White Paper:

Implantable Fabrics Revolutionize Neurovascular Devices

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In the neurovascular device segment, development is focused on minute, precision devices delivered via micro-catheters. The overarching challenge is to create components that maximize performance within a minimal deliverable profile. That's where biomedical textiles come in.

A Growing Need

More than 86,000 neuro-interventional procedures, involving a range of devices, were performed in the U.S. in 2010. Over the next four years, the number of these procedures is expected to grow at an annual rate of 18% to more than 197,000 by 2015.[1]

Most neuro-interventional procedures focus on aneurysm repair. According to The Brain Aneurysm Foundation, nearly 30,000 people suffer a brain aneurysm each year and approximately 40% are fatal. Of those who survive, about 66% suffer some permanent neurological deficit.[3]

Aneurysms are also a major cause of stroke, which is the fourth leading cause of death in the U.S. that affect approximately 800,000 Americans each year.[2] Ischemic stroke, when an artery to the brain is blocked, is by far the most common kind accounting for 88% of all strokes.[4]

Current solutions for aneurysms, such as coiling or clipping, aren't always effective and often have adverse side effects. Coiling, for example, involves a lengthy recovery, as well as a high risk of recurrence and perforating the aneurysm. Clipping procedures, on the other hand, are highly invasive with the possibility of serious complications and damage from opening the cranium.

An Alternative Solution

Implantable medical textiles offer alternative solutions to neurovascular device design that are minimally invasive and provide shape transformation capabilities to allow for low-profile delivery. Specifically, biomedical textiles enable design of solutions for embolic filtration, aneurysm repair, ischemic repair, flow diversion, and various other neurologic disorders.

Textile design engineers have a deep and essential understanding of how various biomedical structures and constituent materials will perform and respond when used in a neurovascular application. Understanding the performance and biological requirements of a medical device, the desired method of delivery and the materials needed to provide the desired properties are essential to the engineering process and ultimate success in delivering an effective device component.

The Neurovascular Design Tool Box

When selecting biomaterials for neurovascular devices, the immediate performance as well as the future state of the biomedical textile structure must be considered at the beginning of the development process. A strong grasp of raw materials options is critical when selecting the most appropriate biomaterial.

Neurovascular devices frequently utilize metal alloys in their designs. Materials such as Nitinol and cobalt-chrome are used extensively due to their stiffness and shape-memory characteristics, desired properties in a neurovascular application. Platinum is also used for radiopacity in procedures where a fluoroscope is utilized. Additionally, standard polymers, or resorbable polymers designed to fully resorb over a given time period can be used. Understanding the advantages and disadvantages of the performance of biomaterials and combinations of these materials, is vital to effective structure design and the resulting performance of the device.

Textile-Forming Option

Aside from material selection, the variety of textile structures and fabric geometries also extend device design possibilities. The selection of biomedical structures must been done thoughtfully in order to address all of the performance and biological variables presented in a critical neurovascular application.

- ***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.

  An ideal textile engineering partner will have capabilities in high end count braiding and extensive experience in working with extremely fine wire sizes. A cylindrical stent implant is an example of a device created with a braided textile that supports vein function and keep arteries open. It is also delivered with instrumentation designed for small delivery sites.

- ***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.

- ***Woven*** structures are formed by the perpendicular interlacing of two yarns or wires. 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), 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.

Biomedical Structure Options

Implantable fabrics can be shaped into tubular and multi-lumen structures, tether or suture geometries, or even near-net shapes that include fenestrations or branches. Metallic materials can behave as stent-like structures when oriented in a helical or cylindrical direction, which is often a critical design feature in neurovascular applications. These materials are very effective in providing the necessary geometries compatible with specific application needs while providing the shape memory abilities needed.

Medical device designers generally have a strong understanding of the neurovascular technology performance requirements of their device but need assistance in understanding how to leverage a biomedical textile to meet those requirements. Through communication and engineering collaboration, textile engineers can bridge the gap between the requirements of the neurovascular application and the possibilities offered by implantable medical textiles.

Source:

(1) M. Thompson. "Neurointerventional Market Shows Growth Potential" Medtech Insight, Vol 13. No. 5, (2011).

(2) T. Neilssien. "ISC 2011: Stroke Device Innovation and Investment" Medtech Insight, Vol 12. No. 3, (2011)

(3) "Brain Aneurysm Statistics and Facts | The Brain Aneurysm Foundation." The Brain Aneurysm Foundation. Web. 29 Feb. 2012. <http://www.bafound.org/Statistics_and_Facts>.

(4) "Ischemic Stroke". The Internet Stoke Center. 5 July 2012. <http://www.strokecenter.org/patients/about-stroke/ischemic-stroke/>

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