

## **Introduction to the Bertram Hip Spacer**

Approximately 200,000 hip replacement surgeries are done every year in United States. Fortunately the incidence of infection is routinely 0.5 percent-1 percent. However this still leaves a large number of patients whose prostheses become infected. If one were to take a ten-year period of time, and accumulate a 1 percent infection rate per year for 10 years, one can appreciate the incidence of infected total hip prosthesis. Using this scenario there may be as many as 20,000 infected hip prostheses at any one time in United States. A more recent number quoted in the AAOS- OKU Specialty Series Hip and Knee Reconstruction manual is over 10,000 patients in the United States in any one year. This was based on a 1% lifetime of the prosthesis infection rate.

The accepted method of treatment currently, for an infected total hip prosthesis, is the exchange Arthroplasty technique. This involves the removal of the infected components and insertion of an antibiotic impregnated spacer. This current method of treatment carries approximately an 85-90 percent success rate. The difficulty with this method is that the patient usually has an ill fitting spacer in place, has very poor function with regards to hip mechanics, and has a significant amount pain during this six to eight week interval before reimplantation. Upon subsequent conversion, it is always difficult to restore the length of the limb, because of the shortening of the femur during the six to eight week period of time that the spacer has been in place. The reason for this is that the surgeon only has 10 to 12 minutes to mold a prosthesis which can fit the patient. This is done by hand, and rarely is the surgeon able to make a functional prosthesis by hand. It is extremely difficult to mold a unipolar component which can fit not only the canal but the acetabulum. It is also nearly impossible to mold a correct neck shaft angle as well as offset which will be functional. Any attempt to make an acetabular component which articulates with a femoral component usually dislocates. Most of the time most surgeons simply place a string of antibiotic impregnated beads in the hip space, which have no functional capacity.

At this time I have designed to a solution to this problem. What we are providing is a mold with an anterior and posterior half, which is fit

together tightly to form a seal, leaving a cavity in the middle which is in the shape of a unipolar prosthesis. We have chosen the size of the femoral stem and acetabular component based on the use of prostheses throughout the country, giving us the most common sizes of the femoral and acetabular portions of the unipolar cement prosthesis. Current sizes for this unipolar spacer are as follows.

Size	Head Size	Neck Length	Femoral Stem Size	Femoral Stem Length
3	52 mm	35 mm	13 mm	140 mm
5	56	40	15	160
7	60	45	17	180

Neck Shaft Angle for all implants is 127 degrees

The technique involves fitting the anterior and posterior halves of the wax mold together on the back table. There is an opening on the mold into which the nozzle of a standard cement gun will fit. The cement is then injected into the mold, filling the mold first distally, and then proximally forming a unipolar prosthesis. The proprietary design of the mold will insure the proper sequence of filling of cement/antibiotic mixture. After time for maturation of the cement, the mold can be opened, and one will have a near perfectly formed unipolar cement/antibiotic hip spacer. Any alterations needed can be accomplished with use of a low speed burr or additional cement where appropriate at the discretion of the surgeon.

We recommend using existing orthopedic literature with regards to the length of treatment for the patients particular infection. We would recommend protected weightbearing in the postoperative period, and the use of an hip abduction orthosis set at a range of motion determined by the surgeon at the time of surgery.

We feel that having this functional spacer will offer the following advantages:

1. Facilitate future conversion to hip replacement by keeping the soft tissues out to length.
2. Allow physiologic flexion and extension of the hip and allow for some hip musculature function, which would normally be electrically silent during this six to eight week period of time.
3. The patients will have less pain and better function. This will extrapolate into less narcotics in the post operative period, decreased hospital stay, and less cost for the initial admission.
4. Also, importantly the subsequent surgical procedure is more easily performed, as the surgeon does not have to spend an inordinate amount of time trying to get the femur out to length. This portion of the conversion surgery always involves a tremendous amount of soft tissue dissection as well as blood loss. This will save time and money. In revision surgery any time saved is welcomed, and any cost savings is a real bonus.

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## **Surgical technique for the Bertram Hip Spacer**

This technique is available on the Internet at website [www.orthotechniques.com](http://www.orthotechniques.com). If not a registered user, the registration process takes less than 60 seconds and is very simple. After logging in, click on Techniques, then the hip portion of the skeleton, and "Bertram Hip Spacer". Or go to the Companies portion of the site, and click on Bertram Enterprises, then "Bertram Hip Spacer".

1. After removal of the infected implant further preparation of the femoral canal as well as acetabular sizing can be accomplished in a number of ways. Any bipolar system could be used to determine the size of the acetabulum. In this system you have three options for sizing of the acetabulum:

**Size 3-52 mm Head (with a 13 mm distal stem, 35mm neck length, 140mm length) 3 batches of cement**

**Size 5-56 mm Head (with a 15 mm distal stem, 40 mm neck length, 160mm length) 4 batches of cement**

**Size 7-60 mm Head (with a 17 mm distal stem, 45 mm neck length, 180mm length) 5 batches of cement**

All implants have 127 degree neck shaft angle, to assist in offset, with improved clearance and mechanics.

2. The femur can be prepared with any number of cylindrical reamers. We recommend overreaming by 1 mm based on the size of your implant chosen, and to prepare the femur for the length as shown above. Osteonics "Restoration" reamers are ideally suited for the preparation of the femoral canal. Acetabular preparation is with basket reamers keeping in mind the sizes above. Exact sizing is not necessary.

3. Depending upon the system that you choose you can assemble a trial prosthesis to check your leg lengths and stability. You need to simply assemble a combination of acetabular sizes neck lengths and distal stem combinations given above. If you find that your patient falls in between the sizes is given above, you can modify the product of the mold to meet your needs. This can be done with a high-speed burr to down size the spacer, or you could use additional cement to

add to a smaller spacer where necessary to fit your patient.

4. Once you have determined the appropriate sized spacer for your patient you are ready to build it on the back table. According to the literature, it is recommended that you add antibiotics to the powder but this is up to the discretion of the operating surgeon. ***The FDA does not condone the use of antibiotics with bone cement at this time in the United States.*** Open the mold, placing the halves facing each other. Take the largest threaded Steinmann pin you have in your set and place it into a chuck. Now using a pair of pliers or vice grips, bend the rod to approximate the angle made by the mold at the neck shaft junction. The implants have a 127 degree neck angle. Lay this into the mold to measure it, and see if it is long enough and if the angle is appropriate. Try to keep the rod as close to the distal tip as possible. This will ensure that you will have purchase on the distal tip should the shaft of the construct crack or break. This has not been a problem, but it is still advisable.

5. Your assistant at this point is mixing together your cement with the antibiotic impregnated mixture. Vacuum mixing of the cement and using modern cement techniques will improve the strength of the cement, adding to the durability of the spacer. However, mixing the cement in a bowl with hand mixing is acceptable.

After the cement has been mixed, and it is in a working consistency, divide the cement batch evenly and apply it to each half of the mold. You want just enough cement to fill up the mold halves so the cement is even with the top. At this time lay your Steinmann pin in one half of the mold, on top of the cement. Now place the mold halves together and apply strong pressure to keep them approximated. No clamps or special devices are needed. In order to keep the Steinmann pin as close to the middle of the mold as possible, you should turn the mold over every 60 seconds alternating positions so it will not sink into one half deeper than the other. After the cement is completely hardened, you can pry apart the halves of the mold, and pry the cement spacer out of the mold. Do not remove the mold before the cement is completely hardened or it will affect the shape of the spacer.

6. At this point you should trim off the thin layer of cement surrounding the spacer. Using thumb and forefinger break off the

cement extending from the proximal part of the prosthesis. Further modifications are at the discretion of the operating surgeon. I have applied additional cement in a doughy state to make the prosthesis fit the calcar region, for improved stability, without any difficulty upon subsequent removal.

7. The prosthesis should be able to be inserted with minimal effort or with a few gentle blows with a nylon or plastic impactor. Try to avoid using a metal impactor as this may propagate a crack in the cement spacer.

### **Recommended Aftercare:**

The use of an Abduction Orthosis is recommended but not entirely necessary. This spacer carries the same risk of dislocation as any other temporary spacer, but does allow significant improvement in mobility and function by the patient. Protected weight bearing is perfectly acceptable, a good guideline is "Weight of Leg" weight bearing or 1/6 of body weight. For instance a 180-lb. patient could place 30 lbs. of pressure on the operated leg. Length of time for the spacer is completely at the discretion of the surgeon. A good guideline is 6-8 weeks of intravenous antibiotics, and a normal Sed Rate and CRP. I would leave the spacer in place until the CRP is normal. We have had one patient with a spacer in place, weight bearing for almost 2 years.

**It is important to note that this is not an FDA approved device or procedure, and we recommend that you inform your patients of this fact. However, we have had excellent feedback from physicians and patients that have used this device, and we feel that this is a better alternative to currently available techniques.**

# Informed Consent Document For Hip Spacer Surgical Patient

1) I fully understand that this surgery has no absolute guarantees with regards to outcome. Expectations on my part have to be realistic. This is an extremely complex and technically demanding operation. The success of this operation in part depends upon the mechanical devices, which are being implanted in my body. I understand these devices can fail, and that this is beyond the control of my surgeon. The success of this operation in part depends upon the quality of the tissues in my body and my pain threshold during the difficult recovery period. I understand that this is beyond the control of my surgeon.

2) I understand that this surgery has statistically known complications which include but are not limited to: Blood clots in the leg, fatal pulmonary embolism, dislocation of the prosthesis, intraoperative and postoperative fractures of my femur, infection, failure of the prosthesis or grafting materials, anesthetic complications, blood transfusion reactions, postoperative leg length inequality, nerve damage or injury, vascular injury and delayed wound healing.

3) I understand that the device being implanted is not FDA approved, however my surgeon feels it is in my best interests to use this product, as my surgeon feels it is superior to currently available alternatives.

4) I understand that this procedure does not guarantee me complete relief of my pain and disability from which I currently suffer.

5) I understand that this device is mechanical and can fail or malfunction just like a car part. It may need to be repaired or redone if such a malfunction occurs. I understand that this may or may not involve surgery to correct such a situation. I understand that there are no guarantees with regards to the longevity of this device, and that it could fail prematurely due to circumstances beyond the control of my surgeon.

7) I understand if I do not follow completely and fully all of my surgeons advice and recommended treatments that I will hold myself responsible for any and all related results that are less than standard, less than hoped for, or less than the expected results.

8) I have read and understand the above. Of my own free will and under no duress whatsoever, I (we) agree to the above and do not have any unanswered questions.

Date: \_\_\_\_\_

Patient Signature: \_\_\_\_\_

Witness: \_\_\_\_\_

Physicians Signature: \_\_\_\_\_

## **Illustrative Case Example**

C.J. is an 80-year-old gentleman with an apparent aseptic loosening of his Right Hip. Work up pre operatively was not indicative of an infection. However, upon entering the hip capsule, gross purulent material was noted. His components were removed, surgical debridement was performed and an antibiotic impregnated hip spacer was inserted. Post op the patient was treated with intravenous antibiotics for 8 weeks, at which time his indices were normal, and clinically the hip looked benign. He was ambulating with crutches, weight bearing as tolerated, without using an abduction orthosis. He reported his pain as minimal to moderate with activities. Our recommendations were to use protected weight bearing and an orthosis, but the patient refused to comply with either.

At the subsequent revision surgery, the spacer was easily removed after dislocating the hip. Three taps of a mallet, and the spacer was removed without injuring the host bone. Preparation and exposure of the acetabulum and the femur was easily performed. The femoral preparation was especially easy, as the hip spacer was a close match with the Restoration stem by Osteonics. The preparation consisted of passing straight reamers up to the templated size and passing two broaches. The final implants were implanted in 44 minutes, and the wound was closed in 58 minutes. Estimated blood loss was 375 cc, approximately 1/3 or  $\frac{1}{3}$  of the usual amount for these types of cases. The patients recovery was greatly facilitated by the fact that he was ambulatory in a very normal fashion for the 8 weeks he was receiving antibiotics. His pain was minimal in the postoperative period, mostly because the surgical dissection was actually minimal and the leg was not lengthened by the revision surgery.

Surgeries performed by the same surgeon, using a technique in which no spacer was used, resulted in operating times of from 120 minutes to 180 minutes, and blood loss of 750cc-1000cc. Pain after this procedure is usually hard to control, and blood loss continues for a few days. This is because the surgical dissection is extensive and the extremity is lengthened by several centimeters to get the center of rotation back to its original position. Lengthening of the operative extremity also carries the risk of nerve injury due to acute traction.

Hip Mold Immediate Post Op x-ray





This is an example of how this problem would be treated before we had access to the spacer. This is an attempt at an articulating spacer. The construct actually worked extremely well for about 72 hours, with the patient having little or no pain, and functioning well. Unfortunately, the spacer articulation dislocated as we see here, and the obligatory shortening of the extremity occurred. The revision surgery was difficult, mostly because of the extensive surgical dissection needed to “get the femur out to length”. Blood loss was around 750cc, and the rehab process was difficult because the hip musculature had been allowed to atrophy, secondary to not being used for the 8 weeks prior to the revision surgery.

