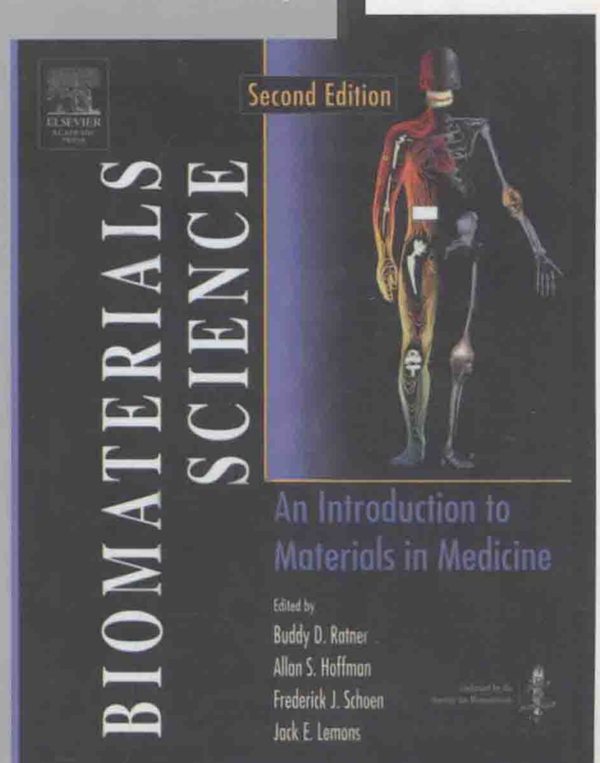
国外大学优秀教材——材料科学与工程系列（影印版）

Buddy D. Ratner, Allan S. Hoffman, Frederick J. Schoen
Jack E. Lemons

生物材料科学
医用材料导论（第2版）

Biomaterials Science:
An Introduction to Materials in Medicine
(Second Edition)



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本书是为满足国内工科院校材料专业学生了解和掌握生物材料及在医学中的应用而引进出版的。

这本书介绍了生物材料和生物技术领域中最新的信息，包括生物材料的加工、结构特征和相关的特性，以及生物合成、生物兼容、生化玻璃和组织工程。除了根据当前的理论解释了很多生物材料领域的概念，还介绍了很多生物材料和生物工艺学的实际应用。

本书内容介绍大多浅显易懂，适合于不同专业背景的读者群，包括整形外科、生物化学、生物工程、材料科学、组织工程学和其他相关医学领域的大学生和研究人员，非专业人士等都可从中受益。它不仅可作为本科生和研究生学习生物材料的教材和教学参考书，而且也可作为研究组织工程学相关课题的参考书。

本书是由数十位生物材料、生物工程和医药学领域的专家共同撰稿编写，因而内容十分广泛。许多作者还是生物材料方面的最前沿的研究者，所以该书包含丰富的最新科研成果。

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英文影印版序

生物材料科学是从经典的材料科学里，根据其在生物以及医学中的应用衍生出来的一门比较新的学科。它的特点是，一方面仍然基于材料科学和工程的研究和发展，另一方面侧重生物医用材料的特点。比如，在工业应用中，我们一般要求材料有尽可能高的机械强度、硬度和杨氏模量。但在生物材料中，我们却要按照特殊的临床应用而考虑相对的机械行为。一个典型的例子是人工骨头的再植，用一种称为羟基磷灰石的生物陶瓷，可以成功地替代人体内的硬组织，如骨骼。临床要求的生物陶瓷具有和人骨相似的密度、强度和硬度。这种与生物体的互容性是生物材料制备的重要特点之一。除此之外，生物材料的另一个重要的特点是生物活性。生物材料的体内移植要求人工材料在与生物体接触时形成一层具有生物活性的中间层。这种材料的生物活性能够诱发人工材料向人体的硬组织转化，并最终完全被人体骨骼吸收。所以，在生物材料的研制过程中就增加了一项非常重要的检测系统：材料在生物体内与体外环境下的生物活性度测量。它的重要性等同于普通工程材料的机械强度的测试。

这本书向读者提供生物材料和生物技术领域中最新的信息。此书重点介绍生物材料和生物工艺学的基本概念和目前的进展。关于生物材料，此书介绍了生物材料的加工、结构特征和相关的特性，包括生物合成、生物兼容、生化玻璃和组织工程。内容介绍大多浅显易懂，非专业人士、大学生都可从中受益。书中根据当前的理论解释了很多生物材料领域的概念。重要的是，此书介绍了很多生物材料和生物工艺学的实际应用。此书不仅结合生物材料介绍了现代医学尖端的技术，而且介绍了材料在医学领域独特的应用。

此书适合于不同专业背景的读者群，包括整形外科、生物化学、生物工程、材料科学、组织工程学和其他相关医学领域的大学生和研究人员。它不仅可作为本科生和研究生学习生物材料的参考书，而且也可作为研究组织工程学相关课题（包括生物结构、复杂系统的相位图表、硬组织弥补、新生物材料加工方法、电脑模拟和新材料性能确定技术）的参考书。此书总体上介绍了生物材料科学和工程，可作为相关领域研究生的教材使用。

此书的第一部分分为两章，主要是较详细的材料科学的一般介绍，针对在此领域没有受过任何训练的人。第 1 章清楚地解释了一般材料的概念，这是生物材料合成领域的基础。高科技含量的、先进的、结构上复杂的新材料促使人们将研究方向从传统工程材料迅速转移到材料科学。医疗工程，也包含在先进技术之列，当然也需要有高科技材料的支持。所有的细节已在生物材料的定义和加工中描述。第 2 章主要介绍材料的分类，包括一般的工程材料。

第二部分共 6 章，侧重生物、生化和医药学。第 3 章主要是生物学的一些基本概念，比如细胞和组织等。第 4 章则描述受体反应和生物材料的生物行为。在第 5 章，作者首先介绍了生物兼容的概念及重要的生物医学问题，详细讨论了主要的反应和副作用、 材料对生理系统的反应，以阐明蛋白质吸附、细胞支持、血液成分和组织材料之间的交互作用，也介绍了影响材料兼容性的关键因素的本质和基本理论。这既是为后续的阐述提供信息源，也有助于更好地理解蛋白质、细胞和材料之间交互的特征。在第 5 章，评定生物兼容性最常用方法就是综合所有因素。外来材料依赖对蛋白质的吸附而与本身生理循环相吻合。因此，材料生物系统表面与蛋白质吸收的问题、材料表面特性怎样影响蛋白质吸收，以及吸收的蛋白质怎样影响后面的细胞支持等问题都是相互关连的。第 6 章主要介绍生物材料(高分子与陶瓷)在生物环境下的分解、腐蚀和化学变化。这是生物材料体内移植的重要一环，因为必须清楚地了解材料在再植后与活体的结合以及其结构与性能的变化。第 7 章介绍生物材料在医学、生物学和人造器官等领域的应用，讲述了生物技术最新的发展，包括人造血、人造器官、整形、缝合、牙齿再植、骨科再植、替换、粘结剂、烧伤与皮肤再造、生物电极、生物传感器、替换材料，等等。第 7 章进而详细介绍了药品运送中材料的准备、步骤和独特方法。在药物和生物制药工业中，主要的研究方向是药品和生化药品经销商有控制的发放系统。现在正在使用的和正在开发的药品运输系统都是将药品分散在聚酯容器内，这些容器可以控制药品的发放，时间从分钟到年。开发一种新的控制发放方式，重点是针对在今天的生物科技发展领域中，新的药品的发现和制造的需要。

本书的最后一部分(第三部分)是关于生物材料的实际临床应用。第 9 章为再植、医疗器件和最新医疗器械

的实验结果。比如消毒设备、人工心脏阀门、牙齿搭桥等技术。最后一章着重介绍医用材料的新产品和医用材料的标准。

本书的特点是各章节由数十位生物材料、生物工程和医药学领域的专家共同撰稿，因而内容十分广泛。大多作者还是生物材料方面的最前沿的研究者，所以该书涉及丰富的最新科研成果。本书的第一、二部分为生物材料的基础部分，可在一个学期内完成(按美国学制的三个学分课时)。第三部分可以作为研究生和科研人员的参考材料。本书可以作为材料科学系、生物工程系，以及相关学科的本科生生物材料课的教科书，也可以作为研究生的初级课程。

生物材料在中国也是一门新兴学科。本书可以为国内的教师和学生提供一本英文原版的参考书，也可以直接用于生物材料课的教科书，而且还可以给读者提供生物材料和临床应用一些实时的、有用的信息。衷心地希望本书的影印本能够在中国的大专院校、科研单位受到欢迎和重视，并在材料学、生物学、医药学的综合研究中起到重要的作用。

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美国俄亥俄州立辛辛那提大学工学院
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2006 年

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PREFACE

The interest and excitement in the field of biomaterials has been validated by sales of the first edition of this textbook: more than 10,000 copies sold. Also, the first edition has been widely adopted for classroom use throughout the world. The concept behind the first edition was that a balanced textbook on the subject of biomaterials science was needed. As with the first edition, the intended audience is multidisciplinary: students of medicine, dentistry, veterinary science, engineering, materials science, chemistry, physics, and biology (not an all-inclusive list) can find essential introductory material to permit them a reasonably knowledgeable immersion into the key professional issues in biomaterials science.

Textbooks by single authors too strongly emphasize their own areas of expertise and ignore other important subjects. Articles from the literature are commonly used in the classroom setting, but these are difficult to weave into a cohesive curriculum. Handout materials from professors are often graphically unsophisticated, and again, slanted to the specific interests of the individual. In *Biomaterials Science: An Introduction to Materials in Medicine*, 2nd edition, we the editors (whose 140+ person-year expertise spans materials science, pathology, and hard- and soft-tissue applications), endeavor to present a balanced perspective on an evolving discipline by integrating the experience of many leaders in the biomaterials field. Balanced presentation means appropriate representation of hard biomaterials and soft biomaterials; of orthopedic ideas, cardiovascular concepts, ophthalmologic ideas, and dental issues; a balance of fundamental biological concepts, materials science background, medical/clinical concerns, and government/societal issues; and coverage of biomaterials past, present, and future. In this way, we hope that the reader can visualize the scope of the field, absorb the unifying principles common to all materials in contact with biological systems, and gain a solid appreciation for the special significance of the word *biomaterial* as well as the rapid and exciting evolution and expansion of biomaterials science and its applications in medicine.

More than 108 biomaterials professionals from academia, industry, and government have contributed to this work. Certainly, such a distinguished group of authors provides the needed balance and perspective. However, such a diverse group of authors also leads to unique complexities in a project of this type. Do the various writing styles clash? Does the presentation of material, particularly controversial material, result in one chapter contradicting another? Even with so many authors, all subjects relevant to biomaterials cannot be addressed—subjects should be included and which left out? How should such a project be refereed to ensure scientific quality, pedagogical effectiveness, and the balance we strive for?

These are some of the issues the editors grappled with over the years from conception of the second edition in 1998 to publication in 2004. From this complex editorial process, a unique volume has evolved that the editors feel can make an ongoing contribution to the development of the biomaterials field. An educational tool has been synthesized here directing those new to biomaterials, be they engineers, physicians, materials scientists, or biochemists, on a path to appreciating the scope, complexity, basic principles, and importance of this enterprise.

What's new in *Biomaterials Science: An Introduction to Materials in Medicine*, 2nd edition? All chapters have been updated and rewritten, most extensively. A large number of new chapters have been added. The curricular organization for teaching the fundamental cell biology, molecular biology, tissue organization, and histology, key subjects that support the modern biomaterials research endeavor, has been restructured. A new, three-chapter section on tissue engineering has been added. The total content and size of the book have been significantly increased. A Web site has been coupled to the book offering supplemental material including surgery movies and homework problems. The graphics design has been upgraded. You have in your hands a new book that can address biomaterials in the 21st century.

Acknowledgments and thanks are in order. First, let us address the Society For Biomaterials that served as sponsor and inspiration for this book. The Society For Biomaterials is a model of "scientific cultural diversity" with engineers, physicians, scientists, veterinarians, industrialists, inventors, regulators, attorneys, educators, and ethicists all participating in an endeavor that is intellectually exciting, humanitarian, and profitable. As with the first edition, all royalties from this volume are being returned to the Society For Biomaterials to further education and professional advancement related

to biomaterials. For further information on the Society For Biomaterials, visit the SFB Web site (http://www.biomaterials.org/).

Next, we offer a special thanks to those who enthusiastically invested time, energy, experience, and intelligence to author the chapters that are this textbook. The many scientists, physicians, and engineers who contributed their expertise and perspectives are clearly the backbone of this work and they deserve high praise—their efforts will strongly affect the education of the next generation of biomaterials scientists. Also, some reviewers assisted the editors in carefully refereeing chapters. We thank Kip Hauch, Colleen Irvin, Gayle Winters, Tom Horbett, and Steven Slack.

The support, encouragement, organizational skills, and experience of the staff, first at Academic Press and now at Elsevier Publishers, have led this second edition from vision to volume. Thank you, Elsevier, for this contribution to the field of biomaterials.

Finally, a unique person at the University of Washington has contributed to the assembly and production aspects of this work. We offer special thanks to Elizabeth Sharpe for her superb editorial/organizational efforts. This volume, deep down, has Elizabeth's intelligent and quality-oriented stamp all over it. Clearly, she cares!

The biomaterial field has always been ripe with opportunities, stimulation, compassion, and intellectual ideas. As a field we look to the horizons where the new ideas from science, technology, and medicine arise. We aim to improve the quality of life for millions through biomaterials-based, improved medical devices and tissue engineering. We editors hope the biomaterials overview you now hold will stimulate you as much as it has us.

Buddy D. Ratner
Allan S. Hoffman
Jack E. Lemons
Frederick J. Schoen
May 2004

CONTENTS

Biomaterials Science: A Multidisciplinary Endeavor

BUDDY D. RATNER, ALLAN S. HOFFMAN, FREDERICK J. SCHOEN, JACK E. LEMONS

BIOMATERIALS AND BIOMATERIALS SCIENCE

Biomaterials Science: An Introduction to Materials in Medicine addresses the properties and applications of materials (synthetic and natural) that are used in contact with biological systems. These materials are commonly called biomaterials. Biomaterials, an exciting field with steady, strong growth over its approximately half century of existence, encompasses aspects of medicine, biology, chemistry, and materials science. It sits on a foundation of engineering principles. There is also a compelling human side to the therapeutic and diagnostic application of biomaterials. This textbook aims to (1) introduce these diverse elements, particularly focusing on their interrelationships rather than differences and (2) systematize the subject into a cohesive curriculum.

We title this textbook *Biomaterials Science: An Introduction to Materials in Medicine* to reflect, first, that the book highlights the scientific and engineering fundamentals behind biomaterials and their applications, and second, that this volume contains sufficient background material to guide the reader to a fair appreciation of the field of biomaterials. Furthermore, every chapter in this textbook can serve as a portal to an extensive contemporary literature. The magnitude of the biomaterials endeavor, its interdisciplinary scope, and examples of biomaterials applications will be revealed in this introductory chapter and throughout the book.

Although biomaterials are primarily used for medical applications (the focus of this text), they are also used to grow cells in culture, to assay for blood proteins in the clinical laboratory, in equipment for processing biomolecules for biotechnological applications, for implants to regulate fertility in cattle, in diagnostic gene arrays, in the aquaculture of oysters, and for investigational cell-silicon "biochips." How do we reconcile these diverse uses of materials into one field? The common thread is the interaction between biological systems and synthetic or modified natural materials.

In medical applications, biomaterials are rarely used as isolated materials but are more commonly integrated into devices or implants. Although this is a text on materials, it will quickly become apparent that the subject cannot be explored without also considering biomedical devices and the biological response to them. Indeed, both the effect of the materials/device on the recipient and that of the host tissues on the device can lead to device failure. Furthermore, a biomaterial must always be considered in the context of its final fabricated, sterilized form. For example, when a polyurethane elastomer is cast from a solvent onto a mold to form the pump bladder of a heart assist device, it can elicit different blood reactions than when injection molding is used to form the same device. A hemodialysis system serving as an artificial kidney requires materials that must function in contact with a patient's blood and also exhibit appropriate membrane permeability and mass transport characteristics. It also must employ mechanical and electronic systems to pump blood and control flow rates.

Because of space limitations and the materials focus of this work, many aspects of device design are not addressed in this book. Consider the example of the hemodialysis system. The focus here is on membrane materials and their biocompatibility; there is little coverage of mass transport through membranes, the burst strength of membranes, flow systems, and monitoring electronics. Other books and articles cover these topics in detail.

The words "biomaterial" and "biocompatibility" have already been used in this introduction without formal definition. A few definitions and descriptions are in order and will be expanded upon in this and subsequent chapters.

A definition of "biomaterial" endorsed by a consensus of experts in the field, is:

> A biomaterial is a nonviable material used in a medical device, intended to interact with biological systems (Williams, 1987).

If the word "medical" is removed, this definition becomes broader and can encompass the wide range of applications suggested above.

If the word "nonviable" is removed, the definition becomes even more general and can address many new tissue-engineering and hybrid artificial organ applications where living cells are used.

"Biomaterials science" is the physical and biological study of materials and their interaction with the biological environment. Traditionally, the most intense development and investigation have been directed toward biomaterials synthesis, optimization, characterization, testing, and the biology of host–material interactions. Most biomaterials introduce a non-specific, stereotyped biological reaction. Considerable current effort is directed toward the development of engineered surfaces that could elicit rapid and highly precise reactions with cells and proteins, tailored to a specific application.

Indeed, a complementary definition essential for understanding the goal (i.e., specific end applications) of biomaterials science is that of "biocompatibility."

> Biocompatibility is the ability of a material to perform with an appropriate host response in a specific application (Williams, 1987).

Examples of "appropriate host responses" include the resistance to blood clotting, resistance to bacterial colonization, and normal, uncomplicated healing. Examples of specific applications include a hemodialysis membrane, a urinary catheter, or a hip-joint replacement prosthesis. Note that the hemodialysis membrane might be in contact with the patient's blood for 3 hours, the catheter may be inserted for a week, and the hip joint may be in place for the life of the patient.

This general concept of biocompatilility has been extended recently in the broad approach called "tissue engineering" in which *in-vitro* and *in-vivo* pathophysiological processes are harnessed by careful selection of cells, materials, and metabolic and biomechanical conditions to regenerate functional tissues.

Thus, in these definitions and discussion, we are introduced to considerations that set biomaterials apart from most materials explored in materials science. Table 1 lists a few applications for synthetic materials in the body. It includes many materials that are often classified as "biomaterials." Note that metals, ceramics, polymers, glasses, carbons, and composite materials are listed. Such materials are used as molded or machined parts, coatings, fibers, films, foams and fabrics. Table 2 presents estimates of the numbers of medical devices containing biomaterials that are implanted in humans each year and the size of the commercial market for biomaterials and medical devices.

Five examples of applications of biomaterials now follow to illustrate important ideas. The specific devices discussed were chosen because they are widely used in humans with good success. However, key problems with these biomaterial devices are also highlighted. Each of these examples is discussed in detail in later chapters.

TABLE 1 Some Applications of Synthetic Materials and Modified Natural Materials in Medicine

Application	Types of materials
Skeletal system	
Joint replacements (hip, knee)	Titanium, Ti–Al–V alloy, stainless steel, polyethylene
Bone plate for fracture fixation	Stainless steel, cobalt–chromium alloy
Bone cement	Poly(methyl methacrylate)
Bony defect repair	Hydroxylapatite
Artificial tendon and ligament	Teflon, Dacron
Dental implant for tooth fixation	Titanium, Ti–Al–V alloy, stainless steel, polyethylene
	Titanium, alumina, calcium phosphate
Cardiovascular system	
Blood vessel prosthesis	Dacron, Teflon, polyurethane
Heart valve	Reprocessed tissue, stainless steel, carbon
Catheter	Silicone rubber, Teflon, polyurethane
Organs	
Artificial heart	Polyurethane
Skin repair template	Silicone–collagen composite
Artificial kidney (hemodialyzer)	Cellulose, polyacrylonitrile
Heart–lung machine	Silicone rubber
Senses	
Cochlear replacement	Platinum electrodes
Intraocular lens	Poly(methyl methacrylate), silicone rubber, hydrogel
Contact lens	Silicone-acrylate, hydrogel
Corneal bandage	Collagen, hydrogel

EXAMPLES OF BIOMATERIALS APPLICATIONS

Heart Valve Prostheses

Diseases of the heart valves often make surgical repair or replacement necessary. Heart valves open and close over 40 million times a year and they can accumulate damage sufficient to require replacement in many individuals. More than 80,000 replacement valves are implanted each year in the United States because of acquired damage to the natural valve and congenital heart anomalies. There are many types of heart valve prostheses and they are fabricated from carbons, metals, elastomers, plastics, fabrics, and animal or human tissues chemically pretreated to reduce their immunologic reactivity and to enhance durability. Figure 1 shows a bileaflet tilting-disk mechanical heart valve, one of the most widely used designs. Other types of heart valves are made of chemically treated pig valve or cow pericardial tissue. Generally, almost as soon as the valve is implanted, cardiac function is restored to near normal levels and the patient shows rapid improvement. In spite of the overall success seen with replacement heart valves, there are problems that may differ with different types of valves; they include induction of blood clots, degeneration of tissue, mechanical failure, and infection. Heart valve substitutes are discussed in Chapter 7.3.

Artificial Hip Joints

The human hip joint is subjected to high levels of mechanical stress and receives considerable abuse in the course of