

Work in Progress: Multidisciplinary, Vertically Integrated Projects Course on 3-D Printed Biomedical Devices

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Abstract

This work in progress paper details the development of a multidisciplinary project-based course focusing on an assistive technology device. The project started as a joint research effort between the school of medicine's rehabilitation center and the school of engineering's makerspace in spring of 2016 to develop custom-fit, affordable orthotics for children with cerebral palsy (CP). To facilitate additional students joining the project and develop a self-sustaining research team, the project became a Vertically Integrated Projects (VIP) Program course in spring 2018. The course is structured as weekly team meetings with the faculty or graduate student lead and additional consultations and patient fittings coordinated with the medical team. Additional meetings with the medical team to provide medical insight for each design iteration, as well as allow the students to personally meet with and fit the brace onto the patients. This continuous collaboration allows for the engineering students and the medical team to develop common language and tools that are understandable and encourage the intrinsic motivation to work on real-world medical applications many of the students cite as inspiration for their participation.

To develop the brace itself, the team uses 3D scanning to create an accurately sized brace. The brace is then 3D printed and tested with the patient. Students practice design iteration and human-centered design principles as they focus on input from each of the various stakeholders: OTs, doctors, patients, and the graduate student and faculty leads. Future work includes development and assessment of student design and soft skills workshops for this non-traditional course. The VIP program director at the university is piloting a series of workshops to build presentation, problem definition, entrepreneurship, and interviewing skills. As students participate in this course and are encouraged to attend the soft skills workshops, the goal is for them to progress as leaders within their sub-team and mentor new students.

Introduction

Assistive technology projects have been used in engineering capstone and project-based courses, often as a way to introduce a real-world problem or client. Several sources cite both the benefits and challenges of working with patients and clients through these projects [1, 2]. For example, solutions or prototypes might often be very limited in scope or number of clients but can often highlight or include a service learning component [2]. Thus, embedding the topic in capstone design can teach students to identify engineering design projects with positive social impact [3]. Overall, these projects are often strongly motivating for students, with student satisfaction reportedly increasing after incorporating assistive technology or real-world medical applications into course projects [3, 4].

Research regarding the development of these real-world biomedical application courses and assistive technology often encourage multidisciplinary teams [1]. One example combined engineering and business students who worked on entrepreneurial assistive technology

prototypes and a business plan [5]. These projects were also used to introduce and involve students in technology transfer opportunities [5, 6]. Another course combined biomechanical engineering and occupational therapy students, with faculty from both disciplines teaching the students and combined design teams. Feedback on the interdisciplinary teaching style was positive, though there was some negative qualitative feedback from students who struggled with interdisciplinary teammates [7]. A few authors have specifically reported using orthotic or prosthetic device design and prototyping as course projects [8, 9].

This work in progress paper details the development of a multidisciplinary, project-based course to design custom 3D printed orthotic braces; specifically, the creation of the course, development and changes in learning outcomes, assessment, and future goals are discussed. It investigates how the Vertically Integration Project (VIP) model can work to foster projects between engineering students in a school makerspace and the university's medical center focusing on real-world, assistive technology topics.

Background

Best Practices for Team-Based Assistive Design Courses

Due to the increasing number of studies highlighting the benefits assistive technology and other real-world biomedical application courses, more of these course types have begun to emerge. As a result, there is a need for best practices and standardization of such courses. Goldberg and Pearlman discuss best practices for team-based assistive technology design courses in a survey paper. They identify and encourage the use of eight best practices:

- 1. Identifying a client through a reliable clinical partner;
- 2. Allowing for transparency between the instructors, the client, and the team(s);
- 3. Establishing multi-disciplinary teams;
- 4. Using a process-oriented vs. solution-oriented product development model;
- 5. Using a project management software to facilitate and archive communication and outputs;
- 6. Facilitating client interaction through frequent communication;
- 7. Seeking to develop professional role confidence to inspire students' commitment to engineering and (where applicable) rehabilitation field;
- 8. Publishing student designs on repositories; incorporating both formal and informal education opportunities related to design;
- 9. Encouraging students to submit their designs to local or national entrepreneurship competitions; and
- 10. Incorporating both formal and informal education opportunities to develop a whole curriculum related to design [1].

The application of these best practices in the VIP course on 3D printed biomedical devices will be discussed in this paper, where a portion of these practices were satisfied from the start of the project due to the nature of the relationship from the medical team and initial course structure and objects, while others were implemented during the progression of the course. In addition, improvements of this course will be discussed where future implementation of aforementioned best practices are indicated.

Vertically Integrated Projects Program

The Vertically Integrated Projects (VIP) program was started at Georgia Tech and has grown to a consortium of international universities. The program supports the creation of 1-credit hour, solely project-based courses to support faculty research and student design teams. It was designed to bridge the gap in project work between first-year and the capstone design experience. The program "provides rich multidisciplinary learning experiences, and it is cost effective, scalable, and sustainable" [10]. The VIP course structure supports large multidisciplinary and multi-year teams.

Motivation for Course Creation

This project and collaboration started in spring of 2017, when a medical team, consisting of doctors and occupational therapists (OTs) from the university's school of medicine, procured funding for a specific project idea. That idea was the creation of custom, low cost, 3D-printed orthotic braces for children with cerebral palsy and other neuromuscular degenerative diseases. The medical team approached a group of faculty members in the school of engineering that focus on assistive technology. Faculty then set up a meeting with one of the co-authors, the school of engineering's makerspace manager and adjunct professor, due to the 3D printing expertise needed. Over the next year, a series of paid student interns, one graduate student and one to two undergraduate students, worked on the project under the supervision of the makerspace faculty member. However, as students graduated or decided to leave the project, a need for a long-term team arose. During the projects development, the VIP program was growing at the school of engineering. The VIP attributes fit the needs of the project and it became the mode of carrying out the projects directives, so in the spring semester of 2018 a VIP course on "3D Printed Biomedical Devices" was offered and implemented.

Methods

This multidisciplinary VIP course is set up as a collaboration between OTs, orthopedic surgeons (OS), and primarily engineering students. The medical team, which consists of the OTs and surgeons, assessed and selected clients for the project based on predetermined standardized criteria. For example, only children with the classification of level 3 to 5 on the Manual Ability Classification System are selected, thus adhering to Goldberg and Pearlman's best practice of identifying a client through a reliable clinical partner [1]. The medical team coordinates all patient trials and fittings. All meetings with the patients and their families are held at the school of medicine's pediatric rehabilitation center under the supervision of the OTs. The OTs work with a patient's family to schedule a visit to the rehabilitation center for the preliminary evaluation visit and fitting. Future visits are then scheduled based on patient availability, usually in the late afternoon or evening, to fit and test the parts of the brace. The student team work on designing and rapidly prototyping the braces as the long-term project for the VIP course.

Student Team Selection and Enrollment

The engineering team consists of university students enrolled in the VIP course ranging in level and major. Course enrollment was advertised by the faculty through departmental emails. Prospective students were required to submit an online application stating interests, objectives and qualifications (although no prior experience was required or specified) for the course. The course faculty evaluated applicants and provided successful applicants registration codes for enrollment.

VIP Course Structure

The VIP course was created with the following learning objectives:

- 1. Computer-aided design (CAD) software;
- 2. 3D printing and scanning;
- 3. Development of design process skills including prototype development, fabrication, and testing;
- 4. Meeting with clients including doctors, OTs, patients, and parents;
- 5. Increased proficiency in the basics of human anatomy and OT as it relates to the specific project; and
- 6. Presentation, writing, and teamwork skills.

The course consists of one-hour, weekly team meetings and independent or small-group work. One of the challenges of a VIP course is that there are not pre-set times for the course through the registrar: meetings times are decided by faculty according to the availability of the team. It can be difficult to find one common meeting time that works for all students. To address this, in spring 2018, the class was split into two meeting times based on the student self-reported availability. Then, each larger group of students was further divided into smaller sub-teams. These sub-teams were comprised of three to four students with specific strengths or majors that complemented one another. For example, one sub-team consisted of a mechanical engineering student who had a strong grasp on 3D modeling, an occupational therapy student who had a strong understanding of anatomy and biomechanics of traditional braces, and a biotechnology student who contributed to both the biomedical and engineering components. The sub-team construction emphasized a multidisciplinary approach to design.

Once established, each of the sub-teams were assigned a specific task for the development of the brace: cuff component, tensioning system, and forearm (see components in Figure 1 below). By working as groups of specialized students, this course allows students to learn from one another in various subjects that they would not be provided if they were taking one course. For example, many of the biomolecular science students involved in the course are not required to take any 3D modeling or human-design centered courses. Through this class, these students are able to learn some of the mechanical engineering aspects of medical devices. Additionally, many of the mechanical engineering students have never taken biology or human anatomy courses.

Although each sub-team was responsible for developing one component of the brace, all the subteams came together during class meeting times to share their progress and suggest improvements on other sub-teams' work. This collaboration helped to ensure that all of the subteams were moving forward in the same direction and encouraged the sub-teams to interact with one another and assemble their individual part together into one streamlined brace. The meetings also allowed the graduate student and faculty member leading the course to conduct workshops, give tips on design methodology, as well as critique the brace design and suggest changes for future designs. This method of meeting encouraged clear communication between the sub-teams and instructors, a best practice for these non-traditional courses [1].

Fabrication of the Orthotic and Design Process

In the first semester of the course, students were provided with the previous project information and work done on the orthotic, including a brace design that was based on an existing open source orthotic device and various open source prosthetic parts. Each semester, the faculty member will coordinate a planning meeting with the OTs about desired design changes and number of new patients. In order for the student team to begin prototyping a brace for a new patient, the OTs will schedule a patient fitting session after their initial assessment. At least two engineering students are present during the fitting visit. The OTs record patient measurements of the arm and hand, and the engineering students take a scan of the patient's arm in order to begin designing the forearm component of the brace. The OTs then schedule a follow-up meeting with the patient for a therapy session. The date of this therapy session becomes the deadline for which the students are to complete the first brace prototype for the patient. At that therapy session, the brace is fitted to the patient and both OTs and engineering students are present working collaboratively to provide feedback for the brace design. The current fabrication process of the brace utilizes 3D scanning and more medical and engineering team collaboration to develop new braces for each patient than at the start of the research project.

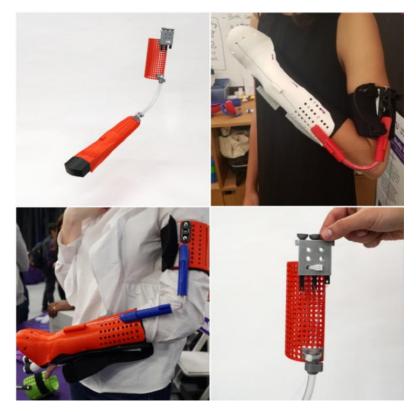


Figure 1: Orthotic Brace

The course was structured so that all of the stakeholders in the project were involved in the evolution of the brace design. The brace went through eight iterations to get to its current state in Spring 2019, with large changes occurring in the forearm, hinge, finger piece, and tensioning system design. The current orthotic brace components and more recent prototypes can be seen in Figure 1.

Student Evaluation

For personal student assessment and grading, each student keeps an engineering notebook detailing their design work and notes from each week. Within the shared Google Drive folder, each student has a folder for their digital notebook, and they create subfolders for design files, pictures, and other documentations. Students are expected to maintain their own notebook throughout the semester, with a mid-semester notebook check and final grade. Students are encouraged to thoroughly document their design process and decisions and to include as many pictures and screenshots as possible. Development of the notebook over multiple semesters allows students to create an evolving project portfolio of their CAD, mechanical design, 3D printing, and design iteration skills.

Preliminary Results and Discussion

Comparing the Design and Fitting Process Pre and Post VIP Course Implementation

The implementation of the VIP course provided the structure which lead to the improvement of the fabrication process of the orthotic and the overall final product for each patient. The course's requirements and set meeting times provided the foundation for increased communication, collaboration, and learning opportunities. This process-oriented, product development approach increased knowledge sharing and competencies of both the medical team and engineering team, which resulted in the development of a multidisciplinary team with cross-disciplinary skills. For example, through this fabrication process, students from the engineering team developed their professional interpersonal skill as they had to interact with clients and professionals in the field. Furthermore, they were required to present and explain fabrication decision and professional receive constructive feedback. Thus, students had to develop their professional role in the engineering and rehabilitation field, another best practice according to Goldberg and Pearlman [1].

Over the past three semesters, the students have created a working prototype for five new patients. Design iteration and improvement has advanced much more rapidly with the creation of the new, larger, multidisciplinary student team that is enabled by the VIP course structure. A completely customized brace can now be delivered to a new patient within one month of their first measurement meeting.

Course Enrollment

As current students presented their work each semester at the school-wide research expo, or a regional conference hosted by VIP consortium universities, more students were exposed to the project and course. The course has slowly grown in enrollment, 11 students the first semester, 13 the next, and 16 in the current semester. The diversity of majors has also increased as more

students become aware of the project and the VIP program at the school in general. Major breakdown per semester can be seen in Figure 2.

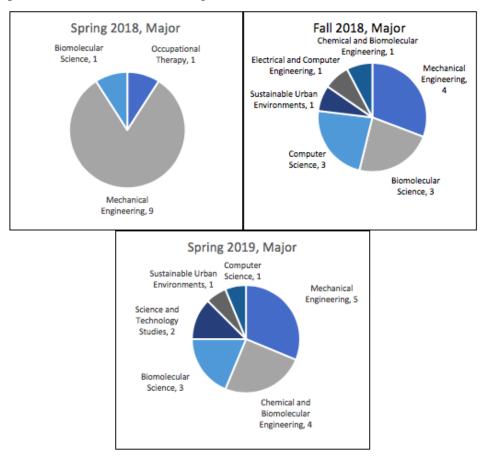


Figure 2: Major Demographics for the Course

Student Course Evaluations

Several improvements have been made based on student feedback and participation since the creation of the VIP course. Preliminary course evaluation results from the students, n = 4, were obtained for Spring 2018 and are displayed below in Table 1. These evaluations included quantitative as well as qualitative results regarding course objectives, course organization, instructor performance, and overall course evaluation. Students were asked to provide feedback on each of the course components by giving values between 1 and 5, with 1 being the lowest score and 5 being the highest score.

Additionally, the students were also asked to provide written feedback for the course overall. Many students enjoyed the course overall. For example, one student stated:

"Gives helpful feedback on the project and major decisions. Using slack as a communication platform was really helpful. Hopefully, next semester, there is a time that everyone can meet up at the same time. I enjoyed learning about the different CAD software such as Rhino and Fusion 360."

Question	Average	Standard Deviation
Overall evaluation of the	4.8	0.5
course		
The course objectives were	4.3	1
clearly stated		
The course was well	4.5	0.6
organized		
Overall evaluation of the	5	0
instructor.		
I have learned how to	5	0
function on multi-		
disciplinary teams.		
I have enhanced my ability	5	0
to use techniques, skills, and		
modern engineering tools.		
I gained the ability to	5	0
synthesize and analyze the		
needs of customers and		
stakeholders		

Table 1: Course Evaluation Preliminary Results, Spring 2018

In course evaluations, students indicated that the component of the course which needed the most improvement was the organization or structure of the course. During that first semester, there was one class section of students, which was further divided into smaller subgroups that worked on individual components of the brace. One patient was the main focus of this first semester, which helped to keep organization and increase efficient communication between the students and the medical team. Over the summer, three students were hired in order to work on the brace as well as streamline the patient, medical team, and student communication. The development of a shared Google Drive folder for each of the patients was tested in order to better organize sharing patient measurements and feedback or comments. This incorporation of more Google-based communication greatly organized and streamlined communications between the students and medical team.

In the second semester of the course, however, enrollment numbers grew, and two class sections of the course were created. Through this change, the two class sections of the students were able to work on the entirety of the brace. Additionally, there were more patients to work with. As the student-medical team communication line had been improved over the summer, the second semester students were able to take on one new patient each month, which better aligns with the OTs' regular schedule for treatment and assessment.

Through this VIP course, students are able to learn and apply human anatomy and occupational therapy concepts through a mechanical engineering application. Learning beyond students' curriculum was reported by the OT student in the first semester, as the university's OT curriculum did not include courses on product design and manufacturing;

the opportunity to be part of the fabrication process increased the OT student's proficiency in ergonomic design process and understanding of material properties and limitations. Engineering, biomolecular science, computer science, and science and technology studies students are able to learn and apply human anatomy and OT concepts.

Conclusions and Future Work

Through the project, the students are able to better work through the rapid design and feedback process. This structure is key to the design and organization of the course. By receiving consistent feedback from the OTs, the patients, and other engineering students, the team is able to continuously innovate and improve the orthotic brace design. Over the past two semesters, the communication system has been developed between the students, the faculty member, and OTs.

Goldberg and Pearlman identified eight best practices for assistive technology-focused projectbased courses. Currently, the course has successfully implemented four of these eight. There is a reliable client base through the medical team (1), with a transparent line of communication between all of the stakeholders involved in the project (2). A multidisciplinary team has been formed (3) that has frequent client interaction (5) through patient fittings and therapy sessions, as well as feedback from the medical team. Over the Fall 2018 semester, Google Drive was better utilized for feedback from patient fittings. The Google Drive organization began as creating specific folders for each of the patients, and was then further refined to include previous documentation for old presentations and pitches, old pictures of the brace, and an entirely new folder for blog documentation for the creation of a website.

While the increased organization on Google Drive has greatly improved the organization of the course, a dedicated project management software, such as Trello, will be explored over the next semester to further organize the course and lines of communication, as well as increase the structure in the course in terms of sub-project deadlines and expectations (4). The general school IP policy is clearly defined for student projects, both extracurricular and curricular, and students own their IP. However, there are complications because the project started with funding from the school of medicine and a clear IP policy was not outlined when the medical faculty first started working with the engineering student team. This will be clearly defined moving forward. Over the Fall 2018 and Spring 2019, several students from the team have worked with medical faculty to enter an entrepreneurial competition (9), with results pending. More formal and informal education opportunities will be incorporated from the medical team so that students may better understand the integration of client-based interactions within engineering disciplines.

Because of the two course sections and the increase in student involvement and interest in the course, it is becoming increasingly difficult to transition new students into the project. A new organization method and plan for design lessons and CAD tutorials are being explored in order to teach new students the concepts of design thinking and the technical skills needed for the project. Older students are working on creating video tutorials for new students and new students are now paired up with 1-2 more experienced student design mentors. Additionally, more emphasis will be placed on the students documenting and keeping track of the evolution of the

brace through their notebooks. A blog or a website is also currently being developed by students to publicize and share their work (8). These improvements to the course design will help improve the application of already implemented Goldberg and Pearlman's best practices as well as provide the opportunity to implement remaining practices. As these are applied within the structure of the VIP model and the university's medical team, the course and design output will continue to be evaluated.

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