

Ceramics for medical applications: A picture for the next 20 years

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Abstract

High-tech ceramics have always been associated to medical devices: they are used today as femoral heads and acetabular cups for total hip replacement, dental implants and restorations, bone fillers and scaffolds for tissue engineering. Here, we describe their current clinical use and propose a picture of their evolutions for the next 20 years. The need for tough, strong and stable bioinert ceramics should be met by either nano-structured, alumina and zirconia based ceramics and composites or by non-oxide ceramics. Nano-structured calcium phosphate ceramics and porous bioactive glasses, possibly combined with an organic phase should present the desired properties for bone substitution and tissue engineering. The position of ceramics in a gradual medical approach, from tissue regeneration to conventional implants, is discussed.

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1. Introduction: clinical use of ceramics, historical highlights and current solutions

Ceramics are generally defined as ‘inorganic, non-metallic materials’. Biomaterials are now defined as ‘natural or synthetic materials suitable for introduction into living tissue especially as part of a medical device’. Considering these definitions, we may argue that ceramics have been used as biomaterials for millenia. In 1972, indeed, Amadeo Bobbio discovered Mayan skulls, some of them more than 4000 years old, in which missing teeth had been replaced by nacre substitutes.¹ Nacre is a natural composite consisting of 95–98 wt.% of calcium carbonate (aragonite, the ‘ceramic’ phase) and 2–5 wt.% of organic matter (fibrous proteins, polysaccharides). In clinical practice, the controlled implantation of bioceramics started late 18th century in dentals with the use of porcelain for crowns and late 19th in orthopedics with the use of Plaster of Paris, or gypsum (calcium sulfate dihydrate) for bone filling.² With the advances in the ceramic technology, the 20th century saw more and more ‘high-tech’ ceramics available for medical purpose.³ Tricalcium phosphate was first proposed in 1920 as a bioresorbable substance to fill bone gaps. However, tricalcium phosphate (TCP) and plaster are

weak ceramics, unable to sustain significant loading. The need for tough and strong ceramics was not met before 1965, when the first alumina (Al_2O_3) material dedicated to hip joints was patented.⁴ Synthetic calcium phosphate ceramics (together with calcium and/or phosphorus containing ceramics and glasses) and zirconia were then proposed as alternatives to TCP and alumina, respectively. After roughly 100 years of clinical use, we come to the conclusion that there is, so far, no tough and strong ceramic able to create a strong, biologically relevant interface with bone. On the other hand, ceramics and glasses able to promote direct bone-implant adhesion without fibrous soft tissue interlayer are all unable to be used as loaded devices. Bioceramics are therefore generally separated in two families, so-called ‘bioinert’ and ‘bioactive’.

Alumina (and zirconia) ceramics are most often considered as ‘bioinert’ (although a material should never be considered as totally inert), since no direct bone–material interface is created. A soft tissue interlayer always shields the bone from the implant. This biological shielding unfortunately leads to mechanical (stress) shielding, known to promote micro-motion and subsequent aseptic implant loosening. Only under compression, with a porous structure and with a good fit with bone cavity (avoiding relative micro-motion), the fibrous tissue at the interface is thin enough and a successful bone ingrowth is achieved. Given these restrictions, ‘bioinert’ ceramics are hardly used as bone fillers.

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Table 1
Mechanical properties of different ceramics

Material	Toughness (K_{IC} , MPa m ^{1/2})	Threshold (K_{I0} , MPa m ^{1/2})	Strength (MPa)	Vickers hardness
Alumina	4.2	2.4	400–600	1800–2000
Zirconia	5.4	3.5	1000	1200–1300
AlOZrOY	5.8	4	700–900	1800
Hydroxyapatite	0.9	0.6	50–60	500
Tricalcium phosphate	1.3	0.8	50–60	900
Mg-PSZ	8	6	600	1000
12Ce-TZP	7.8	5.1	700	1000–1100
Micro-nano-alumina–zirconia	6	5	600	1800
Nano-nano-Ce-TZP–alumina	8.4	4.6	900	1300
Silicon nitride	10*	?	1000*	2500

Toughness (K_{IC}) and threshold stress intensity factor (K_{I0}) were measured by the Double Torsion method (except for values with *, extracted from Ref. 23) and strength by four point bending.

Their major application in orthopedics concerns total hip and knee replacement. The use of bioceramic materials reduces wear rates of bearing components and produces negligible amount of ion release. The clinical success associated to the use of ceramics led to the implantation of more than 3.5 millions alumina components and more than 600,000 zirconia femoral heads worldwide since 1990. There are many reports on fracture rates associated with ceramics, since their intrinsic brittleness is their major drawback.⁵ If, in the pioneering days, the fracture rate was quite high (up to 13% for some series), the *in vivo* failure rate reported by the producer of Biolo^x® alumina is today below 0.01%.⁶ A comparable failure rate was claimed by the producer of Prozyr[®] zirconia heads⁷ before the critical event of 2001, discussed below. The current fracture rate of ceramics is therefore negligible when compared to the overall failure rate of implants (mainly due to aseptic loosening resulting from particles release). If the clinical follow up with current alumina ceramics is very good, it must be kept in mind that their use has been restricted so far to a limited number of designs for which the mechanical loading is less demanding. This is related to their modest mechanical properties (Table 1). In the 1990s, yttria-stabilised zirconia (Y-TZP) became a popular alternative to alumina as structural ceramic because of substantially higher fracture toughness and strength. The use of Y-TZP has opened the way towards new implant designs that were not possible with alumina, more brittle. Examples are 22 mm Y-TZP femoral heads, and the development of Y-TZP knees. Biomedical grade Y-TZP exhibits the best mechanical properties of single phase oxide ceramics: this is the consequence of phase transformation toughening, which increases its crack propagation resistance. The stress-induced phase transformation involves the transformation of metastable tetragonal grains to the monoclinic phase at the crack tip. It is accompanied by volume expansion and induces compressive stresses which hinder crack propagation. On the other hand, due to this meta-stability, Y-TZP is prone to low temperature degradation (sometimes referred to as aging) in the presence of water.⁸ Aging occurs by a progressive tetragonal to monoclinic transformation at the surface triggered by water molecules, which results in surface roughening and micro-cracking. This inevitably impacts the wear performance of hip joint heads, as roughening increases the wear rate of the

antagonist part of the prosthesis, while the coupled effects of micro-cracking and wear generate pull-out of zirconia grains. The extension of the micro-cracked, transformed zone also generates defects, that may grow with the transformed zone and lead to delayed failure. Y-TZP manufacturers considered this problem as a minor issue until 2001, when hundreds of failures of Y-TZP heads were reported within a very short period. Even if limited in time and number, and clearly identified to be process controlled, these events have had a negative impact for the use of zirconia in orthopedics. More important, some clinical reports show that yttria-stabilised zirconia can exhibit a progressive ageing degradation even under ‘normal’ situation, which limits its long-term stability. Orthopedic community now faces the need for tough, strong and stable ceramics as alternatives to alumina and Y-TZP.

Dental applications add aesthetic requirements (colour, translucency) to the mechanical specifications. White to ivory colour gives a clear advantage for oxide ceramics versus metals, which is the reason why research and development are nowadays directed towards metal-free dental prosthetic restorations. Indeed, metal-free restorations preserve soft tissue colour more similar to the natural one than porcelain fused to metal restorations. Moreover, ceramics do not suffer corrosion and/or galvanic coupling as it can be observed for metals. The clinical demand for all-ceramic restoration is increasing and ceramics are becoming important restorative materials in dentistry. Pioneers like Duchateau had only access to conventional porcelain (or more precisely mixture of kaolin, feldspar and quartz), which were later replaced by more translucent feldspathic glasses reinforced by silica inclusions. However, these porcelain based materials still lacked mechanical strength. Therefore, during the last 200 years, a global approach has been to increase the content of ceramic: from silica to alumina reinforced porcelain (in 1960), to glass-infiltrated high strength ceramics (alumina or zirconia) and finally to monolithic ceramics. Translucency of technical ceramics may be achieved with a very fine (sub-micron) grain size and low porosity content (less than 1%). Fully dense, translucent (yttria-stabilised) zirconia ceramics can be processed with grain size less than 0.5 µm and meet the demand for both natural-teeth-looking restoration and high mechanical strength. For the last 10 years Y-TZP has been

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