CRC

FUNCTIONAL BEHAVIOR of ORTHOPEDIC BIOMATERIALS

Volume I
Fundamentals

Paul Ducheyne
Garth W. Hastings

CRC PRESS

Functional Behavior of Orthopedic Biomaterials

Volume I: Fundamentals

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CRC Series in Structure-Property Relationships of Biomaterials

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CRC Press, Inc.
Boca Raton, Florida

Library of Congress Cataloging in Publication Data
Main entry under title:

Functional behavior of orthopedic biomaterials.

(CRC series in structure-property relationships
of biomaterials)
Includes bibliographies and index.
Contents: v. 1. Fundamentals — v. 2. Applications.
1. Orthopedic implants — Materials. 2. Orthopedic
implants — Materials — Corrosion. I. Ducheyne, Paul.
II. Hastings, Garth W. III. Series. [DNLM: Bio-
compatible materials — Therapeutic use. 2. Bone and
bones — Surgery. 3. Implants, Artificial. WE 190 F979]
RD755.5.F86 1984 617'.307 83-3737
ISBN 0-8493-6265-2 (v. 1)
ISBN 0-8493-6266-0 (v. 2)

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

International Standard Book Number 0-8493-6265-2 (Volume I)
International Standard Book Number 0-8493-6266-0 (Volume II)

Library of Congress Card Number 83-3737
Printed in the United States

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.

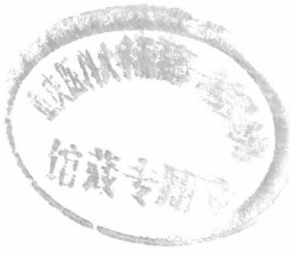
It is not only the materials *per se* which interest the biomaterials scientist, but also the interactions in vivo, because it is at the interface between implant and tissues that the success of a procedure will be decided. This approach has led to the concept of a more aggressive role for biomaterials 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



PREFACE

Once the properties of metals, ceramics, and polymers are known and the biological tissues have been characterized, the next step in the study of biomaterials is the interaction between them. Those interactions can influence the integrity of the implant material as well as cause changes in surrounding tissues or distant organs. The ultimate answer to the efficacy of any given implant material can therefore only be obtained when that material has a functional size and shape and is clinically used. Although the importance of the clinical trial step is stressed here, the previous stages of biomaterials evaluation such as the in vitro experiments and the animal testing must not be overlooked (this is, for instance, discussed in the volumes, *Metal and Ceramic Biomaterials*, of this same series).

The present volume is the first of two volumes that describes some of the interactions between orthopedic implant materials and the human environment. The first chapter of this volume describes in detail what we understand by ''functional behavior''. In addition, it outlines important areas of development and problems that would profit from a greater research effort.

The other chapters of this volume provide data on the properties of the osseous tissues. In these tissues many orthopedic implants are hosted. Carter and Wright (Chapters 2 and 3) describe the ultimate strength of cortical bone and the macroscopic directionality of properties. Those data are essential in the studies dealing with the response of bone tissues and bone structures on external loading stimuli.

Huiskes (Chapter 4) discusses the various methods that are available to analyze the stresses and strains in bones, joints, and implant assemblies. Thus, this chapter deals with the static response to loading stimuli. In contrast, Van der Perre (Chapter 5) discusses the dynamic response; the major parts of that chapter are, first, the fundamental concepts of dynamic response and, second, the dynamic behavior of bone tissues, bone structures, and bone-implant assemblies.

Included in *Functional Behavior of Orthopedic Biomaterials, Volume II: Applications,* are Part I, which assesses the fixation and status of total joint replacements, and Part II, which presents an evaluation of wear behavior, acrylic bone cement, and fixation materials under functional conditions. Included is an analysis of design, geometry, and stresses in artificial joints.

It is obvious that in books of this nature it is impossible to obtain a comprehensive coverage of all subjects that are relevant to its title. Rather a selection of important topics can be proposed. Furthermore, however meaningful the title and its topics could be, the eventual value of the book is to a large extent determined by the value of the separate contributions. Therefore the editors wish to thank all the authors for their hard work, without which these books would never have been published. We hope that their efforts will be rewarded by illuminating the way of all those in the field or those wishing to join it.

P. Ducheyne and G. W. Hastings
January 1983

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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FUNCTIONAL BEHAVIOR OF ORTHOPEDIC BIOMATERIALS

Volume I: Fundamentals

Functional Behavior of Orthopedic Biomaterials
Yield Characteristics of Cortical Bone
Macroscopic Directionality in Bone
Principles and Methods of Solid Biomechanics
Dynamic Analysis of Human Bones

Volume II: Applications

Part I: Assessment of Total Joint Replacement
The Fixation of Permanent Implants: A Functional Assessment
Assessment of the Clinical Status of Total Joint Replacement

Part II: Evaluation of Materials and Devices
Evolution and Evaluation of Materials-Screening Machines and Joint Simulators in Predicting In Vivo Wear Phenomena
Structure and Properties of Acrylic Bone Cement
Design, Fixation, and Stress Analysis of Permanent Orthopedic Implants: The Hip Joint
Biological Fixation of Implants

TABLE OF CONTENTS

Volume I

Chapter 1

FUNCTIONAL BEHAVIOR OF ORTHOPEDIC BIOMATERIALS

P. Ducheyne and G. W. Hastings

TABLE OF CONTENTS

I. FUNCTIONAL BEHAVIOR: DEFINITION

This volume of the series in *Structure-Property Relationships of Biomaterials* deals with orthopedic biomaterials. The scope of this volume is to review the information available to evaluate properly the use of materials for orthopedic surgical use. In previous volumes, a comprehensive treatment was given of the existing biomaterials. Metals, ceramics, glasses, carbons, polymers, and composites were described. Their bulk and surface properties which are of particular relevance to use as an implant or as part of an implanted device were discussed. In addition the tissues of the musculoskeletal system were analyzed. The data presented in those volumes now form the basis for assessing these materials in actual implant form. Not only is it important to study on their own the properties of biomaterials as materials; it is of equal value to consider these materials in size and shape appropriate for implantation and to study the various interactions which can occur among the different materials and the physiological environment. The implant material is part of a whole structure, and its properties can only be fully assessed if it is known how the structure as a whole functions. This basic and fundamental concept is what we call ''functional behavior''.

The example of total hip replacement arthroplasty (THR) may be of help in more clearly delineating the meaning of this concept. THR is performed in an attempt to alleviate pain, reconstruct the joint, and restore normal motion at the hip joint. There are a number of procedures possible, but we can basically look at THR as an operation where, as it stands today in the majority of cases, four types of material interact with one another: an ultrahigh molecular weight polyethylene (UHMWPE) acetabular cup, a metal femoral component, an orthopedic polymethylmethacrylate bone cement, and surrounding tissues. The eventual clinical success of the THR procedure is dependent upon the fixation of the components, the absence of infection which can be foreign material mediated, the stability of the calcar which can be influenced by cytotoxic reactions on wear and abrasion particles or by strain shielding by the stiff metal stem, the mechanical performance of the stem, the stem-cement junction, and the stability of the osseous tissue building. This list of examples is clearly not exhaustive. It is merely intended to show the extent to which the function of the THR is dependent on the different materials and their interactions. Summarizing these input data for the evaluation of artificial hip joint functionality, there is

1. The synthetic material with its own mechanical, physical, and chemical surface and bulk properties
2. The geometry of these materials
3. The effect of a particular type of loading (This loading can vary from patient to patient)
4. The effect of various conditions of body fluids on the chemical and mechanical physical properties of the implant materials
5. The properties of the tissues considering that these properties may be directional and that the tissues contain fluids, organic material, and mineral components

These data are used to describe the biomechanical, biochemical, and possibly bioelectrically triggered processes basically underlying the stability of the artificial hip joint and the overall state of health of the patient.

II. GENERAL REQUIREMENTS OF ORTHOPEDIC BIOMATERIALS

In terms of the implant material, there are generally some six requirements considered for successful biomaterial usage. It depends upon the particular type of application which requirement stands out as the more important one. The requirements of some implants and implant materials will be described in detail in the several chapters of this book. A brief account of the general requirements follows here.

A. Biocompatibility

The term biocompatibility covers a two-way phenomenon associated only with the material itself: implant materials may not be adversely affected by the physiological environment, and the local or remote tissues and organs may not be harmed by the presence of the material. This definition does not include mechanical or geometrical effects. This requirement is the most fundamental since any biomaterial comes into interaction with the physiological environment. Adverse effects on the implant material are, for instance, corrosion of metal and ceramic implants or degradation of polymers by the saline solution of the body. Adverse local effects are necrosis or resorption of tissue, unfavorable cellular reactions, and synergistic action with bacteria to cause infection. Possible systemic reactions are hypersensitivity, toxicity, and carcinogenicity.

B. Sufficient Mechanical Properties

In many uses of biomaterials, especially those in orthopedics, the implants are structural parts subjected to loads which can be high, of cyclic nature, and at different strain rates. Mechanical properties, such as yield and ultimate strength, ductility, modulus of elasticity, endurance limit, and viscoelastic behavior, are therefore important characteristics.

C. Low Friction and Wear

As a result of increasing usage of artificial joints, considerable work has been performed to develop the best combination of materials for the gliding surfaces: a low-friction coefficient and a high-wear resistance are paramount. The minute particles released from the joint surfaces can elicit tissue reactions interfering with the overall joint performance. An artificial joint made by metal against itself is not suited for internal use as a surgical implant.

D. Dimensions Appropriate to its Location

Prostheses must be of such form that they can be implanted without causing undue damage. As an example, a knee prosthesis is mostly made of such a form that only a minimal amount of tissues must be excised.

E. Long-Term Functionality

In certain applications, a controlled surface or bulk reaction of the biomaterial is a beneficial effect one wishes to obtain. Functionality here is defined as fulfilling its intended function over the whole lifetime of the patient for a permanent implant or until its purpose is achieved. As an example, under appropriate conditions bioglasses form a bond to bone as a result of a sequence of reactions at the surface. Hydroxylapatite and tricalciumphosphates can be bioresorbable; this means that they are digested or transported through surrounding cells. The rate of reaction of these bioactive materials should not impair the function to which the implants are intended, thus the rate of reactivity has to be closely controlled.

F. Possibility to be Sterilized

Implants can be sterilized by several methods, including autoclaving (steam at 120 to 140°C), gamma radiation, or sterilization by ethylene oxide. Depending upon the material, one of these methods is used which does not adversely affect the material properties.

III. TESTING PROTOCOL FOR IMPLANTS AND IMPLANT MATERIALS

There are in general five consecutive stages of evaluation which are successfully executed, before any material or design is widely used for clinical purposes:

1. The evaluation by simple in vitro tests

2. The evaluation by complex in vitro tests
3. The experimentation in animals: biocompatibility tests
4. The evaluation in animals as a functional implant
5. The clinical trial step

When considering a new material as a gliding material in a joint replacement, the protocol described above would first typically be the use of simple wear test methods to compare the behavior of the new material with existing materials; if successful this material may then be fabricated in the form of an implant and tested in a joint simulator; at the same time, one may start implantation of this material in unloaded conditions in bulk and in powder form. Again if these steps are satisfactory, one may proceed to the next step which is animal experimentation with the newly developed material in prosthesis form; this is to test its behavior as a gliding material in vivo. If sufficient information is gathered showing that the new device or material has substantial potential for successful, hazard-free clinical performance, a clinical trial step is initiated.

IV. THE DICHOTOMY BETWEEN EXPERIMENTAL AND CLINICAL ASSESSMENT

Depending upon the type of implant material or device, some of the five steps may be redundant. However, it is obvious that successfully carrying through experimental programs to implement new materials and devices requires substantial expenditure. It may therefore be tempting to reduce costs as much as possible. This can be achieved by cutting expenses in each step of a proper protocol and by moving quickly and eagerly to human experimentation. In addition to cost saving, a rationale for doing so is provided by the general and specific lack of comparability between the in vitro and animal experiments on one side and the clinical situation on the other side. For instance, it is well known that some animal models may invariably yield positive results, while human implantation under similar circumstances is bound to failure. There is thus a dichotomy between experimental laboratory programs and human implementation. This dichotomy represents a major challenge to the advancement of understanding the behavior of implants and implant materials. As an example, to understand the fate of metal ion release from metal implants, careful in vitro and animal corrosion studies checked for their relevance to the clinical reality, are needed.

Fast and uncontrolled progression to human use may be queried not just on the basis of ethical concepts, but also by scientific criteria. A closed loop research outline with built-in feedback is indicated to improve progressively the properties and availability of materials and devices. The necessity of excellent research programs, predictive of the fate of materials and devices in clinical reality, becomes even more obligatory considering the ever-increasing time of implantation for which present implants are designed. Fifteen years of life in service may presently be expected. At present we may observe the following areas where careful experimental protocols predictive for long-term clinical situations are very valuable and/or urgently needed.

A. Materials Development

1. Metals with high fatigue limit are being developed for use as the femoral component of stemmed-type total hip prostheses.
2. Ceramics are tested by fracture mechanics methods in order to study the possible degradation by the physiological fluids as a function of time.
3. Composite materials are becoming available for a number of applications. An advantage which is hoped will be used to its full benefit is the reduced modulus of elasticity. Attention is being paid to the effect of the directionality of the properties and to the

interfaces between constituents. These interfaces may well constitute the weak links of the system.

4. Surface-coated materials have received little attention up to now. This is deplorable, since by careful selection of materials for bulk and surface of an implant, a near optimal combination of properties may be obtained. The technology for applying coatings is far more advanced in other engineering fields than in biomedical engineering.

B. Fixation Materials

1. Porous coatings can be made from ceramic, polymer, composite, or metal base materials; these porous structures allow bony ingrowth and thus stable fixation of permanent implants provided there is initial stability and sufficient pore size. Biocompatibility, stress pattern in and around the implant, enhancement of bone ingrowth, and manufacturing methods to obtain sufficient substrate strength and design aspects are being considered for optimal implant functioning.
2. The mechanical, elastic, histological, immunological, and biochemical aspects of bioglasses, hydroxyapatite, and tricalciumphosphates are being scrutinized in order to evaluate predictively the bonding with tissues and the fate of the dissolving ions.

C. In Vitro Test Methods

1. The metals which are used are in the human body in their passive state. Even in this condition, metal ions are released into the physiological environment. However, little is known about the mechanisms of this release, the form under which the metallic elements are subsequently found in the tissues, the transport mechanism to distant organs, and the effect on systemic functions. The onset of a better understanding of these fundamental questions can now be perceived. In vitro corrosion tests, in the presence of suitable concentrations of enzymes, proteins, and lipoproteins, which induce similar effects to those observed in vivo, are urgently needed.
2. New materials are developed for artificial joints, but a reproducible, standardized wear testing procedure which can predict the wear for a service life up to 10 to 20 years is, however, not available.
3. Manufacturers have spent great time and effort to produce metals with high fatigue strength. However, a simple reproducible fatigue testing method to test the fatigue properties of the actual implant shape has not yet been produced, although several are being discussed in national and international standards bodies.

D. Biomechanical Techniques

1. There has been much debate on the value of finite element models for stress analysis of biological structures with implants. It appears essential that some allowance is made for the discontinuous displacement actually occurring at the interfaces in implant systems. In addition if a two-dimensional method is used, the properties of the elements must be carefully selected in order that the model yields realistic results.
2. In vitro tests on the kinematics and stresses of implants are easier to reproduce when instead of cadaveric bones, synthetic material is used to replace the bones in the testing. Some materials, such as glass fiber epoxies and phenolic resin fiber composites, have been proposed.
3. The mechanical properties of tissues surrounding the implants have mostly been measured on fresh ex vivo specimens. The process of preparing these specimens may, however, induce changes in the properties. A full understanding of these changes has not yet been reached.

4. The loading pattern varies significantly from patient to patient. Engineering analyses to provide statistical data on load patterns at the major joints under pathological or replacement arthroplasty conditions would be useful.

E. Animal Experimentation

1. Animal models to evaluate long-term functionality of implants and implant materials are very costly. In addition, problems in interpretation arise because of some dissimilarities: there may be differences in the physiology of the test animal and man; it is also difficult to reproduce in the animals the pathological conditions for which implants are developed; in addition, animal management is largely different from patient treatments. In the field of orthopedic biomaterials, there are few generally accepted protocols for animal experimentations, unlike other fields.
2. The techniques for assessing the interface between implants and tissues are still being improved. This holds both for the mechanical and for the histological evaluation.

F. Clinical Evaluation

1. Eventually new materials are clinically tried. Scientific assessment of the results is greatly facilitated when the clinical trial is confined to "a one-parameter study". Anticipated influential parameters must be kept constant except for the property of the material under study.
2. Clear and uniformly accepted definitions of clinical success are needed. A decisive conclusion on the value of radiolucency at the implant-bone interface with regard to prospective evaluation of total joint replacement arthroplasty would be valuable.
3. Implant retrieval and analysis helps to establish correlations between laboratory results and clinical reality.

V. LIMITATIONS IN ORTHOPEDIC BIOMATERIALS DEVELOPMENT

Few materials can presently be used for temporary and permanent implants, especially when the implant is subjected to high stresses. This lack of a suitable choice of materials frequently hampers the design of new devices. Efforts are made to develop materials for specific medical uses, but experimental and clinical limitations slow down the pace at which new materials become available. Hench[1] discerned six experimental limitations:

1. The required research effort is one at the forefront of both biological and materials sciences.
2. The instrumental tools for the required analyses have only become available within the last few years.
3. The application of these instruments necessitates considerable modifications of the instrumental operating methods.
4. The maintenance of the interface in preparation for analysis is a major variable.
5. The selection of appropriate animal model implant configuration and evaluative test protocols is very complex.
6. Production of a sufficient number of materials in any shape and size necessary for full evaluation is very difficult.

Once human evaluation has started, there are also clinical limitations:

1. The major one is related to the ill-defined quantitative measures for success. Clinical

observations are difficult to assess quantitatively. The main symptom for total joint replacement surgery being pain, how can pain relief after surgery be evaluated quantitatively? How can the degree of symptom recurrence be measured? It is possible that functionality can be assessed more quantitatively by measuring angles of rotation between different segments of the skeleton, but it still cannot be compared to thorough engineering methods which positively discriminate one condition from another. In addition there is the interference of the patient's psychology, e.g., by expressing his opinion on pain level and thus personal degree of satisfaction.

2. Since current tendencies in orthopedic implant applications are towards longer implantation periods, increasingly longer clinical observation periods become necessary. However, this is very difficult since there have continuously been changes and improvements in device design, operative technique, and postoperative treatment. Furthermore, the largest number of implants has been implanted during approximately the last 5 years.
3. New developments are mostly evaluated at centers of excellence. Subsequent general usage means putting the materials and devices into the hands of surgeons who are less experienced with the technique and may reach a lower level of achievement.
4. There may be conflicting requirements between the intended goal of the implant and the operative procedure. Total joint replacements are intended to restore functionality at the joint, but if biological attachment is used, some immobilization is required.

VI. CONCLUSION

The aspects involved in biomedical materials research are so different that projects are conducted by multidisciplinary teams, including material scientists, mechanical engineers, histopathologists, and surgeons. Transfer of knowledge among team members of different disciplines is then paramount. Were past failures of implants related to communication gaps existing among the different professional areas of this field? Implants failed due to wrong design, inappropriate materials choice, deficient production, faulty operative procedure, or incorrect patient management. The knowledge transfer gap probably does not exist anymore in well-established groups. However, just as important, there might still be considerable delay in the transfer of new understanding in the medical disciplines or the engineering sciences to the other profession. A total of 400 types of different knee prostheses currently exist, indicating a high degree of unsatisfactory performance of knee implants as yet. However, the centers where the present clinical experience, the mechanical analyses of the knee joint, and the availability of improved materials result in a fool-proof design are very few.

It is therefore the aim of this volume to present the necessary details for generally defining and assessing any orthopedic material problem. The different chapters are chosen in such a way that they may provide a basic understanding of the various aspects of orthopedic biomaterials. At the same time, they give a full account of the state-of-the-art for the more important areas of development. The electrical effects in osseous tissue associated with some orthopedic procedures are not discussed, since it was felt that this is too far beyond the scope of materials' analysis.

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