The Development of Novel Materials for Medical Devices

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Healthcare consumers continue to demand ever more complex devices for diagnosis and treatment of medical conditions. The development of novel medical devices was traditionally left to surgeon-scientists, who encountered patient suffering and developed medical devices using materials that were available in their local communities and that seemed to exhibit properties suitable for the desired function. Today, the medical device industry increasingly relies on knowledge of materials science and engineering to develop sophisticated replacements for natural tissues. For example, the $3.2 billion cardiac stent market has expanded over the past decade due to the development of flexible polymer balloon catheters that expand obstructed blood vessels; metallic wire meshes that provide structural support to blood vessels; and biodegradable polymers that release antiproliferative pharmacologic agents in order to minimize closure (restenosis) of blood vessels. The medical device industry accounts for nearly $100 billion in revenues, and is expected to increase over the coming decades.

Significant strides are being made in the development of novel materials for use in medical devices. Advances in medical devices and prostheses were made during and after World War II. Biologically inert metals, ceramics, and polymers were developed to mimic the structural performance of natural tissues. During this time, there was limited development of functional medical devices that could reproduce normal physiologic activities. Why? Human tissues exhibit incredible complexity in differentiation, development, adaptation, homeostasis, energy utilization, and structural organization. As a result, abnormalities induced by trauma, disease, or an implanted device at the protein, organelle, cell, tissue, or organ level can cause profound changes in the overall well-being of a human being. The development of miniaturized monitoring instruments for astronauts in the early U.S. space program led to the development of several successful devices for assessing and altering physiologic activities. Many of these medical devices were subsequently adopted for monitoring and treatment of hospitalized patients during the 1970s. Progress has continued over the past 40 years in the development of medical devices that synergistically function with biological processes. Several factors are driving current interest in functional medical devices, including an increase in the number of people suffering from hypertension, osteoarthritis, diabetes, cancer, and other chronic health conditions as well as an increase in concern over biological and chemical warfare agents. For example, the development of portable, real-time monitoring of hormone concentrations, gas concentrations, and other biological processes will enable home-based treatment of individuals who require continuous monitoring of chronic medical conditions.

Novel biomaterials, including biologically derived materials and nanoscale materials, are being developed for advanced prostheses and functional medical devices. These biomaterials will provide integration of multiple functions, miniaturization of devices, an increase in stability, and a decrease in cost. It is anticipated that novel medical devices and prostheses will play a significant role in improving the quality of health care for patients in the United States and in other countries.

Papers included in this topic involve developing processing-structure-property relationships for metals, ceramics, and polymers used in biomedical devices. Pruitt and Furmanski review the structure-property relationships that have been developed for polymers used in several types of implants, including intravascular catheters, breast implants, and total hip replacements. Biomedical applications for metallic materials, including highly elastic and corrosion resistant bulk metallic glasses (Schroers et al.) at one extreme and biodegradable magnesium alloys (Brar et al.) at the other extreme, are also discussed. Miller et al. review the use of laser micromachining for developing novel medical devices. Research on novel chitosan-nanohydroxyapatite scaffolds for bone tissue engineering is presented by Thein-Han and Misra. Nychka describes how mechanical and thermal processing of bioactive glass 45S5 can affect the microstructure and bioactivity of this material. These papers reflect the breadth of current work on biomedical materials and devices.

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