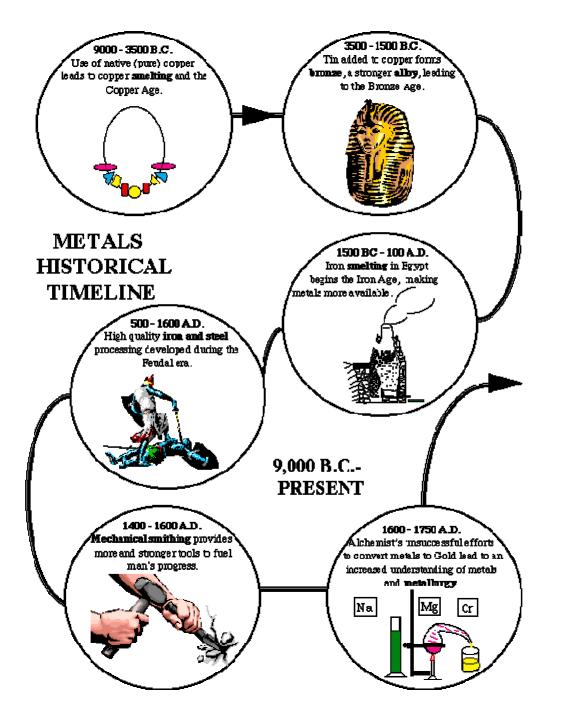


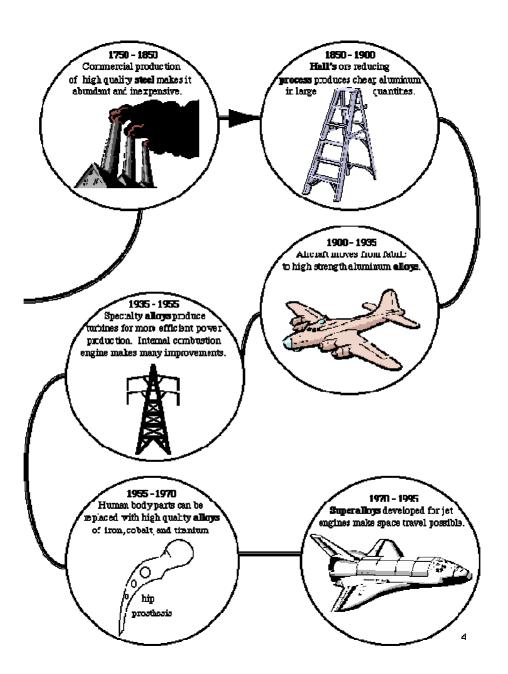
Broad Classification-Types of Biomaterials

- polymers, synthetic and natural
- metals
- ceramics
- composites







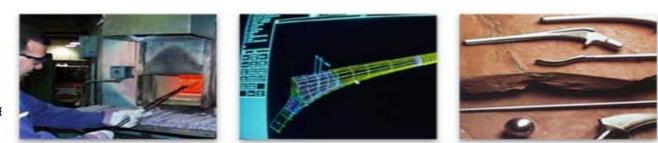




Metals

- load bearing implants and internal fixation devices;
- when processed suitably contribute high tensile, high fatigue and high yield strengths;
- low reactivity;
- properties depend on the processing method and purity of the metal.





3/30/2006

Applications

- Bone and Joint Replacement
- Dental Implants
- Maxillo and Cranio/facial reconstruction
- Cardiovascular devices
 Titanium is regularly used for pacemaker cases and defibrillators, as the carrier structure for replacement heart valves, and for intra-vascular stents.
- External Prostheses
- Surgical instruments



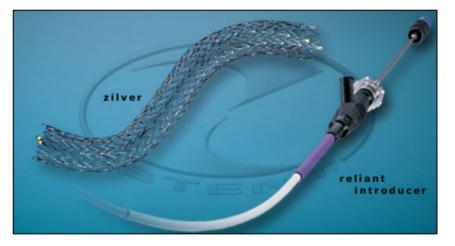
Other Uses



Medical Tubing



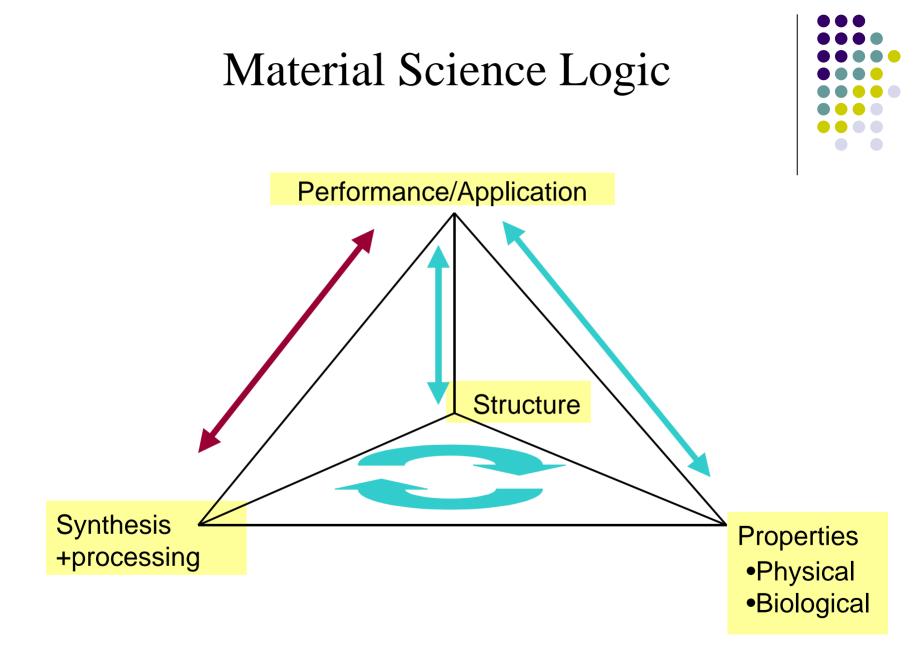




Stents

3/30/2006

Catheters

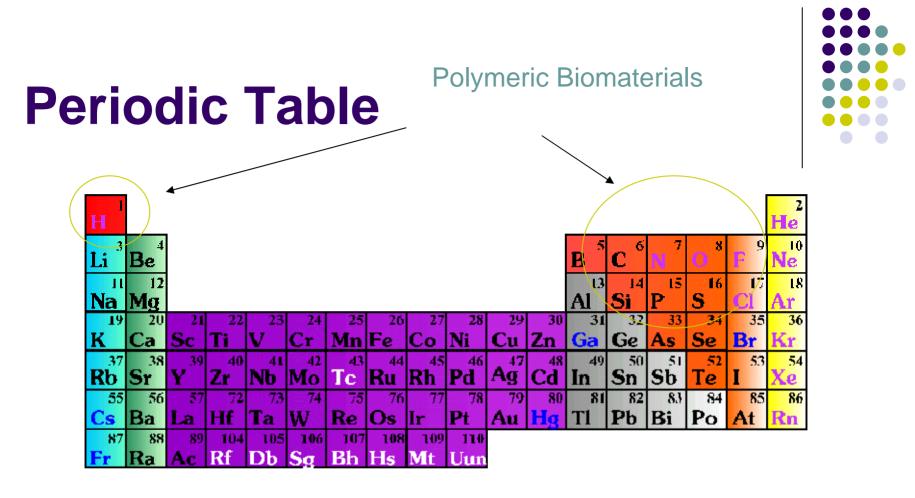


Physical Properties of Metals:

- Luster (shininess)
- Good conductors of heat and electricity
- High density (heavy for their size)
- High melting point
- Ductile (most metals can be drawn out into thin wires)
- Malleable (most metals can be hammered into thin sheets)

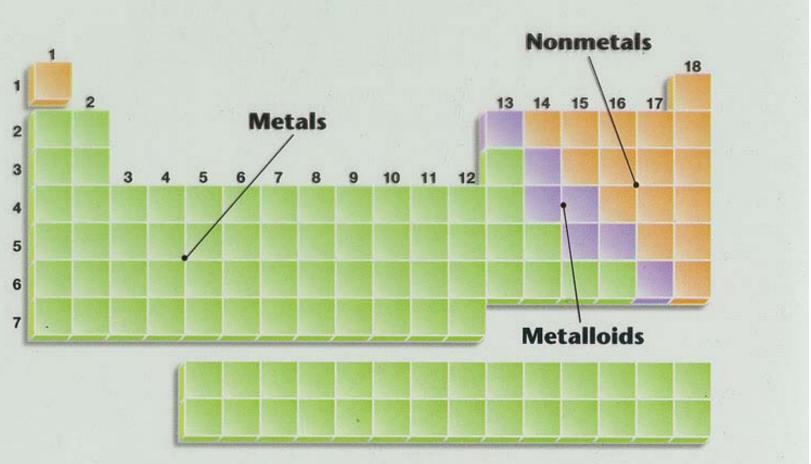
Chemical Properties of Metals:

- Easily lose electrons;
- Surface reactive;
- Loss of mass; (some corrode easily)
 - Corrosion is a gradual wearing away
- Change in mechanical properties



58	59	60	61	62	63	64	65	66	67	68	69	70	71
Ce	Pr	Nd	\mathbf{Pm}	Sm	Eu	Gd	Tb	Dy	Ho	Er	Tm	Yb	Lu
90	91	92	93	94	95	96	97	- 98	- 99	100	101	102	103
Th			1 <u> </u>		Am								Lr

Metals



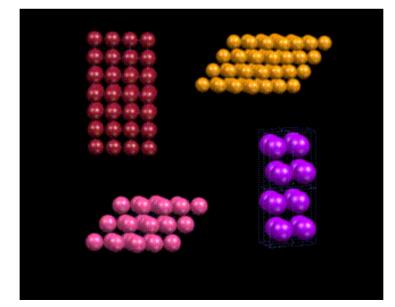
^{3/30/2006} Most elements are metals. 88 elements to the left of the stairstep line are metals or metal like elements



NATURE OF METALS



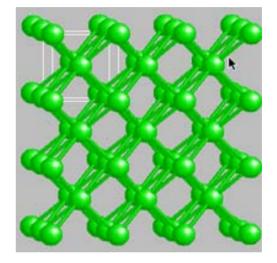
• crystalline solids composed of elemental, positively charged ions in a cloud of electrons



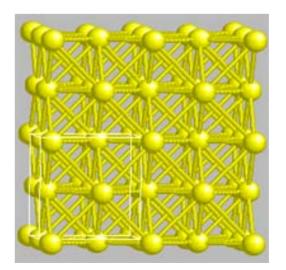


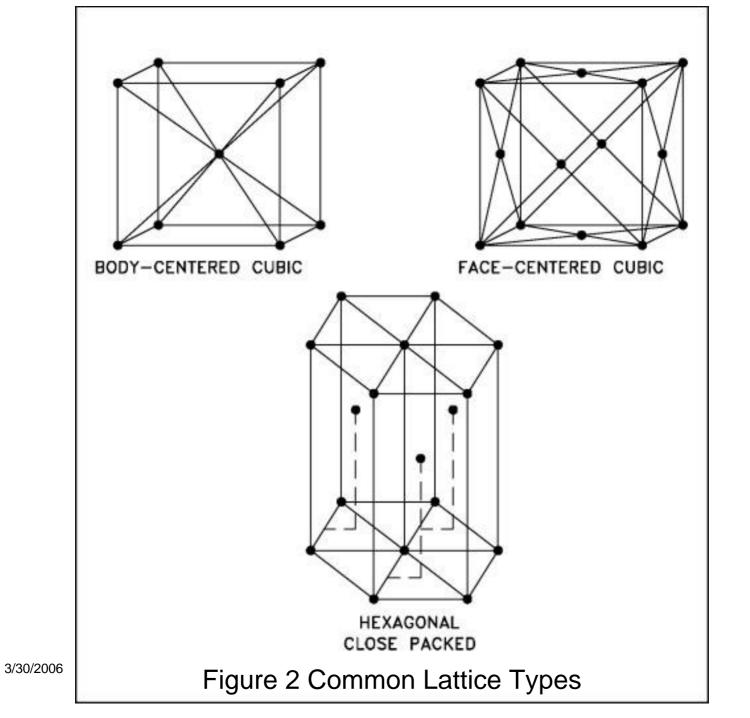
Microstructure of metals

- Basic atomic architecture is a crystal structure
- Different elements have different crystalline architectures and can combine with different partners.













Metals Manufacturing



 machining" and "metal fabrication" are synonymous and refers to the activities and processes that change the shape of a metal workpiece by deforming it or removing metal
 ^{3/30/2006} from it.



Metals Manufacturing

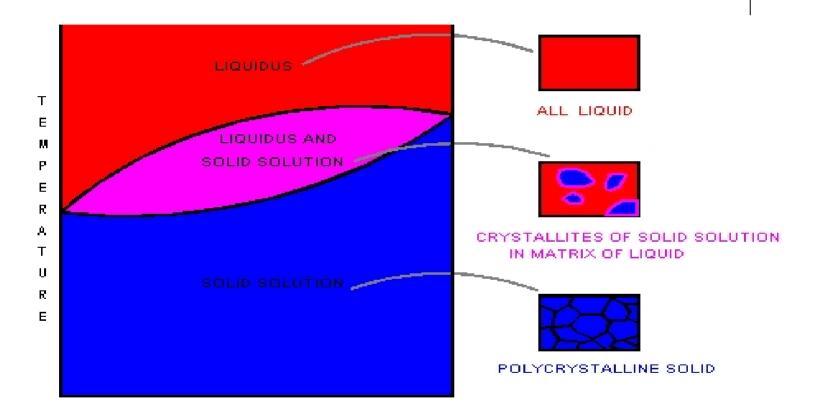


Processing:



- molten metal is cooled to form the solid.
- The solid metal is then mechanically shaped to form a particular product.
- How these steps are carried out is very important because heat and plastic deformation can strongly affect the mechanical properties of a metal.

What Happens When You Cool a Molten Metal?

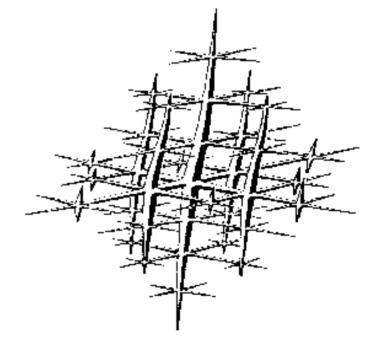




Formation of Crystals

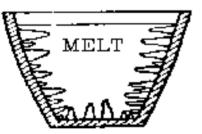
 In the free state growth proceeds simultaneously in all three axes.

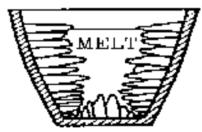


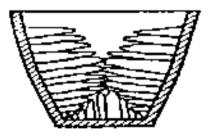


Solidification in Casting Processes: Formation of Crystals

 Contained nucleation starts at edges (where coolest) and grows inward

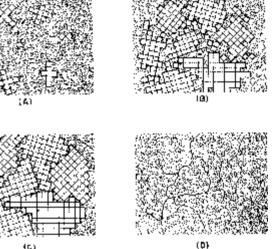






Formation of Crystals

- Nucleation The first unit cell solidifies
- Growth New unit cells attach to existing unit cells.
- Where crystals meet grain boundaries are created.

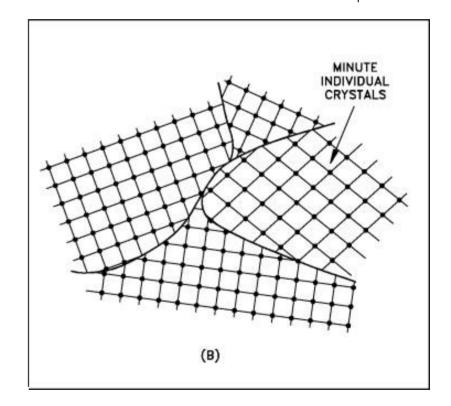




Solidification of Metals (Grain formation)

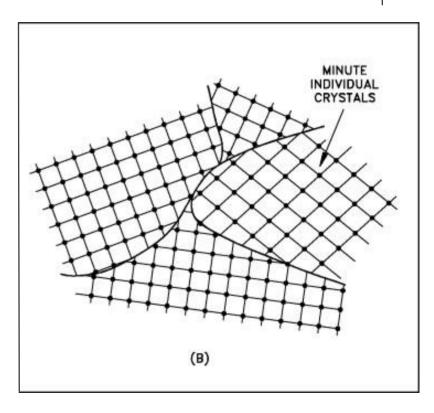


- Crystal will grow naturally (along axes) until they begin to interfere.
- The interference point where crystal structures meet is called the grain boundary.



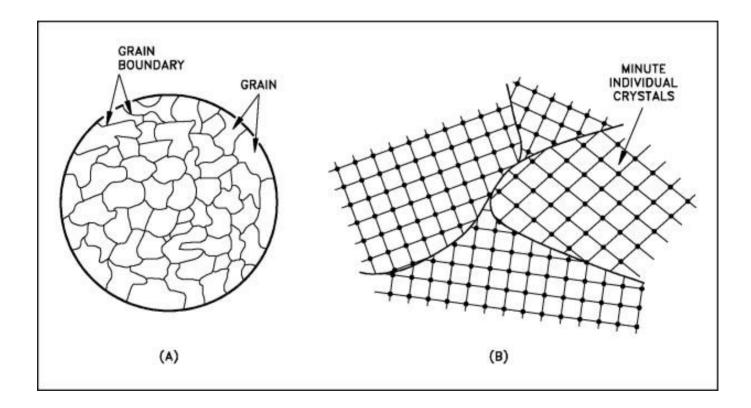
PHASES

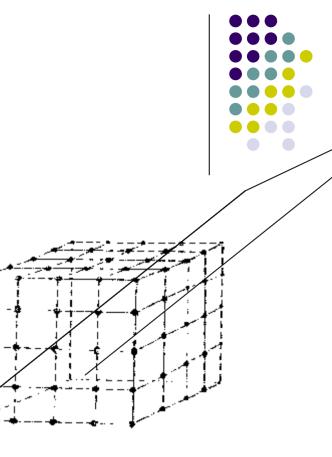
- A *phase* is a homogeneous part or aggregation of the material that differs from another part due to a difference in structure, composition, or both;
- The difference in structures forms an interface between adjacent or surrounding phases;
- These structural defects affect mechanical performance.





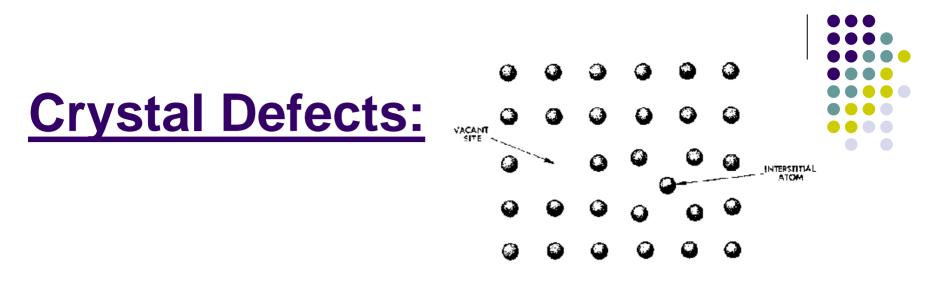
Grains and Grain Boundaries





Creation of Slip Planes

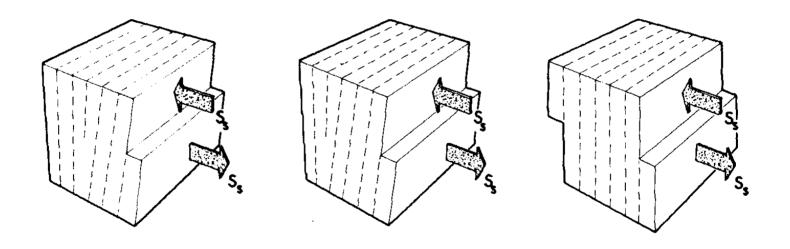
- As crystals form, the unit cells tend to align in patterns.
- The alignment of these internal planes between unit cells creates slip planes.



- Metallic crystals are not perfect.
- Sometimes there are empty spaces called vacancies, where an atom is missing.
- These and other imperfections, as well as the existence of grains and grain boundaries, determine many of the mechanical properties of metals.
- When a <u>stress</u> is applied to a metal, dislocations are generated and move, allowing the metal to deform.

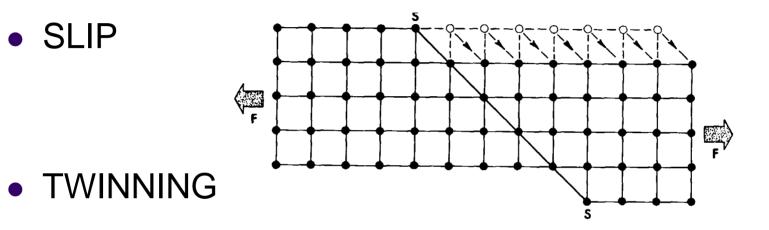
DEFECTS IN CRYSTALLINE STRUCTURE

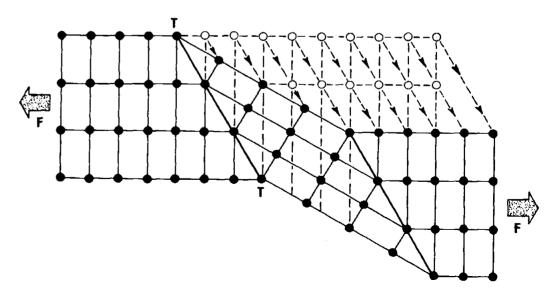
- Dislocations
 - edge dislocation





PLASTIC DEFORMATIONS

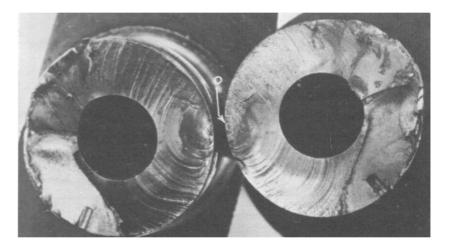




Fatigue

- Stages of Fatigue Failure
 - no harm
 - small cracks
 - "clam shell" effect (note shinney area)
 - fracture





COMBINATION OF SLIP LINES AND TWINNING BANDS

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Fatigue



- <u>Fatigue Limit</u> -" The maximum stress that a metal will withstand without failure for a specified large number of cycles."
- Often more important than tensile or yield strength

Strengthening by Grain Size Reduction



- Finer and more homogenous grain size results in more homogeneous packing of the crystal and impedes dislocation type motion (prevents slip);
- Grain-size reduction usually improves toughness.
- Grain size can be controlled by slowing the rate of solidification and by plastic deformation after soldification.

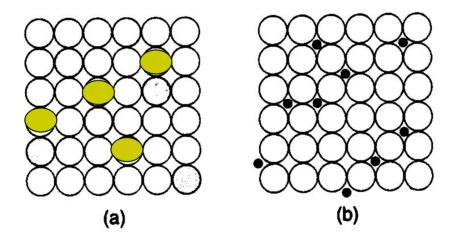
Alloys



- A metal comprised of two or more elements, at least one of which is metallic.
- Generally, metals do not like to mix. When they do they form in one of two ways:
- Substitution
- Interstitial

Alloys are Solid Solutions

(a) substitutional and (b) interstitial



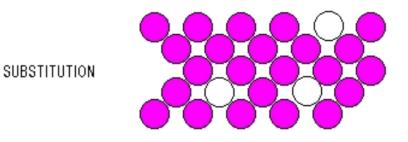
• More abundant element is referred to as the solvent and the less abundant element is the solute.

Filling materials: Silver alloys consisting of Ag-Sn-^{3/30/2006} Cu, mixed with mercury

Substitution Alloys



• Alloys formed through substitution must have similar crystal structures and atomic size.



ALLOYING THROUGH SUBSTITUTION: ATOMIC RADII MUST BE WITHIN 15%



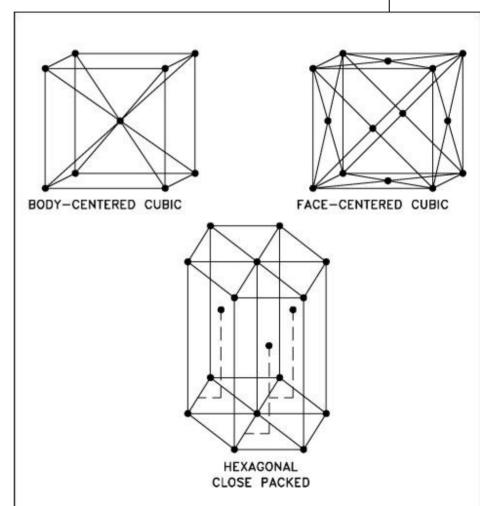
Conditions for substitutional solid solutions :

- The atomic radii of the two elements similar
- Their lattice types must be the same
- The lower valency metal becomes the solvent

Crystalline Architecture Determines Mechanical Properties

BCC, ductile, plastic ie more workable

- FCC, ductile, plastic ie workable
- HCP, lack plasticity





Dental Alloys



Gold-Silver alloy (Type III for crowns & bridges: e.g. 75%Au-11%Ag-9%Cu3.5%Pd)

- 2.882 Å Gold (Au) FCC : FCC (Ag) Silver 2.888 Å
- Silver-Copper alloy (One of the two types of particles in 'admixed' dental amalgam alloys)
- 2.888 Å Silver (Ag) FCC : FCC (Cu) Copper 2.556 Å
 Silver-Tin alloy (Particles in 'low copper' dental amalgam alloys)
- 2.888 Å Silver (Ag) FCC : FCC (Sn) Tin 3.016 Å

Other alloys

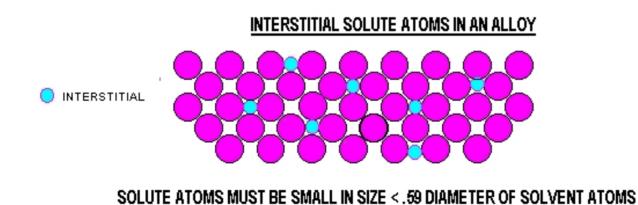


- Co-Cr alloys:
- Co-Cr-Ni alloys:
- Ni-Ti alloys such as Nitinol (Ti-48Ni-2Co) are superelastic wires

Interstitial



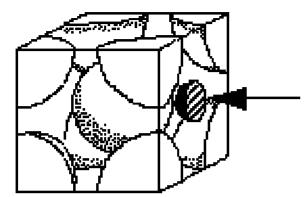
- Size of atom becomes the major factor.
- Solute atoms must be small in size to fit into the spaces between the larger solvent atoms.
- Important interstitial solute atoms are carbon, hydrogen, boron, nitrogen, and oxygen.



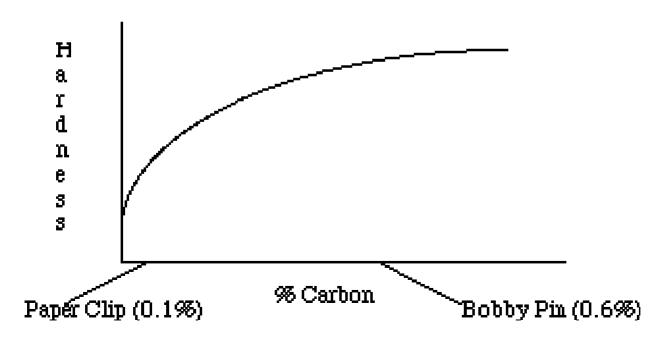
Solid-Solution Strengthening

- Adding another element can increase strength.
- The impurity atoms redistribute lattice strain which can "anchor" dislocations.
- This occurs when the strain caused by the alloying element compensates that of the dislocation, thus achieving a state of low potential energy. It costs strain energy for the dislocation to move away from this state. The dissipation of energy at low temperatures is why slip is hindered.
- Pure metals are almost always softer than their alloys

Example of interstitial solid solution is steel or carbon dissolved in iron



Intersitial Carbon in Iron Since the interstitial sites are so small, the maximum solubility in BCC iron is only one carbon atom for 5000 iron atoms.





Strain Hardening



- Ductile metals become stronger when they are deformed plastically at temperatures well below the melting point (cold working).
- The reason for strain hardening is that the dislocation density increases with plastic deformation (cold work). The average distance between dislocations then decreases and dislocations start blocking the motion of each one.

Recovery - Annealing

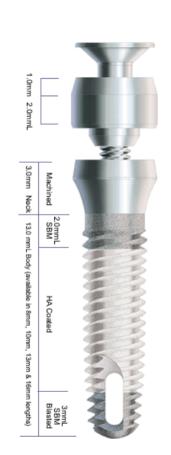


 Heating ->increased diffusion ->enhanced dislocation motion ->relieves internal strain energy and reduces the number of dislocations.

Titanium

- 2.2 million pounds of TI implanted every year
- hip joints, bone screws, knee joints, bone plates, dental implants, surgical devices, and pacemaker cases
- due to its total resistance to attack by body fluids, high strength and low modulus.









- Commercially pure titanium (ASTM F67)
- Ti-6AI-4V (ASTM F136)
- most load bearing permanent implants
- due to their low density, good corrosion
- Poor properties in articulation

Titanium Alloys



 F67-00 Unalloyed Titanium F136-98e1 Wrought Titanium 6-Aluminum 4-Vanadium ELI Alloy F620-00 Alpha Plus Beta Titanium Alloy Forgings F1108-97a Ti6Al4V Alloy Castings F1295-97a Wrought Titanium 6-Aluminum7-Niobium Alloy F1341-99 Unalloyed Titanium Wire F1472-99 Wrought Titanium 6-Aluminum 4-Vanadium Alloy F1580-95 Titanium and Titanium 6-Aluminum 4-Vanadium Alloy **Powders** F1713-96 Wrought Titanium 13-Niobium 13-Zirconium Alloy F1813-97e1 Wrought Titanium 12-Molybdenum 6-Zirconium 2-Iron Alloy





- F75-98 Cobalt-28 Chromium-6 Molybdenum Casting Alloy
 F90-97 Wrought Cobalt-Chromium-15T Tungsten-10 Nickel Alloy
 F562-00 Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy
 F563-95 Wrought Cobalt-Nickel-Chromium-Molybdenum-Tungsten-Iron
 Alloy
 F688-95 Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy
 F799-99 Cobalt-28 Chromium-6 Molybdenum Alloy
 F961-96 Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy
 F1058-97 Wrought Cobalt-Chromium-Nickel-Molybdenum Iron Alloy
 - F1091-91(1996) Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy
 - F1377-98a Cobalt-28 Chromium-6 Molybdenum Powder F1466-99 Iron-Nickel-Cobalt Alloys
 - F1537-00 Wrought Cobalt-28-Chromium-6-Molybdenum Alloy

Stainless Steels



- Types 316 and 316L, are most widely used for implant fabrication
- The only difference in composition between 316L and 316 stainless steel is the content of carbon.
- A wide range of properties exists depending on the heat treatment or cold working (for greater strength and hardness).
- Even the 316L stainless steels may corrode inside the body under certain circumstances in a highly stressed and oxygen depleted region, such as contact under screws or fracture plates.
- Thus, stainless steels are suitable to use only in temporary implant devices, such as fractures plates, screws and hip nails.

Stainless Steel



• F138-97 (316LVM) Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel F139-96 Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless F621-97 Stainless Steel F745-95 18 Chromium-12.5 Nickel-2.5 Molybdenum Stainless Steel F899-95 Stainless Steel F1314-95 Wrought Nitrogen Strengthened-22 Chromium-12.5 Nickel-5 Manganese-2.5 Molybdenum Stainless Steel F1350-91(1996) Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel F1586-95 Wrought Nitrogen Strengthened-21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel



Metal Implant Reliability

depends largely on the:

- corrosion,
- wear, and,
- fatigue resistance of the materials

Knee Replacement Therapy

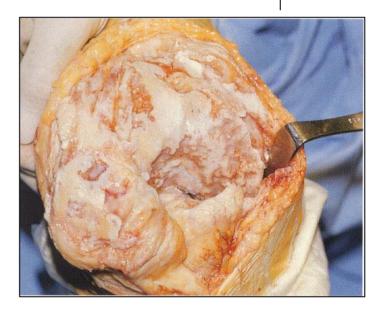


Primary Problem:

- Damaged cartilage leads to various forms of arthritis
- Osteoarthrites: 20.7 million Americans

Symptoms:

- hard, bony swelling of the joints
- gritty feeling
- Immobility



Introduction - Background

- **Solution:** Total Knee Replacement (TKR)
- Nearly 250,000 Americans receive knee implants each year

Results:

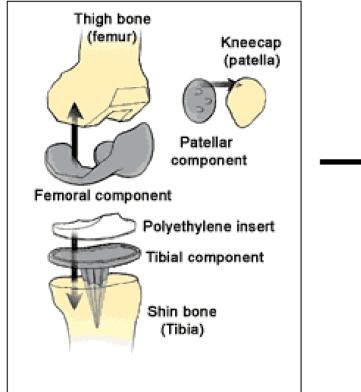
- Stops or greatly reduces joint pain
- Improves the strength of the leg
- Increases quality of life and comfort







Current TKR Design - Assembly





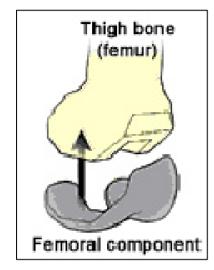
Four Primary Components:

1. Femoral Component _{3/30/200}3. Plastic Insert

- 2. Tibial Component
- 4. Patellar Component 55

Current TKR Design - Components





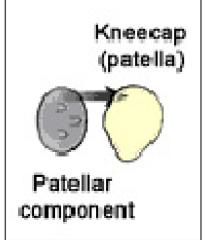
Femoral Component

Materials:

Cobalt-chromium-molybdenum Ti-6Al-4V ELI Titanium Alloy

Interface:

Press fit, biological fixation, PMMA



Patellar Component

Materials:

Polyethylene Cobalt-chromium-molybdenum (Ti Alloy)

Interface:

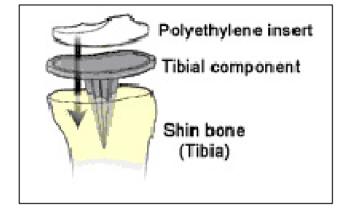
Press fit, biological fixation PMMA

*Modular or singular design



Current TKR Design - Components





Tibial Component

Materials:

Interface:

Cobalt-chromium-molybdenum (cast) Ti-6Al-4V ELI Titanium Alloy Press Fit, Biological Fixation, PMMA

Plastic Insert

Materials:

Polyethylene

Interface:

Press Fit

Current TKR Design - Problems



- #1 Polyethylene "The Weak Link"
 - Articulation wear produces particulates
 - Leading to osteolysis and bone resorption at the implant interface.
 - loosening and eventual malfunction of the implant will occur.
- #2 Metal-Bone Interface
 - Stress-shielding leads to bone degeneration

Average lifespan of 10-20 years

Metals

- One complication that can occur from the use of metals in orthopedic applications is the phenomenon of stress shielding.
- In some situations, such as in TKR or hip replacement, the high strength of the metal in the implant induces it to assume more than its share of responsibility for the load in that region.
- This decreases the load born by the surrounding tissue and therefore shields it from experiencing stress.
- Lack of stress causes bone density to decrease as bone tissue resorbs, and causing complications in the implant/tissue interface.

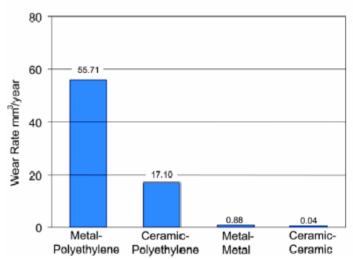






Alternative TKR Design - The Idea

#1 Wear Reduction



#2 Stress Shielding

Material	Young's Modulus (GPa)	Tensile Strength (GPa)
Bone (wet at low strain rate)	15.2	.090
Co-Cr	210	.48
Ti-6Al-4V (40% porosity)	27	.14

Alternative TKR Design - The Idea

- 510(k) status preferred
- Hip replacement surgery is a close relative to Total Knee Replacement

- Metasul has had success with metal-metal interface system
 - 100,000 Implanted Worldwide



Alternative TKR Design - Materials

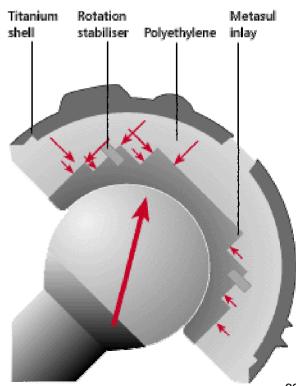


Alternative Design: Metal-Metal Interface using a three-material system

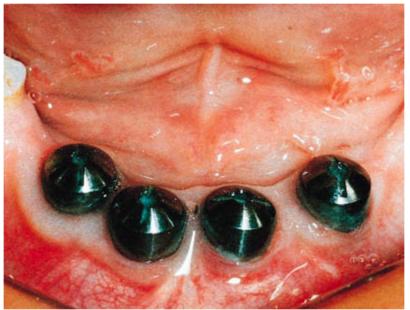
Material: Wrought cobalt-chromiummolybdenum alloy (forged)

Polyethylene Insert

Porous Titanium alloy bone bond



ENDOSSEOUS IMPLANT





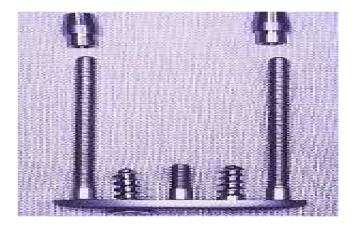
Classification of implants



TRANSOSSEOUS IMPLANT



SUBPERIOSTEAL IMPLANT

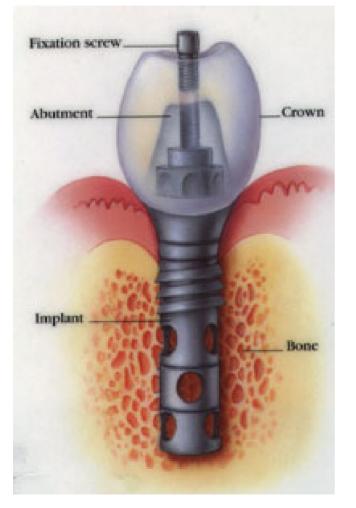


ENDOSSEOUS IMPLANT



The implant system

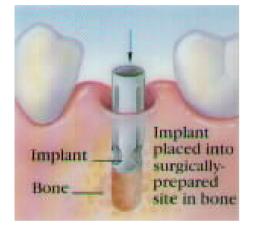


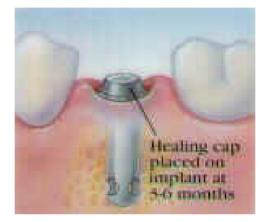


- Drilled and placed into the jawbone.
- Dental implant post or abutment is usually screwed into the top of the dental implant.
- An artificial dental crown can be made to precisely fit onto the implant post.

The implant process

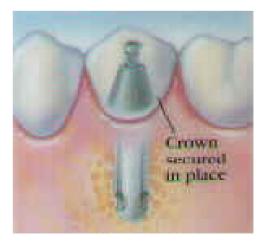












The leap

- 1952 Per Ingvar Branemark,
- Discovered the titanium screw.
- Introduced the concept of Osseointegration

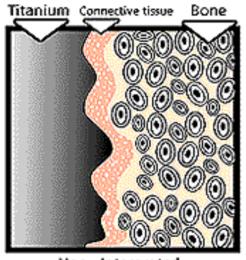
All existing designs based on Branemark Titanium Screw



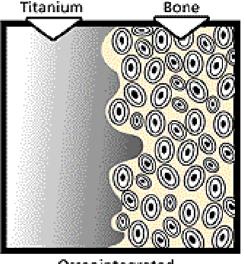


Osseointegration – The Divine Mantra





Non - Intergrated



Osseointegrated

A fixture is osseointegrated if it provides a stable and apparently immobile support of prosthesis under functional loads, without pain, inflammation, or loosening.

Titanium

- Easily available.
- Lightweight, corrosion resistant, easily milled into different shapes, while maintaining its strength.
- Forms layer of titanium oxide, which is a stable and reactive interface that becomes coated with plasma proteins.
- Ti-6AI-4V was alloyed to create a biocompatible material with added strength.



HA coating – surface improvement

- Rapid osseointegration
- Biointegration in 4 weeks 90% of implantbone contact at 10 months.
- In contrast,
- Titanium 10 weeks in to osseointegrate 50% implant-bone contact at 10 months

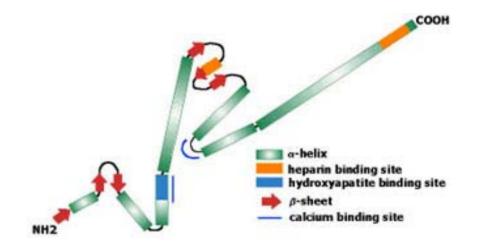
Demerits

• Unstable, susceptible to bacterial infection



Osteopontin – a novel surface

- Osteopontin (OPN) is an extracellular glycosylated bone phosphoprotein with a polypeptide backbone of about 32,000.
- It binds calcium and interacts with the vitronectin receptor.
- Binds covalently to fibronectin. In bone it is produced by matrixproducing osteoblasts, at the mineralization front, and by bone resorbing osteoclasts.



How it enhances osseointegration

- Makes dead metal "come alive". Surrounding cells "don't see an inert piece of metal, they see a protein and it's a protein they know".
- OPN is expressed prior to mineralization and regulated by osteotropic hormones, binds to hydroxyapatite, and enhances osteoclast and osteoblast adhesion.
- Protection against bacterial infection.
- Maintains overall tissue integrity and biomechanical strength during bone remodeling.

Future of implants



• Manufacture "*designer implants*", which could carry different types of proteins, one set to spur soft tissue healing, another to encourage hard tissue growth on another front. Given that dental implants are fixed in the jawbone and inserted through gum tissue, this two-pronged approach would be essential.