White Paper:

Enabling Cardiovascular Designs With Biomedical Textiles

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The current wave of cardiovascular medical device innovation has gone well beyond the traditional materials and structures used in established vascular graft and heart valve sewing cuffs technologies. New technologies are being used to enhance capabilities and performance in the repair of damaged or diseased cardiovascular tissue. New fabrics and geometries with greater variability of properties and performance characteristics have enabled design developments previously unimagined.

Design Structures and Possible Applications

Implantable textiles typically contain polymeric and/or metallic filaments and yarns formed through weaving, knitting, braiding or a non-woven process. Controlled manipulation of materials through unique combinations with distinct performance characteristics, fiber architectures and complex geometries offers a high degree of design freedom and flexibility.

- ***Knitted*** structures are formed by interlocking loops of yarn or metal in a weft (transverse stitching) or warp (longitudinal stitching) pattern to form flat, broad or tubular structures. Knitted materials are generally porous, highly conformable and elastic with high burst and tensile properties. They are well suited for soft tissue and areas with complex anatomies commonly found in cardiovascular applications (i.e. vascular prosthesis, hemostasis products, valve sewing cuff and cardiac support devices) because the surface and open space areas spur tissue in-growth.
- ***Woven*** structures are formed by the perpendicular interlacing of two yarns or wires and have historically been used in endovascular aneurysm repair, transcatheter heart valves, and other catheter-based technologies. Material selection determines the density, the physical and mechanical properties of the finished product, and how the body reacts when the device is implanted.

  Woven structures can be created in a multitude of potential shapes including flat, tubular, tapered or near-net shaped fabrics that often are characterized by low porosity (for containment and cardiovascular fluid transfer), dimensional stability, high tensile strength, and other unique features such as multilumens, fenestrations and tube-in-tube geometries. They also can be manufactured in low-profile fabrics as thin as 40-50 microns, which is important in minimally invasive applications.

- ***Braided*** structures are created by intertwining three or more yarns in a diagonally overlapping pattern. They are often manufactured over mandrels to fix the fabric's internal diameter and to create near-net shapes and/or geometric foreshortening for catheter-based deliveries. In addition, braided structures can be kink-resistant and easily combined with different materials to enhance specific fabric properties. They are ideally suited for applications that need radial reinforcement and expansion, compaction, flexibility, porosity and highly angulated vasculature such as in neurovascular applications, cylindrical stent implants that support vein function and keep arteries open, and instrumentation in small delivery sites.

Unique Capabilities and Potential

Material types and combinations can also impact biologic repair by controlling the degradation or absorption rate of the implantable textile structure to range between 60 days and 12 months. For example, yarn architecture and combinations of monofilament or multifilament non-absorbable materials (i.e. polypropylene, polyethylene terephthalate (polyester), polytetrafluoroethylene, and polyetheretherketone (PEEK)) with absorbables (i.e. polyglycolides (PGA), polylactides (PLLA) and various other copolymers) and can be varied to alter fiber cross-section, stiffening, and create gradient levels of absorption.

Fabric architecture can also serve as a platform for composite properties. For example, regions of specialization within a tissue can be created by using texture to prompt different tissue responses in contiguous areas of the tissue to create a biological seal. Also, biphasic mechanical properties of the composite biomaterials allow for changes in the mechanical property of a textile over periods of time during its resorption by the body.
For a specific ordered and predictable tissue response, a device requires the calculated evaluation of material options including the fiber material and structure, and the overall fabric structural composition. Advances in this area continue to expand the abilities of a lower profile or devices needing predicted porosity, permeability or biologic response rates.

In the cardiovascular device segment, synthetic structures and tissue hybrids are the preferred materials for long-term repairs due to their ability to withstand the biomechanics of a specific application and their ability to promote in-growth. Fabrics can be used as conductive materials and tissue-engineered scaffolds to elicit a specific biologic response. There are also opportunities to use fabrics as a drug-delivery platform by imbedding the dosage into the textile layers and engineering controlled-release kinetics to affect the rate of absorption by the body.

"Off-the-shelf" biomedical textile solutions generally do not work well, making the selection of the most appropriate biomaterial supplier even more crucial to development. And as device designers continue to work with textile engineers to apply more creative, out-of-the-box designs, the cardiovascular device industry will set the pace of innovation in advancing medical technologies and procedures for the patients of tomorrow.

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