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D. Shi (Ed.)

Biomedical Devices and Their Applications

With 89 Figures and 9 Tables

Springer

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Preface

Biomedical devices that contact with blood or tissue represent a wide range of products. Depending on their potential harm to a body, medical devices are categorized according to the degree, so their safety can be assured. All biomaterials are by definition designed to contact with a body for a certain period of time. The nature of the body contact, as well as the duration a material contacts with the body may initiate unwanted biological responses. In comparison with invasive devices (like catheters and medical implants contact directly with tissue or with the circulating blood) non-invasive devices (like wound-dressings and contact lenses contact with the skin, the sclera, and the mucosa or with open wounds) have a lesser risk of hurting a patient.

When blood contacts with a foreign material, plasma proteins become absorpted to the surface within a few seconds. The reactions that follow, the so-called intrinsic pathway lead to the formation of fibrin and activation of platelets and white blood cells, result in blood clot formation. The longer the contact time, the higher the chance the coagulation system becomes activated. Therefore, for a long time engineers of blood pumps focussed only on optimizing the shape of the inside of the pump in their efforts to prevent low-flow conditions and stagnating flow zones. With the introduction of the electromechanical driven pump systems and the clinical demand of chronically implantable heart assist devices, the external shape of the device and the kind of materials used in the pump housing became as important. After pump insertion, the (continuously moving) lungs surround the pump and can easily become traumatized. Traumatized lungs may collapse (atelectasis), get infected (pneumonia) or can leak air (pneumothorax). Also, the material of the pump housing must prevent that the lungs get adhered to the material.

In the artificial larynx, shape and used materials are as important. In this kind of biomaterials application, shape is defined not only by the anatomical dimensions the device should fit in but also by the surgical insertion technique that must be applied to position the device, as well as by the physical and psychological acceptation of a device by a patient. A tissue connector placed between the trachea and esophagus, for fixation of the tracheal-esophageal shunt valve, needs a certain size and shape to ease surgical positioning. The tracheo-esophagal shunt valve itself, needs a certain size and shape to allow the positioning of a voice producing element in its inside. When the tissue connector is too small, the voice-prosthesis will not fit. When the connector it is too large, the esophagus becomes partially compressed, resulting in feelings of discomfort or swallowing disorders. Whereas in the use of implantable blood pumps tissue ingrowth must be prevented, in tissue connectors a tight tissue ingrowth is just wanted. Based on its intentional use, surfaces of the different devices require different surface characteristics. Finally size and shape of a visible device like the tracheo-stoma valve, a device that allows a patient hands-free closing of the tracheostoma, are important in a different way. A large valve positioned on top of the tracheostoma opening may function better than a small valve. However, the large valve will attract more attention fromthird person and therefore makes patients that have to wear these devices feel uncomfortable. The shape and selected materials also depend on preferred manufacturing techniques and the physical properties of the material. Many materials that possess the optimal physical properties, often cannot be used because for a specific application because of their improper biocompatibility characteristics. Materials, size and shape all play a crucial role in the biomaterials applications described in this chapter. The given overview is not complete. During the processing of the book various new applications will have been developed and tested. The latest developments can be traced in the various scientific journals that have been enlisted in the references or in various medical textbooks.

We intend this book to provide up-to-date information in the field of biomedical devices and their applications. The focus of the book is the basic concepts and recent developments in this field. The book will cover a broad spectrum of the topics that include drug delivery, protein electrophoresis techniques, medical devices, and the environment that mimics estrogens. Most of the critical issues are addressed in a straightforward manner so that nonspecialists and university students can benefit from the information. Furthermore, many novel concepts in biomaterials are explained in the light of current theories. An important aspect of the book lies in its wide coverage of biomedical applications.

The book is written for a large readership including university students and researchers from diverse backgrounds such as orthopedics, biochemistry, bioengineering, materials science, tissue engineering, and other related medical fields. Both undergraduate and graduate students will find the book a valuable reference not only on biomedical devices, but also on some important biotechnology topics. Thus, it can serve as a comprehensive introduction for researchers in biomedical science and engineering in general, and can also be used as a graduate-level text in related areas.

Chapter 1 presents the most recent experimental results on medical devices. In this chapter techniques that can be used to decrease the time of development of medical devices are discussed: multidisciplinary approaches in conducting research, medical technology assessment, constructive medical technology assessment and concurrent engineering techniques. Also the use of computer-supported group-decision techniques based on the analytic hierarchy process is illustrated. Finally three research areas are highlighted: mechanical circulatory assist devices, devices that contribute to voice rehabilitation for laryngectomised patients and extendable orthopaedic endoprostheses. The advances that have been made during the past decades will be discussed.

Chapters 2 and 3 are devoted bo biomaterials in drug delivery. They give details of materials preparation, experimental procedures, and novel methods for special ways of drug delivery. A major research thrust in the pharmaceutical and chemical industry is the development of controlled release systems for drugs and bioactive agents. Many of these delivery systems in use and under development consist of drugs dispersed within a polymeric carriers. These carriers are designed to release the drugs in a controlled fashion for times ranging from minuted to years. The emphasis on the development of novel controlled-release devices is in response to the discovery and production of new drugs in today's expanding biotechnology fields. However, due to the cost of production, it is imperative to develop new methods to deliver these drugs in the most effective manner. A major limitation in the pharmaceutical industry is that the current methods for drug delivery, such as injections, tablets and sprays, may not be the most effective method of delivery for certain drugs and as a result, multiple administrations may be required to keep the concentration of the drug in the blood at a therapeutically effective level for reasonable periods of time. Typically with these types of administration, the drug levels rise to a maximum and fall off to a minimum value, at which time another dosing of the drug is required. This is problematic for drugs with a narrow range of therapeutic concentration as the drug levels will continually rise above the effective range into the toxic region during which time increased adverse side effects are likely, and then fall below the minimum effective concentration, during which time the drug is not effective. The goal of

Chapter 3 is to give a general review of the types of drug delivery systems available and discuss the clinical application of these systems to treat localized disease states.

Chapter 4 should be of great interest to researchers studying protein electrophoresis techniques. This chapter reviews the fundamental concepts in protein electrophoresis from the standpoint of the biomaterials scientist. It describes an array of experimental techniques that, while quite familiar to the molecular cell biologists, are usually novel to the biomaterials scientists. It also deals with the author's applications of some of the techniques of protein electrophoresis. The purpose of this chapter is to illustrate by example how one biomaterials researcher sorted through the electrophoresis "palette" and made experimental design decisions.

Chapter 5 deals with chemicals in the environment which mimic estrogens. Estrogens are steroid hormones that are produced by the female gonads and have widespread effects throughout the body. Males also produce small amounts of estrogens by conversion (aromatization) of the male sex hormone testosterone and are sensitive to estrogenic effects. The primary organs that are targeted by estrogens are components of the neuroendocrine-reproductive axis and include the hypothalamus (ventral part of the midbrain), pituitary gland (the master endocrine gland), and the reproductive tract, e.g. uterus and vagina in females and prostate in the male. Other tissues, including mammary glands, cardiovascular system, bone and skin, are also responsive to estrogens, underscoring the profound capability of these compounds to influence most bodily functions.

All authors are prominent researchers and have extensive research experience in diverse fields of biomedical science and engineering. We are grateful to them for these important contributions from which, we trust, many readers shall benefit significantly.

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