



## Three metal-on-metal hip replacement devices from the same manufacturer – A short- to midterm survival.

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The aim of this retrospective study was to evaluate short- to midterm results of three different metal-on-metal hip devices from the same manufacturer. A total of 329 hip operations were performed in a single academic unit between 2004 and 2010 using either Birmingham hip resurfacing or Synergy – Birmingham and Synergy – R3 total hip arthroplasty. The overall survival rate at the end of the follow-up time for Birmingham hip resurfacing was 88%, for Synergy – Birmingham total hip arthroplasty 95%, and for Synergy – R3 total hip arthroplasty 81% ( $p = 0.036$ ). Five revision operations were performed due to adverse reaction to metal debris. Head sizes > 50 mm had lower revision rates compared to smaller ones. Synergy – R3 had a poor survival already at short term. The mid-term survival of Birmingham hip resurfacing arthroplasty was inferior compared to previous studies.

**Keywords :** Birmingham, hip resurfacing arthroplasty, metal-on-metal hip arthroplasty, R3, Synergy, total hip arthroplasty

### INTRODUCTION

Hip resurfacing arthroplasty (HRA) and total hip arthroplasty (THA) with metal-on-metal surface bearings have been used widely during the last decade. Birmingham hip resurfacing (BHR) (Smith & Nephew, Warwick, UK) is the most common HRA device worldwide. BHR HRA has been reported to have decreased risk of revision compared to other HRAs (6). However, all HRAs suffer

from a common complication pattern of femoral neck fractures, aseptic component loosening, and metal complications associated to metal-on-metal bearings : adverse reaction to metal debris (ARMD – reaction) such as metallosis and pseudotumours (4,9,11,21). ARMD may be even more common using metal-on-metal THA than using HRA at least in some devices like ASR (7,19). Due to metal-on-metal complications, national recommendations have been presented not to use metal-on-metal implants until more data from their safety is available (3,15).

BHR HRA was the most common HRA device in Turku University Hospital. The BHR cup was also used with Synergy femoral component as a large-head metal-on-metal THA. The same manufacturer

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Table I. — Patient demographics and pre- and postoperative Harris Hip Scores

	Total amount of patients	Male	Female	Age Mean	Harris Hip Score Mean		
					Preoperatively	3 months postoperatively	1 year postoperatively
BHR HRA	249 (75.7%)	175 (81.4%)	74 (64.9%)	52.0	65.8	93.6	97.8
BHR – Syn THA	39 (11.9%)	21 (9.8%)	18 (15.8%)	57.8	61.9	86.8	92.3
R3 – Syn THA	41 (12.5%)	19 (8.8%)	22 (19.3%)	62.5	61.8	89.4	97.0
Total	329	215	114	54.0	64.9	92.3	97.2

provided also R3 cup with a convertible liner option made of either polyethylene, ceramic, or metal. The aim of this study was to assess the short- to mid-term survival results of metal-on-metal hip devices BHR HRA, Synergy – BHR THA, and Synergy – R3 THA in Turku University Hospital.

## MATERIAL AND METHODS

All BHR HRAs, Synergy-BHR THAs and Synergy-R3 THAs performed between February 2004 and September 2010 in Turku University Hospital were included in the study. There were a total of 329 operations in 313 patients. Mean follow-up time was 4.7 years. Mean follow-up time for BHR – BHR was 6.2 years, for Synergy – R3 2.3 years, and for Synergy – BHR 3.9 years. Demographic data are presented in Table I.

Since 2005 hip replacement information in Turku University Hospital has been collected and saved in an electronic database, called Implant DB by BCB Medical. Information concerning the year 2004 was gathered from Turku University Hospital's electronic medical record database. The study information consisting of operative reports, outpatient visits (Harris Hip Score), blood metal ion measurement levels and radiographs were retrieved retrospectively from these electronic databases and radiograph archives. The follow-up time continued until 31.3.2012. Outpatient follow-up visits were scheduled at two months and at one year after the surgery. Anteversion and abduction angles of the cups were assessed from postoperative radiographs by I.K. and

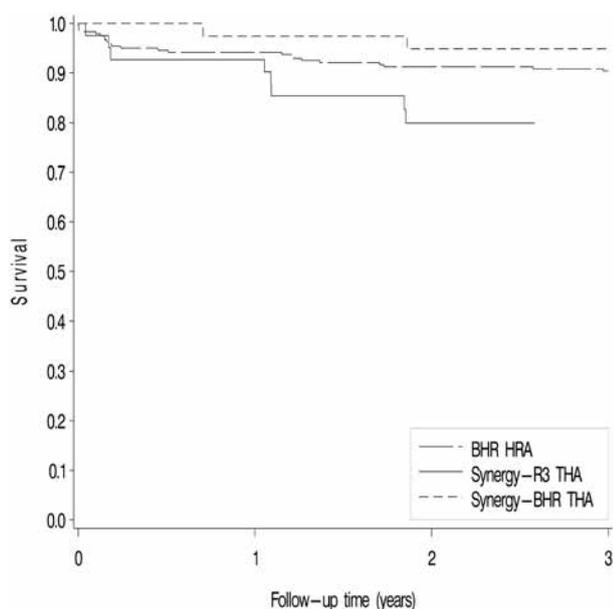
K.T.M. Radiolucency around acetabular and femoral components was evaluated as a sign of loosening. Blood chromium and cobalt levels were assessed from a total of 100 implants. Seventy seven of these were BHR – BHR HRAs, 8 Synergy – BHR THAs, and 15 Synergy – R3 THAs.

The average age of the patients was 54 years. Two-hundred fifteen of the patients were men (65.4%) and 114 were women (34.6%). Sixteen patients had a bilateral operation. The HRAs were performed through a posterior approach and the THAs through a posterior approach or a Hardinge's anterolateral approach.

Implant survival rates at three years and at the end of the follow-up of each device were assessed using Kaplan-Meier survival and log-rank test. Revision for any reason served as an endpoint. The Cox multiple regression model was used to study differences between implants and to adjust for potential confounding factors. These were : age, sex, head size (< 50 mm and ≥ 50 mm), and cup anteversion and abduction angle. Results were expressed using hazard ratios (HR) with 95% confidence intervals (CI). SAS System for Windows (release 9.2, SAS Institute Inc., Cary, NC) was used in statistical analyses. P-values < 0.05 were considered to be statistically significant.

## RESULTS

The overall survival at three years for BHR – BHR HRA was 90.5%, for Synergy – BHR THA 94.9%, and for Synergy – R3 THA 80.5% (log-rank



**Fig. 1.** — Kaplan-Meier survival curves for revision risk at three-years follow-up (log-rank test,  $p=0.048$ ).

test,  $p = 0.048$ ) (Fig. 1). Mean follow-up time for BHR – BHR was 6.2 years, for Synergy – R3 was 2.3 years, and for Synergy – BHR 3.9 years. The overall survival rates of the implants at the end of follow-up for BHR – BHR HRA was 87.6%, for Synergy – BHR THA 94.9%, and for Synergy – R3 THA 80.5%. Synergy-R3 THA had tendency towards a worse outcome compared to the other study devices ( $p = 0.06$ ) The adjusted risk ratios in the Cox model for revision performed for any reason are presented in the Table II. Larger femoral head size was statistically significantly associated

with a lower revision risk ( $p = 0.009$ ). Patient age or sex had no statistically significant association with prosthesis survival ( $p = 0.7$  for age and  $p = 0.3$  for sex). Cup anteversion or abduction angles were not associated with risk either.

Blood cobalt- and chromium-ion levels were assessed from a total of 100 hips. Metal-ion levels were assessed from 77 BHR – BHR hips (30.9% of all BHR – BHR hips), from 8 BHR – Synergy hips (20.5% of all BHR – Synergy hips), and from 15 R3 – Synergy hips (36.6% of all R3 – Synergy hips). Average chromium level considering all three implant types was  $4.0 \mu\text{g/l}$  and average cobalt level was  $6.7 \mu\text{g/l}$ . Average blood chromium level was  $3.5 \mu\text{g/l}$  for BHR – BHR HRA,  $6.6 \mu\text{g/l}$  for Synergy – BHR THA, and  $5.4 \mu\text{g/l}$  for Synergy – R3 THA. Average cobalt level was  $4.7 \mu\text{g/l}$  for BHR – BHR HRA,  $13.2 \mu\text{g/l}$  for Synergy – BHR THA, and  $13.6 \mu\text{g/l}$  for Synergy – R3 THA.

Reasons for revisions are presented in Table III. Five of these revisions were performed for ARMD. Three of these patients had BHR HRA prosthesis and two had a Synergy – R3 prosthesis. For these BHR – BHR prosthesis blood chromium concentrations were  $3.9 \mu\text{g/l}$ ,  $7.2 \mu\text{g/l}$ , and  $10.2 \mu\text{g/l}$  and cobalt concentrations were  $1.6 \mu\text{g/l}$ ,  $4.5 \mu\text{g/l}$ , and  $8.7 \mu\text{g/l}$ . In the one Synergy – R3 hip revised for ARMD chromium level was  $1.2 \mu\text{g/l}$  and cobalt level was  $1.1 \mu\text{g/l}$ . One of these hips that needed revision due to ARMD had a slightly too high abduction angle (56 degrees), but the other abduction angles were within a normal range. A total of eight patients had a radiolucent line under the cup in the follow-up radiographs. However, none of

Table II. — Revision risks. N = number of patients, RR = risk ratio, CI = confidence interval, P = p-value

	3 years follow-up time				Total follow-up time			
	N	HR	CI	P	N	HR	CI	P
Synergy – BHR THA	39	1.00			39	1.00		
BHR HRA	249	2.46	0.57 – 10.52	0.2	249	2.64	0.62 – 11.21	0.2
Synergy – R3 THA	41	4.02	0.85 – 19.03	0.08	41	4.46	0.94 – 21.18	0.06

Table III. — Reasons for revision

	BHR HRA	Synergy – BHR THA	Synergy – R3 THA
ARMD	3	0	2
Aseptic loosening	8	0	3
Infection	3	1	2
Fracture	6	0	1
Other reason	11	1	0

these cups was considered definitely loose. Five of those eight patients with a cup radiolucency are subjectively satisfied. Three are suffering from mild pain and are in further follow-up.

Periprosthetic fracture requiring revision occurred in seven patients. Six of these fractures occurred in BHR HRAs. One patient fell one year after the primary operation and suffered a fragmented periprosthetic fracture, which was treated with a Biomet Reach – Magnum revision prosthesis. The other five patients with a BHR HRA had a spontaneous femoral neck fracture. All of these spontaneous fractures occurred within two to five months postoperatively and were treated by changing the BHR femoral component to a Synergy femoral stem. BHR cups were not changed. The seventh fracture occurred to in a Synergy – R3 THA hip three weeks postoperatively after a trauma. This fracture was treated with Biomet Reach – Magnum revision prosthesis and Dall-Miles wiring.

Six of our patients suffered from a postoperative wound infection or a later stage prosthetic infection that required reoperation during the follow-up time. Two of these patients went through a two stage revision. Four others were managed by lavage and debridement and two required a component exchange. A total of 11 patients suffered from aseptic loosening of one component leading to revision : seven of these were femoral component loosening and four were cup loosening. Samples to exclude infection were taken before or during the revision.

There were a total of 12 revisions for other reasons. These included pain (five hips), malposition (three hips), bleeding (one hip), impingement due to an osteophyte (one hip), lower extremity length difference (one hip), and nervus ischiadicus damage (one hip).

## DISCUSSION

We found that Synergy – R3 had a poor survival already at short term. The mid-term survival of BHR HRA was inferior compared to some previous studies (References). ARMD prevalence of Synergy – R3 was high, but this finding did not reach statistical significance.

BHR HRA has had good midterm results in many studies, especially in young male patients (12, 17). However, complications due to metal bearings remain a concern. High serum metal ion levels may be associated with ARMD – reactions : pseudotumours and metallosis (2,8,9,10). Known risk factors for metal ion complications are female gender, a small femoral component, obesity and a high abduction angle (2,16). In our series a smaller femoral head size was significantly associated to higher revision risk.

Some recent studies have reported as high as 7% revision rates in ten-year follow-up due to pseudotumours in female patients (14).

In our study three BHR HRAs and two of Synergy – R3 THAs were revised for a metal bearing complication. The revision rate due to metal-on-metal complications is 1.5% so far. Revision rate for ARMD for BHR – BHR HRA was 1.2%, for Synergy – BHR THA 0.0%, and for Synergy – R3 THA 4.9% during the whole follow-up time of each implant. These results did not differ statistically significantly due to small patient amounts.

Optimum abduction angle in both THA and HRA has been determined to be between 31 and 50 degrees. Different studies have presented that over 60 degrees abduction angle might be a significant risk factor for increased metal-ion levels and ARMD – reactions (8,18). All five of our ARMD-

patients had < 60 degrees abduction angle. In our study a total of seven patients had 60 degrees or higher abduction angle, but none of them developed ARMD – reaction during the follow-up time.

The weakness of our study is that the metal ion data were not available from all study patients. Systematic screening of all patients with metal-on-metal hip device using metal ion measurements and symptom questionnaires have been recently started at our institution. Further, we were not able to perform magnetic resonance imaging to detect silent metal complications like fluid collections around implants or soft tissue masses. There may be symptomless patients with ARMD that have not yet required revision. ARMD may occur many years after the arthroplasty (9). Our mean follow-up time was 4.7 years and it is probable that all metal complications have not yet occurred in the study population. One of our five ARMD patients did not have his blood metal-ion levels assessed. This revision was performed in 2010 and at that time in many cases synovial fluid chromium and cobalt levels were measured. Only one of the four other ARMD patients had increased chromium and cobalt levels, and one had an increased chromium level. The overall metal-ion levels in the patients studied were high. Close follow-up of all patients with metal-on-metal implant is mandatory.

The study implants were all manufactured by the same company, Smith and Nephew, UK. BHR cup is a chromium-cobalt monoblock component with metallic inner surface. R3 is a modular titanium cup with three liner options : plastic, ceramic and metal. Both BHR cup and R3 with metal liner can be used with Synergy stem, except that the head size using Synergy – BHR THA is on average much larger than in Synergy – R3 THA. The Synergy – R3 THA with metal-on-metal bearing surfaces had remarkably worse outcome compared to Synergy – BHR THA. R3 cup has been already recalled by the manufacturer. Our BHR HRAs survival rates were inferior compared to previous studies from centers and specialized hospitals involved in developing these techniques. (12,17).

Metal hypersensitivity and pseudotumours are a possible source of pain in THA or HRA patients (9, 11). In our study, five patients had to go through

reoperation due to pain. Reasons for pain were thought to be impingement and ileopsoas muscle and tendon problems, and there was no evidence from metal bearing related complications.

Periprosthetic fracture is a serious complication both in THAs and HRAs. Femoral neck fractures after HRA have been reported to occur predominantly early after the operation (11). The overall prevalence for femoral neck fracture in HRA is 1.1% (11). The amount of periprosthetic fractures in our study was similar compared to periprosthetic fracture rates in other studies (1,22). In our material a total of seven patients suffered a periprosthetic fracture that required revision. This is in the same level than incidence as in previous studies (11,18,23).

In conclusion, Synergy – R3 had a poor survival already at short term. BHR HRA survival rate was inferior compared to previous mid-term studies. Metal bearing related complications are a serious concern. Our findings support the decision to abandon metal-on-metal devices.

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