

AC 2009-1549: ACTIVE-LEARNING EXPERIENCES ON MEDICAL DEVICES FOR MANUFACTURING AND NEW PRODUCT DEVELOPMENT

Susana Lai-Yuen, University of South Florida

Susana K. Lai-Yuen is an Assistant Professor of Industrial & Management Systems Engineering at the University of South Florida, USA. She received her Ph.D., M.S., and B.S. (Summa Cum Laude) degrees in Industrial Engineering from North Carolina State University, USA. Her research interests include computer-aided design (CAD), computer-aided molecular design (CAMD), human-computer haptic interfaces, computational geometry for design and manufacturing, and engineering education. She is the director of the Virtual Manufacturing and Design Laboratory for Medical Devices (VirtualMD Lab) at USF.

Kingsley Reeves, University of South Florida

Kingsley Reeves is an Assistant Professor at the University of South Florida in the Industrial and Management Systems Engineering Department. In addition to engineering education, his core research interest centers on the creation of value across the extended supply chain. His current research focus is on inter-organizational and intra-organizational collaboration within the healthcare supply chain.

Active Learning Experiences on Medical Devices for Manufacturing and New Product Development

Abstract

This paper describes the ongoing work of a NSF CCLI project for analyzing the impact of medical device-related active learning pedagogies in manufacturing and new product development courses within the engineering curriculum. The main focus of the study is on the impact of these approaches on students' engagement, retention of material, and conceptual understanding of course material. A project-based learning (PBL) approach was incorporated into a manufacturing processes course through a real-world medical device project to provide students with active learning experiences on medical device design and manufacturing. The course was redesigned to provide a combination of lectures on theoretical concepts and hands-on laboratory sessions focused on medical devices to help students through the learning process and the realization of their projects. Preliminary results show that the redesigned course through integration of a real-world medical device project-based learning approach increased students' interest and understanding of design and manufacturing principles.

1. Introduction

The medical device and equipment industry is one of the fastest growing industries in the world. The U.S. is the largest medical device market and is the global leader of the medical device and technology industry. Medical devices are important for the diagnosis, monitoring, and treatment of disease, and for the compensation for an injury or handicap. The increasing life expectancy and the search for better health care and preventive therapies have influenced the demand growth for medical devices. To remain competitive in the global market, medical device manufacturers need highly qualified engineers to develop innovative and functional products.

Undergraduate engineering students are often taught theoretical concepts without having the opportunity to actually apply these concepts in a real-world context. The National Academy of Engineering (NAE) made the following two recommendations that are relevant to academic institutions: (1) academic institutions should take the steps to cultivate U.S. student interest, and aptitude for careers in engineering, and (2) academic institutions should develop and implement innovative curricula that address the engineering needs of the nation, but do not compromise the teaching of fundamental engineering principles⁷.

Active learning approaches are essential for students to think about what they are learning and to increase their engagement, retention of material, and conceptual understanding. Active learning can be defined as any instructional method introduced into the classroom that engages students in the learning process⁸. Research in the adoption of active learning techniques in engineering courses has demonstrated benefits to student learning outcomes^{2-4, 8}. Along with active learning, problem-based learning (PBL) is an instructional method where relevant problems are presented at the beginning of the course to provide the context and motivation for learning⁸. Through a PBL approach, students learn to address realistic and complex problems instead of academic and

simplified tasks while developing independent learning and collaborative working skills. Moreover, challenging “real-world” projects can greatly motivate students and reinforce knowledge transfer and integration of fundamental principles^{1,5,9}.

This paper describes the ongoing work of a NSF CCLI project that addresses the NAE recommendations and the needs of the medical device industry by employing active learning techniques in two undergraduate engineering courses at the University of South Florida (USF). These two courses, Manufacturing Processes and New Product Development, complement each other as the former course introduces students to the fundamentals of product design and manufacturing processes while the latter course introduces students to the new product development process from identifying customer needs to new product economics. Both courses will be redesigned to include hands-on projects focused on real-world medical device design and manufacturing problems. Figure 1 shows the relationship between the two courses and the proposed integration of active learning activities in the courses in collaboration with medical device industry participants.

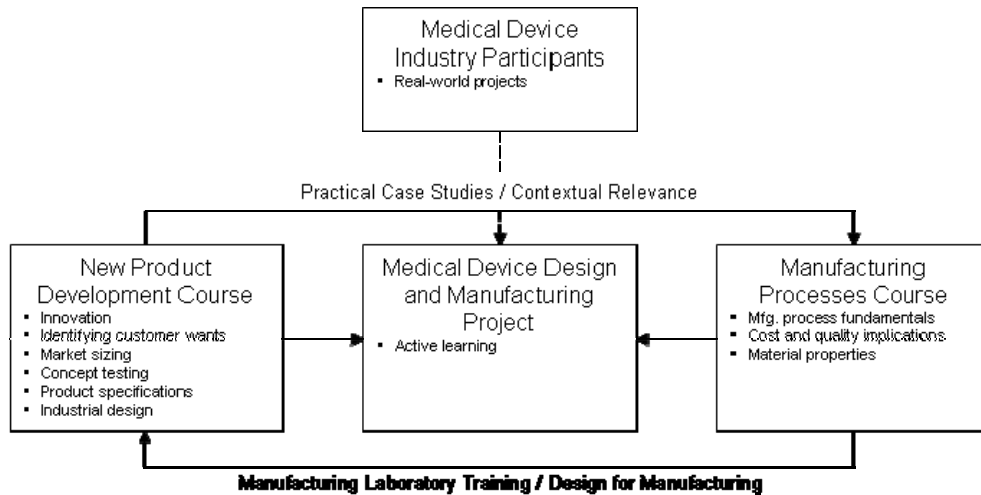


Figure 1. Overview of the project.

The focus of this paper is on our preliminary results from the Manufacturing Processes course, which was taught on two different semesters to two different student groups. The first group was the control group who experienced the original version of the course while the second group was the treatment group who experienced the redesigned version of the course. A project-based learning approach was used in the redesigned Manufacturing Processes course through the incorporation of a real engineering medical device project. The project consisted on designing and prototyping a new medical device to improve a minimally-invasive surgical procedure. The course was redesigned to provide a combination of lectures on theoretical concepts and hands-on laboratory sessions focused on the medical device project to help students through the learning process and the realization of their projects. Data has been collected from the control and treatment groups and will be analyzed to assess the impact of active learning pedagogies on

students' engagement, retention of material, and conceptual understanding of course material in this course.

2. Methodology

The focus of this study is on the impact that medical-related active learning approaches have on students' engagement, retention of material, and conceptual understanding of course material. The study tracks control and treatment groups as they participate in the course. The control group is a cohort of students experiencing the original version of the course. The treatment group is a cohort of students experiencing the redesigned version of the course that integrates active learning strategies based on real-world medical device projects. This paper describes the redesign and preliminary results from one of the participant courses, Manufacturing Processes.

2.1 Manufacturing Processes course

The Manufacturing Processes course at USF is an undergraduate course targeted at sophomore and junior-level students. The course is offered once a year and is a course requirement for the Industrial & Management Systems Engineering B.S. degree. Students learn the mechanical properties of materials and manufacturing processes. The course emphasizes the relationship between design and manufacturing and their impact on the product's quality and cost. The prerequisite of the course is Introduction to Design Graphics where students learn engineering drawing and CAD software.

The original structure of the course taught to the control group consisted of lectures and weekly lab sessions. The course lectures and lab sessions were focused mainly on material properties and manufacturing processes. There were 17 undergraduate engineering students enrolled in the course. In the middle of the semester, a course project was assigned to the control group to design and manufacture the prototype of a new product. Student teams were free to select any specific product subject to dimensional constraints.

2.2 Incorporating a project-based learning (PBL) approach

The Manufacturing Processes course was re-designed to incorporate a project-based learning approach by assigning the treatment group a real medical device project at the beginning of the course. The course was structured so that the class lectures and laboratory sessions provide theoretical and applied learning experiences on product design and manufacturing related to the project. The real medical device project was provided by a medical doctor and practicing surgeon from the USF College of Medicine. The project consisted of designing and prototyping a new medical device to improve a minimally-invasive surgical procedure. The medical doctor introduced students to the problem and desired end product, then, throughout the semester, students worked towards the project's goal by learning fundamental concepts of design and manufacturing through class lectures and lab sessions. This project presented a real application of design and manufacturing with high societal impact. Moreover, it provided an open-ended problem that required interdisciplinary collaboration and problem-oriented approaches.

The medical device project was introduced to the students by the medical doctor through a video and a medical training kit. Students then attended a real surgery at neighboring hospitals to observe on-site surgical operations. This helped the students to better understand the problem and constraints while realizing the impact of the medical device to be designed.

Course lectures were designed and introduced into the course to address the theoretical foundations of design and manufacturing processes with a focus on medical devices. The redesigned course focused not only on manufacturing processes but also on product design. A major difference in the design and manufacturing of medical devices in comparison with other products is the strict regulation on medical devices by the Food and Drug Administration (FDA). The design of medical devices requires students to be aware of federal regulations and to consider them early in the design phase of a project since regulations “affect the way medical devices are designed, developed, and tested”⁶. Topics incorporated into the course included medical device categories, phases in medical device life span, medical device design procedures, and design for manufacturing and assembly (DFM and DFA). During the lectures, a real surgical tool and other medical products used in daily life were used to explain how the different components of the device were manufactured. On one side, these exercises provided students with a better understanding on the various manufacturing processes available and their selection based on the particular component. On the other side, the exercises helped the students on their projects as they tried to identify the appropriate manufacturing process for their own designs.

Course lectures were followed by hands-on laboratory assignments where students were given a problem to solve using the concepts learned in the classroom and utilizing the design and manufacturing facilities at the lab. The first laboratory sessions provided students with hands-on experiences in programming and operating manufacturing equipment such as CNC milling and rapid prototyping machines. The manufacturing laboratories were performed in teams of 2 to 3 students.

Students taking the Manufacturing Processes course have been exposed to CAD software through a pre-requisite course. However, it was observed during the teaching of the control group that their exposure to CAD software was limited and this caused several challenges during the product design stage. For this reason, the redesigned course incorporated laboratory sessions on 3D solid modeling using SolidWorks[®] CAD software, which they were going to use for their projects. This CAD software was incorporated into the course for the first time and was selected due to its 3D design capabilities, easy-to-use graphical user interface, and its popularity in academia and industry. As students have not worked with SolidWorks[®] previously, the materials for these laboratories were developed to gradually provide students with hands-on experiences on the software at the basic and advanced level. Students worked on the design laboratories independently so that each student would acquire proficiency on the software. An evaluation form was provided to the students after they completed the SolidWorks assignments to assess the effectiveness of the laboratory materials in learning the software, and student understanding of design and manufacturing concepts.

Teams of 3 to 4 students were formed to work on the medical device project for a period of 12 weeks. All the teams worked on several design iterations using SolidWorks[®] and had weekly discussions with the instructor and teaching assistant. Teams also consulted their designs with

the medical doctor. Students participated during the lectures by bringing the challenges they were facing in their projects into the classroom for discussion and for understanding the fundamental design and manufacturing principles. Given the nature of the project, students learned independently and collaboratively about medical procedures, commercially available medical devices, and human anatomy for the realization of their projects. Once the designs were approved for fabrication, teams were scheduled at the lab and the designs were fabricated using two rapid prototyping machines: a Dimension[®] Fusion Deposition Modeling (FDM) machine and a ZCorp[®] 3D printer. Through this approach, students had hands-on experiences in operating the machines and assembling their prototypes as shown in Figure 2.



Figure 2. A student making a component for the project in one of the rapid prototyping machines.

3. Preliminary Results

Assessment materials have been developed in collaboration with Dr. Melinda Hess from the Center for Research, Evaluation, Assessment and Measurement at USF. These materials collect students' perception and experiences as well as learning outcomes. Students enrolled in both the control and treatment groups of the course participated in the course evaluation and responded to anonymous questionnaires. Dr. Hess is evaluating this project to determine the impact of the newly developed active learning pedagogies in students' learning outcomes.

Based on the preliminary results of the evaluation conducted to date, Table 1 shows the questions provided to the treatment group after the completion of the design laboratory and the medical device project. Each question used a five-point Likert scale where 5 being "very much" and 1 being "not at all". Figure 3 shows the results from the student evaluations with 24 respondents. It can be observed that on average, students agree that the laboratory was interesting and helped them in understanding design and manufacturing better while also increasing their interest in learning. Figure 3 shows a significant increase in the students' response on the same questions after the completion of the medical device project at the end of the course. This demonstrates the high positive impact of the medical device project on students' motivation and learning. Students also expressed that the course project was very challenging. This is expected as the project was a complex open-ended problem that required additional effort from the students in learning in and outside the classroom. The fact that the project was based on a real medical

device need significantly increased the level of commitment perceived from the engineering students towards the design and manufacturing process of the medical device.

Table 1. Questions in the student evaluation after completion of the design laboratory and medical device project.

Question
1. This activity was interesting
2. This activity enhanced your understanding of product design and manufacturing
3. Did this activity increase your interest in the product design and manufacturing process?
4. Was the activity challenging?
5. Overall, how would you rate this activity?

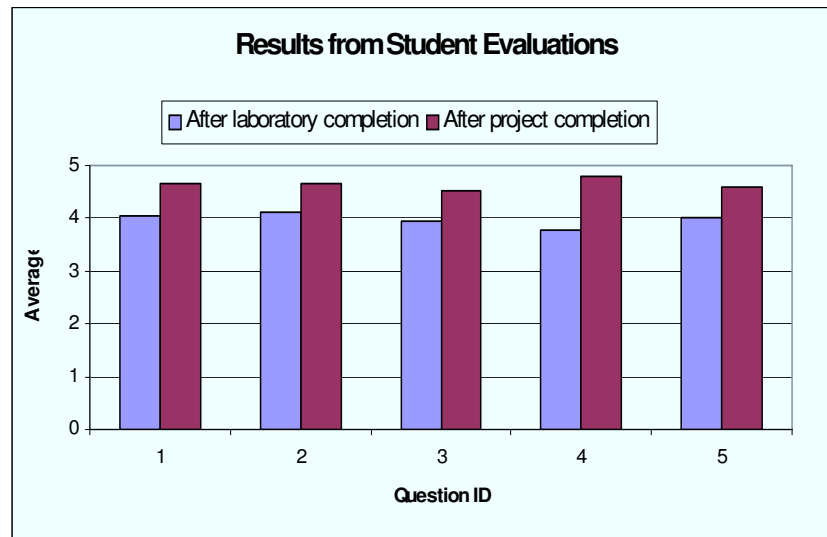


Figure 3. Results from student evaluations after the design laboratory and medical device project were completed.

Other assessment tools to determine students’ level of retention of material and conceptual understanding such as homework, exams, lab assignments, and project reports have been compared between the control and treatment groups. It was found that on average, students from the treatment group performed better than the control group on all tools, particularly on the lab assignments. This provides an indication of the effectiveness of the course redesign by relating fundamental concepts from class lectures to lab sessions through the integration of a real-world medical device project-based learning approach.

4. Summary

This paper presented the ongoing work of a NSF CCLI project for analyzing the impact of medical device-related active learning pedagogies in manufacturing and new product

development courses within the engineering curriculum. A project-based learning (PBL) approach was incorporated into the manufacturing processes course through a real-world medical device project from a medical doctor and practicing surgeon. The course was redesigned to provide a combination of lectures on theoretical concepts and hands-on laboratory sessions focused on medical devices to help students through the learning process and the realization of their projects. Preliminary results show that students in the treatment group found the medical device project to significantly increase their interest and understanding of design and manufacturing. Data from the control and treatment groups have been collected and are currently being evaluated to determine the impact of these active learning approaches on students' learning. It is expected that active learning approaches related to medical devices will increase students' engagement and conceptual understanding of design and manufacturing principles while increasing their awareness on the impact these activities have on the medical device industry and society as a whole.

Acknowledgements

This research was supported by the National Science Foundation (NSF) Grant (DUE-0736950) to the University of South Florida. Their support is greatly appreciated.

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