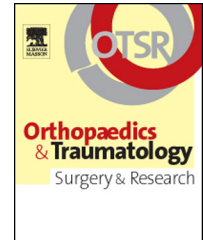




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ORIGINAL ARTICLE

European multidisciplinary consensus statement on the use and monitoring of metal-on-metal bearings for total hip replacement and hip resurfacing

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KEYWORDS

Metal-on-metal bearing;

Summary

Introduction: There is an ongoing debate about the optimal use of metal-on-metal (MoM) bearings in total hip replacement, since there are uncertainties about local and systemic adverse effects due to wear and corrosion of these bearings. Despite various national recommendations,

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Consensus study;
Total hip
replacement;
Hip resurfacing

efforts to achieve international harmonization of specific evidence-based recommendations for best practice are still lacking.

Hypothesis: An international consensus study group should be able to develop recommendations on the use and monitoring of MoM bearings, preferably at the European level, through a multidisciplinary approach, by integrating the perspectives of various stakeholders.

Materials and methods: Twenty-one experts representing three stakeholder groups and eight countries participated in this European consensus study, which consisted of a consensus meeting, subsequent structured discussion, and consensus voting.

Results: The current statement defines first of all benefits, local and systemic risks, as well as uncertain issues related to MoM bearings. Safety assessment after implantation of MoM comprises all patients. A closer follow-up is recommended for large head MoM (≥ 36 mm) and resurfacing. In these implants basic follow-up should consist of x-rays and metal ion measurement of cobalt in whole blood, performed with GF-AAS or ICP-MS. Clinical and/or radiographic abnormality as well as elevated ion levels needs additional imaging (ultrasound, CT-scan and/or MARS-MRI). Cobalt values less than $2 \mu\text{g/L}$ are probably devoid of clinical concern, the threshold value for clinical concern is expected to be within the range of $2\text{--}7 \mu\text{g/L}$.

Discussion: This is the first multinational, interdisciplinary, and multiprofessional approach for developing a recommendation for the use and monitoring of MoM bearings in total hip replacement. The current recommendations are in partial agreement with previous statements regarding the extent of follow-up and imaging techniques. They however differ from previous communications regarding measurement of metal ions and especially the investigated medium, technique, and eventual threshold levels.

Level of evidence: Level V, expert opinion/agreement conference.

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Introduction

As total hip replacement (THR) has been proven to be a highly effective treatment of hip osteoarthritis in the elderly, indications were subsequently extended to young and middle-aged adults as well. Increasing demands in these patient groups due to significant physical activity and higher life expectancy resulted in the development of bearing materials with improved wear characteristics. These “hard-on-hard”-bearings are characterized by potential combinations of highly cross-linked polyethylene, ceramic, or metal cup inserts with ceramic or metal heads.

Metal-on-metal (MoM) bearings have been used with conventional THR for several decades with promising results from early applications [1–4]. Low wear potential of mechanically well investigated prostheses, no relevant risk of material fracture, and a high design variability seemed to justify the application of MoM bearings even in hip resurfacing (HR) and large head hip replacement (LH-THR) [5–7]. Nevertheless, wear and corrosion of these implants may lead to a release of metal products into surrounding tissue and body fluids as well as internal organs. Metal accumulation may result in local “adverse reactions to metal debris” (ARMD) [8], and potentially induce systemic adverse effects (i.e. toxicity, teratogenicity and carcinogenicity) [9–12]. Recent reports on pseudotumor-formation after resurfacing [13–15] and high failure rates of specific HR- and LH-THR-implants [16–19] have initiated a very controversial discussion about the biological effects of MoM implants [20–22].

Since these safety concerns have been raised, several health authorities and scientific societies in different

countries have published recommendations for the use and monitoring of MoM implants [23–27].

However, most of them are focusing on clinical issues and do not take patient perspectives (i.e. appropriate communication) or future research needs into account. Typically orthopaedic surgeons have been involved in national orthopaedic society communications and other disciplines (i.e. allergology, toxicology, biomonitoring) did not contribute significantly. Finally, national recommendations have to take specific regulations of their healthcare systems into account and can therefore not be transferred to a generalized level without adaptations.

We performed an international consensus study on the use of metal-on-metal bearings for total hip replacement. Primary aims of our initiative were:

- to develop recommendations preferably on the European level;
- through a multidisciplinary approach;
- integrating the perspectives of various stakeholders (i.e. patients, clinicians, material science experts, epidemiologists, and regulatory agency representatives).

Material and methods

Material

The study consisted of a consensus meeting and subsequent structured discussion and consensus voting. Overall, 24 experts were invited to participate in the study as panel members. Twenty-one (88%) experts representing three stakeholder groups (physicians, patients regulatory

Table 1 Characteristics of expert panel.

	Invited (number)	Participated (number, %)
<i>Field of expertise</i>		
Orthopaedic Surgery	13	10 (77%)
Biomechanics	2	2 (100%)
Biomonitoring	2	2 (100%)
Basic research/Pathology	2	2 (100%)
Epidemiology/Occupational medicine	2	2 (100%)
Allergology	1	1 (100%)
Patients regulatory representative	1	1 (100%)
Regulatory agency representative	1	1 (100%)
<i>Country</i>		
Germany	12	12 (100%)
Great Britain	3	2 (67%)
Austria	1	1 (100%)
France	1	1 (100%)
Spain	1	1 (100%)
USA	2	2 (100%)
Italy	1	1 (100%)
Netherlands	2	1 (50%)
Belgium	1	0 (0%)
<i>Gender</i>		
Female	2	2 (100%)
Male	22	19 (86%)

representative, regulatory agency representative), and eight countries participated in the initiative (Table 1). Endorsement was given by “European Federation of National Associations of Orthopaedics and Traumatology” (EFORT), “European Hip Society” (EHS), “Arbeitsgemeinschaft Endoprothetik” (AE), and “German Osteoarthritis Society”. On behalf of these institutions, the organizers (KPG, JS) proposed potential panel members based on their expertise and previous scientific work related to the topic.

Methods

The consensus meeting took place on April 15–16, 2012 in Dresden, Germany.

Aim of the expert conference was to develop an evidence- and consensus-based recommendation through a structured, iterative process (Fig. 1).

Prior to the meeting the following five key questions were distributed to the panel members:

- what is the current evidence on the benefits (effectiveness), risks and uncertainties of metal-on-metal (MoM) bearings?
- how is safety assessment of patients after implantation of MoM bearings ensued?
- what are the indications for revision of MoM implants for safety reason?
- what is the appropriate communication/distribution of recommendations to stakeholders?
- what are unmet medical needs for future research?

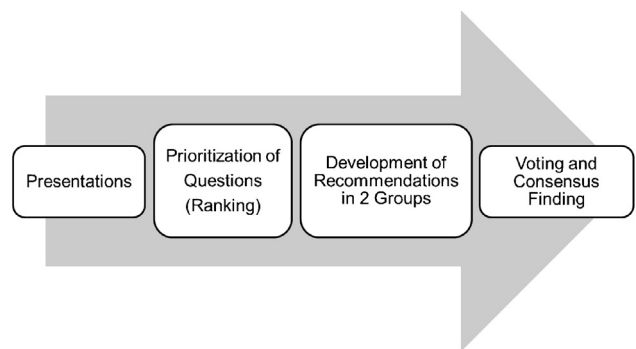


Figure 1 Process of consensus decision-making of statements and recommendations.

Brief opening presentations addressed available surgical interventions for hip osteoarthritis focusing on MoM bearings and currently available national recommendations for the use of MoM implants. They included current evidence on metal ion concentrations in body fluids after MoM THR, the characterization of local tissue response due to metal debris, potential systemic reactions resulting from elevated metal ion levels, as well as the clinical relevance of local and systemic reactions including therapeutic options.

Following the presentations every participant was asked to assess the importance of each question and the availability of information/recommendations in the scientific literature on a Likert-scale ranging from 1 (lowest relevance and availability) to 9 (highest relevance and availability). It was defined that the scale range 1–3 corresponds to a low relevance/availability of recommendations, the scale range 4–6 to a mid-level relevance/availability of

Table 2 Composition of groups.

Group 1	Group 2
Orthopaedics (Moderator)	Allergology/ Epidemiology (Moderator)
Basic research	Pathology
Biomonitoring	Biomonitoring
Epidemiology	Occupational medicine
Biomechanics	Biomechanics
Orthopaedics	Orthopaedics
Orthopaedics	Orthopaedics
Orthopaedics	Orthopaedics
Orthopaedics	Orthopaedics
Regulatory agency representative	

recommendations, and a scale range 7–9 to high relevance/availability of information. Additionally, participants were asked to prioritize up to three most relevant questions related to MoM bearings. Median ratings as well as the interquartile range (25th–75th percentile) of each question were reported back to the expert panel.

The consensus procedure consisted of a double-staged process. Participants were first divided in two interdisciplinary groups (Table 2). Homogeneity was achieved with regard to the distribution of disciplines and competencies within both groups.

Firstly, both groups independently drafted statements and recommendations to the five key questions aiming for high intra-group agreement. Secondly, both groups presented the acquired statements and recommendations to each other. For each question, the statements of both groups were discussed, merged, and critically revised resulting in draft answers for consensus voting by the whole panel.

It was determined a priori, that at least 70% of the participants (equal to 13 participants) had to agree with a statement/recommendation to reach a consensus within the whole group.

During the conference, a consensus was achieved on questions 1, 2, and 3. Working groups for drafting recommendations for the remaining questions 4 and 5 were established (question 4: JS, AH, KPG, WL; question 5 PC, MM, MAW). Subsequent to the conference, the proposals for questions 4 and 5 were sent to all participants for online consensus voting. Proposals for modification were considered, revised suggestions were forwarded until consensus was reached.

Results

Relevance of each question and availability of information/recommendation

In general, the relevance of all five key questions of interest was considered as high by the panel. Availability of information however, was considered moderate at most (Fig. 2).

Research priorities concerning MoM bearings as defined by the panel were:

- incidence and clinical relevance of local and systemic reactions due to metal wear and corrosion, especially with regard to long-term exposure to elevated metal ion concentrations ($n=6$ panel members);
- importance of taper connection in the context of wear and corrosion ($n=3$);
- kind and extent of postoperative monitoring ($n=3$);
- suitable laboratory procedures for determining metal ions ($n=2$);
- threshold levels for concentrations of metal ions in body fluids ($n=1$);

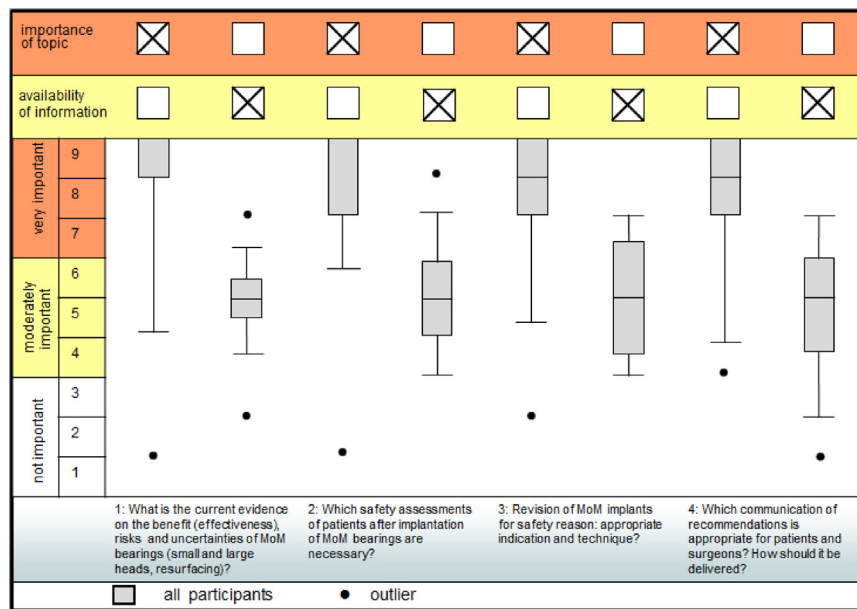


Figure 2 Results of Ranking of the five key questions, showing high relevance and mostly moderate availability of information/recommendation for each of them.

- handling of asymptomatic patients at risk ($n = 1$);
- indications for revision ($n = 1$).

Process of consensus finding

The outcomes of the group work, concerning the drafts of the two groups for the recommendation, were similar for questions 1 to 3. Issues that were particularly relevant to clinical practice such as indications for revision and threshold ion levels had to be discussed extensively to reach consensus.

Recommendations

In the following, the final recommendations of the consensus panel are presented. The results of the voting for questions 1 to 5 are provided in parentheses.

What is the current evidence on the benefits (effectiveness), risks and uncertainties of Metal-on-Metal bearings

What are the benefits (effectiveness)? (20 agreed – 1 abstained – 0 disagreed).

- MoM is currently the only technique for surface replacement;
- there are no polyethylene particles in pure MoM bearings that may cause osteolysis;
- MoM bearings produce less volumetric wear compared to conventional polyethylene;
- there is a reduced risk of fracture in MoM bearings compared to ceramics;
- large head total hip replacement (THR) (36mm head size and larger) as well as hip resurfacing have a reduced risk of dislocation compared to small head THR (28–32mm head size). In large head THR range of motion increases with the head size (only up to 40mm);
- hip resurfacing allows more preservation of bone stock on the femoral side when compared to conventional THR.

What are the known risks? (21 agreed – 0 abstained – 0 disagreed). Local risks:

- due to small wear particle size the joint capsule is exposed to a larger amount of particles compared with polyethylene;
- small heads: little additional risk of adverse reaction to metal debris (ARMD) when compared to conventional bearings;
- large heads: higher risk for ARMD compared to conventional bearings. Elevated risk of taper wear and rim loading;
- resurfacing: risk for ARMD esp. with decreasing size, female patients, and low coverage arc. Risk for femoral neck fracture. Potentially more bone consumption at acetabular side in primary cases and in revision cases.

Systemic risks:

- distribution of metal products to nervous system and other organs through blood circulation;
- accumulation of metal ions in patients with renal dysfunction with unknown consequences.

What are the uncertain issues? (21 agreed – 0 abstained – 0 disagreed).

- Long-term effects of metal products (i.e. particles, ions, metallo-organic compounds) including systemic effects (i.e. carcinogenicity, teratogenicity, and toxicity);
- predictive value of metal ion blood levels for local and systemic adverse effects.

Safety assessment of patients after implantation of MoM bearings

Is systematic follow-up recommended? If yes – for which implants and patients? (20 agreed – 1 abstained – 0 disagreed).

- Yes, for all patients and all implants. For small MoM heads in THR a systematic follow-up comparable to conventional THR is sufficient. For large MoM heads and resurfacing closer follow-up is recommended;

How long and how frequently should asymptomatic patients be monitored? (17 agreed – 3 abstained – 0 disagreed; one expert left the meeting before voting). For the life of the joint:

- small heads: as frequent as conventional THR;
- large heads: annually;
- resurfacing: annually for the first 5 years, then according to local protocols for patients with conventional THR. If metal ion levels are normal at year 1 and 2 post-operatively, the frequency of further annual follow-up investigations may be changed to local protocols for conventional THR. In patients with risk factors such as small size (< 50mm femoral component), female gender, and low coverage arc annually for the life of the joint.

Which imaging techniques should be applied during follow-up? (20 agreed – 0 abstained – 0 disagreed).

- X-rays in all patients;
- in case of clinical/radiographic abnormality additional imaging (ultrasound, CT-scan, and/or MARS-MRI [ordinary MRI without MARS-technique is ineffective]);
- in case of Co-values above a certain threshold (within the range of 2 to 7 $\mu\text{g/L}$; exact level still to be determined): ultrasound, CT-scan, and/or MARS-MRI.

How should monitoring of metal ions be performed: Frequency, sources, (blood/serum), technique, reference values? (17 agreed – 3 abstained – 0 disagreed).

- Frequency: time of regular follow-up in asymptomatic patients; in all symptomatic patients additionally between regular follow-up;

- source: metal ion determination of body fluids can be performed in blood, serum and urine. At present measurement of whole blood is most practical. Co should be monitored as reference substance;
- technique: metal ion measurement must be performed under the rules of internal/external quality control. GF-AAS and ICP-MS are considered as valid. The preferred reporting units should be micrograms/liter (= ppb);
- reference values: Co-values without clinical concern are at the moment: less than 2 $\mu\text{g/L}$. The threshold value for clinical concern is expected to be within the range of 2 to 7 $\mu\text{g/L}$ (exact levels have still to be determined within this range);
- in increased values above the threshold additional imaging even in asymptomatic patients is recommended.

Note: recommendations are based on local effects; critical values for systemic effects have not yet been established for patients after MoM implantation.

What are the indications for revision of MoM implants for safety reasons?

What is the appropriate management for local ARMD? (20 agreed – 0 abstained – 0 disagreed).

- In asymptomatic patients small fluid collections indicative of ARMD need close monitoring (repeated imaging is recommended);
- in symptomatic patients and/or patients with progressive osteolysis, large or expanding pseudotumor, and/or progressive neck thinning, and/or Co-ions above threshold level, revision should be considered.

What is the appropriate management for elevated metal ions in asymptomatic patients? (What is a critical level/cut-off level for clinically relevant complications?) (19 agreed – 1 abstained – 0 disagreed).

- In asymptomatic patients elevated levels at first detection should be confirmed through repeated measurement;
- above a threshold of 2 to 7 $\mu\text{g/L}$ (exact level still to be determined) additional imaging and closer follow-up is recommended. In case of pathological results of additional imaging and/or further significant increase of Co-level, revision surgery should be discussed with the patient, as significant metal accumulation with local ARMD is to be expected (especially in Co-values > 20 $\mu\text{g/L}$);
- in case of excessive elevation (Co approximately 20 $\mu\text{g/L}$ or above), because of potential osteolysis, tissue necrosis, and long-term health effects, revision surgery should be discussed with the patient;
- the individual risk-benefit-ratio should be considered before intervention.

Is routine monitoring of metal ions necessary after removal? (20 agreed – 0 abstained – 0 disagreed).

- Routine monitoring of metal ions after removal of MoM bearings is not recommended, as no effective

interventions can currently be recommended in case of increased metal ions.

Appropriate communication/distribution of recommendations to stakeholders

What is the best approach to communicate with patients? (21 agreed – 0 abstained – 0 disagreed).

- Before intended surgery with MoM bearing implants every patient must be informed comprehensively in written and oral form about the benefits, risks, uncertainties, and recommended monitoring concerning MoM bearings. There should be a dialogue between the patient and the surgeon;
- patients with already implanted large head MoM THR and hip resurfacing should be informed that a higher frequency of monitoring is recommended compared to conventional MoM bearings;
- risks and benefits should be expressed by patient-relevant outcomes such as morbidity, health-related quality of life, and risk of adverse events. Absolute risk estimations are preferable to relative risk estimations. It should be highlighted that a complete (100%) prediction of positive or adverse outcomes is not possible. Uncertainties concerning both, risks and benefits, should be made explicitly;
- ideally, the patient information should be based on a systematic and comprehensive literature review;
- the information should allow patients informed decision-making concerning the implantation of MoM bearings as well as indication for revision in problem-cases;
- different stakeholders including but not necessarily limited to patient organizations, orthopedic surgeons, toxicologists, and epidemiologists should be involved in the development of the patient information. Any potential conflicts of interest of persons involved in the development of the patient information should be declared;
- the access to the information should be possible for free without any cost barrier. Information may be disseminated in different formats, through different media, and/or organizations, but should be identical in content.

How should surgeons be informed? (21 agreed – 0 abstained – 0 disagreed). Information provided to surgeons should:

- cover comprehensively and understandably the benefits, risks, uncertainties, and recommended monitoring concerning MoM bearings including product-related as well as implantation-related aspects;
- include the advice to assess and consider the patient's individual benefit-to-risk-ratio prior to surgery;
- include the recommendations as described above concerning safety assessment of patients after implantation of MoM bearings as well as indication for revision surgery;
- be based on a systematic and comprehensive literature review. The information should highlight the evidence-level of any recommendation (i.e. expert opinion, single RCT, single non-RCT, meta-analysis of randomized/non-randomized studies);
- include a declaration of potential conflicts of interest of persons involved in the development of the information;

- be disseminated in different formats, through different media, and/or organizations, but should be identical in content;
- be provided to other medical disciplines (i.e. neurologists, cardiologists, oncologists) as patients with MoM implants may seek their advice.

Unmet medical needs for future research?

Preclinical research: (21 agreed – 0 abstained – 0 disagreed). It is necessary, to:

- investigate the influence of relevant parameters on wear and corrosion of taper connections (taper size, diameter and length), material, texture, head diameter, joint articulation friction, assembly forces and direction. Wear products from taper interfaces and joint articulation should be differentiated, if possible;
- determine the mechanisms creating particles/ions/metallo-organic compounds or aggregates in large (≥ 36 mm) and small (< 36 mm) MoM bearings functioning under ideal and suboptimal conditions. The distribution of nanoparticles should be determined;
- determine the potential impact of additional metal ions (i.e. titanium);
- investigate the interaction between wear and corrosion of MoM interfaces and to develop appropriate preclinical testing methods; means (by design or metallurgy) to avoid synergistic corrosion effects should be identified;
- establish in vitro models to investigate local and systemic consequences of metal debris (i.e. 3-d scaffolds).

Clinical research (21 agreed – 0 abstained – 0 disagreed). It is necessary, to:

- perform comparative tests to identify reproducibility of metal ion measurements among different labs;
- investigate urine as a screening tool for malfunctioning MoM bearings;
- determine metal ion levels after the implantation of any kind of artificial implant (i.e. knee arthroplasty, spine implants and osteosynthesis devices) and to investigate associations with clinical symptoms;
- establish joint registries with better documentation of revision reasons;
- examine correlations between the presence of wear/corrosion at taper connections and the presence/extent of adverse local tissue reactions (i.e. necrosis, pseudotumor);
- determine true incidence as well as clinical relevance of ARMD in all MoM implants. Adverse reactions from small/large head MoM THR should be compared to that of hip resurfacing;
- determine the local and systemic distribution and pathological effects of particles/ions/metallo-organic compounds produced in MoM bearings;
- investigate effects of long-term exposure to metal ion concentrations between 2 and 7 $\mu\text{g/L}$ by determining the change in circulating T- and B-cells in patients with varying levels of metal ions;

- determine the incidence and clinical relevance of potential systemic effects of metal products including organ toxicity, carcinogenicity and teratogenicity.

Discussion

This is the first multinational, interdisciplinary and multiprofessional approach to develop recommendations for the use of MoM bearings for total hip replacement. Unlike several previous communications [25–27] our consensus study and the resulting recommendations for the use of MoM bearings are based on the opinion of experts from different medical fields and stakeholder groups including patients, clinical experts, methodologists, and regulators. Consensus methods such as explicit rules and an iterative, structured process involving all panel members have been employed to generate consensus. Endorsement of the consensus initiative was given by ‘‘European Federation of National Associations of Orthopaedics and Traumatology’’ (EFORT), ‘‘European Hip Society’’ (EHS), the German ‘‘Arbeitsgemeinschaft Endoprothetik’’ (AE), and ‘‘German Osteoarthritis Society’’.

In addition to these strengths, our study also has some limitations. Although the panel was well-staffed with international and multidisciplinary participants, German participants and orthopaedic surgeons were overrepresented, however German participants represented eight fields of expertise. As up to date systematic reviews or meta-analyses concerning the risks, benefits and uncertainties of MoM bearings are missing, panel members based their votes on individual knowledge of the best available research evidence as well as their clinical experience. Currently, a systematic review is being performed by members of our panel. Preliminary results seem to support the recommendations of the presented consensus study i.e. threshold levels of metal ion concentrations, but heterogeneity in study designs, patient populations, and methodological approaches does not allow a straight forward summary of the published evidence. Therefore, multiperspective and multiprofessional expert knowledge and experience is highly valuable to provide appropriate guidance to clinicians and consumers.

Our recommendation is in partial agreement with previous statements from national societies and institutions [23–28]. In our statement, as well as in other statements, the patient management depends on the type of prosthesis, as the clinical relevance of metal-related problems in small head MoM THR is clearly smaller than the relevance of large head THR (head diameter 36 mm or larger) and resurfacing devices. In the latter, specific design types (i.e. ASR resurfacing) and unfavorable positioning need special attention [23,26,27]. In most recommendations [23,25,26,28] a systematic follow-up for patients with large head THR and resurfacing with annual clinical follow-up examinations (at least for 5 years, if not lifelong) is proposed. The need for appropriate imaging is also an issue where all published statements agree: conventional radiography should be supplemented by ultrasound, CT-scans and/or MRI in order to detect soft-tissue destruction. If MRI is performed, metal artifact reduction sequence (MARS) technique is recommended.

The primary focus of our expert consensus recommendation is the safety of patients, who have received MoM implants in the past or will undergo operations in the future. We are aware that the recommended routine monitoring measures with systematic follow-up investigations including metal ion analysis and imaging may also have economic impact. To address this issue, however, was not the focus of our consensus study. Future health-economic investigations are necessary to evaluate the long-term cost-effectiveness of the recommendations made. Such investigations should not only include the financial burden which is created by diagnostic algorithms but also the economic impact caused by surgical treatment at early versus late stages of local and systemic ARMD. In addition, substantial differences of national reimbursement procedures regarding cost regulation of monitoring programs may be expected amongst different countries.

Recommendations regarding metal ion analysis are controversial: there is no international consensus whether chromium and/or cobalt should be monitored. Threshold levels for further investigations are only provided by some institutions [26,27]. They indicate that a blood metal ion level of larger than 7 ppb indicates potential for soft tissue reaction [27]. Others feel that there is not enough evidence for setting clear cut-off levels in serum or blood that would serve as a trigger for intervention or correlate with adverse systemic effects for individual patients [23,25,28]. While several investigators have provided median concentrations (and ranges) of cobalt/chromium ion levels corresponding with good or bad functioning MoM implants [8,13–15,18,29], only Hart et al. [30] and van der Straeten et al. [31] report precise threshold levels (e.g. in the latter study, 4.97 ppb and 4.0 µg/L for cobalt in unilaterally operated patients) with additional information regarding sensitivity (63% respectively 25%) and specificity (86% respectively 95%) of these values. Taking into account these observations, the previously defined institutional recommendations to set a cut-off level of 7 µg/L are not anymore sufficient and should be changed appropriately.

Currently no evidence exists that cobalt concentrations below a level of less than 2 µg/L are generally associated with metal-related health problems. Therefore we developed the consensus opinion that cobalt should be used as the reference with values less than 2 µg/L representing a level without clinical concern (in the absence of clinical signs or symptoms of local adverse reactions). In addition we have defined a range of 2 to 7 µg/L, where we expect a future threshold value for clinical concern when appropriate evidence becomes available to develop a precise cut-off level.

Our recommendation of a threshold level within the range of 2 to 7 µg/L relates to unilateral MoM hip implants exclusively. Currently there is not enough data available to give any valid statement on cut-off levels neither for bilateral MoM hip implants nor for other metal implants (i.e. knee arthroplasty or osteosynthesis devices).

Hardly any published statement gives a recommendation about the appropriate source of metal ion analysis (i.e. whole blood, serum, urine) measurement technique and information if chromium and/or cobalt ion levels shall be measured [23–28]. Metal ion determination of body fluids can be performed in blood, serum and urine. Our panel

members feel that at present measurement of cobalt levels in whole blood is most practical.

We are aware that the availability of qualified laboratories with the ability to perform routine metal ion analyses may be limited. It may also be difficult to identify appropriate institutions during routine THR follow-up investigations. From our point of view it is necessary, however, to develop individual arrangements on an institutional level to provide qualified and valid mechanisms of metal ion analyses as an important measure of risk assessment.

In addition we have listed detailed proposals for communication with relevant stakeholders. We consider it as very important to inform patients as well as surgeons about the current medical background regarding indication for surgery with MoM implants as well as appropriate monitoring alternatives.

Finally, we made specific recommendations regarding a detailed agenda of research questions which should be addressed in the future. Considering the lack of relevant information in several important areas, it is mandatory to obtain better information through targeted research. An improved MoM patient outcome data base should enable us to extend the aforementioned recommendations in the future and to answer relevant questions more specifically. The recommended research should be supported by the different stakeholder groups.

In summary, we have developed recommendations for MoM bearings based on clinical practice and the best currently available research evidence. The current consensus statement contains information on the appropriate follow-up for patients with already implanted MoM devices as well as detailed recommendations for communication with stakeholders and necessary research activity. We hope that this information contributes to the management of patients with MoM THR or HR and helps to identify future research needs.

Disclosure of interest

Several members of the expert panel (PC, CPD, KPG, AH, CHL, LDJ, MM, MAW) indicate that they have received funding from commercial parties/industry companies related to Metal-on-Metal research (i.e. ATI Allvac, Aesculap, Ceramtec, DePuy, Finsbury, Mathys, Plus Orthopaedics, Smith&Nephew, Stryker, Wright Medical, Zimmer).

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