Massachusetts Institute of Technology MIT 2.782, HST.524 Spring 2021
Tuesdays and Thursdays, 11:00-12:30 PM
Web site:

DESIGN OF MEDICAL DEVICES/IMPLANTS

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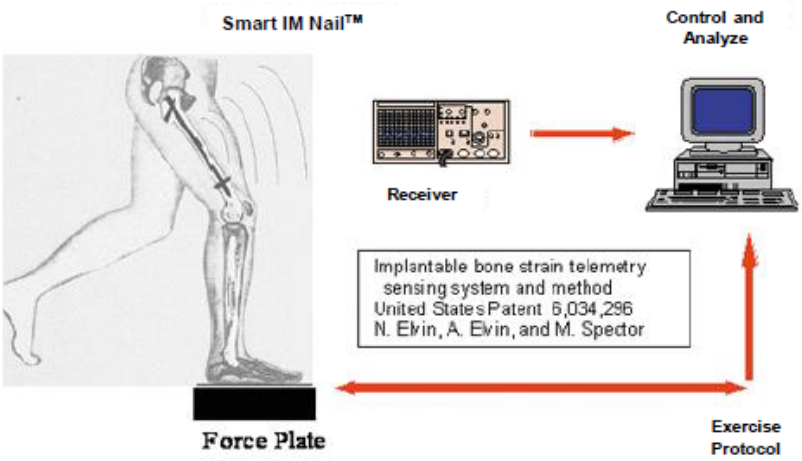
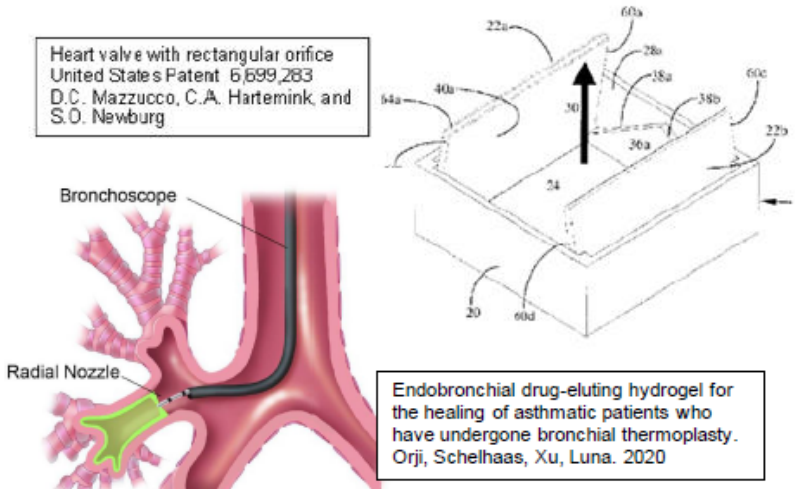
SYLLABUS

DESCRIPTION

A design subject that teaches rational approaches to the development of implantable medical devices. Students work in groups of 3 (or 4, in special cases) to develop the design for a medical device. All lecture materials will be posted on the Stellar class Website.

- Paradigm for design of medical devices/implants
  - Functional requirements
  - Effects of the device on the body
  - Effects of the body on the device
  - Benefit/risk ratio
- Principles related to: the permanent replacement of organs; and tissue engineering/regenerative medicine approaches for organ regeneration; selected issues/organs addressed through case studies
- Considerations of anatomy, histology, physiology, and pathology
- US Food and Drug Administration regulations of medical devices
- The tools available for facilitating improved healing and regeneration: biomaterials matrices, exogenous cells, and regulators (growth factors)
- How to model the clinical problem to guide the selection of the tools; "unit cell processes"





GRADING

The final grade will be based on the following:

- 20% QUIZ (Written)
- 20% Oral Progress Report/Oral QUIZ
  - 10% for Team performance
  - 10% for the individual Oral QUIZ
- 10% FDA Report (Written)
- 25% Final Oral Presentation
- 25% Final Written Report

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PREREQUISITES

Prerequisites are the three Institute requirements in chemistry, biology and physics.

TASKS

The tasks highlighted in yellow are the graded items noted above.

	Task	Due Date
1	Each student offers for discussion 1-3 options for design topic, and background/interests due	Feb 23
2	Quiz	Mar 18
3	Finalize selection of design project and team members	Mar 25
4	Oral Progress Report and Oral Quiz	Apr 13, 15
5	FDA Report due	May 11
6	Final Written Report due	May 18
7	Final Oral Presentation	May 20

DESIGN PROJECTS

The design topic will be determined by the students.

Students will work in groups of 3 or 4 people. All individuals in the group will receive the same grade for the FDA Report, the Final Oral Presentation, and the Written Design Report.

The Designs need be realistic, but the devices will not be fabricated.

Professors Yannas and Spector will allocate a fixed amount of "consulting" time to each group.

COLLABORATION AMONG STUDENTS

The written quiz on March 18 does not permit collaboration among students.

Following the Oral Progress Reports on April 13 and 15, Professors Yannas and Spector will quiz group members individually on their knowledge of their evolving design process. Students will answer with no input from their team members.

The FDA report, final oral presentation, and the final written design report require collaboration among members of a team.

GUIDELINES FOR TEAM CONSULTING WITH INSTRUCTORS

Candidate projects will be discussed in class until the March 25 deadline for the declaration of the membership of teams and the respective design topics; teams can be formed before that date and can begin meeting in their own group sessions virtually.

After March 25, teams will meet separately in consulting sessions with the Professors outside of class, with the following guidelines:

1. Prior to the Oral Progress Report, teams should meet with both Professors, for a total of about 30 minutes per team per Professor. Because the two Professors have had different experiences in the medical device area, we are asking that the teams meet with each of them. Teams will initiate and arrange meetings with Instructors (please use e-mail). Teams should bring specific questions to the consulting sessions.
2. After the Progress Reports have been submitted and 1 week before the Final Oral Presentations, teams should meet with both Professors, for a total of no more than 30 minutes per team per Professor.

QUIZ (Written)

Quiz questions will be drawn from the lectures, related to the principles and practice of medical device design. The 90-min quiz will allow open use of book, notes, and the Stellar Website.

ORAL PROGRESS REPORT/Oral QUIZ

The oral PowerPoint presentation is to be 12 minutes in length, with all members of the group participating in the presentation. The presentation is to define the clinical problem to be addressed by the device, and the current methods of treatment. The rationale and novelty of the Team's approach for the device design need to be presented. Alternative strategies for the design are acceptable at this stage.

Following the 12-min presentation, Professors Yannas and Spector will direct questions to each group member individually for up to 3 min. per member, and grade their responses. The questions could be drawn from topics presented in the lectures, as they relate to the Design. Questions also could deal with: the basic physics principle/phenomenon on which the design is based; the biology of relevant wound healing/regeneration processes; and/or the chemical formulation of the device. Each student will receive a separate grade.

FDA REPORT

One report is to be prepared by each group, dealing with the regulatory issues attendant to the device. The issues related to FDA regulation of medical devices will be presented in 2 class lectures, April 6 and 8. The device design used for the FDA Report will not necessarily be the final design. All members of the group receive the same grade.

Total length is 8 pages, $1^1/_2$ line spacing and Times New Roman 12 or equivalent font; this includes text, all images and references.

FINAL WRITTEN REPORT

The final written report is limited to 10 pages of text; figures and references are not counted in this 10-page limit; $1^1/_2$ line spacing and Times New Roman 12 or equivalent font.

FINAL ORAL PRESENTATION

The final oral PowerPoint presentation is to be 12 minutes in length, with all members of the group participating in the presentation. It will be graded by a Panel comprising the 2 Professors and about 4 other individuals (professors and other professionals) with experience with various aspects of medical devices. Details of the content and mechanics of the presentation will be discussed in class. The presentation will be followed by questions from the members of the Panel.

READING MATERIALS

- Readings posted on the Stellar class Web site:

- Reference books:
  Anatomy, Histology, Physiology, and Pathology reference texts in the library.
  Tissue and Organ Regeneration in Adults, 2015, I.V. Yannas (second edition; reference in the library).

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Lec	Date	Read*		Lecturer
I. PRINCIPLES OF IMPLANT DESIGN (WORKING PARADIGMS)				
1	Feb. 16	1	Intro to Design; Clinical Problems Requiring Implants	Yannas/Spector
2	18	3	The Missing Organ and its Replacement	Yannas
3	23	2,4,5	Principles of Design; Permanent and Absorbable Devices; **Each student offers 1-3 options for design topics, and background/interests due**	Spector
4	25	5	Elements of Applied Organ Regeneration	Yannas
5	Mar. 2	5	Devices for the Regeneration of Tissues/Organs	Spector
6	4	5	Incorporation of Molecular Regulators and Cells into Devices	Spector
	9		**HOLIDAY**	
7	11	7	Tissue Response to Medical Devices: Local and Systemic	Spector
8	16		Review; Discussion of Projects	Yannas/Spector
9	18		**QUIZ (Written)**	
	23		**HOLIDAY**	
II. FORMULATION OF PROJECTS AND REGULATORY ISSUES				
10	25		Discuss Quiz; Discuss Projects; **Finalize selection of design project and team members**	Spector/Yannas
11	30	3	Tissue and Organ Regeneration vs Scar Formation I	Yannas
12	Apr. 1	3	Tissue and Organ Regeneration vs Scar Formation II: A Clinical Application	Yannas
13	6	9	Federal Regulation of Devices I	Spector
14	8	9	Federal Regulation of Devices II	Spector
15	13		**Oral Progress Report/QUIZ (Oral)**	
16	15		**Oral Progress Report/QUIZ (Oral)**	Yannas
	20		**HOLIDAY: Patriot's Day**	
III. DESIGN SOLUTIONS IN USE				
17	22	13	Skin Regeneration	Yannas
18	27	13	Peripheral Nerve Regeneration. Using Literature Data	Yannas
19	29	12	Implants for Musculoskeletal Problems: Bone and Cartilage	Spector
20	May 4	16	Cardiovascular Prostheses: Heart Valves and Blood Vessels	F. Schoen
21	6		Mechanical Forces in Skin Regeneration	Orgill
22	11	14	Biomaterials/Devices for Treating Stroke and Spinal Cord Injury **FDA REPORT Due**	Love/Spector
23	13	14	Biomaterials/Devices for Treating Retinal Diseases	Dromel
24	18	19	Commercialization of Medical Devices **WRITTEN DESIGN REPORT due**	Yannas/Spector
25	20		**Final ORAL PRESENTATIONS (11:00-1:00)**	Mock FDA Panel

*** Readings: Numbers refer to chapters on the Web site. Optional readings on regeneration in Yannas IV, *Tissue and Organ Regeneration in Adults*, 2015 (second edition).**