GRAPHITE FIBER/TFE POLYMER POROUS COMPOSITES IN RECONSTRUCTIVE SURGERY

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Graphite fiber and TFE polymer were combined to produce a porous low modulus composite intended for medical implant use.* The specific methodology for preparation of this novel composite structure has been published elsewhere.[1] The microstructure of this composite is illustrated in Figure 1 at 300X magnification. The structure is an isotropic matrix of polytetrafluoroethylene polymer upon which is superimposed graphite fibers in the range of 50 to 100 micra in length. The composite is approximately 80% void, with average pore diameter of about 300 micra. The open pore structure also exhibits dendritic interpore connections of between 100-200 micra. The bulk physical appearance of the material is that of a stiff sponge of Young's modulus--40 Kg/cm^2 and an ultimate tensile strength--10 Kg/cm^2.

The creation of the composite was premised on 3 requirements: (1) ingredient biocompatibility; (2) bio-functionality through the selection of a modulus close to that of soft tissue and spongey bone; and (3) maximum porosity and interpore connections consistent with appropriate bulk mechanical properties. Initial studies evaluated biocompatibility,[2] tissue ingrowth kinetics and performance of the material as a bulk implant or as a coating on metallic endoprostheses whereby stabilization of the prostheses was provided by tissue ingrowth.[3,4,5]

Very rapid fibrous tissue ingrowth into the material was observed at rates of 600 micra per week for loose immature collagen and 80 micra per week for dense mature collagen. These rates are approximately 5 times those observed with open pore polytetrafluorothylene exhibiting the same porosity and pore architecture as the composite. This difference is now attributed to the surface energy character of the graphite fiber ingredient and specific surface area of the composite which results from the inclusion of that ingredient.

Implant stabilization is directly related to the surface area and geometry of an implant and the interfacial reaction of the implant with adjacent tissue. More area disposed perpendicular to stress direction would decrease the unit loads supporting tissue must sustain and thereby enhance stability. The microporosity of the Proplast composite develops very large surface interaction areas. Although porosity of biologically inert materials is generally known to engender tissue ingrowth,[2] long-term fixation between the implant and tissue has been seen to depend on appropriate selection of modulus for the porous implant; newly forming fibrous tissue within the porosity of the Proplast is not irreversibly traumatized by micro-motion that necessarily must take place between an implant and the implantation site.[6,7]

Proplast composite exhibits a low modulus in order to provide an interface of gradual conversion from the structure and property of the opposed tissue to that of the bulk material of an implant. Under such conditions, stress vectors can be supported by the omnidirectional interlocking of tissue with implant. Moreover, stress would tend to be uniformly dispersed to low unit values. In addition to implant fixation, a viable ingrowth interlocking between implant and adjacent tissue may also serve to prevent extrusion of percutaneous and permucosal implants secondary to epithelial encapsulation.

Histological preparations of composite implants placed in dogs, rabbits, and primates, showed that tissue morphology and rate of organization depend upon the implantation site.[8] Specimens recovered from long bone, femoral head prostheses coatings, and alveolar ridge augmentation, show rapid collagenous ingrowth with some bone formation usually limited to the interface with bone. Multinucleated giant cells or other remarkable cell populations are absent. Implants from mobile soft tissue locations show less rapid collagenization associated with transient presence of giant cells. The latter appear to have no

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* Proplast® implant biomaterial, Vitek, Inc., Houston, Texas 77054.

deleterious effect other than to reduce the rate of collagenation.

Both porous and non-porous forms of the composite were compared with USP Plastic Negative Standard material in long bone of Beagle dogs for 2 years. No findings of toxicological significance were evident in the general observations, opthalmology, body weight, hemotology, and clinical chemistry data, or in the necropsy and histopathological examinations. Implant prototype studies have been reported in 20 publications involving both soft tissue and bone in the rat, cat, rabbit, dog, monkey, and baboon.

The composite was first used in humans in 1970. Pre-commercial clinical studies were carried on through 1974 in more than 190 patients with success rates in excess of 90% for applications involving contour and boney reconstruction of the chin, nose, zygoma, malar, orbit, and mastoid defect. Those cases of failure were associated with the learning curve of operative technique and the usual hospital rates of operative sepsis. Alveolar ridge augmentation with Proplast has been notably less successful (30-70%) with early and late losses from sepsis. The procedure involves extensive intra-oral manipulation in proximity to mucosal tissue. Late losses from mucosal perforation can be minimized by good patient cooperation in oral hygiene and routine denture adjustment. Optimal surgical instructions have been developed to reduce losses. Notwithstanding the occurrence of losses, alternative procedures such as bone grafting are less successful and satisfying to both patient and surgeon.

Clinical publications document efficacy of the composite in Tenon's capsule of the eye, middle ear, facial contour reconstruction, mastoid obliteration, alveolar ridge, TMJ prosthesis stabilization, pectus excavatum repair, and treatment of atrophic rhinitis.[9-15] Prospective studies have been underway for over 3 years in the clinical use of the composite for stabilization of orthopedic joint prostheses, knee ligament prostheses, and hand tendon prostheses. Current research studies in animals involve the use of the composite for reversible sterilization, periodontal pocket obliteration, herniation defect repair, bone prostheses for the bladder, trachea, mandible, and endosseous denture support.

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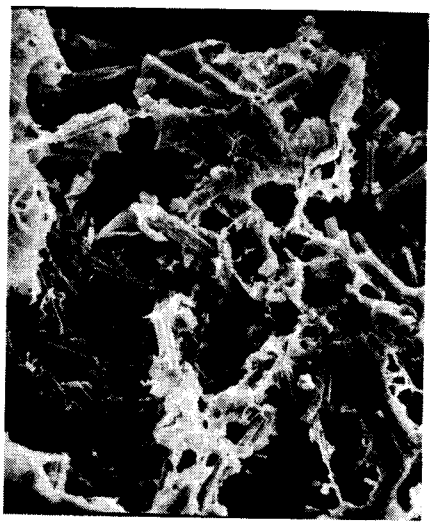
Figure 1



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