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PLASTIC BONE COMPOSITION AND METHOD OF MAKING SAME

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No Drawing. Continuation-in-part of application Ser. No. 60,983, July 6, 1970, which is a division of application Ser. No. 805,400, Mar. 10, 1969, now Patent No. 3,609,867. This application Oct. 4, 1971, Ser. No. 186,442

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6 Claims

ABSTRACT OF THE DISCLOSURE

A plastic bone composition and method of making same, said composition comprising as its basic ingredients a mixture of an acrylic polymer, a foaming agent, N-tributyl phosphate, and grated anorganic bone. The mixture is usable for dental implants, as well as for implants in other parts of the body, and as a coating for metals which may be implanted in the human body for dental purposes, orthopedic prostheses, neurosurgery, etc.

BACKGROUND OF THE INVENTION

This is a continuation-in-part of applicant's copending U.S. application Ser. No. 60,983, filed July 6, 1970, which in turn is a division of applicant's copending application Ser. No. 805,400, filed Mar. 10, 1969, now Pat. No. 3,609,867.

It is well known in the dental art to utilize an acrylic polymer, such as polymethacrylate, for example, in the making of denture bases; and, also, artificial implants have heretofore been made of this material. These acrylic polymers have many characteristics that make them highly desirable for use as an artificial implant, which characteristics include the fact that this plastic material approaches a natural tooth in hardness and rigidity, is not adversely affected by the temperature conditions normally encountered in the human mouth can be worked with facility to any desired shape, retains its color and composition, etc. Perhaps of even greater importance is the fact that it has been found that when an acrylic polymer is used for an artificial tooth replica implant a periodontal membrane forms around the base of the artificial implant much like that which exists around a natural tooth. This periodontal membrane is the structure that acts as a shock absorber, infection limiting mechanism and as a cellular reservoir, and the presence of such a membrane in an artificial implant is extremely important and desirable. It has been found that the membrane which forms about the acrylic polymer artificial implant distributes the forces exerted to the supporting tissues of the tooth in a near-natural manner.

One of the problems that has existed in connection with acrylic polymer dental implants is the fact that the fibrous interlock between the artificial implant and its periodontal membrane is not as deep and penetrating as that which exists with a natural tooth, nor is the pattern of interlock the same. The instant invention overcomes this deficiency and achieves a more effective interlock by more closely approaching the interlock which exists with a natural tooth, thus forming a more healthy periodontal membrane and a more firm and secure mounting of the artificial implant in the alveolar socket.

The instant invention also has utility in overcoming certain disadvantages that exist where metal implants are used in the human body. Metal implants have traditionally been used for dental purposes, as well as in the field of orthopedics and neurosurgery, and one of the

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problems that exist in such metal implants is the fact that metals have corrosive actions in the presence of living tissues, resulting in electrolytic currents being emitted, which in turn results in resorptive and destructive phenomena. It is, therefore, desirable to coat such metallic implants with the plastic bone composition of the instant invention since, once so coated, the implant is resistant to corrosion and hence is non-conductive of the aforesaid electrolytic currents. In addition, the plastic bone coating results in a better fibrous interlock between the metallic implant and the surrounding bone in a biologically acceptable manner.

SUMMARY OF THE INVENTION

It is therefore a primary object of the instant invention to provide a composition of matter for use as an implant in the human body wherein the implant is biologically accepted by the surrounding tissues and interlocks therewith in a firm manner.

Another object is the provision of a composition which may be used in the formation of an artificial dental implant, said composition being such that when the artificial implant is mounted in an alveolar socket, a periodontal-like membrane will form about the roots of the implant much like the membrane which exists around the roots of a natural tooth.

Another object is the provision of a plastic bone composition that may be used as a coating for metal implants.

Still another object is the provision of a plastic bone composition that is structurally strong but yet has sufficient porosity to enable implants or inserts of said composition in the human body to effectively interlock with surrounding bone and other tissues such as connective tissues.

DESCRIPTION OF THE INVENTION

In applicant's copending applications Ser. Nos. 60,983 and 805,400, a plastic bone composition is described comprising as its basic ingredients a mixture of an acrylic polymer and anorganic bone. The bone is grated or ground to powder form and then mixed with the polymer, which may be either a heat process or quick-setting plastic. Any suitable bone may be used, although in practice it has been found that Boplant (registered trademark of Squibb) and Kiel Bone (trademark of Unilab Surgicals) have proven to be highly satisfactory. Boplant and Kiel Bone are sterile, processed, bovine bone or cartilage commonly used for grafting procedures in orthopedic and reconstructive surgery. The plastic may be polymethacrylate, polymethylmethacrylate, or any other acrylic polymer having substantially the same characteristics.

The acrylic polymer in the above mixture imparts rigidity and strength to the composition, wherein its architectural shape is maintained; and, as previously mentioned, acrylic polymers, such as polymethacrylate, have substantially the strength, color, stability, and temperature characteristics exhibited by natural teeth, which, of course, is of extreme importance when the instant composition is used as an artificial dental implant. On the other hand, the anorganic bone in the mixture is degrading and resorptive, thus increasing the porosity of the composition. Thus, the composition becomes more porous as resorption of the bone takes place.

It has now been found—and this is really the basic concept of the present invention—that increased porosity near the outer surface of the polymer implant, where such porosity is most beneficial, may be achieved by adding to the polymer mixture a measured amount of N-tributyl phosphate. As stated, the addition of this chemical has been found to cause the resultant implantable polymer

to have an increased porosity at its outer surface, said increased porosity being produced by the breakdown of one wall of each vacuole, thereby producing a surface network of interconnecting pores. This phenomenon occurs when the total mixture is polymerized as by being invested in a mold, such as a plaster mold, and heated at approximately 300° F. for approximately 30 minutes. After removal from the mold, the resultant processed polymer has an outer skin thereover, which must be removed before the polymer is implanted. The removal of this skin or film, which may be effected by any suitable procedures, such as sandblasting with quartz, changes the surface texture of the molded polymer by opening the pores located adjacent to the surface to the surrounding environment, and when implanted, to the contacting tissues, whereby the tissues penetrate the pores to effect a secure fibrous interlock between the implant and the surrounding periodontal membrane.

The preferred composition of the present invention comprises initially a mixture of an acrylic, such as polymethacrylate, grated anorganic bone, and a foaming agent, such as dinitrosopentamethylene tetramine. Specifically, the mixture of these ingredients involves by weight approximately 65 to 70 percent of polymethacrylate, approximately 10 to 15 percent of the foaming agent, and 20 percent of the grated anorganic bone. To this mixture is added approximately 40 to 70 percent by weight of a monomer, and then approximately 20 to 100 percent by weight of the N-tributyl phosphate. When the total mixture is invested in a plaster mold or the like and heated at approximately 300° F. for 30 minutes, it will be understood that the monomer will cause polymerization of the mixture but will substantially evaporate so as not to appreciably affect the proportionate weights of the ingredients. The N-tributyl phosphate will also evaporate off to some undetermined degree; but it has been found that the resultant polymerized material may comprise by weight somewhere between 33⅓ and 58⅓ percent acrylic polymer, 5 to 12½ percent foaming agent, 10 to 16⅓ to 50 percent N-tributyl phosphate.

As stated in my copending applications, the foaming agent adds to the porosity of the composition, and it has now been found that the foaming agent additionally appears to coact with the N-tributyl phosphate to enhance and promote the desired surface porosity. Thus it is highly desirable to use such an agent, in the proportions above set forth.

It will be understood that the real novelty in the present invention is the introduction of the N-tributyl phosphate into the mixture whereby increased porosity exists in the polymerized composition near the outer surface thereof, said porosity being subsequently exposed by removal of the outer skin from the molded composition, such as by sandblasting, after the composition has been polymerized in a mold and removed therefrom. Obviously, the degree of porosity will be dependent upon the amount of N-tributyl phosphate that is added to the mixture, as well as the amounts of foaming agent and anorganic bone, it being desirable to add a sufficient amount of these ingredients to create the desired porosity, while at the same time not so much as to structurally weaken the material so that it will not effectively function for its intended purpose. In this connection, it has been found that the addition of anywhere between .2 and one milliliter of N-tributyl phosphate for each gram mixture of polymethylmethacrylate, foaming agent, and anorganic bone in the aforesaid proportions has provided clinically satisfactory results.

When the aforesaid compositions are used as an artificial dental implant, the tooth replica implant, after being molded and sandblasted as aforesaid, is placed in the existing alveolar socket as soon after extraction of the natural tooth as possible. As previously stated, an artificial dental implant constructed of this composition has the

highly desirable feature of forming a periodontal-like membrane much like that which exists with an actual tooth. The increased porosity adjacent the outer surface of the implant resulting from the N-tributyl phosphate causes a firm and natural-like interlock between the implant and the periodontal membrane, since the increased porosity permits penetration of surrounding fibrous tissue into the implant. It should be noted, however, that this composition is not limited to use as a dental implant, but rather may be used as a substitute for human tissue wherever necessary and desirable, such as to fill defects or holes in the brain, skull or the like. Expressed differently, my composition may be used as a replacement for depleted bone throughout the body, such as in cranio-plasties and cysts. In addition, this composition is highly desirable for use as a coating material for metals that are used throughout the body for orthopedic prosthesis or which may be used for abutment supports for dental replacements. In other words, the composition of the present invention may be used as an implantable coating for metals and, when so used, results in increased tissue attachment to the implant for the reasons hereinabove described. By utilizing such a coating, the corrosive effects of metal are greatly diminished or eliminated, and heat transfer from the metal to the surrounding contacting tissues is greatly lessened.

The following is a specific example of a formulation from which an artificial dental implant was actually made. Two tenths of a gram of grated anorganic bone (Kiel Bone) was mixed with .15 gram of dinitrosopentamethylene tetramine and with .65 gram of polymethacrylate. To this powdery mixture was added .5 milliliter of a monomer and .2 milliliter of N-tributyl phosphate. The entire mixture was mixed well until it assumed a generally homogeneous gel-like consistency and then was placed in a plaster mold, the cavity of which conformed to the shape of the natural tooth being replaced, the inside of the mold first being coated with an alginate separating medium. The mold was then heated at 300° F. for 30 minutes, after which the now-polymerized composition was removed from the mold and chilled in water. The outer surface of the molded implant was then sandblasted with fine quartz to remove the outer skin therefrom. The resultant implant was characterized by a look and feel closely simulating that of a natural tooth. The implant was implanted into the jaws of a Papio baboon. The implant became firm within a two-to-three month period, and fixation to adjacent natural teeth or to other implants was no longer necessary, and the implant became completely self-supporting.

As this invention may be embodied in several forms without departing from the spirit or essential characteristics thereof, the present embodiment is therefore illustrative and not restrictive, since the scope of the invention is defined by the appended claims rather than by the description preceding them, and all changes that fall within the metes and bounds of the claims or that form their functional as well as conjointly cooperative equivalents, are therefore intended to be embraced by these claims.

What is claimed is:

1. A composition consisting essentially of polymethylmethacrylate, grated anorganic bone, dinitrosopentamethylene tetramine, and N-tributyl phosphate, the mixture comprising by weight 33⅓–58⅓% polymethylmethacrylate, 5–12½% dinitrosopentamethylene tetramine, 10–16⅓% bone, and 16⅓–50% N-tributyl phosphate.

2. The method of making a plastic bone for implant purposes comprising the following steps:

- A. forming a mixture comprising approximately by weight 65–70% of polymethylmethacrylate, 10–15% dinitrosopentamethylene tetramine, and grated anorganic bone in an amount sufficient to provide 10–16⅓% bone in the final product;
- B. adding approximately 40–70% by weight of a monomer to the mixture of Step A;

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- C. adding approximately 20-100% by weight of N-tri-butyl phosphate to the resultant mixture of Step B;
 D. introducing the resultant mixture of Step C to a mold;
 E. heating said mold;
 F. removing the molded mixture from said mold; and
 G. removing the outer skin from the molded mixture.
 3. In the method of claim 2, said heating step being at approximately 300° F. for approximately 30 minutes.
 4. In the method of claim 2, the step of removing the skin comprising sandblasting.
 5. The method of claim 2 further characterized in that the amount of anorganic bone in Step A is approximately 20% of the mixture.
 6. A plastic bone implant made in accordance with the method of claim 2.

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