BIOMATERIALS

Biomaterials is a term used to indicate materials that constitute parts of medical implants, extracorporeal devices, and disposables that have been utilized in medicine, surgery, dentistry, and veterinary medicine as well as in every aspect of patient health care.

The common denominator in all the definitions that have been proposed for biomaterials ‘‘is the undisputed recognition that biomaterials are distinct from other classes of materials because of the special biocompatibility criteria they must meet. Biomaterials are devices or materials that are used in the treatment of physiological, anatomical or biochemical disorders which cannot be corrected by other therapies or procedures. They are used for developing body implants or interfaces which interact with the living tissues and physiological systems of the patient for a significant duration. Therefore, the assessment of the overall safety of the device is of importance so as to minimize the risk to the patient treated with the device. The term biocompatibility refers to the interaction between a biomedical device and the tissues of the patient and it depends on several factors like the chemical and physical nature of its components, the types of patient tissue that will be exposed to the device and the duration of that exposure.

CLASSIFICATION OF BIOMATERIALS

Different classifications of biomaterials are made based on different criteria.

According to the chemical composition, these are broadly classified as.

- Metals

Metals have been used almost exclusively for load-bearing implants, such as hip and knee prostheses and fracture fixation wires, pins, screws, and plates. Metals have also been used as parts of artificial heart valves, as vascular stents, and as pacemaker leads. Although pure metals are sometimes used, alloys (metals containing two or more elements) frequently provide improvement in material properties, such as strength and corrosion resistance. Three material groups dominate biomedical metals: 316L stainless steel, gold, nickel-titanium alloy, cobalt-chromium alloy, cobalt-chromium-molybdenum alloy and pure titanium and titanium alloys are the most commonly metals used as biomaterials.

The main considerations in selecting metals and alloys for biomedical applications are biocompatibility, appropriate mechanical properties, corrosion resistance, and reasonable cost. The main advantages of metals are that they are strong and are resistant to fatigue degradation. They have shape memory and can be sterilized easily before use. The main disadvantage is that metal can corrode due to chemical reaction with the body enzymes and acids. It also can cause metal ion toxicity in the body.

Polymers (natural and artificial)

Polymers are the most widely used materials in biomedical applications. They are the materials of choice for cardiovascular devices as well as for replacement and augmentation of various soft tissues. Polymers also are used in drug delivery systems, in diagnostic aids, and as a scaffolding material for tissue engineering applications. Examples of current applications include vascular grafts, heart valves, artificial hearts, breast implants, contact lenses, intraocular lenses, components of extracorporeal oxygenators, dialyzers and plasmapheresis units, coatings for pharmaceutical tablets and capsules, sutures, adhesives, and blood substitutes Polymers include collagen, nylon and silicones. They are used in tissue repair, heart valves and breast implants.

Polymers can be manufactured and modified easily to adapt to their use. They are also biodegradable, which is both an advantage and a disadvantage. Due to the intensive interaction with the body, they can leach, leading to wear and tear. They also can absorb important nutrients and water from the blood.

Ceramics

Ceramics and glasses are used as components of hip implants, dental implants, middle ear implants, and heart valves. These biomaterials have

been used less extensively than either metals or polymers. Alumina, zirconia and pyrolitic carbon are some of the ceramics used as biomaterials in applications such as orthopedic and dental implants.

The main advantage is that they are strong and chemically inert. They have high compressive strength, which is necessary for bone implants. Some ceramic materials are also biodegradable. Difficulty in manufacturing forms the main disadvantage. They also can minimize bone ingrowth. Sometimes, implants can loosen over time and become dislodged.

- **Composites**

Composite materials are solids which contain two or more distinct constituent materials or phases, on a scale larger than the atomic. The term composite‖ is usually reserved for those materials in which the distinct phases are separated on a scale larger than the atomic, and in which properties such as the elastic modulus are significantly altered in comparison with those of a homogeneous material. Accordingly, reinforced plastics such as fiberglass as well as natural materials such as bone are viewed as composite materials, but alloys such as brass are not. A foam is a composite in which one phase is empty space. Natural biological materials tend to be composites. Natural composites include bone, wood, dentin, cartilage, and skin. Natural foams include lung,

cancellous bone, and wood. Natural composites often exhibit hierarchical structures in which particulate, porous, and fibrous structural features are seen on different micro-scales.

According to the mechanisms of interaction inside body or the functional host response initiation, a novel functional classification is made, which includes.

- **Bio inert Biomaterials**

The term bio inert refers to any material that once placed in the human body has minimal interaction with its surrounding tissue. Generally a fibrous capsule might form around bio inert implants hence its bio functionality relies on tissue integration through the implant.

Examples of these are stainless steel, titanium, alumina, partially stabilized zirconia, and ultra-high molecular weight polyethylene.

- **Bioactive Biomaterials**

Bioactive refers to a material, which upon being placed within the human body interacts with the surrounding bone and in some cases, even soft tissue. This occurs through a time–dependent kinetic modification of the surface, triggered by their implantation within the living bone. An ion-exchange reaction between the bioactive implant and the surrounding body fluids-results in the formation of a biologically active carbonate apatite (CHAp) layer on the implant that is chemically and crystallographically equivalent to the mineral phase in bone.

Prime examples of these materials are synthetic hydroxyapatite [Ca10 (PO4)6(OH)2], glass ceramic and bioglass.

- **Bio resorbable Biomaterials**

Bio resorbable refers to a material that upon placement within the human body starts to dissolve and slowly replaced by advancing tissue (such as bone).

Common examples of bio resorbable materials are tricalcium phosphate [Ca3 (PO4)2] and polylactic- polyglycolic acid copolymers. Calcium oxide, calcium carbonate and gypsum are other common materials that have been utilized during the last three decades.

The need for biomaterials stems from an inability to treat many diseases, injuries and conditions with other therapies or procedures.

- Replacement of body part that has lost function (total hip, heart)
- Correct abnormalities (spinal rod)
- Improve function (pacemaker, stent)
- Assist in healing (structural, pharmaceutical effects: sutures, drug release)

CONTEMPLATION

Since biomaterials are used inside the body, and are used as a supporting element to improve the quality of life and prolong the life, it should be designed thinking few considerations:

- Contact time period inside body (A tongue depressor may be used for a few seconds but an artificial lens goes over 30 years inside)
- Adequate mechanical properties (strength, stiffness, and fatigue properties); appropriate optical properties (used in the eye, skin, or tooth); appropriate density; manufacturability; and appropriate engineering design Integration into surrounding tissue without extensive inflammatory response or support of infection
- Host response to the material
- Immune acceptance
- Biocompatibility
- Bio stability
- Economics and utility

BIOCOMPATIBILITY

Biocompatibility is defined as the property of being biologically compatible by not producing a toxic, injurious, or immunological response in living tissue. The human body has an extraordinary ability to be able to tell whether an object is foreign or not. This is part of the body‘s protection against invasion from an outside organism. If a substance is placed in the body and the body can tell it is foreign, then an immune system response will be generated. When an object is incorporated into the body without any immune responses it is said to be biocompatible. In order for a device to be biocompatible, it must follow a very stringent set of demands from the body.

The device must be very strong so it does not break inside the body. Depending on the circumstances, it may need to be either very hard or very flexible. Anything placed into the body must be able to take a constant physical beating from one's body. For instance, the valves in a heart open and close about 70 - 80 times a minute. Over the course of years and years this adds up to millions of pumps. If the artificial valve cannot meet these standards and fails, the person will die.

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INTERNATIONAL STANDARDS

The development of a risk management system for biomaterials was developed in the framework of the following international standards.

- ASTM Standard
- ISO 14971 « Medical devices – Risk management
- ISO 10993 « Biological evaluation of Medical Devices which specifies requirements and gives guidance on procedures to be followed in the evaluation of the potential for medical (or dental) materials to cause adverse health effect.

The ISO 10993 standard plays an important role in the assessment of biocompatibility of a medical device. In principle a great number of tests have to be undertaken depending on the intended use of the medical device.

The standard describes tests on toxicity, carcinogenicity, haemocompatibility, etc. Some of these tests are simple in-vitro tests, while others require extensive animal experiments. This standard gives a more precise description of non-invasive and invasive use. In general three categories of contact with a human being are distinguished.

1) Surface devices, where contact is made with the skin, intact mucosal membranes and breached or compromised surfaces, for example ECG electrodes

2) External communicating devices, where indirect contact is made with blood, tissue or bone, for example dental filling materials.

3) Implant devices, where direct contact is made with blood, tissue or bone, for example breast implants.

Hence, biocompatibility can be redefined as.

Biocompatibility 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 optimising the clinically relevant performance of that therapy.

Biomaterials are subjected to a battery of *in vitro* and *in vivo* tests described under the collective heading of biocompatibility testing. The *in vivo* tests based on International Organisation of Standardisation (ISO) standard ISO 10993-1: 1992 done directly on the biomaterials comprise systemic acute and chronic toxicity tests, short term and long term implantation tests, sensitisation tests and carcinogenicity tests.