CHAPTER III.1.5

Implant Retrieval and Evaluation

QUESTIONS

1. The following statements characterize, in part, the goals and specific aims of an implant retrieval and evaluation program. Answer True or False.
   a. Determine rates, modes, and mechanisms of implant failure;
   b. Identify effects of patient and prosthesis factors on performance;
   c. Establish factors that promote implant success;
   d. Determine dynamics, temporal variations, and mechanisms of tissue–materials and blood–materials interactions;
   e. Develop design criteria for future implants;
   f. Determine adequacy and appropriateness of animal models.

2. Indicate five patient conditions that may influence orthopedic device failure or success.
   a. Polyarthritis syndromes;
   b. Connective-tissue disorders;
   c. Osteoarthritis;
   d. Trauma;
   e. Infection;
   f. Metabolic disease;
   g. Endocrine disease;
   h. Tumor;
   i. Primary joint disease;
   j. Osteonecrosis;
   k. Recipient activity level.

3. Indicate five patient conditions that may influence cardiovascular device failure or success.
   a. Atherosclerosis;
   b. Diabetes;
   c. Infection;
   d. Hypertension;
   e. Ventricular hypertrophy;
   f. Arrhythmias;
   g. Coagulation abnormalities;
   h. Cardiac function;
   i. Recipient activity level.

4. What are the two common mechanisms of failure of prosthetic heart valves, vascular grafts, and cardiac assist devices?

5. What is the most common mechanism of failure of vascular stents?

6. What is the mechanism of failure of bioprosthetic heart valves that is similar to a natural disease process?

7. True or False?: Analysis of retrieved orthopedic and cardiovascular implants has revealed that PTFE (Teflon®) was a good choice for bearing surfaces and components subject to wear.

8. The wear of polymeric materials often results in particles visible in microscopic evaluation of adjacent tissues.

9. The wear of the polymeric component in a device is commonly evident in visual evaluation of the components.

10. Visual examination of metallic components of a device is sufficient to determine the amount of wear.

11. The wear of metallic materials often results in particles visible in microscopic evaluation of adjacent tissues.

12. Retrieved devices should be thoroughly cleaned before being examined.

13. Infection as a cause of implant failure is diagnosed only by bacterial culture and histological examination of the tissues is not of value.

14. Acute inflammation at the site of an implant in place for seven days (such as a suture) is a sign that the material is inappropriate.

15. Comment on each step in this retrieval analysis: An investigator was given a device in a bucket of formalin and asked to analyze it.
   a. The investigator has neither knowledge of the history of the patient nor why the device was removed.
   b. The investigator removes the device from the formalin, rinses it, and scrapes off the adherent tissue.
   c. All the scraped off adherent tissue is sent to the laboratory for routine embedding in paraffin and histological analysis.
   d. The device is taken to the lab, thoroughly cleaned, and then cut into sections for analysis of material type and processing methods for the various components.
   e. The investigator reports that the material is 316 LVM stainless steel with no evidence of corrosion or failure.

16. Why is it important to consider implant analysis in the context of clinical information?

17. What are the most important complications of cardiovascular implants?
18. True or False: Minor changes in implant design and manufacture are inconsequential.
19. Describe three instances where implant retrieval studies have contributed to improved heart valve prostheses and/or management of patients with these devices.
20. Why retrieve and evaluate implants performing well?

**ANSWERS**

1. a. T  
   b. T  
   c. T  
   d. T  
   e. T  
   f. T
2. Any five (a through k) are true
3. Any five (a through i) are true
4. a. Thrombosis;  
   b. Infection.
5. Intimal hyperplasia.
7. F
8. T
9. T
10. F
11. F
12. F
13. F
14. F
15. No ‘best’, discussion for students or instructor
16. Various diseases/conditions and other patient variables such as recipient activity level, as well as the circumstances occurring during implantation surgery, may affect implant performance (see Table III.1.5.3 of this chapter).
17. Thrombosis and thromboembolism, infection, calcification, and mechanical failure modes.
18. False. There are many instances, some of which are described in this chapter, where minor changes in implant design intended to decrease the propensity to a particular complication, have inadvertently had serious unintended consequences (see case study – Björk-Shiley heart valve prosthesis).
19. See Table III.1.5.8 of this chapter.
20. Important data can accrue from implants serving the patient until death or removal for unrelated causes, provided that a focused question is asked. For example, after implant retrieval studies of a low-profile disk valve composed of a disk and cage fabricated from Teflon® demonstrated poor wear properties of the disk, a new model of this and other valves with parts fabricated from pyrolytic carbon was introduced. Retrieval studies of carbon valves recovered at autopsy or surgery and analyzed by surface scanning microscopy and surface profilometry indicated that compared with valves composed of Teflon®, carbon valves exhibited minimal abrasive wear. This study justified continued use of carbon for the valves and gave patients with the modified valve confidence in the implants they received. Moreover, studies of implants performing well help to elucidate key tissue-biomaterials interactions.