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Introduction

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Biomaterials

Biomaterials are used to make devices to replace a part or a function of the body in safe, reliably economically, and physiologically acceptable manner. A variety of devices and materials are used in the treatment of disease or injury. Commonplace examples include suture needles, plates, teeth fillings, etc.

Term Definitions

Biomaterial: A synthetic material used to make devices to replace part of a living system or

to function in intimate contact with living tissue.

Biological Material: A material that is produced by a biological system.

Bio-compatibility: Acceptance of an artificial implant by the surrounding tissues and by the

body as a whole.

Fields of Knowledge to Develop Biomaterials

1- Science and engineering: (Materials Science) structure-property relationships of synthetic and biological materials including metals, ceramics, polymers, composites, tissues (blood and connective tissues), etc.

2- Biology and Physiology: Cell and molecular biology, anatomy, animal and human physiology, histopathology, experimental surgery, immunology, etc.

3- Clinical Sciences: (All the clinical Specialties) density, maxillofacial, neurosurgery, obstetrics and gynecology, ophthalmology, orthopedics, plastic and reconstructive surgery, thoracic and cardiovascular surgery, veterinary medicine and surgery, etc.

Uses of Biomaterials

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Uses of Biomaterials 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 functional abnormalities Cardiac pacemaker

Correct cosmetic problem

Mastectomy augmentation,

chin augmentation

Aid to diagnosis Probes and catheters

Aid to treatment Catheters, drains

Biomaterials in Organs

Organ Example

Heart Cardiac pacemaker, artificial heart valve, Totally artificial heart

Lung Oxy-generator machine

Eye Contact lens, intraocular lens

Ear Artificial stapes, cochlea implant

Bone Bone plate, intra-medullary rod

Kidney Kidney dialysis machine

Bladder Catheter and stent

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Materials for Use in the Body

Materials	Advantages	Disadvantages	Examples
Polymers (nylon, silicon Rubber, polyester, PTFE, etc)	**Resilient Easy to Fabricate**	**Not strong Deforms with time May degrade**	**Blood vessels, Sutures, ear, nose, Soft tissues**
Metals (Ti and its alloys Co-Cr alloys, stainless Steels)	**Strong Tough ductile**	**May corrode, dense, Difficult to make**	**Joint replacement Bone plates and Screws, dental root Implant, pacer, and suture**
Ceramics (Aluminum Oxide, calcium phosphates, including hydroxyapatite carbon)	**Very biocompatible Inert strong in compression**	**Difficult to make Brittle Not resilient**	**Dental coating Orthopedic implants Femoral head of hip**
Composites (Carbon-carbon, wire Or fiber reinforced Bone cement)	**Compression strong**	**Difficult to make**	**Joint implants Heart valves**

The science of biomedical materials involves a study of the composition and properties of materials and the way in which they interact with the environment in which they are placed.

The number of medical devices used each year is very large.

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The chart below estimates usage for common devices.

Device	Usage Estimate
Contact lens	75,000,000
Hip and knee prostheses	1,000,000
Catheter	300,000,000
Heart valve	200,000
Vascular graft	400,000
Breast implant	300,000
Dental implant	500,000
Pace maker	200,000
Renal dialyzer	25,000,000
Cardiovascular	2,000,000
Intraocular lens	7,000,000
Left ventricular assist devices	100,000

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.

The choice of a specific biomedical material is now determined by consideration of the

following:

1- A proper specification of the desired function for the material;

2- An accurate characterization of the environment in which it must function, and

the effects that environment will have on the properties of the material;

3- A delineation of the length of time the material must function;

4- A clear understanding of what is meant by safe for human use.

Materials Evaluation

As the number of available materials increases, it becomes more and more important to be protected from unsuitable products or materials, which haven't been thoroughly evaluated.

Most manufacturers of materials operate an extensive quality assurance program and materials are thoroughly tested before being released to the general practitioner.

1- Standard Specifications: Many standard specification tests of both national and international standards organizations (ISO) are now available, which effectively maintain quality levels. Such specifications normally give details for:

(a) the testing of certain products,

(b) the method of calculating the results

(c) the minimum permissible result, which is acceptable.

2- Laboratory Evaluation: Laboratory tests, some of which are used in standard specification, can be used to indicate the suitability of certain materials. It is important that methods used to evaluate materials in laboratory give results, which can be correlated with clinical experience.

3- Clinical Trials: Although laboratory tests can provide many important and useful data on materials, the ultimate test is the controlled clinical trial and verdict of practitioners after a period of use in general practice. Many materials produce good results in the laboratory, only to be found lacking when subjected to clinical use. The majority of manufacturers carry out extensive clinical trials of new materials, normally in cooperation with a university or hospital department, prior to releasing a product for use by general practitioners.

The most common classes of materials used as biomedical materials are polymers, metals, and ceramics. These three classes are used singly and in combination to form most of the implantation devices available today.

1- **Polymers**

There are a large number of polymeric materials that have been used as implants or part of implant systems. The polymeric systems include acrylics, polyamides, polyesters, polyethylene, polysiloxanes, polyurethane, and a number of reprocessed biological materials.

Some of the applications include the use of membranes of ethylene-vinyl-acetate (EVA) copolymer for controlled release and the use of poly-glycolic acid for use as a resorbable suture material. Some other typical biomedical polymeric materials applications include: artificial heart, kidney, liver, pancreas, bladder, bone cement, catheters, contact lenses, cornea and eye-lens replacements, external and internal ear repairs, heart valves, cardiac assist devices, implantable pumps, joint replacements, pacemaker, encapsulations, soft-tissue replacement, artificial blood vessels, artificial skin, and sutures. As bioengineers search for designs of ever increasing capabilities to meet the needs of medical practice, polymeric materials alone and in combination with metals and ceramics are becoming increasingly incorporated into devices used in the body.

2- **Metals**

The metallic systems most frequently used in the body are:

(a) Iron-base alloys of the 316L stainless steel

(b)Titanium and titanium-base alloys, such as (i)Ti-6% Al-4%V, and commercially pure ³ 98.9%

(ii) Ti-Ni (55% Ni and 45% Ti)

(c) Cobalt base alloys of four types

(i) Cr (27-30%), Mo (5-7%), Ni (2-5%)

(ii) Cr (19-21%), Ni (9-11%), W (14-16%)

(iii) Cr (18-22%), Fe (4-6%), Ni (15-25%), W (3-4%)

(iv)Cr (19-20%), Mo (9-10%), Ni (33-37%)

The most commonly used implant metals are the 316L stainless steels, Ti-6%-4%V, and Cobalt base alloys of type "i" and "ii". Other metal systems being investigated include Cobalt-base alloys of type "iii" and "iv", and Niobium and shape memory alloys, of which (Ti 45% - 55%Ni) is receiving most attention. Further details of metallic biomedical materials will be given later.

3- **Composite Materials**

Composite materials have been extensively used in dentistry and prosthesis designers are now incorporating these materials into other applications. Typically, a matrix of ultrahigh-molecular-weight polyethylene (UHMWPE) is reinforced with carbon fibers.

These carbon fibers are made by pyrolizing acrylic fibers to obtain oriented graphitic structure of high tensile strength and high modulus of elasticity. The carbon fibers are 6 - 15μm in diameter, and they are randomly oriented in the matrix. In order for the high modulus property of the reinforcing fibers to strengthen the matrix, a sufficient interfacial bond between the fiber and matrix must be achieved during the manufacturing process.

This fiber reinforced composite can then be used to make a variety of implants such as intra-medullary rods and artificial joints. Since the mechanical properties of these composites with the proportion of carbon fibers in the composites, it is possible to modify the material design flexibility to suit the ultimate design of prostheses.

Composites have unique properties and are usually stronger than any of the single materials from which they are made. Workers in this field have taken advantages of this fact and applied it to some difficult problems where tissue in-growth is necessary.

Examples:

Deposited Al2O3 onto carbon;

Carbon / PTFE;

Al_2O_3 / PTFE;

PLA-coated Carbon fibers.

4 – **Ceramics**

The most frequently used ceramic implant materials include aluminum oxides, calcium phosphates, and apatites and graphite. Glasses have also been developed for medical

applications. The use of ceramics was motivated by:

(i) their inertness in the body,

(ii) their formability into a variety of shapes and porosities,

(iii) their high compressive strength, and

(iv) some cases their excellent wear characteristics.

Selected applications of ceramics include:

(a) hip prostheses,

(b) artificial knees,

(c) bone grafts,

(d) a variety of tissues in growth related applications in

(d.1) orthopedics

(d.2) dentistry, and

(d.3) heart valves.

Applications of ceramics are in some cases **limited** by their generally poor mechanical properties: (a) in tension; (b) load bearing, implant devices that are to be subjected to significant tensile stresses must be designed and manufactured with great care if ceramicsare to be safely used.

5 – **Biodegradable Materials**

Another class of materials that is receiving increased attention is biodegradable materials. Generally, when a material degrades in the body its properties change from their original values leading to altered and less desirable performance. It is possible, however, to design into an implant's performance the controlled degradation of a material, such that natural tissue replaces the prosthesis and its function.

Examples include: Suture material that hold a wound together but resorb in the body as the wound heals and gains strength. Another application of these materials occurs when they are used to encourage natural tissue to grow. Certain wound dressings and ceramic bone augmentation materials encourage tissue to grow into them by providing a"scaffold". The scaffold material may or may not resorb over a period of time but in each case, natural tissue has grown into the space, then by restoring natural function. One final application of biodegradable materials is in drug therapy, where it is possible to chemically bond certain drugs to the biodegradable material, when these materials are placed within the body the drug is released as the material degrades, thereby providing a localized, sustained release of drugs over a predictable period of time.

Success and Failure are seen with Biomaterials and Medical Devices

Most biomaterials and medical devices perform satisfactorily, improving the quality of life for the recipient or saving lives. Still, man-made constructs are never perfect.

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Manufactured devices have a failure rate. Also, all humans differ in genetics, gender, body chemistries, living environment, and physical activity. Furthermore, physicians also differ in their "talent" for implanting devices.

The other side to the medical device success story is that there are problems, compromises and complications that occur with medical devices.

Central issues for the biomaterials scientist, manufacturer, patient, physician, and attorney are:

1- what represents good design;

2- Who should be responsible when devices perform with an inappropriate host response;

3- What is the cost/risk or cost/benefit ratio for the implant or therapy?

These five characteristics of biomaterial science-multidisciplinary, multi-material, need driven, substantial market, and risk-benefit, color the field of biomaterials.

What Subjects are Important to Biomaterials Science?

1- Toxicology

A biomaterial should not be toxic, unless it is specifically engineered for such requirements (for example a "smart" bomb" drug delivery system that targets cancer cells and destroy them). Toxicology for biomaterials deals with the substances that migrate out of the biomaterials. It is reasonable to say that a biomaterial should not give off anything from its mass unless it is specifically designed to do so.

2- Biocompatibility

It is the ability of a material to perform with an appropriate host response in a specific application. "Appropriate host response" includes lack of blood clotting, resistance of bacterial colonization and normal heating. The operational definition of biocompatible "the patient is alive so it must be biocompatible".

3-Functional Tissue Structure and Pathobiology

Biomaterials incorporated into medical devices are implanted into tissues and organs. Therefore, the key principles governing the structure of normal and abnormal cells, tissues or organs, the technique by which the structure and function of normal and abnormal tissues are studied, and the fundamental mechanisms of disease processes are critical considerations to workers in the field.

4- Healing

Special processes are invoked when a material or device heals in the body. Injury to tissue will stimulate the well-defined inflammatory reaction sequence that leads to healing. When a foreign body is present in the wound site, the reaction sequence is referred to as the "foreign body reaction". This reaction will differ in intensity and duration depending upon the anatomical site involved.

5- Dependence on Specific Anatomical Sites of Implantation

An intraocular lens may go into the lens capsule or the anterior chamber of the eye. A hip-joint will be implanted in bone across an articulating joint space. A heart valve will be sutured into cardiac muscle and will contact both soft tissues and blood. 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.

6- Mechanical and Performance Requirements

Biomaterials and devices have mechanical and performance requirements that originate from the physical properties of the materials. The following are three categories of such requirements:

i. Mechanical Performance

ii. Mechanical durability

iii. Physical Properties

(A) Mechanical performance.

Device Properties

A hip prosthesis Must be strong and rigid

A tendon material Must be strong and flexible

A heart valve leaflet Must be flexible and tough

An articular cartilage substitute Must be soft and elastomeric

A dialysis membrane Must be strong and flexible but not elastomer

(B) Mechanical durability

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

(C) The physical properties

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

7- Industrial Involvement

A significant basic research effort is now under way to understand how biomaterials function and how to optimize them. At the same time, companies are producing implants for use in humans and appropriate to the mission of the company, earning profits on the sale of medical devices.

Industry deals well with technologies, such as packaging, sterilization, storage, distribution and quality control, and analysis. These subjects are specialized technologies, often ignored by academic researchers.

8- Ethics

A wide range of ethical considerations impact biomaterials. Like most ethical questions, an absolute answer may be difficult to come by. Some articles have addressed ethical questions in biomaterials and debated the important points.

9- Regulation

The patient demands safe medical devices. To prevent inadequately tested devices and materials from coming on the market, and to screen out individuals clearly unqualified to produce biomaterials. The International Standards Organization (ISO) has introduced international standards for world community.