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# Metal-on-metal: history, state of the art (2010)

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**Abstract** The history of metal-on-metal bearing began with K. Mc Kee. Several "episodes" have marked the history of metal-on-metal articulations, and each has contributed to a better understanding of this type of tribology. But to date the indications for this bearing are debated and are subject to reservations because of the existence of permanently elevated levels of circulating metal ions. It therefore appears that the monitoring of our patients, the documentation of our revisions and the collaboration with our industry partners as well as communicating with our biology and pathology colleagues is necessary to help us solve these problems.

## Metal-on-metal: history, state-of the-art (2010)

Typically, the first total hip implant with a metal-on-metal articulation is attributed to P. Wiles who, in 1938, implanted a couple made of steel [53]—but this was prehistory!

The more recent experience starts with McKee whose name will always remain associated with first generation metal-on-metal. However, a high number of failures discredited this metal-on-metal articulation; even more so, because the good tolerance of polyethylene underlined the qualities of the metal-on-polyethylene articulation advocated by J. Charnley who would also became the gravedigger of this first generation.

An elaborate analysis of the failures led Weber to initiate and then promote a second generation of metal-on-metal, cemented at first, then rapidly followed by non-cemented prostheses.

In 1996, a special edition of *Clinical Orthopaedics and Related Research* was dedicated to this bearing. Its particular complication, ALVAL, would be documented by Willert.

The tribology of metal-on-metal, thus better known, reopened the door to bipolar resurfacing, and the complicated treatment of fractured necks led to the development of conventional total hip prostheses with a large diameter head.

It is this evolution towards a large diameter that gave reason to reconsider the consequences of excessive wear of metal-on-metal articulations. The adverse reaction to metal debris (ARMD) also deserves to be analyzed!

Eventually, because of these never resolved uncertainties, which are still a topic due to the high potential risk related to the permanently circulating metal ions, the metal-on-metal bearing appears to be the "bad boy" among the joint bearing made available to surgeons today.

Thus, several "episodes" have marked the history of metal-on-metal articulations, and each has contributed to a better understanding of this type of tribology.

## Metal-on-metal: episode 1

While G.K. McKee stands for metal-on-metal coupling, also K.M. Sivash, P. Ring, J. Scales, A. Hugler, M. Müller and M. Postel deserve mention. They have all participated in the development of this bearing surface and have honestly faced up to the limits and the failures of their work [40].

McKee had to rapidly give up steel for a chrome-cobalt-molybdenum alloy promoted by Venable, and the acetab-

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ular fixation by means of press-fit in favor of acrylic cement. He used this cup in combination with a femoral stem borrowed from Thompson.

The disappointing results, poorly understood, and the extraordinary mentoring of the "low friction" developed by Charnley would 'red line' this metal-on-metal bearing, and consequently, the concept was abandoned before the reasons for its failure had been effectively analyzed. When McKee himself became more interested in ceramic joints, it became belatedly clear that:

1. All failures of the metal-on-metal were not due to the bearing surfaces; the design of the implants and technical errors which led to poor mechanical conditions should have also been taken into account [57]. Also, the analyses of these failures should also be put into the context of a time when hip implants were still a very young invention!
2. The failures of metal-on-metal bearings were to be attributed to the factor of "high friction" resulting from inadequate manufacturing. The analysis of retrieved implants demonstrated that the optimization of the joint movement would be key to a good clinical result [45].

The study of the retrieved implants demonstrated little wear of the articulating surfaces and the small wear particles [55] which occurred were below the activation threshold level for macrophages, and thus outside the sphere of activity of biological processes which are associated with the subsidence of implants. These then lead to friction in an articulating surface and, thus, generate polyethylene debris [21].

And one should—but only in retrospect—recognize that the results of "the McKee" could in fact differ only little from the results of "the Charnley"! [24]

Finally, with regard to this first generation, even if no general complication could be attributed to a high level of circulating metal ions, this poorly understood issue [47], yet already identified at a local level [56], further increased the concerns regarding this bearing surface.

## Metal-on-metal: episode 2

In the beginning of the 1980s, after identifying the "polyethylene disease", Weber, just like the entire orthopedic community, was aware that subsidence is in fact a natural evolution rather than a complication of a prosthetic articulation when using polyethylene as an articulation partner with metal or ceramic.

Intrigued by the good results of certain metal-on-metal configurations [37], he thought that this bearing could be an alternative to polyethylene and deserved a second chance [52]. Research studies based on these observations led to the selection of a forged alloy with high carbon content (0.20–0.25 %) whose hardness would enable precise machining of these devices and optimize joint movement.

It was the poor reputation of the combination of the metal cup in the shell [44] which at first required a polyethylene interface in which a metal insert was pressed; however, the introduction of uncemented versions rapidly proved the compatibility of the different metal backs offered by Weber’s industrial partner.

The results of the combined versions would not fulfill the above-mentioned expectations based on the in vitro studies. If the absence of industrial coherence could perhaps explain certain failures [29], the limitations of cementing these types of cups became rapidly apparent [31]. However, the combination of this same type of insert in a metal reinforcement [16] yielded good results. It is regrettable that Webber's documentation, who first used both versions, of which the one with a metal mesh, was discontinued.

From the beginning of this second generation of implants of implants, serious concerns because of the risks associated with an increased level of circulating metal ions slowed down further development of this bearing, even if, even now no complication could be attributed to this phenomenon.

## Metal-on-metal: episode 3

This is the uncemented version of the second generation, which provides the most significant lessons as it had the highest number of implantations.

Since 1992, Weber himself used his insert in the Zweymüller cup. He remained faithful to his tribology of "forged, high carbon content" even when other tribological configurations were made available to surgeons. This meant that now reference could be made to metal-on-metal bearings in multiple forms. It became quickly evident that the high carbon content was essential to the hardness of an alloy compatible with a machining process that would confirm to the requirements for joint mobility and roughness. The results of low carbon implants [27, 36] or implants of different compositions [39] were rapidly disappointing, with early osteolyses, while the composition initiated by Weber, with a high carbon content, proved mechanically reliable and yielded satisfactory long-term results [11, 15, 20, 46].

The study of retrievals [42] confirmed the tribological qualities of the bearings and backed the run-in phenomenon.

The failures associated with the specific complications in this bearing surface were thus clearly identified; they were of mechanical (cam effect) and biological nature (ALVAL).

In the cam effect, the skirted heads of the very first series were rapidly abandoned [12]; but the cam effect, because of the very conventional 28-mm diameter, is a frequent complication, undoubtedly often underestimated, and which has for a long time contributed to the confusion around the term "metallosis". In fact, the cam effect generates a "titanosis" when the metal-on-metal bearing is placed on an uncemented titanium stem; thus, this is a metallosis that is not specific to a metal-on-metal bearings since it is also described in alumina–alumina joints [41]. This "titanosis" is very different from a metallosis associated with a metal-on-metal bearing: this phenomenon would be perfectly characterized by Willert et al. [54]. They would identify the immunologic response to metal wear and describe it with the term ALVAL. The “primum movens”—primary cause remains unknown, but definitely involves a patient-dependent factor; this complication can indeed occur in a metal-on-metal bearing even when its mechanical functioning is perfectly harmonious. Today, the disease patterns are sufficiently known, in spite of their different types of appearance [35], to enable an experienced practitioner to make an early diagnosis and to intervene with a revision with a good chance of success.

More recently, osteolyses that could be potentially linked to micro-movements of a polyethylene insert in a metal back have been observed [22, 48].

Finally, we note that in this uncemented configuration, no complication could be associated with a permanently high level of circulating metal ions, even if these theoretical risks were indeed listed [26].

## Metal-on-metal: episode 4

The continued work on the tribology of metal-on-metal revealed advantages of larger diameters for better lubrication [43]; evolution would therefore go in this direction, with the promise of better stability, increased mobility and a solution against the cam effect.

Resurfacing in its first form would be influenced by the nostalgic feelings for this arthroplasty. This must have been a strong considering that it was almost forgotten that using resurfacing meant adhering to the metal-on-metal concept. In any case, when this solution developed, one had the impression that all reservations expressed with regard to this concept thus far had vanished.

It became quickly evident that, while metal-on-metal had resolved the problems of acetabular fixation, the challenges of indication and surgical technique had remained the same. It can be said that, compared to a conventional stem with an anatomical head, resurfacing of the cup—before it became autonomous and the second form of the concept—had been promoted to treat fractures of the femoral neck, thus making bipolar resurfacing more complicated. This remains very disputable from a tribological point of view.

However, the evolution towards a very large diameter, driven by Amstutz and McMinn, has revealed the problems associated with this particular metal-on-metal configuration that could lead to serious complications.

This was a question of a local complication and some type of inflammatory pseudo-tumor [7], to be attributed to the release of large quantities of metal debris, which can also be seen in the abnormally high levels of chrome and cobalt in the blood. These are fluid-filled tumors, to be differentiated from liquid-filled articular cysts that are often found in ALVAL. The association with ALVAL is debatable, the pseudo-tumor being considered by some as a toxic manifestation of the same process. To define this type of complication as the ultimate manifestation of hypersensitivity to metal assumes the sensitivity of every patient. While still working on a distinct classification for these manifestations, D. Langton [30] has proposed to group them under the term "adverse reaction to metal debris" (ARDM).

The description of these complications has made it possible to identify several points in resurfacing: indications, necessary experience of the surgeon, surgical technique, and rehabilitation [18, 38], yet the conference consensus 2009 [14] omits two challenges: the manufacturing of the implants and their geometry.

If the high-carbon alloy serves as a reference, the debate between forged and cast alloys persists, and between the two latter, the thermic treatment modalities to be used remain controversial [25].

With regard to the design of the implant, close attention is now being paid to the functional curvature of the cup, which depends on its design, size and in vivo inclination [19].

Alongside the surgical teams involved in the follow-up of their implants, the industrial manufacturers also dedicate their efforts to the research of these topics [23, 32].

Finally, the certainty of abnormally high wear of the components, reflected in a very high level of metal ions, can play an important role in the phenomenon of edge-loading [28].

The large diameter total metal-on-metal prosthesis, in combination with a conventional stem—which should not be considered an alternative to resurfacing, and which has been the subject of scientific publications [1, 34]—has been attributed with only a few complications of the pseudo-tumor type. Yet, perhaps this is only a question of frequency of implantation and follow-up, because the challenges in regards to metallurgy, such as design of the implant and cup inclination are the same. The neck/head junction, with or without head adapter, will probably be a problem in this configuration.

It must again be noted that no general complications related to a high level of circulating metal ions has been reported within the framework of these large diameter metal-on-metal bearings.

### Metal-on-metal: all episodes

Metal-on-metal bearings have always been subject to reservations because of the existence of permanently elevated levels of circulating metal ions authenticated by blood and urine samples. We are not referring to the very high levels in cases of dysfunctioning which are those temporarily elevated levels whose dosage contributes to the indications for revision.

We are referring to the high levels in well functioning metal-on-metal bearings for which regular monitoring of these implants continues to be proposed [13], and this is in spite of the fact that the limitations of such methods are well known [17].

With regard to these reservations, the following can be stated today:

1. All patients with a metal-on-metal hip implant have a permanently raised level of chrome and cobalt metal ions in their blood.
2. These levels are low in normally functioning articulations and far from the levels defined as dangerous in people who are professionally exposed.
3. A large number of parameters can influence these levels (run-in, activity, diameter, etc. [50]), but the only factors that can modify these levels significantly are bilateral implants and implant inclination [4].
4. The elimination of these ions occurs via the kidneys.

We do not have any means to change these reservations today. In an age where every minor sanitary risk factor in food and hygiene products is traced back, it is legitimate to be vigilant in this regard.

However, it can also be stated that:

1. The carcinogenic risk has been eliminated by solid epidemic studies [51].
2. The toxic risk has never been the object of any concern and does not seem to worry our colleagues in toxicology and nephrology.
3. The genetic risk remains purely theoretical.
4. The chrome-cobalt alloys have been used for a long time in human and animal implantology, and to this day no complication related to a high level of circulating metal ions has been expressed.

However, these reservations have led to a disputable scientific consensus. The use of the metal-on-metal bearing is contraindicated in patients with renal insufficiency [10] and in women of child-bearing age for the fully justifiable argument of placental passage of these ions [58].

Yet, this problem does not only concern metal-on-metal hip implants, but should be taken into consideration in a wider context as all our arthroplasties and metal implants expose the patient to a liberation of metal ions [33, 49]. Hence, we note that our colleagues in ortho-pediatrics are aware of this problem with regard to the instrumentation they use in the treatment of their scoliosis cases [9].

### Metal-on-metal: future episode

Practically all industrial manufacturers today offer a metal insert directly mounted in a metal-backed cup in their product range. The advantage obviously lies in the possibility of choosing one of the three modern couples for this metal back. Even if this remains quite contested with regard to the concept, this type of implant combination is widely used and it would be premature to draw any conclusions at this point. Will metal-on-metal be the future? Will the small head with large diameter make metal-on-metal a mature articulation combination? There is no doubt that the technical complications and the lack of understanding of the pseudo-tumors in resurfacing are slowing down the current pursuit of the spread of resurfacing and rather favour the promotion of these cups, with the additional argument that the polyethylene sandwich has been suppressed compared to the previous generation.

The requirement profile of future episodes includes:

1. An alloy of a hardness that enables intra-articular movement and an optimized roughness.
2. An acetabular implant design that enables an efficient coverage of the head.
3. An implantation technique that vigilantly takes into consideration the inclination of the acetabular component.
4. A follow-up of all our patients with a metal-on-metal articulation.

Imposing this intellectual and technical rigor will enable us to best define the indications for the metal-on-metal bearings and to offer our patients a safe and effective service, i.e. a good result and the certainty that there will be no complications. It thus appears that the monitoring of our patients, the documentation of our revisions and the collaboration with our industry partners with consulting our biology and pathology colleagues will enable us to solve these problems. In addition to the compilation of these data, their analysis must be done with a scientific rigor that will not permit any approximation which could lead to hasty conclusions [8]. Is it pertinent to work in the same way on bipolar resurfacing and on conventional implants [5]?

McKee has taught us that this was possible. Weber has shown that the optimization of the alloy and joint movement, as well as fixation without cement, could yield good long-term results with small diameters heads. Willert has explained the local immunological complications.

Amstutz and McMinn have demonstrated the virtues and limitations of large diameters heads. Campbell et al. [6] has clearly demonstrated that, based on the findings from retrieved implants, metal-on-metal has led to satisfactory results if a well designed and manufactured implant is used in combination with a perfect implantation technique.

It is common knowledge that we are still missing many elements; particularly, and contrary to what has just been said, why an optimized, perfectly implanted and well osseointegrated implant can fail!

Maybe we will still be able to reply to the open questions within a time frame that will allow metal-on-metal to prove itself as a viable alternative to a bearing that generates polyethylene debris. Two elements could encumber this future. First, the emergence of a new bearing that could, as was the case for "the Charnley" versus "the McKee", overthrow metal-on-metal before we even have a perfect grasp of its indications [3]. And second, financial considerations [2] that impose their laws in the selection of our implants around the globe.

While awaiting the answers to these questions, one can only bear in mind that the use of this articulation remains the surgeon's decision: the indication and the surgical technique are the common and preliminary denominators for any satisfactory result.

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