

# CeraNews

## Surgical Quality Improvement

Professor Carsten Perka is Assistant Clinical Director of the Center for Musculoskeletal Surgery at the Charité University Hospital in Berlin and Director of the Center's Division for Hip and Knee Arthroplasty. Joint replacement has been the focus of his clinical, scientific and educational work for many years. Perka suggests that achieving further improvements in the quality of joint replacement will depend on the ability to keep the entire surgical process in focus, ensure solid theoretical and practical training, and maintain a precise understanding of the properties of the implants themselves.

**Do surgeons have the time to sit down and carefully prepare for joint replacement surgery?** Not always. What I see – and not only in Germany – is the continually growing significance of the economic factor. For practitioners, this translates into a perceived lack of time, both during the planning stages and in the operating room itself. In many hospitals, more surgical procedures are performed with fewer staff members. Then there are other factors such as higher patient expectations and expanding hospital regulations and their attendant bureaucratic obligations. Many of my colleagues don't have the time for additional training and careful preparation, especially in light of the fact that modern implants permit a higher degree of individualized treatment and therefore require even more planning time.

**How much training does a surgeon need before attempting surgery with a new implant system?** First, you need a solid basic training that includes a thorough knowledge of anatomy and a lot of practice on cadavers. Then you need a good workshop that is devoted to the implant you plan to use – because



Carsten Perka, MD, Berlin

you won't really understand the technical handling of the implant until you've had an opportunity to make a couple of dry runs. And third, you need a good theoretical understanding of the implant's unique features.

**Does each model require the use of a special surgical technique?** Good function, the absence of pain and long survival can only be achieved when you take account of the model's unique features during surgery.

**What are some of the most important differences between implants?** In the case of the femur, there is the anchoring of the stem, the point of entry when preparing the bone cavity, the force exerted when inserting the implant and the special features of the instruments. Do you plan to mill, rasp or only compress? Then there are the small, but often crucial details. For instance, when rasping step by step, there is a tendency to insert a smaller cementless stem too deeply into the femur. While the next size can't be inserted as deeply in such a situation, the proximal bone contact can be significantly reduced.

**What are the crucial differences in cups?** Again, it starts with the type of anchoring. Is the cup to be cemented, screwed or press-fit? There are different geometries with different bone locking characteristics. There are differences when it comes to stability, depending on the type of screw thread used, the shape of the cup or the surface. You have to know to what extent to ream the acetabular cavity for the press-fit cup. Then, depending on the initial fixation achieved, you need to decide whether a 1mm or 2mm underreaming is required or whether additional fixation screws are needed. In the case of minimally invasive insertion, you have to think ahead, and have a clear picture of the differences between instrumentation derived indications and the patient's anatomy.

### Complication Rates for Ceramic Inserts

3



### Demand for Ceramics on the Rise

6



### Revision Upgrades

9



**What role does surgical quality play in the big picture?** When you ask colleagues whether they would choose the best implant or the best surgeon if they had to, almost all of them opt for the best surgeon. Standard hip replacements show survival rates of around 97% at ten years. I don't think conquering the remaining 3% is so much a matter of introducing new implants. Real progress is far more likely to be made in the area of instruments and surgical techniques. Then it will be a matter of carefully implementing these improvements.

**Is progress being made?** In general, yes, but not necessarily in everyday practice. While the rates of implant-related revisions are declining, the rates of revision relating to improper primary implantation are on the rise in relative terms and, based on my daily experience, also in absolute terms. I don't have hard and fast data here, but I see a clear trend from my experience as a practitioner. Recurring dislocation and elevated dislocation-related wear rates are increasingly cited as reasons for revision. Putting it in a nutshell, you could say that the advantages of ever better implants are being neutralized by a lack of precision and insufficient attention to specific factors during surgery.

**Why is that?** Arthroplasty in Germany – and to my knowledge in many other countries as well – is a lucrative field. That is why the number of surgeons who perform joint replacement surgery has risen dramatically. But not all surgeons who perform joint replacement are qualified in terms of specific training and experience. Then there is the not-so-infrequent lack of adequate preoperative planning with respect to component selection and positioning.

**What can be done to improve the situation?** We need a better understanding of the entire process in arthroplasty. We need to pay greater attention to the patients, their pre- and postoperative living circumstances, their expectations and wishes. But, like I said, there is a lot of potential for improvement in the quality of the surgical process itself. The key here is the right theoretical and practical training. This is where we need to do much more. And we need to involve the whole surgical team. Experienced operating room nurses and interns have their own opinions about insertion factors, angle and implant size. They notice departures from norms and can help to avoid most mistakes. Well-trained team members know a lot about implant models and what combinations are matches or mismatches.

**What would an adequate training program for the surgeon look like?** With reference to the German system, the training should go beyond the basic training associated with a specialist in orthopedic surgery. I'm in favor of establishing specific qualification standards, similar to those applied to cardiovascular surgery. Why shouldn't there be an additional program for certifying "joint replacement surgeons"? The patient numbers provide justification enough.

**What role is played by the surgical manuals issued by the implant manufacturers?** The manuals are often very good and precise, in a scientific sense. But they also tend to be extremely extensive, explaining every step in the surgical procedure from the very outset, as if they had been written for beginners. Experienced and overworked surgeons tend to do a bit of skimming. And here it may come to pass that an experienced surgeon overlooks the details that are critical because they represent a variation.

**What can the manufacturers do here to improve?** I would like to see very clear and succinct summaries – one or two pages – of the really important points. All of the other details can be added as reference. We also need clear and comprehensive specifications as to which devices and materials are fully compatible.

**And what do you demand from surgeons?** Surgeons should have a precise understanding of the implants they use. They should plan carefully and follow the specific surgical instructions exactly – even if these have not yet been worked out as clearly and succinctly as I would prefer. Surgical quality is the factor that we can and must improve.



**Heinrich Wecker,**  
Business Manager for  
Central Europe at  
CeramTec's Medical  
Products Division

## Dear Reader,

The wing movement of a butterfly in Brazil can trigger a tornado in the Caribbean. Computer models used by meteorologists clearly demonstrate that even the smallest of causes can bring about monumental effects. Every doctor knows that this proposition also applies to medicine.

Even routine surgical procedures such as primary hip replacement involve a complex interplay of innumerable factors. The implants themselves seem almost simple by comparison. Stem, femoral head, cup, and liner form a clear system. It is precisely here, however, that the small details can make a big difference: a bone particle that gets caught between the femoral head and the taper; an insert that does not entirely snap in place; an instrument is dropped and leaves a nick in the metal taper that escapes the attention of the surgeon. All of these can have serious effects.

In an effort to avoid such risks from the very beginning, implant manufacturers invest a lot of time and resources in the creation of detailed surgical manuals for their products. These manuals describe the standard procedure and point out how mistakes can be avoided, detected on time and corrected.

Many surgeons may find the task of working their way carefully through these extensive manuals somewhat time consuming, especially in light of the time constraints they face in their clinical routines. But careful attention to the manufacturer's recommendations and to proper surgical technique are important means of quality management. This is particularly the case when it comes to new and modular implants. Do the surgical manuals meet the needs of practitioners? Is there room for improvement? In the present issue, we discuss these and other questions with various experts.

We hope you find it of interest.

*Yours truly,*  
*Heinrich Wecker*

## Complication Rates for Ceramic Inserts

Fracture rates in ceramic components following total hip arthroplasty are minimal when compared to other complications for this type of surgery. The introduction of the new material BIOLOX<sup>®</sup>delta has served the purpose of further reducing in vivo fracture rates in all available femoral head designs. This goal has been achieved. The fracture rate for ball heads made of BIOLOX<sup>®</sup>delta is nearly a factor of 10 lower than that for ball heads made of BIOLOX<sup>®</sup>forte.<sup>1</sup>

### Clinical Experience and Options

BIOLOX<sup>®</sup>delta inserts have smaller minimum wall thicknesses, and were introduced to enable the use of larger head diameters together with cups exhibiting small external diameters. The use of larger heads increases postoperative range of motion and significantly reduces the risk of impingement and dislocation. The literature indicates dislocation rates of 1% to 5% following primary hip replacement surgery. Higher rates of dislocation are also reported in larger exterior cup diameters.<sup>2</sup>

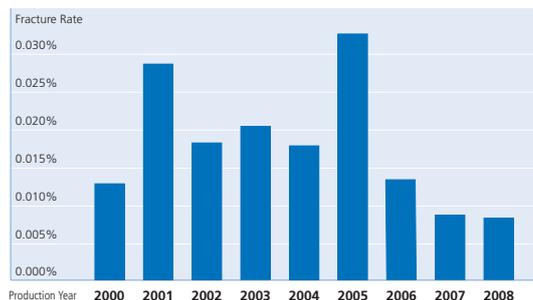
Active patients, in particular, stand to benefit considerably from hip replacement offering a larger range of motion. The advantages of large ceramic ball heads can now also be extended to patients in Asia. Larger ball heads offer increases in both range of motion and stability. This goal has now been achieved. Clinical studies confirm that, at 0.88%, the risk of impingement, subluxation and dislocation associated with ceramic ball heads whose diameters measure 32mm and 36mm is significantly lower than the risk (4.63%) associated with ball heads whose diameters measure 28mm (4.63 %).<sup>4</sup>

Today, around 42% of all BIOLOX<sup>®</sup> insert orders are placed for inserts with a large interior diameter of 36mm (i.e. for articulation with a 36mm ball head). Assuming proper intraoperative handling, the avoidance of impingement conditions and a sufficient range of motion, the ceramic bearing achieves very low wear rates. This represents an essential aspect of the long-term performance of hip replacements, especially in the case of active patients.

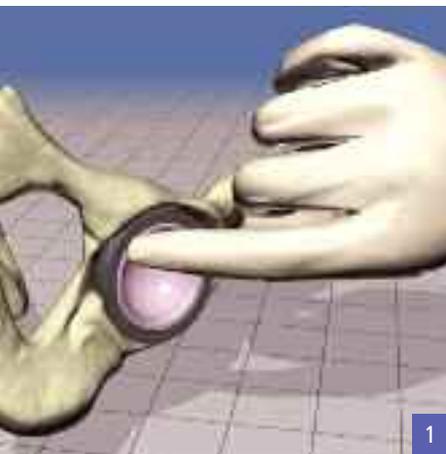
### Comparable Failure Rates

CeramTec delivered around 920,000 inserts between January 2000 and June 2008. The failure rates for standard inserts made of BIOLOX<sup>®</sup>forte and BIOLOX<sup>®</sup>delta are comparable. In the period from January 2000 to June 2008, around 530,000 standard inserts (460,000 BIOLOX<sup>®</sup>forte and 70,000 BIOLOX<sup>®</sup>delta) were delivered.

**In vivo fracture rates for BIOLOX<sup>®</sup>forte standard inserts according to production year (reported between January 2000 and June 2008)**



The complication rate for BIOLOX<sup>®</sup>forte inserts fractured in vivo in the same period was 0.021%. The complication rate for BIOLOX<sup>®</sup>delta inserts fractured in vivo was 0.02% (or 20 in every 100,000).



The surgeon checks the positioning of the insert by running a finger along the rim of the cup. Any necessary corrections can be made. The rim of the metal and ceramic components must be flush. (1) X-ray of a tilted ceramic insert in a 32mm bearing. (2) Tilted ceramic insert that ultimately led to implant failure. (3)

In contrast to the evidence showing improved results for BIOLOX®*delta* femoral heads, no significant complication rate improvements have been shown for BIOLOX®*delta* inserts. In keeping with the trend towards larger ball-head diameters described above, the wall thickness of the metal cups has also been reduced. These may tend to deform when used as press-fit components. This is why the right surgical technique and the greatest level of care and precision during surgery are so crucial. The insertion of the ceramic inserts requires a careful implementation of the surgical procedure. This is described comprehensively in the relevant surgical manual. Any tilting of the insert in the shell can cause the insert to fail. This is clearly supported by the relevant failure analyses (Fig. 2 and Fig. 3). Surgeons can check the position of the insert by running their fingers along the rim of the cup in order to make sure that the insert is fully seated in the shell (Fig. 1).

### Conclusion for Clinical Practice and Outlook

Our goal is to work closely with surgeons and device manufacturers to considerably reduce the failure rates associated with BIOLOX®*delta* inserts.

Complications can be reduced via a better understanding of the unique properties of ceramic materials, the conditions faced by the component designers and the appropriate handling of the ceramic inserts. Clinical experience shows that handling-related complications (e.g. chip fractures) that occur when inserting and positioning an insert can be effectively avoided via appropriate training measures.<sup>3</sup>

Practical measures for the reduction of handling-related complications include:

- The use of special insertion instruments to help avoid insert tilting
- Adherence to manufacturer specifications relating to suitable press-fit options, i.e. with the aim of avoiding excessive press-fit that can lead to deformation in the metal cup
- Use of the training DVD (made available upon request by the implant manufacturer or CeramTec AG) created for surgeons and surgical staff
- Surgeon and surgical staff training in the handling of ceramic components (CeramTec experts are available to provide the relevant training programs.)

### Surgical Live Training DVD



[www.biolo.com/biolo-ceramics-dvd](http://www.biolo.com/biolo-ceramics-dvd)

### Your Contact Partners at CeramTec:

#### Southern Europe

Fabrizio Macchi  
fabrizio.macchi@alice.it  
0039 / 335 / 7 48 82 72

#### France, Benelux

Bernard Masson  
b.masson@wanadoo.fr  
0033 / 6 / 87 60 99 47

#### UK, Ireland

Stephen French  
s.french@ceramtec.co.uk  
0044 / 7774 / 18 63 54

#### Central and Eastern Europe

Sylvia Usbeck  
s.usbeck@ceramtec.de  
0049 / 172 / 9 74 33 71

Petra Burkhardt  
p.burkhardt@ceramtec.de  
0049 / 177 / 8 6747 17

#### North America

Ricardo Heros  
rheros@aol.com  
001 / 901 / 5 50 44 47

#### Australia, New Zealand

Roger Sparks  
r.sparks@xtra.co.nz  
0064 / 27 / 4 95 65 60

#### Brazil

Daniel Stainer  
dstainer@terra.com.br  
0055 / 48 / 99 78 49 42

#### China

Wen Chen  
w.chen@ceramtec.com.cn  
0086 / 0 / 139 01 18 42 44

### References

<sup>1</sup> CeraNews 2/2008: 2

<sup>2</sup> Kelley SS, Lachiewicz PF, Hickman JN, Paterno SM (1998): Relationship of femoral head and acetabular size to the prevalence of dislocation. Clin Orthop 355: 163–170

<sup>3</sup> Beaver RJ, McCormick C, Kop A (2002): Fractures in misaligned ceramic acetabular liners. In: Garino JP, Willmann G (Hrsg.). Bioceramics in Joint Arthroplasty. Thieme Verlag Stuttgart, New York: 65–71

<sup>4</sup> Zagra L, Giacometti Ceroni R, Corbella M (2004): THA Ceramic-Ceramic Coupling: The Evaluation of the Dislocation Rate with Bigger Heads. In: Lazennec JY, Dietrich M (Hrsg.). Bioceramics in Joint Arthroplasty. Steinkopff Verlag, Darmstadt: 163–169

## New Results with Ceramics

**More and more studies have shown that ceramic-on-ceramic bearings offer excellent clinical results. Their special wear resistance, the avoidance of metal ions and polyethylene particles make these bearings a promising solution with long-term potential, especially for active patients. Excellent clinical results have also been achieved with larger head diameters. This is corroborated by a number of recently published studies.**

### Ceramic-on-ceramic in Active Patients

Femoral head necrosis in younger patients is a relatively common diagnosis in South Korea. In a prospective study, Baek and Kim<sup>1</sup> examined 60 patients (71 hips) they had treated an average of 7.1 years earlier with ceramic-on-ceramic bearings when the patients were an average age of 39.1 years. With an HHS of 97, the clinical results recorded at a follow-up of at least 6 years were very good. There were no cases of loosening, osteolysis, dislocation, ceramic fracture or revision. The authors conclude that cementless THR with ceramic-on-ceramic bearings represents a promising procedure for young, active patients. The 74 patients (85 hips), with an average age of 44 at the time of surgery, examined by Tözün et al.<sup>2</sup> in a retrospective study showed an HHS of 98 after 5 years. Here, too, there were no cases of osteolysis, ceramic fracture or detectable wear, leading the authors to conclude that ceramic-on-ceramic bearings offer encouraging results for young and active patients.

An investigation conducted by Hutten et al.<sup>3</sup> shows similar results. After an average follow-up period of 8 years, the authors report a 100% survival rate for cup and stem in the examined patients (average age: 50 years) with aseptic loosening as an endpoint. With only one early dislocation and one late dislocation, the authors conclude that the 32mm femoral heads help to ensure high stability.

In a prospective study, Cruz-Pardos et al.<sup>4</sup> compared the clinical and radiological results of 29 THAs in patients with juvenile idiopathic coxarthrosis (Group 1) and 135 THAs in patients with primary coxarthrosis (Group 2) who had all been treated with ceramic-on-ceramic bearings. Both groups showed good clinical results, with no ceramic fractures and no articulation noise. This study shows that excellent clinical results can be achieved in patients with juvenile idiopathic coxarthrosis using ceramic-on-ceramic bearings.

Garcia Rey et al.<sup>5</sup> report similar results after conducting a prospective multicenter study involving one group of patients under 40 years and one group above 40 years (n = 63/274): good medium-term clinical and radiological results and no noise development for cementless THR with ceramic-on-ceramic bearings.

After conducting a 5-year follow-up study involving 397 patients (average age: 64 years) who were all treated with ceramic-on-ceramic bearings, O’Gorman et al.<sup>6</sup> report a component survival rate of 99.7% with the endpoint of aseptic loosening. In addition, they report no ceramic fractures and 8 cases of minor articulation noise that was not perceived as annoying and gave no cause for revision.

### Large Head Diameter against Dislocation

Zagra and Giacometti Ceroni<sup>7</sup> have implanted more than 600 ceramic-on-ceramic bearings with a head diameter of 36mm. After conducting a 2-year

follow-up investigation, they report no ceramic fractures and no noise development. In their prospective study, they compared the dislocation rate of a 36mm group (Group 1) and a 28mm group (Group 2). Group 1 showed significantly better results, with 1.08% dislocation overall as opposed to 4.48% for Group 2 and 0.27% recurring dislocations that required revision as opposed to 1.34% for Group 2.

### Cup Positioning and Polyethylene Debris

After conducting a retrospective study, Wan et al.<sup>8</sup> report that the cup’s angle inclination had a significant impact on the rate of wear. Using a multiple regression analysis, they identified this as the single most important factor. Inclination angles of greater than 45° lead to elevated wear. In contrast, the usual variances in the determination of the center of rotation showed no measureable effects on wear. As has been shown in earlier studies, ceramic-polyethylene bearings showed less wear than metal-polyethylene bearings.

Needham et al.<sup>9</sup> report on a case involving the complete wearing through of a polyethylene insert and cup. The 49-year-old patient showed atraumatic dislocation 16 years after primary surgery. The reasons the authors cite for the penetration of the ball head through the polyethylene and metal components include young patient age, high activity level, thin polyethylene liner, backside wear, component positioning, polyethylene sterilization with gamma irradiation in air, and lack of appropriate follow-up.

### References

- 1 Baek S-H, Kim S-Y, Cementless Total Hip Arthroplasty with Alumina Bearings in Patients, Younger Than Fifty with Femoral Head Osteonecrosis, J Bone Joint Surg Am. 2008;90:1314-1320
- 2 Tözün I, Erdem M, Dikici F, Alumina ceramic-on-ceramic total hip arthroplasty: 5-6 year follow-up study, Poster EFORT 2008
- 3 Hutten D, Lestrat V, Loriaut P, The alumina-alumina bearing for total hip arthroplasty in patients aged less than 60 years: results with eight years mean follow-up, Poster EFORT 2008
- 4 Cruz Pardos A, Garcia Rey E, Garcia Cimbrello E, Ortega Chamarro J, Alumina-on-alumina THR in patients with juvenile idiopathic arthritis: a five-year follow-up prospective study, Poster EFORT 2008
- 5 Garcia Rey E, Cruz Pardos A, Garcia Cimbrello E, Ortega Chamarro J, Alumina-on-alumina total hip arthroplasty in patients younger than 40 years. A prospective multicenter study, Poster EFORT 2008
- 6 O’Gorman A, Waters T, Walter W, Zicat B, Walter W, ABGII Ceramic-on-Ceramic Total Hip Arthroplasty – 5 Year Minimum Followup, Poster EFORT 2008
- 7 Zagra L, Giacometti Ceroni R, Ceramic-on-ceramic coupling with 36 mm heads, Poster EFORT 2008
- 8 Zhinian Wan, Myriam Boutary, Lawrence D. Dorr, The Influence of Acetabular Component Position on Wear in Total Hip Arthroplasty, Journal of Arthroplasty Vol. 23 / 1
- 9 Needham, J, Burns T, and Gerlinger T, Catastrophic Failure of Ceramic-Polyethylene Bearing Total Hip Arthroplasty, Journal of Arthroplasty Vol. 23 No. 4/2008

## Demand for Ceramics on the Rise

### CeramTec Expands its Production Facilities for Ceramic Components

The demand for ceramic components used in arthroplasty has increased dramatically. The production of high quality ball heads and cup liners is based on complex technology. CeramTec has made substantial investments in new production facilities to meet the growing demand. Karl Billau, Managing Director of the Medical Products Division at CeramTec, explains the situation.



**Karl Billau, Managing Director of the Medical Products Division at CeramTec**

#### What are the growth figures?

The latest figures we have are from the first half years of 2007 and 2008. When we compare the figures for these periods, we see a 23% growth in production. Given that we gear our production to incoming orders, this corresponds almost exactly to the actual growth in demand. We expect to manufacture approximately 650,000 components in the year 2008.

#### Where is the growth coming from?

From around the world. We are seeing steady growth on a dynamic market in North America. We have double-digit growth in Europe. And our growth in Asia is even more dramatic. We are also very well-positioned in newly developing markets in a number of up-and-coming countries in which arthroplasty has not traditionally played a role. Altogether, we have shown growth that is considerably above the market average.

#### A growth rate of almost 25% in only one year – can you manage that from the production side?

Yes, but we have reached the limits of our previous capacity. Our nine production lines – six for ball heads and three for cup liners – are already running at capacity. All the signs indicate that demand will continue to rise sharply.

#### What is CeramTec's response to the growth situation?

We have already responded by commissioning two new production lines, one for ball heads and one for cup liners. An additional production line for ball heads and an additional facility for hiping – the hot isostatic pressing of components – are already in the making. It takes around eight to ten months to plan, set up and begin operating such production lines. Actual production on the new lines will start at the beginning of 2009. Another example of the long-term planning required is the fact that our new production facility in Marktredwitz, which we have operated for around three years, has still not been approved by the FDA for our production to serve customers in the United States.

#### What materials are to be processed on the new lines – BIOLOX<sup>®</sup>forte or BIOLOX<sup>®</sup>delta?

The facilities have been designed to manufacture both materials. But the trend is clearly going in the direction of BIOLOX<sup>®</sup>delta. This material already accounts for around 50 percent of the components we deliver.



Automated production line for ball heads in Marktredwitz, Germany



Hot isostatic press for the compression of ceramic components (photo and cross section)

## Material and Surgical Technique

Bearings in Focus at the EFORT Congress 2008

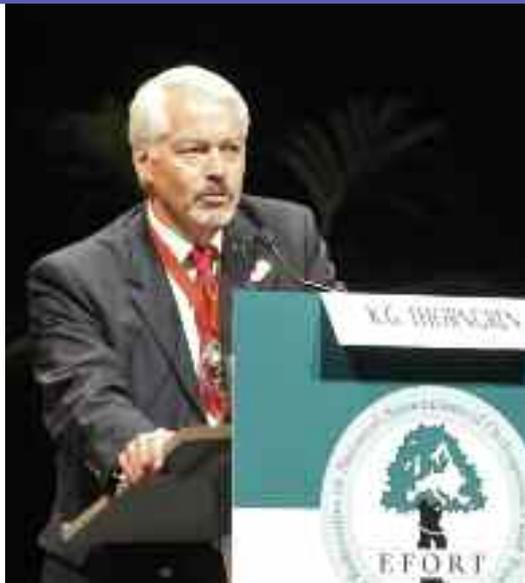
**Wear couples in hip arthroplasty were again among the main topics at this year's EFORT Congress in Nice. Surgical techniques, tribology, and clinical experience with various materials were the subject of lively discussion.**

### Results with metal-on-metal

**Hernant Pandit** (Oxford, UK) reported on pseudotumors associated with MoM hip resurfacing. 20 MoM resurfaced hips in 17 female patients showed a solid or cystic soft tissue mass associated with various symptoms such as nerve palsy, spontaneous dislocation, persisting groin pain, a lump under the scar or in the groin. 12 of the 20 cases were revised to a conventional THA. Histological examinations showed areas of extensive necrosis and dense lymphocytic infiltration with symptoms similar to aseptic lymphocytic vasculitis-associated lesions (ALVAL) described by **Willert**. **Pandit** pointed to this "catastrophic complication of hip resurfacing" which leads to destruction of bone and muscles. He estimated that about 1% of patients develop a pseudotumor in the first 5 years after implantation of MoM hip resurfacing. It can not be detected by normal X-ray and is best imaged with ultrasound. **Pandit** is concerned that the incidence of these pseudotumors will increase.

**Simon Jameson** (Glasgow, UK) reviewed and compared three types of MoM articulations to examine the incidence of ALVAL. He found 5 cases of histologically proven ALVAL in the absence of infection in 961 patients. All cases were in female patients. Activity levels decreased and pain increased at 6–12 months after surgery. A painful straight leg raise was a characteristic finding which may result from the significant effusion found around the hip at each revision. All patients have been revised to CoC bearings with improvements in outcome. **Jameson** implied that the incidence of ALVAL may be underdiagnosed and higher than was thought. He suggested that all patients with unexplained persisting groin pain should have inflammatory marker tests and a hip aspiration performed.

**Xiao Hu** (Leatherhead, UK) reported on the friction behavior of MoM hip joints, comparing different clearances (50, 100 and 200 micron diametral clearance) in a friction simulator. According to the literature, a small clearance with high viscosity should be



EFORT President Karl-Göran Thorngren, MD, giving the inaugural address

ideal for MoM bearings but this study shows that in this case the lubricant film could break and increase the friction. The problem of ideal MoM clearance is not yet solved.

### Cup angles and metal ion levels

Previous studies have shown an association between high cup angles and increased metal ion levels, but a link to clinical outcome has not yet been established. Therefore **Simon Jameson** analyzed 250 hip resurfacings and demonstrated that high cup inclination angles are associated with increased pain and elevated metal ion levels. Cups implanted at lower than 48° inclination had a better clinical outcome and less metal ion release. Males had a significantly higher post-op HHS (97.1) compared to females (91.0). 2.1% of the male and 8.7% of the female patients reported pain. Women seem to be less tolerant to higher cup angles than male patients. Female patients with over 48° inclination had a HHS of 88.0 and significantly elevated serum and whole blood chromium and cobalt levels. 3 female patients with an inclination angle over 50° developed ALVAL. **Jameson** recommended an inclination angle that does not exceed 48°.

### THA bearings: "Which one is the best?"

**Christian Delaunay** (Longjumeau, France) presented a literature study on the benefits and risks for all available bearings in hip arthroplasty, comparing in-vitro and in-vivo volumetric wear, radiology and the toxicity of wear debris. MoM particles are the most toxic and numerous. They have potentially harmful effects on immunity, reproduction, kidney function, carcinogenesis. The effects of crosslinked polyethylene particles are still not known. Looking at 10-year survival, there are significant differences. High carbide MoM showed better results than low carbide MoM. But there was concern about acetabular fixation and radiolucent lines also with the high carbide bearings. The major complication of MoM resurfacing is the risk of neck fracture. **Amstutz** reports 0.75% at 3.5 years. The Australian register shows 1.5% over 5 years.

The figures on articulation noise show an extremely wide span without specifying the type of noise. **Delaunay** recommends inexpensive hard-on-soft wear couples for patients with low activity and life expectancy under 15 years. For younger and more active patients the surgeon should consider the in-vitro tribologic performance of the wear couple and look at the known consequences of wear debris toxicity. When using hard-on-hard bearings the potential benefits must be balanced against additional risks (i. e. hypersensitivity with MoM or ceramic fracture) and the costs.

[www.efort.org](http://www.efort.org)

## New Coupling in THA

### DePuy's Ceramic-on-Metal Bearing Approved for Clinical Use

DePuy Orthopaedics has introduced a new ceramic-on-metal wear couple to the market. It was tribology expert John Fisher of Leeds University who initiated the first tests of this coupling and led the way in its development. He talked to CeraNews about his research and early clinical results. He stresses very strongly that as of now only this specific coupling of ceramic and metal components is approved for clinical use.

#### Why did you start this development?

We need larger size wear couples for younger, more active patients. With larger size ball heads we get higher wear rates of the polyethylene liners, even if they are made of crosslinked poly. Hard-on-hard bearings provide alternatives for the surgeon but there are design limitations for ceramic-on-ceramic and concerns about the risk of hypersensitivity for metal-on-metal. So we started to look for a bearing offering a wide range of design alternatives without producing high levels of metal ions.

#### Why did you develop the idea to combine ceramic and metal?

Engineers normally use two different materials for wear couples in order to reduce wear. I wanted to know if we could use our proven hard materials in a new coupling and achieve lower wear rates. In our experiments with a ceramic ball head and a metallic cup liner we found that the wear of the liner was fifty times lower than that of a metal-on-metal bearing. We also found that ceramic-on-metal had a much lower frictional torque than metal-on-metal, obviously because of the difference in hardness of the materials.

#### Mismatched Metal-on-Ceramic Bearing

Mismatched material combination involving a metal ball head (CoCr) and an alumina oxide ceramic insert (BIOLOX<sup>®</sup>forte): a 65-year-old female patient is hospitalized 6 months after primary surgery (right-side THR). Although the patient is not experiencing pain, she reports persisting articulation noise. The revision shows a heavily worn metal ball head, a high degree of metal debris and severe metallosis.



Mismatched metal-on-ceramic bearing, 6 months in vivo (left) and following explantation (right)

#### References

Steens W, von Foerster G, Kutzer A. Severe cobalt poisoning with loss of sight after ceramic-metal pairing in a hip – a case report. *Acta Orthopaedica* 2006; 77 (5): 830–832. Hinrichs F, Griss P. Retrieved Wear Couple Ceramic-On-Metal: A Case Study. In: Toni A, Willmann G. (Hrsg). *Bioceramics in Joint Arthroplasty*. Proceedings 6th International BIOLOX<sup>®</sup> Symposium, Thieme Verlag Stuttgart, New York, 2001: 99–102



John Fisher, PhD, is Director of the Institute of Medical and Biological Engineering of Leeds University in England.

#### What about corrosive wear?

The metal-on-metal bearing produces a significant amount of corrosive wear which is the mechanism producing the particles and the metal ions. The ceramic head inhibits the corrosive wear of the metal component acting as an insulator.

#### Could a surgeon combine any ceramic ball head with any metal insert of the same diameter?

Absolutely not! It is very important to emphasize that we have used a BIOLOX<sup>®</sup>delta ball head with an Ultamet<sup>®</sup> cobalt-chrome cup insert. The two components have been very precisely matched which is a prerequisite for any wear couple to produce good results. The pre-clinical tests and the clinical studies were carried out with this coupling and it is the only ceramic-metal coupling approved for clinical use. Any other ceramic-metal combination would be a mismatch and a risk for the patient as well as for the surgeon.

#### What are the clinical results?

The first clinical studies in South Africa showed encouraging early results. Of course, long-term follow-up studies have to be carried out before we can come to final conclusions. The metal ion levels in the patients' blood has been generally low. There were a few cases with the cups not positioned ideally. In these cases the levels were a little higher but still much lower than they would have been with a metal-on-metal bearing. This does emphasize nevertheless that also with new technologies it is extremely important that the surgeon implants the components in the right position.

#### How about using a metal ball head with a ceramic liner?

We have tried that combination, but the results were by far not that good. We know of at least one case of mismatching where a metal ball head was coupled with a ceramic insert during a hip revision. Two years later, the ball head was greatly destroyed and the patient suffered from severe chronic cobalt intoxication. I want to stress it once more: only approved wear couples matched by the suppliers may be implanted!

## Revision Upgrades

### Revision with Ceramic Ball Head and In Situ Stem

It is often the case in hip revision that only the cup needs to be replaced. The stem remains firmly anchored. With BIOLOX® OPTION, it is now possible to leave the stem in situ and attach a ceramic ball head. This allows the surgeon to create a bearing that is more wear-resistant than the one originally implanted.

#### Material

The BIOLOX® OPTION system consists of a ceramic ball head and a titanium sleeve. The titanium sleeve compensates for minor damage to the taper and helps to ensure an even load distribution on the inside of the ball head. The ball head and titanium sleeve are then fixed in place with the proven taper connection.

The ball head is made of the high performance BIOLOX® *delta*. This material exhibits exceptionally high fracture resistance and fracture toughness. Its microstructure gives it two mechanisms of reinforcement that prevent the propagation of cracks.

#### Range of Application

Damage to the stem's taper is classified using three grades:

##### Grade 1

No visible damage, unchanged taper form

##### Grade 2

Visible scratches up to a depth of 0.25mm, unchanged taper form

##### Grade 3

Taper form visibly compromised by abrasion or wear (bent, flattened, crushed)

BIOLOX® OPTION can be used for damage grades 1 and 2. This is because the titanium sleeve compensates for the type of damage involved. BIOLOX® OPTION cannot be used for grade 3 damage. The following rule of thumb can be used: it must be possible to place the ball head and the titanium sleeve on the stem taper without meeting resistance.

#### BIOLOX® OPTION for Primary Hip Replacement

BIOLOX® OPTION also extends the range of alternatives available for primary hip replacement. Use of the XL size allows to correct the neck length and create a larger offset. Here, the system's neckless design avoids restrictions in range of motion. Surgeons can also use a BIOLOX® OPTION system if unintended damage to the stem taper occurs during primary surgery.



**Use of a BIOLOX® OPTION system in case of grade 2 taper damage: ball head with titanium sleeve before attachment**

Source: Y. Catonné, J.-Y. Lazennec, A. Nogier, E. Fourniols, B. Masson, Revision strategy after metal on metal THR failure: Conversion to ceramic on ceramic, in: Francesco Benazzo, Francesco Falez, Martin Dietrich, Bioceramics and Alternative Bearings in Joint Arthroplasty, 11<sup>th</sup> BIOLOX® Symposium Proceedings, Steinkopff Verlag Darmstadt



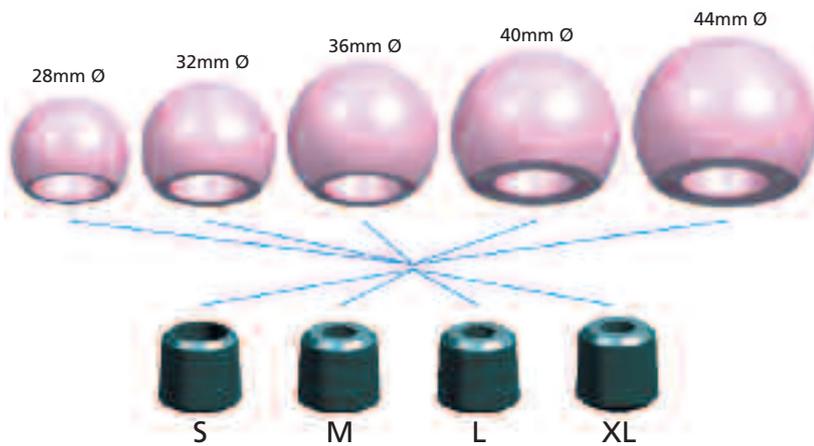
**Grade 3 taper damage: BIOLOX® OPTION cannot be used.** Photo: CeramTec AG

**Material Combinations** BIOLOX® OPTION

Head-Ø	28mm	32mm	36mm	40mm	44mm
BIOLOX® delta					
BIOLOX® forte					
PE / XPE					

BIOLOX® forte BIOLOX® delta Polyethylene / XPE

Numerous possible combinations: the ball heads in the BIOLOX®OPTION system can be combined from a tribological perspective with all of the ceramic cup liners in the BIOLOX® family and with inserts made of conventional and highly crosslinked polyethylene.



The BIOLOX®OPTION system

Further information about the BIOLOX®OPTION system is available at [www.biolox.com](http://www.biolox.com). We would also be happy to send you our BIOLOX®OPTION product brochure. Please use the fax form in the present issue to place your order, or send an e-mail message to: [medical\\_products@ceramtec.de](mailto:medical_products@ceramtec.de).

**References**

Y. Catonne, J.-Y. Lazennec, A. Nogier, E. Fourniols and B. Masson, Revision strategy after metal on metal THR failure: Conversion to ceramic on ceramic, in: Benazzo F, Falez F, Dietrich M (eds), Bioceramics and Alternative Bearings in Joint Arthroplasty, 11<sup>th</sup> BIOLOX® Symposium Proceedings, Steinkopff Verlag Darmstadt: S. 141–144, 2006  
 T. Güttler, Experience with BIOLOX®OPTION revision heads, in: Benazzo F, Falez F, Dietrich M (eds), Bioceramics and Alternative Bearings in Joint Arthroplasty, 11<sup>th</sup> BIOLOX® Symposium Proceedings, Steinkopff Verlag Darmstadt: S. 149–154, 2006  
 K. Knahr and M. Pospischill, Strategies for Head and Inlay Exchange in Revision Hip Arthroplasty, in: Chang JD, Billau K (eds), Bioceramics and Alternative Bearings in Joint Arthroplasty, 12<sup>th</sup> BIOLOX® Symposium Proceedings, Steinkopff Verlag Darmstadt: S. 275–280  
 G. Pignatti, C. Stagni, D. Dallari, V. Boicchio, A. Raimondi and A. Giunti, Modular neck and ceramic on ceramic coupling in revision total hip arthroplasty, in: Benazzo F, Falez F, Dietrich M (eds), Bioceramics and Alternative Bearings in Joint Arthroplasty, 11<sup>th</sup> BIOLOX® Symposium Proceedings, Steinkopff Verlag Darmstadt: S. 145–148, 2006

**Chronic Undersupply**

Low Arthroplasty Figures Even in Industrialized Countries

Arthroplasty has become one of the most important segments in the med-tech sector. Its continued steady growth seems virtually inevitable. However, most countries also show increased competition and the need to cut costs in this area. In his healthcare research, Dr. Karsten Dreinhöfer works on patient outcome, quality, and the macroeconomic efficiency of orthopaedic procedures. CeraNews asked him what implants have the best prospects and how the market will develop in various segments.

What are the most important trends in the global field of arthroplasty?

Even if it scarcely seems possible, we simply don't have many sources of reliable data on this subject. All the same, a number of trends are evident. We are seeing significant increases in hip and knee replacement surgery around the world. In Germany and Western Europe, we have double-digit growth rates, 10–15 percent in the case of hips and 20–25 percent in case of knees.<sup>5</sup> The development in the United States is very similar. In other regions and countries, we can even speak of skyrocketing implant figures. Revision surgery is also showing disproportionately high growth.

Do you expect the curve to become even steeper in light of demographic developments?

While the demographic factor has also played an important role, it alone cannot explain the growth in primary and revision arthroplasty. Another factor appears to me to be far more important: even Western Europe and North America are apparently affected by a clear gap in the provision of treatment.

Don't the figures suggest the very opposite?

No. First, there are hardly any population-based investigations – from anywhere around the world – into how many people are actually confronted by degrees of pain and loss of function that warrant treatment with arthroplasty. Second, we still have no clear and broadly accepted criteria for the relevant medical indication. The usual criteria – pain, significant changes revealed in X-rays, limited mobility



**Karsten Dreinhöfer, MD, is Managing Consultant of the Ulm University Orthopaedic Clinic and Chairman of the EFORT Health Service Research Committee.**

– are usually matters of subjective evaluation. Population-based investigations carried out in Canada<sup>2</sup> and England<sup>4</sup> that incorporate objective scoring systems have shown clear gaps in the provision of treatment. In Canada, only ten percent of those patients who meet the criteria for treatment involving arthroplasty actually receive an artificial joint. It seems fairly safe to assume that the need for treatment, even in countries showing high absolute figures, is very high – probably two to three times higher than the number of actual implants.

### Why is that?

For one, many potential patients appear even today to be afraid of the types of surgery involved.<sup>3,6</sup> In the framework of the EUROHIP study<sup>1,7</sup> we have also found a considerable discrepancy between general practitioners and specialists when it comes to evaluating the need for surgery. Many patients who experience serious osteoarthritis-related pain and discomfort are treated for years with painkillers even as their mobility continues to diminish and they begin to withdraw socially. This leads to very high medium and long-term costs as a result of the need to treat symptoms and the early – and unnecessary – need for nursing care. While the implantation of a high quality and clinically proven artificial joint, including follow-up controls, entails considerable one-time costs, it nonetheless represents the more cost-effective approach in most cases in the medium and long term, particularly because 90 percent of the treated patients will have received a solution for 20 years. Unfortunately, we don't yet have the figures we need to demonstrate this in detail. We will therefore have to expand our research in the area of healthcare provision to arrive at a reliable assessment of current realities and to further improve the quality of healthcare provision.

### What can hospitals do?

They can increase their efforts to communicate with and better inform their patients in the relevant respects. Many patients, family members and primary physicians continue to promote the view that pain and discomfort related to osteoarthritis is a “natural part of getting older” and should simply be accepted. If we succeed at convincing physicians and patients via effective means of raising public awareness and by providing excellent quality, then it is certain that many patients will receive better care.

### What can the industry do?

The standard artificial joints used in the last 10 to 15 years have a very good track record, cemented and cementless. The manufacturers tend to try to win over greater market shares and up their margins by introducing innovations for which there is no more than a limited need. At the moment, I see better prospects for achieving these goals in expanding treatment rates by eliminating the gaps in the provision of treatment. The industry should work together closely in this connection with the hospitals.

### What trends do you see in the case of wear couples?

Surgeons are very sensitized to the problems that can be caused by metal and polyethylene debris. They therefore tend to view ceramic materials as a very positive alternative.

### References

- <sup>1</sup> Dreinhöfer KE, Dieppe P, Stürmer T, Gröber-Gratz D, Flören M, Günther KP, Puhl W, Brenner H (2006) Indications for total hip replacement: comparison of assessments of orthopaedic surgeons and referring physicians. *Ann Rheum Dis* 65:1346–1350
- <sup>2</sup> Hawker GA, Wright JG, Coyte PC, Williams JJ, Harvey B, Glazier R, Wilkins A, Badley EM (2001) Determining the need for hip and knee arthroplasty: the role of clinical severity and patients' preferences. *Med Care* 39:206–216
- <sup>3</sup> Hudak PL, Clark JP, Hawker GA, Coyte PC, Mahomed NN, Kreder HJ, Wright JG (2002) “You're perfect for the procedure! Why don't you want it?” Elderly arthritis patients' unwillingness to consider total joint arthroplasty surgery: a qualitative study. *Med Decis Making* 22: 272–278
- <sup>4</sup> Juni P, Dieppe P, Donovan J, Peters T, Eachus J, Pearson N, Greenwood R, Frankel S (2003) Population requirement for primary knee replacement surgery: a cross-sectional study. *Rheumatology (Oxford)* 42: 516–521
- <sup>5</sup> Merx H, Dreinhöfer KE, Günther KP (2007) Sozialmedizinische Bedeutung der Arthrose in Deutschland. [Socioeconomic relevance of osteoarthritis in Germany]. *Z Orthop Unfall* 145: 421–429
- <sup>6</sup> Sanders C, Donovan JL, Dieppe PA (2004) Unmet need for joint replacement: a qualitative investigation of barriers to treatment among individuals with severe pain and disability of the hip and knee. *Rheumatology (Oxford)* 43: 353–357
- <sup>7</sup> Stürmer T, Dreinhöfer K, Gröber-Gratz D, Brenner H, Dieppe P, Puhl W, Günther KP (2005) Differences in the views of orthopaedic surgeons and referring practitioners on the determinants of outcome after total hip replacement. *J Bone Joint Surg Br* 87: 1416–1419

Justin P. Cobb, MD, President of the 13<sup>th</sup> BIOLOX®-Symposium



## Welcome to Edinburgh

The 13<sup>th</sup> BIOLOX®-Symposium will take place from 4<sup>th</sup> to 5<sup>th</sup> September 2009 in the Scottish capital of Edinburgh. The selection of the congress site is a homage to the great tradition of hip arthroplasty in the United Kingdom. The Symposium will again focus on the subject of wear couples in hip arthroplasty, especially in light of the fact that aseptic loosening remains the most common form of loosening in replacement hips. The latest clinical results and experiences with alternative bearings will be presented at the Symposium, with the subject of ceramic components naturally playing an important role. Justin Cobb has agreed to assume the role of the Symposium's president. Among the most prominent orthopaedic surgeons in the United Kingdom, he is a Consultant Orthopaedic Surgeon at Charing Cross Hospital and a Full Professor for Orthopaedics at the Imperial College in London.

All experts in joint replacement and tribology are welcomed to attend the event in Edinburgh. Abstracts may be submitted until 15 January 2009.

### Deadlines

15 January 2009:	submission of abstracts
15 February 2009:	acceptance of abstracts
15 May 2009:	submission of final manuscripts for publication in the symposium's proceedings

More information about the Symposium, speakers and participant registration is available at [www.biolox-symposium.com](http://www.biolox-symposium.com)

## Cooperation with AE

In the spring of 2008, CeramTec entered into a cooperative agreement with the Arbeitsgemeinschaft Endoprothetik (AE). The AE is a scientific association of orthopaedic and traumatology surgeons in Germany, Austria and Switzerland. The aim of the association is to promote the development of arthroplasty and to establish a specialized training program for practitioners in this field. Ever since its founding in the year 1996, AE has been the only scientific association clearly focusing on arthroplasty. AE has developed its own proven methodology offering a structured training program for young surgeons as well as a forum for the intensive exchange of ideas among experienced experts.

[www.ae-germany.com](http://www.ae-germany.com)

■ **November 23–27**  
93° S.I.O.T.  
Rome, Italy

■ **November 28**  
Masterclass Hüftendoprothetik  
Hildesheim, Germany

■ **December 4–5**  
Journées Lyonnaises de la Hanche  
Lyon, France

■ **December 10–13**  
Current Concepts Winter  
Orlando, Florida/USA

■ **January 31**  
Symposium de l'Institut  
Kerboull 2009  
Paris, France

■ **February 12–14**  
ENDO Kongress  
Berlin, Germany

■ **February 23–24**  
ORS  
Las Vegas, USA

■ **February 25–28**  
76<sup>th</sup> Annual Meeting American Academy  
of Orthopaedic Surgeons (AAOS)  
Las Vegas, USA

■ **March 13–14**  
Endoprothetik Forum  
Münster, Germany

■ **March 19–21**  
ChinaMed  
Beijing, China

■ **March 20–21**  
16<sup>th</sup> Cologne Traumatology Symposium  
Cologne, Germany

■ **March 20–21**  
13<sup>th</sup> AMOU Congress  
Halle, Germany

■ **March 23–27**  
Journées d'Orthopédie de Fort de France  
Fort de France, France

## Imprint

### Published by:

CeramTec AG  
Medical Products Division  
Fabrikstr. 23–29  
D-73207 Plochingen, Germany  
Phone: +49 / 7153 / 6 11-828  
Fax: +49 / 7153 / 6 11 838  
[medical\\_products@ceramtec.de](mailto:medical_products@ceramtec.de)  
[www.biolox.com](http://www.biolox.com)

### Your contact:

Paul Silberer  
Phone: +49 / 71 53 / 611 522  
[p.silberer@ceramtec.de](mailto:p.silberer@ceramtec.de)

### Text and layout:

LoopKomm Infomarketing  
Terlaner Str. 8  
D-79111 Freiburg i. Brsg.  
Phone: +49 / 7634 / 55 19 46  
Fax: +49 / 7634 / 55 19 47  
[mail@loopkomm.de](mailto:mail@loopkomm.de)  
[www.loopkomm.de](http://www.loopkomm.de)

### Concept and coordination:

Sylvia Usbeck  
Heinrich Wecker

**CeramTec**  
THE CERAMIC EXPERTS