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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

Delta was commercialized by CeramTec in 2003. As of December 2011, CeramTec has produced 1,285,000 Delta ball heads, 659,000 Delta inserts and 142,000 Delta revision ball heads for a total 2,086,000 components (Heros, 2012). AZ209 was commercially released by KYOCERA Medical in Japan during 2011. Details about the composition of Biolox Delta and AZ209 are summarized in Table 1. Other medical ceramic suppliers are working on developing ZTA biomaterials for hip arthroplasty, but these new materials have not yet been commercialized.

ZTA composites have mechanical properties that are often better than monolithic alumina or stabilized zirconia. They achieve these properties by using several mechanisms: controlling the phase transformation in the zirconia particles, blocking crack growth by controlling grain shape, and strengthening the alumina phase itself through control of grain size and various additions. These mechanisms are discussed below, in turn.

2.1. *Phase transformation and physical properties*

In zirconia, the stress-induced phase transformation from the metastable tetragonal phase to the monoclinic phase at ambient temperatures results in a 3–5% volume expansion and approximately 7% shear strain (De Aza et al., 2002). The induced volume change and strain oppose crack propagation, thereby improving the fracture toughness of the ceramic (Clarke et al., 2003). This phase transformation may also lead to microcracking, which enhances fracture toughness by effectively distributing the stress ahead of the main crack. However, microcracking is beneficial only if it remains limited; extensive microcracking will reduce strength (Sommer et al., 2012).

Phase transformation on the surface, also known as low temperature degradation or ageing, may have undesirable effects on hip bearing performance (Clarke et al., 2003). The monoclinic phase of zirconia has lower hardness and lower resistance to crack formation compared to the tetragonal phase, making the post-transformation component more susceptible to damage and surface roughening. In vivo, this hydrothermally induced degradation of hardness and strength is especially seen in regions of contact as a result of higher frictional stresses (Clarke et al., 2003). If monoclinic phase transformation occurs at the bearing surface of the zirconia, the surface roughness can increase due to the increase in volume. Increased roughness at this interface leads to an increase in the wear rate (Liang et al., 2007). When phase transformation occurs at the head–trunnion interface, it can initiate fracture (Clarke et al., 2003). Additionally, the effects of the phase transformation toughening mechanism become unusable for prevention of crack propagation as the tetragonal phase becomes consumed by hydrothermal degradation (Santos et al., 2004).

The same transformation mechanism contributes to the increased toughness of ZTA composite ceramics. The factors that contribute to the phase transformation are complex and still not well understood (Clarke et al., 2003); however, with the Desmarquest recall it is known that the performances of these ceramics depend on the ability to control the behavior of transformation through adjustment of composition and the manufacturing process. The fabrication objective for all transformation-toughened ceramics is the production and retention of a metastable phase (tetragonal ZrO_2) that transforms to a stable phase (monoclinic ZrO_2) at or near room temperature when exposed to stress. Controlled composition and processing conditions must produce a component where spontaneous tetragonal-to-monoclinic transformation does not occur during cooling to room temperature (Hannink et al., 2000). To retard phase transformation, monolithic zirconia used in orthopaedic components is stabilized by additions of yttria or magnesia.

The transformation toughening mechanism mentioned previously for zirconia also holds true for ZTA materials. Enhanced crack propagation resistance is achieved due to the transformation in the zirconia phase that occurs around the crack tip, which requires extra energy to propagate the crack through the transformed compressive layer. The theoretical mechanism expected to occur in commercial ZTAs is depicted in Fig. 1. The stress induced by the crack and the loss of constraint by the surrounding matrix leads to tetragonal-to-monoclinic transformation in the zirconia grain (Fig. 1). Studies quantifying the in vitro performance support the existence of this mechanism (Clarke et al., 2009).

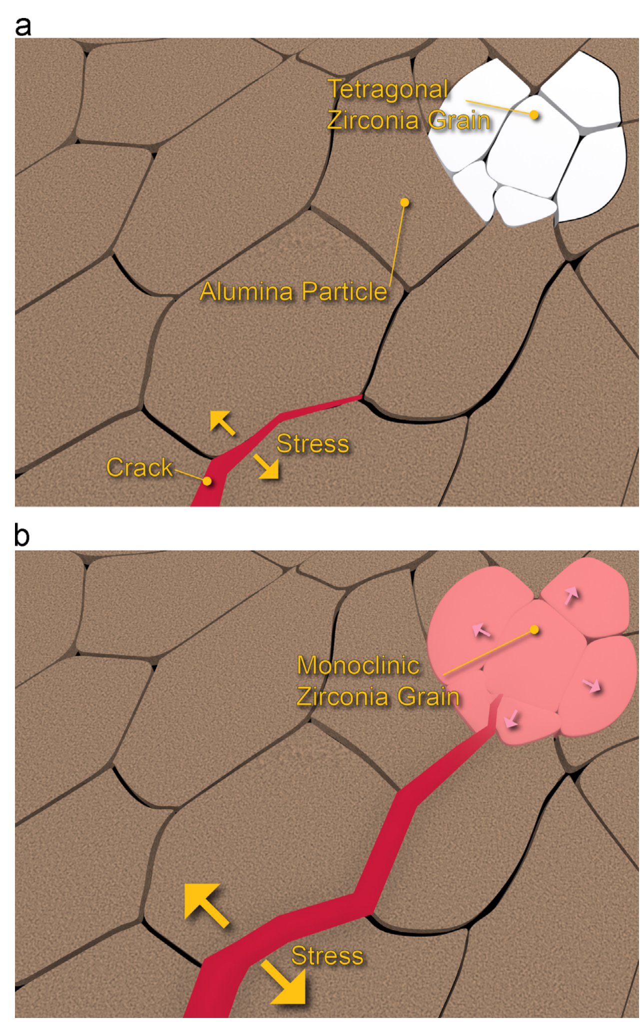

Fig. 1 – Example of phase transformation and crack propagation (Kyocera Medical).

There are some important differences between the transformation mechanism seen in monolithic zirconia and zirconia toughened composites. One of the drawbacks of monolithic zirconia is its instability: Monolithic zirconia is prone to chemisorption when exposed to polar water molecules. Once a grain has transformed, it stresses the neighboring tetragonal zirconia grains, which makes them prone to transform as well. Thus the transformation spreads through the material and leads to the previously mentioned low temperature degradation and deterioration under long-term usage. The composite material has the advantage of possessing a stable matrix phase that encases the phase transformation in a local region and prevents transformation from propagating to neighboring grains. Due to this containment, large uplifts are avoided in the composite material; whereas in pure zirconia, water radicals penetrate the lattice and progressive tetragonal-to-monoclinic transformation at the surface results in surface roughening and micro-cracking (Chevalier et al., 2009). Hence, ZTA composites are more stable and retain their tetragonal zirconia content much better compared to monolithic zirconia components when exposed to simulated hydrothermal conditions in vitro (Chevalier et al., 2011; Pezzotti et al., 2010b).

Zirconia goes through phase transformation through nucleation of monoclinic zirconia grains on the surface; this transformation spreads to other zirconia grains in contact with the ones that have already transformed. Since the transformation mechanism spreads from grain to contacting grain, Pecharromán et al. (2003) have shown that the maximum zirconia fraction to limit the spread of transformation is related to the percolation threshold, or in other words, the interconnectedness of the zirconia phase. This fraction is established to be 16 vol% and KYOCERA Medical has developed their composition according to this percolation threshold (Pecharromán et al., 2003; Ueno, 2012).

Various in vitro studies have been conducted to compare the aging resistance of zirconia and ZTA. Pezzotti et al. (2010b) exposed ZTA and monolithic zirconia components to hydrothermal effects in vitro, in which the encasing mechanism of the alumina matrix provided superior low temperature degradation properties to the ZTA over pure zirconia. After long-term exposure (>50 h) to hydrothermal degradation, the thickness of phase transformation measured on the surface for ZTA components was half that of pure zirconia components. In the same study intermediate exposure times ($10<t<50$ h) had higher transformation thickness on the surface for ZTAs suggesting that low temperature hydrothermal transformation occurs sooner in these components. Inspection of surface roughness of all components after degradation revealed lower roughness for ZTA compared to pure zirconia. It was concluded that even though low temperature degradation occurs faster in the upper layers of ZTA components, it is contained in a shallower layer and does not affect the surface roughness as much as in pure zirconia components (Pezzotti et al., 2010b). This may be explained by the ZTA being below the percolation threshold and the interconnectedness of the zirconia grains being limited by the alumina matrix, making it more difficult for the phase transformation of one grain to trigger that of other grains. However, this phenomenon has not been fully described by the authors.

Concentrating on the surface roughness, inspection of the in vitro stability of commercially available zirconia and ZTA femoral heads after exposure to hydrothermal effects revealed superior performance of ZTA components. It was observed that the tetragonal-to-monoclinic transformation of the zirconia grains in the composite microstructure does not produce significant alterations to the surface topography larger than machining effects. The superiority was attributed to the overall architecture of the composite material, not to the individual property of the zirconia contained within the material (Pezzotti et al., 2011).

The encasing that limits the transformation of zirconia grains in ZTA composites also indicates that they are less susceptible to stress-assisted corrosion in water or body fluids (Chevalier et al., 2011), potentially reducing wear rates and making them better candidates for in vivo applications.

The wear resistance of ZTA composites was investigated in a study that compared the wear performance of ZTA retrievals and samples put into a hip simulator for 5 million cycles. The monoclinic content for all ZTA components plateaued at approximately 30% of the zirconia phase both in the main wear zone and stripe wear zone which suggests that further transformation is suppressed until the alumina matrix undergoes further wear (Clarke et al., 2009). The simulated wear study compared the wear rate of three different component combinations: ZTA/ZTA, ZTA/alumina and alumina–alumina (AL/AL). The ZTA/ZTA combination displayed the highest resistance to wear and lowest amount of surface roughness after 5 million cycles. The AL/AL combination was the most susceptible to wear and resulted in 6–12 times higher wear rates compared to ZTA/ZTA bearings and three times higher rates compared to ZTA/AL hybrid bearings.

The superiority of ZTA composites over both alumina and monolithic zirconia is also supported by the static and cyclic loading experiments comparing the performance of alumina, zirconia and ZTA composite materials (Chevalier et al., 2011). In these experiments, it is seen that the toughness values for zirconia and ZTAs decrease with cyclic loading due to low temperature degradation, while the toughness of alumina remains unaffected. However, the values of toughness and threshold of stress for crack propagation for nano- and micro-composite ZTAs are well above the values for monolithic alumina and zirconia. This observation supports the assumption that the ZTA displays superior toughness primarily due to its overall composite architecture and secondarily due to the specific properties of the zirconia and alumina phases present in its composition.

It is not firmly established in the literature that the improved mechanical properties in vitro will translate into lower rates of wear, fracture and revision in vivo. Hip simulation and other in vitro studies can only partly represent the exposure in the human body and have limitations in representing the effects of the stresses at the bearing surfaces which may also accelerate low temperature degradation in vivo. Surface stability studies of explanted bearings will provide higher accuracy in quantifying the in vivo performance of ZTA components, while longer implantation times and more retrieval studies will make the strengthening mechanism within the ZTA more apparent.

2.2. *Using platelets to block crack growth*

An additional toughening mechanism in ZTAs consists of using platelet-like crystals to block or deflect crack growth. These crystals are depicted in both the KYOCERA Medical AZ209 and the CeramTec Biolox Delta technical documentation. The CeramTec and KYOCERA Medical formula utilizes strontium oxide crystals to enhance toughness and diffuse crack energy (Hamilton et al., 2010; Ueno, 2012). Addition of strontium oxide creates strontium aluminate composites, which form rod structures with higher crack propagation energy. These rods possess a maximum length of 3 μm and account for about 3% of the volume. Fig. 2 illustrates the platelet toughening mechanism with the depiction of the Delta strontium aluminate rod. The frames in Fig. 2 depict crack propagation through alumina grains until the crack is deflected by the strontium aluminate rod. Incorporating multiple reinforcing mechanisms throughout the structure of the material makes the component more reliable because it becomes more effective in deflecting cracks closer to the surface and in avoiding fracture (Kuntz, 2007).

2.3. *Grain size control*

The overall grain size is generally smaller in ZTA materials, which contributes to their higher toughness and generally higher mechanical properties. The alumina grain size, in particular, is reduced due to the addition of zirconia (De Aza et al., 2002). In the first reported study of alumina toughened by zirconia in 1978 higher fracture toughness was measured for the composites compared to alumina which was attributed to the stress-induced transformation toughening and the reduced grain size of the alumina matrix (Wang and Stevens, 1989).

2.4. *Strengthening additives*

In ZTA composites stabilizers are commonly used to maintain the zirconia grains in the tetragonal phase at ambient

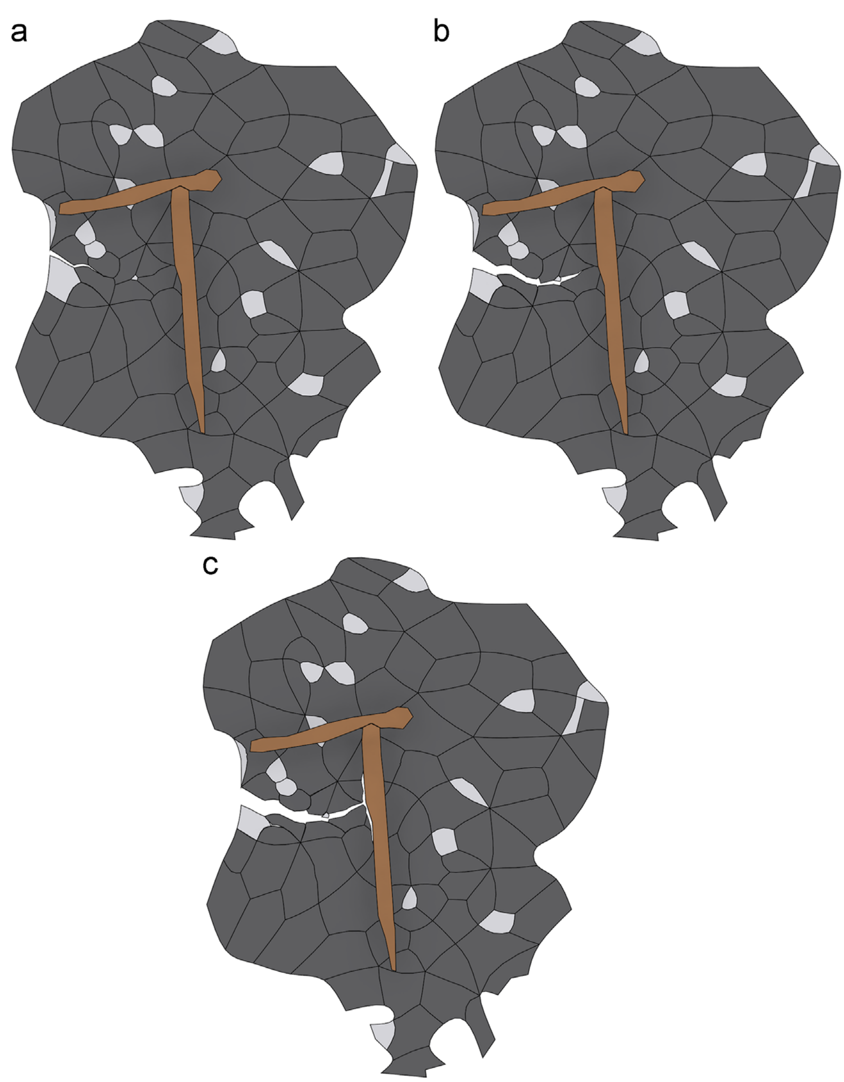

Fig. 2 – An illustration of reinforcing particles, including strontium aluminate and tetragonal zirconia in an alumina matrix (CeramTec).

temperatures. Biolox Delta ZTA, more widely known in the US, contains yttria as stabilizer and other additives such as chromium and strontium to add toughening mechanisms to the product (Hamilton et al., 2010). The yttria content of zirconia grains in Biolox Delta is 1.3 mol%, lower than the content usually necessary for monolithic zirconia due to the stabilization effect of the alumina matrix (Chevalier et al., 2009). KYOCERA Medical also takes advantage of the stabilizing effect of the alumina matrix and does not use any stabilizers in the zirconia phase of AZ209. It is claimed that under controlled zirconia particle size and distribution, the binding force of the alumina to the zirconia enables stability. Upon cooling from the processing temperature, the tetragonal zirconia particles will be constrained from transforming by the surrounding alumina matrix and will be retained in their metastable state (Barsoum, 2003).

The investigation of the effect of yttria content revealed that there is an optimum concentration of yttria that contributes to stability. Any more or less has adverse effects such as increasing the fraction of undesirable cubic phase or monoclinic phase. As shown in Table 2, the sample with 2 M% yttria displayed the highest fracture toughness at 8.1 MPa m$^{1/2}$ while the other two samples did not exceed 6 MPa m$^{1/2}$. All samples contain 50%/w Al_2O_3 and 50%/w ZrO_2 and were sintered at 1450 °C for 1 h, the only variable between these samples is the yttria content (Magnani, 2005). The zirconia–yttria phase diagram also reveals that the fraction of transformable tetragonal phase starts to decrease when the yttria molar fraction is greater than 3% (Fig. 3).

There is little work in the literature with yttria content lower than 2 mol%. Historically, the desired stabilizer content is achieved by blending monoclinic zirconia and 3Y TZP whereas a newer approach is to coat zirconia with yttria. Zirconia stabilized with lower yttria content (1–2%) and yttria coating has been studied by Sommer et al. (2012) and reportedly had comparable fracture toughness with that seen by Magnani (2005). At constant yttria content of 1 mol% the highest fracture toughness was seen in the composite with 17 mol% zirconia due to this being the percolation threshold. Using ISB toughness protocol they report 4–5 MPa m$^{1/2}$ for 10 and 24 vol% and 7–8.5 MPa m$^{1/2}$ for 17 vol% zirconia content depending on sintering dwell time (Sommer et al., 2012).

Chromium oxide is another additive used in Biolox Delta to increase the hardness and wear characteristics (Hamilton et al., 2010). As shown in Table 3, in a study conducted by Magnani (2005) the addition of chromia is reported to lead to an increase in toughness with no change in hardness for ZTA composites with different zirconia and alumina contents. This conclusion in the study was based on comparing toughness in samples with 0.5% chromia to samples without any chromia (no other levels of chromia were investigated). The chromia-containing samples showed a slight increase in fracture toughness, but this increase may not be statistically significant. The mechanism of increase in fracture toughness was described by the formation of an isovalent solid solution between the chromia and alumina. Table 3 shows that there is an interdependence among the properties attributed to the additives and processing techniques (Magnani, 2005).

Chromium oxide added to the alumina phase is also shown to slow down the hydrothermal degradation in the zirconia. Pezzotti et al. (2010a) describe that in ZTA ceramics the alumina is a self-sacrificing phase that traps moisture on its surface and protects the zirconia from undergoing phase transformation. The addition of chromia further enhances this protective effect. Especially in cases of zirconia with yttria and chromia co-doping the hydrothermal attack is reduced because of the strong interaction between the chromia and zirconia phase which prevents the diffusion of oxygen into the zirconia phase. The yttria stabilized zirconia phase is protected from hydrothermal attack at the expense of fast formation of oxygen vacancies in the chromium oxide stabilized alumina matrix (Pezzotti et al., 2010a).

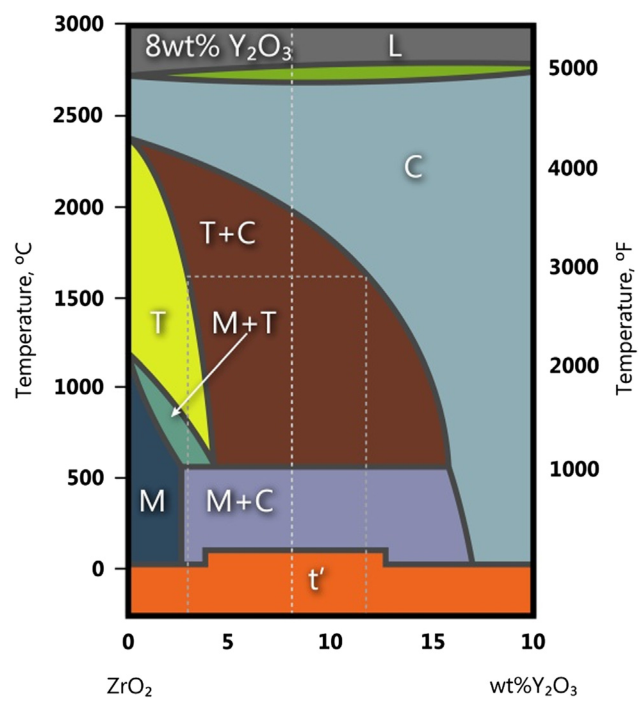

Fig. 3 – Phase diagram of ZrO_2–Y_2O_3 system showing zirconia rich region. T=tetragonal, C=cubic, M=monoclinic, L=liquid phase of zirconia (Taylor and Taylor, 1994; Li et al., 2001).

Table 2 – Density and mechanical properties of samples with different concentrations of yttria (Magnani, 2005).

Sample ID	Yttria (molar ratio)	Tetragonal phase (vol% of zirconia)	Cubic phase (vol%)	Fracture toughness (MPa m$^{1/2}$)
AZ38	2Y	100	0	8.1 (±) 0.1
AZ60	2.5Y	94.6	5.4	5.6 (±) 0.2
AZ35	3Y	98.7	1.3	6.0 (±) 0.1

Table 3 – A comparative look at additives and composition of ZTA ceramic with regards to hardness and fracture toughness (Magnani, 2005).

Sample ID	ZrO_2 (yttria stabilized) (wt%)	ZrO_2 (monoclinic) (wt%)	Al_2O_3 (wt%)	Cr_2O_3 (wt%)	Hardness (GPa)	Fracture toughness (MPa $m^{1/2}$)
AZC4[a] (2Y)	33.6	16.4	49.5	0.5	16.2 (±) 0.2	6.7 (±) 0.2
AZ16[a] (2Y)	33.6	16.4	50	0	16.1 (±) 0.2	6.2 (±) 0.3
AZC25 (2Y)	33.6	16.4	49.5	0.5	15.5 (±) 0.1	9.1 (±) 0.8
AZ38 (2Y)	33.6	16.4	50	0	15.4 (±) 0.2	8.1 (±) 0.1
AZC42	50	0	50	0.5	15.2 (±) 0.5	6.4 (±) 0.2
AZ35	50	0	50	0	14.9 (±) 0.5	6.0 (±) 0.1
AZC112[b]	26.9	13.1	59.5	0.5	15.9 (±) 0.3	6.9 (±) 0.52
AZ26[b]	26.9	13.1	60	0	16.3(±) 0.3	7.0 (±) 0.2

[a] HIP (100 MPa) at 1450 °C for 2 h.
[b] Sintered at 1500 °C for 1 h.

3. Clinical applications and clinical results of ZTA

Despite its widespread use in hip arthroplasty, with over 2 million components produced in the past decade (Heros, 2012), less than a handful of publications are currently available in the peer-reviewed scientific literature documenting the clinical performance of ZTA (Callaghan and Liu, 2009; Hamilton et al., 2010; Lombardi et al., 2010). The available clinical and retrieval data pertaining to ZTA (thus far exclusively Biolox Delta) are summarized in this section.

3.1. *Clinical studies of ZTA*

Clinical studies have been reported for COC bearings incorporating ZTA. Hamilton et al. (2010) performed a Level I, prospective, randomized, multicenter trial of 263 patients (264 hips) at eight centers, comparing Delta ceramic-on-ceramic (COC) bearing with a Delta ceramic head-crosslinked polyethylene bearing combination (COP). There were 177 COC hips and 87 COP hips, all with 28-mm diameter femoral heads. Follow-up of the COC bearings at 3.2 years showed 1.1% insertional (operative) liner failure and 1.1% postoperative liner failure. The liner failures were attributed to eccentric or incomplete seating of the ceramic liner within the metal acetabular shell. The rate of improper positioning of the COC bearings due to difficulty of seating was reported to be very high (16.2%) (Hamilton et al., 2010). It is thought that these liner fractures were related to operation conditions and not to the inherent properties of the material. At 3.2 years follow up this study showed the same survival for both COC and COP bearings, 97.6% and 97.7%, respectively (Hamilton et al., 2010). Recent follow-up of the study revealed squeaking in over 4% of delta-on-delta hips where 2% were reproducible in the office. No correlation was found between the head size and squeaking incidence. There were several incidences of broken delta liners which were attributed to the difficulty of inserting the liners. It is suspected that all of the broken liners were due to canted liners that were not properly seated. The liners are very sensitive to positioning during insertion due to the high taper angle. If misalignment is recognized intra-operatively, the cup should be revised (Nevelos, 2012).

In a Level II therapeutic study, Lombardi et al. (2010) compared the performance of 65 ZTA-on-alumina (Biolox Delta-on-Biolox Forte) articulations inset in polyethylene (sandwich type) with 45 zirconia-on-polyethylene COP bearings. Average follow-up was 6.1 years and the femoral head diameters ranged from 28 mm to 32 mm. In this single center, single surgeon study, the survivorship of the ZTA group was 95%. No cases of osteolysis were observed in the ZTA-on-alumina group, while there was one case for the zirconia-on-polyethylene group. There was also no squeaking reported for the COC delta components (Lombardi et al., 2010).

Callaghan and Liu (2009) described a single surgeon clinical study comparing Delta-on-polyethylene (COP) and cobalt chromium-on-polyethylene (MOP) bearings (133 hips, total). In this study, 70 MOP and 63 COP bearings were implanted with femoral heads ranging from 26 mm to 36 mm. The study was not randomized. A limitation of this study is that the revision rates and clinical findings related to the performance of the bearings were not reported (Callaghan and Liu, 2009).

3.2. *Retrieval studies of ZTA*

The Implant Research Center at Drexel University conducted a retrieval study of 15 ZTA heads obtained from revised COP bearings as part of a multi-institutional, multi-surgeon retrieval program (Sakona et al., 2010). The cause of revision was loosening ($n=8$), infection ($n=4$), instability, hematoma, and pain ($n=1$ for each). Implantation time was 1.1 years (range: 0.04–3.5 year). Surface roughness was analyzed using white light interferometry and microstructural changes were analyzed using Raman spectroscopy. These analyses revealed significant changes in the zirconia microstructure of the ZTA femoral heads, but no significant increase in roughness. These components also showed no regional variation in roughness with the equator, dome, worn and partially worn regions having the same average roughness value. The average roughness was reported to be approximately 3 nm.

This study also suggested a correlation between monoclinic content with implantation time, however, the sample size was too small and implantation time was too short to draw any definitive conclusions.

Esposito et al. (2011) investigated the stripe wear in alumina-on-alumina, ZTA-on-ZTA and ZTA-on-alumina articulations. They received 20 forte and 11 delta components with similar implantation times (14±6 month and 15±12 month, respectively). Reasons for revision were varied, including one squeaking forte–forte component. They reported that the average volumetric wear was lower for delta bearings, with an average wear rate of 0.06±0.10 mm^3/year, compared to forte bearings, with an average wear rate of 0.96±1.87 mm^3/year (Esposito et al., 2011).

In the Lombardi et al. (2010) study, the ZTA ball head for one of the COC bearings fractured 6 years post-operatively. Fracture occurred in a 40-year-old moderately active patient with a BMI of 25.1 kg/m^2 while rising from a commode. Analysis of the fractured delta head demonstrated minimal increase in surface roughness compared to the new condition in the main wear zone (increase from 3 nm to 5 nm). The authors also reported elevated roughness in the stripe wear zone (55 nm).

A small collection of ZTA retrievals was also reported by Clarke et al. (2009). Three case studies involving retrieved ZTA (Biolox delta) components of differing designs were described: (1) 28 mm ZTA-on-alumina (Biolox delta-on-Biolox forte) PE sandwich type cup, implanted for 5 years, with fractured head and liner; (2) 36 mm ZTA-on-alumina (Biolox delta-on-Biolox forte) cup, implanted for 3 years, with both components intact; (3) 36 mm ZTA(Biolox delta)-on-polyethylene cup, implanted 1 year, with both components intact. This study also performed intensive wear analysis on alumina/alumina, ZTA/ alumina and ZTA/ZTA bearing combinations, mentioned in more detail in Section 3.1. The retrievals displayed similar wear zones, surface roughness and monoclinic transformation when compared to the simulator study components. The monoclinic phase content plateaued at approximately 30% both in the main wear zone and stripe wear zone in all components (Clarke et al., 2009). The ability to characterize wear is very accurate; however failure due to impingement and subluxation of components also leads to failure. Retrieval 2 in this study displayed a black metallic line on the femoral head, indicative of impingement, and impingement damage on the liner.

Two case studies have reported Delta liner fracture in COC bearings with an alumina head articulating on a delta liner (Hwang et al., 2008; Taheriazam et al., 2012). In both cases, the patients were male and 51 and 57 years old. For the 51-year-old patient, failure occurred 4 months postoperatively. Radiographs showed dislocation of the liner in the region opposite of fracture, with visible scratches on the femoral head and neck and black metal stains on the femoral head and ceramic liner (Hwang et al., 2008). In the other case study, fracture of the Delta liner occurred 18 months post-operatively (Taheriazam et al., 2012). The fracture mechanism is thought to be due to unacceptable range of motion, disassociation of the locking mechanism during insert implantation, or cracking during implantation (Taheriazam et al., 2012).

3.3. *Overview of clinical and retrieval studies of ZTA*

Assessment of clinical and retrieval studies is more challenging compared to in vitro studies because of the multiple parameters involved in vivo. The limitation of current follow-up studies for ZTA components is that they are short-term. Case studies investigating wear and fracture mechanisms currently have a very small sample size. Longer implantations and long-term retrieval studies will be needed to evaluate whether ZTA will outperform the alumina and zirconia ceramics used as controls in these studies.

4. Summary and conclusions

This review has summarized the variety of factors that are associated with the transformation toughening mechanism and performance of ZTA. With this review, it is shown that at present there is a much better understanding in the scientific literature about the in vivo transformation toughening mechanisms of ZTA as compared to 5 years ago. However, from both a clinical and a retrieval analysis perspective, the scientific track record of ZTA in hip arthroplasty remains extremely limited.

ZTA components potentially offer reducing or eliminating current limitations in the performance of COP and COC bearings due to their higher fracture toughness and higher resistance to wear. The higher fracture toughness of ZTA enables the manufacture of thinner liners and larger femoral heads, components that provide greater range of motion in the joint but may be challenging for alumina due to its lower toughness and mechanical strength. Historically, ZTA use has been complicated by the Desmarquest zirconia components recall and the unpredictability of phase transformation seen in the zirconia phase; however, studies quantifying the performance of ZTA components show promising in vitro and preliminary in vivo results. ZTA composites combine the advantageous properties of monolithic alumina and zirconia by exhibiting higher hydrothermal stability compared to monolithic zirconia and superior wear resistance compared to alumina. However; the present studies are limited in their analysis due to being in vitro or short-term if in vivo. The reported high aging resistance in vitro may be lower in vivo due to factors such as stresses at the bearing surfaces. At present, the knowledge regarding the in vivo performance of ZTA is still far from complete. Longer implantation studies are required to fully determine if ZTA components will outperform their counterparts in total hip arthroplasty applications.

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