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Ceramic Based Bio-Medical Implants

THE AUTHOR

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ABSTRACT

Bioceramics are those engineered materials that are inorganic and non-metallic in nature and find applications in the field of medicine. They are distinct from metals and their alloys and organic polymers but cover non-crystalline glasses and ceramic-based composites. Bioceramic materials are used in the repair and reconstruction of diseased or damaged parts of the musculo-skeletal system. They are useful as joint or tissue replacements, as coatings to improve the biocompatibility of metal implants, as resorbable lattices which provide a temporary structure framework that is dissolved and replaced as the body rebuilds tissue and also even as a controlled drug delivery system.

This paper deals mainly with three different types of biomedical implants made of ceramics, namely in the areas of hip joint femoral heads, orbital implants and bone regenerative dental applications.

KEYWORDS

implants, femoral head, orbital implant, dental implant
Interceram 59 (2010) [2]

1 Introduction

The history of bioceramics is especially interesting. In 1972, Amadeo Bobbio discovered Mayan skulls; some of them more than 4000 years old, in which missing teeth had been replaced by nacre substitutes [1]. Natural nacre has a brick-mortar like microstructure where inorganic calcium carbonate layers (ceramic portion) are held together by organic protein “glue”. The inorganic portion represents 95 % of the volume of nacre; its highly specific properties (in particular its toughness) are due to the interaction of this inorganic component with the organic phase that is found between the calcium carbonate platelets. But the continuity of the evidence of use of ceramics in medical applications was not readily found till the modern era.

2 Uses

Ceramics are more similar to natural skeletal materials, but due to their limitations in mechanical properties, metallic implants are widely used. Improvements in ceramic processing technology in the 1960s led to great scientific interest in bioceramics [2]. A strong interest in the use of ceramics for biomedical engineering applications developed in the late 1960s, exemplified by the work of Hulbert and co-workers [3]. But this interest reached a plateau during the late 1970s and early 1980s, mainly due to conservative governmental regulatory systems which required substantially more clinical experience and successful trials on a long time scale. However, after the initial, highly successful endeavours the last two decades have seen a renaissance in the development and uses of ceramic based biomedical materials.

The use of bioceramics has mainly concentrated on orthopaedics and dentistry. Bioceramics in orthopaedic applications provide the advantage of chemical similarity to natural skeletal materials. Again in dental applications, the chemical similarity with natural dental materials and the excellent compressive load-bearing capacity have made ceramic-based biomaterials an ideal implant.

Based on their chemical reactivity with the physiological environment, bioceramics can be broadly categorized in three types [4]:

Bioinert bioceramics, such as alumina, result in little or no physiological reaction in the human body and tend to exhibit inherently low levels of reactivity which peak in the order of hundreds of years.

Surface reactive or bioactive ceramics, such as bioglass, react in a positive way with local cells, i.e. they form bonds and have a substantially higher level of reactivity, peaking in the order of 100 days.

Resorbable bioceramics are porous or non-porous structures which are slowly and gradually replaced by bone such as tricalcium phosphate, have even higher levels of reactivity, peaking in the order of 10 days.

Bioceramics are needed to alleviate pain and restore normal activity to diseased or damaged parts of the body. As people age, progressive deterioration of tissues requires replacements in many critical applications. Bone is especially vulnerable to fracture in older people because of a loss of bone den-

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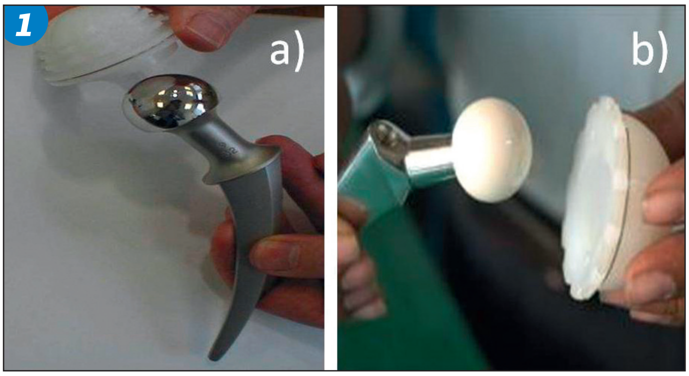

Fig. 1 • The hip joint and its details, with femoral head: a) metallic and b) ceramic (alumina)

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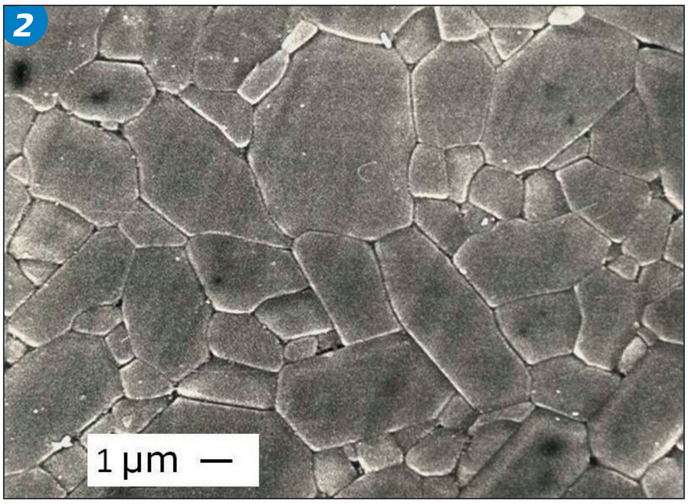

Fig. 2 • Microstructure of alumina hip ball

sity and strength [5]. After successful research and many animal and human trials, various bioceramic products are now commercially available in the medical market as substitutes for the original damaged body parts and for many other critical applications. The major application areas are as follows.

- Replacements for hips, knees, teeth, tendons and ligaments
- Repair for periodontal diseases
- Maxillofacial reconstruction
- Augmentation and stabilization of the jaw bone
- Spinal fusion, bone repair after tumour surgery
- Pyrolytic carbon coatings for prosthetic heart valves
- Treatment of cancer by localised delivery through radioactive glass microspheres

Some of the important ceramic-based implants are detailed below.

2.1 Ceramic femoral head (hip joint ball)

The replacement of broken and worn out bones parts is not a new development. Themistocles Gluck (1853–1942), inventor of artificial biomaterials, changed the concept of contemporary surgery "from being the destructive art to become the reconstructive art". He developed entire artificial joints, fabricated from ivory, and implanted them in many patients [6].

A stainless steel-based artificial hip joint was first implanted by John Charnley in 1960 [7]. Charnley's design, although simple, remained virtually unchanged for three decades, even though the common problems associated with the metallic implants such as corrosion, wear, and loss of bone were known. These problems have restricted the lifespan of metallic implants to 10–12 years and they require revision surgery for many patients. To avoid this and to improve the quality of life, researchers started experimenting with ceramic implants, especially for hip joints.

Ceramic implants have some inherent advantages such as inertness in a biological environment and biocompatibility; they produce nearly no wear debris and can be designed to match the material properties of natural bone. All these result in a much longer life of the prosthesis [8]. Again metal has such high stiffness that the bone surrounding a metallic implant no longer bears the load and the implant carries the entire load. As bone is a living tissue, it begins to resorb when it ceases to carry the load, causing the implant to loosen and eventually require replacement. Ceramics can be tailored to allow bone to grow within their porous structures (scaffolds) and can completely incorporate the scaffold with natural bone within five to seven months.

For the articulating surfaces on hip, knee, and shoulder, alumina- and zirconia-based ceramic implants are important. They are harder than metal, have higher scratch resistance and can be used on both the ball and socket components of an implant, such as the femoral head and the acetabular cup of a hip joint (Fig. 1). The ceramic hip prosthesis provides much longer life, reduces the side effects and is suitable for all patients, especially for younger people who require a longer healthy life without revision surgery. The clinical success associated with the use of ceramics has led to the implantation of more than 3.5 million alumina components and more than 600,000 zirconia femoral heads worldwide since 1990 [9]. Statistics show that more than 0.5 million hip replacement surgeries per year are performed globally. Patients who experience unbearable pain due to osteoarthritis or have broken hips in accidents undergo such operations. This, coupled with increased life expectancy, has triggered multi-directional research activity to identify ideal materials for such implants which will give the desired longevity and comfort. For femoral heads, fine grained alumina (Fig. 2) [10] with engineered properties and fitted with a Ti-Al-V stem is currently established as the best material combination for hip replacement surgeries. Table 1 shows the property requirements of the alumina-based femoral heads as per international standards while Table 2 compares the wear characteristics of alumina-based (ceramic) femoral heads to SS 316 L grade (metallic) [10].

2.2 Orbital implant

An eye surgeon removes the eye-ball from the orbit of a patient when the person's eye is damaged due to injury or disease, to avoid the risk of life or risk to the other eye. To fill up the orbital volume lost, an ocular implant is placed to achieve better cosmetic results and rehabilitation of the anophthalmic patient. The small ocular implant is not visible but it maintains the natural structure of the orbit and provides support to the artificial eye. It also restores the natural appearance of the eye and surrounding tissues.

Though artificial eyes have been made for thousands of years, the first orbital implant was developed only about a century ago. Numerous materials like gold, cartilage, xenogeneic animal eyes, silver aluminium, silicone and glass beads were used to fill irregular cavities in the orbit. Most of these implants were found unsuitable due to various reasons and were discarded one after another. In 1941, an acrylic based, partially exposed orbital implant was introduced by Ruedemann [12], which imparted good motility to the artificial eye, but it was prone

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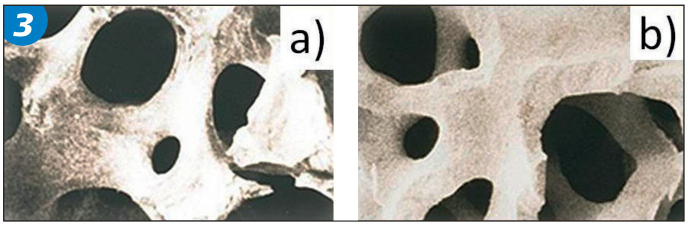

Fig. 3 • Similarity in structure:
a) human bone and
b) hydroxyapatite

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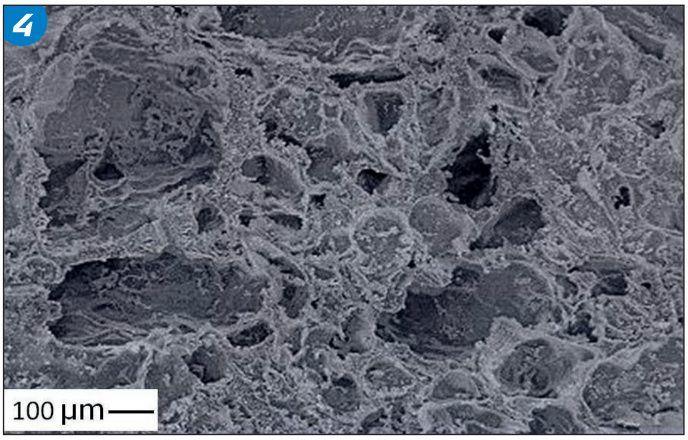

Fig. 4 • SEM photomicrograph of synthetic hydroxyapatite-based ocular implant

to infection, extrusion, and late position problems which had to be corrected. Lack of movement was also a major obstacle in restoring a natural appearance. Also these implants tended to drift in the orbit and were often rejected by the body, requiring further surgery. These problems inspired researchers to continuously search for a better orbital implant.

Hydroxyapatite (HAp) [also known as Hydroxylapatite, $Ca_5(PO_4)_3(OH)$, usually written as $Ca_{10}(PO_4)_6(OH)_2$] is the principal inorganic constituent of bone and teeth. The chemical similarity of HAp to bone and its excellent biocompatibility and bioactivity have attracted the attention of medical professionals [13–14]. Figure 3 shows the microstructural similarity of human bone and hydroxyapatite [10]. For the past few decades, hydroxyapatite-based ceramics have been widely used in the field of orthopaedics and dentistry. Extensive research into the biological and physicochemical properties of this material has widened its scope of application and in recent years it has also found promising applications in many other areas of medical science.

The first-ever hydroxyapatite-based orbital implant was inserted by Dr Arthur Perry in the 1990, after several years of preliminary research [15]. The porous implant was easily attached to the eye muscles and the tissues that covered the implant resulted in much improved motility of the implant, giving it the appearance of a natural eye. Figure 4 shows the microstructure of such an implant and its porous nature [10]. For even better movement, a peg may be used to connect the artificial eye to the implant. In this way, small, darting movements of the natural eye can be imparted in the artificial eye. The result is a more natural-looking artificial eye which is difficult to distinguish from the natural eye.

There are two types of hydroxyapatite-based orbital implants available: the first is natural coral based and the second is synthetically prepared material. Synthetic material based implants allow a much improved control over size, weight, total porosity and porous structure and can easily be tailored to the requirements of better implantation [16–17]. Figure 5 shows different shapes of synthetic hydroxyapatite-based orbital implants and pegs and properties of these implants are provided in Table 3 [18].

The advantages of hydroxyapatite-based orbital implants are [18]:

- inert, biocompatible and biochemically stable,
- light weight to increase motility,
- smooth surface,
- porous structure for tissue in-growth, resulting in improved motility and minimum extrusion,
- resilience.

2.3 Dental implant – bone regenerative material

The working environment of teeth is one of the most inhospitable in the human body. It faces wider temperature variations than most other parts, varying from sub-zero temperatures (for ice-creams) to hot tea/coffee/soup, encounters pH changes in the range 0.5 to 8, and it is a hostile environment filled with various micro-organisms, bacteria and viruses, etc. Added to this are the various forms of stresses associated with

Table 1 • Property requirements of the alumina-based femoral head as per international standards

Properties	ISO Spec. (6474-198L IS: 5347)
Density / g/cm^3	>3.90
Chemical composition	Alumina >99.5 %
Micro-hardness (Vickers) / GPa	20
Compressive strength / MPa	4000
Flexural strength / MPa	400
Young's modulus / GPa	>350
Wear resistance (alumina pin against polished alumina disc, contact pressure MPa, distilled water medium) / mm^3/h	<0.01
Coefficient of friction (Contact pressure: 5.0 MPa; medium: distilled water)	<0.30
Corrosion resistance against Ringer's phosphate bicarbonate (pH 7.0–7.4) / mg·m^2/day	<0.10
Surface finish (Ra) / µm	<0.05

Table 2 • Comparison of wear characteristics of alumina and SS 316L

Material Combination		Wear Factor*	
Femoral head	Acetabular cup	Dry	Wet
Alumina	UHMWPE	0.55×10^{-6}	0.31×10^{-6}
SS 316 L	UHMWPE	3.46×10^{-6}	2.13×10^{-6}

* Wear Factor=FN=V/(N·S), where N=Normal Load (N), V=Volume of Wear (mm^3), S=Distance Slide (m)

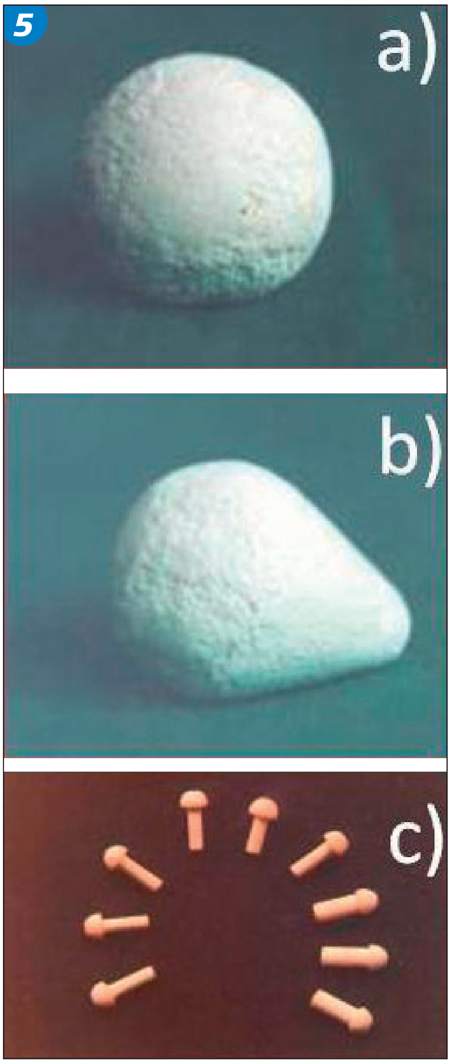

Fig. 5 • Synthetic hydroxyapatite-based orbital implant: a) spherical shape, b) conoidal shape and c) pegs

Table 3 • Properties of synthetic hydroxyapatite-based orbital implants

Composition	Hydroxyapatite
Formula	$Ca_{10}(PO_4)_6(OH)_2$
Bulk density	$0.6–0.7\ g \cdot cm^{-3}$
Specific weight	<2 gms
Porosity	70 %–75 %
Pore size (by SEM micrograph)	100–300 µm
Unit volume	$3–4\ cm^3$
Flexural strength for solid HAp	>25 MPa
Compressive strength for solid HAp	>120 MPa
Sizes	Any size (14, 16, 18, 20 mm …)
Shapes	Spherical, conoidal, or any other
Types	Evisceration, enucleation

chewing where cyclic stresses may vary from 20 to about 100 MPa. Teeth also need to satisfy another important criterion: aesthetics. As our society becomes more and more self conscious, any dental implant must have a colour and translucency as close to natural teeth as possible to maintain the natural look and beauty.

Dental implants are essential alternatives for bridging the gap where a tooth has been lost or removed. With dental implants, the artificial tooth root is placed into the jaw to hold a replacement tooth or bridge. Dental implants are ideal and the best option for people in good oral health who have lost a tooth or teeth due to periodontal disease, failure of endodontics, injury, or some other reason. Dental implants are actually more tooth saving than traditional bridgework, as implants do not rely on neighbouring teeth for structural integrity, shape and stability.

Functions of a dental implant are:

- to provide support for a denture, making it more secure and comfortable;
- to support a bridge and eliminate the need for a removable partial denture;
- to allow replacing one or more damaged teeth without affecting adjacent teeth.

The advantages of dental implants are:

- They prevent bone loss and gum recession, thus tooth saving.
- They look and feel like original teeth and aesthetically they look natural.
- No support from neighbouring teeth is required, giving a long term benefit for oral health.
- They provide a permanent solution, no worries about displaced dentures and messy denture adhesives.
- The success rate of dental implants is highly predictable, hence reliable.

In the human body, bones, teeth and hard tissues have an inorganic component, primarily consisting of hydroxyapatite and an organic component, collagen. Hydroxyapatite is a surface-active material which reacts with its biological surroundings through the exchange of calcium and phosphate ions present in the material. These ions in turn trigger bio-mineralization to form the regenerative crystals through primary and secondary nucleation to form genetically determined hard tissues. There is evidence of bone formation on the implant and occurrences of bone remodelling around the implant which indicates that the characteristics of biological affinity, functional adaptability, and material stability of hydroxyapatite-based implants make it a suitable material for dental applications [19–20].

Therefore, this material shows high potential for osteo-conduction in regenerative surgical modalities. The material offers a physical matrix to guide the in-growth of normal hard tissues into the required area and results in rapid bone formation with a predetermined structural pattern. Thanks to all these many advantages, hydroxyapatite-based dental implants have been widely used globally for more than a decade [21–22]. The interconnected porous structure with engineered optimal porosity provides for the accelerated physical process of dissolution and the biological process of cellular attachment and osteoid deposition. Hydroxyapatite (HAp) can also be used in combination with more bioactive resorbable materials such as beta tri-calcium phosphate (TCP) or bio-glass (BG) for increased resorbability, faster tissue in-growth and bone generation. Hydroxyapatite-based dental implants have the following advantages [23]:

- provide a 3-dimensional porous structure, serving as osteoconductive matrix for bone forming cells;
- no infectious/immunogenic effects, unlike allograft materials;
- no risk of bacterial contamination, viral transmission or immunogenecity;
- no risk of donor site complications and procurement morbidity akin to autograft procedures;
- remains in vivo for a suitable period to maintain bioactive elements at the implantation site and optimize their release rate;
- dough form can be made easily with blood/PRP;
- granules can be placed conveniently and blocks can be reshaped as per application area design.

3 Conclusions

The full potential of bioceramic implants has started to be recognized over the past two to three decades. A special class of ceramic (material) has been developed to perform tailored functional biological activities in living beings. Revolutionary changes have also occurred in reconstructive surgery, which have improved the quality of life for the rehabilitated persons. It is possible, using specially designed and fabricated ceramics, to reconstruct diseased or damaged parts of the body. The ceramics meet the demands of the application requirements along with the biological criteria of compatibility and inertness/resorbability. The tailoring of composition, microstructure, physical properties and molecular surface chemistry of various bioceramic implants are the pillars of the continuing success of these materials and they also open up new avenues for many novel reconstructive surgery techniques that offer the chance of a damage free, pain free, maintenance free stable life for a longer time.

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Received: 24.01.2010

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