SECOND EDITION MAY 2014

CONSENSUS

FROM THE ADVANCED RESURFACING COURSE GHENT, BELGIUM

MAY 2014

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Consensus Advanced Resurfacing Course May 2014, Ghent Belgium

Today, anno 2014, metal-on-metal hip arthroplasty in general and hip resurfacing in particular is finding itself in the eye of the storm. Despite the fact that an estimated 500,000 current generation metal-on-metal hip replacements have been performed over the last 15 years with excellent results from experienced surgeons, there are reports of increasing numbers of revisions for unexplained pain and soft tissue reactions. These have alerted the orthopaedic community, the health authorities and unfortunately the media, who are often taking on their sacred mission of informing the public in a very dubious way. The initiative of several national health authorities, regulatory agencies and orthopaedic associations to issue their recommendations on the use of metal-on-metal (MoM) hip replacement and hip resurfacing implants and on the management of patients when a MoM hip replacement is considered, is commendable. However, many questions arise especially with regard to practical issues including measurement and interpretation of metal ion levels and the logistics of performing this testing on a broad scale.

In the light of the current turmoil, it is extremely important to come forward with the knowledgeable and educated opinion of experienced hip replacement and resurfacing surgeons and researchers in order to frame the current irrefutable facts regarding metal-on-metal hip arthroplasty, point out the issues still under scrutiny and bring back the whole story to its right and correct proportions.

We would like to present you this Consensus booklet reporting on the outcome of the consensus 2014's Advanced Resurfacing Course in Ghent, Belgium. The results will be compared with the consensus of 2009, 2010 and 2012's Advanced Courses. Each time, the opinions of the faculty of the experts and of the audience were recorded with the voting system offering different possible answers to a number of questions, followed by a discussion. The concordant opinions of an international faculty of experienced MoM hip resurfacing surgeons on required experience, indications, surgical technique, rehabilitation and management of problematic cases have already been covered in an annotation published in the British Journal of Bone and Joint Surgery, in March 2010, which you can find in this booklet. Since then opinions have evolved based on growing knowledge and experience.

This consensus booklet does not pretend to deliver the final answers or definitive conclusions on MoM hip arthroplasty in general or hip resurfacing in particular. It is not meant to be 'a way to avoid debate by claiming that the matter is already settled' as Michael Crichton defines 'consensus'. A 'scientific consensus' is sometimes hazardous since we may be wrong collectively. Continuous further research and critical thinking are of the utmost importance as we cannot base our arguments purely on consensus but on scientific facts.

And thus the debate is open again. We wish you all a good use of this informative Consensus Book on MOM Hip Resurfacing of May 2014.



ANNOTATION

Metal-on-metal hip resurfacing

A CONSENSUS FROM THE ADVANCED HIP RESURFACING COURSE, GHENT, JUNE 2009

K. De Smet,P. A. Campbell,H. S. Gill

From ANCA Medical Center, (AMC-Ghent), Ghent, Belgium We report the consensus of surgical opinions of an international faculty of expert metal-onmetal hip resurfacing surgeons, with a combined experience of over 18 000 cases, covering required experience, indications, surgical technique, rehabilitation and the management of problematic cases.

The last decade has seen an increased use of metal-on-metal hip resurfacing arthroplasty as an alternative to contemporary total hip replacement (THR), especially for patients who wish to participate in high-demand activities. Metal-on-metal bearings are also being used more often for THR. In June 2009, the third Advanced Resurfacing Course was held in Ghent, with a faculty that included 21 orthopaedic surgeons whose combined experience included over 18 000 metal-onmetal hip resurfacing arthroplasties. As the meeting served to bring together surgeons, highly experienced in hip resurfacing, from Australia, Europe and the Americas, the opportunity was taken to establish consensus views on issues of required experience, indications, surgical technique and rehabilitation. The aim of this annotation is to disseminate these consensus findings in order to help surgeons who are considering metal-on-metal bearings for both resurfacing and conventional THR. The findings are presented as a majority opinion, with the percentage of the faculty in agreement given in parentheses.

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- H. S. Gill, DPhil, University Lecturer in Orthopaedic Mechanics Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences University of Oxford, Botnar Research Centre, Nuffield Orthopaedic Centre, Oxford OX3 7LD, UK.

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©2010 British Editorial Society of Bone and Joint Surgery doi:10.1302/0301-620X.92B3. 23946 \$2.00

J Bone Joint Surg [Br] 2010;92-B:335-6.

Required experience

The use of metal-on-metal bearings for THR and resurfacing presents a greater technical challenge than that of conventional metal-on-polyethylene bearings. The consensus (81%) was that an orthopaedic surgeon should have a minimum experience of 200 conventional THRs before starting to use a metal-on-metal hip resurfacing arthroplasty. Opinion varied on the number of these operations needed to overcome the learning curve, and ranged from 20 (36%), to 50 (28%) and more than 50 (30%).

Indications

The overall view (100%) was that the ideal candidate for an metal-on-metal hip resurfacing arthroplasty is a relatively young man with normal anatomy and primary osteoarthritis. Being female was not, by itself, a contraindication (89%), but use of a small femoral head (< 46 mm) was contra-indicated (70%). Being female and wanting to have children was a contra-indication (66%), as was being female and having a metal allergy (70%). Grossly abnormal anatomy, regardless of gender, was also agreed to be a contra-indication (83%). There was considerable debate about bone quality, the general view being that 'good' femoral bone is a prerequisite, but no agreement was reached on a working definition of acceptable quality.

Surgical technique

The majority opinion (56%) was that the best type of femoral placement guide is that which encircles the femoral neck. There was general agreement (63%) that the current acetabular placement jigs are inadequate. The overall preference (78%) was for cementing the femoral component with a thin cement mantle with fixation holes drilled in the femoral bone, use of pulsed lavage, and reduction of the hip in less than eight minutes from the start of mixing the cement.

Rehabilitation

Full weight-bearing can be allowed on the first post-operative day (73%) and patients should use crutches for as long as needed (57%). Six weeks is the optimal time to return to normal non-sporting daily activities (44%), and six months for returning to impact sports such as running or tennis (61%).

Managing problematic cases

It was difficult to achieve a consensus on this topic, and only the broad recommendations of the discussion are reported. It was generally agreed that these patients need to be followed up and those with symptoms investigated. There was no agreement on the diagnostic value of measurements of metal ions, but it was felt that 'high' concen-

trations of systematic metal ions indicated a problem with the articulation. Cross-sectional imaging and plain radiographs are required for the investigation of a symptomatic metal-on-metal bearing.

It is hoped that these consensus opinions will prove useful to orthopaedic surgeons and will lead to improved outcomes after surgery for hip replacement.

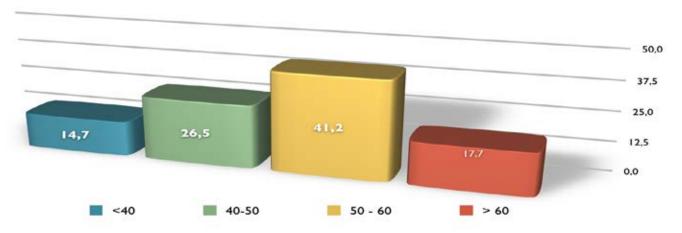


I. Demographics of the Course participants

The total number of Total Hip Arthroplasties done by Faculty and Attendees amounts to 102174. The total number of Resurfacing Procedures approximates 40087. The combined experience of the surgeons and voters demonstrates the importance of this consensus.

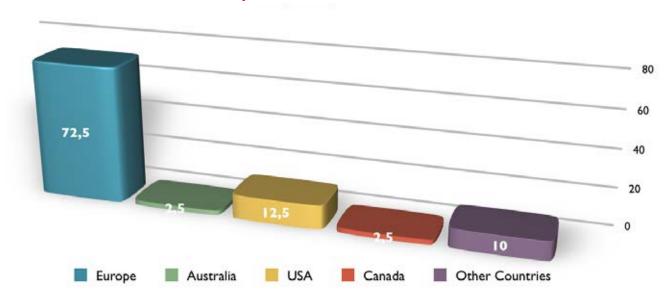
On a total number of approximately 100 surgeon participants 26.5% were between 40 and 50 years old, 14.7 % were younger than 40 and 58.9 % were older than 50.

Age participants



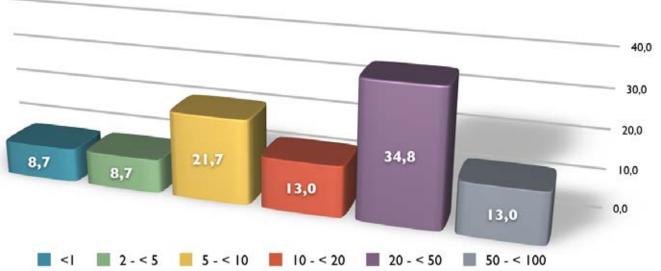
72.5% of all participants came from European countries, 2.5% from Australia, 12.5% from the USA, 2.5% from Canada and 10% from other countries.

Participants Residence



Total Hip Experience (yearly)





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

It increased in 9% of the resurfacing practices.

Most of the people (91%) believe that metal-on-metal (MoM) hip resurfacing should be completely separated from MoM Total Hip (Large Head) replacement. It is a complete different design and has a different behaviour.

98% of the surgeons do NOT think that Hip Resurfacing should be completely stopped.

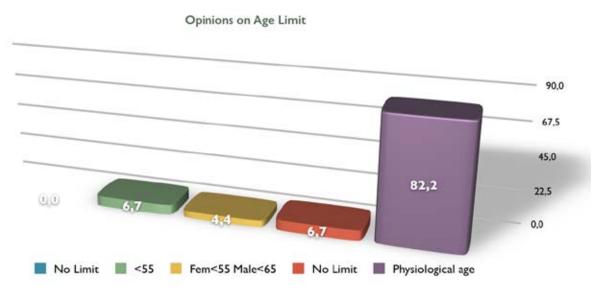
45.5% of all attendees and faculty think that MoM large head total hip can be used if design changes are made, 39% think it should be completely stopped.



II. Indications for hip resurfacing

AGE

Regarding age limits for hip resurfacing, a different age limit for males and females was discussed, as well as a so-called physiological age, with our ageing population remaining more active and healthy for a longer period of time. It was acknowledged that overall there is a higher failure rate in older people and that a safe general recommendation could be not to perform a hip resurfacing in men older than 65 and in women older than 55, but depending on the patient and the bone quality.

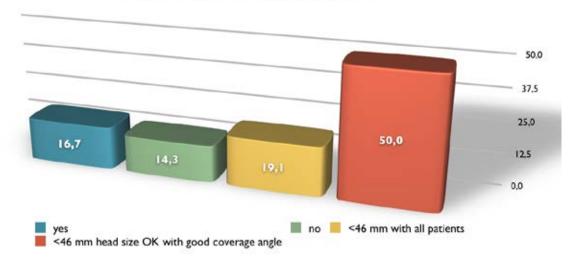


GENDER

Female gender was considered to be an absolute contraindication by 16% of the participants, while 60% did not believe gender was an issue at all. Being a female and being less than 40 years old however was considered an absolute contraindication by 21% of participants. Being a female and older than 55 was not considered an absolute contraindication (71%).

50% believed that a head size smaller than 46mm was not a contraindication in females if the coverage angle of the implant is big enough. 59% think that being female and wanting to have children is an absolute contraindication for medicolegal reasons.

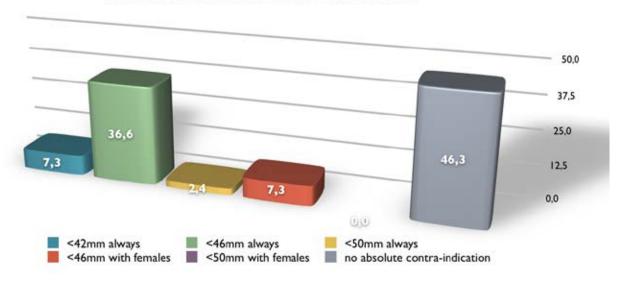
Female and femoral size < 46mm as contra-indication



FEMORAL HEAD SIZE

Regardless of gender, a small head size of less than 46mm was considered an relative contraindication by 46%, after discussion with the whole audience.

Is a small femoral head size an absolute contra-indication?



ALLERGY

General allergy is NOT an absolute contraindication for hip resurfacing. (74%)

Metal allergy is an absolute contraindication for Hip Resurfacing (69%).

INFORMED CONSENT

47% of the surgeons use already an informed consent, where 38% find that it is time to have all patients sign an informed consent document prior to hip resurfacing surgery.

DIAGNOSIS (consensus 2009 - 2012)

Avascular necrosis (AVN) was considered a good indication for hip resurfacing by half of the participants. How big an osteonecrotic lesion can be to allow for a successful hip resurfacing was the subject of a lively discussion. In general, participants agreed that AVN was an indication for hip resurfacing provided enough healthy bone was present for a good femoral head fixation and for the creation of a circumferential seal. The osteonecrotic area could not be larger than 30% or one third of the femoral head. The same criteria would stand for Perthes disease or Slipped Epiphysis as an indication

for hip resurfacing.

Severe cystic osteoarthritic degeneration of the femoral head was considered a relative contraindication in case of very large cysts in the femoral head or neck area. Bone defects larger than 1cm3 are known to have a much higher risk for revision and have been associated with femoral neck fractures and were considered an absolute contraindication.

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 to be an absolute contraindication by 63.6% of the surgeons and grossly abnormal anatomy was thought to be an absolute contraindication by 83.3%.

BONE QUALITY (consensus 2009 - 2012)

41.2% of the participants considered bone quality to be more important than age when deciding on implanting a hip resurfacing or not. It was 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 about mild osteopenia) were classified as contraindications.

ABSOLUTE CONTRAINDICATIONS

Kidney disease was acknowledged by to be an absolute contraindication. Skeletal immaturity and active infection were obvious contraindications. Some surgeons 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 was 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 is considered a contra-indication for hip resurfacing regardless of gender and age. Grossly abnormal anatomy, regardless of gender, diagnosis and bone quality was considered to be a contraindication (83%) and after discussion most participants also agreed metal-on-metal hip replacements should not be used in patients with metal allergy or severe kidney disease.





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CADAVERIC WORKSHOP LEDEGANK UNIVERSITY GHENT

www.resurfacing-congress.org

4th Advanced Resurfacing Course 16-19 June 2010 "Het Pand", Ghent, Belgium

Koen De Smet, MD Course Chairman Visit and bookmark www.resurfacing-congress.com for more information and to register online







5th Advanced Hip Resurfacing Course

13-16 June 2012 Handelsb

Handelsbeurs, Ghent, Belgium

www.resurfacing-congress.com



Koen De Smet, Belgium

Co-chairmen:

Pat Campbell, USA

A. Seth Greenwald, USA

Edwin Su, USA

Catherine Van Der Straeten, Beigium



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6th Advanced Course

New orthopaedic devices overrated in the short-term, underestimated in the long run. Finding an International "Consensus" in the MOM Resurfacing

Course chairman Koen De Smet, Belgium

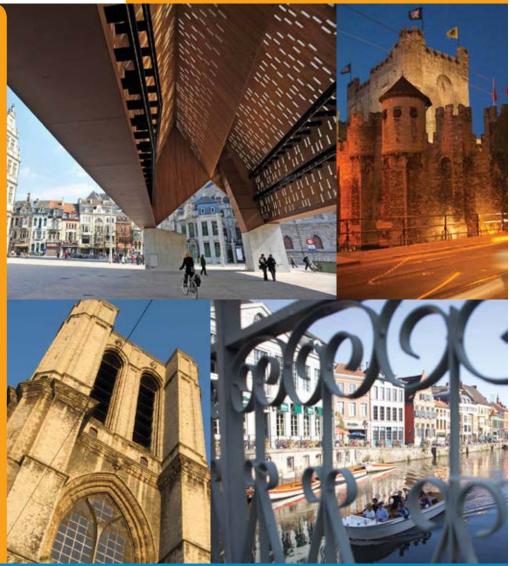
Co-chairmen
A. Seth Greenwald, USA
Edwin Su, USA
Pat Campbell, USA
Catherine Van Der Straeten, Belgium
Jan Victor, Belgium

International Consensus Meeting

28-31 May 2014 Oude Vismijn, Ghent, Belgium

Invited Faculty

Amstutz Harlan Los Angeles, CA, US
Antoniou John Montreal, QC, Canada
Beaulé Paul E. Ottawa, Canada
Breemans Eric Delft, The Netherlands
Brooks Peter Cleveland, OH, US
Calistri Alessandro Rome, Italy
Campbell Pat Los Angeles, CA, US
Cobb Justin London, UK
Daniel Joseph Birmingham, UK
De Smet Koen Ghent, Belgium
Girard Julien Lille, France
Greenwald Seth Cleveland, OH, US
Gross Thomas Columbia, SC, US
Haddad Fares London, UK
Holland Jim Newcastle, UK
Kretzer Jan-Philippe Heidelberg, Germany
Lage Lafayette Sao Paulo, Brasil
Latham Jeremy Southampton, UK
Marin-Peña Oliver Madrid, Spain
McMinn Derek Birmingham, UK
Migaud Henri Lille, France
Moroni Antonio Bologna, Italy
Ribas Manel Barcelona, Spain
Rieker Claude Winterthur, Switzerland
Su Edwin New York, NY, US
Toni Aldo Bologna, Italy
Treacy Ronan Birmingham, UK
Van Der Straeten Catherine Ghent, Belgium
Van Susante Job Arnhem, The Netherlands
Victor Jan Ghent, Belgium
Voodnutt David Swansea, UK

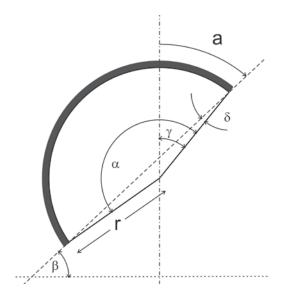


III. Cup Abduction Angle and Coverage Angle

mplant position 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:



INCLINATION 40 degrees inclination (+/- 10°)

ANTEVERSION 15 degrees anteversion (+/- 10°)

These angles are dependent on size of cup and design of the implant.

A possible solution is to use a more scientific rule with **RAIL** (Relative Acetabular Inclination Limit) (Thomas Gross publication)

IV. Implant clearance and metallurgy (consensus 2009/2010/2012)

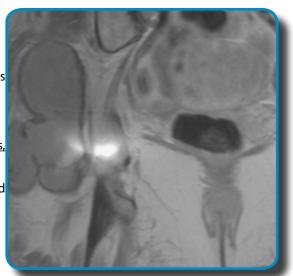
Clearance and metallurgy were believed to be important parameters to avoid wear of the components. 67.6% of participants acknowledged that the optimal clearance for hip resurfacing depends on the diameter going from smaller to higher with larger diameters.

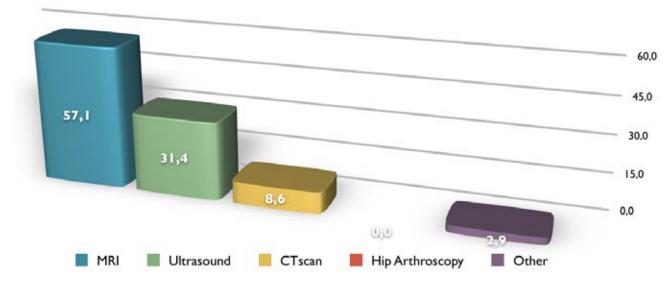
V. ALTR (Adverse Local soft Tissue Reactions)

The incidence of adverse local soft tissue reactions (ALTR) does NOT justify the banning of all MoM hips (89,5%)

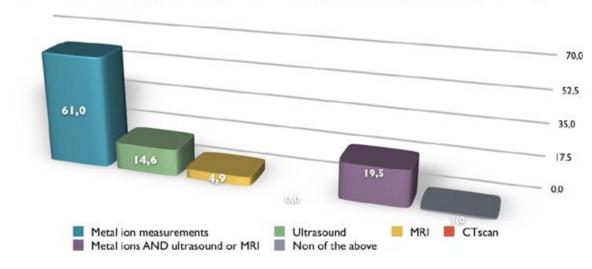
ALTR was always seen as a reason for revision by 44% of the surgeons, sometimes by 36%.

For diagnosing ALTR different exams can be used. Routinely used methods in the surgeons practice are displayed in the next graph.





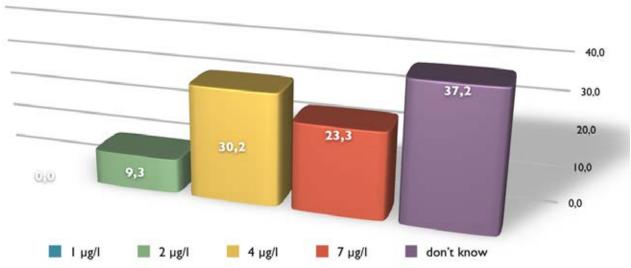
Besides clinical and radiographic follow-up which method do you use routinely to asses a hip resurfacing?



VI. METAL IONS

It has been 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 metal-on-metal bearing surface. Higher ion levels are significantly associated with clinical problems although clinical problems can still occur with low levels. For most of the surgeons there is enough evidence to set an acceptable level of Cr or Co in blood/serum for well-functioning resurfacings.

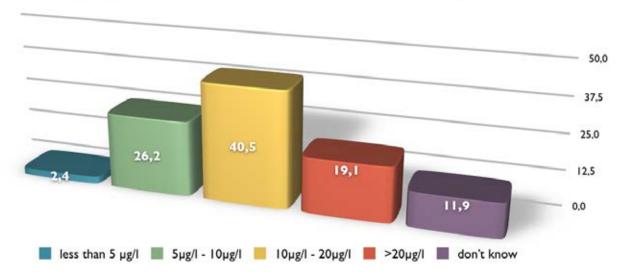






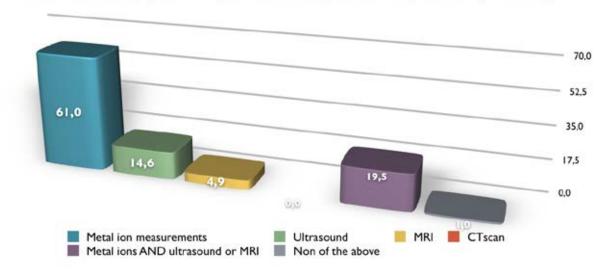
Time frame and follow up in time of the level of metal ions is as important as "the level" itself.





n the future, lon testing is believed to be necessary in all patients at routine follow-up by 16%, only in all high risk patients by 23%, in patients with pain or other problems by 32%, or only as a part of a research study by 2%, and in all of these categories by 27%.

Besides clinical and radiographic follow-up which method do you use routinely to asses a hip resurfacing?



As a follow-up of hip resurfacing patients, a yearly follow-up (36%), a two-yearly follow-up (33%), and only when patients have a problem (28%) when patients have problem seems most indicated.

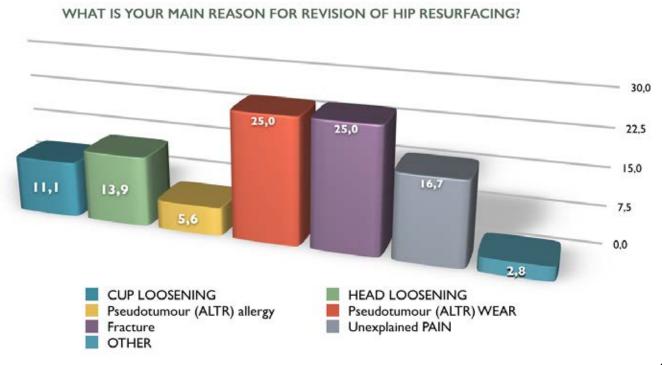
VII. Activity and sports after hip resurfacing

t was generally agreed that the patient with a hip resurfacing can return to impact sports (88%) and that no sports were absolutely contra-indicated (82%). A failure of hip resurfacing because activity and/or sports is rarely seen (22%). It is important however to wait 3 or 6 months to return to impact sports after hip resurfacing.



ost surgeons (65%) see a difference in activity/sports level between total hip arthroplasty and hip resurfacing and do not allow patients with a total hip to perform impact sports (55%)

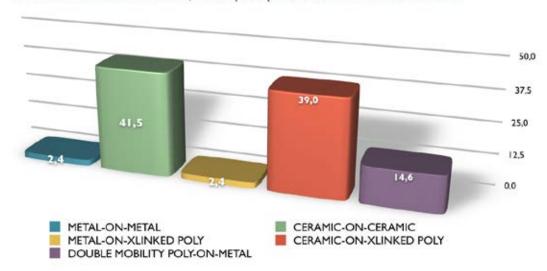
VIII. Revisions of Hip Resurfacing



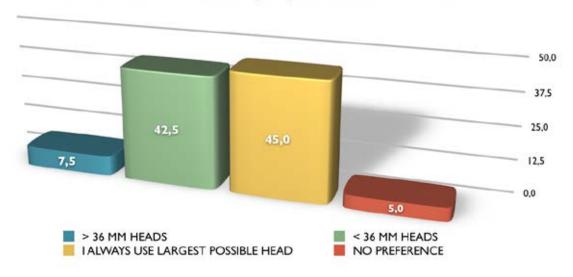
Revision of the acetabular component only was still considered an option in selected cases (43%), while a revision of the femoral component only, was not advised at all anymore by 54%, in selected cases by 31%.

In case of revision to a total hip arthroplasty, the best bearing and size option are illustrated.





IN CASE OF REVISION TO A THA, what in your opinion is the BEST SIZE OPTION?

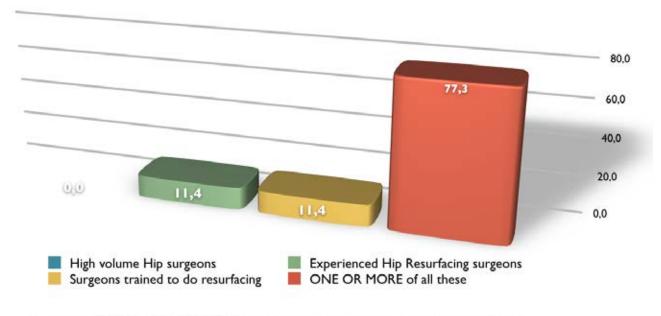


IX. Required Experience

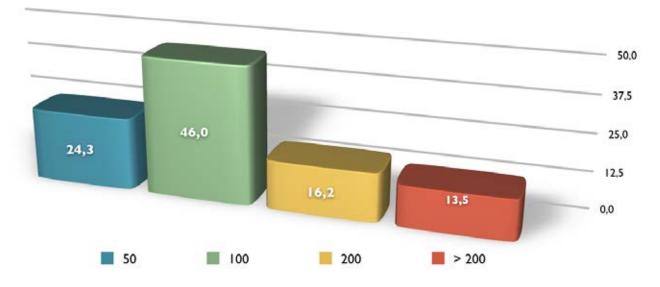
Data from the Australian registry have demonstrated unequivocally that operative experience is of paramount importance for hip resurfacing with a 66% higher risk of revision in hospitals with less than 25 hip resurfacing cases per year.

he 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.

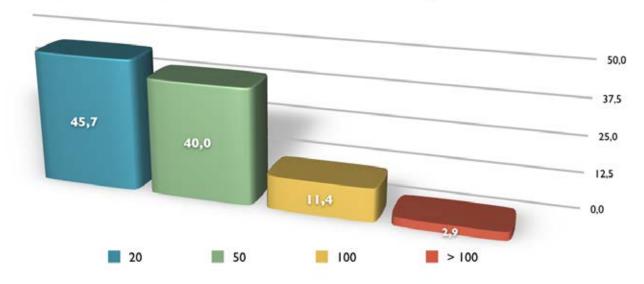
Hip Resurfacing should be limited to:



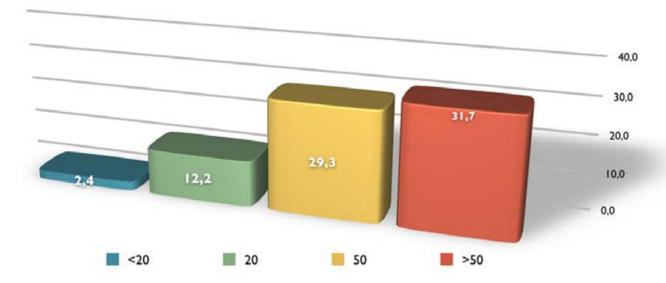
How many TOTAL HIPS PER YEAR qualify a surgeon to start doing hip resurfacing?



How MANY RESURFACING SHOULD YOU DO PER YEAR to be accepted to still do them?



HOW MANY HIP RESURFACINGS are needed to get over the LEARNING CURVE?

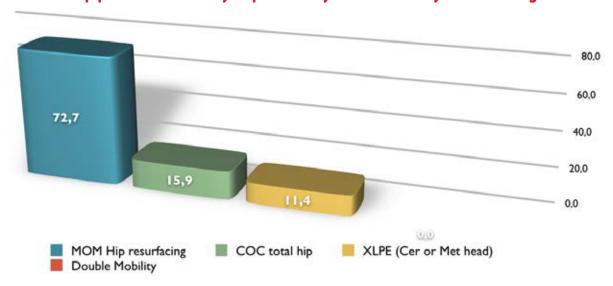


XIV. The Future

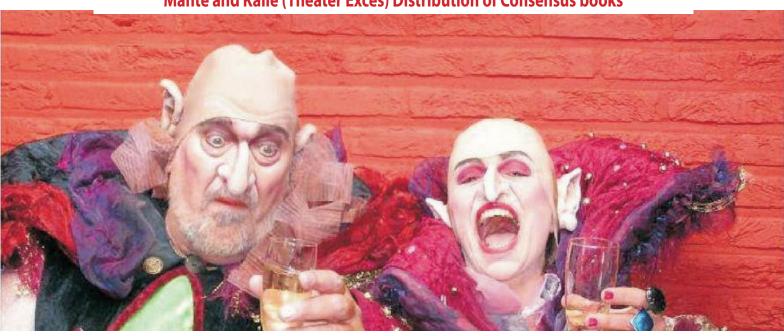
n order to improve the outcome of resurfacing, the consensus was that improvement of prosthesis designs, of instruments and training of surgeons were crucial factors. All participants agreed that the three key factors for a successful hip resurfacing were surgical skill and experience, implant design,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

Overall 27% predict their hip resurfacing practice will increase, 20% believe it will decrease, and 24% think it will stay equal while 20% predict they will be forced to stop.

Which hip prosthesis would you prefer for yourself done by the best surgeon?



Mante and Kalle (Theater Exces) Distribution of Consensus books







Dear participants,

A s co-chairmen of the 6th Advanced Resurfacing Course in Ghent, Belgium we hope you all had a stimulating and instructive course, once again. This booklet is a summary of the 2014 Advanced Course Conensus opinions and insights on technique, education, experience needed, indications, patient follow-up, complications and other items in order to formulate recommendations for the broader orthopaedic community.

We thank you heartily for your participation in the debate and the consensus.

With kind regards,

The co-chairmen

Pat Campbell

Rampbell.

Catherine Van Der Straeten

Seth Greenwald

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Following the success - both scientifically and socially - of the previous Advanced Resurfacing Courses, I am pleased that 2014 with the 6th Advanced Resurfacing Course in the "Old Fishmarket" in Ghent was again a "meeting not to miss"!

The course format remained the same as the meeting always aims to stimulate, educate and instill the most advanced up-to-date information about resurfacing arthroplasty. A prestigious faculty showcased their experience exceeding 15,000 metal-on-metal hip resurfacing arthroplasty procedures combined! Experts addressed the newest insight and bring updates on theory and practice about resurfacing arthroplasty, making it a not-to-miss forum for orthopedic surgeons.

Pertinent basic science and evidence-based elements were presented together with the faculty's practical experience in clinical and technical issues. The consensus of the 2009, 2010 and 2012 meeting were challenged and renewed. At the end of the course this "Consensus book-

let" is a reflection of the discussions and debates an the ultimate "Global Consensus" which will be put forward as recommendations for the metal-on-metal hip resurfacing practice.

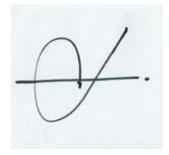


We thank you for your active participation in the 6th Advanced Resurfacing Course and hope you had a wonderful stay in the beautiful city of Ghent.

Warm regards,

Koen De Smet,

Course Chairman



Cartoons by André Nollet andre@nollet-cartoons.be



Text, graphics,
Catherine Van Der Straeten, Koen De Smet

Layout Koen De Smet

A DDENDUM MoM Total Hipreplacement / Large Modular Heads

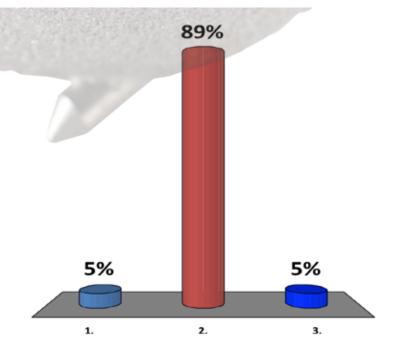
 \mathbf{S} everal Consensus Questions were produced and asked to the attendees and the faculty. The answers and percentages of these results are for us of importance because of the large experience with these implants in the audience and the faculty.

The incidence of Adverse Local soft Tissue Reactions (ALTR) does NOT justify the banning of all MoM hips (89,5%).

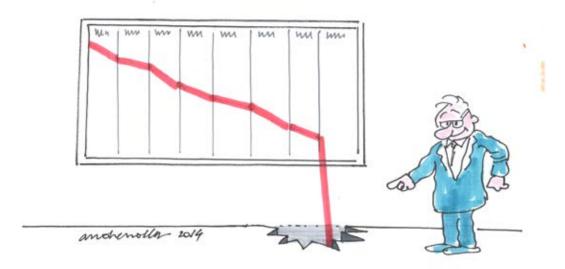


Does the incidence of Adverse Local soft Tissue Reactions justify banning all MoM hips?

- 1. Yes
- 2. No
- 3. No opinion



FAILURES



The opinion that ALTR does not justify the complete banning of all MoM hips is probably based on the place and use of MoM Resurfacing, but the further discussion illustrates that even the use of large MoM heads total hip replacement is not completely disregarded.

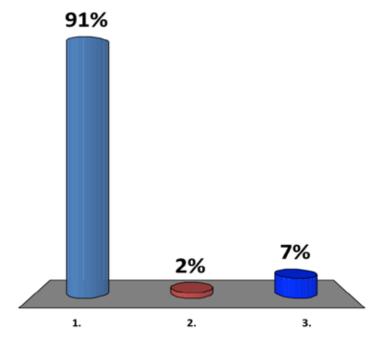
ipresurfacing and MoM total hip (Large Head) replacement should be seen as two complete different entities.



Do you think metal-on-metal (MoM) hip resurfacing should be completely separated from MoM Total Hip (Large Head) replacement?

It is a complete different design and has a different behavior.

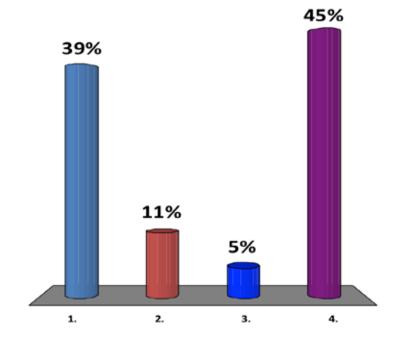
- 1. Yes
- 2. No
- 3. Not convinced



Twice in different sessions of the meeting the opinion on the use of MoM large heads was searched. First more people still could accept the Large MoM Hipreplacements when design changes would be made, but after the presentations and discussions about the "true" problems with these procedures, the banning increased to 67%, with still 33% that saw these prostheses used in special cases and/or with some designs or design changes.

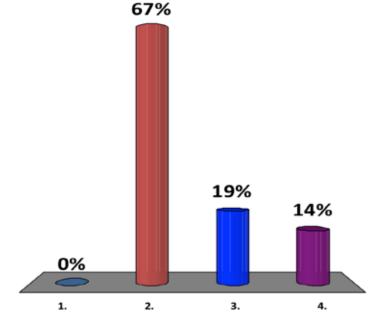
Q7: Do you think MOM large head total hip should be completely stopped?

- 1. Yes
- 2. No
- 3. Not convinced
- Can be used if design changes are made



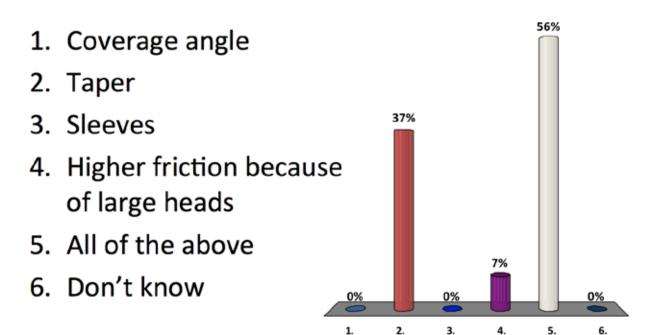
Q41: Is there still a place for large Metal-on-Metal Total hips?

- 1. Yes
- 2. No
- Maybe with some designs
- 4. In special cases



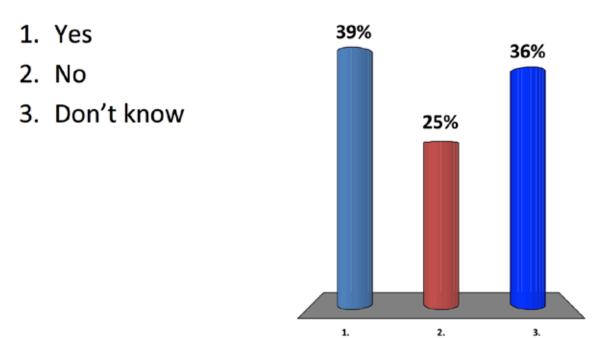
Failures in the large femoral MoM total hip arthroplasties seem to have a clear reason. They seem to find their origin in the higher friction because of the large heads, but transferring this problem to mainly the taper of the stem. There was a clear insight that with time and evolution a lot of tapers of stems have changed without taking in account the possible disadvantages when these designs would be used.

Large femoral head MoM THA failures: what is causing the problems in your opinion?



There are the same concerns in this regard with tapers/ trunnions in large head metal on poly/crosslinked poly (MoP / MoXP) in certain designs. Therefore a question about the fear that the same adverse reactions may occur with large head ceramic heads (today upto 48mm) was asked, even though there have not been any case reports or scientific proof for this so far. The use of Titanium sleeves in the large ceramic heads together with Titanium stems are advised, possibly producing cold welding and so a much larger taper diameter.

Could the same problem occur with large diameter ceramic heads?



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