

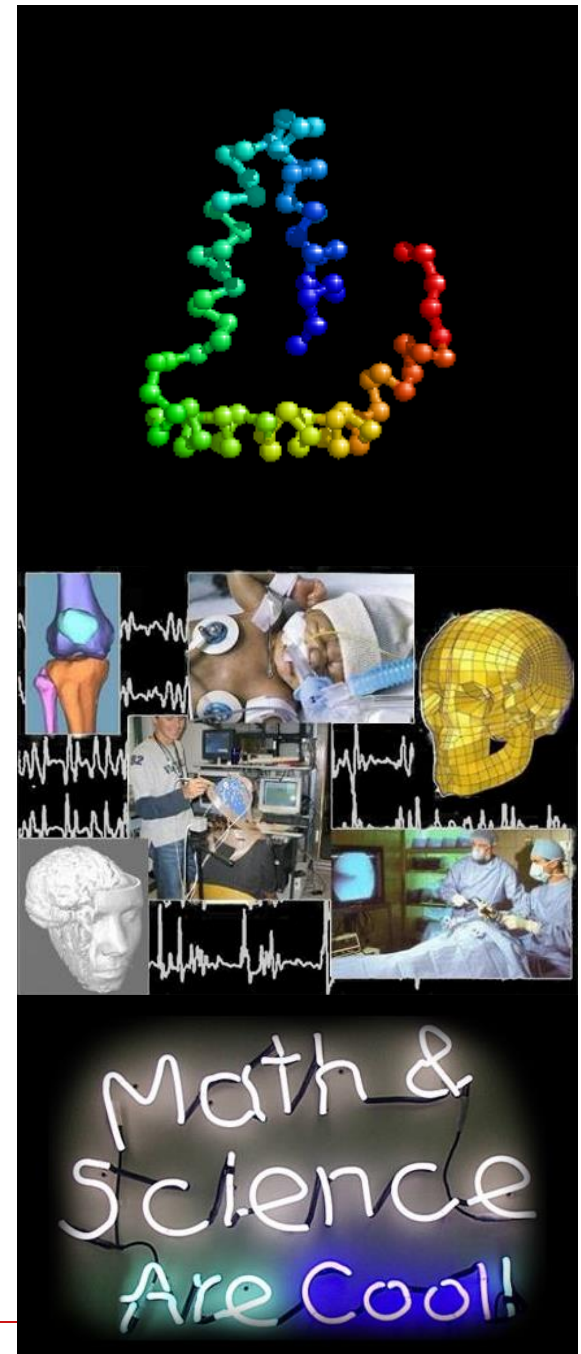


Overview & Introduction

BME 450: Biomedical Engineering Design I

Why do we care about BME design?

- Unlimited number of potential applications for biomedical engineering design
- Engineering can be used to solve challenging design problems
- There is a lot of math and science used
- You can make a lot of money in design
- This course is arguably the most important course for BME students
 - Med school: you have a medical device invention to your credit...patents
 - Grad school: you learn about clinical research and project management
 - Industry: you get practical training on design process, regulatory matters, and problem-solving reality of an engineering profession



Outline for Today

- Why do we care about BME design?
- Quick review: who am I?
- Potential projects
- Course layout: proposals...needs assessment...product development...testing
- Answer your questions!

Quick review: who am I?

- Originally from Florida
- B.S. in Engineering Science from University of Florida in 1996
- Biomedical Engineer for Computer Motion, Inc.
- M.S. in Biomedical Engineering and Ph.D. in Mechanical Engineering from University of Florida in 2003 and 2006
- Postdoc & Engineering Research Associate in Bioengineering at Stanford until 2009
- Associate Professor in Biomedical Engineering



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Potential Projects

- **Safety Trach.** Patients with tracheostomies are at risk for complications and death if their tracheostomies becomes blocked with secretions. This project would detect problems where air stops moving through the tracheostomy due to blockage and sets off an alarm to alert caregivers.
- **Fitted Heater.** Patients sometimes develop hypothermia. A fitted “blanket” with select access to the patient without removing the whole device.
- **Hernia Mesh Explant Analysis.** A patient’s mesh undergoes complex and highly variable reactions in the body. A mesh explant and analysis process is needed to gain information and apply it to the development of new types of hernia meshes that would minimize the likelihood of these kinds of reactions in the body.

Potential Projects

- **Infant Stimulus for Apnea of Prematurity.** A 3-part system to sense breathing, detect if apnea of prematurity is occurring, and provide a stimulatory response to the infant.
- **Wireless Heart Rate Monitor.** A wireless solution to continuously measure heart rate of newborns and automatically notify staff if a problem is detected.
- **Innovative Manikin Storage System.** Healthcare simulation centers possess a fleet of full-body, heavy manikins which are used to simulate healthcare scenarios for education purposes. A storage system for up to 8 manikins is needed to efficiently store them when not in use and assist staff when moving them into place on the patient beds when needed.
- **Wound Camera.** Large wounds often have small openings on the surface and it is difficult to determine what is going on inside the wound.

Potential Projects

- **Deep Wound Measurement Device.** Design a low tech instrument that can measure the volume of deep wounds.
- **Improved Personal Protective Equipment.** Gowns, gloves, and respiratory personal protection equipment (PPE) is prone to self-contamination during removal. New approaches to PPE, or a human factors approach, is needed to ensure safety.
- **Bioburden Precleaning Device.** Orthopedic instruments need "precleaning" to remove bioburden (bone and tissue fragments) before being autoclaved.
- **Low Temperature, Long Lasting Sterilization.** Infections have been linked to inadequately reprocessed special instruments, such as flexible bronchoscopes. New techniques and technology is needed to improve current disinfection and reprocessing machines.

Potential Projects

- **Ocular Emergencies Task Trainer.** Create a task trainer that can mimic an eyeball (round, fluid-filled structure) that you can practice foreign body removal. The task trainer should also have a head with orbits so that a lateral canthotomy can also be performed.
- **Pediatric Chest Tube Model.** Create a task-trainer that a learner can practice chest tube insertion that is a neonate and/or infant. Current available adult chest tube trainers have expensive replaceable inserts. Inserts for the proposed pediatric chest tube trainer would have easy to replace, low-cost inserts.

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- Two-semester course
- List of potential projects; team formation
- Each team progress through 5 phases
 1. Project proposal
 2. Design concepts
 3. Design for manufacturing
 4. Manufacturing
 5. Qualification
- About 30 controlled deliverables (i.e., homework)

team proposals, project planning, scheduling, needs assessment, product requirements, competitive landscape and patent review, business risks, design concepts, and phase reviews

detailed manufacturing specifications, biomaterials review, supplier identification, product feasibility, issues tracking, manufacturing planning, bill of materials, product risks, qualification protocol, IP disclosure, process validation planning, regulatory review, design history file audit, lessons learned, and phase reviews

Outline for Today

- Why do we care about BME design?
- Who am I?
- FUTURE for Team-Based Design in BME Program
- Potential projects
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- **Answer your questions!**