Clinical and radiographic results and wear performance in different generations of a cementless porous-coated acetabular cup

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Abstract We compared clinical results and wear performance in two different generations of a cementless porous-coated cup, analysing the long-term results of 83 uncemented Harris-Galante I cups (32-mm femoral head) and 93 uncemented Harris-Galante II cups (28-mm femoral head). All polyethylene liners were gamma irradiated in air. Polyethylene linear wear was estimated using a software package. The minimum follow-up was 10 years. Nine Harris-Galante I cups and two Harris-Galante II cups were revised due to aseptic loosening or polyethylene problems. The mean femoral head penetration at 6 weeks after surgery was 0.15 ± 0.05 mm for the Harris-Galante I cups and 0.12 ± 0.03 for the Harris-Galante II cups ($p < 0.001$); but mean wear was 0.13 ± 0.23 mm per year for the Harris-Galante I cups and 0.11 ± 0.10 for the Harris-Galante II cups ($p = 0.740$). Most of the metallic shells in both groups showed stable fixation. The so-called second-generation cups had lower initial polyethylene wear that resulted in less polyethylene wear at the latest the follow-up, but the overall wear rate was similar in both groups despite the different femoral head sizes and the improved locking mechanism.

Résumé Nous avons analysé les résultats cliniques et l'usure portant sur deux types de cupules sans ciment différentes. 83 patients ont bénéficié d'une cupule sans ciment type Harris-Galante I (diamètre de la tête 32 mm) et,

93 patients d'une cupule sans ciment type Harris-Galante II (diamètre de la tête 28 mm). Tous les inserts en polyéthylène ont été irradiés aux rayons gamma en atmosphère d'air. L'usure du polyéthylène a été analysée par un logiciel informatique. Le suivi moyen a été de 10 ans. 9 cupules de type Harris-Galante I et 2 cupules de type Harris-Galante II ont été révisées pour un descellement aseptique ou pour des problèmes au niveau du polyéthylène. La pénétration moyenne de la tête fémorale, six semaines après l'intervention a été de $0,15 \pm 0,05$ mm pour la Harris-Galante I et de $0,12 \pm 0,03$ mm pour la Harris-Galante II ($p < 0,001$). L'usure moyenne a été de $0,13 \pm 0,23$ mm par an pour la cupule Harris-Galante I et de $0,11 \pm 0,10$ pour la cupule Harris-Galante II ($p = 0,740$). La plupart des inserts mécaniques n'ont pas présenté de défauts de stabilité. Ces cupules de deuxième génération ont une usure initiale du polyéthylène inférieure à celle de première génération par contre, l'usure moyenne est identique dans les deux groupes au plus long suivi quel que soit le diamètre de la tête fémorale et l'amélioration du mécanisme de fixation de l'insert PE.

Introduction

Since total hip arthroplasty was introduced, different designs have been developed to improve results. Although radiographic bone in-growth is frequently observed in most hemispheric porous-coated titanium cups, polyethylene wear is still the most frequent cause of total hip prosthesis failure [3]. The 32-mm femoral head has been shown to have high wear rate and is usually considered a risk factor for osteolysis [13] and liner fractures [2, 7]. When the locking mechanism is inadequate, movement between the liner and the metal shell can also generate debris and lead to

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polyethylene failure, especially in thin liners [1]. Given the large population of patients with air-sterilised modular polyethylene implants, clinical interest in the long-term effects of polyethylene wear on the performance of modular components is expected to continue throughout the current decade. The aim of this study was to compare clinical and radiographic results and wear performance in two different generations of a cementless porous-coated cups in order to ascertain whether the second generation with a smaller femoral head size and an improved locking mechanism improves on the results of the first-generation design.

Patients and methods

Between January 1986 and December 1995, 110 Harris-Galante I cups and 102 Harris-Galante II cups were implanted consecutively. The minimum clinical and radiographic follow-up required for inclusion in the follow-up study was 10 years. Revised cups with a shorter follow-up are included. Twenty-seven hips were excluded from the Harris-Galante I group; exclusion was due to infection in four hips, death in eight patients and because 15 patients were lost to follow-up despite repeated attempts to contact them. Changes of domicile, either out of city or to a nursing home, lack of interest or advancing age appeared to be responsible for our inability to find them. The remaining 83 cups (67 patients) formed the basis of the follow-up study in the Harris-Galante I group. Nine cups were excluded from the Harris-Galante II group: two because of infection; two because of death; and five because they were lost to follow-up. The remaining 93 cups (75 patients) formed the basis of the follow-up study in the Harris-Galante II group. Oral and written informed consent was obtained from all patients before their operation. The nature and expected effects of the titanium metal fibre coating were fully explained.

The mean duration of clinical and radiographic follow-up until revision or the latest follow-up evaluation was 15.5 (range, 3.4–19.2) years for the Harris-Galante I cups and 10.6 (range, 7.2–12.1) years for the Harris-Galante II cups, with complete radiographs made for all surviving patients for a minimum of 10 years after the index operation. Patient data, including gender, side of involvement, mean age, weight, activity level, diagnosis at the time of the operation and acetabular cup size are given in Table 1. The activity level was classified according to Devane et al. [6].

Both Harris-Galante cup generations have a similar hemispherical metal shell and liner. They are made from a titanium alloy, Ti-6Al-4V (Tivanium, Zimmer, Warsaw, IN, USA), and their outer surface is covered with a porous titanium fibermesh. The mesh has a pore volume of 50% and an average pore size of 300 μm . The shell of the

Table 1 Patient data

	HG I <i>n</i> =83	HG II <i>n</i> =93
Gender (male/female) (no. of hips)	37/46	48/45
Side (right/left) (no. of hips)	46/37	55/38
Mean age (years, standard deviation)	57.3 $\pm$ 9.1	64.1 $\pm$ 5.4
Mean weight (kg, standard deviation)	69.3 $\pm$ 8.3	72.9 $\pm$ 8.8
Activity level (no. of hips)		
Level 1–2	0	1
Level 3	33	4
Level 4	44	68
Level 5	6	20
Diagnosis at the time of operation (no. of hips)		
Osteoarthritis	56	74
Avascular necrosis	15	10
Developmental dysplasia	2	0
Arthritis secondary to Legg-Calvé-Perthes disease	0	1
Post-traumatic arthritis	1	3
Rheumatoid arthritis	4	1
Ankylosing spondylitis	2	4
Acetabular protrusion	3	0
Mean acetabular cup (mm)	51.9 $\pm$ 2.39	52.4 $\pm$ 3.49
Median (range)	52 (48–56)	52 (48–60)
Femoral head (mm)	32	28
Acetabular cup size (no. of hips)		
48 mm	9	18
50 mm	19	22
52 mm	31	15
54 mm	16	16
56 mm	5	9
60 mm	0	3

HG I Harris-Galante I, *HG II* Harris-Galante II

Harris-Galante I cup has different holes for screw fixation (5.1 mm) and a three-tined locking mechanism outside the fibre-mesh-coated titanium shell, which does not interfere with the seating of the liner. The thickness of the polyethylene liner increases with the diameter of the shell, ranging from 5.3 to 11.3 mm. The Harris-Galante I cup was associated with a Harris-Galante I femoral stem using a 32-mm femoral head. The Harris-Galante II cup is made from the same material as the Harris-Galante I cup but is 1-mm thicker and has fewer though larger screw holes (6.5 mm). The locking mechanism has more tines than in the Harris-Galante I design—four to six pairs depending on the size of the shell. The tines are longer and have a lower profile on the Harris-Galante II shells. Harris-Galante II cups were associated with a Multilock femoral stem (Zimmer) with a 28-mm femoral head. All of the polyethylene liners were sterilised by gamma irradiation in air.

All operations were performed through a posterolateral approach. The acetabular cup was implanted after it was line-to-line reamed to fit the same size as the implant and secured to the pelvis with two to four screws, which were

placed cranially and posteriorly. The median acetabular cup size was 52 (range, 48–60) mm (Table 1). Post-operatively, all patients received antibiotics for prophylaxis against infection as well as subcutaneous heparin to prevent thromboembolism. After surgery, partial weight bearing was allowed for 6 weeks.

The clinical evaluation included assessment of pain, function and range of motion according to the 6-level scale described by Merle D'Aubigné and Postel [18]. Standard anteroposterior radiographs of the pelvis and lateral radiographs of the hip were made immediately after the operation; at 6 weeks; at 3, 6 and 12 months; and annually thereafter following the same protocol. The patient was positioned supine with his or her feet together. The X-ray tube was positioned over the symphysis pubis one metre from and perpendicular to the table. To reduce inter-observer error, measurements were made by a single author who was not involved in the surgery (EGR). The cup position was assessed according to the acetabular abduction angle, the height of the centre of the hip (as measured from the centre of the femoral head to the inter drop line) and the horizontal distance of the cup (as measured from the centre of the femoral head to the Köhler line) [10]. The current method of determining radiographic bone in-growth into an acetabular component is by indirect inference based on the absence of the two classic signs of loosening: radiolucent lines and cup migration [20]. The distribution of any radiolucent or radiodense lines or osteolysis at the acetabular bone–prosthesis interface was recorded in the three zones described by DeLee and Charnley [4].

Radiographs were scanned digitally, and linear polyethylene wear was estimated according to the Kim et al. method [12], which—although not totally accurate—was used because of its simplicity [12, 21]. Penetration of the prosthetic head into the polyethylene liner was measured by a computer system (AutoCAD Release 14, Autodesk Inc, Sausalito, CA, USA). Anteroposterior pelvic radiographs were digitised using a scanner (Epson Expression 1680, Seiko Epson Corp., Nagano, Japan). Radiographs were aligned on the digitiser tablet so that the inter-teardrop line was parallel to the edge of the tablet. The operator then digitised three points around the circumferences of the femoral head and the acetabular shell. The computer software fitted circles to these points and determined their centres. The distances between these centres were used to calculate the amount of penetration of the femoral head into the polyethylene liner in the plane of the radiograph [12]. The femoral head size was used as internal reference. Measurements were repeated three times, and the average was recorded. The reliability of the mean of these three measurements was 0.9934 [95% confidence interval (CI) 0.9871–0.9972] [analysis of variance (ANOVA) with repeated measures]. Although

creep occurs probably for 18–24 months [24], the amount of penetration on the 6-week post-operative radiograph was the reference for subsequent measurements [17, 22, 23]. Because the purpose of this study was to estimate displacement between two observations, only the magnitudes were evaluated [25]. Despite all the radiographs being taken according to the same protocol, they were all screened for quality before inclusion in the analysis. Quality criteria excluded radiographs if they were not truly anteroposterior with respect to symmetrical obturator holes or if a low-quality image made it impossible to detect the borders of the cup and the femoral head clearly. These requirements excluded 249 out of the 2,284 radiographs (11%) due to their poor radiographic quality. Head penetration into the polyethylene liner was determined at annual intervals from anteroposterior pelvic radiographs. The mean wear for each patient was calculated as the variation between femoral head penetration at the last evaluation and the reference radiograph divided by the number of follow-up years. The validity of radiographic measurement has been questioned in experimental in vitro studies because the large number of variables in clinical radiographs can render wear measurements invalid [25]. These methods of radiographic measurements are only fit for general estimates.

Statistics

ANOVA with repeated measures was used to estimate the reliability of the three measurements made to calculate the amount of femoral head penetration into the polyethylene liner in the plane of every radiograph. Kaplan–Meier [11] survivorship analysis, with 95% CI, was used to estimate the cumulative probability of not having revision of one or both acetabular components, a polyethylene liner fracture or acetabular osteolysis. Qualitative data were compared using the chi-square test or Fisher's exact test, and quantitative data were compared with Student's *t* test, the Mann–Whitney test, ANOVA or the Kruskal–Wallis test, depending on data distribution. Cox multivariate regression analysis was used to assess the influence of various factors on survival time until some event. The level of significance was $p < 0.05$.

Results

Complications

Post-operative complications included four dislocations that were treated by closed reduction and could remain in the follow-up study. There were six deep infections (four cups in the Harris-Galante I group and two in the Harris-Galante

II group), and these patients were excluded from the follow-up study.

Clinical results

Nine cups were revised in the Harris-Galante I group: five metallic shells were revised because of late polyethylene dislodgement (three cups) or aseptic loosening (two cups), and four polyethylene liners were exchanged due to excessive wear. Two metallic shells were revised in the Harris-Galante II group: one for aseptic loosening and the other for late polyethylene liner dislodgement. Radiographs of cups with late polyethylene liner dislodgement showed an eccentrically located femoral head articulating with the metal shell. All shells were found to have well-fixed components at the time of revision surgery. Black debris from shell wear against the harder alloy of the head was found in all liners. All shells had a fracture of the lateral aspect of the metal structure.

According to the Kaplan–Meier survivorship analysis, the cumulative probability of not having a late polyethylene liner dislodgement was 79.6% (95% CI, 53.6–100%) for the entire series, and 79.7% (95% CI, 53.7–100%) at 15 years in the Harris-Galante I group and 97.9% (95% CI, 93.9–100%) at 9 years in the Harris-Galante II group (Mantel-Cox test, $p=0.8831$). Data on cups with polyethylene liner dislodgement are given in Table 2. The cumulative probability of not having metallic shell revision was 96.9% (95% CI, 92.5–100%) at 15 years in the Harris-Galante I group and 98.3 (95% CI, 95.1–100%) at 9 years in the Harris-Galante II group. (Mantel-Cox test, $p=0.7107$). The cumulative probability of not having a polyethylene liner exchange was 90.7% (95% CI, 81.4–100%) at 15 years in the Harris-Galante I group and 100% at 9 years in the Harris-Galante II group (Mantel-Cox test, $p=0.8070$).

Fifteen cups were associated with level 5 pain in the groin and buttock, ten with level 4 pain and one with level 3 pain in the Harris-Galante I group. Twelve cups were associated with level 5 pain in the groin and buttock and two with level 3 pain in the Harris-Galante II group (chi-square test, $p=0.003$).

Radiographic results

Seventy-nine metallic shells had radiographically stable fixation and four had radiographic loosening with a radiolucent line >2 mm around the entire contour of the cup migration in the Harris-Galante I group. Ninety-one shells had radiographically stable fixation and two had radiographic loosening migration in the Harris-Galante II group (chi-square test, $p=0.020$).

The mean acetabular abduction angle was $44.1\pm6.1^\circ$ for the Harris-Galante I cups and 45.9 ± 3.5 for the Harris-Galante II cups. The mean height of the centre of the hip was 14.4 ± 10.4 mm and 28.2 ± 6.4 , respectively, with the mean horizontal distance of the cup at 32.6 ± 7.5 mm and 32.9 ± 4.3 , respectively. The distribution of radiolucent and radiodense lines, and osteolysis around the acetabular component is shown in Fig. 1. Radiolucent lines were more frequent around the Harris-Galante I cups than around the Harris-Galante II cups in DeLee and Charnley zones 2 ($p=0.016$) and 3 ($p=0.011$). Osteolysis around the acetabular cup was present in seven hips: five Harris-Galante I cups (1 of these had an associated screw rupture) and two Harris-Galante II cups. The cumulative probability of not having acetabular osteolysis around the acetabular cup was 93.8% (95% CI, 88.5–99.2%) at 15 years in the Harris-Galante I group and 97.6% (95% CI, 94.2–100%) at 9 years in the Harris-Galante II group (Mantel-Cox test, $p=0.3930$) (Fig. 2). Acetabular osteolysis was associated with a higher

Table 2 Data on Harris-Galante cups with late polyethylene liner loosening

	Cases			
	1	2	3	4
Age (years)	63	67	60	63
Gender	Male	Female	Male	Female
Diagnosis	Avascular necrosis	Post-traumatic arthritis	Osteoarthritis	Osteoarthritis
Cup type	HGP I	HGP I	HGP I	HGP II
Cup size (mm)	54	50	54	48
Head size (mm)	32	32	32	28
Acetabular abduction angle ($^\circ$)	52	36	40	45
Interval since surgery (months)	171	123	38	86
Pain	Mild	Severe	Mild	Severe
Creep at 6 weeks (mm)	0.22	0.20	0.17	0.11
Mean wear (mm/year)	0.49	0.36	2.14	0.91
Wear at fracture (mm)	7.02	3.85	7.50	6.24
Osteolysis (DeLee-Charnley zones)	I	I	–	II

HGP I Harris-Galante I, HGP II Harris-Galante II

mean annual wear (Mann–Whitney test, $p=0.001$) and higher wear at the previous follow-up (Mann–Whitney test, $p=0.002$) (Table 3).

Mean femoral head penetration on the 6-week post-operative radiograph in patients without late polyethylene liner dislodgement was 0.15 ± 0.05 mm for the Harris-Galante I cups and 0.12 ± 0.03 mm for the Harris-Galante II cups (Mann–Whitney test, $p<0.001$). Mean wear was 0.13 ± 0.23 mm per year for the Harris-Galante I cups and 0.11 ± 0.10 mm per year for the Harris-Galante II cups (Mann–Whitney test, $p=0.740$). Although the mean annual wear was similar for both groups, the second-generation cups had a lower femoral head penetration on the 6-week post-operative radiograph, which resulted in less polyethylene wear at the latest follow-up. The annual sequential

Fig. 1 Distribution of radiolucent and radiodense lines and osteolytic cavities around the Harris-Galante I and II acetabular components (DeLee and Charnley zones) at the most recent follow-up evaluation

Fig. 2 Kaplan–Meier survivorship curves comparing the cumulative probability of not having osteolysis around the Harris-Galante I and II acetabular components. Cross lines represent censored hips. Ranges represent the 95% confidence intervals (CI)

femoral head penetration was similar in both Harris-Galante groups; it was greater during the first post-operative year and then decreased with time (Fig. 3).

There were four late polyethylene liner dislodgements. The average interval from operation to the appearance of liner dislodgement was 113.25 (range, 38–171) months. With the number of available cups, no risk factors could be related to the appearance of late polyethylene liner dislodgement. Femoral head penetration on the 6-week post-operative radiograph was 0.15 for the four cups with late polyethylene liner dislodgement and 0.13 for the 172 cups without late dislodgement. Up until the time at which the late liner dislodgement was diagnosed, mean femoral head penetration was similar in cups that presented dislodgement and those that did not.

Table 3 Polyethylene wear in hips with and without osteolytic cavities around the acetabular cup

	Creep at 6 week post-op ^a	Mean annual wear ^b	Wear at the latest follow-up ^c
With osteolytic cavities			
Harris-Galante I (n=5)	0.17±0.03	0.22±0.16	3.05±2.41
Harris-Galante II (n=2)	0.13±0.02	0.61±0.41	4.12±2.99
Total (n=7)	0.15±0.03	0.33±0.28	3.36±2.37
Without osteolytic cavities (n=169)	0.13±0.04	0.10±0.10	1.14±0.76

^a (Mann–Whitney) $p=0.062$, $p=0.001$, $p=0.002$

^b (Mann–Whitney)

^c (Mann–Whitney)

Fig. 3 Graph showing the mean amount of femoral head penetration over time

Discussion

Radiographic stable fixation was more frequent in the Harris-Galante II cups than in the Harris-Galante I cups in this study. Nevertheless, polyethylene wear remains the most frequent cause of total hip prosthesis failure.

Radiographic methods for manually measuring polyethylene wear are associated with substantial inter-observer and intra-observer errors [5, 17, 22]. Linear polyethylene wear was estimated using a software package. Although we did not validate the digitised method used here, similar digitised methods have been validated previously using phantom models and retrieved cups [22] but not on radiographs obtained in vivo [25]. With a digitised measurement method similar to ours, Sychterz et al. [24] reported mean errors of around 0.14 ± 0.09 mm when measuring optimal radiographs and 0.23 ± 0.22 mm for sub-optimal radiographs. The precision in phantom studies performed with computer-assisted measurement of polyethylene penetration is more accurate than clinical radiographic measurements. In fact, scatter soft tissue absorption of the radiation and in vivo penetration patterns cannot be recreated in the laboratory [25]. A fixed position of the X-ray beam reduces error in phantom studies [25], but in clinical radiographs, patient positioning is slightly different in each radiograph in the follow-up studies. Also, clinical pelvic radiographs contain distortions of the metal shell and head, while computer-assisted measurement of polyethylene penetration assumes that the metal shell and femoral head are true circles on the radiographs. Roentgen stereophotogrammetric analysis (RSA) studies have shown that reference lines around the pelvis even vary up to 1 cm from one radiograph of the same patient to another, depending on the position of the pelvis [9]. So, the use of a digital system improves precision but does not correct errors resulting from different projections of the pelvis on the radiograph

(accuracy). Therefore, it is difficult to compare results between the two study types. Wan et al. [25] report that two-dimensional (2D) computer-assisted radiographic measurements of polyethylene penetration had reproducible measurements on the same radiograph. However, measurements of different clinical radiographs for the same patient were not so precise due to positioning differences mentioned above. So, these methods of radiographic measurements are only fit for general estimates. Different authors have suggested that 2D measurements are sufficient to determine the major wear vector [23]. Three-dimensional (3D) measurements are difficult to obtain because lateral radiographs are frequently of poor quality, and if good, only demonstrate some additional wear in the lateral plane.

New cup designs have improved the locking mechanism between the polyethylene liner and the shell and decreased the initial movement of the liner, thereby reducing polyethylene wear. Our study assessed different generations of a cup design that use polyethylene sterilised by gamma irradiation in the presence of air; the main differences between the two designs were the locking mechanism and the femoral head size. Despite these modifications, mean wear was similar in both generations despite their different femoral head sizes; thus, second-generation cups show less femoral head penetration at the end of the follow-up, but that is due to their lower femoral head penetration on the 6-week post-operative radiograph. The 32-mm femoral head is known to give worse results than the 28-mm femoral head and is usually considered a risk factor for osteolysis [22] and liner fractures [2, 7]. It is also well known that the 32-mm head size is associated with higher rates of volumetric wear [15, 16]. Different series have reported that polyethylene failure is not directly related to head size and have related failure to polyethylene thickness [14]. Lee et al. [15] report that in metal-backed sockets, head size and polyethylene thickness are not independent variables.

Late dislodgement of polyethylene liners is less frequent in the Harris-Galante cups than in other designs [8, 19]. As in other series [8, 19], all metallic components were found to be radiographically well fixed. Despite the wide use of the Harris-Galante cup, it is difficult to calculate the prevalence of liner dislodgement in association with each type of Harris-Galante cup due to a lack of reported data [8]. Most authors [8, 19] have reported that as the liner wears and loosens because of an inadequate locking mechanism, progressive micro-motion occurs, and the load is applied against the rim until the polyethylene deforms and/or fractures. Radiographic evaluation reveals an eccentrically placed femoral head within the acetabular component, so once a liner dislodgement is radiographically diagnosed, revision should be carried out urgently to minimise metal wear. In our study, all failed liners were associated with a well-fixed shell; this made revision

surgery difficult, and it was frequently necessary to use bone allografting.

Osteolysis around the acetabular cup has been related to higher linear wear rates. Orishimo et al. [21] quantified the relationship between the prevalence of osteolysis and polyethylene wear, and they recommend more frequent follow-up visits once a patient's wear rate exceeds 0.2 mm per year so as to better assess osteolysis.

We conclude that most cementless porous hemispheric cups show stable fixation. Although the method used to quantify polyethylene wear here was limited by the need of a radiographic quality that produces clear definition of the cup and femoral head borders and by its inaccuracy in determining relative prosthetic component positions, the so-called second-generation cups show a lower femoral head penetration on the 6-week post-operative radiograph that led to less polyethylene wear at the end of the follow-up. So the wear rate was similar in both groups despite the different femoral head sizes and the improved locking mechanism.

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