Surgical Technique

smith&nephew

BIRMINGHAM HIP®

Resurfacing System

Introduction

The requirements of a surgical approach to the hip for arthroplasty are firstly an adequate exposure allowing good visualization and optimum component insertion, and secondly the minimum of damage to the neuromuscular structures around the hip.

In conventional stemmed total hip replacement it is resection of the femoral head that affords easy visualization of the acetabulum with many surgical approaches to the hip. With resurfacing, this additional help in the surgical exposure is clearly not an option.

In an elderly, inactive patient undergoing THR, a degree of neuromuscular damage, inevitable in certain surgical approaches, seems compatible, at least in some cases with reasonable functional outcome. In a younger active patient undergoing hip resurfacing however, such neuromuscular damage produces an unacceptable limited functional outcome.

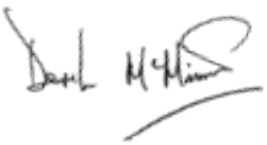
Over the past 10 years I have tried most surgical approaches for hip resurfacing. For reasons of good exposure, rapid rehabilitation and normal hip function, the posterior approach is strongly recommended.

Trochanteric osteotomy gives a splendid extensile exposure and may be useful if a hip ankylosis is to be tackled. The osteotomised fragment should be small, and great care needs to be paid to trochanteric re-attachment and patient rehabilitation if trochanteric escape and non-union is to be avoided.

It is not reasonable to select a highly sophisticated device like the BIRMINGHAM HIP® Resurfacing (BHR®) System and then damage the abductor muscles or their nerve supply in the surgical approach, use forcible retraction causing muscle tearing and heterotopic ossification, malposition the components due to poor visualization, and still expect a good result.

In a personal experience of over 2000 hip resurfacings it has been very gratifying to see patients recover excellent function after this procedure and lead a normal lifestyle, including participation in recreational and competitive sport.

No operative technique manual can be entirely comprehensive, but the steps included in this brochure are considered to be the essential elements in adopting this surgical procedure.



Derek McMinn FRCS

Consultant Orthopaedic Surgeon

BIRMINGHAM HIP◇ Resurfacing System

Table of contents

Nota Bene

The technique description herein is made available to the healthcare professional to illustrate the suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.

Indications for use

The BIRMINGHAM HIP® Resurfacing System (BHR®) 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 who are female
- 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 or 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)
  - Patients with multiple cysts of the femoral head (>1cm)
  - Note: In cases of questionable bone stock, a DEXA scan may be necessary to assess inadequate bone stock
- 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 who, from plain radiograph preoperative templating, appear to require 48mm femoral heads should not be considered as candidates for BHR implantation. Patients requiring a 48mm femoral head size are at a moderately elevated risk of requiring revision surgery earlier than expected. While Smith & Nephew concluded that the increased risk associated with this head size does not outweigh the potential benefit to the patient in the specific circumstance of intraoperative downsizing from a Preoperatively templated 50mm to a measurement of 48mm at the time of surgery, surgeons should use their best medical judgment to consider this information relative to the patient's overall medical history and prognosis in determining its appropriateness as a surgical treatment.
- 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.
- In cases where the physician determines a revision to the primary BHR prosthesis is necessary and if certain conditions are met, a BIRMINGHAM HIP® (BH) Dual Mobility Insert may be used for revision surgeries in cases where an acetabular cup is retained and the femoral component revised. The BH Dual Mobility Insert incorporates an XLPE Insert that interfaces with an existing implanted BHR Cup where the femoral component is deemed necessary for revision. If the conditions outlined below are not met, the BHR acetabular cup must also be revised, even if well-fixed.

– The BH Dual Mobility Insert is not recommended for use in a mal-positioned BHR acetabular cup or where mal-positioning is a contributor to the cause of revision. It is not advised to use a BH Dual Mobility Insert in a BHR acetabular cup with an inclination angle above 55° following supine X-Ray review due to the increased risk of edge loading or dislocation.

– The BHR acetabular cup should be inspected intra-operatively for visible signs of damage. The BHR acetabular cup should be removed if there are any obvious signs of damage, deep scratches or corrosion.

– The fixation of the BHR acetabular cup should be inspected both pre- and intra-operatively. If during pre-operative radiographic assessment evidence of radiolucency, subsidence, migration, changes in angulation or osteolysis are present then the BHR acetabular cup should be removed. The BHR acetabular cup should also be removed if movement can be detected during intra-operative assessment of component stability.

This revision option of the BH Dual Mobility Insert will be used with commercially available Smith & Nephew femoral ball heads and femoral stems. Further information in regards to the labeling or use of the BH Dual Mobility option can be found with the packaged BH Dual Mobility device or upon request from Smith & Nephew.

- Based on literature reports together with the manufacturer's post-market data, the following were identified as risk factors for early revision:

– Patients who receive a 48mm femoral head;

– Patients who receive a device which is incorrectly positioned;

– Patients who have a diagnosis of avascular necrosis;

– Patients who have congenital dysplasia; and

– Patients who are obese

The more risk factors a patient has, the greater the risk of procedure failure requiring a revision of the hipFor additional information on the use of the BHR device, see the Instructions for Use printed at the end of the surgical technique.

The surgical approach

The BIRMINGHAM HIP Resurfacing device may be implanted through various hip surgical approaches. The posterior approach is described in this technique.

Other surgical approaches to the hip may be used however, the posterior approach is favoured by the designer surgeon and his submitted clinical data is based on this approach.

Pre-Operative planning

Templating

BHR® template sets (Figure 1) are used to determine component size and correct implant positioning. The position of the femoral component is a most important Pre-operative consideration. Varus positioning must be avoided and slight valgus is recommended (Figure 2).

To achieve optimal femoral component positioning, place the appropriate BHR template onto the X-Ray. Once happy with the size chosen the medial headneck junction may be identified to set up the correct template positioning. This is aided by using the cut out section on the template which allows implant position markings to be made with the template in situ (Figure 3).

With the head-neck-junction identified, the template is rotated around this point until desired valgus position is achieved with the implant's centre line. One limiting factor for implant positioning is the risk of femoral neck notching. This may be avoided at the templating stage by confirming there is no contact between the superior aspect of the femur and the template.

Once satisfied with the template positioning, the X-Ray may be marked on the lateral cortex of the femur using the appropriate cut-out section (Figure 3). The marked position shows the insertion point for the lateral pin used with the standard Head-Centre- Alignment-Jig.

The distance from the pin insertion point on the lateral femoral cortex to the tip of the greater trochanter is measured with the ruler found on the edge of each template. This measurement is translated intraoperatively onto the patient's femur to achieve optimal pin placement.

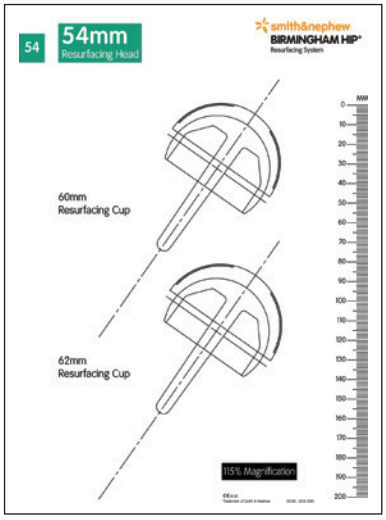


Figure 1

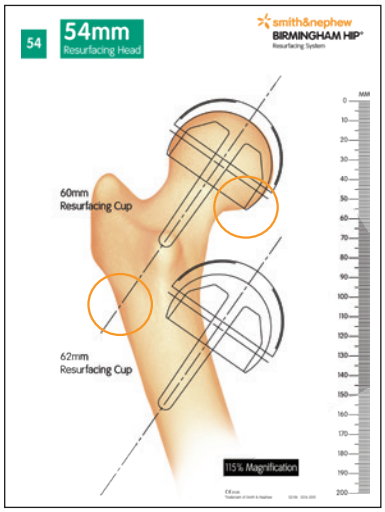


Figure 2

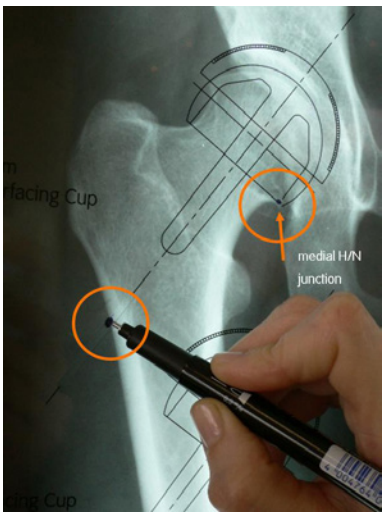


Figure 3

Intra-Operative templating

An assessment is made of the femoral neck diameter using the head/neck template. This provides vital information as to minimum head component size that can be safely used and also the minimum acetabular size that can be utilized. If significant osteophyte formation is present on the femoral neck then this should be removed with rongeurs before definitive assessment of femoral neck diameter is made (Figure 4,5).

Note: Care should be taken to avoid damage to the soft tissue and blood supply during osteophyte removal.

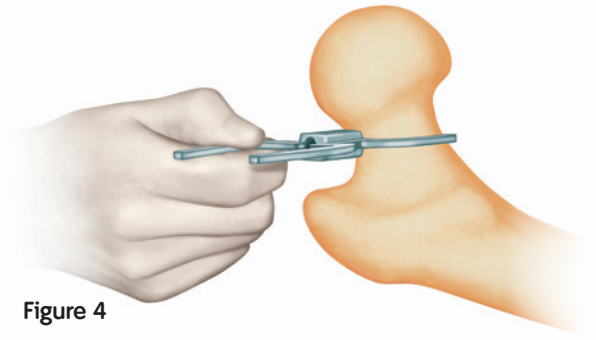


Figure 4

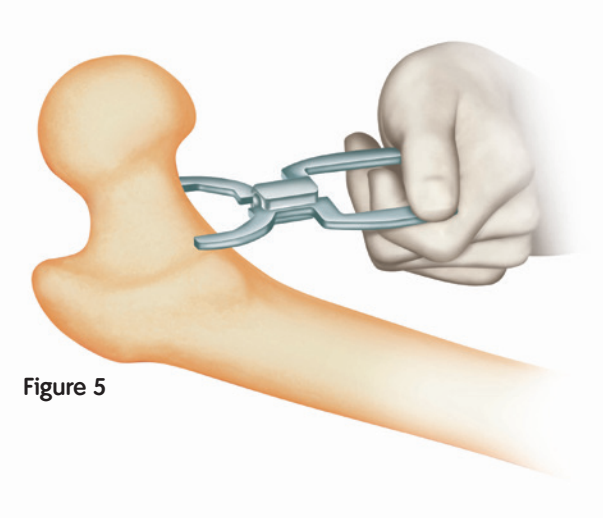


Figure 5

Acetabular preparation

If the antero-inferior capsule is tight an antero-inferior radial capsulotomy is made in line with the psoas tendon. A Hohmann retractor is placed inferior to the radiographic teardrop. The acetabular labrum, transverse ligament and ligamentum teres are excised revealing an unencumbered view of the complete acetabulum and a view of the true floor of the acetabulum. Sequential reaming with hemisperical acetabular reamers is then performed and in normal consistency bone, reaming proceeds to 2mm less than the definitive acetabular component to be inserted (Figure 6).

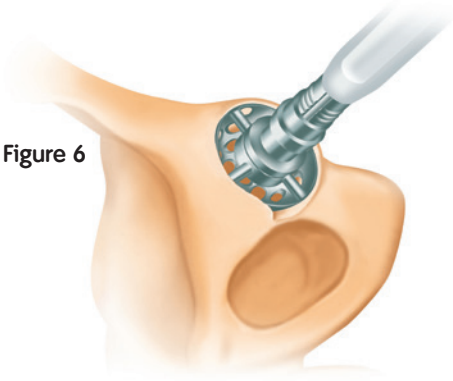


Figure 6

In large patients with soft cancellous bone 3mm under-reaming is recommended. In small patients with sclerotic acetabulae 1mm of under-reaming is recommended.

The cup trial may be used to determine correct implant positioning. If in doubt, medical tweezers can be used to identify optimal seating of the cup. The trial is 1mm smaller than the definitive component size (Figure 7).

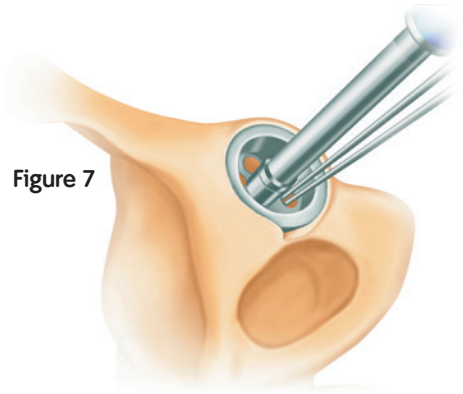


Figure 7

Postero-inferior and antero-inferior osteophytes are excised to allow unobstructed cup insertion. Please note that some designs of acetabular reamers do not have teeth at the periphery and the acetabulum may be unreamed at its periphery making cup insertion difficult (Figure 8).

It is recommended to leave a rim of osteophyte to prevent Psosas impingement on the wall of the acetabular component, avoiding postoperative groin pain.

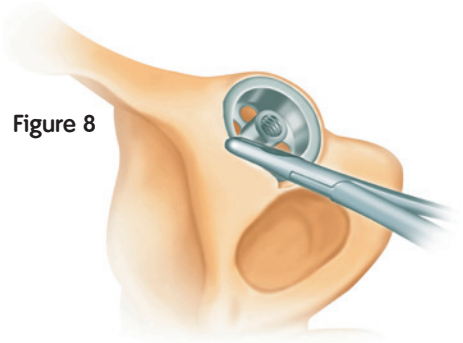


Figure 8

High Performance Cup Introducer Inspection Procedure

The following instructions should be followed to maintain the performance of the BHR® Cup Introducer:

- All instruments should be inspected before use. Any instrument found with a loose or a absent locking screw should be returned to Smith & Nephew for refurbishment. It is particularly important that a thread locking mechanism is used to secure the screws otherwise this problem may recur.
- There should be no excessive free play in the cable tensioning mechanism.

The desired size of acetabular component is mounted on the acetabular introducer and offered up to the acetabular rim. The acetabular cup is rotated so that its anti-rotation splines are adjacent to the ischium and pubis. The acetabular component is then fully impacted with 15-20° of anteversion and 40-45° inclination angle (Figure 9).

The acetabular introducer is removed and the polyethylene impactor cap is retracted at this stage to check that the acetabular component is correctly inserted. Adjustment of the cup position can be made by re-attaching the acetabular introducer. Cup removal is facilitated by the use of the slide hammer extractor attached to the acetabular introducer.

When it is certain that the component is correctly inserted, the cup introducer cables are cut and the cables and the polyethylene impactor cap removed (Figure 10). If the cup must be removed after the cables have been cut then separate cables and extractor assembly are available (code 900201&2). Any protruding osteophytes at the acetabular edge are removed with rongeurs. The femoral head is then reduced into the newly inserted acetabular component.

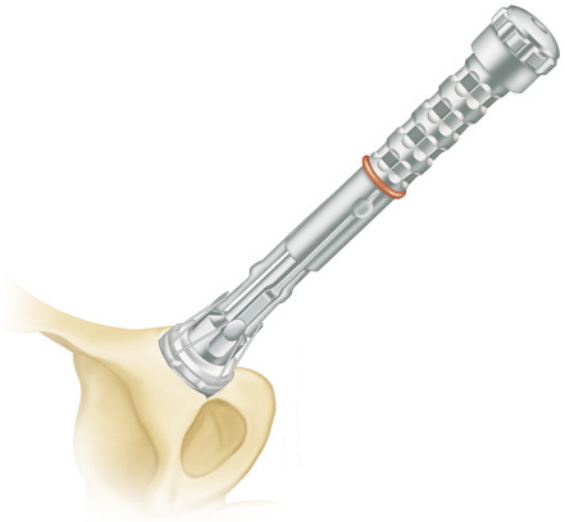


Figure 9

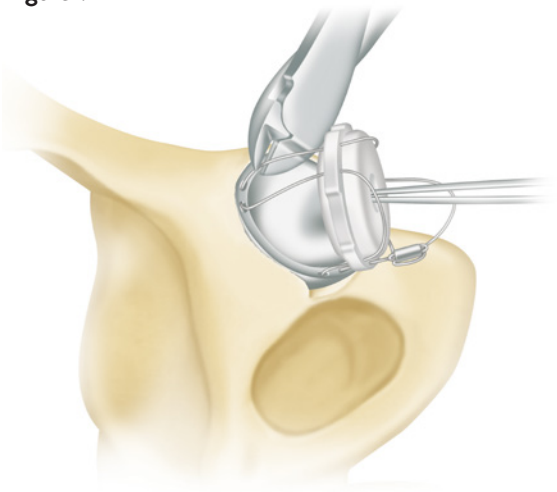


Figure 10

Cautionary statement.

When attaching the cup using the wires and cup introducer, tension should be applied until the cup is securely attached to the introducer assembly. Care should be taken with over tightening and excessive wire tension as this may lead to wire breakage.

Acetabular Cup Introducer Wire Removal Procedure

The following instructions should be followed to minimize the risk of separating the plastic coating when removing the introducer wire.

- Use appropriate wire cutters, in good condition, for the cutting task.
- minimize the number of wormholes the wire is pulled through (multiple cuts).
- Avoid acute angles between the wire and the cup face during withdrawal.
- If the force required to remove the introducer wire is excessive, remove the wire by pulling it in the opposite direction.
- Check that the plastic coating is still present on the wires following the wires removal.

Curved Cup Introducer

These instructions provide important information regarding assembly and wiring for use of the BHR® curved cup introducer.

NOTE: This curved cup introducer is for use with BHR Resurfacing cups only. It is advised that when using Dysplasia cups the standard straight Introducer should be used.

Acetabular Cup Wiring Instruction

The following is the recommended method of attaching the curved cup introducer to the acetabular component.

To ensure correct component fixation, please note that the wire loops are specified as wire loops 1, 2, and 3.

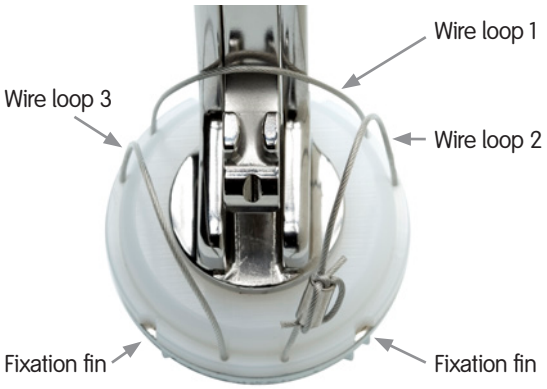


Figure 1

Step 1

The acetabular component is placed over the threaded spigot on the face plate of the introducer, with the introducer passing through wire loop 1.

To ensure correct alignment, check that the fixation fins of the acetabular component are positioned either side of the device (Figure 1, 2).

Figure 2

Step 2

Wire number 2 is then looped over the wire grip (Figure 3).

Note: retracting the wire grip a small way, using the thumb wheel, will apply some tension to the wires and may aid the assembly.

Figure 3

Step 3

As in Step 2, now loop wire 3 over the wire grip (Figure 4).

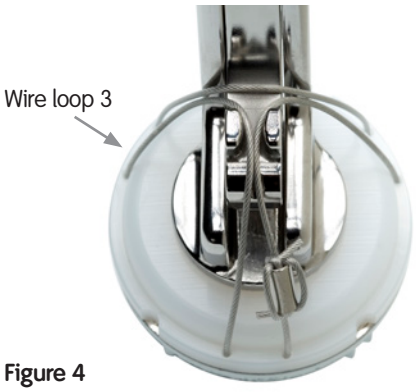


Figure 4

Step 4

With the two opposing wire loops (2 and 3) positioned through the wire grip now capture both wires by passing wire loop 1 over the top (Figure 5).

Figure 5

Step 5

When satisfied that the cup wires are suitably positioned, secure the device by tightening the thumb wheel to a satisfactory tension (Figure 6).

Figure 6

X-Bar

X-Bar (Figure 7)

Figure 7

The X-Bar is attached to the curved Cup Introducer. (Figure 8)

Figure 8

With the patient positioned correctly align the impactor so that the appropriate bar on the guide, left or right, is parallel to the longitudinal axis of the patient while the vertical bar is perpendicular to the floor. This will provide approximately 40-45˚ of abduction and 15-20˚ of anteversion. (Figure 9)

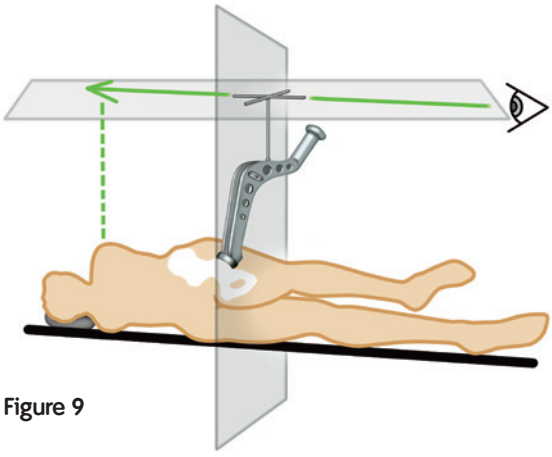


Figure 9

Surgical Tip

- Target acetabular component orientation for optimal bearing function;

  40-45˚ of abduction

  15-20˚ of anteversion

  <45˚ combined stem/cup anteversion

Femoral Preparation

The desired position of the femoral alignment pin will be known from the Preoperative templating. Identify the tip of the greater trochanter through the tissues with a spinal needle.

A ruler is used to measure the desired distance down from the tip of the greater trochanter (Figure 1) and the alignment pin is inserted through the vastus lateralis fibres.

The front and back of the femoral shaft are felt and pin insertion is then started in a transverse direction into the mid-lateral cortex (Figure 2).

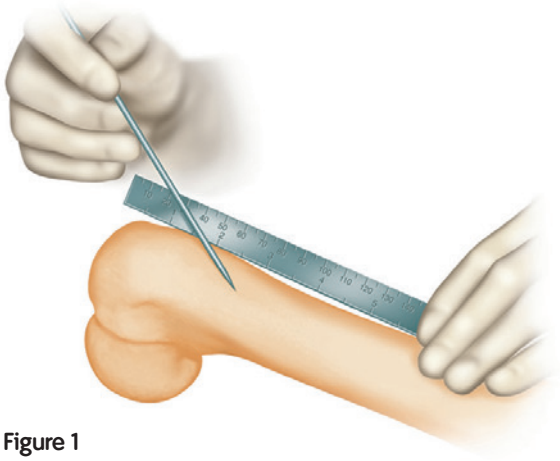


Figure 1

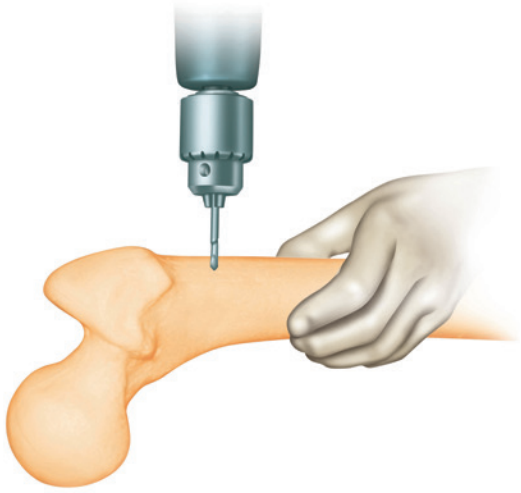


Figure 2

After the outer cortex is breached the drill is angulated so that the alignment pin is directed towards the femoral head (Figure 3).

The alignment pin is left protruding 5mm above the outer fibres of vastus lateralis.

Note: It is recommended that "Pin in Femur" is placed on the nurse's swab count board.

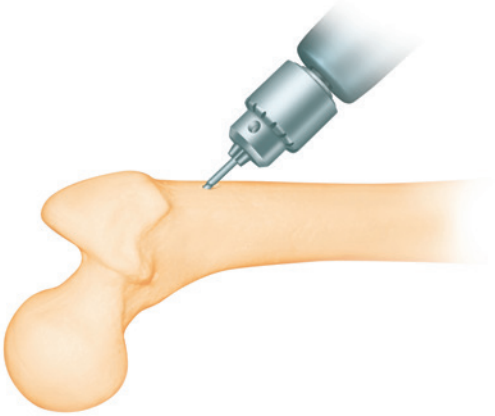


Figure 3

Using the McMinn Alignment Guide

The appropriate head implant size is set up on the head centre stylus. The alignment guide (Figure 4) is hooked onto the alignment pin and the leg fully internally rotated to deliver the femoral head into the centre of the wound.

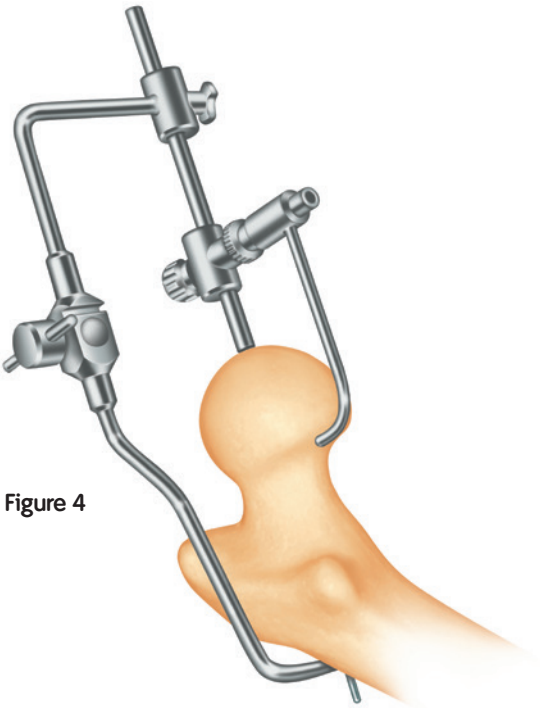


Figure 4

Using the McMinn Alignment Guide *continued*

The adjustable joint in the long arm of the alignment guide is set so that the guide wire will be directed down the mid-lateral axis of the femoral neck (Figure 5a). Bisect the neck with forceps to aid visualization (Not illustrated).

Next the proximal portion of the guide is moved on the femoral head to allow the stylus to be passed around the femoral neck, having first been set to the desired femoral component size (Figure 5b, 5c).

When the stylus can be passed around the femoral neck at an equal distance, then the central cannulated rod is locked into position by impacting the teeth on this rod into the femoral head. Thus the whole assembly is stabilized. Fine-tuning of this position can then occur.

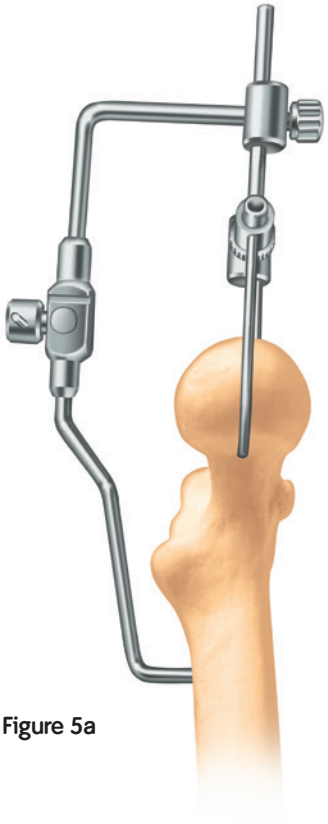


Figure 5a

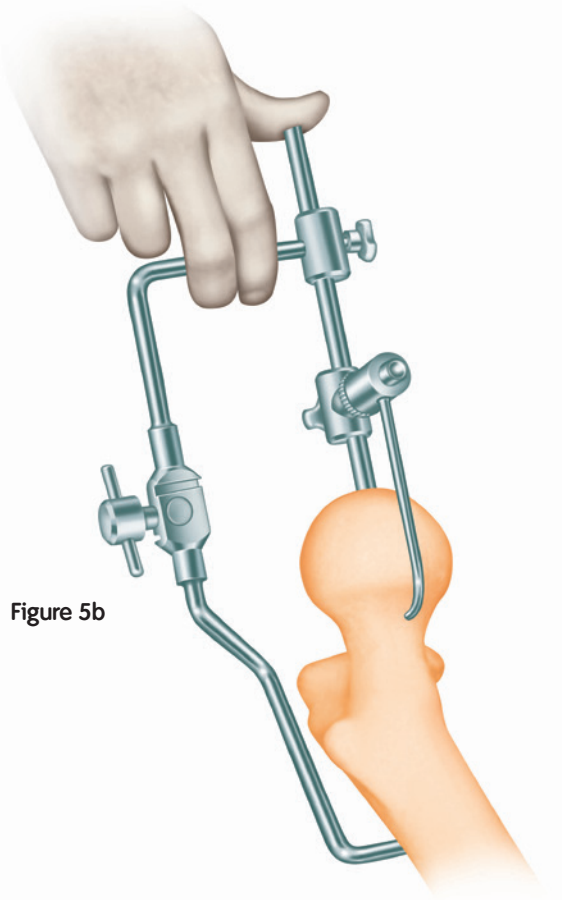


Figure 5b

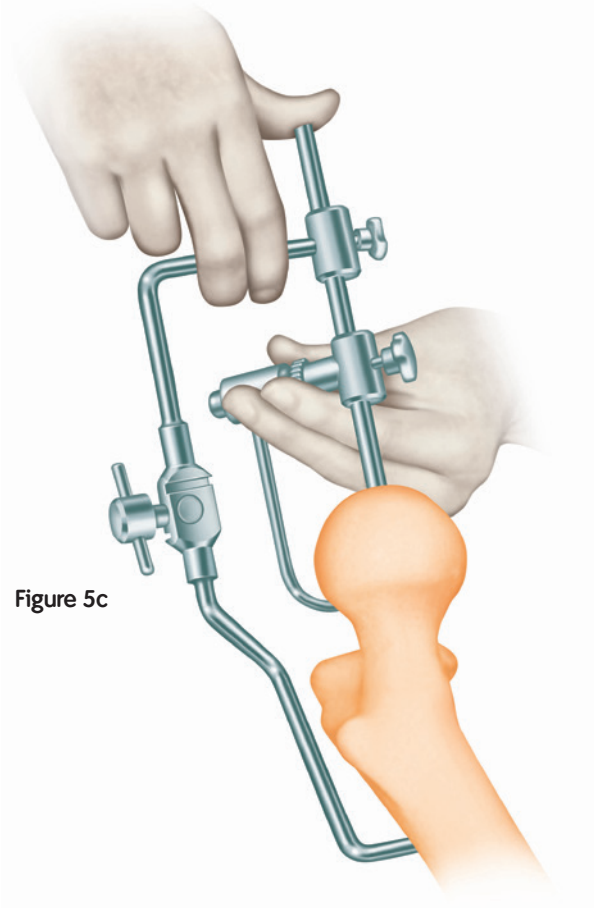


Figure 5c

Templating

BHR® template sets are used to determine component size and correct implant positioning. The position of the femoral component is a most important pre-operative consideration. Varus positioning must be avoided and slight valgus is recommended (Figure 6).

To achieve optimal femoral component positioning, place the appropriate BHR template onto the X-Ray. Once satisfied with the size chosen the medial head-neck-junction may be identified to set up the correct template positioning (A). This is aided by using the cut out section on the template which allows implant position markings to be made with the template in situ.

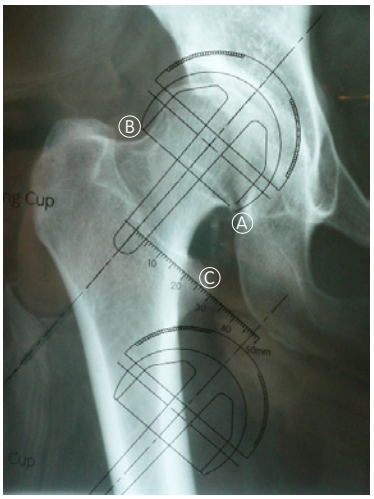


Figure 6

With the head-neck-junction identified the template is rotated around this point until desired valgus position is achieved with the implant's centre line. One limiting factor for implant positioning is the risk of femoral neck notching. This may be avoided at the templating stage by confirming there is no contact between the superior aspect of the femoral neck and the template (B).

When the desired template position has been achieved, the distance from the tip of the lesser trochanter to the centre line of the implant template is measured. The long axis of the ruler template (Figure 7) is overlayed with the centre line of the implant template to identify the pin insertion point on the intertrochanteric crest (C). This measurement is translated intraoperatively onto the patient's femur using the measuring guide (Figure 8) to achieve optimal pin, Jig and ultimately femoral implant positioning. The pin insertion point may be marked using electrocautery or a medical needle to ensure optimal pin, jig and femoral positioning.

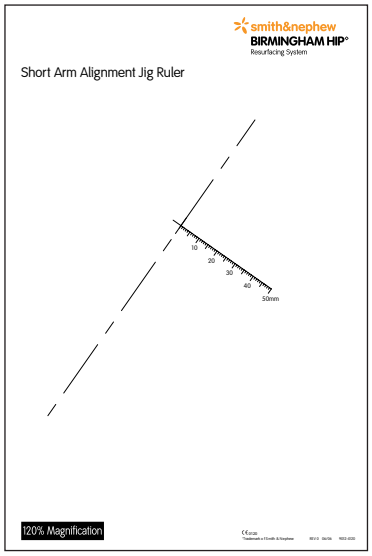


Figure 7

Figure 8

Note: To achieve correct measurement from the tip of the lower trochanter to the pin insertion point, the patient's leg must not be externally rotated while taking the X-Ray in supine position of the pelvis.

X-Ray magnification must be taken into account during this preparation.

Short Arm Alignment Jig Technique *continued*

The measuring guide is placed on the tip of the lesser trochanter translating the Pre-operative measurement on to the intertrochanteric crest. The alignment pin insertion point can now be marked (Figure 9).

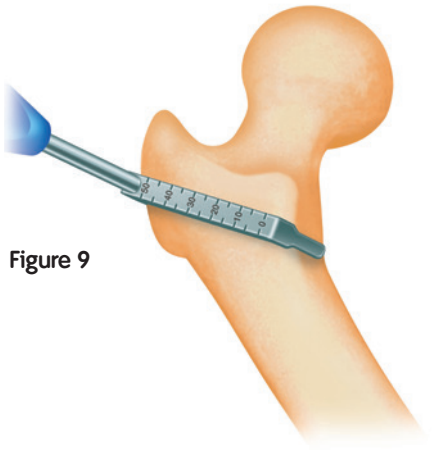


Figure 9

Using the marked insertion point on the intertrochanteric crest, the assembled jig is fixed to the femur by inserting the collared alignment pin through the hole in the distal slot of the alignment arm (Figure 10).

Note: Care should be taken to use the correct collared alignment pin as this differs from the item used with the traditional long arm jig.

The alignment jig can now be used to correctly position the long guide wire and ultimately achieve correct implant positioning (Figure 11).

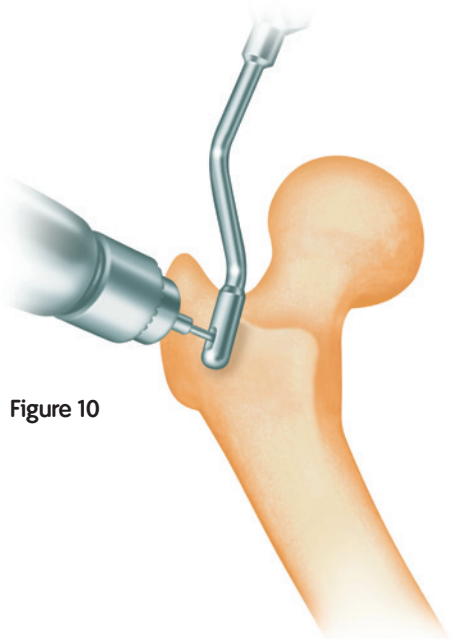


Figure 10

The operation of the short arm jig remains consistent with the traditional McMinn alignment jig as described earlier in this BHR Surgical Technique .

On correct positioning of the long guide wire the alignment guide assembly is released from the femur by first removing the collared pin.

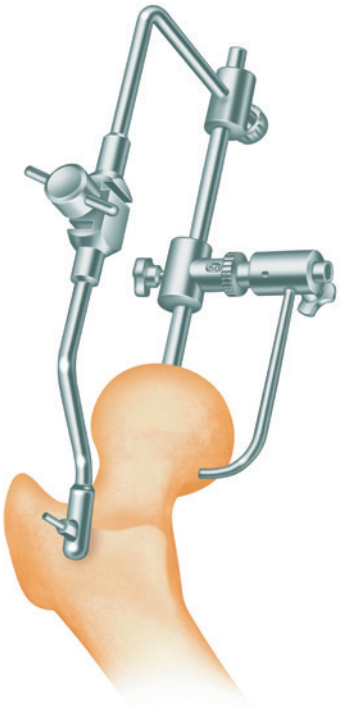


Figure 11

A guide wire is inserted when the desired position of the alignment guide has been achieved. (Figure 12). The central rod is removed and the guide assembly completely removed.

Note: Guide wires are intended for single use only. Re-use of the guide wires may lead to breakage.

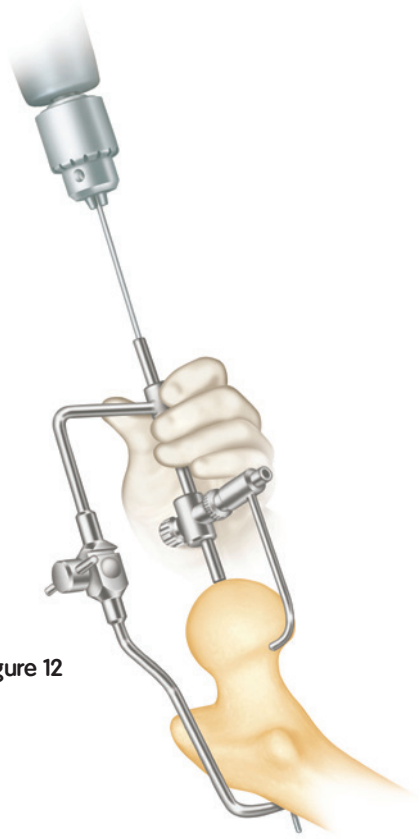


Figure 12

The stylus is re-inserted on the guide wire and a final check made to ensure that the stylus passes comfortably around the femoral neck (Figure 13).

Note: A re-drill guide is available for the correction of minor alignment errors (not illustrated).

Secondly, a check is made to ensure that when the sleeve cut is made some peripheral femoral head support exists. This is not only important with respect to support for the implant, but is very important with respect to the pressurization of cement. Care must be taken in cases of slipped epiphysis, or in pistol-grip deformity where the femoral head is not symmetrically located on the femoral neck.

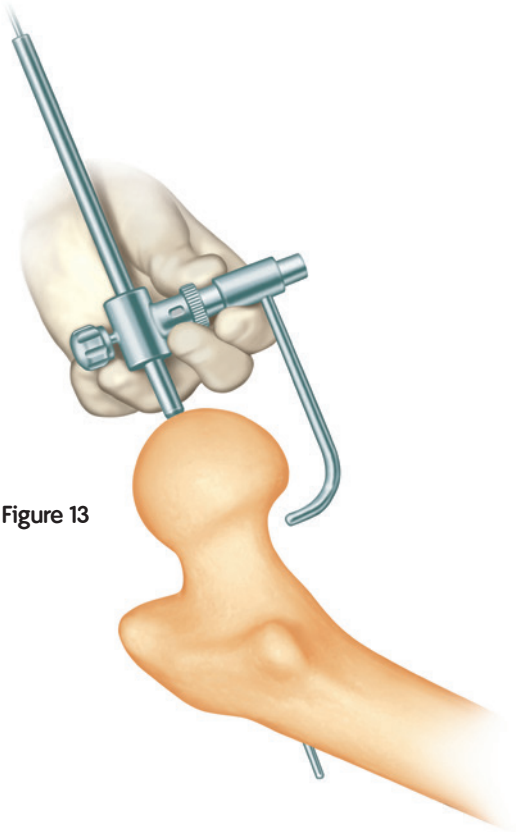


Figure 13

When the desired position of the guide wire has been achieved then the guide wire is overdrilled to the appropriate depth for the implant being inserted (Figure 14).

At this stage a hole is drilled and the vent is inserted into the lesser trochanter and connected to the second suction device (not illustrated). The guide wire is removed and the guide rod inserted (Figure 15).

The most stability is achieved when the thicker lower aspect of the guide rod is placed flush with the bone (Figure 16).

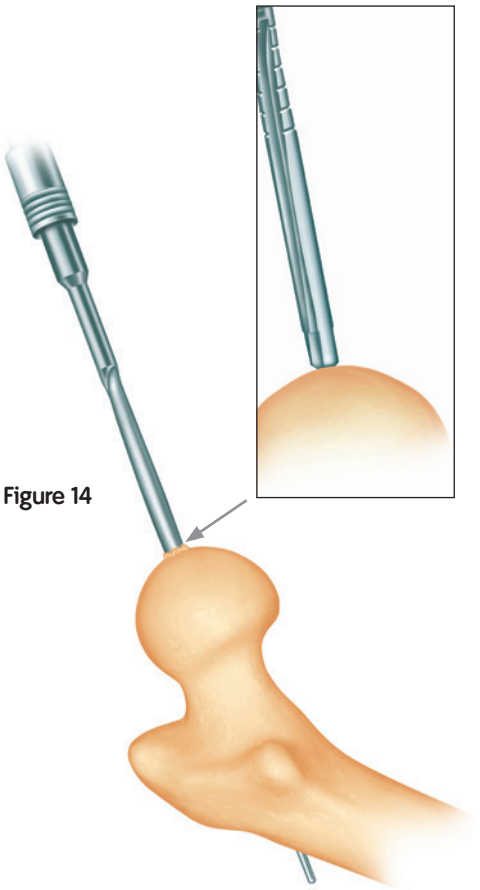


Figure 14

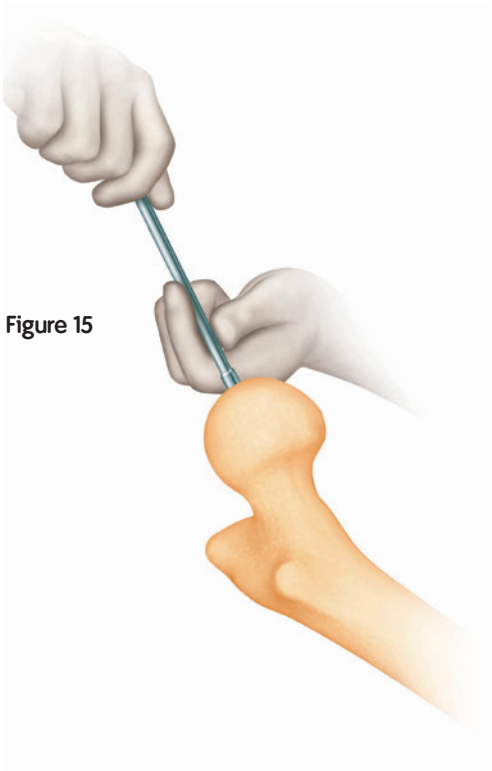


Figure 15

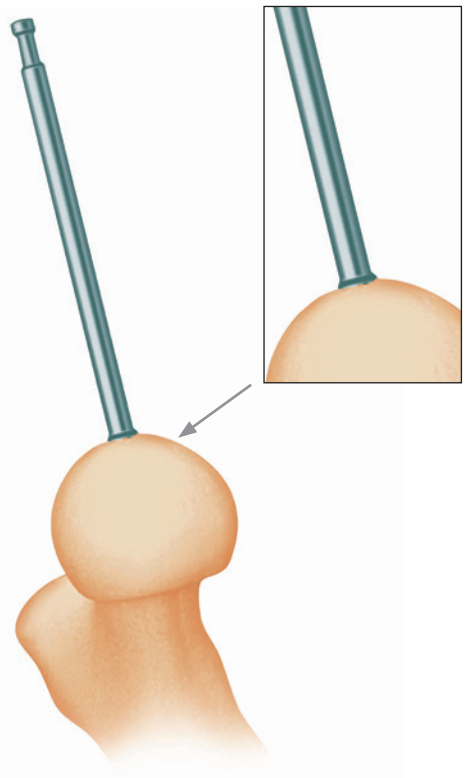


Figure 16

Using the Sleeve Cutter Stop

Smith & Nephew have developed the BIRMINGHAM HIP® Resurfacing (BHR®) Sleeve Cutter Stop to reduce the risk of 'shoot through' and therefore femoral neck notching while preparing the femoral head.

This is achieved by providing a physical method of controlling the distance the sleeve cutter can travel when preparing the femoral head. The sleeve cutter stop stylus allows the surgeon to visualize the sleeve cutting diameter and depth on the patient's femoral neck before performing the sleeve cut.

The sleeve cutter stop stylus is used over the guide rod which has been inserted into the pre-drilled femoral head.

The appropriate head implant size and therefore sleeve cutter is set up on the sleeve cutter stop stylus. This is done in two ways; the first is to set the size using the thumb wheel this allows the chosen size to be read through the stylus window (Figure 17).

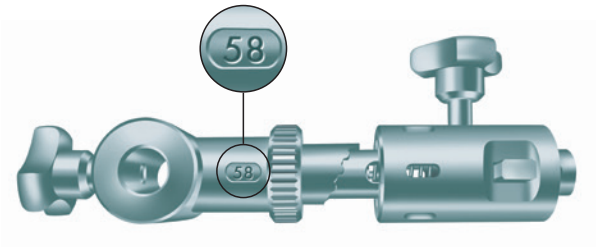


Figure 17

Secondly the stylus arm is set by moving it up or down within the body of the stylus until the correct size is shown on the scale along the top side of the stylus body (Figure 18)

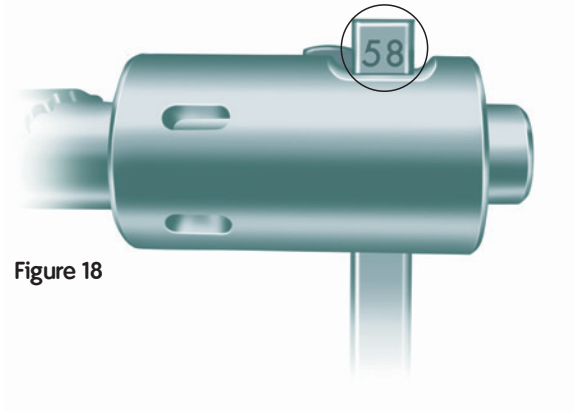


Figure 18

Using the Sleeve Cutter Stop *continued*

The sleeve cutter stop stylus is placed on the guide bar. The stylus arm is passed over the femoral head. It is the superior aspect of the femoral neck which is most prone to notching on 'shoot through' therefore this should be the starting point for positioning the tip of the stylus arm (Figure 19).

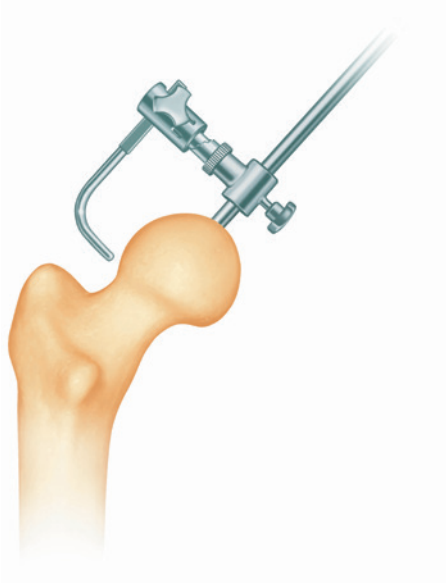


Figure 19

The positioning of the tip of the stylus denotes the depth the sleeve cutter will cut to (Figure 20)

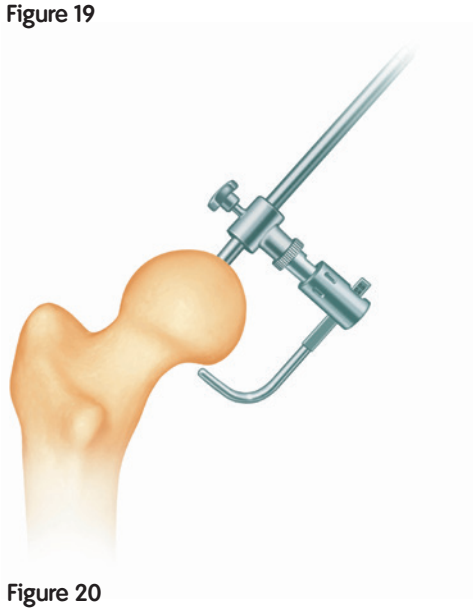


Figure 20

The tip of the stylus arm should be in contact with the femoral head but remain in clearance of the femoral neck.

The thumb screw is then tightened against the guide bar to set the chosen depth.

The stylus should now be passed around the femoral neck to confirm the chosen depth is accurate. (Figures 21 and 22)

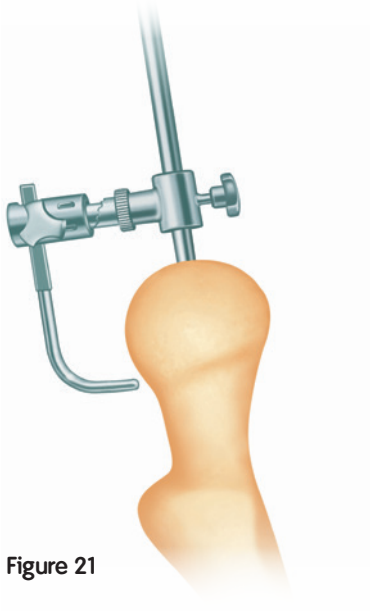


Figure 21

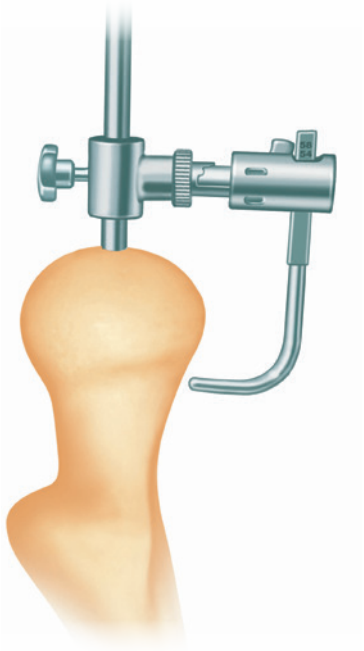


Figure 22

When satisfied with the chosen cutting depth an sleeve cutter stop spacer is selected. The correct size of spacer is determined by the space in between the base of the instrument and the top on the femoral head. This is achieved using two methods; the spacers may be placed into the space until the desired size is selected (Figure 23). Alternatively a ruler may be used to measure the space and then the corresponding sized spacer selected. 6 spacers are provided 10, 12, 14, 16, 18 and 20mm.

The sleeve cutter stop is now removed from the guide bar. The selected spacer is then placed onto the guide bar until it is in contact with the femoral head (Figure 24). The sleeve cutter stop may then be placed over the guide bar and advanced to the top of the spacer. The stylus is now passed around the femoral neck to confirm the intended cut depth is correct and no neck notching should occur. When satisfied the sleeve cutter stop stylus is removed from the guide bar and the spacer left in place.

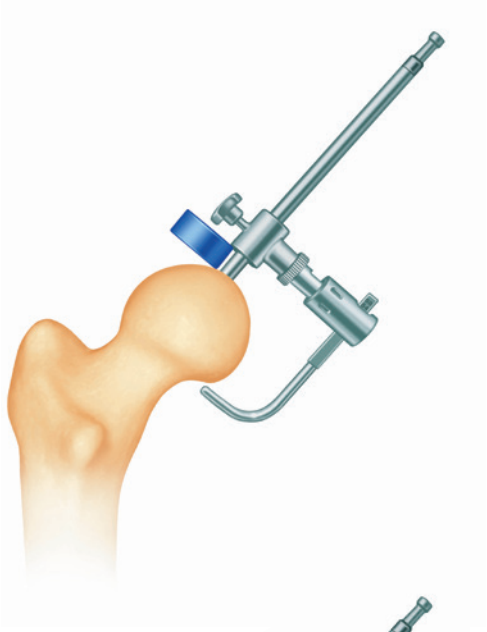


Figure 23

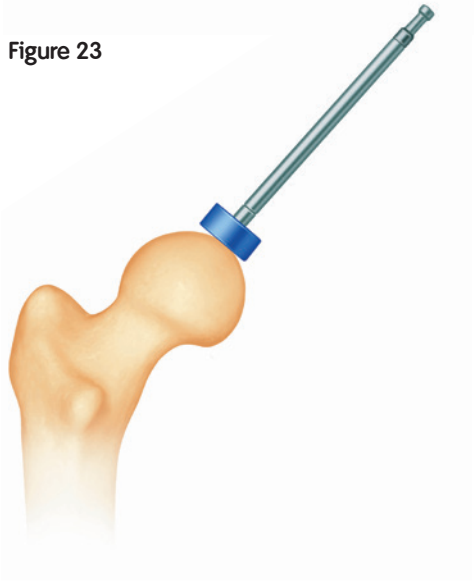


Figure 24

Before femoral head preparation, the base of the femoral neck is packed with wet swabs to prevent bone debris entering the peri-articular soft tissues. However it is important to keep these swabs clear of the head so that they do not catch in the femoral cutter instruments.

The head/neck template is then positioned on the superior femoral neck as a second safe guard, to protect the head/neck junction in the event of 'shoot through' (Figure 25).

The appropriate sleeve cutter is advanced. This should be done slowly and with care to ensure that 'shoot through' does not occur and also to ensure that femoral neck notching is not occurring It should be noted that in most osteo-arthritic femoral heads an eccentric amount of peripheral femoral head is regularly removed.

NOTE: The assistant is key in keeping the femoral head in the centre of the wound.

The sleeve cutter is advanced until it comes up against the spacer and cannot be advanced further (Figures 26 and 27). The sleeve cutter stop spacer is now removed.

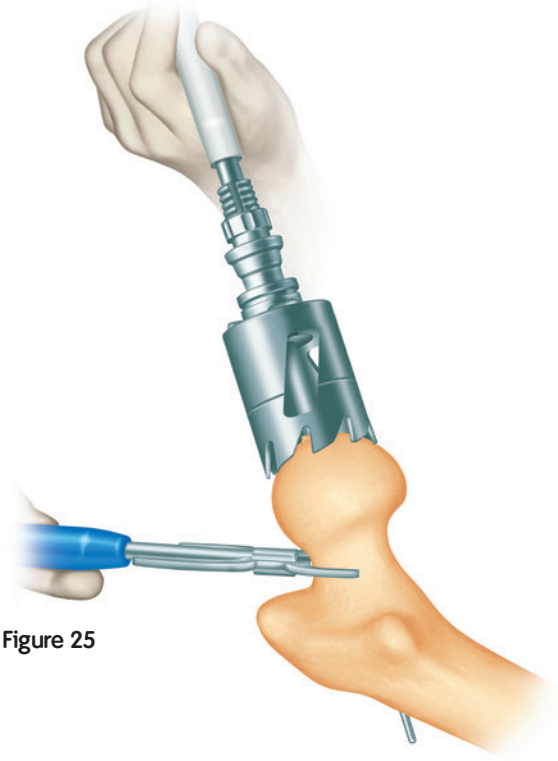


Figure 25

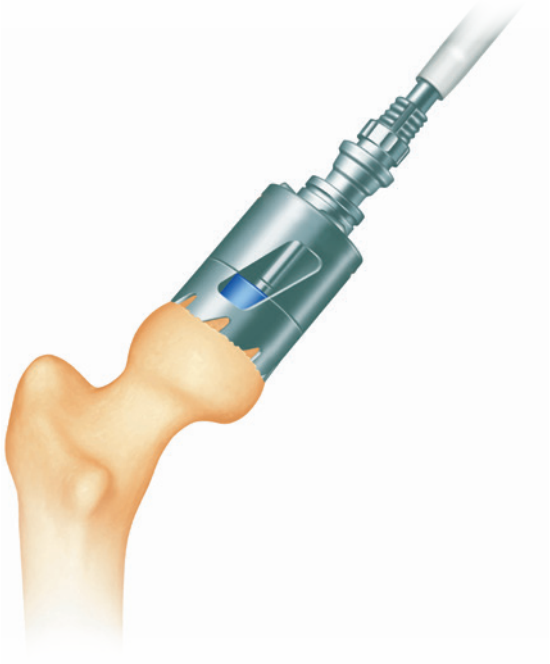


Figure 26

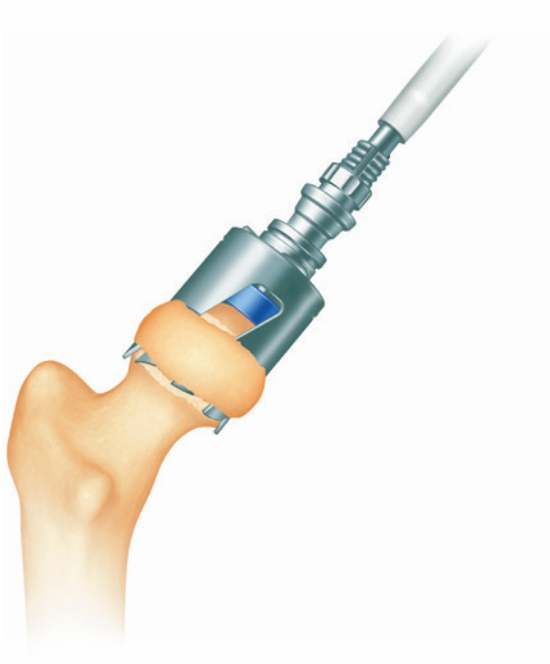


Figure 27

The peripheral bone and any head/neck osteophytes should be trimmed off taking care not to strip any soft tissue attachments from the femoral neck (Figure 28, 29).

The guide rod is pushed down the femur by hand until it is seated at the bottom of the prepared hole and left in its final position (Figure 30). **NOTE: Care should be taken that the thick aspect of the guide bar is now seated below the surface of the bone, as the thick aspect of the guide bar can act as a stop when using the plane cutter.**

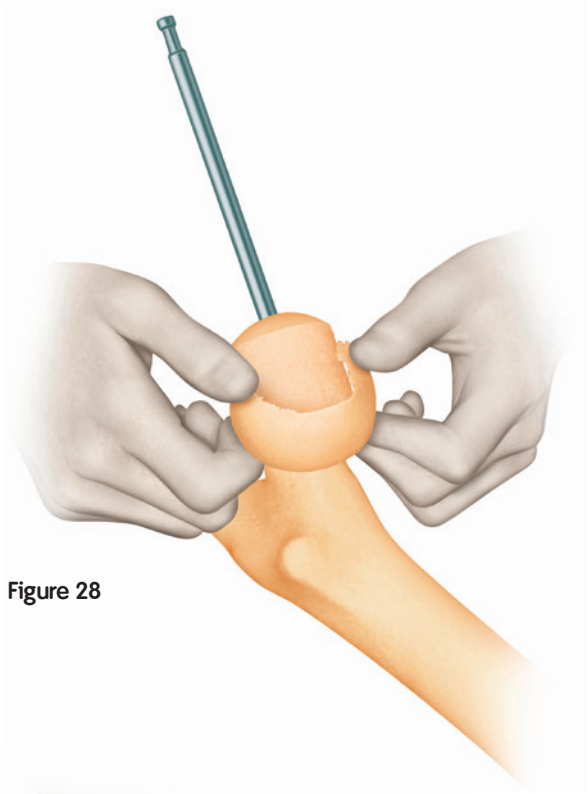


Figure 28

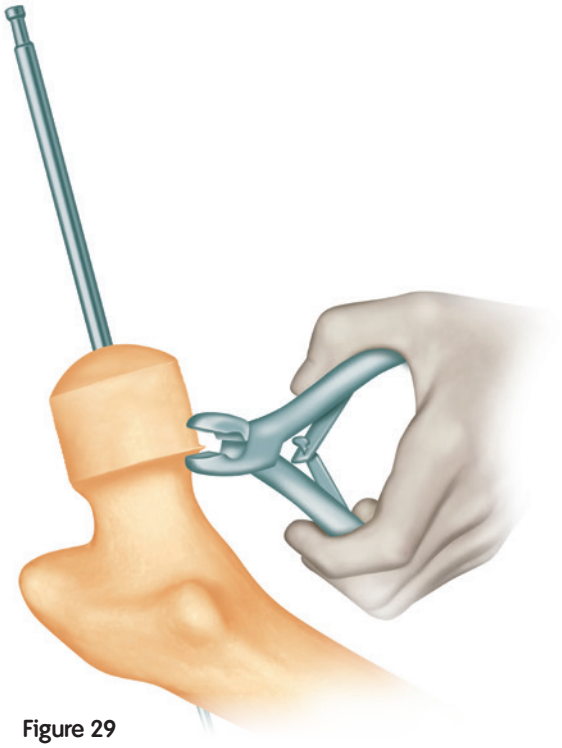


Figure 29

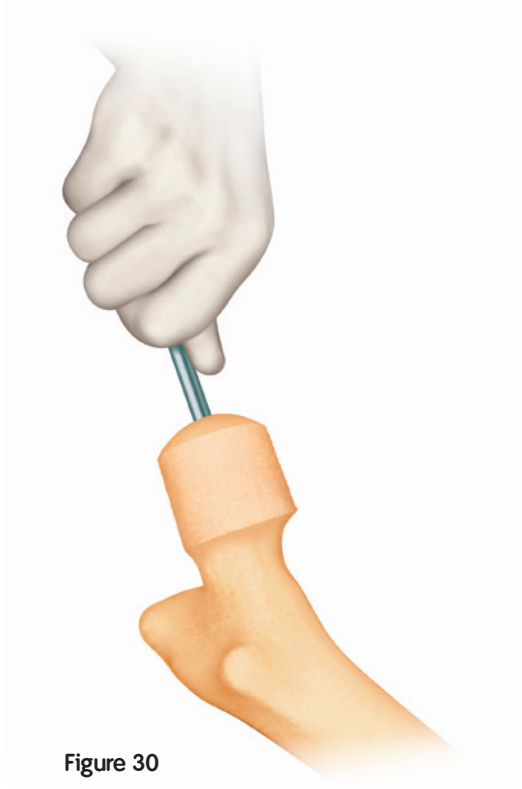


Figure 30

Note: Various methods of templating the desired amount of proximal bone to be removed may be employed.

The sleeve cutter is advanced by hand over the previously prepared femoral head until the teeth meet the medial femoral head/neck junction (Figure 31). Once in correct position, a surgical marking pen is used to mark the resection line on the bone surface through the 'window' in the sleeve cutter. Alternatively, the appropriate head/neck template is advanced over the prepared femoral head until the lower aspect meets with the medial head-neck junction. The surgical marking pen is used to mark the resection height which is indicated on the scale of the device (Figure 32).

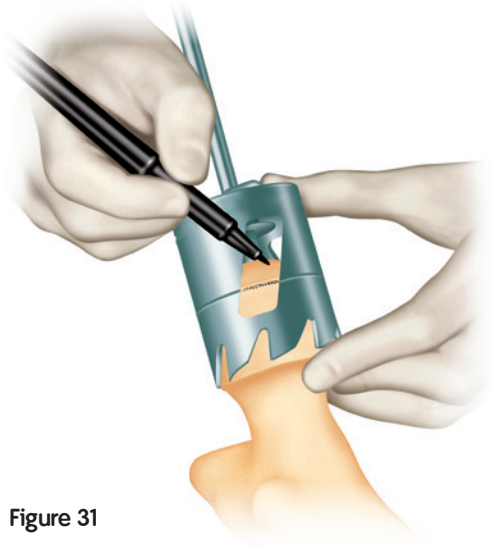


Figure 31

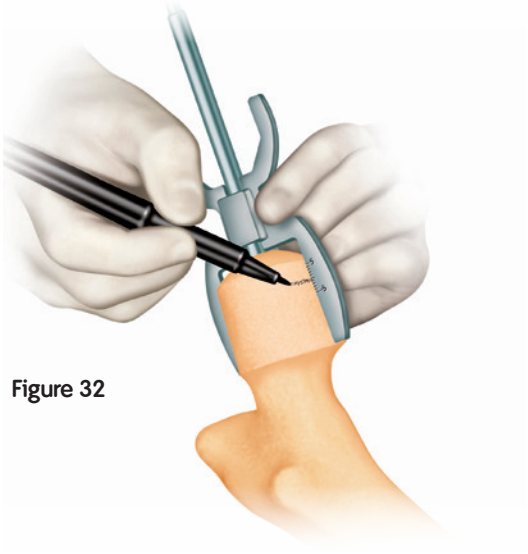


Figure 32

The Plan Cutter is then advanced over the guide rod stopping at the marked resection line (Figure 33). Identify the marked resection line with the guide wire to aid visualization.

To ensure correct bone resection, the head-neck template is to be advanced over the guide rod. Meeting the medial head-neck junction, bone has to point to the neutral (0) position of the device (Figure 34).

The appropriate chamfer cutter is used (Figure 35). It will usually be the case that the eccentricity of the femoral head disappears after chamfer cutting. Great care needs to be undertaken when using this instrument as considerable torque can be generated by the mixture of sclerotic and normal bone in the femoral head, so the instrument is advanced lightly and with regular irrigation. Experience has shown that high speed is advantageous and the powerdriver is set on drill rather than ream, thus giving high speed and low torque.

Note: It is recommended to start all power tools away from bone before advancing over the guide rod. This keeps torque and stress to a minimum.

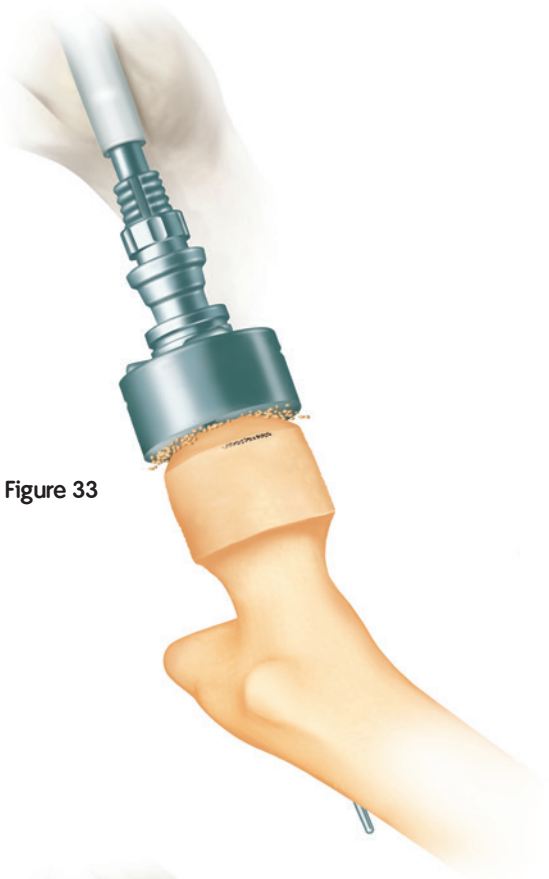


Figure 33

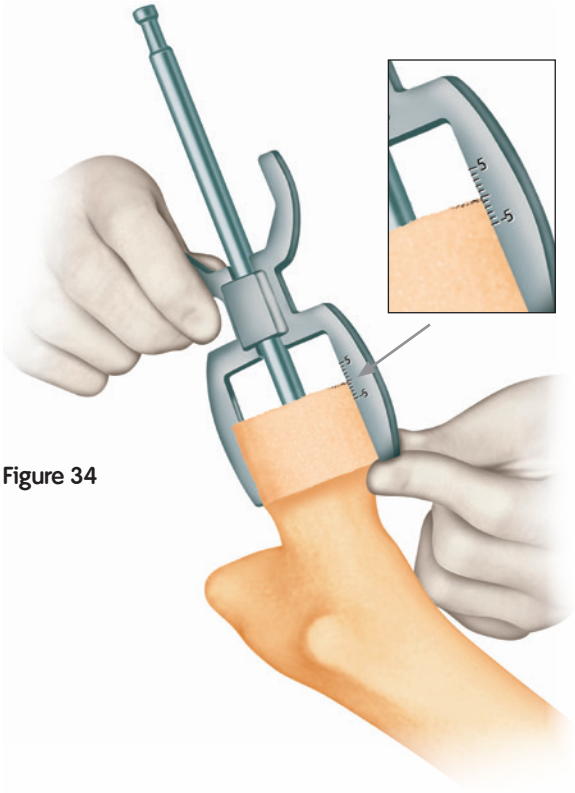


Figure 34

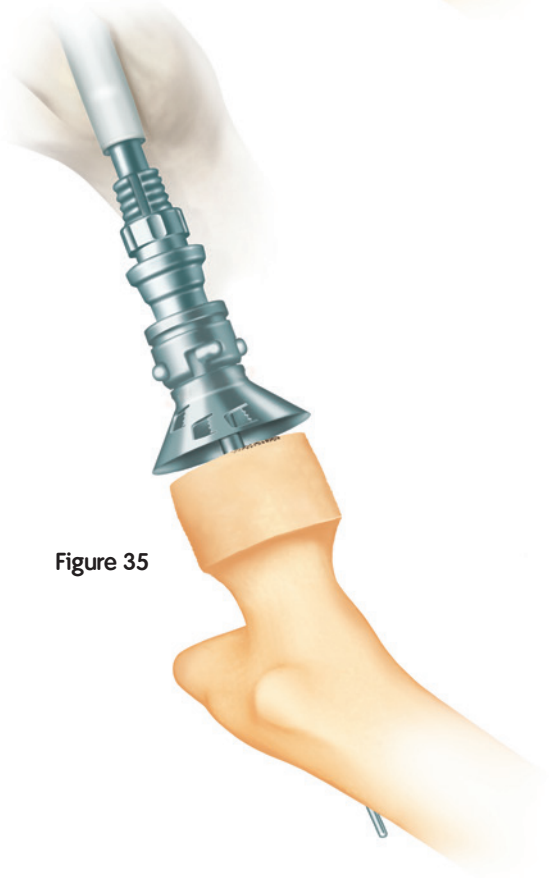


Figure 35

A number of cement keyholes are drilled into the femoral head using the Wroblewski drill (Figure 36). At this stage any cysts are curetted. If the defects are relatively small, they are left and will be filled with cement. If the defects are substantial, they may be grafted with acetabular reamings prior to cementation.

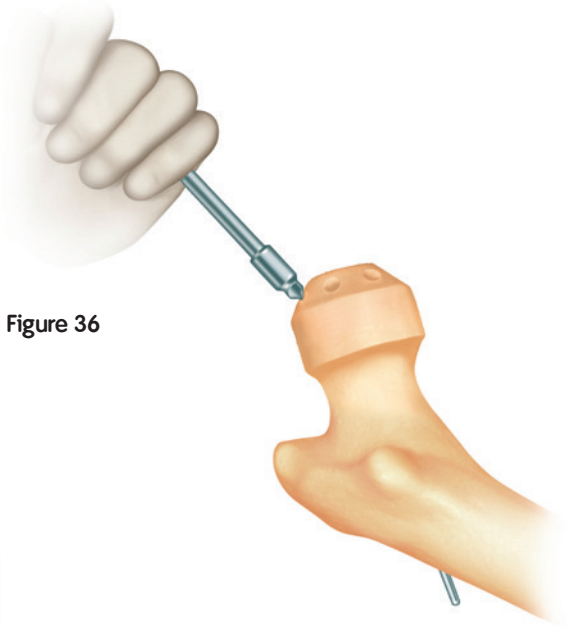


Figure 36

The femoral head is thoroughly lavaged and brushed to open the cancellous network (Figure 37). With maximum rotation on the femur, the suction vent is inserted into the lesser trochanter (Figure 38). The femoral head can usually be kept free of blood until cementation occurs.

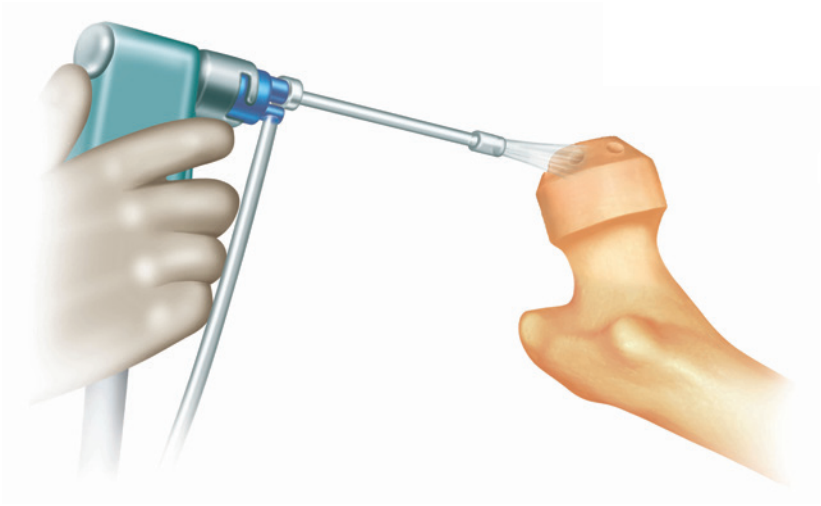


Figure 37

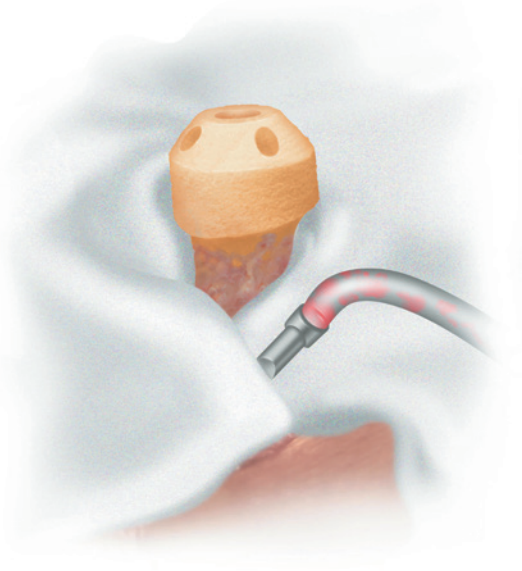


Figure 38

Using the Stem Drill

The appropriately sized stem drill (tapered reamer) is used to enlarge the parallel hole to suitably fit the tapered stem of the femoral component. There are two sizes of stem drill (tapered reamer) which correspond to sized groups of femoral components as follows:

Size 2 = 48-52

Size 3 = 54-62

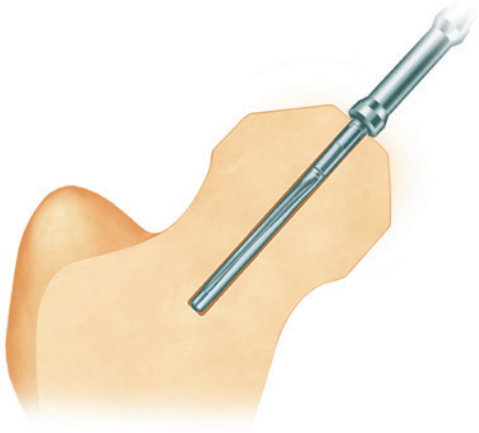


Figure 39

A mark is made on the femoral head-neck junction using the appropriate head-neck template over the guide rod (Figure 40) and surgical marker pen or electro-cautery to determine how far the prosthetic femoral head component should be advanced. Impacting the prosthetic head to this mark ensures optimum pressurization of cement into the open cancellous network, gives good support for the implant and ensures, as far as possible, the correct leg length. The guide bar is then removed. Low viscosity cement is mixed and poured into the head implant. Alternatively, it can be drawn up into a bladder syringe and injected into the femoral component (Figure 41).

Note: Low viscosity cement in sufficient quantity is used. High viscosity cement will prevent correct femoral component seating.

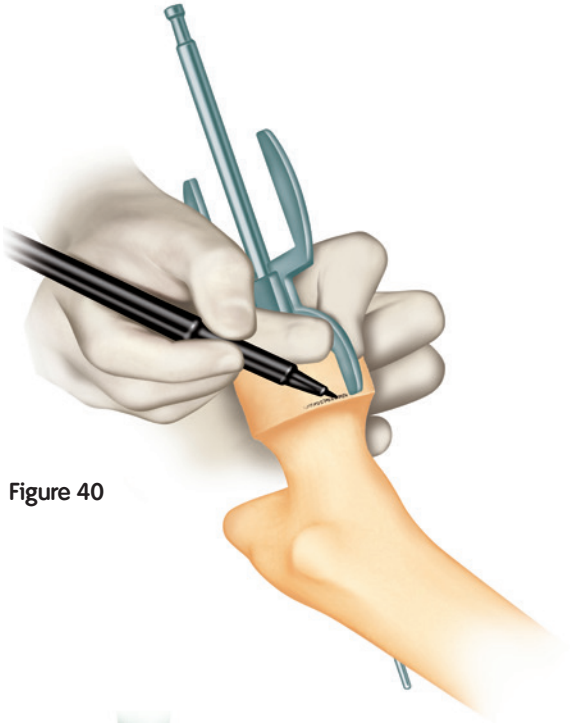


Figure 40

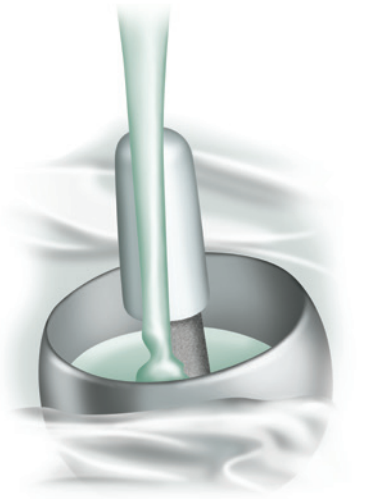


Figure 41

One minute after the start of cement mixing, the femoral component is impacted into position to the previously made mark (Figure 42). It is important to have a swab positioned anteriorly to collect any extruded cement and to prevent this from flowing into the acetabular component. It is important not to get this swab caught between the femoral component and bone.

All extruded cement at the periphery of the femoral component is removed. Any remaining osteophytes at the femoral head-neck junction are excised (Figure 43) and the femoral head thoroughly cleaned with wet swabs and pulse lavage. The acetabular component is also thoroughly cleaned with pulse lavage and preparations made for reduction.

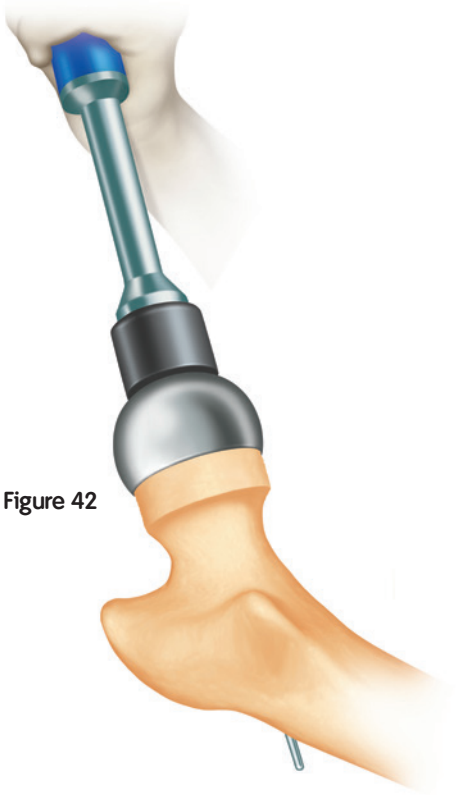


Figure 42

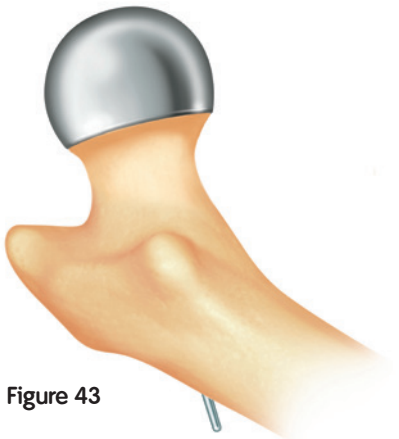


Figure 43

Using the Stem Drill *continued*

When traction and rotation are applied to the femur the femoral component can be cleanly located in the acetabular component. Scratching the femoral component against the edge of the acetabular component should be avoided and without trapping any capsule or synovial tissue between the femoral head and the acetabular component. A check is made to ensure that no entrapment of soft tissue has occurred between the reduced components and a check is also made for stability and range of movement.

The femoral alignment pin is removed from the lateral femoral cortex (Figure 44) and the wound closed in layers using nylon for the fascia lata.

Note: It is vital to remove the alignment pin from the femur and this should be recorded on the swab board.

The patient is mobilized full weight bearing the following day and sticks abandoned between one and three weeks after operation as confidence and a normal gait allow.

Patients are allowed to sit on a normal height toilet seat or chair and sleep on their unoperated side as desired.

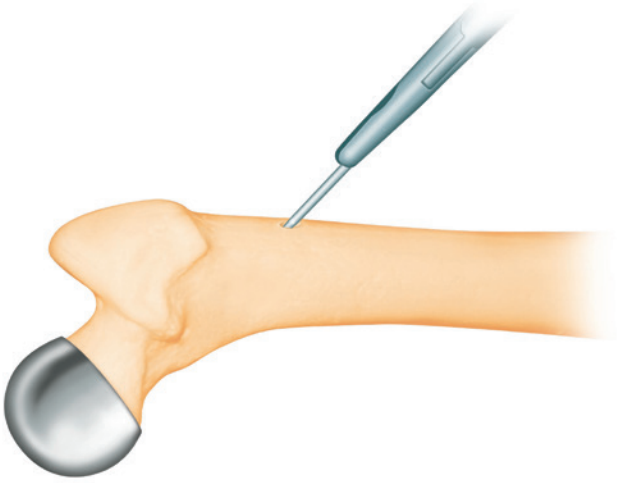


Figure 44

Size Chart

The size charts (available as a wall chart for classic sizes and combined sizes) are presented to remind the surgeon of the femoral head and cup sizes that can be matched (Figure 45).

For example, the size 50mm femoral component can be matched with a size 56mm acetabular cup, a size 58mm acetabular cup, or size 58mm dysplasia cup. All these components have red coloured labels on their boxes.

Never mix colors on heads and cups. Compatible femoral and acetabular components are all the same color.

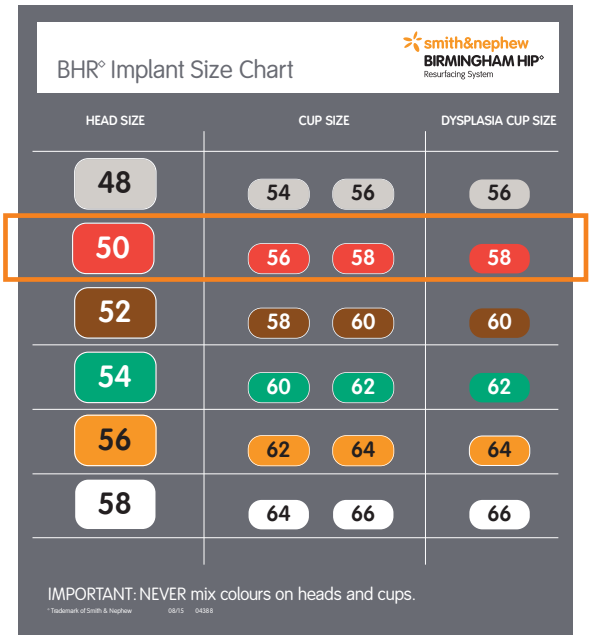


Figure 45 – Implant Size Chart Classic Sizes

Dysplasia Cup

Where there is an obvious superolateral deficiency of the acetabulum, the option exists for the use of the BHR® Dysplasia Cup which uses a unique screw fixation to stabilize the acetabular implant. The acetabulum should be reamed in the true hip centre position. In severe dysplasia it is desirable to bias the acetabular reamers in a posterior direction, to thin the thickened posterior acetabular wall and preserve the deficient anterior acetabular wall. It is recommended to deepen the acetabular floor to the inner table to gain maximum superior cover in dysplasia. On occasions a slightly high hip centre will give enough support for a regular spherical cup. If there is not enough superior support for a spherical cup then the options are either augmentation of the acetabular roof with a structural allograft or the use of a BHR dysplasia cup and morcellised autografting of the acetabular defect.

In order that the screws engage bone, the dysplasia cup should be rotated anteriorly (not anteverted) from the neutral position (Figure 1). The cup is impacted to the floor of the acetabulum.

Note: Do not cut the cables at this stage.

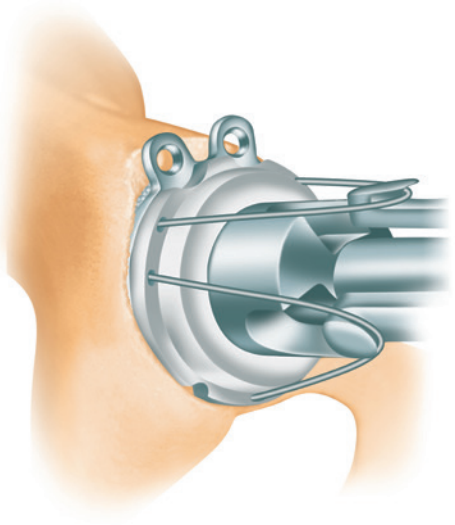


Figure 1

Retract the polyethylene impactor cap and ensure satisfactory cup position. Always drill the posterior lug first as this is the drill hole most likely to miss the posterior ilium (Figure 2). If this happens, re-apply the cup introducer and reinsert the cup with more anterior rotation. Please note that excess anteversion and an excessively closed position of the acetabular component increase the chances of the posterior drill hole missing bone.

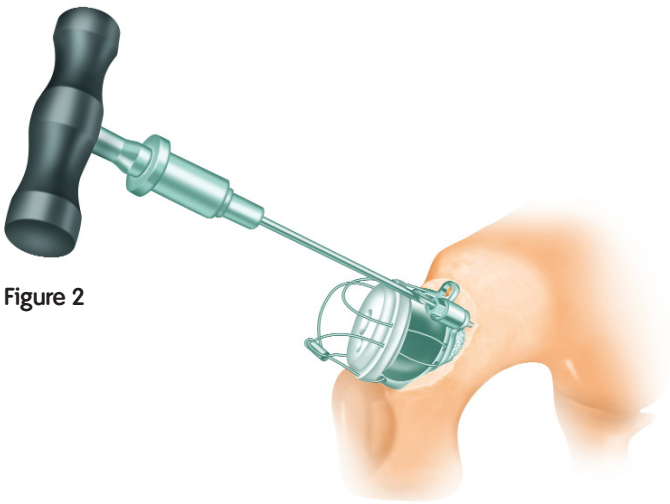


Figure 2

The pilot drill guide should then be screwed into the posterior lug and a 3.2mm drill passed to the inner cortex.

If the cup is positioned satisfactorily the pilot drill guide is then removed and the larger dysplasia screw drill is used to over-drill this hole through the lug, opening the canal to the screw core diameter. A depth gauge is used to gauge screw length. In severe dysplasia maximum screw length is desirable. In less severe dysplasia shorter screws can be used. Please note: these screws are neutralization screws, they are not compression screws and if inserted correctly they are not distraction screws.

A BHR® dysplasia self-tapping screw of appropriate length is then threaded through the lug using the socket provided and the screw driver handle (Figure 3). When the screw reaches the bone longitudinal compression is applied as the screw engages the bone, thus preventing the cup from being pushed out of the acetabulum.

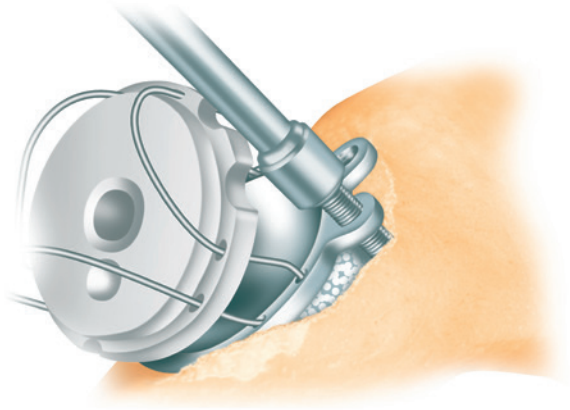


Figure 3

Dysplasia Cup *continued*

Once the screw is securely fixed in bone then power may be used to drive the screw home. This requires the high torque ream setting.

Final tightening is applied using the 'T' Handle and the screw head should sit flush on the lug face. The final tightening is engineered deliberately tight to prevent screw back out. The sequence is then repeated with the anterior lug (Figure 4). When both screws have been inserted the cables are cut and the polyethylene impactor cap removed. The false acetabulum is cleared of all soft tissue with a curette and the bone petalled with a gouge. The defect is grafted by impacting reamings into the defect between the cup and false acetabulum. This is then covered with surgical mesh for stabilization.

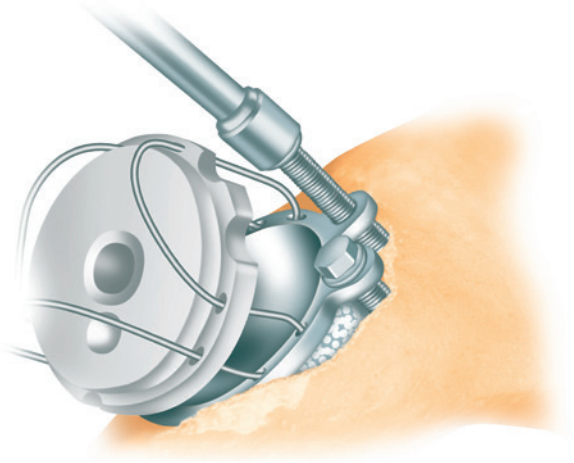


Figure 4

With acetabular dysplasia the surgeon has to exercise judgement regarding the post-operative weight-bearing regime. In severe dysplasia we recommend keeping the patients partial weight-bearing, using elbow crutches for six months, but in less severe dysplasia full weight-bearing is permitted from the first post-operative day.

A typical regime for moderate dysplasia is partial weight bearing using elbow crutches for six weeks, followed by two sticks with gradually increasing activity over the next six weeks. We now have histological evidence of impressive bone ingrowth into the hydroxyapatite coated POROCAST® bone ingrowth cup surface at six weeks. However, in severe dysplasia we recommend to see radiographic evidence of bone graft incorporation in the false acetabulum before allowing the patient to become fully active.

Additional screw fixation of the acetabular component by utilizing the dysplasia cup may be desirable in certain non-dysplastic acetabulae. In these non-dysplastic acetabulae, the edge of the superior acetabulum impinges on the lugs, thus preventing complete seating of the acetabular component. Therefore, the operating surgeon may utilize a surgical burr to facilitate placement of the lugs without compromising the acetabular orientation.

Thrombo-embolic Prophylaxis

It seems clear that thrombo-embolism is much more of a problem following hip arthroplasty than with any type of soft tissue surgery. It is obvious that some factor in addition to venous stasis and endothelial damage is at work. This factor is bone marrow and fat embolization caused by the insertion of a femoral component, particularly a cemented femoral component.

During preparation of the upper femur and insertion of a cemented THR femoral component, pressures up to 1400mm Hg have been measured in the distal femur. These very high intramedullary pressures displace marrow and fat into the venous circulation. During hip dislocation from all surgical approaches the femoral vein is kinked and it is not until reduction of the prosthetic head into the acetabular component that marrow and fat gush into the right heart and pulmonary circulation.

Any surgeon who has observed this fat embolization with trans-oesophageal echocardiography following insertion of a cemented femoral component of a THR cannot fail to be amazed by the resilience of the human to survive such an assault (Figure 1).

It is quite remarkable how few patients develop acute circulatory collapse or clinical fat embolism syndrome following cemented THR. However this displaced marrow is rich in tissue thromboplastin and this acts as a potent activator of the clotting system. It is this activation of the clotting cascade by displaced fat and marrow, in addition to venous stasis and endothelial damage, that gives our thrombo-embolic problems.

Application of the cemented femoral component of the BIRMINGHAM HIP® Resurfacing (BHR®) System also raises the femoral intra-medullary pressure, but the amount of fat displaced is much less than with a cemented stemmed THR (Figure 2).

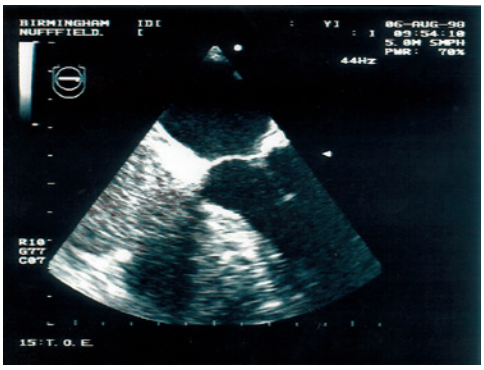


Figure 1 - Snowstorm appearance of major fat embolization with fat entering the right atrium (RA) and right ventricle (RV) following cemented stemmed THR.

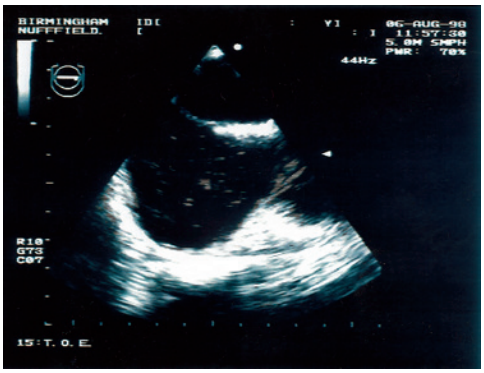


Figure 2 - Trans-oesophageal echocardiograph showing reduced fat embolization following a BIRMINGHAM HIP® Resurfacing.

In an effort to prevent the small amount of fat displacement known to occur with resurfacing, use a method of suction venting of the femur during femoral preparation and component insertion. A hole is drilled through the lesser trochanter and a cannula is inserted into the centre of the femoral canal. This is attached via extension tubing to a second suction unit. During insertion of the cemented femoral component there is an impressive amount of fat and marrow removed from the femur (Figure 3).

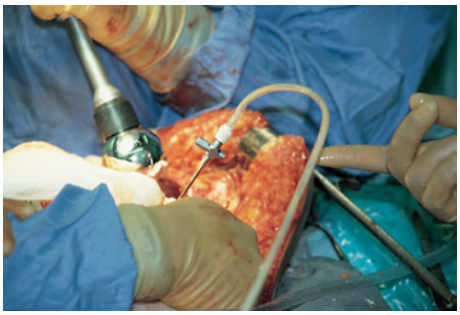


Figure 3

Acetabular Cup Extraction Kit (Cat. no. 900-201)

Instruction for Use

Intended Use

The Acetabular Cup Extraction Kit is intended for use to remove acetabular components of the BIRMINGHAM HIP® Resurfacing device during revision operations.

Sterility

The Acetabular Cup Extraction Kit is provided sterile for SINGLE USE ONLY. The sterilization method is gamma irradiation with a minimum of 25 kGy and a maximum of 35 kGy. The Acetabular Cup Extraction Kit must not be resterilized by the user.

Mixing of Components

This kit should never be used in conjunction with other manufacturer's implants or instruments.

Indications

The indication for use of this kit includes all revision operations where revision of the BHR acetabular cup is necessary.

Contraindications

None.

For more information on the BIRMINGHAM HIP Resurfacing System please see the General Information Leaflet enclosed with each implant and the operative technique.

Introduction

To extract an implanted Smith & Nephew BHR Acetabular Cup, a cable must first be threaded through the 3 wormholes and joined with a metal collar using a special knot. This provides three loops of cable for the extraction/impaction tool to attach to via a plastic spacer. The cup can then be manipulated or hammered out using a slide hammer.

Instructions

Two types of cable are supplied with the extraction kit, a plastic coated cable and an uncoated cable. As a first attempt, lace the acetabular cup with the plastic coated cable. Thread the cable through the worm holes leaving loops large enough to fit over the impaction / extraction tool with the plastic spacer attached, shown in Figure 1.

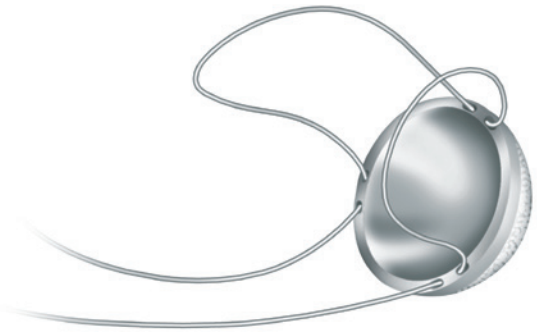


Figure 1

For convenience the knot should be tied without the extraction tool in place. Pass the cable ends through the metal collar, as shown in Figure 2, leaving approximately 5cm (2") of the free ends protruding.

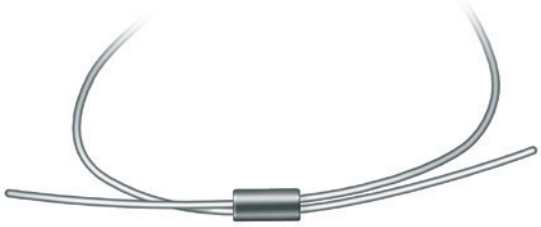


Figure 2

Pass each end back through the metal collar to form small loops, just large enough to pass the cable through. (Figure 3a and 3b). Ensure that there is approximately 4cm (1.5”) of free cable end after it has been passed through the metal collar.

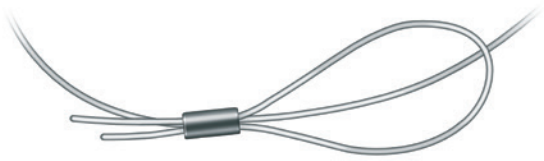


Figure 3a

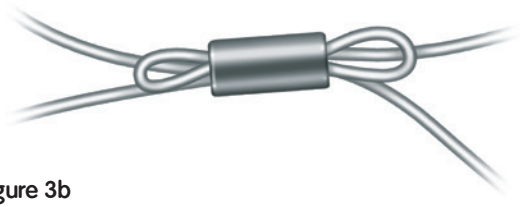


Figure 3b

Pass each free end over the metal collar and back through its own loop (figures 4a and 4b). It may be necessary to pinch the cable down onto the metal collar in order to keep the cable ends within the loops. The knot is now formed and ready to be tightened using the extraction tool.

Figure 4a

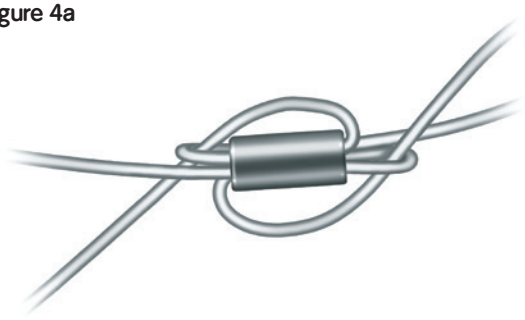


Figure 4b

Once the knot has been formed attach the plastic spacer to the extraction tool and insert the extraction tool into the acetabular cup. Pass the cable loops over the ends of the extraction tool. It may be necessary to adjust the cable lengths to ensure that the cable loops pass over the tool and plastic spacer. It may also be necessary to reposition the knot, so that it lies mid way between the extraction tool and the acetabular cup. Slowly begin to tension the cable loops. As this is done, the knot will begin to tighten. During this process, ensure that the spare cable has been pulled through the loops and that the cable is flush to metal collar. Continue to tighten until the knot is secure. The cup can now be extracted by attaching a slide hammer to the extraction tool. During extraction it may be necessary to re-tension the cables.

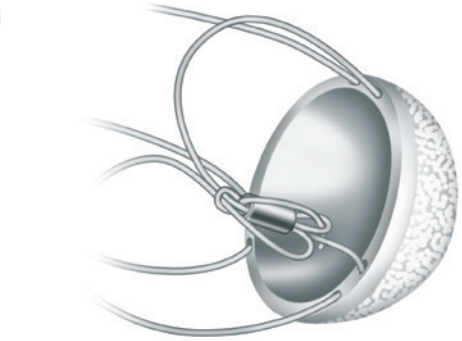


Figure 5

It is recommended to free the components from the host bone with curved rongeurs or appropriate method before proceeding.

If the acetabular cup is well fixed the plastic coated cable may break. If this occurs, remove the broken cable and replace it with the uncoated cable. To help thread the thicker uncoated cable, the ends should be shaped into a curve.

Further Information

For further information on the Acetabular Cup Extraction Kit, please contact Smith & Nephew Orthopaedics Ltd.

Catalog

BHR® Resurfacing Head

Cat. no.	Size
74123148	48mm
74121150	50mm
74123152	52mm
74121154	54mm
74123156	56mm
74121158	58mm

BHR Acetabular Cup

Cat. no.	Size
74122154	54mm (48 head)
74122156	56mm (48 head)
74120156	56mm (50 head)
74120158	58mm (50 head)
74122158	58mm (52 head)
74122160	60mm (52 head)
74120160	60mm (54 head)
74120162	62mm (54 head)
74122162	62mm (56 head)
74122164	64mm (56 head)
74120164	64mm (58 head)
74120166	66mm (58 head)

BHR® Dysplasia Cup

Cat. no.	Size
74122256	56mm
74120258	58mm
74122260	60mm
74120262	62mm
74122264	64mm
74120266	66mm

BHR Cup Screw

Cat. no.	Size
74500024	24mm
74500028	28mm
74500032	32mm
74500036	36mm
74500040	40mm
74500044	44mm
74500048	48mm
74500052	52mm
74500056	56mm
74500060	60mm
74500064	64mm
74500068	68mm
74500072	72mm
74500076	76mm
74500080	80mm
74500084	84mm
74500088	88mm

BIRMINGHAM HIP® Resurfacing (BHR®) System

Important Medical Information

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. The acetabular cups are configured in one-piece designs. 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, and is manufactured from CoCr alloy. 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. 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).

Screws for Acetabular Cups

The dysplasia cup screws are threaded through a threaded lug on the superolateral aspect of the dysplasia 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 4mm increments.

Materials

Component	Material
BHR Femoral Heads	cobalt chrome alloy per ASTM F75 and ISO 5832-4
BHR Acetabular Cups	cobalt chrome alloy per ASTM F75 and ISO 5832-4, HA (coating) per ASTM F-1185
Dysplasia screws	CoCr alloy per ASTM F-1537/ISO 5832-12

Sizing and System Compatibility – Acetabular Cups

Each femoral head resurfacing component is compatible with two standard acetabular cup sizes and one dysplasia 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
48mm	54mm or 56mm	56mm
50mm	56mm or 58mm	58mm
52mm	58mm or 60mm	60mm
54mm	60mm or 62mm	62mm
56mm	62mm or 64mm	64mm
58mm	64mm or 66mm	66mm

Indications 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 who are female
- 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 or 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).
  - Patients with multiple cysts of the femoral head (>1cm).
  - Note: In cases of questionable bone stock, a DEXA scan may be necessary to assess bone stock status.
- 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

℞ ONLY U.S. Federal law restricts this device to sale by or on the order of a physician.

- Patients who, from plain radiograph pre-operative templating, appear to require 48mm femoral heads should not be considered as candidates for BHR implantation. Patients requiring a 48mm femoral head size are at a moderately elevated risk of requiring revision surgery earlier than expected. While Smith & Nephew concluded that the increased risk associated with this head size does not outweigh the potential benefit to the patient in the specific circumstance of intra-operative downsizing from a pre-operatively templated 50mm to a measurement of 48mm at the time of surgery, surgeons should use their best medical judgment to consider this information relative to the patient's overall medical history and prognosis in determining its appropriateness as a surgical treatment.
- 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 for these patients.
- 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.
- In cases where the physician determines a revision to the primary BHR prosthesis is necessary and if certain conditions are met, a BIRMINGHAM HIP® (BH) Dual Mobility Insert may be used for revision surgeries in cases where an acetabular cup is retained and the femoral component revised. The BH Dual Mobility Insert incorporates an XLPE Insert that interfaces with an existing implanted BHR Cup where the femoral component is deemed necessary for revision. If the conditions outlined below are not met, the BHR acetabular cup must also be revised, even if well-fixed.
  - The BH Dual Mobility Insert is not recommended for use in a mal-positioned BHR acetabular cup or where mal-positioning is a contributor to the cause of revision.
  - It is not advised to use a BH Dual Mobility Insert in a BHR acetabular cup with an inclination angle above 55° following supine X-Ray review due to the increased risk of edge loading or dislocation.
  - The BHR acetabular cup should be inspected intra-operatively for visible signs of damage. The BHR acetabular cup should be removed if there are any obvious signs of damage, deep scratches or corrosion.
  - The fixation of the BHR acetabular cup should be inspected both pre- and intra-operatively. If during pre-operative radiographic assessment evidence of radiolucency, subsidence, migration, changes in angulation or osteolysis are present then the BHR acetabular cup should be removed. The BHR acetabular cup should also be removed if movement can be detected during intra-operative assessment of component stability.
- This revision option of the BH Dual Mobility Insert will be used with commercially available Smith & Nephew femoral ball heads and femoral stems. Further information in regards to the labeling or use of the BH Dual Mobility option can be found with the packaged BH Dual Mobility device or upon request from Smith & Nephew.
- Based on literature reports together with the manufacturer's post-market data, the following were identified as risk factors for early revision:
  - Patients who receive a 48mm femoral head;
  - Patients who receive a device which is incorrectly positioned;
  - Patients who have a diagnosis of avascular necrosis;
  - Patients who have congenital dysplasia; and
  - Patients who are obese

The more risk factors a patient has, the greater the risk of procedure failure requiring a revision of the hip.

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 cobalt chrome BHR System components 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.
- If during pre-operative planning an appropriately sized component cannot be found, this type of prosthesis should not be used.

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.
- When performing a hip resurfacing procedure with the BHR acetabular cup, the cup must be used ONLY with a BHR Femoral Head. If the surgeon abandons the BHR resurfacing procedure in favor of a total hip replacement, the BHR cup must not be used.
- 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
- Temporary or permanent device related noise such as clicking or squeaking
- Inflammatory tissue response to high levels of wear debris resulting in peri-prosthetic aseptic lymphocyte dominated vasculitis associated lesions (ALVAL), fluid collections, or soft tissue masses (Pseudotumors)

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 clinical study results are based on the use of the BHR femoral head resurfacing component and a BHR acetabular cup. The use of the BHR femoral head resurfacing component with the modular acetabular cup design has not been studied clinically. 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 (ascore 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 AVNdiagnostic 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 the1,626 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 havecontributed
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

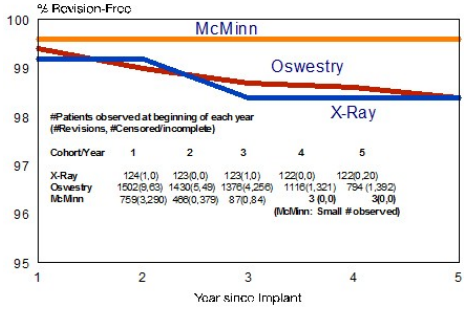
Female[1]	99.4	99.0	98.5	98.2	98.2
Age ≤65 years[1]	99.5	99.2	98.8	98.7	98.5
Age >65 years[1]	99.0	99.0	99.0	99.0	99.0
Dx: AVN[1]	98.9	98.9	96.7	96.7	92.1 (95% CI, 82.2-100%)
Dx: Dysplasia[1]	99.4	99.4	98.9	98.1	98.1
Dx: OA	99.5	99.1	98.8	98.8	98.8 (95% CI, 98.3-99.4%)
Dx: Inflammatory[1]	98.1	98.1	98.1	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)

[2] 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
OSHIP 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	59.4	96.9	96.9	96.6	96.4	95.6

with baseline <80						
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/√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 21).

Table 21: Revisions						
X-Ray/Oswestry Combined Cohort N=1626						
	Preop	**1 year**	**2 years**	**3 years**	**4 years**	**5+ years**
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 22).

Table 22: 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

PMA POST-APPROVAL STUDY

The BHR post-approval UK study was a requirement of PMA approval received on May 9, 2006, for P040033. The purpose of the study was to evaluate the long-term safety and efficacy of the BHR System by following a subset of the PMA population. Specifically, the population was designated as the first 350 subjects (400 hips) implanted with the BHR System by the design surgeon, Mr. Derek J.W. McMinn, FRCS. Results from this study may not represent those obtained by non-design surgeons as the design surgeon has first-hand knowledge, familiarity, and experience using the device.

Study Objective and Assessments

The objectives of the post-approval study were to demonstrate long-term safety and efficacy of the BHR System on a specific cohort implanted first with the device. Safety assessments included revisions, device-related or possible device related adverse events, and deaths for 10 postoperative years. Effectiveness data was collected annually through the OSHIP questionnaire to evaluate self-reported hip pain, function and health problems. At 10 years, 319/353 hips (90.4%) were evaluated by self-reported OSHIP questionnaire. In addition at the 10 year interval, a radiographic and clinical examination was performed to provide evidence of the BHR System's long term hip function and radiographic changes such as radiolucencies, osteolysis, or component migration. Of the original 400 hips, 89.5% of surviving hips were evaluated at 10 years.

Description of the Study Population

The BHR UK post-approval study is a prospective, non-randomized, unmasked, longitudinal follow-up of the first 350 subjects (400 hips) implanted with the BHR System by the design surgeon as an alternative to total hip arthroplasty. All surgeries were performed by Mr. McMinn between July 30, 1997 and October 28, 1998. To determine the study population, the first 350 unique subjects implanted by Mr. McMinn were identified and if a bilateral hip had been implanted within the specified timeframe both hips were included in the study. All procedures were included within the original X-ray and Oswestry cohorts submitted within the PMA data series. Although the study involved prospective follow-up, it should be noted that at the point of study initiation, all subjects were more than 5 years post implantation of their BHR System. Although annual follow-up between years 6 and 10 was planned, by the time of the PMA approval all hips in the post-approval cohort were past 6 years post-implantation.

Data Collection Methods

Subjects in the study population were followed clinically by the McMinn Centre. The Oswestry Outcomes Centre (OOC) registry administered the annual OSHIP questionnaire.

Safety Data Collection Methods

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

- Annual, patient-completed, mail-in OSHIP questionnaire (deaths were identified through attempted follow-up) administered by the Oswestry Outcome Centre;
- Postoperative clinical follow-up (for standard care and the 10 year followup timepoint) by the McMinn Centre and information provided to the clinic in the case of death.

Effectiveness Data Collection

Survivorship Data Collection Method

The primary effectiveness measurement was survivorship at 10 years. At 10 years, the combined implant survivorship was 95.9% with a 95% CI (93.9-97.9). Calculation of survivorship was based upon the Oswestry Outcome Centre OSHIP questionnaire using the method described above for the safety data collection.

Radiographic Data Collection

Clinical evaluation of surviving BHR System hips at 10 years included a radiograph review by a single independent radiologist. A total of 316 hips were radiographically evaluated at ten-years by the single independent reviewer who had previously performed reviews for the PMA series. Radiographic images were acquired by different providers with the majority (radiographs for 302 hips) being performed by the McMinn Centre. An additional 14 subjects who were unable to return to the clinic provided locally acquired images. AP and lateral radiographs from postoperative baseline were compared to those at 10 years to assess radiolucencies and heterotopic ossification (based on Brooker classification). If observed, abnormalities such as femoral neck thinning or resorption, cysts, or other radiographic abnormalities were noted for all radiographs reviewed.

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 > 2 mm in width. Radiolucencies were reported as a numeric score between 0 to 8 according to zone involvement or a score of 9 denoting migration >3 mm in any zone. Scoring for zones in the femoral metaphyseal stem area was performed according to the method described by Amstutz et al.[1] and acetabular scoring was based on the system created by DeLee and Charnley[2].

Radiographic success was defined as having all of the following:

- Absence of radiolucencies or a radiolucency < 2 mm in width in any one or two zones (a score of 0 - 6)
- Component migration < 3 mm

Radiographic failure was defined as the following:

- Presence of incomplete or complete radiolucencies or a radiolucency in all zones (a score of 7-8)
- Migration of the component > 3mm (a score of 9) References

1. Amstutz HA, Beaule PE, Dorey FJ, LeDuff MJ, Campbell PA, Gruen TA. Metal on Metal Hybrid Surface Arthroplasty: Two to Six Year Follow Up Study. Journal of Bone and Joint Surgery. Vol 86-A Number 1 January 2004.
2. DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. Clinical Orthopaedics and Related Research. November-December 1976;121:20-32.

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

A primary component of clinical data in this study was collected by the Oswestry Outcomes Centre (OOC) using an annual, patient-completed, mail-in questionnaire. Responses to questions regarding pain, function, and movement provided data 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 was independently reported on the annual, patient-completed, mail-in OSHIP questionnaire as an additional question.

Patient Demographics

The study population in the post-approval follow-up study was comprised of 258/400 (64.5%) male hips and 142/400 (35.5%) female hips. The primary diagnosis was osteoarthritis in 312/400 hips (78%), dysplasia in 21/400 hips (5.3%), avascular necrosis in 14/400 hips (3.5%), inflammatory arthritis in 10/400 hips (2.5%), and "other" in 43/400 hips (10.7%) (Table 23).

Table 23: Procedure Demographics

	N = 400 hips
Men	258 (64.5%)
Women	142 (35.5%)
Age: mean (range)	53.2 (23-84)
Age ≤ 65 years	356 (89.0%)
Age > 65 years	44 (11.0%)
Dx: OA	312 (78.0%)
Dx: DDH	21 (5.3%)
Dx: AVN	14 (3.5%)
Dx: Inflammatory Arthritis	10 (2.5%)
Dx: Other	43 (10.7%)

The youngest subject implanted with the BHR System was 23 year old male and the oldest subject was 84 year old male. For both genders, the most prevalent age group for BHR System implantation was between 50-59 years old represented by 158/400 hips (39.5%) (Table 24).

Table 24: Distribution of Age and Gender of Hips

Age	**Female N (%)**	**Male N (%)**	**Total N (%)**
20-29	10 (7.0)	4 (1.6)	14 (3.5)
30-39	7 (4.9)	15 (5.8)	22 (5.5)
40-49	21(14.8)	75 (29.1)	96 (24.0)
50-59	64 (45.1)	94 (36.4)	158 (39.5)
60-69	39 (27.5)	56 (21.7)	95 (23.8)
70-79	1 (0.7)	12 (4.7)	13 (3.3)
80-89	0 (0)	2 (0.8)	2 (0.5)
Minimum	25	23	23
Maximum	72	84	84
Mean	53.0	53.3	53.2
Std Dev	10.6	10.0	10.2
Total	142	258	400

Diagnostic Indications for Unilateral and Bilateral Procedures

Of the participants, 300/350 subjects (85.7%) were followed for a unilateral procedure only while both hips were included in the study follow-up for the remaining 50/350 subjects (14.3%). The indication for the majority of cases was osteoarthritis (Table 25).

Table 25: Diagnostic Indications for BHR

Diagnosis	Unilateral Hips N (%)	Bilateral Hips N (%)	Total Hips N (%)
Osteoarthritis	237 (79.0)	75 (75.0)	312 (78.0)
Dysplasia	16 (5.3)	5 (5.0)	21 (5.3)
Avascular Necrosis	8 (2.7)	6 (6.0)	14 (3.5)
Inflammatory Arthritis[1]	6 (2.0)	4 (4.0)	10 (2.5)
Other	33 (11.0)	10 (10.0)	43 (10.7)
Total	300 (100.0)	100 (100.0)	400 (100.0)

[1] Includes diagnoses of rheumatoid arthritis, inflammatory arthritis, and destructive arthritis.

Further stratification of hips contained within the "other" category is provided for greater insight into the study population (Table 26).

Table 26: Expanded Categorization of Other Diagnostic Indications

Diagnosis	**Unilateral Hips N (%)**	**Bilateral Hips N (%)**	**Total Hips N (%)**
Congenital Dislocation of Hip	12 (36.4)	5 (50.0)	17 (39.5)
Slipped Upper Femoral Epiphysis	9 (27.3)	2 (20.0)	11 (25.6)
Dislocation	1 (3.0)	-	1 (2.3)
Perthes	2 (6.1)	2 (20.0)	4 (9.3)
Septic Arthritis	1 (3.0)	-	1 (2.3)
Ankylosing Spondylitis	2 (6.1)	-	2 (4.7)
Femoral Fracture	3 (9.1)	-	3 (7.0)
Protrusio Acetabular	1 (3.0)	1 (10.0)	2 (4.7)
Post Traumatic Arthritis	1 (3.0)	-	1 (2.3)
Not Available	1 (3.0)	-	1 (2.3)
Total	33 (100.0)	10 (100.0)	43 (100.0)

Patient Accounting

The annual patient completed, mail-in OSHIP questionnaire and the 10 year clinical evaluation were independent activities and were not performed as a single event. As a result of timing and ability to complete each component separately, follow-up rates for the OSHIP questionnaire and clinical evaluation were calculated independently. OSHIP follow-up rates for postoperative years 7 through 10 were 93.3%, 82.6%, 88.2%, and 90.4% (Table 27).

Table 27: OSHIP Accounting (per hip)						
	5 Year[6]	6 Year	7 Year	8 Year	9 Year	10 Year
Theoretically Due[4]	400	400	400	400	400	400
Deaths (cumulative)	11	16	18	19	21	28
Revisions (cumulative)	9	9	11	14	16	19
Implants Expected[1,4]	380	375	371	367	363	353
Actual Follow-Up[2]	352	3[5]	346	303	320	319
% Actual Follow-Up[3]	**92.6**	****[5]**	**93.3**	**82.6**	**88.2**	**90.4**

1. Implants Expected= theoretically due minus cumulative revision and deaths during the specified year.
2. Actual Follow Up = Implants with OSHIP Questionnaire at the stated interval. If either death or revision occurred during the year, the OSHIP score would not be counted in the actual follow-up to avoid double counting.
3. Percent Actual Follow Up = Actual F-U/ Implants Expected x 100.
4. OSHIP score data rationale correlates that for "year 1" data collection dates are between day 366-730 while "year 2" data is collected between day 731-1095, etc.
5. Timing for study initiation prevented responses from most subjects since they were already beyond the evaluable time period.
6. OSHIP questionnaires were not obtained at 5 years prospectively for this study but were contained in the data submitted for the PMA.

Clinical evaluation was only scheduled at the 10 year postoperative interval. Of the expected hips, 302/353 (85.6%) were fully evaluated. Additionally, 14/353 cases (4.0%) were unable to return to the clinic but were able to provide locally obtained radiographs. Cumulative evaluation of 316/353 surviving hips at the final scheduled interval resulted in a 89.5% follow-up rate (Table 28).

Table 28: Clinical Evaluation at 10 Years (per hip)	
Theoretically Due	400
Deaths	28
Revisions	19
Implants Expected[1]	353
Actual[2]	302
Actual[3,5]	14
% Actual Follow-Up[4]	**89.5**

[1] Implants Expected= theoretically due minus cumulative revision and deaths.

[2] Hips seen in the clinic for evaluation per protocol

[3] Hips unable to return for clinic evaluation but sent radiographs for evaluation ("all evaluated" accounting)

[4] Percent Actual Follow Up = Actual[2] + Actual[3]/ Implants Expected x 100.

[5] Clinical Evaluation correlates to an interval. Thus "year 10" data represents time around but not equal to the 10 year anniversary date.

Safety Data

Safety: Revisions

During the conduct of the study there were 21 revisions known within the study population, including some beyond final study activity follow-up. The cause of revision for all known revision hips and the time span in which events occurred is provided (Table 29).

Table 29: Cause and Time Span for Revised Study Hips (N = 21)		
Revision Cause	# of Events N (%)	Time Span of events (in years)
Infection	6 (28.6)	2.5-9.5
Collapsed Femoral Head	4 (19.0)	4.9-10.1
Femoral Neck Fracture	3 (14.3)	0.0-0.4
Avascular Necrosis	2 (9.5)	0.7-7.2
Pain	2 (9.5)	8.3-11.0
Pseudotumor	2 (9.5)	10.6-10.9
Acetabular Loosening	1 (4.8)	9.7
Metal Allergy	1 (4.8)	11.03
Total	21 (100.0)	0.0-11.0

Review of reasons for revision presents infection as the most prevalent cause which accounts for 6/21 (28.6%) revisions. Collapsed femoral head led to 4/21 (19.0%) revisions at close to 5 years and beyond. Femoral neck fracture led to 3/21 (14.3%) revisions, with cases occurring shortly after implant while revision for pseudotumors 2/21 (9.5%) did not occur until 10 years in situ.

To determine possible factors associated with revision, a subgroup analyses was performed based on the final status of all implanted hips after 10 postoperative years. For deceased subjects, if the hip was revised prior to death it was counted as revised, otherwise it was considered not revised. For subjects that did not participate in a 10 year study activity, subjects were contacted to ascertain whether the hip had been revised. From the final status of prior revision, hip survival at time of death, and hips remaining in situ, subgroup analysis of baseline variables was performed using Fisher's Exact test to identify potential factors associated with implant revision (Table 30).

Table 30: Age, Hip, Gender, and Femoral Head Size Grouping by Revision		
Characteristic	**Revision**	
	Yes (%)	**No (%)**
Age: ≤ 65	20 (95.2)	336 (88.7)
Age: > 65	1 (4.8)	43 (11.3)
p-value	0.49	
Hip: Bilateral	2 (9.5)	98 (25.9)
Hip: Unilateral	19 (90.5)	281 (74.1)
p-value	0.12	
Gender: Female	14 (66.7)	128 (33.8)
Gender: Male	7 (33.3)	251 (66.2)
p-value	0.004	
Femoral Head: ≤ 44 mm	5 (23.8)	22 (5.8)
Femoral Head: > 44 mm	16 (76.2)	357 (94.2)
p-value	0.009	
Total	21 (100.0)	379 (100.0)

*p-values were based on Fisher's Exact test for two categorical variables

At the time of subgroup revision analysis, 21 revisions were reported by the end of the study (5 hips revised beyond the 10 year timepoint). Subgroup analysis of all known revisions showed significant correlations with gender and femoral head size but no significance from age or whether one or both hips were implanted and followed within the study population.

Safety: Adverse Events

Adverse events were reported through two information sources: clinical follow-up and OSHIP patient self-report. A total of 74 adverse events were reported by the clinic with 64 events potentially related to the study hip. Clinical assessment was performed only at the 10 year interval, but adverse events were attributed to intervals according to the reported date of onset in relationship to date of implantation. Reasons for all revisions prior to the start of the Post Approval Study are summarized within the 5 year interval. A time course distribution of all clinic reported adverse events was provided (Table 31).

Table 31: Clinic Reported Adverse Events (by hip)

Adverse Event [1]	5 Years[2]	7 Years[2]	8 Years	9 Years	10 Years	Total Events
Potentially Related to Study Hip						
Acetabular Fracture	0	0	0	1	0	1
Acetabular Loosening	0	0	0	1	0	1
Femoral Neck Fracture	3	0	0	0	0	3
Deep Infection > 6 Weeks	0	0	0	1	0	1
Deep Infection < 6 Weeks	4	1	0	0	0	5
Pelvic Fracture	0	0	1	0	0	1
HO Grade III or IV	9	0	0	0	0	9
Fluid on Hip	0	0	1	0	0	1
Pain at Operative Site	0	0	1	0	0	1
Hip Noise (squeaking, clicking, etc.)	0	0	0	1	0	1
Bursitis	0	0	2	1	1	4
Pain in Leg, study side	1	0	3	0	2	6
Pain in Hip, study side	0	0	3	2	3	8
Pain in Groin, study side	0	1	1	1	0	3
Pain in Back Related to Hip	0	0	0	0	1	1
Restricted Movement/Impingement	0	0	1	2	0	3
Twinges/Tingling	0	0	0	0	1	1
Femoral Neck Thinning/Erosion	0	0	0	1	1	2
Periprosthetic Effusion	0	0	0	0	1	1
Collapsed Femoral Head	1	0	2	1	0	4
Cyst	0	0	0	1	0	1
Pseudotumor	0	2	0	0	0	2
Reaction to metal debris, metal allergy	0	2	0	0	0	2
Avascular Necrosis	1	1	0	0	0	2
Systematic Events						
Circulatory	0	0	0	2	0	2
Endocrine/Nutritional/Metabolic	0	0	0	2	0	2
Lymphatic	0	0	1	0	0	1
Skeletal	0	0	0	0	1	1
Hematologic/ Immune System	0	0	0	2	1	3
Pain of unknown etiology	0	0	0	0	1	1
Total Adverse Events	19	7	16	19	13	74

[1] Subjects were evaluated in the clinic for the study at the 10th year interval only. Time course of events shows the number of hips with at least 1 complication of the specified type in the specified time period. An event for a hip may appear in more than one time period. Clinic reported adverse events included device-related or possibly device related events. Events include revisions and those with study hip involvement within the 10 year follow up.

[2] Events were attributed to study interval according to the calculated difference between date of surgery and date of onset.

In medical documentation, additional observations for study hips were noted upon monitoring but not considered adverse events by the investigator. Time of onset is not known, but a cumulative picture of adverse events and additional observations is provided for a more robust clinical illustration of device use.

Table 32. Adverse Events and Observations

Adverse Event	Observation	Clinic Reported Adverse Event	Total Events per Type
Pain in Hip, study side	1	8	9
Pain in Groin, study side	1	3	4
Cyst	1	1	2
Impingement	1	0	1
Antalgic Gait	1	0	1
Buttock pain/Soreness	1	0	1
Disability Due to Hip	2	0	2
Groin Fullness	1	0	1
Muscular/ Connective Tissue	4	0	4
Skin/Subcutaneous Tissue	2	0	2
Total Adverse Events	15	12	27

On the annual OSHIP questionnaire, some information was requested about problems with the hip (e.g., blood clots, infection, revision, or dislocation) after surgery. A comment area provided space for write in comments. Of the 127 adverse events reported, 27 potentially involved the study hip. Reported adverse events self-reported on the questionnaire was presented in a time course distribution according to reporting interval (Table 33).

Table 33: Oswestry Reported Adverse Events (by hip)							
Event[1]	5 Years N=352	6 Years N=3	7 Years N=346	8 Years N=303	9 Years N=320	10 Years N=319	Total
Implant Failure	0	0	0	1	0	0	1
Nerve Injury	0	0	0	1	0	0	1
Bursitis	0	0	0	0	1	1	2
Leg Pain	0	0	0	2	1	0	3
Stiffness	0	0	0	0	1	1	2
Hip pain	0	0	0	3	2	5	10
Back pain	0	0	0	1	0	3	4
Limp	0	0	0	0	2	2	4
Systemic							
Circulatory	3	1	0	1	2	12	19
Gastrointestinal/ Digestive	3	1	0	0	0	3	7
Endocrine/Metabolic	0	0	0	0	0	3	3
Nervous	1	0	0	2	0	1	4
Respiratory	0	0	0	1	0	4	5
Skeletal	0	0	0	10	6	21	37
Special Sense	0	0	0	0	0	1	1
Urinary	0	0	1	1	1	5	8
Immune System/ Hematologic	0	0	1	1	1	3	6
Skin/Subcutaneous Tissue	0	0	0	0	0	3	3
Pain, unknown etiology	0	0	0	0	1	0	1
Unknown Cancer	0	1	0	0	0	0	1
Death, unknown cause	2	0	1	0	0	2	5
Total Adverse Events[2]	9	3	3	24	18	70	127

[1] Time course of events shows the number of subjects with at least 1 complication of the specified type in the specified time period. Hips may appear in more than one time period.

[2] All events were self-reported by the subject on the returned annual OSHIP questionnaires or through shared information with the Oswestry Centre. Due to self-report, events were not clinically evaluated or verified.

Safety: Adverse Events- Deaths

There were 23 patient deaths (28 procedures) in the study cohort and no cases were determined to be related to the BHR procedure. The causes of death were reported as: 3 cardiac events, 2 stroke, 7 cancer (2 oesophageal, 1 colon with sepsis, 1 prostate, 1 rectal, 1 adenocarcinoma of the common bile duct, and 1 of unreported type), 1 motor neuron disease, 1 low blood pressure, 1 pyelonephritis, 1 diving accident, 1 acute myeloid leukemia with dementia, 1 pneumonia, 1 peripheral vascular disease, 1 pulmonary disease, and 3 of unknown cause.

EFFECTIVENESS DATA

Survivorship

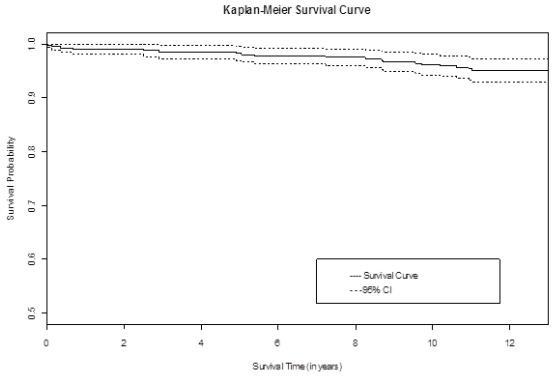
Survivorship estimates were based on the number of hip cases with no revision at specific timepoints. An overall Kaplan-Meier survivorship analyses of the 400 hips was provided (Table 34).

Table 34: Kaplan-Meier Survival of the Study Population				
Time (in years)[1]	Number of hips at risk	Events	Kaplan-Meier Estimate	95%CI
5	389	7	0.982	0.970, 0.995
8	371	4	0.972	0.956, 0.989
9	366	3	0.964	0.946, 0.983
10	362	2	0.959	0.939, 0.979
12	328	5	0.945	0.923, 0.968

[1] Survivorship data for the designated year begins with the first day of the year stated, for example, year 1 survivorship would include data from day 1 to 365 following implantation surgery.

Implant survivorship at 10 years was 95.9% with a 95% CI (93.9-97.9). The Kaplan-Meier curve demonstrates overall survival of long term follow-up beyond 10 postoperative years (Figure 2).

Figure 2: Cumulative % Revision-Free, BHR



Survival analyses for subgroups at 10 years were assessed to determine a possible relationship with hip survival. Variables considered were gender (M, F), diagnostic indication for hip resurfacing (OA, IA, dysplasia, AVN, and other), femoral head size (≤ 44 mm, > 44 mm), age, and whether a single unilateral or both hips were included in the study. Based on a significance level of p-value <0.05, subgroup analyses at 10 years showed significant statistical differences in survival based on gender, diagnostic indication for resurfacing, and femoral head size.

Significant statistical differences were not evident for age, or whether a unilateral or bilateral hips were included in the study population (Table 35).

Table 35: Survival Analyses for Subgroup

	5 years	8 years	9 years	10 years
Male	98.4	98.1	97.2	97.2 (95% CI,95.2-99.3%)
Female	97.2	95.7	95.0	93.6 (95% CI,89.6-97.7%)
				p-value* 0.003
Age ≤ 65 years	98.3	97.2	96.3	95.7 (95% CI, 93.6-97.8%)
Age > 65 years	97.7	97.7	97.7	97.7 (95% CI, 93.4-100.0%)
				p-value* 0.40
Unilateral	98.0	96.6	95.6	94.9 (95% CI, 92.4-97.4%)
Bilateral	99.0	99.0	99.0	99.0 (95% CI, 97.0-100.0%)
				p-value* 0.10
Dx: OA	99.4	98.0	98.0	97.7 (95% CI, 96.5-99.6%)
Dx: Inflammatory Arthritis	100.0	100.0	100.0	100.0 (95% CI, -)
Dx: Dysplasia	90.5	90.5	90.5	85.7 (95% CI, 72.0-100.0%)
Dx: AVN	78.6	78.6	70.7	70.7 (95% CI, 50.2-99.6%)
Dx: Other	100.0	100.0	95.4	95.4 (95% CI, 89.3-100.0%)
				p-value* <0.0001
Femoral Head ≤ 44mm	96.3	92.6	88.9	85.2 (95% CI, 72.8-99.7%)
Femoral Head > 44mm	98.4	97.6	97.0	96.7 (95% CI, 94.9-98.6%)
				p-value* 0.002

*Log-Rank test of equality over hip groups

Subgroup analysis for survival was performed for additional variables (Height and Weight at time of surgery) which had considerable missing data from the retrospective data collection. Steps were taken to evaluate possible influence using the following rationale. Analysis was performed using available data only for each of the variables (Height and Weight). Sensitivity analyses were also performed on each variable to determine if missing data could impact the result. Sensitivity testing was performed by individually evaluating each group as if all missing data had belonged to that category. Grouping for male height was stratified into groups of ≤178 cm and >178 cm and weight was stratified into groups of ≤82.7kg and >82.7 kg. For females, height was stratified into groups of ≤164 cm and >164 cm and weight was grouped by ≤70 kg and >70 kg. Sensitivity analyses on available data did not reveal any statistically significant relationships.

Survival in relationship to BMI was evaluated only on known data with grouping into 3 categories (BMI <25, 25-29.9, and ≥30). Log-rank testing for equivalence of survival performed with available BMI data did not yield any statistically significance difference between any group (p-value 0.53).

Radiographic Data

Radiographs were acquired at 10 postoperative years on 316 of the 353 (89.5%) eligible hips and compared with baseline images taken shortly after implant. Independent evaluation was performed by a single radiographic reviewer, who had previously performed the review for the PMA.

Radiographs were assessed for radiolucencies, implant migration, heterotopic ossification, and visible abnormalities (Table 36).

Femoral radiolucencies: Radiolucencies >2 mm were graded 0-9 (Amstutz scale). Of the hips reviewed, 304/316 (96.2%) were Grade 0, indicating no radiolucency in any femoral zone. Grade 1 (lucency in zone 1) was found in 4/316 cases (1.3%). Grade 2 (lucency in zone 2) was found in 2/316 cases (0.6%). Grade 3 (lucency in zone 3) was found in 5/316 cases (1.6%). No cases of Grades 4 through 6 were found. Grade 7 (lucency in zones 1-3, incomplete) was found in 1/316 cases (0.3%). No case of Grade 8 (complete lucency in all femoral zones) or grade 9 (migration) were found. The patient with Grade 7 femoral radiolucency classified as a radiographic failure was not reported to be exhibiting clinical symptoms.

Acetabular radiolucencies: Radiolucencies were graded 0-9 (DeLee and Charnley scale). Of the 316 hips evaluated, no lucency was found in 302/316 (95.6%) of cases. There were 5/316 cases (1.6%) Grade 1 (lucency in zone I), 3/316 cases (1.0%) Grade 2 (lucency in zone II), 1/316 cases (0.3%) of Grade 3 (lucency in zone III), and 1/316 cases (0.3%) of Grade 4 (lucency in zones I and II). There were 2/316 cases (0.6%) of Grade 5 (lucencies in zones II and III) and 2/316 cases (0.6%) of Grade 6 (lucency in zones I and III). No cases considered radiographic failure (Grades 7 through 9) were found.

Heterotopic ossification: No evidence of heterotopic ossification based on Brooker classification was found in 279/316 (88.3%) of cases. There were 22/316 cases (7.0%) of Brooker I classification, 10/316 cases (3.1%) of Brooker II, and 5/316 cases (1.6%) of Brooker
III. No cases of Brooker IV was found. Clinical significance was defined as Brooker III and IV therefore 5/316 cases (1.6%) having Brooker III HO would be considered significant although none required actual treatment by close of study.

Migration: No case was reported to have migrated based on comparison between early postoperative radiographs and those from the 10 year review.

Table 36: 10 Year Radiographic Findings N=316

Findings	Cases (%)
Femoral Radiolucency Score	
No Finding	304 (96.2)
Failure: Grade 7	1 (0.3)
Other: Grade 1	4 (1.3)
Other: Grade 2	2 (0.6)
Other: Grade 3	5 (1.6)
Acetabular Radiolucency Score	
No Finding	302 (95.6)
Other: Grade 1	5 (1.6)
Other: Grade 2	3 (1.0)
Other: Grade 3	1 (0.3)
Other: Grade 4	1 (0.3)
Other: Grade 5	2 (0.6)
Other: Grade 6	2 (0.6)
Heterotopic Ossification (Brooker Classification)	

No Finding	279 (88.3)
Brooker III	5 (1.6)
Brooker II	10 (3.1)
Brooker I	22 (7.0)

Additional observations: From the 316 hips reviewed at 10 years, radiographic observations included resorption/thinning of the femoral neck, probable acetabular cysts, progressive lucency, and obturator ring fracture. Femoral neck observations were reported in 30/316 cases (9.5%) reviewed at 10 years. Of the 30 femoral neck observations, thinning was reported in 14 cases and resorption was reported in 16 cases (Table 37).

Table 37: 10 Year Radiographic Observations	
No observations	280 (88.6%)
Femoral neck changes (thinning/resorption)	30 (9.5%)
Acetabular cysts	4 (1.3%)
Progressive lucency	1 (0.3%)
Obuturator ring fracture	1 (0.3%)
Total Observations	316 (100%)

The largest number of comments at the 10 year evaluation involved femoral neck changes. To further investigate radiographic observations, baseline characteristics were used to perform a subgroup analysis. Analysis showed that observations were reported more in females 21/30 (70%) than males 9/30 (30%) and subjects implanted when ≤ 65 years old 27/30 (90.0%). Femoral neck observations were also more prevalent among those of femoral heads >44 mm 27/30 (90.0%) and those implanted for osteoarthritis 21/30 (70.0%). Femoral neck comments showed statistical significant correlation only with gender (p-value <0.0001) but did not show significance with other baseline characteristics (Table 38).

Table 38: Subgroup Analysis for Comments of Femoral Neck Resorption/Thinning at 10 Year Review		
	Radiographs without resorption/thinning comments N=286 (%)	Radiographs with thinning/ resorption comments N=30 (%)
Gender: Female	89 (31.1)	21 (70.0)
Gender: Male	197 (68.9)	9 (30.0)
p-value	<0.0001	
Age ≤ 65	257 (89.9)	27 (90.0)
Age > 65	29 (10.1)	3 (10.0)
p-value	0.53	
Hip: Bi-lateral	75 (26.2)	10 (33.3)
Hip: Unilateral	211 (73.8)	20 (66.7)
p-value	0.39	
Femoral Head ≤ 44 mm	15 (5.2)	3 (10.0)
Femoral Head > 44 mm	271 (94.8)	27 (90.0)
p-value	0.40	
Diagnosis: OA	229 (80.1)	21 (70.0)
Diagnosis: DY	11 (3.8)	4 (13.3)
Diagnosis: AVN	5 (1.8)	2 (6.7)
Diagnosis: IA	9 (3.1)	1 (3.3)
Diagnosis: Other	32 (11.2)	2 (6.7)
p-value	0.06	

*p-values were based on Fisher's Exact test for two categorical variables

Observation of resorption or thinning at 10 years were also compared to the 10 year self- reported OSHIP scores. However, since OSHIP reporting and x-rays were not obtained simultaneously collected both were not available for all hips that were radiographically evaluated. Resorption/thinning observations occurred in 27/291 hips but there was no statistically significant correlation to OSHIP responses (Table 39).

Table 39: Comparison of Resorption/Thinning to 10 year OSHIP Score			
Characteristics	Radiographs without resorption/thinning comments N=264 (%)	Radiographs with thinning/ resorption comments N=27 (%)	**p-value**
OSHIP Score ≤ 70	12 (4.5)	2 (7.4)	0.63*
OSHIP Score > 70	252 (95.5)	25 (92.6)	

*p-value was calculated based on Fisher's Exact test

Pain and Function – Oswestry Modified Harris Hip (OSHIP) Score

Annual, self-reported OSHIP scores were obtained between years 7 through 10 for all hips. OSHIP results of unilateral hips (defined by having only one hip followed within the study) are provided along with 5 year scores for the cohort from the PMA. Overall OSHIP scores during study follow-up were considered in the excellent range with mean scores > 90. At postoperative years 5, 7, 8, 9, and 10, the mean score were 94.3 92.5, 92.8, 93.0, and 92.5 respectively (Table 40).

Table 40: OSHIP Scores by Unilateral Hip						
OSHIP Scores	**Statistic**	**5 Year N = 267**	**7 Year N = 261**	**8 Year N = 220**	**9 Year N = 238**	**10 Year N = 241**
Pain (0-44)	Mean	42.9	42.5	42.6	42.5	42.4
	Std Dev	3.3	3.8	3.5	4.5	3.9
	Minimum	20.0	29.0	29.0	0.0	20.0
	Maximum	44.0	44.0	44.0	44.0	44.0
Function Score (0-43)	Mean	39.5	38.7	39.1	39.0	38.5
	Std Dev	6.5	6.2	6.2	5.6	6.4
	Minimum	1.0	13.0	7.0	18.0	14.0
	Maximum	43.0	43.0	43.0	43.0	43.0
Movement (0-13)	Mean	11.9	11.1	11.3	11.1	11.3
	Std Dev	2.2	2.8	2.6	2.7	2.7
	Minimum	0.0	0.0	4.0	0.0	4.0
	Maximum	13.0	13.0	13.0	13.0	13.0
Total (0-100)	Mean	94.3	92.5	92.8	93.0	92.5
	Std Dev	10.2	10.6	10.1	10.0	10.4
	Minimum	30.0	46.0	51.0	22.0	54.0
	Maximum	100.0	100.0	100.0	100.0	100.0

Categorized score accounting over the course of the study show that the majority of cases remained in the excellent or good categories representing a score of 80 or above. At ten years post-implant, 173/241 (71.8%) of the study unilateral hips had an excellent score and 36/241 (14.9%) had a good score. Only 32/241 (13.3%) of the surviving hips at 10 years reported OSHIP scores of 79 or below (Table 41).

Table 41: Summary of OSHIP Scores for Unilateral Hips per Category					
OSHIP Score	**5 Years (N = 267)**	**7 Years (N = 261)**	**8 Years (N = 220)**	**9 Years (N = 238)**	**10 Years (N = 241)**
Excellent (90-100)	226 (84.6)	197 (75.5)	172 (78.2)	174 (73.1)	173 (71.8)
Good (80-89)	13 (4.9)	38 (14.6)	28 (12.8)	43 (18.1)	36 (14.9)
Fair (70-79)	16 (6.0)	12 (4.6)	8 (3.6)	16 (6.7)	20 (8.3)
Poor (60-69)	8 (3.0)	9 (3.4)	8 (3.6)	2 (0.8)	9 (3.7)
Very Poor (< 60)	4 (1.5)	5 (1.9)	4 (1.8)	3 (1.3)	3 (1.3)

Subgroup analysis of 10 year OSHIP scores were analyzed for statistical differences (p-value of <0.05) between covariants. Statistically significant difference in unilateral OSHIP scores was found between gender (M, F). However, difference in age (≤ 65, >65), diagnostic indication for resurfacing (OA, dysplasia, AVN, inflammatory arthritis, other), or the size of the femoral head (≤ 44mm, >44mm) were not significant (Table 42).

Table 42: Oswestry-Modified Harris Hip Score (OSHIP) 10 Year Interval- Unilateral Hips			
Characteristic	**Mean**	**Standard Deviation**	**p-value**
Gender: Female (n=84)	89.7	11.9	0.016*
Gender: Male (n=157)	93.4	9.2	
Age: ≤ 65 years (n=214)	92.1	10.7	0.96*
Age: > 65 years (n=27)	92.2	7.9	
Osteoarthritis (n=194)	92.2	10.3	0.08+
Dysplasia (n=13)	92.3	11.3	
Avascular Necrosis (n=3)	94.0	10.4	
Inflammatory Arthritis (n=6)	85.7	11.3	
Other Diagnosis (n=25)	92.7	10.6	
Femoral Head: ≤44 mm (n=15)	85.5	15.6	0.11*
Femoral Head: >44 mm (n=226)	92.6	9.8	

*p-value was based on two sample t-test for continuous variable

+ p-value was based on one-way ANOVA

Range of Motion

OSHIP responses did not include clinically assessed range of motion measurements. Instead, additional questions were incorporated into the Oswestry-Modified Harris Hip Score to provide insight into motion. At the 10-year interval a clinical evaluation was performed and range of motion was assessed by the clinician. Results at 10 years demonstrate that most hips were generally able to move in all directions (Table 43).

Table 43: Clinicial Assessed Range of Motion at 10 Years (N = 302)			
Range of Motion	Mean	Std Dev	Range
Flexion	127.2°	14.6	45.0-160.0
Abduction	37.2°	6.3	20.0-80.0
Adduction	24.1°	6.1	10.0-40.0
External Rotation	38.4°	7.2	10.0-60.0
Internal Rotation	25.8°	8.7	0.0-50.0

In addition to the statistics of clinician assessed range of motion at the 10 year clinical evaluation, distribution by groups for each parameter was performed. Frequencies of range of motion by groups is provided as an overview of hip performance at the 10 year follow up (Table 44). Subjects with decreased motion in any parameter were examined for possible associated variables that included: age, gender, radiographic findings, adverse events, and self-reported satisfaction of their hip. Of the variables considered, no statistically significant correlation could be determined.

Table 44. Frequencies of Range of Motion	
Characteristic	**N (%)**
Flexion	
0 – 44°	0 (0.0)
45 - 89°	2 (0.7)
90 - 119°	52 (17.2)
120° or Above	248 (82.1)
Abduction	
0 - 14°	0 (0.0)
15 - 29°	17 (5.6)
30° or Above	285 (94.4)
Adduction	
0 - 14°	8 (2.7)
15 - 29°	193 (63.9)
30° or Above	101 (33.4)
External Rotation	
0 - 19°	5 (1.7)
20 - 34°	53 (17.5)
35° or Above	244 (80.8)
Internal Rotation	
0 - 19°	40 (13.3)
20 - 34°	191 (63.2)
35° or Above	71 (23.5)
Total	302 (100.0)

Patient Satisfaction

The patient satisfaction question was an additional question asked in conjunction with the annual self-reported, mail-in OSHIP questionnaire. Five possible responses allowed participants to report varing degrees of satisfaction (Table 45). At the time of 10-year follow-up all subjects reported as being pleased with their BHR System hip, with 30/319 (9.4%) stating extremely pleased and the remaining 289/319 (90.6%) as pleased.

Table 45: Subject Satisfaction						
	Preop N (%)	5 Years N (%)	7 Years N (%)	8 Years N (%)	9 Years N (%)	10 Years N (%)
I am extremely pleased with the operation.	0 (0.0)	327 (92.9)	311 (89.9)	276 (91.1)	286 (89.4)	30 (9.4)
I am pleased with the operation.	0 (0.0)	23 (6.5)	33 (9.5)	25 (8.3)	31 (9.7)	289 (90.6)
I am no different than before the operation.	0 (0.0)	1 (0.3)	2 (0.6)	1 (0.3)	1 (0.3)	0 (0.0)
I am worse than before the operation.	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
I am much worse and would not recommend the operation.	233 (100.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.6)	0 (0.0)
Total	233	352	346	303	320	319

Explant Retrieval

Explant analysis is an objective for any revised BHR System component to assess insight into device function and performance in the body, and possible causative mechanisms for revision. Although the intent was to evaluate all BHR System explanted hips prior to the 10-year follow-up, only 3 from the study cohort were returned for testing. Retrieval analysis showed no findings that were remarkable and of concern. Two primary reasons limited the return of explanted devices in this study: revision of the hip prior to the development of a return process and revisions performed by surgeons other than the clinical investigator. In cases where the revision was performed elsewhere, return of explants to the manufacturer was optional in the UK.

Final Safety Findings

Implant survivorship at 10 years was 95.9% (95% CI: 93.9%, 97.9%) which statistically demonstrated success of the study's primary endpoint. Although the overall survivorship at 10 years was good, subgroup analyses indicated that some factors showed influence on the survival of hip. In particular, decreased survival of the BHR System was found in women, those with the primary diagnosis of avascular necrosis, and implants with a smaller femoral head size.

No unanticipated device-related adverse events were reported during the post approval study. By the end of study, there were 21/400 revisions (5.25%) including 2 revisions reported after the 10 year follow up timepoint.

Study Strengths and Weaknesses

A strength of the study was the retrospective design which utilized a population of the first 350 BHR System subjects (400 hips) implanted by the design surgeon. Prior to the study initiation for long term follow-up, the population was already beyond five years post implantation and the PMA data provided strong insight into the prediction of implant survival and critical variables. Determining accurate study hypothesis was crucial as the initial subjects did not have the benefit of increased surgeon experience with the BHR System and subject selection was not as stringent as later resurfacing criteria. The study was successful in accepting the alternative hypothesis of device survival based upon well-chosen criteria. Although the primary study endpoints were successful, there were limitations on subgroup analysis for cases of small populations as it was not possible to determine significance.

Although the study design facilitated use of the defined retrospective population, a weakness within the study was the plan to collect only prospective data. The study plan included a 6 year time point but subjects were beyond the window when the study was initiated so acquiring data from that time point was not feasible. Additionally prospective surveillance of the study also limited the ability to compare preoperative pain and function to postoperative long term outcomes. There was limited ability to use preoperative variables in the analysis from the
PMA dataset. If missing from the PMA dataset, no additional retrospective information was attainable. Missing data was most prevalent for preoperative height and weight which impacted calculation of body mass index (BMI). As a result BMI determination was possible for only 335/400 hips (83.8%).

Although missing data precluded actual analyses, steps were taken to determine whether a possible correlation could have resulted if all data was available. Kaplan-Meier survival using a sensitivity analysis was performed with the variables of BMI, height and weight by gender.
Specifically, all missing data was attributed to one category and then again to the opposite category. For example, all male hips with missing BMI information were considered to be within the ≤26 BMI group and a Kaplan-Meier survival analysis was performed. Next all missing data for males were considered as >26 BMI and survival analysis was performed again. Comparisons of the sensitivity analysis did not show a statistically significant influence from any variable.

Conclusion

At 10 years, implant survivorship of 95.9%, mean unilateral OSHIP score ≥ 80 for 209/241 (86.7%) of the study population and radiographic success of 315/316 (99.7%) provides reasonable assurance that the BHR System is safe and effective in hip resurfacing.

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:

Dynamic Air Removal (Pre-vacuum) Steam Cycle:
Exposure temperature: 132°C (270°F); Exposure time: 4 minutes Exposure temperature: 135°C (275°F); Exposure time: 3 minutes
Minimum drying time: Wrapped devices - 15 minutes; containerized devices - 30 minutes*

Gravity Displacement Steam Cycle:

Exposure temperature: 132°C (270°F)
Exposure time: 15 minutes for instruments not in a containment device 30 minutes* for devices in a containment device
Minimum drying time: 30 minutes

Immediate Use Steam Sterilization (IUSS) or Flash Steam Cycle:
Exposure temperature: 132°C (270°F)
Exposure time: Dynamic air removal (pre-vacuum): 4 minutes

- DO NOT RESTERILIZE implant components. Contact your local Smith & Nephew, Inc. Sales Representative regarding procedures to return components to Smith & Nephew, Inc.

***This sterilization cycle is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).**

The product is not labeled "pyrogen free".

The BHR femoral head and BHR acetabular cup components are packaged in a dual sterile barrier blister tray to maintain sterility. The products have a five (5) year sterile shelf-life where the sterile barrier is not broken.

MRI SAFETY INFORMATION

Smith & Nephew, Inc. BIRMINGHAM HIP® Resurfacing (BHR) System implants are manufactured from a non-ferromagnetic material, cobalt-chromium-molybdenum alloy. Smith & Nephew has performed non-clinical Magnetic Resonance Imaging (MRI) studies on BHR implants which are determined to be MR Conditional in accordance to ASTM F2503-08, Standard Practice for Marking Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Conditional refers to an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

MR Information

MR Conditional

Non-clinical testing has demonstrated that the BHR System is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla only
- Maximum spatial gradient magnetic field of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of2 W/kg (Normal Operating Mode)
- Cylindrical Quadrature transmit coils only

Under the scan conditions defined above, the BHR System is expected to produce a maximum temperature rise of 7.1 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extended up to 10.2 cm from the BHR system when imaged with a gradient pulse sequence, and up to 7.6 cm from the device when imaged with a spin echo pulse sequence and a 3 Tesla MRI system.

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

Manufacturer

Smith & Nephew Orthopaedics
Harrison Way Leamington Spa
Warwickshire UK CV313HL

www.smith-nephew.com
+1 800 238 7538 U.S. Customer Service

02/2018 81094736 Rev. A

Smith & Nephew Orthopaedics
Harrison Way Leamington Spa
Warwickshire UK CV313HL

Telephone: 1-901-396-2121
Information: 1-800-821-5700
Orders and Inquiries: 1-800-238-7538

www.smith-nephew.com

04727 V2 45670103 REVC 01/18