Redesigning a Biomedical Engineering Capstone Design Sequence to Enhance Student Engagement

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Olga has earned her undergraduate degree in biomedical engineering from the Milwaukee School of Engineering in 1999, and a doctorate degree in biomedical engineering and functional imaging from the Joint Functional Imaging program at Marquette University and Medical College of Wisconsin in 2004. Prior to entering academia full-time in 2009, Olga completed a three-year postdoctoral fellowship in anesthesiology at the Medical College of Wisconsin, where she studied the effects of general anesthetic agents on brain function. She then worked at GE Healthcare as a product development specialist in CT and Molecular Imaging with emphasis on post-processing software applications for neurology, oncology, and cardiology. Olga has over twenty peer-reviewed publications, and three pending patents. Her professional interests include physiological mechanisms of Alzheimer's disease, anesthetic ablation of consciousness, and applicability of medical imaging in stroke and brain trauma.

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Work in Progress: Redesigning a Biomedical Engineering Capstone Design Sequence to Enhance Student Engagement

The Accreditation Board for Engineering Technology Criterion 5 states that an accredited undergraduate engineering curriculum must include a capstone design process to better prepare its graduates for careers in engineering [1]. One common pedagogical approach to teaching design focuses on problem-based learning and includes clinical immersion and educational experiences that simulate a real-world industrial design process and encourage creativity, innovation and teamwork [2-5].

In line with modern practices, our program's design sequence focuses on system engineering, and includes key design phases of project definition, system-level design, prototype development, and verification and validation. In the most recent revision, we restructured our design curriculum to ensure better continuity of design topics, to facilitate collaborative projects with industry partners, and to alleviate various academic challenges noted by faculty and indicated by students in the course evaluation questionnaires. To this end, we reduced the duration of the capstone design sequence by three academic quarters, and delayed its start to the spring term of the junior year, with system design and prototype building phases to be completed during senior year. Here, we present the student assessment data that motivated that change as well as the data regarding the effects of this change on engagement in design and successful project completion.

Rationale for Design Curriculum Modifications

The previous design track consisted of seven design courses totaling thirteen credits and taught over seven consecutive academic quarters, with the first course offered in the spring quarter of the sophomore year. This sequence allowed for an extended project definition phase involving thorough market research, potential customer interviews, regulatory and House of Quality analyses, as well as the opportunity to develop more detailed design specifications and theoretical system and subsystem design and simulations. While team- and project-dependent, the initial bench system design and prototype-building phases were typically expected to start in the third quarter of the junior year and continue into the senior year. Various professional biomedical engineering (BME) topics relevant to medical device development (e.g. FDA and international regulatory compliance, medical device standards, quality control in medical device manufacturing, and healthcare economics) were distributed among seven design courses. The course sequence contained two design reviews conducted in the fall and winter quarters of the senior year. During the reviews, BME faculty met with each design team to discuss their progress and design decisions, and to provide feedback [6].

The learning outcomes of the design courses along with the students' educational experience were routinely assessed using quarterly course evaluations, senior-exit surveys and debriefing. Until the academic year of 2018, these data were collected for internal program assessment and improvement only, and not for public dissemination (no IRB approval). The feedback from the BME program Industrial Advisory Committee (IAC) was also regularly sought to ensure that the design sequence not only met the ABET educational requirements but also provided regular opportunities for industry collaboration and mentorship of student teams and projects. The composite of these data revealed several disadvantages of this track, which served as the motivation for the most recent revision.

1. Sophomore and junior teams experienced challenges proceeding to design and simulations phases without having completed or being enrolled in essential engineering courses offered later in the junior and senior years [6].
2. As the junior year contains the most challenging courses in our curriculum, the teams experienced the most turnover during that time as some students transitioned out of the program or fell behind on the track. Some teams developed interpersonal problems that seemed to exacerbate over time [6].
3. Due to heavy course load in the junior year, the students were often unable to devote as much time to design as necessary, adding to their level of frustration with the process.
4. The extended design sequence made collaborations with the industry challenging. The projects supported by our industrial partners typically require shorter timelines that do not align well with this design track [6].

New Design Sequence

To address the abovementioned challenges, we reduced the duration of the capstone sequence from seven to four academic quarters and delayed its start to the spring term of the junior year with system design and development to be carried out in the senior year. The total credit load was reduced from thirteen to nine credits. As recommended by the IAC, the new track retained the two design reviews. Professional topics such as intellectual property, FDA regulations and standards which were previously covered somewhat superficially and lacked continuity, were moved to two new courses, *Professional Topics in Biomedical Engineering* and *Biomedical Device Evaluation* [7]. The placement of these courses in the program track ensured that the timing and coverage of these topics were well aligned with the students' progression in the design process. Tables 1 and 2 summarize the two design tracks by courses, major outcomes, topics, and timelines [6].

Table 1: Old Design Track

Old Design Track
Course 1 (1 credit) – Spring Term, Year 2 • **Outcome:** assignment of teams and projects • **Topics:** project management, literature review, codes and standards, user needs **Course 2 (1 credit) – Fall Term, Year 3** • **Outcome:** feasibility analysis • **Topics:** market research, FDA regulation, codes and standards, intellectual property, IRB, design controls, CAD and solid modeling **Course 3 (1 credit) – Winter Term, Year 3** • **Outcome:** specifications and system design • **Topics:** interface specifications, system design, funding, biomedical transducers, power budget, technical literature, initial bench design and prototype building

Course 4 (1 credit) – Spring Term, Year 3
• **Outcome:** system design and testing
• **Topics:** bench design and testing, electrical and mechanical safety, design for safety and reliability, electrical noise and interference
Course 5 (3 credits) – Fall Term, Year 4
• **Outcome:** completion of design and subsystems testing
• **Topics:** medical device evaluation, design for usability, medical device software, professional licensure, technical persuasion.
Course 6 (3 credits) – Winter Term, Year 4
• **Outcome:** system integration and testing
• **Topics:** design for manufacturing, statistics in device testing, global impact of design
Course 7 (3 credits) – Spring Term, Year 4
• **Outcome:** completion of system integration and system-level testing, final documentation
• **Topics:** assembly, engineering ethics, biological safety and sterilization processes

Table 2 contains the outline of the new design sequence. Many professional topics listed in the table are now covered in the *Professional Topics* course and are expected to be applied in the new design courses.

Table 2: New Design Track

New Design Track
Course 1 (2 credit) – Spring Term, Year 3
• **Outcome:** assignment of teams and projects, market research, project plan
• **Topics:** design controls, project management, literature research, FDA regulation, codes and standards, intellectual property, user needs, design specifications.
Course 2 (3 credits) – Fall Term, Year 4
• **Outcome:** design specifications, system design and simulations
• **Topics:** system diagrams, interface specifications, hazard analysis, university resources
Course 3 (2 credits) – Winter Term, Year 4
• **Outcome:** subsystem design, system integration, prototype building and bench testing
• **Topics:** power budgets, electrical noise and interference
Course 4 (2 credits) – Spring Term, Year 4
• **Outcome:** completion of system integration and V&V testing, final documentation
• **Topics:** V&V testing

Assessment Protocol

In this study, we evaluated the effects of the design curriculum change on student learning and engagement by assessing the students' ability (a) to apply a systematic approach to identifying design inputs and outputs, and verifying their attainment; (b) to apply appropriate research and analysis tools; (c) to develop a functional prototype; (d) to work functionally as a team; and (e) to stay continuously engaged. We followed a three-pronged assessment approach, which included the following assessment instruments.

1. Senior-exit surveys;
2. Individual student performance questionnaires completed by the instructors;
3. In-person senior-exit debriefing session conducted by the BME program director.

Two student cohorts, one on the old track and one on the new track, were assessed upon completion of their respective design sequences, and the results were compared between the two groups using the Mann Whitney U-test for statistical significance ($p<0.005$). Consistency in responses among the three instruments was sought as an indication of a valid observation.

In May 2018, 42 seniors completed the old sequence and 27 of them participated in the assessment. In May 2019, 43 seniors completed the new sequence and 22 of them participated in the study using the same assessment methods.

The study protocol was reviewed and approved by the Institutional Review Board before the study began.

While the study collected data with each of the three instruments, this paper presents the results from the analysis of the senior-exit survey only. The data from two other instruments are still being analyzed and will be presented at a later time. The senior-exit survey consisted of nine questions designed to assess the students' abilities and perceived knowledge of the concepts (a) through (e). The students were asked to respond to each question as either *Strongly Agree*, *Agree*, *Disagree* or *Strongly Disagree*. The questions and the corresponding possible responses as they appear in the survey are presented in Table 3.

Table 3: Senior-Exit Survey

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. Our team successfully applied a systematic design approach to identify design inputs and outputs.	O	O	O	O	O
2. Our team successfully applied appropriate research and analysis tools to arrive at the engineering solution.	O	O	O	O	O
3. Our team successfully verified the attainment of all design requirements in the final prototype.	O	O	O	O	O
4. Our team successfully completed a functional device prototype appropriate for the level of challenge associated with the project.	O	O	O	O	O
5. Our team functioned well and found effective ways to resolve conflicts.	O	O	O	O	O
6. The design sequence was too long to stay continuously engaged in the design process.	O	O	O	O	O
7. The design sequence was too short to allow for adequate time to complete the project.	O	O	O	O	O
8. Relevant design content was delivered by the instructors in a timely manner, allowing the team to continuously make progress on their project.	O	O	O	O	O
9. A longer design sequence would improve the overall design experience and would result in a better project.	O	O	O	O	O

Assessment Results

The students from both cohorts responded to all questions on the senior exit survey. Their responses expressed as a percentage of *Agree and Strongly Agree (Agree)*, *Neutral*, and *Disagree* *and Strongly Disagree (Disagree)*, are summarized in Figure 1. The comparison of responses expressed as a percent difference in responses between two cohorts is presented in Figure 2.

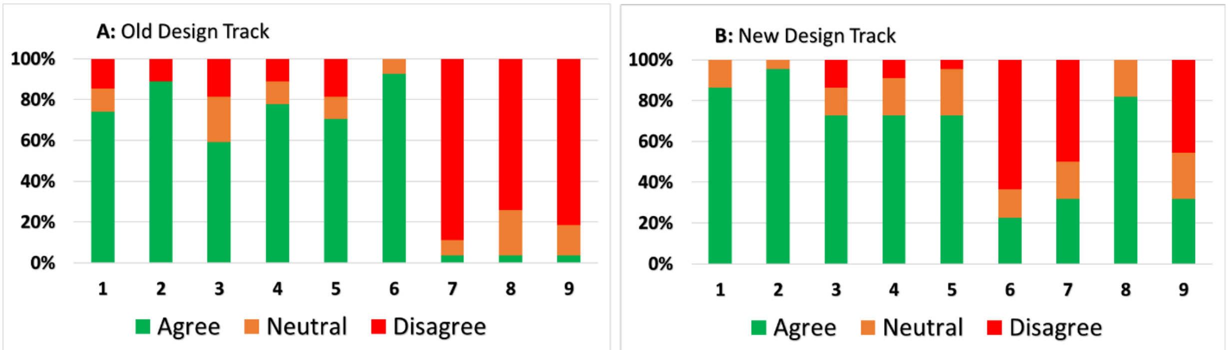

Figure 1: (A) Percentage of responses from students on the old track (N=27) to senior-exit survey questions 1-9. (B) Percentage of responses from students on the new track to senior-exit survey questions 1-9 (N=22). *Strongly Agree* and *Agree* responses were added together forming an *Agree* category. *Strongly Disagree* and *Disagree* responses were added together forming a *Disagree* category.

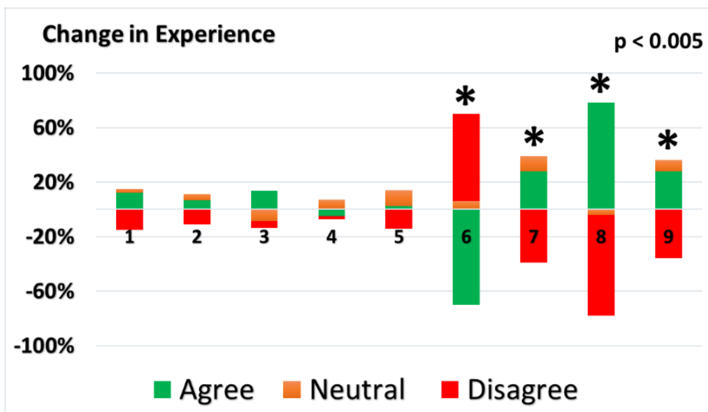

Figure 2: Change in design experience from old to new design track expressed as a percent difference in responses to questions 1-9. *Strongly Agree* and *Agree* responses were added together forming an *Agree* category. *Strongly Disagree* and *Disagree* responses were added together forming a *Disagree* category. As indicated by the Mann Whitney U-test, significant ($p<0.005$) difference between two cohorts was observed in responses to questions 6 through 9, and is indicated by *.

Overall, the results indicate that the curriculum changes significantly ($p<0.005$) improved students' engagement in the design process (questions 6, 7, and 9) and did not affect the students' ability to successfully complete their projects in time for graduation (question 4). Design teams from both cohorts were able to complete their projects in time for graduation, and the quality of projects and the degree of completion did not differ greatly between the two cohorts as indicated by the instructor evaluations of the teams' performance and learning outcome assessments. The results further indicate that the duration of the new design sequence was perceived by students as neither too long nor too short (questions 6, 7 and 9) and allowed for the course content delivery well aligned with the design process (question 8). However, while not statistically significant ($p<0.005$), some students indicated that the duration of the new sequence was not adequate to complete their design successfully; approximately 20% of students indicated that the new sequence was still too long, and approximately 30% of students indicated that the sequence was too short. The explanation of these observations may come out from the analysis of the data from two additional assessment methods. These data will be presented at a later time. **Conclusion**

We conclude that restructuring and shortening of the design sequence from seven to four courses was well motivated, and resulted in the improvement of student engagement in the design process without affecting the students' ability to successfully complete their prototype in time for graduation. It further enabled and optimized the course content delivery to guarantee a timely alignment of the content with the corresponding phases of the design process.

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