Impact of Classroom Surgical Procedure Demonstration Using Artificial Bone in Orthopedic Implant Design

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Abstract

As a part of the existing senior design class for biomedical engineering students, we have implemented the introduction of surgical procedures and demonstration in orthopedic medical device design process. It is aimed at senior biomedical engineering students to increase student interest and understanding in orthopedic medical device design. The objectives of this course are to teach students many aspects of medical device design through hands-on projects with multiple lecture topics such as the FDA design control process. The course includes lectures about various topics and requires that each student group present research and design proposals to address a specific engineering/design need, work in labs for hand-on practice, and complete a project to develop a design and/or working prototype to address the need. The class was assessed in compliance with the design control process, documentation, laboratory reports, final design, and analysis.

For the specific group who chose orthopedic implant, the students were asked to design the devices without consideration of the surgical procedure. After students had a design completed, the surgical procedure was introduced to the groups, and the student groups investigated if there were needs to revise the design based on the consideration of surgical procedure. At the end of the semester, a special assessment was conducted for these groups only, and results showed that consideration of surgical procedure led to changes in final design and a better understanding of orthopedic medical devices. Student self-assessment was completed during three academic years starting in 2014-2015 and the results are presented in this article. This paper also discusses the changes that were made in response to student feedback.

Introduction

The medical device industry is one of the fastest-growing industries in the world[1]. Medical devices are critical for the diagnosis, monitoring, and treatment of disease and injury; and for improving the quality of human life. Increasing life expectancy and the search for better health care and preventive therapies have significantly influenced the growing demand for medical devices. The U.S. is the leader of the medical device technology industry followed by the E.U. and Japan[2]. To remain competitive in the global market, medical device manufacturers need highly qualified engineers to develop innovative and marketable products.

It is very common for undergraduate senior engineering students to be required to take a design course before graduation. For students who are interested in biomedical engineering, a design project can be one of many medical device systems, including orthopedic implants, prosthetics, biomaterials, instruments, etc. In this class, students followed the standard design control process[3] (design input, design output, review, verification and validation, design transfer, design history file), and used many engineering means through development, such as CAD, FEA, 3D printing, machining, and testing.

However, in the case of orthopedic medical device, in design, much of in-class education focuses on the mechanics of implant design itself and sometimes neglects or de-emphasizes other important factors such as surgical procedures and surgical tolls for the system. For a successful implant surgery, following the correct surgical procedure is critical, and the implant with the simplest surgical procedure should be sought in order to minimize complications during and after surgery. In addition, many patients wish to return to normal activity as soon as possible after surgery, which increases the demand of minimally invasive surgery, requiring new surgical tools and procedures. For these reasons, biomedical engineering students should understand not only the mechanics of implant system itself, but also the surgical procedure and the surgical tools that are employed.

Thus, to improve the students' learning and design capabilities for orthopedic medical device design, surgical procedure for orthopedic medical devices was integrated into the existing senior-level design courses, ENGR4520 Design & Manufacturing of Biomedical Devices and Systems. The course is required for all senior biomedical engineering students and was offered in the fall semester. The course included a number of lectures and lab activities to guide students through specific aspects of the FDA design control process, existing engineering tools, and hand-on activities for design. The goal of the ENGR4520 course and project was to understand Design Control[3] (21 CFR 820.30), and to design, implement, and fabricate the prototype of a medical device that addresses current market needs while being easy to use and feasible for manufacturing. Course objectives included the following:

- Design and prototype a medical device using FDA requirements for Design Control.
- Plan, manage, document and execute projects using FDA Design Control Requirements
- Apply various design tools including CAD and modeling software to determine potential design solutions
- Perform risk assessment to illustrate risk based on the product development process.

After students completed this course, they were required to take a capstone design course in the consecutive semester. Some students worked on the same project continuously from ENGR4520 to ENGR4950 for development of final design and prototyping.

Methods

The ENGR4520 course consisted of lectures, student presentations, labs, documents and a major team project that led to final design. The main goal of the team project was to expose students to the design and engineering challenges in the application of biomedical engineering. These challenges were complex and multidisciplinary by nature, and students were required to understand specific medical/biological issues relevant to their projects. In class, students were divided into groups (4-5 students per group) and selected their own project from many different biomedical engineering areas including, but not limited to, orthopedic implants, prosthetics, biomaterials, instrumentation, software, etc. based on their interest and experiences. Once the teams and topics were chosen, teams were asked to address the main engineering design challenges to meet those specific medical needs. The topics for the team projects in class included:

- Topography optimization for 3D printed cast for upper extremity (Figure 1)
- Cost-effective and environment-friendly motorbike helmet (Figure 2)
- Cost-effective insulin pump
- Bone plate system for various fracture type (Figure 3)
- Program for motor control using muscle signal from upper arm.

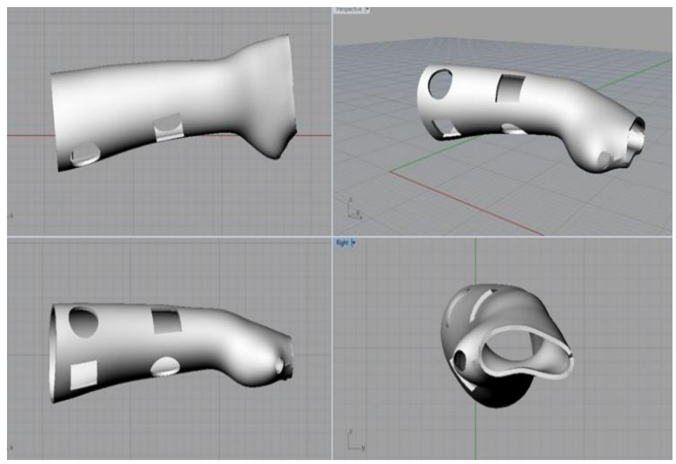

Figure 1 Concept design for 3D printed lower arm cast

All groups were required to have multiple presentations, a final design, and a prototype of working principle to assess the functionality of the device. However, some groups were not able to create the prototype due to technical difficulties and/or limited time and resources. These groups were allowed to complete the final design only. On the last day of class, a self-survey was conducted to assess how the introduction of surgical procedures affected students' interests and understanding of orthopedic medical devices, and the final design.

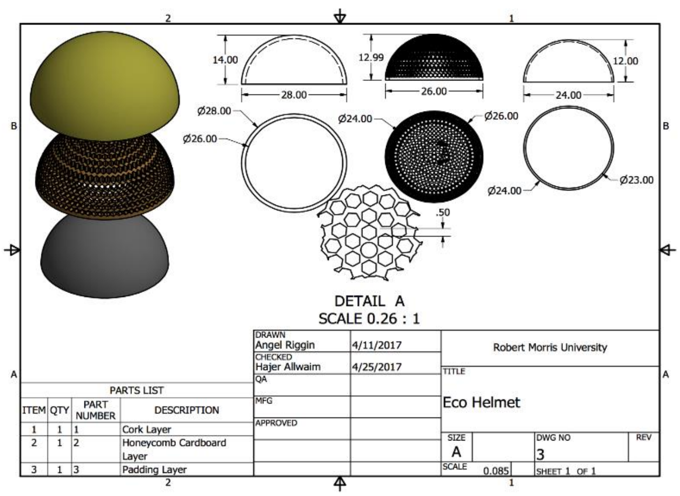

Figure 2. Concept design of cost effective helmet for motorbike

For the groups that selected an orthopedic medical device, such as total joint replacement, trauma plates, or IM nail, a slightly different teaching method was used. The topics for the orthopedic device projects included

- Develop bone plate system for various fracture type (Figure 3)
- Optimize the shape of humeral component for reverse shoulder implant
- Improve intramedullary nail

Same as any other group, students in these specific groups started investigating the market needs and predicate devices, and performed design input, design outputs and design review processes for the final design based on mechanics of system itself, such as strength and bone-implant interface.

After the groups had a design, the surgical procedure and tools for each system was introduced. First, the information was delivered by providing a step-by-step surgical procedure from a manufacturer of similar devices, and video material of a simulated surgery and actual surgery from various websites. In addition, if resources were available, students had an opportunity to observe for in-class demonstration and to have hands-on experiences with surgical procedure using artificial bone (SAWBONES. Vashon, WA USA) to obtain a better understanding of the relationship between implant design and surgical procedures/tools. Instructor had adequate trainings and experiences in surgical procedure for various orthopedic devices during his career in medical device industry, and was able to demonstrate a correct procedure. For the last three academic years, surgical instrument of the IM nail, external fixation for long bone and bone locking plate systems were available for in-class demonstration. Afterwards, students revisited their design with new knowledge from the surgical procedure to investigate the possibility of design improvements. If there was any need for change, students modified the design and then re-evaluated it to determine if the new design worked better with the surgical procedure/tools while still addressing the original needs.

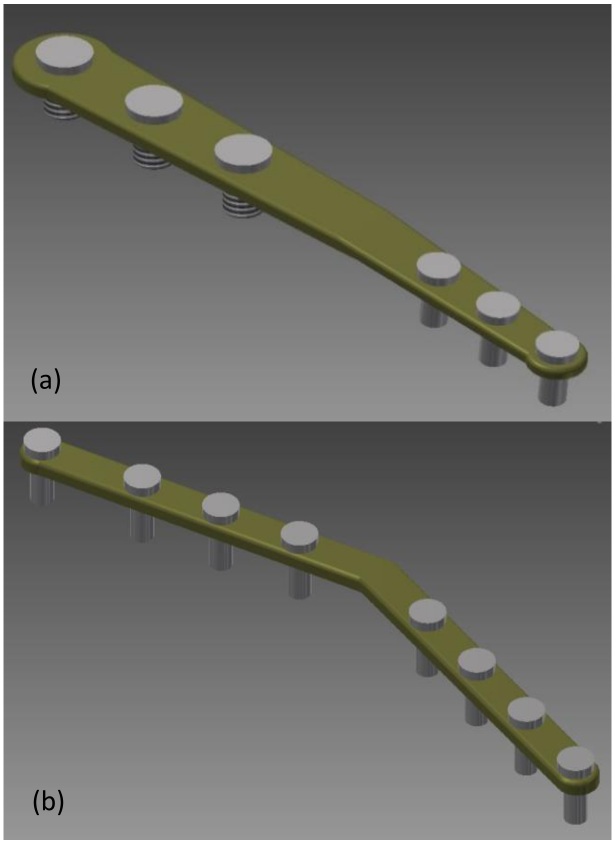

Figure 3. Design of clavicle fracture plate before (a) and after (b) introduction of surgical procedure

Figure 3 shows an example of design changes before and after the introduction of the surgical procedure. A group designed the plate for clavicle fracture based on anatomy, fracture type and sites of clavicle, and the engineering mechanics. They initially concluded that design (a) would be proper because; 1. it fits well on the flatter subclavian groove area on the inferior side of clavicle, 2. the bigger and flatter surface area of subclavian groove area allows for a wider plate design for increased strength, 3. a shorter plate requires a smaller incision and thus a faster recovery, and 4. the straight plate is easier to bend and adjust to the patient's anatomical fit during surgery. After the introduction of surgical procedure, the group changed the design to (b) based on claims of; 1. the inferior subclavian groove area is not easy to access from the incision in the anterior-superior direction, 2. the anterior surface of clavicle is easier to access but it is not flat and straight surface and thus a pre-contoured plate is required, 3. the plate should be narrower to fit on the anterior surface of the clavicle, and 4. a narrower but longer plate with more screws will provide equivalent strength to the previous plate design.

For final presentations, all groups presented a problem statement, market analysis and potential customer, project timeline, design input and output, verification and validation plan, engineering specifications, final design, and prototype. Groups who applied or utilized their learning from the surgical procedure in their final design presented their learning experiences and how that newfound knowledge and experience affected their final design.

Student population and feedback

ENGR4520 is a required course for senior students in biomedical engineering. Table 1 shows that the number of student who enrolled in ENGR4520 during the past three academic years and the number of students who participated in this methodology.

Table 1. Student enrollment (number in parenthesis represents number of group)

Academic year	Total number of Student in ENGR4520	Number of student in this methodology
2014-2015	16 (4)	9 (2)
2015-2016	20 (5)	4 (1)
2016-2017	28 (6)	14 (3)

From the 2014-2015 academic year, a self-survey (Q1-Q5) taken at the end of semester was used to obtain student feedback on the course. In the 2015-2016 and 2016-2017 academic years, a question (Q6) was added to capture more feedbacks from students, and the results are shown on Table 2.

Results showed that the new teaching method was well received and had a positive impact on the students' learning and knowledge. Students strongly agreed (score of 4.59/5) that this experience expanded their view of medical device, indicating that they did not consider surgical procedure or tools at the beginning of class prior to introduction of surgical consideration. However, results also showed that the impact of surgical consideration on their final design was low. Although all other measures showed that students learned a great deal from these experiences, that score (Q4) was unexpectedly low (Table 2). This low score may indicate that students had a hard time implementing their learning into their design.

Table 2. Survey results from AY2014-15, 2015-16 and 2016-17. Numbers in parenthesis shows number of students who answered a question. Q6 was assessed during last two years only. (Scale 1 “not agree at all” – 5 “Strongly agree”).

Question ID	The experience of surgical procedure …	Average Score
1	was interesting	4.23±0.86 (n=26)
2	helped me to understand better about implant design	4.39±0.69 (n=26)
3	helped me to understand on the current challenge in implant design	4.46±0.75 (n=26)
4	had effects on team’s final design	4.08±1.02 (n=26)
5	helped me to prepare an industry job	4.31±0.63 (n=26)
6	helped me to expand the scope of orthopedic medical device	4.59±0.51 (n=17)

Discussion

Many important deliverables in this approach were achieved through demonstration of surgical procedures. Assessment showed that students acquired an expanded knowledge and insight on how the implant they designed can be used in an operation room by surgeons, achieved a better understanding of implant design principles, and learned the importance of surgical procedure and human anatomy in biomedical engineering. It provided realistic engineering experiences for students and increased their interest in biomedical engineering compared to only studying through computer simulation or lecture. This additional task, considering surgical procedure and tools in design, also required students to develop extensive knowledge of human anatomy and problem-solving skills. Students expressed that a higher level of proficiency in these engineering areas were achieved after the course.

It is worth noting that most of the students in this study selected a trauma plate system or intramedullary rod system due to simplicity. These simple systems allowed students to have enough time to complete all tasks that were given in the class and to fully understand its principles in order to apply it to more complex future problems. It was also easier to demonstrate the surgical procedure because of its simplicity relative to other systems (i.e. total knee or hip arthroplasty). Instructors used simplified surgical procedure during demonstration by skipping some surgical step that were intended to access trauma sites or prevent soft tissue damage during bone drilling. Since artificial bone was used during demonstration, such steps or instruments were not necessary (i.e. drill sleeve). However, the importance of soft tissue preservation during surgery was explained during the demonstration, and the core steps of surgical procedure were followed as closely as possible.

Another challenge was managing a course schedule for the groups that involved this study. In the first year, groups completed a final design just as later groups did, after which the surgical procedure was introduced. They were then asked to revise their design. It was a difficult task for them because they had already spent a significant amount of time on their final design. When they tried to revise their design, they felt like they were doing the whole design process all over again, and this additional task made their schedule even tighter compared to other groups who had more time for other tasks. Therefore, since the second year, surgical procedure was introduced in an earlier stage of design process and the instructor provided prompt feedback for the teams. This change gave students time to learn and implement their ideas into the design process and were thus able to remain on track to complete the project on time.

The instructors and the engineering department are planning to expand the choices for medical devices for the project in the future. To support this expansion, it is necessary to have more professors from different disciplines be involved as reviewers and mentors. In addition, mentoring from medical doctors who can evaluate clinical aspects of design will be a crucial addition for students' learning.

This senior-level medical device design course focused on the development of skills and knowledge necessary to pursue further studies in a career in biomedical engineering. In the last three academic years, demonstration and hand-on experience of surgical procedure were added to this course to increase students' interest and understanding of orthopedic medical devices. The feedback and assessments provided by student surveys showed that additional teaching materials and experiences helped students to increase their understanding of medical device systems that they had been working on in the class, their general knowledge, and their interest in biomedical engineering. The integration of realistic experiences into engineering education can contribute significantly to engineering students' interest and development for a successful career. At the same time, it benefits the industry by providing students with an immediately available skill set.

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