CHAPTER 1

Introduction to Biomaterials in Orthopaedic Surgery

1.1 Definition of Biomaterial

A *biomaterial* is a material that interacts with human tissue and body fluids to treat, improve, or replace anatomical element(s) of the human body. Biomaterial devices used in orthopaedics are commonly called *implants*; these are manufactured for a great number of orthopaedic applications. Biological materials such as human bone allografts (transplants of tissue between genetically different individuals) are considered to be biomaterials because they are used in many cases in orthopaedic surgery.

Figure 1.1(a) shows a massive proximal femur bone allograft without a head. It replaces a patient's proximal femur. Figure 1.1(b) shows a femoral stem component of a hip replacement device, which is put in place of the massive femur allograft; this system is called hip alloprosthesis.

1.2 Interaction of Biomaterials with the Human Body

Clinical results in orthopaedics have demonstrated that a great need exists to find new and better biomaterials that will help satisfy the minimum requirements for orthopaedic devices to perform correctly on a long-term basis. The main fundamental requirements that orthopaedic devices must fulfill in order to function adequately are summarized in this section.

1.2.1 Biocompatibility

Biocompatibility is the primary characteristic that a medical device should have in any orthopaedic application; that is, it must not adversely affect the

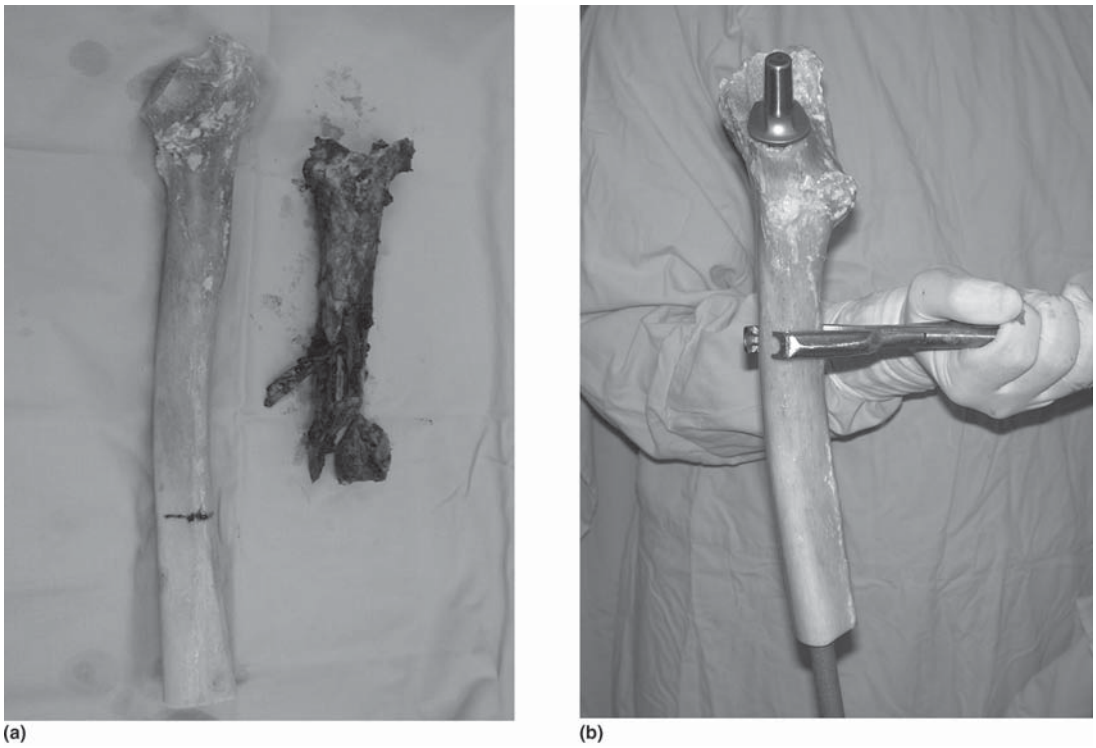

Fig. 1.1 Hip alloprosthesis. (a) Massive proximal femur replacement allograft and patient's femur. (b) Femoral stem component in place. Courtesy of Carlos Cuervo-Lozano M.D.

local and systemic host environment of interaction (bone, soft tissues, ionic composition of plasma, as well as intra- and extracellular fluids).

1.2.2 Appropriate Design and Manufacturability of Implants

Finite element analysis is a powerful analytical tool used in the design of joint replacement prostheses. Currently modern manufacturing processes are necessary to guarantee the quality needed in orthopaedic devices.

1.2.3 Mechanical and Biological Stabilities

The orthopaedic surgeon should seek the biomechanical stability of the implant, and the human body will take care of the biological stability.

1.2.4 Properties of Biomaterials

Some of the most important properties of biomaterials that should be carefully studied and analyzed in their applications are tensile strength, yield strength, elastic modulus, corrosion and fatigue resistance, surface finish, creep, and hardness.

1.2.5 Resistance to Implant Wear and Aseptic Loosening

Implant wear and aseptic loosening are very important failure problems that should be taken into consideration when dealing with long-term prosthetic devices.

1.2.6 Corrosion Resistance

Corrosion of metallic implants that occur within the human body constitutes an ion source that may potentially affect the local and systemic host environment. Therefore, an important property that must be considered is the corrosion resistance of the metallic implants.

1.3 Biomaterial Types in Orthopaedics

It is important for orthopaedic surgeons to understand the nature of biomaterials, their structural configurations, and their properties, as well as the effects of their interaction with soft and hard tissues, blood, and intra- and extracellular fluids of the human body.

The orthopaedics field has benefited from the great efforts of many orthopaedic surgeons, experimental surgery laboratories, and research centers and from research work at universities, academies, societies, scientific organizations, and many interdisciplinary groups. However, many challenges remain to be conquered in the development of new biomaterials that will improve the long-term performance of clinical results in orthopaedic surgery.

The main biomaterials used in orthopaedic surgery are divided into two groups: metals and nonmetals.

1.3.1 Metals

The use of metals in therapeutic procedures dates back several centuries. Metallic implants were used in the 17th century. In the 18th century a metal screw implant was used for the first time.

The majority of elements in the periodic table are metals. Metallic biomaterials have their main applications in load-bearing systems such as hip and knee prostheses and for the fixation of internal and external bone fractures. It is very important to know the physical and chemical properties of the different metallic materials used in orthopaedic surgery as well as their interaction with the host tissue of the human body.

The metallic implants most widely used in orthopaedic surgery are:

- Low carbon grade austenitic stainless steels: 316L
- Titanium and titanium-base alloys: commercially pure titanium (CP Ti), Ti-6Al-4V, and other titanium-base alloys
- Cobalt alloys: Co-Cr-Mo, and other cobalt-base alloys

1.3.2 Nonmetals

Three main subgroups make up this category: polymers, ceramics, and composites.

1.3.2.1 Polymers are organic materials that form large chains made up of many repeating units. Polymers are extensively used in joint replacement components. Currently the polymers most widely used in joint replacements are:

- Ultrahigh molecular weight polyethylene (UHMWPE)
- Acrylic bone cements
- Thermoplastic polyether ether ketone (PEEK)
- Bioabsorbables

1.3.2.2 Ceramics are polycrystalline materials. The great majority are compounds made up of metallic as well as nonmetallic elements; they generally have ionic bonds or ionic with some covalent bonds.

The main characteristics of ceramic materials are hardness and brittleness. They work mainly on compression forces; on tension forces, their behavior is poor.

The main ceramics in orthopaedic surgery and their applications are:

- Alumina, Al_2O_3, used for acetabular and femoral components
- Zirconia, ZrO_2, used for acetabular and femoral components
- Hydroxyapatite, $Ca_{10}(PO_4)_6(OH)_2$, used for coating stem femoral components to integrate the surface material to the bone

1.3.2.3 Composites. Composite biomaterials are made with a filler (reinforcement) addition to a matrix material in order to obtain properties that improve every one of the components. This means that the composite materials may have several phases. Some matrix materials may be combined with different types of fillers. Polymers containing particulate fillers are known as particulate composites.

The following composites are considered in the orthopaedic devices:

- Fiber-reinforced polymers
- Aggregates to polymethyl methacrylate (PMMA)

1.4 Bone Allografts

Bone allografts are commonly used as implants in orthopaedic surgery. They are procured using aseptic techniques and are preserved according to their storage needs:

- *Freeze dried/lyophilized:* tissue dehydrated for storage by changing the water content of frozen tissue to a gaseous state in a vacuum that extracts moisture

- *Fresh:* bone allograft stored for a maximum of 1 week at a temperature of 4 °C
- *Frozen:* bone allograft stored for up to 5 years at a temperature of −70 or −80 °C
- *Cryopreserved:* tissue frozen with the addition of, or placed in a solution containing, a cryoprotectant agent such as glycerol or dimethylsulfoxide
- *Demineralized:* demineralized bone matrix that is osteoconductive and is mainly used for filling bone and/or cavitary defects, not used for structural purposes

1.5 Orthopaedic Implants

Orthopaedic implants can be divided into four main groups:

- Osteosynthesis (stabilization and fixation of bone)
- Joint replacements
- Nonconventional modular tumor implants
- Spine implants

1.5.1 Osteosynthesis

In 1949 Professor Robert Danis M.D. of the Brussels Faculty of Medicine, published his book *Théorie et Practique de L'ostéosynthèse*. His main and most remarkable contribution was the rigid fracture fixation by compressive forces of the main bone fragments previously reduced and then mechanically stabilized with a plate, resulting in an early bone fracture consolidation.

The evolution of modern osteosynthesis started with the publication of Professor Danis. He made great contributions to the scientific development of internal bone fracture fixation. Maurice E. Müller M.D., Martin Allgöwer M.D., Robert Schneider M.D., Hans R. Willenegger M.D., and other colleagues made up a team to extend the basic concepts published by Professor Danis. In 1958 the group Arbeitsgemeinschaft für Osteosynthesefragen (AO) was founded, and in 1984 the Association for the Study of Internal Fixation (ASIF) was constituted. The AO group published in 1969 the first edition of the *Manual of Internal Fixation*. In 1979 the second edition was published; both editions have been reprinted. The third edition was published in 1991.

The main implants used in osteosynthesis are screws, plates, nails, and pins, in a number of different shapes and forms to fulfill the required characteristics to successfully consolidate internal and external bone fracture fixation. Relevant contributions of many orthopaedic surgeons have extended their applications, including stabilizing multitraumatized patients and correcting deformities and longitude discrepancies, among others.

Patient diagnosis, surgical technique, and application of biomechanical and biomaterials knowledge are the fundamental aspects to achieve bone

fracture consolidation. Depending on each clinical case, once these systems (for example, a plate and its screws, a blocked nail, etc.) have consolidated bone fractures, the devices might be removed.

1.5.2 Joint Replacements

Prosthetic devices are implanted in the human body to replace the affected joint in order to eliminate pain and restore its normal function. This manuscript considers mainly hip and knee joint replacements because they are by far the most widely used in orthopaedic surgery. It is well known that femoral stem joint replacements have a mean useful life which, among other factors, is intimately linked to wear particles.

1.5.2.1 Hip Joint Replacements. In the first half of the 20th century, a total hip replacement was designed and used in patients; however, the initial results were not completely satisfactory. The main concerns at that time, besides the implant design, were the surface bearing materials of the metal-on-metal and the metal-on-polymer femoral-acetabular component types. Also, methods for implant fixation (cemented and cementless femoral stem components) needed to be established.

Sir John Charnley did not use the metal-on-metal femoral acetabular component because of frictional torque in the bearing of metallic surfaces. In 1962, he found a high-density polyethylene to be a more adequate bearing surface. For the femoral stem fixation, Dr. Charnley used PMMA bone cement and finger packing as the cement insertion technique. The postoperative problems were the femoral stem subsidence.

In 1979, Carl Zweymüller, M.D., started to use a cementless tapered titanium femoral stem. A great number of total hip replacements, cemented and cementless prosthetic devices, have been developed since the relevant early design of Dr. Charnley's total hip replacement prosthetic device.

The femoral-acetabular component types currently used are:

- Metal-on-polyethylene
- Metal-on-metal
- Ceramic-on-polyethylene
- Ceramic-on-ceramic

An excellent publication that considers cemented, cementless, and hybrid implants with different designs is *The Swedish Total Hip Replacement Register* (see "References for Further Reading"). It incorporates very important clinical results of implant survival in patients with an index diagnosis of osteoarthritis, with revision due to aseptic loosening as the end point.

Currently, persistent problems remain to be solved with total hip replacements, including implant wear, aseptic loosening, and osteolysis.

1.5.2.2 Knee Joint Replacements. There are two types of the knee joint replacement: total and unicondylar.

Types of total knee replacements are:

- Nonconstrained knee replacements
- Semiconstrained knee replacements
- Constrained knee replacements

The unicondylar knee replacement is usually called half replacement. It is recommended when half of the damaged joint is to be replaced.

The implant biomaterials used in total knee replacements are titanium-base alloys, cobalt-chromium alloys, ceramics, and cross-linked ultrahigh molecular weight polyethylene. The improvements on implant materials and manufacturing processes have made great contributions to the long-term performance of these prosthetic devices.

1.5.3 Nonconventional Modular Tumor Implants

The fundamental objective in cases of oncology orthopaedics is the preservation of the affected parts. In these cases the use of bone allografts, the tumor modular prosthesis, or a combination of both is usually required. The main nonconventional modular tumor implants are:

- Nonconventional modular tumor implants with femoral replacement
- Nonconventional modular tumor implants with tibia replacement

For cases of children and adolescents who are still growing and have bone sarcoma tumors in the lower extremities, and where there is a length discrepancy, both noninvasive or invasive extendible tumor modular prosthesis can be used.

The technological development of orthopaedic implants has been extremely important in the successful results of many clinical cases. However, there is still a lot of work left to reach the expected results, which means the continuous search for new and better biomaterials to satisfy the day-to-day needs in orthopaedic surgery.

1.5.4 Spine Implants

Thanks to the instruments designed by Paul Harrington M.D., modern spine surgery started in 1950. From then on, it has been used to correct neuromuscular defects, especially those associated with poliomyelitis. Since the beginning of the 21st century there has been an increase in the manufacturing of sophisticated implants to treat different spine pathologies.

1.6 International Standards for Orthopaedic Devices

The preparation and publication of material standards is an important activity. Test protocols were established by different institutions in different

countries such as ASTM International and the International Organization for Standardization (ISO). The main efforts of all institutions are directed to obtain biocompatible and inexpensive orthopaedic devices, as well as safe and affordable material that responds to the medical requisites of the surgeon and, most important, to the needs of the patient.

Many publications, worldwide conferences, and society and academy meetings have presented clinical results of implants used in orthopaedic surgery. The final results indicate a growing interest and considerable activity in the extraordinary and expanding field of biomaterials in orthopaedic surgery.

1.6.1 ASTM Standards for Orthopaedic Devices*

The ASTM Committee F04 on Medical and Surgical Materials and Devices was created in 1962. The Committee, with a membership of approximately 880 members, currently has jurisdiction of over 250 standards, published in the *Annual Book of ASTM Standards,* Volume 13.01. Committee F04 has 34 technical subcommittees that have jurisdiction over these standards.

The technical subcommittees of F04 collectively encompass the following five primary areas:

- *Resources:* addresses standards for materials such as ceramics, metals, and polymers; it also includes standards to address the information needed on biocompatibility, test methodology, and magnetic resonance imaging.
- *Orthopaedic Devices:* focuses on methods and practices for osteosynthesis, arthroplasty, and spinal devices.
- *Medical and Surgical Devices:* pertain mostly to cardiology, neurology, audiology, gastroenterology, and plastic surgery.
- *Tissue Engineered Medical Products (TEMPs):* focuses on materials needed in, and practices and methods for, the development and applications of TEMPs technologies.
- *Computer-Assisted Orthopaedic Surgical Systems (CAOS):* writes standards for system accuracy.

1.6.2 ISO Standards for Orthopaedic Devices**

The International Organization for Standardization, known as ISO, is an International-standard-setting body composed of representatives from various national standards organizations. ISO was founded on February 23, 1947, and its headquarters is in Geneva Switzerland. The word ISO is based on the Greek word isos meaning equal and is applied for any country

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and in any language. ISO has 157 national members out of the 195 total countries in the world. The ISO catalog includes more than 17,000 published International Standards.

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EDUCATIONAL OBJECTIVES

1. In your own words define a biomaterial. Compare it with the definition given in the book.
2. What is the first and most important property of a biomaterial? Explain.
3. What metallic biomaterials are the most widely used in osteosynthesis?
4. What metallic alloy used in hip and knee replacements is called "the work horse"?
5. What is the most widely used polymer surface bearing material in hip and knee replacements?
6. What are the two main characteristics of the Co-Cr-Mo femoral head components that are usually preferred over other metallic alloys?
7. Which of the bone allografts mentioned in Chapter 1 is osteogenic? Explain.
8. Are bone allografts considered to be biomaterials? Explain.
9. Compare and contrast metallic alloy and a composite biomaterial
10. What metallic biomaterial is the most biocompatible with the human body? Explain.

11. What is the meaning of CP Ti and how many grades of unalloyed titanium are used in orthopaedics?
12. After succeeding with metal on polyethylene as bearing surfaces in the femoral-acetabular components on cemented hip stems, what was the usual problem that Dr. Charnley always had in cemented stems? Explain.