CERAMICS FOR PROSTHETIC APPLICATIONS—ORTHOPEDIC, DENTAL AND CARDIOVASCULAR

SUMMARY

Ceramic materials have shown considerable promise for use in some orthopedic, dental, and cardiovascular applications. Ceramics that presently have promise for use in the orthopedic and dental-implant areas include various calcium aluminates, calcium phosphates, alumina, pyrolytic and vitreous carbon, and possibly some recrystallized glasses.

A clearly identified, viable concept for ceramic orthopedic and dental implants is presently not available. The concepts for permanent ceramic implants which have been evaluated via animal studies include:

(1) A permanent wholly porous implant which achieves skeletal attachment by bone ingrowth into the open porosity.

(2) A dense ceramic implant which achieves skeletal attachment by bone ingrowth into the porous ceramic coating on the implant.

(3) A dense ceramic implant which achieves skeletal attachment by bone ingrowth into macroscopic surface features.

The concept of employing a resorbable ceramic material which is replaced by living bone after being implanted has been advanced to the point where certain oxide phases have been demonstrated to indeed disappear from the implant site in time, while simultaneously being replaced by new bone.

Work with ceramics oriented toward orthopedic applications such as long-bone repair has to date been concentrated on study of porous calcium aluminate, calcium zirconate, and calcium titanate ceramics. Certain calcium aluminate compositions tend to react with the biological environment and, after being implanted, are either surrounded by a fibrous sheath or tend to slowly disappear from the implant site. Implant work with alumina ceramics has clearly demonstrated the stability of this ceramic material in the biological environment. Little is known about the importance of trace impurities in alumina and its stability as an implant. Its superior strength, chemical stability, and well-developed technology clearly make it the prime candidate ceramic for permanent-implant applications at this time.

Much less is known about the so-called resorbable ceramic-implant materials, as only two types have been reported. The calcium aluminate composition reported by Graves[33], et al. reacted with its environment apparently without causing detrimental effects. The limited number of implants that were done did indicate that this ceramic may have real potential if more were known of the relationship between initial phase composition of the ceramic and its resorption properties. The tricalcium phosphate ceramics reported by Bhaskar[38], et al., may have a faster resorption rate than the calcium aluminate material reported by Graves[33]. All experimental data with animals to date indicate that this phosphate material has some novel biological properties that could be medically exploited. The resorption process for both the aluminate and phosphate ceramics and the existence of any adverse effects on other major organs are unknown at this time.

Work on ceramics oriented toward dental applications has centered on development of better cements, stronger jacket and restoration materials, and endosseous implants such as tooth-root replacements. Alumina and vitreous carbon presently appear to be the most promising ceramic materials available for these applications. They will be used either in the form of tooth-root replacements or as endosseous blades. The surgical-implant protocol and particularly suitable fixation techniques required for success are not well established at this time and these must be developed before such a device can achieve high success rates and wide clinical usage. Vitreous-carbon tooth-root replacements are now being used by private practitioners and in dental-school clinics. The use of ceramic materials for repair of periodontal defects has received little attention to date, but some of the resorbable types such as tricalcium phosphate have shown a strong capability for inducing bone growth in long-bone implants and these materials should be thoroughly explored for this application. Ceramics such as alumina, certain calcium aluminates, and perhaps tricalcium phosphate can serve for augmentation of the alveolar ridge of the mandible, but programs directed at these applications have been relatively small, and it is difficult to anticipate the time frame for human application.

Ceramic materials for cardiovascular application and for use as percutaneous leads are essentially restricted to isotropic pyrolytic carbons at this time, and products of these materials are presently being tested for human use.

Up to the present time, most of the research support for the development of ceramic materials for biological applications has come from government sources. Most of

the industrial concerns presently involved in prostheses manufacture and similar product lines have apparently not provided similar funding to R and D activities in this field.[105] This situation is probably due to the relatively long-term nature of the potential return on investment in this field and the relatively small size of the biomedical market. It does appear reasonably certain that at least some of the relatively new ceramic materials discussed in this report will eventually come into clinical use in humans. The first extensive applications will probably be in dental procedures and in very specialized devices such as heart valves, etc. Orthopedic applications of permanent ceramic implants will depend upon clear demonstration that the brittle nature of the material is not a serious detriment to its use, that tissue deposited in relatively deep porosity does not become necrotic in long-term implants, and that reasonably standard fixation techniques and convalescence protocols can be used with the materials. Orthopedic applications of resorbable ceramics will depend upon clear demonstration that the products of resorption cause no adverse effects, that resorption is rapid enough or fixation techniques are sufficient not to require prolonged patient immobilization, and that the strengths of these ceramics are sufficient to accept reasonable stresses immediately after implanting and can continue to serve the required mechanical function during the resorption/bone regrowth process.

The use of recrystallized glass ceramic coatings on metal prostheses for the purpose of passivating the metal or shielding it from the biological environment while simultaneously reacting with the environment sufficiently to achieve tissue attachment is philosophically appealing. Clear demonstration that these types of ceramic materials will perpetually protect the metal (i.e., react as required to induce bone attachment, etc., but then essentially become inert) is required for long-term implants before the real potential value of this type of material can be assessed.

INTRODUCTION

The use of ceramic materials for medical applications has been of interest for several decades. Earlier use of plaster of paris for some bone-repair procedures met with partial success, but the use of this material has not been pursued extensively in recent years. The low strength of plaster of paris essentially precludes its use in any significant stress-bearing application even if it met the physiological requirements. Ceramic materials are of interest for use in dental, orthopedic, and cardiovascular applications, and the present status of ceramics primarily for application in these areas is discussed in this report. One of the oldest areas of the application of ceramics is in the dental field, in such applications as porcelain crowns, dentures, and as cements. This area has seen some improvements in the mechanical properties of the porcelains as well as improved reflectance, color-shading techniques, and mechanical design so that the general functionality of these ceramics has been improved. Cements have been improved in that higher strengths and lower solubility and permeability have been achieved in some systems.

The use of ceramics in dental applications wherein the ceramic material is actually exposed to internal hard and soft tissues, as well as the circulatory system, has not been developed to the point where the materials are used in humans at the present time. Recent research efforts in this area are showing considerable promise for the use of ceramics for such purposes as tooth replacements, mandibular augmentation, etc., and it appears that in the near future some ceramic materials will come into use in this area.

Applications of ceramics in orthopedics include those relating primarily to skeletal repair or replacement and many of the material requirements are very similar to those for certain of the potential dental applications mentioned previously. Most of the reported ceramic-materials research oriented to these applications has involved studies of long-bone implants in animals. Long-bone repair or replacement is one of the principal application areas of orthopedic technology and, thus, implant studies aimed at better understanding of the physiological response of long bone to experimental ceramics was a logical starting point for the research. Much less work has been done regarding the use of ceramics in other types of bone, such as cranial bone where the vascularity is much less than in long bones. Progress toward the use of ceramic materials for various bone-repair applications has been slow and very few investigators in the field feel that they are near to justifying even experimental uses in humans. There are various reasons for this situation. The quantitative definition of the physicochemical and mechanical properties that any material should have in order to be really useful for these applications is presently beyond materials state of the art because of the complexity of the biological environment and the reactions that take place between a given material and this environment. The mechanical properties of various kinds of animal and some human bones in vivo are now reasonably well understood, and so the "target" values for any synthetic material for bone replacement are pretty well defined. The physicochemical properties are another matter, however, and this subject is discussed in more detail later.

The cardiovascular or blood-circulatory system is undoubtedly the most demanding physiological environment for any materials application. The materials objective is basically to have a substance that can be used for indefinite periods of time in contact with blood and that does not in any way trigger the clotting mechanism and does not injure any of the cellular or other constituents of the blood. For applications such as heart valves, the material must also be capable of performing millions of operational cycles without mechanical failure. Quantitative assessment of the thrombogenic potential of a material is presently not a simple matter to determine as there are apparently several related factors that determine this potential for a given material surface in a given blood system at a given point in time.

Presently, only vitreous and certain pyrolytic carbons have shown promise for use in these applications, and some of these products have been used in humans in the form of heart valves.

Ceramic materials, therefore, show promise of potential use in the areas mentioned, and in this report the present status of materials development for these medical applications as perceived by the author is discussed in detail. Considerable effort was made to insure incorporation of the most recent and relevant work, but in any effort of this type there are undoubtedly cases of significant contributions that have been missed.

BIOLOGICAL, CHEMICAL, AND STRUCTURAL CRITERIA FOR USE OF CERAMICS IN BIOLOGICAL SYSTEMS

As stated previously, the chemical criteria for suitable synthetic materials for biological use are very difficult to identify in such a way that they can be used directly to develop materials for specific biomedical applications. The reasons for this are the complexity of living systems and the lack of understanding of certain aspects of materials. The result is that the fact that a given material is found to be suitable for a medical application is usually the result of empirical experimentation, usually starting with an animal model. If the results warrant, progression through the sequence extensive animal screening ⟶ human experimentation ⟶ human clinical trials would represent the logical course of events. The medical community and governmental regulatory bodies, of course, have well-prescribed protocols that provide the necessary experimental format and results as the evolution of a material advances toward contemplated human use.

Even with the relatively advanced state of materials science and technology it is not presently possible to quantitatively model a material-biological system and really obtain a great deal of information which can be used positively toward advancing a material to clinical use. The criteria that any permanent implant material must satisfy have been summarized by Garrington and Lightbody[1] to include:

(1) Biocompatibility. Generally, the implant materials must be inert in the host-tissue environment. There are some recently developed ceramic materials that function by actually resorbing slowly as they are replaced by new bone. These are discussed in detail later. Aside from this exception, an implant material, whether it be ceramic, metallic, or polymeric, is selected on the basis of its inertness. Specifically, suitable materials must be nonallergenic, nontoxic, and noncarcinogenic.

(2) Nonbiodegradability. Of all presently known ceramic materials which have been considered for implant applications there are only two which presumably function either by (1) selective ionic leaching from the surface or by disappearing from the implant site with time. These are certain recrystallized glass-ceramics reported by Hench[2] and the calcium phosphate ceramics reported by Driskell, et al.[3] The other more inert ceramic materials discussed were at least initially selected on the basis of their chemical stability. The manner in which a bioresorbable ceramic material functions while in contact with a traumitized region of bone is presently being determined in various research programs and is discussed in detail later. Other than these relatively recent exceptions, implants should not undergo degradation in the tissue environment, and for most contemplated applications, should not undergo significant deformation or fracture while being stressed during use.

(3) Functional Performance. Implant materials must be capable of performing the mechanical function of the part they replace for the necessary length of time. In the case of so-called permanent implants, the length of time is obviously for the expected life of the patient. Because of the ability of living bone to remodel in order to meet changing stress requirements and its apparent absence of mechanical failure due to fatigue, the development of an inorganic