The Infection Rate of Metal-on-Metal Total Hip Replacement Is Higher When Compared to Other Bearing Surfaces as Documented by the Australian Orthopaedic Association National Joint Replacement Registry

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Abstract *Background:* Despite the well-documented decline in the use of metal-on-metal (MoM) implants over the last decade, there are still controversies regarding whether all MoM implants are created equally. Complications such as elevated serum metal ion levels, aseptic lymphocyte-dominated vasculitis-associated lesion (ALVAL) and pseudotumours have all been well documented, but recent studies suggest increased risk of infection with MoM bearing surfaces. Most of these studies however have small patient numbers. *Questions/Purposes:* The purpose of this study was to examine the cumulative incidence of revision for infection of MoM bearing surfaces in primary hip arthroplasty at a national and single-surgeon level. *Methods:* Data was collected from the Australian Orthopaedic Association National Joint Replacement Registry, which contains over 98% of all arthroplasties performed in Australia since 2001. The cumulative incidence of revision for infection was extracted at a national level and single-surgeon level. *Results:* Two hundred

seventy-six thousand eight hundred seventy-eight subjects were documented in the Australian registry. The 10-year cumulative percent revision for infection of MoM bearing surfaces in primary total hip replacement (THR) was 2.5% at a national level, compared to 0.8% for other bearing surfaces. The senior author contributed 1755 subjects with 7-year follow-up and a cumulative percent revision for infection of MoM bearing surfaces in primary THR of 36.9%, compared to 2.0% for other bearing surfaces. The cumulative percent of revision of MoM bearing surfaces is higher compared to other bearing surfaces; this is especially pronounced in cumulative percent of revision for infection. *Conclusion:* There was a higher cumulative percent of revision for infection in MoM bearings surfaces (in particular, large-head MoM) compared to other bearing surfaces at both the national and individual-surgeon level.

Keywords metal on metal · infection risk · Australian Orthopaedic Association National Joint Replacement Registry · increased risk of revision surgery · large-head metal on metal

Level of Evidence: Therapeutic Study: Level III

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Introduction

Use of metal-on-metal (MoM) implants has dramatically declined in recent years due to the complications and failures that are well documented in the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) [9]. At the start of the 21st century, MoM bearing surfaces were widely used due to expectations of lower bearing surface wear with predictions of lower need for revision, especially for young active patients [10]. However, issues relating to elevated serum metal ion levels, aseptic lymphocyte-dominated vasculitis-associated lesion (ALVAL), and pseudotumour formation have essentially reduced the use of MoM bearing surfaces in Australia from over

Table 1 National data on revision per 100 observation years for large-head MoM (> 32 mm) compared to the other bearing surfaces

Bearing surface	N, revised	N, total	Obs. years	Revisions/100 obs. years (95% CI)
Large-head metal/metal	266	14,420	95,085	0.28 (0.25, 0.32)
Other bearing surface	1545	262,458	1,391,536	0.11 (0.11, 0.12)
Total	1811	276,878	1,486,621	0.12 (0.12, 0.13)

Fig. 1. Frequency of MoM hip arthroplasties performed annually in Australia (reproduced with permission of Australian Orthopaedic Association National Joint Replacement Registry)**Table 2** National registry data on revision diagnosis for MoM total hip replacements

Revision diagnosis	Metal on metal		
	Number	% Primaries revised	% Revision
Metal-related pathology	1284	5.8	41.2
Loosening/lysis	849	3.8	27.3
<i>Infection</i>	<i>341</i>	<i>1.5</i>	<i>10.9</i>
Prosthesis dislocation	177	0.8	5.7
Fracture	169	0.8	5.4
Pain	188	0.8	3.8
Leg length discrepancy	20	0.5	0.6
Implant breakage stem	17	0.1	0.5
Incorrect sizing	16	0.1	0.5
Implant breakage acetabular	15	0.1	0.5
Wear acetabulum	15	0.1	0.5
Malposition	14	0.1	0.4
Tumour	7	0.0	0.2
Instability	6	0.0	0.2
Synovitis	4	0.0	0.1
Wear acetabular insert	4	0.0	0.1
Implant breakage acetabular insert	3	0.0	0.1
Osteonecrosis	2	0.0	0.1
Heterotopic bone	1	0.0	0.0
Other	53	0.2	1.7
N, revision	3115	14.1	100
N, primary	22,088		

The italicised section relates to infection rates on our registry for all metal on metal replacements.

3000 annually at its peak to around 50 in the last few years [9]. Much of this failure was attributed to the articular surface replacement [7] (ASR; DePuy, Warsaw, IN, USA), a prosthesis now withdrawn from the market. Advocates who still use MoM argue that metallurgy, design, alignment, and fixation methods were the reasons why the ASR failed and that the MoM bearing surface still plays an important role in primary hip arthroplasty [8].

Recent research has suggested that all MoM bearing surfaces have a higher risk of developing infection compared to other bearing surfaces [5, 6, 11, 12], but the number of patients in these studies are small. A study performed by Bozic and his colleagues had adequate power, but the findings were limited by the use of an administrative database where modifier codes for bearing surface and other data were optional [2]. It has been postulated that the combination of metal debris, ALVAL, pseudotumour formation, and necrotic tissue provides a unique environment for bacterial proliferation in MoM implants [5].

The aim of this study was to use the resources of the AOANJRR to examine the incidence of revision for infection in MoM bearing surfaces with comparison to all other bearing surfaces following primary hip arthroplasty performed between 2000 and 2014 for the entire nation as well as in the experience of an individual surgeon.

Patients and Methods

Data was obtained from the AOANJRR for the period 2000–2014 that included the nationally collected data as well as the

Table 3 Single surgeon data on observation years for large head MoM (> 32 mm) compared to the other bearing surface

Bearing surface	Number	Revisions	Infection	% of revision	Infection rate (%)
Large-head metal on metal	91	33	5	15.2	5.5
Other bearing surface	1664	20	3	15	0.18
<i>N</i> , primary	1755	53	8	15.1	0.46

specific data for the senior author's practice (MO). Inclusion criteria were primary total hip arthroplasty between 2000 and 2014. Resurfacing procedures were not included. Data obtained included the total number of cases performed, subsequent revisions, reasons for revision, and bearing surface material.

Data that are collected on the AOANJRR are validated through a sequential multi-level matching process against health department record data [1] and successfully tracks over 98% of all joint replacements performed in Australia [1]. Outcomes are based on time to first revision using the Kaplan-Meier survivorship function at that time multiplied by 100. Hazard ratios (HR) from Cox proportional hazard models, adjusting for age and gender, were used to compare the rate of revision between groups. All tests are two tailed at the 5% level of significance. The AOANJRR data identifies revision for infection through a standardized form that is completed at the time of the revision. The reason for revision is entered by the surgeon, but clinical correlation with cultures or haematological markers is not required.

For the patients of the senior author, all surgeries were undertaken at the Mater Hospital, Sydney, Australia, with a posterior approach using a standardized peri-operative protocol involving 4 doses of prophylactic IV cefazolin 1 g starting at the time of induction of anaesthesia. Conditions such as space suits and laminar flow were used in every case. The MoM implant used during this period was ASR/Corail (DePuy, Warsaw, IN, USA). The Pinnacle/Corail (DePuy, Warsaw, IN, USA) with a ceramic-on-ceramic articulation was used for the remaining cases. In the single surgeon data series, subjects who underwent revision for infection after MoM procedure were cross referenced with medical records to confirm the diagnosis.

Results

As of 31st of December 2015, the number of primary total hip replacements performed since 1999 was 363,561 in Australia [1]. Included in the current analysis on a national level were

Fig. 2. Cumulative percent revision for infection of large-head MoM vs other bearing surface from national registry (reproduced with permission of Australian Orthopaedic Association National Joint Replacement Registry)

Fig. 3. Cumulative percent revision for infection of large-head MoM vs other bearing surface for the senior surgeon (reproduced with permission of Australian Orthopaedic Association National Joint Replacement Registry)

276,878 subjects who underwent total hip arthroplasty for osteoarthritis. Of these, 14,420 received a large-head MoM and 262,458 received another bearing surface (Table 1). The use of large-head MoM bearings ceased in 2014. A total of 22,088 MoM implants had been implanted during this period with the peak occurring between 2006 and 2008. Essentially, 3000 primary MoM total hips were implanted each year. This has dramatically fallen to 55 implanted in 2013 and 59 in 2014 (Fig. 1). The cumulative percent revision of these implants is still rising but at a significantly slower rate [9]. At 14 years, the cumulative percent revision for all MoM implants is 19.8% [5]. Nationally, a total of 3115 revisions were performed on MoM bearing surfaces. Of these, the top 3 reasons for revision were metal-related pathology (41.2%), loosening/lysis (27.3%), and infection (10.9%) (Table 2). National data documents that 341 MoM implants were revised due to infection and 266 of these were large-head MoM (76%). Revision hip replacement for infection at our single hospital made up 5.9% of all revisions performed and equated to a revision for infection rate of 0.3%, compared to a national average of 0.68%.

The senior author has performed 1755 primary hip replacements over the same period of 14 years. Out of this group 91 were large-head MoM. Thirty-three or 15.2% of these patients required revision of which 5 had confirmed infection and organism. This equated to an infection rate of 5.5%. When we review the other bearing surfaces, only 20

or 1.5% of total hip replacement (THR) required revision of which 3 (0.18%) were confirmed infections (Table 3).

For national data as a whole, the 10-year cumulative percent revision for infection of MoM bearing surfaces in primary THR was 2.5% compared to 0.8% for other bearing surfaces (hazard ratio 4.5, 95% CI 3.8–5.3, $p < 0.001$) (Fig. 2). The data regarding the senior author's experience documents that the 7-year cumulative percent revision for MoM bearing surfaces in primary THR was 36.9%, compared to 2.0% for other bearing surfaces (hazard ratio 17.08, 95% CI 8.5–34.5, $p < 0.001$) (Fig. 3). At the national level, the cumulative percent revision is significantly higher in MoM bearing surfaces compared to that in other bearings for revisions in general (Fig. 4a) and revisions specifically for infection (Fig. 4b). In Fig. 4b, it can be seen that there is a significant divergence of the curve for MoM bearing surfaces after 3 to 4 years. The findings were similar to the senior surgeon's dataset (Fig. 5).

Discussion

The purpose of this study was to examine the rate of revision of MoM THRs in comparison to all other bearing surfaces with particular interest in the rate of revision for infection. The cumulative percentage of revision for infection in MoM bearing surfaces in hip arthroplasty was significantly higher

Fig. 4. Cumulative percent of revision for any cause (a) and revision for infection (b) of hip arthroplasty based on bearing surface (reproduced with permission of Australian Orthopaedic Association National Joint Replacement Registry)

than that in other bearing surfaces at both the national and single-surgeon level. At the national level, revision for infection was increased by a factor of 4.5 times compared to other bearing surface. This was even more pronounced in the single-surgeon series where that hazard of revision for infection was increased by a factor of 17 times, compared to other bearing surfaces.

Interpretation of the results is difficult on a national level as there are so many different variables to consider which

are not recorded. By analyzing the data at an individual level, we can control constants such as technique, approach, implant choice and post-operative care as well as confirming the organisms responsible for infection.

The AOANJRR published a supplementary report in 2015 examining the reason for the higher incidence of infection in MoM bearings [9]. It highlighted a key problem with the registry in identifying infections. They concluded that a majority of forms completed in theatres had no

Fig. 5. Cumulative percent of revision comparing large-head MoM and other bearing surfaces (where osteoarthritis was initial diagnosis) for the senior surgeon (reproduced with permission of Australian Orthopaedic Association National Joint Replacement Registry)

confirmed organism and often, the diagnosis criteria for infection was not documented [9].

Infections in arthroplasty which present late typically result from haematogenous spread. Therefore, specific implants or bearing surfaces that increase the risk of infection are far more difficult to detect in the national registry compared to an “outlier” implant which has an early failure rate [4]. By using the individual surgeon series, we can confirm with confidence the diagnosis of infection by isolating an organism. Unfortunately, the same level of confidence cannot be applied to the national data.

There are still important variables outstanding when it comes to patient demographics in the registry. Medications, alcohol use, diabetes, peripheral vascular disease, body mass index, and nutrition are just some of the important variables which have been implicated in increasing the infection rate of all arthroplasty surgery [3]. Therefore, the data that is presented here should be treated with caution with the focus on trends rather than absolute figures. Despite this, there is still a clear trend that large-head MoM bearing surfaces have a higher rate of infection particularly in the first 2 years after surgery. This correlates closely with the data collected from the senior surgeon where the average time to presentation for infection was 13.4 months. In addition, one of the major limitations of interpreting the single-surgeon data is the relatively small number of subjects who received a MoM bearing prosthesis ($n = 91$). Despite this, there is clear evidence of the increased rate of infection with the MoM prosthesis.

Metal-on-metal articulations appear to have a greater rate of revision for infection which is evident in the AOANJRR, as well as a large single-surgeon case series. The reasons for this trend have yet to be determined.

Compliance with Ethical Standards

Conflict of Interest: Phil Huang, BEng, MBBS, M-Phil CANTAB; Matt Lyons, MBBS, FRACS, FAOrthA; and Michael O’Sullivan,

MBBS, FRACS, FAOrthA, have declared that they have no conflict of interest.

Human/Animal Rights: The study was approved by the Commonwealth of Australia as a Declaration of Quality Assurance Activity under section 124X of the Health Insurance Act, 1973. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2013.

Informed Consent: N/A

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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