# **CHAPTER 1**

# Clinical Problems Requiring Implants for Solution: Defining the Problem

- 1.1 Objectives of Subject
- 1.2 Related Subjects at MIT
- 1.3 Terminology
- 1.4 How Selected Tissues/Organs Function
- 1.5 Effects of Trauma and Disease on Function
- **1.6 Restoration of Function with Implants**
- **1.7** Applications of Medial Devices and Examples Demonstrating the Successful and Unsuccessful Performance of Medical Devices/Implants
- 1.8 Design Considerations for Medical Devices and Non-medical Structures

#### MEDICAL DEVICE DESIGN PROJECTS

#### **CONNECTIVE TISSUE**

#### Musculoskeletal System

Joint Replacement Prostheses -Ankle prosthesis -Prosthesis for intervertebral disk regeneration Fracture fixation device -"Smart" bone plate Bone Substitute Material Tendon/Ligament Replacement Meniscus Replacement Articular Cartilage Prosthesis

#### **Oral, Maxillofacial, and Otologic**

Dental Implants Temporomandibular Joint Prostheses Ossicular Replacement Prostheses Augumentation of Gingiva

#### **Cardiovascular System**

Angioplasty Balloon Catheter Heart Valve Vascular Prosthesis

#### **NERVE TISSUE**

#### Nervous System Nerve

-Prosthesis for peripheral nerve regeneration

#### **EPITHELIA**

Reproductive System Intrauterine Device

Ophthalmalogic System Prosthesis for Retina Regeneration

#### **1.3 TERMINOLOGY**

#### **Biomaterials**

"Any substance (other than a drug) or combination of substances, synthetic or natural in origin, which can be used at any period of time as a whole or in part of a system which treats, augments or place any tissue, organ or function of the body."

J. W. Boretos and M. Eden Contemporary Biomaterials, 1984

"A non-variable material used in a medical device intended to interact with biological systems."

D. F. Williams Definitions of Biomaterials, 1987

#### Implant

A device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. (FDA, Fed. Register)

#### Tissue

An aggregation of similarly specialized cells united in the performance of a particular function. Cells serving the same general function and having the same extracellular matrix.

#### Organ

Two or more tissues combined to form a larger functional unit.

#### **Connective Tissue**

The matrix-continuous tissue which binds together and is the support of the all of the structures of the body. The predominant structural protein comprising the extracellular matrix of connective tissue is collagen.

#### Regeneration

The renewal of a tissue or organ at the completion of healing.

#### Repair

The formation of scar at a site of injury at the completion of healing.

#### **Remodeling/ Maintenance/ Turnover**

The process by which extracellular matrix is replaced in a process of degradation followed by synthesis.

Clinical Applications of Medical Devices	Numbers used per year in the US	
Ophthalmologic		
Intraocular lenses	1 400 000	
Contact lenses	2 500 000	
Retinal surgery implants	50 000	
Prostheses after enucleation	5 000	
Cardiovascular		
Vascular grafts	350 000	
Arteriovenous shunts	150 000	
Heart valves	75 000	
Pacemakers	130 000	
Blood bags	30 000 000	
Reconstructive		
Breast prostheses	100 000	
Nose, chin	10 000	
Penile	40 000	
Dental	20 000	
Orthopedic		
Hips	90 000	
Knees	60 000	
Shoulders, finger joints	50 000	
Other Devices		
Ventricular shunts	21 500	
Catheters	200 000 000	
Oxygenators	500 000	
Renal dialyzers	16 000 000	
Wound drains	3 000 000	
Sutures	20,000,000	

## 1.7 APPLICATIONS OF MEDICAL DEVICES (Ratner, 1993)

# 1.8 DESIGN CONSIDERATIONS FOR MEDICAL DEVICES AND NON-MEDICAL STRUCTURES

	Non-medical	Medical
Define the problem Problem to be solved	+ Extend human	+ Replace missing
Required Performance	capabilities +	organ +
therm., optical) - Scale of performance (living element)	mm, m (human organism)	nm, µm, mm
- Material selection criteria	(numan organism) +	+
- Geometric considerations	+	+ (anatomic)
Design Parameters	+	+
Effect of the design on the environment	Inert	Inert and bioactive
- Time constant	Years, decades	Days, months, years
- Governmental regulations	+ (EPA)	+ (FDA)
Effect of the environment on the design		
- Mechanical, chemical (+water), thermal, light, ionizing radiation	+	+
- Mechanisms of failure (fracture, wear, corrosion)	+	+
- Permanent vs. temporary (Insoluble vs. soluble)	Permanent	Permanent and temporary (scaffolds for regeneration - tissue engineering)
Laboratory testing/simulation -Models and mock-ups	+ Mech. and chem.	+ Mech. and chem. Cell/tissue culture Animal implantation

\* "+" means a consideration to be addressed.

## Nonedical

## Medical

Mathematical modeling	+ (Often)	Generally not available
Evaluation of performance in use	Controlled use/ instrumented	Clinical trial
Assessment of value	Exceeds safety factor (Threshold risk)	Benefit/risk
Engineering disciplines responsible for product	Aero., chem., civil, mat'l., mech, etc.	Biomedical Engineering
Nonengineering responsibility	None	Physician
Consumer	Varied	Physician
Consumer education	Variable	Variable
Role of marketing	Tech. spec./ aesthetics	Tech. spec. (?)
Cost as an issue	+	+
Cost per pound	Low	High