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BIOMEDICAL AND DENTAL APPLICATIONS OF POLYMERS

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FOREWORD

The development and use of medical and dental materials are highly interdisciplinary endeavors which require expertise in chemistry, materials science, medicine and/or dentistry, mechanics and design engineering. The Symposium upon which this treatise is based was organized to bring members from these communities together to explore problems of mutual interest.

The biomaterials which are used in medical or dental prostheses must not only exhibit structural stability and provide the desired function, but they must also perform over extended periods of time in the environment of the body. The latter is a very stringent requirement. The oral and other physiological environments are designed by nature to break down many organic substances. Also of importance is the requirement that materials used in the prosthesis not have a deleterious effect on body tissues. Most foreign (to the body) substances are somewhat toxic to human tissues; in fact, few factors are more limiting in the medical prosthesis field than the biocompatibility problem. Some of these problems and the attempts to solve them are discussed in this volume.

In this book particular attention is given to polymers as biomaterials. Most engineering behavior of materials is complex and our understanding of the exact mechanisms and molecular processes which are involved is incomplete. The behavior is particularly complicated in polymers because of their complex morphology and the strong dependence of properties upon this physical structure, as well as the chemical structure. Time, for example, takes on particular significance for polymers--not only are polymeric materials susceptible to aging (physical and chemical changes with time) but, in addition, most exhibit viscoelastic behavior. When these materials are to be used as load-carrying structural elements, these time effects must be understood in order to predict performance. This is a very demanding task, particularly when we consider that the prosthesis will often be expected to function for years in a very unfavorable environment and the consequences of malfunction are, to say the least, very undesirable.

Materials behavior may be approached from several different points of view. Traditionally, designers have treated materials as continua and have observed their behavior from a phenomenological point of view. Other researchers have tried to explain behavior on a molecular basis. Both approaches have had their advantages and disadvantages. The former provides information and parameters that, in a comparatively direct and straightforward manner, facilitate sizing, optimization of shape, etc. In addition, this method is closely akin to methodology used to design components in other areas of technology. This may give the researchers the confidence that comes with using methods that have been tried and tested. On the other hand, it can be argued that in order to reliably predict performance, the laboratory conditions under which the phenomenological criteria are established or the design parameters are determined, must almost exactly duplicate the intended service conditions for which the part is to be designed. If considerable extrapolation between testing and service conditions is desired it is important to have an understanding of the basic molecular mechanisms involved in behavior. Only in this way can we with any confidence predict how behavior might be changed if environment, time, and loading conditions differ from the test conditions.

Texts such as this, as well as the symposium upon which it is based, provide a forum in which members of the various communities might present for discussion their findings and ideas. Hopefully, this will result in more rapid development and use of improved biomaterials.

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PREFACE

Nearly three thousand years ago, King David stated, "I will praise Thee; for I am fearfully and wonderfully made: marvelous are Thy works; and that my soul knoweth right well" (Psalm 139:14). Anyone who has considered the design and functions of the human body would readily agree with this observation. Unfortunately, this body is subject to various diseases and/or genetic problems that often produce defects or damage to the body. In such cases, some form of medication or medical treatment is necessary in order to enable the person to pursue a relatively normal life. Through the centuries many approaches have been developed in the attempts to restore health to an ailing human body. In this book we consider the role that polymeric materials are playing in this important line of service.

The present volume is the fruit of seeds planted at the American Chemical Society 179th National Meeting in Houston, Texas, March 23-28, 1980. The symposium from which this present volume is harvested was sponsored by the Division of Organic Coatings and Plastics Chemistry and short versions of most of these papers appeared in their Preprint Volume Number 42. This symposium was unique in that it spanned an unusually wide range of biomedical applications of polymers including artificial organs, cardiovascular uses, dental applications, implants and medication applications. To our knowledge, this was the first American Chemical Society symposium to cover this broad a range of topics and was certainly the first such symposium to dwell at any length on dental applications.

The arrangement of the revised and expanded Chapters in this volume differs considerably from the original order in the symposium in an attempt to make the book more consistent in its development of this broad topic. Basically these thirty five papers have been grouped into four categories: (1) General Biomaterial Applications of Polymers, (2) Cardiovascular Applications of Polymers, (3) Applications of Polymers in Medication and (4) Dental Applications of Polymers. Frequently there is some overlap of the information in one section with that in another section. This is unavoidable and even desirable to an extent. Very often a material used in one application could also have utility in a totally different area.

Likewise, the solution of a problem in one area could aid in overcoming difficulties in another area. One major purpose for this present book, and the original symposium, is to spread information amongst a broader body of scientists then normally would occur at a more specialized meeting which might concentrate nearly exclusively on a more restricted area, such as cardiovascular uses or dental applications. Although not every area of the biomedical applications of polymers is discussed in this book, we do feel that this goal has been accomplished. This book does cover most of the major applications of polymers in medicine, and the papers have been written by leading scientists in these fields.

These chapters present overviews, historical background, state of the art and current results. They represent work done in academic, industrial, government, medical or dental school and research institute laboratories in the United States, Canada, England and Italy and refer to work done in other countries as well. Approximately half the papers are from academic laboratories.

We wish to thank Drs. Robert Lalk, Larry Thompson and the other officers of the Organic Coatings and Plastics Division for their support. We also wish to acknowledge the contributions of the session chairmen: Drs. J. M. Anderson, K. L. DeVries, R. I. Leininger and J. M. Whiteley. We wish to thank the authors and their supporting institutions for their excellent contributions and these are acknowledged in the Table of Contents and in each Chapter heading. Several members of the Central Research Laboratory of Dentsply International, Inc. assisted in presenting the symposium and in preparing this book. Mrs. Rita Loveland was especially helpful. Last, and certainly not least, we wish to thank our families for bearing with us while we were going through 'labor pains' to give birth to this book. Their patience and warm smiles helped far more than any salve we might have used. We hope sincerely that this book will help to advance biomedical science and help to alleviate human suffering.

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SECTION I

GENERAL BIOMATERIAL APPLICATIONS OF POLYMERS

Although this entire book deals with the biomaterial applications of polymers, the cardiovascular, medication and dental applications are grouped together in special sections. This section is concerned with all other biomedical applications of polymers. Basically the plan of this section is to survey the entire biomedical polymer field (Gebelein) and then consider some specific problems with implants (Anderson). Following this, the areas of artificial lungs (Gray), temporary skin substitutes (Wang/Samji), poly(amido-amine) applications (Ferruti/Marchisio) and covalent bonding of collagen and acrylates (Lloyd/Burns) are examined. This section then concludes with a paper on the clinical analysis applications of polymer coated oxygen sensing devices (Hahn et al). Thus this section considers artificial organs (lungs, skin and general considerations), new polymer applications in microclinical analysis (oxygen detection in blood, etc.) and the pathological problems with implants. Some aspects of cardiovascular applications (Anderson, Ferruti) and medication applications (Gebelein) are considered also in this section as minor themes.

BIOMEDICAL POLYMERS IN THEORY AND PRACTICE

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The field of biomedical polymers continues to show steady growth in both the basic research and applications areas. The only limit to the suggested uses of polymers in medicine seems to be a limit in our imagination. Some recent popular articles suggest that nearly all parts of the human body could be replaced by some type of a plastic and/or metal device (1,2). Many major problems remain to be solved before this vision could become fact, however. A large number of recent surveys and books attest to the great interest in this important field of science (3-31). These books but scratch the surface and hundreds of articles are published each year in a variety of journals including such specialized ones as the Journal of Biomedical Materials Research and the Transactions of the American Society of Artificial Internal Organs. Courses in the field of biomedical polymers and biomaterials are now offered at many different universities (32).

Obviously it would not be possible to cover every detail of biomedical polymers in this paper or even in a single book. The basic purpose of this paper is to overview the various uses of polymers in medically related applications and to note some of the advantages and limitations in these uses. Table I shows some typical biomedical polymer applications. The forty five applications listed in Table I do not comprise every possible application, nor do they even cover all the areas under current research, but they merely indicate the wide range of applications being studied. According to statistics from the University Hospitals of Case-Western Reserve University, 9-15% of the autopsies reveal some type of an implant in the patient (33). If these statistics apply to the USA as a whole, this would mean that 20-34 million people would have some type of implant, exclusive of dental fillings, dentures and contact lenses. Each year there are in excess of 400 million dental fillings made with 33-50% of these utilizing polymers. In addition, over eleven million dentures are made annually and most of these materials are acrylic polymers with some polyurethanes and fluoro-polymers. At the present time this dental polymer market is about $50 million per year (34). The contact lense market was over six million lenses in 1974 (35) and many of these involve hydrogel polymers as 'soft contact lenses' (28,36).

The materials requirements for these biomedical applications vary markedly according to the application being considered and it is improbable that any single material would be useful in all these areas. Possibly the most difficult, and the most spectacular, area of application is in artificial organs. Ideally an artificial organ would be capable of implantation into the body and be able to replace totally the function of a diseased or otherwise disabled organ. In actual fact this is seldom possible with our present state of technological development. More frequently, an artificial organ actually consists of an extra-corporal device, such as a hemodialyzer, which can be attached to a patient. Even where devices can be made small enough to permit implantation, such as an artificial heart,

Table 1

TYPICAL BIOMEDICAL POLYMER APPLICATIONS

Artificial Blood	Heart Assist Devices
Artificial Heart	Heart Valves
Artificial Kidney	Hydrocephalus Shunts
Artificial Limbs	Immobilized Enzymes
Artificial Liver	Implantable Pumps
Artificial Pancreas	Inner Ear Repairs
Artificial Penis	Joint Replacement
Biomedical Polypeptides	Pacemakers
Bladder Replacement	Plasma Extenders
Bone Cements	Plastic Surgery
Bone Replacement	Polymeric Drugs
Casts	Polymeric Food Additives
Catheters	Pseudoenzymes
Contact Lenses	Reinforcing Mesh
Controlled Release Drugs	Replacement Blood Vessels
Cornea Replacement	Replacement Skin
Dental Fillings	Soft Tissue Replacement
Dentures	Surgical Adhesives
Drainage Tubes	Surgical Tape
Drug Administration Devices	Sutures
External Ear Repairs	Testicle Replacement
Eye Lense Replacement	Visual Prothesis
	Wound Dressings