CHAPTER 1

Survey of Clinical Cases of Biomaterials-Tissue Interactions: The Paradigm

1.1 Genotype/Phenotype (Fig. 1.1)

- 1.2 The Working Paradigm: The Unit Cell Process/The Control Volume (Fig. 1.2)
 - 1.2.1 Examples of Cell-Matrix Substrate Interactions: An Element of the Unit Cell Process
 - 1.2.2 Classical Approaches for Describing Wound Healing
 - 1.2.3 Additional Classical Approaches for Describing Wound Healing

1.3 Definitions

1.4 Applications of Medical Devices

Genotype Phenotype (genetic make-up) (expressed genes)

Genotype soluble regulators Phenotype soluble regulators

Fig. 1.1

1.2 THE WORKING PARADIGM: THE UNIT CELL PROCESS

- a) Describes a specific **cell-matrix interaction**. Usually it describes the induction of a specific phenotype of the **protagonist cell** by an insoluble **substrate**.
- b) Confined conceptually in a **control volume** dV (Fig. 1.2). Order of magnitude: 10x10x10 μm.
- c) **Regulated by diffusible substances** which enter into and exit from control volume. These substances regulate the cell-matrix interaction. Also regulated by **mechanical forces** which act by deforming the matrix, thereby modulating the cell-matrix interaction.
- d) The cell-matrix interaction is a highly specific process: the **cooperative configurational interaction** between ligand and receptor. Usually both ligand and receptor are macromolecules, each with a highly specific configuration.
- e) Can be **reproducibly** demonstrated (or rejected) *in vitro*. **Falsifiability** of each model of cellmatrix interaction.
- f) **Scale**: small enough to be reproduced *in vitro* and large enough to have significant physiological content.
- g) Forms a conceptual bridge between *in vitro and in vivo* phenomena.

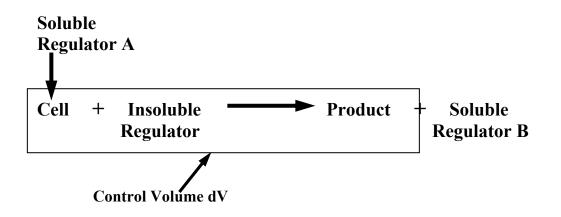


Fig. 1.2 Unit cell process confined conceptually in a control volume, dV. It describes the induction of a particular phenotype of a cell by a soluble regulator and a substrate (acting as an insoluble regulator).

1.3 DEFINITIONS

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

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	

1.4 APPLICATIONS OF MEDICAL DEVICES (Ratner, 1993)

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