

CeraNews

Bearing Size and Surgical Procedure

The influence of intra-operative factors on THA outcome

Dr. Koen de Smet is leading a prospective observational clinical study of a new hip implant with a ceramic-on-ceramic bearing couple. The unique feature of this new device is its non-modular acetabular cup with a pre-mounted insert. He has performed more than 3,000 hip resurfacing procedures and is therefore among the world's most experienced surgeons using hip resurfacing systems. As the director of the Anca Medical Center in the Belgian city of Ghent and the Anca Clinic in the city of Rome, Italy, Dr. de Smet's work is devoted entirely to hip arthroplasty.

Why do the latest reports indicate declining numbers for hip resurfacing? Conventional total hip arthroplasty forgives small deviations from the ideal placement. In contrast, even very small placement deviations can lead to failure in the case of hip resurfacing. At various congresses, some surgeons report failure rates in the range of 5% to 10%. If I were getting such results, I would naturally abandon the method immediately – just as many are doing now, which is reflected in the figures.

But the trend does not apply to the large medical centers. In the eleven years that I have been performing hip resurfacing procedures, I have had only 34 revisions, which is equal to only 1.1%. At the recent EFORT Congress in Vienna, the reports given by surgeons working at specialized hip arthroplasty centers also indicated very good results in young,



Koen de Smet, MD

male patients with osteoarthritis. Hip resurfacing should only be carried out by surgeons who have a lot of experience in conventional hip arthroplasty as well as comprehensive training and experience in the use of this device. Only when these prerequisites have been fulfilled, one can successfully perform this procedure.

How would you explain the high failure rates? There is the unanswered question about allergic reactions to metal debris that can be released from the metal components. But aside from this, it seems to me that the remaining failures arise in connection with the design problems associated with some implants and, of course, improper positioning. The latter problem occurs especially often in smaller sizes, particularly in the case of women. Here, I see an obvious connection between the indication and the experience and skill of the surgeon.

What is your view of the discussions in literature concerning the metal ion issue? This issue is essentially relevant to the use of metal-on-metal bearing couples and not to hip resurfacing per se. In my view, the problems arise as a result of the generation of an excessive amount of wear particles, generally due to the misalignment of the device's components. I expect that we will soon see this problem more frequently in cases of total hip arthroplasty involving the use of large metal-on-metal bearing couples. This would correspond to the trend in favor of total hip replacement with large bearings that came after the trend in favor of hip resurfacing.

Although you often work with metal-on-metal bearing couples when performing hip resurfacing, you are also keenly interested in ceramic-on-ceramic couples for total hip arthroplasty. Why? When I started to work in the field of hip arthroplasty at the University Hospital of Ghent in 1995, we saw a lot of young patients who had received total hip arthroplasty with a larger 28mm or 32mm

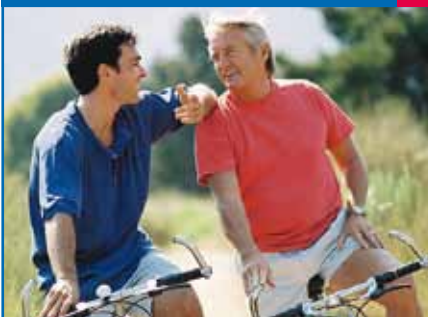
AAOS: Hip replacement trends

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Material for the young patient

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metal head – 22mm ball heads were used previously – and a thin polyethylene cup insert. This bearing couple was the result of the marketing influence of the American industry in the decade before. Within less than ten years, the thin liners were heavily worn out creating dramatic cases of osteolysis – a catastrophe (see fig. 1). This is why I turned to alternative bearing couples. In 1996, I switched to metal-on-metal, and since 1997 I have been using ceramic-on-ceramic. In the case of resurfacing, I accept the need to use metal-on-metal because it allows me to retain bone substance on the femoral side, which gives me an improved revision option in case of failure. Ceramic-on-ceramic bearing couples have become more interesting in recent years because they are now available in larger diameter ball heads.

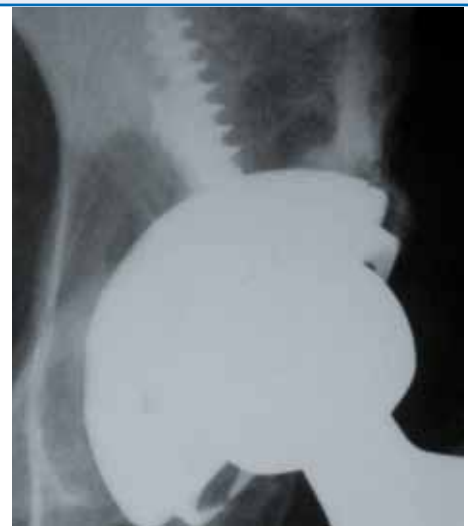
What dislocation rates have you seen in your own patients? When it comes to primary arthroplasty, I have had only one dislocation in a ceramic-on-ceramic bearing couple in the last 5 years. The reasons for successful surgery are always the same: you need a good device, with a ball head diameter which is as large as possible, a good surgical technique which is as minimally invasive as possible to the soft tissues, and a lot of experience.

First 900 resurfacing procedures (up to 2003)	0.7%
Consequent resurfacing cases (n=2100) (2003–2008)	0.0%
Primary metal- or ceramic-on-polyethylene anterolateral approach (n=978)	1.5%
Primary ceramic-on-ceramic BIOLOX® <i>forte</i> 28mm head posterior approach (n=406)	3.0%
Primary ceramic-on-ceramic BIOLOX®<i>delta</i> 28–40mm head posterior approach (n=228)	0.4%
Revision posterior approach up to 2004 (n=141)	14.8%
Revision anterolateral approach up to 2004 (n=159)	13.1%
Revision posterior approach all (n=357)	5.8%
Revision anterolateral approach all (n=228)	6.0%
Revision surgery with large MOM heads (38–58mm) up to 2004 (n=45)	4.4%

Dislocation rate in 5,800 THR, Anca Clinic, K. A. De Smet (1995–2008)

What surgical technique do you use? We use the posterolateral approach. We make the incision as large as is necessary to reliably achieve good implant positioning. Protecting and retaining the joint capsule are also important aspects. Stability in the early phase after primary surgery is reduced in the case of capsule removal. Reconstructing the capsule gives it greater stability, and also gives the patient a better feeling – perhaps not a good neurological proprioception, but a good mechanical one. When I started working in the field of arthroplasty in 1995, we would lengthen the leg to achieve greater stability. When I look back to this approach, it is entirely misconceived, and unnecessary in the case of standard arthroplasty. The proper factors that increase joint stability and make it easier to accurately restore leg length include improved diameter ratios between ceramic head and cup, accurate implant positioning – which also restores the anatomic offset – and the reconstruction of the joint capsule. Taking this approach increases patient comfort and goes further to restoring the patient's quality of life in general. The result is a high degree of patient satisfaction. The overall hospital stay has decreased to three or four days. Patients today want to be able to lead an active life for as long as possible. Meeting this demand requires very high quality results.

What is unique about the ceramic-on-ceramic device you use? It is a monoblock cup¹ with a pre-mounted ceramic insert on the acetabular side. This saves us the task of assembling the shell and the insert intraoperatively. The cups are configured for large head diameters of between 32mm and 48mm. The exterior diameter of the cups is only 10mm to 12mm larger than the head. That means



X-ray: De Smet

Fig. 1: Severe osteolysis after TMA with metal-on-polyethylene wear couple

that we can, for instance, use a 32mm/42mm or a 48mm/58mm combination. Moreover, exterior diameters of up to 66mm are available for the 48mm cup. The geometry of the cup is similar to the geometry of the devices used for hip resurfacing. The big difference is the material – the cup is made of titanium and permits, in my experience, better bone in-growth than the cobalt-chromium alloys that are used in hip resurfacing.

Is there any need at all for bearing couples of 48mm?

Some of my colleagues have suggested that 36mm would be sufficient and that anything larger would entail a risk of soft tissue impingement without offering greater range of motion. I frankly don't share this opinion. In the interest of getting as close to the patient's natural anatomy as possible, I always use the largest possible diameter. While it has not yet been proven in clinical trials for diameters above 36mm, I'm confident that larger diameters are superior. They offer greater stability, better load distribution and more natural biomechanics.

But don't the rates of wear debris increase along with increases in diameter?

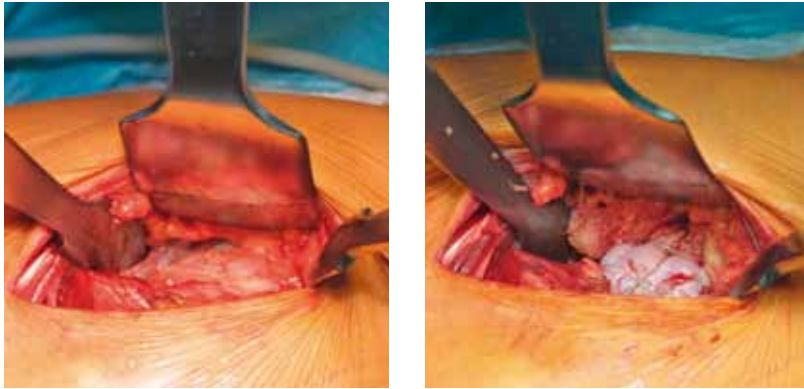
No. This problem was solved by the introduction of the hard-on-hard bearing couples. In the 800 ceramic-on-ceramic bearing couples I have implanted since 1997, I haven't seen a single case of serious wear problems.

Are there any particulars that need to be kept in mind during surgery?

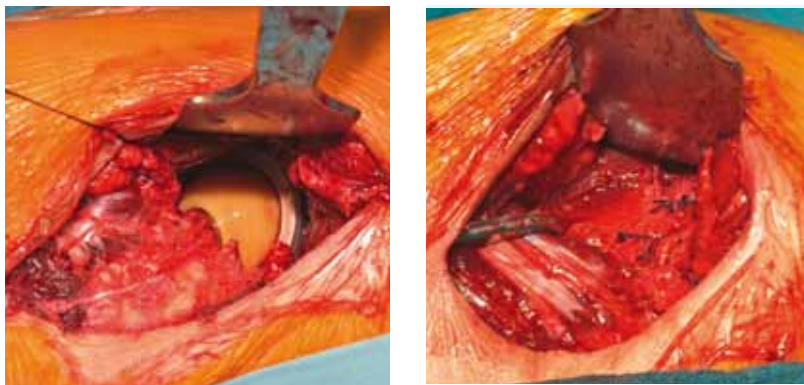
Here, too, it is clear that good training and as much experience as possible are the key prerequisites for good results. The correct positioning of the device is always crucial. It is a press-fit cup that is implanted without screws. Those who are not used to restoring the original leg length might tend – in the case of larger diameters – to wind up with excessive leg lengthening. While efforts should naturally be made to avoid this, it is otherwise a standard implant in terms of handling. Experienced surgeons should have no problems.

¹ DeltaMotion® System, Finsbury Orthopaedics

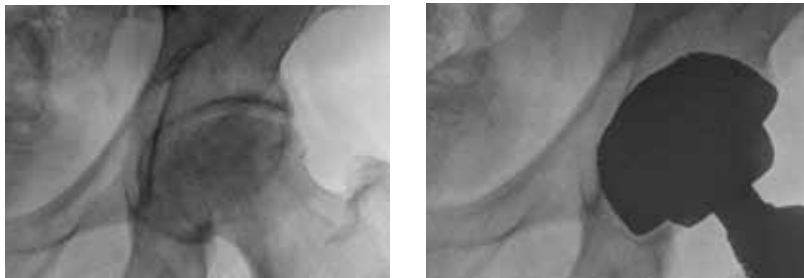
Reconstruction of the hip joint capsule



Hip joint capsule before and after T-shaped incision



Situs before and after reconstruction of the capsule



Pre- and post-operative X-ray of male patient, 47, with secondary osteoarthritis after osteonecrosis of the left femoral head, less invasive non-cemented THA with a 40mm BIOLOX® delta ball head

Pictures:
 Torsten Prietzel, MD, Head of the Department for Less-invasive Arthroplasty and Tumour Orthopaedics, Leipzig University Orthopaedic Clinic, Leipzig, Germany; www.minderinvasive-endoprothetik.de, mdi-tep@uniklinik-leipzig.de

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Additional reference:
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**Heinrich Wecker,
 Managing Director
 Marketing and Sales
 Central and East
 Europe Medical
 Products Division**

Dear Reader,

It has been some time since we delivered our five-millionth component made of BIOLOX® ceramics. The importance of ceramic materials for bearing couples in arthroplasty continues to grow steadily. This development has a lot to do with the work of our researchers, our development and production engineers and all other employees involved in our organization.

Excellence (quality) is ultimately a holistic process. The quality of the result you achieve following this concept depends on the quality of each individual step. This is naturally a self-evident proposition in modern medicine, particularly in the area of surgery. The task of establishing and optimizing the treatment of human beings is far more difficult than in areas involving only industrial applications. Nonetheless, or precisely on account of this, surgeons are doing their utmost to continue to progress in this field.

That's what this magazine is all about. The report on the most recent AAOS Annual Meeting offers us a view of how much we have come to know about tribological factors and their importance for the success of arthroplasty. The interview with Dr. Koen de Smet (pp. 1–2) addresses the importance of experience, surgical skill and technique. Professor Klaus-Peter Günther (pp. 8–9) explains how "perimedical" factors also play a very crucial role. Intensive research is being carried out in all of these areas, and work is underway for new and improved solutions for even better results for the patients we serve.

All of this exemplifies what CeramTec stands for today and in the future.

*Yours sincerely,
 Heinrich Wecker*

Results and Trends in Hip Replacement

A summary from the AAOS Annual Meeting in Las Vegas

The 76th Annual Meeting of the American Academy of Orthopaedic Surgeons (AAOS) in Las Vegas was once again the biggest event of the specialty worldwide: More than 33,000 experts were present, among them 15,402 physicians. There were over 500 technical exhibits, 675 papers, 196 instructional courses were given and 33 symposia held. Among the most widely discussed clinical trends in joint reconstruction were the following topics: hip resurfacing and large diameter bearings, implant reliability and longevity, alternative bearing materials, bearing surface wear and related problems. CeraNews has monitored the talks and discussions to give you an overview of the latest developments concerning wear couples.



after large head THA and hip resurfacing (24:24 cases). The patients showed no differences in gait speed, muscle tension, the quiet standing test and their WOMAC scores at all follow-up times. In the fast stair climbing test however, the results of THA-patients were better, whereas in the far reach test the results of HRA-patients were superior. In most studies the outcome of HRA is better due to patient selection (younger, more active) and to the larger head diameter. HRA with big head diameters are usually compared to 28mm MoM THA. According to Lavigne's study there is no true advantage for HRA. The sparing of bone seems to be no longer an issue considering the extremely good results of modern uncemented stems that are showing high survivorship rates after almost 25 years now.

G. Grammatopoulos (UK) reported on the outcome of THA following the revision of hip resurfacing which he described as worse than that of primary THA. The tissue of pseudo-tumours detected after HRA showed a grey and yellow colour, which spread through the tissue planes, with some of the pseudo-tumours being destructive. No micro-organisms were detected. 50% of the pseudo-tumour group showed complications after revision: 3 nerve injuries, 2 loosening and 3 dislocations. The re-revision rate was 38%. The Oxford hip score as well as the UCLA score showed significantly worse post-revision-results than in the control group. The score results were sometimes similar to pre-primary-OP.

Large head sizes

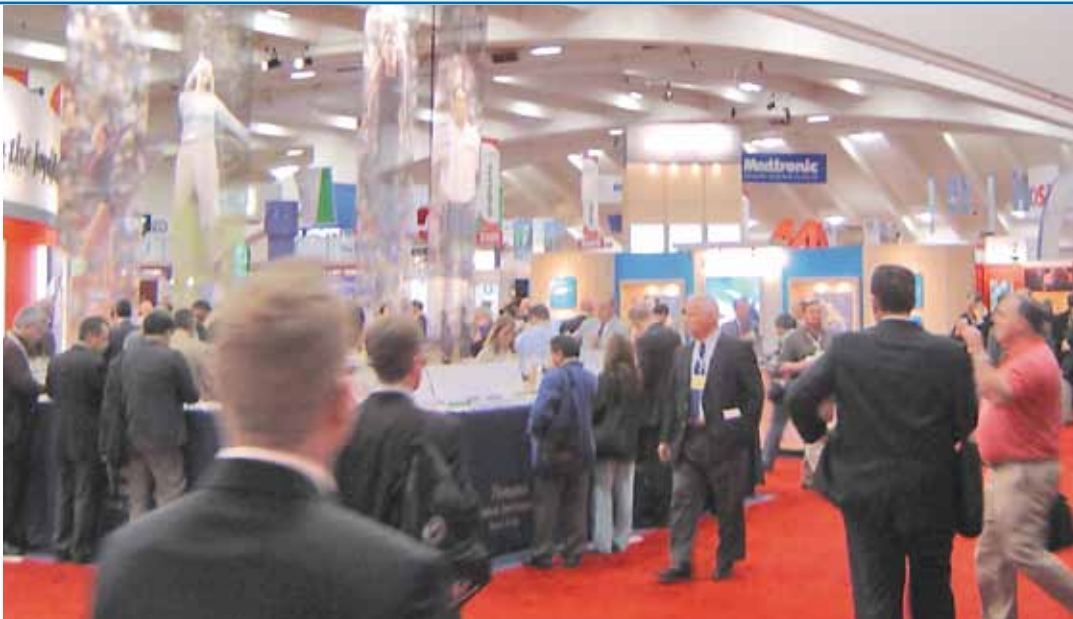
O. Holubowycz (Australia) reported on a multi-center international randomized controlled trial with large head sizes. The trial compared the incidence of dislocation with a 36mm and a 28mm metal ball head on XPE in primary and revision THA one year post-op. The results showed that a 36mm ball head reduces the incidence of dislocation. One year after primary THA with a 36mm articu-



Hip Resurfacing

Andrew Shimmin (Australia) discussed the effect of operative volume on the outcome of hip resurfacing. According to his report, the outcome varies extensively between the different centers due to patient selection, surgical technique, implant design, surgical volume and experience. The Australian register lists approximately 9,000 HRAs in 200 hospitals. While 75% of the hospitals do less than 30 procedures per year (low volume hospitals), 64% of all HRAs are done in only 16 hospitals (high volume hospitals). Shimmin showed that, while the revision rate in low volume hospitals is 6%, it is only 2.7% in high volume hospitals with more than 100 cases per year. A similar report was given by **T. Aulakh** (UK). He presented the results of a 10-year-study which shows that the revision rate strongly depends on the number of HRAs performed.

M. Lavigne (Canada) reported on a comparison of the clinical outcome as well as gait characteristics



Picture: AO Foundation

lation the incidence of dislocation was only 0.8% compared to 4.4% with a 28mm ball head. The incidence of dislocation after revision THA with a 36mm articulation was 4.9% compared to 11.1% with a 28mm ball head.

P. Chavan (USA) gave a talk about optimal cup placement in patients with lumbo sacral deformities. He used different head sizes – 28, 32 and 36mm – in a computer model. The ROM was measured at the point of impingement while performing eight different movements predisposing the hip to anterior and posterior impingement. Increasing the head size from 28 to 36mm led to a reduction in impingement of 43% and provided a functional ROM unless the cup anteversion was also reduced.

Implant reliability and longevity

Stuart B. Goodman (USA) reported on the clinical performance of modern bearing couples. His practical experience indicates that the survivorship of modern hip bearings for up to 15–20 years is 85–90% and even better than the survivorship of conventional ones. For MoPE several studies showed around 50% reduction of the wear volume by comparing conventional UHMWPE with XPE. But the wear particles of XPE are smaller and probably biologically more active. For MoM the studies showed very good survivorship rates: up to 100% after 11 years (L.Dorr). The concerns with MoM, however, are also the wear particles. Up until now there is no reliable data on the biological effects. The number of the particles with MoM was larger by a factor of 10 to 1000 compared to PE wear. On top of that the ion level in the blood increased and pseudo-tumours developed. In addition, fatigue crack propagation occurred, in some cases leading to rim fracture. For CoC the results were altogether good. Here, squeaking, fracturing and material constraints during revision are being discussed.

Bill Walter (Australia) reported on the tribology of ceramic bearings on the basis of almost 10,000 hip replacements in approximately 20 years. The points of discussion regarding ceramics are fracture, noise, stripe wear and the need for very precise positioning. Stripe wear mostly occurs with misoriented cups, where the inclination is more than 45 degrees and the anteversion less than 15 degrees. The average wear volume found was 1.2 mm³/y. Fractures occurred in 0% of the heads, in 0.1% of the inserts after primary surgery and in 2% overall after revision surgery, probably due to the re-use of metal tapers with a ceramic standard head. If squeaking occurred it was due to patient factors (young, tall, heavy), surgical factors (surgical technique, removal of bone and tissue to avoid tissue impingement, clean taper) as well as design factors (thin walled components with low eigenfrequencies).

Alternative bearing surfaces

In this session there was an intense discussion about metal ions and their effects, mostly on the basis of the Oxford results (see above, G. Grammatopoulos). 15% of the female patients developed pseudo-tumours (PT) and revising PT showed extremely poor results. **W. Maloney** (USA) warned that this could very well become a new playground for lawyers. Therefore surgeons should carefully document that the patient was well informed about these risks.

J. D'Antonio (USA) asked whether there is a real advantage to MoM. He emphasized once more the many unknowns about it. According to him the biggest advantage seems to be the opportunity to use large heads. His own MoPE results with 36mm pairings, however, showed lower dislocation rates than the ones usually presented for MoM.

The incidence of noise was also widely discussed. D'Antonio gave an overview of possible reasons and mechanisms. It became clear that the overall



system has to be investigated to find out why there are systems that show a higher incidence of noise than others. D'Antonio said he didn't know why other surgeons had a higher incidence of noise than he himself. There were only five patients in his cohort of about 3,000 who reported squeaking, but none of them could reproduce it.

S. Greenwald (USA) thinks that the results presented by **Rothman**, **Ranawat** and **Murphy** seem to indicate that a certain cup's design might contribute to a higher incidence.

Hip Society Meeting

C. Ranawat (USA) reported on the good to excellent results for ceramic-on-ceramic bearings five to seven years after surgery. He explained in detail the toughening mechanisms of the BIOLOX®*delta* and pointed out the importance of the system design for the longevity of hip implants.

W. Hozack (USA) gave a very detailed and complete overview of noise and squeaking in THA, clearly stating that noise is created with all bearing materials. He said that squeaking in ceramic-on-ceramic bearings seems to be predominantly caused by impingement, mostly in combination with the malpositioning of components, the femoral component selection and the acetabular component design. His own results indicate that the incidence of squeaking is far lower with a heavy titanium stem (0.7%) than with a slim titanium stem (8.7%). He stated that there is no evidence at this time that squeaking adversely affects longevity or wear characteristics.

I. Learmonth (USA) summarized the biological implications of increased metal ion levels after metal-on-metal hip arthroplasty. He alluded to the long latency periods of particle mediated diseases. Nevertheless, the metallic debris may cause pseudo-tumours, varying in incidence between less than 0.15% and more than 20%, depending on the series under consideration.

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- Beaule, P. E. et al.: Technology 2009: Alternative bearing surfaces: The good, bad and indifferent. Instructional course 143, AAOS 2009
- Ranawat, C.: Ceramic-ceramic THA at 10+ years: What have we learned about what works and what does not? Hip Society/American Association of Hip and Knee Surgeons, AAOS 2009
- Hozack, W.: Ceramic squeak: how frequent? What causes it? Can it be avoided? Hip Society/American Association of Hip and Knee Surgeons, AAOS 2009
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Acronyms:

- ALVAL = aseptic, lymphocytic vasculitis and associated lesions
- CoC = ceramic-on-ceramic
- HRA = hip resurfacing arthroplasty
- MoPE = metal-on-PE
- MoM = metal-on-metal
- PT = pseudo-tumour
- ROM = range of motion
- THA = total hip arthroplasty
- UHMWPE = ultra high molecular weight polyethylene
- XPE = crosslinked polyethylene

What is Best for the Young Patient?

Instructional courses and research results:
Bearing surface selection for total hip arthroplasty

The new bearings represent a transforming advance in THA. But each of them has its strengths and weaknesses. Understanding these helps to find the optimal choice of implant for every patient. The instructional courses of Daniel Berry, Steven MacDonald, Peter Sharkey and Jay Lieberman (USA) and the research of John Fisher provide guidelines.

Summary of strengths and weaknesses of bearing options:

Bearing	Strengths	Weaknesses
Crosslinked polyethylene in combination with ceramic ball heads	<ul style="list-style-type: none"> • Good wear characteristics: short to medium term clinical data and parallel lab data show an 80–90% wear reduction compared to conventional PE (In-vitro studies of John Fisher, UK) • Lipped liner configurations available • Multiple head sizes available 	<ul style="list-style-type: none"> • Wear will probably not be as low as with hard-on-hard surfaces. But will it be low enough to eliminate osteolysis in young patients? • Particle size and surface area could influence behaviour. • Risk of liner fracture when polyethylene is thin
Ceramic-on-ceramic	<ul style="list-style-type: none"> • Low wear • No ions 	<ul style="list-style-type: none"> • Sensitive to impingement • Sensitive to wrong cup position • Fracture risk • “Noises” (Paper AAOS 2009)
Metal-on-metal	<ul style="list-style-type: none"> • Low wear • Allows largest femoral head to outside cup diameter ratio • No fracture risk 	<ul style="list-style-type: none"> • Systemic metal ion level elevations – significance uncertain • Metal allergy • Local lymphocytic response (ALVAL) • “Noises” (Paper AAOS 2009)

Source:
Instructional Course, Bearing Surface Selection for Total Hip Arthroplasty: What’s best for the young patient? Daniel J Berry, MD, Rochester, MN, Steven J MacDonald, MD, London, ON, Canada, Peter F Sharkey, MD, Philadelphia, PA, Jay R Lieberman, MD, Farmington, CT; Papers AAOS 2009

Editor’s note:
This review of potential advantages and disadvantages of different bearing surfaces reflects the American perspective considering the fact that some bearing couples (such as BIOLOX® delta-on-BIOLOX® delta) are not available for US physicians.



Rationalized decision making

A. Older patients, low demand patients

Metal-on-polyethylene

- Large head to reduce dislocation risk
- Crosslinked vs. conventional polyethylene
 - No ion risk
 - Little fracture risk
 - Cost reasonable

B. Older, medium or high demand patients

Metal-on-crosslinked polyethylene

- No ion risk
- Low fracture risk
- Cost reasonable
- Low wear

C. Young, active female patients in child-bearing years

1. Consider ceramic-on-ceramic or ceramic/metal-on-crosslinked polyethylene
2. Avoid metal-on-metal (unquantified ion risk to fetus)

D. Young, active male or female patient not in child-bearing years

Metal/ceramic-on-crosslinked polyethylene vs. metal-on-metal vs. ceramic-on-ceramic vs. metal-on-polyethylene

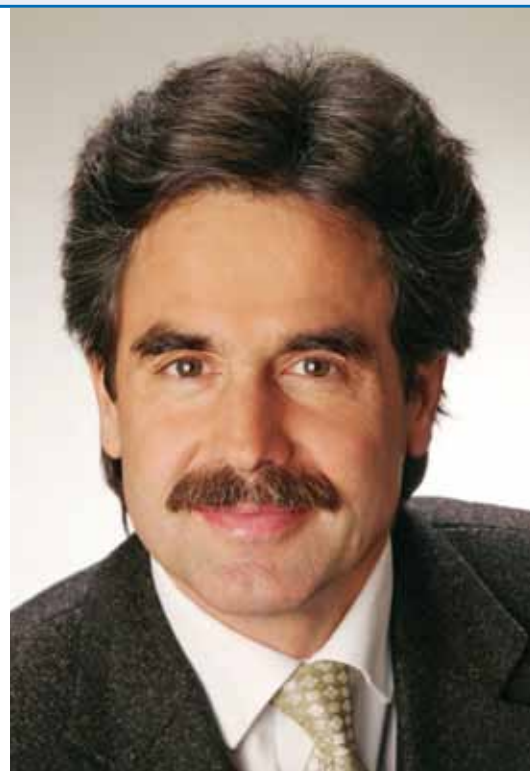
- Ion risk likely to be low
- Metal-on-metal allows biggest head size, no fracture risk
- Note: Metal-on-metal ALVAL type reactions may be more common with women

E. Young, active patients with systemic renal disease or metal sensitivities

1. Consider ceramic-on-ceramic or ceramic/metal-on-crosslinked polyethylene
2. Avoid metal-on-metal (ion risk)

Impact of Patient-specific Factors on THA Outcome

Recent editions of CeraNews have offered reports on the surgical and device-related factors that have an impact on the success of hip arthroplasty. In the present edition, we shift the focus to patient-specific factors. It is commonly assumed that nearly every THA patient has a marked improvement in his quality of life. Numerous studies seem to confirm this, however it is important to keep in mind that most of these studies are carried out at special medical centers with selective patient data. Studies centering on the influence of patient-specific factors on treatment success are far less common. One researcher who is currently examining this issue is Professor Klaus-Peter Günther, M.D. who holds a chair in orthopaedics at the Carl Gustav Carus Medical School at the Technical University of Dresden. He is also the Medical Director of the University's Orthopaedic Clinic and the current President of the German Society for Orthopaedics and Orthopaedic Surgery (DGOOC).



Klaus-Peter Günther, MD

Is arthroplasty as successful as it is generally assumed to be?

Indeed, arthroplasty is very successful, especially hip arthroplasty. The average patient shows outstanding results after surgery. If we were to represent a combination of the factors hip pain and hip function on a scale of 0 (maximum problems) to 100 (no problems), the average patient would show a pre-operative score of somewhere between 40 and 60 and a post-operative score of somewhere between 85 and 95. The implantation of an artificial hip effectively lifts patients to the functional level of an average healthy individual in the same age bracket. This is an outstanding result, and virtually unparalleled in other fields of medicine. As a surgical procedure, arthroplasty shows the greatest degree of success when compared to the resources expended, and continues to show this success over a long period of time.

But there is a statistically significant group of patients who do not fare so well.

The excellent figures for the average patient tend to draw attention away from the experience of patients who show scores just below, or even significantly below, the 80 mark. Taking an entirely sober look at the matter, I think we can assume that around 10% to 15% of all patients do not experience the improvements they had expected. That being said, we do not yet have the data we need to draw proper conclusions.

Are there important distinctions to be made among the reasons for below-average outcomes?

We can safely assume that around 3% of all patients will be worse off after the surgery than they were before. Around 5% to 10% of all patients seem not to profit from arthroplasty and another few percent of all patients will experience only below-average improvements.

What is your explanation of these less favorable results?

Our investigations indicate that 10% to 15% of all patients show no significant improvement in their scores after surgery. A small portion of these cases can be explained in terms of complications and pain relating to the surgical intervention. However, mixed results are certainly more significant in this context and must be kept in mind. For instance, when pain has been reduced following surgery, but function has not been sufficiently restored, or vice versa. This then leads to a relatively low overall score – even if the particular patient is fairly

content with the absence of pain and only modest functional improvements. The evaluation itself lacks a dimension that would connect the objectively gathered data and the subjective expectations of the patient.

The subjective factor is not represented?

The existing methods of evaluation do not sufficiently account for this factor. Some patients are primarily concerned about the absence of pain and far less concerned about function. Other patients want to be able to participate in physical activities and are prepared to accept relatively high levels of pain. Failing to take this into account, the scores (such as the Harris Hip Score) will indicate a favorable result in around 5% to 10% of patients, although the patients themselves are not satisfied. But here, too, we don't have any exact figures. The available methods of evaluation tend to cast all patients in the same mold. The tabulated scores may conceal important aspects of a patient's experience. For instance, there is the WOMAC score, which includes the variable stiffness in addition to the variables function and pain. In 5% to 10% of our patients, this score is not significantly better after surgery than before surgery. Although we do not yet know what the exact reasons are, our data seem to support the few published reports on this subject.

Do we need new methods of evaluation?

Among others, the Osteoarthritis Research Society International (OARSI) and the proponents of the initiative Outcome Measures in Rheumatoid Arthritis Clinical Trials (OMERACT) are currently addressing the issue of new instruments for a better represen-

tation of results in THA. While reports have not yet been published, we clearly need to increase our efforts in this area.

What would the new methods of evaluation look like?

They could represent results in a patient-specific manner with specific weightings for the various dimensions. This, however, would come at the cost of commensurability and would therefore not be suitable for scientific investigations. We have not yet been able to come up with a good solution. At the moment, we are only aware of the deficits.

What progress have you made in investigating these issues at your clinic?

With support provided by the Deutsche Arthrosehilfe (German Osteoarthritis Assistance), we were able to introduce the Dresden Hip Register in 2005. The data in the register is based on standard pre-operative and 6-month post-operative examinations carried out in all of our patients who undergo hip replacement surgery. The examinations include WOMAC questionnaires and other questionnaires pertaining to quality of life. We now have data on nearly 1,500 patients.

What are the results of preliminary evaluation?

We are still in the middle of our investigations and are not able to draw any specific conclusions. On the other hand, there are clear indications. For instance, patients who live alone usually wind up with somewhat worse function and quality-of-life scores than patients who live in a family context. The same seems to apply to the factor work, with those who work tending to have better results. The gender factor seems to be somewhat more complex. We know that women come to surgery with worse pre-operative scores than men, and that they also show slightly worse scores after surgery. However, the discrepancy between the two scores is somewhat larger than in the case of men, meaning that they profit more from surgery without necessarily reaching the absolute values of men. While we expected to see a negative impact in the case of overweight patients, this was only confirmed in the case of pronounced obesity and extremely high body-mass indices. And finally, we see clear psychological factors.

What does psychology have to do with arthroplasty?

In a study that we are currently carrying out with medical psychologists at our clinic, we are investigating the results of hip arthroplasty in a small group of around 300 patients with the help of an elaborate procedure that includes the creation of detailed psychological profiles. We have so far been able to demonstrate that patients who exhibit

higher levels of anxiety before surgery usually show lower scores after surgery, both in terms of function and quality of life, than patients without such fears. In contrast, we have seen that very optimistic, life-affirming individuals – those with a so-called personality type D – tend to achieve scores that are well above average after THA. This emphasizes the importance of paying greater attention to a patient's personality profile.

Have you introduced any clinical responses to these findings?

Not yet. We need to wait for the final results. These data should allow us to identify the factors that are subject to influence. In my view, however, it would make sense to point out in the context of the informed consent discussion that pre-operative anxiety could adversely affect a patient's post-operative results. In other words, a pre-operative WOMAC score that is well below average cannot be expected to turn into a high post-operative score. It would be better in such cases if the patient were to refrain from developing overly high expectations. We are now planning to extend our investigations so as to determine whether specific forms of psychological support given to patients with higher levels of pre-operative anxiety could have a positive impact on the success of surgery.

Can clinical paths improve patient outcomes?

We have carried out such investigations in the area of knee arthroplasty and found that the differences were not as significant as we had expected. This is possibly due to the fact that we started from a very high level. While one often hears that paths introduce significant improvements, I am aware of no investigations that clearly demonstrate additional improvements in clinics where high standards of quality are already maintained.

What is your view of pre-operative strength training?

It has been clearly demonstrated that giving patients training in physiotherapy and providing them with extensive information on a pre-operative basis can improve outcomes. It now appears that pre-operative strength training also has a positive effect on outcomes. However, there are conflicting reports in this regard, and it warrants pointing out that it is usually not possible to differentiate the effect of such training from the effects of parallel intervention such as simultaneous physiotherapy training.

We will pursue this topic in forthcoming issues of CeraNews as the results become available.

Clinical Comparison of Bearing Couples

Polyethylene debris can damage periprosthetic tissue and represents one of the main causes of aseptic loosening in hip arthroplasty. The results of a 20-year study comparing the performance of ceramic and metal heads when combined with polyethylene cups in a THA system have recently been presented. The ceramic-on-polyethylene bearing couple produced significantly less debris and showed lower revision rates. The 20-year study essentially confirms evidence gathered from other studies indicating a correlation between metal heads and osteolysis and higher revision rates. A separate long-term study (also conducted over a 20-year period) showed that ceramic-on-ceramic bearing couples were associated with significantly less wear and osteolysis than the ceramic-on-polyethylene bearing couples.

Ceramic-on-Polyethylene vs. Metal-on-Polyethylene

Ihle et al. (Germany) have reported on the significantly lower rates of wear and debris in ceramic-on-polyethylene bearing couples when compared to metal-on-polyethylene bearing couples after 20 years in vivo. In a prospective study, 93 uncemented total hips of a single type were deployed in 80 consecutive patients. The patients ranged in age from 28 to 82, with an average age of 52. A total of 80 ceramic heads and 13 metal heads with a diameter of 32mm were used. A total of 57 patients (67 hips) were examined post-surgery. The investigators were able to evaluate 55 cases using the EBRA method. The average annual wear rate was 0.107mm for the ceramic head group and 0.190mm for the metal head group. At 13.8%, the revision rate for the ceramic head group was significantly lower than the 46.2% revision rate for the metal head group.

Ihle M, Mai S, Siebert W. Keramik- und Metallköpfe im Dauertest – eine Langzeitanalyse des PE-Abriebs nach 20 Jahren. *Orthopädische Praxis* 2009; 46(5): 221–230

Ceramic-on-Ceramic vs. Ceramic-on-Polyethylene

Hernigou et al. (France) retrospectively reviewed 28 patients (56 hips) with cemented bilateral THA who underwent surgery between 1981 and 1985. Patients younger than 55 years received an alumina CoC THA, patients between 56 and 65 years received an alumina CoP THA contralaterally. The mean age at surgery was 55 (38–61) years. The mean follow-up was 20 (20–25) years. The alumina head was 32 mm. Wear was always less with CoC than with CoP. The average linear wear was 0.05 mm per year (0.03–0.09 mm), the total wear volume for the complete implantation time was 1274 mm³ (684–1984 mm³) in CoP hips. The wear of the CoC hips was significantly lower with a mean decentring of the femoral head of 13 µm per year (0.0–0.20 µm) as linear wear and an average of 124 mm³ (0–519 mm³) for the total wear volume. After the analysis

of 5 implants (none included in this series) the authors demonstrated that this correlated to a wear rate of 5 µm per year on the head and cup. They showed that the low incidence of osteolysis observed on radiographs with CoC is consistent with the results of other reports of CoC THA. They noted that the CT scan provides more accurate information than standard radiographs with regard to the volume of osteolysis. The number of lesions detected with the CT scan was lower with CoC than with contralateral CoP. With CoC hips, the volume of osteolysis was always lower than with CoP hips when the comparison was made on the same patient.

Hernigou P, Zilber S, Filippini P, Poignard A. Ceramic-Ceramic Bearing Decreases Osteolysis: A 20-year Study versus Ceramic-Polyethylene on the Contralateral Hip. *Clin Orthop Rel Res*. Published online 13 March 2009

Ceramic-on-Ceramic

The pathogenesis of failure in patients with CoC bearings has not been well documented. **Savarino et al.** (Italy) reported on clinical, radiographic, laboratory and histopathological data from 30 consecutive patients with failed alumina CoC THAs (28, 32mm) at a median follow-up of 8 years. Retrieved periimplant tissues and prosthesis wear were also analyzed. Loosening was due to malpositioning, primary mechanical instability, trauma or infection. The authors pointed out that variable implant wear and tissue macrophage reaction were present but activation of giant cells/osteoclasts was not induced and no correlation between the histocytic reaction and the level of osteolysis was found. The authors concluded that these findings indicate that, in contrast to MoP bearings, wear debris and occasional osteolysis were not responsible for the loosening and failure of CoC implants. The aseptic cases showed a mechanical cause of failure (malpositioning, trauma, primary mechanical instability).

Savarino L, Baldini N, Ciapetti G, Pellacani A, Giunti A. Is wear debris responsible for failure in alumina-on-alumina implants? *Acta Orthopaedica* 2009; 80(2):162–167

Metal-on-Metal Hip Resurfacing

Harvie et al. (UK) reported on two cases of femoral neuropathy due to pseudo-tumour masses complicating MoM resurfacing arthroplasty. In this study a late presentation of femoral nerve palsy was seen more than 2 years after MoM hip resurfacing. It was caused by the distortion and traction of the femoral nerve through a large pseudo-tumour mass. In case one, a 55-year-old female patient showed hip pain and femoral nerve palsy 3 years after implantation of a MoM hip resurfacing. Plain radiographs showed no abnormality but CT scanning showed a large solid pseudo-tumour mass in the right iliopsoas muscle. The patient underwent a pseudo-tumour excision and revision to a hybrid CoC THA. She mobilised pain free. The femoral nerve biopsy in case

two showed neurohistopathological appearances that have not been reported previously. All viable elements of the nerve tissue had been completely destroyed. Nerve fascicles were replaced by calcified debris.

The authors concluded that these neuro-histopathological findings possibly represent a new form of peripheral nerve pathology resulting from MoM wear debris.

Harvie P, Giele H, Fang C, Ansorge O, Ostlere S, Gibbons M, Whitwell D. The treatment of femoral neuropathy due to pseudo-tumour caused by metal-on-metal resurfacing arthroplasty. *Hip International* 2008;18 (4): 313–320

Hart et al. (UK) reported that circulating levels of cobalt and chromium ions in patients with MoM hip resurfacing are associated with CD8⁺ T-cell lymphopenia. There was also a reduction in CD19⁺ (B-cell) counts. The authors conducted a cross-sectional follow-up study including an analysis of the demographic, clinical and laboratory characteristics of patients with MoM hip resurfacing (unilateral, bilateral), CoC and MoP hip replacement. This study included 164 patients (101 male, 63 female), 106 with MoM hips and 58 with non-MoM hips, who were aged under 65 years, with a pre-operative diagnosis of osteoarthritis and no pre-existing immunological disorders. Laboratory-defined T-cell lymphopenia was present in 13 patients (15%) (CD8⁺ lymphopenia) and in 11 patients (13%) (CD3⁺ lymphopenia) with unilateral MoM hips. There were significant differences in the absolute CD8⁺ lymphocyte subset counts for the MoM groups compared with each control group (p-values 0.024–0.046).

The authors emphasized that this is the first report in man that found a direct link between the level of Co and Cr ions in blood and the numbers of circulating lymphocytes.

Hart AJ, Skinner JA, Winship P, Faria N, Lukinskaya E, Webster D, Muirhead-Allwood S, Aldam CH, Anwar H, Powell JJ. Circulating levels of cobalt and chromium from metal-on-metal hip replacement are associated with CD8⁺ T-cell lymphopenia. *J Bone Joint Surg Br* 2009; 91-B: 835–42

Hart et al. (UK) carried out a metal artefact-reduction MRI to view the periprosthetic soft tissues, a three-dimensional CT measurement of the position of the component and an inductively-coupled plasma mass spectrometry analysis of cobalt and chromium levels in whole blood on 26 consecutive patients with unexplained pain following MoM hip resurfacing. 9 male patients with a mean age of 52.3 years (33–63) and 17 female patients with a mean age of 52 years (38–70) were included. They found 3 clinically relevant results. MRI showed periprosthetic lesions around 16 hips (male, female; symptomatic, asymptomatic), with 14 collections of fluid and 2 soft-tissue masses. 13 of 16 cases were associated with

positions of the component outside the Lewinnek safe zone. The patients with painful MoM hips had higher metal ion levels than those with well-functioning prostheses. The authors concluded that these observations may help to determine the cause of failure, to predict the need for future revision and to aid the choice of revision prostheses.

Hart AJ, Sabah S, Henckel J, Lewis A, Cobb J, Sampson B, Mitchell A, Skinner JA. The painful metal-on-metal hip resurfacing. *J Bone Joint Surg Br* 2009; 91-B: 738–44

Hart et al. (UK) measured the cup inclination angle from plain radiographs and the whole blood ion levels of 26 patients with MoM hip resurfacing using Inductively Coupled Plasma Mass Spectrometry. The authors pointed out that new analytical methods may allow blood metal levels to be used as a realistic biomarker of the in-vivo wear rate of MoM hips. They have shown that the effect of an acetabular inclination angle of more than 50 degrees on wear rates of MoM hips, as measured through blood metal ion levels, appears to be similar to that known of MoP hips. The findings suggest that, concerning their wear rate, MoM hip resurfacings are not tolerant of certain suboptimal positions. The authors concluded that metal levels can be minimized with optimal orientation of the acetabular component. Therefore the authors encouraged surgeons to pay close attention to the inclination angle.

Hart AJ, Buddhev P, Winship P, Faria N, Powell JJ, Skinner JA. Cup inclination angle of greater than 50 degrees increases whole blood concentrations of cobalt and chromium ions after metal-on-metal hip resurfacing. *Hip International* 2008; 18(3): 212–219

Peacock et al. (UK) reported on a case of MoM hip resurfacing complicated by a reactive synovitis and symptomatic large effusion which resulted in groin pain, restricted movement, dislocation, peripheral oedema, as well as swelling of the thigh and ankle swelling. The episodes of pain began 5 months after the operation and lasted for 7 years. After the conversion to a cemented THA the symptoms disappeared. 450 mls of fluid were drained from this patient and a reactive synovial-like membrane was removed. Histological analysis of the retrieved specimens revealed a dense lymphocyte infiltrate. There was no evidence of wear debris. The authors concluded that the effusion is a further manifestation of an immune reaction to submicron metal wear particles. They pointed out that long term immune related complications associated with MoM hip resurfacing could be higher than reported to date. They added that investigating thigh pain and non specific symptoms following MoM hip resurfacing could be problematic given that routine tests may all be normal.

Peacock A, Say J, Lawrence T. Reactive synovitis following hip resurfacing: a case presentation. *Hip International* 2008; 18(3): 224–7

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Medical Products Division
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D-73207 Plochingen, Germany
Phone: +49 / 7153 / 6 11-828
Fax: +49 / 7153 / 6 11 838
medical_products@ceramtec.de
www.biolox.com

Your contact:

Paul Silberer
Phone: +49 / 71 53 / 611 522
p.silberer@ceramtec.de

Text and layout:

LoopKomm Infomarketing
Terlaner Str. 8
D-79111 Freiburg i. Brsg.
Phone: +49 / 7634 / 55 19 46
Fax: +49 / 7634 / 55 19 47
mail@loopkomm.de
www.loopkomm.de

Concept and coordination:

Sylvia Usbeck
Heinrich Wecker
Florence Petkow

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