BIOLOX® delta

Scientific Information and Performance Data
Key Issues in Hip Arthroplasty

Osteolysis

Although total hip arthroplasty is one of the most successful of all surgical procedures, a number of open questions relating to implant design and materials remain. According to the Swedish Register (2012), osteolysis and aseptic loosening are responsible for 68.2 percent of all revisions. The bearing materials used and the volume, size, and biological effects of wear particles play a decisive role in the development of these conditions. The second most frequent complication is dislocation created by prosthetic impingement and insufficient joint stability.

Instability

Component impingement can result in a limited range of motion (ROM). In addition to exact implant positioning, the technical ROM achieved after implantation plays a crucial role. While large ball head and cup-liner diameters increase ROM, they are associated (in the case of PE, XPE and MoM) with an increased volume of wear particles. In a metal-on-metal articulation this can result in an elevated level of metal ions released into the surrounding tissues. Both mechanisms have been the subject of intense scientific discussion.

Hypersensitivity

The incidence of hypersensitivity and allergic reactions to metals is increasing in the world’s industrialized countries. The possible onset of hypersensitive reactions in patients treated with metal-on-metal bearings cannot be completely ruled out in advance. Metal allergies detected post surgery represent an additional burden for patients and insurers. It has therefore become even more important to use implant materials that exhibit a biologically compatible behavior in the body.
Synovial Fluid Lubrication

There remains a limited understanding of the actual processes governing the tribological performance of artificial joints. Unlike natural cartilage, even modern material combinations do not allow for a permanent lubrication film to separate the two surfaces. For that reason wear-resistant materials with optimal surface characteristics play a key role in determining the tribological outcome of arthroplasty.

Taper Corrosion

Corrosion at the head-neck taper has recently been found to be an important factor for the outcomes of THA, and its severity is multi-factorial. There is increasing evidence that in addition to wear reduction, ceramic femoral ball heads are also crucial in mitigating metal taper corrosion on the stem side, while experiencing no corrosion themselves.
More than 40 years of experience in ceramic hip replacements together with more than 11 million BIOLOX® implanted components confirms CeramTec as a world leader in this technology.

Surgeons all over the world put their faith in CeramTec’s pink-colored BIOLOX® delta ceramic. This colour gives surgeons the certainty that they are using implants of the highest quality and reliability for their patients – from CeramTec.

BIOLOX® delta is the only ceramic with 11 years of successful clinical experience and with more than 5 million implanted components.

Ceramic components made of BIOLOX® owe their superior properties to a unique material composition, the most modern production techniques and a multi-stage, comprehensive system of quality control.
Proven High Performance Ceramics

**Extreme Hardness** The purest raw materials and a manufacturing process that has been refined over decades ensure the highest degree of material uniformity, mechanical properties and perhaps most importantly, hardness. This results in excellent wear resistance.

**Exacting Sphericity** The femoral ball heads are produced in highest precision to assure that the articulation design produces the least amount of wear possible.

**Optimal Clearance** An exact, defined clearance between the BIOLOX® ball head and the BIOLOX® cup liner ensures excellent lubricating and gliding properties, minimal wear and outstanding functionality.

**Superior Surface Smoothness** Precisely executed final polishing gives the ceramic components the lowest surface roughness of all implant materials. The highly polished surface of BIOLOX® components demonstrates an average surface roughness of only around 2 nanometers.

**Nearly no Third-Body Wear** Unsurpassed hardness leads to nearly no surface damage to the articulation by third-body wear in ceramic-on-ceramic bearings. Foreign particles are broken down and extruded.

**Scratches** Cement particles and surgical instruments are not able to scratch ceramic surfaces – an important advantage when using cement and minimally invasive procedures.

**Excellent Biological Behaviour** Clinical experience shows no long-term adverse reactions to ceramic particles. Ceramic materials are biologically inert and exhibit unmatched biocompatibility and no known side-effects.

**Supreme Wettability** Hydrogen bonds with ceramic surfaces ensure excellent wettability and the formation of an effective lubricating film.
Superiority in Extreme Conditions

Foreign particles that are harder than the bearing surface lead to high levels of wear (left).

Surfaces made of high-performance ceramics remain largely unchanged (right).

Scratched surfaces increase abrasion in cup liners made of PE, XPE and metal (left).

Only an unscratched, smooth surface of the sort achieved in BIOLOX® ceramics enables optimal wetting, outstanding lubrication and minimal wear (right).

Hydrogen bonds with ceramic surfaces ensure excellent wettablility and the formation of an effective lubricating film.
Molecular Bonding

Loose Metal Structure

The molecular structures of metal alloys and ceramic materials are fundamentally different. In the case of a metal bond, the electrons orbit the atomic nuclei in an irregular manner and with relatively low bonding strength. As a result of this, metal ions continuously exit this molecular structure and are absorbed by the surrounding tissues. This occurrence can result in many different chemical and biological reactions.

Stable Ceramic Structure

In ceramic molecules, the electrons follow exact orbital paths. The electrons’ bonding strength is very high, making the molecules themselves extremely stable. This prevents ion formation and chemical and biological reactions within the body.

Metal bonding: irregular electron orbitals permit the formation of ions (left).

Ceramic bonding: tight electron orbitals largely rule out ion formation and chemical reactions (right).

Source: CeramTec GmbH

Source: CeramTec GmbH
The extremely stable ceramic bond virtually rules out any possibility of plastic deformation. While this permits the desired degree of extreme hardness, it also leads to a relatively high degree of brittleness. However, by optimising the ceramic composition one can achieve both extreme hardness and strength. Such composite models exist in nature and in modern technology.

Damascene steel combines hard and ductile alloys to form a highly firm and resistant material.

The protective pearl shell combines hardness and strength. It consists of hard-brittle aragonite and very elastic layers of protein and chitin.
The MULTIGEN PLUS Ceramic Knee
(Limacorporate, top)

The BPK-S Ceramic Knee
(Peter Brehm GmbH, middle, bottom)
Intelligent Reinforcement Mechanisms

A Fundamental Difference

Material sciences make a distinction between fracture strength and fracture toughness. Fracture strength is the maximum mechanical stress a material can withstand without fracturing. Fracture toughness is the resistance of a material to the propagation of cracks. Ceramic materials that have been in use for a number of years, such as BIOLOX®foote, already have a very high fracture strength.

BIOLOX®delta additionally exhibits an extremely high fracture toughness. It has a much higher capacity than other ceramic materials to resist the onset of cracking and to arrest the propagation of cracks. This property is based on two strengthening mechanisms.

Strength under Peak Stress

The highest degree of material stress in hard-on-hard bearings occurs in small diameters. Here, the strength of BIOLOX®delta offers an extra benefit: the well proven aluminum oxide (more than 80 percent by volume) ensures uncompromising hardness. Additional ceramic reinforcement elements ensure the material’s high resistance against fracture and crack propagation.
The microstructure of BIOLOX® delta: platelets with crack-stopping function (1), aluminum-oxide particle (2), zirconium-oxide particle (3).

Significantly smaller grain size and higher uniformity (compared to BIOLOX® forte, left) make even smoother surfaces possible and enhance the material properties.

The principle of conversion reinforcement: zirconium oxide particles act like airbags by absorbing impacting forces (left).

The principle of platelet reinforcement: platelet-shaped crystals block the propagation of cracks and thereby increase overall strength (right).

Airbag Function
The first strengthening mechanism is derived from the dispersion of tetragonal zirconium oxide particles in the microstructure. These particles, which are homogenously distributed throughout the stable aluminum oxide matrix, produce local pressure peaks in the area of cracks and thereby counteract their propagation.

Counteracting Crack Formation
The second strengthening mechanism is the result of in situ formation of platelet-shaped crystals in the oxide mixture. These platelets reduce cracking and crack propagation by neutralizing the crack energy. As a result of these strengthening mechanisms, BIOLOX® delta allows implant designers to create component geometries that were not possible with previous ceramic materials.
Long-lasting Strength

Improved Properties

The burst strength test assesses ceramic components by exposing them to axial loading until the point of material failure. Ball heads made of BIOLOX® delta (28mm) resist loads of more than 80 kN when tested. Larger ball heads show an even higher burst strength. The burst strength of BIOLOX® delta is considerably higher than that of conventional aluminum oxide ceramics. Furthermore, tests on standard material samples show that the bending strength of BIOLOX® delta is not adversely affected by repeated autoclaving. While hydrothermal instability can occur in objects made of pure zirconium oxide, such instability does not arise due to the alumina matrix present in BIOLOX® delta.

Enhanced Biomechanical Properties

The advantages of ceramic materials are especially apparent in large diameters (≥32mm). Simulator studies show that the rates of wear remain low despite the significantly larger friction surfaces, i.e. significantly lower than those of other materials. With ceramic components, surgeons are no longer forced to compromise wear rates and diameter, and can instead choose the best option for their patients.

Better Tribology

Dramatically reduced wear, enhanced range of motion and increased resistance to dislocation make this bearing the number one choice when it comes to functional improvement, durability and safety. In contrast to bearings with conventional and highly cross-linked polyethylene, the rate of wear does not increase for ceramic-on-ceramic bearings in the case of larger diameters. This leads to a superiority to all other bearing materials.
**Burst strength comparison:**

Burst strength is the point at which the component breaks. This corresponds to a force of more than 8 tons in the case of a ball head made of BIOLOX® delta (left).

BIOLOX® delta shows after 10 hours of autoclaving no changes during the burst test compared to a brand-new ball head.

Source: CT

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**Negative**

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**Positive**

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**Negative effect of increased metal head size** (left): hip joint simulator – highly crosslinked polyethylene, long-term wear rate after 10 million cycles.

**Positive effect of alumina ceramic ball head compared to metal femoral ball head** (right): hip joint simulator – highly crosslinked polyethylene, long-term wear rate after 10 million cycles.

Source: Fisher J, University of Leeds (UK), 2006
More Options

New Geometries

The superior material properties of BIOLOX® delta permit component geometries that were not possible with previous ceramics. Cup liners with thinner wall thickness are still able to offer increased stability and safety as they allow the use of ceramic-on-ceramic bearings in larger diameters. In contrast to metal and polyethylene, ceramic bearings with larger diameters show no significantly increased rates of wear.

Precise Lubrication Clearance

A further advantage of thin-walled ceramic components is the material’s high stiffness. This ensures that the precisely adjusted lubrication clearance between the components, which is necessary for the formation of a lubricating film, is not compromised by any deformation in the thin-walled elements.

Sizes and Material Combinations

The composition of BIOLOX® ball heads and cup liners permits any bearing combination of BIOLOX®forte and BIOLOX® delta from a tribological point of view. Ball heads made of both materials can also be combined with cup liners made of polyethylene and highly crosslinked polyethylene, specifically designed and approved/cleared by the authorities for this combination.

More Options

BIOLOX® ball heads must only be used in combination with femoral stems and stem tapers specifically designed by the implant manufacturers in cooperation with CeramTec and approved/cleared by the Authorities for this combination. BIOLOX® inserts must only be used in combination with acetabular shells specifically designed by the implant manufacturers in cooperation with CeramTec and approved/cleared by the Authorities for this combination. BIOLOX®OPTION ball heads and sleeves must only be used in combination with femoral stems and stem tapers specifically designed by the implant manufacturers in cooperation with CeramTec and approved/cleared by the Authorities for this combination. BIOLOX®DUO Bipolar systems must only be used in combination with BIOLOX®forte and BIOLOX® delta ball heads specifically designed by the implant manufacturers in cooperation with CeramTec and approved/cleared by the Authorities for this combination.

Important: Please keep in mind that there is no international standard defining the design of the stem taper or their nomenclature. For this reason any reference to stem tapers such as 12/14, 10/12 etc. does not necessarily mean that their design is identical. From the tribological point of view, BIOLOX®forte, BIOLOX®OPTION and BIOLOX® delta ball heads can only be used in combination with BIOLOX®forte or BIOLOX® delta inserts or PE or XPE inserts in combinations which are specifically designed by the implant manufacturers in cooperation with CeramTec and approved/cleared by the Authorities for this combination.
Application Diversity

**Optimized Revision**

BIOLOX®OPTION offers a suitable solution for the rare case of ceramic component fracture. The ceramic revision femoral ball head (BIOLOX®OPTION) helps to significantly reduce the rate of wear-related osteolysis following revision hip arthroplasty. In the case of an acetabular cup revision, the surgeon has the option to use a CoP, CoXPE or CoC bearing when a firmly fixed stem remains in situ.* Thus, a bearing couple can be implanted as an upgrade solution which exhibits a greater degree of wear resistance than the bearing couple used for primary hip arthroplasty.

**Knee Arthroplasty**

The geometry of bearings used in knee arthroplasty is significantly more complex than that of the hip joint. The improved material properties of BIOLOX®delta have made it possible to manufacture safe ceramic components for such geometries.

**Shoulder Arthroplasty**

Polyethylene wear, loosening, metal allergy and infection are among the greatest problems in shoulder arthroplasty which makes the use of BIOLOX® ceramic materials a logical choice. Introducing BIOLOX® ceramics into shoulder arthroplasty will extend the clinical applications of these materials.

* The stem taper deformations are described in IFU BIOLOX®OPTION.
Further Applications

Our customers from the medical devices industry are constantly enquiring about new capabilities and uses of bioceramics. The most urgent requests are for wear debris reduction, improving imaging, preventing microbial contamination and providing options for patients with hypersensitivity to metals. Bioinert ceramic components offer proven and potential approaches to solving these problems, and are the focal point of our research and development. The goal of CeramTec Medical Engineering is to create ceramic products for new medical treatment options in areas such as spine, small joints, and dental products.

The Strengths of BIOLOX®delta

- Excellent biological behaviour*
- Significantly low taper corrosion*
- No metal ion release*
- No known pathogenic reaction to particles*
- Resistant to third-body wear*
- Excellent wettability*

*References available on the file at CeramTec GmbH on request
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Literature:


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