



# Life-Saving Fibers

By Glenna B. Musante

**T**oday, textile fiber biomedical implants represent a multi-billion dollar industry worldwide, but as recently as 60 years ago the use of textile fibers to replace body parts was virtually unthinkable. Then, two neighbors living near Philadelphia had a conversation.

According to David Brookstein, former Executive Dean for University Research at Philadelphia University, it was the late 1940's, and a New Jersey, USA, cardiac thoracic surgeon was certain that one of his patients had what is known as a dissecting aneurysm. This is a weakness in the wall of the aorta (a large artery that extends from the heart to the abdomen) that can rupture and cause sudden death.



The doctor's neighbor, a Philadelphia University graduate named William Von Liebig, owned a company that made silk. One day, the surgeon asked Von Liebig if he could construct a fabric tube to replace his patient's aorta. It had never been done before, but Von Liebig was intrigued and approached a professor at Philadelphia University named Thomas Edman, an expert in knitting, and asked if this might be possible. Edman gave it some thought and figured out how to construct a bifurcated aorta from fabric, and gave the design specifications to Von Liebig, who then went back to his mill and constructed what is reportedly the world's first textile implantable. The surgeon implanted the device, it worked fine, the patient lived, says Brookstein, and the rest, as they say, is history. Brookstein adds that Von Liebig went on to form a medical device company that later became Boston Scientific, which (according to a 2012 report from The Freedonia Group, a market research company) was the leading US manufacturer of vascular grafts in 2008.

## A Scientific Synthesis

In the process, a new hybrid field combining textile engineering and medical science was born.

With advances in tissue engineering, nanotechnology, and other innovations, the field of textile biomedical implantables has emerged as a scientific frontier that promises to provide solutions to several of the world's fastest growing health issues, including heart disease.

According to a recent implantables industry forecast from The Freedonia Group, demand for medical implantables in the United States alone will grow 7.7% annually to an estimated US \$52 billion annually by 2015. Cardiovascular implants—an industry segment that includes textile implantables—represents 28% of the demand for implantables and (as with the first implantable) offer fertile ground for the development of innovations that combine fundamentals of textile engineering with medical research.

## The Search for Biocompatible Materials

One of the major issues with which scientists have grappled is finding materials for implantables that the human body will accept.

Gary Bowlin, a professor at Virginia Commonwealth University, specializes in vascular tissue engineer-

## What is Electrospinning?

Think of this as a glorified cotton candy machine. Electrospinning has been around a long time and creates micro or nano-scaled fibers by spinning a polymer solution at high speed. An electric charge is applied and when the electric field becomes strong enough, fluids are drawn out of the polymer, leaving miniscule fibers behind.

ing—specifically, designing small diameter vascular grafts and implants. Like many new innovators in this field, Bowlin is not a textile engineer, and he is not a physician. With training in chemical engineering and biomedical engineering, he refers to himself as a tissue engineer.

According to Bowlin, the polyester-based woven and knitted vascular grafts that have been used since the mid-1950's have worked for many people, but “are far from ideal when used for small diameter blood vessel replacement, such as with pediatrics, or in our arms and legs.”

He says that traditional polyester-based implantables often fail in small vessel situations on implantation, which could cause sudden death.

Bowlin uses electrospinning (see sidebar) to develop tissue-engineered implants. His research includes identifying non-synthetic replacements for polyester, and developing ways to use natural polymers to build the fabric walls for small diameter, nonwoven, seamless textile tube implants to replace and repair blood vessels. Using materials such as dextrose, Bowlin's implantables could be described as scaffolds that promote cell regeneration, then disappear.

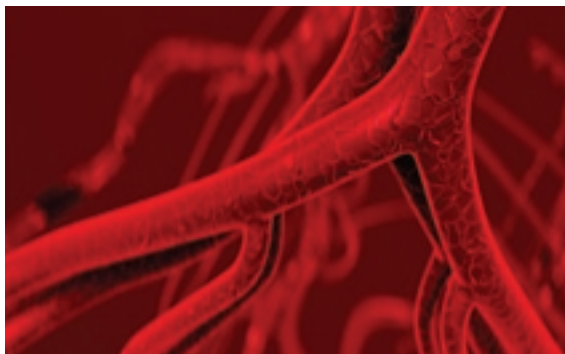
“If you look at your body and take away the water, the cells, the mineral components of your bones,” you are left with an extracellular matrix formed from nanofiber, he says. “So we are nothing but a nanofiber, filled in.”

His work with implantables is based on this prem-

## What are biomedical textiles?

Generally speaking, biomedical textiles are products designed and used for medical purposes inside the human body and include such items as absorbable sutures, vascular grafts, and artificial ligaments.

ise and the notion that the largest component of this extracellular matrix is collagen, which acts as a structural element for cells much like the steel beams in a sky scraper. But there, the metaphor stops because collagen, he says, has the ability to communicate with human cells.



## New Spin on Textiles

Bowlin electrospins dextran to create implantables that human cells will hopefully respond to and grow on. “Cells know what to do in the right environment, so as textile folks, we need to create the right environment,” he explains, adding that the miniscule fibers created by electrospinning “look familiar to human cells.”

One challenge is finding the right polymers. Timing is also a tricky issue. Bowlin’s implantables are designed to provide a structure on which human cells can grow, but have to be in place long enough for that process to fully take place.

“If we use natural materials, cells will recognize that and know exactly how to respond to that,” he says, and the response he is looking for is a willingness by human cells to integrate with his fibers, and create replacement blood vessels.

Matt Phaneuf, president of BioSurfaces Inc., a company specializing in the development of innovative medical devices, is also using electrospinning to create new generation implantables.

Products in his company’s development pipeline include a peripheral artery graft designed to prevent clot formation, a hemodialysis access graft that prevents clotting and unwanted cellular growth, and drug-eluting stent sheaths.

He says that most of today’s implantables are manufactured using standard textile technologies. “For



artificial blood vessels, current grafts are knitted, woven, and extruded,” he explains. “Sutures can be braided or (made into) a monofilament form. While textile use in medical devices sounds very sophisticated, the technology uses basic textile techniques that have been around for many years.”

Phaneuf says electrospinning has also been around for many years, but typically has not been viewed as a viable manufacturing alternative for textiles. “It’s hard to produce things in bulk with electrospinning,” he explains.

But it’s an ideal methodology for creating minuscule nonwoven fabrics, including small implantable arteries. Another benefit to electrospinning is that researchers can weave—or rather, spin—pharmaceuticals into the fiber mix.

## Did you know?

A nanofiber has a diameter smaller than 1000 nanometers. A nanometer (also spelled nanometre) equals one billionth of a meter.



Both Bowlin and Phaneuf say the structures created through electrospinning are not true nanofibers, but at the same time are too small to be called microfibers. The largest fiber created by Phaneuf's lab through electrospinning is five times smaller than a microfiber in diameter. Bowlin says the fibers he creates with electrospinning are similar in size to the fiber component of the human cellular matrix.

### Fighting Infections

Developing biocompatible implantables that won't be rejected by the body presents many challenges. Another concern is infection.

According to Phaneuf, one of the major issues with implantables is bacterial adhesion. "Many great materials have been made, but if they can't be sterilized, it is useless to pursue them for implantation," he says.

A well-reported danger associated with implantables is the risk of the patient developing a life-threatening staph infection from one of the so-called antibiotic-resistant super bugs such as MRSA, which stands for methicillin-resistant *Staphylococcus aureus*. Hospital patients are most at risk of picking up a MRSA infection. According to a recent article in *OR*

*Manager*, a trade publication for hospital operating room administrators, patients undergoing vascular surgery, cardiac surgery, and orthopedic surgery with implants are at high risk.

"Once MRSA becomes attached to the material of an implantable (such as the polyester cover of a stent), the relationship with that substrate makes it impermeable to the body's natural defenses," says Phaneuf. MRSA can hide in the textile, he explains, "and once it gets stuck it protects itself on the material surface." He adds that although only 3-10% of patients contract a MRSA infection, when they do "it's usually very serious," and results in high patient death rates.

The new nanofiber-based implantables his firm is developing with electrospinning include a proprietary technology that can contain various bioactive agents including proteins, genetic compounds or agents with antibiotic (antimicrobial) qualities. "We're using the fibers to release the drugs," he says.

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Mark Farber, a vascular surgeon at the University of North Carolina (UNC) Chapel Hill and director of the UNC Aortic Center, says he would like to see innovations for preventing bacterial adhesion to implantables.

“Some are more bacteria-resistant than others,” he says. “I would like to see textiles in the future that have antibiotics attached to the fabric itself.” Farber adds that some vascular stents are drug-coated, but the scientific community has yet to develop stents where drugs are impregnated into the fabric.

### Passing Multiple Tests

The solution to MRSA infections and other issues may be in the R&D pipeline, but it can take years of development before an implantable is approved for use.

“Many tests have to be conducted on textile-based devices to make sure they can be implanted, from bench top testing to animal implantation studies,” says Phaneuf. For bench top testing, he says, basic qualities such as strength, stretch, burst strength, water permeation, wet-ability, and wicking are evaluated, depending on the use of the device. Materials can also be evaluated for cellular toxicity, cell adhesion, or bacterial resistance.

Phaneuf adds that animal studies are a critical part of the development process, “because many bench top tests can’t mimic the complex biologic processes that happen within the body.” After implantation, he says implantable devices need to be tested again at the bench top level. “These studies do tend to eliminate technologies that more than likely would have failed,” he adds.

Long term durability presents other testing issues. All current aortic devices are tested to last ten years to meet FDA (US Food and Drug Administration) standards,” says Farber. Most cardiac disease is in older patients, where a ten-year shelf life is acceptable. “But if we have a young patient, who is in a car accident and tears an artery, and he’s 30 years old, he needs a device that can last another 30 years,” Farber explains. Aortic devices go through numerous fatigue tests and durability tests, he says, but whether or not one will last 30 or 40 years is often an unknown.

“Today’s litigious environment probably slows down some innovations,” says Brookstein, “but there are

two sides to that coin. Do you as a patient want an unproven technology being used on you?”

### Time for Communication

The good news is that R&D is booming and this includes research related to blending scaffolds with human stem cells to create replacements for human tissue and possibly even organs. Some schools with deep textile roots are even branching into tissue engineering. Philadelphia University, home to the father of textile implantables, recently opened a Biomedical Textiles Structure Laboratory.

“I want people to look at (the new program) as a resource for the biotechnology community,” says Brookstein, who is the former director. “We are not biologists here and we are not biotechnologists. We are textile/mechanical engineers working with people in the bio-engineering field. We are partnering to develop new structures for various clinical applications.”

And collaboration between diverse disciplines is needed. “What it’s really going to take,” says Farber, “is a partnership with engineers or textile experts and medical experts. If you don’t know what the issues are, it won’t be as good a design.”

Phaneuf agrees. “Many of these fields overlap,” he says. “We’re starting to see that a lot. But the biggest drawback is that there is sometimes not a lot of crosstalk between the fields.” Innovation will require what Phaneuf describes as a “synthesis of many disciplines” involving physicians, textile engineers, textile chemists, tissue engineers, and others, working together “with all parties involved thinking outside the box.”

