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Long – term survivorship and clinical results of the navigated withdrawn ASR ™

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ABSTRACT

Introduction: Primary goals of the study were to present the mid – to long - term survivorship and clinical, radiological and metal serological results of the first stem – navigated ASR™ resurfacing at our clinic. Secondary goals were to determine the influence of stem – navigation on the outcome and risk factors for revision in our cohort.

Methods: From Mai 2006 to Mai 2009 46 ASR™ resurfacing hip systems have been implanted in 43 patients with a median age of 55 years. At final follow – up (33 patients with a mean follow –up of 89,6 months) guidelines were followed and HHS and HOOS were completed. Inclination, NSA and SSA were measured on radiographs and signs of loosening were graded. Risk factors for revision were compared in the non – revision and revision group.

Results: Mean cumulative survival of the prosthesis after 99,9 Months was 81,8%. At final follow – up 8 revisions were performed. Median HHS was 97, HOOS was 87,2. Four prostheses showed signs of loosening and nine heterotopic ossifications. All shaft components, except one, were placed in minimal valgus position to avoid risk for fracture. Age and diameter of the femoral component were significantly different between the non – revision and revision group.

Discussion: Survivorship is comparable to numbers found in other studies. Patients with complete final follow – up in general had good objective and subjective scores and few signs of loosening in the radiological follow – up. Navigation might have a positive effect on reduction of risk for fracture. Age and diameter of the femoral component seem to influence the outcome.

1. Introduction

Both the first- (metal-on-polyethylene) and the second-generation (cementless metal-on-metal (MoM)) resurfacings failed because of high rates of wear and aseptic loosening.[1,2] The current third-generation MoM hip resurfacing implants consist of a cemented femoral component and a press-fit acetabular component.[1,2]

When first introduced on the market, MoM articulations using cobalt-chromium-molybdenum alloys reported considerably less wear debris than standard metal-on-polyethelyne components and additionally, the all-metal acetabular component can be made thinner, allowing the use of a larger-diameter femoral head resulting in an increased stability and range of movement compared to implants with small head diameters.[3] Possible additional advantages of the MoM hipresurfacing included resection of less bone and an easier conversion to a secondary procedure if failure occurs, good proprioceptive feedback because it mimics normal hip kinematics and reduced risk of leg length discrepancy.[4–7]

However, for some years the discovery of periprosthetic soft-tissue lesions, called inflammatory pseudotumors, in patients who have had this type of hip resurfacing arthroplasty has been a concern. The presence of these pseudotumors has been associated with elevated levels in the serum of Cobalt (Co) and Cromium (Cr) ions.[5]

Adverse reaction to metall debris (ARMD) is an umbrella term to describe this cascade.

Another disadvantage is the occurence of femoral neck fractures with a reported incidence of 1.5–7.2%. Varus position of the femoral component has proven to be a risk factor for femoral neck fractures.[6] The navigation tool used in our clinic has proven to be helpful in accurate placement of the femoral component of the resurfacing hip

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arthroplasty.[6]

Because of the observed disadvantages, the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom issued a medical device alert in April 2010 for the surveillance of all types of MoM hip protheses and subsequently the prosthesis as used in our clinic was withdrawn from the market. Guidelines for follow –up of the MoM prostheses were developed by the manufacturer. Known factors to influence the outcome of resurfacing hip arhtroplasty inlcude among others younger age, female gender, smaller component size and steeply inclined acetabular components.[2,8,9]

Our primary goals were to present the mid – to long – term survivorship and clinical, radiological and metal serological results of the first stem – navigated ASR™ resurfacing protheses at our clinic. Secondary goals were to determine the influence of stem – navigation on the outcome and determine the riskfactors for revision in our cohort.

2. Material and methods

2.1. Patients

From Mai 2006 to Mai 2009 46 total hip prostheses of the ASR™ Hip Resurfacing System have been implanted in 43 patients. This cohort was retrospectively analysed. Because of the retrospective character of the study permission by the medical ethics committee was not necessary. All patients gave informed consent. The stem component was placed using navigation in all patients, the acetabular component was implanted in a conventional way without navigation. Patient characteristics are listed in Table 1.

2.2. Final follow – up

At final follow – up 35 patients were contacted, one patient had a metastasized pulmonary carcinoma and was unable to visit our clinic, one patient, who had already undergone a revision of one hip, was dissatisfied and refused further follow – up, three patients were unable to be contacted (Fig. 1). Patients were routinely checked every year according to the guidelines by the manufacturer of the resurfacing hip arthroplasty.

2.3. Clinical follow – up

At final follow-up the patients completed the Hip dysfunction and Osteoarthritis Outcome Score (HOOS) and Harris Hip Score (HHS) was filled out by the physician, radiographs of the hip were taken (AP and Lauenstein) and in case of complaints blood was drawn from the patient to determine the Co and Cr ions in whole blood and/or a MARS – MRI was acquired according to guidelines as composed by the manufacturer to rule out a pseudotumor.

Table 1
Patient demographics of the population as a whole.

Variable	*ASR Resurfacing*
Number of hips	46
Number of patients	43
Male:Female	26:17
Age at time of operation (years)[a]	55 (45–74)
Femoral head diameter (mm)[b]	48 (3)
Height (cm)[b]	173.7 (6.84)
Weight (kg)[b]	84 (14.3)
BMI[b]	27.8 (± 4.0)

[a] Median (Range).
[b] Mean (Standard deviation).

2.4. Radiolographic analysis

On the AP radiograph, the acetabular angle of inclination, neck – shaft agle (NSA) and stem – shaft angle (SSA) and the difference between these two angles (varus or valgus positioning) were measured by two observers (author 1 and 2) and the mean angle was used, since good interoberserver reliability exists.[10] Any femoral radiolucencies were classified in the three zones as described by Beaulé et al.[10] Radiolucensies were measured in millimeters and acetabular radiolucency was classified in three zones according to DeLee and Charnley.[11] Heterotopic bone formation was classified as described by Brooker et al.[12] All available digital radiographs of the latest visit to our clinic were used to obtain the measurements.

2.5. Statistical analysis

Descriptive statistics were used to summarize the data. Data were presented as mean (SD), median (range), or n (%). Kaplan-Meier survival analysis was used to estimate the survival for endpoints revision of any component for any reason. Patients lost to follow-up were considered censored at the time of last follow-up. Differences in risk factors in the revision – and non – revision group were tested using Wilcoxon rank-sum (Mann Whitney) test or two - sample t test, where appropriate, a gender analysis was performed using Fisher's exact test. Statistical analyses were performed using STATA 13.1 (StataCorp, College Station, TX, US). P-values < 0.05 were considered statistically significant.

3. Results

3.1. Revisions and long – term survival

At final follow – up eight revisions had been performed. In five patients the ASR prosthesis was revised because of ARMD. In one patient the stem component showed signs of aseptic loosening and was revised and in one patient the stem component was revised after a pertrochanteric fracture due to a direct fall on the hip, in one patient the prothesis because of unexplained persistent complaints. Thus, as depicted in the Kaplan-Meier plot (Fig. 2), mean cumulative survival of the ASR™ Hip Resurfacing System after 99,9 Months was 81,8% (95% CI: 66,6–90,5).

3.2. Final clinical follow –up

Mean follow-up of the 33 implants was 89,6 months (SD 8,6). At final follow – up median HHS was 97 (68–100) (N = 30) and median HOOS was 87.2 (24.4–100) (N = 32). During complete follow-up bloodsamples determining Co and Cr values were only taken in case of complaints or irregularities on the radiographs of the operated hip. Bloodsamples were collected during follow-up. Median Co value was 1.15 (0.3–28.3) ppb. Median Cr value was 0.95 (0.1–11.3) ppb (N = 32) (Table 2).

3.3. Final radiographic follow – up

In four prostheses radiolucent lines were observed. In all prostheses the radiolucent lines were bigger than 2 mm. In all four prostheses the cup was involved, in two the stem in addition. Heterotopic ossifications were observed in nine prostheses. In four prostheses grade I, in two prostheses grade II and in three prostheses grade III ossifications were observed. Cystic changes around the stem were observed in one patient. Mean inclination angle, NSA and SSA are depicted in Table 2. All femoral stem components, with one exception, were placed in a (slight) valgus position.