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Weaving Innovation into Device Design

Biomedical textiles appear to have a promising future in orthopaedic devices.

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Medical device engineers are on a constant hunt for ways to solve critical challenges in their designs. One of the most interesting developments is the rapid growth of woven biomedical textiles for use in orthopaedics and other device applications.

The growth of textile-based devices and implants has been fueled by the material's versatility and the variability of its properties and performance characteristics. Biocompatibility, 2-D and 3-D structures, adjustable macroscopic structures, and the ability to control structural degradation are a few advantages that make implantable biomedical textiles suitable in a broad array of device applications.[1] These materials are improving at a rapid clip and bring with them complex textile structures and efficiencies in component development and manufacturing.[2]

As the pace of innovation in the device industry accelerates, engineers can use biomedical weaving technologies to expand their product's performance characteristics and sharpen their competitive advantage in the market. At the same time, key process advances are helping device makers achieve innovation while speeding their product's path to market. This article explores the possibilities for woven biomedical textiles as a new route to more innovative and effective orthopaedic device designs.

Emerging Design Challenges

The pace of device improvements is rapid, and the challenges faced by device manufacturers are increasing due to the need for more-complex designs. The use of minimally invasive surgical techniques has created expectations by both surgeons and patients for smaller surgical access areas as well as faster recovery and healing times. Today, device development is moving inexorably toward motion-preserving technologies, increased patient comfort, and improved durability of devices and implants over the long term. For these reasons, woven textiles are gaining in popularity among device designers and manufacturers.

Woven textiles occupy a unique place among the current generation of implantable textiles, and their versatility is likely to increase the demand. The array of textile forming technologies is substantial. A brief overview of forming options beyond weaving includes:

- *Knitting:* This process interlaces a series of yarns with loops to control a fabric structure's stiffness, thickness, elongation, and other physical characteristics.
- *Braiding:* This process moves yarns around a central point on a machine in a diagonally overlapping pattern, typically to achieve unique mechanical and geometric properties including variation in density and radial expansion.
- *Nonwoven:* A wide category of textile structures that are formed by interlacing fibers by mechanical, chemical, or thermal means.

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How weaving differs from these approaches is in the varied applications possible from the yarn placement diversity this forming technology imparts. Weaving allows the interlacing of yarns and wires over and under each other, generally oriented at 90° angles, to create enhanced stability. The flexibility achievable by this process makes it appropriate for medical device engineering applications. Weaving enables a high degree of structural customization—including the floating of yarns from one point to another and the gradual or abrupt tapering or flaring of a structure. The technique also enables the creation of near-net shapes (i.e., fabricated in the shape of the final intended use) as well as 3-D and multilayer geometries. Some of the most exciting textile innovations are possible because of weaving.

Depending on the engineering requirements of a medical device, a variety of weaving technologies offer controlled placement of elements within a biomedical woven textile. A brief summary of some of the techniques follows.

Jacquard. The flexibility of this approach lies in the ability to control a single element—one filament at a time—or to move thousands of filaments in a single motion. Jacquard weaving allows the engineer to design a variety of patterns within the same fabric. This is a useful tool for applications that require regions of specialization within the same structure, which enables a final implant, for example, to achieve different mechanical and biological interactions with human tissue. Jacquard structures allow for increased control of directional tissue growth for tissue engineering scaffolds for bone, tendon, and ligament repair, among other applications.

Dobby. For medical applications that require few, if any, specialized regions, dobby weaving is useful. This process involves selecting and moving groups of yarns to create one pattern that is repeated along the length of a textile structure. This technique is used for the manufacturing of tapered, seamless, and bifurcated tubes, which are essential structures in cardiovascular, fluid transfer, and containment applications. Due to dobby weaving's continuously repeating pattern, these weaves are often used for tension-supporting components in a wide variety of applications including spinal kyphosis and scoliosis correction as well as ligament repair.

A Secant Medical textile specialist performs an inspection prior to processing bifurcated graft structures used in the treatment of abdominal aortic aneurysms.

Narrow and Broad Weaving. Depending on the end use, narrow weaving may be appropriate. It involves wrapping a yarn continuously around the construction, yielding a seamless tube with no edge. Applications for narrow weaving include orthopaedic tethers, ligament repair, tendon reinforcement, and other applications in which controlled low elongation is required. Broad weaving, however, enables much wider textile structures but cannot be done on a seamless basis. Due to the sheer speed of this weaving technique, broad textiles are often used when a cut edge does not affect the device design and cost is a major issue. In the area of broad wovens, one example application is surgical mesh used for musculoskeletal reconstruction.

Tailoring Variables of Geometry

Woven biomedical textiles enable device designers to design in key properties by altering or modulating the geometry of the structures and the materials from which they are produced. Due to the interweaving and interdependence of the filaments in a woven structure, device engineers are increasingly adopting woven structures for use in components that require improved strength, stability, and low porosity, or to allow complex near-net shape designs.

The use of near-net shape designs can significantly reduce the postprocessing required for textile components. By weaving the textile in the shape of the final intended use, typical fabric postprocessing methods such as cutting and seaming can be reduced, or in many cases, eliminated. Weaving can currently yield widths from less than 1 mm to as wide as 3–4 m, and tubes as small in diameter as 0.5 mm. In the future, as stronger, thinner biomaterials are developed, even smaller constructions will be possible.

Material Selection

Biocompatible raw materials selection offers another vehicle to augment the properties of a woven structure. A variety of biocompatible polymers and metals can help designers develop complex components for various therapeutic applications. Materials such as polyester, PEEK, ultra-high-molecular-weight polyethylene, nitinol, stainless steel, titanium, and tantalum can be incorporated into evolving textile designs to engineer in radiolucent markers and specialized reinforcement zones. Such zones are strategically placed to aid in anchoring, and the radiolucent markers assist surgeons with placement and visualization.

As biomaterial suppliers offer new product grades and enhanced capabilities, additional material selection options and combinations will be made available to designers and engineers to fit increasingly narrow specifications and design parameters. Combinations of resorbable and nonresorbable materials will be more broadly used to control properties of devices over time. Some textile components under development are being engineered from materials designed to degrade at varying rates over time. In ligament repair applications, for example, this variability would tune fabric degradation to be in sync with the desired tissue-healing rate of the patient.

Developments on the Horizon

As previously mentioned, woven biomedical structures can fulfill a variety of needs in the medical device arena. A number of difficult application niches are now emerging.

One such niche developing for woven textiles is the field of minimally invasive spine surgery. Many device concepts are designed to deliver hydrogels, solids, or bone cements through small cannulae into bone or other structural tissues for support or reconstruction. Designers can achieve near-net shapes by using weaving techniques to create containment structures, which offer the benefit of incorporating injection ports, special reinforcement zones, and controlled permeability. The woven biomedical textiles can be optimized and tuned to the exact containment requirements, isolating treatment areas as needed. Woven structures can also fit into small delivery profiles and can inflate in vivo.

The future for other orthopaedic procedures relying on woven textiles is also promising, particularly for applications that require varying levels of tension and tensile strength. Due to the woven structure, biomedical textile ribbons and tethers in these applications exhibit strength and stiffness in one direction and controllable variability in compliance and compression in other directions. This ability to vary tensile performance in different directions, which is a hallmark of the weaving process, allows for rotation and lateral translation that cannot be achieved with traditional rigid metal or molded components.

Expertise in material selection and textile forming technologies yields structures such as these biluminal, woven polyethylene terephthalate (PET) tubes.

In motion-preserving spinal tethers, weaving enables device makers to vary aspect ratio, size, strength, stiffness, and other characteristics in addition to incorporating anchoring sites and radiopaque markers. The inherent flexibility and compliance allows these tethers to flex with body's natural movement and to provide a limiting force where movement needs to be restricted.

As stated earlier, specialized areas of reinforcement and the ability to create near-net shapes are emerging as key benefits of woven textile components. These capabilities are especially beneficial for creating tissue in-growth regions on structures that serve special functions and add value to the entire structure. In the future, spinal applications using specialized woven structures that contain reinforced holes for screws and other fastening components (which are useful for attaching to a bone plate) may become more common.

In the case of woven tubes, regions of specialization made possible by weaving can be used to create biological seals that contain blood inside the tube. The uniqueness of woven textiles allows the tube to have a smooth, thin-walled interior surface while the exterior contains denser, specialized zones that help to anchor devices and prevent migration in endoluminal fixation. Likewise, the ability to vary sides or regions of a textile can also yield the opposite effect; structures can be woven to prevent or reduce surface adhesion by using specialized raw materials or coatings and weave constructions with optimal properties.

In fluid transfer applications, weaving offers the potential for branching and the fenestration of main vessels into smaller ones—channels that bifurcate (or polyfurcate in many directions) to provide a structure that can be used to maintain the patency of branch vessels. Woven structures can be designed to incorporate interior coating materials to inhibit restenosis, a common problem with small-diameter structures of 4 mm or less. In addition, woven structures possess the radial strength needed to resist compression forces in vivo, to remain patent even in tortuous anatomy.

One area closely linked with the performance of biomedical textiles is material development. Polyesters, polypropylene, and metals have been used a great deal over the years. The next challenge is moving textile materials closer to the realm of biohybrid and fully biologic substrates. Future generations of devices may contain both biologic and synthetic materials, woven together into unique designs capable of providing one state during implantation and a future state that is optimized to work with the fully healed structure in vivo. Current material candidates include collagen fibers woven together with synthetic materials to create a biohybrid woven scaffold. The resorbable fiber imparts strength during implantation, dissolving thereafter to leave the remaining materials in place for ongoing reinforcement.

Although these concepts are now in their early stages, fully biologic but synthetically grown materials are an important element in the future of medical device technology. Weaving enables manufacturers to capitalize on combinations or multiple layers of different materials, integrally interlaced, and the unique properties of biologic and biohybrid structures. Woven scaffolds, for example, can be used as effective cell seeding sites, possibly loaded up with stem cells prior to implantation. The possibilities are numerous.

Note that most fabrics tend to perform poorly in highly compressive environments. Rigid plastics and metals will still play an important role in future medical device designs. However, across the broad spectrum of material options for device design, woven fabrics instill a range of biologic and mechanical properties that few materials can offer.

Conclusion

Innovation, the very lifeblood of the device industry, isn't the province of one material, one technology, or one process. Rather, it is the combination of what is possible—e.g., variability in structure, delivery method, performance, physical composition, resorbability, and many other elements. Biomedical textiles demonstrate what is possible in device design and enable device developments that were unfathomable just a few years ago. Textile technology can help device designers develop a portfolio of more innovative, effective, and commercially successful device designs that allow orthopaedic device manufacturers to achieve competitive advantages in the orthopaedics market, where novelty is the key to success.

References

1. T Gries, "Latest Developments in Medical Textile Products," presentation at Institut für Textiltechnik (Aachen, Germany: 2006).
2. AM Seyam, "Weaving Technology: Advances and Challenges II," *Journal of Textile and Apparel, Technology and Management* 3, no. 1 (2003); available from Internet: www.tx.ncsu.edu/jtatm/volume3issue1/articles/Seyam/seyam_full_26_02.pdf.

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