REINFORCED POROUS CERAMIC BONE PROSTHESIS

This invention relates to structural members used as a prosthesis for human bone and made from composite members. More particularly it is directed to structural members made of composite materials including a matrix material and a reinforcing material embedded in the matrix.

A composite material is made up of a matrix phase and a discontinuous phase. Normally the matrix phase is a continuous phase and the discontinuous phase is made up of discrete pieces of reinforcing material. The reinforcing material may be in the form of filaments, fibers, flakes or powder and is added to the continuous matrix phase to lend some desirable property to the composite material not possessed by the matrix phase alone. For example, if the matrix phase is extremely resilient the reinforcement might be added to provide additional strength while retaining the resiliency of the matrix material.

In the case of ceramic composites the discontinuous phase or reinforcement may be provided for any number of reasons. The general properties of ceramic material can best be described by the terms mechanical brittleness, low tensile strength, rigidity, and high temperature strength. A ceramic has no appreciable yield strength and exhibits brittle failure. It is known that the brittleness and lack of plastic behavior in ceramics can be modified by the addition of a discontinuous phase of reinforcing material such as mild steel. When the proportions are correct, the resultant composite exhibits an elastic-plastic stress-strain curve similar to that exhibited by ductile materials. At the same time it retains many desirable properties of ceramic such as controllable porosity and chemical inertness when a non-reactive reinforcement is used.

As previously mentioned, the present invention finds particular application in the growing field of prosthetics. Bone implants are becoming an increasingly common thing in modern medicine. Several bone substitutes are already available for implant. Among the materials employed have been stainless steels, ceramics and plastics. Each of these materials suffers some limitations when used as a prosthesis. Many plastics are subject to attack by body chemicals or are rejected by the body's natural rejecting mechanism. Stainless steel is non-reacting but it is not well adapted to a knitting with the remaining bone structure in the case of splicing since it is not porous. There is further difficulty in adapting the stainless steel to the socket of an existing joint without having to replace the socket itself. Ceramic materials have been found to be too weak and brittle for the constant flexural stress applied to bones. The novel concept presented herein overcomes these and other difficulties encountered in the implant of a prosthesis.

A better understanding of the present invention will be facilitated by a brief explanation of the function and structure of human bones, which are, of course, the principal structural members of the human body. A natural bone derives its strength from an outer layer of relatively hard material. The material is strong under tensile loading, is durable under flexural loading and is to a certain extent flexible. Inside the outer layer is a softer area of the bone which does not provide much structural support but rather supplies the life needs of the bone. Blood and other body fluids flow within this inner section of the bone.

Bones are attached to each other at joints by means of muscles, tendons and ligaments. In a typical moving joint such as the elbow or the hip, the ends of two bones are placed together in sliding contact with cartilage and lubrication between them. Under normal circumstances, the joint will undergo thousands of flexures in a lifetime without deterioration. The durability of the joint is not due solely to the presence of the cartilage, which is a gelatin-like material. The chief prevention from wear and tear on the cartilage is provided by natural body lubrication which, in a natural joint, is provided by a fluid secreted by the body and called synovial fluid. The major constituent in synovial fluid is the mucin molecule, a cement substance combined with a protein to form an elongated molecule. The mucin molecules exist as polymers of variable lengths. In addition to the mucin molecules, the synovial fluid also contains glucose, amino acids and other cellular nutrients. Therefore the synovial fluid not only acts as a lubricant but also nourishes the cartilage. When the circulation of synovial fluid is stopped for a period of time, the cartilage cells in the region nearest the surface of contact die, eventually causing a bearing type failure of the bone at the joint. This is true even though an artificial lubricant is applied if no nutrition is received by the cartilage.

From the foregoing, it is apparent that any prosthesis which is to be of more than limited success without the total replacement of the cartilage and the mating half of the joint must in some way permit or even assist in promoting the continued presence of synovial fluid in the joint.

Accordingly, an object of the present invention is to provide an improved composite reinforced bone prosthesis.

A further object of the present invention is to provide an improved bone prosthesis made of ceramic composite material.

Still a further object of the invention is to provide an improved bone prosthesis designed to accommodate predetermined stresses through the engineering of the reinforcement phase of a ceramic composite.

Another object of the present invention is to provide an improved bone prosthesis having high strength chemical inertness and having bearing surfaces capable of receiving and retaining a fluid.

Other objects and advantages of the invention will be apparent from the following description taken in connection with the accompanying drawings in which:

FIG. 1 is a partial sectional view taken through a member embodying the features of the present invention; and

FIG. 2 is a sectional view of a prosthesis embodying the present invention.

Briefly the present invention relates to a composite article **10** as illustrated in FIG. 1. The article, regardless of its ultimate use or configuration, includes bearing surfaces at spaced points on the article. For convenience, the article is shown in FIG. 1 as a straight column having the components common to other contemplated configurations. In the illustrated embodiment an inner core **12** of porous material is provided which extends from one end of the column to the other. The core **12** is of sufficient porosity to permit fluid to be forced through the pores from one end of the column to the other under pressure. The core **12** is surrounded by a composite ceramic material **14**. The composite material is illustrated in the form of a circular cylinder which is preferably bonded to the core **12**. The composite material preferably has a continuous matrix **16** of ceramic material with elongate reinforcing material **18** embedded therein. In the embodiment illustrated, the elongate reinforcing material **18** is oriented in parallel fashion running lengthwise of the column.

As briefly described above, the structure shown in FIG. 1 finds its primary use as a prosthesis for human bone. The embodiment illustrated in FIG. 2 shows a prosthesis **20** for a human femur. The core **12*a*** (The subscript "*a*" is employed for elements in FIG. 2 corresponding to elements in FIG. 1.) of porous material has as its chief function the retention and circulation of the body's natural fluids or other added fluids through the structure of the prosthesis to make the fluids available at the joints for proper movement. The material employed for the core is preferably truly porous, that is, the pores communicate to form a network through the material to permit fluid to flow under pressure. An additional function of the core material is to act as a bearing surface for a joint. The joint stresses are primarily compressive and are adequately supported by the porous core **12*a***.

In order to achieve adequate structural integrity as well as porosity, the core **12*a*** is normally formed by conventional casting of an aqueous slurry in a mold with a chemical binder. Casting techniques are preferable to foaming which tends to produce a porous but friable structure. The materials are selected for grain size and consistency to provide the desired