CHAPTER 1

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

1.1 Introduction

1.2 Genotype/Phenotype (Fig. 1.1)

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

1.4 Related Subjects (Fig. 1.3 a, b, and c) and Professions (Fig. 1.3 d)

1.5 Definitions

1.6 Importance of Soluble and Insoluble Matrix Molecules (Fig. 1.4)

Issues related to scale. The biological structure (extracellular matrix) comprises:
1) Molecular structure (10-100 nm)
2) Histology/microanatomy/tissue architecture (10μm - mm's)

1.7 Applications of Medical Devices

1.8 Examples Demonstrating the Interactions of Biomaterials with Tissue

1.9 References

1.2 GENOTYPE/PHENOTYPE

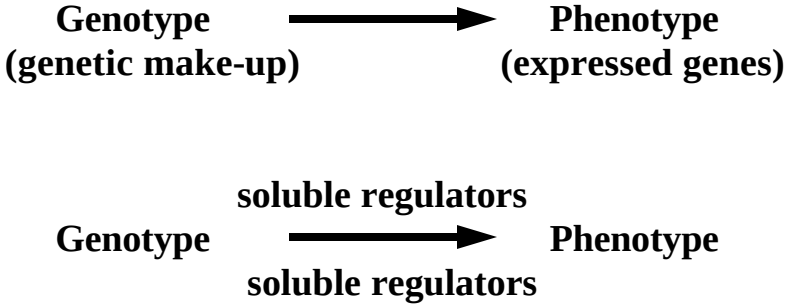

Fig. 1.1

1.3 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 cell-matrix 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.

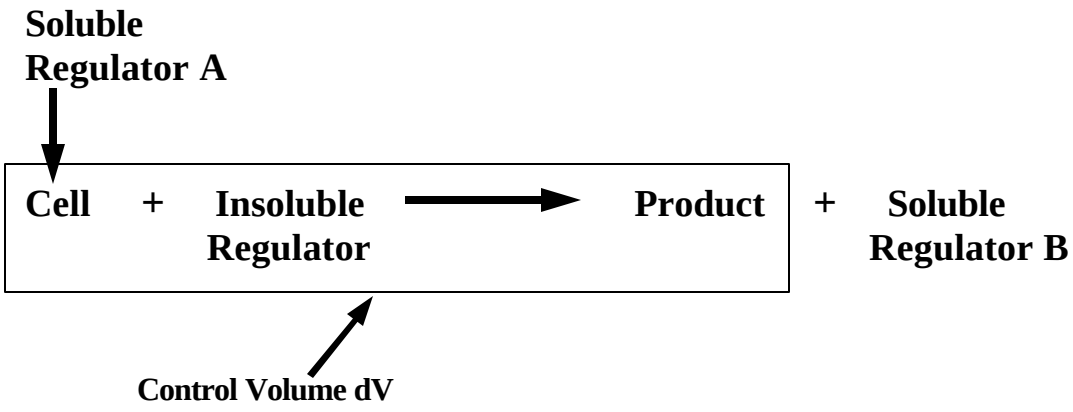

Fig. 1.2 Unit cell process confined conceptually in a control volume, dV. It describes the induction of a particular phenotype of a cell by a soluble regulator and a substrate (acting as an insoluble regulator).

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1.5 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

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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 EXAMPLES DEMONSTRATING THE INTERACTIONS OF TISSUES WITH BIOMATERIALS

1) Skin contraction and scar formation leading to restrictions in joint mobility and lifestyle.

2) The silicone breast implant: scar formation and contraction around the implanted object.

3) Fixation of orthopedic prostheses: bone bonding vs. scar encapsulation.