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REVIEW

Current expert views on metal-on-metal hip resurfacing arthroplasty. Consensus of the 6th advanced Hip resurfacing course, Ghent, Belgium, May 2014

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ABSTRACT

This paper reports the consensus of an international faculty of expert metal-on-metal (MoM) hip resurfacing surgeons, with a combined experience of over 40,000 cases, on the current status of hip resurfacing arthroplasty. Indications, design and metallurgy issues, release of metal ions and adverse soft tissue reactions to particles, management of problematic cases and revisions, as well as required experience and training are covered. The overall consensus is that MoM hip resurfacing should not be banned and should be viewed separately from MoM total hip arthroplasty (THA) with a large diameter head because of the different design and wear behaviour related to the taper/trunnion connection. The use of hip resurfacing has decreased worldwide but specialist centres continue to advocate hip resurfacing in young and active male patients. Regarding age the general recommendation is to avoid hip resurfacing in men older than 65 and in women older than 55, depending on the patient activity and bone quality. Female gender is considered a relative contraindication. Most surgeons would not implant a MoM hip in women who would still like a child. Regardless of gender, there is a consensus not to perform hip resurfacing in case of a femoral head size smaller than 46 mm and in patients with renal insufficiency or with a known metal allergy. Regarding follow-up of hip resurfacing and detection of adverse local tissue reactions, metal ion measurements, MRI and ultrasound are advocated depending on the local expertise. The consensus is that hip resurfacing should be limited to high volume hip surgeons, who are experienced in hip resurfacing or trained to perform hip resurfacing in a specialist centre.

Keywords: Hip resurfacing, Metal-on-metal, Expert consensus

Introduction

Anno 2014, metal-on-metal (MoM) hip arthroplasty in general and hip resurfacing in particular has become controversial (1-3). Despite the fact that an estimated 1,000,000 current generation MoM hip replacements (total hip arthroplasty and hip resurfacing) have been performed worldwide since 1996 (4) with excellent results from experienced surgeons (5-7), there have been many reports of increasing numbers of revisions for unexplained pain and soft tissue reactions, especially with certain designs of hip resurfacing arthroplasty (8) (HRA) and with MoM total hip arthroplasty (THA) with large diameter heads (1-3, 9). Several national health authorities, regulatory agencies, orthopaedic associations and recently the European Commission have issued their recommendations on the use of MoM hip replacement and hip resurfacing implants and on the management of patients with a MoM hip replacement (10-14). However, many questions remain unsolved especially with regard to follow-up evaluations including the measurement and interpretation of metal ion levels, the interpretation of cross-sectional imaging and the logistics of performing these evaluations on a broad scale. Another issue is the management of problematic cases. Therefore, an international faculty of very experienced hip replacement and hip resurfacing surgeons and researchers gathered to reach a consensus opinion on the most important questions on MoM hip resurfacing including indications, design and metallurgy issues, interpretation of metal ion measurements and adverse soft tissue reactions, routine follow-up and practical management of problematic cases and revisions, as well as required experience and training. Furthermore the issues with MoM THA with large diameter heads were addressed. Medical consensus is a public statement on a particular aspect of medical knowledge that a representative group of experts in the matter agree to be evidence-based knowledge

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TABLE I - Demographics of the course participants

	Out of 118 hip surgeons participating in the course				
Age	<40 years	40-50 years	50-60 years	>60 years	
	14.7%	26.5%	41.2%	17.7%	
Residence	Europe	USA	Australia	Canada	Other countries
	72.5%	12.5%	2.5%	2.5%	10%
THA yearly	20-50	50-100	100-200	>200	
	15.4%	30.8%	26.9%	26.9%	
HRA yearly	<10	10-20	20-50	50-100	>100
	29.6%	11.1%	22.2%	11.1%	26.0%
% HRA	<5	5-10	10-20	20-50	50-100
	17.4%	21.7%	13.0%	34.8%	13.0%

and/or state-of-the-art practice at the time the statement is made (15). Its main objective is to advise the medical community on the best possible and acceptable way to diagnose and treat certain disorders or on how to make decisions in particular circumstances. Medical consensus is usually obtained by gathering an independent panel of experts in the specific field, either via a medical association or conference or via a government or regulatory institution. Consensus statements only provide an expert opinion of the state of knowledge on a particular topic, problem, procedure or method at a particular moment in time. Since scientific knowledge and practical experience are rapidly evolving and improving, consensus statements need to be re-evaluated repeatedly. The purpose of consensus statements is to provide a better understanding of specific issues. Therefore, consensus statements are different from medical guidelines. They are not based on unanimity. According to the NIH, "Consensus statements synthesise new information, largely from recent or ongoing medical research, that has implications for reevaluation of routine medical practices. They do not give specific algorithms or guidelines for practice."(16).

The consensus in this paper is specifically referring to the Sixth Advanced Course in Ghent, Belgium in May 2014 where hip resurfacing experts convened.

Methods

At the Advanced Hip Resurfacing Course in Ghent, Belgium, held from 28 to 31 May 2014, the opinions of an international faculty of experts and of the audience were recorded with a voting system offering different possible answers to 47 questions. Each voting was followed by a discussion.

The total number of THA performed by Faculty and Attendees amounted to 102,174. The total number of resurfacing procedures was 40,087. The total number of hip arthroplasties refers to the number placed by all participants together and reflects their whole carreer. Of course some of the participants are older than others and the length of their career is different. For total hip arthroplasties it is therefore difficult to state a period. For hip resurfacings we can fairly state the period runs from 1997 to May 2014.

The combined experience of the surgeons and voters demonstrates the importance of this consensus. The demographics of the course participants are outlined in Table I.

Since 2012, the hip resurfacing practice of the surgeons has decreased in 47% and stayed equal in 25% of hip arthroplasty practices. In 6% the resurfacing practice was stopped voluntary, where in 6% it was stopped by others (government or hospital).

It had increased in 9% of the hip resurfacing practices.

Results of the consensus votings and discussions

Indications for hip resurfacing

Age

Different age limits were discussed for males and females. Since the failure rate of hip resurfacing is thought to be higher in older people, 82.2% of participants agreed that general osteoporosis as confirmed on DEXA bone mineral densitometry (BMD) scans was an absolute contraindication and that a safe general recommendation was not to perform a hip resurfacing in men older than 65 years of age and in women older than 55 years (postmenopausal). At the previous consensus meeting in 2012 there was no agreement with regard to the necessity of performing a DEXA scan in all females older than 55 years (39.4% were advocates, 42.3% found that unnecessary but would assess the bone quality on x-rays and in relation with the patient's general health and activity level and 18.3% would perform DEXA scans in cases of doubt). However, it was advocated in 2012 and in 2014 to primarily consider the physiological age of the patient based on activity level and bone quality at the hip which is confirmed by studies showing no significant difference between THA and HRA especially

in older men (17-19). With our ageing population remaining more active and healthy for a longer period of time, the physiological age is the most stringent argument in the decision whether or not to perform a hip resurfacing. In any case DEXA BMD assessment at the hips (and the lumbar spine for diagnosis of general osteopenia/osteoporosis) was considered the easiest and most reliable way to determine bone quality in the >65 years age group.

Gender

Female gender was regarded as an absolute contraindication by 16% of the participants, while 60% believed gender was not the issue, but size. However, being a female and less than 40 years old was considered an absolute contraindication by 21% of participants because of the possibility of pregnancy and transplacental transfer of metal ions. Although teratogenicity of metal ions from MoM hips has not been demonstrated (20, 21), and systemic metal ions in newborns from mothers with a MoM hip disappear after a few days (22), caution is advocated, since the long-term effect of early life exposure to metal ions is unknown. Being a female and older than 55 was not considered an absolute but a relative contraindication (71%), depending on bone quality and activity level as outlined above.

Femoral head size

Regardless of gender, a small head size of less than 46 mm was considered a relative contraindication by 46,3% of participants, provided the coverage angle of the implant is large enough to avoid edge wear, while for 46,3% of participants head size smaller than 46 mm was an absolute contraindication. 2,4% even considered a head size smaller than 50 mm an absolute contraindication.

Diagnosis

Avascular necrosis (AVN) was considered a good indication for hip resurfacing by 50% of the participants. The consensus was however, that AVN is an indication for hip resurfacing provided enough healthy bone is present for a good femoral head fixation and for the creation of a circumferential seal. The osteonecrotic area cannot be larger than one third of the femoral head. The same criteria stand for Legg-Calvé-Perthes disease or slipped epiphysis as an indication. In hip dysplasia, it was agreed that the centre of rotation of the hip has to be moved to the anatomic position, the cup placed in the true acetabulum if possible and the osteophytes removed. 67.5% of the participants confirmed to use a special dysplasia cup at least in some cases. But for most participants, hip dysplasia was an absolute contraindication for hip resurfacing (84.1%). Rheumatoid arthritis was considered an absolute contraindication by 63.6% of the surgeons and grossly abnormal anatomy by 83.3%.

Bone quality

41.2% of the participants consider bone quality to be more important than age when deciding on implanting a hip resurfacing or not. However, it is difficult to define or quantify acceptable bone stock and quality. Large cysts or osteonecrotic areas, severe bone loss at the femoral head and osteoporosis (no consensus on mild osteopenia) are classified as contraindications as discussed above as well.

Allergy

General allergy was not considered an absolute contraindication for hip resurfacing (74%) but the consensus was that known metal allergy is an absolute contraindication for hip resurfacing in females (69%).

Absolute contraindications

Besides known metal allergy, kidney disease was regarded as an absolute contraindication by all participants. Skeletal immaturity and active infection are obvious absolute contraindications. It was also put forward that patients with malignant tumours, patients treated with immunosuppressive drugs or high dosages of corticosteroids and patients in whom the postoperative recovery and stability of the hip is not ensured due to vascular insufficiency, muscular atrophy, or neuromuscular diseases, should not receive a hip resurfacing.

Conclusions on indications

The general view supported by a 100% concordance was that the ideal candidate for a metal-on-metal resurfacing is a relatively young man with a normal hip anatomy and suffering from primary osteoarthritis. Femoral head size <46 mm was considered a contra-indication for hip resurfacing regardless of gender and age. Grossly abnormal anatomy, metal allergy and kidney disorders were considered to be absolute contraindications (83%).

Informed consent

Asking a preoperative informed consent is customary in the USA but is not done on a routine basis in many European countries. 47% of the participating surgeons already ask an informed consent, and 38% believe it is time to have all patients sign an informed consent document prior to hip resurfacing surgery, explaining possible adverse events and the necessity of follow-up including metal ion measurement and/or cross-sectional imaging.

Implant coverage angle and position

Implant position, i.e. combined inclination and anteversion was considered to be the most important factor for low wear. A largest possible coverage angle was acknowledged to be very important in order to avoid edge loading and wear. Acceptable limits for acetabular positioning were concluded to be: 40 degrees inclination (+/-10°) and 15 degrees anteversion (+/-10°). However, these angles are dependent on size of the cup and design of the implant.

A possible solution to this issue is to use the so-called Relative Acetabular Inclination Limit (RAIL) (23) where the

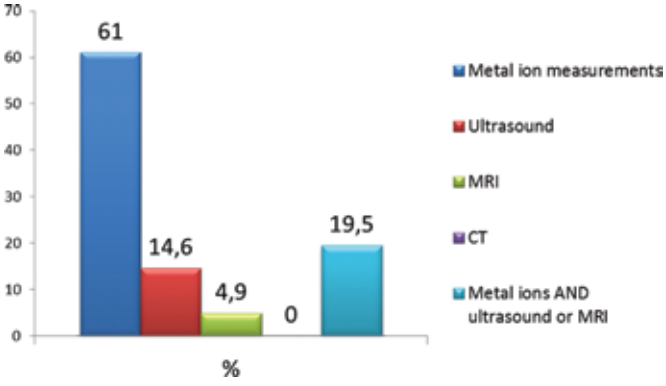

Fig. 1 - Besides clinical and radiographic follow-up, which method do you routinely use to assess a hip resurfacing?

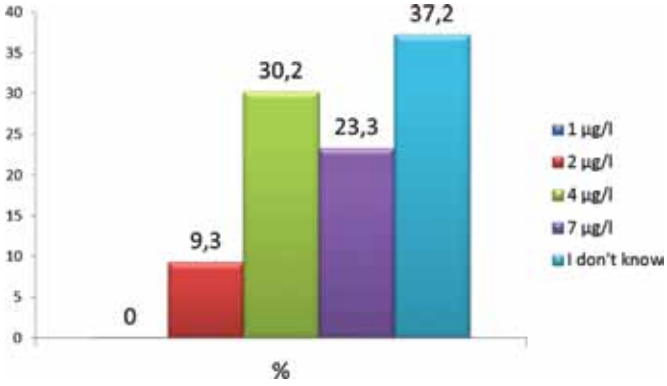

Fig. 2 - What do you consider as an acceptable upper level for Cr or Co ions in blood or serum in a unilateral hip resurfacing?

ideal cup inclination is defined preoperatively based on acetabular size and functional articular arc (coverage angle) of the implant for a particular size.

Adverse local soft tissue reactions (ALTR)

The consensus was that incidence of adverse local soft tissue reactions (ALTR) does not justify banning all MoM hips (89.5%). The diagnosis of ALTR with cross-sectional imaging was seen as a reason for immediate revision, regardless of symptoms by 44% of the surgeons, and as a reason for immediate revision in some cases by 36%. Twenty percent of surgeons would not immediately revise an asymptomatic patient and would wait, re-examine and see. For the diagnosis of ALTR different evaluation methods can be used. Most frequently used methods in the surgeon's practice were MRI (57.1%), ultrasound (31.4%) and CTscan (8.6%). For the routine follow-up of hip resurfacing, surgeons most frequently used metal ion measurements (61%) besides MRI and ultrasound (Fig. 1). CTscan was not used a a routine follow-up method. Both for MRI and CT scan, the necessity of metal artifact reduction sequences (MARS) for correct visualisation of the periprosthetic soft tissues was emphasised. For the practical management of hip resurfacing patients, a yearly follow-up was advocated by 36%, and a 2-yearly follow-up by 33%, while 28% would only advise their patients to come and see them in case of clinical problems. There was no consensus on a stratification according to risk but a general agreement that patients of female gender, and/or with a small head size, and/or less bone stock, and/or a steep cup position, and/or elevated metal ion levels and/or clinical symptoms should be followed more closely and frequently and further assessed with repeated metal ion testing and cross-sectional imaging. If the abnormalities are confirmed and/or deteriorate, a revision is advocated.

Metal ion measurements

Several studies have demonstrated that metal ion levels in whole blood, serum and urine are related to local joint levels and are indicative of the amount of wear of the MoM bearing surface (24, 25). Elevated ion levels have a high specificity and are significantly associated with clinical problems. The sensitivity of ion measurements with regard to hip resurfacing function is low, however, clinical problems can still occur with low ion levels. For most of the surgeons (62.7%) there was enough evidence to set an acceptable level of Cr or Co in blood/serum for well-functioning resurfacings. For 39.5% of the surgeons the upper acceptable level of blood/serum metal ions was ≤4 µg/L (Fig. 2) as published by Van Der Straeten et al (26). Other authors have even decreased the limits to 2 µg/L (27). Metal ion measurements in blood or serum were believed to be necessary in all patients at routine follow-up and additionally in case of problems by 43%, only in high risk patients by 23%, only in patients with pain or other problems by 32%, or only as a part of a research study by 2%. There was no consensus regarding an 'alarm level' indicating a wear related problem but there was a consensus to consider ion levels higher than 10 µg/L as concerning (Fig. 3). Regarding MoM total hip arthroplasties, safe upper limits have not been established yet since the problem is more often corrosion in confined spaces such as modular taper/trunnion connections as opposed to wear. Problems may occur even with metal ion levels below the safe upper limits (27) and follow-up using cross-sectional imaging is advocated. Elevated ion levels higher than the levels established for hip resurfacing are indicating a problem also with MoM THA.

Revisions of hip resurfacings

The reasons for revision of hip resurfacings are displayed in Figure 4.

Revision of the acetabular component only was still considered an option in selected cases (43%). If the acetabular component is loose and in the absence of an adverse local tissue reaction or acetabular osteolysis, the femoral component can be kept provided it is well-placed and well-fixed. That means that the articular surface is a MoM hip resurfacing again.A revision of the femoral component only, which would necessitate the use of a MoM THA with a large diameter femoral head, was not advised at all anymore by 54%, only in selected cases by 31%, such early failures due to fractures of the femoral neck.In case of revision to a total hip arthroplasty, the best bearing options were considered ceramic-

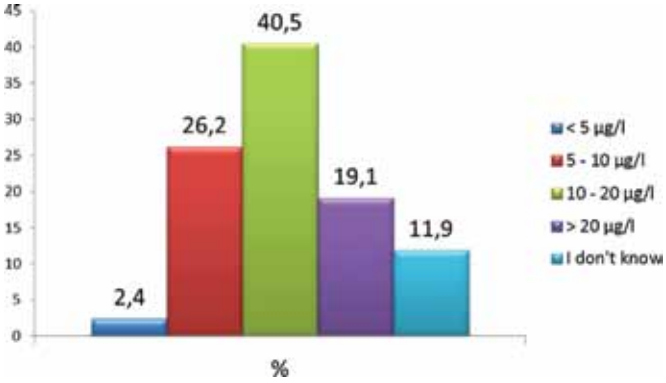

Fig. 3 - What is your personal alarm level of blood or serum ions indicating a wear-related problem?

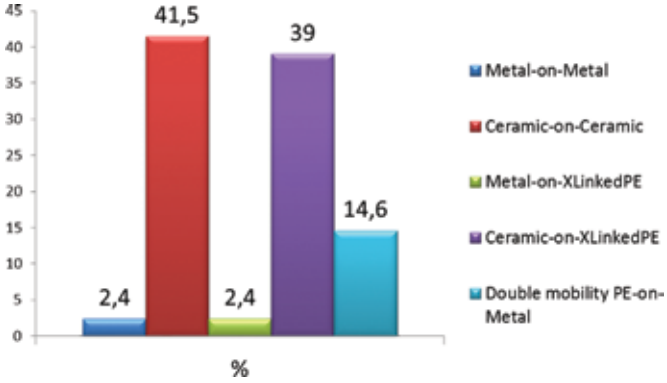

Fig. 5 - In case if revision to a THA, what is the best bearing option in your opinion?

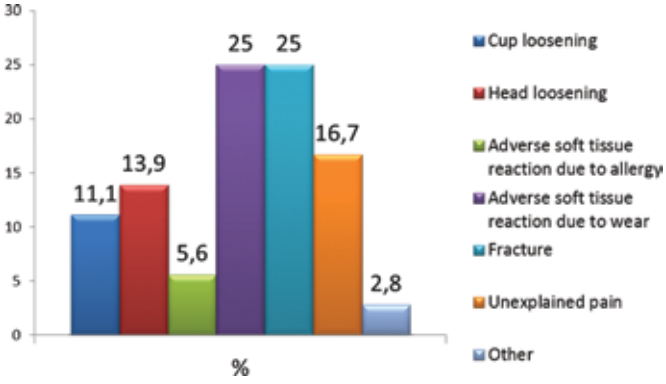

Fig. 4 - What is your main reason for revision of a hip resurfacing?

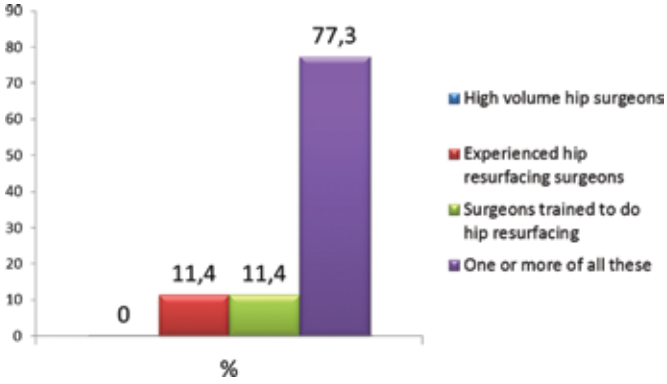

Fig. 6 - Hip resurfacing should be limited to these surgeons.

on-ceramic (41.5%) or ceramic-on-cross-linked polyethylene (39%) (Fig. 5). Regarding head size, 52.5% of surgeons would use the largest possible head (>36 mm) in order to avoid dislocation post-revision, especially in cases of extensive soft tissue debridement for ALTR. 42% would use a head size smaller than 36 mm. The use of a double mobility device keeping the acetabular component of the hip resurfacing is absolutely not advocated.

Activity and sports after hip resurfacing

It was generally agreed that a patient with a hip resurfacing can return to impact sports (88%) and that no sports are absolutely contra-indicated (82%). A failure of hip resurfacing because activity and/or sports is rarely seen (28, 29). It is important however to wait 3 months (31.6%) or even 6 months (57.9%) to return to impact sports after hip resurfacing. Most surgeons (65%) see a difference in activity and sports level between total hip arthroplasty and hip resurfacing and do not allow patients with a total hip to perform impact sports (55%).

Required experience

Data from the Australian registry have demonstrated unequivocally that operative experience is of paramount importance for hip resurfacing with a 66% higher risk of revision in hospitals with less than 25 hip resurfacing cases per year (30, 31). The majority of participants believe that hip resurfacing should be limited to surgeons trained to perform hip resurfacing, high volume hip surgeons and/or experienced hip resurfacing surgeons (Fig. 6). In order to qualify to start doing hip resurfacings, the consensus was that number of THA performed by that surgeon per year should be 100 or more (75.7%). 61% of surgeons considered it takes at least 50 resurfacing procedures to get past the learning curve. On the other hand, the minimum yearly number of hip resurfacings to still be allowed to perform hip resurfacing was a subject of debate (Fig. 7) but 20 per year was considered a minimum.

MoM total hip replacement with large diameter modular heads

The consensus of the meeting was that MoM hip resurfacing and MoM THA with a large diameter head should be seen as two completely different entities (91%), and regarded and discussed separately as a completely different hip design with a different behaviour. After discussion of the frequently seen taper-trunnion wear and corrosion problems (9) and associated high incidence of ALTR with MoM THA with large diameter heads, 67% of surgeons advocated a complete stop of the

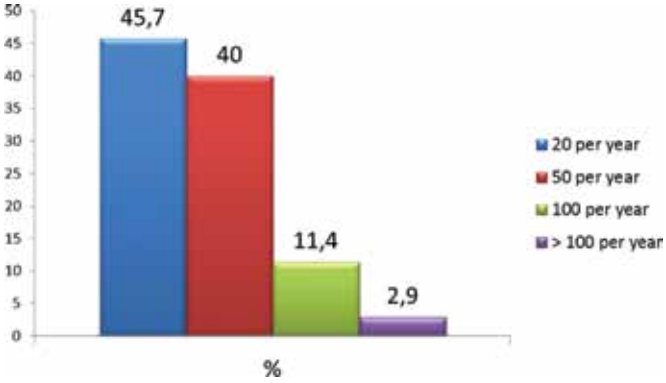

Fig. 7 - How many resurfacings should you do per year in order to be allowed to continue to perform hip resurfacings?

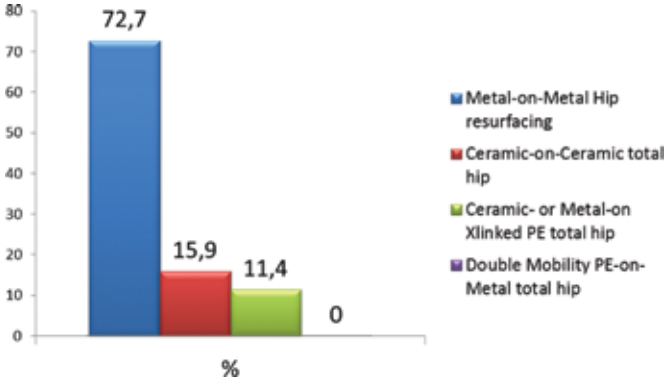

Fig. 8 - Which hip prosthesis would you prefer for yourself implanted by the best hip surgeon?

use of these prostheses while 33% still saw a place for MoM THA with large diameter heads in special cases and/or with some designs or design changes. There was a clear insight that a lot of the tapers of hip stems have changed over time without taking in account the possible disadvantages when these designs would be used with a large diameter femoral head because of the higher friction and the possible toggling motions of the large heads on the ridged necks designed to accommodate ceramic heads. All of these elements have probably contributed to the higher wear and subsequent crevice corrosion with these devices.

Similar concerns were put forward regarding taper-trunnion connections in large diameter head metal on (cross-linked) polyethylene in certain designs and even with large diameter head ceramic heads (today up to 48 mm) with metal sleeves (39%). The use of titanium sleeves in the large ceramic heads together with titanium stems were advised, possibly producing cold welding eventually leading to a much larger taper diameter and possibly less wear and corrosion problems.

Is there a future for hip resurfacing?

In order to improve the outcome of resurfacing, the consensus was that improvement of hip resurfacing prosthesis designs, instruments and training of surgeons were crucial factors. All participants agreed that the three key factors for a successful hip resurfacing were: 1) surgical skill and experience; 2) implant design, size and positioning; and 3) careful patient selection.

Overall 27% predicted their hip resurfacing practice would still increase, 20% believed it would decrease because of fear for MoM problems, 24% thought it would remain equal while 20% predicted they would be forced to stop with hip resurfacing by their government or hospital authorities.

Overall, 90% of surgeons agreed that the incidence of ALTR does not justify the banning of all MoM hips and 98% of the surgeons did not think Hip Resurfacing should be completely stopped. When asked which hip prosthesis they would prefer for themselves performed by the best surgeon, 72.7% answered a MoM hip resurfacing (Fig. 8). It must be specified all of the surgeons were men.

Overall, there was no significant difference between the answers of the faculty and the other delegates and therefore it was not deemed relevant to add the separate answers. The only difference was that very experienced hip resurfacing surgeons were actually even somewhat more severe with indications. Everybody was convinced training, experience and volume are of paramount importance. As proven from the analysis of the Australian Joint Registry, expertise is crucial with regard to the outcome of hip resurfacing being a technically more difficult operation (31). Overall the analysis highlights the remaining issues and the need for collaborative research.

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Disclosures

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