15.1 INTRODUCTION

Before the circulation of blood was discovered by Harvey in 1628 (Lee, 2000) and before Vesalius systematically documented the anatomy of the human body in 1543 (Venzmer, 1968), the structural function of the skeletal system was understood. Bone protected organs such as the brain and provided the frame on which the soft tissues of the body were formed. Based on this basic understanding, the first medical interventions to replace bone—removed due to damage or underlying injury—were seen at least as far back as the time of the Aztecs, who are known to have used gold and silver to replace pieces of the skull following craniotomies (Sanan and Haines, 1997). The fact that bone was a living material that could heal itself was documented over 5000 years ago when the ancient Egyptians recorded techniques for setting fractures on papyrus (Peltier, 1990), and this knowledge has led to interventions designed to manipulate the fracture-healing properties of the tissue.

Our greater understanding of the overall physiology of bone did not develop until much more recent history. The complex and important role of the cellular component of bone, although only a small fraction of the overall material volume, is still being investigated. While the general properties of bone, ligament, tendon, and cartilage have been well characterized over the past century, knowledge of how these properties can be best mimicked or taken advantage of to promote tissue healing remains in its infancy.

Orthopedic tissues are affected by both the stresses that they experience on a daily basis and as a result of trauma and disease processes. Many of these injuries or pathologies require medical intervention that may be assisted through the use of engineered materials. The science behind the selection of these materials has moved from the realm of trial and error to one based on scientific theory and understanding. This chapter will give a brief overview of the natural orthopedic biomaterials—bone, cartilage, tendon, and ligament—before proceeding to a discussion of the historical development and current technology in engineered biomaterials for orthopedic applications.
15.2 NATURAL MATERIALS

15.2.1 Bone

Bone has a diverse set of physiological roles ranging from the obvious structural support and protection to maintenance of calcium homeostasis and hematopoiesis, the production of red blood cells by the bone marrow. As such, both the material and cellular characteristics of bone must be understood in order to fully appreciate the complexity of the tissue. However, to initiate this understanding, it is easier to examine the material and cellular components of bone separately at first.

**Bone’s Material Components.** From a structural standpoint, bone is essentially a composite of organic and inorganic components—namely, collagen and hydroxyapatite. Collagen is a protein with a high tensile strength and viscoelastic properties, whereas hydroxyapatite is a calcium phosphate compound with properties similar to that of a ceramic. Hydroxyapatite crystals, needlelike structures with a size on the order of an angstrom, are embedded in the sides of long collagen fibers. The collagen fibers are then arranged in sheets as parallel structures, which in turn are layered in concentric circles with the collagen fiber orientation varying between layers. The dimension about which these concentric layers of composite, or lamellae, are formed differs with the type of bone involved.

Cortical bone, or compact bone, is the dense form of the tissue that is generally called to mind when an image of bone is produced. It is found on the outer surface of all bones and comprises the majority of the shaft (or diaphysis) of long bones such as the femur. Two basic forms of cortical bone exist in humans: osteonal and lamellar. Lamellar bone is formed when the concentric layers of collagen-mineral composite are wrapped around the inner (endosteal) or outer (periosteal) surfaces of a whole bone structure. Osteonal bone involves a more complex microstructure, with the composite layers wrapped in concentric circles about a vascular, or Haversian, canal (Fig. 15.1). A group of these lamellae with its central Haversian canal form an osteon, the diameter of which can range from 150 to 250 µm for secondary (or remodeled) osteons, whereas primary osteons tend to be smaller. The axis of the osteon is generally oriented along the direction of primary loading in a bone.

![FIGURE 15.1 Scanning acoustic microscopy image of cortical bone from a human femur. Note the circular arrangement of the lamellae around the central haversian canal.](image)

Trabecular bone is formed through a different arrangement of lamellae. An individual trabeculum is a tube of wrapped lamellae on the order of 150 to 300 µm in diameter. Trabeculae can also form in the shape of plates, which have a slightly larger dimension but are again composed of parallel layers of the
collagen-mineral composite. The trabecular plates, beams, and struts are arranged into a three-dimensional structure that mimics the internal skeleton of a modern skyscraper (Fig. 15.2). The beams and plates are generally arranged in the direction of primary loading, whereas the struts provide supporting structures in an off-axis direction in order to minimize buckling. Healthy trabecular bone is “designed” to have an improved strength-to-weight ratio compared with cortical bone—it can carry a substantial amount of load without contributing added weight to the body. It is found at the ends of long bones, in the metaphyseal and epiphyseal regions, as well as in the inner portions of bones such as the vertebrae of the spine, the carpal bones of the wrist, and the flat bones of the ribs and skull.

![FIGURE 15.2 Scanning acoustic microscopy image of vertebral trabecular bone from a young individual. The vertical beams and the horizontal struts form a three-dimensional network to maximize the mechanical properties while minimizing weight.](image)

The mechanical and material properties of bone have been extensively characterized, and representative properties are listed in Table 15.1. The structural and material properties of cortical bone are approximately equal due to its low porosity. However, since the porosity and arrangement of trabecular bone play an important role in the structural properties of this phase, the material modulus may be up to 3 orders of magnitude higher than the structural modulus. It must be noted, however, that unlike those of traditional engineering materials, the properties of bone are not constant. The strength, modulus, and density can vary between individuals, between anatomic locations, and as a result of age or disease processes. Variations in the properties of bone may be a function of changes in either the structure of the tissue (e.g., how many trabeculae are present and how they are arranged) or the material of the tissue (e.g., the properties of the collagen-mineral composite itself). In healthy tissue, the material of bone changes very little, with the mineral density fairly constant at a level of 1.8 to 1.9 g/cc (Kaplan et al., 1994) and the mineral-to-collagen ratio set to about 1:1 by volume. Disease processes such as osteomalacia or osteogenesis imperfecta can affect the collagen or mineral components of bone and, as such, have a profound effect on the underlying properties of the tissue.
The structural properties of bone, even at the microscopic level, can also vary due to anatomic location (which can be seen as a design variation), age, or disease. A prime example of this is the loss of trabecular bone seen in all individuals after age 35 and exacerbated by osteoporosis. It has been shown that in the vertebrae, for example, osteoporosis results in the selective resorption of the horizontal, supporting trabeculae. The trabecular bone, which makes up all but a small fraction of the volume of the vertebral centrum, is weakened as each of the load-bearing beams is then defined by a larger characteristic length. Based on Euler’s theories, these trabeculae will be more susceptible to buckling—and hence failure—at lower loads. Figure 15.3 shows a buckled trabeculae in an image of vertebral trabecular bone from a 75-year-old.

Finally, the properties of a whole bone will be affected by the amounts of trabecular and cortical bone present and their geometric arrangement. As will be discussed later, bone is a living tissue that can

| Table 15.1 Representative Properties of Cortical and Trabecular Bone |
|---------------------------------|------------------|-----------------|
| Cortical bone                  | Compressive strength, MPa | 131–224 longitudinal |
|                                 | Tensile strength, MPa    | 106–133 transverse |
|                                 | Shear strength, MPa      | 80–172 longitudinal |
|                                 | Elastic modulus, GPa      | 51–56 transverse |
| Trabecular bone                | Tissue compressive strength, MPa | 53–70 |
|                                 | Tissue elastic modulus, MPa | 11–20 longitudinal |
|                                 | Material elastic modulus, GPa | 0.5–50 |

adapt to its loading environment. The loss of cross-sectional area in the diaphysis of a long bone, the
reduction in trabecular volume fraction, and the change in shape of a bone all will affect a bone’s
overall properties and likelihood of fracture.

**Bone’s Living Components.** Like liver, kidney, and muscle, bone is a living tissue that responds to its
environment. Two basic processes take place in bone as it responds to physiological demands. Bone
modeling occurs primarily in children and young adults and results in bone growth—both in length
and in cross-sectional area. The growth of bones through the addition of material to the endosteum
or periosteum, which is the result of the modeling process, can also continue throughout life. Bone
remodeling involves the removal and—in general—replacement of bone. This process allows for the
continual recycling of bone, and in healthy tissue it prevents the accumulation of microcracks that
could lead to fatigue failure of the structure. The same general processes are seen in fracture healing.

The cellular component of bone consists of three cell types: osteoblasts, osteoclasts, and
osteocytes. Osteoblasts are the cells in bone that will lay down new collagen matrix, which is then
mineralized to form the lamellae of bone. Osteoclasts remove bone during the normal remodeling
process, which is then replaced through osteoblastic activity. Osteoclasts also act to remove bone due
to changes in the loading environment. This response in bone, which has tremendous implications in
implant design and use, will be discussed further below in the section on Wolff’s law. Osteocytes are
the general cells of bone, acting as communication systems from one location in bone to another.
Connected through cellular processes in the canaliculi of osteonal bone, osteocytes are thought to act
as transducers that sense the mechanical and chemical environment around bone and then relay this
information to the osteoclasts and osteoblasts in order to elicit the necessary cellular response.

**Wolff’s Law.** Developed in 1892 by Professor Wolff (Wolff, 1892), this theory of bone behavior
remains the governing principle behind our understanding of bone physiology. After observing that
the structural orientation of trabeculae in the head and neck of the femur resembled the principal
stress trajectories of a Cullman crane (a mechanical structure with a similar shape and loading
pattern), Wolff hypothesized that bone develops in response to the loading environment that it
experiences. Through the last 100 years, this hypothesis has been reinforced through empirical and
experimental data. Thus bones that are not loaded sufficiently will lose tissue mass, whereas bones
that are loaded at a greater level than previously will add bone in order to reduce the stress experi-
enced. This response does require a time-averaged response—a single day spent in bed or lifting
weights will not change the structure of bone. However, extended periods in a hypogravity environ-
ment, such as the space shuttle, will result in bone loss and therefore a reduction in whole-bone
strength. In loading-related bone remodeling, the changes in bone mass are due to increases or
decreases in the structural arrangement of bone, not a change in the amount of mineral per unit
volume of collagen at the material level.

### 15.2.2 Cartilage

From an orthopedic material viewpoint, the type of cartilage of interest is articular cartilage—located
at the bearing surfaces of the joints. Cartilage provides a covering surface on the ends of bones that
meet to form an articulation, such as the femur and tibia at the knee. It acts to provide a smooth, low-
friction bearing surface, as well as to absorb some of the energy transferred through the joints during
normal activities.

Cartilage is a soft tissue composed of a proteoglycan matrix reinforced with collagen. The
orientation of the collagen varies through the thickness of the structure, with fibers oriented
perpendicular to the articular surface at the deepest level (furthest from the point of joint contact) and
parallel to the surface in the uppermost region (Mankin et al., 1994). Between 65 and 80 percent of
the total tissue weight is due to the water contained within the tissue matrix (Mankin et al., 1994).
Cartilage is predominantly loaded in compression and is viscoelastic in nature. Under initial loading,
the water within the proteoglycan matrix is extruded, and the stiffness of the material is a function of the tissue permeability. In fact, the fluid pressure within the matrix supports approximately 20 times more load than the underlying material during physiological loading (Mankin et al., 1994). Under extended, noncyclic loading, the collagen and proteoglycan matrix will determine the material behavior after the water has been forced from the tissue. Table 15.2 shows representative values for cartilage properties.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poisson’s ratio</td>
<td>0.10</td>
</tr>
<tr>
<td>Compressive modulus, MPa</td>
<td>0.70</td>
</tr>
<tr>
<td>Permeability coefficient, m/s</td>
<td>$1.18 \times 10^{-15}$</td>
</tr>
</tbody>
</table>


The low-friction environment provided by healthy cartilage as an articulating surface is also due to the fluid that is forced from the structure under compressive loading. As the tissue is loaded in compression, the water released from the proteoglycan matrix provides fluid-film lubrication between the two surfaces. During the unloading portion of a motion cycle, the cartilage resorbs a portion of the water, returning it to the matrix.

The principal cell in cartilage is the chondrocyte. Responsible for matrix production during growth and maintenance of the matrix in mature tissue, chondrocytes occupy only about 10 percent of the overall tissue volume (Mankin et al., 1994). Due to the avascular nature of articular cartilage, the provision of metabolites to the cells is assumed to occur via diffusion from the synovial fluid or, to a lesser extent, the underlying bone (Mankin et al., 1994). However, the lack of blood supply severely diminishes the ability of cartilage to heal once it has been damaged.

### 15.2.3 Ligaments and Tendons

Although different structures with different physiological functions, ligaments and tendons often are examined together due to their similar tensile loading patterns. Ligaments connect bones to each other across a joint, whereas tendons attach muscles to bone and provide the anchor necessary for muscles to cause movement. Each is composed of a combination of collagen and elastin fibers arranged primarily in parallel along the axis of loading. However, in the unloaded state, the fibers are slightly crimped. Therefore, initial tensile loading of the structure acts only to straighten out the component fibers—resulting in a region of low stiffness. Once the fibers have been completely straightened, the individual fiber stiffness dictates the overall structural stiffness. The resulting load-deformation curve (Fig. 15.4) exhibits a characteristic low-stiffness toe region followed by a region of increasing stiffness. If loading continues, failure of individual fibers within the structure will result in decreasing overall stiffness followed by rupture.

Table 15.3 shows typical values for the tensile properties of ligament and tendon. Tendon tends to be slightly stiffer than ligament due to the higher concentration of collagen. Both tissues are highly viscoelastic and will fail at lower extensions when loaded at high rates. This behavior explains why a slow stretch will not injure a tendon or ligament, whereas a rapid motion may result in rupture. The properties of both types of tissue vary based on anatomic location, indicating that the structures develop to match normal physiological demands.

Tendons tend to be avascular if they are surrounded by a tendon sheath to direct passage around a sharp prominence of bone, such as is seen in the flexor tendons of the hand. However, the remaining tendons tend to have a reasonable blood supply through surrounding connective tissue (Woo et al., 1994). Ligaments have a very limited blood supply through the insertion sites. In all
cases, tendons and ligaments have a small population of cells (fibroblasts) within the collagen and elastin fibers. The vascular supply that does exist is necessary for the maintenance of tissue properties. Periods of immobilization, such as occur when a limb is casted, result in a decrease in both stiffness and strength in ligaments. The ligament substance can recover in a period of time approximately equal to that of immobilization. However, the strength of the insertion has been seen to reach only 80 to 90 percent of its original strength after 12 months of recovery following 9 weeks of non-weight bearing (Woo et al., 1994).

15.2.4 Autografts and Allografts

In many cases, natural tissues can be used to replace damaged or diseased tissue structures. Natural tissue that is obtained from an individual and will be implanted into the same person is termed an autograft. If the donor is a different individual, the material is referred to as an allograft. Bone grafts,
used to fill bony defects or replace whole sections of bone, can range from morselized bone fragments to an intact hemipelvis. The larger the graft, the more likely the need to obtain it through a tissue bank as opposed to the patient himself or herself. Soft tissue grafts are more likely to be autologous in nature. The use of a portion of the patellar tendon to replace a ruptured anterior cruciate ligament is one example. Tissue grafts face unique problems in terms of viability, tissue matching, and damage to the donor site (for autografts and allografts from living donors) that are not seen with artificial materials.

15.3 ENGINEERED MATERIALS

Treatment of many orthopedic injuries or pathologies includes the introduction of an engineered material to replace a portion of tissue or to augment the structure to assist in healing. These interventions may be permanent or temporary in nature. For the selection of any material for biomedical applications, both the function of the implant and the material’s biocompatibility must be considered. The general concerns of corrosion, leaching, absorption, and mutagenicity must be addressed for orthopedic biomaterials, as they are for other applications. The following subsections provide a brief history of the selection of various material types for orthopedic implant use. The material considerations are discussed, including biocompatibility issues that are specific to orthopedic tissue replacement. The clinical success of an implant depends not only on the material choice but also on the overall implant design; however, clinical studies into implant efficacy have not generally been included.

15.3.1 Hard Tissue

The most common biomaterials applications for the replacement or augmentation of bone are used to treat injuries, particularly fractures. A much smaller proportion of implants are used in the treatment of bony diseases, such as replacing bone resected due to osteosarcoma. Total-joint replacement, such as the hip, knee, or shoulder, can be used to treat both bony fractures and joint disease.

**Stress Shielding.** Beyond the traditional biocompatibility issues, hard tissue biomaterials must also be designed to minimize a phenomenon known as stress shielding. Due to the response of bone remodeling to the loading environment, as described by Wolff’s law, it is important to maintain the stress levels in bone as close to the preimplant state as possible. When an implant is in parallel with bone, such as in a bone plate or a hip stem, the engineered material takes a portion of the load—which then reduces the load, and as a result, the stress, in the remaining bone. When the implant and bone are sufficiently well bonded, it can be assumed that the materials deform to the same extent and therefore experience the same strain. In this isostrain condition, the stress in one of the components of a two-phase composite can be calculated from the equation:

\[
\sigma_1 = \frac{E_1 P}{E_1 A_1 + E_2 A_2}
\]

(15.1)

where \(P\) is the total load on the structure and \(E\) and \(A\) are the Young’s modulus and cross-sectional area of each of the components. Thus the fraction of the load carried by each material, and the resulting stress, is related to its Young’s modulus and cross-sectional area as compared with those of the other components of the composite structure. The stiffer materials in the composite will carry a greater proportion of the load per unit cross-sectional area.

If bone in its natural state is compared with bone with a parallel implant, the effect of this intervention on the stress in the bone, and therefore its remodeling response, can be estimated from Eq. (15.1). The applied load can be assumed to be the same before and after implantation, which yields the following equations for the stress in the bone in the two configurations:
Preimplantation \( (E_{\text{implant}} = 0; A_{\text{implant}} = 0) \):

\[
\sigma_{\text{bone}} = \frac{E_{\text{bone}} P}{E_{\text{bone}} A_{\text{bone}}} = \frac{P}{A_{\text{bone}}}
\]  

(15.2a)

Postimplantation:

\[
\sigma_{\text{bone}} = \frac{E_{\text{bone}} P}{E_{\text{bone}} A_{\text{bone}} + E_{\text{implant}} A_{\text{implant}}}
\]  

(15.2b)

Thus the amount of the stress reduction in bone when an implant is included depends on the modulus and cross-sectional area of the implant. Implants with a higher modulus and a larger cross-sectional area will shield the bone from a greater proportion of its normal physiological stress, resulting in bone loss according to Wolff’s law.

An ideal implant would match the modulus of bone and occupy no greater cross-sectional area than the tissue replaced while meeting all the other design requirements of the implant. Since such a constraint generally cannot be met by current materials or designs, it is necessary to construct an implant that will minimize—if not entirely eliminate—stress shielding.

**Metals for Bone Applications.** Due to the structural role of bone, metals—with their high strength and modulus (Table 15.4)—are an obvious choice for replacement or augmentation of the tissue. The first metals implanted into the body for bony replacement were used in prehistoric times in a nonstructural role to replace cranial defects (Sanan and Haines, 1997). Gold, though of lower modulus than most metals, proved to be a suitable selection for this application because of its lack of reactivity within the body. Structural augmentation of bone using metals to assist fracture healing began in the nineteenth century, when common materials such as silver wires, iron nails, and galvanized steel plates were used to hold fragments of bone together (Peltier, 1990). In the case of metals susceptible to oxidation, such as steel and iron, corrosion led to premature mechanical failure and severe tissue reactions. In 1912, Sherman developed a steel alloy that contained vanadium and chromium (Sherman, 1912), providing it with higher strength and ductility than the previously used tool steels or crucible steels. Studies on cytotoxicity that began in the 1920s (Zierold, 1924) and 1930s (Jones and Lieberman, 1936) led to a reduction in the types of metals used in implants, focusing attention on gold, lead, aluminum, and specific formulations of steels (Peltier, 1990).

**TABLE 15.4** Summary of Properties of Metals Currently Used in Hard Tissue Implants in Comparison with Bone

<table>
<thead>
<tr>
<th>Material</th>
<th>Elastic modulus, GPa</th>
<th>Compressive strength; MPa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stainless steel (316L)</td>
<td>200</td>
<td>505–860</td>
</tr>
<tr>
<td>Cast Co-Cr-Mo</td>
<td>200</td>
<td>655</td>
</tr>
<tr>
<td>Wrought CoNiCrMo</td>
<td>200</td>
<td>600–1790</td>
</tr>
<tr>
<td>Titanium alloy (Ti6A14V)</td>
<td>110</td>
<td>860</td>
</tr>
<tr>
<td>Porous tantalum</td>
<td>NA</td>
<td>Compressive: 63; Tensile: 60</td>
</tr>
<tr>
<td>Cortical bone</td>
<td>11–20</td>
<td>Compressive: 106–224; Tensile: 51–172</td>
</tr>
</tbody>
</table>

*Note: The properties for porous tantalum are taken from a sample composition and will vary substantially based on porosity and structure.*


The first metallic implant for a hip replacement, introduced in 1940, was constructed of Vitallium, a form of cobalt-chromium alloy (Rang, 2000). Along with stainless steel, this became a standard
metal for large-joint replacement and internal fracture fixation. Both materials showed good biocompatibility and excellent structural properties. The choice between the two often depended on the individual opinions of the designing physicians as they balanced biocompatibility and mechanical performance. Multiple medical grades of stainless steel were developed and standardized, including the most common formulation in use today—316L (containing iron, chromium, nickel, molybdenum, and manganese in decreasing concentrations, with additional trace elements). In addition to the cast alloy that is Vitallium (Co-30Cr-6Mb), a wrought alloy was also introduced (Co-20Cr-10Ni-15Tu) that possesses improved tensile strength and ductility (Brettle and Jordan, 1971).

One of the keys to the chemical biocompatibility of stainless steel and cobalt chromium was the formation of a passivation layer in vivo, thus minimizing the amount of corrosion that occurs to the implant. However, as indicated in Table 15.4, while the strength of these two metals reduced the chance for failure within the implant, their elastic moduli are an order of magnitude higher than that seen in healthy cortical bone. This resulted in the occurrence of stress shielding and concomitant bone loss in many patients with large implants.

In the 1940s, the aerospace industry introduced titanium and its alloys into the market. The high strength-to-weight ratio and comparatively low modulus attracted the attention of surgeons and implant designers. Titanium also proved to be chemically biocompatible, forming its passivation layer in air before implantation—thus further reducing the chemical reactions occurring at the implant interface. Despite the higher cost of the bulk material and the difficulty encountered in machining, due to their tendency to seize when in contact with other metals, titanium alloys have proven to be an effective choice for large-joint replacement and some techniques of fracture fixation, including compression plates. The most common titanium alloy used in orthopedic surgery is T318 (Ti-6Al-4V). The strength of the alloy is greater than that of pure titanium, and it maintains titanium’s good biocompatibility (Brettle and Jordan, 1971). Titanium has been shown to promote good bone apposition to its surface when it is implanted, and porous surfaces have proven to be receptive to bone ingrowth. Neither of these features is as apparent in ferrous or cobalt-based alloys.

The latest metal to hit the orthopedic market is tantalum. The benefit of tantalum is the ability to form it into porous foams with a structure on the order of trabecular bone, providing a scaffold that is optimum for bone ingrowth. The mechanical properties of this novel metal depend on its porosity and structure but are sufficient to provide mechanical support during the period of bony integration (Zardiackas et al., 2001). Bone ingrowth into the porous structure after 4 weeks of implantation into cortical bone provided stronger fixation than observed in many other porous structures and progressed to fill over 60 percent of the pores by 16 weeks of implantation (Bobyn et al., 1999). In addition to its strong mechanical attributes, both in terms of initial stability and bony fixation, tantalum has been shown to be virtually inert, provoking a minimal tissue response (Black, 1994). This combination of properties has lead to the development of tantalum structures for the backing of acetabular cups and spinal fusion cages. It shows great promise for future implant development and is sure to be the subject of substantial research and development during the coming decade.

In addition to bulk implants, metals have been used to form the ingrowth surface for total-joint replacements. The design goal of these implants, which use a porous surface on all or part of the bone-contacting portion of the implant, is to better transfer the load from the implant through to the bone. Various companies have developed porous surface systems based on sintered particles, sintered wires, or rough, plasma-sprayed surfaces. The common goal in these systems is to produce a pore size into which bone will grow and become firmly fixed. Due to the substantially increased surface area of the metal in these implants, corrosion becomes a point of increased concern. In addition, it is necessary to maintain a strong bond between the porous surface and the underlying bulk metal in order to allow full load transfer to occur.

Ceramics for Bone Applications. Since bone is a composite consisting essentially of ceramic and polymeric components, and due to the essential inertness of many ceramics, this class of materials was looked to to find truly biocompatible materials for structural applications. However, the brittle nature and low tensile strength of ceramics have led to some concerns regarding the fracture behavior of
these materials, whereas the high modulus again raises the specter of stress shielding for implants with large geometries (Table 15.5).

**TABLE 15.5 Summary of Mechanical Properties of Some Ceramics Used in Orthopedic Applications**

<table>
<thead>
<tr>
<th>Material</th>
<th>Elastic modulus, GPa</th>
<th>Compressive strength, MPa</th>
<th>Tensile strength, MPa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alumina</td>
<td>380</td>
<td>4500</td>
<td>270</td>
</tr>
<tr>
<td>Dense calcium phosphate</td>
<td>40–117</td>
<td>294</td>
<td>—</td>
</tr>
<tr>
<td>Bioglass</td>
<td>—</td>
<td>—</td>
<td>100–200</td>
</tr>
</tbody>
</table>

*Note: Calcium phosphate properties vary depending on formulation (e.g., tricalcium phosphate versus hydroxyapatite). Sources: Boutin et al. (1988) and Park and Lakes (1992).*

Ceramics, particularly alumina, were first introduced as structural orthopedic biomaterials in the late 1960s (Boutin, 1972). However, limitations in processing technology and lack of quality control led to materials with higher than desired levels of impurities and imperfections, including high porosity levels. These defects caused a further reduction in the strength of ceramics in tensile or shear loading, resulting in premature failure in a number of clinical cases (Holmer and Nielsen, 1993; Peiro et al., 1991).

Processing techniques for ceramics improved by 1977, resulting in smaller and less variable grain sizes. As processing technologies improved, the true chemical biocompatibility of these materials caused them to be reexamined for use in orthopedic applications. Alumina and zirconia have become the most popular ceramics for use in total-joint replacement. Zirconia was introduced in an attempt to further reduce the risks of component fracture and wear-particle production (Jazwari et al., 1998). In general, the low tensile strength of both materials has precluded their use in structures subjected to substantial bending, such as the femoral stem of a total-hip replacement. However, highly polished ceramics have shown good success as articulating components in total-joint arthroplasty—with articulation against either a polymer or another ceramic both possible. Implants constructed predominantly of ceramics, particularly for total-knee replacement, are currently being investigated. These designs are particularly useful in patients with demonstrated metal sensitivities, which often precludes the use of a standard implant design.

At the opposite end of the spectrum to the ceramics investigated for their inert nature are a group of ceramic materials that are designed to induce a reaction from the surrounding tissue. These bioactive materials take advantage of the tissue’s cellular physiology and structural component materials to induce bone remodeling, growth, and integration into the implant. An ideal bioactive ceramic would actually spur bone growth adjacent to the implant, promote integration of the bone with the implant structure, and gradually biodegrade as healthy bone tissue replaces the artificial structure. Two general categories of bioactive ceramics have been developed: calcium-based ceramics, such as calcium phosphate, calcium sulfate, and hydroxyapatite; and bioglasses, mineral-rich structures that can be tailored to optimize the tissue response. Bioactive materials such as these can have either *osteoinductive* or *osteoconductive* properties. The former refers to the ability of a material to trigger bone cell differentiation and remodeling in locations where bone cell proliferation and healing would not normally occur (such as a large defect), whereas the latter defines a material that promotes bony ingrowth and vascularization, allowing for integration and remodeling to take place.

Calcium-based composites rely on their similarity to the mineral component of natural bone—hydroxyapatite (HA). The theory behind their use is that the body will see these materials as tissues that need to be remodeled, allowing them to be integrated with and then replaced by bone. Tricalcium phosphate [TCP, \( \text{Ca}_3(\text{PO}_4)_2 \)], calcium sulfate [plaster of paris, \( \text{CaSO}_4 \)], and hydroxyapatite \([\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2] \) are all currently being used to fill bony defects and stimulate or direct bone formation. Calcium sulfate has been used for over a century due to its ready availability and bio
compatibility (Tay et al., 1999). The crystal size (nanometers) of biological HA is much smaller than
the material (Cooke, 1992); however, it has still been shown to be more osteoconductive in nature than TCP (Klein et al., 1983).

TCP, calcium sulfate, and HA can be inserted into a defect in the cortical or trabecular bone in the
form of pellets or particles. The high surface-to-volume ratios of these implants, used in areas where
immediate structural support is maintained through remaining bone or fracture fixation, allows for
more rapid integration and remodeling of the material. The calcium sulfate formulation has been shown to resorb in only 6 to 8 weeks (Ladd and Pliam, 1999).

Less frequently, blocks of calcium-based ceramics are used to replace large segments of bone that
have been resected due to injury or disease. These implants have not proven to become fully replaced
by living bone but serve as a continued structural support that is integrated with the surrounding bone
surface. The blocks can be made porous, to mimic the structure of trabecular bone, and this has been
shown to increase bone ingrowth into the material. One brand of porous hydroxyapatite has been
manufactured from the tricalcium phosphate laid down by marine coral and has been shown to
possess substantial osteoconductive properties, filling over 50 percent of the porosity volume with
bone within 3 months (White and Shors, 1986). Hydroxyapatite has also been combined with
polymethyl methacrylate bone cement (see below) with the goal of inducing bone growth into the
material through the remodeling of these small particles of calcium-based ceramic. Ceramic bone
grafts can be augmented with biological molecules designed to increase their osteoinductive nature,
including transforming growth factor β (TGF-β) and bone morphogenic protein (BMP) (Ladd and
Pliam, 1999). These materials then begin to bridge the gap to tissue engineering.

One of the newest techniques for applying a calcium-based material to assist with fracture fixation
is through the injection of a viscous “cement” that then fully hardens in vivo. Norian SRS (Skeletal
Replacement System), an injectable calcium phosphate material, was introduced in 1995 (Constanzt
et al., 1995). It has been shown to reduce the immobilization time required during fracture fixation
(Kopylov et al., 1999) because it carries a portion of the load during bone healing. After 12 hours in
vivo, Norian has cured to between 85 and 95 percent of its ultimate properties, with a final
compressive strength of 55 MPa (Constanzt et al., 1995). Successful clinical applications have
included the reduction and stabilization of unstable or intraarticular radial fractures (Kopylov et al.,
1999; Yetkinler et al., 1999), complex calcaneal fractures (Schildhauer et al., 2000), and vertebral
compression fractures (Bai et al., 1999) and augmentation of hip screw fixation in unstable fractures
of the the intertrochanteric region of the femur (Elder et al., 2000).

In addition to their use in bulk form, calcium-based ceramics can be coated onto metallic implants
to improve fixation. The ceramic can be applied through plasma spraying, creating a rough or porous
surface approximately 50 μm thick (Cooke, 1992). Hydroxyapatite-coated titanium has shown firm
fixation to bone in implant conditions both in mechanically stable and mechanically unstable
conditions (Soballe et al., 1999), with the fixation occurring at a faster rate than in implants where the
porous coating is manufactured from titanium itself (Thomas, 1994). HA coatings degrade with time
and are replaced with natural bone, allowing close apposition with the underlying implant material.
Clinical studies have shown that inclusion of the additional material layer does not promote increased
wear or osteolysis in a properly designed implant (Capello et al., 1998). While cemented implants and
metallic porous coatings remain the predominant designs of choice for total-joint replacements,
ceramic-coated designs have garnered increasing interest.

Bioglass was introduced to the scientific world in the late 1960s by Dr. Hench. These glass-ceramics,
which contained varied proportions of SiO₂, Na₂O, CaO, P₂O₅, CaF₂, and B₂O₃, were designed
to interact with the normal physiology of bone to allow strong bone bonding (Ducheyne, 1985).
Initial work by Greenspan and Hench (1976) indicated that an alumina implant coated with Bioglass
showed substantially improved attachment to bone and new bone formation when implanted in rats
compared with alumina-only controls. The bonding mechanism was found to depend on the
composition of the glass, and this has sparked the development of other variations of glass-ceramics.
These include Ceravital (which contains K₂O and MgO in place of CaF₂ and B₂O₃) (Ducheyne, 1985)
and a form containing apatite and wollastonite (Nishio et al., 2001).

Glass-ceramics have low tensile strength and fracture toughness, limiting their use in bulk form to
applications subject to purely compressive loading. Attempts have been made to use these materials
as part of composite structures to increase their application. The most common method is to coat a ceramic or metallic implant with the glass to create an osteoinductive surface. The coating may be applied in a pure layer of glass or as an enamel coating with embedded glass particles (Ducheyne, 1985). For the enamel systems, it is important to ensure that the components of the enamel do not interfere with the bone-formation process (Ducheyne, 1985). The glass coating is still a brittle material and must be handled with care—any substantial impact may lead to failure of the entire coating system.

Glass composites have also been investigated using stainless steel fibers (50 to 200 µm thick) to reinforce the glass-ceramic (Ducheyne and Hench, 1982). The goal of these composites follows that of other fiber-reinforced materials—to increase their resistance to fracture by blunting crack growth and introducing a residual compressive stress within the material (Ducheyne, 1985). This procedure was found to make the material significantly more ductile and stronger, thus reducing its tendency to fail catastrophically. In addition, the elastic modulus was reduced from that of the pure glass (Ducheyne, 1985), bringing it closer to the ideal properties for bony replacement.

To date, glass-ceramics have been used clinically for only limited applications. These include material for filling bony defects along the lines of a bone graft (Pavek et al., 1994), reconstruction of the ossicular bones (Hughes, 1987), spine reconstruction (Yamamuro and Shimizu, 1994), and dental reconstruction (Kudo et al., 1990; Yukna et al., 2001).

**Polymers for Bone Applications.** Until recently, the only polymer used to replace or augment bone itself (as opposed to the articulating surfaces, which are actually cartilage replacement) was polymethyl methacrylate (PMMA), or bone cement. This material was introduced to the world of orthopedics in 1951 (Rang, 2000), becoming widely used in the 1960s, and provided good clinical success at maintaining the fixation of a total-joint implant within a medullary canal. Bone cement does not act as an adhesive but rather a space filler. It fills the void left between the stem of an implant and the endosteum of the bone, interdigitating with both the implant and the natural surfaces. This minimizes the need for an exact fit between the implant and the bone, required with press-fit implants, and provides an immediate source of fixation, as opposed to porous-coated implants that require several weeks for bone to grow into the implant surface. Bone cement has been used for over 50 years with little change in its composition and is still the preferred fixation method for some implants—particularly those to be used in patients with poor bone quality. Three negative factors affect the use of bone cement. First, it polymerizes in vivo through an exothermic reaction that elevates the temperature of the surrounding tissues. The effect of this high temperature on cells has not been fully established. Second, it can deteriorate through fatigue and biological processes, resulting in the production of wear debris. These particles of cement can cause osteolysis (bone loss) of the femoral bone or enter the articulating region, promoting third-body wear of the acetabular and/or femoral head components. This latter process would then further exacerbate any debris-related bone loss. Finally, the cement provides an additional material and an additional interface (bone-cement-implant versus bone-implant) at which macroscopic failure can occur. This can result in a reduced life span for the implant.

In the 1990s, researchers and clinicians began to look at polymers for fracture fixation. This work built on the idea of epoxy–carbon fiber composite plates introduced in the preceding decade (Ali et al., 1990). While they do not possess the same mechanical strength seen in the metals traditionally used for bone plates and screws (Table 15.6), they do have some properties that may outweigh this lack of strength. First, the bone plates are less stiff—resulting in reduced stress shielding and less bone loss compared with current plates. Second, the polymers can be designed to degrade with time, allowing the healing bone to eventually take over the entire load-bearing role while avoiding a second surgery for plate removal. While the fixed constructs (bone plus plate) are generally stronger during the initial healing when a metal plate is used, the loss of bone due to the higher stress shielding of stainless steel causes a substantial reduction in bone strength at extended time points (Hanafusa et al., 1995). Degradable plates and screws are typically constructed of poly(lactide-co-glycolide) (PLGA), poly(L-lactide) (PLA), or polyglycolic acid (PGA). The polymer matrix can be augmented with hydroxyapatite to improve the mechanical strength or bonding with bone (Furukawa et al., 2000; Hasirci et al., 2000). Clinical results with these new constructs appear promising for certain
Tissue-Engineered Bone Replacements. The phrase tissue engineering has been applied to bone for a wide range of developments. Interventions can be as straightforward as delivery of osteoinductive factors such as TGF-β and BMP to the surrounding tissue through a porous scaffold. The more complicated designs include cultured bone cells within a three-dimensional matrix. Due to bone’s hard tissue nature, both hard (ceramic) and soft (polymer) scaffolds are being investigated for this application (Burg et al., 2000). In general, all the calcium-based ceramics and the degradable polymers—including natural collagen—have been the subject of research interest for this application. Some polymers may need to be reinforced to provide adequate mechanical stability (Burg et al., 2000). These scaffolds have been seeded with chondrocytes, periosteal osteoblasts, and marrow progenitor cells to determine the best cell type to promote osteogenesis when implanted into a defect site (Burg et al., 2000).

15.3.2 Soft Tissue

As with bone, replacement or augmentation of orthopedic soft tissues can be used to treat injury- or disease-based degradation to the original tissue. Osteoarthritis—characterized by degradation of the articular cartilage that progresses to the bony surfaces themselves—is one of the most common pathologies experienced by the aging population, with up to 20 percent of the aging population showing signs of degenerative joint disease (DJD) (Felson et al., 2000). Ligament damage is generally the result of injury, often (though not exclusively) caused by athletic activity. Many ligaments are designed with redundant systems—the failure of a single ligament need not result in complete instability in a joint. One of the first questions that must be asked following ligament damage is whether a repair is needed or if (given the activity level of the individual) conservative treatment and bracing will provide the needed support to the joint. Tendons are damaged much less frequently than other orthopedic soft tissues and are not the site of common implant-based repair. Thus they will not be addressed in this section.

Polymers for Cartilage Replacement. Given the relatively low stiffness of cartilage and the need for low coefficients of friction, polymers have been the principal material of choice for replacement of articulating joint surfaces or at least one of the surfaces of an articulating joint. Replacements of large joints, such as the hip, knee, and shoulder, are generally designed with a metal or ceramic component articulating against a polymer surface. For smaller joints, such as those of the fingers, polymeric pieces have been used as spacers and hinges.

Silicone, polyethylene (PE), and polyolefin have all been used as a flexible hinge to replace a joint of the hand damaged through injury or arthritis. The most widely accepted implant for this application was designed by Swanson in the 1960s and continues to be used today (Linscheid, 2000). Constructed of Silastic, a form of silicone rubber, it achieves fixation through the planned formation of a fibrous capsule around the implant. Such capsular formation is a standard response to implanted structures in the body, but in many cases it has been determined to be contraindicated for optimal

### Table 15.6: Characteristic Properties of Polymers Used in Orthopedic Implant Applications

<table>
<thead>
<tr>
<th>Material property</th>
<th>Young’s modulus, GPa</th>
<th>Tensile strength, MPa</th>
<th>Compressive strength, MPa</th>
<th>Elongation, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHMWPE</td>
<td>0.4–1.2</td>
<td>44</td>
<td>15.2–24.8</td>
<td>400–500</td>
</tr>
<tr>
<td>PMMA bone cement</td>
<td>1.35</td>
<td>45.5</td>
<td>89.6</td>
<td>4.6</td>
</tr>
<tr>
<td>PLA</td>
<td>1.2–3.0</td>
<td>28–48</td>
<td>NA</td>
<td>1.8–3.7</td>
</tr>
</tbody>
</table>

*Sources: Dumbleton and Black (1975) and Engelberg and Kohn (1991).*
implant performance. In the case of Swanson’s joint replacement, the implant is designed to move within the medullary canal of the connected bones, promoting an enhanced fibrous capsule formation. This fixation avoids the problems seen in the hand with screw fixation or porous coatings designed to promote bony ingrowth (Linscheid, 2000).

Beyond the traditional biocompatibility concerns, which include the effects of leaching and absorption, the greatest obstacle to the use of polymers in the role of articulating surfaces has been wear. The cyclic motion of an opposing implant component or bone against the polymer may produce substantial amounts of wear debris that can then precipitate bone loss and implant failure.

When Charnley introduced his low-friction arthroplasty in the late 1950s, he originally selected Teflon (PTFE, polytetrafluoroethylene) for the acetabular component. However, within a few years, he realized that while Teflon possessed a very low coefficient of friction, its wear resistance was poor (Charnley, 1970). While the observations made on these implants provided substantial information regarding wear processes for plastics in vivo, it was obvious that another material was required. A “filled” Teflon (given the name Fluorosint) was investigated, in which glass fibers or synthetic mica was added to improve the wear resistance of the artificial joint. While laboratory tests using a water lubricant showed that the newly formulated material had a 20-fold reduction in wear, clinical studies showed that the filled Teflon suffered wear at the same rate as the pure version. The clinical picture was worsened, however, because it was discovered that the particles used in the new formulation acted as an abrasive against the stainless steel femoral head (Charnley, 1970). This difference emphasizes the need to conduct laboratory tests in conditions that mimic the physiological environment as closely as possible before progressing to animal and human trials. Charnley hypothesized that the difference in results was due to the action of the extracellular fluids on the Teflon, preventing the formation of a protective surface layer (Charnley, 1970).

After the failure of Teflon, high-density polyethylene (HDP) was investigated as a bearing material. It was shown to be substantially more resistant to wear than PTFE, although the particles produced by the wear that was still expected to occur were a concern of Charnley’s back in 1970 (Charnley, 1970). The creep behavior of HDP under compressive loading was also a concern because this would alter the shape of the articulating surfaces. New or modified materials were thus investigated. In order to counter the problem of creep, Delrin 150 was introduced and used clinically in Europe. This is a high-viscosity extruded polymer that is biocompatible, significantly harder than HDP, and resistant to creep—a property that is extremely important for sites such as the tibia (Fister et al., 1985). Polyester was also examined in the early 1970s for use in trunion designs of implants. However, wear proved to be the downfall of these materials as well (Clarke, 1992; Havelin et al., 1986; Sudmann et al., 1983). Similarly, composites of carbon fiber–reinforced PE were also developed for use as a joint surface with the goal of reducing wear. It proved to be as biocompatible as PE alone (Tetik et al., 1974). However, while the laboratory studies showed improved wear resistance, clinical results proved to be substantially worse (Busanelli et al., 1996; Clarke, 1992).

Today, the density of polyethylene has been increased further from that first used by Charnley, and joint bearings are now typically constructed from ultra-high-molecular-weight polyethylene (UHMWPE). The material has proven to provide good articulation, with the main concern being long-term wear. The problem with wear is not only the mechanical impingement that can occur as a result of a change in the articulating surface geometry but, more importantly, the effect of wear debris on the surrounding tissue. Bone, as a living material, is affected by inflammatory processes. The body reacts to the presence of foreign debris by triggering the immune system; in an attempt to rid the body of this unwanted material, phagocytic processes are set in motion that eventually produce chemicals that adversely affect the surrounding bone. This process of osteolysis and the resulting loss of bone are principal causes of implant failure in the absence of infection. Substantial efforts are still underway to develop an implant system that minimizes the production of wear debris and protects the surrounding tissue.

Metals and Ceramics for Cartilage Replacement. Due to the problems encountered with wear debris from the polymeric components of large-joint implants, a number of designs have appeared that use highly polished hard materials on both articulating surfaces. The initial designs for hard-bearing
surfaces may have been abandoned in part due to the high frictional torques and early failures that were caused by problems in both implant design and material processing (Amstutz and Grigoris, 1996; Boutin et al., 1988). Second-generation metal-metal and ceramic-ceramic bearings generally have similar coefficients of friction to joints with UHMWPE components (Table 15.7). They have proved to be clinically feasible, and studies indicate good long-term survival rates (Boutin et al., 1988; Dorr et al., 2000; Wagner and Wagner, 2000). In small-joint replacement, components manufactured from pyrolitic carbon—a material proven to have exceptional biocompatibility—have also shown good preliminary results in clinical trials (Cook et al., 1999). Both ceramic-ceramic and metal-metal designs have been shown to produce substantially reduced volumes of wear (Boutin et al., 1988; Schmalzried et al., 1996; Wagner and Wagner 2000); however, in both cases, the particles are substantially smaller than those produced from a metal or ceramic articulating against polyethylene (Boutin et al., 1988; Shahgaldi et al., 1995; Soh et al., 1996). In fact, the number of particles produced per step is about the same for cobalt-chromium articulating with either UHMWPE or itself (Wagner and Wagner, 2000). Thus further research must be conducted into the local and systemic effects of these smaller, easily transported particles within the body and on long-term outcomes. Despite questions that still deserve to be addressed, hard-bearing implants for total-joint replacement have gained increasing amounts of interest, especially for application in younger patients for whom the lifetime accumulation of wear debris is of greater concern.

**TABLE 15.7 Coefficients of Friction for Sample Material Combinations Used in Total-Hip Replacement**

<table>
<thead>
<tr>
<th>Material combination</th>
<th>Coefficient of friction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cartilage-cartilage</td>
<td>0.002</td>
</tr>
<tr>
<td>CoCr-UHMWPE</td>
<td>0.094</td>
</tr>
<tr>
<td>Zirconia-UHMWPE</td>
<td>0.09–0.11</td>
</tr>
<tr>
<td>Alumina-UHMWPE</td>
<td>0.08–0.12</td>
</tr>
<tr>
<td>CoCr-CoCr</td>
<td>0.12</td>
</tr>
<tr>
<td>Alumina-alumina</td>
<td>0.05–0.1</td>
</tr>
</tbody>
</table>

*Note: UHMWPE ultra-high-molecular-weight polyethylene; CoCr, cobalt chromium alloy (Park and Lakes, 1992; Streicher et al., 1992).*

**Tissue-Engineered Cartilage Replacements.** The ideal replacement material would be one that would mimic all the functions of the original tissue, including those attributed to the cellular components. Artificial biomaterials cannot meet this goal. However, the new technologies of tissue engineering have opened the door to the development of living replacement tissues that can be “manufactured” in the laboratory. Thus these are not allografts or autografts, with their inherent problems, but materials that can either be banked for use when necessary or grown to meet the needs of a particular individual. Since the majority of past interventions for replacement of cartilage (e.g., not part of a total-joint replacement) have not proved to be successful, tissue-engineered cartilage holds great promise.

The premise behind an engineered tissue is to manufacture a scaffold from a biocompatible and possibly biodegradable material and then to seed this material with appropriate cells. The scaffold supports the cells, allowing them to grow, proliferate, and become integrated with the surrounding healthy tissue. In the case of cartilage, chondrocytes must be harvested and allowed to reproduce in the laboratory to provide the required number of cells. These can be taken from healthy cartilage (articular cartilage or the epiphysis) or isolated as more primitive cells that can be directed to differentiate into the desired form (mesenchymal stem cells or bone marrow stromal cells) (Suh and Fu, 2000). The choice of scaffold is equally challenging, with the goal being to match the property of the normal cartilage matrix. In the case of cartilage, research is being conducted into the construction and application of scaffolds based on collagen,
Polyglycolic acid (PGA) and poly(L-lactic) acid (PLLA) (both alone and as copolymers), hyaluronic acid, and polysaccharide-based hydrogels (Suh and Fu, 2000; Suh and Matthew, 2000; Temenoff and Mikos, 2000b). A three-dimensional scaffold is required to prevent the chondrocytes from dedifferentiating and losing some of their needed properties (Temenoff and Mikos, 2000a). Injectable materials that can deliver chondrocytes to the area of interest without an invasive surgery are also being investigated. Fibrinogen and thrombin can be combined in vivo to provide the necessary stability to the cells (Temenoff and Mikos, 2000a). This research is in its infancy, but it promises great advances during the next decades.

**Polymers and Ceramics for Ligament Replacement and Augmentation.** The most frequently damaged ligament is the anterior cruciate (ACL), located in the knee. Therefore, much of the work that has been done on ligament repair, replacement, and augmentation has examined this anatomic location. However, the knowledge gained through decades of work on the ACL can be transferred to other sites in the body as long as new designs undergo appropriate application-specific testing.

Four schools of thought exist when it comes to repair of damaged ligaments:

1. If sufficient joint stability exists, do nothing and allow collateral structures to maintain the mechanical function of the joint.
2. Use autologous structures to replace the damaged ligament, such as a section of the patellar tendon for the ACL.
3. Provide a bridge that the damaged structure or implanted replacement (allograft or autograft) can use as it heals. This augmentation device also carries a significant portion of the tensile load until the ligament has healed sufficiently.
4. Replace the ligament completely with an artificial material or allograft material.

Much of the debate in this field comes from the healing behavior of ligaments. Because they possess a minimal vascular supply, ligaments heal and remodel slowly. During this healing process, they are not able to carry the normal amount of tensile load. However, ligaments—like bone—also require regular cyclic loading beyond some threshold value to regain and maintain their mechanical properties. Most initial repairs of the ACL involve autograft tissue taken from the patellar tendon, the iliotibial band, or other similar tissues (Schepsis and Greenleaf, 1990). However, donor-site morbidity and the occasional failure of these grafts have driven the need for the development of other implant options. For artificial augmentation or replacement implants, polymeric fabrics have become the material of choice.

The goals for a ligament prosthesis or augmentation device must be to provide the necessary mechanical stability to the joint without premature degradation or failure. Table 15.8 provides a summary of mechanical properties for a number of synthetic grafts in comparison with normal ACL tissue.

**TABLE 15.8** Representative Properties for Normal ACL and Devices Designed to Replace the Ligament or Augment Healing of an Allograft or Autograft

<table>
<thead>
<tr>
<th>Material</th>
<th>Yield force, N</th>
<th>Stiffness, kN/m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal ACL</td>
<td>1750</td>
<td>182</td>
</tr>
<tr>
<td>GoreTex prosthesis</td>
<td>5000</td>
<td>320</td>
</tr>
<tr>
<td>Polypropylene LAD</td>
<td>1500–1730</td>
<td>330</td>
</tr>
</tbody>
</table>

*Note: LAD, ligament augmentation device (Schepsis and Greenleaf, 1990).*

At the beginning of the twentieth century, silk was applied as the first artificial material for ACL replacement (Alwyn-Smith, 1918); however, these implants failed within a few months of implant...
tation. Use of synthetic materials for this application was virtually abandoned until the 1970s, when 
UHMWPE rods were introduced (Schepsis and Greenleaf, 1990). This design, along with the Proplast 
rod of propylene copolymer, had a short life span before fracture or elongation of the prosthetic 
occurred (Ahlfeld et al., 1987; Schepsis and Greenleaf, 1990). Carbon fiber was investigated as a 
potential material for prosthetic ligaments (Jenkins, 1978, 1985); however, its brittle nature and 
tendency to fail became more problematic than the benefits of the biodegradable nature of the fibers. 
The fibers were then coated with PLA to improve handling in the operating room as well as prevent 
failure in vivo (Alexander et al., 1981), but this has not gained wide use.

PTFE ligaments have been seen in clinical studies to provide higher levels of patient satisfaction 
than the Proplast structures (Ahlfeld et al., 1987); however, the failure rate is still higher than 
desirable (Schepsis and Greenleaf, 1990). The most recent material additions to the field of prosthetic 
ligaments have been Dacron (nylon) and a polyethylene braid; results using these implants are mixed 
(Schepsis and Greenleaf, 1990). Despite their promise in terms of mechanical stability and long-term 
outcomes, artificial ligaments have proven to be controversial. There have been substantial numbers 
of cases reported in which the artificial material produced a synovitis—inflammation of the synovial 
fluid in the joint—or failed completely (Christel, 1994). While they have gained acceptance for 
revision surgery for chronically unstable knees—such as may result from failure of a graft—
prosthetic ligaments have not yet met the performance of autografts for primary repairs.

The advent of ligament augmentation devices (LADs) was the result of the observation that 
autografts or allografts experienced a period of decreased mechanical strength and stiffness soon after 
implantation (Kumar and Maffulli, 1999). This degradation results from the natural remodeling 
process that takes place to fully integrate the biologic structure into its new surroundings. One implant 
designed to minimize the chance of failure for the healing graft is constructed of diamond-braided 
polypropylene (Kumar and Maffulli, 1999). Other designs have included PLA-coated carbon fiber 
( Strum and Larson, 1985), knitted Dacron (Pinar and Gillquist, 1989), and polydioxanone (Puddu et 
al., 1993). Despite expectations based on laboratory studies, clinical results have not shown an 
improvement in outcomes when LADs have been used to supplement the biologic reconstruction of 
the ACL (Kumar and Maffulli, 1999). There is concern that an LAD will stress shield a healing 
ligament graft (Schepsis and Greenleaf, 1990), therefore reducing its mechanical properties and 
increasing the likelihood of graft failure.

The state of the art in ligament replacement remains the application of allografts. The use of 
artificial materials in this application is in its relative adolescence compared with fracture fixation and 
total-joint replacement. While artificial structures for total-ligament replacement or graft 
augmentation have not been fully optimized to date, they have proven to be effective in secondary 
repair situations—where a primary graft has failed—or cases of chronic instability. Future 
developments in materials, particularly composites, may produce a structure that can meet the 
mechanical and fixation requirements for ligament replacement with improved clinical outcomes.

15.4 CONCLUSION

Orthopedic injuries and pathologies are among the most common medical conditions. While fractures 
are no longer an anticipated part of a child’s medical history, over 6.2 million fractures occur each 
year in the U.S. population (Tay et al., 1999). Osteoarthritis affects 1 in 5 individuals over the age of 
70 (Felson et al., 2000). These and other conditions—including rheumatoid arthritis, osteosarcoma, 
and ligament tears—often require an intervention that includes the replacement of some portion of 
tissue. Autografts and allografts have proven problematic based primarily on material availability. 
Artificial materials have shown tremendous success in a number of applications, particularly total-
joint replacement, but are not without their downsides, including long-term biocompatibility and 
survivability issues. As is the case in many areas of tissue and organ replacement, the future of tissue 
engineering holds great promise. If orthopedic surgeons are able to replace diseased or damaged 
tissue with a material that will immediately take over the original structural and mechanical function
while it becomes completely integrated with the natural tissue with time, the current gap between natural and engineered materials may be bridged. Until the time when tissue engineering of complex structural tissues is perfected, the need for the continued development, refinement, and investigation of artificial materials for orthopedic applications continues. The material selected plays a large role in the overall success of an implant design—as past failures have so dramatically shown. However, a poor result with a material cannot be divorced from the implant design itself. Boutin provided good evidence of this in his historical discussion of alumina acetabular components—in which loosening rates were reduced from 26 to 0.5 percent based on the position of the stabilizing pegs alone (Boutin, 1988). Thus materials should not be deleted from the database of potential choices until it is determined if a failure was due to material selection or mechanical design. It is also important to have a thorough understanding of the underlying physiological processes in orthopedic tissues in both normal and pathological conditions so that implants of any type can be designed to be optimally integrated into the body from a mechanical and biological standpoint. The combined efforts of materials scientists, tissue physiologists, biomechanists, clinicians, and others will continue to offer developments in the field of orthopedic tissue replacement and enhancement—a discipline that already dates back thousands of years.

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