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Advances in zirconia toughened alumina biomaterials for total joint replacement

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ABSTRACT

The objective of this article is to provide an up-to-date overview of zirconia-toughened alumina (ZTA) components used in total hip arthroplasties. The structure, mechanical properties, and available data regarding the clinical performance of ZTA are summarized. The advancements that have been made in understanding the in vivo performance of ZTA are investigated. This article concludes with a discussion of gaps in the literature related to ceramic biomaterials and avenues for future research.

1. History

Engineering ceramics have been used as components in orthopaedic implants since the 1970s, when Boutin and Blanquaert (1981) began to use an artificial hip joint comprised of alumina, Al_2O_3, in a 10-year study between 1970 and 1980. Around the same time, Shikata et al. (1977) reported their experience with alumina femoral heads articulating against irradiated ultra-high molecular weight polyethylene acetabular components. These two pioneering tribological applications of ceramic biomaterials in artificial hips, namely ceramic-on-ceramic (COC) and ceramic-on-polyethylene (COP) bearings, continue to be used in orthopaedics today. In the 1980s, alumina biomaterials underwent evolutionary changes in manufacturing technology, resulting in greater density, lower porosity, and increased fracture strength. Thus, the technology underlying both the composition and fabrication of contemporary high performance ceramics for orthopaedic implants has evolved over the past four decades.

Researchers in Japan and Europe were first attracted to alumina ceramic bearing materials due to their low friction, wettability, wear resistance, and biocompatibility. However,

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the first applications of alumina in orthopaedics were associated with high fracture rates. In the 1980s, zirconia, ZrO_2, was introduced in orthopaedics because of its improved fracture toughness and mechanical strength relative to alumina. Zirconia owes its higher fracture toughness to a stress-induced phase transformation from its metastable tetragonal phase to its stable monoclinic phase at ambient temperatures. During the 1990s, stabilized zirconia was widely used as ceramic femoral heads in COP bearings because of its higher toughness and strength relative to alumina. However, depending on the manufacturing conditions and hydrothermal effects in vivo, the monolithic tetragonal zirconia may be too unstable and transform catastrophically into the monoclinic phase (Clarke et al., 2003).

In 2001, St. Gobain Desmarquest, the largest manufacturer of zirconia femoral heads, announced a worldwide recall of selected batches due to deviations in thermal processing during their manufacture (Masonis et al., 2004). These recalled batches of zirconia heads were associated with high fracture rates in vivo (Masonis et al., 2004). Although zirconia use would continue in selected markets, such as Japan, the Desmarquest withdrawal resulted in a loss of confidence in zirconia as a reliable orthopedic biomaterial throughout Europe and the United States (Chevalier, 2006). Contemporaneously, alumina ceramic-on-ceramic (COC) bearings were approved in the United States in 2003, but adoption faltered after increasing reports of bearing noise (squeaking) appeared in the scientific literature as well as the lay press. Interest in COC hip implants in the United States, where only alumina was approved, waned. Attention of the surgical community focused on large diameter, metal-on-metal (MOM) bearings as a hard-on-hard alternative to articulations incorporating polyethylene.

To address the clinical issues associated with the available designs, two promising COC alternatives to zirconia emerged for orthopaedic bearings. The first was based on zirconium alloy, which, through oxidation, generated a ceramicized surface a few microns thick. This oxidized zirconium was marketed under the trade name Oxinium™ by Smith and Nephew Orthopaedics (Memphis, TN) (Sheth et al., 2008). Ceramic composites are a second, and more broadly available, alternative to zirconia. Fabricated from mixtures of alumina and zirconia, and known as zirconia-toughened alumina (ZTA), or alumina-toughened zirconia (ATZ) ceramic composites are suitable for both COP and COC applications. ATZ comprises 80% tetragonal zirconia polycrystals (ZrO_2–TZP) and 20% alumina (Al_2O_3) and is reported to have superior mechanical and tribological properties compared to alumina. ATZ components that are developed include Bio-Hips (Metoxit AG, Thayngen, Switzerland) and Ceramys® (Mathys Ltd., Bettlach, Switzerland). Bio-Hip possesses the ability to withstand loads four times greater than conventional alumina implants but is still not commercialized(Chevalier, 2006); whereas Ceramys® has been commercialized in 2007.

ZTA components are comprised of an alumina-rich composition where zirconia is evenly dispersed in the alumina matrix. These ceramics exhibit superior strength and toughness compared to conventional alumina and zirconia, further detailed in this review. Ceramic composites thus represent a major new advancement of clinically available orthopaedic biomaterials. The present review provides an up-to-date overview of zirconia-toughened alumina ceramic components with a summary of its structure, properties, and available data regarding its clinical performance. Previous surveys have described, in detail, the mechanisms of in vivo degradation in zirconia (Chevalier, 2006; Clarke et al., 2003). This article builds on our previous review (Huet et al., 2011) that focused on the design, reliability, and clinical performance of alumina femoral heads. In this article, we concentrate on the advancements that have been made in understanding the in vivo performance of zirconia-toughened-alumina (ZTA). This article concludes with a discussion of gaps in the literature related to ceramic biomaterials and avenues for future research. In this review, we emphasize recent advancements in these topics that have been published in the past 5 years.

2. Composition and properties of ZTA

Zirconia toughened alumina (ZTA), an alumina matrix composite ceramic, in which alumina is the primary or continuous phase (70–95%) and zirconia is the secondary phase (30% to 5%), is a material that combines the advantageous properties of monolithic alumina and zirconia. Under the condition that most of the zirconia is retained in the tetragonal phase, the addition of zirconia to alumina results in higher strength and fracture toughness with little reduction in hardness and elastic modulus compared to monolithic alumina ceramics. Additionally, the excellent wear characteristics and low susceptibility to stress-assisted degradation of high performance alumina ceramics is also preserved in zirconia toughened alumina ceramics (DePoorter and Readey, 1990). Higher fracture toughness allows for the manufacture of thinner liners to reduce risk of impingement and dislocation, and improve stability.

Currently, there are two commercially available ZTA biomaterials for hip arthroplasty applications: Biolox Delta by CeramTec Medical Products (Plochingen, Germany) and AZ209 by KYOCERA Medical (Osaka, Japan) (Table 1). Biolox

Table 1 – Product descriptions and manufacturers for ZTA hip implants, (CeramTec; Kyocera Medical).

Manufacturer	Product name	Availability	% Zirconia	% Alumina	Stabilizers	% Additives
CeramTec AG	Biolox Delta	Currently on the market worldwide	22.5 wt%	76.1 wt%	Yttria	1.4 wt% (chromium, strontium and others)
Kyocera Medical	Bioceram, AZ209	Currently on the market in Japan	19 wt%	79 wt%	No stabilizers for zirconia	2 wt% other