Birmingham Hip Resurfacing◊ (BHR◊) System
Important Medical Information
Warnings and Precautions

DEVICE DESCRIPTION

The Birmingham Hip Resurfacing (BHR) prosthesis is a metal-on-metal hip resurfacing prosthesis. The device consists of a stemmed femoral head resurfacing component designed for cemented fixation, and a hemispherical acetabular cup designed for cementless, press-fit, fixation. Both components are manufactured from high carbon, as-cast, cobalt chrome (CoCr) alloy (ASTM F75 and ISO 5832-4). The acetabular cups are configured in standard, dysplasia, and bridging designs. All acetabular cups have a single layer of integrally-cast CoCr-alloy (ASTM F75 and ISO 5832-4) beads on the outer surface that are coated with hydroxyapatite (HA) (ASTM F1185). Instrumentation sets are provided as standard; several additional instruments are available as options.

Resurfacing Femoral Head

The resurfacing femoral head is supplied in a range of six sizes. The femoral head central stem is parametric and varies proportionally with the external diameter. There are 6 equally spaced internal recesses intended to provide antirotational locking for the cement mantle.

Acetabular Cups

The standard acetabular component is supplied in a range of twelve sizes (two for each femoral head size to address the condition of occasional head cup mismatch). For those patients with a deficiency in the superolateral aspect of the acetabulum, the dysplasia cup is available. The dysplasia cup is designed with two superolateral screw holes that accommodate CoCr-alloy dysplasia cup screws. There is a range of six sizes for the dysplasia cup. A bridging cup is designed with a thicker wall section than the dysplasia cup to allow for mismatch between femoral head size and surgically prepared acetabulum. The bridging cup is also designed with two superolateral screw holes that accommodate the CoCr-alloy dysplasia cup screws. The bridging cup is available in five sizes.

Dysplasia Cup Screws

The dysplasia cup screws are threaded through a threaded lug on the superolateral aspect of either the dysplasia or bridging cup and lock in situ. The screws also lock into the posterior cortical bone of the ilium. Screws are available in sizes ranging from 24mm to 88mm, in 2mm increments.

Sizing and System Compatibility

Each femoral head resurfacing component is compatible with two standard acetabular cup sizes and one dysplasia or bridging cup size (Table 1).

Table 1: BHR Head and Cup Sizing and System Compatibility

BHR Femoral Head Resurfacing Component (identified by head outer diameter)	Mating BHR Standard Cup Sizes (2 cups available per head component size)	Mating BHR Dysplasia Cup Sizes	Mating BHR Bridging Cup Sizes
38mm	44mm or 46mm	46mm	50mm
42mm	48mm or 50mm	50mm	54mm
46mm	52mm or 54mm	54mm	58mm
50mm	56mm or 58mm	58mm	62mm
54mm	60mm or 62mm	62mm	66mm
58mm	64mm or 66mm	66mm	

INDICATION FOR USE

The Birmingham Hip Resurfacing (BHR) System is a single use device intended for hybrid fixation: cemented femoral head component and cementless acetabular component. The BHR system is intended for use in patients requiring primary hip resurfacing arthroplasty due to:

- Non-inflammatory arthritis (degenerative joint disease) such as osteoarthritis, traumatic arthritis, avascular necrosis, or dysplasia/DDH, or
- Inflammatory arthritis such as rheumatoid arthritis.

The BHR System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral hip joint revision.

CONTRAINDICATIONS

- Patients with infection or sepsis
- Patients who are skeletally immature
- Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Patients with bone stock inadequate to support the device including:
  - Patients with severe osteopenia should not receive a BHR procedure. Patients with a family history of severe osteoporosis or severe osteopenia.
  - Patients with osteonecrosis or avascular necrosis (AVN) with >50% involvement of the femoral head (regardless of FICAT Grade) should not receive a BHR.
  - Patients with multiple cysts of the femoral head (>1cm) should not receive a BHR.
  - Note: In cases of questionable bone stock, a DEXA scan may be necessary to assess inadequate bone stock.
- Females of child-bearing age due to unknown effect on the fetus of metal ion release
- Patients with known moderate to severe renal insufficiency
- Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids
- Patients who are severely overweight
- Patients with known or suspected metal sensitivity (e.g., jewelry)

WARNINGS AND PRECAUTIONS

- Patients on medications (such as high-dose or chronic aminoglycoside treatment) or with co-morbidities (such as diabetes) that increase the risk of future, significant renal impairment should be advised of the possibility of increase in systemic metal ion concentration. Preoperative and postoperative monitoring of renal function (such creatinine, GFR, BUN) will be necessary.

- Only physicians who have received appropriate training and are familiar with the implant components, instruments, procedure, clinical applications, adverse events, and risks associated with the BHR System should use this device. Contact Smith & Nephew, Inc. for the surgical technique manual and procedural training protocol.

- Currently, Smith & Nephew, Inc. does not have a commercially available modular metal femoral head for use with a BHR resurfacing shell. Therefore, if the BHR resurfacing head must be revised to a total hip arthroplasty, the acetabular shell should also be revised, even if well fixed.

Preoperative

- Do NOT use any component of the BHR system with another manufacturer's implant components, because designs and tolerances may be incompatible.
- Do NOT use BHR system components (which are cobalt chrome) with any stainless steel components, since corrosion can occur between two dissimilar metals.
- Previous hip surgery such as osteotomy, core decompression, hemiresurfacing, or internal fixation may increase the risk of early failure.
- Examine instruments for wear or damage before use. While rare, intra-operative instrument breakage can occur. Instruments that have experienced excessive use or force may be susceptible to breakage.

Intraoperative

- Implants should be accepted only if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.
- Avoid notching the femoral neck, as this may lead to femoral neck fracture.
- Avoid placing the femoral component in varus. Varus placement of the femoral component has been associated with femoral neck fracture.
- Do NOT re-use an implant. All implants are intended for single-use only.
- Use the recommended instruments and the recommended surgical technique.
- Improper selection, placement, positioning, and fixation of the implant components may result in early implant failure.
- Malalignment of the components and/or soft tissue imbalance may cause excessive wear and early implant failure.
- Associated trials and templates should be used for verification of component size. If an appropriate component size cannot be found during pre-operative planning, do not use this type of implant.
- Complete pre-closure cleaning of the implant site (complete removal of bone chips, bone fragments, metallic debris, etc.) is critical to prevent wear of the articular surfaces.
- Using instruments other than the associated BHR instruments may result in inaccurate placement.

Hydroxyapatite-Coated Acetabular Implants

- Do NOT allow the HA-coated, porous-surfaced acetabular component to contact any substance other than the device packaging, clean gloves, or the patient's tissue.
- Do NOT use cement with these HA-coated, porous-surfaced implants.
- Take care to achieve a stable press fit. The HA-coated, porous surface is not intended to compensate for inadequate implant fixation.

Postoperative

- Excessive physical activity levels, excessive patient weight, and trauma to the joint replacement may cause early failure of the implant.
- Loosening of components may increase production of wear particles and accelerate damage to the bone, making successful revision surgery more difficult.

Patient Education

- Warn the patient of the surgical risks, possible adverse effects, and possible operative complications that can occur with joint arthroplasty.
- Warn the patient of the limitations of artificial joint replacement devices.
- Caution the patient to protect the joint replacement from unreasonable stresses and to follow the treating physician's instructions. In particular, warn the patient to strictly avoid high impact

activities such as running and jumping during the first post-operative year while the bone is healing.

- Warn the patient that artificial joint replacement devices can wear out over time, and may require replacement.

POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Reported Device Related Adverse Effects

The most commonly reported BHR device related adverse events are:

- femoral neck fracture
- femoral head collapse
- infection
- avascular necrosis
- dislocation
- component migration/loosening, and
- impingement

A complete list of the complications and adverse events identified in the case series review is provided below in Summary of Clinical Studies, Table 14.

Potential Adverse Effects

The following adverse effects may occur in association with hip replacement surgery including the BHR System:

- Cardiovascular complications including venous thrombosis, pulmonary embolism, or myocardial infarction .
- Sudden, pronounced, intraoperative blood pressure decrease due to the use of bone cement
- Hematoma or damage to blood vessels resulting in large blood loss
- Delayed wound healing
- Superficial or deep infection. Infections may occur months to years after surgery and these infections are difficult to treat and may require reoperation with removal surgery and later replacement at another time
- Temporary or permanent nerve damage resulting in functional and/or sensory deficits in the affected limb
- Metal sensitivity reactions or allergic reactions or metallosis
- Dislocation or subluxation leading to post-operative joint instability (which may be caused by malpositioning of the implants, or muscle or fibrous tissue laxity)
- Component loosening or migration due to trauma, loss of fixation, malalignment, or bone resorption
- Limb length discrepancy
- Increased hip pain and/or reduced hip function
- Fatigue fracture of the implants as a result of excessive loading, malalignment, or trauma
- Osteolysis and/or other peri-prosthetic bone loss
- Unintended bone perforation or fracture occurring either intra-operatively or post-operatively as a result of trauma, excessive loading, osteolysis, or osteoporosis
- Periarticular calcification or ossification
- Wear or deformation of the articular surface as a result of excessive loading or implant malalignment

Any of these adverse effects may require medical or surgical intervention. Rarely, these adverse effects may lead to death.

SUMMARY OF CLINICAL STUDIES

A clinical data series was used to support the safety and effectiveness of the Birmingham Hip Resurfacing (BHR) system. The BHR was implanted in 2,385 hips by a single investigator, Mr. Derek J.W. McMinn, FRCS. Mr McMinn performed his surgeries at the Birmingham Nuffield and Little Aston Hospitals, Birmingham, United Kingdom from July 1997 through May 2004. Additionally, unpublished data on 3,374 hips implanted by 140 surgeons and published reports from the experience of multiple surgeons implanting over 3,800 hips supported the safety and effectiveness of the BHR System.

Study Objectives and Assessments

The objective of the clinical data series was to demonstrate the safety and effectiveness of the Birmingham Hip Resurfacing (BHR) System. The safety assessments included data on revisions, adverse events, and deaths for the entire series of 2,385 procedures, 919 of which were 5-years post-operative; and, a metal ion literature review that included unpublished and published references. Effectiveness data was collected from the first 1,626 procedures, as they were a minimum of 2-years post-op. Of the 1,626 procedures, survivorship and patient satisfaction data were available for 546 of the 601 BHR procedures expected at 5-years post-op (90.8%). Of the 124 procedures in the X-Ray Cohort, radiographic data were available for 108 of the 118 procedures expected at 5-years post-op (91.5%). Of the 1,111 unilateral procedures evaluated for clinical effectiveness, pain and function data, as evaluated by the Oswestry-modified Harris Hip (OSHIP) Score, were available for 360 of the 395 procedures expected at 5-years post-op (91.1%).

Description of Cohorts and Data Collected

The 2,385 procedures implanted with the Birmingham Hip Resurfacing (BHR) device by a single investigator from July 1997 through May 2004 were divided into the following three main cohorts for the purposes of data analysis:

- **X-ray cohort:** First 124 BHR cases performed from July 1997 through December 1997.
- **Oswestry cohort:** Next 1,502 BHR cases performed from January 1998 through March 2002.
- **McMinn cohort:** Next 759 BHR cases performed from April 2002 through May 2004.

Table 2 outlines the dates of implantation, number of procedures, and types of safety and effectiveness data collected for these 3 cohorts:

Table 2: Cohorts and Data Collected			**Types of Safety and Effectiveness Data Collected**						
			Safety Data Collected			**Effectiveness Data Collected**			
Cohort	Dates of Implantation	Number of Procedures	Adverse Events	Revisions	Deaths	Survivorship	Radiographic	Pain and Function (OSHIP)	Patient Satisfaction
X-ray	7/97-12/97	124	X	X	X	X	X	X**	X
Oswestry	1/98-3/02	1502	X	X	X	X		X**	X
McMinn	4/02-5/04*	759*	X	X	X	X		***	

Note: An X in the table indicates that this data was collected for the respective cohort

* There were 5 cases in the McMinn cohort whose implantations were performed prior to 4/02. These cases should have been part of the Oswestry cohort, but for unknown reasons were not. Therefore, unlike the majority of the McMinn cohort, some of these 5 cases have longer term follow-up.

** See note in Table 3 below regarding the number of procedures contributing to the pain and function (OSHIP) effectiveness data.

*** The pain and function data for the procedures in the McMinn cohort were collected using the Oxford Hip Score evaluation method (and not the OSHIP Score assessment method). Because the 759 procedures in the McMinn Cohort were not tracked by the Oswestry Outcome Center but by the National Health Services (NHS) Center, the FDA and Smith & Nephew, Inc. did not have access to the Oxford hip score data.

As noted in the Table above (with the large bolded "X"), 124 procedures in the X-ray cohort contributed to the assessment of radiographic effectiveness in the PMA. Radiographic evaluations were not provided for the 1,502 procedures in the Oswestry cohort or the 759 procedures in the McMinn cohort.

Where there were common data elements collected in the 3 cohorts outlined above, this information was pooled into the following two combined cohorts:

- **X-ray/Oswestry/McMinn combined cohort or Overall McMinn cohort:** Note that for the rest of this document, this cohort will be referred to as the **Overall McMinn cohort.**
- **X-ray/Oswestry combined cohort**

Table 3 outlines the dates of implantation, number of procedures, and types of safety and effectiveness data collected for these 2 combined cohorts:

Table 3: Combined Cohorts and Data Collected			**Types of Safety and Effectiveness Data Collected**						
			Safety Data Collected			**Effectiveness Data Collected**			
Cohort	Dates of Implantation	Number of Procedures	Adverse Events	Revisions	Deaths	Survivorship	Radiographic	Pain and Function (OSHIP)	Patient Satisfaction
Overall McMinn Cohort	7/97-5/04	2,385	**X**	**X**	**X**	X	*	*	*
X-ray/ Oswestry Combined	7/97-3/02	1,626	X	X	X	**X**	*	**X****	**X**

Note: An X in the table indicates that this data was collected for the respective cohort

* Although data (e.g., x-ray or pain and function) was collected for one of the cohorts identified in this row, it was not collected for all procedures in the combined cohort; therefore, an X is not included in this part of the table.

** 1,111 unilateral procedures in the X-ray/Oswestry combined cohort contributed to the assessment of pain and function effectiveness data, as evaluated by the Oswestry-modified Harris Hip (OSHIP) Score assessment method.

As noted in the Table above (with large bolded "X"s), the 2,385 procedures in the Overall McMinn cohort contributed to the assessment of safety including adverse events, revisions, and deaths. The 1,626 procedures in the X-ray/Oswestry combined cohort contributed to the assessment of survivorship. Also, as noted in the Table above, 1,111 unilateral procedures in the X-ray/Oswestry combined cohort contributed to the assessment of pain and function effectiveness data, as evaluated by the Oswestry-modified Harris Hip (OSHIP) Score. Unilateral procedures were evaluated separately as it is difficult to distinguish pain and function status of each hip separately in patients with bilateral hip involvement. Finally, 1,626 procedures in the X-ray/Oswestry Combined cohort contributed to the patient satisfaction effectiveness.

Additional Data Sources

In addition to the clinical data series cohorts, less complete data was provided on 3,374 BHR cases performed by 140 surgeons worldwide (other than the single investigator). The follow-up for these cases was also contracted to the Oswestry Outcomes Centre and includes primarily the same

parameters as the follow up for the X-ray/Oswestry combined cohort (adverse events, revisions, deaths, pain and function (OSHIP) scores, and patient satisfaction). The Oswestry Outcomes Centre, therefore, collected data on a total of 5,000 BHR cases. These 5,000 cases are referred to as the **Oswestry Worldwide Cohort**. The Oswestry Worldwide Cohort consists of 1) the 1,626 cases of the X-ray/Oswestry cohort (the single investigator), and 2) an additional 3,374 non-McMinn ("all other") cases. The Oswestry Outcomes Centre has provided access to all available data for the BHR cases from its database. Although the data from the 3,374 "all other" cohort was of some value, Smith and Nephew, Inc. and FDA have no ability to independently verify any of the data provided to the Oswestry Outcomes Centre by sites other than the McMinn Center, and have no ability to request additional follow-up or clarifications of any kind from non-McMinn patients or physicians. For these reasons, the analysis on the Oswestry Outcomes Centre worldwide database has some limitations, and is not considered the primary data source.

Several literature references were also included which describe the use of over 3,800 BHR devices implanted by multiple surgeons in several countries around the world. One example is the literature reference by Shimmin and Back (Shimmin AJ, Back D. "Femoral neck fractures following Birmingham hip resurfacing: A national review of 50 cases." *J Bone Joint Surg [Br]* 87-B:463-4, 2005) which was used in the development of the labeling.

Data Collection Methods

Safety Data Collection Methods

The safety data including adverse events, revisions, and deaths were collected by:

- The Oswestry Outcomes Center using an annual, patient-completed, mail-in questionnaire (deaths were identified while attempting to perform scheduled follow-up);
- The McMinn Center by recording the findings of post-operative patient visits to the McMinn Center in patient records; and
- Recording information provided to Mr. McMinn by primary care physicians.

Also, a 100% audit of all 2,385 procedures in the Overall McMinn Cohort was performed.

Effectiveness Data Collection Methods

Survivorship Data Collection Method

The primary effectiveness measurement was the X-Ray/Oswestry combined cohort survivorship study that included 1,626 procedures performed from July 1997 through March 2002 at the Birmingham Nuffield Hospital. These procedures were a minimum of 2 years post-op. Of the 1,626 procedures, data are available for 546 of the 601 BHR procedures eligible for 5-year follow up (90.8%). The data for the survivorship study was collected using the same methods presented above for the safety data collection methods.

Radiographic Data Collection Method

The clinical data used to support this series contained the results of an independent radiographic review of the X-Ray Cohort, the first 124 procedures performed in the series from July 1997 through December 1997. Radiographic evaluations were not provided for the 1,502 procedures in the Oswestry Cohort or the 759 procedures in the McMinn Cohort.

The radiographs were interpreted by an independent radiologist. A prospective protocol was developed and used to assess the radiographs. The 5-year AP and lateral view radiographs were compared with the baseline radiographs for the medial-lateral migration, acetabular orientation (tilt angle), femoral and acetabular radiolucencies, heterotopic ossification (HO), bone resorption,

acetabular protrusion, cysts, buttressing, and other abnormalities. Radiolucency was defined as a lucent area parallel to and in close proximity to the prosthesis/bone interface encompassing at least 50% of the zone and at least 1mm in width.

A radiographic success was defined as having all of the following:
- Absence of radiolucencies or a radiolucency in any one or two zones (a score of 0-6);
- Component migration ≤2mm; and
- Change in acetabular angle <5°

A radiographic failure was defined as the following:
- Presence of incomplete or complete radiolucencies or a radiolucency in all zones (a score of 7 or 8);
- A migration of the component >2mm; or
- A change in acetabular orientation of ≥5°

The individual success criterion was the absence of radiographic findings that suggest revision is necessary.

Oswestry-Modified Harris Hip (OSHIP) Score Data Collection Method

The clinical data used to support this series were collected by the Oswestry Outcomes Center (OOC) using an annual, patient-completed, mail-in questionnaire. The responses to the pain, function, and movement questions in the questionnaire were used to generate the Oswestry-modified Harris Hip (OSHIP) Score.

The main difference between the OSHIP questionnaire and the HHS is that the OSHIP allows patient assessments without direct physician or examiner evaluation. In addition, the OSHIP questionnaire does not include the three HHS questions regarding physician assessment of Range of Motion (5 pts.), Absence of Deformity (4 pts.), and the patient's ability to put on socks/tie shoes (4 pts.) but substitutes a "movement" question (13 pts.) that is intended for the patient to estimate their ability to flex their hip.

Patient Satisfaction Data Collection Method

Patient satisfaction data was also collected using the annual, patient-completed, mail-in questionnaire. For the purpose of the BHR study, an additional question about patient satisfaction was appended to the end of the OSHIP assessment questionnaire.

Literature References

A literature search was performed to find published studies of ceramic-on-ceramic total hip replacements to provide a comparison for the BHR clinical study data. The following two articles were identified:

- D'Antonio J., et al.: New experience with alumina-on-alumina ceramic bearings for total hip arthroplasty. J. Arthroplasty, 17(4): 2002.
- Garino JP: Modern ceramic-on-ceramic total hip systems in the United States: Early results. Clin. Orthop., 379: 2000.

The data in these references have some differences as compared to the data provided for the BHR device in this clinical data series, including:
- Different evaluations, (OSHIP for BHR and HHS for literature)
- Length of follow-up, (18-36mo and 2-4 years for the controls and 2-5 years for the BHR study)

- Mean baseline pain and function scores (e.g., 60 for OSHIP in BHR Oswestry cohort, 44 for HHS Garino study, and not reported for D'Antonio study), and
- Indications for use, (including differences in the rate of dysplasia and AVN diagnostic indications)

However, the literature information provided valuable information on approved ceramic-on-ceramic total hip replacement (THR) systems for comparison purposes including patient demographics, diagnostic indications, patient accounting, adverse events, revision rates, pain, function, and radiographic results. This information is summarized in several sections below for reference purposes.

PATIENT DEMOGRAPHICS

Demographics for X-Ray, Oswestry, McMinn, and Overall McMinn cohorts

Patients in the Overall McMinn cohort were 70.6% men and 29.4% women, ages 13-86 years (average 53.1 years). The primary diagnosis was osteoarthritis in 75.0%, dysplasia in 15.8%, avascular necrosis in 4.1%, inflammatory arthritis in 2.4%, and "other" in 2.7% (Table 4).

Table 4: Procedure Demographics

	X-Ray Cohort	Oswestry Cohort	McMinn Cohort	Overall McMinn
Hips	124	1502	759	2385
Men	81 (65.3%)	1082 (72.0%)	520 (68.5%)	1683 (70.6%)
Women	43 (34.7%)	420 (28.0%)	239 (31.5%)	702 (29.4%)
Age (range)	52.8 (27.8-75.3)	53.0 (13.4-86.5)	53.3 (21.6-79.5)	53.1 (13.4-86.5)
Age ≤65 years	111 (89.5%)	1388 (92.4%)	692 (91.2%)	2191 (91.9%)
Dx: OA	92 (74.2%)	1171 (78.0%)	526 (69.3%)	1789 (75.0%)
Dx: DDH	22 (17.7%)	197 (13.1%)	158 (20.8%)	377 (15.8%)
Dx: AVN	7 (5.6%)	59 (3.9%)	31 (4.1%)	97 (4.1%)
Dx: Inflammatory	2 (1.6%)	39 (2.6%)	16 (2.1%)	57 (2.4%)
Dx. Other	1 (0.8%)	36 (2.4%)	28 (3.7%)	65 (2.7%)

Demographics for X-Ray/Oswestry combined cohort

Patients in the survivorship study (X-ray/Oswestry combined cohort) ranged in age from 13.4 to 86.5 years (mean 53 years); 72% of the patients are male, and 28% are female. Of the 1,626 BHR procedures in this cohort, 1,499 (92%) were performed in patients ≤ 65 years old, and 127 (8%) were performed in patients > 65 years old.

Diagnostic Indications for Unilateral and Bilateral procedures in X-Ray/Oswestry combined cohort

One thousand one hundred and eleven (1,111) of the X-ray/Oswestry combined cohort cases (68%) were unilateral procedures and 515 (32%) were bilateral procedures. The indication for the majority of cases was osteoarthritis. Table 5 provides the breakdown of unilateral and bilateral cases by indication.

Table 5: Diagnostic Indication for BHR

Diagnosis	Unilateral	Bilateral	TOTAL
Osteoarthritis	849 (76.4%)	414 (80.4%)	1263 (77.7%)
Dysplasia	160 (14.4%)	59 (11.5%)	219 (13.5%)
Avascular necrosis	52 (4.7%)	14 (2.7%)	66 (4.1%)

Inflammatory arthritis	18 (1.6%)	23 (4.5%)	41 (2.4%)
Other	32 (2.9%)	5 (1.0%)	37 (2.3%)
TOTAL	1111 (68%)	515 (32%)	1626

Some of the patients with bilateral hip replacements were included in different groups depending on when the second hip procedure was performed (Table 6).

Table 6: Hip Procedures

Cohort	Patients**	Hips***	Unilateral	Bilateral	Contralateral Single Hip Cohort*			Singles
					X-Ray	Oswestry	McMinn	
X-Ray	113	124	83	11	-	11	8	19
Oswestry	1301	1502	1028	201	11	-	61	72
McMinn	685	759	542	74	8	61	-	69

* Patients with bilateral hip replacements with the contralateral hip not included in the first hip replacement's evaluation cohort.

** Number of patients equals unilateral + bilateral + singles

*** Number of hips equals unilateral + (2 x bilateral) + singles

Demographics: Literature References

The study published by D'Antonio *et al.* reported findings from a multicenter study conducted at 22 investigational sites; the study published by Garino was conducted at 11 investigational sites (Table 7).

Table 7: Demographics for Literature References

Author	Patients	Procedures	Age (Average)	Bilateral Procedures
D'Antonio J *et al*	458	514: • 349 ceramic • 165 control	53	19
Garino JP	333 (f=132, m=201)	333	52	0

D'Antonio *et al.* reported the indication for THR as osteoarthritis in 399/514 procedures (77.6%) and avascular necrosis in 82/514 procedures (16%) (Table 8).

Table 8: Indications for Use for Literature References

Diagnosis	D'Antonio
OSTEOARTHRITIS	399
TRAUMATIC OSTEOARTHRITIS / DJD	21
AVASCULAR NECROSIS	82
OTHER / NOT REPORTED	12
TOTAL	**514**

Patient Accounting

The follow-up rates for the Combined X-Ray / Oswestry Cohort, upon which the effectiveness analyses were performed, at the 1-year, 2-year, 3-year, 4-year, and 5-year postoperative evaluation time points were 76.6%, 77.3%, 88.1%, 88.6%, and 90.8%, respectively. There were 546 procedures (hips) evaluated at 5 years in this cohort (Table 9).

Table 9: Patient Accounting Based on the number procedures						
	Baseline	**1 year**	**2 years**	**3 years**	**4 years**	**5 years**
Accounting for Survivorship (% Revision Free)						
Cohort		# Patients observed at beginning of each study year (# revisions, # censored) [1]				
X-Ray	-	124 (1,0)	123 (0,0)	123 (1,0)	122 (0,0)	122 (0,20)[6]
Oswestry	-	1502 (9,63)	1430 (5,49)	1376 (4,256)	1116 (1,321)	794 (1,392)
McMinn	-	759 (3,290)	466 (0,379)	87 (0,84)	3 (0,0)[7]	3 (0,0)[7]
X-Ray Cohort						
Expected[1,8]	124	123	123	122	122	118[3]
Evaluated[2]	82	101	51	122	119	112
F/U %[2]	66.1%	82.1%	41.4%	100.0%	97.5%	94.9%[3]
Evaluated[4]	124	-	-	-	-	108
F/U%[4]	100%	-	-	-	-	91.5%
Oswestry Cohort						
Expected[1,8]	1502	1493	1484	1227	885	482
Evaluated[2]	1229	1137	1192	1067	773	434
F/U %[2]	81.8%	76.2%	80.3%	87.0%	87.3%	90.0%
X-ray / Oswestry Combined Cohort						
Theoretical[1]	1626	1626	1626	1385	1045	647
Deaths (procedures)	0	2	7	16	18	26
Revisions (cumulative)	0	10	15	20	21	23
Expected[1,8]	1626	1616	1607	1349	1007	601
Evaluated[2]	1311	1238	1243	1189	892	546
F/U %[2]	80.6%	76.6%	77.3%	88.1%	88.6%	90.8%
F/U +base[5]	1311	1067/1304	1050/1294	944/1046	660/726	368/397
+base %		82%	81%	90%	91%	93%
F/U –base[5]	315	171/312	193/313	245/303	232/281	178/204
-base %		55%	62%	81%	83%	87%

[1] Note that for the Survivorship data the "year 1" data is starting from day 1 and the "year 2" data is starting from day 366, etc. but for the OSHIP scores, the "year 1" data was collected between day 366-730, the "year 2" data was collected between day 731-1095, etc.

[2] Evaluated by OSHIP score

[3] OSHIP score was available for one hip that was revised shortly after the 5-year follow-up interval, OSHIP data available on 112/119 (94.1%) of hips surviving to 5 years

[4] Evaluated by X-Ray

[5] The follow-up of those who had baseline OSHIP scores (+base) and those without baseline OSHIP scores (-base).

[6] Note that there were 2 revisions in the x-ray cohort at >5 years

[7] There were 5 cases in the McMinn cohort whose implantations were performed prior to 4/02. These cases should have been part of the Oswestry cohort, but for unknown reasons were not. Therefore, unlike the majority of the McMinn cohort, some of these 5 cases have longer term follow-up.

[8] The expected and evaluated values in each interval include hips with a recorded OSHIP even if the subject died or was revised during the interval.

For the unilateral patients in the X-Ray / Oswestry combined cohort, the follow-up rates at the 1-year, 2-year, 3-year, 4-year, and 5-year postoperative evaluation time points were 75.7%, 76.6%, 88.2%, 88.4%, and 91.1%, respectively (Table 10).

Table 10: Patient Accounting
Summary of the Oswestry and X-Ray Cohorts - Unilateral

Based on Available OSHIP Data						
	Baseline	**1 year**	**2 years**	**3 years**	**4 years**	**5+ years**
Theoretical	1111	1103	1100	927	687	395
OSHIP data	892	835	842	818	607	360
%	80.3	75.7	76.5	88.2	88.4	91.1

Accounting identified in the literature references were as provided in Table 11.

Table 11: Patient Accounting: Literature References		
Author	**Mean follow-up (range)**	**Number of hips (patients) included**
D'Antonio	35.2 mo (24 to 48 mo) for ceramic on ceramic. 33.6 mo (24 to 48 mo) for control (metal on polyethylene)	349 ceramic-on-ceramic THR procedures (318 patients) • 335 hips (307 pts) at 24 mos • 243 hips (227 pts) at 36 mos • 72 hips (71 pts) at 48 mos 165 control THR procedures (161 patients), • 149 hips (147 pts) at 24 mos • 111 hips (111 pts) at 36 mos • 26 hips (26 pts) at 48 mos
Garino	Range 18-36 months	"100% follow up for all 333 procedures"

SAFETY DATA

Safety: Revisions

There were 27 procedures that required revision. Two of the 27 revisions occurred beyond the 5-year follow-up time point in the X-Ray cohort (Table 12).

Table 12: Revisions Stratified by Cohort						
	X-Ray Cohort N=124					
	Preop	**1 year**	**2 years**	**3 years**	**4 years**	**5+ years**
Number of procedures*	124	124	123	123	122	122
Revisions	-	1	0	1	0	2
	Oswestry Cohort N=1502					
Number of procedures*	1502	1502	1430	1376	1116	794
Revisions	-	9	5	4	1	1
	McMinn Cohort N=759					
Number of procedures*	759	759	466	87	3	3
Revisions	-	3	0	0	0	0
	X-Ray + Oswestry Combined Cohort N=1626					
Number of procedures*	1626	1626	1553	1499	1238	916
Revisions	-	10	5	5	1	3
	Overall McMinn Cohort N=2385					
Number of procedures*	2385	2385	2019	1586	1241	919
Revisions	-	13	5	5	1	3

* The number of procedures is the number of hips that were surviving at the end of the previous year based on the survival analysis. Note that for the Survivorship data the "year 1" data is starting from day 1 and the "year 2" data is starting from day 366, etc.

There were 10 revisions due to a femoral neck fracture, 6 for femoral head collapse, 1 for dislocation, 2 for AVN (1 led to femoral head collapse and 1 led to a femoral neck fracture), and 8 for infections (2 led to head collapse, 1 led to a femoral neck fracture). Altogether, there were 12 femoral neck fractures that required revisions. Factors that may have contributed to the femoral neck fractures include age-related osteopenia (2 patients), poor preoperative bone quality as evidenced by cysts in the femoral head and acetabulum (1 case), SLE (1 case), severe RA (1 case), infection that led to bone death (1 case), femoral head cysts (1 case), and malpositioned component (1 case). The 9 cases with femoral head collapse (6 primary femoral head collapses, 2 collapses due to infection and 1 due to AVN). Factors that may have contributed to the femoral head collapse include infection (2 cases), AVN (2 cases), femoral head cysts and soft bone (3 cases), osteopenia (1 case), and 1 unknown.

Safety: Revisions Comparison with Literature References

A comparison of the revision rates between the BHR study cohorts and the two literature reference groups was provided. The revision rate for the primary efficacy cohort was 1.47% at 5 years compared to 1.2%, 5.2%, and 1.2%, respectively, for the D'Antonio ceramic-ceramic, D'Antonio metal-poly, and Garino literature reference groups (Table 13).

Table 13: Revision Rate Comparisons

	Cohort					Literature Reference Data		
	X-Ray	Oswestry	X-Ray/ Oswestry Combined	McMinn	Overall McMinn	D'Antonio C/C*	D'Antonio M/P*	Garino
N	124	1502	**1626**	759	2385	338	151	333
Revised	4	20	**24**	3	27	4	8	4
Rate %	3.2%	1.3%	**1.47%**	0.3%	1.13%	1.2%	5.2%	1.2%
f/u years	5	4	4-5	1	3	3	3	1-3

* Revision rates are based on a minimum of 2-year follow-up

Safety: Adverse Events

A time course distribution of adverse events was provided (Table 14). The Overall McMinn Cohort contains the X-Ray, Oswestry, and McMinn cohorts, and can be considered the safety cohort for this study.

Table 14: Adverse Events*
Overall McMinn Cohort

Adverse Event*	Overall McMinn Cohort N=2385					
	Postop	1 year	2 years	3 years	4 years	5+ years
Number of procedures	2385	2157	1667	1378	1018	620
Procedures with AE (%)	1126 (46.2%)	847 (39.3%)	155 (9.3%)	64 (4.6%)	34 (3.3%)	53 (8.5%)
AVN femoral head/neck	31 (1.3%)	2 (<0.1%)	1 (<0.1%)	0	0	1 (0.2%)
Femoral head collapse	7 (0.3%)	3 (0.1%)	3 (0.2%)	1 (<0.1%)	0	1 (0.2%)
Component migration/loosening	1 (<0.1%)	7 (0.3%)	8 (0.5%)	2 (0.1%)	0	1 (0.2%)
Femoral neck fracture	0	10 (0.5%)	0	2 (0.1%)	0	1 (0.2%)
Impingement	2 (<0.1%)	1 (<0.1%)	0	0	0	0
Infection (device related)	0	7 (0.3%)	3 (0.2%)	1 (<0.1%)	1 (<0.1%)	2 (0.3%)
Dislocation	0	5 (0.2%)	0	2 (0.1%)	0	2 (0.3%)
Cardiac event	15 (0.6%)	1 (<0.1%)	0	1 (<0.1%)	0	0

Hg drop	179 (7.5%)	2 (<0.1%)	0	0	0	0
Heterotopic Ossification	0	33 (1.5%)	19 (1.1%)	3 (0.2%)	1 (<0.1%)	3 (0.5%)
Hypotension	33 (1.4%)	4 (0.2%)	0	0	0	0
Limp	0	203 (9.4%)	4 (0.2%)	2 (0.1%)	0	1 (0.2%)
Event at implant site (clicking, etc.)	0	51 (2.4%)	14 (0.8%)	9 (0.7%)	1 (<0.1%)	3 (0.5%)
Reaction at incision site	8 (0.3%)	62 (2.9%)	1 (<0.1%)	1 (<0.1%)	0	2 (0.3%)
Other (see description below)	171 (7.2%)	121 (5.6%)	19 (1.1%)	7 (0.5%)	7 (0.7%)	5 (0.8%)
Thromboembolic event	3 (0.1%)	3 (0.1%)	0	0	0	0
Pain	26 (1.1%)	223 (10.3%)	76 (4.6%)	22 (1.6%)	20 (2.0%)	29 (4.7%)
Deep Vein Thrombosis	5 (0.2%)	1 (<0.1%)	2 (0.1%)	0	0	0
Infection (hip/procedure related)	28 (1.2%)	13 (0.6%)	0	0	0	0
Pneumonia	2 (<0.1%)	0	0	0	0	0
Fever	171 (7.2%)	1 (<0.1%)	1 (<0.1%)	0	0	0
X-ray report comment	0	23 (1.1%)	12 (0.7%)	7 (0.5%)	3 (0.3%)	7 (1.1%)
Stiffness, weakness, flexion deformity, restricted ROM	0	184 (8.5%)	11 (0.7%)	9 (0.7%)	3 (0.3%)	3 (0.5%)
Urinary	234 (9.8%)	1 (<0.1%)	0	0	0	0
Wound exudate	588 (24.7%)	1 (<0.1%)	0	0	0	0

* Time course of events shows the number and % of subjects with at least 1 complication of the specified type in the specified time period. Subjects may appear in more than one time period. Events without time information were not included in the table.

Safety: Adverse Events - Discussion of Infections

The infections identified in the clinical data series were categorized, based on data collection procedures, as hip/procedure-related or device-related based on the time of occurrence. There were 41 infections associated with the index hip resurfacing procedure within 30 days of surgery and were thus categorized as hip/procedure-related. All of these events were wound exudates or wound infections that resolved with antibiotics. There were 15 infections that occurred more than 30 days after surgery and were thus categorized as device-related. Of these 15 infections, 6 required revisions and 9 "resolved with antibiotics." There were two patients who were revised for other indications (component migration and femoral neck fracture) who were found to be infected.

Safety: Adverse Events - Deaths

There were 20 patient deaths (26 procedures) in the Overall McMinn Cohort. It was determined in no case was a death related to the BHR procedure. The causes were reported to be: 2 stroke, 4 cancer, 1 motor neuron disease, 1 esophageal cancer and pneumonia, 1 myocardial infarction, 1 suicide, 1 ruptured aorta, 1 carcinoma prostate with metastases, 1 unconfirmed – either diving accident or myocardial infarction, 7 unreported.

Safety: Metal Ion Literature Analysis

Literature references were provided to address concerns for metal ion release. An unpublished report by Daniel J, Ziaee H, and McMinn D, entitled, "Metal ion studies in patients treated with the Birmingham Hip Resurfacing, a comparable FDA-approved device and historic metal-metal total hip replacements" was provided. The authors conducted 4 metal ion studies in patients who received BHR, Metasul metal-metal total hip replacements, and other marketed (historic) metal-metal total hip replacements. In addition, a summary of literature references pertaining to the medium and long-term safety of cobalt and chromium ion exposure was provided.

The unpublished and published literature demonstrate that serum and urinary metal ion concentrations in patients with total hip replacement in general, and metal-metal implants in particular, increase in the postoperative period. However, there does not appear to be any conclusive evidence that elevated cobalt and chromium levels have any significant detrimental effects in total hip arthroplasty patients.

EFFECTIVENESS DATA

Survivorship

The survivorship estimates were based on the number of patients with no revision. Survivorship analyses were provided for various cohorts and demographic subgroups calculated according to Peto's adjustment method as follows (Table 15):

Table 15: % Survivorship Analyses (no revision)

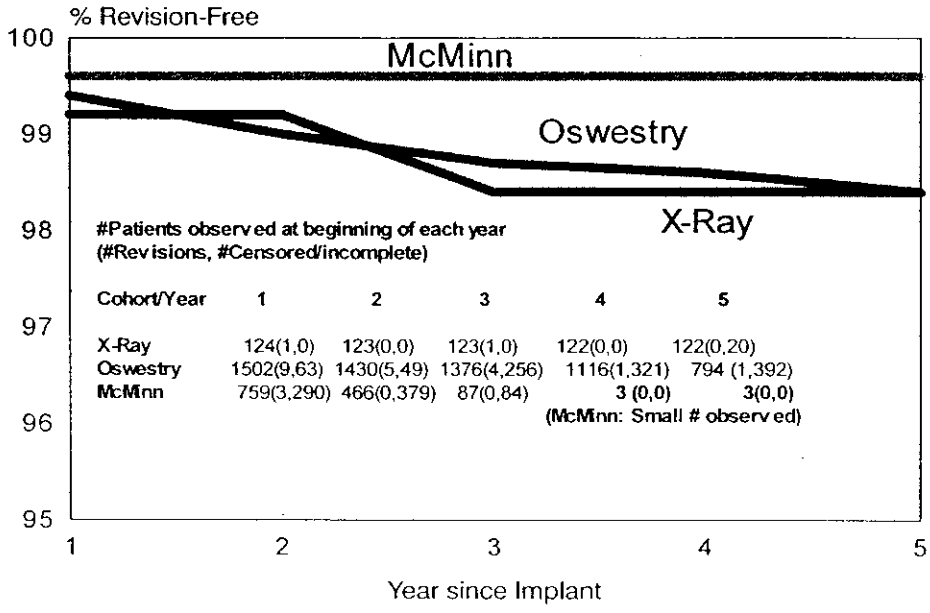
Population	1 year	2 years	3 years	4 years	5 years
X-ray Cohort	99.2	99.2	98.4	98.4	98.4
Oswestry Cohort	99.4	99.0	98.7	98.6	98.4
X-ray/Oswestry Combined Cohort	99.4	99.0	98.7	98.6	98.4 (95% CI, 97.3-99.5%)
McMinn Cohort	99.6	99.6	99.6	99.6	99.6
Overall McMinn Cohort	99.4	99.1	98.8	98.7	98.5 (95% CI, 97.4-99.6%)
Male[1]	99.4	99.2	98.9	98.9	98.6
Female[1]	99.4	99.0	98.5	98.2	98.2
Age ≤65 years[1]	99.5	99.2	98.8	98.7	98.5
Age >65 years[1]	99.0	99.0	99.0	99.0	99.0
Dx: AVN[1]	98.9	98.9	96.7	96.7	92.1 (95% CI, 82.2-100%)
Dx: Dysplasia[1]	99.4	99.4	98.9	98.1	98.1
Dx: OA	99.5	99.1	98.8	98.8	98.8 (95% CI, 98.3-99.4%)
Dx: Inflammatory[1]	98.1	98.1	98.1	98.1	98.1
Dx: Other[1]	100.0	100.0	100.0	100.0	100.0
Unilateral[1]	99.4	99.1	98.8	98.6	98.4
Bilateral[1]	99.6	99.2	98.8	98.8	98.8
Baseline OSHIP ≤63[2]	99.0	98.7	98.7	98.7	98.7
Baseline OSHIP >63[2]	99.8	99.3	98.7	98.3	98.3
Baseline OSHIP missing[2]	99.5	99.5	98.8	98.8	98.3
BMI ≤26[2]	99.7	99.3	99.0	98.8	98.8
BMI >26[2]	99.1	98.9	98.7	98.7	98.3
BMI missing[2]	99.4	99.1	98.1	98.1	98.1

[1] For the Overall McMinn cohort (2,385 hips)

For the X-Ray + Oswestry cohorts (1,626 hips)

There were no statistically significant differences in cumulative 5-year survival (revision-free) probabilities among three study cohorts. The following Figure 1 summarizes these cumulative survival probabilities (all hips):

Figure 1. Cumulative % Revision-Free, BHR



Due to small number of revisions (total 25, ≤ 5-year follow-up) from large numbers in three study cohorts (total of 2,385 hips), there were no statistically significant differences for all pairwise comparisons in 5-year survival (revision-free) probabilities among three cohorts, either by log-rank test, Wilcoxon test, or Cox proportional hazard (PH) regression analysis. Both the Cox PH regression model and the log-rank test require that the two survival probability curves be parallel or nearly parallel (no significant cohort by time crossover).

The above three statistical significance tests were also applied to several clinically important patient covariates, which include age (≤65, >65), gender (M, F), reason for resurfacing (AVN, OA, IA, dysplasia, and others; reference group = OA), baseline OSHIP score (yes, no), hips (unilateral, bilateral). The only marginally statistically significant difference in 5-year survival probability was between the patients with Osteoarthritis (98.8%) and Avascular Necrosis (92.1%) as their primary diagnostic indication. The p-values to compare these two % revision-free curves for OA versus AVN comparison are p=0.0415 (Log-rank) and p=0.2282 (Wilcoxon).

Due to non-parallelism of the Oswestry and X-Ray survival curves, careful clinical interpretation is needed. Both log-rank and Wilcoxon test that the two revision-free curves are equal, and the Cox PH model tests that the ratio of the two hazards (probability of revision) is unity. The log-rank test assigns *equal weight* to *all* follow-up times and the Wilcoxon test assigns *more weight* to the *earlier* follow-up times where more patients are at risk of revision. The log-rank test has optimum statistical power if the parallelism assumption for the two revision-free curves is valid. The Cox PH model is

not appropriate here due to obvious non-parallelism of the two curves in Figure 1. The percentages of revisions are 3.1% (3/97) for AVN, 1.1% for dysplasia (4/377), 0.95% (17/1789) for OA, 1.7% (1/57) for Inflammatory arthritis (IA), and 0% for others (0/65), with a combined 1% (25/2,385) revisions over all diagnostic groups, during 5-year follow-up.

Radiographic Data

The clinical data used to support this series contained the results of an independent radiographic review of the X-Ray Cohort, the first 124 procedures performed in the series from July 1997 through December 1997.

Radiographs were taken on 108 of the 118 procedures expected at 5 years postoperatively (91.5%). Six (6) procedures were not expected at 5 years postoperatively because one patient with bilateral hip implants died from a motor neuron disease unrelated to the BHR procedure; and 4 of the 124 BHR procedures (3.2%) have undergone revision: 3 cases were revised for infection, and 1 case required revision because of a femoral neck fracture. Therefore, 118 procedures (124 hips - 2 hips due to death - 4 revisions = 118 procedures) were eligible for 5 year radiographic evaluation of the BHR. Ten other cases were missing due to lost to follow-up or incomplete film records. Therefore, one hundred and eight (108) of the 118 hips surviving to 5 years had 5 year radiographs available for independent review (91.5%). (Note: An additional bilateral patient died 7 years post-op due to stroke but had 5 year x-rays taken).

Baseline films for the purposes of comparisons were made in each of the 108 cases in the postoperative time period (usually within 3 months, but 8 of the 108 procedures had baseline evaluations performed at time points ranging from 110-860 days).

Radiographic Study: 5-Year Radiographic Assessments

The radiographs were assessed for radiolucencies, bone resorption, heterotopic bone, acetabular angle, medial-lateral migration, and other observations to determine whether a revision surgery was necessary.

Femoral radiolucencies: Radiolucencies were graded 0-9 (Amstutz scale). There were femoral radiolucencies found in 4 cases (4.1%)—1 each with grade 9 (migration), grade 5 (zone 2-3), grade 2 (zone 1) and grade 1 (zone 2). The patient with a grade 9 femoral radiolucency was classified as a radiographic failure.

Acetabular radiolucency: Radiolucencies were graded 0-9 (DeLee and Charnley scale). There were 2 hips with acetabular radiolucencies, both with grade 8 (zones I-III, complete) findings. One hip had preoperative acetabular cysts that progressed over time, and the other had a preoperative dysplastic acetabulum and developed protrusio. Both were classified as radiographic failures. Three patients had insignificant radiolucencies (grade 1 in two hips and grade 2 in one hip).

Heterotopic bone: There were 21 hips that had Brooker I and 5 hips with Brooker II heterotopic ossification (HO). Only 2 hips had "clinically significant HO," (i.e., Brooker III or IV). Both had Brooker III HO. Thus, 28 of the 108 procedures evaluated (28.9%) had any heterotopic bone at 5 years and 2.1% had significant HO. None of the cases with heterotopic bone were determined to require a revision.

Acetabular angle: There was only 1 case that had a change in the acetabular angle >5°. This patient also had the grade 8 acetabular radiolucency (see above). No cases had a change in acetabular angle that was determined to be an indication for a revision.

Medial / Lateral Migration: There were no procedures with a change in medial/lateral acetabular cup position, and no cases with a change in acetabular position that was determined to be an indication for a revision.

Additional observations: Bone resorption at the femoral neck was found in 3 cases. In no case was the resorption associated with any other notable radiographic findings. Bone cysts were found in 2 patients: one, described above, and the other had 3cm cysts associated with a grade 1 acetabular radiolucency. No other significant signs were noted.

Three (3) of the 108 (2.8%) patients for whom radiographs were available were radiographic failures at 5 years (Table 16).

Table 16: Radiographic Findings
Number of procedures (%)

Findings	Number (%)
Femoral radiolucencies	
Failure: Grade 9	1 (0.9%)
Other: Grade 1	1 (0.9%)
Other: Grade 2	1 (0.9%)
Other: Grade 5	1 (0.9%)
Acetabular radiolucencies	
Failure: Grade 8[1]	2 (1.8%)
Other: Grade 1	2 (1.8%)
Other: Grade 2	1 (0.9%)
Change in orientation/migration	
5° change in orientation[1]	1 (0.9%)
Heterotopic ossification	
Brooker IV	0 (0.0%)
Brooker III	2 (1.8%)
Brooker II	5 (4.6%)
Brooker I	21 (19.4%)
Other	
Bone resorption, femoral neck	3 (2.8%)
Femoral or acetabular cyst	2 (1.8%)

[1] Occurred in the same patient

Radiographic Study: Comparison to Literature Reference

The radiographic results were compared with the literature reference group (Table 17).

Table 17: Radiographic Findings
X-Ray Cohort vs. Literature Reference

Radiographic Finding	Overall McMinn Cohort	Garino Reference*	D'Antonio Reference		
			ABC with porous (n=162)**	ABC with HA (n=169)**	Reference Control M/PE (n=149)**
Femoral RL zone 1	1 (0.9%)	-	4 (2.5%)	4 (2.4%)	6 (4.0%)
Femoral RL zone 2	1 (0.9%)	-			
Femoral RL zone 2 & 3	1 (0.9%)	-			
Femoral RL zone 7	0	-	2 (1.2%)	1 (0.6%)	0
Stem subsidence	0	-	0	1[1] (0.6%)	0

Unstable stem	1 (0.9%)	-	0	1[1] (0.6%)	0
Cup RL Zone I	2 (1.8%)	-	10 (6.2%)	1 (0.6%)	10 (6.7%)
Cup RL Zone II	1 (0.9%)	-	3 (1.9%)	0	7 (4.7%)
Cup RL Zone III	0	-	25 (15.4%)	0	35 (23.5%)
Cup RL all 3 zones	2 (1.8%)	-	0	0	0
Cup migration	1 (0.9%)	-	0	0	1[2] (0.7%)
Cup unstable		-	1 (0.6%)	0	1[2] (0.7%)

* No radiographic data.

** Revision rates are based on a minimum of 2-year follow-up and available x-rays.

[1] Same femoral component

[2] Same acetabular component

Pain and Function - Oswestry Modified Harris Hip (OSHIP) Score—Unilateral Procedures Only

FDA believes that it is difficult to assess the pain and function of each hip separately in patients with bilateral hip involvement using the Harris Hip Score or the Oswestry-modified Harris Hip Score (OSHIP), because it is difficult to distinguish the contributions of each hip on functional assessments such as walking or support, walking distance, stair-climbing, sitting, and transportation. Therefore, FDA believes only the unilateral patients should be used in an analysis of pain and function for the purposes of evaluating safety and effectiveness.

The mean OSHIP Scores (unilateral procedures only) improved from a baseline mean of 60.1 to 94.8 at 5 years. For the group of patients who had high baseline OSHIP scores (≥80), the mean OSHIP scores improved from 84.5 to 99.3. The group of patients who had low baseline OSHIP scores (<80), the mean OSHIP scores also improved from 59.4 to 95.6. At postoperative years 2, 3, 4 and 5, the percentage of cases with good or excellent OSHIP scores was 96.9%, 95.8%, 95.2%, and 92.8%, respectively (Table 18).

Table 18: Oswestry-Modified Harris Hip Score (OSHIP) X-Ray / Oswestry Combined Cohort---Unilateral only						
	Baseline	**1 year**	**2 years**	**3 years**	**4 years**	**5 years**
Expected	1111	1103	1100	927	687	395
OHSIP assessments	892	835	842	818	607	360
OSHIP mean	60.1	96.6	96.8	96.2	95.9	94.8
SD*	13.1	6.75	7.3	7.4	8.0	9.7
SE**	0.44	0.23	0.25	0.26	0.32	0.51
95% CI	(59, 61)	(96, 97)	(96.3, 97.3)	(95.7, 96.9)	(95.2, 96.6)	(93.8, 95.8)
AVN OSHIP mean	49.4	91.3	93.6	96.2	94.3	97.4
N, AVN	43	35	38	32	23	14
Dysplasia OSHIP mean	57.7	96.2	96.7	95.2	94.7	90.6
N, Dysplasia	131	123	117	117	81	44
OA OSHIP mean	61.5	97.0	97.0	96.5	96.2	95.3
N, OA	678	642	652	632	484	287
IA OSHIP mean	48.5	95.5	94.9	93.2	91.6	89.3
N, IA	15	11	11	15	10	8
Other OSHIP mean	62.9	96.5	98.3	96.6	98.8	98.4
N, Other	25	24	24	22	9	7
OSHIP mean for procedures with baseline ≥80	84.5	96.1	97.8	97.3	99.6	99.3
N, for baseline ≥80	25	22	22	18	8	3
OSHIP mean for procedures with baseline <80	59.4	96.9	96.9	96.6	96.4	95.6
N, for baseline <80	867	693	686	635	440	240
OSHIP mean for procedures with baseline OSHIP	60.1	96.9	96.9	96.6	96.5	95.6
N, with baseline OSHIP	892	715	708	653	448	243
OSHIP mean for procedures without baseline OSHIP	-	94.8	96.2	94.8	94.1	92.9
N, without baseline OSHIP	-	120	134	165	159	117
Improved ≥10 (%)	-	703 (84.2)	697 (82.8)	645 (78.9)	445 (73.3)	239 (66.4)
Maintained (%)	-	130 (15.6)	142 (16.9)	173 (21.1)	161 (26.5)	121 (33.6)
Deteriorated ≥10 (%)	-	2 (0.2)	3 (0.4)	0	1 (0.2)	0
OSHIP Excel ≥90 (%)	2 (0.2)	757 (90.7)	775 (92.0)	722 (88.3)	529 (87.1)	307 (85.3)
OSHIP Good 80-89 (%)	23 (2.6)	56 (6.7)	41 (4.9)	61 (7.5)	49 (8.1)	27 (7.5)
OSHIP Fair 70-79 (%)	175 (19.6)	12 (1.4)	14 (1.7)	20 (2.4)	16 (2.6)	12 (3.3)
OSHIP Poor 60-69 (%)	349 (39.1)	3 (0.4)	5 (0.6)	9 (1.1)	8 (1.3)	8 (2.2)
OSHIP V Poor <60 (%)	343 (38.5)	7 (0.8)	7 (0.8)	6 (0.7)	5 (0.8)	6 (1.7)

*SD = Standard deviation; **SE = Standard error of sample mean = SD/ $\sqrt{n}$; CI = confidence interval of true OSHIP mean

For the data in the table above regarding the number of procedures who improved ≥ 10 pts., maintained, or deteriorated ≥ 10 pts., that those patients with no baseline scores were counted as "maintained." The table below contains an analysis of the number of procedures who improved ≥ 10 pts., maintained, or deteriorated ≥ 10 pts., when the patients without baseline scores are removed from this analysis and just counted as missing (Table 19).

Table 19: OSHIP Improvement Oswestry and X-Ray Cohorts						
	Change	**1 year**	**2 years**	**3 years**	**4 years**	**5+ years**
Unilateral	Improve ≥10	703 (98.3)	697 (98.4)	645 (98.8)	445 (99.3)	239 (98.4)
	Same <10	10 (1.4)	8 (1.1)	8 (1.2)	2 (0.4)	4 (1.6)
	Worse ≥10	2 (0.3)	3 (0.4)	0 (0.0)	1 (0.2)	(0.0)
	N	715	708	653	448	243
	Missing	388	392	274	239	152

Pain and Function - Comparison to Literature References

In the literature references, the authors used Harris Hip Score, not OSHIP, to collect pain and function effectiveness data. D'Antonio *et al.* reported Harris Hip Scores at 2 - 4 year follow up (mean 3 year) for the ceramic-on-ceramic hip procedures as follows:

- ABC System 1 (porous): 95.4 mean score (n=166)
- ABC System 2 (HA): 96.6 mean score (n= 172)

Garino reported an average increase in Harris Hip Score from 44 pre-operatively to a mean of 97 at follow up.

Patient Satisfaction

The patient satisfaction question is not a standard component of the OSHIP assessment but was an additional question asked for this study in the annual, patient-completed, mail-in questionnaire. At 5 years, 99.5% of the procedures in the X-Ray/Oswestry combined cohort were pleased or very pleased with the operation. At 5 years, 99.2% of the unilateral procedures from the X-Ray/Oswestry combined cohort were pleased or very pleased with the operation (Table 20).

Table 20: Patient Satisfaction X-Ray/Oswestry Combined Cohort						
	X-Ray/Oswestry Combined Cohort N=1626					
	Base	**1 year**	**2 years**	**3 years**	**4 years**	**5+ years**
N	1626	1616	1607	1349	1007	601
Pleased	-	75 (6.1%)	62 (5.0%)	80 (6.7%)	50 (5.6%)	31 (5.7%)
Very pleased	-	1109 (89.6%)	1177 (94.7%)	1100 (92.7%)	839 (94.1%)	512 (93.8%)
X-Ray/Oswestry Combined Cohort - Unilateral Procedures Only						
# All Unilateral	1111	1103	1100	927	687	395
Assessments	892	835	842	818	607	360
Please/Very Pleased (VP)	-	800 (95.8%)	839 (99.6%)	813 (99.4%)	604 (99.5%)	357 (99.2%)
N, AVN	43	35	38	32	23	14
AVN Please/VP	-	35 (100.0%)	38 (100.0%)	32 (100.0%)	23 (100.0%)	14 (100.0%)
N, Dysplasia	131	123	117	117	81	44

Dysplasia Please/VP	-	119 (96.8%)	117 (100.0%)	115 (98.3%)	80 (98.7%)	43 (97.7%)
N, OA	678	642	652	632	484	287
OA Please/VP	-	613 (95.5%)	649 (99.6%)	630 (99.7%)	482 (99.6%)	285 (99.3%)
N, IA	15	11	11	15	10	8
IA Please/VP	-	11 (100.0%)	11 (100.0%)	15 (100.0%)	10 (100.0%)	8 (100.0%)
N, Other	25	24	24	22	9	7
Other Please/VP	-	22 (91.7%)	24 (100.0%)	21 (95.5%)	9 (100.0%)	7 (100.0%)

Additional Data Sources

The main data sources were presented above but additional, less complete data on 3,374 BHR cases performed by 140 surgeons worldwide (other than the single investigator) was summarized. This is called the **Worldwide/Other Cohort**.

Demographic information for the Worldwide/Other Cohort included gender, age, diagnosis, BMI, baseline OSHIP scores. The study cohort demography was similar in the Worldwide/Other Cohort and the X-Ray/Oswestry combined cohort, with the mean age of 53.0 years in the X-Ray/Oswestry combined cohort and 52.5 years in the Worldwide/Other Cohort. The diagnostic indications were somewhat different between cohorts: OA (78% X-Ray/Oswestry combined cohort vs. 90.8% Worldwide/Other Cohort).

A comparison of the revisions and survivorship estimates for the X-ray/Oswestry combined cohort versus the Worldwide/Other Cohort was provided. The primary reason for revision in the Worldwide/Other Cohort was a fracture in 34 cases (1.0%), loosening in 26 cases (0.8%), infection in 7 cases, AVN in 5 cases, dislocation in 5 cases, miscellaneous device failures in 5 cases, pain in 3 cases, and unknown in 3 cases (Table 23).

Table 23: Revisions

	Preop	1 year	2 years	3 years	4 years	5+ years
X-Ray/Oswestry Combined Cohort N=1626						
Number of procedures*	1626	1626	1553	1499	1238	916
Revisions	-	10	5	5	1	3
Survivorship estimates	-	99.4	99.0	98.7	98.6	98.4
Worldwide/Other Cohort N=3374						
Number of procedures*	3374	3374	3051	2888	2493	1417
Revisions	-	35	15	14	7	5
Survivorship estimates	-	98.7	98.0	97.5	97.0	96.3

* The number of procedures is the number of hips that were surviving at the end of the previous year based on the survival analysis. Note that for the Survivorship data the "year 1" data is starting from day 1 and the "year 2" data is starting from day 366, etc.

The Worldwide/Other Cohort patients had slightly lower OSHIP scores at all time points (Table 24).

Table 24: OSHIP Worldwide/Other Cohort

	Baseline	1 years	2 years	3 years	4 years	5 years
Worldwide OSHIP assessments	395	2356	2492	2364	1379	505

Worldwide Mean OSHIP	56.95	91.67	92.47	92.45	91.86	89.77

STERILIZATION

- Implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6}. Metal components are sterilized to a minimum of 25 kiloGrays of gamma irradiation. All components are supplied in protective packaging. Inspect packages for punctures or other damage prior to surgery.
- Instruments used to implant the device system are supplied non-sterile and must be sterilized prior to use using one of the following validated, recommended methods:
  - **Prevacuum Flash Cycle**: 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum exposure time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge
  - **High Temperature Gravity Cycle**: 270°F to 275°F (132°C to 135°C) with a minimum exposure time of 10 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying.
  - **Prevacuum Cycle**: 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum exposure time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying.
- DO NOT RESTERILIZE implant components. Contact your local Smith & Nephew, Inc. Sales Representative regarding procedures to return components.

The product is not labeled "pyrogen free".

The BHR components are packaged in a Tyvek™ vacuum peel pouch to maintain sterility. The product has a five (5) year sterile shelf-life.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

INFORMATION

For further information, please contact Smith & Nephew, Inc.,Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Smith & Nephew, Inc., Orthopaedics Division
1450 Brooks Road
Memphis, TN 38116 USA

Part No. Rev.) MM/YY

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BIRMINGHAM HIP RESURFACING◇ (BHR◇) System

PATIENT INFORMATION

Table of Contents

Glossary of Terms

- Artificial: Man-made.
- Hip Joint: A bone joint made up of a ball head (femoral head) and socket (acetabulum)
- Hip Dislocation: A hip problem resulting from a separation of the ball from the socket in an artificial hip replacement device.
- Migration: A hip complication resulting from a movement of the device out of its original position.
- Degenerative joint disease: A condition that causes the loss of cartilage and bone in a hip joint that eventually leads to increased hip joint pain and reduced hip joint function. Names of some types of degenerative joint diseases include.
  - Hip Dysplasia: An unusually-shaped hip socket.
  - Osteoarthritis: A condition that results in loss of bone and cartilage in the hip joint and/or formation of bone and cartilage in the joint where it normally does not occur (osteophytes).
  - Traumatic arthritis: A condition that results in loss of bone and cartilage in the hip joint after a physical injury to the hip joint has occurred.
  - Avascular Necrosis: Death of the bone in the femoral head due to loss of blood circulation within the bone caused by disease or damage to the hip bone.
  - Rheumatoid arthritis: A condition where the connective tissue (collagen) of the hip joint is slowly destroyed due to the body attacking its own tissue (auto-immune response).
- Femoral Neck Fracture: Breakage of the bone below the hip ball head.
- Femoral Head Collapse: Breakage of the bone within the hip ball head.
- Osteoporosis: A condition resulting in loss of bone that causes bone to become brittle and weak.

- Rehabilitation: After hip surgery, doctor prescribed exercises that help improve hip movement and healing
- Revision: Replacement of an artificial hip device with a new artificial hip device. Revision can be required due to several reasons such as a broken device or infection or incorrect artificial hip device position in the bone.

1.0 What Is the BHR Device?

Your hip is a socket and ball joint where the thighbone and pelvis come together. As your leg moves, the ball of your thighbone (called the femoral head) moves and rotates against the socket portion of your pelvic bone (called the acetabulum). If your hip joint is diseased due to certain kinds of arthritis, or previous damage, it will become less functional and more painful over time. When your hip pain increases to the point that it can not be helped by usual measures such as pain medicine and exercises (physical therapy) and your ability to move your hip decreases, affecting your ability to do your daily activities, it may become necessary to surgically replace the hip joint.

The Birmingham Hip Resurfacing (BHR) device has two parts: a socket in the shape of a shallow cup (acetabular component), and a cap in the form of a ball head (femoral resurfacing component). See Figure 1.

- The cup replaces the damaged surface of your hip socket (acetabulum).
- The cap covers the ball-shaped bone at the top of your thigh (femoral head), and the cap has a small stem that is inserted into the top of your thighbone.

The cap moves within the cup. The surfaces that rub against each other (the bearing couple) are made from highly-polished metal. This type of bearing couple is called a *metal-on-metal* bearing couple.

Figure 1, Birmingham Hip Resurfacing (BHR) device

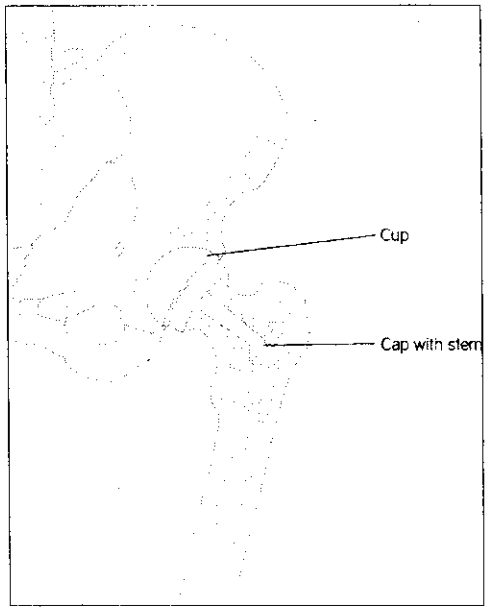
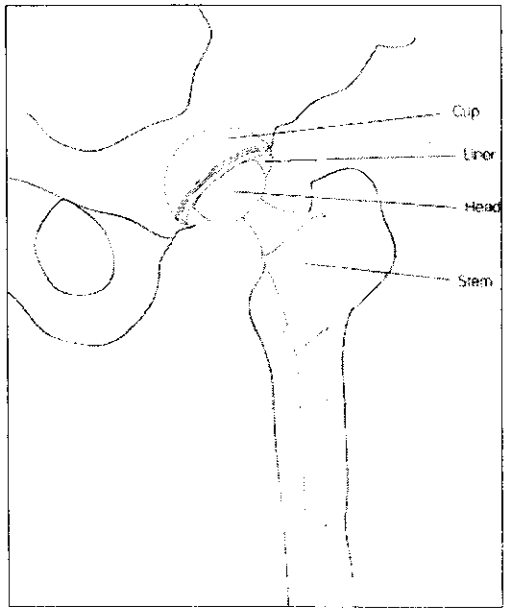


Figure 2, Total Hip Replacement (THR) device



2.0 What Is the Purpose of the BHR Device?

The BHR System relieves hip pain and improves hip function by replacing the parts of your hip that have been severely damaged by degenerative joint diseases. The names of such diseases include osteoarthritis, rheumatoid arthritis, traumatic arthritis, dysplasia, or avascular necrosis.

The BHR System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip replacement due to an increased possibility of requiring future hip joint revision.

3.0 When Should the BHR Device Not Be Used? (Contraindications)

You should not receive the BHR device if:

- You have an infection of the body or blood.
- Your bones are not yet fully grown.
- You have any blood vessel-related disease, muscle-related disease, or nerve-and-muscle-related disease that will prevent the artificial hip joint device from remaining stable or that may prevent you from following instructions during the recovery period.
- Your bones are not strong enough or healthy enough because:
  - You have severe bone loss (osteoporosis) or have a family history of severe bone loss,
  - You have bone loss (such as avascular necrosis) affecting more than half of your femoral head,

  - You have multiple fluid-filled cavities (cysts) greater than 1 centimeter in your femoral head,
  - A test (such as DEXA scan) may be needed to determine your level of bone loss.
- You are a female of child-bearing age. It is unknown whether metal ions released by the device could harm an unborn child.
- Your kidney is not working very well (function is significantly impaired). You will need testing (creatinine, GFR, BUN) before and/or after surgery to test your kidneys.
- You have a suppressed immune system due to diseases such as AIDS or are receiving high doses of corticosteroids.
- You are severely overweight.
- If you have had reactions to wearing metal jewelry, you may have what is called "metal sensitivity."

Your doctor will need complete information about your overall health to determine whether the BHR device is right for you. So, tell your doctor about **any** health problems you have, even if it is not related to your hip, because some medicines as well as diseases (such as diabetes) can affect your kidney or bone strength in the future.

4.0 What Are Some of the Potential Benefits of the BHR Device?

Your surgeon has decided that you will benefit from hip replacement surgery. When thinking about the benefits of the BHR device, you should compare the possible risks and benefits of the device to the risks and benefits of other types of artificial hip replacement devices:

- Hip resurfacing versus a total hip *replacement*:

  With a hip resurfacing device, the surgeon covers your hip socket with a metal cup, and covers your femoral head with a metal cap. (See Figure 1.) The BHR System is a hip resurfacing device. With a total hip replacement device, the surgeon covers your hip socket with a cup and replaces your femoral head with a metal ball attached to a long metal stem. The metal stem is inserted into your thighbone. (See Figure 2.)

- Metal-on-metal versus metal-on-plastic or ceramic-on-ceramic:

  With metal-on-metal systems, the cap (ball) and the socket components are made from highly-polished metal. The BHR System is a metal-on-metal system. Other hip systems can have a metal ball with a plastic-lined socket (metal-on-plastic), or a ceramic ball with a ceramic-lined socket (ceramic-on-ceramic).

Each of the device types discussed above can significantly improve hip pain and function. However, specific potential benefits of the BHR System include:

- The BHR's metal cup will not chip or crack as ceramic components can.
- The BHR does not cause thighbone (femoral shaft) fractures as total hip replacement systems can.

- The BHR may make future revision surgery easier because hip resurfacing surgery leaves your femoral head in place and there is no large metal stem placed in the thighbone. Revision surgery of a total hip replacement where your femoral head has already been removed and a large stem is already in place can be a more difficult operation.
- Dislocation of the ball head from the socket is less common with the BHR device than with total hip replacement devices. In the clinical study, 9 of 2,385 (0.3%) BHR hips experienced dislocation, compared with between 3 of 333 hips (1%) and 7 of 165 hips (4.2%) of total hip replacement patients from comparison studies. (See section 6.0.)

5.0 What Are Some of the Potential Risks of the BHR Device?

The potential risks of any hip joint replacement include:

- Damage to blood vessels, or temporary or permanent nerve damage during surgery,
- Sudden drop in blood pressure during surgery due to the use of bone cement
- Blood circulation problems because of surgery or during recovery including blood clots in the legs or lungs or heart attack.
- Allergic reactions to the device material or to medications you are given,
- Surgical wounds that take a long time to heal due to many reasons such as poor skin condition, infection, poor blood circulation, bad hygiene, etc.
- Infection related to surgery and wound healing. Infections may occur months to years after surgery and these infections are difficult to treat and may require reoperation with removal surgery and later replacement at another time,
- Dislocation of the hip, device loosening/shifting, or device wear/breakage due to muscle and fibrous tissue lack of firmness (laxity). Device placement in the wrong position in the bone, poor attachment of the device to the bone, too much weight or activity put on the device, or accidents affecting the hip joint like falls (trauma),
- Damage to the bones and tissue (tissue necrosis) near the hip joint, including loss of the surrounding bone (osteolysis) or staining of the hip joint fluid (metallosis) due to wearing away of the metal parts over time.
- Change in the length of the leg in which the device is placed,
- Device breakage due to weakening of the metal over time (fatigue fracture),
- Bone breakage due to osteoporosis or accidents (trauma),
- Bone loss or too much bone formation near the implants in response to the surgery or to the presence of the device in the bone.

These potential adverse effects may require medical attention or additional surgery. Rarely do complications lead to death.

The potential risks of the BHR device as compared with a total hip replacement system include:

- The risk of femoral neck scratching (notching) during surgery that can lead to femoral neck fracture after surgery. This occurred in 10 of 2,385 (less than 1%) BHR hips in the clinical study.

- The risk of femoral head collapse. This occurred in 15 of 2,385 (less than 1%) BHR hips in the clinical study.
- The risk of avascular necrosis. This occurred in 35 of 2,385 (1%) BHR hips in the clinical study.
- If the ball cap part of BHR device must be removed (revised), your surgeon will likely put a total hip replacement metal stem in your thighbone (see Figure 2). Since there is currently not a full ball head replacement part available in the US that can be used with a total hip replacement stem, your surgeon will have to remove the socket part of the BHR device even if it is not a part of the problem.

These complications may require surgery to change from the BHR device to a total hip replacement device. You should compare these risks to the potential benefits of a BHR system, as described above. See also *"What Problems May Occur After Your Operation?"*, Section 9.0.

6.0 What Do the Clinical Studies Show?

A clinical study was performed to evaluate the safety and effectiveness of the BHR device. Complication (safety) information was collected from the entire group of 2,385 study hips. Effectiveness information was collected from the first 1,626 of the 2,385 hips because these 1,626 hips have the longest follow-up. There is 5 year follow-up information for 546 of these 1,626 hips.

Safety Data

The overall complication rate and the types of complications in the BHR study group were generally similar to the complications reported for other hip replacement systems. The few differences between different types of complications are discussed under Section 5 - *"What Are Some Potential Risks of the BHR Device?"* and Section 4 - *"What Are Some Potential Benefits of the BHR Device?"*

Complications led to revision surgery in 27 out of 2,385 hips. See Table 1 for a summary of reasons for the revision. The 1.13% (27/2,385) revision rate at 5-years after surgery from all complications was comparable to the revision rates reported for total hip replacement devices. There were no deaths related directly to use of the device in the study. All deaths were from other medical problems.

Table 1: Reasons for Revision Surgeries in BHR Study N=2,385 Hips

Reason for Revision	*Number of Revisions*	Average time to revision in years
Femoral neck fracture	10	0.198
Infection	8	3.119
Collapsed femoral head	6	2.172
Avascular necrosis	2	0.661
Dislocation	1	0.003
TOTAL	27	

Effectiveness Data

Effectiveness was determined by looking at:

- Survivorship: The cumulative percentage of patients that did not need revision of the BHR by 5 years after surgery.
- Oswestry Hip (OSHIP) Score: The OSHIP score asks patients questions about their hip pain, hip function, and hip movement. Based on the patient response to the questions a total score is calculated. The total score ranges from 0 (worst) to 100 (best). A score of 80 or better is generally considered a good clinical result.
- Patient Satisfaction: Patients in the study were asked to rate their satisfaction with the result of the BHR surgery on a scale of 0 (worst) to 4 (best).

The results are shown in Table 2.

Table 2: Effectiveness Measures at 5 years After Surgery

Effectiveness Measure *	5 years after surgery
Survivorship: cases with device in place (not revised)	2,358 of 2,385 (98.5%)
OSHIP score: patients with a good result (80 or better)	509 of 546 (93.2%)
Patient Satisfaction: patients who responded "Pleased" or "Extremely Pleased" with their results	543 of 546 (99.5%)

* Survivorship data was for the safety cohort of 2,385 hips. OSHIP and Patient Satisfaction data were for a subgroup of 1,626 hips. In a unilateral hip analysis, 334 of 360 patients (92.7%) had a good OSHIP score result (80 or better), and 357 of 360 patients (99.2%) were "Pleased" or "Extremely Please" with their result.

7.0 What Can You Do Before Your Surgery?

Your doctor may want you to meet with a Physical Therapist (PT) even before the surgery. The PT may give you some tips on preparing your house for rehabilitation, and on how you should sleep, get out of bed, sit, get up, and walk following surgery. Some things you can do before surgery to prepare for the rehabilitation period are:

- Add extra cushions to couches and chairs. The extra height will make it easier for you to lower and raise yourself from the chair.
- Have armchairs available. During rehabilitation, you may be told only to sit in armchairs, as you will need the arms to help you sit down and get up.
- Arrange to have an elevated toilet seat and/or support bars fitted in your bathroom.
- Move items you may need to reach to shelves or tables above waist level.
- Remove all throw rugs and anything else on the floor that might cause you to slip or trip and fall.

8.0 What Can You Expect After Your BHR Hip Resurfacing Operation?

Most patients are in the hospital from 4 to 6 days. The surgery usually takes 2 to 4 hours to perform. You will use walking support (canes, crutches) for about six weeks after surgery while your hip muscles are healing. You may be told not to bend your hip or waist to more than a 90-degree angle during the healing time (rehabilitation).

Before you go home, your Physical Therapist (PT) will teach you to climb stairs and how to move from a bed, chair, and car. Your PT may also give you a list of exercises to do at home every day. These exercises will help you become as independent as possible in your personal care and daily activities after you return home. Physical therapy will also help prepare you for more difficult exercises, movement, and activity.

Most of your therapy and healing (rehabilitation) will occur once you have checked out of the hospital. Your PT will design an exercise program to increase motion and strength of your hip, and will teach you the exercises, making sure you know proper way to do the exercises before you begin. The success of your rehabilitation is very dependent on how dedicated you are to the physical therapy program.

9.0 What Problems May Occur After Your Operation?

Early Infection

Contact your doctor if you experience any of the following signs of infection:

- Drainage and/or foul smell from surgical cut (incision).
- Fever/temperature above 100.4°F (or 38°C) for two days.
- Redness or swelling or increased pain at or near the surgical cut.

Late Infection

To protect your hip joint from infection after your surgery, you will need antibiotics before the following procedures:

- Internal examinations of the bladder (cystoscopy), colon (colonoscopy) or rectum (proctoscopy).

- Dental work including teeth cleaning.
- Surgery of any kind.
- Placement of a tube into the ureter to drain urine from the body (urinary catheterization).

Infections can travel from other parts of your body to your new hip. If you have any infection in any part of your body, contact your doctor.

Late Pain or Instability

Some pain is normal and expected during your rehabilitation period, and the pain should slowly decrease in the weeks following surgery. If you experience any serious, immediate, constant hip pain or pressure or feeling of unsteadiness, or if you are suddenly unable to put weight on your hip after the early post-operative pain has gone away, you should contact your doctor. These signs (symptoms) may be a signal of a serious problem (such as bone breakage, dislocation, infection, device loosening, movement, or breakage). Any of these problems may require medical attention including additional surgery.

Continuing Evaluation

Follow your doctor's schedule for routine examinations after surgery. Routine examinations will include regular X-ray exams to look for any problems such as hip bone or device breakage, position changes, or anything abnormal. X-rays will also check the progress of bone healing around the implant.

10.0 What Are Some Warnings to Keep in Mind After Surgery?

Take care to protect your joint replacement from too much stress and follow your surgeon's instructions regarding activity level and rehabilitation.

- Do not perform high impact activities such as running and jumping during the first post-operative year while the bone is healing.
- Early device failure (breakage or loosening) may occur if you do not follow your surgeon's limitations on activity level. Early failure can happen if you do not guard your hip joint from overloading due to activity level, failure to control body weight, or accidents such as falls.
- Loosening of the hip joint device may cause too much wear of the metal parts and result in very small metal particles being created. This can result in bone loss around the implant causing more loosening.
- Early device failure or bone loss may require additional surgery to remove the device (revision surgery).
- Artificial hip joints can wear out over time and may require replacement.

11.0 Are There Instructions When You Leave Home or Travel?

Your new hip device may activate metal detector alarms. Tell the security attendant about your artificial hip when passing through security checkpoints in airports, stores, and public buildings.

12.0 Where Else Can You Get User Assistance Information?

Please discuss any questions regarding your hip surgery with your surgeon. For further information regarding the BHR System components, you may also contact the device manufacturer:

Smith & Nephew, Inc.
Orthopaedics Division
1450 Brooks Road
Memphis, Tennessee 38116 USA
Tel: 1-901- 396-2121
1-800-821-5700 (within the USA)
www.smith-nephew.com

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