Version AEM/2

EGT2
ENGINEERING TRIPOS PART IIA

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23 April 2019 9.30 to 11.10

Module 3G5

BIOMATERIALS

*Answer not more than **three** questions.*

All questions carry the same number of marks.

*The **approximate** percentage of marks allocated to each part of a question is indicated in the right margin.*

*Write your candidate number **not** your name on the cover sheet.*

STATIONERY REQUIREMENTS
Single-sided script paper

SPECIAL REQUIREMENTS TO BE SUPPLIED FOR THIS EXAM
CUED approved calculator allowed
Engineering Data Book

10 minutes reading time is allowed for this paper at the start of the exam.

You may not start to read the questions printed on the subsequent pages of this question paper until instructed to do so.

1 (a) Briefly describe the structure of bone at different length scales. [20%]

(b) Bone responds to loading. Explain what this means in the context of the "Mechanostat" theory shown in Figure 1. Hence, describe the "disuse", "adapted" and "mild overload" regions. [15%]

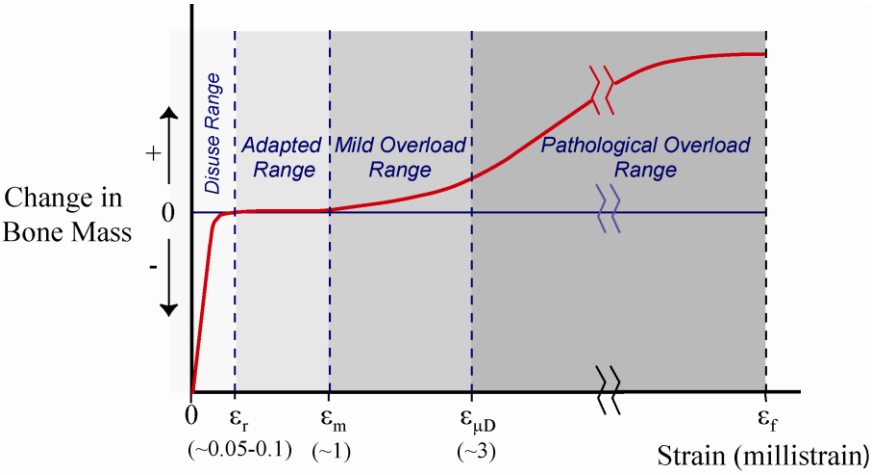

Figure 1

(c) Explain what is meant by the term "stress shielding" when referred to a bone-replacement implant. Compare the stress shielding effect produced by metallic and ceramic implants and contrast their relative mechanical and in vivo biological performances. [15%]

(d) What are the main causes for hip replacement? Sketch and label the components of an implant to be used for total hip replacement. List the materials used for each component. In cases where different classes of materials could be used for the same component, indicate their advantages and disadvantages. [35%]

(e) Briefly describe the mechanical loading, wear and failure modes to which a hip replacement implant is subjected in the human body. [15%]

2 (a) A company is setting up a new operation to make an entirely plastic medical device that administers highly controlled doses of medicinal products upon implantation. All of the dimensions and mechanical properties are precisely defined to ensure the correct dosage is delivered. The company estimates it will make 10 million units per year. The company needs to select one sterilisation technique having narrowed down the options to ethylene oxide sterilisation, steam sterilisation or gamma radiation sterilisation.

(i) Describe briefly any 6 important general considerations a company should take into account when selecting a sterilisation technique. Include comments on the specific device mentioned above where relevant. [30%]

(ii) Explain briefly one advantage and one disadvantage for each of the three techniques, namely ethylene oxide sterilisation, steam sterilisation and gamma radiation sterilisation. Include comments on the specific device mentioned above where relevant. [20%]

(b) Briefly explain each of the three core ethical principles that were defined as a result of the Belmont Report, namely: respect for persons, beneficence and justice. [15%]

(c) Briefly explain the following terms:

(i) Medical device classification;

(ii) biocompatibility of materials;

(iii) parametric release, when sterilising biomaterials. [15%]

(d) Describe any 4 differences between the US and EU in terms of their regulatory processes when bringing a medical device to market. [20%]

3 (a) Two sources of polyethylene, PE-1 and PE-2, are available. PE-1 has a quoted number average molecular weight $M_n \sim 3.5\times10^4$ g mol^{-1} and a polydispersity index PDI = 2.5. PE-2 has a quoted number average molecular weight $M_n \sim 4\times10^6$ g mol^{-1} and a polydispersity index PDI = 1.2. The chemical formula of polyethylene is $(C_2H_4)_n$ where n is the degree of polymerisation. The molar mass of C = 12 g mol^{-1} and the molar mass of H = 1 g mol^{-1}.

(i) Sketch a graph showing a typical molecular weight distribution of a polymer. Label the probable positions of M_n and the weight average molecular weight M_w. [10%]

(ii) Calculate the approximate mean degree of polymerisation *n*, and the weight average molecular weight M_w, for PE-2. [10%]

(iii) Compare the Young's moduli, achievable degrees of crystallinity and melting points of PE-1 and PE-2. Discuss your answer based on the data provided above. [15%]

(iv) Suggest a biomaterial application for PE-2. Briefly state your reasoning. [5%]

(b) For the following applications of polymeric biomaterials, give accounts on why a particular material is used. Comment on the material's crystallinity and/or the polymer structure to support your answer.

(i) Polytetrafluoroethylene (PTFE) for vascular grafts. [15%]

(ii) PGA (90%)/PLA (10%) co-polymer for resorbable sutures. [15%]

(iii) Poly(anhydrides) made into wafers containing chemotherapeutic agents for treatment of brain tumour. [15%]

(iv) Collagen (type-I) fibre scaffold as a haemostatic dressing. [15%]

4. (a) Biomaterials are widely used in drug delivery applications. By taking into account the three main functions of drug delivery, discuss the importance of the drug delivery systems as part of the drug formulation. [25%]

(b) Co-polymers can be used in the form of microparticles or nanoparticles for drug delivery applications.

(i) What is the main function of the co-polymer? Why should the co-polymer be in an amorphous form? [5%]

(ii) List the advantages and limitations of using microparticles or nanoparticles in drug delivery. [20%]

(c) Combining biomaterials with cells *in vitro* prior to implantation offers the opportunity to treat some damaged tissues or organs. Using examples, discuss the strengths and limitations of this approach, identifying the factors that need to be considered when putting together tissue engineered constructs. [50%]

END OF PAPER

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Answers

3. (ii) $n \sim 1.43\times10^5$, $M_w = 4.8\times10^6$ g mol^{-1}.