Porous-coated cups fixed with screws
A 12-year clinical and radiostereometric follow-up study of 50 hips

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Background Excellent mid-term results have stimulated the use of hemispherical porous-coated cups in hip replacement. With longer follow-up, there have been problems related to polyethylene wear and liner fixation, and osteolysis has been documented in reports of selected cases. We evaluated the clinical and radiographic results of 50 patients followed for 12 years.

Patients and methods 58 consecutive patients (58 hips), mean age 55 years, were operated with Harris-Galante (HG) I or II cups using line-to-line fit and additional screw fixation. Polyethylene liners γ-sterilized in air and 32-mm ceramic heads were used. 8 patients died within 12 years, leaving 50 patients with a complete 12-year follow-up. 23 of the cups were also evaluated with radiostereometry (RSA) for migration, liner stability, and wear.

Results All metal shells were still in situ after 12 years. 4 hips had been revised due to femoral loosening. In these revisions, the liner had been exchanged due to wear and/or instability, resulting in a cup survival rate of 89%. 28 cups displayed osteolytic lesions, mainly in relation to screws. RSA revealed minimum translations, but in many cases there were pronounced liner rotations suggesting unstable liners within the metal shell. The annual proximal wear was 0.09 mm and the three-dimensional wear was 0.16 mm.

Interpretation RSA can predict the long-term performance of cup fixation. Low migration during the initial years after implantation indicates excellent long-term results regarding fixation of the metal shell. The main problem with this design appears to be liner instability and osteolysis, factors that are probably interrelated. Because these phenomena are clinically silent, we recommend regular follow-up of patients with HG cups to avoid sudden loosening and complicated revisions.
Heyligers 1999, Gonzalez della Valle et al. 2001, Werle et al. 2002) as a consequence of poor locking, wear and material fatigue (Gonzalez della Valle et al. 2001, Werle et al. 2002). Problems can be expected to mount with increasing implant time. According to Jacobs et al. (2002), the prevalence of liner dissociation seems to be more frequent for the HG II design than the original HG I design.

Periacetabular osteolysis is another potential reason for clinical failure of these sockets (Böhm and Bosche 1998, Ricci et al. 2000, Crowther and Lachiewicz 2002). Progression of osteolysis can lead to acetabular collapse, requiring demanding revision surgery. Alternatives are to fill the lesions with impacted bone in cases with stable metallic shells, or exchange of the implant (Mallory et al. 2000).

We performed a 12-year evaluation of the clinical, radiographic and radiostereometric results of 50 consecutive cases operated with the Harris-Galante cup. We specifically wanted to evaluate the long-term prognostic capabilities of RSA as regards implant fixation, but also to investigate liner stability, wear, and development of osteolysis.

Patients and methods

63 consecutive primary hip arthroplasties in 58 patients (37 men) were performed at Umeå University Hospital between 1987 and 1991. Median age at operation was 55 (38–69) years. 5 patients were operated on bilaterally in staged operations. 45 hips had primary arthrosis and 18 hips had arthrosis secondary to dysplasia (12), physeolysis (1), idiopathic avascular necrosis (4), and septic coxitis (1). 30 patients were Charnley group I (unilateral), 26 were group II (bilateral), and 2 were group III (multifocal joint disease). The first 45 hips received the Harris Galante I cup (HG I) and the other 18 hips received the Harris-Galante II cup (HG II).

For the purposes of this study, only 1 of the hips in the 5 bilaterally operated patients was included, giving 58 hips. By 12 years, 8 patients (8 hips) had died (7 HG I, 1 HG II), which resulted in 50 hips (36 HG I, 14 HG II) that were available for follow-up (Table 1).

Surgical technique

62 hips were operated by 2 of the senior authors (JK, FS) and the remaining patient by another experienced hip surgeon. All operations were done through a posterolateral approach in a clean-air enclosure with laminar flow. Of the hips in this study, 43 received a hemispheric Harris-Galante porous-coated type I cup, and 15 hips were given a type II cup (Zimmer, Warsaw, IN). Both cups are made of a titanium alloy and are supplied with a fiber mesh made of commercially pure titanium. The locking mechanism of HG I, introduced in 1984, consists of 4 pairs of tines in the rim locking with the outer slot of the liner. The HG II, which was introduced in 1988, had more tines. The thickness of the smaller shells was increased from 3.7 to 5.6 mm, and the thickness of the larger shells from 4.7 to 5.6 mm. The liner was made from ram-extruded GUR 1150 polyethylene sterilized with 2-Mrad irradiation in air. The median cup size was 56 (48–64) mm and 2–4 screws were inserted for additional fixation. Reaming was done up to the same diameter as the size of the implant inserted. A modular 32-mm femoral head made of aluminium oxide ceramic was used in all cases. In one case, a screw broke during the operation—probably because of improper centering.

We used 3 different femoral stems. The initial patients were operated with either an anteverted cemented stem of titanium alloy (Lubinus SP II; Link, Hamburg, Germany) or an anteverted cementless stem of titanium alloy (Rippen; Link). Patients

Table 1. Summary of the study material

|   | A | B | C | D | E | F | G |
|---|---|---|---|---|---|---|---|
| Harris-Galante I | 43 | 45 | 43 | 7 | 36 | 11 | 10 |
| Harris-Galante II | 15 | 18 | 15 | 1 | 14 | 3 | 5 |
| Total            | 58 | 63 | 58 | 8 | 50 | 14 | 15 |
who were operated on later received a cemented or uncemented TiFit titanium alloy stem (Smith and Nephew, Memphis, TN); for details, see Kärrholm et al. (1998).

All patients were mobilized on the first postoperative day and were allowed to bear partial weight for 8–10 weeks.

**Conventional radiography**

All patients who attended the last follow-up underwent AP and lateral radiographs. The postoperative anteroposterior (AP) radiographs were available for 17 patients, and the lateral projections were also available for 15. In the remaining cases, the postoperative examinations had been destroyed. All existing radiographs were digitized and measured using Mdesk software (RSA Biomedical, Umeå, Sweden). The cup diameter was used to correct for magnification. We measured cup inclination, vertical cup position as the distance to the tuber line (TL) (Nivbrant et al. 1996), femoral component offset and the height of the femoral head above the tip of the greater trochanter.

Any radiolucency of 1 mm or wider at the cup interface was detected and measured. The entire length of these radiolucent lines was calculated as a percentage of the total length of the interface on the AP view. The acetabular components were divided into 3 regions of 60º each on the AP view and the length of any radiolucent lines in each sector was graded into 4 classes: A) no radiolucent line, B) < 50% of the interface, C) 50–99% of the interface, and D) 100% of the interface (modified Charnley-DeLee regions; Hultmark et al. 2003).

To evaluate development of osteolysis, we compared the AP and lateral views obtained at 12 years with the first available examination at an earlier follow-up. For 17 hips, this was the postoperative examination, for 7 it was the 1-year follow-up, for 11 it was the 2-year follow-up, for 9 it was the 5-year follow-up, and for 3 it was the 10-year follow-up. No previous examination was available for 16 hips. The location of any osteolytic lesions was related to the 3 modified Charnley-DeLee regions described above, and its area was measured digitally and expressed in mm².

**Radiostereometric analysis**

During the operation, tantalum markers of 0.8 mm diameter were inserted into the periacetabular bone and the polyethylene liner for the RSA examinations. These were performed within the first postoperative week, and after 1, 2, 5 and 12 years. All patients attended the 1- and 2-year follow-up examinations, 52 attended at 5 years, and 50 attended at 12 years. For various technical reasons, however, (see below) some of the patients could not be evaluated at 12 years (Table 1).

All measurements of RSA radiographs were done digitally. Thus, the original stereo radiographs from the postoperative and 1-, 2-, and 5-year examinations were scanned and measured using digital technique. This was done to improve the precision of the measurements (Börlin et al. 2002). Unfortunately, there were only 15 hips with acceptable marker configuration (i.e. condition number < 105) and stability (i.e. mean error of rigid body fitting < 0.35) allowing evaluation of cup migration, and 14 hips allowing evaluation of wear at the 12-year follow-up (Table 1). 8 hips could be analyzed for both wear and migration, whereas for the rest of the hips only wear or migration could be analyzed. All computations were done using UmRSA software from RSA Biomedical (Umeå, Sweden). The precision of the measurements was assessed by 19 double examinations with a 10–15 min interval between the examinations, as described by Rans-tam et al. (2000) (Table 2).

During the follow-up of this series, it became evident that in many cases the liner was not stable within the metallic shell. To reduce the effect of any such rotation on the calculations, we decided to measure cup translation only in terms of migration of a fictive point localized at the center of the femoral head at the postoperative examination.

### Table 2. Precision of the RSA examinations based on double examinations

|                     | Migration | Wear  |
|---------------------|-----------|-------|
| Translations (mm)   |           |       |
| Transverse axis     | 0.16      | 0.49  |
| Longitudinal axis   | 0.10      | 0.76  |
| Sagittal axis       | 0.18      | 1.11  |
| Rotations (degrees) |           |       |
| Transverse axis     | 0.60      |       |
| Longitudinal axis   | 0.60      |       |
| Sagittal axis       | 0.37      |       |
If the liner rotated, we speculated that this point would be least influenced because the rotations could be supposed to occur around an axis running through this point. At the follow-up examinations, this point was identified by using its position relative to the liner markers using the so-called “point transfer” function in the UmRSA software (Nilsson et al. 1990, Nilsson 1992).

To facilitate interpretation of cup rotations, we combined RSA information about liner rotation with information based on conventional radiography. Cups in which the rotations exceeded the detection level for only 1 direction, corresponding to significant rotation about only 1 of the cardinal axes, were regarded to have a stable liner. In these cases, the rotations were small and were presumed to have occurred within the first months postoperatively. If there were interface radiolucent lines less than 50% of the interface and 2 rotations around any of the 3 cardinal axes exceeded the detection level, they were classified as possible liner rotation. Significant rotation about all 3 cardinal axes in cups with RLL < 50% was classified as probable liner rotation. If the radiolucencies exceeded 50%, these rotations were classified as liner and/or shell rotations.

Clinical outcome

Harris hip score was determined in all patients at 2 and 12 years.

Statistics

Statistical evaluation of the RSA results was done on signed values with non-parametric Mann-Whitney U or Kruskal-Wallis tests. Changes over time were analyzed with Wilcoxon signed-rank test. Only 1 hip in each of the 5 patients who had bilateral arthroplasties was used. The decision of which hip to include was based on presence of complete radiographs and stereoradiographs. Thus, the first hip to be operated was used in 3 patients, and the second operated hip was used in 2 patients. The effect of weight, sex, fixation of femoral component, and age at operation on the development of osteolysis was analyzed using logistic regression analysis.

Results

Clinical results

Re-operations and complications. 3 hips were re-operated for loosening of the femoral component (6, 11 and 12 years after the primary operation) and 1 hip because of severe pain associated with minor signs of radiolucency around the stem (11 years after the primary operation). In all of these cases, a new femoral stem was inserted with impaction grafting. At the reoperation all metal shells were deemed to be stable, but due to perceived wear and/or instability of the liner, it was exchanged in 3 of the cases and in the fourth an all-polyethylene cup was cemented into the metal shell. The patient who was revised after 6 years was revised a second time 6 years later because of new femoral loosening. At this operation, the liner was considered to be worn or unstable and an all-polyethylene cup was cemented into the stable metal shell. In all 5 revisions (including the re-revision), no RSA beads were inserted into these new liners, thus preventing further RSA analysis at the 12-year clinical and radiographic follow-up.

There was 1 early and 1 late infection (at 6 years). Both were treated successfully with antibiotics alone and did not require further treatment. Radiographically, the patient with late infection developed cystic osteolysis around the cup but to date, the symptoms have not warranted reoperation. Three patients suffered dislocations—1 early and 2 late (after 5 years). These were treated with closed reduction and so far none of them have required revision.

Hip score. The Harris pain and hip scores increased up to a median of 40 (20–44) and 94 (66–100), respectively, at 2 years with no further significant changes up to 12 years (p = 0.7 and 0.4). At 12 years, excluding the patients with femoral component revision, 29 patients did not have any pain in the hip and 8 patients felt only occasional pain with no influence on normal daily activities. 7 patients used analgesics occasionally, and 2 regularly.

The overall cup survival for the HG I cups at 12 years with revision (i.e. liner exchange) as endpoint was 91% (CI ±14) and it was 100% for the HG II cups (Kaplan-Meier analysis). All metal shells were still in situ 12 years after the index operation.
Conventional radiology. Mean (SD) inclination for all cups was 41 (7.8) degrees, mean height above the inter-tuber ischiadicum line was 74 (6.8) mm and offset was 40 (6) mm with no differences between the HG I and HG II designs (p = 0.3, 0.7, 0.5, and 0.9, respectively). No broken tines or other signs of liner dissociation could be found on any of the radiographs.

Osteolysis and radiolucencies. At the 12-year follow-up, 28 of 50 cups had developed acetabular osteolysis. There were no differences between the HG I and HG II designs regarding the numbers or size of the osteolytic lesions (p = 0.4) (Table 3). Most osteolyses were located proximo-laterally, often with a partial extension into the central region. All osteolyses seemed to be in contact with screws. They could be seen in the AP view in all cases, and in the lateral view also in 17 of 42 hips. There was no difference between males and females regarding the size and number of osteolyses (p = 0.9 and 0.3). About one-half of the cups with possible or probable liner instability developed osteolysis.

Radiolucent lines (RLLs) were visible in 22 cups at 12 years, with no difference between the 2 designs (p = 0.3) (Table 4). In 11 of these cups, the radiolucent lines were located in region I, in 4 hips they expanded into region II, and in 16 hips they were visible in region III. There were no gender-related differences (p = 0.6). The mean percentage (± 95% CI) length of RLLs (relative to the total interface length) was 24% (14) and 28% (16) in the HG I and HG 2 cups, respectively. 1 cup displayed a complete circumferential osteolysis/radiolucency. 6 of the cups with unstable liner showed RLLs (Table 4).

Logistic regression showed no relationship between the presence of osteolysis and weight, age at operation, femoral component fixation, or gender.

Radiostereometric analysis

Cup translations. Mean cup translation did not change between 5 and 12 years (Figure). 10 cups migrated over the 95% detection limit in the medial/lateral directions—5 medially and 5 laterally. 14 cups moved significantly along the longitudinal axis—10 proximally and 4 distally. In the sagittal plane, 11 cups migrated above the detection limit—6 anteriorly and 5 posteriorly. There were no differences in direction of translation between the HG I and HG II cups.

Cup rotations. At 12 years, the absolute mean (SD) change in anterior-posterior tilt was 1.8 (0.9) degrees, while mean change in anteversion was 1.4 (1.7) degrees, and change in inclination was 1.9 (2.2) degrees.

All 15 cups showed at least one rotation over the detection limit. 4 cups (3 HG I and 1 HG II) rotated significantly in all 3 directions, and 8 cups (4 in each group) rotated in 2 directions. These cups were classified as having probable and possible liner rotations, respectively. 1 cup displayed RLLs.
slightly over 50% and was therefore classified as liner and/or shell rotation. This cup had migrated 1.48 mm medially, 1.74 proximally and 1.80 posteriorly (Table 5).

Wear. The mean (SD) proximal and 3-dimensional femoral head penetrations were 1.09 (1.60) mm and 1.93 (2.46) mm, respectively. This corresponded to an annual penetration rate of 0.09 mm and 0.16 mm, respectively, with no differences between the HG I and II cups (p = 0.6 and 0.8). Linear regression analysis did not show any influence of cup position on wear.

Discussion

This study is the first long-term follow-up of a cementless porous-coated acetabular component using radiostereometry. We did encounter, however, a number of technical problems relating to the RSA analysis which we had not foreseen when the original study was initiated in 1987. The use of thin polyethylene liners, 32-mm femoral heads, and a slight change in the angulation of the X-ray tubes in the radiostereometric set-up after the 2-year follow-up often made it impossible to visualize the implant markers that had been inserted.

Also, occasional rotation of the liner within the metal shell over time added further to jeopardizing visualization of some markers. As we wanted to make sure of good technical quality of the RSA measurements—and therefore discarded all examinations with poor marker configuration or too few stable markers—this led to the exclusion of many patients.

For this study, marking of the implants for RSA meant that tantalum spheres were inserted into the polyethylene liner but not in the metal shell. This assumed a rigid bond between these two implants, thus permitting analysis of cup migration. During the analysis it became evident that in some cups, the liner was not stable within the metal shell and forced us to modify how cup translations and rotations were measured and interpreted. Normally, cup translations are measured as movements of the gravitational center of the polygon corresponding to the inserted markers, which—with symmetrically placed markers—would correspond in most cases to the center of the cup. If, however, during a follow-up markers are lost due to variations in the positioning of the patient or frank rotation of the liner, this gravitational center will vary from time to time and thus suggest a translation that might never have taken place. To overcome this problem the use of a fictive point and the “point transfer” function in the RSA software was used, as described by Nilsson (1992) and Nilsson et al. (1990). This ensured that in all patients for whom sufficient markers were seen in the liner during

| A | B | C | D |
|---|---|---|---|
| Harris-Galante I (n = 10) | 2 | 4 | 3 | 1 |
| Harris-Galante II (n = 5) | 4 | 1 |   |   |

A Stable liner: ≤ 1 rotation over the detection limit and radiolucent lines < 50% of the length of the interface.

B Possible instability: 2 rotations over the detection limit and radiolucent lines < 50% of the length of the interface.

C Probable instability: 3 rotations over the detection limit and radiolucent lines < 50% of the length of the interface.

D Probable liner/shell instability: 3 rotations over the detection limit and radiolucent lines > 50% of the length of the interface.

The mean (SEM) migration of the cup center. The cups were stable in the vertical and the frontal plane after 5 years (n = 15).
the follow-up, a standardized point for translation measurement was used (i.e. the center of the cup).

Analysis and interpretation of cup rotations were sometimes difficult for the same reasons. Potential liner instability means that measured rotations of the polygon corresponding to the markers in the liner could be interpreted either as migration of the entire insert-shell construct in relation to bone, or rotation of the liner within the metal shell. The exact division between what should be considered pure cup migration on the one hand and pure liner instability on the other is difficult to establish. We therefore decided arbitrarily that cups with no or small rotations and absence of radiolucent lines were to be considered stable, whereas more pronounced rotations in combination with no or small interface radiolucent lines would most probably represent liner rotation within the shell. Rotations in cups with more extensive radiolucent lines could either be liner instability or cup rotation, or both.

Despite these technical difficulties, our findings, however, provide us with some important information about the prognostic properties of RSA. The small early migration observed with this cup design after 2 years (Kärrholm and Snorrason 1992) was compatible with a stable fixation up to 12 years; nor was there any increase in the magnitude of migration over time, and none of the shells were revised or considered clinically loose during the follow-up. Thus, low or no migration at all measured by RSA during the initial 2 years is a good prognostic indicator of stable long-term fixation.

The annual linear proximal and three-dimensional wear rates in this study were 0.1 mm and 0.16 mm, which compares favorably with the study of Önsten et al. (1998) who examined the HG I cup articulating against a 22-mm metal head. Thus, it seems that the smoother ceramic head can compensate for its larger size as regards linear wear. The wear rate was also low, considering the low age of these patients (Maloney et al. 1999). Schmalzried et al. (2000) pointed out that wear is not so much a function of time in situ, but rather a function of use. We did not measure the activity level of our patients, but do not believe that they were any less active than average—especially considering that most of them lived in rural areas of northern Sweden where physical activity is usually a part of daily living. Finally, the low linear wear rate is also remarkable considering (by today’s standard) the inferior quality of polyethylene used.

We found osteolysis around the cups in more than half of the patients, and most osteolytic cysts seemed to be close to the screws. To our knowledge, this is the highest level of osteolysis reported for this cup. From a mid-term standpoint, osteolysis has been reported to be present in 25% of cases (Clohisy and Harris 1999, Soto et al. 2000). Manley et al. (2002) explained the development of osteolysis as a “disease for which access is required”. The Harris Galante cup has multiple holes for versatile screw fixation. Easy access for joint fluid carrying osteolysis-inducing agents through these holes or the fluctuating pressure as such may be of importance (Aspenberg and Van der Vis 1998). Schmalzried et al. (1999) questioned the influence of holes. They examined cups with and without holes and found more osteolysis in the latter group. The discrepancy between that study and ours could be because it may not be the screw holes per se, but rather the screws, which are of importance—since most of the osteolysis was found in association with the inserted screws.

Despite the low linear wear rate, osteolysis was extensive. 32-mm heads give larger volumetric wear than smaller heads for a given linear wear rate, which may be one explanation. Another explanation could be liner instability, leading to back-side wear. In this study, we found evidence of unstable liners, although we could not establish the exact proportion of liners that were unstable, or to what extent. Increased incidence of liner instability for these cup designs has been reported previously (Gonzalez della Valle et al. 2001, Werle et al. 2002) and it has been claimed to be caused by an inefficient locking mechanism. Unstable liners rotating in the shell would result in large volumes of wear particles which would contribute to the osteolysis. Moreover, the movement of the liners could also be expected to induce pressure gradients at the interface, further enhancing the development of osteolysis. We are aware, though, that the low numbers of patients with complete radiographic follow-up somewhat diminishes the impact of our results.

We found an 89% survival rate up to 12 years for the Harris Galante cups, using revision for any reason as endpoint, and a survival rate of 100% for the metal shells. It is worthwhile considering, how-
ever, that the patients with impending osteolysis were old, without clinical symptoms and therefore not earmarked for further surgery. A more aggressive surgical attitude in the treatment of osteolysis would certainly reduce the survival rate. Although the metal socket was found to be stable and probably at least partly ingrown, we anticipate that the high prevalence of liner rotations and osteolysis will result in more revisions in the future.

We conclude that RSA can predict the long-term performance of cup fixation. Low migration during the initial years after implantation indicates an excellent long-term result as regards fixation. The survival of the porous-coated shell of the Harris Galante cup was excellent. Survival, including revision for any reason, was comparable to that for cups cemented with first-generation cementing technique (Callaghan et al. 2000, Halley and Glassman 2003). The main problem seems to be the (lack of) liner stability, with a high number of probable liner rotations within the shell leading to extensive osteolysis. The metal shells were stable despite osteolytic lesions in over 50% of the cases. Most of these changes were clinically silent. We therefore recommend regular follow-up of patients with HG cups to avoid sudden loosening and complicated revisions.

**Contributions of authors**

RSM study design, data collection, analysis, manuscript. BN data collection, manuscript. FS study design, data collection. JK and KGN study design, analysis, manuscript.

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