Editorial 2

BIOLOX® Symposium
Interview with Javad Parvizi, MD 2

Focus on Implant Position and Clinical Outcome with Various Bearing Surfaces
Presentations at the 79th AAOS Annual Meeting 2012 4

Focus on Tribology
Highlights from the 13th EFORT Congress 2012 8

Bearing Couples – The Key to Success?!
Highlights from the 14th International BIOLOX® Symposium 12

Facts and Figures
Complication Rate of Ceramic Components – an Update 16

Science
Clinical Data with Ceramics 20

Increased Interest in Ceramics in Turkey
Interview with A. Mazhar Tokgozoglu, MD, PhD 22

Case Reports
Clinical Experiences with Ceramic-on-Ceramic Bearings by Remzi Tozun, MD, PhD 24

Research, Teaching and Communication
Interview with Robert Streicher, PhD 26

THA Tribology – a Concise Update
Book Review by Philippe Massin, MD, PhD 27
Dear reader,

The use of ceramics in arthroplasty has enjoyed excellent growth in both the United States and Canada in recent years. Proof of this is the fact that the usage of ceramic components in North America equals that of most European countries. During 2011 more than 140,000 BIOLOX® components were implanted in Canada and the U. S. – in other words, roughly 40% of all total hip replacements performed in both of these countries received a ceramic component.

Interest in and usage of ceramics increased as a result of the surgeons focusing more and more on wear reduction for their active patients as a result of the excellent clinical performance of ceramic components. An important contributor has been the strong support given to the training and education of surgeons on the use of ceramics. One of the biggest efforts in this area was the organization of the 14th BIOLOX® Symposium in conjunction with the CCJR in Las Vegas in May of this year. This key meeting was organized by CeramTec in conjunction with Dr. Javad Parvizi, director of research at the Rothman Institute, and Dr. A. Seth Greenwald, director of the Current Concepts in Joint Replacement (CCJR). The scientific program that they organized was a major success, particularly useful to the group of young North American surgeons who received scholarships from CeramTec in order to participate.

An offspring of this effort will be the session concentrating on ceramics that will be an integral part of the upcoming International Congress of the Chinese Orthopaedic Association (COA). Furthermore, the entire fourth issue of the 2012 “Seminars in Arthroplasty” will be dedicated to the use of ceramics in orthopaedic surgery. All of these educational activities have a common goal: to provide patients with the best possible total hip replacement surgery long-term results.

Sincerely yours

Dieter Burkhardt
Now that the Symposium has taken place, do you believe that it accomplished the objectives that you had in mind?

I have no doubt that the participants at the Symposium left the Symposium with some clear conclusions about tribology and bearings in arthroplasty. The first was that large-ball-head metal-on-metal systems are to be used rarely and for very unique patients. Small-ball-head metal-on-metal systems should be used rarely and metal-on-metal resurfacing systems do not perform as well as conventional total hip replacements.

What about ceramics?

Ceramic-on-ceramic systems are increasingly being used in active patients whether young or old. The clinical evidence supporting their use is extensive and has a worldwide foundation. European and Asian surgeons provided much of the long-term data; however, prospective studies in the U.S. are now offering ample proof of excellent performance in active patients with follow-up periods between 13 and 15 years.

Is there any news on polyethylene?

Highly crosslinked poly is performing well and has by far the largest market share in the U.S. However, the data available today generally applies to the overall patient population and not to the highly active or even the active patient. In many cases it is focused on the latest generation of this material not in its earliest renditions. The surgical community continues to develop the “perfect” poly, but we are not there yet, as indicated by the fact that we are now creating new versions with additions of antioxidants such as Vitamin E. We believe that the use of a ceramic ball head in conjunction with the new polys is a worthwhile investment in order to “protect” the poly in active patients likely to have increased wear. I am very pleased that we are conducting studies at both the Rothman Institute (retrospective analysis of more than 600 patients) and the Hospital for Special Surgery (prospective study on 100 patients) in order to provide the convincing clinical proof needed that the use of a ceramic ball head results in a further protective element against wear in the active patient.

“Evidence Based Medicine” was also discussed at the Symposium. What can be done to get more evidence into clinical practice?

We have a number of mechanisms in orthopaedics that help us in evaluating new technologies and their effectiveness. Case evaluations are usually carried out by an expert or designer based on his own experience. However, these types of reports are difficult to compare since they are usually based on a single device or technology, and of course they are not representative of results from all surgeons. Retrospective analyses of patient results with a new technology can be important but their applicability may be limited. The ideal tool is the prospective randomized clinical trial. Clearly, this is the gold standard, but it is very expensive, provides delayed results and in general is not practical in the short term, as it is of limited value unless it has medium to long-term follow-up.

Is there an alternative to randomized trials?

Meta-analysis pooling of well-controlled studies can help; however, again, this has significant limitations, as randomized studies are not available. Finally, we have the data generated by registries. Unfortunately, they also offer delayed responses unless the data clearly indicates a severe problem. Their generalization of the data can often lead to misinterpretation. I believe that proper “Evidence Based Medicine” decisions rely upon a careful analysis of all of the available data generated by these mechanisms prior to making a judgement on the technology.
Focus on Implant Position and Clinical Outcome with Various Bearing Surfaces

Presentations at the 79th Annual Meeting of the American Academy of Orthopaedic Surgeons, San Francisco, February 2012

The outcome with various bearing surfaces was again the subject of much debate at the AAOS congress. International experts discussed the current status of bearing surfaces, particularly regarding local and systemic reactions to metal ions and wear debris-related failures associated with MoM bearings. In this context, John Skinner (UK) said that “all bearings can and do fail.” Hard-on-hard bearings and the consequences of component malpositioning have sparked renewed interest in implant positioning. Component positioning plays an increasingly important role in ensuring the longevity of bearing surfaces and successful clinical outcomes in hip replacement patients.

Focusing on this issue, CeraNews has monitored discussions and here gives an overview of the latest results. We also introduce two new studies on the outstanding long-term outcomes achieved with CoC bearings.

There is no so-called “forgiving material” from a clinical point of view – Outcome in relation to implant positioning

Studies have shown that PE wear can cause subluxation or dislocation and, on the other hand, that instability can cause PE wear.\(^1\)\(^2\) Malpositioning of the acetabular component has been linked to increased PE wear\(^3\)\(^4\)\(^8\)\(^9\), hip instability\(^5\) and XPE liner fracture.\(^6\)\(^7\)

Study:

PE wear is sensitive to implant position

Geraint E. Thomas et al. (United Kingdom) have now presented the results of a prospective double-blind randomized study in 55 patients using radio-stereometric analysis (RSA). The implant position correlated closely to the extent of PE wear (p=0.002). Liner penetration was significantly different at 8 years, measuring 0.55mm in the group with conventional PE liners and 0.33mm in the group with XPE liners (p=0.005).

The authors therefore hypothesized that XPE may be less sensitive to implant position, though the mid- and long-term outcome of XPE in relation to implant positioning is not known.

Fig. 1a–c: 47-year-old female patient, THA due to developmental dysplasia of the hip (Fig. 1a); cup with high inclination, PE wear and decentralization of the femoral ball head (ca. 3mm) as early as one year postoperatively (Fig. 1b). After another six months, decentralization of the femoral ball head (> 8mm) and PE wear have increased (Fig. 1c). Revision with correction of the cup position, stem remains in situ.

Source: With kind permission of I. Shubnyakov, MD, R. R. Vreden Orthopaedic Institute, St. Petersburg (Russia)
Study:

Cup positioning improves with clinical feedback

Young-Min Kwon et al. (USA) pointed out that cup malpositioning correlates with numerous adverse clinical outcomes including dislocation, liner fracture and increased wear. They drew attention to results showing that surgical technique factors were most predictive of PE wear.

The authors analyzed data on 2,061 patients who received THA or HR between 2004 and 2008. These results were compared with data on THA or HR performed by the same surgeons in 385 patients between 2009 and 2010. The purpose was to determine if cup positioning improved as a result of knowledge of the previous cup positioning study.

Kwon et al. were able to show in this study that the accuracy of cup positioning significantly improves over time when surgeons receive increased feedback on the resulting measurements.

Study:

Tighter tolerance for cup anteversion with 36mm MoM bearings

Jacob Elkins et al. (USA) reported that the positioning of MoM bearings involves significant tradeoffs which are not necessarily ideal in terms of reducing contact stress and wear. This applies particularly against the background of adverse reactions to metal wear debris and metal ions.
Their current data for 36mm MoM implants suggests a tighter tolerance for cup anteversion and indicates the need for precise and correct positioning of large diameter MoM THA.

2 Studies:

Stripe wear in MoM bearings – implantation technique is a relevant factor

Stripe wear was first identified in CoC bearings. Stripe wear can now also be demonstrated in MoM bearings in THA. Christopher L. Peters, Ian Clarke et al. (USA) examined the surface topography of 16 retrieved MoM large diameter THA and compared wear surface data with CoC bearing data. All bearings showed stripe wear on the femoral ball head with corresponding stripe wear within the cup. The authors reported that MoM bearings with multiple stripe lines and/or deeply etched stripe lines correlated with histologic findings revealing lymphocytic inflammatory response. All patients were asymptomatic for subluxation (patients did not notice). The authors therefore used the term repetitive subclinical subluxation. They noted that most stripe lines occur from excessive subclinical wear.

According to the authors, surgical technique is a relevant factor for optimal wear situations in large diameter MoM bearings. They pointed out that hip bearings should be carefully positioned and appropriate femoral offset should be used to reduce subclinical subluxation.

In a further study carried out by the same research group, Edward J. McPherson, Ian Clarke et al. (USA) reported on the results of a retrieval analysis of 75 large diameter MoM THA bearings from 4 manufacturers. Analysis of the surface topography demonstrated that all MoM bearings showed stripe wear on the femoral ball head with corresponding stripe wear within the cup. The stripe wear was caused by repetitive subclinical subluxation. In the majority of retrievals, multiple stripe wear sites were visualized. MoM bearings with such multiple stripe lines correlated with histologic reports of lymphocytic inflammatory response. Among other things, the authors recommend optimizing hip biomechanics (offset) and component position to reduce stripe wear.

“To reduce repetitive subclinical subluxation, hip bearings – built of any material design – should be carefully positioned.”

- Christopher L. Peters, MD

The results of two long-term CoC THA studies highlight the benefits of ceramics

Study:

> 10-year results with CoC THA in patients ≤ 30 years

Young-Hoo Kim et al. (South Korea) reported on the excellent long-term clinical and radiographic outcomes of cementless alumina CoC THA (BIOLOX® forte, 28mm). They prospectively reviewed 124 CoC THA in 93 patients with a mean age of 24 ± 5 years. The main diagnoses were osteonecrosis (55.6%) and developmental dysplastic hip (21%). The HHS had increased to a mean value of 96. At the latest follow-up, 100% of the stems and 99% of the cups were well fixed. There were no migrations of the cup and stem. No failure of ceramic components or noises was observed.

The authors concluded that the absence of osteolysis and high survivorship underline the benefits of alumina CoC bearing couples.
"Alumina-on-alumina ceramic bearings provide a high rate of survivorship without osteolysis."

- Young-Hoo Kim, MD, PhD

References:

Low long-term dislocation rate of CoC THA compared to CoP THA – 20-year results

It is known that PE wear debris can lead to an inflammatory response which may result in subsequent instability.10 A study has shown that PE particles may act as a trigger mechanism for an inflammatory process, which leads to increased production of fluid and capsular distension, reflecting the degree of intracapsular synovitis.11

Philippe Hernigou et al. (France) have now presented the latest results from an evaluation of 126 patients who had each received bilateral THA treatment with a cemented CoP bearing couple on one side and a cemented alumina CoC bearing couple on the other. The mean age was 50 (30–60) years at the time of surgery. Only one stem type was used. All patients were treated with 32mm femoral ball heads. The mean follow-up was 20 (15–30) years.

The cumulative risk of dislocation was greater for the CoP group compared to the CoC group. In the CoP group, the cumulative risk of dislocation was 2% at 1 year, 4% at 10 years, 8% at 20 years and 13% at 30 years. In the CoC group, the cumulative risk of dislocation was 2% at 1 year and did not change over 20 or 30 years. In this context, the authors pointed out that better adhesion, absence of wear in the CoC group and the histological changes observed in CoP revisions (e.g. liquid in joint, thin capsule) are probably the most important factors explaining the absence of dislocation in the CoC group at the latest follow-up.

The different histological aspects observed in revisions are probably the most important factors to explain the absence of dislocation at the most recent follow-up in the ceramic group, even in women older than 80 years, in cognitively impaired patients, or in patients with occurrence of a neurologic disease."

- Philippe Hernigou, PhD

Further literature:

References:

References:
Focus on Tribology
Highlights from the 13th EFORT Congress 2012

The 13th congress of the umbrella organization of the orthopaedic societies in Europe (EFORT) was held in Berlin, May 23–25, 2012. More than 9,000 orthopaedic surgeons and scientists from about 100 countries took part. "Tribology Day" was a focal point of the most important European specialist event of the year, which is attracting increasing numbers of participants from countries outside Europe. CeraNews followed the papers and discussions on the latest findings related to bearing couples.

Malpositioning influences outcomes

John Fisher (UK) urged that the everyday challenges associated with unfavorable stresses as well as implant positioning resulting in increased edge loading and subluxation be simulated as early on as during the preclinical phase. The positioning of implants demands the greatest attention alongside other factors such as material fatigue, activity profiles and the constitution of the individual patient. Fisher drew a distinction between rotational malpositioning and translational malpositioning. He reported that rotational malpositioning is easy to detect in radiographs and can be corrected by inclining the acetabular cup at the correct angle. In translational malpositioning, the centers of rotation of the acetabular cup and the femoral stem are incongruent. The cause may lie in the medial malpositioning of the acetabular cup or the lateral malpositioning of the stem in the case of offset malpositioning. Fisher pointed out that edge loading due to translational malpositioning cannot be seen in radiographs and might be the cause of implant failures that so far could not be explained.

Study:

CoC THA in patients < 30 years old – no cases of osteolysis after > 10-year follow-up

Young-Hoo Kim (Korea) performed a prospective analysis of 124 cementless CoC THA (BIOLOX®forte) in 93 patients under 30 years. In all cases a 28mm femoral ball head was used. The mean age at the time of surgery was 23.7 ± 5.2 years. The most common indications were osteonecrosis of the femoral head (55.6%) and dysplasia (21%). After a mean follow-up of > 10 years, there was no radiologic evidence of osteolysis. No ceramic fractures or noises were observed. The survival rate with the endpoint of aseptic loosening was 100%. Kim cited the surgical technique along with the optimal positioning of the components as the reasons for this outstanding result in a young and healthy patient population.

Kim also reported on the medium-term results in another group of 70 patients who underwent 111 cementless CoC THA (BIOLOX®forte, 28mm). After a mean follow-up of 5.7 (5–6.5) years, there have been no cases of osteolysis or loosening observed to date.

"The alumina CoC bearing couple has been well-proven with a high survival rate after a 15-year follow-up. No osteolysis was observed."

- Young-Hoo Kim, MD, PhD

Outcome:

> 7,000 CoC THA – no cases of osteolysis after 15-year follow-up

Aldo Toni (Italy) was able to perform a retrospective analysis of a total 7,474 CoC implantations with different generations of BIOLOX® ceramics since 1994 to determine the long-term results. The revision rate after 15 years totaled 1.2%. There was no evidence of osteolysis.

Since 2006, 2,166 CoC bearing couples made of BIOLOX® delta had been implanted. He hasn’t observed any ceramic fractures in BIOLOX® delta femoral ball heads. Similarly, evaluation of the arthroplasty registry for the region of Emilia Romagna showed that out of 6,004 implantations using BIOLOX® delta femoral ball heads (28, 32, 36mm) there had thus far been no instance of ceramic fracture. By contrast, BIOLOX® delta inserts exhibited a fracture rate of 0.13%.

As causes for this, Toni named intraoperative mistakes made while inserting the ceramic insert into the acetabular cup* and excessively anteverted cup positioning, which results in impingement and microseparation. He used film sequences of surgeries to provide a clear indication of how to implant components correctly. Implantation errors should be corrected during surgery if possible.

The benefits of a reduced dislocation risk and a large range of motion could be well exploited by using large-diameter CoC femoral ball heads. However, in Toni’s estimation, it is necessary to wait for further study results before using femoral ball heads with diameters in excess of 40mm.

* For further information, please see the article “Complication Rate of Ceramic Components – an Update” (pp. 16–19) of this issue.
**Study:**

**CoC reduces the risk of dislocation – 30-year outcomes vs. CoP**

Late-stage hip joint instability is potentially attributable to PE wear. However, not enough is known about the exact mechanism. It is assumed that PE wear particles trigger an inflammatory reaction which can result in capsular loosening and subsequent instability.¹

Philippe Hernigou (France) now reported on the retrospective findings from 126 patients (252 hips), which he had treated 30 years previously with CoC (alumina) in one hip and CoP contralaterally. The average age at the time of surgery was 50 (30–60) years. The same type of cemented femoral stem was implanted in each case with a ceramic femoral ball head (32mm) using the posterior approach. The dislocation rate for the CoP THA rose steadily from 2% after 1 year to 4.5% after 10 years, 8% after 20 years and 13% after 30 years. There was no correlation between the amount of PE wear and the dislocation rate. With the CoC THA the dislocation rate was 2% after 1 year and did not change thereafter.

Hernigou presumes that histological differences in the capsular tissue for the two bearing couples are responsible for this remarkable result. In the case of the CoC THA, the capsular tissue was taut and fibrous (Figure 1) but soft and more elastic in the case of the CoP THA (Figure 2); this was presumably induced by the release of polyethylene particles.

For CoC THA, the taut joint capsule acted to prevent dislocation.

Hernigou was honored for this study by the EFORT Award Committee with the EFORT Free Paper Award 2012.

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**Fig. 1:** Histological image of the capsular tissue from a CoC bearing couple

**Fig. 2:** Histological image of the capsular tissue from a CoP bearing couple
Case study:
Diagnostic assessment in case of a fractured, non-dislocated ceramic insert

Roozbeh Shafafy (UK) reported on an 82-year-old male patient with a cementless CoC THA who experienced squeaking in his hip joint with no explicable cause 10 months after surgery. The patient had minor symptoms. X-ray imaging did not reveal any abnormalities, with the implants well aligned. As the symptoms persisted, an x-ray image intensifier was used for imaging after another 3 months. The intensified images were clearly evaluable and showed the ceramic insert to be fractured but not dislocated. This procedure proved to be effective and simple for the detection of the non-dislocated ceramic fracture. Shafafy argued for the squeaking in the hip joint to be taken seriously and a thorough diagnostic assessment to be performed.

Registry:
10-year outcomes with XPE and PE inserts
Richard de Steiger (Australia) presented 10-year results with XPE and PE inserts from the Australian arthroplasty registry. The revision rate was 4.7% for MoXPE and 7.1% for MoP. For CoXPE, a revision rate of 6.3% was observed, along with an 8.2% revision rate for CoP. However, all reasons for revision were recorded. Therefore, the results cannot directly be attributed to the bearing couples.

Study:
Up to 40% lower XPE wear rate with ceramic femoral ball heads

Javad Parvizi (USA) presented the initial findings from a multicenter study in which 500 patients were treated using a second generation XPE and 150 using a first generation XPE. In both groups, metal and ceramic femoral ball heads (BIOLOX®delta) were used with the same implant system. After 3 years, the group with the second generation XPE exhibited an annual wear rate of 0.125mm for MoXPE and 0.075mm for CoXPE. In the first generation XPE group, annual wear rates of 0.105mm for MoXPE and 0.076mm for CoXPE were obtained. In this study, a 28% reduction in wear could be shown with the use of ceramic femoral ball heads (BIOLOX®delta) in combination with the first generation XPE and a 40% reduction with the second generation XPE.

Study:
Adverse reactions to metal wear in large-diameter MoM implants due to loosening of the taper fixation

The working group of Christoph H. Lohmann (Germany) was honored by the EFORT Tribology Committee with the Tribology Award.

The scientists had analyzed 114 cases of revision of MoM arthroplasties with a large-diameter femoral ball head. The revisions had been performed after an average of 46 (26–68) months. In 61 cases, radiologic findings indicated osteolysis and signs of loosening. Of note were joint effusion with pseudo-tumor formation and extensive areas of necrosis. Lymphocyte infiltration was detected in 106 cases, with macrophages predominating in 8 cases. Cobalt and chromium particles were present in all tissue specimens. In 94% of cases, loosening of the taper fixation was
detected intraoperatively. There was also evidence of corrosion. In all 106 cases, titanium and iron were detected and were interpreted as clear evidence of a problem related to wear in the femoral stem taper and the femoral ball head fixation.

It was shown in this study that the tissue reactions were adverse reactions to the corrosive components which originated from the loosened taper fixation. The scientists concluded that MoM implants with large-diameter femoral ball heads cannot currently be recommended for primary hip arthroplasty.

**Study:**

**Metal wear results from MoM bearing couple and taper fixation**

Antoni Nargol (UK) presented the results of a comparative study of 180 MoP implantations (28mm) and 262 MoM implantations (36mm) performed with the same femoral stem system. The total revision rate from the MoP group was 3.6% after 10 years, while the revision rate for the MoM group was 10.3% after 6.5 years. The reasons for revision were comparable, with 19 of the revisions in the MoM group due to adverse reaction to metal debris (ARMD). The acetabular cups in the ARMD cases were all within the safe zone for inclination and anteversion.

The metal wear resulted both from the bearing couple and from the fixation between the femoral stem and the metal femoral ball head. High magnification microscopic examination of the receptacle detected substantial traces of wear from the titanium femoral stem taper. In his summary, Nargol stated that future follow-up studies examining MoM implants with large-diameter femoral ball heads must focus on evaluation of the taper fixation.

In a further analysis of 111 MoM implant retrievals (large-diameter femoral ball heads) from various manufacturers, Nargol was able to detect abrasion in the taper fixation in 66% of cases. This might explain why wear-induced loosening is observed despite optimal positioning of the acetabular cup. According to Nargol, this problem also applies for the MoP bearing couple and he considered this thought-provoking.

He also pointed out that there is no correlation in the case of MoM between the increase in volumetric wear and the incidence of pseudo-tumors. Therefore, ARMD must be understood in terms of individual immune response.

**Registry:**

Higher revision rates from MoM arthroplasties with large-diameter heads – mix & match may result in wear problems

Keith Tucker (UK) used UK registry data (National Joint Registry for England and Wales) to show that MoM arthroplasties with large-diameter femoral ball heads required revisions after 5 years significantly more frequently than conventional THA. MoM arthroplasties with large-diameter heads exhibited increased metal wear and ARMD. The evaluation of registry data revealed that femoral stems and femoral ball heads from different manufacturers were frequently combined. This can lead to major problems with wear as there is no standard for the 12/14 taper geometry.

Karl Knahr (Austria), the initiator of Tribology Day, explained his views on bearing couple selection at the end of the symposium. He reported that he had given up on MoM articulations 10 years ago. For elderly patients he uses a CoXPE couple. For all other patients, he recommends the use, where possible, of a CoC articulation (BIOLOX®delta) with a 36mm head diameter. With regard to outcome, he alluded to the importance of surgical technique for all forms of implants.

The report was compiled in cooperation with Martin Ihle, MD, Berlin.

Reference:


Literature:

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Bearing Couples – The Key to Success?!
Highlights from the 14th International BIOLOX® Symposium, Las Vegas, Nevada, USA, May 19 – 20, 2012

The BIOLOX® Symposium was held for the first time in conjunction with the Current Concepts in Joint Replacement (CCJR) Spring Meeting in Las Vegas, Nevada, USA, making it possible for participants travelling to Las Vegas from countries worldwide to engage in a lively exchange of expertise. The president of the 14th BIOLOX® Symposium, Javad Parvizi from the Rothman Institute in Philadelphia, and Seth Greenwald, chairman of the scientific committee, endeavored to ensure a challenging scientific program.

In his introductory presentation, Richard H. Rothman (USA) provided an overview of the history and current state of development of hip arthroplasty, which he praised as the most successful procedure in surgical medicine. Some care providing centers located worldwide reported a survival rate of over 99% after 10 years, due to which much had already been achieved. However, they also reported that this was no reason to feel content as there is still a need for more long-term data.

Rothman reminded the audience that new and innovative technologies will as a rule bring with them new risks. Therefore, according to Rothman, surgeons must define precisely which clinical problem they would like to solve and perform a thorough check to determine whether evidence-based data exist which demonstrate that the new technology is superior to the standard procedure. He admits that the MoM bearing couple has no future prospects. Rothman primarily uses the CoC bearing couple for patients under 50 years old. He uses the CoXPE bearing couple for patients aged between 50 and 70 years and the MoXPE bearing couple for patients over 70 years of age.

A current overview of bearing couples was presented in the first session, which was chaired by John Fisher (UK) and Michael M. Morlock (Germany).

Update:

Bearing couples in THA and TKA
Stuart B. Goodman (USA) compared the advantages and limitations of different bearing couple materials for THA and TKA. According to Goodman, publications reporting on wear in large diameter MoM implants resulting from the taper connection give rise for concern. He provided an overview of the large number of crosslinked polyethylenes on the market which differ substantially in terms of their manufacturing processes. Crosslinked polyethylenes exhibit lower medium-term wear rates than traditional polyethylene.

While medium-term outcomes are available for the use of crosslinked polyethylenes in hip arthroplasty, none are available for knee arthroplasty. Steven M. Kurtz (USA) also addressed this in his presentation. One analysis revealed that there are only 2 clinical studies reporting on the short-term outcomes with crosslinked polyethylene in knee arthroplasty. Kurtz demanded more clinical studies examining outcomes from the use of second generation crosslinked polyethylenes in hip and knee arthroplasty.

Justin Cobb (UK) pointed out that MoM bearing couples from different manufacturers also differ significantly, above all in terms of their metallurgy and design. These variables might, combined with surgical errors, explain the unacceptable variability of outcomes among women and for some MoM designs.

Aldo Toni (Italy) addressed the topic of fretting corrosion. He referred to published results from a series of removed shafts with large-diameter metal femoral ball heads (36–40mm) in which corrosion was detected in the taper connection in 42% of all cases.1 He had no concerns of this nature with BIOLOX®OPTION femo-

- Richard H. Rothman, MD, PhD (USA)

A current overview of bearing couples was presented in the first session, which was chaired by John Fisher (UK) and Michael M. Morlock (Germany).

“Total hip replacement is the most rewarding operation in the history of medicine. Keep it safe, effective and durable.”

- Richard H. Rothman, MD, PhD (USA)

Currently, too few clinical studies are available to systematically review the outcomes of second generation highly crosslinked polyethylenes in either the hip or the knee.”

- Steven Kurtz, MD (USA)
ral ball heads (femoral ball head from BIOLOX®delta, titanium casing) with a diameter of 40mm. However, he did demand more clinical data.

Toni described the CoC bearing couple with large diameter femoral ball heads as probably the best choice and reported that so far 3,774 CoC THA with BIOLOX®forte and BIOLOX®delta (32, 36, and 40mm) had been recorded in the Rizzoli Hip Register for the period 2005–2010.

The notion that fatigue fractures in XPE may also play a role in hypersensitivity reactions to metal wear and osteolysis in TKA was demonstrated based on clinical case reports later on in a session moderated by Javad Parvizi (USA), during which Wolfram Mittelmeier (Germany) and Kantilal H. Sancheti (India) were among those who presented papers.

In the second session, which was moderated by Justin Cobb and Atsushi Kusaba (Japan), Thomas P. Schmalzried (USA) provided an overview of the various methods used to measure wear in vivo. John Fisher and James P. Waddell (Canada) presented results regarding wear.

**Study:**

**Less wear with CoC than with CoP in patients < 60 years old after 8-year follow-up**

James P. Waddell (Canada) presented medium-term results from a randomized, prospective long-term study with CoC and CoP THA in 55 patients under 60 years of age. A CoC bearing couple was used in 30 cases and a CoP bearing couple was used in 26 cases. A 28mm diameter head was used.

The CoC group had a mean age of 41.5 (19–56) years, while average age in the CoP group was 42.8 (31–56) years. The mean follow-up was 8 years. There were no differences in medium-term clinical scores between the two groups. However, radiologic analysis revealed significant differences in linear wear rate per year, which was reported as 0.02mm for the CoC group and 0.11mm for the CoP group.

Waddell concluded that the CoC bearing couple is a safe and long-lasting option which can help avoid the potential risks associated with metal ions and osteolysis triggered by PE wear.

**Study:**

**Less wear with CoC than with MoXPE and MoP in patients < 65 years old after 5-year follow-up**

James P. Waddell (Canada) also presented a report on the clinical and radiologic results from a randomized, prospective study with CoC, MoP and MoXPE THA. 102 THA were performed on 91 patients with a mean age of 53 (19 – 64) years. A 28mm diameter head was used in all cases. 87 patients were available for follow-up examination after a period of 5 years. There were no differences in medium-term clinical scores between any of the 3 groups. In the CoC group, 3 cases of squeaking were observed but none of these required revision. However, the radiologic assessment did reveal significant differences in wear rate. The annual linear wear rate in the CoC group was lowest at 0.006mm, followed by 0.059mm for the MoXPE and 0.151mm for the MoP group.

A podium discussion was moderated by William J. Maloney (USA). The participants included Fares H. Haddad (UK), Christian Hendrich (Germany), Richard H. Rothman (USA), Aldo Toni (Italy) and William L. Walter (Australia). They examined the issue of treatment failures associated with different bearing couples, their causes and their clinical management. The discussion of hip problems, complications associated with bearing couples, their solutions and clinical experience

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"Adverse condition simulation testing in vitro, showed lower wear for BIOLOX® delta ceramic compared to BIOLOX®forte ceramic."

- John Fisher (UK)
continued in three further sessions led by James P. Waddell (Canada) and Karl Knahr (Austria), Donald S. Garbuz (Canada) and Stephen B. Murphy (USA) as well as Steven M. Kurtz (USA) and Carsten Perka (Germany).

Experienced experts such as Michael D. Ries (USA), Craig J. Della Valle (USA), Matthew S. Austin (USA), Yonggang Zhou (China), Hee-Joong Kim (Korea), Robert Legenstein (Austria), Jean-Yves Lazennec (France) and Michael Morlock (Germany) analyzed factors including those specific to the implantation procedure, the implant and the individual patient.

Of particular note was the presentation of Raghu Raman (UK), who reported on 4-year outcomes with CoC THA (BIOLOX®delta) and on 3-year outcomes with CoC (BIOLOX®delta) used in revisions.

**Study:**

**CoC in patients ≤ 65 years old – no cases of osteolysis after 4-year follow-up**

Raghu Raman (UK) reported on excellent clinical and radiological results from a long-term, randomized, prospective study involving 519 CoC THA (BIOLOX®delta, 36mm and 40mm) in 502 patients. The mean age was 64.9 (11–82) years. The mean follow-up was 46 months. No dislocations of acetabular insert migrations occurred. In one case, the ceramic insert fractured after an implantation error. CT imaging did not reveal any evidence of wear in the acetabular area. The survival rate with an endpoint of aseptic loosening was 100% after 4 years. Raman concluded that when the implants are handled correctly and the proper implantation technique is used, outstanding clinical performance can be achieved with CoC.

"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 (UK)

**Study:**

**CoC in hip revisions – no cases of osteolysis after 3-year follow-up**

Raghu Raman (UK) also presented clinical results with the ceramic revision ball head (BIOLOX®OPTION, 36mm, 40mm). A BIOLOX®OPTION femoral ball head was used in combination with a BIOLOX®delta- insert in 138 revisions. The survival rate with an endpoint of aseptic loosening was 100% after 3 years. No cases of osteolysis, dislocation or complications associated with the bearing couple were observed.

The selection of bearing couples in Europe, Asia, and North and South America were examined in closer detail in a session moderated by Peter F. Sharkey (USA) and Jun-Dong Chang (Korea).

**Analysis:**

Global distribution of bearing couple use

Gerald Pflüger (Austria) provided an overview regarding the use of bearing couples in Europe. In his analysis, he drew on various sources (registry, Eucomed). In Europe, 4% of the inserts used are metal, 24% ceramic, 39% XPE and 33% PE. With regard to femoral ball heads, the breakdown is approximately 43% ceramic ball heads versus 57% metal. In Pflüger’s view, there are multiple factors affecting the differences in bearing couple use between European countries, with traditions, differences in healthcare systems and populations playing a role. He identified the growing demand for CoC and CoXPE alongside a drop in the shares of MoM and MoP use as clear trends in Europe.

Kyung-Hoi Koo (Korea) explained that femoral head necrosis is one of the most common diagnoses in Asia and that the patients affected are very young, with average ages between 40 and 50 years. He has been using CoC bearing couples since 1998. In his experience, these provide better outcomes than other bearing couples in this patient population. In his view, ceramic fractures and noises can be avoided using the appropriate implant designs and the correct implantation technique.

"The ceramic bearings have superb outcomes in 10-year studies, and the results are better than any other bearings in young patients."

- Kyung-Hoi Koo (Korea)

Jonathan P. Garino (USA) pointed out that the selection of bearing couples in North America continues to be the subject of controversy. Enthusiasm for MoM THA with large-diameter heads has fallen substantially in view of discussions surrounding potential local and systemic risks associated with metal ions. By contrast, CoC bearing couples and XPE bearing couples exhibit good results. However, noises have occurred with certain CoC implant designs and there is a lack of long-term data for the various generations of XPE bearing couples.
Luiz Sergio Marcelino-Gomez (Brazil) predicted that the share of THA performed in South America will grow significantly in the coming decades, especially among the population over 65 years old, which is expected to triple by 2030. In the same period, the 20 to 55 age group will grow to approximately 70 million. In South America, CoC is the most frequently used bearing couple. In Brazil and Argentina, the proportion of CoC bearing couples is already approximately 50%. Marcelino-Gomez pointed out that the selection of bearing couples in South America is influenced by the different healthcare policies in the individual countries.

The contributors agreed on one thing: CoC bearing couples exhibit only minor or negligible wear, meaning that wear-related osteolysis can largely be avoided. Above all, the careful handling of components and the proper implantation technique are decisive for success. However, that is the case for all bearing couples.

“...The advent of multi-bearing cup and questions regarding the long-term durability of highly cross-linked polyethylene will continue to keep ceramic-on-ceramic bearings as a very viable option for younger and active patients.”

- Jonathan P. Garino (USA)

References:
1 Engh CA et al. Metal on Metal Local Tissue Reaction is Associated with Corrosion of Head Taper Junction. Poster 068, AAOS 2012

Best wishes!

Heinz Mittelmeier celebrated his 85th birthday in October. On this occasion, CeramTec would like to wish this pioneer in the use of ceramics in hip arthroplasty the very best and continued excellent health!

In the 1970s, Mittelmeier was one of the first surgeons in Germany to replace the metal femoral ball head in hip arthroplasties to minimize wear. In honor of his lifetime achievement, the German Society for Orthopaedics and Orthopaedic Surgery (DGÖOC) in conjunction with CeramTec awards the annual Heinz Mittelmeier Research Prize on the occasion of the German Congress for Orthopaedics and Trauma Surgery (DKOU).

Photo from: W. Mittelmeier, M. Haeble, Leben für die Orthopädie, Shaker-Verlag 2011
Complication Rate of Ceramic Components – an Update

General complications

The data on the complication rate after hip arthroplasty surgery vary between 2.2% and 27.5%, depending on the case study.\(^1\) Aseptic loosening, dislocation and infection are named as principal causes for hip revision.\(^2\)\(^3\)\(^4\)\(^5\)

Fracture rate of hip implants

Fractures of femoral ball heads and inserts made of BIOLOX® ceramics are rare complications in hip arthroplasty. According to arthroplasty registries, a relatively small share of 1.3 to 3.3% of all revisions are due to implant fractures (metal, PE, XPE and ceramic components).\(^2\)\(^3\)\(^4\)\(^6\) Fractures of inserts (ceramics, metal, PE, XPE) account for 0.6% of all revision causes, according to the Australian registry.\(^7\) Fatigue fractures of metal components in arthroplasty are more frequent than fractures of ceramic components.\(^3\)\(^7\) The risk of femoral stem fracture (Fig.1) is indicated as approximately 270 in 100,000 (0.27%) implanted stems\(^8\)\(^9\) and is thus higher than the risk of fracturing of a ceramic component.\(^4\)

Fracture rate of BIOLOX® components

To document the quality of outcomes, CeramTec made the company’s internal complaint database public more than 15 years ago. All data in the current statistical evaluation of the database relate to complications reported to CeramTec from January 2000 to June 2012 (Fig. 2).

In that time, approximately 4.58 million BIOLOX® femoral ball heads (approximately 2.97 million BIOLOX®\(^\text{forte}\) femoral ball heads and 1.61 million BIOLOX®\(^\text{delta}\) femoral ball heads) as well as approximately 1.79 million BIOLOX® inserts (approximately 0.99 million BIOLOX®\(^\text{forte}\) inserts and 0.80 million BIOLOX®\(^\text{delta}\) inserts) were supplied. The complication rate reported during the same time period for in-vivo fractured BIOLOX®\(^\text{forte}\) femoral ball heads was 0.021% (21 in 100,000), and for in-vivo fractured BIOLOX®\(^\text{delta}\) femoral ball heads it was 0.001% (1 in 100,000). A 20-fold lower fracture rate was achieved with BIOLOX®\(^\text{delta}\) femoral ball heads compared to BIOLOX®\(^\text{forte}\) femoral ball heads. The in-vivo fracture rate for BIOLOX®\(^\text{forte}\) inserts was 0.038% (38 in 100,000), and for BIOLOX®\(^\text{delta}\) inserts it was 0.026% (26 in 100,000).

Meanwhile the BIOLOX®\(^\text{delta}\) material has become established the as standard material both for ceramic femoral ball heads and ceramic inserts. BIOLOX®\(^\text{delta}\) inserts by now account for approximately 90% of all BIOLOX® inserts sold (Fig. 3).

### BIOLOX®\(^\text{forte}\) / BIOLOX®\(^\text{delta}\) (1/2000 – 6/2012)

<table>
<thead>
<tr>
<th>Component / Failure Mode</th>
<th>BIOLOX®(^\text{forte}) / Failure</th>
<th>In %</th>
<th>BIOLOX®(^\text{delta}) / Failure</th>
<th>In %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral ball heads/ in-vivo ceramic failure</td>
<td>21 in 100,000</td>
<td>0.021</td>
<td>1 in 100,000</td>
<td>0.001</td>
</tr>
<tr>
<td>Total number of femoral ball heads sold</td>
<td>2.97 million</td>
<td></td>
<td>1.61 million</td>
<td></td>
</tr>
<tr>
<td>Inserts/in-vivo ceramic failure</td>
<td>38 in 100,000</td>
<td>0.038</td>
<td>26 in 100,000</td>
<td>0.026</td>
</tr>
<tr>
<td>Total number of inserts sold</td>
<td>0.99 million</td>
<td></td>
<td>0.80 million</td>
<td></td>
</tr>
</tbody>
</table>

Fig. 2: In-vivo fracture rates of BIOLOX® components, reported from January 2000 to June 2012.
Source: CeramTec
In contrast to the clinical experiences gained with BIOLOX® delta femoral ball heads, BIOLOX® delta inserts do not yet exhibit a clear improvement of the complication rate. The most common causes for fractures of ceramic inserts are essentially incorrect handling, for instance, misaligned insertion of the insert, contamination of the interface between cup and insert by foreign bodies (e.g., tissue, bone, cement), insufficient fixation of the insert in the cup, intra-operative damage to the acetabular taper (Fig. 4–6), inappropriate combinations as well as impingement.10,11,12,13,14,15,18

Due to the tendency toward larger head diameters, the wall thickness of the metal cups was reduced. These can exhibit a tendency toward deformation in connection with pressfit fixation. It is therefore crucial to employ the correct surgical technique and to take the utmost care when performing an implantation. When inserting the ceramic inserts, the surgeon must perform this procedure precisely. This is described in detail in the respective instructions for use.

The positioning of inserts (ceramics, metal, XPE, PE) in connection with cup and stem implantation is generally highly demanding in terms of surgical technique in order to avoid premature failure and, under certain conditions, deterioration of wear characteristics as well as increased wear of the material. When patient factors are taken into account, it is important for the quality of outcome in hip arthroplasty not only to choose the optimal implant but also to employ the proper surgical technique.

Optimal function and maximum longevity of the hip replacement are primary objectives. With proper handling and avoidance of subluxation and impingement constellations and a sufficient range of motion, very low wear rates can be achieved with the ceramic-on-ceramic bearing couple, thereby avoiding osteolysis due to wear.

Fig. 3: Percentage distribution of BIOLOX®forte and BIOLOX®delta inserts supplied from January 2003 to January 2012
Source: CeramTec

Fig. 4: 51-year-old female, developmental dysplasia of the right hip (Crowe II), cementless CoC THA (BIOLOX®forte), fracture of the ceramic insert 7 years and 6 months after primary surgery

Fig. 5: Implant retrieval, ceramic fragments (BIOLOX®forte)

Fig. 6: The cause of the failure was obvious: the intra-operative picture shows scratches and deformations at the edge of the metal cup (arrows). The metal cup had been damaged due to the use of an unsuitable instrument during primary surgery.
Source: by courtesy of Prof. Atsushi Kusaba, Institute of Joint Replacement and Rheumatology, Ebina General Hospital, Kanagawa (Japan)
Measures for reducing the complication rate

In close cooperation with orthopaedic surgeons and implant manufacturers, CeramTec pursues the objective of further reducing the complication rate of BIOLOX® components, particularly of inserts.

- Experts from CeramTec are available for surgeons and OR personnel for training and education courses with regard to handling of ceramic implants.

- CeraFacts (on USB stick) provides comprehensive information on ceramic implants for primary surgery and for revisions, including handling of the implants (live surgery videos, animations and clinical and technical information). This can be obtained from CeramTec or the implant manufacturers (see fax).

- The website www.biolox.de provides quick access to tips on the secure handling of ceramic implants as well as literature references.

- Implant manufacturers provide insertion instruments which may help avoid the misaligned insertion of the insert.

• NEW: Insertion instrument for BIOLOX® inserts

The inserter (Fig. 7–10) is an instrument that was specifically developed to enable the secure insertion of the BIOLOX® insert into the metal cup. When the instrument is handled correctly, misalignment of the insert during insertion is avoided – even in operations with impaired visibility conditions.

After insertion of the BIOLOX® insert, a final “finger test” (Fig. 10) must be performed, which allows the surgeon to verify the correct position of the insert by palpating the edge of the cup: the edge of the metal component must finish flush with the edge of the ceramic component.

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The insertion instrument is presently going through the approval procedure. Interested surgeons are advised to contact their implant supplier, through whom the instrument can be obtained. Further information on the insertion instrument for BIOLOX® inserts can be obtained directly from the instrument manufacturer.*

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**Design**

Furthermore, modular pre-assembled systems and assembled monoblock systems, in which the metal cup and the ceramic insert are connected so that they are hard to separate, as well as design optimization of modular BIOLOX® delta inserts by rounding of edges, show a clear reduction in the complication rate.

Modular pre-assembled and assembled monoblock systems have the advantage that possible complications due to handling, which can occur in the course of intra-operative insertion of a ceramic insert, are to a large extent avoided.

In modular pre-assembled systems (Fig. 11), a standard ceramic insert (XLW) is pressed into the standard metal cup by means of a special procedure already at the factory. The system is available for head diameters from 28mm to 40mm. Reports of first clinical experiences with pre-assembled systems have been published.10–12

In assembled monoblock systems (Fig. 12), the customer-specific thin-walled ceramic insert is pressed into a customer-specific thin-walled metal cup. The system is available for head diameters from 32mm to 48mm. Thin-walled metal cups allow for a smaller outer diameter to be combined with a larger inside diameter of the ceramic insert. Thus, a larger head diameter can be used even for a smaller pelvis.

With approximately 30,000 BIOLOX® delta inserts sold since 2010 for modular pre-assembled and assembled monoblock systems, no instance of failure has been reported to CeramTec.

In the design optimization of modular BIOLOX® delta inserts by rounding of edges (Fig. 13), the edge strength and the self-centering ability are significantly enhanced by rounding of the edges, and insertion of the insert is facilitated due to the elongated taper portion (b), which enables better guidance of the insert.

The design-optimized modular BIOLOX® delta inserts showed an approximately 80% lower in-vivo fracture rate, based on approximately 100,000 components sold up to now.

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**Fig. 11: Modular pre-assembled system**
Source: CeramTec

**Fig. 12: Assembled monoblock system**
Source: CeramTec

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**References:**

5 Norwegian Arthroplasty Register, http://nrweb.helse.net/njr/default.htm
6 Emilia Romagna Register of the Orthopaedic Prosthetic Implants (Italy), https://ripo.cineca.it
8 Schmalzried TP. How I Choose a Bearing Surface for My Patients. J Arthroplasty 2004;19(8), Suppl.3:514
Clinical Data with Ceramics

**Hari P. Bezwada** (USA) reported on the use of CoC bearing couples in hip arthroplasty at the International Congress for Joint Reconstruction in San Diego. In his judgment, CoC is the best bearing couple option. It exhibits hardly any wear compared with PE bearing couples and it helps prevent wear-related osteolysis. Also, hypersensitivity reactions are not to be expected. He reported that, furthermore, the risk of fracture with fourth generation ceramics is very low and pointed out the possibilities offered by the use of the revision ceramic ball head* in hip revisions. Bezwada also noted the importance of positioning implant components correctly in order to achieve outstanding long-term outcomes.

*BIOLOX®OPTION (CeramTec)

Bezwada HP. Why ceramic-on-ceramic is the best bearing option in THA. Presented at the International Congress for Joint Reconstruction San Diego 2012

**Study:**

**CoC THA – no cases of osteolysis after 10-year follow-up**

**Yeung et al.** (Australia) analyzed 301 cementless CoC THA (BIOLOX®forte) in 283 patients. The mean patient age was 58 years. There were no post-op ceramic fractures. In one case, intraoperative chipping occurred when the insert was being positioned. One patient reported squeaking. However, this could not be reproduced. The most common complication in this series was femoral fracture (2%). No wear-related osteolysis was observed. The survival rate (Kaplan-Meier) with the endpoint of aseptic loosening was 99.6%. The authors concluded that the CoC bearing couple exhibits excellent clinical results after 10 years.


**Study:**

**CoC in patients < 50 years old – no cases of osteolysis after 10-year follow-up**

In a retrospective study, **Hsu et al.** (USA) reported on the results after 82 CoC THA in 64 patients (42 men, 22 women). The mean age was 38.6 (16.3–48.9) years. The mean follow-up was 10.1 (10–12) years. The survival rate (Kaplan-Meier) with the endpoint of all revisions was 96.3%. In two cases, a ceramic fracture (insert) occurred due to trauma. Squeaking was observed in one patient. No cases of instability, signs of loosening or aseptic loosening were observed. The authors concluded that the CoC outcomes in this group of young, active patients are comparable with those for older patients found in the literature.

Hsu JE. Ten-Year Follow-Up of Patients Younger Than 50 Years With Modern Ceramic-on-Ceramic Total Hip Arthroplasty. Semin Arthro 2011;22:229–233

**Study:**

**CoC in patients ≤ 50 years old – no cases of osteolysis after 7-year follow-up**

Steppacher et al. (USA) evaluated outcomes obtained retrospectively from 350 CoC THA (BIOLOX®forte, 28mm in 102 hips, 32mm in 240, and 36mm in 8) in 305 patients with a mean age of 42 (18-50)

Overall, I think ceramic-on-ceramic is the better option for younger patients. 

- Hari P. Bezwada, MD (USA)


**Study:**

**CoC in patients < 50 years old – no cases of osteolysis after 14-year follow-up**

**Sugano et al.** (Japan) evaluated 100 cementless CoC THA (BIOLOX®forte, 28 mm). The mean age was 56 (41–73) years. The survival rate with the endpoint of all revisions was 95.7% after 14 years. One patient reported clicking. However, this did not recur. In one case, a fractured insert (chipping) was observed.

The patient underwent a revision and had a new CoC bearing couple implanted. No osteolysis was observed.

years. A cemented stem was used in 4% of cases. The mean follow-up was 7 (2–14) years. The survival rate with the endpoint of all revisions was 97.2%. Five patients reported squeaking. However, this could not be reproduced in any of these cases. A fractured ball head occurred in one case (due to trauma), while a fractured insert was observed in another case. No cases of dislocation or wear-related osteolysis were observed.

Steppacher SD et al. Absence of Osteolysis in Uncemented Alumina Ceramic-on-Ceramic THA in Patients Younger Than 50 Years After Two to 14 Years. Semin Arthro 2011;22:248–253

The current study shows that ceramic-on-ceramic THAs in the young patient population have a very low revision rate with absence of wear or osteolysis for uncemented stems.

- Steppacher et al. (USA)
  In: Semin Arthro 2011;22:252

Study:

CoC in patients ≤ 20 years old – no cases of osteolysis after 4-year follow-up

Finkbone et al. (USA) reported on short to medium-term outcomes from 24 CoC THA (28, 32, and 36mm) in 19 patients with a mean age of 16 (12–20) years. The main diagnoses were osteonecrosis of the femoral head and juvenile rheumatoid arthritis. The mean follow-up was 4.3 (2–10) years. The survival rate with the endpoint of all revisions was 96%. No ceramic fractures or noises occurred. The authors concluded that the study yielded highly promising results for the CoC bearing couple in this young patient population.


Study:

Higher survival rate and no cases of osteolysis in CoC versus CoP after 10-year follow-up

D’Antonio et al. (USA) compared the data from 144 CoC THAs (BIOLOX® forte, predominantly 32mm) with those from 72 MoP THA (primarily 28mm). The mean follow-up was 10.3 (10–12.4) years. The mean age was 54 (21–75) years. In the CoC group, the revision rate was 3.1%, which was significantly lower than in the MoP group (10.5%). In the MoP group, osteolysis was observed in 26% of cases, while no cases of osteolysis were observed in the CoC group. In the CoC group, 2 patients reported squeaking. However, this could not be reproduced under clinical conditions. The authors concluded that this result supports the use of CoC bearing couples and that these offer a high success rate after more than 10 years of follow-up.


Study:

Less wear with CoC vs CoP after 8-year follow-up

Lewis et al. (Canada) reported on the results from a randomized, prospective, long-term study in which 26 CoC THA and 30 CoP THA were examined to determine the degree of wear in the bearing couples. In all cases a 28mm femoral ball head was used. The mean age was 42.2 (19–56) years. The follow-up was 5–10 years. Linear wear was measured for the CoC bearing couples after an average of 8.3 years and after an average of 8.1 years for the CoP bearing couples. The CoC bearing couples exhibited a mean wear rate of 0.02mm/year. However, wear was only observed in 12 of 23 cases. The CoP bearing couples exhibited a mean wear rate of 0.11mm/year. The authors concluded that the use of CoC bearing couples constitutes a safe and durable option for young patients.


The use of a ceramic-on-ceramic bearing is a safe and durable option in the young patient avoiding the concerns of active metal ions and osteolytic polyethylene debris.

- Lewis et al. (Canada)
With BIOLOX® \textit{delta} the Interest in Using Ceramics Increased Dramatically

An interview with A. Mazhar Tokgozoglu, MD, PhD, Hacettepe University Faculty of Medicine, Ankara

Turkey is a modern, dynamic developing country in the Middle East with a population now approaching almost 75 million. How has hip arthroplasty developed in Turkey in the last few decades?

As in Europe, the early 1960s saw a dramatic change in orthopaedics in Turkey. Orthopaedics, once a subspecialty within general surgery, became a discipline in its own right with fellowship-trained surgeons in the United States and United Kingdom. A paradigm shift occurred and orthopaedics departments were established, first in university medical centers and later in state-owned hospitals. These orthopaedic surgeons maintained their relationships with their mentors and, when total hip arthroplasty became available, they were able to go to the United Kingdom for training. After they returned, total hip arthroplasty was first performed in university hospitals in the early 1970s. The number of total hip arthroplasties performed has since increased dramatically along with training in the area.

What are the hot topics of discussion in THA in Turkey at the moment?

New bearing surfaces and experiences related to them are the hottest topics. Since we have many young patients with hip dysplasia, or patients who have been treated for dysplasia during childhood, we have a lot of patients with early hip arthritis. These patients are now presenting for treatment of their hip pain and they are already armed with a lot of internet-based information regarding new bearing technologies.

Why is dysplasia the major problem?

Being a country with strong attachment to its traditions, babies have always been wrapped in swaddling cloths, especially among the rural population and in the east half of the country. This has resulted in hip dysplasia inadvertently becoming a major problem in Turkey. A thesis study has also recently shown that in Turkey patients with hip dysplasia have a significant mutation of the GDF-5 gene causing joint laxity. This indicates that there is a tendency for hip dysplasia in Turkey, which is probably why total hip arthroplasty has been performed more than total knee arthroplasty. Improvements in prenatal care, effective screening of newborn infants and education to ensure that swaddling is less widespread have reduced the incidence of hip dysplasia in Turkey. Also, with the new obesity epidemic we are now observing an increasing number of knee replacements.

How many hip and knee surgeries are being performed in Turkey?

Unfortunately, since we do not have a registry we do not know the exact number of arthroplasties performed annually. However, we believe that approximately 26,000 primary total hip arthroplasties and 3,000 revisions are performed in Turkey each year. We estimate that the number of knee replacements is now approaching 40,000 a year.

Why are more and more patients undergoing hip replacement surgery in Turkey?

Initially, as elsewhere, total hip arthroplasty was a surgical procedure reserved for individuals with a life expectancy of 10 years. As results have improved, the age at which we perform total hip arthroplasty has come down significantly. Since hip dysplasia has been, and continues to be, a major problem in our country, we have

A. Mazhar Tokgozoglu, MD, PhD, is Professor of Orthopaedics and Traumatology at the Faculty of Medicine of the Hacettepe University in Ankara, Turkey. His main research area is primary and revision arthroplasty focusing on joint reconstruction after infection and tumor. Between 2004 and 2006 Prof. Dr. Tokgozoglu was President of the European Hip Society. Currently he is member of the executive board of the Faculty of Medicine at the Hacettepe University, Delegate of Turkey at the European Federation of Orthopaedic and Trauma Surgery (EFFORT), and member of the EFFORT Finance Committee. Prof. Dr. Tokgozoglu is on the editorial boards of the scientific journals “Hip International” and “Orthopaedics Today Europe”.

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started to employ this procedure in younger and more active individuals. In the last decade, we have faced a demand from individuals in their second and third decades of life seeking help for their early arthritis. Even with the improvement of polyethylene technology it is difficult to provide solutions for these young and extremely active individuals.

**What is going to be the focus of THA in Turkey over the next few years?**

I think most of the discussion is going to be around the new bearing surfaces and the opportunities these technologies will provide. I have seen major interest in using larger femoral ball heads. However, one limitation can be the fact that most young patients have hip dysplasia requiring smaller acetabular sizes, which limits our use of large heads. The interest in minimally invasive surgery has lost some momentum. However, I personally try to minimize my surgical approach, even in revision cases.

**What is the existing clinical experience with BIOLOX® ceramics in Turkey?**

Since the 1980s, we have been seeking an answer in this country to the question of how we can overcome the problems of wear and shortcomings of hip arthroplasty in patients of a less advanced age. With the advent of ceramic technology in the 1980s, a number of Mittelmeier ceramic-on-ceramic hip replacements were performed at our institution. However, problems with the design of the implants and with the quality of the ceramics available at that time left us disappointed with the early results. Later on, in the early 1990s, new implants with alumina ceramics became available in Turkey. However, concerns regarding fracture, and later squeaking, prevented the widespread use of ceramics. With the advent of the new generation of BIOLOX®delta ceramics, there has been a dramatic increase in interest regarding the use of ceramics. Since 2008 we have started to use BIOLOX®delta ceramics in young, active individuals. The Turkish Social Security Administration, the body which oversees government reimbursement for medical treatment, provides reimbursement for the use of ceramics in individuals under the age of 65. We therefore reserve the use of ceramics for young and active individuals. To date, we have not observed any fractures, wear-related issues or squeaking in patients in whom we used BIOLOX®delta ceramics.

**Professor Tokgozoglu, the 14th EFORT congress in 2013 will take place in Istanbul. You are a member of the Local Organising Committee and Scientific Committee. Why should orthopaedic surgeons register for this EFORT congress in particular?**

Well, Istanbul is a beautiful city, being at the junction of Europe and Asia. It has been a place where East meets West for centuries. Istanbul is an unbelievable melting pot, combining centuries of civilizations, different religious beliefs and cultures. It is a center of entertainment and enjoyment. I am sure that those who come to the congress will have their expectations fully met with regard to orthopaedic education while enjoying the city. We are already seeing a high level of enthusiasm for attending the meeting. The scientific program is in its final stages, with exciting symposia, interactive complex case discussions, and sessions on tribology. One of the main topics of the meeting will be an update regarding new technologies, including ceramics in total hip arthroplasty, during tribology sessions. We also hope to present our early results with new ceramics during the scientific paper presentations. I would not miss the opportunity to come to Istanbul.
Clinical Experiences with Ceramic-on-Ceramic Bearings

by Remzi Tozun, MD, PhD

Case 1: CoC THA in Ficat stage IV osteonecrosis of the hip

Diagnosis
29-year-old female with systemic lupus erythematosus (SLE) receiving high-dose steroids. Bilateral femoral head osteonecrosis (ON), with both hips graded as Ficat stage IV (Fig. 1). The patient complained of severe joint pain and a restriction of movements.

Treatment
One stage bilateral cementless CoC THA, BIOLOX® forte, 28mm (Fig. 2). The patient was without pain and showed excellent clinical results with a full range of motion. She now continues to enjoy ballroom dancing, trekking and cycling. After 10 years, both hips were functioning well (Fig. 3).

Remzi Tozun, MD, PhD, is Director of the Department of Orthopaedics, Traumatology and Arthroplasty at Acibadem Maslak Hospital in Istanbul, Turkey. He specializes in hip and knee surgery. He is President of the Turkey Hip and Knee Arthroplasty Society and was President of the Turkish Society of Orthopaedics and Traumatology (TSOT). Remzi Tozun is a member of the American Academy of Orthopaedic Surgeons (AAOS), the European Federation of Orthopaedic and Trauma Surgery (EORT), the European Hip Society (EHS) and the Société Internationale de Chirurgie Orthopédique et de Traumatologie (SICOT). He has authored numerous book chapters and journal articles, mostly on the subject of arthroplasty and reconstructive surgery with a special interest in dysplastic hips, osteotomies and bearing surfaces.

Remzi Tozun started using ceramic-on-ceramic (CoC) bearings as soon as they became available in Turkey in 2001. Until then he had experienced many aseptic failures due to wear related osteolysis. Prof. Dr. Tozun first used BIOLOX®, then BIOLOX®forte and is now using BIOLOX®delta exclusively. He chooses CoC bearings mainly for physiologically young patients with a life expectancy of more than 15 years. For older patients he prefers alumina femoral ball heads (BIOLOX®forte) in combination with PE inserts. Between 2001 and 2011, Remzi Tozun performed 791 CoC THA in 652 patients with an average age of 54 (18–70) years. The mean follow-up is 6.6 (1–11) years.

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Case 2: CoC THA for bilateral Crowe type-IV hip dislocation

Diagnosis
36-year-old female with untreated bilateral developmental dysplasia of the hip (DDH, Crowe IV) (Fig. 1) suffering from a bilateral Trendelenburg gait, with significant pain on the left hip. She had been using a cane on the right for 4 months.

Treatment
A cementless CoC THA (BIOLOX® delta, 28mm) was performed in the left hip after a step-cut shortening femoral osteotomy (Fig. 2). The patient was walking with a toe touch weight bearing for 6 weeks following surgery and, after that, with a gradually increased weight bearing, reaching 100% after another 6 weeks. When she could comfortably bear her full weight on the left hip, 4 months after surgery, a second CoC THA was performed on the right, using a similar technique and similar implants (Fig. 3). The clinical result was excellent, with equal leg lengths, a complete resolution of the Trendelenburg gait and no pain (Fig. 4).

Fig. 1: Pre-operative radiograph, bilateral Crowe IV dislocation
Fig. 2: Post-operative radiograph, left hip, step-cut shortening femoral osteotomy, CoC THA
Fig. 3: Post-operative radiograph, right hip with CoC THA, performed 4 months after CoC THA in left hip
Fig. 4: Post-operative radiograph, 6 months (right hip) and 10 months (left hip) after CoC THA. The patient can carry her full weight without restrictions.

Acronyms and further information:

ARMD = Adverse Reactions to Metallic Debris
CoC = Ceramic-on-Ceramic
CoP = Ceramic-on-Polyethylene
CoXPE = Ceramic-on-XPE
DDH = Developmental Dysplasia of the Hip
HHS = Harris Hip Score
HR = Hip Resurfacing
MoM = Metal-on-Metal
MoP = Metal-on-Polyethylene
MoXPE = Metal-on-XPE
PE = Polyethylene
ROM = Range of Motion
THA = Total Hip Arthroplasty
TKA = Total Knee Arthroplasty
UHMWPE = Ultra High Molecular Weight Polyethylene
XPE = Crosslinked Polyethylene

Please find further information, references and links regarding the topics of this issue of CeraNews at:

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Research, Teaching and Communication

An interview with Robert Streicher, PhD

Robert M. Streicher, PhD, has been working as Vice President Science and Clinical Affairs in the field of medical technology at CeramTec since March 1, 2012. Apart from this, Streicher, who is an expert in the field of biomaterials and tribology, teaches at universities in Italy and Switzerland. He is General Secretary of the International Society for Technology in Arthroplasty (ISTA), a member of numerous specialist societies and of the editorial boards of several scientific journals. CeraNews asked him about his tasks and goals, and about the present controversy over arthroplasty in the German media.

What qualifications and experiences have brought you to CeramTec?

I first studied synthetic material engineering, followed by mechanical engineering, in Vienna, and subsequently worked in a variety of industrial sectors. After a number of jobs in automotive and lighting engineering, I joined a large medical technology company in 1981. I have since then been working in this field, amongst other positions as director of research in the areas of materials and tribology, biomechanics, simulation and clinical research. I have now been working in research and development for orthopaedic implants for more than 30 years in total – in basic research, technical development and clinical testing.

What triggered your interest in tribology?

One of my first assignments in medical technology was to work on improving bone cement and polyethylene. In connection with my work on the optimization of polyethylene, I specifically had to deal with the issue of wear, and so I started at a very early stage to develop test methods and simulators that allow the characteristics of a material to be reliably examined. During this time, we developed and tested several new material combinations, some of which are still on the market today. Thus, I also intensely occupied myself with all known bearing couples used in arthroplasty. In 1993, I wrote my dissertation on the tribology of hip replacements. For more than 10 years, I have focused on tribological and biomechanical issues related to ceramics and published in this field.

Does this also apply to your teaching activities?

Biomechanics, tribology and biomaterials such as ceramics play an important role in my teaching activities, but I also teach on other issues. For example, I give lectures on "Industrial Research and Development at the Interface of Biomaterials and Drug Delivery" as a lecturer at the Faculty of Material Sciences at the Swiss Federal Institute of Technology in Zurich (ETH). I have an additional assignment as Professor for Biomaterials and Biomechanics at the Medical Faculty of the University of Varese, Italy. There, I teach medical doctors specializing in orthopaedics and traumatology. While in Zurich I teach scientists from a variety of specialist fields such as material science, biology and pharmacology.

What are your tasks in your new position at CeramTec?

I am responsible for all research activities in the field of medical utilization of ceramics, both with regard to material science and to clinical evaluation: How do ceramics work in different applications? What don’t we know yet? Where is research most urgently needed? We are continually reassessing the existing technologies and searching for new solutions. My department supervises the large number of scientific studies and manages our cooperation with hospitals, scientific institutes and universities. Of course, we also cooperate very closely with CeramTec’s Technical Development Department. Communicating with our customers – implant companies as well as hospitals and medical doctors – on tribological issues is also very important to me. Their work, and thus our work, can only be successful if they understand precisely what is happening in tribology. In this regard there is still quite a lot of catching-up to do.

Which channels do you intend to use for communication?

A classic channel is that of giving lectures at relevant scientific events. Up to now, I have given more than 700 presentations on a variety of orthopaedic topics, and I will continue this, of course. Publishing research results in the relevant specialist press is another channel, as are articles in CeraNews or other newsletters. Specialist committees, for instance, the Executive Committee of the German Arthroplasty Registry, or
various specialist societies in the field of materials are of course also important panels where I will represent CeramTec. Moreover, we are in the process of setting up a comprehensive training program in tribology for medical doctors. CeraNews will report on this as soon as we have completed planning.

**What are you aiming to achieve with your work at CeramTec?**

My greatest concern is to enable decision makers and users in the field of arthroplasty to make well-considered choices for the benefit of the patient. In order to select the best possible treatment approach, they need to know how the products work and which biomechanical and material science-related aspects should be taken into account when determining indication, implantation technique and follow-up treatment, as well as when making purchase decisions. It is my aim to provide the know-how required and to spread it as widely as possible, even beyond the circle of medical doctors and clinics.

**What are you thinking of in this context?**

The responsible executives at the health insurance companies and in politics are also involved in making decisions on which the well-being of patients may ultimately depend. They should likewise understand the possibilities of modern implant technology and where this technology still has objective limits. It is my aim, with the means at my disposal, in this way also to assuage the doubts triggered by German media reports on allegedly unreliable hip replacements – not only amongst patients, but also amongst physicians and medical technology companies. It must once more become clear to all involved that a high-quality, well-positioned implant works very reliably over decades. This is substantiated by all clinical data and all national arthroplasty registries. The failure rate after 10 years is less than 10%. A success rate of over 90% is an enormous achievement of which one hardly dares to dream in many other fields of medicine. It also shows that reputable implant companies have been manufacturing very good products with utmost diligence for five decades now. These implants help millions of people to reduce pain and improve their quality of life. One should not forget: implantation of a hip replacement is one of the most successful and cost-effective surgical procedures.

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**THA Tribology – A Concise Update**

by Philippe Massin, MD PhD

This book gives an updated review of the most recent advances in the tribology of total hip replacement, such as crosslinked ultra-high molecular weight polyethylene (UHMWPE), metal-on-metal and ceramic-on-ceramic bearings.

**Crosslinked UHMWPE.** In crosslinked UHMWPEs, free radicals can be eliminated by two different methods: remelting and annealing. Annealing has a lesser effect on the crystallinity of the UHMWPE because the melting point of the polymer is not reached during the heating process. As a result, some free radicals remain. This is the reason why long-term clinical studies are mandatory to validate the performance of moderately crosslinked UHMWPE in terms of wear. In this respect, Grimm et al.’s randomized study is highly interesting because it confirms low wear and osteolysis rates using moderately crosslinked and annealed UHMWPE within the first 13 years of use.1

Zietz et al. have shown that crosslinked UHMWPE appears compatible with large femoral ball heads, although wear rates in simulator tests increased in comparison to 28mm-diameter heads.2 However, according to Beck et al., this difference disappeared with a higher degree of crosslinking.3 In any case, the wear rates observed with 36mm- and 44mm-diameter heads against crosslinked UHMWPE stay well below those observed with conventional UHMWPE. It remains to be seen whether the reduced liner thickness resulting from the use of large-diameter ball heads will jeopardize the mechanical strength and fatigue properties of the polymer in vivo.

More recently, antioxidant agents were incorporated into crosslinked UHMWPE in the hope of optimizing the long-term mechanical properties, by suppressing the in-vivo polymer oxidation. As described by Costa et al.4, there are several techniques for infiltrating UHMWPE with Vitamin E. Among these, blended additivated UHMWPE appeared the best solution because of a more homogeneous distribution of the vitamin within the polymer. This particular polymer showed better mechanical properties than conventional crosslinked UHMWPE due to the elimination of the remelting process (which is otherwise required to completely remove the free radicals). Furthermore, the better resistance of the crosslinked UHMWPE to wear was maintained over time in spite of the blend-
ing process. In fact, the amount of oxidation products (ketones concentration) was drastically reduced throughout the extended testing phase.

Because Vitamin E limits the degree of crosslinking due to its scavenging effect on free radicals, an alternative method was proposed by Traynor et al.\(^5\) While Vitamin E was blended into the UHMWPE powder, a fixed dose of irradiation was delivered before the residual free radicals were annealed by a technique involving pure mechanical effects, not thermal. This allowed a crosslinked UHMWPE to be produced, offering a prolonged resistance to oxidation while maintaining optimal mechanical properties.

**Metal-on-metal.** Metal-on-metal bearings were promising but appeared to be very sensitive to edge loading or cup malpositioning. Indeed, vertical cups and suboptimal design (insufficient cover angle, head/cup clearance) explained the production of wear particles leading to adverse reactions to metal debris (ARMMD), as such as synovitis and pseudotumors. An individual patient’s sensitivity to metal debris could also play a major role, as Skinner et al. have remarked.\(^6\)

As reported by these authors, serum ion levels appeared higher in patients implanted with large-diameter metal-on-metal bearings in modular total hip replacements than in patients with hip resurfacing, raising the problem of corrosion at the morse taper junction. This is why most authors nowadays caution against the use of large-diameter femoral ball heads in total hip replacement.\(^7\)

**Ceramic-on-ceramic.** Ceramic fractures have become extremely rare since the introduction of enhanced third-generation ceramics. Squeaking remains the major problem, according to Pokorny and Knahr\(^8\), but it appears to be design-related. Several causes were discerned, such as edge loading whatever the cause, micro-separation and implant positioning. However, developments in contemporary designs make it likely to become as rare as ceramic fractures.

The most recent type of ceramic includes tetragonal zirconium particles (17% of the total volume) with an average grain size of 0.2 micrometers, as Masson and Kuntz explain.\(^9\) The transformation phase of zirconia from the tetragonal to the monocyclic phase helps to stop the propagation of micro-cracks within the substance, as shown by tests after accelerated aging and cyclic loading.

**Finally,** Fisher remarks that, although contemporary bearings (metal-on-crosslinked UHMWPE, metal-on-metal and ceramic-on-ceramic) deliver excellent wear performance in normal walking conditions, substantial differences appear in suboptimal bearing conditions such as edge loading. In this respect, the advantage of ceramic ball heads (involving ceramic-on-ceramic or ceramic-on-metal friction) appears significant.\(^10\)

\(^{1-10}\) Please see www.ceramtec.de/biolox/mediathek/ceranews-plus/ for references.
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