Chapter 1

INTRODUCTION

1.1 Biomaterials

There are different definitions of 'bioengineering' [Berger *et al.*, 1996]. Here, we refer 'bioengineering' to the application of concepts and methods of the physical sciences and mathematics in an engineering approach towards solving problems in repair and reconstructions of lost, damaged or deceased tissues. Any material that is used for this purpose can be regarded as a biomaterial. According to Williams [1987], a biomaterial is a material used in implants or medical device, intended to interact with biological systems. Thus, a biomaterial must always be considered in its final fabricated and sterilized form. Examples of common medical devices are: substitute heart valves and artificial hearts, artificial hip and knee joints, dental implants, internal as well as external fracture fixators, skin repair templates as well as dialysers to support kidney functions or intraocular lenses. A material that can be used for medical application must possess a lot of specific characteristics, of which the most fundamental requirements are related with biocompatibility.

Over the last thirty years, considerable progress has been made in understanding the interactions between the tissues and the materials. It has been acknowledged that there are profound differences between non-living (avital) and living (vital) materials. Researchers have coined the words 'biomaterial' and 'biocompatibility' [Williams, 1988] to indicate the biological

performance of materials. Thus, materials that are biocompatible can be considered as biomaterials, and the biocompatibility is a descriptive term which indicates the ability of a material to perform with an appropriate host response, in a specific application [Black and Hastings, 1998]. Researchers [Wintermantel and Mayer, 1995] extended this definition and distinguished between surface and structural compatibility of an implant. Surface compatibility means the chemical, biological, and physical (including surface morphology) suitability of an implant surface to the host tissues. Structural compatibility is the optimal adaptation to the mechanical behavior of the host tissues. Therefore, structural compatibility refers to the mechanical properties of the implant material, such as elastic modulus (or E, Young's modulus) and deformation characteristics, and optimal load transmission (minimum interfacial strain mismatch) at the implant/tissue interface. Optimal interaction between biomaterial and host tissue is reached when both the surface and the structural compatibilities are met. Furthermore, it should be noted that the success of a biomaterial in the body also depends on many other factors such as surgical technique (degree of trauma imposed during implantation, sterilization methods, etc), health condition and activities of the patient. Table 1.1 summarizes several important factors that can be considered in selecting a material for a biomedical application [Ramakrishna *et al.*, 2001].

Until recently, most medical devices are still made from single-phase homogeneous and isotropic materials such as polymers, metals, and ceramics. A large number of polymers are widely used in various medical applications. This is mainly because they are available in a wide variety of compositions, properties, and forms (solids, fibers, fabrics, films, and gels), and can be fabricated readily into complex shapes and structures. However for load bearing applications, they tend to be too flexible and too weak to meet the mechanical demands of certain applications e.g. as implants in orthopedic surgery. Also they may absorb liquids and swell, and leach undesirable products (e.g. monomers, fillers, plasticizers, antioxidants), depending on the application and usage. Moreover, the sterilization processes (autoclave, ethylene oxide, and ^{60}Co irradiation) may affect the polymer properties. Metals are known for high strength, ductility, and resistance to wear. Most common are stainless steel, cobalt-chromium alloys as well as titanium and titanium base alloys. Major disadvantages of those metals

Table 1.1 Various factors of importance in material selection for biomedical applications [Ramakrishna *et al.*, 2001].

Factors	Description		
	Chemical/Biological Characteristics	Physical Characteristics	Mechanical/Structural Characteristics
1st Level Material Properties	– chemical composition (bulk and surface)	– density	– elastic modulus – shear modulus – Poisson's ratio – yield strength – tensile strength – compressive strength
2nd Level Material Properties	– adhesion	– surface topology – texture – roughness	– hardness – flexural modulus – flexural strength
Specific Functional Requirements (based on application)	– biofunctionality – bioinert – bioactive – biostability – biodegradation behavior	– form & geometry – coefficient of thermal expansion – electrical conductivity – color, aesthetics – refractive index – opacity or translucency	– stiffness or rigidity – fracture toughness – fatigue strength – creep resistance – friction and wear resistance – adhesion strength – impact strength – proof stress – abrasion resistance
Processing & Fabrication	– reproducibility, quality, sterilizability, packaging, secondary processability		
Characteristics of host: tissue, organ, species, age, sex, race, health condition, activity, systemic response			
Medical/surgical procedure, period of application/usage			
Cost			

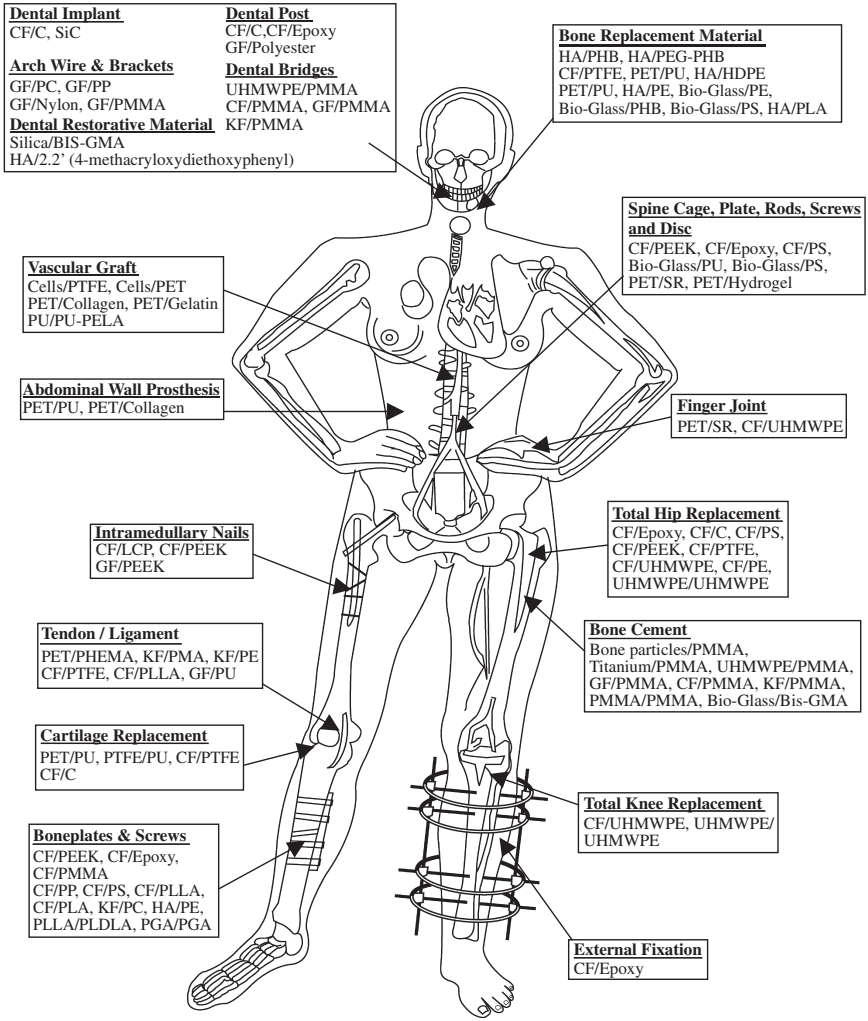
are their high stiffness compared to host tissues as well as their tendency to create severe imaging artifacts in the most advanced diagnostic 3-D imaging procedures i.e. X-ray Computer Tomography (CT) and nuclear Magnetic Resonance Imaging (MRI). Stainless steel and cobalt-chromium alloys are sensitive to corrosion, thus releasing metal ions which may cause allergic

tissue reactions (Nickel and Chromium allergies) [Speidel and Uggowitzer, 1998]. Titanium and its alloys, however, expand their range of applications because of their excellent biocompatibility. Ceramics are known for their good biocompatibility, corrosion resistance, and high compression resistance. Drawbacks of ceramics include brittleness, low fracture strength, difficulty in fabrication, low mechanical reliability and lack of resilience. These drawbacks in the traditional biomaterials have stimulated researchers and engineers to develop composite materials as an alternative choice in bioengineering applications.

1.2 Potential of Biocomposites for Medical Applications

Composites are those materials that contain two or more distinct constituent phases, on a scale larger than the atomic. The term 'biocomposites' specially refers to those composites that can be employed in bioengineering. The constituents retain their identities in the composite. Namely, they do not dissolve or otherwise merge completely into each other although they act in concert. Normally, the constituent components can be physically identified and exhibit an interface between one another. In composites, properties such as the elastic modulus can be significantly different from those of the constituents alone but are considerably altered by the constituent structures and contents. From a structural point of view, composites are anisotropic in nature. Their mechanical properties are different in different directions. Most of the living tissues such as bone, dentin, collagen, cartilage, and skin are essentially composites. Those natural biocomposites are not discussed in this book, but the reader can refer to, e.g. [D. Taylor, 2003]. Synthetic composites are essentially a combination of two constituent phases, i.e. a reinforcing phase such as fiber or particle and a continuous phase called matrix.

The primary motive in the development of biocomposites is that by varying the type and distribution of the reinforcing phases in the composites it is possible to obtain a wide range of mechanical and biological properties, and hence to optimize the structure and performance of the biomedical devices and their interaction with the surrounding tissues. A schematic diagram to show potential use of biocomposites in the repair, reconstruction, and replacement of human hard tissues is given in Fig. 1.1. A number of polymer



CF: Carbon fibers, C: Carbon, GF: Glass fibers, KF: Kevlar fibers, PMMA: Polymethymethacrylate,
PS: Polysulfone, PP: Polypropylene, UHMWPE: Ultra-high-molecular weight polyethylene,
PLDLA: Poly(L-DL-lactide), PLLA: Poly (L-lactic acid), PGA: Polyglycolic acid, PC: Polycarbonate,
PEEK: Polyetheretheketone; HA: Hydroxyapatite, PMA: Polymethylacrylate,
BIS-GMA: bis-phenol A glycidyl methacrylate, PU: Polyurethane, PTFE: polytetrafluoroethylene,
PET: polyethyleneterephthalate, PEA: poltethylacrylate, SR: silicone rubber,
PELA: Block co-polymer of lactic acid and polyethylene glycol, LCP: liquid crystalline polymer,
PHB: Polyhydroxybutyrate, PEG: polyethyleneglycol,
PHEMA: poly(20hydroxyethyl methacrylate)

Fig. 1.1 Various applications of different polymer composite biomaterials.

matrix composite materials were investigated for medical applications over the years. The early composites have been successfully used clinically, e.g. cages for spinal fusion, while the others are still under development. There are a number of factors that led to the development of composite materials. Some specific advantages of polymer composites are highlighted in the following.

In general, tissues are grouped into hard and soft tissues. Bone and tooth are the only examples of hard tissues, whereas skin, blood vessels, cartilage and ligaments are a few examples of soft tissues. As the names suggested, the hard tissues are generally stiffer (with higher elastic modulus) and stronger (with higher tensile strength) than the soft tissues (Tables 1.2 and 1.3). Moreover they are essentially composite materials with anisotropic properties, which depend on the roles and structural arrangements of various components (e.g. collagen, elastin, and hydroxyapatite) of the tissues. For

Table 1.2 Mechanical properties of hard tissues, representative values only, note that tissues show broad variation [Black and Hastings, 1998].

Hard Tissue	Modulus (GPa)	Tensile Strength (MPa)
Cortical Bone (Longitudinal Direction)	17.7	133
Cortical Bone (Transverse Direction)	12.8	52
Cancellous Bone	0.4	7.4
Enamel	84.3	10
Dentine	11.0	39.3

Table 1.3 Mechanical properties of soft tissues, representative values only, note that tissues show broad variation [Black and Hastings, 1998].

Soft Tissue	Modulus (MPa)	Tensile Strength (MPa)
Articular Cartilage	10.5	27.5
Fibrocartilage	159.1	10.4
Ligament	303.0	29.5
Tendon	401.5	46.5
Skin	0.1–0.2	7.6
Arterial Tissue (Longitudinal Direction)		0.1
Arterial Tissue (Transverse Direction)		1.1
Intraocular Lens	5.6	2.3

example, the longitudinal mechanical properties of cortical bone are higher than the transverse direction properties (see Table 1.2). The anisotropy of the elastic properties of the biological tissues has to be considered as one an essential design criterion for implants made from composite biomaterials.

From the mechanical point of view, metals or ceramics seem to be more suitable for hard tissue applications (Tables 1.2 and 1.4), while polymers for soft tissue applications (Tables 1.3 and 1.5). However, a closer look at Tables 1.2 and 1.4 reveals that the elastic moduli of metals and ceramics are at least 10 to 20 times higher than those of the hard tissues. Thus, implants made from these materials tend to be much stiffer than the tissue to which

Table 1.4 Mechanical properties of typical metallic and ceramic biomaterials, representative values only [Black and Hastings, 1998].

Material	Modulus (GPa)	Tensile Strength (MPa)
Metal Alloys		
Stainless Steel	190	586
Co-Cr alloy	280	1085
Ti-alloy	116	965
Amalgam	30	58
Ceramics		
Alumina	380	300
Zirconia	220	820
Bioglass	35	42
Hydroxyapatite	95	50

Table 1.5 Mechanical properties of typical polymeric biomaterials, representative values only [Black and Hastings, 1998].

Material	Modulus (GPa)	Tensile Strength (MPa)
Polyethylene (PE)	0.88	35
Polyurethane (PU)	0.02	35
Polytetrafluoroethylene (PTFE)	0.5	27.5
Polyacetal (PA)	2.1	67
Polymethylmethacrylate (PMMA)	2.55	59
Polyethylene terepthalate (PET)	2.85	61
Polyetheretherketone (PEEK)	3.3	110
Silicone Rubber (SR)	0.008	7.6
Polysulfone (PS)	2.65	75

they are attached. In orthopedic surgery, this mismatch of stiffness between the bone and the metallic or ceramic implants influences the load sharing between the bone and implant. Since the amount of stress carried by each of them is directly related to their stiffness, bone is insufficiently loaded compared to the implant. According to Wolffs law of stress related bone remodeling [Hayes and Snyder, 1981], this may lead to lower bone density and altered bone architecture. In osteosynthesis, this may affect healing of the fractured bones and may increase the risk of refracture of the bone after removal of the osteosynthesis implant, e.g. bone plate.

It has been recognized that by matching the stiffness of implant with that of the host tissues can reduce such negative effects and support desired bone tissue remodeling. In this respect, the use of low-modulus materials such as polymers appears interesting. However, low strength associated with low modulus usually impairs their potential use. Since fiber-reinforced polymers i.e. polymer composite materials offer both low elastic modulus and high strength, they have been proposed for several orthopedic applications. A further merit of composite materials is that by controlling the volume fractions and local and global arrangement of reinforcement phase, the properties and design of an implant can be varied and tailored to suit the mechanical and physiological conditions of the host tissues. It is therefore suggested that composite materials offer a greater potential of structural biocompatibility than the homogenous monolithic materials.

Composite materials offer several other significant advantages over metal alloys and ceramics, e.g. absence of corrosion and release of allergenic metal ions such as Nickel or Chromium, high fracture toughness and higher resistance against fatigue failure [Hastings, 1983; Tayton, 1983; Tayton and Bradley, 1983]. Polymer composite are basically radiolucent materials, however, their radio transparency can be adjusted by adding contrast medium to the polymer. Moreover the polymer composite materials are highly compatible with the modern diagnostic methods such as computed tomography (CT) and magnetic resonance imaging (MRI) as they show very low X-ray scattering and their magnetic susceptibility is very close to that of human tissue. Considering their light weight and superior mechanical properties, the polymer composites are also used as structural components of these imaging devices. For some applications as in dental implants, polymer composites can offer better aesthetic characteristic. Furthermore,

since implants from polymer composites can be manufactured using high throughput technologies e.g. injection molding, net shape pressing and high speed machining, they become competitive to metal implants from the point of view of cost management too.

1.3 Classification of Composite Materials

There are several means which can be used to classify composites in applications. Figure 1.2 shows main types of bio-composites according to their reinforcement forms. From Fig. 1.2, we can see that there are typically three kinds of reinforcements, i.e. short fibers, continuous fibers, and particulates (powders). All of them have been used in the development of composites for bio-medical applications, such as screws and total hip replacement stems made from short fiber reinforcements (Figs. 1.3 [Tognini, Ph.D. Thesis, ETH Zurich, 2001] and 1.4 [Semadeni, Ph.D. Thesis, ETH Zurich, 1999]), orthopedic bone plates fabricated using unidirectional (UD) laminae or multidirectional tape laminates (Fig. 1.5) [Evans and Gregson, 1998], and powder reinforced dental composites [Nicholson, 1998; Moszner and Salz, 2001]. Another classification for biocomposites

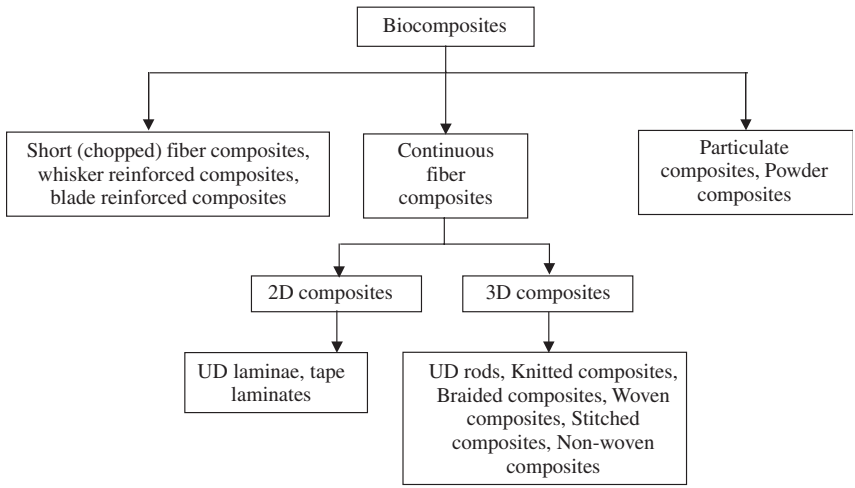


Fig. 1.2 Classification of biocomposites based on their reinforcement form.

Fig. 1.3 Endless carbon fiber reinforced PEEK matrix medical screws made by Composite Flow Molding, carbon fiber volume content 62% (by courtesy of Icotec AG, Switzerland) [R. Tognini, Ph.D. Thesis, ETH Zurich, 2001].

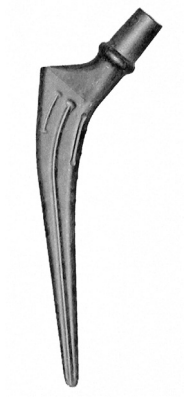


Fig. 1.4 Hip endoprosthesis stem, injection molded, chopped long fiber reinforced PEEK, fiber volume content 50% [M. Semadeni, Ph.D. Thesis, ETH Zurich, 1999].

is based on their biodegradability, i.e. fully resorbable, partially resorbable, and nonresorbable composites, as shown in Fig. 1.6.

Resorbable biocomposites are made from those fibers and matrices both of which are fully absorbable in the body. Those biocomposites are currently and intensively investigated for internal fracture fixation applications. When a metal fixator is used, a second operation generally has to be performed to remove the implants when the fractured bone has healed

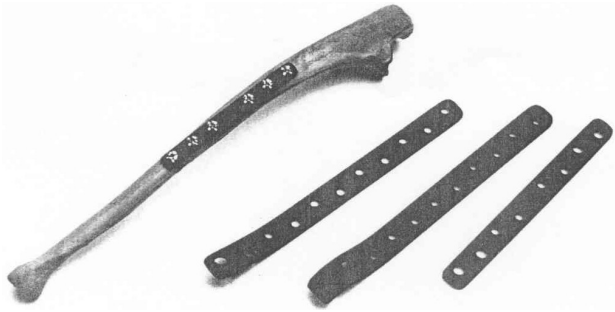


Fig. 1.5 Carbon fiber reinforced epoxy composite bone plates (Evans and Gregson, Biomaterials, Vol. 19, No. 15, pp. 1329–1342, 1998).

completely. This would cause the patient additional risk, pain and expenditure. Such an operation can be avoided if a fully resorbable fixator is used. Most work in the literature on fully resorbable biocomposite fracture fixators has been done based on the group of PLA (polylactic acid) polymers. The reason is that PLAs possess two major characteristics that make them an extremely attractive bioabsorbable material [Alexander, 1996]: (1) they can degrade inside the body in a rate that can be controlled, e.g. by varying molecular weight, the share of their enantiomers L and D-lactide or copolymerising it with PGA (polyglycolic acid) polymer, and (2) and, if crystallization of the PLA-polymer is prevented, their degradation products are nontoxic, biocompatible, and easily metabolized. The main problem of those composites is the coordination of the degradation behavior of both phases and, especially, of the interphase between both.

Partially resorbable biocomposites have been fabricated using non-absorbable reinforcing materials and absorbable matrix materials. Historically, they have been the predecessors of the fully degradable composites. However, due to severe inflammatory tissue reactions on the remaining, non-degradable phase, most of the research on these materials has been stopped. They have been investigated for a number of medical applications such as bone replacements, bone cements and also internal fracture fixators. Particulate reinforced materials which have been practiced include PMMA (polymethylmethacrylate) and PBT (poly(butylene terephthalate)) as non-resorbable matrics in combination with HA or PLA's,

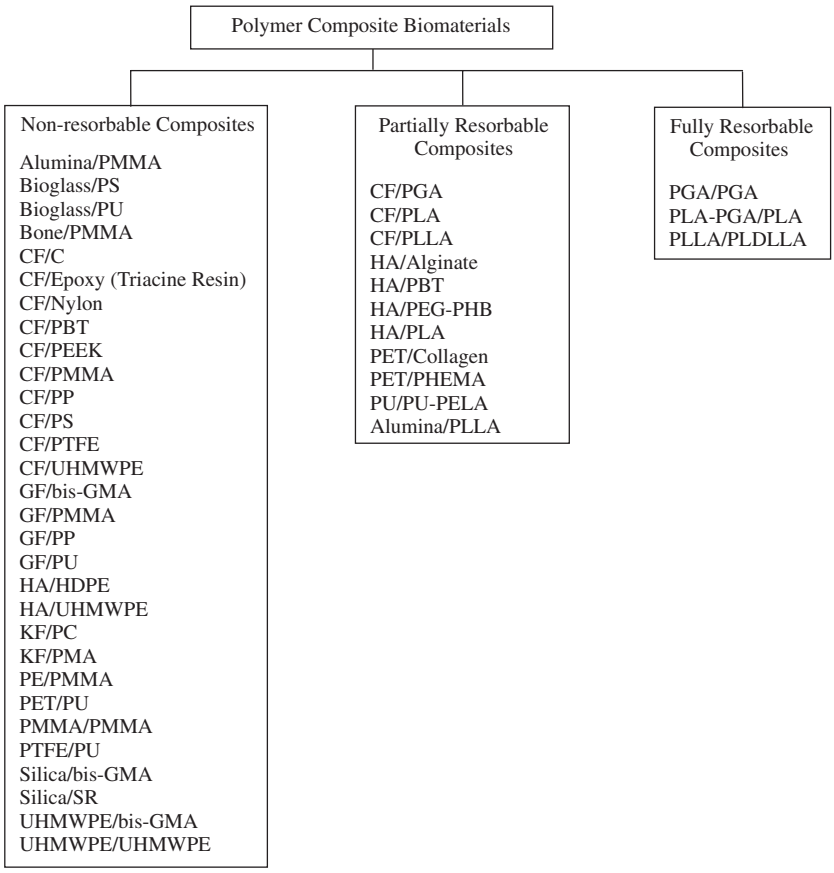


Fig. 1.6 Classification of man-made polymer biocomposites based on biodegradability.

and Polyalkanoates e.g. PHB (polyhydroxybutyrate), combined with non-resorbable filler phases e.g. Alumina or Calcium Carbonate. For internal fixator application, the reinforcing material has been mainly carbon fibers whereas the matrices used have been various PLAs or PLA-PGA copolymers. The only product that raised clinical interest is a composite of polyethylene and HA being applied in some bone graft and replacement applications. In a nonresorbable biocomposite, both the reinforcing phase (fibers or particulate) and the continuous phase are nonresorbable

in the body. There is a large variety of biocomposites which are nonresorbable. They are generally used to provide specific mechanical or clinical properties unattainable with the traditional biomaterials. Currently, the most advanced use of nonresorbable composites is in implants for spinal fusion since they provide superior mechanical stability and allow proper imaging of the reconstructed or stabilized vertebral column. The other potential uses include stems of hip or knee joint prostheses, prosthetic sockets, bone plates, dental posts, external fixators, orthodontic archwires, orthodontic brackets, etc which will be described in Chapter 7 of this book.

1.4 Scope of this Book

This book focuses on polymer composites applied to bioengineering, a topic which has not been systematically addressed in a whole monograph before. There are three purposes for the authors to write the present book. First, a comprehensive survey of biocomposites from the existing literature in various medical applications, primarily focusing on hard tissues related implants, is presented. Second, mechanical (stiffness and strength) designs of various fibrous polymer matrix composites are described only based on their constituent properties. These composites can be tailored to different biomedical applications. For this purpose, a mechanics of composite theory is presented systematically. Finally, a number of typical design and development examples involved with biocomposites are shown in the book.

Although polymer composites have been recognized as potential candidates for medical devices, implants and substitutes, the majority of them are still limited to laboratory investigation level at the present. A great body of studies has accumulated concerning various biomedical applications ranging from the hard tissues to the soft tissues. These study reports have been broadly distributed in many sources of literature publications. There is a need to review and evaluate the contents of these studies so that the non-specialist reader can appreciate the current understanding of polymer biocomposites and that he or she can be stimulated for future investigations in biocomposite science and engineering. Thus, an effort has been made in this book to summarize and survey the various biomedical applications of polymer composites so far achieved.

While a number of issues affect the widespread employment of polymer composites in bioengineering, the technical need for the design and analysis of composite materials and structures remains in place, as an increased use of biocomposites also requires taking full advantages of the material properties together with manufacturing techniques available. For a synthetic composite especially made from continuous or discontinuous fiber reinforcement, its mechanical as well as physiological properties are dependent on a number of variables. The parameters that will influence the composite properties include the mechanical and physiological properties of its constituent materials, constituent contents, reinforcement form, structure, and arrangement pattern in the matrix, interface bonding between the reinforcement and the matrix phases, and so on. Varying these parameters can result in composites with different performances. Thus, a design related problem is to achieve a polymer composite with optimal mechanical as well as physiological performance by choosing suitable values of the design parameters. This is possible only when the composite properties can be quantitatively represented as the functions of those design variables. The micromechanics theory can be applied to accurately estimate the composite properties in terms of its constituent properties and geometrical parameters.

In this book, micromechanics models of the stiffness and strength are presented. Composite elastic behavior, its inelastic and strength properties can be estimated by rigorous application of micromechanics. The detailed development of the model is not shown in the book, but can be found in cited literature [Huang, 2000]. Attention has been focused on its wide applicability. The analysis and designing procedures for various fiber composites including unidirectional lamina, multidirectional tape laminate, woven, braided, and knitted fabric reinforced composites are described in the book. The strength characteristics of any continuous fiber reinforced composite can be simulated, as long as the fiber orientation in the composite can be identified. Prediction of the mechanical properties of a fibrous composite primarily involves an analysis of the geometry of the fibrous structure in the composite. Once an accurate knowledge has been obtained of the relationship between the mechanical characteristics of the composite and the material properties and geometrical structure of its constituents, stiffness and strength designs can be performed. This has been done in the book for composites reinforced with a number of typical fiber preforms and structures.

The third major issue addressed in the book is the design and development examples of several medical devices and implants using polymer composites. These devices are supposed to be used for hard tissue applications, including Prosthetic socket, Dental post, External fixator, Bone plate, Orthodontic archwire, Orthodontic bracket, Total hip replacement, and Composite screws and pins. Fabrication and mechanical testing of them have been shown, with comparisons with other clinically used medical devices if possible. Among them, some devices such as bone plate and archwire are primary load carrying elements. Their ultimate strength behavior must be targeted during the design. It is noted that both of them are mainly subjected to lateral loading (bending) in their clinical application. According to current understanding, the estimation of composite bending strength remains a challenge. In this book, design procedures for those medical devices using continuous fiber reinforced polymer matrix composites are described in sufficient detail. We believe that comparable procedures can be followed if other critical designs are to be made.

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