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Original article

The 21- to 27-year results of the Harris-Galante cementless total hip arthroplasty☆

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ABSTRACT

Background: The Harris-Galante total hip arthroplasty (THA) is a first-generation cementless THA with a porous coating for biological fixation of the implant. Many studies report excellent long-term results for the acetabular cup, but few long-term studies exist for the femoral stem because of relatively poor short-term and midterm results. Here we present the 21- to 27-year results of the cup and the stem of the Harris-Galante THA.

Methods: From 1985 to 1991, 102 Harris-Galante THAs were inserted in 82 patients. At the time of the THA, the mean patient age was 54 years (range, 20–78 years). The primary diagnosis was secondary osteoarthritis due to developmental hip dysplasia (69 [68%] hips). The Japanese Orthopaedic Association (JOA) hip score and thigh pain were measures of clinical outcome. Radiographic review was performed retrospectively. Implant survival was evaluated by Kaplan–Meier analysis.

Results: Of 102 hips, 35 hips were from 31 deceased patients, 5 patients (6 hips) were lost to follow-up, 12 hips were revised, and 49 hips were from patients living at the latest follow-up. Among the living patients, 36 hips had a clinical evaluation and 42 hips had a radiograph obtained more than 21 years. The JOA hip score improved from 42 points preoperatively to 83.5 points at the latest follow-up. Thigh pain was reported in 13 hips. One cup and four stems were loose at the latest radiographic review. Most cup revisions were related to acetabular osteolysis. Fifteen hips showed severe stress shielding. Kaplan–Meier analysis of survivorship with any revision, acetabular reoperation, stem revision, and stem loosening as the end point was 87.0%, 90.3%, 95.7% and 86.4%, respectively, at 24.6 years.

Conclusions: Long-term implant survival and clinical results of the Harris-Galante THA were good. Acetabular osteolysis-related cup loosening was a problem of the cup. Loosening, thigh pain, and stress shielding were problems of the stem.

1. Introduction

By the mid-1980s, cemented total hip arthroplasty (THA) had been already a standard treatment for advanced hip disease, although loosening of the implants and periprosthetic osteolysis were recognized as significant problems. Cementless porous-coated THA was introduced with the hope of solving these problems, especially for young and active patients. The Harris-Galante THA (Zimmer, Warsaw, Indiana) was a first-generation cementless THA that used a porous coating with the aim of biological fixation of the implant [1]. Many reports have supported excellent long-term results of the Harris-Galante I acetabular cup [2,3]. However, because of relatively poor short-term and midterm results of the Harris-Galante stem [4,5], few long-term studies regarding the stem side have been published [6,7]. This study is a long-term follow-up study of the Harris-Galante THA that focused on the cup side and the stem side. The purpose of this study was to

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present the long-term performance of the Harris-Galante THA in Asian patients.

2. Materials and methods

2.1. Patients

From 1985 to 1991 at our institution, 102 Harris-Galante THAs were inserted in 82 patients (seven men and 75 women). Fifty-seven right hips and 45 left hips were inserted. The mean age of the patients at surgery was 54 years (range, 20–78 years). The mean weight, height, and body mass index of the patients were 54 kg (range, 39–79 kg), 150 cm (range, 131–175 cm), and 24.0 kg/m^2 (range, 18.1–39.0 kg/m^2), respectively. Preoperative diagnoses were secondary osteoarthritis due to developmental hip dysplasia (DDH) in 69 hips; primary osteoarthritis in three hips; rheumatoid arthritis in 19 hips; osteonecrosis of the femoral head in seven hips; post-traumatic arthritis in one hips; acromegaly in two hips; and congenital multiple epiphyseal dysplasia in one hip. This retrospective study was approved by the institutional review board of our hospital. In addition, no external funding was used for this study.

2.2. Implants

The Harris-Galante I acetabular cup is hemispherical and composed of a titanium alloy (consisting of titanium, aluminum [6%], and vanadium [4%]). The outer surface of the acetabular cup is covered with a pure titanium fiber metal porous coating (with a pore volume of 50% and a mean pore size of 300 μm). The acetabular cup contains multiple holes for initial fixation using 4.5-mm cancellous screws. The outer diameter of the cup used in this study ranged from 46 to 54 mm (median diameter, 50 mm). The modular acetabular polyethylene liner is made of GUR 4150 resin and was gamma-radiated in air with 25 kGy. The polyethylene liner is locked by three tines around the periphery of the cup. The titanium alloy Harris-Galante femoral stem has a straight cylindrical design with a collar medially. The stem has three pure titanium fiber metal pads on the anterior, posterior, and medial aspects of the proximal third of the stem (i.e., the proximal porous coating is not circumferential for the stem). The distal cylindrical part of the stem has four flutes for rotational stability. The stem size used in this study ranged from 11 to 15 mm (median, 13 mm). A 26-mm modular cobalt-chromium head was used for all patients.

2.3. Operative procedure

All operative procedures were performed using a posterolateral surgical approach. All acetabular and femoral components were inserted without cement. Reaming of the acetabulum was performed line to line without under-reaming. Three to four screws were usually used for the initial fixation of the acetabular cup. The proximal femur was prepared using straight power reamers and hand-driven rasps to achieve a press-fit of the stem. Partial weight-bearing on the operative limb was initiated postoperatively at 4 weeks, followed by full weight-bearing at 8 weeks.

2.4. Clinical assessment

Patients were assessed postoperatively at 3 months, 6 months, and 12 months, and annually thereafter. Clinical data were reviewed retrospectively. The clinical outcome was measured by the Japanese Orthopaedic Association hip score (the JOA hip score) [8]. The score was based on a total of 100 points composed of 40 points for pain, 20 points for range of motion, 20 points for the ability to walk, and 20 points for activities of daily living. In addition, the presence or absence of thigh pain was recorded at each clinical visit. Hospital charts were reviewed for postoperative complications.

2.5. Radiographic assessment

Antero-posterior and lateral (either frog leg or cross table) radiographs of the hip were obtained at each clinical visit. Radiographic reviews were performed retrospectively. For the acetabular side, the distribution of the radiolucent line and osteolysis around the acetabular cup were recorded, based on the three zones of DeLee and Charnley [9]. Stability of the acetabular cup was classified as stable with osseous ingrowth, stable with fibrous ingrowth, or unstable, according to the method of Manley et al. [10]. For the femoral side, the distribution of the reactive line, spot welds, cortical hypertrophy, and osteolysis were defined according to the seven zones of Gruen [11]. Pedestal formation distal to the stem tip was also observed. The status of the biological fixation of the femoral stem was classified as fixation by bone ingrowth, stable fibrous ingrowth, and unstable, using the criteria of Engh et al. [12]. The degree of femoral stress shielding was graded from first to fourth degree, using the criteria described by Engh et al. [12].

2.6. Statistical analysis

The patients' preoperative and latest JOA hip scores were compared using the Wilcoxon signed-ranks test. The Chi-square test was used to define whether the degree of stress shielding was related to presence or absence of thigh pain and pedestal formation. Kaplan–Meier survivorship curves were calculated for the following four endpoints: (1) revision for any reason, (2) acetabular reoperation (i.e., cup revision and polyethylene liner exchange), (3) stem revision, and (4) aseptic loosening of the stem. The 95% confidence interval (CI) was also calculated for each status. In addition, all cases were included for the survival analysis. The accepted probability level for statistical significance was $P < 0.05$. The statistical analyses were performed using the JMP version 10.0.2 software (SAS Institute Inc., Cary, North Carolina).

3. Results

Thirty-one patients (35 hips) died before the time of the latest review for the present study. The average age of the deceased patients at the time of the index surgery was 60 years (range, 38–78 years). The average duration from the operation to the time of death was 15 years (range, 6 months–23 years). Of these, 26 patients (27 hips) had radiographs at a mean of 12 years (range, 2–20 years) after the surgery. Radiologically, one cup and four stems were defined as unstable; however no patient had a revision before death. Five patients (6 hips) were lost to follow-up at a mean of 16.6 years (range, 14–18 years) after the surgery. None of these patients had a revision before they were lost to follow-up.

There were 12 revisions in 11 patients (Table 1). The mean time from the index operation to revision was 15.4 years (range, 11.2–26.2 years). Three polyethylene liners were exchanged because of excessive polyethylene wear. Six acetabular cups were revised because of aseptic loosening. Among the latter, five cups had loosened after advanced acetabular osteolysis. Five femoral stems were revised because of aseptic loosening. All these stems failed to achieve bone ingrowth during the early postoperative period.

The remaining 49 hips were the focus of this study (Fig. 1). Among the 49 hips of the living patients, 36 hips underwent clinical and radiographic evaluations, six hips had a radiographic