Acta Orthop. Belg., 2010, 76, 758-765

ORIGINAL STUDY

Primary metal-on-metal total hip arthroplasty with large-diameter femoral heads : A clinical trial of 59 hips

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Large-diameter femoral heads with nearly anatomical sizes became available for metal-on-metal total hip arthroplasty after recent advances in metal-on-metal technology. We retrospectively studied the clinical and radiological results in 59 hips of 54 patients (32 women and 22 men, mean age 54.4 years) who underwent cementless metal-on-metal total hip arthroplasty with large-diameter heads. Patients were followed for a mean of 48.6 months. Range of motion improved significantly after surgery ($p = 0.001$). Harris hip scores improved from 38.5 points to 90.3 points at latest follow-up. We found no gender-related differences in Harris hip scores, whereas there was a correlation between age and Harris hip scores ($p < 0.001$), with excellent results being observed predominantly in younger patients. Mean acetabular inclination of the acetabular cup was 42.2° (range : 37-51°). Radiologically, a 1 mm thick radiolucency was detected in three acetabula, which were asymptomatic. One acetabulum was revised because of displacement. Three patients reported squeaking within their hips, which however disappeared in a short time. We did not observe any dislocation, deep infection or loosening. Grade 1 heterotopic ossification was detected in one hip. Although the inherent stability and the functional results of large anatomical heads are encouraging, longer follow-up data and larger series are essential to evaluate the real advantages of this type of prosthesis over conventional femoral heads.

Keywords : total hip arthroplasty ; cementless ; metal on metal ; anatomical head ; large femoral head.

INTRODUCTION

Degenerative arthritis of the hip joint is frequently encountered in young and active patients. The aim of surgical treatment is to obtain a painless hip joint with acceptable range of motion in order to improve the patient's quality of life. Historically, the poor longevity of total hip arthroplasty (THA) in younger patients because of polyethylene wear and osteolysis, forced the industry to develop alternative bearings, such as ceramic-on-ceramic and metal-on-metal (*2,4,36*). There is as yet no consensus on the ideal method for THA in young, active individuals.

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No benefits or funds were received in support of this study

Recently, resurfacing arthroplasty has become an attractive option for young patients who want to maintain a high activity level. It involves less resection of host bone on the femoral side and therefore is considered by some to be a conservative bone-preserving arthroplasty for young patients with advanced osteoarthritis (*30*). Large metal-on-metal (MOM) bearings with nearly anatomical head sizes result in improved range of motion and contribute to increased prosthetic joint stability (*13,16,26,37*). When compared with standard THA with a 28 mm head, some authors suggested that hip resurfacing results in improved activity level and function (*38,42*). However, there are also some disadvantages. There is concern about long-term survival of the femoral component (*25,38*). Amstutz *et al* (*1*) reported an overall failure rate of 6 % at 3.5 years follow-up. In addition, The Australian Registry reported that femoral neck fractures after resurfacing continue to be a problem with a rate of 1.46% (*38*).

Revision of resurfacing because of failures on the femoral side has necessitated the development of modular metal femoral heads that maintain the diameter of the resurfacing component but engage a conventional femoral stem component of a total hip prosthesis (*39*). The head-neck ratio of these constructs is far greater than that of a traditional 28 or 32-mm implant. There are scarce reports on the results of MOM THA with resurfacing cups and conventional femoral stems with large-diameter femoral heads (*15,23,39*).

The aim of the current study was to evaluate the short-term clinical and radiological results of a metal-on-metal total hip arthroplasty with a large-diameter femoral head.

MATERIALS AND METHODS

We retrospectively reviewed 59 hips of 54 patients that underwent cementless metal-on-metal THA between January 2005 and June 2007. There were 32 (59.3%) women and 22 (40.7%) men with a mean age of 54.4 years (range : 31-65 years). Five of the patients had bilateral THA in a sequential manner. The diagnosis was primary osteoarthritis in 44 hips, post traumatic arthritis in three, avascular necrosis in three, rheumatoid arthritis in three and ankylosing spondylitis in one. Any patient with severe coxarthrosis who did not respond to conservative treatment, who had functional impairment that affected daily activities and who was deemed suitable for cementless total hip arthroplasty was included in the study. Exclusion criteria were patients older than 65 years, previous hip surgery because of dysplasia, fracture, presence of renal insufficiency, osteopenia or osteoporosis and suspected pregnancy.

All procedures were performed through a posterolateral approach by the same surgeons (HY, KK). For all hips, we used bicoated cementless acetabular cups and femoral stems with a large head (Cormet® cup, Optimom® large head and Corinium® stem ; Corin Medical Ltd., Cirencester, UK). The bicoated acetabular component is made of cobalt chrome ; it is available in a range from 42 to 64 mm outer diameter. The backing comprises a plasma sprayed layer of titanium coated with a further layer of hydroxyapatite. The equatorially expanded cup has a rim which is 2 mm wider than the polar dimension. This provides initial press fit, whilst permitting full seating of the component in the acetabulum. Hollowed femoral heads have a diameter which matches the inner side of the cup, with a range from 36 to 56 mm in 4 mm increments ; they are directly attached to the Morse Eurocone taper of the stem without any additional adaptor. The cementless femoral component is also bicoated (2/3 extended coating) and provides a precise anatomic fit (fig 1).

Patients were encouraged to partial weight bearing on the first postoperative day with walking aids. At the third week, full weight bearing and all daily activities were allowed. Patients were advised against high impact activities.

All patients were evaluated clinically and radiologically. The range of motion of the hips (ROM) was measured clinically with a goniometer. Antero-posterior radiographs of the pelvis, antero-posterior and lateral radiographs of the operated hips were made preoperatively, postoperatively and at all follow-ups, at six weeks, three months, six months, and twelve months and yearly after. Radiographic evaluations were made by the system described by Johnston *et al* (*19*). These radiographs were evaluated for the position of the component, any migration or position change, any radiolucency around the components, any heterotopic ossification or any osteolysis and loosening (fig 2a, 2b). Preoperative and follow-up Harris hip scores and any intra- or postoperative complication were noted. The results were considered as excellent with Harris hip scores between 90 and 100 points, good between 80 and 89 points, fair between 70 and 79 points, and poor under 70 points. Heterotopic ossification was graded as defined by Brooker *et al* (*7*).

Fig. 1. — Photograph of a metal-on-metal THA combining a bicoated cementless resurfacing cup and a femoral stem coupled with a large - diameter femoral head.

Informed consents were obtained from all patients. Ethics committee approval was obtained.

Statistical Analysis

Statistical analysis was done with SPSS software (SPSS Inc, Chicago, USA). Numerical variables were reported as mean ± standard error of the mean (SEM) with range and the nominal variables were reported as observation number and percentage. The stratified subgroups according to the postoperative Harris hip scores were compared with age with one-way Analysis of Variance (ANOVA). If there was a significant difference, a post-hoc Tukey test was done. The Mann-Whitney U test was used to investigate differences between the preoperative and postoperative range of motion of the patients. The nominal variables were evaluated with Pearson's Chi-Square test. A p-value < 0.05 was considered to be significant.

Fig. 2a. — **A**nterior-posterior radiograph of a 58-year-old patient with a painful and stiff osteoarthritic right hip.

Fig. 2b. — Radiograph of the same patient three years after metal-on-metal total hip arthroplasty with a large-diameter femoral head.

RESULTS

The patients were followed for a mean of 48.6 months (range : 28-60 months). The mean Harris hip score before surgery was 38.5 points (range : 31-49 points) ; it improved to 90.3 points (range : 78-97 points) at latest follow-up. Harris hip scores were excellent in 31 (52.5%), good in 23 (38.9%) and fair in 5 (8.5%) hips. There were no poor results.

No statistical correlation was found between postoperative scores and gender ($p = 0.587$) ; however, the relation between final hip scores and age was found to be significant ($p < 0.001$). When the patients were distributed into subgroups with intermediate, good and excellent results based on their Harris hip scores, and these subgroups were compared for age, post-hoc Tukey test indicated that the average age was significantly younger in the excellent group than in the good and intermediate groups ($p = 0.004$ and $p < 0.001$ respectively) (table I). On average, the range of flexion-extension improved from 92.7° to 117.9° ; abduction-adduction, from 31.2° to 55.4° ; and internal-external rotation, from 37.8° to 62.2° (all $p = 0.001$, table II).

Intraoperatively, we observed two nondisplaced split fractures of the proximal femur. They were followed for four weeks without weight bearing and healed well.

There were no radiographic signs of femoral loosening at the latest follow-up. Radiologically, 1mm radiolucency was detected in two patients in acetabular zone 2 and in one patient in acetabular zones 1 and 2. None of these three patients had any complaints about their hips. The mean acetabular inclination was 42.2° (range : 37-51°). Grade 1 heterotopic ossification was detected in one hip. Acetabular component displacement was noted in one hip three weeks after the index operation. The acetabulum was revised to a cementless cup with screws and a polyethylene liner. No deep infection was observed during the follow-up period. Two superficial infections were treated with debridement and antibiotic therapy. Deep vein thrombosis in two patients was treated with low molecular weight heparin and resolved well. We did not observe any pulmonary embolism or neurovascular complications. Three patients reported squeaking in their hips, which disappeared at one month, at 2 months and at 4 months respectively after the operation.

DISCUSSION

We obtained improvement in ROM in all planes after surgery. Documented and published data regarding the use of anatomic diameter components and the clinical demonstration of the advantages of an enhanced head-neck ratio in total hip arthroplasties are limited (*39*). Studies assessing recovery after conventional 28 mm THA demonstrate functional deficits such as reduced range of motion, muscle weakness, decreased gait speed, and lower hip extensor and abductor moments which persist well beyond 1 year after surgery (*23,31*). The use of large diameter femoral heads might more closely approach the kinematics of the normal hip (*31*).

In our study, the mean Harris hip scores progressed from 38.5 to 90.3 points. The majority of the excellent results were noted in younger patients. This result is comparable with the results of conventional cementless THA (metal on polyethylene) in patients younger than 50 years (*20, 28,32*). Although the improvements in clinical scores are similar, higher rates of polyethylene wear and osteolysis, especially on the acetabular side during a follow-up of 8 to 10 years was observed in these series that used conventional friction pairings (*20,32*). The clinical results of metal-on-metal total hip arthroplasties equal or exceed those of conventional articular pairings and are rarely associated with osteolysis, compared with conventional couples (*11*). Our results are also similar with the results of Stuchin *et al* in which the mean scores progressed from 40 to 88 points (*39*). Their study involved 40 hips of 34 patients who underwent THA with a resurfacing socket and a follow-up of one year. To our knowledge, the number of cases and follow-up period in our series was superior when compared to the limited series in the literature.

Biological fixation of cementless cups requires initial implant stability and physical interlocking between the cup and the supporting bone for

Table I. — The subgroups of postoperative Harris hip scores compared for age, gender and operation side

Variables	Fair (n = 5)	Good (n = 23)	Excellent (n = 31)	p values
Age (years)	72.7 ± 1.15	64.7 ± 8.78	51.8 ± 11.30	**< 0.001**
Gender				0.587
Female	2 (66.7%)	9 (42.9%)	11 (36.7%)	
Male	1 (33.3%)	12 (57.1%)	19 (63.3%)	
Operation Side				0.932
Right	2 (66.7%)	10 (47.6%)	14 (46.7%)	
Left	1 (33.3%)	9 (42.9%)	13 (43.3%)	
Bilateral	-	2 (9.5%)	3 (10.0%)	

Table II. — Comparison of pre- and post-operative range of motion (mean, SD, range)

PARAMETER	Pre-operative	Post-operative	p value
Flexion – Extension Arc	92.7 ± 12.0 (50–125)	117.9 ± 13.7 (95–145)	**0.001**
Adduction – Abduction Arc	31.2 ± 7.7 (15–50)	55.4 ± 8.5 (30–70)	**0.001**
Internal–External Rotation Arc	37.8 ± 15.3 (10–70)	62.2 ± 12.4 (40–90)	**0.001**

successful long-term stability (*17*). We obtained successful stability in all hips with this equatorially expanded resurfacing cup without screws. Complications related to the screw, its placement (*24*), and increased time spent on for screw placement during the operation is also avoided. We did not observe any displacement of the cups during the follow-up period except one in which there was clearly a technical fault.

This study revealed no radiographic signs of femoral loosening at final follow-up. The published loosening rate of conventional femoral stems is much lower than that of the femoral component in hip resurfacing (*15*). Regarding acetabula, one mm radiolucencies that we observed in three hips were all asymptomatic and did not progress. Long term follow-up is mandatory for these hips, concerning progression or loosening.

Dislocation of the hip is one of the most common complications seen after arthroplasty. It depends on a number of factors such as surgical technique, approach, implant type and patient characteristics. This may explain the highly variable occurrence rates reported in literature for dislocation, from 0% to 8% after primary THA (*10,14,35*). Larger femoral head diameter is clearly associated with lower cumulative dislocation rates (*5*). In a recent study by Krenzel *et al,* high preoperative range of motion was found to be a significant risk factor for dislocation in primary THA (*21*). Especially in young and active patients, the surgeon should be aware of potential risks during preoperative planning. In this study, no dislocations were observed during the follow-up period. Total hips with larger-diameter femoral heads are more resistant to dislocation. The large diameter head size decreases the dislocation rate by increasing the range of motion available prior to impingement, and by increasing the jumping distance (*40*). Use of larger-diameter femoral heads appears to have the potential to substantially reduce the early risk of dislocation of the prosthetic hip arthroplasty (*11,23,39*).

While heterotopic ossification rates between 3% and 50% have been reported in THA (*9*), this was seen in only one patient. Also, while the incidence of squeaking hips has been reported to be as high as 19.4% (*6*), we observed this phenomenon in only three patients, in whom it was transitory.

Lavigne *et al* reported that they could not demonstrate a clinical benefit of hip resurfacing over large diameter head THA in their study and the only remaining clear advantage of hip resurfacing would

seemingly be proximal femoral bone conservation facilitating revision surgery. However, they concluded that, because more studies now show that uncemented and cemented femoral stems in THA can be long lasting, survivorship of the femoral hip resurfacing component should demonstrate comparable survivorship before proximal femoral bone conservation can be considered a true advantage (*23*). Stuchin *et al* suggested that, although resurfacing maintains the anatomic dimensions of the femoral head, it requires more extensive soft-tissue release. Total hip arthroplasty may better preserve soft tissues at the expense of the femoral bone. Additionally, they reported that limb length and offset may be more easily controlled with THA (*39*).

Recently, there have been increasing concerns about metal-on-metal surfaces, particularly on the release of metal ions and their adverse results in these young and active patients (*3,27,43*). These may include local tissue toxicity, impaired renal function, hypersensitivity, chromosomal damage, and possibly malignant cell transformation (*15*). But today, there are no evidence based clinical results of some of these theoretical potential complications. Hypersensitivity-like reactions termed as aseptic lymphocytic vasculitis associated lesions (ALVAL) and adverse local tissue reactions (pseudotumours) have been attributed to metal debris accumulation (*8,12,34*). Obesity, female gender, component malposition, implant design and size have been found to be possible predisposing factors for such adverse reactions (*22,33*). Nevertheless, the threshold levels of metal ions which can be correlated to clinical adverse reactions have not been established yet. Component malpositioning in certain designs leads to excessive wear and debris release which may result in adverse local soft tissue reaction (*18*). It is not clear whether failures similar to those related to component malposition and excessive ion release would be seen with increasing frequency in longer-term follow-up of well-positioned components. In our series, we did not observe any adverse reaction although the majority of the patients were female. This cohort should be closely followed for long term with increased awareness of unexplained pain and mode of failures.

After a national agency issued an alert on a metal-on-metal hip device (*29*), the pros and cons of metal-on-metal pairings have been questioned. In two recent studies, the metal ion levels were found to be extremely higher in large head metal-on-metal THA groups when compared with MOM resurfacing implants of similar sizes (*15,41*). In the study of Garbuz *et al*, although the same bearing surfaces were used in both groups, the metal ion levels were extremely higher in the THA group than in the resurfacing group (*15*). This attracted the attention to the head shape (open or closed / hollowed or solid) and head-stem connection which were accused for excessive metal ion release by fretting and passive corrosion (*15,41*). In both studies, the design of the implant used involved an adapting sleeve to attach the head to the neck of the femoral stem. This adapter introduces two separate Morse tapers into the head-neck junction, which was considered as a cause for excessive fretting corrosion and consequent higher ion levels, in both studies. In our patients, we used a hollowed head design with a single articulation between the head and femoral stem. We did not observe any adverse reactions in our patients during the follow-up. Two possible explanations of this may be the single-taper-junction and/or different surface finishing technologies used by different manufacturers. Future studies are warranted to verify the differences between the prosthesis designs and metallurgy used by different companies.

This study does have some limitations. With the short follow-up period and limited number of patients, these results are preliminary. These implants have not had significant mid-term and long-term performance results yet. We also did not evaluate the metal ion concentrations, but there have been well documented papers concerning metal ion levels of large head metal on metal surfaces in the literature (*27,43*).

In the future, with the evolution in surgical techniques and implant technologies, the potential drawbacks of hip resurfacing should be diminished. Until that time, new generation metal-on-metal THA with resurfacing cups and femoral stems coupled with large diameter heads might be a valid alternative option, especially in young active

patients. The rationale for using large head metal-on-metal THA are the long term results of articulating couples, the clinical results that are at least the same as the conventional surfaces, the inherent stability and mobility with only concerns about possible long-term effects of metal ions, which have not been proven yet. Our encouraging early results in young active patients should be confirmed with larger series and longer follow-up.

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