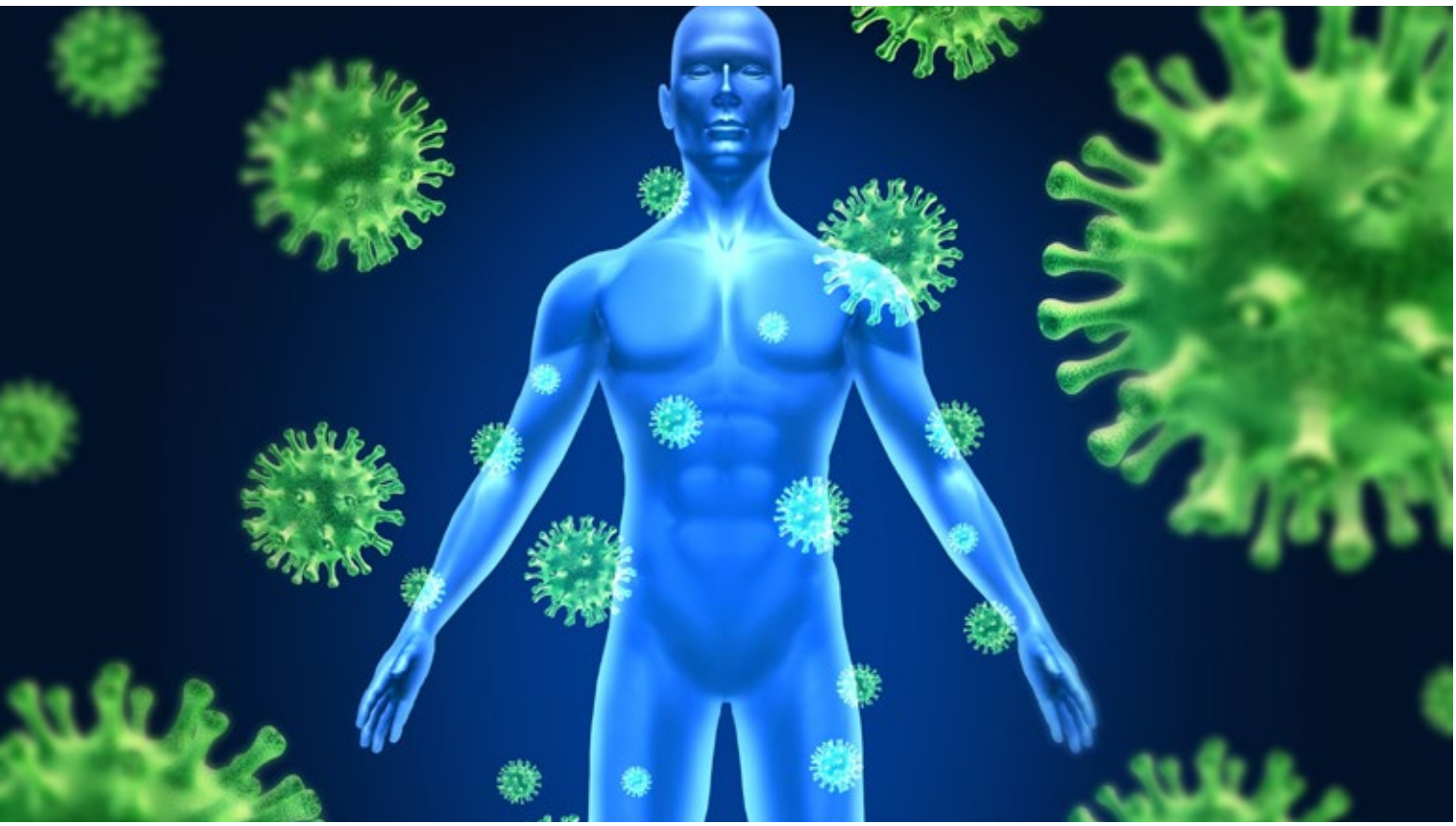
CeraNews

ISSUE 2/2014 The Orthopaedic Landscape Information Journal

Focus:
Psoas Impingement
Periprosthetic Joint Infection



Cover:
© lightwise / 123RF Stockfotos

@ You can download PDFs with additional information to the articles in this issue via the QR codes.

All articles are online at **www.ceranews.com**

Published by:
CeramTec GmbH
Medical Products Division
CeramTec-Platz 1–9
D-73207 Plochingen, Germany
Phone: +49 7153 611-828
Fax: +49 7153 611-950
E-mail:medical_products@ceramtec.de
www.biolox.com

Chief Editor:
Sylvia Usbeck

Concept and editing:
Sylvia Usbeck
Florence Petkow
Leslie F. Scheuber

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

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

Paul Silberer
Vice President Sales and Product Management
Phone: +49 7153 611-522
E-mail: p.silberer@ceramtec

Dear Colleagues,

Arthroplasty remains a key societal issue in 2014, as the cost of delivery of care continues to grow, and the demand for increased spending comes from every sector of healthcare. Within arthroplasty, surgeons have a number of choices to make, and the factors that bear down upon them have never been harder to balance. We all want to do what is best for our patients, at the same time, many of us face controls on our spending. No matter what health care system you work in, a good appreciation of the short, medium and longer term consequences of any choice you make is essential. There are two major elements of this appreciation: the cost of any choice of device or bearing couple to the purchaser, and the value of that choice to the patient. Bizarrely, while in every other element of life, we humans are becoming ever more discerning consumers, in this area, we lag behind. The price of devices has recently seen serious downward pressure as healthcare purchasers demand cost reductions from providers. This is at least in part because patients are living much longer, so to them, the value of these choices is profound, in that they may improve the quality, and even length, of their lives. Several of the elements that can inform the surgeon and his or her patient when selecting a particular bearing couple are played out in the current edition of CeraNews

For a couple of decades now, the 'arthroplasty industry / registry complex' has supported a dumbing down of functionality – everyone scores full marks after a hip replacement, so there is no such thing as a better one – with a devotion to registry defined implant survival as the ground truth, and an unholy fixation upon cement. This same 'industry/registry complex' is highly selective in the collection and definition of failures. So a bearing that needs revising with minimal long term consequences is a failure, while a periprosthetic fracture requiring a long plate and substantial reduction in quality of life metrics is not even mentioned in any registry if the stem is not changed.

So registry conclusions do not always tell the whole story, instead reporting what they see through their particular prism. It is interesting to reflect that the market – surgeons and their patients – do not seem to pay much attention. On the subject of implant fixation, while cement is the darling of the registries, the marketplace has continued to move away from it, half a decade before the registry data confirmed what surgeons and their patients round the world already knew: that cementless fixation is actually more effective and may be safer.

In bearing choice, the same phenomenon seems to be occurring. Ceramic-on-ceramic, and ceramic-on-polyethylene are now the dominant bearing couples of choice. Why is that? Because both surgeon and patient know that a few more pounds saved by using a cheap bearing couple may be a short term fix, not causing any major problems in the first decade. But for the patient, and the healthcare provider, it may represent a false economy if a large cost is envisaged within the patient's lifetime.

Thigh and groin pain with exercise are symptoms that are not necessarily picked up by the registry. In his article in this edition, Harry Rubash brings up the issue of groin pain, a symptom that has existed but been overlooked for a while. Is it surgeon error with component placement, or femoral stem length? Or does it have a biotribological cause?

The following article from the Orhun Muratoglu's group in Boston brings up the intriguing concept of a femoral head design that might reduce groin pain caused by soft tissue impingement on a hard edge. In large diameter metal-on-metal or metal-on-polyethylene bearings this may be the case. The attractive gentle curve he and his group have designed to be kind to tendons and other soft tissue may also also deliver superior tribological performance by improving the entrainment of fluid, particularly in less wettable bearing cou-

ples such as metal-on-polyethylene. Whether this effect can be measurable in a biological system, with smaller ceramic articulations, when the bearing couple is already highly hydrophilic remains to be seen. This space will be intensely interesting and is biotribology on a macro scale.

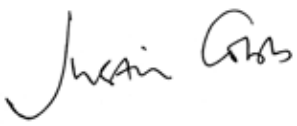
Biotribology is also a key element. Material properties also lie behind the article by Burkhard Summer from Munich. He reports on the varying reaction of the human immune system to particulate debris in joint replacement and its varying presentation. This is highly topical, and in this article we are shown how this condition can be characterized and quantified. The condition does appear to be variable and at one level surprisingly prevalent. So our own immune system does definitely react to the presence of metal nanoparticles or ions at a level that is logarithmically different to any reaction to ceramic particles, making this material even more attractive.

If human cells react unpredictably to wear particles, the interaction between eukaryotic human cells and prokaryotic bacteria is even more complex. Add in a prosthesis and the mixture becomes still more complex. Perhaps the wear particles effect the reaction; perhaps it is the surface characteristics, making some components more prone to biofilm adhesion. In this edition, you will see these issues explored, and the various factors that make patients more prone to developing infection. Perhaps not surprisingly, this includes being too fat, and too thin.

Corrosion has been such a dominant part of the news in the last few years, that no update on bearings would be complete without it. The science is maturing, but in this edition of CeraNews you will see evidence that inflammatory cells may have a role to play in actually generating corrosion, not simply reacting to products of taper corrosion.

So this edition of CeraNews showcases some demanding science, some intriguing developments, and some precious experience. Biotribology is not a word that most orthopaedic surgeons would be comfortable using yet, although we live our life practicing it in many ways. What the articles in this journal show us, is that the wonderfully complex biological system of a human being is interacting with endoprostheses on many levels. And from the molecular to the societal. At a molecular level, enzymes may actually be causing trouble, on a cellular level, wear particles certainly influence inflammatory mechanisms, while at the same time the surface characteristics of materials have a direct effect on how well bacterial biofilm can adhere to them. That slipperiness is also a physical attribute which reduces friction of bearings, reducing torque across the taper trunnion and hence corrosion, while the shape at a macro level may have a measurable impact on iliopsoas tendon function. Now that's biotribology on a scale that orthopaedic surgeons can appreciate. And on the human level, these are all important elements of the decision making we have to share with each patient, while as a society, we have to recognize the value of a bearing that should be part of a lifelong new joint. The patients are the ones who will appreciate value in the short, medium and long term, and the long term is getting longer all the time.

Happy reading.



Justin P. Cobb, BMBCh FRCS MCh

Justin P. Cobb, BMBCh, MCH, FRCS, studied medicine at Magdalen College, Oxford, graduating in 1982. He trained in Oxford, London and Brighton. He wrote his master's thesis on 'Prognostic factors in operable osteosarcoma'. In 1991 he was appointed consultant orthopaedic surgeon at The Middlesex. He was awarded a Hunterian* Professorship in 1992. After 15 years as a consultant at University College London Hospitals (UCLH) and Honorary Senior Lecturer at University College London (UCL), he joined the Imperial College as chair of orthopaedics in 2005. In 1992 the special trustees of The Middlesex, awarded his first grant, which led to the development, with Brian Davies, of Acrobot, the world's first haptic based robotic assistant.

Close links exist between the MSk Lab on the Charing Cross Campus, and the Engineers in South Kensington, which resulted in the OsteoArthritis Centre, funded by an £11m grant from the Wellcome Trust and EPSRC**. The patient base at Charing Cross makes an ideal conduit for combined projects with investigators across college, including Andrew Amis in Mechanical Engineering, Anthony Bull in Biomedical Engineering, Molly Stevens in Material Science, Philippa Cann in Tribology, and Andrew Phillips in Civil Engineering. These collaborations have lead to the current MSk Lab team.
Together with Alison McGregor, he leads a group of more than 25 surgeons, physios, scientists and engineers who work on the same floor as the orthopaedic inpatient ward, translating their benchtop findings straight to the bedside and operating theatre of patients with musculoskeletal problems.

Recently these projects merged in the salvage of injured soldiers. In a world-first, the combination of 3D planning, 3D printing and robotics enabled precise minimally invasive joint salvage surgery***.
This world-first operation was in collaboration with the Defence Medical Rehabilitation Centre Headley Court.

The MSk Lab is funded in part by research councils such as the EPSRC, and substantial charitable trusts such as the Wellcome Trust, ORUK, and the Michael Uren Foundation, but also by donations from patients who come to the lab to allow us to measure their gait as part of a large study of gait and its relationship to joint health and disease.

His principal research interests are in the fields of:
- 3D planning and 3D printing of patient matched instrumentation and robotics to ensure accuracy, precision and cost effectiveness in joint surgery
- modelling bone quality and joint shapes in early joint disease, predicting progression of OA and the design of less invasive and better functioning devices
- PROMs**** and the functional assessment of the injured joint using highly personalized web based tools
- gait analysis in health and disease, using a range of tools to describe the ''perfect'' gait, and that seen as OA develops, and following different sorts of intervention
- cost utility analysis of small precise interventions in comparison with the conventional total joint replacement.

Professor Cobb is a civilian advisor in orthopaedics to the Royal Air Force. He is on the staff of King Edward VII Hospital for Officers, and is Orthopaedic Surgeon to Her Majesty the Queen.

*Hunterian Society: www.hunteriansociety.org.uk
**Engineering and Physical Sciences Research Council
***http://www.telegraph.co.uk/health/healthnews/9730086/Robotic-surgery-gives-soldier-a-new-spring-in-his-step.html
****Patient Reported Outcome Measures

Contact:
Justin P. Cobb, BMBCh, MCH, FRCS
Chair in Orthopaedic Surgery
Imperial College
Charing Cross Campus
South Kensington Campus,
London SW7 2AZ
UK
E-mail: j.cobb@imperial.ac.uk

The Four Most Important Complications in Arthroplasty

an Interview with Harry E. Rubash, MD
Massachusetts General Hospital, Boston, USA

Harry E. Rubash, MD, heads the Department of Orthopaedic Surgery of the Massachusetts General Hospital. He is one of the leading specialists for hip and knee replacement in the USA and worldwide renowned for his outstanding achievements in the field of arthroplasty. As a surgeon, researcher and educator he has made important advances in hip and knee replacement surgery, developing new technologies and improving patient outcomes. CeraNews asked him about the latest trends in research and health care in the field of arthroplasty.

What was the foundation for your commitment to excellence in your career? What was the biggest factor leading to your specializing in orthopaedics and specifically in total joint replacement?

My commitment to excellence in my career was a value that was instilled at an early age by my parents who believed in hard work to achieve what you wanted in life. In our family the primary goal was to be as good as you could be in all aspects of academics and athletics. From the time I was a young boy I had a real inclination and aptitude for mechanics and a passion for automobiles. I worked throughout middle school and high school as an automobile mechanic. I realized at a very early age that medicine was my real calling and that my mechanical skills and proficiency with tools could be applied quite usefully to the field of orthopaedic surgery.

You are deeply involved in work as a researcher, author, speaker, teacher and organizer. As a result of your dedication, you have become a world leader in research in orthopaedics, not just in surgery. Which of these roles do you enjoy the most?

I am deeply dedicated to patient care and the improvement of the lives of my patients. I am passionate about taking clinical problems into the laboratory, and whenever possible, developing innovative solutions, carefully studying appropriate applications of those solutions, and hopefully bringing them back into patient care and education. This translational paradigm has driven and continues to drive my passion in research.

What was the reasoning and philosophy behind the creation of the Harris Orthopaedic Laboratory? What is its mission and when was it founded?

The Harris Orthopaedic Laboratory was established at the Massachusetts General Hospital in 1995. It is currently under the leadership of two talented co-directors, Orhun Muratoglu and Henrik Malchau. It was founded by William H. Harris, an innovative thinker, researcher, and skilled pioneer in orthopaedic surgery who, among other things performed the first successful total hip replacement in a patient with a total congenital dislocation of the hip. The Lab has made enormous contributions in the field of orthopaedic surgery and is dedicated to continuing to make contributions in the field of orthopaedic surgery that will benefit our patients.

What are some of the focus research areas?

The focus is broad-based and spans the breadth of biomechanics, biomaterials, kinematics and outcomes research in hip and knee arthroplasty.

On the one hand, there have been many advances in the field of orthopaedic surgery over past years. On the other hand, it is a fact that the patient population requiring orthopaedic surgery has changed over the last 4 decades as a result of the general increase in longevity in the older population and the higher activity levels. Do you see an upcoming crisis in availability of qualified surgeons to meet the challenge presented by these patients as they "wear out their joints earlier"?

It is true that we have an orthopaedic burden of care that will outstrip the availability of our orthopaedic workforce in the decades to come. For this reason it is important that we maintain our focus on

training and attracting outstanding residents to the field. In addition, we continue to explore new paradigms for orthopaedic education to both improve the surgical skills of orthopaedic surgeons as well as diminish the length of time required to become a practicing orthopaedist. Physician extenders have allowed us to become more efficient in seeing and caring for patients and are an important aspect of our care models. Finally, since many of our treatments involve surgical care, our emphasis on patient safety and patient reported outcomes is incredibly important.

The age of our patients for total hip arthroplasty continues to fall. I remember a time in my practice when the average age was the late 60s; currently the average age is the early 50s. Patients in their fourth or fifth decade of life are very active and committed to their families and careers and understandably want to return to their normal level of functionality as soon as possible. We do our best to modulate their expectations with as precise a definition of the outcome as is feasible.

Do younger patients demand higher skill in the technical aspect of the operation in order to achieve the required longevity to delay or prevent revision surgery?

Managing patients' expectations and results are one of our biggest challenges. Patients know that many of our procedures are highly reproducible and successful operations. Unfortunately, there is also a known burden of complications, which must be both explained to the patient and effectively managed if these complications occur. The concept of shared decision making has made the preoperative education process much more efficient and effective.

I believe that we have four important opportunities to improve total joint arthroplasty surgery today. One is our burden of dislocation after total hip arthroplasty. Second is the occurrence of periprosthetic infection. Third is the inability so far to achieve a high level of satisfaction in our patients after total knee arthroplasty, and fourth is the failure of some of our recent innovations in the field, including metal-on-metal total hip arthroplasty, resurfacing hip arthroplasty, and the introduction of these technologies.

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

Whether you are a 40-year-old or 70-year-old patient you want the best bearing surface with the longest track record and the highest level of success, which is both safe as well as cost-effective. Currently, I utilize hip arthroplasties that have one taper coupled with a ceramic femoral head (on a highly crosslinked polyethylene bearing surface). In my opinion, ceramic heads in conjunction with highly crosslinked polyethylene provide the best bearing couple. When my patient is over the age of 75, I generally switch from a ceramic head to a metallic head.

First generation cross-linked polyethylenes have performed very well for a minimum of ten years post-implantation. We need additional data regarding the longer term to decide whether antioxidant impregnated polyethylene will also last as long.

In many cases bearing materials are qualified as first, second or even third generation. These highlight their improvements over the years, yet as we look back to earlier generations, we realize that some of the earlier problems are not totally resolved with the newer materials. Do you think that the restrictive FDA approval process for these technologies needs to be even more restrictive or whether we should strengthen our post market surveillance process?

The recent problems with metal-on-metal total hips, resurfacing total hip arthroplasty, and now our rising incidents of corrosion with tapers are of great concern within the arthroplasty field. In the former two situations, the introduction of the new technology occurred, based in part, upon data showing that these new constructs were essentially equivalent to other types of surfaces that were on the marketplace. The introduction of new technologies is an extremely critical issue in the world of orthopaedic surgery today. A "stepwise" introduction of technology, as suggested by Henrik Malchau, should be our model for the future.

My impression is that one aspect in the re-organization of our FDA approval process will be post-market surveillance. We know that the architecture, materials, and mechanics of the human body are not ideally replicated by in-vitro techniques. Therefore, we often need to actually implant the new devices into our patients to fully understand their short- and long-term effects. Thus, a strong post-market program, which will be of adequate breadth and length, will give us the necessary inferences that the new technologies are both safe and efficacious. This additional level of surveillance, which occurs even today, will be a requirement for the future. Secondly, the importance of "big databases" and registries is critical to our understanding of what happened in instances of implant failure. Registry data should give us an ability to detect failures earlier and

thus prevent widespread patient exposure to a device that may have an increased failure rate. It is the urgent responsibility of our surgeons to join these large registries – both in the US as well as abroad – to provide as much data as possible so that we are able to interpret results much earlier!

Recently the phenomen of groin pain after THA is under scientific discussion. Your institute has done research in the field of Iliopsoas impingement. What are the findings? Will a new contoured femoral ball head design help to solve the problem or is the cup the problem?

Anterior groin pain after hip arthroplasty is a new area of investigation in our laboratories. Early studies indicate that anterior groin pain of the hip joint may be associated with large diameter femoral ball heads or a prominent acetabular component. This pain may be secondary to tension in the anterior capsule of the hip joint and tendonitis of the iliopsoas tendon as it drapes across the anterior aspect of the hip capsule and the components. Our research has demonstrated that even though large femoral ball heads are not as large as our native femoral head, the location of the femoral head places the anterior capsule and Iliopsoas tendon at risk for impingement. For this reason, we have embarked on a program to re-design the contours of the femoral head to give us the ability to use larger diameter femoral heads with a more anatomically contoured radius at the base of the head. We are in the process of studying this both in the cadaver as well as the laboratory models and have designs that are more soft-tissue friendly, particularly with respect to the anterior capsule.

Patients currently undergoing THA are considerably heavier than were patients who underwent the procedure several decades ago. Recent studies have shown that 24% to 36% of all patients undergoing primary THA are obese. Is this increasing the complications in joint replacement procedures?

Patients today are more active and heavier than patients were two to three decades ago. These factors may add to the difficulty of achieving positive outcomes, despite employing the latest, most effective, most widely accepted, proven, surgical procedures. They also may add a potential hindrance to a smooth and rapid rehabilitation. Couple those factors with studies suggesting that obesity may increase the risk of complications and length of stay after arthroplasty and you have an amalgam of factors that may affect outcomes. For these and other reasons, I try very hard to have my patients understand the risks prior to surgery, with an extensive educational program and an inclusive, shared decision-making process.

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?

Congress recently passed a healthcare bill to basically re-write healthcare laws in our country. The unsustainable growth in healthcare expenditures was one of the primary motives for this legislation. Whether all or some of this legislation will be repealed in the future is unknown. However, providing healthcare for those who cannot afford it is a critically important and desirable outcome of healthcare reform.

A second and equally important aspect of healthcare reform is the meaningful use of the electronic medical record. Despite its enormous expense, it appears that the use of electronic medical records will improve efficiencies in the communication of our care as well as improve the safety of the care we provide. As a result of this new legislation, primary care has been totally retooled and population health management has become increasingly more important for our providers. The next critical step will be payment for episodes of care under bundling paradigms. This will fundamentally change the way we practice surgery. Whether this occurs in three or five years, a fundamental change in reimbursement will have an enormous impact on our field and our sub-specialty. Fortunately, the dedicated and talented women and men who are motivated to go into surgical practice love to take care of patients, enjoy the interaction with successful patients, and are highly motivated to help patients. This aspect of our profession will never change and it is the gold thread that weaves its way through healthcare. Are there changes? Yes. Will these changes have an impact? Yes. Will we, as a society, be able to modulate those changes? I sincerely hope so. The end game is the improved health of our patients and our populations. This is the essence of what we practice in medicine and why we've chosen to be healers.

Harry Rubash, thank you very much for an interesting conversation. ■

The interview was conducted by Dieter Burkhardt (Vice President Sales & Marketing), Heike Wolf (Manager Sales Services America) and Michael Georg (Product Manager Hip), CeramTec GmbH.

Harry E. Rubash, MD, earned his BS Summa Cum Laude in 1975 and his MD Cum Laude in 1979, both from the University of Pittsburgh. He completed his Internship in general surgery followed by a Fellowship and Residency in Orthopaedic Surgery at University of Pittsburgh. Dr. Rubash completed an AO Reconstructive and Trauma Fellowship in Munich, Germany and a Hip and Implant Surgery Fellowship at Massachusetts General Hospital/ Harvard Medical School.

Harry Rubash is the Chief of Orthopaedic Surgery at MGH and the Edith M. Ashley Professor of Orthopaedic Surgery at Harvard Medical School. He specializes in primary and revision hip and knee replacements.

He has earned numerous awards and honors from professional organizations, including the American Academy of Orthopaedic Surgeons, The Orthopaedic Research Society, The Hip Society, The Knee Society and the American Fracture Association. In 2006, Harry Rubash received the Clinical Research Award for Outstanding Orthopaedic Clinical Research by the Orthopaedic Research and Education Foundation.

He has shared his expertise at innumerable conferences, seminars and workshops throughout the world and has published extensively, including serving in editorial capacities for multiple journals and publications.

Harry Rubash has written nine major text books and published over 200 papers.

Contact:
Harry E. Rubash, MD
Chief, Department of Orthopaedic Surgery
Massachusetts General Hospital
55 Fruit Street, Yawkey 3B
Boston, MA 02114
USA

Contoura: A New Anatomically Contoured Femoral Head

by Thomas Zumbrunn, PhD, Michael P. Duffy, MD, Kartik Mangudi Varadarajan, PhD, Andrew A. Freiberg, MD, Harry E. Rubash, MD, Henrik Malchau, MD, Orhun K. Muratoglu, PhD

Massachusetts General Hospital, Department of Orthopedic Surgery,
55 Fruit Street, Boston, MA 02114, USA

Large diameter femoral heads are known in clinical and biomechanical studies to prevent dislocation and improve range of motion following total hip arthroplasty (THA). Consequently, the use of 36mm and greater diameter ceramic heads has increased ten-fold in the last decade (4% in 2003 to 43% in 2013, data provided by CeramTec GmbH). Large femoral heads can impinge against native soft tissues such as the iliopsoas causing tendonitis and activity related groin pain. The iliopsoas wraps anteriorly around the native or replaced femoral head (Fig. 1).

Iliopsoas impingement due to femoral head prominence can lead to chronic anterior hip and groin pain that not only limits daily activities, but athletic endeavors as well. Traditionally, iliopsoas tendonitis and/or impingement has been treated by steroid injection, arthroscopic or open tendon release, or revision THA with a reduction in head size. Steroid injections only treat the symptoms without addressing the cause and iliopsoas release can diminish joint function. Head size reduction has been shown to alleviate anterior hip pain, but may reintroduce the risk of dislocation. There is a clinical need for a femoral head that has a low risk of dislocation and is soft-tissue friendly. A next-generation, anatomically contoured femoral head shape can prevent this type of soft-tissue impingement.

Contoura is a new, anatomically contoured femoral head design that maintains the profile of a large diameter head over the hemispherical portion, and contours the peripheral profile and stability for soft-tissue relief over the inferior half (Fig. 2). The design offers a contoured, non-articulating region of the femoral head which provides iliopsoas tendon relief across the hip joint. This results in full coverage to support a stable articulation, while mimicking the native anatomy by preventing excessive overhang.

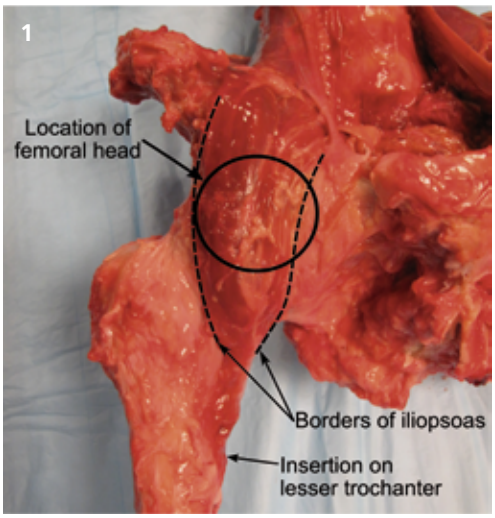
Cadaveric evaluations revealed that contact occurs between the femoral head and the iliopsoas complex with a wide range of head sizes. Contact was visually observed following dissection and THA implantation; further, iliopsoas tenting by conventional heads was found, and was improved with use of the Contoura implant. This was also demonstrated using radiographic images of the hip joint with metal wires embedded in the femoral head and attached to the iliopsoas (Fig. 3).

In addition to improving soft-tissue interaction, preliminary studies suggest that the Contoura head design allows for a reduction in frictional resistance in ceramic-on-ceramic implants. In initial biomechanical tests using a pendulum comparator, the contoured head reduced joint friction by 12% to 19% depending on joint load. Other biomechanical measures such as computational contact analysis, dislocation simulations and physical tests for wear resistance were identical between the contoured head and a conventional head.[1]

Our investigations show that the new Contoura femoral head provides stability in routine use of large diameter femoral heads, while offering the potential to prevent clinically significant soft-tissue impingement. ■

Reference

1 Varadarajan KM, Duffy, MP, Zumbrunn T, Chan D, Wannomae K, Micheli B, Freiberg AA, Rubash HE, MD, Malchau H, Muratoglu OK. Next-generation soft-tissue-friendly large-diameter femoral head. Semin Arthroplasty 2013;24(4):211–217



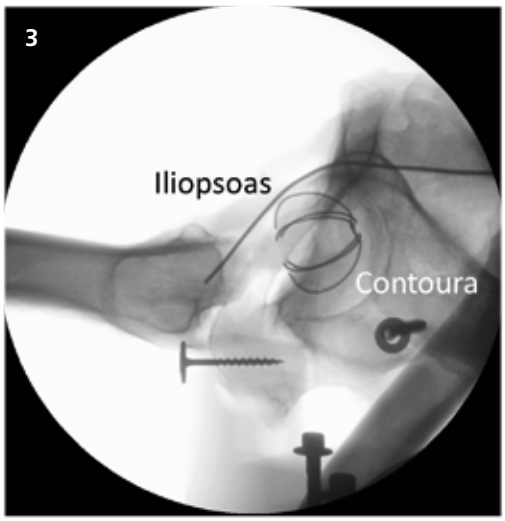


Fig. 1: Anterior hip view showing the iliopsoas wrapping around the femoral head
Fig. 2: Contoura (in front) and conventional implant
Fig. 3: Radiograph showing iliopsoas relief with contoured head

The anatomically contoured ball head BIOLOX® CONTOURA is under development and is not approved by the FDA or other authorities.

ACRONYMS

AAOS	American Academy of Orthopaedic Surgeons
AAS	Atomic Absorption Spectrophotometry
ALVAL	Aseptic Lymphocytic-dominated Vasculitis Associated Lesion
ARMD	Adverse Reactions to Metallic Debris
BMI	Body Mass Index
CFU	Colony Forming Unit
Co	Cobalt
CoC	Ceramic-on-Ceramic
CoCrMo	Cobalt-chromium-molybdenum
CoP	Ceramic-on-Polyethylene
CoXPE	Ceramic-on-XPE
Cr	Chromium
CRP	C-Reactive Protein
CT	Computer Tomography
DGOOC	Deutsche Gesellschaft für Orthopädie und orthopädische Chirurgie (German Society of Orthopaedics and Orthopaedic Surgery)
EPJIC	European Prosthetic Joint Infection Cohort Study
EFORT	European Federation of Orthopaedics and Traumatology
EHS	European Hip Society
ESR	Erythrocyte Sedimentation Rate
FDA	Food and Drug Administration
HHS	Harris Hip Score
HPF	High-Power Field
HR	Hip Resurfacing
ICIC	Inflammatory Cell Induced Corrosion
LTT	Lymphocyte Transformation Test
MARS	Metal Artifact Reduction Sequence
MIS	Minimally Invasive Surgery
MHC	Major Histocompatibility Complex
MoM	Metal-on-Metal
MoP	Metal-on-Polyethylene
MRI	Magnetic Resonance Imaging
Ni	Nickel
PE	Polyethylene
PJI	Periprosthetic Joint Infection
SEM	Scanning Electron Microscopy
THA	Total Hip Arthroplasty
TJA	Total Joint Arthroplasty
TKA	Total Knee Arthroplasty
TKR	Total Knee Replacement
WBC	White Blood Cell
XPE	Crosslinked Polyethylene

Metal Implant Allergy as a Differential Diagnosis of Periprosthetic Joint Infection

by Burkhard Summer, PhD, and Peter Thomas, MD, PhD

Clinic for Dermatology and Allergology, Ludwig-Maximilian-University, Munich, Germany

Introduction

As a consequence of the increasing use of metal implants, we can expect to see more complications. In 2011 in Germany alone 168,486 total knee and 232,320 total hip arthroplasties were performed. Of these, 9.5% and 10.4% respectively were revisions due to complications.[1] In the US the corresponding figures were 702,415 and 465,034 respectively, with revision rates of 8.4% and 10.7%. One of the triggers for complications is periprosthetic joint infection, which has a percentage frequency in the low single-digit range. The figures in the literature range from about 0.5% to 5%, with comorbidities and revision procedures increasing the risk.[2,3] The diagnosis of periprosthetic joint infection becomes a challenge particularly if the bacterial count is low or no microorganisms can be detected, such as is the case with low-grade infections. Another issue that has been attracting more attention in recent years is that of hypersensitivity to implant metals and bone cement components. In the following we would like to discuss these issues from an allergology and immunology perspective.

Does hypersensitivity to metal implants exist?

Cutaneous metal allergy, such as that due to occupational exposure or the wearing of fashion jewelry components, is common. As a result, the rate of contact allergy in the total population is about 13% for nickel (Ni), 3% for cobalt (Co) and 1% for chrome (Cr).[4,5] Women are usually affected more often – particularly against nickel. Implant allergy on the other hand appears to be rare compared to cutaneous metal allergy. However, as early as the 1970s there was a link made between implant failure and metal allergy.[6] These cases were usually isolated or consisted only of small case series as was reported in more recent review papers[7–9], although there are still no clear summary data available. Nevertheless, the Australian joint registry has included metal sensitivity as a cause of implant revision for the first time, and this was recorded as the reason for 0.9% of revisions in shoulder and 5.7% in hip arthroplasty.[10] It must be noted, however, that it cannot be assumed from these figures how often this corresponds to an allergy / hypersensitivity. All the same, we showed in a study funded by the Bavarian State Ministry of Health of 300 implant patients that, compared to implant patients who were free of symptoms, those patients affected by complications had higher allergy rates against alloy metals or bone cement components.[11]

Clinical symptoms

Of course, local or generalized *skin symptoms* direct attention to a suspected allergy. These symptoms include eczema, livid erythema resembling erysipelas, impaired wound healing and isolated cases of vasculitis or urticaria. In these cases a metal allergy is usually identified. Eczema reactions to osteosynthesis material have also been observed (Fig. 1). Skin symptoms resulting from bone cement allergy are possible but providing evidence is difficult.

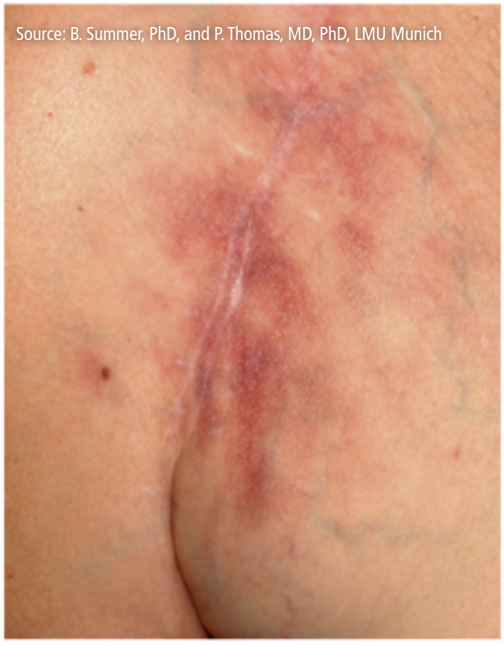


Fig. 1: Eczema developing over osteosynthesis with nickel allergy

Accordingly, the aim should be histological investigation of implant-associated skin symptoms, as described for the example of a pseudoerysipelas-like reaction, to avoid overlooking a periprosthetic infection and other rarer constellations such as reticular erythema or intralymphatic histiocytosis.[12]

Other manifestations of an implant allergy have been described, including impaired wound healing and – particularly for knee implants in our patient collective – pain, recurrent effusions, restricted mobility and loosening without infection.[13] Metal allergy may also play a role in the following constellations, but this is difficult to verify: aseptic implant loosening with peri-implant osteolysis; pseudotumor formation with metal-on-metal hip endoprostheses; excessive periarticular fibrosis (arthrofibrosis).

Clarification of cases of suspected allergy

Common causes, specifically periprosthetic joint infection (see below), must be excluded using differential diagnosis. The following steps are carried out during investigation of cases of suspected metal implant allergy:[14,15]

Epicutaneous testing
This enables standardized detection of metal allergy (specifically against Ni, Co and Cr) and contact allergy against bone cement components. However, a cutaneous allergic reaction cannot be equated 100% with the peri-implant constellation.

Histology
This can identify infection, particle-induced foreign-body reaction, fibrosis and inflammatory lymphocyte surface expression patterns. However, there is no definition of peri-implant histological hypersensitivity symptoms yet, and the causal trigger therefore cannot be identified.

Lymphocyte transformation test (LTT)
A T-cell metal sensitization can be revealed with this in-vitro procedure although it has been the preserve of scientific laboratories to date and requires the clinical relevance to be carefully checked. A recent review shows the diagnostic steps and a corresponding algorithm.[16]

Periprosthetic joint infection

An international consensus conference held in Philadelphia (USA) in 2013 defined joint infection and the steps required for its diagnosis.[2] According to the definition, an implant-associated infection is present if

- the same pathogen has been identified in at least two cultures of periprosthetic tissue *or*
- there is a sinus tract (fistula) communicating with the joint *or*
- three of the following minor criteria are met:
  - elevated C-reactive protein (CRP) concentration *and* erythrocyte sedimentation rate (ESR)
  - elevated synovial white blood cell count *or* change in the leukocyte esterase test strip reaction
  - elevated synovial neutrophil percentage
  - positive histology for the peri-implant tissue
  - a single positive culture

The threshold for the criteria listed above, the culture period, histology criteria and additional instrument-based techniques (such as radiography and sonication) were also defined at this consensus conference.

Figure 2 shows a patient with a suspected periprosthetic joint infection. The histopathology of the tissue samples taken can also provide sensitive information about low-grade infections using the neutrophil threshold (more than 23 in 10 high-power fields [HPF] or normal maximum 5–10 neutrophils per HPF in 5 or more HPF). The values indicated in the paper published by Morawietz et al. in 2009 are therefore within the currently defined limits. Repeat biopsies (as also required for microbiology) are recommended.

Other diagnostic methods may also become available in the near future, such as supplementary analysis of antimicrobial peptides in the synovial fluid or the peri-implant tissue.[17]

In routine clinical practice, however, suspected cases of periprosthetic joint infection often cannot be verified for many patients. False-positive results due to contamination and false-negative results due to too few biopsies or slow-growing microorganisms (which are missed if the incubation period is too short) lead to uncertainty.

The clinical examination also often reveals only minor inflammatory symptoms with moderate warmth, effusion and pain. Consequently, a diagnostic procedure in line with the consensus conference is recommended, whereby the sampling should be repeated in case of doubt.

Fig. 2: Patient with clinically suspected infection (differential diagnosis of implant incompatibility)

Procedure from an allergological perspective

If mechanical causes, misalignment, periprosthetic joint infection and other common differential diagnoses are excluded for arthroplasties affected by complications, then an allergic reaction should be considered as having triggered the symptoms. For this purpose, the summary of the epicutaneous testing and histology is required. The LTT can provide additional information about metal sensitization if it is carried out correctly, but it is not yet a widely used, routine procedure. Several working groups are currently determining other characteristics of patients with implant allergy.[18] What is certain is that metal implant allergy exists but is often overlooked. Follow-up studies will indicate under which conditions patients will benefit from hypoallergenic implants.[19,20] ■

Literature

1. Wengler A, Nimptsch U, Mansky T. Hip and knee replacement in Germany and the USA - analysis of individual inpatient data from German and US hospitals for the years 2005 to 2011. Ärzteblatt Int 2014;111(23-24):9
2. Parvizi J, Gehrke T (editors). Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection. Data Trace Publishing Company 2013
3. Zmistowski B, Della Valle C, Bauer TW, Malizos KN, Alavi A, Bedair H, et al. Diagnosis of periprosthetic joint infection. J Arthroplasty 2014;29 (2 Suppl):77-83
4. Schäfer T, Bohler E, Ruhdorfer S, Weigl L, Wessner D, Filipiak B, et al. Epidemiology of contact allergy in adults. Allergy 2001;56(12):1192-6
5. Thyssen JP, Menne T. Metal allergy – a review on exposures, penetration, genetics, prevalence, and clinical implications. Chemical research in toxicology 2010;23(2):309-18
6. Elves MW, Wilson JN, Scales JT, Kemp HB. Incidence of metal sensitivity in patients with total joint replacements. Br Med J 1975;4(5993):376-8
7. Basko-Plluska JL, Thyssen JP, Schalock PC. Cutaneous and systemic hypersensitivity reactions to metallic implants. Dermatitis 2011;22(2):65-79
8. Granchi D, Cenni E, Giunti A, Baldini N. Metal hypersensitivity testing in patients undergoing joint replacement: a systematic review. J Bone Joint Surg Br 2012;94(8):1126-34
9. Thomas P, Schuh A, Ring J, Thomsen M. Orthopädisch-chirurgische Implantate und Allergien: Gemeinsame Stellungnahme des Arbeitskreises Implantatallergie (AK 20) der Deutschen Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC), der Deutschen Kontaktallergie Gruppe (DKG) und der Deutschen Gesellschaft fur Allergologie und Klinische Immunologie (DGAKI). Orthopäde 2008;37(1):75-88
10. Registry AOANJR. Annual Report. 2012
11. Thomas P, Stauner K, Schraml A, Mahler V, Banke IJ, Gollwitzer H, et al. Charakteristika von 200 Patienten mit Verdacht auf Implantatallergie im Vergleich zu 100 beschwerdefreien Endoprothesenträgern. Orthopäde 2013;42(8):607-13
12. Kulichova D, Gehrke T, Kendoff D, Summer B, Parvizi J, Thomas P. Metal Hypersensitivity Mimicking Periprosthetic Erysipelas-Like Infection. J Bone Joint Surg Case Connect 2014;4(3).
13. Eben R, Walk R, Summer B, Maier S, Thomsen M, Thomas P. Implantatallergieregister – ein erster Erfahrungsbericht. Orthopäde 2009;38(6): 557-62
14. Schalock PC, Menne T, Johansen JD, Taylor JS, Maibach HI, Liden C, et al. Hypersensitivity reactions to metallic implants - diagnostic algorithm and suggested patch test series for clinical use. Contact Dermatitis 2012;66(1):4-19
15. Thomas P, Summer B, Krenn V, Thomsen M. Allergiediagnostik bei Verdacht auf Metallimplantatunverträglichkeit. Orthopäde 2013;42(8):602-6
16. Thomas P. Clinical and diagnostic challenges of metal implant allergy using the example of orthopedic surgical implants. Allergo J Int 2014;23 (in press).
17. Gollwitzer H, Dombrowski Y, Prodinger PM, Peric M, Summer B, Hapfelmeier A, et al. Antimicrobial peptides and proinflammatory cytokines in periprosthetic joint infection. J Bone Joint Surg Am 2013;95(7):644-51
18. Thomas PH, C.v.d., Schopf C, Thomsen M, Frommelt L, Schneider J, Flaig M, Krenn V, Mazoochian F, Summer B. Periimplant histology and cytokine pattern in Metal-allergic Knee arthroplasty patients with improvement after revision with hypoallergenic materials. Sem Arthroplasty 2012;23(4):268-72
19. Dietrich KA, Mazoochian F, Summer B, Reinert M, Ruzicka T, Thomas P.Intolerance reactions to knee arthroplasty in patients with nickel/cobalt allergy and disappearance of symptoms after revision surgery with titanium-based endoprostheses. J Dtsch Dermatol Ges 2009;7(5):410-3
20. Thomsen M, Rozak M, Thomas P. Verwendung von Allergieimplantaten in Deutschland: Ergebnisse einer Umfrage. Orthopäde 2013;42(8):597-601

Burkhard Summer, PhD, is human biologist at the Clinic for Dermatology and Allergology at the Ludwig-Maximilians-University in Munich, Germany. He has been working in the area of metal implant allergy for about 15 years.

Burkhard Summer has developed and evaluated in-vitro tests for the detection of metal hypersensitivity and sensitivity to newly developed biomaterials.

Correspondingly, he has performed many research projects in the field of implant allergy and studies concerning the biocompatibility of implant materials. The scientific goal of his work is the characterization of findings typical for patients' excessive immune reaction to implants. The main methods used are the assessment of mediator production and molecular cytokine expression of patients' blood cells or tissue samples.

Together with Peter Thomas, MD, PhD, Burkhard Summer runs a special outpatient ambulatory for patients with suspected implant intolerance reactions. More than 1,500 patients have already been seen in this special ambulatory.

Burkhard Summer has published the results of research projects and clinical studies in international journals. In addition, he takes active part in the education and supervision of postgraduate students in the fields of immunology and allergology. He is very interested in research contacts and academic discussion with international research groups.

Contact:
Burkhard Summer, PhD
Implant Allergy Working Group Allergomat
Clinic for Dermatology and Allergology
Ludwig-Maximilians-Universität München (LMU Munich)
Laboratory for Allergology U21
Frauenlobstr. 9–11
D-80337 Munich
Germany
Phone: +49 89 4400 56175
Fax: +49 89 4400 56158
E-Mail: implantatallergie.derma@med.uni-muenchen.de
http://allergomat.klinikum.uni-muenchen.de

Changing Paradigm

"Biology's Big Bang" in Arthroplasty

by Sylvia Usbeck and Leslie F. Scheuber
CeramTec GmbH, Plochingen, Germany

"Many of the big problems facing humanity are biological, or are susceptible to biological intervention."

The Economist,
June 14th 2007, p.13

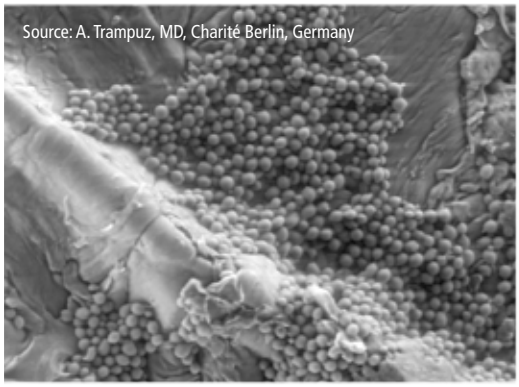
In 2007, "The Economist" opined in a cover article that many of the big human and social problems are biological. The question how to deal with periprosthetic joint infections (PJI) is one example. The article postulated that biology will be to the 21st century what physics was to the 20th century.

A paradigm shift is looming in arthroplasty. While tribology was the central and overriding issue in the 20th century in arthroplasty, in the 21st century it will be biology. The science and multidisciplinary-based research will direct attention more closely on the biological relevance of wear and corrosion products with implants, on systemic risks which have not been adequately researched and on the characterization of interactions between body cells and implant surfaces.

Periprosthetic joint infections (PJI) are biofilm infections and are one of the most complex and unsolved biological problems, also in the context of implants. PJIs are expected to impose a substantial burden on medical and socioeconomic systems in future. In a recent publication[1], scientists stated that PJI remains the leading cause of revision after TKA, affecting 0.4 to 4.0% of primary arthroplasties and that it is the third most common complication after THA, affecting 0.3% to 2.2%. They refer to a study performed in the USA, which estimates that the number of primary TKA and THA will increase by 673% and 174%, respectively, from 2005 to 2030. The annual cost of infected revisions incurred to US hospitals increased from $320 million to $566 million during the time period from 2001–2009 and has been projected to exceed $1.62 billion by 2020.[2] With an increasing number of arthroplasties, a corresponding increase in the number of PJIs is expected. The authors of this study predict that the burden of PJI over this period will increase from 1.4% to 6.5% after THA, and from 1.4% to 6.8% after TKA.

Because of this development, PJI and potential risk factors, corrosion and fretting with modular implants as well as adverse reactions to metal debris (ARMD) have become key issues at international conferences and in the specialist literature. CeraNews summarizes latest results.

Clinical appearance of PJI after THA. Implant-associated infections are a diagnostic, therapeutic and cost-related problem.



Periprosthetic joint infections (PJI) are biofilm infections. Biofilm on implant surface (SEM).

RISK FACTORS, DIAGNOSIS AND NEW FINDINGS OF THE PJI

Preoperative malnutrition is often cited as an independent risk factor for PJI after aseptic revision surgery. This has recently been reconfirmed by 2 studies which demonstrated that malnutrition is a risk factor for acute PJI. A large proportion of patients who undergo arthroplasty are obese. An increased risk of PJI and poorer outcomes are discussed as the tip of the iceberg. Early diagnosis of PJI and accurate identification of the responsible germs is currently being discussed as an essential element of the management strategy. Studies found conventional culture methods based on periprosthetic tissue and synovial fluid to be of poor diagnostic sensitivity.

STUDY

Malnutrition increases the risk of PJI after revision THA and TKA

Cross et al. and Yi et al. (USA) reported that a consecutive series of 375 aseptic revisions (202 TKA, 173 THA) and 126 septic revisions was screened for malnutrition. They found malnutrition in 53.2% of the patients undergoing revision for PJI compared to 32.8% in the patient group undergoing revision for other reasons. 3.2% of the 375 patients with aseptic revision developed acute PJI. The incidence of PJI was 7.3% in the malnourished group compared to 1.2% in the adequately nourished group. Malnutrition was both an independent risk factor for septic revision and acute PJI after aseptic revision.

The authors pointed out that preoperative malnutrition was common in both obese and normal weight patients. They concluded that given the high risk of acute PJI in malnourished patients, surgeons should consider screening patients for malnutrition preoperatively and revision procedures should be performed only after all nutritional parameters have improved.

Future studies should assess the impact of a standardized screening protocol with subsequent correction of abnormal laboratory parameters suggestive of malnutrition on the risk of PJI to determine the potential causal relationship.

STUDY

Malnutrition increases the risk of transfusion and PJI

Chen et al. (USA) evaluated 214 primary TJA (118 knees, 96 hips) in a retrospective study. They found that malnourished patients received more transfusions, and that those who were transfused had a higher risk of PJI.

STUDY

Being overweight increases the risk of PJI after TKA

Swiss scientists have investigated whether obesity correlates with PJI after primary TKA.

Zingg et al. (Switzerland) evaluated 2,816 primary TKA performed in 2,346 patients. The mean follow-up was 86 months. In their prospective study, the authors reported that an increased BMI was found more often in female patients and was associated with increased age and a higher rate of comorbidities. In their study, the authors detected a clear BMI cut-off of 35.

A BMI ≥ 35 was associated with double the risk for revision (any reasons) and PJI. They observed that this effect was stronger in men than in women.

STUDY

Increased rate of PJI after MIS anterior approach (Smith-Peterson MIS)

In a cohort of 601 consecutive MIS THA (551 patients), **Clauss et al.** (Switzerland) found a higher rate of PJI (2.0%) compared to published data in conventional THA. They found a high rate of polymicrobial infection (58%), and among them fecal pathogens were found in 42% of the cases. A relatively high BMI was found for the PJI group. The authors suggested that a more lateral incision leading away from the groin might be beneficial, especially in obese patients.

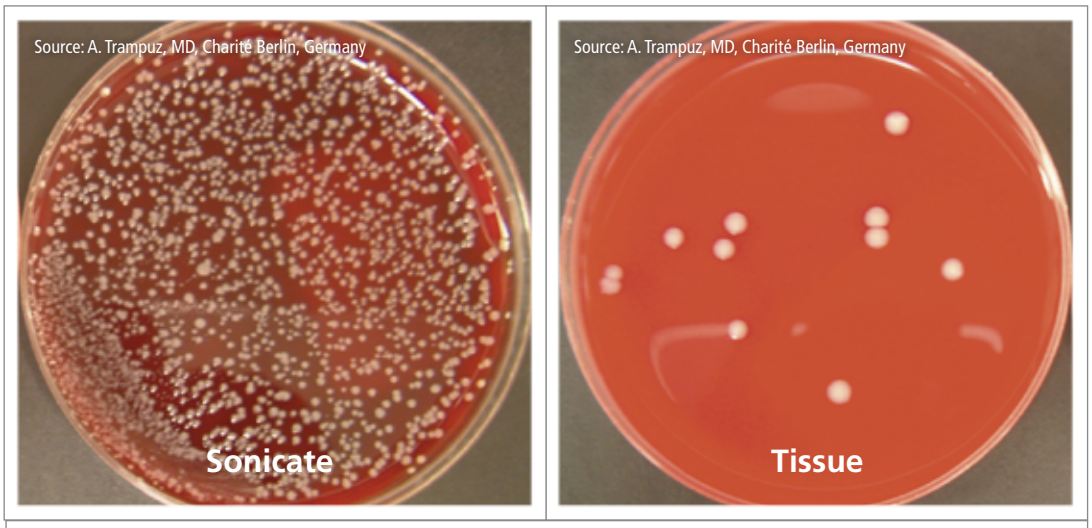
In 2011, **Holinka et al.** *(Austria)[3] tested the sonication method according to recommendations by Trampuz et al.[4] for all retrieved prostheses in their clinical diagnostic routine and confirmed a significant benefit for detecting germs from component surfaces compared with tissue culture. Recently further published studies confirmed that the sonication method is reliable and sufficient for pathogen detection in the clinical diagnostic routine.*

2 STUDIES

Sonication improves the microbiological diagnosis of PJI

Ravn et al. (Denmark) included consecutive revisions of 126 THA and 77 TKA in a prospective study. Based on clinical and serological findings, the authors expected a PJI in 48 revision cases. They compared the sonication fluid culture of the removed prostheses with the conventional periprosthetic tissue culture and synovial-fluid culture. The authors reported that conventional culture methods diagnosed 49 cases of PJI (24%), of which 7 and 5, respectively, were revised due to aseptic loosening and mechanical failure. In contrast, a positive sonicate-fluid culture was found in 68 cases (33%), of which 12 and 15, respectively, were revised due to aseptic loosening and mechanical failure. Among the 48 revision cases indicated by PJI, germs were identified by conventional methods in 37 cases (77%) and by sonication in 41 cases (85%). Contaminations found in revision cases were mainly due to mechanical reasons. The sonication led to fewer cases with contamination compared to conventional methods (15 and 6 cases, respectively).
The authors summarized that sonication detected 19 more positive PJI cultures compared to conventional methods, led to fewer contaminations and gave valuable information on the causative germs in a higher proportion of the revisions due to PJI.

Lepetsos et al. (Greece) investigated 64 patients with THA or TKA that were revised because of loosening of the prostheses. They compared the sonicate-fluid culture of the explanted prostheses with conventional periprosthetic tissue culture for the purpose of microbiological diagnosis of PJI. The authors found a significantly higher sensitivity of sonicate-fluid culture (84.6%) compared to the sensitivity of conventional tissue culture (61.5%).



New methods such as sonication of explanted implant components are revolutionizing the diagnosis of PJI. Cases that were initially interpreted as aseptic loosening can actually be identified as low-grade infections.

2 STUDIES:

Significantly higher bacterial adherence to PE components (TKA) and to XPE components (THA) compared to metal components

Unfortunately, significant clinical studies investigating the bacterial adherence to different explanted septic prosthetic components of knee prostheses, hip prostheses and others are lacking.

To our knowledge, so far the first study which confirmed experimental results of the higher bacterial adherence to conventional PE components (UHMWPE) compared to other implant materials was conducted by an Austrian research group in 2012. **Holinka et al.** (Austria) published important clinical findings of a study which evaluated and quantified the bacterial adherence on 100 different components of explanted total knee prostheses (femoral and tibial component, PE insert, patella) from patients with PJI. They evaluated the bacterial load of these knee component surfaces by counting the colony-forming units (CFU) using the sonication culture method. The authors reported that PE-inserts and tibial components were most often affected by microorganisms, although the difference was not significant in this study. The highest load of CFU was detected on PE components (insert, patella) compared to CoCrMo components. Staph. epidermidis adhered to the highest number of the knee components. Staph. aureus was identified as the pathogen causing the highest CFU count in the sonicate cultures. The authors pointed out that a partial component exchange or an exchange of single PE components in septic revision surgery may not be sufficient.

Recently, this research group published first important clinical results about the differential bacterial load on components of total hip prostheses in patients with PJI. **Lass et al.** (Austria) evaluated and quantified the bacterial adherence to 80 different hip components of retrieved prostheses (stem, cup, femoral ball head, insert) from 24 consecutive patients with PJI. They sonicated 16 titanium-aluminium-niobium alloy (Ti6Al7Nb) stems, 16 pure titanium cups, 24 ceramic femoral ball heads (BIOLOX®*delta*) and 24 XPE inserts.

All 24 prostheses (24 patients) showed positive sonication cultures. Germs were detected in 68 of 80 retrieved hip components. Staph. epidermidis was identified as the pathogen causing the highest CFU count, especially from the XPE inserts and was isolated from the majority of components.

The highest bacterial load was detected on XPE inserts (10,180 CFU; mean 566, range 0–5,000), followed by ceramic femoral ball heads (5,746 CFU; mean 319, range 0–2560), metal cups (5,007 CFU; mean 278, range 0–3000) and stems (1,805 CFU, mean 82, range 0–1000). The highest CFU load per component was detected on XPE inserts (566), followed by the metal cups (417) and ceramic femoral ball heads (338), whereas the CFU load for the pure titanium stems was much lower (164).

The authors pointed out that the important finding of this study was the significantly higher bacterial adherence to XPE inserts compared with metal implant materials (stem, cup), which confirms the lower bacterial adherence to metal (titanium, titanium alloy).

They reported that unequal distribution of CFU between ceramic femoral ball heads and XPE inserts was not significant, but showed that different biomaterials have an influence on the bacterial load.

We are however of the opinion, that evidence-based scientific studies are required that demonstrate significant clinical results and valid data about the bacterial load on different bearing surfaces.

EFFECT OF SMOKING ON FAILURE RATES IN PATIENTS WITH MoM BEARINGS

Cigarette smoke contains traces of cobalt and nickel. It is known that smoking affects both the innate and adaptive immune response. An association between smoking and an increased risk of nickel sensitization is already known from previous studies. For the first time, a study has now identified smoking as a potentially strong risk factor for failure of MoM bearings. This association was not evident in the compared patient group with CoP bearings.

STUDY

Smoking increases failure rate of MoM bearings in contrast to CoP bearings

Lübbeke et al. (Switzerland, USA) investigated the effect of smoking on revision rates in patients with cementless MoM THA compared to patients with cementless CoP bearings of the same cup design and ball head diameter (28mm). The study comprised 1,964 patients (57% female) with a mean age of 71 years. 1,301 CoP bearings and 663 MoM bearings were evaluated. The mean follow-up was 6.9 (1.8–12.8) years. 56 THA were revised.
In patients with MoM bearings the revision rate incurring among ever-smokers was 4 times greater than among non-smokers (95% CI 1.4–10.9). In patients with CoP bearings the incidence rate was significantly lower at 1.3 (95% CI 0.6–2.5). The 6 patients in the study showing ARMD were ever-smokers.

The authors hypothesized that the interaction between smoking and MoM bearings may be related to metal hypersensitivity. The authors concluded that smoking might be a trigger or an effect amplifier for ARMD from MoM bearings.

OUTCOME OF CERAMICS

Ankylosing spondylitis is a form of progressive arthritis caused by chronic inflammation of the spine and sacroiliac joints. It can also affect the hip joints. Data available concerning the outcome of THA with different bearings in patients with ankylosed hips are limited. However, initial clinical studies show significant benefits of CoC bearings in terms of long-term survival. The absence of osteolysis and therefore preserved bone stock might make potential revision surgery easier. The excellent biological behavior of ceramic particles is reflected in the lower risk of wear debris-induced osteolysis.

2 STUDIES

High long-term survival rate of CoC THA in patients with ankylosing spondylitis

Kim et al. (Korea) reported a 30–50% incidence of hip involvement in patients with ankylosing spondylitis. They noted that problems in connection with THA include, among other things, the young age and difficult surgical procedure in these patients.
The authors compared the clinical and radiological results of 49 cementless THA in 35 patients (30 male, 5 female). The mean age at the time of surgery was 32 (20–54) years. The mean follow-up was 9.1 (2.2–18.3) years. MoP bearings were used in 23 cases and CoC bearings were used in 26 cases.

The HHS showed no significant differences between the two patient groups. The radiological investigation showed osteolysis in 13 hips of the MoP group, whereas no osteolysis could be detected in the CoC group. Cup loosening was seen in 10 hips of the MoP group, whereas there was no loosened cup in the CoC group. The mean survival rate after 9.1 years was 100% in the CoC group compared with only 81% in the MoP group. The authors concluded that CoC bearings might be a preferable option in such cases of uncemented THA.

To our knowledge, so far the longest series of cementless THA in patients with ankylosed hips with a mean follow-up of 11 (5–19) years was published by **Rajaratnam et al.** (Australia) in 2009. These authors found similar results with CoC bearings in ankylosed hips.
They evaluated 16 cementless THA in 15 patients (9 male, 6 female) with a mean age of 52 (16–75) years at the time of surgery. In patients operated prior to 1993, a MoP bearing (22.25, 28 mm) was used. Patients operated between 1993 and 1997 received a CoP bearing (28 mm). Patients operated after 1997 had a CoC bearing (28, 32 mm) implanted. All patients showed improved mobility and function postoperatively. However, 9 hips (8 patients) received MoP or CoP bearings. 6 hips (5 patients) showed linear wear between 1 and 3 mm on the latest X-rays. Radiographic osteolysis was seen in 3 hips. A young female patient with MoP bearing (22.25 mm) was revised 5 years after surgery due to aseptic loosening of the cup. The authors postulated that aseptic loosening was due to a combination of high functional demands of the THA in this 16-year old patient at the time of surgery, combined with relatively soft acetabular bone due to juvenile rheumatoid arthritis.

None of the 7 patients (7 hips) who received a CoC bearing showed any radiographic evidence of linear wear or osteolysis at the latest follow-up.
They concluded that cementless THA allows an effective treatment of ankylosed hips with good longterm results.

STUDY

Higher mid-term survival rate for CoC bearings vs. MoP bearings

Radulescu et al. (Romania) reported on mid-term results of a prospective study comparing cementless CoC THA (alumina) in 60 patients (38 female, 22 male) with a mean age of 45.6 (30–62) years and cementless MoP THA in 62 patients (41 female, 21 male) with a mean age of 46.8 (32–64) years. The mean follow-up was 6.2 (4.1–8.9) years.
The radiological investigation showed osteolysis in 4 hips of the MoP group (6.45%), whereas osteolysis could be detected only in a single case of the CoC group (1.67%). The HHS showed no significant differences between the two patient groups.

The authors concluded that CoC bearings have a higher survival rate at 6 years postoperatively than MoP bearings.

STUDY

Retrieval analysis confirms excellent long-term wear behavior of the CoC bearing

Korim et al. (UK) studied 9 retrieved CoC bearings of the first generation of the so called "Mittelmeier prostheses", which were revised for aseptic loosening after a mean of 16 (7–20) years.
The ceramic components were alumina ceramic (BIOLOX®, CeramTec GmbH, Plochingen). The mean age of the patients (6 female, 3 male) was 48 (22–60) years at the time of primary surgery.

The authors reported that only 3 femoral ball heads showed areas of stripe wear with significantly higher surface roughness than minimally worn areas (0.645 µm vs. 0.289 µm). The remaining 6 bearings showed minimal wear (0.289 µm as opposed to smooth surface 0.011 µm).
They concluded that the first generation of CoC bearings still showed less wear over a long time period compared to previous retrieval analyses.

NEW FINDINGS ABOUT CORROSION: INFLAMMATORY CELL INDUCED CORROSION (ICIC) OF CoCrMo HIP AND KNEE IMPLANTS

Corrosion damage affecting the local biological system has been analyzed and discussed in a large number of publications. Recently published new evidence of corrosion damage caused by different inflammatory cell types is confronting scientists and clinicians with completely new questions concerning the clinical consequences of possible interactions between inflammatory cells and CoCrMo implant surfaces. These latest findings may also have an effect on our understanding of ARMD in joint replacements.

STUDY

Inflammatory cells are able to corrode CoCrMo implants *in vivo*

Gilbert et al. (USA) presented new evidence of direct inflammatory cell-induced corrosion of CoCrMo implants from microscopic observations of retrieved hip and knee implants. Of the 69 CoCrMo retrievals from 51 implant systems, including MoM and MoP bearings, corrosion damage caused by inflammatory cells was detected in 51 components (74%).

The authors reported that these observations were not limited to any specific design, alloy microstructure, metal or polyethylene insert material.

They observed different specific patterns of corrosion, which implies that different cell types and/or cell activities were stimulated. Corrosion topographies seem to show that individual cells migrate across CoCrMo implants, attach and seal down their membrane on the surface to drive the corrosion. The authors observed that the attacking cells are between 20 and 300 µm in size. Metallic iron plays an important role in the inflammation of joints; it was found in the areas that had been subject to extensive corrosive attack by the cells.
It is not yet clear, which conditions are necessary and which activation stimuli lead to this type of direct inflammatory cell attack and corrosion.

The authors speculated that activation stimuli may include tribocorrosion on bearing surfaces, modular tapers or other implant regions, particle generation from polyethylene implants, infection or unknown patient-specific factors.

It is still unknown whether such predisposing patient factors also play an essential role, similar to inflammatory diseases associated with a lower pH-value and changes in local environmental conditions. ■

CORRESPONDING AUTHORS:

Sylvia Usbeck (Clinical Affairs Manager)
Leslie F. Scheuber (Senior Product Manager Hip)
CeramTec GmbH
Medical Products Division
CeramTec-Platz 1–9
D-73207 Plochingen
Germany
E-mail: s.usbeck@ceramtec.de
E-mail: l.scheuber@ceramtec.de
www.biolox.com

References

1 Baek SH. Identification and preoperative optimization of risk factors to prevent periprosthetic joint infection. World J Orthop 2014;5(3):362-367 [Open Access Full Text Article]

2 Kurtz SM, Lau E, Watson H, Schmier JK, Parvizi J. Economic Burden of Periprosthetic Joint Infection in the United States. J Arthroplasty 2012;27(8),Suppl 1:61-65.e1

3 Holinka J, Bauer L, Hirschl AM, Graninger W, Windhager R, Presterl E. Sonication cultures of explanted components as an add-on test to routinely conducted microbiological diagnostics improve pathogen detection. JOrthop Res 2011;29(4):617-622

4 Trampuz A, Piper KE, Jacobsen MJ, Hanssen AD, Unni KK, Osmon DR. Mandrekar JN, Cockerill FR, Steckelberg JM, Greenleaf JF, Patel R. Sonication of Removed Hip and Knee Prostheses for Diagnosis of Infection. N Engl J Med 2007;357:654-663 [Open Access Full Text Article]

Literature

Chen AF, Xu PZ, Rothrauff B, Waters JH, Klatt BA. Malnourished Primary Total Joint Arthroplasty Patients Have Increased Transfusion and Infection Rates. Paper 475, AAOS 2014

Clauss M, Kessler B, Zwicky L, Graber P, Ilchmann T. Risk Factors For Infection After Hip Replacement With An Anterior MIS Approach. Abstract 2551, EFORT 2014

Cross BM, Yi P, Della Valle C, Vann E, Frank E, Sonn K, Moric M. Is Malnutrition A Risk Factor For Septic Failure and Acute Postoperative Infection Following Revision Total Joint Arthroplasty? Abstract 1209, EFORT 2014

Gilbert JL, Sivan S, Liu Y, Kocagöz SB, Arnholt CM, Kurtz SM. Direct in vivo inflammatory cell-induced corrosion of CoCrMo alloy orthopedic implant surfaces. J Biomed Mater Res Part A 2014. Online first published, 26 March 2014

Gilbert JL, Sivan S, Liu Y, Kocagöz SB, Arnholt CM, Kurtz SM. Evidence of Direct Cell Induced Corrosion of CoCrMo Implant Systems. Abstract 452, Society for Biomaterials 2014

Holinka J, Pilz M, Hirschl AM, Graninger W, Windhager R, Presterl E. Differential bacterial load on components of total knee prosthesis in patients with prosthetic joint infection. Int J Artif Organs. 2012;35(10):735-741

Kim Y, Hwang, KT, Choi IY, Kim YH. Uncemented Total Hip Arthroplasty In Patients With Ankylosing Spondilitis. Abstract 1181, EFORT 2014

Korim MT, Scholes SC, Unsworth A, Power R. Retrieval Analysis Of Alumina Ceramic On Ceramic Bearing Couples. Abstract 1494, EFORT 2014

Korim MT, Scholes SC, Unsworth A, Power R. Retrieval analysis of alumina ceramic-on- ceramic bearing couples. Acta Orthopaedica 2014;85(2):133-140

Lass R, Giurea A, Kubista B, Hirschl AM, Graninger W, Presterl E, Windhager R, Holinka J. Bacterial adherence to different components of total hip prosthesis in patients with prosthetic joint infection. International Orthopaedics (SICOT) 2014;38:1597-1602

Lepetsos P, Stylianakis A, Argyris D, Anastasopoulos PP, Lelekis M, Michail SP, Schizas N, Macheras GA. Use Of Sonication Of Removed Hip And Knee Implants For Diagnosis Of Prosthetic Joint Infections. Abstract 4077, EFORT 2014

Lübbeke A, Rothman KJ, Garavaglia G, Barea C, Christofilopoulos P, Stern R, Hoffmeyer P. Strong Association between Smoking and the Risk of Revision in a Cohort Study of Patients with Metal-on-Metal Total Hip Arthroplasty. J Orthop Res 2014:1-7 [Open Access Full Text Article]

Radulescu RA. Badila AE, Nutiu O, Manolescu RA, Japie IM, Ciobanu T, Terinte S, Radulescu DM, Papuc A. Medium Term Clinical Results Of Ceramic-Ceramic Uncemented Total Hip Arthroplasties. Abstract 2154, EFORT 2014

Rajaratnam SS, Sexton SA, Waters TS, Walter WL, Zicat BA, Walter WK. Long term results of cementless Total Hip Replacement for reversal of hip ankylosis. HipInt 2009;19(2):120-127

Raven C, Kemp M, Kjaersgard-Andersen P, Overgaard S. Microbiologic Diagnosis Based On Implant Sonication In Hip And Knee Arthroplasty Revison Surgery. Abstract 4383, EFORT 2014

The Economist. Biology's Big Bang, June 16th 2007 [Open Access Full Text Article]

Yi PH, Vann ER, Frank RM, Sonn K, Moric M, Della Valle CJ. Malnutrition Increases the Risk of Acute Periprosthetic Joint Infection after Revision Hip and Knee Arthroplasty. Poster P097, AAOS 2014

Yi PH, Vann ER, Frank RM, Sonn K, Moric M, Della Valle CJ. Is Potential Malnutrition Associated With Septic Failure and Acute Infection After Revision Total Joint Arthroplasty? Clin Orthop Relat Res 2014 May 28 [Epub ahead of print]

Zingg M, Miozzari H, Uckay I, Hoffmeyer P, Lübbeke A. Influence of Obesity On Revision And Infection Rates After Primary total Knee Arthroplasty. Abstract 1496, EFORT 2014

Further literature

Achermann Y, Vogt M, Leunig M, Wust J, Trampuz A. Improved diagnosis of periprosthetic joint infection by multiplex polymerase chain reaction in sonication fluid of removed implants. J Clin Microbiol 2010;48:1208-1214

Borens O, Yusuf E, Steinrücken J, Trampuz A. Accurate and early diagnosis of orthopedic device-related infection by microbial heat production and sonication. J Orthop Res. 2013;31(11):1700-1703

Corvec S, Portillo ME, Pasticci BM, Borens O, Trampuz A. Epidemiology and new developments in the diagnosis of prosthetic joint infection. Int J Artif Organs. 2012;35:923-934.

Font-Vizcarra L, Lozano L, Rios J, Forga MT, Soriano A. Perioperative nutritional status and post-operative infection in total knee replacements: a prospective study of 213 patients. Int J Artif Organs 2011;34:876-881

Holinka J, Bauer L, Hirschl AM, Graninger W, Windhager R, Presterl E. Sonication cultures of explanted components as an add-on test to routinely conducted microbiological diagnostics improve pathogen detection. J Orthop Res 2011;29:617-622

Jaberi FM, Parvizi J, Haytmanek CT, Joshi A, Purtill J. Procrastination of wound drainage and malnutrition affect the outcome of joint arthroplasty. Clin Orthop Relat Res 2008;466:1368-1371

Janz V, Wassilew GI, Hasart O, Tohtz S, Perka C. Improvement in the detection rate of PJI in total hip arthroplasty through multiple sonicate fluid cultures. J Orthop Res. 2013;31:2021-2024.

Janz V, Wassilew GI, Hasart O, Matziolis G, Tohtz S, Perka C. Evaluation of sonicate fluid cultures in comparison to histological analysis of the periprosthetic membrane for the detection of periprosthetic joint infection. Int Orthop. 2013;37:931-936

Larsen LH, Lange J, Xu Y, Schønheyder HC. Optimizing culture methods for diagnosis of prosthetic joint infections: a summary of modifications and improvements reported since 1995. J Med Microbiol 2012;61:309-316

Portillo ME, Salvadó M, Alier A, Martínez S, Sorli L, Horcajada JP, Puig L. Advantages of sonication fluid culture for the diagnosis of prosthetic joint infection. J Infect 2014, March 12 [Epub ahead of print].

Rai J, Gill SS, Kumar BRJS. The influence of preoperative nutritional status in wound healing aftrer replacement arthroplasty. Orthopedics 2002;25:417-421

Update
Bearing Exchange in the Management of Pathologic Findings Associated with Metal Components in Hip Replacement

by Sylvia Usbeck and Leslie F. Scheuber
CeramTec GmbH, Plochingen, Germany

The etiology of adverse biological periprosthetic soft tissue reactions associated with MoM bearings is not fully understood. Furthermore, the precise pathogenesis and prevalence of these complications still remain unclear. The FDA and EFORT / EHS have issued recommendations for the follow-up of symptomatic and asymptomatic patients with MoM hip implants.[4,9] However, there is no standardized diagnostic algorithm for recording and documenting symptomatic and asymptomatic pathologic soft tissue findings in the case of all implanted diameters of metal femoral ball heads. The reported prevalence of symptomatic and asymptomatic inflammatory pseudotumors after large-head MoM hip replacement ranges from 4% to 71%, depending on implant type, patient population and imaging techniques used (ultrasonography, CT, metal artefact reduction sequence [MARS] MR imaging).[1–3,5,6,8,10–15]

The clinical significance of asymptomatic pseudotumors remains uncertain. It is not known, whether and with what frequency asymptomatic patients develop symptoms in the further course of time. Meaningful studies in this regard are lacking. Currently, no consensus exists regarding the optimal surgical treatment of pseudotumors. An improved revision outcome data base possibly may answer relevant questions more specifically and provide appropriate guidance to orthopaedic surgeons.

Fig. 1: Female patient, 65 years old, 4 years post-op, MoM THA on left, symptom-free. An "unclear lymphocytic tumor" was diagnosed at a dermatological department, and the patient underwent surgery twice.

Case reports from the literature and clinical practice (Fig. 1–3b) indicate that the metal-related clinical problems seem to be solved in cases of revision to a bearing with ceramic component. Authors have suggested revising to a CoC, CoP or CoXPE bearing because ceramic implants are the most biologically inert of the current options in THA.

Fig. 2 a–b: Male patient, 65 years old, actively pursuing sports, MoM THA on right, 2 years post-op, symptom-free, swelling in flexion, effusion

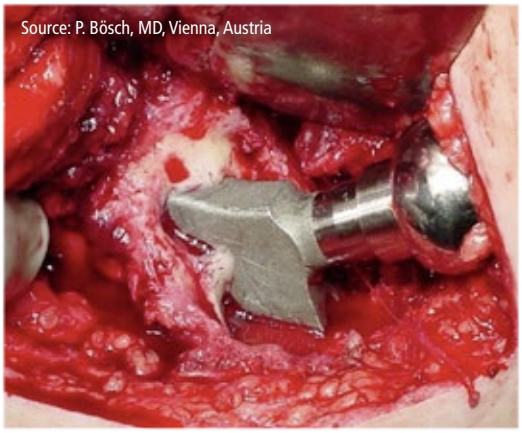


Fig. 3 a–b: Male patient, 59 years old, MoM THA on left, no symptoms, 11 years post-op, massive destructions of soft tissue and bone

CASE REPORTS

Bearing Exchange in the Management of Pathologic Findings Associated with MoM Hip Replacement

Cadossi et al. (Italy) reported on the case of a 59-year-old female patient who developed a benign pelvic pseudotumor 12 months after undergoing a MoM hip resurfacing surgery. She reported no medical history of metal allergies. The patient complained of pain and quadriceps weakness in her left thigh. Radiographs and CT scan showed a well fixed, stable implant and a solid pseudotumor around the femoral neck and proximal femur. A partial femoral nerve palsy was observed.
Moreover, the detailed medical history also showed that the patient had been working as a hairdresser for approximately 30 years and was therefore constantly exposed to chemicals for a long period of time. The authors pointed out that there are many reports on the high rate of allergic contact dermatitis in hairdressers.

Revision:
In the 1st step, the necrotic soft tissue mass was removed through a laparotomic approach. Metal ion levels (Co, Cr) high above normal values were detected in the periprosthetic tissues and in the serum by AAS. While the patient recovered from the operation, the 2nd step revision surgery was scheduled. The patient still complained about pain in her left thigh and no recovery of the partial nerve palsy could be observed. Positive skin reactions to Co and Ni were recorded by patch testing. High Cr and Co levels and a normal Ni level were measured in the serum. A hypereosinophilia was also detected. The prosthesis was stable and the radiographic analysis showed no radiolucent lines. The CT imaging showed the presence of a new iliopsoas mass which was removed during revision surgery.

The MoM hip resurfacing was replaced with a CoC THA. The histological analysis of the periacetabular tissue showed a dense lymphocyte infiltrate, a large number of mast cells and several eosinophils. The histological examination of the biopsy specimens from the iliopsoas mass and reactive tissue between the acetabular component and the iliac bone showed giant cells, macrophages, fibrous-macrophage reaction, fibrous tissue with infiltration of lymphocytes, large eosinophils, hemorrhagic areas and lymphoid follicles. Eosinophils are associated with allergies, tissue homeostasis and immune response. Increased cell count figures ranging from 2.9% to 8.3% showed eosinophilia.

Results:

The revision to CoC removed the source of the clinical problems. The authors reported that after MoM implant removal and implantation of a CoC THA the eosinophil percentage decreased to 7.7% after 10 days and further to 2.1% after 1 month. The pain subsided and merely the femoral nerve palsy was still present. The CT imaging confirmed the disappearance of the pseudotumor. The patient recovered normally without experiencing any new adverse reactions or complications.

Discussion:

The authors suggested that a steep cup positioning as well as a possible combination of 2 immune / inflammatory mechanisms, a macrophage-induced necrosis and a cell-mediated hypersensitivity reaction (delayed-type IV) to metal nanoparticles, have induced this pseudotumor development. In addition, these mechanisms were probably influenced by an occupational pre-sensitization to metals. The authors called for further investigation of the role of nanosized metal wear debris and metal ions in the pathogenesis of pseudotumors.

Sandiford et al. (UK) evaluated the indication and early outcome of 25 patients (13 female, 12 male), who underwent conversion of MoM hip resurfacing to an uncemented THA in a prospective study. One patient was lost to follow-up. The authors reported that intraoperative findings varied depending on the diagnosis. Indications for revision were mainly groin pain (6), unexplained pain after sport (2), pain with clicking (2), pain with effusion (10). The average time to revision surgery was 30.2 months (4–65).

Revision:

A small effusion was detected in all patients, charcoal colored in 3 cases and cream colored in 1 patient. Cystic lesions were observed behind the cup in 3 cases and a loosened cup in one of these cases. A black staining of the pseudocapsule was seen in 3 patients.
All patients with such findings were revised, the MoM bearing was replaced by a CoC bearing.

Results:

The authors reported that all patients were satisfied particularly by their pain relief, had an increased UCLA activity score and returned to their jobs and activities of daily life and sports.The average postoperative Oxford, Harris and Womac hip scores represented statistically significant improvements over the preoperative scores.

Discussion:

The authors pointed out, that the pathogenesis of adverse periprosthetic soft tissue reactions is not fully understood, however, it seems logical to avoid cobalt-chrome components in the bearing couple when revising for such an indication. Osteolytic lesions behind the cup were only observed in female patients. Female patients with smaller diameter bearing surfaces have higher failure rates in this cohort.
They referred to recently presented data from a series of over 1,000 patients (R. Treacy) and suggested that unexplained pain reactions possibly are more common in female patients with smaller diameter MoM bearings.
It has been assumed hitherto that metal-related complications occur less frequently when metal femoral ball heads with smaller head diameters (≤ 32 mm) are used than is the case with larger head diameters, and that these complications mainly affect females. However, there are no meaningful studies that provide information on the rate of symptomatic and asymptomatic complications in connection with MoM bearings and that cover all implant sizes and both genders.

After the publication by **Maurer-Ertl et al.** (2011), **Kawakita et al.** (Japan) presented the 2nd case in the literature involving an unilateral leg edema due to a pseudotumor after MoM THA. The authors reported on a typical inflammatory pseudotumor following a large diameter MoM THA on the left hip. Approximately 1 year after surgery, the 69-year-old female patient complained about a left-sided leg edema. A radiological investigation showed soft tissue swelling. The CT imaging showed a solid mass in front of the iliac fossa in the pelvis measuring 5 cm in diameter and compressing the left external iliac artery and vein.

Revision:

The authors reported that it was not possible to remove the whole soft tissue mass. Therefore they reduced its volume as much as possible. The histological findings were consistent with an inflammatory pseudotumor. The resected necrotic mass showed infiltration of lymphocytes and plasma cells surrounding microvessels with giant cells. The patient's leg edema improved gradually and the volume of the mass was reduced. The dilatation of the external vein disappeared. The patient underwent revision of the left THA simultaneously with primary THA on the right hip.
Surgeons found necrotic tissue inside the large diameter head and around the neck. The histological examination showed no metal wear particles. Metal ion concentrations in the joint fluid and the soft tissue were not significantly elevated. There were no signs of corrosion at the large diameter ball head/neck-taper junction. Osteolytic lesions of the acetabulum or femur were not detected.
The well fixed stem was not revised. The cup was exchanged, and the MoM bearing couple was revised to a CoC bearing couple.

Results:

The patient recovered normally without postoperative complications or any signs of adverse reactions.

Discussion:

The authors hypothesized that possibly a cell-mediated hypersensitivity reaction (delayed-type IV) rather than metal wear debris was the cause of the development of this pseudotumor. A number of studies postulate that metal hypersensitivity could be the cause of pseudotumors. Unfortunately, the question has not been answered if there is an associated threshold level of metal debris that will lead to the development of pseudotumors. However, it is also possible that several reactions (immunological, inflammatory, cytotoxic, hypersensitivity) may overlap in an individual patient with a MoM hip implant.

Johnson et al. (USA) focused on adverse tissue reactions associated with MoM bearings and noted that ARMD are associated with a high degree of morbidity. They presented the case of a 60-year-old female patient with left hip pain, clicking, and swelling 3.5 years after MoM HR. On physical examination, no relevant neurovascular pathology was established, but she showed a painful range of motion of her hip and audible squeaking. The chromium and cobalt levels were 65 and 53 ppb, respectively. The ESR, CRP level and WBC count were within normal limits. The radiological examination showed no loosening of the acetabular or femoral component. The CT imaging showed the presence of a 1.6 x 1.4 cm pseudotumor in the supraacetabular region of the left ilium which was removed during revision surgery.

Revision:

The authors reported that at opening of the capsule, 50 to 60 ml of grayish fluid was released. They observed an extensive pseudocapsule with the grayish staining of metallosis in the posterior and anteroinferior aspects of the hip joint. The histological analysis of the tissue showed a dense fibrous tissue with reactive changes, chronic inflammation and particulate-laden macrophages consistent with an ARMD. The MoM hip resurfacing was replaced with a CoP THA.

Results:

The patient recovered normally without postoperative complications or any new signs of adverse reactions. The authors reported that she had a slight Trendelenburg gait, no instability and a good range of motion of the hip at the 3-month follow-up. ■

„In revision for ARMD, the bearing surface should be revised to a non-MoM bearing to prevent recurrence of ARMD or continued symptoms."

Johnson S et al. Revision of Metal-on-Metal Bearing Surfaces in Hip Arthroplasty. Scuderi GR (ed.). Techniques in Revision Hip and Knee Arthroplasty. Elsevier Saunders 2014 p. 562

CORRESPONDING AUTHORS:

Sylvia Usbeck (Clinical Affairs Manager)
Leslie F. Scheuber (Senior Product Manager Hip)
CeramTec GmbH
Medical Products Division
CeramTec-Platz 1–9
D-73207 Plochingen
Germany
E-mail: s.usbeck@ceramtec.de
E-mail: l.scheuber@ceramtec.de
www.biolox.com

References

1. Bisschop R, Boomsma MF, Van Raay JJAM, Tiebosch ATMG, Maas M, Gerritsma CLE. High Prevalence of Pseudotumors in Patients with a Birmingham Hip Resurfacing Prosthesis. J Bone Joint Surg Am 2013;17(4):1554-1560
2. Bosker BH, Ettema HB, Boomsma MF, Kollen BJ, Maas M, Verheyen CC. High incidence of pseudotumor formation after large metal-on-metal total hip replacement: a prospective cohort study. J Bone Joint Surg Br 2012;94(6):755-761
3. Chang EY, McAnally JL, Van Horne JR, Statum S, Wolfson T, Gamst A, Chung CB. Metal-on-metal total hip arthroplasty: do symptoms correlate with MR imaging findings? Radiology 2012;255(3):848-857
4. Consensus statement "Current evidence on the management of metal-on-metal bearings".HipInt 2013;23(01):2-5
5. Fehring TK, Odum S, Sproul R, Weathersbee J. High Frequency of Adverse Local Tissue Reactions in Asymptomatic Patients With Metal-on-Metal THA. Clin Ortho Relat Res. 2014;472(2):517-522
6. Garbuz DS, Hargreaves BA, Duncan CP, Masri BA, Wilson DR, Forster BB. The John Charnley Award: Diagnostic Accuracy of MRI Versus Ultrasound for Detecting Pseudotumors in Asymptomatic Metal-on-Metal THA. Clin Orthop Relat Res. 2014;472(2):447-423
7. Hart AJ, Satchithananda K, Liddle AD, Sabah SA, McRobbie D, Henckel J, Cobb JP, Skinner JA, Mitchell AW. Pseudotumors in association with well-functioning metal-on-metal hip prostheses: a case-control study using three-dimensional computed tomography and magnetic resonance imaging. J Bone Joint Surg Am 2012;94(4):317-325
8. Kwon YM, Ostlere SJ, McLardy-Smith P, Athanasou NA, Gill HS, Murray DW. 'Asymptomatic' pseudotumors after metal-on-metal hip resurfacing arthroplasty: prevalence and metal ion study. J Arthroplasty 2011;26(4):511-518
9. Metal-on-Metal Hip Implants: FDA Safety Communication. **http://www.fda.gov/MedicalDevices/Safety/Alertsand-Notices/ucm335775.htm**
10. Nawabi DH, Hayter CL, Su EP, Koff MF, Perino G, Gold SL, Koch KM, Potter HG. Magnetic resonance imaging findings in symptomatic versus asymptomatic subjects following metal-on-metal hip resurfacing arthroplasty. J Bone Joint Surg Am. 2013;95(10):895-902
11. Nishii T, Sakai T; Takao M, Yoshikawa H, Sugano N. Ultrasound screening of periarticular soft tissue abnormality around metal-on-metal bearings. J Arthroplasty 2012;27(6):895-900
12. Sabah SA, Mitchell AW, Henckel J, Sandison A, Skinner JA, Hart AJ. Magnetic resonance imaging findings in painful metal-on-metal hips: a prospective study. J Arthroplasty 2011;26(1):71-76, 76.e1-e2
13. Van der Weegen W, Sijbesma T, Hoekstra HJ, Brakel K, Pilot P, Nelissen RGHH. Treatment of pseudotumors after metal-on-metal hip resurfacing based on Magnetic Resonance Imaging, metal ion levels and symptoms. J Arthroplasty 2013;29(2):416-421
14. Williams DH, Greidanus NV, Masri BA, Duncan CP, Garbuz DS. Prevalence of pseudotumor in asymptomatic patients after metal-on-metal hip arthroplasty. J Bone Joint Surg Am 2011;93(23):2164-2171
15. Wynn-Jones H, Macnair R, Wimhurst J, Chirodian N, Derbyshire B, Toms A, Cahir J. Silent soft tissue pathology is common with modern metal-on-metal hip arthroplasty. Acta Orthop 2011;82(3):301-307
[Open Access Full Text Article]

Literature

Cadossi M, Chiarello E, Savarino L, Mazzotti A, Tedesco G, Greco M, Giannini S. Fast growing pseudotumor in a hairdresser after metal-on-metal hip resurfacing: a case report. European Review for Medical and Pharmacological Sciences 2014;18(Suppl 1):29-33
[Open Access Full Text Article]

Johnson S, Babatunde OM, Lee J, Macaulay WB. Revision of Metal-on-Metal Bearing Surfaces in Hip Arthroplasty. Scuderi GR (ed.). Techniques in Revision Hip and Knee Arthroplasty. Elsevier Saunders 2014

Kawakita K, Shibanuma N, Tei K, Nishiyama T, Kuroda R, Kurosaka M. Leg Edema Due to a Mass in the Pelvis After a Large-Diameter Metal-on-Metal Total Hip Arthroplasty. J Arthroplasty 2013;28(1):197.e1-197.e4

Maurer-Ertl W, Friesenbichler J, Liegl-Atzwanger B, Kuerzl G, Windhager R, Leithner A. Noninflammatory Pseudotumor Simulating Venous Thrombosis After Metal-on-Metal Hip Resurfacing. Orthopedics 2011;34(10):e678-e681
[Open Access Full Text Article]

Sandiford NA, Muirhead-Allwood SK, Skinner JA. Revision of failed hip resurfacing to total hip arthroplasty rapidly relieves pain and improves function in the early post operative period. Journal of Orthopaedic Surgery and Research 2010;5:88
[Open Access Full Text Article]

Scuderi GR.Techniques in Revision Hip and Knee. Expert Consult. Saunders 2014

Further Literature

Aboelmagd SM, Malcolm PN, Toms AP. Magnetic resonance imaging of metal artifact reduction sequences in the assessment of metal-on-metal hip prostheses. Reports in Medical Imaging 2014;7:65-74.
[Open Access Full Text Article]

Donell ST, Darrah C, Nolan JF, Wimhurts J, Toms A, Barker TH, Case CP, Tucker JK. Norwich Metal-on-Metal Study Group. Early failure of the Ultima metal-on-metal hip replacement in the presence of normal plain radiographs. J Bone Joint Surg Br 2010;92:1501-1508

Matthies AK, Skinner JA, Osmani H, Henckel J, Hart AJ. Pseudotumors are common in well-positioned low-wearing metal-on-metal hips. Clin Orthop Relat Res 2012;470(7):1895-1906

Makis W, Rush C, Abikhzer G. Necrotic pseudotumor caused by a metal-on-metal total hip prosthesis: imaging charakteristics on F-FDG PET/CT and correlative imaging. Skeletal Radiology 2011;40(6):773-777

Nam D, Barrack RL, Potter HG. What Are the Advantages and Disadvantages of Imaging Moadilities Wear-related Corrosion Problems? Clin Orthop Relat Res, published online 25 March 2014

Nawabi DH, Gold S, Lyman S, Fields K, Padgett DE, Potter HG. MRI Predicts ALVAL and Tissue Damage in Metal-on-Metal Hip Arthroplasty. Clin Orthop Relat Res 2014;472:471-481

Nawabi DH, Nassif NA, Do HT, Stoner K, Elpers M, Su EP, Wright T, Potter HG, Padgett DE. What causes unexplained pain in patients with metal-on metal hip devices? A retrieval, histologic, and imaging analysis. Clin Orthop Relat Res. 2014;472(2):543-54

Parsons TM, Satchithananda K, Berber R, Siddiqui IA, Robinson E, Hart AJ. Magnetresonanztomographische Untersuchungen bei Problemen mit Metall-auf-Metall-Implantaten. [Magnetic resonance imaging investigations in patients with problems due to metal-on-metal implants] Orthopäde 2013;42:629-636
[The English full text version of the article is available online at Springer Link "Supplement" **dx.doi.org/10.1007/s00132-012-2036-2**]

Santos MK, Polezi MB, Engel EE, Pastorello MT, Simao MN, Junior JE, Nogueira-Barbosa MH. Uncommon Presentations of intraosseuous hemophilic pseudotumor in imaging diagnosis. Radio Bras. 2009;42(3):159-163
[Open Access Full Text Article; English and Portuguese]

Trends and Prospects in Shoulder Arthroplasty

an interview with Felix Zeifang, MD, PhD

Department of Orthopaedic and Trauma Surgery, University Hospital of Heidelberg

Shoulder surgery has undergone intensive development in recent years. Case numbers for arthroplastic treatment have increased sharply. As for other types of arthroplasty, the most important issues in this area are wear, infection and allergy. We spoke with Felix Zeifang, MD, PhD about the significance of arthroplasty in shoulder surgery as well as its unresolved issues and prospects.

What are some of the recent developments in shoulder arthroplasty?

Each year about 185,000 shoulder prostheses are implanted worldwide, 20–30,000 of these in Germany. Thus, shoulder arthroplasty is quite a small field compared to hip and knee arthroplasty. However, the number of implantations has increased considerably in recent years. The highest growth can be observed for reverse prostheses.

Why has there been such an increase in the number of reverse prostheses?

With increasing age, degenerative changes develop that ultimately lead to tears in the rotator cuff. This affects both healthy people and patients with arthritis of the shoulder joint (omarthritis). The fraction of patients with a deficient rotator cuff is correspondingly high: At 60 years of age about 10% of people are affected and this figure increases with each additional year by about one or two percentage points. With a reverse prosthesis the muscles of the rotator cuff are dispensable and function is restored primarily using the delta muscle. It therefore benefits predominantly older people.

How has the indication for shoulder arthroplasty changed in recent years?

Along with omarthritis, treatment of comminuted fractures of the proximal humerus is a common indication nowadays. Restoration of function is more effective for this indication with a reverse prosthesis than with a plate.

How do the clinical results look?

The subjective satisfaction of patients is very high. This is true for both anatomical and reverse prostheses. The critical factor is choosing the right type of prosthesis. With the correct choice, we achieve very good values with more than 80% satisfaction – even 10 years after implantation. The revision rates are relatively low. However, there is a lack of studies with high case numbers. In a study that we recently published, no revisions were required for 39 implanted total shoulder prostheses after a mean follow-up period of 13 years.[1]

Nevertheless, radiographic analysis of the anatomical prostheses revealed a high rate of loosening of the glenoid components. This rate was 36% after 13 years in our study. However, the predominantly older patients did not have any symptoms that restricted function. Despite the radiographically verified loosening, they are still satisfied. Fixing the glenoid components permanently is still the greatest challenge for anatomical prostheses.

Do you also see this problem with reverse prostheses?

With reverse prostheses we see considerably less loosening of the glenoid components. We now have the first 10-year results for reverse prostheses. The radiographic examinations show that the glenosphere baseplates are still firmly fixed. In contrast we have a problem with scapular notching, which is characterized by bone erosion on the lower edge of the baseplate. This phenomenon affects about two-thirds of all reverse implants but does not result in loosening of the glenoid components. The causes of scapular notching have not yet been determined. It may possibly be due to mechanical or capsular irritation or wear-induced osteolysis.

For reverse prostheses, loosening is seen rather around the stem. This loosening may possibly be caused by micromotions, larger rotational movements or wear particles. Apart from this, a loss of function is observed with reverse shoulder prosthe-

ses. There is a gradual reduction over time in the strength with which patients are able to hold a weight on an abducted arm. Again, the underlying cause of this has not been definitely determined but it may be due to fatigue of the delta muscle – possibly as a result of changes in the sarcolemma length or increasing fatty degeneration of the muscle.

What is the cause of the high loosening rate for anatomical prostheses?

Some of the loosening is certainly due to the suboptimal design of earlier implants and the learning curve associated with shoulder arthroplasty in general. The range of components available was also too small to adequately adjust to the anatomy of each patient. The systems available nowadays are very good, however, and the surgical technique has also been improved: While the cancellous bone was previously reamed, we now know that the implant is more stable when fixed to the cortical bone.

Cemented PE components are currently the gold standard for the glenoid. However, the fixation options are not optimal because of the relatively small bone. Micromotions can also develop that cause the implant to no longer sit firmly in place. We hope that modern cementing techniques with pressurizing and jet lavage as well as new component designs improve this situation.

Is cementless fixation more stable?

Cementless fixation of the shoulder cup, using metal-backed systems, is associated with a significant wear problem. This causes high rates of loosening that are associated with clinical symptoms, even before ten postoperative years. The revision rate is correspondingly high for cementless fixation: According to an analysis of New Zealand registry data from 2013, the rate is about 4 to 5 times higher than that for cemented fixation.[2]

So cementless fixation is not a good alternative?

Not at the moment unfortunately. However, there is another reason why it would be useful if it were a good alternative: It would simplify the change from an anatomical to a reverse prosthesis. This is necessary if patients who have an anatomical implant fatigue the muscles of the rotator cuff as a result of the normal degeneration process. Removing a cemented cup is problematic, though, because it creates a large hole in the bone that must be filled to enable fixation of a baseplate. Changing the stem can also be very difficult and invasive.

What do you consider needs to be addressed?

I consider developments on the glenoid side as being the most necessary. What would be optimal of course would be if the glenoid component of the anatomical prosthesis already contained a baseplate that was also suitable for fixing a ball head (glenosphere) when exchanging to a reverse prosthesis. However, this causes problems due to the offset for one thing and the fact that the metal-backed components are associated with high rates of wear-induced loosening for another. Bearing couple research for the shoulder is still in its infancy, although we have high hopes that the wear issues can be minimized by using ceramic components, for example.

Are there other problems for which the use of ceramic components has benefits?

For patients with a metal allergy, we have to resort to using titanium implants for now. Ceramic implants would be an improvement for these patients. In shoulder arthroplasty there are also increasing problems due to periprosthetic infections. Along with Staph. aureus and Staph. epidermidis , one microbe that is otherwise rarely seen in arthroplasty is causing us problems: Propionobacterium. This physiological dermal microbe is found in the axillae and was probably often overlooked in the past because cultures to verify its presence have to be incubated for at least 10 days. As results for hip arthroplasty show, the use of ceramic components is associated with lower rates of infection. Ceramic thus may also be of use in avoiding infections in future.

Felix Zeifang, thank you for the discussion. ■

The interview was conducted by Heinrich Wecker (Director Strategic Business Development for Medical Engineering, CeramTec GmbH).

References

1. Raiss P, Schmitt M, Bruckner T, Kasten P, Pape G, Loew M, Zeifang F. Results of cemented total shoulder replacement with a minimum follow-up of ten years. J Bone Joint Surg Am. 2012;94(23):e1711-10
2. Clitherow HD, Frampton CM, Astley TM. Effect of glenoid cementation on total shoulder arthroplasty for degenerative arthritis of the shoulder: a review of the New Zealand National Joint Registry. J Shoulder Elbow Surg. 2014;23(6):775-781

Felix Zeifang, MD, PhD, has been Assistant Medical Director at the Department of Orthopaedics and Trauma Surgery at the University Hospital of Heidelberg since July 2005 and has been in charge of the Shoulder and Elbow Surgery Section since 2010.

The main focus of his work and research lies in the area of shoulder surgery, shoulder arthroplasty, cartilage cell transplantation, treatment of localized cartilage defects, tumor and septic orthopaedics as well as foot surgery.

Felix Zeifang has published more than 40 specialist articles in his research field and received several prizes for them. He is also Assistant Lecturer at the Orthopaedic University Clinic and Director of the Training Center for Shoulder and Elbow Surgery of the German Society for Shoulder and Elbow Surgery.

Contact:
Felix Zeifang, MD, PhD
Head of the Shoulder and Elbow Surgery Section
Department of Orthopaedic and Trauma Surgery
University Hospital of Heidelberg
Schlierbacher Landstraße 200a
D-69118 Heidelberg
Germany
Phone: +49 6221 56 262 24
Fax: +49 6221 56 283 88
E-mail: felix.zeifang@med.uni-heidelberg.de

CONGRESSES & WORKSHOPS

16th EFORT Congress Main Theme: Infection

The main theme of the 16th EFORT Congress Prague 2015 is periprosthetic joint infection. Highlights of the scientific agenda include:

- Bacterial adherence to orthopaedic biomaterials
- Economics of orthopaedic infections
- Infected TKR
- Patient-adapted treatment in TJA infection
- RSA studies in implant research
- Current issues in tribology
- Dual mobility in THA: Indication and limitations.

Prague, Czech Republic,
27–29 May 2015

Information and online registration:
www.efort.org/prague2015

Interdisciplinary Workshop on Prosthetic Joint Infection

The PRO-IMPLANT Foundation (Charité-University Medicine, Berlin) plans to continue their successful interdisciplinary workshops (English) also for 2015, which will cover all the relevant issues in periprosthetic infection from diagnosis to medical and surgical therapy. The courses include presentations by experts, interactive case discussions and practical hands-on workshops.

The European Prosthetic Joint Infection Cohort Study (EPJIC) will also be presented.

The EPJIC is an international multicenter research project including 5,000 patients with PJI to evaluate the long-term outcome regarding infection, function and quality of life

More than 100 hospitals have already expressed their interest in participation in the study.

If you are interested in collaborating, please contact the PRO-IMPLANT Foundation:

E-mail: info@pro-implant-foundation.org

Course dates: March 5–6,
June 1–2,
September 24–25, 2015

Location: Langenbeck Virchow Haus
Luisenstraße 58/59
D-10117 Berlin
(Germany)

Information and online registration:
www.pro-implant-foundation.org

LATEST NEWS

CeraNews App: The Magazine of CeramTec GmbH – The Orthopaedic Landscape Information Journal

The magazine CeraNews from CeramTec is now also available as a free app. This means that besides the already well-known print version, the magazine now also exists in electronic form for mobile access at any time.

The current edition covering PJI is already available as an app. Previous editions can also be obtained from the CeraNews app. Twice a year, the magazine offers its readers free, up-to-the-minute and interesting reports on various major clinical and scientific topics such as implant pathology, tribology and bearing couples. Whether in the clinic or out and about, with the CeraNews app you can follow current topics from the field of hip arthroplasty online!

Key Features:

- Leading themes
- Interviews
- By-lined articles
- Literature reviews
- Basic information
- Case reports

www.ceranews.com
App Store: https://itunes.apple.com/app/id906409794
Google-Play-Store: https://play.google.com/store/apps/details?id=com.pressmatrix.ceranews

PALACADEMY® App: Essentials in Diagnostics of Periprosthetic Joint Infection (PJI)

Periprosthetic joint infection (PJI) is a severe complication in arthroplasty and has a significant impact on patients' well-being and healthcare systems. One of the greatest challenges in its management is the "culture-negative" PJI.

In published case series, the reported rate of culture-negative PJI ranges from 5 to 41%. A number of factors contribute to the failure of microbiological cultures to isolate a pathogen.[1]

With the new PALACADEMY®App "Essentials in Diagnostics of Periprosthetic Joint Infection (PJI)" now available for iPad Heraeus Medical provides an educational tool to learn about the challenges and how to improve the diagnostic outcome.

Key Features:

- CASES – step-by-step along a real case through the diagnostic algorithm
- CHALLENGES – most frequent questions and problems around PJI, practical tips, videos
- MEDIA LIBRARY – commented literature review,
  graphs and figures for download
- CASE REPORTS – clinical cases for exchange

http://heraeus-medical.com/en/diagnostic_app/diagnostic_app_1.aspx

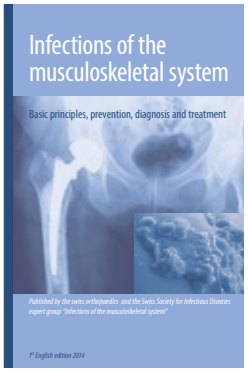
[1] Peel, T. et al. 2013. Management of Prosthetic Infection According to Organism. http://dx.doi.org/10.5772/53244

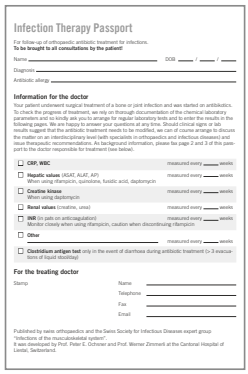
READING TIPS

Infections of the musculoskeletal system: *Basic principles, prevention, diagnosis and treatment*

Infections of the musculoskeletal system are a rare but devastating complication for the patient and the surgeon. This book is the result of a collaborative effort between Swiss Orthopaedics and the Swiss Society for Infectious Diseases. Representatives of these two organizations authored this publication as members of the expert group "Infections of the musculoskeletal system" founded by the two associations.

The book gives a concise overview on the different aspects of this subject. A second objective is to encourage greater cooperation between infectious disease specialists and orthopaedists/trauma surgeons together with microbiologists, pathologists, and plastic surgeons, as necessary, in the handling of these difficult infections.





The free pocket book and the Infectious Disease Passport (English, German) – created to accompany the antibiotic treatment of these patients – can be ordered at:

Heraeus Medical GmbH
Philipp-Reis-Str. 8/13
D-61273 Wehrheim, Germany

www.heraeus-medical.com

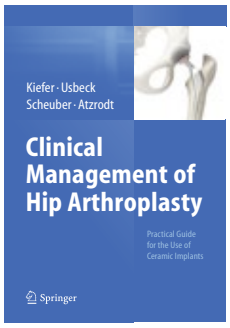
A Practical Guide for the Clinical Use of Ceramic Implants in Hip Arthroplasty

This book is intended to impart practical tips and information on the use of ceramic hip implants in routine clinical work in a concise and clear manner. The strong practical relevance and colorful visual material will enable clinicians to gain a rapid grasp of the most important information.

The volumes of the Clinical Management Guide series are directed at orthopaedic surgeons who want to acquire information rapidly while saving as much time as possible. As a helpful advisory tool, this Pocket Guide concisely and clearly imparts the current state of knowledge on selected issues of everyday clinical practice and, in doing so, concentrates purely on the essential.

In addition, it also addresses medical practitioners and scientists of adjacent specialist disciplines who are not confronted on a daily basis with problems regarding arthroplasty but, when required, would like to access important information on a specific topic.

Kiefer H, Usbeck S, Scheuber L.F., Atzrodt V
Clinical Management of Hip Arthroplasty. Practical Guide for the Use of Ceramic Implants.



1st ed. 2014, 40 p. 24 illus., in color
Springer Heidelberg

Available Formats:

eBook
ISBN 978-3-662-45492-3
Included Format: PDF and EPUB, download immediately

Softcover
ISBN 978-3-662-45491-6

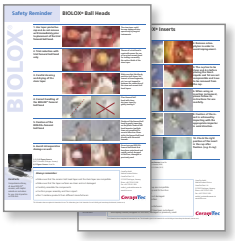
To be published October 2014

Text (News Ticker):
S. Usbeck (Clinical Affairs Manager),
L. F. Scheuber (Senior Product Manager Hip),
F. Petkow (Manager Sales Services International)

Please send this fax to: +49 7153 611 16513 or e-mail at ceranews@ceramtec.de

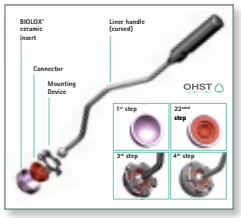
PLEASE SEND ME MORE INFORMATION:

☐ **CeraFacts:** USB stick media library (animations, live surgeries and videos)



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

@ available as PDF



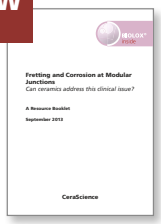
☐ **Information on the inserter instrument** for BIOLOX® inserts

@ available as PDF

☐ **Bearing couple selection** for revisions after a ceramic fracture

@ available as PDF

NEW



☐ **Fretting and Corrosion at Modular Junctions** – Can ceramics address this clinical issue? A Resource Booklet

@ available as PDF

☐ **I am interested in scientific papers on ceramics in arthroplasty.**

☐ **Please contact me via phone/e-mail.**

☐ **I am interested in new medical applications for ceramics. Please send me the brochure "BIOLOX® family – the future in your hand" and contact me via phone / e-mail.**

☐ **I would like to receive CeraNews Online via e-mail (PDF).**

☐ **I would like to receive a printed issue of CeraNews regularly.**

Please fill out using capitals!

First name
Last name
Title
Position
Department
Hospital/institution
Street
Town, postal code
State, country
Phone
Fax
E-mail

Do you have a smartphone? Yes ☐ iPhone ☐ Android ☐ Blackberry ☐ No
Do you have a tablet PC? Yes ☐ iPad ☐ other ☐ No