Biomaterials

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Outline

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- Biocompatibility
- Challenges
- Biomaterials As An Emerging Industry
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Definition

- A biomaterial is a nonviable material used in a medical device, intended to interact with biological systems.
- Defined by their application NOT chemical make-up.

Characteristics of Biomaterials

- Physical Requirements
  - Hard Materials.
  - Flexible Material.
- Chemical Requirements
  - Must not react with any tissue in the body.
  - Must be non-toxic to the body.
  - Long-term replacement must not be biodegradable.

History

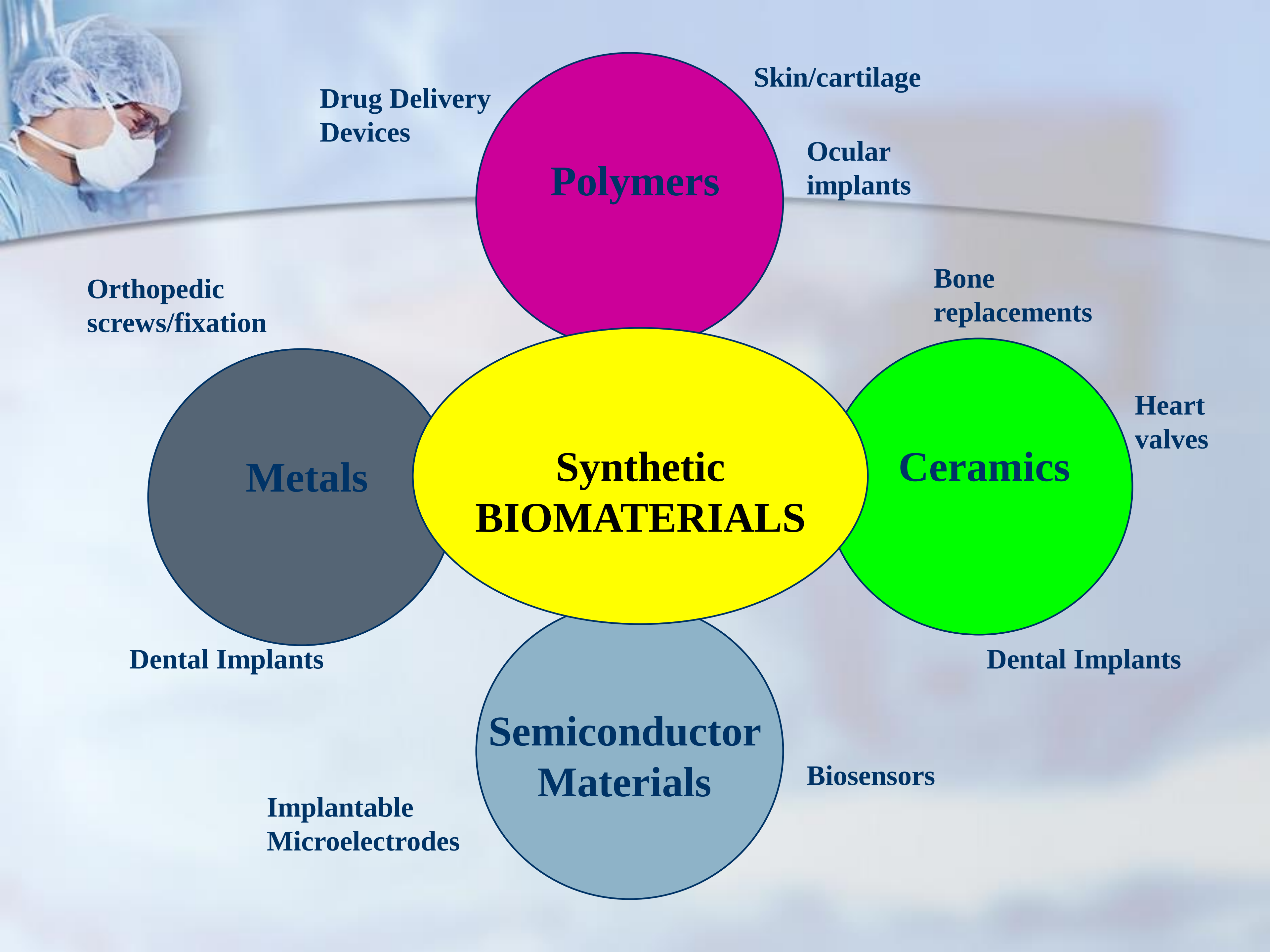
- More than 2000 years ago, Romans, Chinese, and Aztec's used gold in dentistry.
- Turn of century, synthetic implants become available.
- 1937 Poly(methyl methacrylate) (PMMA) introduced in dentistry.
- 1958, Rob suggests Dacron Fabrics can be used to fabricate an arterial prosthetic.

History (Continued)

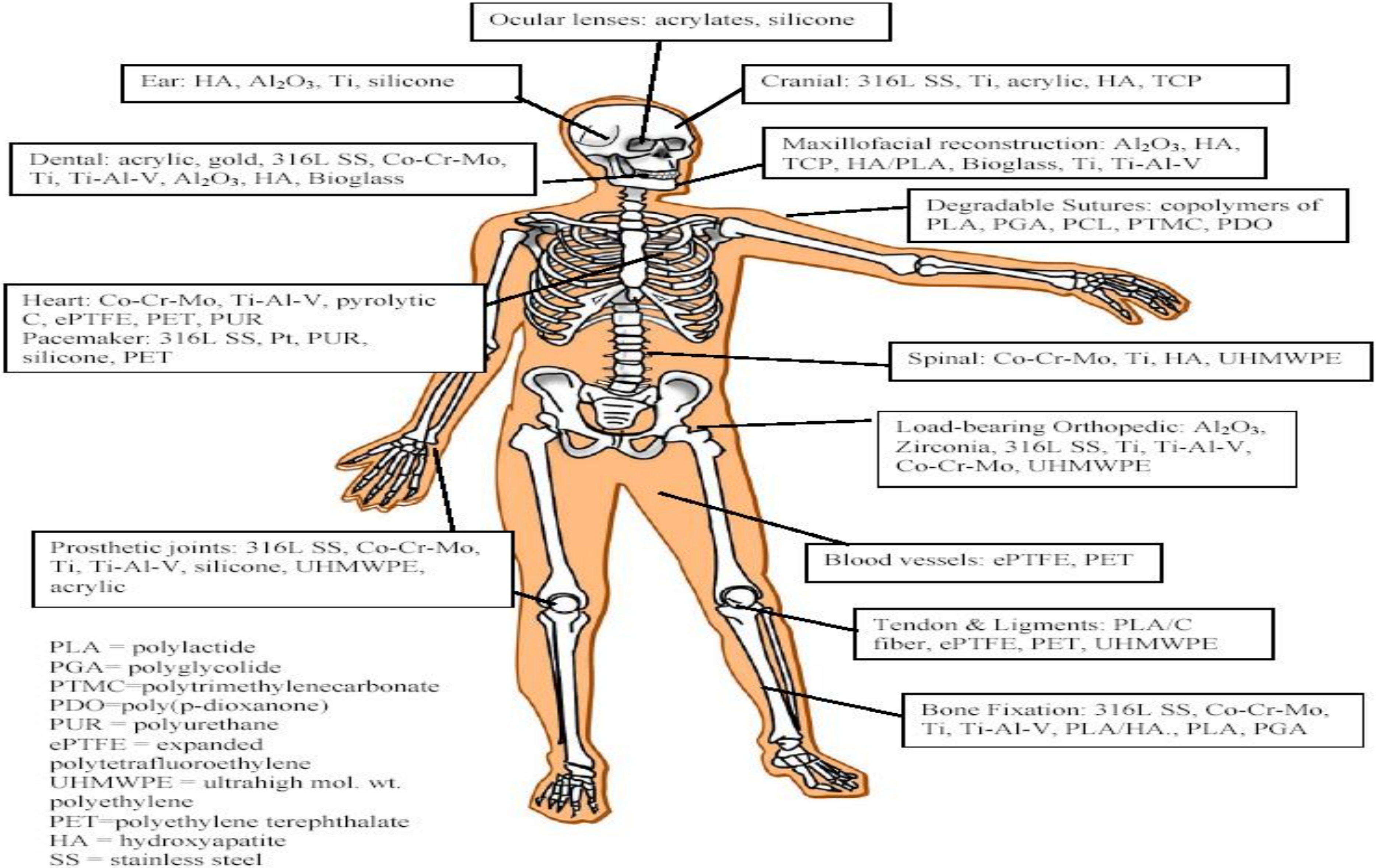
- 1960 Charnley uses PMMA, ultrahigh-molecular-weight polyethylend, and stainless steal for total hip replacement.
- Late 1960 – early 1970’s biomaterial field solidified.
- 1975 Society for Biomaterials formed.

Biomaterials Science

- Grow cells in culture.
- Apparatus for handling proteins in the laboratory.
- Devices to regulate fertility in cattle.
- Aquaculture of oysters.
- Cell-silicon “Biochip”.


Drug Delivery Devices
Polymers
Skin/cartilage
Ocular implants
Orthopedic screws/fixation
Bone replacements
Metals
Synthetic BIOMATERIALS
Ceramics
Heart valves
Dental Implants
Dental Implants
Semiconductor Materials
Biosensors
Implantable Microelectrodes

Biomaterial Science



First Generation Biomaterials

- Specified by physicians using common and borrowed materials.
- Most successes were accidental rather than by design.

Second Generation of Biomaterials

- Developed through collaborations of physicians and engineers.
- Engineered implants using common and borrowed materials.
- Built on first generation experiences.
- Used advances in materials science (from other fields).

Third generation implants

- Bioengineered implants using bioengineered materials.
- Few examples on the market.
- Some modified and new polymeric devices.
- Many under development.

Examples of Biomaterial Applications

- Heart Valve
- Artificial Tissue
- Dental Implants
- Intraocular Lenses
- Vascular Grafts
- Hip Replacements

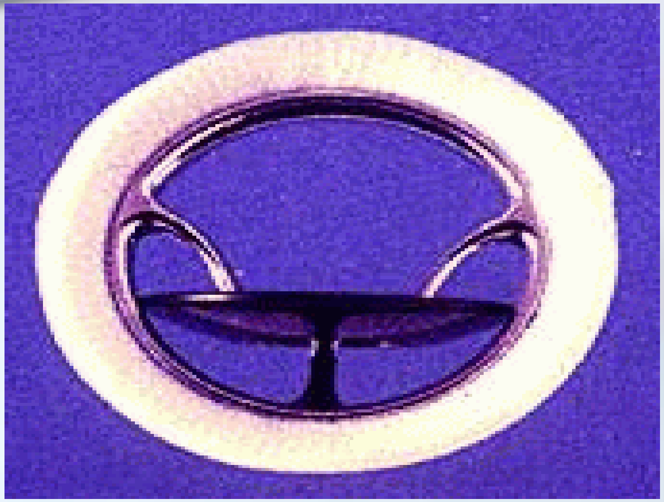
Heart Valve

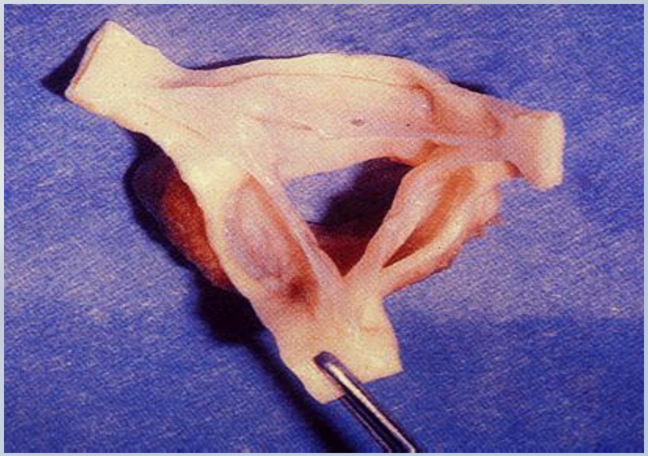
- Fabricated from carbons, metals, elastomers, fabrics, and natural valves.
- Must **<u>NOT</u>** React With Chemicals in Body.
- Attached By Polyester Mesh.
- Tissue Growth Facilitated By Polar Oxygen-Containing Groups.

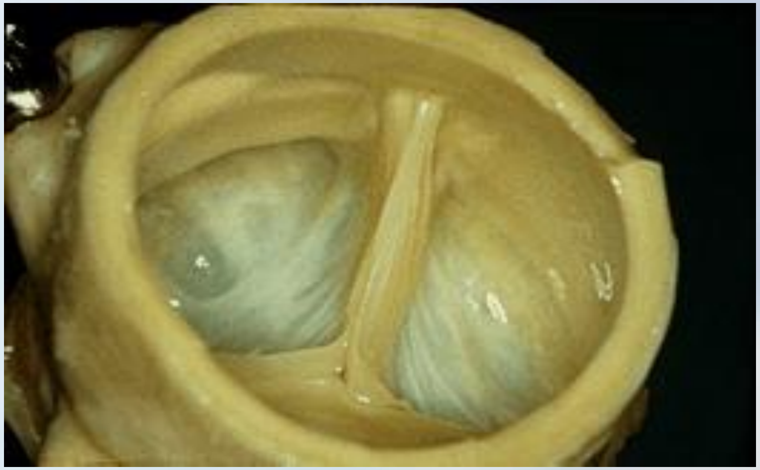
Heart Valve

- Almost as soon as valve implanted cardiac function is restored to near normal.
- Bileaflet tilting disk heart valve used most widely.
- More than 45,000 replacement valves implanted every year in the United States.

Bileaflet Heart Valves





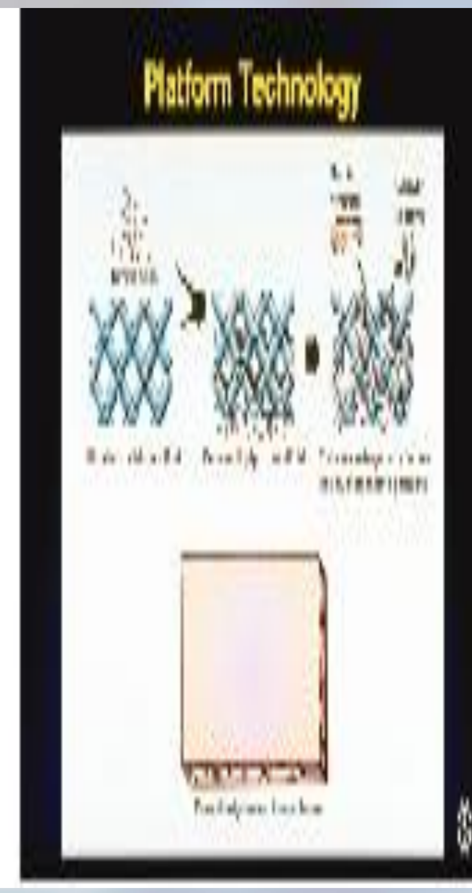


Problems with Heart Valve’s

- Degeneration of Tissue.
- Mechanical Failure.
- Postoperative infection.
- Induction of blood clots.

Artificial Tissue

- Biodegradable
- Polymer Result of Condensation of Lactic Acid and Glycolyic Acid



Dental Implants

- Small titanium fixture that serves as the replacement for the root portion of a missing natural tooth.
- Implant is placed in the bone of the upper or lower jaw and allowed to bond with the bone.
- Most dental implants are: pure titanium screw-shaped cylinders that act as roots for crowns and bridges, or as supports for dentures.

Dental Implants

- Capable of bonding to bone, a phenomenon known as "osseointegration”.
- Bio-inert, there is no reaction in tissue and no rejection or allergic reactions.

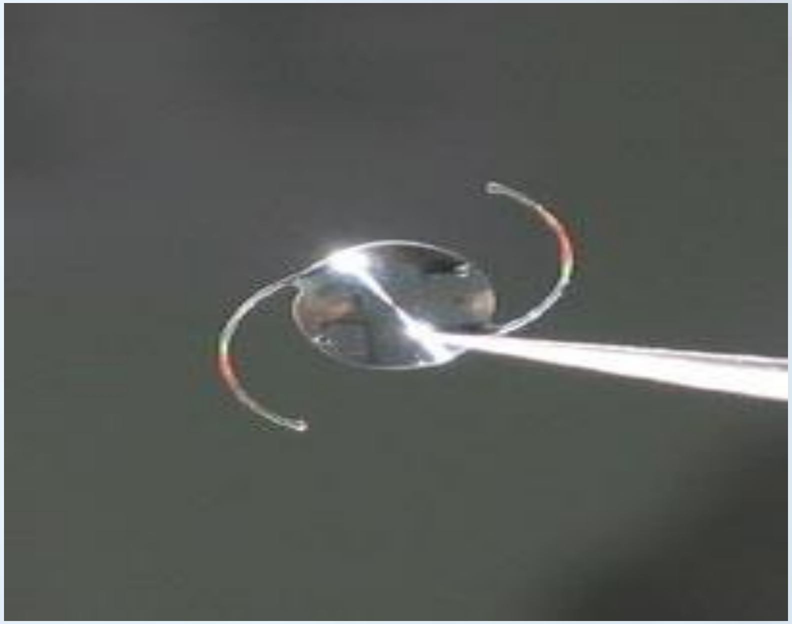
Dental Implants

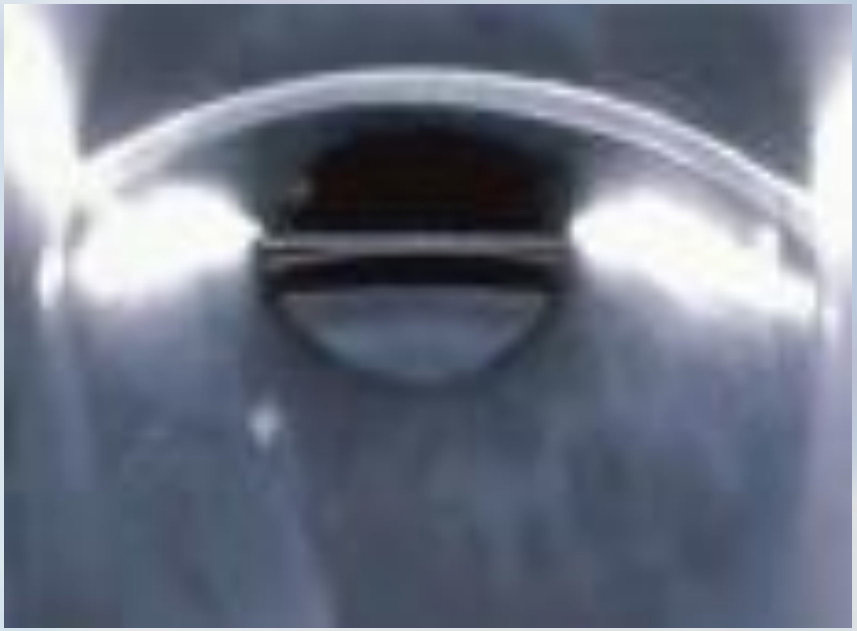
Intraocular Lenses

- Made of PMM, silicone elastomer, and other materials.
- By age 75 more than 50% of population suffers from cataracts.
- 1.4 million implantations in the United States yearly.
- Good vision is generally restored almost immediately after lens is inserted.

Intraocular Lenses

- Implantation often performed on outpatient basis.





Vascular Grafts

- Must Be Flexible.
- Designed With Open Porous Structure.
- Often Recognized By Body As Foreign.

Hip-Replacements

- Most Common Medical Practice Using Biomaterials.
- Corrosion Resistant high-strength Metal Alloys.
- Very High Molecular Weight Polymers.
- Thermoset Plastics.

Hip-Replacements

- Some hip replacements ambulatory function restored within days after surgery.
- Others require an extensive healing period for attachment between bone and the implant.
- Most cases good function restored.
- After 10-15 years, implant loosens requiring another operation.

Hip-Replacements

Vascular Grafts

- Achieve and maintain homeostasis.
- Porous.
- Permeable.
- Good structure retention.
- Adequate burst strength.
- High fatigue resistance.
- Low thrombogenecity.
- Good handling properties.
- Biostable.

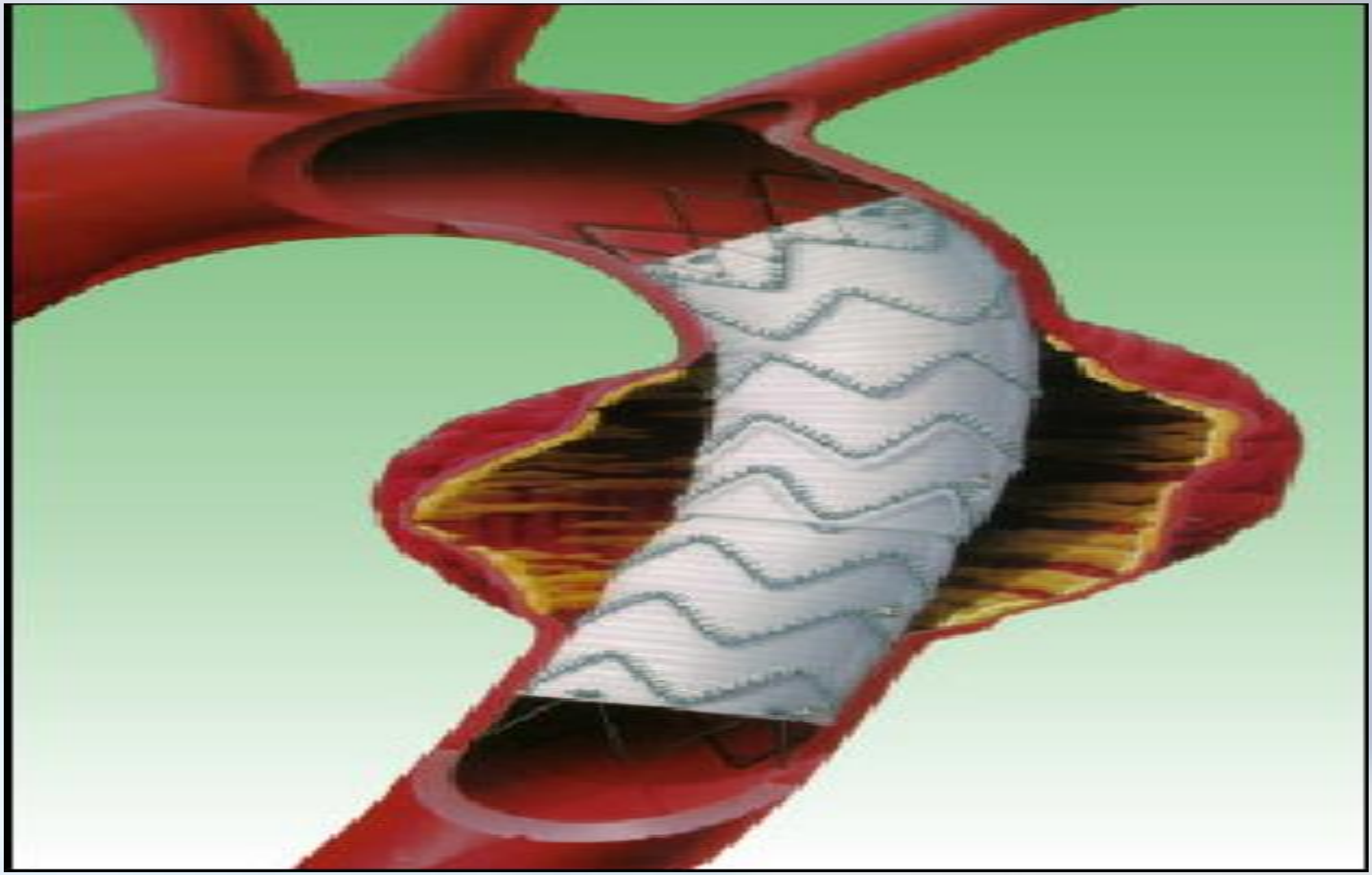
Vascular Grafts

- Braids, weaves, and knits.
  - Porosity
  - Permeability
  - Thickness
  - Burst strength
  - Kink resistance
  - Suture retention
  - Wall thickness
  - Tensile properties
  - Ravel resistance

Vascular Grafts Permeability

- Braids
  - 350 to 2500 ml cm^2/min
- Knits
  - Loosely Woven Knits
    - 1200 to 2000 ml cm^2/min
  - Tightly Woven Knits
    - 2000 to 5000 ml cm^2/min
- Weaves
  - Below 800 ml cm^2/min

Knit Grafts



Filtration and Flow

$$B = \frac{\mu t v}{\Delta p}$$

- μ viscosity of fluid
- t thickness of membrane
- V velocity of fluid
- Δp pressure drop across membrane

$$B = \frac{1}{K_o S_o^{\ 2}} * \frac{\phi^3}{(1-\phi)^2}$$

Void Content Kozeny-Carmen Equation

- K_o is the Kozeny constant.
- S_o is the shape factor.
- Φ is the porosity.

$$B = \frac{1}{K_o S_o^{\ 2}} * \frac{\phi^3}{(1-\phi)^2}$$

Shape Factor

$$S_o = \frac{SurfaceArea}{Volume}$$

Biomaterials: An Example

Biomechanics of Artificial Joints

Normal versus Arthritic Hip

Sir John Charnely: 1960's, fundamental principles of the artificial hip

Frank Gunston: 1969, developed one of the first artificial knee joints.

Hip replacements done in the world per year: between 500,000 and 1 million.

Number of knee replacements done in the world per year: between 250,000 and 500,000.

Of all the factors leading to total hip replacement, osteoarthritis is the most common, accounting for 65% of all total hips.

Normal versus Arthritic Hip

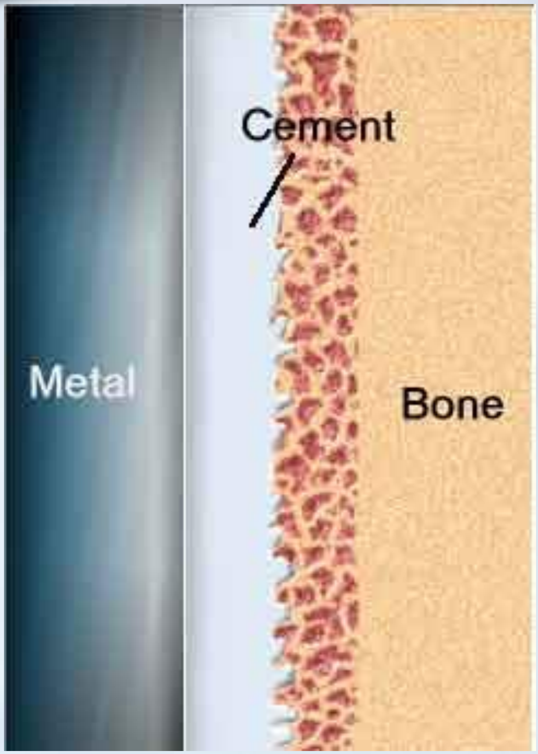
Normal Hip: note the space between the femur and acetabulum, due to cartilage

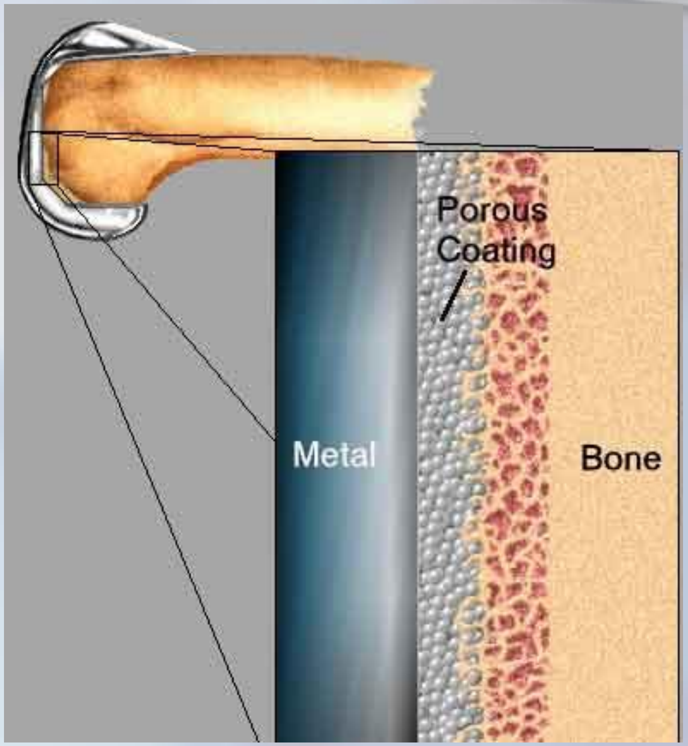
Arthritic Hip: No space visible in joint, as cartilage is missing

Two design issues in attaching materials to bone

1) the geometric and material design of the articulating surfaces
2) design of the interface between the artificial joint and the surrounding bone.

Two attachment methods



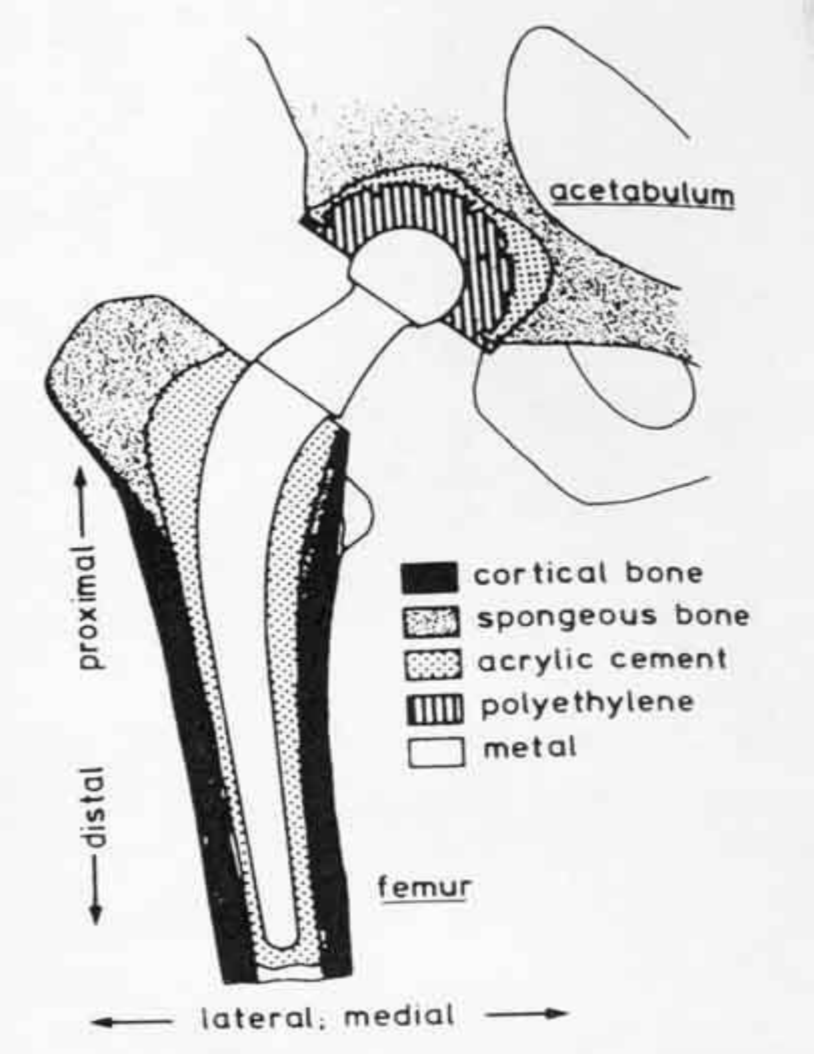


using a Polymethylmethacrylate (PMMA) cement to adhere the metal to the bone

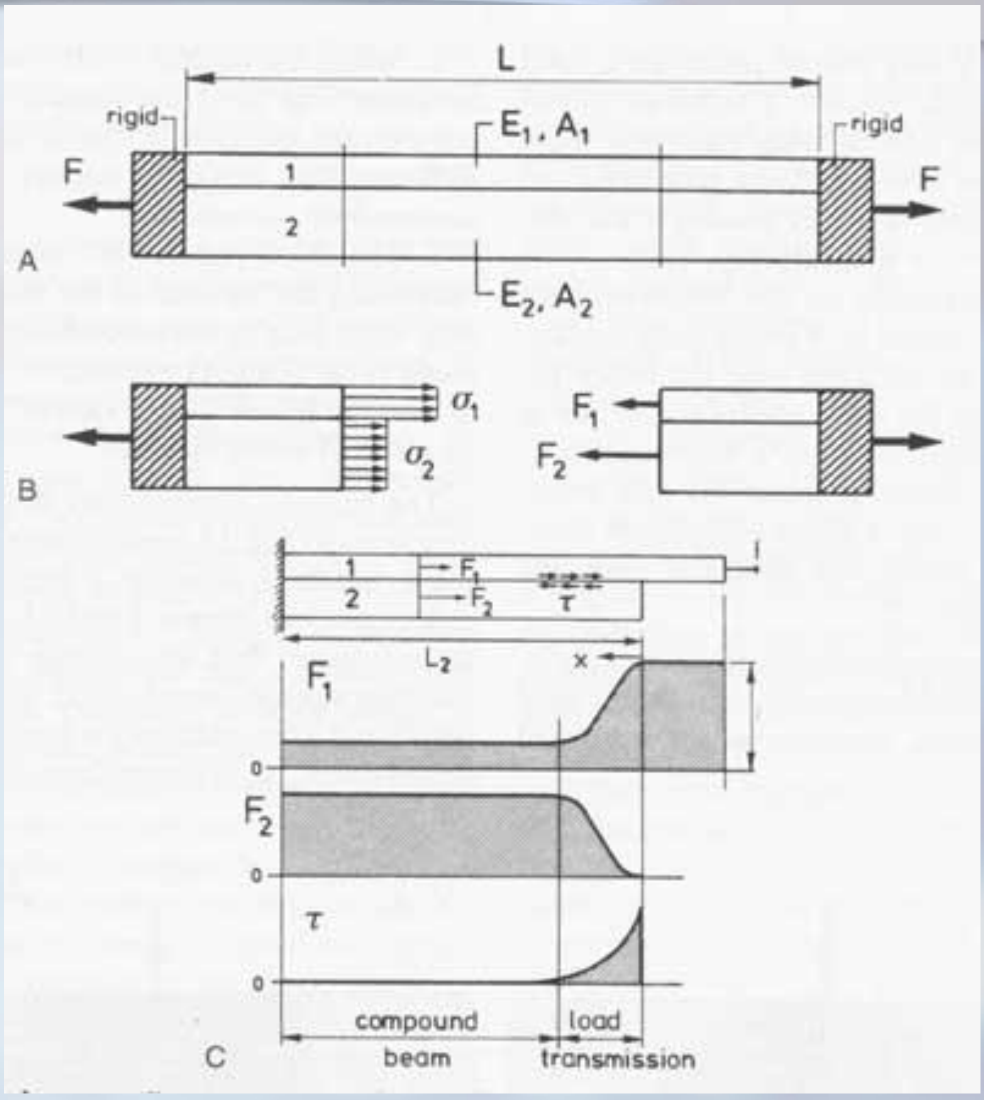
using a porous metal surface to create a bone ingrowth interface

Overview of femoral replacement

the acetabulum and the proximal femur have been replaced. The femoral side is completely metal. The acetabular side is composed of the polyethylene bearing surface

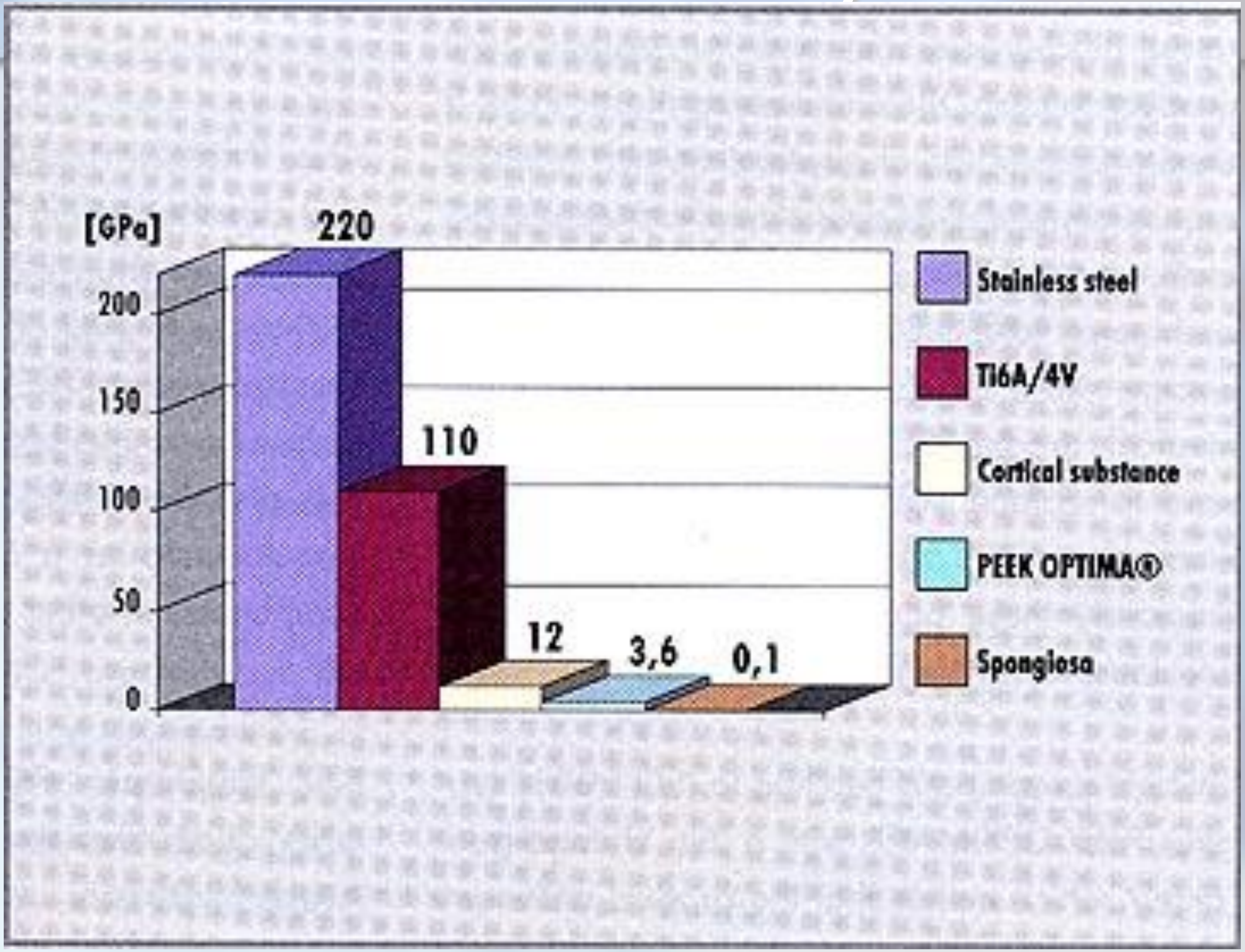


Load transfer in Composite materials



The two materials are bonded and equal force is applied to both

Comparison: Modului of Elasticity

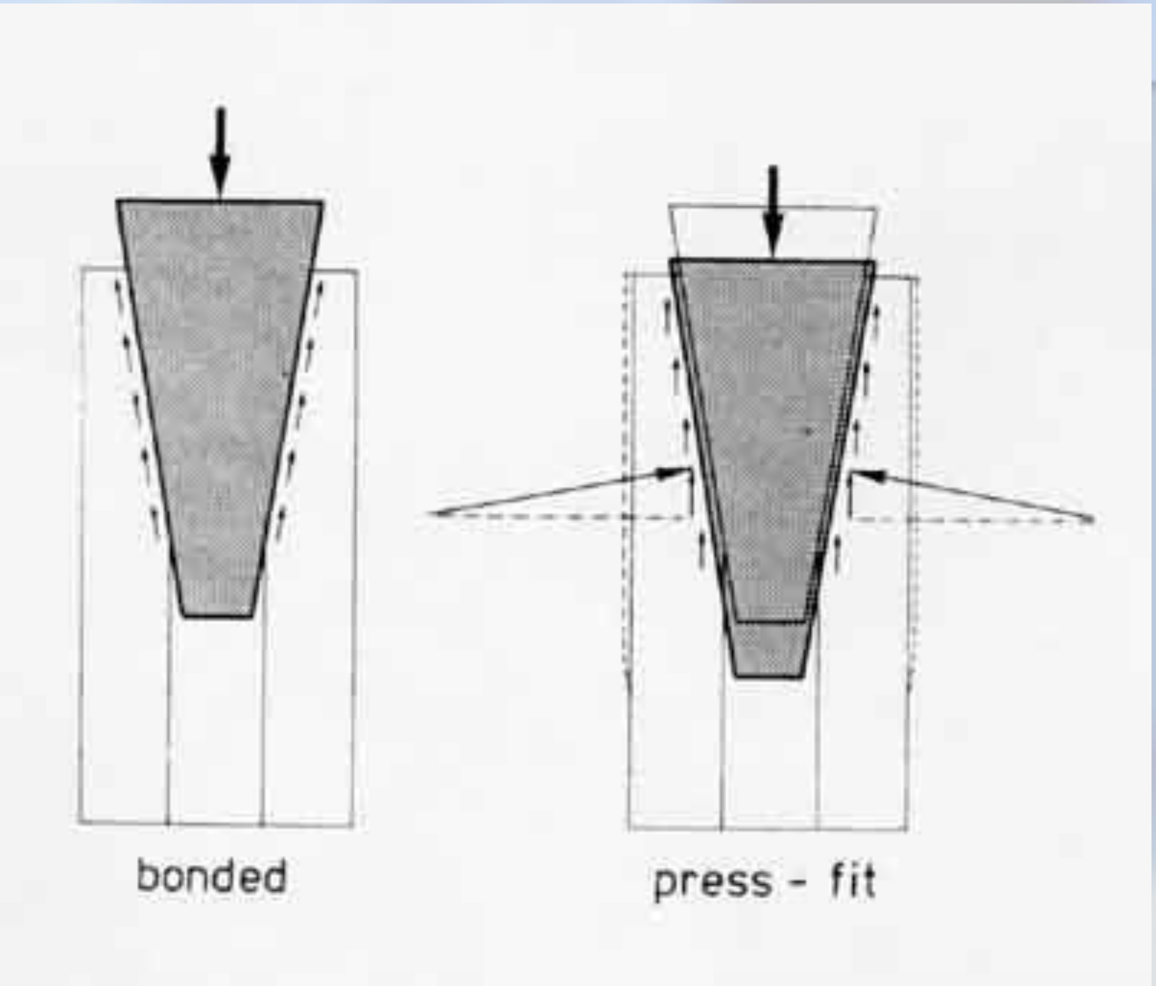


Modulus of elasticity of different implant materials and bone (in GPa)

Implant bonding

A bonded interface is characteristic of a cemented prosthesis (left)

non-bonded interface is characteristic of a non-cemented press fit prosthesis (right)



Degradation Problems

Example of fractured artificial cartilage from a failed hip replacement

Biocompatibility

- The ability of a material to elicit an appropriate biological response in a specific application by **<u>NOT</u>** producing a toxic, injurious, or immunological response in living tissue.
  - Strongly determined by primary chemical structure.

Host Reactions to Biomaterials

- Thrombosis
- Hemolysis
- Inflammation
- Infection and Sterilization
- Carcinogenesis
- Hypersensitivity
- Systemic Effects

What are some of the Challenges?

- To more closely replicate complex tissue architecture and arrangement *in vitro.*
- To better understand extracellular and intracellular modulators of cell function.
- To develop novel materials and processing techniques that are compatible with biological interfaces.
- To find better strategies for immune acceptance.

Biomaterials - An Emerging Industry

- Next generation of medical implants and therapeutic modalities.
- Interface of biotechnology and traditional engineering.
- Significant industrial growth in the next 15 years -- potential of a multi-billion dollar industry.

Biomaterials Companies

- **Baxter International** develops technologies related to the blood and circulatory system.
- **Biocompatibles Ltd.** develops commercial applications for technology in the field of biocompatibility.
- **Carmeda** makes a biologically active surface that interacts with and supports the bodys own control mechanisms
- **Collagen Aesthetics Inc.** bovine and human placental sourced collagens, recombinant collagens, and PEG-polymers
- **Endura-Tec Systems Corp**. bio-mechanical endurance testing ofstents, grafts, and cardiovascular materials
- **Howmedica** develops and manufactures products in orthopaedics.
- **MATECH Biomedical Technologies**, development of biomaterials by chemical polymerization methods.
- **Medtronic, Inc**. is a medical technology company specializing in implantable and invasive therapies.
- **Molecular Geodesics Inc**., biomimetic materials for biomedical, industrial, and military applications
- **Polymer Technology Group** is involved in the synthesis, characterization, and manufacture of new polymer products.
- **SurModics**, offers PhotoLink(R) surface modification technology that can be used to immobilize biomolecules
- **W.L. Gore Medical Products Division**, PTFE microstructures configured to exclude or accept tissue ingrowth.
- **Zimmer**, design, manufacture and distribution of orthopaedic implants and related equipment and supplies