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BIRMINGHAM HIP RESURFACING
VERSUS CONSERVE PLUS
METAL-ON-METAL
HIP RESURFACING

A SURGEON'S
PERSPECTIVE

DR. KOEN DE SMET



Birmingham Hip Resurfacing
versus
Conserve Plus
Metal-on-Metal Hip Resurfacing

A SURGEON'S PERSPECTIVE
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CONTENTS

Introduction	2
Metallurgy	2
Wear and Clearance Measurements	4
Metal Ion Measurements	6
High Wear and High Ions	7
Cup Inclination and Ions	7
Coverage Angle	8
Acetabular Bone Preservation	9
Dysplasia cup / Enhanced fixation cup	10
Differences in the Femoral Part	11
Cement Clearance	
Stem Design	
Instrumentation	12
Acetabular/ Cup instruments	
Femoral instruments	
Clinical Performance	15
Squeaking Hips	15
Summary	16
Bibliography	18
Headlines and article titles	22
Metallurgy addendum	23
Acknowledgements	24

Introduction

I have been performing hip resurfacing procedure since September 1998 and have implanted approximately 3000 implants during those 10 years. I started with the first available system, namely the Birmingham Hip Resurfacing (BHR), but have now implanted 10 different designs. (See table 1) I have the most experience in my clinical practice with the BHR and the CONSERVE Plus since they have the longest clinical history in Belgium and therefore I would like to make a “clean comparison” between those two. The following observations and my personal opinions are based on the data from studies I have conducted using retrievals and metal ion measurements.

DESIGN	HIPS
BHR	1974
CONSERVE PLUS	628
ASR	55
MITCH	18
ADEPT	13
DUROM	12
RECAP	9
ACCIS	9
CORMET 2000	2

Table 1: Experience with different hip resurfacing designs

Metallurgy

It is well known that the Birmingham Hip Resurfacing manufacturer (Smith & Nephew, Memphis, TN USA) states that the cobalt chromium alloy left in the “as cast” condition provides superior wear properties when compared to heat-treated alloys (Box 1). The manufacturer of the CONSERVE Plus (Wright Medical Technology, Memphis, TN USA) states that heat treatment does not affect wear properties and in fact improves stability and strength of the components.

Box 1. The BIRMINGHAM HIP is intentionally left in the metal phase created from the casting process. This process leaves large blocks of hard material, called carbides, made from a mix of carbon and the metal. These blocks are significantly harder than the metal surrounding them, and they provide a significant amount of wear resistance. Heat treating the material causes the carbon to dissolve back into the metal, losing the wear resistance benefits.
<http://www.birminghamhipresurfacing.com/5/46/> accessed July 2008

To demonstrate this fact the company conducted a hip wear simulator experiment comparing 3 types of articulation: heat-treated CONSERVE Plus, “as-cast” CONSERVE Plus and “as cast” BHR [Carroll, 2004] . The results are shown in Figure 1

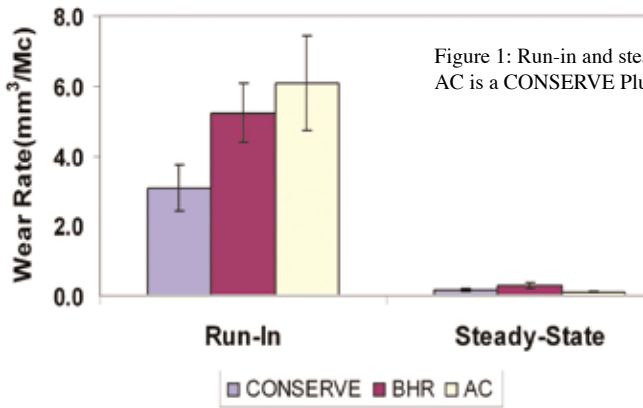


Figure 1: Run-in and steady state wear rates for the 54 mm diameter couples. AC is a CONSERVE Plus left “as cast”.

This work was substantiated by several other sources
(Box 2, Figure 23, Box 3)
page 23

The fact that several independent laboratories came to the same conclusion that heat-treatment does not have negative influence on wear behavior strongly points to the erroneous conclusion by the designers of the BHR device. The fact that the BHR wear data comparison was conducted with the so-called **pin-on-disk** apparatus, which does not provide good representation of the natural joint movement, also supports this premise.

Laboratory data aside, measurement of retrieved devices and measurement of the metal ion levels in patients are more definitive methods of investigating wear properties of different designs.

In 2003 Derek McMinn reported good initial results with the BHR device with the exception of a number of implants produced in 1996 with the double heat treatment method. The manufacturer switched from a single heat treatment to a double heat treatment cycle which resulted in carbide depletion (i.e. melting of carbides into original elements of carbon and metal) which, according to McMinn, resulted in accelerated wear and osteolysis. McMinn's review of four retrievals proposed direct correlation between wear rate and amount of surface carbides. (Fig 2).

Explant Wear versus Volume Fraction

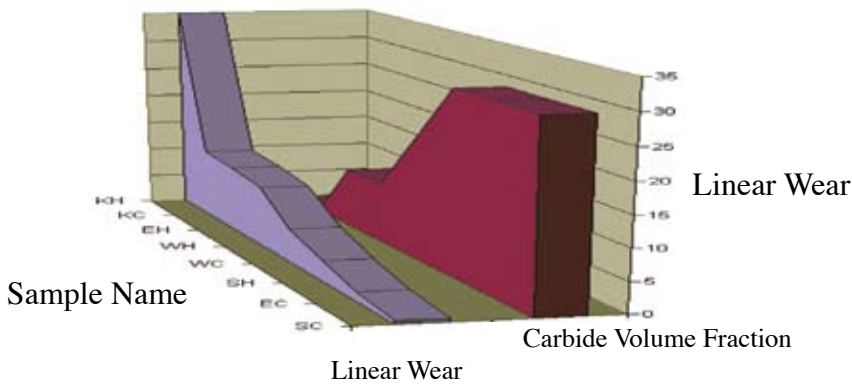


Figure 2: graph of linear wear vs carbide volume fraction of 1996 McMinn devices (with Courtesy of Tim Band MMT/Smith&Nephew) (KH= Karine head and KC= Karine Cup components)

In Figure 3 below, you see the Karine head component of one of these McMinn devices of 1996, which was revised by myself in 2/2001. CMM measurement showed there was high wear of 150µm on the head side.

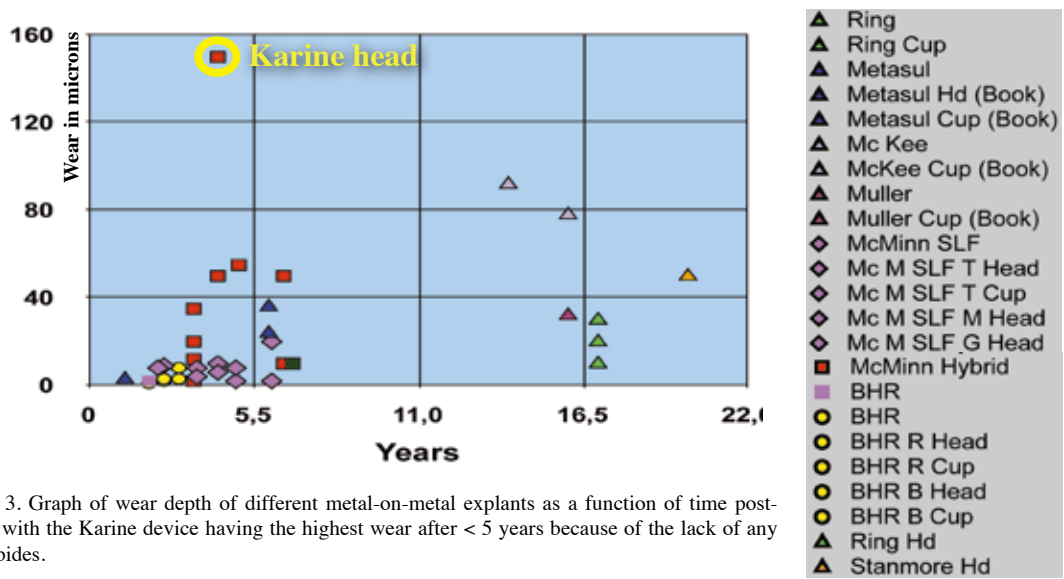


Fig 3. Graph of wear depth of different metal-on-metal explants as a function of time post-op, with the Karine device having the highest wear after < 5 years because of the lack of any carbides.

The puzzling fact that the manufacturer (Corin Ltd. UK) continues to heat treat its resurfacing device components (Cormet 2000) to a present day, seemingly without detrimental effects seen in 1996, has never been explained.

Examination and wear measurements of my retrievals are shown in table 2. The Karine device revised in February of 2001 exhibited gray metal-stained tissue, fluid cyst and osteolytic lesions. Wear scar was measured as 150 micron deep and metallurgical analysis did not find any surface carbides (Fig.4).

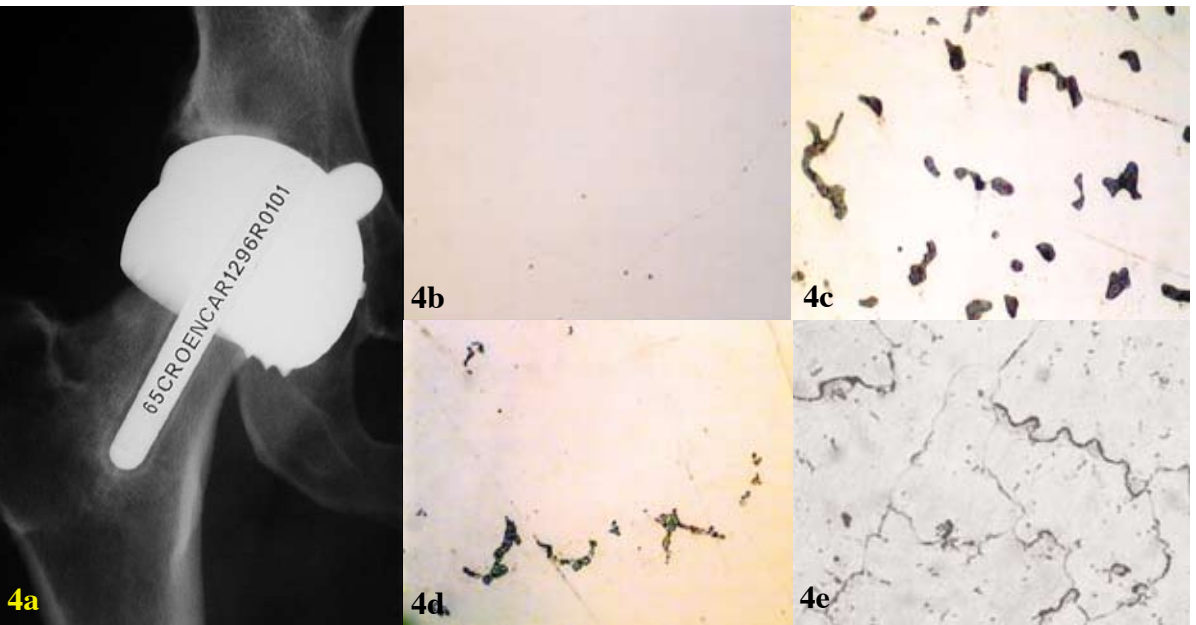


Fig 4 In these figure (4a) we see the 1996 McMinn (Karine) device with osteolysis and the micrograph of the metal showing NO carbide content (4b). In the next figure (4c) you can see how a normal as cast BHR surface contains block carbides. Figure 4d shows the distribution of carbides on a heat treated BHR (fragmented carbide blocks) and figure 4e showing the carbide distribution of a Conserve Plus prosthesis.

Wear and Clearance Measurements

I have been submitting retrieved components for wear measurements by coordinate measuring machine (resolution of 2 to 3 microns [Campbell, 2006] for several years now. Many of the BHRs were revised for malpositioned acetabular components and were, not surprisingly, found to have high wear (Table 2); average of 60 microns on the femoral side, 53 microns on the acetabular side, $n = 17$. The examined retrievals included also prostheses that were removed for failures such as fractures or infection, i.e. where wear or clearance problems had nothing to do with the reason for the retrieval.

Unfortunately I have no wear data on Conserve Plus components revised for acetabular malposition as these are rarely seen. The average maximum femoral and acetabular wear depth of 10 Birmingham Hip Resurfacing components revised for reasons other than acetabular malposition is 15 microns and 5 microns respectively. In the retrievals submitted for CMM, the average maximum femoral wear depth for BHRs was 54.7 ± 49 microns while for Conserve Plus it was 7.03 ± 13.5 microns. The average BHR clearance was 271 ± 66 microns and for the Conserve Plus clearance averaged 173 ± 30 microns [Campbell, 2006]. At the recent "Battle of the Designs" session of the Advanced Resurfacing Course in Ghent, the panel of experts agreed that the smallest diametral clearance possible would be best for a well-functioning metal-on-metal implant. This difference might not be important in a well-functioning implant, but it might make a difference when the implants are not well positioned. I have revised many resurfacings for implant malposition and I know from this experience that malpositioning causes a lot of problems from wear. One of the worst cases of metallosis I saw in my revision series was a BHR with clearance of 400 microns and total wear depth of nearly 200 microns! The higher clearance in the BHR could be one of the factors why this resurfacing is having higher blood metal ion levels than other resurfacings [Back et al, 2005] [Witzleb et al, 2007]. There is no good explanation so far why we would need such a high clearance.

Spec ID.

Ball/Cup

Type

Nominal Dia. (mm)

Diametral Clearance (μm)

Wear Depth (μm from Fitted Dia.)

S1983	Ball	BHR		400	146
S1983	Cup	BHR		400	51
S2004	Ball	BHR	42	184	108
S2004	Cup	BHR	42	184	153
S2014	Ball	BHR	42	222	33
S2014	Cup	BHR		222	92
S2031	Ball	BHR		202	100
S2031	Cup	BHR			37
S2252	Cup	BHR	46	367	78
S2041	Ball	BHR	46	370	66
S2041	Cup	BHR	46	370	n/m
S2044	Ball	BHR	38		25
S2054	Ball	BHR		283	13
S2054	Cup	BHR		283	<2
S2055	Ball	BHR		281	30
S2055	Cup	BHR		281	<2
S2064	Ball	BHR		267	7
S2064	Cup	BHR		267	6
S2066	Ball	BHR		205	6
S2066	Cup	BHR		205	<2
S2067	Ball	BHR		n/a	4
S2252	Ball	BHR	46	367	107
S2233	Cup	BHR	54		5
S2233	Ball	BHR	56		14
S2100	Ball	BHR	50	307	8
S2100	Cup	BHR	50	307	4
S2123	Ball	BHR	46		7
S2125	Ball	BHR	58	275	14
S2125	Cup	BHR	58	275	3
S2126	Ball	BHR	46	265	13
S2126	Cup	BHR	46	265	5
S2230	Cup	BHR	46	257	4,7
S2110	Ball	BHR	46	140	26
S2110	Cup	BHR	46	140	n/m
S2230	Ball	BHR	46	257	5,7
S2145	Ball	BHR	42	n/a	36
S2147B	Ball	BHR	46	546	184
S2147C	Cup	BHR	46	546	62
S2221	Cup	BHR	46	226	3,5
S2221	Ball	BHR	46	226	4,7
S2154	Ball	BHR	42	280	27
S2154	Cup	BHR	42	280	14
S2176	Cup	BHR	42	231	52
S2176	Ball	BHR	42	231	66
S2199	Ball	BHR	38	n/a	12
S2194	Ball	BHR	46	373	66
S2194	Cup	BHR	46	373	40

Table 2: Wear and clearance measurement for 28 revised BHR components.

Metal Ion Measurements

I have been collecting blood from consenting patients prior to revision surgeries (and at routine follow-up), as well as hip fluid taken from the joint at the time of revision surgery. The levels of metal ions have been measured with inductively-coupled plasma mass spectrophotometry with a resolution of 0.5ppb. Looking at the wear and ion data together, it can be shown that chromium and cobalt levels are correlated with the wear of the prosthesis. [De Smet, 2008] (Fig 5)

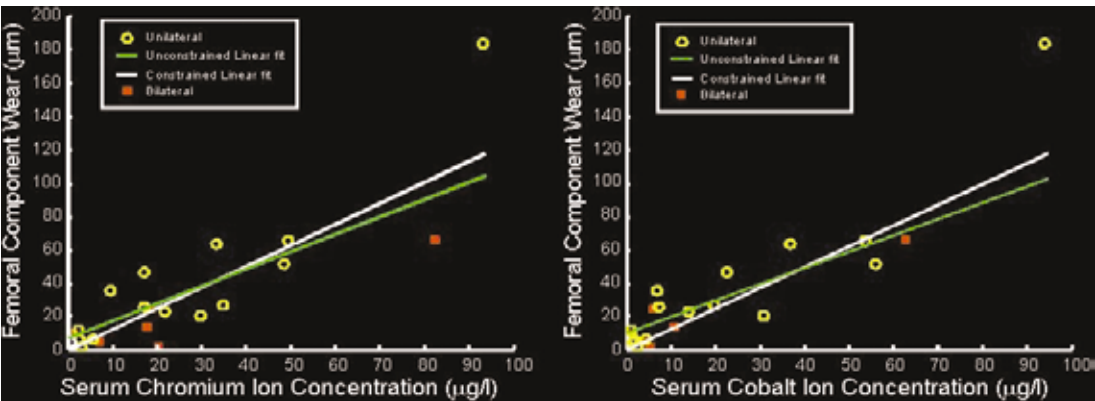


Fig 5. Correlation between femoral component wear depth and serum ion levels.

In the data from the Amstutz Conserve Plus series, and the published study of BHR ion values by Back et al, [Back, 2005] the metal ion levels are measured prospectively and longitudinally in a relatively large cohort of hip resurfacing patients where the same surgeon did the implantations, and the same lab did the metal ion testing. My patient ion data is shown against those data (Fig 6) (ANCA series) and this proof is even more evident. These metal ion levels are from normal, well-functioning resurfacing prostheses where the chromium serum level was not higher than 5 µg/l or 5 ppb. Therefore the claim that implants which have been heat treated after casting will have higher wear, (and therefore higher ions) is not supported by this data.

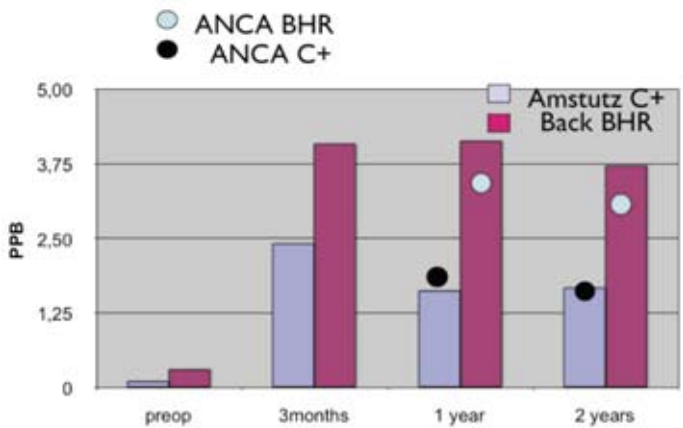


Fig 6. Metal ion levels from the patients in my series compared with those reported with the BHR by Back et. al. and with the CONSERVE Plus reported by Skipor, et. al. All values are reported for blood serum, however it must be noted that the measurements were conducted at different institutions. [Skipor, 2002]

Sample Interval	BHR	Conserve Plus
1 year	2,9 µg/l chromium	1,6
2 year	2,9	1,8
3 year	2,4	2,1
Total Average of CrS	2,4	1,8
Total Count of ID	236	104

Table 3. Results of chromium ion measurements of ANCA hip resurfacing patients

High Wear and High Ions

The ion data from my revision cases with high wear show that the serum metal levels in patients with metallosis are nearly 10 times higher than in patients without metallosis. Measuring the hip fluids showed that the level of chromium was approximately 50 times the serum level, while the joint fluid level of cobalt was approximately 40 times the serum level but ranged to nearly 400 times higher for chromium and nearly 700 times higher for cobalt ! [De Smet, 2008]

Cup Inclination and Ions

The results of the ion measurements showed that there was a strong relationship between the cup inclination angle and the ion levels; cups inclined at 55° or more tended to have higher ion levels, probably because of the higher risk of edge loading. The ions were higher in BHRs with steep cups compared with Conserve Plus with steep cups, especially for the smaller sizes (Fig 7,8). This might be explained if you look at the differences in coverage angle (coverage from the proximal pole of the femoral component to the lateral edge of the cup). This is different between the Birmingham Hip Resurfacing and Conserve Plus: although both sockets are less than a hemisphere, the Conserve Plus is 174° outside and 170° inside, which is more than the 164° subtended by the Birmingham which is 180° outside. Therefore, for any given steepness of cup and component diameter, the Conserve Plus socket will have more cover than the Birmingham. There is much less leeway in terms of safe inclination angle and the use of small component sizes when the coverage angle is less than 170°. The Conserve has a larger margin for error and less risk for edge loading, even if the cup would not be positioned in the ideal position of 40–45 degrees.

This might explain why there is a higher failure rate among female patients with BHRs .

Cobalt in Serum if Cup > 50 degrees

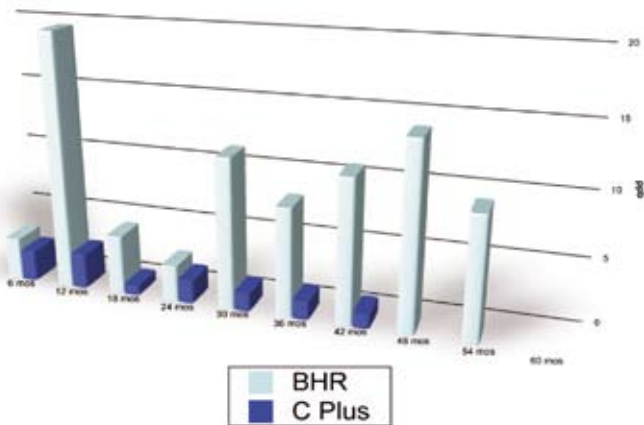


Fig 7. Serum Cobalt levels of BHR and Conserve Plus in steep cups (cup abduction angle > 50°).

Cobalt in Serum if Cup < 50 degrees

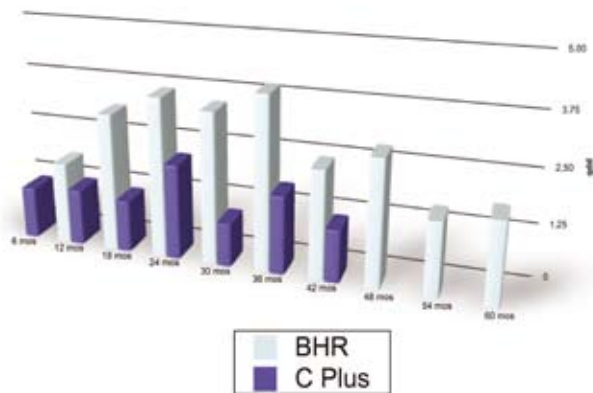


Fig 8. Serum Cobalt levels of BHR and Conserve Plus in well placed prostheses (cup abduction angle < 50°).

Coverage Angle

The alpha angle or coverage angle is a measure that is design specific and is the protection, coverage of the socket on the ball of the metal-on-metal joint. In the old metal-on-plastic joint this was 180 degrees or a full hemisphere, in metal-on-metal it became less because of risk of impingement (two parts damaging each other with range of movement).

Because of this smaller coverage, the angle of implantation of the cup becomes more important.

The coverage of the ball decreases with:

- higher abduction of the cup
- smaller size
- smaller alfa angle of the prosthesis.

Smaller coverage means a smaller surface of the socket is available to cover the ball resulting in higher wear of the metal-on-metal joint.

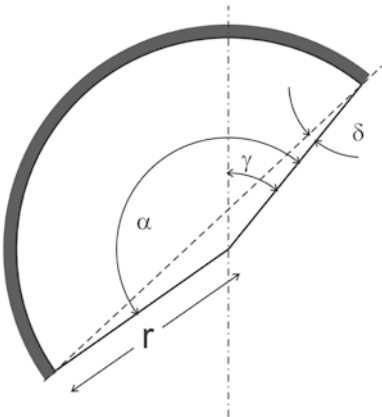


Fig 9. Alpha angle as a function of socket radius.

The importance of these three aspects (cup abduction angle β , head diameter and head coverage angle α) and their influence on wear of the prosthesis is demonstrated in figure 10. One can see from this graph that a Conserve Plus device with 170 degree head coverage angle α can withstand steeper cup placement before encountering an edge-loading condition than the BHR device with a **maximum** of 164 degree head coverage angle, this difference being more pronounced with smaller diameter components (**blue dots**). This is also the case for the ASR device (Articular Surface Replacement)(DePuy J&J) which has even smaller head coverage angle than that of the BHR (**black circles**).

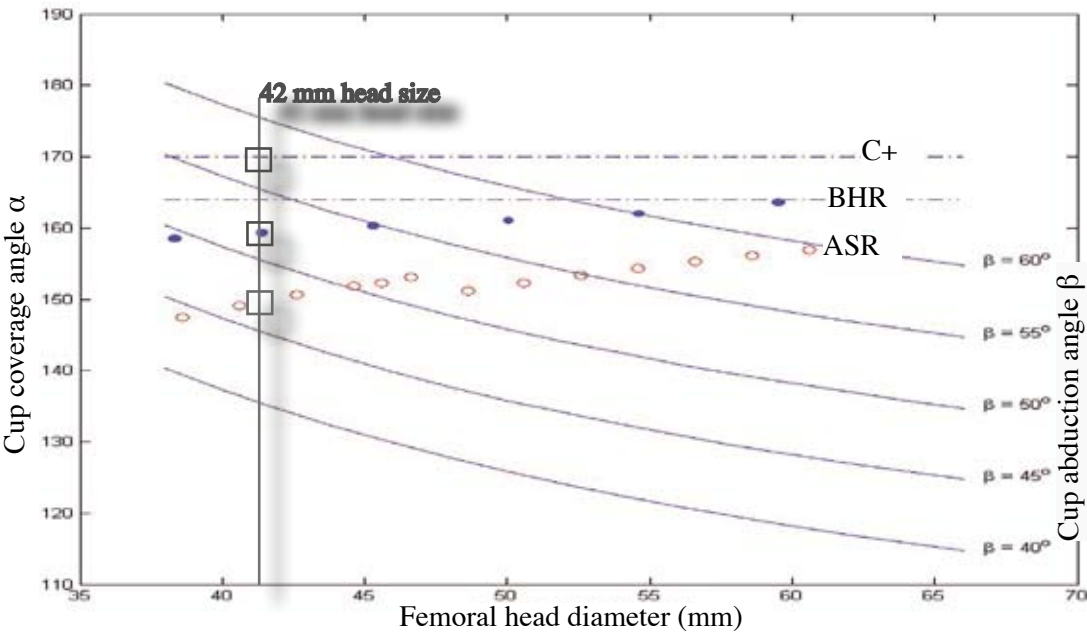


Fig 10. Graph showing the relationship between the head coverage angle alpha, cup abduction angle beta and head diameter. The curved lines are the cut off lines for the coverage angle of the prosthesis needed with a certain abduction angle where the surgeon has placed the cup. For example, a 42 mm ASR device is at risk for edge loading starting 45 degrees of abduction, the BHR device is at risk above an angle of 52 degrees, the Conserve can be put in a 57 degrees steep position before the edge loading and wear starts. (Gray line and rectangles) (R.De Haan 2008, page 24)

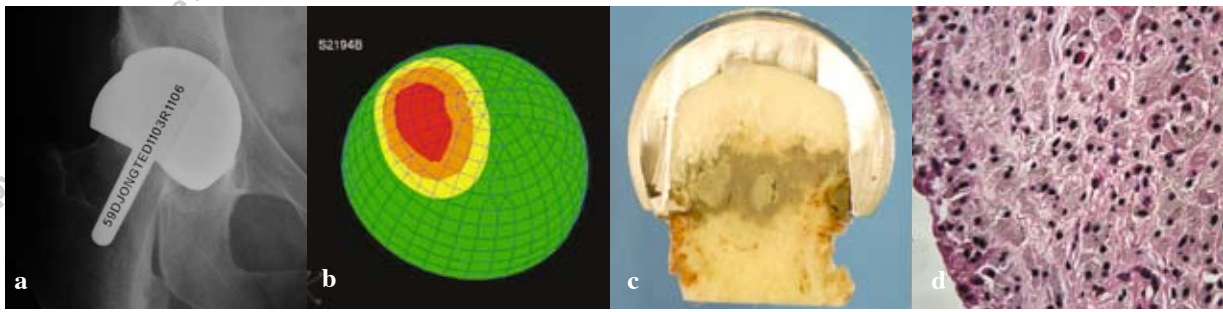


Fig 11. (a) x-ray of a size 46 mm diameter BHR with a steep cup (61° abduction angle), revised for pain from impingement and swelling as a result of the high wear from edge loading (b) The CMM wear measurements showed 66 micron maximum femoral wear. (c) The sectioned femoral head revealed wear-induced osteolysis (d) Histology confirmed the metallosis findings with massive infiltration of macrophages containing wear particles. The serum metal ion levels were 55.0 ppb Chromium, 73.9 ppb Cobalt.

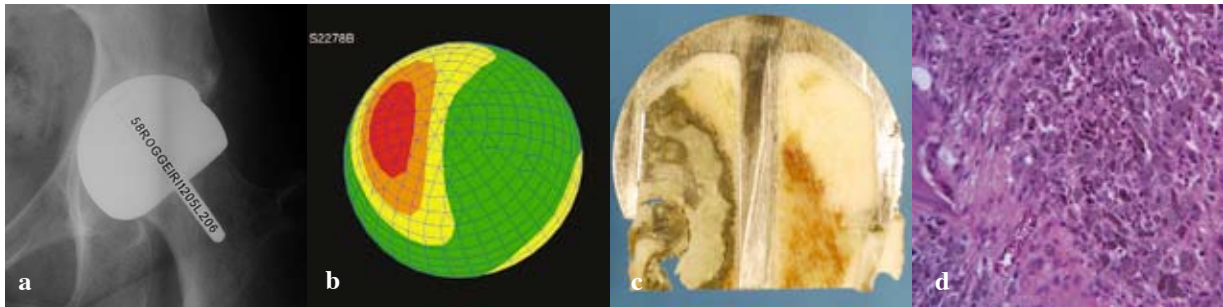


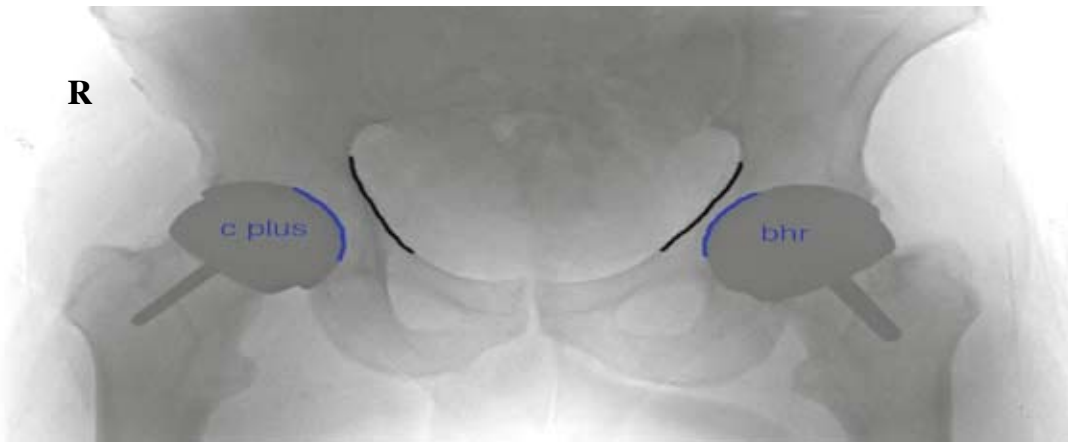
Fig 12. (a) x-ray of a size 47 mm diameter ASR with a steep cup (59° abduction angle), revised for pain as a result of high wear from edge loading (b) The CMM wear measurements showed maximum femoral wear depth of 81 micron. The maximum acetabular wear depth was 26 microns. The diametral clearance was 132 microns. (c)(d) The femoral head is viable and vascular, but is being resorbed by invasive metal-filled macrophages The serum metal ion levels were 56.9 ppb Chromium, 72.4 ppb Cobalt. Revision was performed after 22 months.

Acetabular Bone Preservation

The smaller outside angle of the Conserve design (174 degrees instead of 180 degrees with BHR) means less bone removal from the pelvis and keeps with the ideal of “conservative” resurfacing procedure.

In the USA, the FDA approved BHR is available only in 4 mm size increments; this can lead to an even greater loss of acetabular bone stock (Fig 13). In Europe where the Birmingham is available with the 2 mm increments, this is less of a problem and subsequently the problem of choosing the wrong size of component has also been reduced. The Conserve Plus design has always had the 2 mm increments which allows the surgeon a broader choice.

Fig 13. Pelvic x-ray where the left side is a Birmingham Hip Resurfacing and the right is a Conserve Plus. The hemispherical (180°) socket and 4 mm size increments of the Birmingham Hip Resurfacing design result in more bone loss in the pelvis compared with the Conserve Plus which has a lower profile (174°) and is available in 2 mm increments.



Unlike some other socket designs including the BHR, the edge of the Conserve Plus socket is NOT sharp. The rounded edge of the cup better protects the patient against groin pain caused by “iliopsoasitis”. (local conflict of soft tissue or iliopsoas tendon with the edge of the cup)

The acetabular component should always be well covered anteriorly by bone to prevent this problem, but if this is not possible, then the rounded edge of the Conserve Plus design is advantageous.

This technique dependent problem will be exacerbated when the cup edges are not rounded. It seems intuitive that the sharper the edges are, the more problems are encountered. Reports of painful Durom resurfacings may be related in part to the 3 sharp edges of this socket design (The New York Times newspaper, page 23).



Fig 14 (a,b). Changed edge of cup from sharp to rounded edge design in Conserve Plus. (c) Sharp “knife blade edges” of Durom design resurfacing cup (Zimmer).

Dysplasia cup / enhanced fixation cup

The BHR dysplasia cup has 2 so-called “Mickey Mouse” ears (screw holes) that are threaded and are in line (in the same plane) with the cup, as well in the same plane, with no angle to the neutral plane for anteversion. (fig 15)



The Conserve Plus dysplasia cup design (QUADRAFIX) has a flange with 3 holes (1 cup for both sides) where there is a flange with a small distance away from the edge of the cup (Fig 16). As such it can also be used in non-dysplasia cases, such as in revision of resurfacing or non-dysplastic cases where enhanced fixation is needed. The direction of the screws is angled 20 degrees toward the bone of the acetabulum in abduction, and 20 degrees of retroversion to neutralize the anteversion of the cup. The second screw is neutral to the anteversion angle of the cup.

These improved screw angles direct the screws into the bone with a well positioned cup. In the BHR dysplasia cup the screws tend to go out of the bone or do not reach the bone.

To accomplish good fixation with these 2 screws, there is a risk of placing the socket too steep, and/or not anteverted which leads to higher wear and impingement with the same edge loading wear mechanism described above.

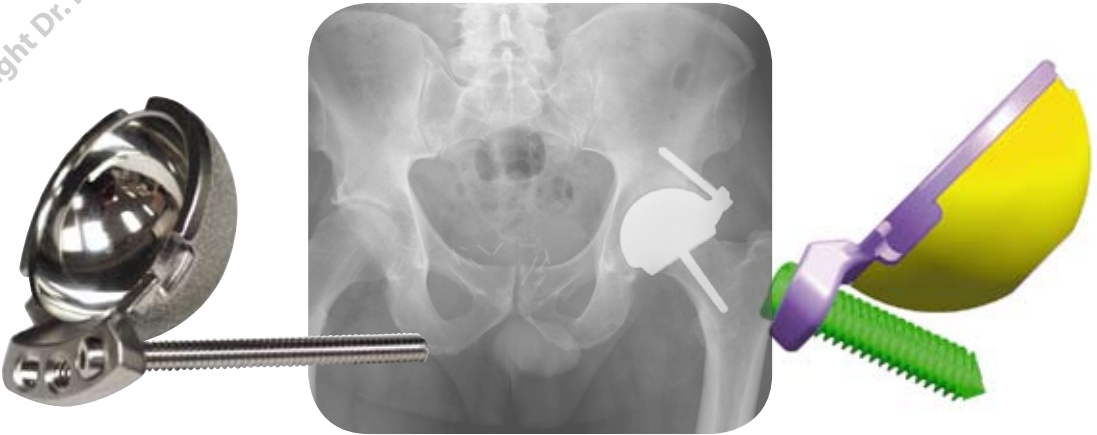


Fig 16. Quadrafix Conserve Plus cup. Implant with flange and one screw, x-ray of an implant and a CAD picture showing the 20 degree angle of the screws. Quadrafix cups are available in 2 mm increments.

Differences in the Femoral Part

Cement Clearance

Another important difference between these two designs is the clearance for the cement. The line to line placement of the BHR means there is a very tight fit and that can lead to heavy hammering! Retrieval studies show that over-penetration with the Birmingham Hip Resurfacing cement technique is common (Campbell et al, 2006). The 0.5 mm clearance with the Conserve, means less impact is needed to seat the component. Less hammering will help to reduce the risk of fracture or over-penetration of cement. Studies done with cadavers have shown that there is better cement penetration with the Conserve Plus cementing technique (H.Gill, 2007 unpublished).

Stem Design

The stem of the Conserve is much thinner than the BHR stem and it changes proportionally with component size, i.e. becoming shorter and having a smaller diameter as the femoral component gets smaller. This allows more correction in the placement of the femoral component and fewer problems of “protrusion” of the stem, “stress shielding”, or femoral fracture risk, because the stem is touching or protruding through the cortex of the femoral neck.

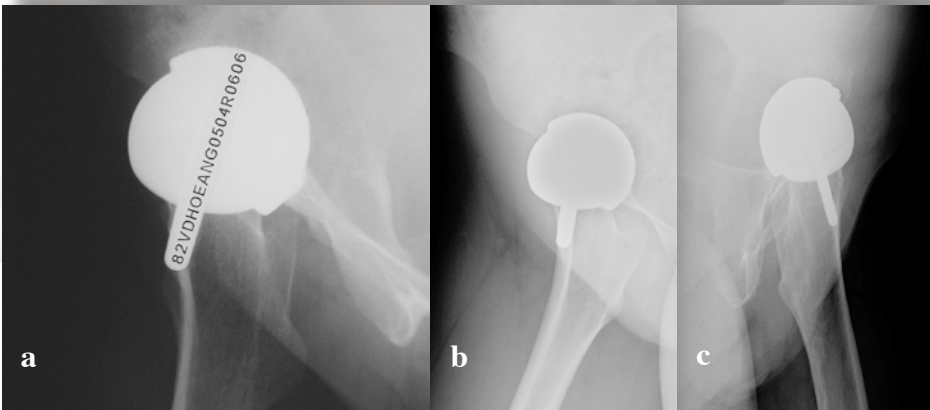


Fig 17. Protrusion of stem in BHR cases (a,b). Thinner stem of Cplus just touching the cortex. (c)

Instrumentation

Having many years of experience with the two systems and their instruments I will try to make a comparison between them. The Birmingham Hip Resurfacing has newer instruments since 2 years and they have stopped using a ring device for the correct leg length and the Precimed® reamers for the femoral bone cuts, but made no change in the femoral position guide. The acetabular cup impactor is still quite bulky and both systems need a good curved minimal invasive surgery impactor to prevent “steep” cup position and “high abduction” impaction by the surgeon.

Acetabular/ cup instruments.

The Birmingham Hip impactor is very bulky and this leads to more “steep cup” positioning, especially when the incision is made too small. The BHR socket still has a cable system impactor, which means once the cup is in place and the cable is cut (or breaks), the cup cannot be repositioned. Having the plastic impactor “pad” on the cup, the edges of the acetabular bone cannot be felt as positioning landmarks. As well as the potential for high wear, the resulting malpositioning can lead to groin pain, especially with sports, often sufficient to cause the patient to reduce or stop their exercise.

In contrast, the Conserve Plus has an impactor where it easily can be reattached if the cup needs repositioning at any stage in surgery, therefore preventing a malpositioned socket.

There is also a trial cup in the Conserve system that can be used to allow the surgeon to look for exact placement of the cup and the extend of the reaming prior to the cup impaction. These tools help the surgeon to avoid malpositioning of the cup which accounts for 67% of the early revisions in resurfacing (see headlines and titles below). The high “iliopsoitis” incidence will certainly be reduced by this.

Femoral instruments.

The BHR femoral surgery starts with a “pin introduction” in the lateral cortex but the pin can stay in the femur and I have 2 cases where that happened. (Fig 18) With a pinless guide this would not have happened.



Fig 18. Follow-up x-ray at 2 years with guiding pin for femoral placement still in the femur.

The BHR femoral guiding instrument gives little or no feeling for the centre of the neck or for anteversion, neutral or retroversion in the femoral implant. A lot of experience is needed to know how much posterior to anterior shift is needed in order to properly align the component. This can lead to malpositioned femoral components. With the Conserve Plus “US style” instruments the pin placement still requires too much “eye balling”.

With the newly designed “lollipop” design attached with the De Smet Goniometer it becomes more of a self-guided introduction by the instrument itself.

The risk of notching has become very small or nonexistent. The varus/valgus angle is correct to within a couple of degrees of the targeted angle. The Lollipop can also be considered as the most

Minimal Invasive Surgery instrument of its type.

It is the most correct way to do the first pin placement in comparison with 9 different resurfacing targeting systems without using navigation.

Only the posterior to anterior shift is sometimes not enough and needs to be adjusted. This problem will be addressed in the further development of the Conserve Plus instruments which have already undergone multiple changes and improvements thanks to the input of the Wright Medical Technology RTAP group of very experienced surgeons.

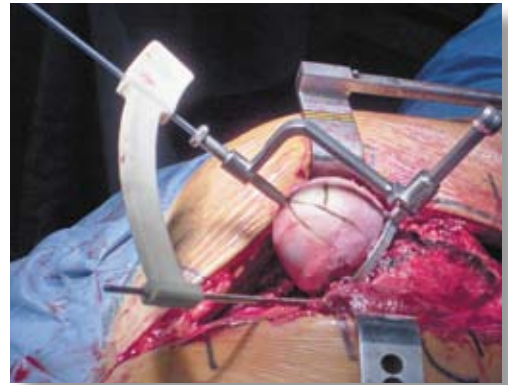


Fig 19. Lollipop device and mounted lollipop/goniometer device for K-wire introduction and exact pin placement for the femoral procedure of Conserve Plus.

It should be stated that no design or set of instruments can give a surgeon 100% guarantee of perfect component placement but, clearly, better instrumentation results in more precise implant placement. The following will all benefit from the WMT Lollipop system: Varus/valgus angulation (which determines stress distribution and risk for femoral fracture and loosening), anteroposterior shift (which will result in better motion and less risk of impingement) and mediolateral shift (meaning less risk of impingement and notching, i.e. reduced fracture risk).

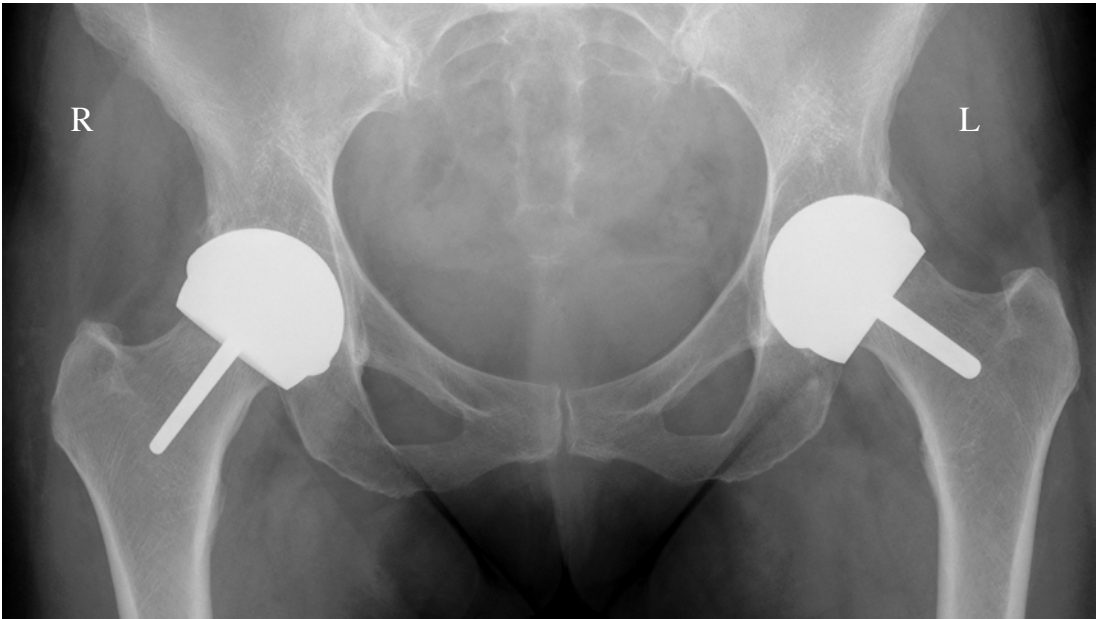


Fig 20. Pelvis x-ray showing a Conserve Plus on the right hip, a BHR implant at the left.

An MIS cup impactor and a lateral approach goniometer are currently in production with Conserve Plus. In figure 20 you can see that the right hip resurfaced with a Conserve Plus and has correct (140 degree) varus/valgus angle, and correct mediolateral placement, i.e. with the same distance medially and laterally in correspondence with the femoral neck. On the left side you can see a Birmingham Hip Resurfacing with a less correct, slightly varus angle and too much shift medially i.e. with more risk for lateral femoral neck notching. This is only one example of the less than ideal positioning of BHR in comparison with Conserve Plus which I attribute to the instrumentation differences. Note again in this example the less conservative treatment of the pelvic bone on the left side Birmingham Hip Resurfacing (i.e. where larger size increments require greater amounts of bone to be removed)

		BHR (all)		BHR 2004/2008		CPLUS 2004/2008	
		%	NUMBER	%	NUMBER	%	NUMBER
Operation Date		> 9/1998		> 1/5/2004		> 1/5/2004	
Number of patients		1884		871		667	
Gender M/F		1267/605		594/277		379/284	
Gender Ratio		2,1		2,1		1,33	
Age (mean)		52,1		53,7		54,5	
Age Min/Max				18/79		13/78	
Bilateral simultaneous		116		65		40	
ETIOLOGY (%)							
OA		91,2		94,7		93,6	
necrosis		5,42		3,40		4,80	
rheumatoid		1,12		0,46		0,45	
CDH		1,49		0,92		0,75	
STAGING (%)							
ON FILE		97,45	1836	97,47	849	99,55	664
Lost to follow up		0,32	6	0,00	0	0,00	0
Dead		0,58	11	0,34	3	0,00	0
Retrieved Infection		0,11	2	0,11	1	0,00	0
Retrieved Traumatic		0,11	2	0,11	1	0,00	0
Failure Total		0,00	0	0,11	1	0,00	0
Clinical Failure		0,05	1	0,69	6	0,00	0
Radiological Failure		0,05	1	0,11	1	0,30	2
Cup Failure		0,05	1	0,00	0	0,00	0
Femoral failure		0,16	3	0,11	1	0,15	1
Revision		0,48	9	0,57	5	0,45	3
Reoperation		0,48	9	0,57	5	0,90	6
Perop Complication		0,16	3	0,11	1	0,15	1
Early Complication		13,44	7	0,57	5	0,75	5
Late Complication		0,80	15	1,26	11	0,30	2
COMPLICATIONS							
Acetabular fissure		0,27	5	0,34	3	0,60	4
Acute infection		0,16	3	0,23	2	0,60	4
Loosening head		0,16	3	0,11	1	0,15	1
Gluteaus Max Atrophy		0,21	4	0,34	3	0,00	0
Hematoma		0,05	1	0,11	1	0,30	2
Hematoma with ischial		0,05	1	0,11	1	0,00	0
Metal sensitivity		0,32	6	0,46	4	0,00	0
Fracture		0,05	1	0,11	1	0,00	0
Post op luxation		0,37	7	0,34	3	0,00	0
Pulmonary embolism		0,11	2	0,11	1	0,00	0
Severe wounddrainage		0,05	1	0,11	1	0,00	0
Chronic dislocations		0,05	1	0,00	0	0,00	0
Guidepin not removed		0,05	1	0,00	0	0,00	0
Ischial nerve palsy		0,32	6	0,00	0	0,00	0
Clunking		2,81	53	2,41	21	2,40	16
Groinpain		0,48	9	0,23	2	0,00	0
Groinpain no sports		0,85	16	0,69	6	0,15	1
Squeaking		5,15	97	5,51	48	0,75	5

Table 4

Table 4. My Birmingham Hip Resurfacing and Conserve Plus follow-up data. To compare the clinical performance, only the Birmingham Hip resurfacing group of 2004/2008 is used.

Clinical Performance

ANCA Clinic Experience

In table 4, my Birmingham Hip Resurfacing and Conserve Plus resurfacing cohort data are presented in detail (age, gender, etiology, staging, complications, etc.) Note that the first column includes all Birmingham Hip Resurfacings performed since 1998. The second and third columns are comparable groups of BHR and Conserve Plus components implanted during the same time period starting in 2004. These groups were selected for comparison in order to reduce the effect of a learning curve and the difference in experience on the clinical results (although it should be noted that my experience with the Conserve Plus design started in May 2004 when I already had 6 years experience doing BHRs). However there should be minimal bias in the comparison as both groups are otherwise comparable in age and etiology, with the exception that there are more females in the Conserve group.

The clinical failures in the BHR group ($N=6$, 0.69%) are mostly due to the larger problems of high wear and metallosis in malpositioned cups, attributed to the smaller coverage angle. These are relatively late complications (ave time to failure is 45.6 months) and the extent of soft tissue damage, can lead to complications for the revision surgery and the total hip (De Haan 2008).

Such wear related problems have yet to be seen in the Conserve Plus group; those failures included 1 malpositioned acetabular component (68 degrees of abduction, this socket was revised at 3 months and the resurfacing was preserved), and 2 femoral loosening at 8 and 9 months as the result of over-penetration of cement. Revision for suspected metal allergy was required in 3 patients (4 hips, all BHRs); the diagnosis was confirmed by histology and normal, low wear or ion measurements. (Fig21)

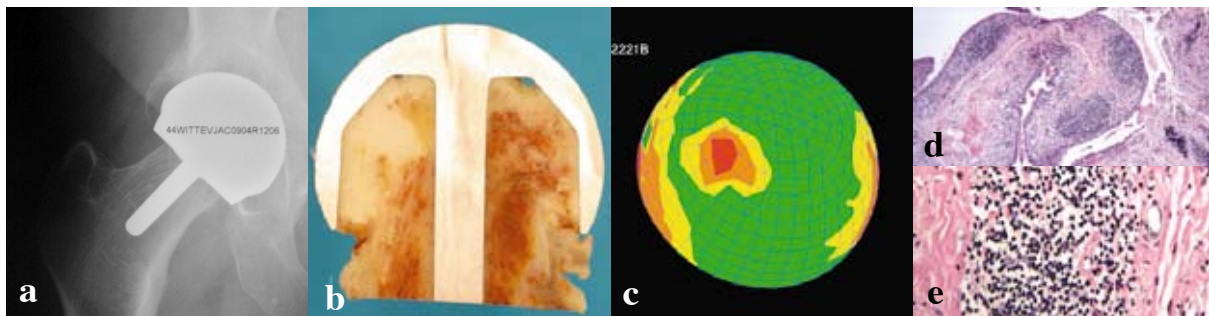


Fig 21 . (a) X-ray of a right BHR in 63 year old female revised for suspected metal sensitivity, osteolysis in the pelvis and femoral neck narrowing (38 months follow-up), (b) mid-section of the retrieved femoral head showing neck narrowing in the absence of wear. (c) CMM measurement of femoral component with maximum femoral wear depth of only $4.7\mu\text{m}$. (d)(e) Villous synovium with extensive lymphocytic infiltration and relatively few macrophages. Taken together, the analyses indicate that this is a case of metal sensitivity. Contrast to the case in figure 10, revised for acetabular malposition and wear.

Groin pain and groin pain with sports, where sports are often no longer able to be performed, are more frequent with BHR because of the full hemisphere (180°) cup with more chance of uncoverage anteriorly, sharp edge of the socket and less possibility of observation of the pelvic bone coverage when impacting because of the bulky impactor and plastic impactor cap. Once the cables are removed no further correction of the BHR cup is possible. This is another reason for the so-called “iliopsoitis”; i.e. the edge of the socket is left to abrade the psoas tendon.

The results of other large Birmingham Hip Resurfacing and Conserve Plus cohorts can be found in the papers listed in the bibliography.

Squeaking Hips

As seen in Table 4, there is a significant difference in the incidence of noticeable squeaking between the BHRs and Conserve Plus hip groups (5.5% vs 0.75% respectively). Squeaking happens in the first 2 years after the implantation. It is usually a single, or rarely recurring incident which scares patients and surgeons. It is an alarming event; the patient often panics and will contact the surgeon for reassurance that the hip is not about to fail. This squeaking in hip resurfacing almost certainly has something to do with the lubrication of the prosthesis, i.e. the two surfaces get dry and produce a loud noise (like a rusty hinge). It is reported to occur in 2–4% in Birmingham Hip Resurfacings.

For example, Back and Shimmin in Melbourne, Australia reported 3.9 % of 230 BHRs squeaked.

In my series I have 5.5% (48/871) squeaking Birmingham's. In my Conserve plus series there are only 0.8% squeakers (5/667). Whether the difference is due to the higher clearance, different metallurgy or cup design in the Birmingham Hip Resurfacing has yet to be established.

Recent articles in the San Diego Union-Tribune and the New York Times about squeaking ceramic total hips are worrisome to the orthopaedic practice (see page 22) because of the possible medicolegal issues and the impact on the patient; i.e. legal action against the surgeons and manufacturers

Patients with squeaking hip resurfacings should be reassured that unlike some of the noisy ceramics, their squeak will most likely resolve quickly. The possible negative effects of the squeaking hip resurfacings are not known.

SUMMARY

Although the Birmingham Hip Resurfacing and Conserve Plus systems have the longest clinical track records of the many second generation hip resurfacing prostheses now available, most of the published knowledge and longer term follow-up reports continue to be dominated by the surgeon inventors and design centers. There are very few independent long-term studies and even fewer comparative studies of the two designs where the prostheses were done by the same surgeon, in the same institution. In this booklet, I have tried to provide an extensive comparison of the two products based on my 10 years of experience with more than 3000 resurfacings, a large number of revisions of referred cases and several years of collecting ion measurements and implant retrieval data.

From this experience, I see several important differences between the two. As a resurfacing surgeon, I want to take a conservative approach to the bone stock, and an important goal is to keep the bone for the next procedure; in this regard, the Conserve Plus provides a clear advantage because of less bone removal from the pelvis as the components have always been available in 2-mm increments. This was not the case when the Birmingham Hip was first introduced although it is now also available in the smaller increments. This avoids the previous problems of excessive bone removal from the pelvis that was often inevitable with the 4-mm increment sizing of the full hemispherical cup. Unfortunately for American surgeons, this problem of preserving bone persists as only the 4-mm increments were approved by the FDA. Another bone conserving design feature of the Conserve Plus is the smaller stem; the effects of long-term bone remodelling around the thicker Birmingham Hip Resurfacing stem in small sized femoral heads remain to be seen.

Retrieval and cadaveric studies have shown that there is a risk of cement over-penetration with both the Birmingham Hip Resurfacing and Conserve Plus cement techniques but with care, this can be avoided. From my extensive experience with both designs, it is clear to me that the cement clearance gap in the Conserve Plus allows easier and less traumatic femoral insertion. This should be beneficial to reduce fracture risk, which remains the most common failure mode for most resurfacing surgeons.

I consider the most important difference between the Birmingham Hip Resurfacing and the Conserve Plus to be that the BHR has more wear. This may be trivial in well-functioning prostheses but the wear difference becomes clinically significant when the BHR cup is not ideally placed, especially in a steep (> 50 degrees) position. This in turn leads to wear related failure modes that are only rarely reported with the Conserve Plus- problems such as "iliopsoitis", groin pain, and the recently reported pseudotumors (Pandit et al, 2008).

With my philosophy of monitoring the wear of the prosthesis by measuring serum metal ions and being aware of the destruction of soft tissues and bone when they are exposed to abnormally high levels of wear products (Fig 22), I once again want to advise surgeons to revise malpositioned, badly done resurfacing prostheses quickly in order to avoid further complications for the patient.



Fig 22. These pictures show the consequences of unrecognized high wear and metallosis: this BHR was implanted with a steep cup and excessive anteversion leading to a total wear depth of more than 200 microns, enlarged black fluid-filled bursa formation, osteolysis of the bone and finally loosening of the femoral component. With routine metal ion measurements and meticulous follow up, this case would have been recognized as having wear, and would have been revised earlier than 56 months.

The malpositioning and high wear of the Birmingham Hip Resurfacing result in part from design features such as the alpha angle and coverage and in part from the difficulty the surgeon faces when placing the components correctly using their instrumentation.

By contrast, with regard to more “wear resistant” design features (better coverage, less risk of edge loading even when implanted steeply), instruments that allow better control over component position and the new innovation of the “A-class” differential hardness material, the Conserve Plus has clear and established wear advantages.

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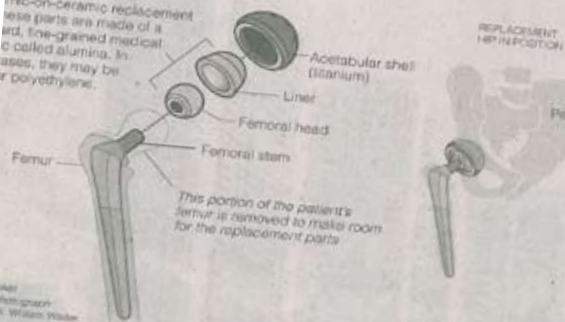
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omy of a Squeak

Patients who have received artificial hips with ceramic components have complained of a squeaking sound. The exact cause of the squeaking is unknown, but "stripe wear" on the ceramic parts suggests that the noise may begin when these parts rub together. The audiotape resulting harmonic vibration of the metal shell or stem.

IC COMPONENTS

On-ceramic replacement hips are made of a hard, fine-grained material called alumina. In some cases, they may be made of polyethylene.



Susan O'Toole's artificial hip developed a squeak, a problem with ceramic parts. Used components show areas of friction.

That Must Be Bob at the Door. I Hear His New Hip Squeaking.

By BARNABY J. FEDER

The first time John L. Johnson's artificial hip squeaked, he was bending down to pick up a pine cone in his yard in Thomsville, Ga. Mr. Johnson looked up, expecting to find an animal nearby.

Susan O'Toole, a nutritionist at Montefiore Medical Center in the Bronx, who first squeaked going up stairs after getting home from her hip-replacement surgery in

their floorboards when he walked through them.

As all three patients — and hundreds of others — discovered once they pinpointed the source of the noises, they had become guinea pigs in an unfolding medical mystery. Their artificial hips are made of ceramic material that were promoted as being much more durable than older models. But for reasons not yet

PERSONAL-HEAD PRESSING AGAINST REAR EDGE OF LINER

CURRENT CASES FOR THE NEW YORK TIMES

That Must Be Bob at the Door. I Hear His New Hip Squeaking.

From Page 1

of adult reconstructive replacement service at Hospital for Special Surgery in New York. More than 250,000 hips get total hip implants each year, a procedure that costs close to \$45,000. Hip implants have a success rate of more than 90 percent, based on achieving relatively good mobility after recovery that range from a few weeks to a year.

Artificial hip can occasionally make a variety of noises. But Stryker, a medical products company, began marketing high-quality ceramic hips in the late 1990s, squeaking extremely rare.

Tens of thousands of cases later — from Stryker's makers that entered the market — many patients say the hips are interlocking daily life. One study in the Journal of Arthroplasty found that 143 of 143 who received ceramic hips in 2003 to 2007 percent, developed

squeaking. Meanwhile, no squeaking occurred among a control group of 45 patients who received hips made of metal and plastic. "It can interrupt sex when my wife starts laughing," said one man, who discussed the matter on the condition that he not be named.

Beyond annoyance and embarrassment, many patients and their surgeons fear that the squeaky ceramic hips may signal that the joints are wearing out prematurely. That could force patients to undergo the very operation — a second replacement of the same hip joint — they had hoped to avoid by choosing ceramics.

Already, dozens of patients have elected to endure subsequent surgeries to replace the noisy hips. Some have sued Stryker, the pioneer and market leader, which some doctors say has been slow to take their patients' concerns seriously.

Last fall, the Food and Drug Administration issued a warning to Stryker, saying it had failed to take the steps needed to prevent squeaking and other problems. Clouding things further, Stryker last year recalled ceramic hip parts made at its factory in



Susan O'Toole noticed an odd sound as she went up stairs.

software executive in Scottsdale, Ariz. Mr. Mueller is so frustrated with squeaks, pain and popping noises for which he blames his ceramic hip that he has displayed his problem on YouTube.

While there have been no reported cases of serious mishaps, some surgeons

told him to consider getting the hip replaced "sooner rather than later."

Stryker says such fears are overblown.

"It is important to keep this perspective," said Aaron Kvitnick, a spokesman for Stryker. "Published research shows squeaking is rare compared with other total-hip-related risks like infection, dislocation and leg length. But plaintiffs lawyers, who have already filed scores of lawsuits on behalf of ceramic hip patients, are gearing up to argue that squeaking is not a minor problem for many who experience it."

"We're in the infancy of this," said Douglas A. Kreis, a personal injury lawyer in Pensacola, Fla., whose clients include Ms. O'Toole and Mr. Johnson, who has had his ceramic hip replaced.

Most artificial hips, whatever material they are made of, share a basic design: a socket implanted in the pelvis, into which a spherical head is fitted. The head is attached to a spike that is driven into the femur, or thigh bone,

ONLINE: SQUEAKING IN ACTION
A graphic showing how the hips are replaced.

Artificial hips that squeak raise concern

By Barnaby J. Feder
NEW YORK TIMES NEWS SERVICE

The first time John L. Johnson's artificial hip squeaked, he was bending down to pick up a pine cone in his yard in Thomsville, Ga.

Mr. Johnson looked up, expecting to find an animal nearby.

Susan O'Toole, a nutritionist at Montefiore Medical Center in the Bronx, N.Y., who first squeaked going up stairs after getting home from her hip-replacement surgery in 2005, said she thought the louder she was gripping needed repair.

And Edward Henry, an aggressive surgeon in Hartford, Pa., said clients sometimes look with embarrassment or concern at their homes.

As all three patients — and hundreds of others — discovered once they pinpointed the source of the noises, they had become guinea pigs in an unfolding medical mystery. Their artificial hips are made of ceramic material that were promoted as being much more durable than older models. But for reasons not yet understood, their hips started to squeak.

SEE SQUEAKING, A13

CASE REPORT

Metal ion levels in a triathlete with a metal-on-metal resurfacing arthroplasty of the hip



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A prospective study of serum and urinary ion levels was undertaken in a triathlete who had undergone a metal-on-metal resurfacing arthroplasty of the hip four years previously. The one month study period included the final two weeks of training, the day of the triathlon, and the two weeks immediately post-race. Serum cobalt and chromium levels did not vary significantly throughout this period, including levels recorded on the day after the 11-hour triathlon. Urinary excretion of chromium increased immediately after the race and had returned to pre-race levels six days later. The clinical implications are discussed.

Reduction of the potential for thermal damage during hip resurfacing

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Resurfacing arthroplasty of the hip is being used increasingly as an alternative to total hip replacement, especially for young active patients. There is concern about necrosis of the femoral head after resurfacing which can result in fracture and loosening. Most systems use a cemented femoral component, with the potential for thermal necrosis of the cancellous bone of the reamed femoral head. We used thermal probes to record



Correction Appended
 Dr. Lawrence Dorr, a nationally known orthopedic surgeon in Los Angeles, realized last year that something was very wrong with some of his patients. Months after routine hip replacements, patients who had expected to live without pain were in agony. “The pain was grabbing me around the back,” said Stephen Csengeri, who is 54, and a lawyer from Torrance, Calif. Dr. Dorr found he had implanted the same metal hip socket in each patient. Several needed surgery again — a replacement for their replacement. The doctor first told the device’s manufacturer, Zimmer Holdings, last year about his concerns but nothing happened. Then in April, Dr. Dorr, who was a highly paid consultant for Zimmer, sounded an alarm to colleagues in a professional association and soon heard back from doctors with similar experiences. “I saw one of Zimmer’s engineers at a meeting, and I told her that you should pull this cup because you are crippling patients,” Dr. Dorr said.

Last week, Zimmer announced it was suspending sales of the device, known as the Durom cup, until it trained doctors how best to implant it. The company said a “low” percentage of the 13,000 patients who got the socket would need replacements, but some doctors fear the number could reach into the hundreds. If those patients lived in other countries where artificial joints were tracked by national databases — including Australia, Britain, Norway and Sweden — many might have been spared that risk. And Zimmer might have suspended sales of the cup months ago. But the United States lacks such a national database, called a joint registry, that tracks how patients with artificial hips and knees fare. The risk in the United States that a patient will need a replacement procedure because of a flawed product or technique can be double the risk of countries with databases, according to Dr. Henrik Malchau of Massachusetts General Hospital.

Metallurgy addendum

Box 2. “Changes in alloy micro-structure (due to double heat-treat cycle of HIPping and Solution Annealing) do not appear to influence the wear behavior of high-carbon cast MOM articulations” Bowsheer, et. al.

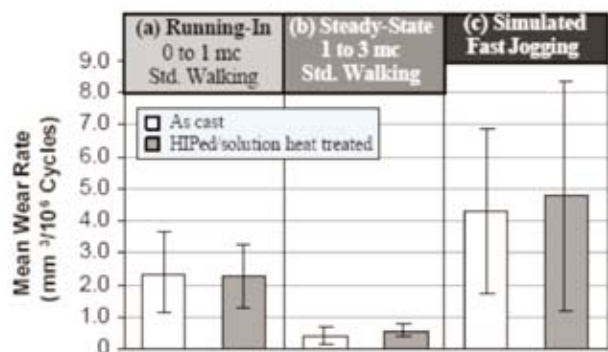


Figure 23: Mean volumetric wear rates of “as cast” and double-heat treated 40mm diameter couples, Cormet 2000.

Box 3. “The results reported (in this study) show that when implants of similar geometrical form are tested in a hip joint simulator, alternative combinations of the currently adopted high carbon CoCrMo alloys (including cast, forged and heat-treated) do not exert a major influence on the magnitude of the running-in wear volume”. Dowson, et. al.

Carroll et. al. Effect of Thermal Processing on Wear Performance of Large Diameter Hip Bearings. 17th Annual Symposium of the International Society for Technology in Arthroplasty”, 2004, Rome.
Bowsheer J., Nevelos J., Williams P., Shelton J. “Severe” wear challenge to “as-cast” and “double heat-treated” large diameter metal-on-metal hip bearings. Proc. IMech E Vol.220 Part H: J. Engineering in Medicine:135-43, 2006.
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Correlation between inclination of the acetabular component and metal ion levels in metal-on-metal hip resurfacing replacement

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We examined the relationships between the serum levels of chromium and cobalt ions and the inclination angle of the acetabular component and the level of activity in 214 patients implanted with a metal-on-metal resurfacing hip replacement. Each patient had a single resurfacing and no other metal in their body. All serum measurements were performed at a minimum of one year after operation. The inclination of the acetabular component was considered to be steep if the abduction angle was greater than 55°.

There were significantly higher levels of metal ions in patients with steeply-inclined components ($p = 0.002$ for chromium, $p = 0.003$ for cobalt), but no correlation was found between the level of activity and the concentration of metal ions. A highly significant ($p < 0.001$) correlation with the arc of cover was found. Arcs of cover of less than 10 mm



Revision of metal-on-metal resurfacing arthroplasty of the hip

THE INFLUENCE OF MALPOSITIONING OF THE COMPONENTS

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We have reviewed 42 patients who had revision of metal-on-metal resurfacing procedures, mostly because of problems with the acetabular component. The revisions were carried out a mean of 26.2 months (1 to 76) after the initial operation and most of the patients (30) were female.

Malpositioning of the acetabular component resulted in 27 revisions, mostly because of

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