Handbook of Biomaterial Properties

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Foreword

Progress in the development of surgical implant materials has been hindered by the lack of basic information on the nature of the tissues, organs and systems being repaired or replaced. Materials' properties of living systems, whose study has been conducted largely under the rubric of tissue mechanics, has tended to be more descriptive than quantitative. In the early days of the modern surgical implant era, this deficiency was not critical. However, as implants continue to improve and both longer service life and higher reliability are sought, the inability to predict the behavior of implanted manufactured materials has revealed the relative lack of knowledge of the materials properties of the supporting or host system, either in health or disease. Such a situation is unacceptable in more conventional engineering practice: the success of new designs for aeronautical and marine applications depends exquisitely upon a detailed, disciplined and quantitative knowledge of service environments, including the properties of materials which will be encountered and interacted with. Thus the knowledge of the myriad physical properties of ocean ice makes possible the design and development of icebreakers without the need for trial and error. In contrast, the development period for a new surgical implant, incorporating new materials, may well exceed a decade and even then only short term performance predictions can be made.

Is it possible to construct an adequate data base of materials properties of both manufactured materials and biological tissues and fluids such that *in vitro* simulations can be used to validate future implant designs before *in vivo* service? While there are no apparent intellectual barriers to attaining such a goal, it clearly lies in the distant future, given the complexity of possible interactions between manufactured materials and living systems.

However, a great body of data has accumulated concerning the materials aspects of both implantable materials and natural tissues and fluids. Unfortunately, these data are broadly distributed in many forms of publication and have been gained from experimental observations of varying degrees of accuracy and precision. This is a situation very similar to that in general engineering in the early phases of the Industrial Revolution. The response then was the publication of engineering handbooks, drawing together, first in general publications and later in specialty versions, the known and accepted data of the time. In this spirit, we offer this *Handbook of Biomaterial Properties*.

Biomaterials, as manufactured for use in implants, do not exist usefully out of context with their applications. Thus, a material satisfactory in one application can be wholly unsuccessful in another. In this spirit, the Editors have given direction to the experts responsible for each part of this *Handbook* to consider not merely the intrinsic and interactive properties of biomaterials but also their appropriate (and in some cases inappropriate) applications as well as their historical context. It is hoped that the results will prove valuable, although in different ways, to the student, the researcher, the engineer and the practicing physician who uses implants.

A handbook like this necessarily becomes incomplete immediately upon publication, since it will be seen to contain errors of both omission and commission. Such has been the case with previous engineering handbooks: the problem can only be dealt with by providing new, revised editions. The Editors would appreciate any contributions and/or criticisms which the users of this handbook may make and promise to take account of them in future revisions.

Introduction

It is a feature of any developing science and its accompanying technology that information relating to different aspects is scattered throughout the relevant, and sometimes not so relevant literature. As the subject becomes more mature, a body of information can be categorized and brought together for the use of practitioners. In providing this *Handbook of Biomaterial Properties* the Editors believe that the latter stage has been reached in several parts of the vast field of biomaterials science and engineering.

Many of the properties of the synthetic materials have been available for some time, for example those of the various metallic alloys used in clinical practice have been specified in various International, European and National Standards and can be found by searching. In the case of polymeric materials, while the information is in commercial product literature and various proprietary handbooks, it is diverse by the nature of the wide range of materials commercially available and the search for it can be time consuming. The situation is much the same for ceramic and composite materials: there the challenge is finding the appropriate properties for the specific compositions and grades in use as biomaterials.

However, when information is sought for on materials properties of human tissues, the problem is more acute as such data are even more scattered and the methods for determination are not always stated or clearly defined. For the established worker this presents a major task. For the new researcher it may make establishing a project area a needlessly time consuming activity. The biomaterials bulletin boards (on the Internet) frequently display requests for help in finding characterization methods and/or reliable properties of natural materials, and sometimes the information is actually not available. Even when it is available, the original source of it is not always generally known.

In approaching their task, the Editors have tried to bring together into one source book the information that is available. To do this they have asked for the help of many colleagues worldwide to be contributors to the *Handbook*. It has not been possible to cover all the areas the Editors had hoped. Some topics could not be covered, or the information was judged to be too fragmentary or unreliable to make it worth including. This is inevitably the sort of project that will continue to be incomplete; however, new information will be provided as more experiments are done and as methods for measurement and analysis improve. The aim has been to make this *Handbook* a ready reference which will be consulted regularly by every technician, engineer and research worker in the fields of biomaterials and medical devices.

We have tried, not always successfully, to keep the textual content to a minimum, and emphasize tabular presentation of data. However, in some cases it has been decided to include more text in order to establish the background of materials properties and use and to point to critical features in processing or production which would guide the worker looking for new applications or new materials. For example, in polymer processing, the need to dry materials thoroughly before fabrication may not be understood by those less well versed in production techniques.

It is hoped that the *Handbook* will be used and useful, not perfect but a valuable contribution to a field that we believe has matured sufficiently to merit such a publication. The *Handbook* is divided into synthetic and natural materials and the treatment is different in each part. More background was felt to be needed for the synthetic materials since processing and structural variations have a profound effect on properties and performance. Biological performance of these materials depends on a range of chemical, physical and engineering properties and the physical form can also influence *in vivo* behavior. We have not attempted to deal with issues of biological performance, or biocompatibility, but have dealt with those other features of the materials which were felt to be relevant to them as potential biomaterials. Only materials having apparent clinical applications have been included.

The biological materials have more dynamic properties since, *in vivo*, they respond to physiological stimuli and may develop modified properties accordingly. The treatment of their properties has been limited to those determined by well characterized methods for human tissues, with a few exceptions where data on other species is deemed to be applicable and reliable. These properties determined almost totally *in vitro* may not be directly predictive of the performance of the living materials *in vivo*, but are a guide to the medical device designer who wishes to determine a device design specification. Such a designer often finds it hard to realize the complexity of the task of dealing with a non-engineering system. What really are the parameters needed in order to design an effectively functioning joint endoprosthesis or a heart valve? Do tissue properties measured post explantation assist? Is individual patient lifestyle an important factor? There is immediately a degree of uncertainty in such design processes, and total reliability in performance cannot be given a prospective guarantee. However, the more we learn about the materials and systems of the human body and their interaction with synthetic biomaterials, the closer we may perhaps become to the ideal 'menotic' or forgotten implant which remains in 'menosis' – close and settled union from the Greek μενω – with the tissues in which it has been placed.

Three final comments:

Although the Editors and contributors frequently refer to synthetic and, in some cases, processed natural materials as 'biomaterials,' nothing herein should be taken as either an implied or explicit warrantee of the usefulness, safety or efficacy of any material or any grade or variation of any material in any medical device or surgical implant. Such determinations are an intrinsic part of the design, development, manufacture and clinical evaluation process for any device. Rather, the materials listed here should be considered, on the basis of their intrinsic properties and, in many cases, prior use, to be *candidates* to serve as biomaterials: possibly to become parts of successful devices to evaluate, direct, supplement, or replace the functions of living tissues.

The Editors earlier refer to absences of topics and of data for particular synthetic or natural materials. While this may be viewed, perhaps by reviewers and users alike, as a shortcoming of the *Handbook*, we view it as a virtue for two reasons:

- Where reliable data are available but were overlooked in this edition, we hope that potential contributors will come forward to volunteer their help for hoped for subsequent editions.
- Where reliable data are not available, we hope that their absence will prove both a guide and a stimulus for future investigators in biomaterials science and engineering.

The Editors, of course, welcome any comments and constructive criticism.

JB
GWH

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