

the infiltrating resin. Referring to FIG. 1, a section of an implant is shown at step 4 comprising an inner core 12, an inhibition outer layer 14 and an infusion channel 14. At step 5, a porous outer layer 16 is shown. Specifically, formation of the inhibition layer is carried out as follows. Polyethylene glycol or polyethylene glycol/water solution is applied on the porous implant surfaces to form the desirable pattern, and if necessary, preserve an infusion channel. The implant is then placed in a furnace and heated to a temperature to cause the polyethylene glycol or polyethylene glycol solution to flow and infuse into the porous implant. The heating time determines the penetration distance. For example, heating treating at 60° C. for 1 hour allows the penetration depth of 500–1000  $\mu\text{m}$  of a fugitive polymer, comprised of a 37.5 wt % solution of 35,000 MW polyethylene glycol in water, into a porous preform with an average pore size of 16  $\mu\text{m}$ .

#### Infusion

To produce a tough inner core of interpenetrating phase composite

In the broadest aspect of the invention, the interpenetrating phase comprises two networks or material which are bound to one another. One network is the porous preform. The other inner core network is any material having a molecular lattice structure in the solid state. In the preferred embodiment, multiple infusion of the other inner core networks are used to precisely tailor the characteristics of the preform.

A tough inner core is produced by infusing the porous preform with a polymer precursor. Infusion is accomplished by using a vacuum chamber which is initially filled with sufficient precursor. Inside the chamber, the samples are secured in a sample holder which is suspended above the liquid. The entire chamber is evacuated until a constant minimum pressure of  $10^{-4}$  to  $10^{-2}$  torr is obtained. The evacuation time depends on the number and size of samples in the chamber. The samples are then lowered into the precursor, which will fill the internal pores via capillary action. The rate of infusion depends on materials properties such as contact angle, viscosity, pore size distribution, and pore volume. After complete infusion, the precursor is treated appropriately to result in polymerization without inducing excessive stresses in the porous preform.

Materials appropriate for infusion include, but not limited to: Monomers (acrylates such as, but not limited to TEGDMA triethylene glycol dimethacrylate, MMA methyl methacrylate, Bis GMA 2,2-bis[4(2-hydroxy-3-methacryloyloxy-propyloxy)-phenyl] propane); thermoplastics (such as, but not limited to styrene, vinyl acetate, vinyl chloride, polyethylene, PTFE polytetrafluoroethylene, polypropylene); epoxies (polyetherketone, polyetheretherketone, polyphenylene oxide); resorbable polymers (such as, but not limited to polylactic acid, polyglycolic acid, polycaprolactone, polytrimethylene carbonate, polydioxanone, polyiminocarbonates, polyamides, polyorthoesters, polyanhydrides, polyhydroxyalkanoates, polyhydroxybutyrate); water soluble/hydrophilic (polyvinyl alcohol, PVA poly vinyl alcohol-based mixtures, collagen gel/poly(alpha hydroxyacids), cellulose, waxes; etc.

Thermosetting of monomers after infusion may be accomplished by adding a peroxide initiator such as, but not limited to benzoyl peroxide or an azo compound such as, but not limited to isobutylnitrile.

Accelerators or chemical initiators may also be used to enhance the setting reaction. An amine accelerating or

initiating agent such as but not limited to triethanolamine, or dimethylaminoethyl methacrylate may be used.

Alternatively a photoinitiator may be used such as but not limited to camphorquinone.

Infusion of soluble or insoluble resins and polymers. The porous part, after external infusion with a soluble or low fusing polymer/monomer is treated with a coupling agent. The part is then placed in a chamber containing the desired individual polymer/monomer or mixture of polymer/monomers. The selected polymer/monomer is in a liquid state and the liquid is drawn into the pores via capillary action with or without the aid of pressure, vacuum, or a combination thereof. The liquid is then cured either by heat, light, chemical or combination thereof. Thermoplastics may be hardened by a decrease in infusion temperature.

Some combination of preform and polymer precursor may require the use of coupling agents to improve the wetting and hence the infusion. Coupling agents are, but not limited to silanes (such as but not limited amine, epoxy, chloroalkyl, mercapto, vinyl, styryl, aromatic, methacrylate, alkanolamine, and isocyanate); and titanates (such as, but not limited to the following classes: isopropyl, phosphate, styryl, amine, and acryl). Coupling agents can be diluted with an alcohol or ether/water mixture which is acidified using an acid such as, but not limited to acetic acid, hydrochloric, phosphoric, or sulfuric.

#### Removal of Inhibition Layer

To reveal the desired surface porosity.

The fugitive material comprising the inhibition layer are then removed by selective dissolution in the appropriate solvents, and/or thermal treatment, depending on the fugitive material. For the preferred fugitive material described in the section on Inhibition Layer, the removal of the layer is achieved by dissolving the fugitive material (polyethylene glycol) in water of a weak acid (acetic, etc.) solution.

#### Implant Features

The implants embodying the invention exhibit a) a porous outer layer, and b) an tough inner core which can contain selected porous regions or features. The implant shape is modified to include pre-tab holes and features that facilitate rigid fixation.

The foregoing description has been limited to a specific embodiment of the invention. It will be apparent, however, that variations and modifications can be made to the invention, with the attainment of some or all of the advantages of the invention. Therefore, it is the object of the appended claims to cover all such variations and modifications as come within the true spirit and scope of the invention.

Having described our invention what we now claim is:

1. A method for forming an implant having an inner core and an outer layer which comprises:
  - fabricating a preform with an open pore network;
  - coating at least a portion of the outer layer of the preform with a fugitive material to form an inhibition layer and to define infusion channels;
  - infusing selected regions of the inner core through the infusion channels with at least one infusing media;
  - forming an interpenetrating phase composite in the inner core; and
  - removing the fugitive material from the outer layer thereby forming a porous outer layer.