

1 Introduction

Goals

After reading this chapter the student will understand the following.

- History of implants and biomaterials.
- Various definitions for biomaterials.
- Different types of chemical bonds.
- Basic families of materials.
- Future directions for the progress in biomaterials.

The Rig Veda, one of the four sacred Sanskrit books of ancient India that were compiled between 3500 and 1800 BC, relates the story of a warrior queen named Vishpla, who lost a leg in battle and was fitted with an iron leg after the wound healed. There is also mention of lacerated limbs treated with sutures. Sushruta, a renowned Indian physician from *circa* 600 BC, wrote a very comprehensive treatise describing various ailments as well as surgical techniques. His technique for nose reconstruction using a rotated skin flap is still used in modern times. Sutures made of vegetable fibers, leather, tendons, and horse hair were commonly used in his time. There are also reports of the use of linen sutures in Egypt 4000 years ago.¹

These ancient records show that, since time immemorial, humans have tried to restore the function of limbs or organs that have ceased to perform adequately due to trauma or disease. Often, this was attempted through the use of materials either made or shaped by humans and used external to the body. These were the earliest form of biomaterials. Although examples of successful external prosthetic devices can be found in history, materials placed inside the body, also known as implants, were usually not viable due to infection. This changed in the 1860s with the advent of aseptic surgical techniques introduced by Dr. J. Lister. The discovery of antibiotics in the mid 1900s also reduced the incidence of infections related to surgery. Today, implants are very successful and are used in a wide

variety of applications in the practice of medicine, improving the quality of life for millions and saving countless lives. However, the successes of today have come after a long history of trial and error and scientific endeavor.

Perhaps the most common implants in ancient times were dental in nature and thus, these implants provide an interesting history of progress over the millennia. Human remains from the first century AD recovered from a Gallo-Roman necropolis in France show the use of an iron implant to replace a tooth. In 1923, an archeological dig in Honduras uncovered pieces of shells that were used as a dental implant for a young woman in AD 600. In the Middle East, ivory implants have been discovered with skeletons from the Middle Ages. In more modern times, in the early 1800s, gold posts were placed in sockets immediately after tooth extraction with limited results. In the years following, other metals such as platinum were also investigated. In the 1940s, the Strock brothers from Boston tested Vitallium dental implants. A major breakthrough came in 1952 when Ingvar Branemark from Sweden tried titanium implants and found them to attach well to bone. Such implants provide a post onto which artificial teeth or crowns can be attached. These implants are in use even today.

Box 1.1

- In coronary artery disease, blood vessels supplying blood to the heart tissue are clogged leading to heart attacks.
- In 1977, Andreas Gruentzig introduced a procedure called balloon angioplasty where a balloon mounted on a catheter is inserted into the artery and inflated at the site of the blockage to compress the plaque against the arterial wall thus restoring blood flow. The procedure was very successful but a large percent of the patients suffered a subsequent narrowing of the artery called restenosis.
- In 1978, after hearing a lecture by Gruentzig, Julio Palmaz conceived the idea of a stent – a metal scaffold inserted into the artery and expanded using a balloon to keep the artery propped open.
- He initially experimented with wires wrapped on pins inserted into pencils, and wires soldered together. He finally got his inspiration from a tool left behind in his garage by a worker.
- Working in San Antonio he partnered with a cardiologist, Richard Schatz, and a restaurateur and investor named Phil Ramono to patent and develop the stent.
- Johnson & Johnson licensed the technology, which was introduced into the market in 1991.
- Today the stent is used in more than two million procedures annually and is credited with saving numerous lives.

Table 1.1 Significant developments in the history of biomaterials

Year	Individual(s)	Development
Prehistoric		Various sutures, metal wires, pins
1860s	J. Lister	Aseptic surgical technique
1886	C. Hansmann	Plates, screws for fracture fixation
1887	Adolf Fick	Glass contact lens
1912	W. D. Sherman	Vanadium steel plates and screws
1930–31	A. S. Hayman, M. C. Lidwill	Portable pacemaker
1936–37	A. E. Strock	Vitallium for dental implants
1938	Philip Wiles	Total hip replacement
1949	Sir Harold Ridley	Intraocular lens
1951	G. K. McKee, J. Watson-Farrar	Biomechanically successful total hip design
1952	Ingvar Branemark	Osteointegration of metal implants
1952	A. B. Voorhees	Prosthetic vascular graft
1958	Earl E. Bakken	Wearable pacemaker
1959	Sir John Charnley	Use of polymer in total joints
1960	L. Edwards, A. Starr	Mitral valve replacement
1981	W. Kolff and others	Implantable artificial heart
1980s	Julio Palmaz	Balloon expandable stent

Adapted from reference 2.

Ever since the introduction of aseptic surgical techniques by Lister in the 1860s, there has been rapid progress in the development of biomaterials and implants for a variety of applications in the body (Table 1.1) including dental implants, artificial total joints for hips (Figure 1.1), shoulders (Figure 1.2), and knees (Figure 1.3), spinal implants (Figure 1.4), fracture fixation rods and plates, cardiac pacemakers, stents to keep blood vessels open, and endovascular grafts to repair aneurysms. Although historically metals have been extensively used as biomaterials, there has been a significant increase in the use of ceramics and polymers over the past 40–50 years, thereby leading to a plethora of implants now available for clinical applications.

4 Introduction



Figure 1.1

An implant for total hip replacement. The long metal stem is inserted into the medullary cavity of the femur. The metal hemisphere is lined with a polymer and is fixed to the acetabulum on the pelvic side. (Courtesy of Exactech, Inc.)



Figure 1.2

An implant for total shoulder replacement. The long metal stem is inserted into the medullary cavity of the humerus. The polymer component serves as a bearing surface. (Courtesy of Exactech, Inc.)

**Figure 1.3**

An implant for total knee replacement. The polymer component is made out of ultrahigh molecular weight polyethylene and serves as a bearing surface (Courtesy of Exactech, Inc.)

**Figure 1.4**

A spinal implant made of the polymer polyetheretherketone (PEEK). The fenestrated design facilitates the introduction of bone graft. (Courtesy of Exactech, Inc.)

1.1 Definitions

Biomaterials do not necessarily have to be natural materials as the name may suggest. In 1974, at the 6th Annual International Biomaterials Symposium held at Clemson University, a biomaterial was defined as

*... a systemically, pharmacologically inert substance designed for implantation within or incorporation with a living system.*³

This definition reflected the understanding of the use and function of implants at that time and it imposed the requirement of inertness on the material. Through the years, as science has progressed and resulted in a better understanding of the interaction between biology and materials in the body, the definition of biomaterials has changed as well.

In 1986, at a consensus conference of the European Society for Biomaterials, a biomaterial was defined as

*a nonviable material used in a medical device, intended to interact with biological systems.*⁴

Perhaps an even more complete definition was provided by Williams⁵ as:

a material intended to interface with biological systems to evaluate, treat, augment, or replace any tissue, organ, or function of the body.

Box 1.2

- Today, hip joint replacement surgery is a common therapy to treat hip joints affected by acute arthritis or trauma. The implants represent a ball and socket joint and often comprise a polymeric cup with a metal or ceramic ball moving in it. But it took a lot of experimentation to reach this point.
- In 1925, M.N. Smith-Petersen, a Boston-based surgeon, tried to re-surface the natural ball of the joint using a glass hemisphere but the glass failed under stress.
- In the 1950s a procedure called hemiarthroplasty was popular. This consisted of leaving the natural cup in place but replacing the ball component of the joint.
- In the 1960s, John Charnley from England developed a full hip replacement implant with a Teflon cup and a metal ball attached to a metal stem that was inserted into the marrow cavity. When the Teflon failed, he tried polyethylene with success. The polyethylene–metal combination is still used to this day.

Thus, the definition of biomaterials has changed over the years as progress in science and technology has made it possible to:

- use implants to rapidly restore organ and/or tissue function,

7 1.3 Types of bonds in materials

- influence the long term viability of implants by better designing the biomaterial–biology interface, and
- drive the inevitable biological response in desired directions.

1.2 Changing focus

Not only has the definition of biomaterials been changed and refined over the years, but so has the emphasis on biology – the *bio* aspect of biomaterials. From the earliest days of biomaterials through the middle of the twentieth century, work on biomaterials concentrated on basic material properties such as strength, stiffness, ductility, fracture resistance, and corrosion. Over the ensuing decades, there was growing realization that biology plays a significant role in the success of an implant and should be taken into account in its design. In more recent years, emphasis has turned to the manipulation and tailoring of the biological response using principles rooted in the natural sciences. Biomaterials do not necessarily have to be inert in the body, but rather should interact with it at the cellular and molecular levels to ensure the success of the implant.

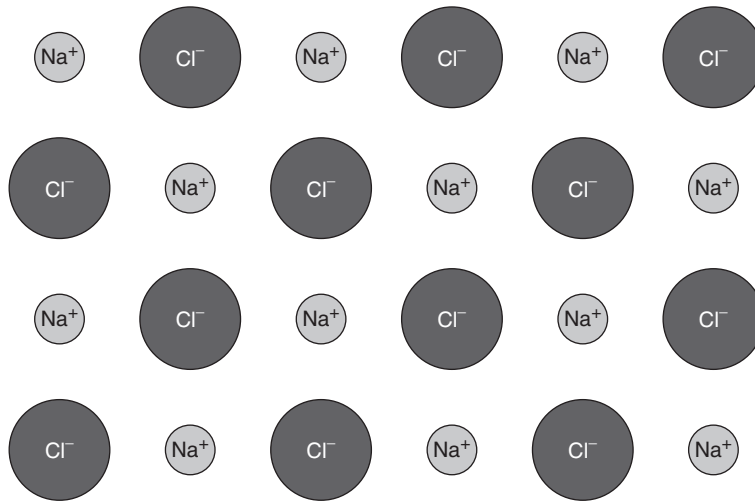
Although the application of biomaterials is unique, they still fundamentally belong to the same families of materials as those used for various other industries including construction, aerospace and sports equipment. In this respect, biomaterials are no different from most other materials. In the next few sections of this chapter, we will cover some of the basics types of chemical bonds that bind atoms to form materials as well as the major types of materials. An understanding of the various bonds is important, as bonds are responsible for a variety of material properties.

1.3 Types of bonds in materials

At a high level of classification, materials can be divided into two classes: natural and synthetic. At a more fundamental level, materials can be separated into different general categories based on their molecular structure and the type of bonding between their atoms. Since the latter plays a primary role in determining the properties of a biomaterial, it is important to first gain an understanding of the different types of bonds.

1.3.1 Ionic bonds

Ionic bonds are based on one atom donating an electron to form a cation and another atom accepting the electron to form an anion. The charged anion and

**Figure 1.5**

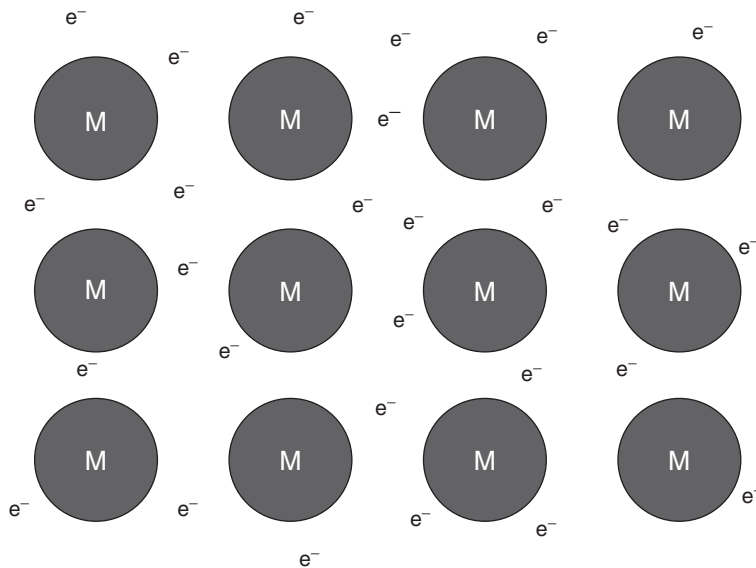
Ionic bonding between Na and Cl atoms.

cation are then held together by strong electrostatic attraction to create an ionic bond. A common example of such bonding is in sodium chloride (NaCl), where the sodium (Na) atom transfers one of its valence electrons to the chlorine (Cl) atom (Figure 1.5). After the transfer of an electron, the Na atom becomes a net positively charged ion and is represented as Na^+ . The transfer of an electron to the Cl atom renders it a negatively charged ion, which is represented as Cl^- . The Na^+ and Cl^- ions are then held together by Coulombic forces.

To reduce the anion–anion or cation–cation repulsion, each anion is surrounded by as many cations as possible and vice versa. In general, ionic bonding is non-directional and the bond has equal strength in all directions. These properties give rise to highly ordered structures, which result in solids that have high strength and stiffness but are relatively brittle due to the inability of atoms to move in response to external forces. Additionally, the electrons are closely held in place and are not available for charge transfer, making the materials bad conductors of electricity and heat. Bonding energies for ionic bonds are generally high and usually range between 600 and 1500 kJ/mol, which is manifested in high melting temperatures.

1.3.2 Metallic bonds

Metal atoms are good donors of electrons and metallic bonds are characterized by tightly packed positive ions or cores surrounded by electrons. As shown in

9 1.3 Types of bonds in materials**Figure 1.6**

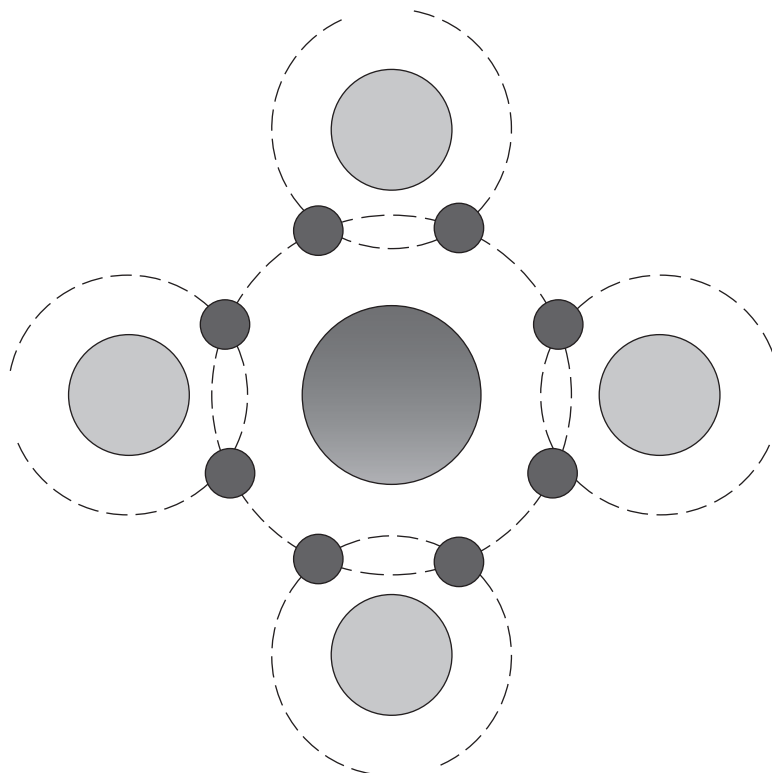
Metallic bonds showing positive ions surrounded by electron cloud.

Figure 1.6, the valence electrons are not firmly attached to any one atom but form an electron cloud to float and drift through the material.

The cores are highly organized structures, which consist of the nuclei and the remaining non-valence electrons. Having a net positive charge, these cores would repel each other were it not for the electron cloud surrounding them and working as an “adhesive.” Additionally, the loose electron cloud allows for good charge transfer, making the metals good conductors of electricity and heat. Bonding energies can vary in metallic bonds, as shown by the examples of mercury (0.7 eV/atom) and tungsten (8.8 eV/atom). The non-directional nature of this bond gives planes of these ions the ability to slide on each other, thereby allowing the materials to deform under applied forces.

1.3.3 Covalent bonds

Some atoms have the ability to share electrons in their outer shells with other atoms. As shown in Figure 1.7, bonds formed by this sharing of electrons are called covalent bonds. Many molecules comprising dissimilar elements use covalent bonds. Examples include organic materials such as ethylene (C_2H_6), which is a gas, or its polymerized form polyethylene, which is a solid. Other non-metallic

**Figure 1.7**

Covalent bonds showing atoms sharing electrons in their outer orbits.

elements also form molecules (Cl_2 , F_2) using covalent bonds. Carbon and silicon use covalent bonds to form molecules such as silicon carbide.

Covalent bonds are strong and highly directional. However, the rotational ability of atoms around bonds based on single-electron sharing (single bonds) generates flexibility, and materials with such bonds usually have good deformational characteristics. As with ionic bonds, the electrons in these bonds are held in place, and these materials are generally not good conductors of electricity and heat.

1.3.4 Secondary bonds

In addition to the three primary bonds described above, there are weaker bonds such as *van der Waals* and *hydrogen bonds*. Such bonds are based on the attraction between atomic or molecular dipoles. Dipoles are formed when there is uneven or asymmetrical charge distribution, causing separation between the