MATSCEN 7193.02, Additive Manufacturing for Biomedical Devices

Spring 2019 Orig *10/11/18; updated 12/21/18*

Instructor: Dr. David Dean (David.Dean@osumc.edu; 614-688-9044)

Credits: 3 credits

Class numbers:

On-campus enrollment: MATSCEN 7193.02 (#10829) “Individual Studies”

Online enrollment: MATSCEN 7193.02 (#10830) “Individual Studies”

Time of offering: Full term SP19, T-Th, 2 x 80-min lectures (no lab), 3:00-4:20

Location: BI668

Description: Survey of Additive Manufacturing (AM) patient data acquisition and medical device Computer Aided Design (CAD), medical research and clinical grade AM materials and AM fabrication methods, quality assurance/management systems and regulatory (FDA) approval process.

Prerequisites: Graduate standing in MGEL, MATSCEN, WELDENG, BME, MAE, or ISE, or permission of instructor

Textbook: No text, supplemental materials will be provided.

Course Goals:

1. Understand the requirements of 3D patient data acquisition, patient-specific CAD and mechanical modeling (i.e., Virtual Surgical Planning), and intra-operative guidance.
2. Understand how 3D fabrication technologies are used in biomedical research.
3. Understand how 3D fabrication technologies are used in the clinic.
4. Understand range of criteria used to design, validate, and use biocompatible, 3D printable, materials.
5. Understand basics of the regulatory process including Quality Assurance (QA) and/or Quality Management Systems, GLP assessment, and GMP production.

Topics:

1. Data Acquisition and Design 5 lectures
    a. Lecture 1-2: 3D image acquisition and processing (slice and surface scanning); medical and industrial imaging
    b. Lectures 3-4: 3D image preparation for 3D printing (CAD); Mechanical Modeling for biological applications
    c. Lecture 5: file set up for 3D printing
2. Materials for AM of Biomedical Devices 9 lectures
    a. Lectures 6-8: biocompatible inert and resorbable solid-cured polymers and hydrogels (photocrosslinking, sintering, extrusion)

b. Lectures 9-10: biocompatible inert and resorbable ceramics
c. Lectures 11-14: biocompatible intert and resorbable metals

3. Fabrication of AM Biomedical Devices 7 lectures
    a. Lectures 15-16: CNC, Electrospinning, FDM
    b. Lecture 17: binderjetting, bioprinting, bioplotting
    c. Lecture 18-19: Vat Photocrosslinking (polymers, ceramics: DLP, LCD)
    d. Lecture 20-21: Powderbed fusion (polymers, ceramics, metals)
4. Regulator of AM Biomedical Devices 7 lectures
    a. Lectures 22-23: biocompatibility in vitro (cytotoxicity) and in vivo (small animal models)
    b. Lectures 24-25: large animal models
    c. Lectures 26-27: FDA (Presubmission, IDE, IND, 510k, PMA)
    d. Lecture 28: Translation to the Clinic

Grading:

Quiz: 15%
Midterm: 30%
Final: 30%
Project: 25%

MATSCEN 7193.02 - Biomedical Device Additive Manufacturing – Spring 2019
Final Project Statement

Instructions

1) Logistics:

(a) Project count for 25% of each student's grade.

(b) Teams consist of two-three students. Students may pick their partner. As soon as you have found your partner, email Prof. Dean your partner assignment so that he understands the layout of the team members.

(c) Project submission is in the form of both an oral presentation in class and the submission of all written and coding work. Oral presentations will be held in class on Apr. 11, 16, and 18, 2019. Presentations should be designed to be 30 minutes long with 5 minutes for questions. The written report will be submitted at the time of presentation. Codes or instruction manuals are to be neatly written and emailed to Prof. Dean before presenting your presentation. It is expected that the presentation is a significantly condensed version of all the work you did for the project.

2) Project Topics:

(a) Ultimately the choice of the project is at the discretion of the team. It is OK to submit draft proposals for feedback before the deadline for final version project topics. Please submit a one paragraph description of your final project topic to Prof. Dean for approval by the end of class on February 14, 2019.

(b) Regardless of the project, the report and presentation will be evaluated on the following components. There are two basic tracks to choose from:

Track 1) Description of the physics of an existing or a new Biomedical AM material and/or process that has not yet been used for Biomedical AM. Propose an AM experiment that would validate the link between the device design (CAD), mechanical analysis/simulation, fabrication process, and post-process in vitro validation prior to its advancement to biocompatibility and in vivo testing.

Track 2) Describe an existing or propose a new Biomedical AM device that is clinically relevant has not previously been confirmed safe and effective for use in patients. Explain the clinical relevance and perform a complete analysis of the assumed fabrication physics and resulting device material properties. Propose an animal model and/or human clinical trial study that would validate the safety and efficacy (regulatory issues) of your proposal.

(c) Regardless of choice of track, each project must have a simulated demonstration component that results in a QA plan for design (CAD and mechanical analysis) and fabrication (e.g., material authentication; process parameters). Students are encouraged, if possible, to choose a final project topic that will complement their graduate school research project; students are not allowed to simply take a conference paper or journal paper they have written and use it as their final project. Ideally, the project is so well done that the project can be converted into a new conference and/or journal paper.

3) Track 1 and 2 Components:

(a) Description of an Existing AM process: Choose an existing AM process and describe one or two aspects of the physics of this process. From this description, devise a set of experiments designed to prove or disprove some of your assumptions on the physics. Assume that you have unlimited experimental resources. Use appropriate simulations to perform a mock experiment.

(b) Devise a new AM process: Devise a new type of AM process. Provide a rationale for this new type of AM process. Provide a detailed vision for the fundamental mechanisms in which material is added in this new AM process. Postulate what physical principles will be important for this new process and perform preliminary simulations on one or two aspects of the physics of this process.

4) Evaluation rubric:

(a) Rationale and Goals for the study of the Biomedical AM material and process (Track 1) or the development of a new Biomedical AM device (Track 2) (15 pts)

(b) Quality of the definition of the theoretical framework and/or mathematical description of the process and methods (25 pts)

(c) Quality of a simulated experiment: definition of assumptions, definition of underlying AM and material physics, definition of the specific test scenarios simulated (30 pts).

(d) Correctness of instructions, equations, and/or code. All code and/or procedural steps will be demonstrated by the team during their presentation (20 pts).

(e) Discussion, Conclusions, and Next Steps (include chemical, mechanical, and/or regulatory testing if useful) of the study (10 pts).

Mental Health Statement

As a student you may experience a range of issues that can cause barriers to learning, such as strained relationships, increased anxiety, alcohol/drug problems, and feeling down, difficulty concentrating and/or lack of motivation. These mental health concerns or stressful events may lead to diminished academic performance or reduce your ability to participate in daily activities. The Ohio State University offers services to assist you with addressing these and other concerns you may be experiencing. If you or someone you know are suffering from any of the aforementioned conditions, you can learn more about the broad range of confidential mental health services available on campus via the ***Office of Student Life Counseling and***

Consultation Services (CCS) by visiting ccs.osu.edu or calling 614-292-5766. CCS is located on the 4th Floor of the Younkin Success Center and 4th Floor of the PAES Building. 24 hour emergency help is also available through the National 24/7 Prevention Hotline at 1-800-273-TALK or at suicidepreventionlifeline.org.

Disabilities/Accommodations Statement
Any student who feels s/he may need an accommodation based on the impact of a disability should contact the OSU Office for Disability Services for assistance in verifying the need for accommodations and developing accommodation strategies. Students with disabilities that have been certified by the Office for Disability Services will be appropriately accommodated, and should inform the instructor as soon as possible of their needs and have any necessary forms signed by the instructor as soon as possible. The Office of Disability Services is located in 150 Pomerene Hall, 1760 Neil Ave. (292-292-3307, TDD 292-0901; www.ods.osu.edu

Student Conduct Statement
Students are expected to conduct themselves in a professional manner throughout the course. Students are expected to appreciate diversity, and to conduct themselves appropriately with members of the opposite gender and/or persons from other cultures. Any form of sexual harassment or intimidation will not be tolerated. The University's Code of Student Conduct and the Sexual Misconduct, Sexual Harassment, and Relationship Violence Policy may be found at: http://studentlife.osu.edu/csc/,

http://hr.osu.edu/public/documents/policy/policy115.pdf.

Academic Integrity (Academic Misconduct) Statement
The Ohio State University's Code of Student Conduct (Section 3335-23-04) defines academic misconduct as: "Any activity that tends to compromise the academic integrity of the University, or subvert the educational process." Examples of academic misconduct include (but are not limited to) plagiarism, collusion (unauthorized collaboration), copying the work of another student, and possession of unauthorized materials during an examination. ***Ignorance of the University's Code of Student Conduct is never considered an "excuse" for academic misconduct***. All students should review the Code of Student Conduct (http://studentlife.osu.edu/csc/), specifically, the sections dealing with academic misconduct. **If an instructor suspects that a student has committed academic misconduct they are obligated under the Faculty Rules and the policies of the Committee on Academic Misconduct (COAM) to report their suspicions to the COAM.** The COAM home and resource pages are:

http://oaa.osu.edu/coam.html and http://oaa.osu.edu/coamresources.html