

Survival, Complications and Outcomes of the Birmingham Hip Resurfacing Compared to Cementless Total Hip Arthroplasty

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ABSTRACT

AIM: Metal-on-metal hip arthroplasty is developed to address specific complications experienced with the use of cementless hip arthroplasty. However, there is a lack of comparative studies. The aim of this study was to evaluate the survival, complications and functional outcome of the Birmingham Hip Resurfacing (BHR) and compare it to the cementless Omnifit hip prosthesis.

MATERIALS AND METHODS: We retrospectively compared a cohort BHR ($n = 104$) and Omnifit ($n = 117$) prostheses. Outcome measures included Oxford Hip Score (OHS), Hip disability and Osteoarthritis Outcome Score - Physical function Short Form

(HOOS-PS) and EuroQol EQ-5D. Survival and complications were registered.

RESULTS: Survival was 86% in the BHR group and 92% in the Omnifit group after six years follow-up. Survival distributions were not significantly different. Prognostic factor for revision in the BHR group was a smaller femoral component size. The BHR group had significantly better OHS, HOOS-PS and EQ-5D scores and less pain in rest and during weight bearing compared to the Omnifit group.

CONCLUSION: The BHR has significant better functional outcome and less pain than the Omnifit cohort, however, because of high revision rates and severe complications, general use is not recommended. Specific complications for the Omnifit femoral component are thigh pain and aseptic loosening, for which a revision offers a solution.

Key words: Hip arthroplasty; BHR; Cementless; Omnifit; Complications; Survival

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INTRODUCTION

Metal-on-metal (MoM) hip arthroplasty is subject of intense scientific as well as public debate because of severe complications that are reported with the use of this prosthesis. Wear of metal can cause loose particles, which can induce serious disease referred as adverse reaction to metal debris (ARMD) or pseudotumors and elevated cobalt concentrations^[1]. The development of MoM total hip arthroplasty (THA) was an attempt to circumvent the specific complications experienced with the use of cementless hip arthroplasty like polyethylene wear and fixation problems. MoM hip resurfacing has theoretical advantages compared to conventional THA. It is a bone-conserving reconstructive option, it preserves bone stock on the femoral side

what may have an advantage for subsequent revision. Furthermore the large radius of the articulating surface is associated with lower rates of dislocation^[2,3].

These theoretical advantages are well less analysed in comparative studies. This study compares the MoM Birmingham Hip Resurfacing prosthesis (BHR; Smith&Nephew, Warwick, United Kingdom) with the cementless proximally hydroxyapatite-coated titanium stem (Omnifit, Stryker Howmedica Osteonics, Allendale, New Jersey). The BHR is the most placed cobalt-chrome molybdenum MoM device and is still used worldwide. National guidelines on the use of MoM prostheses vary between highlighting the risk, implanting in a selected patient population and advising against implantation.

This study presents the survival, revision rates, prognostic factors for revision, complications and functional outcome of a MoM prosthesis compared with an uncemented proximally HA-coated titanium femoral prosthesis.

METHODS

This study includes all BHR procedures performed from 1 January 2006 up to 31 December 2011 in a general, non-designer, district hospital. These procedures were compared with the, in the same period placed, cementless Omnifit stem. All patients with the Omnifit femoral stem had a ceramic on polyethylene bearing surface. All operations were primary total hip procedures, performed by several orthopaedic surgeons via a posterolateral approach. Perioperative and postoperative treatment was similar for both groups. Implant types were used simultaneously and the choice was based on surgeons and patients preferences. Medical charts were checked for patient and hospitalization characteristics, implant specifications, bilateral implants, side of surgery, possible complications, possible revision surgery and clinical findings.

All patients ($n = 221$) were invited by post to complete a follow-up questionnaire including the Oxford Hip Score (OHS)^[4,5] (0-48 scale, 0 = most severe symptoms), the Hip disability and Osteoarthritis Outcome Score, Physical function Short form (HOOS-PS) (0-100 scale, 0 = best physical function)^[6], EuroQol EQ-5D (0-100 scale, 100 = best health condition)^[7] and pain Numeric Rating Scale (NRS) (rating from 0-10, 10 = most severe imaginable pain). Additionally, patients were asked specifically about satisfaction. This was measured with two questions using the following statements: 'I am satisfied with the result of the surgery' and 'If I could do it over, I would choose for the surgery again'. Both questions were scored on a Likert scale (0 to 7 scale, 0 = totally agree, 7 = totally disagree). Furthermore patients were asked about related complications or revision surgery and if so, the complication, indication for revision, date and location were noted. If there was no postal response, patients were contacted by phone and were asked to reply.

Statistics

The differences between the BHR and Omnifit group in demographics, functional outcome, survival and complication rate were analysed using the non-parametric Kruskal-Wallis H test for several independent samples. Cox regression analysis (enter method) were performed to identify prognostic factors for revision. Possible prognostic factors were gender, age, femoral component size and bilateral implants. Survival was analysed with the Kaplan-Meier method and tested for significance using the log rank test. The endpoint of the Kaplan-Meier was revision for any reason. The benchmark criteria of the implants National Institute for Health and Care Excellence (NICE) (> 90% survival after ten years) was defined

as implant success.

RESULTS

In total, 221 patients were included in this study. Two patients died, both in the BHR group. None of these deaths were related to the hip surgery. Patient demographics are shown in Table 1. Groups were significantly different regarding age and gender ($p \leq 0.001$) with the BHR group being the youngest group with the most male patients. Mean follow-up ($p = 0.002$) was significantly different between groups, the BHR group had the longest follow-up. Of all patients, 84% completed the questionnaires.

Revisions and complications

A total of 15 out of 104 procedures (14%) were revised in the BHR group (Table 2). Four of these patients had a bilateral BHR prosthesis; three of them had bilateral revision surgery. Revisions took place at an average of 45 months (1-82 months) after the primary hip implantation. According to our national guideline for MoM prosthesis, all patients were invited for testing cobalt and chrome levels regularly. Mean cobalt level was 54 nmol/L (range 14-353). Mean chrome level was 68 nmol/L (range 11-311). Elevated serum cobalt concentrations (respectively 103, 148, 214, 353 and 381 nmol/L) were indications for revision in five symptomatic patients. Elevated cobalt levels were not a strict indication for revision, asymptomatic patients were monitored at the outpatient clinic. The most severe complication was ARMD. Three hips in two patients developed ARMD with major complications including destruction of surrounding tissues. Other prosthesis specific revision indications were revision for femoral neck fracture and AVN of the femoral head (Table 2). Of the 15 revisions, two femoral neck fractures and the revision for avascular necrosis underwent an isolated femoral component revision, with the existing acetabular component remaining in situ. The remaining hips underwent revision of both the acetabular and femoral components to a non-metal prosthesis.

Further complications in the BHR group included two reoperations, one lavage for infection at five years with retention of the hip prosthesis and one iliopsoas release for psoas tendinopathy. Two patients had a transient sciatic nerve neuropraxia, which fully recovered. Two patients developed partial sciatic nerve paralysis peroneal division of the sciatic nerve. One patient suffered an aystole

Table 1 Patient characteristics of the BHR and Omnifit group.

	BHR	Omnifit	p-value
Number of procedures	104	117	
Number of male (% male)	65 (62.5%)	57 (48.7%)	< 0.001
Indication			
Osteoarthritis	96.20%	87.20%	
AVN	-	6.00%	
Hip dysplasia	3.80%	0.90%	
Late posttraumatic	-	4.30%	
Rheumatoid arthritis	-	1.70%	
Bilateral	14	13	
Age years (mean \pm SD; range)	52.5 \pm 5.8 38-65	57.6 \pm 6.3 30-66	< 0.001
Follow-up months (mean \pm SD; range)	76 \pm 15.6 40-107	70.5 \pm 10.7 49-107	0.002
Revisions	15 (14%)	9 (8%)	

BHR: Birmingham Hip Resurfacing; AVN: avascular necrosis; SD: standard deviation

on the recovery room, for which atropine was administered. The patient recovered completely. Another patient had electrocardiogram deviations during surgery for which anticoagulation therapy was started. No dislocations of the BHR occurred.

Nine out of 117(8%) Omnifit procedures were revised in nine patients. Revisions took place at a mean of 28 months (9-59 months) after the primary implantation (Table 2). Six revisions (5.1%) were for aseptic loosening. Two patients had revision surgery for thigh pain. The femoral stem was revised in all these cases, the acetabular component remained in situ. One patient suffered of a joint infection with fistula formation for which a girdlestone procedure was performed.

Further complications in the Omnifit group were dislocation in one hip for which closed reduction was performed. Another two reoperations were lavage of a wound infection and a relieve of a postoperative haematoma because of sciatic nerve neuropraxia, in both patients the prosthesis remained in situ. Two patients had sensory loss of the skin related to the surgery, one patient of the ipsilateral thigh and the other of the lateral side of the dorsum of the foot. Inserting the Omnifit cementless stem was complicated with proximal femoral fractures in four patients (3.4%). All femoral components could be maintained; one patient was treated with cerclage fixation, the others conservatively.

Outcome scores

Outcome scores on OHS, HOOS-PS, EQ-5D and NRS pain at rest and during load are shown in Table 3, with p-values of the comparison between groups. Non-parametric Kruskal-Wallis test showed that there was a statistically significant difference in the mean rank scores of the HOOS-PS between the prosthesis, with the BHR having the highest score [$\chi^2(2)= 14.584, p \leq 0.001$]. The BHR group scored also significant higher at the OHS [$\chi^2(2)= 9.731, p = 0.002$]. Despite that the median pain scores in rest were 0 points for both groups, there was a significant difference between prostheses [$\chi^2(2) = 6.450; p = 0.011$]. The BHR group had significant lower pain scores at rest and during weight bearing compared to the Omnifit prosthesis [$\chi^2(2) = 4.856; p = 0.028$]. Postoperative quality of life, measured by the EQ-5D, was significant better in the BHR group [$\chi^2(2) = 5.594; p = 0.018$]. Overall results showed that 89% of the Omnifit patients and 88% of the BHR patients were satisfied with the operation result and 89% of the Omnifit and 92% of the BHR patients would decide again for undergoing arthroplasty.

Survival

A log rank test was run to determine if there were differences in the survival distribution for the two types of prostheses. The survival distributions were not statistically significantly different [$\chi^2(2) = 1.610, p = 0.205$] between the Omnifit and BHR prosthesis. Survival analysis showed an estimated survivorship at eight years of 82.2% for BHR (CI 73.6- 90.8%) and 91.5% (CI 86.2-96.8%) for the Omnifit femoral component (Figure 1).

There was a clear distinction between gender, although not statistically significantly different [$\chi^2(2)=2.336, p = 0.126, \text{figure 2}$]. Estimated survival of the BHR after eight years follow-up for male patients was 85.8% (CI 75.5-96.0%), whilst only 76.7% (CI 61.8-91.6%) for female patients. Estimated survivorship of the Omnifit implant after eight years of follow-up for male patients was 96% (CI 90.5-100%) whilst only 87.3% (CI 78.5-96.1%) of Omnifit implants survived in females.

Cox regressions were performed to identify associative factors for revision. There was a significant association between femoral

Table 2 Revision indications of the BHR and Omnifit group.

	Failure mode	n	Time to failure in months; mean (range)	Male / female	Revision acetabular/ femoral component
BHR	Femoral neck fracture	4	6 (1-15)	2 / 2	2 / 4
	Avascular necrosis	1	23	1 / 0	0 / 1
	ARMD	3	49 (28-77)	0 / 3	3 / 3
Omnifit	Raised cobalt level	5	57 (20-82)	2 / 3	5 / 5
	Symptomatic	2	75 (72-78)	2 / 0	2 / 2
	Thigh pain	2	37 (14-59)	1 / 1	0 / 2
	Aseptic loosening	6	28 (17-42)	1 / 5	0 / 6
	Joint infection	1	9	0 / 1	1 / 1

BHR: Birmingham Hip Resurfacing; n: number; ARMD: adverse reaction to metal debris.

Table 3 Outcome scores and the comparison between the Omnifit and Birmingham Hip Resurfacing (BHR).

		NRS pain rest	NRS pain load	OHS	HOOS-PS	EQ-5D
BHR	Median	0	0	47	4.6	1
	IQR	0	1	4	12.7	0.2
	Mean rank	89	90	112	70	101
Omnifit	Median	0	0.5	45	12.7	0.9
	IQR	2	4	9	22.3	0.2
	Mean rank	106	108	84	102	82
p-values		0.011	0.028	0.002	<0.001	0.018

IQR: Inter Quartile Range; NRS: Numeric Rating Scale, OHS: Oxford Hip Score; HOOS-PS: Hip disability and Osteoarthritis Outcome Score - Physical function Short form.

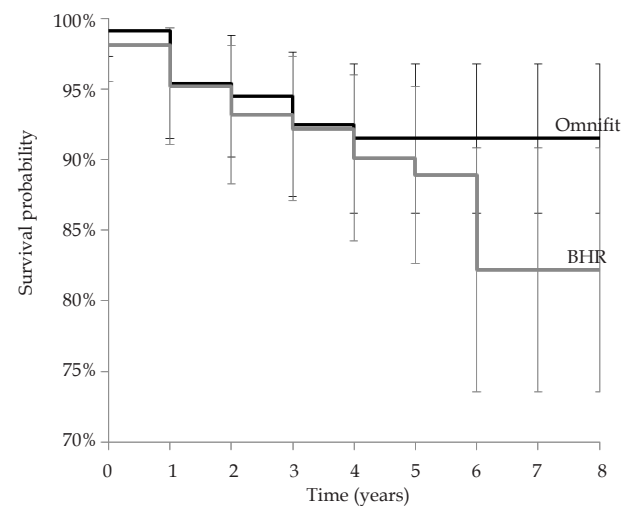


Figure 1 Kaplan-Meier survivorship: Survivorship with 95% confidence interval showing estimated survivorship at eight years was 82.2% for BHR and 91.5% for Omnifit (log rank test, $p = 0.205$).

component size as prognostic factor and the chance of revision of the BHR prosthesis [$p = 0.015; \text{Exp (b); } 95\% \text{ CI, } 0.678\text{-}0.958, \text{table 4}$], smaller femoral component sizes being at risk for revision. Figure 3 shows a female patient with femoral component size 42 in situ. Her BHR prosthesis was revised for a femoral neck fracture. Figure 4 shows an X-ray of a male patient, with bilateral femoral component sizes 56 in situ. He is satisfied and is not aware of his artificial joints. For the Omnifit group, no prognostic factors for revision were identified.

DISCUSSION

The results presented in this study are one of the few comparative studies between BHR and cementless hip prostheses by non-designer surgeons in a district hospital operated by several surgeons. The results obtained from our study contribute to the level of evidence of comparative research for prostheses for this young population and may refine inclusion criteria for the procedures. Survival distribution was not significantly different between both prostheses, corrected for gender and follow-up. Although not significant, these study results suggest the BHR has worse survivorship than the Omnifit prostheses.

The results presented in this study underline the risks of the use of the BHR prosthesis, previously demonstrated by independent centres^[8,9]. The NICE criteria of 90% survival at 10 years is not met (82.2% at eight years), and although 90% is still within the range of the confidence interval (73.6- 90.8%), it seems that this will not be at 10 years follow-up. The BHR has an Orthopaedic Data Evaluation Panel (ODEP) award 10A rating (best possible) for its use with males only and for sizes 48-62 only. However, in the current study, also with the use in this specific indication (male patient, femoral component > 48), the revision rate is too high (11%). Furthermore, the destruction of the tissue seen in ARMD patients are a big concern. Our results do support the evidence in the current literature of high survival rates of the BHR prosthesis in young male patients^[3,10]. Six-years survival of the BHR prosthesis in young (< 50 year) male patients with primary osteoarthritis as operation indication in this study was 94.7% (one revision in 19 patients). However, according to the results of our Cox regression, we support the evidence that not gender, but femoral component size has an association with the chance of revision of the BHR prosthesis^[11]. Our multivariate regression analysis showed that female gender is a confounder in the risk for revision. In general, smaller femoral component sizes were implanted in female patients. So not gender, but femoral component size is a predictive factor for revision, with a smaller size being at higher risk for revision. Survival rate of femoral component sizes ≥ 52 mm was 94.4% (36 patients, one female). Two patients of our cohort without any objective abnormalities or complaints had their BHR replaced for a cemented THA. A possible explanation is that the prosthesis may have a lowered threshold for revision because of the public debate. In this study, four nerve injuries were observed in the BHR series, of whom two patients fully recovered. Compared to conventional THA, the exposure is more complicated in resurfacing procedures due to the retention of the femoral head. The surgeon needs to work around the femoral head to reach the acetabulum. Using a posterolateral approach, the hip is flexed and internally rotated. This results in tightening of the gluteal sling and may cause potential compression of the sciatic nerve against the ischial tuberosity^[12]. To prevent sciatic nerve palsies, the pressure during acetabular exposure has to be released. In our study, this was done by partially release the gluteal sling. A higher nerve palsy rate with hip resurfacing compared to conventional THA was described in literature by Hing *et al*, 2017 (2.2% nerve palsy in hip resurfacing)^[13]. Our incidence is somewhat higher, what can be caused by coincidence (non-significant difference), the surgical approach or due to the inclusion of the learning curve of the surgeons.

Our revision rate for the Omnifit femoral component at 5.9 years of 7.7% was slightly higher than the revision rates at five years for Omnifit with Trident shell in The Australian National Joint Replacement Registry Report 2015 (95% CI 3.6-6.1)^[14]. This might be explained by the fact that in our clinic two patients had thigh pain as indication for revision of Omnifit femoral stem prosthesis. They had no evidence for aseptic loosening; there was no radiographic evidence and

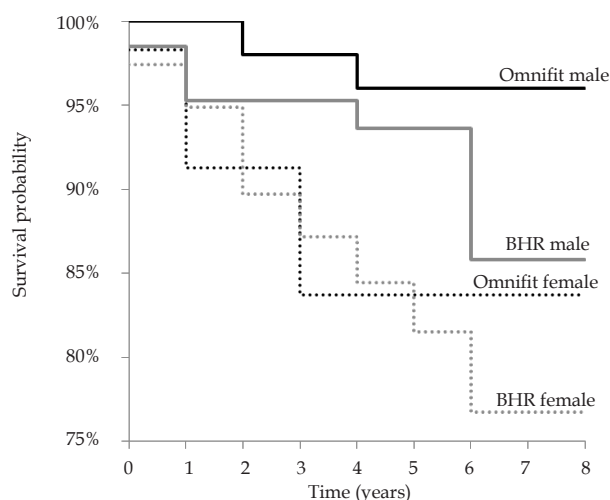


Figure 2 Kaplan-Meier survivorship by gender: Survivorship showing male estimated survivorship at eight years was 85.8% for BHR and 96% for Omnifit prostheses. Female estimated survivorship at eight years was 76.7% for BHR and 87.3% for Omnifit prostheses.



Figure 3 Female patient with femoral component size 42, revised after femoral neck fracture.

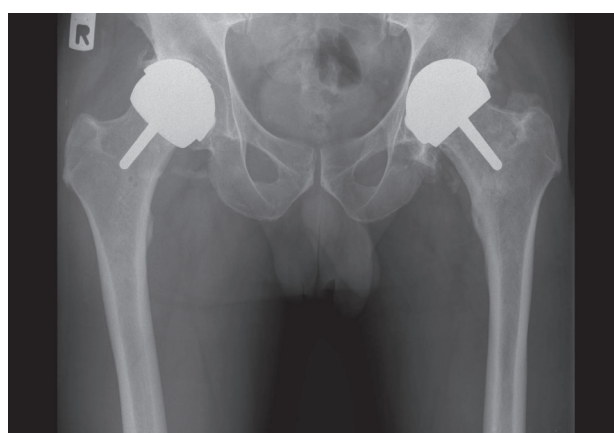


Figure 4 Male patient with femoral component size 56. Excellent clinical results.

they had a negative bone scintigraphy. Both patients had eventually femoral stem replacement for thigh pain, which is not an absolute indication for revision. They were pain free after revision. Aseptic loosening was the number one reason for revision. Question arises if the loose femoral component was at one time well fixed, so if failure of fixation would be a more appropriate description of the mode of

failure. It could be that the prosthesis is less forgiving. Because of the high rate of aseptic loosening and the complaints at the outpatient clinic about anterior thigh pain, the orthopaedic surgeons switched to another uncemented prostheses in 2010.

One of the theoretical advantages of the BHR is less risk of dislocation. For the entire study population, only one dislocation occurred, in the Omnifit group. Based on this result, the large diameter heads of the BHR aren't necessary to achieve adequate stability using a posterolateral approach. Another complication in the Omnifit group were proximal femur fractures, occurring in 3.4% of the procedures. The literature-reported risk of peri-prosthetic fracture in uncemented procedures ranges from 3% to 25%^[15]. The BHR cohort has severe complications concerning elevated cobalt concentrations and ARMD.

Functional outcomes were high after BHR surgery. The BHR group experienced a better physical hip function and felt less disabled compared to the Omnifit group. Possible explanations are a more accurate approximation of the normal human anatomy and a bigger range of motion^[3,16]. Our results showed that patients with the Omnifit prosthesis have significant more pain at rest and during weight bearing. This could be caused by a lack of fixation or thigh pain.

Limitation of this study was that a cohort was studied and so patients were not randomised to a procedure. Since the BHR group was significant younger, this could be a confounder for the outcome measures. However, age was not a predictor for revision. Since pre-operative outcome measure data was not available, no correction was possible for preoperative functional differences.

In conclusion we found a high revision rate and severe complications of the BHR prosthesis, not meeting the NICE nor the ODEP criterion. Re-operation rates of the BHR were higher than published by other groups, but our results in patients with a femoral component size ≥ 52 were comparable to those reported in the literature. The Omnifit prosthesis has prosthesis related complications as thigh pain and aseptic loosening for which revision offers a solution. The theoretical advantages of the BHR (less dislocation, femoral bone preservation) are not relevant, dislocation rate were comparable and revision rate seems to be higher of the BHR. The BHR prosthesis has severe complications and even though revision rates of the larger femoral component sizes seem acceptable and they have better functional outcome and less pain, we suggest refraining from the general use of the prosthesis.

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The Medical Research Involving Human Subjects Act (WMO) does not apply to the above mentioned study and therefore an official approval of this study by the Medical Research and Ethics Committee is not required under the WMO. The protocol was approved by the institutional review board of the St. Antonius Hospital. There are no conflicts of interest.

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