Chapter 3
Outcome Studies for Metal-on-Metal Bearings: What Evidence-Based Medicine Tells Us

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Introduction

Metal-on-metal (MoM) total hip arthroplasty (THA) has a long record of use in the orthopedic community beginning with the McKee–Farrar [1] and Ring [2, 3] metal bearing designs. These articulations provide the theoretical benefit of less linear wear, large-diameter femoral heads, and increased stability [4, 5]. Some early studies [6, 7] demonstrated similar implant survivorship, with a 20-year implant survivorship of Charnley stems using cemented polyethylene acetabular cups being 73 % compared to 77 % for the McKee–Farrar prosthesis (Table 3.1). However, the desire to further reduce wear compared to polyethylene and improve stability led to an impetus to design second-generation MoM components in the late 1990s.

MoM bearings became increasing popular in the early 2000s, and were seen as a potentially ideal bearing option for the young, active patient who was more likely to place increased demand on their joint [8, 9]. Concerns with dislocation, wear, aseptic loosening, and osteolysis with early-generation MoP bearings led some surgeons to seek alternative bearing surfaces in patients whose life expectancy was likely to be longer than the expected longevity of the MoP bearing couple [10]. However, clinical results demonstrated higher revision rates, concerns with higher frictional coefficients and torque, and metal hypersensitivity, which have tempered their use. An overview of these results can be seen in Tables 3.2, 3.3 and 3.4. Overall, the mean implant survivorship at less than mean 5-year follow-up, based on the current literature, is 95 %. This is in line with recent national joint registry data from the United Kingdom and Australia which demonstrate similar revision rates [11–13].

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Table 3.1 Results: First-generation MoM THA

Study	Device	Number of patients (Hips)	Age (Years)	Mean follow-up (Years)	Osteolysis (%)	Revisions (%)	Survival (%)
McKee and Farrar (JBJS Br, 1966)	McKee–Farrar	50 (50)	–	3.0	–	4	96
Dandy et al. (JBJS Br, 1975)	McKee–Farrar	– (739)	–	5.0	–	7	93
August et al. (JBJS Br,1986)	McKee–Farrar	808 (808)	62	20.0	–	8	92
Higuchi et al. (Arch Orthop Trauma Surg, 1997	McKee–Farrar	38 (38)	57	11.3	–	29	71
Gerritsma-Bleeker et al. (JBJS Br, 2000)	Stanmore	135 (146)	70	22.0	–	15	85
Brown et al. (CORR, 2002)	McKee–Farrar	101 (123)	61	28.0	–	26	74
Total		*1,871* (*1,904*)	*62*	*14.9*	–	*15*	*85*

Table 3.2 Results: Second-generation MoM THA (Metasul^{TM}; < 10 years)

Study	Device	Number of patients (Hips)	Age (Years)	Mean follow-up (Years)	Osteolysis (%)	Revisions (%)	Survival (%)
Weber et al. (CORR, 1996)	Metasul	110 (110)	59	3.5	–	5	96
Wagner et al. (CORR, 1996)	Metasul	70 (70)	50	2.8	0	0	100
Hilton et al. (CORR, 1996)	Metasul	74 (74)	71	2.2	0	1	99
Randle and Gordiev (Aust NZ JS, 1997)	Metasul	57 (57)	63	– (0.4–2.6)	0	0	100
Dorr et al. (JBJS Am, 2000)	Metasul	56 (56)	70	5.2	0	5	95
Wagner and Wagner (CORR, 2000)	Metasul	78 (78)	49	5.0	0	4	96
Lombardi et al. (J Arthroplasty, 2001)	Metasul	78 (78)	49	3.3	0	0	100
MacDonald et al. (CORR, 2003)	Metasul	22 (22)	–	3.2	0	0	100
Brodner et al. (CORR, 2003)	Metasul	50 (50)	58	5.0	2	0	100
Delaunay (J Arthroplasty, 2004)	Metasul	89 (98)	60	6.0	1	5	95
Kim et al. (JBJS Am, 2004)	Metasul	62 (70)	37	7.0	3	4	96
Long et al. (J Arthroplasty, 2004)	Metasul	154 (161)	56	6.5	0	4	96
Migaud et al. (J Arthroplasty, 2004)	Metasul	30 (39)	40	5.7	0	0	100
Saito et al. (J Arthroplasty, 2006)	Metasul	90 (106)	58	6.4	0	1	99
Sharma et al. (Hip Int, 2007)	Metasul	– (209)	–	7.3	–	1	99
Dastane et al. (CORR, 2008)	Metasul	80 (82)	52	5.5	0	1	99
Delaunay et al. (CORR, 2008)	Metasul	73 (83)	41	7.3	0	2	98
Carr and DeSteiger (Aust NZ JS, 2008)	Metasul	125 (125)	–	– (3–9)	2	2	98
Berton et al. (JBJS Br, 2010)	Metasul	92 (100)	50	4.8	–	8	92
Long et al. (CORR, 2010)	Metasul	181 (207)	59	1.6	0	15	85
Girard et al. (JBJS Am, 2010)	Metasul	44 (47)	25	9.0	11	4	96
Vigler et al. (Bull NYUHJD, 2010)	Metasul	39 (43)	57	3.5	0	5	95
Nikolau et al. (Bull NYUHJD, 2011)	Metasul	166 (193)	50	7.0	0	7	93
Total		*1,820 (2,158)*	*53*	*5.1*	*1*	*3*	*97*

Table 3.3 Results: Second-generation MoM THA (all other implants; <10 years)

Study	Device	Number of patients (Hips)	Age (Years)	Mean follow-up (Years)	Osteolysis (%)	Revisions (%)	Survival (%)
Lombardi et al. (J Arthroplasty, 2001)	M^2a-Taper	78 (78)	49	3.3	0	0	100
MacDonald et al. (CORR, 2003)	M^2a-Taper	23 (23)	– (40–75)	3.2	0	0	100
Lombardi et al. (J Arthroplasty, 2004)	M^2a-Taper	53 (53)	50	5.7	0	0	100
Cuckler et al., (J Arthroplasty, 2004)	M^2a-Taper	78 (78)	–	5.3	–	–	–
	M^2a-38	555 (616)	–	1.1	–	–	–
Jacobs et al. (J Arthroplasty, 2004)	Ultima	95 (96)	53	3.9	0	1	99
Park et al. (JBJS Am, 2005)	Ultamet	167 (171)	55	2.3	6	1	99
Smith et al. (CORR, 2005)	M^2a-38	327 (377)	56	0.3	0	0	100
Korovessis et al. (JBJS Am, 2006)	Sikomet	194 (217)	55	6.4	6	7	94
Milosev et al. (JBJS Am, 2006)	Sikomet	591 (640)	57	7.1	3	10	100
Vassan et al. (Acta Orth, 2007)	Fitmore	94 (112)	56	7.0	0	3	94
Peters et al. (J Arthroplasty, 2008)	M^2a-Taper	160 (160)	63	4.3	0	–	–
	M^2a-38	136 (136)	56	4.3	0	–	–
	Magnum	469 (469)	54	3.0	0	–	–
Stuchin et al. (JBJS Am, 2008)	Birmingham	34 (40)	57	1.0	0	0	100
Zijlstra et al. (Orthopedics, 2009)	M^2a-Taper	102 (102)	72	5.6	–	3	97
Parmaksizoglu et al. (Hip Int, 2009) [Crowe IV DDH]	Magnum	13 (15)	46	4.1	0	7	93
Paleochorlidis et al. (Hip Int, 2009)	Sikomet	84 (99)	63	9.5	7	5	95
Engh Jr et al. (CORR, 2010)	Ultamet	126 (131)	53	5.6	2	2	98
	Ultamet	126 (131)	–	–	–	1	99
Long et al. (CORR, 2010)	Durom	181 (207)	61	1.0	0	15	85
Berton et al. (JBJS Br, 2010)	Durom	92 (100)	50	3.6	0	7	93

Table 3.3 (continued)

Study	Device	Number of patients (Hips)	Age (Years)	Mean follow-up (Years)	Osteolysis (%)	Revisions (%)	Survival (%)
Cicek et al. (Acta Belg, 2010)	Cormet	54 (59)	54	4.1	0	2	98
Donell et al. (JBJS Br, 2010)	Ultima	545 (652)	57	5.0	–	14	86
Mertl et al. (OTRS, 2010)	Durom	102 (106)	66	2.5	0	0	100
Langton et al. (J Arthroplasty, 2010)	ASR	87 (87)	67	3.4	–	6	94
Langton et al. (J Arthroplasty, 2011)	ASR	87 (87)	67	6.0	–	49	51
Bolland et al. (JBJS Br, 2011)	Birmingham & Adept	185 (199)	58	5.2	12	9	92
Latteier et al. (J Arthroplasty, 2011)	M^{2}a-Taper	300 (352)	57	5.0	–	4	96
	M^{2}a-38	577 (750)	57	5.0	–	7	93
	Magnum	335 (487)	57	5.0	–	4	96
Molli et al. (J Arthroplasty, 2011)	M^{2}a-Taper	304 (351)	56	6.0	–	3	97
	M^{2}a-38	660 (750)	58	3.9	–	5	95
	Magnum	443 (488)	58	2.6	–	3	98
Yalcin et al. (Hip Int, 2011) [Crowe I&II DDH]	Cormet	65 (75)	47	5.2	0	0	100
Total		*7,522 (8,494)*	*57*	*4.3*	*2*	*5*	*95*
Total all second-gen. implant types		*9,342 (10,652)*	*55*	*4.6*	*1*	*4*	*96*

Table 3.4 Results: Second-generation MoM THA (>10 years)

Study	Device	Number of patients (Hips)	Age (Years)	Mean follow-up (Years)	Osteolysis (%)	Revisions (%)	Survival (%)
Metasul Implant							
Grubl et al. (JOR, 2007)	Metasul	98 (106)	56	10.0	4	1	99
Eswaramoorthy et al. (JBJS Br, 2008)	Metasul	100 (104)	61	10.8	0	6	94
Park et al. (J Orth Surg, 2010)	Metasul	37 (39)	55	10.2	18	18	82
Saito et al. (Orthopedics, 2010)	Metasul	77 (90)	56	12.3	0	6	94
Dastane et al. (J Arthroplasty, 2011)	Metasul	124 (127)	64	13.0	13	9	91
Hwang et al. (J Arthroplasty, 2011)	Metasul	70 (78)	40	12.4	4	1	99
Randelli et al. (J Arthroplasty, 2011)	Metasul	111 (149)	50	13.0	0	5	95
All other implants							
Milosev et al. (JBJS Am, 2006)	Sikomet	591 (641)	57	10.0	3	8	92
Neumann et al. (J Arthroplasty, 2009)	Lubrimet	100 (100)	56	10.5	3 cup 4 stem	6	94
JIS Experience	M^2a-Taper	98 (98)	55.8	11	–	10	90
Total		*1,406* (*1,532*)	*55*	*11.7*	*5*	*6*	*94*

While all these potential complications with MoM THAs warrant concern and further evaluation, a large proportion of reports of adverse effects have been single-patient case reports or level IV studies, which may have been susceptible to selection bias [14–16]. Recently several meta-analysis and results for national arthroplasty registries have increased the awareness of the outcomes and potential complications with MoM THA [11–13, 17]. In this chapter we will provide an overview of recently reported survivorship for this bearing option divided into (1) outcomes from the literature and (2) outcomes from national joint registries.

Current Concepts with Metal-on-Metal Bearings

One of the major concerns with metal bearings is the development of local tissue reactions to metal ion debris which has been termed adverse local tissue reaction (ALTR) or adverse reaction to metal debris (ARMD) [18]. These are broad terms that encompass a host of related, but histologically distinct, findings seen at revision surgery which includes metallosis, cystic or solid masses ("pseudotumors"), and aseptic lymphocyte-dominated vasculitis-associated lesions (ALVALs) [19–22]. Although a direct correlation with elevated cobalt and chromium ion levels and ALTR has not been established, both the Hip Society [23] in the United States and the Medical and Healthcare Products Regulatory Agency (MHRA) [24] in the United Kingdom have established 7 parts per billion (ppb) as a cutoff safe level for serum cobalt and chromium ions. However, the United States Food and Drug Administration (FDA) has raised concern about the methodology that was utilized to arrive at this cutoff and has stressed that it may be inherently arbitrary in nature due to the lack of high-level studies on this topic. At this time the FDA has made no recommendation regarding what it considers to be safe serum levels for cobalt and chromium ions [25].

Adverse local tissue reactions may lead to the formation of cystic or solid masses which may have a mass-effect and compress surrounding structures [26]. The prevalence of incidentally found pseudotumors in asymptomatic patients has been reported to be as high as 32 %, while the prevalence of symptomatic lesions has been noted to be less than 1 % [27, 28]. At the time of revision surgery, extensive metallosis has also been observed to result in cellular toxicity which compromises the soft tissue sleeve of the hip joint and the abductor mechanism which may have implications for stability [29].

Cancer is one other potential concern with elevated serum cobalt or chromium ion levels since these metals have been demonstrated to be carcinogenic in animal models [30]. The release of hexavalent chromium (CrVI), which occurs in corroded cobalt–chrome alloys is a concern since this chromium form has been well established as a potential carcinogen [31–34]. However, several studies using national joint registry data have thus far found no evidence to link THA in general, or elevated serum metal ions in particular, to a risk for developing cancer [35–39]. One reason for this finding may be that CrVI is quickly reduced to CrIII within erythrocytes, which is

Table 3.5 Factors that affect serum cobalt and chromium ion concentrations following MoM THA

Prognostic factor	Correlation with serum ion levels
Femoral head diameter	Possible (diameter $>$ 40–50 mm)
Acetabular cup inclination	Increase with steeper inclination angle
Acetabular cup anteversion	$<$ 10 and $>$ 20°
Activity level	No correlation
Duration of implant in situ	Increase in first 2 years; steady state after 2 years
Gender[a]	Women have higher serum metal ion levels

[a] Gender may be confounded by restricted femoral head sizing options

the form needed for normal cellular metabolic processes [37]. A recent analysis by Mäkelä et al. of data from the Finnish Cancer Registry and Finnish Arthroplasty Register demonstrated no increase in the risk for cancer compared to patients with polyethylene or ceramic bearings (incidence ratio 0.95; 95 % CI: 0.85–1.04) at 4-year follow-up [30]. Similar results were reported by Smith et al. following analysis of registry data from the United Kingdom, and particularly observed no increased risk for developing hematological or renal tract cancers which could theoretically be affected by elevated serum metal ion levels [31]. However, one point of concern is the short follow-up period (5 years) for these studies since many cancers have a relatively indolent progression and may not appear for decades.

Diagnosis and management of patients who have MoM THAs may be challenging, particularly if the patient is asymptomatic but ion levels are elevated. Recently, a collaborative effort by the Hip Society in the United States proposed a management algorithm for patients with asymptomatic and symptomatic hips which recommended close surveillance with serial serum ion levels, imaging with metal artifact reduction sequence (MARS) magnetic resonance imaging (MRI), and revision in patients who are symptomatic and have elevated ions [39].

Outcomes from the Literature

The natural history of serum cobalt and chromium metal ion levels following MoM THA has been extensively studied. Various surgeon- and patient-specific factors affect these levels, including head diameter, acetabular cup inclination, anteversion, and activity levels (Table 3.5) [40–47]. Gender has also been implicated with women being at a higher risk for having elevated serum metal ions, however this finding may be susceptible to selection bias since femoral head size correlates with gender [48].

The relationship between femoral head diameter and serum ion levels has been debated. Lavigne and colleagues observed higher serum ion levels with femoral heads greater than 50 mm, but were unable to determine if this was due to head size or somehow related to gender since only men received head sizes of this size or greater [45]. However, in a review of 104 arthroplasties, Bernstein et al. observed no correlation between serum ion levels and femoral head size [49], which is similar to what was reported by Vendittoli and colleagues in a study of 107 total hip resurfacing arthroplasties [47]. However, resurfacing arthroplasties may not be comparable to stemmed MoM implants since the absence of sleeves or metal junctions in resurfacing prostheses eliminate potential interfaces for wear and metal debris [46]. Data from the Australian national joint arthroplasty also did not find a correlation between ion levels and head size, but a higher revision rate was observed for femoral heads greater than 40 mm [13].

Steep inclination angles have been well established as a risk factor for early failure and higher serum cobalt and chromium ions [48–50]. De Haan and colleagues demonstrated that acetabular cups implanted at angles greater than 55° were most likely to cause elevated serum ion levels, likely due to edge loading effects [50]. A similar, though non-significant, conclusion was reached by Brodner and colleagues who reported 10- to 50-fold higher cobalt and 9.5- to 30-fold higher chromium levels in patients who had cups implanted at 58–63° [49]. Similarly, acetabular cup anteversion angles outside of the "safe zone" of 20° anteversion have been shown to affect metal ion levels. Langton and colleagues, in a study of 160 patients, observed that cobalt and chromium ion levels were significantly elevated when acetabular cup anteversion was less than 10° or greater than 20° [47].

Activity levels were evaluated by Pattyn and colleagues who did not observe any correlation between activity levels and metal ion levels [41]. Similar results were reported by Heisel et al. who observed a 3 % cobalt and 0.8 % chromium serum ion level despite a 1,621 % increase in patient activity levels [42].

Temporal trends have demonstrated that serum ion levels commonly reach a steady-state level after several years of implant duration in situ. Bordner et al. observed that serum ion levels peaked at 2-year follow-up, and then decreased to a steady-state level which was 50 % lower than peak levels [43]. Compared to preoperative levels, cobalt levels are approximately 15-fold higher while chromium is 5-fold higher, however, these elevated mean values (1 ppb for both ions) are still well below the cutoff value of 7 ppb [51]. These trends appear to be maintained when ion levels are measured at long-term (> 10-year) follow-up as well [52].

The prevalence of adverse reactions following MoM THA was evaluated by Stürup et al. in a study of 358 patients identified through the Danish Arthroplasty Register. The authors noted that at a mean follow-up of 3 ½ years, 50 patients (14 %) of reported groin pain, and that 15 of these (4 % of total cohort) had elevated serum ion levels [53]. Histologic evaluation of failed MoM arthroplasties showed that up to 85 % of cases had evidence ALVALs, 49 % had synovitis, 15 % had granulomas, and 14 % had evidence of isolated metallosis [51].

Implant survivorship is of paramount importance to both patients and surgeons. Recently published meta-analyses have demonstrated that stemmed MoM implants fail at a higher rate than MoP implants in comparable patient populations. Milošev et al. analyzed 10-year survivorship of metal-on-polyethylene, ceramic-on-ceramic, and metal-on-metal bearings in 469 patients. When revision for aseptic loosening as an endpoint was taken, stemmed metal bearings had significantly lower long-term survivorship (89 %) than polyethylene (99.5 %; $p = 0.001$) or ceramic (99 %; $p = 0.003$) [54]. In a recent meta-analysis comparing outcomes of MoM to conventional THA, Voleti and colleagues observed no differences in functional outcomes between

Table 3.6 Reported long-term revision rates from recent studies and national joint arthroplasty registry data

	Milošev et al.[a] [52] (%; 95 CI)	United Kingdom[b] [59] (%; 95 CI)	Australia[c] [13] (%; 95 CI)
Metal-on-polyethylene	1.6 (0–3.4)	3.6 (3.2–4.1)	8.9 (8.1–9.8)[d] 5.7 (4.8–6.9)[e]
Ceramic-on-ceramic	4.4 (1.7–7.2)	3.9 (3.6–4.5)	5.7 (5.2–6.3)
Metal-on-metal	12.1 (2.7–21.5)	12.5 (11.0–14.1)	14.1 (13.1–15.3)

[a] 10-year follow-up
[b] 8-year follow-up
[c] 11-year follow-up
[d] Reported as revision with conventional polyethylene
[e] Reported as revision with highly cross-linked polyethylene

the two bearings as measured by Harris Hip Scores, but observed significantly greater likelihood of complications (e.g. wound dehiscence, trochanteric bursitis) with metal bearings (OR 3.3; 95 % CI: 1.6–7.3) [17]. In general, implants which use smaller-diameter femoral heads (Table 3.2) have shown comparable long-term survivorship to MoP designs. Saito et al. reported long-term results of 90 hips in which a second-generation, small-diameter metal bearing was used [55]. At a mean follow-up of 12.3 years, the implant survivorship with revision for aseptic loosening was 98.8 %, while revision for any clinical reason was 94.4 %. Of the five revised hips in the study, one was revised for acetabular cup loosening, two were revised for recurrent dislocation, and two were liner exchanges following dissociation with the metal acetabular articulating surface from its polyethylene backing.

Although some specific implant designs have shown comparable survivorship to MoP bearings [54], these utilize small-diameter femoral heads and are prone to dislocate. The advent of larger femoral heads with thinner polyethylene shells brings into question the use of even these bearings which have not demonstrated clear superiority over currently available MoP designs.

Outcomes from National Joint Arthroplasty Registries

National joint arthroplasty registers are particularly useful for recording long-term implant surveillance data and reporting implant survivorship due to the large sample sizes which exceed what a single or multiple research centers may accomplish. Overall, there has been a substantial decrease in the use of MoM bearings. In the United Kingdom registry data have shown that all-metal hips have decreased from a peak annual use of 15,000 total hips in 2008 to less than 1,000 today [13].

Analysis of joint registry data has demonstrated that irrespective of country of origin, metal-on-metal THAs fail at a higher rate than metal-on-polyethylene or ceramic-on-ceramic bearings (Table 3.6) [56, 57]. Evidence of early failure of several MoM bearing designs were reported in the 2007 Annual Report published by the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) [11], and subsequently confirmed by several follow-up studies [58, 59].

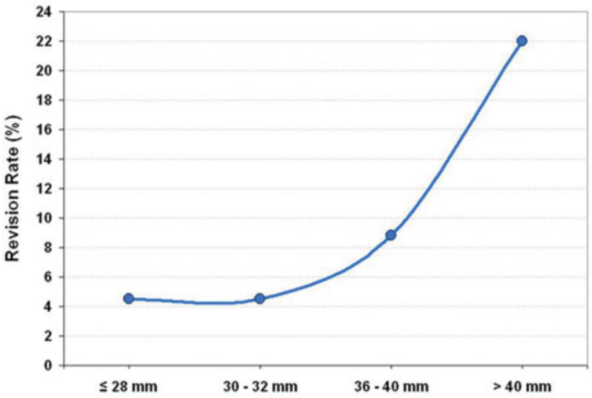

Fig. 3.1 Affect of femoral head size of the revision rates of MoM THAs at a final follow-up of 8 years. Data based on revision results from the Australian National Joint Registry

Data from the National Joint Registry for England and Wales at mid-term (mean 8-year) follow-up have demonstrated significantly higher revision rates of cementless metal-on-metal bearings (12.5 %) compared to cementless metal-on-polyethylene (3.6 %) or ceramic-on-ceramic (3.9 %) bearings at the same follow-up period [13]. These results have been mirrored by data from the Australian joint registry which reported a 14.1 % revision rate for metal bearings at 11 years compared to 8.9 % for metal-on-polyethylene and 5.7 % for ceramic-on-ceramic [13].

The affect of femoral head size has been well studied by the Australian National Joint Registry. At long-term follow-up (11 years), MoM bearings that use femoral head sizes less than 32 mm have similar revision rates compared to highly cross-linked bearings (5.8 % and 4.8 %, respectively), but better survivorship when compared to traditional high molecular weight polyethylene (9 %). However, when femoral head size is increased, a substantial increase in the revision rate at final follow-up is observed for 36–40 mm heads (12.5 % at 10-year follow-up) and > 40 mm heads (22 % at 8-year follow-up; Fig. 3.1).

The affect of modularity of the neck or the stem have also been evaluated by joint registry studies since the presence of a modular junction has been a point of concern [12, 60, 61]. Modular junctions may represent a source of wear between two non-articulating surfaces while at the same time the geometry and fit of the taper junction may create an electrochemical microenvironment which is highly susceptible to corrosion [60–63]. At a follow-up of 10 years the presence of a modular femoral neck was associated with higher revision rates in MoP hips compared to monoblock stems (11 % versus 6 %, respectively) but no difference was seen in the revision rates in MoM total hips at 6-year follow-up with modular or fixed femoral necks (10 % versus 10 %, respectively). However, the revision rate for MoM hips was still substantially higher at nearly half the follow-up period than MoP designs [12].

Conclusion

The role of stemmed MoM THA is greatly limited and potentially (or rapidly) becoming a contraindication for patients needing a THA from these multiple studies. The higher failure rates observed at mid- and long-term follow-up, as well as the risk of adverse local tissue reactions to metal debris, make metal bearings an unattractive clinical treatment option. While the use of a small-diameter femoral head (e.g. 28 mm) have demonstrated similar survivorship compared to MoP bearings, the need to use small head sizes may increase the risk for dislocations. With the recent development of large-diameter MoP bearings which have lower dislocation rates and highly cross-linked polyethylene liners which demonstrate improved wear characteristics, the potential uses for MoM bearings become limited. Although wear continues to be an issue, particularly for young patients who require a THA, metal bearings are likely in the future to continue to be superseded in clinical use by newer-generation ceramic and polyethylene designs.

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