



Midterm results with Birmingham Hip Resurfacing/Synergy stem modular metal-on-metal total hip arthroplasty

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Large head modular metal-on-metal total hip replacement (MoMTHR) has been shown to have increased revision rates in the National joint registry and in literature.

We reviewed 41 consecutive patients with 44 hips who had large head MoM THR using a Birmingham Hip Resurfacing (BHR) cup/Synergy stem combination between June 2005 and Nov 2009 with a mean follow-up of 59.5 months.

In this series we had a revision rate of 6.8% (3/44) for adverse reaction to metal debris (ARMD), persistent groin pain and instability. Kaplan-Meier analysis showed a mean cumulative survival rate of 79.2% (95% CI : 75.5%-82.9%) In addition there is a subset of 5/44 patients (11.3%) with mild grade groin pain who may need revision in the future.

Based on these findings, we do not recommend performance of large head MoMTHR in the future.

Keywords : metal on metal ; hip replacement ; outcome.

and a large diameter femoral head (5). These designs rapidly gained popularity in the early 2000s to the extent that MoM bearings were used in 15% of all primary THRs in England and Wales in 2009 (21), and up to 35% of all THRs in the United States in same year (8).

Recently, concerns were raised about the level of blood cobalt (Co) and chromium (Cr) ions and the adverse soft tissue reactions to metal debris (ARMD) when using metal-on-metal bearing surfaces. This is particularly a problem if the implant is loaded under adverse conditions (vertical cup placement, excessive anteversion) with subsequent increase in wear, resulting in soft tissue and bone destruction (6,9,24).

Further it has been reported that the friction torque and toggle generated at the taper junction/trunnion at the proximal part of the femoral stem would increase the wear rate and affect the survival

INTRODUCTION

The modern era of hip resurfacing began in the early 1990s aiming to improve wear and to allow bone conservation (17). Excellent early results were achieved in young patients with high activity levels (23); however early complications including femoral neck fractures were encountered (10).

To overcome some of these drawbacks, modular metal-on-metal total hip replacement (MoMTHR) was designed using a stemmed femoral component

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of these large-head MoMTHR's when compared to resurfacing (6,16). These reports led the Medical and Health care products Regulatory Agency (MHRA) to issue an alert in 2012 (20) related to the use and management of these implants.

The aim of this study was to review and report the mid-term clinical and radiological results of a consecutive series of patients who had large-head MoMTHR in our institution. We also evaluated the causes and rate of failure and compared it with other studies.

PATIENTS AND METHODS

All patients who had large-head MoMTHR using Birmingham Hip Resurfacing cup/Synergy stem (Smith & Nephew, Warwick, U.K.) in our institution from June 2005 to November 2009 were included in the study. There were 41 patients with 44 hips, 32 (78%) male and 9 (22%) female. The mean age at surgery was 49.9 ± 12.4 years (25-71 years). The preoperative diagnosis is summarized in Table I.

All operations were carried out by trained arthroplasty surgeons. In 37 patients (40 hips) a posterior approach was used, while in 4 patients (4 hips) an anterolateral approach was used. All hips were replaced with large head (≥ 36 mm) MoMTHR using Birmingham hip resurfacing cup/ Synergy stem (Smith & Nephew, Warwick, United Kingdom).

The patients had routine post-operative physiotherapy and were followed up at 6 weeks, 6 months, 1 year and yearly after that. On each visit patients were assessed by clinical review, Oxford Hip Score (OHS) (18), and radiographs including an anteroposterior radiograph of both hips and a lateral radiograph of the hip were taken.

Radiographs were taken postoperatively and at one or two yearly intervals thereafter. The radiographs were assessed for signs of osseointegration, loosening, implant migration and lytic lesions. Additionally, the angle of cup inclination was measured. Data was collected prospectively at regular intervals by a Specialist Arthroplasty Practitioner.

Some patients were additionally investigated by measuring blood Co and Cr levels, and cross sectional imaging in the form of Metal Artefact Reduction Sequence Magnetic Resonance Imaging (MARS MRI) scan was made when patients were symptomatic and/or had rising blood metal ion levels. The images were examined and reported by a specialist musculoskeletal radiologist. Periprosthetic lesions were identified and described according to nature (cystic / solid), diameter, shape and anatomical location of these lesions according to MARS MRI classification described by Anderson *et al* (2).

Statistical analysis

To determine the cumulative probability, a Kaplan Meier analysis with 95% confidence intervals was performed. The implant revision or removal for any reason or intension to revise was defined as the endpoint.

Results were analysed using t test, Spearman's correlation analysis between the independent variables. Statistical significance was set at $p < 0.05$. Statistical analysis was carried out using statistical package XL-STAT (Addinsoft, New York, USA).

RESULTS

The mean duration of follow-up was 59.48 ± 13.5 months (40-84 months). No patients were lost to follow up.

Table I. — Preoperative diagnosis

Diagnosis	Frequency	Percentage
Primary Osteoarthritis	22	50%
Secondary Osteoarthritis	14	31.8%
<i>a-Post traumatic</i>	1	2.2%
<i>b-Perthe's disease</i>	4	9.1%
<i>c-Slipped capital femoral epiphysis</i>	2	4.6%
<i>d-Hip dysplasia</i>	7	15.9%
Avascular Necrosis (AVN)	6	13.6%
Fracture neck femur	2	4.6%
Total	44	100%

Clinical results : The mean Oxford Hip Score (OHS) for all hips increased from 16.3 ± 3.8 (10-26) before surgery to 39.2 ± 8.5 (20-48) at final follow-up. No correlation was found between the preoperative diagnosis and the final OHS. The mean OHS was higher in unrevised patients (40.4 ± 7.5) compared to the revised group of patients (23.3 ± 3.05) before their revision surgery. This difference was considered statistically significant ($p < 0.001$).

Revision rate :

Three hips were revised (3/44, 6.8%) ; indications and details for revision are shown in table II. These three patients had persistent pain interfering with activities of daily living and deteriorating OHS. Head size was > 50 mm in 2 out of these 3 hips, cup inclination was $> 50^\circ$ in one hip. Blood Co and Cr were raised in 2 patients ; it was not measured in the patient revised for recurrent dislocation. The failure rate was 6.8% at mean follow-up of 59.5 months. Kaplan-Meier analysis showed a mean cumulative-survival rate of 79.2% (95% CI : 75.5%-82.9%) (Fig. 1).

Radiological results :

a) Plain radiography : None of the radiographs revealed radiolucent lines, osteolysis, obvious implant migration or destruction. All patients had good osseointegration. The average acetabular cup inclination angle was $41.7^\circ \pm 6.7$ (31° - 54°). There was no statistically significant difference ($p = 0.79$) between the mean cup inclination angles in the revised ($42.7^\circ \pm 9.8$) and the non-revised group of patients ($41.6^\circ \pm 6.6$).

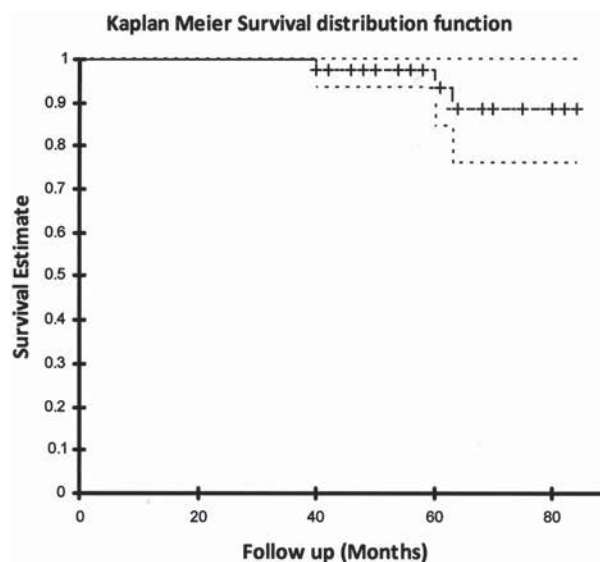


Fig. 1. — Kaplan Meier survival curve of Birmingham hip resurfacing cup/Synergy stem at 84 months. | : Censored data. Area between dashed lines represents 95% confidence interval (CI).

b) Cross-sectional imaging :

Twenty-five patients (28 hips) had an MRI scan. In 24/28 hips findings were classified as consistent with normal postoperative appearances (type A) ; 4/28 scans were considered to be abnormal : 2 of these had a small fluid collection, one in the joint and one in the trochanteric bursa. These were not thought to be typical of an adverse reaction to metal debris. One patient had a peritrochanteric cystic soft tissue lesion (type C1) and another moderate ARMD (type C2). Four of the 24 hips with normal MRI findings were symptomatic (mild unexplained groin pain).

Table II. — Details of the revised hips

Patient	Time to revision (months)	Indication of 1 st surgery	Indication for revision	Diagnosis established by	Cup inclination	Co level ($\mu\text{g/l}$)	Cr level ($\mu\text{g/l}$)
1	40	1 st OA	Instability	Clinical	36°	-	-
2	63	AVN	ARMD (pseudotumour)	MRI Metal ions Clinical	54°	29.4	27.8
3	60	AVN	Groin pain	Clinical Metal ions	40°	18.6	12.2

Table III. — Characteristics of recently published studies of large diameter modular MoM THR

Study	hips (n)	Implant	Clinical Outcome (scoring)	Follow-up (mean)	Failure rate	Revision indication	Complications
Bolland 2011 (7)	199	*BHR/ † CPT/ ‡ MMT head	OHS Sig. imp	5 yrs	15.1%	– ARMD – Pain – Infection – Fracture	– Pain – Periprosthetic fracture (2)
Kindsfater 2012 (13)	95	§ Pinnacle	HHS Sig. imp	6 yrs	2.2%	-	– No pain – Dislocation (1)
Bernthal 2012 (4)	70	¶ ASR	-	Min 2 yrs	17.1%	– Loosening – Pain – Squeaking	– Pain (3) – Squeaking (3) – Grinding (2)
Althuisen 2012 (1)	63	**Durom / Spotorno	good function in 49 hips	3.1 yrs	11% (6 cups, 1 stem)	– ARMD – Pain – Cup loosening – Stem loosening	– Groin pain (7) – Squeaking (1) – Infection (3)
Present study	44	†† BHR synergy	OHS Sig. imp	5 yrs	6.8%	– ARMD – Pain – Instability	– Groin pain (5) – Dislocation (1)

*BHR [Birmingham Hip Resurfacing cup, Smith & Nephew, Warwick, United Kingdom].

†CPT [Collarless polished tapered, Zimmer, Warsaw, Ind].

‡MMT [Midland Medical technologies Ltd, Birmingham, United Kingdom].

§ Pinnacle [DePuy, Warsaw, Ind].

|| HHS (Harris Hip Score).

¶ASR [Articular Surface Replacement, DePuy, Warsaw, USA].

**Durom cup, Spotorno stem [Zimmer, Warsaw, USA].

†† BHR/synergy [Smith & Nephew, Warwick, United Kingdom].

Sig. imp : significant improvement.

Metal ion levels :

The mean Co level was $6.4 \mu\text{g/L} \pm 6.8$ (0.5-29.5), while the mean Cr level was $5.3 \mu\text{g/L} \pm 5.2$ (1.11-27.8). Eight patients had Co level $> 7 \mu\text{g/L}$ (MHRA safe level) (11), while 5 had their Cr level $> 7 \mu\text{g/L}$.

Mean Cr level was higher in symptomatic patients ($7.9 \mu\text{g/L} \pm 6.5$) when compared to asymptomatic patients ($4.07 \mu\text{g/L} \pm 3.5$). This difference was considered statistically significant ($p = 0.048$). Higher blood Co and Cr ion levels were found in patients having cup inclination angles $> 50^\circ$, however the difference with patients having inclination angles $< 50^\circ$ was not statistically significant ($p = 0.48$ and 0.14 respectively).

Unexplained groin pain :

At the final follow up, 5 / 41 patients (5 / 44 hips, 11.3%) continue to experience unexplained groin pain. These patients were investigated for common

causes of groin pain and no cause was identified. The mean OHS in this group was 36.02 ± 1.4 . The mean Co level in this group was $2.5 \mu\text{g/L} \pm 2.2$, while the Cr level was $4.1 \mu\text{g/L} \pm 2.8$. The pain is mild in nature and does not impede their day to day activities, so no intervention has been planned. However this group of patients is being closely monitored for any worsening symptoms and gross elevation of metal ion levels.

We had one dislocation in a patient who who has already had a revision. We have no reported cases of infection, heterotopic ossification or neurovascular injuries.

DISCUSSION

Recent studies and data from the British National Joint Registry have shown an unexpected high failure rate of some of the large head MoMTHR

designs with adverse reaction to metal debris and pseudotumours (4,7,14,22). The cumulative revision rate for the ADEPT® 12/14 modular large head MoMTHR was shown to be 12.1% at 7 years (19). Our study investigates midterm results of large head MoMTHR using BHR cup/ Synergy stem.

In the current study we had 3 revisions, 3/44 (6.8%), and 5/44 (11.3%) of patients have low grade persistent groin pain at a mean follow-up of 5 years. The results from literature for various MoMTHR combinations are summarised in table III.

In most published studies, main indications for revision were ARMD and persistent groin pain. Bolland *et al* (7) reported 14/17 and Althuisen *et al* (1) 4/7 revisions due to ARMD. Barrett *et al* (3) summarising four MoMTHR studies (779 hips) showed that one third of revisions was related to ARMD. In this study 2/3 revisions were due to metal ion related reasons, one due to ARMD and the other for high blood metal ion levels and associated persistent high grade pain interfering with activities.

ARMD may take several years to develop (7, 14). Bolland *et al* (7) reported that the mean time to develop ARMD and requiring revision was 45.5 months. In this study the mean time to develop ARMD and revision was 61.5 months. The longer time to revision in this study could be due to different implants and patient differences.

Groin and lateral hip pain is a potential alarming symptom of adverse soft tissue reaction with subsequent failure especially if associated with high levels of blood metal ions even in the absence of radiological abnormalities. Althuisen *et al* (1) reported that 2/63 patients were revised for persistent groin pain and elevated blood metal ions. Bolland *et al* (7) reported that 10/199 of their patients (5%) were awaiting revision for persistent pain and elevated high blood metal ions level and a further 7/199 hips were kept under continued review. In this study 1/3 of revisions performed was for persistent groin pain and elevated metal ion level. The groin pain in this patient settled down dramatically following revision with alternate bearing surface. Further 5/44 (11.3%) patients have low level groin pain not interfering with their activities. The symptoms in this group may remain unaltered or may get worse in future, requiring revision. At the present stage these

patients do not have high metal ion and do not exhibit signs of ARMD on MARS MRI scan.

Bolland *et al* (7) reported that patients with a failed and painful MoM hip replacement have a trend towards higher blood levels of both Co and Cr compared with patients with well-functioning hips. In this study blood metal ion levels (Co and Cr) were remarkably elevated in the two patients revised for ARMD and pain. Cr ion level was significantly elevated in patients with severe groin pain.

Langton *et al* (15) reported that a higher cup inclination angle in hip resurfacing led to increased blood metal ion levels. In this study the blood metal ion levels did not correlate with acetabular inclination as in 40/44 hips the inclination angle was well within 45 degrees. Similar results were reported by Bolland *et al* (7).

Haddad *et al* (11) and Hart *et al* (12) reported that imaging plays an important role in aiding the diagnosis of early implant failure and soft-tissue complications. In our study we found that MRI analysis was useful in delineating soft-tissue abnormalities and mass lesions when plain radiographs are normal.

Limitations of our study include a small group of patients and follow-up being at a medium term. In addition, the anteversion of the acetabular component was not assessed due to difficulty and uncertainty in measuring this variable in plain radiographs with this type of bearing surface.

In conclusion, our study confirms that large head MoMTHR does have increased revision rates at 5 years, in keeping with the current literature. Although the BHR cup/ Synergy stem combination appears to have a lower revision rate compared to other similar systems on the market, it should be considered with caution as there is a subset of patients in this study with groin pain who may need revision in the future. We do not recommend usage of large head MoMTHR.

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