Premature wear and osteolysis in an HA-coated, uncemented total hip arthroplasty

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The ABG I cementless hip prosthesis has demonstrated unacceptably high rates of wear and osteolysis in our patients. We performed a retrospective study of 97 hips implanted between 1992 and 1998. Radiographic analysis revealed high rates of wear of the polyethylene liner with marked peri-acetabular osteolysis. Clinical examination indicated that many of these patients were initially asymptomatic. Wear-related problems have required ten hips to be revised and a further 13 are awaiting revision.

This gives a failure rate of 24% at a mean follow-up of 69 months. Contributing factors are likely to include poor wear characteristics of the polyethylene liners which were gamma irradiated in air, and increased wear debris caused by a poor fit of the polyethylene liner within the shell. We believe that all ABG I implants should be immediately reviewed and remain under careful, long-term follow-up.

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The ABG I hip prosthesis (Anatomique Benoist Gerard; Stryker Howmedica Osteonics, Newbury, UK) is a cementless, anatomical design comprising an hydroxyapatite-(HA) coated titanium stem, designed for proximal metaphyseal fixation, and an acetabular component comprising an HA-coated hemispherical titanium shell with an ultra high-density polyethylene liner (Fig. 1). The implant was designed to achieve permanent bony ongrowth around the components in order to prevent access of wear particles to the bone implant interface. The initial results suggested that their aim was achieved.^{1,2}

In our hospital, the ABG I hip was used primarily in younger patients and, with time, we became increasingly suspicious that the hip was wearing prematurely. The excessive wear was often coupled with massive but clinically silent osteolysis. We undertook a retrospective review of all ABG I hips we had implanted to evaluate these impressions and collected explanted specimens at revision surgery.

Patients and Methods

We identified 85 patients (97 hips) who had undergone hip replacement using the ABG I prosthesis between 1992 and 1998. There were 51 men (56 hips) and 34 women (41 hips). Three patients with three hips *in situ* had died but are included in the survivorship analysis as withdrawals. Three patients (three hips) were lost to follow-up, but GP records were obtained and showed that the hips had not been revised and therefore were included in the survivorship analysis.

The mean age at surgery was 49 years (26 to 72) and the mean follow-up 71 months (32 to 118). Ceramic heads were used in 60 operations and metal heads in 25; in 12 cases the material was not documented. The pre-operative diagnosis was primary osteoarthritis in 75 patients, secondary osteoarthritis arising from previous developmental dysplasia in two, rheumatoid arthritis in seven and intracapsular fracture of the hip in one patient. Failure was defined as revision surgery or its recommendation (Table I).

Serial radiographs were examined for component position, alignment, fit and fill, evidence of loosening, migration of the component, wear and osteolysis. In 36 cases a radiograph had not been performed within the last 12 months. These patients were recalled and a radiographic and clinical evaluation using the Harris Hip Score (HHS)³ were performed. The site of osteolysis was recorded according to Gruen, McNeice and Amstutz⁴ for the femur and DeLee and Charnley⁵ for the acetabulum. The radiographs were then scanned and digitised, and wear was measured using a dedicated software package (Imagica; Viewtec, Saint-Maurice, France). This uses an edge detection method whereby the operator marks the margins of the femoral head and the acetabular shell. The program then calculated the centre of each component and the relative position of each, and thus any linear wear. The most recent follow-up anteroposterior (AP) radiograph was used, the lateral was not used because

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Fig. 1a

Fig. 1b

Pre- (a) and post-operative (b) radiographs of a 38-year-old female patient with a sedentary lifestyle who underwent hip replacement with an ABG 1 prosthesis.

Table I. Hips revised or listed for revision

Hip	Diagnosis*	Age	Gender	Follow-up (mths)	Revised/Listed	Component†	Reason
1	OA	65	M	102	L		Wear/osteolysis
2	OA	46	F	36	L		Wear/osteolysis
3	OA	55	F	51	R	B	Periprosthetic fracture
4	OA	44	F	96	R	B	Wear/osteolysis
5	OA	49	M	76	L		Wear
6	OA	49	M	51	R	B	Periprosthetic fracture
7	OA	54	F	88	L		Wear/osteolysis
8	OA	30	F	45	L		Wear
9	OA	50	M	60	R	B	Infection
10	OA	56	M	39	R	A	Wear/osteolysis
11	Fracture	51	F	65	R	B	Wear/loosening
12	OA	48	F	39	R	A	Wear
13	OA	52	M	89	R	A	Wear
14	RA	37	F	104	L		Wear/osteolysis
15	RA	37	F	127	L		Wear/osteolysis
16	OA	38	F	54	R	A	Wear/osteolysis
17	OA	58	M	64	L		Wear/osteolysis
18	OA	40	F	66	R	A	Wear/osteolysis
19	OA (DDH)	38	F	24	L		Wear/osteolysis
20	RA	42	F	38	L		Wear
21	OA	67	M	110	L		Wear
22	OA	67	M	90	R	A	Wear/osteolysis
23	OA	62	M	78	L		Wear/osteolysis
24	OA	38	M	82	L		Wear

* OA, osteoarthritis; RA, rheumatoid arthritis; DDH, developmental dysplasia of the hip

† B, both; A, acetabulum

Table II. Lifetable analysis of survivorship

Follow-up (yrs)	Number of hips/year	Failure	Withdrawn	Number at risk	Annual failure rate (%)	Annual success rate (%)	Survival rate (%)	95% CI limits
0 to 1	97	0	0	97	0.0	100	100	98 to 100
1 to 2	97	1	0	97	1.0	99.0	99.0	97 to 100
2 to 3	96	1	1	95.5	1.0	99.0	98.0	95 to 100
3 to 4	94	4	0	94	4.2	95.8	94.0	89 to 99
4 to 5	90	2	2	89.0	2.2	97.8	92.0	87 to 97
5 to 6	86	3	0	86	3.5	96.5	88.8	83 to 94
6 to 7	83	3	0	83	3.6	96.4	85.6	79 to 93
7 to 8	80	4	0	80	5.0	95.0	81.3	73 to 90
8 to 9	76	3	0	76	3.9	96.1	78.1	70 to 86
9 to 10	73	1	0	73	1.4	98.6	75.9	67 to 86
10 to 11	72	1	0	72	1.4	98.6	74.8	66 to 84

the rotation of the films was found to be variable. The initial baseline for the wear measurement was taken as zero for all hips, the centre of the head of the femoral component being assumed to be exactly in the centre of the acetabulum on the first post-operative film. The software used the diameter of the femoral head (28 mm) to calibrate magnification. Each measurement was repeated five times for each radiograph by the same observer (PD) to reduce intra-observer error. This method is similar to that used in other studies of wear in cementless hips.^{6,7}

Intra-operative and post-operative complications were recorded. Any adverse symptoms (particularly pain) were recorded at the most recent clinical review. Outcome data were tested for normality and Spearman correlation co-efficients calculated using SPSS 10.0 software (SPSS, Chicago, Illinois). Wear was compared with the pre-operative diagnosis, the presence of osteolysis, the duration of follow-up, gender, age at implantation, the thickness of the polyethylene, the position of the component and the nature of the femoral head. Survival analysis was carried out using a life-table, excluding the patient revised for infection, and confidence intervals (CIs) were calculated using the formula given by Peto⁸ (Table II).

Results

All implants rapidly became integrated within bone; there was no macroscopic migration of components until failure occurred. The mean inclination of the acetabular cup from the horizontal plane was 52.5° (35 to 66); 83 femoral components were at neutral, two were in valgus and 12, varus. The mean deviation from the femoral long axis was 4° (2 to 8). Fit and fill was assessed by how well the implant abutted the cortices of the proximal femur at two levels on the AP radiograph; it was satisfactory in all cases.

Eleven hips have been revised in six women and five men; six for gross wear or acetabular osteolysis, two for a peri-prosthetic femoral fracture through an osteolytic lesion, one for loosening of the femoral component and one for infection. Thirteen hips are awaiting urgent revision because of osteolysis or wear, to the point at which failure was

deemed to be imminent. Excluding the infected case, 23 of 97 hips (24.0%) have failed due to osteolysis or wear at a mean follow-up of 69 months. (Table I). There was little difference in revision rates between the four operating consultants (20% to 28%), although slight variation in wear rates for their implants was seen. There was no marked demographic differences between patient populations for each of the surgeons. The overall survival of the prosthesis was 74% (CI 64 to 82) at ten years (Fig. 2).

The mean HHS in the 36 patients summoned for radiographic and clinical assessment was 92 (40 to 100); 13 of these had marked wear and osteolysis. In this sub-group of 13 patients, the mean HHS was 81 (22 to 91), the pain score 38 (10 to 44) and the function score, 43 (19 to 47). This indicates that hips with significant wear and osteolysis may remain asymptomatic. The mean wear rate for all hips was high: 0.32 mm/year (0 to 0.95) and 0.45 mm/year (0.12 to 0.95) for those hips awaiting revision or revised. The mean intra-observer variation for wear measurement was 0.11 mm (zero to 0.53). The highest rates of wear were seen in the thinnest polyethylene liners, but were high in all liners

Fig. 2

Graph showing the overall survivorship of the prosthesis as 74% at ten years.

Table III. Liner thickness and wear rate

Depth (mm)	4	5	6	7	8	9	10	11	12	14
Number	2	3	13	12	17	16	21	8	4	1
Wear (mm/year)	0.8	0.54	0.32	0.30	0.29	0.27	0.26	0.33	0.29	0.40

(Table III). All liners associated with osteolysis showed wear, although the converse could not be demonstrated. Osteolysis of the femur was not associated with excessive wear of the liner.

Discussion

The HA coating and design of this prosthesis promotes rapid fixation in bone. Only when massive osteolysis occurs does the prosthesis become loose. In our series ABG I hips have been shown to wear excessively in some patients, who have massive but often clinically silent osteolysis. Creep deformation of the liner due to its visco-elastic properties may account for some of the linear penetration of the femoral head in the first year or so, which is about 0.1 mm in the first million cycles of use.⁹

Measurement of wear was undertaken on AP radiographs only, because lateral films were either missing or of poor quality. This technique may underestimate total wear, as it only accounts for wear in the coronal plane. In addition, as radiographs are not routinely taken of the patient bearing

weight, further underestimation of wear may have occurred.¹⁰ Polyethylene particles liberated from a prosthesis showing wear have been shown to elicit a biological reaction, resulting in osteolysis,¹¹ and the smaller the particle, the greater the reaction.¹² The human cells used in the latter study varied widely in their biological response to particles of the same size. This may explain the presence of wear without osteolysis in some individuals. For the last eight revisions, explanted components have been retained for use in a further study.

Initial particle size analysis from these implants using a laser diffraction technique (Malvern Mastersizer 2000; Malvern Instruments Ltd, Malvern, UK) shows a mean particle size of less than 1 μm , which is smaller than those from cemented (Charnley) hip revisions. Retrieved implants macroscopically showed wear at the head-to-liner articulation (Fig. 3), suggesting that most of the wear debris originated here. However, the liners were also demonstrably loose within the acetabular shell, with marking of the back of the liners from the screw holes suggesting 'backside wear'. Some explanted liners have shown evidence of crack-

Fig. 3a

Fig. 3b

a) Radiograph of the patient in Figure 1 at four years and six months follow-up. There is marked eccentric wear, osteolysis and dissolution of the medial wall of the acetabulum (arrows). A large, soft-tissue granuloma was encountered at revision surgery. b) The explanted polyethylene liner at revision, showing eccentric wear at the superior margin of the socket.

ing as well as excess wear. Excess polyethylene wear has been shown to be associated with metal backing of the acetabular component, but this may, in part, be because the liner has to be thinner inside the metal backing.^{7,13} All these secondary sources of wear generate further submicron-sized wear particles, capable of causing osteolysis.^{14,15} Femoral component fit and fill was satisfactory in our group. The relative acetabular abduction (mean 52.5°) was not significantly related to wear in our study.¹⁶

Other work on uncemented, metal-backed cups has demonstrated increased contact stresses at articular surfaces and backside wear associated with an increased acetabular angle.¹⁷ No difference in mean wear was seen between ABG ceramic and CoCr heads, which were both 28 mm in diameter, confirming the recent work of Kim, Kim and Cho.¹⁸ All ABG I polyethylene liners have been gamma irradiated in air, which has been shown to cause increased oxidative degeneration and impair its wear properties.^{19,20}

The pressure in a joint is higher following arthroplasty than in a normal joint.²¹ The multiple holes in the ABG I shell extend the effective joint space up to what is effectively exposed cancellous bone. Wear debris, therefore, has ready access to the cancellous bone where the resultant inflammatory reaction may lead to osteolysis. The pressure in a joint increases markedly during activity, which might increase the rate of osteolysis by the mechanism described above.²¹ It is unclear, however, why wear should be occurring in some patients and not others. Our patients were a selected 'young' population with a mean age of 49 years. Patient activity is generally higher in younger patients and this has been shown to correlate with wear.²² However, this overall higher activity does not explain the wide variation of wear seen in our patients. It is possible that those wearing most rapidly were exceptionally active, and yet some failures occurred in apparently less active patients (Figs 1 and 3). It is not possible retrospectively to assess the activity levels of any given patient over the lifetime of the implant. This study did not show correlation between age at implantation and wear, but did correlate duration of follow-up with wear. Some younger patients showed little measurable wear over a prolonged period.

We are aware of good medium-term results of the ABG hip published in the European literature.¹ We also note the recent publication of follow-up results on a series of 71 ABG hips in UK patients.²³ Although clinical results were good, as in our patients, eccentric wear of the polyethylene was seen in 60% of hips. At mean follow-up of 4.8 years, total wear varied between 0.4 and 4 mm and wear rate between 0.063 and 0.76 mm/year. No comment was made on the presence or absence of acetabular osteolysis. Our patients seem to be broadly similar to that series with similar, varied wear rates. We suggest careful review of all ABG implants clinically and radiologically with particular reference to polyethylene wear and the initial subtle changes of acetabular osteolysis. Optimal radiographs should include a weight-bearing AP and good-quality, lateral views.

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