A Project Course Sequence in Innovation and Commercialization of Medical Devices

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There exists a need for educational processes in which students gain experience with design and commercialization of medical devices. This manuscript describes the implementation of, and assessment results from, the first year offering of a project course sequence in Master of Engineering (MEng) in Design and Commercialization at our institution. The three-semester course sequence focused on developing and applying hands-on skills that contribute to product development to address medical device needs found within our university hospital and local community. The first semester integrated computer-aided drawing (CAD) as preparation for manufacturing of device-related components (hand machining, computer numeric control (CNC), three-dimensional (3D) printing, and plastics molding), followed by an introduction to microcontrollers (MCUs) and printed circuit boards (PCBs) for associated electronics and control systems. In the second semester, the students applied these skills on a unified project, working together to construct and test multiple weighing scales for wheelchair users. In the final semester, the students applied industrial design concepts to four distinct device designs, including user and context reassessment, human factors (functional and aesthetic) design refinement, and advanced visualization for commercialization. The assessment results are described, along with lessons learned and plans for enhancement of the course sequence. [DOI: 10.1115/1.4036441]

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Introduction

The past 30 years have seen enormous growth in the healthcare industry, led by medical device and biotech companies. In 2014, the medical and healthcare industry constituted 17.5% of the gross domestic product of the U.S.¹ and is estimated to grow to 20% by 2020 [1]. Government and foundation fundings for small medtech businesses have increased in recent years; for example, the NIH awarded over \$700 million in SBIR funding in 2015.² The U.S. is the largest medical device market in the world with a market size of around \$148 billion, and it is expected to reach \$155 billion by 2017.³ Many of the most important medical innovations of the past 25 years, such as magnetic resonance imaging (MRI) and computed tomography (CT) scanning, balloon angioplasty, hip and knee replacement, mammography, and coronary artery bypass grafts, represent engineered solutions [2]. With an aging population that is more obese, clinical and rehabilitation needs continue to present real opportunities for engineers trained in medical device design and commercialization.

The convergence of medical needs and engineering innovation represents a powerful opportunity for multidisciplinary student training. The National Institute for Biomedical Imaging and Bioengineering (NIBIB) supports a global shift in science, technology, engineering and math (STEM) education to an interdisciplinary approach that is attentive to the practical value of new knowledge with a focus on innovative technologies [3]. In addition, there is a growing recognition of the potential for the “Maker movement” to transform how and what people learn in STEM disciplines. According to President Obama and the Educate to Innovate campaign, makers “see the promise of being the makers of

things, and not just the consumers of things” [4]. To ensure America’s position as a world leader in the education of engineering talent, curricula are needed where students master hands-on methods while applying their knowledge to real world engineering design challenges.

The Master of Engineering (MEng) in Design and Commercialization at the University of Alabama at Birmingham (UAB) was designed to support the principles of hands-on learning in interdisciplinary teams and innovative environments begun in our undergraduate capstone experience [5]. The MEng curriculum consists of 24 credit hours in engineering and 12 credit hours from the Master of Business Administration (MBA) program, which earn students a Master’s degree as well as a Graduate Certificate in Technology Commercialization and Entrepreneurship from the UAB Collat School of Business. Teams comprised of engineering students engage in hands-on design and prototyping of Innovation and Commercialization (IC) projects. They partner with MBA students to perform customer discovery and develop business models for their IC projects. In this first year of the MEng, projects were sourced from UAB Hospital, Children’s of Alabama, and Lake-shore Foundation (a fitness facility for people with disabilities), all of which had been previously prototyped as senior design projects in Biomedical Engineering (BME), led by the lead author. The present paper describes the implementation of, and assessment results from, the first offerings of a project course sequence for graduate level master’s students. The sequence provided students the opportunity to develop hands-on skills and to apply them directly in the design and construction of improved prototypes, with emphases on human-factors and product use to generate marketable innovations.

Methods

There were nine students in the original cohort for the MEng program, each of whom participated in the three course sequence. Seven of the students were recent graduates of our undergraduate

¹<https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical.html>

²<https://sbir.nih.gov/statistics/award-data>

³<https://www.selectusa.gov/medical-technology-industry-united-states>

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Fig. 1 Beam with hole activities in which students developed CAD drawings (left), then machined them by hand (center), CNC and 3D printing (right)

program in Biomedical Engineering. One had a bachelor's degree in Mechanical Engineering, while one other had a bachelor's degree in Physics.

EGR 693 Project I. The primary learning outcome for the first course was that students would demonstrate proficiency in the “maker skills” to which they were introduced. The students first reviewed CAD, a natural precursor to fabrication, using CREO software (PTC, Needham, MA). They were tasked to model a beam with a through-hole that contained internal corners. Due to their fun and familiar nature, shapes were selected from the suits of a deck of cards (heart, spade, diamond, or club). Students were then required to each make their “beam with a hole” by hand-machining bars of aluminum alloy using a band saw, drill press, end mill, and hand files. Next, they created their beams by implementing their CAD drawings through a 3D printer (Wan Hau, Replicator, Miami, FL). Finally, they used computer numeric control (CNC) machining, where they were introduced to G-code and CNC mills (Fig. 1). They also received lectures and demonstrations on compression and injection molding of plastics.

Next, the students explored contemporary electronics through hands-on activities using breadboards in conjunction with Arduino (Arduino, LLC, Cambridge, MA) and Raspberry Pi (Adafruit, New York, NY). Students were provided with kits to work on coding examples during class and to encourage further investigations outside of class. Using a Sparkfun RedBoard (Sparkfun, Niwot, CO) and the Arduino IDE software, students programmed a variety of codes with circuits they built to apply integration techniques. Figure 2 illustrates an example completed by a student in which she integrated breadboards, programming, and microcontroller in order to control a multi-light-emitting diode (LED) circuit. Finally, students received instruction and lab experience on soldering PCBs. The students reported how the different maker skills could be applied to their IC projects, which included a weighing scale for wheelchair users, a hemostasis tool, and a recumbent patient weighing system.

EGR 694 Project II. The second semester course, EGR 694 Project II, was developed around the premise of a student-run production facility whose business was to generate multiple medical devices which met the needs of a client. In this case, a colleague in the UAB School of Health Professions had requested the development of multiple weighing scales for wheelchair users to be implemented in an NIH-funded study on the effects of weight monitoring on adherence to a diet and exercise regimen. While a prototype for an affordable wheelchair-accessible weighing scale had been developed previously by BME senior design students [6], a second generation device (Fig. 3) was designed and fabricated after obtaining feedback from physical therapists and wheelchair users at Lakeshore Foundation [7]. The new prototype

Fig. 2 Students used the Sparkfun Redboard as a platform for learning microcontrollers

featured a weight capacity of 800 pounds, structural steel alloy frame, an aluminum alloy access ramp and edge guards, and liquid crystal display (LCD) weight readout. Standards from the Americans with Disabilities Act (ADA) were followed throughout the design by incorporating a wheelchair-accommodating platform that was large enough to accommodate various wheelchair sizes, a sloped platform that provides access to the platform with no abrupt level changes, and edge protection at drop off [8]. An Arduino microcontroller (MCU) unit (Arduino, LLC, Cambridge, MA) acquires weight sensor data from analog sensors (QY Electronic Company, Hanzhong City, China) and transmits data to a Bluetooth module (RedBearLabs, Hong Kong, China) for wireless transmission. To implement this functionality, a linear voltage regulator on board the Arduino MCU supplies a constant voltage source for load sensor excitation, and an HX711 analog to digital converter (Avia Semiconductor, Xiamen, China) translates the analog voltage signal to a digital binary signal after amplification. The Arduino Uno MCU processes the digital input signal and uses a calibration algorithm to convert the digital signal to a weight value, which can be displayed on a smartphone via bluetooth. Throughout the semester, the MEng students put their project skills to work, constructing, and testing eight scales. This effort required hands on machining, brazing, 3D printing, and the wiring, soldering, and testing of electronics, including the load sensors, Arduino, and bluetooth.

EGR 695 Project III. The final project course was led by an industrial design faculty member (Tillman) from Auburn University. The primary learning outcomes were for students to integrate human-centered design approaches, understand and consider product use context, incorporate human-factors design refinements, and visualize product concepts as marketable innovations. Drawing from the discipline of industrial design, the key aims were to improve the overall ease-of-use and perception of prototyped devices, while increasing their potential marketability through more compelling visual communication. Students revisited the wheelchair scale, the hemostasis tool, as well as a cervical pessary in order to refine and better communicate the user benefits of their designs.

The first step involved a complete reassessment and analysis of the existing prototype based on the primary user's perspective. These included the neurosurgeon (hemostasis tool), as well as patients (wheelchair scale, pessary) who are increasingly able to make health-related choices based on the information available to them [9]. Students were challenged to gain insights from users on how well the prototype worked, fit the body, and was visually

Fig. 3 (top) CAD rendering and photograph (right) of the wheelchair accessible weighing scale with LCD readout; (bottom) MEng students worked in teams to build the scales and the associated electronics

perceived. This included developing a detailed sequence-of-use activity analysis to better understand user behavior and use patterns with the concept and to identify potential problems and opportunities for refining the design. Students investigated specific anthropometric considerations (grip diameters, groupings of controls, etc.), and the role that the surrounding context plays in how a product is used, transported, and stored.

Students were next tasked with redesigning and further resolving the physical touchpoints and interfaces of their prototype, based on the results of their use reassessments. This included refinements such as smoothing out protrusions in grip profiles to avoid discomfort and expanding a grip into a “grip zone” to enable more flexible handle orientations. In the case of the wheelchair scale, the project evolved into a combined design with the “Wii Fit scale,” another project being developed by the co-author

Kirkland, as a decision path better enabling its commercialization (Fig. 4). In addition to functional refinements, students were also challenged to simplify, integrate, and unify the forms and features of their prototype designs, in order to bring perceptual clarity to its purpose and use. This included the review of product development case studies that illustrate over-complexity due to feature-creep, a common pitfall that occurs when arbitrary functions are added to a product only as a means of “out featuring” the competition. The approach of Kolko [10] was incorporated which stressed “emotional value propositions” with deliberate decisions about “what the product should do and, just as importantly, what it should not do.” Students studied and crafted the visual semantics of their product by refining its form, and providing stronger visual cues to its use. For the wheelchair scale and the pessary, these efforts focused on creating perceptual improvements such as reducing fear, increasing confidence, or minimizing a negative stigma.

The final focus of project course III was to enhance students’ abilities in effective visual communication of their products and its innovations. This involved both instruction and demonstrations of KEYSHOT 3D rendering software (Luxion USA, Tustin, CA) for creating photorealistic images of their refined 3D CAD model (color, finish, transparency, etc.), as well as the development of a visual narrative that communicated the benefits of the design and a complete product vision. Following this “visual specification,” students used KEYSHOT to render their designs using perspective viewpoints that more closely resemble those of the human eye and to visually explain their designs in an optimal manner.

Fig. 4 The prototype Wii-Fit board was merged with the wheelchair scale to provide a project for the third course

Assessments. To examine the gains in student proficiency during project I, a pre- and postassessment survey was given to each student to score their perceived levels of competency in each maker activity reviewed. Students were also asked to reflect on their experiences, to compare each machining method they experienced and to determine which method(s) would best suit their needs when prototyping for their own IC projects. For each of the three courses, IDEA surveys (IDEA, Manhattan, KS) were given at the course conclusion. For the present manuscript, “progress on relevant objectives” associated with those objectives assigned an

Table 1 Average IDEA survey scores ($n = 9$, maximum score = 5)

Relevant objective	EGR 693	EGR 694	EGR 695
Learning to apply course material (to improve thinking, problem solving, and decisions...)	4.6	4.6	4.9
Developing specific skills, competencies, ... needed by professionals in the field...	4.6	4.4	4.8
Acquiring skills working with others as a team	N/A	4.6	4.6
Developing creative capacities (writing, inventing, designing, ...)	4.6	4.4	4.6

importance rating as “essential” were used to assess student perceptions of achievement (the objectives are listed in Table 1). In addition, the raw scores associated with overall ratings—excellent course collected were used to gauge overall student satisfaction with each course. Program outcomes were assessed in terms of student employability and career progress, as well as new intellectual property disclosures and provisional patents resulting from the students’ work.

Results

Approximately 80% of students in the MEng program had previous experience with using the CREO CAD software; thus, they were able to quickly demonstrate proficiency in this activity. During the hand-machining activity, students experienced the limitations of hand-machining through difficulties creating profiles of card suits, which contain several sharp internal corners. Students found that CNC and 3D printing yielded higher levels of precision in comparison to the hand-machined parts. Students also noted the increased efficiency in the time, cost, and labor required to machine parts using CNC machines and 3D printers. The results of the student surveys indicated substantial increases in the perceived levels of competency among the various maker activities upon completion of the course (Fig. 5). A dependent t -test (Excel, Microsoft Corp., Redmond, WA) indicated that the increases in perceived proficiencies were significant ($p < 0.05$) for hand machining, 3D printing, Arduino, Raspberry Pi, and PCB.

In addition, the students’ knowledge, retention, and personal investment were seen to improve based on the increased interest outside the classroom. For example, some students have invested in 3D printing for personal work outside of the course requirements. Similarly, the same involvement beyond the classroom can be seen in their use of Raspberry Pi and embedded Linux systems. These investments by the students point to the intrinsic motivation inspired by the class.

The results of the IDEA surveys (Table 1) indicated that the essential learning objectives were met in EGR 693 Project I, with scores all at 4.6/5, with 86% of students rating a 4 or 5. The

average overall rating for “excellent course” was 4.4/5, which reflected strong student satisfaction with the course activities. Notable written comments from the students included, “... one of the best courses I have ever taken... enjoyed everything I learned,” and notably, “wish we had this as an undergraduate.”

In EGR 694 Project II, the students completed eight weighing scales for wheelchair users, calibrated and performed validation testing, and delivered the scales to the client, who is currently using them in a 5-yr NIH study on weight control in people with spinal cord injuries. The benefits of working on the eight scales were that it permitted the students to work as a simulated production facility, where the labor was divided among the students, allowing them to work to their strengths (manufacturing, electronics, and quality control) and meet a production deadline. An example of one finished wheelchair scale, completed in EGR 694, is shown in Fig. 6 complete with the program logo developed by one of the MEng students (Caitlin Lawson).

The results from the IDEA assessments (Table 1) indicated that the essential learning objectives were met in project II as well, with scores ranging from 4.4 to 4.6/5 with 80% of students rating a 4 or 5. The average overall rating for “excellent course” was 4.6/5, which again reflected strong student satisfaction with the course activities. No written comments were provided by the students.

In EGR 695 Project III, three devices were advanced toward commercialization. A new hemostasis tool for endoscopic surgery was refined, which included designing distinct controls for the fingers in order to better differentiate their unique functions (Fig. 7, left), providing a more intuitive understanding of the separate functions for the physician, enabling improved concentration

Fig. 5 Perceived competency levels (mean + standard deviation) as reported by the students reveal substantial increases following training in the first project course

Fig. 6 One of eight wheelchair accessible weighing scales completed in EGR 694

Fig. 7 Photorealistic KEYSHOT renderings were developed including the hemostasis tool and the Wii-Fit gaming device with improved hand rails

Fig. 8 Photorealistic KEYSHOT renderings were employed to explain the prototype's use and benefits through a visual narrative poster

on the medical procedure. These design revisions led to an intellectual property (IP) disclosure. In the case of the wheelchair-accessible weighing scale prototype, students expanded its rehab functionality into a Wii Fit gaming device for the Lakeshore Research Collaborative. This created an opportunity to incorporate the Nintendo Wii visual brand language into the design effectively repositioning the original design toward a more active product centered around play (Fig 7, right).

The deliverables for project III included visual posters that realistically demonstrated the students' final designs, how they worked, and their core innovations. The goals of producing these visual narrative posters were to better enable faculty and students to "pitch" their designs for commercialization opportunities, as well as to advance their own professional work portfolio for gaining employment. Figure 8 shows a representative example from the team focused on a cervical cerclage pessary (cervical cap), with colors, clear materials, and form refinements were refined to be perceived as more friendly to anxious, expectant mothers. The

results of these efforts are renderings that are far more realistic than those directly from most 3D CAD packages.

The IDEA surveys yielded even higher student score for EGR 695 Project III. Here, the scores averaged 4.9/5 for "excellent course," while scores for the essential learning objectives ranged from 4.6 to 4.9, producing the highest average (4.7) among the three courses with 94% of students rating a 4 or 5. Notable student comments included, "... enjoyed the industrial design ... excellent perspective on aesthetics ... really enjoyed learning about product perception and display."

Student comments (off the record) indicated that they felt more employable as a direct result of the course sequence. In fact, upon graduation, two of the MEng students were hired by a local company (Evonik Corp., Birmingham, AL) with whom they had interned as part of their MEng program. Another student was accepted into further graduate study in a Master of Research program in Medical Device Design and Entrepreneurship (Imperial College, London, UK). One other student already had a full-time

job. Of the remaining students, one has continued in Graduate School, and one works in a dental office with whom she worked prior to the MEng. The whereabouts of the remaining three students are unknown.

Discussion

This manuscript described the initial offering of a course sequence designed to provide students with hands-on skills, ranging from maker activities to industrial design, with opportunities to apply these skills to solve clinical problems presented by clients at local hospitals and facilities that cater to people with special needs. Such problem-based learning enhances students' ability to apply their knowledge in the long term, linking concepts and principles to application at the highest level of knowledge [11], where it is better understood and retained longer when presented in a real world context [12]. The assessment results suggest that the course content and delivery of the Project Course sequence met targeted learning objectives and were highly appreciated by the students who took the sequence as part of their Master of Engineering coursework.

EGR 693 Project I was focused on training the hands-on skills that students (and professionals) need to "make stuff," skills that are needed to support our country as a leader in engineering, manufacturing, and health care [3,4]. These skills included important activities that the vast majority of the students (eight out of nine) had not completed during their previous undergraduate degree. The content was deemed appropriate by participating faculty and students, and led to increased student competencies in contemporary methods used for prototyping innovative technologies. The two-pronged approach that included both manufacturing and electronics provided students with the skills to build their own prototype devices containing structural and electrical components. While not formally assessed, these activities should further allow students to comprehend the necessary steps needed to manufacture a market-ready, commercial device. Considering lessons learned, we recognized the importance of instructor experience with the various tools, and numerous guest lecturers were required to cover the topics. There are no plans for enhancement of this course.

In EGR 694 Project II, the students were turned loose to apply their skills on the development of multiple wheelchair scales. The students elected to run this activity as a virtual production company (which they named EnginD). The coincidental request from the colleague in Health Professions for eight of the previously prototyped devices provided an ideal platform for the course. The students divided up the labor and established an assembly line in order to complete the job. Using their "adaptive expertise," the students had an ideal opportunity to apply prior engineering knowledge to solve new problems [13]. Benefits included the chance for students to master specific techniques, such as soldering, brazing, drilling, and tapping holes. The downside came about three-quarters of the way into the semester when burn-out set in. The electronics associated with the bluetooth transfer of data proved troublesome, and long hours were spent to ensure the scales functioned consistently and accurately. The lesson learned in this case was that multiple projects, with multiple opportunities to apply the different skill sets, may enhance the student experience and help prevent burn-out. This approach will be implemented with the next cohort of students.

The introduction of industrial design (ID) for the final semester course, EGR 695 Project III, surpassed all expectations. Having worked on their own projects in the first project course, and persisted through the scale manufacturing in the second, the students welcomed the opportunity to study the artistic elements of ID. They were ready to get back to the CAD drawing board, and happy to spend time re-evaluating their original design concepts with a fresh eye on ease and logic of use. (The students were concurrently enrolled in another course that emphasized design for

manufacture and assembly (DFMA), which provided additional incentive for re-evaluation of their designs.) The inclusion of their final KEYSHOT renderings, designed for commercial advertising of their user friendly devices, made for an ideal closure to the course and the students' design portfolios. The only challenge presented by this course offering was the involvement of the instructor, who is full time faculty member at Auburn, a 2-h drive from our institution. While the course delivery was undoubtedly enhanced by the presence of the instructor, financial and time constraints may prohibit such delivery in the future.

The selection of projects for pursuit by students in a program such as our MEng presents an interesting dilemma. Should students be tasked with needs finding and developing solutions from scratch, or should they pursue projects that have been prototyped previously? The former may result in better student buy-in, while the latter presents an opportunity to move devices that much closer to commercialization. As director of the MEng program, the lead author elected to pursue the latter, with the hemostasis tool, recumbent weighing scale, and wheelchair scale all devices that had been piloted in senior design. These projects were sourced locally, from UAB Hospital, Children's of Alabama, and Lakeshore Foundation. While the students in the MEng were presented problems for which prototypes had already been completed, they were still required to meet with the original clients to re-identify the problems, confirm the original need, and discuss the limitations of the prototype. In the future, we hope to expand our reach to local companies as an alternative source of projects and expertise, and provide real-world experiences that better enable them to prosper as engineers and product designers in the 21st century.

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