Biomaterials and Application (7)

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The National Institutes of Health Consensus Development Conference defined a biomaterial as ‘‘Any substance (other than a drug) or combination of substances, synthetic or natural in origin, which can be used for any period of time, as a whole or as a part of a system which treats, augments, or replaces any tissue, organ, or function of the body’’ (Boretos and Eden, 1984). Use of biomaterials dates far back into ancient civilizations. Artificial eyes, ears, teeth, and noses were found on Egyptian mummies [1]. Chinese and Indians used waxes, glues, and tissues in reconstructing missing or defective parts of the body. Over the centuries, advancements in synthetic materials, surgical techniques, and sterilization methods have permitted the use of biomaterials in many ways [2]. Medical practice today utilizes a large number of devices and implants. Biomaterials in the form of implants (ligaments, vascular grafts, heart valves, intraocular lenses, dental implants, etc.) and medical devices (pacemakers, biosensors, artificial hearts, etc.) are widely used to replace and/or restore the function of traumatized or degenerated tissues or organs, and thus improve the quality of life of the patients.

In the early days all kinds of natural materials such as wood, glue and rubber, and tissues from living forms, and manufactured materials such as iron, gold, zinc and glass were used as biomaterials. The host responses to these materials were extremely varied. Under certain conditions (characteristics of the host tissues and surgical procedure) some materials were tolerated by the body, whereas the same materials were rejected in another situation. Over the last 30 years considerable progress has been made in understanding the interactions between the tissues and the materials. It has been acknowledged that there are profound differences between non-living (avital) and living (vital) materials.

A wide range of materials encompassing all the classical materials such as Metals (gold, tantalum, Ti_6Al_4V, 316L stainless steel, Co-Cr Alloys, titanium alloys), Ceramics (alumina, zirconia, carbon, titania, bioglass, hydroxyapatite (HA)), Composite (Silica/SR, CF/UHMWPE, CF/PTFE, HA/PE, CF/epoxy, CF/PEEK, CF/C, Al2O3/PTFE), Polymers (Ultra high molecular weight polyethylene(UHMWPE),

Polyurethane(PE), Polyurethane (PU), Polytetrafuoroethylene (PTFE), Polyacetal (PA), Polymethylmethacrylate (PMMA), Polyethylene Terepthalate (PET), Silicone Rubber (SR), Polyetheretherketone (PEEK), Poly(lactic acid) (PLA), Polysulfone (PS)) have been investigated as biomaterials. Researchers also classified materials into several types such as bioinert and bioactive, biostable and biodegradable, etc. [4]. In broad terms, inert (more strictly, nearly inert) materials prohibited or minimal tissue response. Active materials encourage bonding to surrounding tissue with. Degradable or resorbable materials are incorporated into the surrounding tissue, or may even dissolve completely over a period of time. Metals are typically inert, ceramics may be inert, active or resorbable and polymers may be inert or resorbable [5]. Biomaterials must be nontoxic, non- carcinogenic, chemically inert, stable, and mechanically strong enough to withstand the repeated forces of a lifetime.

II. 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. The design and selection of biomaterials depend on different properties which are characterized in this section.

A. Host Response:

Host response is defined as the response of the host organism (local and systemic) to the implanted material or device [6].

B. Biocompatibility:

Researchers have coined the words 'biomaterial' and 'biocompatibility' [7] to indicate the biological performance of materials. Materials that are biocompatible are called biomaterials, and the biocompatibility is a descriptive term which indicates the ability of a material to perform with an appropriate host response, in a specific application [8]. In simple terms it implies compatibility or harmony of the biomaterial with the living systems. Biocompatibility is the ability to exist in contact with tissues of the human body without causing an unacceptable degree of harm to the body. It is not only associated to toxicity, but to all the adverse effects of a material in a biological system [9, 10]. It must not adversely affect the local and

systemic host environment of interaction (bone, soft tissues, ionic composition of plasma, as well as intra and extracellular fluids) [11]. It refers to a set of properties that a material must have to be used safely in a biological organism. It should be non-carcinogenic, non-pyrogenic, non-toxic, non-allergenic, blood compatible, non-inflammatory. The operational definition of biocompatible is "The patient is alive so it must be biocompatible".

C. *Bio functionality [11]:*

Bio functionality is playing a specific function in physical and mechanical terms. The material must satisfy its design requirements in service:

- Load transmission and stress distribution (e.g. bone replacement)
- Articulation to allow movement (e.g. artificial knee joint)
- Control of blood and fluid flow (e.g. artificial heart)
- Space filling (e.g. cosmetic surgery)
- Electrical stimuli (e.g. pacemaker)
- Light transmission (e.g. implanted lenses)
- Sound transmission (e.g. cochlear implant)

D. *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 [12].

E. *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 [12].

F. *Appropriate Design and Manufacturability:*

Biomaterials should be machinable, moldable, extrudable. Finite element analysis is a powerful analytical tool used in the design of any implants. Currently modern manufacturing processes are necessary to guarantee the quality needed in orthopedic devices.

G. *Mechanical Properties of Biomaterials:*

Some of the most important properties of biomaterials that should be carefully studied and analyzed in their applications are tensile strength, yield strength, elastic modulus, corrosion and fatigue resistance, surface finish, creep, and hardness. Physical properties are also taking in to account while selecting materials. 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.

H. *High corrosion resistance:*

Singh & Dahotre [13] did research on corrosion resistance as is an important issue in selection of metallic biomaterials because the corrosion of metallic implants due to the corrosive body fluid is unavoidable. The implants release undesirable metal ions which are nonbiocompatible. Corrosion can reduce the life of implant device and consequently may impose revision surgery. In addition, the human life may be decreased by the corrosion phenomenon. Okazaki & Gotoh [14] expressed the fact that dissolved metal ions (corrosion product) either can accumulate in tissues, near the implant or they may be transported to other parts of the body.

I. *High wear resistance:*

The low wear resistance or high coefficient of friction results in implant loosening [15, 16]. Wear debris are found to be biologically active and make a severe inflammatory response that lead to the destruction of the healthy bone which supports the actual implant. Corrosion caused by friction is a big concern since it releases non compatible metallic ions. Mechanical loading also can result in corrosion fatigue and accelerated wear processes [15].

J. *Long fatigue life:*

The fatigue strength is related to the response of the material to the repeated cyclic

loads. Fatigue fracture leads some of major problems associated with implant loosening, stress-shielding and ultimate implant failure and it is frequently reported for hip prostheses [17]. Fatigue characteristics are strongly depending on the microstructures. The microstructures of metallic biomaterials alter according to the processing and heat treatment employed [6].

K. *Adequate Strength:*

Strength of materials from which the implants are fabricated has influence the fracture of artificial organ. In adequate strength can cause to fracture the implant. When the bone implant interface starts to fail, developing a soft fibrous tissue at the interface can make more relative motion between the implant and the bone under loading [9]. This fact causes pain to the patient and after a certain period, the pain becomes unbearable and the implant must be replaced, by a revision procedure [15].

L. *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 modulus close to that of human bones [19, 20]. The magnitude of bone modulus varies from 4 to 30 GPa depending on the type of the bone and the measurement direction [21]. Large difference in the Young's modulus between implant material and the surrounding bone can contribute to generation of severe stress concentration, namely load shielding from natural bone that may weaken the bone and deteriorate the implant/bone interface, loosening and consequently failure of implant [9, 22]. The modulus is considered as a main factor for selection of any biomaterials.

TABLE 1 MECHANICAL PROPERTIES OF HARD TISSUE [25]

Hard tissue	Modulus (GPa)	Tensile Strength (MPa)
Cortical bone (longitudinal direction)	**17.7**	**133**
Cortical bone (transverse direction)	**12.8**	**52**
Cancellous bone	**0.4**	**7.4**
Enamel	**84.3**	**10**
Dentine	**11.0**	**39.3**