

degree of porosity and strength. The temperature and pressure of molding is also chosen to provide the optimum properties of porosity desired for the flow of lubricant. These parameters are well known in the art. At the present time ceramics appear to be best suited for forming the central core 12a. The reason for their desirability is a combination of ease of forming and chemical inertness both to rejection by the body and to attack by body fluids. At the same time porous ceramics exhibit high compressive strength needed to support the body's weight in the joints. It is possible that in the future a plastic or other porous material will be discovered which will be equally suitable from the standpoint of strength and chemical compatibility with the body fluids.

In a structural application such as a prosthesis for a human femur the core 12a is preferably formed into joints 22, 24 at each end of the prosthesis and is continuous through the length of the prosthesis (FIG. 2). For other lower stress applications in which it is not necessary for the fluid to be communicated to both ends of the prosthesis a porous core may be employed for the joint which extends only partially into the structure of the prosthesis thereby retaining the lubricant though not permitting flow through the prosthesis.

Many ceramics known today are suitable for forming the porous core material of the present invention. Examples of suitable materials include alumina, synthetic aluminum silicates, glass compositions, and various pure mineral silicates. These can be cast in a mold using an aqueous vehicle and an inorganic chemical binder such as sodium silicate, phosphoric acid, or aluminum phosphate. They can also be pressed as a free flowing powder by die or isostatic pressing. These cast and molded or pressed ceramic bodies can be made resistant to body fluids by curing at an elevated temperature of at least 300° F., preferably 700° to 800° F. The resultant structures possess high porosity and good dimensional stability.

As mentioned previously, the porous material is primarily for the retention and flow of lubricating fluids for the joint. The fluid is retained in the pores and is pumped to the cartilage under pressure in a manner similar to squeezing a sponge. The presence of natural body fluids is a particularly beneficial feature of the present invention. Because the natural fluids are disposed near the joint where they can squeeze onto the cartilage, the necessity of replacing the entire joint and cartilage is avoided. The importance of the natural fluids was mentioned earlier. They serve the dual function of lubrication and nourishment of the cartilage. Just lubrication is not enough. Without nourishment the cartilage disintegrates and the joint will fail.

The outer layer of material is preferably formed of a ceramic matrix 16 having fibrous or filamentary reinforcing material 18 disposed within it. The material employed for the matrix 16 may be the same as or different from the material used in the core 12. The same materials listed above for the core are among those suitable for the matrix. The matrix is preferably formed by slip casting techniques. It is usually desirable that the matrix 16 be less porous than the core material 12. Porosity in any ceramic is easily controlled by proper selection of grain size, distribution and viscosity during forming in a manner well known in the art.

The reinforcing material 18 is discontinuous and is embedded in the low porosity matrix. In the illustrated embodiment reinforcement is provided by stainless steel oriented primarily in the direction of highest tensile stress on the member. The length of the reinforcing material may vary from relatively short fibers 18 (FIG. 1) to elongated filaments 18a (FIG. 2) extending the length of the member to be reinforced. It may also be randomly oriented if in a particular application the stresses will not be great enough to warrant the expense of orienting the fiber. For reasons of weight, reinforcing material 18 should preferably be limited to approximately 25 percent by weight of the composite 14. This limitation may require fiber orientation in certain applications where high strength is required. If fiber orientation is desirable, any technique is suitable, such as manual, magnetic or electrostatic orientation

depending on the material employed. Other high strength materials may be substituted for stainless steel without departing from the scope of the invention. Examples of such materials are glass and boron fibers. As in the case of the matrix 16 and core 12 the reinforcing material 18 should be inert to body fluids since porosity in the matrix cannot be entirely eliminated.

If an elevated temperature process is employed the coefficient of expansion of the reinforcing material 18 is preferably greater than that of the matrix. For maximum effectiveness the reinforcing material 18 is then under tension for normal no load conditions.

The matrix 16 has been described as relatively nonporous. It should be pointed out that there are situations where porosity in the matrix is desirable. One example of the desirability of a porous matrix is the implant of a partial bone. This type of implant is in the nature of a splice. If the prosthesis is porous, the natural bone will actually knit with the prosthesis forming a strong bond of bone interwoven in the pores of the prosthesis. In this application a suitable prosthesis might include a ceramic of uniform porosity from center to surface having reinforcement embedded close to the surface.

It has been previously mentioned that all materials employed in a prosthesis must be immune to attack by body fluids. The chief factor in chemical attack by body fluids is the free chloride ion. Therefore a suitable material whether reinforcement, matrix or core should be relatively immune to attack by chloride ions.

The advantages of the present invention over existing prostheses are multiple. The materials are all free from reaction with and rejection by the body. The tensile strength of the ceramic is greatly improved by the reinforcement as is the flexural strength. The ceramic, even in its porous state, provides adequate compressive strength for joints while providing a path for maintaining natural body fluids in communication with the joint. Also, the replacement of the cartilage in the joint is avoided.

The following is an example of a prosthesis embodying the principles of the present invention.

EXAMPLE

A cylindrical core was first formed from a blend of an alumina and phosphoric acid. The alumina was composed of 3 parts of a -48 mesh and 1 part of a -325 mesh particle gradation. The acid was of an 85 percent concentration and admixed in the proportions of 1 part acid to 10 parts of the oxide. The mixture was placed in a rubber bag three-fourths inch in diameter and 5 inches long and the opening was sealed. The bag was placed in an isostatic press and subjected to 30,000 psi pressure. The pressed piece was placed in an oven at 100° C. for 4 hours and cured at 400° C. for 4 hours. This core was machined after curing to a proper prosthetic configuration and was permeable as formed.

A -325 mesh alumina powder was suspended in water by use of a household type mixer and stainless steel fibers were added in the amount of one-fourth the weight of the alumina. Phosphoric acid was added to make 10 percent of the solids. The paste was forced about the core section in a mold to form a thickness of one-fourth inch. This was allowed to dry for 24 hours in the opened mold, then heated 4 hours at 100° C. and 4 hours at 400° C. to cure the covering.

While the foregoing description has been directed primarily to use as a prosthesis the present invention finds other uses in any environment requiring structural integrity and nonreactivity with the environment.

We claim as our invention:

1. A prosthesis for human bone comprising a composite material of a predetermined configuration, said composite material comprising a matrix material and flexible, elongated reinforcing material, said reinforcing material and said matrix material being adapted to withstand contemplated tensile and bending forces applied to said prosthesis, and