
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**

1.1 OBJECTIVES OF THE SUBJECT

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

Augmentation 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

Ophthalmologic 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.

1.7 APPLICATIONS OF MEDICAL DEVICES (Ratner, 1993)

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

1.8 DESIGN CONSIDERATIONS FOR MEDICAL DEVICES AND NON-MEDICAL STRUCTURES

	Non-medical	Medical
Define the problem	+	+
Problem to be solved	Extend human capabilities	Replace missing organ
Required Performance (Mech., chem., electr., therm., optical)	+	+
- Scale of performance (living element)	mm, m (human organism)	nm, μ m, mm (cell)
- Material selection criteria	+	+
- Geometric considerations	+	+(anatomic)
Design Parameters	+	+
Effect of the design on the environment	Inert	Inert and bioactive (biocompatibility)
- 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.

	Nonmedical	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