb some of the stresses on the polyethylene, which could be one reason for reports of higher penetration rates in uncemented designs (Mattingly et al. 1985, Cates et al. 1993, Berry et al. 1994, Nashed et al. 1995). In our regression analysis, the use of uncemented fixation had no effect on the penetration rate. Some uncemented cups may show an increase in penetration in the long-term perspective due to the commoner occurrence of late problems such as poor liner locking mechanisms and third-body wear, as mentioned above.

The tendency to an increased penetration in our cases with pure hydroxyapatite on the porous coating is an interesting observation. Thanner et al. (1999) found no such effect in a case-control study of Harris-Galante cups with or without ceramic coating. In their cases, a mixture of hydroxyapatite and tricalcium phosphate had been used in the study group. This coating resorbs faster than pure hydroxyapatite. With such a mixture, particles released from the coating dissolve faster than the pure hydroxyapatite used on the Reflection design. Several authors have been concerned about excessive wear and osteolysis related to the disintegration of HA coatings (Bloebaum and Dupont 1993, Bloebaum et al. 1994, Litner et al. 1994, Røkkum and Reigstad 1998). However, it is not clear whether these observations are related to the use of hydroxyapatite or other problems related to implant design, such as thin polyethylene or insufficient liner lockings.

Bal et al. (1998) found that femoral stems of similar geometry made of different metals and with a dissimilar porous layer and modularity not were associated with the same amount of annual linear wear. We could not evaluate the effects of stem design and surface treatment in the total material because few, if any, variations in stem design in each subgroup of cup design were included. The amount and quality of particles produced by stem micromovements and the magnitude of these movements, however, may vary depending on stem shape, surface finish and the type of fixation principle used. More prospective and randomized studies are needed to clarify this issue.

Historically, the term linear wear has been used synonymously with linear penetration. However, the measurement of linear penetration includes wear in terms of removal of material and creep (Isaac et al. 1996). The latter is thought to be greatest in the early postoperative period. It declines with time and becomes negligible by 12–18 months (Schmalzried and Callaghan 1999). This deformation has been described as an initial running-in of the bearing, which results in better conformity, lower contact stresses and a lower rate of wear (Bartel et al. 1986, Wroblewski et al. 1996). For these reasons, short-term evaluations of linear penetration should result in higher annual wear rates. The combined effect of wear and early cold-flow would imply an early high penetration rate followed by a lower steady-state level. None of our 4 groups showed such a decelerating pattern of proximal penetration. In the uncemented Reflection group, we, in fact, found an increase of the proximal wear after 6 months. This may have been due to the substitution of deformation from creep by true wear as the patient's activity increased in the postoperative period. It could also be that creep mainly occurs very early during the first postoperative days or is very small and evenly distributed during the postoperative years, and therefore could not be distinguished from wear up to 2 years after the operation.

The 3-dimensional penetration in our cases showed an early rise in our "wear" diagrams, which could be interpreted as an effect of a "wear in" period. It should, however, be pointed out that this parameter corresponds to the length of a vector. It cannot have a negative value. This means that even if the penetration is zero, the measurement error will be added to the recordings. This is particularly important in the interpretation of the first recording. If the mean error of this parameter is 0.1 mm, the first follow-up will show a penetration of 0.1 mm even if there is no true penetration at all. If a signed value is studied (e.g., proximal/distal wear), the corresponding error may have both negative and positive values, which will usually not affect the mean value, but will instead contribute to the scatter of the data. Thus, the 0–6 months 3-dimensional wear observed is difficult to interpret and cannot be said to represent a "wear in" period without reservations.

Gamma radiation in air causes an increase in oxidation and degradation of the mechanical properties of polyethylene with time (Sutula et al. 1995, Collier et al. 1996b, Bargmann et al. 1999). In a hip simulator study, McKellop et al. (2000) tested artificially-aged polyethylene sterilized by gamma irradiation in air, gamma irradiation in a reduced oxygen environment and gas plasma. They suggested that for at least 10 years of clinical use, the in vivo wear of cups sterilized with gamma irradiation in a reduced oxygen environment will be substantially lower than that of cups sterilized without irradiation. Similar results have been reported by

Greer et al. (1998) who compared artificially-aged polyethylene sterilized with ethylene oxide or gamma irradiation in a vacuum foil package. If these laboratory studies are applicable also to the clinical situation, gas plasma or ethylene oxide-sterilized polyethylene may be better in the long term. On the other hand, if a cup without cross-linking fails during the first decade because of wear-induced osteolysis, no long-term benefit will be derived from its greater resistance to oxidation.

Another factor, which determines the ultimate effect of polyethylene wear, is the biological response to these particles. Experimental studies (Scott et al. 2001) have shown that particle diameter, surface area and volume are higher with ethylene oxide-sterilized components. The biological response of macrophages to polyethylene particles varies, and depends on these factors. It has also been shown that oxidized polyethylene particles are more efficiently phagocytized than nonoxidized ones, which cause a higher release of IL-1 (Kamikawa et al. 1998). The biological response to wear particles is therefore difficult to predict.

We found that ethylene oxide-sterilized polyethylene doubled the penetration rate, as compared with gamma sterilization in a reduced oxygen environment. Due to the complex interaction of polyethylene oxidation, particle quality and production, the long-term effects of this observation on the clinical results is not entirely clear. However, we are concerned about the use of less wear-resistant polyethylene in young patients who have uncemented cups and thin polyethylene.

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