Biomaterials

Lecture

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About Materials

"Understanding the history of materials means understanding the history of mankind and civilization"

"Who can master the materials, can master the future"

Content of course

Introduction- What is Biomaterial?

Biomaterial (Biomedical Material): definition is still controlversial

* *(Williams, 1987), (B.D.Radner, 1996)*

1. A nonviable material
2. Used in a medical device
3. Interact with biological system

* *(Other)*

1. Synthetic or natural material
2. Used to replace part of a living system or
3. To function in intimate contact with living tissue

Introduction- What is Biomaterial?

*** *(J.Enderle et al, 1999)***

1. Any material, natural or man-made

2. Comprises a whole or part of a living structure or a biomedical device

3. Performs, augments or replaces a natural function

*** *(S.I.Stupp et al, 1997)***

"Either naturally occurring materials in living organisms or materials designed to repair humans"

- ***Note: different from other "biomaterial" (biological materials, bio-based materials)***

  Biological materials: produced by a biological system (wood, jute, bone, skin…

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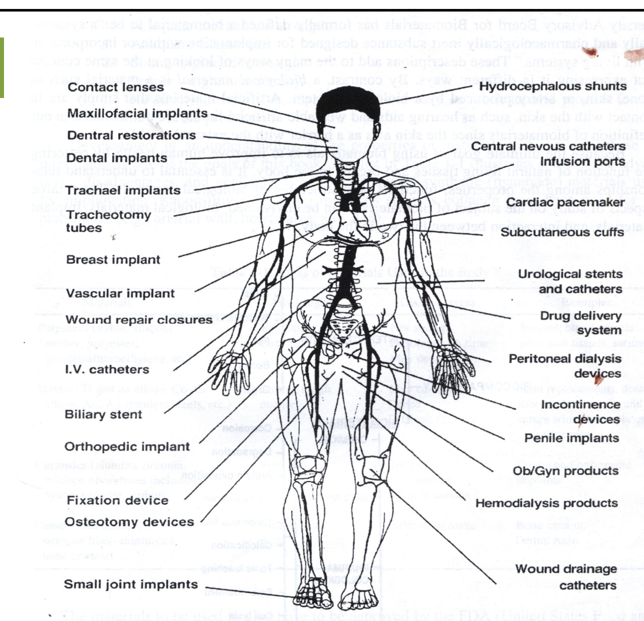

Fig.1. Illustrations of various implants and devices used to replace or enhance the function of diseased or missing tissues and organs

Introduction- Applications of Biomaterials

The Biomaterials & Healthcare market in US

	(USD/year)
Total US health care expenditures (2000):	1,400,000,000,000
Total US health research & development (2001):	82,000,000,000
Total US medical device market (2002):	77,000,000,000
US market for disposal medical supplies (2003):	48,600,000,000
US market for biomaterials (2000):	9,000,000,000
Individual medical device sales	
- Cardiovascular devices (2002)	6,000,000,000
- Orthopedic-musculoskeletal surgery US market (1998)	4,700,000,000
- Wound care US market (1998)	3,700,000,000
- In vitro diagnostic (1998)	10,000,000,000

Introduction- Applications of Biomaterials

The Biomaterials & Healthcare market in US

	(Number/year)
Number of employees in the medical device industry (2003):	300,000
Registered US medical device manufacturer (2003):	13,000
Number of devices (US)	
- Intraocular lenses (2003):	2,500,000
- Contact lenses (2000) :	30,000,000
- Vascular grafts:	300,000
- Heart valves:	100,000
- Pacemaker:	400,000
- Blood bags:	40,000,000
- Catheters:	200,000,000
- Coronary stents:	1,500,000
- Dental implants (2000):	910,000

Examples of biomaterials applications

- *Heart Valve Prostheses:* carbons, metals, elastomers, plastics, animal or human tissues…
- *Artificial Hip Joints:* titanium, stainless steel, special high-strength alloys, ceramic, composite…
- *Dental Implants:* titanium integrated with bone
- *Intraocular Lenses (IOLs):* poly(methyl methacrylate), silicone elastomer, soft acrylic polymer…
- *Left Ventricular Assist Device (LVAD):* broad range of synthetic materials

Table 1: Class of materials used in the body

Materials	Advantages	Disadvantages	Examples
Polymers (nylon, silicone rubber, polyester, polytetrafuoroethylene, etc)	Resilient Easy to fabricate	Not strong Deforms with time May degrade	Sutures, blood vessels other soft tissues, sutures, hip socket, ear, nose
Metals (Ti and its alloys, Co–Cr alloys, Au, Ag stainless steels, etc.)	Strong, tough ductile	May corrode Dense Difficult to make	Joint replacements, dental root implants, pacer and suture wires, bone plates and screws
Ceramics (alumina zirconia, calcium phosphates including hydroxyapatite, carbon)	Very bio-compatible	Brittle Not resilient Weak in tension	Dental and orthopedic implants
Composites (carbon–carbon, wire- or fiber- reinforced bone cement)	Strong, tailor-made	Difficult to make	Bone cement, Dental resin

Introduction- What is Biocompatibility?

*** (Williams, 1987)**

Biocompatibility is the ability of a material to perform with an appropriate host response in a specific application

*** (Other)**

1. Acceptance of an artificial implant by the surrounding tissues and by the body as a whole

2. Must not be degraded by the body environment

3. Must not harm tissues, organs or system

4. If degraded (as designed), degradation products must be not harmful for body

Introduction- Biocompatibility

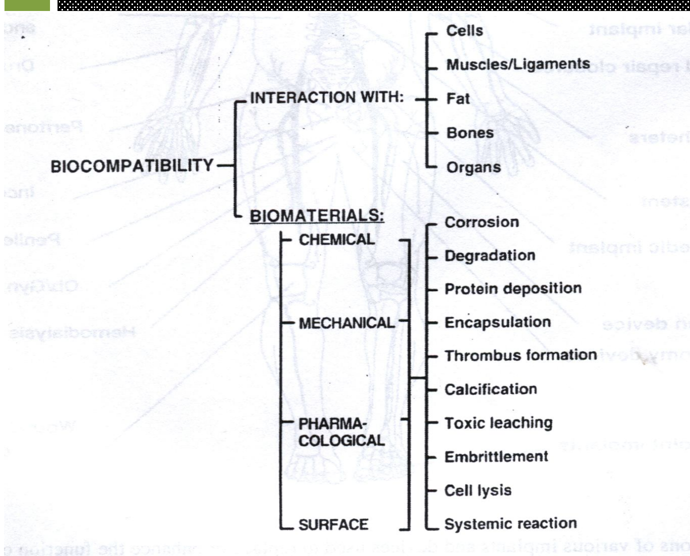

Fig. 2. Schematic illustration of biocompatibility

Introduction- Requirements for a biomaterial

1. **Acceptance of the material to the tissue surface**
2. **Pharmacological acceptability (non-toxic, non-allergenic, non-immunogenic, non-carcinogenic, etc.)**
3. **Chemically inert and stable (no time-dependent degradation**
4. **Adequate mechanical strength**
5. **Adequate fatigue life**
6. **Sound engineering design**
7. **Proper weight and density**
8. **Relatively inexpensive, reproducible, and easy to fabricate and process for large-scale production**

Note: 1+2+3: biocompatibility

Introduction- Requirements for medical device

Actual Requirements of Implants

Compatibility

- -Tissue reactions
- -Change properties in mechanical, physical, chemical
- -Degradation leads to local deleterious changes
- -Harmful systemic effect

Mechanical properties

- Elasticity
- Yield stress
- Ductility
- Toughness
- Time-dependent deformation
- Creep
- Ultimate strength
- Fatigue
- Hardness
- Wear resistance

Manufacturing

- Fabrication methods
- Consistency & conformality
- Quality of raw materials
- Technique to obtain excellent surface, finish or texture
- Capability of materials to be safe and efficient sterilization
- Cost of products

Introduction- Biocompatibility

Table 3: Guidance on biocompatibility assessment

A. Data required to assess suitability
   1. Material characterization. Identify the chemical structure of a material and any potential toxicological hazards. Residue levels. Degradation products. Cumulative effects of each process.
   2. Information on prior use. Documented proof of prior use, which would indicate the material(s) suitability.
   3. Toxicological data. Results of known biological tests that would aid in assessing potential reaction (adverse or not) during clinical use.

B. Supporting documents
   1. Details of application: shape, size, form, plus time in contact and use.
   2. Chemical breakdown of all materials involved in the product.
   3. A review of all toxicity data on those materials in direct contact with the body tissues.
   4. Prior use and details of effects.
   5. Toxicity tests [FDA* or ISO (International Standard Organization guides)]
   6. Final assessment of all information including toxicological significance.

*FDA internet address: http://www.fda.gov/cdrh/index.html.
CDRH (Center for Devices and Radiological Health of the FDA) administers medical devices.
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Introduction- What is Biomaterials Science?

Biomaterials Science is

1. Physical and biological study of

- Materials &
- Interaction of materials with the biological environment

2. Multidiscipline

- Indentify needs
- Design
- Materials synthesis
- Testing materials
- Fabrication
- Sterilization & packaging
- Device testing
- *Regulatory, Clinical use, explant analysis*

Introduction- History of Biomaterials

• Foundation: largely between 1920-1980

• Widely used throughout medicine, dentistry and biotechnology: at down of the 21st century

BEFORE WORLD WAR II (development of implant from metals and alloys- from iron to Ti)

-Spear point embedded in the hip of "Kennewick Man"

-Roughly 600 A.D: Dental implants: sea shells for fashioned nacre teeth of Mayan people

-About 200 A.D.: iron dental implants (in Europe)

-Roughly 1860: glass contact lenses; 1936-1948: plastic contact lenses (from PMMA)

-1950s: artificial heart patented, 1957: tested in animals (Dr. Paul Winchell & Dr. Willem Kolff

-Basic concepts of biocompatibility

Metals & alloys

Late 18th- 19th century (1829): gold, silver, lead, *platinum*

1886: Ni-plated steel fracture plate (H.Hansmann)

1893-1912: Steel screws and plates for fracture fixation (W.A Lane)

1912: Vanadium steel plate, first alloy developed foe medical use (Sherman)

1924: study of tissue reactions to various materials (A.A. Zierold): Stellite (CoCrMo alloy)

Introduction- History of Biomaterials

1926: 18-8s Mo (2-4% Mo) stainless steel for greater corrosion than s.s. (M.Large)

1929-1931: Vitallium alloy (65%Co-30%Cr-5%Mo) (M.N.Smith-Peterson)

1936: first total hip replacement (P.Wiles)

1947: Ti and its alloys (J.Cotton)

Plastics

1940s: Acrylic for corneal replacement

Development of some plastics: nilon, cellophane (for blood vessels), PMMA, PE, teflon

POST WORLD WAR (Surgeon-development of other materials-ceramics, plastics to nano)

-1949: Intraocular lenses for human (Harold Ridley)

-1956: Total hip from metal cemented (Mc.Kee, Watson-Farra)

-1958: First use of acrylic bone cement (PMMA) in total replacement; high-molecular PE hip (Dr. Charnley)

-(1968-1972):Total knee prostheses replacement (F. Gunston, J. Insall)

-1887-1952: Dental implants from various metals, 1952: from Ti and its alloys

Introduction- History of Biomaterials

- 1960: First artificial kidney as “washing machine artificial kidney (W.J.Kolff)

- 1921-2003: Major advances in Kidney diallysis (Dr. Belding Scripner)

- 1960: Heart valves (A. Starr, M.L. Edward); 1970: Experimental total artificial heart replacement (Kolff); 1966: left ventricular assist device implantation from PU (Dr.D.Cooley); 1982-1985: Jarvik heart (Dr. W. Vries)

- Since 1950: breast implant from PVA (poor results); since 1960s: from silicone (T.Cronin & F. Gerow), then 1999: from silicone rubber-silicone gel (Bondurant et al.)

-1952: First human implant of prosthetic vascular graft from silk handkerchief & Vinyon N, then from PE (1954, Egdah et al.)

- Since 1978: study on Stents; 1983-1986: stents test on animals

- 1990s: Controversy over silicone mammary implants

- 2000s: Nano-scale materials