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POOR SURVIVAL OF ABG I HIP PROSTHESIS IN YOUNGER PATIENTS

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Background: Hydroxyapatite coated (HAC) hip implants have been used in clinical practice for more than two decades. However, the majority of studies have reported only intermediate term outcomes that are not reliable for predicting long-term behavior in all implants. The aim of this study was to determine the performance of HAC total hip arthroplasty in younger patients over a 10-year follow-up period.

Methods and Results: This was an observational retrospective study of a 137 consecutive hips with the ABG I prosthesis. Of these, 128 were available for the last investigation. Median duration of follow-up was 10.9 years. The mean age at time of index surgery was 46±6.7 years. Probability of implant survival was estimated using the Kaplan-Meier method. The overall 12-year cumulative survival was 0.55 (95% CI, 0.443-0.659). Periprosthetic osteolysis (57 %) was the most frequent reason for failure followed by aseptic loosening (28 %). When only aseptic loosening was included in the analysis, the same figures for cup and stem were 0.873 (95% CI, 0.808-0.938) and 0.992 (95% CI, 0.976- 1.0), respectively. Patients with a smaller cup size were those at high risk for revision due to wear-related complications (odds ratio, OR=4.3; 95% CI, 1.734-10.555).

Conclusion: This study reports one of the poorest 12-year survivorship data for cementless acetabular component in the literature. The main reason for premature failure was osteolysis, strongly related to high wear rate of polyethylene.

INTRODUCTION

Hydroxyapatite coating (HAC) was introduced into clinical practice in the 1980s in order to improve the fixation quality of cementless total hip arthroplasty (THA). In support of this concept, a number of studies were conducted at a preclinical level showing effective osteo integration despite the evidence for initial interface gap or instability as a direct result of HAC influence[1]. However, the published clinical results have not been consistently favourable, especially in regard to the cups[2, 3]. Concerns relate to variables conjoined with the HAC such as thickness, porosity, crystallinity, chemical and physical stability while others associate to design and/or material features as well as to patient and surgeon factors.

The ABG I prosthesis was designed in the mid-eighties as a press-fit hemispherical cup and anatomical stem with HAC. Marketing began in Europe in 1989 and in the Czech Republic in 1993. The first studies on this implant reported mid-term results that were highly affirmative[1, 4]. However, ourselves and others have found poor results for ABG I prostheses that failed predominantly due to high wear rate of polyethylene (PE) with early development of periprosthetic osteolysis (OL)[5-7].

The purpose of this paper was to present a 12-year survival analysis for a consecutive series of ABG I hips with special attention to the reasons for their failure.

PATIENTS AND METHODS

Patients

One hundred and twenty seven patients (84 women and 43 men) with 137 hip joints were consecutively operated on at a single institution (Olomouc, Czech Republic) from 1994 to 1995. Mean age of the patients at the time of the index procedure was 46.5 years (range, 21 to 65 years, SD 6.7). Preoperative diagnoses are shown in Table 1. The majority of dysplastic hips (90 %) were Hartofilakidis type I[8], the remaining ones were type II.

All procedures were performed by four experienced surgeons via an anterolateral approach. Patients were protected from weight-bearing with crutches for the first four weeks which was followed by a period of partial bearing as tolerated and full loading was permitted twelve weeks after the surgery. All patients had routine perioperative antibiotics and prophylaxis against thromboembolic disease using subcutaneous heparin.

The local ethics committee approved the study protocol and all revisions were performed under standard conditions with the written informed consent of the patients.

Prosthesis

The Anatomique Benoist Girard (ABG, Howmedica, Inc., Staines, England) hip prosthesis was used in this study[4]. Fixation was achieved initially by press-fit which

Table 1. Shows the relationship between the size of the cup and primary diagnosis. *OA- osteoarthritis; D- dysplastic hip; T- traumatic hip; AVN- avascular necrosis of the femoral head; IA- inflammatory arthritis; SCFE- slipped capital femoral epiphysis.*

		Cup size [mm]									Total
		46	48	50	52	54	56	58	60	62	
Primary diagnosis	OA	0	5	13	11	11	7	9	3	1	60
	D	6	13	13	14	3	1	1	1	0	52
	T	0	0	1	3	4	2	0	0	0	10
	AVN	0	1	1	2	2	1	0	1	0	8
	IA	0	1	1	2	0	0	0	0	0	4
	SCFE	0	0	1	1	0	0	0	1	0	3
Total		6	20	30	33	20	11	10	6	1	137

Table 2. Technical details of ABG prosthesis. *Appr.= approximately, NA = not assigned.*

Characteristics for cup/ ball	Report	Characteristics for stem	Report
Cup alloy	Titanium Alloy (Ti-6Al-4V)	Stem alloy	Titanium Alloy (Ti-6Al-4V)
Geometry	Hemispherical	Geometry	Anatomical
Holes	12 holes for spikes	Fixation	Press-fit
Fixation	Press-fit	Proximal part	Macro-relief scaled surface
Surface roughness	Ti/HA (Ra=appr. 6μm)	Coating	Composite
Coating	Composite	Details of coating	1st layer: pure titanium 2nd layer: $Ca_{10}(PO_4)_6(OH)_2$
Details of coating	Identical to stem	Distal part	Grit blasted (Ra=appr. 2.6 μm)
Polyethylene (PE)	Hostalen GUR 4150	Thickness of coating	Appr. 0.070 mm
Manufacturing	Ram-extrusion	Porosity	2% (maximum)
Sterilization	Gamma irradiation in air	Pore size	NA
Design	Standard or hooded	Thickness of HA layer	0.06 ± 0.01 mm
Locking mechanism	Central plug, snap fitting	Crystallinity of HA	Range from 98% to 99%
Thickness of the PE	Range from 5 to 13 mm	Purity of HA	More than 99.99%
Head material	Co-Cr alloy or zirconia	Tensile strength of HAC	Range from 62 to 65 MPa
Head diameter	28 mm	Shear strength of HAC	NA

was followed by osseous integration mediated by HAC. At the time of surgery, available were cup sizes ranging from 44 to 62 mm and stems of 9 sizes. In all of the hips a 28-mm femoral head made from cobalt-chromium alloy was inserted. The PE liner was ram-extruded from Hostalen GUR 4150 and air-sterilized with 25 kGy gamma irradiation, and then placed in oxygen-permeable packaging. The PE thicknesses ranged from 4.9 to 12.9 mm. Details of the ABG I design are presented in Table 2.

Clinical and radiographic analysis

Clinical and radiographic evaluation was performed preoperatively and then 3, 6 and 12 months postoperatively. Although regular follow-ups at one or two-year intervals were planned for all patients, the compliance was poor. As part of the purpose of the current study, our local register was scrutinized for patients avoiding routine follow-up. Those were contacted and invited for clinical and radiographic examination. This included a

Table 3. ABG I survival at 5, 7, 10, and 12 years with different end points; *95% confidence intervals for each value are in the bracket.*

Follow-up Interval	Any revision	Worst-case scenario	Osteolysis	Cup loosening	Stem loosening
5 years	0.951 (0.916-0.986)	0.951 (0.916-0.986)	0.988 (0.970-1.0)	1.0 (0.988-1.0)	1.0 (0.988-1.0)
7 years	0.825 (0.760-0.890)	0.825 (0.760-0.890)	0.887 (0.832-0.942)	0.978 (0.951-1.0)	0.992 (0.976-1.0)
10 years	0.704 (0.626-0.782)	0.704 (0.626-0.782)	0.820 (0.751-0.889)	0.915 (0.862-0.968)	0.992 (0.976-1.0)
12 years	0.551 (0.443-0.659)	0.432 (0.314-0.550)	0.711 (0.603-0.819)	0.873 (0.808-0.938)	0.992 (0.976-1.0)

Table 4. List of reasons for revision of ABG I prosthesis. *OL-osteolysis.*

Reasons for revision	Frequency	Percent
OL around stable prosthesis	29	56.9
Cup loosening	13	25.5
Stem loosening	1	2.0
Periprosthetic fracture	4	7.8
Instability	3	5.9
Deep sepsis	1	2.0
Total	51	100

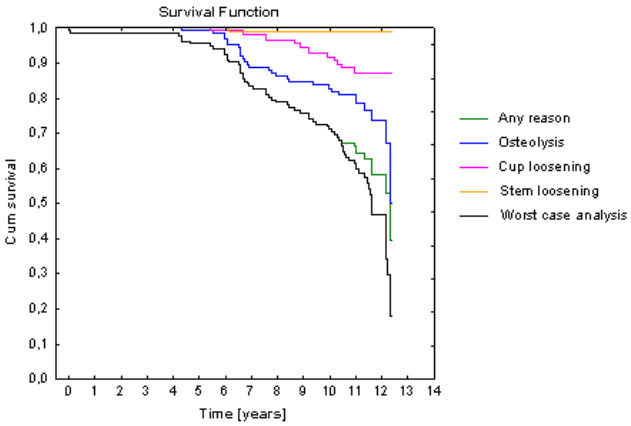

Fig. 1. Survivorship curves of ABG I hip arthroplasty with any revision, aseptic loosening and osteolysis as the end points. Worst case curve was constructed after including the results of radiographic analysis.

short interview on patient satisfaction and complaints, routine physical examination, completion of the Harris Hip Score, and radiography of the hip.

The reason for any revision was prospectively recorded and retrieved cups underwent detailed examination that included *in vitro* wear measurement using a Universal-type measuring microscope[9]. To exclude sepsis as a reason for failure, erythrocyte sedimentation rate, C-reactive protein, intra-operative cultures and histology for all revised hips were routinely investigated.

Anteroposterior radiography was performed within the immediate postoperative period, during regular examinations and at the last follow-up. The first postoperative view was compared with the latest one, to evaluate prosthetic stability, development of OL, radiolucent and/or sclerotic lines. A traditional zone analysis, as described by DeLee and Charnley and Gruen, was used to record changes in bone morphology and bone-implant interface. Components were graded as stable or unstable according to the previously published rules[10, 11]. Cup migration was measured manually in relation to interteardrop line while stem migration was assessed by measuring any change in the distance between tip of the greater trochanter and lateral part of the implant. OL was defined as sharply demarcated radiolucency surrounding the bone-prosthesis interface that exceeded at least 5 mm in diameter. Radiographic failure was defined as gross prosthetic migration and/or complete radiolucency, and/or gross OL extending at least one zone including impending fracture through osteolytic lesion.

Study design

This was a retrospective observational one-centre follow-up study of a consecutive series of hip prosthesis with HAC. Probabilities of implant survival were estimated by the Kaplan-Meier method using revision for any reason, revision due to OL and loosening as the end points for failure. The worst case scenario was calculated when radiographic failures were included in the analysis. Patients without revision were registered at date of last follow-up or death. The Chi-squared, Fisher's exact probability and t-tests for equality of means were used for comparison of age, gender, primary diagnosis, Harris Hip Score, size of the cup and type of PE liner, in revised and unrevised cases. Risk for revision was expressed in terms of odds ratio and relative risk. To investigate whether the primary diagnosis influences the survival of the prosthesis, life-tables were calculated for different groups of diagnoses (dysplastic hips versus the others). Survival data derived for particular groups were compared using the log rank

Table 5a. ABG I survival at 5, 7, 10, and 12 years with different end points in dysplastic hips (N=52); *95% confidence intervals for each value are in the brackets.*

Follow-up Interval	Any revision	Worst-case scenario	Osteolysis	Cup loosening	Stem loosening
5 years	0.941 (0.876-1.000)	0.941 (0.873-1.000)	0.979 (0.938-1.000)	1.000 (0.961-1.000)	1.000
7 years	0.741 (0.619-0.862)	0.741 (0.619-0.863)	0.788 (0.670-0.906)	0.957 (0.900-1.000)	1.000
10 years	0.580 (0.443-0.717)	0.580 (0.443-0.717)	0.653 (0.516-0.790)	0.906 (0.849-0.963)	1.000
12 years	0.494 (0.343-0.644)	0.282 (0.127-0.436)	0.602 (0.443-0.761)	0.865 (0.749-0.981)	1.000

Table 5b. ABG I survival at 5, 7, 10, and 12 years with different end points in cases with other diagnoses (N=85); *95% confidence intervals for each value are in the brackets.*

Follow-up Interval	Any revision	Worst-case scenario	Osteolysis	Cup loosening	Stem loosening
5 years	0.988 (0.964-1.000)	0.975 (0.939-1.000)	1.000 (0.973-1.000)	1.000 (0.975-1.000)	1.000 (0.981-1.000)
7 years	0.902 (0.837-0.967)	0.884 (0.813-955)	0.949 (0.900-0.998)	0.987 (0.962-1.000)	0.987 (0.961-1.000)
10 years	0.791 (0.703-0.879)	0.813 (0.727-0.899)	0.920 (0.859-0.981)	0.915 (0.850-0.980)	0.987 (0.961-1.000)
12 years	0.638 (0.509-0.767)	0.583 (0.450-0.716)	0.821 (0.703-0.939)	0.885 (0.810-0.960)	0.987 (0.961-1.000)

test. All tests were performed using the statistical software SPSS, v.14.0 (SPSS Inc., Chicago, USA) with an accepted significance level of 0.05. The 95% confidence intervals were calculated according to Sachs[12].

RESULTS

1. Survival analysis

At the time of latest follow-up, in the present study, 120 patients (128 hips) could be clinically investigated. Three of the patients were lost to follow-up (four hips; 3 %) and we were unable to locate them. Four patients (five hips; 3.8 %) had died for reasons unassociated with hip surgery, thus their data could be included in the clinical evaluation. The mean time of follow-up was 9.7 years (range from 0.02 to 12.44, SD 2.7) with a median follow-up time of 10.9 years. Survivorship curves derived with the Kaplan-Meier method are presented in Figure 1. This analysis revealed OL as the main reason for failure in ABG I prosthesis. When only aseptic loosening was included in the analysis, the twelve year survival curves appear much better especially with regard to the stem. Corresponding data pertinent to each reason for revision and their 95% confidence intervals are included in Table 3.

2. Reasons for failure

In the entire cohort of 137 hips, there were 51 hips (37.2 %) revised during the period of follow-up. Of these, 36 cups (70.6 %) and 48 stems (94 %) were stable at the time of revision. The majority of revisions were done due to OL (57 %) associated with excessive PE wear (Table 4). Mean wear-rate, found in retrieved PE liners, was 0.293 mm per year (range, 0.03 to 0.92, SD 0.22) and 134 mm^3 per year (range, 11 to 431, SD 118). Significant differences were found in size of the original cup (t-test, $p = 0.006$) and primary diagnosis (chi-squared, $p = 0.001$), between those that were and those that were not revised, with smaller cups and dysplastic hips being more frequent in the revised group. Odds ratio and relative risk for revision were 4.278 (95% CI, 1.734-10.555) and 2.135 (95% CI, 1.437-3.171), respectively, when cases were subdivided into a group with cup sizes below 50 mm and a group with cup size equal to or above 50 mm. When cases were subdivided into a group with dysplastic hips and a group with other diagnoses, a significant difference was found in survivorship between the groups with the end points: any revision (log rank test; $p = 0.01$), worst-case scenario ($p = 0.001$) and osteolysis ($p = 0.0004$). The details are shown in life-tables (5a and 5b). On the other hand, age, gender and type of PE liner were not significant factors in relation to the risk of revision.

3. Radiographic evaluation

A minimum ten-year radiographic follow-up evaluation was performed on 78 hips that were not revised or lost up to the time of latest follow-up. All of these hips were stable, both at the acetabular and femoral site at one-year check-up. At the latest follow-up one cup was radiographically loosened with complete radiolucent line and migration

above 2 mm (0.7 %) awaiting revision surgery. Extensive retroacetabular OL was seen in 15 hips (11 %) and large femoral OL was detected in 7 hips (5.1 %) including one case with impending fracture of the greater trochanter. Based on these data, a worst case survivorship curve was constructed for both components (Fig. 1). There was no OL reaching distally to the inferior margin of the lesser trochanter in any hip. Minor osteolytic lesions located at the periphery of Gruen 1 and/or 7 zones as well as signs of bone hypertrophy observed in Gruen zones 2 and 6 were not introduced into the analysis. The reason for this was the belief that these factors did not significantly compromise the fate of the hip at the time of follow-up.

4. Clinical results

Of unrevised hips that were available, the HHS improved from a mean of 54 points (range, 10 to 77) to 87 points (range, 66 to 95) at the last clinical examination (t-test, $p < 0.0001$). There were only 8 satisfactory or poor results among those who were not revised in contrast to 43 such cases in the revised patients resulting in overall lower HHS in the latter group (chi-square, $p < 0.0001$). As was expected, excellent and good outcomes prevailed (chi-squared test, $p = 0.009$) in patients without positive radiographic findings (n = 41) in contrast to those waiting for revision surgery (n = 9). In addition, the vast majority of unrevised patients claimed to be satisfied with the outcome of the surgery after a minimum of 10 years follow-up.

DISCUSSION

We found a poor 12-year survival for 137 consecutive ABG I prostheses operated at one centre. The main reason for failure was periprosthetic OL around the stable THA. On the one hand, this conclusion is close to studies reporting outcomes after a minimum of ten-year follow-up with the same implant[13, 14]. On the other hand, other centres have provided significantly better data[15-17]. Furthermore, when only aseptic loosening was included, the survivorship for ABG I prosthesis in this study was comparable with the best results published for ABG I especially at the site of the stem. Thus, the question arises how the observed differences for the same implant can be explained?

OL and aseptic loosening pointed predominantly to accelerated wear rate[9]. It has been disclosed that PE liners made from GUR 415 resins and sterilized by gamma irradiation in air, can undergo significant deterioration in their mechanical and chemical properties after long-term *in vivo* functioning[18]. Another factor may be the air-permeable packaging and longer shelf-life of PE liners, both suspected in our cases. In addition, a poor locking mechanism of the PE liners in ABG I cups was repeatedly observed during the surgery. This could lead to repetitive generation of screw-hole fluid pressure at levels greatly exceeding the threshold for OL induction[19]. However, such pathways like other HAC-related variables should be the same for all ABG I prostheses performed everywhere without compromising only distinct cohorts.

Secondly, wear-rate could be accelerated by patient-related factors[20]. Of these, the level of activity is the most frequently accepted but is not easy to evaluate reliably in clinical practice. In this regard, the age of the patient at the time of surgery might be a useful marker of activity, assuming that the older patients are less physically active. Indeed, Oosterbos et al. found significantly better survival for ABG I prosthesis in patients with a mean age of 72 years when the youngest was 55 years old[15]. In contrast, others[17, 21] used the same prosthesis in a wider spectrum of patients including those younger than 60 years and found much better survival than in the current study suggesting the reasons for observed differences might be more complex. Primary diagnosis is another factor that could influence the prosthetic survival (Tables 5a, b). In this study, there was a high rate of postdysplastic hips (38 %) and a significantly larger number of these were among the revised cases ($p = 0.001$). This significantly compromised the survival of the prosthesis in spite of the fact that the vast majority of these cases were those of the Hartofilakidis type I which should result in survivorship comparable to primary osteoarthritis[22]. Moreover, Castoldi et al. used ABG I in 49 postdysplastic hips (31.2 %) and they did not report inferior results for that group of patients[17]. In addition, smaller cups were implanted more often in dysplastic cases (Table 1) resulting in the risk for revision being more than 4 times higher in cases with cups of 46 or 48 mm in size than in those with a larger cup. Taken together, there is a disparity in the long-term results of the ABG I prosthesis only partly explainable by patient variability (e.g., young age and dysplastic hip). As a result, some design and material weaknesses must play a key role in the high rate of OL and aseptic loosening observed in the ABG I prosthesis.

The choice of implant undoubtedly is an important factor in the survival of THA with NICE criteria being understood as a useful tool[23]. The overall survivorship for ABG I prosthesis was very much below 90 % in this study raising the question how quickly the failure was detected. We observed the first wear-related problems associated with the ABG I prosthesis in 1998 and the first revision for OL was performed in the spring of 1999.

It has been recommended that prospective randomized studies should be conducted before wide-range implementation of any new prosthesis in order to provide a final quality control[24]. International multi-centre prospectively designed studies were performed in the case of ABG I[4, 15, 21]. However, none of these revealed any design or material weaknesses in the ABG I prosthesis on time. Paradoxically, these authors published excellent results after nine years of follow-up with reported survivorship of 0.97 and 0.99 for the cup and stem, respectively. Unfortunately, these figures are in marked contrast to ours. Other authors similarly report disappointing outcomes with the ABG I prosthesis[13, 14]. Advocates of national arthroplasty registries argue that register-reported warnings should contribute to monitoring the behaviour

of new prostheses. Indeed, the Swedish register in particular has had a major influence on total hip and knee practices in Sweden predominantly in terms of revision rate[25]. However, reports on the survival of ABG I prosthesis after 5 and 7 years were highly affirmative and the first warning data came from Scandinavian registries long after the prosthesis was withdrawn from the market (online data available).

In conclusion, this study reports poor twelve-year survival of the ABG I prosthesis in younger patients. The main factor limiting the longevity of the prosthesis was high PE wear and poor locking mechanism of the PE liner. Further, the story of the ABG I prosthesis demonstrates the importance of adjustment to the checking-points as neither prospective cohort studies nor registry reports revealed such failure on time.

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