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Excellent survival of two anatomically adapted hydroxyapatite coated cementless Total Hip Arthroplasties. A mean follow-up of 11.3 years

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There are many different types of cementless anatomically adapted Total Hip Arthroplasties (THAs) on the market, the Anatomic Benoist Gerard (ABG) I and II are such types of cementless THAs. In this retrospective single-centre study we evaluated the overall survival with revision for any reason and aseptic loosening as endpoint at more than 11 years follow-up. Between 2000 and 2004, 244 cementless THAs were performed in 230 patients in a primary care hospital. At a mean of 11.3 years follow-up (range 9.8 – 12.8 years) clinical examination, plain radiography and Patient Reported Outcome Measures (PROMs) were obtained and analysed. The PROMs consisted of the Oxford Hip Score (OHS) and the Western Ontario and McMaster University Index (WOMAC). At a mean of 11.3 years follow-up 32 patients (13.1%) had died of unrelated causes. Of the remaining cohort all 198 patients (212 THAs) have been reached for evaluation. There were no patients considered as lost to follow-up. At a mean of 11.3 years 11 patients (11 THAs) have had a revision of either the femoral implant or acetabular component resulting in an overall survival of 95.5%. There was no statistically significant difference (*p*=0.564) in survival between the ABG I and II THAs. Radiographic there were no changes between the ABG I and II last follow up. The ABG II performed statistically significant better in PROMs. We concluded that both anatomically adapted hydroxyapatite coated cementless THAs show excellent survival at more than 11 years follow-up.

Keywords: cementless; femoral implant; long-term follow-up; survival; total hip arthroplasties; anatomically adapted.

INTRODUCTION

Different types of cementless femoral implants with variable shapes are on the market. Based on shape and geometry the femoral implants can be divided in 6 groups according the classification of Khanuja et al. (2011)[1]. They are all thought to lead to sufficient bone-ingrowth onto the total hip arthroplasties (THA) and thereby creating a physiological stress distribution to the host bone. According to Wolffs law, the implantation of a THA, with or without cement fixation, will induce remodelling of the host bone in response to the changing stress transmission[2]. Optimally the stress distribution of the cementless femoral implant and acetabular component (AC) must be in the same range as the physiological femoral and acetabular stress distribution[3, 4]. The use of an anatomically adapted THA might reduce stress shielding, theoretically resulting in less failure and osteolysis of the THA. Examples of an anatomically adapted femoral implant are the Anatomic Benoist Girard (ABG) I and II. The main difference between the ABG-I and II femoral implants is the reduction of the overall length by 8% and the reduction of 10% of the proximal and distal diameter of the ABG-II. The ABG-I and II have widely been used for many years and are analysed in several studies with variable years of follow-up[5-9], however a comparative study between these two cementless femoral implants has never been published. This retrospective single-centre study was designed to evaluate the survival and clinical follow-up of these THAs. The primary aim of this study was to evaluate the overall survival with revision for any reason and aseptic loosening as endpoint. The secondary aim was the clinical and radiological evaluation of both femoral implants and the AC.

PATIENTS AND METHODS

This retrospective single-centre study comprises of 244 primary cementless THAs implanted between May 2000 and December 2004 in 230 patients. Patient characteristics are summarized in Table 1. Initial diagnosis for THA was primary osteoarthritis in 237 patients (97.1%), secondary osteoarthritis in 1 patient (0.4%), congenital hip dysplasia in 2 patients (0.8%)

Table 1. — Details of the patient characteristics

	Total n=230	*ABG-I n=167*	*ABG-II n=63*	*p-value*
Mean age at operation (range)	62.3 (36.4-83.1)	63.0 (36.4-83.1)	60.3 (37.6-72.6)	0.002
THA, n (%)	244	178 (73)	66 (27)	
Left, n (%)	116 (47.5)	81 (45.5)	35 (53.0)	0.300
Mean follow-up, yr (range)	11.3 (9.8-12.8)	11.4 (9.8-12.8)	11.0 (9.9-12.6)	0.016
Male, n (%)	117 (48.0)	80 (44.9)	37 (56.1)	0.125

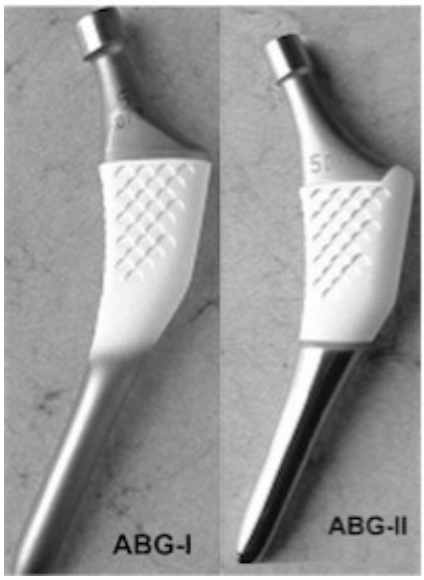

Figure 1. — Differences between the Anatomic Benoist Girard I (left) and II (right).

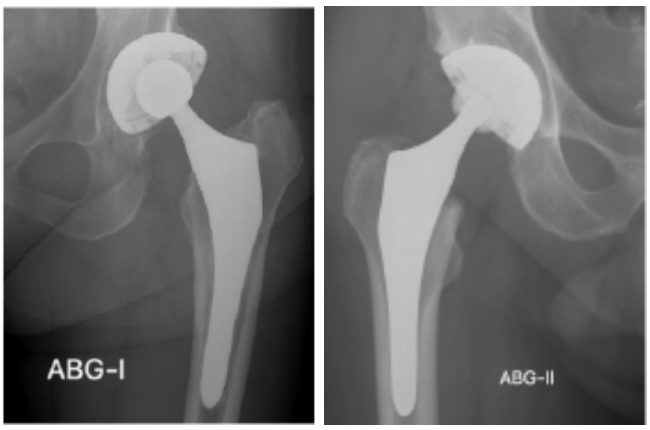

Figure 2. — Radiological differences between the Anatomic Benoist Girard I (left) and II (right).

and a fracture of the proximal femur in 4 patients (1.6%). Approaches used during operation were a lateral approach (n= 167, 68.4%), posterior approach (n= 70, 28.7%) or an anterolateral approach (n= 7, 2.9%). Clinical and radiographic follow-up was at 6 weeks, 1 year and 2 years after initial surgery without obtaining Patient Reported Outcome Measurements (PROMs).

The cementless femoral implants of the ABG-I and II (Stryker, Herouville Saint Clair, France) are made out of titanium alloy (Titanium Molybdenum Zirconium Ferrum, TMZF) and are both anatomically shaped (Figure 1 and Figure 2). The implants are designed for proximal fixation. The anatomical shape with 7° anteversion in the metaphyseal area and 5° anteversion in the femoral neck is important to obtain proximal anatomic press-fit and proximal rotational stability[7,8,10]. Proximal fixation is achieved by the hydroxyapatite coating on the proximal third of the femoral implant and by the proximal anatomic press-fit which lead to a close contact and fixation in the cancellous metaphyseal bone. The main difference between the ABG-I and II femoral implants is the reduction of the overall length by 8% and the reduction of 10% of the proximal and distal diameter of the ABG-II (Figure 1 and Figure 2)[5,11]. There is no difference in the operation technique between both femoral implants. Bearings used were cobalt/chromium (CrCo) in 190 patients (77.9%) and oxide ceramic (Al_2O_3) femoral heads in 54 patients (22.1%) both articulating with highly cross-linked nitrogen-irradiated polyethylene.

Clinical and radiological evaluation was at a mean follow-up of 11.3 years. Patients received an invitation for follow-up and two different PROMs; the Western Ontario and McMaster University Index (WOMAC)[12,13] and the Oxford Hip Score (OHS)[14-16]. The WOMAC can be scored from 0-100 (best score = 100, worst score = 0) and the OHS can be scored from 12-60 (best score = 12, worst score = 60). An overall questionnaire was used in which patients could indicate if they have had revision surgery of their THA, if they experienced pain of the THA using the Visual Analogue Scale[17] and whether they were able to walk unaided. If patients were unable to attend the follow-up appointment the information of the different PROMs returned by the patients was used. These patients were

classified as a partial follow-up. Patients, without a reaction to the invitation for the follow-up appointment and who did not return the PROMs, were consulted by phone to make inquiries on possible revision surgery of their THA. These patients were also classified as partial follow-up. When patients could not be reached or if the patients were deceased during the follow-up, their general practitioner (GP) was contacted and questioned on possible revision surgery of the THA. In case of no patient related information from the GP patients were considered lost to follow up.

Adverse events (AE) during follow-up were classified as patient related (e.g. psychological problems), wound related (e.g. wound leakage, post operative bleeding), prosthesis related (e.g. dislocation, fracture and loosening) and surgery related (e.g. infection). If an AE led to death or revision surgery of the THA it was classified as a serious AE.

Antero-posterior and lateral X-rays were taken of the operated side(s). Radiographs were examined for periprosthetic osteolysis and radiolucency. Radiolucencies were defined as a radiolucent line between the implant and bone of 1mm or more and were described according the Gruen zones[18] for the femoral implant and the zones of Delee and Charnley[19] for the AC. Varus- or valgus malpositioning of the femoral implant was also assessed as well as cortical bone hypertrophy or resorption. We also assessed whether the femoral implant was undersized. Total polyethylene (PE)-wear at follow-up and the wear angle of the AC insert was measured using Roman software[20]. All radiographs were examined by 3 different observers (two orthopaedic surgeons and one radiologist).

Statistical evaluation and analysis was performed using SPSS 21.0 software (IBM SPSS, NY, USA). Kaplan-Meier survivalship analysis was used for revision for any reason and aseptic loosening as endpoint. The 95% confidence intervals (95% CI) were calculated. Log-rank (Mantel-Cox) test was used to determine the statistical differences between different survivorship outcomes in the different groups. A generalized linear mixed model (GLMM) approach was used to estimate the effect of type of femoral implant adjusted to age on the different PROMs. With a GLMM statistical analyses the outcomes could be adjusted for specific co-variables[21]. We considered *p*-values of ≤0.05 to be statistical for all statistical analysis.

RESULTS

After a mean of 11.3 years follow-up 32 patients (32 THAs, 13.1%) had deceased of unrelated causes. All

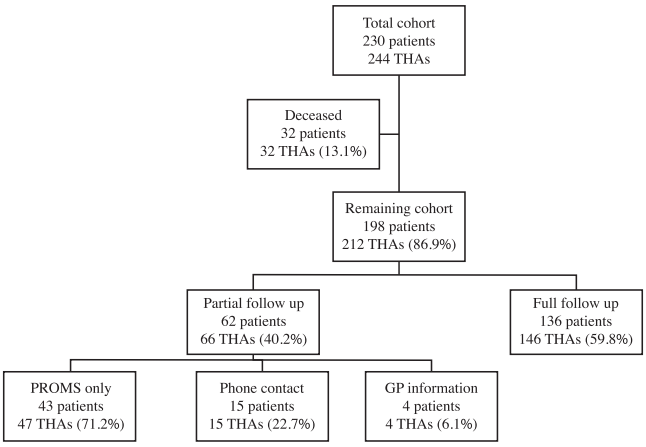

Figure 3. — Flow-chart of patients in this study.

Table 2. — Number of revisions for the ABG-I and ABG-II femoral implant p = 0.564.

Type of femoral implant	N	Revisions	Survival (CI 95%)
ABG-I	178	9	94.9% (91.6-97.8)
ABG-II	66	2	97.0% (92.4-100)
Overall	244	11	95.5% (92.6-98.0)

the 198 patients (212 THAs, 86.9%) of the remaining cohort were reached and additional information about possible revision surgery was obtained, resulting in no patients considered lost to follow-up (Figure 3).

Eleven patients (11 THA, 4.5%) had undergone revision surgery of the femoral implant and/or AC at a mean of 11.3 years follow-up. The mean time to revision surgery was 57.6 months (range 1.0-135.6) or 4.8 years after initial surgery. The reasons for revision surgery were a periprosthetic fracture in six patients (2.5%), aseptic loosening in three patients (1.2%), infection (0.4%) and recurrent dislocations (0.4%). This results in an overall survival for any reason of 95.5% (CI 95%, 92.6-98.0) and for aseptic loosening of 98.8% (CI 95%, 97.1-100). In four patients both the femoral implant and the AC were revised, in five patients the femoral implant was solely revised and in two patients the AC was solely revised. The initial diagnosis of the patients, which had revision surgery, was primary osteoarthritis (n=10) and a fracture (n=1). There was no relation between the approach used during surgery and revisions.

The ABG-II femoral implant had a (p = 0.564) higher survival rate at 11.3 years follow-up compared with the ABG-I femoral implant (Table 2). Indication for both revisions of the ABG-II femoral implant was a periprosthetic fracture. Survival for aseptic loosening

Table 3. — Radiographic results at a mean of 11.3 years follow-up. There was no statistically significant difference between the ABG-I and ABG-II femoral implant

Radiographic result	Overall n=146	ABG-I n=105	ABG-II n=41	*p*-value
Varus malpositioning (%)	2 (1.4)	1 (1.0)	1 (2.4)	0.573
Undersized femoral implant (%)	2 (1.4)	1 (1.0)	1 (2.4)	0.573
Radiolucent line (%)	2 (1.4)	2 (1.9)	0	0.158
Total PE-wear (mm, range)	0.92 (0.0-2.7)	0.90 (0.0-2.2)	0.96 (0.0-2.7)	0.607
Wear-angle (degrees, range)	30.7 (0.0-84.9)	30.3 (0.0-84.9)	31.9 (0.0-81.5)	0.670

Table 4. — Results of the PROMs at a mean of 11.3 years follow-up. Because of a significant difference in age at operation between the two groups a GLMM approach was used to adjust for age.

PROMs	Mean Overall (SD)	Mean ABG-I (SD)	Mean ABG-II (SD)	*p*-value GLLM
WOMAC Total Score	74.6 (21.3)	72.1 (21.4)	80.9 (19.9)	0.000
WOMAC Functional	74.3 (26.3)	70.2 (27.0)	82.7 (24.1)	0.047
WOMAC Pain	81.1 (12.2)	78.2 (23.6)	86.9 (21.4)	0.079
WOMAC Stiffness	71.2 (25.1)	68.8 (26.4)	75.2 (23.1)	0.030
Oxford Hip Score	30.3 (12.2)	33.7 (25.4)	21.5 (22.3)	0.013

of the ABG-II implant is 100% compared with 98.3% for the ABG-I implant ($p = 0.313$). In total six ABG-II AC were revised resulting in a survival of 97.5% (CI 95%, 95.5-99.2).

The radiographic results at 11.3 years follow-up are summarized in Table 3. Radiolucent lines of >1mm were located at the greater trochanter of the femoral implant at Gruen zone 1 (2 THAs, 1.4%). There was no statistically significant difference in PE-wear and wear angle (Table 3).

PROMs were returned by 172 patients (186 THAs), response rate of 92.5%. Fifteen patients were consulted by phone, to assess if revision surgery occurred, without obtaining the PROMs (Figure 3). With GLMM statistical analysis the ABG-II femoral implant performed statistically significant better in the PROMs, except for the WOMAC pain score (Table 4).

During follow-up an AE occurred in 33 patients (33 THAs, 13.5%), two patient related (0.8%), twelve wound related (4.8%), sixteen prosthesis related (6.4%) and three surgery related (1.2%). There was no difference in the AE between the ABG-I and II femoral implants.

DISCUSSION

In this retrospective single centre study we investigated and compared the survival at a mean of 11.3 years follow-up of two cementless anatomically adapted THAs. The mid- and long-term survival of the ABG-I femoral implant, published in other studies, showed excellent survival rates up to 99.2% at 5 years, 98% at 9 years and 98.6% at 15 years follow-up[8, 22, 23]. Compared to these studies the overall survival of the ABG-I femoral implant is slightly lower in this present study. The design and anatomical geometry of the ABG-I femoral implant is based on the principle of proximal fit and fill. In a radiosterometric analysis by Nysted et al. the ABG-I femoral implant was compared with a different type of cementless anatomically adapted femoral implant[10]. Nysted et al. observed in-growth mainly proximally and a small amount of movement of the cementless ABG-I femoral implant[10]. They observed a better fit and fill in a Dorr type B (regular) or a Dorr type C (stovepipe) shape of femur at 5 years follow-up[24,25]. Failure of proximal in-growth with a tight distal fit and a loose proximal fit were seen in patients with a Dorr type A femur (champagne-flute). Questions rose if the ABG-I femoral implant might cause problems for patients with a non-conformity femur[10]. The adjustments of the ABG-I cementless THA into the ABG-II cementless THA was mainly because of high failure rates of the ABG-I AC with excessive PE wear. Adjustments of the femoral implant were made resulting in the ABG-II. Reduction of the total length and a polished distal end of the femoral implant had to prevent distal bone in-growth and better proximal fit and fill in Dorr type A shaped femurs. The

survival of the ABG-II femoral implant in this study was excellent and consistent with other studies[5,7,9]. We observed no patients with aseptic loosening of the ABG-II femoral implant, which is also consistent with other studies[5,9]. The absence of patients with aseptic loosening of the ABG-II femoral implant in this study might suggests a reliable fixation of the proximal end of the ABG-II femoral implant.

Radiological radiolucent lines in Gruen zone 1 were seen in two patients with an ABG-I femoral implant, compared to the complete absence of these lines in patients with an ABG-II femoral implant. These radiolucent lines are caused by the stress-shielding phenomenon, which is common to all cementless femoral implants and in the ABG-I femoral implant they are mainly located in Gruen zone 1[22]. The reduction of the total length and the altered distal design of the ABG-II femoral implant are thought to minimize the stress-shielding, resulting in a decreased number of radiolucent lines[7]. No radiolucent lines were observed round the ABG-II AC. The mean PE wear of the ABG-II AC found in this study was acceptable (<1mm) and consistent compared with other studies[7,9].

Patients with the ABG-II femoral implant performed better than patients with the ABG-I femoral implant on the PROMs, also when adjusted for age at operation and follow-up time there was a statistical difference in the outcomes of the PROMs.

This study had some limitations. There was a significant difference in the follow-up time and age at operation between the two patients groups. Retrospectively there is adjusted for age at operation and time of follow-up with a GLMM[21]. A relative small number of patients (136 patients with 146 THAs, 68.9%) attended the follow-up appointment with clinical and radiographic examination, however the response rate of the PROMs was 92.5% of the contacted patients, with no patients lost to follow-up. The most frequent reason not to attend the follow-up appointment were financial restrictions. As this study had no financial support, a number of patients had to pay the costs of radiographic examination themselves.

In conclusion, this study showed an excellent survival rate for both anatomically adapted cementless femoral implants and cementless AC. A reduction of the total length and the polished distal end might be the reason for a better proximal bone ingrowth and a better overall survival, although there was no statistically significant difference between both anatomically adapted femoral implants. Patients with the ABG-II femoral implant performed significant better on PROMs than patients with the ABG-I femoral implant, also when retrospectively adjusted for age at operation and follow-up time.

Conflict of interest: No competing interests declared.

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