



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.

A handwritten signature in black ink, appearing to read 'Derek McMinn', with a long horizontal flourish underneath.

Derek McMinn FRCS
Consultant Orthopaedic Surgeon

BIRMINGHAM HIP[◇]

Resurfacing System

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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 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 >30% 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
- Females of child-bearing age due to unknown effect on the fetus of metal ion release
- Patients with known moderate to severe renal insufficiency
- Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids
- Patients who are severely overweight
- Patients with known or suspected metal sensitivity (e.g., jewelry)

Warnings and precautions

- Patients on medications (such as high-dose or chronic aminoglycoside treatment) or with co-morbidities (such as diabetes) that increase the risk of future, significant renal impairment should be advised of the possibility of increase in systemic metal ion concentration. Preoperative and postoperative monitoring of renal function (such creatinine, GFR, BUN) will be necessary.
- Only physicians who have received appropriate training and are familiar with the implant components, instruments, procedure, clinical applications, adverse events, and risks associated with the BHR[®] system should use this device. Contact Smith & Nephew, Inc. for the surgical technique manual and procedural training protocol.
- Currently, in the USA, Smith & Nephew, Inc. does not have a commercially available modular metal femoral head for use with a BHR resurfacing shell. Therefore, if the BHR resurfacing head must be revised to a total hip arthroplasty, the acetabular shell should also be revised, even if well fixed.

For additional information on the use of the BHR device, see the Instructions for Use printed at the end of this surgical technique.

The surgical approach

The BIRMINGHAM HIP Resurfacing device may be implanted through various hip surgical approaches. The posterior approach, as described by Derek McMinn FRCS is described in this operative 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 head-neck 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.

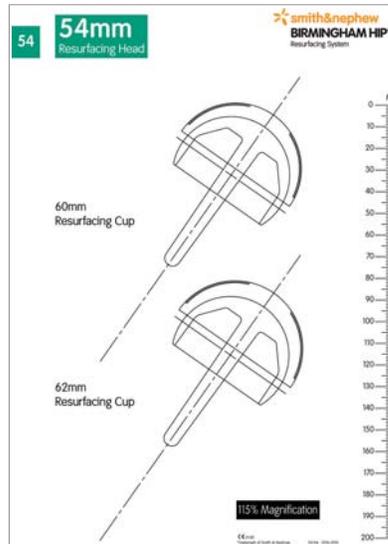


Figure 1

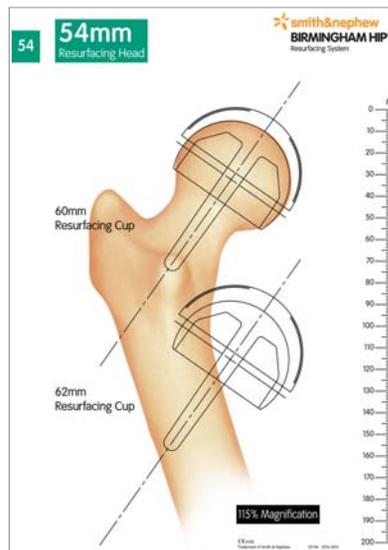


Figure 2

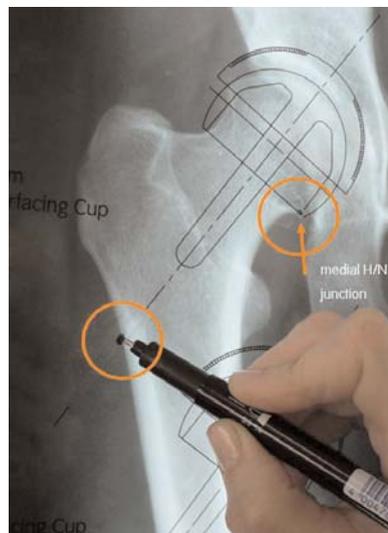


Figure 3

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.

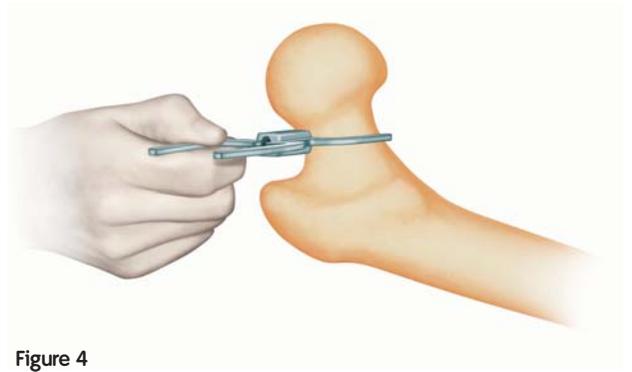


Figure 4

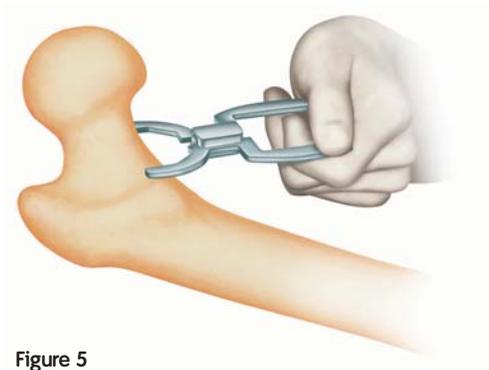


Figure 5

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 hemispherical 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).

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).

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 Psoas impingement on the wall of the acetabular component, avoiding post-operative groin pain.

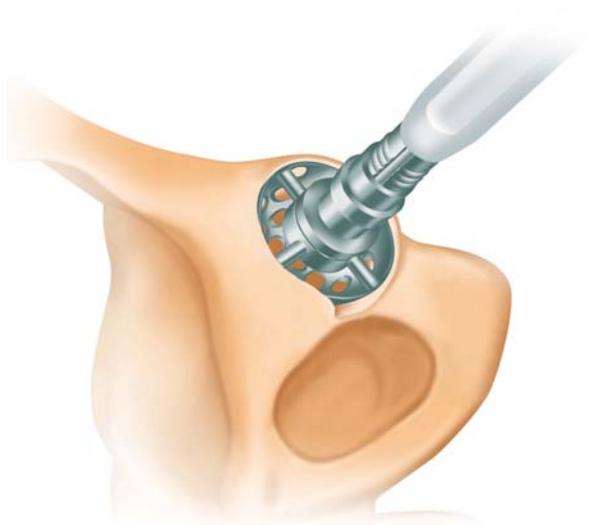


Figure 6

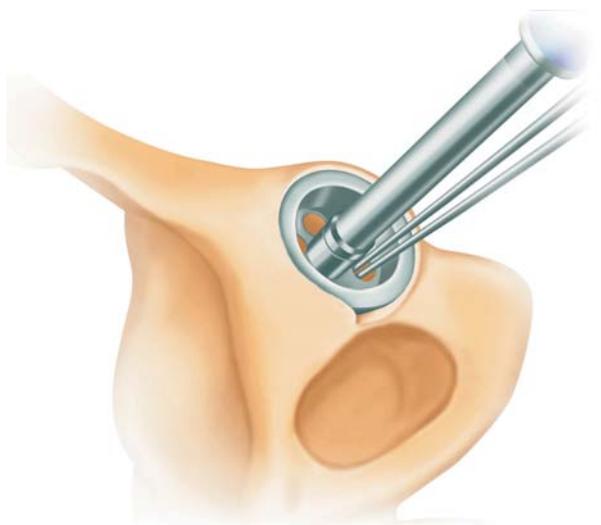


Figure 7

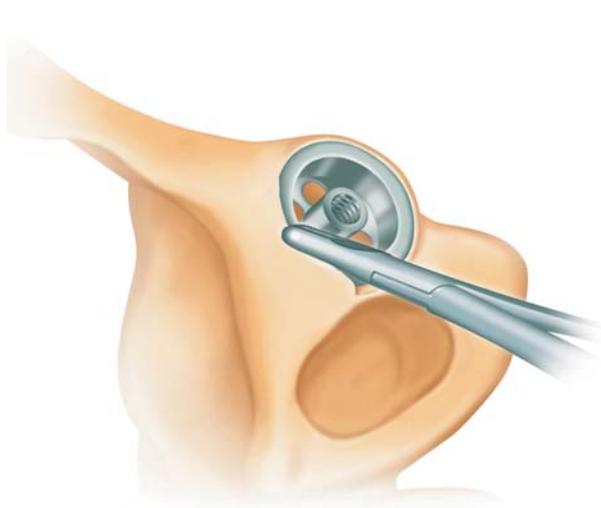


Figure 8

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 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.

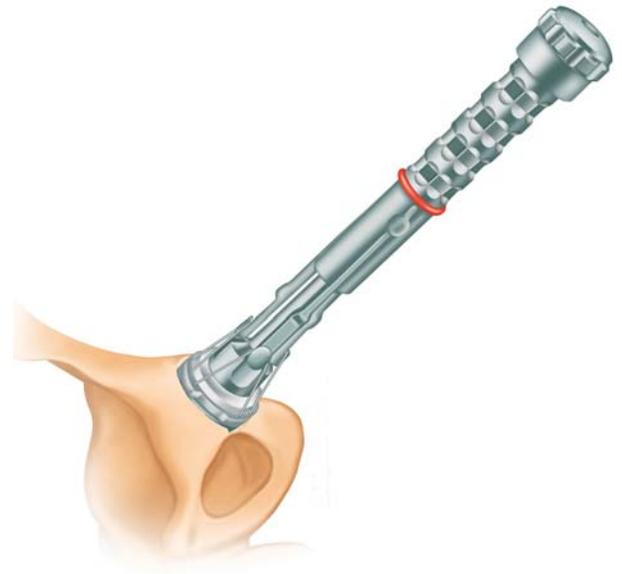


Figure 9

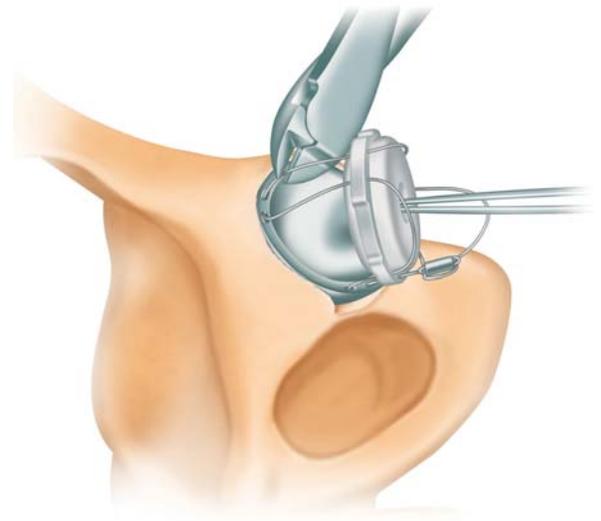


Figure 10

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 & Bridging 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.

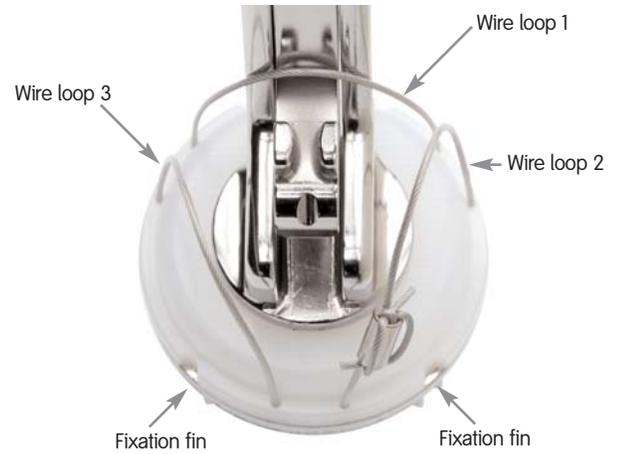


Figure 1

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&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)

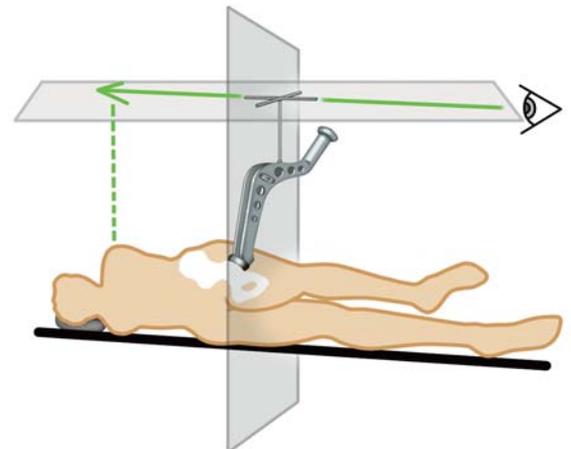


Figure 9

Femoral Preparation

The desired position of the femoral alignment pin will be known from the pre-operative 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).

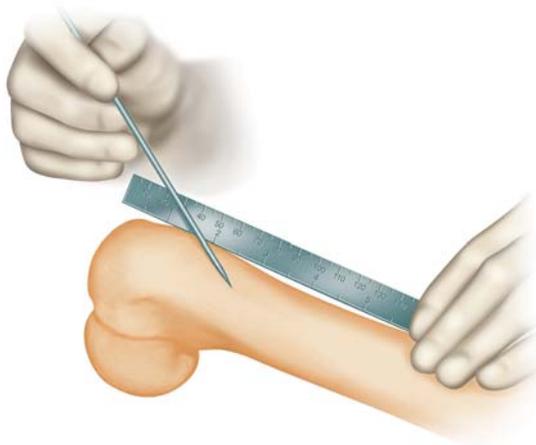


Figure 1



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.

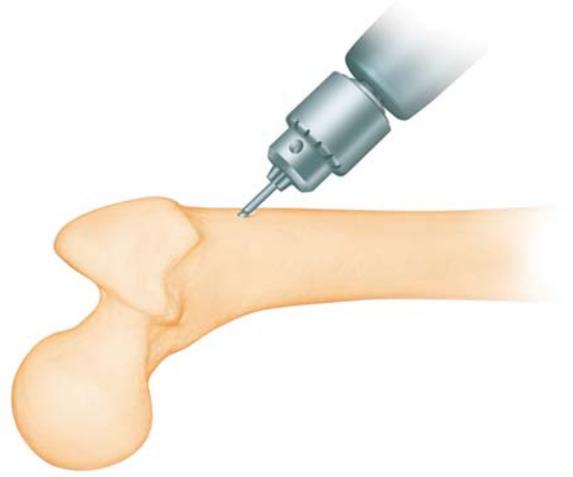


Figure 3

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.

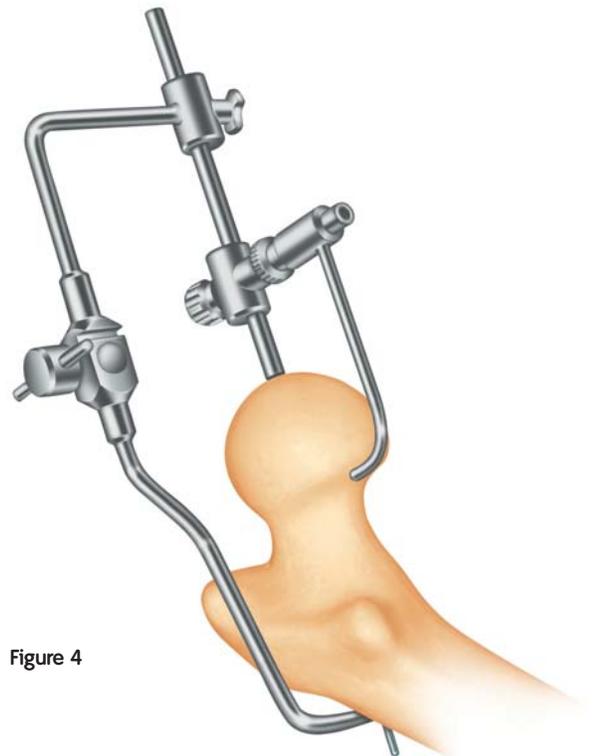


Figure 4

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.

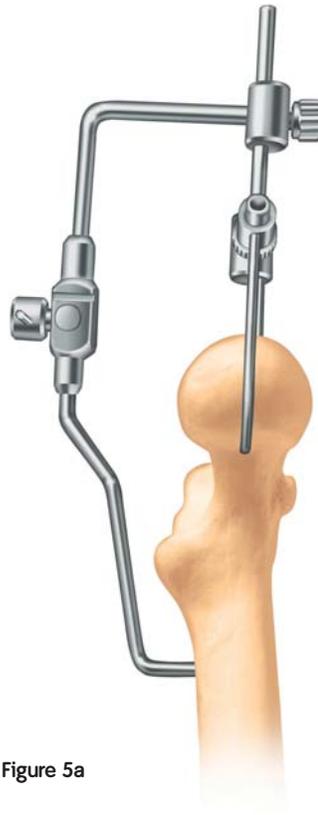


Figure 5a

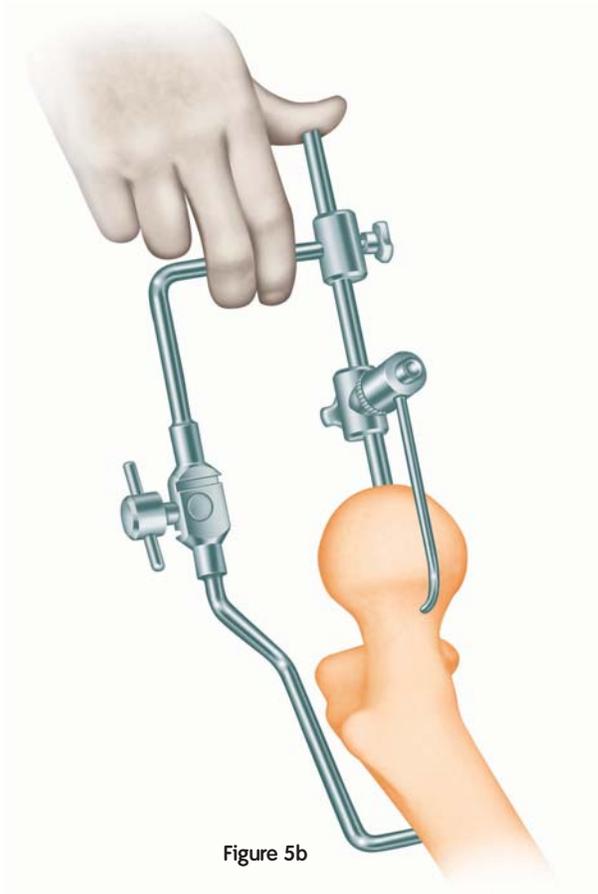


Figure 5b

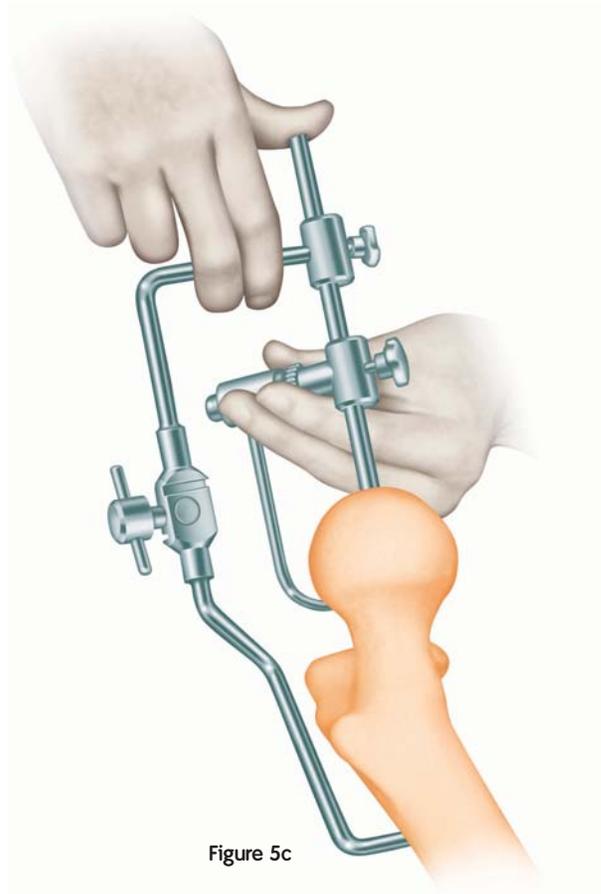


Figure 5c

Short Arm Alignment Jig Technique

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.

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 overlaid 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.

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.



Figure 6

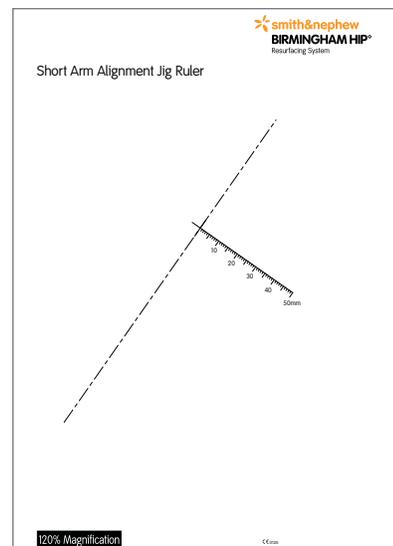


Figure 7 - Short Arm Alignment Jig Ruler
IMAGE NOT TO SCALE



Figure 8 - Measuring Guide

Short Arm Alignment Jig

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).

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).

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.

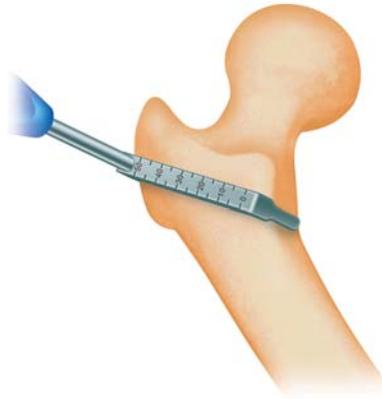


Figure 9



Figure 10

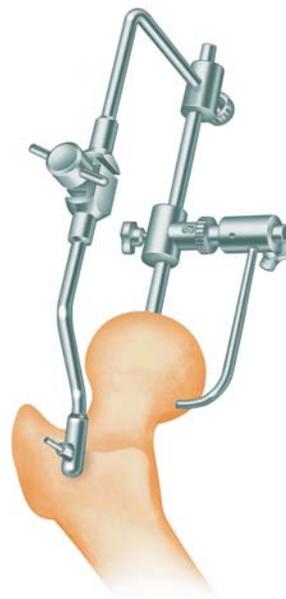


Figure 11

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.



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.

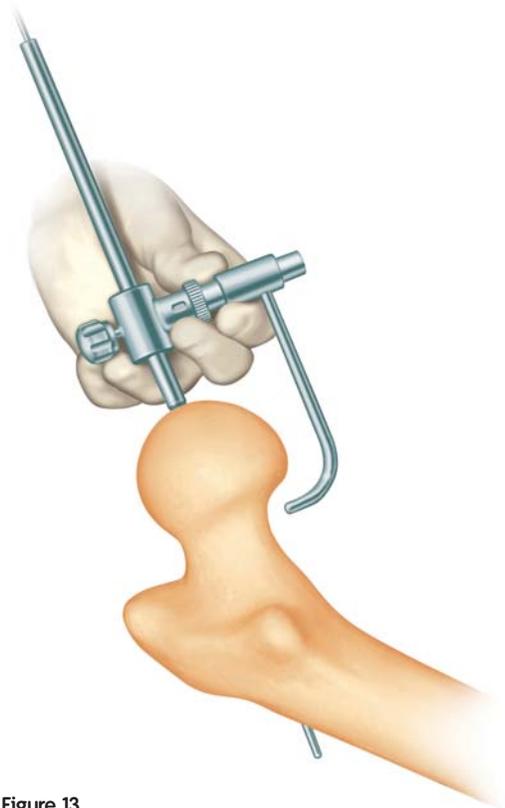


Figure 13

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).

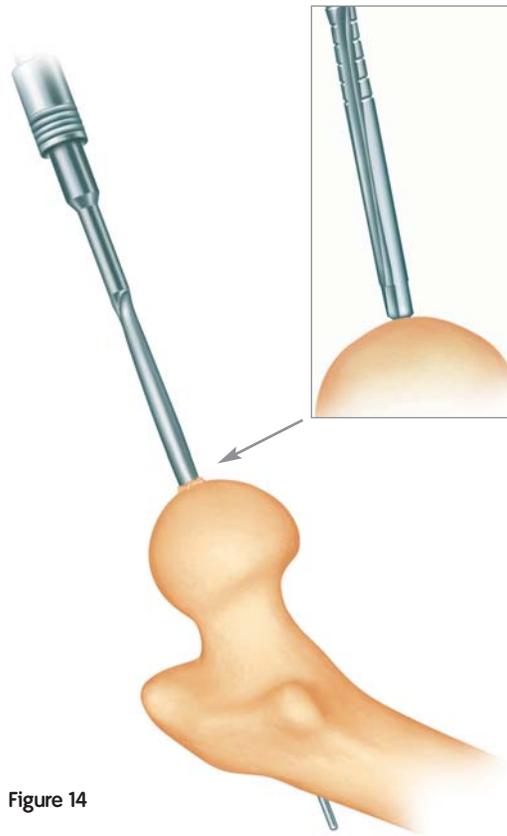


Figure 14



Figure 15

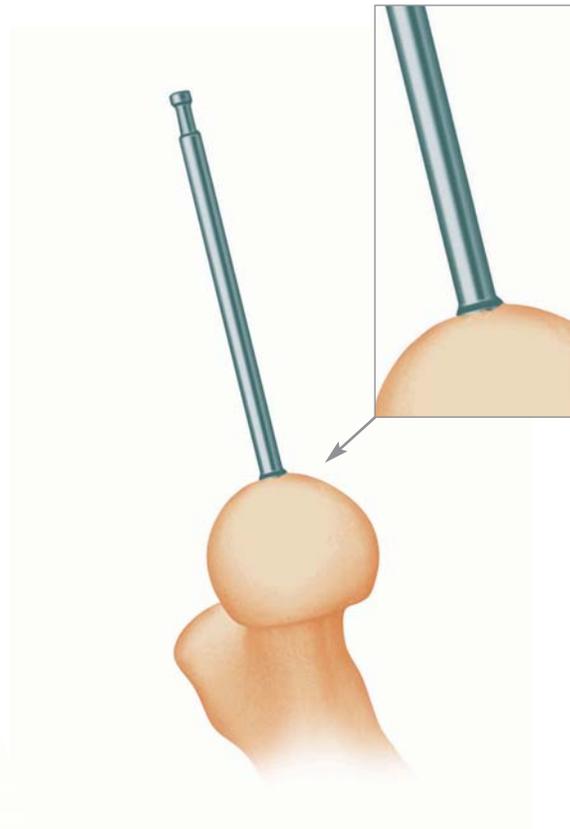


Figure 16

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).

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)

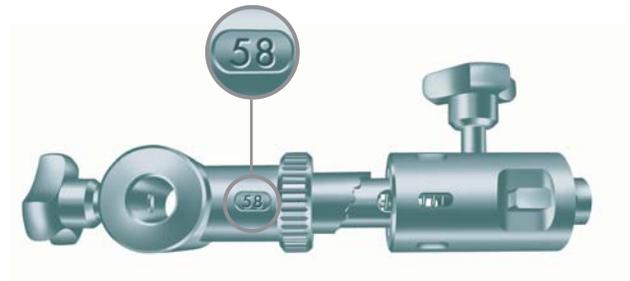


Figure 17

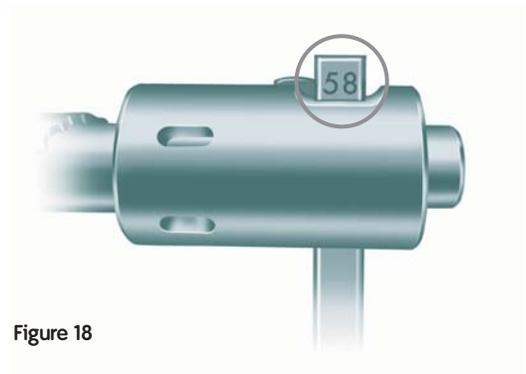


Figure 18

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).

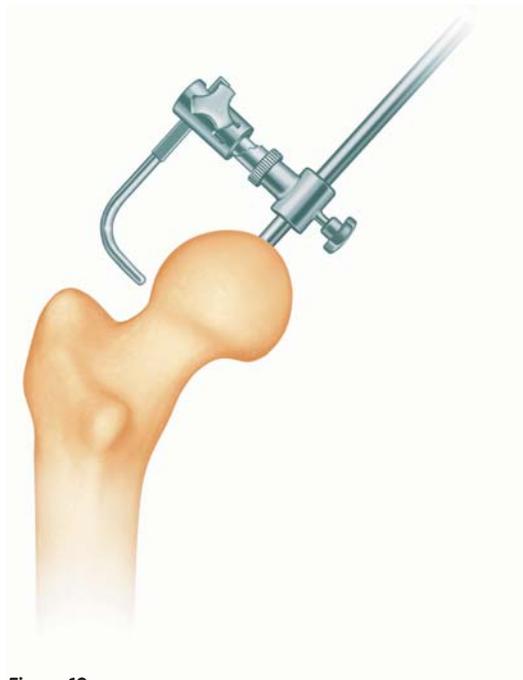


Figure 19

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

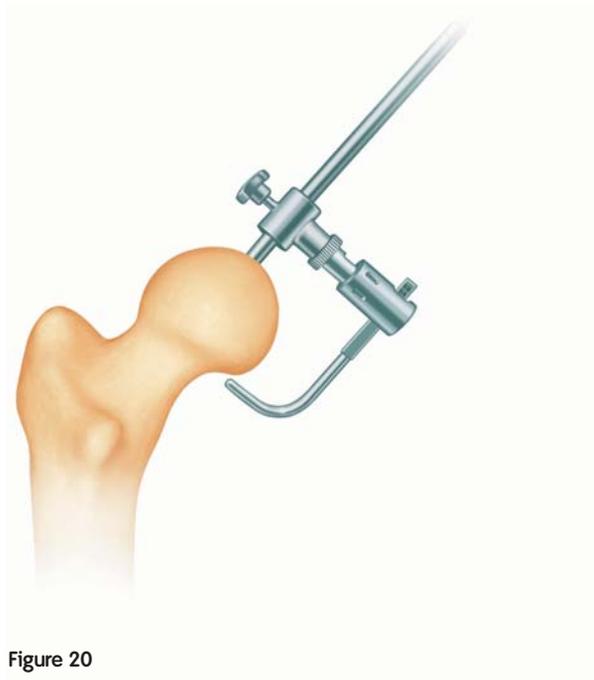


Figure 20

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. (Figure 21 & 22)

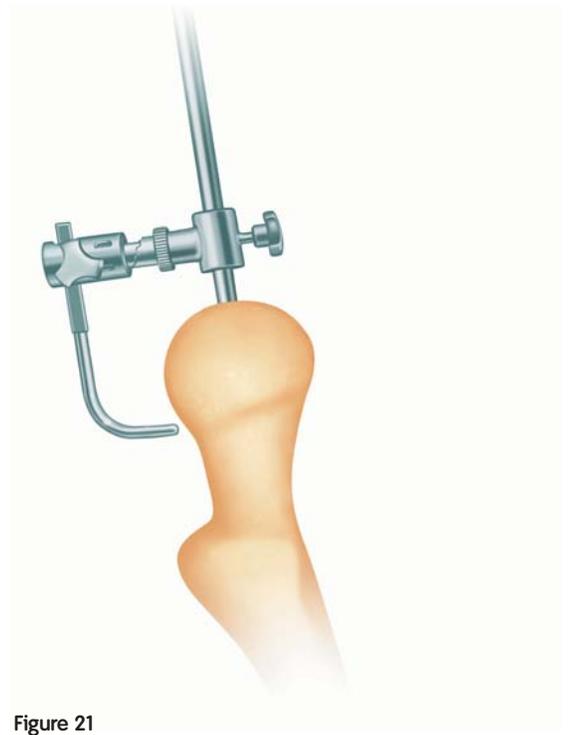


Figure 21



Figure 22

When satisfied with the chosen cutting depth a 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 maybe 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.

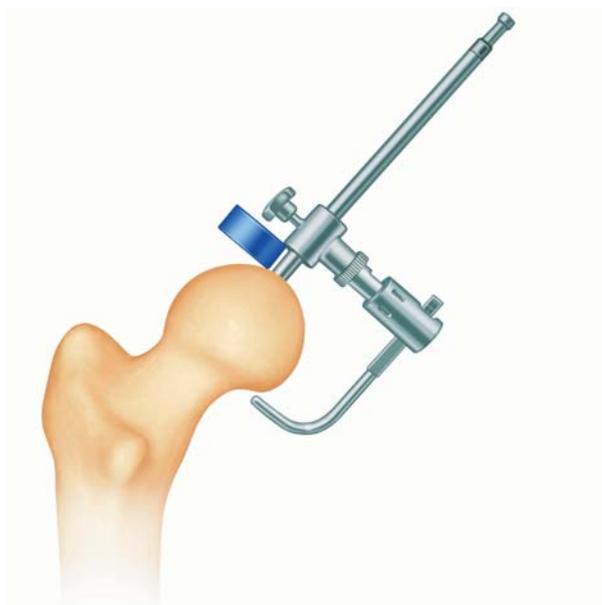


Figure 23



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 (Figure 26 & 27). The sleeve cutter stop spacer is now removed.

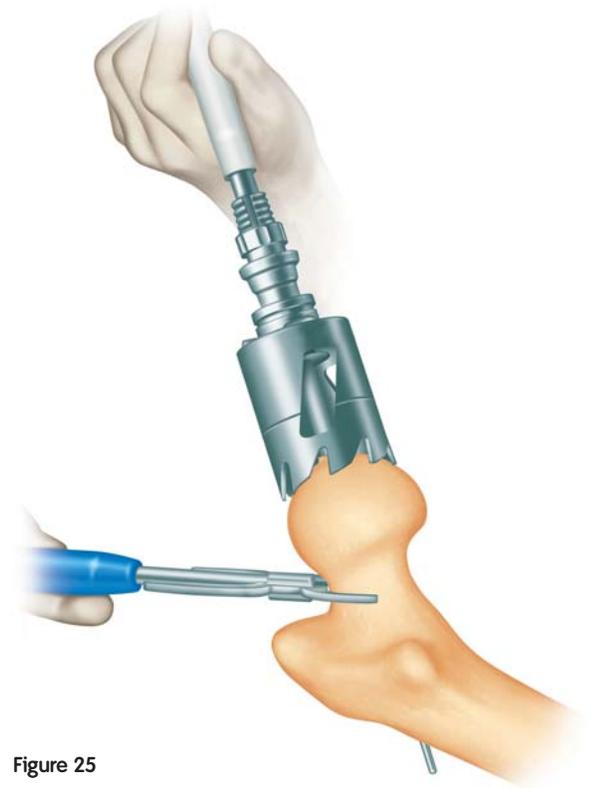


Figure 25

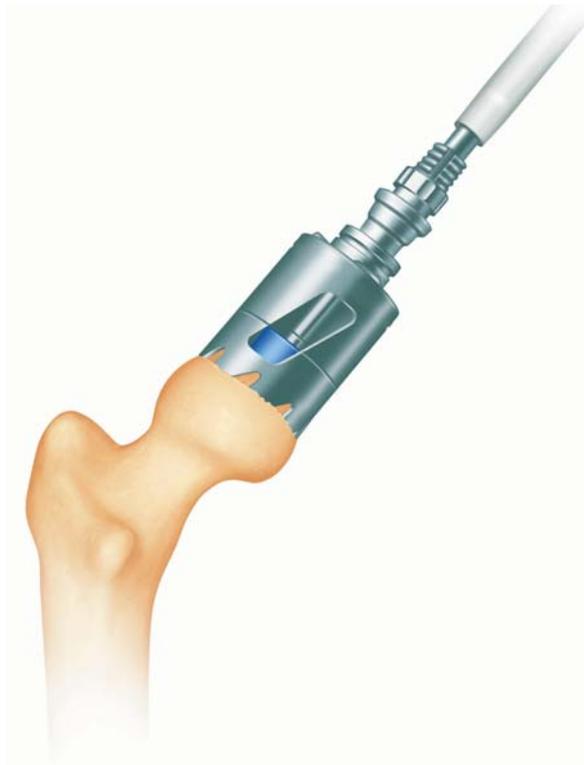


Figure 26

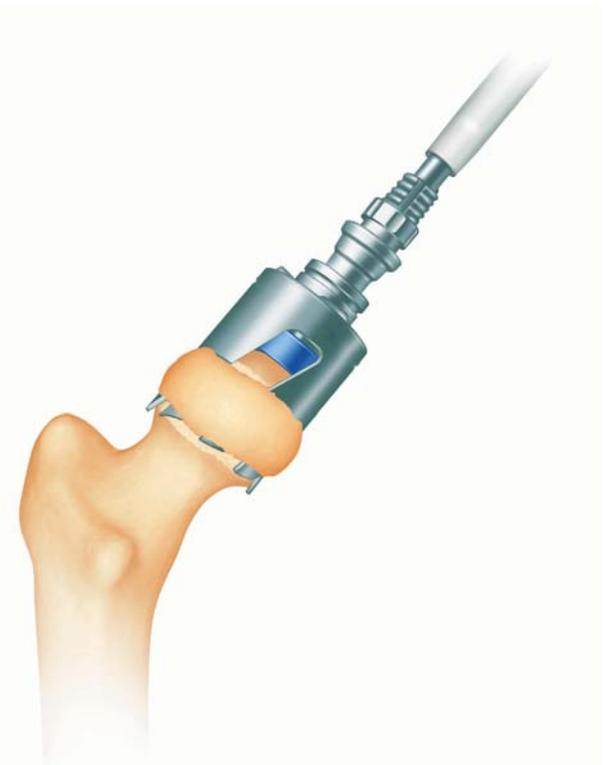


Figure 27

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.

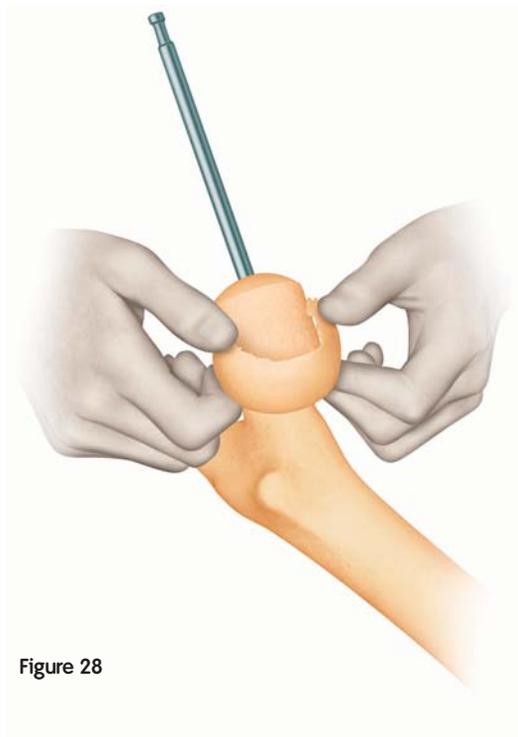


Figure 28

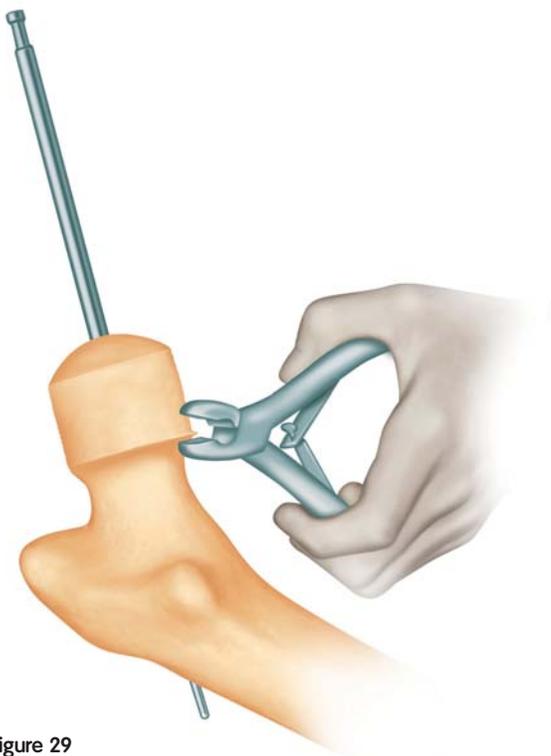


Figure 29



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).

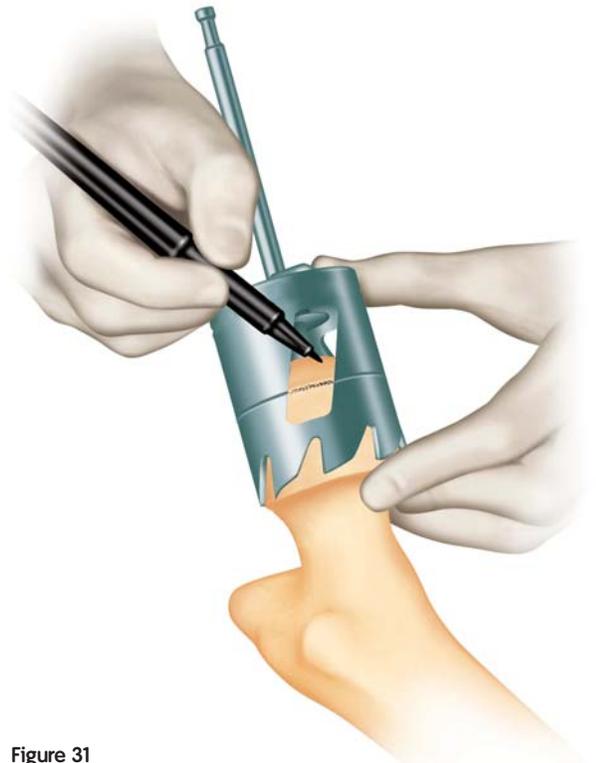


Figure 31

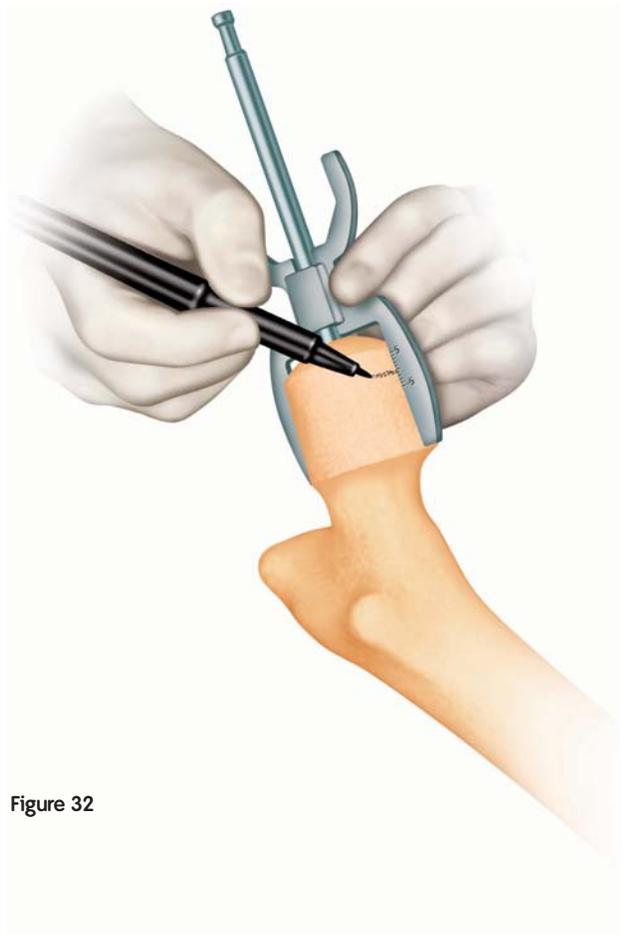


Figure 32

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

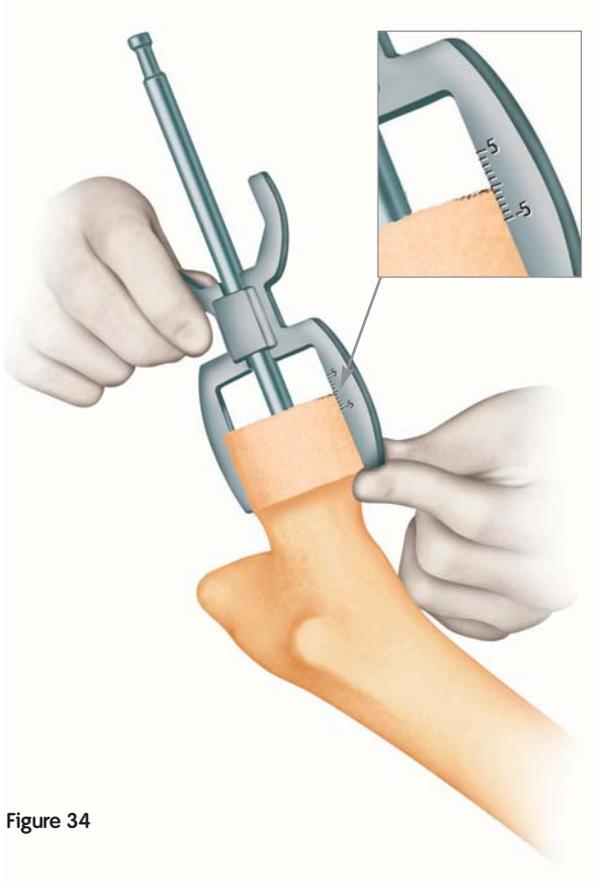


Figure 34



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.

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.

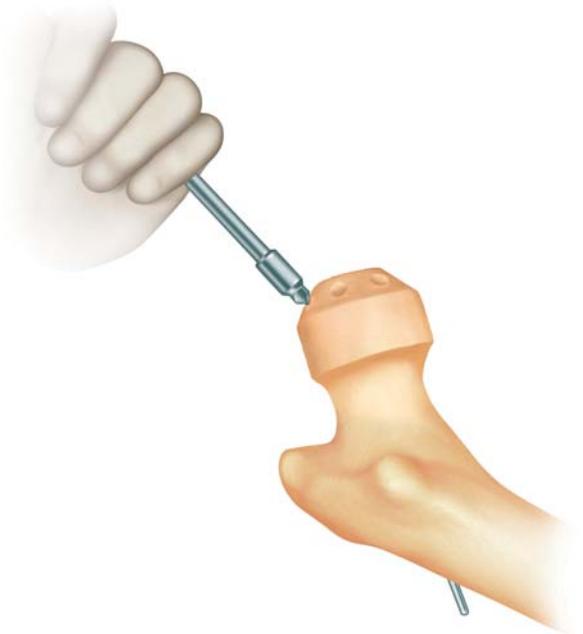


Figure 36



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 three sizes of stem drill (tapered reamer) which correspond to sized groups of femoral components as follows:-

Size 1 = 38-44

Size 2 = 46-52

Size 3 = 54-62

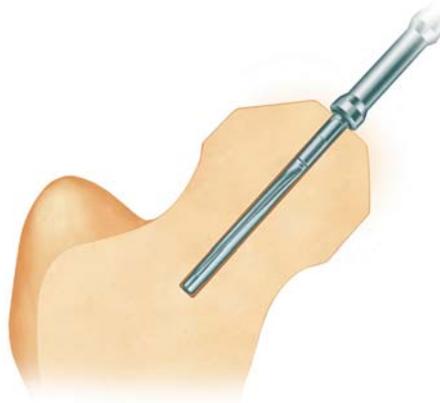


Figure 39

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.

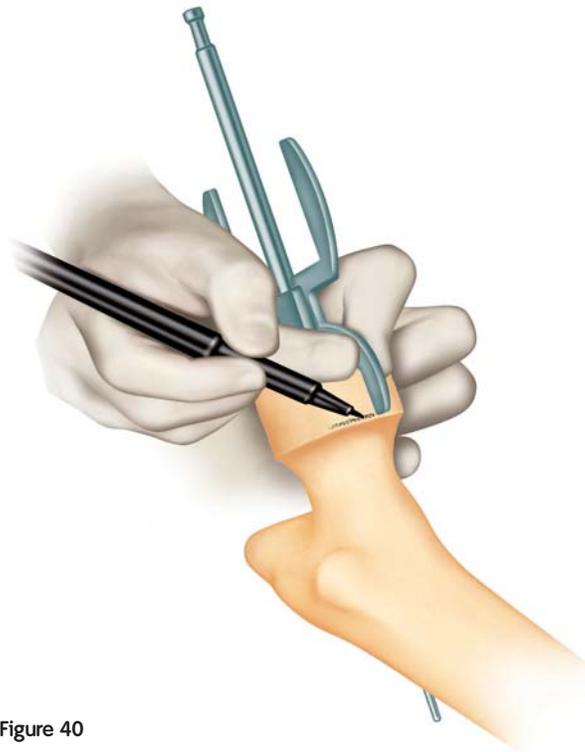


Figure 40



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

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.

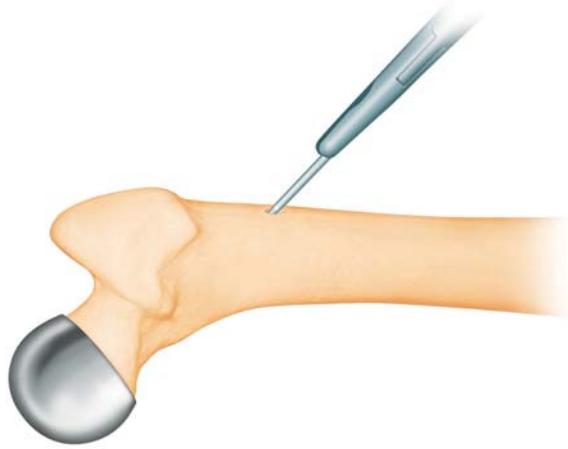


Figure 44

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 & 46).

For example, the size 50mm femoral component can be matched with a size 56mm acetabular cup, a size 58mm acetabular cup, a size 58mm dysplasia cup, or a size 62mm bridging 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.

Implant Size Chart			
Head Size	BHR Cup	Dysplasia Cup	Bridging Cup
38	44 46	46	50
42	48 50	50	54
46	52 54	54	58
50	56 58	58	62
54	60 62	62	66
58	64 66	66	

IMPORTANT: NEVER mix colors on heads and cups. Trademark of Smith & Nephew 11/05 0216-1903

Figure 45 - Implant Size Chart Classic Sizes

BHR® Implant Size Chart		
HEAD SIZE	CUP SIZE	DYSPLASIA CUP SIZE
38	44 46	46
40	46 48	
42	48 50	50
44	50 52	
46	52 54	54
48	54 56	
50	56 58	58
52	58 60	
54	60 62	62
56	62 64	
58	64 66	66

IMPORTANT: NEVER mix colors on heads and cups. Trademark of Smith & Nephew 11/05 0216-1903

Figure 46 - Implant Size Chart Combined 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.

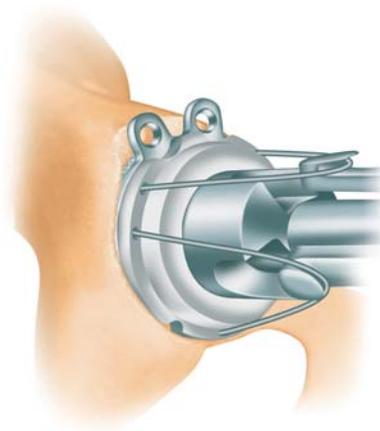


Figure 1

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.

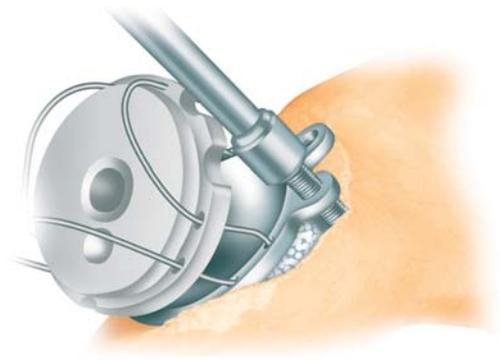


Figure 3

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.

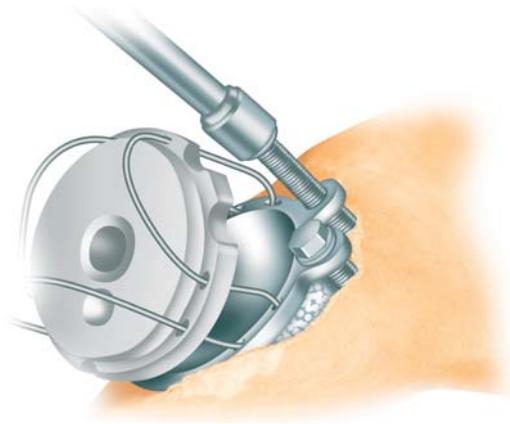


Figure 4

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. For example, in old fractures of the posterior acetabular wall, the bridging acetabular cup (useful in gross femoral head/acetabulum size mis-match) also has superolateral lugs for screw fixation. 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.

In an effort to prevent the small amount of fat displacement known to occur with resurfacing, the author has been using 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

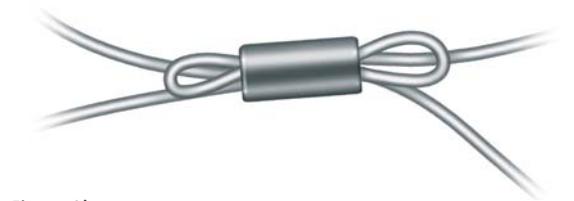


Figure 3b

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

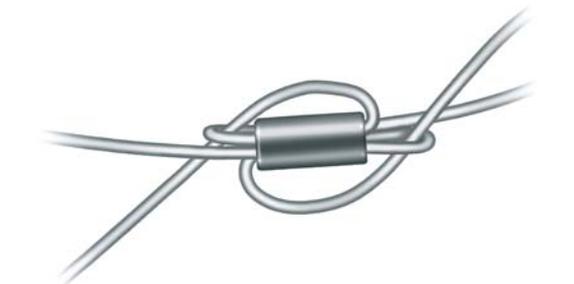


Figure 4b

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.

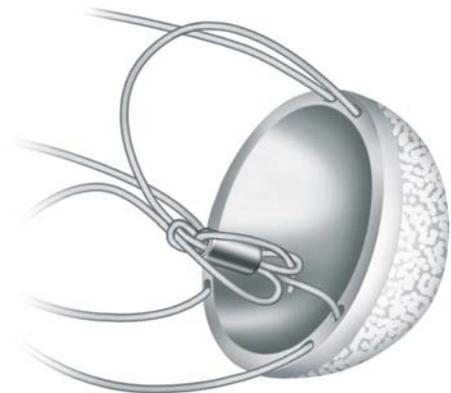


Figure 5

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
74121138	38mm
74123140	40mm
74121142	42mm
74123144	44mm
74121146	46mm
74123148	48mm
74121150	50mm
74123152	52mm
74121154	54mm
74123156	56mm
74121158	58mm



BHR Acetabular Cup

Cat. No.	Size
74120144	44mm (38 head)
74120146	46mm (38 head)
74122146	46mm (40 head)
74122148	48mm (40 head)
74120148	48mm (42 head)
74120150	50mm (42 head)
74122050	50mm (44 head)
74122152	52mm (44 head)
74120152	52mm (46 head)
74120154	54mm (46 head)
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
74120246	46mm
74122248	48mm
74120250	50mm
74122252	52mm
74120254	54mm
74122256	56mm
74120258	58mm
74122260	60mm
74120262	62mm
74122264	64mm
74120266	66mm



BHR Bridging Cup

Cat. No.	Size
74120350	50mm
74122352	52mm
74120354	54mm
74122356	56mm
74120358	58mm
74122360	60mm
74120362	62mm
74122364	64mm
74120366	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

Warnings and Precautions

DEVICE DESCRIPTION

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

Resurfacing Femoral Head

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

Acetabular Cups

The standard acetabular component is supplied in a range of twenty two 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 eleven sizes for the dysplasia cup. A bridging cup is designed with a thicker wall section than the dysplasia cup to allow for mismatch between femoral head size and surgically prepared acetabulum. The bridging cup is also designed with two superolateral screw holes that accommodate the CoCr-alloy dysplasia cup screws. The bridging cup is available in ten sizes.

Dysplasia Cup Screws

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

Sizing and System Compatibility

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

BHR Femoral Head Resurfacing Component (identified by head outer diameter)	Mating BHR Standard Cup Sizes (2 cups available per head component size)	Mating BHR Dysplasia Cup Sizes	Mating BHR Bridging Cup Sizes
38mm	44mm or 46mm	46mm	50mm
40mm	46mm or 48mm	48mm	52mm
42mm	48mm or 50mm	50mm	54mm
44mm	50mm or 52mm	52mm	56mm
46mm	52mm or 54mm	54mm	58mm
48mm	54mm or 56mm	56mm	60mm
50mm	56mm or 58mm	58mm	62mm
52mm	58mm or 60mm	60mm	64mm
54mm	60mm or 62mm	62mm	66mm
56mm	62mm or 64mm	64mm	68mm
58mm	64mm or 66mm	66mm	

INDICATION FOR USE

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

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

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

Contraindication

Patients with infection or sepsis
Patients who are skeletally immature
Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery

Patients with bone stock inadequate to support the device including:

- Patients with severe osteopenia should not receive a BHR procedure. Patients with a family history of severe osteoporosis or severe osteopenia.
- Patients with osteonecrosis or avascular necrosis (AVN) with >50% involvement of the femoral head (regardless of FICAT Grade) should not receive a BHR.
- Patients with multiple cysts of the femoral head (>1cm) should not receive a BHR.
- Note: In cases of questionable bone stock, a DEXA scan may be necessary to assess inadequate bone stock.

Females of child-bearing age due to unknown effect on the fetus of metal ion release

Patients with known moderate to severe renal insufficiency
Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids
Patients who are severely overweight
Patients with known or suspected metal sensitivity (e.g., jewelry)

WARNINGS AND PRECAUTIONS

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

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

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

Preoperative

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

Intraoperative

Implants should be accepted only if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.
Avoid notching the femoral neck, as this may lead to femoral neck fracture.
Avoid placing the femoral component in varus. Varus placement of the femoral component has been associated with femoral neck fracture.
Do NOT re-use an implant. All implants are intended for single-use only.

Use the recommended instruments and the recommended surgical technique.
Improper selection, placement, positioning, and fixation of the implant components may result in early implant failure.
Malalignment of the components and/or soft tissue imbalance may cause excessive wear and early implant failure.
Associated trials and templates should be used for verification of component size. If an appropriate component size cannot be found during pre-operative planning, do not use this type of implant.
Complete pre-closure cleaning of the implant site (complete removal of bone chips, bone fragments, metallic debris, etc.) is critical to prevent wear of the articular surfaces.
Using instruments other than the associated BHR instruments may result in inaccurate placement.

Hydroxyapatite-Coated Acetabular Implants

Do NOT allow the HA-coated, porous-surfaced acetabular component to contact any substance other than the device packaging, clean gloves, or the patient's tissue.
Do NOT use cement with these HA-coated, porous-surfaced implants.

Take care to achieve a stable press fit. The HA-coated, porous surface is not intended to compensate for inadequate implant fixation.

Postoperative

Excessive physical activity levels, excessive patient weight, and trauma to the joint replacement may cause early failure of the implant.

Loosening of components may increase production of wear particles and accelerate damage to the bone, making successful revision surgery more difficult.

Patient Education

Warn the patient of the surgical risks, possible adverse effects, and possible operative complications that can occur with joint arthroplasty.

Warn the patient of the limitations of artificial joint replacement devices.

Caution the patient to protect the joint replacement from unreasonable stresses and to follow the treating physician's instructions. In particular, warn the patient to strictly avoid high impact activities such as running and jumping during the first post-operative year while the bone is healing.

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

POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Reported Device Related Adverse Effects

The most commonly reported BHR device related adverse events are:

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

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

Potential Adverse Effects

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

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

SUMMARY OF CLINICAL STUDIES

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

Study Objectives and Assessments

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

Description of Cohorts and Data Collected

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

X-ray cohort: First 124 BHR cases performed from July 1997 through December 1997.

Oswestry cohort: Next 1,502 BHR cases performed from January 1998 through March 2002.

McMinn cohort: Next 759 BHR cases performed from April 2002 through May 2004.

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

Table 2. Cohorts and Data Collected	Types of Safety and Effectiveness Data Collected								
	Safety Data Collected				Effectiveness Data Collected				
Cohort	Dates of Implantation	Number of Procedures	Adverse Events	Revisions	Deaths	Survivorship	Radiographs	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:

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 Centre 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 ≤ 2 mm; and
Change in acetabular angle $< 5^\circ$

A radiographic **failure** was defined as the following:
Presence of incomplete or complete radiolucencies or a radiolucency in all zones (a score of 7 or 8);
A migration of the component > 2 mm; or
A change in acetabular orientation of $\geq 5^\circ$

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

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

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

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

Patient Satisfaction Data Collection Method

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

Literature References

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

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

The data in these references have some differences as compared to the data provided for the BHR device in this clinical data series, including:

- Different evaluations, (OSHIP for BHR and HHS for literature)
- Length of follow-up, (18-36mo and 2-4 years for the controls and 2-5 years for the BHR study)
- Mean baseline pain and function scores (e.g., 60 for OSHIP in BHR Oswestry cohort, 44 for HHS Garino study, and not reported for D'Antonio study), and
- Indications for use, (including differences in the rate of dysplasia and AVN diagnostic indications)

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

PATIENT DEMOGRAPHICS

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

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

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

Demographics for X-Ray/Oswestry combined cohort

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

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

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

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).

Cohort	Patients**	Hips***	Unilateral		Bilateral		Contralateral Single Hip Cohort		Singles
			X-Ray	Oswestry	X-Ray	Oswestry	McMinn	8	
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).

Author	Patients	Procedures	Age (Average)	Bilateral Procedures
D'Antonio J <i>et al.</i>	458	514: 349 ceramic 165 control	53	19
Garino JP	333 (n=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).

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).

Cohort	Accounting for Survivorship (% Revision Free)					
	Baseline	1 Year	2 Years	3 Years	4 Years	5 Years
X-Ray	-	124 (1.0)	123 (0.9)	123 (1.0)	122 (1.0)	122 (1.0)
Oswestry	-	1502 (9.6)	1430 (9.4)	1376 (9.2)	1116 (7.3)	794 (5.0)
McMinn	-	759 (5.2)	466 (3.2)	87 (0.6)	3 (0.0)	3 (0.0)
X-Ray Cohort						
Expected*	124	123	123	122	122	118*
Evaluated†	82	101	51	122	119	112
F/U %‡	66.1%	82.1%	41.4%	100.0%	97.5%	94.9%
Evaluated†	124	-	-	-	-	108
F/U %‡	100%	-	-	-	-	91.5%
Oswestry Cohort						
Expected*	1502	1493	1484	1227	885	482
Evaluated†	1229	1137	1192	1067	773	434
F/U %‡	81.8%	76.2%	80.3%	87.0%	87.3%	90.0%
X-Ray / Oswestry Combined Cohort						
Theoretical	1626	1626	1626	1385	1045	647
Deaths (procedures)	0	2	7	16	18	26
Revisions (cumulative)	0	10	15	20	21	23
Expected*	1626	1616	1607	1349	1007	601
Evaluated†	1311	1238	1243	1189	892	546
F/U %‡	80.6%	76.6%	77.3%	88.1%	88.6%	90.8%
F/U +base*	1311	1067/1304	1050/1294	944/1046	660/726	368/397
+base %	-	82%	81%	90%	91%	93%
F/U -base*	315	171/312	193/313	245/303	232/281	178/204
-base %	-	55%	62%	81%	83%	87%

- 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.
- Evaluated by OSHIP score
- 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
- Evaluated by X-Ray
- The follow-up of those who had baseline OSHIP scores (+base) and those without baseline OSHIP scores (-base)
- Note that there were 2 revisions in the x-ray cohort at >5 years
- 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.
- 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).

	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 was as provided in Table 11.

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 patient), 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).

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

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

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

Safety: Revisions Comparison with Literature References

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

	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.

Adverse Event*	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	2 (<0.1%)	10 (0.5%)	0	2 (0.1%)	0	1 (0.2%)
Implantation	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
Hip 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	0	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

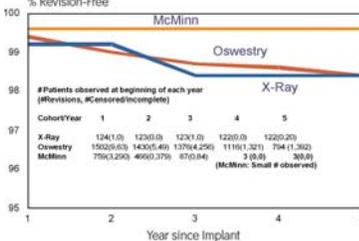
Population	1 Year	2 Years	3 Years	4 Years	5 years
X-ray Cohort	99.2	99.2	98.4	98.4	98.4
Oswestry Cohort	99.4	99.0	98.7	98.6	98.4
X-Ray / Oswestry Combined Cohort	99.4	99.0	98.7	98.6	98.4 (95% CI, 97.3-99.5%)
McMinn Cohort	99.6	99.6	99.6	99.6	99.6
Overall McMinn Cohort	99.4	99.1	98.8	98.7	98.5 (95% CI,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

Peto's adjustment method as follows (Table 15):

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

Figure 1. Cumulative % Revision-Free, BHR



survival probabilities (all hips):

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 protrusion. 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 >5P. 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).

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	2 (1.8%)
Other: Grade 1	2 (1.8%)
Other: Grade 2	1 (0.9%)
Change in orientation/migration	
Sp change in orientation	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 of acetabular cyst	2 (1.8%)

¹ Occurred in the same patient

Radiographic Finding	Overall McMinn Cohort	Gairino Reference ¹	D'Antonio Reference		
			ABC with porous (n=162)**	ABC with HA (n=151)**	Reference Control M/PE (n=49)**
Femoral RI, Zone 1	1 (0.9%)	-	4 (2.5%)	4 (2.4%)	6 (4.0%)
Femoral RI, Zone 2	1 (0.9%)	-	-	-	-
Femoral RI, Zone 2 & 3	1 (0.9%)	-	-	-	-
Femoral RI, Zone 7	0	-	2 (1.2%)	1 (0.6%)	0
Stem subsidence	0	-	0	1 (0.6%)	0
Unstable stem	1 (0.9%)	-	0	1 (0.6%)	0
Cup RI, Zone I	2 (1.8%)	-	10 (6.2%)	1 (0.6%)	10 (6.7%)
Cup RI, Zone II	1 (0.9%)	-	3 (1.9%)	0	7 (4.7%)
Cup RI, Zone III	0	-	25 (15.4%)	0	35 (22.5%)
Cup RI, all 3 zones	2 (1.8%)	-	0	0	0
Cup migration	1 (0.9%)	-	0	0	1 (0.7%)
Cup unstable	1 (0.9%)	-	1 (0.6%)	0	1 (0.7%)

Radiographic Study: Comparison to Literature Reference

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

* 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

	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 ¹	13.1	6.75	7.3	7.4	8.0	9.7
SE ²	0.44	0.23	0.25	0.26	0.32	0.31
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
N, Dysplasia	57.7	96.2	96.7	95.2	94.7	90.6
N, Dysplasia OSHIP mean	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	96.3	96.6	98.8	98.4
N, Other	25	24	24	22	9	7
OSHIP mean for procedures with baseline <80	84.5	96.1	97.8	97.3	99.6	99.3
N, for baseline <80	25	22	22	18	8	3
OSHIP mean for procedures with baseline <80	59.4	96.9	96.9	96.6	96.4	95.6
N, for baseline <80	867	693	686	635	440	240
OSHIP mean for procedures with baseline OSHIP	60.1	96.9	96.9	96.6	96.5	95.6
N, with baseline OSHIP	892	715	708	653	448	243
OSHIP mean for procedures without baseline OSHIP	-	94.8	96.2	94.8	94.1	92.9
N, without baseline OSHIP	-	120	134	165	159	117
Improved >10%	-	703 (84.2)	697 (82.8)	645 (78.9)	445 (73.3)	239 (66.4)
Maintained (%)	-	130 (15.6)	142 (16.9)	173 (21.1)	161 (26.5)	121 (33.6)
Deteriorated <=10%	-	2 (0.2)	3 (0.4)	0	1 (0.2)	0
OSHIP Exact <=90 (%)	2 (0.2)	757 (90.7)	775 (92.9)	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 (19.7)	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)

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

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).

	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)	9 (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 (0.0)	
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).

	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 Assessments	1111	1103	1100	927	687	395
N	892	835	842	818	607	360
Pleased/Very pleased (NP)	-	800 (95.8%)	839 (99.6%)	813 (99.4%)	604 (99.5%)	357 (99.2%)
N, AVN	43	35	38	32	23	14
AVN Pleased/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 Pleased/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 Pleased/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 Pleased/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 Pleased/VP	-	22 (91.7%)	24 (100.0%)	21 (95.5%)	9 (100.0%)	7 (100.0%)

Additional Data Sources

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

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

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

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

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

	Baseline	1 Year	2 Years	3 Years	4 Years	5 years
Worldwide OSHIP assessment	395	2356	2492	2364	1379	505
Worldwide Mean OSHIP	56.95	91.67	92.47	92.45	91.86	89.77

STERILIZATION

Implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6} . Metal components are sterilized to a minimum of 25 kiloGrays of gamma irradiation. All components are supplied in protective packaging. Inspect packages for punctures or other damage prior to surgery.

Instruments used to implant the device system are supplied non-sterile and must be sterilized prior to use using one of the following validated, recommended methods:

- * **Prevacuum Flash Cycle:** 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum exposure time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge
 - * **High Temperature Gravity Cycle:** 270°F to 275°F (132°C to 135°C) with a minimum exposure time of 10 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying.
 - * **Prevacuum Cycle:** 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum exposure time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying.
- DO NOT RESTERILIZE implant components. Contact your local Smith & Nephew, Inc. Sales Representative regarding procedures to return components.

The product is not labeled "pyrogen free".

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

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

INFORMATION

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

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