Biomaterials

By

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Lecture No. (2)

Selection, Uses and Requirements of Biomaterials

Selection of Biomedical Materials

The process of material selection should ideally be for a logical sequence involving:

1. Analysis of the problem.
2. Consideration of requirement.
3. Consideration of available material and their properties leading to:
4. Choice of material.

Uses of biomaterials according to purpose:

Purpose of Uses	Example
Replacement of diseased and damaged part	Artificial hip joint, kidney dialysis machine
Assist in healing	Sutures, bone plates and screws
Improve function	Cardiac pacemaker, intra-ocular lens
Correct cosmetic problem	Chin augmentation, orthodontic
Aid to diagnosis	Probes and catheters
Aid to treatment	Catheters, wound stickers

Uses of biomaterials according to organs:

Organ	Example
Heart	Pacemaker**,** artificial heart valve, totally artificial heart
Lung	Oxy-generator machine
Eye	Contact lens, intraocular lens
Ear	Artificial stapes, cochlear implant
Bone	Fixation plates
Kidney	Kidney dialysis machine
Bladder	Catheters

The number of medical devices used each year is very large which are arranged as shown below:

1- Catheters.
2- Contact lens.
3- Renal dialyzer.
4- Intraocular lens.
5- Cardiovascular.
6- Hip and knee prostheses.

The biomaterials should be either not degrade and not harming the living tissues or organ, or degrade and not harm the tissues or organ.

Generally, when a material degrades in the body its properties change from their original to less desirable performance, for example suture material that hold a wound together but resorb in the body as the wound heals. Also one of application of biodegradable materials is in drug therapy.

Sterilization Methods of Biomaterials

- Moist heat (121-125^{o}C, 15-30 min).
- Ethylene oxide (CH_2CH_2O).
- Radiation (60 C^{o} & Electron Beam).
- Dry heat > 140^{o}C.
- Others (UV, Ozone, X-ray. etc.).

In vitro: An in vitro test is one done in the laboratory in glass test tube, usually involving isolated tissues, organs, or cells.

In vivo: A test performed in a living body or organism.

Implant: Any medical device made from one or more materials that is intentionally placed within the body, either totally or partially. **The types of implants** in the body are:

1- Permanent Implants: prosthetic devices manufactured from synthetic materials such as: Titanium and Al_2O_3 use as joint replacement.

2- Transient Implants (Transplantation): replacement of tissue or organ from human or animal donor such as:

Allograft—human donor (e.g., kidney, liver, heart)

Xenograft—animal donor (e.g., porcine aortic valves)

3- Auto-graft: Donor is also recipient such as skin grafts, nerve grafts, breast reconstructions.

4- Regenerated Tissues/Organs: cells grown on a scaffold device e.g., (skin and cartilage).

General criterion for biomaterial selection

1- Mechanical and chemicals properties.

2- No undesirable biological effects carcinogenic, toxic, allergenic or immunogenic.

3- Possible to process, fabricate and sterilize with a good reproducibility.

4- Acceptable cost/benefit ratio.

Deterioration of Biomaterials

- Corrosion.
- Degradation.
- Calcification.
- Mechanical loading.
- Combined.

Selection parameters for biomaterials:

A biomaterial used for implant should possess some important properties in order to long-term usage in the body without rejection. Therefore, the design and selection of biomaterials depend on different properties which are:

1- Host Response: Defined as the response of the host organism to the implanted material or device.

2- Toxicology: A biomaterial should not be toxic and no carcinogen.

3- **Biocompatibility:** When the materials are biocompatible are called biomaterial.

4- **Biodegradability**: It is simply a phenomenon that natural and synthetic biomaterials are capable of decomposing in the body conditions without leaving any harmful substances behind.

5- **Biofunctunality:** is playing a specific function in physical and mechanical terms.

6- **Functional Tissue Structure:** Incorporated of medical devices or implant biomaterials into tissues and organs.

7- **Healing:** Special processes are doing when a material or device heals in the body. Injury to tissue will stimulate the well-defined inflammatory treated reaction sequence that leads to healing.

8- **High wear resistance.**

9- **Long fatigue life.**

10- **Low cost and good esthetics.**

11- **Appropriate Design and Manufacturability:** Biomaterials should be machinable and moldable.

12- **High corrosion and degradation resistance:** corrosion can reduce the life of implant device.

13- **Ethics**: A wide range of ethical considerations impact of biomaterials.

14- **Elastic Modulus equivalent to that of bone:** For major applications such as total joint replacement, higher yield strength is basically coupled with the requirement of a lower elastic modulus close to that of human bone. The magnitude of bone modulus various in range of (4- 30 GPa.) depending on type of the bone and the measurement direction.

15- **Dependence on Specific Anatomical Sites of Implantation**

a) A hip-joint will be implanted in bone space.

b) A heart valve will be sutured into cardiac muscle and will contact both soft tissues and blood.

c) A catheter may be placed in an artery.

Each of these sites challenges the biomedical device designer with special requirements for geometry, size, mechanical properties, and bio-responses.

16- **Failure of Biomaterials:** Although several biomaterials meet the requirements of biocompatibility for medical use, unluckily, some of the biomaterials do not possess sufficient mechanical durability in a large number of cases. Thus, change surgeries are necessary in approximately 7% of hip and 10% of knee replacements after 10 years of use.

17- **Mechanical and Performance Requirements of Biomaterials:** the design and selection of biomaterials also depend on their mechanical and non-mechanical characteristics includes:

a) Mechanical Performance and Device Properties

1- A hip prosthesis must be strong and rigid.
2- A tendon material must be strong and flexible.
3- A heart valve must be flexible and tough.
4- An articular cartilage substitute must be soft and elastomeric.
5- A dialysis membrane must be strong and flexible but not elastomer.
6- A sutures, must be tensile strength, flexibility and non-irritating.

b) Mechanical Durability

1- A catheter may only have to perform for 3 days.
2- A bone plate may fulfill its function in 6 months or longer.
3- A heart valve must flex 60 times per minute without tearing for the lifetime of the patient (for 10 years).
4- A hip joint must not fail under heavy loads for more than 10 years.

c) Physical Properties

1- The dialysis membrane has a specified permeability.
2- The articular cup of the hip joint has high lubricity.
3- The intraocular lens has clarity and refraction requirements.

d) Mechanical properties

The mechanical properties play an important role in material selection for application in the human body such as:

1) Compressive strength.
2) Shear stress.
3) Hardness.
4) Tensile strength.
5) Modulus of elasticity.
6) Elongation (strain).
7) Fracture resistance.
8) Fatigue strength or life.

e) Non-mechanical requirements

The non-mechanical requirements which have significant role in performance of the material in the human body such as:

1) High corrosion resistance.
2) High wear resistance.
3) Biocompatibility.

f) Biological Testing

1) In vitro assessment.
2) In vivo assessment.
3) Functional assessment.
4) Clinical assessment.

All organ of human body as shown in below Figure: