Proof-of-Concept Presentation

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

ENSC 405W :: Capstone Group :: Team 5

– Outline –

- Introduction
- Business Case and Costs
- Technical Work
- Risk Analysis
- Standards Adherence
- Self–Reflections
- Plan for ENSC 440
- Conclusion
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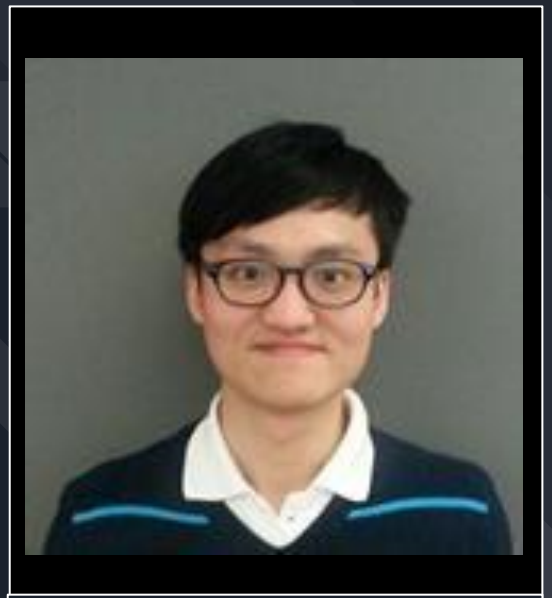
Personnel (1 of 6)

- 4th year Systems Engineering SFU student
- Interested in exploring engineering in a context of biomechanics, performance measurement and athletic feedback systems in the hopes of helping people realize their athletic pursuits
- Strong understanding of movement
  - Due to competition climbing background
  - 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

Maria Celkova

Personnel (2 of 6)

- 5th year Computer Engineering SFU student
- Firmware Engineer at Sierra Wireless
  - Developed software to facilitate the manufacturing process
- Familiar with C, C++, Python and Linux
- Projects involving embedded systems, mobile applications, designing/training a neural network
- Quality Assurance Co-op at PNI Media
  - Gained knowledge in Agile development cycle and team work
- Keen to problem solving, willing to do everything he can to contribute to the success of the project



Gary Chung

Personnel (3 of 6)

- 5th year Computer Engineering SFU student
- Intrigued by computers and digital technology
- Ambition is to become an exceptional software development engineer
- Software Developer Co-op at PNI Digital Media
- Worked in an Agile-Scrum software environment
- Developed back-end components of 2 separate RESTful APIs & CQRS design pattern based API
- Familiar with C, C++, C#, Swift, SQL, JavaScript & Arm Assembly
- Used Visual Studios, Git, XCode, & Jira
- Hopes that his abilities will greatly help the team and that the product shall be successful

Angus Chen

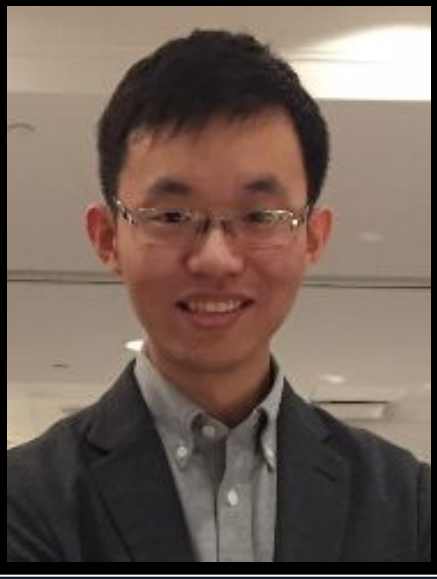
Personnel (4 of 6)

- 5th year Biomedical Engineering SFU student
- Interests in medical devices and cybernetics
  - Intersects with a want to help people
  - Why he went into engineering in the first place
  - Sees ACLeeve as an extension of this want
- The product will provide patients with much needed feedback on their recovery
- Also possibly alerting them to issues before they become a major problem
- Hopes his background in medical technology and project management will help create a cohesive and successful product

Harry Draaisma

Personnel (5 of 6)

- 5th year Electronics Engineering SFU student
- Co-ops at Glentel and Sierra Wireless
  - Developed hardware skills involving practices with analog and digital circuits
  - Developed software skills involving C/C++ programming and powershell scripting
- Will apply his knowledge and expertise in analog circuit design to ensure ACLeeve product will succeed in the market



Peter Xu

Personnel (6 of 6)

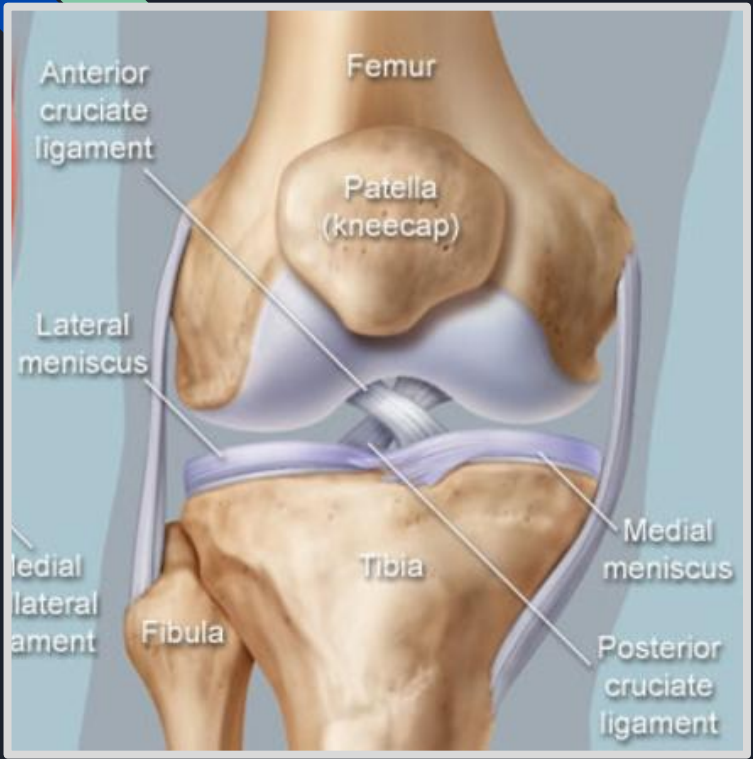
- 5th year Electronics Engineering SFU student
- Interest has been in fixing and building anything
  - Led him to pursue studies in Engineering
- 1st research co-op at SFU Menrva Lab
- Tested SMART sensors the lab was developing
- Modified a Linear Stage system using motors, motor drivers, Arduino microcontroller, circuitry
- Enhanced programming skills in Arduino IDE
- Software Test Engineer Co-op at Sierra Wireless
- Worked in an Agile team environment
- Developed Python scripts to test AMM product
- He hopes to use all mentioned skills to benefit the progress & outcome of the ACLeeve product

Nathan Batke

Background

- Most common knee injury is a sprain
- Worst-case scenario: a complete tear of the anterior cruciate ligament (ACL)
- Surgical reconstruction usually required to restore patient's QOL
- Postoperative period: common for patient to experience arthrogenic muscle inhibition in the quad muscle & other muscle imbalances
- One of the main areas of focus during ACLR is the strengthening of the muscles surrounding the knee joint
    - "limb symmetry is an indicator of patient progress" [1]
    - Limb symmetry can be used as one of the criteria for returning to sport post injury [2]

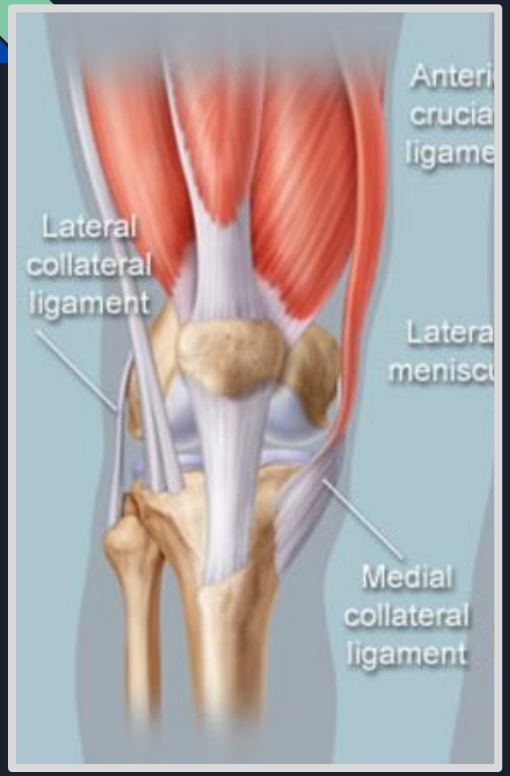
Background (1 of 2)



www.webmd.com/pain-management

- Most common knee injury is a sprain
- Worst-case scenario: a complete tear of the anterior cruciate ligament (ACL)
- Surgical reconstruction usually required to restore patient's QOL

Background (2 of 2)



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Purpose

- Our product ACLeeve will help patients monitor their ACLR progress as they strive towards a minimum of 80-90% limb symmetry
  - Specifically monitoring quadricep muscles
  - Minimum of 80-90% limb symmetry signifies full recovery [1]
- By providing real-time feedback and long-term analysis, our product ACLeeve will quicken rehabilitation process
  - Motivational tool for patient
  - Provides patient a basis to make crucial decisions
    - Changing rehabilitation exercises
    - Adjusting movements so execution is correct
- ACLeeve will be accessible to the user in a non-clinical setting
  - Allows patients to use the product anywhere, anytime

Motivation

- All 3: Commerce, research, and curiosity!

- Commerce:
  - Competitors charge a hefty price
  - Our product ACLeeve is significantly less expensive
- Research:
  - General interest in correlating the strength of muscle excitation signal readings with long-term ACLR analysis
- Curiosity:
  - Desire to help quicken people's physical recoveries
  - Desire to help reduce people's physical inhibitions

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Market

- ACL injuries are highly prevalent in North America
  - Around 100,000–200,000 ACL ruptures every year in the US alone [3]
  - Most often with athletes in high intensity sports (i.e. football, basketball, soccer, etc.)
- Athletes will be able to afford ACLeeve without insurance coverage
- Marketing focus is on the patients primarily because:
  - Product affordability
  - Commonality of ACL injuries
- Marketing towards physicians and therapists will also be important
  - Professional recommendations increase patients' trust

Competition & Pricing

- ACLeeve functions as a portable EMG but can also monitor ACLR
- Currently no similar device on the market
- Although an abundant amount of portable EMG units available
- “MyoTrac 3 dual channel sEMG” developed by ThoughtTechnology
  - “highly sensitive, portable, computerized, dual-channel sEMG interface” [4]
  - Currently listed at $1600
- ACLeeve significantly more affordable ~ $300–$500
  - May have less accurate sEMG readings
  - Nature of product is displaying rehabilitation progress
  - Monitoring clear ACLR is primary, accuracy is secondary

Financing (1 of 2)

- Engineering Science Student Endowment Fund (ESSEF)
  - Administered by Engineering Science Student Society (ESSS) [5]
  - Offers 4 categories of awards, 2 are of interest to us:
    - Category B “Entrepreneurial”
    - Category C “Class”
  - We meet the criteria of both of these categories
  - No expected difficulties for receiving funding through ESSEF
  - If parts such as development boards are purchased with ESSEF, the ESSS may require them to go into their loanable parts library

Financing (2 of 2)

- Wighton Development Fund:
  - Administered by Dr. Andrew H. Rawicz [6]
  - Will assist in obtaining additional funding if our project is chosen
  - Proposal submission required, will be evaluated by the fund's committee
- Personal Funding:
  - Only if previous funding sources are unable to cover all costs
  - Contribution amount from each group member will be negotiated based on the following:
    - Remaining amount of funds needed
    - Each member's financial situation
  - Max $50 each → max total of $300 in additional funding

Ideal Customer

- Obvious but essential:
  - A person in post–ACL injury recovery
  - A person with 1 injured and 1 healthy quadricep
- A person who has access to a physiotherapist
- A person who owns an electronic mobile device capable of downloading Android apps
- A person with previous experience using any mobile app
- A person committed to performing rehabilitation exercises on a daily basis

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Overall Design

- PoC structure of the device will follow closely to the provided visual aid on the right →
- PoC will have no enclosures shielding the electronics
- PoC will only have enough of a “sleeve” to show that:
  - Entire system can be worn on the leg without issue
  - Wireless transmission of EMG data is successful

ACLeeve Product
Front View (left) & Rear View (right)

Customer Considerations

- Product provides a strong indication for how it should be worn on the leg based on constraints.
- The surface electrode placement guides are easily followed
- It will be immediately obvious if device is worn incorrectly
- App is designed in such a way that it conforms with standard smart device design so that user can learn to work the app on the fly
- Data will be represented in such a way that it is easy to understand
- Visual feedback on the sleeve itself indicating when the device is turned on, connected correctly, or recording data.

Materials (1 of 2)

- The sleeve is constructed from material that does not impede range of motion in the knee joint and is comfortable to wear
- Made of a flexible material such as light neoprene so that material does not slide around when placed on sweaty skin
- Sleeve utilizes Velcro as a secondary measure for keeping it in place
- EMG electrodes that are adhesive backed (single use)
- Various electronic components such as header pins, cables, battery compartment
- EMG Myoware Muscle Sensor
- ESP32 Thing Development Boards
- Batteries

Materials (2 of 2)

- Cradle-to-Cradle Design Consideration
  - Removable/Replaceable batteries to allow for recycling
  - Removable electrical components to allow for washing/re-use of sleeve

- Differences between Proof of Concept and Engineering Prototype
  - Rechargeable Lithium Ion Cell
  - Enclosure to isolate most electrical components
  - Custom made EMG sensor

Functionalities (1 of 2)

- From two AgCl electrodes, one positioned at a reference point, the other at the quads, we acquire the muscle activation signal
- Myoware muscle sensor amplify and filters out the raw signal and is sent to the ESP32 board
- Data can be accessed wirelessly via bluetooth/wifi

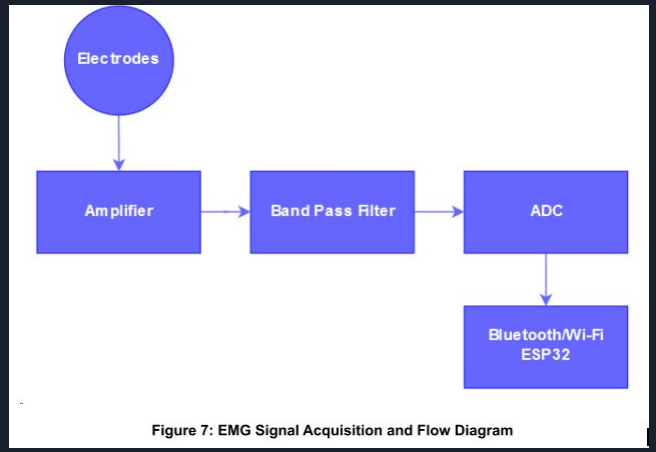
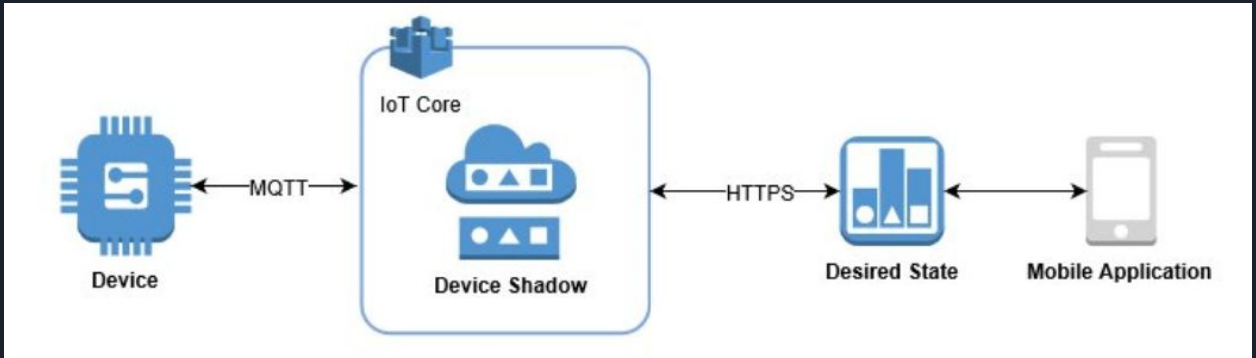


Figure 7: EMG Signal Acquisition and Flow Diagram

Functionalities (2 of 2)

- Embedded systems upload data to cloud servers, which provide data analysis and storage
- Companion app allows users to access data, provided in user-friendly format
- To be implemented in 440



Costs (1 of 2)

- **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

Costs (2 of 2)

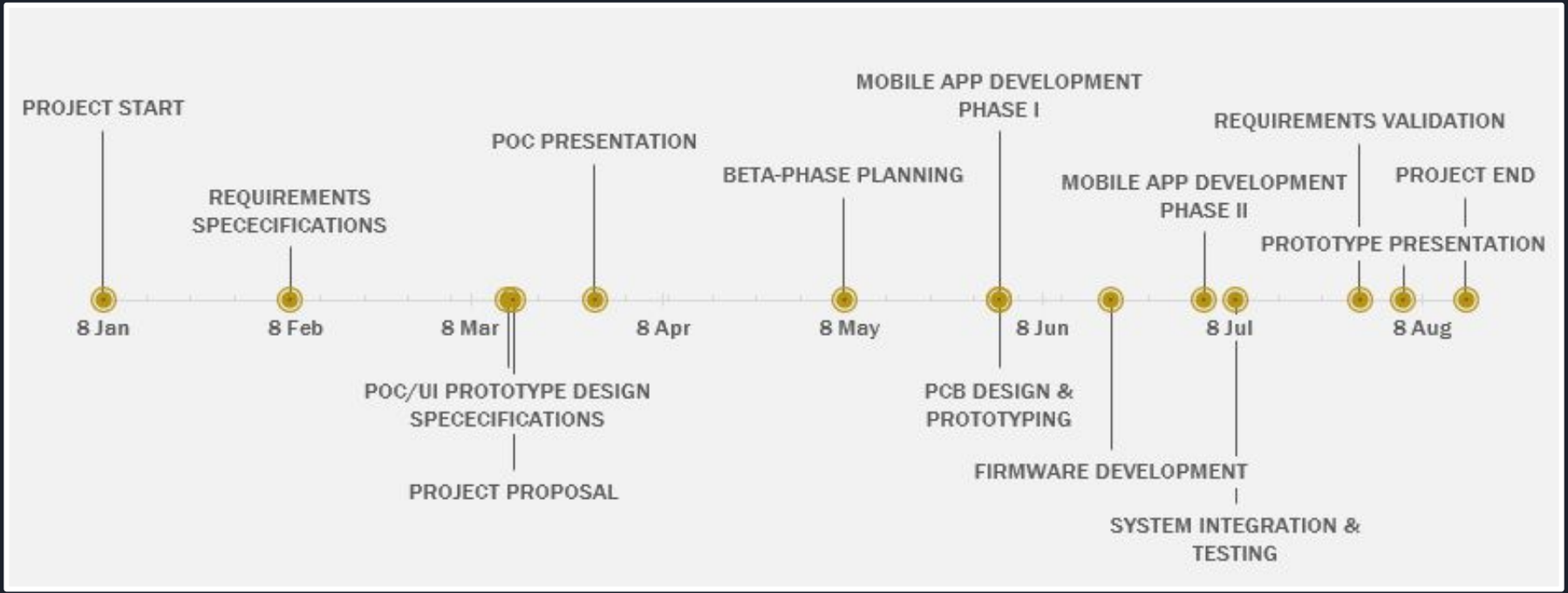
- **Final Functional Prototype Design Costs (Estimate)**

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

Part	Description	Cost (CAD)
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

Scheduling

- **Project timeline with milestones**



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Business Risks

- Business Risks
  - Must go through medical device certification
    - Clearance for testing from ethics board
    - Verification of medical benefits
    - Certification from FDA and Health Canada
  - Failure to penetrate physiotherapist market
    - Mitigate by showing substantial benefit of ACLeeve

Potential Risks & Hazards

- Electricity
- Heat
- Device not fitting correctly and causing damage to the knee

Risk Mitigation Strategies

- Following IEC standards
- Preventing users from accessing hazardous components
- Adding sufficient insulation to protect user from heat of device
- Ventilating all components that get hot in a sufficient manner
- Provide user with ability to adjust fit of sleeve

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Engineering Standards (1 of 2)

- [Req 3.1.1 -a] The device shall follow ISO 60601 -Section 1-11 -General medical device requirement for basic and essential performance
- Device is safe for home use regardless of home's age, structure and location.

- [Req 3.2.1 -a] The device shall be a low-voltage system following IEC 60038
- The device is powered on a battery pack

Engineering Standards (2 of 2)

- [Req 3.3.1 -a] The device shall follow IEC 62304 :2006 outlying the software life cycle process
- Software development process follows the standard

- [Req 3.4.2 -a] The device shall follow IEEE 802.15 Bluetooth Standards
- The device uses bluetooth on processor to communicate according to standard

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Learned much, we have!

- Weekly meetings were effective, we accomplished the most when we determined an agenda for the meeting ahead of time.
- Team is composed of members who have varied skill sets.
- Communication within the team is very important, especially when big deadlines are approaching.

Development Process Changes

- Group could benefit from doing more problem solving / development as a group or as two smaller groups vs having people work on things completely individually.
- Team could benefit from having the schedule visible further in advance. This means that instead of planning one week in advance based on weekly meeting discussions we will be able to “see” several weeks in advance. (Now possible since timeline was created for project proposal document)
- May need to meet more frequently during next stages of the project

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ENSC 440 Plans (1 of 2)

- Implement the amplifier and filter we designed. Start from breadboard functionality test, then integrate it on to a PCB
- Implement all signal processing requirements. Starting with the root mean square (rms) filter. Implement using MatLAB
- Decide on the On-Off determination threshold and test with real data on performance
- Create a refined version of the wearable ACLeeve similar to what is shown on conceptual sketches.

ENSC 440 Plans (2 of 2)

- Set-up back-end database
- Develop ACLeeve companion application, which provides:
  - Short term analysis (Direct comparison with un-injured leg)
  - Long term comparison of injured leg EMG (to track recovery process)

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Conclusion

- Difference in EMG signals based on muscle geometry/size allows for tracking of muscle size, which changes due to atrophy/therapy
- Objectives to work towards in 440:
  - Development of EMG sensor
  - Integrating software backend
  - Implement features to allow for a smoother customer experience, including companion app

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

[2] C. Zwolski et al, “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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References (2 of 3)

[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].