Polyethylene Terephthalate and the Pillar™ Palatal Implant: Its Historical Usage and Durability in Medical Applications

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Historical Usage of PET

Polyethylene terephthalate (PET) is a linear, aromatic polyester which was first manufactured by Dupont in the late 1940s. It was trademarked as Dacron®; this nomenclature is commonly used when referring to PET, although alternate suppliers of PET are prevalent. The chemical structure of PET is shown in Figure 1.

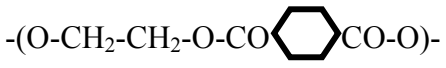

Fig. 1 Chemical structure of PET

Current medical applications of PET include implantable sutures,[1, 2] surgical mesh,[3-5] vascular grafts,[6-8] sewing cuffs for heart valves,[9,10] and components for percutaneous access devices.[11]

PET sutures were first introduced in the 1950s and are used for critical procedures where high strength and predictable long-term performance is emphasized.[12] Mersilene® polyester fiber sutures were the first synthetic braided suture shown to last indefinitely in the body.[13]

Woven PET is commonly used as surgical meshes for abdominal wall repair and similar procedures where surgical "patching" is required. A PET velour fabric patch was first introduced in the 1970s.

Synthetic vascular prostheses are constructed of both woven and knitted PET and have been used clinically since the 1960s. They are used in the repair of the thoracic aorta, ruptured abdominal aortic aneurysms, and to replace iliac, femoral, and popliteal vessels.

Heart valves have incorporated PET by using it as a sewing cuff around the circumference of the valve to promote tissue ingrowth and to provide a surface to suture the valve to the surrounding tissue. Over one million heart valves have been implanted since their inception in the late 1970s.

Percutaneous tunneled catheters incorporate a PET cuff to stabilize catheter location and minimize bacterial migration through the skin. In addition, braids and similar constructions made of multifilament PET yarns have shown promise for repairing tendons and ligaments[14, 15] and for fixation of intraocular lenses.[16]

Biological Response

The notable biological characteristics of PET include: biostability,[17] promotion of tissue ingrowth,[18] a well characterized fibrotic response,[19,20] and a long history of human implantation.[21, 22]

The biostability of PET is a result of its chemical structure which promotes resistance to hydrolysis due to hydrophobic aromatic groups and high crystallinity.[23]

The promotion of tissue ingrowth is achieved in PET by the creation of a porous matrix. The vascular prosthetic applications of PET are characterized by either woven or knitted surfaces; both provide a porous surface that encourages tissue ingrowth. Tissue ingrowth prevents relative motion between the tissue bed and the implant. This permanent anchoring serves to retain the implanted device and maintain proper function. Scanning electron micrographs of the surface structure of several commercial products are illustrated in Figure 2. The porous structure of the graft, fabric for cardiovascular repair, and catheter cuff encourages the tissue ingrowth that serves to permanently anchor the implant in the soft tissues.

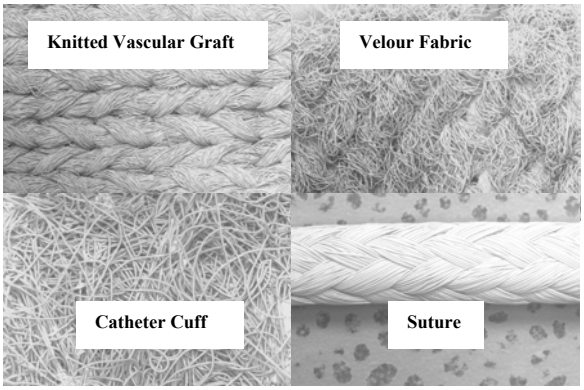

Fig. 2. Surface Appearance of PET Materials (30x)

Durability of Response

The biological response to PET is characterized by a chronic inflammatory response, fibrous capsule formation, and granulomatous tissue with an intercellular matrix infiltrating the fabric.[24-26] Fibrous capsule formation is typically complete by 4 weeks.[27] Implantation of PET causes a permanent alteration in the tissue into which it is implanted. The inflammatory cascade results in the "walling off" or encapsulation of the material; this capsule remains intact for the life of the biomaterial.[23] Countless animal studies have been conducted in the analysis of the host response to PET.[1,10,18,25-27] The Dacron backed silicone breast implant is perhaps the most widely analyzed PET containing implant explanted from humans.

From sutures to vascular prostheses, the use of polyethylene terephthalate in medical devices has endured for more than 50 years and is one of the few materials that has demonstrated continuing efficacy with minimal complications in numerous clinical applications.

Polyethylene Terephthalate and the Pillar Palatal Implant (continued)

The Pillar Palatal Implant

The palatal implant shown in Fig. 3 was designed to address palatal snoring by stiffening the soft palate using biomechanical means, namely, a permanent implant and its associated fibrotic response.

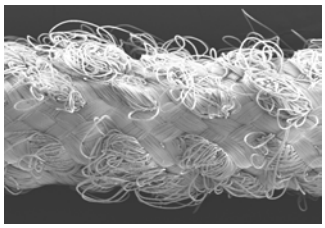

Fig. 3. The Pillar Palatal Implant

It has been engineered using PET to achieve a delicate balance between inherent stiffness, porosity, and texture. The PET material elicits a well-characterized foreign body response resulting in an encapsulated, permanent and safe implant. Its inherent stiffness contributes to the overall stiffening of the soft palate and allows it to be implanted using a delivery tool in an office setting. Its porosity and texture encourage tissue ingrowth to minimize the relative motion between the implant and the soft palate tissue, resulting in a permanent placement. In addition, the porosity of the entire structure is engineered to accommodate removal of the implant if so desired. Animal studies have verified the histological response to the implant, its safety and its removability. Clinical studies have validated the efficacy of the implant.

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