Early Polyethylene Wear and Excessive Acetabular Granuloma in an Uncemented HA-Coated Total Hip Arthroplasty—Midterm Results of a Prospective Study

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Abstract This is a prospective review of 135 HA-coated ABG I total hip arthroplasty (THA) systems with a mean clinical and radiographic follow-up of 8.5 years. The 5-year survival rate was 85%, but 22% of the patients were dissatisfied. Revision THA was already indicated in 28% of the patients, with 26% indicated for cup loosening. PE wear was detected by x-ray in 42%. Disproportionate substantial wear with an average linear loss of 2.6 mm at the inner rim of the insert was observed in 23% of the cases. The mean annual wear rate was calculated 0.1–0.25 mm/year. Laboratory examination of the retrieved PE revealed polishing, cracks, and subsurface delamination. Radiographic evidence of acetabular cysts were found to be excessive granuloma during surgery. Polarization microscopy revealed debris particles phagocytized by reticuloendothelial cells. Results confirm the general opinion that aseptic osteolysis is a cell-mediated process driven by the presence of particles generated from wear debris. The findings also suggest that the main reasons for the failure of the first-generation ABG hip system were an insufficient locking mechanism and poor PE congruency, and not solely poor PE quality.

Key words cement-free total hip arthroplasty · THA · polyethylene · wear · osteolysis · loosening · revision · ABG I

Introduction

Excellent results for the cementless ABG I system (Anatomique Benoist Giraud, Howmedica) have been reported by the international multicenter ABG research group, with moderate levels of revision rates and high Harris hip and Merle d'Aubigné scores reported in the literature [1–15]. Despite the mostly favorable clinical outcome at early and mid-term follow-up, some authors express concern regarding the high rate of PE wear, reported at 60–100% [12, 13, 16–18]. The primary suspected reason for excessive PE wear inducing osteolysis, especially at the acetabular site, is the friction pair and associated occurrence of debris [19–22]. Concomitantly, there is an international consensus that aseptic osteolysis is a cell-mediated process driven by the presence of wear debris particles [21].

The ultrahigh-molecular weight polyethylene (UHMWPE) used in the ABG I system has been extensively enhanced as a result of reports about wear and accelerated aging [31, 32]. The modified processing and radiation sterilization in nitrogen with postannealing led to amplification of the PE cross-linking and reduction of potential degradation in the ABG II system. Various risk factors were excluded. The inserts were thickened and had improved UHMWPE. The internal shell surface was polished and the congruency was improved. The metal-back was free of holes to reduce backside wear and migration of particles.

This prospective study was originally designed to accompany the clinical and radiographical outcome evaluation of consecutive cement-free ABG I system THA beginning in 1992. In the course of time, unexpected complaints and surprisingly high rates of radiolucent lines and cyst formation led to a systematic evaluation. A correlation between these clinical findings and polyethylene wear leading to cup loosening was suspected. To prove this hypothesis, the study was directed to assess the amount of radiographic wear and to relate wear to various individual factors and to intraoperative and laboratory findings.

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Reflecting the literature and the recent improvements in ABG II, it became necessary to investigate if wear was actually caused by poor design of the ABG I implant or if there was any other predominant reason, such as cup positioning.

Patients and methods

A total of 148 consecutive cases of primary ABG I total hip arthroplasty were prospectively controlled for up to 13 years. Eleven patients died before a minimum follow-up of 5 years was attained, and two patients refused follow-up examination for personal reasons. These cases were excluded from the evaluation. The mean follow-up period for the remaining 135 patients was 8.5 years (5–13 years). The preoperative diagnosis was primary osteoarthritis in all cases, except for two younger patients who had developmental dysplasia of the hip. The mean age of the 72 male patients included in the study was 55 years (43–70 years). The 63 female patients were slightly older, with a mean age of 59 years (43–78 years). Mean body mass index was 29 (26–35) for women and 28 (24–34) for men, and mean height was 169 cm (155–179 cm) for women and 178 cm (165–198 cm) for men. Eighteen patients had both hips replaced (but not simultaneously). Sufficient clinical and radiographic follow-up could be obtained for 111 prostheses. Twenty-four cases were excluded from evaluation as a result of perioperative complications unrelated to the implants. Some were attributable to an accident, noncompliance, or poor quality of externally provided radiographs and other data.

All patients underwent operation after painstaking preoperative planning by using templates and proportional radiographs (scale 1:1.5). A standardized anterolateral approach was performed, followed by total capsulectomy. To prevent rotation of the acetabular component, two spikes or two screws were routinely inserted. For most cases, the zirconium version of the femoral head with a 32-mm diameter was chosen as the standard. In only 15 cases was a diameter of 28 mm preferred because of a small shell size, between 44 and 48 mm. The 42-mm insert was not used and the 62-mm insert was used only once. The size of 88% of the implanted shells ranged 48 and 58 mm. Femoral overreaming was also routinely performed. Subjects were instructed to use partial weight bearing with two crutches for at least 6 weeks.

Clinical follow-up focused on the assessment of articular function, pain, mobility, and walking ability, as reflected by the Merle d'Aubigné scoring system that was applied pre-, peri-, and postoperatively. The patients were asked to classify themselves as either content or dissatisfied with the outcome of their THA.

A radiographic analysis was regularly performed via anteroposterior pelvic and lateral x-rays. Evaluation of the stem was based on the zonal scheme of Sarmiento and Gruen [24], whereas the cup was judged according to the system of DeLee and Charnley [25].

The unidirectional PE wear at the cranialateral inner circumference of the insert (x) was determined by measuring the cranial (a) and the caudal (b) thickness of the PE layer between the outer circumferences of the artificial femoral head and of the insert in the acetabular plane (Fig. 1).

$$x = (b - a)/2$$

$$x > 0 (b > a)$$

The craniomedial rise of the femoral head toward the center of the insert consequent to wear (y) was measured as the distance between the center of the head and opening plane of the cup.

The ensuing three-dimensional drift of the prosthetic head (R) was taken into account via the method described by Scheier and Sandel [23].

$$R = \sqrt{(x^2 + y^2)}f$$

$$R > 0 (x, y \neq 0)$$

The original method implies a proportionality factor f , so that R expresses the amount of wear as a vector of a certain length. This equation, however, is based on the assumption that all x-rays were taken exactly from the same angle and distance. As this standard cannot always be guaranteed, it is far more accurate to express wear as a dimensionless value R expressing the relation of measurable distances in any x-rays of unknown parameters. Hence, units were deliberately suppressed to reduce the risk of falsification due to a flaw projection. This, naturally, made the use of f unnecessary.

$$R = \sqrt{(x^2 + y^2)}$$

$$R > 0 (x, y \neq 0)$$

Accordingly, the unidirectional PE wear at the inner circumference of the insert is more precisely expressed by an equally dimensionless value (A).

$$A = a/b$$

$$A < 1 (b > a)$$

Fig. 1. Radiographic wear analysis, a modified method of Scheier and Sandel

Hence, the loss of substance at the PE insert through wear is illustrated by approximating R ($R > 0$) and A values ($A < 1$).

The postoperative position of the components and possible migration was scrutinized as suggested by Johnston et al. [26]. Besides, radiographic evaluation concerned signs of osseous remodeling, sclerosis, cancellous and cortical thickening, lysis, cysts, radiolucent lines, subsidence, and loosening.

Results

Three of 135 cases became infected, and one case had recurrent dislocation requiring revision shortly after primary implantation. One patient had to undergo revision of both replaced hips because of an accident. In 18 cases, radiographic follow-up was insufficient for various reasons. These cases were excluded from evaluation. In total, 111 patients were fully tracked.

Clinical follow-up revealed that after 5 years 25 patients (22%) were dissatisfied with the outcome of their THA, whereas only 8 patients (7%) had stated their dissatisfaction 1 year after the operation. Although the Merle d'Aubigné score had improved from 8 points (range, 6–12 points) preoperatively to 16 points (range, 5–18 points) at the longest follow-up, there were as many as 40 patients (36%) who complained about their hips at a mean follow-up of 4.8 years.

The *survival rate* of the ABG I system at 5 years was 85%, with 17 revisions being performed. In 31 cases (28%), revision surgery was either performed or at least indicated after the last clinical and radiographic review with a mean survival age of 5.2 years (range, 1–10 years; $SD=2.46$). In 29 cases (26%), there were radiographic signs of loosening of the cup. These included radiolucent lines, bone resorption, or important cystic formation. In 7 cases (6%), the stem needed to be exchanged, but only 3 cases indicated subsidence of the stem as the primary reason for revision.

Radiographic evaluation at the time of the last follow-up showed 47 (42%) of the reviewable 111 x-rays to have a decentralized head, suggesting substantial PE wear. In 26

Fig. 2. X-ray, 5 years: AP view of the hip demonstrating wear with cranial translation of the prosthetic head and excessive osteolytic cyst in the acetabular bone socket.

cases (23%), R value exceeded the benchmark of 0.2, with an average of 0.3. In addition, the mean A value of 0.7 described excessive dimensions of wear as well (Table 1). Accordingly, the mean eccentric wear in these cases measured 2.6 mm. Additionally, vast acetabular cysts were repeatedly observed (Fig. 2). Wear was radiographically detected in 20 of the 29 cups, with radiographic signs of loosening and in two of the three subsided stems. The mean annual wear ranged between 0.1 and 0.25 mm/year.

In the AP plane, 55 of all 111 acetabular components showed a lateral opening of $40 \pm 10^\circ$, known as the Lewinnek safe zone of inclination [27]. To the same extent, 56 cups were implanted with an angle of more than 55° . Anteversion of the cup could not be adequately calculated as the anteroposterior tilt of the pelvis was usually unknown. Thus, implantation within the safe zone of $15 \pm 10^\circ$ of anteversion could only be grossly estimated.

Of all 55 cups implanted within the safe zone of inclination, 17 (31%) displayed PE wear. For 8 of them

Table 1. Synopsis of results

Cup inclination	45±10° (N=55)		>55° (N=56)		Total (N=111)		
	$R \neq 0$	$R \geq 0.2$	$R \neq 0$	$R \geq 0.2$	$R \geq 0$	$R \neq 0$	$R \geq 0.2$
PE wear	17 31%	8 15%	30 54%	18 32%	111 100%	47 42%	26 23%
x (mm)	—	—	—	—	0.8	1.9	2.6
A value	—	—	—	—	0.9	0.78	0.7
R value	—	—	—	—	0.09	0.22	0.3
Loosening (revised)	16 (11) 29% (20%)	—	13 (9) 23% (16%)	—	29 (20) 26% (18%)	—	—
Revision indicated	—	—	—	—	31 28%	—	—
Satisfied	—	—	—	—	25 22%	—	—

Fig. 3. Substantial PE wear: articular gap formation

(15%), the R value was greater than 0.2. For the other 56 cups with an opening angle of more than 55° , this ratio was 30 (54%) and 18 (32%). Eleven cups (20%) in the first group and 9 cups (16%) in the second group turned out to be loose. No correlation regarding anteversion, age, or sex was found. No connection was verified regarding the in situ time of the prosthesis.

The *intraoperative findings* at revision surgery provided evidence of the radiographically diagnosed wear in all cases. The wear disclosed at the PE insert was even greater than the x-rays had suggested. Inserts that were explanted after 6 years showed a loss of material at the inner circumference, resulting in a gap of several millimeters as to the prosthetic head that was analogously floating (Fig. 3). Articulation of the artificial head with inserts retrieved after 10 years displayed gaps of up to 5 mm. A secondary bearing surface was often present, worn out of the cranial PE wall by the

Fig. 5. Intraosseous granuloma penetrating metal back holes and spreading under the PE insert

unstable head constantly switching the center of rotation. Macroscopically, the PE and also some of the zirconia heads showed dull reflections in areas of maximal weight bearing and of presumable high friction. PE at the rim and at the bottom of the insert often appeared discolored and brittle (Fig. 4). The articular surface was polished in some areas, and in others it showed subsurface delamination as a typical response to milling and shoving forces. Signs evocative of deformation were only present in specimen that equally showed extensive wear with consequent formation of a secondary center of rotation. Multiple cracks were repeatedly found, especially on the rim of the insert. Asymmetric cold flow of PE was predominant near the holes in the metal back, where backside wear was also present.

Fig. 4. PE insert looking brittle in the rim, showing multiple continuous cracks, local polishing, and subsurface delamination in the articular surface

Fig. 6. Specimen of granuloma and synovial tissue

Acetabular cysts seen on x-ray turned out to be excessive intraosseous granuloma (Fig. 5) that had edged out the trabecular bone. In part, granulation tissue was also present within the holes of the metal shell spreading under the insert (Fig. 6). For the few cups that did not appear loose at first sight intraoperatively, fixation was at least questionable and/or at stake, as the granuloma left only punctually the osseous support intact.

The *histomorphologic aspect* of granulocytes, lymphocytes, and macrophages indicated an inflammatory character of the tissue. Finally, polarimetric microscopy revealed abundant PE particles surrounded by a few giant cells (Fig. 7).

Discussion

Most of the reports dealing with THA using the ABG I system are based on European multicentric studies that started in 1989 and 1990 [10–13]. Early results reflected an excellent clinical outcome. Most patients were satisfied. As a new anatomic hydroxyapatite-coated stem design was introduced, the scientific interest for remodeling changes at the femur became predominant. Radiographic analysis after 5 years produced mainly favorable results regarding the metaphyseal ingrowth and the general response of the bone to the implant [5, 10, 11, 13]. Reactive lines were only observed around the non-HA-coated zones of the implant, and proximal stress shielding was reported to be rare or moderate. The Swedish and Finnish hip registries showed a high rate of survival of the ABG I hip system, but did not monitor pain or osteolysis [14, 15]. With time, concern was expressed by some authors about excessive polyethylene wear and osteolysis they had observed after an average of 5 years with the ABG I system [12, 16–18]. The 10-year French multicenter study group reported 17% of osteolysis in their collective of 294 patients [12]. Just recently, the British group around P. Duffy touted “unacceptably high rates of wear and periacetabular osteolysis” in a retrospective review of 97 ABG I hips, culminating in a failure rate of 24% at a mean follow-up of 69 months [28].

Although several reports exist about the issue of PE wear initiating osteolysis, the consequences are mostly

described as asymptomatic. Those observations were disturbingly different when compared to this prospective survey of 135 patients with pain being an indicator for subsequent revision. In this study, almost one-fourth of the patients developed complaints within 5 years. The majority were highly satisfied at the earlier follow-up. The main concern was the rate of cup loosening of 26% after an average of 5.2 years. The stem itself caused revision in only 3 cases, and was actually exchanged in 7 cases (6%). The 5-year survival rate was only 85%, with a 15% rate of revision being done before then. However, revision was indicated in 28% at that point, which points to an actual survival rate of only 72% after a mean follow-up of 62 months. These data essentially correspond with those published by Duffy.

Other authors report survival rates of more than 95% at the same point [17, 18]. They also infer an excellent clinical outcome determined by high ranking improvements of the Merle d’Aubigné score of 16 or 17 points at the latest follow-up. The mean Merle d’Aubigné score in this study was likewise 16 points at the latest follow-up, but the clinical outcome was hardly excellent. Revision was primarily performed because of persistent pain in cases of obvious migration, subsidence, or loosening, but also if wear was excessive and radiolucent cysts suggested lytic destruction of the acetabular socket. Under the recurrent impression of excessive intraoperative findings, revision was gradually indicated at less striking radiographic changes. Yet it revealed a hardly less alarming morphology.

The clinical follow-up was marked by redundancy of a typical constellation: a patient complaining of pain only a few years after THA with radiographs that suggested a cup highly indicative of loosening with a broad cystic formation in the acetabular socket; a decentralized head was regularly encountered; and values of both *R* and *A* deviated remarkably from normal levels. These radiographic findings per se describe a dislocation of the center of rotation with a consequent excentric shift of the axes of movement, which may also contribute to all kinds of mechanical problems

Fig. 7. Polarization microscopy (200× amplification): PE particles surrounded by cells of the reticuloendothelial line

that, for example, may secondarily lead to loosening. Plastic deformation along with wear can be causative factors. Yet, the latter obviously produces bone resorption and enhances the proliferation of granulation tissue, whereas deformation does not. In this study, wear was regularly detected intraoperatively as well as granuloma within areas of osseous defects. Also, laboratory findings did not suggest higher rates or degrees of deformation.

The rate of radiographically detected PE wear was 42% at a mean follow-up of 7 years, with a rate of severe wear ($R > 0.2$) of 23% and a mean eccentric measurement of 2.6 mm. These results match those published by Nourissat in 2000 [12], after an interval of 10 years. He reported measurable wear in 75% and excessive wear in 22% of the study population, which he estimated as 1.3–3 mm. Moreover, he found corresponding high rates of osteolysis, which were particularly visible from the fifth year onwards.

The mean annual wear of the first-generation ABG I modular cup in this study ranged between 0.1 and 0.25 mm/year. As wear may well be present, but not perceptible, on x-rays, the true ratio is likely higher. This is based on those cases showing wear of any dimension, rather than to the smaller one, which is related to the entire collection. Recent reports confirm annual wear rates of 0.24 [18] and 0.25 mm/year [17] for ABG I, contradicting previously published data that reported much smaller rates [12].

The intraoperative findings underline the importance of regular radiographic follow-up as destruction of the PE inserts and the bone in some cases were disastrous. The results confirm that wear in vivo exceeds its radiographic appearance as previously pointed out by other authors [3, 17]. This supports the thesis that, despite the use of the proportional factor, measurements are often incorrect. Correspondingly, bone loss is often underestimated, as it becomes radiographically perceptible only beyond the threshold of roughly 30%. Even if some of the cups were not completely loose intraoperatively, indication of revision surgery was strengthened by the detection of massive acetabular osteolysis gathered by granuloma that was also often present in the screw holes and extended between the shell and the insert.

Cold-flow, backside wear, polishing, cracks, scratching, and other aging marks found on the explanted PE liners indicate tribological problems and a poor fit of the insert within the shell. The capture mechanism leaving perceptible scope to the liner in the shell is to be considered a serious problem in this context. The literature reflects these conclusions based on similar findings [28].

In this series, the occurrence of radiographically detectable wear was almost twice as high in the group of cups that were implanted with an inclination of more than 55° than in the group of cups within the safe zone of Lewinnek. Still, with an inclination of $45 \pm 10^\circ$, patients with detectable wear accounted for 31%. After all, the rate of cup loosening differed only slightly between groups. Different degrees of anteversion had no influence on the results. Obviously, a steep position of the cup enhances the emergence of wear, but this cannot be the sole reason. A positive correlation between wear and the time after

implantation could be established. Yet, other commonly cited risk factors for wear [29] were not corroborated by this study. There were none regarding the patient's age, weight, height, or sex. It must be noted that patients in this study were rather young and tall, which may be possible contributing factors on the occurrence of wear. On the other hand, they were not extremely heavy and their usual level of activity was low. Still, these findings are in line with results in recent reports [17, 18].

The redundant use of big 32-mm zirconia heads and, as a consequence, relatively thin inserts in this study may be of importance. Skyrme et al. (unpublished data) found a higher wear rate for this combination than with smaller heads and thicker inserts. Still, the predominant factors for the failure of ABG I must be the material characteristics of the first-generation PE gamma irradiated in air and an insufficient fit of the liner within the shell [28]. The polishing of the articular surface noted in several specimens suggests low resistance to adhesive wear [30]. Wear debris particles of significant size and amounts were detected histologically. Subsurface delamination discovered in the weight-bearing areas indicates premature material fatigue. Cracks in the rim as well as asymmetric cold flow relative to the screw holes were attributable to stress and strain likely caused by the unstable connection of the insert and the metal back.

Laboratory and clinical findings demonstrate lower wear rates for the ABG II system [2, 33]. Our own short-term experience with only a small cohort of patients underlines the probability that the tribological problem has been successfully encountered. Long-term results of the ABG II system should be compared to the findings of this study, as various risk factors have been excluded. The formation of debris and the incidence of wear still need to be observed carefully.

Conclusion

It must be assumed that in former studies the solitary proof of wear had no significant influence in the concluding valuation of the outcome, if patients were content and clinical scores had adequately improved. The experience with this prospective study suggests that early radiographic signs of wear should be taken as first indicators of the onset of aseptic loosening. This should be seen as a serious warning of destruction of the bone stock. Revision should not unnecessarily be postponed as the situation encountered intraoperatively is often worse than predicted, and the cup replacement only becomes more complicated. Results of this study point out the serious problem of backside wear in a first-generation PE liner that suffers from an insufficient locking mechanism and poor congruency with the metal cup.

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