DePuy Synthes
COMPANIES OF Johnson & Johnson

BIOLOX® *delta*

CMC
matrix-composite ceramic

PINNACLE®
HIP SOLUTIONS

MATERIAL RATIONALE

INTRODUCTION

Alumina ceramic femoral heads have been used since the 1970s as an alternative bearing material in total hip arthroplasty (THA). Alumina ceramic heads offer extreme hardness, exacting sphericity, optimal clearance and superior smoothness. With over 4 million ceramic ball heads implanted worldwide, a significant amount of clinical follow-up is available.[1]

While the clinical experience with alumina ceramic femoral heads has been generally good, there have been component fracture failures resulting from material issues in first generation alumina ceramics. Incremental material and processing changes have been implemented to reduce this risk. The introduction of high purity, chemically derived, sub-micron alumina powders — as well as improved processing technologies, such as hot isostatic pressing (HIPing) — has significantly improved material properties of alumina ceramics. The current generation of alumina material for orthopaedic applications, BIOLOX® *forte* (CeramTec GmbH), has been available since 1994.

While improvements to early alumina ceramics have been significant, limitations in the mechanical properties of pure alumina ceramics coupled with the higher demands of today's younger patients required the development of an advanced ceramic material. The result of that development is BIOLOX® *delta* Ceramic, manufactured by CeramTec GmbH, a world leader in ceramics and the leading company in the manufacturing of bioceramics for orthopaedic applications.

AN ADVANCED MATERIAL

BIOLOX *delta* is a zirconia-toughened, platelet-reinforced alumina ceramic (ZPTA), designed to incorporate the wear properties and stability of alumina with improved material strength and toughness and a distinctive color. BIOLOX *delta* material contains approximately 82 percent alumina, 17 percent tetragonal zirconia particles, 0.5 percent strontium aluminate, and 0.5 percent chromium oxide. All values are approximate values by volume composition.

An alumina ceramic matrix provides BIOLOX *delta* with increased hardness and material stability over previous generation ceramic materials. In zirconia-toughened alumina (ZTA) materials, some of the original hardness of the alumina material is lost. The addition of chromium oxide imparts the material with its distinctive "mauve" color. Finally, strontium oxide (SrO) added to the material forms strontium aluminate platelets during the sintering process. These platelets prevent microcracks in the material from advancing by dissipating crack energy. This results in a further increase of material strength and strength distribution, as well as an increase in fracture toughness.[1,2]

Alumina matrix

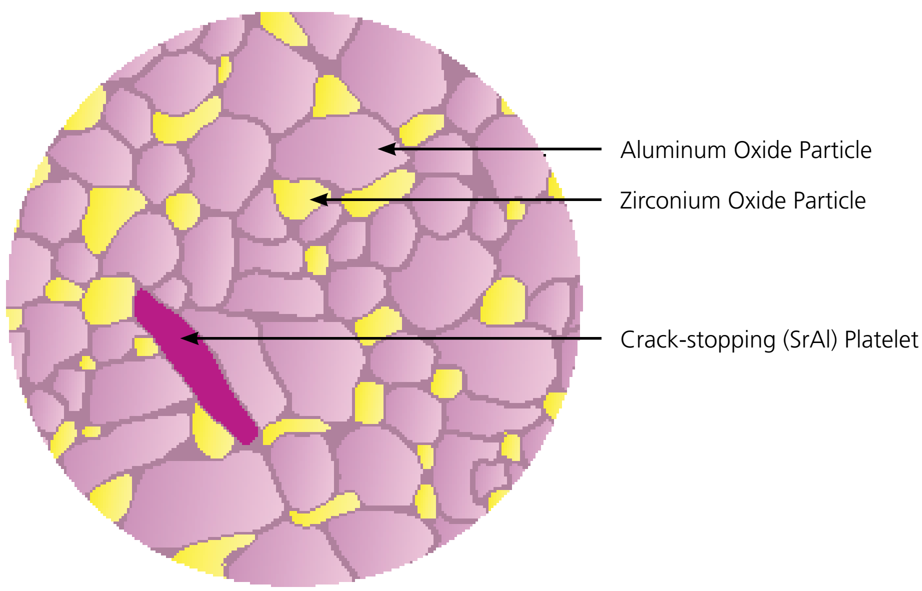
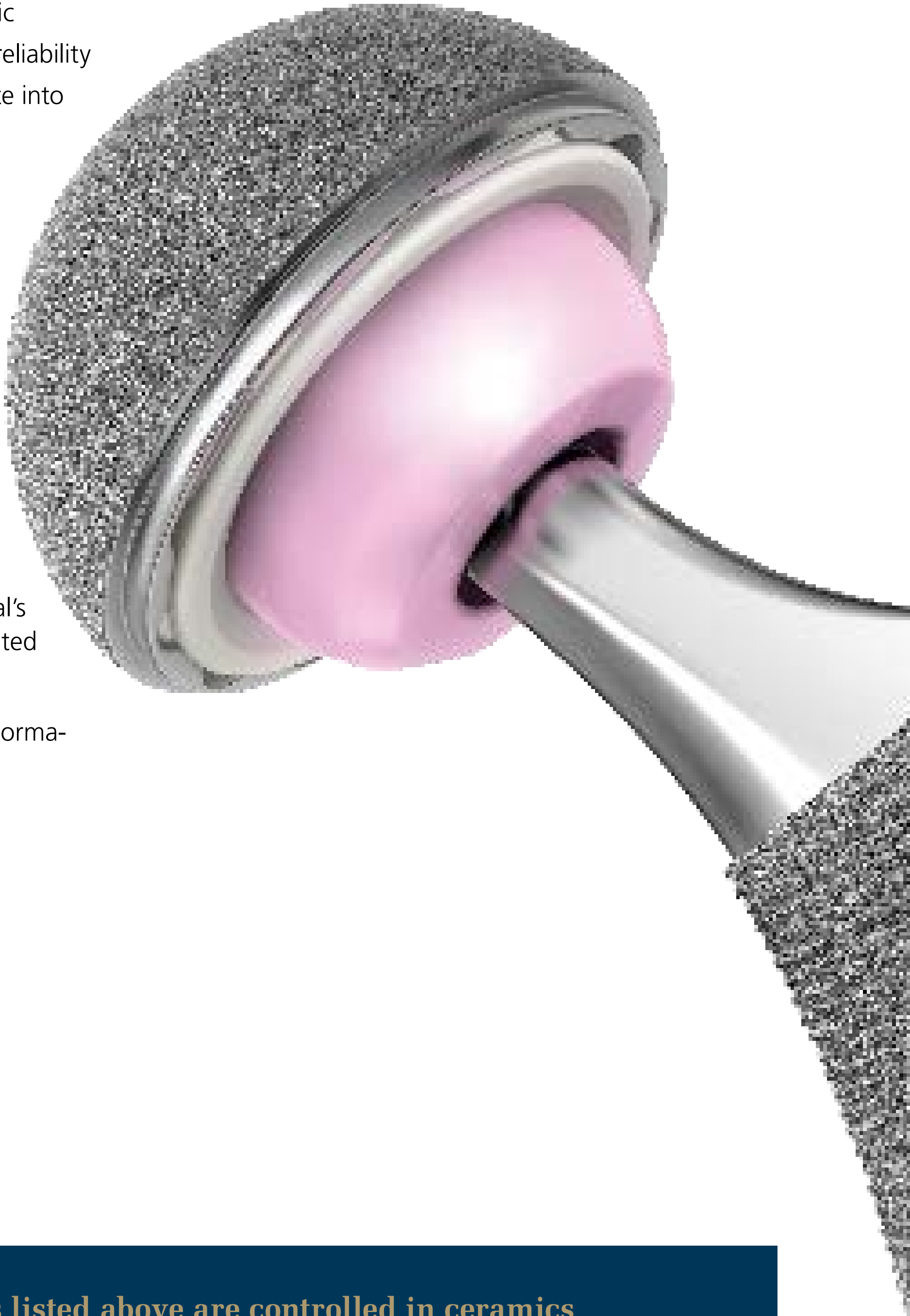


Figure 1

The final product is a high-strength material with high hardness and high toughness, a material well suited for applications in THA.

MATERIAL PROPERTIES OF CERAMICS

Important characteristics of successful orthopaedic implants include good mechanical performance, reliability and wear resistance. These characteristics translate into the engineering material properties of strength, fracture toughness, stability and hardness.



- **Strength** refers to a material's ability to withstand applied loads.
- **Fracture toughness** is a measure of a material's resistance to crack propagation under stress.
- **Stability**
  - **Chemical stability** indicates a material's resistance to microstructural changes during the service life of the implant.
  - **Hydrothermal stability** indicates a material's resistance to change when exposed to elevated temperatures and humidity.
- **Hardness** is the resistance of a material to deformation and relates to a material's wear resistance.

The material properties listed above are controlled in ceramics by managing material composition, density, porosity and grain size.

STRENGTH

Strength refers to a material's ability to withstand applied loads. Strength is controlled by the material grain size and sintered density. A reduction in grain size contributes to an increase in strength.[3] Advances in the manufacturing of alumina ceramics have decreased the grain size considerably over early generation alumina ceramics. These advances have also increased density by reducing the material's porosity. BIOLOX *delta* takes advantage of these manufacturing advances and offers an alumina matrix with a grain size less than 1.5 µm. Additionally, the zirconia particles in the matrix have a grain size of 0.2 – 0.6 µm.

One measure used to test the strength of a ceramic femoral head is a burst test, which measures the load required to fracture a ceramic head assembled on a stem taper. Due to their unique material composition, BIOLOX *delta* Femoral Heads exhibit substantially improved burst strength compared to early generation alumina ceramic heads (See Figure 2 & Figure 3).[2,3]

Burst Strength[2]

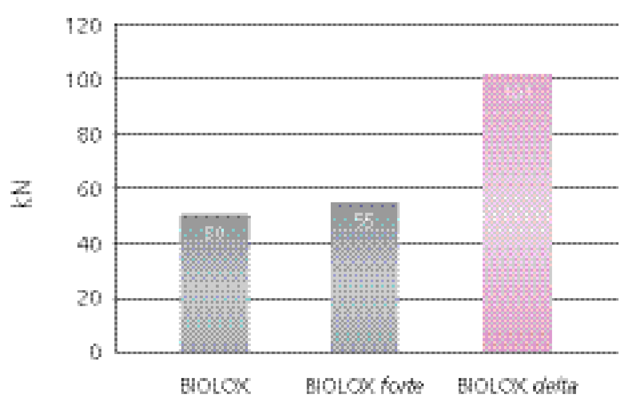


Figure 2

Flexural Strength[3]

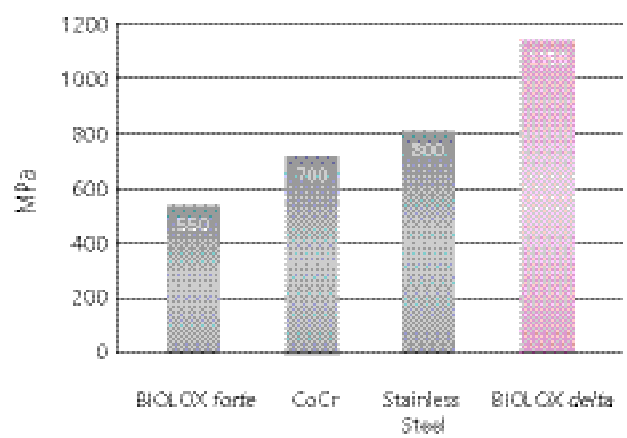


Figure 3

Strength refers to a material's ability to withstand applied loads.

FRACTURE TOUGHNESS

Fracture toughness is a measure of a material's resistance to crack propagation under stress. Metal and ceramic implants exhibit scratches and microcracks as a result of polishing and finishing. Maximizing fracture toughness reduces the opportunity for these scratches and microcracks to propagate, potentially resulting in component failure. The addition of zirconia particles and strontium oxide to the alumina matrix provides this increase in fracture toughness to BIOLOX *delta* (Figure 4).

This increase in fracture toughness for the BIOLOX *delta* material over pure alumina is shown in Figure 5 below. The toughness is demonstrated in both the burst strength and flexural strength of BIOLOX *delta* mentioned previously (Figure 2 & Figure 3).

Biolox *delta* Particle Reinforcement Mechanism for Increased Fracture Toughness

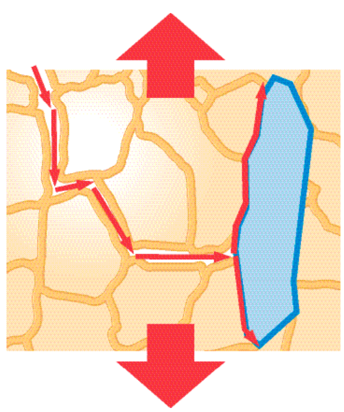


Figure 4
In the event that a microcrack advances through the material, the crack energy is dissipated by large grains (mixed oxide platelets).

Fracture Toughness[3]

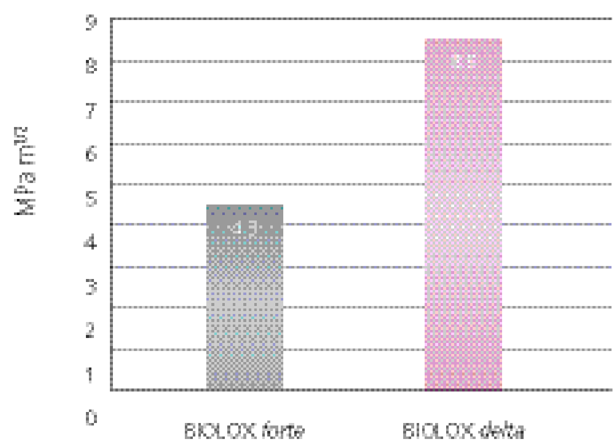


Figure 5

Fracture toughness is a measure of a material's resistance to crack propagation under stress.

STABILITY

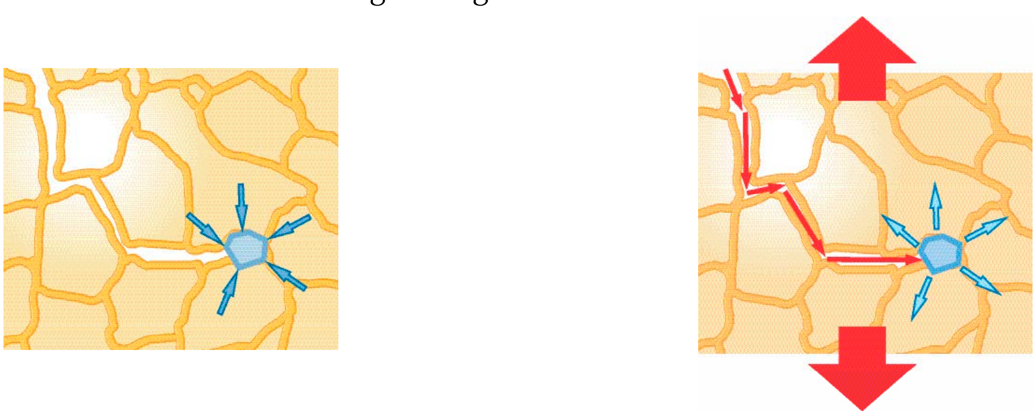
Reliability is the extent to which a product yields the same result on repeated uses; it is a measure of the predictability of a product's performance. Two key factors for the long term in vivo performance of ceramic implants are chemical and hydrothermal stability.

Chemical stability indicates a material's resistance to microstructural changes during the service life of the implant. Oxide ceramics (alumina and zirconia) are well known and accepted in biomedical applications with respect to their chemical stability and biocompatibility. These ceramics exhibit corrosion resistance in vivo. In addition, the biocompatibility of oxide ceramic bulk materials and particulate debris has been demonstrated through years of clinical use.

Hydrothermal stability indicates a material's resistance to change when exposed to elevated temperatures and humidity. BIOLOX *delta* is based on an alumina matrix. Microstructurally, medical grade alumina is a single-phase material and therefore offers excellent phase stability.

In contrast, zirconia ceramic is a complex, multi-phase material. One benefit of this material, if manufactured appropriately, is increased fracture toughness through a process called "transformation toughening." If a microcrack in the material reaches a tetragonal phase particle, a phase transformation changes the zirconia particle from a tetragonal to a monoclinic state, where the particle increases in volume approximately 3 to 4 percent. The resulting increase in volume can close the microcrack, making the material more fracture resistant (Figure 6).

BIOLOX *delta* transformation toughening mechanism for increased fracture toughness



A metastable zirconia particle maintains its tetragonal phase due to compressive forces within the surrounding alumina matrix.

If the leading edge of a microcrack encounters a tetragonal zirconia particle, the crack energy causes a phase transformation, increasing the particle volume and closing the crack tip.

Figure 6

Chemical stability indicates a material's resistance to microstructural changes during the service life of the implant.

Under some hydrothermal conditions (elevated heat and humidity) an uncontrolled phase transformation of zirconia ceramics can occur. An uncontrolled phase transformation affects multiple particles simultaneously, creating internal strains and reducing material strength.[5]

The distribution of the zirconia particles allows the benefits of transformation toughening to close microcracks, but because the zirconia particles do not share grain boundaries with each other, a chain effect of transformation is prevented. Compressive forces within the alumina matrix prevent an uncontrolled phase transformation of the zirconia particles in the absence of a microcrack because there is no room for volume expansion.

BIOLOX *delta* benefits from the improved strength of transformation toughening, while maintaining hydrothermal stability. Multiple cycles in an autoclave show no degradation in the mechanical strength of the material, as compared to a non-sterile control.[7]

Material Stability[6]

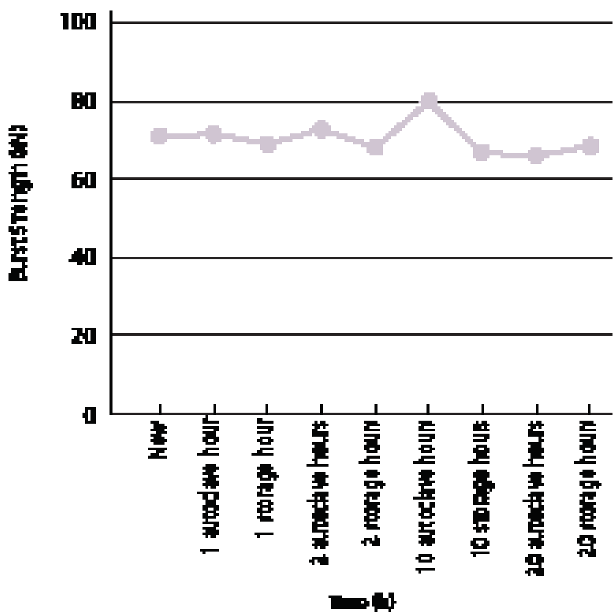


Figure 7

Hydrothermal stability indicates a material's resistance to change when exposed to elevated temperatures and humidity.

HARDNESS

Hardness is the resistance of a material to deformation and relates to a material's wear resistance. In order to minimize wear at the articular surface of a total hip replacement, it is essential to use femoral heads with a smooth surface finish. An exceptionally smooth surface can be achieved with high hardness materials such as BIOLOX *delta* through precise polishing processes. The BIOLOX *delta* Ceramic offers a material hardness of about 2000 HV, nearly as hard as diamond (Figure 8).[3,4,7]

In addition, this high level of hardness can provide substantial resistance to surface scratching from third body particulate and the potential for wear reduction benefits in vivo.

Material Hardness[3,4,7]

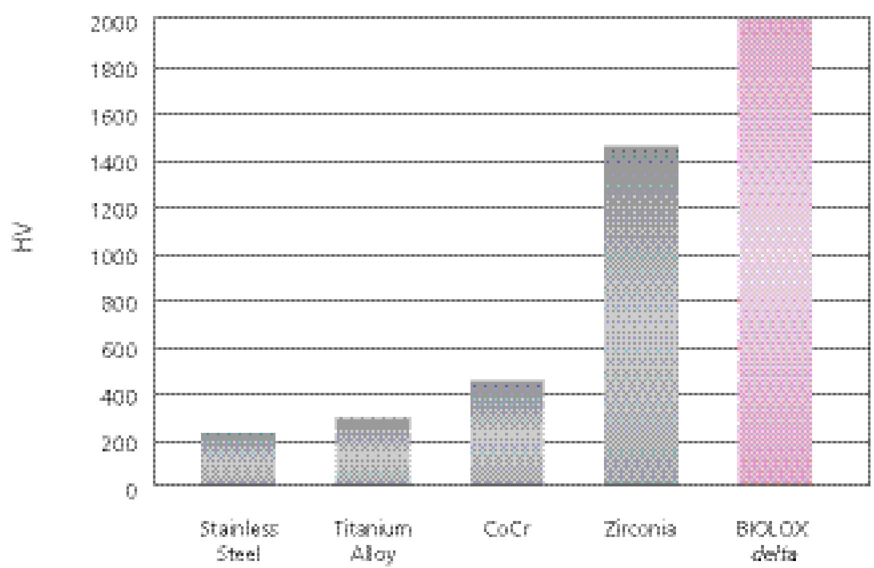


Figure 8

Hardness is the resistance of a material to deformation and relates to a material's wear resistance.

TESTING

All BIOLOX *delta* Ceramic Femoral Heads are 100 percent Proof Tested. Each femoral head produced is subjected to an overload in a manner that ensures the part is not damaged in any way, yet minimizes the possibility of an internal flaw not being discovered. The Proof Test is only part of an entire quality system, which performs several specific and ongoing checks throughout the entire manufacturing process. Product characteristics such as chemical composition, microstructure (grain size, density, homogenous distribution of elements), surface finish and dimensional compliance are inspected to ensure design specifications are consistently met (Figure 9). This standard of quality provides high product reliability.

BIOLOX - Comparison of Three Generations[1]

		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*	MPa	500	45	631	38	1384	67
E-module	GPa	410	1	407	1	358	1
Fracture toughness K_{Ic} **	MPa $m^{1/2}$	3.0	0.45	3.2	0.4	6.5	0.3
Hardness HV1	GPa	20	–	20	–	19	–

* Average values measured for BIOLOX *delta* from 2006.

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

Figure 9

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