

CeraNews

Present Future

An interview with Jun-Dong Chang ,
the president of the
12th BIOLOX[®] Symposium

Why did you support the holding of the symposium in Seoul?

Nearly half of the world's population lives in Asia. With its increasing economic power and changing patterns of life, arthroplasty is growing at a phenomenal rate in Asia. Sitting with crossed legs and squatting is more common than in the West, which makes impingement and wear even more significant problems in Asia. When I attended the 11th BioloX symposium in Rome last year, I was very impressed by its specific contents addressing these problems and by its high quality. I proposed having this meeting in Seoul and to my pleasure, CeramTec's CEO Dr. Zimmermann accepted.

What will be the impact of the symposium in your region?

The questions regarding bearing surfaces are among the most important in arthroplasty. Asian researchers are very keen to adopt the latest innovations in terms of technology and quality. I think that the BioloX symposium will stimulate the academic enthusiasm of Asian researchers, and it will help provide scientific confirmation on the use of ceramics.

What was new at this symposium?

With 10 sessions and plenary lectures and with a total of 52 presentations, there were too many new things to list here. Total knee arthroplasty with ceramic components was certainly something new to most Asian surgeons. As far as the hip is concerned, even though larger diameter heads is a widely discussed topic, we learnt quite a few new things about their mechanical and clinical performance.



Jun-Dong Chang, M.D., Ph.D., is Past President of the Korean Hip Society, Past President of the Korean Musculoskeletal Transplantation Society, Professor and Chief of the Department of Orthopaedic Surgery at the Hangang Sacred Heart Hospital, Hallym University College of Medicine in Seoul.

This was very important especially looking at Asian patients who require a great range of motion (ROM) of the hip joint.

Which were the most important take-home messages for the participants?

There is no single perfect bearing surface yet. Among the three available bearing surfaces, ceramic-on-ceramic bearing has the lowest biological activity, but there have been concerns about breakage. The recently developed BioloX delta, with its higher stability, makes larger diameter bearings possible, thus lowering the risk of impingement. It seems that the use of this material will dramatically reduce the incidence of ceramic fracture. Moreover, it will be a good choice for the Asians for whom ROM is very important.

How is arthroplasty developing in South Korea?

The latest available data are from 2005, when a total of 34,966 total knee arthroplasties were performed. From 2001 to 2005 this number grew by 226%. With a rapidly aging population and increasing economic power, we shall certainly see a steady and steep rise in the demand for total knee arthroplasty in the future. The most common cause for total hip arthroplasty in Korea today is osteonecrosis of the femoral head (ONFH), but its incidence doesn't seem to be increasing, due to a change of life patterns. At the same time, with prolonged life expectancy, the incidence of hip fractures related to osteoporosis is rising dramatically. Consequently, arthroplasty is expected to expand fast.

BIOLOX[®] Symposium Seoul

3



Better material

7



World of Ceramics

11



Focus on tribology

Prof. Yong-Sik Kim on the APOA 2007 Congress

What should we know about the APOA?

The APOA has 19 member countries (Australia, Bangladesh, China, Hong Kong, India, Indonesia, Japan, Korea, Malaysia, Myanmar, New Zealand, Pakistan, Philippines, Singapore, Taiwan, Thailand, Vietnam, Turkey and Sri Lanka). The congress is held every three years, and orthopaedic surgeons from young surgeons to experienced veterans meet to share their experiences for improving orthopaedic practices. The APOA also welcomes young ambassadors from each country and traveling fellows. We have sections for the different specialty fields.

What do you think about the fact that the CeramTec Symposium was held on the eve of your congress and in the same city?

A symposium with a long history like that of the CeramTec Symposium being held on the eve of our congress was a good opportunity for APOA participants to get to know the art and science of ceramic articulation in depth.

What was the focus of this year's congress?

The APOA congress has sections for all specialties; however, at the APOA 2007 congress, there were symposiums, special lectures and in-depth discussions especially about articulation in THA. Ceramics was a central focus for the congress. Tribology was the highlight of the hip and knee reconstruction section, which concentrated particularly on the pros and cons of metal-on-metal and ceramic-on-ceramic.

What are the main tribology trends in Asia?

The majority of patients in Asia are young and active since there are more cases of THA resulting from the sequelae of avascular necrosis or dysplastic hip than from primary osteoarthritis. Therefore choosing a joint with minimum wear and the ability to reduce osteolysis is essential; that's why ceramic-on-ceramic and metal-on-metal are far more attractive than polyethylene. For this reason, in Korea more than 60% of people choose ceramic-on-ceramic in THA.

How do you see your organization's prospects?

Our member countries are currently experiencing rapid scientific and clinical im-

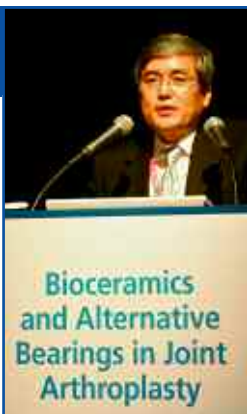


Prof. Yong-Sik Kim, General Secretary of the Asia Pacific Orthopaedic Association (APOA), is a hip specialist at the Department of Orthopaedic Surgery at the Kangnam St. Mary's Hospital of the Catholic University in Korea in Seoul.

provements and swiftly growing economies, which translates into an increased interest in medical care. Most importantly, more than 150 renowned speakers from all over the world and many orthopedic surgeons from developing countries were invited, so the APOA 2007 congress was an outstanding occasion for sharing knowledge and experience.

Where will the 16th congress be held?

The decision has not yet been confirmed; however Taiwan and India are two of the countries suggested for the 16th Triennial Congress of APOA, which will be held in 2010.



Interview (continued)

How is arthroplasty financed in Korea?

The national medical insurance system controls the total expenses related to arthroplasty. In general, patients have to pay about 20% of the arthroplasty surgery itself, and the other expenses are covered by the national medical insurance.

What are the most important trends in arthroplasty in your country and in the wider region of East Asia?

The main points of interest are alternative bearings, minimal invasive surgery and computer-assisted orthopaedic surgery. Many Korean arthroplasty

surgeons are actively accumulating experience in these fields. At the same time, we see two – possibly divergent – developments in medical technology: mass production, low-price implants and procedures versus advanced technology and expensive, patient-specific procedures. Both trends will allow for dynamic changes in the near future. Regional companies are beginning to develop implants and devices for arthroplasty. We are watching the impact of these trends on the regional arthroplasty market with keen interest.



Paul Silberer is Business Manager of CeramTec Medical Products for Italy, the Middle East, Asia and Australia/New Zealand

Dear Reader,

The success of BIOLOX® products in Europe in recent years has proven that innovative, high-quality products can succeed on the market despite widespread cost-cutting measures in the healthcare sector. Our policy of working together closely with the users of BIOLOX® ceramics and with our partners in the medical device industry has helped to offer patients access to an optimized array of treatment alternatives.

After establishing solid bases in Europe and North America, we now turn our attention to the burgeoning markets of Asia where the field of joint replacement is experiencing tremendous rates of growth. Just a few weeks ago, our BIOLOX® Symposium took place in Seoul, South Korea. It was the first time that the Symposium was held in Asia, the largest and most populated region in the world.

The Asian markets present special challenges for the manufacturers of the components used in hip arthroplasty. The traditional sitting positions still common throughout the region require an especially large range of motion in the hip joint. At the same time, bone and joint sizes are significantly smaller than in Europe and North America. Smaller size strictly limits the possible outer diameter of the metal cup.

These anatomical factors and motion patterns mean that especially wear-resistant bearings are required, possibly with large diameters. Indeed, this was one of the main topics at the BIOLOX® Symposium in Seoul. The positive response generated by the event was overwhelming – an outcome largely owing to the outstanding work of the Symposium's president Prof. Jun-Dong Chang, and of all the speakers and chairpersons. With their help, we were able to significantly intensify our dialogue with key partners in Asia. The success of the event marks a move towards improvement in the arthroplastic treatment alternatives available to Asian patients.

Yours sincerely,
Paul Silberer



The Right Position

Bioceramics and Alternative Bearings in Joint Arthroplasty
12th International BIOLOX® Symposium
Seoul, South Korea, 7–8 September 2007

Asia has come to play an increasingly important role in the development of medicine. This was very apparent at the BIOLOX® Symposium in the South Korean capital of Seoul, where numerous Asian experts offered fascinating reports on their work in the field of joint arthroplasty. The level of the professional exchange that took place between surgeons from Asia, Europe, America and Australia was generally very high, and included a number of intensely debated issues. CeraNews reports on some of the highlights of the Symposium's extensive scientific program.

Osteolysis

Offering an overview of various epidemiological issues, **Hartmuth Kiefer** (Bünde, Germany) called attention to the significant differences in the prevalence of arthroplastic treatment. While the annual rate of hip replacements for every 100,000 individuals in South Korea is 0.3, the rate in the United States is 1.4, and 1.5 in Great Britain. The highest annual hip replacement rates are found in Germany at 2.2, and in Austria and Switzerland at 2.1.

Sang-Soo Lee (Gangwon, South Korea) presented new findings on the cellular mechanisms of osteolysis as well as a number of factors that influence these mechanisms. He described the role of ceramic wear particles, in particular with respect to the latest generation of ceramics, as insignificant, indicating that such particles do not trigger adverse reactions owing to their granular size in the nanometer range and their chemical inertness. This contrasts strongly with the behavior associated with polyethylene particles, which are responsible for the large majority of cases involving prosthesis-related osteolysis. **Lucian Solomon** (Adelaide, Australia) recommended the use of quantitative CT scans so as to detect osteolysis at an early stage. While his research indicates that large osteolytic lesions increase in size more rapidly than small lesions, he found no correlation between osteolysis



Sang-Soo Lee
(Gangwon, South Korea)



Christian Hendrich
(Werneck, Germany)

and cup migration. He also suggested that ball head size and patient activity play a significant role in osteolytic development in connection with polyethylene cup liners.

However, in an extensive study carried out by **Christian Hendrich** (Werneck, Germany) and **John Martell** (Chicago, USA), these latter factors were shown to be significantly less important than the articulation material. Using sophisticated methods of tracking, and analyzing ball head movement and mi-

gration, Hendrich and Martell provided convincing evidence that the influence of the articulation material on the types and rates of wear was significantly larger than that of higher activity levels. Given that patients show different reactions to wear particles, no clear threshold has been defined for the triggering of osteolysis. However, Hendrich suggested that a particle volume of less than 1 cubic millimeter per year could be used as a benchmark for establishing a maximum threshold for debris from the articulation material, below which osteolysis is not likely to occur. If one uses a BILOX® ball head instead of a CoCr head in conjunction with regular polyethylene, the linear wear is reduced by 64%. A further reduction of 58% resulting in not more than 0.031 mm linear wear per year can be achieved with the BILOX®/XPE combination.

BILOX®delta Composite Ceramic

Ian Clarke (Loma Linda, USA), a world renowned expert in the field of ceramics, designed and conducted the most difficult in vitro wear test (simulation with severe micro-separation) in order to examine the wear related properties of BILOX®delta. He presented superb results, confirming the excellent wear characteristics and exceptional fracture resistance of the material. His multi-year study compared not only the delta and forte materials, but also tested mixed combinations of the two materials in a 36 mm wear couple. His results clearly confirmed that the BILOX®delta wear couple has the lowest wear of all ceramic combinations available.

His presentation was complemented by **Vicki Corfield** (Swindon, UK) and **Giuseppe Pezzotti** (Kyoto, Japan) who analyzed the samples tested by Clarke and supported his conclusions, expressing their belief that BILOX®delta behaves quite differently from yttria-stabilized zirconia previously used in orthopaedics. In the case of BILOX®delta, the zirconia transformation process enhances the fracture toughness and microcrack resistance of the material as a result of the fact that the zirconia particles are homogenously distributed within a stable alumina matrix. This is not the case in the yttria-stabilized zirconia material. The presence of the alumina matrix controls the behavior of the material and prevents material degradation. In addition, the hydrothermal aging of the material was studied in great detail, in order to be able to prove that there is no material degradation due to thermal aging.

Ceramic/PE

According to the results of the comparative studies presented on this topic, ball heads made of an aluminum-oxide ceramic material perform considerably better than metal or zirconium-oxide ball heads. **Joon-Soon Kang** (Incheon, South Korea) found a very low linear wear rate of 0.032 mm per year in his 4 to 6 year follow-up investigations of ceramic/XPE bearings. **Young-Ho Kim** (Gyunggido, South Korea) compared two groups of 28 young patients who had been treated with either ceramic/XPE or metal-on-metal bearings. During the course of 111 months, 3 patients in the latter group showed unexpected groin pain. One of these



Young-Ho Kim
(Gyunggido, South Korea)

Opening Ceremony with Ceramic Knee

The reconstruction of the Rostock University Orthopedic Clinic was brought to completion this year – the same year that the Clinic celebrated its 100th anniversary. Numerous guests, including Harald Ringstorff, the governor of the German federal state of Mecklenburg-Vorpommern, attended the opening ceremony to mark the completion of the extensive renovation. Receiving ample instructions from the Clinic’s Medical Director, Wolfram Mittelmeier (right), the governor himself used a plastic bone model to perform the implantation of a femoral component of the Multigen Plus Delta Ceramic knee system (manufactured by the Lima-Lto Company) made of BILOX®delta. The artificial knee is currently being implanted in Rostock in the context of a controlled, randomized clinical trial (see p. 7).



BILOX®OPTION – New Brochure

The rate at which revisions are performed in the field of hip arthroplasty continues to increase. In light of the steady growth in the rates of primary-implant surgery and increasing life expectancy, this trend can be expected to grow even stronger. Thanks to the BILOX®OPTION System, physicians and patients now have the option of optimizing the bearings during revision. This includes the use of a ceramic ball head when a stem is to remain in situ. The system and the deployment possibilities it enables are described in detail in our new brochure.

You may request a copy of the brochure here: www.biolox.com/option/en





patients had to undergo hip revision as a result of metal hypersensitivity. Kim drew the following conclusion, "While both bearings are very well-suited to the needs of young patients, ceramic/XPE is safer." He also indicated that one should avoid exposing the ceramic ball heads to the metal transfer that can arise from contact with surgical instruments or from closed reduction after dislocation. In the context of examining explants, **Young-Ho Kim** (Gyunggido, South Korea) found that metal transfer onto the ceramic ball heads can lead to increased polyethylene wear.

Large Diameters

A consensus was reached that larger ball head diameters tend to provide additional protection against subluxation and impingement as a result of the larger range of motion (ROM). A consensus in favor of ceramic-on-ceramic bearings was also reached on the issue of wear particles. The wear rate is extremely low – especially in the case of BIOLOX® *delta*. **Thomas Pandorf** (Plochingen, Germany) reported that ceramics are not subject to any appreciable increase in wear-particle volume resulting from the increase of ball head diameter. Based on the results of his finite-element (FE) analysis, **Paolo Dalla Pria** (Vilanova, Italy) recommended the use of BIOLOX® *delta* for cup liners because its superior mechanical properties help prevent the occurrence of rim chipping. **Karl-Heinz Widmer** (Schaffhausen, Switzerland) pointed out that the safe zone for the implantation of acetabular cups (ideal inclination and anteversion) can be increased with the use of a larger diameter wear couple. However, this increase is not linear, i.e. the gain in ROM becomes smaller with increasing size and is also limited by negative side effects such as bone impingement. In the case of a primary arthroplasty, he sees a reasonable threshold at a head diameter of 44 mm.

Jürg Oehy (Winterthur, Switzerland) called attention to what he regards as significant manufacturer-specific differences in various bearing materials. Highly crosslinked polyethylene (XPE) may exhibit very different mechanical and wear properties depending on the methods used in its production. The differences between the particular alloys used in metal-on-metal bearings can also play a very important role. Laboratory studies have shown that low-carbon alloys release significantly more ions than high-carbon alloys. This conclusion has also been confirmed by recent clinical findings relating to Metasul®.

Knee Arthroplasty

Wear particles and their consequences also play an important role in the area of knee arthroplasty. The search for alternative bearings for our largest joint

was regarded as an urgent matter. As shown by **Myung-Chul Lee** (Seoul, South Korea), the polyethylene liners that are used in combination with femoral components made of ceramic materials exhibit a significantly smoother surface when viewed under an electron microscope. One reason for this is certainly the different forms that surface damage can take. These have been analyzed by **Hi-norobu Oonishi** (Osaka, Japan), the pioneer of ceramic knee arthroplasty, in femoral components. Scratches in the case of metal can lead to increased surface roughness that can cause polyethylene to develop cracks, while scratches are associated only with recesses having little effect on surface roughness in the case of ceramics. Oonishi sees the future of knee arthroplasty in improved ceramic materials and optimized design. According to **Wolfram Mittelmeier** (Rostock, Germany) and **Francesco Benazzo** (Pavia, Italy), this future has already begun. They both participate in the first clinical study of knee components made of BIOLOX® *delta*. On the basis of FE analyses, Wolfram Mittelmeier showed that the material and design of these implants help to avoid pressure spikes and offers high safety.

Rothman's Gaze into the Future

On the evening of the Symposium's first day, **Richard Rothman** (Philadelphia, USA) gave a very lively and highly regarded presentation of wear couple trends in the United States. In light of the fact that today's fifty-year-old patients stand a good chance of reaching their 100th birthday he uses metal/XPE bearings only for very old patients – and this mostly for economic reasons. He regards ceramic/XPE bearings as today's gold standard. For younger and more active patients, he prefers ceramic-on-ceramic bearings, and insists that, for him, metal-on-metal bearings do not even come up for consideration.



Richard Rothman
(Philadelphia, USA)

Ceramic-on-ceramic

A series of clinical studies with ceramic-on-ceramic bearings has generated very mixed and to some extent contradictory data. The South Korean speakers in particular distinguished themselves for frankness during the Symposium when discussing problems of planning and surgical technique. For instance, one South Korean speaker described his discouraging results, namely cup-liner chipping when attempting to correct the position of an already implanted cup with a ceramic liner by striking the edge of the cup with an instrument which resulted in liner chipping.

Chipping as a result of component impingement and subluxation was reported by several Asian speakers to be a complication of greater frequency in Asia than in Europe (e.g. **Kyung-Hoi Koo**, Seoul, **Soo-Ho Lee**, Seoul, **Byong-Woo Min**, Daegu, South Korea). They explain this greater frequency in terms of typically Asian habits and their demand for THA designs with increased range of motion. One additional reason for the higher frequency, as reported in these often very self-critical analyses, was excessive cup anteversion.

Other speakers – including **Shin Yoon Kim** (Daegu, South Korea), **Taek-Rim Yoon** (Chonnam, South Korea) – pointed out that they have thus far seen no fractures of ceramic-on-ceramic bearings in their practice.

However, a consensus was reached on a number of issues in this context. These include the following: ceramic-on-ceramic articulations show either no or extremely low measurable wear; osteolysis only occurs in extremely rare cases; exacting surgical technique is necessary for the success of this type of bearing; all contact with metal instruments should be avoided; any application of excessive, narrowly focused force should be avoided; no bodily tissue, bone chips, bone cement or liquids should be allowed to come between the ceramic components and the stem cone or metal cup; and the cup must be properly positioned so as to rule out impingement.

Joong-Myung Lee (Seoul) presented an interesting new approach in order to avoid impingement between the stem and the edge of the cup. He uses a hip stem whose neck exhibits an eccentric oval cross section. This design has the effect of significantly increasing the range of motion of the prosthesis. This femoral stem used in combination with a ceramic-on-ceramic bearing with as large a diameter as possible correctly positioned, is an excellent solution for Korean patients who often assume squatting or cross-legged positions.

Jonathan Garino (Philadelphia, USA) emphasized that the ceramic-on-ceramic bearing is associated with the lowest revision rates in young patients. He expects a considerable increase in the demand for this combination in the United States as soon as the BIOLOX®*delta* cup liner receives FDA approval.



Jonathan Garino
(Philadelphia, USA)

Metal-on-metal

Peter Bösch (Wiener Neustadt, Austria) was not available to present his findings on the use of low-carbon metal-on-metal bearings in person (see CeramNews 2/2007). He was represented by **Jean-Yves Lazennec** (Paris, France) who later also presented his own findings on the use of a high-carbon alloy. Both talks centered on double-digit revision rates after only 5 to 6 years post-op. The authors attribute these revision rates to significant osteolysis in connection with metal hypersensitivity. Many participants expressed their doubts about this conclusion in what proved to be a very lively discussion. They pointed out that the results of other studies involving metal-on-metal bearings did not indicate such high rates of failure. Lazennec received support from **Gerald Pflüger** (Vienna, Austria) who found a 10% revision rate after 4.1 years in 477 cases involving a low-carbon alloy. He anticipates that the coming years will show a further increase in the revision rate.

Sandwich

Another subject of intense discussion was the sandwich cup in which an additional layer of polyethylene is placed between the metal cup and the ceramic liner. **Kenji Kawate** (Nara, Japan) reported on a "tragedy" involving a Japanese manufacturer's implant of this type. Module dissociation and fracturing of the ceramic cup liner has been found thus far in 463 cases out of a total of 4,000 units implanted (11.8%) between 1998 and 2000. He therefore issued an urgent appeal to refrain from using this type of cup. In contrast, Soo-Ho Lee



Kenji Kawate (Nara, Japan)

expressly recommended its use for revisions. He regards the elasticity of the dampening interim layer of polyethylene as a big advantage. Gerald Pflüger traced the high rate of sandwich cup failure to technical problems that have not yet been mastered by certain manufacturers. He indicated that he has never encountered a problem with this same cup type despite high implant numbers. **Mohammad Azizbaig Mohajjer** (Stolzalpe, Austria) also reported a survival rate of 100% after 10 years.

Access

Taek-Rim Yoon (Jeonnam, South Korea) reported very positive findings with the minimally invasive 2-incision access and large ceramic ball heads. He indicated that this method, given proper patient selection, is "safe and effective". Gerald Pflüger presented a modified uncemented stem for minimally invasive surgery. After more than 1,000 implantations since 2004, he is convinced that this stem offers excellent performance when used with a ceramic-on-ceramic bearing and a minimally invasive surgical technique. His wish, "to be able to implant larger heads in smaller cups", is already a matter of reality thanks to BIOLOX®*delta* components.

Tribute to Heinz Mittelmeier

As a young physician, Heinz Mittelmeier turned his attention to wear particles – of the Judet prosthesis – as early as 1956 and was the first to describe wear disease. Having recognized back then that polymers are not resistant to fatigue, he began to look for alternative materials to use in arthroplasty. He found what he was looking for in high performance ceramics and became the foremost pioneer of this implant material. Mittelmeier was the driving force supporting a whole series of implant developments. CeramTec honored him for his lifework by dedicating the plenary session of the BIOLOX® Symposium in Seoul to him. The eulogy was given by Karl Knahr (Vienna, Austria). Mittelmeier himself gave a well-received lecture on the history of ceramics in hip arthroplasty.

BIOLOX® Award

This year's BIOLOX® Award was also conferred in honor of Heinz Mittelmeier. Based on his work on ceramic bearings in hip arthroplasty, Jeong-Joon Yoo of the Seoul National University Hospital was selected as the recipient of the award on the occasion of the Symposium.



Heinz Mittelmeier, award recipient Jeong-Joon Yoo, CeramTec CEO Ulf-D. Zimmermann, Symposium President Jun-Dong Chang and Karl Billau, Managing Director of CeramTec's Medical Products Division at the award ceremony (from left to right)

The presentations given at the 12th BIOLOX® Symposium are also available as reprints: Jun-Dong Chang, Karl Billau (Ed.), *Bioceramics and Alternative Bearings in Joint Arthroplasty – 12th BIOLOX® Symposium*, Steinkopff Verlag 2007

You may order the volume from CeramTec (see fax form) or access the presentations on the Internet:

www.biolo.com > Medical Professionals > Literature&Brochures > Conference Proceedings

Better material

Gabriele Lualdi,
President of the Lima Group,
talks about the ceramic knee

The new Multigen Plus Delta Ceramic knee, developed by the Italian prosthesis manufacturer Lima-Lto in collaboration with CeramTec, marks an important step into the future of arthroplasty. CeraNews asked the President of the Lima Group, Gabriele Lualdi, about the Multigen Plus concept.

Why did you choose this specific implant?

The Multigen Plus system has been on the market since 1994. We developed a femoral component made of Biolox delta for this system, based on the well-known and tested design of femoral components made of CoCrMo alloy. The main goal was to create a ceramic knee with shapes and dimensions equal to CoCrMo components in order to maintain the acquired clinical experience, to guarantee the application of the same surgical technique and the same instrument set, thus allowing a wide intraoperative choice of materials. Consequently, the Multigen Plus Delta Ceramic knee has been realized preserving the features of the CoCrMo Multigen Plus – multi-radius, bicondylar, symmetric and in the cemented version.

Why do we need a ceramic knee?

Tribological investigations have demonstrated that ceramic femoral components have an excellent performance and better material properties than CoCrMo alloy models. Biolox delta coupled with polyethylene can significantly reduce polyethylene wear when compared to metal. It avoids the potential detrimental effects of wear particles and, unlike metal surfaces, the ceramic material guarantees the absence of scratches due to abrasion. The incidence of allergies to metal ions is constantly growing and not all possible biological effects of metal ion release have already been detected. Ceramics is a very valuable alternative to CoCrMo alloy, especially in the case of young and active patients, and a fundamental solution for patients with allergies.

Why did you choose CeramTec for this project?

Biolox delta was the most adequate ceramic for creating the Multigen Plus Delta Ceramic knee, thanks to its superior material properties and enhanced performance. In fact, this new Alumina composite compensates the mechanical and impact strength limits of Alumina, which has been the only ceramic material used for the manufacturing of prosthesis components for the past years.

How is the clinical trial progressing?

The study is still in the enrolment phase as the nine participating centers in Italy, Germany and Spain are going ahead with the utmost care. Each center is working to recruit patients according to the requirements of the study protocol. The participants of the study are collecting clinical data in the Li.Me.S Clinical Database, a web-based system supported by Lima-Lto. All study investigators and both companies are confident that they will acquire excellent clinical evidence from this study. We expect a significant reduction of polyethylene wear, which is still one of the major causes of failure in total knee replacement.



Gabriele Lualdi

Participants of the clinical implementation trial

Germany

Wolfram Mittelmeier (study group leader), University of Rostock, Dirk Ganzer, Dietrich Bonhoeffer Klinikum Altenreptow, Christoph Lohmann and Wolfgang Rüther, University of Hamburg

Italy

Francesco Benazzo, University of Pavia, Claudio Zorzi, and Vincenzo Madonna, Sacro Cuore Don Calabria, Negrar/Verona, Armando Giunti and Domenico Tigani, Istituti Ortopedici Rizzoli, Bologna

Spain

Eladio Saura Mendoza, University of Elche, Alejandro Lizaur Utrilla, Hospital General de Elda, José Couceiro Follente, University of Santiago de Compostela, Eduardo Garcia Cimbrello and Carlos Rodriguez Merchan, University of Madrid

The femoral component of the Multigen Plus Delta Ceramic knee is made of BIOLOX[®]delta.



Vicious Circle

Severe problems with high-carbon metal-on-metal

Jean-Yves Lazennec is senior surgeon of Orthopaedic Surgery at the Teaching Hospital Pitié Salpêtrière in Paris, in the same department as Yves Catonné. The Pitié team started to implant the second generation metal-on-metal wear couples in 1994. The high-carbon alloy variety with a 28mm head was used until 2005. Then, due to extremely high rates of delayed complications, the Pitié team stopped using this bearing. CeraNews asked him about his experiences.



Jean-Yves Lazennec

What is the basis for your findings? We conducted a prospective follow-up study with two consecutive groups of patients: the first group includes cemented cups and femoral stems, and the second only uncemented implants. We had the opportunity to organize a blood sampling from all of the patients accepting an additional “biological” follow-up: The evolution of Cobalt and Chromium serum levels is available since the beginning of our experience. Matching the clinical and radiological data with those biological results provides interesting information on the evolution of each patient by itself.

How did the metal ion levels develop? The cobalt and chromium levels are high in the run-in period, followed by a decrease. After 4 to 6 years we observed a secondary increase of the ion levels.

Why did you stop using metal-on-metal? We were alerted by unexpected findings during our systematic THA follow-up. Analyzing the very first 97 cases which already had a follow-up of about ten years we observed unusual clinical symptoms and we discovered worrying osteolysis after a “honey moon” of about 5 to 7 years. Of these 97 cases, 12 already had been revised and 30 more cases will have to be revised in the very near future. Those first cases were fully cemented implants. The second, uncemented THA group is now reaching the end of the “honeymoon” time and we are now facing cases with osteolysis.

What is your explanation? First, we noticed an unusual increased rate of subluxation and some strange sensations of hip swelling. This, of course, goes hand in hand with edge loading and increased wear, followed by an increase in ion levels. Patients experiencing a higher release of metal seem to have more liquid in the joint and a higher rate of subluxation. It looks like a vicious circle. We suspect that the osteolysis observed mainly around the cups could be a side effect of the “effective joint space” phenomenon with progression of the hip joint liquid in the bone as well as around the joint, for example along the ilio psoas muscle.

What did you see on the retrieved implants? The retrievals were studied by Ian Clarke and his team. We observed stripe wear that is typically linked to subluxation. On the taper side we did not observe any abnormalities. This seems logical as we did not notice an increase of the titanium levels in those patients

What are the first clinical signs of joint dysfunction in your experience? The problem is that there are no signs or only very faint ones! Precise questioning of the patients is important. Some of the patients experience a swelling of the hip with very slight pain. They can have difficulty to reach full extension due to pain in the ilio psoas muscle. Sometimes, there is a little inflammatory pain anterior to the hip. But they can walk and have normal activity. Some patients describe unusual subluxations during normal activity. Those subluxations may appear after 3 or 4 years post implantation. The pain due to joint hyper pressure is frequently improved or suppressed by the use of anti-inflammatory

medications. Pain caused by excess liquid in the joint can suddenly vanish as the liquid disappears in the cystic lesion of the acetabular bone. On the X-ray some opacity probably caused by the metal ions can be observed. In our preliminary experience, we missed the early development of radiolucent lines and cystic lesions around the cups due to the opacity of this special joint liquid. Punction of the joint may be very efficient for the diagnosis, showing a grey and sterile liquid. With ultrasonography we can detect a very heterogeneous liquid inside the joint. This can be a significant argument to convince the patient for joint punction. Another sign is small calcifications in the soft tissue.

How about the bone? We see very faint radiolucent lines, mostly at the top of the cup. For a safe diagnosis you need a CT scan: then you can see much more worrying osteolysis in the acetabular roof, in the iliac bone and beyond, regardless of diameter of the cup or orientation of the implants. There is much less osteolysis on the femoral side, probably because we revised the patients early. In the revisions, we could mostly leave the femoral stems in place.

What is your revision policy? If there are signs of progressing osteolysis, we have to convince the patients of revision as early as possible in order to avoid further bone loss. In our experience, the stability of the femoral stems was excellent. During the revision we remove a lot of fibrose tissue around the implants to clear all of the osteolytic areas. This means an extensive dissection with potential post-op instability, leading us to use 32mm or 36mm heads. In our very first cases we moved to metal-on-polyethylene wear surfaces, changing the femoral head. We had to re-revise one patient because of a haematoma. To our surprise the polyethylene insert was black, obviously because of remaining metal particles. Therefore, our policy today is to change to alumina-on-alumina using sleeved heads on the femoral stem in situ. This is possible as the tapers are intact. With this bearing change, immediately after surgery, we observe the immediate disappearance of the inflammatory pains and swelling. Until now, we had no failure.

Avoiding Revisions

The need for revisions is certain to increase. Strategies for avoiding, delaying and mastering revisions are discussed by the author in an article that offers an overview of the problems associated with hip revisions based on data available in Scandinavian Arthroplasty Registers and other sources.

The main factor behind the need to replace primary implants is polyethylene wear particles and the partly necrotizing epithelioid cell granuloma they induce. The wear particles from other implant materials can also trigger inflammatory processes and osteolysis. "Ceramic materials, however, exhibit both the greatest biocompatibility and the least osteolytic potential, as investigations and many years of clinical experience have shown."

In contrast, metal particles can trigger excess lymphocyte reactivity. This then leads to granulomatous necrotizing inflammation. Despite the minimal debris associated with metal-on-metal bearings, this development can be observed in the case of both low-carbon and high-carbon alloys. "Occasionally, septic loosening is feigned" in the absence of a bacterial infection, explains the author. For this reason, he recommends "the use of alternative bearings, i.e. on account of possible hypersensitivity" when revising metal-on-metal bearings.

Metal-polyethylene bearings show a rate of wear that is almost twice as high as ceramic-polyethylene bearings. Ceramic-on-ceramic bearings show the best long-term results when it comes to debris. Large-diameter wear couples minimize the risk of impingement, subluxation and luxation. Owing to their wear resistance, ceramic-on-ceramic bearings allow the use of ball heads with diameters of more than 28 mm without increasing the risk of debris.

Kuschnig M, Herausforderung Hüftendoprothesenwechsel, in: ORTHODOC, 3, 2007: 17-20

More Re-revisions after Liner-only Exchange

It has been common practice until now to replace only the polyethylene liner when performing revisions involving a firmly fixed cup. The authors compared three groups of patients who underwent hip revision between 1987 and 2005 (Norwegian Arthroplasty Register). In Group 1, only the polyethylene liner was replaced. In Group 2, the firmly seated cup was also replaced. In Group 3, loose implants were revised. Compared to the other groups, the need for subsequent revision was almost twice as high for the patients who underwent the simpler surgical procedure (Group 1), on account of instability (dislocation), pain and loosening. The most important reasons for the re-revision included dislocation and pain. The authors recommend: "Our results suggest that the threshold for revising well-fixed components in the case of liner wear and osteolysis should be lowered."

Lie S A, Hallan G, Furnes O, Havelin L I, Engesæter L B, Isolated acetabular liner exchange compared with complete acetabular component revision in revision of primary uncemented acetabular components – A study of 1649 revisions from the Norwegian Arthroplasty Register, J Bone Joint Surg [Br] 2007;89-B:591-4.

Excellent Results with Ceramic-on-Ceramic

The authors examined 310 hips during this multicenter study performed in Spain. With an average follow-up period lasting 4.7 years, it proved necessary to revise 4 hip replacements: 2 on account of dislocation associated with deficient surgical methods, 1 on account of trauma, and 1 on account of a fracture in the ceramic liner owing to a horizontal acetabular angle (35°). The radi-

ographic difference between the centers of the femoral head and the cup showed no change in the course of the study. The penetration of the femoral heads into the cups remained below the threshold of detection. The authors' conclusion: "These data demonstrate that Alumina-on-Alumina prostheses show excellent results after 5 years."

Garcia-Cimbrelo E, Murcia-Mazon A, Blanco-Pozo A, Marti E, Alumina-on-alumina total hip arthroplasty, A multicenter prospective study, Presentation EFORT Congress 2007

Material for Young Patients

The general success of arthroplastic treatment has permitted to expand the indications to younger patients. Higher life expectancy has led to more exacting applications, not only with respect to the implants themselves, but also to the appropriate indication and surgical planning. In assessing this development, the authors attribute a special significance to ceramic materials. "The degree of particle-related wear can be minimized with modern ceramics." Increases in the incidence of allergic reactions and hypersensitivity to arthroplastic components are to be limited preoperatively by taking them into account during the surgical planning stage. "Here, too, ceramic components offer advantages over metal components." The artificial joint's range of motion plays a decisive role – particularly in the case of younger patients – both in terms of quality of life and the avoidance of impingement and early loosening.

Kircher J, Bergschmidt P, Bader R, Kluess D, Besser-Mahuzir E, Leder A, Mittelmeier W, Die Bedeutung der Gleitpaarung beim jüngeren Endoprothesenpatienten, Orthopäde 2007 36:337-346

Open Access to Clinical Feedback Data

Since the 1st BIOLOX® Symposium in 1996, it has been CeramTec policy to publish pertinent data received from the users on clinical complications such as fracture rates, intraoperative chipping and others involving BIOLOX® components¹. This policy assures the orthopaedic surgeon that he will have timely clinical feedback, as required in Evidence Based Medicine.

In the upcoming editions of CeraNews we shall provide concise reports on complication rates in hip replacement.

1. Bioceramics and Alternative Bearings in Joint Arthroplasty, BIOLOX® Symposium Proceedings 1996-2007. Jonathan Garino, Mohamed N. Rahaman, B. Sonny Bal, The Reliability of Modern Alumina Bearings in Total Hip Arthroplasty, Seminars in Arthroplasty, 17:113-119, 2006

Ceramic Upgrade

CeramTec Satellite Symposium in Florence

Europe's orthopaedists met in Florence, Italy, on May 11–15 to attend the 8th EFORT Congress, presided by Wolfhart Puhl (Oberstdorf, Germany). An attendance of more than 8000 participants together with the scientific program featuring 945 presentations and 22 instruction courses made it the largest meeting to date. One of the 38 industry symposia was sponsored by CeramTec. It dealt with the "Influence of material in total hip and knee replacement". The speakers presented interesting new data and findings on the subject. Chairman Renato Laforgia wrote this brief report for CeraNews.

Francesco Benazzo (Pavia, Italy) presented his first experiences with a cemented BIOLOX[®]delta ceramic femoral knee component designed by Lima-Lto to articulate with a fixed platform polyethylene component. The system is designed to reduce wear and to prevent allergic reactions in patients with metal sensitivity. Benazzo emphasized the lengthy process of design verification, testing and safety evaluations. As clinical use has started only recently, it is too early to report results. (see also p. 7)

There is a growing demand for implants with larger diameter wear couples providing a greater range of motion. Thomas Pandorf (Plochingen, Germany) presented the results of various tests performed in different institutions throughout the world demonstrating the excellent mechanical properties of large size BIOLOX[®]delta ball heads (36mm diameter) when compared to similar sized BIOLOX[®]forte ball heads and smaller BIOLOX[®]delta diameter heads. In addition, he presented the results of a severe micro-separation simulator test. This is one of the most severe wear tests carried out to date. The results showed BIOLOX[®]delta performing better than any other wear couple used in orthopedic surgery.

Thomas Pandorf, Renato Laforgia, Jean-Yves Lazennec, Wolfram Mittelmeier and Francesco Benazzo (from left)



Wolfram Mittelmeier (Rostock, Germany) emphasized that revision surgery offers the surgeon an opportunity to analyze and improve or upgrade implant quality. With the introduction of the BIOLOX[®]OPTION system, the surgeon now has the possibility to address issues of wear couple type, range of motion and stability. Most importantly, with this system he can optimize the longevity of the new construct. He highlighted the fact that with the new BIOLOX[®]delta ceramics, a larger wear couple can be chosen for smaller acetabular components due to the thinner inserts, made possible by the improved material properties.

Jean-Yves Lazennec (Paris, France) pointed out the growing number of problems emerging from the clinical use of metal-on-metal articulations. He recalled having been convinced that this wear couple was an ideal solution. He even implanted one in his father. But after 5–6 years post-op, he began to notice osteolytic lesions, an elevated level of metal ions and localized macrophage formation due to metallic particles around the acetabular external bone. These reactions however did not result in the loosening of components initially. The retrieved titanium stems did not show any wear on the neck or on the cobalt chrome head contact areas. Cemented implants performed worse than uncemented implants in his series. CT scans clearly confirmed the suspected osteolytic lesions. As a result of his findings, Lazennec has stopped further use of any metal-on-metal articulation systems. (see also p. 9)

Renato Laforgia

Full Speed Ahead

Ceramic Seal Rings in Ocean Liners and Small Pumps

At 345.03 meters, the Queen Mary 2 is the longest passenger ship in the world. It displaces around 76,000 tons of water and cruises at nearly 30 knots (or 56 kilometers per hour) across the Atlantic. Four gondola propulsion units sporting a total of 157,000 horsepower propel this ocean giant to its top speed, which is exceedingly fast for a large ship. Four gigantic propellers apply this engine power to the water while turning up to 140,000 times per day.



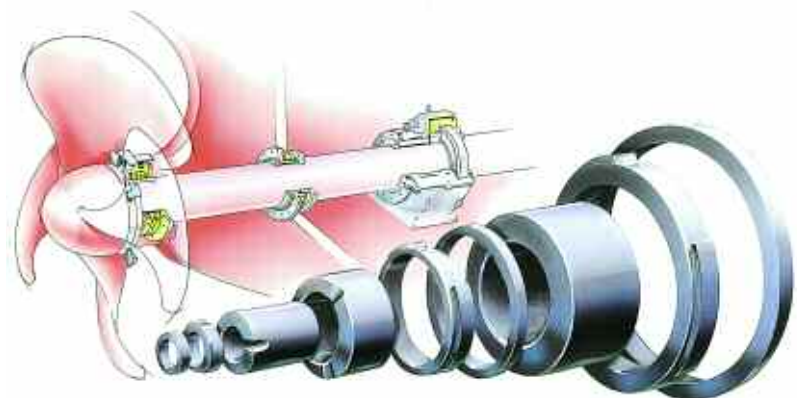
Naturally, the propellers are to perform this feat as smoothly as possible. At the same time, the engines whose power is transferred to the propellers by the shafts must be protected from the seawater while no motor oil is to be allowed to escape into the ocean. Sliding bearings with ceramic sliding ring

seals manufactured by CeramTec provide both the nearly frictionless drive and the secure seal between the ocean and the engines.

The decisive components in the sliding bearing are two interacting sliding rings. One of the two rings has a fixed position in the housing. The other is attached to the rotating shaft. The rings are required to meet extremely demanding specifications: minimal friction, maximum seal, and extremely long service life. These specifications can best be met using high-performance ceramics. In the case of the propeller shafts for ships of the QM 2 class, the material is certainly provided by CeramTec: no other manufacturer produces rings in diameters of up to



The propeller shafts on the Queen Mary 2 run on ceramic seal rings manufactured by CeramTec.



Sliding bearing (yellow) as used in shipbuilding

1,005 millimeters. Depending on their specific design, the rings can withstand pressure of up to 200 bars, temperatures of -200 to $+450$ °C and sliding speeds of up to 150 m/s.

Similar rings are also deployed in large pumps of the sort found in chemical plants, refineries, centrifuges, water turbines, and oil and gas extraction facilities. But ceramic sliding ring seals also guarantee lasting and secure operation in smaller applications, including, for instance, gasoline and cooling water pumps in automobiles and pumps in dishwashing machines. And should something happen to fail here, it is not likely to be the seal rings – their service life usually exceeds that of the appliances housing them many times over.



Cooling water pump with ceramic seal rings

Between the Alps and Sicily

Spreading ceramics know-how in Italy



Fabrizio Macchi

Italy has seen a huge increase in the use of ceramic components for arthroplasty in the recent past. Besides the superior properties of the BIOLOX® products this is due to Fabrizio Macchi's work of talking and teaching about ceramics, day by day, from the Alps to Sicily.

When he began working for CeramTec in the year 2000 he started out on an almost empty field. Not many surgeons in Italy knew the company, and the use of ceramic components was quite limited. Since then, the situation has changed significantly. "Today, surgeons and implant company representatives have a much better understanding of the use of BIOLOX® technology as well as ceramics in arthroplasty in general", the Rome-based CeramTec representative is convinced.

Fabrizio Macchi teaches and trains the implant company representatives in his country who have BIOLOX® products in their portfolio. He regularly holds presentations and lessons about ceramics at a number of Universities, as for example in the Istituto Ortopedico Rizzoli, the Scientific University of Chemistry in Turin or at the Brindisi University, as well as at the important orthopaedic congresses.

Probably even more frequently, he is giving training courses and hands-on workshops for surgeons and nurses. There, he provides background knowledge about ceramic materials, their clinical results and demonstrates the proper handling of ceramic components in the OR. "Of course, we have lots of very good information available in print and online", Fabrizio Macchi says, "but the personal contact with the surgeons, clinical personnel and our industry customers is still the best way to communicate the important details and share practical experience."

Upcoming Events

- **October 5–6, 2007**
GESTO-GRECO 2007
Marseille, France
- **October 24–27, 2007**
German Congress of Orthopaedics and Traumatology
Booth CeramTec: 15-1/12
Berlin, Germany
- **November 2–4, 2007**
AAHKS 17th Annual Meeting
Dallas, USA
- **November 5–8, 2007**
82nd Annual Meeting SOFCOT
Stand CeramTec: N5
Paris, France
- **November 8–11, 2007**
Chinese Orthopedic Association
Zhengzhou, China
- **November 9–10, 2007**
9th Update Orthopaedics and Traumatology
Neuss, Germany
- **November 11–15, 2007**
92nd S.I.O.T.
Booth CeramTec: 18
Bologna, Italy
- **December 12–15, 2007**
Current Concepts in Joint Replacement
Orlando, USA
- **January 28–31, 2008**
Arab Health
Dubai, UAE
- **March 5–9, 2008**
AAOS
San Francisco, USA
- **March 17–21, 2008**
Journées d'orthopédie de Fort de France
Martinique, France

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