March 28th, 2019

Craig Scratchley
School of Engineering Science
Simon Fraser University
British Columbia, V5A 1S6

RE: ENSC 405W/440 Proposal for ACLeeve

Dear Mr. Scratchley,

This project proposal document for ACLeeve was written by the members of Embrace Technologies for the Simon Fraser University capstone course ENSC 405W/440. Our capstone project will develop the product called ACLeeve; which is a Smart Sleeve that will significantly improve and shorten the rehabilitation process relating to ACL injuries.

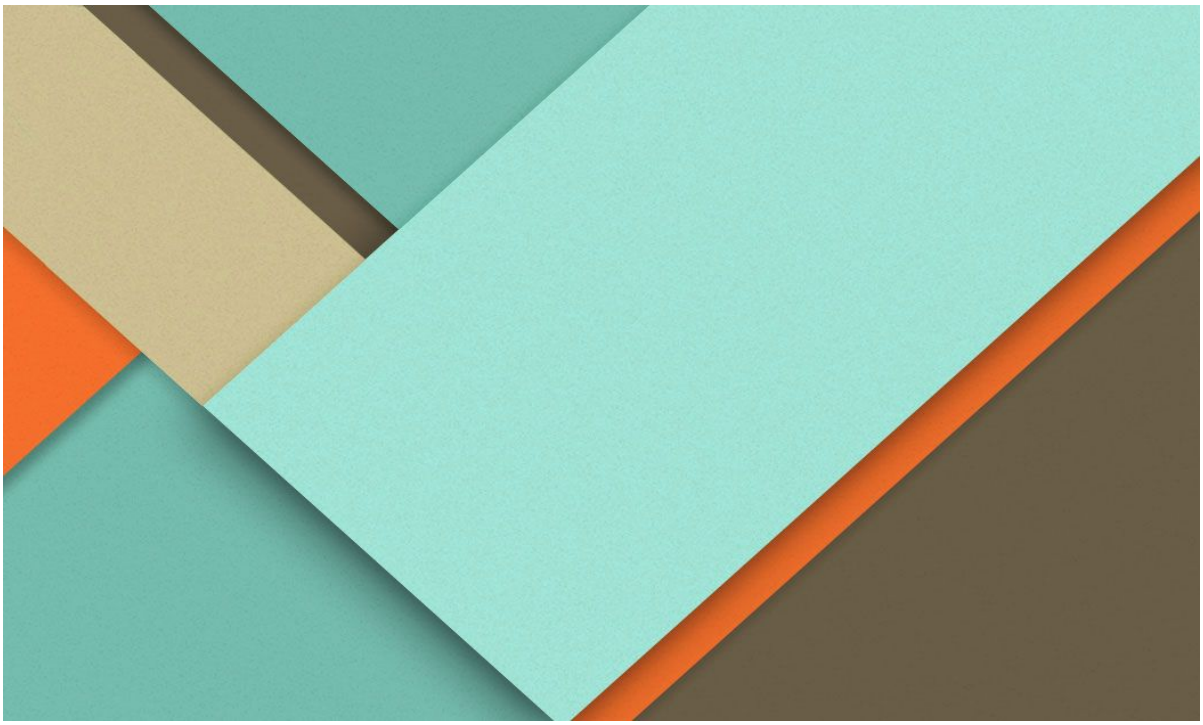
ACLeeve will monitor the user's movements of both quadriceps using surface EMGs (sEMGs). These aforementioned devices will be actively transmitting the collected data to a microprocessor, which will then process and send the data to an external device for further software analysis. The ACLeeve will then provide real-time feedback to the user (audio or visual) regarding the performance of their movements, which will allow the user to physically adjust in order to achieve better long-term results. Furthermore, our software will perform long-term analyses which will evaluate the progress of obtaining the goal of 80-90% asymmetry between the user's ACL-injured quadricep and their other healthy quadricep.

This project proposal document will first of all contain an introduction to our ACLeeve product and the purpose behind the project. Secondly, this document will describe in detail the risks and benefits of our ACLeeve product. Thirdly, this document will outline the current market for commercializing our ACLeeve product, including the present competition to our product. Additionally, this document will summarize the primary processes and milestones of our ACLeeve product. Lastly, this document will provide an overview of all cost considerations relating to our ACLeeve product.

All members from Embrace Technologies greatly appreciate your willingness in taking the time to read our project proposal document for our product ACLeeve. If you have any questions, please do not hesitate to email me at nbatke@sfu.ca.

Sincerely,

Nathan Batke
Embrace Technologies



ACLeeve Project Proposal

EMBRACE TECHNOLOGIES

—

Members: Maria Celkova, Gary Chung, Angus Chen, Harry Draaisma, Peter Xu, and Nathan Batke

ENSC 405W :: Capstone Group :: Team 5

Executive Summary

The ACLeeve is a portable and easy-to-use surface electromyography (sEMG) device, and it is to be actively used during ACL injury recovery to significantly aid and speed-up the rehabilitation process. The ACLeeve is wrapped around the user's leg using a knee sleeve and sEMG electrodes. During physical exercises, the ACLeeve will wirelessly transfer the sEMG data, using Bluetooth and WiFi connections, to an external server and the data can then be viewed by the user on their mobile device through our specifically designed ACLeeve Companion App. Furthermore, our App will display the long term progress the user has gained towards obtaining 80-90% symmetry between the user's injured leg and the healthy quadricep; which is the quantifiable basis of a good recovery [1]. To achieve proper functionality, the ACLeeve will be small, lightweight, easy-to-use, have the required electronics and software capable of detecting accurate sEMG readings, have the capability of transmitting this data over a secure wireless connection, and also have a user-friendly ACLeeve Companion App that will correctly and efficiently display the user's data. Furthermore, our ACLeeve product will be safe for the user to use and conform to all relevant safety and engineering standards. This project proposal document will first of all contain an introduction to our ACLeeve product and the purpose behind the project. Secondly, this document will describe in detail the risks and benefits of our ACLeeve product. Thirdly, this document will outline the current market for commercializing our ACLeeve product, including the present competition to our product. Additionally, this document will summarize the primary processes and milestones of our ACLeeve product. Lastly, this document will provide an overview of all cost considerations relating to our ACLeeve product.

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Glossary

ACL: Anterior cruciate ligament

ACLR: Anterior cruciate ligament reconstruction

ADC: Analog-to-Digital Converter

App: Short for Application

Electromyography: the recording of the electrical activity of muscle tissue, or its representation as a visual display or audible signal, using electrodes attached to the skin or inserted into the muscle. Commonly abbreviated to EMG.

Electrocardiography: the process of producing an electrocardiogram (ECG or EKG), a recording - a graph of voltage versus time - of the electrical activity of the heart using electrodes placed on the skin

I2C: Inner-Integrated Circuit

MCU: Abbreviation of Microcontroller

PoC: Proof-of-Concept

Quadriceps: Shorthand for the Quadriceps Femoris muscle group

sEMG: Surface Electromyography

1. Introduction/Background

One of the most common knee injuries is a sprain, or in the worst-case scenario, a complete tear of the anterior cruciate ligament (ACL). Often times, surgical reconstruction is necessary in order to return the patient to their previous quality of life. During the postoperative period, it is common for the patient to experience arthrogenic muscle inhibition in the quad muscle as well as other muscle imbalances. Due to this phenomenon, one of the main areas of focus during ACL recovery is the strengthening of the muscles surrounding the knee joint. According to scientific literature, “limb symmetry is an indicator of patient progress” [1]. More importantly, limb symmetry can be used as one of the criteria for returning to sport post injury [2].

Our product ACLeeve will help patients monitor their ACL rehabilitation progress as they strive towards a minimum of 80-90% limb symmetry [1], specifically the quadricep muscles, over the long term. Achieving this specific percentage of limb symmetry means that the patient has finally reached an effectively full recovery from the injury. Furthermore, the product will be accessible to the user in a non-clinical setting during rehabilitation exercises. Regarding the short term application, the product will give the user sensory feedback as rehabilitation exercises are completed and alert the user when they are not using their injured muscles in an effective manner. On the other hand, the product will track the user’s progress over the long term with the purpose of being used as a motivational tool to speed up the recovery process. Furthermore, the ACLeeve will quicken the rehabilitation process because the long term data will provide the user a basis in order to make important decisions on when/if to change their types of rehabilitation exercises.

2. Scope

The ACLeeve is meant to be used as an aid in post-ACL injury recovery. The device monitors the EMG activity of quadriceps as the user engages in rehabilitative exercises. The EMG data provides a quantifiable way to measure muscle activity, and by comparing this activity with the uninjured leg it provides the user a quantifiable measure as to how well their recovery is progressing. Furthermore, we will be displaying this data to the user through our ACLeeve Companion App. The ACLeeve is meant to be used by the patient in conjunction with a physiotherapist and physiotherapy, to motivate recovery by showing improvements over time. The ACLeeve will alert the patient of possible issues; such as if they need to adjust their physical movements, or if the ACLeeve’s metrics stall out and reorientation of the ACLeeve is required by the user. For the purpose of helping to develop a visual representation of what our ACLeeve product will look like, please see Figure 1 below.

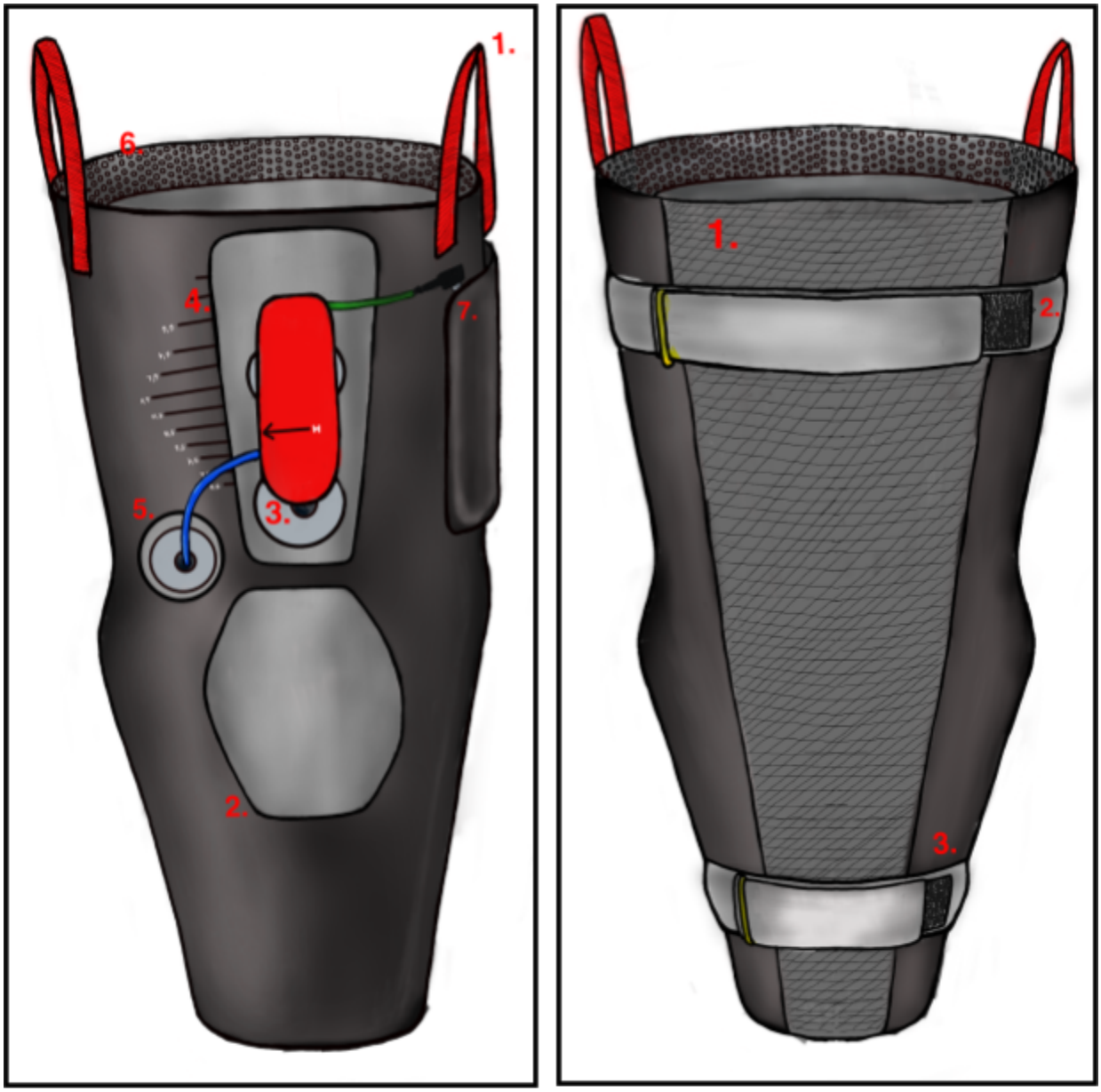


Figure 1: Appearance Prototype of ACLeeve
Frontal View (Left) and Rear View (Right)

3. Risks/Benefits

3.1 Benefits

3.1.1 - Convenience

The issue with the conventional ACL recovery process is that it is difficult to know how well the patient's injury is recovering without regular examinations by a physician or physiotherapist. These examinations are therefore limited by the schedules of the examiner, which may make it difficult for the patient to see them on a consistent basis. Our product, the ACLeeve, is a solution that allows the user to track their recovery at their convenience and anywhere with a WiFi connection. To make the sleeves as user friendly as possibly, the product is lightweight, highly portable and few parts consisting only of the two sleeves and a mobile phone.

3.1.2 - Ease of Understanding

During the progress of ACL recovery, the user often wonders if their progress is going well and the usual answer is whether it is or it isn't based on the opinion of the professional. But that can be vague sometimes as the metrics aren't necessarily explained to the user or is hard to quantify. Our device's metric on progress is based on limb symmetry. This simple metric compares the quadriceps' strengths and displays a percentile number to the user. This is easily explained to our users because it provides a quantifiable metric that is easily tracked over the period of recovery.

3.2 Risks

3.2.1 - Improper Use

A major risk of our product is that is may give the user an impression that causes them to overestimate their own abilities causing damage to the injured knee. This can be caused by the misunderstanding that the correlation between ACL recovery progress and limb symmetry is simply a correlation and isn't the full situation. Another reason is faulty data that can be caused by improper use or faulty components such as sensors. This can be mitigated by warning the user that the device is only meant to be used to track recovery progress and consultation with a trained professional should be carried out before taking any risks that may hinder the integrity of the recovery progress. Our product requires users to complete basic exercises. Depending on the user's stage of recovery, the user may not be in a condition where those exercises are necessarily conducive for recovery. Again, we will warn users to consult a professional on whether they are in a condition to do light exercises such as leg extensions, squats, etc.

3.1.2 - Physical

The only physical risks that exist in our product is the electricity and heat from the electronic components. These risks are mitigated by following IEC standards that requires a case that protects users against accessing hazardous components, and adding insulation where needed to protect against heat on the user's knee.

4. Market/Competition

4.1 Market

ACL injuries are highly prevalent in North America. Statistics indicate there are around 100,000 to 200,000 ACL ruptures every year in the US alone [3]. It happens most often in athletes performing in high intensity and contact sports such as soccer, basketball, football, etc. Athletes as a targeted market group will be able to afford our device without insurance coverage necessary, which makes it possible to market directly towards patients instead of through physician recommendation.

As a medical device, we will focus our market on the patients primarily but marketing towards physicians and therapists will also be important for our product to succeed. The reason we will focus on marketing towards patients is because of product affordability and, the commonality of ACL injuries. Self-diagnosing has become quite common in this age of wide-spread and easily accessible information through the internet. Compared to a rare injury where often expert advice is sought after, patients going through ACL rehabilitation can easily monitor their recovery progress using our device without complication and extensive knowledge into the field. However, marketing towards professionals will be done as a secondary measure since recommendations for our product from physicians will help increase patients' confidence in our product. This is important because trust and confidence in the device is vital for patients.

4.2 Competition

Our device functions much like a portable EMG unit with the added function of monitoring recovery suffered from an ACL injury. Currently, there is no similar device on the market, but there is an abundant amount of portable EMG units which we can perform market analysis on. The MyoTrac 3 dual channel sEMG is a device developed by ThoughtTechnology which is marketed as a “highly sensitive, portable, computerized, dual-channel sEMG interface” [4] and it is currently listed for $1600. In comparison, our product offers a more affordable price tag of $300-$500 which is a lot more affordable for patients without going through insurance coverage. Our product may be less accurate in the sEMG readings themselves, but the nature of our product as a rehabilitation progress monitor means that accuracy is secondary as long as we can monitor clear progress for the patient in their rehab phases.

5. Company Details

We are Embrace Technologies, a startup medical device company. Embrace Technologies was founded in 2019 by 6 like-minded engineering students at Simon Fraser University, each with a passion for creating innovative technology. Our first prototype, the ACLeeve, is a portable, affordable rehabilitative device expected to be completed in August 2019. Joint and equal team effort was put into the production of this project proposal.

5.1 The Team

Harry Draaisma

Harry is currently a 5th year engineering student pursuing a Biomedical Engineering degree. His interest in medical devices and cybernetics often intersects with a want to help people, which is why he went into engineering in the first place. He sees the ACLeeve as an extension of this want, providing patients with much needed feedback on their recovery and possibly alerting them to issues before they become a major problem. He hopes his background in medical technology and project management will help create a cohesive and successful product.

Gary Chung

Gary is a 5th year Computer Engineering student at Simon Fraser University. In the past, he worked as a Firmware Engineer at Sierra Wireless where he developed software to facilitate the manufacturing process. He is familiar with C, C++, and Python programming language and have plenty of Linux development experience. He has worked on many personal projects, including embedded systems and mobile applications, as well as designing and training a neural network. Through his Quality Assurance Co-op at PNI Media, he gained valuable knowledge about Agile development cycle and team work. He is keen to problem solving and is willing to do everything he can to contribute to the success of the project.

Maria Celkova

Maria is currently a 4th year systems engineering student at SFU. She would like to explore engineering in a context of biomechanics, performance measurement and athletic feedback systems in the hopes of helping people realize their athletic pursuits. Maria has a strong understanding of movement since she comes from a competition climbing background where she spent several years representing Canada and Slovakia on the World Cup circuit. This project is a way to bring her interests in engineering and sports into one tightly knit project.

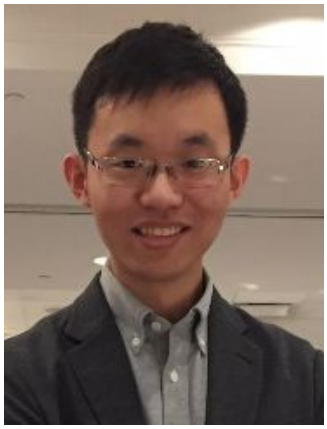
Nathan Batke

Nathan is currently a 5th year electronics engineering student at SFU. His interest has always been into fixing and building anything, which led him to pursue studies in engineering. In his first research co-op job at SFU Menrva Lab, he worked on testing a specific SMART sensor the lab was developing. In order to test the sensor, he had to modify a system using motors, motor drivers, an arduino microcontroller, and program in the Arduino IDE. Additionally, he also worked as a Software Test Engineer Co-op at Sierra Wireless, where he worked in an Agile team environment and developed Python scripts to test the specific AMM product of Sierra Wireless. With all these skill sets mentioned, he hopes to use them to benefit the progress and outcome of the ACLeeve product, which he is helping to develop alongside all of the other members of Embrace Technologies.

Angus Chen

Angus is a 5th year student at Simon Fraser University and is expected to graduate with a computer engineering degree by late 2019. Growing up in a early digital technological age, he has been intrigued by computers and digital technology which leaded him to study computer engineering. Angus' current ambition is to become an exceptional software development engineer as that is his chosen career path after graduation. In his co-op at PNI Digital Media as a software developer, he was working in a fast-paced team environment utilizing Agile-Scrum software development methodologies. Angus developed back-end components of two separate RESTful APIs and a CQRS design pattern based API that runs all internal tools and all front-end programs such as staples and Costco print websites and phone applications. He is familiar with C, C++, C#, Swift, SQL, JavaScript and Arm Assembly and have used tools such as Visual Studios, Git, XCode and Jira. He hopes that his abilities will be of great help to the team and that the product shall be successful.

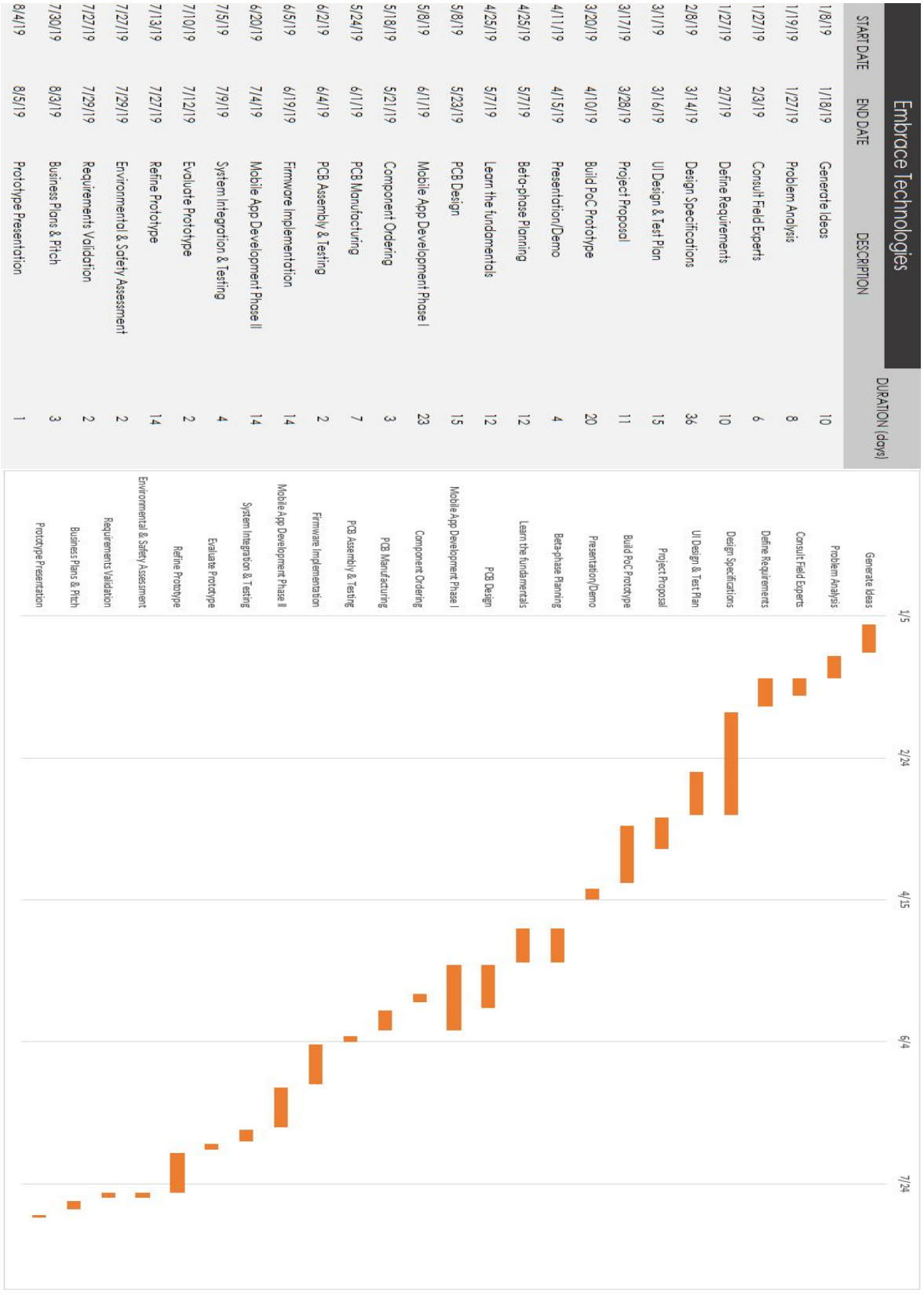
Peter Xu



Peter is currently a 5th year Electronics Engineer student at Simon Fraser University. Through his previous co-ops at Glentel and Sierra Wireless Peter has developed skills in both hardware, involving practices with analog and digital circuits and software, involving C/C++ programming and powershell scripting. Peter will apply his knowledge and expertise in analog circuit design to ensure ACLeeve product will succeed in the market.

6. Project Planning

Figure 2 is a Gantt Chart that illustrates the overall timeline of the project. The ACLeeve project spans from January 2019 to August 2019. We adapted the engineering design process and developed a series of tasks that will allows us to complete the ACLeeve project within the time frame. The completion date for beta-phase planning indicates the end of design phase. We will use an iterative approach to develop the software, a waterfall approach to develop the hardware. Notice how software and hardware are developed in parallel during the first month of the implementation phase. It would be hard to make changes to the hardware once the PCB is manufactured but the firmware person would at least be able to program the chip starting in June. The first phase of mobile app development involves developing pages in the user flow and adding charts to display data from the pre-build sensors. The second phases of mobile app development involve adding new features and improving user interface. We plan to complete prototyping and integrate it with the software stacks by July 10, 2019. That will leave us with 2 weeks to refine and improve our engineering prototype. We may need to use that period to change the design of our sensors or fix intermittent system integration errors so reserving time for unexpected tasks is crucial to the success of the ACLeeve project.



Embrace Technologies

START DATE	END DATE	DESCRIPTION	DURATION (days)
1/8/19	1/18/19	Generate Ideas	10
1/19/19	1/27/19	Problem Analysis	8
1/27/19	2/3/19	Consult Field Experts	6
1/27/19	2/7/19	Define Requirements	10
2/8/19	3/14/19	Design Specifications	36
3/1/19	3/16/19	UI Design & Test Plan	15
3/17/19	3/28/19	Project Proposal	11
3/20/19	4/10/19	Build PoC Prototype	20
4/11/19	4/15/19	Presentation/Demo	4
4/25/19	5/7/19	Beta-phase Planning	12
4/25/19	5/7/19	Learn the fundamentals	12
5/8/19	5/23/19	PCB Design	15
5/8/19	6/1/19	Mobile App Development Phase I	23
5/18/19	5/21/19	Component Ordering	3
5/24/19	6/1/19	PCB Manufacturing	7
6/2/19	6/4/19	PCB Assembly & Testing	2
6/5/19	6/19/19	Firmware Implementation	14
6/20/19	7/4/19	Mobile App Development Phase II	14
7/5/19	7/9/19	System Integration & Testing	4
7/10/19	7/12/19	Evaluate Prototype	2
7/13/19	7/27/19	Refine Prototype	14
7/27/19	7/29/19	Environmental & Safety Assessment	2
7/27/19	7/29/19	Requirements Validation	2
7/30/19	8/3/19	Business Plans & Pitch	3
8/4/19	8/5/19	Prototype Presentation	1

Figure 2: Gantt Chart for the ACLeeve Project

Figure 3 shows the milestones of the project and Figure 4 shows the expected completion date of each milestone.

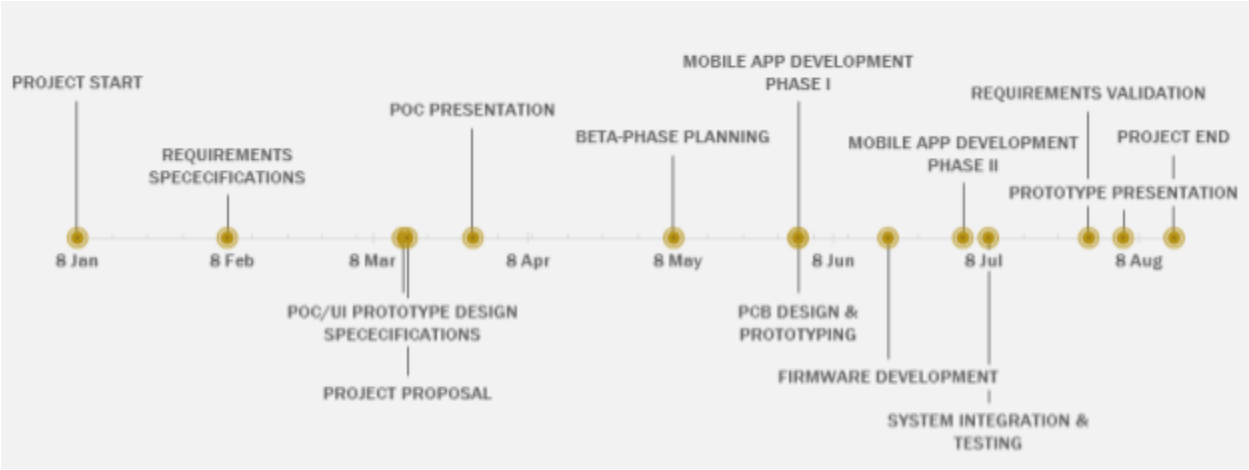


Figure 3: Project timeline with milestones

DEADLINE	MILESTONE
8-Jan	Project Start
7-Feb	Requirements Spececifications
14-Mar	PoC/UI Prototype Design Spececifications
28-Mar	Project Proposal
15-Mar	PoC Presentation
7-May	Beta-phase Planning
1-Jun	Mobile App Development Phase I
1-Jun	PCB Design & Prototyping
19-Jun	Firmware Development
4-Jul	Mobile App Development Phase II
9-Jul	System Integration & Testing
29-Jul	Requirements Validation
5-Aug	Prototype Presentation
15-Aug	Project End

Figure 4: Deadlines and Milestones

7. Cost Considerations

7.1 Costs to Date and Future Estimations

Below is a tabulation of all the costs of the materials used in the Proof-of-Concept Prototype:

Table 1: Proof of Concept Prototype Costs

Part	Description	Cost (CAD)
MCU w/ Wireless Tx and ADC	ESP32 Thing Development Board x 2	$54.43
EMG Sensor	Myoware Muscle Sensor	$57.12
EMG Electrodes (10 pk) x 3	Adhesive backed EMG Electrodes	$40.32
Electronic Components	Header Pins, Cables, Battery Compartment	$9.91
Prototyping Components	Breadboards	$15.40
Batteries, Alkaline	Power Source	$7.83
Knee Sleeve	Fabric and thread to create prototype knee sleeve	$30
Total		$215.01

An initial estimate of the costs to create the final functional prototype can be seen in the table below:

Table 2: Final Functional Prototype Design Costs (estimated)

Part	Description	Cost (CAD)
MCU w/ Wireless Tx and ADC	ESP32 or similar, I2C ADC x 2	$120
Electronic Components	Operational Amplifiers, Voltage Regulators, Resistors, Capacitors and auxiliary parts to support MCU	$75
EMG Electrodes (10 pk) x 3	Adhesive backed EMG Electrodes	$50
Battery, Lithium	Power Source	$30
Shipping	Cost of shipping ordered components to Canada	$40
PCB	PCB manufacturing by contract manufacturer	$50
Enclosure	3D Printed Enclosure for electronics	$30
Knee Sleeve	Fabric knee sleeve with sections for other components	$40
Total		$465

7.2 Potential Funding Sources

7.2.1 Engineering Science Student Endowment Fund

The Engineering Science Student Endowment Fund (ESSEF) is a fund administered by the Engineering Science Student Society (ESSS) [5]. The fund offers four categories of awards with Category B “Entrepreneurial” and Category C “Class” being of interest. We do not expect any difficulties in obtaining funding from the ESSEF as we meet the criterion in these two classes. However, if parts such as development boards are purchased with the ESSEF, it may be required that they be returned to the ESSS for inclusion into the loanable parts library.

7.2.2 Engineering Science Student Endowment Fund

The Wighton Development Fund is administered by Dr. Andrew H. Rawicz [6]. The fund will assist in obtaining additional funding not yet covered (if our project is chosen to be funded and funding is still available). A proposal will have to be submitted and will be evaluated by the fund's committee.

7.2.3 Personal Funding

If the funding sources listed above are unable to cover the full costs of the project, personal funding may be applied to cover any remaining costs. The funding that each member of the group will contribute shall be negotiated based on amount needed, and each member's financial situation, with no member being obligated to provide more than $50, providing a possible $300 in additional funding.

8. Conclusion

Despite the prevalence of ACL injuries, very few devices exist that aid in the entire healing process, outside of mobility aids only used in the first few weeks of recovery. During the latter stages of the healing process, there exists no quantifiable way to track a patient's recovery outside of possibly unreliable self-reporting to a physician or physiotherapist. This lack of quantifiable feedback may provide the patient with an incorrect assessment of their recovery, leading to possible re-injury (from overestimating how well the injury has healed) and/or loss of motivation (due to a perceived lack of recovery progress). This lack of quantifiable feedback is a problem Embrace Technologies intends to solve.

Our solution is the ACLeeve. The ACLeeve is a medical device designed to improve the user's ACL recovery process in regards to two major methods: increasing the user's motivation to perform their required exercises by showing their progress towards full rehabilitation status, and increasing the rehabilitation rate (decreasing the time it takes to become fully recovered i.e. 80-90% quadricep symmetry [1]) by providing constructive feedback to the user in how they should perform their exercises in a more effective way through visual and auditory methods.

As already mentioned in detail regarding the marketability of our ACLeeve product, the risks and benefits, the competition in the market, cost considerations and analysis, and as well the overall planning of our project -– we, the members of Embrace Technologies, believe that our ACLeeve product will meet all standards and expectations relating to each of the aforementioned categories. Moreover, an important highlight of our ACLeeve product is that it will be a significantly lower-cost alternative to other products in the current market. With all these factors taken into consideration, the members of Embrace Technologies are confident and determined in the development of our product ACLeeve.

9. References

[1] “Quadriceps symmetry after ACL reconstruction,” November, 2015. [Online]. Available: https://lermagazine.com/article/quadriceps-symmetry-after-acl-reconstruction. [Accessed March 2019]

[2] “The Utility of Limb Symmetry Indices in Return-to-Sport Assessment in Patients With Bilateral Anterior Cruciate Ligament Reconstruction,” May, 2016. [Online]. Available: https://www.ncbi.nlm.nih.gov/pubmed/27257127. [Accessed March 2019]

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[6] A. H. Rawicz, "FUNDING AVAILABLE FOR STUDENT PROJECTS," [Online]. Available: http://www2.ensc.sfu.ca/~whitmore/courses/ensc305/pdf%20files/Wighton_Fund.pdf. [Accessed March 2019].