SERIES PREFACE

Biomaterials science is concerned with surgical implants and medical devices and their interaction with the tissues they contact. Their study, therefore, includes not only the properties of the materials from which they are made, but also those of the tissues which will accept them. Metals, ceramics, and macromolecules are the artifacts. Bone tendons, skin, nerves, and muscles are among the tissues studied. Prosthetic materials, implants, dental materials, dressings, extra corporeal devices, encapsulants, and orthoses are included among the applications.

It is not only the materials *per se* which interest the biomaterials scientist, but also the interactions in vivo, because it is at the interface between implant and tissues that the success of a procedure will be decided. This approach has led to the concept of a more aggressive role for biomaterials in the actual treatment of disease. Macromolecular drug delivery systems are receiving considerable attention, especially those with the capacity for targeting specific sites in the body. Sensing and control of body processes is a logical extension of this. There is much to be done before these newer developments become established.

The science of biomaterials has grown and developed over the last few years to become an accepted discipline of study. It is opportune, therefore, to systematize the study of biomaterials in order to improve their application in medical science, since that is the end point of all studies. That is the aim of this series of books on *Structure-Property Relationships in Biomaterials*. Knowledge of structure and the influence on properties is fundamental to any materials science study; it is a more complex problem to obtain the knowledge from tissue materials, as the living organism has a great capacity for change and adaptation in response to a stimulus. The stimulus may be chemical, electrical, or mechanical. The biomaterials scientist endeavors to identify and to use these stimuli and responses to improve the in vivo acceptability of the materials.

Many institutions and agencies have promoted the science of biomaterials. Societies now exist for this purpose. The Biological Engineering Society (U.K.) founded in 1960 formed a Biomaterials Group in 1974. In the same year the Society for Biomaterials was founded in the U.S. The European Society for Biomaterials (1976) was followed by Canadian and Japanese Societies (1979). All societies play a major role in disseminating knowledge through conferences and publications.

This series is complementary to these society activities. It is hoped that it will not only provide a basis of knowledge, but also its own stimulus for further progress. The series is inevitably selective. In part this is due to the editors' choice, in part to the availability of authors. The editors wish to thank those who fulfilled their agreements. Without them this series would not have been possible.

G. W. Hastings
Series-Editor-in-Chief

Library of Congress Cataloging in Publication
Main entry under title:

Metal and ceramic biomaterials.

(CRC series in structure-property relationship of biomaterials)
Bibliography: p.
Includes index.
Contents: v. 1. Structure — v. 2. Strength and surface related behavior.
1. Ceramics in medicine. 2. Metals in surgery.
I. Ducheyne, Paul. II. Hastings, Garth W. III. Series.
R857.C4M47 1984 610'.28 83-15018
ISBN 0-8493-6261-X (v. 1)
ISBN 0-8493-6262-8 (v. 2)

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Direct all inquiries to CRC Press, Inc., 2000 Corporate Blvd., N.W., Boca Raton, Florida, 33431.

International Standard Book Number 0-8493-6261-X (v. 1)
International Standard Book Number 0-8493-6262-8 (v. 2)

Library of Congress Card Number 83-15018
Printed in the United States

VOLUME PREFACE

The understanding of the in vivo performance of synthetic materials is largely dependent upon a profound knowledge of the properties of the materials in question. Analogous to materials science in its broadest sense, the basis for biomaterials science is formed by microstructural theory. It is, therefore, that in this series on structure-property relationships in biomaterials a substantial part is devoted to the analysis of the basic properties of the various synthetic biomaterials. In addition, the effect of microstructural aspects on properties is considered at great length.

The study of metallic and ceramic biomaterials is intimately interlinked because the microstructural aspects and the research methodologies are founded on the same basis. This is demonstrated first in the chapter of Dr. Heimke, who discusses the structure of metals and ceramics, and second, in the chapter of Drs. Arkens and Ducheyne who analyze some of the more recent surface analytical techniques. Those techniques have been equally employed for metals and ceramics. Two subsequent chapters deal with the influence actual manufacturing has on both the microstructure and the properties of either metals (authored by Dr. Pilliar) or ceramics (written by Dr. Doremus).

The second volume of *Metal and Ceramic Biomaterials* builds upon the foundation laid in the first volume by analyzing various properties and by discussing these in light of the microstructural theory outlined in the first volume. Strength related behavior is treated first. Dr. Semlitsch surveys the mechanical properties of implant metals used for artificial hip joints. Drs. Soltesz and Richter describe the mechanical behavior of various bioceramic materials. A third chapter relating mechanical behavior to microstructural detail deals with the shape memory alloys which have considerable potential as biomaterials. In addition to the description of strength aspects, Dr. Kousbroek summarizes the various biocompatibility studies on these metals. These studies are, quite naturally, related to the surface properties which are presented in the second part of Volume II. Drs. Lycett and Hughes survey the corrosion behavior of metals. Drs. Van Raemdonck, Ducheyne, and De Meester analyze the bioreactivity of a typical class of ceramics, viz. calcium phosphate. An effort is made to relate the bioreactivity to the microstructural chemical and physical detail. Drs. Dumbleton and Higham analyze the field of surface coatings and point to the great potential for the field of biomaterials of many existing technologies.

The editors have enjoyed collaborating with the contributors to these volumes. We owe great appreciation and gratitude to those who eventually made it possible to have these books produced. Without each single contributor it would have been hard, if not impossible to present the information on some of the more important properties of biomaterials. Due thanks are also expressed to Rita De Laet who diligently took care of the secretarial work.

Last but not least, thanks go to our families. We may think that without their delightful distraction we could have finished these books sooner. However, they rightfully claim that without them we would never have had the perseverance needed to edit this series.

Paul Ducheyne
Garth Hastings

Metal and Ceramic Biomaterials

Structure

Strength and Surface

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CRC Series in Structure-Property Relationship of Biomaterials
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CRC Press, Inc.
Boca Raton, Florida

Metal and Ceramic Biomaterials

Volume I
Structure

THE EDITORS

Garth W. Hastings, D.Sc., Ph.D., C.Chem., F.R.S.C., is a graduate of the University of Birmingham, England with a B.Sc. in Chemistry (1953) and a Ph.D. (1956) for a thesis on ultrasonic degradation of polymers. After working for the Ministry of Aviation he became Senior Lecturer in Polymer Science at the University of New South Wales, Sydney, Australia (1961 to 1972). During this time he was Visiting Professor at Twente Technological University, Enschede, The Netherlands (1968-69), advising on their program in biomedical engineering. While in Australia, he became associated with Bernard Bloch, F.R.C.S., Orthopedic Surgeon, Sydney Hospital, and began a fruitful collaboration in the uses of plastics materials in surgery.

In 1972 he returned to England as Principal Lecturer in the Biomedical Engineering Unit of the North Staffordshire Polytechnic and the (now) North Staffordshire Health District with responsibility for research. With a particular interest in biomaterials research his own work has encompassed carbon fiber composites for surgical implants, adhesives, bioceramics, prosthesis performance in vivo, and electrical phenomena in bone. He is a member of British and International Standards Committees dealing with surgical implants and of other professional and scientific bodies, including Companion Fellow of the British Orthopaedic Association and Editor of the international Journal *Biomaterials*. He was elected President of the Biological Engineering Society in the U.K. (B.E.S.) in October, 1982. He was awarded a D.Sc. from the University of Birmingham in 1980 for a thesis in the field of biomedical applications of polymers. He has recently been appointed Acting Head of the department.

Paul Ducheyne, Ph.D. obtained the degree of metallurgical engineering from the Katholieke Universiteit Leuven, Belgium, in 1972. Subsequently he worked at the same university towards a Ph.D. on the thesis "Metallic Orthopaedic Implants with a Porous Coating" (1976). He stayed one year at the University of Florida as an International Postdoctoral N.I.H. Fellow and a CRB Honorary Fellow of the Belgian-American Educational Foundation. Thereafter he returned to the Katholieke Universiteit Leuven. There he was a lecturer and a research associate, affiliated with the National Foundation for Scientific Research of Belgium (NFWO). He recently joined the University of Pennsylvania, Philadelphia, as an Associate Professor of Biomedical Engineering and Orthopedic Surgery Research.

Dr. Ducheyne has published in major international journals on mechanical properties and design of prostheses, porous materials, bioglass, hydroxyapatite, and microstructural methods of analysis of biomedical materials. He is member of the editorial board of *Biomaterials, Journal of the Engineering Alumni of the University of Leuven, Journal Biomedical Materials Research,* and *Journal Biomechanics and Comtex System for Biomechanics and Bioengineering.*

He became active in various societies and institutions and has held or is holding the positions of Chairman-Founder of the "Biomedical Engineering and Health Care Group" of the Belgian Engineering Society, Secretary of the European Society for Biomaterials and member of the Board of Directors of Meditek (Belgian Institution to promote biomedical industrial activity).

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Chapter 1

THE STRUCTURE, PROPERTIES, AND FUNCTIONAL BEHAVIOR OF BIOMATERIALS

P. Ducheyne and G. W. Hastings

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I. THE SCIENCE OF BIOMATERIALS

The science of biomaterials has previously been defined as the science dealing with the development, evaluation, and application of special substances to meet specifications for research and practice in biology and medicine, with particular reference to materials which come into contact with tissue. In order to be more explicit than this general definition, it is useful to consider the description of bioengineering, formulated by the National Academy of Engineering, Washington, D.C., in 1971:

1. The *application* of bioengineering concepts and technology to scientific inquiries into biological phenomena as a basis for advancing the understanding of biological systems and medical practices
2. The *utilization* of engineering concepts and technology in the development of instrumentation, materials, diagnostic and therapeutic devices, artificial organs, and other constructs relevant to applications in biology and medicine
3. The application of engineering concepts, methodology, and technology to the improvement of health service delivery systems in the broad context of interrelated institutions (hospitals, clinics, governmental units, universities, industries, etc.) as well as within the specific confines of individual components of the health care system

In its broadest sense, the science of biomaterials studies only biological materials (as described in the listing above) (1) and manmade materials (2) and is clearly not involved in the activities described in (3).

As an example we may consider the medical discipline of orthopedic surgery. An important area of study is the development and improvement of temporary and permanent implants made of metals, polymers, or ceramics. This study relates to the utilization of technology. A further area of intensive research is concerned with biological materials. The mechanical and elastic properties of bones and bone tissue are determined. Subsequently these properties are correlated with the function of the structures or tissues. This study relates to the application of engineering concepts to biological phenomena. The understanding of how tissues and body structures behave is largely aided by using straightforward engineering test methods such as compression, tension, and torsion tests. The knowledge of the functional behavior of body tissues is a prerequisite for the development of implant devices and materials. In other words, the knowledge is also essential to improve upon those surgical procedures where temporary or permanent devices are used to aid or restore the function of the diseased or weakened skeletal part.

The above example from orthopedics based on experimental and clinical evidence can be easily generalized to one of the most fundamental aspects of biomaterials science: interactions between the implant materials and designs and the biological host do occur. As such, the interactions are an integral part of any biomaterials study, once the separate foreign and host systems are sufficiently characterized.

II. THE INTERDISCIPLINARITY OF BIOMATERIALS

In the second half of the 15th century it was possible for a man like Leonardo da Vinci to cover comprehensively all existing knowledge of science and philosophy. This remained so during the Renaissance and also later on until the end of the last century. It was not uncommon at all that creative and inventive individuals were active in different fields of endeavor.

Another example may be provided by the person of Thomas Young, who is remembered today mainly for his work on the wave theory of light and because the modulus of elasticity of materials is named after him. During his lifetime, he was not only a professor of physics, but also a practicing physician. In addition, he also wrote authoritatively on blood circulation, including wave propagation in arteries.

Today, the amount of knowledge available is so vast and the rate of increase so rapid that science has continuously split into smaller and smaller fragments; life sciences and engineering are today separately existing, well-developing disciplines of science which are characterized by largely differing subjects of study and very different problem solving techniques.

The separation caused by specialization has now assumed new importance. During the last 10 to 20 years, materials scientists and engineers have made considerable contributions to the understanding of physiological phenomena and the use of man-made materials for implants. There has been a strong stimulus for collaborative research between physicians or life scientists and engineers or materials scientists. However, at the same time the field became increasingly difficult for all those who had only limited training in the other disciplines involved.

This series of books entitled *Structure-Property Relationships in Biomaterials* attempts to alleviate this problem by dealing first with the basic aspects of materials science and engineering for a number of different materials: metals, ceramics, and polymers. Subsequently the fundamental properties of the biological materials are described *(Natural and Living Biomaterials)*. Only when this information is gathered is it possible to describe the direct interaction between implant materials and the host tissues. In *Functional Behavior of Orthopedic Biomaterials* behavior of orthopedic implant materials is thus covered. As such the aim of the present series is threefold:

1. To provide a basic insight into the factors which govern the functional behavior of the man-made materials used in surgery
2. To describe the properties of the host, important to the use of foreign materials in the human body
3. To assess and discuss the more important interactions of those implant systems where a sufficient degree of understanding has been acquired or where high-quality evaluation techniques have become standard practice

III. FUNCTIONAL BEHAVIOR OF BIOMATERIALS

What does constitute failure of any given foreign material in an implant application? Factors are many and can be traced back to a range of diverse phenomena. Without being comprehensive, possible mechanisms include wear or fatigue, failure of bonding, or untoward tissue reactions to the presence of the implant, corrosion, or static overload. Examples of these failure mechanisms are described herewith.

1. Wear: Teflon® acetabular components of total hip prostheses wear out and revision surgery to remove the prosthetic part is imposed.
2. Fatigue: Fatigue failures of bone fracture plates are frequently observed.
3. Bonding: present day fixation techniques rely on the use of poly(methylmethacrylate) cement; debonding either at the bone-cement or the cement-prosthesis interface is a precursory mechanism for implant loosening, eventually requiring revision as a result of clinical symptoms such as pain.
4. Tissue reactions: Polyethylene wear particles of the acetabular component and abraded bone cement particles are phagocytosed within the joint capsule; upon proliferation of this tissue into the cement bone interface loosening may occur.
5. Corrosion: The mechanisms of corrosion of implanted metals are fairly well recognized,

but the effect of corrosion products on local tissues or systemic functions is still a matter of debate, e.g., what causes the discoloration of the tissues in the neighborhood of titanium implants?

6. Overload: Bending of intramedullary nails shortly after implantation is indicative for overload failure. Overload failure can also occur without any deformation as is the case for fractured alumina components of total hip prostheses.

How can the performance and the success of materials implanted in the human body be analyzed? To answer that question, we consider what the finality of biomaterials science is. It is to apply materials in the clinical environment. In that respect, it has been suggested that the evaluation of the functionality is the more important criterion for assessing failure or success. In some clinical areas a high degree of clinical success has been reached. It is of a particular value to note that in those fields one is induced to wonder what the value of basic science might be. Does a basic science approach enhance the understanding of how successfully an implant functions? Apart from providing a sound basis for established procedures, it may help to improve existing materials and techniques. In addition, and equally important, the fundamental assessment of phenomena with one particular type of implant may enhance the understanding of the behavior of other devices. The example of acrylic bone cement in orthopedic surgery may clarify this point. The literature really abounds with studies on properties and structure-property relationships of acrylic bone cements. The data provided by these investigations have been very useful to determine the causes of loss of fixation with knee prostheses. Many of the early mechanisms of loosening knee prostheses were phenomenologically similar to loosening mechanisms of hip prostheses. While it was possible to observe characteristic loosening phenomena early on (about 2 years) with knee implants, it was only after 5 to 10 years that similar observations could be made with total hip prostheses. Thus, the fundamental understanding of poly(methyl methacrylate) (PMMA) properties led to the evaluation of mechanical failures of knee prostheses and eventually yielded prospective assessment of total hip prosthesis functionality.

The basic science approach can take numerous forms in biomaterials science. There are contributions both from the life sciences and from the engineering sciences. To name but a few, there are histology, histochemistry, histopathology, immunology, biochemistry, and electrophysiology for the life sciences; mechanics, ceramic engineering, polymer science, and metallurgy for the engineering sciences. One of the important questions in biomaterials science is who is going to provide the requirements these materials have to fulfill and who is going to relate fundamental life science aspects into materials design and engineering. The least one can say is that an understanding of each one's techniques, results, and limitations among the different disciplines is required. This does not necessarily mean that engineers should be able to perform, for example, histochemical or biochemical tests, but at least a basic level of understanding is necessary. However, one may be tempted to query this statement. Would it not be advantageous to combine the fundamental understanding of several sciences and preferably from life sciences and engineering within individual scientists? Would the insight into available knowledge and into the limitations of different disciplines not have a triggering effect on the advance of biomaterials science? Numerous examples of areas which could potentially benefit from this approach could be cited. For example, it is possible that there is an effect of proteins, lipoproteins, and enzymes on the ion release from metal implants. Experiments to address this hypothesis require an understanding of the physiological systems and of corrosion phenomena. The discovery of new concepts of controlled drug release systems requires knowledge of polymer and drug chemistry, the pharmacological action, and the nature of the diseases that may be treated. A third example is of total joint replacement where successful development of new designs depends upon a knowledge of patient factors as well as of engineering and materials science principles.

Major advances are still possible and only now do we begin to glimpse what may be ahead. This series of books intends to provide the basis for the interdisciplinary biomaterials research by reassembling the current understanding, both in the engineering and life science disciplines. First metals, ceramics, and polymers are discussed. In subsequent volumes, the tissues and the implant procedures are discussed with major attention on the interactions between materials and host and the processes which may be triggered by the insertion of a foreign material.

IV. STRUCTURE-PROPERTY RELATIONSHIPS OF FUNCTIONAL BIOMATERIALS

The failure mechanism as summarized above may be related to bulk aspects such as mechanical properties (fatigue, yield strength, ductility) or to surface-related properties (corrosion, biocompatibility, wear, etc.). The understanding of how synthetic materials behave in vivo and how they eventually may fail is intimately related, first to the development of new and improved materials and second to the design of better functioning devices and constructs. Analogous to materials science in its broadest sense, the basis is formed by microstructural theory. The understanding of all materials aspects, whether it is strength or fatigue failure resistance, wear tenacity, or corrosion resistance, is founded on a thorough knowledge of structure and properties on atomic size and microscopical level. Therefore this book starts off with a description of the organization of matter on both atomic size level and microscopic level. The relationship to macroscopic properties is outlined in different subsequent chapters dealing with each one of the separate material properties as they refer to implant surgery. Subjects which are thus treated are the strength and relationship to structure of metals and ceramics, the shape memory alloys, the principles of corrosion and electrode functioning, wear, surface coatings, and surface active materials.

Chapter 2

STRUCTURAL CHARACTERISTICS OF METALS AND CERAMICS

G. Heimke

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