MEDICAL DESIGN BRIEFS

Cardiovascular Applications of Biomedical Materials

Fig. 1 — Pellets, film, disk, and tubing made of thermoplastic polycarbonate-urethane are shown.

Every day, a healthy human heart pumps 2,000 gallons of blood through 60,000 miles of blood vessels. Given this demanding workload, it's not surprising that people can suffer heart complications. People are living longer lives and the number of patients with cardiovascular disease is growing. As the average age and weight of the population increases, so does their propensity to develop cardiovascular disease. Significant advancements to minimally invasive cardiovascular treatments are improving physicians' ability to treat heart disease, while specialized interventional cardiovascular techniques are becoming increasingly important to slow its progression.

In a world where cardiovascular disease affects more of the global population than any other disease, pressures on healthcare systems and costs are soaring. Healthcare systems worldwide are faced with finding ways to offset these spiraling costs. Patients need hospitals and outpatient clinics to provide their clinicians with access to the latest advances in medical technology, while medical device manufacturers need access to the latest advancements in the biomaterials that are integral to the performance of those devices. Devices made from cutting-edge biomaterial technologies allow clinicians to provide highly sophisticated and less painful procedures as well as more targeted treatments.

Challenges of Navigating the Cardiovascular System

Cardiovascular therapies need to be robust and durable, yet delicate, due to the complex vasculature of the heart. The intricate network of vessels and the sensitive nature of endothelial surfaces in the cardiovascular system require simplified navigation and manipulation inside the body. Cardiovascular devices located in the blood stream require non-thrombogenic surface chemistry in order to prevent clot formation and blockages.

When foreign materials are implanted into the body there is always a risk of bacterial and fungal infections, particularly catheter-related infections, which significantly contribute to the increasing problem of nosocomial infections. To reduce the incidence of intravascular catheter-related bloodstream infections, it is important that biocompatible material technology continues to advance so that its potential contribution to these complications can be reduced or eliminated.

In the face of these anatomical and operational challenges, medical device manufacturers are continuously searching for smaller components that enable the development of low-profile devices. These devices benefit not only clinicians who must maneuver the complicated anatomy of the cardiovascular system, but also patients seeking faster recovery times. One of the biggest trends in medicine and minimally invasive surgery (MIS) relies on innovative devices that are smaller and work well in complex vasculature.

Medical devices designed for MIS make procedures easier and less time-consuming for clinicians, while also reducing the risk of tissue damage. Patients find value in MIS because it can mean reduced postoperative pain, hospitalization, and scarring, as well as a faster return to a normal life. MIS has evolved into the gold standard for efficient, low-risk cardiovascular procedures that reduce the possibility of error.

Driving the development of biomedical material solutions is a thorough understanding of how advanced materials can be used in the human body to strengthen or replace body parts and accurately deliver medicines. There are four major platforms of biomedical materials that are changing the way cardiovascular device manufacturers develop novel products — polyurethanes, coatings, fibers, and drug delivery technologies.

Polyurethanes

Biostable polyurethanes are a crucial component in cardiovascular medical devices and have a proven track record in human implantations. These specialized elastomeric materials are not only flexible, but also, strong, lightweight, durable, and interact safely with the human body making them ideal materials for long-term implantation. Polyurethanes, having extensive property and structural diversity, are one of the most biocompatible materials known today. These materials have played a major role in the development of a wide variety of cardiovascular medical devices ranging from central venous catheters to the total artificial heart. Properties such as durability, elasticity, fatigue resistance, compliance, and acceptance or tolerance in the body during healing are crucial given that the heart beats an average of 70 times per minute.

Additionally, the potential for bulk and surface modification with a hydrophilic and hydrophobic balance is possible through modification of the chemical end groups typical in a polyurethane structure. These end group modifications can be designed to mediate and/or enhance the acceptance and healing of the device or implant.

Biostable polyurethanes have diverse capabilities in cardiovascular applications because they can endure many different, innovative processing techniques that are used to manufacture complex devices. Polyurethanes can be processed by extrusion and injection molding techniques to become part of devices that feel and behave like natural tissue, giving them an important role in next-generation devices.

Thermoplastic polycarbonate-urethane (PCU) is well known as a medical grade polymer due to its long-term durability in implants. PCU, shown in Figure 1, has many clinical applications because of its biostability, biocompatibility, and oxidative stability. When compared to conventional silicone elastomers, its abrasion resistance makes it ideal for use in pacemaker leads, heart pump membranes, and stent coatings. PCU also has the potential to replace porcine tissue in next-generation heart valves, which has the potential to reduce the risk of foreign material rejection.

Coatings

Medical-grade coatings have become an important feature in many catheter and guidewire tools used to deliver implants, such as stents, stent grafts, and heart valves. Catheters and guidewires used to deliver these devices require low-friction, flexible, and durable delivery systems. Catheter delivery systems may require insertion through narrow pathways and the delivery system itself must not damage the surrounding vasculature, making it crucial that the coatings on guidewires and catheters drastically reduce friction.

Like the medical devices that they enhance, there is no "one size fits all" coating. Customizable coatings allow for specialized features such as hydrophilic coatings, silver-based antimicrobial coatings, and hemocompatible antimicrobial coatings. Hydrophilic coatings are designed to enhance the handling of catheters during insertion by maintaining lubricity throughout the surgical procedure. They also offer greater maneuverability for various devices such as guidewires, guiding catheters, balloon catheters, stent, and stent graft delivery systems. Antimicrobial coatings retain lubricious, hydrophilic coating performance and are designed to delay the onset of biofilm formation on devices such as Foley catheters, central venous and dialysis catheters, peripheral intravenous catheters and peripherally inserted central catheters. (See Figure 2)

Advanced medical coatings can enable clinicians to maintain a environment that helps ease placement of the insertion dilator, introducer sheath, and the catheter itself, which can lead to more accurate device implantation, prevention of unnecessary tissue damage, and reduction in discomfort for patients. By making it easier for physicians to move and accurately place devices in the body, costs can be lowered, surgery times can

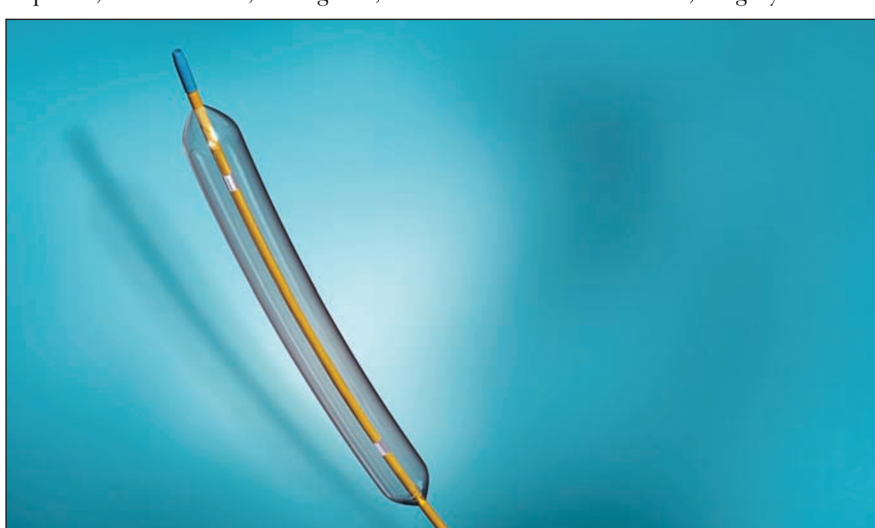

Fig. 2 — ComfortCoat® hydrophilic coating is used on a balloon catheter to advance device deliverability.

be shortened, and devices can start working to help patients faster.

UHMWPE fibers

Recent breakthroughs in medical textiles have enabled manufacturers to create various implantable devices ranging from innovative sutures to improved cardiovascular devices. Ultra-high-molecular-weight polyethylene (UHMWPE) fiber has the highest impact strength of any thermoplastic currently produced. UHMWPE fibers have the potential to aid in therapeutic repairs that last longer, increase comfort, and exhibit stronger mechanical performance. UHMWPE fiber is extremely strong, yet soft and highly pliable, allowing the fibers to be processed into many two- and three-dimensional constructions for the development of devices such as high-pressure balloon catheters, stent grafts, pacing leads, and heart valves. (See Figure 3)

UHMWPE fiber is ideal for transcatheter cardiovascular applications because of its proven biocompatibility and hemocompatibility. Its extremely low friction coefficient facilitates sliding against other materials inside a catheter, while its softness and smaller size reduces the invasive nature of implantable devices, lowering tissue inflammation and irritation.

Meeting the growing need for smaller, lower profile implants, UHMWPE fiber helps provide access to smaller vascular structures in a fast and reliable way. Devices that incorporate UHMWPE technology not only have the potential to reduce device profile, but can also enable better short and long-term performance and enhance medical outcomes and cost efficiency. Active, ongoing investments by materials manufacturers in the development of new grades of UHMWPE fibers are a reflection of a larger commitment to support device manufacturers in meeting their goals of developing better-performing products.

Fig. 3 — Examples of UHMWPE fibers.

Drug Delivery Technology

Resorbable biomaterials that also provide biocompatibility play an important role in implantable and injectable drug delivery platforms, which are designed to add a controlled drug release feature to medical devices. In cardiovascular applications, biocompatible drug delivery technology enables controlled sustained release of a drug without evoking immune responses and reduces unwanted side effects like scar tissue formation in blood vessels, which can occur when using non-biocompatible compounds.

Bioresorbable polymers can be designed to provide zero-order release, the ability to release equal quantities of therapeutic agents gradually over time. In cardiovascular vasculature, endothelial cells of vessel walls are sensitive, so ensuring even dosing of a drug over the entire release timeframe is important. Bioresorbable drug delivery technology platforms allow for sustained release of immunosuppressants from a coronary stent. For example, Svelte® Medical Systems, Inc., a privately held company developing next generation endovascular therapies, uses DSM's proprietary bioresorbable amino acid-based drug carrier in the design of a non-thrombogenic, non-inflammatory, drug-eluting stent.

Bioresorbable polymers are suitable to deliver a range of active pharmaceutical agents including preventative blood clotting agents and immunosuppressants. For example, combining drug delivery technology and well-established sirolimus drugs has the potential to minimize the need for dual anti-platelet therapy and improve patient safety.

The Value of Partnerships

The goal of partnerships between medical device manufacturers and materials developers is to enable the delivery of high-quality outcomes amid continuously changing healthcare dynamics. These partnerships drive innovation that enables the achievement of consistent, high-quality patient care, optimized resources, and lower costs.

Specialized materials developers enable medical device manufactures to bring cardiovascular devices to market faster because of their deep understanding of quality, processing, and regulatory requirements. The estimated six million people with implanted devices that contain DSM's biomaterials are a testament to the value of these co-developments and partnerships.

DSM provides innovative biomaterials that enable medical device manufacturers to design less invasive devices, which can speed recovery, shorten hospital stays, and reduce the need for revision surgery. This helps hospitals reduce costs while simultaneously improving patient care. Medical device manufacturers and materials providers consistently collaborate with the goal of delivering more advanced clinical procedures that ultimately have the potential for improved patient outcomes, helping people lead longer, healthier, and more active lives.

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