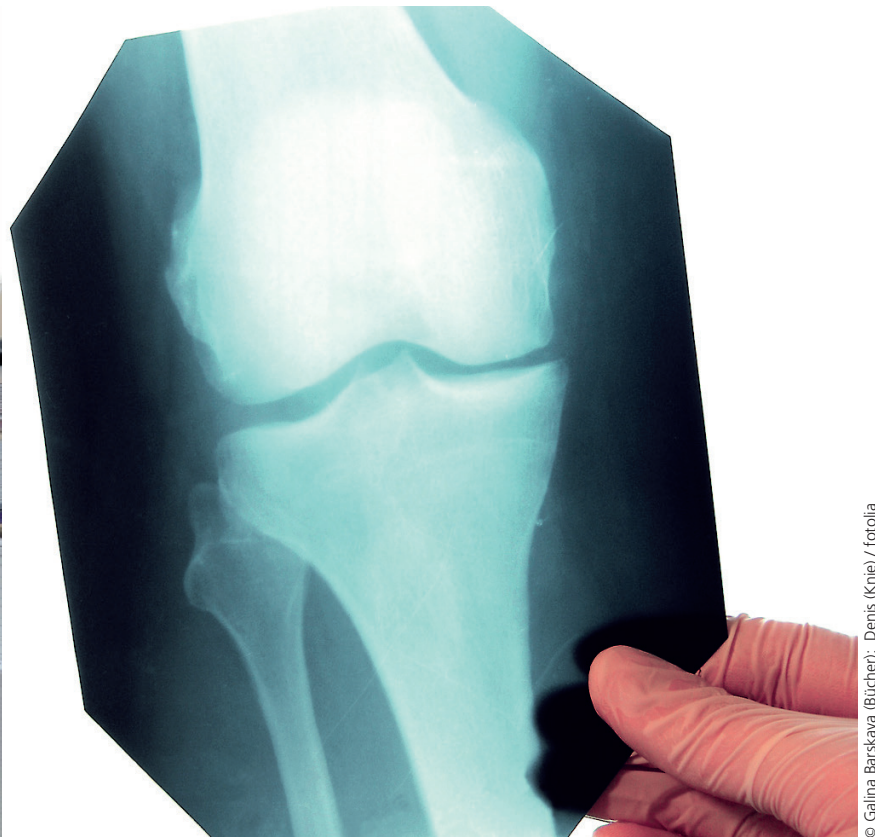


CeraNews

ISSUE 1/2015

The Orthopedic Landscape Information Journal

Focus: Knee Arthroplasty Evidence-based Medicine in Orthopedics



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Total Knee Arthroplasty is currently Experiencing a New Phase

By Benazzo F, MD, Pavia, Italy

The number of prostheses implanted worldwide every year is constantly increasing for several reasons:

- *more surgeons are being educated to perform this particular class of operation;*
- *more patients now have a longer life span and increased articular damage as a consequence of the extended utilization of their joints;*
- *extension of the indications for TKA in a range of young, active patients with damaged knees,*
- *and implants are becoming more easily available in emerging countries.*

Together with the growing number of surgeries, an increased incidence of related problems is also becoming evident, including:

- *residual symptoms in a high percentage of patients (almost 20%), such as pain, stiffness, and instability, along with other minor but annoying symptoms;*
- *material-related problems such as wear in young and active patients; and allergies.*

Thus, it is evident that efforts must be made to improve designs (with a strong shift toward more natural kinematics of the knee), materials (that are not harmful for the patients and have a long and wear-free life), and techniques and methods of implantation (robotics). There is also new interest being shown in partial prosthetic replacement of the affected knee (uni-compartmental, bi-unicondylar, patellofemoral joint replacement).

The BioloX[®]delta composite ceramics, owing to their manufacturing features such as bending strength and stress load capacity, could be the new benchmark of biomaterials available for clinical use, as demonstrated by the cohort of patients treated with knee devices made of BioloX[®]delta. New scenarios are therefore opening, specifically in the so-called small-implants field of partial knee replacement.

However, the safety and reliability of new implant products for patients must be guaranteed. No longer can we allow the success of a device to be validated on the basis of biased, by definition, expert opinion. All the new phases of applied research entail the problem of demonstrating efficacy and safety, clearly and incontrovertibly. Therefore, they must be validated under the umbrella of the evidence-based medicine (EBM). The evidence pyramid should be the basis for evaluating the properties and quality of any device, material, or surgical method. Critical evaluation has received enhanced attention with metal-on-metal (MoM) failure and consequent clinically devastating effects, such as adverse reactions to metal debris (ARMD). Critical evaluation has been extended to the "new" materials such as cross-linked polyethylene (XPE), (for which the claimed lack of wear was not demonstrated), and to new phenomena, such as corrosion of the metal junction in all prosthetic designs.

Together with the awareness of the potential drawbacks that any innovation could bring, and of the harm any patient could suffer, research on new applications of proven materials such as BioloX[®]delta ceramics will continue and will be monitored in accordance with the EBM principle.

This is the message that the new issue of CeraNews wants to bring to the customers.



Francesco Benazzo, MD



Francesco M. Benazzo, MD, studied medicine at the University of Pavia, graduating in 1980. He devoted himself to electron microscopy during his studies and early in his career. He pioneered the application of special techniques such as freeze-etching and freeze-fracture to the connective tissue, and in particular to cartilage and tendons.

He trained as an orthopedic surgeon in Pavia, completing his education in orthopedics and traumatology in 1985 with a thesis on a rare genetic disease involving the long bones (Lipomembranous osteodystrophy), including an electron microscopic evaluation of the lesions. During the residency program, he was introduced by his mentor, Prof. Boni, both to cervical spine surgery and to sports traumatology.

Benazzo served as assistant in the Sports Traumatology Section of the orthopedic clinic and finally assumed an academic position as assistant professor in 1990. In 2000 he became full professor of orthopedics and traumatology, and two years later Chairman of the Orthopedic and Traumatology Department of the University of Pavia, San Matteo Hospital. Since then, he has also chaired the Program of Residency in Orthopedics and Traumatology. In 2002, he became consultant to the Football Club Internazionale Milano, where he served until 2014 as surgeon.

His main fields of scientific and clinical interest are connective tissue structure and mechanics, tendinopathies in athletes and functional overload injuries, spinal osteoarthritis, cementing techniques, hip and knee prosthetic surgery, the development of MIS surgical techniques and tools for total knee replacement, and tissue engineering with the use of SAOS-2 and stem cells.

In 2005, Benazzo became President of the EFOST (European Federation of National Associations of Orthopedic Sports Traumatology). He is a member of IRCS (International Cartilage Repair Society), of ISAKOS (International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine), and of the European Hip Society, and secretary and member of the Italian College of Professors of Orthopedics and Traumatology.

He designed 3 different hip stems, and one knee prosthesis. Benazzo has been a visiting surgeon (Australia, France, South Korea) and an instructor on cadavers for total knee arthroplasty and unicompartmental replacement.

ACRONYMS

AAOS	American Academy of Orthopaedic Surgeons	HHS	Harris Hip Score
ARMD	Adverse Reactions to Metallic Debris	HOOS	Hip dysfunction and Osteoarthritis Outcome Score
ASTM	American Society for Testing and Materials	HR	Hazard Ratio
BMI	Body Mass Index	HV	Hardness Vickers
Co	Cobalt	KSS	Knee Society Score
CoC	Ceramic-on-Ceramic	LTT	Lymphocyte Transformation Test
CoCr	Cobalt-Chromium	MoM	Metal-on-Metal
CoCrMo	Cobalt-Chromium-Molybdenum	MoP	Metal-on-Polyethylene
CoP	Ceramic-on-Polyethylene	OKS	Oxford Knee Score
Cr	Chromium	PE	Polyethylene
CT	Computer Tomography	RoM	Range of Motion
DGOOC	Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (German Society of Orthopedics and Orthopedic Surgery)	SCC	Squamous Cell Carcinoma
DGU	German Association for Trauma Surgery	SF-12®	Short Form, Health Survey Score
EBM	Evidence-Based Medicine	THA	Total Hip Arthroplasty
EFORT	European Federation of Orthopaedics and Traumatology	TJA	Total Joint Arthroplasty
EHS	European Hip Society	TKA	Total Knee Arthroplasty
FDA	Food and Drug Administration	XPE	Crosslinked Polyethylene
		ZTA	Zirconia Toughened Alumina

The Future of Knee Endoprosthetics: Ceramic Components Find Their Place

Interview with Wolfram Mittelmeier, MD, Rostock, Germany

Whereas ceramic materials have already been accepted in hip arthroplasty, knee arthroplasties are still frequently carried out using MoP bearings. However, there are some good arguments in favor of using ceramic knee components: For example, in patients with known allergies or where replacements are required as a result of septic loosening, Prof. Mittelmeier recommends full ceramic or ceramic coated components. The modern alumina matrix composite ceramics demonstrate enhanced bending strength and stress-load capacity and are therefore appropriate even for the kinematically demanding artificial knee. Current 5-year data from a European multicenter study verify that a BioloX®*delta* ceramic femur condyle shows stable fixation and convincing durability.

Why is a knee TEP patient so often dissatisfied?

Mittelmeier: The frequency of patients' dissatisfaction is higher in knee endoprosthetics than in hip endoprosthetics. This is very likely due above all to the highly complex kinematics of the knee joint and to the kinematically more demanding operative technique. There is also probably a certain connection with the metal/polyethylene procedure, which is still being carried out, while ceramic components are the gold standard in hip endoprosthetics.

In hip endoprosthetics the problem of metal abrasion, corrosion, and fretting with modular prostheses is currently under intensive discussion, and the use of ceramic-on-ceramic or ceramic-on-polyethylene is suggested. Do you think this will also be an issue in knee endoprosthetics?

Mittelmeier: The initial euphoria regarding the use of metal in hip endoprosthetics has given way to disillusionment in recent years. In particular, large metal/metal bearings have been the target of criticism because of pronounced granulomas and increased incidents of early loosening. These problems of metal ions and metal abrasion apply equally to knee endoprosthetics, whereby the larger joint volume with greater capsule surfaces probably constitutes a higher level of tolerance, however. Nevertheless, the long-term application of knee endoprostheses with the well-known increase in allergy problems in our population makes it reasonable to expect similar problems, although probably not of the same magnitude.

For which patients would you choose a ceramic prosthesis rather than a metal prosthesis?

Mittelmeier: If an allergy is known and a ceramic solution is available appropriate to the kinematics, I would favour it. Since no such kinematically perfected ceramic solution is available for revisions, improved ceramic coatings must be considered as an alternative. I would also advise that these ceramic-coated knee components be used for patients who require a septic revision of their endoprosthesis and have been treated with intermittent cement spacer. In these cases there is an accumulation of zirconium oxide particles in the normal bone cement, which cannot be reliably removed by joint lavage even with the most intensive efforts.


Are there differences in the follow-up care of ceramic and metal implants?

Mittelmeier: No.

Do you see any clinical differences between all-ceramic and ceramic-coated knee components?

Mittelmeier: In this regard we have carried out and published a retrospective study (comparison of cohorts) comparing a particular coated, older type of knee with our ceramic components [1]. These differences are almost impossible to document in short-term clinical trials, but in some cases there is slightly increased abrasion with coated components, at least for the type of implant studied by us. In the long term, however, I would expect to see a significant advantage for the ceramic monoblock solution, because the thin coatings on the market to date are subject to constant abrasion and their wearing out is foreseeable. Newer multiple coatings could yield better results, but they must still be tested in clinical practice.

What must be taken into consideration when a ceramic component is implanted?

Mittelmeier: The alumina matrix composite (Bio-*lox®delta*), from which the current knee components – Multigen Plus Ceramic Knee (Limacorporate S.p.A.)  (Fig. 1), BPK-S ceramic knee (Peter Brehm GmbH) – are manufactured, demonstrate considerably greater bending strength and stress-load capacity. Nonetheless, as with every material, a certain maximum load limit remains. The ce-

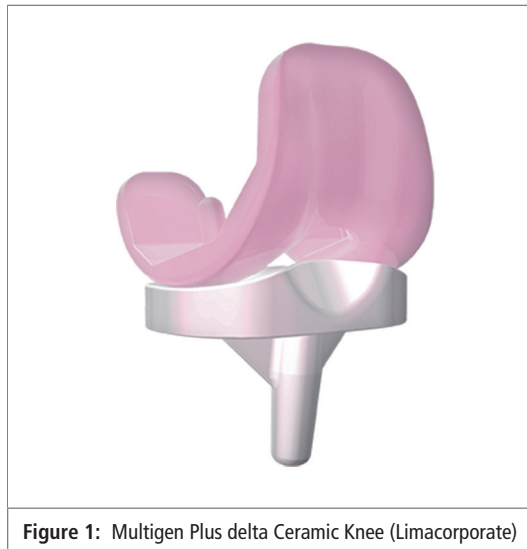


Figure 1: Multigen Plus delta Ceramic Knee (Limacorporate)

ramic components should be inserted without a so-called wedge load and thus without a strong press fit. Hammer blows should be used very cautiously, analogous to proven practice for ceramic heads in hip arthroplasty.* Likewise, the saw cuts in the knee joint must be precisely executed. It should be noted that we now know to what extent a strong press fit situation and sharp blows on metal components lead to internal stress with possible consequential damage. In the past few years we have learned to be even more careful with all of our implants, particularly with all instruments.

What is your experience with the Multigen Plus Ceramic Knee following 5 years of clinical use?

Mittelmeier: We began to introduce the Delta Ceramic Knee Joint (femur condyle made of Bio-*lox®delta*) very carefully in 2007. By carefully I mean that we worked under strict observation criteria as part of a multicenter study. The patients were informed in detail and the surgeons were selected and appropriately trained. Our experience with the ceramic knee here in Rostock and the experiences of the various centers in Germany, Italy, and Spain that participated in the study have meanwhile been published [2]. The 5-year results are very convincing. In

* According to the LIMA operation surgical technique, the weight of the recommended hammer, eventually used, must be less than 500 gr.

the German center there was one ceramic fracture; otherwise we observed a very convincing stable fixation and durability of the implants. The recorded fracture that took place during the study observation was the direct result of a trauma and was treated accordingly [3]. The 10-year results will hopefully be published in good time.

How important is cement-free knee arthroplasty in your opinion?

Mittelmeier: In the majority of cases, particularly with older patients, we can perform cemented knee arthroplasty without hesitation. The frequency of cement allergies in the population appears to be increasing; however, we still do not know enough about the extent to which the cement allergy actually affects the tissue. The release of ions and particles (particle surface) is clearly decisive for the development of the allergy. Since the cement should not lie in the primary situation of the frictional load of the joint surfaces, the cement allergy will probably not be as significant as the metal allergy. Nevertheless, cement-free knee replacement should be able to draw upon stable, safe solutions as well, also in relation to ceramics. For this reason we will also need cement-free ceramic solutions for the knee joint.

Does an ideal treatment cascade already exist in knee arthroplasty? How does it look, in your opinion?

Mittelmeier: I very much hope that we will have ceramics available in the various treatment cascades, that is, from unicompartamental knee arthroplasty, to total knee replacement, up to and including posterior stabilized prostheses and all revision endoprostheses.

How does the future of ceramic knee arthroplasty look to you?

Mittelmeier: There were several failures in the development of ceramics in hip arthroplasty more than 40 years ago, which were the fault of the early material development. Ceramic materials have been significantly improved in the meantime and offer considerably better conditions for hip and for knee arthroplasty. I expect that there will have to be a new, very strong trend to develop ceramic knee arthroplasty with regard to long durability, the least possible ion release and solutions for revision arthroplasty. Current solutions already being tested in laboratories are very promising.

Partial resurfacing of the knee or preferably corrective osteotomy – where are the indication boundaries?

Mittelmeier: A surgical intervention for corrective osteotomy must also have a sufficiently long-lasting effect. The same is true for partial knee arthroplasty. The two interventions must be carefully

weighed with regard to the patient's needs and the condition of the joint. The best possible joint-preserving solution via corrective osteotomy takes priority in making the decision for younger patients. It is my personal view that the early implantation of metallic or metal/polyethylene partial components in the knee joint is not yet a perfected mode of treatment. Here as well we will be able to choose ceramic solutions and then have a presumably wider indication. The effects of metal ions and particles on the surrounding, still largely intact cartilage cannot be considered beneficial.

Robotics at the knee – a necessity or just marketing?

Mittelmeier: The very adverse results of using robotics on the hip joint in the past have led to a great deal of mistrust towards the use of robots in endoprosthetics. The newer types of robots that are presently being used in abdominal surgery under the optical and tactical control of an experienced surgeon promise a better development. It is still not clear to what extent these modern robot types will actually become established on the market in our country, because the profits that can be made with endoprostheses – a prerequisite for further useful developments – have already reached the bottom limit. A relatively large amount is being, and must be, saved on implants nationwide instead of making room for qualitatively better developments. On the other hand, a possible future form of robot-supported endoprosthetics will have to undergo very rigorous clinical testing in advance with respect to applicability, application errors and error tolerance. In addition, there must then also be a detailed clinical evaluation of the extent to which a robot system actually offers advantages compared with standard treatment by an experienced surgeon.

Knee arthroplasty with preservation of the anterior cruciate ligament – is that the future?

Mittelmeier: The preservation of the anterior cruciate ligament may be a sensible approach in knee arthroplasty. To date, however, it has been very difficult to achieve kinematically satisfactory solutions, as the kinematics of the knee joint is physiologically very individual, and for the anterior cruciate ligament in particular, very high standards are set regarding the surgical technique and the implant.

How do you envision the future of knee replacement?

Mittelmeier: I believe that, as international developments show, knee replacement will have to be refined. Along with the continually increasing number of knee replacement worldwide – with the exception of the German region – the number of



Wolfram Mittelmeier, MD, is a professor of orthopedics and the Director of the Orthopedic Clinic and Polyclinic at the University Medicine in Rostock.

Following his doctoral studies and his qualification as a specialist in orthopedics, Mittelmeier worked first as a consultant and later as a senior consultant at the University Hospital of Lübeck, before moving to the Technical University of Munich as senior consultant in the Hos-

pital for Orthopedics and Sports Orthopedics. There he established the biomechanics laboratory and the cell laboratory. In 1999 he received his postdoctoral lecturing qualification; 4 years later he accepted a chair at the University of Rostock in the field of orthopedics. Since 2004 he has served as the director of the orthopedic division of the University Hospital in Rostock.

His main clinical focus is on arthroplasty, revision surgery, children's orthopedics, and joint-preserving operations. His scientific focus is on biomechanics, implant technology, and worst-case simulations. Since 2005, he has been a member of the board of the German Society of Orthopedics and Orthopedic Surgery (DGOOC) and of the board of the Association for Orthopedic Research, where he served as president from 2009 until 2013.

Mittelmeier developed the basis of a quality management system for endoprosthesis centers, which became EndoCert; it is audited by committees of the German Society for Orthopedics and Trauma Surgery (DGOU) and has been implemented nationwide since 2012. Since 2011 he has been the deputy chairman of the advisory board on orthopedic technology of the German Association of Orthopedic Technology.

In 2014 he served as president of the OTWorld / World Congress of Orthopedic Technology.

revisions will obviously also increase temporarily. It will be important to establish good procedures that are as long-lasting as possible with very well-trained operators in order to keep the revision load as small as possible. ■

References

1. Bergschmidt, Philipp et al., Total knee replacement system with a ceramic femoral component versus two traditional metallic designs: a prospective short-term study, *J Orthop Surg (Hong Kong)*. 2013 Dec;21(3):294-9.
2. Bergschmidt, Philipp et al., Prospective multi-centre study on a composite ceramic femoral component in total knee arthroplasty: Five-year clinical and radiological outcomes, *The Knee* 2015, DOI: <http://dx.doi.org/10.1016/j.knee.2015.02.003>
3. Krueger A P et al., Ceramic Femoral Component Fracture in Total Knee Arthroplasty: An analysis using fractography, fourier-transform infrared microscopy, contact radiography and histology, *J Arthroplasty* 2013, doi: 10.1016/j.arth.2013.11.003



Primary Knee Arthroplasty in Patients with Suspected or Confirmed Metal Allergy


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CASE REPORT 1

Primary TKR for advanced arthritis


Diagnosis

A 68-year-old woman with a history of hypertension, coronary artery disease, and multiple allergies (asthma, dust). The patient had had a painful right knee due to arthritis for two years. The preoperative X-rays clearly showed severe valgus osteoarthritis with involvement of the lateral compartment and patellofemoral joint as well as a lateralization of the mechanical axis  (Fig. 1a).


Indication was for primary TKR with a Multigen Plus ceramic knee implant (Lima) to avoid cross-linked reaction due to suspected metal allergy.

Therapy

Surgery was performed via a mini mid-vastus approach. Replacement of the knee was done with a fixed Ti tibial plate (size 2) and a ceramic CR femoral

component (BioloX[®]delta Multigen Plus, size 3) and a poly liner with a height of 12 mm  (Fig. 1b).

Postoperative therapy included a femoral nerve block (naropin) for analgesia and fast rehabilitation of the knee: The patient began to exercise to regain range of motion on the first postoperative day, and she walked with two canes on the second postoperative day. She took non-steroidal anti-inflammatory drugs (indomethacin) for 3 weeks, as did the other patients who underwent TKR.

After 4 weeks she was able to do without one cane and she had very mild pain, which had disappeared at the 3-month follow-up. The range of motion was 0–115° and the excellent results were confirmed at the last follow-up. X-rays showed a good restoration of limb alignment and no radiolucent lines at 6 years of follow-up  (Fig. 1c). The final clinical KSS was 98 points (excellent), the final functional KSS was 100 points (excellent), and the final OKS was 47.

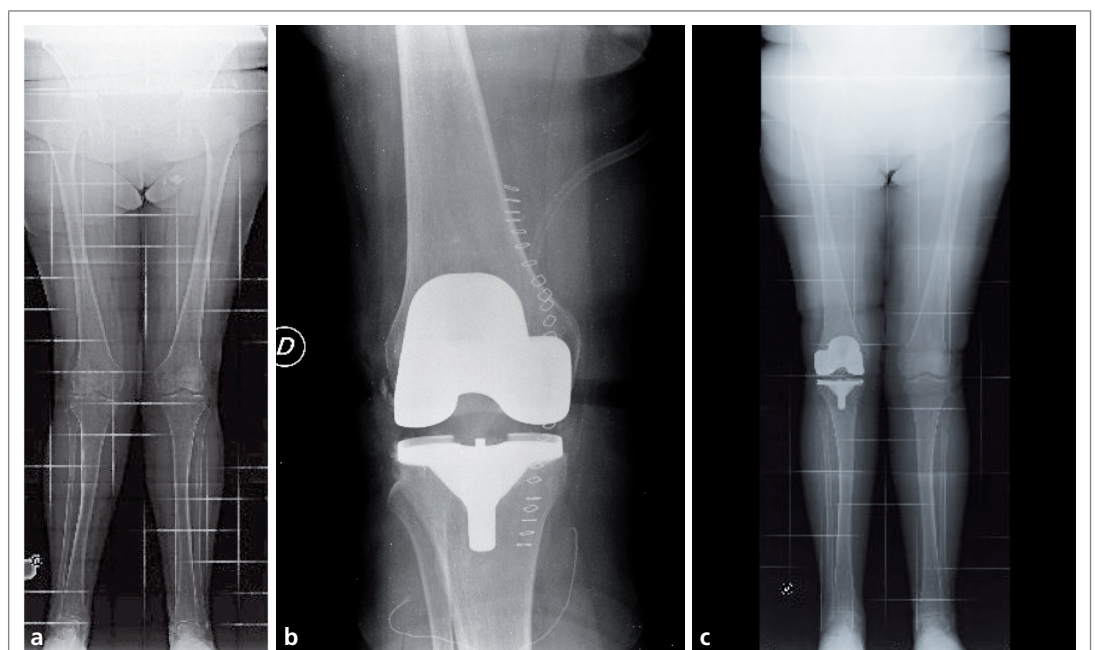


Figure 1: Primary TKA 68-year old woman: a) lateralization of mechanical axis preoperative, b) postoperative situation, c) follow-up after six years: good limb alignment (© Benazzo)

CASE REPORT 2

Primary TKR for advanced arthritis

Diagnosis

The patient was a 75-year-old woman with a history of hypertension, pancreatic neuroendocrine cancer, diabetes and glaucoma. She had had diffuse pain in the left knee for 4 years which had been treated without success with hyaluronic acid injections. The X-rays showed a primary knee arthritis and a varus knee. The cartilage degeneration involved all three compartments **▶ (Fig. 2a)**, particularly the medial side and the patellofemoral joint, and the mechanical axis was medialized. She also had a metal allergy (nickel), so we decided to use a the Multigen Plus delta ceramic knee.

Therapy

Surgery was performed via a mini mid-vastus approach to the knee. Replacement of the knee was performed with a fixed Ti tibial plate (size 1) and a ceramic CR femoral component (BioloX®*delta* Multigen Plus, size 1) and a poly liner with a height of 12 mm **▶ (Fig. 2b)**.

Postoperative drug therapy consisted of peridural analgesia, which allowed fast rehabilitation of the

knee: The patient began to exercise to restore the range of motion on the first postoperative day, and she walked with two canes on the second postoperative day. She took, as usual after a TKA, non-steroidal anti-inflammatory drugs (indomethacin) for 3 weeks.

After 4 weeks she was able to do without one cane and she had no pain. The range of motion was 0–110° and increased to 0–120° at 6 months.

The excellent results were confirmed at the last follow-up at 2 years, and X-rays showed no radiolucent lines, a good patellar height and good patellofemoral tracking **▶ (Fig. 2c)**. The final clinical KSS was 99 points (excellent), the final functional KSS was 100 points (excellent), and the final OKS was 46. ■

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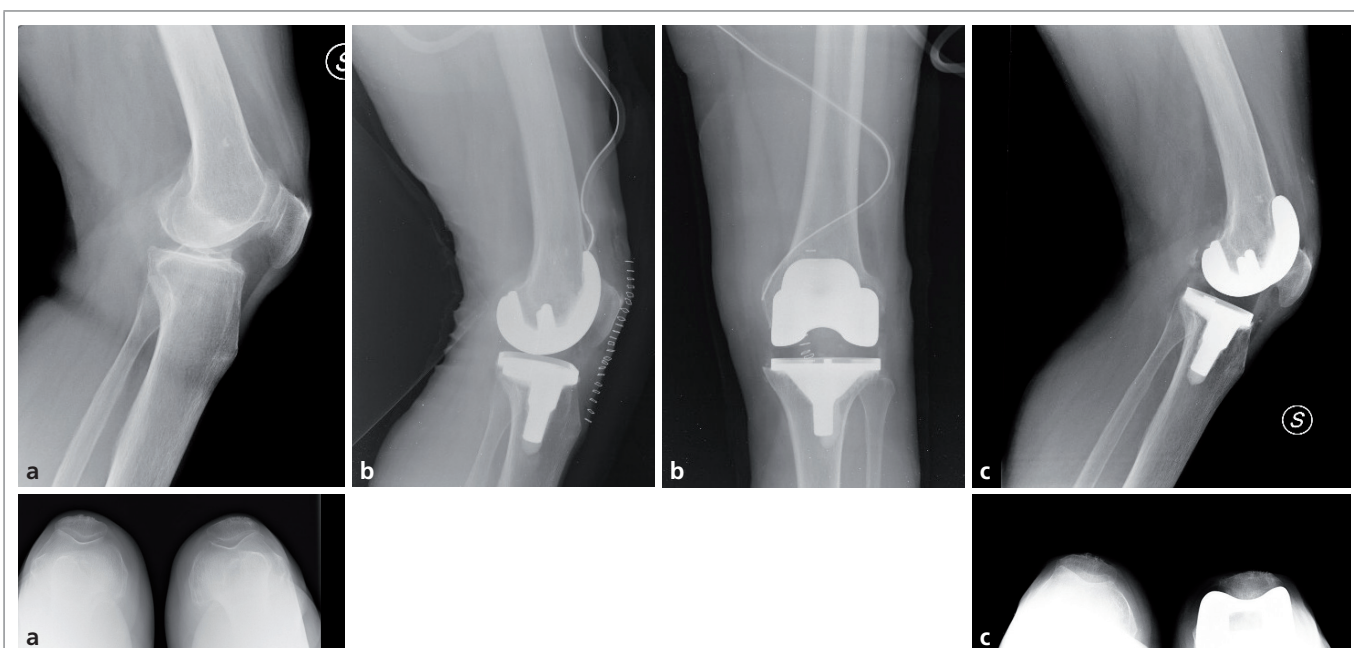


Figure 2: Knee of a 75-year old woman: a) preoperative status (lateral/patella), alle three compartments show arthritis damage, b) postoperative with fixed tibial plate and ceramic femoral component (lateral/frontal), c) two years after surgical intervention (lateral/patella) (© Benazzo)

Evidence-based Decision-Making and Biological Reactions Related to Materials

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TOPIC 1: EVIDENCE-BASED MEDICINE IN ORTHOPEDICS: WHERE IS THE EVIDENCE?

Evidence-based medicine continues to grow in importance. Evidence-based medicine came to the fore in the early 1990s and has been defined as "the integration of best research evidence with clinical expertise and patient values" (Sackett et al. 2000) [1]. Evidence has always contributed to clinical decision-making. Murray et al. reviewed the evidence for THA in 1995 [2]. They found that only 30% of hip-joint replacements available contained any evidence and emphasized the need for evidence-based data.


Additional researchers have concluded that the need for good-quality evidence in the orthopedic literature has remained vital. Unfortunately, the continuous lack of a level of evidence has been established in many publications. The quality of these publications is very heterogeneous, making it difficult for clinicians to evaluate the actual evidence level of individual results and recommendations. However, efforts are being made, e.g. by scientific journals, to bring more quality and transparency to the subfields of orthopedic surgery and considerably improve knowledge

transfer ("knowledge translation") of science and research into concrete medical practice.

National joint registers have been established to monitor and improve the outcomes. However, registers differ in methods of data analysis and reporting, which limits the interpretation of the data. These differences make comparisons among registries difficult or impossible.

Konan and Haddad, University College Hospitals London, 2013 summed up the situation in a paper, saying [3]: "We now routinely rely on registry data to guide our debates and decisions but we would be wise to remember that they have inherent weaknesses that limit the interpretation of the data. Compliance issues associated with any data collection and reporting process limit the quality of the registry data. No robust system is in place to tackle confounding data, and to capture underreported or unreported outcomes. Registries were set up to monitor survival but the ancillary data that are collected are not validated. Caution must therefore be exercised when using registries as high-level evidence. In particular, registry-based results cannot infer causal relationships. Any trend identified should be used as a trigger for further study rather than as a rigid conclusion."

Evidence-based data should be founded both on results of well-designed studies and on registers that are able to collect data in large populations and to identify trends.

Evidence-based medicine includes a classification system that enables a defined evaluation, based on the so-called evidence level, of the quality of the studies and particular publications. This system of grading offers clinicians a simplified rating for clear comparison of performance based on relevant clinical criteria  Fig. 1).

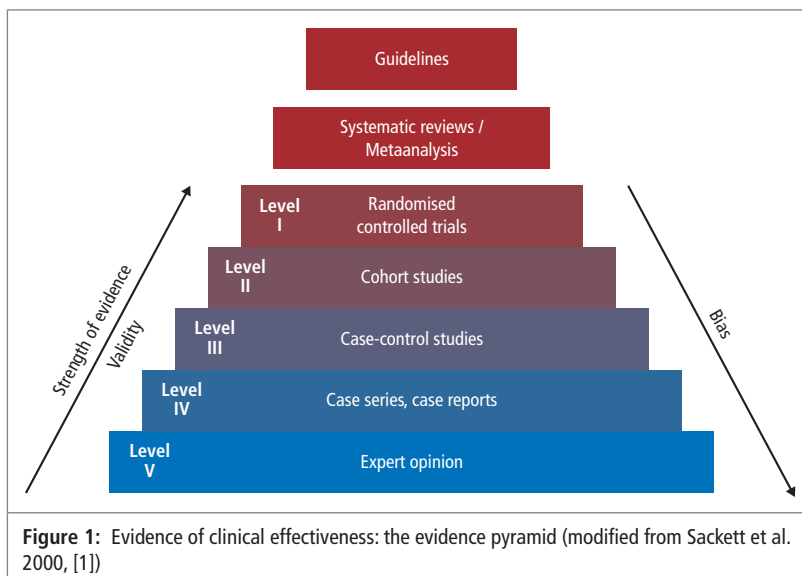


Figure 1: Evidence of clinical effectiveness: the evidence pyramid (modified from Sackett et al. 2000, [1])

The Dutch Strategy

Verheyen et al. 2014 and **Poolman et al. 2015** [4, 5] reported about the Dutch strategy at a meeting of the European Hip Society 2014 and in a current publication (2015). Problems with large numbers of MoM hip replacements prompted Dutch orthopedic surgeons to re-evaluate patient safety. The Dutch Orthopedic Association (Nederlandse Orthopeedische Vereniging, NOV) initiated a taskforce to classify the quality of hip replacements

based on survivorship. New implants or prostheses that do not meet the criteria may be implanted only in the scope of a research program with approval by the institution's medical ethics review board. NOV offers patients insights into evidence-based quality of the hip implants. The authors are convinced that this will facilitate shared decision-making by empowering patients with knowledge about available hip implants.

TOPIC 2: XPE-INDUCED OSTEOLYSIS AND SURFACE DAMAGES

Low wear rates and longer lasting bearing surfaces with biologically inert characteristics are of specific interest in addressing the needs of patients with a long life expectancy and a high activity level. Highly cross-linked polyethylene (XPE) has been used in an effort to combat osteolysis and aseptic loosening. Although XPE is more resistant to wear than conventional polyethylene, it remains unknown whether XPE decreases wear-associated failure of THA and improves longevity at mid-term to long-term follow-up. It is hypothesized or predicted in publications that the substantial reduction in wear rates observed for XPE compared with conventional PE may have the biological effect of reducing the rate of periprosthetic osteolysis after THA.

*However, at the AAOS 2014, researchers reported about their concerns with XPE in THA in long-term use. **Holubowycz, Howie et al.**, presented the results of a randomized controlled trial showing that XPE articulations lead to periacetabular osteolytic lesions at 7–10 years after primary THA [6, 7]. Osteolytic lesions were detected in the absence of clinically significant wear. Moreover, in that study, the incidence was similar in articulations with 28-mm and 36-mm ball head diameter.*

A systemic review of randomized controlled trials has now found that wear advantages of XPE did not translate into less osteolysis and aseptic loosening. XPE-induced osteolysis seems to occur without substantial wear. There is a need to better characterize factors that influence the development of osteolysis with XPE articulations. There are numerous different XPE materials on the market, produced with various manufacturing methods which may influence the clinical performance. We also currently know very little about the bioactivity of these XPE wear particles.

SYSTEMATIC REVIEW OF LEVEL-1 RANDOMIZED CONTROLLED TRIALS

XPE does not decrease osteolysis and wear-related revision rate

Shen et al. 2014 included eight randomized controlled trials (RCT) with mid- to long-term follow-ups comparing XPE with PE in THA [8]. The follow-up periods of the RCT ranged from 5 to 12 years; 735 patients were included in their study. The studies reviewed were published between 2009 and 2012. This meta-analysis of RCT demonstrated for the first time that the linear wear rate was lower in the XPE group than in the PE group, but the incidence of osteolysis and wear-related revision incidence did not differ significantly between the XPE and PE groups. Although wear of XPE inserts appears to be lower than of conventional PE inserts, the risk of periacetabular osteolysis around articulations with XPE has not been eliminated, and the true incidence remains unknown.

Hence the authors emphasized that XPE has no advantage or clinical benefit over conventional PE in terms of reducing osteolysis and wear-related revision. This meta-analysis demonstrated that reduced in vivo XPE wear rates did not improve the clinical outcome. For this reason, the researchers called for further long-term RCT on this topic.

The concept of the so-called osteolytic wear threshold remains controversial. **Dumbleton et al. 2002** suggested that osteolysis is infrequent with a wear rate less than 0.1 mm/year and almost absent at a wear rate less than 0.05 mm/year [9]. Osteolysis is a complex process and depends on many factors, including the biological activity of generated wear particles. Although much is known regarding wear

properties of cross-linked polyethylenes, there is little information and knowledge regarding the biological activity of the wear particles generated. **Illgen et al. 2008** demonstrated that XPE particles exhibited an altered bioactivity which was unrelated to particle size [10]. The scientific issue of whether and how XPE particles interact with various types of cells must be investigated further. Some researchers have demonstrated that XPE wear particles are smaller than 1 μm and more inflammatory than conventional PE particles. In vitro cell culture studies predicted that submicron wear debris from XPE might show osteolytic potential comparable to

that of conventional PE over time. It will therefore be important to understand the bioactivity of XPE wear particles compared with conventional PE wear particles, since there is little information and a paucity of available data so far.

To understand the biological response to XPE wear particles and to determine which material factors, wear characteristics, and other mechanisms have a substantial impact on the pro-inflammatory activity of these particles, further studies and research in this area are needed, as the number of young patients receiving THA continues to grow.

RETRIEVAL STUDY

XPE demonstrated surface damage similar to PE

Pang et al. 2015 compared wear and surface damage in matched retrieved XPE and PE inserts. The XPE inserts represented all the FDA-approved XPE inserts of a specific design implanted for at least 1 year [11]. This XPE group was matched to a PE group of identical design retrieved in the same time period. The authors found no difference between the groups for total damage score or for the bearing, rim or backside surface damage scores. Moreover, in that study, the most common damage modes in the XPE group were abrasion, scratching, and cold flow.

The most common damage modes in the PE group were burnishing, abrasion, and cold flow. The mean abrasion damage score was significantly higher in the XPE group than in the PE group. With respect to the lesser amount of volumetric wear measured in the XPE group compared with the PE group, these findings were similar to those of other studies.

This paper pointed out the need for further investigations and long-term studies to determine the effects on implant longevity.

References

1. Sackett DL, Straus SE, Richardson WS, Rosenberg W, Haynes RB. Evidence-based medicine: how to practice and teach EBM. 2nd ed., Churchill Livingstone, Edinburgh 2000
2. Murray DW, Carr AJ, Bulstrode CJ. Which primary total hip replacement? *J Bone Joint Surg Br* 1995;77:520-527
3. Konan S, Haddad FS. Joint registries. A Ptolemaic model of data interpretation? *Bone Joint J* 2013;95-B:1585-1586
4. Verheyen CCPM, Schreurs BW, Born PA, Verhaar JAN, Nelissen RGHH, Goosen J, Poolman RW. Selecting the right hip implant for our patients. The Dutch strategy. Abstracts from 11th EHS Congress, Stockholm, Sweden, 9-11 October 2014, *Hip Int* 2014;24(5):526
5. Poolman RW, Verhaar JAN, Schreurs BW, Bom LPA, Nelissen RGHH, Koot HWJ, Goosen JHM, Verheyen CCPM. Finding the right hip implant for patient and surgeon: the Dutch strategy – empowering patients. *HipInt* 2015; DOI: 10.5301/hipint.5000209
6. Holubowycz O, Howie D, Solomon LB, Moran CR. Osteolysis and wear of large and standard metal on highly cross-linked polyethylene articulations. *AAOS* 2014: Paper 253
7. Howie DW, Holubowycz OT, Moran CR, Solomon LB. Osteolysis and wear of large and standard metal on highly cross-linked polyethylene articulations. Annual Meeting ORS 2014: Poster 1773
8. Shen C, Tang ZH, Hu JZ, Zou GY, Xiao RC, Yan DX. Does cross-linked polyethylene decrease the revision rate of total hip arthroplasty compared with conventional polyethylene? A meta-analysis. *Orthop Traumatol Surg Res* 2014;100(7):745-750
9. Dumbleton JH, Manley MT, Edidin AA. A literature review of the association between wear rate and osteolysis in total hip arthroplasty. *J Arthroplasty* 2002;17(5):649-661
10. Illgen RL, Forsythe TM, Pike JW, Laurent MP, Blanchard CR. Highly cross-linked vs conventional polyethylene particles – an in vitro comparison of biologic activities. *J Arthroplasty* 2008;23:721-731
11. Pang HN, Naudie DDR, McCalden RW, MacDonald SJ, Teeter MG. Highly crosslinked polyethylene improves wear but not surfaces damage in retrieved acetabular liners. *Clin Orthop Relat Res* 2015;473:463-468

TOPIC 3: CORROSION

*The issue of taper wear and corrosion at the head-neck junction is not a new phenomenon, but the problems detected with the use of larger metal femoral ball heads in THA have made it more prevalent. Corrosion of metal in medical devices could cause health problems to patients. It has been demonstrated by a research group led by **Hallab and Jacobs 2010** that both soluble metal ions and metal debris produced during corrosion induce pro-inflammatory responses in human monocytes/macrophages [12]. Corrosion at the taper junction is still poorly understood as regards relevant clinical pictures and entities. A comprehensive systematic review of the medical publications that determine patient characteristics, implant designs, symptomatology, clinical pictures and treatment strategies regarding corrosion at this interface is still lacking in the literature. This gap is now being filled by a recent publication from Canadian researchers.*

SYSTEMATIC REVIEW AND CASE SERIES

Clinically significant corrosion at the taper junction

Carli et al. 2015 illustrate in a systematic review and case series that symptomatology following corrosion tends to occur in the intermediate follow-up period and most often presents within the clinical picture of aseptic loosening, unexplained thigh pain or an adverse reaction to metal debris (ARMD) [13]. A total of 24 articles represented 776 cases (754 patients) with documented head-neck corrosion found at revision surgery. The bearing couples most frequently utilized were MoM (419; 53.9%) and MoP (351; 45.4%), with 13 being cross-linked polyethylene. The head diameters in MoM bearings were larger (median and mode of 46mm) than those used in MoP (median and mode of 36mm).

12 articles of this review representing 24 cases reported that the trunnion (or male taper) was found intact. In 15 cases this led to revision of only the femoral ball head and the acetabular component, while the stem remained in situ. Ceramic femoral ball heads were used with ceramic or polyethylene inserts. Since the trunnions were used, the recommendation to ensure safe usage of ceramic femoral ball heads would be to use one with a sleeve (**Helwig et al. 2013**) [14].

However, **Carli et al.** remark that sleeves provide an additional interface for micro-motion and ion exchange to occur. Concerning this aspect it might be useful to take further data into account. Yet **Thorey et al. 2012** pointed out that they had followed up a relatively large cohort of patients (91) who had undergone revision from MoP (53), MoM (2), CoC (15), and CoP (21) bearings to a CoC or CoP bearing with a sleeve, mostly due to acetabular component loosening [15]. They did not observe any ceramic ball head fractures or complications related to the sleeve-taper junction such as corrosion / fretting. **Jack et al. 2013** used ceramic ball heads with titanium sleeves in revision surgeries, placing the sleeves on used trunnions [16]. They did not record any metal ions or radiological evidence of metal wear debris. In a case report by **Whitehouse and Duncan 2014**, the authors describe the case of a patient with a painful MoXPE THA [17]. Hip

arthroscopy confirmed the diagnosis of trunnion corrosion. Due to persistent symptoms, the patient was revised to a CoXPE bearing, utilizing a ceramic femoral ball head with a sleeve, which was placed on the corroded trunnion. This relieved the patient's symptoms.

In an in-vitro study, **Preuss et al. 2012** also addressed the issue of taper fretting and corrosion for large ceramic bearings used with an adapter sleeve (made of Ti-6Al-4V) [18]. The aim of this study was to investigate the risk of fretting corrosion and wear and the risk of loosening of the head-taper junction of such large-diameter CoC bearing devices for revision surgery. The current results from this study confirm that an accurate placement and assembly of the components as given by the instructions for use by the manufacturer result in sufficient resistance of the interfaces against fretting corrosion and wear.

In their retrieval analysis **Huot Carlson et al. 2012** also found that metal femoral ball heads were significantly more prone to corrosion of the head taper (54%) as compared with titanium-sleeved ceramic ball heads (18%) [19]. Metal femoral ball heads were also more associated with corrosion of the stem compared with ceramic or sleeved ceramic ball heads. To summarize, there is still a need for further research and evidence including clinical conditions.

Carli et al. 2015 describe the symptoms among patients in their own case study group as consisting of groin pain, a palpable mass, recurrent dislocation and adverse local soft-tissue reactions [13]. They also found disproportionately elevated serum cobalt levels relative to chromium in their case series. They point out that this finding has also been reported in a large randomized series involving large-diameter MoM implants. The authors hypothesize that this disproportion could potentially serve as a diagnostic indicator of an ongoing corrosive process, and they therefore call for additional studies. Further analysis is also needed to investigate the overall prevalence of clinical symptomatology.

Corrosion in large femoral ball heads

Level-I studies support the use of large femoral ball heads in order to decrease the risk of postoperative instability following primary and revision THA. When selecting the appropriate head diameter in hip surgery, the surgeon must balance the potential risk for dislocation in his patient with the risks inherent in large femoral ball heads. Corrosion at the modular head-neck taper has been identified as a potential concern. Symptomatic adverse local tissue reactions can occur secondary to metal debris resulting from corrosion of the head-neck taper and have been described in the literature.

SYSTEMATIC REVIEW AND CASE SERIES

Ceramic femoral ball heads are more protective against ARMD

Cooper and Della Valle 2014 pointed out in their paper that ceramic femoral ball heads reduce the risk of modular taper corrosion at the head-neck junction [20]. According to the authors, retrieval studies by various researchers have demonstrated that the risk of corrosion is not completely eliminated; however, the degree of metal release from taper junctions is significantly lower compared with met-

al femoral ball heads. Ceramic femoral ball heads, which are excellent electrical insulators, resulted in less stem taper corrosion than reported with metal femoral ball heads. To summarize, it must be emphasized that ceramic femoral ball heads are more protective against ARMD than metal femoral ball heads.

TOPIC 4: IMMUNO-ALLERGOLOGICAL INTOLERANCE REACTION TO METAL DEBRIS

RETRIEVAL STUDY

Scratching on MoM bearings as a cause for ARMD

A recent study by **Burbano et al. 2014** evaluated the bearing surface characteristics of MoM implants revised due to ARMD using different microscopy techniques [21]. The modular taper junctions were also evaluated. The aim was to analyze possible failure mechanisms associated with MoM implants and their correlation to the formation of ARMD.

Severe mechanical scratching was a common characteristic found in all of the MoM retrievals evaluated. The remarkable level of scratching detected indicates that these MoM implants generated a large amount of metal particle release in vivo. The lack of evidence of corrosion in the interfaces evaluated suggested that mechanical factors (scratching, wear) seemed to be a major trigger for ARMD. The authors pointed out that severe scratching, wear and metal ion release may have been the principal cause for adverse peri-implant tissue reactions in the revised cases. Third-body wear (i.e. bone fragments) could also have played a role.

Amini et al. 2014 pointed out that a better understanding of the diagnosis and treatment of metal hypersensitivity is essential for orthopedic surgeons [22]. The authors noted that metal hypersensitivity is estimated to be responsible for 5% of TJA failures. The Medline literature database was searched

to identify articles related to patch testing or LTT for metal hypersensitivity with TJA. They reviewed 14 TKA and 6 MoM THA case reports involving metal allergy. Half of the patients had a previous metal allergy. One patient had a history of dermatitis or eczema. The most common presenting symptoms were pain (55%), swelling (45%), and warmth (20%). Eczema over the surgery was present in 35% of cases. 90% of these symptoms presented in the first 3 months after implantation. Cobalt and nickel were found to be the most common metals causing allergic reactions.

The authors emphasized that metal hypersensitivity is a diagnosis of exclusion, and that other potential diagnoses should be carefully excluded. Patch testing and LTT remain the tools of diagnosis both in patients for TJA and in patients with implant failure. They concluded that options in THA include the use of CoP and CoC bearing surfaces to minimize the risk of a hypersensitivity reaction.

The diagnosis, treatment, and clinical outcome of patients with metal hypersensitivity remains an active area of research.

CASE REPORT

Chromium-induced diffuse dermatitis and lymph-node involvement by Langerhans cell histiocytosis: CoC THA led to resolution of symptoms

Bizzotto et al. 2014 hypothesized that microparticles of cobalt-chromium and PE may elicit lymphadenopathy with histiocytosis, but a combined diffuse dermatitis and lymph-node involvement by Langerhans cell histiocytosis induced by chromium after MoM hip resurfacing have not been previously described [23].

General clinical signs such as skin redness, prolonged generalized pruritus, and psoriatic-like dermatitis with desquamation may be related to delayed type-IV hypersensitivity reaction. The authors reported that lymphadenopathy with diagnosis of special Langerhans cell histiocytosis may be due to prolonged activation of the type-IV immune response.

In their reported case, a 60-year-old male patient presented with a 3-year history of diffuse dermatitis 5 years after implantation of MoM hip resurfacing. The symptomatic patient had a prolonged pruritus unresponsive to antihistamines and corticosteroids. Dermatological treatments were not successful. The patient had no past history of atopy or metal-contact dermatitis. Diffuse lymphadenopathy on both sides of the inguinal region was detected. A skin

biopsy showed nonspecific perivascular lymphocytic infiltrate in the upper dermis associated with histiocytes. A patch test revealed chromium-sulfate hypersensitivity. Higher chromium and cobalt levels in serum were measured. The biopsy of an inguinal lymph node demonstrated large aggregates of Langerhans cells, suggesting delayed type-IV hypersensitivity.

The authors pointed out that only replacement of the hip implant using non-MoM surfaces may definitely resolve such clinical symptoms. Metallosis was observed intraoperatively. The stable MoM hip implant was replaced by a cementless THA using a CoC bearing (BioloX®*delta*). The dermatitis resolved 3 months after revision surgery. The lymph nodes decreased in volume. The serum chromium level normalized, and the patient was completely free of any symptoms 1 year after revision surgery.

The authors are concerned that chromium and cobalt toxicity may be under-recognized and that physicians who are not familiar with this issue may therefore misdiagnose systemic symptoms and lack adequate treatment.

CASE REPORT AND ANIMAL STUDY

Chronic allergic contact dermatitis caused by an orthopedic metal implant promotes skin cancer

Long-term consequences of chronic contact dermatitis caused by an orthopedic metal implant are still poorly understood. This remains an active area of research.

Dehmeri et al. 2014 presented a rare clinical case of an invasive squamous cell carcinoma (SCC) that developed in the context of nickel allergy from a subcutaneous metal implant [24]. The 46-year-old woman had no history of skin cancer. An ankle fracture was repaired with open reduction and internal fixation with placement of a metal rod on the lateral aspect of her fibula for stabilization. The patient developed a non-healing skin lesion on her left ankle overlying the metal implant and surgical wound site. She was allergic to nickel in the metal implant. The implant was removed 1 year after surgery, but the skin lesion persisted. The patient presented to the hospital with a 3-year history of the ulcerated skin lesion. A biopsy demonstrated a well-differentiated, invasive SCC consistent with a Marjolin ulcer. The SCC was surgically excised and did not recur during a 2-year follow-up period.

The authors concluded that the development of a SCC in a patient without history of skin cancer strongly suggested the chronic allergic contact dermatitis surrounding the surgical wound culminated in cancer formation. They initiated an animal study (mice) to examine the tumor-promoting potential of contact dermatitis. Findings confirmed that chronic exposure to a hapten-producing allergen induces tumor-promoting inflammation in the skin.

Furthermore, the researchers examined the immune environment of the SCC that developed in the patient and found that the patient's inflammation was the driver of the carcinogenesis and not secondary or reactive to cancer development itself. The authors therefore concluded that these findings provide clear evidence for the tumor-promoting property of chronic allergic contact dermatitis. A chronic allergic contact dermatitis caused by constant exposure to an allergen can lead to the development of an aggressive and invasive SCC in areas where a significant burden of preexisting cancer-initiated cells is present (i. e., sun-exposed skin).

It is interesting to note that contact allergy to metal dental restorations is discussed in scientific publications as a potential risk factor for development of intraoral squamous cell carcinoma (**Hougeir et al. 2006, Weber et al. 2012**) [25, 26].

Moreover, this rare clinical case highlights the importance of patch testing prior to the implantation of medical devices especially in patients with a reported history of metal allergy. The authors suggested a close monitoring of patients with such implants placed in close proximity to the skin to avoid a chronic allergic dermatitis and the possibility of developing SCC. ■

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► References

12. Caicedo MS, Pennekamp PH, McAllister K, Jacobs JJ, Hallab NJ. Soluble ions more than particulate cobalt-alloy implant debris induce monocyte costimulatory molecule expression and release of proinflammatory cytokines critical to metal-induced lymphocyte reactivity. *J Biomed Mater Res* 2010;93A:1312-1321
13. Carli A, Politis A, Zukor D, Huk O, Antoniou J. Clinically significant corrosion at the head-neck taper interface in total hip arthroplasty: a systematic review and case series. *Hip Int* 2015;25:7-14
14. Helwig P, Konstantinidis L, Hirschmuller A, Bernstein A, Hauschild O, Sudkamp NP, Ochs BG. Modular sleeves with ceramic heads in isolated acetabular cup revision in younger patients-laboratory and experimental analysis of suitability and clinical outcomes. *Int Orthop* 2013;37:15-19
15. Thorey F, Thiengwittayaporn S, Thiengwittayaporn S, Windhagen H. Early results of revision hip arthroplasty using a ceramic revision ball head. *Semin Arthroplasty* 2011;22:284-289
16. Jack CM, Molloy DO, Walter WL, Zicat BA, Walter WK. The use of ceramic-on-ceramic bearings in isolated revision of the acetabular component. *Bone Joint J* 2013;95-B:333-338
17. Whitehouse MR, Duncan CP. Arthroscopy as a diagnostic tool for painful trunnion corrosion after hip arthroplasty. *Knee Surg Sports Traumatol Arthrosc* 2014;Jul 22 [Epub ahead of print]
18. Preuss R, Haeussler KL, Flohr M, Streicher RM. Fretting corrosion and trunnion wear – is it also a problem for sleeved ceramic heads? *Semin Arthroplasty* 2012;23:251-257
19. Huot Carlson JC, Van Citters DW, Currier JH, Bryant AM, Mayor MB, Collier JP. Femoral stem fracture and in vivo corrosion of retrieved modular femoral hips. *J Arthroplasty* 2012;27:1389-1396
20. Cooper HJ, Della Valle CJ. Large diameter femoral heads. Is bigger always better? *Bone Joint J* 2014;96-B(11 Suppl A):23-26
21. Burbano M, Russell R, Huo M, Welch R, Roy D, Rodrigues DC. Surface characterization of retrieved metal-on-metal total hip implants from patients with adverse reaction to metal debris. *Materials* 2014;7:1866-1879
22. Amini MH, Mayes WH, Tzeng A, Tzeng TH, Saleh KJ, Mihalko WM. Evaluation and management of metal hypersensitivity in total joint arthroplasty: a systemic review. *J Long-Term Eff Med Implants* 2014;24:25-36
23. Bizzotto N, Sandri A, Trivellin G, Magnan B, Micheloni GM, Zamò A, Bernardi P, Sbarbati A, Regis D. Chromium-induced diffuse dermatitis and lymph node involvement by Langerhans cell histiocytosis after metal-on-metal hip resurfacing. *Br J Dermatol* 2014;10, doi: 10.1111/bjd.13517 [Epub ahead of print]
24. Demehri S, Cunningham TJ, Hurst EA, Schaffer A, Sheinbein DM, Yokoyama WM. Chronic allergic contact dermatitis promotes skin cancer. *J Clin Invest* 2014;124:5037-5041
25. Hougeir FG, Yiannias JA, Hinni ML, Hentz JG, El-Azhary RA. Oral metal contact allergy: a pilot study on the cause of oral squamous cell carcinoma. *Int J Dermatol* 2006;45:265-271
26. Weber ME, Yiannias JA, Hougeir FG, Kyle A, Noble BN, Landry AM, Hinni ML. Intraoral metal contact allergy as a possible risk factor for oral squamous cell carcinoma. *Ann Otol Rhinol Laryngol* 2012;121:389-394

► Further Reading

- Callary SA, Holubowycz O, Howie D. Wear of large metal on highly cross-linked polyethylene articulations measured by RSA. *AAOS* 2014: Paper 250
- Endo M, Tipper JL, Barton DC, Stone MH, Ingham E, Fisher J. Comparison of wear, wear debris and functional biological activity of moderately crosslinked and non-crosslinked polyethylenes in hip prostheses. *Proc Inst Mech Eng H* 2002;216:111-122
- Fisher J, McEwen HM, Tipper JL, Galvin AL, Ingram J, Kamali A, Stone MH, Ingham E. Wear, debris, and biologic activity of cross-linked polyethylene in the knee: benefits and potential concerns. *Clin Orthop Relat Res* 2004;428:114-119
- Griffin XL, Haddad FS. Evidence-based decision making at the core of orthopaedic practice. *Bone Joint J* 2014;96-B:1000-1001
- Ingram JH, Stone M, Fisher J, Ingham E. The influence of molecular weight, crosslinking and counterface roughness on TNF-alpha production by macrophages in response to ultra high molecular weight polyethylene particles. *Biomaterials* 2004;25:3511-3522
- McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC, et al. No surgical innovation without evaluation: the IDEAL recommendations. *Lancet* 2009;374:1105-12
- Padman M, Ingram JH, Shaw DL, Fisher J, Ingham E. Biological reaction to conventional and cross-linked UHMWPE's in vivo. *Annual Meeting ORS* 2005: Poster 1688

Mid-term Results of Modern Ceramic-on-Ceramic Total Hip Arthroplasty

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The use of CoC bearings in total hip arthroplasty is growing worldwide. Especially bearings larger than 32 mm have been confirmed as a valid option for increased range of motion (RoM) and stability combined with extremely low wear, and some authors are suggesting that this coupling is the gold standard in hip arthroplasty. To characterize the outcomes of modern CoC bearings, a retrospective study was performed on patients who underwent hip arthroplasty with alumina composite in 3 clinical centers located in the Puglia region of Italy.

► The abstract is based on results of a clinical trial (Level of Evidence III)

Materials and Methods

142 patients who underwent hip arthroplasty with CoC bearings (BioloX[®]delta, CeramTec, Germany) were enrolled in this study, carried out at 3 clinical centers located in Puglia, Italy. Mean follow-up time was 47.6 months (SD: 7.9; minimum 11.7, maximum: 68.4). Mean patients' age was 68 (SD: 11; minimum: 38, maximum: 86). 63 patients (44.4%) were male, and the mean BMI was 27.6 (SD: 4.2; minimum: 18.8, maximum: 45.0).

74 bearings had a diameter of 36 mm (52.1%), and 55 bearings a diameter of 32 mm (38.7%), while bearings of 40 mm and 28 mm in diameter were implanted in eight (5.6%) and five (3.5%) cases, respectively.

A descriptive analysis of the sample was carried out in terms of mean, standard deviation (SD), and range for continuous variables and absolute and relative frequencies for qualitative ones. An assessment of the difference in distribution of the main demographic and clinical characteristics of the patients was performed. The Wilcoxon-Mann-Whitney and Kruskal-Wallis tests were used to evaluate differences between groups for quantitative variables. The chi-square test was used to compare data from qualitative variables.

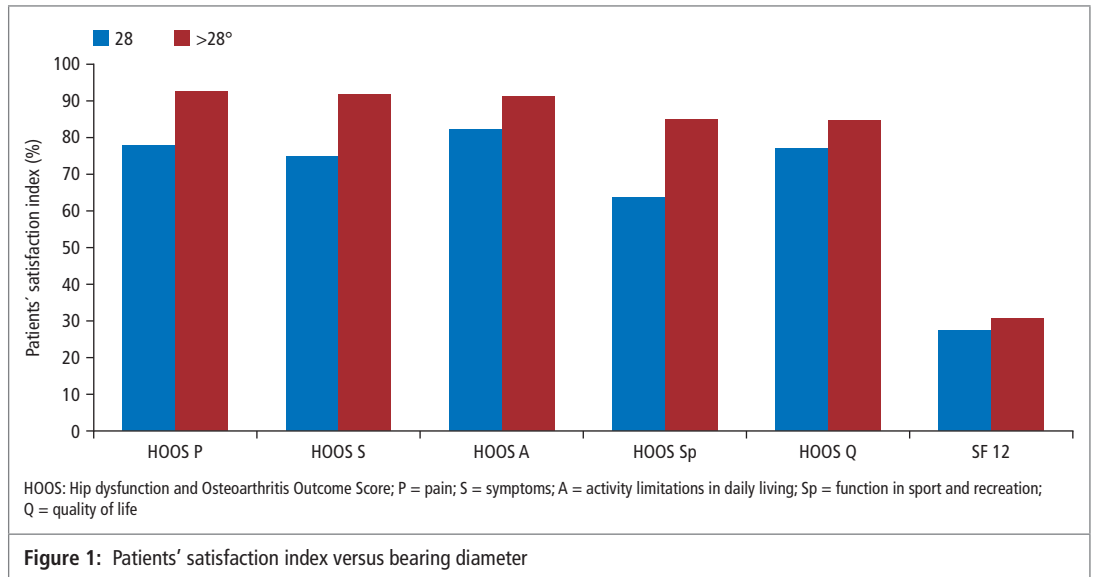
The association between quality of life (in terms of HOOS and SF-12 scores) and bearing characteristics was tested with linear regression models. Gender, BMI, and all variables associated with the analyzed outcomes with a p-value lower than 0.25 were introduced in the linear regression models. Analysis was performed with the SPSS 13.0 for Windows software. Statistical significance was set at p=0.05.

Results

The main clinical outcomes are described in ► **Table 1**. No cases of osteolysis and socket instability were observed. One patient suffered from

Socket inclination, degrees [mean (SD)]		45.4 (4.4)
Osteolysis [n (%)]		0 (0)
Socket instability [n (%)]		0 (0)
Stem position [n (%)]	Neutral	127 (89.4)
	Non-neutral	15 (10.6)
	Valgus	3 (2.10)
	Varus	12 (8.5)
Stem instability [n (%)]		1 (0.7)
Leg length discrepancy [n (%)]		25 (17.6)
Leg length discrepancy, mm [mean (SD)]		11 (9)
HOOS P [mean (SD)]		92.4 (10.5)
HOOS S [mean (SD)]		91.5 (11.3)
HOOS A [mean (SD)]		91.2 (11.8)
HOOS Sp [mean (SD)]		84.5 (18.5)
HOOS Q [mean (SD)]		84.6 (18.0)
SF12 [mean (SD)]		31.0 (2.7)
Reported noises (all not reproducible at control)	Squeaking [n (%)]	3 (2.1)
	Clicking [n (%)]	3 (2.1)
	Snapping [n (%)]	0 (0)
	Popping [n (%)]	0 (0)
	Grinding [n (%)]	1 (0.7)

Table 1: Main clinical outcomes of the DESIT (DElta Study Italy) patients (n=142)



stem instability (0.7 % of all patients). 15 stems (10.6 %) were in a non-neutral position. 25 patients (17.6 %) showed leg length discrepancy, with the average difference in length being 11 mm (SD: 9 mm). Although 3 patients reported squeaking (2.1 %), a further 3 reported clicking, and one other patient (0.7 %) grinding, none of these noises could be replicated at control. No patients reported either snapping or popping.

Variables tested for association with quality of life in terms of HOOS and SF-12 at the univariate analysis were patient type, follow-up time, socket inclination, stem position (neutral vs. non-neutral – varus and valgus), and leg length difference (in mm). Os-

teolysis, socket instability and stem instability were excluded from the analysis because of low or null variability among the patients.

Higher BMI values were associated with better quality of life according to the SF-12 scale, while leg length discrepancy was associated with a worse outcome. Age was the only variable associated with health quality outcomes in terms of HOOS and SF-12 in the multivariate analysis. Specifically, on multivariate analysis older age was associated with worse health quality outcomes in terms of both SF-12 and four of the five patient-relevant dimensions of the HOOS questionnaire – i. e., pain (HOOS P), symptoms (HOOS S), activity limitations



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in daily living (HOOS A), and function in sport and recreation (HOOS Sp). None of the analyzed variables was associated with the HOOS Q outcome at the multivariate analysis.

No statistically significant differences were observed between unilateral and bilateral interventions in terms of SF-12 and between pain, other symptoms, function in daily living and function in sport and recreation according to the HOOS score. However, statistically significant differences were observed between the unilateral (mean score: 85.2) and bilateral intervention (mean score: 78.8) in terms of quality of life according to the HOOS Q score. Patients with THR bearings larger than 28mm in diameter showed higher HOOS and SF-12 scores. The differences were statistically significant (▶ Fig. 1).

Conclusions

In summary, the only bearing-related complications reported by the patients included in the DESIT study at about 4 years' mean follow-up are transient noises. Bearing diameter larger than 28 mm was shown to improve patients' satisfaction with their hip re-

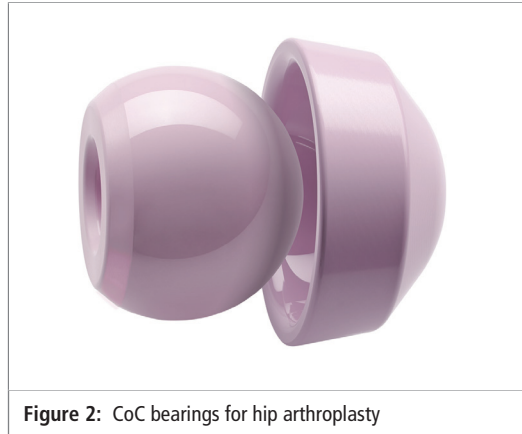


Figure 2: CoC bearings for hip arthroplasty

placements, while absence of osteolysis and of ceramic fractures confirms the excellent mechanical and wear behavior of CoC bearings (▶ Fig. 2). ■

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2015 Update on an Evolving Perspective for Taper Corrosion in Total Hip Arthroplasty

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Taper corrosion is an old issue for today's modern implants. In recent years, however, taper corrosion has re-emerged as a clinical concern, first with certain large-head metal-on-metal hip designs, then also with modular femoral necks, and even in selected cases with modern metal-on-polyethylene bearing couples. Our group was among the first to identify ceramic femoral ball heads as a potential solution to taper corrosion [1]. In the past few years we have pursued research to better understand and quantify the amount of metal that is released from contemporary ceramic and CoCr femoral ball heads. The purpose of this article is to briefly summarize some of our latest findings, presented at the ASTM Symposium on Taper Corrosion 2014 [2] and in posters at the 2015 Meeting of the Orthopedic Research Society [3, 4]. We want to continue to share an evolving perspective on this topic based on our group's recent research.

Our group began to study the hip implant retrieval collection at the Implant Research Center at Drexel University to compare taper corrosion in ceramic head systems with that in metal head systems [1]. We have spent a few years studying carefully matched implants in the two 50-implant cohorts (100 patients total) to account for all the variables influencing taper corrosion and to focus on the difference between ceramic-metal and metal-metal tapers. First of all, we excluded from the study any hip implant systems with modularity besides the head-neck interface. This means that there were no ceramic heads with metal sleeves in the study, nor were there modular necks or modular stems. The ceramic heads were all BioloX®, BioloX®forte or BioloX®delta heads produced by CeramTec. We observed significantly less corrosion among the stems in the ceramic head cohort as compared with the metal head cohort, and we published these data in 2013 [1].

Reduced metal release with ceramic

What we didn't know at the time was to what degree ceramic heads reduced metal release, and whether metal release was mitigated at the head taper, stem taper, or both. We spent over a year developing and validating a highly sensitive technique to measure the microscopic volumes of metal that are released in CoCr femoral ball heads and metal stem tapers [4]. After re-examining our previous matched 50–50 cohort of ceramic and femoral ball heads, we found that the ceramic cohort exhibited over 90% less metal release, in terms of volumetric material loss, when compared with the CoCr cohort. When focusing on the CoCr head cohort, we found that the vast majority of the metal release – again, over 90% – was liberated from the femoral ball head rather than from the stem taper. These CoCr heads were all on MoP bearings.

Mechanical integrity influences corrosion

Retrieval research on taper corrosion continues to be challenging because of the many relevant and potentially confounding factors: The implantation time and flexural rigidity of the stem are two such factors. We were curious to see if the mechanical integrity of the taper connection would influence the corrosion at the head-neck interface [3]. In the laboratory, previous researchers had shown that impaction force can affect the amount of micromotion, fretting, and corrosion under in vitro conditions [5]. We asked if such a situation might also be applicable in vivo. To answer this question, we studied 46

Interested in Retrieval Research? How You Can Help.

As our retrieval research continues, access to explanted ceramic heads and stem pairs with over ten years in vivo, as well as to ceramic heads incorporating metallic sleeves (e.g., Delta option heads), would be extremely useful. If you are interested in collaborating with our multi-institutional retrieval research program by providing explanted devices and associated (de-identified) clinical data, please do not hesitate to contact the author (skurtz@drexel.edu). We have established protocols for the shipping of retrieved implants internationally, and we currently collaborate with over 15 clinical centers in the USA and Europe.

retrieved hip systems that did not have the head-stem taper intraoperatively disassembled. These devices had been revised for infection, loosening, and periprosthetic fracture. We found that for devices implanted for between 5 and 10 years, there was an inverse correlation between the corrosion damage of the taper and the strength of the taper junction, recorded as the force required to disassemble the head from the stem taper. In other words, the weaker the interlock between head and the taper, the more corrosion was observed at the retrieved modular taper junction. Keep in mind that this is a pilot study, but these preliminary data do lend further support to the plethora of factors – some well-known for years, others only being discovered today – that influence clinical manifestations of corrosion at the head-neck interface.

Trunnion surface morphology not relevant

One design factor, namely stem surface roughness, has recently been suggested to influence taper corrosion based on in vitro experiments [6]. For this reason, we also decided to study the effect of this variable on taper corrosion in explanted hip components with CoCr femoral ball heads [2]. We asked whether components with "microgrooved" stem tapers have higher fretting-corrosion damage scores than components with "smooth" stem tapers. In order to answer this question, we performed a retrieval analysis of 398 paired femoral ball head and stem THA components. Using multivariate analysis of covariance, we found that implantation time ($p < 0.0001$), apparent engagement length ($p < 0.0001$), flexural rigidity ($p = 0.008$), and head size ($p = 0.04$) were significant factors in fretting-corrosion head-damage scores. Following adjustment for these factors, surface topography ($p = 0.97$) was not associated with fretting-corrosion damage. Overall, the results of this study do not support trunnion surface morphology as a contributing factor to fretting and corrosion damage at the modular CoCr head-neck interface.

Our group's ongoing retrieval research continues to uncover important implications for metal debris generation in modular hip systems. It is now clear that ceramic heads eliminate the potential for metal release from the CoCr head and reduce tribo-corrosion of metal stem tapers to a level that is exceedingly challenging to measure today. Our pilot research with retrieved CoCr heads suggests that mechanical integrity of the taper could play an important role in its susceptibility to taper corrosion in vivo. Furthermore, our retrieval data do not support stem taper morphology (i.e., smooth vs. microgrooved stem tapers) as a significant factor to explain fretting and corrosion taper damage in vivo. Expect future updates on the status of taper corrosion research at conferences in the coming year. ■

► **Acknowledgements:** The author would like to thank Sevi Kocagoz, Christina Arnholt, Genymphas Higgs, and Dan MacDonald, Drexel University, and Richard Underwood, Ph.D., Exponent, for their contributions to the corrosion research summarized in this article, as well as for their insights and many helpful discussions.

► References

1. Kurtz SM, Kocagoz SB, Hanzlik JA, Underwood RJ, Gilbert JL, Macdonald DW, Lee GC, Mont MA, Kraay MJ, Klein GR, Parvizi J, Rimnac CM, Do ceramic femoral heads reduce taper fretting corrosion in hip arthroplasty? A retrieval study. *Clin Orthop Relat Res* 2013;471:3270–3282
2. Arnholt C, Underwood RJ, MacDonald DW, Higgs G, Chen AF, Klein G, Hamlin B, Lee GC, Mont M, Cates H, Malkani A, Kraay M, Rimnac CM, Kurtz SM, Does micro-grooved surface topography influence fretting corrosion of tapers in THA? Classification and analysis of surface topography. *ASTM Symposium on Taper Corrosion in Total Hip Replacement Devices 2014*, New Orleans, USA
3. Higgs GB, Siskey RL, Gilbert JL, Mihalko WM, Rimnac CM, Kurtz SM, What effect does the strength of the taper connection have on taper damage in retrieved total hip devices? *Trans Orthop Res Soc* 2015; Poster Session PS2-154:1741
4. Kocagoz SB, Underwood RJ, MacDonald D, Gilbert JL, Rimnac CM, Kurtz SM Metal release in ceramic and CoCr heads at the modular junction: a matched cohort retrieval study. *Trans Orthop Res Soc* 2015; Poster Session PS1-065:0887
5. Mroczkowski ML, Hertzler JS, Humphrey SM, Johnson T, Blanchard CR, Effect of impact assembly on the fretting corrosion of modular hip tapers. *J Orthop Res* 2006; 24:271–279
6. Panagiotidou A, Meswania J, Hua J, Muirhead-Allwood S, Hart A, Blunn G, Enhanced wear and corrosion in modular tapers in total hip replacement is associated with the contact area and surface topography. *J Orthop Res* 2013;31:2032–2039

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Fretting and Corrosion Discussion of Methods for Assessment and Testing

Report on the Symposium on Modularity and Tapers in Total Joint Replacement Devices, November 10, 2014, New Orleans, USA

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In recent years, fretting and corrosion of modular connections in hip endoprosthetics have been more and more under discussion, leading to an increased number of publications related to the topic. Also modular connections with ceramic ball heads on stem tapers or ceramic ball heads with sleeves on stem tapers for revision surgeries have been investigated in this framework. Nevertheless, the experts are still not in agreement on the means and methods for qualitative and quantitative assessment of the corrosion events occurring at the taper connections. Moreover, the in-vitro reproduction of the clinically observed corrosion phenomena is a topic of ongoing research. To address these issues, the American Society for Testing and Materials (ASTM) and the American Academy of Orthopedic Surgeons (AAOS) organized a symposium held in New Orleans on November 10, 2014, with notable experts on the podium.

The main purpose of the symposium was to provide a forum for scientific exchange and an opportunity to find consensus on common methods for the assessment and testing of fretting and corrosion, possibly leading to the development of appropriate international standards. Many aspects were taken into account, with special emphasis on the following subjects:

- Characterization of fretting, corrosion and the resulting adverse tissue reactions,
- significance of explants,
- current and prospective test procedures, and
- design parameter for taper connections in joint endoprostheses.

Approximately 200 participants from science, from industry, from the Food and Drug Administration (FDA), and from several legal organizations followed the 27 presentations which were divided into five different sections according to their main focus. At the end of each section, the participants had the opportunity to intensively discuss the contents of the presentations with the presenters. Furthermore, altogether 15 research groups took the opportunity to present their newest results within a poster session. Organizers and chairmen of the symposium were **A. Seth Greenwald** (Cleveland), **Steven Kurtz** (Philadelphia), Jack Lemons (Birmingham), and **William Mihalko** (Memphis).

Adhesion of inflammatory cells could cause corrosion

In his presentation, Lemons showed the difficulty of distinguishing between the different possible corro-

sion mechanisms, such as galvanic corrosion, fretting corrosion, crevice corrosion, and pitting corrosion, and of simulating these mechanisms in vitro. **Jeremy Gilbert** (Syracuse) reported that inflammatory and immune cells attach to CoCrMo surfaces in vivo and start or amplify corrosion processes. Microscopical investigations of explanted hip components (MoM, MoP) and knee implants supplied for the first time evidence for this type of corrosion. These corrosion processes have been observed independent of the metal alloy, implant design, and type of polyethylene. It is largely unknown which stimuli trigger the cell activity.

With the help of 843 examined retrievals, Kurtz illustrated in his presentation that the loss of volume due to corrosion processes is much larger on the metal ball head tapers than on the stem tapers. Furthermore, using 398 explanted stems from MoP-bearings, he provided evidence that the surface topography of the stem tapers does not influence the qualitative and quantitative degree of corrosion on either on the metal ball head tapers or the stem tapers.

Legal aspects: large product range, demand on improved test methods

Carlos Lavernia (Miami) complained about the large number of different taper designs which may exist within the product range of a single prosthesis company, harboring the risk of mix-and-match. He used the term "lawyeritis", which may prevent further proper scientific investigation of the topic.

John Goode from the FDA noted that improved test methods are urgently necessary because all the implants exhibiting clinically relevant problems have successfully passed the standardized testing prior to market release. Two representatives of a US law office stated that appropriate standards and guidelines might significantly ease possible litigations. The currently common active recruitment of patients for litigations increasingly falsifies the available data and affects the scientific root cause analysis.

Several important conclusions have been drawn on the basis of contemporary knowledge: in the test procedures, more and more attention is given to the selection of those test parameters having the greatest influence on the simulation of clinically relevant failure modes, e. g., the test fluid or the loading scenario. In order to assess these clinically relevant failure modes with the help of retrievals, it is necessary to establish uniform cleaning procedures for the tapers. Only then it is possible to assess the retrievals on the basis of qualitative scores and quantitative measurements.

Impact of fretting and corrosion on clinical results

The scientific and technological meeting showed that remarkable progress has been made in assessing and testing fretting and corrosion since the last meeting of this kind in November 2013. It also revealed that the complex relationships and the large number of influencing factors leading to the clinically observed failure modes can be simulated only roughly in vitro. There was agreement that the importance of fretting and corrosion related to clinical problems for patients requires further exam-

ination: So far, only a few revision surgeries have been performed due to symptoms which are related exclusively to fretting and corrosion, whereas a large number of retrievals show clear signs of these phenomena. A necessity to develop different stem taper designs for ceramic and metal ball heads – with respect to either the shape or the surface – is not seen by the experts at this time. ■

References

1. Lemons JE. Experience & Opinions on Modular Connections for Surgical Implant Devices. ASTM International Symposium on Modularity and Tapers in Total Joint Replacement Devices, New Orleans 2014, Abstract (talk 1)
2. Kurtz SM et al. Is Taper Fretting Corrosion a Threat to the Clinical Performance of Large-Diameter Highly Crosslinked Polyethylene Bearings? ASTM International Symposium on Modularity and Tapers in Total Joint Replacement Devices, New Orleans 2014, Abstract (talk 9)
3. Higgs GB et al. Characterizing the Strength of the Taper Connection & its Effect on Taper Damage in Retrieved Total Hip Devices. ASTM International Symposium on Modularity and Tapers in Total Joint Replacement Devices, New Orleans 2014, Abstract (talk 10)
4. Gilbert JL. State-of-the-Art Understanding of In Vivo Modular Taper Corrosion & In Vitro Testing. ASTM International Symposium on Modularity and Tapers in Total Joint Replacement Devices, New Orleans 2014, Abstract (talk 18)
5. Laverna CJ et al. The Role of Design Parameters and Microstructure in the Corrosion and Fretting of Hip Taper Interfaces: A Retrieval Study. ASTM International Symposium on Modularity and Tapers in Total Joint Replacement Devices, New Orleans 2014, Poster

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Does Bearing Influence Septic Loosening of primary Total Hip Arthroplasty?

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RIPO Register c/o Medical Technology Laboratory, Istituto Ortopedico Rizzoli, Bologna, Italy

✦ The abstract is based on results of a clinical trial (Level of Evidence III)

A cohort of 36,396 implants of primary total hip arthroplasties was considered, extracted from the Italian Register of Prosthetic Orthopedic Implants (RIPO). Of these, 49 % have CoC articular coupling, 23.4 % CoP, 19.5 % MoP, and 8 % MoM. Survival analysis was performed, the end point being revision due to sepsis. It was shown that age at surgery and body mass index do not influence septic loosening, while articular coupling and male gender do. In detail, CoC coupling reduces the risk of septic failure compared with MoM. Men have a higher risk than women.

Beginning on January 1, 2000 a Register for Orthopedic Prosthetic Implants (RIPO) was established in the Italian region of Emilia Romagna. The register collects data on all primary hip replacements and revision surgery performed in public and private hospitals of the region [1]. Surgeons provide data on specific register forms, which are completed before patients are discharged. The

register capture rate is nearly 98 %. The principal outcome measure is time to revision surgery, defined as removal or exchange of at least one single component. Among reasons for revision, septic loosening represents 6.3 % of all possible causes. This is not such a high percentage, but septic loosening often has the worst outcome for the patient.

Coupling	Number of implants (n)	Age, mean (years) and range	Prop. of obese (%)	Prop. of female (%)	Revisions for septic loosening (n)
CoC	17,858	65.7 (13–93)	65	59	22
MoP	7,104	71.1 (20–95)	67	62	13
CoP	8,524	70.3 (22–92)	65	62	13
MoM	2,910	61.4 (16–87)	64	48	14

Table 1: Cohort of 36,396 uncemented primary implants analyzed statistically

	Hazard ratio	95% lower bound	95% upper bound	p-value
Gender (reference male)	0.6	0.3	0.9	0.03
BMI class (reference obese)	0.9	0.7	1.3	0.97
Bearing (reference CoC)	0.98	0.95	1.0	0.09
MoM	3.1	1.6	6.2	0.003
MoP	1.2	0.6	2.3	0.66
CoP	1.2	0.6	2.3	0.66

Table 2: Results from Cox model: A hazard ratio (HR) >1 indicates risk increase, a HR <1 risk reduction (significant data are in boldface)

The aim of the analysis was to determine whether there is an influence of articular coupling on septic loosening.

Methods

To achieve this aim, only uncemented total hip arthroplasties implanted in the period from January 2000 to December 2013 in primary coxarthrosis and coxarthrosis secondary to developmental dysplasia were considered due to a possible bias related to the presence of antibiotic in the cement. The final dataset is presented in **Table 1**.

Possible risk factors for sepsis are not equally distributed among the four groups, so the Cox proportional hazard method was applied, with revision of total hip arthroplasty (THA) for septic loosening as the end point.

Results

The analysis showed that age at surgery and body mass index (BMI) do not influence septic loosening, while type of articular coupling and gender do. More specifically, CoC coupling reduces significantly the risk of septic failure compared with MoM with a hazard ratio of 3.1 (1.6–6.2). CoC

does not influence the risk compared with CoP or MoP. Women have approximately half the risk of men (➤ **Table 2**).

The results are unchanged when only late infections (revision surgery after at least 60 days from implant) are considered.

Conclusions

It can be concluded that articulation without metal components reduce the risk of precocious and late septic failure of THA, although significance was only reached in comparison with MoM. Male gender shows a higher risk for septic loosening compared with female gender. A limitation of this study is that comorbidities that may affect the outcome of sepsis were not considered.

➤ **Acknowledgements:** All surgeons of orthopedic units in the Region Emilia Romagna are gratefully acknowledged for sending their data to the register.



Barbara Bordini, senior statistician of the Register, has a statistics degree from the University of Bologna. Since 1999, she has been working at the Istituto Ortopedico Rizzoli, at the Medical Technology Laboratory. She is responsible for the statistical analysis of the Register of Prosthetic Orthopedic Implants (RIPO). She identifies groups of patients to start on clinical experiments also by surveying the regional and local data banks.

➤ References

1. RIPO annual report, <https://ripo.cineca.it>, last downloaded February 15, 2015

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AWARD

Pauwels Commemorative Medal 2014

Werner Zimmerli, MD, was awarded the Pauwels commemorative medal by the German Society for Orthopedics and Orthopedic Surgery (DGOOC). His lecture during the award ceremony was entitled: "Orthopedic Prosthetic Joint Infections: Pathogenesis und Therapy".

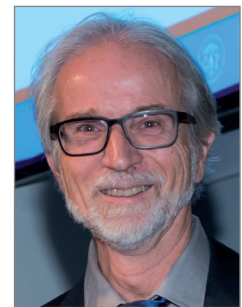
Zimmerli is a well-known infectious diseases specialist with more than thirty years working experience in the field of internal medicine and infectious diseases. Since 1979 his research focus has been on the pathophysiology and treatment of implant infections. A major breakthrough in the treatment of these infections was the proof of rifampicin's effectiveness against biofilm infections. Working together with the orthopedist Peter Ochsner and the infection specialist Andrej Trampuz he developed a treatment algorithm for prosthetic-joint infections [1].

Zimmerli was also a member of the commission of the Infectious Diseases Society of America (IDSA), that published guidelines for the diagnosis and treatment of prosthetic joint infections. These are based on the published treatment algorithm and have since become the international standard.

Since retiring as a medical chief physician Zimmerli has been working as a medical consultant for orthopedic infections at the Kantonsspital Liestal, Switzerland.

He is a advisory board member of the Pro-Implant Foundation and teaches in the foundation's workshops (<https://www.pro-implant-foundation.org/en/about/who-we-are>).

Reference: 1. Zimmerli W, Trampuz A, Ochsner PE. Prosthetic-Joint Infections. *N Engl J Med* 2004;351:1645-1654



The Effect of Chromia Content on Hardness of Zirconia Platelet Toughened Alumina Composites

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BioloX[®]delta is a zirconia toughened alumina ceramic (ZTA) for biomedical applications. The success of this material relies on its extraordinary combination of material properties such as strength, toughness, hardness and biocompatibility. The composition of **BioloX[®]delta** includes SrO, Y₂O₃, and Cr₂O₃. Strontia is added for the formation of platelets inside the matrix, which support the toughness of the material. Yttria is added in order to control the transformation mechanism of the zirconia phase.

According to Burger et al., it was previously stated that the addition of chromia leads to improved hardness in a ZTA material [1]. However, later studies on this subject reveal a measurable increase in hardness only at a chromia content much higher than is present in **BioloX[®]delta** [2]. Further scientific literature suggests that the addition of chromia within a limited range does not influence the hardness of a ZTA material [3]. CeramTec undertook a comprehensive investigation in order to isolate the impact, if any, of chromia on hardness in **BioloX[®]delta**. The results of this analysis are described here.

Description of tests and results

A test series of 4 ZTA variants with different chromia content was produced in the CeramTec laboratory. The chromia content in **BioloX[®]delta**, as a reference, is 0.32%. For comparison, samples with lower and higher chromia content and even 0% chromia have been produced. Manufacturing conditions like milling, pressing, sintering and hard machining for all specimens are identical. The ceramic microstructure, i.e., grain size and grain distribution of the material components alumina, zirconia, and platelets, are within the normal range. As an example, **Figure 1** shows the microstructure of a speci-

men with 0% chromia content versus **BioloX[®]delta** reference.

Hardness of ceramics is usually measured using the Vickers 4-sided diamond pyramid. Today the use of a test load of HV 1, or Hardness Vickers load balance of 1 kg (=9.8 N), is recommended. In the past, several studies also used other test loads like HV0.5 or HV10. It was thus decided to include these 3 load levels in this study.

Furthermore, the preferred unit of hardness values has been changed over time. Today, using the ratio of load versus projected imprint area for the hard-

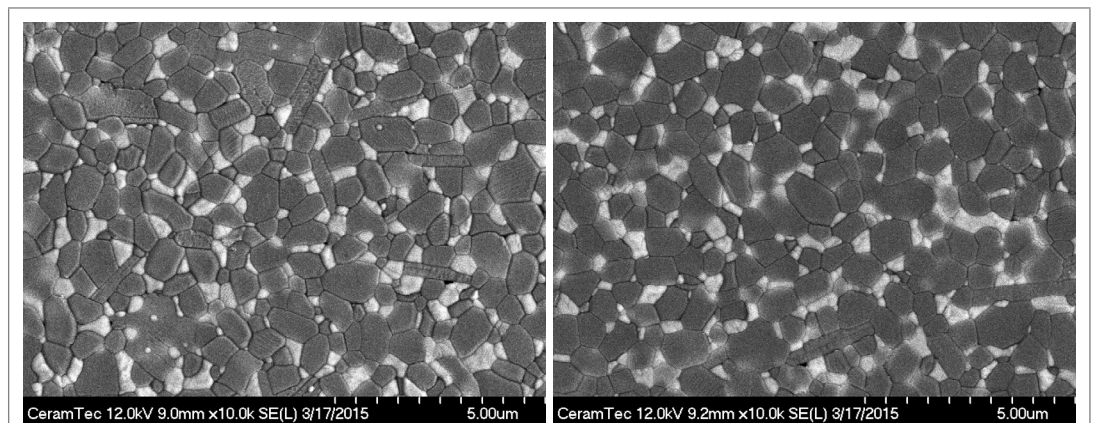


Figure 1: Microstructure of 2 specimens with different Cr₂O₃ content; left: 0,00 %; right: 0,32 % (© CeramTec)

ness value is recommended, which makes gigapascal [GPa] the relevant unit. In historic data, a unitless number was preferred. Such numbers can be directly compared using the factor 0.009807. As an example, a hardness value of 2000 [-] equals 19.61 GPa.

Figure 2 shows the results of the analysis. Mean values ± 1 x standard deviation with the error bar are plotted. As already well known, the hardness values are higher at lower load levels of the indentation (at least within the load range of this study). For all load levels, no measurable influence of the chromia content to hardness is found. For the reference hardness value HV1, all results are virtually identical.

Influence of test load and strontia

These results demonstrate that the presence or non-presence of chromia in a ZTA material that is otherwise identical to BioloX[®]delta has no influence on the hardness of the material, at least in the range of the amount of chromia investigated here (0–0.5 % by weight). For the study of Burger et al., the load level HV0.5 was used which is not recommended today [1]. This may be one source of inaccurate results due to high measurement uncertainty. In addition, the sample in [1] that contained chromia, also contained SrO, which was absent from the chromia-free sample. Unfortunately, the result of the study [1] from 2001 has often been cited in publications referring to the material profile of BioloX[®]delta. However, the statistically substantiated test results discussed here demonstrate that the chromia content of BioloX[®]delta does not measurably influence the hardness. ■

References

1. Burger W, Richter HG, High Strength and Toughness Alumina Matrix Composites by Transformation Toughening and „In Situ“ Platelet Reinforcement (ZPTA) – the New Generation of Bioceramics, Key Engineering Materials 2001;191-195:545–548
2. Bradt RC, Cr2O3 Solid Solution Hardening of Al2O3, Journal of the American Ceramic Society 1967;50:54–55
3. Magnani G, Brillante A, Effect of the composition and sintering process on mechanical properties and residual stresses in zirconia alumina composites, Journal of the European Ceramic Society 2005; 25:3383-3392
4. ISO 14705 Fine ceramics (advanced ceramics, advanced technical ceramics) – Test method for hardness of monolithic ceramics at room temperature

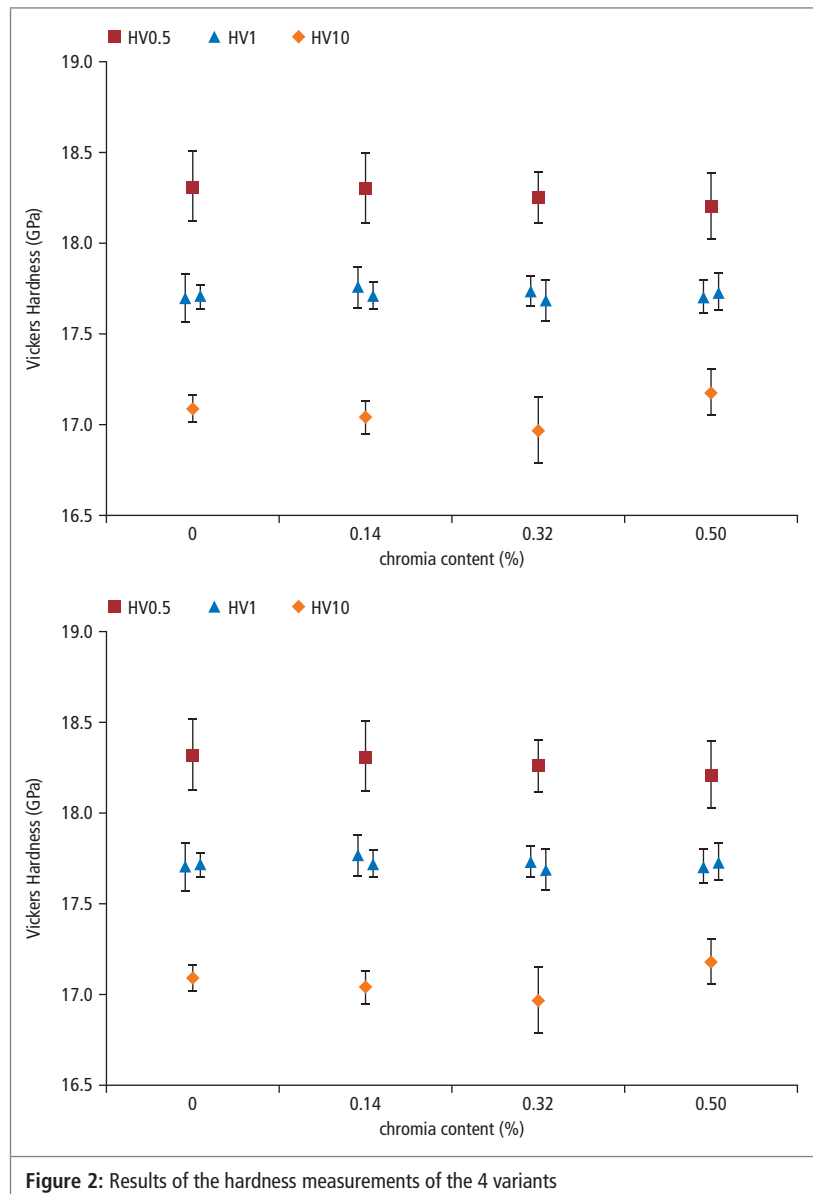


Figure 2: Results of the hardness measurements of the 4 variants

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What's New in Endoprosthetics in Russia?

8th Vreden's Readings Conference, St. Petersburg, Russia

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In recent years, the "Vreden's Readings" conference has developed into an excellent forum for Russian orthopedics, and the number of participants from abroad grows year by year. Approximately 800 orthopedists from various regions of Russia and numerous visitors from 29 countries, among them the USA, France, Germany, Italy, Great Britain, Austria and Japan, took part in the eighth conference. The Eastern European states were represented by specialists from Lithuania, Latvia, the Ukraine, Belarus, and Kazakhstan.

On three days, 102 scientific presentations and six lectures were held on the subject of endoprosthetic replacements of the large joints. The lectures were delivered in Russian and English and simultaneously translated. The conference was accompanied by an exhibition by the 60 leading enterprises in the medical technology industry. Numerous workshops were devoted to the newest methods in endoprosthetics and to the conservative treatment of pathologies of the locomotor system.

The topics with which Russian specialists and experts are currently dealing in the field of endoprosthetics are also the main focus of orthopedics worldwide:

- complex revision surgery,
- the therapy of infection-related complications,
- highly complex pathologies of the large joints,

- the optimization of care of young and active patients
- and issues of safety and quality in endoprosthetics.

Russian orthopedists are also confronted with specific problems regarding the treatment of frequently occurring dysplasias in certain regions (☒ **case report**), above all in the southern regions of Russia, and the traditionally determined preference for classical solutions (e.g., osteotomy rather than endoprosthesis).

Focus: Basic and advanced training

The rapid development of endoprosthetics in Russia, with an average yearly growth of 15–20 %, in some regions even 40–50 %, must be accompanied by rigorous schooling and advanced training of orthopedic surgeons. The conference made clear that continuous basic and advanced training are of particular importance for the professional competence of the operating surgeon, for results analysis, and for the comprehensive assurance of rehabilitation, without which high-quality results cannot be achieved.

During the conference, attention was focused in particular on implant pathologies and implant allergies and on the role played by implant materials and designs in adverse reactions to abrasion and corrosion products. It became apparent that the problems in their complexity can be solved only on a multidisciplinary basis, and that the experts in the specialized disciplines must join forces to meet this challenge. As a result of an interesting discussion about contributions by Russian and German experts it was agreed to carry out further studies together.

9th Vreden's Readings Conference 2015: 8–10 October 2015, St. Petersburg, Russia

This year's conference will take place in St. Petersburg from the 8th to the 10th of October. One topic of the scientific program will be periprosthetic joint infection (PJI). The infection expert Prof. Andrej Trampuz, Charité Berlin (<https://www.pro-implant-foundation.org/en/>) will organize the PJI session with German and Russian experts, who will present and discuss the modern concepts of prevention, diagnosis, and therapy. The subject area foot surgery will be included in the scientific program for the first time. The results of the conference will be published and made accessible to all interested persons (congress link <http://www.vreden-readings.org/eng/program.php>)

We invite you to a stimulating conference with interesting encounters.



R.M. Tikhilov, MD

Some of the contributions to the "Vreden's Readings" conference 2014 were published in the journal *Traumatology and Orthopedics of Russia* (issues 3 and 4, 2014, Russian and English) and can be downloaded (http://journal.rniito.org/num_en.html).

References

1. Krenn V, Thomas P, Thomsen M, Usbeck S, Scheuber L, Boettner F, R  ther W, Hopf F, M  ller S, Krukemeyer MG, Gehrke T, Kendoff D, Tiemann A, Huber M. Implant-associated pathology: an algorithm for identifying particles in histopathology synovialis / SLIM diagnostics. *Traumatology and Orthopedics* 2014;3:1
2. Thomas P, Thomsen M, Krenn V, Summer B. Patients with suspected metal implant allergy: Potential clinical pictures and allergological diagnostic approach (review). *Traumatology and Orthopedics* 2014;3:142–146

3. Thomsen M, Krenn V, Thomas P, Kretzer JP. Clinical cases of patients with arthroplasty and heightened blood concentration of metal ions. *Traumatology and Orthopedics* 2014;4:85–89

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@ Contributions on the subjects of implant allergies, implant pathologies and hip revision can be accessed here in Russian and in English with the QR code.



CASE REPORT

Treatment of dysplastic coxarthrosis

Diagnosis

A 47-year-old female patient with left-sided dysplastic coxarthrosis (Fig. 1) had been treated conservatively during her childhood. This involved retention with a plaster cast in order to reduce the luxation of the left hip. On admission to the hospital she complained of pains, reduced leg length, and restricted mobility in her left hip joint. The patient was barely able to walk due to the one-sided leg length difference (3 cm) and the flexion contraction in the hip joint. She had a pronounced limp and required a walking aid. In addition, there was pain in the area of the lumbar spine.

Therapy

The left hip joint was replaced with a cement-free endoprosthesis via lateral access. Because of the pa-

tient's age and her activity demands a ceramic-ceramic bearing was used. Reconstruction of the cup was done with autologous bone material (Fig. 1).

It was decided not to perform a complete leg-length equalization due to the existing changes in the lumbar spine. The resulting leg-length difference was 0.8 cm (Fig. 1). The Harris Hip Score had improved from 38 to 92 points at the time of the most recent follow-up examination.

Two years following the operation the cup and the stem are stable, and no postoperative complications are detectable. The flexion contraction has improved significantly. The patient can walk normally, requires no walking aid, and is satisfied with the result. ■

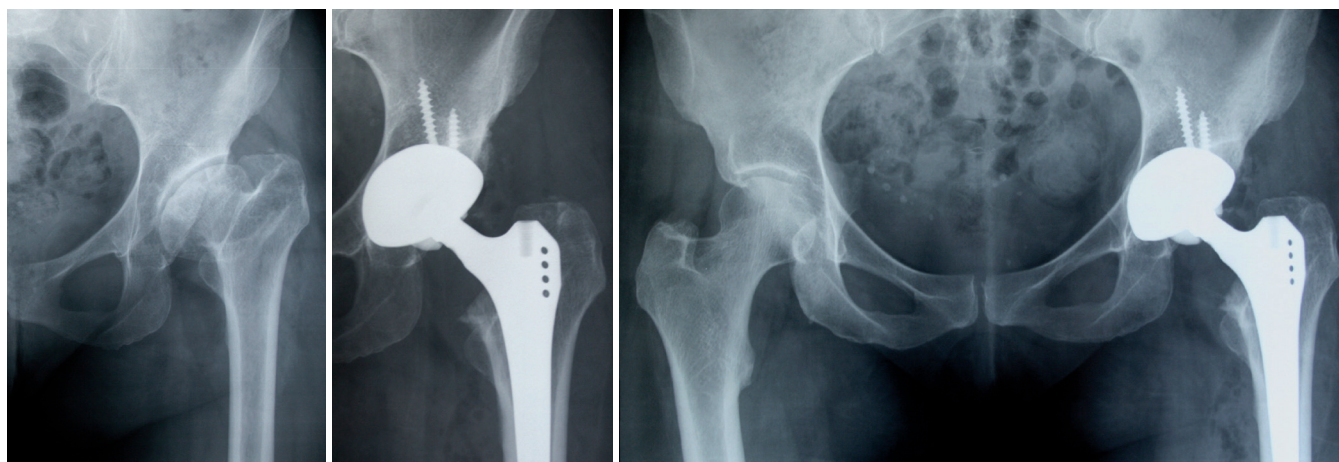


Figure 1: Female patient with dysplastic coxarthrosis Crowe II, from left to right: preoperative X-ray image, postoperative X-ray image, X-ray image 2 years postoperatively (  Tikhilov)

Tribology: Science and Practice in Korea

Pick from a Bearing Congress in Seoul (South Korea)

Zimmermann M, Graessel M

CeramTec GmbH, Plochingen, Germany

Although total hip arthroplasty (THA) is a very successful type of surgery, it is well-recognized that clinical outcomes are influenced, among other factors, by the quality of the implants used. In particular, the choice of materials for the bearing couple plays an important role. In order to provide the latest updates in this regard, Jun-Dong Chang, MD, Chairman of Department of Orthopaedic Surgery and Director of Arthroplasty Center of Hallym University Dongtan Sacred Hospital, Seoul (South Korea), organized a full-day congress dedicated specifically to "Tribology: Science and Practice". The event was held at his hospital and was attended by more than 150 Korean surgeons. Eight international faculty members from Germany, Italy, Switzerland, the USA, China, Japan and India highlighted the meeting with their contributions.

According to Chang, the most important issue in THA in Korea is to minimize wear and impingement. Tribology of the bearing surfaces is a topic that continues to be discussed. Therefore, the scientific program of the "Tribology: Science and Practice" congress focused on issues regarding materials, wear particles, taper corrosion, infection risks related to bearing surface, current status of bearing surface, evolution of ceramic bearings, differences between Asian and Western patients, technical aspects, and registry.

Given that patients today have a substantially longer life expectancy, it is anticipated that wear-related issues will predominate. Furthermore, it is well-known that Korean as well as other Asian patients differ from Western patients in their specific anatomies and lifestyles. Their daily routine requires a particularly large range of motion, and a large proportion of Asian patients are young: Such differences should be considered as the important issue in arthroplasty in Korea.

Asked about the bearing choice algorithm in Korea, Chang stated: "All these considerations explain why the clinical results with conventional polyethylene in Korean patients were poorer than those in Western patients. Accordingly, alternative bearing surfaces have been predominantly used for THA in Korea. Among the alternative bearing surfaces, MoM, often used for resurfacing, has been associated with an increased risk of osteolysis, local soft-tissue reactions, tissue and bone necrosis, and potential long-term toxicity. These adverse effects led to a substantial decrease in the use of this kind of hard-on-hard

bearing surface for hip arthroplasty. This explains why the use of ceramic bearings has become very popular in Korea, showing the most reliable results up to now among Korean patients. Another reason for the popularity of CoC bearing couples in Korea is the cost-effectiveness with the nationally controlled insurance system."

"Finally, the introduction of BioloX[®]delta ceramic in Korea substantially improved the clinical outcomes in comparison with previous pure alumina ceramic generations, especially regarding breakage and squeaking. This enhanced ceramic also allowed the use of a large ball head to improve stability and reduce impingement in patients with small sockets, which is common in Koreans. Breakage of BioloX[®]delta is very rarely reported in Korea, and I have never experienced any fractures of liner or femoral head with BioloX[®]delta ceramic." The acceptance of ceramic bearings in Korea is very high, with an 85,46 % share of CoC used in primary THA (data on file, South Korea Health Insurance Review and Assessment Service 2014). Thus, clinical outcomes and issues were extensively analyzed and discussed at the meeting. The Korean situation was reflected in the presentations by Kyong-Ho Moon, MD, Inha University, Incheon, and Kyung-Hoi Koo, MD, Seoul National University Bundang Hospital.

Long-term results of third-generation CoC bearings in Korea

Moon presented the long-term results with the third generation of CoC bearings. From April 2001 to January 2008, 349 cementless THA were per-

formed with CoC (BioloX[®]forte, alumina) bearings in 331 patients. The patients' mean age at the time of surgery was 54.6 years (range: 23–87 years). The most common indication was osteonecrosis, in 191 cases. After a mean follow-up of 8.9 years (range: 6.5–13 years), there was no radiologic evidence of osteolysis or cup migration. The two main observed complications were dislocation in nine cases (2.9 %) and periprosthetic fracture in seven cases (2.2 %). In three cases (0.9 %) a fracture of the ceramic component was observed, including one case observed intraoperatively (liner chipping). In five cases (1.6 %) squeaking occurred, however, without requiring revision. In conclusion, the long-term results of third-generation CoC bearings in cementless primary THA were excellent.

Delta ceramic bearing: Will it guarantee better results?

Koo reported on the retrospective findings from several cohorts of patients all treated with CoC bearings but with different stem and cup systems [1, 2, 3] (Level of Evidence III and IV).

Between 1998 and 2008, he used the BioloX[®]forte ceramic and since March 2008 he is using BioloX[®]delta. The lessons learned from 10 years' experience with the third generation of ceramic articulation are that we should

- not use sandwich-type ceramic liners,
- not use 28-mm-short neck heads,
- not use metal shells with an elevated rim, and finally,
- we should inform the patients not to squat.

Between March 2008 and September 2011, 570 BioloX[®]delta CoC hips were implanted in 492 patients. The mean age of the patients at surgery was 50 years (range: 16–83 years), with osteonecrosis being the main reason for surgery in 311 cases. After a mean follow-up of 42 months, neither osteolysis nor wear has been observed. The only case of ceramic liner fracture was due to intraoperative malpositioning of the liner. The use of ceramic ball heads 32 mm or 36 mm in diameter clearly reduced the risk of dislocation compared with 28-mm ball heads [4] (Level of Evidence I). ■

- Lee YK, Ha YC, Koo KH. Comparison between 28 mm and 32 mm ceramic-on-ceramic bearings in total hip replacement. *Bone Joint J* 2014;96-B(11):1459–63 [Level of Evidence I Study]

Additional Selection of recently published ceramic bearing related papers of Korean Surgeons,

Kang BJ, Ha YC, Ham DW, Hwang SC, Lee YK, Koo KH (2014) Third-generation alumina-on-alumina total hip arthroplasty: 14- to 16-year follow-up study. *Oct 2*. pii: S0883-5403(14)00729-3. doi: 10.1016/j.arth.2014.09.020. [Level of Evidence IV]

Kim YH, Park JW, Kim JS (2012) Cementless metaphyseal fitting anatomic total hip arthroplasty with a ceramic-on-ceramic bearing in patients thirty years of age or younger. *J Bone Joint Surg Am* 94:1570–1575 [Level of Evidence IV]

Kim Y, Kim YH, Hwang KT, Choi IY (2014) Isolated acetabular revision with ceramic-on-ceramic bearings using a ceramic head with a metal sleeve. *J Arthroplasty online accepted manuscript* [Level of Evidence IV]

Lee YK, Ha YC, Koo KH (2014) Comparison between 28-mm and 32-mm ceramic-on-ceramic bearings in total hip replacement. *Bone Joint J* 96-B:1459–1463 [Level of Evidence I]

Park YS, Moon YW, Lee KH, Lim SJ (2014) Revision hip arthroplasty in patients with a previous total hip replacement for osteonecrosis of the femoral head. *Orthopedics Dec*; 37(12):e1058-62. doi: 10.3928/01477447-20141124-51 [Level of Evidence IV]

Shin YS, Han SB, Jung TW (2014) Comparison between preassembled and modular cups in primary cementless total hip arthroplasty: a two-year minimum follow-up study. *J Arthroplasty* 10 [Level of Evidence II]

Yoo JJ, Yoon PW, Lee YK, Koo KH, Yoon KS, Kim HJ (2013) Revision total hip arthroplasty using an alumina-on-alumina bearing surface in patients with osteolysis. *J Arthroplasty* 28:132–138 [Level of Evidence IV]

Yoon HJ, Yoo JJ, Yoon KS, Koo KH, Kim HJ (2012) Alumina-on-alumina THA performed in patients younger than 30 years: a 10-year minimum follow-up study. *Clin Orthop Relat Res* 470:3530–3536 [Level of Evidence IV]

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References

- Ha YC, Koo KH, Jeong ST, Joon Yoo J, Kim YM, Joong Kim H. Cementless alumina-on-alumina total hip arthroplasty in patients younger than 50 years: a 5-year minimum follow-up study. *J Arthroplasty* 2007;22:184–8 [Level of Evidence IV study]
- Ha YC, Kim SY, Kim HJ, Yoo JJ, Koo KH. Ceramic liner fracture after cementless alumina-on-alumina total hip arthroplasty. *Clin Orthop Relat Res* 2007;458:106–10 [Level of Evidence III study]
- Koo KH, Ha YC, Jung WH, Kim SR, Yoo JJ, Kim HJ. Isolated fracture of the ceramic head after third-generation alumina-on-alumina total hip arthroplasty. *J Bone Joint Surg Am* 2008;90:329–36 [Level of Evidence III study]

Heinz-Mittelmeier Research Award for Study on Ceramic Implant Applications in Arthroplasty

Daniel MacDonald, Research Associate of the Implant Research Center at Drexel University's School of Biomedical Engineering, Science, and Health Systems, Philadelphia, USA, was awarded the Heinz Mittelmeier Research Award 2014. The award, which is endowed with 5,000 Euros, was presented by Fritz-Uwe Niethard, MD, at the German Congress of Orthopaedics and Traumatology (DKOU) on 29. October 2014. McDonald is specialized in analyzing implant performance and material degradation in artificial hip and knee joints under clinically relevant conditions. He has investigated the role of ceramic materials in reducing the amount of corrosion observed in modular junctions in total hip arthroplasty and received the honor for his study entitled "What Factors Influence Fretting Corrosion in Total Hip Arthroplasty with Ceramic Heads?"

ABSTRACT



Figure 1: Heinz-Mittelmeier Scientific Award laureate 2014 Daniel MacDonald, Philadelphia, USA, presenting his results at DKOU 2014 in Berlin (© Starface)

Corrosion at the femoral head-stem taper interface has recently re-emerged as a clinical concern in total hip arthroplasty. In severe cases, the metal debris and metal ions released can cause adverse tissue reactions, even with MoP components. Prior studies regarding head-neck taper corrosion were based largely on cobalt-chrome alloy femoral ball heads. Less is known about taper corrosion with ceramic femoral ball heads.

Our research group recently conducted several retrieval studies to investigate the role ceramics play in taper corrosion. We asked

- whether ceramic ball heads result in less taper corrosion than CoCr ball heads;
- what device and patient factors influence taper fretting corrosion;

- whether the mechanism of taper fretting corrosion in ceramic ball heads differs from that in CoCr heads;
- what is the difference in taper angle clearance and contact location between ceramic and CoCr ball heads;
- does taper angle clearance influence the severity of fretting corrosion;
- what is the prevalence of fretting corrosion in retrieved adaptor sleeves; and
- what device and patient factors influence the sleeve fretting corrosion?

Since 2000, we have retrieved more than 3,000 THA components from revision surgery as part of a multi-institutional, IRB approved retrieval program. From these, 50 ceramic femoral head-stem pairs were matched with 50 CoCr femoral head-stem pairs based on implantation time, lateral offset, stem design, and flexural rigidity. Additionally, we analyzed 35 titanium sleeves that were used in conjunction with a ceramic femoral head. All of the components were inspected for evidence of fretting and corrosion using a visual scoring technique based on severity and extent. Taper angle and clearance were assessed using a high-resolution roundness machine.

Predictors: stem alloy and flexural rigidity

Fretting and corrosion scores were lower for the stems in the ceramic ball head cohort. We observed dark corrosion deposits outside the head-

neck taper junctions in three of 50 (6%) of the MoM taper cohort and zero of 50 (0%) of the CoM taper cohort. Stem alloy and flexural rigidity were predictors for stem corrosion damage. Taper angle clearance was not a predictor of corrosion scores. The corrosion mechanism was similar in both cohorts, although for ceramic ball heads only the metal stem was engaged in the corrosive process. For the sleeved ceramic ball heads, moderate to severe fretting-corrosion scores (score ≥ 2) were common, and were observed in 97% (34/35) of internal tapers. These scores were similar to levels observed in prior studies of tapers in CoCr ball heads. However, it is generally accepted that titanium debris is less biologically active than cobalt or chromium debris.

New focus beyond wear and tribology

Fretting-initiated crevice corrosion observed in tapers is a complex problem, and the severity depends on multiple factors. Retrieval studies that isolate variables in devices and patients can be designed to identify device and patient factors that aggravate or mitigate corrosion damage at the taper interfaces. We hypothesized that ceramic femoral ball heads, which are electrical insulators, would lead to lower stem taper corrosion than previously reported with CoCr femoral heads; indeed, this ap-

pears to be the case. Despite prior suggestions that taper angle clearance would influence the behavior of fretting corrosion, we observed no evidence in either cohort to support this claim. The results of these studies suggest that there could potentially be a new focus in ceramic component research in hip arthroplasty, beyond wear and tribology, to better understand the role of ceramics in mitigating modular taper corrosion. ■

Daniel W. McDonald, Master of Science, earned his Bachelor of Science in 2006 and his MS in 2010, both from Drexel University in biomedical engineering with a focus on biomechanics.

He currently serves as a Research Associate of the Implant Research Center at Drexel University's School of Biomedical Engineering, Science, and Health Systems where he manages an orthopedic implant retrieval program. He is responsible for the data collection, analysis, and verification of multiple large-scale studies investigating the in-vivo performance of orthopedic biomaterials, as assessed through human retrieval specimens.

His involvement in retrieval analysis has been instrumental in understanding the performance of various orthopedic device designs and materials. Specifically, McDonald has investigated the factors that can mitigate the in-vivo degradation of polymeric and metallic biomaterials used in total hip and knee arthroplasty. His expertise and analysis of retrieved orthopedic devices have been presented at international conferences and workshops.

Heinz-Mittelmeier Research Award 2015

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

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

The winner is chosen by a DGOOC jury. The 2015 research award will be presented during the congress jointly sponsored by the DGOOC, the German Association for Trauma Surgery (DGU), and the Professional Association of Orthopaedists and Trauma Surgeons (BVOU), from October 20 to 23, 2015 in Berlin.

How to participate

To participate in the competition send your work in German or English by July 31, 2015, with a corresponding declaration that it has not been distinguished with a similar award, solely via email to: info@dgooc.de.



34th Annual Meeting of the European Bone and Joint Infection Society

Estoril, Portugal
10–12 September 2015

Information and online registration:
<http://www.ebjis2015.org/>

This educational Congress will focus on:

- Economical impact of the "Septic Patient" – How to prevent costs?
- Quality Management for Septic Surgery – Is there an European Approach?
- Diagnostic tools in MSK infections
- Revision Surgery in infected joint replacement

The Scientific Program will include overviews, state of the art lectures, and controversial debates. Outstanding faculty members will present both pro and con positions while further challenging and exploring the optimal treatment for patients, with emphasis on the appropriate use of new and emerging treatment options. The previous congress, held in Utrecht, The Netherlands, established a new record with more than 600 participants.

36th SICOT Orthopaedic World Congress

Société Internationale de Chirurgie Orthopédique et de Traumatologie
Guangzhou, China
17–19 September 2015

Information and online registration:
<http://www.sicot.org/guangzhou>

This will be first time that the SICOT Orthopaedic World Congress will be held in mainland China. The congress will lay down the blueprints for important issues of today's orthopaedic development and address our role in re-evaluating current controversies in orthopaedics, as congress president **Guixing Qiu** says. He expects in-depth discussions covering all orthopaedic subspecialties, enhancing international academic exchange. Numerous instructional courses will be held for young surgeons and trainees from China and all over the world.

International Society for Technology in Arthroplasty

ISTA Congress 2015
Vienna, Austria
30 September to 3 October 2015

Information and online registration:
http://www.istaonline.org/?page_id=3139

ISTA's annual meeting has become the hub where comprehensive analysis of the past, present and future of joint replacement technology and related science is presented. It is where the most extensive and engaging scientific discussions occur between orthopaedic surgeons, scientists and engineers from academia and industry. Atypical of other meetings, ample time is given for such discussions in both podium papers and e-posters. Interaction of this kind facilitates good education and inspires technological innovation. Theme of this year's congress is "Innovation Meets Classic".

Vreden's Readings

9th Annual Conference
Saint Petersburg, Russia
8–10 October 2015

Information and online registration:
<http://vredenreadings.org/eng/program.php>

The conference is organized by R.R. Vreden Russian Scientific Research Institute of Traumatology and Orthopedics. This year's scientific program focusses on the current status of the arthro-

plasty in Russia and its particular challenges, such as

- surgical activity: quality versus quantity
- modern "premium" implants versus budget implants
- arthroplasty registers: new aspects
- economic aspects and ways to optimize the management in the joint arthroplasty.

Various aspects of arthroplasty of hip, Knee, shoulder joint, and ankle will be discussed as well as arthroscopic techniques and bone oncology. Solutions for reactions to the implant and current concepts in the periprosthetic infection are further subjects of the conference.



Initiative for Quality and Safety – Endoprothetik 2015

Congress of the Arbeitsgemeinschaft Endoprothetik GmbH
Frankfurt/Main, Germany
05–06 November 2015

Information and online registration:
<http://www.ae-gmbh.com/ae-veranstaltungen/ae-kongresse/eventeinzelheiten/82/-/kongress-qualitaets-und-sicherheitsinitiative-endoprothetik-2015-frankfurt-main-05-06-11-2015>



The subject of safety and quality in endoprosthesis is still being discussed publicly. The focus is on implant failure, material intolerances, and taper and wear issues.

The conference was conceived by physicians, representatives of the medical technology industry, engineers, and basic researchers to present and debate the strengths, weaknesses and boundaries of endoprosthesis. Case presentations will be discussed, as will appropriate communication with the patient in case of adverse events, or the legally correct way to deal with incidents and failure analyses.

The limits of biomechanical tests and the influence of combination implants that have not been tested together will be examined. The economization of medicine in general, and specifically in the field of endoprosthesis, is to be considered.

Last but not least, the informative value of joint registers and patient-oriented quality standards will be addressed.

International combined Meeting

British Hip Society and Società Italiana Dell' Anca
Milan, Italy
26–27 November 2015

Information and online registration:
www.sidabhs-jointhip.com

The British Hip Society and the Società Italiana dell'Anca will hold their first combined meeting. It will be the very first time that two distinguished national speciality societies have integrated to organize a joint congress that will combine their traditions, current practices, and future clinical and research trajectories.

By sharing experiences in both primary and revision hip arthroplasty, discussing different techniques (bony fixation, tribology, and more), examining the results of hip preserving surgery and arthroscopy, or simply considering everything about the hip, it will be a unique opportunity to improve surgical skills and understand current state of the art clinical practice.

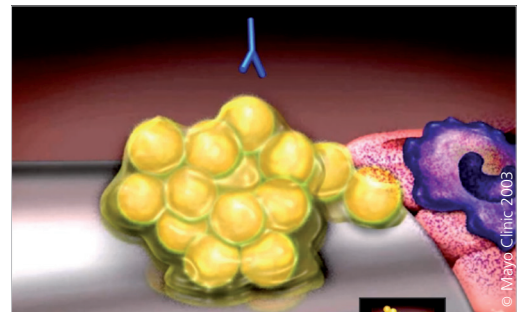
Pro-Implant Foundation – Educational Plattform

Information:
<https://www.pro-implant-foundation.org/en/education/publications>

Short video on biofilms:
<https://www.pro-implant-foundation.org/en/education/general-information>



The web page of the Pro-Implant Foundation offers useful publications, guidelines, and poster/presentations on bone and joint infections. By watching the video entitled "Formation of Biofilm on Implant Surface" you can learn more about the role of biofilms in prosthetic joint infection. The foundation is a non-profit organization of the German civil right and dedicated to supporting research, education, global networking, and care of patients with bone, joint or implant infection. The aim of the foundation is to improve the quality of patient lives.



Clinical Management

Thomas P, Stea S

Metal Implant Allergy and Immuno-Allergological Compatibility Aspects of Ceramic Materials

32 pages, 15,5 x 23,5 cm

First Edition 2015

Springer-Verlag Berlin Heidelberg 2015

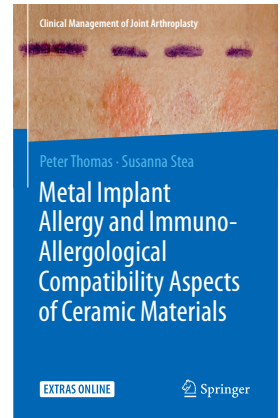
Print (Softcover): ISBN 978-3-662-47439-6

E-book: ISBN 978-3-662-47440-2

Date of Publication: June 2015

This pocket guide presents background information and ways to proceed in patients when an implant allergy is suspected as diagnostic criteria of hypersensitivity to metal implants are inconclusive. To rule out other diagnoses, an orthopedic examination has to take place.

For the first time, a clinical algorithm has been developed for procedures in clinical practice for when an implant allergy is suspected. The algorithm is presented as a laminated loose insert. The flow chart contains additional information on the histopathological particle algorithm, according to Krenn.



Clinical Management

Walter W et al.

Practical Guide for Handling Noises in Hard-on-Hard Bearings

22 pages, 15,5 x 23,5 cm

First Edition 2015

Springer-Verlag Berlin Heidelberg 2015

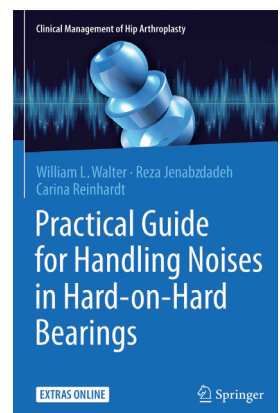
Print (Softcover): ISBN 978-3-662-46026-9

E-book: ISBN 978-3-662-46027-6

Date of Publication: May 2015

This book provides recommendations and a clinical algorithm for the assessment of noise in total hip arthroplasties with hard-on-hard bearings. It covers all aspects from diagnostics to therapy and adequate management, as well as monitoring, possible prevention, and patient information.

- Current thinking and scientific knowledge regarding noises including squeaking in hard-on-hard bearings
- Clinical algorithm on how to treat a patient with noisy THR
- Case reports.



BioloX® Inside App



Download

Get the BioloX® App for your Smartphone or Tablet.

The BioloX® Inside app (33MB) is available for iOS (5.1.1 or higher) devices like the iPad and iPhone free of charge in the Apple App Store.

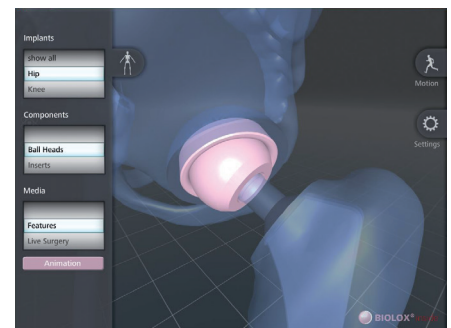


The BioloX® Inside app (23MB) is also available for Android tablets und smartphones (2.2 or higher).



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What must be taken into consideration when handling and implanting ceramic components? Which wear couple can be used in the rare event of a ceramic fracture? You will find answers to these questions and more information within the new BioloX® Inside app which lets you access information on BioloX® implants quickly from anywhere.



Based on live surgeries, 3-D animations, and literature reviews, BioloX® Inside compiles the current knowledge about the use of ceramics in orthopedics. Originally developed with orthopedic surgeons for orthopedic surgeons, practitioners of all levels and specialties, the app is a condensed reference and educational tool.

With the BioloX® motion capture mode, track the ceramic joint replacement in three dimensions and identify the joint angle and position in different motion patterns.

By being a comprehensive reference, this is your must-have app for quick review on the wards, or at home.

BioloX® Inside is organized into sections by joint. Explore the different sections each containing:

- Clinical and material information
- Live surgical videos
- 3-D animation
- Features
- Handling
- Literature