The Harris-Galante porous-coated, hemispherical, polyethylene-lined acetabular component in patients under 50 years of age

A 12- TO 16-YEAR REVIEW

M. R. Utting[†],
M. Raghuvanshi,
R. Amirfeyz,
A. W. Blom,
I. D. Learmonth,
G. C. Bannister

*From Southmead
Hospital, Bristol,
England*

We have reviewed 70 Harris-Galante uncemented acetabular components implanted as hybrid hip replacements with cemented stems between 1991 and 1995 in 53 patients whose mean age was 40 years (19 to 49). The mean follow-up was for 13.6 years (12 to 16) with no loss to follow-up. We assessed the patients both clinically and radiologically.

The mean Oxford hip score was 20 (12 to 46) and the mean Harris hip score 81 (37 to 100) at the final review. Radiologically, 27 hips (39%) had femoral osteolysis, 13 (19%) acetabular osteolysis, and 31 (44%) radiolucent lines around the acetabular component. Kaplan-Meier survival curves were constructed for the outcomes of revision of the acetabular component, revision of the component and polyethylene liner, and impending revision for progressive osteolysis.

The cumulative survival for revision of the acetabular component was 94% (95% confidence interval 88.4 to 99.7), for the component and liner 84% (95% confidence interval 74.5 to 93.5) and for impending revision 55.3% (95% confidence interval 40.6 to 70) at 16 years.

Uncemented acetabular components with polyethylene liners undergo silent lysis and merit regular long-term radiological review.

■ M. R. Utting (deceased)[†],
FRCS(Orth), Western Australian
Arthroplasty Fellow
Royal Perth Rehabilitation
Hospital, 6 Selby Street,
Shenton Park, Western
Australia 6008, Australia.

■ M. Raghuvanshi, MRCS,
Clinical Research Fellow in
Orthopaedic Surgery
Department of Orthopaedics
■ R. Amirfeyz, MRCS,
Specialist Registrar in Trauma
and Orthopaedics
■ A. W. Blom, MD, PhD,
FRCS(T&Orth), Head of
Orthopaedic Surgery
■ I. D. Learmonth,
FCS(SA)Orth, Professor of
Orthopaedic Surgery
■ G. C. Bannister, MD,
Professor of Orthopaedic
Surgery
Avon Orthopaedic Centre
Southmead Hospital,
Westbury-on-Trym, Bristol
BS10 5NB, UK.

Correspondence should be sent
to Mr A. W. Blom at; e-mail:
ashley.blom@nbt.nhs.uk

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One of the most difficult problems in total hip replacement (THR) is the management of the young patient. Failure of the acetabular component is the principal cause of revision in THR.¹ Whereas newer generations of cementing techniques and improved design have increased the survival of cemented femoral components,² they have not increased the longevity of cemented acetabular components in younger patients.¹ Ballard et al³ found 36% of combined revision and radiological loosening of cemented acetabular components at a mean follow-up of 11 years, and Barrack, Mulroy and Harris,⁴ a 44% combined revision and radiological loosening rate at a mean follow-up of 12 years in patients under the age of 50 years. Boeree and Bannister⁵ noted a revision rate of 12.7% at 12 years for cemented acetabular components, with 27% of cases showing radiological evidence of failure in patients under the age of 50.

Based on laboratory evidence of bone ingrowth into a porous surface⁶ and good intermediate-term results of uncemented metal-backed polyethylene-lined acetabular components, hybrid THR with cemented femoral and uncemented acetabular components has been used increasingly.⁷⁻¹⁴ Despite early encouraging results, the long-term durability of uncemented

acetabular components in the young and active patient is yet to be proved. The aim of this study was to establish whether hybrid THR with the Harris-Galante I (Zimmer, Warsaw, Indiana) acetabular component gave improved results in the young, active population under 50 years of age.

Patients and Methods

Between February 1991 and August 1995, 70 Harris-Galante porous Type I acetabular components were implanted in 53 patients in a regional orthopaedic centre under the direct supervision of five consultants. There were 29 women and 24 men. All were under 50 years of age at the time of operation. The mean age was 40 years (19 to 49). The diagnoses before the THR are recorded in Table I. In 36 patients unilateral THR was undertaken and in 17 staged bilateral procedures were performed. In total, 56 acetabular components were implanted by consultants and 14 by senior trainees. A total of four different types of femoral component were used in conjunction with these implants (Table II).

In nine hips (six patients) prior surgery had been conducted, including three internal fixations of acetabular fractures, three containment osteotomies, one core decompression

Table I. Pre-operative diagnoses

Diagnosis	Number of hips
Idiopathic osteoarthritis	29
Developmental dysplasia of the hip	18
Avascular necrosis	8
Post-traumatic arthritis	5
Ankylosing spondylitis	3
Psoriatic arthropathy	2
Rheumatoid arthritis	1
Post-septic arthritis	1
Slipped capital femoral epiphysis	1
Spondyloepiphyseal dysplasia	1
Renal osteodystrophy	1

Table II. Cemented femoral components used

Femoral component type	Number of hips
Collarless polished tapered (Zimmer, Warsaw, Indiana)	31
Exeter (Howmedica International, London, UK)	29
Sheehan (Zimmer)	8
Charnley (DePuy International, Leeds, UK)	2

for avascular necrosis, and two cannulated screw fixations for intracapsular fracture.

The Harris-Galante hemispherical component has a commercially-pure titanium shell covered externally with a mesh of titanium fibre and has multiple holes for supplementary screw fixation. In 68 hips (51 patients) the component was inserted with under-reaming of 2 mm, and in two hips (two patients) in a line-to-line fashion. In 54 hips (40 patients) the acetabular components were secured with between two and five 4.5 mm diameter titanium screws. In 16 hips (13 patients) no screws were required. The surgical approach used was posterior in 52 hips (37 patients), transgluteal in 17 (15 patients), and transtrochanteric in one. In 43 hips (31 patients) a 28 mm femoral head was implanted, in 20 hips (15 patients) a 22 mm head, and in seven hips (seven patients) a 32 mm femoral head, in each case matched to the appropriate size of the polyethylene liner, which is held in place by a tine mechanism.

Second-generation cementing techniques were used,¹⁵ and a cemented femoral component was employed in all cases. All patients were allowed to bear full weight as tolerated immediately after their operation. All operations were performed in a vertical laminar flow enclosure, but without a body exhaust system.

All patients gave informed consent to be included in the study, and approval was obtained from the local research ethics committee. Demographic data were recorded for each patient, and clinical and radiological evaluations were carried out at three months, and then annually until the latest follow-up. Both Oxford¹⁶ and Harris hip scores¹⁷

were recorded. For the Oxford hip score (OHS) the best possible score was 12 points and the worst 60; for the Harris hip score (HHS) the best possible score was 100 points and the worst zero points. At the final follow-up, the senior author (GCB) evaluated the radiographs using the technique of Johnston et al,¹⁸ and was blinded to the operating surgeon for these patients. Anteroposterior (AP) and lateral radiographs of the hip were evaluated for the inclination of the acetabular component on the AP view, the presence of retroacetabular, marginal or screw-associated osteolytic lesions, and radiolucent lines. The femoral components were then examined for osteolysis, radiolucent lines, migration, subsidence, fracture of the component and subsidence of the cement mantle. Linear wear was also calculated, and the measurements of wear and osteolysis were corrected for radiological magnification by determination of the real and radiological size of the femoral head as described by Livermore, Ilstrup and Morrey.¹⁹ The senior author examined the final AP and lateral radiographs of the hip for the presence of radiolucent lines and osteolysis according to DeLee and Charnley²⁰ for the acetabular component, and Gruen, McNeice and Amstutz²¹ and Johnston et al¹⁸ for the femoral implant. The thickness of the polyethylene component for each combination of linear and femoral head was obtained from the manufacturers.

Radiological failure of the acetabular component was defined as a change of position either vertically or horizontally of more than 2 mm, or a 2° change in the angle of inclination taking the inter-teardrop line as a fixed landmark, as described by Massin, Schmidt and Engh.²² A radiolucent line of more than 2 mm affecting the whole interface between the acetabular component and bone was also classified as radiological failure.⁸ For the femoral component, subsidence of more than 5 mm was classified as loosening and osteolysis was defined as a radiolucent zone more than 2 mm wide.¹⁰

Statistical analysis. Survival of the acetabular component was determined by Kaplan-Meier survival analysis and presented with 95% confidence intervals (CI). Chi-squared tests were used to determine whether there were significant differences in the head size and polyethylene thickness between the failed and the surviving acetabular components. The inclination of the acetabular component was tested for normality using a Kolmogorov-Smirnov test, and a *t*-test was used to compare the inclination in the failed and surviving groups. Statistical significance was set at $p < 0.05$.

Results

The mean OHS at final follow-up was 20 (12 to 46) and the mean HHS was 81 (37 to 100). No patients died, and none were lost to follow-up.

Revisions. At a mean follow-up of 13.6 years (12 to 16), 11 hips (11 patients) had undergone acetabular revision. In total, five acetabular components were revised and six liners were changed. In two patients the acetabular component was revised for aseptic loosening, in one where it was

Fig. 1a

Fig. 1b

Fig. 1c

Anteroposterior and lateral radiographs of a patient with Harris-Galante acetabular components a) retroacetabular osteolysis is present, most marked in the right hip, b) following an initial revision in the presence of a medial wall defect, the right acetabular component has migrated into the pelvis and c) following further revision and medial wall grafting.

found not to be osseointegrated during exploration of a nonunion of the greater trochanter, and in one which was found to be loose in a patient with recurrent dislocation of the hip. The other reasons for revision were for deep infection, recurrent dislocation due to retroversion of the acetabular component and one for massive retroacetabular osteolysis (Fig. 1a). In this latter case, the component was revised to an uncemented implant which subsequently migrated into the pelvis because of a defect in the medial wall (Fig. 1b) and further revision with bone grafting to the medial wall was required (Fig. 1c).

Taking revision of the acetabular component for any reason as an endpoint, 65 of the 70 hips survived at a mean

Fig. 2

Kaplan-Meier survival graph with 95% confidence intervals taking revision of the acetabular component as the endpoint.

follow-up of 13.6 years (12 to 16), giving a cumulative survival of 94.0% (95% CI 88.4 to 99.7) (Fig. 2).

Revision of the liner. Liners were exchanged in three patients due to polyethylene wear and where the acetabular components were found to be well fixed. Two were exchanged for longer posterior wall liners owing to recurrent dislocation and one because of deep infection which was successfully treated with a radical debridement. There were no cases of dislocation of the liner.

Taking revision of the acetabular component for any reason as an endpoint, 11 (11 patients) of the 70 hips were revised, giving a cumulative survival of 84.0% (95% CI 74.5 to 93.5) at a mean of 13.6 years (12 to 16) (Fig. 3).

Intention to revise. Radiologically, another four of the 70 acetabular components require revision imminently. The first patient has a circumferential lucent zone more than 2 mm wide around the acetabular component in the presence of a worn liner, although he continues to function well with an OHS of 14 and a HHS of 86. Two patients have retroacetabular osteolysis in DeLee and Charnley zones 1 and 2, although so far there has been no migration of the component. In the fourth patient there is linear wear of 7.5 mm.

Including the additional four radiological failures, 15 of 70 acetabular components had or require revision, giving a cumulative survival or planned revision rate of 78.7% (95% CI 67.4 to 90.1) at a mean of 13.6 years (12 to 16) (Fig. 4).

Impending revision. Radiological analysis identified osteolysis around the femoral component in 27 hips (39%), the most commonly in Gruen zone 7. As osteolysis in this zone is indicative of polyethylene wear, there was cumulative survival of 55.3% (95% CI 40.6 to 70.0) at 16 years for combined actual revision, intention to revise and impending revision surgery.

Fig. 3

Kaplan-Meier survival graph with 95% confidence intervals taking revision of the acetabular component or liner as the endpoint.

Fig. 4

Kaplan-Meier survival graph with 95% confidence intervals taking revision of the acetabular component, liner and impending revision as the endpoint.

Wear, lucent lines and acetabular osteolysis. There was no identifiable linear wear in 30 hips (43%, 22 patients). One patient showed linear wear of 7.5 mm (28 mm head) and awaits revision surgery. The remaining 39 hips (56%, 30 patients) showed linear wear between 0.5 mm and 2 mm. Three acetabular components (4.3%) were revised for polyethylene liner wear. Two had a femoral head diameter of 32 mm and one of 28 mm.

Non-progressive radiolucent lines of less than 2 mm were present around the acetabular component in 31 hips (44%). Radiolucent lines around the periacetabular area of the femoral component were seen in only three hips (4%).

Osteolysis was seen around the acetabular component in 13 hips (19%), most commonly centred on the screws, and only ten hips (14%) had neither radiolucent lines nor osteolysis around either component.

Other surgery. One patient had a hindquarter amputation because of peripheral vascular disease. Before this, his hip had functioned well for six years with no evidence of radiological loosening. One patient had excision of heterotopic bone.

Failure relating to head size, polyethylene thickness and acetabular component inclination. No statistically significant difference was found between head size alone and failure of the acetabular component (chi-squared test, $p = 0.37$). The mean initial polyethylene thickness of the liner was 8.7 mm (4.3 to 15.3). In the failed acetabular components the mean polyethylene thickness was 9.0 mm, and in the surviving group it was 8.6 mm. Comparing the acetabular components which had failed with those that had survived, using chi-squared tests, there was no statistically significant relationship between the thickness of the polyethylene component and survival of the acetabular component in the 22 mm ($p = 0.792$) and

28 mm ($p = 0.479$) head sizes, but there was statistically significantly greater failure in the 32 mm head group ($p = 0.009$) with thinner polyethylene.

The mean inclination of the shell of the acetabular component in the frontal plane was 31.7° (17° to 58°). In the failed acetabular components the mean inclination was 35.2° (22° to 45°) and in the surviving group it was 32.0° (17° to 58°). The Kolmogorov-Smirnov test showed that the angles of inclination of the acetabular component were normally distributed: t -tests showed no association between component inclination and failure ($p = 0.594$).

Discussion

The results of cementless acetabular components from selective studies in patients under 50 have shown revision rates between 0% and 14% after five to nine years (Table III). This study, with its longer period of follow-up, shows significantly higher rates of revision or planned revision. The rate rises significantly ten years after implantation. Berger et al,⁷ in their series of 79 hips followed up for a mean of 8.8 years, found no cases of aseptic loosening of the acetabular component and reported a combined rate of revision and acetabular osteolysis of 13%. Similarly, Dunkley et al,²³ in a series of 55 Harris-Galante acetabular components followed up for a mean of seven years, had no cases of revision for aseptic loosening and an 18% combined rate for revision and polyethylene wear. Although the series was also from this centre, the two cohorts of patients were not the same. The patients reported by Dunkley et al²³ had surgery between 1986 and 1991.

The short- to medium-term success of hybrid THR in all age groups, with a cemented femoral component and an uncemented acetabular component, is well reported in the literature. In a series of 65 hybrid THRs by Harris¹³

Table III. Selected studies of uncemented acetabular components used in the under 50-year age group

Authors	Number of patients (hips)	Mean age of patients	Mean follow-up (yrs)	Femoral component	Acetabular component	Liner revisions	Acetabular component revisions	Other (%)
Berger et al ⁷	79	37 (20 to 49)	8.8	All Harris-Galante (uncemented except two)	Harris-Galante I	2	2 (none for aseptic loosening)	7 (7) acetabular osteolysis
Dunkley et al ²³	50 (55)	41 (21 to 50)	7	Various cemented	Harris-Galante I	4 (all 32 mm heads)	0	
Kim and Kim ⁸	55 (64)	43.4	9.4	Elite or Elite Plus (cemented)	Duraloc	0	1 due to infection	4 (6) hips had acetabular osteolysis
Dowdy et al ¹¹	36 (41)	42 (19 to 50)	5.3	Mallory-Head (uncemented)	Mallory-Head	0	3 (2 for loosening 1 for wear)	20 (49) had polyethylene wear and 12 (27) had acetabular osteolysis
Archibeck et al ¹²	91 (100)	39 (14 to 50)	9	Multilock (uncemented)	Harris-Galante II and Trilogy	5 (2 for dislocation and 2 for wear and osteolysis)	8 (2 for aseptic loosening, 1 for osteolysis, 1 for wear)	
Sporer et al ⁹	37 (45)	41 (25 to 49)	8.2	Iowa precoat (cemented)	Harris-Galante I	0	0	8 femoral components revised for aseptic loosening
Current study	53 (70)	40 (19 to 49)	13.6	Various cemented	Harris-Galante I	6	5 and 4 more planned for revision	19% acetabular osteolysis 39% femoral osteolysis

followed up for a mean of 6.6 years there were no revisions for acetabular or femoral aseptic loosening. The overall rate for revision and acetabular osteolysis was 6%. Maloney et al²⁴ reviewed 1081 primary THRs in 944 patients using Harris-Galante I cementless acetabular components with screw fixation and a mean follow-up of 81 months. The overall rate of pelvic osteolysis was 2.3%, but this was inversely related to the age at the time of operation, with 15 hips (22%) in patients younger than 50 having osteolysis at a minimum of ten years of follow-up.

Relatively few studies describe the long-term survival of uncemented acetabular components. In part this is due to regular changes in design of prostheses and the difficulties in following a cohort of patients over protracted periods. In a recent study of 93 uncemented RM acetabular components the cumulative survival with any acetabular revision as the endpoint was 82.7% at 19.8 years.²⁵ Gaffey et al²⁶ found no aseptic loosening or migration of the acetabular component in 70 hips at a follow-up of 13 to 15 years. Five had pelvic osteolysis and three had revision of a well-fixed acetabular component because of pelvic osteolysis secondary to polyethylene wear. They stated that Harris-Galante I acetabular components had less acetabular loosening than cemented Charnley components, although their rate of polyethylene wear was greater. In comparison, a 20- to 26-year follow-up of cemented Charnley low-friction arthroplasty in patients under 50 years of age showed a cumulative survival of 76% for the acetabular component for all causes of failure.²⁷ This study has a significantly longer follow-up than those in Table III, which may account for the relatively high rate of revision

of the acetabular component, planned and impending rates of revision and the high rate of acetabular and femoral osteolysis. The prevalence of femoral osteolysis (39%) in our series is significantly higher than that in earlier reports, which ranged from 9% to 12%.^{10,28,29} Because of the use of lateral radiographs and Gruen zones 8 to 14, the sensitivity of detection of femoral osteolysis may have increased. This may have been under-reported in other series, as they used only AP views and the prosthesis itself may have concealed some osteolysis. In the series by Sporer et al,⁹ osteolysis of at least 5 mm was observed in 13 hips (35%) in Gruen zone 7. This was associated with a rate of loosening of the femoral component of 24% at five to ten years in a similar population. Acetabular osteolysis with cementless acetabular components has been reported to be between 17% and 46%.⁷ In our series, acetabular osteolysis was present in 13 of 70 hips (19%). This has led to revision of one acetabular component and another three cases where revision will be required. Peri-acetabular osteolysis and in Gruen zone 7 is related to polyethylene wear and hence failure of the acetabular component, and is the main factor influencing the longevity of the acetabular component in the young population. Importantly, the OHS and HHS of the patients in this study remain good, even in the presence of significant osteolysis, suggesting that the process is silent. Highly cross-linked polyethylene and hard-on-hard bearings such as ceramic and metal-on-metal articulations may improve the longevity of acetabular components in the future, although premature failure of one type of highly cross-linked polyethylene has been reported already.^{30,31}

In this series there were no cases of dislocation of the liner, which relates to breakage of the tines constituting the locking mechanism between the polyethylene liner and the metal shell, and has been reported as a mode of failure of the Harris-Galante acetabular component.^{32,33}

A large proportion of the revisions were for exchange of the liner. Accelerated wear of the liner has been shown to be more prevalent with large-diameter femoral heads.³⁴ No statistically significant difference was found between head size alone and failure of the acetabular component in this study. Although revision of the liner is a more benign procedure than revision of the acetabular component, it has been associated with a high rate of dislocation.³⁵ In the presence of liner wear and osteolysis well fixed acetabular components should probably be revised.³⁶ There is no statistically significant difference between the surviving and the failed acetabular components with respect to acetabular inclination, although the limited number of hips in our series may not have been sufficient to demonstrate this. There was, however, a statistically significant difference in polyethylene thickness in the group with 32 mm heads, with thinner polyethylene being found in the failed components.

The best implant for the young patient requiring THR remains unresolved. Cemented acetabular components tend to fail over time by a process of aseptic loosening, and cause groin pain. High-density polyethylene-lined metal acetabular components such as the Harris-Galante rarely loosen, do not give groin pain, but do cause symptomatic silent osteolysis and loss of bone stock. Preservation of bone stock is the key objective in the young patient. This is one of the longest follow-up studies of uncemented acetabular components in patients under 50 years of age and indicates that these patients require regular clinical and radiological review so that reconstruction may be attempted before significant bone loss occurs.

The authors regret to announce the death of the first author, Matt Utting, whilst on a Fellowship in Australia. He will be sorely missed and is mourned by his colleagues.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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