INFLAMMATION, CARCINOGENICITY, & HYPERSENSITIVITY

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Introduction

- Biomaterials are generally not rejected when placed inside the human body.
- Every implanted biomaterial stimulates a tissue response.
- Our body's response is well known; how biomaterials affect that response is not.

Carcinogenicity

- Sarcomas due to implanted biomaterials are seen in a number of animal models but are rare in humans.
- Carcinogenicity testing is defined as the means to determine the tumor-causing potential of a biomaterial by either a single or multiple exposures over the total lifespan of the test animal.
- A number of factors may influence the potential for cancerous development: size, shape, chemical make-up, and surface finish.

Granulation Tissue

- Granulation tissue defines inflammation during healing and four components have been identified: active macrophage cells, neutrophil activity, angiogenesis, and fibroblast cell activity.
- An implant is typically chosen because of its stable, non-reactive nature, but it will still disrupt the development/progression of the granulation tissue.

Repair

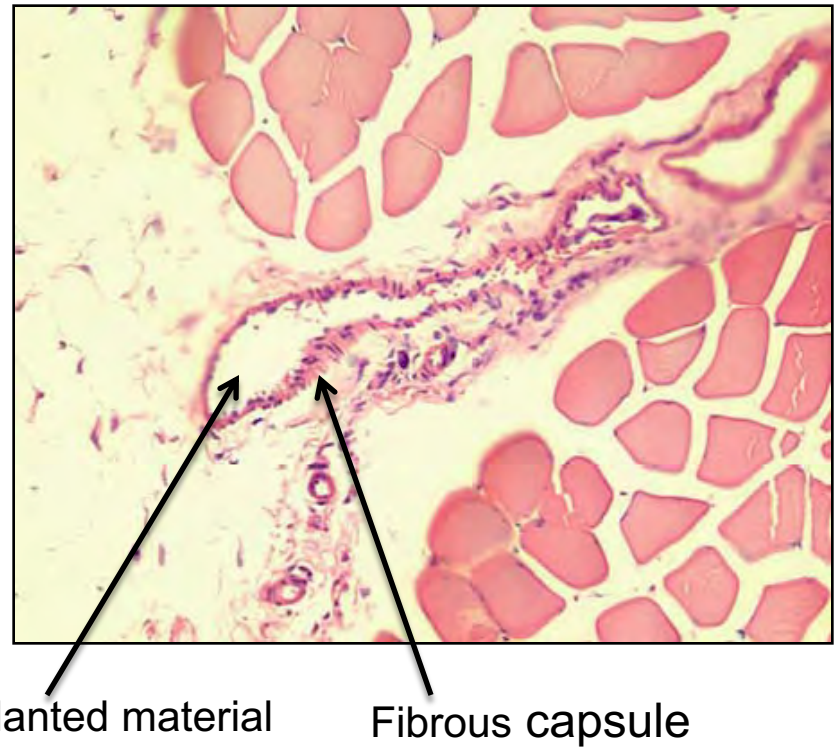
- Small injuries typically heal by the regeneration of normal tissue; however, the more common, sever injury will lead to the formation of scar tissue as well.
- Implanted biomaterials may induce fibrous encapsulation formed by fibroblast cells and collagen.

Infection

- A ten percent infection rate is seen in patients with implanted biomaterial, and nosocomial infection rates are much higher with an added, serious risk to the patient.
- It is also true that the simple presence of an implanted material can heighten the virulence of an invading micro-organism.

Soft and Hard Tissue Responses

- An implant provides a physical barrier to the wound healing process and allows for protein deposits and eventual fibrous encapsulation.



- An implant put into bone will stimulate a wound healing response like that seen after a fracture or other bone injury.
- Hard tissue healing timetable: 6 weeks, woven callous; 18 weeks, lamellar compaction and interface remodeling; and 54 weeks, mature compact bone.