Learning Objectives

After studying this case study, you should be able to do the following:

1. List and briefly explain six biocompatibility considerations relative to materials that are employed in artificial hip replacements.

2. Name the four components found in the artificial hip replacement, and, for each, list its specific material requirements.

Photograph showing the components of an artificial total hip replacement (in exploded perspective). These components are (from left to right) as follows: femoral stem, ball, acetabular cup insert, and acetabular cup. (Photograph courtesy of Zimmer, Inc., Warsaw, IN, USA.)

CS4.1 ANATOMY OF THE HIP JOINT

As a prelude to discussing the artificial hip, let us first briefly address some of the anatomical features of joints in general and the hip joint in particular. The joint is an important component of the skeletal system. It is located at bone junctions, where loads may be transmitted from bone to bone by muscular action; this is normally accompanied by some relative motion of the component bones. Bone tissue is a complex natural composite consisting of soft and strong protein collagen and brittle hydroxyapatite, which has a density between 1.6 and 1.7 g/cm$^3$. Bone is an anisotropic material with mechanical properties that differ in the longitudinal (axial) and transverse (radial) directions (Table CS4.1). The articulating (or connecting) surface of each joint is coated with cartilage, which consists of body fluids that lubricate

<table>
<thead>
<tr>
<th>Property</th>
<th>Parallel to Bone Axis</th>
<th>Perpendicular to Bone Axis</th>
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</table>
| Elastic modulus, GPa (psi)      | 17.4  
(2.48 × 10$^9$) | 11.7  
(1.67 × 10$^9$) |
| Ultimate strength, tension, MPa (ksi) | 135  
(19.3) | 61.8  
(8.96) |
| Ultimate strength, compression, MPa (ksi) | 196  
(28.0) | 135  
(19.3) |
| Elongation at fracture          | 3–4%                  | —                           |

and provide an interface with a very low coefficient of friction that facilitates the bone sliding movement.

The human hip joint (Figure CS4.1) occurs at the junction between the pelvis and the upper leg (thigh) bone, or femur. A relatively large range of rotary motion is permitted at the hip by a ball-and-socket type of joint; the top of the femur terminates in a ball-shaped head that fits into a cuplike cavity (the acetabulum) within the pelvis. An x-ray of a normal hip joint is shown in Figure CS4.2a.

This joint is susceptible to fracture, which normally occurs at the narrow region just below the head. An x-ray of a fractured hip is shown in Figure CS4.2b; the arrows show the two ends of the fracture line through the femoral neck. Furthermore, the hip may become diseased (osteoarthritis); in such a case, small lumps of bone form on the rubbing surfaces of the joint, which causes pain as the head rotates in the acetabulum. Damaged and diseased hip joints have been replaced with artificial

Figure CS4.1  Schematic diagram of human hip joints and adjacent skeletal components.

Figure CS4.2  X-rays of (a) a normal hip joint and (b) a fractured hip joint. The arrows in (b) show the two ends of the fracture line through the femoral neck.
or prosthetic ones with moderate success, beginning in the late 1950s. Total hip replacement surgery involves the removal of the head and the upper portion of the femur, as well as some of the bone marrow at the top of the remaining femur segment. Into this hole within the center of the femur a metal anchorage stem is secured that has the ball portion of the joint at its other end. In addition, the replacement cup socket must be attached to the pelvis. This is accomplished by removal of the old cup and its surrounding bone tissue. The new socket is affixed into this recess. A schematic diagram of the artificial hip joint is presented in Figure CS4.3a; Figure CS4.3b shows an x-ray of a total hip replacement. In the remainder of this section, we discuss material constraints and materials that have been used with the greatest degree of success for the various artificial hip components.

**CS4.2 MATERIAL REQUIREMENTS**

In essence, there are four basic components to the artificial hip: (1) the femoral stem, (2) the ball that attaches to this stem, (3) the acetabular cup that is affixed to the pelvis, and (4) a fixation agent that secures the stem into the femur and the cup to the pelvis. The property constraints on the materials to be used for these elements are stringent because of the chemical and mechanical complexity of the hip joint. Some of the requisite material characteristics will now be discussed.

Whenever any foreign material is introduced into the body environment, rejection reactions occur. The magnitude of rejection may range from mild irritation or inflammation to death. Any implant material must be biocompatible; that is, it must produce a minimum degree of rejection. Products resulting from reactions with body fluids must be tolerated by the surrounding body tissues such that normal tissue function is unimpaired. Biocompatibility is a function of the location of the implant, as well as its chemistry and shape.

Body fluids consist of an aerated and warm solution containing approximately 1 wt% NaCl in addition to other salts and organic compounds in relatively minor concentrations. Thus, body fluids are very corrosive, which for metal alloys can lead not only to uniform corrosion but also to crevice attack and pitting and, when
stresses are present, to fretting,\(^1\) stress corrosion cracking, and corrosion fatigue. It has been estimated that the maximum tolerable corrosion rate for implant metal alloys is about 0.01 mil per year (2.5 \times 10^{-4} \text{ mm per year}).

Another adverse consequence of corrosion is the generation of corrosion products that either are toxic or interfere with normal body functions. These substances are rapidly transported throughout the body; some may segregate in specific organs. Even though others may be excreted from the body, they may nevertheless persist in relatively high concentrations because of the ongoing corrosion process.

The bones and replacement components within the hip joint must support forces that originate from outside the body, such as those due to gravity; in addition, they must transmit forces that result from muscular action such as walking. These forces are complex and fluctuate with time in magnitude, direction, and rate of application. Thus, mechanical characteristics such as modulus of elasticity, yield strength, tensile strength, fatigue strength, fracture toughness, and ductility are all important considerations relative to the materials of choice for the prosthetic hip. For example, the material used for the femoral stem should have minimum yield and tensile strengths of approximately 500 MPa (72,500 psi) and 650 MPa (95,000 psi), respectively, and a minimum ductility of about 8\%EL. In addition, the fatigue strength [for bending stresses that are fully reversed (Figure 8.17a of Introduction; Figure 9.23a of Fundamentals)] should be at least 400 MPa (60,000 psi) at \(10^7\) cycles. For the average person, the load on the hip joint fluctuates on the order of \(10^6\) times per year. Ideally, the modulus of elasticity of the prosthetic material should match that of bone. A significant difference can lead to deterioration of the surrounding bone tissue and implant failure, which requires a second surgery and another prosthetic implant.

Furthermore, because the ball-and-cup articulating surfaces rub against one another, wear of these surfaces is minimized by using very hard materials. Excessive and uneven wear can lead to a change in shape of the articulating surfaces and cause the prosthesis to malfunction. In addition, particulate debris will be generated as the articulating surfaces wear against one another; accumulation of this debris in the surrounding tissues can also lead to inflammation.

Frictional forces at these rubbing counterfaces should also be minimized to prevent loosening of the femoral stem and acetabular cup assembly from their positions secured by the fixation agent. If these components do become loose over time, the hip joint will experience premature degradation that may require it to be replaced.

Three final important material factors are density, property reproducibility, and cost. It is highly desirable that lightweight components be used, that material properties from prosthesis to prosthesis remain consistent over time, and, of course, that the cost of the prosthesis components be reasonable.

Ideally, an artificial hip that has been surgically implanted should function satisfactorily for the life of the recipient and not require replacement. For current designs, lifetimes range between 15 and 25 years. Although this is a substantial improvement from the previous 5- to 10-year figures, longer lifetimes are still desirable.

Several final comments are in order relative to biocompatibility assessment. Biocompatibility of materials is usually determined empirically; that is, tests are conducted wherein materials are implanted in laboratory animals and the biocompatibility of each material is judged on the basis of rejection reactions, level of corrosion,

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\(^1\)Fretting is a combination of corrosion and wear in which corrosion produces small debris (generally oxide particles) that increases the friction and induces greater abrasion.
generation of toxic substances, and so on. This procedure is then repeated on humans for materials that were found to be relatively biocompatible in animals. It is difficult to predict the biocompatibility of a material. For example, mercury, when ingested into the body, is poisonous; however, dental amalgams, which have high mercury contents, have generally been found to be very biocompatible. Because of this biocompatibility assessment issue, most manufacturers select only materials that have been approved for biomedical use.

One final requirement for implant materials is that they be nonmagnetic [i.e., do not exhibit ferromagnetic or ferrimagnetic behavior (Chapter 20 of Introduction; Chapter 18 of Fundamentals)]. A frequently used medical diagnostic tool is MRI (magnetic resonance imaging) spectroscopy, a medical test in which the patient is subjected to a very strong magnetic field. The presence of any ferromagnetic/ferrimagnetic materials implanted in the patient will disrupt the applied magnetic field and render MRI spectroscopy unusable. In addition, the magnitudes of these magnetic fields are such that significant forces may be brought to bear on any magnetic implant materials; these forces may loosen the implant and/or harm the patient. Ferromagnetic materials that should be avoided for implant applications include some ferrous alloys (i.e., ferritic and martensitic stainless steels) and alloys with high contents of nickel and/or cobalt.

CS4.3 MATERIALS EMPLOYED

Femoral Stem and Ball

Early prosthetic hip designs called for both the femoral stem and ball to be of the same material—a stainless steel. Subsequent improvements have been introduced, including the use of materials other than stainless steel and constructing the stem and ball from different materials. Indeed, stainless steel is rarely used in current implant designs. The opening photograph of this case study shows one hip replacement design.

Currently, the femoral stem is constructed from a metal alloy of which there are two primary types: cobalt–chromium–molybdenum and titanium. Some models still use 316L stainless steel, which has a very low sulfur content (< 0.002 wt%); its composition is given in Table 11.4 of Introduction (Table 13.4 of Fundamentals). The principal disadvantages of this alloy are its susceptibility to crevice corrosion and pitting and its relatively low fatigue strength. As a result, its use has decreased.

Various Co–Cr–Mo alloys are used for artificial hip prostheses. One that has been found especially suitable, designated F75, is a cast alloy that has a composition of 66 wt% Co, 28 wt% Cr, and 6 wt% Mo. Its mechanical properties and corrosion rate range are listed in Table CS4.2. The corrosion and fatigue characteristics of this alloy are excellent.

Of the metal alloys that are implanted for prosthetic hip joints, probably the most biocompatible is the titanium alloy Ti–6Al–4V; its composition is 90 wt% Ti, 6 wt% Al, and 4 wt% V. The optimal properties for this material are produced by hot forging; any subsequent deformation and/or heat treatment should be avoided to prevent the formation of microstructures that are deleterious to its bioperformance. The properties of this alloy are also listed in Table CS4.2.

Recent improvements for this prosthetic device include using a ceramic material for the ball component rather than any of the aforementioned metal alloys. The ceramics of choice are a high-purity and polycrystalline aluminum oxide or zirconium.
oxide, which are harder and more wear resistant than metals and generate lower frictional stresses at the joint. However, the elastic moduli of these ceramics are large and the fracture toughness of alumina is relatively low. Hence, the femoral stem is still fabricated from one of the above alloys and is then attached to the ceramic ball; this femoral stem–ball component thus becomes a two-piece unit.

The materials selected for use in an orthopedic implant come after years of research into the chemical and physical properties of a host of different candidate materials. Ideally, the material(s) of choice not only will be biocompatible but also will have mechanical properties that match the biomaterial being replaced—bone. However, no synthetic material is both biocompatible and possesses the property combination of bone and the natural hip joint—low modulus of elasticity, relatively high strength and fracture toughness, low coefficient of friction, and excellent wear resistance. Consequently, material property compromises and trade-offs must be made. For example, recall that the modulus of elasticity of bone and femoral stem materials should be closely matched such that accelerated deterioration of the bone tissue adjacent to the implant is avoided. Unfortunately, synthetic materials that are both biocompatible and relatively strong also have high moduli of elasticity. Thus, for this application, it was decided to trade off a low modulus for biocompatibility and strength.

### Acetabular Cup

Some acetabular cups are made from one of the biocompatible alloys or aluminum oxide. More commonly, however, ultra-high-molecular-weight polyethylene (Section 15.19 of Introduction; Section 13.16 of Fundamentals) is used. This material is virtually inert in the body environment and has excellent wear-resistance characteristics; furthermore, it has a very low coefficient of friction when in contact with the materials used for the ball component of the socket. A two-component cup assembly is shown for the total hip implant in the opening photograph for this case study. It consists of an ultra-high-molecular-weight polyethylene insert that fits within the cup; this cup is fabricated from one of the metal alloys listed in Table CS4.2, which, after implantation, becomes bonded to the pelvis.

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**Table CS4.2** Mechanical and Corrosion Characteristics of Three Metal Alloys That Are Commonly Used for the Femoral Stem Component of the Prosthetic Hip

<table>
<thead>
<tr>
<th>Alloy</th>
<th>Elastic Modulus [GPa (psi)]</th>
<th>0.2% Yield Strength [MPa (ksi)]</th>
<th>Tensile Strength at Fracture Limit [MPa (ksi)]</th>
<th>Elongation (%)</th>
<th>Fatigue Strength or Corrosion Rate, $10^7$ Cycles [MPa (ksi), mpy]</th>
<th>Corrosion Rate (mpy)$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>316L Stainless steel</td>
<td>200 (29.0 × 10^3)</td>
<td>689 (100)</td>
<td>862 (125)</td>
<td>12</td>
<td>383 (55.5)</td>
<td>0.001–0.002</td>
</tr>
<tr>
<td>Co–28Cr–6Mo</td>
<td>210 (30.0 × 10^3)</td>
<td>483 (70)</td>
<td>772 (112)</td>
<td>8</td>
<td>300 (43.4)</td>
<td>0.003–0.009</td>
</tr>
<tr>
<td>Ti–6Al–4V</td>
<td>120 (17.4 × 10^3)</td>
<td>827 (120)</td>
<td>896 (130)</td>
<td>10</td>
<td>580 (84.1)</td>
<td>0.007–0.04</td>
</tr>
</tbody>
</table>

$myp$ means mils per year, or 0.001 in./yr.

Fixation

Successful performance of the artificial hip joint calls for the secure attachment of both the femoral stem to the femur and the acetabular cup to the pelvis. Insecure attachment of either component ultimately leads to a loosening of that component and the accelerated degradation of the joint. A fixation agent is sometimes used to bond these two prosthetic components to their surrounding bone structures. The most commonly used fixation agent is a poly(methyl methacrylate) (acrylic) bone cement that is polymerized in situ during surgery. This reaction must be carefully controlled, because the heat released during polymerization can lead to damage to the bone tissue.

This acrylic bond cement has, in some cases, contributed to femoral stem loosening because it is brittle and does not bond well with the metallic implant and bone tissue. It has been found that a more secure implant–bone bond is formed when the stem and cup are coated with a porous surface layer consisting of a sintered metal powder. After implantation, bone tissue grows into the three-dimensional pore network and thereby fixates the implant to the bone. Such a coating has been applied to the upper stem and outer acetabular cup regions of the hip replacement shown in the opening photograph for this case study.

SUMMARY

In this case study, the artificial total hip replacement was explored. The hip anatomy was first presented, which was followed by a discussion of the components and material requirements for the artificial replacement. Implant materials must be biocompatible with body tissues and fluids, corrosion resistant, and mechanically compatible with interfacing replacement/body components. The femoral stem and ball are normally made of a cold-worked stainless steel, a cast Co–Cr–Mo alloy, or a hot-forged titanium alloy. Some recent designs call for a polycrystalline aluminum oxide or zirconium oxide ball. Ultra-high-molecular-weight polyethylene is commonly used for the acetabular cup, whereas acrylic bone cement is normally the fixation agent for attachment of the femoral stem (to the femur) and acetabular cup (to the pelvis).

REFERENCES


DESIGN QUESTION

CS4.D1 The transdermal patch has recently become popular as a mechanism for delivering drugs into the human body.

(a) Cite at least one advantage of this drug-delivery system over oral administration using pills and caplets.

(b) Note the limitations on drugs that are administered by transdermal patches.

(c) Make a list of the characteristics required of materials (other than the delivery drug) that are incorporated in the transdermal patch.