Chapter 10
Why Metal-on-Metal: What Laboratory Tests Have Shown Us

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Introduction

Given the demographic changes of the populations in particular in western countries, there is an increasing demand for hip arthroplasty. Already now, more than one million artificial hip joints are implanted worldwide. Rates for primary and revision total hip arthroplasty are even outnumbering initial projections [14].

The increasing use of joint replacements in young and active patients further stresses the need of implant durability. For the selection of suitable materials, three main types of materials are used: ceramics, metals and polymers. The bearing surfaces of implants undergo friction and wear. Metal-on-metal (MoM) bearings were reintroduced in hip arthroplasty to face the issues of polyethylene wear with its potential of inflammatory tissue reactions resulting in bone loss and implant loosening. The prevalence of MoM bearings—in the form of resurfacing arthroplasty and conventional arthroplasty—was rising in part also due to their popularity amongst young and active patients. However, even patients with well-functioning MoM arthroplasty may show increased blood cobalt (Co) and chromium (Cr) levels that often reach a steady state after about 2 years. Such ion and particle release may lead to intolerance reactions including hypersensitivity. Accordingly, a spectrum of adverse local

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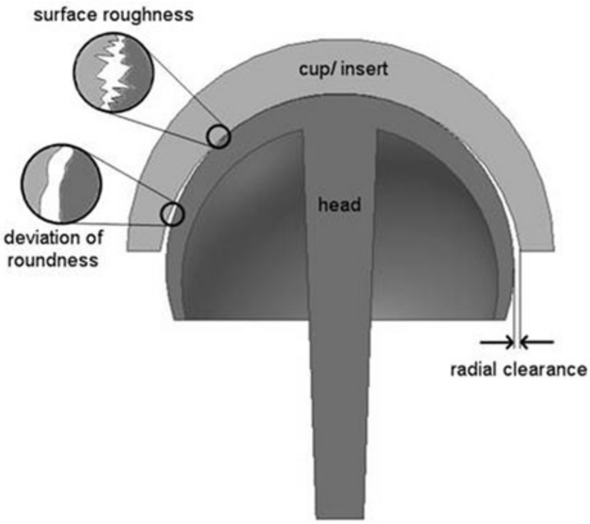

Fig. 10.1 Scheme of MoM implant. (Adapted from Kretzer P. [12])

tissue reactions to metal debris has been described and an immune response may result in complications like pain, osteolysis, loosening and—in a small number of patients—formation of so-called pseudotumors.

Aspects of Materials and Tribology

With regard to the **implant geometry,** ideally, head and cup are ball-shaped elements with slightly differing diameters. The small space between head and cup is described as radial clearance. Even under best polishing and manufacturing conditions, the surfaces are not completely spheric and smooth. Thus, the head and cup may present slight deviations of roundness. The geometric indicators for description of bearing partners include diameter, clearance, deviation of roundness and surface roughness.

Figure 10.1 shows a schematic cut through a MoM surface replacement.

When assessing **metallurgy,** the most widely used alloy in MoM implants is Co28Cr6Mo due to its good wear properties and high corrosion resistance. Traces of nickel, manganese or iron may also be included. The main manufacturing- and material-dependent criteria influencing the mechanical and metallurgical properties of hip implant bearings include: *carbon content of the alloy* (low carbon, lc, $< 0.15\,\%$; high carbon, hc, $\geq 0.15\,\%$), *primary manufacturing method* (cast or wrought) and heat treatment. The carbon content influences the formation of carbides within the matrix material, which increases toughness and wear resistance of the alloy. Using casting technique, larger "blocky" carbides are achieved that are in a size range of some hundreds of microns, whereas wrought material shows smaller carbides that are typically about one magnitude smaller compared to cased carbides.

Hip **simulator wear studies** performed in the last decade—as summarized in a meta-analysis [13]—allow the below listed statements regarding design and manufacturing related parameters and their impact on the wear of MoM bearings:

- For implants with a diameter of 36 mm and above, an increase in head size will result in less running-in wear. If lubrication is not sufficient and components are not at least partly separated by a fluid film, wear might increase due to the longer wear path. Therefore, sufficient lubrication is essential.
- A smaller clearance leads to reduced running-in wear. However, there are limits for the minimum clearance and equatorial contact has to be avoided.
- A smooth surface (low roughness) and a highly spherical geometry (low deviation on roundness) reduce wear.
- The influence of alloy carbon content remains unclear.
- The manufacturing method (wrought vs. cast) seems to not affect wear.
- Heat treatment processes increase wear, at least during the steady-state wear phase.

In general, a direct comparison of different simulator studies is difficult. This is due to the fact that wear of similar implant designs can differ significantly between different investigators. An example of such difference can be seen when directly comparing the findings of Dowson et al. [4] and Chan et al. [1], who investigated an identical implant design. Dowson et al. defined a mean running-in wear rate of 2.3 $mm^3/10^6$ cycles, whereas Chan et al. reported a running-in wear rate about one order of magnitude lower (0.24 $mm^3/10^6$ cycles). These data may explain the restrictions that apply to the comparability of wear studies from different investigators.

Many parameters add to minimising wear and improving outcomes apart from purely technical characteristics of artificial joints. Important factors encompass positioning and orientation of implant components during surgery. Wear of MoM implants increases with increasing cup inclination angle [9]. The risk of impingement (contact of implant neck with implant cup) or luxation (dislocation of the joint) is also influenced by the orientation of the implant components. Additionally, patient-specific aspects such as body weight and activity level are also assumed to impact wear. For example, Kamali et al. showed experimentally, that the gait velocity and also resting periods impact the wear performance of a MoM bearing [10].

Different **wear modes** are used to classify the wear mechanisms of artificial joints. The four wear modes depend on the bearing partners in use. The classification is independent of the bearing partner materials and is thus valid for different types of artificial joints. A schematic overview of the four modes is shown in Fig. 10.2. Mode 1 is represented by articulation of primary bearing surfaces only. Despite production of wear, this mode reflects the ideal conditions implants are designed for. Modes 2–4 stand for malfunctioning implants. In mode 2, a bearing surface articulates with a secondary non-bearing surface. Such a scenario could be found when the head of the implant (sub)luxates and then makes contact with the rim of the cup. This mode 2 can provoke massive wear and rapid failure of an artificial joint. Mode 3 represents the articulation of primary bearing surfaces in the presence of third bodies in the joint space, causing increased abrasive wear. Typical third bodies are metal particles,

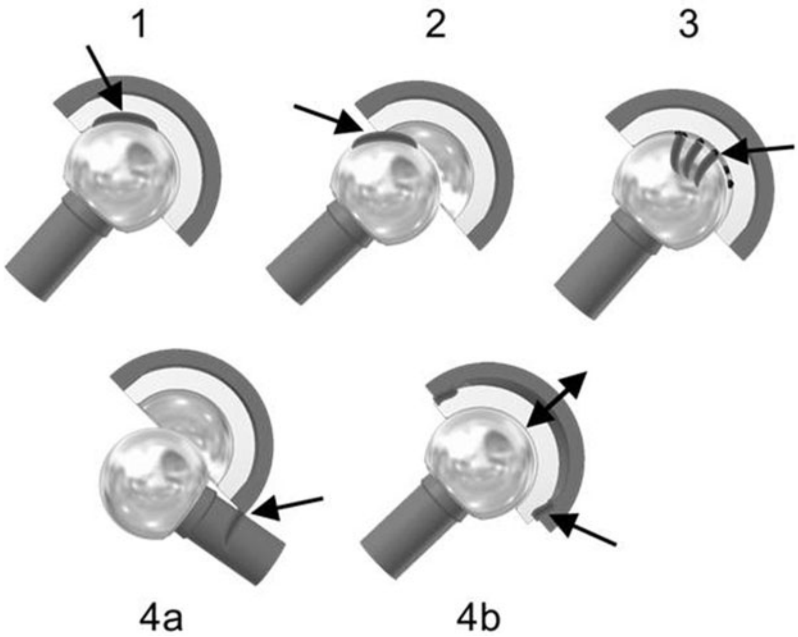

Fig. 10.2 Wear modes (*1–4*) of hip replacements, adapted from [12, 20]

ceramic fragments, bone cement and bone fragments. Third bodies can strongly enhance wear formation. Mode 4 is characterised by articulation of two non-bearing surfaces, for example as impingement or “backside” wear. Backside wear may arise from many conditions including wear between the polyethylene acetabular liner and the metal shell, fretting at the site of modular junctions, and friction between the implant stem and the surrounding bone or bone cement. Fragments and particles generated in mode 4 can reach the joint space and subsequently produce third body wear.

The Metal Ion Concern

Laboratory tests may assess a large number of parameters in accurate and reproducible manner, if standardized procedures and well-functioning laboratory equipment are applied. However, it is important that the test scenario is covering the “real situation“ and that we can assign clinical significance to the test data. This general approach is also valid for MoM arthroplasty. Larsson et al. stressed the potential of disease registries to use outcome data amongst others for learning about the significance of laboratory and clinical data [16]. For example, analysis of data from the national joint registries for England and Wales—as reported by Smith A. J. et al.—showed that (1) hip resurfacings only resulted in similar survivorship to other surgical options in men with large femoral heads, and (2) inferior implant survivorship occurred particularly in women [22]. From a clinical point of view, asymptomatic patients with MoM arthroplasty may also have suboptimal component position and elevated blood ion levels so that an algorithmic approach to diagnosis and management of MoM arthroplasty was suggested [18].

Blood/serum ion levels reflect systemic exposure to metal ions and implicate also local exposure to corrosion products. However, the extent of such exposure is not showing a linear or direct relation to the potential of local adverse tissue reactions. The rare solid pseudotumors are mostly observed with resurfacing procedures—in particular in women. In 2010 Delaunay et al. stated that "... MoM bearing couples are contraindicated in cases of metal allergies or end stage renal dysfunction and small size resurfacing should cautiously be used" [3]. Delaunay also indicated, that "the rate of circulating Co and Cr ions is low when the bearing couple functions well (Co < 1 μg/L)". In contradistinction, the ability of blood metal ion values to discriminate between well-functioning and failed hips is not well known. The British Medicines and Healthcare products Regulatory Agency (MHRA) has suggested a cut-off level of 7 parts per billion (ppb). A. J. Hart and coworkers found in a pre-revision group (mixed with matching controls with well-functioning hip) that the 7 ppb cut-off level had 89 % specificity—but only 52 % sensitivity for detecting a preoperative unexplained failed MoM hip replacement [8]. Accordingly, laboratory tests of blood metal ion level are not regarded by every orthopaedic centre to be the only significant factor in the decision of when to revise a MoM large head total hip replacement. Lingen et al. reported on 10 patients with the highest Co level (18–153 μg/L) within their over 600 patients that had received a stemmed large head MoM arthroplasty: "They were asymptomatic and without signs of neurological, cardiological, thyroid or renal dysfunction" [17]. In contrast, Langton and co-authors found in 35/40 of their patients with hip resurfacing and blood Co levels > 20 μg/L prior to revision "some degree of bone loss" [15]. Finally, in the recent European multidisciplinary consensus statement, the current recommendations for use and monitoring of MoM bearings in hip replacement differ amongst others regarding the eventual threshold level; the threshold level for clinical concern is expected to be within the range of 2–7 μg/L—but needs additional imaging [7]. Thus, laboratory testing has shown us that additional parameters—including several not yet identified patient-related factors—have to be integrated in evaluation.

This statement also applies for the assessment of **peri-implant tissue response.** Apart from the different mechanisms leading to osteolysis [19], we have to remember, that the histological picture only gives a snapshot-view on the actual stage of a dynamic peri-implant process. Krenn et al. had proposed by a consensus classification to subdivide the peri-implant tissue reaction patterns in a particle-dominated foreign body like response (Type I), a granulocyte-dominated infectious type (Type II), the mixture of Type I and II (combined type, Type III) and a paucicellular fibrotic reaction (Type IV, indifferent type) [11] (Figs. 10.3 and 10.4). Threshold levels for neutrophilic infiltrate (23 neutrophils/10 high power fields), indicative of infection, were postulated [21].

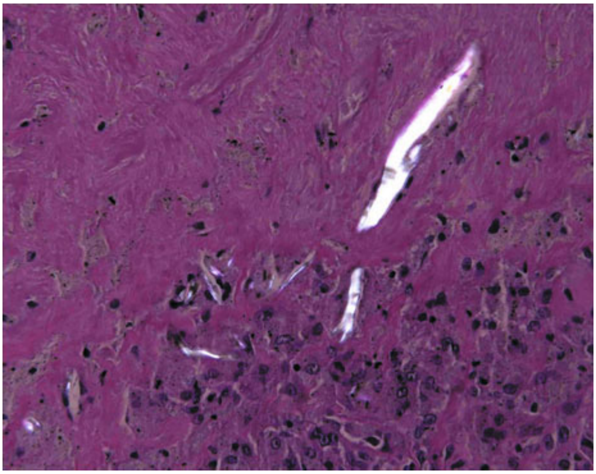

Fig. 10.3 Wear-induced inflammatory reaction, in the center polyethylene fragments (Type I reaction)

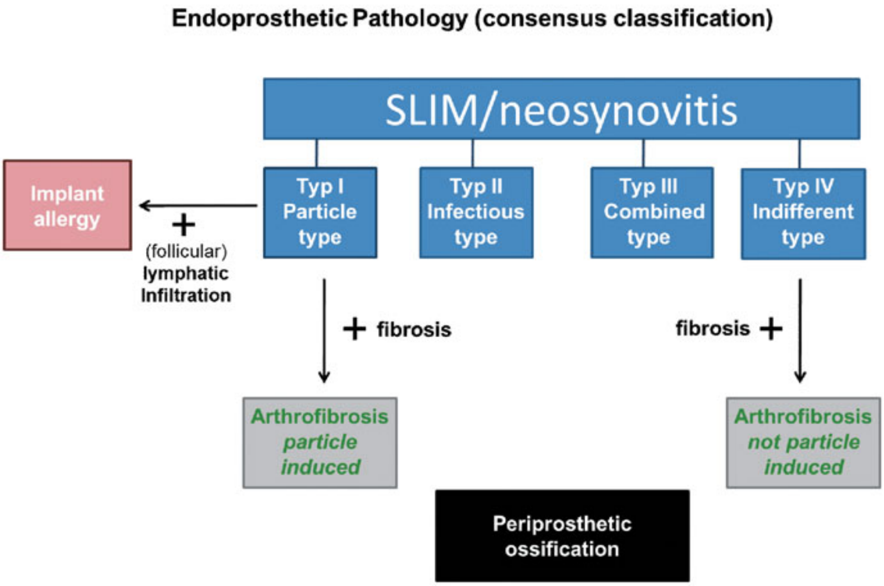

Fig. 10.4 Revised consensus classification according to Krenn et al. [11]. *SLIM* synovial-like interface membrane

Early reports had pointed to the role of lymphocyte-dominated inflammation in loosened MoM arthroplasty [2, 24]—a subtype of peri-implant reactivity, which has been included in the recent revised consensus classification [11]. Delayed type **hypersensitivity**—as reflected by positive patch test reactions and enhanced lymphocyte transformation test (LTT) reactivity to metals—was detected as a potential elicitor of failed MoM-arthroplasty in some patients [23]. Metal sensitivity could be responsible for an overall earlier failure of arthroplasty, but laboratory test results would not always allow identification at the single patient level [5]. Hallab and co-workers pointed to the enhanced LTT reactivity to metals in many implant bearing patients [6]. However, again, further tools are needed to specify the clinical meaning of such enhanced LTT reactivity.

Conclusion and Outlook

Hip arthroplasty has evolved to one of the most frequent and successful elective surgical procedures. Since all materials and their combinations have advantages and drawbacks, a spectrum of materials is in use. Metals are rather wear and fracture resistant—but increased wear can occur especially in the case of imprecise implantation or errors in positioning of components. There is an ongoing discussion on biological effects of metal ions and particles—and risk scenarios of MoM pairing are focus of actual research. This discussion emphasizes the need of objective outcome measures, joint registries and integrated view of clinical findings to interpret the significance of laboratory test parameters.

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