Long – term survivorship and clinical results of the navigated withdrawn ASR™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 implants 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-polyethylene 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 hip resurfacing 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 Chromium (Cr) ions.⁵

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

Another disadvantage is the occurrence 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 prostheses 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 arthroplasty include 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 prostheses 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. Radiologic analysis

On the AP radiograph, the acetabular angle of inclination, neck – shaft angle (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 interobserver reliability exists.¹⁰ Any femoral radiolucencies were classified in the three zones as described by Beaulé et al.¹⁰ Radiolucencies 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 peritrochanteric fracture due to a direct fall on the hip, in one patient the prosthesis was revised because of unexplained 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.

Fig. 1. Flowchart of the implants.

3.4. MARS –MRI

According to the Depuy follow – up guidelines, a MARS – MRI was arranged only when patients either had complaints, had signs of loosening on the radiographs or had high levels of Co and/or Cr in blood. One prosthesis in which a pseudotumor in MARS – MRI has been detected, has not been revised, because the patient experiences no complaints. In one patient the MARS – MRI showed an edema in the femoral neck, possibly as a result of loosening of the femoral component. But, while the patient experiences no complaints, no revision has been performed.

3.5. Risk factors

Known risk factors to influence the outcome of resurfacing hip arthroplasty have been compared in the revised- and non – revised group

and listed in Table 2. Patients in the revised group were significantly younger and had a significantly smaller diameter of the femoral component. Although not significant, there was a trend towards female gender in the revised group. As expected Co and Cr values in whole blood were significantly higher in the revised group, because highly elevated metal ions in blood are a reason to discuss a revision.

4. Discussion

When the third generation MoM resurfacing hip arthroplasty was introduced, advantages such as less wear and less bones resection propelled many surgeons to adapt the MoM resurfacing hip arthroplasty quite early, despite a lack of evidence for a good prosthesis.

In contrast to the latest guidelines as developed by the MHRA, according to the Depuy recall guidelines of the ASR™ resurfacing hip system, routine Co and Cr serum tests are not warranted unless the

Fig. 2. Kaplan – Meier plot: Cumulative survival of 46 hip resurfacings, with revision surgery defined as failure event. The small vertical spikes represent the censored data.

Table 2
Comparison of the risk factors.

Variable	Implants in situ (N = 33, included)	Revisions (N = 8, drop – out)	P – Value
Age at surgery (yrs.)	55 (45–74)	52 (47–55)	0.0345
BMI (kg/m ²)	27.6 (4.4)	28.0 (2.5)	0.82
Cup inclination (degrees)	47.3 (5.0)	48.9 (6.3) ^a	0.50
Cobalt (ppb)	1.15 (0.3–28.3) ^b	36.9 (6.96–73.3) ^c	0.0005
Chromium (ppb)	0.95 (0.1–11.3) ^b	8.52 (6.08–32.8) ^c	0.0006
Diameter femoral component (mm)	48.2 (2.2)	45.3 (4.7)	0.0125
Gender (male/female)	20/13	2/6	0.12
Difference NSA – SSA (degrees)	– 6.7 (– 22.2–0.35) ^d	– 4.3 (– 6.3 to – 4.1) ^e	0.35
Stem Shaft Angle (degrees)	137.9 (131.8–151.2) ^b	137.5 (133.3–145.0) ^c	0.93
Neck Shaft Angle (degrees)	131.2 (111.4–141.2) ^d	130.9 (129.0–131.2) ^e	0.52

^a 2 missing.

^b 1 missing.

^c 3 missing.

^d 7 missing.

^e 5 missing.

patient experiences complaints of the operated hip.¹³ A recent studie, however has shown that in the long term not only symptomatic patients with elevated metal ion levels who have the highest prevalence of pseudotumors (63%), but also asymptomatic patients with elevated ion levels (42%) and symptomatic patients with nonelevated metal ions (11%) are at risk of developping a pseudotumor. This result suggests that routine metal ion measurement should be combined with clinical assesment in asymptomatic patients as well.¹⁴

In 2012 the European Federation of National Associations of Orthopaedics and Traumatology (EFORT) had a consensus meeting about MoM resurfacing hip arthroplasty. Consensus was reached recommending annual check-up of the prothesis for the first five years, followed by regular check-ups after hip arthroplasty. In case of the presence of riskfactors for revision (e.g. female gender, small femoral component < 50 mm) an annual check-up for the lifespan of the prothesis is recommended.¹⁵ A routine Co and Cr serum test is also recommended in asymptomatic patients during annual check-ups.¹⁵

However not all resurfacing prostheses have high failure rates. The ASR™ hip resurfacing has a higher failure rate compared with the BHR™ (Smith and Nephew orthopaedics, Warwick, UK). The ASR™ was recalled by its manufacturer in August 2010 because of the high failure rates reported by multiple sources.^{2,16}

For example data from the National Joint Registry of the United Kingdom has shown a five-year revision rate of 12% for the ASR™ Resurfacing. In contrast the comparable rate for the BHR system, which has the lowest five-year revision rate of all current generation resurfacing systems, was 4,3%.¹⁷ These findings are similar in studies analysing the Australian National joint registry data with revision rates at five years of 10,9% for the ASR™ compared to 4,0% for the rest of the resurfacing implants.¹⁸ A similar revision percentage was found in this study, showing a cumulative percent revision at 99 months of 18,2%. The ASR™ however has a reduced cup articular arc angle and clearance compared with the BHR™, and the rim of the acetabular component has a smaller radius. These factors increase the theoretical risk of edge contact and high wear and the higher posibility of revision of the prosthesis.¹⁷

Pseudotumors are associated with increased wear at the MoM articulation. The most important question is if asymptomatic patients with these pseudotumors should undergo a large revision operation, of which we know the outcome will be worse than in primary total hip arthroplasty with a re-revision rate of 25% being reported within five years after revision surgery.^{5,19} A recent study has shown that these

asymptomatic pseudotumors show little change over time in MRI after MoM hip resurfacing, but cause muscle atrophy in their surroundings.^{19,20} It has to be further investigated what the effects of these pseudotumors combined with elevated serum Co and Cr ion levels are. Thus it is unknwn whether asymptomatic resurfacings with high ion levels really warrant revision.²¹ A recent study conducted by Van Lingen et al. showed that asymptomatic patients with highly elevated Co and Cr serum levels did not develop any adverse reactions in the short term. They therfore conclude that a large revision is not indicated in asymptomatic patients with highly elevated blood metal ions.²²

Christian et al. demonstrated that the toxicological weight of evidence suggests that MoM hip implants are unlikely to be associated with an increased risk of systemic cancers, which is consistent with published and ongoing epidemiologic studies investigating the relationship between elevated Co and Cr serum levels and increase in systemic cancers.²³ Paustenbach et al., who examined the connection between Co serum concentrations and adverse biological effects, concluded that only under very unusual circumstances biologically important systemic effects might occur in MoM hip implant patients with Co serum concentrations of less than 300 ppb. Patients with MoM hip implants who exhibit signs or symptoms potentially related to polycythemia, hypothyroidism, neurological or cardiac dysfunction should be clinically evaluated for these conditions.²⁴

There are several limitations to this study. First, it was a retrospective non-randomized study and secondly no learning curve was taken into account. Another limitation of the study was the low number of implants. Although confirmation of the already existing insights of the ASR in terms of revisions and complications was presented in this study, navigation of the stem might be helpfull in placing the femoral stem component in an optimal slight valgus position, which might be beneficial for the resurfacing hip protheses which are still available on the market for implantation.

5. Conclusions

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 femoral neck fracture. Age and diameter of the femoral component seem to influence the outcome.

Declarations of interest

None.

Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jor.2018.08.013>.

References

- van der Weegen W, Hoekstra HJ, Sijbesma T, Bos E, Schemitsch EH, Poolman RW. Survival of metal-on-metal hip resurfacing arthroplasty: a systematic review of the literature. *J Bone Joint Surg Br.* 2011;93:298–306.
- Jameson SS, Baker PN, Mason J, Porter ML, Deehan DJ, Reed MR. Independent predictors of revision following metal-on-metal hip resurfacing: a retrospective cohort study using National Joint Registry data. *J Bone Joint Surg Br.* 2012;94:746–754.
- Hug KT, Watters TS, Vail TP, Bolognesi MP. The withdrawn ASR THA and hip resurfacing systems: how have our patients fared over 1 to 6 years? *Clin Orthop Relat Res.* 2013;471:430–438.
- De Haan R, Campbell PA, Su EP, De Smet KA. Revision of metal-on-metal resurfacing arthroplasty of the hip: the influence of malpositioning of the components. *J Bone Joint Surg Br.* 2008;90:1158–1163.
- Kwon YM, Glyn-Jones S, Simpson DJ, et al. Analysis of wear of retrieved metal-on-metal hip resurfacing implants revised due to pseudotumours. *J Bone Joint Surg Br.* 2010;92:356–361.
- Schnurr C, Michael JW, Eysel P, Konig DP. Imageless navigation of hip resurfacing

- arthroplasty increases the implant accuracy. *Int Orthop*. 2009;33:365–372.
7. Kruger S, Zambelli PY, Leyvraz PF, Jolles BM. Computer-assisted placement technique in hip resurfacing arthroplasty: improvement in accuracy? *Int Orthop*. 2009;33:27–33.
 8. Glyn-Jones S, Pandit H, Kwon YM, Doll H, Gill HS, Murray DW. Risk factors for inflammatory pseudotumour formation following hip resurfacing. *J Bone Joint Surg Br*. 2009;91:1566–1574.
 9. Langton DJ, Jameson SS, Joyce TJ, et al. Accelerating failure rate of the ASR total hip replacement. *J Bone Joint Surg Br*. 2011;93:1011–1016.
 10. Beaulé PE, Dorey FJ, Le Duff MJ, Gruen T, Amstutz HC. Risk factors affecting outcome of metal-on-metal surface arthroplasty of the hip. *Clin Orthop Relat Res*. 2004;87–93.
 11. DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. *Clin Orthop Relat Res*. 1976;20–32.
 12. Brooker AF, Bowerman JW, Robinson RA, Riley Jr LH. Ectopic ossification following total hip replacement. Incidence and a method of classification. *J Bone Joint Surg Am*. 1973;55:1629–1632.
 13. Olsen M, Davis ET, Waddell JP, Schemitsch EH. Imageless computer navigation for placement of the femoral component in resurfacing arthroplasty of the hip. *J Bone Joint Surg Br*. 2009;91:310–315.
 14. Reito A, Puolakka T, Elo P, Pajamaki J, Eskelinen A. Outcome of Birmingham hip resurfacing at ten years: role of routine whole blood metal ion measurements in screening for pseudotumours. *Int Orthop*. 2014;38:2251–2257.
 15. DGOOC. Metall-on-Metall"-Hüftendoprothesen. <https://dgooc.de/presse/stellungnahmen/stellungnahmen-beitraege/88-stellungnahme-der-dgooc-und-der-ae-zu-qmetall-on-metallq-hueftendoprothesen-3April2012>.
 16. Reito A, Puolakka T, Elo P, Pajamaki J, Eskelinen A. High prevalence of adverse reactions to metal debris in small-headed ASR hips. *Clin Orthop Relat Res*. 2013;471:2954–2961.
 17. Underwood R, Matthies A, Cann P, Skinner JA, Hart AJ. A comparison of explanted articular surface replacement and birmingham hip resurfacing components. *J Bone Joint Surg Br*. 2011;93:1169–1177.
 18. Benjamin-Laing H, Haddad FS. Metal-on-metal hip arthroplasty: going, going, gone... - opposes. *J Bone Joint Surg Br*. 2012;94:78–81.
 19. van der Weegen W, Brakel K, Horn RJ, et al. Asymptomatic pseudotumours after metal-on-metal hip resurfacing show little change within one year. *Bone Joint Lett J*. 2013;95-B:1626–1631.
 20. Berber R, Khoo M, Cook E, et al. Muscle atrophy and metal-on-metal hip implants. *Acta Orthop*. 2015;86:351–357.
 21. Dunbar MJ, Prasad V, Weerts B, Richardson G. Metal-on-metal hip surface replacement: the routine use is not justified. *Bone Joint Lett J*. 2014;96-B:17–21.
 22. van Lingen CP, Ettema HB, Timmer JR, de Jong G, Verheyen CC. Clinical manifestations in ten patients with asymptomatic metal-on-metal hip arthroplasty with very high cobalt levels. *Hip Int*. 2013;23:441–444.
 23. Christian WV, Oliver LD, Paustentbach DJ, Kreider ML, Finley BL. Toxicology-based cancer causation analysis of CoCr-containing hip implants: a quantitative assessment of genotoxicity and tumorigenicity studies. *J Appl Toxicol*. 2014;34:939–967.
 24. Paustentbach DJ, Galbraith DA, Finley BL. Interpreting cobalt blood concentrations in hip implant patients. *Clin Toxicol*. 2014;52:98–112.