A Biomedical Engineering Design Experience from Freshman Year to Senior Year

Lisa M. Milkowski, Ph.D., P.E., Vincent R. Canino, Ph.D., P.E.
Milwaukee School of Engineering (MSOE)

Abstract

This paper presents a methodology of integrating design throughout the engineering student's years of study.

Students have sufficient time to learn and achieve more in a design experience starting with a two credit freshmen course, continuing with one credit courses throughout the sophomore and junior years, and ending with two credit design courses in each term of the senior year. With sufficient sink time, students absorb and learn about the project objective, practice developing different solutions, and practice working in teams. Working on the same project throughout the design sequence, the students are learning to function as part of a design team and to be tolerant and respectful of individual team member differences. Additionally through this process student teams advance their design to final product levels. The teams prepare for and experience a series of design reviews, develop appropriate documentation, and apply techniques common in industry. The four year design experience relates directly to ABET outcomes such as: recognizing the need for life-long learning, developing professional skills, working productively in an engineering design team, and recognizing ethical, legal and social issues.

Design course lecture content is related to issues the students can apply to their designs at their particular educational level. For example freshmen and sophomores learn about literature searching, keeping an engineering logbook, and conducting team meetings. Seniors learn about hazards associated with medical device design such as electrical, mechanical, radiological, and infection control issues. Additionally seniors learn about design for maintainability and reliability and codes, standards and regulations including FDA compliance issues as they apply to engineering design.

I. Introduction

The Accreditation Board for Engineering and Technology (ABET) Engineering Criteria 2000 states a requirement for "a major design experience…incorporating engineering standards and realistic constraints" (1). This requirement along with the fact that many outcomes and assessment requirements of ABET relate to engineering design, indicate the importance of design within the engineering and biomedical engineering curriculum.

Most biomedical engineering programs have implemented some form of senior design or senior thesis experience. Additionally many programs have recently added courses with design experiences for freshmen (2). These freshmen experiences have been set-up to motivate students early in the curriculum, and to introduce students to engineering skills.

At MSOE the faculty have incorporated design throughout the biomedical engineering curriculum to allow the students to develop their design competence as they mature technically and to allow them to experience design in a more realistic fashion. Because the students are learning in design lecture about design, they apply many of the components of the Kolb cycle as they relate to their specific project (3).

Eight years ago we started the freshmen to senior design sequence and have continuously refined the sequence. The original motivations were to: make design a more complete experience that is more representative of all the stages of the design process, and to provide motivation to freshmen about biomedical engineering. One of the ways that we foresaw of making design a more fulfilling experience for the students was to apply all phases of the design process to their design projects. This was difficult to achieve within the senior-level sequence without sacrificing the technical components of the design project. We now have the time for students to adequately address all design issues discussed in the lecture portion of the course. Many of these lecture topics are requirements listed in the ABET engineering criteria 2000 (1) including “economic; environmental; sustainability; manufacturability; ethical; health and safety; social; and political”.

Under the previous senior-level design sequence, there was insufficient time for students to address all these design topics and bring their projects to completion. The teams already had to act fast to acquire and order necessary equipment or parts. This gave the student little time to formulate specifications, consider alternative designs, and conduct tests to determine the optimal design. Additionally, projects related to testing of human or animal subjects were started ahead of schedule or not feasible. These projects were not feasible because of the time needed for receiving Institutional Review Board (IRB) approval for testing to begin.

II. Methods

Curriculum Structure for Design

The distribution of design credits throughout the curriculum is illustrated in Table 1. The design teams continue on the same project from product conceptualization in their freshmen year to pseudo-product release right before graduation.

Table 1: Lecture and Laboratory Curriculum Structure. Credits indicated in parentheses.

	Fall quarter	Winter quarter	Spring quarter
Freshmen	--	Lecture & Lab (2)	--
Sophomore	Lecture (1)	Lecture (1)	Lecture (1)
Junior	Lecture (1)	Lecture (1)	Lecture (1)
Senior	Lecture & Lab (2)	Lecture & Lab (2)	Lecture & Lab (2)

In the first design course, the instructor provides general open-ended team project descriptions. The students write a resume and apply for a position on one of the projects. The instructor for the course, referred to as the Chief Engineer, gives lectures on maintaining an engineering logbook, introductory software tools, and conducting team meetings. At the end of the course, the students give a team oral presentation describing their project. Each of the six-team members receives one team grade.

After the initial freshmen course, the students are required to continue meeting as a design team and required to make progress on their projects. In the sophomore year, the students participate in lecture courses covering topics of literature searching, project management, process modeling, and laboratory experimenting/ testing. At the end of the sophomore year each team has completed a written project definition and preformed a comprehensive literature review. The team members have also documented all work in their engineering logbooks, developed initial design concepts, and practiced working together as a team of professionals. Each student accepts responsibility for some part of the design.

During the junior year, the students continue to take lecture courses expanding their technical and non-technical knowledge. More technical issues such as prototype testing, Institutional Review Board applications, and human factors are presented in the design courses and applied to their design. At the beginning of the second quarter of the junior year, the teams present their oral and written design progress at a 'Junior Design Show'. By this point in time the team has developed their detailed specifications and initial system design has begun.

During the final year, the students work on their designs in the laboratory, and they are learning how to apply engineering design topics such as: codes, standards, regulations; economic analysis, and sensitivity analysis. The students prepare for two design reviews, a preliminary system review and a complete detailed design review. The reviews are conducted by the biomedical engineering faculty. Several prototype subsystems are built and tested to prepare for the complete detailed design review. After the design reviews are completed, the team integrates the subsystems into the final design product. Their final design product is presented and demonstrated at a campus wide design show attended by underclassmen, faculty, alumni, parents, engineers from local industry, and other campus visitors.

Lecture Content and Student Work

In Table 2 is a layout of the lecture content for the design sequence of courses. Each course has one lecture hour per week or 10 lecture hours per quarter. These topics are team taught by the core biomedical engineering faculty. Each faculty member can therefore develop and maintain expertise in specific areas.

The student work is broken down into milestones that the team needs to achieve for progression as shown in Table 3. Many options and ideas from the team are started very early so they can experiment and learn from these ideas. System diagrams and design options are started in the early sophomore year, but are not required until midway of the junior year. This gives the team time for design ideas to mature and to spur new candidate solutions.

Table 2: Lecture content for design sequence courses.

	Freshmen (Winter)	Sophomore (Fall)	Sophomore (Winter)	Sophomore (Spring)	Junior (Fall)	Junior (Winter)	Junior (Spring)	Senior (Fall)	Senior (Winter)	Senior (Spring)
Introduction to Engineering Design, Team Formation, & Project Assignments	■									
Maintaining an Engineering Logbook	■									
Design Team Meetings and Management	■									
Resume, Memos, & Report Writing	■									
Use of Matlab, pSpice, Visio software	■									
Scientific Calculator Usage	■									
Literature Searching; Product & Component Literature		■	■							
Project Management Concepts		■								
Patent Process & Patent Searches			■							
BE Career Opportunities		■	■	■	■	■				
Developing Test Procedures & Experiments			■	■	■					
Design Process Modeling					■					
Obtaining Project Funding				■						
Team Conflict Resolution				■						
FE Exam						■	■			
Human Factors in Design							■			
Development & Testing of Design Prototypes						■	■			
Institutional Review Board Process							■			
Codes, Standards, Regulations					■			■	■	
Moral, Ethical, & Legal Implications of Design										■
Engineering Economy									■	
Sensitivity & Worst Case Analysis									■	
Design Documentation and Review Process								■		
Software Design Standards									■	
Medical Device Safety										■

Table 3: Major project milestones during the design sequence.

Milestone	Completion Time
Team Formation & Initial Presentation	End of Freshmen Course
Comprehensive Literature Review Complete & Project Definition	End of Sophomore Year
Junior Design Show & Detailed Project Specifications	Midpoint of Junior Year
Prototype development & review	End of Junior Year
Senior Design Review	Midpoint of Senior Year
Senior Design Show	End of Senior Year

Faculty Involvement

The design teams are organized mimicking an industry structure and the structure starts with the faculty. One faculty member serves as the Vice President of Engineering and four faculty members serve as Chief Engineers. The Vice President of Engineering oversees all the design teams in biomedical engineering and provides continuity between the different class years. The Vice President of Engineering and the Chief Engineer handle personnel and student team assignments. Because students may fall back one or more years academically or transfer into the program, the Vice President of Engineering determines where these students fit into the design sequence.

The Chief Engineer is the faculty member working closely with all of the design teams within a given class of students. The Chief Engineer stays with the design teams as they move through the curriculum. This person is the assigned instructor for all the design courses as the class proceeds through the sequence. When acting in the capacity of the Vice President of Engineering or Chief Engineer, the faculty member makes it clear to the students that they are engineering associates. This clarification is necessary because the faculty member could have the same students in another academic course where the teacher-student relationship is the accepted model.

The faculty involvement includes: participation in team-taught lectures, participation and evaluation of several student oral presentations and written reports, and rotating through the design sequence as Chief Engineer. The Chief Engineer coordinates the design course lecture schedule. As shown in Table 3, several of the major milestones involve special presentations and reports. Many of these, such as the Junior Design Show, Preliminary Design Review and Report, and Final Design Review and Report, are best evaluated by a team of faculty.

Student Team Structure

One student from each class serves as the Group Manager. This student ensures that all teams for that year are making progress toward their design goals, and communicates to the Chief Engineer any team conflicts or problems. The Group Manager also coordinates and hosts design presentations, and is a one-half time engineer on one of the design teams.

The student teams are organized with a Project Manager, Associate Project Manager and Engineers. The Project Manager assumes responsibility for organizing, coordinating, and planning the activities of the team in addition to design responsibilities. The Associate Project Manager assumes responsibility of the Project Manager whenever that individual is not able to complete their tasks and is responsible for keeping all design team records. The Engineer is responsible for particular design assignments as agreed to by the team members and to assume the role of other team members if they cannot complete their responsibilities. Initially the teams are organized with approximately 6 people, but the teams fluctuate in size with time because of student drop out and changing majors. Transfers into the program are assigned to teams with open slots.

We have found that it is important as the team practices professional teamwork skills to instruct the teams that professional teams make decisions together. The Project Manager does not unilaterally make decisions. He/She simply coordinates the discussion as the team makes decisions.

Grading

The grade earned by the team is the grade all team members receive for a course. The ability is reserved for the Chief Engineer to assign different grades if a particular student is documented as not contributing. This is reserved purely to make sure a team member does not completely rely on the efforts of his/her teammates for their grade. The contents of the team member's engineering logbook are the major determining factor in judging if a student has earned a passing grade for the specific design course.

Our emphasis is clearly on team grading to encourage teamwork and not individual efforts. The design team with some high achievers and some low achievers must work out their own solutions similar to a team in industry or other professional environment. Therefore, instructing teams on how to resolve team conflicts and make team decisions is important to learning effective teamwork.

During the senior year, in order to keep the team's emphasis on actual results, grades are not finalized for the entire year until the completion of all three senior design courses. At the end of each quarter however, the teams are given a written grade assessment of their performance to that point. This grade is not listed on their report card and is not used for any other purpose than to give the teams some feedback on their progress. At the completion of all the courses, and after the senior design show the following items are evaluated to determine the final grade for all three quarters of the senior year: 1) quality of the final product, 2) final written design reports, 3) the teams oral presentation at the design show, and 4) appropriate engineering documentation and work in engineering logbooks.

III. Results

To evaluate the effectiveness of the design sequence several assessments are used. We wanted to evaluate the design sequence both in terms of addressing our ABET outcomes, and the lack of time issues usually encountered in the shorter-term (one year) capstone design.

ABET Goals

One of our ABET goals is that the student develop an ability to design and conduct experiments, as well as to analyze and interpret data. To determine if this was effectively being addressed by the design sequence, seven final design reports were studied. All seven included information related to designing experiments, conducting, and collection of data used to test and validate the operation of their project. Because each project was unique, each report addressed these topics in a different way. Some reports contained a complete “test plan” from initial component modeling to complete system integration. Other reports had a more loose structure in this regard with sections on component testing and overall testing.

Another goal that we wanted to highlight in the new sequence was that the student recognizes ethical, legal and social issues. Here the design reports were again studied as will as an exit survey of the graduating seniors about their compliance with the goals. From the final design reports, four of the reports included content related to safety analysis in their design. Three of the reports included failure mode analysis or fault tree analysis. Other reports discussed proper material selection for safety considerations. From the exit surveys, there was also an indication that this goal was more effectively addressed. Example comments include, “I think the program did a good job of what legal requirements there are through different government institutions such as FDA, ISO9000, etc.” and “One good example of this would be my ability to maintain an engineering logbook, which is considered to be a legal document in any engineering company and/or research facility”. Additionally, this goal was addressed more thoroughly by requiring all design teams to submit and gain IRB approval for their design project. Even if their project appeared not to involve animal or human subjects, they were required to submit an IRB packet and gain approval or exempt status.

The comprehension of how codes, standards, and regulations are related to design were also evident and included ethical, legal, and social issues. Two of the design reports discussed their compliance with specific codes, standards, and regulations. Three mentioned NFPA, UL, and OSHA in their reports.

Another one of our goals was having the students develop the ability to work productively in an engineering design team. From the exit survey, comments similar to the following were frequent, “A lot of teamwork was learned from the Biomedical Engineering Design team assignment” and “the development of the design project provided us with the opportunity to work with different people of very different cultural backgrounds which will help in the future as we work in a global market”.

Lack of Time Issues

By changing the sequence from one to four years, a greater number of the projects go beyond functional prototypes to final products useable by their customer. Now teams consider how they will ‘manufacture’ their project and what supporting materials the customer will need. Safe use, safe product failure, and packaging are now being considered as part of the design process, as well as how the customer will maintain their product. Many of these issues were discussed in design lecture but were not practiced by the teams until the structure change to the four-year model.

With the longer design sequence, the time needed to acquire and order parts has no longer been a serious issue. Now the problem is finding funding for very expensive components. The teams are also choosing design alternatives requiring more expensive equipment. These teams have solicited funds through project awards or industrial donations to complete their project. Additionally, with the longer design sequence all teams are required to file an IRB even if their project appears exempt, as previously mentioned.

Examples

A sample design project is described in the following abstract written by the team (4). This abstract was for the design show where the project was presented and demonstrated to visitors (Figure 1).

> “When a patient suffers from severe head trauma, or a disease such as hydrocephalus, their intracranial pressure (ICP) may become elevated. In order to reduce this increase in ICP a physician may insert a catheter into the cranial cavity. While in the intensive care unit (ICU) nursing interactions influence a patient’s ICP. These interactions include head rotation, bed elevation, and cerebral spinal fluid drainage. Monitoring these physical characteristics is necessary to prevent a patient’s ICP from reaching dangerously elevated levels that may cause damage or even death.
>
> An intracranial pressure monitoring simulation has been designed as a teaching tool for the nursing department at the Milwaukee School of Engineering (MSOE). This simulation provides normal and abnormal representations of the intracranial pressure waveform. Nursing students will gain a substantial understanding of nurse-patient interaction and the resulting intracranial pressure waveform.”

Figure 1: A student design team with their final project at the design show. The project is an intracranial pressure monitoring simulation.

Another sample design project is described in the following design show team abstract (5). Figure 2 shows members of the team demonstrating their project to visitors. This project was more technically challenging and therefore the final product was not developed to the point that a ‘customer’ could use the end product.

> “A system for the non-invasive measurement of blood flow in the coronary arteries is being developed. Blood flow through the coronary arteries can indicate the presence of physiologically damaging conditions affecting the cardiovascular system. As the medical community moves more toward non-invasive or minimally invasive surgical techniques, the desire to obtain a blood flow measurement without having to puncture the vascular system is growing. In response to this demand, a proof-of-concept system for the quantification of blood flow in the coronary arteries that will not require the insertion of any device or solution into the vascular system is being designed. This proof-of-concept project involves the design and application of a far-infrared detection system to determine the quantitative blood flow in a coronary artery. Data from a model of the coronary artery network is acquired using a pyrometer. The pyrometer detects natural, infrared radiation emissions caused by the temperature of warm, moving fluid within the artery model. The correlation between the wavelength and intensity of the radiation emissions, the fluid’s temperature profile, and the fluid’s flow rate is calculated. Fluid flow rate

> is displayed to the user. The proof-of-concept will support future directions for this project. These directions include the clinical application of the system and upgrading the components of the design for use in the clinical environment."

Figure 2: A student design team demonstrating their project at the design show. The project is measurement of the blood flow in the coronary arteries using far-infrared thermography.

We have found that the freshmen to senior design sequence has many educational benefits including more satisfaction for the students, and a more complete representation of the design cycle. However, the design sequence can make course scheduling more complex for transfer students and students off the traditional curriculum track. The sequence also requires commitment and coordination from all the biomedical faculty. With each class of students participating in design at some level, a greater number of faculty are involved in the instruction and evaluation of the student progress.

IV. Bibliography

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LISA M. MILKOWSKI
Lisa M. Milkowski is an Associate Professor in the Electrical Engineering and Computer Science Department at MSOE. She received a bachelor's degree in biomedical engineering from MSOE and a master's degree and Ph.D. in biomedical engineering from Marquette University. Her teaching and research interests include signal processing, biomedical computing, engineering design, and physical biomechanical modeling. Milkowski is involved in IEEE – EMBS and is a registered professional engineer in the state of Wisconsin.

VINCENT R. CANINO
Vincent R. Canino is currently a Professor in the Electrical Engineering and Computer Science Department at the Milwaukee School of Engineering. His positions include Biomedical Research Institute, Program Director of Biomedical Engineering, and Program Director of Master of Science in Perfusion. Canino received his Ph.D. in Electrical Engineering (Biomedical Option), from Marquette University. He was responsible for developing the Biomedical Engineering Program and the Perfusion program at MSOE. He is a registered professional engineer in the state of Wisconsin.