

# Technology Assessment



**Technology  
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## Horizon Scan on Hip Replacement Surgery

**Agency for Healthcare  
Research and Quality  
540 Gaither Road  
Rockville, Maryland 20850**

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# **Horizon Scan on Hip Replacement Surgery**

**Prepared by  
ECRI Evidence-based Practice Center**

**David Snyder, Ph.D.  
Richard Chapell, Ph.D.  
Wendy Bruening, Ph.D.  
Karen Schoelles, M.D., S.M.  
Janice Kaczmarek, M.S.  
Evelyn Kuserk, M.L.S., M.A.  
Eileen Erinoff, B.A.  
Vivian Coates, M.B.A.**

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# Table of Contents

Tables .....	i
Background .....	1
Total Hip Replacement .....	1
Hemiarthroplasty.....	1
Hip Resurfacing .....	2
Primary Arthroplasty .....	4
Indications.....	4
Operative Approaches.....	4
Minimally Invasive Approaches .....	5
Computer/Robotic Assisted Surgery.....	6
Short-term Outcomes .....	7
Adverse Events .....	8
Thrombosis .....	9
Infection .....	9
Fracture .....	9
Heterotopic Ossification .....	9
Dislocation .....	10
Long-Term Outcomes.....	11
Revision .....	11
Dislocation .....	11
Sepsis .....	11
Wear .....	12
Loosening.....	15
Breakage .....	15
Influence of Patient Factors .....	16
Weight.....	16
Activity .....	16
Bone Quality .....	16
Age.....	16
Effects of the Clinical Environment .....	18
Types of Replacement Hips .....	19
Design .....	19

Materials .....	19
Metal-on-plastic .....	19
Highly cross-linked polyethylene .....	20
Metal-on-metal.....	20
Ceramic-on-ceramic.....	21
Ceramic-on-Plastic.....	22
Ceramic-on-Metal.....	22
Cushion Bearings .....	22
Surface Coatings .....	22
Fixation Methods .....	23
Coatings .....	24
Effects of Femoral Head Size .....	24
Bipolar Designs.....	24
Hip Replacement Revision .....	25
Difficulties in Interpreting Studies of THR .....	28
Ongoing or Planned Clinical Trials of THR.....	29
References and Included Studies .....	34
Appendix A. Inventory of Prosthetic Hips Currently Available.....	41
Appendix B. Literature Search Strategies.....	64

## **Tables**

Table 1.	Contraindications to Hip Replacement Surgery(26,27).....	4
Table 2.	Short-Term Outcomes.....	8
Table 3.	Short-Term Complications.....	8
Table 4.	Risk Factors for Hip Instability.....	10
Table 5.	Reported Linear Wear Rates of Different Implant Materials .....	14
Table 6.	Reported Patient Ages at initial THA .....	17
Table 7.	Reported Hip Revision Rates Under various Conditions .....	26
Table 8.	Ongoing or Planned Randomized Controlled Trials of THR .....	29

## **Disclaimer**

This report is a horizon scan on hip replacement surgery and hip implant technology. The purpose of a horizon scan is to compile a broad overview on existing and future technologies from reviews, guidelines, studies and news reports on the subject. A horizon scan is not a full technology assessment and does not provide a systematic review and critical synthesis of the clinical studies of the technology under consideration.

## **Background**

Over the past 30 years, total hip replacement (THR) surgery, also known as total hip arthroplasty (THA), has become commonplace in the United States and throughout the world. It has been described as the greatest achievement in orthopedic surgery in the twentieth century.(1)

Although no surgery is without risk, the utility of THR to relieve pain and restore function among patients with damaged or degenerated hips and chronic pain is well-accepted as indicated by the large number of procedures that take place in the United States each year.(2,3) In 2003 alone, 201,545 THR procedures and 34,688 revisions of THR were performed in the United States.(4) From 1990 through 2002, the number of THR procedures per 100,000 individuals in the United States increased by 46%, from approximately 45 to 66 per 100,000 individuals.(5) The same study reported a 60% increase in revisions of THR during the same time period. The rates of both primary and revision THR are expected to continue to increase. A recent report estimates that the annual number of THR revision surgeries will increase 137% by 2030.(6)

This horizon scan looks at some of the important issues facing orthopedic surgeons and other healthcare providers as they plan for the increasing utilization of THR. Areas of concern include:

- The selection of operative approaches (standard vs. minimally invasive or computer/robotic assisted)
- The design of the replacement prosthesis (metal-on-plastic, metal-on-metal, ceramic-on-ceramic, or some other combination)
- The surface coating of the prosthesis (untreated vs. treated)
- Cemented vs. uncemented fixation of the prosthesis.

### ***Total Hip Replacement***

The THR procedure generally involves removal of the head of the femur and its replacement with a metal or ceramic prosthesis that fits into the remaining bone. The ball end of the artificial femur then fits into a cuplike socket (acetabular cup) that is installed in the patient's pelvis. Hip replacement can be unilateral (one hip) or bilateral (both hips). The longevity of currently available implants, the rate at which surgical revisions are needed to replace failed implants, and the ease with which implants can be replaced are primary concerns noted in the hip replacement literature. Artificial hips may work loose, break, wear out, or dislocate. Any of these occurrences may require revision surgery and replacement of part or all of the implant. Determining the primary reasons for revision surgery is difficult because some published studies report the reasons for revisions while others report only the number of revisions performed. Revision surgery tends to be more dangerous and less successful than primary surgery.(7-11)

The development of new implant materials has focused primarily on extending longevity in order to avoid revision. A secondary consideration is preserving the integrity of the remaining bone, to make future revision surgery easier.

### ***Hemiarthroplasty***

Hemiarthroplasty refers to the replacement of only the femoral head and is most often performed in elderly patients who have sustained a displaced femoral neck fracture.(12) In this situation, the femoral head is at risk for avascular necrosis. Patients undergoing hemiarthroplasty have shown



faster recovery of function and better function than patients treated only with internal fixation.(13) Some orthopedic surgeons have expressed a concern that hemiarthroplasty may not be the best option for active individuals expected to have long life expectancies.(14) Acetabular cartilage erosion from hemiarthroplasty leading to persistent pain and discomfort will occur if the device remains in place for longer periods. Therefore, younger more active individuals with a displaced femoral neck fracture may benefit more from THR than hemiarthroplasty.

In hemiarthroplasty the femoral head is usually replaced with a bipolar prosthesis. The bipolar prosthesis has an additional joint that allows movement to occur both at the prosthesis-acetabular interface and within the prosthesis. A proposed advantage of the doubled-jointed bipolar prosthesis is a reduced risk of dislocation.(15) If pre-existing arthritis has damaged the acetabular cartilage, THR should be performed instead of hemiarthroplasty.

Hemi-resurfacing is similar to hemiarthroplasty, but only the surface of the femoral head is removed and replaced. Resurfacing arthroplasty involves minimal femoral head removal rather than resection of the entire femoral head and neck. The prosthesis forms a cap over the remaining femoral head and is secured with a stem inserted into the femoral head and neck bone. Hemi-resurfacing of the femoral head has a role in treating young patients with osteonecrosis of the hip in order to delay the need for THR in these patients.(16-18) The ideal candidate is less than 40 years old and has minimal acetabular cartilage damage. Patients receiving hemi-resurfacing arthroplasty rather than THR achieve higher activity levels but may experience more groin pain related to wear of the acetabular cartilage.

### ***Hip Resurfacing***

Total hip resurfacing, involving resurfacing of both the femoral head and acetabular cup, is an alternative to THR. It is performed primarily on younger patients who would be expected to live long enough and remain active enough to wear out several THR devices.(19) Better stability and range of motion than THR has been cited as an advantage of this procedure.(20) With this procedure, the femoral head is preserved, reshaped, and capped with a metal shell. The socket is fitted with a prosthetic cup, as is the case with THR. This procedure can only be performed if the patient has sufficient healthy bone stock to support the resurfacing prosthetic. The ideal candidate for this procedure is less than 60 years old, has normal proximal femoral bone geometry and bone quality, and is expected to outlive any current conventional prosthesis.(21)

Sales in resurfacing implants are a fast-growing market worldwide, but the procedure has seen limited use in the United States.(22) In the United States, only one manufacturer has obtained FDA approval to market its hip resurfacing system. Smith & Nephew Orthopaedics received premarket approval from the FDA on May 9, 2006 for the Birmingham Hip Resurfacing system.(23,24) Femoral head resurfacing systems are cleared for marketing in the U.S. for use in hemi-resurfacing arthroplasty as discussed above.

Clinical data on the efficacy of total hip resurfacing are limited. A systematic review of studies on hip resurfacing was conducted by the U.K. National Health Service in 2002. They found that the data describing the procedure were too limited for firm conclusions to be reached.(19) Two studies, both published in 2004, have been cited as indicating good success rates but data were only available at 4 years of follow-up.(17) The average patient age in both studies was 48 years. Periprosthetic fracture of the femoral neck is the most common complication with hip

resurfacing systems, but better patient selection and improved surgical technique have reduced the frequency of this complication.(21,22)

# Primary Arthroplasty

## Indications

Indications for hip replacement include radiological evidence of joint damage and persistent pain and/or disability that is not adequately relieved by nonsurgical treatment such as analgesics or physical therapy. Joint damage leading to hip replacement may be the result of inflammatory or degenerative disorders, or of trauma such as hip fracture.(25) Contraindications for THR include conditions that would limit or prevent the success of the procedure.(26) These are listed in Table 1. The main absolute contraindication is active infection.(27)

Generally, patients between 65 and 80 years of age have been considered candidates, but in recent years the age range has expanded at both ends. Patients as young as 19 and as old as 90 have undergone THR.(27) Rheumatoid arthritis and other inflammatory arthritides typically affect patients younger than age 65, and may lead to joint replacement when patients are in their 50s or younger.(27)

**Table 1. Contraindications to Hip Replacement Surgery(26,27)**

Absolute Contraindications	Relative Contraindications
Acute or active infection (includes localized septic arthritis and osteomyelitis as well as regional and systemic infection elsewhere in the body)	Previous history of local infection such as septic arthritis, or thought to be at high risk of infection due to co-morbidities
Skeletal immaturity	Neuropathic arthritis
Bone stock inadequate to support the device due to severe osteoporosis or severe osteopenia	Vascular insufficiency, muscular atrophy, co-morbidities, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
Patient inability to follow preoperative and postoperative instructions	Family history of severe osteoporosis or severe osteopenia

## Operative Approaches

Several surgical approaches to THR are possible. The surgeon's choice appears to be largely a matter of personal preference. Surgeons may choose an anterolateral, direct lateral, transtrochanteric, or posterolateral approach. A posterolateral approach may be associated with a higher rate of postsurgical dislocation.(28)

Regardless of the approach, the acetabulum of the pelvis is reamed to the appropriate size and depth to accept the prosthetic cup. When a cemented cup is used, cement fixation holes are drilled before the cup is fitted and cemented in place. An osteotomy of the femoral neck is performed and the medullary canal within the femur is reamed to accept the stem of the prosthetic femoral head. The canal is plugged below the level into which the stem protrudes to prevent bone cement from spreading into the canal. The artificial hip is then assembled using trial components to test for range of motion and eliminate potential impingements that may interfere with hip function. When the test motions are satisfactory, the permanent components are screwed, cemented or otherwise fitted into place. Test motions are again performed and the surgical site is closed. Performing a capsular repair on the joint rather than allowing scar tissue to form a pseudocapsule may reduce the incidence of dislocation.(29)

## Minimally Invasive Approaches

Many surgeons employ minimally-invasive techniques, and those who perform THR are no exception. In general, proponents of these minimally invasive techniques believe that they lead to faster recovery and less short-term morbidity than traditional techniques. Two basic approaches have been proposed; one involves a single incision and the other involves two incisions.(30) The incision length in minimally-invasive surgery is less than 10 centimeters, while the incision length in conventional surgery is 15-25 cm.(30,31) Surgeons can also work around muscles and soft tissue instead of cutting through them.(32) Minimally invasive surgery may be associated with less blood loss and a lower prevalence of gait disturbance at early followup. However, minimally invasive techniques, with the restricted field of view of the working area, can be difficult to perform. A recent review of the two-incision approach examines the complications that can occur with this approach even when performed by experienced surgeons.(33) Femoral fracture is the most common complication with this approach, especially in the individual with osteoporotic bone. Such individuals are therefore not good candidates for this surgical technique. Excess fat and muscle can limit the minimally invasive approach to the hip and abnormal hip anatomy can complicate the placement of the prosthesis. The ideal patient is a thin individual with normal hip anatomy and thick femoral cortices.

Although minimally invasive surgery can lead to cost savings and more rapid recovery for many patients, a recent study of the two-incision approach found a higher rate of complications compared to open surgery.(32) This retrospective study, which was presented at the 2005 meeting of the American Academy of Orthopedic Surgeons, found that 14% of patients receiving THR by the two-incision method experienced an early complication, compared to 3.75% in the open surgery group. We did not identify any information in the examined literature regarding the effect of patient age on the incidence of complications among patients undergoing minimally invasive surgery.

Minimally invasive surgery requires special training of the surgeon. A learning curve is associated with the procedure before surgeons may be considered adept.(30) Some clinicians believe that minimally invasive surgery is being marketed to patients faster than evidence supporting its use can be found.(34) This may lead to increased demand from patients who may pressure surgeons to adopt the technique whether or not the evidence supports its use.

Several recent reviews have cited the general lack of data on long-term outcomes in patients treated with minimally invasive THR.(22,35-37) Pour et al. (35) cites 16 separate studies of minimally invasive THR, including three randomized controlled trials, but only five of the studies (two RCTs) reported follow-up data more than six months after surgery. Hou and Gilbert (36) cited many of these same studies when they concluded that advocates of minimally invasive surgery should collect and publish long-term data to compare with the supposed short-term advantages of this procedure. Weng and Fitzgerald (37) cited data from two RCTs (also mentioned in Pour et al.) to conclude that “we do not yet know the long-term outcomes of a smaller incision.”

Both the National Institute for Health and Clinical Excellence (NICE) in their examination of two-incision THR(38) and the Canadian Coordinating Office for Health Technology Assessment in their examination of minimally invasive hip resurfacing(39) have cited the lack of evidence on the long-term safety and efficacy of minimally invasive procedures. NICE identified four case series studies (517 patients) of minimally invasive two-incision THR and has concluded that the

evidence is not sufficient to recommend the procedure without special arrangements.(38) NICE did find sufficient evidence to recommend single mini-incision THR.(40) Their recommendation was based on evidence from two randomized controlled trials (279 patients) and five non-randomized comparative studies reporting significantly less intraoperative blood loss with the mini-incision than with the standard THR procedure.(41) The Cochrane collaboration has recently begun a systematic review of the subject, but the results of this review are not yet available.(42) The Canadian Coordinating Office for Health Technology Assessment report, searched in November 2004, found no trials, case reports, or abstracts that assessed the harm or benefit of minimally invasive procedures for hip resurfacing.

## **Computer/Robotic Assisted Surgery**

Computerized surgery systems have been used in THR for two purposes.(43) The first is to position the acetabular cup in such a way that the prosthesis has maximal range of motion without impingement. This may have the effect of decreasing wear and reducing the potential for dislocation. The second application for computer-assisted surgery is precision reaming of the medullary cavity of the femur so that it makes maximal contact with the stem of the prosthesis. This may increase initial stability and improve bonding of bone to prosthesis.

Newly marketed computer-assisted navigation systems are designed to aid in implant positioning. They provide surgeons with both preoperative and intraoperative information by displaying three-dimensional computer images of patient anatomy.(44) Computer-assisted navigation involves three processes: data acquisition, registration, and tracking. Fluoroscopic, CT-guided, magnetic resonance imaging (MRI)-guided or imageless systems facilitate data acquisition. Image data are then used for registration and tracking. Registration is the means of establishing a spatial relationship between all image locations and the corresponding locations on the patient. Tracking occurs during the actual surgery, as sensors and measurement devices provide real-time feedback regarding the orientation and position of instruments and implants relative to bone anatomy. For THR, computer-assisted navigation systems use the registered landmarks to navigate the needed surgical tools (cup reamer, cup inserter, stem rasp, bone saw, and implant) to the planned position so that the prosthesis is properly placed.

Computer-assisted surgery has also contributed to the development of minimally invasive surgical techniques for THR.(45) Many surgeons believe that the standard, large incision approach, is necessary to adequately visualize the surgical area and properly align the implants. Computer-assisted surgical navigation overcomes the need for a large visual field by providing patient-specific anatomical data and proper instrument positioning without direct visual contact. Computer-assisted minimally invasive surgery may be able to provide the benefits associated with less invasive surgery while insuring proper implant alignment and better long-term outcomes. However, data available to support this claim are sparse.

ECRI has systematically reviewed and assessed the available literature on computer-assisted navigation for THR and can therefore comment on the totality of this evidence base.(44) ECRI did not identify any randomized, controlled trials (RCTs) comparing computer-assisted navigation to other alternatives, and no study reported long-term followup of patients who underwent THR using computer-assisted navigation. Most of the evidence came from meeting abstracts and uncontrolled case series performed in Europe. Due to the lack of RCTs, ECRI also considered single-arm studies (case series). In conditions that are not likely to improve without intervention, such as with degenerative hip disease, single-arm studies may provide useful

information about treatment efficacy. Only four reports met the inclusion criteria: two controlled studies and two prospective case series. The evidence base was limited by the lack of prospective RCTs, short follow-up periods, small patient numbers, and unique patient populations that may have results that are not generalizable to a broader population. In addition, the use of different navigation systems and various traditional and minimally invasive surgical approaches limited the interpretation of the results. ECRI concluded that insufficient evidence is available to determine whether using computer-assisted navigation systems for THR reduces postprocedure complications (e.g., increased wear, reduced range of motion, dislocation, and need for revision). A few nonrandomized European studies suggest that use of these systems improves the accuracy of prosthesis placement, but improvements in accuracy have not yet been shown to improve longevity of the devices.

Our examination of the literature did not identify any information regarding the effect of patient age on the incidence of complications among patients undergoing robotic or computer-assisted surgery.

### ***Short-term Outcomes***

Short-term outcomes typically assessed following hip replacement include pain and ability to walk unassisted and without a limp. Instruments commonly used to assess outcomes in hip replacement include those designed specifically for assessing THR, those designed to assess hip-related difficulties, and general health questionnaires. Occurrence of adverse events is also an important measure of short-term outcome. Some common outcome measures are listed in Table 2, and adverse events are listed in Table 3.

Many validated instruments are available for assessing the outcome of hip surgery. The earliest of these is the numerical grading system introduced by d'Aubigne and Postel in 1954.(46) This scale assesses pain, walking, range of motion and overall patient satisfaction. It has subsequently been modified numerous times, and other instruments may be based in part on the d'Aubigne model.(1) The Harris Hip Score is the most commonly used hip scoring system.(47) It was developed to assess the results of hip surgery in general, not just THR. Harris scores range from 0 to 100, with higher scores indicating greater health. The Oxford Hip Score (OHS) was developed specifically to assess outcomes of THR.(48) This validated questionnaire consists of two subscales (pain and function) containing six questions each. Five response categories for each question are summed to yield scores of 6 to 30 for each subscale.(49) Higher scores indicate more pain and impaired function. The WOMAC (Western Ontario and McMaster Universities) Osteoarthritis Index for hips consists of 24 items grouped into three categories: pain (five questions), stiffness (two questions) and physical function (17 questions). Lower scores indicate greater disability. The Charnley hip score relies on surgeon assessments of patients' pain, mobility, and walking, with lower scores indicating greater disability.(50) A hip-rating questionnaire published by Johanson et al.(1992) scores patients in four domains: Pain, Walking, Function, and Overall impact of arthritis.(51) Final scores range from 16 (Worst) to 100 (Best).

The outcome evaluation questionnaire developed by the American Academy of Orthopedic surgeons provides information on patient motivations and experiences, but does not provide a single score or a rapid method of comparing outcomes between patient or treatment groups.(52)

Instruments designed to measure general health and health-related quality of life include the Medical Outcomes Study Short Form-36 (SF-36), the Nottingham Health Profile and the

Sickness Impact Profile. Such scales tend to be long, and may include factors or utilities of questionable relevance to THR patients.(50)

**Table 2. Short-Term Outcomes**

<b>Pain Measures</b>	<b>Function Measures</b>	<b>Instruments</b>
Visual analog scale	Distance walked	Harris hip score
Verbal ratings	Presence of limp	WOMAC score
McGill Pain Questionnaire	Ability to perform various tasks	Oxford hip score
		d'Aubigne score
		Charnley hip score
		The American Academy of Orthopedic Surgeons total hip arthroplasty outcome evaluation questionnaire
		Unnamed scale by Johanson et al.(51)
		Any number of general scales

## Adverse Events

Short-term adverse events include those events that may occur, albeit rarely, following any surgery. Allergic reactions, anesthesia reactions, migration of blood clots, excessive bleeding, infection, heart attack, and pneumonia are all possible. The occurrence rates of these events are not well reported in the literature.

Adverse events specific to hip replacement include dislocation, loosening or breakage of the implant, reaction to the implant materials, breakage of the bone surrounding the implant, locking of the joint and change in the length of the affected leg.(53) Pain, stiffness and nerve damage may occur. In rare cases, leg amputation may be necessary. Adverse event rates are commonly believed to vary according to the surgical approach, the surgical experience of the operating team, implant model used and implant design. Some adverse events may result in a need for additional surgery, including revision of the implant.

**Table 3. Short-Term Complications**

<b>General Surgical</b>	<b>Procedure-Specific</b>
Thromboembolism	Cement reaction
Fat or marrow embolism	Fracture
Infection	Early dislocation
Reaction to anesthetic	Peripheral nerve injury
Poor wound healing	Loosening
Excessive bleeding	Change in leg length
Pneumonia	Heterotopic ossification

## **Thrombosis**

Deep vein thrombosis (DVT) is a common complication following THR. Many incidents are minor and not clinically evident. Without prophylaxis, asymptomatic DVT will develop in 40% to 60% of patients having THR.(54) Risk factors for thrombosis after THR include increasing age (modest increase with age), sex (women may be at more risk), previous thromboembolism (two to three fold increase in risk), and obesity (twofold with BMI greater than 25). Symptomatic thrombosis often occurs in the calf, leading to local pain and swelling. Most surgeons advocate some form of anticoagulant therapy to help prevent thrombosis or embolism. The ideal agent for prophylaxis has not been identified yet, but randomized controlled trials have shown that low-molecular-weight heparin (LMWH), warfarin, and fondaparinux are safe and effective in reducing the risk of thrombotic events after THR.(54) The American College of Chest Physicians (ACCP) recommends that patients undergoing THR receive a thromboprophylaxis agent for at least ten days, preferably for 35 days, after surgery.(55)

Pulmonary embolism is the most common surgical adverse event that can lead to death. It occurs most often during the second week after THR and risk declines sharply by the fourth week.(53)

## **Infection**

The most significant early complication of THR is sepsis. It can lead to catastrophic failure requiring explantation.(56) In some cases, permanent resection arthroplasty (Girdlestone arthroplasty) may be necessary to control infection. Improvements in sterile technique and prophylactic antibiotics have dramatically reduced the incidence of sepsis following hip replacement compared to when the technique was first introduced.

## **Fracture**

Bone fracture can occur in the area around the prosthesis, either during the implantation procedure or shortly thereafter. This occurs with approximately 0.1% to 1.0% of cemented implants and 3% to 17.6% of uncemented implants.(53) Risk of fracture increases when bone integrity is compromised by arthritis or other diseases or by previous implantation. Periprosthetic fracture may require revision surgery.(57)

## **Heterotopic Ossification**

Formation of bone in inappropriate places can occur as a result of stress on the bone. Thickening, spur formation and ankylosis are all forms of heterotopic bone formation referred to as heterotopic ossification (HO). A few weeks after THR, HO begins, and formation is usually complete within three months.(53) While normally harmless, HO can cause pain and may impede joint motion. A recent systematic review of studies of THR found that HO occurred in approximately 42% to 44% of patients.(58) This is significantly more common than was reported in earlier narrative reviews, which reported that one fourth to one third of patients experience HO. The recent review did not indicate how often heterotopic bone led to motion difficulties. However, severe HO or bony ankylosis occurred in 9% of patients. Low dose radiation is frequently used to prevent HO.(53) HO can also be prevented or inhibited by administration of nonsteroidal anti-inflammatory drugs.(58) Radiation and NSAIDs can be used in a combined approach to reduce the incidence of HO after THR.(59)



## Dislocation

Dislocation of the prosthetic hip has been reported at rates ranging from less than 1% to more than 15%.<sup>(28,60)</sup> This wide range is probably attributable to the different patients, different devices, and different surgical procedures used in different studies. Rates are similar for THR and hemiarthroplasty, but after hip replacement revision surgery, dislocation rates may be higher than 25%.<sup>(28)</sup> Most dislocations occur shortly after hip replacement surgery, with 60% to 70% occurring within the first 4 to 6 weeks after surgery.<sup>(28)</sup>

The most important risk factor for dislocation is previous dislocation. Recurrent dislocation occurs in approximately 33% of cases.<sup>(61)</sup> Other factors include patient characteristics, variations in surgical technique, and implant design. THRs performed following hip fracture are at higher risk for dislocation than elective THRs. Instability is also associated with THRs performed by less experienced surgeons.<sup>(60)</sup> A list of commonly-reported factors contributing to hip instability is given in Table 4. Some factors may be interrelated. For example, increased age may be associated with decreased cognitive function, which may be associated with inability to adhere to recommended precautions. Other factors may be part of design trade-offs. For example, a rim around the acetabular cup may decrease hip instability, but also decrease range of motion.

**Table 4. Risk Factors for Hip Instability**

Patient Factors	Surgical Factors	Implant Design Factors
Female gender	Posterolateral approach	Head to neck size ratio
Increased age	Component malposition	Poor head to acetabular cup size matching
Increased height	Soft tissue tension	Decreasing femoral offset
Replacement due to hip fracture	Failure to reconstruct soft tissue envelope	Lack of an acetabular cup rim and elevated posterior wall
Previous hip surgery	Surgeon inexperience	Unipolar design
Muscular weakness	Cement fixation	
Nonadherence	Revision surgery	
Substance abuse		
Cognitive impairment		
Previous dislocation		

Most dislocated hips can be relocated without surgery, a process known as closed reduction.<sup>(61)</sup> After closed reduction, the patient may wear a brace or cast for a period so that lax tissue has a chance to tighten as it heals.

Revision surgery is generally reserved for those patients experiencing three or more dislocations. Total revision THR is reportedly successful among these patients in 60% to 75% of cases.<sup>(60)</sup> Fortunately, the use of modular hip components has made total revision unnecessary in many cases. Instead, hip components can be exchanged. Use of a larger femoral head, or a lipped cup liner can often end an instability problem.<sup>(61)</sup> Tightening the abductor tissue through trochanteric advancement (moving the point of attachment of the muscle to the femur), using a

longer femoral neck or lateralizing the acetabular cup can also be effective. During the surgery to exchange components, the surgeon can also alleviate any soft tissue or bony impingement that may contribute to the instability. Such surgery is reportedly successful in 69% to 96% of cases.(60) Use of modular systems in primary THR may also reduce the risk of dislocation.(62)

Recurrent dislocation can also be addressed by replacing the acetabular liner with a constrained polyethylene liner.(29,60,63,64) Constrained liners are designed with an extended polyethylene lip that restrains the femoral head within the liner. The capture mechanism reduces the incidence of dislocation but also reduces the range of motion. The greater surface area in contact with the head increases the amount of polyethylene wear. The liner is placed within the acetabular shell component using cement or screws. Constrained liners are still subject to failure due to loosening, dissociation, breakage, or recurrent dislocation. Reported failure rates range from 4% to 29%.(64)

## ***Long-Term Outcomes***

### **Revision**

The most important long-term outcome of hip replacement is surgical revision. The need for surgical revision is the primary definition of failure of a THR.(65) Undergoing additional surgery to repair or replace an implant is extremely inconvenient for the patient and can be dangerous. For this reason, most of the technical innovations in THR have been intended to reduce the need for revision. A more complete discussion of revision surgery can be found below.

### **Dislocation**

Dislocation is usually a short-term complication. However, some patients experience hip instability many years after implantation, despite having never experienced it before. Late dislocation may be associated with increased range of motion and wear of the acetabular cup.(28) Stretching of the soft tissue surrounding the hip by repeated extremes of motion may decrease joint support. Weight loss, decreased muscle mass, or chronic disease (cancer, rheumatoid arthritis) may also contribute to instability.(64) Dislocation rates have also been reported to increase after surgical replacement of the acetabular cup liner.(30)

### **Sepsis**

Infection associated with implanted prostheses can develop years after surgery and is considered a major complication.(66) The Swedish National Hip Arthroplasty Register annual report for 2004 listed deep infection as the third most common reason for revision surgery (7.9% of all revisions).(67) Deep infection was responsible for 19% of revisions during the first three years after surgery and 1.2% of revisions at more than 10 years after surgery. Management of periprosthetic infection after THR can involve several different approaches but the standard procedure in North America has been the two-stage exchange revision.(66) The two-stage procedure starts with removal of the infected prosthesis followed by a minimum course of six weeks of parenteral antibiotics. Resolution of the infection is confirmed by repeated aspiration of the hip. A temporary spacer of antibiotic-loaded cement can be inserted during the first operation and then removed during the second operation when a new prosthesis is put in place. The two-stage revision approach is well accepted but does have some controversial aspects. These include the timing of the procedure, the use of the antibiotic loaded cement at the

second stage, the role of allograft bone grafting, and the use of uncemented components. Other treatment options include antibiotic suppression in patients unable to undergo revision arthroplasty, operative debridement and retention of the infected prosthesis for acute infections, and single-stage exchange revision with post-operative parenteral antibiotics.

## **Wear**

Wear is the loss of prosthesis material at the interface between the ball of the femur and the acetabular cup. Component wear eventually leads to revision, either because of the component actually wearing out (e.g., the ball breaking through the cup) or because of implant loosening due to osteolysis brought about by wear particles.(68,69) The particles are engulfed by macrophages, which respond by releasing cytokines that encourage resorption of bone. Most often, implants are revised because of osteolysis and implant loosening.(65) Implant wear correlates with osteolysis, loosening and revision.(65) Osteolysis associated with wear debris is the most common cause of revision of prostheses using polyethylene.(70)

Wear can be caused by adhesion of the two components, abrasion caused by the components rubbing against each other or against particles that may find their way between them, or through fatigue. Cracking, pitting or delamination is due to fatigue caused by cyclic stresses placed on the bearing surface.(68)

Wear is often assessed by measuring the linear penetration of the femoral head into the acetabular cup, reported as mm/year.(71) However, some penetration of the femoral head is the result of “bedding-in,” rather than true wear. “Bedding-in” refers to the settling of the polyethylene liner within the acetabular shell and the permanent deformation of the plastic due to compression.(72) The deformation due to compression is also known as “creep.” Bedding-in is not considered wear because no material is lost. It slows down within one or two years after implantation.(65) Most of the linear penetration measured after this period is the result of true wear and therefore the wear rate can only be determined after the bedding-in period.(72) Measurements of linear penetration (as reported in Table 5) are difficult to interpret because the extent of bedding-in may not be accounted for.

In laboratory tests, wear can be measured accurately. However, the relevance of laboratory measurements to wear as it occurs *in vivo* is unclear. In a clinical situation, wear must be deduced radiologically.(1) Radiologic measurements are inaccurate and insensitive to small changes. Under the best of conditions, meaningful measurements of the penetration of the ball into the socket can only be made when they reach depths of 0.5 mm or more.(1) This level of wear is normally observed years after implantation. Wear of metal-on-metal bearings cannot be measured radiographically at all.(65) Accurate measures of wear can only be made when components are explanted during revision surgery.

Table 5 presents some linear wear rates as reported in various recent reviews and other published reports. At the current time, no national registries or other national data sources are available that provide information on wear rates for different prosthesis and their impact on revision rates in clinical practice across the United States. The tabled data only illustrate the range of rates reported and the difficulty of comparing rates reported from different sources. Wear rates reported at different follow-up times may not be comparable because the contribution of the bedding-in process to the overall penetration rate will be different. At shorter follow-up times, linear penetration will be primarily the result of bedding-in rather than true wear. At longer follow-up times, a greater proportion of the penetration will be the result of wear. In addition,

attempts to combine data from studies using the same implant materials may not be valid because of other differences between studies, particularly patient characteristics. Younger, more active patients have higher rates of wear than older, sedentary patients.(65)

Wear can be reduced by using well-fitted components and wear-resistant materials.

Retrieval studies (studies of implants retrieved after revision surgery) suggest that metal-on-metal prostheses appear to wear more slowly than metal-on-plastic.(65) Simulator studies have shown as much as 200 times less wear of metal-on-metal than metal-on-plastic devices.

Ceramic-on-ceramic prostheses may wear even more slowly than metal-on-metal.(65)

Ceramic-on-plastic may wear more slowly than metal-on-plastic.(1) Because surface wear and the subsequent local and systemic effects remain the major cause of THR failure and the need for revision surgery, research into alternative bearing surfaces that minimize wear is still ongoing.(22) Controversies remain about which type of bearing surface is the most durable.

Each surface has its advantages and disadvantages. New developments in bearing surfaces will be discussed in the section on types of replacement hip designs.

**Table 5. Reported Linear Wear Rates of Different Implant Materials**

Implant Material	Linear Wear Rate	Follow-up Time	Reference Source
Metal-on-Plastic (Polyethylene)	0.202 mm/year 0.20 mm/year	2 Years	Heisel et al., 2004(65)
	0.110 mm/year	Not Reported	Dowson, 2001(1)
	64-77% had a wear rate of <0.2 mm/year	Up to 108 Months	Zichner and Willert, 1992(73)
	0.135 mm/Year	Up to 44 Months	Harris, 2004(74)
Metal-on-Plastic (Highly Cross-linked Polyethylene)	0.094 mm/year 0.18 mm/year	2 Years	Heisel et al., 2004(65)
	Between 0.15 and 0.25 mm/year	Not Reported	Dowson, 2001(1)
	0.011 mm/year	Mean: 15.5 Years, Range: 14-22	Santavirta et al., 2003(75)
	After an initial bedding-in of 0.2-0.4 mm/year, average penetration rate decreased to 0.02 mm/year	10 Years	Santavirta et al., 2003(75)
	0.008 mm/year	Up to 44 Months	Harris, 2004(74)
Metal-on-Metal	0.005 mm/year	3 Years	Heisel et al., 2004(65)
	0.020-0.025 mm/Year 0.005 mm/year	1 Year After 1 Year	Santavirta et al., 2003(75)
	0.005 mm/year after the third year	Up to 8 years	Dorr et al., 2004(76)
Ceramic-on-Ceramic	0.016 mm/year	Mean 12.7 Years, Minimum 10	Schweppe, 1999(77)
	0.0026 mm/year in a stable implant 0.068 mm/year in a loose implant	Mean 144 Months	Boehler et al., 1994(78)
	0.002 to 0.020 mm/year	Not Reported	Dowson, 2001(1)
	0.005 to 0.009 mm/year	Not Reported	Bizot et al., 2000(79)
	0.0039 mm/year in well-positioned joints and 0.0065 mm/year in joints with loosening or malpositioning	Not Reported	Santavirta et al., 2003(75)
Ceramic-on-Plastic (Polyethylene)	95% had a wear rate of <0.2 mm/year	Up to 102 Months	Zichner and Willert, 1992(73)

## **Loosening**

Over time, fixation of the implant to the bone can decline. Micromovements can lead to fragmentation of acrylic cement, and phagocytosis of acrylic particles can activate macrophages, which respond by releasing cytokines leading to osteolysis. Additional debris derived from friction between the femoral head and the acetabular cup contributes to this process as well.(1,80)

Patients undergoing hip or knee replacement in their 40s or 50s report more rapid onset of loosening, which may be related to increased polyethylene wear.(27) Techniques for prolonging cement life have been developed over the years and incorporated into standard surgical technique. These include warming the implant prior to cementing,(30) and reducing the porosity of the cement surface. Good surgical technique and avoiding mixing wet cement with blood can help prevent loosening.

Femoral loosening has been associated with small femoral stems implanted into large intramedullary canals.(56) Other patient characteristics associated with loosening include patient weight, unilateral disease, youth and high activity.

While radiographic monitoring is considered an essential part of THR aftercare, radiographic evaluation frequently underestimates the extent of osteolysis, particularly in the pelvis.(81) Considerable bone loss has to occur before it can be detectable either as radiolucent lines or other cystic changes.(82)

## **Breakage**

The Swedish National Hip Arthroplasty Register annual report for 2004 listed implant fracture as the sixth most common reason for revision surgery. From 1979 to 2004, 1.6% of revisions were needed because of implant breakage.(67) Lindahl et al. analyzed the data in this registry, and concluded that the majority of patients who suffered implant fractures had loose stems at the time of the fracture.(83) The authors of this report suggest that routine radiographic followup to detect loose implants may help prevent implant breakage.

Early ceramic implants were known for their relatively high fracture rates. Later improvements in quality and reductions in grain size appear to have overcome this problem, and more recent surveys have found only one or two breaks in alumina ceramic devices in 10,000 patients.(68) Zirconia ceramic balls are even harder. One survey found only two fractures out of 300,000 implanted devices.(68) However, the quality of zirconia ceramics is highly dependent on the precise manufacturing process used. A change in manufacturing process in 1988 led to an unacceptably high breakage rate (as high as one in three devices from one lot). Nine lots of zirconia balls were eventually recalled.(84) This catastrophic experience was unique to a single type of ball manufactured in a specific manner, but it illustrates the importance of precise control over manufacturing processes and rigid quality control.

Femoral stems can also break. Stem fractures in the early Charnley type prosthesis appeared in the late 1960s.(85) This led to changes in the design and geometry of the stem to improve corrosion resistance and fatigue properties.

## ***Influence of Patient Factors***

### **Weight**

Other factors being equal, heavier patients place more stress on their prostheses than lighter patients. This may lead to greater wear and a higher propensity of the implant to break. At the same time, heavier patients may be less active, which could reduce wear.

### **Activity**

Wear is the result of activity. More active patients will wear out their implants faster.(65) Wear debris contributes to aseptic loosening. Activity also increases micromovement of the implant, leading to release of cement particles and further aseptic loosening. All of these lead to a more rapid need for surgical revision.

### **Bone Quality**

Patients with severe degeneration of the bone due to osteoarthritis, Paget's disease or other conditions may be more prone to implant loosening, and may lack sufficient structural support for the prosthesis. Patients with weak bone may not be candidates for rigid ceramic prostheses, which do not absorb shocks and may lead to bone damage. Bone thickness is classified according to the system of Dorr et al.(86) from thickest, healthiest cortices (Class A) to thinnest, class C. Dorr class C bone is considered a predictor of less successful THR.(25)

The outcome of THR is also affected by the patients' Charnley categories.(47) This simple classification scheme describes the extent of patient disability before THR. Category A includes patients with unilateral hip disease, category B includes those with bilateral hip disease, and category C includes patients with multiple joint disease or other disabilities impairing their walking capacity. The results of different clinical trials of THR cannot be compared unless the patients were in comparable Charnley categories. Moreover, patients may move into new Charnley categories as they age. Therefore, clinical trials should report Charnley categories not just at the time of surgery, but at each time of follow-up.(47)

### **Age**

Age by itself is not a factor in deciding whether to perform THR or in deciding which type of implant to use.(87) However, age correlates with other factors that appear to influence THR outcomes. Older patients may not be as active as younger patients, making their prostheses less prone to wear and breakage.(65) Lower wear, in turn, may mean lower incidence of aseptic loosening.(27)

Older patients tend to have lower quality bone, due to ongoing arthritis and osteoporosis. This may influence the type of prosthesis chosen and the longevity of the device. Older patients are also more likely to undergo THR following hip fracture, which is associated with worse outcomes than the typically elective THR performed for other indications in younger individuals. Finally, older patients have shorter life expectancy than younger patients, reducing the number of loading cycles the implants must endure.(65) Younger patients are therefore more likely to outlive their implants, necessitating one or more revisions.

Table 6, below, lists the ages of patients at initial THR reported in recent reviews and other published reports. Because the information was not assembled in a systematic manner, ECRI cannot determine the extent to which the information presented is representative of typical medical practice in the United States. Rather, the table is presented to illustrate two key points. First, patients as young as 19 and as old as 90 have been treated with THR. Younger patients will want prostheses with a long functional life-time in order to delay the need for revision surgery. Mean ages in Table 6 range from 45 to 70. Second, the published literature rarely reports data in a way that enables a separate examination of information grouped according to age (for example, patients over 65 years old). While the mean age of patients in a given study may be close to 65, the study will almost certainly include younger and older patients. The effect that age outliers may have on the reported outcomes of a study often cannot be determined.

**Table 6. Reported Patient Ages at initial THA**

<b>Age at Implantation</b>	<b>Reference Source</b>
Mean: 45 Years, Range: 19-63	Schweppe, 1999(77)
Mean: 53 Years	Murphy 2002(70)
Mean: 63.8 Years, Range: 31-80	Boehler et al., 1994(78)
Mean: 67.9 Years	Canadian Joint Replacement Surgery Registry 2004 Report(88)
Mean: 65 Years, 52% of patients were older than 65.	Clarke, 1992(82)
Mean: 64.8 Years, Range: 18.7-92.1	Nizard et al., 1992(89)
Mean: 52 Years, Range: 36-65	Winter et al., 1992(90)
Mean: 69.5 Years	Swedish National Hip Arthroplasty Register Annual Report, 2003(91)
Mean: 60 Years, Range: 34-79 in Women Mean: 58 Years, Range: 33-75 in Men	Lizaliturri et al., 2004(92)
Mean: 68.8 Years	Quintana et al., 2000(93)
Mean: 62 Years, Range: 35 to 72	Torisu et al., 2003(94)
Mean: 70 Years, Range: 40-90	Callaghan et al., 2004(95)



## ***Effects of the Clinical Environment***

Clinics in which a large number of THR procedures are performed tend to have lower rates of complications or mortality compared to centers with a lower surgical volume.(96,97) Moreover, individual surgeons who perform many procedures a year tend to have superior outcomes compared to surgeons who perform fewer procedures. This phenomenon is particularly noticeable when dislocation rates are examined.(60,98) However, the relationship between surgical volume and complication rates is not strictly linear. In at least one study, the complication rate reached a floor, with no further decrease at higher volumes.(96)

Other factors that may influence between-center differences in complication and mortality rates include the analgesics used, favored surgical methods, favored types of replacement hips, the types of patients typically seen in that facility, and whether or not the facility is a teaching or a research hospital. An analysis of data from the Swedish National Hip Arthroplasty Register indicates that differences in types of patients seen in a facility may account for differences in revision surgery rates between facilities. The Swedish National Hip Arthroplasty Register records both the number of procedures performed and revision rates at a hospital-by-hospital level. The data from the registry are analyzed by the Department of Orthopaedics at Sahlgrenska University Hospital and presented in an annual report. A Cox regression analysis presented in the 2004 Annual Report indicates that revision surgery is approximately 27% higher in patients younger than 60 years of age, older than 75 years of age, or with diagnoses other than primary osteoarthritis. Thus differences in hospital revision rates may be due to differences in the proportion of patients of these types seen by each hospital.

Patients 60 to 75 years of age with primary osteoarthritis represent the most common patient category seen in the Swedish Hip Register.(67) They accounted for 41% of all hip arthroplasties and 3.2% of these patients underwent revisions. The authors of the 2004 Annual Report used this index group of patients as a first step in looking for patient characteristics that could account for differences in THR outcomes between facilities. They compared this group to all other patients and found a significant difference in revision rates between the groups as described above. They also found that this index group varied considerably depending on the type of hospital. In rural and private hospitals, there were more patients in this group and these hospitals tended to have somewhat better implant survival rates. Future analyses will focus on whether having a higher proportion of patients in this index group correlates with reduced medical costs and better outcomes.

That high volume centers may provide superior outcomes may lead more patients or other stakeholders to choose such centers for their procedures. The effect on surgical outcomes of restricting patients to high-volume centers has not been determined. Further increasing the volume at centers that are already working to capacity may lead to increased complication rates due to increased workload. Further research is needed to address this issue.

## **Types of Replacement Hips**

Prosthetic hips come in a wide array of designs. Many models of prosthetic are available in modular designs, so that various combinations of features can be selected to best fit patient needs and clinician preferences. A detailed list of available models and features can be found in the Appendix. A systematic review conducted by the U.K. National Health Service in 1998 noted the “striking paucity of clear and relevant evidence on which to make well-informed choices about prostheses for primary THR.”(99)

### **Design**

The basic design of the hip prosthesis has not changed drastically since hip replacement surgery was introduced decades ago. The most common design features a stem topped by a ball component that is implanted into the top of the femur to replace the degenerated femoral head that surgeons have removed. The ball fits into a socket (acetabular cup component) placed in the hip bone. Different models vary in details of design, materials and cost. Each component may come in a variety of sizes to accommodate differently-sized patients.

### **Materials**

Over the years, the metal-on-plastic (ultra-high molecular weight polyethylene) design has emerged as the gold standard of hip prostheses.(100,101) In this design, the ball component is metal, while the cup component is lined with plastic. In past years, alternative materials suitable for orthopedic bearings, such as new metal alloys and ceramics, were studied in an attempt to develop more durable joints that provided the same level of functionality. Early metal and ceramic bearings were abandoned for technical and design deficiencies.(102) The first generation of metal-metal joints were abandoned because of early loosening of the acetabular cup resulting from imprecise fit of the metal ball in the metal socket, while ceramic joints may have had higher fracture rates. Subsequent developments may have reduced or eliminated such problems.(103)

### **Metal-on-plastic**

The first metal-on-plastic hips failed rapidly as the femoral head penetrated the cup.(1) These cups were made of Teflon. Later, polyethylene cups proved to be more durable, but long-term wear remains a problem. Conventional ultra-high molecular weight polyethylene (UHMWPE) cups typically last for 10 to 15 years or longer, depending on the age and activity level of the patient, but the wear and osteolysis remain a problem in individuals who are expected to live longer than this time span.(104,105) This device lifespan is not favorable for younger, more active patients who may require at least one revision procedure in their lifetime to replace a failed prosthetic joint.

The most common cause of metal-on-polyethylene hip joint failures is aseptic inflammatory reaction to the microscopic polyethylene particles released due to joint wear.(70)

This inflammation can cause bone resorption and loosen the bond between bone and prosthesis, causing pain and impairing proper joint function.(1) Loss of bone tissue during the initial device implantation and lower bone quality due to inflammation near the implant means that revision surgery to replace the damaged prosthetic joint is typically more challenging than the initial implantation.

### **Highly cross-linked polyethylene**

More recently, researchers have developed a more durable material called “highly cross-linked polyethylene” (UHMWPE modified in an attempt to change its mechanical properties to decrease wear) to produce next-generation metal-on-plastic hip joints. The use of harder metals and higher levels of cross-linking in the polyethylene may have improved longevity, but have not eliminated the problem of wear. Highly cross-linked UHMWPE is made by exposure to gamma or electron beam irradiation.(106) In addition to the cross-linking, the radiation exposure also forms free radicals, which would normally lead to oxidative damage and greater wear of the polyethylene. The free radicals are removed by re-melting the material. The resulting substance has greatly increased wear resistance. This product was first introduced in 1998.(107) Different types of UHMWPE have different biomechanical characteristics. These differences may account for differences in clinical performance. Other factors that may influence wear rates include cross-linking method and sterilization method.(30)

Available data are mixed as to whether highly cross-linked polymers last longer than older materials. A radiographic study comparing conventional and highly cross-linked polyethylene at two-year followup found a 65% reduction in two-dimensional linear wear rate associated with the highly cross-linked polymer, as well as a 54% reduction in three-dimensional wear rate and a 38% reduction in volumetric wear.(30) However, another study that compared polyethylene liners that had been surgically retrieved for reasons other than wear found no difference in damage scores between conventional polyethylene and highly cross-linked polyethylene.(30,68)

Although lower wear rates would lead to less wear debris given off by the implant, highly cross-linked polyethylene wear particles tend to be smaller than those given off by standard polyethylene.(65) These submicrometer particles may induce a greater inflammatory response than larger particles. The question of whether fewer but more active particles lead to more or less osteolysis and implant loosening remains to be answered. The number, size and shape of the particles released by the polyethylene liner depends on the material used, the mode of cross-linking, and patient-related wear factors.(65) Only clinical studies of each specific polyethylene component, controlled for differences between patients, can determine whether cross-linked polyethylene leads to more favorable clinical outcomes.

Highly cross-linked UHMWPE has many proponents.(108) The lack of metal ion production in particular has been cited as advantage over metal-on-metal systems. However, long-term studies are needed to determine if the purported advantages lead to less wear and longer device life span.(22,106,107)

### **Metal-on-metal**

Early efforts at implanting metal-on-metal prostheses were plagued by rapid dislocations and cup deformation.(109,110) By 1975, metal-on-metal designs had been phased out in favor of the metal-on-polyethylene designs. However, concerns over osteolysis attributed to polyethylene wear debris led to a reintroduction of newer metal-on-metal designs. More recently, new metal-on-metal joints seem to have corrected the previous issues.(111,112) The later generation of metal-on-metal joints has a more precise fit that allows the proper space for lubrication. This has apparently solved the early cup-loosening problem. In particular, a number of manufacturers are marketing metal femoral heads that have a larger diameter than the traditional metal models; these larger heads are designed to decrease the probability of dislocation.(22) Prostheses are available that are made from stainless steel, titanium, or cobalt chrome.(99)

Titanium is no longer a popular choice as a bearing surface due to debris accumulating in tissues as surface oxides detach from the bearing surface.(113) These particles may be associated with a high rate of aseptic loosening. Titanium remains popular as a femoral stem in modular prostheses.(113)

Some experts have expressed concern that over the long term, the metal ions that are gradually released by these new metal alloys in metal-on-metal couplings may promote some types of systemic or blood-borne cancers or damage internal organs, such as the kidneys.(114) Although cobalt and chrome particles have been shown to induce carcinoma in animal models, epidemiologic studies have not found any increased risk of cancer among patients with metal-on-metal hip or knee prostheses.(115,116) Toxicity still remains a concern and long-term clinical observations are necessary to determine if the wear resistance of metal-on-metal systems outweighs any associated risks.(117)

Metal-on-metal implants tend to wear rapidly during the period immediately after implantation.(68) However, this phenomenon is transitory, and wear tends to be slow when considered over the life of the implant. Metal-on-metal joints reportedly have wear rates that are substantially better than metal-on-polyethylene joints, but not quite as good as ceramic-on-ceramic.(65) Metal-on-metal implants may also have the ability to self-heal.(68) Friction between the two components may polish out any imperfections introduced by subluxation or third-body particles.

Proponents of metal-on-metal implants cite this design's long history, better wear characteristics, and lack of observed biological complications from metal particles or ions.(109,118) Other authors cite concerns over acquired hypersensitivity to metal particles, mutagenicity, and carcinogenicity as reasons not to recommend metal-on-metal designs.(107,110) Long-term comparison studies are needed to determine the extent to which the purported advantages of metal-on-metal lead to better clinical outcomes and if a biological response to metal ions becomes a clinically relevant concern.(22,103,107,117)

### **Ceramic-on-ceramic**

The need for more wear-resistant materials has led to the introduction of ceramic hips. Several types of ceramic have been used for the femur-cup interface, the most popular of which is alumina (aluminum oxide). Although alumina hips have been used, primarily in Europe, for more than 30 years, data derived from these earlier designs may not be relevant because of improvements in manufacturing and materials since that time.

Alumina hips implanted in the 1970s were less dense and more porous than more recent models, with larger grain sizes.(119) Grain size has been reduced from about 40 microns in the earliest models to below 3 microns.(113) This means that the size of flaws in the ceramic structure is likewise reduced, and the surface of the bearing is smoother.(113) In addition, designs, manufacturing techniques and quality controls have improved.(119) These properties may cause more recent hip joint models to be less prone to breakage and wear than older models.(90) The earliest ceramic models used a ceramic ball mounted on a metal stem with an epoxy resin. Disconnection of ball from stem was a frequent problem, and this design was abandoned in favor of a locking mechanism between ball and stem.(82)

Ceramic-on-ceramic implant joints have the lowest wear rates of any combination investigated thus far.(65,119) Ceramics are hydrophilic, so that the surface of a ceramic joint is more wettable

than other joints, ensuring smooth spread of lubricating synovial fluid throughout the joint. Moreover, ceramics are harder than metal, and can be polished to a smoother finish. Finally, experiments have suggested that ceramic friction debris does not activate macrophages to the same extent as observed for plastic debris.(120) This may lead to greater hip longevity because fewer cytokines and other factors responsible for osteolysis and implant loosening will be released by macrophages. Decreased osteolysis also makes revision surgery easier, should it become necessary.

These properties of greater wear resistance and lower bioactivity may not translate into lower revision rates for ceramic implants. Ceramic components may migrate after a period of firm integration,(90) leading to tilting and malpositioning. In cases of cup malpositioning, loosening, or manufacturing defects leading to increased friction, ceramic hips can produce considerable wear debris.(65,119) Surgical placement must therefore be performed with great precision.(68) Patient complaints of an irritating squeak developing around two years after implantation of ceramic-on-ceramic joints was reported in a presentation at the 2006 meeting of the American Academy of Orthopaedic Surgeons. No formal study has been conducted of this adverse event, but it appears to affect less than 1% of implants.(121)

Ceramic-on-ceramic systems also have their proponents, especially for young active patients.(122,123) Reduced osteolysis and simpler revision surgery along with reduced cost and reduced risk of ceramic fracture have been cited as ceramic-on-ceramic advantages. Again long-term studies are needed to determine if the wear characteristics lead to extended device use.(101,103,107)

### **Ceramic-on-Plastic**

When zirconia ceramics are used for femoral heads, an ultra-high molecular weight polyethylene cup is used. Zirconia ceramics tend to wear rapidly when they slide against other ceramics.(113) Some researchers believe that polyethylene acetabular cups wear more slowly when coupled with ceramic heads than with metal heads.(1,68) However, not all research supports this contention.

### **Ceramic-on-Metal**

A ceramic ball in a metal cup is said to produce “ten times less metal wear” compared to metal-on-metal.(124) The ceramic ball may act as a polishing stone, further smoothing the cup and decreasing friction with use.(1) Because this design is unusual, data describing wear rates and other factors influencing implant longevity may be difficult to acquire.

### **Cushion Bearings**

Attempts to duplicate the smooth, yielding properties of the natural cartilage joint are ongoing.(1) As far as we have been able to determine, no THR procedures have been performed using such joints. However, a clinical trial is underway comparing a cushion bearing femoral head hemiarthroplasty with bipolar hemiarthroplasty.(125)

### **Surface Coatings**

A prosthesis that combines the wear properties of a ceramic surface with the bulk properties of metal would be highly desirable. Early attempts to cover a metal surface with a ceramic coating failed when the coating failed to adhere to the metal.(113)

Implants, especially cementless femoral stems, have been coated with hydroxyapatite to stimulate bone growth and seal the interface between stem and bone.(126,127) The seal is believed to prevent wear debris from collecting between the stem and bone and thereby reducing the potential for osteolysis. Osteogenic protein coatings have also been proposed to stimulate bone growth, enhance healing, and promote prosthesis stability.(128)

## **Fixation Methods**

Early prostheses were implanted without cement, and frequently worked loose. The development of a cemented prosthesis in the early 1960s was considered to be a great innovation. However, fragmentation of acrylic cement due to micromovements of the implant relative to bone can lead to shedding of acrylic particles.(56) Phagocytosis of these particles can activate macrophages, which respond by releasing cytokines leading to breakdown of the surrounding bone, the so called “cement disease.”(82) For this reason, researchers continue to develop cementless fixation methods.

Both the femoral stem and the acetabular cup can be implanted with or without the use of bone cement. Cementless components may be wedged or screwed in place, and may be molded or surfaced in such a manner as to encourage bone growth to further secure the joint. Press-fit prostheses are designed to snap into place without cement. Threaded components designed to screw into bone have been developed as well. Various coatings and textures have been used to encourage growth of bone into the surface of the prosthesis for firm fixation.(22) Hybrid prostheses, with cemented femoral stems and cementless acetabular cups are now available. The use of cement has declined in recent years, with 66.2% of stem fixations using cement in 1995, compared to only 38.6% in 2001.(30) Cementless techniques are now the preferred method for the majority of acetabular components while either fixation method may be used for the femoral stem.(101) However, cementless implants may be contraindicated in patients taking medications that affect bone remodeling.

Cementless prostheses are considered desirable for younger (<70 years) patients.(25) Such patients are more likely to live long enough to require revision surgery at some point in the future. A cementless prosthesis may have less potential for bone loss, thus providing superior bone stock in which to implant the replacement prosthesis. Some researchers believe that cement should not be used where it might compromise revisions in the future.(129) In particular, long-stemmed cemented prostheses may lead to significant bone loss and make further revision extremely difficult. Such procedures are recommended only for low-demand patients unlikely to require further revisions.

A recent Cochrane review found that cemented prostheses were less likely to lead to continued pain a year after arthroplasty for proximal femoral fractures, and had less risk of failure to regain mobility.(130) The review noted the poor quality, limited followup and small size of the studies used to support this conclusion. One of the studies used hemiarthroplasty rather than THR. The evidence was therefore described as “limited.” No other statistically significant differences were detected during the analysis of the five studies included in this systematic review.

Another systematic review found that better short-term (less than 2 years) clinical and functional outcomes were obtained from cemented femoral fixation than from uncemented femoral fixation.(131) Results were less clear for mid-term (2 to 10 years) clinical outcomes. A total of 29 publications were included in their analysis. The outcomes examined included pain, thigh pain, hip score, gait, quality of life, and osteolysis. The authors suggested that randomized trials

together with large cohort studies and registries are needed to determine the long-term durability, safety, and performance of cemented versus uncemented prostheses.

### **Coatings**

To improve fixation of cementless implants, prostheses may be coated with various substances thought to enhance bone ingrowth or adhesion. Porous coatings may be multilayered beads or mesh,(25) and may be composed of titanium or chrome-cobalt. Coatings may cover the entire prosthesis, just the proximal end, or may be arranged in rings or patches.

Coated cementless prostheses may be contraindicated if the patient has a condition that affects bone growth, such as osteoporosis, osteomalacia, osteonecrosis, Gaucher's disease, Paget's disease, or conditions requiring chemotherapy, radiation treatments, indomethacin or bisphosphonates.(25)

Bone/prosthetic interfaces may also be coated with hydroxyapatite (HA), a calcium and phosphate-rich material that promotes bone growth.(126) Bone grows toward and into HA coatings, allowing a less intimate initial fit between prosthetic and bone. As bone grows into the HA coating, it forms a tight seal, preventing foreign particles, including polyethylene and cement particles, from migrating between bone and prosthetic. This may help prevent osteolysis and bone resorption.(126)

While HA may improve implant longevity by inhibiting bone loss, care must be taken that HA particles do not break free of the implant during surgery. Free particles can lodge between the femoral ball and the acetabular cup, leading to greatly increased wear rates.(126)

### **Effects of Femoral Head Size**

A larger femoral head may make for a more stable joint, because it is less likely to dislocate.(29) However, a larger head also means more surface area, which leads to more friction in metal-on-polyethylene bearings.(132) This may increase the wear rate. In contrast, larger femoral head sizes lead to lower wear rates with metal-on-metal implant joints.(65)

A study of THR using ceramic-ceramic prostheses found that smaller (22 mm) femoral heads had a greater tendency to fracture than larger heads.(89) However, this study examined materials manufactured early in the development of ceramic materials. As noted previously, subsequent improvements in the manufacture and quality of ceramic components may have alleviated this problem.

### **Bipolar Designs**

Some joints are designed to allow movement not just at the acetabulum, but at a joint within the femur component itself.(130) These second joints are normally of the ball and socket, metal-on-plastic design, and appear to be most commonly used in hemiarthroplasty procedures when an acetabular cup is not used. A recent Cochrane review found no advantage of the bipolar design over unipolar in hemiarthroplasty following proximal femoral fractures.(130)

Bipolar designs may also be used in revision THA due to instability of the original implant. The additional joint may relieve pressure at the standard joint, reducing the incidence of dislocation.(133) An articulating acetabular cup liner may also be used to form a tripolar joint.(64,95)

## Hip Replacement Revision

No artificial device can be expected to last forever. Any prosthesis will fail if the patient survives long enough. When prostheses fail, revision surgery is usually required. Causes of failure include breakage, dislocation, loosening, infection, or the joint simply wearing out. Factors contributing to these processes are discussed in the relevant sections of this report. Revision rates are commonly believed to vary depending on the type of implant, its fixation method, surgeon experience, and patient characteristics. The individual contributions of each of these factors to revision rates cannot be determined because of the large number of factors involved and the complexity of relationships between them. For the same reason, revision rates vary widely. The U.K. National Institute for Clinical Excellence has set a revision rate of 10% or less over 10 years as its benchmark for treatment success.(134) The Swedish National Hip Arthroplasty Register reports an overall ten-year survival rate of 92.5% for the observation period of 1992 to 2003.(91)

Revision surgery is considerably more difficult than primary THR. The surgeon must remove existing implants as well as cement, screws, cables, wires and plates.(10) Then the new prosthetic components are implanted along with any necessary additional fixation or reinforcement hardware that may be required. In cases of significant bone loss, which is common, structural allografts must be performed. During these time-consuming procedures, the surrounding soft tissues and musculature must be preserved as much as possible in order to preserve blood supply to the bone, stability against dislocation, and ability to walk.(10) Revision THR also has a higher rate of intraoperative fractures than primary THR.(57)

Aseptic loosening of the implants is the most common reason for revision surgery.(22,135) The Swedish National Hip Arthroplasty Register Annual Report for 2004 reported that overall 73% of revisions between 1979 and 2004 were due to aseptic loosening.(67) Dislocation and deep infection were next, each with about 8%. For revisions performed within the first three years after implantation, aseptic loosening was responsible for 48% of revisions, deep infection for 19%, and dislocation for 17.5% of revisions.. The Finnish Arthroplasty Register(136), the Norwegian Arthroplasty Register(137), and the Canadian Joint Replacement Registry(138) all list aseptic loosening as the leading cause for revision surgery (82%, 68%, and 55%, respectively).

Revision rates are thought to be affected by hip design, materials and fixation methods, as well as patient age and activity level. Because wear and loosening are progressive processes, revision rates increase with length of followup, regardless of the hip design, materials, or fixation methods. This can make comparisons of different models and designs of prosthetic hips difficult, because newer models do not have sufficient duration of followup to ascertain their long-term revision rates. Patient characteristics may also differ for studies of newer vs. older models.



**Table 7. Reported Hip Revision Rates Under various Conditions**

Implant Material	Revision Rate	Follow-up Time	Reference Source
Cementless Ceramic-on-Ceramic	5.9%	Mean: 144 Months	Boehler et al., 1994(78)
	25%	Mean: 9.8 Years, Range: 5 to 16	Wu and Shih, 1998(139)
	25%	10-14 Years	Winter et al., 1992(90)
Cemented Ceramic-on-Ceramic	12.8%, with 20.8% of patients lost to follow-up	10 Years	Nizard et al., 1992(89)
	17%	10 Years	Bizot et al., 2000(79)
	30% 15% Among patients under 50	15 Years 15 Years	
Porous-coated metal stems, metal-on-metal, patients aged 50 or younger	11%	10 Years	McAulet et al., 2004(140)
	40%	15 Years	

Aseptic loosening due to osteolysis also presents the greatest challenges to successful revision. Loss of bone around the previous implant may mean that there is insufficient bone left to support a new prosthesis. This can lead to bone breakage during or shortly after the procedure,(30) or poor contact between implant and bone. Two hip reconstruction techniques are available to restore bone stock: impaction bone-grafting and structural allografts.(141)

In impaction bone-grafting, crushed or morselized bone (usually fresh-frozen cadaveric bone) is compacted against host bone.(141) Ideally, this will achieve a stable implant and subsequently allow restoration of living bone through bone ingrowth. Cement can be used in the construction of the graft, but must not interfere with the host/graft interface, as this would impair the host's bone cells ability to penetrate and remodel graft bone.(129) Combining the morselized bone with a very large ("jumbo") cementless cup seems to be a viable option for acetabular revisions when sufficient pelvic bone is still present to support the cup.(30) The large cup size provides more contact with host bone to increase cup stability.(142)

Major acetabular bone deficiencies (bone loss involving more than 50% of the acetabulum) require a combination of structural allograft and pelvic reinforcement cages.(22,142-144) A structural allograft, obtained from acetabular bone, has the potential to restore bone stock to normal levels but must be protected by a cage. The procedure involves removal of the old acetabular prosthesis and debridement of the area. Then the acetabular allograft is trimmed to fit the defect. Cartilage is removed but subchondral bone is left intact. The graft is fixed to host bone using screws. The protective cage has flanges that extend over the ilium and into a slot formed in the ischium. The cage is placed over the graft and secured with bone screws via the ilium flange. A polyethylene cup prosthesis is cemented into the cage.

In many cases, an ingrown metal acetabular cup can be difficult or impossible to remove during revision. When this occurs, a new plastic liner can be cemented into the metal component.(63) The development of modular prosthetic components may, in some cases, make revision surgery easier in the future.

Outcomes after revision arthroplasty have been reported to be substantially worse than after primary arthroplasty.(3,141,145) This is largely due to poor quality of the remaining bone stock. Patients having revision surgery also tend to be older than those undergoing primary surgery. In addition, revision surgery takes longer and tends to involve more blood loss, in part because the older prosthesis must be removed before a new one can be implanted. Revision surgery is associated with increased rates of dislocation compared to primary hip replacement.(3,28,145)

## Difficulties in Interpreting Studies of THR

A guideline prepared by the U.K. National Institute for Clinical Excellence (NICE) in 2000 stated that evidence regarding THR is generally poor and difficult to interpret.(134) Few studies were of the best design, and few included long-term follow-up data. Other reviewers agree.(146)

NICE recommends follow-up times of at least 10 years for studies of THR.(134) This duration of followup would enable researchers to determine whether revision rates are lower than 10% at 10 years, which is NICE's benchmark for quality. Even when 10-year follow-up time is available, the prostheses used 10 years earlier may not be manufactured any longer, and incremental changes in design or technique over the intervening 10 years may affect the results of more recently performed procedures.(146) These factors limit interpretation of the results of even well-designed, long-term studies.

The design of the prosthesis is only one factor that may influence THR outcome. Patient characteristics, surgeon characteristics, surgical technique and quality of postsurgical care may also be important. While the effects of some of these factors have been investigated, the effect of interactions among and between factors is largely unknown.(134) Different studies are likely to have different patient inclusion criteria, different criteria defining success, and different criteria for determining whether revision surgery is necessary.(146) Charnley categories, patient age, sex, and activity level all influence the outcome of THR. Unless these factors are taken into account, the generalizability of the study cannot be determined, and the validity of comparing the results of one study to those of another is highly questionable.

## Ongoing or Planned Clinical Trials of THR

Table 8 presents a list of randomized controlled trials of THR that are currently being conducted, are being planned, or were recently completed. These trials were identified by searching Controlled Clinical Trials. The trials are organized according to the major clinical question being addressed.

**Table 8. Ongoing or Planned Randomized Controlled Trials of THR**

Name of Trial	Target Enrollment	Anticipated Start and Finish Dates	Outcomes and Other Study Information	Follow-up Period	Sponsor	Location
<b>Minimally Invasive Surgery</b>						
1. Minimally invasive surgery in total hip arthroplasty: the 2-incision technique versus conventional total hip arthroplasty.	110	11/2005 to 01/2009	Functional effectiveness measured by Harris Hip Score	12 months	Zimmer (USA)	Netherlands
2. Does a small incision at the time of total hip replacement confer an advantage to patients by comparison to a standard incision?	128	9/2003 to 12/2005	Blood loss, need for transfusion, length of hospital stay, pain measurement	6 months	Royal Devon & Exeter Healthcare NHS Trust	United Kingdom
3. Minimally invasive surgery of the hip versus standard approach	40	6/2003 to 12/2010	Length of hospital stay	Not reported	Zimmer	Canada
4. Randomized, prospective, post-market surveillance study comparing the outcomes of minimally invasive and conventional surgical procedures in subjects requiring primary total hip arthroplasty for osteoarthritis	Not reported	Not yet recruiting	Post-operative rehabilitation and mobilization	Not reported	DePuy International	Not reported
5. Single versus dual incision minimally invasive hip arthroplasty	Not reported	Not reported	Not reported	Not reported	Perth Orthopaedic Institute	Australia

Name of Trial	Target Enrollment	Anticipated Start and Finish Dates	Outcomes and Other Study Information	Follow-up Period	Sponsor	Location
<b>Hip Resurfacing or Hemiarthroplasty versus Total Hip Replacement</b>						
1. Comparison of hip resurfacing to large femoral head total hip arthroplasty	108	Recruiting	Quality of life between patients with Durom (Zimmer) hip resurfacing versus those with THR using a large-head, metal-on-metal articulation	24 months	University of British Columbia	Canada
2. A comparison of two total hip replacements: hip resurfacing system (ReCap from Biomet Merck) versus Mallory-Head/Exeter	50	1/2005 to 1/2014	Metal ion release in urine, inflammatory response in plasma correlated with metal ions in urine, bone mineral density	24 months	University of Aarhus, Denmark Biomet Merck Aps	Denmark
3. Prospective randomized study comparing the Furlong uncemented total hip replacement with the Birmingham resurfacing prosthesis.	100	9/2000 to 9/2005  Data collection ongoing	Harris hip score and prosthesis longevity	Not reported	Not reported	United Kingdom
4. A randomized prospective trial comparing unipolar hemiarthroplasty, bipolar hemiarthroplasty and total hip replacement in the treatment of displaced intracapsular femoral neck fractures.	Not reported	6/2003 to 6/2008	Mortality, pain at each follow-up, mobility and walking aids, complications	Not reported	East Sussex Hospitals NHS Trust	United Kingdom
5. Primary ceramic-on-ceramic total hip replacement versus metal-on-metal hip resurfacing in young active patients	400	Recruiting	Functional results and fastness of revalidation	Not reported	University Hospital Ghent	Belgium

Name of Trial	Target Enrollment	Anticipated Start and Finish Dates	Outcomes and Other Study Information	Follow-up Period	Sponsor	Location
<b>Method of Fixation: Cemented and Noncemented, Surface Material</b>						
1. Optimum socket fixation at total hip replacement	Not reported	11/1999 to 11/2004 Data collection ongoing	Cemented versus uncemented socket longevity determined by radiostereometry, implant loosening, implant migration, and excessive wear	Not reported	Royal Devon and Exeter NHS Trust R D & E Healthcare NHS Trust	United Kingdom
2. Is a pre-cemented cup an improvement on a cemented cup?	40	11/2003 to 11/2013	Migration and wear of acetabular component. Objective measures.	Not reported	Robert Jones and Agnes Hunt Orthopaedic Hospital NHS R&D Support Funding	United Kingdom
3. Safety of non-delayed weight bearing after total hip replacement with noncemented Zimmer fiber metal taper stem	33	5/2003 to 6/2007	Effect of immediate weight bearing on femoral stem subsidence on X-ray, return to work, walking without assistive device	24 months	Vanderbilt University Zimmer	United States
4. A comparison of two surface materials (Tantalum versus Titanium Fiber Mesh) of acetabular components in hip arthroplasty	50	9/2004 to 1/2009	Acetabular component migration evaluated by radiostereometry	24 months	University of Aarhus Zimmer	Denmark
5. A randomized prospective trial comparing modular and straight neck femoral components in fully hydroxyapatite coated (HAC) uncemented primary total hip replacement	Not reported	4/2002 to 4/2007	Better functional outcome and improved survival of the prosthesis	Not reported	East Sussex Hospitals NHS Trust	United Kingdom

Name of Trial	Target Enrollment	Anticipated Start and Finish Dates	Outcomes and Other Study Information	Follow-up Period	Sponsor	Location
<b>Bearing Surfaces</b>						
1. Ceramic-on-ceramic hip study (compared with metal-on-metal)	240	Recruiting	Success / Failure Harris Hip, Complications	Not reported	DePuy Orthopaedics	United States
2. Prospective clinical evaluation of three prosthesis: ReCap, M2a-Magnum, and C2a-Taper	Not reported	Not yet recruiting	ReCap is a femoral resurfacing system, M2a-Magnum is a large metal-on-metal articulation, and C2a-Taper is a ceramic-on-ceramic acetabular system (all made by Biomet).	Not reported	Frederiksberg University Hospital	Denmark
3. Improving the bearing surface in total hip replacement: the use of oxidized Zirconium and highly cross-linked polyethylene – a randomized controlled trial	200	9/2004 to 9/2009	THR using either cobalt chrome or oxinium femoral heads and either standard or highly cross-linked polyethylene liners. Radiographic wear, measuring linear and volumetric wear	Not reported	University College London Hospitals NHS Trust  Discretionary grant from Smith & Nephew to fund salary of MD student	United Kingdom
4. Metal-on-metal versus ceramic-on-metal hip replacement	384	Recruiting	Success / Failure Harris Hip, Complications	Not reported	DePuy Orthopaedics	United States
5. A multi-center, randomized, parallel group, controlled study to compare the performance of the Future Hip against three currently used implants in total hip replacement.	Not reported	Recruiting	Evaluate clinical and radiological performance	Not reported	DePuy Orthopaedics	Austria
6. A prospective, randomized, controlled, single center, blinded study of the wear characteristics of two polyethylene bearing surfaces, Enduron vs. Marathon	No longer recruiting	Not reported	Evaluate the linear and volumetric wear of the two polyethylene materials	Not reported	DePuy International	United States

Name of Trial	Target Enrollment	Anticipated Start and Finish Dates	Outcomes and Other Study Information	Follow-up Period	Sponsor	Location
<b>Revision Surgery</b>						
1. A randomized multi-center controlled trial of large diameter versus conventional diameter femoral heads for the prevention of post revision arthroplasty dislocation	400	Recruiting	Dislocation rate, polyethylene wear, functional and quality of life measures, radiographic findings, rate of re-revision	24 months	University of British Columbia	Canada
2. A randomized controlled trial comparing a titanium to a cobalt chrome femoral stem in revision hip arthroplasty: a pilot study	Not reported	10/2001 to 12/2010	Solution Stem (cobalt chrome, a DePuy product) without a hydroxyapatite coating versus the Restoration hip stem (a Stryker product) made of titanium alloy with a roughened surface and allows for a hydroxyapatite coating. Bone mineral density, rates of osteolysis/radiolucent lines on radiographs, Harris Hip Score, rate of revision.	Not reported	Ottawa Health Research Institute Stryker	Canada



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## **Appendix A. Inventory of Prosthetic Hips Currently Available**

The appendix contains a listing of commercially available prosthetic hips, their features and characteristics, and their current regulatory (US FDA and CE Mark) status. These data, which were acquired through a survey of manufacturers conducted by ECRI,(147) are current as of April, 2005 unless otherwise noted. While this list is as complete as we are able to make it, the data in the charts derive from suppliers' specifications and have not been verified through independent testing by ECRI or any other agency. Because test methods vary, different products' specifications are not always comparable. Moreover, products and specifications are subject to frequent changes. ECRI is not responsible for the quality or validity of the information presented or for any adverse consequences of acting on such information.



SUPPLIER	AESCULAP	AESCULAP	AESCULAP	BAUMER ORTOPEdia
MODEL	BICONACT Universal Hip System	Centrament Hip System	Excia Hip Stem	Alpha Modular System
WHERE MARKETED	Worldwide, except Canada and USA	Worldwide, except Canada and USA	Worldwide, except Canada and USA	Worldwide
FDA CLEARANCE	No	No	No	Submitted
CE MARK (MDD)	Yes	Yes	Yes	Submitted
CEMENTED/CEMENTLESS SYSTEM	Both	Cemented	Both	Cemented
CEMENTLESS SYSTEM TYPES	Plasma sprayed (PLASMAPORE coating)	N/A	Plasma-sprayed (PLASMAPORE u-CaP)	NA
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Ti6Al4V (coated), cobalt chromium alloy (uncoated)	ISONIC FeCrNiMoN alloy	Ti6Al4V (coated), CoCr29Mo (uncoated)	ASTM F-138, CrCoMo, ASTM F-75
Coated, uncoated	Both	Uncoated	Both	Uncoated
Coating material	Pure titanium; partial coating	NA	Pure titanium, partial u-CaP coating	Polished
Number of stem length sizes	11 Standard, S-Series, 8 SDSeries, 10 N-Series	6	11	0.5, 0, 1, 2, 3,
Stem length, mm	130-180	130-220	122-172	120-150
Neck angle,	135	135	135	125
Neck length/neck offsets, mm	40.1 Standard, SDSeries, 40-50 S-Series, 30-35 N-Series	40	37-49	35-37
FEMORAL HEAD	ISODUR cobalt chromium alloy, Biolox (Al2O3)	ISODUR cobalt chromium alloy, Biolox (Al2O3)	ISODUR cobalt chromium alloy, Biolox (Al2O3)	ASTM F-138, CrCoMo
Number of sizes	5 cobalt chromium (S, M, L, XL, XXL), 3 ceramic (S, M, L)	5 cobalt chromium (S, M, L, XL, XXL), 3 Biolox (S, M, L)	5 cobalt chromium (S, M, L, XL, XXL), 3 Biolox (S, M, L)	22, 25 (M, L neck) 26, 28, 32 (S, M, L, XL neck)
Diameters, mm	22.2, 26, 28, 32	22.2, 28, 32	22.2, 28, 32	22, 25, 26, 28, 32
ACETABULAR SHELL	Titanium (PLASMACUP cup system)	UHMWPE	Titanium (PLASMACUP cup system)	UHMWPE
Coating material	PLASMAPORE pure titanium	NA	PLASMAPORE pure titanium	NA
Number of sizes	15 SC-Series	9	15 SC-Series	10
Range of sizes, mm	40-68	42-58	40-68	40-58
Fixation	3 screw holes	Cemented	3 screw holes	Cemented
ACETABULAR INSERT	UHMWPE, Biolox ceramic	NA	UHMWPE, Biolox ceramic	Not specified
Number of sizes	NA	NA	NA	Not specified

SUPPLIER	BAUMER ORTOPEDIA	BAUMER ORTOPEDIA	BAUMER ORTOPEDIA	BAUMER ORTOPEDIA
MODEL	Charnley Total Hip System	Interlock Muller Total Hip System	Logical Modular Hip System	New Moore Total Hip System
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Submitted	Submitted	Submitted	Submitted
CE MARK (MDD)	Submitted	Submitted	Submitted	Submitted
CEMENTED/CEMENTLESS SYSTEM	Cemented	Cemented	Both	Cemented
CEMENTLESS SYSTEM TYPES	NA	NA	Press-fit, porous coating, plasmasprayed, hydroxyapatite	NA
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Titanium 6Al4VELI, ASTM F-138, CrCoMo	Titanium 6Al4VELI, CrCoMo, ASTM F-138	Titanium 6Al4VELI, CrCoMo, ASTM F-75	Titanium 6Al4VELI, ASTM F-138, ASTM F-75
Coated, uncoated	Uncoated	Uncoated	Both	Uncoated
Coating material	NA	NA	Hydroxyapatite, titanium, CrCoMo	NA
Number of stem length sizes	11; 5-15 mm diameter	7; 5-20 mm diameter	8-17 mm diameter	2
Stem length, mm	136-140	137-162	142-182	165-203; 10 mm diameter
Neck angle	130	135	138	132
Neck length/neck offsets, mm	25-32	30-42	30-42	30-42
FEMORAL HEAD	ASTM F-138, CrCoMo, ASTM F-75	ASTM F-138, CrCoMo, ASTM F-75	ASTM F-138, CrCoMo, ASTM F-75	ASTM F-138, CrCoMo, ASTM F-75
Number of sizes	22, 25 (M, L neck); 26, 28, 32 (S, M, L, XL neck)	22, 25 (M, L neck); 26, 28, 32 (S, M, L, XL neck)	22, 25 (M, L neck); 26, 28, 32 (S, M, L, XL neck)	22, 25 (M, L neck); 28, 32 (S, M, L, XL neck)
Diameters, mm	22, 25, 26, 28, 32	22, 25, 26, 28, 32	22, 25, 26, 28, 32	22, 25, 28, 32
ACETABULAR SHELL	UHMWPE	UHMWPE	Titanium alloy/ CrCoMo, ASTM F-75, ASTM F-67	Bipolar systems: titanium 6Al4VELI, ASTM F-138
Coating material	NA	NA	Titanium, Cr Co Mo	NA
Number of sizes	4	4	15	10
Range of sizes, mm	40-54	40-54	40-68	40-58
Fixation	Cemented	Cemented	Screw, press-fit	Partial cup
ACETABULAR INSERT	UHMWPE	UHMWPE	UHMWPE	UHMWPE
Number of sizes	Not specified	Not specified	5	3

SUPPLIER	BIOMET	BIOMET	BIOMET	BIOMET
MODEL	Bi-Metric	Healey Flanged Revision Acetabular	Integral	Mallory-Head
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	Yes	Yes	Yes	Yes
CEMENTED/CEMENTLESS SYSTEM	Both	Cementless	Both	Both
CEMENTLESS SYSTEM TYPES	Plasma-sprayed porous coating	Plasma-sprayed porous coating	Plasma-sprayed porous coating	Plasma-sprayed porous coating
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Titanium alloy	NA	Titanium alloy (porous), cobalt chromium (nonporous)	Titanium alloy (porous), cobalt chromium (nonporous)
Coated, uncoated	Both	NA	Both	Both
Coating material	Titanium plasmasprayed, proximal 1/3	NA	Titanium plasmasprayed, proximal 1/3	Titanium plasmasprayed, proximal 1/3
Number of stem length sizes	11 press-fit, 6 nonporous	NA	13 press-fit, 5 nonporous	14 press-fit, 6 nonporous, 5 smooth
Stem length, mm	115-185 press-fit, 115-165 uncoated	NA	115-175 coated, 125-165 uncoated	135-180 press-fit, 135-180 uncoated, 140-180 smooth
Neck angle,	135 collarless, 140 collared	NA	140	135 standard, 50 lateral
Neck length/neck offsets, mm	28-46/35-50	NA	28-46/35-50	28-46/34-53 (coated), 34-51 (uncoated)
FEMORAL HEAD	Cobalt chromium metal, zirconia ceramic	NA	Cobalt chromium metal, zirconia ceramic	Cobalt chromium metal, zirconia ceramic
Number of sizes	7 metal, 5 ceramic	NA	7 metal, 5 ceramic	7 metal, 5 ceramic
Diameters, mm	22, 26, 28, 32	NA	22, 26, 28, 32	22, 26, 28, 32
ACETABULAR SHELL	NA	Titanium alloy	NA	NA
Coating material	NA	Titanium alloy plasma spray	NA	NA
Number of sizes	NA	12	NA	NA
Range of sizes, mm	NA	48-70, 2 mm increments	NA	NA
Fixation	NA	Porous-coated flange with screw holes; dome screws	NA	NA
ACETABULAR INSERT	NA	ArCom polyethylene (compression molded)	NA	NA
Number of sizes	NA	8 liner sizes (22, 26, 28, 32 mm ID), 5 liner configurations	NA	NA

SUPPLIER	BIOMET	BIOMET	BIOMET	BIOMET
MODEL	Mallory-Head RingLoc Acetabular Series	MARS	Par-5	Ranawat/Burstein
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	Yes	Yes	Yes	Yes
CEMENTED/CEMENTLESS SYSTEM	Cementless	Cementless	Both	Both
CEMENTLESS SYSTEM TYPES	Plasma-sprayed porous coating	Plasma-sprayed porous coating	Plasma-sprayed porous coating	Plasma-sprayed porous coating
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	NA	NA	Titanium alloy	NA
Coated, uncoated	NA	NA	NA	NA
Coating material	NA	NA	NA	NA
Number of stem length sizes	NA	NA	NA	NA
Stem length, mm	NA	NA	NA	NA
Neck angle	NA	NA	NA	NA
Neck length/neck offsets, mm	NA	NA	NA	NA
FEMORAL HEAD	NA	NA	NA	NA
Number of sizes	NA	NA	NA	NA
Diameters, mm	NA	NA	NA	NA
ACETABULAR SHELL	Titanium alloy	Titanium	NA	Titanium alloy
Coating material	Titanium-alloy plasma spray	Titanium-alloy plasma spray	Titanium-alloy porous plasma spray	Titanium-alloy plasma spray
Number of sizes	21	9	5	21
Range of sizes, mm	40-80, 2 mm increments	52-72, 2 mm increments	56-72 mm, 4 mm increments	40-80, 2 mm increments
Fixation	Peripheral fins, rim and dome screws	Full and half metallographs with screw holes, rim, and dome screws	Dome screws	Porous
ACETABULAR INSERT	ArCom polyethylene (compression molded)	ArCom polyethylene (compression molded)	ArCom polyethylene (compression molded)	ArCom polyethylene (compression molded)
Number of sizes	8 liner sizes (22, 26, 28, 32 mm ID), 5 liner configurations	8 liner sizes (22, 26, 28, 32 mm ID), 5 liner configurations	5 liner sizes (28 mm ID), 5 liner configurations	8 liner sizes (22, 26, 28, 32 mm ID), 5 liner configurations

SUPPLIER	BIOMET	BIOMET	BIOMET	BIOMET
MODEL	Rx90	Stanmore	Taperloc	Universal RingLoc Acetabular Series
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	Yes	Yes	Yes	Yes
CEMENTED/CEMENTLESS SYSTEM	Cemented stem	Cemented	Cementless	Cementless
CEMENTLESS SYSTEM TYPES	Plasma-sprayed porous coating	NA	Lateralized stem plasma-sprayed option, porous coated	Plasma-sprayed porous coating
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Forged cobalt chromium	Forged cobalt chromium	Titanium alloy	NA
Coated, uncoated	Uncoated	Uncoated	Coated	NA
Coating material	Smooth	NA	Titanium plasmasprayed, proximal 1/3	NA
Number of stem length sizes	5	5 straight, 5 lateralized	7 press-fit	NA
Stem length, mm	115-155	123-157	135-170 coated	NA
Neck angle	140 standard and lateral	130 standard and straight	135	NA
Neck length/neck offsets, mm	NA	28-46/29-49 straight, 28-46/38-60 lateral	28-46/30-52; 38-60 lateralized	NA
FEMORAL HEAD	Cobalt chromium metal, zirconia ceramic	Cobalt chromium metal, zirconia ceramic	Cobalt chromium metal, zirconia ceramic	NA
Number of sizes	7 metal, 5 ceramic	7 metal, 5 ceramic	7 metal, 5 ceramic	NA
Diameters, mm	22, 26, 28, 32	22, 26, 28, 32	22, 26, 28, 32	NA
ACETABULAR SHELL	Titanium	NA	NA	Titanium
Coating material	Titanium-alloy plasma spray	NA	NA	Titanium-alloy plasma spray
Number of sizes	16	NA	NA	21
Range of sizes, mm	40-70, 2 mm increments	NA	NA	40-80, 2 mm increments
Fixation	Dome screws	NA	NA	Peripheral rim flare, rim and dome screws
ACETABULAR INSERT	ArCom polyethylene (compression molded)	NA	NA	ArCom polyethylene (compression molded)
Number of sizes	8 liner sizes (22, 26, 28, 32 mm ID), 5 liner configurations	NA	NA	8 liner sizes (22, 26, 28, 32 mm ID), 5 liner configurations

SUPPLIER	BIOPRO	CENTERPULSE	CENTERPULSE	CENTERPULSE
MODEL	PSL Total Hip System	Alloclassic Hip System	Allofit	Apollo Hip System
WHERE MARKETED	Worldwide	Worldwide	Worldwide	USA
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	No	No	No	No
CEMENTED/CEMENTLESS SYSTEM	Both	Cementless	Cementless	Both
CEMENTLESS SYSTEM TYPES	Press-fit, porous coated	Grit-blasted titanium alloy	Available with or without sealable screw holes	Grit-blasted finish/ matte
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Cobalt chromium	Not specified	NA	Cobalt chromium alloy
Coated, uncoated	Both	Uncoated	NA	Uncoated
Coating material	Cobalt chromium, proximal portion	NA	NA	NA
Number of stem length sizes	10 press-fit short, 10 press-fit long, 4 cemented	14	NA	6
Stem length, mm	136-202 coated, 136-202 uncoated	110-168	NA	140-165, 5 mm increments
Neck angle	135	131 standard; 121 offset stem	NA	130
Neck length/neck offsets, mm	Not specified	24-37/33-50	NA	36/42
FEMORAL HEAD	Cobalt chromium, zirconia	Cobalt chromium, zirconia, metasul	Cobalt chromium, zirconia, metasul	Cobalt chromium, zirconia, metasul
Number of sizes	10 metal, 5 ceramic	25 cobalt chromium, 6 zirconia, 4 metasul	25 cobalt chromium, 6 zirconia, 4 metasul	25 cobalt chromium, 6 zirconia, 4 metasul
Diameters, mm	28, 32	22, 26, 28, 32, 38, 44 CoCr heads; zirconia/metasal option	22, 26, 28, 32, 38, 44 CoCr heads; zirconia/metasal option	22, 26, 28, 32, 38, 44 CoCr heads; zirconia/metasal option
ACETABULAR SHELL	Titanium alloy	NA	Titanium	UHMWPE
Coating material	Titanium	NA	Grit-blisted titanium surface	NA
Number of sizes	16 porous coated	NA	12	9
Range of sizes, mm	44-81	NA	46-68 in 2 mm increments	42-62, 6 mm increments
Fixation	4 screw holes, fins	NA	Press-fit	7 cement spacers
ACETABULAR INSERT	UHMWPE	NA	UHMWPE, Durasul, Metasal	NA
Number of sizes	23 metal backed, 12 all poly	NA	Available in 12 sizes, standard and hooded	NA

SUPPLIER	CENTERPULSE	CENTERPULSE	CENTERPULSE	CENTERPULSE
MODEL	APR Hip System	CLS System	Converge Acetabular System	FracSure Hip System
WHERE MARKETED	Worldwide	Worldwide	Worldwide	USA
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	No	No	Yes	Yes
CEMENTED/CEMENTLESS SYSTEM	Both	Cementless	Cementless	Not specified
CEMENTLESS SYSTEM TYPES	Proximally porous coated, HA over porous coating, fully textured	Available in 2 offsets	Cancellous structured titanium (CSTi)	Fenestrated CoCr
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Titanium alloy (porous), cobalt chromium alloy (nonporous)	Titanium alloy with grit-blasted surface	NA	HIP'ed cast CoCr
Coated, uncoated	Both	Uncoated	NA	NA
Coating material	Cancellousstructured titanium (CSTi)	NA	NA	NA
Number of stem length sizes	6 porous, 5 nonporous	13	NA	4 solid and 6 fenestrated
Stem length, mm	135-160, 5 mm increments	135.6-189.6	NA	Solid 130-175, fenestrated 130-190 in 15 mm increments
Neck angle,	130	135 and 145	NA	135
Neck length/neck offsets, mm	35-40/42-47	Neck axis ranges from 49.7-83.5	NA	34/35-43
FEMORAL HEAD	Cobalt chromium, zirconia, metasal	Cobalt chromium, zirconia, metasal	Cobalt chromium, zirconia, metasal	Cobalt chromium, zirconia, metasal
Number of sizes	25 cobalt chromium, 6 zirconia, 4 metasal	25 cobalt chromium, 6 zirconia, 4 metasal	25 cobalt chromium, 6 zirconia, 4 metasal	25 cobalt chromium, 6 zirconia, 4 metasal
Diameters, mm	22, 26, 28, 32, 38, 44 CoCr heads; zirconia/metasal option	22, 26, 28, 32, 38, 44 CoCr heads; zirconia/metasal option	22, 26, 28, 32, 38, 44 CoCr heads; zirconia/metasal option	22, 26, 28, 32, 38, 44 CoCr heads; zirconia/metasal option
ACETABULAR SHELL	NA	NA	Titanium	NA
Coating material	NA	NA	Cancellousstructured titanium (CSTi)	NA
Number of size	14	NA	17 primary, 20 revision	NA
Range of sizes, mm	41-67, 2 mm increments	NA	39-71 mm or 43-81 mm in 2 mm increments	NA
Fixation	Cancellous structured titanium (CSTi)	NA	Press-fit with screw and rim flare options	NA
ACETABULAR INSERT	Standard, durasul, and metasal inserts	NA	UHMWPE, Durasul, metasal	NA
Number of sizes	NA	NA	Inner diameters of 22, 26, 28, 32, 38, 44; outer dia 39-81	NA

SUPPLIER	CENTERPULSE	CENTERPULSE	CENTERPULSE	CENTERPULSE
MODEL	MS-30 Hip	Natural-Hip System	Precedent Revision Hip System	SL Revision System
WHERE MARKETED	Worldwide	Worldwide	USA	Worldwide
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	No	Yes	Yes	No
CEMENTED/CEMENTLESS SYSTEM	Cemented	Both	Cementless	Cementless
CEMENTLESS SYSTEM TYPES	NA	Proximally porous coated, HA over porous coating, fully textured	With or without hydroxyapatite	Distally fluted
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Highly polished protasul-S30	Titanium alloy (porous), cobalt chromium alloy (nonporous)	Titanium alloy, nonporous, HA over grit-blasted titanium	Titanium, grit blasted
Coated, uncoated	Uncoated	Both	Both	Uncoated
Coating material	NA	Cancellous structured titanium (CSTi)	Hydroxyapatite (1/3 coating)	NA
Number of stem length sizes	6	9 porous, 9 nonporous	41 (10-175 mm, 13200 mm, 18-250 mm) in lefts/rights	12
Stem length, mm	102-141	115-195 porous, 105-180 nonporous	175, 200, 250	Implant length 190, 225, 265, 305, 345, 385
Neck angle	130-135 (each size increase 1°)	130	135	145
Neck length/neck offsets, mm	32-37/38-43	33-41/36-43 (additional offset available)	45, 49, 53/40, 43, 46	Neck axis 56-58.5, offset 32.1-36.2
FEMORAL HEAD	Cobalt chromium, zirconia, metasul, stainless steel	Cobalt chromium, zirconia, metasul	Cobalt chromium, zirconia, metasul	Cobalt chromium, zirconia, metasul
Number of sizes	25 cobalt chromium, 6 zirconia, 4 metasul	25 cobalt chromium, 6 zirconia, 4 metasul	25 cobalt chromium, 6 zirconia, 4 metasul	25 cobalt chromium, 6 zirconia, 4 metasul
Diameters, mm	22, 26, 28, 32, 38, 44 CoCr heads; zirconia/metasil option	22, 26, 28, 32, 38, 44 CoCr heads; zirconia/metasil option	22, 26, 28, 32, 38, 44 CoCr heads; zirconia/metasil option	22, 26, 28, 32, 38, 44 CoCr heads; zirconia/metasil option
ACETABULAR SHELL	NA	NA	NA	NA
Coating materia	NA	NA	NA	NA
Number of sizes	NA	NA	NA	NA
Range of sizes, mm	NA	NA	NA	NA
Fixation	NA	NA	NA	NA
ACETABULAR INSERT	NA	NA	NA	NA
Number of sizes	NA	NA	NA	NA



SUPPLIER	CERAVER	CERAVER	CORIN MEDICAL	CORIN MEDICAL
MODEL	Cerafit Uncemented Hip Prosthesis	Osteal Cemented Hip Prosthesis	Cenator Total Hip System	C-Fit Total Hip System
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	No	No	Yes	Yes (Cemented Only)
CE MARK (MDD)	Yes	Yes	Yes	Yes
CEMENTED/CEMENTLESS SYSTEM	Cementless	Cemented	Cemented	Both
CEMENTLESS SYSTEM TYPES	Not specified	Not specified	NA	Press-fit, porous coated, hydroxyapatite coated
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Titanium	Titanium	Cobalt chromium alloy	Cobalt chromium alloy
Coated, uncoated	Both	Uncoated	Uncoated	Both
Coating material	Hydroxyapatite total	Not specified	NA	Porous, nonporous
Number of stem length sizes	12	12	6	10 press-fit, 10 porous, 10 HA
Stem length, mm	124-165	127-190	126.6-128.9 monoblock, 126.6-128.9 modular head	138.5-166.5 coated and uncoated
Neck angle	132	132	50	42
Neck length/neck offsets, mm	38-51	29-45	28/35-40 monoblock, 24/35-40 modular head	23
FEMORAL HEAD	Steel-alumina	Steel-alumina	Cobalt chromium, zirconia ceramic	Cobalt chromium alloy, zirconia ceramic
Number of sizes	13 metal, 6 ceramic	13 metal, 6 ceramic	3 neck lengths for each diameter in CoCr and zirconia ceramic	3 neck lengths for each diameter in CoCr and zirconia ceramic
Diameters, mm	22.2, 28, 32 metal; 28-32 ceramic	22.2, 28, 32 metal; 28-32 ceramic	22, 26, 28, 32 CoCr; 28, 32 zirconia ceramic	22, 26, 28, 32 CoCr; 28, 32 zirconia ceramic
ACETABULAR SHELL	Titanium coated and not	UHMWPE	UHMWPE	Cobalt chromium metal back component with UHMWPE liners
Coating material	Hydroxyapatite	Not specified	NA	Porous, HA
Number of sizes	Not specified	Not specified	4 sizes in 4 options	0 porous, 10 HA
Range of sizes, mm	Not specified	22.2, 28, 32	40-52	42-60
Fixation	Not specified	Not specified	Cement	4 cement spacers on cemented cup; screw holes; patented central hammer-in peg
ACETABULAR INSERT	Polyethylenealumina	Not specified	NA	UHMWPE
Number of sizes	Not specified	Not specified	NA	Neutral and 10° liners with 22, 26, 28, 32 mm diameters

SUPPLIER	CORIN MEDICAL	CORIN MEDICAL	DEPUY	DEPUY
MODEL	Cormet Hip Resurfacing System	Trifit Total Hip System	AML Total Hip System	Endurance Total Hip System
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	No	Yes	Yes	Yes
CE MARK (MDD)	Yes	Yes	Not specified	Not specified
CEMENTED/CEMENTLESS SYSTEM	Cemented Femur, Un-cemented Cup	Cementless	Cementless	Cemented
CEMENTLESS SYSTEM TYPES	Cup is dual coated with plasma-sprayed metal and hydroxyapatite	Porous & dual coated, plasma-sprayed titanium metal and hydroxyapatite	Press-fit, extensively porous coated	NA
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Cobalt chromium alloy, nonporous; femoral resurfacing head	Titanium alloy	Cobalt chromium	Forged cobalt chromium
Coated, uncoated	Uncoated	Coated	Coated	Uncoated
Coating material	NA	Plasma-sprayed titanium metal and hydroxyapatite	Cobalt chromium beads, porocoat	NA
Number of stem length sizes	1; 5 head diameters in press-HA	6	1	5 standard, 5 high offset
Stem length, mm	NA	NA	165; 10.5-19.5 diameters (increments of 1.5)	105, 112.5, 120, 127.5, 135
Neck angle	NA	132	135	135
Neck length/neck offsets, mm	NA	NA	30, 35, 37, 40-52	28-54/33-60, both incremental
FEMORAL HEAD	Cobalt chromium	Cobalt chromium, zirconia ceramic	Cobalt chromium, Bilox delta ceramic	Cobalt chromium, Bilox delta ceramic
Number of sizes	5	3 neck lengths for each diameter in CoCr and zirconia ceramic	20 cobalt chromium, 10 Bilox delta ceramic	20 cobalt chromium, 10 Biolo delta ceramic
Diameters, mm	40, 44, 48, 52, 56	22, 26, 28, 32 CoCr; and 28, 32 zirconia ceramic	22.225, 28, 32, 36 cobalt chromium; 28, 32, 36 ceramic	22.225, 28, 32 cobalt chromium; 28, 32, 36 ceramic
ACETABULAR SHELL	Cobalt chromium alloy	Not specified	Titanium alloy (Pinnacle acetabular cup system)	Titanium alloy (Duraloc Cup System)
Coating material	Bi-coating, titanium or HA plasma-sprayed	Not specified	Sintered titanium beads and DuoFix HA coating	Sintered titanium beads
Number of sizes	9 press-fit, 9 HA	Not specified	See footnote <sup>1</sup>	See footnote <sup>1</sup>
Range of sizes, mm	46-62, 2 mm increments	Not specified	See footnote <sup>2</sup>	See footnote <sup>2</sup>
Fixation	Cementless, HA and superomedial peg and antirotation spines	Not specified	See footnote <sup>3</sup>	See footnote <sup>3</sup>
ACETABULAR INSERT	Metal on metal articulation	Not specified	Enduron	Enduron
Number of sizes	NA	Not specified	22.2, 26, 28, 32 mm ID; 48-66 mm OD	22.2, 26, 28, 32 mm ID; 48-66 mm OD

<sup>1</sup> 10 for Bantam series, 10 for Sector, multi-hole and series 100 and 300

<sup>2</sup> 37-46 mm for Bantam series, 48-66 mm for Sector, multi-hole and series 100 and 300.

<sup>3</sup> 100 Series, no holes; Sector, 3 holes; 300Series, 3 spikes; multi-hole, 12 holes

SUPPLIER	DEPUY	DEPUY	DEPUY	DEPUY
MODEL	Prodigy Total Hip System	Replica Total Hip System	Solution System Total Hip System	S-Rom Hip System
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	Not specified	Not specified	Not specified	Yes
CEMENTED/CEMENTLESS SYSTEM	Cementless	Cementless	Cementless	Cementless
CEMENTLESS SYSTEM TYPES	Press-fit, extensively porous coated	Press-fit, combination fixation	Press-fit, extensively porous coated	Proximal porous coating, HA
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Cobalt chromium	Cobalt chromium	Cobalt chromium	Titanium alloy
Coated, uncoated	Coated	Coated, digital splines, coronal slot	Coated	Coated
Coating material	Cobalt chromium beads	Cobalt chromium beads	Cobalt chromium	Titanium or HA
Number of stem length sizes	3	3	5	17
Stem length, mm	155, 160, 165; 10.5-19.5 mm diameters (increments of 1.5)	155, 160, 165; 10.5-18 mm diameters (increments of 1.5)	160, 178, 203, 229, 254; 10.5-22.5 mm diameters (increments of 1.5)	115, 130, 150, 160, 165, 175, 205, 215, 225, 230, 240, 255, 275, 300, 315, 325
Neck angle	125, 135	125, 135	135	135
Neck length/neck offsets, mm	27, 28, 30, 32, 36/ 40, 43, 45, 52	27, 28, 30, 32, 36/ 40, 43, 45, 52	30, 35, 36, 40-45	30, 30+4L, 36, 36+6L, 42, 36+8L, 36+12L, 36+21
FEMORAL HEAD	Cobalt chromium, Biolox delta ceramic	Cobalt chromium, Biolox delta ceramic	Cobalt chromium, Biolox delta ceramic	Cobalt chromium, Biolox delta ceramic
Number of sizes	20 cobalt chromium, 10 Biolox delta ceramic	20 cobalt chromium, 10 Biolox delta ceramic	20 cobalt chromium, 10 Biolox delta ceramic	20 cobalt chromium, 9 Biolox delta ceramic
Diameters, mm	22.225, 28, 32 cobalt chromium; 28, 32, 36 ceramic	22.225, 28, 32 cobalt chromium; 28, 32, 36 ceramic	22.225, 28, 32 cobalt chromium; 28, 32, 36 ceramic	22.225, 28, 32, 36 cobalt chromium; 28, 32, 36 ceramic
ACETABULAR SHELL	Titanium alloy (Duraloc Cup System)	Titanium alloy (Duraloc Cup System)	Titanium alloy (Duraloc Cup System)	Titanium alloy (Duraloc Cup System)
Coating material	Sintered titanium beads	Sintered titanium beads	Sintered titanium beads	Sintered titanium beads
Number of sizes	See footnote <sup>1</sup>	See footnote <sup>1</sup>	See footnote <sup>1</sup>	See footnote <sup>1</sup>
Range of sizes, mm	See footnote <sup>2</sup>	See footnote <sup>2</sup>	See footnote <sup>2</sup>	See footnote <sup>2</sup>
Fixation	See footnote <sup>3</sup>	See footnote <sup>3</sup>	See footnote <sup>3</sup>	See footnote <sup>3</sup>
ACETABULAR INSERT	Enduron	Enduron	Enduron	Enduron
Number of sizes	22.2, 26, 28, 32 mm ID; 48-66 mm OD	22.2, 26, 28, 32 mm ID; 48-66 mm OD	22.2, 26, 28, 32 mm ID; 56-80 mm OD	22.2, 26, 28, 32 mm ID; 48-74 mm OD

<sup>1</sup> 10 for Bantam series, 10 for Sector, multi-hole and series 100 and 300.

<sup>2</sup> 37-46 mm for Bantam series, 48-66 mm for Sector, multi-hole and series 100 and 300

<sup>3</sup> 100 Series, no holes; Sector, 3 holes; 300Series, 3 spikes; multi-hole, 12 holes.

SUPPLIER	ENCORE ORTHOPEDICS FAILED TO RESPOND <sup>1</sup>	ENCORE ORTHOPEDICS FAILED TO RESPOND <sup>1</sup>	ENCORE ORTHOPEDICS FAILED TO RESPOND <sup>1</sup>	ENCORE ORTHOPEDICS FAILED TO RESPOND <sup>1</sup>
MODEL	FOUNDATION HIP	Linear HIP	Revelation HIP	Vitality HIP
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	Yes	Yes	Yes	Yes
CEMENTED/CEMENTLESS SYSTEM	Both	Cementless	Cementless	Cemented
CEMENTLESS SYSTEM TYPES	Grit blasted, 3DMatrix coating	3DMatrix coating	Grit blasted, 3DMatrix	Grit blasted
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Cobalt chromium alloy (cemented), porous Ti6Al4V (cementless)	Porous Ti6Al4V	Porous Ti6Al4V surface roughness	Cobalt chromium alloy
Coated, uncoated	Coated	Coated	Coated	Uncoated
Coating material	3DMatrix nonspherical porous beads	3DMatrix nonspherical porous beads	3DMatrix nonspherical porous beads	NA
Number of stem length sizes	8 cemented hi-demand & 6 cemented lowdemand, 6 cementless collared & 6 cementless collarless	11 porous collarless standard offset, 11 porous collarless enhanced offset	8 cementless collarless rights, 8 cementless collarless lefts	6 collarless
Stem length, mm	125-165	110-140	100-136	138-158
Neck angle	132	135	130	130-132
Neck length/neck offsets, mm	61-68/40-45; 12/14 taper type	60-67/38-52; 12/14 taper type	49-64/35-49; 12/14 taper type	28-33/42-44
FEMORAL HEAD	Cobalt chromium, ceramic	Cobalt chromium, ceramic	Cobalt chromium, ceramic	Cobalt chromium, ceramic
Number of sizes	12 metal, 6 ceramic	2 metal, 6 ceramic	12 metal, 6 ceramic	12 metal, 6 ceramic
Diameters, mm	22, 28, 32; 12/14 taper type	22, 28, 32; 12/14 taper type	22, 28, 32; 12/14 taper type	22, 28, 32; 12/14 taper type
ACETABULAR SHELL	Ti6Al4V	Ti6Al4V	Ti6Al4V	Ti6Al4V
Coating material	3DMatrix nonspherical porous beads	3DMatrix nonspherical porous beads	3DMatrix nonspherical porous beads	3DMatrix nonspherical porous beads
Number of sizes	16 porous, textured; 12 all poly	16 porous, 12 all poly	16 porous, 12 all poly	16 porous, 12 all poly
Range of sizes, mm	90-70	40-70	40-70	40-70
Fixation	Screw holes, spikes, cemented cups, no holes	Screw holes, spikes, cemented cups, no holes	Screw holes, spikes, cemented cups, no holes	Screw holes, spikes, cemented cups, no holes
ACETABULAR INSERT	UHMWPE	UHMWPE	UHMWPE	UHMWPE
Number of sizes	22; 0/10/20°	22; 0/10/20°	22; 0/10/20°	22; 0/10/20°

<sup>1</sup> Specifications current as of August 2003

SUPPLIER	ESOP FAILED TO RESPOND <sup>1</sup>	EXACTECH	EXACTECH	EXACTECH
MODEL	Total Hip System	AcuMatch P-Series/ C-Series	L-Series Fracture Stem	M-Series
WHERE MARKETED	Europe, USA	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	Yes	Yes	Yes	Yes
CEMENTED/CEMENTLESS SYSTEM	Cementless	Both	Both	Cementless
CEMENTLESS SYSTEM TYPES	Anatomic design, press fit, plasma-sprayed with HAP	Plasma-sprayed, porous beads	Press-fit	Press-fit, plasma spray modular
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Modular
FEMORAL STEM	TiAl6V4	Titanium alloy/ forged CoCr	Titanium alloy/cast CoCr	3 part (neck segment /metaphyseal body/ distal stem) modular stem, titanium
Coated, uncoated	HA coated	Both	Not specified	Coated (metaphyseal segment)
Coating material	1/3 coated	Titanium plasma-sprayed, proximal 1/3	Not specified	Plasma spray (metaphyseal segments)
Number of stem length sizes	Left or right = 10 sizes x 2	8 press-fit; 5 cemented	7 press-fit; 5 cemented	6 distal stem diameters (11-21 mm), 21 metaphyseal segment, 8 neck segment options
Stem length, mm	Not specified	130-160 press-fit; 125-145 cemented	130-160 press-fit; 125-145 cemented	135, 165, 200, 250, 300 distal stem; implant construct lengths 120-300
Neck angle,	135	131	131	131
Neck length/neck offsets, mm	Offset 32-52	30-55; 32-59 extended offset	30-55	43-64.6/32-49
FEMORAL HEAD	Cobalt chromium, stainless steel, aluminum	CoCr, zirconia, alumina	CoCr, zirconia, alumina	CoCr, zirconia, alumina
Number of sizes	22, 28, 28, 32; 6 metals, 3 aluminum	7 CoCr, 5 zirconia, 5 alumina	7 CoCr, 5 zirconia, 5 alumina	7 CoCr, 5 zirconia, 5 alumina
Diameters, mm	22, 28, 28, 32	22, 28, 32, 36 CoCr; 28, 32 zirconia and alumina	22, 28, 32, 36 CoCr; 28, 32 zirconia and alumina	22, 28, 32, 36 CoCr; 28, 32 zirconia and alumina
ACETABULAR SHELL	Titanium alloy TA6V	Titanium	Titanium	Titanium
Coating material	HA plasma-sprayed	Titanium porous sintered beads	Titanium porous sintered beads	Titanium porous sintered beads
Number of sizes	18	16	16	16
Range of sizes, mm	40-72	40-70, 2 mm increments	40-70, 2 mm increments	40-70, 2 mm increments
Fixation	6 screw; 3 press-fit	No-hole, cluster hole (3), multi- hole (dome and peripheral)	No-hole, cluster hole (3), multi-hole (dome and peripheral)	No-hole, cluster hole (3), multi-hole (dome and peripheral)
ACETABULAR INSERT	UHMWPE and aluminum	Compression molded UHMWPE	Compression molded UHMWPE	Compression molded UHMWPE
Number of sizes	12 sizes 50-72; 14 sizes 46-72; 18 sizes 40-72	7	7	7

<sup>1</sup> Specifications current as of August 2003.

SUPPLIER	EXACTECH	JOINT REPLACEMENT INSTRUMENTATION	KINAMED	MATHYS FAILED TO RESPOND <sup>1</sup>
MODEL	Novation Press Fit	Total Hip Prosthesis System	Option Hip System	CBC With CBF Cup
WHERE MARKETED	Worldwide	Worldwide	USA	Worldwide, except Canada and USA
FDA CLEARANCE	Yes	Yes	Yes	Not specified
CE MARK (MDD)	Yes	Yes	No	Yes
CEMENTED/CEMENTLESS SYSTEM	Cementless	Both	Both	Cementless stem
CEMENTLESS SYSTEM TYPES	Plasma-sprayed	Hydroxyapatite (vacuum spray)	Press-fit straight stem, plasma-sprayed porous, HA, Osteoblast (grit-blasted) <sup>2</sup>	Press-fit
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Titanium alloy	Titanium alloy	Porous titanium alloy, nonporous CoCr, titanium alloy (TiN coated)	Titanium TAN
Coated, uncoated	Coated	Both	Both	Both
Coating material	Titanium plasmasprayed, proximal 1/3	Hydroxyapatite (vacuum spray)	HA, titanium (CP), partial 2/3 coating, titanium nitride	Hydroxyapatite
Number of stem length sizes	10	3	13 cemented, 27 press-fit, 24 porous, 27 HA	13
Stem length, mm	120-145 tapered; 130-155 splined	150, 200, 250 H-A.C. coated, 135-300 cemented	111-253 coated, 111-324 uncoated	135.6-189.6
Neck angle	131	140, 143	133	145
Neck length/neck offsets, mm	30-49; 36-59 extended	30-40	24-53 coated, 25-48 uncoated	37-51/not specified
FEMORAL HEAD	CoCr, zirconia, alumina	Cobalt chromium, stainless, ceramic, Al <sub>2</sub> O <sub>3</sub>	Cobalt chromium metal, zirconia ceramic, alumina ceramic	Stainless steel/CoCr Mo/ceramics hemiprosthesis head/ bipolar hemi-head
Number of sizes	7 CoCr, 5 zirconia, 5 alumina	4 metal neck lengths, 3 Al <sub>2</sub> O <sub>3</sub> neck lengths	16 metal, 6 ceramic	2; 3 neck lengths
Diameters, mm	22, 28, 32, 36 CoCr; 28, 32 zirconia and alumina	22-25, 28, 32 metal; 28, 32 ceramic	CoCr 22, 26, 28, 32; alumina 32; zirconia 28	Hemi-head, 50, 52, 54, 56, 58 <sup>3</sup>
ACETABULAR SHELL	Titanium	Titanium alloy, UHMWPE	Titanium alloy (Ti6Al4V ELI), UHMWPE	Ti6Al4V
Coating material	Titanium porous sintered beads	HAC	TiCP	TiCP
Number of sizes	16	12 coated, 6 UHMWPE	20 low profile, 12 full profile	12
Range of sizes, mm	40-70, 2 mm increments	44-80	40-78 low profile, 46-68 full profile	46-68 in 2 mm increments
Fixation	No-hole, cluster hole (3), multi-hole (dome and peripheral)	Screws, press-fit, hydroxyapatite, screw-in cup option	3-9 screw holes	2 screws, press-fit (screw version), press-fit (fin version)
ACETABULAR INSERT	Compression molded UHMWPE	UHMWPE, ceramic, Al <sub>2</sub> O <sub>3</sub>	UHMWPE	UHMWPE
Number of sizes	7	16	35 (10-30°)	12

1. Specifications current as of April 2002.

2. Also porous-coated acetabular shell.

3. Bipolar head has diameters of 42, 44, 46, 48, 50, 52, 54, 56, and 58 mm.

SUPPLIER	MATHYS FAILED TO RESPOND 1	MATHYS FAILED TO RESPOND 1	OSTEOIMPLANT	OSTEOIMPLANT
MODEL	CCA With CCE Roof Reinforcement Ring	Fullfix Stem With CBF Cup	ALFA	ALFA II
WHERE MARKETED	Worldwide, except Canada and USA	Worldwide, except Canada and USA	Worldwide	Worldwide
FDA CLEARANCE	Not specified	Not specified	Yes	Yes
CE MARK (MDD)	Yes	Yes	Yes	Yes
CEMENTED/CEMENTLESS SYSTEM	Cemented stem	Cemented	Both	Cementless
CEMENTLESS SYSTEM TYPES	NA	NA	Press-fit, porous coated, available with or without HA coating	Press-fit, porous coated, available with or without HA coating
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	CCA straight-stem FeCrNiMnMoNbN, CoCrMo	Cemented	Cobalt chromium alloy	Not specified
Coated, uncoated	Uncoated	Uncoated	Both	Both
Coating material	NA	FeCrNiMnMoNbN	HA on porous coating	HA on porous coating
Number of stem length sizes	FeCrNiMnMoNbN, 8 sizes standard and lateral; CoCrMo, 9 sizes standard and lateral	5 standard, 5 lateral	3 (9 sizes, including revision lengths)	3 (9 sizes, including revision lengths)
Stem length, mm	137-157.5 FeCrNiMnMoNbN, 137162 CoCrMo	130-170	160, 200, 250 bowed	160, 200, 250 bowed
Neck angle,	135	135	135; 8 anteversion	8, 12, 15 anteversion
Neck length/neck offsets, mm	40-48 standard, 50-58 lateral	41-45 standard, 46-51 lateral/ not specified	35, 38	32, 35, 38, modular neck
FEMORAL HEAD	Stainless steel/CoCr Mo/ceramics hemiprosthesis head/ bipolar hemi-head	Stainless steel/CoCr Mo/ceramics hemiprosthesis head/ bipolar hemi-head	Finite treated F-79 alloy	Finite treated F-79 alloy
Number of sizes	2: 3 neck lengths	2: 3 neck lengths	4 neck lengths	4 neck lengths
Diameters, mm	50, 52, 54, 56, 58, Hemi-head, 42, 44, 46, 48, 50, 52, 54, 56, 58, Bipolar head	50, 52, 54, 56, 58, Hemi-head, 42, 44, 46, 48, 50, 52, 54, 56, 58 . Bipolar head	22, 26, 28, 32, 38	22, 26, 28, 32, 38
ACETABULAR SHELL	TiCP	Ti6Al4V	Not specified	Not specified
Coating material	Uncoated	TiCP	Vitox aluminum ceramic	Vitox aluminum ceramic
Number of sizes	12	12	3 neck lengths	3 neck lengths
Range of sizes, mm	Not specified	46-68 in 2 mm increments	28, 32	28, 32
Fixation	3-6 screw holes	2 screws, press-fit (screw version), press-fit (fin version)	Tri-spike, cluster screw, press-fit	Tri-spike, cluster screw, press-fit
ACETABULAR INSERT	UHMWPE (cemented PE cups)	UHMWPE	UHMWPE	UHMWPE
Number of sizes	59 (low profile, full profile, special version)	12	8	8

<sup>1</sup> Specifications current as of April 2002.

SUPPLIER	OSTEOIMPLANT	OSTEOIMPLANT	OSTEOIMPLANT	OSTEOIMPLANT
MODEL	CLP	CLP II	CLP III	LSF
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	Yes	Yes	Yes	Yes
CEMENTED/CEMENTLESS SYSTEM	Both	Both	Both	Cementless
CEMENTLESS SYSTEM TYPES	Press-fit	Press-fit	Press-fit	Proximal biological fixation
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Cobalt chromium alloy	Cobalt chromium alloy	Cobalt chromium alloy	Cobalt chromium alloy
Coated, uncoated	Uncoated	Uncoated	Coated	Both
Coating material	NA	NA	Titanium plasma spray	HA coating over porous beads
Number of stem length sizes	6	6	6	7, including revision stems
Stem length, mm	130-197	130-197	130-197	140, 145, 155, 200, 250 bowed
Neck angle,	Not specified	Varying 8 and 12 of anteversion	Varying 8 and 12 of anteversion	135; 8 anteversion
Neck length/neck offsets, mm	Not specified	32, 35, 38, modular neck	32, 35, 38, modular neck	35, 38
FEMORAL HEAD	Finite treated F-79 alloy	Finite treated F-79 alloy	Finite treated F-79 alloy	Finite treated F-79 alloy
Number of sizes	4 neck lengths	3 neck lengths	4 neck lengths	4 neck lengths
Diameters, mm	22, 26, 28, 32, 38	22, 26, 28, 32, 38	22, 26, 28, 32, 38	22, 26, 28, 32, 38
ACETABULAR SHELL	Cobalt chromium	Cobalt chromium	Cobalt chromium	Not specified
Coating material	Vitox aluminum ceramic	Porous coated	Porous coated	Vitox aluminum ceramic
Number of sizes	3 neck lengths	16	16	3 neck lengths
Range of sizes, mm	28, 32	46-76	46-76	28, 32
Fixation	Tri-spike, cluster screw, press-fit	Tri-spike, cluster screw, press-fit	Tri-spike, cluster, screw, press-fit	Tri-spike, cluster screw, press-fit
ACETABULAR INSERT	UHMWPE	UHMWPE	UHMWPE	UHMWPE
Number of sizes	8	8	8	8



SUPPLIER	OSTEOIMPLANT	OSTEOIMPLANT	OSTEOIMPLANT	SMITH & NEPHEW FAILED TO RESPOND <sup>1</sup>
MODEL	R120	R120PC	Vintage	12/14 Spectron EF Hip System
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	Yes	Yes	Yes	Yes
CEMENTED/CEMENTLESS SYSTEM	Cemented	Cementless	Cemented	Cemented
CEMENTLESS SYSTEM TYPES	NA	Proximal biological fixation	NA	NA
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Cobalt chromium alloy	Cobalt chromium alloy	Cobalt chromium alloy	Forged cobalt chromium alloy
Coated, uncoated	No	Both	No	Uncoated
Coating material	NA	HA coating over porous beads	NA	NA
Number of stem length sizes	6 blasted with collar, 6 highly polished no collar	7	6	5 sizes, 3 lengths
Stem length, mm	120, 130, 140, 150, 160, 170	132, 142, 152, 162, 175, 200, 250 bowed	120, 130, 140, 150, 160, 170	115, 125, 135
Neck angle	8, 12, 15 anteversion	8, 12, 15 anteversion	Straight-neck design	131
Neck length/neck offsets, mm	32, 35, 38, modular necks	32, 35, 38, modular necks	35	27-60/32-63, both incremental
FEMORAL HEAD	Finite treated F-79 alloy	Finite treated F-79 alloy	Finite treated F-79 alloy	Cobalt chromium metal, zirconia ceramic
Number of sizes	4 neck lengths	4 neck lengths	4 neck lengths	20 metal, 8 ceramic
Diameters, mm	22, 26, 28, 32, 38	22, 26, 28, 32, 38	22, 26, 28, 32, 38	22, 26, 28, 32
ACETABULAR SHELL	Not specified	Not specified	Not specified	Titanium cementless, polyethylene cemented
Coating material	Vitox aluminum ceramic	Vitox aluminum ceramic	Vitox aluminum ceramic	Sintered, commercially pure titanium beads (cementless)
Number of sizes	3 neck lengths	3 neck lengths	3 neck lengths	14 cementless, 6 cemented
Range of sizes, mm	28, 32	28, 32	28, 32	42-68 cementless, 2 mm increments, 40-61 mm cemented, 3 mm increments.
Fixation	Tri-spike, cluster screw, press-fit	Tri-spike, cluster screw, press-fit	Not specified	Hemispherical and peripheral buildup(InterFit) for cementless
ACETABULAR INSERT	UHMWPE	UHMWPE	UHMWPE	EtO-sterilized UHMWPE
Number of sizes	8	8	Not specified	7 with 0° overhang, 7 with 20° overhang

1. Specifications current as of February 1999.

SUPPLIER	SMITH & NEPHEW FAILED TO RESPOND <sup>1</sup>	SMITH & NEPHEW FAILED TO RESPOND <sup>1</sup>	SMITH & NEPHEW FAILED TO RESPOND <sup>1</sup>	STELKAST
MODEL	Echelon Revision Hip System	Matrix Hip System	Synergy Tapered Hip System	ProClass
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	Yes	Yes	Yes	Not specified
CEMENTED/CEMENTLESS SYSTEM	Both	Both	Both	Cementless
CEMENTLESS SYSTEM TYPES	Porous coated	Circumferential, proximal porous coating	Press-fit (gritblasted), porous coated, HA coated	Standard and lateralized
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Porous cobalt chromium alloy, forged cobalt chromium alloy	Titanium alloy cementless, cobalt chromium cemented, press-fit	Forged titanium alloy (cementless), cobalt chromium (cemented)	Titanium alloy
Coated, uncoated	Both	Both	Both	Uncoated
Coating material	Cobalt chromium sintered beads	Sintered, commercially pure titanium beads (cementless)	Sintered, commercially pure titanium beads; HA	Titanium
Number of stem length sizes	28 porous straight, 42 porous bowed, 18 cemented	10 collared, 10 collarless porous, 8 collared cemented, 5 collared press-fit	10 collarless standard and high offset (7 standard and high offset for cemented)	12 standard, 12 lateralized
Stem length, mm	190 porous straight, 260 porous bowed, 175, 225 cemented	125-170 cementless, 120-155 cemented, 120-160 press-fit	135-180 cementless, 110-140 cemented	117-169
Neck angle°	131	131	131	123, 131
Neck length/neck offsets, mm	37-41/40-50	27-56/32-57 cementless, 25-52/30-53 cemented, 25-53/30-54 press-fit	26-58/32-61, both incremental	Standard and lateralized
FEMORAL HEAD	Cobalt chromium, zirconia	Cobalt chromium metal, zirconia ceramic	Cobalt chromium metal, zirconia ceramic	Cobalt chromium, zirconia ceramic
Number of sizes	20 metal, 8 ceramic	14 metal, 6 ceramic	20 metal, 8 ceramic	1 cobalt chromium, 4 ceramic
Diameters, mm	22, 26, 28, 32	22, 26, 28, 32	22, 26, 28, 32	22, 26, 28, 32
ACETABULAR SHELL	CP titanium rings	Titanium cementless, polyethylene cemented	Titanium cementless, polyethylene cemented	Titanium alloy
Coating material	None	Sintered, commercially pure titanium beads (cementless)	Sintered, commercially pure titanium beads (cementless)	Titanium, plasma sprayed
Number of sizes	9 reinforcement, 3 reconstruction	14 cementless, 6 cemented	14 cementless, 6 cemented	14 coated
Range of sizes, mm	44-68 reinforcement, 50-62 reconstruction, 40-61 mm cemented, 3 mm increments	42-68 cementless, 2 mm increments, 40-61 mm cemented, 3 mm increments	42-68 cementless, 2 mm increments, 40-61 mm cemented, 3 mm increments	46-72
Fixation	Multiple screw holes; flanges on reconstruction ring	Hemispherical and peripheral buildup (InterFit) for cementless	Hemispherical and peripheral buildup (InterFit) for cementless	3 screw holes
ACETABULAR INSERT	Not specified	EtO-sterilized UHMWPE	EtO-sterilized UHMWPE	UHMWPE
Number of sizes	Works with all poly cups	7 with 0° overhang, 7 with 20° overhang	7 with 0° overhang, 7 with 20° overhang	7

<sup>1</sup> Specifications current as of February 1999.

SUPPLIER	STELKAST	STELKAST	STELKAST	STELKAST
MODEL	Proform GA	Progeny	Protract	Provident
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	Not specified	Not specified	Not specified	Not specified
CEMENTED/CEMENTLESS SYSTEM	Cemented	Cemented	Cementless	Cementless
CEMENTLESS SYSTEM TYPES	NA	Standard and lateralized cemented	Standard and lateralized, plasmasprayed and HA	Standard and lateralized plasma sprayed
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Cobalt chromium alloy	Cobalt chromium alloy	Titanium alloy	Titanium alloy
Coated, uncoated	Uncoated	Uncoated	Coated	Coated
Coating material	None	None	Titanium, HA	Titanium
Number of stem length sizes	5 cemented	6 standard, 5 lateralized	8 standard, 7 lateralized	11 standard, 10 lateralized
Stem length, mm	110-180	100-160	110-165	130-165
Neck angle, °	133.25	135	135	135
Neck length/neck offsets, mm	Not specified	Standard and lateralized	Standard and lateralized	Standard and lateralized
FEMORAL HEAD	Cobalt chromium, zirconia ceramic	Cobalt chromium, zirconia ceramic	Cobalt chromium, zirconia ceramic	Cobalt chromium, zirconia ceramic
Number of sizes	7 cobalt chromium, 4 ceramic	7 cobalt chromium, 4 ceramic	7 cobalt chromium, 4 ceramic	7 cobalt chromium, 4 ceramic
Diameters, mm	22, 26, 28, 32	22, 26, 28, 32	22, 26, 28, 32	22, 26, 28, 32
ACETABULAR SHELL	Titanium alloy, UHMWPE	Titanium alloy, UHMWPE	Titanium alloy	Titanium alloy
Coating material	Titanium beads	Titanium beads	Titanium, plasmasprayed	Titanium, plasmasprayed
Number of sizes	16 coated, 10 uncoated	14 coated, 10 uncoated	14 coated	14 coated
Range of sizes, mm	46-76	46-76	46-72	46-72
Fixation	0, 3, multiple screw holes	0, 3, multiple screw holes	3 screw holes	3 screw holes
ACETABULAR INSERT	UHMWPE	UHMWPE	UHMWPE	UHMWPE
Number of sizes	7	7	7	7

SUPPLIER	WRIGHT MEDICAL	WRIGHT MEDICAL	WRIGHT MEDICAL	ZIMMER
MODEL	Infinity Hip System	Lineage Hip System	PERFECTA Hip System	CPT 12/14 Hip System
WHERE MARKETED	Worldwide	Not specified	Worldwide	Worldwide
FDA CLEARANCE	Yes	Not specified	Yes	Yes
CE MARK (MDD)	Submitted	Not specified	Submitted	Yes
CEMENTED/CEMENTLESS SYSTEM	Cementless	Not specified	Both	Cemented
CEMENTLESS SYSTEM TYPES	Press-fit, porous coating, HA	Not specified	Press-fit, plasma sprayed, HA	CoCr/stainless steel
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Titanium alloy	Not specified	Ti alloy (plasma sprayed), Ti alloy and CoCr alloy (nonporous)	Not specified
Coated, uncoated	Both	Not specified	Both	Uncoated, polished finish
Coating material	HA, titanium beads	Not specified	HA, titanium plasma spray (1/3)	Not specified
Number of stem length sizes	10 HA-coated, 10 press-fit, 7 porous	Not specified	9 plasma sprayed, 6 nonporous	8
Stem length, mm	130-230	Not specified	120-180 coated, 130-180 nonporous	85 (small)-260 (revision)
Neck angle, °	135	Not specified	132.5	Not specified
Neck length/neck offsets, mm	23-33, 33-43 HA coated & press-fit, 28-33, 38-43 porous	Not specified	25-35/30.25-39.25 coated, 30-35/30.25-38.5 nonporous	23-41/28-50
FEMORAL HEAD	Cobalt chromium metal, ceramic	Not specified	Cobalt chromium, ceramic	Cobalt chromium, Alumina ceramic
Number of sizes	5 cobalt chromium, 3 ceramic	Not specified	5 cobalt chromium, 4 ceramic	29 metal, 9 alumina
Diameters, mm	22, 28, 32, 36	Not specified	22, 28, 32, 36	Metal 12/14 taper 22, 26, 28, 32, 36, 40, 5 neck lengths; 6° taper 22, 26, 28, 32, 36, 5 neck lengths; ceramic 12°/14° taper 26, 28, 32, 3 neck lengths
ACETABULAR SHELL	Titanium	Titanium	Titanium alloy and UHMWPE	NA
Coating material	Titanium	Titanium	Titanium and HA	NA
Number of sizes	19 coated, 13 uncoated	14	14 porous, 9 UHMWPE	NA
Range of sizes, mm	42-86	46-74	47-73 porous, 48-64 UHMWPE	NA
Fixation	3-12 screw holes	0-12 screw holes	0-4 screw holes	NA
ACETABULAR INSERT	UHMWPE and DURAMER brand UHMWPE	UHMWPE, metal	UHMWPE and DURAMER brand UHMWPE	NA
Number of sizes	19	4 groups, 28, 32, 36 mm	14	NA

SUPPLIER	ZIMMER	ZIMMER	ZIMMER	ZIMMER
MODEL	Epoch Hip System	M/L Taper Hip System	Mayo Hip System	TM Modular/ Monoblock/ Revision Cup System
WHERE MARKETED	Worldwide	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Yes	Yes	Yes	Yes
CE MARK (MDD)	Yes	Yes	Yes	Yes
CEMENTED/CEMENTLESS SYSTEM	Cementless	Cementless	Cementless	Cementless
CEMENTLESS SYSTEM TYPES	CoCr core, polyaryletherketone layer	Titanium	Titanium	Titanium
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified	Not specified
FEMORAL STEM	Not specified	Not specified	Not specified	Not specified
Coated, uncoated	Coated	Coated	Medial, anterior, and proximal pads	NA
Coating material	Fiber metal mesh	Plasma-sprayed titanium	Fiber metal mesh	NA
Number of stem length sizes	8	24	4	NA
Stem length, mm	130-159	109-144, dependent on size	81-107	NA
Neck angle, °	135	131	131	NA
Neck length/ neck offsets, mm	24-53/32-57	26-53/30-58	30-34/38-46	NA
FEMORAL HEAD	Cobalt chromium, alumina ceramic	Cobalt chromium, alumina ceramic	Cobalt chromium, alumina ceramic	Cobalt chromium, alumina ceramic
Number of sizes	27 metal, 9 alumina	24 metal, 9 alumina	24 metal, 9 alumina	26 metal, 9 alumina
Diameters, mm	Metal 12/14 taper 22, 26, 28, 32, 36, 40, 5 neck lengths; 6° taper 22, 26, 28, 32, 36, 5 neck lengths; ceramic 12°/14° taper 26, 28, 32, 3 neck lengths.	Metal 12/14 taper 22, 26, 28, 32, 36, 40, 5 neck lengths; 6° taper 22, 26, 28, 32, 36, 5 neck lengths; 12°/14° taper 26, 28, 32, 3 neck lengths.	Metal 12/14 taper 22, 26, 28, 32, 36, 40, 5 neck lengths; 6° taper 22, 26, 28, 32, 36, 5 neck lengths; ceramic 12°/14° taper 26, 28, 32, 3 neck lengths.	Metal 12/14 taper 22, 26, 28, 32, 36, 40, 5 neck lengths; 6° taper 22, 26, 28, 32, 36, 5 neck lengths; ceramic 12°/14° taper 26, 28, 32, 3 neck lengths.
ACETABULAR SHELL	NA	NA	NA	Titanium
Coating material	NA	NA	NA	Trabecular metal/ tantalum
Number of sizes	NA	NA	NA	22
Range of sizes, mm	NA	NA	NA	36-80
Fixation	NA	NA	NA	Press-fit
ACETABULAR INSERT	NA	NA	NA	UHMPWE, N <sub>2</sub> packed gamma, UHMWPE crosslinked gas plasma
Number of sizes	NA	NA	NA	22-40 mm ID; neutral 10°, 20° elevated

SUPPLIER	ZIMMER	ZIMMER	ZIMMER
MODEL	Trilogy Acetabular Cup System	Versys Total Hip System	ZMR Total Hip System
WHERE MARKETED	Worldwide	Worldwide	Worldwide
FDA CLEARANCE	Yes	Yes	Yes
CE MARK (MDD)	Yes	Yes	Yes
CEMENTED/CEMENTLESS SYSTEM	Cementless	Both	Cementless
CEMENTLESS SYSTEM TYPES	Titanium	Forged CoCr (cemented), titanium (porous fiber), CoCr (beaded)	Titanium
MODULAR OR BIPOLAR	Not specified	Not specified	Not specified
FEMORAL STEM	NA	Not specified	Not specified
Coated, uncoated	NA	Coated	Coated
Coating material	NA	Titanium, Co Cr	Plasma spray/ corundumized surface
Number of stem length sizes	NA	165 beaded primary, 28 beaded revision, 138 porous-fiber metal, 35 cemented	5 stem lengths, 4 body heights
Stem length, mm	NA	120/300	115-260
Neck angle	NA	125, 135	Not specified
Neck length/ neck offsets, mm	NA	26, 53/33, 57 (cemented); 24, 60/ 30, 60 (porous); 24, 60/30, 60 (beaded)	75-100 (body heights); 36-46 (body offsets)
FEMORAL HEAD	Cobalt chromium, alumina ceramic	Cobalt chromium, alumina ceramic	Cobalt chromium, alumina ceramic
Number of sizes	25 metal, 9 alumina	23 metal, 9 alumina	30 metal, 9 alumina
Diameters, mm	Metal 12/14 taper 22, 26, 28, 32, 36, 40, 5 neck lengths; 6° taper 22, 26, 28, 32, 36, 5 neck lengths; ceramic 12°/14° taper 26, 28, 32, 3 neck lengths.	Metal 12/14 taper 22, 26, 28, 32, 36, 40, 5 neck lengths; 6° taper 22, 26, 28, 32, 36, 5 neck lengths; ceramic 12°/14° taper 26, 28, 32, 3 neck lengths.	Metal 12/14 taper 22, 26, 28, 32, 36, 40, 5 neck lengths; 6° taper 22, 26, 28, 32, 36, 5 neck lengths; ceramic 12°/14° taper 26, 28, 32, 3 neck lengths.
ACETABULAR SHELL	Titanium	NA	NA
Coating material	Fiber metal mesh	NA	NA
Number of sizes	23	NA	NA
Range of sizes, mm	36-80	NA	NA
Fixation	Press-fit	NA	NA
ACETABULAR INSERT	UHMWPE, N <sub>2</sub> packed gamma, UHMWPE crosslinked gas plasma	NA	NA
Number of sizes	22-40 mm ID; neutral 10°, 20° elevated	NA	NA

## Appendix B. Literature Search Strategies

### Electronic Database Searches

The following databases have been searched for relevant information:

<b>Name</b>	<b>Date limits</b>	<b>Platform/provider</b>
The Cochrane Central Register of Controlled Trials (CENTRAL)	Inception through 2006, Issue 2	<a href="http://www.thecochranelibrary.com">www.thecochranelibrary.com</a>
The Cochrane Database of Methodology Reviews (Methodology Reviews)	Inception through 2006, Issue 2	<a href="http://www.thecochranelibrary.com">www.thecochranelibrary.com</a>
The Cochrane Database of Systematic Reviews (Cochrane Reviews)	Inception through 2006, Issue 2	<a href="http://www.thecochranelibrary.com">www.thecochranelibrary.com</a>
Database of Abstracts of Reviews of Effects (DARE)	Inception through 2006, Issue 2	<a href="http://www.thecochranelibrary.com">www.thecochranelibrary.com</a>
ECRI Health Devices Alerts	1977 through March 2006	ECRI
ECRI International Health Technology Assessment (IHTA)	Inception through March 2006	ECRI
ECRI Library Catalog	Inception through March 2006	ECRI
ECRI TARGET (Technology Assessment Resource Guide for Emerging Technologies)	Inception through March 2006	ECRI
Embase (Excerpta Medica)	1974 through March 21, 2006	OVID
Health Technology Assessment Database (HTA)	Inception through 2006, Issue 2	<a href="http://www.thecochranelibrary.com">www.thecochranelibrary.com</a>
MEDLINE	1966 through March 21, 2006	OVID
PubMed (PreMEDLINE, Publisher)	1966 through April 25, 2006	<a href="http://www.pubmed.gov">www.pubmed.gov</a>
U.K. National Health Service Economic Evaluation Database (NHS EED)	Inception through 2006, Issue 2	<a href="http://www.thecochranelibrary.com">www.thecochranelibrary.com</a>
U.S. National Guideline Clearinghouse™ (NGC™)	Through March 2006	<a href="http://www.ngc.gov">www.ngc.gov</a>

## Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI's collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

## Search Strategies

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across Embase, Medline, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

## Medical Subject Headings (MeSH), Emtree, PsycINFO and Keywords

### Conventions:

#### OVID

- \$ = truncation character (wildcard)
- exp = "explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)
- .de. = limit controlled vocabulary heading
- .fs. = floating subheading
- .hw. = limit to heading word
- .md. = type of methodology (PsycINFO)
- .mp. = combined search fields (default if no fields are specified)
- .pt. = publication Type
- .ti. = limit to title
- .tw. = limit to title and abstract fields

#### PubMed

- [mh] = MeSH heading
- [majr] = MeSH heading designated as major topic
- [pt] = Publication Type
- [sb] = Subset of PubMed database (PreMedline, Systematic, OldMedline)
- [sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)
- [tiab] = keyword in title or abstract
- [tw] = Text word



**Embase/MEDLINE**  
**English language, human**

<b>Set Number</b>	<b>Concept</b>	<b>Search statement</b>
1	Hip	Hip.de. or hip joint.de. or hip\$ or femoral or acetabul\$ or acetabulum\$
2	Arthroplasty	exp arthroplasty/ or acetabuloplasty.de or arthroplast\$ or replace\$ or implant\$ or prosth\$ or endoprosth\$ or hemiarthroplast\$
3	Combine sets	1 and 2
4	Hip replacement (see note below)	arthropasty, replacement, hip.de. or hip prosthesis.de. or hip arthroplasty.de. or hip prosthesis.de. or total hip prosthesis.de.
5	Combine sets	3 or 4
6	Limit by publication type	5 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.)
7	Guidelines	6 and (st.fs. or guideline.pt. or consensus.pt. or practice parameter or position statement or position paper or policy statement or standard\$.ti. or guideline\$.ti. or white paper or clinical pathway or practice guidelines.de. or exp practice guideline/ or consensus development.de.)
8	Systematic reviews & metaanalyses	6 and ((systematic review or meta analysis).de. or ((evidence base\$ or methodol\$ or systematic or quantitative\$ or studies).mp. and (review.de. or review.pt.)))
9	Reviews	6 and (review\$.ti. or review.de. or review.pt.)
10	Combine sets	7 or 8 or 9
11	Remove overlap	Remove duplicates from 10

We used controlled vocabulary terms and keywords to represent the concept of hip replacement surgery. The term “hip surgery” if used would include an excess number of citations which have no bearing on this report.

**MEDLINE (PubMed) – 1/1/66 through 7/24/06**

**English language**

<b>Set Number</b>	<b>Concept</b>	<b>Search statement</b>
1	Arthroplasty	Arthroplast* OR replace* OR implant* OR prosth* OR endoprosth* OR heimarthroplast*
2	Hip	Hip OR femoral OR acetabul*
3	Combine sets	#1 AND #2
4	Limit by subset	#3 AND premedline[sb]
Additional concepts		Bipolar* OR tripolar* OR “cushion bearing” OR “surface treated” OR “surface modified” OR ceramic OR