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Ceramics in Orthopaedics

Rashid M. Tikhilov, MD, PhD

Javad Parvizi, MD, PhD, is Vice Chairman of Research and Director of Joint Research at the Rothman Institute in Philadelphia, USA.

Dear Colleagues,

Along with the increased use of surgical procedures in TJR whose benefits are widely recognized, comes the reality that severe complications can affect our patients. They are creating a tremendous burden on our patients as well as the healthcare system. Their treatment must be effective and able to fully resolve the complication. It is our responsibility to work together and to develop a well-structured methodology for transferring established know-how and promising innovations to healthcare professionals worldwide. The participation of Prof. Tikhilov in a recent consensus meeting on the treatment of infection in Philadelphia was an excellent example for such cooperation.

We also need the help of colleagues from other fields. The allergologist Prof. Thomas developed an approach for the assessment of implant-tissue interaction. The pathologist Prof. Krenn gives us a practical guide to classify potential failure mechanisms in TJR focusing on peculiar tissue reaction patterns and the potential role of particles. His particle algorithm adds a valuable tool to help understand and interpret implant and tissue interaction.

We also have to face the challenges presented by the clinical challenge of implant loosening, the management of overweight patients, infection and by metal ion generation in modular connections. Recent research such as the one conducted at Drexel University, Philadelphia, presents us with compelling argument to consider using ceramic components in order to minimize metal ion release from these interfaces.

As we gain further understanding of such issues by ongoing interdisciplinary research, it is imperative that we work in unison and that our scientific information and knowledge be transferred effectively. It has to be directed at helping surgeons around the world to utilize improved methods to address complications and improve the quality of care when faced with TJR complications.

Javad Parvizi, MD, PhD

The 3-Pillar Concept of the Vreden Institute

An Interview with Rashid Tikhilov, MD, PhD

Rashid Tikhilov is the Managing Director of the Association of Orthopaedists and Traumatologists of the Russian Federation. CeraNews spoke with him about arthroplasty in his country, cooperation with other national orthopaedic societies, as well as "Vreden's Readings", a prestigious orthopaedic conference that his institute has hosted each year since 2008.

Prof. Tikhilov, what does it mean to you to work in the tradition of Roman Romanovich Vreden, whose name your institute bears?

Indeed, we are backed up by a solid tradition from which patients, research and teaching all benefit. R. R. Vreden was nominated as the first director of the Institute in 1906. I must add, however, that the idea of founding the institute did not come from him. The conditions for the construction of the facility had already been created in 1901 when the former court physician of Tsarina Alexandra Feodorovna, Karl Christian Horn (1851–1905), was ordered by her to set up a model modern orthopaedic facility. The building was constructed between 1902 and 1906. Horn died in 1905, shortly before the completion of the forward-looking project. R. R. Vreden, who enjoyed an excellent reputation as a military physician and scientist, was subsequently delegated to head the facility. He placed the focus on the development of surgical methods to treat orthopaedic deformations. This had a critical influence on the conceptual development of the institute. At the start of the 20th century, the Vreden Institute was the first facility in Russia to carry out a wide range of orthopaedic surgeries and is still one of the most modern clinics of its type in the world.

Which challenges does the Vreden Institute face today in orthopaedics, particularly in arthroplasty?

Today, we consider it equally our task and a challenge to maintain the Vreden tradition across various areas in orthopaedics. We evaluate the results of our activities in order to further increase our already high standards in arthroplastic surgical techniques and to ensure high quality results. We consider the primary task of our institute to evalu-

Rashid Tikhilov, MD, PhD is the Managing Director of the Association of Orthopaedists and Traumatologists of the Russian Federation as well as an honorary member of several national professional associations for orthopaedics and trauma surgery. In 1988 he was appointed head of the Department for Orthopaedics and Trauma Surgery in the tradition-steeped S. M. Kirov Clinic of the Military Medical Academy in St. Petersburg. He continues his teaching and research activities there.

Since 2003 Tikhilov has been the Director of the R. R. Vreden Research Institute for Traumatology and Orthopaedics in St. Petersburg. In this role he is responsible for the medical, scientific and economic development of the institute.

Tikhilov has specialized in hip and knee joint surgery and carries out about 500 operations each year. His scientific activities mainly focus on basic research and epidemiological studies in the area of joint pathology, arthroplasty and reconstructive joint surgery.

He is the chief editor of the journal published by the Vreden Institute "Orthopaedics and Trauma Surgery in Russia" and is a member of the editorial board of other Russian journals.

Since 2008 the Vreden's Readings meetings have taken place under his direction. They encourage the exchange of scientific and practical experience and enjoy a high standing among orthopaedic specialists in Russia and abroad. As one of the leading orthopaedic specialists in Russia, Tikhilov is an expert contact person for the Ministry of Health.

Contact:
R. R. Vreden Russian Research Institute
of Traumatology and Orthopaedics
Acad. Baikov Str. 8
195427 St. Petersburg, Russia
Phone: +7 812 670 8687
Fax: +7 812 670 8905
e-mail: info@rniito.org

Website "Vreden's Readings":
www.vredenreadings.org

The R. R. Vreden Research Institute for Traumatology and Orthopaedics in St. Petersburg

ate surgical methods and orthopaedic implants that have been developed by us, by our colleagues and industry across the world.
With this goal in mind, we initiate clinical trials to determine the short-term and long-term results of various treatment methods for trauma and diseases of the musculoskeletal system. We not only carry out total joint reconstructions in our institute, but keeping up with our established tradition, our specialists also master the art of complex joint preserving surgery.
Our particular focus is on the continuous education and professional development for specialists without whom the high quality of results cannot be achieved. The rapid development of arthroplasty in Russia, which is growing annually by 15–20% on average and in some regions by as much as 40–50%, must be accompanied by keeping a high standard of education for all involved experts. It is therefore our explicit goal to familiarize our colleagues with both the relevant benchmarks of training in our institute and with the experience of our colleagues in the European countries.

What has been achieved to date?

The most modern methods in trauma surgery and for the treatment of diseases of the musculoskeletal system are currently applied in our institute. We closely follow the development of methods from which the best results can be achieved for patients and then introduce them to our facility.
As mentioned previously, the systematic professional development and training of orthopaedic surgeons play an important role in our activities. More than 400 surgeons from all parts of Russia and abroad are given the opportunity every year to complete professional development by taking part in courses or in customized programs. Depending on the task, the surgeons can complete a training program in periods of several days to up to 8 weeks in our institute. We are convinced that without theoretical and practical instruction, without systematic training and an intense exchange of experience, the quality of results suffers. The range of services offered by our institute includes hip and knee arthroplasty and revision arthroplasty. Our surgeons carry out replacement surgery as well as complex primary surgery. Revision cases are referred

to us from all parts of the country. As a result of the increase in the number of primary procedures across the country, the number of revisions is also increasing and already makes up more than 18% of all surgery carried out in our institute.

How is the scientific exchange and the cooperation with international orthopaedic societes structured?

Cooperation with our colleagues is still not that easy for us in a number of respects. On one hand, there is the language barrier and on the other hand, for historical reasons we were not able to integrate ourselves into the system of extensive cooperation between the national societies which had grown over decades. Nevertheless, we are already enjoying the first fruits of a successful international cooperation. As part of the follow-up of an implant, we are involved in a longitudinal multicenter study run by leading arthroplasty manufacturers. The exchange of experience at international conferences has also become a fixed part of our work. During these exchanges we have noted that the surgical procedures we have carried out have been met with enormous resonance among experts from abroad. We encourage active cooperation with international orthopaedic societies, such as EFORT and SICOT. We now welcome many foreign surgeons as consultants and instructors to our events. There is an increasingly closer liaison between colleagues at a national level. This is also encouraged by the fact that already more than half of the Russian orthopaedic specialists are members of the new orthopaedic society founded in 2010.

How has arthroplasty developed in Russia and what do you expect from the future?

Thanks to a special government program targeting improvements in patient care using high-tech medicine, arthroplasty in Russia has undergone an extremely dynamic development over the last 6 to 8 years. The facts speak for themselves. For example, several large orthopaedic centers have been built to the highest standards, while existing clinics have been modernized and equipped with the latest technology. This has allowed a large increase in the number of operations. The costs for surgical treatment of patients are borne by the state.
In 2012 more than 60,000 endoprostheses were implanted in Russia. In the Vreden Institute in the same year about 23,000 patients were treated and of these, 20,000 were treated surgically. We have carried out arthroplasty procedures on hip and knee joints in more than 5,000 patients. Increasing numbers of patients with highly complex pathologies are also coming to us. The Vreden three-part philosophy – education, therapy, analysis of results – continues to form the basis for the qualification of physicians.

Which role do other large centers in orthopaedic care play in Russia?

The large orthopaedic centers have embraced not only a special therapeutic but also a methodological role. Renowned orthopaedic institutes such as CITO in Moscow, the National Surgical Center N.I. Pirogov, also in the capital, the institutes in Saratov and Nizhny Novgorod, the Ural Institute in Yekaterinburg, the Novosibirsk Institute for Trauma Surgery and Orthopaedics and the Ilizarov Institute in Kurgan work at an advanced specialist level across the country. Each center has specialized without, however, neglecting the care of the population with a wide range of trauma surgery and orthopaedic treatments. The Central Institute for Trauma Surgery (CITO) has traditionally been very strong in arthroscopy and in the treatment of osseous pathologies. The Nizhny Novgorod Institute has long focused on hand surgery while the Novosibirsk Institute has accumulated extensive experience in spinal surgery. Although the Ilizarov Center still concentrates on the further development of the Ilizarov method, it has increasingly focused its attention on reconstruc-

Arthroplasty in Russia

According to information from the health authorities in Russia, about 2.2% of the approximately 143 million citizens suffer from osteoarthritis. The number of arthroplasty procedures is estimated at 100,000 annually with about 60,000 hip and knee arthroplasties implanted in 2012. Young and active patients are increasingly treated with ceramic/XPE and ceramic/ceramic bearing couples. The metal-on-metal bearing couple has hardly been used. The care of patients is done mostly in large orthopaedic centers, which increasingly take on the rehabilitation of patients as well.

The Vreden Institute

The R. R. Vreden Institute for Traumatology and Orthopaedics is a modern orthopaedic center that is directly managed by the Russian Ministry of Health. Founded in 1906, the medical expertise of the Vreden Institute is based on a rich tradition. With 22 specialist departments and 830 beds, it is one of the largest orthopaedic centers in Russia. Of 23,000 patients in 2012, almost 20,000 were treated surgically with about 5,000 hip and knee endoprostheses implanted. More than 400 physicians from Russia and abroad participate in educational training programs in the Vreden Institute each year. Connecting research, teaching and health care at the highest level is the trademark of the Vreden Institute.

tive spinal and joint surgery as well as arthroplasty. While all the major sub-specialties are represented in the Vreden Institute, we are particularly experienced in the area of complex reconstructive surgery of large joints. The newly built centers in Cheboksary, Barnaul and Smolensk are also pursuing a similar development. In each of these centers several thousand procedures are carried out each year.

Prof. Tikhilov, how are patients admitted in one of the large centers?

After the diagnosis has been made by a specialist and a positive decision has been taken by the local medical selection committee, the documents are sent to the regional health authority. The health authority then sends the documents to a relevant orthopaedic center. The treatment plan is prepared in the center. The procedure is then done relatively soon. In most regions of Russia there are no long waiting periods. Because of the large proportion of older patients, the situation is a little different in the metropolis of St. Petersburg, with its million-strong population. Only about one third of the patients come to our institute from St. Petersburg.

Which trends are there in tribology in Russia?

Fortunately, in Russia we have not followed every fashionable trend. The problems that have developed in recent years with metal-on-metal bearing couples have therefore played a rather minor role for us. As far as bearing couples with ceramics are concerned, evaluation of the literature shows that outstanding results can be achieved when combined with XPE as well as with ceramics. For this reason we use ceramics particularly for young, active patients. I am assuming that the proportion of ceramics used in the care of patients will increase with rising case numbers but only if the costs for ceramic implants can be borne by the hospitals. We will also track and evaluate these results long term. There is nothing as valuable as one's own clinical experience.

Most European countries, Australia and Canada maintain a joint registry and in China it will become obligatory for all qualified clinics over the course of this year. How do you assess the situation in Russia?

We are also convinced of the importance of a joint registry. Reliable data collected over the long term make a significant contribution in terms of the quality of results and patient safety. In our institute there has already been a functional registry for 7 years. Currently the large centers in Cheboksary and Barnaul link to our registry. Of course, such a registry is effective only when 90–95% of all arthroplasty procedures in the country are recorded. Unfortunately, there are still some prerequisites that are not being met. On one hand, digital documentation is still not used in some centers, and on the other, such a registry cannot be comprehensively implemented without overarching federal administrative regulations. The additional time required also plays a role, time that is not compensated financially. A national registry requires cooperation between the professional orthopaedic society and the Ministry of Health in order to be fully realized.

What can the participants at this year's annual Vreden conference in St. Petersburg expect?

I am looking forward to an interesting conference with inspiring papers and lively discussions. For the first time, we are placing the emphasis on the systematic transfer of knowledge. More than 20 experts from across the whole world, including the U.S., Canada and Europe, will discuss various aspects of hip and knee arthroplasty with their colleagues from Russia. On the first day of the conference the participants will be able to familiarize themselves in workshops with the latest arthroplasty systems from various companies under the guidance of experienced instructors. On the following 2 days all the participants will be able to discuss the latest scientific issues and economic questions regarding orthopaedic care. The papers and contributions to the discussions will be interpreted synchronously into English or Russian and we are pleased that participants from abroad have registered. We would like to increase the proportion of participants from abroad significantly for future conferences. Of course, an important prerequisite for this is the integration of the Vreden's Readings meeting into the existing European system of conferences and congresses mentioned previously, as well as the accreditation as an educational event. I believe that in the future it will be an attractive option for European physicians to combine attendance at our Vreden's Readings meeting with a visit to our beautiful city of St. Petersburg.

Prof. Tikhilov, thank you very much for an interesting conversation.

The interview was conducted by Volker Atzrodt, PhD (Scientific Consultant, CeramTec GmbH).

Periprosthetic Tissue Responses with Bearing Couples and Corrosion/Fretting with Modular Metal Taper Connections

The issue of corrosion and fretting in modular metal taper connections as well as the etiology and histopathology of adverse reactions to metal debris (ARMD) play an increasingly important role and were recently the subject of lively debates at international congresses. There was consensus that a better understanding of the pathogenetic mechanisms is necessary to be able to better classify adverse reactions to implant materials and also to improve the currently inconsistent terminology. In the literature various terms are used to describe the range of histopathological changes that are observed in connection with implant materials. CeraNews summarizes the latest results.

Study:

Pathogenesis of pseudotumor formation

It is not yet clear whether pseudotumors develop because of particle-induced cytotoxicity, hypersensitivity (type IV) or a combination of both. The body of data is inconsistent.

The aim of a retrospective study by Grammatopoulos et al. (UK) was to investigate the histopathological changes in periprosthetic tissue from 56 failed hip resurfacing implants in connection with the metal wear. At the time of the primary procedure the mean age of the patients was 56 years. The mean survival time of the endoprostheses was 4.7 years.

It was predominantly women who had to have revision surgery. Symptomatic pseudotumors (n=45) were the most common cause for the revisions. In 80% of the pseudotumors with tissue necroses and pronounced macrophage responses, high wear values were determined. This suggests a direct nonspecific cytotoxic action of the metal ions that depends on their concentration. Perivascular lymphocytic infiltrates (ALVAL) as an individual, specific immune response were more common in the cases with low wear and they appear to favor the formation of pseudotumors.

The authors concluded that although the formation of pseudotumors may be reduced by minimization of metal wear, even under optimal conditions unwanted pseudotumors may develop due to an increased individual immune response.

Study:

Pseudotumor formation due to cytotoxic response to metal wear

Hasegawa et al. (Japan) investigated 108 MoM THA with large head diameter (Ø 44mm) in 98 patients (81 female, 17 male) with a mean age of 65 years.

MRI showed pseudotumors in 9 patients (10 hips, 9%). Revision surgery was performed in 5 symptomatic cases and in 2 cases of cup loosening with perivascular lymphocytic infiltrates and diffuse lymphocyte distribution (ALVAL). The metal ion concentration in 12 patients with pseudotumors or ALVAL (12 hips) was compared to those patients with no adverse reactions (96 hips). It was demonstrated that adverse reactions correlated with increased metal wear.

The authors concluded that hypersensitivity (type IV) is probably not the dominant biological response in pseudotumor formation but rather the cytotoxic response to metal wear is likely to play a primary role.

Study:

Different failure mechanisms with ARMD

Reito et al. (Finland) investigated 90 patients (90 hips) who underwent revision surgery due to ARMD and whose complete clinical data were available. The researchers carried out a semi-quantitative analysis of the histological samples (synovia, pseudotumor) including determining the fibrin content of the synovial fluid and the number of macrophages and perivascular lymphocytes.

The Finnish researchers discovered that pseudotumors can be traced back to a lymphocyte-dominant immune response while intracapsular responses are macrophage-dominant foreign body reactions, which are reflected in different MRI images. The inflammatory response appears to be either macrophage-dominant, lymphocyte-dominant or both.

Study:

Different lymphocyte responses to metal wear

Matharu et al. (UK) pointed out that the term ALVAL is used in the literature to encompass different lymphocyte responses in failed MoM implants.

Therefore, it was the aim of their histological investigations to develop a uniform classification to characterize these lymphocyte responses. For this purpose, they analyzed 71 MoM hip revisions with suspected ARMD that were carried out between 1998 and 2011.

In all cases macrophage infiltration with intracellular metal wear particles was verified. Lymphocytes were present in 69% of the cases (n=49) and were characterized as lymphocytic aggregates (37%, n=26) as well as diffuse lymphocytic infiltrates with perivascular lymphocytes (15%, n=11) and without perivascular lymphocytes (17%, n=12). In the cases with lymphocytic aggregates, perivascular and diffusely distributed lymphocytes were present. In 31% of the cases (n=22) phagocytosis but no lymphocytic infiltrates were verified. In 2 patients with a known metal allergy, a diffuse lymphocytic immune response without formation of lymphocytic aggregates was identified.

In the majority of the revised MoM cases, different lymphocytic cellular responses were verified, which represent the various pathological courses. A correlation between the histopathological results and the clinical findings, such as contact allergy, could not be found.

The authors called for further investigations to characterize lymphocytic responses in connection with metal wear to better understand the pathogenetic mechanism.

Study:

Women are at higher risk of ARMD

Using a large series of MoM THA it has been demonstrated for the first time that women have a higher risk of developing adverse reactions to metal wear (for example, pseudotumors, necroses, cysts, metallosis) regardless of cup positioning or the femoral ball head size.

In a prospective study Briant-Evans et al. (UK) investigated 1,159 primary MoM THA (38mm) in 1,041 patients (703 female, 446 male) with a mean age of 67 years. The mean follow-up was 5.4 (2–8.6) years. 17 patients were not available for the follow-up examination. 53 patients were revised due to ARMD after a mean 4.3 years, and a further 8 revisions are planned. The incidence of ARMD was 5.8% overall with the rate twice as high in female as in male patients (7.9% vs. 3.1%; p=0.002). No statistically significant correlation between ARMD and the external cup diameter or the positioning of the cup was determined. An increased risk between low patient age and revision due to ARMD (p=0.005) was determined, which can be ascribed to the possibly higher levels of activity and increased wear.

The authors called for further investigations of the pathogenesis of ARMD, particularly in light of the higher rate of complications in women.

Study:

Periprosthetic tissue responses with MoM and MoP

Hwang et al. (South Korea) carried out a retrospective analysis of the extent, characteristics and causes of soft tissue masses with MoM and MoP THA. Of the patients who received THA between 2000 and 2007, 5 patients with MoM THA and 5 patients with MoP THA were followed up.

The enormous mean extent of the soft tissue masses was 14.6cm x 6.2cm x 7.2cm. Osteolysis was detected in 3 cases each with MoM and MoP. In all cases acute or chronic signs of inflammation and granulomatous tissue changes were observed. Lymphocytes and eosinophilic granulocytes were present in the MoM group and macrophages in the MoP group. The mean concentration of cobalt and chromium ions was 1.43g/L and 1.57g/L in the MoM group and 0.73g/L and 0.84g/L in the MoP group.

The authors concluded that osteolysis and soft tissue masses after THA are accompanied by foreign-tissue responses to PE wear particles and a hypersensitive response to metals.

Study:

Higher survival rates for CoC vs. MoM

Barbosa et al. (Portugal) compared the results of 22 MoM large head arthroplasties in 20 patients, (14 male, 8 female) which were implanted between 2007 and 2009, with 37 CoC THA in 32 patients (23 male, 14 female) implanted between 2002 and 2007.

In the MoM group there were more complications than in the CoC group, which corresponded to the lower survival rate of 77% for the MoM group. In the MoM group there were infections in 3 cases as well as 1 case each of pseudotumor and acetabular osteolysis. In the CoC group a femoral ball head fractured in one patient and noise developed in 2 cases. The HHS was lower in the MoM group (88) than in the CoC group (91). In the CoC group 95.2% of the patients were satisfied or very satisfied with the result, whereas only 82% of the patients in the MoM group reported the same. Osteolysis was not detected in any patients in the CoC group.

The authors concluded that the absence of osteolysis appears to be a good predictor for the long-term behavior of the CoC bearing couple. The excellent biological behavior of ceramic particles is reflected in the lower risk of osteolysis.

Study:

Ceramic femoral ball heads appear to reduce taper corrosion

Baleani et al. (Italy) investigated 83 hard-on-hard bearing couples for signs of corrosion. These included 46 MoM bearing couples with head diameters of 28–54mm and 37 CoC bearing couples with head diameters of 28–40mm. In 19 MoM cases and 4 CoC cases the femoral ball head had a titanium sleeve. Both groups were comparable in terms of the time since implantation (MoM 4.8 years, CoC 4.6 years). Of 83 stem tapers, 58% showed corrosion damage: 25% mild, 13% moderate and 4% more severe damage. None of the stem tapers showed extreme corrosion damage.

It was established that the level of damage due to corrosion increased over time. Likewise, the material and the diameter of the femoral ball head play a role in taper corrosion. The authors emphasized that ceramic femoral ball heads appear to reduce taper corrosion.

> **“Additionally the ceramic head seems to reduce the damage rate on the taper surface.”**
>
> – Baleani et al.,
> Proceedings, AAOS 2013:484

The paper “Update to taper corrosion: what role do ceramic femoral ball heads play?” by Steven M. Kurtz, MD, PhD, was published in CN 1-2013 (pp 11–13) and can be downloaded via QR code.

William Hozack (USA) stated in a paper on CoC bearing couples that taper corrosion in ceramic femoral ball heads probably plays a rather minor role while in metal femoral ball heads on titanium stems it can actually be a real problem. He also pointed out that CoC bearing couples show significantly less wear compared to XPE bearing couples.

> **“Wear reduction with XLP is only by a factor of 10, not like CoC where it is 1000 x less.”**
>
> – William Hozack, MD,
> Proceedings, AAOS 2013:136

Study:

Histological investigation confirms excellent biological behavior of the CoC bearing couple

Esposito et al. (Australia) reported about the particle response of the capsular tissue in 21 patients with a CoC bearing couple (alumina ceramic, BIOLOX®*forte*, 28 and 32mm femoral ball head diameter) after a mean 5.5 years in vivo. The 19

female and 2 male patients had a mean age of 68 years. In all cases the pseudocapsule was examined histologically. No patient had to be revised due to osteolysis or complications resulting from wear.

In the majority of the patients (19 of 21), mild or moderate synovitis was observed. No clinical or intraoperative signs of adverse local tissue responses were detected in any of the patients as can typically occur with MoM THA where it either manifests as tissue masses that appear necrotic (inflammatory pseudotumor) or as an unusually cloudy, white joint effusion. Only one patient had an implant impingement that was conspicuous; however, no extensive necrosis was detected as has been described in patients with MoM implants and high ALVAL scores. The results of this study correspond to those of previous histological investigations of the periprosthetic tissue of CoC THA, which describe a low number of macrophages predominantly in the fibrous connective tissue, multinucleated foreign-body giant cells only in rare cases and minimal necroses.

“With the potential for unforeseen wear debris-related complications in all types of hip arthroplasties, the results of this study should provide some assurance to the orthopaedic community that adverse local tissue reactions are unlikely to occur in patients with CoC THAs … A healthy synovial surface may be important in the maintenance and lubrication of the prosthesis, and may represent one of the reasons for the relative success of these CoC THAs.”

– Esposito et al.,
J Arthoplasty 2013, 28(5):866

The histological picture of the inflammatory response to implant materials is influenced by the quantity and quality of the particles. Ceramic particles are inert, nontoxic, do not cause any degenerative cellular changes and in this respect appear to occupy a special position.

Concept and text: S. Usbeck

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Literature:
The marked papers can be downloaded using the QR Code.

www.ceranews.com/plus

Peter Thomas, MD, PhD, has worked in the area of metal implants and allergy for about 15 years. Together with his team, he offers special consultation hours, which more than 1,000 patients with implant allergies or suspected allergies have already attended.

The scientific focus is to identify the characteristics of these patients. In particular, the team researches the mechanisms of lymphocyte reactivity including mediator production and molecular cytokine expression which lead to an excessive reaction (delayed type hypersensitivity) or tolerance.

Together with Marc Thomsen, MD, PhD, Peter Thomas heads the Implant Allergy Working Group of the German Society of Orthopaedics and Trauma Surgery (DGOU), for which he also acts as an expert allergologist. He is the lead author of the interdisciplinary statement on implant allergy published in 2008 by the DGOU, the German Contact Allergy Group (DKG) and the German Society for Allergology and Clinical Immunology (DGAKI). Interested physicians as well as patients can find more detailed information about implant allergies on the Allergomat information platform, which is linked to these scientific societies.

The results of the interdisciplinary research efforts have been widely published and recognized internationally. A diagnostic algorithm for patients with suspected implant allergy has been developed.

Contact:
Implant Allergy Working Group Allergomat

Email: implantatallergie.derma@med.uni-muenchen.de

http://allergomat.klinikum.uni-muenchen.de/en/

New Steps in Assessing Implant Tissue Interaction

P. Thomas, B. Summer

Hospital and Outpatients' Clinic for Dermatology and Allergology, Ludwig Maximilian University, Munich

Given worldwide demographic changes, it is not only the number of arthroplasties that is increasing but also the number of cases of implant failure caused by complications. The rates of primary and revision arthroplasty are already outnumbering recent initial projections.[5] The term adverse effects is often used to describe the range of unsatisfactory clinical outcomes to metal ions and debris from arthroplasties. Clinicians require practical guides on how to handle their respective individual patients. An example is the suggested algorithmic approach for diagnosing and managing MoM arthroplasty by Lombardi et al.[6]

However, the available literature provides no such guide on how to differentiate between the various pathomechanisms, in particular between hypersensitivity/exaggerated inflammatory reaction and, for example, smoldering "low-grade" infection. The role of increased immune reactivity to peri-implant or systemic metal ion and particle exposure, which are all causes of implant failure, is alluded to in numerous case reports and cohort studies. From an allergist's point of view, it is interesting to realize that firstly the use of materials in joint replacement seems to differ somewhat between various countries. Secondly in Europe, clinical observations and research efforts on nickel contact allergy have led to political awareness of nickel-linked risk constellations, which resulted in the European Nickel Directive.[1] Regulatory actions of this kind don't seem to exist in North America or other countries.

The fact that many aspects concerning local and systemic reactions to metal exposure caused by arthroplasty are not well defined is also highlighted by the latest consensus statement by Hannemann et al.[3] Early reports had suggested that lymphocyte-dominated inflammation also plays a role in loosened MoM arthroplasties.[2] In addition, delayed type hypersensitivity which is indicated by a positive patch test and increased lymphocyte transformation test (LTT) reactions, was described as a potential elicitor of such failure.[7]

However, in allergological diagnostics, while it is important to use evaluated patch test preparations, unstandardized metal discs or particle preparations should not be used. Assessing the histological picture of a peri-implant tissue response provides a snapshot-like view of what is actually happening

during this dynamic process. Krenn et al. have created a consensus classification to act as a practical guide for evaluating potential failure mechanisms.[4] This histopathological classification of diseases associated with joint arthroplasty lists, among others, peculiar reaction patterns, e.g. lymphocyte-driven reactions and the potential role of particles. In order to interpret the findings as a whole, the clinical findings should ideally be examined alongside the histological picture and further techniques used to provide a functional analysis or reveal an underlying pathomechanism.

An example is the integrated examination of metal exposure, the histological picture and functional immunological-allergological diagnostics, including the molecular mediator expression.[8,9] In terms of the actual particle algorithm, it is well known that particle characterization adds further precious pieces to the puzzle of understanding and interpreting implant-tissue interaction. Correspondingly, this algorithm complements the increasing clinical experience gained on the range of adverse reactions to metal ion and particle exposure.

Corresponding author:

Peter Thomas, MD, PhD
Klinik und Poliklinik für Dermatologie und Allergologie
der Ludwig-Maximilians-Universität München
Frauenlobstr. 9–11
80337 München
Germany
Phone: +49 89 5160 6175
Fax: +49 89 5160 6206
e-mail: peter.thomas@med.uni-muenchen.de

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Are you interested in interdisciplinary research into increased immune reactivity/ implant allergy? You can help!!

For our ongoing research projects into mechanisms of exaggerated inflammatory reactions and implant allergy, any access to patients in whom no "classic causes" for discomfort or implant loss can be found would be very helpful.

If you are interested in collaborating in the form of providing blood and tissue samples as well as (anonymized) clinical data as part of our interdisciplinary research program, please do not hesitate to contact the author (peter.thomas@med.uni-muenchen.de).

We have drawn up appropriate dispatch and processing protocols and are already working with several centers in Europe.

Veit Krenn, MD, PhD, has been the expert pathologist for the Implant Allergy Working Group of the German Society for Orthopaedics and Trauma Surgery (DGOU) since 2012.

His scientific work focuses on the development of scoring and typing systems as well as histopathological classifications for joint pathology. Further areas of his research include implant and infection pathology.

Between 2002 and 2005 Krenn and his colleagues from the Charité University Hospital in Berlin developed the histopathological synovitis score, which considers the various immunological processes in synovitis and describes the spectrum of inflammatory and non-inflammatory diseases using simple, semi-quantitative criteria. This uniform histopathological grading system allows standardized, reproducible diagnostics combined with specific information for orthopaedic surgeons about the origin of the inflammation.

The various pathomechanisms behind implant loosening are defined in the consensus classification for implant pathology. This provides information about the etiology of the failure and the survival time of the implant. Krenn developed the addition to the consensus classification together with partners from clinical practice and pathology using histopathological criteria for implant allergy (immunological type IV hypersensitivity) and the histopathological grading and typing of arthrofibrosis. Both histopathological classification systems are recognized internationally.

Histopathological Particle Identification (The Krenn Particle Algorithm)

V. Krenn[1], P. Thomas[2], M. Thomsen[3], M. Huber[4], J.P. Kretzer[5], S. Usbeck[6], L. Scheuber[6], R. Streicher[6]

1 MVZ Center for Histology, Cytology and Molecular Diagnostics, Trier
2 Hospital and Outpatients' Clinic for Dermatology and Allergology, Ludwig Maximilian University, Munich
3 DRK Hospital, Baden-Baden
4 Institute of Pathology and Bacteriology, Otto Wagner Hospital, Vienna, Austria
5 Laboratory of Biomechanics and Implant Research, Hospital for Orthopaedics and Trauma Surgery, Heidelberg University Hospital
6 CeramTec GmbH, Science Department, Plochingen

Introduction

Implant-associated pathologies in hip and knee arthroplasty are a clinical and socio-economic problem. Particle-induced (aseptic) and infection-related (septic) loosening are fundamental pathomechanisms behind these pathologies. Particularly for revision arthroplasty, the histopathological evaluation is recommended as a diagnostic parameter for etiological clarification of the implant failure.[50]

Histological differentiation of the tissue changes gives the orthopaedic surgeon important indicators about the localization of the cause of the patient's symptoms. Full clarification of implant-associated pathologies is done in the review of the histopathological diagnosis as well as biomechanical, clinical[3], microbiological[35,39], allergological and imaging results.[7] It ideally also includes a macroscopic assessment of the retrieved implant.

The Work Manual of the Implant Allergy Working Group of the DGOOC ( ) provides the surgeon with assistance in terms of histopathological differential diagnostics for adverse reactions to implant materials, complications due to biomechanical/mechanical causes, periprosthetic infection, implant-associated arthrofibrosis and osseous pathologies as well as with the choice of examinations needed and the classification of the results.[32]

Standardized histopathological classification

The histopathology consensus classification of the periprosthetic membrane in the original and the expanded versions[29,30,31,43,44] includes all pathological changes that may occur following arthroplasty of major joints and which lead to reduced survival time of the arthroplasty. This comprises aseptic and septic loosening, implant-associated arthrofibrosis, parti-

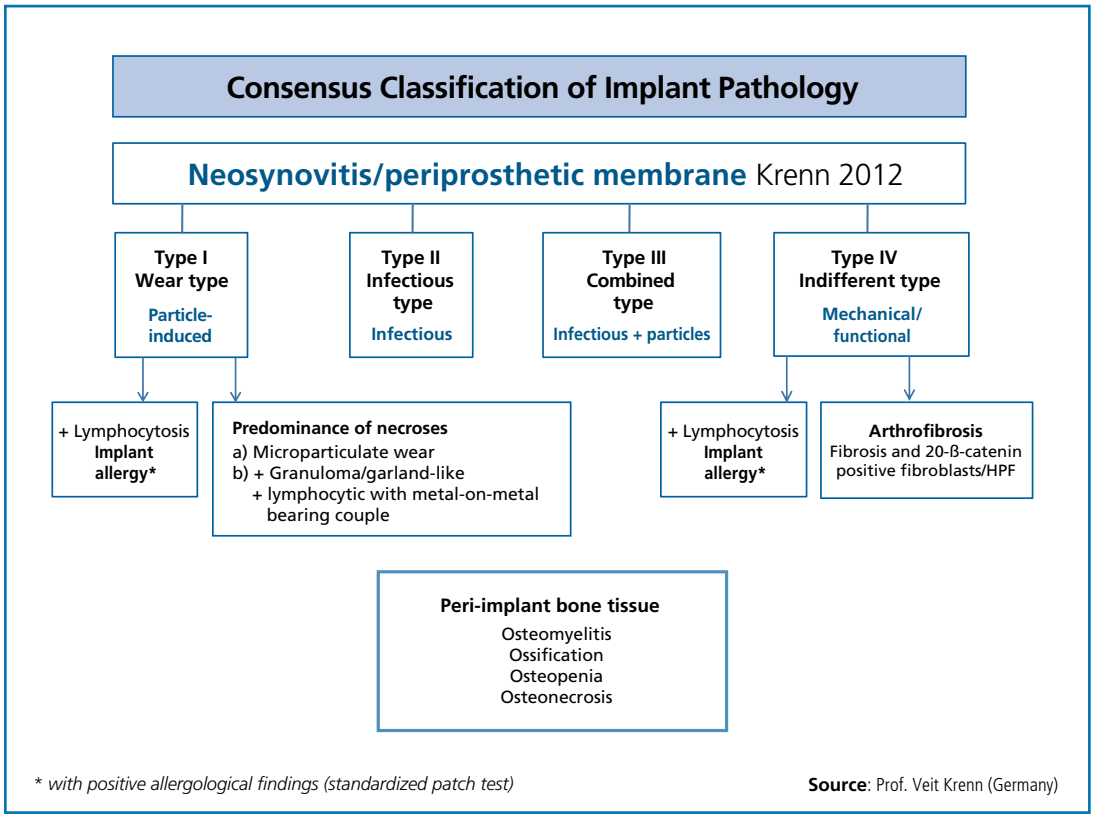

Fig. 1: Histopathological consensus classification of the 4 types of neosynovitis/ periprosthetic membrane

cle-induced, immunological, allergic and toxic mechanisms, functional causes and osseous pathologies.

In the expanded consensus classification of the periprosthetic membrane, the spectrum of arthroplasty-associated pathologies is classified by defining highly reproducible histopathological diagnostic criteria (Fig. 1).

For the first time, the neosynovitis/periprosthetic membrane of the indifferent type (type IV) is described and defined.[29,43,44] The etiology of this membrane type is diverse. Suboptimal implant positioning and functional causes, among others, are also considered.

Histopathological particle identification

In the Anglo-American literature the term **SLIM** (**s**ynovial-**l**ike **i**nterface **m**embrane) is often used to refer to the neosynovial tissue and interface tissue or the peri-implant tissue respectively.[8,9,17,18] The SLIM has a heterogeneous structure and is directly involved in bone destruction.[25,34,37,46,47,49,65] Wear particles in the SLIM are formed heterogeneously because of the different implant materials and the high variability of the immunological/inflammatory response.[11,21,26,34,35,38,41,48,49,58,61,62,63,64]

The Krenn histopathological algorithm summarizes the particle characteristics, their importance for histopathological particle identification and differentiation from non-wear particles (Fig. 2).[29]

This allows identification of the particles for guidance. The particles and wear particles are characterized using conventionally stained HE paraffin-embedded sections based on three criteria: light-microscopic/morphological characteristics with a guide to sizing and color determination, polarization optical properties and enzyme-histochemical characteristics (oil red O staining and Prussian blue reaction). The Krenn particle algorithm includes the differential diagnosis of non-wear particles in addition to the light microscopic/enzyme-histochemical properties and sizing information for wear particles.

Definition of the particle size

Information about the particle sizes is based primarily on data from animal experiments.[34] A uniform definition for macroparticles and microparticles has not been established because of the diversity of methods used. Histopathological particles of the SLIM are identified using the resolution capabilities of the light microscope. Microparticles and metal ions are not detected.

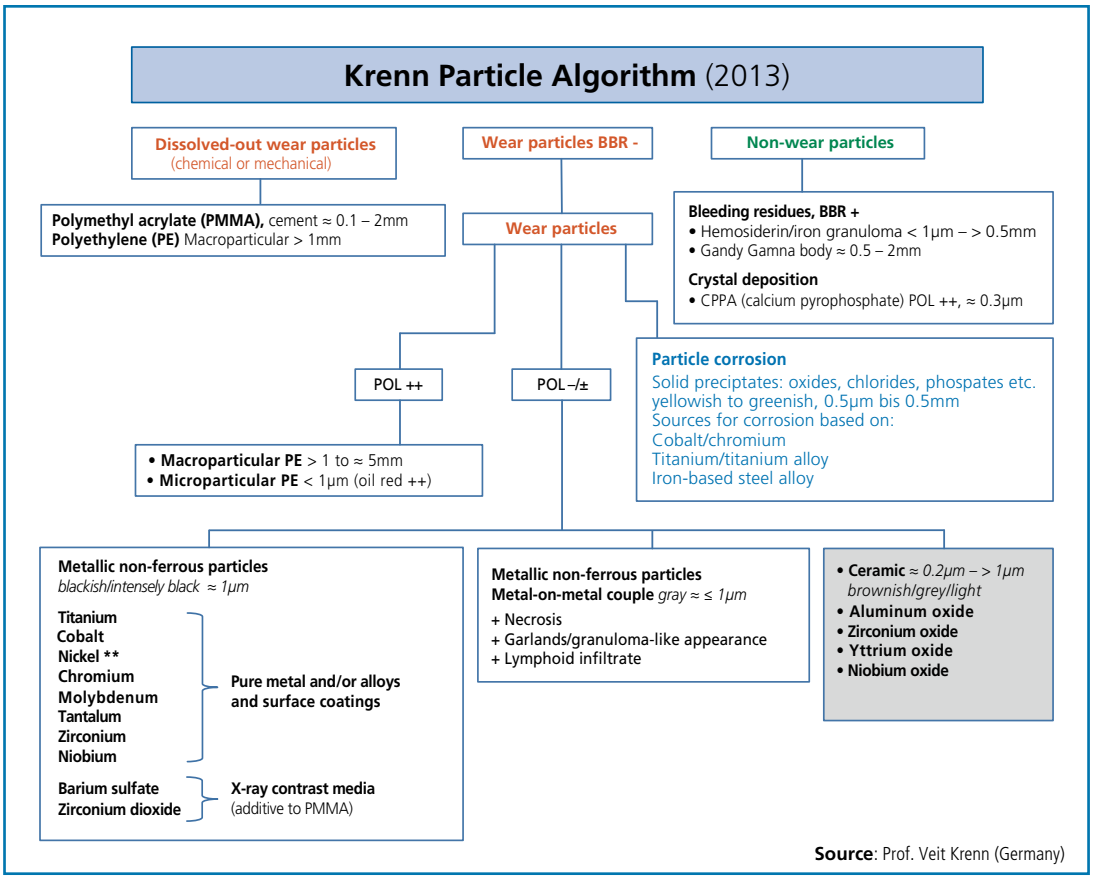

Fig. 2: Krenn histopathological arthroplasty particle algorithm.
The assessment is done using HE sections, Polarisation Optical Analysis (POL), Prussian blue reaction (PBR), oil red O.

For reasons of histopathological practicability, it is suggested that macroparticles (phagocytosed in multinucleated giant cells and/or extracellular, ≥ 5µm to several mm) and microparticles (phagocytosed in macrophages, ≤ 5µm) are differentiated. The particle sizes are determined using a computer-guided interactive morphometric analysis (Leica DM 2005, microsystems framework 2007). A definitive material identification of wear particles, particularly of metal and ceramic particles, is only possible using physical procedures such as Energy Dispersive X-ray Spectroscopy (EDX) and/or Fourier Transform Infrared Microspectroscopy (FTIR).[33]

Histological characterization of the wear material

Polyethylene particles

Light microscopy particle findings

Depending on the type of polyethylene, polyethylene particles can be highly crosslinked or non-highly-crosslinked and, depending on the mechanical loading of the implant, they are long, clasp-like and visible under the light microscope (Fig. 3).[45,65] The majority of highly cross-linked polyethylenes are microparticulate and the majority of non-linked polyethylenes are macroparticulate, whereby the mechanical loading affects the particle size.

Depending on the particle size, it is possible to differentiate macroparticles (> 5µm) from microparticles (< 5µm). Oil red O staining allows detection of intracytoplasmic, microparticulate polyethylene.[45]

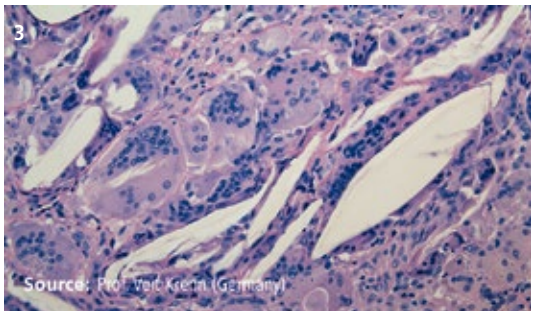

Fig. 3: Polyethylene macroparticles: light, whitish, clasp-like polyethylene macroparticles in multinucleated giant cells of the foreign body type. Original magnification 350x, HE staining

Metal particles

Light microscopy particle findings

Non-ferrous metals and their alloys are used predominantly in arthroplasty while ferrous metals (steel) are rarely used. The non-ferrous metals and metal alloys include titanium, aluminum, vanadium, cobalt, molybdenum, chromium, niobium and nickel in various combinations. Metal particles are very small if they are not present in aggregated form and they have a mean diameter of about 0.05µm to 3.9µm.[34] The shape varies from round to polygonal sharp-edged. The intrinsic color is a deep black. Metal particles rarely have minimal peripheral birefringence.

Because of their small diameter, metal particles may penetrate the superficial and deep compartments of the SLIM and the peri-implant tissues where they can be detected (Fig. 4). In rare cases metal particles may also be detected in the regional lymph nodes.

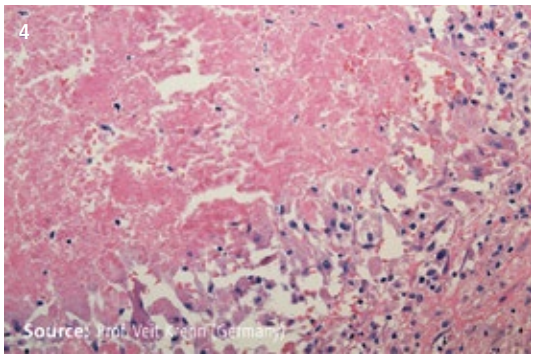

Fig. 4: MoM: macrophage accumulations with microparticulate metal deposits in a SLIM, type I, evidence of a fibrinoid necrosis. Original magnification 350x, HE staining

Metal ions

Due to the small size of metal ions, these elude histopathological detection and can only be detected using physical methods.[33]

The weakly cytoplasmic Prussian blue reactivity in the macrophages immediately adjacent to metal-particle deposits is possibly due to a cellular reaction mode to a large metal ion load *(personal observation by Krenn).*

Ceramic particles

Light microscopy particle findings

In hip arthroplasty ceramic is generally used in combinations of ceramic/polyethylene or ceramic/ceramic bearing couples. **A pathogenic reaction to ceramic particles is unlikely.** Ceramic is made up mostly of alumina ceramic (Al_2O_3), zirconia ceramic (ZrO_2) or mixed oxide ceramic with additional components such as yttrium oxide (Y_2O_3), strontium oxide (SrO) or chromium oxide (CrO).[15] The particle size varies with wear-induced ceramic particles occurring in sizes of 20–100nm. They are detected using high-resolution scanning electron microscopy (such as FEG-SEM) or transmission electron microscopy (TEM). Data from animal experiments show a particle size of up to 3.9µm.[34] There is weak peripheral birefringence in the polarization optical analysis. The color of the particles varies but is usually yellowish-brownish to gray-brown to blackish (Fig. 5). The color and the particle diameter make the histopathological differentiation from metal particles difficult, particularly with a gray-black appearance. Physical procedures such as energy dispersive X-ray spectroscopy (EDX) and/or Fourier transform infrared microspectroscopy (FTIR) are indicated here for definitive identification.[33]

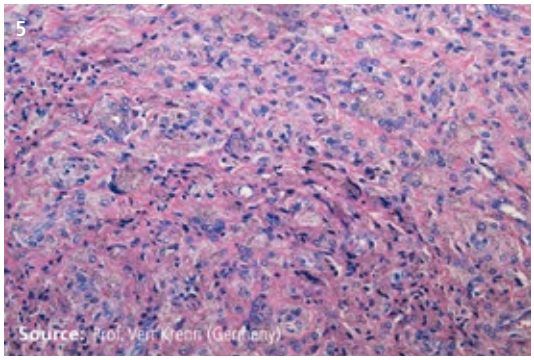

Fig. 5: CoC: ceramic microparticles in a SLIM, type I, as brownish, round to polygonal intracytoplasmic microparticles. Original magnification 350x, HE staining

The Work Manual of the Implant Allergy Working Group of the DGOOC features high resolution versions of these figures, see also QR-Code at the end of this article ( ).

Corrosion of metal particles

There is a growing number of reports of corrosion associated with metal implants. This involves the release of metal alloy components which can be detected in the joint, the peri-implant tissue and in bodily fluids. These carry the risk of adverse local and systemic side effects.

Metal-on-metal bearing couples and modular connections between femoral ball head and implant taper are a considerable source of corrosion.[24,50,63,65,66] **Allergic reactions to metallic implant materials have been described.**[52,57,58,59,60] **Corrosion products may favor third-body wear and lead to premature implant failure.**[24]

The frequency and clinical relevance of the corrosion problem have not yet been adequately inves-

tigated. The presence of corrosion products in periprosthetic membranes/neosynovia may be an expression of reduced implant material durability or excessive mechanical loading. It is thus dependent on the design, positioning and loading of the endoprostheses. Corrosion products can be detected as oxides, chlorides or phosphates depending on the metal. For example, solid corrosion products of cobalt-chromium-molybdenum alloys are made up of chromium orthophosphate.[24] They appear yellowish to greenish in color in the light microscopy analysis and vary in size (<1µm to 500µm). Chromium orthophosphate macroparticles are demarcated from foreign-body giant cells (Fig. 6). Microparticles are located intracytoplasmically in mononuclear macrophages, occasionally mixed with metal wear particles.[24]

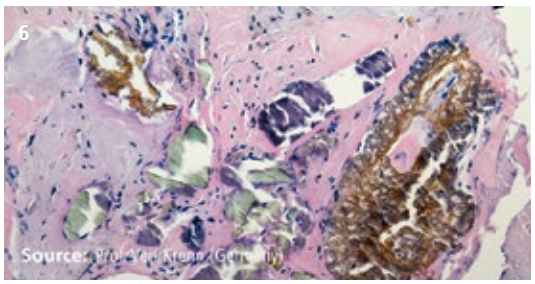

Fig. 6: Chromium orthophosphate macroparticles: corrosion macroparticles from a cobalt-chromium-molybdenum alloy apparent as greenish to orange-colored deposits localized predominantly extracellularly. Original magnification 350x, HE staining

Wear-particle-induced arthroplasty pathologies

The particle-induced, inflammatory/immunological and toxicity reaction mode in the SLIM is determined by particle quality (for example, material, size, surface), particle quantity as well as tissue and cellular particle permeation opportunities.[33] There is probably a genetic basis underlying the immunological response to foreign particulate material.[38]

Metal particles possibly have a special position in terms of immunology.[4]

Special reaction pattern with metal particles

Possible correlations with immunological, inflammatory and toxic mechanisms in the SLIM

Corrosion products from cobalt-chromium-molybdenum alloys, metal wear particles and metal ions can, depending on the concentration, cause a toxic or immunological reaction.[12,19,26,33,57,58,59,60]

In hip arthroplasty elevated levels of metal ions (chromium, cobalt) were detected in the blood serum and whole blood of patients with MoM bearing couples and were associated with persistent pain, adverse local tissue reactions, loss of function, osteolysis and premature implant failure.[10,20] The significance of elevated levels of metal ions in the serum and their correlation with local and systemic reactions has not been adequately investigated. Metal wear in vivo resulting from modular implant-taper connections in hip arthroplasty (for example, neck-femoral ball head or neck-stem connection) due to fretting or corrosion, which can lead to adverse local tissue reactions and implant failure, is currently the subject of much discussion.[13,19,36,42,62] The clinical appearance and symptoms of a hypersensitivity reaction to metal particles may be similar to those of an infection. This must be excluded using differential diagnostics.[57] **Histopathologically, a possible allergic reaction is determined based on the presence of a characteristic immunological tissue pattern.** An allergic reaction to metallic or non-metallic antigens in the form of contact dermatitis (for example, nickel allergy) is a relatively common disease and is considered a cell-mediated delayed-type (type IV) hypersensitivity reaction. **Metal-reactive T lymphocytes play a central pathogenic role here.** In particular, the pathogenic correlation between metal exposure, lymphocyte activation, skin inflammation, histopathological findings and symptoms has been defined.[57]

Because the skin is an immunocompetent organ but the SLIM has a different tissue structure, the immunological mechanisms and histopathological patterns are probably not directly transferrable. In a retrospective study of patients with revised metal-on-metal bearing couples, it was apparent, however, that if peri-implant lymphocytic infiltrates were present, two thirds of the patients showed metal sensitization.[54]

The relationship between toxic, non-immunological mechanisms (particle overloading) and immunological hypersensitivity reactions is not clear. It is assumed that a peri-implant hyper-

sensitive allergic reaction is linked to specific functional T cell characteristics (including cytokine pattern).[60]

In a recent analysis a CD3-positive lymphatic infiltrate with a characteristic cytokine pattern was described in patients with metallic implants.[60] In this work and in other studies a significant improvement in the symptoms could be achieved after revision using non-sensitive implant materials.[2,4,12,22,27,54]

Inflammatory pseudotumor

Histopathological pattern of the SLIM with metal-on-metal bearing couple

A pathogenic reaction to particular components of metal implants may occur. However, this must be clarified using a clinical assessment and additional microbiological and allergological diagnostic methods. Reduced survival time has been described for certain hip implants with metal-on-metal bearing couples.[33,37]

In the SLIM of metal-on-metal bearing couples with implant failure, pronounced, often subtotal necroses are detected along with lymphocyte infiltrates.[38,41] **The pathological changes are not consistent.** As also described for corrosion phenomena[13,19,24,36], there is apparently a connection to the material composition, the non-physiological force transmission (for example, large head diameter, incorrect positioning of the implant) and the level of activity of the patient.

In the typical pathological cases with metal-on-metal bearing couples, in addition to necroses and macrophage infiltrates (with intracytoplasmic metal microparticles), pronounced, lymphocytic and in some cases also lymphofollicular inflammatory infiltrates can be detected.[41,66] Due to tissue interfoldings of the subtotal necrotic tissue, granuloma-like structures develop, noticeably in metal-on-metal bearing couples and corrosion phenomena, which may appear clinically as pseudotumors and should be described as inflammatory pseudotumors.[57]

The pathogenesis of the necrotic-lymphocytic pattern or the inflammatory pseudotumor has not been fully clarified. In addition to direct toxicity due to metal particles in the sense of overloading of the tissue with microparticles, there is discussion of a possible (secondary) hypersensitivity reaction (type IV) to components of metal implants.[59, 60]

In the literature, for patients treated with arthroplasty with conspicuous symptoms and with a positive implant material allergy status, it is recommended to change to ceramic or surface-treated implants (for example, nitrides, oxynitrides)[60], which offer outstanding biological conditions. For adverse reactions to components of metal implants, improvements in the symptoms and falling metal ion levels have been described after revisions using metal-free materials (for example, ceramics, highly cross-linked polyethylene) in hip arthroplasty[1,2,12,13,14,19,22,27,28,40,53,55,63,64] as well as non-sensitive metal materials (surface-treated implants) and ceramics in knee arthroplasty[4,5,6,16,51,56,58,60].

Prospects

Differential analysis of tissue changes is usually indicatory to determine the treatment of the patient in most cases. Continued use of histopathological differential diagnostics and the Krenn particle algorithm will help to better understand implant pathology and to improve diagnostic information for the surgeon. This is critical for the development of causal treatment approaches. The overall problem and complexity of the issue requires further research across those related specialty disciplines.

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Corresponding author:

Veit Krenn, MD, PhD
Zentrum für Histologie, Zytologie und Molekulare Diagnostik
Max-Planck-Straße 5, D-54296 Trier, Germany
Phone: +49651 99258320
Fax: +49651 99258383
e-mail: krenn@patho-trier.de

Literature:

The list of references can be downloaded via QR code. It is also available from the author.

DGOOC Work Manual:

The Work Manual of the Implant Allergy Working Group of the DGOOC can be downloaded in English and German using the QR Code.

Fretting and Corrosion – A Problem with the BIOLOX®OPTION System?

R. M. Streicher, L. Scheuber, M. Flohr, R. Preuss

CeramTec GmbH, Plochingen

Introduction

The problem of corrosion and fretting at the interface between modular femoral ball heads and implant tapers is being increasingly discussed.[1,2,3] With metal-on-metal taper connections, corrosion/fretting can lead to a massive release of metal ions and metal particles with corresponding biological consequences.[4,5,6,7] With ceramic femoral ball heads, on the other hand, there is clinically a clear reduction in the incidence of fretting and corrosion.[9,10]

Ceramic femoral ball heads for hip revisions (BIOLOX®OPTION)[8] are designed for diameters up to 48mm and have a metallic interface to the stem taper because a taper sleeve adapter made from a titanium-aluminum-vanadium alloy is used. This means, there are concerns in terms of fretting, corrosion and clamping force.

Materials and methods

The tests were done using large ceramic femoral ball heads (BIOLOX®*delta*, Ø ≥ 40mm, CeramTec GmbH, Plochingen, Germany) combined with taper sleeve adapters and tapers made from a titanium-aluminum-vanadium alloy (TiAl6V4)[8], cobalt-chromium-molybdenum (CoCrMo) and implant stainless steel (SS). Three different tests were carried out:

- Test 1: Standard fretting/corrosion test in accordance with ASTM F1875 (Fig. 1)
- Test 2: Fatigue/corrosion test (ASTM F2345) under in-vivo loading conditions
- Test 3: Moments stress test (frictional torsion test using rotation and bending) under approximate in-vivo conditions in the hip simulator[8] (Fig. 2)

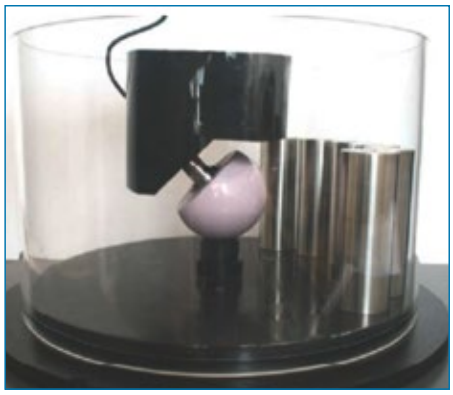

Fig. 1: Standard fretting/corrosion test in accordance with ASTM F1875 (Source: Endolab®)

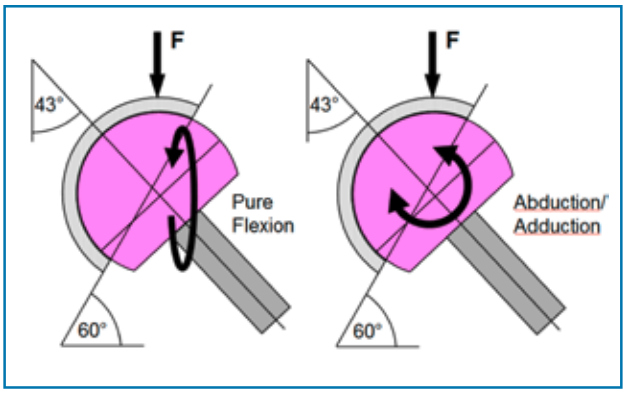

Fig. 2: Moments stress test (frictional torsion test using rotation and bending) under approximately in vivo conditions in the hip simulator[8] (Source: CeramTec)

Results

The fretting-corrosion test (Test 1) showed decreasing galvanic currents for all taper materials (TiAl6V4, CoCrMo, SS). The currents measured were all low and indicate a minor corrosion potential for the taper connections investigated.

The corrosion tests under in-vivo loading conditions (Test 2) indicated that for the BIOLOX®OPTION System no significantly increased retention forces can be expected. In cases of revision surgery, it should be possible to remove the femoral ball head and the adapter sleeve from the stem taper.

The moments stress tests (Test 3) were carried out using the hip simulator (EndoLab®, Thansau, Germany). No noteworthy taper damage was detected, regardless of the taper material investigated. There were only slight micromovements with no indications of corrosion.

Summary

All three investigations (fretting/corrosion test in accordance with ASTM F1875, corrosion test under in-vivo loading conditions, moments stress test)[8] showed that the fretting, corrosion and wear behavior at the interfaces between ceramic femoral ball head (large diameter), adapter sleeve and stem taper did not have any significant effect on the functionality of the BIOLOX®OPTION system. Even under worst-case conditions (unfavorable material combinations, high forces, high torque, corrosive medium), there were no critical effects.

There were no negative consequences recorded due to fretting and corrosion with the BIOLOX®OPTION System for any of the taper materials investigated, whether cobalt-chromium-molybdenum or titanium-aluminum-vanadium alloys.

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This article, more information about BIOLOX®OPTION and clinical pictures on this subject can be obtained here.

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Michael M. Morlock MD, PhD, is professor of biomechanics and head of the Institute of Biomechanics at the Technical University Hamburg-Harburg (TUHH). He is the coordinator of the medical engineering course; co-founder of the regeneration, implants and medical technology research focus group; and director of the Hamburg Research Center for Medical Technology.

The Institute of Biomechanics conducts research and teaching in three areas: joint replacement, biomaterials and osteosynthesis. In joint replacement research, the scientists focus on implant fixation in the bone and optimization of endoprosthesis implantation and positioning as well as training for surgeons. The areas of research have been derived from the knowledge gained by analyzing implants retrieved in revision and autopsy, which gives the group a strong connection to clinical practice.

Prof. Morlock is actively involved in numerous international and national scientific societies including the International Society of Biomechanics, the Orthopaedic Research Society and the Committee for Arthroplasty and Osteosynthesis of the German Institute for Standardization (DIN). He is a reviewer for the most renowned biomechanical and orthopaedic journals and has published more than 200 journal articles and book chapters as well as 500 abstracts.

Do Overweight Patients have a Greater Risk of Fracture of Ceramic Components in THA?

M. M. Morlock, E. Hoenig, A. Hothan

Institute of Biomechanics, Technical University Hamburg-Harburg

Introduction

Although a connection between obesity and the development of osteoarthritis is considered certain[1–10], the effect of body weight on the success of total hip arthroplasty (THA) is hotly debated. As part of a meta-analysis it was investigated if and to what extent patient weight affects the result of total hip arthroplasty or whether the bearing couple chosen plays a role. The background of this investigation was the question of whether the increased joint forces in overweight patients[11] per se lead to an increased risk of fracture of the ceramic implants.

In addition to a literature analysis, experimental friction analyses were carried out for commonly used bearing couple materials for patients with normal weight and overweight patients.

Meta-analysis

The literature database PubMed/MEDLINE was searched for publications which described the effect of BMI or body weight on the result of THA or ceramic fractures. Conference papers were also included in the literature review. A total of 55 articles and conference papers that conformed to the search criteria were found and their key statements were summarized in terms of

- biological complications
- mechanical complications (for example, fracture)
- functional analyses, activity and pain
- quality of life or satisfaction
- patient age
- surgery time, length of hospitalization and rehabilitation.[12–66]

Some studies reported poorer results for THA regarding one or more of the parameters investigated. Other studies, however, did not show any effect due to weight (Fig. 1). An increased incidence of biological complications (particularly infections), a lower mean age of the patients and longer surgery times are clearly cited with greater frequency for obese patients.

Parameters		Result for overweight patients **poorer** [number of publications]	Result for overweight patients **same** [number of publications]
Biological complications	Infection	13	5
	Thrombosis	3	1
	Wound healing	3	0
Mechanical complications	Position of cup	2	4
	Dislocation	5	2
	Osteolysis	2	7
	Survival rate	1	8
	Position of stem	2	0
Functional analysis	Function	4	12
	Pain	1	2
	Activity	1	0
Quality of life & satisfaction		0	6
Patient age		3	0
Hospitalization	Surgery time	4	2
	Hospitalization	2	4
	Rehabilitation	1	0

Fig. 1: Summary of the literature review on the effect of weight on the result of hip replacement (number of publications)

The positioning of the implant components was worse for obese patients in half of the studies that investigated this parameter (4 of 8). About 70% of the studies detected an increased rate of dislocation. Osteolysis caused by friction-induced foreign body reactions was, however, observed more frequently in obese patients compared to patients with normal weight in only 2 of 9 studies.

In terms of the cause of femoral ball head or insert fractures, body weight is often cited as a possible cause but has not been verified in any clinical trials. Quantitative investigations show increased stresses particularly with unfavorable component positioning combined with excess weight[67–71] or an increased frequency of noise development also in clinical use[72,73].

Experimental investigation

Increased joint friction is currently discussed in relation to implant loosening, taper problems and noise development. For this reason, the friction coefficients of various combinations of materials established in hip arthroplasty (ceramic-on-ceramic, BIOLOX®*delta*, CeramTec; metal-on-metal, ULTAMET®, DePuy; ceramic-on-metal, DePuy; highly crosslinked polyethylene, Marathon®, DePuy, combined with ceramic and metal femoral ball heads) were investigated using a head diameter of 28mm and a cup inclination of 45° with a pure flexion-extension movement of a sinus-shaped course and a frequency of 1Hz in both dry and lubricated (25% bovine serum) states for joint forces of 500N, 1500N and 2500N.[74]

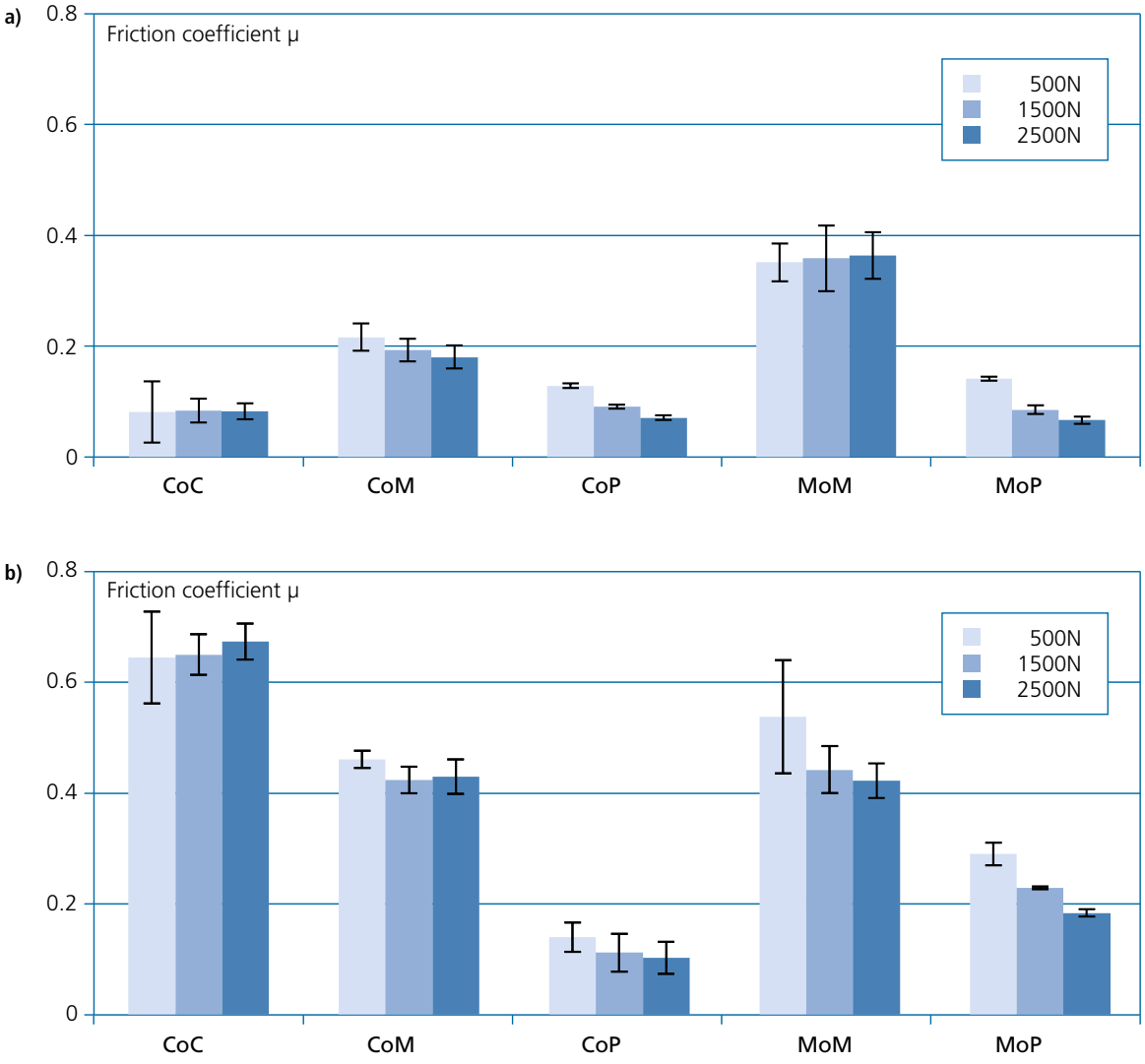

Fig. 2a, 2b: Friction coefficients for various material couples in (a) lubricated and (b) dry state

In the lubricated state there was

- no effect of the joint force observed for hard-on-hard bearing couples (CoC: $p = 0.527$; CoM: $p = 0.066$; MoM: $p = 0.912$) and
- an effect of the joint force for hard-on-soft bearing couples: the friction value fell with increasing joint force ($p < 0.001$). (Fig. 2a)

In the dry friction state, deviating slightly from the lubricated state,

- no effect of the joint force for bearing couples with at least one ceramic component (CoC: $p = 0.750$; CoM: $p = 0.053$; CoP: $p = 0.344$) was observed and
- an effect of the joint force for bearing couples without ceramic components (MoM and MoP: falling friction coefficient with increasing joint force; $p < 0.02$) was stated. (Fig. 2b)

In the lubricated state the lowest friction occurred with low and moderate forces in the ceramic-on-ceramic bearing couples. With high forces, however, the hard-on-soft bearing couples had the lowest friction. This is possibly due to the deformability of the polyethylene and the subsequently modified contact area. With hard-on-hard bearing couples the force in the lubricated state did not have any effect on the friction that developed. Metal-on-metal bearing couples had a greatly increased friction value and thus entered an area which may be problematic for the fit of the cup in terms of the moments developing at high joint forces.

The absence of a lubricating film increased the friction coefficient significantly in all bearing couples ($p < 0.035$). The effect was greatest in ceramic-on-ceramic bearing couples where the friction coefficient increased by a factor of 7.

Discussion: Material couples in obese patients

The poorer results in terms of dislocation as a reason for revision would indicate the implantation of a larger femoral ball head in obese patients. However, this is associated with increased wear with hard-on-soft bearing couples[75]: in terms of the wear the use of a ceramic-on-ceramic bearing couple would consequently be favored. At this point it must be noted that correct cup and stem positioning is an essential prerequisite to prevent dislocation, subluxation and impingement. Such adverse events can lead to problems, particularly for cup inserts made from thin highly crosslinked polyethylene or ceramic.

The fact that osteolysis in obese patients does not occur more often may be due to the reduced level of activity of obese patients, compensating for the greater joint force that would actually be expected to result in increased wear (wear is proportional to the applied load, the sliding path and the integral of the time).[76]

The results from the experimental investigation confirm that ceramic-on-ceramic bearing couples with lubricated conditions have the lowest friction coefficient or friction coefficients that are just as low as those of hard-on-soft bearing couples with high forces. However, they are characterized by a high sensitivity for insufficient lubrication. Incorrect positioning of the implant components may favor a tear in the lubricant film; this risk appears to be increased in overweight patients. The associated dramatic increase in the friction in the bearing couple may result in problems in terms of fixation and noise development – both of which can be traced back to increased friction – particularly for larger head diameters.[77]

For obese patients, therefore, the same argument applies as for patients with normal weight: provided a correct implantation situation can be ensured, ceramic-on-ceramic bearing couples should be favored from a tribological point of view. If the correct implant position cannot be guaranteed, a hard-on-soft bearing couple should be preferred to a hard-on-hard bearing couple. As a result of the improved material properties of the available ceramic composites and the taper problem, particularly with larger metal femoral ball heads, a ceramic femoral ball head should be used. This statement should in no way be interpreted to mean that incorrect positioning of implants could be corrected with hard-on-soft bearing couples. This would instead shift the problem to a later point in time: the use of a hooded PE insert may reduce the dislocation rate, but it increases the wear at the same time which may have negative consequences in the long term. With incorrect positioning, the implant position – which is the actual cause – should always be corrected.

Finally, it may be concluded that correct implant fixation and positioning play a bigger role in the long-term success of the hip joint replacement than the bearing couple chosen.[78]

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A literature list is available from the author.

Corresponding author:
Univ. Prof. Dr. habil. Michael M. Morlock
Institut für Biomechanik
Technische Universität Hamburg-Harburg
Denickestraße 15
21073 Hamburg
Germany
Phone: +49 40 42878 3253
e-mail: morlock@tuhh.de
www.tu-harburg.de/bim

Acronyms

AOS	**A**merican **A**cademy of **O**rthopaedic **S**urgeons
ALVAL	**A**septic **L**ymphocytic **V**asculitis **A**ssociated **L**esions
ARMD	**A**dverse **R**eactions to **M**etallic **D**ebris
BVOU	**B**erufs**v**erband der Fachärzte für **O**rthopädie und **U**nfallchirurgie (Professional Association of Orthopeadic and Trauma Surgeons)
CoC	**C**eramic-**o**n-**C**eramic
CoCrMo	**C**obalt-**cr**omium-**mo**lybdenum
CoM	**C**eramic-**o**n-**M**etal
CoP	**C**eramic-**o**n-**P**olyethylene
DDH	**D**evelopmental **D**ysplasia of the **H**ip
DGOOC	**D**eutsche **G**esellschaft für **O**rthopädie und **O**rthopädische **C**hirurgie (German Society of Orthopaedics and Orthopaedic Surgery)
DGU	**D**eutsche **G**esellschaft für **U**nfallchirurgie (German Society of Traumatology)
FDA	U.S. **F**ood and **D**rug **A**dministration
HE	**H**ematoxylin-**E**osin
HHS	**H**arris **H**ip **S**core
MoM	**M**etal-**o**n-**M**etal
MRI	**M**agnetic **R**esonance **I**maging
PBR	**P**russian **B**lue **R**eaction
PE	**P**oly**e**thylene
POL	**Pol**arisation Optical Analysis
SLIM	**S**ynovia **L**ike **I**nterface **M**embrane
THA	**T**otal **H**ip **A**rthroplasty
TJR	**T**otal **J**oint **R**eplacement
XPE	**Cross**linked **Poly**ethylene

Survival analysis of 2,395 hip arthroplasties with hard-on-hard bearing couples in cases of DDH

To date there have been very little data derived from large case series with medium- to long-term results from cementless primary total hip arthroplasty in young and active patients with developmental dysplasia of the hip.

Atsushi Kusaba MD, PhD, (Ebina General Hospital, Kanagawa, Japan) investigated the survival time of 2,395 THA with hard-on-hard bearing couples (552 metal-on-metal, 1,843 ceramic-on-ceramic – BIOLOX®*forte*, BIOLOX®*delta*). The paper was evaluated as good above average in an anonymized review procedure by the German Orthopaedic and traumatology societies DGOOC, DGU and BVOU. An official notification from the congress presidents announced its acceptance as a presentation in the program of the upcoming German Congress of Orthopaedics and Trauma Surgery (DKOU).

Prof. Kusaba will present his results on October 25, 2013, at the DKOU in Berlin.

Approval of the ceramic-on-ceramic bearing couple (BIOLOX®*delta*) in Japan

Aesculap, Biomet and DePuy received approval for the ceramic-on-ceramic bearing couple (BIOLOX®*delta*) in recent months and successfully introduced the products to the market. Other renowned implant manufacturers are also currently working on the approval of the ceramic bearing couple BIOLOX®*delta*.

Histopathological differential diagnostics with implant-allergic reactions

The manual of the Implant Allergy Working Group of the DGOOC provides the surgeon with comprehensive assistance with

- histopathological differential diagnoses of adverse reactions to implant materials
- complications with biomechanical and mechanical causes
- periprosthetic infection
- implant-associated arthrofibrosis
- osseous pathologies
- choosing the necessary examinations and classifying the results.

The manual can be retrieved in both German and English using the QR code.

What to do with patients with noise phenomena after THA?

William Walter, MD, (Sydney, Australia) has developed a clinical algorithm to demonstrate the treatment options available for these patients. The paper is available in English in a series of publications from Springer and is also available as an e-book.

FDA approval of a hip implant system in the U.S. with 36mm ceramic-on-ceramic bearing couple from BIOLOX®*delta*

DePuy Orthopaedics, Inc. announced on May 3, 2013, that the company received FDA Pre-Market (PMA) Supplement Approval for its CERAMAX® Total Hip System with BIOLOX®*delta* Ceramic-on-Ceramic (CoC) 36mm large femoral head. The PMA supplement approval comes after initial PMA approval of the 28mm size in 2010.

The safety and effectiveness of the CERAMAX® System were evaluated in a prospective, multi-center, non-randomized, controlled clinical study of 264 patients who required hip replacement surgery for a non-inflammatory degenerative joint disease that compared the CERAMAX® System to ceramic-on-polyethylene hip replacement.

The study, which was part of the company's PMA application, found no significant differences in adverse events or survivorship between the two groups, and patients experienced similar pain relief, improved function and range of motion.

The FDA concluded that the CERAMAX® System was safe and effective.

Source: DePuy Orthopaedics, Inc.

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Internet: www.biolox.com

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Your contact:
Dieter Burkhardt
Vice President Sales and Marketing
Phone: +49 7153 611-485
e-mail: d.burkhardt@ceramtec.de

Paul Silberer
Vice President Sales
Phone: +49 7153 611-522
e-mail: p.silberer@ceramtec

Chief Editor:
Sylvia Usbeck

Concept and editing:
Sylvia Usbeck
Florence Petkow
Leslie Scheuber

Layout and production:
LoopKomm Infomarketing GmbH
Phone: +49 7634 55 19 46
e-mail: mail@loopkomm.de

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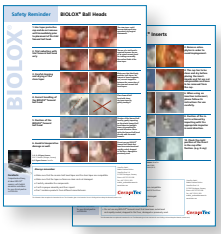
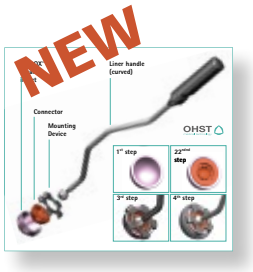


☐ **Safety Reminder** (A4)
What a surgeon should bear in mind when implanting BIOLOX® inserts and BIOLOX® femoral ball heads



☐ **Information** (A4)
on the inserter instrument for BIOLOX® inserts

☐ **Bearing couple selection for revisions after a ceramic fracture** (A4)

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