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Long-Term Outcomes of a New Model of Anatomical Hydroxyapatite-Coated Hip Prosthesis

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ABSTRACT

This prospective study was designed to evaluate 196 Anatomique Benoist Giraud (ABG II) total hip arthroplasties which were implanted between September 1999 and December 2000. A minimum 11 years follow up was completed in 183 cases. The bearing surfaces were polyethylene–zirconia in 84 cases, polyethylene–metal in 42 and ceramic–ceramic in 57. Changes in the femoral stem design, in relation to the previous ABG I model, have led to a significant improvement in stress-shielding. Polyethylene wear rate was lower by more than 50% compared with non-crosslinked polyethylene. Excellent and good results were obtained in 90.32% of cases, and implant survival was 98.39% at the end of follow-up.

Uncemented hip arthroplasties emerged in the 70's as an alternative to cemented prostheses in order to achieve longer survival rates. The first models had similar results to those obtained with cemented implants. In the late 80's, new designs were improved with the introduction of coated surfaces, new alloys, hemispheric acetabular cups, etc.

In our Department, several types of uncemented hip implants were used in that period looking for better clinical outcomes and longer rates of survival. The use of hemispheric acetabular cups and anatomic femoral stems in patients treated in our Hospital started in 1990. Both implants were designed for an uncemented press-fit fixation with hydroxyapatite coating (proximal coating in the femoral stems) (prosthesis Anatomique Benoist Girard (ABG-I)). More than 1600 patients were treated with these arthroplasties from 1990 to 1999. High rates of implant survival and excellent clinical outcomes were found in the 10 year follow-up [1,2]. Nevertheless, image studies showed high rates of femoral stress-shielding and polyethylene wear, associated to granulomatous lesions in the proximal femur and acetabulum.

In 1999, significant changes in both components were introduced to the new model ABG-II, but the initial design – hemispheric cups and anatomic femoral stems with hydroxyapatite coating – was maintained. From September-1999 to December-2000, 196 ABG-II prostheses were implanted in 168 patients in our Department. The aim of this survey was to assess, in a minimum 11 year follow-up (12.25 years maximum, mean of 11.3 years), the clinical outcomes in patients treated with an ABG-II total hip arthroplasty.

Material and Methods

Implants

ABG-II implants are made of a Titanium TMZF alloy, consisting of titanium molybdenum, zirconium and ferrous (iron). The Young's modulus (74÷85 GPa) is slightly lower than in the ABG-I (Wrought Titanium (Ti 6Al-4V) alloy, 110 GPa). The hemispheric acetabular cup is provided with 5 holes allowing fixation with spikes or screws for rotational stability and can be sealed with obturator screws if they remain vacant.

The anatomic ABG-II femoral stem was redesigned reducing both the anteroposterior diameter and the total length. The "shoulder" of the stem is higher for a better contact and fixation with the cancellous metaphyseal bone. The diaphyseal region of the stem has a smaller diameter and is highly polished to avoid diaphyseal fixation. It has 7º of anteversion in the metaphyseal area and 5º of anteversion in the femoral neck.

The hemispheric acetabular cup and the metaphyseal area of the stem are coated with 99.99% pure hydroxyapatite with high

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crystallinity (98%–99%). A patented plasma spraying process is used by the manufacturer (Stryker) for the implants coating. High cross-linked polyethylene (nitrogen irradiation, annealing) or ceramic inserts in the acetabular cups and metallic or ceramic femoral heads were used.

From September 1999 to December 2000, 196 arthroplasties were implanted in 168 patients in our Department. By the end of 2011, 156 of these patients with 183 total hip prostheses had completed the follow-up period. A total of 12 individuals (7.14%) were lost for the follow-up. Nine patients died because of medical morbidities not related to the surgery and three changed their address and could not be located.

For the clinical assessment, the Harris Scale [3] and the EuroQol Group EQ-5D questionnaire [4] were used, as well as a subjective self evaluation of the patients. Clinical, functional and radiologic measurements were recorded in the preoperative evaluation and during the follow-up period (1st - 3rd month, 1st - 3rd - 5th – 7th – 11/12th years).

Technique and postoperative protocol

All patients received preoperative intravenous antibiotic prophylaxis with 2nd generation cephalosporins. Low molecular weight heparin was also administered as antithrombotic prophylaxis. The surgical approach used for the total hip replacement was posterolateral in all cases. All the polyethylene inserts were placed with a 10º anti-dislocation lip placed in the postero-superior area. The acetabular reaming was performed to obtain subchondral bone in 120 cases (61.22%), cancellous bone in 21 (10.71%) and both in 55 cases (28.07%). In 21 patients, cancellous bone autografting from the femoral head was added. All the intraoperative and postoperative complications were recorded including dislocation, loosening and infection.

All patients in this study were included in the standard postoperative protocol used in our Department: 48 postoperative hours of bedrest with hip in abduction and external rotation, drainage removal at 48 h, sitting up in a chair at 48–72 h and walking with partial weight-bearing 5 days after the intervention.

Anteroposterior and axial radiographs with neutral rotation of both hips were taken and the following data were recorded: acetabular angle, rotation centre of the hip, rotation centre height with respect to the greater trochanter tip, femoral cortical thickness, cortico-medullary index at three areas (lesser trochanter (LT), 8 and 12 mm distal to LT), and osteoporosis severity according to the Singh index [5].

In the postoperative radiographs the acetabular angle and the rotation centre of the prosthetic hip were measured. They were considered to be adequate with a difference of 3 mm or less when compared to the healthy side. With differences of more than 3 mm the rotation centre was considered to be high, low, medial or lateral depending on the direction of displacement. A digital caliper was used for the radiographic assessment. A varus or valgus malposition of the femoral stem was considered to exist when a difference of 4º or more with the femoral diaphyseal axis was found.

A classification of the stem size in relation to the femoral canal was made. When the stem remained at 2.75 to 3.25 mm from the internal femoral cortex it was classified as “adequate”. With more than 3.25 mm it was considered to be a “small” stem and with less than 2.75 mm it was classified as a “big” stem.

To study the remodeling changes that occurred after the prosthetic implantation preoperative X-rays were compared with those obtained in the follow-up. The proximal femur and the acetabulum were respectively divided into the seven zones described by Gruen [6] and the three zones described by De Lee and Charnley [7]. Heterotopic ossifications were classified according to Broker [8]. The polyethylene wear was evaluated using the method described by Livermore [9]. In our Hospital, all image studies are digitalized and the radiographic comparisons were made using a computerized program. The femoral stem sinking into the canal was assessed by measuring the distance from the greater trochanter tip to the stem based on the initial postoperative X-rays.

The presence of osteolytic lesions in the proximal femur was assessed according to the scale proposed by Goetz [10] in the radiographs obtained at the end of the follow-up. A “limited” osteolysis was defined as that involving two or less zones of Gruen with less than 2.5 cm^2. “Mild” osteolysis was that involving from 3 to 5 zones of Gruen with 2.5 to 10 cm^2 and “severe” osteolysis that involving 6 or more zones of Gruen with more than 10 cm^2.

Six experienced surgeons carried out the total hip replacements in all patients included in the study. The clinical and radiological assessment was made by the first author.

Statistical Analysis

Statistical analysis was performed using χ^2 analysis for categorical data and percentages comparison; Student t test was used for the comparison of means of isolated data or between pairs of related data as appropriate, with Pearson correlation. The level of significance was set at $P < .05$.

Results

From September 1999 to December 2000, 196 total hip ABG-II arthroplasties were implanted in 168 patients (bilateral replacement in 28 cases). In the unilateral total replacements, 84 were of the right and 56 of the left hip joint. In 122 cases the etiology was primary osteoarthritis (72.62%), in 22 (13.09%) rheumatoid arthritis (RA), in 4 (2.38%) psoriatic arthritis, in 5 (2.97%) postraumatic osteoarthritis and in 3 (1.80%) femoral neck fractures.

The gender distribution was 119 males (70.83%) and 49 females (29.17%). At the end of the study period (11–12 years), 156 patients with 183 arthroplasties (bilateral in 27 cases) completed the follow-up. The mean age of the sample was 58.84 years ± 11.26 (SD) (from 23 to 77 years).

The bearing surfaces used in the implants were distributed according to Fig. 1. All ceramic on ceramic arthroplasties were implanted in patients under 60 years of age with good physical and functional status.

The sizes of the implanted acetabular cups were distributed according to Fig. 2. The prosthetic acetabular cups were uncemented with press-fit fixation in all cases. Anti-rotation spikes were added in 163 cases. In 145 of them 2 spikes of 7 mm and one of 9 mm were placed in the 11, 12 and 1 o'clock positions; in 18 cases only 2 spikes of 7 mm were used. Additional screws for acetabular fixation were necessary in 18 patients (two screws in 15 cases and three in the other 3 patients). The holes that remained vacant were sealed with

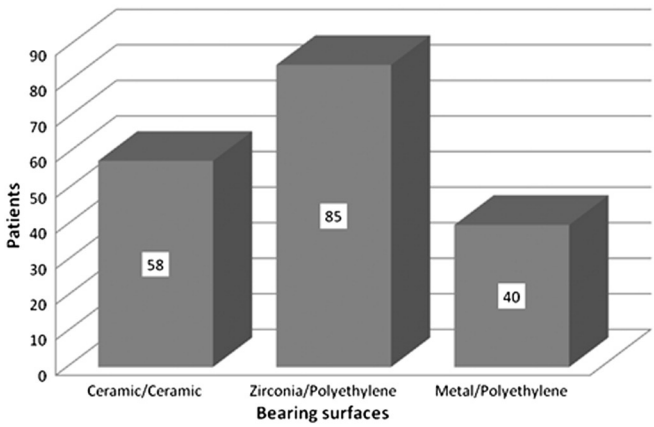

Fig. 1. Distribution of bearing surfaces in the prostheses.