

# Health Technology Assessment

## Hip Resurfacing

### Public Comments and Responses

October 23<sup>rd</sup>, 2009

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## 1. SPECTRUM RESEARCH RESPONSE TO PEER REVIEW COMMENTS

### Jason Weisstein, M.D., Assistant Professor, University of Washington, Spine Service

*Dr. Weisstein comment 1 response:* Background section, page 25. We removed the sentence that stated HR was a less invasive surgery.

*Dr. Lee's comment 2 response:* Background section, page 25. We removed the reference to the trochanteric approaches.

## 2. SPECTRUM RESEARCH RESPONSE TO PUBLIC COMMENTS

Responses to Industry Association Comments

### Alliance for Orthopedic Solutions Comment 1

*Failure to Break the Analysis into Categories to Distinguish FDA-Approved Devices Ignores the FDA-Mandated Training Physicians Receive Prior to Using Such Devices*

Response 1:

**We added the following paragraph as section 1.5,**

We included data from studies that used both FDA approved and non FDA approved total HR devices that otherwise met our inclusion/exclusion criteria. Our clinical experts believed that total HR devices are similar enough that including all devices in this review was appropriate, and that the results using one device could be reasonably generalized to other devices as well. Including all devices in this review provides more information to inform readers of this report on efficacy, effectiveness and safety of the the procedure of hip resurfacing. Nevertheless, in our results, we attempt to identify which devices were used in each study.

### 2. Alliance for Orthopedic Solutions Comment 2:

For your convenience, we have listed the products approved for partial hip resurfacing in Section IV. We are including the information on partial hip resurfacing procedures because there may be some concern regarding coding, coverage, and payment. As an example, all products in the attachment are approved only for hemiarthroplasty involving the femoral side of the hip joint. We believe this should be noted in the Draft Report to prevent any confusion by readers.

**Response 2:**

This report deals only with total hip resurfacing; partial hip resurfacing was in our exclusion criteria. In order to make this clearer, we added the word “total” prior to hip resurfacing in the narrative. We avoided the use of the initials THR for total hip resurfacing so as not to confuse readers that may be accustomed to THR meaning total hip replacement.

**3. Alliance for Orthopedic Solutions Comment 3:**

Page 12, Metal Ion Safety - “However, an association between HR and cancer and metabolic disorders has yet to be reported.” Because there are no data to support an association between THR and cancer and metabolic disorders, this language should be clarified and revised...

**Response 3:**

We clarified our point with the following:

“However, an association between total HR and cancer or metabolic disorders has not been reported with the current length of follow-up.”

**4. Alliance for Orthopedic Solutions Comment 4:**

*Page 16, Section 1.1, Appraisal, Rationale*

*Use of the term “high” in this context is subjective and unclear. There is no basis of comparison specified for use of this term.*

**Response 4:**

We clarified the paragraph to remove the subjectivity of the words “high” and “higher”.

**5. Alliance for Orthopedic Solutions Comment 5:**

*Page 21, Section 1.4.4, Professional Considerations*

*Consistent with our comments provided in Section II, Section 1.4.4 of the Draft Report should be modified...:*

**Response 5:**

We clarified the comment to underscore FDA approved devices.

### 3. Spectrum Research Response To Washington State Agency Comments

	Section (page)	HTA Text of interest	State Agency Comment	Spectrum Research Response
1.	Executive Summary (8)	“HR maintains normal joint biomechanics and load transfer”	Compared to THA which does not?	Changed to “hip resurfacing <i>was designed to more closely mimic</i> normal joint biomechanics and load transfer”
2.	Executive Summary (8)	“objective of this comparative effectiveness review”	Health Technology Assessment	Changed to Health Technology Assessment
3.	Executive Summary (10)	“may have higher significantly higher”	Missing/extra word	Deleted repeating word
4.	Executive Summary (10)	“patients treated with HR may have significantly higher postoperative activity levels than those who received THA”	But results for the UCLA measure were mixed in the higher quality studies according to RCT findings...	This statement is in the effectiveness section, whereas the RCTs were addressed in the efficacy section
5.	1.4.1 (20)	“Much of the literature on THA is written by "advocates" of the procedure”	On THA or on HR or both?	Changed to “Much of the literature on <i>HR and THA</i> is written by "advocates" of the procedures”
6.	1.4.1 (20)	“Total hip resurfacing is a bone sparing procedure best done in males under the age of 55 years with good bone stock, good health, an active lifestyle, and minimal	Maybe this paragraph should remind the reader these are the opinions/experiences of the clinical experts	Qualified statement with “many clinical experts believe that total hip resurfacing is...”)

		femoral deformity or leg length discrepancy.”		
7.	1.4.1 (20)	“the surgeon is trained and experienced in hip-resurfacing surgery”	Is there a threshold of experience? Should there be 20 or ?? done as training?	This is clinical expert comment; please see section 4.2.3 for more on what is published for learning curve
8.	1.4.2 (21)	“hard-on-hard bearings”	What does this include?	Changed to metal-on-metal
9.	1.4.3 (21)	Revision rate for resurfacing is LOWER than for THA for men under 65 years.	Repeated	Deleted repeated text
10.	2.1 (22)	“HR ... <i>maintains</i> normal joint biomechanics and load transfer”	Attempts to	Changed to “attempts to maintain . . .”
11.	2.2 (23)	“patients tend to <i>recovery</i> more quickly”	Word	Changed to “recover”
12.	2.12 (32)	Medicare	I find that CMS has hip resurfacing listed as a potential NCD topic here: <a href="http://www.cms.hhs.gov/mcd/npcv_view_document.asp?id=19">http://www.cms.hhs.gov/mcd/npcv_view_document.asp?id=19</a>	Added the information

## 4. PEER REVIEW COMMENTS

### A. Jason Weisstein, M.D., M.P.H, F.A.C.S.

#### INTRODUCTION Comments

**While reviewing this section please keep the following questions in mind, but please comment on any point:**

- Overview of topic is adequate?    yes
- Topic of assessment is important to address?    yes
- Public policy and clinical relevance are well defined?    yes

#### BACKGROUND Comments

**While reviewing this section please keep the following questions in mind, but please comment on any point:**

- Content of literature review/background is sufficient?  
Yes. My only criticism is page 25. In paragraph 2, it is stated that hip resurfacing is a less invasive surgery. This is absolutely false. Hip resurfacing is a more invasive surgery requiring more soft tissue dissection than traditional total hip replacement. In paragraph 3 transtrochanteric and trochanteric flip/slide are listed as other operative approaches. I have never seen these utilized in clinical practice. In the United States, the posterior approach is the most common approach, with lateral and anterior approaches being less common.

#### REPORT OBJECTIVES & KEY QUESTIONS Comments

**While reviewing this section please keep the following questions in mind, but please comment on any point:**

- Aims/objectives clearly address relevant policy and clinical issue?    yes
- Key questions clearly defined and adequate for achieving aims?    yes

#### METHODS Comments

**While reviewing this section please keep the following questions in mind, but please comment on any point:**

- Method for identifying relevant studies is adequate?    yes
- Criteria for the inclusion and exclusion of studies is appropriate?    yes
- Method for Level of Evidence (LoE) rating is appropriate and clearly explained?  
yes
- Data abstraction and analysis/review are adequate?    yes

#### RESULTS Comments

**While reviewing this section please keep the following questions in mind, but please comment on any point:**

Amount of detail presented in the results section appropriate?   yes

Key questions are answered?       yes

Figures, tables and appendices clear and easy to read?   Yes

Implications of the major findings clearly stated?       Yes

Have gaps in the literature been dealt with adequately?

Yes. The most striking gap is the lack of long term data. This is very well stated in many sections in this report. Clearly, long term follow up will yield the most insight about all important questions asked in this report.

Recommendations address limitations of literature?

Yes. Again, limitations that are clearly stated include lack of long term data, only average intermediate term data, and few randomized control trials.

### **CONCLUSIONS Comments**

**While reviewing this section please keep the following questions in mind, but please comment on any point:**

Are the conclusions reached valid?       yes

### **OVERALL PRESENTATION and RELEVANCY Comments**

**While reviewing this section please keep the following questions in mind, but please comment on any point:**

Is the review well structured and organized?       yes

Are the main points clearly presented?   yes

Is it relevant to clinical medicine?       yes

Is it important for public policy or public health?       yes

### **QUALITY OF REPORT**

#### **Quality Of the Report**

(Click in the gray box to make your selection)

**Superior XX**

**Good**

**Fair**

**Poor**



**B. Seth S. Leopold, MD, Professor and Vice Chair, Department of Orthopaedics and Sports Medicine, University of Washington School of Medicine**

**From:** SETH S. LEOPOLD [mailto:leopold@u.washington.edu]

**Sent:** Tuesday, October 13, 2009 4:03 PM

**To:** Dr. Joseph Dettori

**Cc:** PAUL A. MANNER

**Subject:** RE: HTA peer review

Actually, Joe, had a delay bet'n cases, and reviewed this document. It is truly remarkable. I am going to save it for my own reference -- I've never seen something so thorough. You have an amazing system. I have nothing to add or subtract.

Best,

Seth

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## 5. Public Comments

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October 12, 2009

By Electronic Mail – [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)

Leah Hole-Curry, J.D.  
Director, Health Technology Assessment Program  
Washington State Health Care Authority  
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### Comments to Health Technology Assessment “Draft” Report on Hip Resurfacing

Dear Ms. Hole-Curry:

The Alliance for Orthopedic Solutions (Alliance) thanks you for this opportunity to comment on the Health Technology Assessment Draft Report on Hip Resurfacing (“the Draft Report”). We appreciate the opportunity to comment on the Draft Report, and for the efforts of the Washington Health Care Authority (“WSHCA”) to commission a critical, evidence-based review of the safety, efficacy, and economic impact of total hip resurfacing (“THR”) relative to existing alternative therapies, such as total hip arthroplasty (“THA”) or physical therapy. The Alliance is a national organization that collaborates with leading clinical experts and researchers in orthopaedics and includes the leading developers and manufacturers of innovative orthopaedic devices and implants. The Alliance is dedicated to ensuring that issues impacting orthopaedics, especially innovative technology and new orthopaedic treatments are given appropriate consideration in the formation of health care and reimbursement policy.

In brief, we have concerns regarding the focus of the WSHCA analysis because the clinical benefits of total hip resurfacing are well-documented. Hip resurfacing is indicated for relief of pain and restoration of function in patients with degenerative joint disease of the hip, is clinically proven and non-controversial. Numerous payors have issued positive coverage determinations and the highly respected Blue Cross Blue Shield Technology Evaluation Center has concluded that total hip resurfacing “improves net health outcomes.” For these reasons, we recommend that the WSHCA:

- Modify, as indicated below, the draft report on THR before finalizing the report;
- Educate physicians and hospitals on the proper coding for THR procedures;

- Issue a positive coverage determination for THR procedures that involve FDA-approved devices that are implanted by surgeons who have undergone the necessary rigorous training; and
- Ensure that patients have continued access to total hip procedures.

Set forth below is a discussion on the clinical benefits of THR as well as our concerns, and comments directed to specific language or findings in the Draft Report.

## **I. Clinical Benefits of THR are Well-Documented and Recognized by Insurers**

Total hip resurfacing offers potential advantages to selected patients—especially young, active, high-demand patients. The benefits of resurfacing include the following:

- bone retention for future revisions
- less stress shielding
- fewer dislocations than conventional total hip arthroplasties
- fewer postoperative activity restrictions, based on physician preference

Hip resurfacing procedures fall into two categories. In a partial resurfacing arthroplasty, a shell or “cap” is implanted over the femoral head. A total resurfacing arthroplasty involves both the implantation of the femoral head shell and the insertion of an acetabular cup.

Coverage policies for total hip resurfacing are almost uniformly positive. For example, Aetna “considers metal-on-metal hip resurfacing a medically necessary alternative to total hip arthroplasty for physically active members with osteoarthritis of the hip, or osteonecrosis of the femoral head.”<sup>1</sup> The insurer notes –

Compared to total hip replacement, femoral resurfacing allows preservation of much more of the patient's own bone. The advantages of femoral resurfacing over total hip replacement is that it is less invasive, there is reduced thigh pain since there is no stem in the femoral canal, and that it may allow patients to be more active (an advantage especially for younger patients because the risk of dislocation is theoretically reduced because of the larger ball.

Similarly, Regence writes –

Metal-on-metal total hip resurfacing with a fully FDA approved total hip resurfacing device (e.g., the Birmingham Hip Resurfacing System and Cormet device), may be considered medically necessary when both of the following criteria are met:

- Patient is likely to outlive a traditional prosthesis and
- Patient would otherwise require a total hip replacement

A partial list of other insurers that cover hip resurfacing includes –

- CareFirst;
- CIGNA;
- Harvard Pilgrim Health Care;
- HealthPartners;
- Humana;
- Medica; and
- UnitedHealthcare.

### Failure to Break the Analysis into Categories to Distinguish FDA-Approved Devices Ignores the FDA-Mandated Training Physicians Receive Prior to Using Such Devices

In light of the evolution of these products and the technique for total hip resurfacing, which impacts clinical outcomes, it is vitally important that the WSHCA evaluate the procedures involving FDA-approved devices separately from other procedures and devices claiming to be resurfacing solutions. Clinical outcome, including the rate of revision for HR, is tied the appropriate technique employed by the physician.

For example, we are concerned that hip resurfacing has become a catch-all for a wide variety of treatment alternatives related to hip replacement. However, there are currently only 2 products<sup>1</sup> which can be marketed in the United States as THR:

- Smith and Nephew's Birmingham Hip Resurfacing System, and
- Stryker's Corin System.

Note any total hip resurfacing procedure that involves products other than those named above would be considered “off-label use,” because there are no other total hip resurfacing implants that have been approved by the FDA. Although some providers may not consider “off-label use” a major concern, we believe that the WSHCA should carefully consider the rigorous training required to certify a physician fit to perform a FDA-approved THR procedure and recognize that surgeons doing procedures using “off-label” products have not undergone this rigorous training.

In addition to developing a positive coverage policy for total hip resurfacing using FDA-approved products, we believe that the WSHCA should educate hospitals and physicians regarding proper coding for these procedures and advise hospitals that they may be subject to review/audits of the records to ensure that the proper codes are reported and only FDA-approved implants are used.

For your convenience, we have listed the products approved for partial hip resurfacing in Section IV. We are including the information on partial hip resurfacing procedures because there may be some concern regarding coding, coverage, and payment. As an example, all products in the attachment are approved only for hemiarthroplasty involving the femoral side

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<sup>1</sup> DePuy, Wright Medical, and Zimmer are expected to have FDA-approval for THR products in the near future.

of the hip joint. We believe this should be noted in the Draft Report to prevent any confusion by readers.

### Comments on Specific Language or Findings

#### *Page 12, Metal Ion Safety*

“However, an association between HR and cancer and metabolic disorders has *yet to be* reported.”

Because there are no data to support an association between THR and cancer and metabolic disorders, this language should be clarified and revised to the below:

“However, an association between HR and cancer and metabolic disorders has *not been* reported.”

#### *Page 16, Section 1.1, Appraisal, Rationale*

“However questions remain about the unknown longevity and durability of the procedure; the reported high failure rates; the appropriate patient selection criteria (e.g., age, gender, tried and failed therapies); impact on long term health outcome; higher surgical risks and complications from multiple surgeries and the health system impacts of a surgery designed to delay but not eliminate need for later surgery.”

Use of the term “high” in this context is subjective and unclear. There is no basis of comparison specified for use of this term.

The phrase “higher surgical risks and complications from multiple surgeries” is also imprecise, because it could be interpreted to mean that there exist higher surgical risks upon revision of HR compared to THA. In fact, the Draft Report states that morbidity is lower upon revision of HR compared to THA, and that the surgical procedure is less complicated for HR should allow for simpler revisions due to bone conservation.

It is unclear why the statement “the health impacts of a surgery designed to delay but not eliminate the need for later surgery” is included in the Draft report, because the focus of the review is comparative effectiveness. The comparator in this case is THA, and that statement would be true for the comparator as well.

Accordingly, we suggest changing the paragraph to read:

“However questions remain about the unknown longevity and durability of the procedure; *the magnitude of* the reported failure rates; the appropriate patient selection criteria (e.g., age, gender, tried and failed therapies); impact on long-term health outcome; and *the additional* surgical risks and complications from multiple surgeries and *the impacts of the health care system, economic and otherwise.*”

#### *Page 21, Section 1.4.4, Professional Considerations*

Consistent with our comments provided in Section II, Section 1.4.4 of the Draft Report should be modified to read:

“Because hip resurfacing devices have received approval only recently in the United States, many communities do not have surgeons trained in this procedure. The device manufacturers of *FDA-approved* devices *are* required to conduct specific training mandated by FDA for surgeons who implant their devices be properly trained for technique. There is a definite learning curve for this procedure. *It is well documented that surgeon experience and training in the procedure can impact clinical outcome*<sup>2</sup>. [cite reference 13] To reduce complications, this procedure should be performed by surgeons with extensive experience in this surgery, *preferably those that have been trained under the FDA mandate or a similarly rigorous and evolving training program.*”

#### Devices Approved for Use Only in Hemiarthroplasty Involving the Femoral Side of the Hip Joint (Partial Hip Resurfacing)

- Cormet 2000 Hemi Hip Metallic Resurfacing Prosthesis made by Corin U.S.A.
- Depuy ASR Resurfacing Femoral Heads made by Depuy Orthopaedics, Inc.
- Press-Fit Head Resurfacing Device made by Biomet Orthopedics, Inc.
- Contoured Articular Prosthesis (CAP) Femoral Head made by STD Manufacturing, Inc.
- Cemented Femoral Head Resurfacing Device made by Biomet Orthopedics, Inc.
- Nelson Resurfacing Head made by Biomet, Inc.
- Modular Unipolar made by Intermedics Orthopedics
- Orthomet Resurfacing Femoral Component made by Orthomet, Inc.
- Modified New Jersey Femoral Hip Resurfacing Compo made by Endotec, Inc.
- Biopro Proximal Femora Articular Replacement made by Biopro, Inc.
- Bipolar Hip System made by Orthomet, Inc.
- LSF (R) Total Hip System-Bipolar Component made by Implant Technology, Inc.
- New Jersey Femoral Resurfacing Component made by Endomedics, Inc.
- Tillman Hip Resurfacing Replacement Prosthesis made by Waldemar Link GMBH & Co.
- Resurface Prostheses for Hip Joint made by Holco Instrument Corp

## V. Recommendations

The benefit of total hip resurfacing is clear and well documented in the scientific and clinical literature. For these reasons, we recommend that the WSHCA:

- Modify, as recommended, the draft report on THR before finalizing the report;

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<sup>2</sup> See Mont MA, et. al., Hip Resurfacing Arthroplasty. J Am Acad Orthop Surg. Aug. 2006;14(8);454-463.

- Educate physicians and hospitals on the proper coding for THR procedures as well as the importance of surgeon training; and
- Issue a positive coverage determination for THR procedures that involve FDA-approved devices that are implanted by surgeons who have undergone the necessary rigorous training.

Patients should continue to have access to total hip resurfacing procedures.

Please let us know if we can provide any further information to assist in your review and consideration of the above comments. We appreciate your consideration of our comments.

Sincerely,

*Eric Rugo*

Eric Rugo  
Executive Director, Alliance

cc: Alliance members (via email)

<sup>1</sup> Aetna, like other insurers mentioned in this letter, cites numerous scientific articles as support for its positive coverage determination. For example, Aetna writes:

“Daniel and colleagues (2004) stated that the results of conventional hip replacement in young patients with osteoarthritis have not been encouraging even with improvements in the techniques of fixation and in the bearing surfaces. Modern metal-on-metal hip resurfacing was introduced as a less invasive method of joint reconstruction for this particular group. The authors presented their findings of a series of 446 hip resurfacings (n = 384) performed by one of the authors using cemented femoral components and hydroxyapatite-coated uncemented acetabular components with a maximum follow-up of 8.2 years (mean of 3.3 years). Their survival rate, Oxford hip scores and activity levels were reviewed. Six patients died due to unrelated causes. There was one revision (0.02 %) out of 440 hips. The mean Oxford score of the surviving 439 hips is 13.5. None of the patients was told to change their activities at work or leisure; 31 % of the men with unilateral resurfacings and 28 % with bilateral resurfacings were involved in jobs that they considered heavy or moderately heavy; 92 % of men with unilateral hip resurfacings and 87 % of the whole group participate in leisure-time sporting activity. The extremely low rate of failure in spite of the resumption of high level occupational and leisure activities provided early evidence of the suitability of this procedure for young and active patients with osteoarthritis.

“Lilikakis, et al. (2005) reported preliminary results of an uncemented, hydroxyapatite-coated femoral implant for metal-on-metal hip resurfacing. The pre-operative diagnosis was osteonecrosis in 1 patient, chondrolysis in 1 patient, and osteoarthritis in the remaining 64 patients (68 hips). The survival rate of 70 implants after at least 2 years follow-up was 98.6 %, with an excellent clinical outcome. There have been no femoral fractures, aseptic loosening, or radiolucencies around the stem. Thinning of the femoral neck at the inferomedial cup-neck rim has been a frequent radiological finding but with no clinical implication so far.

“Pollard, et al. (2006) compared the 5- to 7-year clinical and radiological results of the metal-on-metal Birmingham hip resurfacing with a hybrid total hip arthroplasty in two groups of 54 hips, matched for gender, age, body mass index and activity level. Function was excellent in both groups, as measured by the Oxford hip score, but the Birmingham hip resurfacings had higher University of California at Los Angeles activity scores and better EuroQol quality of life scores. The total hip arthroplasties had a revision or intention-to-revise rate of 8 %, and the Birmingham hip resurfacings of 6 %. Both groups showed impending failure on surrogate end-points. Of the total hip arthroplasties, 12 % had polyethylene wear and osteolysis under observation, and 8 % of Birmingham hip resurfacings demonstrated migration of the femoral component. Polyethylene wear was present in 48 % of the hybrid hips without osteolysis. Of the femoral components in the Birmingham hip resurfacing group which had not migrated, 66 % had radiological changes of unknown significance.”

The full citation for these articles are

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.* 2004;86(2):177-184.

Lilikakis AK, Vowler SL, Villar RN. Hydroxyapatite-coated femoral implant in metal-on-metal resurfacing hip arthroplasty: Minimum of two years follow-up. *Orthop Clin North Am.* 2005;36(2):215-222, ix.

Pollard TC, Baker RP, Eastaugh-Waring SJ, Bannister GC. Treatment of the young active patient with osteoarthritis of the hip. A five- to seven-year comparison of hybrid total hip arthroplasty and metal-on-metal resurfacing. *J Bone Joint Surg Br.* 2006;88(5):592-600.



**From:** Steven Teeny [mailto:smteeny@comcast.net]  
**Sent:** Wednesday, October 07, 2009 10:45 AM  
**To:** HCA ST Health Tech Assessment Prog  
**Subject:** Hip Resurfacing Key Questions

To Washington State Health Care Authority Health Technology Assessment Program:

As an orthopaedic surgeon in Washington State whose practice is primarily one of lower extremity joint replacement and has experience in hip surface replacement surgery, I would like to comment on the Health Technology Assessment of hip resurfacing surgery.

First I want to acknowledge that the assessment of the literature is satisfactory with regards to the results of surgery, revision rates, complications and functional outcomes as measured by standard assessment tools. Understanding these results is an important part of deciding what therapy to recommend to a person with severe hip arthritis who is contemplating surgery.

The patients who are possible candidates for hip resurfacing are younger (generally males less than 55 -60, females less than 50), are likely to be physically active, and have the appropriate anatomy to accept this prosthesis. Although my practice is devoted primarily to hip and knee surgery, this procedure represents less than 10% of all this replacements I perform, and less than 1/2 of those patients less than 55 years old.

However for the properly selected patient, this operation is of great benefit. These patients tend to be the most active and energetic. They are the ones who are likely to return to sporting activities, hiking, and other joint stressful activities. They are the ones most likely to have a complication with a conventional hip replacement for the very same reason. Beyond this, my impression is that these patients have a more comfortable hip, especially with joint impacting activities.

Please note, that although the upper ages for surface replacement are often noted to be 55 years in males and 50 years in females, but this should not be a rigid guideline, as now, many patients in the upper 50's and 60's are very active, and physiologically are acting younger.

The discussion in the assessment of metal ion concerns is helpful, but you should be aware that this concern is present for all metal on metal hip replacements, not just surface replacements. A fairly large percent of conventional hip replacements are metal on metal with large heads, and the concerns with ion release are the same.

Surface replacement surgery does require some additional technical skill to perform reliably and skillfully, but this skill is being taught in orthopaedic residency and through continuing medical education courses. The ability to do surface replacement surgery may be in the skill set of an orthopaedic surgeon who does hip replacement surgery on a regular basis.

In summary, hip resurfacing is an accepted surgery (world wide), and has a proper place in the armamentarium of treatments for patients with hip arthritis. It should continue to be allowed to be performed in properly selected patients by skilled surgeons, and be paid for by insurance plans, just as conventional hip replacement is.

Thank you for allowing me to comment on this assessment.

Steven M. Teeny, MD  
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January 6, 2009

Leah Hole-Curry JD  
Director of Health Technology Assessment  
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Dear Director and Health Care Authority Members,

Smith & Nephew Inc. is pleased to respond to your memorandum dated December 12, 2008 in which hip resurfacing is selected for an evidence based review for 2009 and appreciates the opportunity to provide additional information on hip resurfacing.

We believe several issues should inform your review of hip resurfacing technology. Those issues are supported by accompanying peer reviewed documentation and registry data for clinical effectiveness and cost effectiveness. A brief history of joint resurfacing is also included. In brief, based on the overwhelming preponderance of the clinical evidence, our recommendations are as follows:

- Washington State Health Care Authority (WSHCA) should develop a positive coverage policy for total hip resurfacing using FDA-approved products
- Educate hospitals and physicians regarding proper coding for total hip resurfacing procedures
- Recognize that surgeons doing procedures using "off-label" products have not undergone this rigorous training
- Advise hospitals/physicians that they may be subject to review/audits of the records to ensure that the proper codes are reported and only FDA-approved implants are used.

By way of background, hip resurfacing is neither a new concept nor a new procedure. For as long as hip replacement has been a standard for relief pain and debilitation of osteoarthritis, physicians have recognized the benefit of preservation of bone and soft tissue in this invasive treatment. The 1970's spawned attempts to preserve bone when performing total hip procedures. However, while these early attempts to preserve bone and tissue preservation were well reasoned and consist with improved clinical outcomes, the techniques were not supported by the technology or implants of the 1970's.

Over the years, advances in clinical practice and changes in implant materials made the "parts" exponentially more reliable. In turn, these developments revived physician interest in furnishing bone sparing total hip procedures. Thus, by the mid 1990's, the new materials (implants) and refined procedures provided patients, too young for traditional hip replacement, a safe and effective alternative surgical treatment. More importantly these changes in total hip resurfacing resulted in improved patient outcomes

that are equivalent to or better than the "traditional" total joint replacement. The clinical benefits related to hip resurfacing are described in great detail in peer reviewed literature, and supported by registry data which extends for more than 10 years. In addition to being safe and effective, there is ample evidence vis-à-vis cost effectiveness modeling, which demonstrates that hip resurfacing is a compelling alternative to the traditional treatment management plans (i.e., hip replacement and watchful waiting combined with palliative medication).

In light of the evolution of the products and technique for total hip resurfacing which impact clinical outcomes, it is vitally important that the Washington State Health Care Authority evaluate the procedures involving FDA-approved devices separately from other procedures and devices claiming to be resurfacing solutions.

For example, we are concerned that hip resurfacing has become a catch all for a wide variety of treatment alternatives related to hip replacement. However, there are only 2 products which can be marketed in the United States as Total Hip Resurfacing:

- Smith and Nephew's Birmingham Hip Resurfacing System, and
- Stryker's Corin System.

Note any total hip resurfacing procedure that involves other products than those named above would be considered "off-label use" because there are no other total hip resurfacing implants that have been approved by the FDA. While some providers may not consider "off-label use" a major concern, we believe that the Washington State Health Care Authority (WSHCA) should carefully consider the rigorous training required to certify a physician fit to perform an FDA-approved Total Hip Resurfacing procedure and recognize that surgeons doing procedures using "off-label" products have not undergone this rigorous training.

In addition to developing a positive coverage policy for total hip resurfacing using FDA-approved products, we believe that the WSHCA should educate hospitals and physicians regarding proper coding for these procedures and advise hospitals that they may be subject to review/audits of the records to ensure that the proper codes are reported and only FDA-approved implants are used.

For your convenience, we have listed the products approved for partial hip resurfacing in Attachment 1. We are including the information on partial hip resurfacing procedures because there may be some concern regarding coding, coverage, and payment. As an example all products in the attachment are approved only for hemiarthroplasty involving the femoral side of the hip joint.

An article appearing as recently as this month in JBJS entitled [The Epidemiology of Revision Total Hip Arthroplasty in the United States](#), by Bozic et. al. reviews the most prevalent reasons for revision of total hip replacement among 51,345 revision cases. The most common causes for all component revision surgery are instability/dislocation 22.5%, mechanical loosening 19.7%, and infection 14.8%. The top two and arguable the third reason for revision are mitigated by performing total hip resurfacing rather than total hip replacement in the proper patient population. The 2008 Australian registry data indicates revision for instability/dislocation of 28.7% for conventional hip replacement and revision for instability/dislocation of 3.3% for hip resurfacing.

As explained above, the two approved total hip resurfacing systems are Smith and Nephew's Birmingham Hip Resurfacing System and Stryker's Corin System. The surgical training required by the FDA are very stringent. Post market surveillance is a requirement placed on FDA approved devices not required of other, so called, resurfacing devices.

Evidence of the efficacy and effectiveness of FDA approved Total Hip Resurfacing are found among the following attachments to information respectfully submitted to the Authority.

- Birmingham Hip Resurfacing Arthroplasty A minimum of 5 Year Follow-Up, Treacy et.al.
- A Five Year Radiostereometric Follow-Up of Birmingham Hip Resurfacing Arthroplasty, R Iteyam et. al.
- The Results of Primary Birmingham Hip Resurfacings at a Mean of Five Years An Independent Prospective of the First 230 Hips, Shimmin, et. al.
- The Influence of Surgical Approach on Outcome in Birmingham Hip Resurfacing, McBryde et. al.
- Hip Resurfacing the Australian Experience, Begeri et. al.
- The Five-Year Results of the Birmingham Hip Resurfacing Arthroplasty, An Independent Series, Steffen et. al.
- Treatment of the young active patient with osteoarthritis of the hip. A Five to Seven Year Comparison of Hybrid Total Hip Arthroplasty and Metal-on-Metal Resurfacing, Pollard et. al.

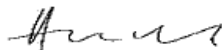
Cost effectiveness of hip resurfacing is offered in an article published in the Journal of Managed Care Medicine.

- Cost-effectiveness of Hip Resurfacing in Younger Adults in the United States, Buckland and Posnett.

The above clinical and cost information is among 100+ articles and references which report on hip resurfacing. The preponderance of available evidence is from outside the United States because development of bone sparing procedures was undertaken abroad. Smith & Nephew currently has several post-approval studies, including 1 major 10 year study underway to remain compliant with Class III FDA post approval requirements. The Corin product is under the same PMA requirements and should be conducting similar trials.

Hip resurfacing is a procedure for which the clinical benefits are well documented in U.S. peer-reviewed literature when furnished to appropriately selected patients by well trained surgeons. It is important for WSHCA to recognize that this procedure may be the only viable, safe, effective treatment for some patients.

Respectfully,



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Chief Medical Officer

