5 Key Considerations for Working with Biomedical Textiles

Todd Blair

As concerns over many implant materials, including metals, grow, medical device engineers are increasingly looking to biomedical textiles to aid in device design and implant performance. The advantages for more biomimetic functions are vast, but in order to satisfy performance requirements, there are a number of key considerations engineers must be prepared to address. Every decision, from biomaterial selection to processing technique, must be carefully assessed by a contract manufacturing partner with specialized medical textile expertise to develop a device that both delivers clinically and meets all compliance standards for regulatory approval.

1. It’s All About the Fiber

From polypropylene to PEEK, there are a multitude of fibers used to create permanent and bio-absorbable textile structures for use in medical device design. The current most common include nylon, ultra-high-molecular-weight polyethylene (UHMWPE), polyester (PET), polyetrafluoroethylene (PTFE), PEEK, and PEKK (polyether ketone ketone) for permanent applications, and PGA, PLLA, PDO, PLGA, and many other copolymers for devices with degradation requirements. Choosing the correct fiber is the first step to achieving the desired performance requirements, and becomes even more critical as an increasing quantity of biomaterials become available for implant use. While options abound, the precise mechanical characteristics of each demands an attention to detail and sophisticated understanding of their impact on performance. Characteristics such as density, strength, abrasion resistance, hydrolic response, heat shrink, elongation, and many others directly affect the ability of each fiber to deliver upon certain performance requirements, as well as its suitability to specific types of engineering processes for textile development. The most important for device developers are:

- Denier—The linear density of the fiber (or fiber bundles within multifilament fibers), which generally has an effect on strength and the subsequent possibilities for processing, such as device thickness
- Tenacity—The strength per denier of the fiber, which plays a major role in determining implant performance in load-bearing applications
- Elongation—The tendency of fiber to allow for stretch or maintain its shape over time, which is critical to sustained implant performance
- Heat Shrink—The amount of shrinkage over time under certain temperature conditions, which is an important factor for post-processing requirements and sterilization

2. Do I Stay or Do I Go?

Not all bio-absorbable fibers are created equal. To successfully deliver a device that

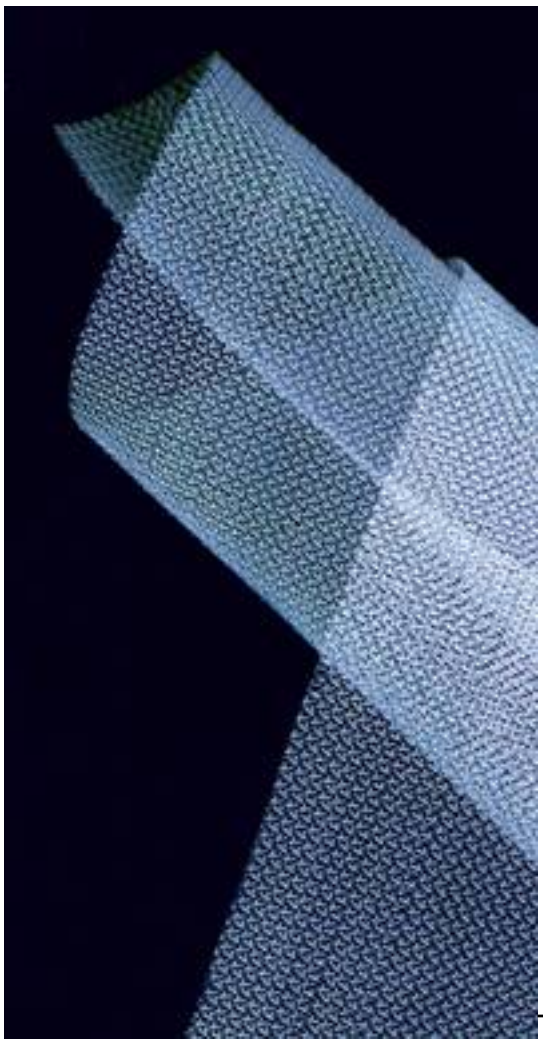
performs as intended in the body, consideration of lifespan is of primary importance. A repair application for a tendon or tissue regeneration of a heart valve, for example, will require support for cell regrowth for a specific duration of time in order to ensure optimal healing and the recovery of as natural a function as possible. Wound treatments, on the contrary, must disintegrate more quickly to keep from hindering the growth of new cells on a particular surface. Degradation profiles can range from days to more than a year depending on the polymer type, so engineering to deliver to device specifications is critical for performance and may present challenges for engineers more familiar with working with metals and alloys than with polymeric biomaterials.

3. The Proof Is in the Processing

Specialized textile engineering techniques enable device developers to capitalize on the unique properties of each material through processes that magnify strength, texture, flexibility, and other characteristics as they create customized textile fabrics. Knowing when to use each is the single most critical consideration for successfully designing with biomedical textiles. The primary forms include braiding, knitting, weaving, and non-woven structures.

Braiding

Braiding is completed by the manipulation of fibers, usually at least three, in a maypole fashion to interlace the strands in a specific pattern. Braids can be composed of a combination of fibers (such as mixing polyester with an absorbable material for partial degradation over time) and formed into hollow tubes, tethers, or flat structures, depending on the device application.

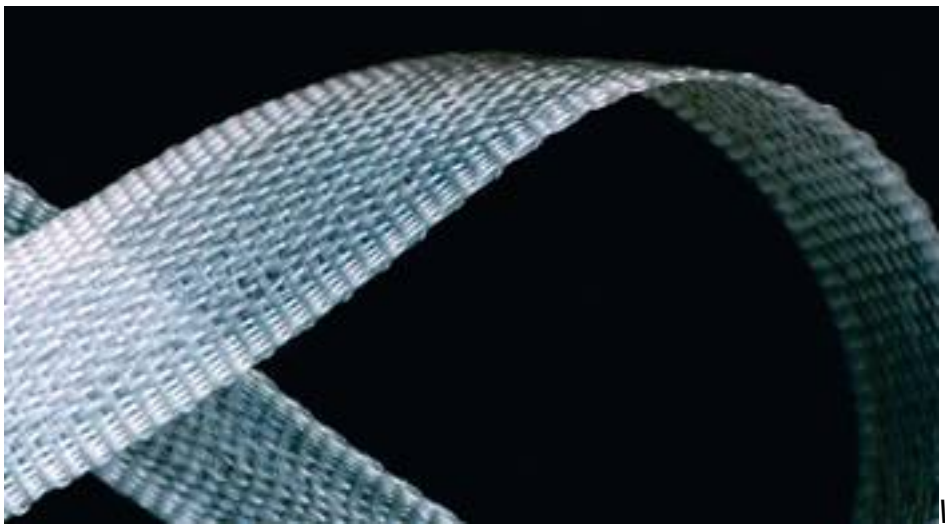


The braiding process produces a structure with a high degree of strength and flexibility, but without a large surface area. For applications that require a compact form factor, braids can be engineered in thin, light structures able to expand and compress as necessary without sacrificing axial strength when bearing a constant load. Applications especially suited to braiding include sutures, as well as knee, shoulder, and small joint arthroscopic procedures, because strength and other performance characteristics can be created according to the needs of the particular joint.

Knitting

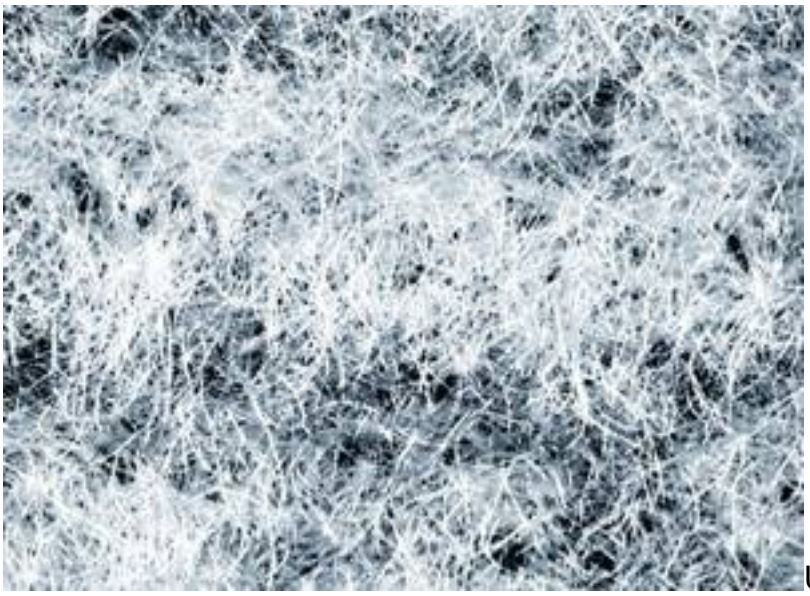
At the simplest level, knitted textiles are based on a series of organized loops hooked together via different processes such as warp or weft. Knitting usually involves a greater number of individual fibers than braiding and is used to develop a more intricate structure with highly specific performance capabilities.

Knitted textiles can be designed to possess good stretch and high strength, thanks to the interstitial spaces between fibers that provide a concentration of power. From flat meshes with high conformability to designed apertures to allow for cutting or other alteration without sacrificing edge integrity, the variety of constructions for knits is vast. Applications that require a higher degree of performance and undergo more severe instances of movement and stretch, such as containment sleeves for spinal disk repair and replacement or implants and procedural assistance pieces for the knee, shoulder, and spine, are all well-suited to knitted structures.


Weaving

Weaving allows for a wide array of textile styles, from single plain patterns to thicker, stronger, or shaped multidimensional weaves. Woven structures consist of longitudinal fibers held together by perpendicular cross-fibers, which allows them to provide thickness and strength without the stretch of knitted or braided fabrics. With high tenacity, they are lightweight and stable, but hold their shape for support, repair, and replacement functions that must retain their original form, such as vascular grafts, spinal restoration, and tendon repair. Applications of these kinds all require strength that is maintained over time and protected against elongation with age or use.

Non-Wovens


Usually designed as a felt created by a carding and needle-punch process, non-woven structures provide greater surface area than most other textiles, as well as a unique 3D architecture. Because of their potential for encouraging tissue growth, non-wovens are currently expanding outward from their traditional use in classic tissue engineering to orthopedic reconstruction and cardiovascular indications.

The construction of non-wovens helps to encourage cellular in-growth and proliferation for repair functions with carefully designed layers of entangled fibers and extensive void volume. Degradation profile is particularly important for non-wovens, which are especially useful in providing support for a limited amount of

time before being absorbed by the body and replaced with natural cells.

4. Twist and Shape

Beyond structure development, meeting device requirements may mean specialized engineering. In order to fully take advantage of the characteristics intrinsic to each kind of fabric and manufacturing technique, device OEMs must consider all available techniques to enhance biomimetic function.

Manufacturing processes that can maximize performance to precise specifications include texturing (adding crimp or bulk to straight material), twisting, plying, and precision cutting techniques such as die, laser, ultrasonic, and staple cutting. Shaping, also a finishing method for molded compositions, allows for different geometries such as tubes, cones, disks, and cylinders for implantation, while fusing combines two dissimilar materials into a single structure, and may often entail creating a heterogeneous material from non-woven, woven, or knitted fabrics. Sewing can also be used in a similar way to join biomaterials together in a hem, termination, or multilayer system by connecting multiple finished textiles into a larger structure for implantation where necessary.

5. Innovative Design Must Deliver Every Time

Often overlooked when considering top-line design considerations, a robust quality system and integrated processes that mitigate risk ultimately determine not only the feasibility for manufacturing, but even the eventual regulatory approval of the device. Beyond the design specifications, devices containing biomedical textiles must pass biocompatibility testing, demonstrate efficacy in clinical trials, and much more. As a baseline, biomaterials should be fabricated in clean rooms and undergo testing via ASTM methods as part of the regular protocols for development and manufacturing throughout. To ensure traceability and reproducibility even at the volume manufacturing scale, a focus on quality throughout the design process must form the foundation for the entire development cycle.

Conclusion

From choice of fiber and lifespan to advanced engineering, working with biomedical textiles requires careful consideration of a multitude of factors. For device engineers, choosing the right contract manufacturing partner is key to maximizing on the power of biomaterials for the next generation of device design.

Todd Blair is the director of sales and marketing for Biomedical Structures (BMS) *[1].*

Source URL (retrieved on *07/23/2014 - 12:28am*):
http://www.mdtmag.com/articles/2013/01/5-key-considerations-working-biomedical-textiles?qt-most_popular=0&qt-recent_content=0&qt-video_of_the_day=0

Links:
[1] http://www.bmsri.com/