1/2008

The Magazine of CeramTec AG, Medical Products Division

CeraNews

Ceramics in Orthopaedics

Avoiding Articulation Noise

Michael M. Morlock, Ph. D., is the Director of the Institute for Biomechanics at the Technical University of Hamburg-Harburg. Arthroplasty is one of the main focus points of his work. CeraNews discussed the issue of shell and cup deformation as well as articulation noise in hip arthroplasty.

How much primary stability does a press-fit cup need?
The rule of thumb used to be that one should be able to lift the patient from the table using the inserter attached to the implanted cup. But to actually reach this level of primary stability could force the surgeon to excessively deform the cup – which would be counterproductive in the case of hard-on-hard bearings.

Is this a reason for using hard-on-soft bearings?
The trend is shifting toward larger heads because they offer superior function. In order to avoid the increased wear associated with large heads, one should opt for hard-on-hard bearings. Lubrication on hard-on-hard bearings with large diameters is superior when compared to hard-on-soft bearings, which helps to ensure very low wear rates.

What then is the problem?
The use of bigger heads forces surgeons to use thinner cups because it is also essential to conserve as much of the bone as possible. Press-fitting a cup in the hip always causes a degree of cup deformation. While it is primarily the bone that is deformed when the component is hammered in, the metal, too, does not remain entirely unchanged. Furthermore, given that the hip is not a homogeneous piece of material, the deformation tends to be uneven, particularly in the area of the posts that give the cup a slightly ellipsoid form. The important thing here is to keep this deformation as small as possible so as not to adversely affect the lubrication clearance. We believe that the range for optimal lubrication is between 50 and 100 micrometers.

Is this tolerance sufficient for all standard cases?
A small degree of cup deformation has been taken account of in the component design, and will not limit function. But here the emphasis is on "small"!

How can a surgeon stay on the safe side?
The surgical instructions issued by the manufacturers usually specify a press fit of one millimeter. The bone for a 59mm cup is therefore prepared using a 58mm reamer. It turns out, however, that it is difficult to achieve such precision by hand, and the hole winds up with a larger diameter of roughly 58.5 millimeters. If the quality of the bone is good, the remaining half-a-millimeter is easily sufficient for primary stability. Things are different when the bone is osteoporotic or when the bone cavity itself is not circular.

And what if the bone cavity is too small?
Then the cup can't be hammered in entirely. It will get stuck on the equator and the pole will have no contact to the bone. If the congruence between the bone cavity and the implant were perfect, the contact would be 100%, but there would be no press fit. Here, too, it is necessary to achieve the right balance – that is, ensure as much contact as possible without sacrificing a large degree of primary stability. The right surgical technique and the exercise of great care when placing the implant are crucial. We know from our work with retrievals that the origin of most failures can be found in the implantation procedure. Today, failures caused by product or material defects are very rare exceptions.

What can you tell us about hip noise?
It is important to draw a clear distinction between squeaking and clicking. Clicking arises as a result of subluxation – when the ball head is pressed back into the cup. This may be a preliminary stage of squeaking, for instance, when

the head slides over an edge with each load cycle and causes what we refer to as stripe wear. The latest research suggests stripe wear leads over time to increased friction that can ultimately cause a squeaking sound. An especially steep cup position can also lead to stripe wear without subluxation.

Where exactly does the squeaking sound come from?
The squeaking sound is no more than friction-induced vibration. Increased friction means that a part of the energy generated by each movement in the system is converted into friction energy. The system is exposed to greater stimulation and can vibrate as a result. A door hinge that does not swing freely, and is thus exposed to excess energy, will also vibrate. If the vibration reaches a frequency between 20 and 20,000 Hertz, and if the amplitude is strong enough, we hear a squeaking sound. The same can happen in any bearing.

Even in hard-on-soft bearings?
Hard-on-soft bearings may squeak if the shaft rubs on the cup. In the case of hard-on-hard bearings, the energy transfer in the articulation can be large enough to produce noise.

How can that be prevented?
The size of the lubrication gap, the sphericity and the roughness of the bearing partner are decisive factors. That is why it is important to prevent excessive cup deformation at the moment of implanting the device. Such deformation can reduce the size of the contact surface in the wear couple. The smaller this contact surface is, the higher the focused transfer of energy and the risk of noise development. Correctly implanted bearings – those in which good lubricating and low-friction properties have been established thanks to a proper clearance between head and cup – will not squeak because they cannot squeak.

What do the latest data say?
While there are as yet no conclusive data out there, the subject has gained greater attention. All of two articles appeared in PubMed on the subject in 2006. In 2007, the number of articles climbed to six. All of the relevant studies have confirmed that squeaking is associated with friction and improperly positioned implants. It appears that individual aspects of implant design can increase the likelihood of squeaking.

What aspects?
When the engineers who construct automobiles notice that something squeaks, they make the relevant components stiffer and heavier. There is a clear inference here: it is easier to generate vibrations in a thin cup. In contrast, there are thick, heavy cup models that are very resistant to deformation even when exposed to extreme force. It takes a lot more energy to generate vibrations in such models. The chance that they will begin to squeak is naturally much lower.

So it's the risk of squeaking against the extent of bone resection?
If you look only at the material side, yes. And one has to consider deformation.

Prof. Michael Morlock: proper cup positioning and soft-tissue tension prevent squeaking.

Are there regional differences in the development of noise in hip joints?
The occurrence of squeaking seems to vary in different countries. In Germany and Korea, for instance, squeaking is more or less a subject of anecdotal reports, placing it in the one-per-thousand range. In contrast, the literature indicates an incidence of three to seven percent in the United States.

What is your recommendation?
Proper cup positioning and a properly adjusted soft-tissue tension. If you get these factors right, then you can safely assume that the joint will not squeak.

Karl Billau, President of the Medical Products Division at CeramTec AG

Dear Readers,

With the present issue, CeraNews enters the third year of its publication. In addition to the original German, English and French editions, the magazine now also appears in Italian and Chinese. With a total circulation of around 8,000 issues, CeraNews reaches the world's most important orthopaedic surgeons.

The proven concept in publishing this magazine has remained unchanged: we are committed to maintaining a venue for the presentation of scientific reports and expert opinions as well as the discussion of open questions. In upholding this commitment, we also do not shy away from controversial issues. The BIOLOX® Symposium in Seoul this past September demonstrated once again that openness is in demand. Only sound scientific and frank discussion of the controversial issues associated with the use of various materials will serve to generate trust and spur advances in the field of arthroplasty.

The variety of material combinations used in the area of hip arthroplasty has increased in recent years. With each new development, questions arise as to their relevant necessity and the real advantages they offer to patients. We are also very interested in soliciting and publishing scientific articles on all types of new developments in this area. It is essential, for instance, to consider the tribological properties of new material combinations. In light of the fact that offering wear solutions for the younger more active patients in need of joint arthoplasty is our core business, we are in a position to make important contributions in this area. The present issue of CeraNews offers you concise information, clearly expressed opinions and perhaps a few answers to questions that have been unanswered up until now. I wish you an enjoyable and rewarding read!

Yours sincerely,
Karl Billau

More Possibilities

The BIOLOX® product portfolio at a glance

The new material, BIOLOX®*delta*, widens the spectrum of ceramic product designs. This material makes additional sizes for ceramic components in total hip arthroplasty possible. Furthermore, BIOLOX®OPTION allows the use of a ceramic ball head for revisions involving a fixed-anchored stem which remains in situ.

Ball heads
BIOLOX®*forte* and BIOLOX®*delta*

Ball head Diameter	S	M	L	XL
28mm				BIOLOX® OPTION
32mm				
36mm				
40mm				
44mm				

Material combinations
BIOLOX®OPTION

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

Standard cup inserts
BIOLOX®*forte* and BIOLOX®*delta*

Ø Ball head / Cup Ø (int.)	28mm	32mm	36mm	40mm
35mm				
37mm				
39mm				
41mm				
44mm				
48mm				
52mm				

Material combinations
BIOLOX®*forte* and BIOLOX®*delta*

Ball head: BIOLOX®*forte* BIOLOX®*delta*	BIOLOX®*delta*	BIOLOX®*forte*	PE / XPE	PE / XPE
Insert: BIOLOX®*forte* BIOLOX®*delta*	BIOLOX®*forte*	BIOLOX®*forte*	BIOLOX®OPTION	BIOLOX®OPTION

BIOLOX®*forte* BIOLOX®*delta* Polyethylene (PE) / crosslinked polyethylene (XPE)

SOFCOT

Société Française de Chirurgie Orthopédique et Traumatologique, Paris, November 5–8, 2007

The Consensus Conference held during the congress dealt with the question "Which prosthesis for over 75-year-olds?". The panel of experts classified three types of patients, according to their respective levels of activity: 1. high level of activity, 2. medium level of activity, and 3. no activity (handicap). The recommendation for type 1 and 2 was to use ceramic/PE or a bipolar implant if there is a risk of dislocation.

Patrick Boyer (Paris) presented his findings with ceramic-on-ceramic bearings in THA for patients under 60 years. The clinical study with a follow-up of 8 years showed very good results for the 60 young and active patients included. With 99% survival, no osteolysis or loosening occurred.

The bipolar prosthesis received a great amount of interest on this congress. In the hip session on Monday, five out of eight presentations dealt with this implant. This type of device is used in 33% of all total hips in the French market and the figures are constantly growing.

The SOFCOT has developed a national registry for hip arthroplasty in collaboration with the MEM Research Centre for Orthopaedic Surgery (Berne, Switzerland). The preliminary phase was started on January 1st, 2006, with the participation of 20 clinics. The registry has been open since September 2006 to all clinics in France. In Paris, the data from 2332 total hip procedures, performed between January 1st, 2006, and June 30th, 2007, were presented. The preliminary results show that in France more than 30% of the wear couples are ceramic-on-ceramic.

COA

Chinese Orthopaedic Association, Zhengzhou, November 8–11, 2007

More than 5,000 participants, among which 200 delegates from abroad, came together at the Second COA Convention in Zhengzhou (Henan province), chaired by Professor Guixing Qiu (Beijing). The scientific program included 824 lectures by 212 renowned guest speakers; 929 posters were put on display and 20 satellite symposia were held. In total, 110 companies participated in the orthopaedic industry exhibition, thus making this convention the largest orthopaedic venue in China.

Fuxing Pei (Chengdu), Chairman of the COA Arthroplasty Committee

At the COA Convention, 667 scientific papers were focused on the subject of joint replacement. According to Fuxing Pei (Chengdu), Chairman of the COA Arthroplasty Committee, four major trends are currently emerging: 1. Alternative bearing surfaces are increasingly being used in China (Me/Me, Ce/Ce and Ce/PE); 2. There is an increased focus on medium- and long-term clinical results; 3. There is also an increased focus on improving surgical techniques for revisions; 4. The use of minimally-invasive techniques and navigation fosters the development of increasingly precise surgical techniques.

With a population of 1.3 billion and a medical market growing by more than 15 percent annually, China is proving to be one of the largest potential markets in the world, with approximately 13,000 orthopaedic surgeons active in this specialty. In order to meet the growing demand and to facilitate and increase the exchange of technical expertise among them, the COA Convention will be held on an annual basis from now on. In 2008, the city of Suzhou will be hosting the event.

S.I.O.T.

Societa Italiana di ortopedia e traumatologia, Bologna, November 11–15, 2007

The medieval towers of Bologna – two famous landmarks of the city

After 17 years, the 92nd congress of the S.I.O.T. returned to the home of one of the oldest schools of medicine in the West, the city of Bologna. With 3,500 surgeons attending, the congress was a great success for the presidents, Sandro Giannini (Bologna) and Aldo Toni (Bologna). The scientific program focussed on the topics: "Articular Reconstructive Surgery" and "Results in Arthroplasty". The congress featured a great number of symposia, a large poster exhibition and many instruction courses.

Fabrizio Macchi, the CeramTec expert present in Bologna, registered a great deal of interest in the latest products, i. e. the ceramic revision system BIOLOX® OPTION and the new 40mm BIOLOX® *delta* bearing. There was also great demand for the "BIOLOX® Ceramics in Hip Arthroplasty" DVD Version 0.1, offering comprehensive information on the subject. Many of the participants have already ordered the final version that will be ready in the second quarter of 2008. The Italian Hip Registry Project, presented by Marina Torre (Rome) and Susanna Stea (Bologna) showed a significant increase in the use of ceramic-on-ceramic wear couples in Italy as well as a decrease of metal-on-metal implants.

BIOLOX® Award France

The correct positioning of the acetabular cup is crucial for the function of a total hip arthroplasty. This was stressed once again in a study analyzing the impact of the inclination angle and its effect on lateral dislocation and edge loading in ceramic-on-ceramic wear couples. The author, Elhadi Sariali (Hôpital La Pitié Salpêtrière, Paris, center), received the French BIOLOX® Award for this work at the recent SOFCOT meeting in Paris from CeramTec representatives Dominique Metz (left) and Bernard Masson.

Heinz Mittelmeier Award

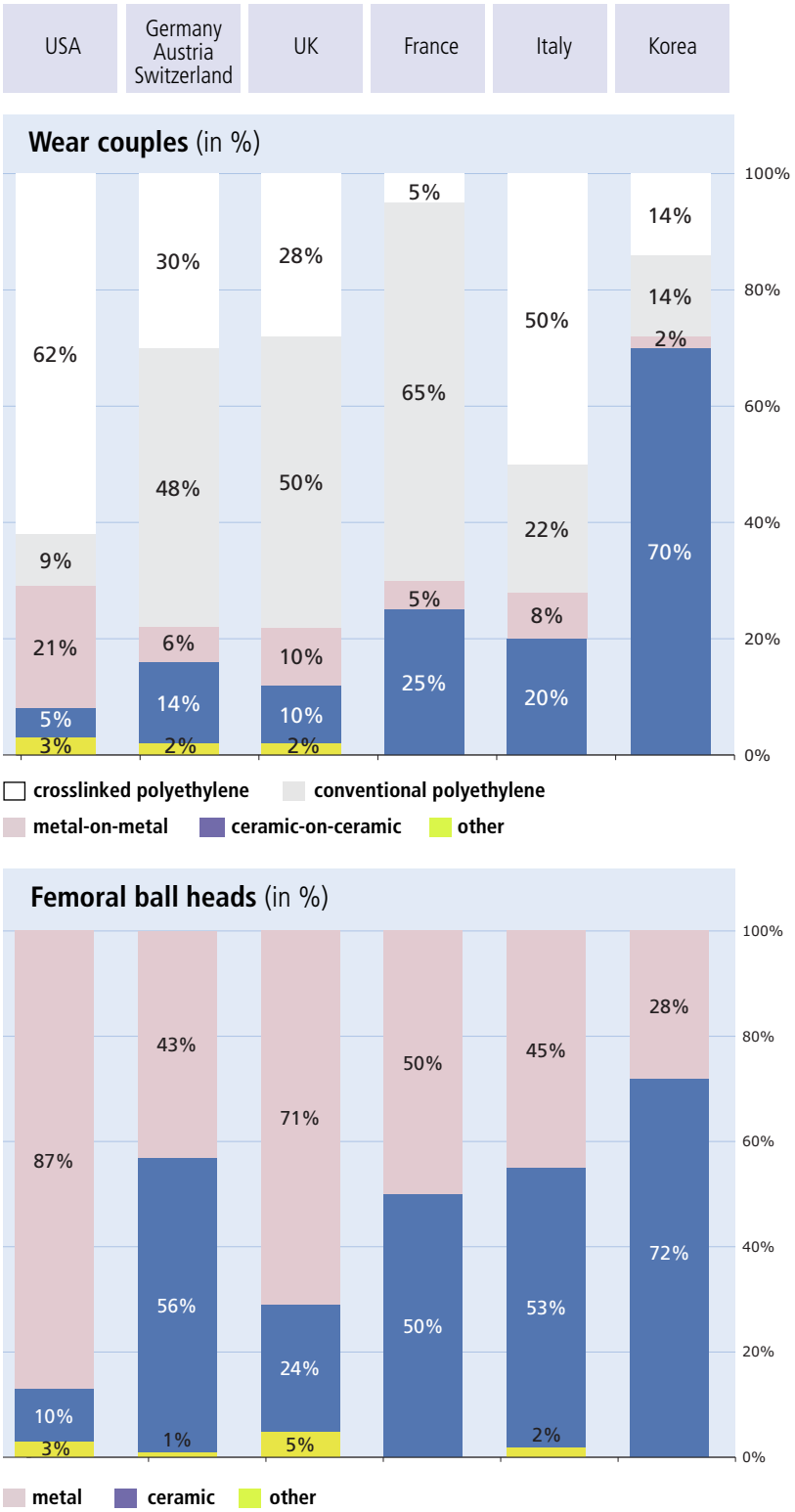
Nicole Wollmerstedt of the Orthopaedic Clinic at the University of Würzburg (Germany) received the Heinz Mittelmeier Research Award 2007 of the German Association for Orthopaedics and Orthopaedic Surgery (DGOOC). The € 5,000 award is funded by CeramTec. It was conferred to Dr. Wolmerstedt for her work on real life activity levels of patients with arthroplasty. Her study group found out that these patients have much higher activity levels than previously thought. In other words, her work showed that wear couples are subjected to a lot more load cycles than assumed in common simulation models. The picture shows Heinz Mittelmeier and Nicole Wollmerstedt at the ceremony in Berlin.

1. Wollmerstedt N: The daily activity Questionnaire (DAQ) – A novel questionnaire to assess patient activity after total hip arthroplasty. (The study is currently waiting for publication. The full text can be ordered at CeramTec.)

2. Wollmerstedt N, Nöth U, Mahlmeister F, Lotze A, Finn A, Eulert J, Hendrich C.: Aktivitätsmessung von Patienten mit Hüfttotalendoprothesen. Orthopäde 2006, 35:1237–1245

Wear Couples around the Globe

Surgeons of different regions tend to use very different wear couples in hip arthroplasty. Our chart gives an overview of tribological preferences in the USA, Korea and Europe. The data available is not detailed but it serves to illustrate general trends in these countries.



Sources: Avicenne, BVMed, EUCOMed, Global Markets Direct, CeramTec

The Best of Both Worlds

BIOLOX®*delta* satisfies seemingly incompatible requirements

The development of arthroplasty is a unique success story. Millions of people who once faced suffering and disability have recovered their capacity for pain-free mobility. And their numbers are growing. Nonetheless, a number of unanswered questions remain with respect to arthroplastic bearings. In this area, BIOLOX®*delta* offers novel answers. This nanocomposite combines hardness and wear resistance with tremendous stability and toughness. Its combined properties make this material fracture resistant and very reliable.

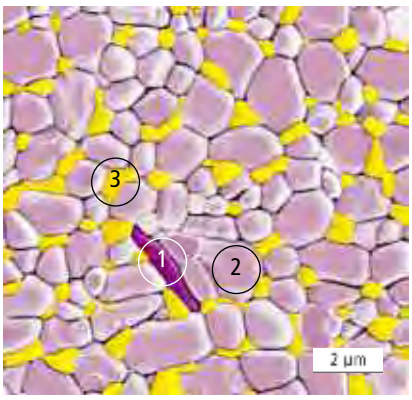
Avoiding the Need for Revision

According to the Swedish Register, osteolysis and aseptic loosening are responsible for more than 75 percent of all revisions. Even the new highly-crosslinked polyethylene (XPE) is subject to wear and its long-term in vivo performance is still unknown. The unavoidable leaching of metal ions that is associated with metal-on-metal bearings harbors risks that are difficult to anticipate. Given the current trend towards the use of larger head diameters, the significance of these unanswered performance questions has grown.

Decades of clinical experience have proven the suitability of components made of high-performance ceramic materials for use in hip arthroplasty. Thanks to their extremely smooth and scratch-resistant surfaces, ceramic ball heads perform far better than ball heads made of metal when it comes to ensuring significantly decreased rates of wear in cup liners made of polyethylene. Their hydrophilic properties also help to ensure a significantly higher degree of synovial fluid lubrication. Furthermore, as ceramic materials harbor no risk of ion leaching, they remain biologically neutral within the body. As a result of its relative brittleness, however, some physicians have had reservations about using ceramics, despite the fact that materials such as BIOLOX®*forte* have been clinically proven to have a very high degree of fracture resistance.

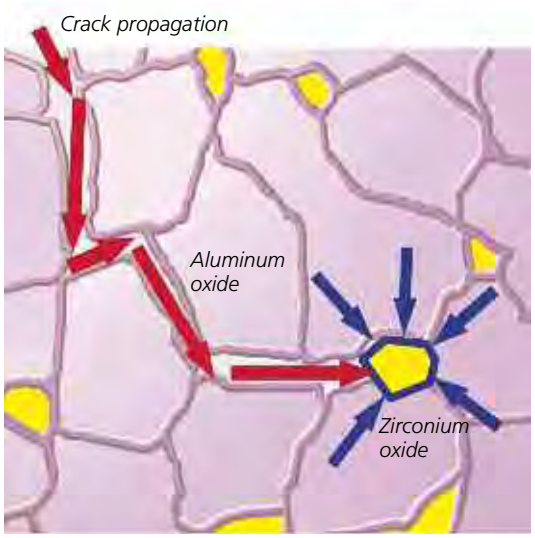
Ceramics with Energy-Dissipating and Crack-Stopping Function

The term fracture strength refers to the maximum mechanical stress a material can withstand without fracturing. The new BIOLOX®*delta* is not only extremely fracture resistant, it also exhibits a very high degree of fracture toughness. This is the term material scientists use to refer to a material's resistance to crack propagation. BIOLOX®*delta* is much better than most other ceramic materials at resisting cracking and arresting crack propagation. This property is primarily based on two strengthening mechanisms.

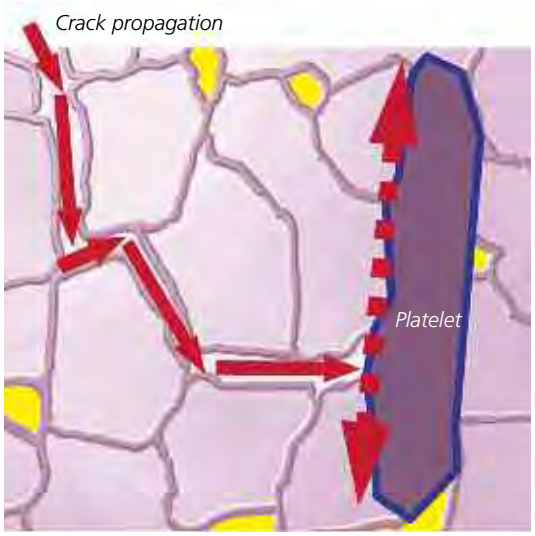


A detailed view of the BIOLOX®*delta* structure: platelets with crack-stopping function (1), aluminum oxide particle (2), zirconium oxide particle (3)

The first is based on the energy dissipating action of the tetragonal zirconium oxide nanoparticles dispersed in the stable aluminum oxide matrix. When these particles are exposed to strong cracking forces, they change their crystalline structure and thereby increase their volume. This expansion creates local pressure peaks that block crack propagation. The second strengthening mechanism is achieved via platelet-shaped crystals that are also dispersed in the oxide mixture. These platelets effectively deflect and absorb cracking energy. Thanks to its exceptional properties of fracture strength and fracture toughness, BIOLOX®*delta* offers a high degree of safety.



The principle of conversion reinforcement: zirconium oxide particles dissipate crack energy and absorb impacting forces.



The principle of platelet reinforcement: platelet-shaped crystals block crack propagation and thereby increase the strengthening effect.

Resistance to Stripe Wear

Stripe wear is a phenomenon that is associated with all hard-on-hard bearings. If an acetabular cup is not implanted in a physiologically correct position or if muscle tension is compromised, the motion cycle may lead to microseparation in the bearing components. This results in a high degree of edge

BIOLOX®*delta* is clearly superior when it comes to the following crucial parameters: grain size, bending strength, and fracture toughness.

		BIOLOX® (since 1974)		BIOLOX®*forte* (since 1995)		BIOLOX®*delta* (since 2004)	
Variable	Unit	Average	Variance	Average	Variance	Average	Variance
Al_2O_3	Vol.-%	99.7	0.15	> 99.8	0.14	81.6	0.17
ZrO_2	Vol.-%	n.a.	–	n.a.	–	17	0.1
Other oxides	Vol.-%	Rest	–	Rest	n.a.	1.4	0.01
Density	g/cm³	3.95	0.01	3.97	0.00	4.37	0.01
Grain size Al_2O_3	µm	4	023	1.750	0.076	**0.560**	0.036
4-point bending strength[1)]	MPa	500	45	631	38	**1384**	67
E-module	GPa	410	1	407	1	358	1
Fracture toughness K_{Ic}[2)]	MPa $m^{1/2}$	3.0	0.45	3.2	0.4	**6.5**	0.3
Hardness HV1	GPa	20	–	20	–	19	–

[1)] Average values measured for BIOLOX®*delta* from 2006

[2)] Fracture toughness refers to the capacity of a material to resist crack propagation; K_{Ic} is the corresponding characteristic value.

loading at the head and cup. In the case of hard-on-hard bearings, stripe wear may develop. In tests designed to simulate very severe microseparation during the motion cycle, significant differences were seen in the performance of BIOLOX®*forte* and BIOLOX®*delta*. Stripe wear was optimally reduced in BIOLOX®*delta*/BIOLOX®*delta* bearings. As a result of the extremely low wear and excellent biocompatibility this type of wear scar does not represent a risk for patients.

Less Wear and Greater Stability

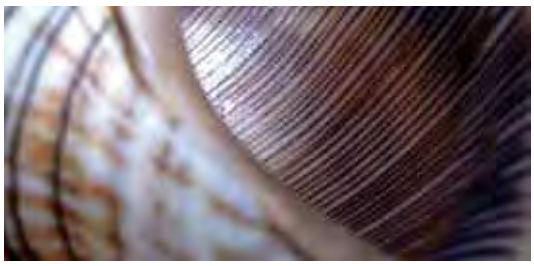
With a grain size in the nano-range, BIOLOX®*delta* offers a degree of structural uniformity that is unprecedented in comparable ceramic materials. The surfaces are even smoother and more wear resistant. Moreover, the burst strength of BIOLOX®*delta* is considerably higher than that of conventional aluminum oxide ceramics. Tests on standard samples of the material also show that the bending strength of BIOLOX®*delta* is not adversely affected by repeated autoclave sterilization.

New Possibilities

The superior material properties of BIOLOX®*delta* permit component geometries that were not possible using other ceramic materials. Thinner cup liners and increased stability and safety now permit the use of ceramic-on-ceramic bearings with larger diameters. Even the complex geometries that are required in knee arthroplasty are now possible with BIOLOX®*delta*. This effectively opens new areas of application for ceramic materials in arthroplasty.

Dr. Thomas Pandorf

Thomas Pandorf, Ph. D., Director Research, CeramTec Medical Products



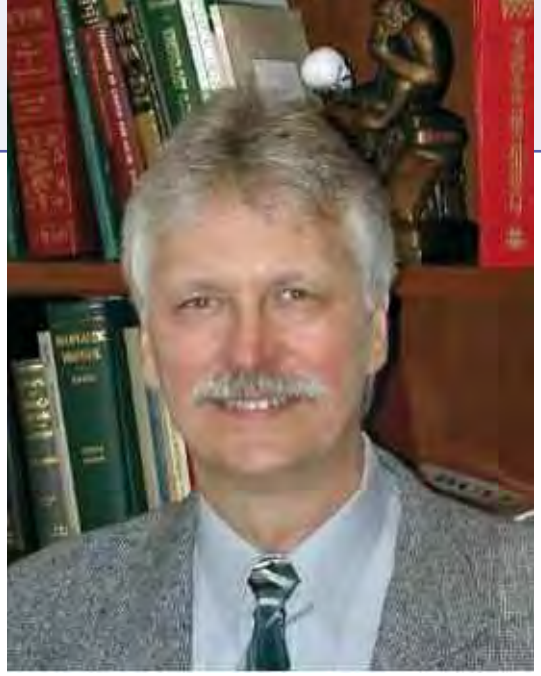
Using nature as a guide: hard aragonite and elastic chitin make the sea snail's mother-of-pearl both strong and tough.

The Strengths of BIOLOX®*delta*

- Increased fracture toughness
- Increased fracture strength
- Crack-stopping function
- Excellent biocompatibility

Ceramics Pass Tumbling Test

Harry A. McKellop, Ph.D., is the Vice President for Research at the Orthopaedic Hospital in Los Angeles, Director of the J. Vernon Luck Orthopaedic Research Center, and a Professor in the UCLA-Orthopaedic Hospital Department of Orthopaedic Surgery. Dr. McKellop's areas of research include the biomechanics of the musculoskeletal system and the development of improved materials and designs for orthopaedic implants, particularly joint replacements. A major focus of his research has been minimizing wear and wear-debris induced osteolysis in total joint replacements.



Harry A. McKellop, Ph.D.: Wear reduction of up to 90% with ceramic ball heads gives patients a greater margin of safety.

Which role do ceramics play in your research?

Our Tribology Laboratory collaborates with many implant manufacturers in evaluating the friction and wear performance of current and proposed bearing materials for prosthetic joints. We have tested nearly all of the bearing couples presently available for hip arthroplasty, including metal-on-metal, ceramic-on-ceramic and, particularly, metal or ceramic with the crosslinked polyethylene that was developed at the J. Vernon Luck Center. In the latter case, we have extensively evaluated the wear resistance of the crosslinked polyethylene under "clean" conditions, and in tests intended to simulate the third-body abrasion that commonly occurs in-vivo. For example, in an early hip simulator study[1], acetabular cups of a moderately crosslinked polyethylene (GUR 1050 crosslinked with 5mrads of gamma radiation and remelted) wore about 85% less than non-crosslinked cups when tested against polished femoral heads. When the heads were severely roughened with silicone carbide paper (a simple method of simulating third body damage in vivo), wear increased substantially for all of the cups, but the crosslinked polyethylene still wore about 28% less than the conventional poly.

In a more recent study[2], we used a more sophisticated method to model third body abrasion, and included a comparison between metal-on-polyethylene and ceramic-on-polyethylene bearings.

Zhen Lu, PhD, Manager of the Tribology Laboratory of the J. Vernon Luck Center, supervised the simulator tests comparing CoCr and BIOLOX®*delta* femoral ball heads.

How did you choose this method of modelling third-body wear?

In a preliminary study, we tumbled the femoral heads in a variety of abrasive grits for various durations, an approach that has been used in other laboratories. For the full study, we chose the type of grit (bauxite/alumina) and duration of tumbling (30 minutes) that produced a roughness comparable to what we have seen on retrieved implants. However, because tumbling scratches the entire head, whereas in vivo it is typically confined to a portion of the surface, this should be considered a model of relatively severe third-body damage.

What were the results?

With highly polished metal heads, the wear rate of the crosslinked polyethylene (GUR 1050 – 5mrad – remelted) again was about 85% lower than with non-crosslinked polyethylene. In addition, the wear rate of crosslinked polyethylene was lower with the BIOLOX®*delta* ceramic heads than with the metal heads, by about 10% with 28mm diameters, and 32% with 36mm diameters. Tumbling the heads in the abrasive grit generated extensive scratching on the metal heads, but negligible damage on the much harder ceramic heads. When the wear test was resumed, the wear rate of the crosslinked polyethylene showed a much larger increase with the metal heads, such that the wear rates averaged about 86% and 84% lower with the 28mm and 36mm ceramic heads than with the metal heads, respectively.[2]

A parallel hip simulator study[3], conducted by the tribology group at one of the big orthopaedic implant manufacturers, evaluated the wear rates of acetabular cups fabricated from GUR 1020 UHMWPE crosslinked at 7.5mrads and remelted, which has the same toughness but about 50% less wear than the GUR 1050 – 5mrad polyethylene. Again, tumbling induced extensive abrasive damage on cobalt-

chrome heads, but negligible damage on the BIOLOX®*delta* ceramic heads. Prior to tumbling, the wear of the 7.5mrad crosslinked polyethylene was about 33% lower with the ceramic heads than with metal heads, and about 90% lower after abrasive tumbling.

What is your conclusion from this?

The results of these comparisons indicated that harder ceramic heads should provide a greater margin of safety in vivo against accelerated wear caused by third body particles. I don't think any artificial hip joint is completely free of third body particles, which can include fragments of a porous coating, acrylic cement, bone, and even all three. Most of our retrievals exhibit at least some third-body damage on the metal heads.

What can you say about the difference between BIOLOX®*delta* and other ceramic materials?

We haven't conducted tests of our own to compare different ceramic materials. But according to published data, BIOLOX®*delta* appears to be an ideal direction to go in the improvement of ceramics for joint replacement. We know that there were problems with some types of zirconia with respect to the long-term stability in vivo. Although zirconia is tougher than alumina, gradual phase transformation – a changing in the structure and shape of the crystals – could lead to roughening and higher wear in combination with polyethylene. Alumina has been improved substantially over the years, but still has a significantly lower fracture strength than zirconia. According to the published data, BIOLOX®*delta* represents the "best of both worlds," that is, the stability of alumina and the toughness of zirconia, a very sophisticated combination for use in prosthetic joints. Clinically, this should translate into a greater margin of safety, especially when it comes to third-body wear, such that the patients will obtain the full benefit of the lower wear offered by the crosslinked polyethylene.

References:

1. McKellop H, Shen F-W, DiMaio W, Lancaster J. Wear of gamma-crosslinked polyethylene acetabular cups against roughened femoral heads. Clinical Orthopaedics and Related Research. 1999; 369: 73–82.
2. McKellop, H, Liao, Y.-S., Shen, F.-W., McGarry, W., Trans. Orthopaedic Research Society, 2006
3. Liao, Y.-S., Greer, K., Effect of head material and roughness on the wear of 7.5mrad crosslinked – remelted UHMWPE acetabular inserts. Trans. Orthopaedic Research Society, 2008

AAOS
AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

Hall D
Booth 5586

Welcome to San Francisco

At the AAOS Annual Meeting in San Francisco CeramTec will be present with a large island booth located in Hall D (booth number 5586). One of our focus points will be range of motion, featuring our large femoral ball heads in sizes of 40 and 44mm, as well as the new 40/48 and 40/52 acetabular inserts. We will also exhibit our BIOLOX® OPTION revision system and other innovative products. Our new BIOLOX®*delta* brochure and our new comprehensive training DVD will be available. CeramTec Medical Products experts will be ready to answer your questions, and all of the key management from our organization, including President Karl Billau, will be there to meet with you to discuss our products and plans for the future. We look forward to your visit!

Heinz Mittelmeier Award 2008

CeramTec AG and the German Society for Orthopaedics and Orthopaedic Surgery (DGOOC) jointly have created a € 5,000 fund award in honor of the lifetime work of ceramics pioneer Heinz Mittelmeier. The Heinz Mittelmeier Award is conferred to physicians, engineers and researchers of up to 40 years of age for outstanding research and development work in the area of bio-ceramics and wear-related problems in arthroplasty. Applicants may submit work that has been published in a book or scientific journal. Unpublished manuscripts that are intended for publication or whose publication is forthcoming will also be considered as well as advanced academic dissertations. A panel of experts appointed by the DGOOC will select the recipient of the price.

Interested individuals are requested to submit their applications to the following address by July 31st, 2008: CeramTec AG, Medical Products Division, DGOOC Research Prize, Attn.: Florence Petkow, Fabrikstr. 23–29, 73207 Plochingen, Germany. Applications may also be submitted online at www.ceramtec.com → Divisions → Medical Products → Medical Professionals → News & Events → Research Award

Surgical Training DVD

The new CeramTec DVD on the use of ceramic materials in arthroplasty is now available from the company upon request. The DVD contains comprehensive information for surgeons who wish to learn more about this area. The DVD includes:

- Surgery videos and instructional animation
- Tips and tricks
- Instructions on the handling of ceramic components
- A general guide to material combinations
- Materials science facts
- Bibliography

www.biolox.com/biolox-ceramics-dvd

Excellent Results for Ceramic-on-Ceramic

99% survival at seven years shows the excellent performance of ceramic-on-ceramic wear couples in this study. The authors analyzed a series of 301 third generation alumina-on-alumina (BIOLOX® *forte*) cementless primary total hip replacements in 283 patients. The average age at the time of implantation was fifty-eight years. The same surgical technique and the same implant were used in each case at a single center. 251 patients available for follow-up were assessed clinically and radiographically. All retrieved bearings were analyzed for wear.

The mean Harris hip score was 95 points. All surviving implants showed radiographic evidence of stable bone ingrowth. Nine revisions of one or both components were necessary. The reasons included periprosthetic fractures, psoas tendonitis, a femoral shortening osteotomy, one case of aseptic loosening at two months and one case of impingement and osteolysis. With revision because of aseptic loosening or osteolysis as the end point the rate of survival of both components was 99% at seven years. The retrieved femoral heads showed an early median wear rate of 0.2mm³ per year. The authors conclude: "Cementless primary total hip prostheses with a third-generation alumina-on-alumina bearing showed very low wear and were associated with minimal osteolysis at the time of follow-up, at a minimum of five years."

P.J. Lusty, C.C. Tai, R.P. Sew-Hoy, W.L. Walter, W.K. Walter, B.A. Zicat, Third-Generation Alumina-on-Alumina Ceramic Bearings in Cementless Total Hip Arthroplasty, J Bone Joint Surg Am. 2007;89:2676–83

Metal Head Doubles PE Wear

The authors state that the use of ceramic heads against conventional polyethylene (PE) can contribute greatly to reducing wear. But this positive effect has not been conclusively documented in the literature and is still a matter of discussion. The prospective study compares the wear rates of conventional polyethylene articulating with ceramic ball heads and ball heads made of CoCr.

87 patients were operated consecutively by the same surgeon with the same surgical technique. All patients received a cemented all-polyethylene cup sterilized with irradiation in inert atmosphere and a cemented stem. Head size was 28mm in all cases. 40 patients received a CoCr head and 47 patients an aluminum oxide head. Ten patients died in the group with ceramic heads and 12 in the one with CoCr heads. The patients were subjected to Radio Stereometric Analysis (RSA) postoperatively, at 2 months, 1, 2, 5 and 10 years. Clinical evaluations were done with the HHS. Wear and stability were analyzed by RSA.

At 0.93mm, mean linear wear was more than double in the CoCr group as compared to 0.43mm in the aluminum oxide group ($p = 0.001$). The study leaders stress that "PE irradiated in an inert atmosphere is already an advanced sterilization process leaving the material partly cross-linked and with only few free radicals. Still, we could detect a significant difference. We contribute this to the high precision of the RSA method. The wear results in the control group correlates well to values in the literature." They conclude that the significantly reduced wear for ceramic heads, in comparison to CoCr, "could be beneficial for young and active patients".

J Dahl, B Nivbrant, P Søderlund, L Nordsletten, S M Röhrl, Less wear with 28mm Aluminiumoxid heads against conventional PE - A 10 year RSA study, 60th annual meeting of the Norwegian Orthopaedic Society, 24.–26. October 2007, Oslo, Norway

Navigation for Better Cup Position

Achieving the right position for the acetabular cup is a decisive factor, irrespective of the wear couple material utilized in the arthroplasty. Using only ceramic-on-ceramic bearing couples, the authors carried out total hip replacements both with and without computer navigation between 1998 and 2001 at the Osaka University Hospital in Japan. At an average of 6 years post surgery, the authors examined 59 of the navigated and 111 of the non-navigated hips. While all of the acetabular cups in the navigated group were in the safe zone (Lewinnek), 31 cups in the second group were positioned outside of this zone. The non-navigated group also showed a significantly higher rate of dislocation, with 7 hips exhibiting impingement problems and 2 of these seven requiring revision. The authors indicate that "no such problems occurred in the navigated group."

Sugano N, Nishii T, Miki H, Yoshikawa H, Sato Y, Tamura S, Mid-term results of cementless total hip replacement using a ceramic-on-ceramic bearing with and without computer navigation, J Bone Joint Surg [Br] 2007;89-B:455–60

Expert Recommendation on Implant Allergies

A recommendation on the subject of implant allergies was issued at the beginning of the year 2008 by the Implant Allergy Working Group of the German Society for Orthopaedics and Orthopaedic Surgery (DGOOC), the German Contact Allergy Group (DKG) and the German Society for Allergology and Clinical Immunology (DGAKI). According to their joint statement, titanium components should be used for osteosynthesis in cases of known metal allergy. For planned hip replacements, they recommend ceramic-polyethylene wear couples. Ceramic femoral ball heads have been clinically proven for more than 30 years.

P. Thomas, A. Schuh, J. Ring, M. Thomsen, Orthopädisch-chirurgische Implantate und Allergien, Der Orthopäde 1, 2008

Web-Based Implant Allergy Information

Implant Allergy Working Group (AK20) of the German Society for Orthopaedics and Orthopaedic Surgery (DGOOC): www.dgooc.de/Verband/Arbeitskreise/ (Working Group 20, Implant Allergies)

German Society for Allergology and Clinical Immunology (DGAKI): www.dgaki.de

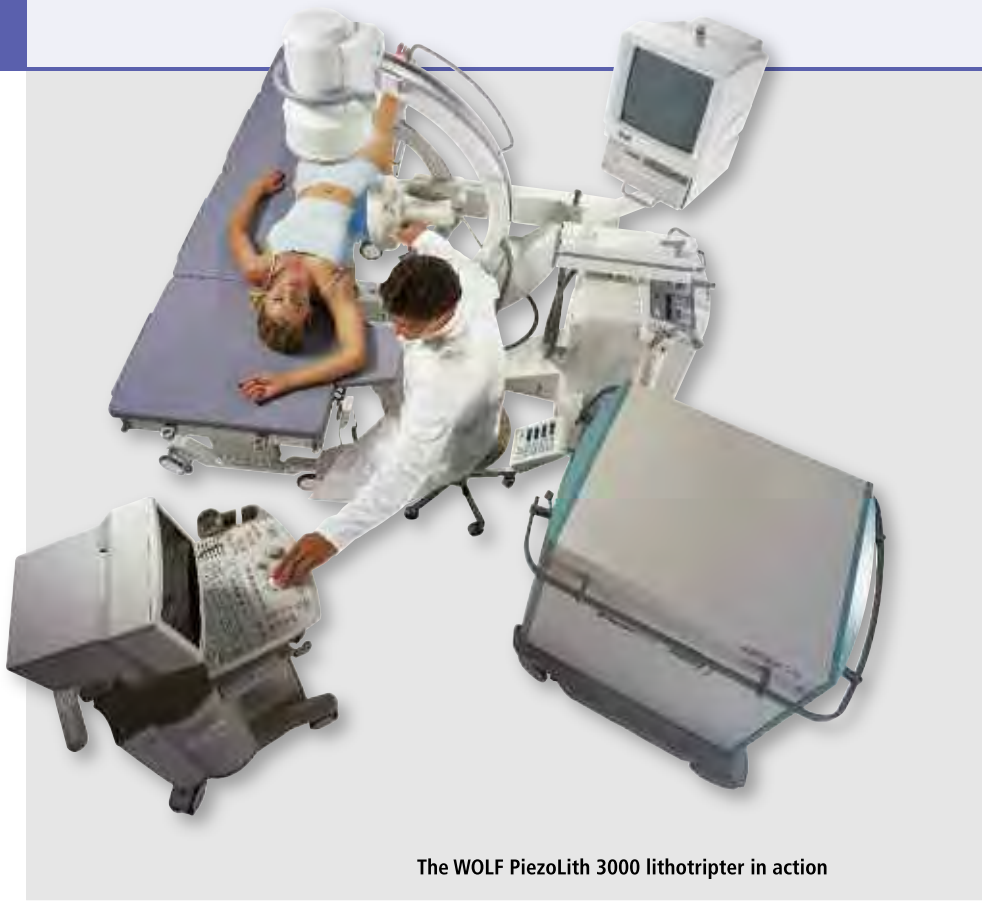
German Contact Allergy Group (DKG) of the German Dermatology Society: www.ivdk.gwdg.de/dkg/

Implant Allergy Register and Implant Allergy Information Platform (Implant Allergy Working Group at the LMU in Munich): http://allergomat.klinikum.uni-muenchen.de

Focused Healing Power

Piezoelectric ceramics ensure efficient shockwaves

The introduction of extracorporeal shockwave lithotripsy (ESWL) in the 1980s marked a milestone for medicine and medical technology. It was no longer necessary to surgically remove painful stones from the gallbladder and kidneys because these stones could be destroyed noninvasively with ultrasound shockwaves. Shockwave therapy has since been introduced to other areas of medicine and the range of its applications continues to grow. The technology itself has improved considerably over the years. This has been made possible by the use of piezoelectric ceramic elements.

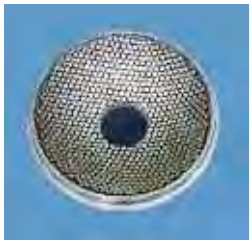


The WOLF PiezoLith 3000 lithotripter in action

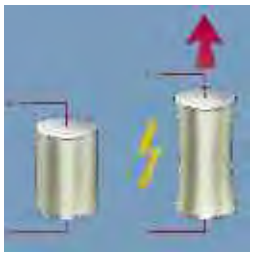
The functional principle behind piezoelectric shockwave devices is simple: around 2,000 piezoelectric cylinders are placed like a mosaic in a spherical shell. A high voltage pulse of up to 10,000 volts triggers an expansion of the elements. This gives rise to high energy ultrasound. The ultrasonic pulse is transferred to a focal point within the body (e.g. a kidney stone) via a water or gel cushion. In order to ensure sufficiently strong action and minimal side effects, the pulse must be both strong and exactly focused.

Piezoelectric devices are superior to competing technologies when it comes to these decisive characteristics. In the case of devices that essentially operate according to the principle behind spark plugs, it is necessary to replace the electrodes after around 20,000 pulses. Given that the pulverization of a stone takes around 3,000 pulses, one is left with just enough pulse capacity for seven treatments. In contrast, electromagnetic devices offer (depending on the particular manufacturer) up to 2 million pulses before it becomes necessary to replace the relevant components.

Compact ESWL device for orthopaedic use



Piezoelectric converter with a concave arrangement of elements



Function of piezoelectric ceramic elements

The piezoelectric shockwave method permits even greater pulse capacity. The lithotripter manufacturer Richard WOLF uses this technology to guarantee five million shockwaves, or two years of functioning. Thanks to the ceramic elements, the strength of the pulses remains virtually constant during this service period and the precision focusing remains entirely intact. Given that shockwaves with pressure amplitudes of up to 1,500 bar are reached at the focal point, this latter feature is especially important. The targeting precision of the piezoelectric converter ensures that the surrounding tissue is not exposed to damaging waves.

Extracorporeal shockwave lithotripsy (ESWL) continues to make inroads in the area of orthopaedics. In the case of pseudarthrosis, for instance, the shockwaves generate microfractures that stimulate bone healing. ESWL appears to be developing into the noninvasive treatment of choice for calcaneal spurs. The treatment is also used to alleviate chronic pain syndrome in various joints. Here, however, the exact mechanisms involved are not yet fully understood and are currently being examined in various clinical studies. The piezoelectric ceramic components in compact shockwave devices for use in orthopaedics come from the same source as those of the lithotripter: from the Franconia-based Multifunction Ceramics Division of CeramTec.

Photography: Richard Wolf GmbH

Historical perspective

Promoting ceramics in the country of pioneers

Bernard Masson

Bernard Masson had worked in the medical field for eight years before joining CeramTec as a scientific consultant in 1999. "It was quite a challenge to find a way of informing approximately 3,000 French orthopaedic surgeons about developments in ceramics for arthroplasty," he recalls. He reaches his customers by participating in medical congresses, giving lectures and presentations there and in the hospitals. He is also the author of scientific publications about ceramics and arthroplasty. "My job is to be an interface between the industry and the orthopaedic community. I try to find the common ground between the surgeons' needs and the industry's possibilities," he stresses. Due to its role as the pioneering country of ceramic applications in orthopaedics, there is great interest in France for developments in this field. "This also gives me a chance to place the continuing improvement of our technology in historical perspective and discuss it with extremely well-informed and experienced surgeons."

New on the staff

Dieter Burkhardt is CeramTec's new Business Manager for the US market. He holds a degree in Medical Engineering and has a track of more than 20 years experience in the healthcare industry where he has been holding senior sales and marketing positions. Prior to joining CeramTec he worked for several global players, among them one of the big orthopaedic implant manufacturers.

Justin Waugh represents CeramTec as a Product Manager in the American Market. His background includes a Bachelor of Science degree in Mechanical Engineering. He worked for four years as a Product Development Engineer in the hip development group at one of the orthopaedic implant companies.

Peng Zeng achieved her PhD degree in Materials Science at the University of Sheffield, UK. Her thesis focused on the wear mechanisms of alumina-on-alumina hip prostheses. Since January 2008 she has been working for CeramTec as scientific consultant for the UK market, supporting surgeons in all questions regarding ceramics.

Upcoming Events

- **March 5–9**
  AAOS
  San Francisco, USA
- **March 17–21**
  Journées d'Orthopédie de Fort de France, France
- **April 3–5**
  Berner Hüftsymposium
  Berne, Switzerland
- **April 22–26**
  11ème congrès de l'AOLF 2008
  Marrakech, Marocco
- **May 1–4**
  56. Süddeutscher Orthopädenkongress
  Baden-Baden, Germany
- **May 8–9**
  V. Convegno Internazionale
  Rome, Italy
- **May 18–21**
  Current Concepts Spring
  Las Vegas, USA
- **May 22–25**
  81st Annual Meeting of the Japanese Orthopedic Association
  Sapporo, Japan
- **May 29–June 1**
  EFORT
  Nice, France
- **June 5–7**
  101° S.O.T.I.M.I.
  Naples, Italy
- **June 11–13**
  European Hip Society
  Madrid, Spain
- **June 12–14**
  57. Norddeutscher Orthopädenkongress
  Hamburg, Germany
- **June 12–14**
  SOO 2008
  Le Havre, France
- **June 12–14**
  39° O.T.O.D.I.
  Monastier, Italy
- **June 20–22**
  2nd Shanghai International Congress on Orthopedics
  Shanghai, China

Imprint

Published by:
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