UTD	**Course**	MECH 4V95.004/6V49.004
	Course Title	*Biomechanics for Medical Devices*
	Professor	Kristin S. Miller, Ph.D.
	Term	Spring 2024
	Meetings	
Office Phone	972-883-4679	
Office Location	NSERL 4.706	
Email Address	Kristin.Miller@utdallas.edu	
Office Hours		
Other Information		
Pre-requisites, Co-requisites, & other restrictions	Junior or above standing. Basic concepts of undergraduate-level calculus, matrix algebra, differential equations, and mechanics of materials will be necessary	
Course Description	This course introduces the fundamental mechanical engineering, materials science, and biological principles that impact engineering design of medical devices, biomaterials, and tissue-engineered products to advance human healthcare. Topics addressed will include biosolid and biofluid mechanics concepts applied to native biological tissues, medical devices, and tissue engineering strategies. This include, but are not limited to: Nonlinear structure-property relationships of materials and biological tissues, biosolid and biofluids methods to determine and evaluate design criteria relevant to human conditions, physical phenomena at biological interfaces, degradation of materials, and kinetic states of biological tissues and implants. Mechanics concepts will include stress, motion, balance of mass, balance of linear momentum, and their constitutive relations for both permanent and resorbable medical devices.	

Concurrent Course Justification and Rationale	For the graduate students, additional Student Learning Outcomes are included that require critical analysis, synthesis, and communication of both basic knowledge and advanced application of their knowledge compared to undergraduate learning outcomes. Specifically, graduate students are required to complete a research proposal that clearly summarizes the state of the field, including critical analysis and identification of limitations within the field, and then to subsequently propose design criteria to overcome these limitations with robust justification. Simultaneously offering this course to both undergraduate and graduate students provides additional opportunities for students to work in teams of various backgrounds to establish goals, plan tasks and meet objectives while using engineering judgement to draw conclusions, thereby meeting multiple ABET program level outcomes (c.f., outcomes 5 and 6). Further, it provides additional opportunities for students to take project-based electives that they are interested in throughout their academic career to aid in progress towards graduation.

Graduate Level Learning Outcomes	**(1)** Students will learn the fundamental principles of tissue engineering and medical devices, including concepts of tissue and biomaterial scaffold structure-function relationships and functional strategies for tissue engineering and regenerative medicine. a. *Relevancy to ME: Students will be introduced to manufacturing techniques for permanent and degradable materials, selected material applications, and design tradeoffs in these systems. Students will understand how variations in material selection, chemical and structural properties, and manufacturing dictate material properties, with a focus on nonlinear and anisotropic materials.* **(2)** Students will apply biosolid and biofluid mechanics principles, such as stress analysis, equations of motion, balance of mass and linear momentum, and validation of constitutive relations to evaluate medical devices and native biological tissues. a. *Relevancy to ME: Students will build upon their solid and fluid mechanics fundamentals to perform stress and deformation analysis of elements subjected to multiaxial loading conditions, including tension, compression, torsion, and pressure loads. Students will leverage constitutive relations to quantify local stress concentrations.* **(3)** Students will learn how to identify and prioritize design criteria for biomedical applications to improve healthcare, including evaluating and critiquing the functionality, performance, and safety of biomedical device, as well as assessing which variables may contribute to biological variability for robust study design. a. *Relevancy to ME: Students will build on prior knowledge in mechanical engineering design and mechanics of materials to prioritize product design requirements, evaluation of stress and deformations in materials with complex geometries under multiaxial loads, and selection of optimal product manufacturing to meet those design criteria.* **(4)** Students will apply fundamental principles of functional tissue engineering to explore contemporary issues such as identifying appropriate degradation profiles and kinetic design criteria for resorbable medical devices leveraging balance relations, constitutive relations, and stress analysis. a. *Relevancy to ME: Students will evaluate stress and deformations at interfaces of two different materials. Students will leverage introductory*

	constrained mixture theory to quantify evolving stress profiles in dynamic materials, including both production of new material and degradation of resorbable materials to prevent gross material failure. **(5)** Students will critically analyze, develop, and present a unique research idea leveraging biomechanics to advance medical device design. a. *Relevancy to ME: Students will identify a critical technology gap and then design a proposed solution to an open-ended mechanical engineering design problem related to healthcare grounded in mechanics of materials and nonlinear elasticity.* **(6)** Students will demonstrate the ability to effectively communicate and justify design criteria for medical devices. a. *Relevancy to ME: Students engineering communication skills and use of writing as a critical-thinking and learning tool will be refined and iteratively evaluated.*
Program Level Outcomes	Student Outcomes (ABET Outcomes) criteria in this course are: **6 pts Outcome (1): an ability to identify, formulate, and solve complex engineering problems by applying principles of engineering, science, and mathematics** **1 pt Outcome (5): an ability to function effectively on a team whose members together provide leadership, create a collaborative and inclusive environment, establish goals, plan tasks, and meet objectives** **2 pts Outcome (6): an ability to develop and conduct appropriate experimentation, analyze and interpret data, and use engineering judgement to draw conclusions.**

<table>
<tr><td>Relevance to Bioengineering and Program Specific ABET Criteria for Bioengineering</td><td>If any students from Bioengineering choose to take the course, then the BME ABET Program Specific Criteria are as listed below:
3 pts (PGM-A): Applying principles of engineering, biology, human physiology, chemistry, calculus-based physics, mathematics (through differential equations), statistics, and fluid mechanics
1pt (PGM-B): Solving bio/biomedical engineering problems, including those associated with the interaction between living and non-living systems
5 pts (PGM-C): Analyzing, modeling, designing, and realizing bio/biomedical devices, systems, components, or processes

Concepts relevant to bioengineering fundamentals include:
• Introduction to extracellular matrix biology to understand how changes in biological tissue structure, physical and chemical properties dictate the nonlinear response of biological tissues.
• Introduction to tissue kinetics and how traditional materials implanted within the human body may degrade over time due to repetitive mechanical loads, inflammatory response, and bodily fluids etc.</td></tr>
<tr><td>Relevance to Mechanical Engineering</td><td>This course addresses topics relevant to the mechanics of materials and design innovation and manufacturing tracks. Concepts related to these mechanical engineering fundamentals include:
• Build upon solid and fluid mechanics fundamentals to perform stress and deformation analysis of elements subjected to multiaxial loading conditions, including tension, compression, torsion, and pressure loads.
• Understand how variations in material selection, properties, and manufacturing dictate material properties, with a focus on nonlinear and anisotropic materials
• Leverage constitutive relations to quantify local stress concentrations in nonlinear materials and material interfaces
• Introduction to degradable scaffold manufacturing techniques, selected scaffold applications, and design tradeoffs
• Critically evaluate and prioritize design criteria to minimize compliance mismatch and gross failure at material interfaces</td></tr>
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Cross-disciplinary Learning Benefits to Students	This course seeks to introduce fundamental bioengineering concepts to ME students, while building on ME fundamentals of mechanics of materials, materials science, and device design to facilitate the rational-design and evaluation of complex, real-world problems related to healthcare and the medical device industry. By integrating bioengineering fundamentals, the course provides real-world applications and motivation to master stress and deformation analyses in materials with complex geometries, under complex loading conditions, that exhibit nonlinear, elastic and viscoelastic behavior. Furthermore, it will build student confidence of cross-disciplinary applications of their ME fundamentals while reinforcing classic engineering design approaches to complex problems. Lastly, it will provide opportunities to connect fundamental mechanics of materials concepts to extracellular matrix biology to understand why and how fiber-matrix composites dictate certain nonlinear elastic responses, as well as practice in engineering communication to articulate and justify design criteria to cross-disciplinary audiences. In summary, by providing these cross-disciplinary opportunities, students will exponentially advance their abilities to function effectively in teams while clearly communicating their ME knowledge to equip students for cross-disciplinary careers. Students will be particularly well equipped to work in the medical device and biotechnology industries.
Required Texts & Materials	Open Source Chapter from Alberts et al., Molecular Biology of the Cell 4th edition, https://www.ncbi.nlm.nih.gov/books/NBK26810/ Butler et al., 2000, Functional tissue engineering: the role of biomechanics: https://www.ncbi.nlm.nih.gov/pubmed/11192376 (Links to an external site.). Chan & Leong, 2008, Scaffolding in tissue engineering: general approaches and tissue-specific consideration: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2587658/ (Links to an external site.). Additional reading assignments for journal clubs will be added to the calendar. Several videos and online resources from open access sources will be used throughout the semester to supplement lectures.

From the percentage points, letters grades will be assigned accordingly

Grading:

For **graduate** students, all graded assignments and examinations will be weighted as follows:

Attendance and active participation in discussions, case studies, brainstorms, and engagement for motivation	10 %
Homework and in-class activities and problem sets	20 %
Video, Reading, and Review Quizzes	5 %

Fundamentals midterm exam	15 %
Case study analysis and summaries	10 %
Graduate research proposal	10 %
Analysis of medical device reports	10 %
Analysis of medical device final poster presentation	20 %
TOTAL	100 %

Final grades will be assigned according to the following thresholds:

A+	97 - 100%	B+	87 – 89.9%	C+	77 – 79.9%	D+	67 – 69.9%
A	93 - 96.9%	B	83 – 86.9%	C	73 – 76.9%	D	63 – 66.9%
A-	90 - 92.9%	B-	80 – 82.9%	C-	70 – 72.9%	D-	60 – 62.9%
						F	<60.0

For graduate students:

Attendance and Active Participation in Discussions, Case Studies, Brainstorms, Engagement for Motivation. Students will be required to attend class, participate actively in discussions either in class live or via e-learning discussion board to engage with the instructor, peers, and course content. These discussions include follow-ups to brainstorms, learning activities, case studies, and short videos. Frequently, brainstorming activities will be required, wherein students can work in groups but must submit unique, individual summaries of the brainstorm written in their own words. This component will count for 10% of the final grade.

Homework and in-class Learning Activities and problem sets. Most modules will feature at least 1 homework assignment to be completed at home. These activities will be assigned to both reinforce and expand upon lecture/discussion/video material in-class and on e-learning. The assignments may include brief summaries, literature searches, designing assessment, short answer reflections, selecting and justifying design criteria, and/or problem sets. Assignments must be uploaded to e-learning as either text, doc/docx, or pdf files unless otherwise specified (e.g., video or podcast). No credit will be given for assignments turned in late. This component will count for 20% of the final grade.

Video, Reading, and Review Quizzes. Reading assignments, video assignments, and lecture material may also include short online quizzes. These low-stake quizzes serve as both learning activities and assessment opportunities to reinforce and solidify student engagement and retention of course material. This component will count for 5% of the final grade.

(~Midterm) Exam. Assessment of fundamental course material before moving on to case studies and contemporary applications. This component will count for 15% of the final grade.

Case Study Analyses and Summaries. Students will summarize and present the relevant biological and technical concepts of cutting-edge research in biomechanics of tissue engineering, biomaterials, and regenerative medicine to their peers. These presentations must be both instructive and generate discussion. Students must upload either text, word, pdf, video, or podcast summaries of their case studies. The case studies will allow students to apply their knowledge of fundamental concepts to

understand the current state-of-the-field techniques. This component will count for 10% of the final grade. **Graduate Research Proposal.** Students will identify a novel research area in the field of biomechanics of medical devices and clearly communicate a research proposal, including robust design criteria. The research proposal will consist of 3 total pages + references. This will include 1 NIH style Specific Aims page detailing a 2-3 year project at the cutting edge of biomechanics in tissue engineering and regenerative medicine and then a 2 page research strategy. The topic can either be a basic science of technological advance to the field but must be novel, unique, and the independent work of the graduate student. The proposal must include robust description and justification of the device design criteria that clearly maps to the medical device requirements. This component will count for 10% of the final grade. **Final Research Project to Analyze a Medical Device (20%) and Checkpoint Reports (10%).** One research project will be assigned in order to emphasize specific applications and for students to critically evaluate an existing medical device. Students will be assigned to groups according to common interests near the first one-third of the semester. The device selected must be either on the market or in clinical trials. Groups will be required to turn in brief progress reports throughout the latter half of the semester, which will account for 10% of the final grade. Then, teams will prepare a poster presentation and a poster session will occur during the final exam period. (Or in the event that an in-person live poster session is not possible, a 7 minute video presentation due at the time of the final exam is the alternative option with prior instructor approval in writing at least 3 weeks before final exam date). This presentation should articulate the key findings to a general lay audience. Further specific details pertaining to progress reports and presentations will be provided. The poster session final will account for 20% of the final grade.	
Class Materials	The instructor may provide class materials that will be made available to all students registered for this class as they are intended to supplement the classroom experience. These materials may be downloaded during the course, however, these materials are for registered students' use only. Classroom materials may not be reproduced or shared with those not in class, or uploaded to other online environments except to implement an approved Office of Student AccessAbility accommodation. Failure to comply with these University requirements is a violation of the Student Code of Conduct.
Class Attendance	The University's attendance policy requirement is that individual faculty set their course attendance requirements. **Regular and punctual class attendance is expected.** Students who fail to attend class regularly are inviting scholastic difficulty. In some courses, instructors may have special attendance requirements; these should be made known to students during the first week of classes. Faculty have the discretion to set an attendance policy for their in-person meetings, but the absences due to COVID-19 will not be counted against a quarantined student.
Class Participation	Regular class participation is expected. Students who fail to participate in class regularly are inviting scholastic difficulty. **A portion of the grade for this course is directly tied to your participation in this class.** It also includes engaging in group or other activities during class that solicit your feedback on homework

	assignments, readings, or materials covered in the lectures (and/or labs). Class participation is documented by faculty. Successful participation is defined as consistently adhering to University requirements, as presented in this syllabus. Failure to comply with these University requirements is a violation of the Student Code of Conduct.
Class Recordings	Students are expected to follow appropriate University policies and maintain the security of passwords used to access recorded lectures. Unless the Office of Student AccessAbility has approved the student to record the instruction, students are expressly prohibited from recording any part of this course. Recordings may not be published, reproduced, or shared with those not in the class, or uploaded to other online environments except to implement an approved Office of Student AccessAbility accommodation. Failure to comply with these University requirements is a violation of the Student Code of Conduct. The instructor may record meetings of this course. These recordings will be made available to all students registered for this class if the intent is to supplement the classroom experience. If the instructor or a UTD school/department/office plans any other uses for the recordings, consent of the students identifiable in the recordings is required prior to such use unless an exception is allowed by law.
Life Policy	Life happens and personal situations can introduce complications, especially during a pandemic. Please talk to the instructor if you need assistance regarding class or class assignments. The instructor wants you to succeed and early communication is key.
Make-up Exams	Missed exams or project presentations, etc without advanced, written notice to the instructor's UTD email will received a zero. Missed exams/presentations with prior, written notification via UTD email for documented reasons (E.g., illness with doctor's note) can be replaced by a make-up assignment. The email reply documenting acceptance of reason for missing or rescheduling the assignment will set the time and nature of the make-up.
Extra Credit	Occasionally extra credit assignments, mainly opportunities for expanded analysis and reflection of brainstorms and case studies will be provided. These will be communicated in class and posted on eLearning with respective due dates, credit possible, and which learning assessment the points would be added to.
Late Work	All assignment due dates will be listed on eLearning. Assignments turned in after the due date and time will be assessed a penalty of 20% per 24 hrs. Email the assignment to the instructor's UTD email directly if you experience or expect an error submitting an assignment on eLearning. Late work will not be accepted without the prior consent of the instructor, with allowances for exceptional documented circumstances. In such circumstances, late work will be dealt with on a case by case basis. Contact the instructor by UTD email as soon as practical if these circumstances may apply to you. The email reply documenting acceptance of reason and documentation for late work will set a new deadline.
University Closure	In the event of emergency university closure due to weather-related or other reasons, all assignments will be canceled and/or moved to

	other due dates when the university re-opens. Please keep in mind that in event of power outages etc, the instructor likely also does not have access to change assignment due dates. Noting that assignments will only be due when the university is open.
Classroom Citizenship	Be respectful of your peers at all times. Keep discussion comments (both in person and online discussion board) constructive and on-topic.
Cheating	Do not cheat. Do not copy assignments, do not post assignments or make answers public, do not upload research data provided to complete projects, do not plagiarize, do not use the internet or outside sources when you are not allowed to (and ensure that you properly reference them when you are allowed to). If the instructor suspects academic dishonesty, they will follow UTD procedures with the Office of Community Standards and Conducts (OCSC) from which point forward the instructor will no longer be involved in the investigation or results. The instructor will not notify a student of a report to OCSC, nor will they discuss pending investigations with the student.
Comet Creed	*This creed was voted on by the UT Dallas student body in 2014. It is a standard that Comets choose to live by and encourage others to do the same:* *"As a Comet, I pledge honesty, integrity, and service in all that I do."*
Academic Support Resources	*The information contained in the following link lists the University's academic support resources for all students.* *Please go to http://go.utdallas.edu/academic-support-resources.*
UT Dallas Syllabus Policies and Procedures	*The information contained in the following link constitutes the University's policies and procedures segment of the course syllabus. Please review the sections regarding the credit/no credit grading option and withdrawal from class.* *Please go to http://go.utdallas.edu/syllabus-policies for these policies.*
Technical Requirements	In addition to confident level of computer and internet literacy, certain minimum technical requirements must be met to enable a successful learning experience. Please review the important technical requirements on the Getting Started with eLearning webpage.

The descriptions and timelines contained in this syllabus are subject to change at the discretion of the Professor. List of topics in order of appearance listed below.

1. Introduction to Tissue Engineering and Regenerative Medicine: Why Do Biological Tissues Not Always Heal?
    a. What are Medical Devices
    b. What is Tissue Engineering
    c. What is Regenerative Medicine
    d. What are Biomaterials
    e. Potential definitions of Biomechanics and Mechanobiology
2. General Anatomy and (Patho)Physiology
    a. Biological Tissue Equilibrium (Homeostasis) and Key Physiological Function(s)
    b. How do Constraints such as Biological Age Contribute to Tissue Equilibrium and Dynamics and Need for Medical Devices?
3. Establish Theoretical Framework: How to apply nonlinear elasticity and fluid mechanics to the human body
    a. What is Functional Tissue Engineering? How do we apply 1st Principles of Mechanical Engineering to Biology?
    b. Mechanics of Materials Review
        i. Application to *Dynamic* Nonlinear Soft Materials
    c. Biofluid Mechanics Review
        i. E.g., Blood flow and Newtonian vs non-Newtonian assumptions
    d. Fluid-Solid-Interactions
    e. Examples across medical devices of why and how local stress (normal and shear) are critical for biological tissues to maintain equilibrium
4. General Biology of the Extracellular Matrix and Primarily Building Blocks of Biological Tissues
5. Structure-Function Relationships and Functional Tissue Engineering
    a. How to Identify, Evaluate, and Prioritize Design Criteria
    b. Investigation of constitutive relations for medical devices and biological tissues
6. Scaffolding and Design Criteria for Health and Medicine
    a. Biosolid and Biofluid mechanics analysis of polymer or biological scaffolds
    b. Constitutive equations to describe degradable scaffolds
    c. Constitutive equations to describe neotissue formation
7. Wound Healing and the Foreign Body Response
    a. Design Criteria to Tune and Control Foreign Body Response
8. How to Design Experiments that Consider all Key Components of Biological Variability, Diversity, and Biological/Anatomical Constraints
9. Communication in an Interdisciplinary Space and Putting Together a Professional Poster Presentation
10. Case Studies:
    a. Principal Investigators
    b. Peer-Reviewed Articles
11. Critique and next-steps for existing medical devices