

# CeraNews

ISSUE 1/2016

The Orthopaedic Landscape Information Journal

## “The Best Technology is One that is Proven.”

Bryan Springer, MD



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**Published by:**

CeramTec GmbH  
Medical Products Division  
CeramTec-Platz 1–9  
73207 Plochingen (Germany)  
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69121 Heidelberg (Germany)  
E-Mail: sabine.jost@springer.com

**Printing Office:**

Druckpress GmbH  
Hamburger Straße 12  
69181 Leimen (Germany)

## Joint Arthroplasty Registries – A Tool to Improve Patient Safety in Joint replacement

By Kjærsgaard-Andersen P, Vejle, Denmark

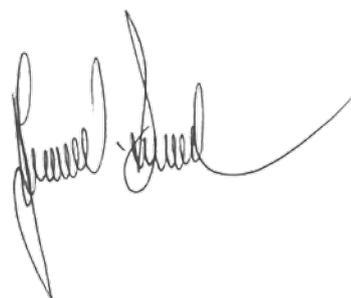
*Joint replacement, with a main focus on total knee and total hip replacement, has been a central treatment modality in all orthopedic communities for 40–50 years. During this period, reconstruction of the degenerated hip and knee has developed from being a unique treatment for selected cases to an operation offered not only for the senior patient but also for younger and elderly patients. The indications for surgery have developed further; joint replacement has become a procedure that is well known even to non-medical persons and is regularly discussed in the non-medical media, so that today, everyone knows that a degenerated hip or knee can potentially be replaced – and our patients have high expectations that this intervention will "get their life back"! In this same period the number of total hip and knee replacements performed worldwide has risen exponentially, and today we are faced with a large number of different potential implants to select for our patients.*

*How should we select the right implant for our patient? What criteria should be used for our selection? Is there a need for so many different implants? How can we maintain an overview of all these implants and make sure that they function? We should work with evidence-based treatment modalities, and we should use proven implants for most of our patients. All surgeons and authorities agree on this. But what is a proven implant? Can we base our decision on reports / publications from the developer of the implant, or from single institutions where a few surgeons implant a large number of a particular type each year? Certainly not; we need information from a much more detailed database to get the details, and the answer to that is national joint replacement registries.*

*Today several countries – Australia, the Netherlands, the United Kingdom and all the Scandinavian countries in particular – have well-established national registries on many types of joint replacement. The best examples are the different national Hip Replacement Registries. They have succeeded in establishing national reporting of nearly 100% of all hip replacements performed in each country, making the outcome of the registries' database as reliable as possible. For example, in Sweden the outcome of the Hip Arthroplasty Registry has resulted in a national strategy for cementing techniques, and this has significantly improved survival of the cemented total hips over time. Also, open discussion between hospitals on the percentage of surviving implants has led clinics to compete in order to improve their outcome / survival rates even further in the coming years.*

*Joint-replacement registries will surely be a central tool for surgeons, clinics, national societies and also government bodies in making future decisions on the selection of safe treatment strategies for our patients. It is therefore important for the national registries to make sure that they create the minimum data set to enter in the registries so that that cross-national comparison can take place. EFORT has established a committee for a Network of Orthopedic Registries in Europe (NORE) to assist in actions across Europe related to joint-replacement registries. A comparison of outcomes between different registries requires not only input of the same minimum data set but also unique names / codes for a given implant to be sure what details within an implant we try to compare.*

*Today, it is mainly surgeons and the industry who use reports from the registries. Within a few years, however, this will certainly expand to also involve national authorities such as those of the EU. It is therefore extremely important that surgeons and national orthopedic societies, as well as the industry, all support each other in getting the right information at each data input for the safety of future joint-replacement patients.*



**Per Kjærsgaard-Andersen,  
MD, Ass. Professor**



**Ass. Prof. Per Kjærsgaard-Andersen, MD**, is an associate professor of orthopedic surgery at the University of Southern Denmark and head of the Sector for Hip and Knee Replacement, Department of Orthopedics, Vejle Hospital, Denmark. He has worked in the field of orthopedic surgery at several Danish hospitals in various positions, among others as an administrative consultant.

He graduated from Aarhus University in 1982 with a licence to practice medicine and was certified as a specialist in orthopedic surgery in 1995 by the Danish National Board of Health. Since 1998 he has been an expert advisor on the Danish Health Authorities Patient Complaints Board. He has served as president of both the Danish Society for Hip and Knee Surgery and the Danish Orthopedic Society.

In 2011 Kjærsgaard-Andersen served as president of the 12th EFORT congress, and in 2012 he became the secretary general of EFORT. He is chairman of the Danish National Board of Health task group on specialist planning in orthopedic surgery, and he advises the governments of Norway and Denmark.

Kjærsgaard-Andersen has lectured annually since 2002 on hip-joint arthrosis for orthopedic residents, and has been a clinical lecturer at the University of Southern Denmark since 2004. He has supervised research for several doctoral candidates, and has delivered more than 300 lectures on orthopedic subjects at national and international meetings of orthopedists.

## The Best Technology is One that is Proven

Interview with Bryan D. Springer, MD, Charlotte, USA

**The numbers of joint arthroplasty interventions in the population are continually increasing. The patients are both getting younger and growing older, adding to the demand for joint arthroplasty, and the spectrum of technologies is widening. This is a challenge for orthopedic surgeons: They have to choose the right implant for each patient, they have to keep up their skills with new technologies, and they have to consider cost issues at the same time. Here, one of the top American knee surgeons gives answers on how orthopedic surgeons should cope with these problems to meet the demands of the future. "I try to balance the safety for the patient with the best-proven technology", says Bryan Springer, MD, from OrthoCarolina Hip & Knee Center, North Carolina.**

**Patients are living longer and their activity level has increased substantially. Do you see an upcoming crisis in the availability of qualified surgeons to meet the challenge of an increased number of patients as they 'wear out their joints'?**

**Springer:** I don't think there is any question that the demand for total joint arthroplasty is increasing. As technology improves, our willingness to offer total joint arthroplasty to younger and more active patients is expanding. There is concern about the 'workforce'

of available surgeons able to meet this demand as well as about the willingness of surgeons to continue to perform total joint arthroplasty, given the current health-care shortcomings. However, we have seen the number of applicants for hip and knee arthroplasty fellowships increase substantially over the past 3 years. So there appears to be more interest in our residents wanting to train in total joint replacement. In addition, our improvements in efficiency, length of stay, and patient recovery should help increase the 'throughput' for total joint replacement. Given all of

these factors, I am certainly more optimistic about meeting the demand than I was 5 years ago.

**Does arthroplasty for the younger patient demand greater skill in the technical aspect of the operations in order to achieve the required longevity to delay or prevent revision surgery?**

**Springer:** There is no question. While total joint arthroplasty is a very forgiving operation, many failures that we see are unfortunately technique-related and complications that could be prevented with good surgical technique. I think we all understand that the longevity of total joint arthroplasty is multifactorial, but how well the surgery is done technically goes a long way to improving that longevity.

**Is it difficult to justify using the most advanced technology for your high-demand patients today? How do you offer convincing proof?**

**Springer:** Yes, and it is becoming even more difficult. 'New technology' is also 'unproven' technology. While everybody wants the latest greatest, how do we really know that this 'new' technology is the right technology that will produce lasting results and not end up being a failure in the short term? This is exactly what we went through with the metal-on-metal debacle. The use of new technology has to be a balance. Safety of the patient always comes first. I look at new technology nowadays obviously with a skeptical eye, because of the metal-on-metal issue. What I want is proven technology that has been enhanced throughout the years with innovation and research. I am okay to wait a little longer to show that this technology is proven and safe, and I think that most patients accept and understand that.

**Does it limit your ability to select the best technology for your patient?**

**Springer:** No, because I think the best technology is one that is proven. This means proven through basic science research, clinical research, and patient outcomes. So the best technology for my patients is one that meets those standards. If I can't answer yes to those questions with clinically and research-proven technology, then I am not doing my patients a service. In addition, much more research is now being done on the cost-effectiveness of new technology. Although it may be more expensive in the short term, in the long run it may prove to lower failure rates and thus be more cost-effective over the life of the patient. For example, our group, led by Dr. Susan Odum and Dr. Thomas Fehring, demonstrated in a Markov model that a ceramic on highly cross-linked bearing couple, although more costly than a standard bearing, is actually cost-effective in the long run for patients less than 70 years of age in lower long-term revision

rates, thus justifying its immediate costs. More research needs to be conducted on these lines to evaluate new technology.

**Are you generally pleased with the results of hip replacement in the young patient? What is the biggest challenge?**

**Springer:** In the short term, yes. The beauty of hip replacements is that these young patients tend to recover very quickly and have high satisfaction. The challenge, of course, is going to be the long-term durability of the hip replacement. We tend to focus so much nowadays on how quickly the surgery can be done, how short the incision can be, where the incision is, whether the patient can go home the same day, etc. We are losing sight of what is really important, and that is the long-term durability of a hip replacement in a young patient. I try to redirect the focus of young patients to that goal, but it is a challenge and they tend to focus on the short term.

**The introduction of Advanced Bearing Technologies has been a transforming advance in this field, as they promise longevity for the younger and the older but more active patient. What is your algorithm for the use of these technologies in your patients?**

**Springer:** Again, I try to balance the safety for the patient with the best-proven technology. There is no question that the advanced bearing technology with highly cross-linked polyethylene and new-generation ceramics has been a game-changer in terms of wear and longevity with very low risk. As patients continue to live longer and stay active longer, we have to shift how we think about how we treat 'young patients'. A 70-year-old has the potential to live another 15–20 years, and I don't think 'conventional technology' solves this problem. In my mind, any patient aged 70 and below gets a ceramic-on-X-polyethylene bearing. Greater than 70, they will get ceramic on poly with 36-mm heads until we have a better understanding of the trunion issues.

**In the young or very active patient, what would be your articulation choice?**

**Springer:** This is a very challenging group of patients because of their life expectancy and activity level. These young patients can expect to need 40–50 years of service from a bearing surface. While highly cross-linked polyethylene is an excellent choice, we don't know what the 20–30 year data will show with regards to wear, oxidation and osteolysis. In these patients, I would favor the use of a ceramic-on-ceramic articulation as it is the lowest wear articulation and has the least likelihood of particle induced osteolysis over the long term. We know however that with the use of a ceramic-on-ceramic bearing, appropriate position of com-





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Since 2011 he has been Fellowship Director of the OrthoCarolina Hip & Knee Center in Charlotte, North Carolina. Springer is named as one of the top 22 North American knee surgeons and is involved in numerous scientific research projects regarding all aspects of joint arthroplasty. He has published and co-authored more than 75 articles in the scientific literature.

ponents to avoid impingement is critical to ensure the best long term possible result with this bearing couple.

**Each of the Advanced Bearing Technology options has benefits and risks associated with their use. Is your approach to apply the technology with the highest likelihood of success and the least likelihood of failure?**

**Springer:** Yes, I think that is what we all are looking for. I don't think we should be risk-takers when it comes to total joint arthroplasty. We have solutions that we know work well and can give our patients a high likelihood of success and low failure risk for more than 20 years. We should be taking advantage of that in every case.

**Do you think that the restrictive regulatory approval process for new technologies needs to be even more restrictive in order to prevent the introduction of poorly performing implants?**

**Springer:** I am actually in favor of a system much like that in England, where implants with a proven track record that meet benchmark 10-year standards set forth by the National Institute on Clinical Excellence (NICE) make the most sense. How many large-diameter metal-on-metal total hip arthroplasties were put in, in this country, even after we began to see catastrophic early failures? I think implants with proven track records should be given priority, and new technology should undergo a longer and more scrutinized process.

**Much has been said about implant registries; do you think they are reliable indicators of implant performance?**

**Springer:** I think they are the best we have. There are limitations. Many are based on administrative codes and all of the inherent weakness associated with using them, and in addition, they are only as good as the submitted data. I think the most im-

portant function of a registry is to serve as an early-warning system for poor implant performance. I am not in favor of a registry being utilized to directly compare surgeons or hospitals until we have an adequate risk-adjustment program in use.

**Ceramic implant technology has evolved and improved substantially over the years; is this easily recognized by surgeons?**

**Springer:** Definitely, I think when you look nationally and globally at the use of ceramic bearings, it is increasing. This is in part a reaction to the issues with trunnionosis and concerns about the use of large-diameter metal heads. However, there is now also a fair bit of basic science data as well as clinical data that show the benefits of both ceramic-on-ceramic bearing couples and ceramic against highly cross-linked polyethylene. Today, I think a ceramic-on-polyethylene bearing has not only a proven track record but is also the safest bearing couple available.

**You have been very involved in teaching the importance of technical proficiency in the operation, as revision rates seem to be quite high. What else can be done to have a positive impact in this area?**

**Springer:** As I mentioned earlier, unfortunately, many of the failures of total joint arthroplasty are surgeon-related. Whether it's malalignment, component position, instability, etc., these are all potentially preventable causes of failure. I do think that, to an extent, we have become reliant on technology to make up for poor surgical technique, whether it is large heads or navigation. Rather than to enhance the procedure, new technologies are utilized to make up for poor technique, and that is where we get into trouble. The focus should also be on appropriate patient selection and surgical technique, remembering that the basic fundamentals of surgery will trump technology. When you can appropriately combine the two, that will be a win every time. We need to emphasize patient selection, to understand that as surgeons, it is okay to say no to a patient and optimize them. Ultimately, this is in the best interest of the patients.

**The recent reports concerning the metal-on-metal articulation have been devastating. It seems that we did not pay attention to the warning signs from European surgeons. In your opinion, what happened?**

**Springer:** I recently heard someone say that metal-on-metal has been an epic failure of engineering, marketing, and our culture. I think it is one of the biggest 'black eyes' in the history of orthopedics. I like to say that we were all seduced by the promises of metal-on-metal. Big heads and low wear would solve all of our problems. The industry, which saw the potential that bearing couples could have

on its bottom line, raced to push any design to the market, with us not understanding that subtle differences in manufacturing (carbon content, clearance, etc.) made a huge difference in performance. A huge marketing push from the hip-resurfacing camps and our insatiable appetite for new technology created the perfect storm. In addition, thinking of large-diameter metal-on-metal heads as extremely forgiving, not dependent on component position, led to disastrous consequences that we will be dealing with for many years to come.

**Recent studies have shown that 24–36 % of all patients undergoing primary THA are obese. How much of a challenge do these patients present?**

**Springer:** It is one of the biggest issues we currently face in joint replacement. These patients are not only technically challenging, but metabolically challenging as well. The surgery is more difficult to do; they have more complications, stay longer in the hospital, and generally have a 'ceiling effect' with their recovery. I firmly believe that patients have to take some accountability for their health care, and we as physicians have to be responsible for whom we choose to operate on. We must work with these patients, not against them. We have to try and provide them with resources for managing their weight prior to surgery. We should not be adversarial but

take the approach that it is best for them and their outcome. I think making a firm cutoff for BMI has to be individualized. We know that a BMI of more than 40 kg/m<sup>2</sup> is associated with a substantially increased risk of complications. However, a patient with a BMI of 41 kg/m<sup>2</sup> and no medical comorbidities is probably at less risk than a patient with a BMI of 38 kg/m<sup>2</sup> who has uncontrolled diabetes, smokes, and has heart disease. Using a strict cutoff does not differentiate between these patients; therefore, we must look at them individually, work with them, but also require that they take some responsibility for their health care.

**The new healthcare initiatives that have been passed by Congress are likely to have a profound effect on the future of many surgeons entering this field. Do you have any 'words of wisdom' for them?**

**Springer:** The initiatives will be tough. There are some good things. Better access for patients and a shift from volume to value-based health care are changes in the right direction. I do think eventually we will be rewarded for doing high-quality, cost-effective work. I still believe that joint replacement is the best operation in all of medicine, that our ability to relieve pain and restore a patient's mobility is something we can provide like no other specialty can. ■

## Interpretation of Register Data: Complex and Catchy

Van der Straeten C, MD, PhD

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Arthroplasties are common surgical interventions with generally successful outcomes regarding pain relief, restoration of function, and quality of life. Although the basic principles have not changed drastically over the last several decades, technological advances regarding materials, implant designs, fixation modes, manufacturing techniques, and precision instruments are continuously altering the practice of arthroplasty. However, outcome is related not only to implants but also to indications and surgical and patient factors, which vary geographically and also evolve over the years. Following the success of the Swedish Registers in improving the practice of joint replacements (JR), National Arthroplasty Registers (AR) worldwide have taken a prominent position in the evaluation of implants and techniques. Still, the interpretation and comparison of their data remains a complex undertaking.



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crucial when making survivorship comparisons between subgroups of implants used more frequently in younger or older patients. Finally, the emphasis lies primarily on implant surveillance, while surgical and hospital experience and care are equally as important determinants of outcome.

Despite these flaws, AR undoubtedly have a positive impact on JR practice. By pointing out inferior outcomes and their reasons, Swedish Registers have led to a reduction of the revision burden by more than 50%, which is associated with annual savings of 12 million euros for the health-care system [2]. Early detection of inferior products such as certain low-viscosity cement brands or inferior survivorship of designs such as the ASR have led to early market withdrawal [3, 4]. Recently, several AR have added in-depth analyses regarding implant designs with higher-than-expected revision rates, the effect of patient factors, and the importance of hospital and surgeons' skills and experience [5–8]. The influences of implant characteristics including modularity, material, bearing couple, and component size on short-term complications such as dislocation and on long-term survival have been highlighted [6]. Conclusions from all these reports have significantly improved JR surgery.

According to the EFORT European AR, the definition of an AR is the registration in a central database of all primary and revision arthroplasties in a defined geographical area [1]. The implant is followed until it has to be revised or the patient dies or emigrates. Failure is defined as revision of at least part of the implant by removal, addition, or exchange of implant component(s) [1].

### Tasks and impact of AR

This definition carries the flaws of AR in itself. First of all, an AR refers to a defined geographical area, usually a single country, reflecting the standards and preferences of the (public) health system, surgical procedures, and product designations. Second, the quality and conclusiveness of the data depend heavily on the completeness and the correctness of the registration. Third, collaboration with migration and mortality databases is not self-evident but may be

### Problems and limitations of AR interpretation

Registry data on revision rates focus primarily on implants and not usually on correct indications, techniques, or experience, which may have a greater influence on survival rates. This may lead to in-

consistencies between different AR. The same implant may have a significantly higher revision rate in a country where it is used by many low-volume surgeons when compared with another country where only a few high-volume surgeons implant it [9]. Other problems include ambiguous product designation with similar names referring to different designs, making an unequivocal evaluation impossible [10].

Methods of defining and reporting revisions also differ between AR [6]. In some, a simple superficial re-intervention without component exchange or removal is considered a revision, while others report revision rates for component combinations, such as a hip cup-and-stem combination, instead of separate revision rates, even if only one component was revised. Kaplan-Meier statistics may be plotted as cumulative revision rates or as survival rates, but some AR prefer to use hazard ratios or revisions per 100 observed component years. The latter method provides an objective failure assessment even in the short term but does not show a possible change in revision rate over time.

The most important limitation of AR is that their main measure of effectiveness is the time to first revision of the implant, which is a rough and incomplete evaluation of performance [9]. This approach disfavors less-invasive procedures such as unicompartmental knee arthroplasty and hip resurfacing with a lower revision threshold, despite better patient-reported outcomes [11]. Recently, some AR have started collecting PROM to overcome this bias, but confounding factors remain difficult to account for [12]. Badly performing implant designs may have a deleterious effect on the global survivorship of a certain arthroplasty method. In the case of hip resurfacing, contrary to the predictions following failure of certain brands, AR are now reporting excellent 10-year survivorship data of the BHR in young and active males [6, 13]. It is expected that restriction of hip resurfacing to centers of excellence and narrowed indications will lead to even better results in the future. AR have certainly played a role in this evolution. Similarly, AR are confirming improved survival rates of cross-linked (XL) PE compared with conventional PE and decreased fracture rates of mixed ceramics (Al-Zr) compared with pure Al ceramics, both with excellent longer-term survival [6]. However, the same materials, such as oxidized Zr, may perform inconsistently in different prostheses or designs. For TKA, it is still controversial whether or not XLPE should be advocated.

## Conclusions and future perspectives

AR provide high-quality information on implant survival, as they refer to whole populations and decrease the bias of publications of specific series.

Both the impact of multiple simultaneous determinants and the effect of changes in JR practice are assessed [14]. Surgeons should use the reports from their own country's AR to evaluate and adjust their own performance.

Although AR make an essential contribution to advances in arthroplasty, their data depend on the local situation. Extrapolations are valid only after cross-evaluations with other AR and clinical studies have been done. Harmonization of data collection, analysis, and interpretation of AR via supranational coordination will facilitate the comparison and pooling of conclusions [15]. In addition, AR compile a wealth of information that should be exploited scientifically. ■

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# Reduced Risk of Revision for Infection for Total Hip Arthroplasty with a Ceramic Bearing Surface

An Assessment of 177,237 Procedures from the Australian Orthopaedic Association National Joint Replacement Registry

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**This analysis of 177,237 primary total hip arthroplasty procedures from the Australian Registry (AOANJRR) was performed to determine whether revision for infection varied depending on the type of bearing surface used. Three bearings – ceramic on ceramic (CoC), ceramic on highly cross-linked polyethylene (CoXP), and metal on highly cross-linked polyethylene (MoXP) – were compared. Patients aged 70 years or less had a lower revision rate for infection when a CoC bearing was used. This difference was independent of gender, and prostheses selection. No difference was evident if the femoral component was cemented or if a head size of 28 mm was used.**

Periprosthetic joint infection (PJI) remains a serious complication following primary total hip arthroplasty (THA). Many factors, including primary diagnosis, comorbidities, and duration of procedure, are known to influence the rate of infection [1–3]. Although the association between patient and surgical factors is increasingly well understood, little is known about the role of the prosthesis. PJI is caused by the attachment of the infecting organism to the implant surface and the subsequent formation of biofilm [4]. Thus, it would be expected that the affinity of different pathogens to attach onto different biomaterials surfaces would vary.

A recent international consensus study based on the available medical literature concluded that the incidence of PJI does not differ between cemented (without antibiotics) and uncemented arthroplasty components, nor does the presence of hydroxyapatite influence the incidence of infection [5]. The study also concluded that the incidence of PJI is higher following the use of a metal-on-metal (MoM) bearing [5]. However, the relationship between the use of other bearing surface materials in THA and PJI is still unknown. The importance of registry data

in providing valuable information about issues related to the bearing surface has been emphasized [6].

The aim of the current study was to analyze data from the AOANJRR to determine whether revision for infection varied according to the bearing surface used during primary THA.

## Materials and Methods

The AOANJRR started collecting data in 1999 and includes data on more than 98 % of the arthroplasty procedures performed in Australia since 2002 [7]. Registry data are validated against patient-level data provided by each of the state and territory health departments in Australia using a sequential, multilevel process of matching. The matching program is used on a monthly basis to search for all primary and revision arthroplasty procedures recorded in the registry that involve the same side and joint of the same patient, thus enabling each revision to be linked to the primary procedure. Data are also matched biannually with the National Death Index of the Department of Health and Ageing to obtain information about the date of death. The registry also records the reasons for revision and the type of revision THA.

Three different bearing surfaces were compared: CoC, CoXP, and MoXP. The study population included all primary THA procedures undertaken for osteoarthritis using these bearing surfaces and reported to the AOANJRR over a 14-year period (between 1999 and 2013).

Kaplan-Meier survivorship curves were compiled with revision for infection as the end point. Hazard

Bearing surface	Revised [n]	Total [n]	Observation time [years]	Revisions / 100 Observation years (95% CI)
CoC	253	57,839	276,435	0.09 (0.08; 0.10)
CoXP	130	24,269	86,334	0.15 (0.13; 0.18)
MoXP	536	95,129	425,417	0.13 (0.12; 0.14)
<b>Total</b>	<b>919</b>	<b>177,237</b>	<b>788,186</b>	<b>0.12 (0.11; 0.12)</b>

**Table 1:** Revision rates for infection of primary total hip arthroplasty by bearing surface

ratios (HR) from Cox proportional-hazards models were used to compare revision rates between the three groups. A sub-analysis examining the effects of age, gender, fixation of the femoral stem, and femoral head size was also performed. To ensure that there was no confounding due to differences in femoral and acetabular component selection, a further analysis was undertaken, which compared the three different bearings with the same stem and acetabular component combinations. Statistical analysis was performed using SAS software version 9.3.

## Results

During the study period there were 177,237 primary THA procedures reported to the registry that met the inclusion criteria (57,839 CoC, 24,269 CoXP and 95,129 MoXP) (Table 1). When all procedures were included it was found that both MoXP and CoXP had higher revision rates for infection compared with CoC (HR 1.46 [1.25, 1.72],  $p < 0.001$  and HR 1.42 [1.15; 1.75]  $p = 0.001$ , respectively) (Fig. 1). There was no difference in the revision rate for infection when MoXP and CoXP were compared (HR 0.97 [0.80, 1.18],  $p = 0.742$ ).

Of the 57,839 CoC hips, 27,753 hips were zirconia-toughened alumina ceramic-on-ceramic (DoD). The revision rates for infection for both MoXP and CoXP were also higher than for this DoD subgroup (HR 1.56 [1.24; 1.95],  $p < 0.001$  and HR 1.47 [1.13; 1.92]  $p = 0.004$ , respectively).

There was an age variation, with the observed lower revision rate for infection in CoC hips being evident for patients aged 70 years or younger but not for patients older than 70 years (Fig. 2a, b). Both men and women had a lower revision rate when CoC was used. Interestingly, the difference was evident when a cementless femoral stem was used but not when the stem was cemented. The differ-

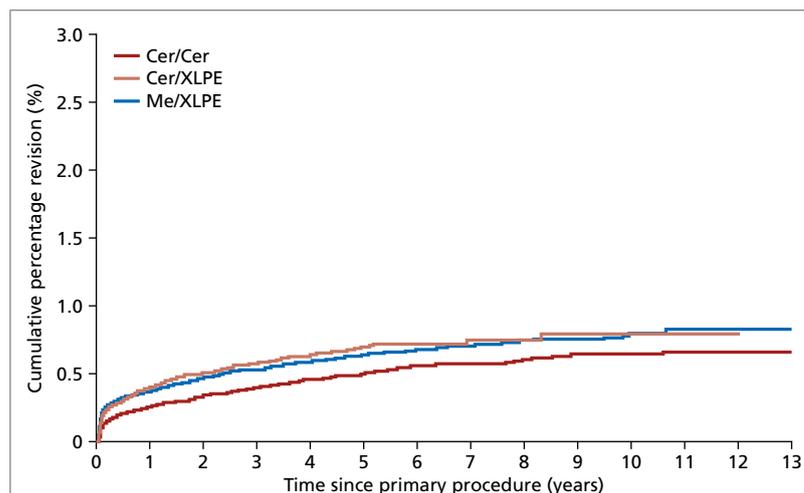


Figure 1: Cumulative percent revision for infection of primary total hip arthroplasty by bearing surface over a period of 13 years from index surgery

ence was also evident for most head sizes (32 mm or larger), with the exception of 28-mm heads. The CoC hips also had a lower revision rate for infection when the same femoral stem and acetabular component combinations were compared with regard to the three bearing surfaces.

## Discussion and Conclusion

This registry study aimed to determine whether revision for infection varies according to the bearing surface used during primary total hip arthroplasty. The results showed that patients aged 70 years or younger have a significantly lower rate of infection when a CoC bearing is used when compared with both CoXP and MoXP bearings. This difference was independent of gender and of femoral as well as acetabular component selection. The difference also remained significant for a subset of patients with a modern DoD ceramic bearing. However, no difference was observed for cemented femoral components or for hips with a small femoral component head size of 28 mm.

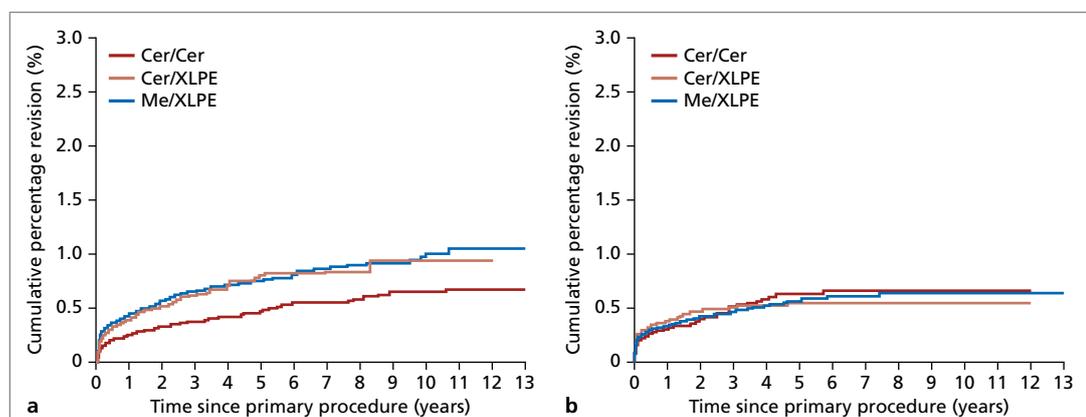


Figure 2: Cumulative percent revision for infection of primary total hip arthroplasty by bearing surface, stratified by age  $\leq 70$  years (a) and  $> 70$  years (b)

The use of a MoM bearing surface has been associated with a higher incidence of PJI [8]. Some possible reasons for this are the high incidence of adverse local tissue reactions and associated soft tissue destruction, which may provide a favorable environment for bacterial growth [9]. There is also some evidence that the metal particles generated by MoM bearings may also increase the risk of PJI by modulating the host immune system and bacterial growth [10]. Yet there are few data on the differences in the risk of PJI for other bearing surfaces in the literature. A recent paper from the New Zealand Joint Registry reported a trend for lower rates of revision for infection in CoC hips [11].

The incidence of revision for infection was not reduced for patients older than 70 years with a CoC bearing. This finding may be due to other risk factors for PJI associated with comorbidities in this older patient group. The reduced incidence of revision for PJI was not evident when small head sizes (28mm) were used. Wear particles released from the bearing and taper junction may explain this [12]. Ceramic particles are known to be very bio-tolerant, whereas corrosion products of metal particles can cause substantial tissue damage. Large head sizes are associated with a higher risk of mechanically assisted crevice corrosion as a consequence of high torque conditions at the taper junction. Furthermore, ceramic heads have been shown to be associated with less corrosion than CoCr heads [13]. Larger head sizes are also associated with larger vol-

umetric wear of highly XPE. Thus, these issues may not be as relevant for small head sizes, as observed in the current study. Finally, the lack of observed differences for cemented femoral components may be due to the confounding effect of antibiotic use in cement. Almost all cements used in Australia contain antibiotics, which could overshadow protective effects of a superior bearing surface regarding wear and corrosion.

This study had some limitations. The possible impact of medical comorbidities on the rate of revision for infection was not assessed. However, the study did account for confounders such as age, component head size, gender, stem type, and fixation. Furthermore, the significance of the findings was further reinforced by similar lower rates of revision for infection in the sub-cohort of patients with DoD ceramic bearings. To our knowledge, this is the largest study to date comparing the rates of revision for infection for different bearing surfaces. In addition to the large number of procedures, the use of population-based data and the long-term follow-up are noteworthy strengths of the current study.

The use of a CoC bearing is associated with a lower risk of revision for infection in patients younger than 70 years but not for small head sizes or cemented femoral components. Data from other registries, together with laboratory studies assessing the role of bearing surface in bacterial adhesion and host defenses, will be valuable in confirming and further appreciating these findings. ■



**Prof. Stephen E Graves** is an orthopaedic surgeon. He qualified in 1988 and received a DPhil from Oxford University in 1991. He is director of the Australian Orthopaedic Association National Joint Replacement Registry, which he established in 1999. He is a founding member and the inaugural president of the International Society of Arthroplasty Registers. He remains on the executive board of that society.

Graves is a member of numerous professional organisations, including the International Hip Society, and an honorary member of the British Hip Society. He is chair and / or member of a number of Australian government committees related to the regulation and pricing of prostheses as well as health-care delivery. He advises governments and regulatory authorities around the world, including the FDA, on health-care monitoring, particularly in relation to the use of registries.

He runs a number of major research projects both in Australia and internationally. He has received over 30 million US dollars funding support in the past 10 years.

He has presented and published extensively on the outcomes of joint replacement surgery and basic musculoskeletal biology.

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He received his Bachelor of Science from Rensselaer Polytechnic Institute in Materials Science and completed his doctoral work at the Massachusetts Institute of Technology in the Program for Polymer Science and Technology.

Prof. Muratoglu played a key role in the discovery of highly cross-linked UHMWPE, a more wear-resistant polymeric material for load-bearing applications in total joints. He also pioneered the use of the antioxidant vitamin E to further stabilize the highly cross-linked UHMWPE. Prof. Muratoglu continues his research on UHMWPE and cartilage repair using hydrogels. He also directs research in the design of more functional joint implants at the TIRC.



**Prof. Henrik Malchau**, is an orthopedic surgeon trained at Sahlgrenska University Hospital in Gothenburg, Sweden. With Peter Herberts as mentor, he became involved in the Swedish Hip Arthroplasty Register, where he also had a leadership role for many years. He has acted as advisor for setting up registries in Australia, Canada, New Zealand, England and USA. Parallel to this he was also engaged in radiostereometric analysis (RSA) in THA. His PhD thesis on the "Importance of Stepwise Introduction of New Hip Implant Technology", was completed in 1995.

In 2000–2001 he was invited as visiting professor and guest researcher at the Harvard Medical School (HMS) and the Harris Laboratory, at Massachusetts General Hospital (MGH). That year led to a position as attending surgeon at MGH and also as co-director at the Harris Orthopedic Laboratory, a joint position with Orhun Muratoglu. During 10 years in these positions Malchau continued his efforts to improve the evidence base for new total joint implants by the use of RSA and registries.

Malchau was recognized for his efforts with an appointment as full professor at HMS and was also granted the Alan Gerry chair. He has published 200 peer-reviewed papers, been presidential guest lecturer at the US Hip Society twice, and received three Hip Society awards. He was a co-founder of the International Society for Arthroplasty Registries, is president-elect of the International Hip Society, and is an honorary fellow of the British Hip Society. He has received several other awards as well.

## Ceramic Bearings Improve Outcomes in Revision total Hip Arthroplasty

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We investigated the utilization and outcomes of ceramic bearings for revision total hip arthroplasty (R-THA). Administrative data were analyzed from a total of 31,809 elderly Medicare patients (65+) who underwent R-THA between 2005 and 2013 with known bearing types using the Medicare 100% inpatient sample. The results indicate that, after adjusting for selection bias and various confounding patient-, surgeon-, and hospital-related factors, Medicare patients treated in a revision scenario with ceramic bearings exhibit at least similar, and in some cases, improved risk of rerevision, dislocation, infection, or mortality as those treated with MoP bearings.

### Level of Evidence: Level III, retrospective comparative study

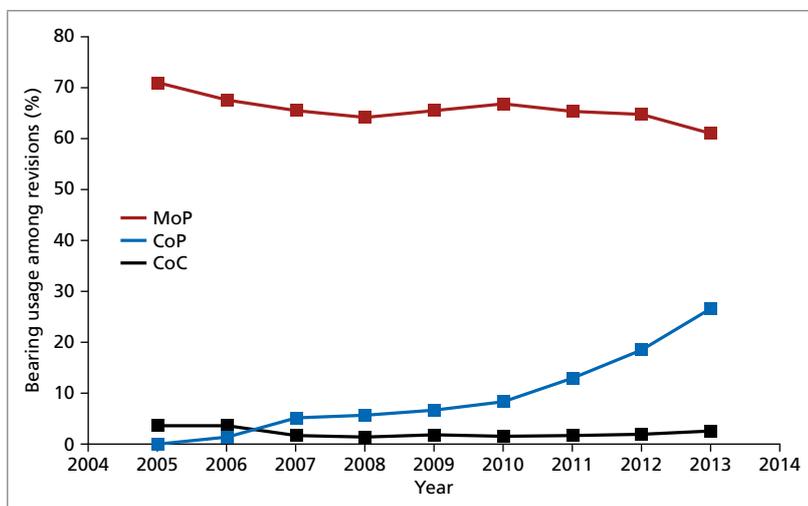
Currently over 50,000 revision total hip procedures are performed annually in the United States, and the demand for revisions is projected to increase in the coming decade, especially among younger patients [1–3]. Ceramic bearings have a long clinical history in primary total hip replacement, and many published studies and international registries have documented successful long-term survivorship of these implants. However, less is known about the utilization and outcomes for patients treated with ceramic bearings during revision surgery. Our group's recent research using the 100% Medicare database, presented at the 2015 ISTA meeting in Vienna [4], found that Medicare patients treated

in a revision scenario with ceramic bearings exhibit similar risk of rerevision, infection, or mortality as those treated with metal-on-polyethylene (MoP) bearings. We also found an association between the use of specific ceramic bearings in R-THA and reduced risk of readmission (ceramic-on-polyethylene, CoP) and dislocation (ceramic-on-ceramic, CoC).

Aside from case reports and review articles, relatively few studies have previously been published exploring outcomes of ceramic bearings in revision THA [5–12]. Previous studies focused on revision outcomes during special circumstances, such as revision after ceramic fracture [7, 12]; revision in patients with osteolysis [8]; or revision after failed metal-on-metal (MoM) hip arthroplasty [5]. As the demand for revision surgery is expected to increase, there has been interest in studying revision surgery outcomes for ceramic bearings in the general patient population [6, 9, 11]. For these reasons we sought to explore the utilization and outcomes of ceramic bearings in revision total hip arthroplasty (R-THA) for the US Medicare population.

### Methods

We used the 100% Medicare inpatient sample administrative database to identify 31,809 Medicare patients who underwent R-THA between 2005 and 2013 with known bearing types. The relative usage of ceramic bearings varied over this time period, coinciding with the decrease in popularity of MoM bearings due to reports of adverse local tissue reactions to metal debris [13] (Fig. 1). The usage of both CoP and CoC bearings in revision surgery increased



**Figure 1:** Reported bearing usage in revision total hip arthroplasty in the U.S. Medicare population between 2005 and 2013 (percentage of all patients with revision codes)

substantially during this time period to 26.6 % and 2.5 %, respectively, in 2013.

We used Cox regression incorporating propensity score stratification to evaluate the impact of bearing surface selection on outcomes, after adjusting for patient-, hospital-, and surgeon-related factors. We used a propensity score approach to adjust for surgeon bias in the selection of bearing types, because usually ceramic bearings are favored in younger, more active patients. By incorporating propensity scores into our statistical analysis, we accounted for surgeon preferences in assigning bearings to patients in the Medicare population. This allows for one of the most rigorous comparisons between patient cohorts treated with ceramic bearings and those with MoP bearings.

## Results

For R-THA patients treated with CoP bearings, there was reduced risk of 90-day readmission (Hazard Ratio, HR 0.90 [95 % CI: 0.84–0.96];  $p=0.007$ ). We also observed a trend for reduced risk of infection with CoP (HR 0.88 [95 % CI: 0.74–1.04]) that did not reach statistical significance ( $p=0.14$ ). For R-THA patients treated with CoC, there was reduced risk of dislocation (HR 0.76 [95 % CI: 0.58–0.99];  $p=0.04$ ). There was no significant difference in risk of re-revision or mortality for either the CoP or CoC bearing cohorts when compared with MoP.

## Discussion and Conclusions

In this study of all comers for revision total hip surgery in the elderly Medicare population, we asked how the use of ceramic bearings changed over time and whether the type of ceramic bearing influenced outcomes relative to MoP. Between 2006 and 2013, we observed an increase in the reported usage of CoP bearings in revision surgeries for Medicare beneficiaries. We found no evidence to suggest that ceramic bearings were associated with worse outcomes than MoP when used in revisions. Conversely, we found support for our hypotheses that ceramic bearings may improve certain outcomes after revision surgery, such as 90-day readmission, dislocation, and perhaps infection; however the results were bearing- and outcome-specific. The findings of

this study support further research into the association between ceramic bearings in R-THA and lower risk of hospital readmission, dislocation, and, potentially, infection. ■

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## Delta Ceramic Femoral Component – Safe and Efficient

Successful clinical use in a five-year follow-up

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The use of ceramic bearings such as CoC or CoP in total hip replacements is currently state of the art [12]. The worldwide experience and evaluations in clinical and experimental studies underline the advantages of ceramics: their high chemical and mechanical stability, their extreme resistance to wear and corrosion due to the lack of an electrochemical reaction, and their excellent tribology [3]. The use of ceramic components in total knee replacement (TKR) is less common. However, material advantages of the ceramics should also be expected in TKR. The wear of PE can be reduced up to 4–5 times with CoP bearings in TKR in comparison to MoP due to the low friction of ceramic surfaces [4, 5]. Particle-induced aseptic loosening and hypersensitivity to implant materials (e.g., chromium, cobalt and nickel) is still an issue for implant failure and can be a cause for knee revision [6–8]. A composite ceramic material (BioloX<sup>®</sup>delta) represents a promising solution for patients with allergies to metallic implant materials and an alternative bio-inert material [9]. This all meets the demands for application in TKR. The two-year follow-up of the Multigen Plus Ceramic Knee showed good clinical and radiological results as well as no adverse outcomes [10]. In addition a prospective short-term study compared the short-term outcome of the TKR system with those of two metallic TKR systems and demonstrated comparable clinical and radiological results two years postoperatively [11]. The aim of the international prospective multicenter study was to evaluate clinical and radiological outcomes as well as survival of the ceramic knee at mid-term (5-year) postoperative follow-up [12].

### Materials and Methods

The Multigen-Plus Ceramic Knee (Lima Corporate, Villanova di San Daniele del Friuli, Italy) is a cemented posterior cruciate ligament retaining and symmetric femoral component that consists of composite ceramic material (BioloX<sup>®</sup>delta). A fixed-bearing ultra-high-molecular-weight polyethylene (UHMWPE)

articulating surface is combined with a cemented metal (TiAl6V4) tibial tray (Fig. 1). The usage of an all-polyethylene-tibia is optional.

### Study group

The inclusion criterion for the international prospective multicenter study was the indication for primary TKA due to primary osteoarthritis or rheumatoid arthritis. Contraindications were age >75 years, BMI >33 kg/m<sup>2</sup>, severe instability or deformity without the possibility for a stable surface replacement, any kind of infection, severe osteoporosis, and previous tumors. Post-traumatic osteoarthritis and contralateral TKA or joint replacement of the operated limb within one year were determined as further contraindications for enrollment [13]. Also excluded from the study were patients with severe chronic and progressive diseases, patients with neurosensory or neuromotor deficits, hemophilic patients, and patients with known incompatibility or allergy to the used products.

A patient group of 107 (109 knees) underwent TKR with the Multigen-Plus Ceramic Knee in combination with a cemented titanium tibial tray at seven



**Figure 1:** Multigen-Plus knee with delta ceramic femoral component

centers in three countries (3 in Germany, 3 in Italy, and 1 in Spain) [14]. Clinical and radiological evaluations were carried out preoperatively and postoperatively at 3, 12, 24, and 60 months, using HSS, WOMAC-Score, SF-36 and standardized radiographs.

### Intra- and postoperative management

At each center one or two experienced orthopedic surgeons used the standard surgical procedure and the Payr approach for patient surgery. All surgeons had adequate experience with the identical metallic femoral component of the Multigen-Plus Knee System. Therefore the learning curve was reduced. Shaping of the patella and optimal gap balancing were obligatory in all cases. All components were cemented with high-viscosity bone cement. Postoperative procedure was standardized, beginning on the second postoperative day after drain removal with free range of motion and full weight bearing with two crutches [14].

### Clinical and radiological evaluation of the patients

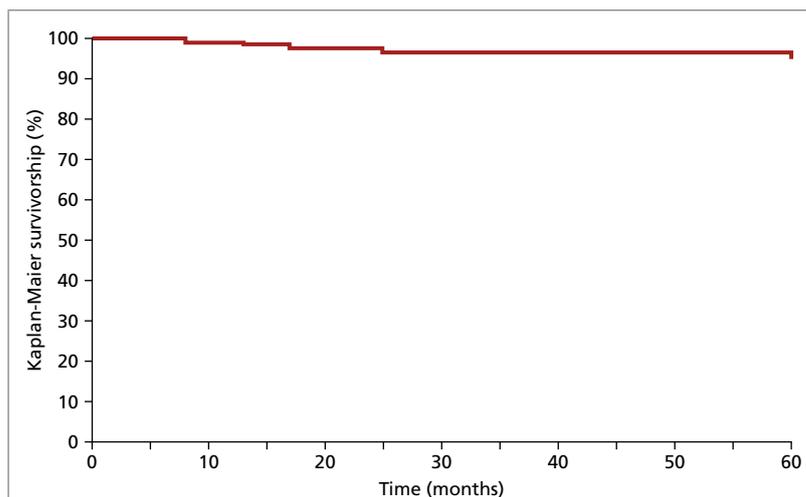
Using HSS, WOMAC, and SF-36 the clinical evaluations were carried out preoperatively and at 3, 12, 24, and 60 months postoperatively. Standard anterior-posterior (a.p.) and lateral radiographs were taken preoperatively and on the fifth day after surgery and at each follow-up. In accordance with the "Knee Society Roentgenographic Evaluation and Scoring System", radiolucent lines, osteolysis and implant positioning were evaluated by one independent observer [15].

### Statistical analysis

The statistical analysis included means and standard deviations (SD) of continuous variables, frequencies and relative frequencies of categorical factors. Presented were the intervals mean and range variables. Using the ANOVA F-test with cluster sandwich (Huber-White), variance-covariance estimator comparisons between the different time-points of clinical and radiological evaluations were performed. Values of  $p < 0.05$  were considered to be statistically significant. Kaplan-Meier survival analysis was performed using the revision of the ceramic femoral component as the end point, with a 95% confidence interval (CI) (Fig. 2).

### Results

Mean HSS and WOMAC increased significantly, from  $55.1 \pm 11.5$  (21–83) and  $48.1 \pm 16.6$  (3–90) preoperatively to  $85.6 \pm 9.6$  (49–98) and  $73.3 \pm 20.4$  (17–100), respectively, at 60 months (Fig. 3). Mean SF-36 showed significant improvements in patients'

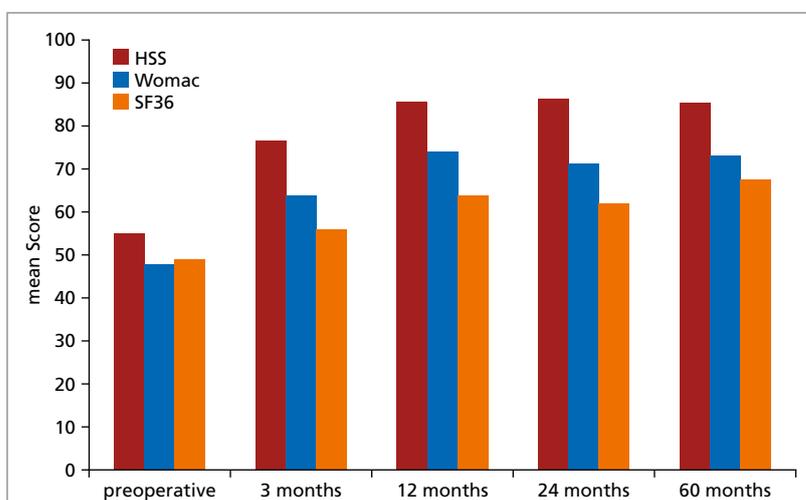


**Figure 2:** Kaplan-Meier survival curve (with 95% confidence interval): end-point revision of the ceramic femoral component

quality of life ( $49.1 \pm 17.6$ ) (12–96) preoperatively versus  $67.7 \pm 23.1$  (12–100) at 60 months [12]. Overall, in terms of HSS, the results were "excellent" in 64% of the cases, "good" in 30%, "fair" in 4% and "poor" in 2% at a mean follow-up of 49 months. Four cases (5.1%) showed radiolucent lines around the ceramic femoral component.

### Discussion

Survival of implants was reported as 94% at a mean follow-up of 5.8 years for alumina ceramic and between 97.4 and 100% at 5–10 years for oxidized zirconium femoral components [17–19]. Radiolucent lines are described in 3.6–35.7% of cases with follow-ups between 4 and 13.5 years [20–25]. Thus, the Multigen-Plus Ceramic Knee has demonstrated clinical and functional outcomes and survival comparable to those of other metallic and ceramic TKA at mid-term follow-up [26]. Furthermore, an experimental study evaluated the wear of tibial UHMWPE inserts of an unconstrained TKA system with metallic and ceramic femoral components under third-body



**Figure 3:** Mean HSS-, WOMAC and SF-36-Score to all time-points of evaluation

wear conditions initiated by bone cement particles containing zirconium oxide. The wear simulation tests demonstrated that the wear of polyethylene inserts using ceramic femoral components was lower under third-body wear conditions. This should be taken into account for two-stage septic revisions using bone cement interim spacer [28].

In summary, ceramic knee implants represent a promising solution not only for patients with allergies to metallic components, but also for the general patient population [27]. Considering its excellent friction properties, and therefore increased wear resistance – both in general and in the presence of third-body wear particles, ceramic is a favorable material for femoral components of TKA, providing good biocompatibility and non-allergic implant material properties [28]. Long-term studies are recommended to confirm the positive mid-term clinical results and implant survival rate.

### Key messages

- The five-year implant survival rate of the ceramic knee is comparable to those of other metallic and ceramic unconstrained TKA systems.
- Neither migration nor loosening of femoral and tibial implant components were observed.
- The ceramic implants represent a promising solution for patients with allergies to metallic components
- The ceramic implants demonstrate high wear resistance, especially to third-body abrasive wear. ■

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During this time, Bergschmidt also moved ahead with his academic career: In 2008 he was awarded a doctorate from the University of Rostock, and in 2013 he wrote his postdoctoral thesis in orthopedics and trauma surgery on the subject of "Preclinical and clinical testing of a bicondylar knee endoprosthesis with a new type of ceramic femoral component". In the same year, Bergschmidt completed his training as a specialist for orthopedics and trauma surgery. He received the *venia legendi* (permission to teach as a private lecturer) for orthopedics and trauma surgery from the University of Medicine of Rostock in 2014.

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## ACRONYMS

<b>AAOS</b>	American Academy of Orthopaedic Surgeons	<b>FDA</b>	Food and Drug Administration
<b>ANSM</b>	Agence National de Sécurité du Médicament et des Produits de Santé; French National Agency for Safety of Drugs and Medical Products	<b>HR</b>	Hazard Ratio
<b>AOANJRR</b>	Australian Orthopaedic Association on National Joint Replacement Registry	<b>ISAR</b>	International Society of Arthroplasty Registries
<b>AR</b>	Arthroplasty Register	<b>MGH</b>	Massachusetts General Hospital
<b>BHR</b>	Birmingham Hip Replacement	<b>MoM</b>	Metal-on-Metal
<b>BMI</b>	Body Mass Index	<b>MoP</b>	Metal-on-Polyethylene
<b>Co</b>	Cobalt	<b>PE</b>	Polyethylene
<b>CoC</b>	Ceramic-on-Ceramic	<b>PJI</b>	Periprosthetic Joint Infection
<b>CoCr</b>	Cobalt-Chromium	<b>PROM</b>	Patient Reported Outcome Measures
<b>CoP</b>	Ceramic-on-Polyethylene	<b>R-THA</b>	Revision Total Hip Arthroplasty
<b>Cr</b>	Chromium	<b>RIPO</b>	Registro dell'implantologia Protesica Ortopedica; Register of Orthopaedic Prosthetic Implants in the Region of Emilia Romagna
<b>DGOOC</b>	German Society of Orthopedics and Orthopedic Surgery	<b>RSA</b>	Radiostereometric Analysis
<b>DGU</b>	German Association of Trauma Surgery	<b>THA</b>	Total Hip Arthroplasty
<b>DoD</b>	Delta-on-Delta	<b>TKA</b>	Total Knee Arthroplasty
<b>EFORT</b>	European Federation of Orthopaedics and Traumatology	<b>TIRC</b>	Technology Implementation Research Center
		<b>X(L)PE</b>	Cross-linked Polyethylene



# Supra-macroparticulate PE Resulting from Abnormal Mechanical Loading of Hip Joint Endoprostheses

New PE wear particle type, detected macroscopically and microscopically

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In the diagnostics of joint prosthesis malfunction, histopathology is an important tool. Identification of particulate prosthetic material components [3, 6, 24, 25, 29, 33] and diagnostic evaluation of inflammatory changes in the synovial-like interface membrane (SLIM) combined with microbiological, biomechanical, imaging, and clinical data allow clarification of the underlying cause [22, 24, 33, 26]. In this article we describe a polyethylene (PE) particle with a previously unreported size and type of localization and presentation and suggest the name "supra-macroparticulate PE" or "PE vacuole". Regarding the PE particle size, various sizes depending on the method are indicated in the literature with a focus on micro PE particles of several micrometers [4, 7, 11, 18, 20, 21, 23, 27, 42, 46]. A PE particle size of more than 1,000 µm has not been reported, or has not been systematically described, in hip joint endoprostheses to date [36, 25].

## Ethics approval

The study is approved by the ethics committee of the regional medical association Landesärztekammer Rheinland-Pfalz (nr. 837.230.15; 9998).

## Study design

Level of Evidence: 3b

### Histopathological diagnostics

The histopathological and immunohistochemical diagnostics were carried out under accredited condi-

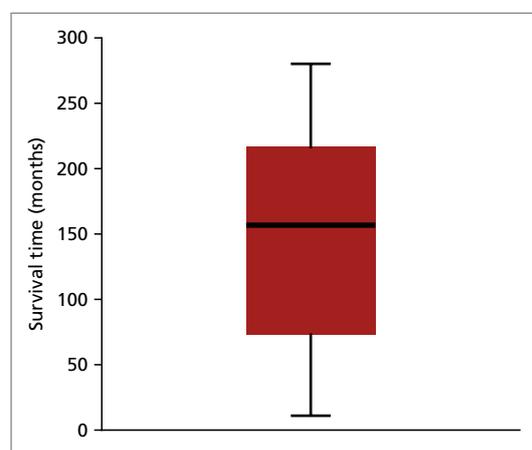
tions (DIN EN ISO/IEC 17020) in the Center for Histology, Cytology and Molecular Diagnostics (ZHZMD Trier, Germany). No additional staining and/or further processing steps were done that are not part of the diagnostic algorithm. The classification and typing of the synovial membrane/SLIM and the particle characterization were carried out in accordance with the SLIM consensus classification and the particle algorithm.

### Exclusion criteria

Cases with two or more joint endoprosthesis revisions, cases of bacterial infections, and cases with prior radiation synovectomy were not included in the analysis.

### Inclusion criteria

As part of the routine histopathological diagnostics in a diagnostic center operating throughout Germany that focuses on orthopedic pathology (ZHZMD Trier, Germany), peri-implant tissue or synovial membrane (SLIM) samples removed during revision procedures were diagnostically evaluated to identify the cause of endoprosthesis failure. Histopathological diagnostics were done in accordance with the SLIM consensus classification and the particle algorithm [24, 25, 33]. To further specify the PE particles with abnormal sizes, only SLIM type I cases were considered. Information about the material combinations, survival rate, and intraoperative find-



**Figure 1:** Boxplot concerning survival time in months in hip cases with supra-macroparticulate polyethylene

ings were available for all the hip joint endoprostheses (Table 1).

### **HE staining, Prussian blue reaction, PAS staining, and oil red O staining**

The HE and PAS staining and the Prussian blue reaction were completely automated using the Leica ST 4040 staining module. The oil red O staining was done manually in accordance with the published staining protocol [18, 25].

### **Polyethylene particle (PE) determination**

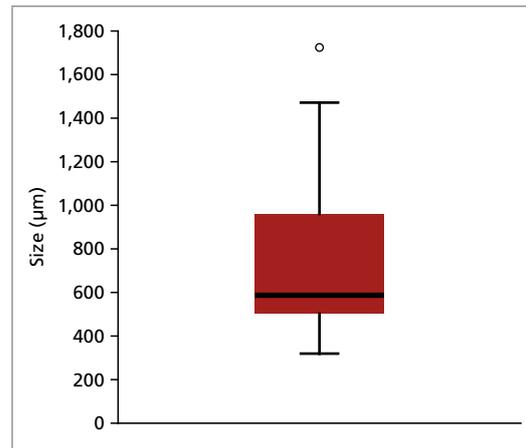
The characteristic optical polarization property and the staining behavior in the oil red O staining are described in the literature and defined as classifying criteria for particle identification in the particle algorithm [18, 27, 25, 36].

### **Particle size definitions according to the particle algorithm**

The particle algorithm suggests differentiating between microparticles (phagocytized in macrophages,  $\leq 5 \mu\text{m}$ ) and macroparticles (phagocytized in multinucleated giant cells,  $\leq 100 \mu\text{m}$ ) [25].

### **Micromorphometric determination of the size of the PE particles**

The particle sizes were determined using a computer-aided interactive morphometric analysis (Leica DM 2500, Leica Application Suite V4.7.1). This also allowed the size of those particles with a non-linear structure to be determined. The lengths of 2–5 of the largest PE particles or vacuoles were determined.



**Figure 2:** Boxplot concerning length of supra-macroparticulate PE

### **Macroscopic re-evaluation of the paraffin block material**

If large crevice-shaped cavities ( $\geq 1,000 \mu\text{m}$ ) corresponding to the shape of the PE particles that appeared to be completely empty were seen in the microscopic analysis, the surface of the paraffin block material was subsequently re-evaluated macroscopically by preparing a scanning image (Epson, perfection, v 200 Photo) in order to directly identify PE macroparticles.

### **Statistical methods**

The prosthesis survival rates and the micromorphometric data for the PE particle length were statistically analyzed using SPSS 17 (IBM, SPSS, Chicago, USA). Box plots were prepared.

Sex	Intraoperative findings	Localization	PE particles, mean length [ $\mu\text{m}$ / mm]		Survival time [months / years]	
			$\mu\text{m}$	mm	months	years
F	Recurrent dislocation	Hip	1,470	1.470	72	6
F	Polyethylene wear	Hip	320	0.320	156	13
M	Large-scale acetabular loosening	Hip	531	0.531	216	16
F	Acetabular roof loosening	Hip	525	0.525	12	1
F	Fracture	Hip	663	0.663	120	10
M	Acetabular loosening	Hip	838	0.838	168	14
F	Mechanical complication	Hip	958	0.958	24	2
F	PE inlay wear	Hip	435	0.435	240	20
M	Acetabular loosening	Hip	594	0.594	144	12
M	Acetabular loosening	Hip	353	0.353	60	5
M	Acetabular loosening	Hip	1,726	1.726	264	22
M	Acetabular loosening	Hip	1,023	1.023	279	23.25
F	Acetabular loosening	Hip	504	0.504	168	14

**Table 1:** Included cases with supra-macroparticulate polyethylene

## Results

### Prosthesis survival rate

The mean hip joint survival time was 147 months (Fig. 1, Table 1), with the shortest survival time being 12 months and the longest 276 months.

### Supra-macroparticulate PE

The particles ranged in size from more than 100  $\mu\text{m}$  to more than one mm (maximum value: 1,910  $\mu\text{m}$ ). The mean had a minimum value of 320  $\mu\text{m}$  and a maximum value of 1,726  $\mu\text{m}$  (Fig. 1, Table 1). PE supra-macroparticles were detected in all cases ( $n=13$ ) (Fig. 2, 3 and 4). The shape of the supra-macroparticulate PE was variable, with long, slightly curved and even polygonal particles present in some cases (Fig. 3, 4).

### PE vacuoles: Completely dissolved supra-macroparticulate PE

The analysis revealed in some cases large ( $\geq 1,000 \mu\text{m}$ ), visually empty crevice-shaped cavities corresponding to the shape of the PE particles that were directly adjacent to the supra-macroparticulate PE ( $n=3$ ). The margins of the cavity were made up of fibroblasts, histiocytes, and multinucleated cells (Fig. 5a). The fibroblasts in particular were aligned along the surface (polar orientation). The name "PE vacuole" is suggested for the completely dissolved supra-macroparticulate PE. The PE vacuoles have a length of up to several millimeters.

Macroscopic re-evaluation of the paraffin block material containing microscopically verified PE vacuoles. The paraffin block material from cases with microscopically verified large PE vacuoles ( $\geq 1,000 \mu\text{m}$ ) was subsequently re-evaluated macroscopically, and in all cases ( $n=3$ ) macroscopically light and whitish-colored particles (Fig. 5b) with a length of up to about 2 mm were detectable on the surface of

the preparation, in the tissue in the paraffin block material (with the area corresponding to the HE section). The supra-macroparticulate PE (PE vacuole, Fig. 5a) that was completely or partly dissolved out of the HE section as a result of the technique can thus be directly verified by subsequent macroscopic re-evaluation of the surface of the paraffin block material (Fig. 5b).

## Discussion

### Supra-macroparticulate PE and PE vacuoles

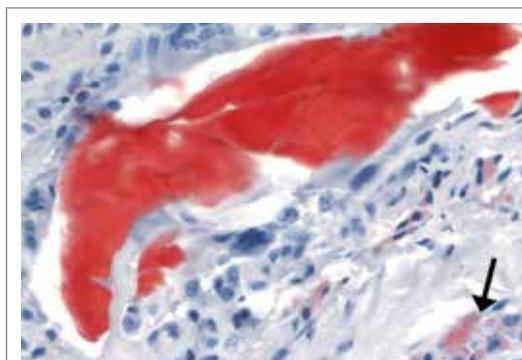
An as yet unrecorded PE particle size and type of localization and manifestation (dissolved PE particle: PE vacuole) in dysfunctional hip joint endoprostheses is systematically described and the descriptors "supra-macroparticulate PE" and "PE vacuole" are defined. That these PE vacuoles are not tissue artifacts in the sense of tissue dehiscence but rather dissolved supra-macroparticulate PE particles was verified by obtaining direct evidence of the particles using subsequent macroscopic re-evaluation of the paraffin block material surface.

### Supra-macroparticulate PE particles and abnormal mechanical loading as pathogenetic factor

A comparison with the clinical data revealed the presence of loosening of the hip endoprosthesis and macroscopically detectable damage to the PE inlays in all cases. It can thus be concluded that abnormal mechanical loading may be the cause of the supra-macroparticulate PE particles. The highly variable prosthesis survival rates suggest that with long survival rates large-scale mechanical loosening develops only in the final phase of prosthesis failure. In contrast, with short survival rates, the evidence of supra-macroparticulate PE and PE vacuoles in the SLIM can be considered an expression of a mechanical problem that had already developed in the initial stages.



**Fig. 3:** Three PE supra-macroparticles in a peri-implant membrane of the wear-induced type (hip joint, survival time of the joint prosthesis 279 months) with intense birefringence in the polarization-optical analysis (POL): The linear and convexly curved clasp-shaped PE particles have maximum lengths of 1,900  $\mu\text{m}$ , 913  $\mu\text{m}$ , and 196  $\mu\text{m}$ . The cavities adjacent to the PE particles are so-called retraction artifacts (arrow) (HE staining, polarization-optical analysis, original magnification about 100 $\times$ ).



**Fig. 4:** A possible polygonal PE supra-macroparticle (maximum length 249  $\mu\text{m}$ ) and PE microparticles in a peri-implant membrane of the wear-induced type (hip joint, survival time of the joint prosthesis 168 months) in the oil red O staining. A PE supra-macroparticle and PE microparticle,  $\leq 5 \mu\text{m}$  (bottom right quarter, arrow) with intense oil red positivity (oil red O staining, original magnification about 400 $\times$ ).

### **Mechanical complications and pathogenesis of supra-macroparticulate PE**

Conventional polyethylene (UHMWPE) and cross-linked PE are in clinical use for hip and knee arthroplasty. PE wear usually generates relatively small wear particles (sub-microparticulate PE) [11, 42]. In 1995 **William Harris** succinctly summed up the knowledge gained about the relationship between aseptic loosening and PE wear: "The problem is osteolysis" [17]. This led to the development of cross-linked polyethylenes. **Hirakawa et al.** [20] showed in 1996 that over time the PE can degrade with the material being delaminated and large PE fragments being released from the material.

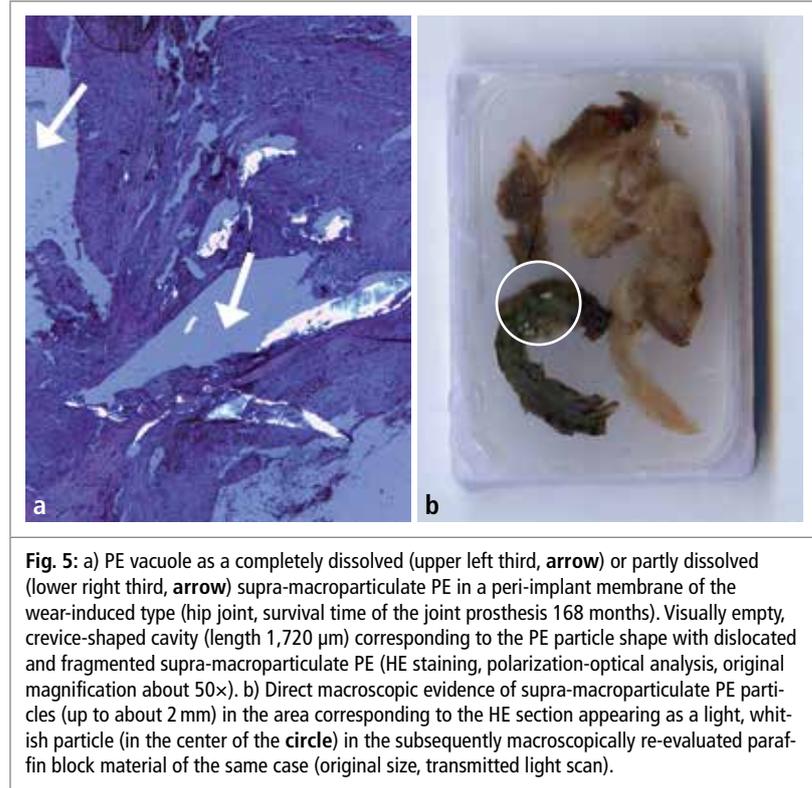
### **Cross-linked polyethylenes**

The PE is cross-linked using gamma or electron beam irradiation. The cross-linked polyethylene from different manufacturers varies in the manufacturing procedure used and in the intensity and duration of the irradiation. The free radicals produced during the irradiation can lead to an oxidation-related aging process of the material (artificial aging). For this reason, the cross-linking procedure is generally followed by additional processing steps to minimize unwanted material changes (e.g., reduction in the fracture strength and elongation at rupture). Cross-linked polyethylenes are subjected to heat treatment for this purpose. However, with heating below the melting point (annealing), free radicals that can trigger an oxidation process and result in premature material failure can remain in the material [39, 40]. Alternatively, heat treatment above the melting point (remelting) is possible, but even though it almost completely eliminates free radicals, the risk of material fatigue is also increased because the mechanical properties (e.g., the fracture strength) can be negatively affected. Due to abnormal mechanical loading or increasing oxidation of the PE, the risk of changes to the material or surface (tears, roughness) increases, leading in turn to possible changes in the wear behavior of the material and the generation of particles (size, shape, quantity). To what extent the survival rate of the endoprosthesis is affected has not been adequately investigated to date.

Some manufacturers of cross-linked polyethylenes add antioxidants (e.g., vitamin E) because by binding free radicals one is assured of a higher resistance to oxidation while the mechanical strength is preserved. These polyethylenes have been in clinical use for only a short time, however, and as yet there is no evidence that this material is associated with increased stability and longevity.

### **Hip arthroplasty**

Secondary wear mechanisms such as surface damage, tears, and rim fractures have been described in the literature for both conventional PE and cross-



**Fig. 5:** a) PE vacuole as a completely dissolved (upper left third, **arrow**) or partly dissolved (lower right third, **arrow**) supra-macroparticulate PE in a peri-implant membrane of the wear-induced type (hip joint, survival time of the joint prosthesis 168 months). Visually empty, crevice-shaped cavity (length 1,720  $\mu\text{m}$ ) corresponding to the PE particle shape with dislocated and fragmented supra-macroparticulate PE (HE staining, polarization-optical analysis, original magnification about 50 $\times$ ). b) Direct macroscopic evidence of supra-macroparticulate PE particles (up to about 2 mm) in the area corresponding to the HE section appearing as a light, whitish particle (in the center of the **circle**) in the subsequently macroscopically re-evaluated paraffin block material of the same case (original size, transmitted light scan).

linked PE [2, 5, 10, 13–16, 19, 37, 38, 43, 44], although the etiology and the prevalence have not yet been fully clarified. It is known that secondary wear phenomena are not encouraged by the degradation of the material but rather by limiting suboptimal biomechanical conditions. Dislocation, subluxation, and impingement can result in surface damage and tears in the material [5, 10, 13] which in turn can lead to the release of larger PE fragments [4].

With malpositioning of the acetabulum (e.g., the abduction inclination is too high), signs of material fatigue can develop that lead to increased material wear [30, 31, 45], hip instability [9], fractures of cross-linked PE inserts [15, 32, 43, 44], accompanied by noises (clicking) [2, 28], and early or late failure of the hip endoprosthesis.

Breaks on the acetabular rim of the material (rim fracture) can lead to changes in and fragmentation of the polyethylene [12]. Supra-macroparticulate PE particles may possibly develop as a consequence of third-body wear in which, e.g., bone cement particles enter the joint space, where they cause large-scale erosion of the material by scratching the material surface.

### **Knee arthroplasty**

Whether supra-macroparticulate PE can also be detected in dysfunctional knee endoprostheses requires studies. The use of cross-linked polyethylene in knee arthroplasty is considered controversial because of the different biomechanics of the knee joint, which, compared with the hip joint with

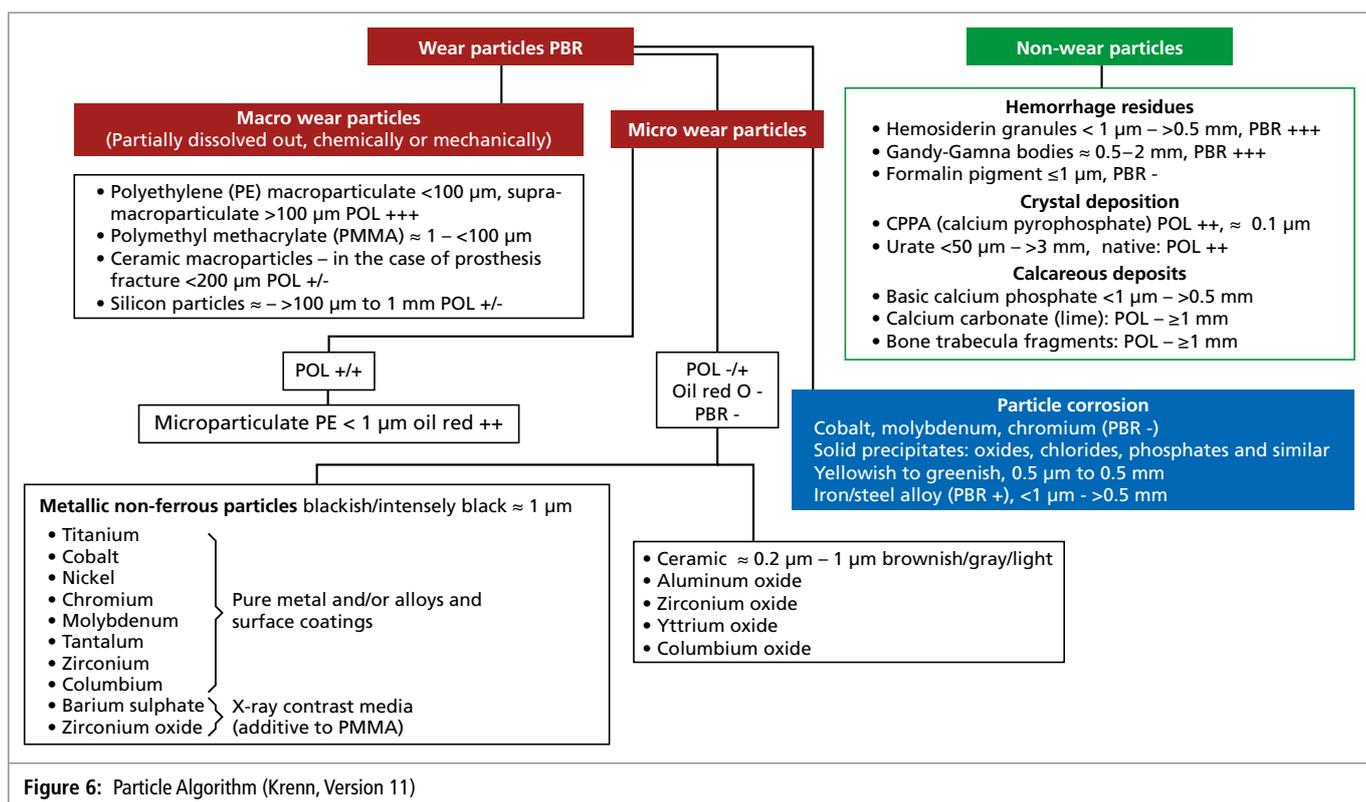
its sliding motions, has dynamic roll-sliding motions with resultant higher mechanical loading and a comparably greater risk of material fatigue (delamination, material fracture, wear) [8]. It is known from previous studies that the roll-sliding motions can lead to fractures close to the surface of the PE [34, 35]. Whether high-demand patients or very overweight patients (BMI >40) possibly have a risk constellation in knee arthroplasty due to secondary wear mechanisms in cross-linked PE has not been adequately investigated. There are very few valid clinical data available on the use of cross-linked PE in knee arthroplasty, but its US market share seems to be growing. The American Joint Replacement Registry (AJRR) reflects this trend in its first report (2013). With 20,524 implanted knee arthroplasties recorded, cross-linked PE was the most used tibial bearing component at 75 % [1].

### Summary

The newly described supra-macroparticulate PE is included in the expanded particle algorithm (version 11) (▶ Fig. 6). Pathogenetically, supra-macroparticulate PE in the SLIM can be interpreted as a consequence of abnormal mechanical loading. The variability in the size of the PE particles may be an expression of the different damage mechanisms. Clarifying this, as well as whether cross-linked PE and non-cross-linked PE show differences in particle morphology, particularly in the supra-macroparticulate PE, as a result of abnormal mechanical loading, is a subject for further analyses. The inflammatory

response induced by supra-macroparticulate PE in the form of macrophage infiltration and giant cells corresponds largely to that previously described for micro- and macroparticles, but the precise biological effect on the peri-implant tissue must be clarified.

By applying the histopathological particle algorithm (Krenn et al. 2014), a new type of PE particle (supra-macroparticulate PE) with a previously unrecorded and unusual size and type of presentation (dissolved PE: PE vacuole) was detected macroscopically and microscopically in the SLIM in dysfunctional hip joint endoprostheses (13 cases). The minimum mean of the particle length was 320 µm, the maximum mean of the particle length was 1,726 µm, and the individual particle maximum length was 1,901 µm. Along with an intracellular localization in multinucleated giant cells of the foreign-body type, particles that dissolved out as a result of the histology technique left a negative image behind (PE vacuole) in the SLIM. The paraffin block material with large PE vacuoles (≥1,000 µm) was subsequently re-evaluated macroscopically, and in all cases (n=3) (with the area corresponding to the HE section) macroscopically detectable light and whitish particles with a length of up to about 2 mm were seen in the tissue in the paraffin block material on the surface of the preparation. The supra-macroparticulate PE completely dissolved out of the HE section can thus be directly verified by subsequent macroscopic re-evaluation of the surface of the paraffin block material. The prosthesis survival times were highly variable, ranging from 12 to 276 months



(mean prosthesis survival time 147 months). Clinically, all cases showed loosening of the prostheses, and there was macroscopically detectable damage to the PE inlay. Abnormal mechanical loading of the PE components with shearing off of large PE particles must be considered a possible origin of the supra-macroparticulate PE particles. The highly variable prosthesis survival rates suggest the following interpretation:

- 1) In cases with a high prosthesis survival rate, large-scale mechanical loosening with abnormal loading of the PE occurs only in the final phase of failure of the hip joint prosthesis.
- 2) The histopathological evidence of supra-macroparticulate PE and PE vacuoles in the SLIM of hip joint prostheses with lower survival rates may be an expression of a mechanical or even functional problem that developed in the early stages. ■

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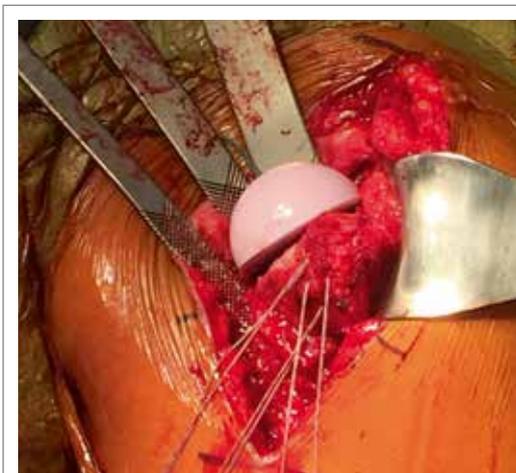
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## First Biolox®*delta* Shoulder Implanted

On April 10, 2015, an anatomical shoulder made of Biolox®*delta* ceramic was implanted for the first time. Owing to the patient's high allergy risk, it was not possible to use a metallic implant head. CeramTec therefore developed, produced, and tested together with its customer a ceramic humeral head for this patient. The implant is the result of an ongoing development project being carried out by CeramTec together with an implant manufacturer. A specimen from the pre-production series was employed for the patient mentioned, with special authorization for clinical use. The operating surgeon and the patient are very satisfied with the course of the operation and the treatment result to date.



**Figure 1:** Implantation of the first Biolox®*delta* components for the shoulder

CeramTec works together with several well-known implant manufacturers to develop ceramic components for shoulder endoprosthetics, with the aim of utilizing the advantages of ceramic materials, which have contributed to a significant improvement in hip endoprosthetics, for shoulder endoprosthetics as well. The development includes both anatomical implants and glenopheres for reverse shoulders. Some of these are already undergoing the approval process.

The material used for the shoulder implants is Biolox®*delta*, which has achieved excellent results in hip endoprosthetics and is accepted as the standard for ceramic ball heads, with more than 4 million implantations worldwide. The characteristics of Biolox®*delta* ceramic are:

- Excellent biological behavior\*
- No known pathogenic reaction to ceramic particles\*
- No known risk of allergy\*
- Reduced risk of infection\*
- Safe in terms of metal ion release\*
- Significantly lower fretting corrosion\*
- Excellent wettability\*
- Cartilage friendly\*
- Minimized polyethylene wear\*
- Highly scratch-resistant articulation surface\*
- Resistant to third-body wear\*

(\*References available on file at CeramTec GmbH on request.)

# Systemic Cobaltism Associated with Wear or Corrosion of Cobalt-Chrome Components

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*» The extent to which beliefs are based upon evidence is very much less than believers suppose. «*

(Bertrand Russell, *Sceptical Essays*, 1928)

The prevalence of metal toxicity in hip and knee arthroplasty is unknown, and evidence-based guidelines have not been formulated. There is a lack of data to define the burden of metal toxicity, to guide clinical decision-making, and to determine the cost-effectiveness of various screening and management strategies. To our knowledge, there is no consensus regarding the management of patients with systemic symptoms of metal toxicity, and clinical response to these treatments is not well-documented in the current medical literature. Since cobalt has been shown to be carcinogenic and mutagenic in animal and human models, the potential for systemic toxicity and long-term adverse biological effects (e.g. immune modulation, end-organ deposition) is a valid safety concern for patients with cobalt alloy components in arthroplasty.

Current available evidence demonstrates that cobalt-chrome hip replacement components have been associated with adverse reactions to metal release, including inflammatory pseudotumors, soft-tissue abnormalities, hypersensitivity reactions, and osteolysis. Besides adverse local effects, metal implants can also induce systemic effects resulting from continuous exposure to, and the circulation and distribution of solubilized metals.

Well-functioning cobalt-chrome-containing prostheses can release soluble metallic products (i.e. wear particles, corrosion by-products, ions, metallo-organic compounds) into the systemic circulation over a prolonged period after surgery and have been found in the serum, blood, and urine of patients. The average metal ion levels in patients with a well-functioning MoM hip prosthesis can exceed those in patients with MoP THA [1]. Investigations by **Hartmann et al.** and **Holland et al.** [2, 3] showed that steady-state median blood chromium and cobalt concentrations over 10 years in patients with well-functioning MoM devices are 5- to 10-fold higher than the normal physiological level. A study by **Prentice et al.** [4] showed that the blood, plasma, and urinary cobalt and chromium levels were 5- to 50-fold higher in well-functioning MoM hip replacement devices than in matched controls with MoP or CoC THA. Furthermore, differences in cardiac function in the MoM hip replace-

ment group were detected compared with patients with MoP or CoC THA. Interestingly, **Prentice et al.** pointed out that this finding in the MoM group is consistent with a Finnish study by **Linna et al.** [5], which found evidence for abnormal echocardiographic changes in cobalt-exposed Finnish workers who had mean blood cobalt levels of  $>2.5 \mu\text{g/l}$  and a mean duration of exposure of 8 years, similar to the exposure in the studied MoM group.

The essential relationship between the length of metal exposure, peak metal ion levels, and symptoms of toxicity remains unclear. There is still no established and generally accepted threshold value above which blood concentrations of cobalt and chromium are known to be toxic in patients with joint replacement.

Persistently elevated cobalt and chromium serum levels resulting from taper corrosion were also detected in patients with well-functioning MoP THA 10 years postoperatively [6] and up to 6 years post-op when a second MoP THA was performed after primary THA [7]. This observed finding needs further investigation with larger clinical trials in order to analyze its clinical significance. Retrieval studies observed significantly less taper corrosion among stems with ceramic ball heads (Biolox®*delta*, Biolox®*forte*) compared with cobalt-chromium (CoCr) ball heads in THA [8, 9].

Given the potential for cytotoxic, genotoxic and immunotoxic effects of CoCr wear particles, there are concerns about the potential long-term health effects of chronic metal exposure on systemic organ function in patients with metal implants, and their clinical relevance must be critically discussed and remains to be evaluated. We hope that 2016 will bring more interdisciplinary research and knowledge in this difficult area.

### Arthroprosthetic cobaltism – a multisystem disease

Systemic cobaltism has been documented in several case reports, mainly in hip arthroplasty. However, the prevalence of arthroprosthetic cobaltism is unknown. Case reports describe a systemic disease in patients with cobalt alloy-containing implants, termed "arthroprosthetic cobaltism" [10].

It cannot be ruled out that systemic effects evaluated in patients with metal hip implants could be caused mainly by cobalt. A recent animal study by **Apostoli et al.** [11] seems to support the thesis. Intravenous injections of high doses of cobalt, but not chromium, in rabbits were able to reproduce neurotoxic effects similar to those observed in patients exposed to an abnormal release of cobalt and chromium from metal hip implants.

Patients with cobalt-containing hip implants developed similar manifestations that affected numerous organ systems [10, 12–16]. **Thomsen et al.** [17] reported on a patient with knee arthroplasty and clinical symptoms of cobalt intoxication. Diagnostic histological investigations using the **Krenn** clas-

sification [18] showed massive necrosis due to toxic metal reactions.

The symptoms of cobalt toxicity documented in the medical literature are variable but typically involve neurological, cardiovascular, or endocrinological dysfunction. Patients had notably high blood cobalt levels (cobaltemia) and developed medical problems consistent with cobalt poisoning (cobaltism) during their period of cobaltemia [10, 13, 14]. The case reports demonstrated how systemic symptoms of cobalt toxicity including nonspecific manifestations (fatigue, weight loss, headaches), neurological symptoms and diseases (deafness, hand tremor, depression, incoordination, hearing loss, visual changes), cardiac diseases (cardiomyopathy, arrhythmias), and allergic or endocrine symptoms may masquerade as other serious health problems, and can occur within months and worsen over time if untreated. There are concerns that cobalt toxicity may be under-recognized [13]. Therefore, **Gessner et al.** [19] propose that surgeons and general practitioners receive training on the potential risk of arthroprosthetic cobaltism.

There are few data regarding the management and clinical course of arthroprosthetic cobaltism. Evidence-based guidelines are not available. The main objective in treating symptomatic patients is revision, i.e., replacement of the cobalt-containing implants, and to treat the systemic symptoms supportively. Case reports have demonstrated that circulating cobalt ion levels declined, symptoms improved, or medical problems resolved following removal of the MoM bearing and implantation of a CoP bearing [13, 14]. ■

## CASE REPORTS

### Cobalt toxicity related to MoM hip replacement: Metal ions cross the blood-brain barrier. Revision to CoP improves patients' health significantly

**Mao et al.** and **Sotos et al.** reported on three patients with elevated serum cobalt levels and symptoms consistent with cobalt toxicity related to MoM hip replacement. Patients' serum cobalt levels were reduced following removal of the MoM-containing bearing and implantation of a CoP bearing.

#### Case 1

**Mao et al.** [13] presented a 73-year-old female patient with systemic manifestations of cobalt toxicity such as neurological symptoms (cognitive decline, memory difficulties, depression), a continuous metal taste in her mouth, and general complaints (headaches, anorexia, weight loss) 5 years after surgery. With the exception of mild groin pain she had no further clinical symptoms related to her hip. X-rays

showed a well-fixed cementless hip implant. The serum cobalt level was 410 nmol/l (reference range, 0–20 nmol/l) and the serum chromium level was 240 nmol/l (reference range, 0–100 nmol/l).

Revision surgery was performed because of her systemic symptoms and elevated metal ion levels. The metal ball head was changed to a ceramic ball head. The metal cup was removed and an all-PE cemented cup was implanted. The authors reported that 30 ml of turbid joint fluid was aspirated and metal-stained tissue was debrided. The measured cobalt level in the joint fluid was 4,218 nmol/l and the chromium level was 217,000 nmol/l. The concentration of cobalt in the cerebrospinal fluid was 9 nmol/l, that of chromium was 13 nmol/l

(no reference range). The authors pointed out that these findings show that metal ions had crossed the blood-brain barrier in this patient. At 2 months following revision surgery, her general condition of health and ability had improved significantly. The authors reported that the metallic taste in her mouth had gone; she had less fatigue and more energy, had gained weight, and had a normal appetite. Her serum cobalt level was reduced from a value of 410 nmol/l prior to revision surgery to 60 nmol/l following surgery.

### Case 2

In another case, a 60-year-old healthy male patient developed systemic symptoms 3 years following surgery including painful muscle fatigue in all limbs, dyspnea, decline in cognitive function (loss of concentration, poor memory), and lower physical and intellectual capacity. His stable hypertension became uncontrolled and required additional medication. The authors reported a normal serum chromium level of 88 nmol/l. The measured serum cobalt level was 185 nmol/l and remained consistently elevated between 213 nmol/l and 258 nmol/l. The chromium level was never elevated. The patient had no painful hip or other hip symptoms, but the radiological findings showed markedly less bone around the cup.

The MoM bearing was replaced by a CoP bearing because of the systemic symptoms. The stem was retained. At 2 months following revision surgery, the patient reported a significant improvement of his general condition and a decrease in muscle pains. His serum cobalt level was reduced from a value of 258 nmol/l prior to revision surgery to 42 nmol/l postoperatively.

The authors pointed out that in the case of persistently elevated metal ions and symptoms of toxicity, and if other causes are excluded, revision surgery is the only treatment strategy to decrease the metal ion level.

### Case 3

**Sotos et al.** [14] presented a case of a 49-year-old male surgeon who developed general symptoms 3 months following the implantation of a MoM hip replacement. He developed behavioral changes, became uncustomarily irritable, excitable, and anxious. Following physical exertion in hot, humid conditions, he noted painful rashes in his groin and axillae. Multiple symptoms worsened and disability resulted 18 months postoperatively. Progressive pain and noise at the prosthetic hip were also findings. The serum cobalt and chromium levels remained high until the MoM implant was replaced by a CoP implant at 43 months following primary surgery. Elevated concentrations of cobalt and chromium were found in periprosthetic tissues and cerebrospinal flu-

id. A progressive improvement of his general condition and clinical symptoms, e. g. in mood and cognition, was observed at 66 months. His professional productivity returned to about two-thirds of the pre-cobaltism level.

### Effect of circulating cobalt and chromium on the brain

Obviously, cobalt and chromium cross biological barriers, such as the extremely restrictive blood-brain barrier. Interestingly, **Clark et al.** [20, 21] found that chronic exposure to cobalt and chromium may indicate subtle brain dysfunction. They showed in a cross-sectional study that clinically asymptomatic patients with chronic exposure to elevated circulating concentrations of cobalt and chromium following MoM hip replacement had differences in brain structure compared with a matched non-MoM THA group and metal levels similar to normal physiological levels. Subtle structural changes in the visual pathways and basal ganglia were detected in the MoM hip replacement group. These patients showed a trend to gray matter attenuation in the occipital cortex and basal ganglia and a smaller optic chiasm area. The scientists pointed out that these data suggest that moderately elevated circulating metal concentrations for 8 years following MoM hip replacement are associated with imaging features in keeping with possible cell loss in the visual system. Further examinations are required to determine the relationship between metal exposure and structural or functional changes in the brain and their clinical relevance. ■

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# The Influence of Stem Taper Re-use upon the Failure Load of Ceramic Heads

Awarded the Heinz-Mittelmeier Research Award 2015

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Today, fracture of ceramic femoral heads in total hip replacement is a very rare event. Modern composite ceramic materials have considerably reduced the fracture risk. This still leaves a high number of older components made from pure  $\text{Al}_2\text{O}_3$ , which have been implanted in the last decades, in patients. As a consequence, revision of fractured  $\text{Al}_2\text{O}_3$  ceramic femoral heads will continue to be of clinical relevance for many years. When revising a fractured femoral head, there is some uncertainty about whether or not to replace a well-fixed stem. Ceramic is a brittle material, and even small damages to the stem taper may lead to stress concentrations, which could cause premature failure of a new ceramic femoral head placed on the used taper. Clinically, ceramic femoral heads placed on well-fixed used stem tapers at revision did not show an overall increased re-fracture risk, but single incidents were reported [1, 2].

The aim of this study was to directly determine the in-vitro fracture load of new ceramic femoral heads paired with re-used tapers that have been subject to prior femoral head fracture [3]. The fracture strength of  $\text{Al}_2\text{O}_3$  ceramic femoral heads (BioloX<sup>®</sup>forte; Ø28mm, L) was determined by application of an axial force. Tests were performed on a custom-made test rig designed according to ISO 7206-10 with a Zwick Z400 test device (Zwick GmbH). Five 12/14 tapers made from Ti6Al4V (representing the Aesculap Metha<sup>®</sup> design) with matched femoral heads (taper angle mismatch 0.09°) were subject to three subsequent fracture tests. This gave a total number of 15 fractured femoral heads and two re-uses per each of the five stem tapers. Before and after every fracture test, head and stem tapers



Heinz-Mittelmeier Research Award ceremony: Paul Silberer (CeramTec GmbH), laureate Julian Guehrs (TUHH Hamburg), Prof. Dr. Bernd Kladny, General Secretary DGOOC (from left to right)

With courtesy of Prof. Dr. Morlock, TUHH

were inspected visually, and changes in surface geometry were determined using a coordinate measuring device (Mitutoyo<sup>®</sup> DtlD. GmbH) and focus variation microscopy (FVM, Alicona<sup>®</sup> Imaging GmbH).

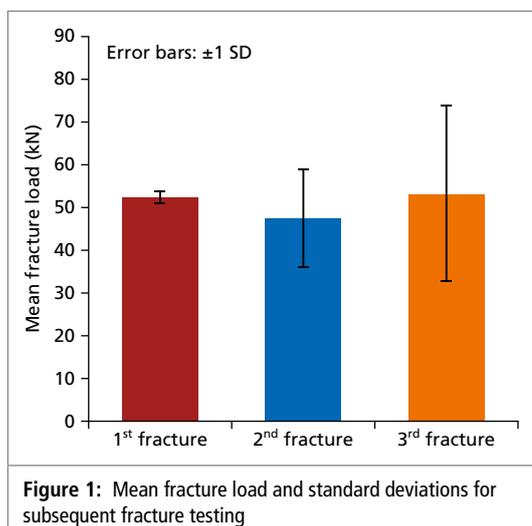
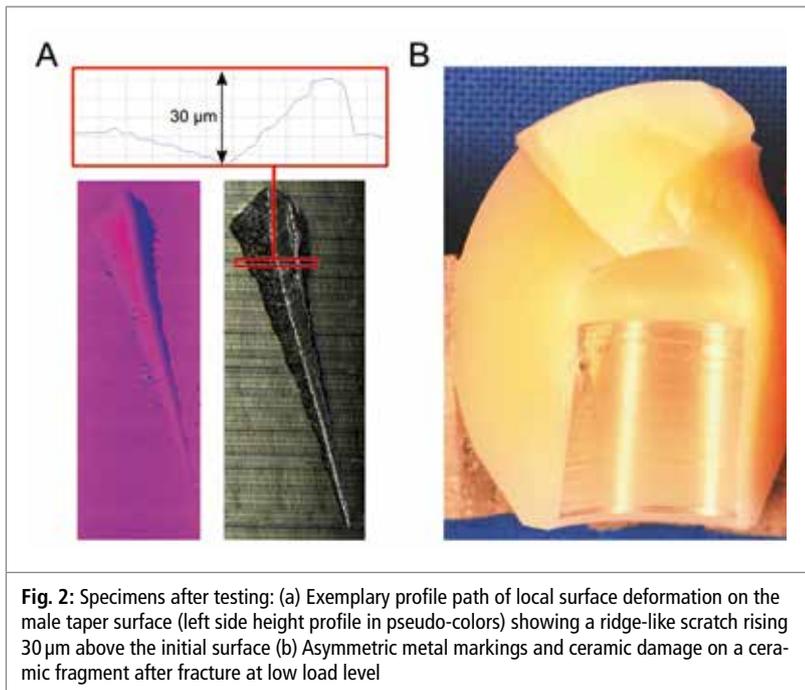


Figure 1: Mean fracture load and standard deviations for subsequent fracture testing

The taper re-use influenced the fracture strength of the ceramic femoral heads. For the subsequent re-use testing, no significant change of the mean fracture load was detected (Tamhane's T2 Post hoc test,  $p \geq 0.77$ ) and the three group means (52.48kN, 47.40kN and 53.12kN) were above the required failure strength, but with every taper re-use, the standard deviation of the mean fracture load increased considerably (Fig. 1). For the first fracture test, standard deviation was 1.52 kN, for the second 11.67 kN, and for the third 20.86 kN. The fracture loads for the third test (second re-use of taper) ranged from 17.8kN to 70.4kN.

Visible damages were found on all tapers but did not allow prediction of subsequent fracture load.



**Fig. 2:** Specimens after testing: (a) Exemplary profile path of local surface deformation on the male taper surface (left side height profile in pseudo-colors) showing a ridge-like scratch rising 30 µm above the initial surface (b) Asymmetric metal markings and ceramic damage on a ceramic fragment after fracture at low load level

Local deformations rising above the taper surface were visible using tactile and FVM surface analysis  (Fig. 2a). In cases of low fracture loads, asymmetric metal markings and points of crack initiation were detected on the ceramic fragments  (Fig. 2b). These could have not been identified in a clinical examination during surgery.

The increasing deviation in fracture strength with re-use of stem tapers indicates a higher fracture risk for some of the specimen despite little variation in the mean fracture load. The lowest fracture strength observed (17.8 kN) was close to reported in-vivo forces [4]. Since visual inspection of the taper surface was not sufficient to predict the failure strength of a new head, it is strongly advised that tapers not be re-used with plain ceramic femoral heads. Since metal femoral heads are not an option for revisions following ceramic fracture [5], ceramic revision femoral heads with a sleeve are probably the best possible solution in order to maintain a well-fixed stem taper. In these so-called Biolox® Option femoral heads, a metal sleeve (titanium alloy) is positioned between the new ceramic femoral head and the old taper surface to provide a fresh surface capable of adjusting to acceptable local deformations of the used taper. First results are very promising [6, 7], but the long-term outcome with this metal-metal interface needs to be monitored carefully. ■

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### Heinz-Mittelmeier Research Award 2016

The German Society for Orthopaedics and Orthopaedic Surgery e.V. (DGOOC) presents the 5,000-Euro Heinz-Mittelmeier Research Award in collaboration with CeramTec GmbH each year. The award is offered to young doctors, engineers, and scientists aged 40 and under for outstanding research and development work in the field of bioceramics and the problem of wear in joint replacements, and in combination with clinical results of ceramic implants.

Work may be published in scientific journals or in book form. Unpublished manuscripts that are intended for publication or have already been submitted for publication are also accepted, along with graduate theses, dissertations, and post-doctoral dissertations. Only work that has already received a similar award is excluded from the competition.

The winner is chosen by a DGOOC jury. The 2016 research award will be presented during the congress jointly sponsored by the DGOOC, the German Association for Trauma Surgery (DGU), and the Professional Association of Orthopaedists and Trauma Surgeons (BVOU), from October 25 to 28, 2016 in Berlin.

#### How to participate

To participate in the competition send your work in German or English by **July 31, 2016**, with a corresponding declaration that it has not been distinguished with a similar award, solely via email to: [info@dgoc.de](mailto:info@dgoc.de).



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