Metal-on-Metal Total Hip Resurfacing

Tec

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Executive Summary

Background

In patients with debilitating degenerative joint disease of the hip for whom conventional approaches (analgesics, assistive devices, weight loss) are no longer effective, a total hip replacement procedure (arthroplasty) is indicated to relieve pain and restore patient function. Total hip arthroplasty (THA) involves removal of the femoral bone head and neck, revision of the diseased acetabulum, and implantation of a prosthesis with a stemmed femoral component and press-fit acetabular cup. THA is a reliable surgical intervention, with high success rates for joint survivorship and improved function at 5–10 years follow-up using current metal-on-metal (MoM) prostheses. Complications of primary THA are predictable and relatively minor when balanced against beneficial outcomes. By contrast, revision THA is reportedly more complex than primary THA, with significantly longer lengths of stay, higher rates of perioperative complications, unexpected surgical findings, and often a poorer prognosis than the primary procedure.

With advancements in technology, there is renewed interest in total hip resurfacing (HR) using a metal alloy femoral head cap and acetabular cup as an alternative to traditional THA. HR, compared to traditional THA, retains the native femoral bone neck and head and typically removes a comparable amount of bone from the acetabulum, thereby replacing damaged cartilage and associated joint structures. Because the native femoral bone is conserved, revision of a resurfaced joint to a stemmed THA is typically easier and less complicated than revision of a primary THA. Thus, HR may be an advantageous option for younger and/or more active individuals likely to outlive the functional lifespan (10 years or more) of a traditional hip replacement device. However, questions exist about the relative health benefits and harms of HR compared to THA, in the intended population.

Objective

To evaluate available evidence on the benefits and harms of HR as an alternative to THA in comparable patients. The Assessment will consider relative symptomatic and functional improvement, and complications of HR. Key considerations are the durability of HR reflected by revision rates due to joint failure. Throughout the Assessment, unless otherwise indicated, it will be assumed "HR" and "THA" refer to the use of MoM prostheses

Search Strategy

MEDLINE (via PubMed) search through January 2007 using search string "(resurface OR resurfacing) AND (hip OR hips OR acetabulum OR acetabular)"; additional text searching EMBASE for full-length reports of clinical trials that describe health outcomes (benefits and harms) of HR. Systematic reviews, meta-analyses, manufacturers websites, registries, and the U.S. Food and Drug Administration (FDA) website were additional sources of information.

Selection Criteria
Studies of individuals with advanced DJD of the hip who receive a HR device that report data on clinical outcomes (benefits or harms). Relevant benefits include pain relief and functional improvement; harms include perioperative complications, femoral bone neck fracture, and joint failure requiring revision to THA.

Main Results
The following Summary Table shows the body of evidence on outcomes of HR, organized by data source.

Clinical Data Summary on HR and THA in Patients Younger than 65 Years of Age

Data Source	No. Hips	Mean F/U Yrs (range)	Mean % Revision (range)	Clinical Improvement from Baseline Average Scores*	Perioperative Complications or Postoperative Adverse Events
Comparative HR Data					
RCT	107 HR 103 THA	1	1.94 HR 0.98 THA	82% HR 79% THA	7% HR 13% THA
AOA Registry HR THA	 6,712 74,609	 5	 2.2** 1.7	 NR	 NR
HR Clinical Series					
12 Published Clinical Series	2,076	3 (<1–12)	2.7 (0.3–22)	55–228%	5% (0.3–14%)
BHR PMA McMinn Cohort	2,385	3 (1–5)	1.13	58% (n=1,111)	8.5%
BHR PMA Worldwide Cohort	3,374	1–5	2.25	58%	NR
THA Clinical Series* **					
1st-generation MoM	1,646	10–28	15–40	NR	NR
2nd-generation MoM	526	2–9	1.3–6.5	94–255%	0–12

AOA: Australian Orthopedic Association; BHR: Birmingham Hip Resurfacing System; HR: hip resurfacing; MoM: metal-on-metal; PMA: premarket approval; THA: total hip arthroplasty;
* Validated measures including Harris Hip score, Oswestry-Modified Harris Hip Score;
** p<0.01 vs. THA
*** Selected primary series that provided clinical and health outcome data in patients younger than 65 years of age

One published RCT in patients aged 49–51 years showed substantial and equivalent postsurgical functional improvement in HR and THA recipients, with no significant difference in the rates of revision and perioperative complications at 1 year of follow-up. Australian Orthopedic Association (AOA) Registry data showed a significantly higher 5-year revision rate for HR than for THA in a large number of patients, 90% of whom were younger than 65 years of age. However, the registry data do not distinguish between MoM and other types of THA prostheses, nor are patient demographics well characterized.

Results from 12 published, uncontrolled series of HR consistently demonstrated symptomatic and functional improvements from baseline using standard outcome measures at 2–3 years of follow-up. Individual study revision rates ranged from 0.3% to 5% for most studies, with an overall revision rate of 2.7%. Exceptions were the two smallest studies (60 patients each), which reported revision rates of 8% and 22%. Femoral bone neck fracture accounted for nearly 25% of

HR revisions, but its risk can be reduced by patient selection criteria (e.g., adequate bone density, no obesity or prior hip surgery) and experienced surgical technique. Perioperative complications were consistent among the series.

Clinical data in a premarket approval (PMA) application to the FDA by the manufacturer of the Birmingham Hip Resurfacing System (BHR) showed substantial symptomatic and functional improvement from baseline values at 5-year follow-up in a large cohort of patients younger than 65 years of age. Five-year revision rates of 1.13% and 2.25% were reported in two separate BHR cohorts comprising 2,385 (McMinn) and 3,374 (Worldwide) cases, respectively. An overall 8.5% incidence of perioperative complications was reported for the McMinn cohort.

Author's Comments and Conclusions

A substantial body of evidence shows HR is associated with consistent and strong symptomatic and functional improvements at follow-up times up to 5 years. HR results are comparable to those obtained with current generation THA at similar time points in patients younger than 65 years of age. HR differs procedurally from THA in conserving a patient's native femoral bone neck. When HR patients subsequently require revision to THA, the operation is technically similar to primary THA and likely avoids the complications of revision of a primary THA. Thus, the benefits comprise initial HR results as good as THA and a simpler revision to THA when needed. Although longer-term (i.e., greater than 5 years) data on the relative durability of HR compared to THA are unavailable, current evidence is sufficient to conclude that HR is a safe and effective means for initial surgical treatment in younger, properly selected patients who require a total hip replacement. Primary use of HR in the indicated patient subpopulation thus defers standard THA.

Based on the available direct and indirect evidence, the Blue Cross and Blue Shield Association Medical Advisory Panel made the following judgments about whether HR meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.

1. **The technology must have final approval from the appropriate governmental regulatory bodies.**

The Birmingham Hip Resurfacing (BHR) System was approved for marketing by FDA on May 9, 2006. It is a single-use device, intended for hybrid fixation, using a cemented femoral head component and cementless acetabular component, intended for use in patients who require primary HR arthroplasty due to:

- non-inflammatory arthritis (DJD) such as osteoarthritis, traumatic arthritis, avascular necrosis, or dysplasia; or
- inflammatory arthritis such as rheumatoid arthritis.

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

Two other Class B, non-experimental MoM hip resurfacing devices have received investigational device exemptions. The Cormet Hip Resurfacing System (Corin Medical) was deemed approvable with conditions by an FDA Advisory Panel February 22, 2007; a final FDA decision was not available at the time of this writing. The Conserve® Plus Total Resurfacing Implant (Wright Medical Technology) may be considered for approval sometime in 2007.

2. **The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.**

Evidence for the safety and efficacy of HR is available from more than 14,000 cases with mean follow-up times up to 5 years. Published series of THA using current-generation MoM prostheses (n=526) provide indirect evidence to compare HR and THA in patients younger than 65 years of age. Older series with longer follow-up of first-generation MoM THA (n=1,646) provide guidance on the potential durability of MoM prostheses. However, as the older series include prostheses that are outdated and no longer in clinical use, complications and revision rates may be overestimated and any comparisons must be viewed cautiously. Nonetheless, taken together, sufficient direct and indirect scientific evidence exists to permit conclusions about symptomatic and functional benefits of HR in properly selected patients for whom hip replacement is indicated.

3. The technology must improve the net health outcome
4. The technology must be as beneficial as any established alternatives.

Key Assessment Question: Does HR improve health outcomes, such as pain, joint function, and activities of daily living, among patients with DJD who require hip replacement and are likely to outlive a traditional prosthesis, compared with THA?

A single RCT with 1 year of follow-up provides good direct comparative evidence that HR improves the net health outcome and is as beneficial as THA in comparable patient samples. Additional data from uncontrolled series, the BHR FDA submission, and the AOA Registry, with indirect comparisons to THA, support these conclusions.

Thus, the total body of evidence outlined in this Assessment is sufficient in magnitude of change and consistency of direction to conclude that HR improves the net health outcome and is as beneficial as THA in properly selected individuals who require a total hip replacement and, because of younger age and/or higher activity levels, are likely to outlive the 10 years or more functional lifespan of a traditional prosthetic device. Because HR leaves the femoral bone head and neck largely intact, subsequent revision to THA is typically less complicated than a procedure to replace a primary THA. Therefore, based on published clinical experience with improved current generation MoM THA, and similar 5-year survivorship rates, HR represents a safe and effective means to defer a first THA in properly selected patients who require a total hip replacement and are subsequently likely to require replacement of the ipsilateral hip due to normal wear processes.

5. The improvement must be attainable outside the investigational settings.

Evidence for the safety and effectiveness of HR comes from a range of settings including the device designers and individual practitioners worldwide. An ongoing clinical training program for U.S. orthopedic surgeons is available from the manufacturer of the FDA-approved BHR System and its establishment was a condition of FDA marketing approval. Given this, it may be concluded that clinical benefits of HR will be attainable outside the investigational settings.

Based on the above, use of an FDA-approved metal-on-metal total hip resurfacing device as an alternative to THA in patients who are likely to outlive the 10 years or more functional lifespan of a traditional MoM prosthesis meets the TEC criteria.

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Assessment Objective

In patients with debilitating degenerative joint disease of the hip for whom conventional approaches (analgesics, weight loss, assistive devices) are no longer effective, a total hip replacement procedure (arthroplasty) is indicated to relieve pain and restore patient function. Total hip arthroplasty (THA) involves removal of the femoral bone head and neck, revision of the diseased acetabulum, and insertion of a prosthesis with a stemmed femoral component and press-fit acetabular cup. THA is a highly successful surgical intervention in terms of the balance between benefits and harms. When indicated and performed technically well, the outcomes and complications of THA are predictable, with success rates in terms of joint survivorship and improved function above 90% at 10 years or more follow-up using current MoM prostheses. However, for a variety of reasons that include normal wear and deterioration of the device material, as well as fit and function issues, especially in younger or more active recipients who place more stress on their device than do older or less active patients, prosthetic joints often must be replaced in a second operation. Revision of a first THA to a second THA is a more difficult surgery that results in poorer outcomes than first THA.

With advancements in metallurgical technology, there has been renewed clinical interest in total hip resurfacing (HR). HR uses a metal alloy femoral head cap and acetabular cup as an alternative to traditional THA, essentially replacing damaged cartilage with metal articulating surfaces. By contrast to THA, HR retains the basic native femoral bone anatomy and typically removes less bone from the acetabulum. In the event a resurfaced joint fails, it is replaced with a traditional stemmed prosthesis. Because the initial HR procedure conserves a patient's native bone structure, revision to a THA is typically easier than is replacement of a traditional stemmed device with a second THA. Therefore, in this context, HR may be an advantageous primary option for individuals who require hip replacement and who would likely outlive the 10 years or more lifespan of a traditional hip replacement device. However, because there is substantially less accumulated evidence for HR than for THA, questions exist about the relative health benefits and harms of these technologies.

This Assessment will evaluate available evidence on the benefits and harms of HR as an alternative to THA in younger or more active patients who are likely to outlive a traditional hip prosthesis. The durability of the resurfaced joint, and subsequent revision rates due to joint failure are key outcomes to be compared to those of THA. The Assessment will also consider relative symptomatic and functional improvement, and complications of HR and THA.

Background

Degenerative Joint Disease

Osteoarthritis (OA), also known as degenerative joint disease, is the most common form of arthritis. It is a slowly progressive disease that afflicts more than two-thirds of Americans older than 55 years, becoming more prevalent with advancing age (http://www.aaos.org/Research/documents/oainfo_hip.asp). Pain and loss of function are characteristics of hip OA that increase with progression of the disease. OA of the hip affects the ability to ambulate to a greater extent than any other degenerative joint disease except OA of the knee. While 43 million individuals have OA, the U.S. Centers for Disease Control and Prevention (CDC) estimated that by the year 2030, nearly 67 million (25%) of U.S. adults will have diagnosed arthritis (http://www.cdc.gov/arthritis/arthritis/index.htm). In addition, CDC estimates that adults with meaningful activity limitation due to OA will increase from 16.9 million (7.9%) to 25 million (9.3% of the U.S. adult population) by 2030. CDC projections suggest an increasing burden on the health care system and society in general. Thus, in 2003, the total cost attributed to arthritis and other rheumatic conditions in the U.S. was $128 billion, up from about $86 billion in 1997, comprising $81 billion in medical care expenditures and $47 billion in earnings losses, which increased from $35 billion in 1997. Although OA is more common in older people, it can develop in younger individuals, usually secondary to a joint injury, a joint malformation, or a genetic defect in joint cartilage.

OA occurs in men and women, but before age 45, it is more prevalent in men than in women; after age 45, it is more common in women, who comprise 67% to 75% of cases. It is also more likely in overweight people and in those with jobs that stress particular joints. It has been estimated that OA of the hip may affect about 1.5% of the adult population in the U.S., which currently would translate to about 4.5 million individuals (http://www.aaos.org/Research/documents/oainfo_hip.asp). A second degenerative joint disease, rheumatoid arthritis (RA), is a systemic inflammatory disease which manifests itself in multiple joints of the body including the hip. The inflammatory process primarily affects the lining of the joints (synovial membrane), but can also affect other organs. The inflamed synovium leads to erosions of the cartilage and bone and possibly joint deformity. Pain, swelling, and redness are common joint manifestations. Although the definitive causes are unknown, RA is believed to be the result of a faulty immune response. RA can begin at any age and is associated with fatigue and prolonged stiffness after rest. Other less-common conditions associated with degenerative joint disease include gout, systemic lupus erythematosus, and fibromyalgia.

Treatment of Degenerative Joint Disease of the Hip

There is no cure for degenerative joint disease of the hip. Noninvasive treatment options include pain management, reduction of joint mobility (e.g., braces, wraps), exercise, and weight reduction. Joint replacement surgery is indicated when conservative medical management has failed and the patient becomes severely limited. Many factors influence outcomes of total hip replacement, including patient age, gender and diagnosis, the type of prosthesis and the surgical techniques. Superimposed on this, is the rapid rate of change in medical technology. There is continual development and use of new types of prostheses and surgical techniques, the results for many of which remain uncertain (Huo and Gilbert 2005).

Total Hip Arthroplasty

Total hip arthroplasty (THA) using a stemmed femoral component has a decades-long history in the treatment of advanced degenerative joint disease of the hip. It has evolved through a number of bearing surfaces that include high-molecular weight polyethylene (PE), ceramics, and totally metal articulations. A number of metal-on metal (MoM) articulations using alloys of Co, Cr, and Mo were widely used in the 1960s (Dumbleton and Manley 2005). Due to mechanical problems, high acetabular loosening rates, and concern over possible biological reactions to metallic wear particles, the first-generation MoM prostheses were phased out in favor of metal-on-polyethylene (MoP) bearings. However, by the late 1980s, MoM bearings were reintroduced because the PE acetabular cup liner in MoP joints demonstrated a high amount of wear-generated debris that caused pain, osteolysis, and implant failure (MacDonald 2004). Ceramic-on-ceramic (CoC) bearings have also been used, and they demonstrate the lowest in vivo wear rates of any combination coupled with excellent lubrication properties. However, initial results in the U.S. limited to a CoC design that is now recognized as less than optimal were generally less than satisfactory than those with established MoP devices, and thus those CoC bearings were not subsequently used widely in the U.S. (Heisel et al. 2004). An in-depth comparison of various joint bearing combinations is beyond the scope of this Assessment, but a balance of relative benefits and potential is shown in Table 1 (Heisel et al. 2004).

Prosthetic joint durability and survival are outcome measures of key importance in evaluating any bearing couple. In older or less-active patients (>75 years), conventional THA using a modern MoM articulation may last for their remaining lifetime. Experience with first-generation MoM articulations is extensive, with joint survivorship of 71% to 85% over 10 to 28 years (Table 2). Although manufacturing problems led to abandonment of the technology used in first-generation articulations, many still function well after more than two decades without significant wear. However, optimal fit of the articulation and continued good function of first-generation articulations are now viewed as a being due to manufacturing tolerance variations among individual devices rather than to optimal design.

Since 1988, more than 300,000 of one second-generation THA device have been implanted (Dorr and Long 2005). A number of other devices are available as well. Published results with second-generation MoM implants suggest that the vast majority of patients experience pain relief and functional improvement over a follow-up of 2-9 years, as measured by a number of standard validated scoring systems (Table 3). Joint survival, measured by the revision rate, can be estimated at 93.5% to 98.7%, although some failures are due not to mechanical failure but may be secondary to dislocation. However, complications with these

Table 1. Risks and Benefits of Alternate Bearing Combinations for THA (adapted from Heisel et al. 2004)

Material	Benefits	Risks
Metal-on metal	– Very high wear resistance – Large diameters reducing wear – Long clinical experience	– Metal ion levels – Delayed-type hypersensitivity – Carcinogenesis
Cross-linked polyethylene	– High wear resistance – No toxicity – Relatively low cost – Multiple liner options	– Reduction in other material properties (material failure) – Bioactivity of wear particles
Ceramic-on-ceramic	– Highest wear resistance – No toxicity – Long clinical experience	– Position sensitivity – Liner chipping – Fracture risk

Table 2. First-Generation THA Joint Survivorship in Patients Younger Than 65 Years of Age (adapted from Dumbleton and Manley, 2005)

Study No.	Mn F/U (yrs)	Percent of Hips Surviving w/Revision as Endpoint	Total No. Hips in all Series	Mn Age at Surgery (yrs)
1	28	82	1,646	57–63
2	20	60		
3	14	85		
4	10	71		

Table 3. Outcomes of Selected Series of Second-Generation THA in Patients Younger Than 65 Years of Age

Study (Yr) [device]	No. Hips	Mn Age Yrs (rng)	Mn F/U Yrs (rng)	% Revised	Periop Comp (%)	Mean Percent Improvement from Baseline	
						HHS	MAP
Wagner and Wagner (2000) [Metasul]	78	49	5 (4–7)	1.3*	0	38.6/98.6 (255)	9.0/17.9 (99)
Kim et al. (2004) [Metasul]	70	37	7 (5–9)	2.9**	2 (2.9)	49/95 (94)	NR
Long et al. (2004) [Metasul]	161	56	6.5 (2–9)	3.7***	12 (7.5)	NR/98 (NR)	NR
Korovessis et al. (2006) [Sikomet]	217	55	6.4 (5–9)	6.5****	6 (2.8)	45/88 (96)	

HHS: Harris Hip Score; MAP: Merle d'Aubigne-Postel Score
* deep infection
** deep infection, 1 at 2 yrs, 1 at 4 yrs
*** 5 acetabular, 1 femoral; 2 due to pain and hypersensitivity, 1 recurrent dislocation, 1 infection, 1 liner disassociation
**** 9 aseptic loosening, 2 technical failure, 3 septic failure

devices are primarily mechanical in origin, with no proven biologic effects from metal particles or ions, such as carcinogenesis due to circulating cobalt ions (Visuri et al. 2006; Silva et al. 2005; MacDonald 2004). A suggestion that MoM implants may cause more pain than other articulations because of hypersensitivity to circulating and deposits of metal ions has not been confirmed in clinical studies (Learmonth et al. 2006; Dorr and Long 2005).

As modern surgical procedures evolved and restored near-normal quality-of-life to disabled patients, THA usage was extended to younger, more active patients. In these active patients, however, conventional joint durability became a significant issue with increased wear leading to earlier failure, necessitating a revision from a first to a second THA (McMinn et al. 2005). However, revision THA is a problematic, more difficult procedure than a primary operation. On average, revision THA is associated with significantly longer postsurgical hospital lengths of stay, higher rates of perioperative complications, unexpected surgical findings, and often a poorer prognosis than the primary procedure (Saleh et al. 2003; Mahomed and Katz 1996). Furthermore, management of surgical complications at THA revision often requires special instruments, implants, bone grafts, and other unanticipated materials or procedures (Barrack and Burnett 2006). Therefore, because of the substantial problems associated with revision THA, alternatives to first THA that would ameliorate such problems in younger, more active patients have been sought.

MoM Hip Resurfacing

The demand for hip arthroplasty in younger, usually more active, patients who would outlive the 10 or more years expected functional lifespan of a traditional THA, coupled with difficulties of revision THA, has led to a resurgence of interest in HR. This procedure retains the native femoral bone neck and head and typically removes less bone from the acetabulum than traditional THA, essentially replacing damaged cartilage and associated joint structures with articulating metal surfaces (Hodge and Fitts 2006; Treacy 2006; Beaule 2005). Modern alloys with improved manufacturing and machining processes have resulted in improved HR devices with larger diameter than previously available and better wear characteristics than earlier iterations, suggesting applicability to younger, more physically active patient groups. The surgical procedure for HR is viewed as more challenging than traditional THA, especially in the exposure and preparation of the femoral bone head and accessing the acetabulum without damaging adjacent nerves or the femoral head vasculature (Hodge and Fitts 2006). However, these problems have been addressed in an updated surgical procedure reported by a group of investigators who have substantial experience with HR (Amstutz et al. 2006). A list of suggested indications and contraindications for HR, based on current results and experience, has been proposed, as shown in Table 4 (Hodge and Fitts 2006).

Current Practice Guidelines

The United Kingdom's sNational Institute for Clinical Excellence (NICE) issued guidance on the use of HR in 2002 (http://www.nice.org.uk/pdf/HipResurfacing-FinalGuidance.pdf). The Institute recommends HR as one option for people with advanced degenerative joint disease of the hip who would otherwise receive and are likely to outlive the typical 10 or more years lifespan of a conventional THA device. They further recommend that surgeons con-

Table 4. Indications and Contraindications for HR

Indication	Contraindication
– Patients younger than 65 years who are likely to outlive a traditional THA – Patients with stable osteonecrosis I <30% of the femoral bone head – Patients with adequate proximal femoral bone stock and bone quality – Patients with minimal hip deformity	– Patients older than 75 years – Patients with impaired renal function or women of child-bearing age – Patients with rheumatoid arthritis, hip dysplasia of high Crowe types, and osteonecrosis with >40% femoral bone head involvement, or who may develop further osteonecrosis under the implant head – Patients with metal sensitivity or inability to clear metal ions due to underlying disease – Individuals who have or may have unrecognized osteopenia or osteoporosis

sider the activity level of potential recipients in the context of current evidence that is principally in individuals younger than 65 years of age. If appropriate, however, NICE recommends HR be performed only by surgeons who have been trained specifically in this technique and under the auspices of ongoing data collection as part of a U.K. national joint registry. Patients should be apprised that less is known about medium- and long-term safety and reliability of HR or the likely outcome of revision surgery than for conventional THA, with complete informed consent.

FDA Status. The Birmingham Hip Resurfacing (BHR) System was approved for marketing by the U.S. Food and Drug Administration (FDA) on May 9, 2006. The BHR system uses a cemented femoral head component and cementless acetabular component; it is intended for patients who require primary total arthroplasty due to advanced degenerative joint disease and who, due to relatively younger age or increased activity level, may be expected to outlive a traditional prosthesis.

Two other Class B, non-experimental devices are available under investigational device exemption. The Cormet Hip Resurfacing System (Corin Medical) was deemed approvable with conditions by an FDA Advisory Panel February 22, 2007. The Conserve® Plus Total Resurfacing Implant (Wright Medical Technology) may be considered for approval in 2007.

Methods

Search Methods

The MEDLINE® database was searched (via PubMed) through January 2007 using the search string "(resurface OR resurfacing) AND (hip OR hips OR acetabulum OR acetabular)." Text searching in EMBASE was performed using the same strings. The search was limited to full-length, English-language citations involving human subjects. In addition, bibliographies of key articles were reviewed for relevant citations. Recent review articles and systematic reviews were obtained to provide background material and comparative data for THA. Unpublished materials on the Birmingham Hip Resurfacing System were obtained from the FDA website (http://www.fda.gov/cdrh/pdf4/p040033.html). Australian Orthopedic Association (AOA) Joint Registry data were obtained from the AOA website (http://www.aoa.org.au/docs/njrrrep06.pdf).

Study Selection

Prospective, comparative clinical trials with random allocation of well-defined patient samples (randomized, controlled trials, RCTs) to HR versus THA are the best means to directly compare clinical outcomes with these technologies. In the absence of RCTs, results from quasi-experimental trials using concurrent controls or consecutive series that provide sufficient detail of patient demographics and time-course outcome data can be used to evaluate the safety and efficacy of HR.

For this Assessment, studies will use a HR device and provide data on clinical outcomes (benefits or harms). Primary outcomes are joint durability and subsequent revision to THA. Other relevant outcomes include pain, function, and perioperative complications. In addition to published, peer-reviewed data, information available from the FDA on a HR device will be considered in evaluating this technology. Selected study reports, systematic reviews, meta-analyses, and consensus or position papers of relevant organizations will be used to provide background and summary comparative information on THA.

Medical Advisory Panel Review

The Blue Cross and Blue Shield Association Medical Advisory Panel (MAP) reviewed this Assessment on February 21, 2007. In order to maintain the timeliness of the scientific information in the Assessment, literature search updates were performed subsequent to the Panel's review (see "Search Methods," above). If the search updates identified any additional studies that met the criteria for detailed review, the results of these studies were included in the tables and text where appropriate.

Formulation of the Assessment

This Assessment will evaluate available evidence on the benefits and harms of HR as an alternative to THA in patients for whom a total hip replacement is indicated but who are likely to outlive a total prosthesis. The relative durability of the HR joint and need for subsequent revision to THA are the most important, objective endpoints. The Assessment will also consider symptomatic and functional improvement, and complications.

Patient Indications

Total hip replacement is indicated for reduction or relief of pain and to improve hip function in skeletally mature patients with the following conditions:

- non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- inflammatory degenerative joint disease such as rheumatoid arthritis; correction of functional deformity; and,
- revision procedures where other treatments or devices have failed.

HR has been proposed as an alternative to THA for patients in whom THA is indicated and who are likely to outlive the 10 or more years functional lifespan of a traditional prosthesis.

Technologies to be Compared

A. HR using hybrid fixation
   1. Birmingham Hip™ Resurfacing (BHR) System has received FDA marketing approval
   2. Two other MoM products are under investigation in the U.S. for HR:
      a. Conserve® Plus (IDE)
      b. Cormet 2000™ (deemed approvable with conditions by FDA on February 22, 2007)
   3. Other devices available worldwide but not in the U.S. will be mentioned briefly in the background but will not be evaluated.

B. THA using hybrid fixation of any current generation prosthesis

Health Outcomes

Benefits. Symptomatic relief, primarily pain, and functional improvement are the primary health benefits expected from this procedure. Improvement in those outcomes can be expected to enhance quality of life and permit return to vocational, recreational, and social function. Because HR is bone-conserving, subsequent revision of a resurfaced joint to THA is not operationally different from a primary THA. HR is intended as a means to “buy time” for younger recipients who would outlive a traditional prosthesis, thus permitting a later simpler revision from HR to THA, which can be considered a health benefit in itself because it avoids the more difficult THA to THA revision and its associated poorer outcomes.

Harms. Harms include perioperative complications such as infections and pulmonary embolism (PE), fracture and prosthetic dislocation. Joint failure may result from prosthetic loosening secondary to osteolysis caused by inflammatory reaction to wear particles in the joint space; deep infection; and, fracture secondary to stress shielding. Adverse effects (toxicity, carcinogenicity, teratogenicity) of metal ions released by joint wear have been postulated with the use of MoM bearing surfaces.

Specific Assessment Question

Does HR improve health outcomes, such as pain, joint function, revision rates, and perioperative complications among patients with DJD who require hip replacement and are likely to outlive a traditional prosthesis, compared with THA?

Review of Evidence

Randomized Clinical Trial of HR versus THA

One RCT that compared HR with THA was identified in the published literature search (Vendittoli et al. 2006). Table 5 shows that patients in this RCT were younger (mean age 49–51) than those who traditionally have undergone THA. The sample comprised more men (63–68%) than women. Three-quarters of entrants had advanced osteoarthritis (OA). Their body mass index (BMI) ranged from 17-49 kg/m^2, with a statistically significant difference between groups (THA > HR group). The HR device used is not approved for marketing in the U.S., although it is available in the EU and elsewhere and is technically equivalent to currently available devices. This RCT was of “fair” quality according to criteria adapted from the USPSTF, primarily because the report did not provide details on intention-to-treat or other statistical analysis, clinical outcomes evaluations were not reported as masked, nor was any information provided on allocation concealment. Details of the study design, other patient characteristics, study inclusion and exclusion criteria, and outcomes are provided in Appendix Tables B and C.

Table 6 shows key clinical findings from this RCT. At 12 months’ follow-up, only 2 patients (1.9%) required revision of the resurfaced hip to traditional THA, both for femoral head aseptic loosening at 6 and 9 months after implantation. One case of THA (0.98%) required revision because of recurrent dislocation secondary to a malpositioned acetabular component. No femoral bone neck fractures were reported. Both functional outcomes measures, the WOMAC functional score (Bellamy et al. 1988) and Merle d'Aubigne Postel score (d'Aubigné and Postel 1954) showed substantial improvement from the preoperative status, with no difference between the mean values for each group. It is possible the scores achieved by these young and active patient cohorts might cause a ceiling effect such that, if most obtain near maximal scores, it would be difficult to demonstrate a difference between groups. However, the more specific UCLA activity score (Amstutz et al. 1984) was significantly higher in the HR group than the THA group (p=0.037) suggesting a superior outcome for HR. Patient satisfaction was very high in both groups with 98% very satisfied or satisfied.

While the clinical benefits of HR appeared nearly identical to those of THA, significant differences were observed in several perioperative results (Table 7).

The average surgical time was significantly longer in the HR group than in the THA group (p<0.001). A significantly longer surgical incision was required for HR than for THA (p<0.001). However, the mean hospital length of stay was shorter for HR patients (5.0 days) than for THA patients (6.1 days). The incidence of complications was not significantly different in the HR group compared to the THA group (p=0.151). Two cases of deep vein thrombosis occurred in each group, and 2 deep infections without recurrence were noted in the THA subjects. There were no significant intergroup differences in mean total blood loss or transfusion rate.

Table 5. Patient Characteristics of Vendittoli et al. (2006)

Group	Prosthesis	No. hips	F/U %	Mn age (yrs)	% M	% F
HR	DUROM™	107	96	49	63	37
THA	Zimmer	103	99	51	68	32

Table 6. Clinical Outcomes at 12 months follow-up, from Vendittoli et al. (2006)

Group	% Revised	Femoral Neck Fractures	Postoperative Functional Improvement* WOMAC	Merle d'Aubigne Postel	UCLA Activity Score**
HR	1.94	0	82%	55%	7.1
THA	0.98	0	79%	63%	6.3

* Improvement relative to mean preoperative score; WOMAC: Western Ontario McMaster osteoarthritis index
** p=0.037

Table 7. Perioperative Characteristics and Complications, from Vendittoli et al. (2006)

Group	Mn Surgical Time in min (rng)*	Mn Incision Length in cm (rng)*	Mn LOS (days)**	Complications*** All (%)	DVT (%)	Infec (%)	Blood Loss mL (rng)	% Transfused
HR	101 (61–185)	17.2 (103–300)	5.0	7	2 (1.9)	0	524 (100–2,200)	4.7
THA	85 (50–155)	14.5 (60–352)	6.1	13	2 (1.9)	2 (1.9)	482 (100–3,300)	9.7

* p <0.001; ** p<0.01; *** NSD in any complication or overall

Published Noncomparative Series of HR

Twelve published series reported clinical outcomes of HR, as shown in Table 8. Full details are summarized in Appendix Tables C-E. Studies were performed beginning in 1994, some ending in 2005. Three used the only device approved for marketing by FDA, the Birmingham Hip Resurfacing System (Back et al. 2005; DeSmet 2005; Treacy et al. 2005). A total of 2,076 patients, 71% male, with mean age range from 34 years to 57 years, were enrolled in the studies. Advanced OA comprised about 80% of all cases, but there were some differences in diagnosis among a few studies. One study enrolled patients who had femoral head osteonecrosis (FHON) (Revell et al. 2006). A second study included an even mix of OA and FHON (Mont et al. 2006). A third group included OA, FHON, and developmental hip dysplasia as the prominent diagnoses (Beaule et al. 2004). The proportion of enrolled patients available at follow-up ranged from a low of 22% (Siebel et al. 2006) to 100% (Back et al. 2005; Revell et al. 2006; Daniel et al. 2004) with most reporting 90–100%. Generally, mean follow-up duration was around 3 years, but ranged from less than 1 year (Siebel et al. 2006) to 12 years (Revell et al. 2006). Proportions of patients available at discrete follow-up points were not explicitly provided in most reports.

Revision and Femoral Neck Fracture after HR. Table 8 shows that among a total 2,076 individuals who underwent HR, 57 (2.7%) required revision to a THA during the follow-up period. The proportion of cases that required revision in the 12 series ranged from 0.3% over 3 years (Daniel et al. 2004) to 8.3% over 6 years (Revell et al. 2006). One study reported a revision rate of 22% over 4 years, although this result appears to be an outlier and not consistent with the others (Cutts et al. 2005). Revision was typically performed because of femoral bone neck fracture (FNF) or component loosening, as shown in Appendix Table D. In one study of 300 hip resurfacings, revision rates for all reasons appear to follow a steep learning curve, with revision rates of 5% for the first 100 cases, decreasing to 2% in the next 100 and to 1% for the last 100 patients (Siebel et al. 2006). Other investigators dispute this, based on a national review of 3,397 BHR cases performed in Australia (Shimmin and Back 2005). Among these cases, a total of 50 FNF requiring revision to THA occurred, an incidence of 1.46%. Overall, FNF occurred an average of 15.4 weeks (0-56 wks) postsurgery; women fractured at a mean of 18.5 weeks (range 0-56 wks) and men at 13.5 weeks (range 1-56 wks). No relationship was discerned between the experience of the surgeon and the time in their series when a fracture occurred. All fractures were treated by revision to THA. An additional 12 revisions were performed for malposition of the acetabular component, 4 for aseptic loosening, 2 for infection, and 1 for presumed metal hypersensitivity. Overall, this series had a revision rate of 2.01%, similar to other series results.

Symptomatic and Functional Outcomes of HR. Postoperative clinical improvement was scored using several different measures that included the Harris Hip Score (Harris 1969), SF-12 questionnaire (Ware et al. 1995), Oxford Hip Score (Dawson et al. 1996), UCLA activity score (Amstutz et al. 1984) and range of motion (ROM). Preoperative and postoperative data are provided in raw form in Appendix Table E, converted to percent improvement for display in Table 8. Little consistency is evident between the reports in terms of outcome measures used. Nonetheless, the aggregate data available suggest that HR patients who did not require a revision during the follow-up period realized substantial symptomatic improvement of pain and hip function compared with their preoperative status. Moreover, HR patients have been reported to return to significant activity levels. In one study, 87% of 369 HR recipients played a sport after implantation, including 62% with a unilateral and 51% with bilateral procedures who reported participating in impact sports (Daniel et al. 2004). Among women in this study, about one-third played a sport postsurgery, and among the entire study about 59% participated in these activities more than twice weekly and 24% did so at least twice weekly. Another group reported that among a total of 130 cases, 90% of HR patients were playing a sport after surgery and 85% were employed at 5 years of follow-up (Treacy et al. 2005).

Patient Selection. Appropriate patient selection has been identified as a key factor for the success of HR. Several independent patient characteristics have been correlated with premature joint failure in patients who are 40 years of age or younger, expressed as a surface arthroplasty risk index (SARI) (Beaule et al. 2004). Application of SARI is intended to optimize patient selection and to predict implant survivorship. As shown in Table 9, with this system, a score greater than 3 was correlated with a 12-fold increased risk of early failure or

Table 8. Published Uncontrolled Studies of HR*

Study (Yr) [Device]	No. Pts. (hips)	Mn Age (yrs)	Mn F/U (yrs)	% F/U	% Revised at F/U	% FNF at F/U	Postoperative Improvement from Baseline*				
							HHS	SF-12	OHS	UCLA	ROM
Back et al. (2005) [BHR]	230	52	3	100	0.4	2.2	Charnley A:* 55% Charnley B: 77% Charnley C: 32%	SF-12 Physical Charnley A: 74% Charnley B: 80% Charnley C: 53% SF-12 Mental Charnley A: -2.9% Charnley B: - 4.6% Charnley C: 7.1%	NR	NR	Flexion 21%
De Smet (2005) [BHR]	252 (268)	50	2.8	99	1.2	0.4	> 60%	NR	NR	NR	NR
Treacy et al. (2005) [BHR]	130 (144)	52	Min 5	74	2.3	0.7	NR	NR	NR	NR	NR

Table 8. Published Uncontrolled Studies of HR* (cont'd)

Study (Yr) [Device]	No. Pts. (hips)	Mn Age (yrs)	Mn F/U (yrs)	% F/U	% Revised at F/U	% FNF at F/U	Postoperative Improvement from Baseline*				
							HHS	SF-12	OHS	UCLA	ROM
Mont et al. (2006) [Cons]	77 (84)	42	3.4	94	5	3.9	OA grp: 60% ON grp: 75%	NR	NR	NR	Flexion: OA grp 45% ON grp 42% Abduction-adduction in extension: OA grp 97% ON grp 46% Rotation arc in extension: OA grp 55% ON grp 36%
Schmalzried et al. (2005) [Cons]	79 (91)	48	2.6	93	1	0.0	94	NR	NR	91%	NR

Table 8. Published Uncontrolled Studies of HR* (cont'd)

Study (Yr) [Device]	No. Pts. (hips)	Mn Age (yrs)	Mn F/U (yrs)	% F/U	% Revised at F/U	% FNF at F/U	Postoperative Improvement from Baseline*				
							HHS	SF-12	OHS	UCLA	ROM
Amstutz et al. (2004) [Cons]	355 (400)	48	3.5	99	3.4	0.9		SF-12 Physical: 60% SF-12 Mental: 13%	NR	Pain: 271% Walking: 60% Function: 65% Activity 71%	Flexion: 43% Abduction-adduction in extension: 229% Rotation arc in extension: 398%
Beaule et al. (2004) [Cons]	83 (94)	34	3.0	98	3.6	1.2	NR	SF-12 Physical: 58% SF-12 Mental: 14%	NR	Pain: 293% Walking: 209% Function: 57% Activity: 29%	Flexion and extension: 46% Abduction and adduction in extension: 242% Rotation in extension: 369%
Daniel et al. (2004) [Cons]	384 (446)	48	3.3	100	0.3	0.0	NR	NR	NR	NR	NR
Revell et al. (2006) [Cor]	60 (73)	43	6.1	100	8.3	0.0	NR	NR	NR	NR	NR

Table 8. Published Uncontrolled Studies of HR* (cont'd)

Study (Yr) [Device]	No. Pts. (hips)	Mn Age (yrs)	Mn F/U (yrs)	% F/U	% Revised at F/U	% FNF at F/U	Postoperative Improvement from Baseline*				
							HHS	SF-12	OHS	UCLA	ROM
Cutts et al. (2005) [Cor]	60 (65)	56	4.2	98	22	9.4	NR	NR	NR	NR	NR
Lilikakis et al. (2005) [Cor]	66 (70)	52	2.4	91	3	0.0	Pain: 228% Function: 52%	NR	NR	NR	NR
Siebel et al. (2006) [ASR]	300 (NR)	57	202 ± 155 days	78 (satisfaction) 22 (health outcomes)	2.7	1.7	102%	NR	NR	52%	NR

* Unless noted, the majority of cases had OA (osteoarthritis); FNF: femoral neck fracture; F/U: follow-up; ON: osteonecrosis; ROM: range of motion
Charnley category: A: affected 1 hip; B and C: both hips or other conditions impeding mobility
HHS: Harris Hip Score: 0–100, higher score is better
OHS: Oxford Hip Score: 12–60, higher score is worse
SF-12: 12–60, higher score is better
UCLA: UCLA Activity Score: 0–10, higher is better

adverse radiological changes. In another study of 400 HR cases, among individuals with a SARI greater than 3, joint survivorship was 89% (95% CI: 80–98) at 4 years, compared with 97% (95% CI: 94–100) among those who had a SARI of 3 or less (Amstutz et al. 2004).

Smith & Nephew PMA Submission to FDA

One HR device, the Birmingham Hip Resurfacing (BHR) System (BHR System), received FDA marketing approval in May 2006. The premarket application submission for the BHR System describes results achieved with this device in a large series of patients treated by one surgeon in Birmingham, England, and is available at the FDA website (http://www.fda.gov/cdrh/pdf4/p040033b.pdf).

The objective of the clinical data series was to demonstrate the safety and effectiveness of the device. The safety assessments included data on revisions, adverse events, deaths and a metal ion literature review. The effectiveness assessments included survivorship and radiographic data, pain and function data as evaluated by the Oswestry-modified Harris Hip (OSHIP) Score, and patient satisfaction data. The BHR System was implanted in a total of 2,385 hips (Overall McMinn Cohort) by a single investigator (McMinn). McMinn performed his surgeries at the Birmingham Nuffield and Little Aston Hospitals, Birmingham, U.K. from July 1997 through May 2004. The 2,385 procedures were divided into the following three main cohorts for the purposes of data analysis:

- X-ray cohort: First 124 BHR cases performed from July 1997 through December 1997.
- Oswestry cohort: Next 1502 BHR cases performed from January 1998 through March 2002.
- McMinn cohort: Next 759 BHR cases performed from April 2002 through May 2004.

For the safety and effectiveness analysis, data from these cohorts were pooled into two combined cohorts, the Overall McMinn Cohort (n=2,385 hips), and the X-ray/Oswestry Combined Cohort (n=1,626 hips). Unpublished data on 3,374 hips implanted by 140 surgeons and published reports from the experience of multiple surgeons implanting over 3,800 hips supported the safety and effectiveness of the BHR System (“Worldwide Cohort”).

As presented in Table 10, patients in the McMinn Cohort were 71% men and 29% women, ages 13–86 years (average 53 years). The primary diagnosis was osteoarthritis in 75%, dysplasia in 16%, avascular necrosis in 4%, inflammatory arthritis in 2%, and “other” in 3%. Detailed demographics of the Worldwide Cohort were not provided in the PMA submission, but were reported as comparable.

In the McMinn Cohort, at 5 years of follow-up, 27 revisions to THA were performed for reasons shown in Table 10. FNF was the most common reason for revision. Factors that may have contributed to FNF include age-related osteopenia (2 patients), poor preoperative bone quality as evidenced by cysts in the femoral bone head and acetabulum (1 case), systemic lupus erythematosus (SLE) (1 case), severe rheumatoid arthritis (RA) (1 case), infection that led to bone death (1 case), femoral head cysts (1 case), and malpositioned component (1 case). The 9 cases with femoral head collapse included 6 primary femoral head collapses, 2 due to infection and 1 due to AVN. Factors that may have contributed to the femoral head collapse include infection (2 cases), AVN (2 cases), femoral head cysts and soft bone (3 cases), osteopenia (1 case), and 1 unknown. Other adverse events in the McMinn Cohort included non-device and non-procedure related adverse events, such as dizzy spells, rashes, illnesses, ankle fracture, prostate cancer, or other pre-existing medical conditions. Table 10 shows the Worldwide Cohort experienced a total of 76 revisions at 5 years follow-up, for a rate of 2.26%. Reasons for revisions were similar to those in the McMinn Cohort. Other complications of HR were not explicated in the PMA Summary.

The Oswestry-Modified Harris Hip Score (OSHIP) was developed by the Oswestry Outcomes Center by combining elements of both the Harris and Merle d’Aubigne Postel scores. The OSHIP produces an overall index score similar to that of the Harris score between 0 (worst) and 100 (best). Both the OSHIP and Harris Hip Score (HHS) are made up of the three domains of pain, function, and hip movement, with function being further divided into gait (walking, limp, and distance), and activity (stairs, sitting, and transport). The main difference between the OSHIP questionnaire and the HHS is that the OSHIP permits patient assessments without physician

Table 9. Surface Arthroplasty Risk Index (from Beaule et al. 2004)

Risk Factor	Points
Femoral head cyst >1 cm	2
Patient weight <82 kg	2
Previous hip surgery	1
UCLA activity score > 6	1
	max 6

Table 10. BHR System Cohort Data from FDA Submission

Patients and Outcomes*	Overall McMinn Cohort		Worldwide Cohort	
Demographics				
– Hips	2,385		3,374	
– Men (%)	1,683	(71)	NR	
– Women (%)	702	(29)	NR	
– Mn age (rng)	53	(13–86)	52	(NR)
– Age ≤ 65 yrs (%)	2,191	(92)	NR	
– Dx OA (%)	1,789	(75)	3,070	(91%)
Follow-up				
– Years	3–5		5+	
– Percent available	> 90		NR	
Clinical Outcomes				
– Total no. of revisions (%)	27	(1.13)	76	(2.25)
FNF	10	(0.4)	34	(1.0)
Infection	8	(0.3)	7	(0.20)
Collapse femoral head	6	(0.25)	NR	
Dislocation	1	(0.04)	5	(0.15)
AVN	2	(0.08)	5	(0.15)
Loosening	NR		26	(0.77)
Pain	NR		3	(0.089)
Misc device failures	NR		3	(0.089)
Unknown	NR		3	(0.089)
5-yr joint survivorship % (95% CI)	98.5 (97.4–99.6%)		96.3 (NR)	
Percentage improvement in pain and function (OSHIP) scores at 5 yrs F/U	58**		58	

* AVN: avascular necrosis of femoral head; FNF: femoral neck fracture; F/U: follow-up; OA: osteoarthritis; OSHIP: Oswestry-modified Harris Hip Score
** X-ray/Oswestry Cohort n=1,626

or examiner evaluation. In addition, the OSHIP questionnaire does not include the three HHS questions regarding physician assessment of range of motion (5 points), absence of deformity (4 points), and the patient's ability to put on socks/tie shoes (4 points) but substitutes a "movement" question (13 points) that is intended for the patient to estimate their ability to flex the hip. Symptomatic and functional improvement reflected by OSHIP scores for the McMinn and Worldwide cohorts are shown in Table 10. The mean OSHIP Scores (unilateral procedures only) for the X-ray/Oswestry Cohort improved from a baseline mean of 60.1 to 94.8 (58%) at 5 years, identical to those of the Worldwide Cohort (58%).

A summary of literature publications were provided to the FDA pertaining to safety of the BHR System. In total, the studies demonstrate that serum and urinary metal ion concentrations in patients with total hip replacement in general, and MoM implants in particular, increase in the postoperative period. However, the data do not show any conclusive evidence that elevated cobalt and chromium levels have any significant detrimental effects in total hip arthroplasty patients. Finally, 20 patient deaths (26 procedures) occurred in the Overall McMinn Cohort. In no case was a death related to the BHR procedure.

Australian Orthopedic Association (AOA) National Joint Replacement Registry

The AOA Registry receives information from all Australian hospitals (public and private) undertaking joint replacement, currently numbering approximately 288 institutions. The 2006 Annual report is based on the analysis of a total 92,210 primary total hip replacement procedures. In this category of hip replacement were 84,872 primary conventional total hips and 7,205 MoM resurfacing, with a procedure date on or before December 31, 2005 (http://www.aoa.org.au/docs/njrrrep06.pdf). It should be noted that it is unclear whether or not these data are included in the Smith & Nephew PMA Worldwide Cohort. Nonetheless, the comparative findings versus THA are instructive.

In a subcomparison of HR and THA, gender and age differences were apparent. Resurfacing procedures were undertaken more frequently in males and younger patients than primary conventional THA. Primary conventional total hips were used more commonly in women (56% in 2005), with 65% undertaken in individuals 65 years or older. Resurfacing procedures were used most often in males (73% in 2005), with 90% of procedures undertaken in individuals younger than 65 years. At 5 years' follow-up, conventional total hips were revised less often than resurfacing procedures, (hazard ratio adjusted for age and sex: resurfacing versus conventional = 1.427 [95% CI: 1.184–1.720] (p=0.0002) (Table 11). It should be noted, however, that these figures do not necessarily reflect THA prostheses, nor are patient demographic characteristics available for comparison.

Discussion

Does HR improve health outcomes, such as pain, joint function, revision rates, and perioperative complications among patients with DJD who require hip replacement and are likely to outlive a traditional prosthesis, compared with THA?

One RCT is available in the published literature that compared HR with THA (n=210 hips) in patients under 65 years of age (Vendittoli et al. 2006). As shown in Table 12, symptomatic and functional health benefits of HR in this RCT were at least as good as those achieved with second generation THA, based on mean WOMAC, Merle d'Aubigne Postel, or UCLA hip scores 12 months after surgery. There were no statistically significant differences in revision rates or perioperative complications. Additional evidence from 12 published uncontrolled series (n=2,076 cases), the AOA Joint Registry (n=6,712 cases), and the Smith & Nephew PMA (n=5,759) shows that despite differences in measures used to assess outcomes, HR patients realized consistent, meaningful symptomatic and functional postsurgical improvements.

Indirect comparisons using HR data and results from uncontrolled series of THA suggest HR improves symptomatic and functional outcomes at least as well as THA over 5 years follow-up, with no substantial differences in revision rates, among patients younger than 65 years old who are likely to outlive the reported 10 years or more functional lifespan of a traditional prosthesis. Furthermore, because HR is a bone-conserving procedure that leaves the femoral bone head and neck largely intact, subsequent revision from HR to THA is likely to be less complicated and result in better outcomes than revision of a THA to a second THA. Thus,

Table 11. AOA Joint Registry Revision Rates of Conventional THA and HR

Type of Implant	No. Hips	No. Revised	% Revised
HR	6,712	148	2.2
THA	74,609	1,294	1.7

* data from 2001–2005; only patients with osteoarthritis, excluding revisions for infection

Table 12. Clinical Data Summary on HR and THA in Patients Younger than 65 Years Old

Data Source	No. Hips	Mean F/U Yrs (rng)	Mean % Revision (rng)	Clinical Improvement from Baseline Average Scores*	Perioperative Complications/ Adverse Events
Comparative HR Data					
RCT (Vendittoli et al. 2006)	107 HR 103 THA	1	1.94 HR 0.98 THA	82% HR 79% THA	7% HR 13% THA
AOA Registry HR THA	 6,712 74,609	 5	 2.2** 1.7	 NR	 NR
Uncontrolled HR Clinical Series					
12 Published Clinical Series	2,076	3 (< 1–12)	2.7 (0.3–22)	55–228%	5%
BHR PMA McMinn Cohort	2,385	3 (1–5)	1.13	58% (n=1,111)	8.5%
BHR PMA Worldwide Cohort	3,374	1–5	2.25	58%	NR
Selected THA Clinical Series* **					
1st-generation MoM	1,646	10–28	15–40	NR	NR
2nd-generation MoM	526	2–9	1.3–6.5	94–255%	0–12

AOA: Australian Orthopedic Association; BHR: Birmingham Hip Resurfacing System; HR: hip resurfacing; MoM: metal-on-metal; PMA: premarket approval application; THA: total hip arthroplasty
* Validated measures including Harris Hip score, Oswestry-Modified Harris Hip Score;
** $p < 0.01$ vs. THA
*** Primary series that provided clinical and health outcome data in patients younger than 65 years old

considering the evidence of equivalent symptomatic and functional outcomes at 5 years, and likely simpler revision of HR to THA, it is reasonable to conclude that the net health benefits obtained with HR outweigh its potential harms—those intrinsic to HR and those inherent to revision of THA.

Summary of Application of the Technology Evaluation Criteria

Based on the available direct and indirect evidence, the Blue Cross and Blue Shield Association Medical Advisory Panel made the following judgments about whether HR meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.

1. **The technology must have final approval from the appropriate governmental regulatory bodies.**

The Birmingham Hip Resurfacing (BHR) System was approved for marketing by FDA on May 9, 2006. It is a single-use device, intended for hybrid fixation, using a cemented femoral head component and cementless acetabular component, intended for use in patients who require primary HR arthroplasty due to:

- non-inflammatory arthritis (DJD) such as osteoarthritis, traumatic arthritis, avascular necrosis, or dysplasia; or
- inflammatory arthritis such as rheumatoid arthritis.

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

Two other Class B, non-experimental MoM hip resurfacing devices have received investigational device exemptions. The Cormet Hip Resurfacing System (Corin Medical) was deemed approvable with conditions by an FDA Advisory Panel February 22, 2007; a final FDA decision was not available at the time of this writing. The Conserve® Plus Total Resurfacing Implant (Wright Medical Technology) may be considered for approval sometime in 2007.

2. **The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.**

Evidence for the safety and efficacy of HR is available from more than 14,000 cases with mean follow-up times up to 5 years. Published series of THA using current-generation MoM prostheses (n=526) provide indirect evidence to compare HR and THA in patients younger than 65 years of age. Older series with longer follow-up of first-generation MoM THA (n=1,646) provide guidance on the potential durability of MoM prostheses. However, as the older series include prostheses that are outdated and no longer in clinical use, complications and revision rates may be overestimated and any comparisons must be viewed cautiously. Nonetheless, taken together, sufficient direct and indirect scientific evidence exists to permit conclusions about symptomatic and functional benefits of HR in properly selected patients for whom hip replacement is indicated.

3. **The technology must improve the net health outcome; and**
4. **The technology must be as beneficial as any established alternatives.**

Key Assessment Question: Does HR improve health outcomes, such as pain, joint function, and activities of daily living, among patients with DJD who require hip replacement and are likely to outlive a traditional prosthesis, compared with THA?

A single RCT with 1 year of follow-up provides good direct comparative evidence that HR improves the net health outcome and is as beneficial as THA in comparable patient samples. Additional data from uncontrolled series, the BHR FDA submission, and the AOA Registry, with indirect comparisons to THA, support these conclusions.

Thus, the total body of evidence outlined in this Assessment is sufficient in magnitude of change and consistency of direction to conclude that HR improves the net health outcome and is as beneficial as THA in properly selected individuals who require a total hip replacement and, because of younger age and/or higher activity levels, are likely to outlive the 10 years or more functional lifespan of a traditional prosthetic device. Because HR leaves the femoral bone head and neck largely intact, subsequent revision to THA is typically less complicated than a procedure to replace a primary THA. Therefore, based on published clinical experience with improved current generation MoM THA, and similar 5-year survivorship rates, HR represents a safe and effective means to defer a first THA in properly selected patients who require a total hip replacement and are subsequently likely to require replacement of the ipsilateral hip due to normal wear processes.

5. The improvement must be attainable outside the investigational settings.

Evidence for the safety and effectiveness of HR comes from a range of settings including the device designers and individual practitioners worldwide. An ongoing clinical training program for U.S. orthopedic surgeons is available from the manufacturer of the FDA-approved BHR System and its establishment was a condition of FDA marketing approval. Given this, it may be concluded that clinical benefits of HR will be attainable outside the investigational settings.

Based on the above, use of an FDA-approved metal-on-metal total hip resurfacing device as an alternative to THA in patients who are likely to outlive the 10 years or more functional lifespan of a traditional MoM prosthesis meets the TEC criteria.

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Appendix

Appendix Table A. Current MoM Total HR Systems

	Bearing		Acetabulum				Femur			
System (FDA status)	Process	Heat Treatment[a]	Diameters (mm)	Size Increment (mm)	Shape	Surface[b]	Diameters (mm)	Size Increment (mm)	Cement Mantle (mm)	Stem
Birmingham Hip Resurfacing System (BHR) Smith & Nephew (approved 2006)	Cast	None	44–66	2	Hemisphere	Co-Cr beads, cast in, ± HA	38–58	4	0	Not defined
Cormet Hip Resurfacing System (CHR) Corin Medical (Class-B, non-experimental, Investigational Device deemed approvable with conditions by FDA panel February 22, 2007)	Cast	HIP/SHT	46–64	2	Equatorial expansion	Ti, VPS, + HA	40–56	4	0 (cementless option)	Not defined

Appendix Table A. Current MoM Total HR Systems (cont'd)

	Bearing		Acetabulum				Femur			
System (FDA status)	Process	Heat Treatment[a]	Diameters (mm)	Size Increment (mm)	Shape	Surface[b]	Diameters (mm)	Size Increment (mm)	Cement Mantle (mm)	Stem
Conserve® Plus Total Resurfacing Implant (Cons) Wright Medical Technology (Class-B, non-experimental, Investigational Device, approval possible first half 2007)	Cast	HIP/SHT 46–64	2		Truncated hemisphere	Co-Cr beads, sintering, ± HA	36–54	2	1	± load bearing
ADEPT Hip System (AHS) Finsbury Orthopaedics (not approved)	Cast	None	44–66	2	Hemisphere	Co-Cr beads, cast in, ± HA	38–58	2	Minimum	Non-load bearing
Articular Surface Replacement (ASR) DePuy Orthopaedics (not approved)	Cast	HIP	44–70	2	Truncated hemisphere	Co-Cr beads, sintering, ± HA	39–63	2	0.5	Non-load bearing
DUROM™ (DUR) Zimmer (not approved)	Wrought-forged	None	44–66	2	Truncated hemisphere	Ti, VPS	38–60	2	1	Non-load bearing

Appendix Table A. Current MoM Total HR Systems (cont'd)

	Bearing		Acetabulum				Femur			
System (FDA status)	Process	Heat Treatment[a]	Diameters (mm)	Size Increment (mm)	Shape	Surface[b]	Diameters (mm)	Size Increment (mm)	Cement Mantle (mm)	Stem
ICON Hip Resurfacing (IHR) International Orthopaedics (not approved)	Cast	None	44–66	2	Hemisphere	Co-Cr beads, cast in, ± HA	38–58	4	0	Not defined
ReCap™, Biomet (not approved)	Cast	None	44–66	2	Hemisphere	Ti, VPS, + HA	36–54	2	0.5 (cementless option)	Not defined

a HIP, hot isostatic pressing; SHT, solution heat treatment
b HA, hydroxyapatite; VPS, vacuum plasma spraying

Appendix Table B. Design Characteristics of Vendittoli et al. 2006

Study (Yr)	Study Years	Trial Hypothesis	Fixation	Treatment Allocation	Inclusion Criteria	Exclusion Criteria	Outcome Measures	Follow-up Duration	Study Quality
Vendittoli et al. (2006)	August 2003 – January 2006	Improved short-term functional recovery favors HR when compared to THA	THA: uncemented femoral and acetabular components HR: cemented femoral, uncemented acetabular component	Prospective, block randomization for each of 3 surgeons	Age 18 to 65 years, with degenerative hip disease who were candidates for HR or THA	Proximal femoral deformity preventing HR, hip arthrodesis, renal insufficiency, known or suspected metal allergy, osteopenia or osteoporosis of the hip	Clinical function: WOMAC OA index, Merle d'Aubigne-Postel score, UCLA activity score Other outcomes: perioperative complications, dislocation and fracture rates, patient satisfaction, hospital LOS	Clinical function at 3, 6, and 12 months after surgery	Fair No mention of patient or evaluator masking, allocation concealment, ITT analysis

Appendix Table C. Clinical Outcomes of Vendittoli et al. 2006

Study (Yr)	Groups	Revisions (%)	Mn Age yrs (rng)	Mn BMI kg/m² (rng)	Dislocations (%)	Fractures (%)	Aseptic Loosening (%)	Mean WOMAC OA Index	Mean Merle d'Aubigne-Postel Score (max 18)	Mean UCLA Activity Score
Vendittoli et al. (2006)	HR	2/103 (1.9) Both for femoral head aseptic loosening, 6 and 9 mos	49 (23–64)	27.2 (17.6–44.9)	0	0	2 (1.90)	Preop: 52.6 3 mos: 19.9 6 mos: 13.9 12 mos: 9.2	Preop: 10.8 3 mos: 16.2 6 mos: 17.2 12 mos: 16.7	12 mos: 7.1 (p<0.037)
	THA	1/102 (0.99) For recurrent dislocation secondary to malpositioned acetabular component	51 (24–65)	29.6** (17.4–49.1)	2 (1.96) traumatic w/ out recurrence 1 (0.99) recurrent	0	0	Preop: 54.8 3 mos: 19.2 6 mos: 11.3 12 mos: 11.7	Preop: 10.2 3 mos: 15.8 6 mos: 17.1 12 mos: 16.6	12 mos: 6.3

Appendix Table D. Patient Characteristics of Uncontrolled Studies of Hip Resurfacing

Study (Yr) [Device]	Study Period	No. Pts. (hips)	Mn Age Yrs (range)	Sex (%)	Primary Dx* No. (%)	Mn BMI kg/m^2 (range)	Mn F/U Yrs (range)	No. Hips Available for Follow–up (%)
Back et al. (2005) [BHR]	1999–2001	230	52.1 (18–82)	M: 150 (65) F: 80 (35)	OA: 203 (88.3)	27.0 ± 4.2 (NR)	3 (2–4.4)	230 (100)
De Smet et al. (2005) [BHR]	Sept 1998–Apr 2004	252 (268)	49.7 (16–75)	M: 176 (70) F: 76 (30)	OA: 203 (80.6)	27.1 ± 4.3 (18.8–47.9)	2.8 (2–5)	249 (98.8)
Treacy et al. (2005) [BHR]	1997–1998	130 (144)	52.1 (17–76)	M: 107 (74) F: 37 (26)	OA: 125 (87)	NR	Minimum 5	107 (74)
Mont et al. (2006) [Cons]	Nov 2000–Nov 2003	77 (84)	42 (18–64)	M: 53 (69) F: 24 (31)	OA: 41 (53) FHON: 36 (47)	28.3 (18.8–42.9)	3.4 (2–5.1)	79 (94)
Schmalzried et al. (2005) [Cons]	Oct 2000–Dec 2004	79 (91)	48 (30–67)	M: 56 (71) F: 23 (29)	OA: 87 hips (95%)	27.3 (20.5–44.8)	2.6 (2–4)	85 (93)

Appendix Table D. Patient Characteristics of Uncontrolled Studies of Hip Resurfacing (cont'd)

Study (Yr) [Device]	Study Period	No. Pts. (hips)	Mn Age Yrs (range)	Sex (%)	Primary Dx* No. (%)	Mn BMI kg/m² (range)	Mn F/U Yrs (range)	No. Hips Available for Follow–up (%)
Amstutz et al. (2004) [Cons]	Nov 1996–Nov 2000	355 (400)	48.2 (15–77)	M: 259 (73) F: 96 (27)	OA: 262 (66)	M: 27.8±4.5 (19.2–46.4) F: 25.1±4.3 (17.5–42.3)	3.5 (2.2–6.2)	352 (99)
Beaulé et al. (2004) [Cons]	NR	83 (94)	34.2 (15–40)	M: 59 (71) F: 24 (29)	OA: 20 (24) Trauma: 15 (18) FHON: 15 (18) DHD: 16 (19)	NR	3.0 (2.0–5.6)	92 (98)
Daniel et al. (2004) [Cons]	1994–2001 (excluding 1996)**	384 (446)	48.3 (27–55)	M: 302 (79) F: 82 (21)	OA: 384 (100)	26±3.4 (NR)	3.3 (1.1–8.2)	384 (100)
Revell et al. (2006) [Cor]	June 1994–December 1996	60 (73)	43 (17–69)	M: 42 (70) F: 18 (30)	FHON: 60 (100)	NR	6.1 (2–12)	73 (100)
Cutts et al. (2005) [Cor]	Jan 1996–July 2002	60 (65)	56 (22–71)	M: 41 (68) F: 19 (32)	NR	NR	4.2 (3–9)	64 (98)

Appendix Table D. Patient Characteristics of Uncontrolled Studies of Hip Resurfacing (cont'd)

Study (Yr) [Device]	Study Period	No. Pts. (hips)	Mn Age Yrs (range)	Sex (%)	Primary Dx* No. (%)	Mn BMI kg/m² (range)	Mn F/U Yrs (range)	No. Hips Available for Follow–up (%)
Lilikakis et al. (2005) [Cor]	June 2001–July 2002	66 (70)	51.5 (23–73)	M: 37 (59) F: 29 (41)	OA: 64 (97)	26.3 ± 3.8 (19.8–37.2)	2.4 (2.0–3.2)	60 (91)
Siebel et al. (2006) [ASR]	Aug 2003–Apr 2005	300 (NR)	56.8 (18–76)	M: 192 (64) F: 108 (36)	OA	27.6 (19–41)	202 ± 155 days	234 (78) for satisfaction survey 66 (22) for health outcomes

DHD: developmental hip dysplasia; FHON: femoral head osteonecrosis; F/U: follow-up; NR: not reported; OA: osteoarthritis

Appendix Table E. Clinical Outcomes of Uncontrolled Studies of HR*

Study (Yr) [Device]	No. Hips at F/U (%)	Mn F/U Yrs (range)	Revision No. (%) Reason	FNF No. (%) Reason	Osteolysis No. (%)	FHON No. (%)	AVN No. (%)	Other Complications No.
Back et al. (2005) [BHR]	230 (100)	3 (2–4.4)	1 (0.4) Loose acetabular component	5 (2.2) 4 stress fractures	0 (0.0)	0 (0.0)	0 (0.0)	5 notched femoral neck 5 nerve palsy 3 vascular injury 11 superficial infection 9 UTI 11 DVT 2 PE 5 sinus tachycardia 14 hypotension 4 pressure sores
De Smet et al. (2005) [BHR]	249 (98.8)	2.8 (2–5)	3 (1.2) 1 FNF at 3 wks 1 AVN at 2 yrs 1 low grade infection at 2 yrs	1 (0.4)	2 (0.8)	1 (0.4)	1 (0.4)	1 each: DVT, PE, infection 2 sciatic nerve palsy 1 dislocation
Treacy et al. (2005) [BHR]	107 (74)		3 (2.3) 2 loosening due to deep infection 1 subcapital fracture due to deep infection	1 (0.7) Deep infection	0 (0.0)	1 (0.7)	1 (0.7)	NR

Appendix Table E. Clinical Outcomes of Uncontrolled Studies of HR* (cont'd)

Study (Yr) [Device]	No. Hips at F/U (%)	Mn F/U Yrs (range)	Revision No. (%) Reason	FNF No. (%) Reason	Osteolysis No. (%)	FHON No. (%)	AVN No. (%)	Other Complications No.
Schmalzried et al. (2005) [Cons]	85 (93)	2.6 (2–4)	1 (1.0) Femoral loosening	0 (0.0)	NR	NR	NR	33 acetabular radiolucencies
Amstutz et al. (2004) [Cons]	352 (99)	3.5 (2.2–6.2)	12 (3.4) 7 femoral loosening 3 FNF 1 recurrent subluxation 1 late hematogenous infection	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	3 dislocations 4 reoperations – 1 cup exchange from component mismatch, 2 removal heterotopic bone, 1 with trochanteric bursitis to remove wire
Beaulé et al. (2004) [Cons]	92 (98)	3.0 (2.0–5.6)	3 (3.6) 1 component loosening at 29 mos 1 FNF at 2 mos 1 subluxation at 50 mos	1 (1.2)	2 (2.0)	0 (0.0)	0 (0.0)	1 subluxation 1 socket exchange because of component mismatch 1 required surgery for trochanteric bursitis and nonunion
Daniel et al. (2004) [Cons]	384 (100)	3.3 (1.1–8.2)	1 (0.3) avascular necrosis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 PE

Appendix Table E. Clinical Outcomes of Uncontrolled Studies of HR* (cont'd)

Study (Yr) [Device]	No. Hips at F/U (%)	Mn F/U Yrs (range)	Revision No. (%) Reason	FNF No. (%) Reason	Osteolysis No. (%)	FHON No. (%)	AVN No. (%)	Other Complications No.
Revell et al. (2006) [Cor]	73 (100)	6.1 (2–12)	5 (8.3) 1 subtrochanteric fracture at 86 mos 1 acetabular fracture at surgery, revised at 3 mos 1 femoral head collapse at 69 mos 1 hematogenous infection	0 (0.0)	NR	NR	NR	7 Brooker class 1 (3), 2 (3), 3 (1) hetertopic ossification 15 notched femoral neck 1 DVT
Cutts et al. (2005) [Cor]	64 (98)	4.2 (3–9)	14 (22) 6 FNF at 1.5–17 mos 4 loosening of acetabular component at 48 hrs, 3, 4, 53 mos AVN at 13 mos Ongoing pain at 15 mos Deep infection at 6 mos	6 (9.4)	NR	NR	1 (1.6)	1 deep infection

Appendix Table E. Clinical Outcomes of Uncontrolled Studies of HR* (cont'd)

Study (Yr) [Device]	No. Hips at F/U (%)	Mn F/U Yrs (range)	Revision No. (%) Reason	FNF No. (%) Reason	Osteolysis No. (%)	FHON No. (%)	AVN No. (%)	Other Complications No.
Lilikakis et al. (2005) [Cor]	60 (91)	2.4 (2.0-3.2)	2 (3.0) 1 aseptic loosening at 15 mos 1 infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	16 intraoperative notching 1 cup displacement 1 PE 1 superficial infection 1 wound hematoma
Mont et al. (2006) [Cons]	79 (94)	3.4 (2-5.1)	4 (5) 3 FNF at 3, 18, 20 mos 1 Aseptic loosening of femoral component at 30 mos	3 (3.9)	NR	NR	NR	2 Brooker class IV heterotopic ossification 6 nonprogressive radiolucencies
Siebel et al. (2006) [ASR]	234 (78) for satisfaction survey 66 (22) for health outcomes	202 ± 155 days	8 (2.7) NR	5 (1.7)	NR	2 (0.67)	NR	NR

AVN: avascular necrosis; FHON: femoral head osteonecrosis; FNF: femoral neck fracture; F/U: follow-up; NR: not reported

Appendix Table F. Health Outcomes of Uncontrolled Studies of Hip Resurfacing

Study (Yr)	No. Hips at F/U (%)	Mn F/U Yrs (range)	Harris Hip Score	SF-12	Oxford Hip Score	UCLA Activity Score	Mean Range of Motion in Degrees (range)
Back et al. (2005) [BHR]	230 (100)	3 (2–4.4)	Charnley Category A:* Preop 63.0 Postop 97.7 Charnley Category B: Preop 56.2 Postop 99.4 Charnley Category C: Preop 64.8 Postop 85.5	SF-12 Physical Charnley Category A: Preop 31.1 Postop 54.1 Charnley Category B: Preop 30.0 Postop 54.1 Charnley Category C: Preop 31.5 Postop 48.2 SF-12 Mental Charnley Category A: Preop 58.6 Postop 56.9 Charnley Category B: Preop 60.5 Postop 57.7 Charnley Category C: Preop 52.2 Postop 55.9	NR	NR	Improved in all pts Mean flexion Preop 91.5 (25–130) Postop 110.4 (80–130)

Appendix Table F. Health Outcomes of Uncontrolled Studies of Hip Resurfacing (cont'd)

Study (Yr)	No. Hips at F/U (%)	Mn F/U Yrs (range)	Harris Hip Score	SF–12	Oxford Hip Score	UCLA Activity Score	Mean Range of Motion in Degrees (range)
De Smet et al. (2005) [BHR]	249 (98.8)	2.8 (2–5)	Preop all < 60 Postop 97.2 (41–100)	NR	NR	NR	NR
Treacy et al. (2005) [BHR]	107 (74)	5	NR	NR	At F/U: Median 2.1 Interquartile range 0–10.4	NR	NR
Mont et al. (2006) [Cons]	79 (94)	3.4 (2–5.1)	OA: Preop 57 Post op 91 Osteonecrosis: Preop 52 Postop 91	SF-12 Physical Preop NR Postop 51 (31–62) SF-12 Mental Preop NR Postop 56 (27–88)	NR	NR	Flexion: Preop 88 Osteo/84 OA Postop 125 Osteo/122 OA Abduction–adduction in extension: Preop 39 Osteo/31 OA Postop 57 Osteo/61 OA Rotation arc in extension: Preop 36 Osteo/33 OA Postop 49 Osteo/51 OA

Appendix Table F. Health Outcomes of Uncontrolled Studies of Hip Resurfacing (cont'd)

Study (Yr)	No. Hips at F/U (%)	Mn F/U Yrs (range)	Harris Hip Score	SF–12	Oxford Hip Score	UCLA Activity Score	Mean Range of Motion in Degrees (range)
Schmalzried et al. (2005) [Cons]	85 (93)	2.6 (2–4)	Preop 49 (27–63) Postop 95 (60–100)	NR	NR	Preop 4.3 (2–9) Postop 8.2 (4–10)	Flexion: Preop 35–125 Postop 80–160
Amstutz et al. (2004) [Cons]	352 (99)	3.5 (2.2–6.2)	Overall postop: 93.5 (41–100) Charnley Category A: 95.2 (61–100) Charnley Category B: 93.3 (66–100) Charnley Category C: 80.7 (41–100)	SF-12 Physical: Preop 31.2 (16.8–54.8) Postop 50 (17.6–62.7) SF-12 Mental: Preop 46.8 (4–68.5) Postop 53.1 (10.5–67.1)	NR	Pain: Preop 3.5 (1–8) Postop 9.5 (2–10) Walking: Preop 6.0 (2–10) Postop 9.6 (3–10) Function: Preop 5.7 (1–10) Postop 9.4 (3–10) Activity Preop 4.5 (1–10) Postop 7.7 (2–10)	Flexion: Preop 85.5 Postop 122 Abduction-adduction in extension: Preop 30.5 Postop 69.8 Rotation arc in extension: Preop 18.5 Postop 73.7

Appendix Table F. Health Outcomes of Uncontrolled Studies of Hip Resurfacing (cont'd)

Study (Yr)	No. Hips at F/U (%)	Mn F/U Yrs (range)	Harris Hip Score	SF–12	Oxford Hip Score	UCLA Activity Score	Mean Range of Motion in Degrees (range)
Beaulé et al. (2004) [Cons]	92 (98)	3.0 (2.0–5.6)	NR	SF-12 Physical: Preop 29.9 Postop 47.4 SF-12 Mental: Preop 44.8 Postop 51.1	NR	Pain: Preop 3.1 Postop 9.1 Walking: Preop 4.4 Postop 9.2 Function: Preop 5.8 Postop 9.1 Activity: Preop 5.5 Postop 7.1	Flexion and extension: Preop 79.5 Postop 116.2 Abduction and adduction in extension: Preop 28.9 Postop 70 Rotation in extension: Preop 20.2 Postop 74.5
Daniel et al. (2004) [Cons]	384 (100)	3.3 (1.1–8.2)	NR	NR	Mean score of surviving hips: 13.5	Activity: All pts who completed F/U had score ≥ 5	NR
Revell et al. (2006) [Cor]	73 (100)	6.1 (2–12)	NR	NR	NR	NR	NR
Cutts et al. (2005) [Cor]	64 (98)	4.2 (3–9)	NR	NR	NR	NR	NR

Appendix Table F. Health Outcomes of Uncontrolled Studies of Hip Resurfacing (cont'd)

Study (Yr)	No. Hips at F/U (%)	Mn F/U Yrs (range)	Harris Hip Score	SF–12	Oxford Hip Score	UCLA Activity Score	Mean Range of Motion in Degrees (range)
Lilikakis et al. (2005) [Cor]	60 (91)	2.4 (2.0–3.2)	Pain: Preop 12 (0–30) Postop 39.3 (0–44) Function: Preop 28.3 (3–42) Postop 43.1 (9–47)	NR	NR	NR	NR
Siebel et al. (2006) [ASR]	234 (78) for satisfaction survey 66 (22) for health outcomes	202 ± 155 days	Preop 44 ± 11 Postop 89 ± 13 (3 mos postop, n = 66)	NR	NR	Preop 4.0 ± 1.5 Postop 6.1 ± 1.2 (3 mos postop, n = 66)	NR

* Unless noted, the majority of cases had OA (osteoarthritis); F/U: follow–up; NR: not reported; ON: osteonecrosis; ROM: range of motion
Charnley category: A: affected 1 hip; B and C: both hips or other conditions impeding mobility
Harris Hip Score: 0–100, higher score is better
Oxford Hip Score: 12–60, higher score is worse
SF-12: 12–60, higher score is better
UCLA Activity Score: 0–10, higher is better

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