CALIFORNIA TECHNOLOGY ASSESSMENT FORUM®

METAL ON METAL TOTAL HIP RESURFACING AS AN ALTERNATIVE TO TOTAL HIP ARTHROPLASTY

A Technology Assessment

INTRODUCTION

The California Technology Assessment Forum is asked to review the scientific evidence for the use of metal on metal total hip resurfacing as an alternative to total hip arthroplasty in comparable patients.

BACKGROUND

Disease affecting the hip joint is usually caused by osteoarthritis (OA), the most common form of joint disease[1]. OA is chiefly a disease of aging; 90% of all people have radiographic features of OA in weight-bearing joints by age 40[2]. It is characterized by changes to the structure of the entire joint, particularly degeneration of cartilage and hypertrophy of bone at the articular margins[3]. The presenting symptom of osteoarthritis of the hip is generally pain, which may be associated with a limited range of motion; though pain in the hip may be referred from other regions of the body, referred to other structures (such as the knee) or may be confused with other etiologies such as trochanteric bursitis.[4]

Hereditary and mechanical factors may be involved in the pathogenesis of OA. Obesity is a risk factor for knee osteoarthritis and probably for the hip. Participation in competitive contact sports increases risk as do jobs requiring frequent bending and carrying; for example, farming carries a significantly increased relative risk for OA[5].

OA of the hip joint contributes to morbidity for the individual and costs to society. Overall, OA is the sixth leading contributor worldwide to total years lost to disability, or disability adjusted life years (DALYs)[5]. Individuals with hip OA may suffer from pain, stiffness and loss of function, adversely impacting their health related quality of life. The direct and indirect societal costs attributable to OA are enormous. For example, Individuals with OA are more likely to reduce work hours or take early retirement. Older adults with symptomatic arthritis report greater medical utilization and health care costs compared with people not reporting arthritis[6].

Rheumatoid arthritis (RA), an inflammatory arthropathy, may also lead to degeneration of the hip joint, but because it is a systemic condition is unlikely to affect the hip joint alone. Involvement of the hip joint in RA occurs in ten percent to 40% of individuals[1]. Other conditions that can cause secondary OA are

avascular necrosis, congenital dislocation, Pagets disease, anklyosing sponodylitis and traumatic arthritis.

Treatment for degenerative disease of the hip includes pharmacological and non-pharmacological measures, including lifestyle interventions. Analgesics such as acetaminophen and narcotics can treat the pain associated with the disease and improve function; non-steroidal anti-inflammatory medications, such as ibuprofen, can also be used and are more effective in more advanced disease but are less safe. Corticosteroid injections are a mainstay of treatment for OA and RA, though injections into the hip joint often need to be done under radiographic guidance[7]. Lifestyle interventions used to prevent or ameliorate the progression of OA include weight loss, exercise and physical therapy. Surgical interventions include arthroscopy, metal on metal (MoM) hip resurfacing arthroplasty (HRA) and total hip arthroplasty (THA). More than 168,000 total hip arthroplasties are performed annually in the United States[8] Approximately 50,000 total hip replacements are performed annually in England and Wales; the majority for OA of the hip (www.nice.org.uk).

METAL ON METAL HIP RESURFACING

Hip resurfacing is indicated for younger patients with end-stage OA of the hip or RA, traumatic arthritis, hip dysplasia or avascular necrosis for whom conventional total hip arthroplasty (THA) is not expected to last their lifetime. The concept of hip resurfacing dates back to 1923 when Smith-Petersen covered the femoral head with a cup made of Pyrex glass. In the 1950's the concept of resurfacing the arthritic socket, as well as the femoral head, emerged, but the material used (first Teflon and then methacrylate cement) and design flaws led to numerous device failures and adverse events, such as avascular necrosis[9] . The third generation of hip resurfacing emerged in England in the 1990s and currently there are at least nine different MoM hip resurfacing systems marketed or in clinical trials in North America, Europe and Asia; these include the Birmingham Hip Resurfacing System (BHR) manufactured by Smith & Nephew, Inc in the U.S., the Cormet Hip Resurfacing System (CHR), manufactured by Corin USA and marketed by Stryker and the Conserve Plus (Wright Medical Technology, Arlington, Tennessee). While most of these newer systems use MoM articulations with cobalt-chromium (Co-Cr) cementless acetabular fixation and cemented femoral fixation, there are differences in design and materials used so that a surgeon trained in one device will not generally use others[10]. To date, only the BHR and the CHR are FDA approved. Both of these systems use a MoM Co-Cr articulation and a hydroxyapatite powder coating for the acetabulum press fit. The number of hip resurfacing procedures had been steadily increasing in the US from an estimated 36,000 in 2005 to 45,000 in 2006[11].

While there are differences in materials and design, all hip resurfacing devices consist of two parts: a cup shaped acetabular component and a cemented femoral cap with a stem that inserts into the femur. Most surgeons prefer a posterior approach because it spares major and important muscle groups, but some will approach the hip anteriorly and a recent paper reports on the use of a minimal incision approach[12]. One surgeon describes his technique as follows[13]. After surgical dislocation of the hip and release of the capsule, the femoral head must undergo progressive cylindrical reaming to prepare for placement of the femoral head component. The femoral cap is placed over the smoothed femoral head and the metal cap is held in place with a small peg that fits into the bone. Care must be taken to avoid notching of the femoral neck which can lead to femoral neck fracture. The acetabulum is similarly prepared with a reamer to remove the cartilage. The acetabular component is held in place by friction until new bone growth can hold it in place (eOrthopod.com). Patients usually are given post-operative prophylactic antibiotics for one day and DVT prophylaxis. Walking commences on the first postoperative day and patients generally return to driving and work three to four weeks later. Low impact sports are permitted at three to four months[13]. Potential complications of the procedure include infection, femoral neck fracture, loosening or dislocation of the device, leg length inequality (this can be corrected for in THA) and deep venous thrombosis (DVT)[13].

The potential advantage of MoM hip resurfacing over THA is that is allows for most of the femoral head to be preserved and only replaces the surface of the joint; this maintains the femoral canal and makes revision surgery, if necessary, less complex[14]. However, one expert points out that the posterior approach favored in resurfacing devascularizes the femoral head, possibly permanently, potentially leading to avascular necrosis over time[15]. Preservation of the femoral canal may also result in less blood loss and decreased risk of fat emboli. Other potential advantages of hip resurfacing over THA include earlier return to function and less restriction on function compared to THA, reduced risk of leg lengthening (a major cause of malpractice claims following THA) and lower rate of dislocation[10], though this latter claim is called into question by some experts[16]. Hip resurfacing is considered by most to be a more challenging operation for the surgeon than THA and requires specialized training and a significant learning curve[11, 16, 17].

This assessment reviews the published peer reviewed literature to assess the safety and effectiveness of the two FDA approved devices, the Birmingham Hip Resurfacing System (BHR) manufactured by Smith & Nephew, Inc. and the Cormet 2000 manufactured by Corin, USA. The general literature on hip resurfacing and use of other devices has been reviewed and will be discussed when relevant, but there is sufficient heterogeneity among these devices that they should be assessed independently. In addition, as this

assessment can only consider published, peer-reviewed literature, while the manufacturer's PMA submissions to the FDA have been reviewed they cannot be considered in the assessment of the CTAF TA criteria.

TECHNOLOGY ASSESSMENT (TA)

TA Criterion 1: **The technology must have final approval from the appropriate government regulatory bodies.**

The Birmingham Hip Resurfacing (BHR) System (Smith & Nephew, Memphis TN) received FDA premarket approval (PMA) on May 9, 2006 with Conditions of Approval. These conditions include a study to evaluate longer-term safety and effectiveness of the BHR; a study to evaluate the learning curve, training program and longer-term safety and effectiveness of the BHR System in the US; to implement a training program and provide an analysis of adverse events and complaints.

The Cormet Hip Resurfacing System (Corin USA, Tampa, FL) received FDA PMA approval on July 3, 2007 with Conditions of Approval including two post-approval studies and implementation of a training program. One post-approval study is to be designed to evaluate the long-term safety and effectiveness of the Cormet Hip Resurfacing System; the second is to be designed to examine the performance of the Cormet Hip Resurfacing System under actual conditions of use. Adverse events are to be collected for both studies.

Expiration dating for both devices has been established and approved at five years.

TA Criterion 1 is met.

TA Criterion 2: **The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.**

The Medline database, Cochrane clinical trials database, Cochrane reviews database and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words "hip", "resurfacing", and "metal on metal" from 1966 to August 2007. The bibliographies of systematic reviews and key articles were manually searched for additional references. Abstracts of citations were reviewed and all relevant articles reviewed in full.

The peer-reviewed literature of the BHR and Cormet 2000 devices consists primarily of level five evidence, case series conducted at one site generally by a single surgeon. It is not possible to conclude from this research whether hip resurfacing is as safe or efficacious as total hip arthroplasty in comparable patients. A multi-center randomized clinical trial with adequate follow-up (level 1 evidence) is the gold standard for establishing the safety and efficacy of hip resurfacing compared with THA. Patients have been successfully recruited for two prior randomized clinical trials (RCTs) of hip resurfacing compared with THA[18, 19], and there are numerous examples of well designed RCTs that have evaluated new and emerging orthopedic technology [20, 21,22, 23]. A multi-site RCT of hip resurfacing using the BHR and/or Cormet 2000 devices versus THA in comparable patients is a feasible and necessary strategy to generate the evidence we need to reach conclusions regarding the safety and effectiveness of the technology regarding health outcomes.

While evidence from level 1 studies are the preferred basis for deciding whether CTAF criterion are met, in the absence of Level 1 studies, technologies may meet criteria if, overall, level 2-4 studies indicate that: 1) The technology provides substantial benefits to important health outcomes, and 2) the new technology has been shown to be *safer or more beneficial* than existing technologies. There is one published study[15] that retrospectively matched patients who had BHR with historical patients who had THA operated on by the same surgeon at the same institution (level 4 evidence). However, the patients were matched on only three domains (age, BMI and UCLA activity level), and no information was provided regarding the preoperative characteristics of the patients as to other clinical characteristics and indications for surgery, pain and quality of life. It is not clear how similar these two groups of patients truly were at baseline and therefore whether hip resurfacing was an equal or superior option for them.

Outcomes assessed in trials of hip resurfacing include cumulative device survival, adverse events and other clinical and patient centered outcomes that assess general joint specific pain, quality of life and activity level (e.g. Charnley, 1995[24]). Most studies rely on joint specific measures such as the Oxford hip score (OHS), the Harris Hip evaluation[25] and the Hip Disability and Osteoarthritis Outcome Score (HOOS). The OHS consists of 12 questions about pain and disability experienced over the past four weeks. Each item has five response categories, given a score of between 1–5 (low disability to high disability). Scoring involves adding the total for each item to produce a final score between 12–60, with a higher score indicating greater disability. In addition, many of the studies assess patients using the UCLA Activity Level Scale (see Table I).

Table 1. University College Los Angeles Activity Level Scale modified to include activities relevant to the patient population [26]

Modified UCLA Activity Scale

Level	*Activity*	*Examples*
1	Inactive	Wholly inactive. Dependent on others. Cannot leave residence.
2		Mostly inactive. Restricted to minimum activities of daily living.
3	Mild activity	Sometimes participates in mild activities such as walking, limited housework and shopping.
4		Regularly participates in mild activities. *Sedentary occupational work.*
5	Moderate activity	Sometimes in moderate activities such as swimming and can do unlimited housework or shopping.
6		Regularly participates in moderate activities. *Light occupational work.*
7	Active	Regularly participates in active events such as bicycling, *aqua-aerobics. Gardening or working out in the gym once or twice a week.*
8	Very active	Regularly participates in very active events such as bowling, golf. *Riding, hunting, aerobics. Gardening or working out in the gym three times per week or more. Moderately heavy occupational work. Farming.*
9	Impact sports	Sometimes participates in impact sports such as *running,* jogging, tennis, *cricket, baseball, rugby, football, hockey, racquet sports, judo, karate and other martial arts,* skiing, acrobatics, ballet dancing, backpacking and *mountaineering. Heavy occupational work.*
10		Regularly participates in impact sports as described above.

 Daniel J, Pynsent PB, McMinn DJ. Metal-on-metal resurfacing of the hip in patients under the age of 55 years with osteoarthritis. *J Bone Joint Surg Br.* Mar 2004;86(2):177-184.

Level of Evidence: 4, 5

TA Criterion 2 is not met for BHR or Cornmet 2000.

TA Criterion 3: The technology must improve net health outcomes.

Randomized Clinical Trials

There are no published RCTs of MoM hip resurfacing compared with THA that use the FDA approved BHR device or the FDA approved Corin device (Cormet 2000). There is one published RCT that compares MoM hip resurfacing using an earlier device manufactured by Corin Medical Ltd.; Gloucestershire, UK with THA[18]; this trial was stopped early because of a high incidence of device failure. In addition, there is one published RCT that compares a hip resurfacing device manufactured by Zimmer, Winterthur, Switzerland with THA[19]. Both of these studies will be discussed below.

Case Series

Nishii et al (2007) describe the results of 50 MoM resurfacing procedures on 45 Japanese patients between February 1998 and 2000[27]. Most patients (70%) had developmental dysplasia; only four percent had osteoarthritis without dysplasia. The average age at surgery was 51, with a range of 19 to 73 years. The device survival rate at five years was 96% and they report significantly improved pre- post- hip pain and function scores using the Merle d'Aubigne and Postel hip scores. The authors note that their results may not be generalizable to European/American patients given the unique indications for surgery in this population.

Back et al (2005) report on the results of the first 230 patients (150 men and 80 women) who received BHR at their center in Australia between April 1999 and June 2001[28] . Patients were offered BHR if they were active men under the age of 75 and active women under the age of 60 who otherwise met criteria for a THA (i.e. pain, limp and limitation in activities of daily living). All operations were performed by one of three surgeons at the center. Female patients were screened with bone density scans and were referred for THA if they had evidence of osteopenia or osteoporosis (i.e. T score < -1). Patients with renal insufficiency (not defined) were also excluded;

there were a number of other relative contraindications left to the discretion of the surgeon and patient. Patients were assessed with the Harris Hip score, the short form-12 score, the Charnley grades and with the Oxford hip score. Most patients had a preoperative diagnosis of OA. Mean age of patients was 52.1 years. Length of stay was 7.25 days. At a mean follow up of three years they report a 99.14% survivorship (one patient died of unrelated and unspecified causes, one patient required revision to THA due to a loose acetabular component). The Harris Hip Score improved from a mean of 62.54 (8-92) to 97.74 (61-100). Complications included post -operative hypotension in 14 patients, superficial wound infections (4.8%),

DVTs (4.8%), five nerve palsies, one femoral neck fracture, among others. They report that 22.9% were "clickers"—i.e. aware of a clicking feeling in their groin and 3.9% were "squeakers", isolated and self-limited episodes when picking up a heavy load or maximally flexed at the hip. Six patients had evidence of notching on post-operative radiograph; this is thought to be a precursor of femoral neck fracture. These results seem promising but are limited by a lack of comparison to contemporaneous or historical control patients.

Treacy et al (2005) report on a series of patients who underwent BHR performed by one surgeon between August 1997 and May 1998[29]. One hundred thirty patients were offered hip resurfacing; 11% received bilateral procedures. Mean age at operation was 52.1 years (17-76); they do not report on male/female. Four patients died from "unrelated" causes and were not included in further analysis. Three patients required revision to a THA secondary to deep infections and avascular necrosis. Of 107 hips available for radiographic follow up, 28% showed evidence of heterotopic ossification. (Heterotopic ossification is a process by which the soft tissues around the hip become ossified. It occurs when primitive mesenchymal cells in the surrounding soft tissues are transformed into osteoblastic tissue and eventually into mature lamellar bone. Heterotopic ossification is common after THA and when low grade is generally asymptomatic. Stiffness is the most common complaint; pain is rarely a problem.) Overall, they report a survival rate of 98% after five years. The lack of rigorously collected pre and post procedure outcomes limit the generalizabily of these findings.

De Smet (2005) report on the experience of a single surgeon in Belgium with BHR from 1998 to 2004[30]. They report on outcomes of the first 252 patients treated; they had a mean age of 49.7

years (16-75 years) and were 68.9% male. Mean duration of follow-up was 2.8 years. Three patients died of unreported causes and three additional patients required revision or reoperation. They report that at the most recent follow up, 97.8% of patients had "no pain" and 61% performed "strenuous activities". The Harris Hip Score averaged 97.24 (range 41-100) but there are no preoperative scores reported for comparison. They report that 19.4% experienced a clicking or clunking noise in the first six months after surgery, 1.2% reported transient squeaking and 2.8% had persistent slight groin pain. Other complications included nerve palsy with permanent foot drop in two patients, and other uncommon complications, such as DVT, in one patient and dislocation in another patient. The author concludes that: "Meticulous surgical technique and planning are the key factors to an excellent postoperative result". The lack of pre- and post-comparisons make it difficult to assess these findings.

In a retrospective matched cohort design, Pollard et al (2006)[15] compare clinical and radiological outcomes in two groups of 54 hips who underwent BHR or hybrid THA performed by a single surgeon between 1996 and 2001. Patients were matched for age at surgery within five years, gender, BMI and pre-operative activity level using the UCLA activity score. The mean age of the hybrid THA patients was 50.4 years and for BHR 49.8 years; mean BMI for THA was 27 kg/m^2 and BHR 25.7 kg/m^2 and the UCLA preoperative activity level was 8.9 points out of ten for the THA group and nine points for the BHR group. The groups appear similar but no statistical comparisons between the groups were performed. The THA had a revision or intent to revise rate of 8% compared with 6% in the BHR group. Both groups had excellent post-operative function. The Oxford hip scores were not significantly different while the mean UCLA activity score and the Euro QoL scores favored the BHR group. The UCLA activity score in the THA group declined post operatively while the BHR group remained the same; this is due to the fact that the THA group was advised to decrease their high impact physical activity post operatively so as to prolong the life of the prosthesis, so it is logical that the patients would have reported to the physician researchers that they had done so. Radiological outcomes were also reported and appear to be similar between the two groups. However, the authors report that several abnormalities on radiographs in the BHR group were noted that may eventually lead to device failure (e.g. pedestal signs in 60% of the BHR) and urge longer follow up. In addition, there was no preoperative assessment of quality of life or of the Oxford hip score so it is difficult to interpret the significance of these scores postoperatively.

Narvani et al (2006) report on a small uncontrolled study of sports activity following BHR. They surveyed 50 patients and 43 responded (86% response) with a minimum of six months of follow up[31]. With total hips as the unit of analysis rather than patients (eight patients had bilateral BHR) they conclude that there was a significant increase in sports participation following BHR.

Daniel et al (2004) report on the experience of one surgeon between 1994 and 2002 who carried out 446 resurfacing procedures on 384 patients (302 men) less than 55 years of age with OA of the hip[26]. From 1994 to 1996 he used the McMinn Resurfacing Hip Arthroplasty (Corin Medical Ltd., Cirencester, UK) and from 1997 to 2002 the BHR prosthesis was used . However, all 186 patients operated on in 1996 are excluded from this analysis as “a unique pattern of failure occurred in the implants used with high metal wear, metallosis and osteolysis . . . due to problems in their manufacture.” Mean follow up was 3.3 years. The mean age at operation was 48.3 years (26.8 - 54.9) Six patients died of “unrelated causes”. They report

that only one hip had to be revised due to avascular necrosis eight months after the operation (for a cumulative 99.8% survival). They report surprisingly few adverse events consisting only of one non-fatal pulmonary embolism. The problem with this and other similar studies is that they do not discuss how the patient's eligibility for hip resurfacing was assessed. It is not clear that these patients would have undergone THA if hip resurfacing had not been an option. In addition, UCLA activity levels and Oxford hip scores are not reported preoperatively; it is not possible to ascertain to what extent these improved without benefit of a pre- post- comparison.

DeSmet et al (2002) appears to be reporting on earlier results from the same cohort discussed above[30].

Cormet 2000 Case Series

Lilikakis et al (2005) report on their experience using hydroxyapatite coating as a means of fixation of the femoral head in hip resurfacing in 66 patients from June 2001 to July 2002 done by a single

surgeon[32]. They used the Cormet 2000 as the hip resurfacing device. Mean follow up was 28.5 months. Overall survival rate of the prosthesis was 97.1%. Clinically, the mean Harris hip scores for pain and function preoperatively were 12 (0-30) and 28.3 (3-42); postoperatively these increased significantly to 39.3 and 43.1 respectively. They report that four patients were dissatisfied with the outcome of the procedure. About one fourth of the hips demonstrated notching on radiographic follow up and 27% demonstrated neck thinning. While the clinical significance is not clear, they report that notching has been implicated in femoral loosening and fracture of the femoral neck and conclude that longer follow up is needed to interpret the clinical significance of neck thinning. Other researchers have also concluded that notching is a risk factor for femoral neck fracture[17]

Other Randomized Clinical Trials

Howie et al (2005) report on the results of an RCT of hip resurfacing and THA in patients 55 years of age and younger conducted between October 1993 and August 1995[18]. Patients were randomized intraoperatively to receive a THA or a MoM cemented low profile McMinn acetabular component and a mini stemmed McMinn femoral resurfacing component (Corin Medical Ltd.; Gloucestershire, UK) cast from cobalt/chromium. The trial was stopped after two years of recruitment due to a high failure rate of the hip resurfacing arm. At a median follow up of 8.5 years, eight of the 11 hip resurfacing devices had been revised to a THA. The authors conclude that: "The place of RHR (hip resurfacing) would best be determined

by way of randomized clinical trials to demonstrate it is as good or better than primary THR, which now has good mid- to long term results in young patients."

Vendittoli et al (2006) randomly assigned 210 hips to THA (CLS femoral stem and Allofit acetabular cup (Zimmer, Winterthur, Switzwerland) or a MoM hip surface replacement system (Zimmer, Winterthur, Switzwerland)[19]. They conclude that THA and hip resurfacing had similar patient satisfaction rates and overall similar complication rates but hip resurfacing led to better postoperative functional performance. Three revisions were performed during the study period (follow up was six to 40 months), one in the THA group and two in the hip resurfacing group.

Indications and Contraindications

According to the PMA application to the FDA for the BHR and the Cormet Hip Resurfacing System the indications for use of these devices includes patients who otherwise would be eligible for a total hip arthroplasty because of advanced:

1. Non-inflammatory arthritis such as osteoarthritis and avascular necrosis
2. Inflammatory arthritis such as rheumatoid arthritis
3. Traumatic arthritis and dysplasia/developmental dislocation of the hip (DDH) (in the BHR PMA only)

In addition, both manufacturers state that the hip resurfacing systems are "intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral hip joint revision."
Contraindications include:

1. Infection
2. Patients who are skeletally immature
3. Severe osteopenia or a family history of severe osteopenia/osteoporosis
4. Multiple cysts of the femoral head
5. Females of child bearing age due to unknown effects of metal ions on the fetus
6. Moderate to severe renal insufficiency (due to the concern about elevated serum metal ions accumulating more rapidly in patient with renal insufficiency and contributing to the decline in renal function)
7. Severely overweight

Adverse Events and Safety

According to the FDA Summary of Safety and Effectiveness data, the most commonly reported device related adverse events (AE) are: femoral neck fracture, femoral head collapse, infection, avascular necrosis, dislocation, component migration and impingement. In a national review of femoral neck fractures associated with 3497 BHRs implanted between 1999 and 2003, Shimmin and Back (2005) report an incidence of 1.46% with higher rates in women (1.91%) than men (0.98%)[33].

Another safety concern that has been discussed widely in the hip resurfacing literature is the issue of increased plasma ion levels caused by friction at the metal on metal interface[34 35-39]. With a MoM prosthesis, one expert reports that over a million micro-particles are generated with every step that the patient takes[14]. Chronic exposure to some metal ions such as chromium and cobalt, the metals used in both the BHR and the Cormet 2000 devices, has been associated with carcinogenicity, autoimmune disease and mutagenicity[38]. A recent review followed patients prospectively following unilateral hip resurfacing (BHR) and unilateral and bilateral total hip replacement. They found that patients with the BHR had a greater increase in serum chromium and cobalt compared with a 28- mm MoM THR[36]. Dumbleton and Manley (2005) review the results of approximately a dozen studies of metal ion release following MoM resurfacing[40]. They conclude that the general finding is that metal ions are increased when compared with other surfaces or un-operated individuals and that the levels of cobalt and chromium have been shown to exceed the regulatory norms in some patients. However, the adverse effects may be subtle, if they are present at all, and therefore may require follow up of 20-30 years in large numbers of patients to determine the level of risk[40]. Allan et al (2007) report on a prospective study designed to monitor serum cobalt and chromium levels following hip resurfacing with the Cormet 2000 device[35]. Serum levels were measured pre-operatively and then periodically up to three years out from surgery in 35 subjects. They found that subjects had significant increases in serum concentrations of Co and Cr with peak levels at one year; at three years, levels appeared to be trending down in the 16 patients tested but the differences were not statistically significant. In addition, a few “outliers” were identified with persistently elevated levels in whom the authors identified radiographic evidence of excessive cup tilt, a possible contributing factor. Overall, the long term health implications of the increased low level exposure to metal ions with regards to biological responses, hypersensitivity, mutagenicity and carcinogenicity is not clear but should be carefully monitored and reported in post marketing surveillance by the manufacturers, by the FDA and by independent investigators when possible. As hip resurfacing devices are intended primarily for younger patients, these patients may be exposed to elevated levels for many years increasing their risk of adverse effects.

In sum, the existing peer reviewed literature on hip resurfacing is limited primarily to uncontrolled case series with relatively short follow-up, representing the experience of a small number of orthopedic surgeons and institutions. While some of these early results are promising, the evidence to date does not support the conclusion that hip resurfacing using the devices currently approved by the FDA improves health outcomes according to CTAF criterion # 3.

TA Criterion 3 is not met for BHR or Cormet 2000.

TA Criterion 4: The technology must be as beneficial as any established alternatives.

Local and systemic analgesics and anti-inflammatories

Treatment of degenerative disease of the hip generally starts with analgesic or anti-inflammatory medication for mild to moderate disease. Patients with mild disease generally treat symptoms of pain and decreased mobility with acetaminophen (2–4 g/day). Non-steroidal anti-inflammatory drugs (NSAIDs) should be considered for patients who do not respond to acetaminophen; and are generally the drugs of choice for patients with more severe or inflammatory disease. They are more toxic, however, particularly in older patients where adverse effects such as renal and gastric toxicity can contribute to morbidity and mortality. For some patients, an intra-articular injection of steroids may obviate the need for NSAIDs or analgesics, though this strategy is best done with radiographic guidance in the hip.

Surgical Measures

When conservative treatment fails to alleviate hip pain and dysfunction, THA can provide significant pain relief and improve patient function and quality of life[8]. The indications for THA are incapacitating arthritis confirmed by the appropriate radiologic findings. Patients who have pain following activity, pain that awakens them at night, who are unable to walk more than a few blocks without stopping and who have difficulty climbing stairs, and whose pain is not controlled with medication are generally considered candidates for hip replacement[41]. In the United States, more than 170,000 total hip arthroplasties are performed annually, the most common indication is advanced osteoarthritis. Primary THA is generally not a high risk operation, with overall in hospital mortality less than one percent [42 8, 43]. Complications of THA include deep venous thrombosis, fracture or perforation of the femoral shaft, infection, instability (dislocation), heterotopic bone formation and nerve palsies[41]. Mahomed et al (2003) report that the rates of complications occurring within ninety days after primary total hip replacement were 1.0% for mortality, 0.9% for pulmonary embolus, 0.2% for wound infection, 4.6% for hospital readmission, and 3.1% for hip

dislocation[43].

Jones et al (2005) report "near perfect survivorship" (98%) at 10 years and 93% at 25 years for femoral component; acetabular component survival is 85-94% at 15 years.[44] Long term cohort studies and the Scandinavian hip registries demonstrate long survival after 20 years of follow up for primary THA, with revision rates between 2% and 8% over ten years [45, 46] [8]In general, patients report high satisfaction rates following THA, and more than 90% of patients are pain free at least ten to15 years postoperatively [47] Aseptic loosening, particularly of the acetabular component, has been the most common cause of failure of THA[48]. As cementless acetabular components have become standard of care, early and late failure rates have declined[49] .

Younger, more active patients place more stress on their prosthesis and historically have higher rates of revision arthroplasty[8]. Smith et al (2000) present the 20-year experience of 47 hips in 40 patients aged 50 years or younger with cemented primary THA using second-generation femoral cementing techniques[50]. Average follow-up duration in the 23 patients living at least 17 years was 18.2 years. Overall, 18 hips (38%) had components revised or removed for any reason, at an average duration of 12.6 years. Patients surviving at least 17 years without revision had sustained relief of pain and improved function. Callaghan et al (1998) evaluated the results twenty to twenty-five years after ninety-three consecutive, nonselected Charnley total hip arthroplasties performed with cement in sixty-nine patients who were less than fifty years old at the time of the procedure[51]. Seventy of the seventy-two hips in the living patients were followed radiographically for at least twenty years. Twenty-seven hips (29 percent) had a revision or a resection of the prosthesis during the follow-up period. The revision or the resection was performed because of aseptic loosening in twenty-one hips (23 %), infection in four (4 %), dislocation in one (1%), and fracture of the femur in one. They conclude that this study demonstrates the long-term durability of total hip arthroplasty performed with cement in an active population of patients. These results are likely to improve as THA techniques continue to evolve.

Revision Total Hip Arthroplasty

Revision THA is a more complex procedure than primary THA and has more short term complications, higher rates of unexpected findings and higher rates of failure when compared with primary THA[42, 43, 52]. Hip resurfacing has been suggested as a preferable option for younger and more active patients who would otherwise qualify for a THA because these patients are more likely to outlive their primary prosthesis and the clinical success of revision THA procedures historically has been inferior to the results of primary

THA. A potential advantage of hip resurfacing is that since it allows for more bone preservation, it would improve outcomes for revision hip arthroplasty when hip resurfacing eventually fails; however currently there is no solid data to support this claim. (Some experts argue that in fact more acetabular bone may be removed with resurfacing than with THA thereby complicating future revision surgery[53]. Improved techniques in revision THA have improved outcomes over time. For example, cementing femoral stems led to improved results with cemented femoral revision. Only 14% of revised cemented femoral components were loose radiographically in one series after an average of six years. Other series indicate a revision rate of approximately ten percent at ten years, which is much improved from earlier series but inferior to those obtained with primary cemented stems[54]. Likewise, the introduction of cementless acetabular components has led to improved outcomes with rates of failure reported up to 1.6% after four years[41].

Ball et al (2007) report on results comparing patients who had MoM hip resurfacing converted to THA compared with primary THA in comparable patients.[55] Twenty patients received 21 MoM hip resurfacing (with the Conserve Plus device) compared with 58 pts who had 64 THA during the same time-period by the same surgeon. The patient's average age was 50.2 years and average follow-up was 46 to 57 months. They report that there was no significant difference between the conversion arthroplasty group and the conventional arthroplasty group with regard to operative time, blood loss, complication rates, pain or activity level. They conclude that conversion of a hip resurfacing with a femoral-side failure to a total hip arthroplasty appears to be comparable with primary total hip arthroplasty in terms of surgical effort, safety, and early clinical outcomes. While these results are "encouraging" the authors state that they "need to be confirmed" in a larger cohort of patients with longer follow-up.

In sum, primary THA, the current surgical gold standard for debilitating hip arthritis, is a relatively safe procedure that provides 90% of patients with at least a decade, and often longer, of pain relief and improved function. Disadvantages of THA particularly in younger patients are that it does not permit resumption of full contact activity likely to put significant stress on the joint; device survival is decreased when compared with older patients, and younger patients are more likely to require revisions which are more complex and less successful than primary THA. Metal on metal hip resurfacing has the potential to address these shortcomings by allowing patients much less or no restriction on activity and by potentially improving outcomes when revision becomes necessary. However, to date, no studies have compared patients who have undergone primary THA vs MoM hip resurfacing to compare outcomes following revision and there is insufficient data to conclude that patient satisfaction and clinical outcomes are equivalent with either the

BHR or Cormet 2000 hip resurfacing systems compared with THA in younger patients.

TA Criterion 4 is not met for BHR and Cormet 2000

TA Criterion 5: The improvement must be attainable outside of the investigational setting.

MoM hip resurfacing with the devices currently approved by the FDA has not been shown to improve health outcomes in the investigational setting, so improvement is not possible outside of this setting.

TA Criterion 5 is not met.

CONCLUSION

Interest in total hip resurfacing has fluctuated over the past 80 years as earlier high rates of device failure have led to innovations in design and surgical technique. As the technology has evolved, there has been renewed interest in hip resurfacing as an alternative to THA, particularly for younger and more active patients who are likely to outlive their hip prosthesis. Unfortunately, the peer-reviewed research has not kept pace with the evolving technology. There are no randomized clinical trials with either of the two currently approved FDA devices that address the question of whether hip resurfacing is as safe and efficacious as THA in comparable patients. The peer-reviewed literature consists primarily of level five case series that report on the experience of a single surgeon operating at a single center with relatively short follow up.

Generally, it is CTAF policy not to evaluate technology that does not meet CTAF criteria # 1, i.e. that have not been approved by the FDA. This assessment proceeded on the assumption that the various MoM hip resurfacing systems are not equivalent and that each must be assessed individually as to its safety and efficacy. The FDA implicitly made a similar judgment when it required a PMA evaluation rather than a 510(k) for both of the currently approved devices. Whether to assess a class of devices or individual technology within that class depends on a number of factors such as the level of evidence available to assess the technology, its' stage of maturity, evidence to date of differences in outcomes with various devices within the class etc. We concluded that there is sufficient heterogeneity among the current MoM hip resurfacing devices, most of which are not yet FDA approved, that it was more prudent at this stage to consider them separately. As one proponent and surgeon/researcher of the BHR system argues: "Not all hip resurfacing

designs are the same. The design and metallurgy of the BHR is not serendipitious. . . . Revision hip clinics are littered with the victims of copied or 'improved' implant designs." . . . "Any device other than the BHR must provide its own evidence to justify its use."[56]

Several important questions remain unanswered about MoM hip resurfacing such as: What is the long term durability of the resurfaced hip compared with THA? What will be the short and long term results when this generation of younger patients who have undergone hip resurfacing are eventually converted to THA? Will there be unforeseen long term complications that will make this revision more problematic than anticipated? What are the long term health consequences of increased low levels of circulating metal ions produced by MoM hip resurfacing? Many experts have cautioned of the need for long term metal ion monitoring and epidemiological surveillance in younger patients who have received metal on metal joints[12] as cobalt and chromium wear particles have been shown to cause cancer in animal models[57].

While no clear health consequences have emerged to date, this issue must be closely monitored. And finally, as direct marketing to consumers and surgeons leads to the spread of this technology to lower volume practices and inevitably to a broader range of patients, what will be the impact on perioperative complications and rates of device failure? Experts point out that hip resurfacing is much more technically demanding than THA and calls for hands-on training with surgeons who have performed more than 50 prior procedures[58]. Siebel et al (2006) emphasize that a significant "learning curve" was evident in their research that demonstrated a significant reduction in the need for revisions in their cohort from the first 100 procedures with a new resurfacing system which led to five revisions to the third set of 100 procedures in which only one revision was necessary[17]. The two surgeons in this study had significant experience with an earlier device but still demonstrated a steep learning curve, according the authors. And Morlock et al (2006) report on biomechanical, morphological and histological analysis of early failures in hip resurfacing and also conclude that early failures were due to a significant 'learning curve"[11]. We are concerned that the uptake of the technology among surgeons has been much more rapid than the capacity to train them properly (e.g. the Smith and Nephew website provides links to 18 surgeons in the vicinity of the 94143 zip code who presumably offer BHR hip resurfacing).

Randomized clinical trials are the gold standard for evaluating new medical technology in medicine, including orthopedics. In fact, recent new technologies in orthopedics such as bone morphogenetic protein[20] and the interspinous process distractor or 'X-stop'[59] as well as many others have been examined in RCTs to

demonstrate their improvement in net health outcomes. The lead investigator of the RCT of hip resurfacing that was stopped secondary to increased device failures argues that: "Large sample sizes are needed to demonstrate that (hip resurfacing) is better than THR and multi-center trials are necessary to achieve these sample sizes in young patients"[18]. It is not possible to conclude from the current peer reviewed literature that the currently approved hip resurfacing systems in the United States improve health outcomes comparably with the current standard of care, total hip arthroplasty.

RECOMMENDATION

It is recommended that metal on metal hip resurfacing using the BHR or Cormet 2000 devices does not meet CTAF criteria 2-5 for safety, efficacy and improvement in health outcomes.

The California Technology Assessment Forum voted unanimously to approve the recommendation.

October 17, 2007

RECOMMENDATIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)

In June 2007 the BCBSA Medical Advisory Panel determined that MoM hip resurfacing may be appropriate as an alternative to THA in patients who are candidates for THA and who are likely to outlive a traditional prosthesis.

Centers for Medicare and Medicaid Services (CMS)

A search of the CMS web site did not uncover any national or local coverage determinations specific to the use of this technology.

California Orthopaedic Association (COA)

A COA representative attended the meeting and participated in the discussion regarding this technology. The COA does not have a formal opinion regarding hip resurfacing.

National Institute for Clinical Excellence (NICE)

"Metal on metal (MoM) hip resurfacing arthroplasty is recommended as on option for people with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement. MoM should be performed only by surgeons who have received training specifically in this technique". They also recommend that outcomes become part of a UK national joint registry. For the full recommendation see Technology Appraisal Guidance No. 44, Issue date June 2002, Review date February 2005 (www.nice.org.uk)

Ontario Health Technology Advisory Committee (OHTAC)

In 2006 OHTAC recommended, in part, that:

- Given the lack of long-term follow up data for MOM hip arthroplasty, OHTAC cannot make a recommendation regarding its clinical utility or complication rates at this time.
- The decision to use MoM hip resurfacing arthroplasty should be made between the surgeon and patient after weighing benefits against complications
- This technology should be re-examined once longer-term outcomes are available.

ABBREVIATIONS USED IN THIS REVIEW

OA: Osteoarthritis

DALYs: Disability adjusted life years

BHR: Birmingham Hip Resurfacing System

CHR: Cormet Hip Resurfacing System

Co-Cr: Cobalt-chromium

DARE: Database of Abstracts of Reviews of Effects

OHS: Oxford hip score

HOOS: Hip Disability and Osteoarthritis Outcome Score

DDH: Dysplasia/developmental dislocation of the hip

AE: Adverse events

NSAIDS: Non-steroidal anti-inflammatory drugs

RA: Rheumatoid arthritis

THA: Total hip arthroplasty

RCT: Randomized control trials

MoM: Metal on metal

PMA: Pre-market approval

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