High Failure Rates Of A Hybrid Large-Diameter Head Metal-On-Metal Total Hip Replacement: A Case Series Of Fifteen Patients

B Akinola, C Lawrence, M Weston, R Rodrigues, S Bhargava, A MacDowell

Citation

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Abstract

We present the preliminary results of our experience of the use of a hybrid large-diameter head metal on metal hip replacement system. A series of fifteen patients is presented. We have observed an unusually high failure rate which currently stands at over 20% within 5 years of implantation. These results have been observed with a femoral stem that otherwise has an excellent track record as well as a 10A ODEP rating. There have also been incidences of catastrophic failure in a couple of our patients who have remained asymptomatic and their failing prostheses were discovered when they were recalled for surveillance radiographs. Some other of our patients have gone on to develop pseudo tumours. 9 patients have now been revised. Based on our experience we wish to highlight the problems associated with a cemented femoral stem coupled with a large-diameter head metal on metal articulation and would strongly discourage its use.

INTRODUCTION

The introduction of large-diameter head metal-on-metal (MoM) total hip replacement (THR) in the early 1990s [1] was intended to address problems such as osteolysis and loosening that were associated with polyethylene from mid to long term follow up studies. Large-diameter head MoM THR were perceived to hold an advantage over conventional metal-on-poly THR, including better wear properties [2], lower dislocation rate [3, 4], and a greater range of motion [5], as well as technically less demanding than resurfacing arthroplasty.

More recently, however, reports have been emerging of high failure rates and a high incidence of adverse reaction to metal debris (ARMD) with MoM articulations [1, 6]. This has prompted the Medicines and Healthcare products Regulatory Agency (MHRA) to issue an alert for an urgent review of all metal-on-metal articulations [7].

This case series is the preliminary report of our ongoing review of all large-diameter hybrid MoM THR performed at our hospital. This has become necessary in the light of an unexpected and unacceptable early failure rate. It is probable that final failure rates will be significantly higher after a full review of the whole cohort of patients.

PATIENTS AND METHODS

Between July 2005 and May 2009, a total of 66 hybrid MoM total hip replacements (THRs) were implanted by 2 of the authors (AM and SB). The decision to implant a large-diameter hybrid MoM THR in selected patients was based on its perceived advantages over more conventional couplings. The femoral stem on which the large head was combined was already being used with other bearing couplings and had previously given excellent results. There were 12 females and 48 males (6 bilateral cases – all males) in the cohort. The mean age at surgery was 61 years (37 – 79).

Implants. The implanted stem in all patients was a collarless polished tapered cemented stem with a 12/14 cone (CPT; Zimmer, Warsaw, IN); the head was a large-diameter cobalt chrome modular head (Metasul; Zimmer, Warsaw, IN) requiring a sleeve adaptor to accept the 12/14 cone; the acetabular component was an uncemented hip resurfacing cup (Durom; Zimmer, Warsaw, IN). Palacos R + G bone cement (Heraeus Medical GMbH, Hanau, Germany) was used for all the cases. All operations were undertaken through a standard posterior approach in a laminar flow operating theatre.

Case Series. To date, we have identified 15 patients requiring revision surgery for a failure of their prosthesis. 9 patients have already been revised, 5 are awaiting revision, and 1 lost to local follow up. All patients were reviewed in clinic up to 1 year and were recorded to have progressed well clinically with satisfactory radiological analysis. At that stage, the patients were discharged from formal clinic review with plans for radiological and patient satisfaction questionnaires at 5 years following surgery. Of the cases of failures identified, the majority were identified when called for review following concerns over metal-on-metal articulations (1 case was infected and not strictly failure but intra-operatively, there was evidence of metallosis / corrosion and osteolysis around the calcar).

2 patients had displaced non-traumatic periprosthetic femoral fractures which were mildly symptomatic but remained undetected until they were recalled for surveillance radiographs. 1 patient had a traumatic periprosthetic femoral fracture, although in retrospect this might have been a non-traumatic failure presenting after moderate trauma. Although these patients admitted to mild pain, it had not been severe enough to warrant them to seek medical attention. Demographic and operative data for all revision / awaiting revision patients are presented in Table 1; radiographic, clinical presentation and time to failure data are presented in Table 2.

Clinical analysis. A number of patients admitted to mild groin discomfort and / or trochanteric pain, but no patient had actively sought medical attention and all appeared relatively content with their hip function.

Radiological analysis. Features of failure include periprosthetic fracture (Figure 1), bone resorption in the medial calcar region with progressive lucency in Gruen zone 1 (Figure 2), and stem subsidence (Figure 3). In each case of failure identified, the radiographic changes were of failure of the femoral component. The Durom acetabular shell in each case appeared radiologically stable with no signs of loosening. Magnetic resonance imaging (MRI) scans were performed on most patients.

Metal ion analysis. Serum metal ion levels (cobalt and chromium) were assayed in 12 patients and sent for analysis at a trace element laboratory. The reason that all patients did not have metal ion levels measured is that we did not immediately recognise the problem as possible ARMD in our earliest cases. Results are presented in Table 2.

Joint fluid analysis. Joint fluid was aspirated in 4 cases at the time of revision surgery and sent for analysis. Results are presented in Table 2.

Intraoperative finding. In most cases, there was abundant greyish fluid within the joint which was aspirated and sent for metal ion analysis. In some patients this was under high pressure. We found true pseudo-tumours (Figure 4) in 7 hips (including the 2 hips that had atraumatic periprosthetic fractures). The pseudo-tumours were multilobulated, well encapsulated and commonly found overlying the abductors and vastus lateralis, with tumour capsule infiltrating the joint through the site of posterior repair or the femur via the fracture. After dissecting out the tumour capsule, happily we found the underlying muscle to be well preserved. The content of the pseudo-tumour was a caseous, cheesy material (Figure 5) which histology revealed was necrotic material with variable amounts of metal debris. In some cases, no definite pseudotumour was evident, but a universal finding was of caseous cheesy tissue within the hip joint.

There was no significant acetabular bone loss in our series of revisions. The Durom acetabular shells were all removed with ease, requiring a firm blow on a punch to extract, despite initially appearing to be stable radiographically. On extraction, there was no evidence of bony in growth into any of the shells suggesting a complete absence of osseointegration. This finding is documented in other series [8]. Despite this, there was no evidence of instability or migration of the acetabular component. The bearing surface between the modular femoral head and the acetabular component was macroscopically free of corrosion or other evidence of wear.

On removal of the femoral head, black markings were macroscopically visible at the trunnion / modular head interface (Figure 6) with evidence of eccentric wear of the trunnion and reciprocal wear on the sleeve of the head adaptor. The stem had evidence of black staining on its surface, as well as evidence of corrosion along its length (Figure 7). In some cases, black staining of the cement mantle was noted. In several cases, there was fragmentation of the cement with caseous tissue in the cement / bone interface, particularly at the greater trochanteric region.

DISCUSSION

The failure rate in our series is over 20% within 5 years of implantation. This is worse than other reported series [9, 10] as well as published data from the National Joint Registry

for England and Wales [11], where revision rates quoted for large-head MoM hybrid THR was 7.8% at 5 years. The final failure rate may very well be much higher as we are yet to conclude our recall programme. We however felt the need to highlight this unusually high early failure rate of this hybrid combination.

The reason for these poor results is not immediately apparent. We would suggest that component orientation and surgical technique is not a contributing factor, as evidenced by the measured abductor angle of the acetabular component and evaluation of the cementing techniques of the femoral component (Table 1). The CPT stem has got a proven record when used with a conventional bearing surface and with head sizes up to 36mm. It has a 10A ODEP rating and excellent survivorship [12]. However, in this series, we have found catastrophic failure of the femoral component in combination with a large metal-on-metal articulation, in several cases. The Durom acetabular component, both in our series and in other published work [8], has not shown evidence of osseo-integration. However this did not appear to be the mode of failure in our cohort.

Retrieval analysis of a similar hybrid system to ours has identified the trunnion-head interface as a potential source of metal ion debris and suggested a mechanical cause from excess force at the interface [10]. The presence of a large head on a 12/14 taper could be to blame for this excessive force. It has been reported that when metal is tested on polyethylene, torsional forces at the trunnion increase as the head size increases [13]. Macroscopic evaluation of the trunnions of all the explanted femoral stems in our series also demonstrated evidence of abnormal wear with reciprocal changes in the femoral part of the sleeve component. In their series, Bolland et al [10] identified pain as a prominent feature of failure, accompanied by radiological abnormalities. This appears to be the case in our series as well although the pain was so mild that it did not warrant the use of regular analgesia or the need for medical consultation. There is a growing concern that some patients may be in the community, relatively satisfied with the function of their arthroplasty, but harbouring a potentially very serious problem with their hip. Indeed 2 of our patients had catastrophic failure of their femoral component with displaced periprosthetic fracture, yet were unaware and were not intending to seek medical review until contacted by our department.

With regards to metal ions, Bolland et al [10] found that elevated pre-revision serum Cobalt (Co) levels were significantly associated with revision / the need for revision. However joint fluid aspirated at surgery showed markedly elevated Chromium (Cr) levels. Their explanation was that the probable source of the Cr metal debris was stem corrosion. This appears to be corroborated by their analyses of metal particulate matter from tissues of failed metal-on-metal articulations which showed that Cr was the predominant ion. This further raises the question as to whether the predominant source of metal ion production is the trunnion-head interface or the passive stem corrosion. It was also suggested by them that due to the low levels of metal ion production one would expect from a trunnion-head interface compared to the bearing surface, the threshold level of 7parts per billion (ppb) for MoM hybrid THR may be too high and may therefore give the surgeon a false sense of reassurance. Our series does tend to correlate with this observation as even in those cases with catastrophic failure, the pre-operative serum Co and Cr levels were generally only moderately raised.

A contributing factor to the mode of failure may be increased mechanical stresses. Coupling of a large-diameter metal head on a cemented femoral stem may lead to excessive torsional forces on the cement-implant interface. In several of our cases, we were able to demonstrate evidence of radiological lucency at Gruen zone 1 and subtle calcar resorption, suggesting loosening. Intraoperatively this correlated with finding a caseous necrotic tissue in the cement-bone interface in zone 1 with osteolysis of the calcar. Mechanical torsional forces are probably only partly contributory, with all of the explanted femoral stems in this series showing evidence of widespread corrosive changes.

A weakness of our study is that we do not have a full data set of functional hip scores and metal ion levels in all of our patients. This is due to our relative lack of appreciation in the early failures as to the potential modes of failure.

Our case series highlights an unacceptable high and early failure rate occurring with a femoral stem that otherwise has a proven record. In our group of patients, we have found that the combination of a MoM bearing with a large diameter articulation has led to a very high failure. We await full retrieval analysis of the explanted components, but macroscopically the main articulation between the large head / cup appears to show little wear while there is evidence of significant wear of the trunnion and widespread corrosion along the length of the polished stem.

Surveillance remains the key to identifying at-risk patients and subtle symptoms, especially pain, should not be overlooked. Co and Cr levels may be useful in assessment but they are not specific or predictive of failure [10] and may give false reassurance if only modestly raised. Our concern is that there are potentially patients in the community who are asymptomatic or minimally symptomatic who have quite advanced pathology, as evidenced by our 2 patients with non-traumatic periprosthetic fractures, who need urgent investigation and treatment of their failing large-diameter MoM hips. We fully support the MHRA guidance [7] of vigilant attention to patients with MoM articulations and strongly discourage the use of a large diameter MoM articulation, in particular a hybrid combination of cemented polished tapered stem with uncemented cup.

Table 1

Demographic and Operative data for patients who have been revised / awaiting revision

Number of Patients (N)	15
Gender Distribution	Male 11 Female 4
Age Distribution	Mean age: 61 years (41 – 75 years)
Femoral Head Diameter	Median head diameter 50mm < 50mm 7 >/= 50mm 8
Acetabular Cup Inclination	Mean inclination: 41.6 degrees (33 – 46)
Cementing Technique	Barrack Grading A 11 Barrack Grading B 2 Barrack Grading C 2

Table 2

Radiographic, clinical presentation, time to failure and metal ion levels data

Patient	Date of Revision	Time to Revision (Months)	Clinical Presentation	Radiological Modality of Investigation	Pre-operative Radiological Findings	Pre-operative serum metal ion concentration (ppb)	Post-operative joint fluid metal ion concentration (ppb)
JH1	19/12/2011	48	Mild thigh pain Catastrophic failure on x-ray	MRI X-ray	Pseudo tumour Periprosthetic fracture	Co 5.1 Cr 4.5	Co 992.2 Cr 2178.8
DB	20/01/2012	35	Moderate trochanteric pain	MRI USS X-ray	Pseudo tumour Stem subsidence	Co 5.7 Cr 5.8	Co 1358.4 Cr 566.8
TW	04/01/2011	31	Moderate trochanteric pain	X-ray	Normal	Co 24.8 Cr 9	None
MD	29/11/2011	48	Asymptomatic Catastrophic failure on x-ray	MRI X-ray	Pseudo tumour Periprosthetic fracture	Co 6.4 Cr 3.3	Co 572.3 Cr 72.3
PO	18/10/2011	35	Deep infection	X-ray	Normal	Co 6 Cr 2.6	None
ME	15/11/2011	45	Significant groin and thigh pain	MRI USS X-ray	Pseudo tumour Medial cuff or resorption	None	Co 1256.7 Cr 130.5
JH2	13/04/2012	49	Mild trochanteric pain	MRI USS X-ray	Pseudo tumour	Co 12.7 Cr 2.8	None
CP	03/01/2012	48	Mild postero-lateral thigh pain	MRI X-ray	Pseudo tumour	Co 2.3 Cr 2.1	None
KH	09/2009	30	Traumatic periprosthetic fracture	X-ray	Periprosthetic fracture	None	None
AM	Awaiting Revision		Asymptomatic	MRI X-ray	Pseudo tumour	Co 5.3 Cr 1.1	
AA	Awaiting Revision		Occasional mild trochanteric pain	MRI X-ray	Pseudo tumour	Co 7.1 Cr 3.1	
JD	Awaiting Revision		Asymptomatic	MRI X-ray	Pseudo tumour	Co 6.4 Cr 2.2	
PF	Awaiting Revision		Mild trochanteric pain	MRI X-ray	Pseudo tumour	Co 6.9 Cr 2.7	
BS	Awaiting Revision		Asymptomatic	MRI X-ray	Pseudo tumour	Co 5 Cr 3.4	
PD	Lost to local follow up						

Figure 1

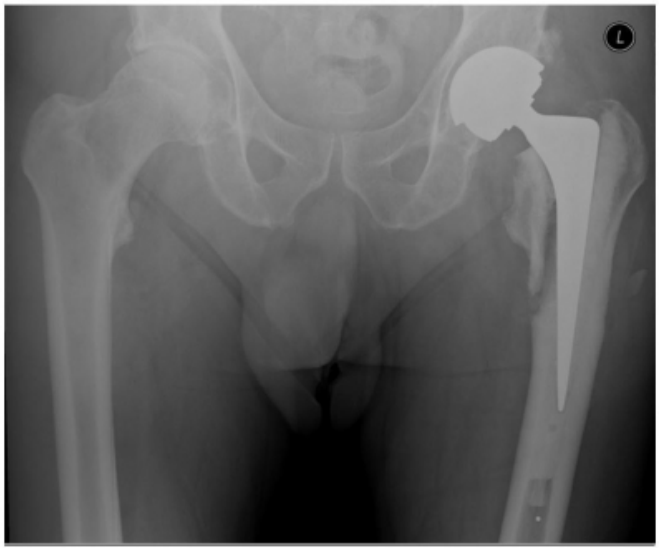

Figure 2

Figure 3

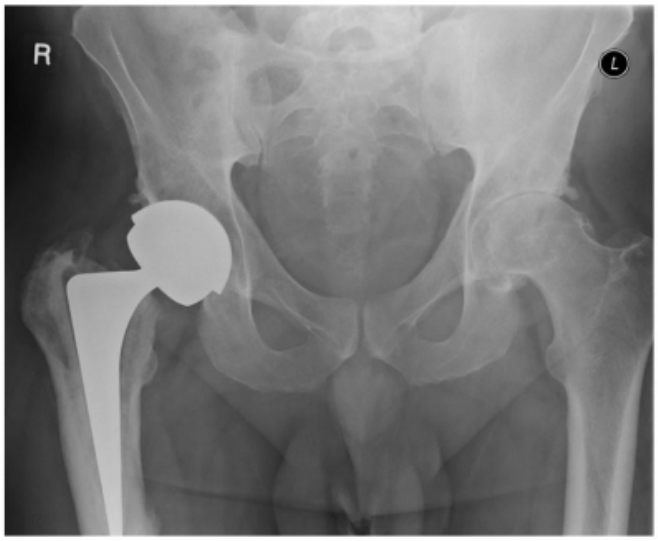

Figure 4

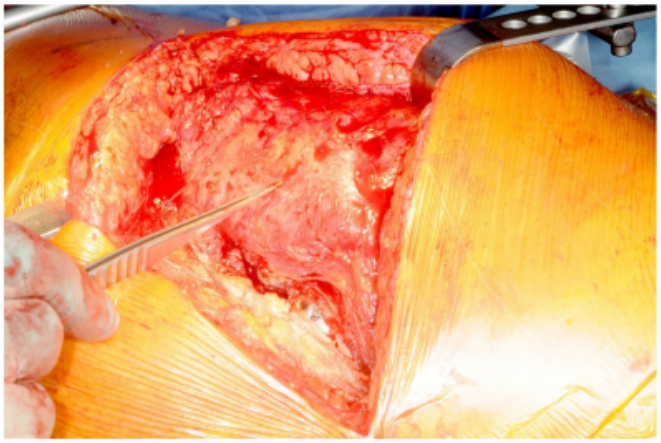

Figure 5

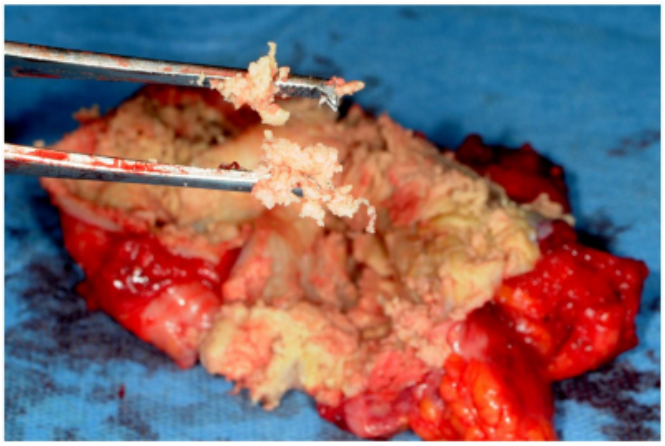

Figure 6

Figure 7

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Author Information

Bola Akinola, MRCS, MSc.
Department of Orthopaedics and Trauma, Addenbrooke's Hospital
Cambridge, UK

Chris Lawrence, MRCS
Department of Orthopaedics and Trauma, Broomfield Hospital
Chelmsford, UK

Matt Weston, MRCS
Department of Orthopaedics and Trauma, Broomfield Hospital
Chelmsford, UK

Roddy Rodrigues, MBBS
Department of Orthopaedics and Trauma, Broomfield Hospital
Chelmsford, UK

Satya Bhargava, FRCS
Department of Orthopaedics and Trauma, Broomfield Hospital
Chelmsford, UK

Andrew MacDowell, FRCS (Orth.)
Department of Orthopaedics and Trauma, Broomfield Hospital
Chelmsford, UK