AC 2009-422: INTEGRATING REAL-WORLD MEDICAL-DEVICE PROJECTS INTO MANUFACTURING EDUCATION

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Integrating Real-World Medical Device Projects into Manufacturing Education

Abstract

This paper describes the integration of real-world medical device projects into manufacturing education to increase students' interest and hands-on experiences in product design and manufacturing while exposing them to real engineering challenges. Teams of undergraduate students in a Manufacturing Processes course worked with a medical doctor and practicing surgeon on a project to design and create the prototype of a new medical device to improve a minimally-invasive surgical procedure. The medical device project provided students with real engineering and interdisciplinary learning experiences with clinical exposure and high societal impact. The end goal is to prepare students with skills in design and manufacturing, problem solving, teamwork, and communication for successful careers in industry. This will benefit the growing medical device industry by bringing qualified engineers with the technical knowledge and experience in working with medical doctors in the development of innovative medical device products.

1. Introduction

Results from several industry surveys and academic studies show that graduating engineers are inadequately prepared for careers in industry [1-3]. The Society of Manufacturing Engineers (SME) conducted a survey in the advanced manufacturing sector that identified the competency gaps as project management, specific manufacturing processes, product/process design, problem solving, communication, and teamwork, among others [4]. For this reason, it is imperative for universities to provide students with learning experiences on real engineering problems so they can develop the necessary skills to address complex open-ended problems and to meet the industry need for highly qualified engineers to compete in a global market.

The medical device industry is currently one of the fastest growing, highly innovative, and intensely competitive industries in the U.S. and the world. The U.S. leads the medical device industry in the world, followed by the European Union and Japan. The increasing life expectancy and the search for better health care and preventive therapies have influenced the growth in the demand for medical devices. Medical devices are important for the diagnosis, monitoring, and treatment of disease, and for the compensation for an injury or handicap. These devices can range from orthopedic and cardiac implants to nanotechnology-based drug delivery devices. Figure 1 shows the percentage distribution in annual sales among the major segments of the medical device industry in the U.S. that was over $100 billion in annual sales in 2004 [5].

The U.S. medical device industry has been growing at an average annual rate of 9% for the past 10 years [6]. To remain competitive in the global market, medical device manufacturers need highly qualified engineers to develop innovative and marketable products. For this reason, engineering education should be proactive to industry needs so that graduating engineers are adequately prepared for careers in industry.

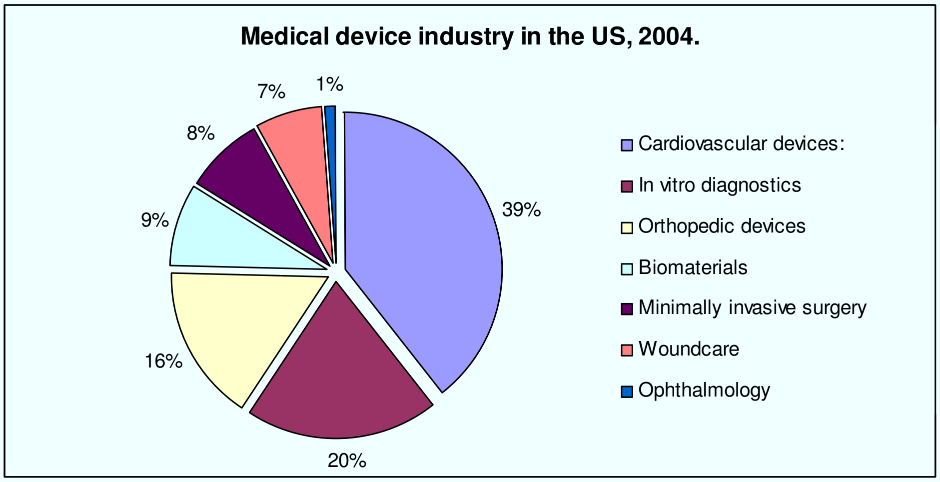


Figure 1. Percentage distribution in annual sales among the major segments of the U.S. medical device industry in 2004 [5]

Researchers from different engineering areas have proposed the integration of real-world projects in a course to promote student engagement through practical involvement [7]. Manufacturing, Mechanical and Biomedical engineers have proposed interdisciplinary approaches and learning strategies through industry-academic partnerships to facilitate the integration of real applications into engineering courses [8-12, 14-15]. These strategies enable undergraduate students to learn skills and apply their engineering knowledge for solving real problems from industry. Virtual laboratories have also been established to motivate engineering students to pursue collaborative research with professionals from different disciplines by simulating real environments [17, 18]. In the case of the medical device industry, it is necessary to provide students with real engineering problems related to medical devices that will help students in developing the necessary skills for the medical device environment. This will require students to become familiarized with clinical environment, medical procedures, federal regulations particular to medical devices, and to work with medical personnel who know best the requirements for new medical devices.

This paper presents a case study of integrating a real-world medical device project in a manufacturing processes course at the University of South Florida (USF). Undergraduate students worked together with a medical doctor and practicing surgeon in the design and prototype of a new medical device to improve a minimally-invasive surgical procedure. The project exposed students to a real engineering problem in a clinical environment by attending an on-site surgery that increased their understanding of the problem, the constraints, and the impact of the device. Students worked in teams at a newly established Virtual Manufacturing and Design Laboratory for Medical Devices (VirtualMD Lab) that provided design and manufacturing software and equipment for the realization of the projects. Results were collected and analyzed based on the students' skills in design and manufacturing processes, problem-solving, teamwork, and communication.

2. Case study: Integrating a real-world medical device project into the Manufacturing Processes course at USF

2.1 Course and laboratory description

The Manufacturing Processes course offered by the Industrial & Management Systems Engineering department at USF is an undergraduate course for sophomores and junior-level students. Students learn about material mechanical properties and manufacturing processes. The course consists of lectures and two-hour laboratory sessions per week. The newly project-integrated course had an enrollment of 24 undergraduate engineering students.

Given the need to provide students with hands-on experiences on medical device applications, a new laboratory has been established at USF named Virtual Manufacturing and Design Laboratory for Medical Devices (VirtualMD Lab). The laboratory is an interdisciplinary facility with technologies in the areas of product design and manufacturing with emphasis on medical devices. Its main goal is to provide students with hands-on experiences on equipment and software related to product design and manufacturing for the realization of medical device projects. The VirtualMD Lab is a collaborative effort of experienced faculty from the departments of Industrial & Management Systems Engineering and Mechanical Engineering, the Center for Applied Research in Medical Devices (CareMed), and the Rehabilitation Engineering & Technology Center at USF. Facilities include CNC lathes and milling machines, a fused deposition modeling (FDM) machine, a 3D printer, a 3D laser scanner, virtual haptic interfaces, and CAD/CAM software. The Manufacturing Processes course is the first from a set of undergraduate engineering courses that incorporates the VirtualMD Lab to enhance students' skills for careers in industry through the realization of real-world medical device projects.

2.2 Project description

A real-world project on medical devices was integrated into the Manufacturing Processes course at USF. The project was performed in collaboration with a medical doctor and practicing surgeon from the USF College of Medicine who presented the need for a new medical device to improve a minimally-invasive surgical procedure. The objective of the project was to design, implement, and fabricate the prototype of a new medical tool that will address the functionalities specified by the medical doctor while being easy to use and feasible for manufacturing. A prototype of the proposed design was requested to assess the functionality and appearance of the device. Students were asked to design the mechanism, its components, and the frame that will enclose the mechanism. No sensors or other electrical components were required for the device. In addition to the specified requirements, students were asked to take into account the variability among patients of different body complexion.

The designs from the medical device projects presented in this paper are currently being refined in a subsequent undergraduate course to incorporate into the design aspects such as green manufacturing, product life cycle, and economics. Once the designs are refined, successful designs will be submitted for patent. For these reasons, details on the specific problem addressed by the device, its functionality, and student teams' designs have been omitted in the paper for confidentiality purposes.

2.3 Methodology

The medical doctor introduced the medical device problem to the students through a video of the surgery so students could get familiarized with the surgical procedure and the current medical devices used in surgery. The medical doctor also showed students the operation of the devices and the current drawbacks during surgery using a medical learning kit that is used to teach medical students. Students had the opportunity to practice using the medical learning kit to better understand the maneuvers needed during surgery and the requirements for the new medical device.

Once students were familiar with the surgery, groups of at most five students attended and observed on-site surgeries in the operating room at neighboring hospitals. For engineering students, attending an on-site surgery can be a very challenging experience but students learned a lot from the experience. Students who attended the on-site surgery stated that they understood the problem better and became more aware of the importance of a good medical device design after observing the on-site surgery.

The President and CEO of a local medical device company with years of experience in medical regulatory affairs introduced students to the medical device regulations and good manufacturing practices from an industry perspective. Teams of 3 to 4 students were formed for the realization of the course project that took 12 weeks to be completed. Each team prepared and submitted an initial proposal describing their proposed medical device, its mechanism and components. Feedback from the instructor was provided on a weekly basis so that students could redefine their designs and make the necessary changes. Teams of students met with the teaching assistant at the VirtualMD Lab every week to work on their designs and obtain feedback. Students also received feedback from the medical doctor during the realization of the project.

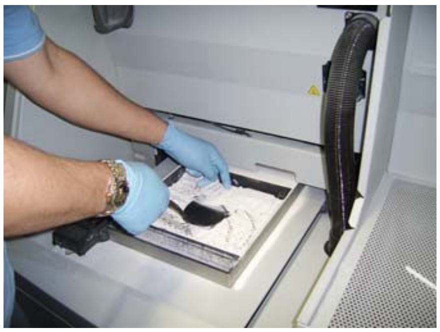
(a) Fusion deposition modeling (FDM) machine

(b) 3D printing machine

Figure 2. Rapid prototyping equipment at the VirtualMD Lab.

Students worked with SolidWorks® for creating their CAD files during the design stage. Several design iterations were needed until the design was approved for fabrication. Once the design was approved, teams were scheduled at the VirtualMD Lab to fabricate their prototypes. Two rapid prototyping machines were used for this project: a fusion deposition modeling (FDM) from Dimension® and a 3D printing machine from ZCorp® as shown in Figures 2(a) and (b), respectively.

During the prototype fabrication, students learned about the characteristics and procedures of both rapid prototyping machines. Parts that were very thin, small, or required functionality testing were fabricated in the FDM machine while bigger parts were sent to the 3D printer. This provided students with a hands-on experience on the selection of manufacturing machines based on the requirements of the particular component. Figures 3 (a)-(d) show undergraduate students working on their projects using both rapid prototyping machines.



(a) Student working on the 3D printer

(b) Student working on the FDM machine

(c) Making a component in the FDM machine

(d) Final component

Figure 3. Students working on their medical device team projects.

2.4 Project report and presentation

Teams submitted their project written reports with the following information: problem definition and potential customers; product design and engineering specifications; material requirements, proposed manufacturing process plan; project timeline and results; and future development plan for mass production. Each team presented their project results via a formal presentation and demonstration of their prototypes. Students were instructed to use interactive media technology to present their results and all members of the team were required to present. The instructor and medical doctor provided feedback on the teams' designs.

3. Results and Analysis

At the end of the project, a project evaluation form was provided to collect students' data and feedback. This survey was taken by all the 24 students in the class. Another evaluation was provided to gather their experience working on their team and the contribution of each member to the project. Relevant questions from the project evaluation are as follow:

ID	THE PROJECT…
1	Was interesting
2	Helped me to understand better Product Design and Manufacturing concepts
3	Stimulated my interest in learning design and manufacturing
4	Helped me to relate and apply design and manufacturing to real-life applications
5	Increased my awareness on the current design and manufacturing challenges in the medical device industry
6	Provided hands-on experiences on product design software and manufacturing equipment
7	Increased my proficiency on product design software and manufacturing equipment
8	Stimulated my problem solving skills
9	Provided an opportunity for developing teamwork and communication skills
10	Helped me to prepare better for an industry job
11	Was challenging

Each question was rated using a scale from 1 to 5, where 1 = "Not at all" and 5 = "Very much". Figure 4 presents the average rating obtained from the students for each question on the survey.

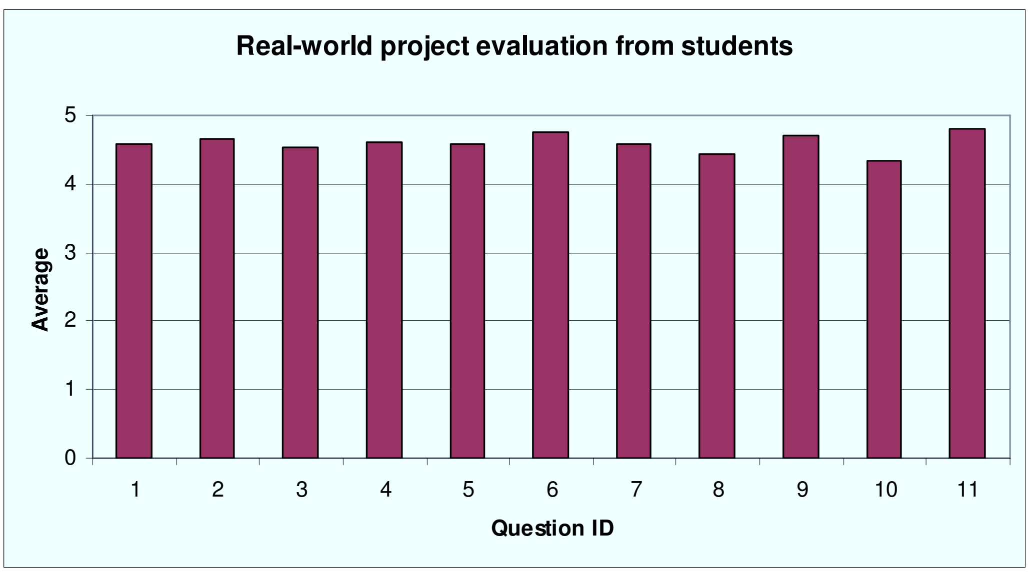


Figure 4. Results from the students' project evaluation.

Results in Figure 4 show that the experience of a real-world project on medical devices was well received by the students in the Manufacturing Processes course. The average response was higher than 4.2 for all questions in the evaluation where 5 is the highest rate. Below is the summary of the findings:

- Students found the medical device project to be very interesting so their commitment towards the project was very strong
- The project helped them understand better product design and manufacturing processes, and to relate and apply design and manufacturing concepts to a real-life medical device problem. The project also significantly increased their awareness on the current design and manufacturing challenges in the medical device industry
- The project provided them with a lot of opportunities to work with product design software such as SolidWorks and manufacturing equipment such as the FDM and 3D printing machines. They felt that their proficiency in these software and equipment increased significantly after completing the project
- Skills for collaborative work are the greatest benefit that students obtained from this real-world project
- Students found the project to be very challenging. This is expected as the medical device project was a complex open-ended problem that required students to search for additional information for the project on their own. Moreover, students needed to get familiarized with the surgery, medical devices, and human anatomy for the project. This stimulated students to adopt an interdisciplinary approach to the problem while also provided them with the opportunity to collaborate with a medical doctor. Therefore, students also felt that the project greatly stimulated their problem solving skills and helped them in preparing for industry jobs.

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. During the design process, students realized that not only it is necessary to design a functional product, but the design also needs to meet other demands such as esthetical and ergonomic requirements. Given that the medical device design required a number of components to be assembled, students recognized the need to minimize the number of components in their designs. Students also recognized the importance of the design dimensions and tolerances as well as the particular machine capabilities to obtain components that could fit together. Based on the plans for mass production presented by each team, students were able to visualize, understand and apply manufacturing concepts learned in the classroom to their particular designs. A main challenge in this real-world project was time management. Time became a tight constraint as it was easy to find teams spending much more time on the conceptual design. Therefore, it was important for the instructor and the teaching assistant to provide a weekly-based feedback so teams could remain on track and complete the project.

The medical device designs that resulted from this course mainly focused on the design and manufacturing aspects. As mentioned in Section 2.2, the student designs from this course are currently being refined in a subsequent undergraduate engineering course to incorporate into the design additional concepts that students learn through their curriculum. Examples of these concepts include economic considerations, product life cycle, and green manufacturing. Once the designs are refined, successful student designs will be submitted for patent. For these reasons, details on the specific problem addressed by the device, its specific functionality, and student teams' designs were omitted in this paper for confidentiality purposes.

4. Conclusions

This paper presented our experience in integrating a real-world project on medical devices in a manufacturing processes course at the University of South Florida (USF). The project consisted on designing and prototyping a new medical device to improve a minimally-invasive surgical procedure. The medical device project promoted interdisciplinary collaborative work and motivated students to learn on their own beyond the classroom about surgeries, medical devices, and human anatomy. Benefits for the students consisted in: (1) increased knowledge and hands-on experiences in design and manufacturing concepts, software and equipment; (2) increased awareness and exposure to real challenges in the medical device industry; and (3) increased problem solving, teamwork, written and oral communication skills. The integration of real-world medical device projects into manufacturing education can benefit the medical device industry through new product ideas from students with related experience in a medical environment. At the same time, real engineering projects contribute significantly to engineering education by preparing students for successful careers in industry.

Acknowledgments

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References

1. American Society for Engineering Education, "Summary report on evaluation of engineering education," *Journal of Engineering Education*, September 1995, pp. 25-60.
2. Lang, J. D., Cruse, S., McVey, F. D., and McMasters, J., "Industry expectations of new engineers: A survey to assist curriculum designers," *Journal of Engineering Education*, January 1999, pp. 43-51.
3. Davis, D.C., Beyerlein, S.W., and Davis, I.T., "Development and use of an engineer profile." *Proceedings of the American Society for Engineering Education Annual Conference & Exposition*, Portland, OR, 2005.
4. Society of Manufacturing Engineers, http://www.sme.org/cgi-bin/find-articles.pl?&04fem010&ME&20040201&&SME&
5. Rosen, M., "Medical device industry growing in importance in the Midwest". Yer Biotech Blues. http://wistechnology.com/articles/2100/
6. Clapp, D., "Gold standard locations for medical device manufacturing," Business Facilities, http://www.businessfacilities.com/bf_04_12_special1.asp
7. Arjomandil, M., Gibson, B.A., Valiyff, A., Chartier, B.J., Missingham, D., "The Role of 'Hands-on' Practice in Aerospace Engineering Education," *47th AIAA Aerospace Sciences Meeting Including the New Horizonx Forum and Aerospace Exposition*, Orlando, FL, 2009.
8. Simpson, M., Burmeister, J., Boykiw, A., and Zhu, J., "Successful Studio-Based Real-World Projects in IT Education," *Proceedings of the fifth Australasian Conference on Computing Education (ACE2003)*, Conferences in Research and Practice in Information Technology Series, Vol. 20, 2003.

9. Doerry, E., Bero, B., Larson, D., and Hatfield, J., "Northern Arizona University's Design for (4) Practice Sequence: Interdisciplinary training in engineering design for the global era," *Educating the Engineer for the 21st Century*, D. Weichert, B. Rauhaut and R. Schmidt, Eds. Norwell, M.A: Kluwer Academic Publishers, 2001.
10. Leon-Rovira, N., Garcia-Gardea, E., "Innovation in Engineering Education at ITESM". *Second LACCEI International Latin American and Caribbean Conference for Engineering and Technology (LACCET'2004) "Challenges and Opportunities for Engineering Education, Research, and Development"*, June 2-4, 2004, Miami, Florida, USA.
11. MacGillivray, M., Domina, T., Lerch, T., and Kinnicutt, P., "Engineering Design Process – An Interdisciplinary Approach," *International Conference on Engineering Education – ICEE*, 2007.
12. Savin-Baden, M., *Problem-based learning in Higher Education: Untold Stories*, Open University Press: Buckingham, U.K, 2000.
13. Evans, D., "Stimulating Change," *Proceedings of the 2002 ASEE/IEEE Frontiers in Education Conference*, 2002.
14. Waks, S., and Frank, M. "Engineering curriculum versus industry needs – A case study," *IEEE Transactions on Education*, Vol. 43, 2003, pp 349-352.
15. Göran Salerud, E., Ilias, M.A., and Häggblad, E., "Design-build courses and student-centered-learning in biomedical engineering education," *World Transactions on Engineering and Technology Education*, Vol. 5, No. 2, 2006.
16. Crockett, R., Whited, J., and Walsh, D., "MEDITEC: An industry/academy partnership to enable multidisciplinary, project-based learning in biomedical engineering," *Proceedings of the American Society for Engineering Education Annual Conference & Exposition*, Honolulu, Hawaii, 2007.
17. Way, T.P., "A Virtual Laboratory Model for Encouraging Undergraduate Research," *SIGCSE'06*, Houston, Texas, 2006.
18. Koretsky, M., and Gummer, E., "The Role of Virtual Laboratories in Capstone Engineering Courses," *Research in Engineering Education Symposium*, 2008.