The Journal of Arthroplasty xxx (2017) 1–9

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

A Randomized Seven-Year Study on Performance of the Stemmed Metal M2a-Magnum and Ceramic C2a-Taper, and the Resurfacing ReCap Hip Implants

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ARTICLE INFO

Article history:
Received 6 June 2017
Received in revised form
8 November 2017
Accepted 26 November 2017
Available online xxx

Keywords:
ceramic prostheses
chromium
cobalt
hip resurfacing
metal-on-metal prostheses
total hip arthroplasty

ABSTRACT

Background: The large-diameter metal-on-metal hip prostheses were expected to have low wear and reduced dislocation rate compared to the traditional metal-on-polyethylene implants. We compare 2 such prostheses, the ReCap resurfacing implant and the M2a-Magnum stemmed implant, with the C2a ceramic-on-ceramic stemmed implant as to clinical performance, serum concentrations of prosthesis metals, and the durability of the implants in a randomized, controlled clinical trial at 7 years of follow-up.
Methods: All included patients had osteoarthritis. Preoperatively, the size of the implants was estimated from a magnetic resonance imaging (MRI) scan. Follow-up data included serum cobalt and chromium concentrations, Oxford and Harris Hip Scores, leg press and abduction force, 6-minute walk distance, WOMAC and SF-36 self-assessment scores, and from the 7th postoperative year also ultrasonography (US) examination of the soft tissue adjacent to the implant as well as MRI with metal artifact reduction sequence (MARS-MRI) when indicated.
Results: One hundred fifty-two hips in 146 patients were included. The serum cobalt and chromium concentrations were significantly higher for the 2 metal-on-metal prostheses than for the ceramic-on-ceramic, with the M2a-Magnum as the highest. No significant difference was found between the groups concerning physical performance measurements and scores as well as dislocations and prosthesis survival. Five revisions were done and concerned all groups, for reasons of pain, high serum cobalt and chromium concentrations, cystic fluid collection around the joint, and infection. Metal concentrations, US, and MARS-MRI contributed to the decision making regarding prosthesis revision.
Conclusion: Metal concentrations were significantly higher for the metal-on-metal prostheses than for the ceramic-on-ceramic. The clinical performance was good in all 3 prosthesis groups. Metal concentrations, US, and MARS-MRI findings were of use to identify hips needing revision.
ID Number in ClinicalTrials.gov PRS: NCT00284674

Replacement of a degenerated hip joint with a prosthesis is most often successful and will relieve pain, nearly restore the range of motion of the hip, and increase the patient's ability to walk, thereby maintaining muscle strength, joint mobility, and ability to cope with physical activities. In 2005, a substantial part of the hip prostheses needed revision within 10 years of the primary arthroplasty. The major cause for this was aseptic loosening, which accounted for 56.5% of the revisions in the Danish hip registry annual report 2005, where the average 10-year survival rate in hip arthroplasty due to osteoarthritis was 91%, and for patients below

The execution of the study was fund supported by Biomet, Inc. This company was not engaged in preparation of the study protocol or interpretation and reporting of data and results. None of the authors have a conflict of interest to disclose.

No author associated with this paper has disclosed any potential or pertinent conflicts which may be perceived to have impending conflict with this work. For full disclosure statements refer to https://doi.org/10.1016/j.arth.2017.11.061.

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https://doi.org/10.1016/j.arth.2017.11.061
0883-5403/

50 years of age it was 86.3%. This is in accordance with international findings as reviewed by MacInnes et al [1].

The aseptic loosening is preceded by osteolysis adjacent to the implant, caused by wear particles of the implant materials or the occasionally used bone cement. The particles that can induce osteolysis are sized from 10-μm diameter down to nanometer size, or present as dissolved ions from the prosthesis metals as reviewed by Sansone et al [2]. At the beginning of the century it was found, from tests in hip simulators, that the volumetric wear from the bearings could be reduced by using metal-on-metal or ceramic-on-ceramic bearings instead of bearing couples with one part being ultra high molecular weight polyethylene. The volumetric wear was low in vitro even in large bearings as long as fluid lubrication was present. This led to the assumption that large bearings would have low volumetric wear in vivo and consequently implants with such large bearings were introduced, designed as either resurfacing prostheses where a large diameter was necessary or as traditional stemmed implants. The resurfacing prostheses provided the possibility to preserve the viscoelastic properties of the femoral neck at the cost of a more extensive detachment of the gluteus maximus and limited possibilities for correction of neck length, neck angle, neck anteversion, and off-set.

Elevated serum concentrations of cobalt and chromium had been found in patients with 28-mm metal-on-metal hip implants with titanium stems [3]. Despite the hip simulator measurements which indicated a low volumetric wear of metal-on-metal hip implants with a larger diameter ($\geq$36 mm), the clinical use of these implants also resulted in numerous patients having elevated serum concentrations of the prosthesis metals, in particular cobalt and chromium. These occurrences were reported by among others Langton et al [4] later than the period in which the surgical operations in the current study took place. They identified that femoral head diameter, acetabular cup inclination [5], and implant design characteristics such as the cup articular arc angle [6] are important determinants for implant wear, and with it the serum concentrations of cobalt and chromium [7]. A review on resurfacing hip implants [8] states that excessive wear-related failures with high metal ion levels and adverse local tissue reactions occur, mostly due to a poor design and inadequate placing of the acetabular component. An expert consensus acknowledges that resurfacing metal-on-metal hip prostheses can be used with advantage in some patients [9]. Moreover, an 11-year follow-up of a single-surgeon series of 373 metal-on-metal hip resurfacing arthroplasties demonstrates a 93% prosthesis survival rate and underlines that personal expertise is necessary for obtaining such good results [10].

This study is a randomized, controlled comparison of the ReCap resurfacing prosthesis, the metal-on-metal M2a-Magnum/Bimetric stemmed, modular neck prosthesis, and the ceramic-on-ceramic C2a-Taper/Bimetric stemmed, modular neck prosthesis, based on 7 years of follow-up. It was designed to compare long-term clinical performance, wear, and stability of the articulating surfaces as well as wear or corrosion of tapers by measurement of serum concentrations of primarily cobalt and chromium, and secondarily other metallic elements used in the implant alloys. The formal null hypothesis was that there was no difference between the 3 prostheses regarding serum metal concentrations. Secondary outcome variables were the function of the hips as evaluated by physical function tests, scores of hips function, and the patients' physical performance, rate of dislocations, and number of revisions.

Methods

Study Design

The study was approved by the local ethics committee as protocol KF 01-157/04. Calculation of the cohort size was based on serum concentrations of cobalt and chromium, assuming the mean and standard deviation values of the natural logarithm of the concentration of each metal to be 1.6 and 0.6, respectively. Ability to detect an ln concentration difference of 0.5 between 2 groups in a 2-sided significance test with an α error level of 0.01 and a power of 0.9 required 45 completing patients in each group, to which were added 5 patients in each group to compensate for possible withdrawal of informed consent or other causes for termination of follow-up, resulting in 50 patients in each group.

Inclusion of Patients

All patients scheduled for primary hip arthroplasty in our department due to osteoarthritis were screened for inclusion and exclusion criteria. The inclusion criteria were primary osteoarthritis of the hip in patients scheduled for arthroplasty, age below 70 years, American Society of Anesthesiologists class I or II, magnetic resonance imaging (MRI) showing no necrosis of the femoral head, and dual-energy X-ray absorptiometry showing no osteoporosis in the femoral neck. Exclusion criteria were a short femoral neck or severe deformity of the femoral head or acetabulum, presence of large cysts (>1 cm^3), previous fractures in acetabulum or femur, diseases or medical treatment affecting local and general bone metabolism, or inability to comply with written and verbal instructions in Danish language. If these criteria were met the patient was informed about the purpose of the study.

The inclusion and surgery ran from March 2006 to November 2007. One hundred seventy-five patients were assessed for eligibility and 26 were not included, of which 7 had avascular necrosis of the femoral head and 5 had large cysts as detected in MRI. One hundred forty-nine patients representing 155 hips were included. Patients were randomly and sequentially allocated to 1 of the 3 groups by draw with replacement of the lot. The patient flow in allocation and the later surgery and follow-up is shown in Figure 1. Updating of the database was concluded by the end of October 2015. Three patients wanted to have their operation postponed, resulting in 146 patients who were operated within the scheduled time frame and constitute the cohort that was followed. Six patients had both hips operated, at subsequent time points between 1.4 and 12 months after the first hip. Three had a M2a-Magnum and 3 a ReCap. The cohort represents 152 hips, of which 51 had ReCap, 47 M2a-Magnum, and 54 C2a-Taper prostheses.

Implants

Group A: ReCap

The femoral head is made of cobalt-chromium-molybdenum alloy (ASTM F1537-94) with high carbon content (0.2%-0.3%) and microstructure as cast. The inside of the femoral component is geometrically formed from a spherical dome and a cylindrical region, and its surface has a closed-pore porous coating of sprayed titanium alloy. The cap was cemented using Refobacin bone cement with gentamicin. The acetabular cup is in one-piece made of cobalt-chromium-molybdenum alloy (ASTM F1537-94) with high carbon content, microstructure as cast. The back of the cup has a closed-pore porous coating of sprayed titanium alloy. The version without hydroxyapatite coating was used.

Group B: M2a-Magnum

The femoral head is composed of a reinforced dome, and in the sizes exceeding 40 mm a large taper adapter (trunnion) fits into the dome and accommodates the neck length option of the stem. The dome is made of the same cobalt-chromium-molybdenum alloy as ReCap. The taper adapter is made of titanium-aluminum-vanadium alloy Ti6Al4V. The same acetabular cup is used as in ReCap.