POLYMER RE-INFORCED ANATOMICALLY ACCURATE BIOACTIVE PROTHESES

CROSS-REFERENCE TO RELATED APPLICATION(S)

This application claims priority to U.S. Provisional Pat. Appln. Ser. No. 60/182,825 filed Feb. 16, 2000 and U.S. Provisional Pat. Appln. Ser. No. 60/135,009 filed May 20, 1999.

BACKGROUND OF THE INVENTION

Over 80,000 craniofacial reconstructions are performed annually in the United States. Although allograft and autograft tissues are the most commonly utilized graft materials, they have a failure rate ranging from 13–30%. Synthetic materials that can be produced in large quantities have been developed in numerous forms as alternatives to the traditional bone derived graft materials. Ceramic materials such as hydroxyapatite (HA), bioglasses, and tricalcium phosphate, and polymeric materials including polyethylene and silicone are available commercially in a wide variety of craniomaxillofacial procedures. All commercially available systems have at least one of the following shortcomings; 1) poor adaptation to recipient sites, 2) insufficient biological fixation, and 3) inadequate mechanical properties. The ability to manufacture implants that can simultaneously address all three problems is both commercially and medically significant.

Implants which do not match the unique anatomical constraints of the defect sites often require manual modification (grinding) of the implants, and/or the recipient bone. Additional modification is often necessary on the external surfaces to produce the appropriate facial contours. Although manual alteration can be trivial in some cases, extensive modifications are often necessary. Pre-fabricated elastomeric silicone implants adapt easily to the recipient sites, but they are generally characterized by soft tissue encapsulation, bone resorption, migration, and distortion (drooping). The latter problems are believed to be related to the lack of biological fixation, or tissue penetration into the implant surface. Porous implants allow tissue penetration, but their porous nature severely degrade their mechanical properties. This is particularly true for porous ceramics implants, which tend to break during extensive manual modifications. Dense ceramic materials typically have greater load bearing ability than their porous counterparts, but their excessive stiffness (high modulus) may induce stress shielding.

In summary all commercially available systems have at least one of the following shortcomings; 1) poor adaptation to recipient sites, 2) insufficient biological fixation, and 3) inadequate mechanical properties. Implants which can simultaneously address all three problems can be both commercially and medically significant.

BRIEF SUMMARY OF THE INVENTION

This invention embodies implants comprising a porous surface layer and a tough inner core of interpenetrating phase composite, offering several advantages over currently available implants utilized for the replacement or augmentation of the craniofacial bones. The porous surface layer enhances the biocompatibility, tissue ingrowth, and implant stability over commercially available polymer implants, while the tough inner core improves the mechanical properties of the implant by allowing for a higher fracture

toughness and a lower modulus than commercially available ceramic implants. The anatomical accuracy of the implants will minimize the intra-operative manipulation required to maintain a stable host bone-implant interface, which is important in gaining surgeon and patient acceptance by reducing surgical time and enhancing the ability of porous surface layer to support bone formation.

Broadly the invention comprises implants having internal regions of high fracture toughness. The internal regions are one or more interpenetrating phases.

Anatomically shaped, porous preform are fabricated, and subjected to secondary post-processing steps depending on preform material and desired preform properties. The preform comprise continuous network of partially fused particles. Next, an inhibition layer is produced along desired surfaces of the preform by selectively coating the preform with a thin layer of fugitive material. The inner core of the preform is infused with a polymer precursor. The infused samples are processed to convert the precursor to a polymer, resulting in a interpenetrating phase composite in the inner core of the preform. Finally, the fugitive material is eliminated from the preform, leaving an open porous layer.

In a preferred embodiment, the phases are hydroxyapatite and polyethylene. Hydroxyapatite has been used extensively due to its chemical and crystallographic similarities to human bone minerals. With a flexural strength of 100 MPa, a fracture toughness (K_{Ic}) of ~1 MPa $m^{1/2}$, and a modulus of ~100 GPa, hydroxyapatite per se is too brittle and stiff for applications other than coatings and non-weight bearing implants. For comparison, human femur has a flexural strength of 170 MPa, a modulus of 15 GPa, and a fracture toughness (K_{Ic}) of 6.4 MPa $m^{1/2}$. The fracture toughness of human cortical bone has been reported to range from 2 to 12 MPa $m^{1/2}$. Numerous attempts have been made to toughen hydroxyapatite.

In this preferred embodiment, interpenetrating phase implants are produced by first fabricating a proper preform shape with hydroxyapatite powder, partially sintering the hydroxyapatite particles, and finally infusing the interparticulate pores with the polymer. Because only slight sintering is necessary, near net-shape implants can be produced with minimal anisotropic shrinkage and non-uniform residual stress distribution that are often encountered during complete densification of complicated shapes. The surface porosity can be preserved for tissue ingrowth by first filling the surface pores with a temporary filling material prior to infusion, and removing the temporary material to reveal the surface pores. Many FDA-approved polymers can be utilized for the filling material, e.g. polyethylene glycol, waxes, hydrogels, acrylic latexes, and other water-soluble or water-dispersible materials.

One alternative embodiment of the invention comprises multiple infusion of polymer/monomer combinations to create an implant which contains a gradation of resorbable polymers such that the rate at which the polymers resorb varies across the implant.

Another alternative embodiment of the invention comprises infusion of active/monomer, active/polymer, active/monomer/polymer, active/polymer/monomer/inorganic combinations where the active can be selected from the group consisting of drug molecules, growth factors, adhesion peptides, promoters, activators and other regulators of gene expression.

Still another alternative embodiment of the invention comprises infusion of polymer/monomer combinations with inorganic material dispersed in the polymer/monomer mix-