993

Ollscoil na hÉireann, Gaillimh
National University of Ireland, Galway

Semester II Examinations, 2004/2005

Exam Code(s)	4BG1
Exam(s)	4th Biomedical Engineering
Module Code(s)	ME421
Module(s)	Medical Implant and Device Design
Paper No.	1
Repeat Paper	Special Paper
External Examiner(s)	Professor D. Williams
Internal Examiner(s)	Professor J.F. McNamara
	Dr. D. Apatsidis
	Dr. T. Joyce
	Mr. Shane McNally
Instructions:	Answer 5 questions in total. Answer at least one question from section B. All questions will be marked equally.
Duration	3hrs
No. of Answer Books	1
Requirements:	
Handout	
MCQ	
Statistical Tables	
Graph Paper	
Log Graph Paper	
Other Material	
No. of Pages	7 including cover
Department(s)	Mechanical and Biomedical Engineering
Course Co-ordinator(s)	Dr. D. Apatsidis, Dr. T. Joyce

Section A

1. (a) Define the terms "Design Verification" and "Design Validation" for both the USA and the EU, and explain the difference between them. **(5)**

(b) For a Coronary Balloon Catheter make a list of 15 design inputs and possible outputs with at least 4 points under each of the headings:

Safety/ Functionality

Dimensional

Essential Requirements

(15)

2. (a) For the case presented below (Figure 2.1), indicate whether you would suggest to a clinical team the use of conservative or operative treatment of the fracture and why. What type of medical device would you suggest as a result of your recommendation and what would be the benefits of using this device, in relation to alternative devices? **(8)**

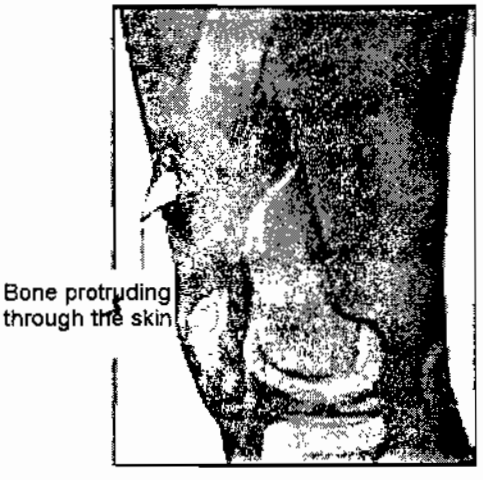

Figure 2.1

(b) What are common considerations in the design and development of orthopaedic implants, both in terms of the host environment and the device characteristics? What are a surgeon's selection criteria for adequate fracture fixators?

(6)

(c) The x-ray shown in Figure 2.2 belongs to a 28-yr old male with severe osteoarthritis. The patient experiences severe pain, even whilst seated or lying flat. He has been on pain management for 2 years, but standard pain medication is no longer adequate. He has been scheduled for immediate operation on the hip. What is the most appropriate implant and immediate plan of action and what implant is suggested for the long-term management of this patient for each of the future interventions (up to the second revision surgery)? What are the advantages and disadvantages of each implant and what will have to be considered when progressing from the least to the most invasive? **(6)**

Figure 2.2

3. (a) What are the main requirements from a modern, manual, self-propelled wheelchair for use by paraplegic individuals? How are these requirements fulfilled in terms of the materials that are used? **(6)**

(b) Which are the two commonest types of wheelchair frames and what are the differences between them? Explain the meaning and physical consequence of castor flutter, castor float, tracking and alignment in manual, self-propelled wheelchairs. **(6)**

(c) What are the two functions that knee joint mechanisms of above-knee prostheses have to fulfil? Describe how the mechanical knee mechanisms (monocentric and polycentric) and the electronically controlled knee mechanism (C-Leg) achieve this. What are the disadvantages of the mechanical mechanisms over the C-Leg? **(8)**

4. Many different designs of artificial finger joint have been proposed over the past fifty years. As an implant design engineer you have been given the task of designing a new prosthesis for the metacarpophalangeal joints of the fingers. It is to have a metallic metacarpal component and a polymeric phalangeal component.

(a) List the three metals and one polymer which would likely be your starting point in terms of biomaterials. **(2)**

(b) Describe your design of the metacarpal and the phalangeal components in detail, noting sizes and shape of the implant and justifying your choice of two biomaterials for the finger implant. How is fixation to be achieved? **(10)**

(c) Given your design, how would you go about testing the implant prior to any animal or clinical trials? In particular, what test parameters would you apply, what would be the specific values you would choose and why? **(8)**

5. 'The long-term clinical results of the Charnley low friction arthroplasty (LFA) remain excellent even in young patients'. This quote has been taken from an article entitled 'Charnley LFA in patients under the age of 51 years', Wroblewski et al, 2002, Journal of Bone and Joint Surgery, 84B, 540-3. The quote above refers to the Charnley design of total hip replacement. More recently a type of total hip replacement, known by trade names such as the McMinn, the Birmingham or the Cormet 2000, has been proposed and implanted.

(a) Describe the key engineering features of each prosthesis design including the biomaterials used. **(8)**

(b) Supporting your argument with clinical data where appropriate, what are the advantages and disadvantages of each design? **(10)**

(c) Compared with the types of design which the Charnley and the McMinn represent, state an advantage and a disadvantage which a ceramic-on-ceramic total hip replacement might offer. **(2)**

Section B

6. You are a design engineer with a manufacturer of external fracture fixators. The company has decided to follow recommendations published by workers at the AO Foundation in the Journal of Orthopaedic Research, which stipulated that a cyclic compressive displacement of the fracture gap (2mm) can significantly accelerate the callus formation and its progressive stiffening. Your task is to advise the company on the appropriate length of their Ilizarov external Fixator (figure 6.1), so that a displacement of 2mm of the fracture gap will be achieved in the worst case of loading during gait. 4 pins attach to each of the fixator's rings, which in turn are connected by stiff rods. Note that the two fragments merely need to come into contact during the compression displacement.

From gait analysis in the biomechanics laboratory it has been established that the following are true for males of 70kg body mass:

Gait Cycle Instance	Resultant Ground Reaction Force	Angle X (at the hip)
Heel Strike	4 x Body Weight	+30°
Mid Stance	2 x Body Weight	0°
Toe Off	3 x Body Weight	-30°

Distances between the various components of the Ilizarov fixator as well as average limb dimensions are shown in Figure 6.2 and Table 1. The available pins are made of stainless steel (316L) and have a solid circular cross section of 5 mm in diameter. E_{316L} = 200 N / m^2. Consider the pins to be fully constrained within the bone, as well as the rods onto the rings.

(20)

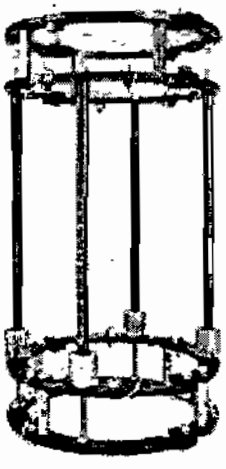

Figure 6.1

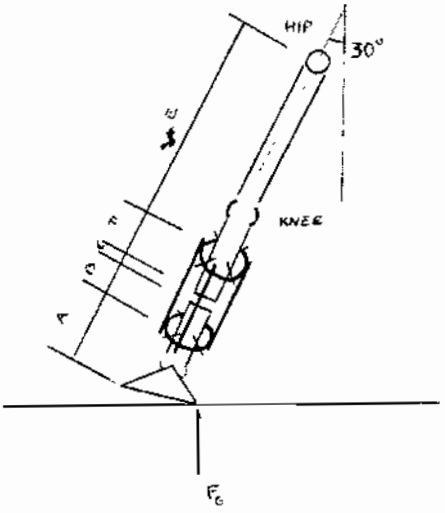

Figure 6.2

A	98 mm
B	150 mm
C	2 mm
D	150 mm
E	520 mm

Table 1

Given: $x = (F * L^3) / (24 * E * I)$, for calculating deflection **x** at free end of pin under cantilever bending. **L** is the required pin length, $I = (\pi d^4) / 64$ is the moment of inertia for circular cross- sections.

7. You are the designer of an implant for the wrist joint. Having considered the biomechanics of the wrist joint you have decided that the implant is to consist of a two-piece design. One component, which you have named the ball, will fit inside the radius. It is to have a part-spherical head which is designed to articulate against a carpal component. The carpal component consists of a socket with a conforming concave surface to accommodate the ball. You are aware that a number of material combinations could be employed in your new wrist prosthesis and you have tabulated them below. The three combinations are metal-on-metal, ceramic-on-ceramic and metal-on-polymer.

You have designed the joint such that the diameter of the socket is 12mm and that of the ball as 11.9mm. You have determined that the viscosity η of the lubricant in the wrist joint is 0.01 Pa s, that the entraining velocity will be a constant value of 5mm per second, and the load will be a constant of 150N. Use this data to calculate:

(a) the theoretical minimum film thickness under these conditions. **(12)**

(b) and thus the predicted lambda ratios. **(3)**

(c) How is the lambda ratio indicative of a particular lubrication regime? **(3)**

(d) If improved lubrication is desired, how does the minimum film thickness equation indicate for a set material couple of a set size and with a set lubricant that this can be achieved? **(2)**

Ball component material	Socket component material	Compound surface roughness σ (μm)	v ball and v socket	E ball and E socket (GPa)
Cobalt chrome	Cobalt chrome	0.08	0.3/0.3	210/210
Alumina	Alumina	0.006	0.29/0.29	392/392
Cobalt chrome	UHMWPE	1.29	0.3/0.4	210/1

The required equations are:

$$\frac{1}{R_x} = \frac{1}{R_1} - \frac{1}{R_2}$$

$$\frac{1}{E^*} = 0.5\left(\frac{1-\nu_1^2}{E_1} + \frac{1-\nu_2^2}{E_2}\right)$$

$$\frac{h_{\min}}{R_x} = 2.80\left(\frac{\eta u}{E^* R_x}\right)^{0.65}\left(\frac{w}{E^* R_x^2}\right)^{-0.21}$$

$$\lambda = \frac{h_{\min}}{\sigma}$$