1/2006

The Magazine of CeramTec AG, Medical Product Division

CeraNews

Ceramics in Orthopaedics

A Matter of Design

Professor Dr. Laurent Sedel is one of the foremost pioneers of ceramics in arthroplasty. He has worked with Dr. Pierre Boutin who was the first to use alumina components in hip joints. Prof. Sedel has more than thirty years of clinical experience with this material. CeraNews asked him to take a look back at the development of this highly successful medical technology.

Prof. Dr. Laurent Sedel is Head of the Department of Orthopaedics and Traumatology at the Hôpital Lariboisière in the French capital of Paris and Director of the Laboratory for Biomechanics at the Denis Diderot University.

When did you begin working with alumina? That was in 1974. I was a young resident then and I spent quite some time in the research lab for biomechanics and biomaterials. Prof. Boutin who worked in Pau, a small town in the southwest of France, came to me to talk about ceramic fractures and the biological tolerance of the material. We soon found out that the problem was neither related to wear nor to the mechanical properties nor to osteolysis. The real difficulty was the fixation of the ceramic on the metal component. For the ball head this was essentially solved when Prof. Mittelmeier adapted the Morse taper for ceramic heads, which resulted in a large decrease in the rate of head fracture. But despite these early difficulties ceramics provided the best solution to the more significant problem of wear debris in artificial hip joints. And the overall clinical results were already very promising.

What about ceramic liners in acetabular cups? We had a similar development there. We started implanting our first ceramic liners in 1983 using a threaded cup with a very sharp thread. This led to high stresses in the bone and, ultimately, in many cases to cup loosening. But in 600 liners implanted with this cup we did not have even one liner fracture. When we changed to a press-fit cup this problem was eliminated. With more than 2,000 press-fit cups implanted we have had only two fractures in eleven years, one of which was related to an injury.

You mean, material fracture is not a significant problem? Not if you look at the overall figures. The material was vastly improved during the 70s and early 80s and we have reached a quality level in alumina that makes the material extremely safe. In my experience, ceramic fracture has almost always been related to some mistake during implantation or to unsuitable design of the alumina or the metal component. In thirty years, we have seen a total of only five unexplained ceramic fractures.

Why is design so important? Take ceramic liners, for example. The fixation of the first liners in the metal back was copied from the fixation of polyethylene liners. But applying the PE design created points of excessive stress in the ceramic liners, potentially inducing cracks in the material. By creating a specific design for the fixation of ceramic liners these high stress points were altogether eliminated. To summarize these experiences, the problems I have encountered in more than thirty years of using alumina components were not caused by the material but by the design. And these are problems of the past.

Do you always use ceramics? No, it depends on the sum of life expectancy and level of activity of the patient. For the elderly, not very active patient a conventional wear couple can be sufficient.

Do you see any weaknesses in ceramics technology? Yes, there is one weakness – the surgeon must adapt to it. If you implant ceramic components you have to be aware of the specifics of the material, something that is not as simple as it

Well Tested

Manuela Muhr-Schenk coordinates the knee development program

Project Manager Manuela Muhr-Schenk is pleased with the speed of her project: "The enormous commitment of the team was the key to success."

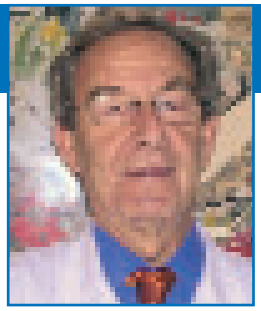
It has taken only a year for CeramTec's first ceramic knee implant to progress from the prototype stage to production. This very rapid progress was made possible by a team of twelve experts headed by Project Manager Manuela Muhr-Schenk.

The challenge was to take a clinically-proven bicondylar femoral component made of metal and to reproduce it in ceramic. This transfer process was very complicated and involved many different functional areas.

Above all, due to the complexities of ceramic production technology, a considerable effort was required to prepare for production. Since at the time no established test existed for knee femoral components, the team had to develop a method of its own.

"Before leaving production, each individual component is subjected to an overload test, designed to eliminate weak components", explains Manuela Muhr-Schenk. The former laboratory technician has worked for twelve years as a product development manager in the medical device industry, the past two years for CeramTec. As the Project Leader she is responsible for fitting the interfaces together and coordinating the many parties involved. Therefore, above all her job consists of asking the right people the right questions, she remarks with a twinkle in her eye. "The extensive knowledge and commitment of the team are the keys to success" she explains, thinking back while already looking forward to her next project with the same team – the development of a matching tibial component – which is already well underway.

**Bioceramics and Alternative Bearings in Joint Arthroplasty.
The 11th International BIOLOX Symposium (June 30 – July 1, 2006, Rome).
Friday, June 30,2006, Session 4: Ceramic knee. www.biolox-symposium.com**



Interview (continued)

may sound. You can't do trials as easily as with metal heads, for example. There are some design limitations, too, and you have to be very careful with your preoperative planning as well as with your surgical technique. On the other hand, a ceramic wear couple can make revision far easier. Usually it is only one component that makes revision necessary, and in this case, with a ceramic wear couple, you can leave the other component in place. Thus you can reduce trauma, operating time and cost, which is not insignificant these days.

What do you think of highly crosslinked polyethylenes? To me, they are a cause for concern. We have only a few years of clinical experience and I am rather pessimistic about the material properties. The material is not as strong as regular PE and I'm afraid we'll see brittle fractures in the future. This is especially true if it is a metal back design with a large head which reduces the thickness of the plastic.

What do you think about ceramics for joints other than the hip? We already have very interesting developments for the knee and I can imagine that we may soon see alumina components for the shoulder, elbow or the ankle. Here again, I think it is a matter of design. You cannot simply copy a metal component. The design has to be adapted to the material properties of ceramics. The Japanese have shown that it can be done and I am certain that we will see more of this in the near future.

Why has alumina ceramics not been as successful in the USA as it has been in Europe and Japan? The lengthier FDA approval procedures play a role here, of course, but the real answer is quite simple – it is because of the American culture of litigation. In the States, hospitals prefer ten slow failures to one acute fracture. A slow failure will have no legal consequences because it is in the range of the accepted clinical outcomes. The very rare acute fracture however may trigger damage claims which, as we know, in the US often involve enormous sums of money. So many American surgeons think they can't afford to take this risk, even though the risk involved in the use of regular wear couples is far higher for the patient. Fortunately, this attitude is changing and I'm quite sure that in the long run, alumina will also be widely accepted in America as the superior material that it is.

Dr. Martin Dietrich is Managing Director of CeramTec's Medical Products Division.

Dear Reader,

The triumphal march of ceramics into joint replacement has taken place rather quietly. We did not need large advertising campaigns to spread the word about the superior properties of our products. They'll continue to speak for themselves, but all the same we want to provide a broader platform for them.

With the re-launched CeraNews, which you are now holding in your hand, we want to open up an informative communication channel focussing on doctors who are familiar with joint replacement as surgeons or referring practitioners. We also would like to promote networking among ceramic experts around the world.

As you can see, our newsletter has a new appearance and has a few more pages than before. But we haven't merely changed it on the outside. It has a new structure and we will regularly present clinical and scientific information on important topics in it. Also, the people who work with ceramics and joint replacement will have their views represented in it.

But above all, you are important to us – your interests and perspectives should be the guiding theme for this publication. For this reason we are looking forward to your comments, criticisms and contributions, and to the lively exchange of ideas to which CeraNews will contribute.

Yours sincerely,
Dr. Martin Dietrich

Growing Numbers

AAOS Meeting in Chicago, March 22-26, 2006

The 11,663 orthopaedic surgeons and nearly the same number of allied health participants attending the 2006 Academy Meeting will remember Chicago as the place to get in touch with recent developments in the field. Arthroplasty, of course, and wear reduction technology were among the most widely discussed subjects. The key message this year was the quest for longer lasting implants to prevent or delay revision procedures.

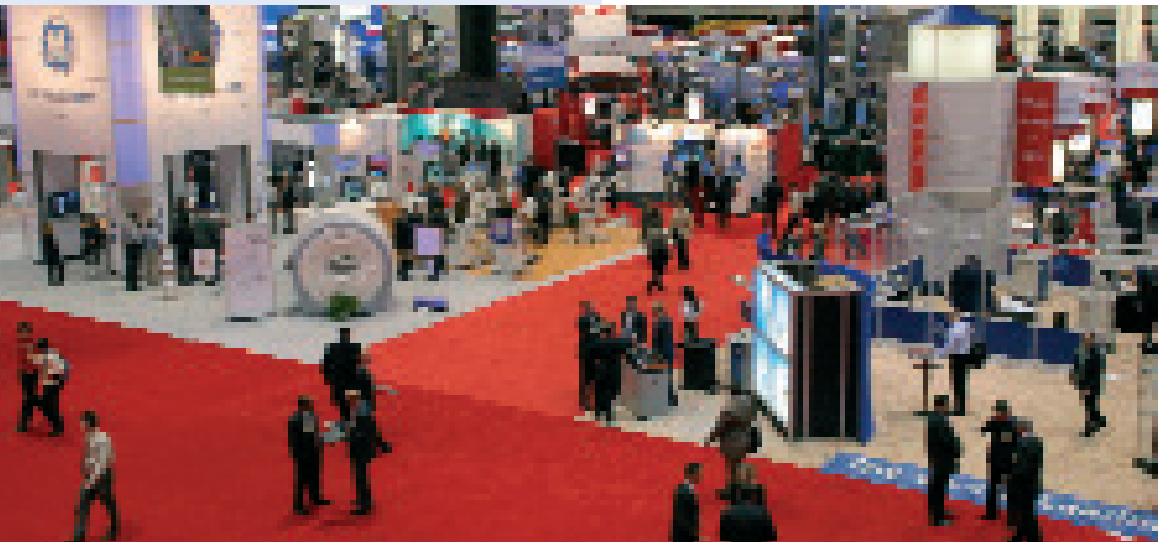
A study conducted by Dr. Steve Kurtz of the Exponent company strongly emphasized this message. He used the National Inpatient Sample and U.S. Population Census data in order to estimate the primary and revision surgeries per year as far out as the year 2030 with astounding results (see table).

Year	THA primaries	THA revisions	TKA primaries	TKA revisions	Total
2010	253,367	47,814	663,007	55,250	1,019,438
2020	384,324	67,607	1,520,348	120,928	2,093,207
2030	572,088	96,736	3,481,977	268,157	4,418,958

There were no revolutionary product introductions this year – with one big exception. The release of gender-specific implants by two of the biggest companies is expected to create a lot of interest in the field. Their marketing concept is based on the difference in the anatomy of male and female joints. Both companies have released knee systems with male and female designs.

Alternative bearing technologies for the hip and knee were in the focus of attempts to reduce wear. The second generation of highly cross-linked polyethylene (HXPE) was introduced in Chicago while problems with the mechanical properties of some of the first generation HXPEs were discussed in the scientific program. Alternative bearing technology was also the most commonly displayed item in the exhibit hall. Every orthopaedic implant company devoted a substantial part of their booth to showing their entire range of options for wear reduction. BIOLOX technology is recognized as one of the key technologies in this area. It is now available from all big implant companies, following recent FDA approvals and market entries.

Once again, minimally invasive surgical techniques and instrumentation drew a lot of interest, with the emphasis shifting from incision size to optimal implantation quality. Further refinements in computer assisted surgery systems and biological products for bone enhancement and replacement were also widely discussed, without substantial breakthroughs reported.



Richard F. Kyle, professor of orthopaedic surgery at the University of Minnesota, was elected President of the AAOS in Chicago.

Highly Resistant

New option for revision hip surgery

Professor Wolfram Mittelmeier of the University Hospital in Rostock has been using the new BIOLOX® Option revision heads since July 2005. CeraNews asked him about his experiences with the new ceramic system for hip revision.

Prof. Wolfram Mittelmeier, Director of Orthopedics at the University Hospital in Rostock (Germany) has achieved very good results with the BIOLOX® Option Revision System.

How many BIOLOX Option heads have you implanted so far? Around 60 as of the end of April 2006.

For you, what is the most significant technical innovation that the system offers? The new mixed ceramic BIOLOX delta, from which BIOLOX Option heads are made, has a higher strength, which can be very important in various loading situations, especially when you think about fracture. We need this higher strength, since we want to put heads on already-used stem tapers, leaving the existing stem in situ. With the new material we can do that with a good conscience based on the results of the load tests.

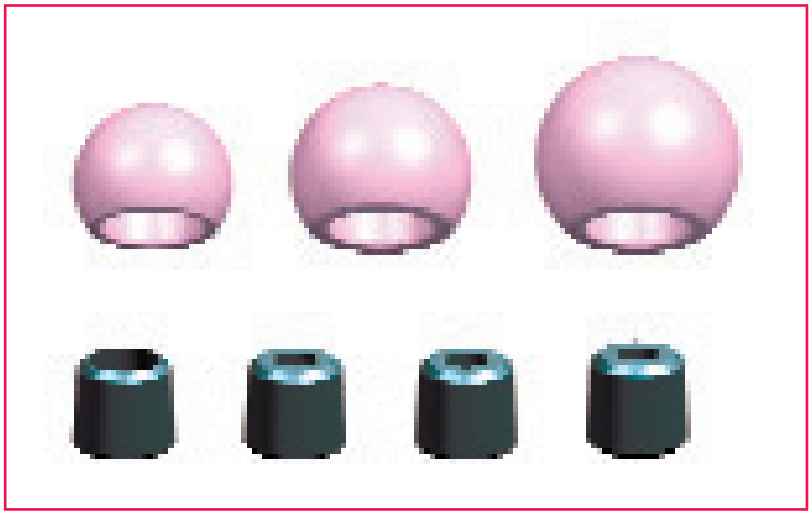
How precisely do you know the mechanical properties of the material? In our biomechanics lab we work on questions such as this and we are also testing implants. Throughout my career I have worked with materials scientists. In this case we have checked the data with our specialist colleagues, but we did not repeat the tests on the heads ourselves.

How would you describe the actual handling of the revision heads? Generally they are easy to use, following known procedures without special techniques. But the stem taper should be not more than moderately damaged and must be carefully protected during the revision operation. Asymmetric metal sleeves are also available and using these, many problems of impingement can be solved.

In your opinion what advantages does the product offer? The Option head can also be used when there has been a ceramic fracture of the primary prosthesis. In older patients, who had an older type of ceramic implant, very occasionally a fracture of the ceramic head or insert could occur. At revision, even after very careful cleaning of the site, microscopic ceramic particles can be found in the joint. For this reason in such cases the use of a metal head is contra-indicated. Only highly resistant ceramic heads should be used. If no ceramic particles are present, a metal head from the original manufacturer could be used. But even in this case, it is preferable to switch to ceramic on account of the lower wear rate. With this system you can find a good solution in most situations.

You are hosting a workshop in Warnemünde near Rostock (September 7 – 9) on the topic of revision. Will the BIOLOX Option also play a part at this workshop? Yes. Among other things it will be covered under the topic of Revision in Difficult Cases. There will also be a product presentation and a discussion. Topics of particular importance will be Range of Motion and Impingement. Both are topics that we are working on in Rostock. For good results the head size and neck length must be correctly selected and the implant position must be correctly adjusted. These topics will play an important part in the workshop in September and also in the BIOLOX Symposium in Rome, where I will be presenting a paper on this subject.

The BIOLOX® OPTION System consists of ballheads and titanium sleeves, specially developed for revision, which are intended to be placed on the taper of a hip stem remaining in situ. All head and sleeve sizes can be combined with one another. The titanium sleeves can compensate for surface irregularities in the taper.



By combining the various sizes of sleeves and heads, a broad range of options is obtained. These options help the surgeon reduce the risk of subluxation and impingement.

Long Term Survival with Ceramics

Heidelberg study of hip replacement in younger patients

Scientists at the Orthopaedic University Hospital in Heidelberg showed for the first time in a clinical study that hip replacement prostheses in patients under 55 years of age can last for 20 years largely without problems. They presented their results in March at the meeting of the American Academy of Orthopaedic Surgeons (AAOS) in Chicago.

"The number of patients who require a hip replacement at a relatively young age has been increasing over the years," explains Professor Volker Ewerbeck, Medical Director at the Orthopaedic University Hospital in Heidelberg. In younger patients, who often still want to be active and take part in sport, higher demands are placed on the load bearing capacity of the prostheses.

In a long term study, Dr. Peter Aldinger, Orthopaedic Consultant at the Orthopaedic University Hospital in Heidelberg, investigated the 15 to 20 years performance of a total of 141 patients aged 23 to 55 at the time of implantation. All these patients had a cementless titanium prosthesis with a ceramic head. Roughly 95% of the prostheses were still functioning after an average of 17 years. Investigations and direct questioning of the patients showed that over 90% were still very satisfied with the result after more than 15 years. X-rays indicated that in only 3% of cases had the implanted stem loosened. "This study showed that younger patients also do very well for at least 10 and probably for even more than 20 years," said Dr. Aldinger.

Literature:

Aldinger PR, Thomsen M, Mau H, Ewerbeck V, Breusch SJ. Cementless Spotorno tapered titanium stems: Excellent 10-15-year survival in 141 young patients. Acta Orthop Scand. 2003 June; 74(3):253-8.

Aldinger PR, Breusch SJ, Lukoschek M, Mau H, Ewerbeck V, Thomsen M. A ten- to 15-year follow-up of the cementless Spotorno stem. J Bone Joint Surg Br. 2003 Mar;85(2):209-14.

Aldinger PR, Jung A, Thomsen M, Ewerbeck V, Parsch D. Long term (15-20 year) results using uncemented titanium hip stems in young patients. AAOS 2006, Chicago, Illinois, USA, Poster presentation, P087.

Dr. Peter Aldinger, Orthopaedic Consultant at the Orthopaedic University Hospital in Heidelberg

Prof. Volker Ewerbeck, Medical Director at the Orthopaedic University Hospital in Heidelberg

AAOS – Selected Papers

Dr. Derek McMinn, Birmingham, UK, presented the results of their study showing that the metal ions from a metal on metal articulation do in fact cross over from a mother to the foetus through the placenta. This previously unreported finding was only possible as a result of new techniques developed for the detection of metallic ions. (Paper 320)

Dr. Stephen Tower, Anchorage, Alaska, presented his analysis of three explanted highly crosslinked polyethylene cup inserts with extensive cracking in the rim area. He explained that the lower mechanical properties of this material coupled with a near vertical cup placement created a situation where the brittle cracking could occur. (Paper 323)

Dr. Jeong Joon Yoo, Seoul, Korea, evaluated the results in 57 revision cases of young patients (average age 46). His results were excellent and he highly recommends the use of the ceramic on ceramic articulation for these patients. (Paper 472)

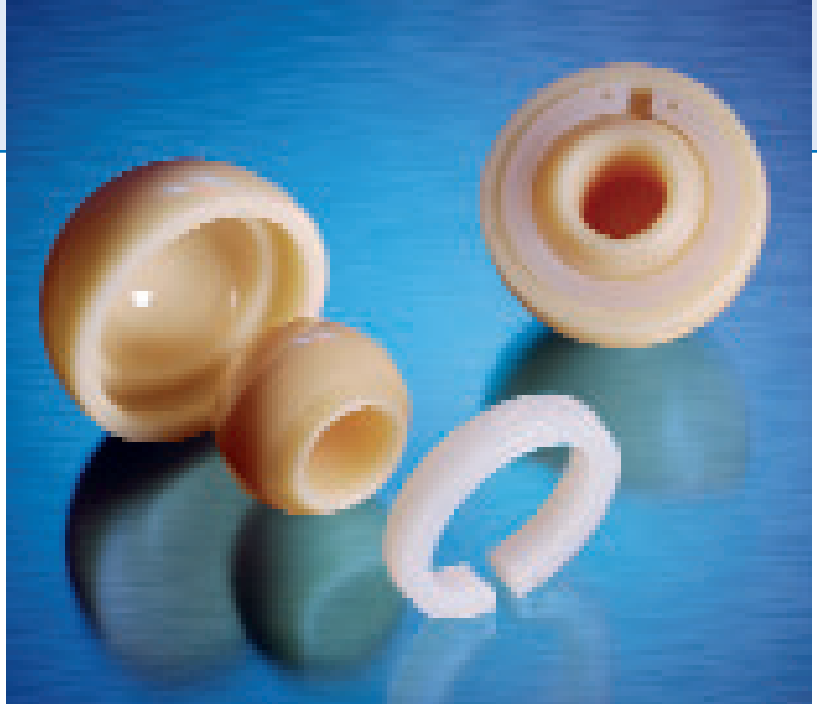
All AAOS abstracts are available at:
www.aaos.org/wordhtml/anmt2006/education.htm

The Convention Center in Chicago was the venue of this year's AAOS Meeting.

Double Rotation

With ceramic the bipolar effect is enhanced

Bipolar prostheses have been used successfully in the treatment of femoral neck fractures in older patients for many years. Now, with the introduction of DUOLOX®, a ceramic bipolar prosthesis is available. Professor Friedrich F. Hennig has the most extensive experience with this implant.



The DUOLOX® System combines the design advantages of modern bipolar prostheses with the excellent material properties of BIOLOX® ceramic.

What are the reasons for using a bipolar prosthesis? It minimizes surgical trauma to the joint capsule and acetabulum and therefore the patient's sense of proprioception remains intact. Rehabilitation is faster, especially in the less adaptable elderly patients.

What is the difference between DUOLOX and conventional bipolar prostheses? The DUOLOX is the first bipolar prosthesis with a hard-hard wear couple. The outer head is attached with a polyethylene fixation ring, which is outside the loaded region.

What has been your experience with the product so far? We helped to develop the implant and we implanted the first ones five years ago. But in the beginning the product was not available in all sizes. From the start of this year we have the full range of sizes.

What advantages does the implant offer? The biggest advantage concerns the inner head´s capacity to rotate. This capacity is greater than in metal bipolar prostheses.

Why? We did an experimental mechanical study to investigate this. Metal bipolar prostheses have a polyethylene liner as the counterface. The thickness of the polyethylene liner is limited by the size of the outer head and may be very small. Therefore cold flow and a slight deformation of the plastic often occur. The inner head penetrates into the outer head and so the bipolar effect is lost. We can also observe this in abduction experiments, which we did one year after implantation using a fluoroscope. With metal heads we find that the rotation of the inner joint is restricted and partially lost, while with a ceramic bipolar head it is retained.

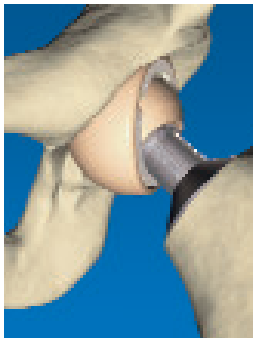
Why does the use of ceramics ensure that the bipolar effect is retained? The geometry of the ceramic components remains practically unchanged and its high wettability ensures good sliding.

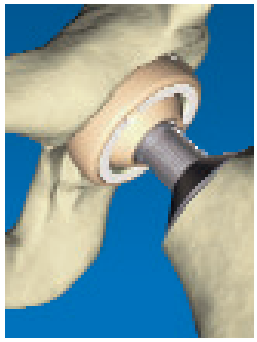
Is the hard ceramic of the outer head well tolerated by the soft acetabular cartilage? The outer head is the same size as the natural femoral head so the surface pressure distribution is the same as that which occurs naturally. Here too, the enhanced wettability ensures low friction and good sliding.

Does overloading or degeneration occur? Yesterday I revised a DUOLOX prosthesis which had been in place for five years – the stem had loosened. The histological findings demonstrated that the cartilage was intact. Actually, it was partially fibrous, but stable and capable of load-bearing.

Given the improved properties of DUOLOX are you now using it for a wider range of indications? We have also used DUOLOX in some young patients with femoral head necrosis. Of course, each individual case has to be carefully assessed. We have even treated a recreational football player in whom the ceramic bipolar has proved very successful. Dr Alexander Olk, a surgeon in our department, will be presenting our findings at the forthcoming BIOLOX Symposium in Rome.

Prof. Friedrich F Henning, Department of Orthopaedics and Accident Surgery, Head of the Department of Traumatology at the University Hospital in Erlangen, Germany.





The separation of the centers of rotation ensures that the bipolar shell does not tilt into an extreme varus position. Under load the shell gradually returns to its correct position.

Precision Impulses

Ceramic transducers use the piezo-electric effect

Piezo-ceramic components help to destroy kidney stones, include micro-oscillations in surgical knives, provide the necessary pulses for ultrasonic cleaners, warn drivers about parking obstacles and scare away burglars. Modern ceramic technology allows us to take advantage of the complete potential of the piezo-electric effect.

The application of a force to certain materials generates an electric charge on their surface. For example, the spark in a cigarette lighter arises by means of this piezo-electric effect. Conversely, an inverse piezo-electic effect will cause these materials to undergo a change in shape when an electric field is applied. Piezo-electric components convert mechanical energy into electrical energy and vice versa.

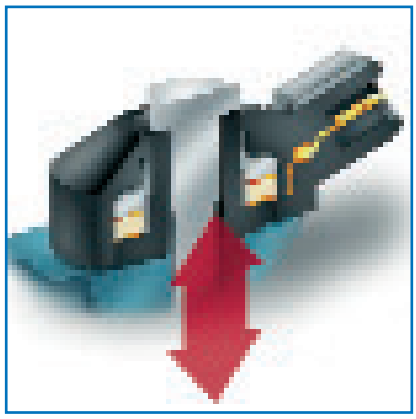
However, attempting to induce such behaviour in a ceramic requires numerous manufacturing steps. The key here is the mixing of the various raw material oxides as specified by the composition. The composition determines the final material and thus its range of application. The possible forms are also as various as the compositions of the raw materials. Whether it is disks, rods or spheres – the resulting ceramic blanks or green parts as they are called, have to be sintered at temperatures between 1000°C and 1300°C. The basis for the piezo-ceramic properties is established during the final cooling stage. This process involves a distortion in the microscopic cells of the material's crystal structure and a formation of dipoles. Dipoles consist of two physically separated poles with different electrical signs, just as in a bar magnet. In any case, these dipoles are not aligned and are randomly arranged.

A distance sensor, built into the bumper, warns the driver about hidden obstacles.

High tech ceramics have as much to do with crockery and the potter's wheel as the Mars probe has to do with a donkey cart. Varying the composition and manufacturing processes enables one to produce ceramic materials with a wide range of properties. Many technical applications would be impossible today without the use of ceramic components. Such components are produced according to the highest quality standards by CeramTec and are used worldwide.

Order – and as a result the piezo-electric effect – is produced by polarization. The ceramic is ground to shape before the electrodes are attached. Then, at temperatures between 20°C and 400°C an electrical field is applied. Under the influence of this field the dipoles in the material align themselves parallel to one another. This polarization remains in effect even after the field is switched off.

The piezo-electric elements can now be used in sensors and actuators. When used in sensors they convert applied forces into electrical signals, for example, in microphones, gas lighters and burglar alarms. When applied in actuation, the inverse piezo-electric effect is used to produce mechanical forces, for instance, in medical devices used to destroy kidney stones or whose functioning involves the oscillation of surgical blades. However, the two two types of effect are often combined, as in the case of distance sensors, which represent a kind of piezo-electric sonar devices. The ceramic component creates high frequency sound waves and receives the echo from these waves. The reliable conversion of very fine impulses, even at very high frequencies, is one of the particular strengths of piezo-ceramics. Ceramic materials typically work with the greatest of accuracy and they practically never wear out.



Knock sensors help save gas.

Piezo-electric elements arranged in a parabola create strong sound waves that converge on a focal point. The high energy of these waves can be used to destroy kidney and gall stones – without surgical intervention and virtually painlessly.

Support for Doctors and Hospitals

Close and confidential collaboration with doctors and researchers is a CeramTec tradition. CeramTec supports you by providing information, training, training materials and much more. Here is a short list of the services we provide:

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Services provided by CeramTec

- Training for doctors and theatre staff on the use of ceramic components in hip replacement including theory (material properties, product information, clinical results, latest developments and research) and practice (handling and use of BIOLOX® implants, "Do's and Don'ts").
- Support for theses, dissertations and post-doctoral research on subjects including bioceramics in joint replacement, abrasion and wear in prostheses, biocompatibility of materials (literature information, photographic materials).
- Support for publications (textbooks, articles, posters) and presentations by means of information on the current status of the professional literature and provision of photographic materials and animations on the problem of abrasion and wear.
- Reprints of abridged versions of scientific papers (theses, dissertations, articles, etc) and their summary in the form of abstracts on the topics of bioceramics in joint replacement, wear in prostheses, biocompatibility of materials.
- Provision of materials for use in the training of medical students
- Provision of photographic materials for websites
- Provision of photographic materials for physicians, hospitals and clinics for advertising and marketing purposes (for example for information sheets, patient brochures or hospital magazines)
- Tours of manufacturing facilities in Plochingen and Marktredwitz upon request
- Publication of short articles on ceramics in joint replacement for CeraNews – we look forward to receiving your contributions.

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