BioMedtrix Total Hip Replacement Systems



An Overview

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KEYWORDS

- Cementless THR BioMedtrix THR systems Universal THR Micro THR
- Nano THR Collared BFX stem Lateral bolt BFX stem

KEY POINTS

- Total hip replacement (THR) has become an accepted veterinary orthopedic procedure for treating a variety of coxofemoral joint disorders in companion animal patients.
- BioMedtrix, an industry leader in joint replacement, has developed THR systems to address the hip replacement needs of patients weighing from 2 kg to 80 kg.
- The most common complications associated with THR include luxations for both cemented and cementless THR procedures, aseptic loosening for cemented THR procedures, and femoral fissures and fractures for cementless THR procedures.
- Complications often require additional surgical procedures, but good patient outcomes and return of function is still achievable.
- A success rate of approximately 90% is a reasonable expectation for most THR procedures in small animal patients performed by experienced THR surgeons.

Total hip replacement (THR) has become a highly successful veterinary orthopedic procedure for canine and feline patients affected by various abnormalities of the coxofemoral joint. In 1990, the BioMedtrix company (Whippany, NJ) emerged onto the marketplace with release of its first THR implant system, the CFX (cemented fixation) system. The CFX system replaced the only commercially available canine THR system at that time, the Richards II system. The CFX system had implant modularity with 3 components: an acetabular cup, a femoral stem, and a femoral head. The cups and stems were available in different sizes but all matched a common femoral head size (17 mm diameter). The head attached to the femoral stem via a Morse taper fit. The 17 mm femoral heads were available as +0, +3, and +6 mm sizes to optimize femoral neck

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length to achieve appropriate joint tightness on hip reduction. The modularity of this system allowed better customization of implants to each patient. Improved surgical instrumentation was also developed, allowing a more precise THR surgical procedure. BioMedtrix has been an industry leader in veterinary joint replacement over the past 27 years. A variety of THR implant systems and designs, surgical instrumentation, and surgical instructional education programs have been developed to meet the changing needs of veterinary orthopedic surgeons and their THR patients. BioMedtrix manufactures THR implants and instrumentation for patients ranging in size from 2 kg to 80 kg. Implant designs and materials have changed over time in response to advancing clinical research and knowledge and surgeon needs in the area of veterinary THR procedures. The company estimates that approximately 28,650 CFX, 8900 BFX (biologic fixation), and 700 Micro THR and Nano THR procedures have been performed since the introduction of each implant system to the market place. This article is brief review of the BioMedtrix THR systems that are currently commercially available, the surgical procedure for their placement, and their associated complications and outcomes.

CEMENTED VERSUS CEMENTLESS IMPLANTS

Historically, THR implants relied on cement fixation using polymethylmethacrylate to achieve implant stability within the bone. 1-4 The 2004 Liska study of 730 consecutive CFX THRs provides the most comprehensive study data available describing this procedure, patient outcomes, and complications. 4 Collectively, these studies all reported high levels of procedure success and similar complications have been described, including dislocations, infections, femoral fractures, sciatic nerve neuropraxia, and aseptic implant loosening. The primary benefit of a cemented THR system is the immediate stabilization of the implants within the bone at the time of surgery. With resolution of their hip pain and hind limb dysfunction, patients are able to return to an active lifestyle with a relatively quick recovery period of 6 to 8 weeks. During the 1980s, aseptic implant loosening was identified as a significant issue in cemented THR patients.^{2,5} Despite advancements in the surgical and cementing techniques of the THR procedure, the risk of aseptic loosening persisted.⁶ Between 1986 and 1992, significant work in the area of cementless canine THR was carried out at the North Carolina State University College of Veterinary Medicine. 7-12 The Canine PCA (porous-coated anatomic) Total Hip System by Howmedica, Inc (Rutherford, NJ) was used very successfully for research and in clinical applications. This implant system was never made commercially available but data gained from its use resulted in the development and commercial release of the BioMedtrix BFX THR system in 2003. Cementless implants rely on osseointegration of patient bone into and or onto the implant surface. 13 Initial implant stabilization in these cementless systems is through press-fit. Precision acetabular reamers and femoral broaches are used for bone preparation. The implants are firmly and tightly seated into a prepared bone bed. The precise match of geometry and support by adjacent bone around the implant, combined with specific implant design features, works to maintain the implant position within the bone. A process similar to secondary bone healing is thought to occur with initial fibrous tissue ingrowth into the porous implant surfaces that then changes to bone ingrowth once a stable implant-tissue interface is achieved. Although initially less stable than a cemented implant, the biologic nature of cementless fixation has the potential benefits of a bone-implant interface that is stabilized by vital tissues with the potential for decreased risks of infection and aseptic loosening complications. In 2007, the BFX and CFX total hip systems were combined to form the Universal total hip system (Fig. 1). There was a standardization of the surgical approach and

instrumentation for implant placement, and recognition that implants from both systems could be combined for hybrid THR procedures in which both cemented and cementless implants could be applied to a single patient for the best possible clinical outcome. No single THR system can meet the needs of every potential THR patient and having implant systems that work together with common surgical placement techniques benefits not only the surgeon providing these procedures but also the patients receiving them.

Implant selection for a THR patient will depend on a variety of factors, including surgeon experience and training, patient factors of size and body weight, disease process affecting the coxofemoral joint, bone quality, femoral morphology, and primary versus revision procedures. The application of cement in fixation of a THR implant can overcome some bone quality issues when present or in cases in which use of a cementless implant may be considered risky because conditions for initial press-fit cannot be achieved. Femoral stem subsidence describes a settling or distal migration of a cementless femoral stem postoperatively. Femoral stem subsidence and rotational positional changes into retroversion can be a significant concern to a THR surgeon in the early postoperative patient while tissue integration into the porous surface of the stem is developing. Subsidence of a few millimeters is often insignificant to the patient but greater distances and significant rotational position changes may result in coxofemoral luxations, femoral fractures, and malaligned implants. Complex revision



Fig. 1. BioMedtrix Universal THR Implants. Universal THR System consists of the BFX cementless cup and stem (*A*), a common femoral head (*B*), and the CFX cemented cup and stem (*C*). Multiple implant sizes are available to maximize for application in a variety of patient and bone sizes. (*Courtesy of BioMedtrix*, LLC, Whippany, NJ.)

procedures are often required to resolve these problems. Preoperative and operative decision-making regarding using cemented or cementless implants and surgical technique are key to avoiding these situations.

The Universal Total Hip Replacement System

The BioMedtrix Universal THR system includes BFX and CFX implants of various sizes that can be intermixed. A common surgical approach and technique for bone preparation and common surgical instrumentation have been developed for implant placement. Implant sites are initially prepared using the precise technique for placement of a press-fit BFX implant. If a decision is then made to use a CFX implant, minor modifications of the bone bed are required for a cemented acetabular component but the femoral canal will already be appropriately prepared to receive a cemented stem. This is a 3-component modular system, including an acetabular cup, a femoral stem, and a femoral head. A common femoral head will fit a BFX or CFX femoral stem and match a BFX or CFX acetabular component within a particular implant size category. Table 1 illustrates the implant sizes and combinations available. The broad range of implants and ability for hybridization or combining both cementless and cemented implants provide significant implant flexibility and allows surgeons to choose what implants or combination of implants best meets the needs of their THR patient. Table 2 lists the implant materials and manufacturing method.

Universal total hip replacement surgical procedure

Preoperatively, patients are radiographed with inclusion of a magnification marker placed at the level of the bone of interest. Knowledge of magnification and knowing

Table 1 BioMedtrix Universal total hip replacement implants								
Stem		Head		Cup				
CFX	BFX	12 mm + 0	CFX	12 mm l.D.	BFX			
#4: Maximum	#4: Maximum	12 mm + 3	18 mm		20 mm			
patient weight	patient weight				22 mm			
60 lb (27.3 kgs)	30 lb (13.6 kgs)	_						
CFX	BFX	13 mm + 1	CFX	13 mm I.D.	BFX			
#4 or #5	#5	13 mm + 3	19 mm		20 mm			
#4 stem/#5 neck	#6	13 mm + 5						
Maximum patient	#7	Additional 13	3 mm trial	heads and o	:up			
weight 80 lb (36.4 kgs)	#8	impactors i	required					
#5	#9	14 mm + 1	20 mm	14 mm I.D.	22 mm			
#6	#10	14 mm + 3						
#7	#11	14 mm + 5						
#8	#12	17 mm + 1	23 mm	17 mm I.D.	24 mm			
#9		17 mm + 3	25 mm		26 mm			
#10		17 mm + 6	27 mm		28 mm			
		17 mm + 9	29 mm		30 mm			
		17 mm + 13	31 mm		32 mm			
		Special order			34 mm			
		22 mm + 0		22 mm I.D.	30 mm			
		22 mm + 3			32 mm			
		22 mm + 6			34 mm			
Additional 22 mm trial heads and cup impactors required					cup			

Abbreviation: I.D., internal diameter.
Courtesy of BioMedtrix, LLC, Whippany, NJ.

Table 2 BioMedtrix total hip replacement implant materials, manufacturing method					
Component	Material	Manufacturing Method	Implant Surface		
BFX Femoral Stem	ASTM F136 grade 23 titanium Ti6Al4V ELI	Electron beam melting (EBM) machine taper, hand finish stem	NA		
BFX Collared Femoral Stem	ASTM F136 grade 23 titanium TiBAl4V ELI	EBM machine taper, hand finish stem	NA		
BFX Lateral Bolt Femoral Stem	ASTM F136 grade 23 titanium TiBAl4V ELI	EBM machine taper, hand finish stem	NA		
BFX Lateral Bolt	ASTM F136 grade 23 titanium TiBAl4V ELI	Conventional machining from bar stock	NA		
BFX Acetabular Cup Shell	ASTM F1472 Ti6Al4V ELI	EBM machined	NA		
BFX Acetabular Cup Liner	ASTM F648 UHMWPE	Machined polyethylene			
CFX Femoral Stem	ASTMF75 cobalt-chrome	Cast cobalt-chrome Machine taper, hand finish stem	Bead blast Matte finish		
CFX Acetabular Cup	ASTM F648 UHMWPE	Machined polyethylene	Radial and circumferential grooves		
Universal THR Femoral Head	ASTM F799 wrought cobalt-chrome	Machined cobalt-chrome from wrought bar stock			
Micro THR and Nano THR Femoral Stem	ASTM F799 wrought cobalt-chrome	Machined cobalt-chrome	Bead blast Matte finish		

Abbreviations: ASTM, American Society for Testing and Materials; ELI, extra low interstitials; NA, not applicable; Ti, Titanium; UHMWPE, ultra-high molecular weight polyethylene.

Courtesy of BioMedtrix, LLC, Whippany, NJ.

as accurately as possible the size of the bone to help choose the implant that appropriately fills the confines of the proximal femoral metaphysis and diaphysis, and the cranial to caudal width of the acetabulum, are key to successful implant selection and application. Although equally important in both cemented and cementless implants, the templating process for cementless implants is the start of surgical decision-making and planning. Four radiographic images of the pelvis and femur are taken preoperatively. A square ventrodorsal view of the pelvis with the magnification marker located at the level of the acetabulum is used for acetabular component templating. The standard lateral view of the pelvis is used to assess the shape of the pelvis and the relative dorsal position of the femur in relation to the acetabulum (Fig. 2A). A true representation of the femur is achieved by taking craniocaudal and open leg lateral views of the femur (see Fig. 2B). The magnification marker is positioned regionally at the proximal one-third of the femur in line with the level of the bone and it is essential that the length of the femur is parallel to the radiographic beam and plate. Implant sizing is carried out using calibrated acetate overlays or digital templates. Poorly positioned radiographs and inaccurately placed magnification markers can misrepresent the bone and may affect the surgical procedure and the incidence of operative and postoperative complications. Based on the work done with the Canine PCA cementless system, a femoral implant that fills approximately 85% of the femur is recommended to minimize the risk of implant subsidence postoperatively. 12 The appropriately sized acetabular component should match the cranial to caudal width of the acetabulum with the medial pole of the implant coming to or nearly to the medial acetabular wall.

At surgery, patients are positioned into lateral recumbency with superimposed hemipelvi in the sagittal plane. The patient is secured in this position through the use of a positioning device such as the BioMedtrix positioning board or a vacuum-assisted moldable bag. Stable and referential pelvic positioning is essential for accurate acetabular preparation and implant placement.

The operative procedure of the Universal THR system involves a modified craniolateral approach to the hip joint. 14 A femoral head and neck osteotomy is performed using a neck-cutting guide. The femur is positioned at 90° of external rotation and the neckcutting guide positioned along the cranial aspect of the femoral neck, referencing off the long axis of the femur. Attention to the neck cut angle is important if placing a collared CFX femoral stem because the cut angle will dictate the alignment of the stem within the medullary canal when the collar contacts the bone edge during final implant seating. The final neck cut should be at least a few millimeters above the level of the lesser trochanter. Making a high neck cut that preserves cortical and cancellous bone proximally may contribute to better initial cementless femoral implant stability and torsional resistance while osseointegration is occurring. 15 Typically, the procedure then proceeds with acetabular reaming and implant placement; followed by femoral canal preparation and implant placement; a trial femoral head reduction to assess appropriate hip tightness and stability on reduction; and, finally, placement of the final metal femoral head with joint reduction and soft tissue closure. The same radiographic views of the pelvis and femur are repeated postoperatively to confirm implant positioning and evaluate the bone for any potential fissure lines or abnormal disruptions.

Surgical visualization and exposure of the acetabulum is established through the strategic use of Meyerding and Hohman retractors placed around the acetabular rim and on the proximal femur. The true acetabulum is identified through noting the location of the ventral transverse acetabular ligament. Reaming in this location is necessary to provide the most available bone stock for implant placement and achieving a stable interference fit between the bone and the BFX cup at its cranial

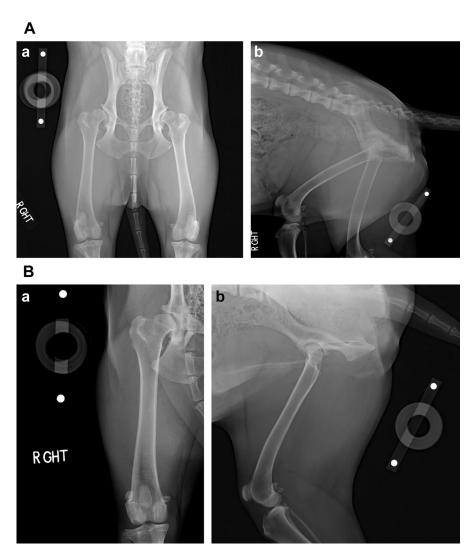


Fig. 2. (A) Preoperative radiographic pelvis. Ventrodorsal (VD) and lateral radiographs of the pelvis are obtained preoperatively. A 10 cm magnification marker is placed at the area of interest, parallel with the level of the bone for templating. The VD view (a) is used determine appropriate cup size. The walking lateral view (b) gives an indication of femoral head position relative to the acetabulum. (B) Preoperative radiographic femur images. Fully extended craniocaudal (a) and true open leg lateral (b) views of the femur are obtained to be able to accurately template the size of the femur. The magnification marker is placed at the level of the proximal one-third of the femur. Implant sizing is performed and evaluation of the central axis of the femur in both planes is determined.

and caudal poles. The ideal prepared bone bed, for optimal bone ingrowth, has exposure of healthy, bleeding cancellous bone cranially, dorsally, and caudally within the acetabulum.

Acetabular reaming is a 2-step process. A cheese grater-type starter reamer is initially used to remove subchondral and cancellous bone, and to achieve appropriate

depth and approximate width of the preparation. The finishing reamer is a more robust, solid, and precise reamer. This reamer does not cut depth but simply finishes the prepared bed surface and width to within the 1 mm tolerance needed to allow press-fit of the particular size of BFX cup.

Specific attention to the process of reaming is key to meeting the goal of a placing a press-fit cup with proper anatomic axis. Instrumentation is used to ensure proper alignment and orientation relative to cup retroversion and closure angles. Reaming must be performed with minimal surgeon and reamer movement to ensure the precision in the size of the final bone bed. Ultimately, a prepared press-fit acetabular bed will be 1 mm smaller in diameter than the implant that will be placed within the bed. The BFX cup design is a hemisphere until the last 3 mm of the cup edge where it then becomes a cylinder. This change in shape is what provides the interference fit at the cranial and caudal poles of the implant that is achieved when the cup is seated to its full depth and becomes level with the adjacent bone edge. The metal-backed shell of the BFX cup provides additional support to the ultra-high molecular weight (UHMW) polyethylene liner and means less overall dorsal boney coverage is necessary to achieve adequate implant stability. 16 Needing less available pelvic bone for implant placement and the interference fit design makes the BFX cup very versatile and the preferred choice compared with a cemented CFX cup in almost all operative situations. When necessary, careful removal of the medial acetabular wall can be performed and a BFX cup can be medialized to ensure appropriate cup seating to engage the cranial and caudal cup poles level with the adjacent acetabular bone without risking the stability of the bone and pelvis. 17 The acetabular reamer for a particular size of BFX acetabular implant is used for trial sizing because the 2 have matching profiles for depth and width. Following final bone bed preparation, a trial CFX acetabular cup, 1 size smaller than the proposed BFX cup size, can be used to visually confirm desired cup position and confirm cup fit with the prepared bone bed. Using an impactor instrument and mallet, the cup is driven into the bone bed until final seating and depth are achieved. A significant benefit of the cementless BFX cup is that, if correct alignment and orientation are not initially achieved, minor position adjustments can be made or the cup can be completely removed and reinsertion performed again.

In rare situations in which a CFX cup is favored, the prepared acetabular bed is modified to create defects in the bone for cement intrusion and anchoring. Bone cement is cohesive, not adhesive. Three small key holes are created into the cancellous bone of the cranial, dorsal, and caudal aspects of the acetabular rim for cement movement into the bone to increase the shear strength at the bone to cement interface. The bed is lavaged and dried as best as possible. Bone cement is mixed and placed with the bed and a CFX cup 1 to 2 sizes smaller than the corresponding size of the Universal finishing reamer is placed in the correct retroversion, inclination, and closure angles while cement hardening occurs.

The femoral canal is now prepared. A common surgical technique for either a BFX or CFX stem is used until the final implant choice is made. Ideal implant alignment matches the long axis of the femur in the cranial to caudal and medial to lateral planes. Entry into the femoral canal is achieved along the long axis of the femur through the trochanteric fossa, using an intramedullary pin. Sequentially, this opening is expanded using a drill bit, tapered power reamers, and increasing sized BFX femoral broaches until the final size of broach is reached to achieve the expected fit and fill based on the radiographic templating and the feel of adequate press-fit for a BFX stem. Each numbered broach correlates with a BFX stem size and the broach serves as the stem trial for sizing. The broaching technique must be precise. Broach alignment, in both planes, with advancement into the medullary canal creates the internal envelope

and will dictate stem alignment and position. There is a significant learning curve for broaching technique and in recognizing adequate press-fit for the novice cementless THR surgeon. In general terms, with the final broach, the last 5 to 10 mm of broaching should be met with definite resistance to achieve final seating. This resistance is often coupled with a sound pitch change as the broach gets tighter within the bone. The femoral preparation for a cementless BFX stem relies on visual, auditory, and touch senses for assessing the adequacy of press-fit. It is during the final broaching procedure that the accuracy of radiographic templating is recognized. If excessive resistance is noted, one may be concerned that the broach is too large for the medullary canal or malaligned, and impending fracture or fissure of the bone could occur if broaching continues. Easy broaching or lack of resistance to broaching may be the result of underestimating the size of the bone or a general lack of cancellous bone quality and resistance to the broaching procedure. If resistance to broaching is lacking, this will not improve with placement of the implant. A decision to place a cementless stem where adequate press-fit has not been achieved risks significant postoperative complications associated with unscripted implant position changes. Femoral fissures, comminuted fractures, subsidence, and malalignment are common sequelae of inadequate realization of sufficient initial press-fit stabilization. The femoral stem is impacted to the desired depth within the femoral canal preparation with an impactor instrument and a mallet. The final resting position of the stem should be at the same level or within a few millimeters of the level of insertion into the femoral canal achieved with the final broach.

When press-fit cannot be achieved or patient factors dictate the use of a cemented implant, a cemented CFX stem is placed. CFX stem trials are available and are used before cementing in the actual femoral component. Trial stem placement is used to practice implant positioning within the femoral canal, to ensure the neck cut and the collar meet with the appropriate angle, to ensure axial placement of the implant within the femoral canal in both planes, and to check a trial reduction of the hip. This last procedure protects against cementing in a final implant only to discover that hip reduction cannot be accomplished and an adjustment of the height of the femoral neck cut was needed to shorten the femoral length and ease hip reduction tension. The femoral canal is flushed and suctioned to remove debris and fluids as much as possible before cement infusion into the canal. Placing a femoral cement restrictor is recommended for medium-sized and large-sized patients for implant sizes #5 to 12. This restrictor is made of polyethylene and is positioned at a specified level within the medullary using a specific measuring inserter device. The purpose of the restrictor is to keep the cement within the proximal regions of the femur and improve the ability for pressurization of the bone cement within the femoral canal, forcing it into the interdigitations of the cancellous bone and manufactured surface of the implant once it has been placed. The size of CFX femoral stem placed will typically be 1 to 2 sizes less than the final sized BFX broach used in canal preparation. This downsizing will allow at least a 2 to 4 mm cement mantle between the endosteal surface of the bone and the implant. In preparation for placing the CFX stem, a premade cement centralizer can be positioned over the tip of the stem. Care should be taken when handling the final stem. Studies have shown a greater than 80% decrease in the bonding strength between a stem and the cement if the stem is wet or contaminated with marrow or fat. 19 The stem centralizer has 1 mm wings that prevent direct contact between the metal stem edge and the cortical bone, and allow cement to encircle the tip of the stem between it and the edge of the cortical bone. Direct contact between the stem tip and the cortical bone has been suggested to predispose to cemented femoral implant aseptic loosening.6

Once the femoral and acetabular components are placed, trial femoral heads are used to assess the reduction tension of the hip joint. Optimal reduction should not be too tight or too loose. Also assessed during trial reduction is the match of femoral stem anteversion to acetabular retroversion, with the leg held in a neutral walking position, and identification of areas of potential impingement across the joint during range of motion. Failure to identify impingement intraoperatively, particularly on external rotation and adduction of the hip, could contribute to postoperative hip luxation issues. Lengthening the femoral neck through head size choice is carried out until appropriate tightness with full range of motion is achieved. The trial head is removed and replaced with a metal chrome-cobalt head. The surface of the final femoral head is highly polished to minimize surface defects that could result in abnormal wearing of the polyethylene cup surface. Care is taken to avoid contact of the newly placed femoral head during hip reduction with any metallic or abrasive surfaces to prevent creating accidental surface defects and scratches on it. Once final hip reduction and assessment are complete, the soft tissues of the surgical field are closed, in sequential layers. Postoperative radiographs are taken with attention to achieving the same position of the bones for implant evaluation as was achieved preoperatively.

A more extensive description of the Universal total hip surgical procedure has been reported. $^{\rm 20}$

The postoperative care following a THR procedure involves limiting activities to controlled leash walks for 6 to 8 weeks, with a gradual return to full activity typically by 12 weeks. Patients are usually partially weightbearing on their operated limb within 24 to 48 hours of surgery and show a steady improvement in function over time. Body harnesses and belly slings are recommended to help provide rear limb stability during the initial few weeks of postoperative recovery. Acute changes in gait and weightbearing, especially during the first 2 to 3 weeks following a cementless THR procedure, often indicate a potential and sometimes significant complication and reassessment with radiographs should be performed. On successful full recovery, most THR patients will return to a full, normal active lifestyle with little to no limitations.

Universal total hip replacement complications and outcomes

The clinical outcome of cemented CFX THR procedures has been reported by several investigators. 4,21,22 Omstead's prospective case series of 51 cases had a complication rate of 7%.²¹ Bergh reported retrospectively on 97 hips and reported a revision rate of 12.1% for the first side THR procedure.²² Liska's 730 consecutive CFX THR procedures reported a successful outcome in 96% of cases.⁴ The most commonly reported complications with cemented THRs are aseptic loosening and luxation. Less commonly, infection and femoral fracture complications can occur. Skurla and colleagues²³ reported on aseptic loosening in 38 THRs performed in 29 dogs. Postmortem evaluation was performed on these cases. Only 4 cases were found to have both stable acetabular and femoral components, whereas 14 dogs had loosening of both components. Femoral stem loosening occurred most commonly at the cementimplant interface. Edwards and colleagues⁶ noted a similar site of loosening in 11 aseptically loose implants in 10 dogs. The mean time to aseptic loosening in these 10 patients was 30 months postoperatively. Postoperative luxation has been associated with several factors. Dyce and colleagues²⁴ suggest that cup orientation with an increased angle of lateral opening predisposes to dorsal luxation. Another study suggested that the angle of lateral opening and degree of cup retroversion were poor indicators of luxation risk.²⁵ Body type, size, breed, short femoral neck, and cup orientation were identified as risk factors for luxation by Nelson and colleagues.²⁶ Hayes and colleagues²⁷ identified that pre-existing hip subluxation or tissue laxity were significant contributing factors to postoperative hip luxation. Liska²⁸ reported a femoral fracture rate of 2.9% in 684 consecutive CFX THR cases.

Outcomes for the BFX cementless THR system have also been extensively studied. Roe and Marcellin-Little²⁹ reported on the short-term outcome of 204 cases performed over a 6 years. Forty-eight percent of patients had a zero complication rate. Minor complications that required no additional surgery occurred in 25% of patients. These included subsidence and stem rotation with and without associated fissures. Major complications occurred in 11% of patients, most commonly luxations (8.4%). Femoral fractures occurred in 4.4%. One case of sciatic neuropraxia was recorded. Two cups failed to achieve stable bone ingrowth and 1 was cultured positive for a Staphylococcus organism. No femoral stems showed lack of bone ingrowth. Return to normal weightbearing on the operated leg was noted by 3 months postoperatively in 35 BFX THR cases evaluated by Lascelles and colleagues³⁰ using a pressure-sensing walkway. Ganz and colleagues³¹ reported on the risk factors for femoral fracture in cementless THR procedures. Older dogs and dogs with a lower canal flare index showed a higher risk of femoral fracture in cementless total hip arthroplasty procedures. In 219 BFX THR procedures performed in 183 dogs, a total complication rate of 31.1% was reported by Kidd and colleagues.³² Catastrophic and major complications occurred in 17.8% of cases. Femoral fissures (46), femoral fractures (15), and coxofemoral luxation (9) were noted. Full return to function was achieved in 88.1% of cases with a median follow-up of 42 months.

Cementless BFX THR procedures have been successful but there is a learning curve. Case selection and adherence to precise surgical technique is important for minimizing fissure and fracture complications. These types of complications can decrease with experience. Roe and Marcellin-Little²⁹ noted a decline in their fissure rate from 30% in their first 50 patients to 4% in their last 50. Some surgeons have chosen to perform more hybrid procedures, opting for a cementless cup and a cemented stem to lessen the risk of femoral fissure complications. Gemmill and colleagues³³ reported on 78 hybrid THR procedures in 71 dogs. Major postoperative complications occurred in 5% (4) cases. Only 1 intraoperative femoral fissure was reported. The postoperative complications included 1 luxation, 1 femoral fracture, 1 implant fracture, and 1 case of aseptic femoral component loosening.

Micro and Nano Total Hip Replacement Systems

Functional restoration of a diseased hip joint through a THR procedure should be the goal for all potential patients, regardless of their size. Small dogs and cats are affected by pathologic conditions affecting the hip joint similar to those of larger patients. Avascular necrosis, degenerative osteoarthritis, femoral head and neck fractures, and coxofemoral subluxations and luxations create painful hip conditions and rear limb dysfunction for these smaller patients. In June 2005, the Micro THR system for small (<12 kg) canine breeds and cats was introduced. The Nano THR system followed in 2010. The Micro THR and Nano THR procedures allow restoration of normal hip biomechanics and function due to painful osteoarthritis and traumatic hip injuries in patients ranging in size from 2 kg to 12 kg.

The Micro THR system mimics the traditional BioMedtrix CFX THR system. It consists of the same 3-component modular system, an UHMW polyethylene cup, a tapered and collared femoral stem, and a femoral head (Fig. 3). As can be seen in Table 3 there are different implant sizes to address different patient body weights, femoral and acetabular morphologies, and different sized femoral heads to match with different stems and cups.



Fig. 3. BioMedtrix Micro THR and Nano THR implants. (*A*) The Micro THR system consists of a cemented cup, a modular femoral head, and a chrome-cobalt femoral stem. The surface of the stem is bead blasted to increase bonding of cement to the implant. (*B*) The Nano THR is a monoblock chrome-cobalt stem with a bead blasted surface. The 6 mm head fits with a 10 mm cemented cup (not shown) that is identical in design to the Micro THR and CFX cemented cups. (*Courtesy of BioMedtrix, LLC, Whippany, NJ.*)

The Nano THR system was developed for the smallest canine THR patients, in the 2 to 5 kg size range. This system uses a monoblock collared femoral stem with a 6 mm fixed femoral head (see Fig. 3) and a 10 mm UHMW polyethylene cup that is an identical but scaled down version of the traditional CFX cup. The femoral stem comes in 3 sizes reflecting different neck lengths +0 mm, +2 mm, and +4 mm.

The small size of these implants and the patients they are placed in necessitates that implants are stabilized by bone cement. The surgical approach to these patients is similar to that of larger THR patients. Templating of presurgical radiographs, taken in the same positions as for larger patients is performed to assess appropriate

Table 3 BioMedtrix Micro total hip replacement or Nano total hip replacement implants						
	Stem	Head	Cup			
Micro THR	CFX #2: Maximum patient weight #3: 40 lb (18.2 kg)	8mm + 0 8mm + 2	CFX 8 mm l.D. 12 mm 14 mm 16 mm			
	Stem		Cup			
Nano THR	CFX #1 + 0: 1 piece stem or head #1 + 2: Maximum patient weight #1 + 4: 20 lb (9.0 kg)		CFX 6 mm l.D. 10 mm			

Abbreviation: I.D., internal diameter.
Courtesy of BioMedtrix, LLC, Whippany, NJ.

implant sizing. The surgical preparation of the patient necessitates securing the patient in a positioning device to maintain pelvic alignment for proper implant placement and orientation. Specific instrumentation and trial implants have been developed and the procedure is largely performed similarly to a Universal THR procedure for placing cemented implants, with the primary exception that implant site preparations are done almost entirely through manual manipulations of surgical tools versus using power. Acetabular preparation is performed with solid fixed reamers on a shaft used in a Jacobs chuck. A high-speed burr can also aid in careful bone removal in acetabular site preparation. The femoral canal is opened using a small cutting awl and tapered reamer only under hand power to prevent accidental fracture of small femurs. A femoral canal cement restrictor is not used. Typically, the acetabulum is prepared, the cement mixed and delivered, and the acetabular component placed within the prepared bed. Attention to the same boney landmarks and matching the implant with the patient's acetabular axis and anatomy are as important as they are in larger patients for best outcome. Once prepared, the femoral canal is dried through suction. Cement is mixed and delivered into the femoral canal, achieving pressurization whenever possible and the femoral implant is positioned in axial alignment, in both planes within the femur. For a Micro THR, a modular femoral head is then chosen based on trial reduction and determining the correct tissue tightness across the joint. For a Nano THR, there are trial stems with fixed femoral heads of different lengths for use to determine the correct sized implant for cementing in place based on hip reduction tightness.

Reported outcomes of these miniaturized THR procedures has been reported as good to excellent in approximately 90% of patients. 34–36 The most commonly noted postoperative complications for the Micro THRs were coxofemoral luxation (9%–10%), femoral fractures (2% Marino), 1 case of sciatic neuropraxia, and 1 cup aseptic loosening. The luxation and fracture complications in these studies were managed either through a revision or explantation procedure. In his case series, Liska reported a 6% explantation rate and that no correlation was noted between luxation and angle of cup lateral opening. Undersizing and oversizing implants was the most common recognized cause of luxations. The most common complication reported for the Nano THR procedure was postoperative femoral fracture and this occurred in 3 out of 12 patients. One case of medial acetabular displacement occurred in this series of cases. Despite this 33% complication rate, all patients were thought to return to a good to excellent level of function by 12 weeks after surgery with either a

revision procedure performed (fracture fixation) or a conservative therapy plan (cup displacement). All investigators comment that early technical surgical errors associated with the small size of these patients contributed to the postoperative complications that were noted. Increased surgeon experience and ongoing improvement of surgical instrumentation and techniques are expected to benefit the overall outcome of these types of THR cases.

Customized Cementless Femoral Stems

BioMedtrix has undertaken customization of the BFX femoral component to address unique patient presentations and surgeon desire to increase the overall level of confidence of implant stability in a newly placed cementless component. These customizations include a collared EBM (electron beam melting) titanium BFX stem (Fig. 4) and a Lateral Bolt EBM Titanium BFX stem (Fig. 5).

The additional of a collar or a lateral bolt to the traditional BFX femoral stem was driven by surgeon desire to provide additional protection against implant subsidence in the early postoperative and implant stabilization periods, especially in larger patients with more stove-pipe femoral morphology. Both implant designs have been used by multiple surgeons in multiple centers and have been shown to be successful. Minor modifications in the surgical technique are required for their use. During stem placement for a collared BFX stem, the final seated position of the stem is when the collar is within 2 to 3 mm of the osteotomy cut. It is expected that if a minor amount of implant subsidence occurs, the collar will come to rest on the bone and will prevent further movement of the implant distally into the medullary canal. It is essential to recognize that achieving adequate press-fit is still required for this stem to be successful. In the presence of insufficient resistance to broaching and implant impaction, suggesting inadequate press-fit, the mere presence of the collar will not guarantee against significant subsidence or implant rotation and the implant and collar can be driven distally through cancellous bone into the medullary canal of the femur. The collar should be oriented over the cortical bone to be most effective at preventing minor subsidence. Liska and Doyle³⁷ reported good results on the use of this stem with no significant subsidence issues in 110 consecutive cases.

The lateral bolt BFX stem brings in a fourth component to the modular Universal THR system. This system has just recently been made commercially available. The stem has been modified to allow placement of a screw-in straight bolt that is placed from the lateral cortex of the femur into the lateral aspect of the stem. The femoral component is placed using standard Universal THR techniques and is inserted to the desired level in the bone. A trial reduction of the hip is performed to confirm that hip reduction is appropriate for the level of the stem before preparing the bone to receive a lateral bolt. A drill bit and then a guide pin are oriented through a central canal in the femoral neck and body of the stem. The drill bit and pin are driven under power to exit on the lateral aspect of the femur, distal to the greater trochanter. A cannulated drill bit is then used to create a bone tunnel from the lateral femoral cortex toward the stem edge and the insertion site for the bolt. A depth gauge is used to measure the length of bolt necessary to fill the distance between the lateral cortex of the femur and the lateral edge of the femoral stem. An additional 2 to 3 mm of length is added to this measurement in choosing the size of the bolt to place. The bolt is inserted and screws tightly into the femoral stem. The bolt provides an additional locking mechanism for the stem and protects against both stem subsidence and rotation. Adequate bone quality and achieving acceptable press-fit stability are still required for this implant to be successful. Surgeons using the lateral bolt have expressed



Fig. 4. BioMedtrix collared BFX stem and cup. (A) The collared BFX EBM titanium stem has a collar extended from the cranial aspect of the implant. The underside of this collar is porous to allow bone ingrowth. The collar is positioned at or just above the cortical bone edge of the neck cut and functions to potentially decrease the risk of subsidence. (B) A 3-month postoperative radiograph of a BFX collared stem in a 45 kg, 3-year-old German Shepherd dog. (Implant image Courtesy of BioMedtrix, LLC, Whippany, NJ.)

high satisfaction with it. This stem design allows a safer use of cementless femoral stems in larger weight patients and in patients with stove-pipe femoral morphology in which less matching of implant to bone geometry occurs when a cementless stem is placed, and in which the risk of implant movement is more concerning early in patient recovery.

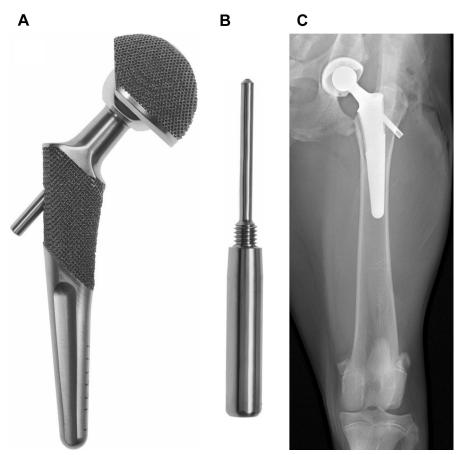


Fig. 5. BioMedtrix Lateral bolt BFX stem and bolt. (A) The lateral bolt BFX EBM titanium stem uses (B) a screw-in titanium bolt to provide an additional anchor point of the implant through the lateral cortical wall of the femur. (C) A radiograph of a 1-year-old, 42 kg hound mix taken 3 months postoperatively. (Implant images Courtesy of BioMedtrix, LLC, Whippany, NJ.)

SUMMARY

Within the BioMedtrix total hip systems there are many implant combinations that can be used to address a variety of patient presentations. Overall, cemented, cementless, or hybrid THR procedures can be very successful. Surgeon experience and adherence to the surgical principles of each THR system are key to surgical outcome. No single system is perfect or without the risk of some complications. Complications are usually manageable and it is reasonable to expect that most THR patients will achieve a satisfactory or better outcome with surgery. Future clinical and basic research will no doubt drive improvements in biomaterials, surgical technique, and revision THR procedures, providing patients with even better outcomes.

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