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Ceramics in Orthopaedics

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Dear Reader,

Medicine and industry have been working together on the enhancement and optimization of joint replacement for about five decades. Surgical procedures have thus become more and more sophisticated, implant systems have become better, but also more complex.

At the same time, pressure on clinics and doctors has increased in many countries. The endeavor to achieve economic efficiency has reduced available time. Unfortunately, one of the areas affected is training for surgeons. All too often it is at the expense of the already tight budgets of clinics or the equally short leisure time of doctors.

If the time spent on training is no longer sufficient to also learn the fine points of complex implant systems and their implantation techniques, the quality of treatment is bound to suffer. The competition is won, though, by clinics that have documentary evidence of achieving the best quality. In countries with an arthroplasty register it can already be monitored independently and objectively.

Industry makes a major contribution to surgeons’ training, which is normally not remunerated. But in light of a global price decline for implants the resources available are becoming increasingly scarce. Hospitals are therefore well-advised to invest in the professional training of their surgeons themselves and to give their employees sufficient time for it. They will continue to have at their disposal the indispensable specific know-how of the manufacturers.

Sincerely yours,

Heinrich Wecker

Interview

What Matters is How You Master Your Craft

Dr. Thomas Schmalzried is among the most prominent orthopaedic surgeons in the USA. After graduating from Stanford University, he earned his medical degree at the Medical School of the University of California in Los Angeles (UCLA). He was the hip and implant fellow at Harvard University and an Assistant in Orthopaedic Surgery at the Massachusetts General Hospital. Currently, Dr. Schmalzried is the Director of the Joint Replacement Institute at St. Vincent Medical Center in Los Angeles. He specializes in the diagnosis and treatment of diseases of the adult hip and knee, with a focus on total joint replacement. Dr. Schmalzried is the author of over 160 scientific manuscripts and is on the editorial review board of several scientific journals. He is a three-time recipient of the Sir John Charnley Award for pioneering research in total hip arthroplasty. CeraNews met him at the Current Concepts in Joint Replacement meeting in May 2011.

Could you give us an overview about the Joint Replacement Institute?

The Joint Replacement Institute was established by Dr. Harlan Amstutz in 1991. I joined him there in 1991, following my fellowship in Boston. We have four surgeons doing roughly 1,000 arthroplasty cases a year. We operate more on hips than on knees, and the percentage of revision surgery is in the 15-20% range. Most of our revision cases have had their primary arthroplasties elsewhere. We focus on patient care, research and education. Our mission is excellence in all three.

How can you combine them at all?

The resources are all on the same campus. The patient clinic area and the research facilities are under the same roof, and the hospital is just a short walk away. I also have an appointment at the Harbor-UCLA Medical Center, which is a different campus in a different location. We have a freestanding residency program there. We take four residents a year and train them in orthopaedic surgery.

Where does the funding for your research come from?

We receive some support from St. Vincent Medical Center. I have a private foundation that supports research, and we have some support from industry. Over time we have had other funding sources. I have had funding from the Orthopaedic Research and Education Foundation and others. Dr. Amstutz has had funding from different sources.

How did you reach your personal level of excellence?

I was fortunate to have an outstanding educational path. I did my internship and residency at the Univer-
sity of California Los Angeles where I worked closely with Harlan Amstutz, one of the real pioneers in arthroplasty. The UCLA Department of Orthopaedic Surgery had a strong focus on arthroplasty and was one of the leading centers in the United States. I had the chance to take time out of my residency to do research in joint replacement, with funding from the National Institutes of Health. Following completion of my residency, I went to the Massachusetts General Hospital and worked under the direction of William Harris and was heavily involved in his research work. To have these two prominent, distinguished mentors and work closely with them at a young age, I think that was the foundation for my career.

**Are there any distinct lessons that you took from people like Dr. Amstutz and Dr. Harris?**

During my early years, the issue of periprosthetic osteolysis was “the” issue in orthopaedic surgery. We more or less knew that some kinds of particles were involved but there were some issues that had to be explained: why did it occur in this case but not in that, why in this location but not in that? At UCLA, I was involved in Dr. Amstutz’s investigation of a hip resurfacing system using porous ingrowth on both the acetabular and femoral sides, with a titanium femoral component articulating against a large-diameter, non-crosslinked polyethylene insert. As you can imagine, the volumetric wear would be high, and we were seeing osteolysis in the femoral head and neck at a four-year post-operative timeframe. Then I went to Boston and found myself operating with Dr. Harris, doing revisions for osteolysis. But because it was a total hip, the osteolysis was down in the diaphysis. The systems that Dr. Amstutz and Dr. Harris were using were both made by the same manufacturer, produced with the same materials. The heads were cobalt-chrome in the total hip embodiment, but the substrates were titanium alloy, and the porous ingrowth material was commercially pure titanium. So literally, I went from one week, revising cases with the same materials where the osteolysis was confined to the neck and head, to the next week revising cases where the osteolysis was more globally distributed down the femoral canal. This double experience led to the concept of the effective joint space. The article that we published on this is still very often referred to. The fluid and the wear particles simply seek the path of least resistance. In the resurfacing, because the entire articulation is contained within the pseudocapsule, the only access that the fluid and the wear particles have is to the head and neck. It is a dynamic process where muscle contraction and joint movement actually create forces that change the pressure and drive the fluid around the effective joint space.

You were very active in athletics, namely in basketball. Did that play a role in your career?

I think that there are some common elements. In serious sports there is a high level of dedication, commitment and discipline. I think that in orthopaedic training there is a carryover. It is a long process. You have to make a commitment to it. If you look across all specialties, in orthopaedic surgery you will find more ex-athletes than in most other specialties.

How did you find your specialization in orthopaedics?

My father worked in the pharmaceutical industry. He liked orthopaedic surgeons best, because they were more regular, normal people, and he had more difficulty with internists that he found to be more intellectual. I just wanted to be one of those guys that my dad thought were good guys. There was a second point of influence. When I was fifteen-years old, I had a bicycle accident that resulted in a severe shoulder injury that required surgery. I was a good basketball player, and I anticipated a university scholarship, and so everyone was very concerned: was this injury going to somehow hurt my opportunities? I remember being in the hospital – a very large man came into my room, but very gentle, very soft-spoken. He mentioned that he had seen me play and I was a pretty good player. Then he just said, “You know, I don’t want you to be worried about your shoulder, because we can fix it. You are going to be fine, and you are going to be able to play.” I thought: what a great thing to be able to do. I didn’t grow up wanting to be a doctor; I grew up wanting to be an orthopaedic surgeon.

And why did you focus on arthroplasty?

I was going to be a sports doctor, to take care of athletes. But, during the time at UCLA, because of Dr. Amstutz, the focus of the program was on joint replacement. I was completely enamored with the fact that you could put metal and plastic inside someone’s body, and that it could basically replace the natural joint function.

Dr. Amstutz and Dr. Harris were the stars of competing universes on the East and the West Coast. How did you manage to bridge that?

I am the only one to have trained with both of them. I knew they were competitive. When I went to Boston, it was very clear that one of the things that Dr. Harris wanted was to learn as much as he could about Dr. Amstutz’s philosophy. He kept asking me how the department was set up and managed, and what Dr. Amstutz thought about this, that, and the other thing. When I came back from Boston, I went to work again with Dr. Amstutz, and it was the same: What does Harris think about this; how does Harris do that? But there was never anything inappropriate. I never felt uncomfortable. I think both of them, without ever saying it, recognized that it was a good thing that there was at least one guy who had the opportunity to be with both of them.

Are there still different cultures on both coasts?

The differences have diminished. There are still debates on smaller issues, but there is more agreement I think as the industry has grown up, and there is more consensus today because we have more experience and more data.

How do you see the state of the debate on hip resurfacing (HR) today?

It seems somewhat blurred to me. Just look at some of the contra arguments we heard in today’s CCJR crossfire session. The impression was created that there is this high revision rate in hip resurfacing and that adverse tissue reactions are the main problem. The truth is that it is high compared to some other things, but whether or not it is absolutely high is debatable. Actually, the minority of HR revisions are for adverse local tissue reactions. The majority of metal-on-metal revisions that are documented in the Australian registry are due to cup loosening. It is not even really loosening because the cups have never ingrown initially. Is it because of the ingrowth surface, is it because of cobalt-chrome rather than titanium? Is it because of the higher frictional torque from the bearing? We don’t know exactly. Surgeons who don’t have any resurfacing patients don’t have any exposure to the absolutely amazing outcomes in patient function. They see only HR patients having problems. A common denominator for patients having problems has to do with the orientation of the implants. Well-fixed implants with a good function fall within a certain window of implant position. When the function isn’t good, or there is a local problem, it is usually because the position is outside that window. Colleagues without direct experience tend to think that the problems are related only to the technology. The truth is that there are at least three legs to the stool: one is the patient, the other is the surgical implantation, and the third is the technology.

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Are you generally pleased with the results of hip replacement in the young patient?

Yes.

But there are problems – what are the challenges?

Historically, arthroplasty surgeons have put a priority on the durability of the operation. I am wholly supportive of that. But that philosophy has led to some, perhaps unintended, consequences. One of those is withholding treatment to younger patients. If you
say: “You are too young, you should wait” you are putting a higher value on the patient’s quality of life later in life than on the quality of the patient’s life in the here and now. I think that is philosophically flawed, because tomorrow is promised to no one. I had a patient who was living near a major city with a number of prominent orthopaedic surgeons. He had consultations with them. They told him: “You are too young to have a total hip replacement, and you should wait”. He came to see me and said, “My boys are 12 and 14 years old, and there are things that I want to do with them, but I cannot because of this hip. As far I am concerned, the time for hip replacement is now.” I did a hip resurfacing on him. He is coming up on ten years and hasn’t had another operation on that hip. About five years after the operation he sent me an e-mail that basically said: if it fell apart tomorrow, I would have no regrets, because it gave me these great times with my boys. He was the ideal patient for resurfacing, others are not. You have to choose the patients carefully. There are patients that have been on the Internet and they seek out resurfacing, but their anatomy or bone quality, is not appropriate for it. They still want to return to skiing, tennis or surfing. This, of course, is also possible with modern total hip replacement. So I tell them: “If you want to do these things, I know that the technology is capable”.

Without restrictions?

We did a survey of the membership of the American Association of Hip and Knee Surgeons (AAHKS), about what recommendations they gave patients after total joint surgery. The only thing they all agreed on was there wasn’t much data to guide or support their recommendations. If you take a 65-year old Medicare patient, I am going to be very close to saying that we have evidence that he can do whatever he wants and will die before the implant does. But what nobody has data on is: how long is this generation of technology going to last under the heavy loading conditions that are involved in some of the high impact sports that young and very active patients want to practice? The patients ask: “How long is it going to last?” But what they really want to know is: how long is it going to last in me? The short answer is: nobody knows. One of the reasons why we don’t know is, because for two generations of surgeons, the philosophy has been to tell your patients not to do things in order to increase the longevity of the implants. That was probably reasonable advice in the early days of arthroplasty. We didn’t have today’s materials and we didn’t have good fallback operations. There wasn’t the revision technology that exists today. Fortunately, all this has evolved, so I think we need to evolve our recommendations, too, while assessing the in-vivo conditions more closely. I want to know how many cycles the current generation total hip replacement technology will be good for.

“ There are some very active patients who put five million cycles on their prosthesis in a year.”

Can you tell us about your research on activity levels?

We have gathered some data that we are planning to present at next year’s academy meeting. We have used a small two-dimensional waterproof accelerometer that measures the motion of the leg in real time that can go for about two weeks without a recharge. We can distinguish swimming from cycling, from walking, from running and start to make some extrapolations, considering also the bending moments and the forces on the implant. There are only 25 patients on the study because it is very time and resource consuming. The devices are expensive, and it isn’t easy to get people to commit to doing this. There are some very active patients who put five million cycles on their prosthesis in a year. People are generally quite active in their 60s. They do slow down over time, though. The drop-off in activity between 70 and 80 is impressive. But, if you start with a young patient, you can catch them in a decade where they are consistently active. The reason why I think these studies can become important is: we might be able to really shed light on what the functional capability of current generation technology is, based on data.

There is a broad range of technology available. Are there criteria for choosing a certain type of technology?

If you have a Medicare patient, the hospital is going to get a Diagnosis Related Group (DRG) payment. In these cases the hospital prefers that the joint replacement technology be as inexpensive as possible due to the fact that they receive a global payment for the entire surgery. Some organizations employ the concept of “patient demand matching”. This assumes that if a patient is 65 they are not going to be very demanding, and you don’t need to use premium technology. What our data shows is that age of the patient is not the best criterion to use in selecting technology for each patient. In fact, Body Mass Index (BMI) is a much better predictor. People in need of arthroplasty don’t tend to change their weight over time. A patient that is thin and fit will tend to be active, and a person that is overweight will not.

Regarding all this, do you have an algorithm for choosing a hip replacement implant?

Yes and no. Right now, for hip replacement, the substrates are always the same. I use the same titanium alloy tapered stem and the same titanium alloy porous ingrowth shell almost always with the same crosslinked polyethylene. I use ceramic heads in anyone that has some history of superficial reac-
tion to jewelry or metal exposure – or any case that I am revising, because they had an issue with a cobalt-chrome implant. I will also use that in smaller females that have a high activity level. More commonly in large males I use cobalt-chrome heads. It is just the issue of the wear resistance versus the fracture risk. I know the fracture risk is low with the BIOLOX® delta material. I try to avoid using ceramic femoral ball heads when the taper engagement is short. For total hips I examine if aggregate benefit-risk ratio is more favorable for a ceramic or a metal head. I certainly know an argument can be made that the wear resistance of the ceramic outweighs the risk of fracture.

But why young and old; why the difference there?

I guess it reflects my experience with crosslinked polyethylene. The data we have over ten years would indicate that the wear rate of crosslinked polyethylene against a metal head is low enough, and that the risk of a wear-related problem, in a patient of Medicare age, 65 or older, is accordingly also very low. So looking at the budget for our hospital: can I be cost effective and save some money with a metal head and still give the patient the technology that will keep them revision free?

Price is an issue?

Price is an issue in some patient groups. The health care financing in America is not consistent. For Medicare patients, the hospital gets a bundled payment for the service. So, any increase in the cost of the device is a decrease in the profitability of the hospital. On the other hand, there are private insurance models that actually are incentivizing indirectly the use of a more expensive technology. The surgeon has to be conscious of the payer’s and the hospital’s budget. If there is a mechanism for the technology to be paid for without it being a cost to the hospital, then I like to use the best technology available. But I am sensitive to the cost issue.

Years ago, Harlan Amstutz told us he would have preferred ceramic resurfacing, but the technology wasn’t available. What if it will be in the near future?

Ceramic-on-ceramic resurfacing is something that I remain very interested in. The challenge is the socket. One of the things that we learned from this generation of hip resurfacing is: if you are going to have a cementless acetabular component, the total wall thickness has to be 5 mm or less, if you want to be competitive with the bone removal for a total hip in that same patient. At the same time it is essential, especially for ceramic implants, that the femoral component is well supported either by bone or cement. One thing that the last ten years taught us is that the concept of resurfacing is very viable and highly functional. We have to separate out the fact that it was done with metal-on-metal bearings.

Where do you think hip replacement is going to in the next five to ten years? What are your plans for the future?

In the United States there is going to be a slowdown in the evolution of technology as it is becoming increasingly difficult to get new technology into the American market. New technology is going to be introduced outside the United States. This is disappointing for me, because I would like to be at the cutting edge – but that is the reality.

New technology is going to be introduced outside the United States. This is disappointing for me, because I would like to be at the cutting edge – but that is the reality.

I will continue to do the things I am doing now. I enjoy doing surgery. I want to continue research on patient activity, function and durability. The unique contribution that we can make is reporting our results not just in terms of years, but in terms of quantitative activity. I will continue with my research on resurfacing. I have a metal-on-metal resurfacing experience: four different devices, same surgeon. I am in a good position to make the case that the most important variable is the patient. The next most important variable is the surgical technique. Then, there are some device-specific issues, but they are taking a backseat to proper patient selection and surgical technique.

Is it possible to improve patient selection?

If there was a big enough market for resurfacing, we could develop devices that you could use in a broader cross section of patients. So, right now, for metal-on-metal resurfacing, all the data indicates that the best results are in larger statured and relatively young people. Ceramic-on-ceramic might work well in smaller patients and could turn out to be a good treatment for the young woman with arthritis due to dysplasia.

There is a tremendous confidence in highly crosslinked polyethylene. The eventual marker would be osteolysis. Is that issue already resolved?

No. There is a tendency for people to sort of get complacent about crosslinked polyethylene. But five-year data is not ten-year or twenty-year data.
We just have to recognize the limitations of what we really know. There is a Swedish report of the McKee-Farrar at twenty-years versus the Charnley at twenty-years. The McKee-Farrar lost market share early, because it had a higher five-year revision rate than the Charnley. But at twenty-years the survival is the same. Don’t forget that registry data is heavily influenced by short-term results. What happens over the first five years influences what is done subsequently. This needs to be recognized.

Are there any differences in surgical technique for young and very active patients?

My surgical technique does not differ based on the characteristics of the patient. People talk about less invasive, minimally invasive, but what we are all talking about is trying to reduce the aggregate trauma of the surgery – and an important component of that is homeostasis. So, you want to respect the tissue and the tissue planes and keep the wound dry. Many patients will ask questions like: do you use the anterior or the posterior approach, because that is something that they find debated on the Internet. I use an analogy as an answer to this: We have a TV channel called the Food Network, and they have cooking competitions. There are three identical kitchens with three identical sets of ingredients. In the first kitchen we have the Iron Chef, who is very famous for his Asian style cuisine. In the second kitchen we have Paula Deen, also very famous for her classical Southern food. And in the third kitchen we have Jessie James, who is an auto mechanic. They are going to make soup, using the same ingredients. The Iron Chef will produce a spicy soup which is really good, while Paula Deen makes a heavy cream-based soup, totally different, but also absolutely delicious. Jessie James’ soup tastes terrible. He doesn’t know how to put the ingredients together because he is an auto mechanic - not a chef. I don’t think there is any one element of surgical technique that is always correct or better. What matters is how you put all the ingredients of surgery together.

How do you deal with the more and more informed patients?

The patients will come in, and they will either have their questions listed or they will present me with things that they have downloaded off the Internet. The first thing you have to realize is that they are very proud and have confidence in the research that they did. You must respect the research they did. If you dismiss any of it, they will dismiss you. I will give you an example. It is a Thanksgiving dinner at my house. A close relative is there, who has known me since he was about ten years old. He is a smart guy, graduated from UCLA, having his own business. He watched me go to medical school and do all my training. He has no reason but to trust me – we are related. After dinner he tells me about his heel pain. I examine him right there at the dining room table, he takes off his shoe and sock, and I press on the bottom of his heel, then I pinch the back of his Achilles tendon – no pain. But it hurts very much when I push on the back of his heel because he suffers from Retrocalcaneal Bursitis. Hearing this he shakes his head and says, “Are you sure that I don’t have Plantar Fasciitis?” I said, “Well, if you had Plantar Fasciitis it would hurt when I push here. Does that hurt?” He says, “No”. I say, “It hurts here, doesn’t it?” He says, “Yea, that hurts!” “Well, that is Retrocalcaneal Bursitis.” “Are you sure that I don’t have Achilles tendonitis?” I say, “Well, if you had Achilles tendonitis it would hurt when I pinch here. Does that hurt?” He goes, “No”, “But it hurts here?” “Yes, that hurts; don’t do that!” “Well, that is Retrocalcaneal Bursitis.” He has got this funny look on his face, and I ask him, “What’s the matter?” He says, “I didn’t see that one on the Internet.”
Amongst the most widely discussed clinical trends in hip joint reconstruction were:

- adverse reactions to metal debris (ARMD) in MoM THA and hip resurfacing,
- large bearing diameters,
- revision rates of bearing surfaces and results of revisions,
- risk factors in aseptic revision,
- implant reliability and longevity.

CeraNews has monitored the discussions to give an overview of the latest developments concerning wear couples.

**AAHKS surgeons performed fewer total joint arthroplasties (TJA) in 2009 than 2008.** A study projected fewer orthopaedic specialists in the future.

Richard Iorio et al. (USA)\(^{16}\) presented the results of a comprehensive survey, which was conducted by the American Association of Hip and Knee Surgeons (AAHKS) in late 2009. The AAHKS asked its members (48.1% response rate, 458/953) to evaluate the effects of the economic downturn on adult reconstruction surgery in the United States.

The authors stated that 33.6% of the surveyed AAKHS surgeons reported a decrease and 10.8% an increase in surgical volume. A total of 31.1% reported changing their TJA procedures due to declining reimbursement. The authors reported that 49–57% of AAHKS surgeons would be unable to provide Medicare patients with TJA if Medicare reimbursement would drop by 15–20%. They estimated that in 2009 the TJA volume for the AAHKS membership was 294,067. This is a 0.5% decrease compared to the projected 2008 TJA volume of 295,430. While the economy is recovering, many senior AAHKS surgeons are going to retire, with fewer young surgeons to replace them. As a result, the authors fear that without an increase in reimbursement there may be an access problem for patients in the United States seeking TJA in the future.

**Experts report a decrease in demand for primary total joint arthroplasties (TJA) in patients with rheumatoid arthritis (RA) in the United States from 1992–2005.**

The Nationwide Inpatient Sample (NIS) database\(^{33}\) was started in 1988. It is the largest U.S. database of inpatient hospital stays containing data on more than 7 million hospital stays per year from approximately 20% of U.S. community hospitals (appr. 1,000 hospitals).

Using this database, Marc W. Hungerford et al. (USA)\(^{13}\) determined the total numbers of TJA for hip (THA), knee (TKA), shoulder (TSA) and elbow (TEA) and the number of procedures for RA patients performed during the period of 1992–2005. In total, there were 2,416,563 THA, 4,164,465 TKA, 125,810 TSA and 21,816 TEA. RA patients received 77,736 (3.2%) THA, 153,501 (3.7%) TKA, 8,725 (6.9%) TSA and 6,097 (27.9%) TEA. Hospitalizations increased by 92% from 186,813 (1992) to 358,261 (2005). In contrast, the proportion of TJA performed on RA patients decreased in the same period: THA (39.3%), TKA (20.7%), TSA (22.9%) and TEA (46.9%). The authors concluded that these changes in RA patients may reflect changes in disease severity and management in the treatment of RA.
Total Hip Arthroplasty (THA) aseptic revision risk factors: analysis of a US registry with 25,377 primary THA

Robert S. Namba et al. (USA)\textsuperscript{28,29} reported that factors affecting the outcome of THA and TKA in the United States are still poorly understood. The authors stated, that based on current trends, the number of revision THA will increase over the next 20 years from approximately 40,800 in 2005 to 96,700 in 2030. The TJR registry was developed in 2001 and modelled after the Swedish registry. The registry has been implemented at 50 hospitals in 6 regions. 112,000 TJR cases were registered as of December 2010.

As of March 31, 2009, 26,466 primary THA and 3,298 hip revisions were captured. The majority of the patients were female (57%). 30% of primary and 28% of revision cases were performed in patients younger than 60 years. Osteoarthritis was with 89% the most common diagnosis among primary THA. Instability (27%), aseptic loosening (24%), PE wear (20%) and osteolysis (18%) are the main reasons for hip revisions.

Metal femoral ball heads were still used in the majority of cases for both primary (76.7%) and revision (75.7%) procedures. MoXPE accounted for 53.9% primary and 43.9% revision cases. 32mm was the most commonly used femoral ball head size for primary (36.2%) and revision (32.4%) surgery. The authors reported that trends show a decrease in the use of 32mm in favour of 36mm diameter. The use of femoral ball head sizes of ≥36mm increased over the years from 4.8% in 2002 to 54.4% in 2008.

The survival rate (Kaplan-Meier) and the risk of aseptic revisions were evaluated in 25,377 primary THA. The patients were predominantly female (57.4%) and 44.4% were younger than 65 years. The cumulative survival rate was 97.4% at 5 years. The following risk factors for aseptic revision were identified:

- diagnoses other than osteoarthritis (p=0.007),
- MoP bearing surface (p=0.011),
- femoral ball head size smaller than 36mm (p=0.001).

In this context, the authors pointed out that the CoXPE bearing surface was a protective factor concerning the risk of aseptic revision.

Metal-on-metal bearings

Recent reports in the scientific literature have associated adverse reactions to metal debris (ARMD) like metallosis, pseudotumors and aseptic lymphocytic vasculitis associated lesions (ALVAL) with MoM implants. However, the effects of the presence of metal ions in blood, urine and organs of patients after MoM hip replacement are not yet fully understood. Even though it is known that exposure to heavy metals may lead to problems with the reproductive system, not much is known about possible effects of cobalt (Co) and chromium (Cr) levels on sperm parameters of young males with MoM prostheses. Several experts presented latest study results on these subjects at the AAOS 2011.


Steven M. Kurtz et al. (USA)\textsuperscript{19} used the Nationwide Inpatient Sample (NIS) database of the years 2005–2007 to identify primary MoM THA. During this period, MoM THA increased from 32 to 38% in the US. The use of MoM in females increased from 44 to 49%. In 2007, 57% of MoM patients were younger than 65 years. 43% of primary MoM THA were covered by Medicare, the authors reported. They pointed out that despite uncertain indications for their use, MoM bearings are increasingly used in females and elderly patients.

Metal ion levels and wear rates in large diameter MoM hip replacements

Ajay Malviya et al. (UK)\textsuperscript{24} measured the whole blood metal ion levels in patients with large diameter MoM hip resurfacing and 28mm MoP THA after 1 year post-operatively. The authors demonstrated that 17% of MoM patients had metal ion levels higher than the recommended United Kingdom MHRA Action Levels.\textsuperscript{27} They concluded that the use of large femoral ball head MoM THR is limited due to metal ion issues and no proven functional benefits.
David Langton et al. (UK) reported that they have frequently observed the highest blood metal ion levels in patients with large diameter MoM implants. The authors investigated a series of 43 explanted MoM implants (39 adverse reactions to metal debris, 2 infections, 2 avascular necrosis).

The annual volumetric wear rate ranged from 1.15 to 95.5mm³. The femoral ball head diameter \((r=0.579, p<0.001)\) and UCLA activity score \((r=0.629, p=0.003)\) correlated with wear. The multiple regression analysis (MRA) showed a R² value of 0.66 \((p<0.001)\). The R² value subsequently increased to 0.80 using MoM explants with typical rim loaded patterns of wear.

The authors concluded that the results suggest increased volumetric wear in large diameter bearings of rim loaded MoM hip prostheses. This correlated with increasing patient activity and bearing diameter.

Alister Hart et al. (UK) presented latest findings of the multi-disciplinary London Implant Retrieval Centre (LIRC). The Centre was founded in 2007 with the aim of investigating the failure mechanisms of MoM hip replacements. LIRC now has the largest collection of retrieved current generation MoM hip replacements in the world (>850 failed MoM components).

320 patients with failed MoM hip resurfacing (HR) were prospectively examined. The authors found no differences in wear rates between different MoM HR prostheses. The majority of implants was well fixed and aligned, not infected and failed for unexplained reasons. Edge-loading was observed in 2/3 of the hips. The measured blood metal ion levels were significantly higher in the failed MoM HR compared to 88 patients with well functioning MoM HR. Interestingly, ALVAL was found in all types of failed MoM HR. As a result, cup edge-loading was the most common finding of wear analysis of failed MoM HR. But the authors emphasized that in most cases high cup inclination angles were not the reason. The pre-revision blood metal ion levels were measured using inductively coupled plasma-mass spectroscopy (ICP-MS). At least half of the failed MoM HR showed metal ion levels above 7 parts per billion (parts per billion – equivalent to micrograms/l or nanograms/ml). The authors suggest that blood metal ion screening may be more useful than radiographs to identify and follow patients with an increased risk for failure following MoM HR.

A multivariate analysis of 138 consecutive MoM explants conducted by Alister Hart et al. confirmed strong positive correlations between cup inclination and cup wear rate \((p=0.001)\), as well as edge-loading and cup wear rate \((p<0.0001)\). There was no evidence of a correlation between femoral ball head size and wear rate.

Complications in MoM hip resurfacing (HR) associated with metal ion toxicity

Neurological symptoms, including hearing loss, have been described in patients with MoM implants and elevated blood metal ion levels. Possible effects of the presence of metal ions in blood, urine and organs of patients after MoM hip replacement are not yet fully understood.

Now, a population-based observational study by Simon Jameson et al. (UK) suggests that an association may exist between the use of MoM implants and known complications of metal toxicity. They explained that metal toxicity may also result in a higher risk of renal tract malignancy and lymphoma.

13,585 patients aged between 16 and 60 years were included in this study. They received MoM hip resurfacing (HR) between 2005 and 2009. The control group (132,855 patients) underwent carpal tunnel release (CTR). The authors used UK statistics data to...
identify the primary procedure and rates of hearing loss, lymphoma and renal tract malignancy. Multiple myeloma (MM) has no known association with metal toxicity and was used as control diagnosis.

Patients in the MoM HR group showed a significantly higher rate of hearing loss (0.23% vs. 0.09%, p<0.001) and renal tract malignancy (0.10% vs. 0.05%, p=0.038) compared to patients in the CTR control group. The lymphoma rate was higher in the MoM HR group (0.10% vs. 0.06%, p=0.100). No difference in MM rates was found between both groups (0.02%).

Risk of adverse reactions to metal debris (ARMD) in MoM hip resurfacing (HR)

David Langton et al. (UK, Belgium) reported on results of a prospective multicenter study involving 4,226 MoM HR performed between 1998 and 2009. 58 MoM HR failed due to ARMD. The median CrCo ion concentration in the ARMD group was significantly higher than in the asymptomatic control group (n=881). The authors demonstrated that increased metal wear was associated with an increased failure rate due to ARMD.

Gulraj Matharu et al. (UK) identified all patients with MoM HR revised for unexplained pain from their database (2003–2010). They reported that of 149 revised MoM HR, 22 hips (n=19) were revised for unexplained pain (prevalence 14.8%). The mean age was 54.6 years. 55% of the patients were female (n=12). The mean time from MoM HR surgery to revision was 3.9 (0.35–14.2) years. ARMD (50%, n=11), bone impingement (18%, n=4) and femoral component failure (14%, n=3) prevailed as diagnoses for revision surgery. ARMD was the most common indication for revision in the presence of unexplained pain. According to the authors, the findings suggest that ARMD probably is a heterogeneous phenomenon containing still unknown subgroups.

Edward Ebramzadeh et al. (USA, Belgium) observed ARMD in patients with metal allergy or high metal wear. They investigated a total of 308 retrieved MoM HR. ARMD were observed in 39 patients (29/162 female, 10/145 male). ARMD occurred in 22 patients with no suspected metal allergy, in 15 patients with histologically diagnosed metal allergy and in 2 patients for unknown reasons. The risk of ARMD was 75% in patients with known metal allergy, 22.2% in patients with possible metal allergy and 7.89% in patients with no metal allergy.

Elevated inflammatory cytokines in patients with adverse reactions to metal debris (ARMD)

In a case control study Scott T. Ball et al. (USA) characterized the cytokines driving the underlying inflammatory response in 10 patients with suspected ARMD from MoM implants. 3 patients with osteolysis due to PE wear served as control group. Hip synovial fluid from 6 patients with osteoarthritis (OA) served as a baseline control. The authors reported that levels of IL-6, IL-8 and IP-10 were more than 15 times higher than in the PE group, and more than 40 times higher than OA controls. There was no correlation between Co and Cr levels and cytokine levels. They concluded that these findings show that an inflammatory reaction in ARMD cases is much more intense than observed in cases with PE wear.

Incidence and prevalence of pseudotumors in MoM THA

Aaron J. Johnson et al. (USA) systematically reviewed the current literature (Medline, Embase databases) and found 25 studies that reported cases with pseudotumors.

The reported prevalence of hypersensitivity reactions after MoM THA ranged from less than 1% to 10%, whereas females were mostly affected. The authors concluded that metal hypersensitivity and pseudotumors are probably fairly rare complications.

Richie H.S. Gill et al. (UK) reported an incidence of revisions due to pseudotumors of 4% overall at 8 years (9% in females). The prevalence of asymptomatic pseudotumors was 4% overall (10% in females). Serum metal ion levels were significantly higher in patients with pseudotumors (p<0.001) compared with those in patients without pseudotumors. Linear wear was significantly higher for MoM retrievals from patients with pseudotumors (p<0.002).
Edge-loading wear on the cup components was detected. In summary, these findings indicate that pseudotumors are associated with increases in wear occurring at the MoM articulation. The authors suggest that a pseudotumor is a biological, local cellular response to increased metal wear debris and that patient motion patterns may also increase the risk. They concluded that a pseudotumor is a significant problem and its occurrence is probably underestimated.

**Osteolysis associated with metal hypersensitivity in MoM THA – conversion to CoC THA**

Youn Soo Park et al. (Korea) reported an unexpectedly high rate of periprosthetic osteolysis after 149 cementless MoM THA (146 patients). The mean age was 52 (21–80) years at the time of surgery. The mean follow-up was 8.5 years. Osteolysis was detected in 13 hips (8.7%). Of these, 5 patients (3.3%) with a persistent groin pain were revised after a mean period of 57 (49–74) months postoperatively. Intraoperative examinations, histopathologic findings and immunohistochemical analysis suggested hypersensitivity to metal. All 5 Patients received a CoC articulation. The groin pain disappeared at a mean follow-up of 33 (24–42) months. The authors recommended that in patients with persistent hip pain and osteolysis after MoM THA, surgeons should consider an exchange of MoM to a non-metal articulation.

**Do MoM hip implants affect metal ion levels in sperm and sperm viability?**

Vassilios S. Nikolaou et al. (Canada) investigated the effects of Cobalt (Co) and Chromium (Cr) ions on the semen of young males of child fathering age with MoM hip replacement. They measured Co and Cr concentrations in both blood and seminal plasma of 10 patients with well functioning MoM THA. The mean age was 45.9 ±3.0 years. An inductively coupled plasma-mass spectroscopy (ICP-MS) was used. None of the patients showed any radiological sign of osteolysis in the follow-up periods.

The measured Co and Cr concentrations were significantly lower in the seminal plasma than in the blood. The results were comparable to the observed results in a control group of 5 men matched for age. The authors concluded that both Co and Cr ions cross over to the semen at low concentrations, but had no detrimental effect on sperm parameters of young male patients with MoM THA.

The viability of the sperms, however, was lower than observed in a fertile male population without prostheses (41±19%), as Nikolaou had reported last year in his presentation at the 11th EFORT/SECOT Congress 2010 in Madrid. He concluded that the clinical significance of this finding is still unknown and further longitudinal studies are necessary to conclusively determine the effects of metal ions generated from MoM implants on sperm parameters.

**Clinical results with CoC THA**

**12-year results with CoC vs. MoP THA**

James A. D’Antonio (USA) reported on long-term clinical results with alumina CoC THA compared to MoP THA. The prospective, randomized, controlled, multicenter trial with 289 THA (n=278) was initiated in 1996. Squeaking was noted in 2 CoC THA (0.9%) and 1 liner fracture occurred. Osteolysis was observed in 17.6% of the MoP control group, but none in the CoC group. The Kaplan-Meier survivorship for any reason at 12 years was 96.8% for CoC THA compared to 91.3% for MoP THA (p=0.0046).

**10–13-year results with CoC THA**

Jason Hsu et al. (USA) evaluated long term outcomes of active patients under the age of 50 years. They retrospectively reviewed 110 consecutive CoC THA in 88 patients (54 male, 34 female) performed as a part of IDE trials by a single surgeon from 1997 to 2000. The average age was 38.8 years. 3 CoC hip designs were used. The stems were cemented, all cups were uncemented designs. The mean follow-up was 11.2 (10–13.2) years. 1 patient was lost to follow-up, 1 patient died. There were no signs of radiolucent lines. Failures of CoC THA were seen in 5 patients (1 femoral ball head fracture, 1 liner fracture, 1 dislocation, 2 aseptic loosening). Squeaking was observed in 2 patients. The survivorship of CoC THA was 95.5% at a minimum follow-up of 10 years.

“Alumina ceramic bearings for THA in a young and active patient population have performed well up to 12 years with a high survivorship and a low rate of complications.”

- James A. D’Antonio, MD

The author concluded that alumina CoC showed excellent clinical and radiographic results, a high survivorship and a low complication rate at 12-year follow-up.

“Modern ceramic-on-ceramic THA in active patients under the age of 50 is durable at minimum 10-year follow up with low rates of complications.”

- Jason Hsu, MD
9-year results of CoC vs. CoP THA

Richard De Steiger et al. (Australia)\(^7\) reported on results with 27,310 CoC THA and 13,138 CoP THA using the national database. The cumulative revision rate was 4% for CoC THA and 5.9% for CoP THA at 9 years. There were 33 revisions for liner fractures and 14 for femoral ball head fractures in both groups together.

5-year results of CoC vs. CoP THA

Andrei Manolescu et al. (Canada)\(^25\) reported on results of a randomized, controlled clinical trial with 92 patients (50 male, 42 female) younger than 60 years. The median age was 52.4 years. 5-year follow-up data were available for 78 patients who received either an alumina CoC THA or CoP THA. The authors reported excellent clinical and functional results in both groups. No statistically significant difference between the 2 groups (p>0.05) has been found yet during this short-term follow-up. A longer follow-up period is necessary to determine if the liner type (PE, ceramic) affects the long term survival of THA in young patients, the authors concluded.

5-year results with CoC THA

In contrast, Taek Rim Yoon et al. (Korea)\(^40\) reported a higher fracture rate of alumina ceramic liners (0.9%) and femoral ball heads (1.2%) in their study. Squeaking occurred in 8 hips (1.4%). The authors retrospectively reviewed 576 CoC THA (n=526) which were performed with one type of acetabular cup and different types of stems. The mean follow-up was 4.8 years. However, the authors reported excellent clinical and radiographic results.

5-year results of CoC THA vs. MoM hip resurfacing in young patients

Luthfur Rahman et al. (UK)\(^34\) evaluated 100 MoM hip resurfacing (HR) and 100 uncemented CoC THA performed by a single surgeon. Both cohorts were matched for age, sex, BMI, preoperative functional hip scores and activity levels. The mean age of the patients was 47 years. The mean follow-up was 81 months. The survival rate (Kaplan-Meier) was 100% for CoC THA and 97% for MoM HR at a minimum follow-up of 5 years.

Implant retrieval analysis of BIOLOX\textsuperscript{®} forte vs. BIOLOX\textsuperscript{®} delta ceramic femoral ball heads – 2-year in-vivo results

William L. Walter et al. (Australia, UK)\(^39\) presented results of an implant retrieval analysis of ceramic femoral components (28mm, 32mm, 36mm). BIOLOX\textsuperscript{®} delta femoral ball heads (n=5) with 1–28 months in vivo were compared to BIOLOX\textsuperscript{®} forte femoral ball heads (n=21) with less than 24 months in vivo. There was no significant difference (p>0.05) in age, gender, time to revision and femoral ball head diameter between both patient groups. The authors reported that 18 BIOLOX\textsuperscript{®} forte femoral ball heads and 4 BIOLOX\textsuperscript{®} delta femoral ball heads showed edge-loading wear (p=0.75). They explained that normal concentric loading of ceramic bearings produces extremely low wear. Edge-loading wear occurs when the femoral ball head articulates with the edge of the ceramic liner. The average volumetric wear rate for BIOLOX\textsuperscript{®} forte was 0.911mm\(^3\)/year (median 0.125mm\(^3\)/year) compared to 0.034mm\(^3\)/year (median 0.008mm\(^3\)/year) for BIOLOX\textsuperscript{®} delta.

The authors concluded that edge-loading wear volumes and wear rates are smaller in bearings with BIOLOX\textsuperscript{®} delta ceramic femoral ball heads compared to BIOLOX\textsuperscript{®} forte ceramic femoral ball heads. Walter et al. noted that these findings are consistent with hip simulator studies\(^5,35\) which have shown that BIOLOX\textsuperscript{®} delta has better wear resistance under these more severe conditions than BIOLOX\textsuperscript{®} forte.
### 18-year results of 8,022 primary CoC THA: Revision of fractured ceramic components

Francesco Traina et al. (Italy) presented long-term results of 8,022 primary CoC THA performed at the Istituto Ortopedico Rizzoli (Bologna). The 18-year survival curve (Kaplan-Meier) was 98.8% using revision for ceramic failure as the endpoint. 40 failures were reported. A femoral ball head fracture occurred in 16 patients (28mm, neck length s, 15 cases; 32mm, neck length l, 1 case). There were no fractures with BIOLOX® delta femoral ball heads. A liner fracture occurred in 24 patients. There were 22 fractures with BIOLOX® forte liners and 2 fractures with BIOLOX® delta liners.

In case of revision, the authors used BIOLOX® OPTION revision femoral ball heads as a safe solution for the rare case of ceramic component fracture. They examined the results of ceramic revision to suggest some tips and tricks to perform an easier ceramic revision and to draw an algorithm for diagnosis and treatment of fracture of a ceramic component.

> *Greater damages to the stem taper will rule out the use of the BIOLOX® OPTION system*

<table>
<thead>
<tr>
<th>Couple chosen at revision</th>
<th>Number of patients</th>
<th>Average Follow-Up</th>
<th>Results</th>
<th>Case Report</th>
</tr>
</thead>
</table>
| Cer-Cer                  | 30                 | 3.3 Yrs. (1–4)    | • No osteolysis  
                          |                    |       | • No radiographic failures  
                          |                    |       | • 93.3% good results       | ![Images](Images1.jpg) |
| Cer-Pol                  | 2                  | 7.5 Yrs. (4–11)   | • No osteolysis  
                          |                    |       | • No radiographic failures  
                          |                    |       | • Both good results         | ![Images](Images2.jpg) |
| Met-Pol                  | 8                  | 6.1 Yrs. (4–9)    | • 6 Poly wear + osteolysis  
                          |                    |       | • 1 revision                
                          |                    |       | • 87.5% bad results         | ![Images](Images3.jpg) |

Traina F et al. Revision of a Ceramic Hip for Fractured Ceramic Components. Scientific Exhibit No. SEO9, AAOS 2011
Francesco Traina and his co-authors win Award of Excellence

Of the more than 80 scientific exhibits at the AAOS Annual Meeting 2011, 3 have been selected by the AAOS Exhibits Committee to receive an Award of Excellence. The Committee has announced that the selected exhibits will be submitted to The Journal of Bone and Joint Surgery (JBJS) for publication later this year. One of the selected scientific exhibits was the study by Francesco Traina and his colleagues from the Istituto Ortopedico Rizzoli (Bologna, Italy). They examined the results of ceramic revisions and proposed a guideline for diagnosis and treatment in the case of fracture of a ceramic component.

Scientific Exhibit 09 – Revision of a Ceramic Hip for Fractured Ceramic Components by Francesco Traina, MD, Enrico Tassinari, MD, Marcello De Fine, MD, Barbara Bordini, MD, Aldo Toni, MD.

http://www3.aaos.org/education/anmeet/anmt2011/se/se_cat.cfm

In-vivo oxidation of XPE bearings

Barbara H. Currier et al. (USA) investigated the in-vivo oxidation of 120 retrieved XPE bearings. The authors noted that oxidation has been reported in both annealed and remelted XPE retrievals and may change the material’s wear resistance. Therefore they claimed that the effectiveness of these stabilization methods in preventing in-vivo oxidation and to forecast the future performance of XPE bearings requires the analysis of all types of XPE retrievals. According to the authors, 50% of retrieved XPE showed an in-vivo oxidation. The free radical concentration (FRC) was measured in retrievals of annealed XPE and antioxidant XPE. The authors found no measurable FRC in remelted XPE. They concluded that a longer term of in-vivo performance of XPE is required.

Early clinical performance of Oxinium vs. metal (CoCr) femoral balls heads articulating with XPE and conventional PE in THA

Oxinium™ is a CoCr alloy whose surface was treated with a 5µm coating of a niobium-zirconium alloy. When used in combination with XPE, this material enables a significantly lower wear rate compared to conventional PE, Azad Hussain (UK) reported last year at the 11th EFORT/SECOT Congress 2010 in Madrid.14

Now, Richard W. McCalden et al. (Canada) presented first results of a randomized controlled trial comparing Oxinium femoral ball heads and metal (CoCr) femoral ball heads articulating with conventional PE and XPE. 40 patients with identical hip replacements were randomized (10 patients in each group). The authors reported that femoral ball head penetration was higher with conventional PE compared to XPE, but there was no significant difference between Oxinium and metal femoral ball heads.

The authors concluded that XPE shows a significant improvement in wear compared to conventional PE with no clear advantage of Oxinium femoral ball heads over metal femoral ball heads.

*Oxinium™ is a trademark of Smith&Nephew, Inc.

Dislocation – which factors affect the outcome?

Aaron Carter et al. (USA) reviewed 154 patients (156 hips) who had undergone a revision surgery for instability. The average follow-up was 67 (24–119) months. 33 hips (21.2%) dislocated at a mean of 455 (3–1,905) days after surgery.

The dislocation rate in hips with cup revision was lower than in hips that had received a liner exchange (34%, p=0.004). 15% of the hips dislocated after primary revision. 32% of the hips with previous revisions dislocated. The highest dislocation rate was observed with 28mm femoral ball heads (44%) compared to larger femoral ball head sizes (11.8%). The failure rate increased by a factor of 4 if a 28mm femoral ball head was used. The authors concluded that liner exchange, previous revisions and smaller femoral ball heads are associated with a higher failure rate.
Clinical Results with Ceramics

2–7-year results of CoC and CoP THA in patients with anatomical deformities

Benazzo et al. (Italy) prospectively reviewed the clinical and radiological results of 239 primary THA in 222 patients (172 female, 50 male) using CoC bearing couples (BIOLOX® delta, BIOLOX® forte) in 135 cases and CoP bearing couples in 104 cases. 28, 32 and 36 mm ceramic femoral ball heads were used. The main diagnoses were coxarthrosis associated with anatomical deformity (72 coxa vara, 40 coxa valga, 8 dysmorphism of the proximal femur) and developmental dysplasia of the hip in 99 cases (25 Crowe 1, 25 Crowe 2, 29 Crowe 3, 20 Crowe 4). The average age at the time of surgery was 57.6 (22–94) years. The mean follow-up was 5 (2–7) years. No cases of periprosthetic osteolysis were detected. The HHS improved from 35 preoperatively to 96.6 at the final follow-up. The Kaplan-Meier survival rate was 98.28% at 5 years.

10–11-year results of CoC THA in patients with osteoarthritis

Kress et al. (Germany) prospectively analysed clinical and radiological results of 75 consecutive unselected primary cementless THA (71 patients) using alumina CoC bearing couples. Indications were primary and secondary osteoarthritis. The average age at the time of surgery was 58 (34–77) years. 62 THA in 27 women (30 hips) and 31 men (32 hips) were available for follow-up. The mean follow-up was 10.5 (10.1–11.4) years. No failure of ceramic components could be observed. Ceramic wear was undetectable. All cups were stable. In one case a non-progressive osteolysis was observed around a screw of a cup. One stem was revised for aseptic loosening. The authors concluded that the absence of measurable wear and only 1 case of non-progressive osteolysis underline the benefits of CoC bearing couples in comparison to other bearing surfaces.

6-year results of CoC THA in patients with displaced intracapsular fractures of the femoral neck (FFN) – a retrospective cohort study

From March 1996 to March 2006, Solarino et al. (Italy) performed 117 primary THA in patients with FFN. The mean age at the time of surgery was 66 (47–75) years. They noted that the risk of dislocation is higher both after a hip fracture and in elderly patients. The authors reported that a large femoral ball head articulating against a PE insert can lead to more wear, osteolysis and a higher failure rate. Therefore, alumina CoC bearing couples with 32 mm femoral ball heads were used in 35 patients (31 female, 4 male) without co-morbidities and metal disease. Of these fractures, 17 were classified as Garden III and 18 as Garden IV. Of 35 hips studied, 33 were available for clinical and radiological follow-up. The mean follow-up was 80 (24–144) months. The HHS had increased to a mean value of 97.5. At the latest follow-up, none of the implants needed a revision for any reason.

Ceramic wear was undetectable. Dislocations or ceramic fractures were not observed. The authors concluded that these results confirm that 32 mm CoC bearing couples can protect the hip from early or late dislocation.

3-year results with ceramic revision femoral ball heads

Lazennec et al. (France) reported on clinical and radiological results of 42 revisions (39 patients) using ceramic revision femoral ball heads (BIOLOX® OPTION). The mean age was 59.2 years. No failure of ceramic components could be observed. The authors noted that serum titanium levels remained under the detection limit. They reported on 3 failed procedures due to septic complications (2 hips) and failed cementless fixation (1 hip). They observed 4 dislocations due to neurological deficiencies (2 cases) and suboptimal previous femoral implantation (2 cases). The authors concluded that in the case of an acetabular cup revision and a firmly fixed stem that is to remain in situ a treatment with CoC bearing couples can be considered.


From a tribological point of view, BIOLOX® OPTION femoral ball heads can be used in combination with all of the ceramic liners in the BIOLOX® family as well as with approved liners made of PE and highly crosslinked PE.

Further information on BIOLOX® OPTION femoral ball heads is available on the Surgical Live Training DVD and in the CeraNews issue 2/2010 (pages 18–23) that you can order online (http://www.ceramtec.com/de/index/geschaftsbereiche/medizintechnik/aerzte/literatur_und_broschueren/broschueren_und_prospekte/04054,0123,0349,4042.php) or using the enclosed order form.
Dr. Carlo Callea is an orthopaedic surgeon with 39 years of experience in hip and knee prosthetic surgery, who is currently in charge of the Department of Orthopaedic Surgery at the Giovanni XXIII Clinic in Monastier di Treviso (Italy). He is also a consultant for the Department of Prosthetic Surgery at the Città di Udine Clinic and the Villa Salus Clinic in Trieste (Italy). He annually performs more than 1,200 hip and knee prosthetic surgery operations for both first implants and revisions.

Looking at the Italian arthroplasty patient, can you give us an overview of the most important socio-demographic aspects, the most common hip diseases and average loading cycles?

The most important reason for hip replacement is osteoarthritis, followed by inflammatory conditions, trauma and dysplasia. There is a high incidence of dysplasia in the region of Emilia Romagna.

You have been performing arthroplasty for 39 years. Which were the most “revolutionary” developments for you?

In the early 1970s we focused mainly on the morphology of the hip and the bone. Research was concentrated on the design of the prosthesis. Implant failure was mainly attributed to the design and not to the materials used. It certainly was a kind of revolution when we arrived at a deeper analysis of failure mechanisms and started to look at the materials, too. The recognition of polyethylene wear and of problems with cup fixation, which both lead to failures, opened the way for new developments. The standard shape of the acetabular component changed from cylindrical to conical to hemispherical. By combining metal shells with an insert the concept of modularity was introduced. On the femoral side the analysis showed that stem fixation should be mainly in the proximal part of the bone. Recent developments directed at size and design changes in order to reduce the bone loss have contributed to the improvement of arthroplasty. The latest important breakthrough is the evolution of implant materials and especially of ceramics. With BIOLOX® delta we have a bearing material at the highest level of research and production technology available.

You don’t see resurfacing as an important evolution, then?

I never believed in that solution. Our hospital had some experience with about 800 McKee/Farrar prostheses implanted in the early 1970s, with a high rate of early loosening. At that time we thought the cement was responsible and only later found out it was rather due to the material of the bearing couple. Resurfacing doesn’t make sense for three main reasons. First, I don’t see any reason to preserve the femoral head. The lack of a femoral head is not related to the later possible failure mechanisms of total hip arthroplasty. Second, when a hip resurfacing needs revision, problems on the acetabular side are very common because of the large size of the cup. Third, hip resurfacing can only be done with metal-on-metal so far, and that is not a good solution for hip arthroplasty. For young patients a short stem implant with a ceramic-on-ceramic bearing is a far better option. Ironically, it was the McKee/Farrar experience, which led us to the use of ceramics.
How did that happen?

As I mentioned, we made the cement responsible for the early failures. So we switched to the Mittelmeier design mainly because it gave us a cementless option. But this also gave us our first experience with ceramics, a material that allowed us to reduce wear and adverse biological reactions. Although the Mittelmeier design didn’t prove to be very successful either, we soon discovered the great contribution that ceramic materials could make to minimize aseptic loosening.

More than 1,300 fellows have already come to your hospital for training. Can you tell us about major changes over the “generations” concerning countries of origin, level of skills and priorities of interest like approach, MIS, implants etc.?

I didn’t notice a difference of interest depending on the countries, but rather depending on personal experience of the surgeons. I noticed great interest coming from German surgeons who tend to be very serious about what we were doing. French surgeons were easier in the management of the meetings and in their approach to medical questions.

Based on experience I noticed that when I was to receive a group of surgeons things are very different. The relationship would be less deep, and also the questions and topics discussed would not go into detail as much. We’ll talk about more general questions rather than having intense exchanges as we would in a one-to-one situation.

You perform an average of 800 THA a year. You obviously have accumulated a huge experience. Patient, surgical technique, surgical ability and material are key factors for the success of a THA. Do you have a set of “most important” recommendations or tips that you give to young surgeons on training?

My first advice to young colleagues is to start a primary arthroplastic surgery with the very clear thought in mind that even if with the best implants this will probably not be the last operation on that joint. Whatever you do, one day there will probably be a revision. You have to inform the patient about this, too. Nevertheless, choose the prosthesis as if it would be the final implant. For a young patient you have to choose the best implant you can get because the implant will have to last a very long time. I am convinced that the best solution is cementless titanium with a ceramic-on-ceramic bearing. If it’s an old patient – old meaning over 85 – in case of failure the problems that I have to confront are huge. Any revision becomes a very serious procedure. There is a great risk that the old patient won’t get up any more after a revision. So again, I have to use the best material in order to be as sure as possible that there will be no need for a revision. My other recommendation for young surgeons is that if they have decided to use a certain type of implant and surgery to not change them too easily. If you want to be a good surgeon, you have to achieve a deep knowledge about the components and materials you are using. You need a great amount of routine in your special surgical technique. If you follow fashions and change too easily, you never get the really deep knowledge and routine which is a prerequisite for good long term results.

When using ceramic-on-ceramic bearings you have to take special care of the right insertion and positioning of the insert into the cup. After insertion we stick a suction pad on the insert and pull. If the pad doesn’t come off, the insert is well placed and you can impact safely.

Which surgical approach do you prefer? Have you moved towards less invasive or minimally invasive surgery with smaller incisions over time?

When I started hip arthroplasty I used the Watson-Jones approach. I changed to a postero-lateral approach when I introduced a new type of implant. I have been using this approach since then. Over time, I reduced the size of the approach and could make the surgery less invasive. But to me it seems that the issue of minimally invasive surgery is mainly an American phenomenon. The US health care system compels the surgeons to reduce the hospital stay to an absolute minimum. We don’t have this urge in Italy. After three months all types of approach have similar results. I see no good reason for minimally invasive surgery as it makes surgery more difficult for the surgeon, there is a higher risk of malpositioning of components, and it takes longer. Normally, I need 25 to 30 minutes for a primary hip – from incision to suture. The duration of surgery also plays an important role – if it is shorter, it is an advantage for the patient.

It is said that THA is a “forgiving” procedure. But this is not true for the bearing couple. Which requirements should a bearing couple fulfill?

The ideal bearing couple is the one that produces the smallest amount of wear and wear particles. It should also have good lubrication characteristics. Obviously, ceramic-on-ceramic couples are best
in fulfilling these requirements. Although I have implanted more than 3,000 BIOLOX®-delta ceramic-on-ceramic bearings I have had only two or three cases of squeaking. Hip noise is included in our follow-up questionnaire, but we practically never get a positive answer.

When did you first implant a ceramic component in THA? Which were the reasons for doing so? How many have you implanted since then?

We were among the first in Italy to implant the first version Mittelmeier ceramic hip prosthesis in 1974 but stopped as the results proved unsatisfactory. I have used ceramic components regularly since 1975. They came from several manufacturers who by now have disappeared from the market. The results with these components were not always satisfactory. This made me switch completely to BIOLOX® products since the early 1980s.

I used mainly ceramic-on-polyethylene which already then worked very well. I was convinced that it was superior to metal-on-polyethylene in terms of wear and wear particles. And this was vindicated by the results, showing practically no material-specific problems or complications. Since then, I implanted about 8,500 ceramic ball heads.

Are ceramic components widely used in Italy?

Until five, six years ago ceramics were not used very widely in Italy, with the exception of some surgeons who always have been absolutely convinced of the material. Costs were clearly an important limiting factor. There used to be another one as not all required sizes were available, but this has been solved some years ago. In spite of costs, the use of ceramics has grown strongly over the last years. The quality of the products and their excellent clinical performance has convinced many colleagues. There is no fear of risks specific to the material any more. Ceramic components are now considered as premium products that have their price. Today, surgeons and hospitals look at the balance of what they invest and what they get in terms of results.

You have started with the very first BIOLOX® material which had significant limitations concerning available sizes and combinations. You moved to BIOLOX®-forte and later to BIOLOX®-delta, each offering new, substantially improved material properties and component options. Please tell us about your view of this development in medical technology and its implications for your clinical practice.

The size limitations of the first generation ceramics didn’t stop me using that material. When BIOLOX®-forte was introduced, I was using 28mm bearing couples, because at that time other sizes were not available. The results were so convincing that I moved from using ceramics in 20-30 per cent of the cases to almost a hundred percent already with BIOLOX®-forte. Since BIOLOX®-delta came on the market I use ceramics in all hip arthroplasties. This material represented a big step forward from the point of view of safety. And thanks to the BIOLOX®-OPTION revision ball heads we now have a ceramic solution for revision arthroplasty. This has given me a new approach to revision.

In which way?

I am convinced that in the case of revision you have to implant the best possible. For me, this is ceramic-on-ceramic. Even if the revision could be solved easier using a metal-on-polyethylene implant, I organize the procedure so that I can use a ceramic-on-ceramic bearing.

Could you give an example for that?

I had a 78-year-old patient with a Zweymüller stem and a metal-on-polyethylene bearing with a dislocation. The cup was not much anteverted. The stem was positioned in zero-anteversion and there was femoral impingement, adding up to the obvious reasons for the dislocation. The easiest solution to reduce the risk of renewed dislocation would have been to put a cemented polyethylene cup in the right position. But I decided not to do that. I removed the metal shell although it was still stable, and implanted a new titanium cup with a ceramic liner in order to get a ceramic-on-ceramic bearing. The general view is that revision doesn’t have to last as long as the first implant. My view is the opposite: I am convinced that you have to act as if the revision will have to last longer than the primary implant. I am looking for the best solution possible in order to achieve good long-term results. And even in the very rare event of a ceramic fracture it is easy to do a revision. You only have to remove the parts and then put in either a new ceramic BIOLOX®-delta insert or an insert in polyethylene and a revision ball head. It’s better to have a revision after a ceramic fracture than after aseptic loosening because of polyethylene wear or metallosis.

1 Autophor, Osteo, Switzerland
Did you have any ceramic fractures?

I had about 20 fractures with the first generation of BIOLOX®. Then I had 10 to 15 cases using BIOLOX® forte ball heads and only one case with a BIOLOX® forte insert. Since I’m using BIOLOX®delta, no fracture case occurred until now. Though very rare, these fractures confronted us with a big problem in the past. Using metal ball heads in revision included the risk of their destruction by third-body wear. Today, the fracture risk is much lower and at the same time, with the BIOLOX®OPTION system we now have a very good solution for revision.

Have you ever modified your surgical technique or your choice of implant and materials due to recurring complications in THA?

One important change was in the posterior approach, where you have a higher risk of dislocation. I take special care to reduce the risk of impingement when using this approach: that means the correct positioning of the components and removing all factors of impingement. I also started to reconstruct the external rotators which I didn’t do in the beginning. This helps reducing the risk of dislocation further.

Do you see many allergies? Are they a legal issue in Italy?

In my own experience the number of allergic patients is very low due to the fact that I use titanium and ceramic implant components, the materials with the lowest risk for causing allergies. Of course, we have allergic patients in Italy, with a higher incidence in females. I am being sued at the moment for having implanted a metal ball head 10 years ago in a patient who developed an allergy after surgery. It was a revision, and at that time we didn’t have the option of using a ceramic ball head on the well fixed stem.

As the results of arthroplasty get better and better, the focus is shifting to the remaining “small” problems. Would you say that infection is assessed differently today? How do you deal with infection in your clinical practice?

Even if infections lead to the highest complication rate, I don’t see them as a real problem. The problem of infection is going to be reduced more and more over time due to the antibiotic procedures, as well as the preparation of the patient before an operation.

You are one of the first surgeons who implanted the Lima Multigen Delta ceramic knee. Can you tell us about your experience with this implant?

I have implanted about 35 ceramic knees in three years and have had no complication. I always make sure to have a very good and homogenous distribution of the cement. We use the implant for allergic and very young patients.

Is there any case, in which you would use anything else than ceramics?

No, I am convinced that there is no case, in which you cannot use ceramic-on-ceramic. I had a 75-year-old patient recently, a former marathon champion, who returned to hospital four months after surgery for a standard follow-up, and he was already doing seven-hour-runs. After one year he did a 24-hour-run! After this very demanding case, I don’t see why you should not implant a ceramic-on-ceramic bearing.
Revision Options with Ceramic-on-Ceramic Bearings

Case reports on the treatment of osteolysis and cup migration

by Carlo Callea, MD, Giovanni XXIII Clinic, Monastier di Treviso, Italy

Case 1: Bilateral revision to CoC after cup migration of a bilateral CoP THA

Diagnosis
57-year-old female, 21 years after left THA and 23 years after right THA with CoP (32mm). The hip was painful.

Left side:
Mixed screwed cup and cemented stem. Evident migration of the cup.
Right side:
Screwed cup, non-cemented stem, mobilisation and migration of the cup.

Treatment
Right hip: Treatment with revision of the acetabular component and femoral ball head. The stable modular stem was left in situ, only the taper was replaced. Cementless pressfit cup stabilised with 2 screws on extended bone graft. Bearing couple: CoC, BIOLOX® delta femoral ball head (36mm), BIOLOX® delta insert.

Left hip: Treatment with osteotomy of the trochanter for a better approach. The acetabulum has been repaired with bone chips. Cementless pressfit cup with augments and screws. Bearing couple: CoC, BIOLOX® OPTION femoral ball head (36mm), BIOLOX® delta insert.

Posttreatment period, left and right hip
Radiological evaluation showed neither radiolucent lines nor signs of loosening. The patient did not suffer from hip pain that impaired her quality of life.
**Case 2: Revision to CoC after acetabular and femoral loosening of a CoP THA**

**Diagnosis**
65-year-old female, normal life, painful arthroplasty, 20 years after left THA with CoP. Evident periprosthetic osteolysis and polyethylene disease.

**Pre-op X-ray**

**Treatment**
Treatment with a cementless pressfit cup, stabilised with screws. Revision of the femoral components, revision stem. Bearing couple: CoC, BIOLOX® delta (36mm).

**Posttreatment period**
Radiologically, the stem and the cup were stable and well osteointegrated with no signs of radiolucent lines or osteolysis. The patient was fully satisfied with the clinical outcome.

**Post-op X-ray 1 month after revision**

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"Ceramic Bearings in THA – Pros and Cons"

CeramTec Lunch Symposium at the SICOT

CeramTec is offering a lunch symposium at the SICOT Triennial World Congress, that will take place in Prague, 6–9 September 2011, titled “Ceramic Bearings in THA – Pros and Cons”.

The symposium is scheduled for Wednesday, September 7th, between 12:30 and 1:30 pm.

After the symposium Prof. Zweymüller and Prof. Dungl will be pleased to answer your questions at our booth. We’re looking forward to seeing you in Prague!

**Chairman:**
- Prof. Karl Zweymüller (Austria)

**Co-Chairmen:**
- Prof. Pavel Dungl (Czech Republic)
- Prof. Tomáš Trč (Czech Republic)

**Topics and Speakers:**
- **Dr. Rihard Trebše** (Slovenia):
  "Basics of Tribology in THA"
- **Prof. Carsten Perka** (Germany):
  "Combination of Bearing Materials and Sources of Error”
- **Dr. Radovan Kubeš** (Czech Republic):
  "Is Squeaking in THA really a Problem?"
- **Prof. Gerald Pflüger** (Austria):
  "Clinical Experience with Ceramic Bearings"
Dear Colleagues

We are pleased to announce a very special Symposium to be held in Las Vegas, Nevada, May 19th and 20th, 2012. The Symposium will be held in conjunction with the 13th Annual Current Concepts in Joint Replacement (CCJR) Spring Meeting allowing participants the opportunity to participate in both meetings.

"Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence."

The key objectives of the Symposium are to provide a conduit to bring together the latest research, as well as, the most up-to-date clinical results in the field of modern bearings for Total Joint Replacement, and to make available all of the information shared in the conference to the orthopaedic community all over the world. The Symposium will bring together globally renowned clinical and scientific faculty and will feature symposia and case presentations. It will also feature several discussion periods in order to address questions and issues related to modern bearing surfaces. The single venue for the Bearing Surface Options in Total Joint Replacement: The Experts Provide the Evidence and the CCJR Spring Meeting will allow participating orthopaedic surgeons to gain a more complete learning experience on clinically relevant issues.

The two events are a perfect match. At the CCJR Meeting orthopaedic surgeons and healthcare professionals will be exposed to a complete update on clinically relevant topics particular to hip, knee and shoulder reconstruction. By arriving just one day earlier one also acquires a deep insight into the key subject of the bearing surface options in TJR. The 2011 CCJR Spring Meeting recently held in Las Vegas attracted more than 1,000 orthopaedic surgeon attendees from 46 different countries.

The active involvement from you and your colleagues in educational venues such as this has been an important supporting element to the excellent clinical results enjoyed globally by the patients that have had TJR surgery. It is our intent to continue to build upon the clinical benefits of advanced bearings for years to come. All clinical and scientific experts involved in the field of joint replacement are welcome not just to attend the Symposium but also to submit abstracts to the scientific committee no later than the 30th September 2011.

We hope that you will join us in Las Vegas for what we know will be an excellent learning experience.

Javad Parvizi, MD, FRCS
President, Advanced Bearings Symposium
Professor of Orthopedic Surgery at the Thomas Jefferson University
Rothman Institute, Philadelphia, Pennsylvania

A. Seth Greenwald, DPhil (Oxon)
Chairman of the Scientific Committee, Advanced Bearings Symposium
Course Director, CCJR
Orthopaedic Research Laboratories, Cleveland, Ohio

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☐ Please send me a copy of the brochure edited by CeramTec with scientific information on Bearing Couples.

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Do you have a tablet PC? Yes. ☐ iPad ☐ others ☐ No