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ORIGINAL ARTICLE

A retrieval analysis of explanted Durom metal-on-metal hip arthroplasties

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Abstract: *Given the recent reports of high failure rates, an improved understanding of the mechanism of failure of large diameter metal-on-metal hip arthroplasties is essential. We present clinical data and tribological analysis of a consecutive series of 74 failed large diameter metal-on-metal hips, comparing the Durom (Zimmer) with the Birmingham hip resurfacing (BHR) (Smith and Nephew). We retrospectively analysed pre-, intra-, and post-operative clinical data and measured the linear wear and component form of the explanted components using a roundness measuring machine. A significantly higher proportion of hips in the Durom group failed as a result of acetabular loosening (p=0.001) and this was supported by evidence of reduced bone in-growth on the backside of the cup. Comparison of roundness measurement revealed that the Durom hip was significantly lower wearing than the BHR (p<0.05) but the Durom femoral components were subject to significantly greater form errors (p<0.001), the pole of the head being flattened by up to 31 microns. Although the Durom hip is low wearing, reduced sphericity of the femoral component may have resulted in equatorial bearing, leading to an increased frictional torque at the cup-bone interface, preventing bone in-growth, and culminating in acetabular loosening. This supports recent clinical findings of high revision rates as a result of acetabular loosening for the Durom metal-on-metal hip system.*

Key words: *Metal-on-metal, Hip arthroplasty, Retrieval analysis*

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INTRODUCTION

Despite the well-documented benefits of both metal-on-metal (MoM) hip resurfacing and large diameter total hip arthroplasty, recent data from the National Joint Registry (NJR) for England and Wales has shown higher than expected revision rates; higher than for other bearing surface combinations (1). Of particular concern is the high rate (43%) of unexplained failure (2), which is thought to be associated with adverse soft tissue reactions to metal wear debris (3-5). Several retrieval studies of current generation MoM hips have shown that edge wear, as a result of high cup inclination, is an important mechanism responsible for generating high levels of metal ions (6-9). This is one of the reasons suggested to explain the higher metal ion levels and wear rates of the ASR hip system, which was designed with a cup articular arc angle lower than any other current generation design (10, 11). Therefore, comparison of different MoM hip designs will improve our understanding of failure mechanisms and help identify design features that may improve ‘in vivo’ wear performance and clinical outcome.

Three recent clinical studies have suggested that specific design features of the Durom acetabular component may increase its susceptibility to aseptic acetabular loosening due to reduced bone ingrowth at the cup-bone interface (12-14). In a series of 187 patients with 207 Durom MoM hips, Long et al reported a revision rate of 15% for acetabular loosening, with 72% of revisions demonstrating evidence of radiographic loosening. Similarly, in a series of 100 patients Berton et al observed that 35% patients demonstrated post-operative gaps following implantation of the Durom cup. Although, the authors attribute these findings to design features of the cup rim causing difficulty in seating the cup in the acetabulum, there may be other mechanisms resulting in an increased susceptibility to acetabular loosening. There are no studies in the current literature concerning retrieved Durom MoM hips.

The aim of this study was to compare clinical data and roundness data for a group of retrieved Durom hips and compare this to a control group of Birmingham hip resurfacings (BHR), which has the lowest reported five-year failure rate of the current generation MoM hip designs (15).

MATERIALS AND METHODS

Component selection

This was a retrospective study of 74 (148 components) consecutive cases sent to our retrieval laboratory during the period February 2008 to September 2010, comparing the Durom MoM hip with the a control group of BHR MoM hips. We performed both cross-sectional comparison and matched comparison using the following criteria; gender, femoral diameter (+/- 2mm), cup inclination angle (+/- 5°) and time to revision (+/- 2 months). A summary of the patient demographics, clinical and component details is given in Table I. The laboratory operates with approval of the Human Tissue Authority and local institutional ethical committee.

Clinical analysis

Clinical analysis included cup position as measured on plain radiographs or CT scan, measurement of pre-revision whole blood chromium and cobalt levels by inductively coupled plasma mass spectrometry (ICPMS) (4), and diagnosis of the clinical cause of failure (reason for revision). The categories of failure used were the same as those outlined in the National Joint Registry for England and Wales (2). The criteria used to diagnose the cause of failure are outlined in Table II.

Visual inspection

All components were inspected prior to roundness measurement. We inspected the bearing surface for any macroscopic evidence of wear, and the backside of cups for evidence of reduced bone in-growth as has been reported in other studies of the Durom hip (12-14). Findings were recorded using a qualitative grading system.

Roundness measurement

Measurement of sphericity (or form) and wear was performed using a Talyrond 365 Roundness Machine (Taylor

TABLE I - RELEVANT PATIENT AND CLINICAL INFORMATION

	Durom group	**BHR group**	**Matched BHR group**
Number of patients	24 (48 components)	50 (100)	24 (48)
Gender ratio (m:f)	1:2	1:2	1:2
Patient age	65 (40 to 83)	55 (23 to 68)	54 (38 to 68)
Head size (mm)	46 (42 to 56)	46 (42 to 58)	46 (42 to 54)
Months implanted	26 (6 to 48)	51 (10 to 121)	32 (10 to 54)
Cup inclination (°)	48 (43 to 64)	50 (24 to 73)	49 (40 to 69)
Cup version (°)	16 (-22 to 42)	23 (-47 to 43)	20 (0 to 40)
WB chromium (ppb)	2.7 (0.1 to 8.6)	4.2 (0.4 to 183.0)	4.24 (0.4 to 183.0)
WB cobalt (ppb)	5.8 (0.6 to 13.4)	8.8 (0.9 to 167.0)	14.5 (0.9 to 167.0)

Values given are median (range).

Hobson, UK). The Talyrond is a stylus instrument used to measure deviation from a perfectly round profile. We performed three separate sets of measurements for each hip joint according to a previously described protocol (9, 11, 16).

In order to accurately measure wear it is important to be able to distinguish this from form error. Form error refers to deviation from the nominal spherical shape of the component as a result of the manufacturing process or plastic deformation in vivo, whereas wear is the loss or transfer of material from the bearing surface. We were able to separate wear and form error by superimposing multiple measurement profiles of the same component. This allowed wear patches (typically, localised deviations from round extending over few profiles) to be distinguished from reduced sphericity (or form error), which is seen as generalised deviation from round occurring uniformly over all profiles. Superimposing the polar profiles provides a good estimate of the shape (sphericity) of the component. Wear rates were calculated based on the time in situ, and edge wear (edge loading) was defined as wear extending over the rim of the cup. The roundness measurement profiles in Figure 1 demonstrate the difference between wear and form error.

Statistical analysis

Normality was not observed in the distribution of wear or metal ion data and so we adopted a non-parametric approach, using the Mann-Whitney U-test to compare these outcomes. For comparison of binary data (cause of failure analysis) we used Fisher's exact test. All tests were two-sided and a p value ≤ 0.05 was considered to be significant.

TABLE II - CRITERIA USED FOR DIAGNOSING THE CLINICAL CAUSE OF FAILURE IN MOM HIPS

	Diagnostic criteria
Unexplained (+/- pain)	Absence of: • Intra-operative loosening of components • Infection (see below) • Gross malalignment (see below) • Component size mismatch • Fracture (on imaging / seen intra-operatively)
Acetabular loosening	Intra-operative diagnosis (pre-operative imaging has a high false negative rate)
Femoral loosening	Intra-operative diagnosis (pre-operative imaging has a high false negative rate)
Infection	Positive if: • Post-operative cultures positive for infection Negative if: • Pre-operative CRP < 10mg/L or, • Pre-operative CRP > 10mg/L but post-operative culture was negative for infection
Dislocation	Patient reported (+/- radiographic evidence)
Periprosthetic fracture	Radiographic evidence
Mal-alignment	Imaging (CT or X-ray) shows: • Cup inclination > 70° • Cup version associated with impingement
Component mismatch	Post-operative assessment of components

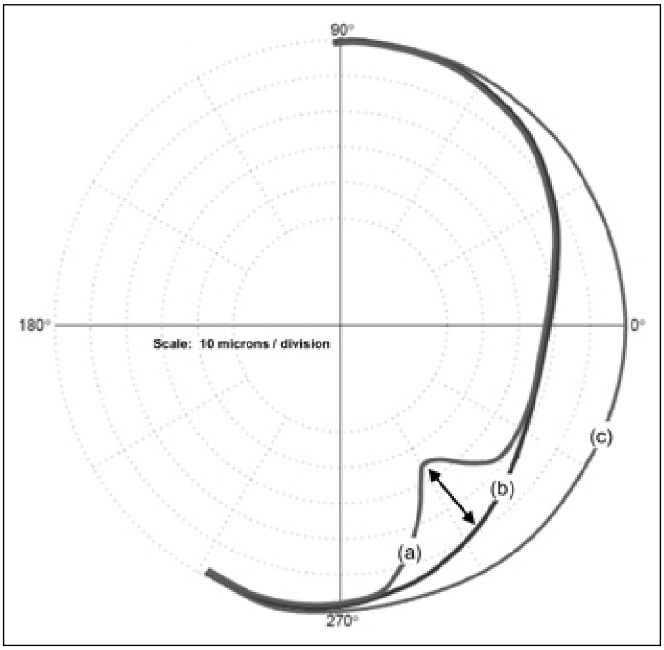

Fig. 1 - *Two superimposed polar measurement profiles demonstrating both a typical area of wear (profile (a)) and a typical form error (profile (b)). The third line (c) represents a perfect hemisphere (the desired manufactured shape). For clarity we have included only two measurement profiles, but true separation of wear and form requires all measurement profiles to be superimposed.*

RESULTS

Clinical analysis

Plain radiographs or CT imaging was available for 66 / 74 patients, and pre-revision whole blood metal ion levels were available for 60 / 74 patients. There was sufficient clinical data to reliably diagnose the reason for revision for all patients in this study. All of the clinical results are shown in Table III.

Visual inspection

Visual inspection of the components revealed a trend towards reduced bone in-growth on the backside of the Durom acetabular components (Fig. 2).

Roundness measurement

Results of the roundness measurement are also shown in Table III. Both the cup and head components of the Durom hip were significantly lower wearing than the BHR. However, the Durom head components demonstrated significantly greater form errors (reduced sphericity) compared to the BHR. In both groups form errors of the cup were undetectable.

DISCUSSION

In this retrieval study of large diameter MoM hips, we showed that the Durom has significantly improved in vivo wear performance when compared to the Birmingham Hip Resurfacing (BHR). However, there was a significant reduction in sphericity of the femoral component, whereby the pole of the Durom head component was flattened by up to 31 microns. This form error may contribute to the significantly increased rate of aseptic acetabular loosening shown in the Durom group.

Clinical analysis revealed two important findings; a high prevalence of unexplained (+/- pain) failure for both hip types included in the study, and a significantly higher proportion of Durom hips having failed due to aseptic acetabular loosening. This supports data from the National Joint Registry for England and Wales, where 43% of failures were classified as unexplained (2), and recent reports in the literature that have suggested that the Durom hip may be susceptible to aseptic acetabular loosening (12, 13). We matched for variables known to influence clinical performance, such as gender (17) and femoral diameter (17) and this had no effect on our results.

Wear analysis showed that the Durom hip was significantly lower wearing when compared to the BHR. Again, the groups were well matched for variables known to influence wear performance, such as cup inclination (6-9) and the time to revision (18). It is difficult to identify the factors responsible for the difference in wear rate but we suggest that design features such as the increased cup articular arc angle (19) (Fig. 3) and lower clearance (20) (Fig. 3) compared to the BHR may be responsible.

It is known that reduced femoral coverage as a result of a reduced cup articular arc angle (CAAA) increases the risk of edge contact (6, 10), and much higher wear rates in MoM hip replacements (8, 9). The Durom cup has a constant CAAA of 165°, whereas for the BHR this is variable (158° to 164°) depending on the internal diameter of the cup used; larger cups have increased CAAA (19). These values are relatively similar, and much improved compared to other designs such as the ASR, which has a CAAA of

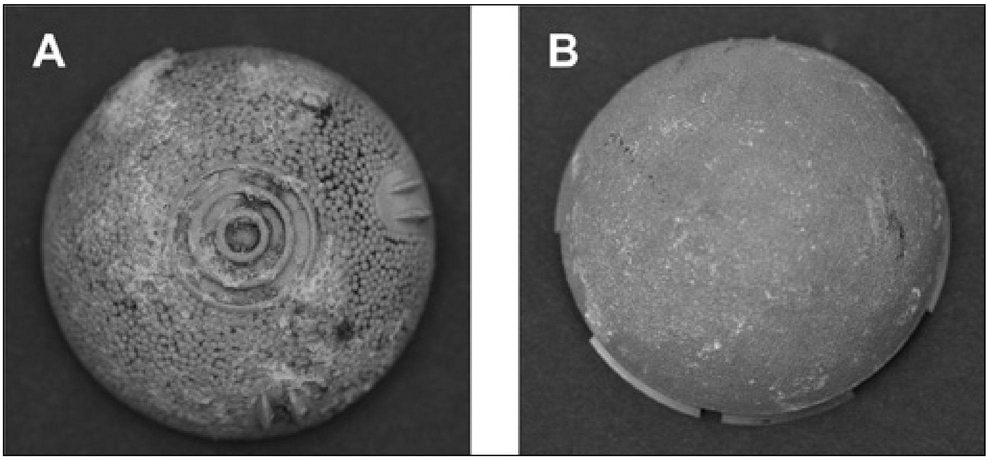

Fig. 2 - *Photographs comparing the backsides of a BHR* **(A)** *and Durom* **(B)** *acetabular component, showing typically reduced bone ingrowth on the Durom cup. From this Figure it is also possible to see the difference in the backside coating, with the BHR cup using a much courser beaded structure.*

TABLE III - COMPARISON OF THE CLINICAL AND ROUNDNESS MEASUREMENT DATA

	Durom (n = 24)	BHR (n = 50)	Sig*	Matched BHR (n = 24)	Sig§
Cup inclination (°)	48 (43 to 64)	50 (24 to 73)	p = 0.95	49 (40 to 69)	p = 0.97
Cup version (°)	16 (-22 to 42)	23 (-47 to 48)	p = 0.82	20 (0 to 40)	p = 0.75
WB chromium (ppb)	2.7 (0.1 to 8.6)	4.2 (0.4 to 183.0)	p = 0.04	4.24 (0.4 to 183.0)	p = 0.06
WB cobalt (ppb)	5.8 (0.6 to 13.4)	8.8 (0.9 to 167.0)	p = 0.06	14.5 (0.9 to 167.0)	p = 0.02
Cause of failure:					
• Unexplained (+/- pain)	14	32	p = 0.80	19	p = 0.21
• Acetabular loosening	9	2	p < 0.01	1	p = 0.01
• Femoral loosening	0	4	p = 0.30	1	p = 1.00
• Infection	1	6	p = 0.42	3	p = 0.61
• Fracture	0	2	p = 1.00	0	-
• Malalignment	0	4	p = 0.30	0	-
Cup linear wear rate (μm/year)	1.8 (0.0 to 13.9)	22.7 (0.0 to 153.7)	p < 0.01	21.3 (0.0 to 141.0)	p = 0.03
Head linear wear rate (μm/year)	1.0 (0.0 to 7.5)	9.2 (0.0 to 52.4)	p < 0.01	9.3 (0.7 to 52.4)	p < 0.01
Edge worn	29%	62%	p < 0.01	62%	p < 0.01
Head form error (μm)	14.0 (0.0 to 31.0)	2.0 (1.0 to 7.0)	p < 0.01	2.0 (1.0 to 6.0)	p < 0.01

Values are median (range) except for cause of failure and edge wear.
* significance refers to comparison of Durom and BHR hips.
§ significance refers to comparison of Durom and matched BHR hips.

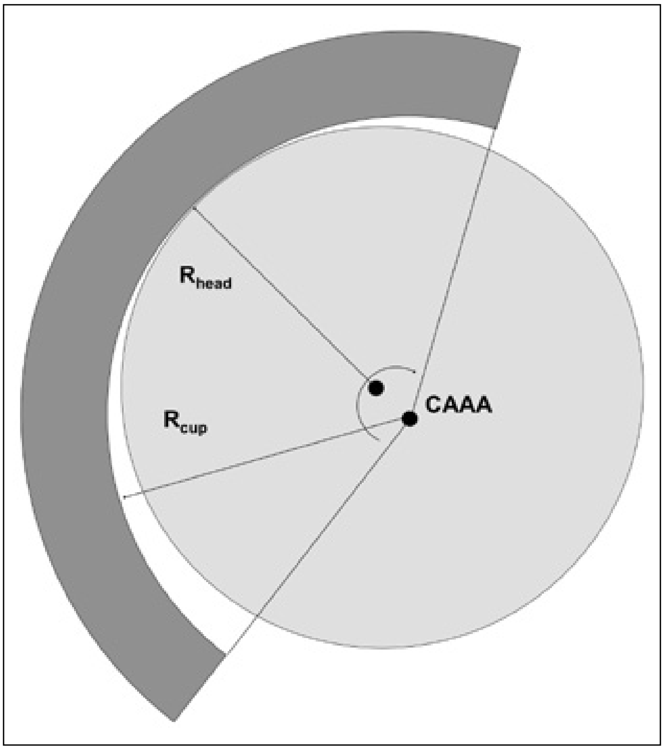

Fig. 3 - *Design features associated with wear performance: the radial clearance (Rcup - Rhead) and the cup articular arc angle (CAAA). The Durom cup has a constant CAAA of 165 degrees, compared to the BHR cup that has a CAAA of between 158 and 164 degrees depending on diameter. The Durom also has a lower average radial clearance (70μm), compared to the BHR (110μm).*

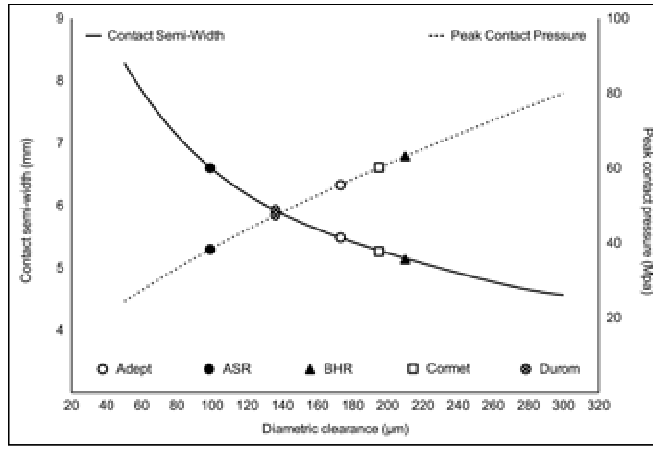

Fig. 4 - *This line graph shows the peak contact pressures and contact patcH semi-widths for 5 current generation MoM hip designs, including the Durom and BHR. This clearly shows how by increasing the clearance of a MoM hip joint the contact pressures are increased and the size of the contact area is reduced.*

between 146° and 152° (19). We suggest that the difference in CAAA between the Durom and BHR may contribute to the difference in wear performance, particularly for smaller diameter hips.

The clearance of MoM hips is an important factor affecting the contact patch geometry and has a more complicated role on the tribology of the joint. By applying the Hertz Theory of Elastic Contact (21) to MoM hip joints, we are able to predict the effect of clearance on the size (or width) of the contact patch and the pressure distribution between the acetabular and femoral components. Reduced clearance results in a more conformal contact between the components and therefore reduced peak local contact pressures. However this is at the expense of a larger contact size (width), which increases the risk of edge contact and much increased wear rates. Application of the Hertzian equations (21) to predict the effect of clearance on the contact pressures and distributions is shown in Figure 4. This clearly shows how the radial clearance of the Durom hip (70μm) provides improved peak contact pressures compared to the BHR (110μm), but a larger contact patch diameter. For the purpose of comparison we have included the contact pressures and distributions for five leading current generation MoM hip designs in Figure 4. Our calculations are consistent with those previously performed for McKee-Farrar devices, also based on Hertz Contact Theory (22).

There is a large discrepancy in clearance between all of the current generation MoM hip designs, but 'optimal' clearance may be a balance between reducing the contact pressure without greatly increasing the risk of edge loading. Additionally, the clearance must be large enough to avoid negative clearance resulting from component deformation. Further studies quantifying the effect of clearance on wear rates and edge loading will be important given that there is much variation in the clearances of current generation MoM hips (20).

For the Durom hip, the combination of a relatively low clearance and a high CAAA may provide an optimal balance of reducing the peak local contact pressure without greatly increasing the chance of edge contact.

Roundness measurement also showed that the Durom femoral heads were susceptible to significant flattening in the region of the pole, which may occur as a result of manufacturing or implantation techniques. This is an important finding as it is likely to disrupt the contact mechanics of the hip joint. A three-dimensional finite element study would help quantify the effects of reduced femoral component sphericity, but is beyond the scope of this study. Future work may test the hypothesis that significant flattening of the femoral pole may result in equatorial contact as opposed to the desired polar contact, which in turn may result in increased frictional torque across the joint. This could lead to micro-motion enough to disrupt the cup-bone interface as well as motion and mechanical wear at the taper-stem junction of large diameter heads.

It has already been shown that inferior frictional performance of hip joints can result in small increases in micromotion at the cup-bone interface and disrupt bone ingrowth (23), and this supports the theory that significant reductions in femoral sphericity may be responsible or contribute to failure due to aseptic acetabular loosening and the observed reduction in bone in-growth on the back of Durom cups (Fig. 4). In large diameter MoM hips, primary acetabular fixation is achieved through an interference (or press) fit at the cup-bone interface. As the acetabular bone remodels, bone in-growth is required to provide secondary fixation. In additon to the proposed mechanism by which flattening of the Durom femoral head may lead to poor cup fixation, another design difference between the two hip types may also be a contributing factor. There is a significant difference in the backside coatings of the two cup components. The Durom cup has a fine porous structure, whereas the BHR cup has a course beaded porous structure (bead diameter 2mm). This may also contribute to the observed disparity in bone in-growth and affect secondary fixation of the acetabular component.

Form errors are poorly understood and it is difficult to distinguish whether they may have occurred during the manufacturing process or as a result of another cause such as impaction deformation. In our study the estimated reduction of sphericity for Durom femoral components was up to three-times greater than the recommended ‘departure from round’ (< 10 microns) for manufactured components (24). All BHR femoral components had form errors of less than 10 microns. Future work may involve comparison of explant sphericity with a control group of new implants.

Our findings support those of other studies relating to the performance of the Durom hip, which have also noted poor bone in-growth on revised cups, and an increased rate of acetabular loosening (12-14). This had been attributed to surgical technique and the relative difficulty in seating this particular cup design in the acetabulum, which may reduce the cup-bone contact and prevent bone in-growth. However there are likely to be many factors responsible for this, which may include reduced sphericity of the femoral components.

There are several limitations to our study, with the main limitation being the low number of Durom hips (n=24); however this is the first published study of explanted Durom MoM hips. Secondly, the assessment of bone in-growth on the cup-bone interface was qualitative and although this allowed us to recognise a clear trend when comparing the implant types, future work may involve determining an objective scoring system for quantifying bone in-growth. We suggest future work combining data from explanted hips with 3-D finite element analysis may confirm the findings of this study and also reveal further mechanisms of failure. Further studies analysing the sphericity of explanted components, and perhaps the role of impaction deformation, may help in understanding clinical failure and the wide variation in component wear rates observed in the current literature.

The main conclusion from this study is that failed Durom MoM hips had significantly lower wear rates when compared to a matched group of failed BHR MoM hips. We have suggested factors that may be involved including differences in specific design features. The increased cup articular arc angle at all cup sizes for the Durom hip reduces the theoretical risk of edge loading, a mechanism associated with increased wear rates. Additionally, the clearance of the Durom hip may provide an optimal balance of reduced peak local contact pressures, without greatly increasing the contact patch size and the subsequent risk of edge contact.

However, despite superior wear performance, the Durom femoral components were subject to significantly reduced sphericity when compared to the BHR femoral components. This may adversely affect the contact mechanics of the joint and increase the risk of aseptic acetabular loosening. This would be consistent with the observed reduction in bone in-growth on the acetabular components and the significantly increased proportion of Durom hips having failed due to acetabular loosening.

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Conflict of interest: There are no potential conflicts of interest.

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