CHAPTER II.3.4

In Vivo Assessment of Tissue Compatibility

QUESTIONS

1. Why is the in vivo assessment of a medical device carried out?
2. What biomaterial components and characteristics may affect the overall biological responses of a medical device?
3. In the selection of tests for tissue compatibility, what are the two major categories that are used?
4. Identify six in vivo tests used for determining tissue compatibility.
5. The Oppenheimer effect refers to what biological process?
6. Several different types of biocompatibility tests utilize histological assessment techniques to determine biological response parameters. Identify four biological response parameters.
7. What healing process in vascular grafts is found with all animal and nonhuman primates, but not in humans?
8. The choice of animal model for bioprosthetic heart valve evaluation must consider what significant pathological problems?
9. Immunotoxicology testing and the determination of immune effects and responses are required for what general type of medical devices?
10. What are the components of risk related to inadequate biocompatibility?
11. Why might in vivo preclinical biocompatibility testing results be misleading and underestimate risk in some patients?

ANSWERS

1. To determine that the device performs as intended, and presents no significant harm to the patient or user simulating clinical use.
2. See Table II.3.4.1.
3. a. Tissue contact
   b. Contact duration.
4. See Table II.3.4.3.
5. Carcinogenicity or tumor formation.
6. See Table II.3.4.4.
7. Endothelialization.
8. a. Accelerated calcification
   b. Thrombosis.
9. Combination products or devices – those that combine a biological component, i.e., proteins, cells, etc., with a synthetic component, i.e., polymer, metal, ceramic, etc.
10. a. Assessment of the hazard (effects and manifestations);
    b. Assessment of the exposure (duration of implant and expected timing of complications); and
    c. Probability and consequences of an adverse effect (frequency, outcome, patient factors, cost).
11. a. Application of the biomaterials may be different than originally tested;
    b. Fabrication changes and interactions between biomaterials may be important;
    c. The site of original testing may not reflect interactions that occur at the actual implantation site;
    d. Patient-specific factors may play a role.

TRUE/FALSE

1. A biomaterial considered compatible for one application is considered compatible for other applications. (False)
2. Cytotoxicity, sensitization, and irritation tests must be carried out on all medical device materials. (True)
3. Biomaterials, medical devices, and prostheses should be tested in the final product form and/or end-use application. (True)
4. Carcinogenicity testing of a biomaterial in a medical device may not be necessary. (True)
5. In the in vivo assessment of a medical device, a single animal model may not assess all pertinent clinically important complications. (True)