Clin Orthop Relat Res (2014) 472:2217–2230
DOI 10.1007/s11999-014-3556-3

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

SURVEY

Hip Resurfacing versus Total Hip Arthroplasty: A Systematic Review Comparing Standardized Outcomes

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Received: 24 September 2013 / Accepted: 25 February 2014 / Published online: 4 April 2014

Abstract

Background Metal-on-metal hip resurfacing was developed for younger, active patients as an alternative to THA, but it remains controversial. Study heterogeneity, inconsistent outcome definitions, and unstandardized outcome measures challenge our ability to compare arthroplasty outcomes studies.

Questions/purposes We asked how early revisions or reoperations (within 5 years of surgery) and overall revisions, adverse events, and postoperative component malalignment compare among studies of metal-on-metal hip resurfacing with THA among patients with hip osteoarthritis. Secondarily, we compared the revision frequency identified in the systematic review with revisions reported in four major joint replacement registries.

Methods We conducted a systematic review of English language studies published after 1996. Adverse events of interest included rates of early failure, time to revision, revision, reoperation, dislocation, infection/sepsis, femoral neck fracture, mortality, and postoperative component alignment. Revision rates were compared with those from four national joint replacement registries. Results were reported as adverse event rates per 1000 person-years stratified by device market status (in use and discontinued). Comparisons between event rates of metal-on-metal hip resurfacing and THA are made

This study was funded by a Canadian Institutes of Health Research (CIHR) Knowledge Synthesis grant (grant number 228369). The study funder had no involvement in the study design, collection, analysis, or interpretation of the data.
All ICMJE Conflict of Interest Forms for authors and *Clinical Orthopaedics and Related Research* editors and board members are on file with the publication and can be viewed on request.
This work was performed at the University of Calgary, Calgary, Alberta, Canada.

Electronic supplementary material The online version of this article (doi:10.1007/s11999-014-3556-3) contains supplementary material, which is available to authorized users.

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using a quasilikelihood generalized linear model. We identified 7421 abstracts, screened and reviewed 384 full-text articles, and included 236. The most common study designs were prospective cohort studies (46.6%; n = 110) and retrospective studies (36%; n = 85). Few randomized controlled trials were included (7.2%; n = 17).

Results The average time to revision was 3.0 years for metal-on-metal hip resurfacing (95% CI, 2.95–3.1) versus 7.8 for THA (95% CI, 7.2–8.3). For all devices, revisions and reoperations were more frequent with metal-on-metal hip resurfacing than THA based on point estimates and CIs: 10.7 (95% CI, 10.1–11.3) versus 7.1 (95% CI, 6.7–7.6; p = 0.068), and 7.9 (95% CI, 5.4–11.3) versus 1.8 (95% CI, 1.3–2.2; p = 0.084) per 1000 person-years, respectively. This difference was consistent with three of four national joint replacement registries, but overall national joint replacement registries revision rates were lower than those reported in the literature. Dislocations were more frequent with THA than metal-on-metal hip resurfacing: 4.4 (95% CI, 4.2–4.6) versus 0.9 (95% CI, 0.6–1.2; p = 0.008) per 1000 person-years, respectively. Adverse event rates change when discontinued devices were included.

Conclusions Revisions and reoperations are more frequent and occur earlier with metal-on-metal hip resurfacing, except when discontinued devices are removed from the analyses. Results from the literature may be misleading without consistent definitions, standardized outcome metrics, and accounting for device market status. This is important when clinicians are assessing and communicating patient risk and when selecting which device is most appropriate for individual patients.

Introduction

Metal-on-metal hip resurfacing is an alternative surgical approach to THA, which generally is used for younger and more active patients [95, 143]. Unlike with a THA, the head of the femur is not completely removed in metal-on-metal hip resurfacing but is reshaped to accept a new metal head that fits a metal acetabular component (also referred to as metal-on-metal [MoM] implants). Still considered in the early stages of dissemination, with a limited number of metal-on-metal hip resurfacing studies now reaching 5 years of followup, emerging papers in the literature are a source of critically needed information to determine the degree and severity of adverse events.

Study heterogeneity, inconsistent outcome definitions, and unstandardized outcome measures challenge our ability to compare arthroplasty outcomes studies [124, 136, 143]. To date, there is limited evidence in the literature that compares adverse events across studies using a standardized metric. Without standardized metrics, it is not possible to make valid comparisons that account for differences in study sample sizes and followup times, which can have a substantial effect on the results. Therefore, it is critical to use a standardized metric such as person-years; however, to date this is not common practice in the arthroplasty literature. Additionally, it has not been common practice to analyze outcomes of medical devices according to market status. Our underlying assumption was that market status is a critical factor in assessing safety issues given that currently in-use metal-on-metal hip resurfacing and THA devices likely have greater efficacy and fewer adverse events. As a result, we organized our data analysis based on device market status.

The primary purpose of our systematic review was to compare studies of metal-on-metal hip resurfacing with THA among patients with hip osteoarthritis to determine rates of: (1) early revision or reoperation (within 5 years of surgery) and overall revisions; (2) revisions reported in four major joint replacement registries; (3) adverse events; and (4) postoperative component malalignment. In this review, we used the standardized metric, per 1000 person-years, to address gaps not previously addressed in the literature to compare outcomes between THA studies that had longer-term followups with metal-on-metal hip resurfacing studies with limited followup.

Materials and Methods

Search Strategy and Criteria

Our review protocol was based on well-established guidelines developed by the Centre for Reviews and Dissemination [24]. The following electronic databases were searched: MEDLINE, PubMed, EMBASE, the Cochrane Library, BIOSIS Previews, and Web of Science from 1997 to 2011.

Using the PICO (patient problem or population [P], intervention [I)], comparison [C)], outcome(s) [O)]) framework to define our exclusion and inclusion criteria [116], we defined our population as adult patients (≥ 18 years) with primary osteoarthritis of the hip. Where study population included patients with hip and knee osteoarthritis, the study was included only if results were subdivided into hip and knee groups. The intervention was primary metal-on-metal hip resurfacing prosthesis and the comparator THA. Type of prosthesis used (ie, material components and prosthesis type) was recorded for comparative analysis. Study outcomes reported included adverse events, safety issues, or revision rates (Appendix 1. Supplemental material is available with the online version of CORR®).

Studies were excluded if they were: not English language; studies with fewer than 10 participants or populations younger than 17 years; hemiarthroplasty; preoperative or postoperative interventions for joint arthroplasty (eg, physiotherapy, rehabilitation, drug trials); management of osteoarthritis or related symptoms; variations on specific surgical techniques/procedures in THA or metal-on-metal hip resurfacing; focused on prosthesis modifications (except where studies looked at cement versus cementless prosthesis); or in vitro/in situ studies.

Primary outcomes were adverse events including revisions, reoperations, infections/sepsis, femoral neck fractures, other femoral fractures, dislocations, and mortality (all-cause, within 30 days of surgery). Revision is commonly defined as surgery where the patient underwent a subsequent surgery on their primary prosthesis where the component was replaced. Reoperations are commonly defined as a subsequent surgery on the primary prosthesis but the component was not replaced. These definitions are not standardized and sometimes the terms revision and reoperation are used interchangeably. We report definitions of adverse events as they were presented in the original studies. Rates of early failure outcomes included revisions/reoperations within 5 years after primary THA or metal-on-metal hip resurfacing. Postoperative component alignment data, for acetabular and stem device components, were extracted and included varus alignment, valgus alignment, and mean neck- and stem-shaft angles. Postoperative component alignment was important to include since clinical evidence of poor alignment as a predictor of device failure has been highlighted in the literature [33].

Initial searches revealed few relevant randomized controlled trials. Consequently, we included all quasiexperimental and observational study designs.

Data Extraction

Abstracts were screened by two independent reviewers (DAA, MCM), and each full-text article was screened by one of three reviewers (SH, DAA, MCM). Data were extracted by two independent reviewers (DAA, MCM) and extracted values were compared to identify discrepancies. Data were extracted as reported in the study. Data were quality-checked to reconcile any known discrepancies to the final approved digital data template.

Prosthesis device types were extracted from each article and sorted by market status: those currently in use and those discontinued. The term "in use" referred to metal-on-metal hip resurfacing and THA devices that were available for surgical use in North America when this research was conducted. Conversely, "discontinued" referred to devices not available for surgical use.

We identified 7421 abstracts, screened, and reviewed 384 full-text articles and included 236 (Fig. 1). Primary reasons for exclusion were: patients younger than 18 years, focus on surgical techniques, or adverse events not reported. None of the articles reviewed reported their findings using a standardized metric (per 1000 person-years). The most common study designs (Table 1) were prospective cohort studies at 46.6% (n = 110) followed by retrospective studies at 36% (n = 85).

We used the most recent registry reports available to extract revision data from four major joint replacement registries as a comparison for revision findings: the Australian Orthopaedic Association National Joint Replacement Registry, New Zealand National Joint Register, Swedish Hip Arthroplasty Register, and National Joint Registry for England and Wales [9, 47, 98, 102]. These registries were selected because of the homogeneity of available data (revision rates and followups) compared with other registries.

Data Analysis Methods

The observed counts of adverse events are assumed to have a Poisson distribution with a rate parameter for each study and/or adverse event given in units of events per 1000 person-years. Estimates and 95% CI for each rate parameter are made using the relationship between the chi-square and Poisson distributions as per Ulm [135]. Comparisons between adverse event rates for metal-on-metal hip resurfacing and THA are made using a quasilikelihood generalized linear model with log link [64], with p values less than 0.05 considered statistically significant. The quasilikelihood generalized linear model accounts for the significant overdispersion of the data; the data are observed to be overdispersed in that the mean and variance of event counts for each adverse event are not near equal. Thus, we use the quasilikelihood model p values to determine statistical significance of comparisons, as this method accounts for the overdispersion of the data. We also included 95% CIs for reference.

Results

Rates of Early Revisions/Reoperations (within 5 years of surgery) and Average Time to Revision

For all devices, revisions occurred earlier in patients treated with metal-on-metal hip resurfacing devices (3.0 years; 95% CI, 2.95–3.1) compared with THA (7.8 years; 95% CI,

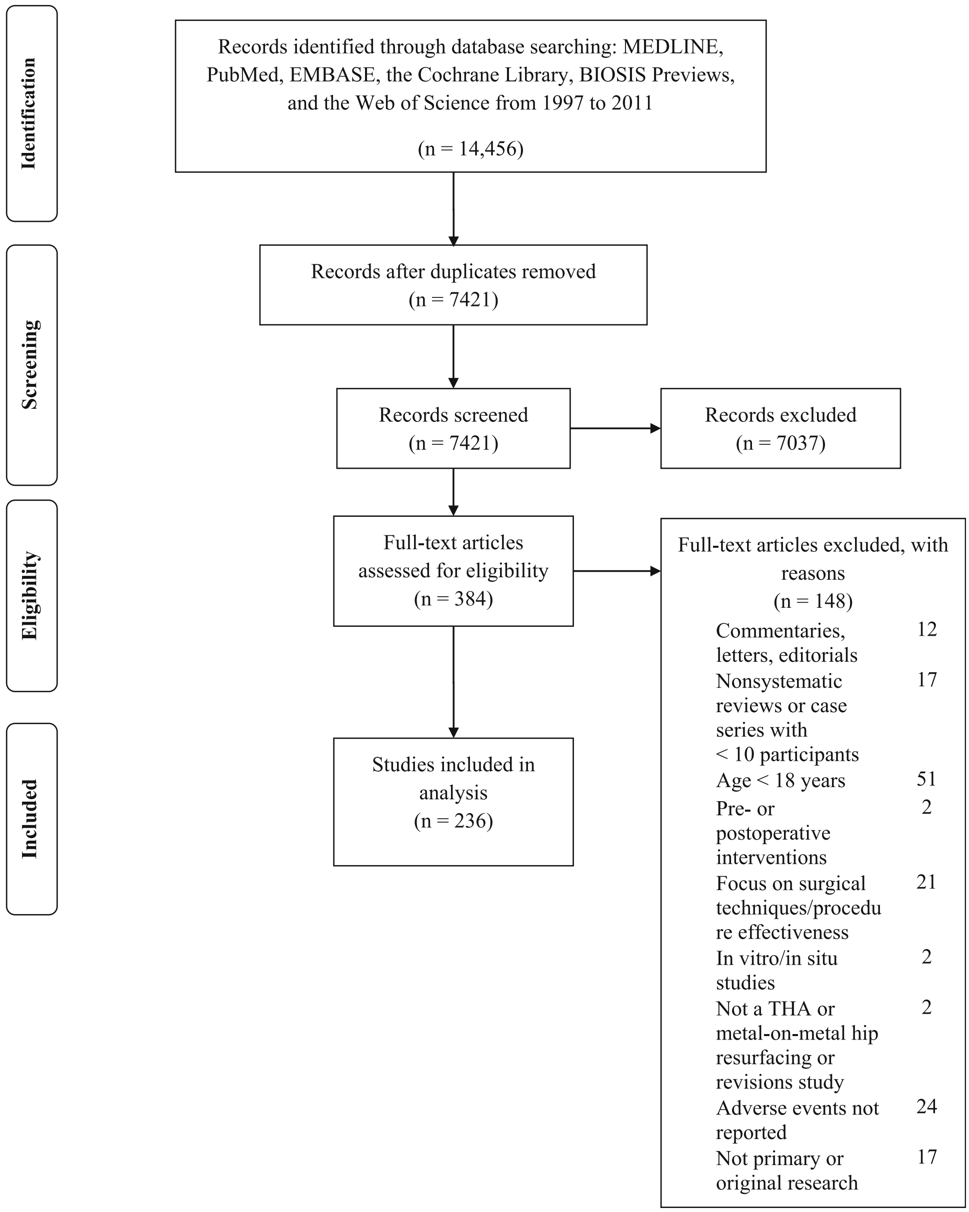

Fig. 1 The flow of articles through the systematic review process using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [93] is shown.

7.2–8.3; $p < 0.001$) (Table 2). When discontinued devices were removed from the analysis, revisions still occurred earlier in metal-on-metal hip resurfacing devices (Table 2).

Early revisions/reoperations (within 5 years of surgery) were more frequent for metal-on-metal hip resurfacing (14.5 per 1000 person-years; 95% CI, 12.7–16.5) compared with THA (3.1 per 1000 person-years; 95% CI, 2.3–4.2; $p = 0.003$) for all devices (Table 2). When discontinued devices were removed from the analysis, early revisions/reoperations were still more frequent for metal-on-metal hip resurfacing compared with THA, with nonoverlapping CIs, but a nonsignificant p value (Table 2).

Revisions

The average number of revisions per 1000 person-years was greater for all metal-on-metal hip resurfacing devices (10.7; 95% CI, 10.1–11.3) than for THA devices (7.1; 95% CI, 6.7–7.6; $p = 0.068$), with nonoverlapping CIs, but a nonsignificant p value (Table 2). For currently in-use devices, revisions per 1000 person-years were greater for THA (7.6; 95% CI, 6.5–8.8) than for metal-on-metal hip resurfacing (5.7; 95% CI, 5.2–6.2; $p = 0.268$). When discontinued devices were removed from the analysis, the average number of revisions for THA devices increased from 7.1 revisions per 1000 person-years (95% CI, 6.7–7.6)

Table 1. Distribution of study designs for articles included in systematic review

Study design	Number of full-text articles	
	Number	Percent
Randomized control trial	17	7.2
Case control	14	5.9
Prospective cohort*	110	46.6
Retrospective cohort†	85	36
Prospective observational (multigroup)‡	4	1.7
Retrospective observational (multigroup)‡	4	1.7
Case series (with more than 10 participants)	2	0.8
Total	236	100

* Nonrandomized, observational study that follows a group of participants through time to determine the association between a specific exposure and/or intervention (treatment, implanted device, etc) and an outcome, only single intervention-group studies fall in this category.

† Nonrandomized, observational study that uses historical data for a group of participants to determine the association between a specific exposure and/or intervention (treatment, implanted device, etc) and an outcome, only single intervention-group studies fall in this category.

‡ Study designs are similar to the prospective and retrospective cohort but include more than one group of participants.

(Table 3), (Fig. 2. Supplemental material is available with the online version of CORR®) to 7.6 (95% CI, 6.5–8.8) (Table 4), (Fig. 3. Supplemental material is available with the online version of CORR®). For metal-on-metal hip resurfacing, removing discontinued devices decreased the average number of revisions from 10.7 per 1000 person-years (95% CI, 10.1–11.3) (Table 5), (Fig. 4. Supplemental material is available with the online version of CORR) to 5.7 (95% CI, 5.2–6.2) (Table 6), (Fig. 5. Supplemental material is available with the online version of CORR).

Three national registries (Australia, Sweden, and England and Wales) reported higher revision rates for metal-on-metal hip resurfacing devices compared with THA devices. The New Zealand registry was the only registry that showed a higher revision rate per 1000 person-years for THA (2.7; 95% CI, 2.6–2.8) compared with metal-on-metal hip resurfacing (2.4; 95% CI, 1.7–3.4) (Table 7). The registry revision rates were lower than those found in our systematic review for THA and metal-on-metal hip resurfacing devices, with the exception of THA and metal-on-metal hip resurfacing revision rates for the England and Wales registry (Table 7).

Reoperations

For all devices, reoperations were more frequent in metal-on-metal hip resurfacing (7.9 per 1000 person-years; 95% CI, 5.4–11.3) than THA devices (1.8 per 1000 person years; 95% CI, 1.3–2.2; $p = 0.084$) (Table 2). When discontinued devices were removed from the analysis,

Table 2. Summary of findings comparing market status groups

Adverse events	All devices (in-use and discontinued)			Currently in-use devices		
	THA (95% CI)	Metal-on-metal hip resurfacing (95% CI)	p value (THA vs metal-on-metal hip resurfacing)	THA (95% CI)	Metal-on-metal hip resurfacing (95% CI)	p value (THA vs metal-on-metal hip resurfacing)
The average time to revision (years)	7.8 (7.2–8.3)	3.0 (2.95–3.1)	<0.001	5.7 (5.0–6.6)	2.9 (2.8–3.0)	< 0.001
Number	10	9		2	7	
Early revisions/reoperation within 5 years of surgery (per 1000 person-years)	3.1 (2.3–4.2)	14.5 (12.7–16.5)	0.003	3.9 (2.4–6.1)	10.0 (8.3–11.9)	0.121
Number	21	19		8	12	
Revisions (per 1000 person-years)	7.1 (6.7–7.6)	10.7 (10.1–11.3)	0.068	7.6 (6.5–8.8)	5.7 (5.2–6.2)	0.268
Number	85	52		24	36	
Reoperations (per 1000 person-years)	1.8 (1.3–2.2)	7.9 (5.4–11.3)	0.084	4.7 (2.2–8.9)	8.1 (5.5–11.4)	0.455
Number	15	8		3	7	
Dislocations (per 1000 person-years)	4.4 (4.2–4.6)	0.9 (0.6–1.2)	0.008	4.8 (3.5–6.5)	1.1 (0.8–1.6)	0.010
Number	55	28		12	22	
Infections/sepsis (per 1000 person-years)	2.1 (2.0–2.3)	1.4 (1.1–1.8)	0.160	3.2 (2.0–4.8)	1.2 (0.8–1.8)	0.180
Number	43	30		10	22	
Femoral neck fractures (per 1000 person-years)	2.9 (1.6–4.8)	2.0 (1.6–2.6)	0.654	1.7 (0.04–9.7)	2.4 (1.6–3.4)	0.912
Number	7	22		2	15	

Table 3. Revision rate per 1000 person-years for each THA study (all devices) with 95% confidence intervals

Study	Sample size (n)	Upper bound	Lower bound	Revision rate
Fowble et al. [44]	44	33.5	0.0	0.0
Lachiewicz & Soileau [77]	65	28.4	0.0	0.0
Nayak et al. [99]	226	4.1	0.0	0.0
Zywiel et al. [147]	33	29.8	0.0	0.0
Kim [71]	601	1.7	0.1	0.6
Lübbeke et al [82]	2495	2.1	0.9	1.4
Kim [70]	140	6.6	0.2	1.8
Konstantoulakis et al. [74]	102	10.3	0.0	1.8
Nilsdotter & Isaksson [103]	151	6.8	0.2	1.9
Kalairajah et al. [66]	196	7.4	0.2	2.0
D'Lima et al. [39]	174	6.3	0.4	2.2
Garcia-Cimbrelo et al. [46]	104	7.5	0.5	2.6
D'Angelo et al. [31]	225	6.1	0.8	2.6
Mella-Sousa et al. [92]	417	5.8	1.1	2.8
Nilsdotter et al. [105]	198	10.1	0.3	2.8
Nilsdotter & Lohmander [104]	196	10.2	0.3	2.8
Ragab et al. [114]	97	10.5	0.4	2.9
Vendittoli et al. [139]	102	16.4	0.1	2.9
Schreiner et al. [121]	335	5.7	1.4	3.0
Bascarevic et al. [13]	157	11.0	0.4	3.0
Devane et al. [38]	139	11.3	0.4	3.1
Jacobs et al. [61]	171	11.4	0.4	3.2
Clohisy & Harris [27]	90	9.0	1.0	3.5
Herrera et al. [53]	232	7.3	1.4	3.5
Callaghan et al. [18]	327	5.1	2.5	3.6
Korovessis et al. [75]	350	8.7	1.5	4.0
Clohisy & Harris [26]	100	10.2	1.1	4.0
Tarasevicius et al. [130]	1597	4.9	3.2	4.0
Vendittoli et al. [138]	100	15.5	0.5	4.3
Castoldi et al. [23]	135	9.7	1.6	4.4
Saito et al. [119]	90	10.5	1.5	4.5
Saito et al. [120]	38	12.0	1.3	4.7
Firestone et al. [43]	149	10.8	1.8	5.0
Paleochorlidis et al. [109]	99	12.4	1.7	5.3
Long et al. [81]	161	12.5	2.1	5.7
Horne et al. [55]	104	12.6	2.1	5.8
Streit et al. [128]	354	8.1	4.1	5.8
Nagi et al. [96]	102	11.5	2.5	5.9
Neumann et al. [101]	94	13.2	2.2	6.1
Ollivere et al. [107]	234	9.8	3.8	6.2
Sinha et al. [123]	123	14.6	2.0	6.3
Fender et al. [42]	1080	9.0	4.5	6.5
Aldinger et al. [1]	321	9.6	4.2	6.5
Gollwitzer et al. [48]	76	17.1	1.8	6.7
Radcliffe et al. [113]	65	20.8	1.5	7.1
Sharma et al. [122]	209	12.8	3.6	7.2
Nercessian et al. [100]	52	18.8	2.0	7.3
Baker et al. [11]	69	15.2	3.3	7.7
Kim et al. [73]	219	11.2	5.4	7.9
Parvizi et al. [110]	90	14.7	4.1	8.2
Callaghan et al. [19]	138	12.1	5.6	8.4
Delaunay [35]	98	19.8	2.8	8.5
Archibeck et al. [7]	92	17.1	3.8	8.7
Beldame et al. [15]	106	19.3	3.2	8.8
Vassan et al. [137]	94	19.8	3.3	9.1
Descamps et al. [37]	117	20.3	3.4	9.3
Stulberg et al. [129]	266	21.9	3.1	9.4
Lazennec et al. [80]	134	17.4	5.1	10.0
Gaffey et al. [45]	120	15.8	5.9	10.0
Russell et al. [118]	127	18.2	5.7	10.7
Hulleberg et al. [57]	138	17.2	6.8	11.1
Mont et al. [94]	54	41.2	1.4	11.4
Pollard et al. [111]	51	30.1	3.2	11.8
Laupacis et al. [79]	250	18.8	7.3	12.1
Haraguchi et al. [51]	119	18.1	8.1	12.3
Haidukewych et al. [50]	21	71.7	0.3	12.9
Kim et al. [72]	116	21.0	7.6	13.1
Tompkins et al. [132]	173	21.3	8.6	14.0
Bjorgul et al. [17]	151	21.4	10.4	15.1
Baker et al. [12]	54	29.6	7.1	15.6
Nakamura et al. [97]	50	27.8	8.2	15.9
Almeida et al. [2]	75	27.9	8.3	16.0
Corten et al. [28]	238	20.7	13.1	16.6
de Kam et al. [34]	168	25.6	11.9	17.8
Dearborn & Murray [32]	86	31.2	9.2	17.9
Vigler et al. [141]	43	58.3	4.1	19.9
Cho et al. [25]	86	36.9	11.5	21.6
Sporer et al. [126]	45	42.7	9.4	21.7
Howie et al. [56]	13	79.3	5.6	27.1
Meldrum et al. [91]	125	37.3	21.1	28.3
Langdon & Bannister [78]	35	44.2	17.5	28.6
McLaughlin & Lee [90]	94	52.1	31.0	40.6
Illgen et al. [58]	163	88.5	17.3	42.9
McLaughlin & Lee [89]	114	75.6	46.3	59.6
Theis & Beadel [131]	12	301.0	10.1	83.3
Grouped revision rate		7.6	6.7	7.1

reoperations remained higher in metal-on-metal hip resurfacing devices (Table 2). The most common reasons reported for reoperation in metal-on-metal hip resurfacing were fracture (femoral neck, greater trochanter, subtrochanteric femur fracture), heterotopic ossification, and component mismatch. The most common reasons reported

Table 4. Revision rate per 1000 person-years for each THA study (currently in-use devices) with 95% confidence intervals

Study	Sample size (number)	Upper bound	Lower bound	Revision rate
Fowble et al. [44]	44	33.5	0.0	0.0
Nayak et al. [99]	226	4.1	0.0	0.0
Zywiel et al. [147]	33	29.8	0.0	0.0
Garcia-Cimbrelo et al. [46]	104	7.5	0.5	2.6
D'Angelo et al. [31]	225	6.1	0.8	2.6
Vendittoli et al. [139]	102	16.4	0.1	2.9
Bascarevic et al. [13]	157	11.0	0.4	3.0
Herrera et al. [53]	232	7.3	1.4	3.5
Korovessis et al. [75]	350	8.7	1.5	4.0
Vendittoli et al. [138]	100	15.5	0.5	4.3
Castoldi et al. [23]	135	9.7	1.6	4.4
Saito et al. [119]	90	10.5	1.5	4.5
Paleochorlidis et al. [109]	99	12.4	1.7	5.3
Neumann et al. [101]	94	13.2	2.2	6.1
Radcliffe et al. [113]	65	20.8	1.5	7.1
Nercessian et al. [100]	52	18.8	2.0	7.3
Baker et al. [11]	69	15.2	3.3	7.7
Delaunay [35]	98	19.8	2.8	8.5
Stulberg et al. [129]	266	21.9	3.1	9.4
Mont et al. [94]	54	41.2	1.4	11.4
Laupacis et al. [79]	250	18.8	7.3	12.1
Corten et al [28]	238	20.7	13.1	16.6
Vigler et al. [141]	43	58.3	4.1	19.9
Theis & Beadel [131]	12	301.0	10.1	83.3
Grouped revision rate		8.8	6.5	7.6

for reoperation for THAs were heterotopic ossification, osteolysis, excessive polyethylene wear, and infection.

Dislocations

Dislocations were more frequent for THA than metal-on-metal hip resurfacing devices for currently in-use devices (4.8; 95% CI, 3.5–6.5 versus 1.1, 95% CI, 0.8–1.6 per 1000 person-years; $p = 0.01$) and all devices (4.4; 95% CI, 4.2–4.6 versus 0.8, 95% CI, 0.6–1.2 per 1000 person-years; $p = 0.008$) (Table 2).

Other Adverse Events

For currently in-use devices, infections/sepsis per 1000 person-years were more frequent for THA (3.2 per 1000 person-years; 95% CI, 2.0–4.8) compared with metal-on-metal hip resurfacing (1.2 per 1000 person-years; 95% CI, 0.8–1.8; $p = 0.18$) (Table 2). When discontinued devices were

Table 5. Revision rate per 1000 person-years for each metal-on-metal hip resurfacing study (all devices) with 95% confidence intervals

Study	Sample size (n)	Upper bound	Lower bound	Revision rate
Ollivere et al. [108]	98	7.4	0.0	0.0
Xu et al. [144]	63	63.6	0.0	0.0
Yang et al. [145]	21	87.8	0.0	0.0
Zywiel et al. [147]	33	31.9	0.0	0.0
Back et al. [10]	230	8.1	0.0	1.4
McBryde et al. [87]	909	2.5	0.8	1.5
Hing et al. [54]	230	6.3	0.2	1.7
Amstutz et al. [3]	686	4.0	1.4	2.4
Aulakh et al. [8]	202	6.5	1.1	3.0
Treacy et al. [133]	144	12.2	0.9	4.2
Rahman et al. [115]	329	8.5	2.2	4.6
Carrothers et al. [21]	5000	5.9	4.4	5.1
Carrothers et al. [22]	106	13.6	1.4	5.3
Vendittoli et al. [140]	64	32.2	0.1	5.8
Vendittoli et al. [139]	103	21.1	0.7	5.8
Amstutz & Le Duff [5]	1000	8.2	4.1	5.9
Heilpern et al. [52]	110	15.8	1.7	6.2
Fowble et al. [44]	50	34.8	0.2	6.3
Treacy et al. [134]	144	11.7	3.1	6.4
McAndrew et al. [86]	179	18.8	1.3	6.4
Khan et al. [67]	679	10.2	4.8	7.1
Ollivere et al. [106]	463	13.3	4.2	7.8
Vendittoli et al. [138]	109	20.1	2.1	7.9
Amstutz et al. [4]	400	15.9	4.9	9.3
Pritchett [112]	561	11.0	7.8	9.3
Amstutz et al. [6]	100	16.8	4.7	9.4
Spencer et al. [125]	40	34.1	1.1	9.4
Marulanda et al. [85]	230	28.7	2.0	9.8
Witzleb et al. [142]	300	21.8	3.7	10.0
Baker et al. [12]	54	24.0	3.3	10.3
Madhu et al. [84]	110	20.5	4.5	10.4
Mont et al. [94]	54	41.2	1.4	11.4
Pollard et al. [111]	63	32.0	3.4	12.5
Jameson et al. [63]	231	28.4	6.2	14.4
Kim et al. [68]	97	45.2	3.2	15.5
McGrath et al. [88]	165	34.5	8.3	18.2
Bergeron et al. [16]	209	37.7	8.3	19.1
Jameson et al. [62]	214	35.3	12.9	22.1
Isaac et al. [60]	77	66.5	7.1	26.0
Kim et al. [69]	200	45.2	14.7	26.9
Gross & Liu [49]	19	72.8	7.8	28.4
Della Valle et al. [36]	537	50.3	16.4	30.0
Falez et al. [41]	60	72.8	10.1	31.2
Stulberg et al. [129]	337	53.0	22.8	35.6
Beaulé et al. [14]	42	64.3	20.9	38.3
Costi et al. [29]	268	53.3	40.2	46.4

Table 5. continued

Study	Sample size (n)	Upper bound	Lower bound	Revision rate
Cutts et al. [30]	65	85.0	27.7	50.7
Meldrum et al. [91]	141	64.1	44.5	53.6
Duijsens et al. [40]	114	76.4	45.5	59.5
Ritter et al. [117]	65	89.2	46.4	65.2
Howie et al. [56]	11	168.6	36.9	85.6
Yue et al. [146]	75	137.9	83.2	108.0
Grouped revision rate		11.3	10.1	10.7

removed from the analysis, infections/sepsis remained higher in THA devices (Table 2).

For all devices, femoral neck fractures were more frequent for THA devices (2.9 per 1000 person-years; 95% CI, 1.6–4.8) compared with metal-on-metal hip resurfacing (2.0 per 1000 person-years; 95% CI, 1.6–2.6; p = 0.654) (Table 2). For currently in-use devices, femoral neck fractures were more frequent for metal-on-metal hip resurfacing devices compared with THA (Table 2). Although femoral neck fractures are extremely rare with THA devices, they still were reported in studies (N = 2 for currently in-use THA devices and N = 7 for all THA devices) as adverse events.

There was a lack of comparable data to analyze other femoral fractures and mortality (all-cause, 30-day).

Rates of Postoperative Component Alignment

We were unable to draw conclusions for postoperative component alignment owing to limited comparable data in both market status groups.

Discussion

In the United States, nearly 203,000 primary hip surgeries were performed in 2003 and this figure is projected to increase to more than 500,000 surgeries annually by 2030, and consequently the number of revisions will increase [76]. The majority of individuals who require primary hip replacement undergo THA [9, 47, 98, 102]. Metal-on-metal hip resurfacing is used less often, targeted toward younger, more active patients as an alternative to THA, but remains controversial [65, 124, 127, 136, 143]. We believe there is limited evidence thus far in the literature that compares adverse events across studies of metal-on-metal hip resurfacing and THA using a standardized metric. Without standardized metrics, it is not possible to make valid comparisons that account for differences in study sample sizes and followup times, which can have a substantial effect on the results. In this review, we used the standardized metric, per 1000 person-years, to address gaps not previously addressed in the literature to compare outcomes between THA studies that had longer-term followups with metal-on-metal hip resurfacing studies with limited followup. We aimed to determine rates of (1) early revision or reoperation (within 5 years of surgery) and overall revisions; (2) revisions reported in four major joint

Table 6. Revision rate per 1000 person-years for each metal-on-metal hip resurfacing study (currently in-use devices) with 95% confidence intervals

Study	Sample size (n)	Upper bound	Lower bound	Revision rate
Ollivere et al. [108]	98	7.4	0.0	0.0
Yang et al. [145]	21	87.8	0.0	0.0
Zywiel et al. [147]	33	31.9	0.0	0.0
Back et al. [10]	230	8.1	0.0	1.4
McBryde et al. [87]	909	2.5	0.8	1.5
Hing et al. [54]	230	6.3	0.2	1.7
Amstutz et al. [3]	686	4.0	1.4	2.4
Aulakh et al. [8]	202	6.5	1.1	3.0
Treacy et al. [133]	144	12.2	0.9	4.2
Rahman et al. [115]	329	8.5	2.2	4.6
Carrothers et al. [21]	5000	5.9	4.4	5.1
Carrothers et al. [22]	106	13.6	1.4	5.3
Vendittoli et al. [140]	64	32.2	0.1	5.8
Vendittoli et al. [139]	103	21.1	0.7	5.8
Amstutz & Le Duff [5]	1000	8.2	4.1	5.9
Heilpern et al. [52]	110	15.8	1.7	6.2
Fowble et al. [44]	50	34.8	0.2	6.3
Treacy et al. [134]	144	11.7	3.1	6.4
McAndrew et al. [86]	179	18.8	1.3	6.4
Khan et al. [67]	679	10.2	4.8	7.1
Ollivere et al. [106]	463	13.3	4.2	7.8
Vendittoli et al. [138]	109	20.1	2.1	7.9
Amstutz et al. [4]	400	15.9	4.9	9.3
Amstutz et al. [6]	100	16.8	4.7	9.4
Spencer et al. [125]	40	34.1	1.1	9.4
Marulanda et al. [85]	230	28.7	2.0	9.8
Witzleb et al. [142]	300	21.8	3.7	10.0
Madhu et al. [84]	110	20.5	4.5	10.4
Mont et al. [94]	54	41.2	1.4	11.4
Kim et al. [68]	97	45.2	3.2	15.5
McGrath et al. [88]	165	34.5	8.3	18.2
Kim et al. [69]	200	45.2	14.7	26.9
Gross & Liu [49]	19	72.8	7.8	28.4
Della Valle et al. [36]	537	50.3	16.4	30.0
Stulberg et al. [129]	337	53.0	22.8	35.6
Cutts et al. [30]	65	85.0	27.7	50.7
Grouped revision rate		6.2	5.2	5.7

Table 7. Revisions per 1000 person-years

Procedure	National Joint Replacement Registry	Number of revisions during registry period	Time (years)	Revisions (per 1000 person years)	95% CI	p value (THA vs metal-on-metal hip resurfacing)	Current study revisions (per 1000 person-years; all devices)	95% CI	p value (THA vs metal-on-metal hip resurfacing)
THA									
	AOANJRR	6321	10	3.2	3.1–3.3				
	NZNJR	2278	12	2.7	2.6–2.8				
	SHAR	27,134	31	2.64	2.61–2.7				
	NJREW	6104	827,276 observed years	7.4	7.2–7.6				
	Grouped			3.01	2.98–3.03	0.350	7.1	6.7–7.6	0.068
Metal-on-metal hip resurfacing									
	AOANJRR	660	10	4.6	4.3–5.0				
	NZNJR	32	12	2.4	1.7–3.4				
	SHAR	72	10	4.1	3.2–5.1				
	NJREW	867	61,170 observed years	14.2	13.2–15.1				
	Grouped			6.9	6.6–7.3	0.350	10.7	10.1–11.3	0.068

AOANJRR = Australian Orthopaedic Association National Joint Replacement Registry; NZNJR = New Zealand National Joint Registry; SHAR = Swedish Hip Arthroplasty Register; NJREW = National Joint Registry for England and Wales.

replacement registries; (3) adverse events; and (4) postoperative component malalignment using standardized metrics and stratifying results by device market status.

The literature on joint arthroplasty is challenging because definitions of outcomes are not consistent (eg, revisions versus reoperations). Additionally, metrics are not standardized or comparable (eg, studies have varying followup periods). We were able to draw comparisons between heterogeneous studies by reporting averages per 1000 person-years. This is unique in the arthroplasty literature. Other limitations include underreporting of prosthesis type, some studies were not able to be grouped into market status categories and therefore were excluded from our analysis, and exclusion of non-English literature.

Furthermore, studies did not report outcomes consistently (eg, number of hips operated on versus number of patients). We standardized adverse event rates to the extent possible by using the number of participants in the study population and, if this was not available, the number of hips. Patients who receive metal-on-metal hip resurfacing devices tend to be male, younger, and more active compared with those who receive THA devices. Finally, when analyzing data from the literature, the inclusion of discontinued devices can dramatically skew findings. To date, it has not been common practice to analyze outcomes of medical devices according to market status. Our findings suggest that this type of analysis is important for continued implementation of medical devices or adoption of new devices. For example, we noted higher revision rates for all metal-on-metal hip resurfacing devices compared with currently in-use devices, which may reflect the inclusion of devices that have been discontinued. By removing discontinued metal-on-metal hip resurfacing devices, the average revisions per 1000 person-years was lower.

Revisions are more frequent (all devices market status group) and occur much earlier for all metal-on-metal hip resurfacing devices (in-use and discontinued market status groups). The average time to revision would be considered poor for metal-on-metal hip resurfacing and THA devices which supports the ongoing need for long-term followup studies on clinical outcomes. Four of five metal-on-metal hip resurfacing systematic reviews published since 2006 noted promising revision rates and pain relief [65, 124, 127, 136, 143]. Time to revision (in years) has not been reported in other reviews comparing metal-on-metal hip resurfacing with THA [65, 124, 127, 136]. According to data from the Canadian Joint Replacement Registry [20, 83], 88% of patients who received metal-on-metal hip resurfacing were younger than 65 years. Smith et al. [124] determined it is unclear how patient age might influence the incidence of adverse events when comparing THA and metal-on-metal hip resurfacing devices.

Lower revision rates noted among most registries, in comparison to our review, may reflect the larger sample size and higher participation rates in registry data. The International Society of Arthroplasty Registries requires national registries to have greater than 90% of procedures reported to obtain a full membership [59]. Additionally, registries may define revisions differently than clinical studies and lack study protocols with controlled followup.

As anticipated as a result of the ball and socket design of THA devices, dislocation rates were higher than metal-on-metal hip resurfacing for both market status groups. This is consistent with other reviews of this literature [65, 124, 127, 136]. The number of femoral neck fractures was greater for metal-on-metal hip resurfacing devices (currently in-use devices) and these findings are consistent with the literature [65, 127].

Postoperative component alignment was not commonly reported in the literature, and thus no comparisons could be made. This finding is important because, even with the large number of studies included in our analysis, we still were unable to draw any conclusions regarding postoperative component malalignment in both market status groups. Methods of measuring component alignment are not standardized, further complicating comparisons across studies. Further studies assessing component alignment are needed in this area of research since the clinical evidence of poor alignment as a predictor of device failure has been highlighted in the literature [33].

The strengths of our study were threefold. First, we used averages per 1000 person-years to standardize findings and make valid comparisons. Second, we examined a large body of evidence, and third, we analyzed results by market status. The findings from our systematic review show that revisions and reoperations are more frequent and occur much earlier for metal-on-metal hip resurfacing, except when discontinued devices are removed from the analyses. Dislocations are more frequent with THA, even after removing discontinued devices from the analyses. We found that outcome definitions were reported inconsistently in the studies we identified, and that those studies rarely differentiated their findings regarding adverse events according to the market status of the device(s) in question. These deficiencies can result in clinicians drawing misleading conclusions and misinforming patients. We tried to mitigate the risk of this by using specific design elements in this study, including stratification by market status and standardization of event frequencies per 1000 person-years. Standardized comparative outcomes for metal-on-metal hip resurfacing and THA should be considered when selecting which device is most appropriate for individual patients.

Acknowledgments We thank Denis Ako-Arrey DAA; MHA, MPH (McMaster University, Hamilton, Ontario, Canada), and Monica Cepoiu-Martin MCM; MD (University of Calgary, Calgary, Alberta, Canada) for their work reviewing abstracts and full-text articles for this systematic review. We also thank Gavin Steininger BSc, MASc, PhD (University of Victoria, Victoria, British Columbia, Canada) for biostatistics expertise and assistance.

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