Version YYSH/4

EGT2
ENGINEERING TRIPOS PART IIA

Monday 25 April 2022 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.

You may not remove any stationery from the Examination Room.

1 (a) Explain how balloon expandable and self-expanding stents are deployed *in vivo*. In each case, state the mechanism responsible and list the material(s) used. What advantages does a self-expanding stent have over a balloon expandable stent in terms of its delivery? [25%]

(b) Explain briefly the difference between diffusive and martensitic phase transformations and how this difference is being exploited in self-expanding stents. Sketch the changes in the percentage of martensite formation as a function of temperature in the context of martensitic phase transformations. Define all transformation temperatures. [25%]

(c) The schematic in Figure 1 shows the "unit cell" of the tubular wall structure of an expanded cylindrical stent, unwrapped so that it is planar. The members with length L (= 4 mm) all lie at an angle of θ to the axial direction. All members have both a width and a thickness of t (= 0.2 mm). Imposed over the image is the unexpanded unit cell, shown with dashed lines.

(i) Estimate the metal volume fraction in the wall of the expanded stent if the inclination angle θ is 10°. [15%]

(ii) When the inclination angle θ is 10°, the unit cell contracts by 20% in the axial direction. Estimate the axial contraction ratio of the stent from the relative increase in the radius and the relative decrease in length. [15%]

(iii) Discuss the disadvantages of this stent wall design. [20%]

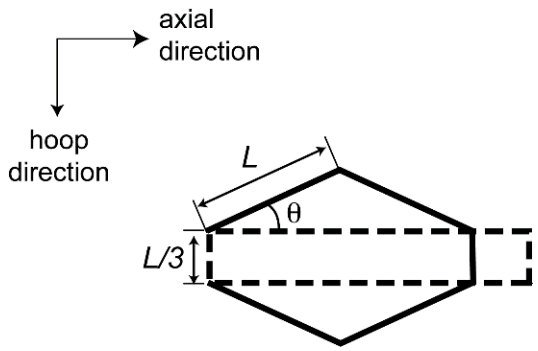

Figure 1

2 A firm has created a new process to treat bone defects with a tissue engineered bone construct. They created software that converts a CT scan of the bone into a file for 3D printing. They use this to 3D print a porous polymer scaffold that perfectly fits the defect. They add cells and proteins that promote bone growth, move the scaffold to a bioreactor for one week and then send the final product to the hospital for implantation into the patient.

(a) Describe how you would assess biocompatibility of this product. [25%]

(b) (i) Describe what is meant by 'sterilisation' when making biomaterials or medical devices. Include in your description how to validate that sterilisation has taken place and why sterilisation will be important for the product above. [20%]

(ii) Describe any two challenges you would anticipate when deciding on a sterilisation process for the product above. [15%]

(c) (i) Describe any two steps in the regulatory approval process for a medical device. [15%]

(ii) Apart from sterilisation and biocompatibility, describe any 5 other challenges you anticipate will be faced when bringing this product to market, specifically because it is made by tissue engineering. [25%]

3 Polymers are used extensively in drug delivery applications.

(a) State and discuss the main design considerations when determining the selection of polymers for drug formulation. [30%]

(b) Poly(anhydride) is a water hydrolysable co-polymer which can be used as a carrier for localised delivery of brain cancer drugs.

(i) Briefly describe the characteristics of hydrolysable polymers. What are the key advantages of using co-polymerisation to form a hydrolysable polymer? [15%]

(ii) What are the possible advantage(s) and disadvantage(s) of localised delivery of brain cancer drugs? [20%]

(iii) Discuss the reasons why poly(anhydride) is used for localised cancer drug delivery in the brain? [15%]

(c) A new hydrolysable co-polymer is synthesized to be potentially used for localised delivery of brain cancer drugs. This new co-polymer was measured to exhibit a critical thickness (W_c) for bulk vs. surface erosion of 10 μm.

(i) Based on practical considerations, sketch the likely delivery profiles for this new polymer (i.e. rate of drug release, and total mass of drug released over time). State your assumptions. [15%]

(ii) Based on (i), suggest whether this new co-polymer could be suitable for localised cancer drug delivery in the brain. Briefly state your reasoning. [5%]

4 (a) Collagen is a naturally-derived biomaterial.

(i) Give an example tissue engineering application of collagen, account for why collagen is used in place of other materials, and explain how the processing method of collagen might determine the intended application. [25%]

(ii) Collagen can be made into the form of a ‘hydrogel’ or a ‘sponge’. Discuss the key physical characteristic differences between a collagen sponge and a collagen hydrogel. [25%]

(b) Currently, implantable glucose sensors are replaced on a regular basis (generally, every seven days) to ensure the continuous glucose monitoring system is properly functioning.

(i) Describe the cascade of events that result in normal localised tissue healing and wound repair upon skin injury. [35%]

(ii) Based on (i), account for why current implantable glucose sensors are not used as permanent implants. [15%]

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Numerical answers:

Q1 c(i) 0.17; c(ii) 0.20

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