



BIOMATERIALS - UNIT 1

Objective

- To introduce the different biomaterials used in Biomedical Engineering.
- To provide some fundamentals properties of these materials,
- And indicate how they are used.

Background

- Historically, biomaterials consisted of materials common in the laboratories of physicians, with little consideration of materials properties.
- Early biomaterials:
 - **Gold:** Malleable, inert metal [does not oxidize], used in dentistry.
 - **Iron, Brass:** High Strength Metals, rejoin fractured femur
 - **Glass:** Hard ceramic, used to replace eye [cosmetic]
 - **Wood:** Natural composite, high strength to weight, used for limb prostheses.
 - **Bone:** Natural composite.

History

- 1860's - Lister develops aseptic surgical technique
- Early 1900's: Bone plates used to fix fractures.
- 1930's: Introduction of S.S, cobalt chromium alloys.
- 1938: First total hip prosthesis
- 1940's: Polymers in medicine: PMMA bone repair, cellulose for dialysis, nylon sutures.
- 1952: Mechanical heart valve
- 1953: Dacron [polymer fiber] vascular grafts
- 1958: Cemented [PMMA] joint replacement
- 1960: first commercial heart valve
- 1970's: PEO protein resistant thin film coating
- 1976: FDA amendment governing testing & production of biomaterials / devices

What is a Biomaterial?

- *A biomaterial is a nonviable material used in a medical device, intended to interact with biological systems (Williams, 1987)*

[OR]

- Any material of natural or of synthetic origin that comes in contact with tissue, blood or biological fluids, and intended for use in prosthetic, diagnostic, therapeutic or storage application without adversely affecting the living organism and its components.

Need for Biomaterials

- Millions of patients suffer end stage organ and tissue failure annually.
- \$400 billion annually for treatment.
- 8 million surgical procedures.
- Treatment options include transplantation, reconstruction, mechanical devices.

The options and Limitations

- Transplantation
 - Critical donor shortage
 - 3000 livers annually for 30000 people in need
 - Disease Transmission
 - HIV
 - Hepatitis
 - Other transmittable diseases.

- Surgical Reconstruction
 - Not always possible
 - Complications

Continues...

- Mechanical Devices
 - Engineering approach – engineer new tissues, systems
 - Limited by
 - Complexity of the human body
 - Multiple functions
 - Living components versus non living components
 - Materials?
 - Tissue based
 - Polymers
 - Metals
 - Ceramics

Commonly Used Biomaterials

<u>Material</u>	<u>Applications</u>
■ Silicone rubber	Catheters, tubing
■ Dacron	Vascular grafts
■ Cellulose	Dialysis membranes
■ PMMA	Intraocular lenses, bone cement
■ Polyurethanes	Catheters, pacemaker leads
■ Hydrogels	Ophthalmological devices, Drug Delivery
■ Stainless steel	Orthopedic devices, stents
■ Titanium	Orthopedic and dental devices
■ Alumina	Orthopedic and dental devices
■ Hydroxyapatite	Orthopedic and dental devices
■ Collagen (reprocessed)	Ophthalmologic applications, wound dressings

Significance of Biomaterials

- Replace diseased part – Dialysis
- Assist in Healing – Sutures
- Improves Function – Contacts
- Correct Function – Spinal rods
- Correct Cosmetic – Nose, Ear
- Aids – Probes / Catheters
- Replace rotten – Amalgam
- Replace dead ~ Skin

First Generation Implants

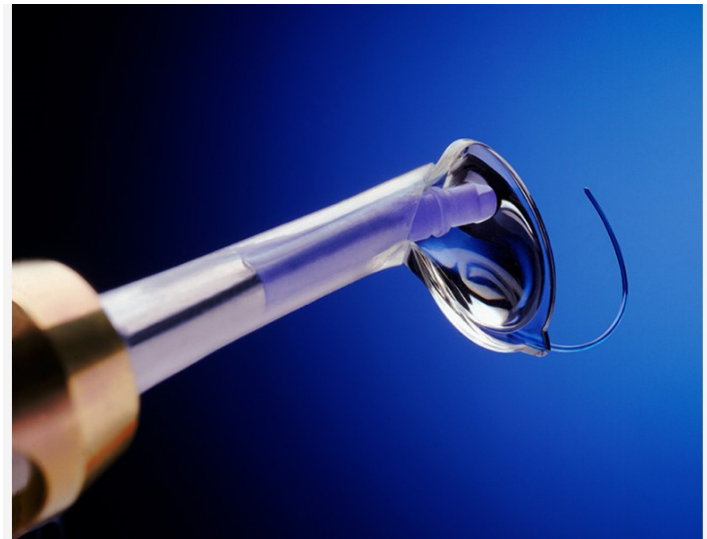
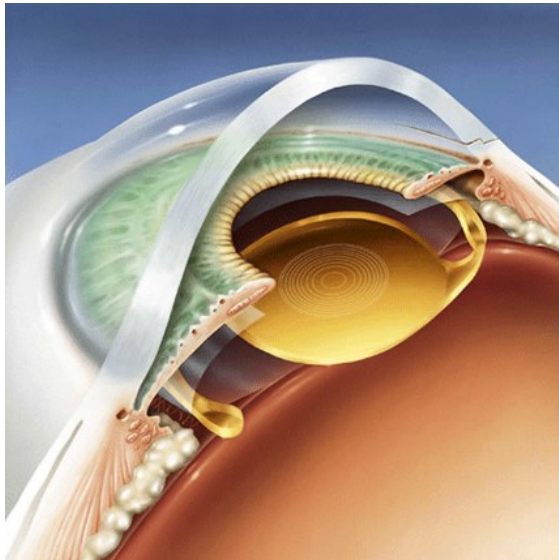
- ‘Ad-hoc’ [unplanned] Implants
- Specified by physicians using common and borrowed materials
- Most successes were accidental rather than by design

Examples – First generation Implants

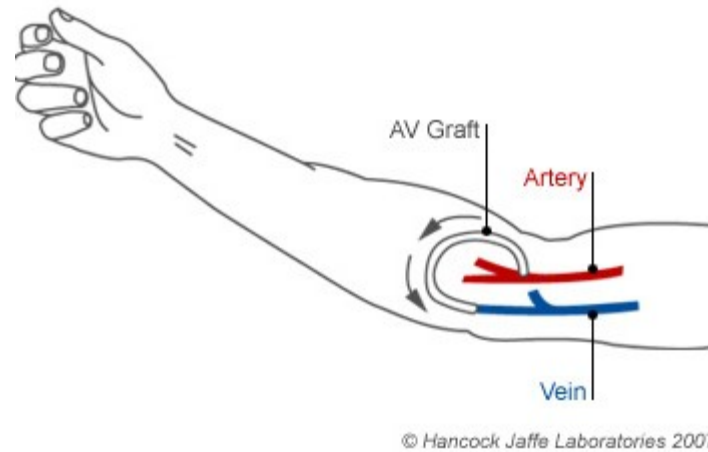
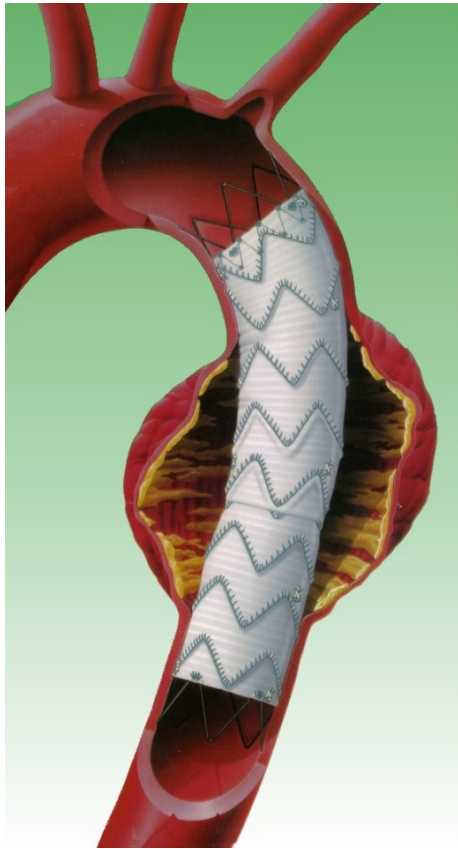
- Gold fillings, wooden teeth, PMMA dental prosthesis
- Steel, gold, ivory, bone plates etc.
- Glass eyes and other body parts

Intraocular Lens

3 basic materials – PMMA, Acrylic, silicone



Vascular Grafts



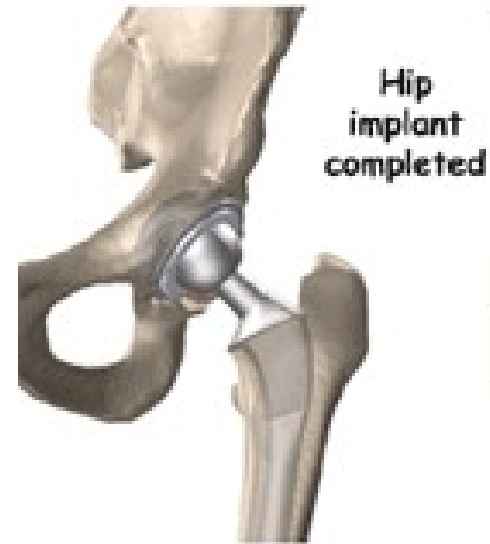
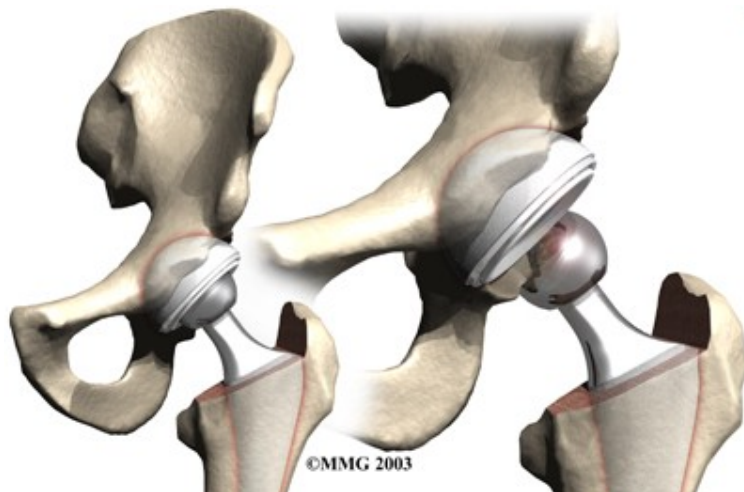
Second generation Implants

- Engineered implants using common and borrowed materials
- Developed through collaborations of physicians and engineers
- Built on first generation experiences
- Used advances in materials science

Examples – Second generation implants

- Titanium alloy dental and orthopedic implants
- Cobalt-chromium implants
- UHMW polyethylene bearing surfaces for total joint replacements
- Heart valves and Pacemakers.

Artificial Hip Joints



Third Generation Implants

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

Example – Third generation implants

- Tissue engineered implants designed to re-grow rather than replace tissues
- Some resorbable bone repair cements
- Genetically engineered ‘biological’ components.

Heart Valves



Biological valve
(human or porcine)



Mechanical valve



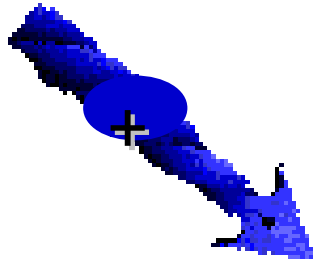
Synthetic Polymer Scaffolds



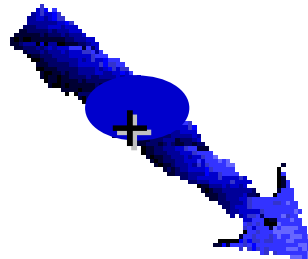
...In the shape of a nose [left] is seeded with cells called chondrocytes that replace the polymer with cartilage over time [right] to make a suitable implants.

Evolution of Biomaterials

Structural



Soft Tissue
Replacements

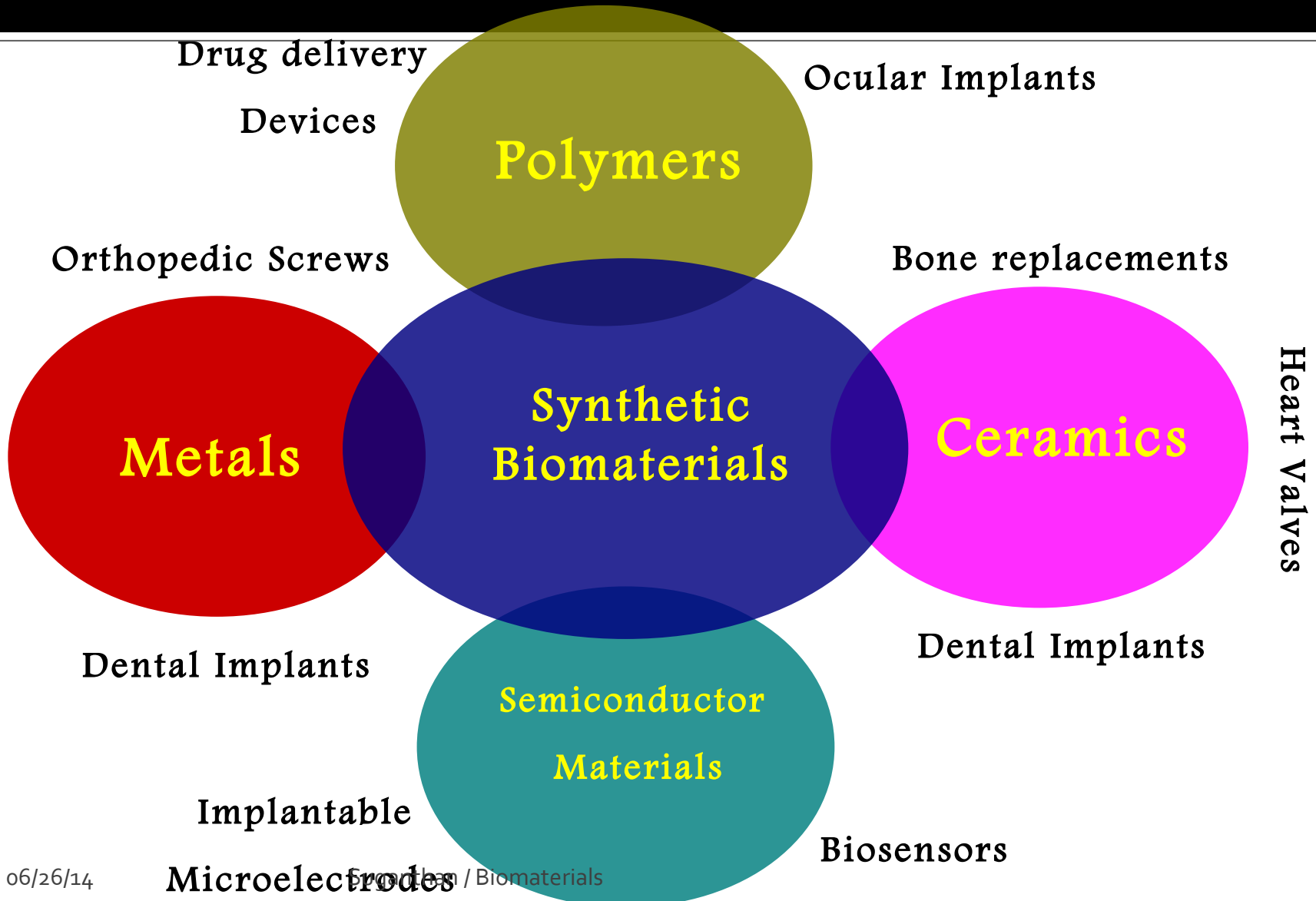


Functional Tissue
Engineering
Constructs

Advances in Biomedical Technology

- Cell matrices for 3-D growth and tissue reconstruction
- Biosensors, Bio-mimetic and Smart devices
- Controlled Drug Delivery / Targeted Delivery
- Bio-hybrid organs and Cell Immuno-isolation
 - New biomaterials – bioactive, biodegradable, inorganic
 - New processing techniques

Classification

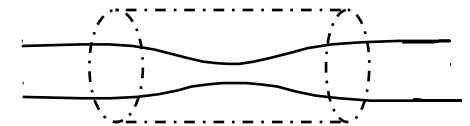


Biomaterials for Tissue Replacement

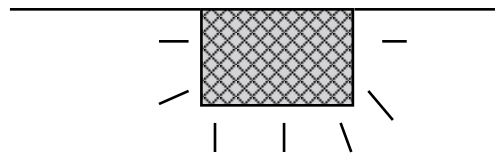
- Bioresorbable Vascular Graft



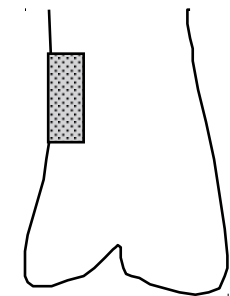
- Biodegradable nerve guidance channel



- Skin Grafts



- Bone Replacements



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.

Applications of Biomaterials

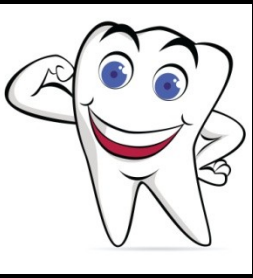
Therapeutic Devices



Examples of biomaterials used in orthopaedic applications include:

- Joint replacements (hip, knee)
- Bone cements
- Bone defect fillers
- Fracture fixation plates
- Artificial tendons and ligaments.





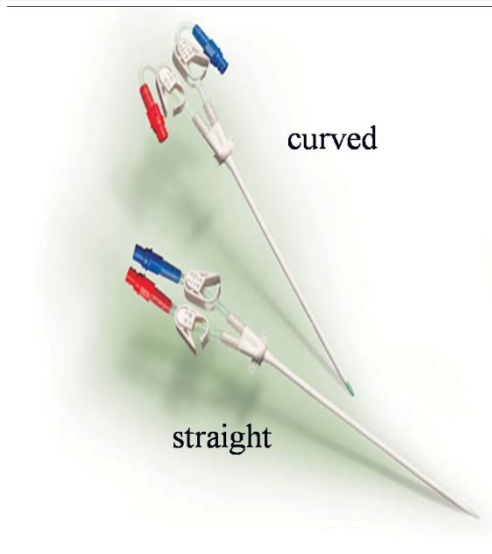
Dentistry



Examples of biomaterials used in dental applications include:

- Pins for anchoring tooth implants and also part of orthodontic devices.
- Dentures made from polymeric biomaterials.

Cardiovascular System

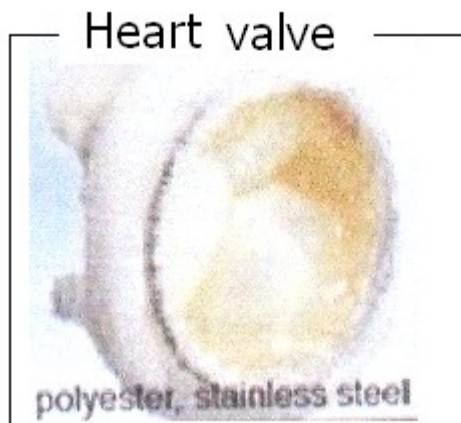


Biomaterials are widely used in cardiovascular equipment and devices to be inserted into biological systems.

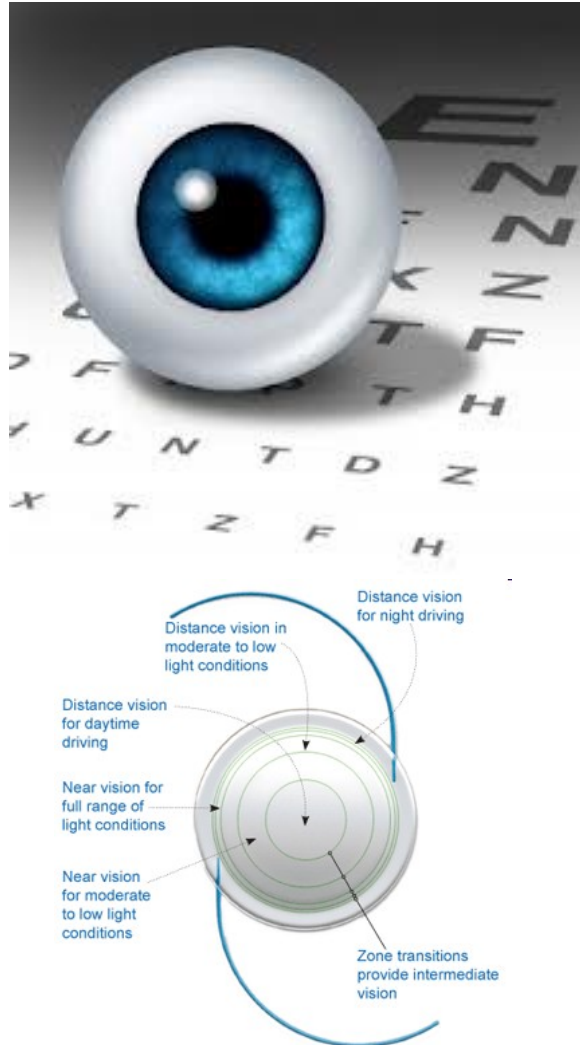
Examples include:

- Carbon used in heart valves
- Polyurethane for pace makers.

Their use depends on the specific application and the design.



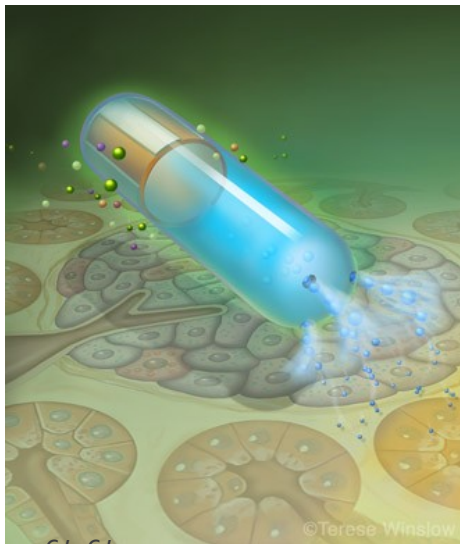
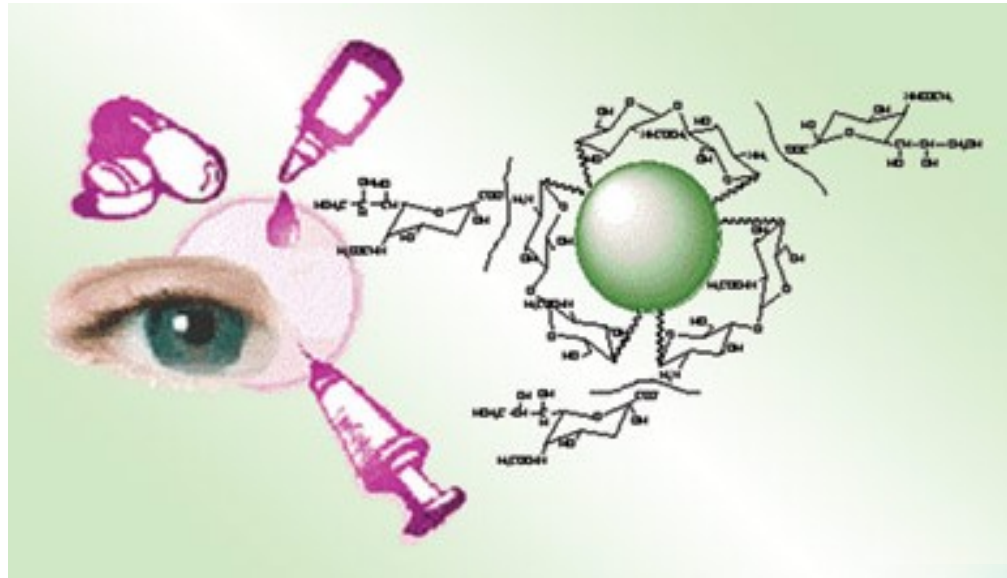
Ophthalmology



Examples of biomaterials used in ophthalmic applications include:

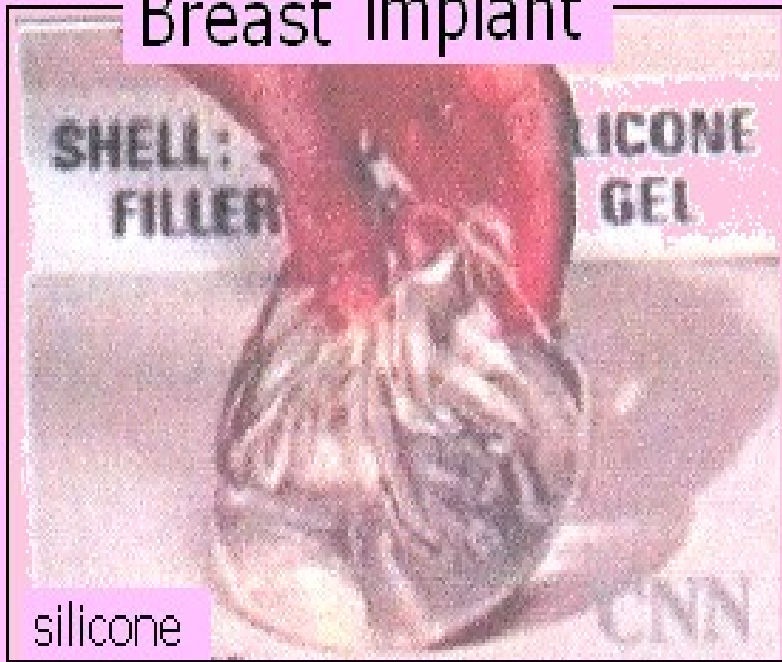
- Contact lenses
- Corneal implants
- Artificial corneas
- Intraocular lenses

Drug Delivery



Cosmetic Applications

Breast implant



Examples of biomaterials used in cosmetic applications include:

- Silicones for breast enlargement.
- Artificial skin

General applications of biomaterials

- Storage of fluids, tissues and other biological products.
- Diagnosis
- Monitoring
- Therapy

Medical Devices

A medical device is a product which is used for medical purposes in patients, in diagnosis, therapy or surgery

Classification of Medical Device

Based on the duration of the device use, invasiveness and risk to the user.

CLASS I devices: crutches, bedpans, tongue depressors, adhesive bandages etc. – minimal invasiveness, does not contact the user internally.

CLASS II devices: Hearing aids, blood pumps, catheters, contact lens, electrodes etc. – higher degree of invasiveness and risk, but relatively short duration.

CLASS III devices: Cardiac pacemakers, intrauterine devices, intraocular lenses, heart valves, orthopedic implants etc. – considerably more invasive and can immense risk to the user-implantables.

Biomaterial or Medical Device?

- Although FDA recognizes that many of the currently available biomaterials have vast utility in the fabrication of medical devices, the properties and safety of these materials must be carefully assessed with respect to the specific application in question and its degree of patient contact.
- An important principle in the safety assessment of medical devices is that a material that was found to be safe for one intended use in a device might not be safe in a device intended for a different use

Continues...

- Accurate characterization is an essential step in selecting a material for a medical device, but ultimately the final assessment must be performed on the finished product, under actual use conditions.

Biomaterials Research in Industry

- It is dominated as much
 - By the regulatory approval process and
 - Submission requirements as by the
 - Physical
 - Mechanical and
 - Chemical properties of the medical device.

Biomaterial Science is an Interdisciplinary Affair

Biomaterials include

- Physical scientists,
- Engineers,
- Dentists,
- Biological scientists,
- Surgeons, and
- Veterinary practitioners in industry-government,
- Clinical specialties and academic settings.

Biomaterials Scientists

- Study the interactions of natural and synthetic substances and implanted devices
- With living cells, their components and complexes such as tissues and organs.

...We...

- Develop and characterize the materials used to measure, restore and improve physiologic function, and enhance survival and quality of life.

The Society for Biomaterials

A professional society which promoted advances in all phases of materials research and development by encouragement of co-operative educational programs, clinical applications, and professional standards in the biomaterials field.

www.biomaterials.org

Relevant Biomaterials Journals

- Journal of Biomedical Materials Research
- Biomaterials
- Journal of Biomaterials Science
- Journal of Biomaterials Applications
- Journal of Material Science: Materials in Medicine



Compatibility

- Biocompatibility is related to the behavior of biomaterials in various environments under various chemical and physical conditions.
- The term may refer to specific properties of a material without specifying where or how the material is to be used.
- For example, a material may elicit little or no immune response in a given organism, and may or may not integrate with a particular cell type or tissue.

Continues...

- The ambiguity of the term reflects the ongoing development of insights into how biomaterials interact with the human body and eventually how those interactions determine the clinical success of a medical device.
- A material should not be toxic unless specifically engineered to be so-like ‘smart’ drug delivery systems that target cancer cells and destroy them.

Biocompatibility - Definitions

- *The ability of a material to perform with an appropriate host response in a specific application (Williams, 1987). **OR***
- The quality of not having toxic or injurious effects on biological systems. **OR**
- Comparison of the tissue response produced through the close association of the implanted candidate materials to its implant site within the host animal to that tissue response recognized and established as suitable with control materials. **OR**

Continues...

- Refers to the ability of a biomaterial to perform its desired function with respect to a medical therapy, without eliciting any undesirable local or systemic effects in the recipient or beneficiary of that therapy, but generating the most appropriate beneficial cellular or tissue response in that specific situation, and optimizing the clinically relevant performance of that therapy. **OR**
- Biocompatibility is the capability of a prosthesis implanted in the body to exist in harmony with tissue without causing deleterious changes.

Properties of Biomaterials

- Bulk Properties
- Surface Properties
- Characterization

Bulk Properties

- The bulk elastic properties of a material determine how much it will compress under a given amount of external pressure.
- The ratio of the change in pressure to the fractional volume compression is called the bulk modulus of the material.

$$\text{Bulk Modulus } B = \frac{\Delta P}{\frac{\Delta V}{V}}$$

Surface Properties

- These are the most important property that a biomaterial possesses.
- This is due to the fact that, when a device is implanted to tissues, the surface chemistry will be determined, how the material [or] the surrounding fluid interact.
- The surface of metal implant corrode inside the system liberating the metallic ions into the solution.

Continues...

- Polymeric materials doesn't corrode, but leach the constituents such as lubricants, monomers from their interiors.
- Inorganic glasses and clay's undergoes a process of ion – exchange.
- Thus, proper surface properties are important to have desirable biocompatibility of implant materials.

Characterization

- a. Thermal treatment.
- b. Surface Improvement.
- c. Sterilization.

Thermal treatment

- a. The toughness of a biomaterial can be increased by this treatment below the melting temperature of the material, for a predetermined period, of time and this process should be followed by controlled cooling. This is called *Annealing*.
- b. The other method is that, the heat treatment step is completed, the alloy is rapidly cooled. This is called *quenching*.

Surface Improvement

- **Ammonization** is one of its method. It means an oxide film formation on the metal.
- **Nitrating** is another method.
 - Generally, oxygen or nitrogen alloys on Aluminum or Titanium base alloys are done by placing them in an electrolytic bath and passing electric current.
- **Grinding** is another process, that results in surface layer which is used to remove surface impurities.
- **Polishing** is used to polish the surface of the metal.

Sterilization

- The surgical implants must be freed from microorganisms by post manufacturing sterilization.
- This will destroy most of the bacteria. **Dry Sterilization.**
- The pathogens are killed by heating at $160^{\circ} - 190^{\circ}\text{C}$.
- This should be followed by moist heat sterilization and is performed in autoclaves.
- Generally a 15mins exposure at 120°C with steam at a pressure of 0.1 atmosphere is the most common treatment.