Version Final

EGT2
ENGINEERING TRIPOS PART IIA

Monday 4 May 2015 9.30 to 11:00

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

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

1 (a) (i) Explain the key features of an electrocardiogram for measuring normal heart physiology. [30%]

(ii) Describe the types of pacemakers. Explain how a pacemaker restores heart function. [20%]

(b) (i) Describe the key features of the disease type I diabetes mellitus. Describe the current medical device technologies used in the treatment of diabetes and their operating principles. [40%]

(ii) How do biological responses create obstacles to the function of diabetes treatment devices? [10%]

2 (a) Write brief notes to explain the following:

(i) cytotoxicity and biocompatibility; [10%]

(ii) the classification of medical devices according to risk; [10%]

(iii) the principles of bioethics; [10%]

(iv) how nanoparticles for drug delivery applications are characterised, define 'targeting' in the context of nanoparticle drug delivery; [10%]

(v) PEG and PEGylation; in particular, why PEG is used with nanoparticles in drug delivery. [10%]

(b) A drug delivery patch is employed for transdermal drug delivery.

(i) Considering the patch as a diffusion controlled delivery device, sketch a suitable patch design which will result in a constant rate of drug delivery. Based on your sketched design, state and label the key geometrical factors and the boundary conditions which will affect the rate of delivery. [15%]

(ii) Assuming a constant rate of drug delivery a is sustained over time, sketch a graph describing the amount of drug released into the skin as a function of time. Label any asymptotic limits and state your assumptions. [15%]

(iii) A drug loaded in the patch has an exponential decay characteristic with a half-life of five-day clearance in the body. The toxic level for the drug in the body is 100mg, and the minimum effective level is 10 mg. Calculate the range of delivery rates which should be designed for this drug. [20%]

3 Polylactic acid (PLA) – polyglycolide (PGA) co-polymers are one of the most widely used hydrolysable implant materials for tissue engineering scaffolds. Figure 1 below shows how the degradation half-life ($T_{1/2}$) and the crystallinity of the co-polymer vary with the PLA and PGA composition.

(a) Define hydrolysis. What are the common factors that influence hydrolysis? Explain how these factors can account for the shape of the curve seen in Figure 1. [20%]

(b) Based on Figure 1, suggest what PLA-PGA co-polymer ratio or composition you will use for the following applications, stating the reasons for your choice:

(i) resorbable sutures; [10%]

(ii) resorbable capsules for drug delivery; [10%]

(iii) resorbable screws for bone graft. [10%]

(c) When implanted, a PLA-PGA co-polymer will undergo erosion in the body. Assume a hydrolysis rate constant of $\lambda=5\times10^{-6}$ s^{-1}, a diffusion coefficient of $D=10^{-8}cm^2$, and the volume containing one degradable bond to be $V=3\times10^{-22}$ cm^3:

(i) Determine the critical thickness W_C for bulk *vs*. surface erosion, to the nearest millimetre. [25%]

(ii) Assuming the implant to be a slab of 2 cm thick, suggest the dominating erosion mechanism. [10%]

(iii) Based on your erosion mechanism suggested in (ii), sketch how the mass and the molecular weight of the slab implant will change over time. Briefly explain the key features of your sketch. [15%]

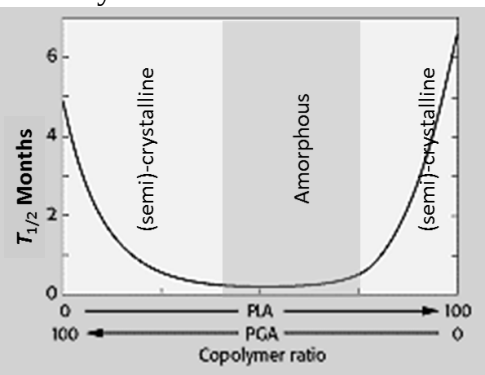

Figure 1

4 (a) The diagram in Figure 2 shows part of the tubular wall structure of an unexpanded cylindrical stent, unwrapped so that it is planar. The individual members all lie at angles of $\pm\theta$ to the axial direction. They all have both a width and a thickness of w (=0.2 mm), and a spacing between crossover points of D (=2 mm).

(i) Sketch a "unit cell" of the wall structure, which has its sides parallel to the axial and hoop directions. Estimate the metal volume fraction in the wall of the unexpanded stent if the inclination angle θ is 20°. [15%]

(ii) Estimate the relative increase in the radius, and the relative decrease in length, when the inclination angle θ is 50°. Hence estimate the axial contraction ratio of the stent, [15%]

(iii) Explain the disadvantage of this stent wall design in terms of its mechanical properties, and how they may be undesirable from a surgical point of view. [20%]

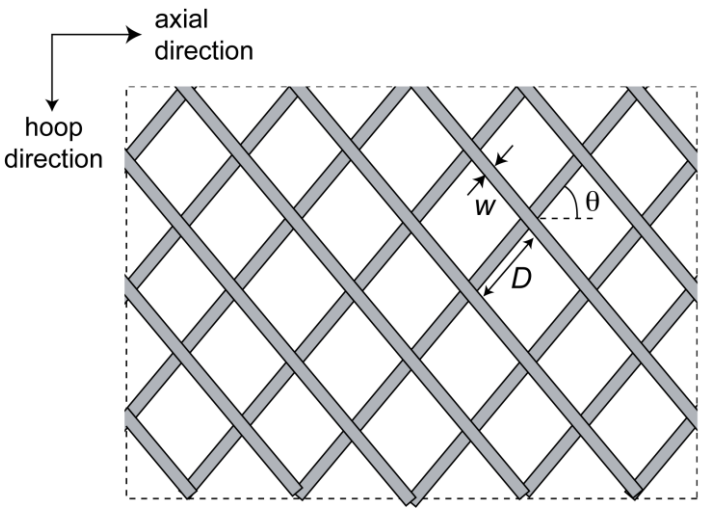

Figure 2

(b) Consider an endovascular stent made of a superelastic alloy. Describe the superelastic effect by sketching the form of the stress-strain curve typically exhibited by such a material, and explain why it has this form. Using a hoop force – stent diameter diagram, explain how the superelastic effect is utilised in stents. [50%]

END OF PAPER

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