COMPOSITE IMPLANT MATERIALS AND PROCESS FOR PREPARING SAME

FIELD OF THE INVENTION

The invention relates to composite implant materials, particularly composite materials of apatite useful for artificial prostheses in orthopedic and dental fields, and to a process for the preparation thereof.

BACKGROUND OF THE INVENTION

Various metallic, plastics and ceramic materials have hitherto been used as an implant material for a bone or tooth in the orthopedic and dental fields. However, these conventional materials are not satisfactory since they are poor in compatibility to bone in a human or animal body.

Apatite is represented by the formula $Ca_{10}(PO_4)_6(OH,F,Cl)_2$, which may further contain 1 to 10% of carbonate ion (CO_3^{--}). Such an apatite substance constitutes a main component of the minerals of bones and teeth in vertebrate and has chemical properties such as being soluble in an acid, little or slightly soluble in water and highly stable in an alkali. It is known, on the other hand, that sintered apatite materials obtainable by sintering apatite at a high temperature have no toxicity and are excellent in compatibility to bone in a human or animal body. Therefore, the sintered apatite materials have increasingly become of great interest in the orthopedic and dental fields. However, the sintered apatite materials have insufficient mechanical strength, paricularly low impact strength, and therefore, must be improved in strength in order to make it possible to employ them as an implant material for a part to which body weight is to be loaded, for example (see, H. Aoki et al, Ceramics, "Apatite as a Biomaterial", 10 [7] 1975, PP. 57–66).

SUMMARY OF THE INVENTION

It has now been found that the use of a plastics material in combination with a sintered apatite material makes it possible not only to improve the strength inherent to the sintered apatite material but, also, to moderately control the compatibility of the sintered apatite material to bone, and; hence, composite materials of a sintered apatite material with a plastics material can provide very useful implant materials.

Thus, the principal object of the present invention is to provide composite implant materials which can avoid the above-mentioned drawbacks encountered with the conventional implant materials and are excellent in both physical and chemical properties.

According to the present invention, a composite implant material comprises a sintered apatite material and a thermoplastic or thermosetting resin, at least said sintered apatite material existing in a continuous phase and the respective phases of said sintered apatite material and said thermoplastic or thermosetting resin being exposed, in part, to the surface of said implant material.

The present invention also provides a process for preparing the composite implant material according to the invention, which process comprises forming a sintered apatite material and filling or impregnating a thermoplastic or thermosetting resin into the pores or holes of the sintered apatite material, which have been formed during the formation of said sintered apatite material or perforated into a desired configuration after the formation of said sintered apatite material.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1** through **3** schematically illustrate the embodiments of the arrangement of the sintered apatite material phase and the thermoplastic or thermosetting resin phase in the composite implant material formed into a columnar shape.

DESCRIPTION OF PREFERRED EMBODIMENTS

Apatite to be employed in the present invention may preferably be hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$). Hydroxyapatite may contain a certain amount of whitlockite ($Ca_3(PO_4)_2$), if desirable from the view point of the affinity to bone or the strength. The preparation and the sintering of apatite may be carried out, for example, by a method as described in the Japanese publication hereinbefore mentioned. The sintered apatite material may, thus, be obtained in a porous or dense state. The composition of the resulting sintered apatite material can be desirably controlled by appropriately selecting the composition of the starting material or the condition for the preparation or sintering of apatite. Likewise, the porosity of the resulting sintered apatite material can also be desirably controlled.

The thermoplastic or thermosetting resins usable for the present invention may be selected from those which are well known in the art. Examples of such resins include polyethylene, polypropylene, polymethyl methacrylate, polyurethane, polyester, acrylonitrile-butadiene-styrene resins, fluorocarbons, polyamides, polyacetals, polycarbonate, polysulfone, epoxy resins, silicone resins, diallyl phthalate resins and furan resins. These resins may contain reinforcing materials such as carbon, silicon carbide, glass, alumina, magnesia, zirconia, tungsten, molybdenum, stainless steel and the like, and other fillers. It is desirable that these resins and reinforcing materials be selected so as to provide desired properties, such as mechanical strength and stability, to the resulting composite material, according to the intended use thereof. However, it is important that they be selected in careful consideration of innocuity against a living body and of good processability.

Where the sintered apatite material is as dense as to have a porosity of not more than 20%, the resin may not be or very scarcely be impregnated into the sintered apatite material. However, where the sintered apatite material has a porosity above 20%, the resin may be directly impregnated into the pores of the sintered apatite material. That is to say, in the process of the present invention, the sintered apatite material may be formed into a porous state so that the resin may be impregnated into the pores to obtain a composite material. Alternatively, if the sintered apatite material is so dense that the resin may not be impregnated, or if an additional amount of the resin is to be impregnated, or the resin is to be filled into the sintered apatite material in a desired configuration, the sintered apatite material may be formed with a desired porosity, perforated into a desired configuration by mechanical perforation, or chemical treatment, or by perforation by means of an ultrasonic wave vibration, laser, water jet or the like, and then, filled or impregnated with the resin into the pores or holes. Then, the resin may be hardened or cured by a conventional method.