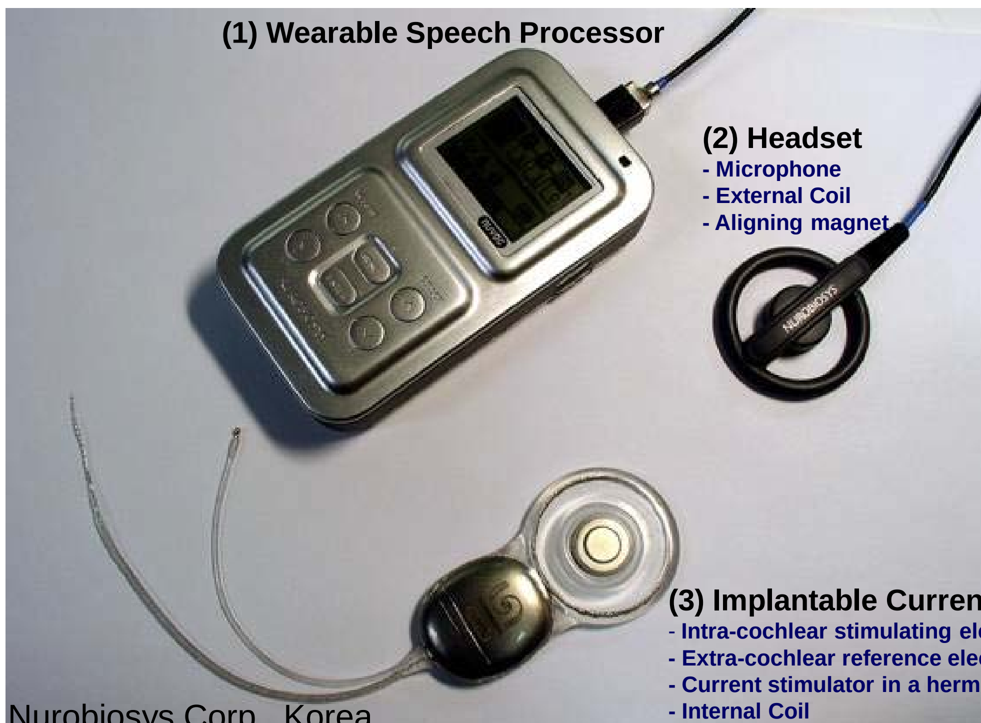
Biomaterials

Examples of Biomaterials used in modern Biomedical Devices: examples (Cochlear Implant)



What is Biomaterial?

- Biomaterial:
  - a material,
  - natural or man-made, that comprises whole or part of a living structure or
  - a device that augments natural functions that has been lost thru disease or injury.
  - Thus it may be inert or from a biological source.

A Biomaterials Lecture at Berkeley

http://www.youtube.com/watch?v=p4QRSUrhQzA

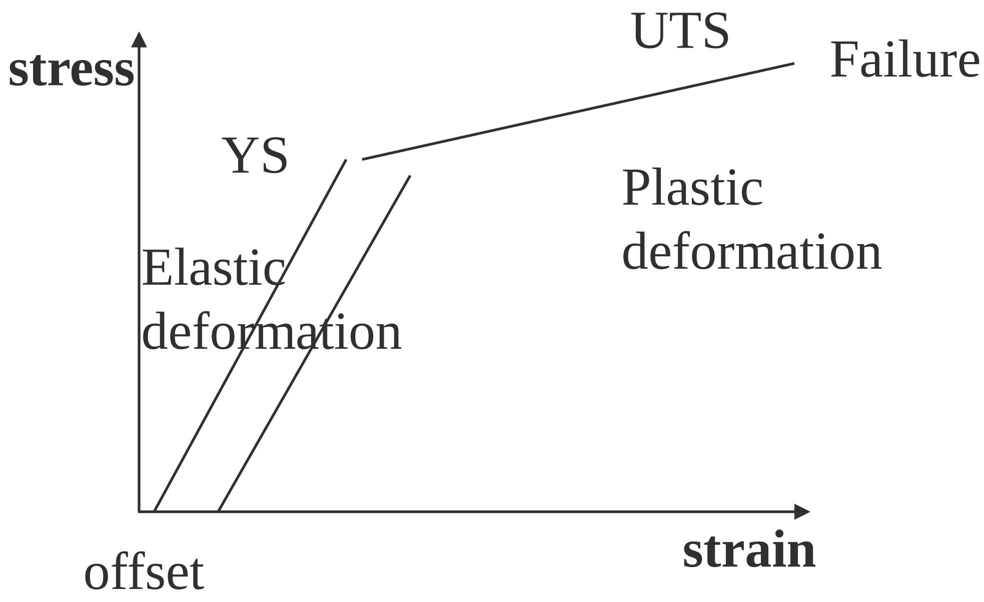
It is still a material, so we need to learn its Mechanical Properties.

- To determine mechanical properties, we usually pull a specimen apart and measure the force and deformation. The result is called the stress-strain relation.
- There are what are called the Standard test protocols and these are mostly from the American Society for Testing and Materials –ASTM.
  - Metals :ASTM E8
  - Rubber Materials :ASTM D412

Tensile testing according to ASTM E8

- Form a "dog-bone"-shaped specimen
  - Stress (N/m2 or Pascals) =force/cross-sectional area
  - Strain (%) =[(deformed length - Original length) /original length] X 100%
  - With a small stress, a metal will deform elastically. (Elastic modulus(E) or Young's modulus)
- **E= stress/strain** (a measure of stiffness of the material)

Typical stress-strain curve for a metal



- The yield point(YS) : at which the metal begins to deform permanently. An offset point may be used instead (when plastic deformation starts to occur, release the stress to measure offset).
- For metal, offset yield is typically 0.2%, whereas for plastics, offset is often 2%.
- The peak stress before rupturing is called the tensile or ultimate tensile strength(UTS).
- The metal will break at the failure or fracture strength(FS).

Other terms

- **Stiffness: the slope of the elastic portion, the elastic modulus**
- **Ductile: the metal stretches a great deal before failure.**
- **Brittle: the material does not deform or yield much before failure.**
- **Toughness: units of energy in the area under the curve (see Fig.)**

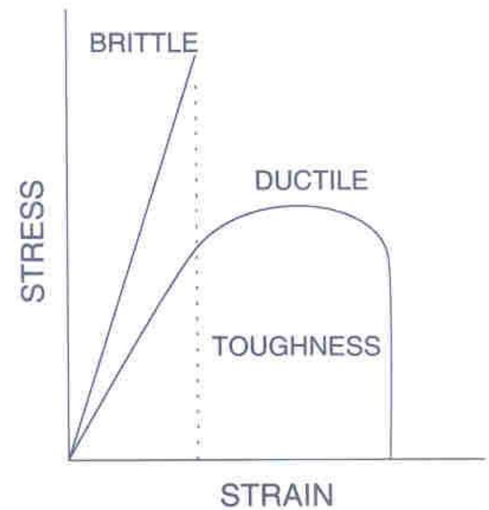


Fig. 11.3 Brittle materials reach failure with only a small amount of deformation (strain), whereas ductile materials stretch or compress a great deal before failure. The area under the stress–strain curve is called toughness and is equal to the integral from ε_0 to ε_f $\sigma\, d\varepsilon$.

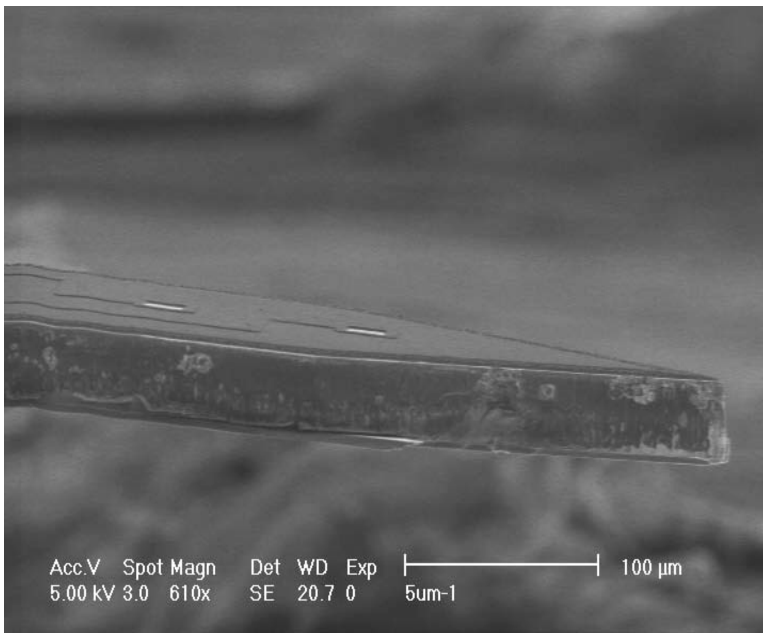
Other terms

- **Hardness: related to the strength of a material and tested by measuring the indentation caused by a sharp object dropped onto the surface. The most important property in a material's wear resistance.**
- **Fatigue strength or endurance limit: theoretically there is a stress level below which the part can be loaded and unloaded infinitely without failure. In reality, a fatigue limit is a specific number of cycles. It is a critical property in the design of load-bearing devices such as total hips.**

What if a dog-bone sample is not available:

Neural Depth Probe, a MEMS Structure, for example.

(A)

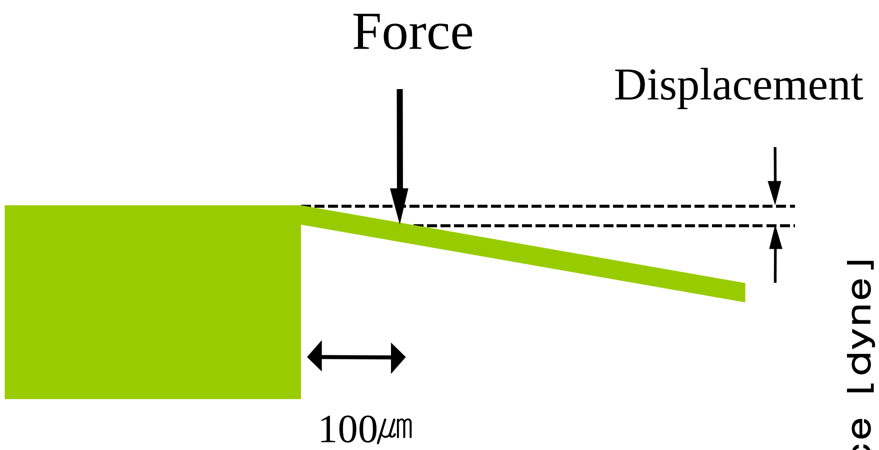


(B)

(A) A view of the probe tip using scanning electron microscope. (B) Silicon micro-electrode packaged on a printed circuit board. The SEM microphotograph of a 30㎛ thick, 200㎛ wide shank and the photograph of a probe bonded to a PCB are shown in (A) and (B), respectively.

Intro BME

Fracture Strength Test

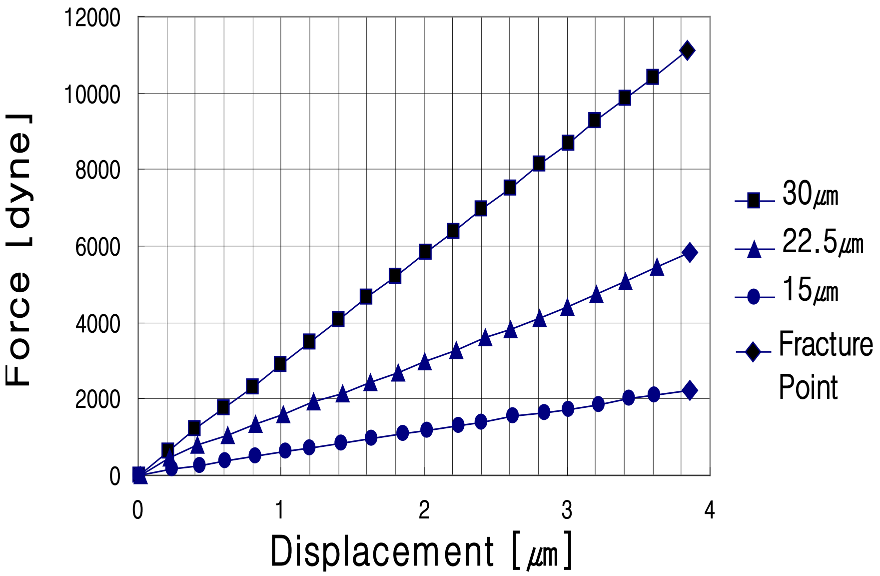


■Displacement rate : 0.5 um/sec

$F=(5.23t^2-78.4t+588)*d$

t : shank thickness [um]

d : displacement [um]



Results of the fracture strength test performed on probes with shank thickness of 15 , 22.5, and 30㎛. It is noted that the amount of force which a probe shank can take increases for thicker shanks, while the amount of displacement (bending) for a given force increases for thinner shanks.

TABLE 11.1 Mechanical Properties of Some Materials[a]

Material	Yield (Mpa)	Utimate Tensile Strength (Mpa)	Deform (%)	Modulus (GPa)
Metals				
High-strength carbon steel	1600	2000	7	206
F138, annealed	170	480	40	200
F138, cold worked	690	860	12	200
F138, wire	—	1035	15	200
F75, cast	450	655	8	200
F799, forged	827	1172	12	200
F562, hot forged	1000	1200	10	200
F136, Ti64	795	860	10	105
Gold		2–300	30	97
Aluminum, 2024-T4	303	414	35	73
Polymers				
PEEK		93	50	3.6
PMMA cast		45–75	1.3	2–3
Acetal (POM)		65	40	3.1
UHMWPE		30	200	0.5
Silicone rubber		7	800	0.03
Ceramics				
Alumina		400	0.1	380
Zirconia, Mg partially stabilized		634		200
Zirconia, yttria stabilized		900		200
Carbons and Composites				
LTI pyrolytic carbon + 5–12% Si		600	2.0	30
PAN AS4 fiber		3980	1.65	240
PEEK, 61% C fiber, long		2130	1.4	125
PEEK, 61% C fiber, ±45		300	17.2	47
PEEK, 30% C fiber, chopped		208	1.3	17
Biologic Tissues				
Hydroxyapatite (HA) mineral		100	0.001	114–130
Bone (cortical)		80–150	1.5	18–20
Collagen		50		1.2

[a] Literature values or minimum values from standards.

Materials used in medical devices

- Metals and metal alloys
- Ceramics and Glasses
- Polymers
- Composites

Metals

- **Titanium**
- **Stainless Steel**
- The chromium forms a passivation layer of chromium(III) oxide (Cr_2O_3) when exposed to oxygen. The layer is too thin to be visible, which means that the metal remains lustrous. It is, however, impervious to water and air, protecting the metal beneath. Also, this layer quickly reforms when the surface is scratched. This phenomenon is called passivation and is seen in other metals, such as aluminium and titanium.

Stainless Steel for medical applications

- The designing of stainless steel(an alloy of iron, carbon and other elements)
  - iron in the FCC from
  - A minimum of 12% chromium is added to make steel "stainless", but chromium at wrong concentration, will reduce the corrosion resistance of the steel.
  - Nickel is added since it stabilize the FCC form of iron and keep carbon in solution.
  - Surgical stainless steel (F138) : 17-19% chromium, 13-15.5% nickel, and 2 or 3% molybdenum for improved corrosion resistance.
  - low concentration of carbon (0.08 –0.03%) Better with low (0.03%) carbon because Cr23C6 compound will reduce Cr concentration.

Passivation of SS

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Ceramics and Glasses

- Ceramics are composed of atoms iono-covalently bound into compound forms.: no conductivity of heat or electricity
- Very high melting point (generally over 1000º C) and brittle –very expensive to melt ceramics and impossible to cold work them.
- Some ceramics form inorganic glasses which have no regularly arranged repeatable structure(amorphous), and will not melt at a distinct temperature, but will get softer.

Making of Ceramics

- High purifying process for biomedical application of ceramic powder and mixing a batch of appropriate amounts of raw material powders, then forming a shape that is similar to the final part.
- Green Ceramic: The unfired ceramic is called a green body. Through sintering, the powder coalesces into a hard material. Then the sintered parts are machine-grinded into their final shape.

Ceramics

- Common ceramics : metal oxides(alumina, sapphire(Al_2O_3), and silica(SiO_2)),
- Ceramics are brittle and not- bendable
- Ceramics are typically strong and hard-
- excellent wear resistance

The biomedical applications of ceramics

- **Advantage: corrosion resistance and good wear properties and electrical insulation**
- **Disadvantage: brittleness with catastrophic failure**

Polymers

- Polymers are made up of many “mers” or basic building blocks.
- Formed in long, sometimes branching chains with a backbone of carbon or silicon atoms that are held together with covalent bonds.
- The number of mers(*n*) will determine many of the properties of the polymer.
- $(C2H4)n$:polyethylene
  - Low-molecular forms of :soda pop bottle,
  - ultrahigh-molecular-weight polyethylene: the bottom of snow skis and the plastic-bearing component of total joint replacements.

Polymers

- A Plastic is a polymer with any number of additives.
  - For look, colorants are added.
  - For stability, antioxidants
  - For softness, plasticizer
- In spite of their low cost manufacturability, Plastics are not frequently used as biomaterials. Reasons?
  - By products
  - Reactivity (with environment) and the corresponding Long term degradation
  - Loss of desired mechanical properties: rigidity etc.
  - Less hermatic

Composites

- Mixing or joining two or more materials for the combination of properties of the individual components.
- Three categories: particulate(concrete), fiber(fiberglass), and laminar(plywood)
- Many biological materials are composites.
  - Bone: a composite of mineral hydroxyapatite(HA-strong, rigid, and brittle) and collagen fibers(much lower modulus) – The composite bone is a strong and more flexible material.
  - Artificial Bone: Composite technology has been used to tailor materials to match bone.
    - The 30% chopped-carbon PEEK has a modulus close to that of bone and has been considered for use as a moderately flexible device to hold a fracture together during healing.
    - The long fiber composites are stiffer than bone.
    - Stainless steel or cobalt alloys are very stiff and have been considered for high-strength devices to replace a bone or joint section.

Material Degradation

Metallic Corrosion

- For implant, corrosion resistance is one of the most important properties of metals.
  - Galvanic Corrosion(mixed-metal) occurs when two dissimilar metals in electrical contact are immersed in an electrolyte – an anode, a cathode, an electrolyte, and an external electrical conductor are must. –
  - Two total hip replacements(THRs) made of one alloy material is not subject to mixed metal corrosion, but a THR made of two alloys, or a fracture plate of one metal fixed with screws of another metal may be susceptible.

Metallic Corrosion

- **Passivation: a process of corrosion resistance by forming stable, passive oxide films.**
- **Self-passivation in metal such as stainless steel using Cr.**

Polymer Degradation

- Causes of Polymer degradation: hydrolysis, some enzymes and ionizing radiation.
- Chemical degradation starts with breaking the long polymer chain into smaller fragments, or chain scission
- The polymer may be reduced in molecular weight, increasing its solubility, and potential for further breakdown, or it may become harder and more brittle due to cross-linking.

Wear

- **Mechanical damage and release of small particles due to wear**
  - **The surface of an implant is not perfectly smooth on a microscopic scale. - localized pressures on the asparities, and fusion or adhesion between asparities of two surfaces – These asperities then break off as particulate debris.**
  - **Repeated loading and unloading causes cyclic shear stress under the contact point. This may lead to the formation of fatigue cracks parallel to the joint surface, and these flake off and produce particulate debris due to fatigue wear.**

Biological Effects

Cells Involved in Responses to Biomaterials.

- White blood cells(leukocytes):involved in the body's immune response. They are present at 8500/mm3.
  - Some of WBC's (PMN(poly) and Macrophage)are phagocytic cells and are capable to engulf and destroy foreign substances.

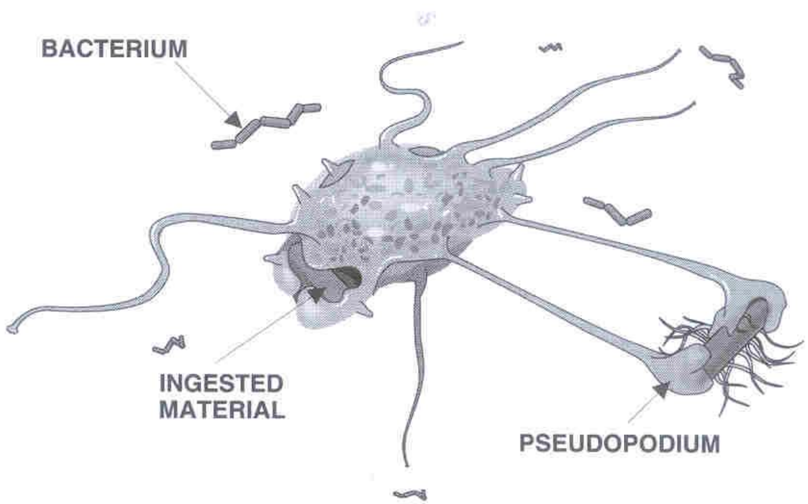

Fig. 11.9 In this figure, a macrophage is ingesting foreign material and has pseudopodia that are preparing to help bring another foreign body to the cell. In a real macrophage, the pseudopodia would flow out and around the bacterium or tissue debris and would engulf it without forming such long, thin connections to the cell.

Phagocytic Leukocytes

- Granulocyte (often called PMN (poly-morpho-nuclear leukocyte)):8 micro meter in diameter, discrete bodies called granules in their cytoplasm, and multilobed nuclear material, which makes the cell appear to be multinucleated under the microscope observation.
- Monocyte: a single nucleus with characteristic features
  - 10 micro meter in size
  - When it leaves the blood, it changes into a macrophage (histiocyte) that is a large cell, up to about 20 micrometer in size, and actively phagocytic.
  - When an attempt to phagocytize material fails, it coalesces with other cells and forms a multinucleated giant cells in several types, one of which is a foreign body giant cell.
    - The presence of giant cells indicates that the phagocytic system is incapable of ridding the body of foreign matter, and that tissue destruction often occurs and results in loss of normal tissue, loss of function of the organ, or significant bone resorption, depending on the site of inflammation.

Inflammation-- Acute inflammation is a normal reaction to the foreign body.

It is the first response of any vascularized tissue to tissue damage.

Four cardinal signs associated with the inflammatory response

1. **The tissue turned red(rubor). – the presence of RBCs under the skin**
2. **The site became swollen(tumor). – fluid with blood**
3. **The site became warm(calor). – warm blood and some fever(pyrogenic response) from release of tissue substances**
4. **The site became painful(dolor) – impingement on and damage to local nerve networks**

Wound Healing (If the biomaterial is a degradable or phagocytizable material)

- **Acute inflammation.**
- **The polys (PMN's) go into the tissue to clean up the damaged tissue and foreign material.**
- **The platelets form clots to prevent further leakge of blood.**
- **The remaining debris is phagocytized by the polys, and actual tissue repair began. – Fibroblasts(tissue cells) come in and start to synthesize collagen, which forms a structural network called granulation tissue .**

If the biomaterial stays (healing in the presence of biomaterial),

- The fibroblasts in the healing response to lay down layers of fibrous tissue around the material(fibrous capsule) –The thinner the fibrous capsule, the more biocompatible.
- The inflammatory response to continue as a chronic inflammatory response and to progress to giant cells and granulomas. –the material is not biocompatible.

Infection

- The presence of infection will prevent the wound healing response from completing and excessive scarring will result.
- The impact of the presence of a foreign body(implanted device) on the infection
  - The combination of insertion injury and the presence of the foreign material will initiate the inflammatory response. – The presence of a foreign body greatly increase the infection risk and markedly decreases the number of bacteria required to cause an infection from 1E6 to 1E2.
  - The only way to cure the infection is to remove the device.