University Of California, Berkeley
Department of Mechanical Engineering

ME C215/Bio Eng C222: Advanced Structural Aspects of Biomaterials (4 units)

Graduate Course

Syllabus

CATALOG DESCRIPTION

This course covers the structure and mechanical functions of load bearing tissues and their replacements. Biocompatibility of biomaterials and host response to structural implants are examined. Quantitative treatment of biomechanical issues and constitutive relationships of materials are covered in order to design implants for structural function. Material selection for load bearing applications including reconstructive surgery, orthopedics, dentistry and cardiology are addressed. Case studies of clinical failures, designs, and material behavior are presented.

EXPANDED DESCRIPTION

Graduate students will participate in advanced project topics that involve medical device design in orthopedics, dentistry and cardiology. Graduate students will be expected to research historical evolution of various medical implants, to work on unique implant designs that utilize material selection and detailed stress analysis, and to work on a range of case studies addressing clinical failures. Projects will culminate in a technical written report and oral presentation.

COURSE PREREQUISITES

ME C85 or Bioengineering 102 or equivalent courses.

TEXTBOOK(S) AND/OR OTHER REQUIRED MATERIAL

Mechanics of Biomaterials: Fundamental Principles for Implant Design, L. Pruitt and A. Chakravartula, Cambridge University Press, Cambridge, UK, 2011.**TOPICS COVERED**

PART ONE: Overview of Biomaterials, Tissues and Regulatory Issues
Overview of biomaterials used in medical devices
Review of structural materials: metals, ceramics, polymers, and composites
Review of structural tissues and constituents: bone, cartilage, vascular tissue, and dental tissues
Biocompatibility and Sterilization

PART TWO: Constitutive Behavior and Biomechanical Design Issues
Elastic behavior, multiaxial loading, time-dependent behavior
Yield criteria and permanent deformation in devices
Fracture criteria and design concerns with brittle materials/stress concentrations
Fatigue: Total life and defect-tolerant philosophies
Friction, Wear and Lubrication

PART THREE: Clinical Issues
Regulatory Issues: FDA testing and product development
Orthopaedics: total joint replacement, soft tissue repair, and spinal implants
Cardiovascular: catheters, stents, grafts
Dental: implants, TMJ, restoration
Soft Tissues: reconstruction and augmentation
Intellectual property: patents, device development, legal and ethical issues

CLASS/LABORATORY SCHEDULE

Three hours of lecture and 1 hour of dsicussion per week.

ASSESSMENT OF STUDENT PROGRESS TOWARD COURSE OBJECTIVES

(30%) Project I (Historical evolution of medical devices)
(30%) Project II (Structural analysis, device failures and recalls)
(40%) Project III (Medical device design and clinical issues)

ROOM SHARE & GRADUATE CONTENT:

Both ME C117/BioE C117 and MEC215/BioEC222 will share same lectures. Both will have three design projects. However for MEC215/BioEC222, graduate students will be assigned more extensive project deliverables for their design projects. The graduate requirements will include extensive literature reviews, assessment of intellectual property development, and oral presentation (in additional to a written technical report) of their findings to the class. Undergraduates in ME C117/BioE C117 will have simpler requirements for their design projects.

PERSON(S) WHO PREPARED THIS DESCRIPTION

Professor Lisa Pruitt, November 25, 2011

ABBREVIATED TRANSCRIPT TITLE (19 SPACES MAXIMUM): ADV STR ASPT BIOMECH
TIE CODE: LECS
GRADING: Letter
SEMESTER OFFERED: Spring
COURSES THAT WILL RESTRICT CREDIT: ME C117 and Bio Eng C117
INSTRUCTOR(S): Pruitt
DURATION OF COURSE: 14 Weeks
EST. TOTAL NUMBER OF REQUIRED HRS OF STUDENT WORK PER WEEK: 12
IS COURSE REPEATABLE FOR CREDIT? No
CROSSLIST: Bio Eng C222

ME 215 COURSE SYLLABUS

This course covers the structure and mechanical functions of load bearing tissues and their replacements. Biocompatibility of biomaterials and host response to structural implants are examined. Quantitative treatment of biomechanical issues and constitutive relationships of materials are covered in order to design implants for structural function. Material selection for load bearing applications including reconstructive surgery, orthopedics, dentistry and cardiology are addressed. Case studies of clinical failures and designs are presented.

TEXTBOOK(S) Mechanics of Biomaterials: Fundamental Principles for Implant Design, L. Pruitt and A. Chakravartula, Cambridge University Press, Cambridge, UK, 2011.

Week	Topics covered	Relevant Reading
1	**I.** Overview of biomaterials used in medical devices; biocompatibility and sterilization ***Project I assigned***	**Chapter 1**
2	Review of crystalline materials: metals, ceramics (strengthening and toughening mechanisms)	**Chapters 2,3**
3	Review of polymers and structural tissues (bone, cartilage, vascular tissue, and dental tissues)	**Chapters 4,5**
4	**II.** Constitutive Behavior and Biomechanical Design Issues Elastic behavior, multiaxial loading, time-dependent behavior	**Chapters 6,7**
5	Yield criteria and permanent deformation in devices ***Project I due . Project II assigned.***	**Chapter 8**
6	Fracture criteria and design concerns with brittle materials stress concentrations	**Chapter 9**
7	Fatigue: Total life and defect-tolerant philosophies	**Chapter 10**
8	Tribology: Friction, Wear and Lubrication	**Chapter 11**
9	**III.** Regulatory Issues: FDA testing and product development Intellectual property: patents, device development, legal and ethical issues	**Chapter 12**
10	Orthopaedics: total joint replacement, soft tissue repair, and spinal implants ***Project II due. Project III assigned.***	**Chapter 13**
11	Cardiovascular: catheters, stents, grafts	**Chapter 14**
12	Dental: implants, TMJ, restoration	**Chapter 15**
13	Soft Tissues: reconstruction and augmentation	**Chapter 16**
14	Intellectual property: patents, device development, legal and ethical issues **Project III due**	

Project Descriptions

Project I: ***30% Course Worth***
Biomaterials used in medical devices
Each team has been given a structural material that is utilized in the body as part of a load-bearing device. Each team will write up a succinct (6 pages) professional report that addresses the historic development of this structural material as a medical grade biomaterial. The project will elucidate the origins of the use of this material in the body and how the material has evolved (special alloying changes, heat treatments, strengthening mechanisms, etc). The report should describe problems encountered with this material and how such problems have been addressed from a biomaterials engineering perspective. The report should highlight the benefits and limitations of the materials and present a case study exemplifying how the material is used in a modern-day medical device. Each team should plan to review at least 5 archival journal papers and two relevant patents as part of this project. These should be included in the Appendix of your report. Each group will make a 10-minute oral presentation to the class. All team members must submit a confidential team assessment form.

Each team much address the following questions:
How did this structural material develop as biomaterial?
Provide a brief history of how this material is used in medical applications. Have these materials evolved in the design evolution of medical devices? What changes have been made to improve the properties of the polymer? Describe the processing and sterilization methods utilized.
Focus on one specialty medical device in the body that utilizes this material. *What special attributes does the material offer in the medical device? What are its basic mechanical properties? How are the mechanical properties utilized in the medical device? What have been the clinical successes of this material?*
What did you learn from this project?

Technical Report:
6 pages: Single-spaced, 12 point Times font, in .pdf format. References should be in Harvard or Vancouver format and are not included in the 6-page limit. Please hand in a hard copy in class and also e-mail a soft copy to lpruitt@me.berkeley.edu.

Elements: ***(i) executive summary***, ***(ii) statement of initial design objectives***—how has the material developed as a biomaterial? How is it utilized in medical device applications? ***(iii) background***—discuss the material's use in a specific medical device and its structural requirements, ***(iv) manufacturing***- how is the product made and sterilized? What special processing is utilized to achieve desired properties of the material? ***(v) structural performance***-- materials selection, mechanical properties, design and performance, ***(vi) lessons learned***- what did you learn from this project? ***(vii) references, (viii) Appendix- copy of at least 5 relevant archival journal papers and 2 patents that were reviewed for the project, material data sheets, supplemental information.***

Technical Presentation: Each group will make an oral presentation to the class (10 minutes per group), presentation in PowerPoint format.

Peer-evaluation: Each group member will fully evaluate the participation and contribution of the other group members.

Project evaluation: Each project will be assessed for knowledge, analysis, synthesis, and approach to problem solution.

Project II: ***30% Course Worth***

Analysis of medical device failures

Each team has been assigned a failure of a medical implant. Develop a detailed case study (6 pages) that describes and illuminates the root cause of failure for the particular medical device assigned to your group. The case study should address the structural function of the implant, the basic stress analysis of the implant (in its physiological environment), and the associated material properties needed from the implant material(s) utilized. Your report should describe the material-design-manufacturing-clinical combinations that likely resulted in the failure of the device. Have any lessons been learned and carried forward? Each team should plan to review at least 5 archival journal papers and two relevant patents as part of this project. These should be included in the Appendix of your report. Each group will make a 10-minute oral presentation to the class. All team members must submit a confidential team assessment form.

Each team much address the following questions:

What are the structural requirements of the implant?

Did the design-material selection enable the function to be delivered?

What was the shortcoming of this device design-material combination?

What was the root cause of failure? Could this have been avoided?

How has this problem been solved in modern-day versions of this implant?

Do the lessons from this failure teach us anything that can be utilized in other disciplines or systems?

What did you learn from this project?

Technical Report:

6 pages: Single-spaced, 12 point Times font, in .pdf format. References should be in Harvard or Vancouver format and are not included in the 6-page limit. Please hand in a hard copy in class and also e-mail a soft copy to lpruitt@me.berkeley.edu.

Elements: ***(i) executive summary***, ***(ii) background***- Provide a description and illustration of the medical deviceand its function in the body. Discuss the significance of the failure of this medical implant. ***(iii)* describe the design and materials utilized-** Describe the implant design and the materials utilized. Identify the key properties required and clearly state the goal of the implant design. *What is the structural requirement of the implant?* ***(iv) stress analysis and associated material property requirements-*** Assess the design, structural requirements and materials selection process. Evaluate trade-offs in properties and performance. *What was the shortcoming of this device design-material combination?* ***(v) root cause of failure or design evolution*** - evaluate the source of failure, and indicate whether the root cause lies in the design, material, manufacturing process, or some combination thereof. *What might have been done differently given the knowledge and resources available at the time that the implant was developed?****(vi) lessons learned***- Describe the lessons learned from this failure. *How might we carry this information forward in future designs?* ***(vii) references, (viii) Appendix- copy of at least 5 relevant archival journal papers and 2 patents that were reviewed for the project, material data sheets, supplemental information.***

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Project evaluation: Each project will be assessed for knowledge, analysis, synthesis, and approach to problem solution.

Project III: ***40% Course Worth***

Historic evolution of medical devices

Each team has been given a modern medical device that restores function to a diseased or damaged tissue, organ or joint space in the body. Each team will write up a professional report (8 pages) that addresses the historic development of this medical device. The project report should address the disease etiology that mandates the needs for the implant and should highlight the associated structural functions or requirements of the medical device. Initial designs, materials utilized, clinical outcomes, and FDA regulatory processes should be reviewed. The project report should elucidate the evolution of the particular medical device. The case study should address the need for the original implant and the structural function of the implant. Your report should describe the current trends and future directions for the specific field that utilizes this implant (orthopedics for a total hip replacement).

Each team much address the following questions:

What clinical needs mandate the use of the implant? What is the disease etiology that ultimately requires the need for a medical device?

What are the functional requirements of the tissue, organ or joint being replaced? What is the structural requirement of the implant?

What designs (and materials) were initially used in the medical implant? How have these designs and materials changed with time?

What have been the clinical outcomes for the medical device?

How is the medical device classified by the FDA? What regulatory requirements are in place for this device?

What is the current trend in this field? *Is tissue engineering a viable solution to replace the medical device in the future? Are there other alternative materials or designs being developed in the near future?*

What did you learn from this project?

Technical Report:

8 pages: Single-spaced, 12 point Times font, in .pdf format. References should be in Harvard or Vancouver format and are not included in the 6-page limit. Please hand in a hard copy in class and also e-mail a soft copy to lpruitt@me.berkeley.edu.

Elements: ***(i) executive summary***, ***(ii) statement of initial design objectives***—how has the medical device developed since its inception? How is it utilized in modern medical device applications? ***(iii) background***—discuss the disease etiology of the organ, tissue or joint that is replaced and the structural function of the medical device. What are the structural and physiological requirements of the implant?, ***(iv) regulatory issues***- how is the medical device classified by the FDA? What regulatory requirements are in place for this medical implant? ***(v) clinical performance***—review the clinical outcomes for the medical device, ***(vi) what is the current trend in this field?*** *Are there other alternative materials or designs being developed in the near future?* ***(vii) lessons learned***- what did you learn from this project? ***(viii) references, (ix) Appendix- copy of at least 5 relevant archival journal papers and 2 patents that were reviewed for the project, material data sheets, supplemental information.***

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