CHAPTER 2

Principles of Implant Design (The Paradigm): Design Parameters

2.1 Functional Performance of the Device (and Attachment to Tissue)

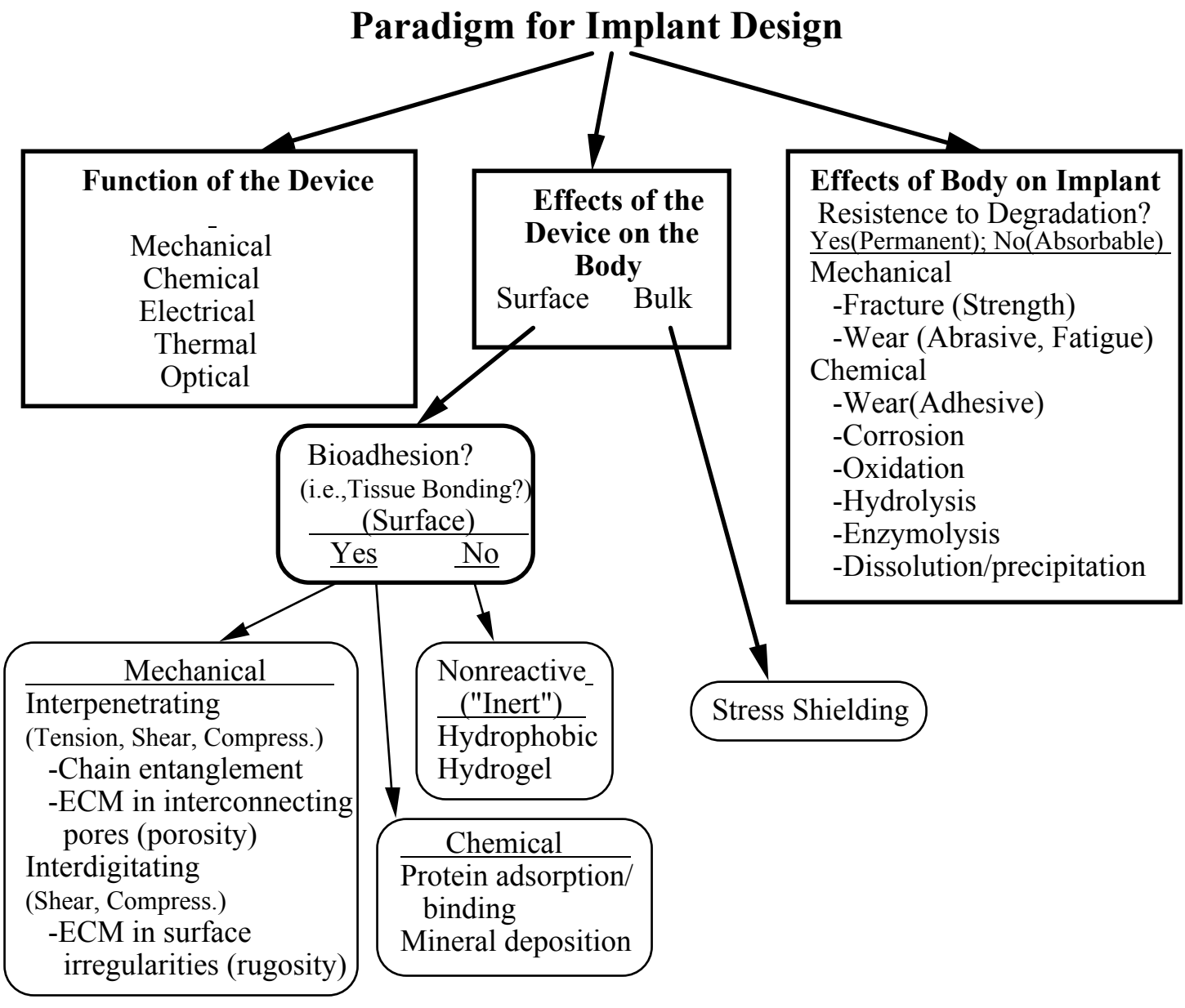
- 2.1.1 Mechanical
  - 2.1.1.1 Strength and Modulus of Elasticity: Modulus Matching
  - 2.1.1.2 Tribology
  - 2.1.2.3 Kinematics
- 2.1.2 Chemical
  - 2.1.2.1 Drug Delivery/Controlled Release System
  - 2.1.2.2 Matrices to Facilitate Tissue Regneration
- 2.1.3 Attachment Vehicle
  - 2.1.3.1 Grouting Agents
  - 2.1.3.2 Topography/Porosity
  - 2.1.3.3 Surfaces/Coatings for Chemical Bonding of Tissue

2.2 Effects of the Implant on the Body ("Biocompatibility")

- 2.2.1 Local Effects
- 2.2.2 Systemic Effects

2.3 Effects of the Body on the Implant (Degradation of the Device)

- 2.3.1 Corrosion of Metals
- 2.3.2 Degradation of Nonabsorbable Polymers
- 2.3.3 Degradation of Absorbable Polymers


Paradigm for Implant Design
Function of the Device
Mechanical
Chemical
Electrical
Thermal
Optical
Effects of the Device on the Body
Surface
Bulk
Effects of Body on Implant
Resistence to Degradation?
Yes(Permanent); No(Absorbable)
Mechanical
-Fracture (Strength)
-Wear (Abrasive, Fatigue)
Chemical
-Wear(Adhesive)
-Corrosion
-Oxidation
-Hydrolysis
-Enzymolysis
-Dissolution/precipitation
Bioadhesion?
(i.e.,Tissue Bonding?)
(Surface)
Yes
No
Mechanical
Interpenetrating
(Tension, Shear, Compress.)
-Chain entanglement
-ECM in interconnecting pores (porosity)
Interdigitating
(Shear, Compress.)
-ECM in surface irregularities (rugosity)
Nonreactive ("Inert")
Hydrophobic
Hydrogel
Chemical
Protein adsorption/ binding
Mineral deposition
Stress Shielding

2.1 IMPLANT DESIGN CRITERIA: FUNCTION/PERFORMANCE OF THE DEVICE

A. Mechanical

1. Kinematics, mechanics (strength and modulus), and tribology of total joint replacement prostheses.

2. Pumping devices (*e.g.*, artificial heart).

B. Chemical

1. Dissolution characteristics (*e.g.*, drug delivery systems)

2. Sensing characteristics (*e.g.*, "intelligent" drug delivery systems)

C. Optical

Optical characteristics of implants for the eye (*e.g.*, intraocular lens) and transparent wound covering materials

D. Electrical

Characteristics for sensing and sending electrical signals (*e.g.*, cardiac pacemaker electrode tips)

E. Thermal

2.2 IMPLANT DESIGN CRITERIA: EFFECTS OF THE IMPLANT ON THE BODY (BIOCOMPATIBILITY/SAFETY)

A. Chemical

1. Molecules/Ions Released (Toxicity)

    a. Direct effects of molecules/ions on cells

        1. Co, Cr, Ni, Si, AL, V

        2. Polymer fragments?

    b. Binding of molecules/ions to proteins to form complexes that elicit adverse biological response

        1. Metal ion binding to existing antibodies to elicit immune response (these metal ions act as haptens)

        2. Metal ion-protein complexes that facilitate transport of metal ion through the cell membrane

2. Alteration of Adsorbed Macromolecules Causing them to have an Adverse Effect

    a. Change in conformation of adsorbed proteins (*e.g.*, on hydrophobic surfaces) causing them to be immunogenic

    b. Cleavage/fragmentation of adsorbed proteins such as complement molecules thus activating the alternative pathway of the immune response

B. Mechanical: Alteration on Strains in Surrounding Tissue ("Modulus Mismatch")

1. "Hard Tissue"

    High modulus (stiff) implants in bone result in an alteration of the distribution of strain in surrounding bone (*i.e.*, stress transfer is altered). Bone in areas in which strain has been reduced decreases in mass (*i.e.*, becomes more porous-atrophies - osteopenia) due to "stress shielding." Bone in areas of increased stress can increase in thickness and density (*i.e.*, less porous) and thereby hypertrophy.

2. "Soft Tissue"

    Elastic behavior (*e.g.*, stiffness) of artificial blood vessels affects their performance with respect to endothelialization and integrity of the anastomosis.

C. Electrical

1. Electrically conducting implants might short out "strain generated potentials" in surrounding tissues (*e.g*., bone)?

2. Electrical currents produced by the device (*e.g*., pacemakers) could adversely affect cells.

D. Thermal

1. Heat resulting from exothermic polymerization reactions (*e.g.*, PMMA-"bone cement") can cause tissue necrosis.

2. Thermal conductivity and heat capacity (*i.e*., thermal diffusivity) could affect how heat generated by implants (*e.g*., functional heat from artificial joints) is dissipated?

2.3 IMPLANT DESIGN CRITERIA: EFFECTS OF THE BODY ON THE IMPLANT (DEGRADATION)

A. Chemical

1. Corrosion of metals: metal ion release due to an anodic (reduction) reaction
   a. Pitting and crevice corrosion and "concentration cell" effect at sites of depleted oxygen

   b. Galvanic corrosion due to contact of dissimilar metal. The more reactive metal (in the Galvanic series) becomes the anode.

   c. Stress corrosion due to accelerated metal ion release at a crack tip where the strain is high.

   d. The oxide "passivation" layer reduces potential for corrosion.

   e. Corrosion facilitates cracks initiation and thereby weakens the device.

   f. Ranked according to their potential for corrosion:
   Stainless steel > Co-Cr alloy > Ti alloy.

2. Oxidation of polymers
   Oxidation of polyethylene results in chain scission and a reduction in the average molecular weight. This causes increases in the density, modulus of elasticity, and percent crystallinity. Oxidation can be determined by detecting the carbonyl groups that are formed.

3. Hydrolysis of polymers
   Ester linkages (*e.g.*, polylactic and polyglycolic acid) are attacked by water leading to chain scission.

4. Water absorption
   Water absorption can lead to an alteration in the mechanical properties of certain hydrophilic thermoplastic polymers (*e.g.*, polysulfone).

5. Lipid absorption
   Absorption of lipid by certain hydrophobic polymers (*e.g.*, polydimethyl siloxane).

6. Dissolution
   The effect of water and pH in dissolving certain substances (*e.g.*, calcium phosphates)

7. Precipitation
   Deposition of calcium salts (calcification).

8. Enzymolysis
   Natural polymers (*e.g*., collagen) used as an implant materials can undergo degradation as a result of the action of enzymes (*e.g*., collagenase).

B. Mechanical: Mechanical loading applied by the body can lead to wear (erosion) and fatigue fracture of the device.

1. Fatigue testing of implants.

2. Wear due to rubbing of tissue (*viz*., bone) against the device.