

BONDING OF BONE TO MATERIALS PRESENTING A HIGH SPECIFIC AREA, POROUS, SILICA-RICH SURFACE

BACKGROUND OF THE INVENTION

Biologically active silicon dioxide (silica)-based glasses and glass-ceramics are known to the art. These materials are characterized by their ability to form a direct chemical bond of excellent strength with bone in vivo. The bond strength is not strongly dependent upon the degree of crystallinity of the biologically active material. However, the use of a partially or fully crystallized glass-ceramic is often preferred because devitrification increases the strength of the biologically active material itself. It has been proposed to construct a variety of dental and surgical implants for cement-free implantation from these biologically active glasses and glass-ceramics and of stronger materials such as aluminum oxide and surgical implant alloys coated therewith. The silica-based biologically active glasses and glass-ceramics of the prior art generally contain about 40 to 60 weight percent silica as the network former plus substantial levels of soluble modifiers such as sodium oxide, potassium oxide, calcium oxide, magnesium oxide, phosphorus pentoxide, lithium oxide and calcium fluoride. Boron oxide may be substituted for some of the silicon dioxide. A particularly preferred composition of the prior art, designated as composition 45S5, contains 45 weight percent silicon dioxide, 24.5 weight percent sodium oxide, 24.5 weight percent calcium oxide, and 6 weight percent phosphorus pentoxide. The chemical bond between a biologically active glass or glass-ceramic material and bone is to be distinguished from the mechanical type of bond formed by the ingrowth and interlocking of bone tissue within a macroscopically porous implant surface. Until now, it has been generally believed that a biologically active glass or glass-ceramic material possesses its activity because of its surface reactivity in physiological solutions. That is, soluble ions such as the sodium and calcium ions are selectively leached from the glass or glass-ceramic material, thereby causing the surrounding physiological fluid to become more alkaline. The alkaline solution then attacks the glass or glass-ceramic material, forming a silica gel layer thereon. It is to this silica gel layer, according to this proposed mechanism, that the fresh growing bone bonds [Hench, L. L., Splinter, R. J., Allen, W. C. and Greenlee, T. K., *J. Biomed. Mater. Res. Symp.*, No. 2 (Part I), pp. 117-141 (1971); Hench, L. L. and Paschall, H. A., *J. Biomed. Mater. Res. Symp.*, No. 4, pp. 25-42 (1973); Hench, L. L. and Paschall, H. A., *J. Biomed. Mater. Res. Symp.*, No. 5 (Part I), pp. 49-64 (1974); Piotrowski, G., Hench, L. L., Allen W. C. and Miller, G. J., *J. Biomed. Mater. Res. Symp.*, No. 6, pp. 47-61 (1975); Clark, A. E., Hench, L. L. and Paschall, H. A., *J. Biomed. Mater. Res.*, 10, pp. 161-174 (1976); U.S. Pat. Nos. 3,919,723; 3,922,155; 3,981,736; 3,987,499; 4,031,571].

It is of course known to achieve the fixation of dental or surgical implants to the bone of the recipient by utilizing organic resin cements such as polymethylmethacrylate. However, there are known disadvantages in the use of such cements related to reactivity in vivo, toxicity, and loosening of the fixation. It is also known to strengthen an implant resin cement by incorporating therein various types of reinforcing material including particles of glass (see e.g. U.S. Pat. No. 3,919,773).

Glass reinforced hardened inorganic cements (e.g. Portland cement) are also known (see U.S. Pat. No. 3,147,127).

Summary of the Invention

A novel dental or surgical implant having a surface for bonding to the bone of a recipient has now been discovered in which said bonding surface comprises a biologically compatible glass, glass-ceramic or ceramic material comprising at least about 80 weight percent silicon dioxide and having a specific surface area of at least about 80 square meters per gram, a porosity of from about 10 to about 50 volume percent, and an average pore diameter of from about 20 to about 300 Angstroms.

The present invention also includes a dental or surgical implant having a surface for bonding to the bone of a recipient in which said bonding surface comprises a biologically compatible inorganic material of adequate physical characteristics for the intended use, other than a silicon dioxide-based glass or glass-ceramic containing less than about 80 weight percent silicon dioxide, that is capable of developing a porous silica-rich surface layer having a specific surface area of at least about 80 square meters per gram within about 10 days' exposure to aqueous tris(hydroxymethyl)aminomethane buffer at a pH of 7.2 and a temperature of 37° C. Materials contemplated within this second aspect of the invention include certain ceramics and hardened inorganic cements, e.g., Portland cement.

Additionally, the present invention includes an improvement to a process for fixing a dental or surgical implant to bone comprising placing a wet cement between the surface of the bone and implant and allowing said cement to harden. Said improvement comprises using a biologically compatible inorganic cement which, in the hardened state, is capable of developing a porous silica-rich surface layer having a specific surface area of at least about 80 square meters per gram within about 10 days' exposure to aqueous tris(hydroxymethyl)aminomethane buffer at a pH of 7.2 and a temperature of 37° C. Portland cement is one inorganic cement which may be used. In a preferred embodiment of this improvement, the wet cement is mixed with particles of a biologically active silicon dioxide-based glass or glass-ceramic. In another preferred embodiment, the bonding surface of said implant in contact with said inorganic cement comprises a biologically active silicon dioxide-based glass or glass-ceramic.

DETAILED DESCRIPTION OF THE INVENTION

We have now surprisingly discovered that biologically active silica-based glass and glass-ceramic materials fabricated by standard casting and crystallization techniques bond strongly to bone by virtue of their ability to develop in vivo a porous silica-rich surface layer having at least a minimum specific surface area. Silica-based glass and glass-ceramic materials which do not develop a surface layer in vivo with the above characteristics generally form poor chemical bonds, or none at all, with bone. The high area silica-rich surface layer (roughly about 25 to 100 microns thick) apparently provides a vast number of sites for deposition and interaction of various of the organic and inorganic components of healing bone. In vivo biological activity may be predicted by a convenient in vitro test. Thus, a silica-