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Roadmap to Early-Stage Medical Device Design through Experiential Learning and Role-Play

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Abstract

Purpose: Biomedical engineers that have the ability and skill sets to comprehend and retain basic anatomy and physiology (A&P) knowledge, apply fundamental engineering principles, use critical thinking, and communicate effectively across multiple disciplines to facilitate successful development and clinical translation of medical devices. The authors created an undergraduate medical device design course that follows a roadmap for developing novel devices and/or innovative technology from concept to clinical product with the course focusing on the early-stage of the development process.

Methods: A holistic approach is taught from the unique perspective of inventors, investors, and surgeons (IIS) by integrating interactive presentations, guest lectures, labs, field trips, and role-playing activities into a 15-week curriculum and meets ABET student learning objectives. Individual assignments require oral presentations and written reports that mimic project leaders on design teams, and group assignments are completed through IIS role-playing. These activities culminate with individual student design projects that help build self-confidence in their ability to successfully jump into and navigate the medical device development process. This is accomplished by identifying a clinical need, formulating an innovative concept, defining design criteria, fabricating a prototype to demonstrate proof-of-concept, bench testing to demonstrate feasibility, completing an invention disclosure, making an elevator pitch with constructive classroom critique, and writing an executive summary and detailed report emulating a NIH SBIR Phase I grant.

Results: Course effectiveness was demonstrated by: (1) 204% improvement in A&P knowledge, (2) positive role-playing evaluations (98.7% of students reporting that it was a useful educational experience, written feedback), and (3) favorable course evaluations.

Conclusions: A roadmap for early-stage development of medical devices using a holistic, experiential learning approach is presented to prepare undergraduate bioengineering students for future healthcare careers as engineers, scientists, clinicians, and/or entrepreneurs.

Keywords

biomedical engineering, experiential learning, undergraduate, device, design

Introduction

Role of the Biomedical Engineer

The history of engineering education in the United States dates back to the separation from England during the American Revolution, when Congressman John Adams recognized the need for a school of engineering to support military efforts, manufacturing, and civil infrastructure (Grayson, 1980, Hazarika et al., 2019), the latter of which was being accomplished either by Americans with no formal training or foreign-educated engineers (Mann, 19; Reynolds, 1992; Lee, 1963). Adams wrote a letter to General William Heath in 1776 that read in part:

> *Engineers are very scarce, rare and dear. We want many, and Seem to have none. I think it high Time We should have an Academy for their Education. (Klosky & Klosky, 2013; Smith 1976).*

General George Washington himself was a talented surveyor but similarly with no formal engineering training and recognized this need, thus leading Congress to establishing the Military Academy at West Point in 1802, where the cadets would provide military support while also assisting with public works (Grayson, 1980). The Academy's educational structure was modelled after the French Ecole Polytechnique's curriculum which emphasized civil engineering and design through didactic instruction (Grayson, 1980, Reynolds, 1992). Advances in transportation, communication, agriculture, and civil infrastructure facilitated westward expansion and, as machinery increased in complexity, led to engineers specializing in areas including mining, dynamics, metallurgy, and mechanics (Mann, 1918). From 1860 to 1880, the number of engineering schools in the United States increased from 4 to 85 (Mann, 1918), and by 1890 nearly ten thousand engineering students were enrolled (Grayson, 1980).

At the start of the 20th Century, more than 30,000 students were enrolled in engineering schools (Grayson, 1980). Instruction shifted from didactics to laboratory-based learning, as design-based work was replaced by electrical, mechanical, and transportation technologies that focused on production and which required hands-on instruction and generated graduates who could be immediately useful to their field (Grayson, 1980; Hazarika et al., 2019; Groumpos, 2021). As a result of the rapidly diversifying engineering subspecialties, The Society for the Promotion of Engineering Education recommended the Joint Committee on Engineering Education be assembled to evaluate all engineering education in the United States. Their report, released in 1918, recommended a unification of curricula and a return to engineering fundamentals (Mann, 1918). Following completion of WWII, technologies previously used to advance military goals became repurposed for the domestic front (ex. radar, which went on to become standard tools of meteorology, medical ultrasound, air traffic control monitoring, and numerous other uses (Sarkar et al., 2016). The 1960s led to a pivot in engineering education away from the prior focus on national defense to now tackling domestic and social challenges by developing "engineers of tomorrow" that required collaboration with scientists, economists, lawyers, politicians, and physicians to expand the human aspect of engineering (Grayson, 1980). It was physician concerns over the electrical safety of hospital equipment that resulted in engineers entering the biomedical arena for the first time (Bronzino, 2005).

Medical Device Design Course Considerations

Today's biomedical engineers need to be lifelong learners (Lucky, 1990; Broo et al., 2022; Singh et al., 2018) with both transdisciplinary (Baturalp et al., 2024; Montesinos et al., 2023) and interdisciplinary (Singh et al., 2018; Van den Breent et al., 2020) literacy to facilitate effective communication with clinicians, patients, scientists, entrepreneurs, legal and regulatory agents, clients, and stakeholders in order to advance medical devices. An applicable and conceptual approach to the medical device design process consists of Design, Conduct, Evaluation, and Feedback (Wolfe & Byrne, 1975). Core elements of medical device design include the ability to:

- Identify clinical need, define patient population, and communicate with clients and stakeholders.
- Identify current knowledge gaps and technology limitations.

- Evaluate competitors and analyze market opportunity, assess benefit vs risk, and explore funding opportunities.
- Estimate costs and forecast project timelines.
- Convey novel concepts and confirm intellectual property with broad claims with freedom to operate.
- Define design criteria and advance development via multiple design iterations to achieve a design freeze.
- Carefully evaluate human factors, ethical, and legal considerations.

This strategy emulates, in part, the medical device design process funded by the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program Phase I (proof-of-concept, feasibility), Phase II (design freeze, commercial plan), and Phase IIB (final preparations for clinical trial, including Validation and Verification or V&V, Good Manufacturing Practices or GMP, Good Laboratory Practices or GLP) studies (Figure 1). In this undergraduate Medical Device Design course, the authors focus on the early-stage development process and considerations (Phase 0 and Phase I).

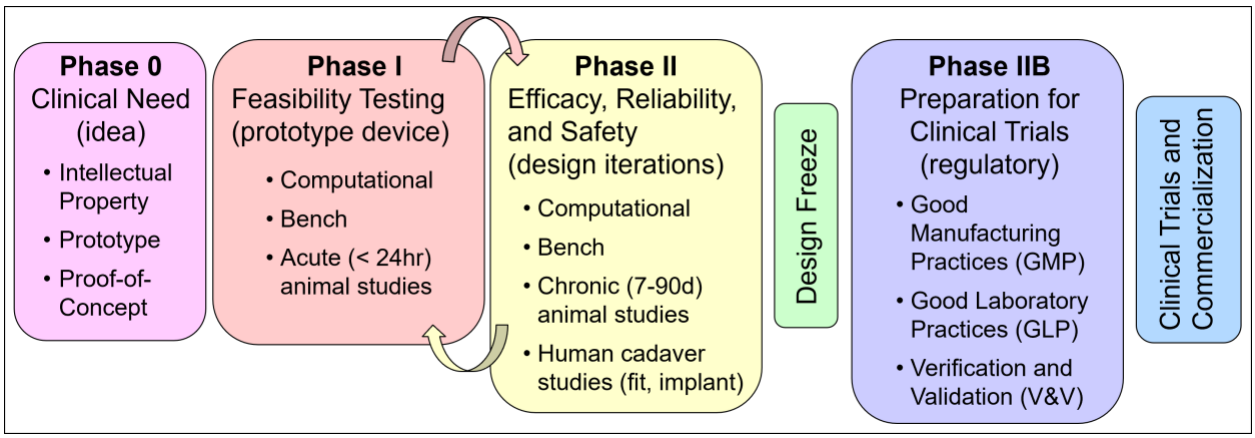

Figure 1. Illustration of the medical device development process emulating National Institutes of Health (NIH) Small Business Innovative Research (SBIR) program: idea, proof-of-concept, prototype, feasibility, multiple design iterations, pre-clinical testing, design freeze, and good laboratory practices (GLP), good manufacturing practices (GMP), and/or other federal regulatory requirements to demonstrate device efficacy, reliability, and safety in preparation for clinical trials approved by the Food and Drug Administration (FDA).

In this article, we present an innovative approach to actively engage students and spark their creativity, practice critical thinking, and learn early-stage medical device design through a variety of fun, hands-on, and practical experiential activities. Our teaching paradigm emphasizes active learning through pre-class preparation (recent journal articles, real-world assignments), in-class student presentations and discussion as individuals and teams, guest speakers and off-site field trips (Foo & Foo, 2022; Scarce, 1997), organ dissection (Elizondo-Omaña et al., 2005; Kaiser et al., 2023) and medical device labs, role-playing (McSharry & Jones, 2000; Brown & Chidume, 2023) and improvisation (Wendland & Worthington, 2024), and a device design project. Ultimately, the primary objective is to successfully train students to understand and apply a holistic approach to medical device design and gain self-confidence in their ability to apply their engineering knowledge and skills. The course didactic content and

experiential learning activities (Staehle et al., 2023), student comprehension and evaluation results, and lessons learned and future considerations from our own experiences as researchers and instructors are presented.

Methods

Course Structure

The Medical Device Design elective course (BE 480, 3 credits) was first created and taught by the authors in 2008 and has been offered annually in the Spring semester to third-year undergraduate bioengineering students for the past seventeen years (Table 1). The course meets three times per week (50 min per class) in a forty-seat lecture room equipped with digital projector and whiteboards. The primary goal is for students to have a comprehensive and holistic understanding of the medical device design process development from the unique perspective of an inventor, investor, and surgeon as well as other important clients and stakeholders. This is accomplished through active participation in experiential learning lectures, labs, field trips, and individual and paired student assignments (Table 2). The course culminates with individual student device design projects due at the end of the semester to demonstrate their clear understanding and ability to apply the medical device design process from idea to proof-of-concept and feasibility (Phases 0 and 1).

Table 1. Bioengineering student (n=234) demographics completing the BE 480 undergraduate medical device design course from 2008-2023 (n=17 courses).

Gender	139 female, 190 male
Race	10 African-American, 34 Asian, 8 Hispanic, 256 White, 11 two or more, 3 non-resident alien, 2 unknown
1st Generation to Attend College	28 yes, 296 no
Residency	268 in-state, 56 out-of-state
Graduates	136 BEng, 167 BEng and MEng, 21 no degree

Table 2. Medical Device Design course content and associated assignments.

Class Activity	Assignment (graded)
Lecture 1 – Introduction Medical Device Design	
Lecture 2 – Real-World Examples and Opportunities (guest)	
Lecture 3 - Creativity and Innovation	Individual written summary and presentation
Lecture 4 - Failure	Individual written summary and presentation
Lecture 5 – Ethics (guest conflict of interest)	
Lecture 6 - Intellectual Property (guest patent attorney)	Individual Invention Disclosure (2 iterations)
Lecture 7 – Design of Experiments (DOE – guest)	Team experiment, analysis report, presentation

Lecture 8 – Design, Reliability, Manufacturability (DRM - guest)	Team experiment, analysis report, presentation
Lecture 9 – mini-Design Project (human factors)	Team written summary and presentation
Lecture 10 - Artificial Ear	
Lecture 12 - Artificial Heart	
Lecture 12 - Artificial Kidney	
Lecture 13 - Artificial Lung	
Lecture 14 - Artificial Pancreas	
Lecture 15 - Breast and Prostate Cancer	
Lecture 16 – Neurosurgery (guest)	
Lecture 17 - Prosthetics	
Lecture 18 – Surgical Tools	
Lecture 19 – Wearable Health Monitoring Devices	
Lecture 20 – Mobile Apps, Artificial Learning, Machine Learning	
Lab 1 – Organ Dissection	Team Project
Lab 2 – "Inventor, Investor, Surgeon" role-play lab	Team Project (role play)
Field Trip 1 – Heart Hospital	
Field Trip 2 – Neurosurgery Hospital	
Field Trip 3 – Pre-clinical Testing Facility	
Field Trip 4 – Local Medical Device Industry	
Field Trip 5 – Observe Clinical Case (office, surgery)	Individual Volunteer(s)
Device Design Project ('elevator pitch' – in class)	prototype demonstration (2 iterations) invention disclosure (2 iterations) elevator pitch (final presentation) written summary (2 iterations) written report (final submission)

Medical Device Design Course Roadmap

The authors developed a curriculum modelled from their own expertise and experiences based in part upon their collaborations with over one-hundred industry partners ranging from early-stage start-ups (< 500 employees) to well-established companies (> 10,000 employees), including their own small businesses. For start-ups, the primary funding paths were through NIH SBIR grants, angel investors, and/or venture capital, and industry contracts with large medical device companies. For Class III medical devices, it may take up to 10-15 years and over $500M to successfully develop a novel medical device from concept to FDA-approved clinical-grade commercial product(s). The complete roadmap for medical device is presented at the start of the semester with focus throughout the course on early-stage development (Phases 0-1) that typically takes 6-12 months to achieve.

We assume students have no prior knowledge and experience with medical device design at the start of the semester with the goal of achieving basic knowledge and self-confidence in their ability to understand the process and to acquire and apply critical thinking and

communication skills. Our objective is to realistically simulate the medical device development process within the constraints of a 15-week course using individual student semester-long design projects as the primary learning vehicle. The roadmap for navigating the medical device design course (Figure 2) starts with introduction to biomedical engineers and the device development process followed by didactic instruction, experiential learning, and real-world experiences designed to actively engage and instruct undergraduate bioengineering students. Collectively, these learning modalities throughout the semester provide the vehicle to acquire knowledge, develop and practice communication and engineering skills, appreciate risk-reward, feel empathy, and build self-confidence. By the end of the semester, students should be well-prepared to confidently, passionately, and successfully complete and share their device design projects.

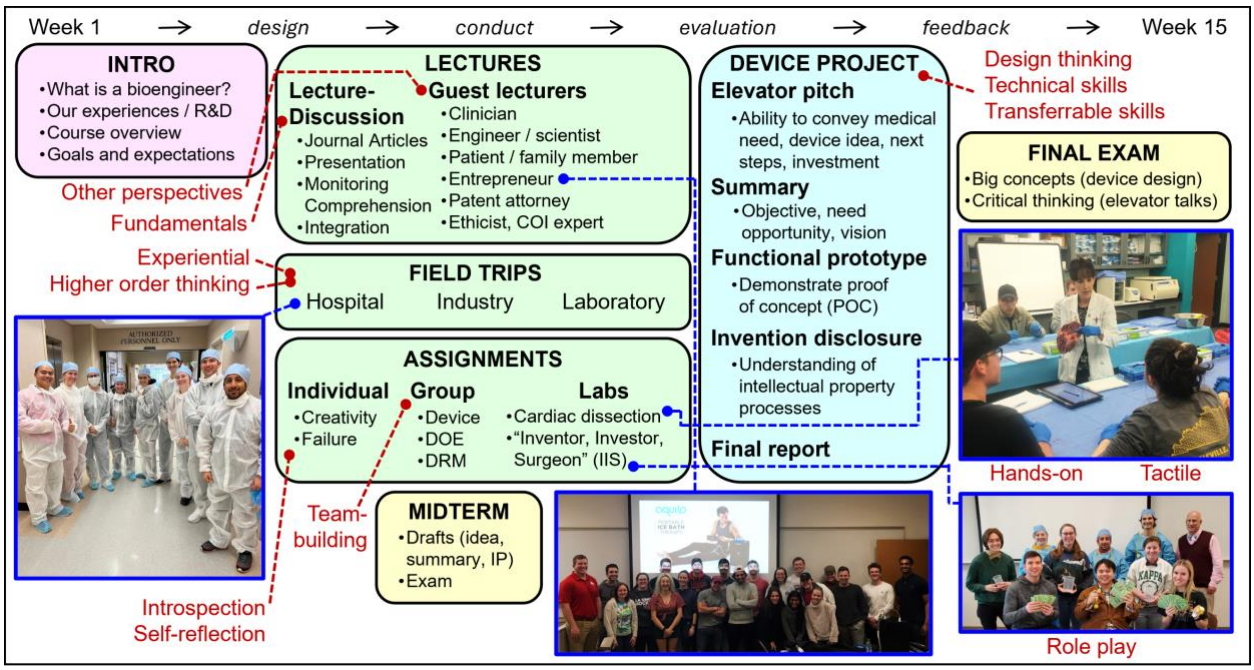

Figure 2. Medical Device Design course roadmap. R&D, research and development; DOE, design of experiments; DRM, design, reliability, manufacturability; COI, conflict of interest; IP, intellectual property.

Start of Learning Adventure

During the first week (week 1) of the semester: (1) students are asked to introduce themselves, share their interest in taking the course, what they hope to learn, and their future career goals; (2) the role of biomedical engineers, career opportunities, and an overview to the medical device development process is presented; and (3) authors share examples of the medical device development process from concept to design freeze, and highlight the successes, failures, and lessons learned from our own experiences. Administratively, the week concludes by presenting course goals, objectives, and expectations while emphasizing the extraordinary experiential learning opportunities scheduled throughout the semester to generate excitement and interest.

Didactic Lectures

A series of didactic lectures presenting an overview of 12-15 assorted technologies (Table 2) is designed for students to learn how to apply critical thinking skills to the medical device design process and evaluation criteria from a holistic perspective. Each presentation follows the same general outline for medical device design to encourage design thinking (Davies et al., 2023) and careful consideration of the following factors:

- Review anatomy, physiology, and targeted disease
- Identify knowledge gaps and clinical need
- Identify current technology with limitations and opportunities
- Define design criteria and engineering requirements
- Understand targeted patient population and potential markets
- Research existing intellectual property, define new claims (broad vs narrow), and defend freedom to operate
- Evaluate human factors and design with empathy
- Review legal and ethical considerations

At the start of class lectures, each student is required to present to the class one of these key consideration points, which then segues into the lecture presentation and student discussion. The selection of topics varies based upon student interest with emphasis on broad understanding of process rather than rigorous in-depth analyses of the medical device. To help ease students into this format, well-established devices (e.g. hearing aids, limb prosthetics, mechanical circulatory support devices) are presented first and then extended in complexity to current emerging technologies (e.g. wearable sensors, mobile apps, artificial intelligence / machine learning) later in the semester. Course content and structure has evolved annually through iterative cycles of student evaluations, guest lectures, field trips, external advisory board feedback, and instructor self-analysis and reflection for continuous improvements.

Guest Lectures

Guest lectures are integrated into the curriculum with experts in their respective fields sharing their experiences, feedback, and guidance providing their unique perspective of medical devices. The lecturers are provided in an open format ranging from informal storytelling and question/answer (ex. fireside chat) to formal presentation (PowerPoint slides) and focused discussion. Guest lecturers have included:

- Surgeons that share current unmet clinical device needs for their patients, risk vs benefit, and their future predictions for emerging technologies and potential applications.
- Patients (and their family members) who have received lifesaving Class III medical devices (ex. left ventricular assist devices, total artificial hearts, stimulation leads) that talk about their disease condition, share their stories and needs, discuss human factors and challenges related to their device, and provide valuable insights into the importance of designing with introspection, reflection, and empathy (Davies, et al., 2023; Radović et al., 2023).
- Entrepreneurs (Ita et al., 2023; Jaworski & Cho, 2023) that share insights and tips on how to transform ideas into practice cost-effectively and efficiently, and to secure

funding to support early-stage proof-of-concept prototypes to late-stage clinical-grade products.
- Business and community leaders (Jaworski & Cho, 2023) that showcase opportunity and impact.
- Scientists involved with the hands-on development and testing of medical devices, including experts in pre-clinical animal testing to discuss FDA requirements including GLP, the challenges and realities of in vivo research, oversight of humane care (OLAW), and the concepts of Reduce, Refine, Replace as the principles for best practice (Hubrecht & Carter, 2019).
- Patent attorneys that present intellectual property (IP) concepts and how-to steps, demonstrate the importance of protecting IP with case studies of past failures and successes, identify potential legal risk factors and their unintended consequences, role of IP and academic research in medical device development (Heus et al., 2017), and lead discussions by asking/answering student questions (Garris & Garris, 2017).
- Experts on ethics and conflict of interest that present important concepts, cases studies, and discuss the Biomedical Engineering Society's (BMES) Code of Ethics with focus on the diverse group of people potentially impacted by medical devices (Martin et al., 2021)
- Former students practicing medicine, working in industry or government agencies, and/or running their own companies share their experience with students and ask/answer their questions.

Field Trips

To reinforce concepts presented and discussed in the classroom didactic and guest lectures, the authors incorporate several field trips into the curriculum to create unique experiential learning opportunities and enhance students' higher order thinking skills (Foo & Foo, 2022; Scarce, 1997; Billiar et al., 2022). Field trips include visits to:

1. Hospitals, where students dress in medical scrubs and visit diagnostic imaging facilities, surgical operating rooms, and intensive care units (ICU) while also meeting with teams of clinicians (surgeon, anaesthesiologist, nurses, perfusionists), patients and their families and caregivers, and/or hospital administrators.

2. Medical device companies (local), where students meet with senior leaders (entrepreneurs, chief executive officers, chief technology officers), engineers (R&D inventors, manufacturing, quality control, regulatory and safety), and business and commercialization associates (finance, sales, marketing).

3. Development and testing facilities (ex. research laboratories, imaging, human cadaver, and animal facilities).

Experiential Activities (Lab-Based)

The authors incorporate two practical, interactive hands-on labs during the course:

1. Organ dissection lab, designed to improve anatomy and physiology knowledge retention through hands-on experiences (Abeyratne, 2008) and realistically simulate a medical device study to identify design criteria, assess fit, and evaluate surgical technique. In preparation for

the dissection lab, students are given a pre-lab 'surprise quiz' to test their knowledge of organ features and function (Supplemental Resource 1). Students are handed back their graded pre-lab quiz and a medical device design assignment with detailed instructions and deliverables to complete prior to the scheduled lab (Supplemental Resource 2). During the lab, the instructors lead gross organ (e.g. heart) dissection while engaging with the students by asking them to identify key features, structure, and function (covering the material in the pre-lab quiz) while students touch, hold, probe, and/or photograph the organ (Figure 3). Next, paired student teams are each assigned a medical device (e.g. cardiac) to define design criteria, assess fit, and evaluate surgical approach, which they document and write-up in a summary report. An identical post-quiz (again unannounced) is administered to the students approximately one week after the dissection lab to assess their knowledge retention. At the end of the organ dissection lab, students complete course evaluations (1-5 Likert scale, 1=poor, 5=excellent) with qualitative open-ended written feedback, Supplemental Resource 3).

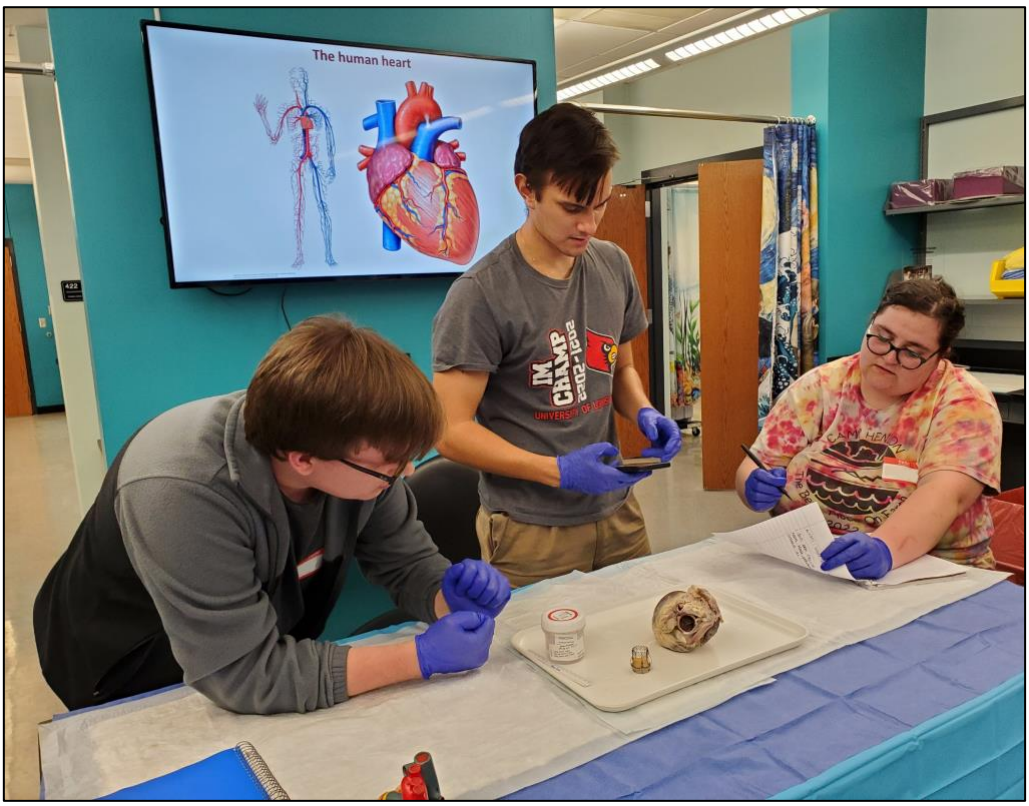

Figure 3. Photo of student team during the organ dissection lab (heart). Here, students are examining a Perceval stented aortic valve (Corcym, Milan, Italy). The valve is visible on its own on the table and also implanted in situ in an explanted pig heart.

2. "Inventor, Investor, Surgeon" (IIS) lab. Here, students are encouraged to evaluate clinically approved and/or emerging pre-clinical medical devices from the view of an inventor, investor, and a surgeon (IIS) through the use of role-play. Role-play and improvisation (McSharry & Jones, 2000; Brown & Chidume, 2023; Wendland & Worthington, 2024) are simple, adaptable, interactive, and cost-effective means of enhancing student engagement and injecting light-hearted fun into often quite technical topics. We designed our IIS lab (1.5hrs) to be engaging, interactive, and presented in multiple modalities to encompass auditory, visual, and tactile forms of learning (Monreal et al., 2014; Monreal & Koenig, 2025). Students were first provided

a review of cardiovascular anatomy/function, heart failure (HF) pathophysiology, and a discussion of mechanical circulatory support device (MCS) therapy for HF. Next, they held and assessed MCS devices including the AbioCor total artificial heart (Abiomed, Danvers, MA), Impella 2.5 (Abiomed), HeartMate XVE (Thoratec, Pleasanton CA), HeartMate II (Thoratec), HeartMate 3 (Abbott, Abbott Park IL), HVAD (Medtronic, Minneapolis MN), and SynCardia total artificial heart (SynCardia Systems LLC, Tucson AZ). Students were then split into teams of three with each person assuming one of the following roles (Figure 4):

- The Inventor (props included bowties, beakers) selects an MCS device, articulates their rationale, and makes a convincing elevator pitch to the Investor.
- The Investor (toy money and toy sports cars) evaluates whether to fund and champion the device and then convinces the Surgeon to adopt its use.
- The Surgeon (surgical caps, stethoscopes) weighs device efficacy, clinical applications, and assesses risk-benefits for their patients.

Students remain in the above roles as each team is given ~15 minutes to present their rationale for why they selected their device and make a compelling case to the instructors and rest of the class for their device's superiority. After all IIS teams have presented, the instructors and fellow classmates ask challenging questions (while still in their roles) that spark provocative debates that require critical thinking, analysis, and improvisation. At the end of the IIS lab, students complete course evaluations (1-5 Likert scale, 1=poor, 5=excellent) and the opportunity to also provide qualitative open-ended written feedback (Supplemental Resource 3).

Figure 4. Group photo of three student teams still in character during participation in the "Inventor, Investor, Surgeon" (IIS) role-play lab. During the activity, the Inventors (wearing bowties and holding beakers) had to select an MCS device, articulate their rationale, and make a convincing elevator pitch to the Investor. The Investors (holding toy money and pirate coins) had to evaluate whether to fund and champion the device and then convince the Surgeon to adopt its use. The Surgeon (wearing surgical caps, gowns, and stethoscopes) then had to weigh device efficacy, clinical applications, and assess risk-benefits for their patients.

Assignments

Lecture, lab, and device design project assignments provide multiple opportunities for students to integrate lecture, lab, and engineering knowledge, apply critical thinking, continue development of communication skills, and actively practice design development exercises using a real-world approach. For example, instructor lectures, journal articles, and student discussion have included:

Individual Exercises:

1. Creativity. What is creativity and why is it important (Egan et al., 2017)? How does one come up with creative and innovative ideas (ex. using biomimicry, toys, etc as inspiration)? The creativity assignment requires each student to independently identify their own example of something creative in the medical device world and its global impact, write a 1-page summary, and make a 5-min presentation to the class. The creativity exercise also helps students identify potential topics for their medical device design projects.

2. Failure. What is failure and why is it important (Laksov & McGrath, 2023)? The failure assignment requires each student to independently identify their own example of a past medical device failure and its global impact (ex. catastrophic adverse events, FDA recall notification, negative publicity, etc), write a 1-page summary and make a 5-min presentation to the class. The failure exercise shows students how often failure occurs, the importance of learning from and overcoming failure, and builds self-confidence, which encourages students to start, stay committed, and overcome many of the unanticipated challenges and failures they will experience with their own device design projects.

Team Exercises:

1. To encourage team-building and communication skills (Billiar et al., 2022; John, 2022; Marasi, 2019), paired student teams are assigned to a mini-project where each team is tasked to propose device/technology solution to help patients overcome disease symptoms in everyday life. Paired student design teams write a 1-page summary and make a 5-min presentation.

2. Paired student teams complete Design of Experiments (DOE) and Design, Reliability, and Manufacturability (DRM) assignments using industry standard software (Minitab, State College PA). These engineering development tools help students define medical device design criteria for simple medical devices and help build self-confidence.

End of the Journey (Device Design Projects)

Students work on their individual medical device design projects over the course of the semester, where they learn and practice early-stage device design process from conceptual idea to demonstrating proof-of-concept and feasibility. The expectations are that:

1. Students identify a clinical need of interest to them, reflecting on their own personal experiences (through their own or a loved one's health condition, through something they may have seen or experienced during a co-op, etc). The expectation is for students to identify area of interest and clinical need within first few weeks of the course.

2. By mid-semester, students complete a patent search, their first draft of an invention disclosure form (using university template) and write a draft summary (one page) of their

proposed medical device which the instructor assigns an initial grade with written feedback. Students have the opportunity to then revise both their initial invention disclosure forms and project summary documents with submission of their final device design written reports.

3. At the end of the semester (week 15), students are randomly selected for an “elevator pitch” to present their idea and device prototypes with the goal of convincing the instructors and fellow students to invest a requested amount of funding (e.g. $100k) in their start-up company along with rationale and projected milestones, deliverables, and timeline. The students then have one week to use the in-class critiques following their “elevator pitch” to make last-minute improvements to their final project reports.

4. The final written report is a comprehensive presentation of student medical device design from idea to proof-of-concept prototype. In addition to the project summary and invention disclosure forms, the written report includes the key elements in the early-stage of medical device development presented and learned over the entire semester, including clinical need, disease, critique of current diagnostic/therapeutic modalities, devices, and technologies, patient population and market, prototype design and testing, and human factors, ethical, and legal considerations (Online Resource 4). Supporting references from rigorous literature review and patent searches are also required.

All assignments are graded numerically (0-5 scale oral, 0-5 scale written) along with instructor written comments identifying strengths and weaknesses designed to offer consistent, constructive feedback and guidance.

Exams

Midterm and final exams are designed as new learning experiences for students to integrate and apply multiple concepts with open-ended questions that they may answer using equations, illustrations, models, and/or written responses to demonstrate their understanding and ability to apply critical thinking. An example mid-term exam question may ask students to identify key challenges and propose solutions for gaining widespread clinical approval of a medical device that may not have been presented in previous lectures (ex. automated insulin delivery). A final exam question may ask students to select student design project (other than their own) they would not invest funds in, while providing rationale from the perspective of multiple stakeholders and clients, and then clearly and concisely state what they may potentially do to address the clinical need and/or improve upon the proposed technology.

Results

Course Effectiveness and Student Satisfaction

As others have shown (Montesinos et al., 2023; Tembrevilla et al., 2024), we hypothesized that retention and comprehension of anatomy and physiology knowledge taught in previous course(s) would greatly improve with experiential learning. Data demonstrated a mean 204% improvement in students’ pre- and post-test scores following hands-on participation in the cardiac dissection lab (pre 27.9 ± 19.6% vs post 84.7 ± 17.4%, $p<0.0001$ via paired t test) (Figure 5a). Lab evaluations were extremely positive (Figure 5b). Participants self-reported that it was a fun educational experience (98.7% responded to this question with a 5-excellent or 4-very good) and that they learned new things (98.7% responded to this question with a 5-excellent or 4-very good).

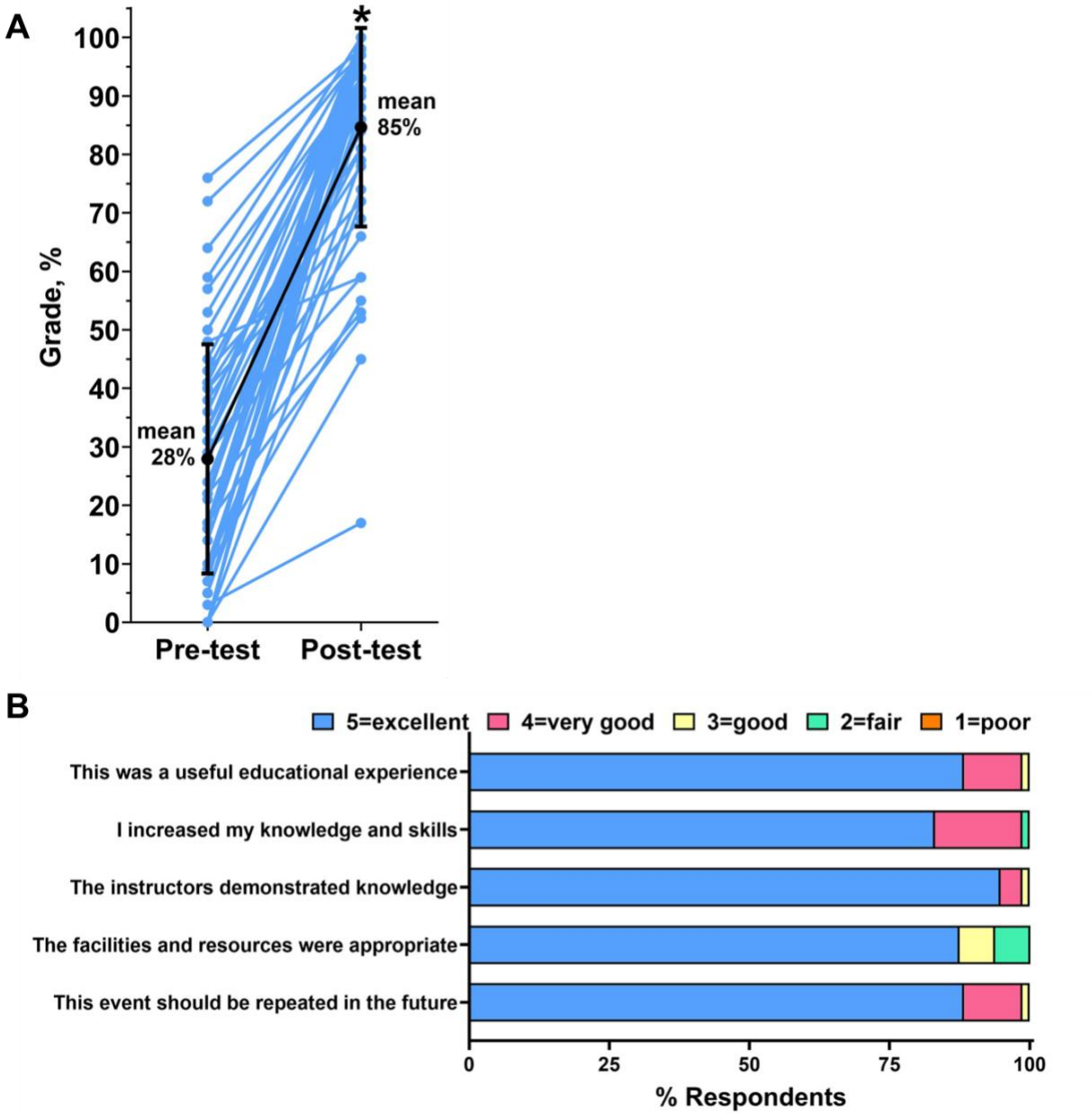

Figure 5. A, Pre- and post-organ dissection lab quiz (Online Resource 1) scores (2020 and 2022 students only; no lab in 2021 due to the COVID pandemic; no pre- or post-quiz in 2023). Results demonstrated significant improvement in knowledge and understanding of heart anatomical features and function. Data are presented as individual students' paired results (gray lines) and as the mean ± SD (black line). *p<0.0001 via paired t test. B, Results of the lab evaluations (n=79 participants, n=77 responses), with questions rated on a scale of 1 (poor) to 5 (excellent). Data are presented as stacked percentages of respondents.

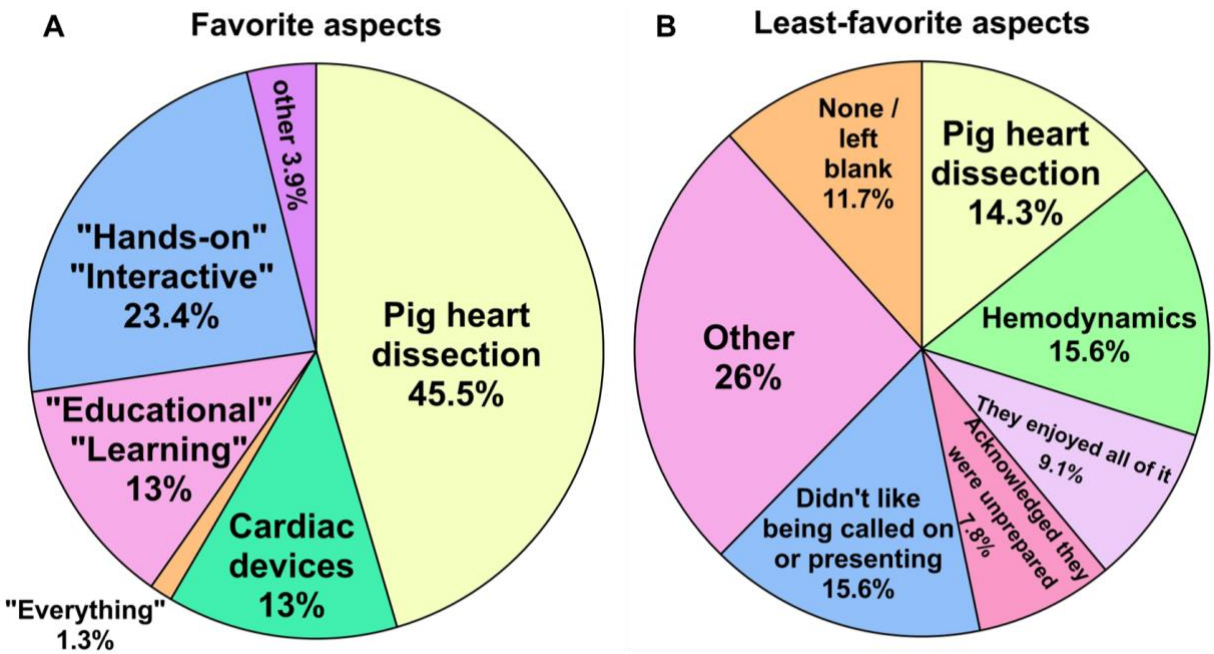

Figure 6. Students' favorite (A) and least-favorite (B) aspects of the cardiac dissection and "Inventor, Investor, and Surgeon" (IIS) labs as self-reported on their evaluations. Data presented as percent breakdowns of responses (Prism v10.3.0 (507), GraphPad Software, Boston MA).

Space was provided within the evaluation forms for students to describe their favorite and least-favorite aspects of the labs. As shown in Figure 6a, students really enjoyed the pig heart dissection (45.5% enjoyed this part the most), as well as the hands-on (23.4%) and educational (13%) aspects of the labs. Least-favorite aspects (Figure 6b) included the pig heart dissection (14.3% reported this was their least-favorite part) and learning about hemodynamics. Space was also provided on the evaluation forms for open-ended written comments (Figure 7). Students self-reported that they really enjoyed the lab events, including the heart dissection and role-playing experience in the IIS lab. Particularly in the IIS labs, students were interactive, had fun wearing/using the props for their respective roles, and engaged in highly animated discussions defending the device they chose, critiquing the others, and considering alternate viewpoints. The labs were light-hearted and filled with laughter, which was also observed during role-play activities by Brown & Chidume (2023). Open-ended comments were extremely positive, with written comments that emphasized "fun", "hands-on", "educational", and "awesome."

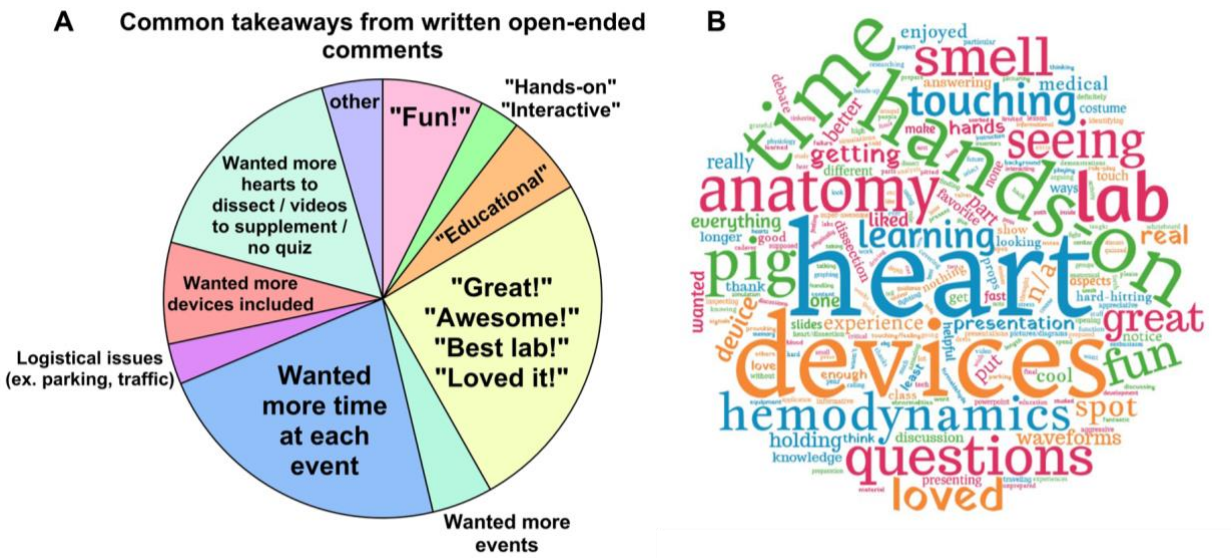

Figure 7. Common themes in the open-ended written comments of lab evaluations. A, Data are presented as percent breakdowns of responses (Prism v10.3.0 (507), GraphPad Software, Boston MA). B, The same data presented as a wordcloud visual representation of the participants' open-ended written comments on their evaluation forms. The larger the size of the words, the higher the frequency of the repeated comments. Participant open-ended comments were transcribed by the authors and the wordcloud was generated using www.wordclouds.com (Zygomatic, The Netherlands).

Students benefited from multiple opportunities to continue to develop their critical thinking, engineering, and communication skills through multiple learning modalities, which align with the Accreditation Board for Engineering and Technology (ABET) Student Outcomes: (1) identify, formulate, and solve complex engineering problems, (2) apply engineering design, (3) effective communication, (4) ethical and professional responsibilities, (5) function on teams (and independent), (6) conduct experiments and analyze data, and (7) acquire and apply new knowledge (Table 3).

Table 3. Student assignments, deliverables, and associated Accreditation Board for Engineering and Technology (ABET) student learning outcomes: 1 - identify, formulate, and solve complex engineering problems, 2 - apply engineering design, 3 - effective communication, 4 - ethical and professional responsibilities, 5 - function on teams, 6 - conduct experiments and analyze data, and 7 - acquire and apply new knowledge.

Assignment	Description	ABET Criteria
Creativity	Identify, summarize, and present example of medical device idea from biomimicry, toys, and/or other sources	2, 3, 4, 7
Failure	Identify, summarize, and present example of past medical device failure, lessons learned, and propose solution(s)	2, 3, 4, 7
Design of Experiments (DOE)	Conduct computational experiments and analysis to aid in defining design criteria	1, 2, 3, 4, 5, 6, 7

Design, Reliability, Manufacturability (DRM)	Develop function model, boundary diagram, interface dictionary, and P-diagram for medical device component	1, 2, 3, 4, 5, 6, 7
Mini-Design Project (human factors)	Design a device to improve patient quality of life, write summary, and present to class	2, 3, 4, 5
Prototype Device (proof-of-concept)	Design, fabricate, and bench test project device that conveys concept and demonstrates potential	1, 2, 3, 4, 6, 7
Intellectual Property	Complete University Invention Disclosure form	3, 7
Device Project Presentation	Present Device Project via 'Elevator Pitch' to investors	3
Device Project Summary Report	Written report (one-page) succinctly summarizing proposed device development project targeting potential investors	3
Device Project Development Report	Written report presenting medical device design project using holistic approach and development process	1, 2, 3, 4, 6, 7

The course evaluation data spans the pre- and COVID pandemic era. The pandemic's lockdown and subsequent reduction of in-person activities left its mark on students and their exposure to innovative hands-on educational opportunities (Asgari et al., 2021). We were curious if the cohort of students who had taken the brunt of the pandemic (freshmen and sophomore bioengineering students during COVID, 2022 course) would place greater emphasize or value on educational aspects that perhaps the pre-pandemic students (2020 course) took for granted. Indeed, 34% of the pandemic students emphasized the appeal of "hands-on" in their course evaluations, compared to 11% of the pre-pandemic cohort ($p<0.0292$ via a Fisher's Exact test, data analyzed using Prism v10.3.0 (507), GraphPad Software, Boston MA).

Cumulatively, this course demands significant student commitment, effort, and time management. The authors continuously solicited student feedback over the entire semester. On the 1st day of class, each student was asked why they signed up for class, area of interest in bioengineering, and post-graduate plans, which enabled us to tailor lectures accordingly (e.g. devices/technologies presented in lectures). Students had the opportunity to voluntarily complete mid-semester course evaluations (Supplemental Resource 5) to evaluate course content, instructors, and self-assessment of their performance by providing anonymous Likert score and written responses. Mid-semester evaluations (2023) demonstrated the course was a useful, educational experience (4.6 of 5.0 scale) and increased student knowledge and skills (4.4 of 5.0); the instructors demonstrated knowledge (5.0 of 5.0), provided valuable feedback (4.9 of 5.0), acted professionally (4.9 of 5.0), and were accessible (5.0 of 5.0); and students reported their own class preparation (3.6 of 5.0), class participation (4.4 of 5.0), and time completing assignments (4.5 of 5.0). This information enabled the authors to address any potential concerns to improve their educational experience over the second half of the semester rather than waiting until final end-of-semester evaluations, which are helpful for future classes but have no impact for the current class of students. Averaged final course evaluations (2019-2023)

demonstrated favorable review of the instructors (4.4 of 5.0 scale), content and value (4.5 of 5.0), and meeting seven ABET criteria (4.6 of 5.0).

Lessons learned and future considerations

A holistic critical thinking approach to medical device development from early-stage prototypes through design freeze is needed to successfully translate effective, reliable, and safe clinical-grade commercial products into clinical practice to improve patient outcomes and quality of life. Biomedical engineering graduates may continue to pursue their interest in medical device development via one of many distinct, yet interconnected pathways. They may choose to develop medical devices as engineers and scientists, entrepreneurs and/or small business owners, clinicians that identify unmet need(s) in practice (or active lifestyle) and formulate innovative solution(s), patent attorneys or litigators filing and protecting intellectual property, or hospital administrators stratifying projected risk and associated costs. The value of a multidisciplinary approach to medical device design by grouping teams of engineering, medical, and business students was demonstrated by the high percentage of biomedical engineering students that pursue productive and impactful healthcare careers (Denend et al., 2021). Specifically, long-term follow-up with post-graduate surveys of Stanford students that completed their Biodesign course (Yock et al., 2015) was shown to be influential in choosing their career direction and impactful in their career (Denend et al., 2021).

Knowledge retention, comprehension, and the ability to apply fundamental engineering concepts in combination with basic human anatomy and physiology and introductory engineering courses from completed pre-requisite courses is required to enroll in our Medical Device Design course. In a traditional engineering didactic lecture-based approach, focus may be placed on engineering-driven course content with a structured curriculum that follows a medical device design textbook. There are a number of informative medical device design textbooks that the authors carefully considered (Yock et al., 2015; Chan, 2023; King et al., 2018); however, the authors chose to create content by developing their own lectures, choosing recently published journal articles, and experiential activities as the primary learning vehicle to follow as the medical device design roadmap (Figure 2). Diagnostic and therapeutic medical devices, emerging technologies, and clinical paradigms change rapidly in a highly competitive, fast-paced industry. Thus, using recently published journal articles (review, emerging technologies) allows course content to be flexible and updated annually.

Since creating and first offering the course in 2008, content, format, presentation, style, and structure have been critically evaluated and modified for continuous improvement annually. The instructors actively solicit and review feedback and guidance to identify strengths and weaknesses from multiple stakeholders, including authors contacts with clinicians and patients, industry partners, government officials (e.g. FDA, NIH), guest lecturers, student and ABET course evaluations, and our university ABET external advisory board comprised of five education and industry leaders. Initially, the course followed traditional a textbook format supplemented with didactic lecture (e.g. slides) and interactive classroom discussions. Guest lectures by invited experts and field trips were later integrated into the course curriculum to provide multidisciplinary and multi-institutional perspectives in response to student feedback for more hands-on experiential learning opportunities with added benefits of networking (coop, employment) and evaluating their future career path. Course content evolved with advances in technology and clinical practices along with changes in ABET guidelines and

improvements in defining student learning outcomes by identifying emerging areas of emphasis and need (e.g. ethics, societal perspectives). In 2019, the authors observed a concerning pattern of declining student retention of prerequisite (e.g. anatomy and physiology) and fundamental engineering knowledge (e.g. critical thinking) required to successfully apply to medical device design and development. Subsequently, an organ dissection lab was added, which students overwhelmingly valued. They also requested additional hands-on labs be integrated into the course. Based upon this student feedback, the IIS lab was added in 2021, which built upon the authors industry and SBIR experiences and expertise and featured new learning modality (role-play). Student course (mid- and end-semester) and lab evaluation data have shown strong student interest and demonstrated their ability to learn, retain, and apply knowledge.

Challenges identified have included: (1) time constraints with classes often running long; (2) travel requiring extra time and resources needed for off-site labs and tours; (3) time and effort to complete the large number of assignments and labs. To address these concerns, we have considered extending one of the weekly classes to 120 min and/or reduce number of weekly classes to two 90-min meeting times to accommodate off-site labs and field trips. We are also considering development of a follow-on graduate course with students having the opportunity not only develop prototypes, but to extend the process further by demonstrating feasibility. The roadmap for the graduate course may focus on Phase II and provide a learning vehicle for students to write an abstract and/or manuscript and prepare a NIH SBIR Phase II grant application in support of their independent graduate research.

Declarations

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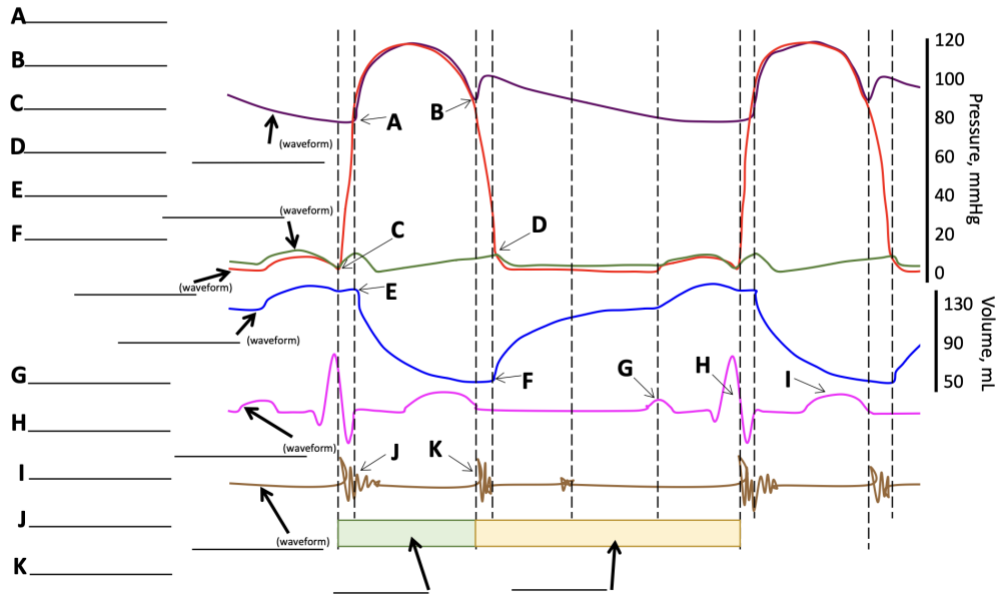
SUPPLEMENTAL MATERIAL

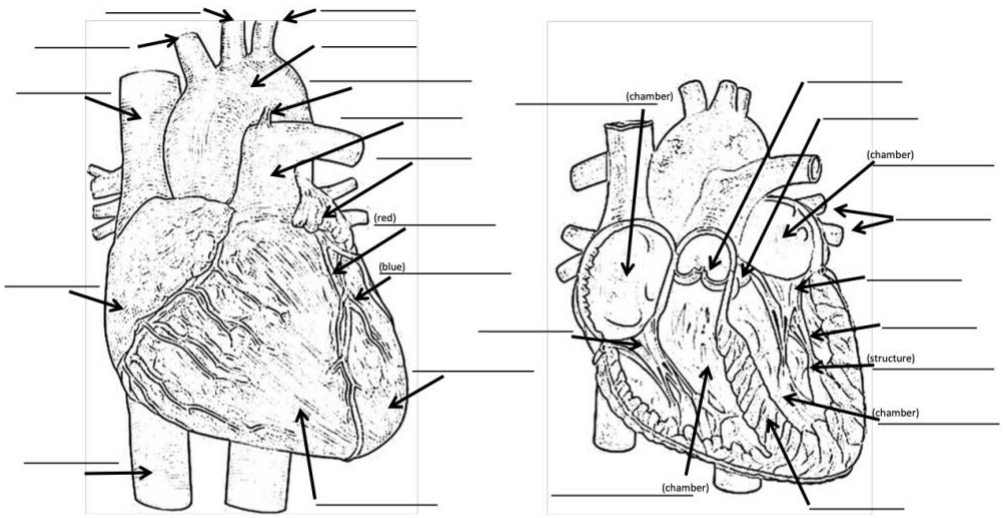
Supplemental Resource 1. Example quiz requiring students to identify heart anatomy and function. Students were given a surprise quiz before and one week after heart dissection lab to assess their ability to retain and apply basic anatomy and physiology in preparation for medical device design assignment.

Name_____ Date_____

Question 1: Please label the waveforms and key points to the best of your ability.



Question #2: Please label the anatomy / structures to the best of your ability:



Question #3: Please write the pathway of the blood through the heart and structures below:

vena cava → _____ (chamber) → _____ (valve) → _____ (chamber) → _____ (valve) → _____ (vessel) → _____ (organ)

→ _____ (vessels) → _____ (chamber) → _____ (valve) → _____ (chamber) → _____ (valve) → _____ (vessel) → _____ (organs)

Supplemental Resource 2. Example assignment with detailed instructions for preparation, execution, and completion of group device design lab. Each team was comprised of three students who were then randomly assigned the role of Investor, Inventor, and Surgeon (IIS) for interactive role-play and written summary.

Lab Assignment (Heart Anatomy, Physiology, and Devices)
BE 480 Medical Device Design (Spring 2023)

Learning Objectives:

1. Basic knowledge, understanding and application of cardiac *anatomy*, *physiology*, and *hemodynamics*
2. Practical 'hands on' experience with dissection of porcine heart for visualization of cardiac *anatomy*, *tissues*, and *structures*
3. Application of porcine heart model for development of cardiac medical devices, including defining device *design criteria* and *anatomic fit* as well as anatomy, hemodynamics, physiology, structure and tissues (objectives 1, 2)
4. Careful consideration and understanding of device development from the prospective of the *clinician-patient*, *inventor*, and *investor* (deliverables - summary document, oral panel presentation).

Assignment:

As starting level biomedical engineers at Medtronic (Minneapolis MN) working in the Heart Failure Cardiac Devices Division, you've been assigned to travel to pre-clinical medical device development facility to engage with and learn from cardiac surgeon(s), cardiologist(s), engineer(s), and scientist(s) to evaluate the potential development of next generation cardiovascular medical devices. Course instructors will provide an orientation using an explanted porcine heart model and presentation of three current cardiac devices (HM III, Impella, Valve). You are expected to achieve each of the 4 learning objectives listed above. In addition, three teams (3 students per team) will be randomly assigned a specific cardiac device to study and apply your new knowledge. Each team member will be randomly assigned the role of (1) inventor, (2) investor, and (3) surgeon. As a team, you'll need to carefully define the following: (1) clinical need, (2) patient population, (3) anatomic fit, (4) interventional and/or surgical delivery-retrieval, and (5) design criteria (e.g. dimensions, diameter, length, thickness, sizes, weights, materials; and hemodynamic requirements – e.g. pressures, flows, volumes). You're expected to (1) record presented information and observations during lab, (2) submit a 2-page summary report for review (due by 4pm Wednesday, March 8, 2023), and (3) present your device as a panel and answer questions from the audience (instructors, students) during class (Wednesday, March 8, 2023) while playing each of your assigned roles (inventor, investor, surgeon)

Pre-Lab Procedures:

1 – Review Cardiac Anatomy, Physiology, Hemodynamics, Function, and Structure (complete worksheet)

2 – Bring Notebook, Pencil/Pen, Camera, Ruler, Caliper, other?

3 – Prepare List of Questions

In-Lab Procedures:

1 – Please DRESS appropriately (*long pants – no shorts; sleeves – no tank tops; *closed toe shoes – no sandals)

2 – Listen, Observe, and Record information critical to completing your travel assignment

3 – Consider taking any photo(s) that may be of assistance in defining design criteria and assessing anatomic fit for your randomly assigned medical device

4 – When provided opportunity, actively participate in 'hands on' evaluation of porcine heart

5 – Ask prepared and/or unanticipated questions

6 – Complete brief post-lab survey (one page)

7 – Clean Up and Wash your hands

Post-Lab Procedures:

1 – Research your assigned medical device, carefully consider device development from the prospective of your assigned role, and meet as a 3-member team to review, discuss, and prepare your deliverables (item 2 below).

2 – Complete Summary Report (e-mail PDF by 4pm on March 8, 2023), including background, methods, medical device and design criteria, and key findings and observations (*Lab Notes may be attached as an appendix to your summary report) and Panel Presentation (e-mail PPT talk and present in class on March 8, 2023).

Supplemental Resource 3. Example of student evaluation completed after in class lab assignment. Questions are graded on Likert scale (1-5) with opportunity for students to provide written feedback. The student evaluations demonstrated positive experiential learning experiences.

Bioengineering 480
Inventor, Investor, Surgeon lab

Evaluation of event and instructors

	Poor				Excellent
1. This was a useful educational experience	1	2	3	4	5
2. I increased my knowledge and skills	1	2	3	4	5
3. The instructor(s) demonstrated knowledge	1	2	3	4	5
4. The facilities and resources were appropriate	1	2	3	4	5
5. This event should be repeated in the future	1	2	3	4	5

What was your favorite part?

What was your least favorite part?

Ways to improve this event:

Additional comments:

Please place in the envelope provided when finished

Supplemental Resource 4. Example of independent student design project to be completed over the entire semester. Students are required to select their own clinical need, formulate concept for, design, and fabricate medical device to demonstrate proof-of-concept, complete invention disclosure form, present elevator pitch to class, and write summary and project report.

Medical Device Design (BE 480)

Project Instructions

Assignment - Identify a clinical need for a novel medical device design (or improvement of existing device) and design/develop/test 'proof-of-concept' prototype. Propose your solution in a 'white paper' that may be presented to your project manager, investors, and/or Small Business Investigator Research (SBIR) grant. Additionally, you will have the opportunity to demonstrate your prototype and 'pitch' your idea in a 5-minute oral presentation. Please use the following template as a guide toward completing this project. **Grade** (40% = 5% aims, 5% IP, 5% prototype, 5% talk, 20% written report)

A. Specific Aims (1 pg) – executive summary of overall project
   - Clinical Need and Significance
   - Current diagnostics/therapy(s) and their limitations
   - Design or Approach – what makes it novel/innovative?
   - Description of your concept/medical device, including advantages/benefits and weaknesses
   - Project Development short-term goal(s)/aim(s) and long-term objective/vision
     consider embedding/including CAD, illustration, and/or photo of device

B. Background and Significance (~2 pgs)
   - Describe disease process and target patient population
   - Clinical Need
   - How is clinical need currently being addressed? What are the limitations?
   - Market Analysis (opportunity, competition) and potential Economic Impact
   - How much will your device cost to make? How much could you sell it for? What are your anticipated development challenges? How many patients/physicians may benefit?
     **consider using illustrations, figures, tables, graphs, flow charts, etc*

C. Innovation (~1-2 pgs)
   - How will this change clinical practice? New clinical paradigm?
   - What is the potential clinical impact?
   - Describe improvements to existing and/or advantages of your technology. What is novel?
     **consider using photos, illustrations, figures, etc as well as Tables and/or bullet key items*

D. Preliminary Data and Design (~4-5 pgs)
   - Proposed prototype design (CAD, illustrations, schematics, photos, etc)
   - Detailed description of your proposed design, including function, design specifications, benchmarks, metrics (Tables, Bullet items)
   - Propose how you may test device to demonstrate proof-of-concept and/or feasibility
   - Intellectual Property (IP) review, Freedom to Operate (Appendix – UofL invention disclosure)
   - Description of human factors, safety, and ethical considerations with your design
     **consider using photos, illustrations, tables, graphs, figures, etc*

E. References
   - Minimum of 20 citations (peer-reviewed journals) and 5 related technology (patent search, patent numbers, key claims)

1 – UofL Invention Disclosure (IP) due by 5pm EDT on Friday, February 17, 2023 (e-mail PDF)

2 – Specific Aims due by 5pm EDT on Friday, March 10, 2023 (e-mail PDF)

3 – Prototype Demonstrations April 10/12, 2023 (e-mail PDF)

4 - Elevator Pitch April 19/21, 2023 (e-mail talk PDF)

5 - Written Reports due by 5pm EDT on Monday, April 25, 2023 (e-mail PDF)

Name: _____ Date: _____

Criteria	Comments	Grade
Oral Presentation (in class)		
Intellectual Property (patent search, claims, freedom-to-operate)		
Specific Aims (summary)		
Concept (innovative idea)		
Device Prototype (proof-of-concept, in class)		
Design Criteria (specifications)		
Clinical Application (need, application, impact)		
Cost & Market Analysis (expenses, sales, patient populations		
Human Factors (end-users, design issues)		
References (journal articles, patents)		

Overall Grade:
UofL IP Disclosure (5%) =
Aims/Summary (5%) =
Device Prototype (5%) =
Oral Presentation (5%) =
Written Report (20%) =

Supplemental Resource 5. Example of student course evaluation completed at mid-semester to evaluate course content, instructor performance, and self-assessment of student performance. Questions are graded on Likert scale (1-5) with opportunity for students to provide written feedback. These data enable instructors and students to improve course content and performance over the second half of course semester.

BE 480 Medical Device Design

Mid-Semester Course Evaluation (Spring 2023)

Q1 – How would you rate Course Content and Assignments?

	Poor				Excellent
1. Course has been a useful educational experience	1	2	3	4	5
2. I have increased my knowledge and skills	1	2	3	4	5

What has been your favorite part?

What has been your least favorite part?

What improvement(s) to course would you recommend?

Q3 – How would you rate Instructor?

	Poor				Excellent
1. The instructor has demonstrated knowledge	1	2	3	4	5
2. The instructor has provided valuable feedback	1	2	3	4	5
3. The instructor has acted professionally (prepared, on-time)	1	2	3	4	5
4. This instructor has been accessible (e-mail, office hours)	1	2	3	4	5

What has Instructor done well?

What has Instructor done poorly?

What improvement(s) would you recommend for Instructor?

Q3 – How would you rate Student (your) performance?

	Poor				Excellent
1. Have you been prepared for each class	1	2	3	4	5
2. Have you actively participated in class	1	2	3	4	5
3. Time spent completing assignments	1	2	3	4	5

What have you as student done well?

What have you as student done poorly?

What area(s) as student can you improve?

Additional comments:

Please place in the envelope provided when finished