Interactive Strategies Used to Teach an Online Medical Device Design Course

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***Abstract*— Medical device design entails the fundamental concepts of determining a need, understanding the diseased state, identifying a market and stakeholders while considering the limitations imposed by the FDA, intellectual property and reimbursement agencies. While this can be difficult to convey in a traditional classroom setting, it can be even more challenging when conveying this information online. Some online courses are inclined to have higher attrition rates than on-campus. With the rapidly growing innovations in the medical field, many students from various backgrounds and majors have shown interest in understanding how to design a medical device. This study introduces interactive techniques used to successfully deliver an online medical device design class while using student engagement approaches. Student performance in course content, discussion threads and ABET outcome c was assessed before and after these strategies were implemented. Results of this study have found an increase in student performance and participation after integration of these methods.**

***Index Terms*— medical device design, online teaching, student engagement approaches.**

Introduction

According to the Bureau of labor and statistics, biomedical engineering is one of the most rapidly growing fields in comparison to other engineering disciplines. Biomedical engineers are projected to have a 27% job growth between 2012 and 2022 [1]. Colleges and universities are trying to keep up with the rapid development and innovation in the medical field by equipping graduates with the necessary skill sets to become successful engineers. Numerous undergraduate programs have been developed and accredited in the past 20 years. Since January 2015, there have been 92 accredited biomedical/bioengineering programs alone. Due to this high demand and growing industry, students from various disciplines have also shown interest in acquiring graduate degrees, certificates or taking electives in biomedical engineering.

To keep up with the increased interest in biomedical engineering, universities have been transitioning from traditional face-to-face classes into fully online, blended, or web-facilitated courses to maintain a competitive edge and make classes more accessible to the growing, diverse student populations [2]. Increasing the availability of online engineering degrees can potentially increase the number of qualified employees in the workforce [3] which may in turn produce better innovation as new perspectives are introduced. Online education has provided a multitude of job opportunities, knowledge and increased skill sets for the world's population[4]. For the adult learner with constraints such as their job, family obligations or campus distance, the online platform becomes the ideal solution for life-long learning [4].

Despite the large transition from traditional to online classes, there are still some hurdles that have caused universities and colleges to not fully adopt online learning. This is due to factors such as the higher attrition rates experienced by online courses [4, 5]. Attrition rates have shown to be higher in distance learning courses than their traditional face to face counterparts [6]. This may be due to issues such as: time management, workload, isolation felt by the online student, lack of student engagement or the level of difficulty [4, 6, 7].

Student engagement and learner centered approaches have been shown to improve the attrition rates in distance learning classes [8]. Both techniques are used for both traditional and non-traditional delivery mechanisms and have demonstrated success over various curriculums. Some of the basic principles are methods that include: (1) establishing a curriculum that is designed for learning and is well thought out by connecting students with topics that are relevant to their interests and overall goals (2) creating meaningful assignments where students see the value; students should be given assignments to solve real-world problems with greater context (3) building relationships with students [9, 10].

Due to the high interest in biomedical engineering, many engineering schools have developed medical device design courses for the non-biomedical engineer. This course is typically provided as a course for a certificate programs, or an elective for other engineering majors that may be interested in learning how to develop a medical device. Topics introduced explore the various constraints involved in their design process, with include: FDA regulations, reimbursement, and physiological limitations. In this paper, the implementation of student engagement and learner centered approaches are used to develop an online medical device design course and demonstrate the efficacy of using such methods to potentially increase retention rates online and improve student learning outcomes.

METHODS

The medical device design course is administered over a 14-week academic period online and is available to senior and masters level students. The course introduces

students to the fundamental concepts associated with developing a medical device. The course objectives were the following: 1) identify methods and strategies to come up with a medical need 2) determine the diseased state and treatment options of an identified need, 3) determine the diseased state and treatment options of an identified need, 4) discuss regulatory and intellectual property basics, 5) construct a market analysis and business model.

These learning outcomes were assessed using three exams, weekly discussion topics and a final project that entailed writing a grant to ask for funding. In this study, the effect of student engagements techniques was examined before and after strategies were implemented. Student performance in examinations, discussion threads and ABET outcome c (the ability to design a system, component, or process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability and sustainability) were investigated. Student performances were assessed Fall 2015, n= 11 and Spring 2016, n=10 before any pedagogy was used. After implementing student engagement approaches into the curriculum, student performances were assessed in the Spring 2017, n= 13 and Fall 201, n= 15. In all four semesters, less than 10% of the students were business majors and the rest were engineering majors from various disciplines. Student engagement approaches included enhanced components to the course as shown in Table I.

TABLE I.
STUDENT ENGAGEMENT APPROACHES

Student Engagement Approaches
1. **Building toward an end goal.** This approach was implemented by giving several small assignments that build up to a final project. These assignments were components of the grant proposal that was assigned as the final project. Students were reminded several times in announcements, on the syllabus and throughout the semester that the grant was the end goal.
2. **Discussions on "hot topics" and current events in weekly threads.** This strategy peaks the student's interest by discussion topics that are both relevant to the course and society. This engagement approach makes students feel more connected to the courses' contents.
3. **Using technology to enhance learning.** Students were given the optional choice to listen to entrepreneurial podcasts. This engaged students through the technology avenue. Some students enjoyed podcasts outside of class and were intrigued by the new content introduced in this course.
4. **Finding their passion and solving a real-world problem.** By asking students thought-provoking questions, students were able to identify a medical need they felt passionate about. As a result, they were more motivated to come up with a solution to a real- world personal problem.

RESULTS

Paired t-tests were used to investigate if statistical differences were demonstrated after student engagement tactics were used. The average of three exams were compared amongst the four semesters. Each exam was a multiple-choice exam that assessed the course learning objectives. A statistically significant increase was shown between the Fall 2015 semester (prior to using student engagement approaches, p=0.03, M= 86, SD= 8.1) and the Fall 2017 semesters (p=0.03, M= 93.2, SD= 8.9). A difference was also observed in the Spring 2017 semester as well shown in Figure 1.

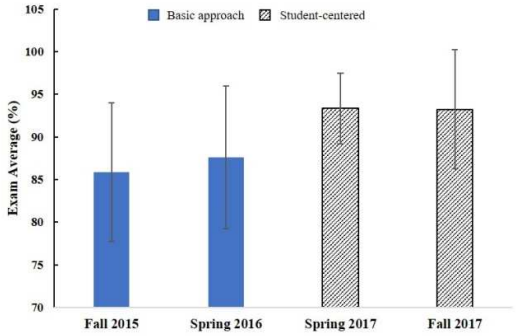

Figure 1: The mean +/- the standard deviation of all three exam averages before and after student engagement approaches were implemented into the course.

The weekly discussion threads were initially conducted by asking students to answer a question pertaining to the topic being taught for the week. For example, if the topic covered was a marketing analysis, a question such as what type of marketing strategy would you use to analyze your medical devices market? Grading rubrics are outlined in Table II. When observing the impact student engagement had on the discussion threads, after adding podcasts and "hot topic" questions, a significant increase was also seen in discussion thread performance (p=0.01, M= 86.5, SD= 7.5 in the Fall 2015 semester and M= 95.3, SD= 7.6) Students increased their average by approximately 10% after these techniques were utilized.

To determine the overall effect on ABET outcome c, "the ability to design a system, component, or process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability and sustainability", the final grant project was used for this assessment. Students were assessed on a scale of 1 to 4 with 1 being unsatisfactory and 4 being exemplary. No statistical differences were demonstrated before and after the pedagogy was implemented into the course. However, the average scores were above 3.0 consistently throughout the semesters. This was considered to be satisfactory for the course.

TABLE II:
DISCUSSION POST GRADING RUBRICS USED FOR ASSESSMENT OF WEEKLY POSTS.

Online Discussion Grading Rubric				
Performance Criteria	**0**	**1**	**2**	**3**
Delivery	Poor spelling and grammatical mistakes in post.	Minor spelling and grammatical mistakes.	Acceptable grammatical usage and delivery of post.	Excellent usage of sentences and structure.
Topic relevance	Post does not relate to the topic question posed	Response has minor relevance to topic.	Acceptable relevance to topic.	Excellent connections and relevance to topic.
Contribution to the discussion topic with primary response	Does not make effort to contribute additional knowledge.	Makes minimal contribution to the discussion topic.	Contributes to topics in several instances using examples or content from textbook.	Contributes to topic using several examples, studies, and content from textbook.
Quantity of responses	Responded one time.	Responded two times.	Responded three times.	Responded four or more times.
Initiative to peer responses	Does not add any value.	Adds little value in their response.	Adds at least two valuable points or examples in their response.	Adds many instances of value to peer response.

DISCUSSIONS

Based on the results of this investigation, adding engagements techniques have shown to improve learning outcomes and discussion thread performances. Students have demonstrated an improvement in learning the content of the course with these strategies. By keeping students part of the online community, establishing a sense of real-world context to the course and giving the course an end goal, student performances were significantly improved. Medical device design is a challenging course to teach both online and on-campus and using creative techniques to improve learning outcomes is essential. Due to the challenges that many online courses face, this study recommends successful approaches to improving the online experience when teaching a medical device course to non-biomedical engineering majors. The following are steps of the courses' delivery sequence and how strategies were integrated into the course:

1. Organization is key. It is important that students get an idea of what the course will entail, and this should be communicated at the beginning of the course. This is one of the most crucial elements of any online course. The instructor of the course should not only outline the learning outcomes in the syllabus, but they should clearly convey the skill sets that students should expect to acquire at the end of the semester. This can be implemented in the syllabus or the introductory email at the beginning of the course. As an instructor, the key is to have a vision of what skill sets students should acquire from the course.

In this course, students were asked to complete various assignments throughout the semester that were necessary for the final project of the course. The goal of the project was to develop a medical device and write a grant to ask for funding from an investor. Students were given a clear message as to what the end goal of the course is which is shown in Figure 2. This was implemented as one of the strategies by introducing this in the first week of class, on the syllabus and in periodic announcements.

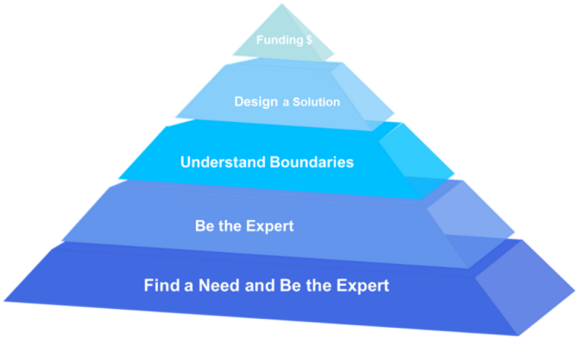

Figure 2: Sequential flow of how the course is administered. Students are introduced to the concept that their end goal is to ask for funding. Each assignment builds on the other to achieve the final goal.

2. Keep students engaged with "hot topics" and weekly thought-provoking questions. Each week students were asked to discuss topics that are outlined in the week but with a twist. For instance, when discussing topics such as reimbursement, questions were posed from current events. For example, how will the health care bills being passed by the government affect your medical design? Suggest an ideal reimbursement plan that would benefit medical device companies and the government. Why are some medical devices not being reimbursed but still have FDA clearance? Other topics such as the FDA, included questions such as: what is the biggest hurdle the FDA is imposing that may hinder your medical device and how can you overcome it?

These were a few of the thought-provoking questions that students were asked to answer on a weekly basis. As the instructor, it is imperative to have periodic checks as to how the discussion board is going. If the right questions are asked, students will be excited to participate in the weekly threads.

3. Using technology to think like an entrepreneur. It is vital that students get excited about the fact that their design can be commercialized. Using technology such as the PODCAST application (i.e. available on any smartphone) was introduced as an "optional" but highly recommended exercise. Students were asked to listen to the NPR "How I Built This" podcast and comment. These podcasts have been one of the most interesting features of the class. Famous and successful business owners such as: Mark Cuban, Kate Spade, Five Guys chronical their business stories. They discuss how they started, their challenges and what ultimately made them successful entrepreneurs. Students listen to how some of the most renowned brands have become successful businesses. Once they have listened to the podcast of their choice, they are asked to comment on which skill set made this person successful. Was it their marketing skills? Their customer service skills? Was it their drive? This helps students

identify an area that they may be successful in their pursuits of owning their own medical device company. It also allows students to feel connected to the classroom and wanting to share their thoughts with their peers, therefore creating more of an online community that they belong to.

4. Discovering a medical need and their passion. Allowing the context of the course to converge with real life is one of the student engagement approaches used in this course. When designing a medical device, one of the most difficult tasks for both the online and traditional class learner is identifying a need. To improve this component of the course, one of the best strategies implemented was asking students emotionally connected questions such as: have you or a family member struggled with a medical condition and were not satisfied with the diagnosis or treatment?, have you ever witnessed something in the emergency room, your doctor's office, dentist or any medical environment that seemed to be dated or primitive? Is there a better way of doing it? Tapping into their passion is the key. This will allow students to become passionate about solving the need that they have identified and creates a connection to the course.

5. Become an expert (almost). Once students have identified a need, students should become experts on the disease. Excellent strategies on how to research diseased states are outlined in many textbooks. They should be able to understand the system in a normal and diseased state and the impact that is endured as a result. They are also introduced to the stakeholders that are involved in the process and how these stakeholders can hurt or help the outcome of their success. The targeted market and population using the proposed device must also be identified. In the online environment, it is important to emphasize why this information is pertinent to allow them to invest more time into the project.

6. Know your boundaries. Concepts such as reimbursement, the Food and Drug Administration (FDA) should also be introduced. Students must understand some of the boundaries that medical devices entail. Before proposing a solution to their medical need, they must understand the restrictions the FDA has on Class I, II and III devices along with the monetary limitations that exist. In addition, understanding how intellectual property can affect their business model, design and strategy is key. The best way to implement this online is through short videos or case studies.

7. Time for a solution. Throughout the semester, weekly assignments should allow students to gather all of the mentioned components to develop a device. With this information, students should now be ready to propose a solution. The unique part of this course is that you do not have to be an engineer to propose a design. Students can articulate their design through diagrams developed on Power Point, Paint or SolidWorks. Recommendations of how to articulate a design are discussed prior to this exercise. Students were required to illustrate the design, label features, and demonstrate how a patient, nurse or physician will interact with the device. An intended use description is also required. Students must articulate how the design should be used. This technique solidifies their understanding of their design especially when legal ramifications of a well written Intended use description is mentioned.

8. The end goal. The final stage of the semester is the grant writing final project. This has been the moment that the course has been building up to. Students are given tutorials and examples of how to write a Small Business Innovation Research (SBIR) grant. The assignments that were given throughout the semester are encouraged to be integrated in the grant proposal. The market, diseased states significance, and their proposed solutions are implemented into the final argument. Key points that are highlighted: a) tap into your passion about this need and why your proposed solution is the answer b) the chances of this being commercialized c) intellectual property potential or filing d) expertise to accomplish technical goals outlined d) devising a budget that makes sense e) present a reasonable timeline.

CONCLUSIONS

Medical device design has generated a lot of interest in the past decade. With companies training employees and expecting greater skill sets, many adult learners are entering the academic world through the online platform. It is essential for faculty to keep students engaged by using innovative techniques. This study has shown that students have performed significantly better once student engagement approaches were used. These strategies can also be implemented in the traditional classroom setting to build students with a more rewarding experience. This study can be further validated with larger sample sizes. In addition, more assessment tools can be used such as instructor ratings or mid-semester performances.

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