CHAPTER 8

Design Parameters

8.1 Biomaterials: Relative Properties

8.2 Bulk (Mechanical) and Surface Properties

8.3 Reactivity: Molecular Interactions

8.4 Bioadhesion (Tissue Bonding): Physical and Chemical Mechanisms

8.5 Factors Affecting Biomaterials

8.1 BIOMATERIALS: RELATIVE PROPERTIES

	ADVANTAGES	DISADVANTAGES
METALS		
Stainless Steel	Strength Ease of manufacturing Availability	Potential for corrosion High modulus of elasticity
Cobalt-Chromium	Strength Corrosion resistance Relative wear resistance	Unknown long-term effects of Co and Cr ions High modulus
Titanium (6Al-4V)	Strength Low modulus Corrosion resistance	Low wear resistance
CERAMICS		
Alumina	Resistance to chemical degradation Wettability Resistance to wear	Low tensile and flexural strength
Calcium Phosphates (Slightly Soluble and Resorbable)		
Hydroxyapatite	Bone-bonding Slight solubility	Low tensile and flexural strength Slight solubility
Whitlockite	Bone-bonding Solubility	Low tensile and flexural strength Solubility
Natural (Resorbable)		
Bone Apatite	Bone-bonding Resorbability	Low strength

POLYMERS

Synthetic

Thermoplastics

PTFE (Teflon)	Resistance to chemical degradation Hydrophobicity Low friction	Low wear resistance Hydrophobic Does not display typical thermoplastic flow behavior
UHMWPE	Relatively high wear resistance	Subject to oxidation
PET (Dacron)		Subject to hydrolysis Low MW contaminants
PMMA	Polymerization *in vivo*	Low fatigue strength (for load-bearing applications)
PSF	High strength thermoplastic	Water absorption (dec. strength in water)
PEEK	High strength (> PSF) Low water absorption	Unproven
C/PSF; C/PEEK	Very high strength Relatively low modulus	Unproven

Elastomers

PDMS	High flex life Ease of manufacture Range of mechanical properties	Low wear resistance Release of low MW PDMS Immunogenicity?

Polyurethane	High flex life Range of mechanical properties	Uncertain molecular structure-property relationships Surface radically different from bulk (high mobility of "soft segments") Low MW contaminants Subject to hydrolysis, oxidation, and calcification
Hydrogel		
P-HEMA	Low reactivity Transparent	Low strength
Absorbable		
PLA/PGA	Programmable absorption Metabolizable degradation products	Uncertain biological response to bolus-release of metabolites Low strength
Natural		
Collagen	Replicates ECM components	Immunogenicity?
Hyaluronan	Replicates ECM component	Unproven
Chitosan	Substitutes for GAG (e.g., hyaluronan)	Unproven

PTFE polytetrafluoroethylene, UHMWPE, ultra high molecular weight polyethylene PET polyethylene terephthalate; PMMA, polymethyl methacrylate; PSF, polysulfone; PEEK, polyetheretherketone; PDMS, polydimethyl siloxane; P-HEMA, poly hydroxyethyl methacrylate; PLA, polylactic acid; PGA, polyglycolic acid.

8.2 BULK (MECHANICAL) AND SURFACE PROPERTIES

8.2.1 Properties Dependent on Atomic Bonding in the Bulk and Surface of Materials

BULK

Mechanical

-Strength
-Elasticity/Plasticity/Viscoelasticity
-Wear (Abrasive and Fatigue)

SURFACE

Mechanical

-Wear (Adhesive)
-Friction/Lubrication

Chemical

-Corrosion
-Oxidation
-Hydrolysis
-Enzymolysis
-Dissolution

Bioadhesion

-Mechanical
-Chemical

8.2.2 Bulk (Mechanical) and Surface Properties

	BULK		SURFACE		
	Mechanical		Mechanical	Chemical	
	Strength (MPa)	Modulus (GPa)	Wear (0-++++)	Reactivity (0-++++)	Comment
METALS					
Stainless Steel	500-1000	200	+	+	Tension
Cobalt-Chromium	700	240	+	+	
Titanium (6Al-4V)	900	110	++	+	
CERAMICS					
Alumina	4000	380	0	0	Compress.
	259				Tension
Calcium Phosphates					
Hydroxyapatite	<900	<100	NA	++*	Compress.
Whitlockite			NA	+++*	
Natural					
Bone Apatite	140	18	NA	+++*	Compress.
POLYMERS					
Synthetic					
PTFE (Teflon)	14-34	0.4	++++	0	
UHMWPE	21	1	++	+	
PET (Dacron)	<40		+++	+	
PMMA	55	3	+++	+	
PSF	70	2.5			Tension
PEEK	90	3.6			Tension
C/PSF; C/PEEK	500	60			Composites
PDMS	2.4-7	<.01	++++	0	
Polyurethane	1-69	.07-6.9	NA	0	
P-HEMA			NA	0	
PLA			NA	++++**	
PGA			NA	++++**	
Natural					
Collagen			NA	++++**	
Hyaluronan	NA	NA	NA	++++**	
Chitosan	NA	NA	NA	++++**	

PTFE polytetrafluoroethylene, UHMWPE, ultra high molecular weight polyethylene PET polyethylene terephthalate; PMMA, polymethyl methacrylate; PSF, polysulfone; PEEK, polyetheretherketone; PDMS, polydimethyl siloxane; P-HEMA, poly hydroxyethyl methacrylate; PLA, polylactic acid; PGA, polyglycolic acid.

* Soluble

**Absorbable

8.3 REACTIVITY: MOLECULAR INTERACTIONS

8.3.1 Surface Modifying/Degradative Interactions: Effects of the Body on the Biomaterial

8.3.1.1 Water
- 8.3.1.1.1 Absorption (e.g., high water absorption by hydrogels is desired but even low water absorption by thermoplastics polymers can adversely affect mechanical properties)
- 8.3.1.1.2 Hydrolysis (e.g., of ester linkage of polymers)
- 8.3.1.1.3 Water as electrolyte solution facilitates corrosion of metal
- 8.3.1.1.4 Dissolution of certain substances (e.g., calcium phosphates)

8.3.1.2 Oxygen
- 8.3.1.2.1 Oxide formation (e.g., on metals)
- 8.3.1.2.2 Oxidative degradation of polymers
- 8.3.1.2.3 Corrosion of metal (e.g., sites of depleted oxygen undergo anodic, reduction, reaction)

8.3.1.3 Cations and Anions Contributing to Corrosion, Dissolution, and Precipitation (e.g., mineralization/calcification)

8.3.1.4 Enzymes (e.g., enzymolysis of natural polymers such as collagen)
Macromolecule Absorption (e.g., lipid absorption)

8.3.2 Molecular Interactions with Biological Molecules: Effects of the Biomaterial on the Body

8.3.2.1 Water
- 8.3.2.1.1 Hydrophobic interactions

8.3.2.2 Charge Interactions
- 8.3.2.2.1 Ionic (primary bonding)
- 8.3.2.2.2 Secondary
  - 8.3.2.2.2.1 Hydrogen bonding
  - 8.3.2.2.2.2 Van der Waals interactions

8.4 BIOADHESION (TISSUE BONDING): PHYSICAL AND CHEMICAL MECHANISMS

8.4.1 Physical/Mechanical

8.4.1.1 Entanglement of macromolecules (nm scale)
8.4.1.2 Interdigitation of ECM with surface irregularities/porosity (μm scale)

8.4.2 Chemical

8.4.2.1 Primary
8.4.2.2.1 Ionic

8.4.2.2 Secondary
8.4.2.2.1 Hydrogen bonding
8.4.2.2.2 Van der Waals

8.4.2.3 Hydrophobic Interactions

8.4.3 Size and Time Scales for Bioadhesion

Size Scale	Tissue Level	Mechanism of Bonding	Time Constant	Measurement(s)
mm-cm	Organ	Interference Fit Grouting Agent Tissue (Bone) Ingrowth Chemical Bonding	Weeks-Months-Years	Radiographic (qualitative) Mechanical Testing (quantitative)
mm	Tissue	Same	Weeks	Mechanical Testing Light Microscopy/Histology (qualitative) Scanning Electron Microscopy (qualitative and quantitative)
μm	Cell	Integrin	Days-Weeks	Histology Transmission Electron Microscopy (qual.)
nm	Protein GAG	Secondary Bonding Hydrophobic Interactions	Seconds-Minutes-Hours-Days	Immunohistochemisty (qual.) Adsorption Isotherm (quan.)
nm	Mineral crystallites	Epitaxy Ionic Bonding	Seconds-Minutes-Hours-Days	Transmission Electron Microscopy *In vitro* Precipitation (quan.)

8.4.4 Characteristics of Porous Materials for Selected Applications

Device Function/ Purpose	**Tissue**	**Cell**	**Cell Process(es)**	**Pore Size (μm)**	**Pore Geometry/ Orientation**
Facilitate dermal regeneration/ Prevent contraction	Dermis	Fibroblast	Contraction	20-120	(3-D) Isotopic or planar isotropic (?)
Facilitate nerve regeneration/Axon elongation	Nerve	Nerve	Migration	1-10	Uniaxial
Attachment of prosthesis to bone/Bone ingrowth	Bone	Osteoblast	Mitosis Synthesis	100-600	Isotropic

8.4.5 Types of Bonding and Biomaterials for Implants in Bone

Types of Bonding	Materials
Press Fit (Interference Fit)	Titanium Alloy Cobalt-Chromium Alloy
Grouting Agent	Polymethylmethacrylate Cement (Bone Cement)
Bone Ingrowth	Porous Cobalt-Chromium Alloy Porous Titanium Alloy Porous Commercially Pure Titanium
Bone Bonding	Plasma Sprayed Hydroxyapatite
Screw Fixation	Stainless Steel Cobalt-Chromium Alloy Titanium Alloy
Bone Interdigitation	Cobalt-Chromium Alloy Titanium Alloy

8.5 FACTORS AFFECTING BIOMATERIALS

8.5.1 Exposure to Air (*e.g.*, hydrocarbon contaminants).

8.5.2 Handling (*e.g.*, contamination with particles and alteration of topography).

8.5.3 Storage Time (*e.g.*, residual stresses can result in dimensional changes).

8.5.4 Sterilization

8.5.4.1 Autoclave (steam)
Effects of temperature and absorbed water in altering mechanical properties of certain thermoplastics.

8.5.4.2 Dry heat (prolonged high temperatures)

8.5.4.3 Gas (ethylene oxide)
Prolonged period of aeration required for certain polymers.

8.5.4.4 Gamma radiation
Scission, crosslinking, and oxidation (when performed in air) of polymers.