smith&nephew

BIRMINGHAM HIP◊

Resurfacing System

Driven by experience

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The BIRMINGHAM HIP™ Resurfacing System (BHR™) is the global market leading hip resurfacing system with over 50,000 implantations worldwide. Introduced in 1997, the BIRMINGHAM HIP Resurfacing System was designed using knowledge gained from first generation metal-on-metal total hips and a thorough understanding of hip resurfacing principles.

This successful, bone conserving total hip system is well documented through independent clinical and laboratory studies. Additional clinical evidence supporting the BIRMINGHAM HIP Resurfacing System is published in multiple registries.

This bone conserving procedure, combined with the virtual elimination of dislocation and excellent survivorship make the BIRMINGHAM HIP Resurfacing ideal for the younger or more active patient

Clinical results

The BIRMINGHAM HIP™ Resurfacing (BHR™) has demonstrated exceptional clinical results worldwide as shown on the opposite page. High survival rates of 98% or better were achieved in clinical centers around the world.[1,2,3,4,5]

In addition, the recently published Australian Orthopaedic Association National Joint Replacement Registry reports BHR as having the lowest revisions per 100 observed 'component' years when comparing all resurfacing implants used in the country.[6]

Other clinical studies have focused on predictive measurements to project long-term survivorship of the resurfaced femoral head. Researchers at the University of Oxford, England used roentgen stereophotogrammetric analysis (RSA) to measure the stability of the femoral head. At 24 months, the total three-dimensional migration of the head was not statistically significant at 0.2mm.

Previous studies have shown that implants that loosen quickly have rapid early migration. According to the authors, these results suggest the BHR femoral component is an inherently stable device predicting a good long-term performance.[7,8]

It is widely accepted that the Bone Mineral Density (BMD) of the proximal femur generally decreases after cementless THA using standard designs of femoral components. However, BMD studies conducted at Osaka University, Japan reported the post-operative BMD in the proximal femur was significantly greater in patients treated with the BHR system compared to the conventional system. The patients treated with the BHR system demonstrated preservation of the BMD in Gruen zone 1 and an increase in zone 7.

These results suggest that transfer of load to the proximal femur was more normal after surface replacement with the BHR system. These findings also show the BHR system preserves the bone stock of the proximal femur after surgery.[9]

Survivorship data

Author	Site	*n*	Survival	Follow Up (months)
Shimmin *et al* [1]	Melbourne	231	99.14%	33 (25-52)
Ebied *et al* [2]	Liverpool	100	99.00%	17 (mean)
De Smet *et al* [3]	Ghent	200	99.50%	6-42
Treacy *et al* [4]	Birmingham	144	98.00%	60 (minimum)
McMinn *et al* [5]	Birmingham	1,626	98 40%	60 (minimum)

1. Back DL Dalziel R Young D Shimmin A. Early results of primary Birmingham hip resurfacings. An independent prospective study of the first 230 hips. J Bone Joint Surg Br (2005 Mar) 87(3):324-9
2. Ebied A, Journeaux SF, Pope JA. Hip Resurfacing Arthroplasty: The Liverpool Experience. International Conference Engineers & Surgeons – Joined at the Hip. (Jun 2002) 1.
3. De Smet KA, Pattyn C, Verdonk R. Early results of primary Birmingham hip resurfacing using a hybrid metal-on-metal couple. Hip International (2002)12:2:158-162.
4. Treacy RB McBryde CW Pynsent PB Birmingham hip resurfacing arthroplasty. A minimum follow-up of five years. J Bone Joint Surg Br (2005 Feb) 87(2):167-70
5. FDA Review Memo, Page 59

Australian Nation Joint Registry Annual Report 2005 (Clinical Results)[6] : Resurfacing Hip systems requiring revision

Resurfacing Head	Resurfacing Cup	Number Revised	Total Number	% Revised	Observed component years	Revisions per 100 observed 'component' years
ASR	ASR	5	206	2.4	111	4.5
BHR	BHR	93	4640	2.0	8435	1.1
Conserve Plus	Conserve Plus	1	33	3.0	45	2.2
Cormet 2000	Cormet 2000	9	247	3.6	372	2.4
Durom	Durom	7	220	3.2	142	4.9
Recap	Recap	1	26	3.8	9	11.5

Radiographic Studies

Author	Type	*n*	Findings
Glyn-Jones *et al* [7]	RSA	22	Femoral migration <0.2 mm at 2 years
Itayem *et al* [8]	RSA	20	Vertical migration femoral component < 0.5 mm at 2 years Vertical migration acetabular component< 0.5 mm at 2 years
Kishida *et al* [9]	BMD	26	BMD preserved/improved in proximal femur at 2 years

7. Glyn-Jones S, Gill HS, McLardy-Smith P, Murray DW. Roentgen stereophotogrammetric analysis of the Birmingham hip resurfacing arthroplasty. The Journal of Bone and Joint Surgery (Br) (March 2004), 86-B: 172-6
8. Itayem RA, Nistor L, McMinn D, Lundberg A. Stability of the Birmingham hip resurfacing arthroplasty at two years. A radiostereophotogrammetric analysis study. Journal of Bone and Joint Surgery (Br) (February 2005), 87(2): 158-62
9. Kishida Y, Sugano N, Nishii T, Miki H, Yamaguchi K, Yoshikawa H. Preservation of bone mineral density of the femur after surface replacement of the hip. The Journal of Bone and Joint Surgery (Br) (March 2004), 86-B: 185-89

Metallurgy

The First Generation Metal-on-Metal bearings manufactured in the 1950s and 1960s were produced by the investment casting process (Ring and McKee Farrar prostheses). From these devices we have recorded the longest benign clinical history of cobalt chrome alloys with extremely low linear wear rates.

Forensic studies of these successful first generation Metal-on-Metal bearings were conducted to determine the material chemistry, micro-structural condition, bearing clearance, and evidence of the wear mechanism. These implants were typically produced from the investment casting process from high carbon Cobalt Chrome in the As Cast condition. The material contained large block carbides.

The BHR™ is produced using the investment casting process from high carbon cobalt chrome in the As Cast micro-structural condition.

Wear studies have shown that Cobalt Chrome in its As Cast form has superior wear resistance to other forms of the alloy.[10, 11, 12]

Heat treating, which includes hot isostatic pressing (HIP), solution heat treatment (HT), wrought forging or sintering modifies the microstructure, reducing the block carbides in both quantity and quality. This directly affects the wear resistance of the metal, as shown in diagram A.[13, 14, 15]

The importance of carbide structure has been demonstrated in independent testing with other devices. A recent publication highlighted the difference in the wear rates of heat treated and As Cast products. The cumulative linear wear rate data showed substantially more wear with the heat treated metallurgy when compared to the As Cast devices.[16]

First generation Metal-on-Metal implant retrieved after 26 years.

Diagram A: Micro-abrasive Wear of Cobalt Chrome Alloys.[15]

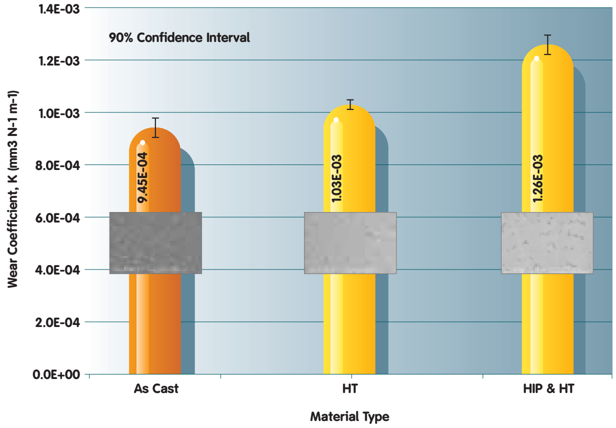
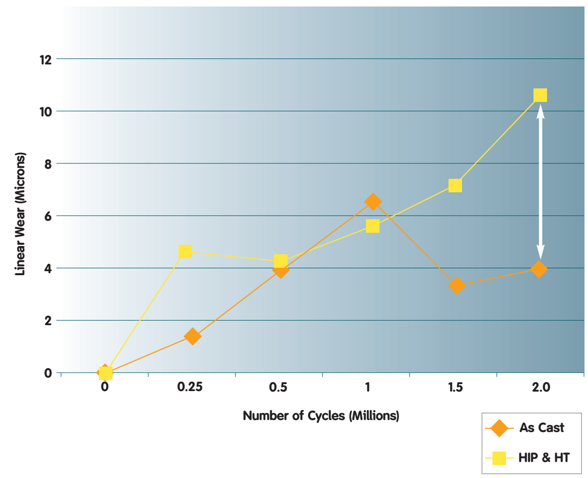


Diagram B: Linear Wear of As Cast device compared to HIP & HT device.[16]



Typical Microstructures of First Generation Metal-on-Metal.

This image shows a cross-section micrograph through the articulating surface and shows the coarse primary, block carbide in the Cobalt Chromium matrix.

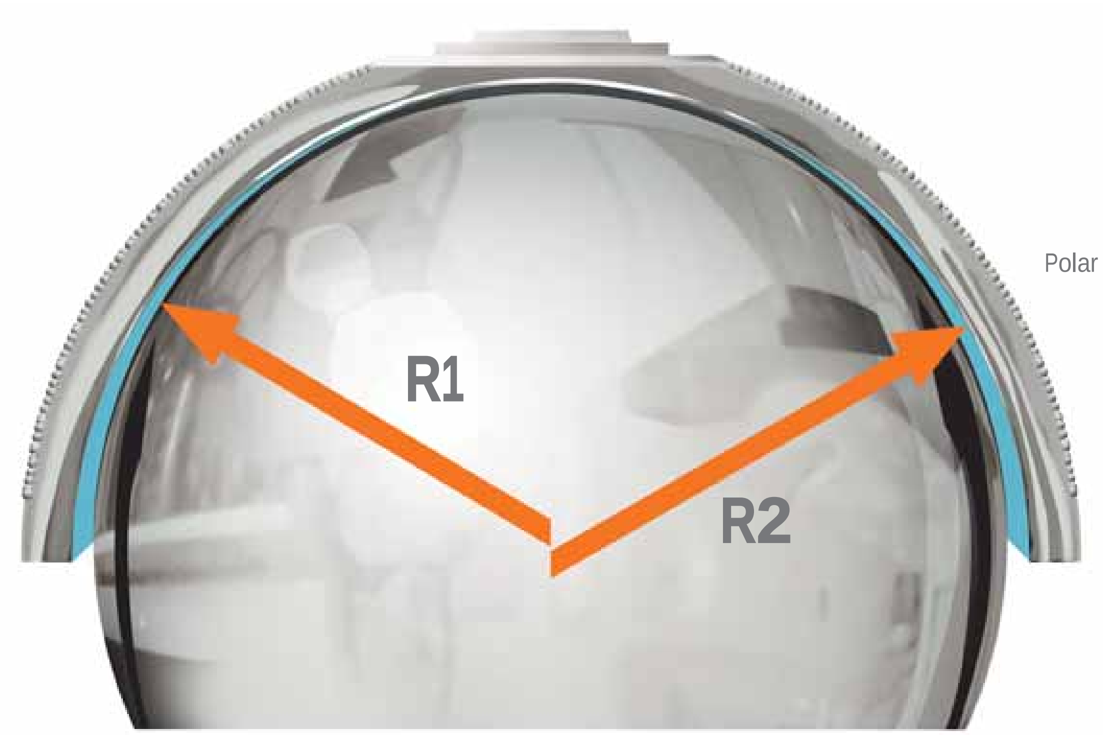
The BHR™ has a hemispherical cup design with a cast-in porous ingrowth surface called Porocast™. This ingrowth surface does not require a heat treatment to attach the beads and therefore preserves the carbide structure.

Peter Webb
Two BHR™ implants
Completed the 2005 London, England Marathon

Clearance

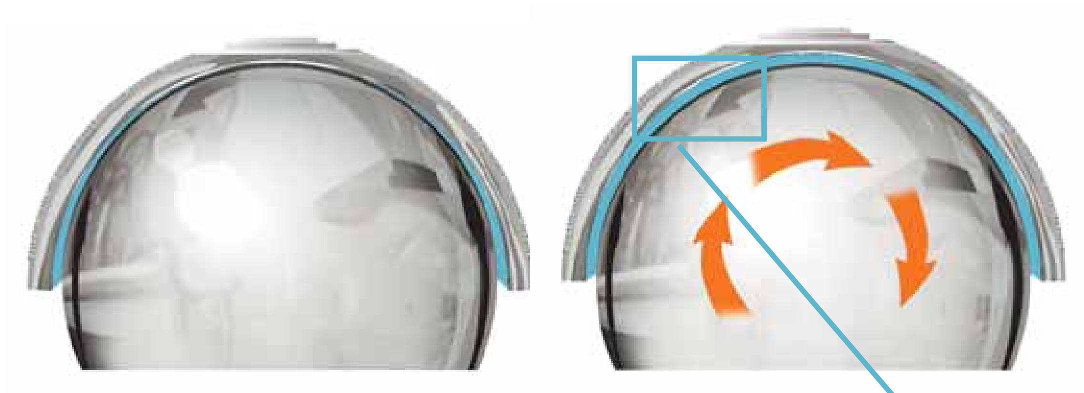
Clearance is the term used to describe the effective gap between the femoral head and acetabular cup in a Metal-on-Metal bearing. It is calculated by subtracting the radius of the femoral head from the radius of the acetabular cup. This difference in radii is used to describe the gap at the equatorial position on the bearing when the femoral head is in contact with the acetabular cup in a polar orientation. Polar bearings operate with a large apparent contact surface area. However the real contact surface area is very small. It is at this point where the articular surfaces interact creating friction and wear.

What is Clearance?



Radial Clearance = $R_2 - R_1$

Generation of fluid film



A fluid film is present when the two articulating surfaces are separated by the lubricant.

It is the clearance (entrainment) angle and motion which generates the fluid film.

What is the optimal clearance?

As well as a value of the difference between head and cup radii, clearance can be expressed as a ratio to head diameter.

There is an optimal clearance associated with each head diameter. Although low clearances work well in laboratory conditions, there may be an issue in the clinical environment. Factors such as bone density, implant position and post surgery may all effect the ability of the bearing to generate a fluid film. With low clearances, there is reduced tolerance for correct function in less than perfect implantation or patient conditions.

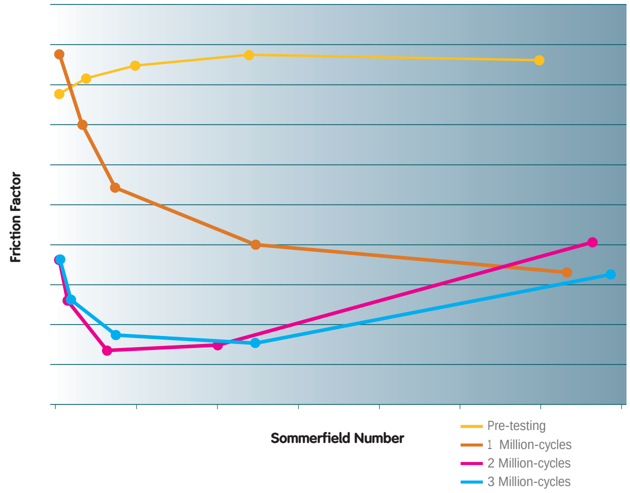
As a Metal-on-Metal bearing is not in continuous motion, it operates in a mixed lubrication regime and its longevity is linked to its ability to generate and sustain a fluid film. Laboratory evidence confirms the BHR™ generates fluid film lubrication.

Small clearances increase friction and may cause micromotion in the cup. This may hamper bony ingrowth resulting in impaired fixation.[17]

The Stribeck Curve is a graphical representation of the measured frictional forces occurring in a bearing. From the shape of the curve, deductions can be made concerning the lubrication operating conditions of the bearing.

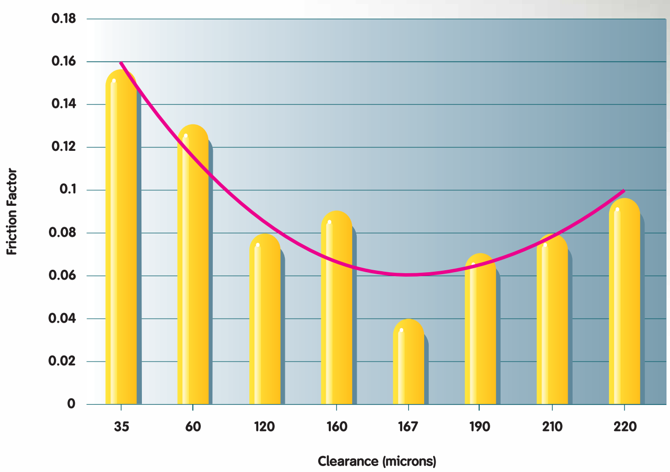
Results of friction testing of the BHR are shown below in Graph A. The friction tests suggest boundary lubrication pre-testing but at 1 million cycles, a mixed lubrication regime was evident. By 2 million cycles, the classical Stribeck curve had formed indicating a considerable contribution from fluid film, which continued to be evident at 3 million cycles.[18]

Stribeck Curve graph A



Changes in Friction and Lubrication during a 3 Million-cycle wear test on a CoCrMo/CoCrMo Hip Resurfacing Device.
Unsworth, K Vassiliou, APD Elfick, SC Scholes Centre for Biomedical Engineering, University of Durham, England.

Effect of clearance on friction factor



A Unsworth, K Vassiliou, APD Elfick, SC Scholes
Centre for Biomedical Engineering, University of Durham, England

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5. FDA Review memo, page 59.

6. Australian Orthopaedic Association National Joint Replacement Registry Annual Report 2005.

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