CeraNews

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Ceramics in Orthopaedics

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William L. Walter, MD

Heinrich Wecker, Director Marketing and Sales Central and East Europe, Medical Products Division

Dear Reader,

As the indication for hip arthroplasty has been continually extended to younger patients and with the rise in life expectancy, the number of hip revisions has grown constantly. Moreover, the number of re-revisions is also on the rise.

In contrast to primary hip arthroplasty, a largely routine procedure today, revisions often involve considerable challenges for the orthopaedic surgeon, especially in cases with serious bone defects. The admonition that revisions are to be avoided continues to have top priority.

Aseptic implant loosening remains the most common cause of implant failure and the need to perform revision hip arthroplasty. Although periprosthetic, wear-related osteolysis limits the long-term success of hip arthroplasty, it can often be avoided by using wear resistant bearing couples with ceramic components. This also applies to revision hip arthroplasty.

Given the general increases in life expectancy and the increasing number of younger patients, the revision hip implant must also make a long survival time possible. In the light of the fact that around 1.4 million hip replacements are performed each year worldwide, the enormous medical and economic significance is obvious. Dr. Walter, Dr. Zagra and Dr. Thorey have put the point succinctly: ceramic products are the right choice for hip revision, too.

Yours sincerely

Heinrich Wecker

The Best Choice

Interview with William L. Walter, MD

William L. Walter is a member of the Royal Australian College of Surgeons, the Australian Orthopaedic Association (AOA) and the Arthroplasty Society of Australia. As one of only two Australians he was invited to become a member of the American Association of Hip & Knee Surgeons by the then President of the association, William Hozack. He has been appointed Associate Professor with the University of Notre Dame and is highly regarded for his outstanding research, documented in numerous publications, among others in the Journal of Arthoplasty and the Journal of Bone & Joint Surgery. Together with his father, William K. Walter, who is one of the most experienced orthopaedic surgeons of his country, he works in the Specialist Orthopaedic Group in Sydney and the Mater Hospital, one of the largest joint replacement hospitals in the southern hemisphere.

Can you give us a general overview on joint replacement in your country?
In a population of 22 million people we had 33.800 hip replacements and 40.600 knee replacements in 2008. The number of knee replacements has been increasing at a faster rate than hips. In hip replacement there is a clear trend toward using larger bearing diameters. Ten years ago the vast majority was 28 millimeters, today, almost all bearings are larger than that. There is also a trend away from cemented an towards cementless fixation. About 85% of hip replacements are done for osteoarthritis. When it comes to using ceramic components Australia is closer to Europe than to the USA.

What are the main topics of medical discussion?
We've had a lot of talk about metal-on-metal lately. That's a hot topic at the moment. Many surgeons do have good results with metal-on-metal hip resurfacing, but others are reporting local tissue reactions to metal debris. Noise production was a topic a few years ago but nobody seems to be interested in that any more. It has never been a significant clinical problem for us. In our group, we have more than 4,000 ceramic-on-ceramic bearings implanted. We identified 70 patients with noises from the hip. They are mostly younger, more active patients with a higher range of motion, with equal or better Harris Hip Scores than the average as well as good satisfaction scores. The noise normally is an infrequent occurrence that doesn't have a significant impact on their lives. We had only one single patient revised because of the noise.

You are continuing a family tradition in joint replacement. When did this tradition start?
My father started implanting artificial joints in the early 1970s. We estimate that my father has probably done about 10,000 joint replacements in his career. He was joined by Bernard Zicat in 1990, I joined the

William L. Walter, MD

practice in the year 2000. Dr. Zicat began recording all the data, starting retrospectively from the year 1988. To date, our database includes about 7,000 hip replacements and 1,800 knee replacements.

Which data do you collect?
We keep a consistent and meticulous record of all the surgeries that we do. We calculate the usual clinical scores from data collection forms that patients fill out for clinical evaluation. We collect clinical data pre- and postoperatively at different intervals, 6 months, 2, 5 and 10 years, our longest followed patients on the database are now out to 20 years. We also collect operative information about the type of implant we use as well as on the surgery itself – including surgical approach and any difficulties. We keep all the radiographs scored with a scoring system. We also collect the retrieved implants. This enables us to analyze the success of the joint replacement in our practice, and we have used the data for our research. I've also used the database for my Ph. D. thesis, which was investigating the difference between hip simulator movements and the in-vivo environment of hip replacement.

Can you tell about the difference?
The most interesting thing that I found was that wear in ceramic-on-ceramic bearings is usually not related to walking. Hip simulators that simulate walking are not testing the right action. Ceramic-on-ceramic bearings have very low wear, which usually is too small to measure. When there is enough wear to measure, it is due to edge loading. Edge loading is seen in about 85% of retrievals and it is most commonly posterior edge loading that occurs with rising from a chair or climbing a stair. Antero-superior edge loading that occurs during walking only accounts for less than one third of these edge loading retrievals. Hip simulators have changed since I wrote my Ph.D. and they now include edge loading as part of the testing for hip bearings.

Why do you continue your own data collection when there is a national registry?
The registry shows only the implant type and whether it was revised or not. Our strength is that we are able to draw more complex conclusions, e. g. by correlating the radiographic findings with the clinical outcomes and retrieval analysis.

Can a registry help to prevent large series of failure?
It can certainly pick up early failures of devices, but we have to be cautious about how we use the registry. It doesn't record much detail about the patient and doesn't reveal any detail about the surgeon. Quite a few of the factors, which the registry doesn't record have a huge impact on the outcome of the surgery. It's risky to use it to measure the performance of a device when there may be factors that could be confounding the results.

When were ceramic bearings first used in the Specialist Orthopaedic Group practice?
The first ceramic bearings were implanted in July 1997. We have now done 4,500 ceramic-on-ceramic hips. We have a cohort of 300 patients with a minimum of 10 years follow-up submitted for publication and we are collecting 10-year data on a further 700 patients, so we will soon have 10-year data on our first 1,000 patients.

> **"My father started using ceramic-on-ceramic bearings in 1997 in order to avoid the problem of osteolysis. It turned out to be one of the best decisions he ever made because it almost completely eliminated osteolysis as a reason for revision."**

Why was ceramics introduced in your clinic?
In the 1990s osteolysis caused by polyethylene debris was the major cause for revision. Ceramics appeared to have lower wear, so my father started using ceramic-on-ceramic bearings in 1997 in order to avoid the problem of osteolysis. It turned out to be one of the best decisions he ever made because it almost completely eliminated osteolysis as a reason for revision.

Do you have an algorithm for choosing wear couples in your clinic?
I do hip resurfacing in patients under 65 years without significant deformities. About 25% of my patients qualify for resurfacing.These patients obviously receive metal-on-metal bearings. All other patients get ceramic-on-ceramic.

Which wear couples are most commonly used in Australia?
Metal-on-polyethylene is still number one though it has decreased in the last 10 years from 65% to

slightly over 50%. Metal-on-metal became popular and peaked in 2007, followed by a significant dropping of numbers since then. The number of ceramic-on-ceramic bearings was increasing ten years ago, remained stable for a long time, experienced a slight drop two or three years ago because of the noise discussion and is now increasing again at around 20%. Ceramic-on-polyethylene has a share of about 10%.

“Ceramic hips are mostly revised for incidental problems like recurrent dislocation, periprosthetic fracture or some other problem unrelated to the bearing. Polyethylene bearings are usually revised for osteolysis. Metal-on-metal is connected to both incidental reasons as well as wear debris.”

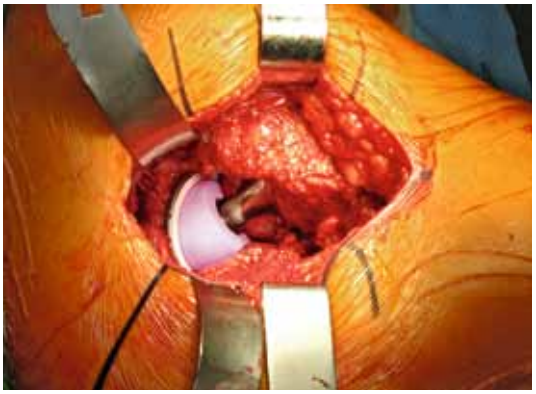
You have been using a new type of acetabular cup with a pre-mounted ceramic insert since December 2008. What are your experiences?
We generally use ceramics because it has the lowest wear rate and the most benign wear debris. Monoblock cups[1] with a pre-mounted ceramic insert additionally allow us to use larger diameter bearings. We have done over 300 of these cups now and we have followed up a cohort of 200 with minimum 6 months after surgery. We initially thought we'd do 20 and see how it went. But we were so happy with the results that we kept going. That has proved to be a good decision. We had one dislocation in an elderly lady after a fall. Two other patients had to be re-operated, one had a broken trochanter, the other suffered a fall and a periprosthetic femoral fracture. There have been no revisions related to the bearing, no cup loosening or migration. There are two great advantages. The larger diameter makes the hip more stable, and there is no second interface as the cup and insert are factory assembled. Ceramic hips are mostly revised for incidental problems like recurrent dislocation, periprosthetic fracture or some other problem unrelated to the bearing. Polyethylene bearings are usually revised for osteolysis. Metal-on-metal is connected to both incidental reasons as well as wear debris.

What do you do to keep the dislocation rate low?
I think it's mainly a question of surgical technique. The two most important things are soft tissue balancing and avoiding anterior impingement that could force the hip out at the back. We are also very careful with the repair of soft tissues, having developed specific techniques for that. Last but not least, we are also using larger diameter bearings.

How would you summarize your experience with hip revision? What are the critical points?
10 years ago we saw high numbers of loose cemented femoral components to be revised. Since then the number of loose cemented femoral components has fallen drastically, we rarely see those now. We are still performing revisions for osteolysis, but they are becoming less and less common as it is ten years since we implanted polyethylene. We occasionally revise a hip for periprosthetic fracture. Looking at our collection of explants from the past 10 years, we have a large number of hips with polyethylene liners revised for wear. We have about 100 ceramic-on-ceramic bearings, most of which were sent to us, and a growing collection of metal-on-metal implants.

“It always comes down to the same three things: choosing the right procedure for the right patient; doing the surgery technically as well as it can be done and choosing the right implant and materials.”

What is left to be improved?
There is still a small number of complications that should be reduced. We have a one, two percent risk of things going wrong in the first 10 years, including dislocation and other complications. It always comes down to the same 3 things:



CoC bearing couple: monoblock cup with a pre-mounted BIOLOX®*delta* liner and femoral ball head (BIOLOX®OPTION system)[1]

choosing the right procedure for the right patient; doing the surgery technically as well as it can be done – we are still finding little ways to improving the surgical technique – and choosing the right implant and materials. Education plays an important role in all of these aspects.

“Ceramic-on-ceramic is the best choice for revision, too.”

Which bearings do you use in hip revision?
Just occasionally there is a reason to use a polyethylene liner because of acetabular component fixation. If we find a well fixed acetabular component in combination with poor bone quality it may be prudent to cement a new poly liner into the well fixed shell. But normally we use a cementless cup with a ceramic-on-ceramic bearing. We often face situations with a well fixed femoral component and a loose acetabular cup. The femoral component may have been originally designed for a metal head. We have several hundred cases where we put a ceramic head onto that, using a sleeve[2], with good results. With conventional BIOLOX®*forte* we had a femoral ball head fracture rate of 1% in these cases. Since we introduced the new BIOLOX®OPTION revision system with the BIOLOX®*delta* material we haven't seen a single fracture. Anyway, the alternative would be to remove the femoral component with a 100% chance of damaging the femur. The other option would be to use metal-on-polyethylene. But we have seen patients where the osteolysis has recurred after that choice. It seems much more sensible to use ceramic-on-ceramic when you are revising for osteolysis than implanting another poly liner. Ceramic-on-ceramic is the best choice for revision, too.

[1] DeltaMotion®System, Finsbury Orthopaedics
[2] BIOLOX®OPTION, CeramTec GmbH

Highlights of the Annual Meeting of the American Academy of Orthopaedic Surgeons (AAOS)

New Orleans, March 9–13, 2010

The educational programs offered in this year's Congress included 24 symposia, 720 podium presentations, 89 scientific exhibits, 567 poster presentations and 196 instructional courses. In addition, orthopaedic companies from all over the world put more than 500 technical exhibits on display.

A total of 12,548 orthopaedic surgeons came to the New Orleans meeting hoping to explore and become more familiar with the most recent developments in joint reconstruction, spinal surgery, trauma and sports medicine. Of these 7,632 were from the USA, 710 from Canada, 881 from Central and South America, 2,035 from Europe, 1,200 from Asia and the South Pacific and 81 from Africa. Additionally, there were 1,954 allied health professionals making a total of 14,502 professional participants. They were joined by 11,548 company exhibitors.

The exhibition highlighted important trends like less invasive arthroplasty systems, management of younger, more active patients, new techniques for revision surgery, the latest in orthobiologics, spine surgery and alternative bearing surfaces. It was, however, difficult to walk away without being aware of the key message to take home this year: The quest for longer lasting implants to prevent or delay revision procedures.

Implant reliability and longevity continue to be the most important thought in the mind of the orthopaedic surgeon. Increasingly more active and younger patients, clinical results arguing for earlier and earlier joint replacement and the difficulties faced in revision surgery are creating a strong focus on alternative bearing surfaces.

Experts forecast a rise in demand for primary and revision THA in the coming decades

THA was conceived by Sir John Charnley as a procedure for elderly patients with low activity levels. Over the past decades, the indications for hip joint arthroplasty have expanded to include both elderly patients with higher activity levels and more younger patients. The incidence of joint replacement has increased in older and also in younger patients. More young and active patients are requiring total hip replacement (THR).

More than 600,000 total joint replacements (TJR) are currently performed in the US each year. By 2030, the demand for primary THA is estimated to grow annually from 209,000 to 572,000. The rise in primary THA will be a 174% increase by that time. The future demand for total joint arthroplasty in patients under 65 years is projected to be 52% of primary THAs. The demand for primary THA in the age category from 45 to 54 years was projected to grow by a factor of 5.9 (2006-2030). By 2015, the annual hospital charges will increase to $17.4 billion for primary THA. Total hip revision procedures are projected to grow from 40,800 in 2005 to 96,700 in 2030. The projected increase for total hip revisions is 137%.[1,2,3]

The aging of the baby boomer generation is an important factor in increasing future demand for hip replacement in the United States.

> **"There is a need for hip replacements that provide more durable results than were required in the past."**
>
> – John J. Callaghan, MD

John J. Callaghan (USA)[4] reviewed the reported results of changing demographics and activity levels of patients requiring hip replacement. He emphasized that in the future, due to the baby boomer generation, there will be more younger, active, heavier patients undergoing hip replacement. Patients are better educated, more likely to be female, live 25% longer, are 20% heavier and more physically active, with a wide variability (Ø 2 million cycles/year, some patients twice that amount). He pointed out that implants will need to provide more durable results than required in the past.

A group of orthopaedic surgeons[5] (USA) prospectively collected the results for 182 revision THAs in 132 young and active patients up to 50 years old. There were 137 cases with a minimum of 2 years follow-up (mean 10.8 years). Component failure due to aseptic loosening requiring re-revision was used as the endpoint.

There were 56 revision failures that required re-revision at a mean time to failure of 93 months. Component loosening was observed in 53 cases. 53 revision failures led to re-revision arthroplasty. The overall survivorship for 182 revisions was 69.2% at a

mean follow-up of 10.8 (2-24.9) years. The survivorship for 123 cup revisions was 75.6% and for 160 stem revisions was 77.2%.

Paul T.H. Lee et al. concluded that hip revision in young patients is challenging. They recommend the restoration of bone stock in view of likely re-revisions.

“Revision hip arthroplasty in young and active patients poses a challenge due to higher activity levels and the likely need for multiple re-revisions.”

– Paul T.H. Lee, MD

The total economic costs of primary and revision THA in the United States

Based on results of the Millenium Research Group in 2009 Ryan M. Graver et al. (USA)[6,7] stated that substantial growth in revision procedures in the US will continue between 2007 and 2013 with a 23% increase in hip revisions projected during this period.

The authors provided in their study the total economic burden of patients undergoing primary THA and revision THA in the US. The data were derived from the Thomson Reuters MarketScan® databases. Patients who underwent a THA procedure from January 1, 2003 through December 31, 2006 were included in this analysis.

29,225 patients with primary THA were studied. The majority of THA patients were female (54.9%). The mean age was 65.8 (± 11.9) years at the time of primary THA. Primary THA patients consumed a mean of $80,484 in total economic costs during the study period, of which $35,168 (43.7%) was related to orthopaedics. The direct orthopaedic cost for THA may have approached $4.43 billion in 2003 and increased to $5.56 billion in 2006. This 20% increase represents a 12% change in volumes and a 10% change in annual costs, the authors summarized.

3,326 patients with revision THA were studied. Females were the majority of patients (55.2%). The mean age was 68.3 (± 12.5) years at the time of revision. Revision THA patients consumed a mean of $104,719 in total economic costs during the study period, of which $47,407 (45.2%) was orthopaedic related.

The authors summarized that in 2003 the direct orthopaedic cost for revision THA may have approached $898 million and increased to $1.04 billion in 2006. This 14% increase represents a 3% change in volumes and an 11% change in annual costs.

First results of a total joint replacement register in the US

Liz Paxton et al. (USA)[8] reported on first results of a Total Joint Replacement Registry (TJRR), developed in 2001 by surgeons of the largest healthcare system and implemented at 50 hospitals in 6 regions. The TJRR was modeled after the Swedish Total Hip Replacement Register. As of March 31, 2008, there were 21,548 (88.5%) primary THAs and 2,809 (11.5%) revision THAs registered.

Female patients accounted for 56.1% of primary THA and 55.4% of revision THA. 44.7% of primary and 38.5% of revision THA were patients younger than 65 years old. 8.7% of primary THA patients and 7.9% of revision cases had a co-morbidity of diabetes. Osteoarthritis was seen as the most common indication (89.7%) for primary THA.

Metal femoral ball heads were used for both primary THA (73.9%) and revision THA (69.6%). Smaller femoral ball head sizes (28mm) had a 57% increased risk of revision. Higher revision rates with smaller femoral ball head sizes resulted in a reduction of their use. Larger femoral ball head sizes (> 32mm) are being used increasingly. The most common indications for revision THA were instability (31.1%), aseptic loosening (28.3%), PE wear (22.0%), osteolysis (21.2%) and infection (11%).

Ceramic-on-Ceramic THA – Clinical and radiological outcome

There is consensus that clinical results of CoC THA are characterized by proven low wear rates and a significant reduction of osteolysis, especially in younger and active patients.

Young-Hoo Kim et al (Korea)[9] reported on clinical and radiographic outcomes of CoC (alumina ceramic) THA to determine the incidence of osteolysis in a series of patients younger than 45 years. They performed 93 consecutive cementless THAs in 64 patients (93 hips), 55 male (84 hips) and 9 female (9 hips). The average age at the time of surgery was 38.2 (24–45) years. The indication was

osteonecrosis of the femoral head. Osteolysis was determined using radiographs and CT scans. The average follow-up was 9.1 (7–10) years.

The preoperative HHS improved from 52.9 (22–58) to 96 (85–100) points at the final follow-up. No acetabular or femoral osteolysis could be observed at the latest follow-up. The survival rate was 100% at 9.1 year follow-up, aseptic loosening taken as endpoint.

Eduardo Garcia-Rey et al. (Spain)[10] evaluated clinical and radiological results in patients with juvenile idiopathic arthritis (JIA) using CoC THA (alumina ceramic). The authors pointed out that THA is a concern in JIA due to young age of patients and poor bone stock. They performed 32 THAs in 20 patients with JIA. The mean age was 31.8 (14–45) years. The mean follow-up was 5.6 (4–9) years. Bone autograft was used in 14 hips with a moderate-severe acetabular protrusion. There were 2 intraoperative femoral fractures and 1 cup revision due to loosening. Good clinical results were observed in all other hips. The authors concluded that CoC THA provides good mid-term results in very young patients with JIA.

Ceramic on XPE THA – Clinical and radiological outcome

Young-Hoo Kim et al. (Korea)[11] reported on results with primary cementless THAs using CoXPE in 71 patients (73 hips) in patients younger than 50 years with avascular necrosis (AVN) of the femoral head. Alumina ceramic was used. There were 48 men (51 hips) and 23 women (23 hips) with an average age of 45.5 (20–50) years at the time of surgery. The mean follow-up was 6.5 (5–7) years. The mean preoperative HHS improved from 50.6 (27–55) to 96 (85–100) points at the final follow-up. The mean XPE liner penetration was 0.05 ± 0.02 (0.02–0.08) mm/year. Radiographs and CT scans showed no femoral or acetabular osteolysis.

Ceramic-on-metal vs Metal-on-metal – Short-term clinical results and metal ion levels

Thomas P. Schmalzried (USA)[12] reviewed studies available on CoM. He discussed that hip simulator studies with CoM demonstrated a lower friction, wear and metal ion levels compared to MoM. In a clinical study, chromium levels were significantly lower than in MoM at 12 months. But a significant difference in cobalt levels could not be observed. There were 4 outliers in each group due to component malposition.

Steven J. MacDonald et al. (Canada)[13] participated in an FDA approved multicenter prospective, randomized, double-blinded clinical trial. They performed 194 CoM THAs and 196 MoM THAs. Metal ions were evaluated in 36 CoM THAs and 36 MoM THAs. At 2 years, no statistically significant difference in metal ion levels could be observed between the two groups. The median metal ion level was very low. The authors noted that CoM is still a new bearing surface in North America and currently not FDA approved.

Metal-on-metal bearing surfaces – Adverse reactions to metal debris (ARMD), incidence and risk factors

The incidence of ARMD and risk factors for the development of pseudotumors are still unknown and the pathoetiology of pseudotumors is not well understood yet.

Douglas Van Citters et al. (USA)[14] evaluated high carbon CoCrMo devices of a single design retrieved from 13 patients and investigated for in-vivo corrosion. 4 of 13 cups showed in-vivo corrosion. All femoral ball heads showed mild galvanic corrosion. The authors reported that in-vitro testing suggests that cups differ in hardness and are therefore more susceptible to corrosion than femoral ball heads. They noted that high corrosion rates of MoM devices might directly result in increased metal ion release and wear rates. They recommend monitoring these effects prospectively.

Patrick Deprez et al. (Belgium)[15] evaluated 120 MoM THA with large femoral ball head diameter in a retrospective study. The mean follow-up was 46 months. They observed a high early revision rate of 8%. 7 patients (6 female, 1 male) described a swelling in the groin and had slight to moderate pain. No signs of infection or loosening could be found. Macroscopy showed large cysts with hypertrophic synovial tissue. The formation of these cysts was the main reason for the revisions.

In another study, Alister Hart et al. (UK)[16] pointed out that studies have shown that in such cases with a soft tissue inflammation, delaying the revision may result in massive soft tissue (muscle) destructions that are very difficult to reconstruct. Microscopy showed a chronic reactive synovitis with lymphocytic infiltrates. Metal particles were found.

The authors concluded that these findings correlate with pseudotumor formation described in literature about MoM HR. They recommend to perform post-operative sonography routinely.

The aim of the study by Sion Glyn-Jones et al. (UK)[17] was to determine the incidence and risk factors for pseudotumors. 1,419 MoM HR were performed between 1999 and 2008 and all revisions were identified. A Kaplan-Meier survival analysis was performed. The revision rate due to pseudotumor increased with time and was 4% at 8 years. Female gender was a risk factor for pseudotumors. The revision rate in men was 0.5%, in women over 40 years it was 6% and in women under 40 years it was 25% at 8 years. Other risk factors were small components and dysplasia.

In contrast to the incidence of pseudotumors reported by Glyn-Jones et al. and also recently reported by other groups, a study by Paul E. Beaulé et al. (Canada)[18] determined a lower incidence of pseudotumors at a mean follow-up of 3.02 years. 3,400 MoM HR performed between 2002 and 2008 in 9 Canadian centers were analyzed. 3 pseudotumors were observed. The incidence was 0.09%. The authors recommend close monitoring to determine risk factors for pseudotumors.

A study by Young-Min Kwon (USA), Sion Glyn-Jones et al. (UK)[19] confirmed that pseudotumors are associated with increased wear. 8 MoM HR revised due to pseudotumor (pseudotumor group) and 22 MoM HR revised due to other reasons for failure (control group) were investigated. Compared to the control group the pseudotumor group was associated with a significantly higher median linear wear rate of the femoral (8.1 µm vs 1.97 µm) and acetabular component (7.36 µm vs 1.28 µm).

The authors pointed out the fact that pseudotumors occur due to increased metal wear at MoM articulation. They concluded that edge loading (the femoral component comes into contact with the edge of the cup) may be the dominant wear mechanism in patients with a pseudotumor.

Another in-vivo study by Young-Min Kwon et al. (USA)[20] suggests that edge loading is an important in-vivo mechanism responsible for high metal wear and increased metal ion levels in MoM HR patients with pseudotumors during functional activities (walking, chair-rising, stair-climbing). Edge loading occurred in the pseudotumor group with significantly longer duration (4-fold increase) and greater force (7-fold increase) compared to the non-pseudotumor control group. The authors observed that duration and force of the edge loading depended on activity, with a proportionally greater difference during stair climbing.

In a prospective study David Langton et al. (UK)[21] examined the rate of ARMD in 510 patients with MoM HR devices of the 4th generation. The mean follow-up was 35 months. The group performed a metal ion analysis and a component position analysis using the EBRA method. They compared these results with results of a similar study of the author's 3rd generation MoM HR group (n=155, FU=60 months). The authors defined ARMD as pain associated with large sterile joint effusion and characteristic histological findings. They found 17 failures (3.3%) as a result of ARMD in patients with 4th generation MoM HR and no failures in the 3rd generation MoM HR. Tissue specimens from revisions showed varying degrees of ALVAL and high numbers of histiocytes. The median chromium and cobalt levels were 29 and 69 µg/l respectively in the ARMD group compared to 3.9 and 2.7 µg/l in the asymptomatic group. Explant analysis confirmed higher wear rates than expected by the authors. Langton pointed out that lymphocyte proliferation studies showed no hyperreactivity to chromium and cobalt in vitro. According to the authors the reduced arc of cover of the cup led to an increased failure rate due to more metal debris.

David Langton et al. (UK)[22] investigated 585 serum metal ion results in patients with unilateral HR prostheses, which were performed in 2 centers. Metal ion results were correlated to size and orientation to cup and stem. The EBRA method was used. The authors concluded that the device providing the smallest acetabular coverage arc was associated with the highest metal ion levels. Lowest metal ion levels were associated with cups with a radiological inclination of 40–50° and an anteversion of 10–20°.

George A. Grammatopoulos et al. (UK)[23] investigated the relationship between cup orientation and development of pseudotumor. In a matched-pair study, 31 patients with confirmed pseudotumor were compared with a non-pseudotumor control group (n=60). Anteversion and inclination with respect to the safe zone by Lewinnek were measured using the EBRA method. A wide range in cup orientations was observed, the mean anteversion and inclination were similar in both groups. The authors found

that cup orientation plays an important role in the development of pseudotumors. They recommend the optimal cup placement of 20° anteversion and 40° inclination. Cups placed in this zone ±10° had a significantly lower incidence of pseudotumors (6/27) compared to those outside this zone (25/31).

MoM HR and MoM THA – Do cobalt and chromium ions cross the placenta barrier?

Joshua J. Jacobs et al. (USA)[24] evaluated concentrations of titanium, nickel, cobalt and chromium in the maternal and fetal serum of 3 mothers with MoM THAs. They used inductively coupled plasma mass spectrometry (ICP-MS). The control group were 7 women without metal implants. There was no statistical difference of metal ion levels between control mothers and control babies. The authors observed that mothers with MoM THA had higher serum chromium and cobalt levels than control mothers ($p < 0.05$). Babies from mothers with MoM THA had higher serum cobalt levels ($p < 0.05$) and higher serum chromium levels ($p = 0.053$) than control babies. They concluded that cobalt and chromium cross the placental barrier. Potential effects on pregnant female patients with MoM bearing surfaces or the fetus are still unknown. Furthermore, the authors pointed out that the carcinogenity of elevated metal ions is still unknown.

Hena Ziaee et al. (UK)[25] performed a controlled cross-sectional study of 25 women with MoM HR. The mean age was 32 years. The control group were 24 women without metal implants and a mean age of 31 years. Cobalt and chromium were detected in whole blood specimens and cord blood specimens in both cohorts. The difference between maternal and cord levels in the control group was only 5 to 7%. The authors concluded that these differences indicate that the placenta allows an almost free passage of metal ions. In the study group, the cord levels were significantly lower than maternal levels (cobalt $p < 0.05$, chromium $p < 0.0001$). According to the authors, the placenta has a modulatory effect on metal transfer.

Does MoM hip resurfacing optimize outcomes?

Robert T. Trousdale (USA)[26] reported that randomized controlled trials comparing HR and standard THA have shown that HR was no better in any outcome measure. HR had worse ROM (flexion) than standard THA.

Gareth Prosser et al. (Australia)[27] investigated the cumulative revision rate of revised HRs. They used data from the Australian National Joint Replacement Registry, which had collected information on 12,093 primary HR implantations. The cumulative percent revision (CPR) of primary HR was 4.3% at 5

years. The revised hips had a re-revision rate with a CPR of 10.8% at 5 years. Compared to this result, the CPR for a conventional THA is 2.7% at 5 years. The authors concluded that these data from the Australian Registry do not support the statement that a failed primary HR can be simply revised to a conventional THA.

Based on the same Australian database, Stephen Graves et al. (Australia)[28] reported that the risk of revision at 8 years after HR is significantly greater than after primary THA. Only in male patients under 55 years with the diagnosis of osteoarthritis requiring a femoral resurfacing component size of 50mm or bigger, is the revision rate comparable to that of primary THA.

XPE – News about material performance Are femoral ball head sizes related to wear?

Numerous methods of cross-linking have been introduced in order to improve PE wear resistance and to reduce osteolysis. The 1st generation XPE was introduced in 1998 and showed significantly reduced wear. The 2nd generation was introduced in 2005 to reduce the free radical content and to improve mechanical strength.

Clinical trials showed a lower femoral ball head penetration rate with XPE liners compared to conventional PE liners. Surprisingly, a follow-up report by Cale Jacobs et al. (USA)[29] showed a greater femoral ball head penetration with annealed XPE liners during the first postoperative year ("bedding-in" period) that has been attributed to material changes due to creep and may increase the risk of rim fractures with a more vertical cup position. The authors evaluated intraoperative, clinical and radiographic data of 54 consecutive THA patients (62 hips). The femoral ball head penetration during the first postoperative year was significantly related to age, limb lengthening and cup inclination. They concluded that a potential risk of complications with XPE liners due to improper cup placement and/or limb lengthening is a reminder that improvements in PE are not a substitute for correct surgical technique.

Orhun K. Muratoglu et al. (USA)[30] emphasized that due to a reported increase in the femoral ball head penetration with XPE they analyzed explanted XPE liners. They detected a reduced oxidation resistance of 47 retrieved XPE liners (41 melted, 6 annealed). All explanted liners showed areas with increased oxidation. The oxidation levels increased during shelf storage. The areas with oxidation showed a decrease in crosslink density and an increase in cristallinity. These changes correlated with ex-vivo duration. The authors postulated that free radical formation during cyclic loading or an oxidation cascade initiated by absorbed lipids reduced the oxidation resistance of XPE. They concluded that further studies were necessary to determine the impact of these mechanisms on in-vivo stability of XPE.

In a matched-pair study David T. Schroder et al. (USA)[31] examined 78 XPE liners and 79 conventional PE liners collected from revision. These liners were from a single manufacturer with similar geometry. 22 pairs were created by matching revision diagnosis, length of implantation (1.53 years), patient age, BMI and femoral ball head size. The cup inclination was not significantly different. The authors reported that wear damages were present on XPE liners. Atypical scratches or furrowing in XPE liners were observed. Screw hole creep was present in 15 of the XPE (68%) and in 14 of the standard PE (64%). Rim cracks were observed in 4 XPE retrievals. Rim impingement was present in 6 XPE and in 17 PE rims. The authors concluded that these wear damages require a longer clinical and radiographic follow-up.

Daniel S. Heckman et al. (USA)[32] advised caution using large metal femoral ball heads in combination with XPE in young or active patients and those with a low risk of dislocation. 90 patients (102 hips) with an electron beam irradiated XPE liner were evaluated. The mean age was 61.1 years. The mean follow-up was 5.7 (5–8) years. They found a greater mean volumetric wear rate with 36- and 40-mm (156.6mm^3/year) metal femoral ball heads compared to 26-mm (52.2mm^3/year), 28-mm (53.8mm^3/year) and 32mm (57.6mm^3/year) head sizes.

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Bearing Couples and Noises in Total Hip Arthroplasty

Presentations related to this topic at the AAOS meeting in New Orleans, 2010

The orthopaedic surgical community's recent interest in advanced bearings as a means to reduce wear and resulting osteolysis in the young and active patient has been clearly reflected in clinical use. As a result of their widespread use over the last 8 to 10 years, new complications have surfaced. One of these is the development of noises during motion in THA patients. Recent publications by Glaser et al. and Clarke et al. indicate that all types of bearings can emit acoustic sensations.[1] At the AAOS meeting in New Orleans a limited number of presentations dealt with the subject.

Researchers and surgeons alike have focused on the subject of hip noises and have been able to isolate the key factors that create noises in general and squeaking in particular in total hip replacement surgery. William Hozack presented a comprehensive recap of these during his symposia. In addition there were presentations by Robert Trousdale, Thomas Schmalzried, John Currier and others. A recap of their presentations is herein presented:

1. There is a large variation in the incidence of reported noises with groups such as D'Antonio[2] and Murphy[3] reporting less than 1% while others report a higher incidence (Ranawat – 11%[4], Keurentjes – 21%[5]).

2. Impingement appears to be central to the cause, but others play a role including microseparation of the femoral ball head from the liner, improper locking, impingement between the neck and the acetabular rim, metal debris in the articulation, edge loading and wear scars.

	Hard-on-Soft		Hard-on-Hard	
Noises	**MoP**	**CoP**	**MoM**	**CoC**
Pops	Yes	Yes	Yes	Yes
Snaps	Yes	Yes	No	No
Knocking	Yes	Yes	Yes	No
Crunching	No	Yes	Yes	No
Cracking	No	No	Yes	Yes
Squeaking	No	No	Yes	Yes
Duration of Sound	Isolated	Isolated	Sustained	Sustained

References: acc. to Komistek, R Personal Communication, 2009
(see references alongside)

3. Component position can also be a factor as it promotes impingement and edge loading, both of which are central to the issue.

4. Femoral component selection appears to be a factor. William Hozack's own series showed a marked difference when he used a femoral stem of a new titanium alloy, TMZF, and a reduced section neck and taper (8.6% squeakers) versus 0.7% squeakers when he used a conventional titanium alloy with a thicker neck and longer taper[6].

5. William Hozack also reported a similar difference when he compared his patients with a protected ceramic insert versus a non-protected taper locked ceramic insert acetabular component.

6. At this point in time there is no evidence to suggest that squeaking adversely affects the longevity or the wear of the total hip system.

THA noise, especially squeaking has become a recognized complication in advanced bearings total hip replacement systems. As a result, any potential patient should be informed on the possibility of occurrence. If it occurs in a patient, closer follow-up may be needed and counselling on the avoidance (if possible) of causative activities.

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11th EFORT Congress 2010

Tribology Day

This year's EFORT Congress, held in cooperation with the Spanish Society of Orthopaedic Surgery and Traumatology, June 2–5, 2010 in Madrid, was attended by more than 8,000 physicians and scientists. The Congress encompassed 4,462 submitted abstracts, 1,716 posters, 27 symposia, 20 instructional courses and an industry exhibition with 150 participants. One of the main topics was tribology and its various clinical aspects. With Professor Karl Knahr presiding, a "Tribology Day" was held for the first time at this year's congress.

Keynote talks on tribology

Professor Michael Morlock, Institute of Biomechanics at the Hamburg University of Technology

Professor John Fisher, Director of the Institute of Medical and Biological Engineering at Leeds University in England

Using the biomechanics of the hip joint as a point of reference, Michael Morlock (Germany) explained the main possibilities of applying arthroplasty to reconstruct joint physiology. During his talk, he considered the topics of implant design, implant fixation, surgical tissue management and component positioning. Focusing in particular on the relationship among the variables femoral ball head size, wear, dislocation risk, and range of motion (ROM), he emphasized the importance of taking a balanced approach to femoral ball head size selection and encouraged his listeners to join the "36mm club." Morlock pointed out that patient expectations with respect to implant durability and range of motion have increased significantly and that these expectations represent a new challenge for medical science. His conclusions served as the central thread for the Tribology Day: There is always a risk that a new solution solves one problem at the cost of creating at least one other.

John Fisher (UK) provided an overview of the available bearing couples and their performance in relation to wear particles. In order to exploit the various advantages, he proposed the use of hard-on-soft bearing couples with XPE liners for "lower demand" patients above the age of 50 and hard-on-hard bearing couples for younger and more active patients. He suggested that CoC bearing couples were the least problematic in terms of wear, but he also pointed out the associated problems of microseparation, stripe wear and implant fracture. He maintained a critical view in the case of MoM bearing couples owing to the potentially harmful effects of metal ions released in the body. Here, it is essential to reduce wear debris. Fisher went on to point out that it is absolutely necessary to consider the positioning of the components and an appropriate reconstruction of the physiological offset. He also presented hip simulator results (normal gait) indicating that CoM bearing couples enable a 90% reduction in metal wear particles when compared to MoM bearing couples and an 83% reduction in edge loading impact.

Short presentations on various bearing couples

CoC THA in patients > 60 years

Drawing upon data from numerous clinical case studies, Raghu Raman (UK) showed that the use of large femoral ball head diameters (36mm, 40mm) in CoC THA (BIOLOX®*delta*) can help to lower the risk of dislocation and secure a large range of motion. This also applies to patients older than 60 with insufficient muscular stability. A total of 319 consecutive primary THAs in 302 patients with an average age of 65 (11–82) years were clinically and radiologically examined at a follow-up of 12 months. A femoral ball head diameter of 36mm had been used in 96% of the cases. No dislocations and no cases of aseptic cup loosening were observed.

> **"The results of this study show an excellent clinical and functional outcome and support the use of a fully coated prosthesis with ceramic bearing couples."**
>
> – Raghu Raman, MD

MoM bearing couples and large diameters

Young-Min Kwon (UK) reported on pseudotumor formation in connection with MoM bearing couples (resurfacing). Increased amounts of metal debris resulting from improperly positioned components are a key factor. MRI screening of 201 asymptomatic THAs indicated a pseudotumor prevalence of 4% and a significant correlation between pseudotumor formation and increased levels of cobalt and chromium. An examination of 30 explants (8 of which were related to pseudotumor formation, 22 to other causes) showed significantly elevated levels of metal debris and pronounced signs of edge loading in the cases of pseudotumor formation.

> **"This study provides the first direct evidence to confirm that pseudo is associated with increased wear at the MoM articulation."**
>
> – Young-Min Kwon, MD, PhD

Sion Glyn-Jones (UK) compared the wear particle rates in 18 MoM bearing couples that needed to be replaced on account of pseudotumor formation to the particle rates in 18 other MoM revision explants. Compared to the control group, the pseudotumor group showed significantly increased volumetric

wear and a higher incidence of both edge loading and impingement. This identifies metal wear particles as one of the main causes of pseudotumor formation, although the exact mechanism remains unclear. Glyn-Jones went on to point out that there are exceptions, such as pseudotumor formation in the absence of increased metal wear and the presence of increased metal wear particles without pseudotumor formation.

Amir Kamali (UK) investigated 50 MoM explants (resurfacing). 22 explants that showed edge loading were compared to 28 that showed normal loading. Linear metal wear in the explants showing clear signs of edge loading was ten times higher in both the acetabular and femoral components. A clear correlation between increased acetabular cup anteversion and metal wear was shown.

> **“We suggest that pseudotumors are caused by high concentrations of metal wear debris, which have been shown to have a toxic effect on osteocytes and macrophages.”**
>
> – Sion Glyn-Jones, MA, MBBS

Karel Hamelynck (Netherlands) offered an account of achieving a significant reduction in component wear, and therefore also a reduction in ion levels, by treating the surfaces of large-diameter metal femoral ball heads with a titanium-niobium-nitride coating.

9-year results of CoXPE THAs

Young-Hoo Kim (South Korea) reported on a series of 68 young femoral-head-necrosis patients who were treated with cementless CoXPE THA. The average age of the patients was 45.5 (20–50) years. 28mm femoral ball heads made of BIOLOX®*forte* had been used in all cases. The average follow-up was 10.5 (10–13) years. Radiological and CT examinations revealed no acetabular or femoral osteolysis.

10-year results of CoP and MoP THAs

Geir Hallan (Norway) reported on the results of 9,113 cementless acetabular cups (7 different designs) that were implanted in 7,937 patients between 1987 and 2007 (Norwegian Arthroplasty Register). All of the cases involved conventional polyethylene liners and metal femoral ball heads (steel, CoCr) or ceramic femoral ball heads (aluminum oxide). In terms of aseptic loosening as an endpoint, the survival rate of the acetabular cups ranged from 87% to 100% after 10 years. None of the cementless cups with polyethylene liners showed satisfactory long-term results. Aseptic loosening, wear, osteolysis and dislocation were identified as the main problems. The hip systems in which CoP bearing couples were used showed better results than those with MoP bearing couples.

Inflammatory response to polyethylene and XPE particles

Using intravital microscopy, Sandra Utzschneider (Germany) investigated the tissue response in mice to polyethylene particles, 85% of which were in the submicron range. Wear particles were first gathered from three different XPE liners and one conventional polyethylene liner after 5 million cycles in a knee simulator and then injected into the mice. A significant inflammatory immune response was observed in all of the polyethylene and XPE cases. No significant differences in the type of immune response were observed between the groups.

“Bearing performance – development and evaluation” was the idea behind the presentation of results from the field of material research and their connection with clinical follow-up. The relevant materials included metal, ceramics and polyethylene.

John Fisher (UK) pointed out that a distinction is to be made between surface wear and aging in the case of polymers. Aging is determined by oxidation processes, while surface wear is determined by contact area, load, crosslinking density, shear force and surface roughness. Both aging and surface wear lead to the release of polyethylene particles and the associated consequences.

Ingrid Milosev (Slovenia) reported on the results of her follow-up examination of 640 MoM THAs at 11 years and 377 CoC THAs at 8 years. The CoC bearing couples showed higher survival rates and a significantly lower revision rate of 3.4% compared to the 9.8% revision rate for the MoM bearing couples. Ceramic fractures accounted for 50% of the cases of revision in the CoC THAs, while aseptic loosening and osteolysis were the weak points in the MoM THAs.

CoC vs CoP THA

Philipe Hernigou (France) presented the results of an evaluation of 21 patients who had each received bilateral THA treatment with a cemented CoP bearing couple on one side and a cemented CoC bearing couple on the other. Only one stem type was used and all of the patients were treated with 32mm femoral ball heads. During the 20-year follow-up (average) none of THAs had loosened or proved to be in need of revision. While X-ray examination revealed only 2 cases of femoral osteolysis in the CoC group, 5 cases of acetabular osteolysis and 21 cases of femoral osteolysis were found in the CoP group. An additional CT examination revealed 3 acetabular lesions in the CoC group and 16 in the CoP group. The annual polyethylene wear rate was 0.07mm, while the CoC bearing couples showed no measurable wear. Although the patients whose implants showed a high degree of wear also showed an increased rate of osteolytic lesions, pain was not shown to be linked to osteolysis.

What's new in tribology?

Claude Rieker (Switzerland) began this session by first citing encouraging 10-year survival rates for MoM hip resurfacing and then proceeding to offer a critical overview of the latest investigations on pseudotumor formation and metal-ion development associated with improper acetabular cup positioning. He emphasized the negative effects of edge loading. Cups exposed to risk can be detected by analyzing the acetabular roof coverage and the inclination respectively. Improper positioning leads to a reduced fluid film and a diminished hydroelastic lubrication, both causing greater friction, particularly as the diameter increases. Pseudotumors are observed mainly in female patients. Their exact pathogenesis remains unclear. Elevated ion levels may play a role in their development as the situation progresses from an allergic to a toxic state.

Thomas Pandorf (Germany) concluded that the demand for stable and long-lasting hip arthroplasty underscores the value of ceramic materials. Numerous studies with ceramic femoral ball heads (BIOLOX®*forte*) have shown outstanding long-term results in combination with polyethylene and ceramics. Compared to MoP bearing couples, CoP bearing couples generate only half as much polyethylene wear. Moreover, CoC bearing couples show almost no measurable wear after 20 years, irrespective of femoral ball head size. BIOLOX®*delta* was developed to further reduce wear, enable the use of larger femoral ball head diameters and liners with lower wall thicknesses, as well as to increase component fracture strength. The more than 600,000 implanted femoral ball heads have offered proof of the expected advantages. Although this new ceramic material is more resistant to microseparation, he emphasized that it is nonetheless essential to carefully consider positioning when implanting hard-on-hard bearing couples. Impingement, subluxation and edge loading with high spot pressure and minimal lubricating film as well as band tension and stem positioning have been observed to play a role in rare complications such as ceramic fracture and squeaking. The excellent wettability and the extremely low wear make modern ceramics a material of the future.

Robert Streicher (Switzerland) named the requirements for modern polyethylene bearing couples. Further reductions in the wear rates of the classic hard-on-soft bearing couples have become urgent in light of the increased loads due to higher activity levels of today's patients. New technical procedures involving radiation and thermal treatment (remelting and annealing) have given rise to 2 new generations of XPE. Reductions in wear rates of 60% to 80% have been observed in simulator studies. Here, researchers have attempted to strike a balance between strength, wear resistance and oxidation/degradation resistance. Adding vitamin E as an antioxidant in a 3rd generation of XPE has brought good experimental results. The biological activity of XPE particles remains unclear.

Graham Isaac (UK) offered an evaluation of the new CoM bearing couple[1]. Compared to MoM bearing couples, Isaac anticipates a shorter running-in phase and generally reduced quantities of metal particles. He also expects fewer problems in cases of unfavorable loading compared to CoC bearing couples. When tested in a simulator, this particular combination of materials of unequal hardness has shown a 90% reduction in wear particles compared to MoM bearing couples. The CoM bearing couples also proved to be more stable when exposed to edge loading, with the ceramic femoral ball head made of BIOLOX®*delta* showing no wear whatsoever. The reduction in the degree of friction corresponded to that of the CoC bearing couple. In an initial clinical study, the results achieved in a CoM bearing couple (28mm) were compared to those of a MoM bearing couple. Clinical and radiological data, survival rates and serum-ion levels were considered. Two ceramic femoral ball heads (explants) were examined and showed no appreciable degree of damage. While the metal ion concentrations associated with CoM tended to be lower than those in the MoM group, the difference was not significant.

[1] Ceramic-on-metal bearing couple, Pinnacle® CoMpleteTM Acetabular Hip System, DePuy Orthopaedics Inc.

Tribology: Meeting the experts

Throughout this session, a panel of 4 clinical experts brought their experience as users to bear in the discussion with the speakers. They addressed issues ranging from the latest in materials research to the significance of surgical skill in achieving long-term implant success.

Pascal A. Vendittoli (Canada) began by presenting a study whose results indicate that there is no difference in terms of serum ion concentrations between MoM bearing couples with femoral ball head diameters of 28mm and MoM hip resurfacing. He then moved on to discuss a clinical comparison of a modular stem with a large femoral ball head of CoCrMo and the various components used in hip resurfacing. Despite the use of the same bearing couple, considerable differences turned up in the measured serum metal ion levels. The open femoral ball head design and its associated passive corrosion caused a difference of 67%. The friction on the plugged modular neck accounted for a difference of 157%. Two distinct sources of metal ion release were ascertained. By way of summary, Vendittoli called for an increased awareness of the problem and an intensified search for solutions before dismissing the MoM concept altogether.

"We keep seeing patients with maximum polyethylene wear and surgeons in Europe still use metal with polyethylene. This is unacceptable. We have to say that this is not acceptable anymore."

– Roberto Binazzi, MD (Italy)
Source: Orthopaedics today Europe.
The Official Newspaper of EFORT. 13(4), 2010:10

Orhun Muratoglu (USA) presented the results of his evaluation of 41 explanted liners made of 1st generation XPE. He was able to show that while no oxidation took place during preoperative storage and in vivo, a significant degree of surface oxidation relative to the ex vivo period has taken place after explantation. A reduction in the crosslink density was also measured. By way of explaining this susceptibility, he cited the material changes brought about by cyclic loading in vivo and the penetration of autologous lipids into the XPE surface. All 4 of the examined types of 1st generation XPE were equally affected.

Raghu Raman (UK) described the advantages of using larger femoral ball head diameters, including a reduced risk of dislocation, greater stability in anatomically unfavorable situations, and

a greater range of motion for functionally more demanding patients. Raman presented the results from a 2-year follow-up evaluation of 219 CoC THAs (BIOLOX®*delta*). A 36mm femoral ball head was used in 94% and a 40mm femoral ball head in 6% of the cases. Revision was necessary in 2 cases as a result of periprosthetic fracture and infection respectively.

Raman then outlined the results of a matched-pair analysis involving 110 patients each treated with CoC or MoM bearing couples in combination with a cementless standard stem. The 3-year follow-up evaluation showed one pseudotumor-related revision in the MoM group. The radiological results were unremarkable in both groups and the patients in both groups could resume their sports activities equally quickly and without problems.

George Grammatopoulos (UK) described once again the significance of acetabular cup positioning in hip resurfacing. Impingement and edge loading can lead to elevated levels of metal wear particles and promote the formation of pseudotumors. In the context of a comparative study, he attempted to identify a safe range for cup positioning that would ensure a minimal risk of complications. 31 implantations that had led to pseudotumor formation were compared to 58 control implantations. Acetabular cup inclination and anteversion were measured. Average inclination was 46° and average anteversion was 15°, with the individual measurements in the pseudotumor group showing considerable variability. A total of only 60% had an acceptable acetabular cup position, reflecting the difficulty of intraoperative judgment. The radiological position tends to depart from the operative position, a factor to be considered during surgery. In contrast to the Lewinnek safe zone, the study results showed an angle ratio of 40°/25° (± 10°) as the optimal operative safe zone and an angle ratio of 45°/20° as the resulting radiological safe zone. Grammatopoulos called upon his listeners to bear in mind the significance and consequences of malpositioning.

In addition to material properties, numerous congress participants emphasized the importance of surgical experience and skill in achieving long-term implant success. Careful surgical planning, soft-tissue management and physiological joint reconstruction have to be considered, as well as the limits and specific indication profiles of the component materials. Specialists who use modern high performance materials can be expected to apply similarly exacting standards when it comes to surgical procedures.

A further factor is the growing number of younger, more active "high demand" patients. It is clearly important to take an individualized approach and involving the patients in the selection of the treatment option that will best suit their needs. Individual consultation and decision-making are indispensable. After all, in addition to the technical aspects, the expectations of the patients themselves will tend to influence their motivation and satisfaction after surgery.

Professor Karl Knahr, MD, Director of the 2nd Orthopaedic Department at the Orthopaedic Hospital Vienna-Speising in Austria

Dr. Martin Ihle, Berlin, Germany

The next EFORT Congress is set to take place from the 1st to the 4th of June 2011 in Copenhagen, Denmark.
www.efort.org/copenhagen2011

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Thomas G et al. The 7 year in vivo wear of highly cross-linked polyethylene. A double blind RCT. Abstract F253, EFORT 2010

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Raman R et al. Funcional and clinical outcome of cementless primary arthroplasty of the hip using large diameter ceramic bearing couples. Abstract F700, EFORT 2010

Grammatopoulos G The role of acetabular component positioning in the development of inflammatory pseudotumors. Abstract F394, EFORT 2010

Clinical Results with Ceramics

5- to 19-year results of CoC, CoP and MoPbearing surfaces in cementless THA for reversal of hip ankylosis

Rajaratnam et al. (Australia) presented the longest series of cementless revisions of ankylosed hips, with a mean follow-up of 11 (5–19) years.
16 consecutive ankylosed hip joints in 15 patients (9 male, 6 female) were converted to a cementless THA. The mean age was 52 (16 to 75) years at the time of reversal of ankylosis.
In patients operated prior to 1993, a MoP (22.25, 28mm) articulation was implanted. Patients operated between 1993 and 1997 received a CoP (28mm) articulation. Patients operated after 1997 had a CoC (28, 32mm) articulation implanted.
All patients showed improved mobility and function postoperatively. 9 hips (8 patients) received a MoP or CoP articulation. 6 hips (5 patients) showed linear wear between 1 and 3mm on the latest X-rays. Radiographic osteolysis was seen in 3 hips. A young female patient with a MoP (22.25mm) THA was revised 5 years after implantation due to aseptic loosening of the acetabular component. The authors postulated that aseptic loosening was due to a combination of high functional demands of the THA in this 16-year old patient at the time of primary surgery, combined with relatively soft acetabular bone due to juvenile rheumatoid arthritis.
7 patients (7 hips) who received a CoC articulation did not show any radiographic evidence of linear wear or osteolysis at the latest follow-up. The authors also mentioned their published data on very low wear rates in CoC cementless THA (28mm, 32mm) at a mean follow-up of 6.5 (5–9.2) years*.
They concluded that ankylosed hips can be effectively converted to cementless THAs with good long term results.

Rajaratnam SS, Sexton SA, Waters TS, Walter WL, Zicat BA, Walter WK. Long term results of cementless Total Hip Replacement for reversal of hip ankylosis. Hip Int 2009; 19(2): 120–127
*Lusty PJ, Tai CC, Sew-Hoy RP, Walter WL, Walter WK, Zicat BA. Third-generation alumina-on-alumina ceramic bearings in cementless total hip arthroplasty. J Bone Joint Surg (Am) 2007; 89(12): 2676–83

4-year results of cementless CoC and MoXPE THA in identical hip systems – A comparative, prospective randomized study

Bascarevic et al. (Serbia) evaluated 150 patients with a mean age of 54.7 years at the time of surgery. In the study group with 78 Patients (82 hips) CoC alumina bearing couples (28mm) were used. In the control group with 72 patients (75 hips) MoP bearing couples were implanted. In 7 cases 32mm metal femoral ball heads were implanted. The mean age was 54.7 years at the time of surgery. The mean follow-up was 50.4 months. Small cortical erosions of the proximal femoral zones were found only in 2 cases (2%) in the CoC group, while in the MoXPE group they were found in 8 cases (11%). There was no statistically significant difference. The authors suppose that the reason for the lack of significant statistical difference is probably due to the use of XPE, while in other comparative studies conventional PE was used.
These early results show no statistically significant changes in clinical and radiographic parameters in both groups. The mean postoperative HHS was 95.1 in the CoC group and 93.8 in the MoXPE group, respectively.
The authors concluded that the potential of this CoC bearing couple seems to be high and especially suited for THA in younger and active patients.

Bascarevic Z, Vukasinovic Z, Slavkovic N, Dulic B, Trajkovic G, Bascarevic V, Timotijevic S. Alumina-on-alumina ceramic versus metal-on-highly cross-linked polyethylene bearings in total hip arthroplasty: a comparative study. International Orthopaedics, published online on November 1, 2009

5–7 years results of cementless CoC and CoXPE THA in the same patient

So far, no study compared cementless CoC and CoXPE THA in the same patient. Kim et al. (Korea) compared the clinical and radiographic results and the prevalence of osteolysis after 200 primary bilateral simultaneous THAs in 100 patients (66 male, 34 female). Alumina ceramic femoral ball heads (BIOLOX®forte, 28mm) were used. The mean age at the time of surgery was 45.3 (21–49) years. The mean follow-up was 5.6 (5–7) years.
The mean rate of XPE linear penetration was 0.06 ± 0.03mm (0–0.08mm) per year. No detectable penetration was found in the CoC group. There was no aseptic loosening of any acetabular or femoral component in either group. Pre- and postoperative HHS were not significantly different in both groups. Functional activities were similar in both groups. CoC and CoXPE THA showed excellent clinical and radiographic outcomes. The results suggest a predictably good prognosis for these patients.
The authors concluded that at this short follow-up time, no difference would have been expected in terms of aseptic loosening and complication rates. Longer follow-up is needed to evaluate the long-term performance of these THAs.

Kim YH, Kim JS, Choi YW, Kwon OR. Intermediate Results of Simultaneous Alumina-on-Alumina Bearing and Alumina-on-Highly Crosslinked Polyethylene Bearing Total Hip Arthroplasties. J.Arthroplasty 2009; 24 (6): 885–891

Abstract: Press Fit Cups

More stability with screws?

Latest results from a research group of the Orthopaedic University Hospital in Düsseldorf, Germany, once more confirm that the stability of acetabular cups is not enhanced by the use of screws. The main reason for adding screws to a press fit cup is the surgeon's endeavor for a subjective feeling of security.

Abstract

Migration pattern of press fit cups in the presence of stabilizing screws

Marcus Jäger, Christoph Zilkens, Sima Djalali, Bernd Bittersohl, Clayton Kraft, Rüdiger Krauspe

Introduction:
The use of screw fixation for cementless porous-coated acetabular components for primary total hip arthroplasty (THA) remains controversial. Aim of this study was to evaluate initial acetabular implant stability and late acetabular implant migration with screw fixation of the acetabular component in order to answer the question whether screws are necessary for the fixation of the acetabular component in cementless primary THA.

Methods:
In a prospective study, 102 patients (107 hips) were available for follow up after primary THA using a cementless, porous-coated acetabular component. Patients were followed up at 6 and 12 weeks, 6 and 12 months and annually thereafter to an average of 2.6 ± 1.7 years. A total of 428 standardized radiographs were analyzed by the Einzel-Bild-Röntgen-Analyse (EBRA)-digital method. Additionally, the Harris Hip Score (HHS, 0-100) was assessed at the latest follow-up.

Results:
101 (94.4%) implants did not show significant migration of more than 1mm of the acetabular component. Six (5.6%) implants showed a migration of more than 1mm: in 3 cases (2.8%), migration was progressive during follow-up and led to a revision surgery due to aseptic loosening. In 3 cases, migration came to a halt and cups were claimed stable. Individuals without cup migration had an average HHS of 78.4 ± 22.9, whereas patients who showed a cup migration of > 1mm had 53.3 ± 24.2. Statistical analysis did not reveal preoperative patterns that would identify future migration.

Discussion and Conclusion:
Our findings show that the use of screw fixation for cementless porous-coated acetabular components for primary THA does not prevent cup migration.

Source: EFORT, Abstract F 240, Madrid, 2-5 June 2010

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Acronyms:

ALVAL = **A**septic **l**ymphocytic **v**asculitis **a**ssociated **l**esion
ARMD = **A**dverse **r**eactions to **m**etal **d**ebris
CoC = **C**eramic-**o**n-**c**eramic
CoM = **C**eramic-**o**n-**m**etal
CoP = **C**eramic-**o**n-**p**olyethylene
CoCr = **C**obalt **cr**onium
CoCrMo = **C**obalt **cr**onium molybdenum
EBRA = **E**inzel-**B**ild-**R**öntgen-**A**nalyse (single picture x-ray analysis)
HHS = **H**arris **h**ip **s**core
HR = **H**ip **r**esurfacing
ICP-MS = **I**nductively **c**oupled **p**lasma-**m**ass-**s**pectrometry
MoP = **M**etal-**o**n-**p**olyethylene
MoM = Metal-**o**n-**m**etal
JIA = **J**uvenile **i**diopathic **a**rthritis
MRI = **M**agnetic **r**esonance **i**maging
THA = **T**otal **h**ip **a**rthroplasty
UHMWPE = **U**ltra **h**igh **m**olecular **w**eight **p**olyethylene
XPE = **Cross**linked **p**oly**e**thylene

Leaving the Stem in Situ

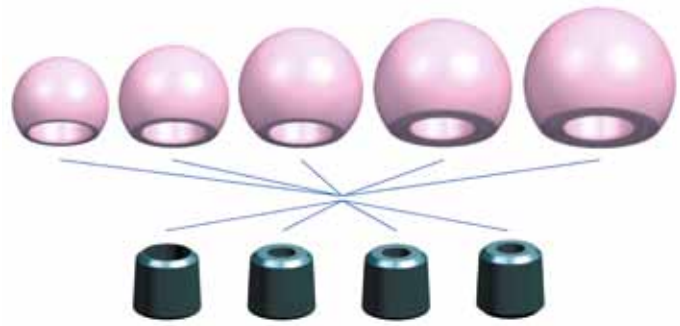
More options with BIOLOX®OPTION

Implant loosening

The growing numbers in primary arthroplasty, especially for the younger patients, have the unavoidable consequence that the percentage of patients who will need to undergo one or more surgical revisions in the course of their lives is rising. Indeed, revision hip arthroplasty already accounts for around 20% of all causes of hip arthroplasty.[1] Aseptic loosening remains the most common case of implant failure. In the Swedish National Hip Register, aseptic loosening accounts for 75% of all hip revisions.[2] Moreover, the acetabular cup component is affected twice as much as the stem component. Among other factors, this is related to a sharp increase in Paprosky-type III defects.[3]

The bearing couple is one of the major factors influencing the revision rate. The components most susceptible to wear are those made of polyethylene. Wear-related osteolysis and implant loosening significantly undermine the prospects for long-term implant success.

MoP bearing couple after 10 years in vivo showing massive polyethylene wear, damage to the metal cup taper, and metal debris. The patient complained of implant squeaking.
Source: CeramTec GmbH

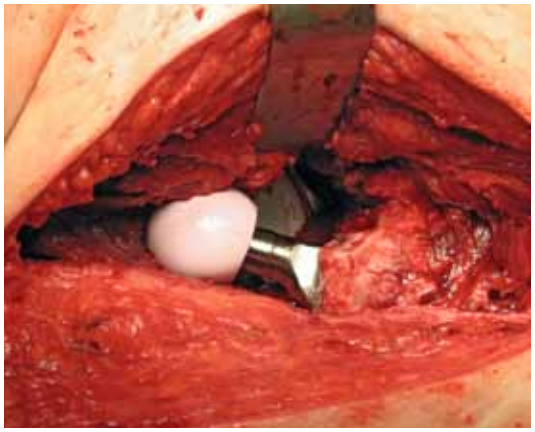


Femoral ball head diameters of 28mm to 44mm and neck lengths of S, M, L, and XL allow choosing the right offset.

Optimizing revisions

The ceramic revision femoral ball head (BIOLOX® OPTION) helps to reduce the rate of wear-related osteolysis following revision hip arthroplasty significantly.

- The surgeon is given the option of using a CoP, a CoXLPE or a CoC bearing couple in the case of an acetabular cup revision and a firmly fixed stem that is to remain in situ. Thus a bearing couple can be implanted that exhibits a greater degree of wear resistance than the bearing couple used for primary hip arthroplasty.
- The surgeon is given the option of switching to a larger femoral ball head diameter in order to achieve greater stability and to lower the risk of postoperative dislocation.
- BIOLOX®OPTION offers a safe solution for the rare case of ceramic component fracture.



Revision surgery using the BIOLOX®OPTION system

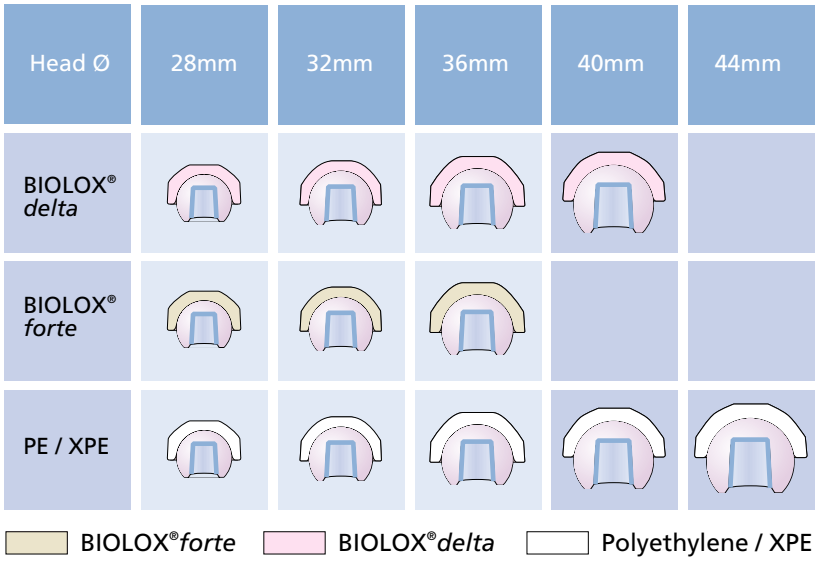
Expanded applications for primary surgery

- Option of correcting neck length
- If the stem taper is inadvertently damaged during surgery the surgeon can react by using the BIOLOX®OPTION system.

Taper Diameter (mm)	Taper Angle
8/10	5°46′
10/12	6°
12/14	5°46′

Material and structure

The BIOLOX®OPTION system consists of 2 components: a ceramic femoral ball head and a titanium sleeve. The system's neckless design helps to prevent range of motion restrictions. The sleeve, which is made of the titanium alloy $TiAl_6V_4$, a material well-proven in arthroplasty, compensates for cases of minor damage to the stem taper* and helps to ensure an even load distribution on the inside of the femoral ball head.



The femoral ball head is made of the high-performance ceramic material BIOLOX®*delta*, which exhibits extraordinarily high fracture strength and fracture toughness. The material's structure is enhanced by two strengthening mechanisms that help to reduce and absorb cracking energy in case of microcracks. BIOLOX®*delta* is therefore much more effective than other ceramic materials at resisting and stopping crack propagation.

The femoral ball head and titanium sleeve are fixed using the proven taper fixation.

Secure taper fixation

The femoral ball heads used in the BIOLOX®OPTION system were subjected to extensive testing during their development. In addition to the usual strength tests (burst load and fatigue), the system's developers focused on the establishment of a secure fixation of the ceramic femoral ball head on the outside of the sleeve and of the inside of the sleeve on the metal stem. Testing was carried out to establish an optimally secure mechanical fixation (pull-off test and rotation test) and to account for the phenomenon of **fretting**. The term fretting refers to the micromovements between two (metal) surfaces that can lead to wear and corrosion in both the wear particles and the newly altered metal surfaces. Such conditions can lead to significantly increased wear in the bearing couple (third-body wear).

Fretting can also lead to corrosion-related crack development and propagation as a result of recurrent loading as the patient moves about (propagation of fatigue-related cracks). Investigations have clearly demonstrated that with the BIOLOX®OPTION system no negative effects of fretting are to be expected, no matter if CoCr or titanium stems are used.

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

Material combinations

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 liners made of polyethylene and highly crosslinked polyethylene.

Further information is available on the Surgical Live Training DVD that you can order using the enclosed order form.

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[2] The Swedish National Hip Register. Annual Report 2008

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Revision Strategies

Case reports of hip revisions with BIOLOX®OPTION

by L. Zagra, MD

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Case 1: Revision to CoC after acetabular loosening of a CoP THA

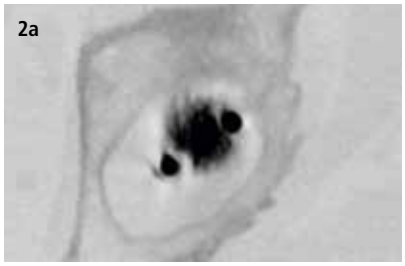
Diagnosis:
49-year-old male, 11 years after left THA with 28mm CoP (Fig 1). The hip was painful under full weight bearing. The CT scan clearly showed osteolysis around the screws of the cup and in the proximal part of the femur (Fig 2a–2c).

Pre-op X-ray

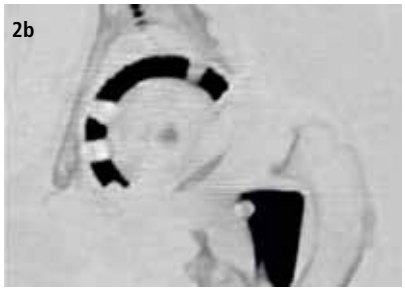
Post-op X-ray

Indication for revision at least of the liner and of the femoral ball head or, preferably, for an exchange of the cup and converting to a hard-on-hard bearing.

Treatment:
Postero-lateral approach. The cup was not stable, the stem was well fixed. Revision of the cup with a high porosity implant and a CoC BIOLOX®*delta* bearing (36mm BIOLOX®OPTION femoral ball head with L neck, Fig. 3). Accurate debridement of the membranes inside the cysts.



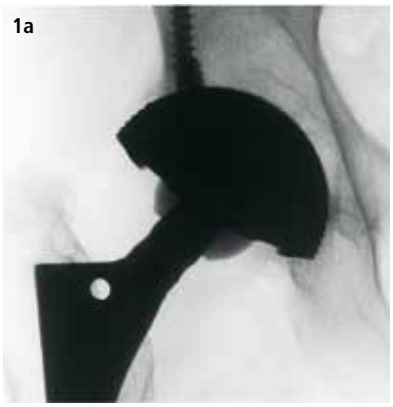
Pre-op CT scan



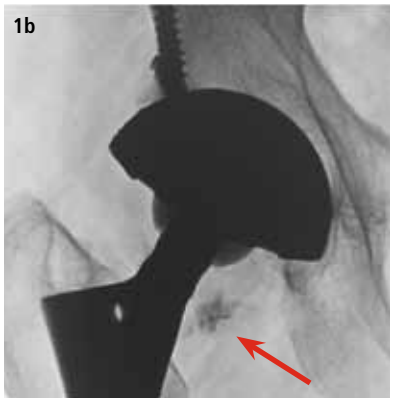
Case 2: Revision to CoP after ceramic fracture

Diagnosis:

71-year-old female, 12 years after a right THA with CoC (sandwich ceramic liner). Sudden appearance of noise and hip pain. Fig 1a shows the X-ray one year before the event and Fig 1b the recent X-ray. A CT scan was performed (Fig 2), confirming the fracture of the ceramic liner.

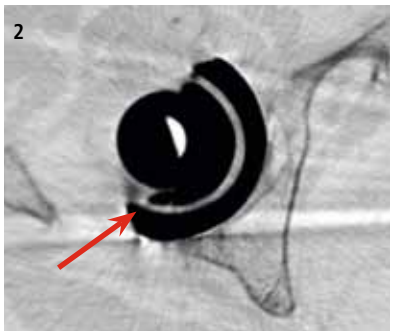


X-ray one year before the event



The red arrow points to ceramic fragments.

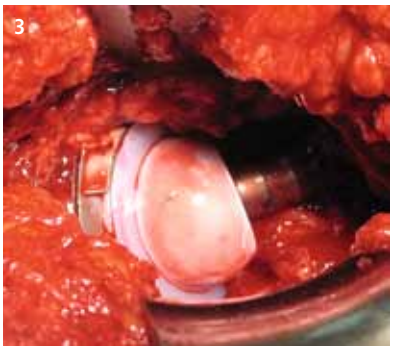
Indication for revision as soon as possible, exchange of the liner and probably of the femoral ball head, which is usually damaged in such cases.



The CT scan confirms the fracture of the liner.

Treatment:

Postero-lateral approach. Removal of all the ceramic fragments and of the rest of the liner (the sandwich is easy to remove with a small chisel). Aggressive debridement of the periarticular soft tissues in order to remove the membranes and all the small ceramic fragments and washings. Removal of the screws from the metal-back of the cup. The cup and the stem look absolutely stable, but the femoral ball head is obviously macroscopically damaged and must be exchanged. Implantation of a PE liner and of a 32mm BIOLOX®OPTION femoral ball head, XL neck to improve stability (Fig 3, 4).



The new liner with a BIOLOX®OPTION femoral ball head

Post-op X-ray

Case 3: Revision to CoXPE after acetabular loosening of a MoM THA

Diagnosis:

72-year-old female, severe Alzheimer disease, no other co-morbidities. Operated 2 years earlier, left THA with MoM bearing (Fig 1).

The patient is painful since the operation, now shows great difficulties in walking with weight bearing. The cup looks completely loose, acetabular osteolysis.

Indication for revision of the cup, the stem looking well fixed. The patient is at risk for post-operative dislocation because of the neurological disease (poor compliance) and because of the large diameter metal femoral ball head. For this reason another large femoral ball head or, alternatively, a double-mobility bearing is indicated.

Pre-op X-ray

Treatment:

Postero-lateral approach, cup revision with hemispherical porous cup, size 54 and XPE liner. The stem was absolutely stable and the metal femoral ball head exchanged for a 36mm BIOLOX®OPTION femoral ball head with an XL neck. Immediate full weight bearing, no more pain, no dislocations. Membranes with evidence of metallosis were present (Fig. 2).

Post-op X-ray

Revision Strategies

Case reports of hip revisions with BIOLOX®OPTION

by F. Thorey, MD, PhD

Fritz Thorey is a consultant orthopaedic surgeon in the Department for Arthroplasty and Reconstruction at the Orthopaedic Clinik of the Medical University of Hannover in Germany. He is a member of the German Society of Orthopaedics and Orthopaedic Surgery (DGOOC) where he is also involved in the Basic Research Section. He regularly acts as an instructor at national and international workshops dealing with minimally invasive hip arthroplasty, revision hip arthroplasty and navigation. Dr. Thorey has held more than 90 talks at international congresses and authored more than 50 journal articles, mostly on the subject of hip arthroplasty.

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Case 1: Revision to CoC after acetabular loosening of a CoP THA

Diagnosis:
Female patient, 45 years, BMI 27, 7 years after primary THA with acetabuloplasty after dysplastic osteoarthritis, BIOLOX®*forte* femoral ball head (32mm), PE insert, aseptic loosening of the cup (Fig. 1).

Pre-op X-ray

Treatment:
Surgical treatment algorithm for this diagnosis: removal of the cup, synovectomy, removal of possible PE particles, lavage.

After revision: threaded cup because of defect at the anterior part of the acetabulum, removal of the screws and lateral bone, BIOLOX®*forte* insert, BIOLOX®OPTION femoral ball head (32mm, size M). X-ray after 12-month follow-up, patient is fine (Fig. 2).

Post-op X-ray

Case 2: Revision to CoP (dysplasia insert) after repeated dislocations

Diagnosis:

Male patient, 76 years, BMI 32, 6 years after primary THA via posterior approach, threaded cup, BIOLOX® *forte* femoral ball head (32mm), BIOLOX®*forte* insert, repeated posterior dislocation of the right hip (Fig. 1).

Pre-op X-ray

Treatment:

Removal of BIOLOX®*forte* femoral ball head and BIOLOX®*forte* insert, implantation of PE insert with posterior shoulder to prevent dislocation. BIOLOX®OPTION femoral ball head (32mm, size L). X-ray after 9-month follow-up, patient is fine (Fig. 2).

Post-op X-ray

Case 3: Revision to short stem implant with CoP after ceramic fracture

Diagnosis:

Male patient, 60 years, BMI 29, 14 months after primary THA, short stem, threaded cup, BIOLOX®*forte* insert, BIOLOX®*forte* femoral ball head (32mm) (Fig. 1).

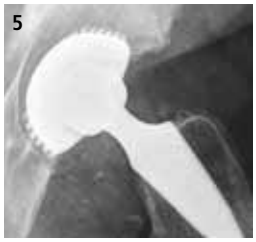
Decentration of head center, fracture of insert due to trauma, ceramic particles in hip joint (Fig. 2 u. 3).

Postoperative x-ray after primary surgery

Treatment:

Surgical treatment algorithm for this diagnosis: Removal of all ceramic particles, lavage, fluoroscopy to find most of the particles. Surgical technique and procedure: Synovectomy, if cup is not damaged => ceramic insert, if cup has a small damage => PE insert.

After revision: PE insert (Cup remained and taper slightly scratched), BIOLOX®OPTION femoral ball head (32mm, size M). Remaining ceramic particles in soft tissue around hip joint. X-ray after 7-month follow-up, patient is fine (Fig. 4 u. 5).



Modern Trends in THA Bearings

A book review by Dr. Miquel Pons

In the preface, Prof. Justin P. Cobb defines the starting point of this book: "Hip replacement remains one of the most cost-effective operations available today". Unfortunately, there is still no such thing as perfect total hip arthroplasty. Problems with wear debris from the bearing couples destroying fixation interfaces and inducing aseptic loosening, impair what are generally good results. Therefore, the most important developments can be expected in the design and the materials of bearing couples.

In this book, internationally renowned experts describe our up-to-the-minute knowledge of ceramic bearings in hip arthroplasty. The topics covered include general considerations regarding indications and bearing combinations, the foundations of successful surgery, materials, technical and clinical complications, the phenomenon of noises and its relevance. Several chapters feature in-vitro and in-vivo tribology studies not only with ceramics, but also with metal and polyethylene, including long term experience with ceramics. The final chapter offers an extensive preview of upcoming developments and future applications.

Many of the studies have level II or III evidence and show long-term clinical results. Each paper includes an abstract, a description of material and methods, results and a conclusion, which makes for a comprehensive and easy read. Extensive figures and tables offer complementary information. The book has a large bibliography and is available on CD.

Professor Justin P. Cobb is Chair of Orthopaedics at the Imperial College in London and is on the board of Acrobot, an Imperial College spinoff. In addition, he is a civilian advisor on orthopaedics to the Royal Air Force. Professor Cobb is on the staff of King Edward VII hospital for officers, and is an orthopaedic surgeon to the Royal Family. His principal research interests are in surgical accuracy and precision, modeling joint surfaces, damaged joint reconstruction, cost utility analysis, computer-assisted surgery.

The book gives a valuable overview of bearing materials, focusing on ceramics in hip arthroplasty. It is useful for both experienced surgeons and juniors or residents. Orthopaedic surgeons with experience in ceramic couples will find a great number of reasons to continue in this practice.

Young or experienced surgeons with doubts about ceramics will find many of their questions answered. This book may prompt those who prefer other bearing couples to reconsider their choices.

Dr. Miquel Pons is an orthopaedic surgeon and a specialist for hip and knee surgery. He is Director of the Department for Joint Infections at the San Rafael Hospital in Bacelona, Spain. Since 2005 he has been General Secretary of the Spanish Hip Society and he is a member of several medical societies. Dr. Pons has given more than 300 presentations at international congresses and has published more than 30 articles in international journals.

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Modern Trends in THA Bearings
Material and Clinical Performance

Cobb, Justin P. (Ed.)

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