

New Generation Ceramics for Hip Joint Prostheses

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Introduction Alumina exhibits excellent hardness and wear properties, however it is a brittle material with an inherent risk of fracture. The objective of this study was to investigate the feasibility of a new Alumina based ceramic with improved toughness for artificial hip joint articulation against PE, itself or Alumina whilst maintaining all other properties such as hardness, stability and chemical inertness. This objective can be achieved through the addition of Zirconia to Alumina. Addition of approximately 25% Zirconia to Alumina (Zirconia Toughened Alumina, ZTA) during the manufacturing process is promising to achieve the objectives.

Materials and Methods Two candidate Zirconia Toughened Alumina (ZTA) ceramics were obtained from two manufacturers. The samples were supplied in the form of flat polished coupons, 45 x 4 x 3 mm bars and ball heads as well as inserts for modular cups with 28 mm internal diameter. For the mechanical evaluation 10 samples per test and for the wear test three samples each were used.

One ZTA (NZTA) had a composition of 75% Alumina and 25% Zirconia, the other one, (CZTA) had a composition of 74% Alumina, 24% Zirconia and 1% mixed oxides. To characterize the two new ZTAs several methods were used. Alumina served for all tests as a reference. Mechanical testing involved: hardness (HV), flexural strength (ASTM C1161) and indentation fracture toughness determination. X-ray diffraction (XRD) was used to measure the crystalline phase composition of the ZTAs and was also used to monitor any transformation during aging. Determination of stability was conducted by accelerated aging (5 hrs at 134°C in a steam autoclave, equivalent to 20 years in vivo) and real time aging for one year in Ringer's solution at 37°C. Wear simulator testing has been carried out applying a six-station physiological hip simulator, described elsewhere. The simulator testing was done using standard conditions and in micro-separation mode that has been shown to achieve similar wear pattern as retrievals [1]. All test data was analyzed by descriptive statistics where applicable.

Results The results obtained for the unaged ZTA specimen are summarized in table 1. The indentation fracture toughness was determined to have K_{IC} values of 4.1 MPa*m^{1/2} for both ZTA ceramic materials as opposed to 2.78 MPa*m^{1/2} for Alumina. Although the value is identical for both ceramics NZTA has a significantly lower flexural strength than CZTA. However even this value is between 50% to 75% stronger than Alumina; statistically significant at $p < 0.05$. The ZTA ceramics maintain almost the same hardness values as the base Alumina, statistically not significant at $p < 0.05$.

Table 1. Mechanical test results for unaged ceramics

Test	Units	Alumina	CZTA	NZTA
Flexural Strength	MPa	466 ± 106	1203 ± 101	800 ± 131
Fracture toughness	MPa*m ^{1/2}	2.78	4.1	4.1
Hardness	HV(30)	1878 ± 60	1840 ± 60	1840 ± 60

The two ZTA ceramics differ in the crystalline form of Zirconia seen at the surface when measured by XRD. NZTA contains Zirconia in a purely tetragonal crystalline form with no measurable monoclinic phase present. CZTA contains Zirconia with up to 35% of the monoclinic phase present at the surface. No further transformation in the Zirconia phase was observed after accelerated aging and up to 12 months real time aging for both ZTAs. This indicates the ZTA is a chemically stable ceramic.

The wear testing, in standard hip joint simulator mode, showed that both ZTA - ZTA couples articulating against themselves have lower wear than even Alumina - Alumina couples which has been reported before [2]. Using a micro separation simulator set-up, similar results for both ZTA - ZTA combinations were obtained. Although the overall wear rate was increased in this mode, it also reached a steady state after 0.5 million cycles. The ZTAs wore in this test set-up - statistically not significant - again less than the Alumina - Alumina combination.

Discussion The objective for the development of a new generation of fracture and wear resistant ceramics was achieved through the addition of ca. 25% Zirconia to the Alumina matrix. The hardness is not affected but the toughness and the flexural strength of the ceramic has been increased by up to 50% compared to Alumina thus reducing the risk of fracture with such implant components. The two different ZTAs investigated demonstrate their superior properties and maintain them during accelerated and normal aging. The wear properties under standard and adverse tribological conditions also demonstrate an improvement over Alumina, although statistically not significant. Zirconia Toughened Alumina is a promising ceramic for the next generation of fracture and wear resistant ceramic articulation for hip and eventually knee joint prostheses.

[1] J.E. Nevelos et al; J. of Arthroplasty, 2000, in press

[2] J.E. Nevelo et al; 46th ORS annual meeting, Orlando, March 12-15, 2000