Designing With Implantable Fabrics

Fabrics used in medical implantation have come a long way since the days when they were first used in early open surgical procedures. Today, implantable fabrics are commonplace in the projects and designs of device engineers, and use continues to grow across orthopedics, cardiology, tissue regeneration and general surgery. Understanding the benefits of various fabric structures, and the inherent characteristics that are tied to their manufacturing processes, will enable today's engineers to fully leverage this key device component—for the benefit of product manufacturers and patients alike.

As specialized textile manufacturing technologies have evolved, the very definition of a "medical fabric" has changed as well. The current generation of device engineering professionals now has a much broader array of features and benefits from which to choose, in unique fabric combinations, never before available.

Designing-in Value

Medical textile manufacturers capable of producing specialized fabric structures often are capable of meeting the specialized support demands of the device industry as well. Some have tailored their operations around the heavily regulated requirements of implantable devices—to include ISO 13485:2003 certification, the addition of strong process validation services and the introduction of risk analysis as important options.

What's more, today's medical textile manufacturers now can deliver a host of value-added services that extend so far beyond the 19th century roots of traditional textile production that one can barely conceive they have a common origin. These include services to transition products from R&D to production, materials characterization, procedure-specific yarn and fabric testing, specification development and other services required by the healthcare field.

Advanced Structures Yield Different Design Options

Innovation is a common denominator in the complex array of fabric techniques, or forming technologies, used to produce implantable fabric structures—the most common being ***weaving***, ***knitting*** and ***braiding***. These three popular fabric geometries form the core offering available for device engineers, and each imparts a unique set of physical and performance characteristics.

Woven structures probably are the easiest to envision for non-textile professionals and deliver some important design characteristics. ***Weaving***, which is the interlacing of yarns (or wires) over and under each other, helps create a very stable fabric structure—one that permits additional manipulation to enable the following structural variables:

- *3-D and multi-layer:* Fabrics that are pre-shaped or have multiple layers can be used where empty space is required to be maintained or filled—an important attribute in applications where fluid containment or direction is needed, or in designs intended to elicit tissue growth through the fabric
- *Tapering/flaring:* This take on weaving involves producing a flat or tubular fabric form with either a gradual or dramatic tapering in dimension. Designing-in this variable enables the sealing or closing-off of large areas or delivers needed structural support; it also permits subtle tapering to follow the diameter of an aortic artery in cardiovascular applications

Jeffrey Koslosky

• *Floating:* This complex manipulation of fabric weaving involves fluctuating the interlacing and orientation of yarns from one side of a fabric to the other, yielding dual fabric surfaces, each with different properties, and an attractive option for device engineers

Knitting, the process for stitching together a series of yarns, can be a useful approach for selected device designs and offers the ability to "tweak" some important design variables:

• *Controlled porosity/permeability:* Specific properties—such as stretch, flexibility and pore size—can be adjusted by taking groups of yarns and sending them in opposite directions to one another. The complex motion we call knitting essentially moves the yarns from side to side, at same time as they are wrapped around the needles

• *Controlled stiffness, thickness or elongation:* Both physical and mechanical properties of a knitted fabric can be altered significantly by changing the raw materials used in the design. For example, rigid monofilament fibers can be oriented along either or both axes to make a fabric less compliant

• *Hybrid properties:* Utilizing various polymer or metallic fibers together in one structure—each with different material properties—imparts unique characteristics to a fabric. By carefully manipulating the knit structure during manufacturing, one can achieve composite fabrics with preferential sidedness, specific reinforcement zones or properties that change over time

Braiding, where yarns are moved around a central point on a machine to produce a textile, has long been a mainstay of the industry, as evidenced by the popularity of braided sutures in the medical field. This process also is useful in reinforcing catheters with wire to prevent kinking or other problems during implantation. Key braiding characteristics helpful in device engineering include:

• *High density:* Modern braiding techniques permit the incorporation of hundreds of elements (yarns, wires or both) into one fabric structure to create a highly dense and complex structure for specialized medical applications

• *Radial expansion:* The ability to have a fabric that can expand radially is another exciting possibility with braiding. Like a Chinese finger puzzle, braided fabrics can compress and expand radially depending on the direction of force delivered. Braids can be packed down to a very small diameter in catheter delivery systems, for example, and then undergo a shape transformation when they are in position within the body

• *Specialized constructions:* Some of the newest innovations in braiding make it possible to apply platinum, or other radiopaque materials, in with metal or polymer fibers—enabling physicians to visualize the location of the device component during deployment and placement. Creation of substantial hoop strength is another development—made possible by combining metals and polymers in a high-density tubular shape

When Engineers Collaborate

In the manufacture of implantable fabrics, "off the shelf" solutions rarely work well. To be sure, this is a unique field—one that requires an unusual mix of textile production know-how and a dash of medical science expertise. Because of this, collaboration between device engineers and textile engineers is absolutely essential.

Many device designers are not even aware of the versatility of implantable fabric structures and how the characteristics of given materials and forming processes can be combined for a variety of treatment modalities. Once aware, designers tend to quickly see the possibilities for using implantable fabrics in future medical device concepts.

Perhaps the most important aspect of a design incorporating fabric structures is the collaboration with medical textile manufacturers. These types of manufacturers have a history of collaboration with engineers at their medical device clients. Working closely with such experienced textile engineers can mean the difference between successful device design and another "good idea" that simply didn't work. Such engineer-to-engineer interactions also can facilitate rapid problem resolution and, if needed, key adjustments in development or production efforts along the way. There are a significant amount of variables that can influence the final physical and mechanical properties of a textile by varying inputs such as raw material, density and filament orientation as well as quantity—and textile experts know these variables inside and out.

There are literally dozens of variables to assess for each fabric structure and end-use application—all of which can be adjusted to drive performance toward primary device requirements. In materials selection, forming techniques and manufacturing processes, there is an almost limitless ability today to engineer effective solutions for widely diverse medical treatments.

Truly, what was once just a potential is fast becoming a reality in the use of implantable fabrics. There is little doubt that ongoing dialogue and collaboration between the device world and the textile world will yield more than just a few future surprises for us all. ❖

Jeffrey Koslosky is director of Research & Development at Secant Medical, LLC, where he is responsible for heading up new business strategies and corporate technology and development initiatives. Koslosky first joined Secant Medical's parent company, Prodesco, Inc., in June 2000 as a quality engineer and was named R&D engineer in September 2002. He subsequently served as both senior R&D engineer and R&D manager before assuming his current role in November 2005. Previous experience includes posts with Secant Medical and with Bally Ribbon Mills. Koslosky holds a Bachelor of Science degree in Textile Engineering from Philadelphia University, with a concentration in Biomaterials. For more information about Secant Medical, visit www.secantmedical.com.