CLINICAL ARTICLE

A five-year clinical and radiographic follow-up of bipolar hip arthroplasty with insertion of a porous-coated anatomic femoral component without cement

Cheng-fu Cao MD, Jun-jie Zhou MD, PhD, Jin-hui Pang MD, Xian-qi Chen MD

Department of Orthopaedic Surgery, Putuo Hospital of Shanghai University of Traditional Chinese Medicine, Shanghai, China

Objective: To evaluate the clinical and radiographic outcomes of bipolar hip arthroplasty with a cementless porous-coated anatomic femoral component.

Methods: Fifty-nine patients (86 hips) with a minimum 3.5-year follow-up were followed up for a mean of 5.2 years (from January 2005 to January 2007). Standard clinical evaluation utilizing the Harris hip score and radiographic evaluation based on the criteria of the Hip Society were used in this prospective study. Radiographic assessment included evaluation of calcar remodeling and pedestal formation.

Results: The average age of the patients (24 men and 35 women) at the time of surgery was 71.4 years (range, 69–84 years). The average preoperative Harris hip score was 48.5 ± 4.0 (range, 25–65) points, pain score 15.2 ± 3.9 (range, 0–20) points and functional score 26.7 ± 4.6 (range, 9–40) points. At the time of the latest follow-up, the average Harris hip score was 96.1 ± 2.1 (range, 67–100) points, pain score 42.6 ± 6.3 (range, 32–54) points and functional score 45.5 ± 4.7 (range, 29–56) points. Five hips (5.81%) had pain in the anterior part of the thigh. Two hips (2.33%) required revision of the femoral component because of aseptic loosening and periprosthetic fracture. Radiographic assessment revealed consistent evidence of proximal bone ingrowth. No completely radiolucent lines were identified, except around stems that had loosened. Twenty-seven femoral components (31.4%) had associated slight pedestal formation. No osteolytic lesions of the femur were identified. Nonprogressive pelvic osteolysis was identified in four hips, none of the lesions being ≥ 2 mm in diameter.

Conclusion: An anatomically designed prosthesis can provide good clinical results, with low incidence of thigh pain and loosening of the component.

Key words: Arthroplasty, replacement, hip; Femur; Follow-up studies; Treatment outcome

Introduction

Aseptic loosening of a cemented femoral component after hip arthroplasty is a potential cause of pain and loss of function, resulting in the subsequent need for a revision^{1–3}. The extent of bone growth into the porous surface, abnormal bone remodeling due to stress-shielding, and bone resorption or osteolysis are other unresolved issues that can occur.

Many different methods for evaluation of the clinical outcomes of hip arthroplasty have been described^{4–6}. Clinical scoring systems based on the patient's perception of pain, function, and functional activities have been proposed^{7–9}. Radiographic evaluations have typically quantified radiolucent lines at the prosthetic interface; the fit, fill, and alignment of the implant; and the presence or absence of remodeling associated with stress-shielding and instability of the stem^{10–13}. Although there are other patient-directed outcome measures, these clinical and radiographic outcome measures provide an adequate basis for a database for assessing the results of a specific implant¹⁴.

The purpose of the present study was to assess the outcomes of bipolar hip arthroplasties in which anatomically designed femoral components with circumferential

Address for correspondence Jun-jie Zhou, MD, No. 164 LanXi Road, Department of Orthopaedic Surgery, No. 14 Ward of Inpatient Department, PuTuo Hospital of Shanghai University of Traditional Chinese Medicine, Shanghai, China 200062 Tel: 0086-21-33602968; Fax: 0086-21-33602968; Email: boysroger@126.com

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proximal coating were used without cement. The hips were studied prospectively, using standardized clinical and radiographic scoring systems, for a mean 5.2-year follow-up.

Materials and methods

Fifty-nine patients (86 hips) with femoral neck fracture underwent hip arthroplasty with an anatomically designed stem (Fig. 1a,b) without cement at our institution from January 2005 to January 2007, the operations being performed by the most senior of the present authors (Dr Cheng-fu Cao). The 86 stems were reviewed by an author who had not been involved with the operative procedure (Dr Jin-Hui Pang). One patient died of unrelated causes but was included in the follow-up analysis; the hip had functioned satisfactorily up until the time of death. Two hips that had been revised for nonmechanical reasons (one periprosthetic fracture, and one limb length discrepancy) were excluded from the analysis. Failure of the hip prosthesis was defined as a revision for any mechanical complication. The average duration of follow-up was 5.2 years (range, 3.5–6.0 years). The average age of the patients was 71.4 years (range, 69–84 years) at the time of the index operation. The average weight of the patients was 76.8 kilograms (range, 54–103 kilograms). Twenty-four patients were male and thirty-five female. The clinical indications for use of the implant were: (i) a chronological age of greater than sixty-five years or a life expectancy of approximately ten years according to the Metropolitan Life Insurance Company (new York, New York, USA) life expectancy tables; (ii) a femur that was classified radiographically as type A or B according to the criteria of Dorr *et al.*¹⁵; (iii) the selected intraoperative

rasp corresponding to the implant to be inserted had to be torsionally stable as determined by use of a torque wrench by the surgeon, as will be described. If all of these criteria were not met, the stem was not used.

Surgical procedure

The procedure was performed in a laminar airflow operating room, and the surgeons wore body-exhaust isolation suits. Prophylactic antibiotics were administered i.v. (one dose preoperatively and for forty-eight hours postoperatively). All patients received prophylactic anticoagulation with warfarin for five, six, or seven days; wore thrombo-embolic hose; and were managed with sequential compression devices.

All procedures were performed through a standard lateral approach and with a femoral component that is proximally and circumferentially coated with a commercially pure titanium fiber-metal porous surface (Stem, model C JY/JX-HA, without collar; Montagne, Beijing, China). The design features of the stem, which have been previously described, emphasize matching of the geometric and mechanical properties of the proximal part of the femur. The structural rigidity of the stem was optimized by use of a titanium-based material and distal fluting. The torsional stability of the implant was determined intraoperatively by applying a commercially available torque wrench to the rasp after full seating. The adequacy of the metaphyseal fit and fill and the stability of the rasp were determined by an absence of movement of the rasp under a torsional load of 180 inch-pounds (20.3 newton-meters). The femoral head used had a bipolar component (inner head for bipolar, TS; Montagne).

Figure 1 Anteroposterior radiographs of (a) pre-operative and (b) frog-leg lateral radiographs performed 5 years after implantation of an anatomically designed femoral component. The postoperative Harris hip score was 96 points.

Clinical evaluation

The clinical performance of the stem was assessed with the Harris hip score system¹⁶ preoperatively, at three and six months postoperatively, and then at yearly intervals. A Harris hip-rating of 90 points or more was considered excellent; one of 80 to 89 points, good; one of 60 to 79 points, fair; and one of less than 60 points, poor. In addition to the Harris hip score, the guidelines of the Hip Society¹⁷ were used to evaluate the level of activity, working capacity, ability to stand from a sitting position, and patient satisfaction. Pain in the thigh was graded as mild when it was occasional, did not interfere with daily activities, and did not necessitate the use of pain medication; as moderate when it led to a modification of daily activities and the occasional use of nonsteroidal anti-inflammatory medication; and as severe when it was constant, necessitated the use of narcotics, and interfered with daily activities.

Radiographic evaluation

Standard anteroposterior and lateral radiographs of the involved hip with magnification markers and an anteroposterior radiograph of the pelvis were taken preoperatively and at each follow-up examination. Radiographic

evaluation was performed according to the guidelines of the Hip Society¹⁷. This assessment includes evaluation of calcar remodeling and pedestal formation. The quality of the femoral bone was evaluated preoperatively by rating the cancellous trabeculae in the proximal part of the femur according to the guidelines of the Hip Society^{18,19}. These guidelines were also used to classify the fixation of the implant as bone ingrowth, stable fibrous or unstable fibrous.

Radiodense and radiolucent lines around the femoral component were evaluated and their locations identified according to the zones described by Gruen *et al.*²⁰ (Fig. 2). Osteolysis of the femur was evaluated according to a modification of the system developed by the American Academy of Orthopaedic Surgeons, as described by Weber *et al.*²¹ Defects were considered important if they measured ≥ 2 mm in diameter.

Vertical migration (subsidence) of the femoral component was evaluated by measuring the change in the distance between the most proximal point of the lesser trochanter and the most superomedial point of the femoral component on sequential radiographs. Five mms or more was considered to indicate subsidence, as described by Callaghan *et al.*^{22,23} The classification system

Figure 2 Drawing showing the radiographic measurements and zones that were used in this study. Gruen zones I–VII.

of Brooker *et al.*²⁴ was used to grade heterotopic ossification when it was present.

Osteolysis of the pelvis was assessed as previously described for osteolysis of the femur according to the zones described by DeLee and Charnley^{25,26}. One of us (the first author) performed all of the measurements.

Results

Clinical findings

The average preoperative Harris hip score was 48.5 ± 4.0 points (range, 25–65 points), with an average pain score of 15.2 ± 3.9 points (range, 0–20 points) and an average functional score of 26.7 ± 4.6 points (range, 9–40 points). At the time of the most recent follow-up visit, the average Harris hip score was 96.1 ± 2.1 points (range, 67–100 points), with an average pain score of 42.6 ± 6.3 points (range, 32–54 points) and an average functional score of 45.5 ± 4.7 points (range, 29–56 points). The result was excellent for 71 hips, good for 12, and poor or a failure for 3. Thus 83 hips yielded a good or excellent result. The patients resumed daily activities, obtained their desired goals from the operation, and were capable of standing from a sitting position. Eighteen patients needed walking aids, and six walked with an occasional limp. All patients were able to put on their shoes and socks. Five hips (5.81%) had pain in the anterior part of the thigh or the groin, or both, including three patients with pain in the thigh only, and two with pain in both the thigh and groin. The pain was mild in four patients, but severe in one, who had aseptic loosening. We detected no association between pain in the thigh and the size of the implanted stem. The patient who died during the follow-up period had, at his last visit nine months after the operation, a Harris hip score of 81 points and no pain in the thigh or the groin.

Radiographic assessment of the femoral components

Preoperatively, the quality of the femoral bone, as assessed radiographically by the guidelines of the Hip Society²⁷, was grade 6 in 36 hips (41.9%), grade 5 in 31 (36.0%), grade 4 in 12 (13.9%), and grade 3, 2, or 1 in 7 (8.2%). At the most recent follow-up, 43 (61.2%) of the 86 stems were fixed by bone ingrowth, 14 (16.3%) had stable fibrous fixation, and 2 (2.3%) had had unstable fibrous fixation and had been revised. The remaining 27 hips showed no evidence of bone ingrowth or fibrous fixation on radiography but were very stable and did not require revision. One of the unstable stems subsided over 5 mm during the first 24 months after the operation. Twenty-seven (31.4%) of the femoral components had slight asso-

Figure 3 Pedestal formation at the distal end of the prosthesis (arrow).

ciated pedestal formation, as seen on both the anteroposterior and the lateral radiographs (Fig. 3). However, because all 27 stems were stable, the slight pedestal formation was not considered an important finding. Only one stem that had subsided was associated with extensive pedestal formation, and this was visible in both the anteroposterior and lateral radiographs.

Nineteen stems had been implanted in neutral, and three in varus, angulation. The remaining stems were in the correct (valgus) position. Except for the subsided stem, which was associated with a 3 mm thick radiolucent line, no femoral component was associated with a complete radiolucent line >2 mm thick. However, non-progressive radiolucent lines <2 mm in thickness were seen adjacent to eight stems, in zones I and II. There was no osteolysis around any of the femoral components. Resorption of the calcar, which averaged 1.3 mm, was observed in association with 43 stems. As assessed on the lateral radiograph, the press-fit was excellent in 56 hips and poor in one hip in which the femoral component had subsided. Calcar-rounding was identified in association with 34 stems. Heterotopic ossification was identified in 19 hips. It was class III in six hips, however no hip had class-IV ossification.

Complications

Dislocation did not occur in any of the hips. Deep vein thrombosis developed after two arthroplasties. Class-III

heterotopic ossification developed in six hips, without sequelae. Complications that led to a revision operation included a hematogenous infection that developed in one hip three years after the index procedure and a fracture adjacent to one femoral component that occurred three years after the index procedure. The latter component was replaced with a larger and longer prosthesis. One patient had a revision operation because of a 3.45-cm limb-length discrepancy two years after the operation. Only two revisions were performed because of mechanical failure; therefore, the total rate of mechanical failure was 2.3%.

Discussion

The outcome of porous-coated anatomic femoral component without cement

Our study of 86 consecutive bipolar hip arthroplasties with insertion of an anatomically designed femoral component without cement demonstrated improved clinical and radiographic outcomes. Excellent or good pain relief and function were obtained in more than 95% of these hips, all operations having been performed on active patients. The average Harris hip score was 98 points.

The influence of the design of the implant on the clinical results of hip arthroplasty without cement has been emphasized by Haddad and Bridgens²⁸. In their comparison of three different types of porous-coated hip replacements without cement, the highest average Harris hip score and the lowest incidence of pain in the thigh (8%; four stems) were observed in the 50 hips in which anatomically shaped femoral components had been implanted. The similar design features of the stems used in our study may have contributed to our favorable clinical results.

The role of selection of patients in assessment of the arthroplasties

Another factor that may be of importance in determining the outcome of arthroplasties without cement is patient selection. Rheumatoid arthritis, avascular necrosis, and congenital hip dysplasia can influence the biological integration of the implant and bone-remodeling, thereby affecting the overall outcome. We studied a relatively homogeneous group of patients, and with the stem that we used there was an improved Harris hip score and a reduction in the incidence of both pain in the thigh and subsidence of the femoral implant. The decreasing incidence of pain in the thigh with increasing length of follow-up suggests that bone-remodeling around the tip of the stem is a prolonged process. Pain in the thigh may relate to the stability by three-point fixation with an anatomic or curved design without a collar. In our series,

thigh pain did not limit function, usually occurred with prolonged activity, and was relieved by sitting.

The biological fixation of cementless porous-coated anatomic femoral components

The success of biological fixation depends on the initial stability as well as the design of the femoral component. In a study with a minimum five-year follow-up, Heekin *et al.* reported that bone ingrowth was observed in 94% of 100 primary arthroplasties with a circumferential coating and curved stem²⁹. These data, when compared with those reported in the present study, suggest that improved osseous integration of stems occurs when there is an extensive circumferential porous surface.

Extensive pedestal formation is considered another potential radiographic sign of instability of the implant³⁰. In our present study, slight pedestal formation was seen on the anteroposterior and lateral radiographs of 31.4% (27) of all stems. However, only one stem in our study subsided notably. Femoral osteolysis was not seen in our study.

The problem of cementless anatomic femoral component utilization in clinic

Our study had a number of limitations. The hips, although consecutive, were nonrandomized and selected, which could have biased the results. Furthermore, although the radiographs were standardized, differences in the technique could have resulted in an underestimation of the presence of osteolytic lesions or radiolucent lines. In addition, all operations were performed by the same surgeon and these results may not necessarily be reproducible by other surgeons. We considered performing a Kaplan–Meier survivorship analysis with revision because of a mechanical complication or radiographic evidence of loosening of either the femoral component or the bipolar head as the end points.

In conclusion, the outcome of hip arthroplasty without cement is determined by multiple factors, including the design of the component, the selection of the patients, and the operative technique. The results of the procedure must be evaluated in long-term studies because many reconstructions without cement are performed in younger, healthy patients. Our study suggests that anatomic femoral implants without cement can provide satisfactory clinical and radiographic outcomes after an intermediate duration of follow-up. The circumferential proximal porous surface and the anatomical design provide reliable initial biological fixation, osseous integration, and few femoral or acetabular osseous changes. However, longer clinical observation is mandatory to determine the long-

term results of hip arthroplasty with this type of implant and to understand the role and applicability of this technology to hip replacement.

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Disclosure

No benefits in any form have been, or will be, received from a commercial party related directly or indirectly to the subject of this manuscript.

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