BIOACTIVE COMPOSITE MATERIAL PROCESS OF PRODUCING AND METHOD OF USING SAME

CROSS-REFERENCES TO RELATED APPLICATIONS:

The present application is related to the following copending applications:

Ser. No. 471,891 of HEINZ BROEMER, HANS-HERBERT KAES, and EMANUEL PFEIL, filed May 21, 1974, now U.S. Pat. No. 3,922,155 and entitled GLASS CERAMIC MATERIAL AND PROCESS OF MAKING AND USING SAME and

Ser. No. 576,797 of HEINZ BROEMER, HANS-HERBERT KAES, and EMANUEL PFEIL, filed May 12, 1975, now U.S. Pat. No. 3,981,736 and entitled GLASS CERAMIC MATERIAL AND PROCESS OF MAKING AND USING SAME, said application being a division of the aforementioned application Ser. No. 471,891. Said applications are incorporated by reference into the present specification.

BACKGROUND OF THE INVENTION

(1) Field of the Invention

The present invention relates to a novel and useful bioactive composite material for prosthetic purposes, to a process of making same, and to the use of the resultant material in dental and bone surgery.

(2) Description of the Prior Art

In order to fix, i.e. firmly attach, for instance, endoprostheses and other bone replacements in the animal or human body it is known to use a so-called "bone cement" consisting of a plastic having a base of methacrylate. For instance, in the "Zeitschrift fuer Orthopaedie" vol. 112 (1974), pages 419–426, there is described a plastic "Palakav" which contains silica gels in addition to methyl methacrylate and an organic catalyst. The ratio of methyl methacrylate to silica is 58:42 in said bone cement. The inorganic gels added to said cement serve merely as filler for the plastic matrix.

Although with the use of this composite material there have already been achieved more favorable bonding effects in the sense of a micro-meshing effect of the "Palakav" on the adjoining bone substances than with the bone cements previously used such as, for instance, "Palacos," said known bone cement is merely able to bring about a certain macro-anchoring or -meshing effect with the adjoining bone substance. It has not been possible, however, to solve with the composite materials known up to the present time the basic problem of achieving fully satisfactory anchoring or bonding between the replacement material and the bone wall in the sense of stable, chemical, principal valence-like bondings which are capable of withstanding to a substantial extent even continuous compression, tension, shear, and/or torsional stresses.

SUMMARY OF THE INVENTION

It is one object of the present invention to create a biocompatible composite material which not only has a certain "adhesiveness" but is also bioactive while avoiding the disadvantages inherent in the known materials, and thus results in a complete intergrowth at the corresponding contact surfaces between said material and the bone wall.

Another object of the present invention is to provide an appropriate method for the manufacture of a bioactive composite material in accordance with the present invention.

Still another object of the present invention is to use such a biocompatible composite material in surgery, orthopedics, and dentistry.

Other objects of the present invention and advantageous features thereof will become apparent as the description proceeds.

In principle, these objects are achieved according to the present invention by providing a composite material which consists of a plastic matrix having a base of methacrylate and of at least one bioactive material. Preferably said bioactive material is a glass ceramic material as described and claimed in U.S. Pat. No. 3,922,155 (patent application Ser. No. 471,891 mentioned hereinabove). Such a glass ceramic material with an apatite crystal phase consists, in weight percent, of

about 20% to about 60% of silicon dioxide SiO_2,
about 5% to about 40% of phosphorus pentoxide P_2O_5,
about 2.7% to about 20% of sodium oxide Na_2O,
about 0.4% to about 20% of potassium oxide K_2O,
about 2.9% to about 30% of magnesium oxide MgO, and
about 5% to about 40% of calcium oxide CaO.

Such glass ceramic material may additionally contain between about 0.005% to about 3.0% of fluorine F_2.

A preferred glass ceramic material of this type is composed (in weight percent) of the following components:

about 30% to about 60% of silicon dioxide SiO_2,
about 5% to about 20% of phosphorus pentoxide P_2O_5,
about 3% to about 10% of sodium oxide Na_2O,
about 3% to about 10% of potassium oxide K_20,
about 5% to about 20% of magnesium oxide MgO, and
about 10% to about 30% of calcium oxide CaO.

Such a preferred glass ceramic material may additionally contain between about 0.5% and about 2.5% of fluorine F_2.

Said glass ceramic material is comminuted, preferably to a particle size between about 50 μm. and about 500 μm. preferably between about 90 μm. and about 250 μm., and is added in such a finely comminuted form to the plastic matrix, wherein it is distributed either homogeneously (isotropic particle distribution) or in a precisely predetermined non-homogeneous manner (anisotropic particle distribution). Advantageously the proportion of bioactive material in the composite material is between about 10% and about 70%, by volume, and preferably between about 30% and about 60%, by volume.

It is also possible for the composite material according to the present invention to contain in addition at least one reinforcing component, preferably consisting of a fiber material, for instance, of glass fibers of known composition, in order to improve its mechanical properties.

According to an embodiment of the present invention, first there is added a pulverulent or liquid material which acts as a hardening agent, preferably an oganic peroxide, in known manner to a liquid monomeric methacrylate, preferably methyl methacrylate. Thereupon the finely comminuted bioactive glass ceramic material described hereinabove is admixed. In this connection it is of advantage, in order to achieve a precisely