

Purpose of the BHR device

The Birmingham Hip Resurfacing (BHR) Device is intended for patients who are having their hip joints resurfaced to relieve hip pain and improve hip function of hips damaged by:

- Non-inflammatory degenerative joint diseases such as osteoarthritis,
- Avascular necrosis,
- Dysplasia/DDH, and
- Inflammatory degenerative joint diseases such as rheumatoid arthritis.

Hip resurfacing arthroplasty is intended as a primary joint replacement for patients who are at risk of requiring more than one hip joint replacement over their lifetimes. While it is impossible to predict which patients will require more than one joint replacement, factors that are known to increase risk for revision surgery include age <55 at initial surgery or high activity level.

Description of the BHR device

The BHR device consists of two parts: an acetabular component (or cup), and a femoral resurfacing component (or head).



- Acetabular component: The cup is used to replace the damaged surface of your hip socket. The cup is mechanically fixed to your hip socket without the use of bone cement. Bone screws may be used in some cases to provide additional fixation.
- Femoral resurfacing component: The head is used to cover the ball of your hip (the ball-shaped part of your hip at the top of your thighbone). The head component features a small stem that is inserted into the top of your thighbone. The head is fixed to your thighbone using bone cement.

The BHR head swivels within the BHR cup. The surfaces that rub against each other are both made from highly-polished metal. This type of hip device, therefore, is called a *metal-on-metal* hip replacement device.

When the BHR device should not be used

The BHR device should not be used in patients:

- Who have an infection of the body or blood,
- Whose bones are not yet fully grown,
- Who have any blood vessel-related disease, muscle-related disease, or neuromuscular-related disease that the physician believes is severe enough to compromise implant stability or to interfere with the patient's ability to follow the postoperative recovery regimen, and
- Who have bones that are not strong enough or healthy enough to adequately support the device.

Potential Benefits of the BHR device

The potential benefits of *any* hip replacement system are relief of pain, restoration of function, and correction of deformity. As compared to a traditional total hip replacement system with a metal-on-plastic socket, however, the potential benefit of the BHR device is that its metal-on-metal socket has shown less wear in laboratory testing. These lab test results suggest that the BHR device's metal-on-metal socket may last longer.

There are total hip systems that feature metal-on-metal sockets. When compared with these devices, the potential benefit of the metal-on-metal BHR device is that the BHR device leaves your femoral head in place. This means that if you eventually wear out your first BHR hip replacement, your surgeon will have an easier time replacing your hip in the future. With a *total* hip replacement, however, your surgeon must remove your femoral head and insert a new ball and stem into your thighbone. This means that if you eventually wear out your first total hip replacement, your surgeon will have a harder time replacing your hip, because your surgeon will have to remove the original ball and stem (which may take some additional bone with it) from your thighbone.

Additional benefits specific to the BHR device as compared with other contemporary total hip replacement systems are:

- The metal socket components are not subject to chipping/bursting (as ceramics are).
- The BHR device is not subject to femoral shaft fractures.
- Clinical data suggests that the BHR device may result in fewer complications involving blood clots of the legs/lungs.
- Clinical data suggests that the BHR may result in fewer complications involving component dislocations (the ball popping out of the socket).

Potential Risks of the BHR device

The potential risks of any hip joint replacement include: damage to blood vessels, delayed wound healing, infection, temporary or permanent nerve damage, allergic or sensitivity reactions to the component materials or to medications, dislocation of the hip, component loosening/shifting, implant wear/fracture, bone fracture, bone loss or excessive bony formation, a sudden drop in blood pressure during surgery due to the use of bone cement, and cardiovascular complications such as blood clots in the legs or lungs,

and heart attack. Any of these potential adverse effects may require medical attention or additional surgery. Rarely, complications may lead to death.

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

- The risk of femoral neck fracture (breakage of the bone below the ball of the hip).
- The risk of femoral head collapse (breakage of the bone in the ball of the hip).
- The risk of avascular necrosis (death of the bone in the ball of the hip).

Each of these complications would require additional surgery to convert from a BHR device to a total hip replacement device. (Compare these risks to the potential benefits of a BHR system, as described above.)

Clinical Studies

The safety and effectiveness of the BHR device were evaluated through a clinical study. The BHR device was implanted in 1,626 cases. All of these cases were followed for at least 2 years, with 454 of the cases having been followed for 5 years.

Safety Data

Safety was determined by evaluating all of the adverse effects that occurred within the study group, and by comparing the frequency and severity of these adverse effects against the known adverse effect rates reported for other existing hip replacement systems.

Within the study group, adverse effects lead to 24 out of 1,626 patients requiring additional surgery to replace the BHR device. The types of adverse effects that lead to revision surgery included femoral neck fracture, head collapse, avascular necrosis, dislocation, and infection. The revision rate from all adverse effects is comparable to the revision rates reported for other contemporary total hip replacement devices. There were no device-related deaths within the study.

Effectiveness Data

Effectiveness was determined by looking at:

- **Survivorship:** The number of BHR devices still in place (that did not need revision) at 5 years after surgery.
- **Oswestry Hip (OSHIP) Score:** The OSHIP score is a score based on a patient's hip pain, hip function, and hip motion. Based on a patient's response, a score is generated with 0 being the worst possible score and 100 being the best possible score. A score of 80 or better is considered a good result.
- **Patient Satisfaction:** Patients in the study were asked to rate their satisfaction with the BHR device on a scale of 0-4, with 0 being the worst possible score and 4 being the best possible score.

Survivorship

Based on the revision surgery rate experienced within the study, it is estimated that approximately 98% of the 1,626 BHR devices will remain free from revision at 5 years after surgery.

OSHIP Scores

Of the study patients who had reached 5 years after implantation of the BHR device, 92% had OSHIP scores greater than 80.

Patient Satisfaction

Of the patients in the clinical study who provided this data, 96% reported that they were pleased or extremely pleased by one year after surgery, and >99% reported that they were pleased or extremely pleased by five years after surgery.

What to expect after your BHR hip resurfacing operation

Most patients are hospitalized from four to six days. The surgery generally takes two to four hours to perform. Patients must use support in two hands for about six weeks after surgery while their muscles are rehabilitating.

Before you go home, your Physical Therapist (PT) will teach you to climb stairs and transfer from a bed, chair, and car. Your PT may also give you a list of exercises to be performed at home, every day. The objective is to help you become as independent as possible in your personal care and daily activities before you return home. Physical therapy will also help prepare you for more intensive rehabilitation.

The majority of your therapy and rehabilitation will occur once you have checked out of the hospital. Your PT will design an exercise program to increase the motion and strength of your hip, and will teach you the exercises, making sure you know proper form before you begin. The rate and effectiveness of your rehabilitation is critically dependent on your commitment to the physical therapy program.

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

Some things you may wish to do before surgery:

During your rehabilitation period, you will be instructed to avoid bending your hip to more than a 90-degree angle. Some things you can do before surgery to prepare for the rehabilitation period are:

- Add extra cushions to couches and chairs to ensure that you will be sitting high enough to accommodate your new hip during your rehabilitation period. During rehabilitation, you should only sit in armchairs, as you will need the arms to help you sit down and get up.
- Arrange to have an elevated toilet seat and/or support bars fitted in your bathroom.
- Move items you may need to reach to shelves or tables above waist level.
- Remove all throw rugs and anything else on the floor that might cause you to slip or trip.

Take care to protect your joint replacement from unreasonable stresses and to follow your treating physician's instructions regarding activity level. Avoid high impact activities such as running and jumping, particularly during the first pre-operative year while the bone is healing. Excessive loading of the implant can lead to device failure (breakage or loosening). Artificial joint replacement devices can wear out over time, and may require replacement.

Special precautions

Watch for changes around your incision and contact your surgeon if you develop any of the following symptoms:

1. Drainage and/or foul odor from incision.
2. Fever/temperature above 100.4°F (or 38°C) for two days.
3. Pain, redness or swelling.

It will always be important to protect this new part of your body from infection.

If you ever have any of the following procedures, you will need antibiotics before these procedures to help protect the joint from the possibility of infection.

1. Cystoscopy, colonoscopy or proctoscopy.
2. Dental work, including teeth cleaning.
3. Surgery of any kind.
4. Urinary catheterization.

If you have any infection in any part of your body, contact your physician.