Using External Business Plan Competitions to Drive Innovation and Effective Cross-Disciplinary Collaboration

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***Abstract*—The integration of entrepreneurial aspects in biomedical engineering undergraduate programs is still at its infancy. It is difficult to integrate business specific classes in engineering program due to curriculum constraints and often student do not have any exposure to entrepreneurship. We present the result of two case studies which leveraged an alternative approach. An inter-universities business plan regional competition was utilized to establish and integrated collaboration between the biomedical and entrepreneurship program at Gannon University. The activity focused on a series of seminars in different classes where students were exposed the creation of a marketing plan, pricing model, organizational design and go-to-market strategies, which are common aspects of a business plan. The active interaction between Engineering and Business fostered innovation that resulted in a positive outcome in the "Shark-Tank" style competition.**

I. Introduction

Biomedical engineering (BME) is a field still in its infancy compared to other mature and well defined disciplines, e.g., electrical or mechanical engineering. Students who graduate from a BME bachelor program often progress in their career by going to medical or graduate school with the goal of becoming clinicians or academics. BME students often use the BME program to fulfill the requirements for a pre-medical certificate because classes like calculus, chemistry, and biology satisfy both the engineering and pre-medical curricula. For those students more interested in following the academic route towards a Masters or PhD, classes that focus on experimentation and research are offered to better prepare the students for becoming scientists. These classes are also useful for those that decide to work in research and development (R&D) within industry.

Nevertheless, since BME is becoming a mature discipline, the possibility for the student to conceive an innovative product is very concrete [1]. Therefore, students should also be encouraged to follow an entrepreneurial career. The accreditation body ABET Inc. requires each BME program to expose the students to the four main steps of the process of bringing a new medical device to market: (1) *In vitro* testing, (2) animal testing, (3) clinical trials, and (4) Food and Drug Administration (FDA) approval. *In vitro* experimental setups are first presented to measure the biocompatibility of materials, e.g. thrombogenicity, allergic response. Then, the ethics of animal testing are discussed, which is the next step of process after testing *in vitro*. Then, clinical trials are studied as a means to measure how the material performs in humans. The aspects of experimental design and how to write a clinical trial protocol are discussed. Finally, FDA regulations are presented to show how this clinical trial data is used to apply for approval to market and sell the new biomedical device.

These regulations provide guidance on the safety compliance of the product but do not teach the student how to make their idea a successful product that addresses a market need. Unfortunately, in many programs, the latter aspect is not properly integrated into the curriculum. Often there is not a real opportunity to add more classes to the curriculum to specifically teach students how to be successful entrepreneurs and protect their intellectual property. Thus, we propose a project-based learning approach where different projects are developed within various classes and its potential business applications are emphasized.

To catalyze the interest of the students at Gannon University, we utilize an extracurricular business plan competition. We are located in Erie (PA) within a two hour drive of Cleveland (OH), Buffalo (NY), and Pittsburgh (PA). In 2014, the Innovation Collaborative, an Erie-based non-profit organization, commissioned a study to assess Northwest Pennsylvania's (NWPA) entrepreneurial ecosystem. The study was completed by JumpStart, Inc. based in Cleveland (OH) [2]. The study provided numerous recommendations on how to fully develop an entrepreneurial ecosystem and included specific recommendations pointing out the need for collaboration between the region's colleges and universities. The collaboration could occur through clubs, competitions, events, and internships. Based on this recommendation, the first NWPA collegiate business plan competition was created in 2014 called the Erie Collegiate Innovation Showcase (Showcase) [3]. This competition occurs yearly and involves numerous universities such as Gannon University, Edinboro University, Mercyhurst University, Pennsylvania State University at Behrend, and the Lake Erie College of Osteopathic Medicine (LECOM).

The Showcase is a competition where two student groups from each school present a business plan for the creation of a real business. We hypothesize utilizing this external competition could foster the collaboration between the BME program and the school of business' Entrepreneurship program at Gannon University. In this work, we present two case studies conducted in the last two years. The first case study involves a group of BME students that developed a camera based system to track the movement of people with disabilities. This particular system can be used to track the movement of people with disabilities in small settings, like chiropractor's offices or physical therapist studios. The revenue of these small businesses does not allow them to buy very expensive equipment that is often acquired by large hospitals for the tracking of movement. Utilizing a low-cost system based on webcams and using a software recognition algorithm would cut the investment cost significantly.

The second case study analyzes a promising idea proposed by students to create a bone fixation system that can deliver antibiotics locally. A common medical practice to treat long bone fractures of the femur, tibia, or humerus bones is the use of an intramedullary nail. These orthopedic implants are designed to be inserted into the central marrow canal of the bone and across the fracture site. The nail gives structural support and maintains proper alignment while the bone heals. Current methods of adding antibiotics to intramedullary nails are reactionary and a strenuous process for the patient and medical team. Theoretical solutions have been suggested for preventive delivery of antibiotics through intramedullary nails. This project proposed a set of practical applications for the direct delivery of antibiotics at the fracture site.

We will analyze how the collaboration between the BME program and the Entrepreneurship program have been established through these competitions how entrepreneurial aspects and engineering innovation can be integrated leveraging extra-curricular activities.

II. Case Studies

A. *Assessment of Hygienic Movements Using Digital Video Cameras*

Common clinical assessments consist of visual observations of impaired individuals by a trained clinician to monitor the reachable space of their hands. The capability of individuals to perform tasks of everyday life such as combing or feeding one-self are used to build a clinical scale that assesses the degrees of their impairment. If a person is not able to perform simple tasks, they are depending on somebody else to accomplish the task for them, hence losing their independence. Thus, the possibility to have an objective measure of the reachable space is paramount for a proper diagnosis and to choose an optimal treatment.

Movement analysis is a topic of extreme importance, especially when considering impairments caused by injury or neuro-muscular diseases. The possible output parameters of motion capture studies include, but are not limited to, joint angles, velocity, and acceleration of upper and lower extremities. By using these data as inputs for modeling software, it is possible to infer the relative elongation and the force generated by the muscles performing said action.

In small healthcare facilities, it is uncommon to have sufficient resources that would allow for the purchasing of a commercial motion capture apparatus. The high cost of such equipment tends to limit the ability of small facilities to have a full practical experience with such technology. The work presented at the Showcase in 2014 serves as proof that simple movements can be analyzed using low-cost digital cameras as well as a set of open-source free-ware software.
The project was divided in three modules. 1) Design of a camera-based setup and acquisition of raster video data. 2) Extraction of limbs' trajectories from raster images via free-ware software 3) Processing of kinematic data as input for a refined musculo-skeletal model to calculate muscles' properties during the movement. The students presented a study on how to assess the movement required for eating as one of the basic motions necessary for individuals to live independently and experience a sufficient quality of life [4]. This technology can be used to acquire clinically valuable information to assess quality of movement and level of impairments for a more objective diagnosis. Other potential area of clinical application of the developed system may be in tele-medicine and tele-rehabilitation realms.

It is well-known that high-end motion capture solutions have only been readily available to successful research laboratories, large production firms, or motion capture industries. The equipment is expensive, and often prohibitive when pursued by small enterprises hoping to gain a greater insight into motion analysis.

According to META Motion, this type of equipment can range anywhere from $15,000 to $500,000 [5], far exceeding the monetary capabilities of small cost-conscious firms. "Module 1" presented the setup procedure of a passive motion capture system built using two inexpensive 1080p, 60fps digital cameras. The cost of each camera with such capabilities ranges from $70 to $200. The camcorders frames rate that was selected is comparable with a few entry-level commercial motion capture system that use reflective markers technology.

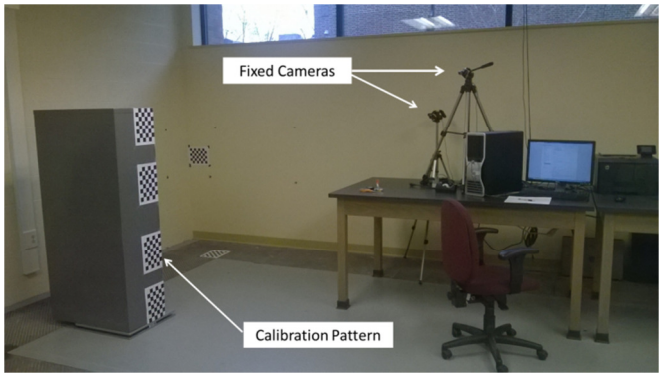

Figure 1: Example of the calibration setup for the camera-based vision system [6]

The students implemented a system to analyze hygienic movements that can be used as an assessment tool to objectively determine the degree of impairment of individuals that have experienced trauma or are affected by

neurological diseases. The product aims at a specific need for clinical facilities to have an affordable and easy-to-use setup to diagnose the impairment and elaborate a proper treatment. To date, this process is done by clinicians either by visual inspection or by using expensive systems that many small facilities and practitioners cannot afford. This system is specifically targeted to be used by chiropractors and physical therapists that own their small business and would like to use an objective measure of the impairment of their patients. Other potential area of clinical application of the developed system may be in tele-medicine and tele-rehabilitation realms.

Observations during the Showcase highlighted the high preparedness of the students in considering all the technical aspects of their solution, but also exposed an insufficient understanding of important business aspects of moving the concept into the marketplace. While the students were able to properly identify a customer segment where their idea could be successful (i.e., chiropractors and physical therapists that own their small business), the students could not adequately address the Showcase judges' questions regarding the business side of their idea including expanding on a marketing plan, pricing model, organizational design and go-to-market strategy, which are common aspects of a business plan. The team ended up tying for third place at the Showcase and won $500 in prize money [7, 8].

This event sparked the interest to expose BME students to the business side of innovation using the help of the Entrepreneurship program. The exposure of students during the following year could happen via a series of seminars that would be integrated within key courses throughout the curriculum. It was decided that since most of the exposure to market regulations of medical devices are presented in the Biomaterial class, formal lectures concerned with FDA regulations would be followed by guest lectures of faculty members from the business school to address how to create a successful biotechnology business.

B. Antibiotic elution from a porous rod

In the second edition of the Showcase, a different group of students presented a project, entitled BioConduit, for an internal bone fixation that can deliver antibiotics locally. Compound fractures that occur after a traumatic event cause the bone to break and pierce the soft tissues leaving the wound open to the external environment. Due to the nature of these injuries surgery is the only option for repair. During this procedure surgeons insert a metal rod into the bone through the marrow cavity. The operation realigns the afflicted bone so it will properly mend and provide structural support. The nail is inserted into the intramedullary canal and attached to the proximal and distal ends of the long bone. Around the fracture, the shards of bone are often secured to the nail. This allows the patient to move the fractured limb while the bone is healing. An intramedullary nail allows the patient freedom to walk on the fractured limb while it heals. Due to the nature of the injury it is common for the bone to become infected, leading to further surgeries or even limb amputation.

To prevent infection, patients are prescribed antibiotics. These antibiotics are usually ingested or injected. The students' research hypothesizes to construct a rod that will be of the same structural requirements as the currently employed method but will be porous. This rod will then be impregnated with polymeric matrix manufactured to have a controlled time release of antibiotics. The students proposed to identify the specific level of porosity in the rod and polymeric matrix that releases the antibiotics so that the concentration of antibiotics is at the optimum level of infection prevention for a longer duration.

The current technology has its limitations. Due to the nature of the injuries infection occurs frequently creating a need to remove the nail and treat the infection. BioConduit is a proposed idea which aims at eliminating the chance of infection. BioConduit is an intramedullary nail which can be fabricated using a vitreous Tantalum alloy as the primary component. This alloy is porous which could allow the embedding of a polymeric matrix capable of encapsulating and diffusing the antibiotic in the proximity of the bone to fight any infections before they become serious.

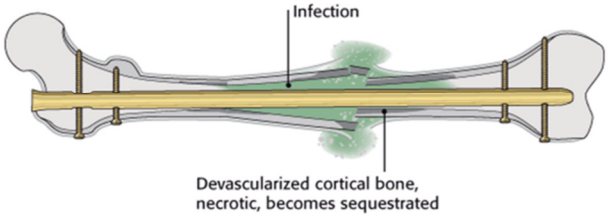

Figure 2: Infection example in intramedullary rod [9]

In this instance, the students were not only technically prepared, but were coached by students and faculty from the Entrepreneurship program. A series of meetings during regular class time helped to focus the BioConduit team's attention not only on the technical application, but also helped them addressing the "business" perspective that both competition judges and investors use to evaluate the viability of ideas. The team was able to successfully reorient their approach from a technology-focused discussion of their solution to a market-opportunity-focused presentation of a customer-driven need solved by an innovative and responsive technology solution. The team ended up being awarded the grand prize at the Showcase winning $2,000 in prize money and another $1,000 in "in-kind" prizes [10-14].

III. DISCUSSION

Collaboration across educational disciplines (i.e., between the business and engineering fields) is a focus within the College of Engineering and Business (CEB) at Gannon University. Often collaboration aims at offering classes from one educational area to another (e.g., a School of Business class to engineering students); however, because of the structural limitations of each educational area's degree requirements, the aforementioned strategy is not always viable. Historically focused on liberal arts education (e.g., English, Philosophy, Theology, etc.), our institution requires between 48-56 undergraduate credits of general education.

Furthermore, accreditation requirements of the Engineering disciplines impose a minimum on 48 discipline-specific credits. Thus, students are limited on the amount of "free electives" classes they can take. Because of these factors, it is difficult to find courses that could lead to cross-collaboration between business and engineering faculty and students. Such limitations in cross-course collaboration can be overcome using extracurricular opportunities to drive student and faculty collaboration.

At our institution, we have used external business plan competitions to drive partnerships between business and engineering students and faculty. In the first Showcase, two teams from Gannon University approached the competition from a "silo" perspective (i.e., an all-engineering team competed separately from an all-business team). The teams tied for third place and while that was encouraging, it was not satisfactory. A year later, a closer and more flexible collaborative approach yielded two Gannon teams that earned Grand prize and 1st runner up positions. The new approach consisted of pairing business and engineering students, resources and faculty. The innovative approaches used in the second year included:

- Leveraging undergraduate research grants to both drive and fund innovation.
- Faculty outreach resulting in partnering a business student who had a technical idea with two engineering students that could help him execute his idea.
- Having an engineering student team working on a class project guided by an engineering professor partner with a business professor and a student-member of Gannon's Entrepreneurship Club to ensure the technology and business sides of the idea were equally addressed.

We believe that partnering business and technology students, faculty and resources with the aim of competing in external business plan competitions is a viable means for driving technology innovation and fostering effective cross-disciplinary collaboration.

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