

Hip Re-Surfacing (Re-review)

Public Comments & Responses to Draft Report

October 14, 2013

Health Technology Assessment Program (HTA)

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Report Section	Reviewer's comments	SRI Response
<p>General</p>	<p>We are concerned that the methodology used by Spectrum Research Inc. examines the performance and outcomes of resurfacing implants as a class, without adequately differentiating the results of different manufacturers' hip resurfacing technologies (some of which have been recalled or withdrawn). This is a significant flaw, which limits the usefulness of the draft report as a basis for any decision which you may make concerning the future of MoM hip resurfacing in Washington State.</p> <p>We note that the significant design and superior clinical performance differences between BHR and other devices in the resurfacing arthroplasty class appear to have been disregarded during the review.</p> <p>Several of the focus publications refer to studies describing or comparing hip resurfacing outcomes alone or to total hip arthroplasty (THA) that were conducted with competitor devices, which three national hip arthroplasty registers have shown to have significantly inferior revision outcomes compared to the BHR</p>	<p><i>Thank you for your comments.</i></p> <p><i>It was beyond the scope of this report to evaluate individual manufacturer-specific hip resurfacing or total hip arthroplasty devices.</i></p>
<p>KQ4 (in the executive summary and page 7, but KQ 5 in section 4.4 on page 89)</p>	<p>The draft report fails to identify hip resurfacing brand as a significant differentiator. Jameson, et.al, determined that brand was an independent predictor of revision in 27,871 patients receiving hip resurfacing procedures.</p> <p>An analysis of revision rates reported in revisions per 100 observed patient years taken from de Steiger, et.al. and from the three national registries identified in the draft report, the 2012 Australian Orthopedic Association National Joint Replacement Register, the 2012 National Joint Registry of England and Wales, and the 2011 Swedish Hip Arthroplasty Register, all confirm these findings.</p>	<p><i>Thank you for your note. The discrepancies in the numbering of Key Questions between the executive summary and full report have been edited.</i></p> <p><i>Jameson et al. reports on risk factors for revision using the NJR for England and Wales. This does not answer the question of differential efficacy or safety. Rather, this amounts to a retrospective cohort study, in part, comparing the effect of different manufacture-specific hips, and is beyond the scope of this report.</i></p> <p><i>With respect to de Steiger et. al. (2010), the purpose of their paper was to investigate the outcome of primary resurfacing hip</i></p>

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		<i>arthroplasties that had been revised. This article is reviewed and summarized in section 4.3., KQ3 (efficacy/safety of revisions of HR compared with revisions of THA)</i>
	Furthermore, BHR was the only hip resurfacing implant supported by 10 years' actual revision data: All other implants required appropriate data extrapolation to allow a 10 year comparison. This should have been taken into account in Spectrum Research, Inc.'s analysis.	<i>We did not use extrapolated data in our analysis. We used 10 and 11 year data from the Australia Registry as reported irrespective of manufacturer device.</i>
General	Recognition should also have been given to the fact that experience with BHR, measured by total patients treated or total observed years implanted, is the highest among all hip resurfacing implants in the three cited registries. Of those receiving hip resurfacing, BHR accounts for 68% of the patients and 74% of the observed patient years in the Australian registry and 55% of the patients and an estimated 57% of the observed patient years in the Swedish registry. There, while BHR was used in 58% of patients overall, in 2011 it was used in 83% of patients receiving a hip resurfacing device. BHR alone among these devices has a significant body of clinical evidence supporting its effectiveness in both the joint registries and the peer-reviewed literature. In summary, 21 publications report on a total of 13,789 BHR implants and 128,617 observed component years. Weighted average follow-up among these study populations is 9.3 years, with a weighted average survivorship of 95.6 %. A total of 9,287 patients and 102,453 observed component years are reported at a minimum of 10 years follow-up with a weighted average survivorship of 95.5%.	<i>It was beyond the scope of this report to evaluate individual manufacturer-specific hip resurfacing or total hip arthroplasty devices with respect to which device is most often used. However, we attempted to identify the device used in the comparative studies listed in tables 11 and 12 when specified by the authors.</i>
General	We are also concerned by the fact the Draft Evidence Report focuses on a simple comparison of revision rates between hip resurfacing procedures and THA. Because hip resurfacing offers different benefits from THA, based upon patient characteristics, needs and treatment goals determined between the patient and the surgeon, the Draft Evidence Report should have compared hip resurfacing to conservative medical management in patient populations with diseases in which hip resurfacing is indicated.	<i>The report answers the key questions which detail the comparison of interest: HR vs. the gold standard of THA.</i>

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	<p>Additionally, while metal on polyethylene (MoP) bearings may be appropriate for THA patients who are more elderly and less active, by contrast, the use of metal-on-metal (MoM) technology for resurfacing has significant advantages, especially for younger, more active patients. These advantages include the following:</p> <ul style="list-style-type: none"> • Elimination of proximal femoral stress shielding • Elimination of polyethylene induced osteolysis • Reduced risk of dislocation, as compared to traditional THA • Reduced risk of postoperative leg length discrepancy • Physiological restoration of hip offset, supporting normal function • Return to an active lifestyle is possible and sustained to at least 10 years <p>The fact that the draft report recognises certain of the advantages of hip resurfacing over THA in indicated populations – noting that hip resurfacing allows for easier revision than would a THA (page 20) and that patients recover more quickly after hip resurfacing surgery than after THA surgery (page 20) – itself indicates a simple comparison of revision rates between hip resurfacing and THA to be inappropriate.</p>	<p><i>Potential or theoretical advantages are listed in the background – this serves to motivate the undertaking of the HTA. Appeals to any benefit or advantages should come from the results of the HTA. We added the word “Potential” to the title to improve clarity.</i></p>
	<p>For the reasons set out above, we consider that the evidence provided to the Washington Health Authority for the re-review of the HTA for hip resurfacing contains significant methodological limitations and fails adequately to take into account the superior evidence base for, and performance of, the BHR system, by comparison with competitor devices. Indeed, the draft report fails adequately to distinguish between different hip resurfacing brands at all, preferring instead to rely on a flawed comparison of revision rates of hip resurfacing as a class with THA. To that extent, we would suggest that the Draft Evidence Report, as it presently stands, is an insufficient basis for any decision at this stage.</p> <p>The BHR system is distinguished by over 14 years of superior clinical performance²⁶, and is the only resurfacing prosthesis with over 10 years of registry data.</p>	<p><i>Thank you for your comments.</i></p>

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	<p>When implanted in the right patient and in accordance with the surgical technique, Smith & Nephew considers that the BHR continues to offer a bone-conserving and clinically proven alternative to conventional THA in patients requiring a high level of post-operative function. Smith & Nephew is confident that the BHR is a safe device, which does not exhibit the same performance issues that have been identified for some competitor devices due to its superior metallurgy and design.</p> <p>We will continue to recommend the use by surgeons of the BHR system for appropriate patients. Typically, these are active male osteoarthritis patients under the age of 65, who have no bone or biomechanical contra-indications and require a head size 48 mm or larger. Used in compliance within the approved product label, BHR can bring significant advantages to appropriate patients when compared with conventional THA.</p> <p>We are grateful for the opportunity to provide you with this information. We feel strongly that category-level analyses or generic alerts and advisories that fail to distinguish the very real differences between different brands of hip resurfacing devices are neither warranted nor in the best interest of public health.</p>	
	<p>Finally, on an editorial note, we have observed inaccuracies in the information presented in the report. While these are most likely of formatting origin, we feel that their uncorrected presence may be misleading to the reader. An example is the transposition in labelling in figure 7 in section 4.1.2, where the histogram shows the 71-month EQ-5D scores from Pollard as 0.9 for THA and 0.78 for HR and the 120-month EQ-5D scores from Baker as 0.84 for THA and 0.78 for HR. For each, the reverse is true. We recommend further proof-reading of the text to ensure elimination of other errors of this type.</p>	<p><i>Thank you for your comment. Correction made to the figure.</i></p>

Alfred Blue

Report Section	Reviewer's comments	SRI Response
General	<p>HR is just another name for a cup arthroplasty. The THR was developed to overcome the problems with cup arthroplasty.</p> <p>1930s</p> <p>This procedure and its problems go back to 1930s.</p> <p>Why allow the procedure? It will have the same rate of failure and problems that have already been demonstrated</p>	<i>Thank you for your comments</i>

Clinical Reviewers

Jason Weisstein, MD, MPH, FACS

Report Section	Reviewer's comments	SRI Response
INTRODUCTION	<p>The topic overview is excellent. See below for some minor comments related to this portion of the manuscript. The topic is critically important to address as the use of metal on metal bearings has received widespread attention internationally.</p> <p>The scientific understanding of total hip resurfacing has increased significantly since the prior HTA report.</p>	<i>Thank you for your comment.</i>
Page 7	<p>Gender: You might consider mentioning that in an article published in JBJS British (J Bone Joint Surg Br. 2012 Sep;94(9):1180-6) that retrospectively reviewed ten year survival of a cohort of 554 patients who underwent Birmingham hip resurfacing, the results in women were so poor that the authors recommended against the use of metal on metal resurfacing in women.</p>	<i>Section 4.4, KQ 5 of the report on page 90, (differential effectiveness and safety), addresses the issue of the effect of gender on revision rates following THA and HR: females receiving HR have significantly higher revision rates than females receiving THA or males receiving HR or THA (P < .00001).</i>
Page 8	<p>Obesity: Hip Int. 2012 Jan-Feb;22(1):107-12 This study found no correlation between increased BMI (body mass index) and higher cobalt/chromium levels.</p>	<i>We did not evaluate the effect of obesity on blood ion levels which are a surrogate outcome measure.</i>

Report Section	Reviewer's comments	SRI Response
BACKGROUND	Literature review is excellent. The articles and studies cited and reviewed are well documented and the bibliographic detail is extensive.	<i>Thank you for your comment.</i>
OBJECTIVES AND KEY QUESTIONS	Questions are clearly defined and more than adequate for addressing the topic.	<i>Thank you for your comment.</i>
Appraisal - Page 10, paragraph 1	When discussing younger patients the following point might be considered. Patients who are younger are more likely to have a diverse set of causes leading them to undergo total hip replacement. For example, osteonecrosis is a common cause of hip pain in younger patients. Traditionally, patients with osteonecrosis have had worse outcomes after total hip arthroplasty than patients with osteoarthritis.	<i>Point incorporated into paragraph 1.</i>
Page 10, last paragraph	Another proposed benefit of hip resurfacing is improved implant durability.	<i>Incorporated into last paragraph on page 10.</i>
Page 11	Many joint arthroplasty experts are now using the phrase adverse local tissue reactions to encompass both pseudotumors and ALVAL.	<i>Incorporated the phrase on page 11.</i>
Page 11, paragraph 2	Does the 2.5% in 2011 refer to the United States?	<i>This refers to the national Joint Registry of England and Wales. We clarified in the text.</i>
Page 15	End of sentence stating potential bias needs to be taken into account might be followed with: For example, advocates of the Birmingham hip have recently published excellent survival and functional results in men into the second decade, with good results achieved in appropriately selected women (Bone Joint J 2013;95-B:1172-7).	<i>There are examples of industry sponsored trials in the report, and potential conflicts with industry listed in tables 11 and 12 of the report.</i>
Page 15, Section 1.4.1	Patients with a strong history or family history of metabolic bone disease (osteoporosis) should not undergo hip resurfacing. Lastly, patients who are immunosuppressed should not undergo hip resurfacing.	<i>Incorporated on page 15.</i>
Page 20	The section on primary or secondary osteoarthritis is confusing. The current paragraph explains primary wear and tear osteoarthritis well. Secondary osteoarthritis is arthritis that results from a specific cause such as injury (i.e., a fracture of the acetabulum) or obesity.	<i>Clarified in the text on page 20.</i>

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Page 21	Total HR is relatively contraindicated if osteonecrosis affects more than half of the femoral head. Still, some surgeons prefer total HR in this setting especially if the patient is very young.	<i>Included as the 6th bullet on the list of contraindications.</i>
Page 21	In the section hip dysplasia, sometime should be sometimes.	<i>Thank you for your comment, a change has been made.</i>
Page 21, Section 2.6	Interestingly, recent data suggest that there is up to a 31% incidence of adverse local tissue reactions even in asymptomatic patients who have undergone total HR (Clinical Orthopaedics and Related Research, Aug, 2013).	
Page 23, Heterotopic Ossification	Total HR involves more <i>muscle trauma</i> for adequate exposure which may predispose to and increased risk of heterotopic bone formation.	<i>Incorporated on page 23.</i>
Page 23, last sentence	I believe that long-term should be followed with the word follow-up.	<i>Thank you for your comment, a change has been made.</i>
Page 24	The word or should be inserted between fissure and proximal. It reads now with the word of.	<i>Corrected.</i>
Page 25, operative approach	The statement that an incision is made on the side of the thigh should be changed to "an incision is made on the upper part of the thigh." Most orthopaedic surgeons do the procedure via a posterolateral approach, however, there is a subset of surgeons who do the surgery via a direct anterior or anterolateral approach.	<i>Corrected.</i>
Page 25-26	The following sentence is inaccurate. The anterior approach does preserve blood flow to the femoral head but makes visualization of the socket difficult. The anterior approach makes visualization of the socket easy while visualization of the femur is more difficult.	<i>Corrected.</i>
Page 26	Typographical error. Please change may to many. This technique is also unfamiliar to many surgeons and may require a specialized surgical table. ¹⁴⁶	<i>Thank you for your comment, a change has been made.</i>
METHODS	Level of evidence and review are extensive and well-illustrated both graphically and via statistical analysis interpretation.	<i>Thank you for your comment</i>
Page 47	typographical error. Ankylosing spondylitis.	<i>Corrected</i>
Page 48	typographical error. Developmental dysplasia, not dysplasia. Also should be hip dysplasia, not hip dysplasia.	<i>Thank you for your comment, a change has been made.</i>
RESULTS	The results are clinically sound and all questions posed are answered in great detail. Any discrepancy in the literature has been dealt with appropriately. Where insufficient evidence exists, it is clearly stated.	<i>Thank you for your comment</i>

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Page 80	Immune cellular function has also been shown to be affected by high metal ion levels. For example, CD4 and CD8 cell counts have been shown to be decreased in patients with high metal ion concentrations.	<i>Immunological responses are discussed on page 85.</i>
Page 86	patients may have worse outcomes after THA for a pseudotumor especially if there has been significant soft tissue destruction. There may be resultant abductor muscle damage that can impair hip strength and ambulatory ability.	<i>The limited evidence for this is detailed in the last paragraph on page 86.</i>
Page 87, first paragraph	Please delete the words "explored whether."	<i>Rearranged text to clarify</i>
Page 87	<u>Hip Int</u> 2013 Mar-Apr;23(2):181-6 Authors showed that development of children born from mothers who had metal on metal hip resurfacing was normal.	<i>This study reports on 8 mothers who had MoM HR and who returned a survey about their pregnancies. From the 8 women, there were 17 pregnancies resulting in 14 births. Three of the births were complicated resulting in 2 premature births. No children were born with birth defects. This is consistent with our statement in the report that "To date, there has never been a report of birth defects/fetal malformation associated with MoM hip implants."</i>
Page 110	The definition of heterotopic ossification should say unwanted bone growth <i>in the soft tissues</i> around an implant.	<i>Thank you for your comment, a change has been made.</i>
CONCLUSIONS	The conclusions are valid. There are several sections that are unable to draw definitive conclusions and state that further research is warranted. This is completely true.	<i>Thank you for your comment.</i>

Creighton C. Tubb, MD

Report Section	Reviewer's comments	SRI Response
Executive Summary and Introduction	The topic of hip resurfacing arthroplasty (HR) is comprehensively reviewed as a part of this summary and the introduction to this update. There is a growing body of research involving hip resurfacing and other forms of hip arthroplasty to address the trend toward some form of hip replacement in a younger and presumably more active patient population with severe hip disease. It is important to realize that data suggest a higher revision rate for total hip arthroplasty (THA) in a young patient cohort. However, there is difficulty in interpreting the relevance of the literature with respect to long term implant survival in the face of continual technological and implant changes. It also must be stated that comparisons between hip resurfacing and total hip arthroplasty requires some consideration for the various implant designs (for both procedures) and bearing surfaces in the latter procedure. This report addresses some of these concerns in its analysis of the available evidence. I recognize the authors are constrained by the available literature.	<i>Thank you for your comment.</i>
Background Rationale Section 1.1	It is worth noting in the Rationale Section 1.1 that the acetabular component (socket) can be uncemented (press-fit) or cemented as stated in the description of THA. For completeness, uncemented acetabular components may or may not use screw fixation as well. Additionally, the report mentions bearing couples of metal-on-metal, metal-on-plastic (polyethylene), and ceramic-on-ceramic. There is also a trend to use a ceramic-on-plastic bearing couple in young patients undergoing THA. Additionally, it is worth noting that traditional polyethylene acetabular liners can be used but there is also growing evidence to utilize a highly cross-linked form of the polyethylene. Each of these bearing couples represents attributes and limitations in wear characteristics and durability.	<i>Included comments into the rationale section.</i>
Background Section 2.2 Advantages of HR versus THA	In Section 2.2 (Advantages of HR versus THA) realize that there is removal of the femoral head in THA; however, this can be replaced with a metal ball as noted but could also be replaced with a ceramic or ceramicized metal ball.	<i>Added comments in section 2.2.</i>
Background Section 2.10 Operative	Section 2.10 (Operative Approach) discusses the various operative approaches for hip resurfacing. The posterior approach does not have to disrupt the femoral head blood	<i>Corrected, thank you.</i>

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Approach	supply and really should not for resurfacing procedures in order to avoid femoral head osteonecrosis. I do not believe that the posterior approach would increase the risk for femoral nerve palsy and am not familiar with evidence to suggest that. There may be an increased risk for sciatic nerve palsy with the posterior approach compared to other approaches. Finally, some would argue that the anterior approach does not make acetabular visualization more difficult. The technique does require some training and expertise in the approach.	
Report Objectives / Key Questions	This update has clearly defined objectives and has crafted Key Questions to reach these objectives.	<i>Thank you for your comment.</i>
Key Question #3	Key Question #3 reads "What is the evidence of efficacy, effectiveness and safety of revisions to hip resurfacing compared with revisions of THA?" It may be better worded as "What is the evidence of efficacy, effectiveness and safety of revisions of hip resurfacing compared with revisions of THA?"	<i>Thank you for your comment, a change has been made.</i>
Methods	The method for analyzing the available literature reveals a systematic and unbiased approach to selecting available, quality data. The grading of evidence is appropriate and clearly presented in the report and even more so in Appendix D. Summary statements about the included studies provide a solid foundation for later interpretation of the results. The breakdown of which types of studies were utilized to answer each of the key questions highlights the care taken to ensure the best and most relevant research is utilized for that particular area of concern. The rigorous evaluation of the presented data and level of evidence lends credibility to the conclusions drawn.	<i>Thank you for your comment.</i>
Results	The results presented in this update are inclusive and carefully answer each of the key questions beginning with the best available evidence. Though on initial read this section seems overly detailed, the presentation of results in text, table, and graphic format allows for clear understanding of the evidence with respect to the questions being asked.	<i>Thank you for your comment.</i>
Results Section 4.2.1 Midterm Causes for Revision	I do have some concern about the reporting of findings in Section 4.2.1 (Midterm Causes for Revision) specifically looking at the results from the cohort studies. <u>The text and table 17 appear to have listed the complications found with the hip resurfacing under the THA category and vice versa.</u> In review of references 10 and 137, this seems to be the case. The ultimate conclusions drawn suggest that this is merely a	<i>Thank you for your comment, this has been corrected.</i>

Report Section	Reviewer's comments	SRI Response
	clerical error rather than a true error in interpretation of the results from these studies.	
Results (General)	Ultimately, the implications from the findings in the studies analyzed are clearly stated in relation to the key questions. There are gaps in the literature specifically in relation to the quality of studies available and most notably in the studies specifically looking at cost effectiveness of HR versus THA. These limitations are noted throughout the update. Where appropriate, recommendations regarding these deficiencies are put forth.	<i>Thank you for your comment.</i>
Results (General)	One area of bias that is potentially rampant in the recent literature with respect to HR and any metal-on-metal hip arthroplasty is the sensitive trigger to proceed to revision of a metal-on-metal device in light of recent implant recalls and resultant media attention or patient concerns. This report does not specifically address that issue. However, as reports of revision rates become more available for these devices, care must be taken in analyzing the design of the study to look for this potential selection bias favoring revision in a metal-on-metal implant.	<i>Point noted.</i>
Conclusions	The conclusions drawn in this update are valid and represent a clear understanding of the best available evidence with respect to hip resurfacing in young patients with hip disease.	<i>Thank you for your comment</i>
Overall	This update provides a well structured and analytical approach to a topic that is not only acutely relevant in clinical practice but also with respect to healthcare policy. There are knowledge deficits related to the current body of research that are addressed in the study. This can make policy making more of a challenge. However, the report synthesizes conclusions based on what is known using the best available evidence. These conclusions provide a basis for at least better understanding hip resurfacing at the present time.	<i>Thank you for your comment</i>

Howard Chansky, MD

Report Section	Reviewer's comments	SRI Response
Appraisal 1.1 Rationale	Solid metal cups may also be used in MoM hip replacements – this is important because these must be completely removed during revision of the cup, whereas other implants may permit just an exchange of the liner.	<i>Incorporated into rationale</i>
Key considerations 1.2.1 Intervention Metal ion concern:	There is in fact an increase in chromosomal aberrations in those with MoM hips	
Background 2.1 History of Hip Resurfacing	With correct patient selection, surgeon education, and operative technique, survivorship at five years was thought to be comparable with that of conventional hip replacements. ^{12,169} (I don't feel this is the case as of 2013 – see results from Key Question 2 on page 5). However, with longer clinical follow-up it now appears that the revision rate for total HR exceed those of THA.	<i>Incorporated into section 2.1.</i>
Background 2.1 History of Hip Resurfacing Last sentence	Survivorship in younger patients has been reported to be 99.8% at a mean of 3.3 years in 446 osteoarthritic hips ³⁷ ; 94.4% at 4 years in 400 hips ¹ ; and 99.1% at a mean of 5 years follow-up in a prospective study of 230 resurfaced hips. ⁷⁵ (not sure I understand this last sentence, survivorship of what implant? 99.1% survivorship of resurfaced hips is not representative of most studies)	<i>99.1% is from Hing et al (reference 75 in the report) after 3 years. This was corrected in the text.</i>
Background 2.2 Advantages of Hip Resurfacing versus Total Hip Replacement	With total HR, the cup consists of a solid single piece of metal. With MoM THA the cup is either solid metal or a metal cup that accepts various liners.	<i>Corrected in section 2.2.</i>
Background 2.2 Advantages of Hip Resurfacing versus Total Hip Replacement	The comment that patients tend to recover more quickly following total HR surgery than they do after THA is subtle and may not be of clinical significance	<i>Sentence removed</i>
Background 2.2 Advantages of HR vs THA Last sentence	NOT true – in fact metal wear debris and osteolysis are problems with resurfacing.	<i>Statement removed</i>
Background 2.4 Indications for Hip Resurfacing	In general, most now believe that only primary and secondary OA are the main indications for total HR. Inflammatory arthritides can cause cysts and softening of the bone which can compromise surface HR with early loosening or neck fractures	<i>This note of precaution is added to this section.</i>

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Background 2.6 Metal-on-metal bearings and current safety concerns	Aug 31, 2013: Depuy voluntarily removed from the world-wide market the modular metal liner for their Pinnacle cup system	<i>Noted.</i>
Background 2.10 Operative approach	Disruption of blood flow does not lead to nerve palsy	<i>Corrected.</i>
Overall	Multiple grammatical and typographical suggestions were made in the document itself using track changes	<i>Thank you for your notes – changes made.</i>

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By email and post

30 September 2013

To:

Josh Morse, MPH
Director, Health Technology Assessment Program
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Washington Healthcare Authority
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RE: Health Technology Assessment, Hip Resurfacing Re-review

Smith & Nephew is a global medical technology business specializing in Orthopaedics (Trauma and Total Joint Reconstruction), Endoscopy and Advanced Wound Management. Smith & Nephew is a leading global innovator in the development and manufacture of devices used in hip arthroplasty.

We appreciate that the Washington State Health Care Authority Health Technology Assessment Program has invited comments on the draft evidence report for the re-review Health Technology Assessment (HTA) on metal-on-metal (MoM) Hip Resurfacing conducted by Spectrum Research, Inc. ('the Draft Evidence Report')

We offer below Smith & Nephew's views and observations on the conclusions set out in the draft report. These comments complement the information we submitted on January 10, 2013, concerning Smith & Nephew's BIRMINGHAM HIP[®] Resurfacing System (BHR).

We are concerned that the methodology used by Spectrum Research Inc. examines the performance and outcomes of resurfacing implants as a class, without adequately differentiating the results of different manufacturers' hip resurfacing technologies (some of which have been recalled or withdrawn). This is a significant flaw, which limits the usefulness of the draft report as a basis for any decision which you may make concerning the future of MoM hip resurfacing in Washington State.

We note that the significant design and superior clinical performance differences between BHR and other devices in the resurfacing arthroplasty class appear to have been disregarded during the review. For example:

(1) Several of the focus publications refer to studies describing or comparing hip resurfacing outcomes alone or to total hip arthroplasty (THA) that were conducted with competitor devices, which three national hip arthroplasty registers have shown to have significantly inferior revision outcomes compared to the BHR;

(2) For Key Question 4 (in the executive summary and page 7, but KQ 5 in section 4.4 on page 89), the draft report fails to identify hip resurfacing brand as a significant differentiator. Jameson, et.al, determined that brand was an independent predictor of revision in 27,871 patients receiving hip resurfacing procedures.¹ (Figure 1).

An analysis of revision rates reported in revisions per 100 observed patient years taken from de Steiger, et.al.² and from the three national registries identified in the draft report, the 2012 Australian Orthopedic Association National Joint Replacement Register, the 2012 National Joint Registry of England and Wales, and the 2011 Swedish Hip Arthroplasty Register, all confirm these findings (Figure 2).

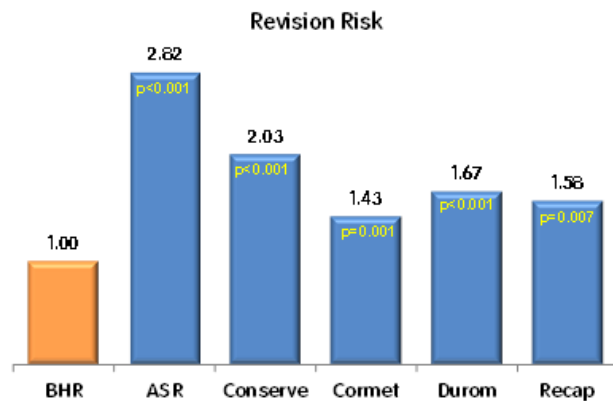
Furthermore, BHR was the only hip resurfacing implant supported by 10 years' actual revision data: (Table 1) All other implants required appropriate data extrapolation to allow a 10 year comparison. This should have been taken into account in Spectrum Research, Inc.'s analysis.

Recognition should also have been given to the fact that experience with BHR, measured by total patients treated or total observed years implanted, is the highest among all hip resurfacing implants in the three cited registries (Figure 3). Of those receiving hip resurfacing, BHR accounts for 68% of the patients and 74% of the observed patient years in the Australian registry and 55% of the patients and an estimated 57% of the observed patient years in the Swedish registry. There, while BHR was used in 58% of patients overall, in 2011 it was used in 83% of patients receiving a hip resurfacing device.

BHR alone among these devices has a significant body of clinical evidence supporting its effectiveness in both the joint registries and the peer-reviewed literature. In summary, 21 publications report on a total of 13,789 BHR implants and 128,617 observed component years. Weighted average follow-up among these study populations is 9.3 years, with a weighted average

Figure 1.

Implant Brand As a Predictor of Revision Risk



Source: Jameson SS, Baker PN, Mason J, et al. Independent predictors of revision following metal-on-metal hip resurfacing: A retrospective cohort study using national joint registry data. The Journal of Bone and Joint Surgery 2012;94-B:746-754.

Figure 2.

BHR is associated with a lower revision rate than other hip resurfacing implants

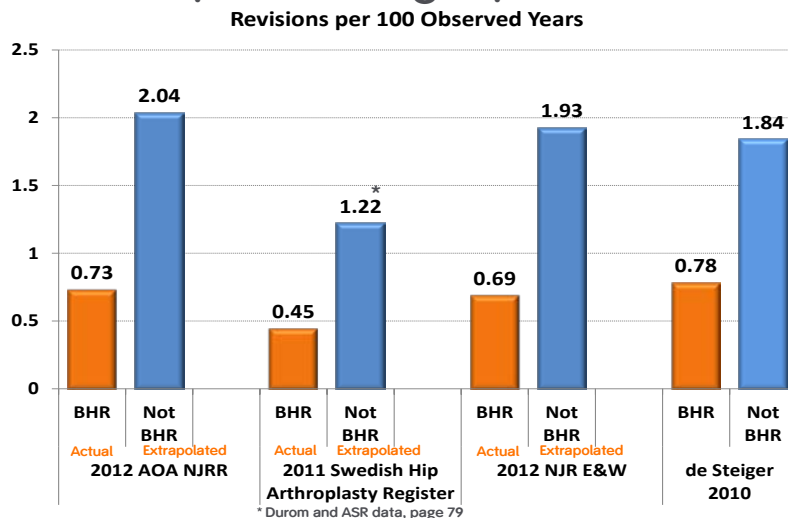
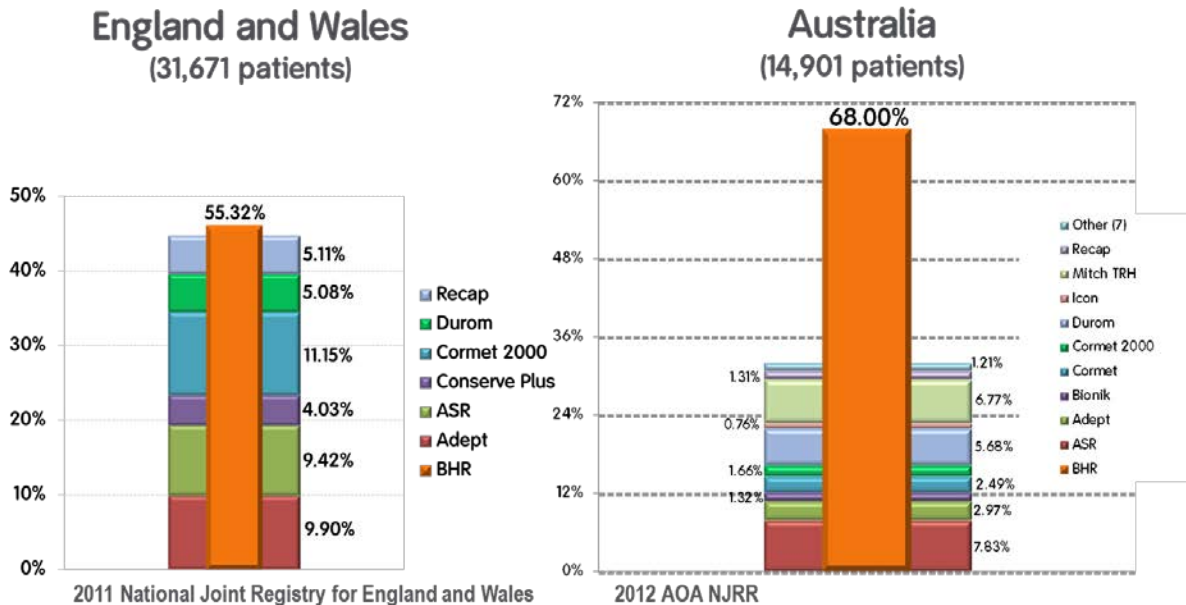


Table 1.

10 Year Revision Rate of BHR

Source	10 Year Revision Rate	Actual or Extrapolated
Australia (AOA NJRR 2012)	6.7%	Actual
England and Wales NJR 2011	7.1%	Extrapolated (5.1% Actual @ 7 Yrs)
Sweden (Hip Arthroplasty Register 2011)	6.2%	Actual

Figure 3.
BHR is implanted in more patients than other hip resurfacing devices combined



survivorship of 95.6 %. A total of 9,287 patients and 102,453 observed component years are reported at a minimum of 10 years follow-up with a weighted average survivorship of 95.5%³⁻²¹

We are also concerned by the fact the Draft Evidence Report focuses on a simple comparison of revision rates between hip resurfacing procedures and THA. Because hip resurfacing offers different benefits from THA, based upon patient characteristics, needs and treatment goals determined between the patient and the surgeon, the Draft Evidence Report should have compared hip resurfacing to conservative medical management in patient populations with diseases in which hip resurfacing is indicated.

Additionally, while metal on polyethylene (MoP) bearings may be appropriate for THA patients who are more elderly and less active, by contrast, the use of metal-on-metal (MoM) technology for resurfacing has significant advantages, especially for younger, more active patients. These advantages include the following:^{15,22-24}

- Elimination of proximal femoral stress shielding
- Elimination of polyethylene induced osteolysis
- Reduced risk of dislocation, as compared to traditional THA
- Reduced risk of postoperative leg length discrepancy
- Physiological restoration of hip offset, supporting normal function
- Return to an active lifestyle is possible and sustained to at least 10 years.²⁵

The fact that the draft report recognises certain of the advantages of hip resurfacing over THA in indicated populations – noting that hip resurfacing allows for easier revision than would a THA (page 20) and that patients

recover more quickly after hip resurfacing surgery than after THA surgery (page 20) – itself indicates a simple comparison of revision rates between hip resurfacing and THA to be inappropriate.

Conclusions

For the reasons set out above, we consider that the evidence provided to the Washington Health Authority for the re-review of the HTA for hip resurfacing contains significant methodological limitations and fails adequately to take into account the superior evidence base for, and performance of, the BHR system, by comparison with competitor devices. Indeed, the draft report fails adequately to distinguish between different hip resurfacing brands at all, preferring instead to rely on a flawed comparison of revision rates of hip resurfacing as a class with THA. To that extent, we would suggest that the Draft Evidence Report, as it presently stands, is an insufficient basis for any decision at this stage.

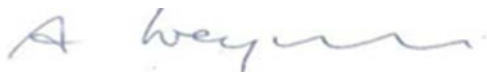
The BHR system is distinguished by over 14 years of superior clinical performance²⁶, and is the only resurfacing prosthesis with over 10 years of registry data. When implanted in the right patient and in accordance with the surgical technique, Smith & Nephew considers that the BHR continues to offer a bone-conserving and clinically proven alternative to conventional THA in patients requiring a high level of post-operative function. Smith & Nephew is confident that the BHR is a safe device, which does not exhibit the same performance issues that have been identified for some competitor devices due to its superior metallurgy and design.

We will continue to recommend the use by surgeons of the BHR system for appropriate patients. Typically, these are active male osteoarthritis patients under the age of 65, who have no bone or biomechanical contra-indications and require a head size 48 mm or larger. Used in compliance within the approved product label, BHR can bring significant advantages to appropriate patients when compared with conventional THA.

We are grateful for the opportunity to provide you with this information. We feel strongly that category-level analyses or generic alerts and advisories that fail to distinguish the very real differences between different brands of hip resurfacing devices are neither warranted nor in the best interest of public health.

Finally, on an editorial note, we have observed inaccuracies in the information presented in the report. While these are most likely of formatting origin, we feel that their uncorrected presence may be misleading to the reader. An example is the transposition in labelling in figure 7 in section 4.1.2, where the histogram shows the 71-month EQ-5D scores from Pollard as 0.9 for THA and 0.78 for HR and the 120-month EQ-5D scores from Baker as 0.84 for THA and 0.78 for HR. For each, the reverse is true. We recommend further proof-reading of the text to ensure elimination of other errors of this type.

Yours sincerely,



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Advanced Surgical Devices Division

Smith & Nephew

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From: Alfred Blue <aiblue@aol.com>
To: HCA ST Health Tech Assessment Prog
Sent: Tue 8/27/2013 5:22 PM
Cc:
Subject: Public Comment for Hip Resurfacing Re-review

HR is just another name for a cup arthroplasty. The THR was developed to overcome the problems with cup arthroplasty.

1930s

This procedure and its problems go back to 1930s.

Why allow the procedure? It will have the same rate of failure and problems that have already been demonstrated

Peer Review: Hip Resurfacing Update by Spectrum Research, Inc.

Jason Weisstein, MD, MPH, FACS

Health Technology Assessment

Introduction: The topic overview is excellent. See below for some minor comments related to this portion of the manuscript. The topic is critically important to address as the use of metal on metal bearings has received widespread attention internationally. The scientific understanding of total hip resurfacing has increased significantly since the prior HTA report.

Background: Literature review is excellent. The articles and studies cited and reviewed are well documented and the bibliographic detail is extensive.

Objectives and Key Questions: Questions are clearly defined and more than adequate for addressing the topic.

Methods: Level of evidence and review are extensive and well illustrated both graphically and via statistical analysis interpretation.

Results: The results are clinically sound and all questions posed are answered in great detail. Any discrepancy in the literature has been dealt with appropriately. Where insufficient evidence exists, it is clearly stated.

Conclusions: The conclusions are valid. There are several sections that are unable to draw definitive conclusions and state that further research is warranted. This is completely true.

Page by Page analysis of Hip Resurfacing Update:

Gender – page 7: You might consider mentioning that in an article published in JBJS British ([J Bone Joint Surg Br.](#) 2012 Sep;94(9):1180-6) that retrospectively reviewed ten year survival of a cohort of 554 patients who underwent Birmingham hip resurfacing, the results in women were so poor that the authors recommended against the use of metal on metal resurfacing in women.

Obesity – page 8: Hip [Int.](#) 2012 Jan-Feb;22(1):107-12 This study found no correlation between increased BMI (body mass index) and higher cobalt/chromium levels.

Appraisal – page 10, paragraph 1: When discussing younger patients the following point might be considered. Patients who are younger are more likely to have a diverse set of causes leading them to undergo total hip replacement. For example, osteonecrosis is a common cause of hip pain in younger patients. Traditionally, patients with osteonecrosis have had worse outcomes after total hip arthroplasty than patients with osteoarthritis.

Page 10 – last paragraph. Another proposed benefit of hip resurfacing is improved implant durability.

Page 11 – Many joint arthroplasty experts are now using the phrase adverse local tissue reactions to encompass both pseudotumors and ALVAL.

Page 11, paragraph 2- Does the 2.5% in 2011 refer to the United States?

Page 15, end of sentence stating potential bias needs to be taken into account might be followed with: For example, advocates of the Birmingham hip have recently published excellent survival and functional results in men into the second decade, with good results achieved in appropriately selected women (Bone Joint J 2013;95-B:1172-7).

Page 15, Section 1.4.1 Patients with a strong history or family history of metabolic bone disease (osteoporosis) should not undergo hip resurfacing. Lastly, patients who are immunosuppressed should not undergo hip resurfacing.

Page 20. Total HR is relatively contraindicated if osteonecrosis affects more than half of the femoral head. Still, some surgeons prefer total HR in this setting especially if the patient is very young.

Page 20. The section on primary or secondary osteoarthritis is confusing. The current paragraph explains primary wear and tear osteoarthritis well. Secondary osteoarthritis is arthritis that results from a specific cause such as injury (i.e., a fracture of the acetabulum) or obesity.

Page 21. In the section hip dysplasia, sometime should be sometimes.

Page 21, section 2.6: Interestingly, recent data suggest that there is up to a 31% incidence of adverse local tissue reactions even in asymptomatic patients who have undergone total HR (Clinical Orthopaedics and Related Research, Aug, 2013).

Page 23, heterotopic ossification. Total HR involves more *muscle trauma* for adequate exposure which may predispose to and increased risk of heterotopic bone formation.

Page 23, last sentence. I believe that long-term should be followed with the word follow-up.

Page 24. The word or should be inserted between fissure and proximal. It reads now with the word of.

Page 25, operative approach. The statement that an incision is made on the side of the thigh should be changed to "an incision is made on the upper part of the thigh." Most orthopaedic surgeons do the procedure via a posterolateral approach, however, there is a subset of surgeons who do the surgery via a direct anterior or anterolateral approach.

Page 25-26, The following sentence is inaccurate. The anterior approach does preserve blood flow to the femoral head but makes visualization of the socket difficult. The anterior approach makes visualization of the socket easy while visualization of the femur is more difficult.

Page 26, Typographical error. Please change may to many. This technique is also unfamiliar to many surgeons and may require a specialized surgical table.¹⁴⁶

Page 47, typographical error. Ankylosing spondylitis.

Page 48, typographical error. Developmental dysplasia, not dysplasia. Also should be hip dysplasia, not hip dysplasia.

Page 80, Immune cellular function has also been shown to be affected by high metal ion levels. For example, CD4 and CD8 cel counts have been shown to be decreased in patients with high metal ion concentrations.

Page 86, patients may have worse outcomes after THA for a pseudotumor especially if there has been significant soft tissue destruction. There may be resultant abductor muscle damage that can impair hip strength and ambulatory ability.

Page 87, first paragraph. Please delete the words “explored whether.”

Page 87, Hip Int 2013 Mar-Apr;23(2):181-6 Authors showed that development of children born from mothers who had metal on metal hip resurfacing was normal.

Page 110. The definition of heterotopic ossification should say unwanted bone growth *in the soft tissues* around an implant.

Creighton C. Tubb, M.D.**EXECUTIVE SUMMARY AND INTRODUCTION:**

The topic of hip resurfacing arthroplasty (HR) is comprehensively reviewed as a part of this summary and the introduction to this update. There is a growing body of research involving hip resurfacing and other forms of hip arthroplasty to address the trend toward some form of hip replacement in a younger and presumably more active patient population with severe hip disease. It is important to realize that data suggest a higher revision rate for total hip arthroplasty (THA) in a young patient cohort. However, there is difficulty in interpreting the relevance of the literature with respect to long term implant survival in the face of continual technological and implant changes. It also must be stated that comparisons between hip resurfacing and total hip arthroplasty requires some consideration for the various implant designs (for both procedures) and bearing surfaces in the latter procedure. This report addresses some of these concerns in its analysis of the available evidence. I recognize the authors are constrained by the available literature.

BACKGROUND:

It is worth noting in the Rationale Section 1.1 that the acetabular component (socket) can be uncemented (press-fit) or cemented as stated in the description of THA. For completeness, uncemented acetabular components may or may not use screw fixation as well. Additionally, the report mentions bearing couples of metal-on-metal, metal-on-plastic (polyethylene), and ceramic-on-ceramic. There is also a trend to use a ceramic-on-plastic bearing couple in young patients undergoing THA. Additionally, it is worth noting that traditional polyethylene acetabular liners can be used but there is also growing evidence to utilize a highly cross-linked form of the polyethylene. Each of these bearing couples represents attributes and limitations in wear characteristics and durability.

In Section 2.2 (Advantages of HR versus THA) realize that there is removal of the femoral head in THA; however, this can be replaced with a metal ball as noted but could also be replaced with a ceramic or ceramicized metal ball.

Section 2.10 (Operative Approach) discusses the various operative approaches for hip resurfacing. The posterior approach does not have to disrupt the femoral head blood supply and really should not for resurfacing procedures in order to avoid femoral head osteonecrosis. I do not believe that the posterior approach would increase the risk for femoral nerve palsy and am not familiar with evidence to suggest that. There may be an increased risk for sciatic nerve palsy with the posterior approach compared to other approaches. Finally, some would argue that the anterior approach does not make acetabular visualization more difficult. The technique does require some training and expertise in the approach.

REPORT OBJECTIVES / KEY QUESTIONS:

This update has clearly defined objectives and has crafted Key Questions to reach these objectives. Key Question #3 reads "What is the evidence of efficacy, effectiveness and safety of revisions to hip resurfacing compared with revisions of THA?" It may be better worded as "What is the evidence of efficacy, effectiveness and safety of revisions of hip resurfacing compared with revisions of THA?"

METHODS:

The method for analyzing the available literature reveals a systematic and unbiased approach to selecting available, quality data. The grading of evidence is appropriate and clearly presented in the report and even more so in Appendix D. Summary statements about the included studies provide a solid foundation for later interpretation of the results. The breakdown of which types of studies were utilized to answer each of the key questions highlights the care taken to ensure the best and most relevant research is utilized for that particular area of concern. The rigorous evaluation of the presented data and level of evidence lends credibility to the conclusions drawn.

RESULTS:

The results presented in this update are inclusive and carefully answer each of the key questions beginning with the best available evidence. Though on initial read this section seems overly detailed, the presentation of results in text, table, and graphic format allows for clear understanding of the evidence with respect to the questions being asked.

I do have some concern about the reporting of findings in Section 4.2.1 (Midterm Causes for Revision) specifically looking at the results from the cohort studies. The text and table 17 appear to have listed the complications found with the hip resurfacing under the THA category and vice versa. In review of references 10 and 137, this seems to be the case. The ultimate conclusions drawn suggest that this is merely a clerical error rather than a true error in interpretation of the results from these studies.

Ultimately, the implications from the findings in the studies analyzed are clearly stated in relation to the key questions. There are gaps in the literature specifically in relation to the quality of studies available and most notably in the studies specifically looking at cost effectiveness of HR versus THA. These limitations are noted throughout the update. Where appropriate, recommendations regarding these deficiencies are put forth.

One area of bias that is potentially rampant in the recent literature with respect to HR and any metal-on-metal hip arthroplasty is the sensitive trigger to proceed to revision of a metal-on-metal device in light of recent implant recalls and resultant media attention or patient concerns. This report does not specifically address that issue. However, as reports of revision rates become more available for these devices, care must be taken in analyzing the design of the study to look for this potential selection bias favoring revision in a metal-on-metal implant.

CONCLUSIONS:

The conclusions drawn in this update are valid and represent a clear understanding of the best available evidence with respect to hip resurfacing in young patients with hip disease.

OVERALL:

This update provides a well structured and analytical approach to a topic that is not only acutely relevant in clinical practice but also with respect to healthcare policy. There are knowledge deficits related to the current body of research that are addressed in the study. This can make policy making more of a challenge. However, the report synthesizes conclusions based on what is known using the

best available evidence. These conclusions provide a basis for at least better understanding hip resurfacing at the present time.