

Biomaterials – Tissue Interactions

Homework #9

You have been hired by a start-up company to assist in identifying applications for their new polymer (Vitafilm) which can be made into sheets 1 to 3 mm in thickness. The polymer film can be made to be porous or nonporous, and can be made absorbable or nonabsorbable.

- a) One application suggested for Vitafilm is treatment of shallow, partial thickness skin wounds. Which variation of the product would you use? Explain.
- b) For deep full thickness skin wounds would there be the value in employing a second form of Vitafilm in addition to the product you proposed in (a)?
- c) In a clinical trial in which one of the nonabsorbable formulations of Vitafilm was used for the application in (b), the finding was made of an increase in the amount of contracted scar. Further investigation of the Vitafilm implant revealed that it had shed small particles, less than $10\ \mu\text{m}$ in diameter. One of the consultants suggested that there was likely no connection between the particles and the contacted scar, and therefore the findings did not need to be reported to the FDA as an “adverse event.” Do you agree?
- d) In one of the patients in whom the implant in (c) was used, there was a complete disintegration of the Vitafilm. After debriding the implant site (*i.e.*, removing the implant debris and contracted scar tissue), the surgeon reported that there would likely be no further issues related to the particulate debris. Do you agree?
- e) During the process of debridement in (d), the surgeon noted that the tissue fluid at the implant site displayed a slippery feel, much like synovial fluid. How would you explain this finding?

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