Metal-on-Metal Bearing: Is This the End of the Line? We Do Not Think So

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Abstract *Background:* Recent studies have recommended the discontinuation of metal-on-metal (MoM) components in total hip arthroplasty (THA) because of adverse effects reported with large-diameter MoM THA. This is despite favorable long-term results observed with 28 and 32 mm MoM bearings. *Questions/purposes:* The aim of this study was to assess the value of calls for an end to MoM bearings as THA components. Specifically, we wish to address the risks associated with MoM bearings including adverse soft tissue reactions, metal ion release, and carcinogenic risk. *Methods:* The study evaluates the arguments in the literature reporting on MoM (adverse soft tissue reactions, metal ion release, and carcinogenic risk) and the experience of the current authors who re-introduced

these bearings in 1995. They are balanced by a benefit–risk review of the literature and the authors’ experience with MoM use. *Results:* Adverse reactions to metallic debris as well as metal ion release are predictable and can be prevented by adequate design (arc of coverage, clearance), metallurgy (forged instead of cast alloy, high-carbide content), and appropriate component orientation. There is no scientific evidence that carcinogenicity is increased in subjects with MoM hip prostheses. MoM articulations appear to be attractive allowing safe hip resurfacing, decreasing the risk of THA revision in active patients, and providing secure THA fixation with cement in cages in severely deformed hips. MoM bearings in women of child-bearing age are controversial, but long-term data on metallic devices in adolescents undergoing spinal surgery seem reassuring. *Discussion:* Adequate selection of MoM articulations ensures their safe use. These articulations are sensitive to orientation. Fifteen years of safe experience with 28- and 32-mm bearings of forged alloy and high-carbide content is the main reason for retaining them in primary and revision THA.

The study was conducted at the Lille University Hospital, Lille, France.

Level of Evidence: Level IV Therapeutic Study

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Introduction

Total hip arthroplasty (THA) with metal-on-metal (MoM) bearing is an ongoing controversy [1]. Those in favor of the MoM articulation site reports of high complication rates and poor component durability (especially in young, active patients) resulting from polyethylene wear in metal on polyethylene THA's [2]. Hard-on-hard (MoM or ceramic-on-ceramic (CoC)) bearings with excellent tribological properties were introduced to solve this problem and appear to be attractive alternatives and should be considered [3]. Ceramic-on-ceramic bearings have the advantage of chemical inertness, but cup fixation and head or insert fracture risk are

major concerns [4, 5]. In contrast, MoM bearings have no concerns regarding breakage and do not adversely influence component fixation [6, 7].

MoM bearings have been problematic since their appearance with McKee–Farrar THA in the 1960s [8]. The frequency of acetabular loosening was one of the reasons why they were given up in the 1970s [9]. This loosening was essentially attributed to articular joint jamming [8], but stress transmission to the thin cement mantle between acetabular bone and the metallic cup interface was another unrecognized issue. Excellent tribological improvements led Weber [3] to reintroduce MoM bearings at the end of the 1980s. A metallic insert was set in a polyethylene cup, and bone fixation was achieved with acrylic cement. These bearings were produced as cementless versions in the beginning of the 1990s, the sandwich being fixed to the acetabulum by press-fit or screw cup [10–14], or without polyethylene sandwich in hemispherical cementless cups [15–17].

Despite favorable results reported since their reintroduction, some arguments today call for an end to MoM bearing use. Indeed, two major concerns are soft tissue reactions which include aseptic lymphocyte-dominated vasculitis-associated lesions (ALVAL) [18], pseudotumors [19], squeaking [20], adverse reactions to metal debris [18, 21–23], and metal ion release into the circulation [24, 25]. The purpose of this review is to analyze the literature and the authors' experience in using MoM THA. This review delivers a rebuttal to the proposed discontinuation of MoM bearing by taking a comprehensive approach to all criticisms.

Methods of Assessment of Literature Selection

A references search was done with PubMed using the key words “hip prosthesis” “metal on metal” with the following limits: English language, Clinical Trials, and/or Meta-Analysis. Of the 200 papers selected, 146 were discarded because they were not directly related to MoM bearings, leaving 54 articles that are the basis of the current review. Eight papers not collected by the former research were added because the current authors published them about MoM. Thirty-three additional papers were included because the initial selection did not bring knowledge regarding specific issues of MoM (pregnancy, potential chromosomal mutation, carcinogenicity) as well as papers comparing MoM versus different bearing surfaces or historical data.

Results

Are Arguments for MoM Discontinuation Sound?

Soft tissue reactions are a major concern after MoM bearing implantation. ALVAL seems to be unpredictable, but the rate is very low (less than 1/10,000) and below the frequency of ceramic breakage [18]. The pseudotumors are more common than ALVAL, but some protection exists when adequate design and metallurgy is incorporated with ideal component orientation, especially for cup inclination [19, 21–23, 25, 26].

Blood metal ion levels are another major concern [27–30]. In fact, metal ion evaluation in the post-operative period after MoM insertion serves as an indicator of bearing performance and is also important in assessing device safety [31, 32]. Nevertheless, acceptable cobalt (Co), chromium (Cr), and titanium (Ti) levels have not yet been adopted by the orthopedics community.

It is noteworthy that MoM articulations are affected by metal ion release, but all of them are not similar in terms of ion release [25, 33]. Adequate design and metallurgy make possible a limited elevation of ion production. Brodner et al. [31] reported Co concentration of 0.7 µg/l in serum at 5-year follow-up of 28-mm MoM bearings. Likewise, McKee–Farrar MoM prostheses generated very low Co concentration of 0.9 µg/l at 25 years of follow-up [34]. Vendittoli et al. [33] described the results of 57 MoM THA with 28-mm-diameter heads and 64 MoM RSA (replacement surface arthroplasty) with the same bearing (high-carbon content, forged metal alloy). Co concentration in whole blood was 0.67 µg/l in the THA group and 0.84 µg/l in the RSA group ($p=0.2$). Similarly, using different MoM bearings (forged 28-mm-diameter versus cast large-diameter heads) in THA, Daniel et al. [35] did not find a significant difference at 1-year in blood as well as urine in Co and Cr concentrations.

Do These Arguments Justify the End of MoM Bearings?

Tissue Reactions (ALVAL, Pseudotumors, etc.) and Carcinogenic Risk

Pseudotumors appear to be more common than metal hypersensitivity reactions. Pseudotumor risk is estimated to be 0.1–3% in patients who undergo MoM resurfacing within 5 years after implantation [19, 23]. A large hip resurfacing series involved 3,432 procedures with mean 3.4 years of follow-up identified 0.1% prevalence of pseudotumors [19].

Pseudotumors may derive from cell toxicity from particulate wear debris. Risk factors, such as female gender, age <40 years, small component size, and edge-loading with vertical cups, are now well-recognized [26, 36]. The precise etiology of pseudotumors remains unknown, and their association with metal hypersensitivity reactions is possible. Pseudotumors are reported to mainly occur in patients with MoM large-diameter heads [26]. To the best of our knowledge, only one case with a small-diameter MoM (28 mm) has been reported [37]. Pseudotumors are rare with forged high-carbide MoM bearings, even after 10 years of follow-up [12, 14, 32, 38]. Moreover, they may arise with other bearings, such as CoC and metal-on-polyethylene (MoP), etc. [39, 40]. MRI has been accepted as a reproducible tool to measure soft tissue changes around MoM hip replacements [41]. However, synovial reactions may be observed using MRI in asymptomatic MoM hip replacement, and the pathological value of these changes should be confirmed in large populations [42].

Increased of T cell lymphocytes concentrations were related to blood Co concentrations in patients receiving MoM replacements [43]. In contrast, chromosomal modifications are not currently related to Cr and Co blood

concentrations in patients receiving MoM articulations [44]. There is no scientific evidence that carcinogenicity increases in patients with MoM hip prostheses compared to those receiving MoP hip prostheses (relative risk of cancer 0.95% for MoM prostheses and 0.76% for MoP prostheses, the difference not being significant) or in the general population [45, 46].

Concerns Regarding Blood Metal Ion Levels

Vendittoli et al. [47] measured metal ion concentrations in 29 MoM large-diameter head THA (LDH-THA) patients. Mean Cr, Co, and Ti levels were, respectively, 1.3, 2.2, and 2.7 $\mu\text{g/l}$ at 12 months. The open femoral head design released significantly higher Co concentrations than the closed design (3.0 versus 1.8 $\mu\text{g/l}$, $p=0.037$). Co levels were significantly higher with LDH-THA than with RSA devices possessing exactly the same bearing characteristics (2.2 versus 0.7 $\mu\text{g/l}$, $p<0.001$) [48]. The addition of sleeves with modular junctions and open femoral head design caused more Co release than bearing surface wear (157 and 67%, respectively).

Elevated metal ion levels expose patients to theoretical risks, such as metal hypersensitivity, periprosthetic osteolysis, pseudotumors, chromosomal mutation, carcinogenicity, and fetal contact [18, 22, 23, 31, 32, 47, 48]. On the other hand, different implant characteristics may influence MoM bearing wear: bearing diameter, rugosity, component sphericity, radial clearance, manufacturing process (forged versus cast components), and metal-carbon content [49–53]. Metal ions can be released from different sources, namely bearing wear, modular junctions, taper performance, and passive corrosion. Taper performance is influenced by implant factors, such as materials (Cr versus Ti), taper geometry (low tolerance with minor contact), contact surface area (short taper and slim neck), lever arm (neck length, importance of femoral offset, large-diameter head), and surgical factors, such as the cleanliness of the taper (with the risk of blood or fat debris) and the type of impaction (according to force and direction) [25]. Lavigne et al. [25] determined that all taper junctions did not perform equally, and that metal junctions could release significant amounts of metal ions. Similarly, Garbuz et al. [54] confirmed that THAs using large-diameter heads produce higher Cr and Co blood levels than hip resurfacing using the same bearing components. Isaac et al. [55] suggest that individual factors are involved to explain variation of Co and Cr blood levels despite using a single design of hip resurfacing in a multicenter study.

Besides bearing surface wear, passive corrosion of exposed surfaces markedly influences metal ion concentrations locally and in the systemic circulation [56, 57]. Passive metal corrosion is strongly correlated with exposed metallic surfaces, porous surfaces, and head diameter. Corrosion occurs when the protective, passive film is disrupted by fretting or micro-motion, leading to contact between the metallic implants [58, 59]. Also, as mentioned earlier, corrosion between taper junctions is a known source of elevated metal ion levels [25]. This phenomenon occurs with all THA modular implants, whatever the bearing type, and its

severity is associated with the number and quality of metallic junctions. Asencio et al. [60] found significant metal ion release in modular femoral neck THA (ABG 2, Pusignan, France) with CoC bearings (mean Co in whole blood, 7 $\mu\text{g/l}$). It originated from a source other than the bearing (i.e., modularity with Cr and Co taper), and it had adverse local effects, such as pseudotumors, with CoC bearings.

Notwithstanding these data, surprisingly few concerns have been raised regarding the potential adverse effects of metal ions other than from hip arthroplasty [61–63]. However, in the same way as pseudotumors could occur whatever the type of bearing used, it is necessary to specify that, although ion levels (Ti, Co, Cr, etc.) are elevated after MoM bearing implantation, they are comparable to values recorded after total knee arthroplasty (Cr 0.92 $\mu\text{g/l}$ and Co 3.28 $\mu\text{g/l}$ in whole blood) [61], conventional THA (Ti level was 4.13 $\mu\text{g/l}$ with the Harris–Galante II porous-coated cup) [59], or spinal surgery [64]. Indeed, the systemic distribution of metal debris has been demonstrated by measuring serum metal ion levels in patients with Ti spinal implants. Richardson et al. [65] reported Cr and Ti levels of 10.5 and 3.36 $\mu\text{g/l}$, respectively, in 30 patients at a mean of 26 months after surgery. These authors underlined that young females often undergo spinal surgery before the child-bearing age. Zeh et al. [66] noted Co and Cr levels of 4.8 and 1.1 $\mu\text{g/l}$, respectively, at 14.8 months after implantation of a MoM artificial Maverick type lumbar disc. They emphasized that “concentrations of metallic ions in serum are similar to the values after MoM THA or exceed values in the literature.” Moreover, these authors stated that young females submitting to spinal surgery still go through the child-bearing period with metallic implants [65, 66].

Concerns Regarding the Use of MoM Hip Resurfacing

Hip resurfacing is primarily indicated for osteoarthritis in young, active male patients [1, 67, 68]. Few studies are reporting results of hip resurfacing in rheumatoid arthritis [69], necrosis of the femoral head [70, 71], developmental dysplasia of the hip [72], or Perthes disease [73]. At least equal or higher functional scores are expected after hip resurfacing [74–76] but at the cost of a higher revision rate [75, 77–79]. However, on the basis of a prospective randomized study comparing MoM THA and hip resurfacing, Vendittoli et al. [80] did not confirm a higher revision rate but revealed that the reasons for revision were different. In RSA, revision was required predominantly for early aseptic loosening. Because of an eventual higher risk of adverse tissue reaction to metallic debris, the outcome of revised hip resurfacings is expected to be lower than a primary THA [81], but this issue is not widely accepted and many studies advocate the results are equal [82, 83]. Femoral component fixation and orientation appeared as the major challenge when reintroducing hip resurfacing in the late 1990s [77, 79, 84, 85]. However, cup fixation was also a frequent reason for hip resurfacing failure when fixed with cement [86]. Additionally, inappropriate orientation is known to lead to excessive wear of the MoM bearing and is more likely to produce adverse tissue reaction [21, 22].

The Authors' Experience with MoM Bearings

MoM THA for Patients Under 30 Years Old

The current authors reported the results of 48 MoM THAs (28-mm-diameter head) performed as primary hip arthroplasties in patients under the age of 30 years [12]. We evaluated the 10-year survivorship rate in this specific group [12]. Only two revisions were undertaken in this MoM group (one for impingement secondary to cup malpositioning and the other for acetabular loosening with osteolysis) despite a high activity level (Devane score 4 or 5; 87%). Ten-year survivorship was 94.5% with MoM bearings (95% confidence interval (CI) 80–98.4%). We conclude that these encouraging medium-term results in our patients indicate that THA with 28-mm MoM bearings may be a good solution for young patients with hip osteoarthritis.

Hip Resurfacing in Patients Under 30 Years Old

The concept of hip resurfacing is very attractive for this specific population by combining hard-on-hard bearing components limiting wear, a large femoral head limiting the risk of dislocation, and femoral bone stock preservation. We studied 24 hips in 22 patients [68]. Mean age at operation was 24.9 years (17.1–29.9). No revisions were required at an average follow-up of 24.6 months (18–34). University California Los Angeles activity score improved from a mean of 5.5 (1 to 9) pre-operatively to 7.6 (1 to 10) post-operatively ($p < 0.001$). Mean Harris hip score increased from 43.9 (19–67) to 89.3 (55–100) ($p < 0.001$), and no dislocation occurred in this group. Despite the challenge of performing hip resurfacing in young, active patients, the clinical and radiological short-term results in our series are encouraging and demonstrate outcomes comparable to standard THA at this early stage.

Our study supports MoM hip resurfacing as a suitable alternative to conventional THA for this group of very young and active patients. Moreover, the specific advantages of hip resurfacing (bone stock preservation, excellent stability, low risk of dislocation, large-diameter articulation, etc.) have made the procedure a very attractive option for young patients.

MoM THA for Young, Active Patients Under 50 Years Old

The current authors have also reported [14] on 39 MoM 28-mm THA fixed without cement (30 patients with a mean age of 39 years (23–49)) which were compared to a control group, of 39 metal on polyethylene 28-mm hip replacements also implanted without cement (32 patients with a mean age of 40 years (15–49)). Mean follow-up was 151 months (144–166). Mean Oxford score was 15.3 points (12–35) at revision. Median Co concentration was 1 $\mu\text{g/l}$ (0.4–4.8), and median Cr concentration was 1.2 $\mu\text{g/l}$ (0.1–5.6). Twelve-year survivorship with revision for any reason as endpoint was 70% (95% CI 63–77%) for the metal on poly cohort versus 100% for the MoM cohort ($p = 0.003$). MoM bearings improved arthroplasty survivorship and reduced the rate of

osteolysis compared to hard-on-soft bearings in young, active patients after minimum 12-year follow-up (Fig. 1).

MoM Bearings for Difficult Primary Cases and/or Revisions

We also reported 23 THAs with MoM cups cemented into Muller™ reinforcement rings. Mean follow-up was 6.1 years (5–10) [87]. At final follow-up, Harris hip score increased

Fig. 1. Metal-on-metal bearing (Metasul™, Zimmer, Warsaw, IN, USA) with 28-mm-diameter head and cementless components at 14.5 years of follow-up. At last review, Harris hip score was 100 points in this active 48-year-old man. Close anteroposterior and lateral view of the cup did not identify osteolysis or/and radiolucencies

from 62.2 (39–85) to 95.2 (84–100, $p=0.01$). Revision was not needed for aseptic loosening or fixation failure. Considering re-operation and bearing revision as endpoints, survival rates were, respectively, 95.8 and 100%. Mean blood Cr, Co, and Ti concentrations were, respectively, 1.85, 1.24, and 9.62 $\mu\text{g/l}$. The possibility of hard-hard bearings coupled with reinforcement rings gives a promising perspective to MoM bearings. Indeed, these systems motivate us to propose hard-hard bearings for young, active subjects when acetabular bone stock does not allow metal-back cementless cups (acetabular deformity, especially in revision cases) but requires reinforcement rings and bone grafts (Fig. 2).

MoM Bearing Components Prevent THA Revision in Patients Younger Than 30 Years

The current authors performed a case-control study to assess risk factors for THA revision in patients under the age of 30 years [88]. Fifty-five patients who underwent revision of THA inserted at less than 30 years of age were compared to a non-revised group, including 819 THAs in patients younger than 30 years. Multivariable analysis identified three factors related to a high risk of revision: young age at primary THA [odds ratio (OR) 1.14 (1.07–1.19)], a large number of earlier surgeries [OR 5.41 (2.67–10.98)], and the use of hard-on-soft bearings instead of hard bearings (mainly MoM) [OR 3.42 (1.91–6.1)]. This study of a large population identified low THA survivorship (the 10-year survival rate

was 36% (95% CI 21–51%)) and reaffirmed our interest in MoM articulations to reduce the risk of revision [88].

Discussion

These data confirm that implant design, component position, metallurgy, and the tribological properties of MoM bearings are major issues in the reduction of adverse effects. Metallurgy (better wear resistance of forged instead of cast alloys, favorable effect of high-carbide content) is a key factor in the success of MoM bearings that was not adequately addressed by other designs that induced severe and short-term adverse events, even with small-diameter heads [21, 23, 26, 89, 90]. Likewise, the MoM coupling design (arc of coverage, adequate clearance) is critical and may promote early failure when not appropriate [21, 22, 49, 89]. The use of large-diameter heads does not excuse unsuitable orientation which leads to edge-loading and excessive secondary metallic debris production. To the current authors, “MoM insertion is not an easy, straightforward procedure.” In fact, MoM bearings are very sensitive to malpositioning (edge-loading in LDH-THA and impingement with small-diameter heads). The dislocation rate with large-diameter heads is very low and is a common reason to use these components, but the main concern is the occurrence of pseudotumors secondary to wear

Fig. 2. Revision of a loosened THA with severe bone loss around the protruding, loosened cage in a 38-year-old woman (who underwent two earlier THA revisions). Ten years after revision with a Burch-Schneider cage, cemented Metasul™ 28-mm-diameter component and cementless stem (Metasul™, Zimmer). The anti-protrusion cage improved hip centering and the cemented hard bearing avoided recurrence of osteolysis despite the patient's high level of activity

resulting from vertical cup placement. Modularity with taper junctions dramatically increases ion production. On the other hand, some points need to be clarified today. MoM bearings in women of child-bearing age remain a controversial subject. However, it is reassuring that metallic devices have been deployed in spinal surgery in adolescents for a long time without any adverse outcomes. Metal allergy is still a contentious issue, and the pre-operative diagnosis is very challenging. If metal allergy testing is positive, THA possibilities are limited to Ti implants and hard on polyethylene bearings and very restricted for knee arthroplasty, spine surgery, and internal fixation.

MoM articulations nevertheless retain strong advantages. They are the only way to securely perform hip resurfacing. With adequate design and appropriate tribological properties, MoM bearings constitute highly resistant articulations. Because MoM may be cemented into cages (not directly into the acetabulum [86, 91]), it is the only hard-on-hard bearing that can be implanted in difficult primary cases (such as protrusio, hip dysplasia, etc.) and revision surgery [87, 88]. Unlike CoC bearings, squeaking is rare (close to zero for most authors) and compares favorably with the 2.7 to 21% rate observed with CoC bearings [92, 93]. Similarly, the rate of component breakage after MoM bearings is zero but reaches 0.1–7.4% with CoC coupling [94, 95]. The new generation of correctly designed, small-diameter MoM has endured for 10 years [10, 32] and has almost reached 15 years of follow-up [14, 38] without serious adverse effects, in spite of the fact that these components are mainly used in young, active patients [14]. This uneventful follow-up is, in the authors' opinion, a major reason for continuing with MoM articulations as long as they are well-designed, manufactured, and inserted correctly.

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