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Metal-on-Metal Hip Resurfacing Arthroplasty: An Analysis of Safety and Revision Rates

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Health Quality Ontario (HQO) is an agency funded by the Ministry of Health and Long-Term Care. An essential part of HQO's mandate is to provide evidence-based recommendations on the coordinated uptake of health care services and health technologies in Ontario to the Ministry of Health and Long-Term Care and to the health care system. This mandate helps to ensure that residents of Ontario have access to the best available and most appropriate health care services and technologies to improve patient outcomes.

To fulfill its mandate, HQO conducts systematic reviews of evidence and consults with experts in the health care services community. The resulting evidence-based analyses are reviewed by the Ontario Health Technology Advisory Committee, and published in the *Ontario Health Technology Assessment Series*.

About the *Ontario Health Technology Assessment Series*

To conduct its comprehensive analyses, HQO systematically reviews the available scientific literature, making every effort to consider all relevant national and international research; collaborates with partners across relevant government branches; consults with clinical and other external experts and developers of new health technologies; and solicits any necessary supplemental information.

In addition, HQO collects and analyzes information about how a new technology fits within current practice and existing treatment alternatives. Details about the technology's diffusion into current health care practices add an important dimension to the review of the provision and delivery of the health technology in Ontario. Information concerning the health benefits; economic and human resources; and ethical, regulatory, social, and legal issues relating to the technology assist in making timely and relevant decisions to optimize patient outcomes.

The public consultation process is available to individuals wishing to comment on an analysis prior to publication. For more information, please visit: http://www.hqontario.ca/en/mas/ohtac_public_engage_overview.html.

Disclaimer

This evidence-based analysis was prepared by HQO for the Ontario Health Technology Advisory Committee and developed from analysis, interpretation, and comparison of scientific research and/or technology assessments conducted by other organizations. It also incorporates, when available, Ontario data and information provided by experts and applicants to HQO to inform the analysis. While every effort has been made to reflect all scientific research available, this document may not fully do so. Additionally, other relevant scientific findings may have been reported since completion of the review. This evidence-based analysis is current to the date of the literature review specified in the methods section. This analysis may be superseded by an updated publication on the same topic. Please check the HQO website for a list of all evidence-based analyses: http://www.hqontario.ca/en/mas/mas_ohtas_mn.html.

Abstract

Background

Metal-on-metal (MOM) hip resurfacing arthroplasty (HRA) is in clinical use as an appropriate alternative to total hip arthroplasty in young patients. In this technique, a metal cap is placed on the femoral head to cover the damaged surface of the bone and a metal cup is placed in the acetabulum.

Objectives

The primary objective of this analysis was to compare the revision rates of MOM HRA using different implants with the benchmark set by the National Institute of Clinical Excellence (NICE). The secondary objective of this analysis was to review the literature regarding adverse biological effects associated with implant material.

Review Methods

A literature search was performed on February 13, 2012, to identify studies published from January 1, 2009, to February 13, 2012.

Results

The revision rates for MOM HRA using 6 different implants were reviewed. The revision rates for MOM HRA with 3 implants met the NICE criteria, i.e., a revision rate of 10% or less at 10 years. Two implants had short-term follow-ups and MOM HRA with one of the implants failed to meet the NICE criteria.

Adverse tissue reactions resulting in failure of the implants have been reported by several studies. With a better understanding of the factors that influence the wear rate of the implants, adverse tissue reactions and subsequent implant failure can be minimized. Many authors have suggested that patient selection and surgical technique affect the wear rate and the risk of tissue reactions.

The biological effects of high metal ion levels in the blood and urine of patients with MOM HRA implants are not known. Studies have shown an increase in chromosomal aberrations in patients with MOM articulations, but the clinical implications and long-term consequences of this increase are still unknown. Epidemiological studies have shown that patients with MOM HRA implants did not have an overall increase in mortality or risk of cancer. There is insufficient clinical data to confirm the teratogenicity of MOM implants in humans.

Conclusions

Metal-on-metal HRA can be beneficial for appropriately selected patients, provided the surgeon has the surgical skills required for performing this procedure.

Plain Language Summary

There are many young patients with hip diseases who need to have hip replacement surgery. Although a traditional hip replacement is an acceptable procedure for these patients, some surgeons prefer using a newer technique in young patients called hip resurfacing. In this technique, instead of removing the head of the femoral bone, a metal cap is placed on the femoral head to cover the damaged surface of the bone and a metal cup is placed in the hip socket, similar to the cups used in traditional hip replacement.

The analysis of the revision rates (i.e., how soon and in how many patients the surgery needs to be redone) and safety of resurfacing implants showed that generally these implants can last 10 years or more for the majority of young people. Good outcomes can be expected when skilled surgeons perform the surgery in properly selected patients.

However, since these implants are made of metal (cobalt and chromium alloy), there is concern about excess metal debris production due to friction between the 2 metal components leading to high levels of metal ions in the blood and urine of patients. The production of metal debris may result in inflammation in the joint or development of a benign soft tissue mass leading to implant failure. However, it has been shown that this risk can be reduced by proper positioning of the implant and the careful selection of patients for this procedure.

Little is known about the long-term biological effects of high levels of metal ions in the blood and urine of patients who have received metal implants. There is concern about potential increases in the risk of cancer and the risk of fetal abnormalities, but these effects have not been established yet. However, since cobalt and chromium can pass the placental barrier, implants that are not metal-on-metal are recommended for women at childbearing ages if they need a hip replacement.

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List of Abbreviations

ASR	Articular Surface Replacement
BHR	Birmingham Hip Resurfacing
CI	Confidence interval
CPR	Cumulative percent revision
HR	Hazard ratio
HRA	Hip resurfacing arthroplasty
MOM	Metal on metal
MOP	Metal on polyethylene
NICE	National Institute of Clinical Excellence
OA	Osteoarthritis
RA	Rheumatoid arthritis
SARI	Surface Arthroplasty Risk Index
SMR	Standardized mortality ratio
THA	Total hip arthroplasty

Background

Objective of Analysis

The primary objective of this analysis was to compare the revision rates of metal-on-metal (MOM) hip resurfacing arthroplasty (HRA) using different implants with the benchmark set by the National Institute of Clinical Excellence (NICE).[1] (1) The secondary objective was to review the literature regarding adverse biological effects associated with implant material.

Clinical Need and Target Population

Total hip arthroplasty (THA) is one of the most commonly performed operations and has long been considered the treatment of choice for advanced osteoarthritis (OA) of the hip in older patients. This procedure has a high success rate and has consistently provided good outcomes in terms of joint function and risk for revision in this patient population. (2)

In younger people, MOM HRA has been advocated as an option for the treatment of degenerative hip disease. The primary goal of MOM HRA is to buy time until an age at which conventional THA would be suitable for the patient. (3) McMinn et al (3) have indicated that if MOM HRA can offer around 10 years of good function without jeopardizing the possibility of later conversion to THA, it would be a viable conservative option.

Younger and more active people have higher expectations with respect to the use of their joints and it is perceived that MOM HRA results in a greater range of motion and would better suit the active lifestyle of younger people who place additional stress on their prostheses and for a longer period of time. (4) While some surgeons recommend that patients refrain from running and participating in high-impact activities after THA, patients undergoing MOM HRA are allowed to perform high-impact activities such as jogging. (5) Daniel et al (6) reported an extremely low rate of failure of MOM HRA in spite of the resumption of high level occupational and leisure activities, and provided early evidence of the suitability of this procedure for young and active patients with hip arthritis.

The aim of MOM HRA is to preserve the proximal femoral bone and to restore the normal anatomy and biomechanics of the joint. In this technique, a metal cap is placed on the femoral head to cover the damaged surface of the bone, and a metal cup is placed in the acetabulum. Surgeons who are in favour of the technique point to the advantages of conserving the femoral bone stock and the reduced risk of dislocation due to the large diameter of the components. However, MOM HRA is technically demanding and there is a learning curve associated with this procedure. Since retention of the proximal femoral bone limits operative access to the socket, it increases component placement errors and creates a weak spot that results in early or late failures. (3)

Mechanism of Failure

Metal-on-metal HRA failures fall into one of 2 categories: mechanical failures (such as femoral neck fracture) and bearing-related failures (such as soft tissue reactions and osteolysis). (3) The most

[1]The benchmark for selection of prostheses for primary total hip arthroplasty set by the NICE is a revision rate of 10% or less at 10 years.

commonly reported reasons for failure of MOM HRA requiring revision include femoral neck fracture, collapse of the femoral head, and component loosening.

McMinn et al (3) have described 3 risk factors (patient-related, surgeon-related, and implant-related) that are detrimental to survivorship of MOM HRA implants, and have indicated that surgeon's error in component positioning is a major risk factor for excess wear of the implant and failure of HRA. Suboptimal component positioning has been correlated with increased levels of serum metal ions, soft tissue reactions, and increased failure of MOM bearings. (7;8) Several studies have demonstrated a direct relationship between a larger acetabular inclination and an increase in metal ions. (8;9)

A large body of literature describes the relationship between higher surgeon and hospital procedure volumes and better outcomes after hip and knee arthroplasty, and suggests a correlation between higher surgeon and hospital procedure volumes and improved patient outcomes in total joint arthroplasty. (10)

Description of Disease/Condition

Osteoarthritis is a joint disease caused by the degeneration of the articular cartilage covering the joint bones. In advanced forms, the cartilage wears away completely and the bones rub against each other, causing pain and discomfort. Over the last 20 years OA has come to be recognized as a complex disease involving most tissues of the joint. (11) Epidemiological studies and molecular investigations have confirmed a major heritable component in its etiology, but no disease-modifying therapies have yet been developed. Osteoarthritis is still principally diagnosed once radiographic changes in joint tissues are detected, often reflecting irreversible damage. (11)

Selection of Ideal Patients

The most common indication for MOM HRA is end-stage OA in young active patients. In these patients, having good bone quality in the femoral head and neck and proper anatomy around the joint produces excellent outcomes if the surgeon has the appropriate skills and training for MOM HRA. (3) Patients with avascular necrosis of the femoral head or a femoral head cyst are not good candidates for HRA. (3) Loss of bone stock may compromise the stability and oseointegration of the implant.

Beaule et al (12) have developed the Surface Arthroplasty Risk Index (SARI) as a guide for patient selection for HRA. The risk of implant failure is high if the SARI is greater than or equal to 3. The authors applied the SARI in a study of young patients undergoing MOM HRA and showed its impact on clinical outcomes. They found that the SARI was significantly higher in patients with a failed implant compared to patients in whom the implant was performing well (4.7 vs. 2.6, $P = 0.001$). Factors included in the SARI are femoral cysts larger than 1 cm, activity level, previous surgery, and weight.

Global Prevalence and Incidence

According to the National Joint Registry of England and Wales' 8th Annual Report, (13) between January 1, 2010, and December 31, 2010, MOM HRA accounted for 22% and 6% of the hip arthroplasty procedures in male and female patients under 55 years of age, respectively. It accounted for less than 1% of hip arthroplasty procedures in both male and female patients over 75 years of age.

In Australia in 2005, MOM HRA accounted for 29% of primary hip arthroplasties in patients under 55 years of age. (14)

Technology/Technique

The current third generation of MOM HRA implants consists of a cemented femoral component and a press-fit acetabular component. (15) The implants for MOM HRA are made of cobalt-chromium alloy, and a body of literature has shown a rise in the concentration of cobalt and chromium ions in the blood and urine of patients following MOM HRA. Although this increase in the blood level of cobalt and chromium has never been linked to serious systemic disease, it is generally believed that the rise in these levels should be minimized. (16)

Regulatory Status

Currently, the following MOM HRA implants are licensed in Canada:

- Birmingham Hip Resurfacing (BHR) (Smith & Nephew Orthopaedics Ltd, Memphis, Tennessee)
- ConservePlus (Wright Medical Technology Inc, Arlington, Tennessee)
- Cormet (Corin Ltd, Cirencester, Gloucestershire)
- Durom (Zimmer Inc, Warsaw, Indiana)
- ReCap (Biomet Orthopedics, Warsaw, Indiana)

The Articular Surface Replacement (ASR) implant (Depuy International Ltd, Leeds, Yorkshire) was originally issued a license by Health Canada, which was subsequently cancelled in November 2010 due to a high rate of revision for MOM HRA with this implant reported by the national registries.

Evidence-Based Analysis

Research Questions

1. Is the revision rate of MOM HRA using different implants lower than the benchmark set by the NICE?
2. What are the biological effects and consequent clinical significance of exposure to high levels of metal ions and metal debris?

Research Methods

Literature Search

Search Strategy

A literature search was performed on February 13, 2012, using OVID MEDLINE, OVID MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, EBSCO Cumulative Index to Nursing & Allied Health Literature (CINAHL), the Wiley Cochrane Library, and the Centre for Reviews and Dissemination database, for studies published from January 1, 2009, until February 13, 2012. Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

To address the question of what the adverse outcomes of MOM HRA are, the recent literature was examined to identify systematic reviews, overview articles, and review articles discussing the biological effects of metal implants. Data on mortality and cancer risk were extracted from more recent large trials.

Inclusion Criteria

- English language full-reports
- studies published between January 2009 and February 13, 2012
- clinical studies reporting survival or revision rates of MOM HRA with different implant
- studies with ≥ 6 months follow-up

Exclusion Criteria

- studies on double heat–treated implants
- studies on hemiarthroplasty
- studies reporting outcomes following revisions
- retrieval studies for explanted and failed implants
- studies reporting technical aspects of the technology only
- studies reporting laboratory findings only
- histological studies
- in vitro studies
- simulation studies
- bioengineering studies

- radiological/imaging studies
- studies on periprosthetic bone density
- case reports
- phantom studies
- primary research studies reporting adverse reactions to metal debris, the immunological profile of lymphocytes, ion levels in blood/serum/urine, histological findings from tissues obtained at revision arthroplasty or from failed implants, and periprosthetic tissue reactions

Outcomes of Interest

- revision rates and/or survival rates for MOM HRA using different implants

Statistical Analysis

For comparative studies, results were pooled using Review Manager Version 5.1. (17) For single arm studies, charts were created for graphical presentation of the data. Descriptive statistics were used to present the adverse outcomes where applicable.

Quality of Evidence

The quality of the body of evidence for each outcome is examined according to the GRADE Working Group criteria. (18) The overall quality is determined to be very low, low, moderate, or high using a step-wise, structural methodology.

Study design is the first consideration; the starting assumption is that randomized controlled trials are high quality, whereas, observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision, and publication bias—are then taken into account. Limitations or serious limitations in these areas result in downgrading the quality of evidence. Finally, 3 main factors are considered which may raise the quality of evidence: large magnitude of effect, dose response gradient, and accounting for all residual confounding. (18) For more detailed information, please refer to the latest series of GRADE articles. (18)

As stated by the GRADE Working Group, the final quality score can be interpreted using the following definitions:

High	Very confident that the true effect lies close to the estimate of the effect
Moderate	Moderately confident in the effect estimate—the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Confidence in the effect estimate is limited—the true effect may be substantially different from the estimate of the effect
Very Low	Very little confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of effect

Results of Evidence-Based Analysis

The database search yielded 1,498 citations published between January 1, 2005, and February 13, 2012. Only studies published between January 1, 2009, and February 13, 2012 (total of 777 studies after duplicates were removed) were considered for analysis. Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment. Figure 1 shows the breakdown of when and for what reason citations were excluded in the analysis.

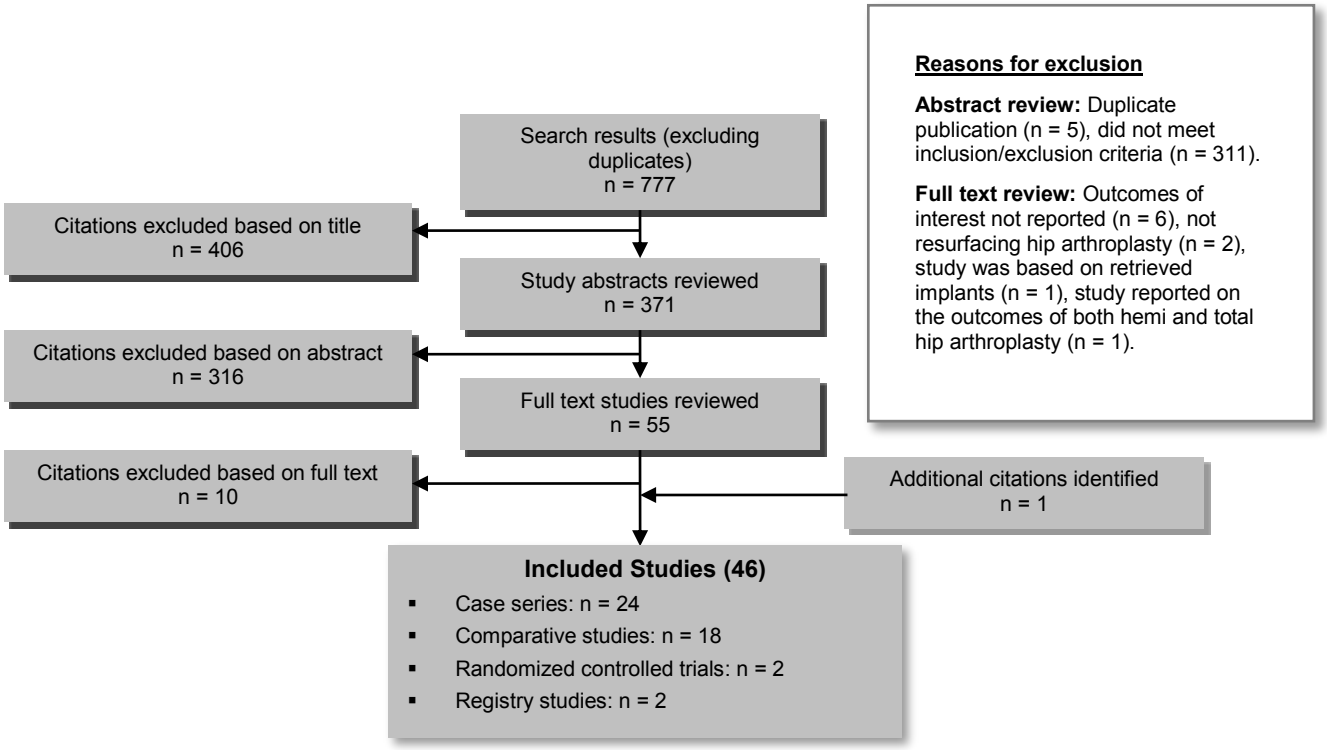

Figure 1: Citation Flow Chart

Forty-five studies met the inclusion criteria. One study (19) was identified through the AutoAlert function of the search and was included in this review.

For each included study, the study design was identified and is summarized below in Table 1, which is a modified version of a hierarchy of study design by Goodman. (20)

Table 1: Body of Evidence Examined According to Study Design

Study Design	Number of Eligible Studies
RCT Studies	
Systematic review of RCTs	
Large RCT	
Small RCT	2
Observational Studies	
Systematic review of non-RCTs with contemporaneous controls	
Non-RCT with non-contemporaneous controls	
Systematic review of non-RCTs with historical controls	
Non-RCT with historical controls	18
Database, registry, or cross-sectional study	2
Case series	24
Retrospective review, modelling	
Studies presented at an international conference	
Expert opinion	
Total	46

Abbreviation: RCT, randomized controlled trial.

Two randomized controlled trials (RCTs) (21;22) and 6 comparative studies (23-28) compared 1 MOM HRA implant with THA. Three comparative studies (29-31) compared 2 or more MOM HRA implants.

Five studies (32-36) compared revision rates for 2 hip conditions, from which 3 (32-34) compared the results in patients with osteonecrosis with those in patients with OA, 1 (35) compared the results in patients with rheumatoid arthritis (RA) with those in patients with OA, and 1 (36) compared the results in patients with RA with those in patients with non-RA conditions.

From the remaining comparative studies, 1 (37) reported the outcomes in ideal patients versus patients with risk factors, 1 (38) compared results in male versus female patients, 1 (39) compared results in patients with and without femoral neck narrowing, and 1 (40) compared results for 2 different stem designs.

For the purpose of generating the graphs for this review, results for OA patients were selected where the outcomes were reported for 2 types of hip disease. For studies comparing ideal patients versus patients with risk factors, the results for “ideal patients” were selected.

Table 2 summarizes the study design and patient characteristics for each included study.

Table 2: Study Design, Implant Type, and Patient Characteristics of Included Studies

Study, Country	Study Period	Study Design	Implant(s)	Centres/ Surgeons	Number of Hips (Patients)	Condition Number of Hips	Male/Female N (%)	Mean Age, Years (Range)
2012/2011 Studies								
Gross et al, 2012 (19) United States	Jan 2000–Mar 2005	Single arm	Cormet	1 senior surgeon	373 (329)			
McMinn et al, 2011 (3) United Kingdom	1997–2009	Single arm	BHR	1 senior surgeon	3,095	NR	NR	53 (13–86)
de Steiger et al, 2011 (30) Australia	Jan 2003–Dec 2009	Comparative Australian Orthopedic Association National Joint Registry (AOANJRR) ASR implant vs. other MOM HRA implants	ASR Other MOM HRA implants	206 hospitals performed MOM HRAs (59 performed HRA-ASR)	ASR: 1,167 Other MOM HRA implants: NR	OA: 1,109 Other: 58	829/338 (hips)	ASR: 53 (16–93) Other MOM HRA implants: 53 (13–82)
Amstutz et al, 2011 (37) United States	1996–2008	Comparative Group 1 (ideal patients) vs. Group 2 (patients with risk factors)	ConservePlus	1 senior surgeon	1,100 (964) Group 1: 468 (413) Group 2: 632 (551)	NR	Group 1: 404/9 Group 2: 323/228	Group 1: 52.1 (25.4–77.5) Group 2: 49.1 (NR)
Amstutz et al, 2011 (38) United States	Nov 1996–Jul 2007	Comparative Male vs. female	ConservePlus	1 senior surgeon	1,107 (923)	NR	681/242	Male: 50.3 (15.3–77.5) Female: 49.5 (14.1–78.1)
Hulst et al, 2011 (41) United States	Nov 1996–Oct 2003	Single arm (End point: revision of acetabular component)	ConservePlus	1 senior surgeon performed surgery at different centres	643 (580)	OA: 424, HD: 64, ON: 51, Trauma: 51, IA: 19, Other: 32	435/145	48.9 (14–78)

Study, Country	Study Period	Study Design	Implant(s)	Centres/ Surgeons	Number of Hips (Patients)	Condition Number of Hips	Male/Female N (%)	Mean Age, Years (Range)
Takamura et al, 2011 (39) United States	1996–2002	Comparative Patients with FNN vs. patients without FNN	ConservePlus	1 senior surgeon	500 (431)	OA: 315, ON: 41, HD: 57, Trauma: 39, IA: 21, LCP: 13, SCFE: 9, Other: 5	319/112	With FNN: 49 (15.3–78.1) Without FNN: 46 (18.2–68.1)
Costa et al, 2011 (24) United States	Started Nov 2007	Comparative Cormet implant vs. THA	MOM HRA: Cormet THA: Accolade stem and Trident cup (Stryker Orthopedics, Mahvash, New Jersey)	1 senior surgeon who previously performed over 1,600 HRAs	210 (192) Cormet: 73 (67) THA: 137 (125)	NR	Cormet implant: 63/4 THA: 65/60	Cormet implant: 51 (21–84) THA: 54 (14–89)
Aulakh et al, 2011 (35) United Kingdom	1997–2002	Comparative RA vs. OA International registry	BHR	51 centres from 13 countries	192 (178) RA: 54 (47) OA: 138 (131)	RA: 54 OA: 138	RA: 23/24 OA: 61/70	RA: 43.1 (19.5–66.7) OA: 43 (16.1–67)
Treacy et al, 2011 (42) United Kingdom	Aug 1997–May 1998	Single arm	BHR	1 senior surgeon	144 (130)	OA: 125, AVN: 10, HD: 3, RA: 2, Other: 4	107/37 (hips)	52 (17–76)
Giannini et al, 2011 (43) Italy	Jan 2001–Oct 2004	Single arm	BHR	1 centre, 2 senior surgeons	140 (132)	OA: 90, HD: 28, AVN: 8, PTA: 6, RA: 6, SCFE: 1, LCP: 1	52/80	50.3 (16–72)
Hull et al, 2011 (44) United Kingdom		Single arm	Cormet	1 centre, 2 surgeons	135 (131)	OA: 126, HD: 2, RA: 2, SCFE: 1	84/47	60 (34–77)
Madhu et al, 2011 (45) United Kingdom	Feb 1999–Dec 2002	Single arm	BHR	1 senior surgeon	117 (101)	Primary OA: 73 Secondary OA: 44	59/42	54 (20–74)

Study, Country	Study Period	Study Design	Implant(s)	Centres/ Surgeons	Number of Hips (Patients)	Condition Number of Hips	Male/Female N (%)	Mean Age, Years (Range)
Baker et al, 2011 (23) United Kingdom	Jan 1996–Apr 2001	Comparative BHR implant vs. Hybrid THA	MOM HRA: BHR THA: cemented CPT femoral component and uncemented acetabular component Harris-Galante II (Zimmer Inc, Warsaw, Indiana), ABG II (Stryker Orthopedics, Mahvash, New Jersey), Zweymuller (PLUS Orthopedics, Rotkreuz, Switzerland), PFC, Hedrocel (Depuy International, Leeds)	1 senior surgeon	108 (104) BHR: 54 (51) THA: 54 (53)	Primary OA	BHR: 40/11 THA: 40/13	BHR: 49.8 (17–67) THA: 50.4 (21–66)
Gross et al, 2011 (46) United States	Mar 2007–Oct 2007	Single arm	Combined ReCap uncemented femoral component and Magnum uncemented acetabular component (Biomet Orthopedics, Warsaw, Indiana) (experience with first 100 cases)	1 senior surgeon	100 (95)	OA: 72, HD: 13, AVN: 6, Trauma: 3, RA: 2, LCP: 2, Other: 2	74/21	49±8 (28–66)
Naal et al, 2011 (47) Switzerland	June 2003–November 2004	Single arm	Durom	2 senior surgeons	100 (91)	OA: 79, HD: 9, ON: 6, PTA: 4, IA: 2	66/25	52 (20–72)

Study, Country	Study Period	Study Design	Implant(s)	Centres/ Surgeons	Number of Hips (Patients)	Condition Number of Hips	Male/Female N (%)	Mean Age, Years (Range)
Smolders et al, 2011 (21) Netherlands	Jun 2007–Jan 2010	RCT ConservePlus implant vs. THA	MOM HRA: ConservePlus THA: Zweymuller Classic (Zimmer Orthopedics, Warsaw, Indiana), together with a Metasul (Zimmer Orthopedics, Warsaw, Indiana)	3 experienced surgeons	(71) ConservePlus: 38 THA: 33	ConservePlus vs. THA: OA: 35 vs. 31 AVN: 1 vs. 0 HD: 2 vs. 2	ConservePlus: 21/17 THA: 21/12	Median ConservePlus: 58 (24–65) THA: 59 (37–65)
Delport et al, 2011 (29) Belgium	1997–2002	Comparative BHR implant vs. ReCap implant	BHR implant on one side, ReCap implant on the other side	1 senior surgeon	56 (28)	NR	23/5	52 (38–74)
Madadi et al, 2011 (34) Iran	Feb 2002–May 2007	Comparative ON vs. OA	Cormet	1 surgeon	52 (52)	ON: 28 OA: 24	ON: 15/13 OA: 13/11	ON: 30.86 ± 7.5 OA: 47.88 ± 12.6 *P* = 0.003
Wisk et al, 2011 (36) United States	1997–2007	Comparative RA vs. non-RA	ConservePlus	1 senior surgeon	RA: 13 (10) Non-RA: 1,061 (886)	RA: 13 Non-RA: 1,061	RA: 6/4 Non-RA: 656/230	RA: 36.4 (16–48) Non-RA: 50.2 (14–78)
2010 Studies								
Prosser et al, 2010 (48) Australia	Sept 1999–Dec 2008	Australian Orthopedic Association National Joint Replacement Registry (AOANJRR) MOM HRA vs. THA	MOM HRA: BHR ConservePlus ASR Cormet 2000 Durom ReCap THA: NR	Multicentre	MOM HRA: 12, 093 (10,489) THA: 147,422 (129, 992)	MOM HRA: OA: 9,860	NR	NR

Study, Country	Study Period	Study Design	Implant(s)	Centres/ Surgeons	Number of Hips (Patients)	Condition Number of Hips	Male/Female N (%)	Mean Age, Years (Range)
Johanson et al, 2010 (49) Nordic countries	1995–2007	Nordic Arthroplasty Register Association (NARA) MOM HRA vs. THA	MOM HRA: BHR (780), Durom (344), ASR (296), ReCap (191), Adept (14), Cormet +/- HAP (7), McMinn (6) THA: Cemented, non-cemented, hybrid, inverse hybrid	3 national joint replacement registries (Denmark, Norway, Sweden)	HRA: 1,638 THA: 172,554	MOM HRA vs. THA OA: 89% vs. 85% IA: 2.2% vs. 4.3% Childhood diseases: 6.5% vs. 6.1% Idiopathic FH necrosis: 0.9% vs. 2.7% Other: 1% vs. 2.1%	HRA: 1,113/525 THA: 74,198/ 98,356	HRA: 51 (15–73) THA: 62 (12–73)
Carrothers et al, 2010 (50) United Kingdom	Jul 1997–Nov 2002	Single arm	BHR	81 hospitals, 141 surgeons	5,000	NR	3,346/1,654	52.5 (13–87)
McBryde et al, 2010 (51) United Kingdom	Jul 1997–Dec 2008	Single arm	BHR	1 centre, multiple surgeons	2,123 (1,826)	OA: 2,123	1,324/799	55 ± 9.2
Amstutz et al, 2010 (52) United States	1996–2006	Single arm	ConservePlus	1 centre, multiple surgeons	1,000 (838) ON: 85 (70) Others (ON, HD, PTA, IA, childhood disorders): 915 (768)	ON: 85 Other: 915	ON: 57/13 Others: 560/208 *P* = 0.1	ON: 40.1 (14–61) Others: 50.9 (15–78) *P* = 0.001
Langton et al, 2010 (31) United Kingdom	BHR: 2002–Apr 2004 ASR: Apr 2004–Jan 2009 ASR-THA: Apr 2004–Jan 2009	Comparative BHR implant vs. ASR implant vs. ASR-THA implant	BHR ASR ASR-THA	NR	660 BHR: 155 ASR: 418 ASR-THA: 87	NR	BHR: 88/67 ASR: 234/184 ASR-THA: 34/53	BHR: 51 (32–67) ASR: 56 (28–77) ASR-THA: 67 (25–85)
Marker et al, 2010 (53) United States	NR	Single arm	ConservePlus	1 senior surgeon	361	OA: 269, PTA: 14, HD: 13, ON: 56, IA: 9	257/104 (hips)	50 (18–79)

Study, Country	Study Period	Study Design	Implant(s)	Centres/ Surgeons	Number of Hips (Patients)	Condition Number of Hips	Male/Female N (%)	Mean Age, Years (Range)
Sandiford et al, 2010 (25) United Kingdom	Aug 2000–Nov 2002	Comparative BHR implant vs. THA	MOM HRA: BHR THA: custom uncemented CADCAM stem	1 senior surgeon	BHR: 141 (137) THA: 141 (134)	OA: 282	BHR: 93/44 THA: 75/59	HRA: 55.3 (28.4–64.6) THA: 53.9 (24.8–64.6)
Jameson et al, 2010 (54) United Kingdom	Apr 2004–Sept 2006	Single arm	ASR	1 senior surgeon	214 (192)	OA: 145, AVN: 59, HD: 10	114/78	56 (28–74)
Vendittoli et al, 2010 (22) Canada	Jul 2003–Jan 2006	RCT Durom implant vs. THA	MOM HRA: Durom THA: titanium, uncemented CLS Spotorno femoral stem and Allofit acetabular cup with a 28 mm Metasul	1 centre, 3 surgeons	Durom: 109 THA: 100	Durom vs. THA OA: 84 vs. 78 HD: 10 vs. 7 IA: 5 vs. 8 LCP: 3 vs. 3 ON: 3 vs. 2 PTA: 3 vs. 2 Post-septic arthritis: 1 vs. 0	Hips Durom: 69/40 THA: 68/32	Durom: 49.2 (23–64) THA: 51 (24–65)
Aulakh et al, 2010 (32) United Kingdom	1997–2002	Comparative OA vs. ON	BHR	Multicentre registry	202 (192)	OA: 101 (97) ON: 101 (95)	OA: 71/26 ON: 73/22	OA: 43 (16–67) ON: 42 (16–65)
Ollivere et al, 2010 (55) United Kingdom	Jun 2001–Feb 2004	Single arm	BHR	1 centre, 2 senior surgeons	104 (94)	NR	NR	56 (36–68)
Amstutz et al, 2010 (56) United States	Nov 1996–Dec 1998	Single arm	ConservePlus	1 centre, surgeons performed first 100 MOM HRAs	100 (89)	OA: 64, ON: 20, HD: 7, LCP: 1, SCFE: 1, PTA: 1, Juvenile RA: 1, Other: 5	59/30	49.1 (15–71)

Study, Country	Study Period	Study Design	Implant(s)	Centres/ Surgeons	Number of Hips (Patients)	Condition Number of Hips	Male/Female N (%)	Mean Age, Years (Range)
Bose et al, 2010 (57) India	May 2000–2005	Single arm	BHR	1 surgeon	96 (71)	AVN: 96	60/11	39 (18–69)
2009 Studies								
Stulberg et al, 2009 (33) United States	Apr 2001–May 2006	Comparative ON vs. OA	Cormet	Multicentre (12 cites)	ON: 116 (101) OA: 1,023	ON: 116 OA: 1,023	NR	NR
Amstutz et al, 2009 (40) United States	Nov 1996–Sept 2006	Comparative 2 different stem designs	ConservePlus	NR	1,000 (838) (Group 1: cemented metaphyseal stem (400), Group 2: press-fit stem (600)	NR	Group 1: 262/138 Group 2: 482/118	Group 1: 50.8 (14–78) Group 2: 49.6 (15–72)
Khan et al, 2009 (58) United Kingdom	1997–2000	Single arm	BHR	Multicentre, 58 nonpioneering surgeons from 8 countries	679 (653)	Predominantly OA	392/261	51 (15.8–87.9) (median)
Della Valle et al, 2009 (59) United States	June 2006–Oct 2006	Single arm	BHR	89 surgeons (first cases)	537	Reported for 466 patients OA: 414, ON: 27, HD: 14, PTA: 8, Other: 3	Reported for 471 patients 334/137	Reported for 471 patients 52 (16–82)
Ollivere et al, 2009 (60) United Kingdom	2001–2007	Single arm	BHR	2 centres, 5 surgeons	463 (463)	NR	307/156	56 (20–70)
Bergeron et al, 2009 (61) Canada	Mar 2004–May 2006	Single arm	ASR	Single surgeon	228 (209)	OA: 222, ON: 2, HD: 1, RA: 1, AS: 2	168/41	54 (25–73)

Study, Country	Study Period	Study Design	Implant(s)	Centres/ Surgeons	Number of Hips (Patients)	Condition Number of Hips	Male/Female N (%)	Mean Age, Years (Range)
Swank and Alkire, 2009 (26) United States	Jul 2006–Dec 2008	Comparative BHR vs. minimally invasive THA	MOM HRA: BHR THA: NR	Single surgeon	BHR: 128 (128) THA: 106 (105)	OA: 126, HD: 1, PTA: 1	100/28	BHR: 51 (38–60) THA: (23–60)
Beaule et al, 2009 (62) Canada	Aug 2001–Jun 2007	Single arm	Conserve Plus	Single surgeon	116 (106)	OA: 86, ON: 6, HD: 5, PTA: 4, LCP: 2, RA: 1, IA: 1, SCFE: 1	86/20	46.5 (19–62)
Killampalli et al, 2009 (63) United Kingdom	Feb 2003–Feb 2006	Single arm	Cormet	NR	100 (100)	OA: 97, IA: 2, HD: 1	61/39	56 (21–74)
Mont et al, 2009 (27) United States	Nov 2002–Jan 2005	Comparative ConservePlus vs. THA	MOM HRA: ConservePlus THA: Stryker Howmedica Osteonics Trident cup with an Accodale femoral component (Stryker Orthopedics, Mahvash, New Jersey)	1 senior surgeon	ConservePlus: 54 THA: 54	OA/ ON/ HD	ConservePlus: 36/18 THA: 36/18	ConservePlus: 55 (35–79) THA: 55 (35–79)
Larbpaiboonpong et al 2009 (64) Thailand	Jan 2006–Dec 2008	Single arm	BHR	1 surgeon	40 (38)	OA: 14, ON: 21, HD: 2, PTA: 2, AS: 1	23/15	41.3 (24–59)
Fowble et al, 2009 (28) United States	NR	Comparative ConservePlus vs. THA	HRA: ConservePlus THA: cementless femoral and acetabular components (Summit and Pinnacle,Depuy Orthopedics, Warsaw, Indiana) with either a cross-	1 senior surgeon	ConservePlus: 50 (50) THA: 44 (35)	ConservePlus vs. THA OA: 48 vs. 40 ON: 1 vs. 3 Other: 1 vs. 1	31/19 14/21	ConservePlus: 46 (30–64) THA: 55 (27–75)

Study, Country	Study Period	Study Design	Implant(s)	Centres/ Surgeons	Number of Hips (Patients)	Condition Number of Hips	Male/Female N (%)	Mean Age, Years (Range)
			linked polyethylene bearing (Marathon, Depuy Orthopedics, Warsaw, Indiana), or a metal bearing (Ultamet,Depuy Orthopedics, Warsaw, Indiana)					

Abbreviations: ASR, Articular Surface Replacement; AVN, avascular necrosis; BHR, Birmingham Hip Resurfacing; CADCAM, custom computer aided design computer aided manufacture; FH, femoral head; FNN, femoral neck narrowing; HAP, hydroxyapetite; HD, hip dysplasia; IA, inflammatory arthritis; LCP, Legg-Calve-Perthes; MOM HRA, metal-on-metal hip resurfacing arthroplasty; N, number; NR, not reported; OA, osteoarthritis; ON, osteonecrosis; PTA, post-traumatic arthritis; RA, rheumatoid arthritis; SCFE, slipped capital femoral epiphysis; THA, total hip arthroplasty.

Outcomes Reported by Registry Studies

The Australian Orthopedic Association National Joint Replacement Registry (AOANJRR) (48) reported a revision rate of 3.6% for all MOM HRAs, including MOM HRA with BHR, ConservePlus, ASR, Cormet 2000, Durom, and ReCap implants, performed between September 1999 and December 2008. The Nordic Arthroplasty Register Association (49) reported a revision rate of 2.4% for all MOM HRAs, including MOM HRA with the BHR implant (48%), the Durom implant (21%), the ReCap implant (12%), the ASR implant (18%), the Cormet implant (0.4%), and the McMinn implant (0.4%), performed between 1995 and 2007.

Fracture of the femoral neck and implant loosening were the 2 most common reasons for revision in both the Australian registry (48) and the Nordic registry. (49) Figures 2–3 show the percentage and cause of revisions reported by the 2 registries.

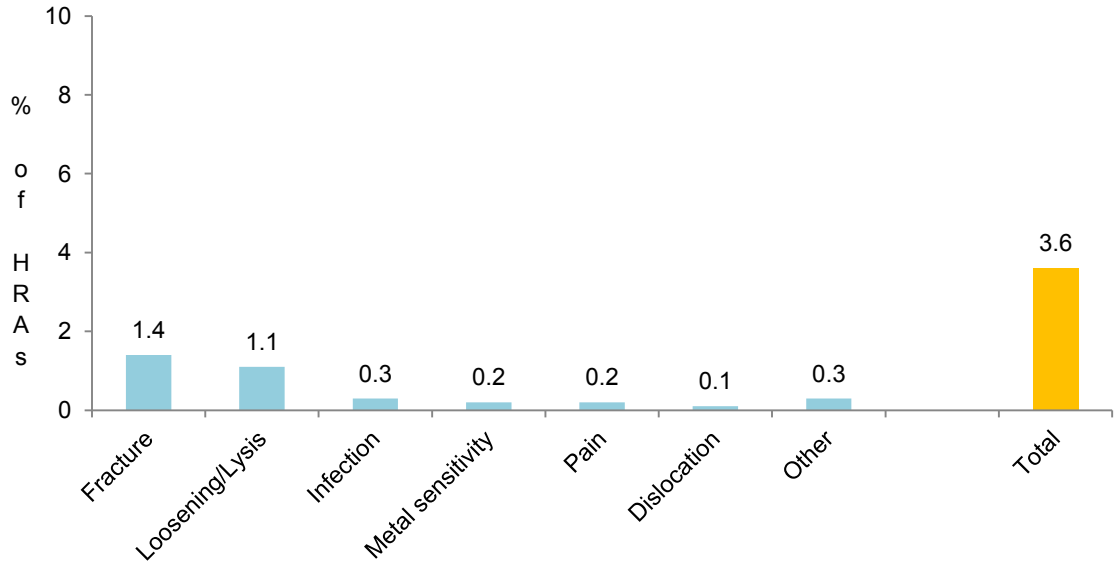

Figure 2: Revision Rates (by Causes) Following MOM HRA Reported by the Australian Registry

Abbreviations: HRA, hip resurfacing arthroplasty; MOM, metal-on-metal.
Source: Prosser et al, 2010 (48)

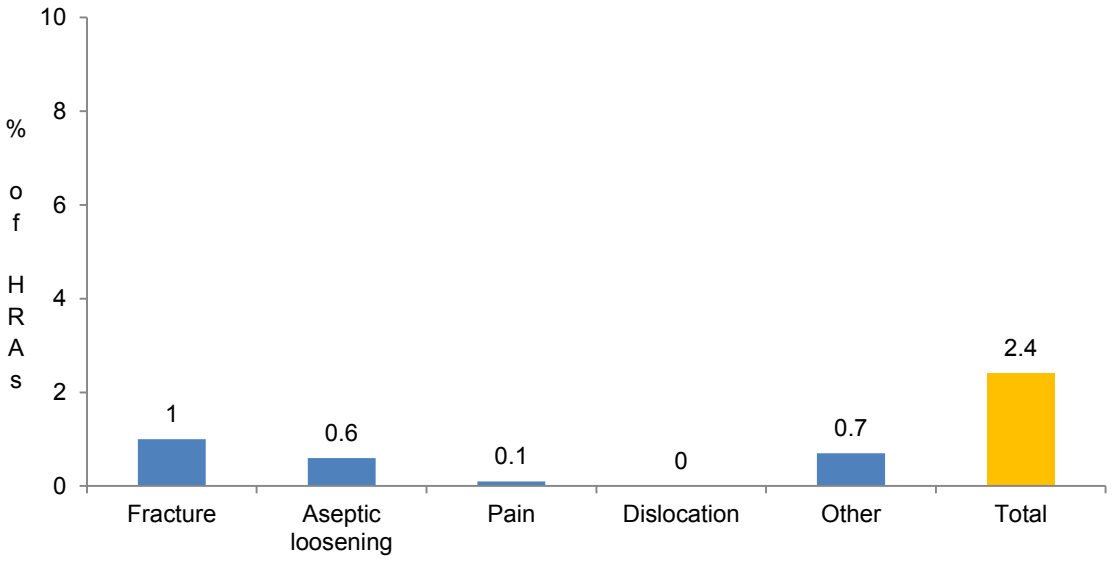

Figure 3: Revisions Rates (by Causes) Following MOM HRA Reported by the Nordic Registry

Abbreviations: HRA, hip resurfacing arthroplasty; MOM, metal-on-metal.
Source: Johanson et al, 2010 (49)

The Australian registry (48) reported that patients with developmental hip dysplasia had a higher rate of revision than patients with OA (hazard ratio [HR], 2.1; 95% confidence interval [CI], 1.4–3.1). The 5-year cumulative percent revision (CPR) for developmental dysplasia and OA was 12% (95% CI, 8–17) and 4.1% (95% CI, 3.7–4.6), respectively. (48) The difference between the rates of revision for avascular necrosis and OA was not significant (HR, 1.6; 95% CI, 0.9–2.9). (48)

Figure 4 shows the 5-year CPR for 4 hip conditions reported by the Australian registry. (48)

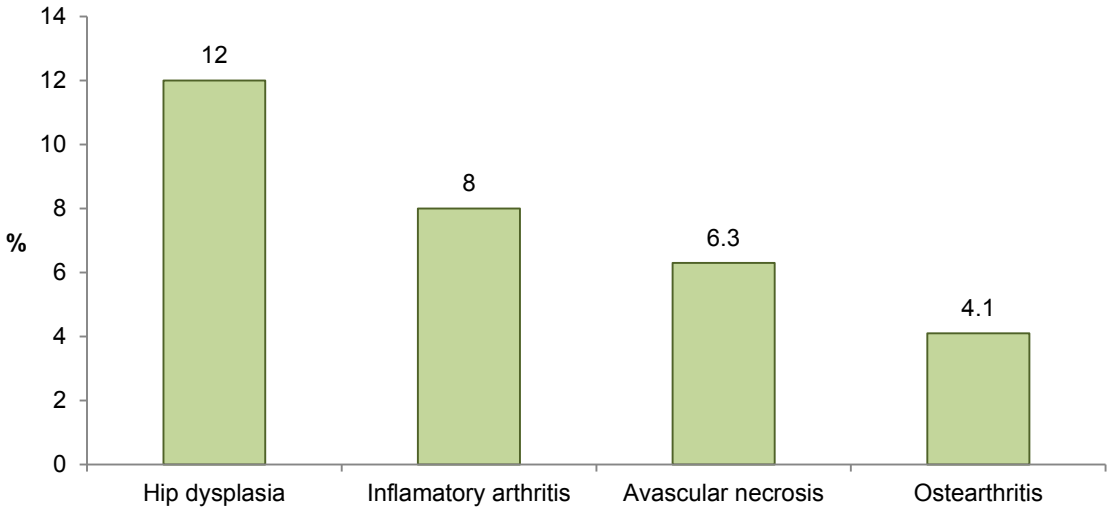

Figure 4: Five-Year Cumulative Percent Revision Following MOM HRA Reported by the Australian Registry

Abbreviations: HRA, hip resurfacing arthroplasty; MOM, metal-on-metal.
Source: Prosser et al, 2010 (48)

The Australian registry (48) reported the 8-year CPR for MOM HRA versus THA as 5.3% and 4%, respectively (age and sex adjusted HR, 1.4; 95% CI, 1.2–1.6) (see Figure 5).

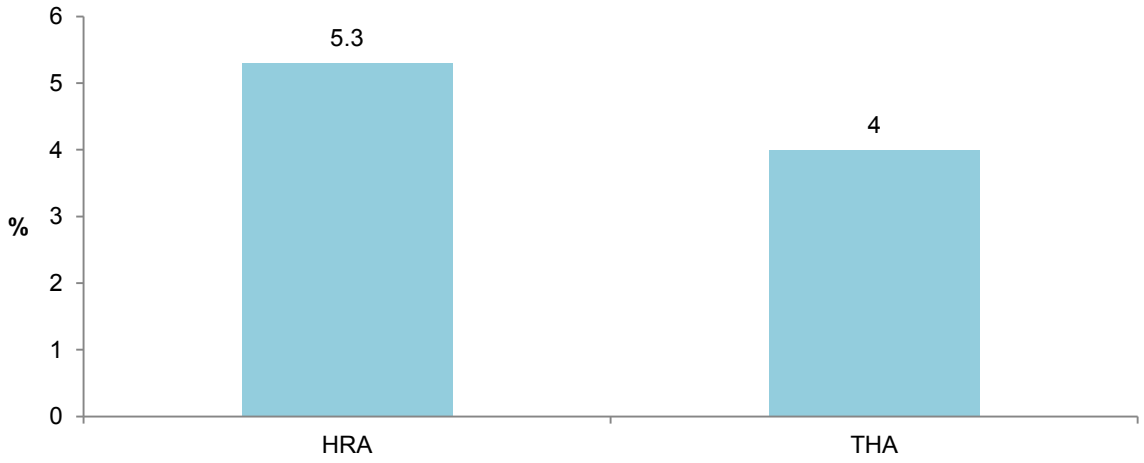

Figure 5: Eight-Year Cumulative Percent Revision Following MOM HRA and THA Reported by the Australian Registry

Abbreviations: HRA, hip resurfacing arthroplasty; MOM, metal-on-metal; THA, total hip arthroplasty.
Source: Prosser et al, 2010 (48)

The Nordic Arthroplasty Register Association (49) showed that implant survival at 2 years for the 4 most common types of MOM HRA implants is higher in hospitals where 70 or more MOM HRAs are performed annually compared with hospitals where less than 70 MOM HRAs are performed annually. Cumulative survival rates for MOM HRA in hospitals with 70 or more MOM HRAs annually and hospitals with less than 70 MOM HRAs annually were 98.8% (95% CI, 97.9–99.8) and 95.5% (95% CI, 93.7–97.2), respectively ($P < 0.001$) (see Figure 6). (49)

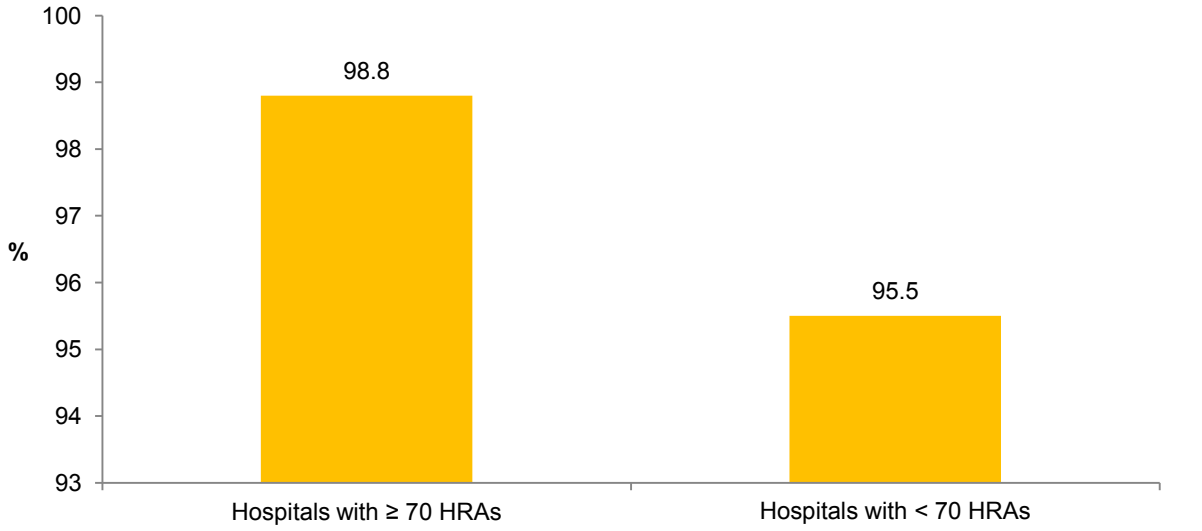

Figure 6: Survival at Two Years of MOM HRA Using Different Implants as Reported by the Nordic Registry, According to Hospital Production Volume

Abbreviations: HRA, hip resurfacing arthroplasty; MOM, metal-on-metal.
Source: Johanson et al, 2010 (49)

Results of Randomized Controlled Trials and Comparative Studies

Two RCTs (21;22) and 6 comparative studies (23-28) compared the performance of HRA implants with that of THA.

The mean duration of follow-up for the majority of these studies was less than 5 years. The study by Baker et al (23) reported results at a mean follow-up of 9 years (range, 8.2–10.3 years) for MOM HRA with the BHR implant and 10.7 years (range, 7.5–14.5 years) for THA. One RCT (22) had a mean follow-up of 4.7 years for both MOM HRA with the Durom implant and THA.

Three comparative studies (29-31) compared the performances of 2 or more MOM HRA implants. One of these studies was a matched pair study that compared the BHR implant with the ReCap implant in 28 patients who underwent bilateral MOM HRA with the BHR implant on one side and the ReCap implant on the other side. (29) This study reported that there was no revision in either arm at a mean follow-up of 4.8 years for the BHR implant and 1.4 years for the ReCap implant. (29) Another study analyzed a series of 660 procedures consisting of MOM HRA with the BHR implant, MOM HRA with the ASR implant, and THA with the ASR implant. (31) This study reported that 17 patients (who all had ASR bearings) required revision surgery. Revision rates for MOM HRA with the BHR implant, MOM HRA with the ASR implant, and THA with the ASR implant groups were 0%, 3.2%, and 6%, respectively. (31) de Steiger et al (30) compared the ASR implant with other MOM HRA implants using the Australian registry database. The cumulative revision rate at 5 years was 10.9% (95% CI, 8.7–13.6) for MOM HRA with the ASR implant and 4% (95% CI, 3.7–4.5) for other MOM HRA implants. The cumulative revision rate due to metal sensitivity was 1.7% (95% CI, 0.9–3.1) for MOM HRA with the ASR implant versus 0.3% (95% CI, 0.2–0.5) for MOM HRA with other implants. (30)

Table 3 shows survival and revision rates for HRA using different implants and for THA, as reported by RCTs and comparative studies.

Table 3: Survival and Revision Rates of MOM HRA Using Different Implants Reported by Comparative Studies

Study	Mean Duration of Follow-up, Years (Range)	Implant Survival % (95% CI)	Number of Revisions (%) Reason for Revision (N)
Randomized Controlled Trials Comparing MOM HRA With THA			
Smolders et al, 2011 (21) Netherlands	1.7 for both ConservePlus implant and THA	NR	ConservePlus implant: 1 (2.6) Aseptic loosening due to AVN: 1 THA: 2 (6) Dislocation: 2
Vendittoli et al, 2010 (22) Canada	4.7 (3–6) for both Durom implant and THA	NR	Durom implant: 4 (3.7) FHC: 4 THA: 2 (2) Infection: 1 Dislocation: 1 *Durom implant vs. THA: P* = 0.47

Study	Mean Duration of Follow-up, Years (Range)	Implant Survival % (95% CI)	Number of Revisions (%) Reason for Revision (N)
Comparative Studies Comparing MOM HRA With THA			
Sandiford et al, 2010 (25) United Kingdom	BHR implant: 1.6 (0.25–3.1) THA: 1.1 (0.25–3.2)	NR	BHR implant: 0 (0) THA: 0 (0)
Costa et al, 2011 (24) United States	Cormet implant: 2.4 (2–3.1) THA: 2.3 (2–2.9)	NR	Cormet implant: 0 (0) THA: 3 (2.2) Fracture: 1 AC loosening: 2
Baker et al, 2011 (23) United Kingdom	BHR implant: 9 (8.2–10.3) THA: 10.7 (7.5–14.5)	NR	BHR implant: 5 (9.3) FHC secondary to AVN: 5 THA: 9 (16.7) Osteolysis: 8 Recurrent dislocation: 1 *BHR implant vs. THA: P* = 0.2
Swank and Akire, 2009 (26) United States	2 for both BHR implant and minimally invasive THA	NR	BHR implant: 1 (0.8) FNF: 1 THA: 0 (0)
Mont et al, 2009 (27) United States	ConservePlus implant: 3.3 (2–5) THA: 3.3 (2–4.7)	NR	ConservePlus implant: 2 (3.7) FNF: 1 AC loosening: 1 THA: 2 (3.7) AC loosening: 1 Infection: 1
Fowble et al, 2009 (28) United States	ConservePlus implant: 3.2 (2–4.2) THA: 2.5 (2–4)	NR	ConservePlus implant: 1 (2) AVN: 1 THA: 0 (2.3)
Comparative Studies Comparing Two or More MOM HRA Implants			
De Steiger et al, 2011 (30)	Post-operative follow-up: 5	NR	Cumulative revision rate: ASR HRA implant: 10.9 Other MOM HRA implants: 4
Delport et al, 2011 (29) Belgium	BHR implant: 4.8 (2.3–7.4) ReCap implant: 1.4 (0–3.7)	NR	BHR implant: 0 (0) ReCap implant: 0 (0)

Study	Mean Duration of Follow-up, Years (Range)	Implant Survival % (95% CI)	Number of Revisions (%) Reason for Revision (N)
Langton et al, 2010 (31) United Kingdom	BHR implant: NR ASR implant: 2.9 (0.7–4.8) ASR-THA implant: 3.4 (0.8–4.8)	NR	Revisions due to ARMD in minimum of 6 months: ASR implant: 12 (3.2) ASR-THA implant: 5 (6) BHR implant: 0 (0)

Abbreviations: AC, acetabular component; ARMD, adverse reaction to metal debris; ASR, Articular Surface Replacement; AVN, avascular necrosis; BHR, Birmingham Hip Resurfacing; FHC, femoral head collapse; FNF, femoral neck fracture; MOM HRA, metal-on-metal hip resurfacing arthroplasty; N, number; NR, not reported; THA, total hip arthroplasty.

Figure 7 shows pooled estimates for revision rates for MOM HRA using different implants and for THA, derived from studies with different follow-up durations.

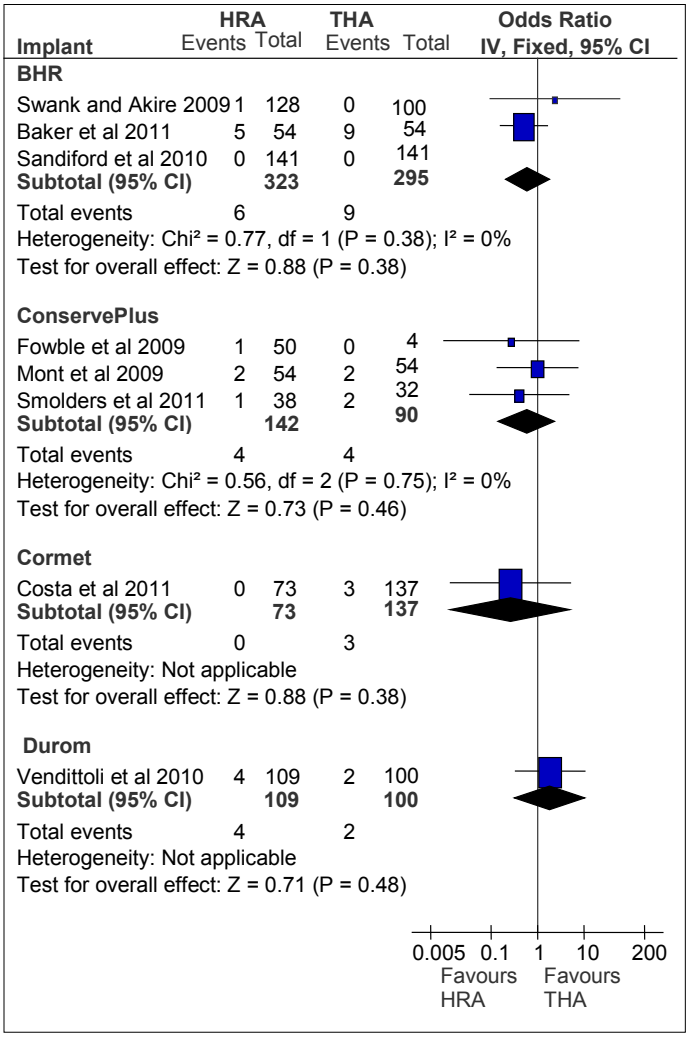

Figure 7: Revision Rates by Implant Type Following MOM HRA and THA

Abbreviations: BHR, Birmingham Hip Resurfacing; CI, confidence interval; HRA, hip resurfacing arthroplasty; MOM, metal-on-metal; THA, total hip arthroplasty.

Results of Single Arm Studies, Registry Studies, and Studies Comparing Conditions Other Than Implant Type

The results of 24 single arm studies, 2 registry studies, and 9 comparative studies (in which conditions not related to the implant type were compared) are shown in Table 4.

Table 4: Survival and Revision Rates of MOM HRA Using Different Implants, Reported by Single Arm Studies, Registry Studies, and Studies Comparing Conditions Other Than Implant Type

Study	Mean Duration of Follow-up, Years (Range)	Implant Survival, % (95% CI) (Number Available for Follow-up)	Revision, N (%) Reason for Revision (N)
Gross et al, 2012 (19) United States	8 (6–1)	At 8 years: 93	21 (5.6) FNF: 5 FC loosening: 7 AC loosening: 5 Late deep infection: 2 Wear reaction: 2
McMinn et al, 2011 (3) United Kingdom	8 (0.7–13)	All patients: At 5 years: 99 (n = 2,703/3,095) At 10 years: 97 (n = 957/3,095) At 13 years: 96 (n = 302/3,095) OA patients < 55 years old: At 10 years: 99 (n = 310/403) At 13 years: 98 (n = 93/403)	68 (2.2) FNF: 12 FHC: 25 Infection: 14 Dislocation: 2 Cup loosening: 2 ARMD: 10 Osteolysis: 1 PP: 2
Madadi et al, 2011 (34) Iran	3.4	NR	ON: 3 (10.7) OA: 3 (12.5) All due to either FNF or AC failure
Aulakh et al, 2011 (35) United Kingdom	RA: 8.1 (6.5–11.1) OA: 8.4 (6.5–11.1)	At 8 years RA: 96.3 (n = 45/47) OA: 97.8 (n = 129/131) *P* = 0.45	RA: 2 (3.7) FNF: 1 Infection: 1 OA: 3 (2.2) Aseptic loosening: 2 Metalosis: 1
Wisk et al, 2011 (36) USA	8.1 (3.1–13.1)	NR	RA: 0 (0) Non-RA: 41 (3.9)

Study	Mean Duration of Follow-up, Years (Range)	Implant Survival, % (95% CI) (Number Available for Follow-up)	Revision, N (%) Reason for Revision (N)
Takamura et al, 2011 (39) United States	8 (0.12–13.4)	At 7.7 years With FNN: 86.7 Without FNN: 93.6	With FNN: 7/25 (28) Without FNN: 34/475 (7.2) With FNN vs. without FNN: Acetabular loosening: 2 vs. 1 Femoral loosening: 3 vs. 20 FNF: 1 vs. 5 Recurrent dislocation: 0 vs. 1 Sepsis: 0 vs. 1 Osteolysis: 0 vs. 4 Component size mismatch: 0 vs. 1 Socket loosening: 0 vs. 1 Local tissue reaction and high metal ions: 1 vs. 0
Treacy et al, 2011 (42) United Kingdom	10.9 (10.2–12.2)	At 10 years 93.5 (89.2–97.6) (n = 117/144)	10 (6.9) AVN: 3 Infection: 3 FNF: 1 FC loosening: 1 Recurrent dislocation: 1 Trauma causing FNF: 1
Giannini et al, 2011 (43) Italy	6 (5–8.8)	At 6 years 97.8 (93.5–99.3)	5 (3.6) AVN: 1 FNF: 3 Aseptic femoral component loosening and metalosis: 1
Hull et al, 2011 (44) United Kingdom	2.9 (2–5)	NR	0 (0)
Madhu et al, 2011 (45) United Kingdom	7 (5–9.4)	At 7 years All cause revision: 91.5 (97.6–85.4) Aseptic revision: All: 92.7 (98.3–87) Primary OA: 95.9 (91.4–100) Secondary OA: 88.1 (76.3–99.8) Acetabular component: 100	8 (6.8%) FNF: 5 FHC due to previous ON: 2 Sepsis: 1
Gross et al, 2011 (46) United States	2.9 (2.7–3.3)	At 1 year: 99 At 2 years: 98 At 3 years: 98	2 (2) FNF: 1 FHC: 1

Study	Mean Duration of Follow-up, Years (Range)	Implant Survival, % (95% CI) (Number Available for Follow-up)	Revision, N (%) Reason for Revision (N)
Naal et al, 2011 (47) Switzerland	5 (3.9–6)	At 5 years 88.2 (84.3–92.1) Male vs. female: 90.8 (85.5–96.1) vs. 81.5 (71.1–91.9)	11 (11) FNF: 4 Femoral loosening: 2 Cup loosening: 1 Impingement: 2 PP: 2
Prosser et al, 2010 (48) Australia	NR	NR	Period of 8 years HRA: 437 (3.6) Fracture: 172 Loosening/lysis: 128 Infection: 39 Metal sensitivity: 28 Pain: 23 Dislocation: 14 Other: 33 THA: NR 8 years CPR and 95% CI HRA vs. THA: 5.3 (4.6–6.2) vs. 4 (3.8–4.2)
Johanson et al, 2010 (49) Nordic countries	BHR implant: 2.1 (0–8.1) Durom implant: 2.1 (0–5.8) ASR implant: 1.1 (0–3.1) ReCap implant: 1.1 90–2.8)	At 2 years: For 4 most common type of MOM HRA implants: Hospitals with ≥ 70 HRAs: 98.8 (97.9–99.8) Hospitals with < 70 HRAs: 95.5 (93.7–97.2) *P* < 0.001 For BHR implant: 98.8 (97.9–99.7)	2 years for aseptic revision rate HRA: 40 (2.4) THA: 1,954 (1.1) HRA vs. THA: Aseptic loosening: 10 vs. 497 Fracture: 16 vs. 176 Dislocation: 0 vs. 967 Pain only: 2 vs. 88 Other: 12 vs. 226
Carrothers et al, 2010 (50) United Kingdom	7.1 (0.2–11)	At 7 years: 96.3 (95.7–96.8) (n = 4,707/5000) At 10 years: 95.3 (94.5–96)	182 (3.6) FNF: 54 AC loosening: 32 FHC: 30 FC loosening: 19 Infection: 17 Metalosis: 15 Loosening both components: 5 Dislocation: 5 Mal-position of AC: 3 Unknown: 2

Study	Mean Duration of Follow-up, Years (Range)	Implant Survival, % (95% CI) (Number Available for Follow-up)	Revision, N (%) Reason for Revision (N)
McBryde et al, 2010 (51) United Kingdom	3.46 (0.03–10.9)	At 5 years: 97.5 (96.3–98.3) (n = 655) At 8 years: 95.5 (92.1–97.1) (n = 139/2,123) At 10 Years: 95.5 (86.8–97.1) (n = 20/2,123)	48 (2.3) FNF: 13 ON: 6 AC loosening: 9 Acetabular fracture: 1 Component mal-alignment: 2 Infection: 4 Pain: 7 Unknown: 6
Amstutz et al, 2010 (52) United States	ON: 7.6 (2.2-12) Others: 6.4 (2.2-12)	ON vs. others At 3 years: 97.5 (90.3–99.4) vs. 98.4 (97.1–99.1) At 5 years: 95.7 (87–98.6) vs. 95.4 (93.1–96.9) At 8 years: 93.9 (84.1–97.7) vs. 93.4 (90.4–95.5)	ON: 4 (4.7) Others: 35 (3.8) *P* = 0.6
Marker et al, 2010 (53) United States	4.9 (2.3–7.3)	NR	23 (6.4) FNF: 13 AC loosening: 2 FC loosening: 4 FC fracture: 2 Acetabular protrusion: 2
Jameson et al, 2010 (54) United Kingdom	3.6 (2.5–4.75)	At 3.6 years: 93 (80–98) According to AC size: ≥ 56 mm: 97 (80–98) < 56 mm: 89 (82–96)	12 (5.6) FNF: 4 FHC secondary to AVN: 2 Metal debris: 6
Aulakh et al, 2010 (32) United Kingdom	OA: 7.3 (2.2–9.8) ON: 7.5 (2.9–10)	At 7 years: OA: 95 ON: 97.7 *P* = 0.19	OA: 4 (4) Infection: 1 FHC: 1 FNF: 1 Loosening of the prosthesis: 1 ON: 2 (2) FNF: 2
Ollivere et al, 2010 (55) United Kingdom	5.1 (3.2–6.3)	At 5 years: 100	0 (0)
Amstutz et al, 2010 (56) United States	11.7 (10.8–12.9)	At 5 years 93.9 (86.9–97.2) At 10 years: 88.5 (80.2–93.5) At 10 years by component size: > 46 mm: 95.6 (83.6–98.9) 44–46 mm: 83.8 (62.4–93.6) ≤ 42 mm: 78.9 (56.6–90.7)	11 (11) FC loosening: 8 FNF: 1 Recurrent subluxation: 1 Infection: 1

Study	Mean Duration of Follow-up, Years (Range)	Implant Survival, % (95% CI) (Number Available for Follow-up)	Revision, N (%) Reason for Revision (N)
Bose et al, 2010 (57) India	5.4 (4–8.1)	At 5.4 years 95.4	3 (3.1) FHC: 2 AC migration: 1
Stulberg et al, 2009 (33) United States	1.7	At 1.7 years ON: 95.8 OA: 95.9 *P* = 0.46	ON: 8 (6.9) OA: 35 (3.4) ON vs. OA FNF: 3 vs. 18 FC loosening: 3 vs. 8 AC loosening: 0 vs. 8 Deep infection: 1 vs. 1 Dislocation: 1 vs. 0
Amstutz et al, 2009 (40) United States	Whole cohort: 5.8 (1.4–11.2) Group 1 (cemented metaphyseal stem): 4.1 (1.4–10.3) Group 2 (press-fit stem): 6.1 (1.4–11.2)	At 5 years: Group 1: 98.2 (95.4–99.3) Group 2: 94.4 (91.4–96.4) *P* = 0.1	34 (3.4) Group 1: 5 (1.3) FNF: 3 Sepsis: 1 AC protrusion: 1 Group 2: 29 (4.8) FC aseptic loosening: 20 FNF: 7 Sepsis: 1 Recurrent subluxation: 1
Khan et al, 2009 (58) United Kingdom	6 (5–8) (median)	At 8 years: 95.7	29 (4.3) Aseptic loosening: 14 FNF: 11 Infection: 3 Metalosis: 1
Della Valle et al, 2009 (59) United States	0.87	NR	14 (2.6) FNF: 10 *(8 within the surgeon's 10 first cases)* Dislocation: 2 AC loosening: 2
Ollivere et al, 2009 (60) United Kingdom	3.6 (0.5–7.5)	At 3.5 years: 96.7 (94.3–98.1) At 5 years: 95.8 (94.1–96.8)	13 (2.8) Pain: 7 Fracture: 3 Dislocation: 2 Infection: 1 (9/13 had histological evidence of metalosis)
Bergeron et al, 2009 (61) Canada	2.9 (2–4.6)	At 4.6 years: 96.9	8 (3.6) Infection: 5 FNF: 1 ON: 1 FC loosening: 1

Study	Mean Duration of Follow-up, Years (Range)	Implant Survival, % (95% CI) (Number Available for Follow-up)	Revision, N (%) Reason for Revision (N)
Beaule et al, 2009 (62) Canada	3.2 (1–7)	NR	2 (1.7) FC loosening: 1 AC loosening: 1
Killampalli et al, 2009 (63)	Minimum 2 years (2–5)	NR	0 (0)
Larbpaiboonpong et al, 2009 (64) Thailand	1.4 (0.25–2.8)	At 1.4 years: 97.5	1 (2.5) FNF: 1

Abbreviations: AC, acetabular component; ARMD, adverse reaction to metal debris; ASR, Articular Surface Replacement; AVN, avascular necrosis; BHR, Birmingham Hip Resurfacing; CI, confidence interval; CPR, cumulative percent revision; FC, femoral component; FHC, femoral head collapse; FNF, femoral neck fracture; FNN, femoral neck narrowing; MOM HRA, metal-on-metal hip resurfacing arthroplasty; N, number; NR, not reported; OA, osteoarthritis; ON, osteonecrosis; PP, persistent pain; RA, rheumatoid arthritis; THA, total hip arthroplasty.

Figures 8 to 13 show the survival rates of MOM HRA using different implants, reported by all studies for the different resurfacing implants.

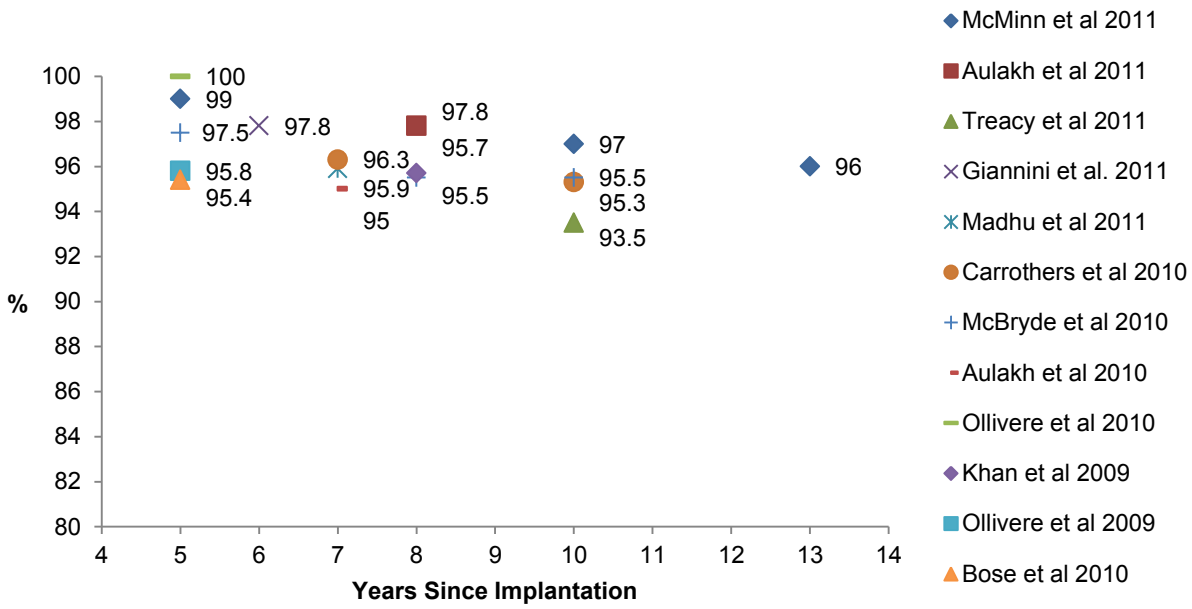

Figure 8: Survival Rates of MOM HRA Using BHR Implants Reported by Different Studies

Abbreviations: BHR, Birmingham Hip Resurfacing; MOM HRA, metal-on-metal hip resurfacing arthroplasty.

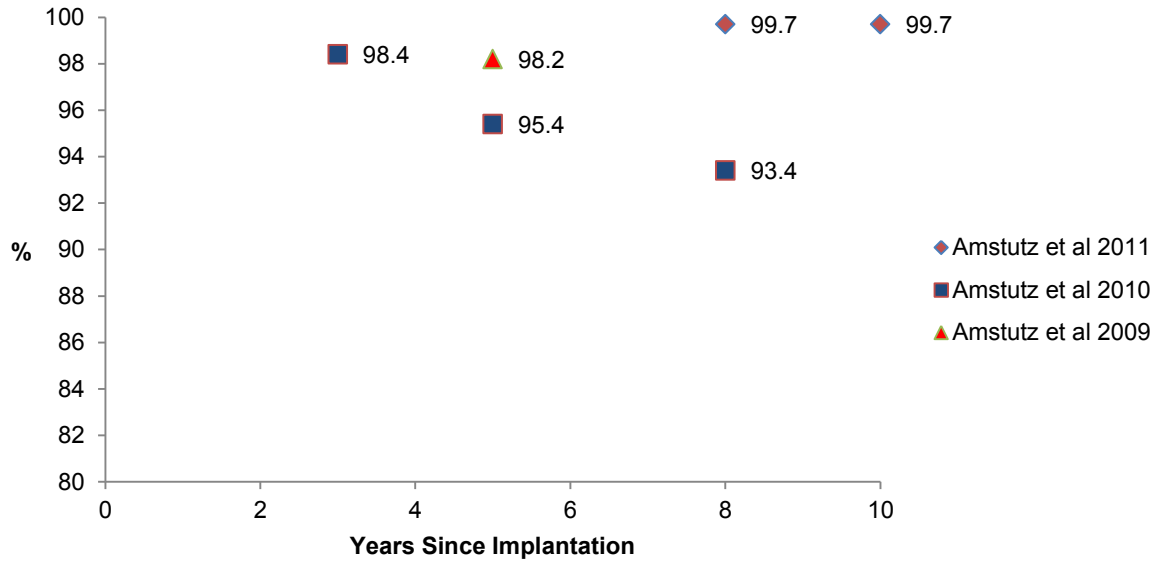

Figure 9: Survival Rates of MOM HRA Using ConservePlus Implants Reported by Different Studies

Abbreviation: MOM HRA, metal-on-metal hip resurfacing arthroplasty.

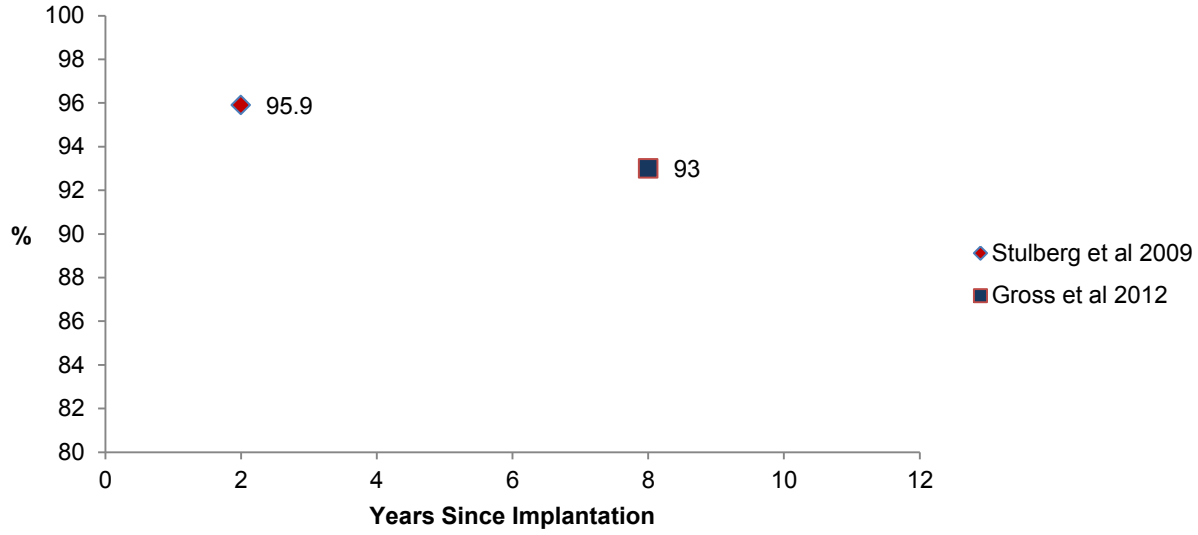

Figure 10: Survival Rates of MOM HRA Using Cormet Implants Reported by Different Studies

Abbreviation: MOM HRA, metal-on-metal hip resurfacing arthroplasty.

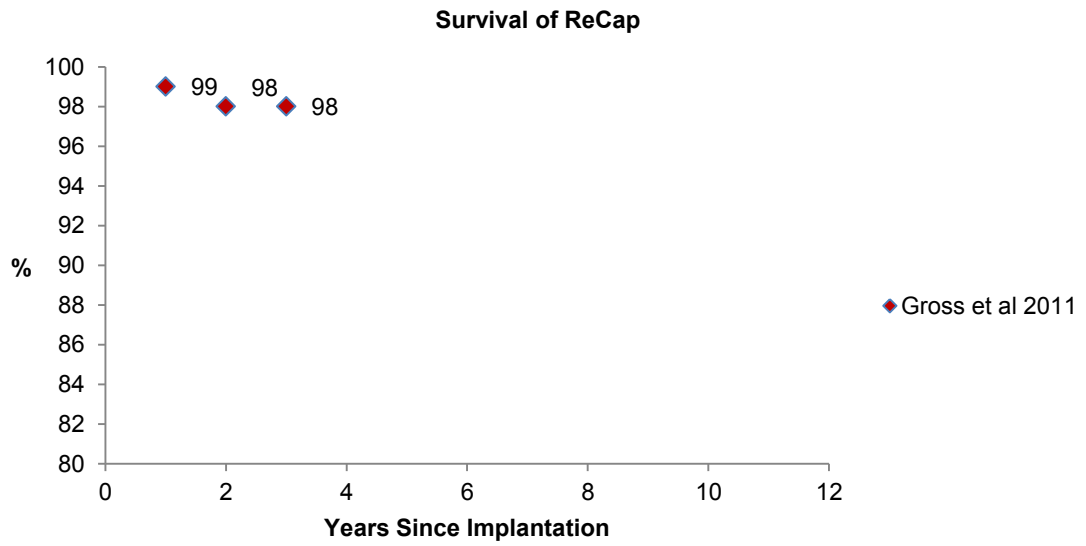

Figure 11: Survival Rates of MOM HRA Using ReCap Implants

Abbreviation: MOM HRA, metal-on-metal hip resurfacing arthroplasty.

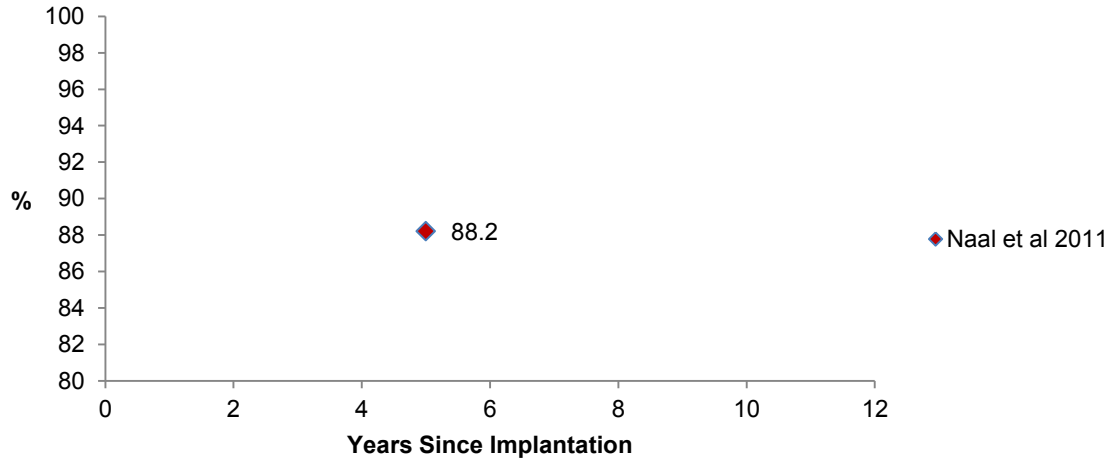

Figure 12: Survival Rates of MOM HRA Using Durom Implants

Abbreviation: MOM HRA, metal-on-metal hip resurfacing arthroplasty.

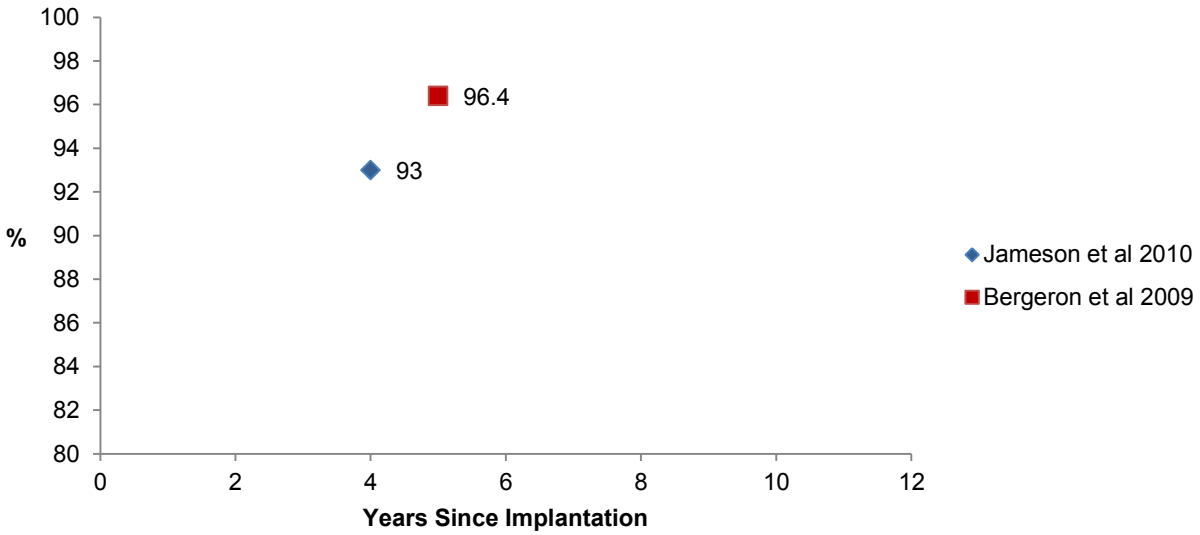

Figure 13: Survival Rates of MOM HRA Using ASR Implants Reported by Different Studies

Abbreviations: ASR, Articular Surface Replacement; MOM HRA, metal-on-metal hip resurfacing arthroplasty.

Figures 14 to 19 show the revision rates following MOM HRA using different implants.

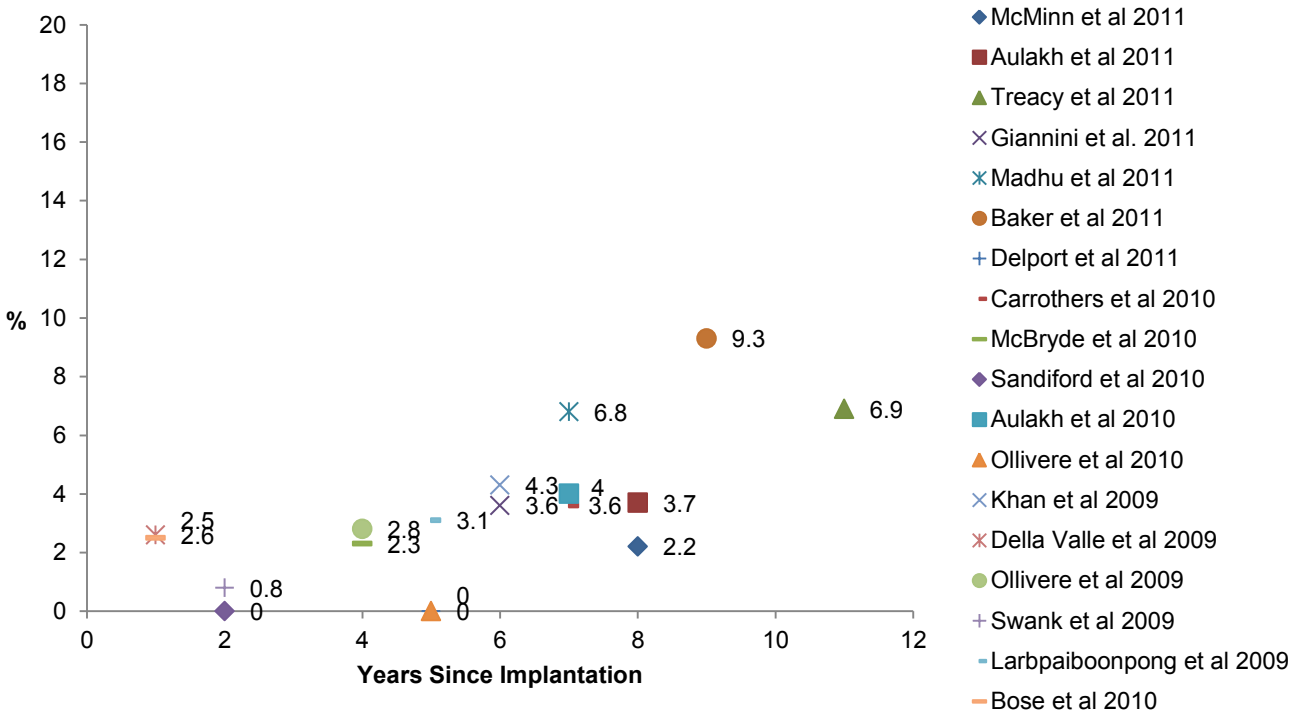

Figure 14: Revision Rates Reported by Studies With Birmingham Hip Resurfacing Implants

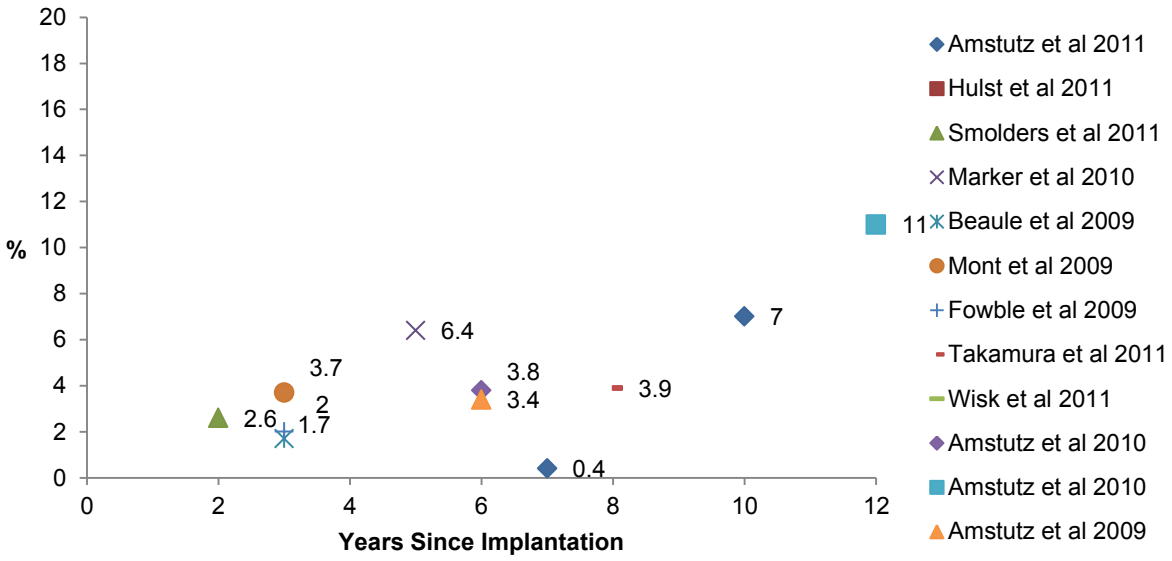

Figure 15: Revision Rates Reported by Studies With ConservePlus Implants

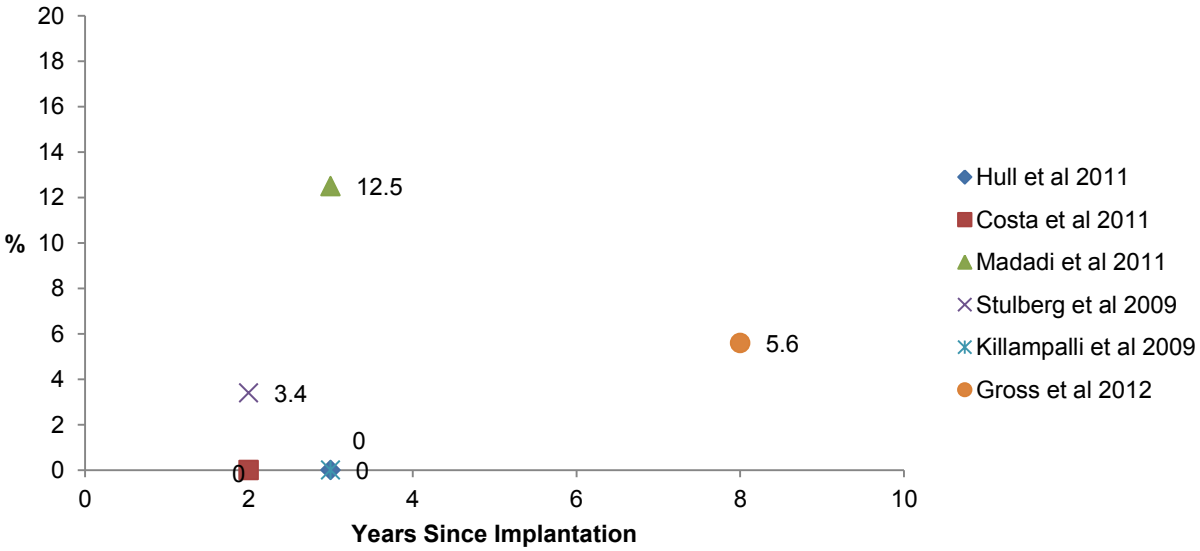

Figure 16: Revision Rates Reported by Studies With Cormet Implants

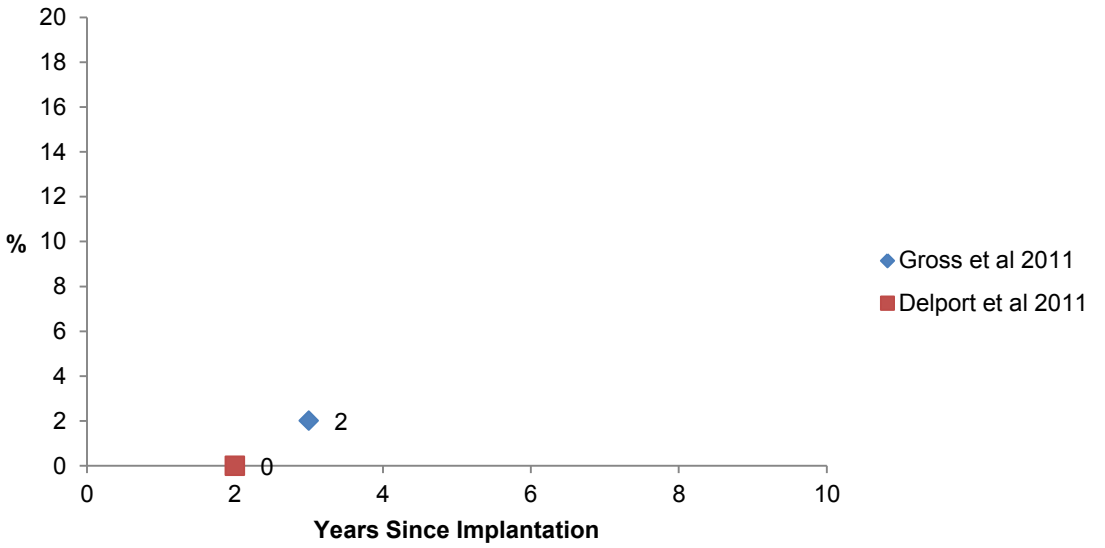

Figure 17: Revision Rates Reported by Studies With ReCap Implants

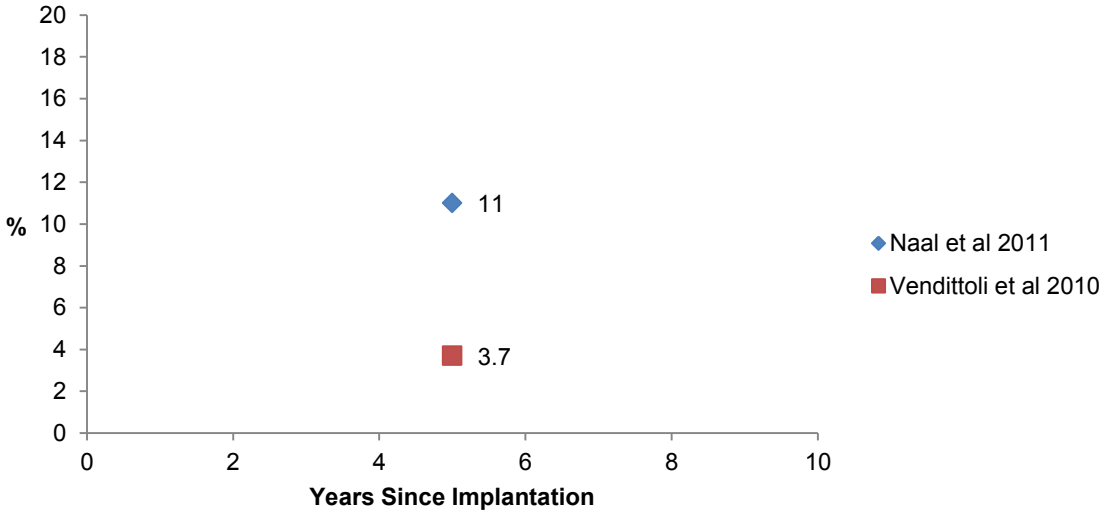

Figure 18: Revision Rates Reported by Studies With Durom Implants

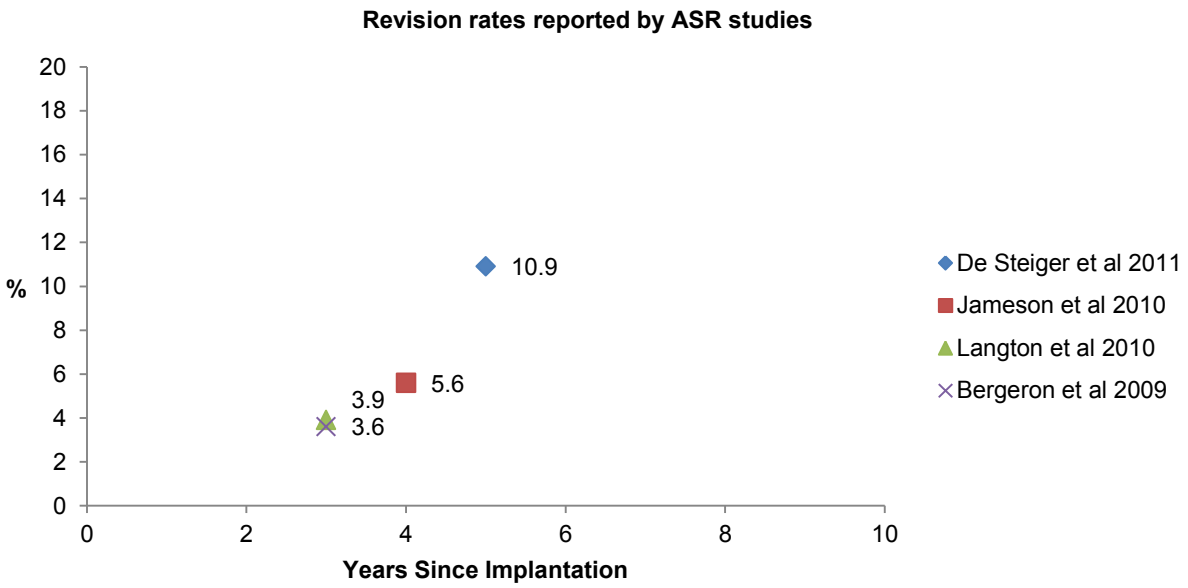

Figure 19: Revision Rates Reported by Studies With Articular Surface Replacement Implants

Biological Effects of Cobalt-Chromium Bearing Surfaces

High Metal Ion Levels

One of the most contentious issues surrounding MOM hip implants is the release of metal ions from the MOM implant due to surface wear. (65) A body of literature has shown a rise in the concentration of cobalt and chromium ions in the blood and urine of patients following MOM HRA and MOM THA. Cobalt and chromium particles can be generated from wear of the articular surfaces of these implants and can disperse into the blood circulation. Patients are then exposed to higher than usual levels of these metals, which can be measured in patients' blood and urine following surgery. The exact level of metal ions required for a pathologic response is still difficult to determine. (66)

There is a consensus that the blood cobalt and chromium levels of patients with well-functioning MOM implants are approximately 2 µg/L (equivalent to 2 parts per billion) and 2 ng/ml, respectively. (67) The expert advisory group of the Medicine and Healthcare Products Regulatory Agency (68) has recommended monitoring of patients with metal ion levels greater than 7 parts per billion, which is equal to 119 nmol/L for cobalt and 134.5 nmol/L for chromium. Normal renal function is needed to excrete the excess metals produced by the MOM implant; therefore, MOM bearings are contraindicated in patients with abnormal renal function.

Little is known about the biological effects of elevated levels of cobalt and chromium. (67;70) However, hypersensitivity reaction, local soft tissue toxicity, bone loss, and neurological symptoms have been reported. (14) Cardiomyopathy due to cobalt exposure has been reported in alcoholic cobaltism and industrial poisoning. (69) Since MOM HRA is used in younger active patients whose life expectancy is considerably longer than that of elderly patients, there is a concern about the unknown risks of long-term exposure to metal ions and metal debris. This highlights the importance of long-term clinical studies in this area. At the current time, there is no clear evidence linking MOM implants with long-term systemic problems. According to Delaunay et al, (71) there is no scientific or epidemiological data that indicates a risk of carcinogenesis or teratogenesis related to the use of a MOM bearing implant.

There is evidence to suggest that high levels of cobalt and chromium are influenced by specific implant design, the positioning of the implant which is influenced by the technical skills of the surgeon, and the diameter of the implant. (15) A smaller component size has been shown to be associated with increased metal wear due to poor fluid lubrication and reduction of the arc of cover. (67)

Metal Hypersensitivity

Hypersensitivity to metal implants is still not well understood. Although 20% to 25% of total joint arthroplasty patients develop metal sensitivity, only a few (< 1%) exhibit symptoms. (72) Metals known to cause immunological reactivity include beryllium, nickel, cobalt, and chromium. Occasional sensitivity has been reported to tantalum, titanium, and vanadium. (73) However, there is no universally accepted diagnostic test for metal allergy and no validity for a positive skin test. (72)

Periprosthetic Biological Reactions

Periprosthetic reactions to wear particles comprise a spectrum of inflammatory changes that have been described in the literature using different terminologies such as metalosis, pseudotumor, aseptic lymphocytic vasculitis–associated lesions, and adverse reactions to metal debris. However, the use of these terms is controversial and there is no clear consensus in the literature defining the boundaries of each term. These abnormal soft tissue reactions have been attributed to 2 etiologies: wear-related cellular toxicity and hypersensitivity. (67)

Metalosis is the macroscopic staining of the soft tissues and is associated with abnormal wear of the bearing surfaces. (67) Pseudotumors are sterile inflammatory masses or cysts found in the soft tissues surrounding MOM and metal-on-polyethylene (MOP) implants. The pathogenesis of these tumors remains unclear, but they are related to the failed prostheses. (74) Various names such as cyst, bursae, and inflammatory mass have also been used to describe these tumors. Aseptic lymphocytic vasculitis–associated lesions are a lymphocyte-dominated immunological response within the periprosthetic tissues around MOM implants. Haddad et al (67) have described adverse reactions to metal debris as an umbrella term that includes metalosis, aseptic lymphocytic vasculitis–associated lesions, and pseudotumors. However, these terms all appear to cover different parts of the spectrum of reactions to metals. In most cases, pseudotumors seem to be the result of the large amount of cobalt-chrome wear debris rather than metal ions, which have a local toxic effect. (75) Matthies et al (76) have suggested patient susceptibility as an important factor in the etiology of these tumors rather than increased wear or increased metal ion levels. The term "pseudotumors" may even include lesions that are not related to metal articulation.

Pseudotumors

Clinical cases of periprosthetic soft tissue masses, either solid or cystic, have recently been reported as a serious complication of MOM HRA and MOM THA. Carli et al (77) found similar adverse soft tissue reactions in non-MOM THAs which were then successfully treated by revision of the loose components. The most common symptoms associated with pseudotumors are pain and discomfort in the region, presence of a mass, skin rash, and nerve palsy. The common histological features are extensive necrosis and an inflammatory response dominated by macrophages and lymphocytic infiltration. (75) The expert advisory group of the Medicine and Healthcare Products Regulatory Agency has recommended annual follow-up of patients for the first 5 years, as there appears to be a higher incidence of pseudotumors during the first few years after surgery. (68)

Risk Factors

Several factors contribute to the increase in wear rate and the development of pseudotumors. These include patient factors, surgical factors, and implant factors. Patient factors include being female, and particularly being female and less than 40 years of age, small component size, and hip dysplasia. In the study by Glyn-Jones et al, (78) the revision rate for pseudotumors in men was 0.5% (95% CI, 0–1.1) at 8 years, whereas it was 6% (95% CI, 2.3–10.1) at 8 years for women over 40 years and 13.1% (95% CI, 0–27) for women under 40 years of age. The investigators have recommended that MOM resurfacing be undertaken with great caution in women, particularly those under 40 years of age. (75;78)

Literature indicates that the most important surgical risk factor for development of a pseudotumor is acetabular component orientation. (79) It has been reported that 64% of revisions are performed because of malpositioning of the acetabular component. (80) Murray et al (75) have suggested that the optimal orientation of the acetabular component is an inclination of 40° to 45° and anterversion of 20° to 25°. They have emphasized that the further the component is from this position, the more likely it is that a pseudotumor will develop in the joint. There is greater difficulty in placing the acetabular component when performing MOM HRA compared with THA because preservation of the femoral head, which is necessary in resurfacing, makes it more difficult to place the cup in exactly the optimal position.

Malviya et al (81) have recommended good component positioning and alignment and the clearing of protruding osteophytes in order to prevent the development of pseudotumors. They suggested an acetabular inclination of 45° and anteversion of 10° to 20°, with a femoral stem shaft angle between 5° and 10°, coupled with good soft tissue clearance and osteophyte excision, as well as patient positioning and identification of anatomical landmarks.

Other risk factors for the development of a pseudotumor include abnormal femoral anatomy (e.g., hip dysplasia) and a high femoral head-neck ratio. In the study by Murray et al, (75) no women with a femoral head-neck ratio less than 1.3 developed pseudotumors. The authors suggested that it is safe to perform MOM HRA in women with such proximal femoral anatomy.

Prevalence of Pseudotumors

The prevalence of pseudotumors is much higher in women than in men. Since studies used different definitions for pseudotumors, different methods of diagnosis, and different lengths of follow-up, the incidence of pseudotumors has varied across the studies.

Prevalence of Symptomatic Pseudotumors

The Canadian Hip Resurfacing Group (82) reported the prevalence of pseudotumors in patients who received MOM HRA in Canadian academic centres. Nine centres which performed more than 100 MOM HRA were surveyed. A total of 3,432 MOM HRAs were performed between 2002 and 2008. The mean age of patients was 51.2 years (range, 16–83 years), and 76.9% of the patients were male. Osteoarthritis was the primary diagnosis in 90.1% of the patients. A pseudotumor was defined as a destructive soft tissue or bone reaction adjacent to the MOM implant confirmed by a revision surgery. At a mean follow-up of 3.4 years (range, 2–9 years), there were 4 surgically confirmed pseudotumors, and therefore the prevalence was 0.1%. Three of the 4 cases were women.

Prevalence of Asymptomatic Pseudotumors

A Canadian study investigated the prevalence of pseudotumors in asymptomatic patients as detected by ultrasound. (83) Seventy-five patients were evaluated, of which 20 had undergone MOM HRA, 31 had undergone MOM THA, and 24 had MOP THA. The minimum duration of follow-up was 2 years. Solid or cystic masses were found in 10 (32%) of those with MOM THA, in 5 (25%) of those with MOM HRA, and in 1 (4%) of those with MOP THA. The difference between MOM THA and MOP THA was significant ($P = 0.015$), but the difference between MOM HRA and MOP THA was not significant ($P = 0.07$). There was no significant difference between the median serum levels of cobalt and chromium of patients with and without pseudotumors ($P = 0.07$ for cobalt and $P = 0.08$ for chromium).

Kwon et al (84) investigated the incidence of asymptomatic pseudotumors in 201 hips (158 patients) that had undergone MOM HRA using imaging techniques. With a 5-year follow-up, they found a prevalence of 4% for asymptomatic pseudotumors, and also reported an association between elevated cobalt and chromium levels and the development of a pseudotumor.

Synovial Cysts

Synovial cysts are not common and have been reported in relation to MOM, MOP, and ceramic-on-ceramic hip implants. Malviya et al (81) found only 3 cases reported in the literature and they reported 1 case of a large synovial cyst and 1 case of a pseudotumor in their series of 670 MOM HRAs. While the case of the pseudotumor had obvious features of metalosis with definitive evidence of impingement, edge loading, and wear, there was no evidence of metallic wear in either bone or soft tissue in the case of the synovial cyst.

Risk of Local Malignant Tumor

According to a literature review conducted by McDonald et al in 2002, (85) there were a total of 36 cases of malignancy associated with orthopedic implants, of which 25 were associated with knee or hip implants and 11 were associated with other metallic implants. Neoplasms arose around implants made of stainless steel, cobalt-chromium alloy, and titanium implants. The authors reported 2 cases of angiosarcoma that developed adjacent to stainless steel plates for the fixation of a femoral fracture more than 40 years after implantation. The authors indicated that the latency period is usually longer for development of neoplasms after nonarthroplasty implants compared with those occurring after total joint arthroplasty (mean, 19.4 years and 6.0 years, respectively). (85)

Teratogenicity

Undertaking a prospective trial to investigate the teratogenicity of any substance in humans would never be practical. (86) However, according to Cobb et al (86) and Delaunay et al, (71) there has never been a report of fetal malformation associated with MOM implants. Although exposure to cobalt and chromium induces teratogenicity in animal studies, there is insufficient clinical data to confirm this in humans. (67)

Cobalt and chromium ions generated from metal implants can pass the placental barrier, (71) and several authors have recommended against the use of MOM implants in women at childbearing ages. Although the potential effects of transplacental metal ion transfer are not clear at the present time, it is important to educate young female patients to avoid issues in the future. (87)

Chromosomal Damage

Chromosomal translocation and aneuploidy are genetic changes that occur in the general population. These changes are known to accumulate with time as a result of increasing age and environmental factors such as smoking. A study by Doherty et al (88) investigated whether there is any evidence of cumulative mutagenic damage in the peripheral blood lymphocytes of patients undergoing revision arthroplasty compared with those undergoing primary arthroplasty. The authors found a 3-fold increase in aneuploidy and a 2-fold increase in chromosomal translocations in patients who had MOP THA and a 2.5-fold increase in aneuploidy and a 3.5-fold increase in chromosomal translocation in patients with cobalt-chrome prostheses. In patients with titanium-vanadium-aluminum prostheses there was a 5-fold increase in aneuploidy but no increase in chromosomal translocation. There was no increase in either aneuploidy or chromosomal translocation in 6 patients who had prostheses made of stainless-steel. However, the authors stated that the mechanism of the changes observed is not clear and the study does not prove that it is the metal in the wear debris which is responsible for these genetic changes.

Dunstan et al (89) analyzed peripheral blood leukocytes for chromosomal aberrations in 3 groups of patients. The authors found a significantly elevated number of chromosomal aberrations, both aneuploidy gain and structural aberrations, in patients with MOM hip implants compared with an age-and sex-matched control group, but indicated that the clinical consequences of the chromosomal aberrations are unknown.

Risk of Death and Cancer Death

Researchers have queried whether metal exposure from metal implants could lead to increased mortality or risk of cancer. Visuri et al (90) investigated mortality rates among patients who received MOM THA and MOP THA and compared those with the mortality rate in the general population. In this study, only patients with OA were selected. The MOM THA group comprised 579 patients who received a MOM implant made from cobalt-chromium-molybdenum (the same materials used in the current generation of HRA implants), and the MOP THA group comprised 1585 patients. The metal stem of the prosthesis in

the latter group was made of cobalt-chromium-molybdenum. The mean follow-up times for the MOM THA and MOP THA groups were 17.9 years and 16.7 years, respectively.

Overall, both groups had a mortality rate slightly below the national average. The standardized mortality ratios (SMR) were lower in both groups as compared to the general population (SMR, 0.95; 95% CI, 0.87–1.02 for MOM THA and SMR, 0.90; 95% CI, 0.85–0.95; $P < 0.001$ for MOP THA). Mortality in both groups was significantly reduced during the first year after MOM THA and MOP THA as compared to the general population (SMR, 0.59; 95% CI, 0.34–0.96; $P < 0.05$ for MOM THA and SMR, 0.37; 95% CI, 0.26–0.51; $P < 0.001$ for MOP THA). It also remained significantly below the rate for the general population for the rest of the first decade. During the second decade, both groups had the same mortality rates as the general population (SMR, 0.94; 95% CI, 0.81–1.06 for MOM THA and SMR, 0.96; 95% CI, 0.89–1.04 for MOP THA). The mortality rate was significantly higher after 20 years in both groups (SMR, 1.20; 95% CI, 1.04–1.37; $P < 0.05$ for MOM THA and SMR, 1.38; 95% CI, 1.23–1.53; $P < 0.001$ for MOP THA).

The reduction in the mortality rate after THA was also reported in previous studies, although these had a follow-up of only 10 years. (91;92) A "healthy patient effect" was assumed to be the reason for this observation. Two Scandinavian studies have shown that patients undergoing THA are generally healthier and have a longer life expectancy than the general population. (91;93)

Visuri et al (90) also investigated cancer mortality among patients who had received MOM THA and MOP THA and compared the results with the cancer mortality rate in the general population. Overall, cancer mortality in both groups was lower than that reported for the general population. However, this difference was only significant for the MOP THA group (SMR, 0.97; 95% CI, 0.78–1.18 for MOM THA and SMR, 0.76; 95% CI, 0.66–0.87; $P < 0.001$ for MOP THA). During the first year, the SMR was 0.35 (95% CI, 0.04–1.27) for MOM THA and 0.14 (95% CI, 0.03–0.41; $P < 0.001$) for MOP THA. Cancer mortality remained below the rate in the general population for the rest of the first decade.

During the second decade, cancer mortality was higher in the MOM THA group than in the general population (SMR, 1.19; 95% CI, 0.86–1.59) but this difference was not significant. However, it was lower than the rate in the general population after 20 years (SMR, 0.84; 95% CI, 0.5–1.03). During the second decade, cancer mortality remained below the rate in the general population in the MOP THA group (SMR, 0.84; 95% CI, 0.67–1.02) and remained low after 20 years (SMR 0.89; 95% CI, 0.61–1.24).

Risk of Cancer

Although cobalt and chromium wear particles have been shown to induce carcinoma in animal studies, epidemiological studies on metal implants did not demonstrate an increased risk of cancer in humans. (94)

A wide range of metals and their alloys, polymers, ceramics, and composites are used in medical devices and dental implants. Most implanted devices are composed of more than one kind of material (implants of complex composition). (95) Major classes of metals used in medical devices and dental materials include stainless steels, cobalt-chromium alloys, titanium metal, and titanium alloys. Metal alloys may also be used in prosthetic heart valves, pacemakers, and vascular endoprostheses. (95) In 2000, the consensus of the International Agency for Research in Cancer meeting was that the carcinogenicity of metal implants could not be assessed with the current knowledge. Orthopedic implants of complex composition were included in the "Group 3" classification (not classifiable as to their carcinogenicity to humans). (95)

In a recent study, data from the National Joint Registry of England and Wales were combined with National Health Services statistics data in order to compare the risk of cancer in patients in the first 7 years after either MOM HRA or stemmed MOM THA with the risk of cancer in the general population

and in patients with non-MOM implants. (96) The expected 1 year incidence of cancer in the age-and sex-matched general population was estimated at 1.65 (95% CI, 1.60–1.70). Overall, the incidence of new diagnoses of cancer in the first year after all hip arthroplasties was lower than in the age-and sex-matched general population (incidence rate, 1.25; 95% CI, 1.21–1.30).

At 5 years, patients who had MOM HRA had a lower observed incidence of cancer than those who had stemmed MOM THA or non-MOM implants (incidence rate, 3.34; 95% CI, 3.01–3.72 for MOM HRA; incidence rate, 5.65; 95% CI, 5.13–6.23 for stemmed MOM THA; and incidence rate, 8.17; 95% CI, 8.00–8.36 for non-MOM implants). The rate of cancer was particularly lower in younger patients with resurfacing MOM implants.

At 5 years, patients who underwent MOM HRA had a much lower incidence of prostate cancer compared to the other 2 groups (incidence rate, 0.91; 95% CI, 0.71–1.16 for MOM HRA; incidence rate, 1.92; 95% CI, 1.52–2.42 for stemmed MOM THA; incidence rate, 3.09; 95% CI, 2.91–3.27 for non-MOM implants). Patients who underwent MOM HRA did not have an increased incidence of malignant melanoma, hematological cancer, or renal cancers at 5 years.

Conclusions

There have been long-term follow-up studies for MOM HRA with 3 implants (BHR, ConservePlus, and Cormet). The revision rates for MOM HRA with these implants appear to meet NICE criteria for a revision rate of 10% or less at 10 years. Metal-on-metal HRA with the ReCap implant had excellent outcomes at a mean follow-up of 2.9 years. One RCT with a mean follow-up of 4.7 years compared the revision rate of MOM HRA using the Durom implant with that for THA and reported a higher revision rate for MOM HRA with the Durom implant than for THA, but the observed difference was not statistically significant. One implant (ASR) failed to meet NICE criteria.

Several criteria must be met in order for a MOM HRA to be successful. These include careful selection of patients, and surgeons having appropriate surgical skills and adequate training. There is a learning curve associated with MOM HRA and it has been shown that malpositioning of the acetabular component results in an increased rate of wear and implant failure.

The ideal patients for MOM HRA are young male patients with end-stage hip osteoarthritis, good bone quality, and proper anatomy around the affected joint. In addition, a smaller component size has been shown to be associated with increased metal wear and risk of failure.

Normal renal function is required to excrete the excess metals produced by the MOM implant; therefore, MOM bearings are contraindicated in patients with abnormal renal function.

The potential complications of MOM HRA are high cobalt and chromium ion levels in the blood and urine of patients and periprosthetic tissue reactions to wear particles, described in the literature as adverse reactions to metal debris. This term includes pseudotumors, aseptic lymphocytic vasculitis–associated lesions, and metal sensitivity. The precise biological pathway that leads to these reactions is still unknown. Risk factors for development of pseudotumors have been reported as: being female, particularly being female and less than 40 years of age, small component size, and hip dysplasia. The incidence of symptomatic pseudotumors in Canadian academic centres is reported as 0.1%.

Studies have shown an increase in chromosomal aberrations with MOM articulations, but the clinical implications and their long-term consequences are still unknown. Epidemiological studies have shown that patients who underwent MOM HRA did not have an overall increase in mortality or risk of cancer.

There is insufficient clinical data to confirm the teratogenicity of MOM implants in humans. However, since cobalt and chromium can pass the placental barrier, non-MOM bearing surfaces have been recommended for women at childbearing ages who require hip arthroplasty.

Acknowledgements

Editorial Staff
Irina Alecu

Appendices

Appendix 1: Literature Search Strategy

Database: Ovid MEDLINE(R) <1946 to January Week 4 2012>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <February 02, 2012>, Embase <1980 to 2012 Week 04>
Search Strategy:

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1 exp Arthroplasty, Replacement, Hip/ use mesz (13792)
2 exp hip arthroplasty/ use emez (32551)
3 exp Hip Prosthesis/ (43446)
4 or/1-3 (58855)
5 exp Metals/ use mesz (782270)
6 exp Metal/ use emez (925808)
7 exp metal implantation/ use emez (2114)
8 or/5-7 (1709064)
9 4 and 8 (5469)
10 (metal on metal adj2 (hip* or resurfac* or arthroplast*)).ti,ab. (1288)
11 (hip adj4 (BHR or Conserve Plus or Durom or Cormet or ASR or ReCap)).ti,ab. (145)
12 9 or 10 or 11 (5987)
13 limit 12 to english language (5306)
14 limit 13 to yr="2005 -Current" (2701)
15 limit 14 to (case reports or comment or editorial or letter or news or note) [Limit not valid in Ovid MEDLINE(R),Ovid MEDLINE(R) In-Process,Embase; records were retained] (231)
16 Case Report/ use emez (1763013)
17 14 not (15 or 16) (2303)
18 remove duplicates from 17 (1514)

****

Cochrane

ID	Search	Hits
#1	MeSH descriptor **Arthroplasty, Replacement, Hip** explode all trees	1243
#2	MeSH descriptor **Hip Prosthesis** explode all trees	935
#3	(#1 OR #2)	1922
#4	MeSH descriptor **Metals** explode all trees	12411
#5	(#3 AND #4)	104
#6	(metal on metal NEAR/2 (hip* or resurfac* or arthroplast*)) or (hip NEAR/4 (BHR or Conserve Plus or Durom or Cormet or ASR or ReCap))	47
#7	(#5 OR #6), from 2005 to 2012	66

CRD

Line	Search	Hits
1	MeSH DESCRIPTOR Arthroplasty, Replacement, Hip EXPLODE ALL TREES	212
2	MeSH DESCRIPTOR Hip Prosthesis EXPLODE ALL TREES	75
3	#1 OR #2	241
4	MeSH DESCRIPTOR Metals EXPLODE ALL TREES	337
5	#3 AND #4	11
6	((metal on metal adj2 (hip* or resurfac* or arthroplast*))) OR ((hip adj4 (BHR or Conserve Plus or Durom or Cormet or ASR or ReCap)))	4
7	#5 OR #6	13

Appendix 2: GRADE Tables

Table A1: GRADE Evidence Profile for Metal-on-Metal Hip Resurfacing Arthroplasty Studies With Long-Term Follow-up

No. of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
BHR Implant							
1 (Comparative)	Serious limitations (-1)	No serious limitations	No serious limitations	No serious limitations	Undetected	Long-term follow-up	⊕⊕ Low/
6 (Case series)	Very serious limitations (-2)	No serious limitations	No serious limitations	No serious limitations	Undetected		⊕ Very Low
ConservePlus Implant							
4 (Case series)	Very serious limitations (-2)	No serious limitations	No serious limitations	No serious limitations	Undetected	Long term follow-up	⊕ Very Low
Cormet Implant							
1 (Case series)	Very serious limitations (-2)	No serious limitations	No serious limitations	No serious limitations	Undetected	Long-term follow-up	⊕ Very Low

Abbreviations: BHR, Birmingham Hip Resurfacing; No., number.

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