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MECHANICAL PROPERTIES OF IMPLANTABLE BIOMATERIALS

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OVERVIEW

Biomaterials are formally defined as natural or synthetic materials that replace the function of hard or soft biologic tissues. In many instances, the primary function of an implantable biomaterial is to provide the structural support offered by the biologic material it is replacing. For this reason, it is imperative to use biomaterials that possess mechanical properties capable of withstanding the forces and motions experienced by the normal tissue. Moreover, these biomaterials should have sufficient fatigue strength to ensure long life of the implant in vivo. This article introduces methods traditionally used by biomedical engineers to identify the mechanical properties of biomaterials, discusses the design issues encountered in traditional implant designs, and reviews the mechanical factors that govern the fatigue life of an implantable biomaterial. It is presented as an overview to highlight the salient features of choosing the appropriate biomaterial for implant designs and can serve as an introduction to more detailed reading in the subject area.

CHARACTERIZATION OF MATERIAL BEHAVIOR AND DEFINITIONS

If a force is applied to an object, the object will move in space until it is acted on by another force. If, however, one end of the object is fixed in place when the force is applied, the object will not move freely in space but will deform or distort as a result of the applied force. The

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manner in which the object deforms and the maximum allowable force that can be applied before that material fractures are both governed by the physical properties of the material. In this section, the terms used to determine the physical characteristics of biomaterials are defined. Where possible, examples of common biomaterials are used to clarify concepts used to classify material behavior.

When an object is fixed in place, applied forces can cause a material to deform in several directions. If a force is applied perpendicularly to the surface of a specimen, the force is classfied as a normal force (Fig. 1). *Compressive* normal forces cause the material to decrease in length, whereas *tensile* normal forces cause the material to elongate in the direction of the applied force. If a force is applied transverse to the surface of a material, it is termed a *tangential* or shear force. Tangential or shear forces cause the material to distort in a direction parallel to the surface of the material, as shown in Figure 1.

Although the type and magnitude of force applied to a material indicates the direction of deformation, it does not completely describe the exact amount of deformation or the fracture threshold for the material. For example, consider two different cylindrical pieces of stainless steel that are the same length but have different diameters. A succession of increasing tensile forces are applied to the pieces in a testing machine and the resulting elongation (displacement) until fracture is measured for both specimens (Fig. 2). A plot of the force-elongation shows that significantly different fracture forces are required for the pieces, even though the material is exactly the same in both tests. The apparent disparity between the two tests can be resolved when the *stress*, defined as the ratio of the applied force to the area over which the force acts, is plotted versus elongation (see Fig. 2*B*). Because of the apparent differences that can occur in force-elongation tests, stress is used to describe the applied loading condition in a material test and determine the physical properties of the material. Similar to forces, stresses are classified as either normal or shear, depending upon the direction in which they are applied to the material.

Likewise, *strain* (ϵ) is a measure used to normalize the deformation caused by an applied stress and is described as either tensile, compressive, or shear. Tensile and compressive strains are defined as the amount

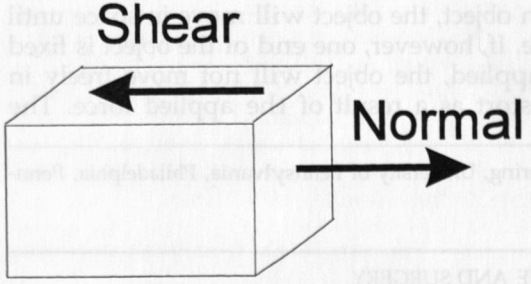

Figure 1. Forces that can be applied to objects are considered either normal or shear (tangential).

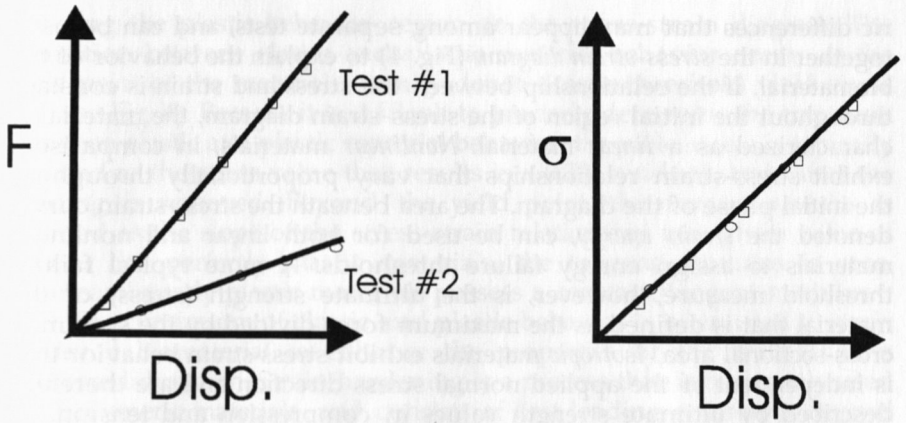

Figure 2. Results from mechanical tests of a material machined into two test pieces, where the pieces have a different cross-sectional area. Stress is used to normalize the results from the two different tests.

of displacement divided by the original specimen length in the direction of the applied force:

$$\epsilon = \frac{\delta}{l_{initial}} = \frac{l_{final} - l_{initial}}{l_{initial}} \quad (1)$$

where ϵ is strain, δ is amount of displacement, and l is length, and can also be expressed as the percent change in length of the specimen:

$$\% \text{ change in length (percent strain)} = \epsilon \times 100 \quad (2)$$

Normal stresses cause strains not only in their applied direction, but also create strains in the transverse direction (ϵ_t). The ratio of the transverse and longitudinal strains is called the Poisson's ratio (v), and is defined as:

$$v = \frac{-\epsilon_t}{\epsilon} \quad (3)$$

Shear strains are usually described by the change in angle of two sides of the test piece after the force is applied (Fig. 3).

The measures of stress and strain are vital to account for the geomet-

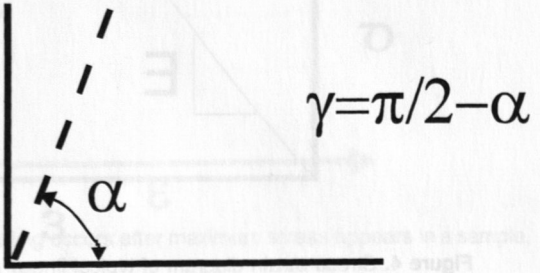

Figure 3. Shear strain is the deformation caused by shear stresses and describes the distortion of the deformed material *(dashed line)* compared with its undeformed shape *(solid line)*.

ric differences that may appear among separate tests, and can be used together in the *stress-strain diagram* (Fig. 4) to explain the behavior of the biomaterial. If the relationship between the stress and strain is constant throughout the initial region of the stress-strain diagram, the material is characterized as a *linear* material. *Nonlinear* materials, in comparison, exhibit stress-strain relationships that vary proportionally throughout the initial phase of the diagram. The area beneath the stress-strain curve, denoted the *strain energy*, can be used for both linear and nonlinear materials to assign energy failure thresholds. A more typical failure threshold measure, however, is the ultimate strength (stress) of the material that is defined as the maximum force divided by the specimen cross-sectional area. *Isotropic* materials exhibit stress-strain behavior that is independent of the applied normal stress direction and are therefore described by ultimate strength values in compression and tension. In comparison, *anisotropic* materials show fundamentally distinct behavior in different testing directions and usually possess several ultimate strength criteria that depend upon the loading direction.

Elastic material behavior, whether linear or nonlinear, refers to a condition where the material returns to its original shape after the applied forces are removed. For a linear elastic material, the ratio between the normal stress and normal strain is the elastic modulus, or *Young's modulus (E)* for the material. On a stress-strain diagram, the elastic modulus can be calculated by determining the slope of the relationship between the stress and strain. Similar to normal stress, the ratio between the shear stress and shear strain is constant for a linear elastic material and is termed the shear modulus *(G)*.

Plastic material behavior occurs when the strain is no longer proportional to the applied stress. As a result, a specimen that experiences plastic behavior does not return to its original length after removing the applied loading. Commonly, a material exhibits elastic behavior before

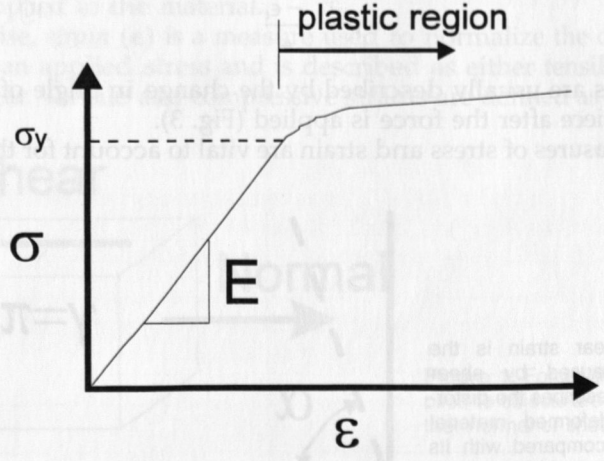

Figure 4. Stress-strain diagram of typical linear elastic, linear plastic material.

entering the plastic behavior region on the stress-strain diagram. The transition between elastic and plastic material behavior occurs at the *yield point* of the material, usually denoted as a threshold yield stress (σ_y, see Fig. 4). Because it is difficult to precisely determine the transition between elastic and plastic material behavior, the yield stress is typically defined as the stress value that results in a 0.2% residual strain after the loading is removed. Beyond the yield point, the *tangent modulus* is defined as the slope of the stress-strain relationship at a given value of strain. For perfectly plastic materials, the tangent modulus is zero, whereas linearly plastic materials possess a constant tangent modulus.

The continuum of elastic and plastic behavior is often used to *strain harden* a biomaterial to enhance the properties of the material in a preferred direction. Strain hardening is a process that is commonly used for polymeric materials, and consists of first loading a material beyond its yield point but below its ultimate strength. After unloading the material, any successive reloading of the material will follow elastic behavior until the maximum stress level used in the original test is reached. Beyond this stress level, plastic behavior occurs. In this manner, strain hardening allows a designer to modify the yield point of a material. The principal disadvantage of strain hardening, however, is that the energy required to cause material fracture is lower after strain hardening.

At some point in the plastic portion of the stress-strain curve, the calculated stress, defined as the uniaxial force divided by the original cross-sectional area, begins to decrease for increasing levels of strain (Fig. 5). This phenomena, termed *necking*, coincides with a rapid decrease in the actual cross-sectional area on the test piece. For metallic materials, necking usually occurs in small region of the test piece immediately prior to failure that occurs in the necked region. For polymers, necking occurs in a larger section of the test piece that elongates considerably

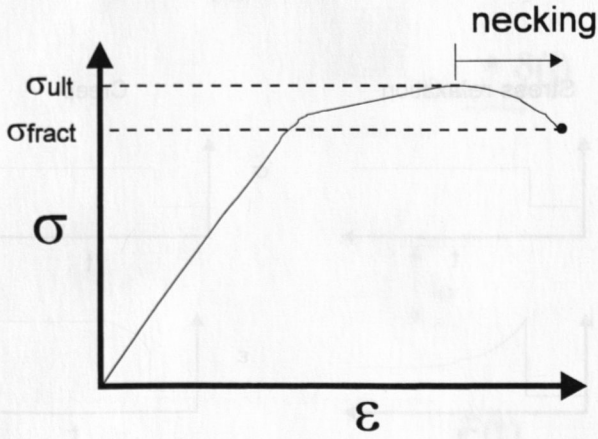

Figure 5. Necking of a material. Necking occurs after maximum stress appears in a sample, and continues until fracture.

before failure. This elongation in the necking phase for polymers, termed *drawing*, represents a reorganization of the ultrastructure that produces a much stiffer polymer material.

Viscoelastic behavior is a common characteristic of biologic tissue and describes the phenomena where the response of the material behaves as a combination of fluid (viscous) and solid (elastic) behavior. The response, measured as the resulting strain (stress) after an applied stress (strain), depends upon the elapsed time after the loading is applied and the rate at which the load is applied. If a viscoelastic material is quickly compressed or elongated and maintained at that level of strain, the measured stress will decrease, or relax, over time (Fig. 6*A*). This behavior, termed *stress relaxation*, is used to determine if the viscoelastic material can be characterized as a fluid (long-term stress is zero) or solid (permanent value of long-term stress) material. If, on the other hand, a viscoelastic material is subjected to a constant level of stress, the resulting strain response will change over time (see Fig. 6*B*). This phenomena, termed *creep*, will continue indefinitely for a viscoelastic fluid and will eventually reach a permanent value of strain for a viscoelastic solid. Common testing procedures for viscoelastic material include either stress relaxation, creep, or forced vibration and will be discussed in the next section.

DETERMINATION OF MATERIAL BEHAVIOR

Classifying the behavior of biomaterials requires rigorous investigation of the properties in the laboratory. Although there are many different testing methods to define the physical properties of materials, only the most prevalent material-testing procedures are focused on in this article. Where applicable, a distinction is made between time-independent and time-dependent material testing protocols.

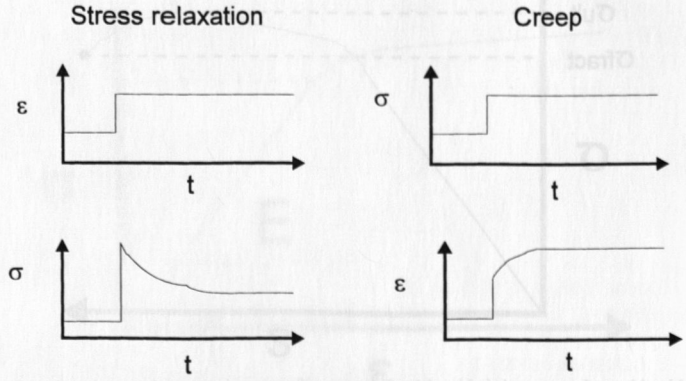

Figure 6. Stress relaxation and creep for a viscoleastic material.

Time-Independent Material Behavior

Uniaxial Extension and Compression

Tensile or compressive uniaxial loading is perhaps the most common method of material testing and is used to determine several material property characteristics that include, but are not limited to, (1) linear or nonlinear behavior, (2) material isotropy or anisotropy, (3) time-independent or time-dependent behavior, (4) fatigue strength, and (5) fracture limit. Traditionally, either cylindrical, rectangular, or square cross sections are used for the test pieces. Moreover, the geometry of the test piece is designed to create an area of reduced cross section that is monitored to measure the displacement of the sample in response to an applied tensile or compressive force (Fig. 7).

For time-independent material behavior, increasing levels of compressive or tensile forces are slowly applied to the test specimen, and instruments such as extensometers are used to precisely measure the strain from the change in length of two points within the testing section:

$$\epsilon = \frac{l_{final} - l_{initial}}{l_{initial}} \tag{4}$$

If large strains ($\epsilon > .05$) are measured before fracture occurs, it is common to calculate the true strain (ϵ_{true}):

$$\epsilon = \ln(1 + \epsilon) = \ln\left(\frac{l_{final}}{l_{initial}}\right) \tag{5}$$

In addition, it is sometimes desirable to monitor the change in the width of the specimen during the test using extensometers to calculate the transverse strain during the elastic loading phase, which can then be used to calculate the Poisson's ratio of the material. Determining the

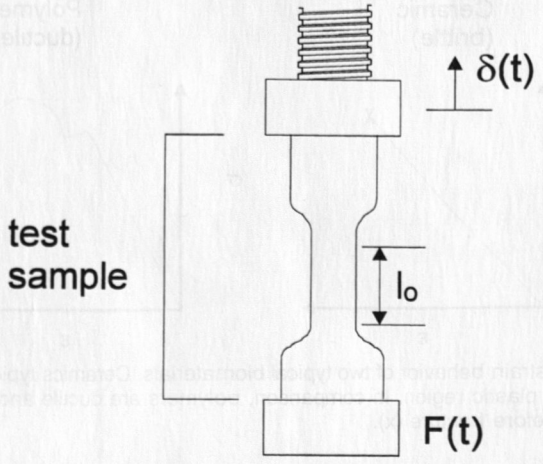

Figure 7. Typical uniaxial testing system.

Poisson's ratio is useful for determining the distribution of stresses within an implant design.

Fracture strength (σ_{ult}) is determined from the force required to cause failure (F_{fail}) and the original cross-sectional area (A_o):

$$\sigma_{ult} = \frac{F_{fail}}{A_o} \tag{6}$$

whereas the energy required to cause fracture is termed the toughness:

$$\text{Toughness} = \int \sigma d\epsilon \tag{7}$$

Test results from typical ceramic and polymer biomaterials appear in Fig. 8.

Torsion

Although measurements of the material properties in tension and compression are important for design considerations, the combination of normal and shear stresses that commonly coexists in an implant dictates that the shear properties must also be measured. A common method for determining the shear modulus and ultimate shear strength is the torsion test. In this test, the specimen is located between two crosshead grips and torque is applied to one end of the specimen while the opposite end is held stationary. Both the angle of twist (θ) in the bar and the applied torque (T) is recorded. similar to uniaxial tests, the torque-angle of twist relationship can show both an elastic and plastic region (Fig. 9).

For a torsion test using a solid cylindrical specimen without any notches or fillets, the shear stress (τ) at a point (r) from the center is

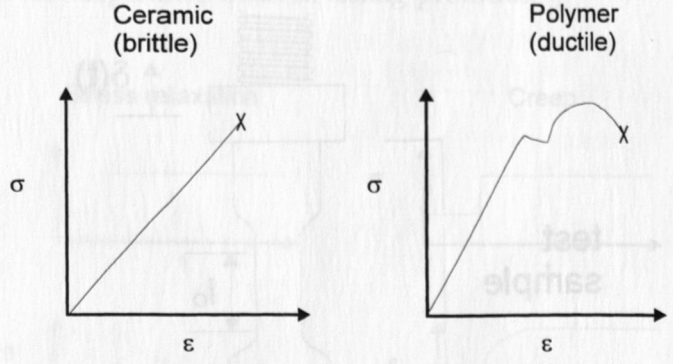

Figure 8. Stress-strain behavior of two typical biomaterials. Ceramics typically exhibit brittle behavior, with no plastic region. In comparison, polymers are ductile and exhibit considerable elongation before fracture (x).

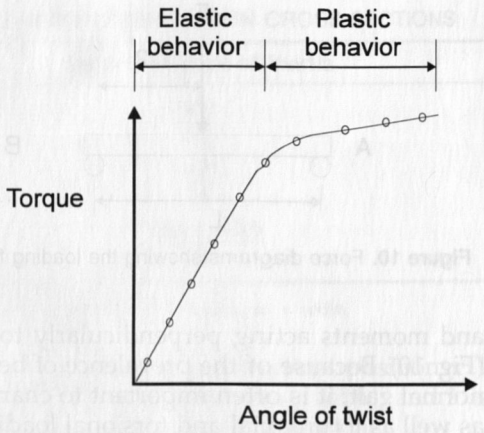

Figure 9. Typical torsion test result.

dependent upon the applied torque and the polar moment of inertia (J) according to the relation:

$$\tau = \frac{rT}{J} \tag{8}$$

The shear modulus (G) can be calculated easily by including the measured angle of twist (θ) and the length of the bar, using test data below the proportional limit:

$$G = \frac{TL}{J\theta} \tag{9}$$

where:

$$J = \frac{\pi R^4}{2} \tag{10}$$

If a hollow circular shaft with an inner radius (R_i) and outer radius (R_o) is used, the polar moment of inertia (J) is affected,

$$J = \frac{\pi}{2}(R_o^4 - R_i^4) \tag{11}$$

but the remaining relations can be used to calculate G.

The above relations change slightly if the test specimen is machined to have a region of smaller cross-sectional area, similar in shape to uniaxial test pieces discussed earlier. In this configuration, adjustments need to be made in the test apparatus to ensure that the angle of twist for the region of reduced cross-sectional area is accurately measured and used in the relation above.

Bending

Many long bones in the human body experience both compressive and bending loads. Bending commonly refers to the condition of forces

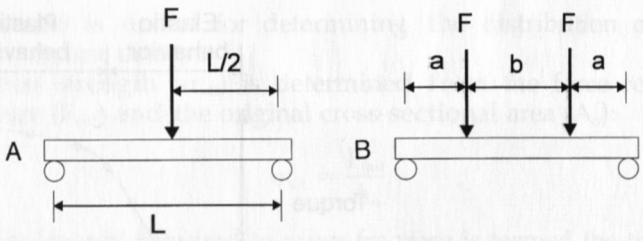

Figure 10. Force diagrams showing the loading for *(A)* 3 point and *(B)* 4 point bending.

and moments acting perpendicularly to the longitudinal axis of beams (Fig. 10). Because of the prevalence of bending loads experienced during normal gait, it is often important to characterize biomaterials in bending as well as in uniaxial and torsional loading. In bending, the result of the perpendicular forces and moments causes a mixture of normal and shear stresses throughout the beam material. If the perpendicular forces acting along the length of the beam are defined by a function, q(x), then it can be shown that the average internal shear force, V, acting along the beam is given by:

$$V(x) = \int_0^x q(x)dx \tag{12}$$

In turn, the internal bending moment (M) along the beam length (x) is a product of the internal shear force:

$$M(x) = -\int_0^x V(x)dx \tag{13}$$

It can be shown that for long, isotropic beams of constant cross-sectional area, the flexural, or normal, stress acting at a point along the beam ($\sigma_{flexural}$) is given by:

$$\sigma_{flexural} = -\frac{My}{I} \tag{14}$$

where M is internal moment acting at the point x, y is vertical distance from the bending axis, and *I* is area moment of inertia for the beam cross section.

The bending axis is defined as the point on the beam cross-section where the flexural stresses are zero. Both the position of the bending axis and the area moment of inertia change for different beam shapes. The location of the bending surface for each beam cross section is along the center of the beam, whereas the second area moment of inertia for common cross sections is shown in Table 1.

Shear stresses (τ) that are caused by bending loads also vary along the vertical distance of the cross section, and are given by the relation:

$$\tau = \frac{VQ}{Ib} \tag{15}$$

Table 1. SECOND AREA MOMENT OF INERTIA FOR COMMON CROSS SECTIONS

Beam Cross Section	Second Moment of Inertia
Rectangle	$\frac{wh^3}{12}$
Circular	$\frac{\pi D^4}{64}$
Circular shaft	$\frac{\pi(D_o^4 - D_i^4)}{64}$

D = diameter, D_o = outer diameter, D_i = inner diameter, h = height, w = width.

where V is average internal shear force at the longitudinal position x, I is area moment of inertia, Q is first moment of inertia ($\int ydA$), and b is width of the beam cross section at the desired vertical position.

Table 1 contains the formulas for the first moment of inertias of common beam cross sections.

The combined loading and support conditions on the beam can be used to calculate not only stresses throughout the material but also the transverse displacements that occur along the length of the beam. Through geometric considerations, it can be shown that the beam deflection, δ, at a position of the beam is related to the internal moment (M) at that point, the elastic modulus of the beam (E), and the area moment of inertia (I), according to the relation:

$$\frac{d^2\delta}{dx^2} = \frac{M}{EI} \tag{16}$$

This formula applies for small deflections of the beam, where the maximum deflection is much less than the beam thickness. For treatment of large-beam deflections, the reader is referred to several excellent texts: Green and Zerna,[3] Timoshenko,[6] and Sokolnikoff.[4]

These theoretic expressions can be applied to design several bending tests to characterize the behavior of biomaterials. Of the possible bending test conditions, two are most common—three-point bending and four-point bending. In three-point bending, the material is suspended horizontally across two supports, and a vertical load is applied at the center of the beam (Fig. 11). In this configuration, compressive normal stresses are maximum along the top surface of the beam, and maximum tensile stresses appear along the bottom surface of the beam. The magnitude of the normal and shear stresses can be calculated according to the previous relationships (Equations 14 and 15).

The internal moment in the beam is maximum at the centerpoint of the beam, which in turn causes the beam deflection to be greatest at the center of the beam (Equation 16). The centerpoint beam deflection, therefore, can be used to calculate the elastic modulus of the material being tested in three-point bending:

$$v_{max} = \frac{FL^3}{48EI} \tag{17}$$

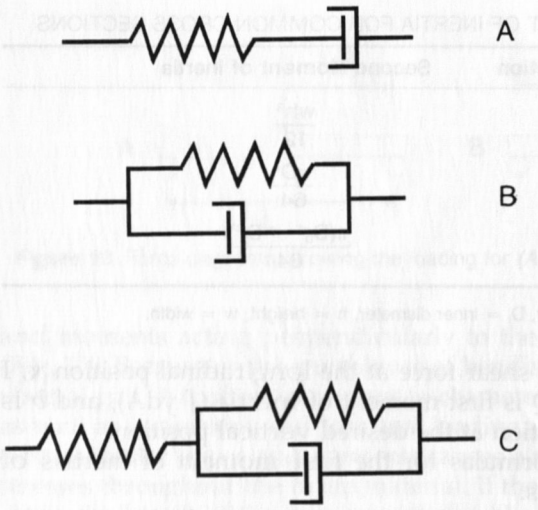

Figure 11. Common viscoelastic material models: *(A)* Maxwell fluid, *(B)* Kelvin Voigt solid, and *(C)* standard linear solid.

where V_{max} is the centerpoint deflection of the beam, F is the applied force, and L is the length of the beam.

Four-point bending is slightly different than three-point bending, because two vertical loads are applied to the test piece instead of the single load used in three-point bending. Flexural stresses occur along the entire beam and are calculated using previous relationships.

Because of the nature of the loading, shear stresses in the beam do not exist in the beam section between the applied loads. Rather, the only nonexistent shear stresses appear between the beam supports and the vertical loading point. The midspan of the beam, between the vertical loads, is therefore an area where only normal stresses appear in the beam. This is the primary advantage of four-point bending and is a feature that is utilized by many experimentalists to characterize the behavior of materials to purely normal stress patterns. In four-point bending, the centerpoint deflection of the beam is monitored and is used to calculate the elastic modulus in bending:

$$E = \frac{Pa}{24\, v_{max}\, I}(3L^2 - 4a^2) \tag{18}$$

where P is the load applied to the beam and L is the beam length; *a* denotes the distance from the edge of the beam where the loading is applied (see Fig. 10).

Time-Dependent Material Behavior

Because most biologic tissues exhibit viscoelastic behavior, it is important to understand the time-dependent response of the tissue and its intended biomaterial replacement. Three different types of loading

are used to determine the viscoelastic behavior of materials—the instantaneous step loading, the forced vibratory input, and the free vibratory response. Each mode of loading will produce a unique time-dependent response that is analyzed to assign the elastic and viscous properties of the material.

Both linear and nonlinear viscoelastic material models have been used to describe tissue behavior. For this article, I focus only on the linear material models (see Findley, Lai, and Onaran[1] for a discussion of nonlinear viscoelastic material modeling). Unlike linear elastic materials, a wide range of material models exist for simulating linear viscoelastic materials. In their native form, the linear viscoelastic models are classified as either empirical or continuum. *Mechanical models* approximate the viscoelastic material as behaving as part solid and part fluid. They are often used by investigators because the model results appear more intuitive. For the elastic material component, the stress is a linear function of the strain:

$$\delta = E\dot{\epsilon} \tag{19}$$

whereas the stress in a fluid component is proportional to the rate of strain:

$$\sigma = \eta\dot{\epsilon} \tag{20}$$

where both E and η are termed the elastic and viscous constants, respectively. Mechanical models consist of arranging elastic and fluid elements to approximate the behavior of a material. If an elastic element and fluid element are "connected" in series (see Fig. 11*A*), the differential equation that describes the overall stress-strain relationship is given as:

$$\eta\dot{\sigma} + E\sigma = E\eta\dot{\epsilon} \tag{21}$$

This material model, known as a *Maxwell fluid*, is the simplest model to describe the behavior of viscoelastic fluids.

If, on the other hand, an elastic element is connected in parallel with a viscous element (see Fig. 11*B*), a *Kelvin Voigt solid* model is formed and the resulting stress-strain relationship is as follows:

$$\sigma = E\epsilon + \eta\dot{\epsilon} \tag{22}$$

More complex empirical models can be made by combining more elastic and viscous elements together, developing increasingly complex strain-strain relationships. For example, a *standard linear solid* consists of a Kelvin Voigt element in series with an elastic element (see Fig. 11*C*) and is one of the most versatile, yet simple, models of a viscoelastic solid and is used often when studying biologic tissue behavior.

Integral models of linear viscoelastic behavior, on the other hand, use a mathematical framework to describe the response of a viscoelastic material to any generalized loading condition. An advantage of these models is their ability to more accurately predict the response of a viscoelastic material to a prescribed loading condition in comparison to empirical models. The fundamental principle of an integral model is

that the stress response ($\sigma[t]$) of a viscoelastic material to a sudden, or step input in strain ($\Delta\epsilon$) is given by:

$$\sigma(t) = Y(t)\Delta\epsilon \tag{23}$$

where $Y(t)$is called the relaxation modulus. Conversely, the strain response, $\epsilon(t)$, to step input in stress is calculated according to the relation:

$$\epsilon(t) = J(t)\Delta\sigma \tag{24}$$

where $J(t)$ is called the creep compliance.

The utility of the integral modeling approach becomes apparent when one realizes that *any generalized input loading condition can be approximated as a successive series of infinitesimal steps in stress or strain.* For example, the input strain loading condition shown in Figure 12*A* consists of two separate increases in strain that occur at 0 and 4 seconds, respectively.

Mathematically, the stress in the viscoelastic material caused by this loading condition would be:

$$\sigma(t) = Y(t)\Delta\epsilon_1 \; ; \; t < 4 \text{ seconds} \tag{25}$$

$$\sigma(t) = Y(t)\Delta\epsilon_1 + Y(t-4)\Delta\epsilon_2 \; ; \; t \geq 4 \text{ seconds} \tag{26}$$

where $Y(t - 4)$ represents the relaxation modulus shifted in time by 4 seconds to account for the addition of strain at $t = 4$ seconds. For a more general strain input (see Fig. 12*B*), the response in time would be a superposition of the response from a series of infinitesimal steps, or

$$\sigma(t) = \epsilon_0 Y(t) + \int_0^t Y(t-\tau)\frac{d\epsilon}{d\tau} \tag{27}$$

where $_0$ is the instantaneous strain at time $t = 0$.

If one desired the strain response to a prescribed stress function, $\sigma(t)$, the approach outlined above would yield the following:

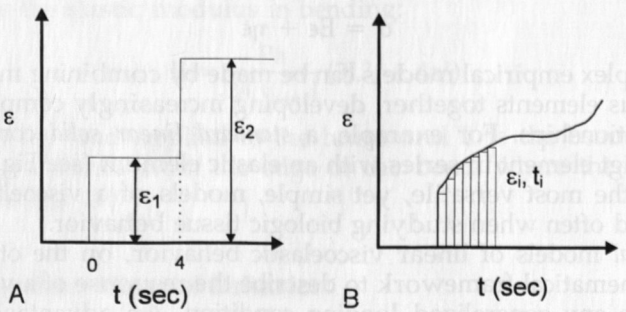

Figure 12. Simple *(A)* and more complex *(B)* loading conditions that can be accurately analyzed using continuum models of viscoelastic behavior.

$$\epsilon(t) = \sigma_0 J(t) + \int_0^t J(t - \tau) \frac{d\sigma}{d\tau} \tag{28}$$

where σ is the instantaneous stress at time $t = 0$.

It should be kept in mind that neither the creep compliance function nor the relaxation modulus function need to be based on many theoretical assumptions, because both functions can be measured in the laboratory.

With this as background material, several common testing methods are reviewed in the following paragraphs. Each method reviewed can be used to develop either empirical or continuum models of viscoelastic materials.

Stress Relaxation and Creep

The most common type of viscoelastic material testing consists of applying a known stress or strain to a material and monitoring the response of the material over time. If the applied loading is an instant change in stress, then the test monitors the creep response in strain. On the contrary, if the applied loading is a step change in strain, then the stress relaxation response is measured. In both tests, loading is applied in a manner to avoid inertial effects from the material mass. A typical creep experiment configuration is shown in Figure 13*A*, where the known compressive force is placed on the sample and allowed to compress the sample over time. The compression response of the material is measured using a linear variable differential transformer (LVDT) transducer and is converted to a strain response by dividing the measured displacement ($\delta[t]$) with the sample gage length (l_0):

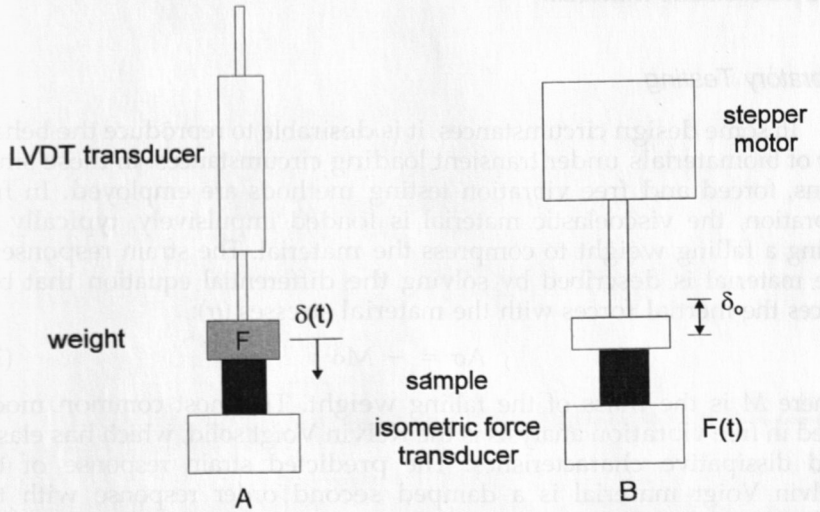

Figure 13. Typical *(A)* creep and *(B)* stress relaxation testing configurations.

$$\epsilon(t) = \frac{\delta(t)}{l_0} \tag{29}$$

From this data, the creep compliance function can be calculated directly:

$$J(t) = \frac{\epsilon(t)}{\sigma_0} = \frac{\delta(t)A_0}{Fl_0} \tag{30}$$

where F is the applied and A_0 is the cross-sectional area of the specimen. If a lumped parameter model is desired, then elastic and viscous constants are chosen to best approximate the creep compliance data.

For stress relaxation, an instantaneous displacement is applied to the specimen with a programmable stepper motor, and the resulting force is converted to stress by dividing by the cross-sectional area. The relaxation modulus ($Y[t]$) can be calculated directly using the measured data and applied magnitude of strain:

$$Y(t) = \frac{\sigma(t)}{\epsilon_0} = \frac{F(t)L_0}{A_0\delta} \tag{31}$$

Properly fitting the relaxation modulus yields a function that can be used for a continuum model of material behavior. More sophisticated fitting procedures are required to determine the elastic and viscous coefficients appearing in a empirical model.

With current testing equipment, it is possible to perform both creep and stress relaxation experiments without difficulty. Investigators should be aware, however, that a true step loading function cannot be achieved in the laboratory. Because of this, the results from most relaxation and creep tests are better suited to predict the long-term ($t > 1$ second) response of materials. Vibratory testing procedures, in comparison, are better methods to predict the short-term or dynamic response of a viscoelastic material.

Vibratory Testing

In some design circumstances, it is desirable to reproduce the behavior of biomaterials under transient loading circumstances. In these situations, forced and free vibration testing methods are employed. In free vibration, the viscoelastic material is loaded impulsively, typically by using a falling weight to compress the material. The strain response in the material is described by solving the differential equation that balances the inertial forces with the material stresses (σ):

$$A\sigma = -M\ddot{\delta} \tag{32}$$

where M is the mass of the falling weight. The most common model used in free vibration analysis is the Kelvin Voigt solid, which has elastic and dissipative characteristics. The predicted strain response of the Kelvin Voigt material is a damped second order response with the following characteristics:

$$\text{natural frequency} = \omega_n = \frac{2\pi}{T(1 - \zeta^2)^{1/2}} = \sqrt{\frac{AE}{ML}} \tag{33}$$

$$\text{damping ratio} = \zeta = \frac{\Lambda}{\sqrt{4\pi^2 + \Lambda^2}} = \eta \sqrt{\frac{A}{4\,MLE}} \tag{34}$$

Figure 14 shows a typical material response for a free vibration test, and the selection of several points on the diagram to determine the natural frequency and damping ratio. These response characteristics can be used to solve for the elastic and viscous coefficients of the Kelvin Voigt material using Equations 33 and 34.

It is worth mentioning that uniaxial loading is not the only type of loading that can be used for free vibration testing shown above. Torsional pendulums are useful for determining the properties of viscoelastic materials in shear, and follow the same principles of analysis above. Moreover, the free vibration testing method is not restricted to simple empirical models. However, methods for solving more complex material models will not be discussed in this article, but can be found elsewhere.[2]

The remaining vibratory testing method, termed *forced vibration*, is a method employed to directly investigate the behavior of materials to a range of dynamic inputs. A material sample is subjected to a periodic stress (strain), and the resulting strain (stress) is measured simultaneously with the input. Mathematically, the force generated in the material at a given frequency (ω) is a product of the modulus of the material, $E(\omega)$, and the applied magnitude of strain (ϵ):

$$\sigma(t) = E(\omega)\,\epsilon(t) \tag{35}$$

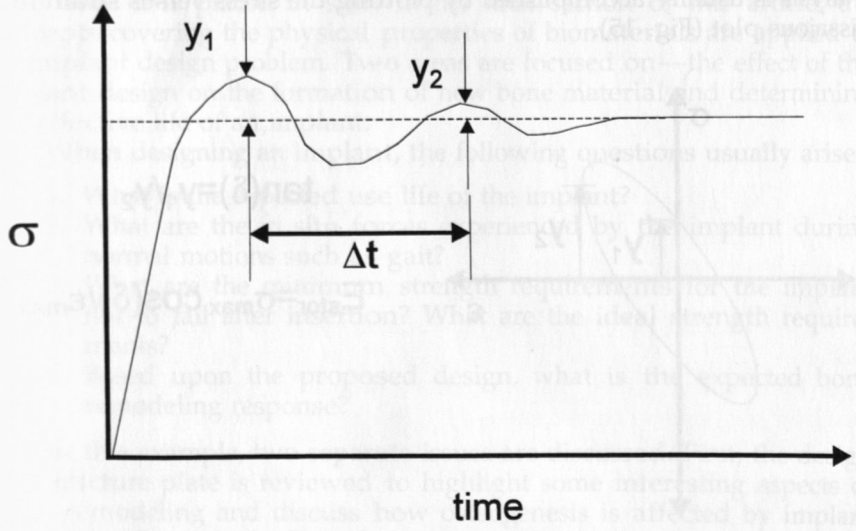

Figure 14. Free vibration test response, where the measured parameters (Dt, L) are used to calculate the natural frequency (ω_n) and damping ratio (ζ).

For a complex strain input, $\epsilon^{i\omega t}$, the resulting stress is a product of the strain and the complex modules, where

$$E(\omega) = E_1(\omega) + i\,E_2(\omega) \tag{36}$$

denotes the storate ($E_1[\omega]$) and loss ($E_2[\omega]$) modulus, respectively. Separating the real component of the stress response, we find that

$$\sigma(t) = \epsilon\,(E_1\cos[\omega t]E_2\sin[\omega t]) \tag{37}$$

describes the response of a viscoelastic material to the strain input, $\epsilon\cos(\omega t)$. Experimentally, the measured stress lags the input strain function by an angle ϕ:

$$\sigma(t) = \sigma_0\cos(\omega t + \phi) \tag{38}$$

Comparing this equation with the previous equation, one can rearrange the equations using trigonometric identities to yield:

$$\begin{aligned}\sigma(t) &= \sigma_0\,(\cos(\omega t)\cos(\phi) - \sin(\omega t)\sin(\phi)) \\ &= \epsilon(\cos(\omega t)\,E_1 - \sin(\omega t)\,E_2)\end{aligned} \tag{39}$$

Inspecting the equation, one can define the loss tangent (δ) as the ratio between the loss modulus and storage modulus to describe the phase shift in the stress response:

$$\delta = E_2/R_1 \tag{40A}$$

and, therefore

$$\sigma(t) = \sigma_0\cos(\omega t + \phi) = \epsilon(\cos(\omega t + \delta)) \tag{40B}$$

In the laboratory, the experimenter adjusts the testing apparatus so that the phase difference between the stress and strain is apparent. This analysis is usually accomplished by plotting the stress versus strain in a Lissajous plot (Fig. 15).

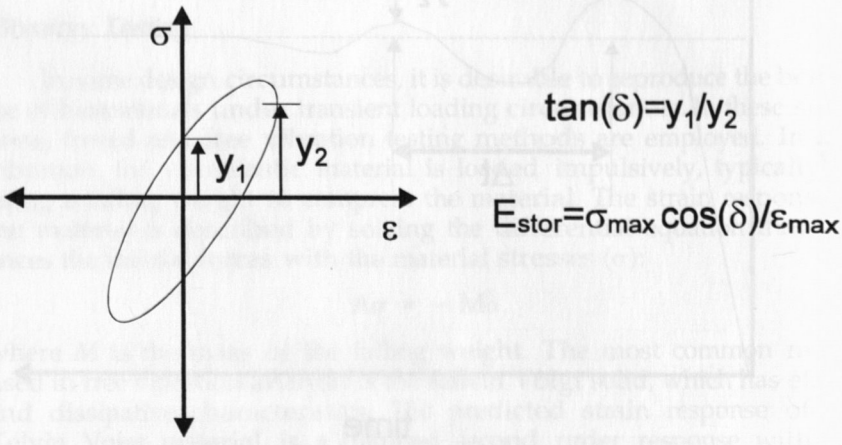

Figure 15. Lissajous (σ-ϵ) plot from a forced vibration test of a viscoelastic material. Loss tangent (δ) A and storage modulus (E_1) can be calculated directly from the test results.

On a Lissajous plot, the loss tangent is determined from the maximum stress value (σ_1) and the value of stress (σ_2) when the driving strain is zero:

$$\phi = \text{acos}\,(\sigma_2/\sigma_1) \tag{41}$$

Moreover, the value of the storage modules can be determined from the equation:

$$E_1 = \frac{\sigma_{max}}{\epsilon_{max}} \cos(\delta) \tag{42}$$

Typically, the storage and loss modulus are characterized over a broad frequency range and used to develop either continuum or empirical viscoelastic models. In turn, these models can be used to predict the response of the material to a wide range of loading conditions.

As a result of the tests used in this section, an investigator can describe the behavior of a biomaterial and use the information to aid in deciding if the material is sufficient to use as an implant. In the next section, the information contained in this section is applied to the design of an implant, and problems encountered with implant materials are reviewed in more detail.

MECHANICAL DESIGN CONSIDERATIONS FOR IMPLANT MATERIALS: AN EXAMPLE

One of the important steps in designing implants is not only understanding the mechanical properties of the implant material, but also characterizing the mechanical environment that the implant will experience once it is placed in situ. In the final section of this article, the concepts covering the physical properties of biomaterials are applied to an implant design problem. Two areas are focused on—the effect of the implant design on the formation of new bone material and determining the effective life of an implant.

When designing an implant, the following questions usually arise:

1. What is the expected use life of the implant?
2. What are the in situ forces experienced by the implant during normal motions such as gait?
3. What are the minimum strength requirements for the implant not to fail after insertion? What are the ideal strength requirements?
4. Based upon the proposed design, what is the expected bone remodeling response?

In this example, two separate issues are discussed. First, the design of a fracture plate is reviewed to highlight some interesting aspects of bone remodeling and discuss how osteogenesis is affected by implant properties. Second, the fatigue properties for plates are considered and the expected time to failure is determined.

Consider the design of a fracture plate for the repair of a human tibia. Assume that two fracture plates are used in a normal surgical procedure, and that the maximum load transferred through the tibia/plate arrangement is specified as the weight of the body *(W)*. Two separate biomaterials are being considered for the final production design, a titanium alloy with an elastic modulus of 220 GPa (σ_{ult} = 80 MPa), and a reinforced polymer with a modulus of 55 GPa (σ_{ult} = 20 MPa). The shape of the implant is identical for the two plates, with a cross-sectional area of 1 cm^2.

For this design, three questions need to be addressed. First, with the available data, will the plates fail once loads are applied to the tibia? Second, what is the anticipated bone remodeling response for both designs? Third, if a load is cyclically applied to the plates, how many times can the load be applied before it fractures?

To determine if the plate will fracture under these loads, it is assumed that the weight of the person is transferred completely to the injured tibia. Moreover, it is assumed that the two plates bear the complete weight of the individual. Although this load distribution is not exactly correct, it is providing the worst case. From equations given previously, the stress in each plate is:

$$\sigma_{plate} = \frac{W}{2A} \tag{43}$$

For a 70-kg male, the plate stress corresponds to 3.4 MPa. For both materials, this plate stress is below the ultimate compressive strength of the material.

With the fracture plates in place, the forces transmitted to the tibia are actually borne by the plates and the existing bone:

$$F_{total} = 2\,F_{plate} + F_{tibia} \tag{44}$$

Because of their parallel connection, both the bone and the plates experience compressive loading. Therefore, the total load is shared over the bone and the plates, so

$$F_{total} \propto (E_{plate}\,A_{plate} + E_{bone}\,A_{bone}). \tag{45}$$

Because the only difference between the two designs is the modulus of the two implant materials, this analysis suggests that the metal implant would bear more of the total load when compared to the composite material.

The difference in load sharing, or *stress shielding*, that occurs for the metal implant design has a direct impact on the bone remodeling process. Wolff's law states that the bone remodeling process is stimulated in direct proportion to the stress applied to the bone, and vice versa. In the example above, less osteogenic activity would be expected for the metal implant owing to the decreased load transferred to the bone matrix. Cortical bone would be resorbed and appear thinner once the implant was removed. Although the exact mechanism to explain Wolff's law has yet to be determined, several experimental efforts have proven

the deleterious effects of stress shielding the bone matrix with an implant.

Finally, of concern are the fatigue properties of the materials and how test information can be applied to assess the useful life of an implant. Although both materials will not fracture from a single application of stress, it is not known how long either material will survive in vivo before fracturing from fatigue. The *fatigue limit* is a value of stress, below the ultimate strength of the material, that is dependent upon the magnitude of applied stress, the duty cycle, and the environment in which the material is tested.

To evaluate the fatigue limit, an alternating series of tension and compression loads are placed on a specimen until failure. A number of tests are conducted to determine the total cycles required to produce fracture at different stress levels. A plot of the fracture stress versus the number of cycles to failure is constructed for each material (Fig. 16). This plot, known as the S-N plot, can be modified to include more complex loading conditions if needed. For metals, the S-N plot usually asymptotically approaches a stress value known as the *endurance limit*. The endurance limit denotes stress levels below which fatigue failure is not observed.

With the applied stress level to the plates (3.4 MPa), the S-N plots for the two different materials show that although titanium is well below its endurance limit, the polymer can withstand only approximately 10^5 cycles before failing from the repeated application of stress. This cycle limit is approximate and is modified slightly by adjusting the loading conditions used in the fatigue test to more closely resemble the stresses experienced in vivo. Nevertheless, in the practical use of the implant, this approximate cycle limit will likely not be exceeded.

Therefore, this mechanical analysis of the two implant designs indicates that the polymer biomaterial is a better choice for use in the implant. Not only will the polymer withstand both a single expected stress level and the anticipated cyclic stress loading, the bone remodeling response predicted from Wolff's law will be more prolific with the

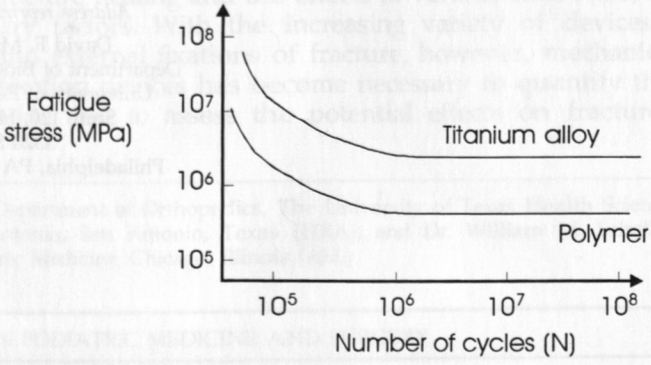

Figure 16. S-N plots for titanium alloy and polymer materials.

polymer based design. Naturally, additional factors such as biocompatibility and cost will contribute to the final design choice.

SUMMARY

This chapter was intended to review many of the terms used to describe the behavior of biomaterials including linear elastic, plastic, and viscoelastic behavior. Common testing methods for evaluating the behavior of biomaterials were also reviewed. Uniaxial loading, perhaps the most common testing procedure, can characterize both time-independent (i.e., linear elastic and plastic) and time-dependent (viscoelastic) materials with a controlled loading condition. Bending tests, because of their ease, are also popular and can describe linear elastic and plastic behavior fairly well. Vibratory methods to measure viscoelastic behavior, on the other hand, are less popular but are essential if the expected loading condition of the biomaterial will be fairly rapid. Taken together, these tests form the foundation for understanding the applicability of a specific material for use as an implant, and can be used to predict not only the failure thresholds for the implant but also the expected remodeling response of the bone once the implant has been placed in situ. For this reason, characterizing the mechanical properties of implant materials has been and will continue to be an important step in implant design.

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