MD&DI
Medical Device & Diagnostic Industry

Implantable Fabrics for Orthopedic Device Applications

Advances in implantable textiles technology have enabled design engineers to explore new fabrics with improved flexibility for design.

Jeffrey Koslosky

Orthopedic procedures and devices continue to evolve to meet changing requirements and technical advances. One of the cutting-edge areas in orthopedic devices is the incorporation of implantable fabrics that have been specially designed to help minimize surgical invasiveness and improve patient recovery time.

For engineers, implantable textiles can be adopted for a range of orthopedic applications including devices to treat spinal fractures, trauma, and maxillofacial conditions.

The fabrics can be made with varying features to enable flexibility for device designs and capabilities. For example, density and porosity should be considered when designing with fabrics. Engineers using implantable fabrics have the ability to implement designs with small pores, sometimes as small as 25 µm across, to facilitate fluid movement through a tube or to separate dissimilar tissue planes inside the body.

Engineers demonstrate braiding (the intertwining of three or more yarns), a technique to make fabrics for various medical device applications.

Alternatively, a fabric can be made highly porous, with a lattice-like structure of interconnected filaments that share loads in unison to provide structural reinforcement to weakened or ruptured tissue.

Among the most exciting and innovative uses of textiles inside the body are designs that facilitate a minimally invasive delivery, but when unsheathed and actuated by a physician undergo a shape transformation to an expanded state.

Design Avenues for Engineers

As the biomedical engineering field evolves, new technologies are in a prime position to augment the traditional hardware long used in orthopedic procedures. Designers today have an incredible array of choices in approaching new devices, including advances in fabric structures, manufacturing techniques, and materials.

Specialty textile manufacturers have a reputation for their close collaboration with

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medical device engineers. The results include significant developments in key areas such as heart valves, hernia repair, sutures, and, of course, orthopedics. Many of these products could not provide the necessary structural support and biological response without textile technologies.

Even though the words used to describe the forming processes of implantable fabrics sound quite old-fashioned—weaving, knitting, and braiding—the way these textile mainstays have evolved for orthopedic devices is anything but boring.

Designers can incorporate fabrics in ways that go beyond planar, two-dimensional structures. Near-net-shaped, three-dimensional geometries and through-the-thickness constructions are more structurally stable approaches that open up a variety of previously unavailable design options for emerging devices.

Engineers developing spinal implants, for example, are beginning to realize the value of custom-designed textile structures. Trends in dynamic stabilization, joint disease treatment, and a variety of treatments for degenerative disk disease all provide avenues of opportunity to leverage the flexibility of fabrics.

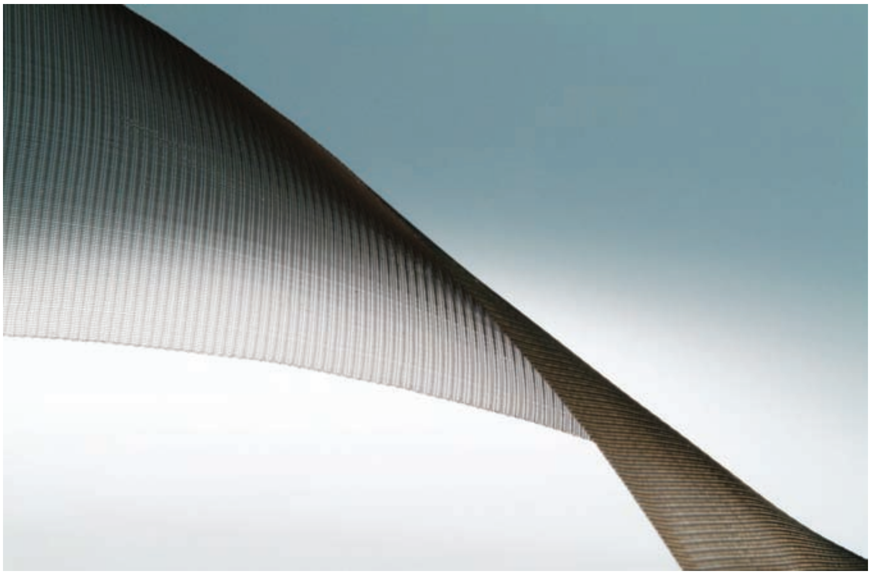
Fabric cords braided from high-strength polymers and metals are increasingly acknowledged as ideal structures for high-tensile applications, where cyclic loading and durability are paramount engineering considerations. Often based on high-tenacity polyester and polyethylene technology, these structures compare favorably to the rigid rod systems that have been used in orthopedics for many years.

Braided-cord fabrics can range in diameter from 1.5 to 5 mm and are designed to minimize elongation and creep over time. The main advantage a braided cord delivers is flexibility during surgical implantation. It enables a smaller incision and, therefore, less trauma is likely to occur.

When Not to Use Fabrics

Keep in mind that implantable fabrics are not necessarily appropriate for every orthopedic application.

Fabric technologies can be limited in applications in which stability is required in all directions. The nature of a woven, knitted, or braided structure is to be compliant, which is what makes them ideal for more traditional uses in apparel and upholstery. Although fabrics can be designed to have specific high-stress and low-strain properties in one direction, they rarely demonstrate the isotropic features of solid materials.



A woven metal fabric, made from a monofilament nitinol wire. The fabric was annealed to maintain a uniform pore size throughout.

As a result, textile materials will not overtake orthopedic mainstays such as hip stems or knees in the near future. More likely, manufacturers may be able to introduce flexible fabrics into an orthopedic device to elicit a specific biologic response while the structural element absorbs loads and stresses in multiple planes.

Integrating Fabrics into a Cohesive Design Strategy

The real challenge in the use of fabric structures and their incorporation into orthopedic devices is during the design phase. First, most device designers are not even aware of the versatility of fabric constructions and how the characteristics of given materials and forming processes lend themselves to a variety of treatment modalities. However, designers tend to quickly recognize the possibilities for integrating implantable fabrics into their own device ideas.

Perhaps the most important aspect of a design incorporating fabric structures is collaboration with medical textile manufacturers. Working closely with textile engineers can mean the difference between successful device design and a good idea that simply did not work. Many variables can influence the final physical and mechanical properties of a textile including such factors as raw material, density and filament orientation, and quantity. The following engineering considerations are just a sampling of what needs to be addressed up front.

Space and Delivery Issues. A key consideration in design is the fact that implantable fabric technology must be able to work within the confines of a delivery system, a requirement in the shift toward minimally invasive devices. A general example of the limited confines within which some fabrics must operate is found when looking at devices as simple as catheters or cannulae.

It is a typical requirement to fit an entire complex woven structure into a delivery system that has an inner diameter of 2 mm or smaller. The same fabric is expected to undergo a shape transformation that may expand it to 800% of the delivery size without sustaining any loss of properties or shape retention while prepackaged in the delivery sheath. This very limited space puts pressure on the fabric manufacturing process and requires very careful collaboration with the device maker to ensure proper implantation and deployment. A delicate balance must be achieved between the strength and density properties of the fabric and the size of the delivery system.

Geometric Considerations. Textile fabrics fall into four major categories: woven, knitted, braided, and nonwoven. Each of these generic forming technologies creates a different structure by controlling the orientation and interaction of the constituent yarns. Differences in device design and engineering requirements will influence how the structure is formed in various ways.

Weaving is the interlacing of polymeric or metallic filaments at right angles to one another in an over-under pattern. The interaction of these filaments to one another is what holds the structure together and usually results in a system that exhibits such fabric characteristics as strength, stability, and low porosity. These fabrics can also be modified to incorporate tapers, to have significant thickness, or to be cylindrical in nature allowing for significant flexibility in design. Woven fabrics are commonly used in abdominal aortic stent grafts because of their low porosity and their abrasion-resistant structure.

Knitting is the controlled entangling of filaments, typically in a looped configuration. This fabric-forming technique generally results in a structure that is very conformable and has well-defined pores and controlled strain properties. Devices such as heart valves, hernia repair meshes, and products for incontinence treatment often employ knit structures.

Braiding is the interweaving of three or more filaments in a diagonally overlapping pattern, usually 45° off the central axis of the structure. Advanced braids are usually manufactured over a forming mandrel resulting in a cylindrical structure that has a unique geometrical feature called foreshortening. Foreshortening transfers axial forces to radial forces and makes braiding suitable for catheter-based delivery systems.

Nonwoven fabrics are fabrics that are processed from short, staple-length fibers or fabrics that are made directly by extrusion, rather than from continuous filaments of fiber or metal. They are used frequently for surgical caps, gowns, drapes, and scrubs. These fabrics characteristically have low strength and elongation but have a very high surface area and adsorption capacity. These properties make the structures useful for orthobiologic and tissue-engineering applications.

Materials Selection

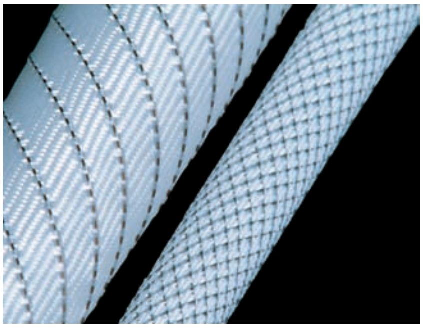
Early implantable fabrics for orthopedics and other applications have typically been bulky and very porous. Little variation was available across the spectrum of possible fabric characteristics. Although some of these older fabrics are still in use today, textile and materials science has given designers an incredible range of materials—from traditional choices, such as polyester and polypropylene, to more exotic options, such as bioabsorbable polymers and polymers with high-modulus, low-elongation, and low-creep properties.

Fabrics constructed from absorbable and bioactive polymers, for example, are often used for tissue-engineering and orthobiologics applications requiring high surface area for tissue growth or support while the body repairs itself. Metals such as stainless steel, nitinol, platinum, and titanium exhibit superior mechanical properties for certain applications when compared with polymeric-based fabrics. It is possible to create fabrics entirely from metal filaments or to achieve a balance between metallic and polymeric fabric geometries. Purity, chemical inertness, and mechanical properties are all key drivers in selecting the right material. And textile engineers are key allies in assisting with these design choices.

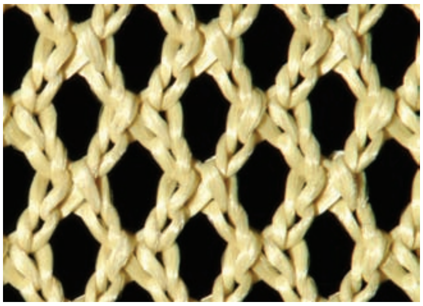
Engineer to Engineer

The benefits of collaboration for fabric engineering cannot be overstated. A strong peer-to-peer working relationship between engineers at the device house and their counterparts in textile manufacturing firms enables a cohesive design, development, and production process. By connecting the technical capabilities of device manufacturers with those of textile manufacturers, a broad range of potential problems can be minimized or avoided entirely. For example, up-front design choices such as fiber orientation or raw material biocompatibility must be discussed to ensure that the finished device will work exactly as required. Both teams need to build lines of communication across the design function on a given project from day one to go beyond typical customer and vendor relationship. Doing so will ensure that key project milestones and critical deadlines are more easily achieved. In addition, technical troubleshooting becomes more effective when human relationships are already established between the two design teams. Problems can be resolved quickly and key adjustments can be made in development and production efforts with minimal disruption.

As textile engineers and their colleagues in the major orthopedic device firms move toward closer collaboration in the development and deployment of effective devices, the trend toward innovation can become even stronger and positively affect the health of orthopedic patients. ■



Fabric technology has improved to enable the creation of 2-D and 3-D structures to enhance device design.



Knitted fabrics result in a lattice-like structure that provides support to weakened or ruptured tissue.

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