White Paper:

Designing Functional Fabrics for Today's Heart Valves and Beyond

Ryan Heniford
Business Development Director

Peter Gabriele
Director, Emerging Technology

secantmedical®

How fabrics can be used in heart valves, now and in the future, and design considerations during product development.

Heart valve disease affects nearly 5 million Americans, a figure that is expected to double in the next 25 years, according to the Mayo Clinic. The most advanced of these cases, nearly 98,000 in the United States each year, require heart valve surgery.[1] Prosthetic heart valves, whether traditional or transcatheter, are designed to restore function to a damaged heart valve and ultimately prevent heart failure. These devices will continue to evolve as research unlocks the exciting potential of implantable materials in heart valves and their ability to allow the body to repair itself.

Heart valve replacement falls into two procedural categories—open surgery (traditional) and transcatheter replacement—the latter segment includes transcatheter aortic valve replacement (TAVR) and transcatheter mitral valve replacement (TMVR).

Within both traditional and catheter-based heart valve implants, the fabric structure is a component that serves to enhance the mechanical function of the valve. Textiles help promote tissue ingrowth, prevent paravalvular leakage and enable a low-profile design for confinement, which is a crucial requirement for transcatheter valve replacement (TVR) devices.

Implantable fabrics can be precisely designed to limit motion in a targeted direction, to stretch to a specific length, or to provide flexibility throughout the entire range of motion. In a TVR device, a properly designed fabric will transform to a desired shape profile after passing through a catheter to enable the valve to function properly and facilitate required tissue ingrowth.

Fabrics can be used in several parts of traditional and transcatheter heart valves, including:

- Skirts
- Sewing rings
- Paravalvular seals
- Functional anchoring components
- Protective sleeve for working components

Design Considerations

Textile structures enable different stent-leaflet combinations by offering nearly limitless near-net shape possibilities, extremely thin profiles and versatile attachment methods. They also create more room for these functional components. Ideally, when designing a heart valve, a design engineer should partner with a textile engineering company at the earliest phase of the product development process. This will enable complete incorporation of stent requirement expectations (i.e., deployment goals when working with transcatheter valves) into the overall design.

After reviewing the valve design, the textile engineers can recommend the most appropriate medical fabric based on several factors, including application (traditional or transcatheter); anchoring requirements; delivery profile; and potential stresses on the fabric. Fabric conformability is a key factor to the success of the application. The textile partner can design an appropriate structure and manufacturing method based on the functional requirements of the valve (e.g., a knitted fabric stretches much more than a woven fabric, which typically provides a thinner profile). Fiber structure and density can be tailored to accommodate a wide array of delivery profiles.

Suturability and attachability (to the stent or other functional valve components) characteristics are important parts of the design process. For example, an implantable fabric can be designed to have specific anchoring sites. It can be reinforced or have inherent retention properties that prevent the suture from pulling out of the structure. Sutures can be designed to match a fabric’s elasticity or elongation for optimal performance in the valve.

The fabric also acts as a sealant for the heart valve, isolating the working portion of the device from aggressive tissue ingrowth. Depending on the desired outcome, tissue growth for in situ modeling is modulated through rapid encouragement, prevention and control:

- **Encouraging Tissue Ingrowth.** When encouraging rapid tissue ingrowth, the goal is to facilitate aggressive scarring in a specific area without affecting the working parts of the valve. There are several ways to achieve this: by optimizing the pore size and shape, changing the structure of the fabric or using the most suitable biomaterial. The conformance properties of the fabric will also encourage growth. Other methods of promoting ingrowth include applying chemical coatings (e.g., Haluronin) to the fibers or using surface modification techniques (e.g., plasma treatment).

- **Discouraging Tissue Ingrowth**. The fabric’s geometric structure can be designed to protect the functional components of the valve, whether it’s the stent, leaflets or other component, from embedding in the tissue. This action will allow the critical parts of the device to function properly. In addition, coatings can be applied to the fiber surface to inhibit growth. Certain coatings that fill the pores of a fabric could reduce the amount of ingrowth induced.

- **Controlling Tissue Ingrowth**. This next-generation approach involves using a bioresorbable polymer material that is structured to merge the tissue with the heart valve. As the structure degrades over time, it encourages rapid tissue integration and allows cells to penetrate and ultimately form a healthy heart valve or annular tissue, for example.

Keeping a Low Profile. Transcatheter heart valve design can present challenges to a manufacturer due to low-profile requirements. The current driving trend in the industry is to fit functionally effective devices into small catheters. Minimally invasive procedures lower the risk of infection and cause less trauma to patients, which means faster recovery times. When designing TVR devices, fabrics are typically woven and compressed to minimize the profile while optimizing the pore size and shape to promote tissue ingrowth. Textile engineers can mirror the functional characteristics of traditional heart valves while ensuring the fabric is elastic enough to stretch, fold or pleat into catheters as small as 12 French. Fabrics measuring 50 µm or thinner can be manufactured.

Fabrics can also be optimized to have a certain surface chemistry or for use with coating technology. For example, the fabric can be designed to absorb a material between the fibers instead of into the polymer when used with an anti-calcification coating.

The Future: Intelligent Materials Design for Heart Valves

The future of biomaterials is an investment in understanding the physiological, economic and bioengineering constraints of materials. Most current heart valves that have synthetic components at the device or native tissue interface use polyester or PTFE because, along with a proven history, these materials have been deemed biocompatible by the FDA. However, current materials are limited by low durability and long-term degradation (leading to premature device failure), calcification and cusp stiffening.[1] These limitations can impact the long-term performance of heart valves and require that patients take anticoagulants daily due to the risk of clotting.

When looking into the future of cardiovascular materials engineering, it is important to develop materials that promote long-term indigenous physiological activity. On average, the heart pumps an estimated 2000 gallons of blood each day. Materials that are used in heart valve replacements, therefore, undergo a tremendous amount of hemodynamic stress.

Heart valves of the future need to be biologically smart, meaning that they must incorporate polymers that are biomimetic. The new material must be able to perform its service function while surviving in the body without causing a shift in homeostasis. Through intelligent materials design, such a polymer will be engineered to provide early-stage mechanical and performance properties while gradually allowing the body to regenerate the anatomical part.

Other properties that must be considered for a next-generation polymer include:

- Mechanical strength: elastogenicity, burst strength, hemodynamic adaptation, fatigue strength and durability, and suturability
- Compliance/compressibility
- Vasoactivity
- Low thrombogenicity
- Degrees of freedom in fatigue
- Resistance to infection, inflammation and hyperplasia
- Promotion of healing
- Minimization of capsule formation
- Flexibility

Fabrics or textile components could be made out of next-generation polymers for use in the heart valve leaflet and the stent. Achieving the right loading conditions while the valve is working, along with the right degradation times and proper cell growth, could lead to the creation of an all-fabric valve that degrades over time in the body and thus creates a new valve, enabling the valve to heal itself.

Regenerative medicine technologies will provide materials with the ability to degrade over time and be replaced by functional tissue. To meet this promise, however, a serious mechanical challenge with resorbable materials must be addressed: Can a valve construct be designed to manage the mechanical stress of life support while at the same time promote the remodeling as a regenerative process? This truly is the barrier to the development of future heart valve polymers.

References

1. Seifalian, A M, et al., "Current Developments and Future Prospects for Heart Valve Replacement Therapy," *Journal of Biomedical Materials Research Part B: Applied Materials* (pp. 290-300). doi: 10.1002/jbm.b.31151.

Ryan Heniford is Business Development Director and Peter Gabriele is Director, Emerging Technology, at Secant Medical, Inc.

About Secant Medical: Secant Medical®, Inc. custom designs and manufactures biomedical textiles and other structures for implants in orthopedic, cardiovascular, regenerative medicine, neurovascular and general surgery applications. Built on a 70-year history, the company uses polymeric, metallic and resorbable biomaterials to create high-performance structures that help device manufacturers solve product design challenges. Secant Medical is a business unit of Fenner PLC, a worldwide leader in reinforced polymer engineering headquartered in Yorkshire, England.

www.secantmedical.com

877-774-2835